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Howard B. Goldman *Editor*

Complications of Female Incontinence and Pelvic Reconstructive Surgery

Second Edition

Humana Press

Current Clinical Urology

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With deep appreciation to all of my former and current residents and fellows.
I hope you have learned as much from me as I have learned from you.

Howard B. Goldman, M.D., F.A.C.S.

First Foreword

This second edition of Dr. Howard Goldman's *Complications of Female Incontinence and Pelvic Reconstructive Surgery* updates the outstanding first edition which included a multinational authorship related to those issues of quality and safety that are pertinent to female pelvic surgical reconstruction. The second edition updates the first edition by including discussions related to specific procedures, but also more global issues related to surgical reconstruction and risks thereof associated. The first chapter of the book summarizes taxonomic classifications for complications both generally and specifically. The next two chapters—Patient Consent and Perception of Complications and Medical Malpractice—define the importance of the engaged and informed patient and the issues surrounding the importance of obtaining appropriate informed consent from the standpoint of avoiding medical–legal concerns. The last general chapter deals with Medical and Other Types of Complications Related to Pelvic Surgery (and in fact inherent to all surgeries). Following these first four chapters, there then follow chapters on various prolapse repair concerns followed by incontinence concerns and finally specific issues related to management of other lower urinary tract symptom complexes and/or anatomic abnormalities.

It is abundantly clear that surgery is only one aspect of approaching complex female disorders. There is an extremely important presurgical time frame which not only involves the subjective and objective estimation of the patient's condition, bother, and ongoing life burden but also involves the objectification of those symptoms through appropriate, focused, and informed testing which will help the surgeon in his or her preplanning for the surgical procedure. There has been a great deal of discussion and research into the value of certain types of testing modalities (i.e., urodynamics). It is incumbent upon the surgeon, for the unique patient, to make the appropriate choice of objective testing. The wary surgeon is cautioned that operating for symptoms only is fraught with the potential of not completely understanding what is causing those symptoms and complicating the initial symptoms with secondary symptoms arising from surgical intervention. Preoperative preparation, education, and realistic expectation setting are critical for not only the perioperative time frame but also the chronic postoperative time frame where the patient experiences (we hope) some resolution or improvement of their symptoms. Part of urologic pelvic reconstruction is the acknowledgement that rarely is success equivalent to cure but rather remediation and improvement. The successful surgeon is one who counsels his or her patient that they

are embarking upon a journey together which hopefully will result in overall improvement, but that the surgeon will stand by their patient regardless of outcome for purposes of helping chronically manage any persistent and/or new conditions that may arise as a direct result of treatment for the initial inciting condition.

This book is a very important contribution and should be used by all who venture into the world of pelvic reconstruction for purposes not only of self-education and edification but also of guidance given the authorities who are listed in this book and their expertise in the various areas of concern.

This text should serve as a fundamental reference book for not only those in training but also those who have mature careers who are looking for a rapid update on specific issues related to female incontinence and pelvic reconstructive surgery and complications resulting therefrom. I personally find this book an outstanding resource. I hope that you will too.

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Second Foreword

Female Pelvic Medicine and Reconstructive Surgery (FPMRS) has made significant strides in the last decade, including official subspecialty designation by the American Board of Medical Specialties and an ever expanding armamentarium for treating women with urinary incontinence, pelvic organ prolapse, and other pelvic floor disorders. As pelvic reconstructive surgeons, our goal is to perform safe and effective procedures that improve the quality of lives of women suffering from these disorders. Avoiding and, when necessary, effectively managing perioperative complications are essential goals, particularly in this era of Quality and Safety. The FDA's 2011 public health notification on transvaginal mesh and the resultant media and medico-legal storm has heightened patients' awareness of the potential for surgical complications and made comprehensive knowledge of informed consent, patient selection, and avoiding, recognizing and managing mesh-related complications all the more important. No one understands this better than Howard Goldman, M.D., Vice Chair of Quality and Patient Safety for the Glickman Urologic Institute at the Cleveland Clinic and internationally recognized expert on pelvic surgical complications. In the first edition of *Complications of Female Incontinence and Pelvic Reconstructive Surgery*, Dr. Goldman brought together highly experienced pelvic reconstructive surgeons to share their expertise on the prevention, recognition, and management of a broad spectrum of surgical complications. In this second edition, this novel and highly valuable resource has been expanded significantly to include new chapters exploring the medico-legal implications of surgical complications as well as the informed consent process and patient perception of complications. Additionally, the coverage of sling complications has been vastly expanded and includes separate chapters on complications from midurethral, transobturator, fascial, and single-incision slings and retropubic procedures.

In my opinion, *Complications of Female Incontinence and Pelvic Reconstructive Surgery, Second Edition*, is an essential text that should be on the bookshelves of all FPMRS specialists. It provides practical, real-world advice that should improve your ability to provide high-quality care to your patients.

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Taxonomy of Complications of Pelvic Floor Surgery

1

Joshua A. Cohn, Alexander Gomelsky, Laura A. Chang-Kit, and Roger R. Dmochowski

Introduction

The etymology of the word "taxonomy" is from the Greek *taxis*, meaning orderly arrangement, and *nomos*, meaning law. Stedman's Medical Dictionary defines "taxonomy" as the systemic classification of living things or organisms; however, more recently, the term has come to mean any specialized method of classifying objects or events. The aim of taxonomic classification of surgical complications is to permit comparison of adverse outcomes and assist in risk stratification. In this chapter, we review the existing broader surgical classification systems that may be applicable to female pelvic medicine as well as those systems specifically developed for female reconstructive procedures.

The Need for Taxonomy of Complications

Complications are an unfortunate but inevitable aspect of patient care and surgery in particular. Complications are usually multifactorial and can accompany even the most minor, least-invasive and routine procedures. The tracking and reporting of surgical complications is essential to identifying areas for quality improvement. Historically, reporting of complications has been inconsistent and therefore outcomes difficult to compare. To this end, Martin and colleagues developed a list of ten critical elements of accurate and comprehensive reporting of surgical complications [1]. These criteria included: (1) providing the methods for data accrual, (2) duration of follow-up, (3) outpatient information, (4) definition of complications, (5) mortality rate and cause of death, (6) morbidity rate and total complications, (7) procedure-specific complications, (8) severity grade, (9) length-of-stay data, and (10) risk factors included in the analysis. The authors found that of 119 articles published between 1975 and 2001 reporting data on 22,530 patients who had undergone pancreatectomy, esophagectomy, and hepatectomy, none reported

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all ten criteria, and only 2% reported nine out of ten. The most frequently omitted criteria were outpatient information (22%), definitions of complications (34%), risk factors included in the analysis (29%), and severity grade (20%). Similarly, Donat and colleagues found that only 2% of 109 studies between 1995 and 2005 encompassing 150,000 patients following urologic oncology procedures met nine or more of the ten criteria [2]. Seventy-nine percent failed to report definitions for complications, 67% complication severity, 63% outpatient data, 59% comorbidities, and 56% duration of reporting period. Both studies highlighted the need to develop standardized systems for reporting complications and disseminate these systems.

Reporting of complications in female pelvic reconstruction suffers from similar challenges. Depending on the type of procedure and definition of complication, the prevalence of complications in reconstructive pelvic surgery varies significantly. For example, a meta-analysis [3] of randomized controlled trials (RCTs) for midurethral sling (MUS) reported rates of bladder penetration of 0–24%, hematoma formation 0–16.1%, bladder erosion 0–13.1%, and vaginal extrusion 0–5.9%. Postoperative storage and voiding lower urinary tract symptoms (LUTS) were reported in 0–41.3% and 0–55.1% of women, respectively. Furthermore, many of the RCTs did not report any data on the above-mentioned complications. In a meta-analysis of RCTs in the treatment of pelvic organ prolapse (POP), Maher and coworkers [4] similarly reported that only 16 out of 56 (29%) RCTs evaluating 5954 women reported data on the impact of surgery on bladder outcomes.

The reporting of complications in surgery, and in female reconstructive surgery in particular, may be inconsistent for several reasons. First, a complication by one surgeon's consideration may not be seen as one by another surgeon and therefore may not be consistently reported. Second, specific abnormal cutoff values for measures such as estimated blood loss and postvoid residual volume (PVR) are not universally agreed upon, complicating reporting of outcomes such as hemorrhage and urinary retention, respectively. Third, prior studies had primarily focused outcomes such as anatomic success in POP repair or resolution of incontinence in MUS placement, failing to note other potential sequelae of surgery, such as voiding dysfunction or dyspareunia, which may have a significant impact on quality of life (QoL).

The connection between outcomes reporting and health care delivery is garnering ever-increasing attention. The Centers for Medicare and Medicaid Services (CMS) via the Physician Quality Reporting System (PQRS) [5] are scheduled to begin negative payment adjustment in 2017 for many physicians failing to report required quality data. Though not yet required, as it relates to the treatment of female pelvic floor disorders (i.e., relevant quality measures for obstetrics and gynecology and urology), CMS encourages physicians via PQRS to report data on (1) assessment for urinary incontinence in women over age 65, (2) performance of cystoscopy at the time of hysterectomy for POP, (3) the proportion of patients sustaining bladder injury at the time of POP repair, (4) the proportion of patients sustaining a major viscus injury at the time of POP repair, (5) the proportion of patients sustaining a ureteral injury at the time of POP repair, (6) the percent of women over age 65 with incontinence with a plan of care documented every 12 months, and (7) the percentage of patients undergoing non-emergency surgery who had a personalized risk assessment using a clinical data-based, patient-specific calculator and had these risks discussed with them prior to surgery. These represent the 2016 version of the Specialty Measure Sets, which will continue to evolve, are likely to expand, and may become mandatory in the near future.

Despite the growing federal focus on quality improvement initiatives, physicians may continue to underreport complications as has historically been the case [6, 7]. In 2007, Deng and coworkers [8] identified significant discrepancies between the severity of complications associated with MUS surgery reported in the literature between 2001 and 2005 versus those reported in the U.S. Food and Drug Administration (FDA) manufacturer and user facility device experience (MAUDE). Reasons for underreporting may include lack of centralized registries for reporting

complications, disincentives to report such as professional embarrassment or retribution, the cumbersome nature of reporting complications in a busy clinical practice, or complications occurring remote from surgery of which the provider may not be aware. The ideal classification and reporting system would mitigate any of these potential reasons, resulting in increased reporting of complications and greater opportunity for quality improvement.

Existing Complication Classification Systems

In 1992, Clavien and coworkers [9] proposed a classification system for surgical complications that would in conjunction with subsequent work by Dindo and colleagues [10] develop into the predominant classification scheme for reporting adverse outcomes. Clavien and colleagues distinguished between three types of negative outcomes: complications, failure to cure, or sequelae [9]. Complications were defined as any deviation from the normal postoperative course, which also took into account asymptomatic complications such as arrhythmias and atelectasis. A sequela was defined as an "after effect" of surgery that was inherent to the procedure. Failure to achieve a cure meant that the original purpose of the surgery was not achieved, even if the surgery had been executed properly and without complications. What has come to be known as the Clavien–Dindo classification of complications considers only complications and not treatment failures or sequelae.

The Clavien–Dindo classification system consists of five grades [10]. Grade I complications include any deviation from the normal postoperative course without the need for any pharmacological treatment or surgical, endoscopic, or radiological intervention. Grade I therapeutic regimens include replacement of electrolytes, physiotherapy, and medications such as antiemetics, antipyretics, analgesics, and diuretics. Wound infections that are opened at the bedside also fall into this grade. Grade II complications require pharmacological treatment with medications other than those allowed for grade I complications. Transfusion of blood products and total parenteral nutrition constitute grade II complications. Grade III complications require surgical, endoscopic, or radiological intervention. This category is subdivided into IIIa (not under general anesthesia) and IIIb (under general anesthesia). Grade IV complications are life threatening and require intermediate or intensive care management. Central nervous system complications such as brain hemorrhage, ischemic stroke, and subarachnoid bleeding are included in this category, while transient ischemic attacks are not. Category IV is subdivided into IVa (single-organ dysfunction, with or without dialysis) and IVb (multiorgan dysfunction). Death of a patient is a grade V complication. The suffix "d" (for "disability") is added to the respective grade of complication if the patient suffers from a complication at the time of discharge. This label indicates the need for follow-up to fully evaluate and grade the complication.

In essence, the grading of complications using the modified Clavien system is related to the intensity of the treatment directed at correcting the complication [10]. The intent is a link between severity of complication and its associated morbidity. Dindo and colleagues validated the modified Clavien classification in 6336 patients undergoing elective surgery in their institution over a 10-year period. Adjusting for surgical complexity, the authors found that the Clavien grade of complications significantly correlated with the duration of the hospital stay, a surrogate marker of outcome. A strong correlation was also observed between the complexity of surgery (and assumed higher complication rates) and the frequency and severity of complications. Furthermore, over 90% of surgeons in an international survey conducted by the authors found the classification system to be simple, reproducible, and logical and reported that they would support the introduction of the classification system into their clinical practice. The modified Clavien system has now become the most widely used complication classification system across surgical disciplines [11], including urology [12].

In 2011, a classification of complications directly related to the insertion of prostheses (meshes, implants, tapes) or grafts in female pelvic floor surgery was introduced [13]. Following this

initial joint effort of the International Urogynecological Association (IUGA) and International Continence Society (ICS), classification systems were published in 2012 for complications related to native tissue female pelvic floor [14] and POP repair [15].

The 2011 prostheses complication report specifically combined the input of members of the Standardization and Terminology Committees of the IUGA and the ICS and a Joint IUGA/ICS Working Group on Complications Terminology and was assisted at intervals by many expert external referees [13]. An extensive process of 11 rounds of internal and external review took place with exhaustive examination of each aspect of the terminology and classification. The decision-making process was conducted by collective opinion (consensus). The classification of each complication is broken down into three parts: category (C), time (T), and site (S). The category (C) is stratified by location of compromise (vagina, urinary tract, bowel or rectum, skin or musculoskeletal system, and hematoma or systemic compromise) and symptom severity (asymptomatic, symptomatic, presence of infection, and abscess formation). The timing of complication (T) is subdivided into four groups (intraoperative to 48 h, 48 h to 2 months, 2–12 months, and >12 months), while the site of complication (S) includes vagina (at or away from the suture line), due to trocar passage, other skin or musculoskeletal site, and intra-abdominal location. A patient may have more than one complication, and the most severe end point and corresponding time point are chosen for each. Additionally, grades of pain may be assigned as a subclassification of complication category. The subjective presence of pain by the patient only may be graded from a to e (asymptomatic or no pain to spontaneous pain). Each complication is assigned a CTS code consisting of three or four letters and four numerals and should theoretically encompass all conceivable scenarios for describing operative complications and healing abnormalities. There is notably no classification of functional issues or urinary tract infection (UTI).

The 2012 IUGA/ICS Joint Terminology and Classification of the Complications Related to Native Tissue Female Pelvic Floor Surgery was written by the same lead author as the 2011 joint report and proposed a slightly modified CTS system [14]. The CTS system for native tissue repair is virtually identical on its surface to the system developed for insertion of prostheses. However, because there is no mesh, tape, or other implant in native tissue repair, the definitions for "exposure" and "extrusion" are applied to permanent suture material "visualized through separated vaginal epithelium" and "protruding into the vaginal cavity," respectively. In addition, the terms "granulation" (i.e., "fleshy connective tissue projections on the surface of a wound, ulcer, or inflamed tissue surface") and "ulcer" (i.e., "lesion through the skin or a mucous membrane resulting from loss of tissue, usually with inflammation") were added to the terminology. As with the earlier proposal for classification of implant complications, functional issues and UTIs were omitted from the classification system. A subsequent joint IUGA/ICS report [15] proposed that Clavien–Dindo grade and functional outcomes such as postoperative pain, LUTS, bowel dysfunction, sexual dysfunction, other de novo symptoms, and backache should be reported along with the CTS classification.

The Challenge of Implementing a Classification System of Complications

Inherent to the definition of taxonomy is that the classification system should reduce complexity by presenting a logical and hierarchical representation of categories. The classification should likewise provide a means for organizing and accessing vast quantities of data in an intuitive and streamlined manner. Perhaps owing to the complexity of female pelvic reconstruction and any associated standardized schema, the adoption of classification systems in female pelvic surgery has historically lagged.

The most prominent example is the Pelvic Organ Prolapse Quantification (POP-Q) system. While classification systems for pelvic organ support have existed since the 1800s, no system had gained widespread acceptance. In 1996, Bump and colleagues [16] introduced POP-Q,

the first and only classification system to be recognized by the ICS, the American Urogynecologic Society (AUGS), and the Society of Gynecologic Surgeons (SGS). Despite extensive study and reportedly excellent inter- and intraobserver reliability [17, 18], 8 years after its introduction only 40% of members of the ICS and AUGS reported using POP-Q in clinical practice [19]. Some of the reported reasons for not consistently employing the POP-Q were that the system is too confusing and overly time consuming and that colleagues are not using it. While some of these reasons are not supported by literature [17], it suggests that even the most rigorous and well-conceived classification systems may not achieve widespread use owing to concerns regarding simplicity of use, established practice patterns, and unfamiliarity. Nevertheless, with the passage of time and persistence from relevant professional organizations, use of the POP-Q system has increased, with 76% of respondents reporting using the system routinely in a survey published in 2011 [20]. The 2016 IUGA/ICS Joint Report on the Terminology for Female Pelvic Organ Prolapse is the most recent example of attempts to simplify the POP-Q system, improve education, and ultimately increase its routine use [21].

The IUGA/ICS classification system for complications related to prosthetic and native tissue repair pelvic floor surgery is likely to face even greater challenges to widespread adoption. While comprehensive, the CTS system may be cumbersome to use and does not immediately appear to reduce the complexity of organizing complications. Furthermore, the CTS classification does not account for the presence of de novo or worsened storage or voiding LUTS commonly associated with surgery for stress urinary incontinence and POP. Multiple studies have reported significant challenges with retrospective coding of complications and poor interobserver reliability with all of the CTS components. Approximately one-third of mesh erosions were reported as unclassifiable [22, 23] and interobserver reliability observed to be as low as 14.3% for category (C), 28.6% for timing (T), and 0% for site (S) [24]. Furthermore, CTS classification was not found to correlate with patient outcomes or need for further intervention [23], an important benefit of the widely used modified Clavien–Dindo classification system [10]. For proponents of the IUGA/ICS system, these issues may not be insurmountable but will require widespread increase in knowledge of the system and its application. Haylen and Maher [25] have suggested that "record issues" rather than the classification system were responsible for poor interobserver reliability in one study and suggested with improved data and appropriate application of the system, interobserver reliability may have been as high as 87% [22]. More recently, Haylen and coworkers reported markedly improved confidence and ability in scoring all three CTS components following a formal 15-min instructional lecture with eight clinical case examples [26]. In 2015, the first study [27] reporting mesh complications via the IUGA/ICS classification system (and not aiming to evaluate the system itself) was published, although one of the authors on this retrospective study contributed to the IUGA/ICS joint document detailing the system. Challenges certainly remain in the application of the CTS system and questions continue to exist regarding its applicability and utility.

Despite its merits, the modified Clavien classification, while simpler to integrate, appears to be constructed for grading surgical procedures with a significant prevalence of postoperative intervention, reoperation, and morbidity. It can certainly be argued that because pelvic reconstructive surgery is often performed in otherwise healthy individuals, it is associated with lower prevalence of "traditional" morbidity. Thus, the modified Clavien classification may not be sensitive enough to classify the complications typically associated with pelvic reconstructive surgery.

Complications in urologic pelvic surgery may be classified as general or specific, by their temporal relationship to the surgery itself and by their relationship to a technique or specific material used in the procedure. These are summarized in Table 1.1. Taking into account these complications, a modification of the Clavien classification could combine the benefits of the well-regarded Clavien system with the specificity to pelvic surgery of the IUGA/ICS joint classification system (Table 1.2).

Table 1.1 Common complications in pelvic reconstructive surgery

Time	General	Specific	Reoperation
Perioperative	Acute bleeding		Hematoma drainage
	Transfusion		
	Organ injury		Repair organ injury
	Pneumonia, atelectasis		
	Ileus		
	Arrhythmia, MI, CVA, PE, DVT, death		
Postoperative <30 days	MI, CVA, PE, DVT, death	UTI	I&D wound
	Incisional pain	Wound infection	Sling revision
	Pelvic pain	AUR	
	PSBO	Leg pain	
		Storage LUTS	
		Voiding LUTS	
		Extrusion	Sling/mesh revision
		Erosion into GU tract	
Postoperative >30 days	Incisional pain	Storage LUTS	Sling/mesh revision
	Pelvic pain	Voiding LUTS	
		Dyspareunia	
		Extrusion	
		Erosion into GU tract	
		Leg pain	

MI myocardial infarction, *CVA* cerebrovascular accident, *PE* pulmonary embolism, *DVT* deep vein thrombosis, *UTI* urinary tract infection, *I&D* incision and drainage, *AUR* acute urinary retention, *PSBO* partial small bowel obstruction, *LUTS* lower urinary tract symptoms, *GU* genitourinary

Table 1.2 Proposed pelvic reconstructive surgery modification of the Clavien system

Grade	Description	Examples
I	Deviation from normal course (no need for additional intervention)	Trocar bladder puncture, replaced; no formal repair
		Perioperative antipyretics
		Postoperative pelvic floor exercises
IIa	Pharmacological intervention (other than for Grade I)	Antibiotics for UTI or wound infection; antimuscarinics
		Transfusion of blood products
		Analgesics for incisional, pelvic, or leg pain
IIb	Short- or long-term complication, no operative intervention	De novo or worsened storage LUTS
		De novo or worsened voiding LUTS
		Incisional, pelvic, or leg pain
III	Operative intervention required	
	IIIa: Postoperative, office	Incision and drainage wound infection; partial excision extruded sling/mesh
	IIIb: Intraoperative/immediately postoperative	Repair organ injury (bladder, ureter, colorectal, vascular); endovascular embolization for bleeding
	IIIc: Postoperative, operating room	Sling/mesh incision/revision/excision; urethrolysis; laparotomy for small bowel obstruction; SNM
IV	Life-threatening event	
	IVa: Single-organ dysfunction	DVT, PE, MI, CVA/CNS, admission to ICU
	IVb: Multiorgan dysfunction	
V	Death	

UTI urinary tract infection, *LUTS* lower urinary tract symptoms, *DVT* deep vein thrombosis, *PE* pulmonary embolism, *MI* myocardial infarction, *CVA* cerebrovascular accident, *CNS* central nervous system event, *ICU* intensive care unit, *SNM* sacral neuromodulation

Conclusions

A practical taxonomic classification of complications in pelvic reconstructive surgery would be a valuable instrument for reporting outcome measures and quality indicators. While both the modified Clavien and the IUGA/ICS classification systems contain valuable components, at present, a single, comprehensive, user-friendly, and widely accepted system does not exist. The determination of an optimal classification system would lead to an improved ability of surgeons to learn from each other's experiences and compare and share data.

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Patient Consent and Patient Perception of Complications

2

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History of Informed Consent

The informed consent process that we have today is born through the medicolegal affairs of the twentieth century. While most of us can recall the dictum of "primum non nocere" or above all first do no harm, most physicians would probably be astonished to know that Hippocratic teaching also includes provisions from withholding the necessary details of treatment from the patient, "concealing most things from the patient … revealing nothing of the patient's future or present condition" [1, 2]. This recalls the time paternalism was the dominant model of practicing medicine whereby physicians knew best. Early medicine often depended on withholding information from patients. Treatment prior to the turn of the nineteenth century was based on anecdotal and sometimes even baseless evidence. It was not until that late twentieth century that evidence-based medicine was conceived and became popularized [3, 4]. As treatment options and knowledge flourished with the scientific method and rigorous study design, our model for healthcare delivery has also evolved into one of shared decision making. Shared decision making though is not to be confused with overwhelming patients with information and then letting them choose among the myriad options [2]. After all, patients depend on physicians to be their fiduciary in such matters to guide them through treatment options. To that regard, the informed consent process has evolved in regards to what a physician is expected to disclose.

Unfortunately, the topic of informed consent cannot be broached without referring to the medicolegal affairs that have framed the discussion. Multiple landmark cases have molded what constitutes our modern day informed consent. The three most discussed cases are *Schloendorff v. The Society of New York Hospital* (1914), *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957), and *Canterbury v. Spence* (1972). In the case of Mary Schloendorff, the patient consented to an "ether exam" but subsequently underwent a hysterectomy for a fibroid tumor. The patient sued the hospital because she had not consented to surgery. The defendant's claim was that the surgery was done on part of beneficence of the patient [5]. Judge Cardozo's opinion on the case stated "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for

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which he is liable in damages" [6]. The decision ruled in favor of the defendant (the hospital) not being liable for the negligence of its physicians who were independent contractors of the hospital. More importantly, patient autonomy was reaffirmed and most of us are familiar with lack of consent equaling assault and battery.

The Salgo case involved the use of sodium urokon dye for an aortogram with the complication of permanent paralysis afterward. Although a rare complication inherent with the procedure, it was not disclosed prior. Justice Bray wrote "that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent" [7]. Katz points out the contradiction within this legal statement of discretion and full disclosure [2]. Indeed, this first mentioning of informed consent was born of the idea that a physician be required to fully disclose the discretionary risks to a patient for a certain procedure. Given this apparent contradiction, it is little wonder why we have so many models of informed consent.

Lastly, in *Canterbury v. Spence*, the "reasonable patient" model of disclosure was born. The plaintiff underwent spine surgery for a ruptured disc with postoperative disability with mobility, urinary incontinence, and bowel problems [8]. It was alleged that the neurosurgeon did not mention the small risk of serious disability. In this regard, the physician should discuss and disclose information based on what a reasonable person would need to know in order to make an informed decision. This contrasts the "professional model" in which a physician should discuss and disclose information based on what other colleagues would disclose in similar circumstances (Table 2.1) [5, 9].

Although these and many other legal cases highlight the need for good documentation, informed consent is not only based on legal safeguards but also ethical principle. Childers and colleagues suggest three main components for ethical informed consent consisting of disclosure, patient understanding, and patient decision making. Disclosure encompasses the patient and physician discussion regarding the details of a treatment or procedure, the indicated need, and also the attendant risks [9]. As discussed earlier, several models of disclosing risk to a patient exist from the professional model to the reasonable model and some amalgam in between. Patient understanding is gauged by the physician and through communication to assess comprehension [10, 11]. Lastly, patient decision making encompasses shared decision making and incorporating the capacity of the patient to make decisions along with their values and preferences [9]. Indeed, the Declaration of Helsinki and the

Table 2.1 Models of informed consent

Model	Definition and problems
Professional model	Disclosure and discussion based on what other physicians would disclose in similar circumstances
	Problem: Promotes generalizations and diminishes importance of individual patient values and interests
Reasonable model	Disclosure and discussion based on what a reasonable patient would want to know
	Problem: What is reasonable to one patient may be unreasonable to the next
Subjective model	Disclosure and discussion based solely on specific interests, values, and life plan of patient
	Problem: Difficult to know every important detail of patient's life; cumbersome to implement consistently
Balanced model: reasonable and subjective	Disclosure and discussion based on the most important and relevant interests, values, and goals of the patient, as identified by both patient and physician

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Nuremburg Trials demonstrate that informed consent is an ethical standard in allowing patients with capacity to make informed decisions about their own care instead of having treatments imposed upon them. This capacity to give consent is based on the ethical principle of patient autonomy. While physicians may scoff at the idea that patients know how best to be autonomous in their decisions, we have an obligation to be open about the risks, benefits, and alternatives of a procedure and guide them in their decision making process [12–14]. At the heart of shared decision making, physicians serve as facilitators of care who disclose information about treatment options but take into account their patient's preferences to help them come to a conclusion. The decision algorithm for pelvic organ prolapse surgery illustrates this concept. Although quite a prevalent condition, the majority of women with prolapse are not symptomatic [15]. Therefore for a symptomatic patient, no single treatment option serves to be the "right one." Instead the female pelvic medicine reconstructive surgeon elicits a history to further elucidate her preferences as to whether a reconstructive versus obliterative surgery might serve her better. And again (based on what the patient's beliefs and preferences are), the reconstructive treatment algorithm further branches out into uterine sparing versus nonuterine sparing and discusses different surgical approaches. Gone are the days of paternalistic surgeon privilege when a one-size-fit-all approach was administered to every patient without any input. This evolution reflects the myriad surgical options we have and also the evidence that one surgical approach is not necessarily superior to another.

Informed Consent in FPMRS

Given the different treatment options for disease processes in female pelvic medicine and reconstructive surgery, it is important for the physician to foster a relationship with the patient. When surgical treatment options are presented, this decision is impacted by the physician and patient relationship. Multiple papers have evaluated the role of the physician's relationship on impacting patient care [16–18]. Nowhere is that more true than during procedures that effect quality of life. With these elective procedures, it is important that communication be transparent and deliberate [10]. Tamblyn and colleagues found a significant correlation between low clinical skills examination scores (based on physician communication) and prediction of likely complaints against physicians in Ontario and Quebec [18]. The difficulty in establishing this relationship and communicating effectively manifests in today's medical environment. Quality patient encounters can be hampered by time constraints of the modern doctor's visit. But, we should consider that given the time to talk, most patients speak for 2 min or less while most physicians interrupt within the first 22 s [19, 20]! While quality of care can be determined by patient-driven opinion-dominated metrics, it becomes increasingly more important for the physician to communicate effectively during the limited time with the patient. Studies have demonstrated that patients respond positively to the doctor who addresses their questions and needs [21–24]. Simple portions of the interview such as allowing the patient uninterrupted time to address their concerns, asking for additional questions, and demonstrating empathy improve the physician–patient relationship. All of this trust built during the relationship culminates in the shared formulation of a treatment plan. Often the treatment plan involves shared decision making on a therapeutic intervention. Intervention takes many forms in female pelvic medicine and reconstructive surgery. A prime example of this is the treatment of overactive bladder. Surgery is just one option among many including behavioral modification and medications. Often, education and behavioral modification are all that are needed to make a meaningful impact in one's quality of life. Discussion with a patient regarding caffeine intake reduction and fluid intake modification can make a therapeutic difference without surgical intervention. Regardless of the treatment plan, shared decision making between patient and physician is paramount. This involves education regarding the diagnosis, treatment options including the option of no treatment, open dialog between the physician and patient,

and lastly mutual decision making on the treatment option that should be pursued. Numerous studies have demonstrated that information presented in multiple modalities can serve to enhance the patient's knowledge and satisfaction with the shared decision-making experience [25]. Long gone are the paternalistic doctoring models where only one decision was the correct decision. Today's medicine involves taking into account patient's and family's preferences and wishes. Part of the difficulty with informed consent is based on how much risk to divulge to the patient. There is a fine line between giving enough information so the patient can make an informed decision versus overburdening a patient with superfluous details. Already presented with the *Canterbury v. Spence* case was the model of the reasonable patient. But rather than placing all decisions in a rigid matrix, a combined approach taking into account patient preferences and values in addition to what a reasonable patient would want to know is probably the best method of informed consent. In this regard, the surgeon would discuss the risks for a surgery that a reasonable patient would want to know and also include any additional risks, however low risk they may be, that may be in accordance with a patient's values. Framed in this context of overactive bladder treatment, a patient may best be served by sacral neuromodulation for overactive bladder if the risk of urinary retention with another treatment is unacceptable to the patient. This model can only be utilized if a physician has spent time elucidating the patient's preferences and goals through building the physician–patient relationship.

Another difficulty regarding informed consent is the realization that this process happens before any paperwork is signed for surgery. Informed consent as it applies to surgical procedures is typically the piece of paper or document in the medical record that has the patient's signature. In reality, the signature documents that the discussion took place prior between the physician and patient. *It does not replace this discussion*. And it is during this discussion that the physician has the ability to impact the patient's perception of any outcome of a surgery. The informed consent should take place in a non-hurried setting where the physician has a chance to explain the procedure, the patient has the chance to ask questions, and the physician has a chance to answer these questions and check for comprehension and understanding [11]. The documentation itself should not be trivialized because it serves as an objective part of the medical record. Components that should be included in any documentation include a description of the procedure in understandable terms, details of the risks/benefits documentation that the risks/benefits and alternatives were discussed including the option of no surgical intervention, and then an attestation that the patient had a chance to ask questions [9, 10]. With most shared decision in FPMRS cases, we enjoy the luxury of discussing treatment options in our office without emergent need for an operation. For more complex decisions regarding surgical treatment options, it would serve us well to educate our patient so that they can be an integral part of the shared decision making process and be diligent about all steps of the informed consent process. An example of this can be found in subtleties of informed consent in any procedure using synthetic mesh.

Informed Consent and Patient Perception in the Realm of Mesh

Patients need to be able to comprehend the treatment options at hand and informed consent needs the understanding of both parties to proceed. The physician should use empathy to try and understand the patient's preferences while the patient needs to be able to understand the risks/benefits and alternatives to any procedure. Unfortunately with all the litigation surrounding mesh-based prolapse repair, patient education between fact and fiction can often times be difficult. Multiple studies have demonstrated that patients are misinformed regarding the use of synthetic mesh in prolapse repair and also the litigation involved using synthetic mesh. Unfortunately, patients also are deriving most of their information from sources other than their physicians demonstrating a need for increased patient education [26, 27].

Pelvic organ prolapse and incontinence are difficult concepts for the patient to clearly understand and recall at baseline [28]. Given the difficulty in understanding this subject, jargon should be kept at a minimum. Language should not be condescending and risks and benefits of a procedure explained in a simple and concise manner. Regarding procedures, the more information afforded to the patient the better. Given the misconception about synthetic mesh, informational tools such as FAQs from AUGS and SUFU can be used for further patient education. The joint FAQ on mesh mid-urethral slings for stress urinary incontinence highlights the important role of professional societies to also provide information to help patients make informed decisions [29]. These tools serve as an adjunct to informed consent and are not meant to replace discussion between physician and patient but rather to reinforce patient knowledge. Patients are then empowered to make an informed decision regarding their care. The International Urogynecological Association published a consensus paper with a sample consent for use with transvaginal prolapse surgery repair [10]. Again it should be noted that such an extensive consent serves a twofold purpose, as evidence that a shared decision-making process took place and that informed consent was obtained. Studies have demonstrated that patients better understand informed consent when given information in multiple modalities [25, 30]. This agrees with principles in learning and teaching that not only auditory processing but also visual processing matters as well to enhance comprehension [31]. Interestingly, it is assumed that patients will be able to read their after-visit summary for further information and instructions regarding a procedure. But it should be noted that patient's preferences for receiving information should be ascertained prior to ending a visit because some patients may be illiterate and too ashamed to mention this when receiving their after-visit summary [28, 32, 33]. While many of these considerations are assumed during an office visit or during a process such as informed consent, all of these must be considered to ensure that the patient has all the tools available to be involved in the shared decision making process.

Conclusion

Informed consent refers to the process by which the physician and patient agree to a plan formulated concerning the patient's care. There are two key components to informed consent—one, that the physician inform and disclose information to the patient and two, that the patient consents to this formulated plan of care. The heart of informed consent lies within the shared decision making between the physician and the patient. Informed consent has both a medicolegal and ethical basis. In female pelvic medicine and reconstructive surgery, shared decision making should take place between the physician and patient with clear communication and established rapport to come to a decision that is both acceptable to everyone in regards to treatment outcomes and also patient's preferences. To that extent, multiple modalities provided by professional societies should be used such as published FAQ's and other resources. These can be used to clearly communicate and inform patients so that shared decision making becomes the cornerstone of any treatment plan and expectations regarding benefits and complications are clearly understood.

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Medical Malpractice: Analysis of Factors Driving Litigation and Insight into Reducing Risk

3

Matthew J. Donnelly

Introduction

Most physicians have heard the saying: "It is not if you get sued, but when you get sued." Furthermore, if a physician gets sued early enough in his or her career, there is also the chance that physician may get sued a second and third time before retirement. Moreover, physicians in certain specialties are more likely to get sued than their counterparts in other specialties.

A study published in the *New England Journal of Medicine* found that roughly 11% of urologists, 8% of gynecologists, and 15.3% of general surgeons nationwide face a medical malpractice claim annually [1]. The same study found that by the age of 65, 75% of physicians in low-risk specialties had faced a malpractice claim, compared to 99% of physicians in high-risk specialties [1]. Urology is considered a moderate- to high-risk specialty [2].

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Medical Malpractice Defined and Explained

There is oftentimes confusion about what legally constitutes medical malpractice or medical negligence. While the exact definition may differ from state to state, it is generally understood as a physician's deviation from the accepted standard of care when rendering medical services to a patient, thereby causing harm to the patient. In order to successfully prosecute a claim for medical malpractice, a claimant must prove four elements. These elements are as follows: [1] the medical professional owed a duty to the patient, [2] the medical professional breached that duty, [3] the breach of the duty proximately caused injury to the patient, and [4] damages caused by the alleged injury.

Proving that the medical professional owed a duty to the patient is the easiest hurdle to overcome. Once the physician–patient relationship is established, the physician owes a duty of reasonable care to the patient. Usually the most contentious point in medical malpractice litigation comes when the claimant attempts to prove the second legal requirement. Once duty is established, the claimant then must prove that the physician breached that duty by failing to meet the acceptable standard of medical care. In order to do this, a claimant must show that the physician failed to act as a reasonably prudent physician would under the same or similar circumstances. In order to prove or defend this element, the vast

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majority of the time the parties will retain the services of expert witnesses. Expert witnesses are necessary in medical negligence lawsuits because the jury in such cases is overwhelmingly staffed with laypeople who have little to no medical knowledge. Expert witnesses that opine on the standard of care are generally of the same specialty as the medical provider(s) accused of negligence.

The third element, causation, is also a hotly contested issue in medical negligence trials. In order for a plaintiff to meet his or her burden for this element, he or she must prove that the breach of the aforementioned duty was a proximate cause of the claimed injury. Interestingly, even if a jury finds that the physician breached the standard of care, it can find that the breach did not proximately cause the claimant's injuries and therefore still render a verdict for the physician. In some instances, medical providers even admit their negligence, but defend the entire case on causation. A simple illustration of this type of defense can be found in the following failure to diagnose scenario. Suppose a physician identifies a lesion on the patient's kidney following a CT scan but fails to act upon that finding. Approximately 3 months later, a different physician identifies the lesion and diagnoses the patient with renal cell carcinoma. The first physician was certainly negligent for failing to diagnose and treat the lesion, but that breach of the standard of care caused no harm to the patient, as this patient was correctly diagnosed and treated only 3 months later. In this scenario, if the jury finds that the 3-month delay caused no injury to the patient, the jury should find in favor of the first physician based on that physician's causation defense.

The final element in a medical negligence claim is damages. Damages come in three general forms—economic, noneconomic, and punitive. Economic damages may include past and future medical bills, past and future lost wages, and other quantifiable monetary damages. Noneconomic damages include pain and suffering, mental anguish, and loss of consortium. While rarely sought, punitive damages are another remedy available to claimants that are designed to punish a defendant for willful, wanton, or malicious conduct. They are also designed to deter future misconduct. Importantly, punitive damages are usually not covered by insurance. Expert witnesses such as economists, vocational specialists, and life care planners are used by parties to show potential damages.

The plaintiff has the burden of proof in medical malpractice cases. In other words, the plaintiff has the burden to prove that medical malpractice occurred. The physician does not have to prove that it did not. The plaintiff must prove that it was "more likely than not" that malpractice occurred. This burden applied in civil cases is called "by a preponderance of the evidence" as opposed to the better known and heightened criminal burden of "beyond a reasonable doubt."

In order for a claimant to bring a lawful claim of medical negligence, he or she must do so within a certain amount of time under the law. This time limitation is known as the statute of limitations and it varies greatly from state to state. There may also be differences in the amount of time a claimant can bring a negligence claim as opposed to a wrongful death claim. For example, in Ohio a claimant has 1 year from the accrual of the alleged negligence to bring a claim for medical malpractice [3], yet there is a 2-year timeframe in which to bring a claim for wrongful death arising out of the alleged malpractice [4]. The medical malpractice statute of limitations can be tolled due to a patient being a minor or of unsound mind [5].

Malpractice Claim Frequency and Severity Trends

Recent data from the National Practitioner's Databank show favorable trends in claim frequency and severity [6]. The frequency of all paid claims is down quite significantly since 2001. However, claims with a value of $500,000 or more have remained steady, yet are much less frequent than claims with a lesser value (Fig. 3.1). This illustrates that the more frivolous or lesser value cases are being brought less often, while the meritorious claims are still brought at

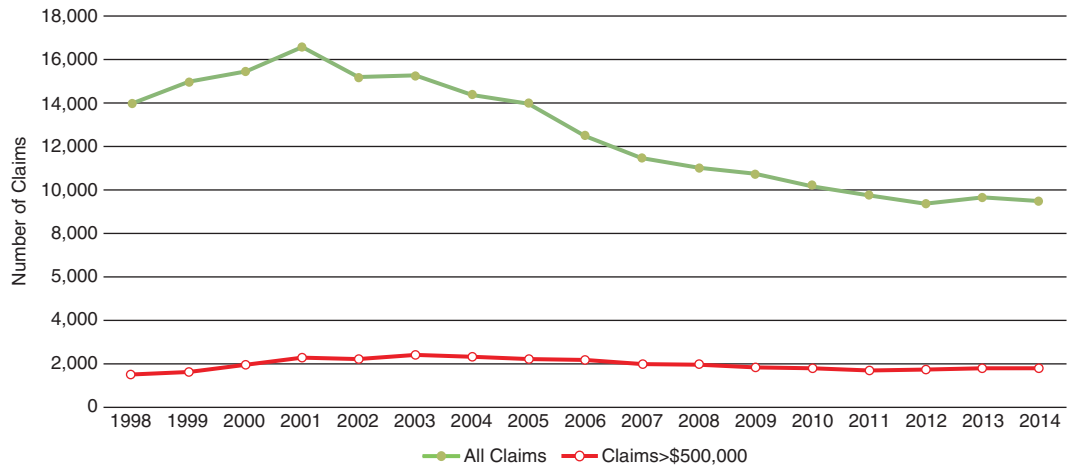

Fig. 3.1 Countrywide frequency, physicians. (Source: National Practitioner Data Bank. https://www.npdb.hrsa.gov/)

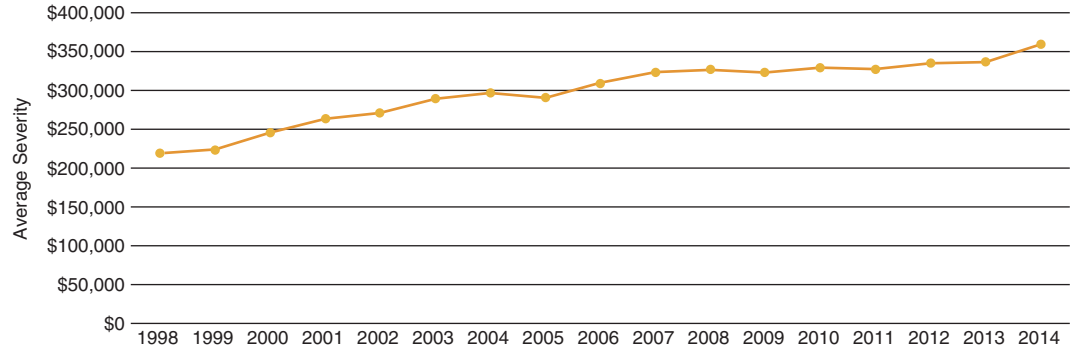

Fig. 3. 2 Countrywide severity, physicians. Annual severity trend since 2004: +1.5%. (Source: National Practitioner Data Bank. https://www.npdb.hrsa.gov/)

the same rate. Accordingly, one can hypothesize that while tort reform has had an effect on these lesser value cases, it has had relatively little impact on the frequency of valid claims.

With respect to severity, the country has seen a slight uptick over the past 15 years, but only at an annual rate of 1.5% (Fig. 3.2). There are several reasons for this increase. The general cost of prosecuting and defending these cases has grown over time with increases in expert witness and attorney's fees. In some specialties such as neurosurgery, expert witnesses are charging over $1000 an hour. Obviously, the wages of injured or deceased patients have increased over this period of time, making the value of corresponding loss of future wage claims go up. Moreover, as the cost of healthcare has increased, so has the cost of life care plans that provide future care for disabled claimants. Accordingly, when considering the rate at which the cost of healthcare has accelerated, the fact that the severity of medical malpractice claims has only increased at a minor annual rate should be viewed favorably.

Despite the positive trends noted earlier, more can be done to decrease these numbers even further. Proactive risk management, quality, and patient safety programs ensure that better care is being delivered. Furthermore, increased focus on the patient experience and caregiver engagement has led to a better physician–patient relationship

and overall experience of both the patient and caregiver. Continued advancements in these fields should lead to even more favorable outcomes—in patient care and litigation—in the future.

Why Patients Sue

Patients sue their physician or healthcare provider for a myriad of reasons. There certainly are instances where the care rendered was substandard and a suit is brought to compensate the patient for the harm done. More often, however, there are other factors that influence a claimant's decision to bring a lawsuit. Physicians with a significant history of litigation share a number of the following patient complaints: failure to listen to their patients, failure to return telephone calls, rudeness, and a lack of respect [7]. It has been suggested that physicians who are at high risk for litigation should better understand environmental and behavioral risk factors that contribute to their risk [7].

Communication

Communication or lack thereof is the most common theme found in medical malpractice litigation. George Bernard Shaw once famously said: "The single biggest problem in communication is the illusion that it has taken place." Proper communication is necessary among all participants in a patient's care, including communication with the patient. Obviously, physicians must communicate adequately with their patients so that the patients are able to make informed decisions about their healthcare. Proper communication is not only necessary prior to a treatment or procedure, but is just as important during and after the treatment process. Communication among caregivers is also vital to the proper management of a patient. This includes physician-to-physician, physician-to-nurse, and shift-to-shift communications. Oral and written communications are equally important and must be given their proper attention pursuant to the circumstances. Discussions with a patient's family members, especially at the time of discharge, also have an impact on whether poor communication influences a patient's decision to sue.

A recent study by CRICO Strategies directly linked patient deaths to poor communication. The study analyzed over 23,000 medical malpractice claims and suits and found that at least one specific breakdown in communication that contributed to patient harm was present in almost one-third of the cases [8]. Twenty-seven percent of those cases involved surgery [8]. An in-depth review of more than 7500 surgery-related cases revealed that 26% involve significant communication errors [8].

The breakdown between the inpatient and ambulatory settings was fairly even at 44% and 48%, respectively [8]. There was also a fairly even distribution of cases where the breakdown of communication was between two or more healthcare providers or between the providers and their patients [8] (Table 3.1).

The opportunity for communication errors in surgical cases can occur before, during, and after the surgery. Prior to surgery, failing to properly educate the patient on the procedure's risks, benefits, alternative treatments, and potential outcomes—better known as the informed consent process—is one allegation that occurs frequently in medical malpractice suits. The potential for communication miscues during a surgical procedure is endless. Such errors can occur in writing—whether failing to follow written surgical protocols or clearly documenting in the medical record. Verbal mishaps are also of great potential, ranging from miscommunication concerning instruments and equipment to failing to communicate the patient's status. Finally, postoperative communications can occur in a myriad of ways between caregivers, between caregivers and the patient (and/or family members), and in the written medical chart.

Perceived Arrogance or Lack of Caring

Patients are more likely to sue arrogant and less caring physicians than they are to sue kind and compassionate physicians. The decision to sue one's physician is usually a very personal

Table 3.1 Communication breakdowns

Miscommunication between two or more healthcare providers	Miscommunication between providers and patients	Miscommunications that fall into both categories
57%	55%	12%

Data from CRICO Strategies. Malpractice risks in communication failures 2015 Annual Benchmarking Report. 2015

and difficult decision to make—especially when that physician is well liked by the patient. When the physician is arrogant, or seems not to care about the patient, the consideration of the personal relationship between the patient and physician is less of a factor. When it is considered, however, and the relationship is viewed in a negative light, it can become a catalyst to sue. In one survey of over 225 patients that sued their physician, a number of respondents stated that in addition to the injury, the lack of sympathy and poor communication that occurred subsequent to the incident was influential in the decision to sue [9].

In the eyes of the patient, the arrogant and dismissive physician does not have time for the patient. The patient is of the mind-set that the physician did not carefully discuss the risks, benefits, and alternatives to the treatment; did not allow the patient to ask meaningful questions; and provided an overall negative experience for the patient. When a complication occurs, the patient often refers back to the interactions with the physician and concludes that the physician did not care about the patient, had no interest in learning about the patient's unique circumstances, and therefore the surgical technique must have been careless and hurried. Arrogance and the lack of caring during postoperative visits solidifies these thoughts and pushes the patient even further in the direction of suing the physician.

In contrast, a physician who has compassion and takes time to communicate with the patient establishes a much better rapport and level of trust. The patient does not feel like he or she is "just another number" and has a better understanding of the treatment in question. The patient also feels that he or she and the physician are on the same team and that they are going through the treatment process together.

Unexpected Outcome

At the outset, it is important to recognize that patients seek medical attention to find a cure. Sometimes this expectation is warranted, sometimes it is not. It is also important to recognize that when patients seek assistance from institutions or physicians with certain name recognition or reputations, they believe they will be cured. In fact, they may have been to several previous physicians who praised these healthcare providers and advised the patients that only a select number of physicians can solve their problem. The patients sometimes pay large sums of money and travel long distances to seek this treatment. Certainly, after all of this trouble, they expect to be cured. If they are not, or if a complication occurs, they believe the physician must have done something incorrectly.

Scenarios like the aforementioned play out in the minds of patients throughout this country every day. One manner in which to prevent the patient from immediately accusing a physician of negligence upon the occurrence of a complication is to properly and thoroughly educate that patient. Patients have high expectations, and rightfully so, but they also need to understand that complications do occur in the absence of negligence. Patients must understand the risks, benefits, and alternatives to a procedure or surgery. They must understand that the possible outcomes can range from death (in some cases), to complete cure, and all potentials in between. When these factors are communicated to the patient, an unexpected outcome should not come as a complete surprise. Setting these expectations should immediately lessen the knee-jerk reaction that negligence occurred. Involving the patient's family members (when appropriate) in the informed consent process is also prudent. Obviously, documenting that the informed con-

sent process took place is necessary and will greatly assist in the defense of medical negligence allegations.

Significant Damages

Every so often a patient or family will experience damages or a loss so significant that they feel that a lawsuit is the only option. Significant complications and death can devastate a family emotionally and financially. Even when no negligence has occurred, it is this devastation that leaves the patient or family feeling as if litigation is the only option. Such instances include the incapacitation or death of a family's main breadwinner. The shock of the loss is overwhelming. Next come questions about how the family will survive financially and how it will pay for future expenses such as mortgages, college educations, and retirement. Patients and families are left to believe that absent a large settlement or verdict resulting from litigation, they are forever financially doomed. Hopefully such scenarios are few and far between for patients, their families, and physicians, but they do exist.

Patients/Families Need Answers

Many plaintiffs' lawyers have said that their clients turned to litigation because the hospital or physicians would not answer their questions. When complications or unexpected outcomes occur, patients and family members desire to understand how and why. When they do not receive the answers they seek, or when they feel that hospitals and physicians are hiding evidence, they believe they have no choice but to turn to litigation. Transparency with patients and family members can avoid the need to turn to litigation to seek answers.

To Prevent a Similar Event from Happening Again

A number of patients cite the desire to prevent similar incidents of perceived or actual malpractice from happening again [9]. Injuries due to adverse outcomes or medical negligence can have devastatingly long-term effects. This can create a patient's desire to prevent future similar outcomes. When a patient feels that there is a lack of cooperation from a physician or hospital system, litigation may be the only avenue to affect change. Accordingly, it behooves healthcare providers to investigate adverse outcomes, either through peer review or other protected mechanisms. Under the proper circumstances, quality and process improvements may be shared with the patient without breaching legal protections provided to the peer review process. These discussions can demonstrate to patients that processes have been put in place to prevent a similar occurrence from happening again in the future, which should lessen the chance of litigation.

Types of Patients Who Sue

Wealthy Patients

It is a misconception that low-income patients are more likely to sue their physicians than their more well-off counterparts [10]. Wealthy patients are likely to sue a physician when things go wrong for a number of reasons. Wealthy patients are usually well educated and have researched their medical condition and physician. They have high expectations and view unexpected outcomes with skepticism. In addition, economic damages such as past and future lost wages are greater for wealthy patients, and therefore the potential settlement or verdict range is much higher than it is for middle class or poor patients. As a practical matter, a wealthy patient's economic damage claim is much more attractive to a plaintiff's attorney than an indigent patient's lower value claim.

Patients with Medical or Legal Connections

Patients with medical or legal connections are more likely to sue [11] because they use those resources when contemplating legal action. Having a physician or attorney as a family member or neighbor makes it easy for the patient to

call on that expertise. That physician or attorney may then direct the patient to additional contacts that will further facilitate the investigation into the care in question. Patients without such contacts may find it too burdensome or expensive to seek such guidance on complicated issues such as medical care whereas the patient with medical or legal connections has free access to medical and legal opinions.

Demanding and Hard-to-Satisfy Patients

Physicians often recognize a future problem when they encounter a patient who demands certain medications, a certain procedure, or is overall difficult to satisfy. These types of patients should raise red flags immediately and should be treated with extra attention [11]. When dealing with the demanding or hard-to-satisfy patient, a physician may need to spend additional time communicating with the patient and documenting those communications. In addition, the physician must not get "pushed around" by the patient or talked into prescribing unnecessary medication or performing an unwarranted procedure. It is important to stick to sound medical decision making and thoroughly document the rationale for doing so. If such measures are taken, the physician will be well protected against the allegations of this troublesome patient.

Patients Who Have Sued Other Physicians

This may seem obvious, but patients that have sued their past physicians are not averse to suing their present or future physicians [11]. However, just because a patient has been involved in prior litigation does not mean that a physician should refuse to see that patient. The patient may have had completely valid reasons for the prior suit or certain unknown circumstances could have prompted the litigation [11]. Accordingly, prior litigation does not automatically mean that the patient is overly litigious or likely to sue. Prior litigation is reason to be cautious and additional communication and medical record documentation is advised.

Causes of Action in Surgical Cases

Medical malpractice lawsuits against any surgeon generally involve claims that include failure to diagnose, surgical technique, informed consent, and failure to monitor. However, some variations of these general causes of action appear more frequently in urologic surgery cases. The causes of action most often filed against a urologic surgeon include improper performance of a procedure, error in diagnosis, failure to recognize a complication, failure to supervise or monitor a case, failure to create a proper follow-up plan, and failure to perform a proper preoperative workup of the patient [2, 12].

One type of claim criticizes the activities of the surgeon even before the surgery begins. A number of intraoperative and postoperative adverse events can be traced to the preoperative workup of the patient. When an expert witness is reviewing a patient's medical chart who experienced an adverse event in the surgical setting, the patient's preoperative records are well studied. On certain occasions the expert will criticize the preoperative workup for a number of reasons. First, the expert may find that the surgeon failed to obtain a complete history and physical. It may also be alleged that the surgeon failed to order appropriate testing such as cardiac clearance, or performed inappropriate or inadequate testing. This is especially true in cases where the patient suffered a respiratory or cardiac event during or subsequent to the operation in question. When arriving at preoperative testing decisions, it is advised to properly document the decision-making process. To that end, the previously mentioned lack of informed consent claim is also a presurgical issue that is often the subject of litigation.

The failure to recognize a surgical complication is a popular claim against surgeons. The failure to recognize postoperative bleeding is a commonly pled postoperative complication. It is

important to recognize that this allegation implicates several members of the team that cares for the postoperative patient, including the surgeon, trainees, anesthesia, and nursing staff. It is frequently claimed that the patient's lab results, blood pressure, and clinical picture revealed an internal bleed that went unnoticed and unacted upon by the team. A similar allegation involves failing to recognize injury to adjacent structures, organs, or nerves.

Every so often a patient will experience a complication which leads the patient to believe that the attending surgeon allowed trainees to perform the procedure or surgery without proper supervision. This is especially true in cases where the attending surgeon is "world renowned" and the patient has the mistaken belief that complications are impossible in that surgeon's hands. Accordingly, when an adverse outcome presents itself, the patient believes that the only possible manner in which such an outcome can occur is if the attending surgeon allowed unsupervised trainees to perform the surgery. It is important to educate the patient on the various roles of the team members and that the attending surgeon may not be the only individual performing portions of the surgery.

Surgical Mesh Litigation

A major source of litigation indirectly involving pelvic floor surgeons is the product liability lawsuits filed against the manufacturers of surgical mesh used to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Fortunately, surgeons do not usually get sued in ordinary product liability cases, but the lessons learned from the tens of thousands of cases filed against the surgical mesh manufacturers serve as valuable reminders to those operating in this space.

It is well documented that as early as 2008 the U.S. Food and Drug Administration (FDA) issued a Public Health Notification about adverse events relating to urogynecologic use of surgical mesh to treat POP and SUI [13]. The FDA updated this communication in 2011 and warned surgeons that complications from surgical mesh used to repair POP include vaginal mesh erosion, pain, infection, urinary problems, and bleeding [14]. The FDA also warned that organ perforation due to surgical instruments was a more frequently reported complication [14]. Of note, the 2011 update dealt only with complications of transvaginal placement for POP.

Importantly, the FDA's 2011 communications on the subject cautioned that the agency's 5-year review of relevant literature revealed that "transvaginally placed mesh in POP repair does NOT conclusively improve clinical outcomes over traditional non-mesh repair" [15]. Furthermore, before recommending the placement of surgical mesh, a surgeon should consider the following:

- Nonsurgical alternatives
- Nonmesh surgery
- Abdominal placement of mesh
- Transvaginal placement of mesh when no preferable alternatives exist [14]

When recommending mesh surgery to patients, surgeons must ensure that their patients understand the permanency of mesh and the significant complications that could materialize. It may also be useful to provide patients with outcomes data or literature on these complications.

In addition to making recommendations to surgeons, the FDA also issued recommendations to patients [14, 15]. Accordingly, urogynecologic surgeons may experience more detailed and advanced questioning from patients. Likewise, the increased media attention and attorney advertisements concerning surgical mesh litigation are likely to further bring awareness to the public on the issues surrounding transvaginal surgical mesh.

As with any surgical procedure, the decision to proceed with abdominally or transvaginally placed surgical mesh should be one made with careful deliberation and in consultation with the patient. Documentation of this decision making and consultation process is an absolutely necessary practice to undertake.

Conclusion

Certainly, providing a higher quality of care with better outcomes lessens a physician's chances of being sued. But as discussed in this chapter, care, treatment, and outcomes are not the only factors that influence a patient's decision to sue. Recognizing other dynamics such as communication style and setting expectations can certainly change a patient's outlook on the entire medical treatment process. If physicians can combine enhanced surgical technique with proper communication while recognizing what types of patients are more likely to sue when something goes wrong, the physician should be successful in implementing a proactive approach to avoid litigation while rendering appropriate care to the patient.

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General Complications of Pelvic Reconstructive Surgery

4

Ellen R. Solomon and Matthew D. Barber

Assessing Perioperative Risk

Before a patient undergoes pelvic reconstructive surgery, the risk of potential complications should be carefully assessed and addressed with the patient. Complications may occur during or after the procedure and it is imperative to recognize high-risk patients and minimize risk from surgery before a patient is brought to the operating room. The lifetime risk of a woman undergoing prolapse or incontinence surgery by the age of is 19% [1, 2]. The prevalence of perioperative complications among women undergoing reconstructive pelvic surgery has been reported to be as high as 33% [3]. There are a multitude of factors that are found to increase perioperative risk. A large retrospective cohort study including 1931 women who had undergone prolapse surgery found an overall complication rate of 14.9% [4]. The complications identified included infection, bleeding, surgical injuries, pulmonary, and cardiovascular morbidity. These complications were associated with medical comorbidities (odds ratio 11.2) and concomitant hysterectomy (odds ratio 1.5). Risk factors for complications after pelvic reconstructive surgery are listed in Box 4.1.

Obesity is an increasingly important risk factor for perioperative complications. The prevalence of obesity continues to rise in industrialized countries [5]. With obesity, there is an increase in comorbid conditions including incidence of cardiac disease, type two diabetes, hypertension, stroke, sleep apnea, and some cancers [6]. One study of obese and overweight women found that obese women had significantly increased estimated blood loss and operative time [7]. In a retrospective cohort study from 2007, obese patients who underwent vaginal surgery were matched to patients who were of normal weight and perioperative comorbidities and complications were analyzed. This study found that there was no difference in perioperative complications between obese and nonobese patients; however, there was a higher rate of surgical site infection in the obese population [8].

In obese women undergoing hysterectomy, the abdominal approach results in significantly higher rates of wound infection than those receiving a vaginal hysterectomy [9]. In a recent systematic review, it was found that compared with vaginal and laparoscopic hysterectomy, patients with a BMI over 35 who underwent abdominal hysterectomy had

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Box 4.1 General risk factors of pelvic reconstructive surgery

- Risk factors
- Age
- Central nervous system disease
- Coronary heart disease
- Diabetes
- Hypertension
- Obesity
- Peripheral artery disease
- Pulmonary disease

increased postoperative complications and longer hospitalizations [10]. Overall, vaginal surgery appears to be a safer approach for obese women [11]. It is important to assess BMI when planning route of surgery and to consider increased risks with this population. In a large retrospective cohort study performed in Sweden, it was found that women who had a BMI ≤25 were more likely to have increased blood loss, and longer duration of surgery and women with a BMI ≥35 were more likely to have postoperative infections [12]. Furthermore, in a large retrospective study where data were abstracted from the American College of Surgeons National Safety and Quality Improvement Project registry, 55,409 women who underwent hysterectomy for benign conditions were studied and it was found that patients with BMIs 40 or higher had five times the odds of wound dehiscence, five times the odds of wound infection, and 89% higher odds of sepsis compared to women with BMIs under 25 [13]. Furthermore, in a large retrospective study of over 18,800 women undergoing hysterectomy for benign conditions, the rates of TAH increased from 45.7% in patients with ideal body weight to 62% in morbidly obese patients, which has higher morbidity than laparoscopic and vaginal approaches [14].

Age is also an important element to consider when assessing perioperative risk. The median age of patients who undergo pelvic reconstructive surgery is 61.5 years [15]. Increasing age corresponds with increasing medical comorbidities including chronic illness, hypertension, coronary heart disease, diabetes, pulmonary disease, and central nervous system disease [16]. A retrospective cohort study of 264,340 women undergoing pelvic surgery found that increasing age is associated with higher mortality risks and higher complication risks. Specifically, elderly women (>age 80) were found to have increased risk of perioperative complications compared with younger women [17]. In this same study, elderly women who underwent obliterative procedures (e.g., colpocleisis) had a lower risk of complications compared to patients who underwent reconstructive procedures for prolapse. In a prospective study of 2-year postoperative survival, survival was worse among 80-year-olds who experienced a postoperative complication [18]. In a retrospective chart review of patients ≥75 years old, 25.8% of patients had significant perioperative complications including significant blood loss, pulmonary edema, and congestive heart failure. Independent risk factors that were predictive of perioperative complications in this patient population included length of surgery, coronary artery disease, and peripheral vascular disease [19]. In a retrospective cohort study including 508 women undergoing urogynecologic surgery, women who were older than age 65 had an increased risk of postoperative complications on the Dindo–Clavien scale when compared to women who were younger than age 65 [20]. When choosing to perform a prolapse or incontinence procedure on an elderly patient, it is important to review the patient's comorbidities.

Cardiac risk factors also impact postoperative morbidity in pelvic surgery. In a retrospective cohort study by Heisler and coworkers [21], perioperative complications were increased in patients with a history of myocardial infarction or congestive heart failure, perioperative hemoglobin decrease greater than 3.1 g/dL, preoperative hemoglobin less than 12.0 g/L, or history of prior thrombosis. In a retrospective analysis of cardiac comorbidities in pelvic surgery by Schakelford and coworkers [22], hypertension and ischemic heart disease were statistically significant risk factors for perioperative cardiac morbidity. It is important to ensure that a patient's cardiac status is optimized prior to proceeding with surgery [23]. In a retrospective cohort study of 4,315 patients undergoing elective major noncardiac surgery,

predictors of major cardiac complications included high-risk types of surgeries, history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and a serum creatinine of ≥2.0 mg/dL [24]. To further decrease cardiac morbidity in patients undergoing surgery, it has also been shown that continuing beta blockers in the perioperative period in patients with chronic beta blockade will decrease cardiovascular mortality [25]. Consultation with the patient's primary care physician or cardiologist prior to surgery is often warranted in patients with cardiac disease.

In conclusion, when considering pelvic reconstructive surgery, it is important to examine and evaluate the whole patient, including her medical comorbidities in order to appropriately assess her perioperative risk. This knowledge will help determine whether or not surgery is appropriate and, when appropriate, what route of surgery and procedure may be best for the individual patient. In high-risk patients, the vaginal route is often the lowest risk approach. In elderly patients no longer interested in sexual activity, obliterative procedures should be considered because of their quick surgical times and low risk of complications relative to reconstructive procedures.

Venous Thromboembolism

Deep venous thrombosis (DVT) and pulmonary embolism (PE), jointly referred to as venous thromboembolism (VTE), are among the leading causes of preventable perioperative morbidity and mortality. In the perioperative period, the risk of death after VTE is approximately 3–4% [26]. During surgery, the combination of epithelial damage, venous stasis, and hypercoagulability, collectively referred to as Virchow's triad, increases the risk of any patient undergoing surgery. Many pelvic reconstructive surgeries require the dorsal lithotomy position and steep Trendelenburg positions which exacerbate the risk of venous stasis. The postoperative risk of VTE may be elevated up to 1 year after the initial procedure has been performed but is highest in the immediate perioperative period [27].

The risk of VTE has been well studied in the general surgery, urology, and gynecologic oncology population. Recently, there have been large studies that have addressed this issue in the population of patients who undergo pelvic reconstructive surgery. In a large cohort study by Montoya and coworkers, it was found that the risk of VTE in this patient population that used intermittent pneumatic compression devices as the main form of postoperative thromboprophylaxis was 0.25% [28]. This is similar to a smaller study by Solomon and colleagues where the risk of VTE was 0.3% [29]. In a large systematic review by Rahn and colleagues, it was found that intermittent pneumatic compression devices provide sufficient prophylaxis for most patients undergoing pelvic reconstructive surgery [30]. Risk factors that the authors determined should have additional chemoprophylaxis with intermittent compression devices were patients with two out of the three risk factors assessed: age over 60, history of cancer, or history of past venous thromboembolism.

In another retrospective cohort study of 1356 patients undergoing sling and/or prolapse procedures, the rate of VTE was 0.9% in women who had a sling alone and 2.2% in women who had concomitant prolapse surgery (p =0.05) [31]. While this study gives rise to concern of concomitant procedures, it remains unclear if any of the patients received thromboprophylaxis during this study, and therefore it is difficult to assess actual patient risk. In a retrospective review by Nick and colleagues [32], the incidence of DVT was assessed among patients who underwent laparoscopic gynecologic surgery and found to be 0.7%. Overall, it seems that the risk is below 1% in the population undergoing urogynecologic procedures.

A number of risk factors for VTE have been suggested for women undergoing pelvic surgery. In a retrospective review of 1232 patients who underwent surgery for gynecologic conditions in Japan, it was found that malignancy, history of VTE, age greater than 50, and allergic-immunologic disease were all statistically significant risk factors for VTE [33]. However, this study only found three episodes of VTE in patients with benign disease making it signifi-

cantly underpowered for this patient group. In a questionnaire study by Lindqvist and colleagues [34] that included 40,000 women, it was found that moderate drinkers and women who engaged in strenuous exercise most days were at half the risk of VTE compared to women who were heavy smokers and lead sedentary lifestyles (increased risk of 30%).

In a retrospective review of gynecologic surgery patients, 1862 patients given VTE prophylaxis with intermittent compression devices alone, incidence of VTE was 1.3%. The risk factors associated with VTE were diagnosis of cancer, age over 60, anesthesia over 3 h. Patients with two or three of these variables had a 3.2% incidence of developing VTE vs. 0.6% in patients with zero or one risk factor [35].

The question of which thromboprophylactic modality is best in the perioperative period is difficult to answer for women undergoing pelvic reconstructive surgery. As mentioned previously, in the study by Montoya and colleagues [28], the rate of VTE among patients who underwent pelvic reconstructive surgery was 0.25% where the only thromboprophylaxis used was sequential compression devices placed during the perioperative period. The American College of Obstetricians and Gynecologists [36] follow the recommendations provided by the American College of Chest Physicians from the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy, published in 2004. The ACCP has since updated its recommendations for prophylaxis in all surgical patients (Table 4.1). Furthermore, they recommend chemothromboprophylaxis in patients who are moderate and high risk. Most female pelvic reconstructive surgery patients fall into the "high"-risk category; therefore, it is now recommended that patients in our population should receive chemothromboprophylaxis [37]. However, the rate of thromboprophylaxis is below 1.5% in our population and it could be argued that our patients fall into the very low-risk category, where no specific recommendations for prophylaxis are made.

It is essential to be able to recognize the symptoms of VTE in the postoperative patient. While many patients who have VTE may be asymptomatic, the symptoms of dyspnea, orthopnea, hemoptysis, calf pain, complaints of calf swelling, chest pain, and tachypnea may signify a thrombotic event [38]. The physical signs that suggest VTE include hypotension, tachycardia, crackles, decreased breath sounds, lower extremity edema, tenderness in lower extremities, and hypoxia [39]. Although the signs and symptoms of VTE are well known, it is difficult to rule out VTE by clinical diagnosis alone. A systematic review evaluating the d-dimer test used in combination with clinical probability to rule out VTE found that the d-dimer test is a safe and relatively reliable first-line test to use. After a 3-month follow-up, only 0.46% of patients were later diagnosed with PE [40]. However, d-dimer test is not useful in pregnant patients, the elderly, and hospitalized patients due to decreased specificity [41].

Compression ultrasonography is a noninvasive, easy, and cost-effective procedure for the diagnosis of DVT in the lower extremities. The sensitivity and specificity for detecting DVT using compression ultrasonography in symptomatic patients is 89–96%, although the sensitivity is decreased in patients with calf DVT or asymptomatic patients [42]. Compression ultrasonography may also be used in conjunction with other diagnostic tests if PE is suspected [43]. If compression ultrasound is negative but the patient remains symptomatic, venography may be used to further rule out DVT [44].

Indicated imaging for patients presenting with signs and symptoms of PE includes ventilation perfusion scanning (V/Q), computed tomography (CT), pulmonary angiography, and spiral CT of the chest. The V/Q scan was the imaging modality of choice for decades; however, due to lack of ease of use and potential for indeterminate testing, CT has become the modality of choice [45]. CT angiography has specificity of 96% as well as 83% sensitivity [38]. This has become the gold standard for PE diagnosis. CT looking for PE may vary across centers due to type of CT used and radiologist's ability to make the diagnosis.

It is important to start anticoagulation immediately once VTE has been diagnosed; furthermore, if there is high suspicion for PE, anticoagulation

Table 4.1 American College of Chest Physicians risk for venous thromboembolism in patients undergoing surgery

Level of risk	Definition[a]	Recommended prevention strategy
Very low	<0.5% risk of VTE (Most outpatient or same-day surgery)	No specific recommendations
Low	Minor surgery (1.5% risk) (ex: spinal surgery for nonmalignant disease)	Mechanical prophylaxis, preferably with SCDs
Moderate	Major surgery includes most general, open gynecologic, and urologic cases (3% risk) (gynecologic noncancer surgery, cardiac surgery, thoracic surgery, spinal surgery for malignant disease)	LMWH, LDUH, plus mechanical thromboprophylaxis with ES or SCDs
High	Major surgery, or patients with additional VTE risk factors[b] (6% risk) (bariatric surgery, gynecologic cancer surgery, craniotomy, traumatic brain injury, spinal cord injury)	LMWH or LDUH, plus mechanical prophylaxis; use mechanical prophylaxis until bleeding risk diminishes
High-risk cancer surgery		LMWH or LDUH plus mechanical prophylaxis and extended-duration prophylaxis with LMWH postdischarge.
High risk, LDUH and LMWH contraindicated or not available		Fondaparinux or low-dose aspirin (160 mg); mechanical prophylaxis with SCDs, ES or both.

Modified with permission of Elsevier from Gould MK, Garcia DA, Wren SM, Karanicolas PJ, Arcelus JI, Heit JA, Samama CM; American College of Chest Physicians. Prevention of VTE in nonorthopedic surgical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012 Feb;141(2 Suppl):e227S–77S

Bid twice daily, *LDUH* low-dose unfractionated heparin, *LMWH* low-molecular-weight heparin, *tid* three times daily, *VTE* venous thromboembolic events, *SCDs* sequential compression devices, *ES* elastic stockings

[a]Descriptive terms are purposely left undefined to allow individual clinician interpretation

[b]Additional risk factors include major trauma or lower extremity injury, immobility, cancer, cancer therapy, venous compression (from tumor, hematoma, arterial anomaly), previous VTE, increasing age, pregnancy and postpartum period, estrogen-containing oral contraceptive or hormone replacement therapy, selective estrogen receptor modulators, erythropoiesis-stimulating agents, acute medical illness, inflammatory bowel disease, nephritic syndrome, myeloproliferative disorders, paroxysmal nocturnal hemoglobinuria, obesity, central venous catheterization, and inherited or acquired thrombophilia

may be started even before the diagnosis is confirmed. Acute PE should be treated initially with a rapid onset anticoagulant which may be followed by treatment with a vitamin K antagonist for at least 3 months [40]. For rapid onset anticoagulation, patients may be started on IV unfractionated heparin, subcutaneous unfractionated heparin, subcutaneous low molecular weight heparin, and subcutaneous fondaparinux. The American College of Chest Physicians recommends using subcutaneous low-molecular-weight heparin for the initial treatment of acute, nonmassive, PE. If the patient has decreased kidney function, morbid obesity, or is pregnant, IV unfractionated heparin may be used due to its shorter duration and titratability [45]. Once anticoagulation therapy has been established, the patient may continue on subcutaneous therapy or can be bridged to warfarin for at least 3 months. Warfarin may be more acceptable to patients because of its oral route and ease of use; however, warfarin requires continuous monitoring and titration [46]. If the patient has contraindications to anticoagulation therapy, an inferior vena cava (IVC) filter can be considered.

Pulmonary Complications

Postoperative pulmonary complications are a frequent cause of morbidity and mortality. Postoperative pneumonia, atelectasis, pneumothorax,

and respiratory failure increase length of stay and are more common than postoperative cardiac complications [47]. The incidence of postoperative pulmonary complications in gynecologic patients has been reported to be between 1.22 and 2.16% [48]. There are multiple risk factors that may increase pulmonary complications in the postoperative surgical patient. In a prospective randomized trial of patients who underwent nonthoracic surgery, multivariate analysis showed four risk factors for postoperative pulmonary complications which were age greater than 65, positive "cough test," perioperative nasogastric tube, and duration of anesthesia (procedures lasting longer than 2.5 h) [49]. A retrospective review of patients undergoing gynecologic laparoscopy found that operative time greater than 200 min and age greater than 65 contributed to hypercarbia. Predictors of the development of pneumothorax included pneumoperitoneum CO_2 pressure greater than 50 mmHg and operative time greater than 200 min [50].

In a retrospective review of 3226 patients who underwent hysterectomy for benign conditions, it was found that the overall incidence of pulmonary complications in the benign gynecologic patient population was extremely low −0.3% (95% CI, 0.17–0.57%) [51].

Surgical approach is also a contributing factor for the development of a postoperative pulmonary complications. A study of patients undergoing abdominal surgery found that age greater than 60, smoking history within the past 8 weeks, body mass index greater than or equal to 27, history of cancer, and incision site in the upper abdomen or both upper/lower abdominal incision were identified as independent risk factors for postoperative pulmonary complications [52].

In a prospective randomized control trial involving 994 patients by Xue and colleagues [53], patients were divided into three groups (1) elective superficial plastic surgery, (2) upper abdominal surgery, and (3) thoracoabdominal surgery. It was found that the incidence of hypoxemia in the postoperative period was closely related to the operative site, where upper abdominal and thoracoabdominal sites gave the greatest risk. When evaluating this study, patients undergoing pelvic reconstructive surgery would most likely fall into the low-risk category similar to elective superficial plastic surgery, with a low risk of hypoxemia in the postoperative period.

Another risk factor associated with postoperative pulmonary complications is smoking. In a prospective cohort study of patients referred for nonthoracic surgery, the risk for postoperative pulmonary complications was increased by age of greater than 65 years or more and smoking of 40 pack-years or more [48]. In a retrospective review performed on 635,265 patients from the American College of Surgeons National Surgical Quality Improvement Program database, current smokers had increased odds of postoperative pneumonia and unplanned intubation [54]. Pulmonary complications significantly decrease after 8 weeks of smoking cessation [55]. Chronic obstructive pulmonary disease patients are at increased risk of having postoperative pulmonary complications. Preoperative pulmonary function tests may help to identify patients with increased pulmonary risk [56]. Patients with COPD were found to be 300–700 times more likely to have a postoperative pulmonary complication in a prospective cohort study [48]. Nasogastric intubation instead of orogastric intubation increases risk of pneumonia in this patient population as well [57].

Sleep apnea is an additional risk factor for postoperative pulmonary complications. Obstructive sleep apnea is defined as partial or complete obstruction of the upper airway during sleep [58]. The prevalence of sleep apnea is around 5% [59]. In an additional study evaluating the prevalence of sleep apnea in the general surgery population, 22% of surgical patients were found to have obstructive sleep apnea [60]. Therefore, we can hypothesize that obstructive sleep apnea is a prevalent and important risk factor for postoperative pulmonary complications in our population as well. In a retrospective cohort study of orthopedic and general surgery patients by Memtsoudis and colleagues [61], 51,509 patients with sleep apnea who underwent general surgery procedures were assessed for postoperative pulmonary complications. It was found that patients with sleep apnea developed pulmonary

complications more frequently than their matched controls. Due to relaxation of the pharyngeal muscles from anesthetic agents, sedatives, and opioids, patients with obstructive sleep apnea may have increased airway collapse in the postoperative period [62]. The supine position that occurs during surgery and in the postoperative period may worsen obstructive sleep apnea [63]. Anesthesia may also blunt the hypercapnic and hypoxic respiratory drive as well as the arousal response. In a study performed by Bolden and coworkers [64], the frequency of postoperative hypoxemia was measured in OSA patients in the postoperative period where 16% of the patients studied found multiple measured postoperative desaturations.

To avoid hypoxemia in OSA patients, it is necessary to encourage patients to bring with them their home continuous positive airway pressure (CPAP) machines, or to order home CPAP settings for CPAP hospital machines. Careful evaluation of the patient is essential to preventing postoperative complications. If a patient is suspected to have OSA but has not been diagnosed, it is useful to place the patient under continuous pulse oxygen saturation monitoring for the first 24 h after surgery [58].

Atelectasis and hypoxemia are common after surgery especially surgeries that involve the abdomen or thorax. Early on, atelectasis may result from soft tissue edema from the upper pharynx due to intubation and tongue manipulation. Later, especially in patients who have undergone abdominal surgery, there is decreased ability to take in deep breaths or cough due to postoperative pain. Postoperative patients have decreased functional residual capacity [65]. These factors lead to hypoventilation. Diagnosis of atelectasis may be made clinically and/or via imaging tests. Atelectasis may present as postoperative fever, decreased breath sounds at the lung bases, and can be found on chest-X-ray or CT.

Pre- and postoperative incentive spirometry is the most common prevention and treatment intervention for atelectasis. Incentive spirometry used in the perioperative period enhances postoperative functional residual capacity and reminds patients to continue to take in large breaths. If the patient becomes hypoxic from atelectasis, bronchoscopy may be performed to remove secretions from the airway [66]. Continuous positive airway pressure (CPAP) can be used in the postoperative period and has also been shown to decrease intubation in patients who are at high risk of hypoxemia from atelectasis after abdominal surgery [67].

Postoperative pneumonia is a common postoperative pulmonary complication. Hospital-acquired pneumonia refers to pneumonia that develops after 48 h in the hospital. Diagnosing postoperative pneumonia can be difficult. Infiltrates from atelectasis, pulmonary edema, and acute lung injury can all look identical to pneumonia on chest X-ray. Diagnosis should be suspected if patient has new onset fever, purulent sputum, leukocytosis, hypoxemia, and infiltrate on chest X-ray (American Thoracic Society, 2002) [68]. In a prospective case series of patients presenting with postoperative pneumonia within 14 days of surgery, 61% of patients developed pneumonia within the first 5 days postoperatively. The most common etiologic agents were *Staphylococcus aureus*, *Streptococci*, and *Enterobacter* [69].

Treatment of postoperative pneumonia should begin with broad-spectrum antibiotics given the polymicrobial nature of hospital-acquired pneumonia. Recommendations by the American Thoracic Society and the Infectious Disease Society of America include coverage for aerobic bacteria as well as anaerobic coverage. Most hospitals have guidelines for treating hospital-acquired pneumonia based on regional microbial infection.

Urinary Tract Infection

Urinary tract infections (UTIs) are one of the most common infections seen in the postoperative period. The incidence of UTIs rises with increasing age. Eighty percent of UTIs are caused by bladder instrumentation, with catheter-associated UTI (CAUTI) being most common [70]. The rate of bacteruria after undergoing an anti-incontinence procedure has been estimated

to be between 17 and 85% [71]. Reconstructive pelvic surgery almost always involves bladder instrumentation via cystoscopy and/or catheter placement, thereby increasing the risk of UTI in these patients. Additional risk factors for UTI include inefficient bladder emptying, pelvic relaxation, neurogenic bladder, asymptomatic bacteriuria, decreased ability to get to the toilet, nosocomial infections, physiologic changes, and sexual intercourse, all seen commonly in the reconstructive pelvic surgery population [72]. Development of a fever in the postoperative period after female pelvic reconstruction should warrant a urinary tract evaluation; however, it is rare that lower UTI causes fever in itself.

There have been multiple trials evaluating risk of UTI after urogynecological procedures including the SISTEr trial of Burch vs. autologous sling for treatment of stress urinary incontinence, where the reported rate of UTI was 48% in the sling cohort and 32% in the Burch cohort during the first 24 months of follow-up [73]. In the TOMUS trial, retropubic midurethral slings were associated with significantly more UTIs than transobturator slings in the first 6 weeks after surgery (13% vs. 8%, $p = 0.3$) and after 24 months follow-up (21% vs. 13%, $p = 0.02$) [74]. In a case–control study of women undergoing surgery for stress urinary incontinence and/or pelvic organ prolapse, 9% of women developed UTI and the risk of UTI was significantly increased by previous history of chronic or multiple UTIs, prolonged duration of catheterization, and increased distance between the urethra and anus [75].

Signs and symptoms of UTI in women are varied. Common cystitis symptoms include frequency, urgency, nocturia, dysuria, suprapubic discomfort, hematuria, and occasional mild incontinence. Fever, chills, general malaise, and costovertebral angle tenderness are associated with upper UTI [71]. There are multiple ways to diagnose UTI. Urine dipstick testing can detect the presence of leukocytes, bacteria, nitrates, and red blood cells. It also measures glucose, protein, ketones, blood, and bilirubin. In the office, the dipstick test can be used as a rapid diagnostic test. It can measure leukocyte esterase nitrates, hematuria, and pyuria. In the setting of leukocytosis, and/or nitrites and hematuria, the sensitivity to detect UTI is 75%, but the specificity is 66% with a positive predictive value of 81% and a negative predictive value of 57% [76]. The most important predictor of UTI measured by microscopy is leukocytosis; however, leukocytosis alone is not sufficient to diagnose UTI [77]. The gold standard to diagnosing UTI is a urine culture. The traditional diagnosis of UTI by culture is greater than 100,000 colony forming units/mL (CFU); however, many women may have asymptomatic bacteriuria. In a study performed by Schiotz [78], 193 women who underwent gynecologic surgery and had a Foley catheter for 24 h were assessed for bacteriuria; 40.9% of patients had asymptomatic bacteriuria, while only 8.3% of patients actually developed UTI. In contrast, those with fewer than 100,000 CFU but symptoms of UTI can also be appropriately diagnosed as having a UTI.

The most common pathogen causing complicated and uncomplicated UTI is *E. coli*. The definition of complicated UTI is associated with a condition that increases the risk of acquiring infection or failing first-line treatment. Many patients with pelvic floor disorders with UTI may fit into the complicated category because they are status/postcatheterization and procedures [79]. Other uropathogens include *Klebsiella*, *Pseudomonas*, *Enterobacter*, *Enterococcus*, and *Candida*. The initial therapy for treatment of UTI traditionally has been Trimethoprim–Sulfamethoxazole (TMP–SMX) if the resistance in the population is less than 20%. However, due to empiric treatment of UTIs in the past, resistance for TMP–SMX and amoxicillin is high and has been reported to be up to 54% for TMP–SMX and 46% for penicillins. Nitrofurantoin has been well studied and is an additional agent used frequently to treat UTIs. It is a cost-effective agent that may be used in the setting of fluoroquinolone and TMP–SMX resistance [80]. *When treating a postoperative reconstructive patient, it is important to evaluate the antimicrobiogram in the specific hospital setting and to prescribe accordingly.*

It is clear that patients who undergo female pelvic reconstructive procedures require antibiotics prophylaxis at the time of the procedure [81]. The American Urologic Association Best Practice Guidelines [82] recommend antibiotic prophylaxis for vaginal surgery to prevent both

Table 4.2 American Urological Association recommended antimicrobial prophylaxis for urologic procedures

Procedures	Organisms	Antimicrobials of choice	Alternative antimicrobials	Duration of therapy
Vaginal surgery and/or slings	*E. coli*, *Proteus* sp., *Klebsiella* sp., *Enterococcus*, skin flora, and Group B *Strep*.	First/second-generation cephalosporin	Ampicillin/sulbactam	≤24 h
			Fluoroquinolone	
		Aminoglycoside+ metronidazole or clindamycin		

Modified with permission of Elsevier from Wolf JS Jr., Bennett CJ, Dmochowski RR, Hollenbeck BK, Pearle MS, Schaeffer AJ. Urologic surgery antimicrobial prophylaxis best practice policy panel. J Urol. 2008;179(4):1379–90. Erratum in J Urol. 2008;180(5):2262–3

postoperative UTI and postoperative pelvic infection (Table 4.2). A prospective randomized trial by Ingber and coworkers [83] found that patients who were given single-dose antibiotic therapy for midurethral slings had a low rate of postoperative UTI (5.9%). Clinical trials have been mixed about whether multiple doses of antibiotics in the perioperative period decrease UTI rates beyond single-dose therapy [84]. What is also unclear is the need for prophylactic antibiotics beyond the perioperative period in patients who will require prolonged catheterization. In a randomized, double-blind controlled trial by Rogers and coworkers [81], 449 patients who underwent pelvic organ prolapse and/or stress urinary incontinence surgery and had suprapubic catheters placed were given either placebo or nitrofurantoin monohydrate daily while the catheter was in place to assess rate of UTI. The study found that there was a significant decrease in positive urine cultures, as well as symptomatic UTI at suprapubic catheter removal with nitrofurantoin prophylaxis; however, there was no difference in symptomatic UTIs at the 6–8 week postoperative visit. A similar trial evaluating nitrofurantoin daily prophylaxis in patients with prolonged transurethral catheterization after pelvic reconstructive surgery found that daily nitrofurantoin during catheterization did not reduce risk of postoperative UTI [85].

Surgical Site Infections

Infection complicating pelvic surgery can occur in three different settings: (1) fever of unknown origin, (2) operative site infection, and (3) infection remote from surgery. The pathological source of most surgical site infections is from bacteria located on the skin or in the vagina. Skin flora is usually aerobic gram positive *cocci*, but may include gram negative, anaerobic, and/or fecal flora if incisions are made near the perineum and groin [86]. Pelvic reconstructive surgery almost always involves the vagina and perineum and therefore places all of our patients at increased risk for surgical site infections. Other patient comorbidities that may increase the risk of surgical site infections include advanced age, obesity, medical conditions, cancer, smoking, malnutrition, and immunosuppressant use [87, 88]. Other risk factors for surgical site infection include poor hemostasis, length of stay, length of operative time, and tissue trauma. Specific risk factors for obese patients include increased bacterial growth on skin, decreased vascularity in the subcutaneous tissue, increased tension on wound closure due to increased intra-abdominal pressure, decreased tissue concentrations of prophylactic antibiotics, and a higher prevalence of diabetes with poor glucose control and longer operating time [89]. In a retrospective chart review of patients who underwent midline abdominal incisions, patients with increased subcutaneous fat were 1.7 times more likely to develop a superficial incisional infection [90]. In a prospective study of 5279 patients who underwent hysterectomy, it was found that obese patients who underwent abdominal hysterectomy were five times more likely to have wound infection. Route of surgery was an additional risk factor for infection with the highest risk in patients who underwent abdominal hysterectomy. Patients who underwent laparoscopic or vaginal hysterectomy were

more likely to have remote pelvic infections compared with abdominal hysterectomy [88]. In a large retrospective study of over 22,000 patients undergoing hysterectomy, the rate of surgical site infection overall was 2.04% and it was found that β-lactams given prior to incision were associated with the lowest rate of surgical site infections [91]. It is therefore advised that patients with penicillin allergies should be questioned on their reaction thoroughly and may necessitate penicillin allergy testing prior to surgery to avoid alternate antibiotics if possible. In another large retrospective study of over 55,000 patients undergoing hysterectomy, it was found that compared with those of normal BMI, women with BMIs 40 or higher had five times the odds of wound dehiscence, five times the odds of wound infection, and 89% higher odds of sepsis [13]. Women should be counseled of these findings prior to undergoing hysterectomy.

Use of synthetic mesh may be an additional risk factor for surgical site infection. There have been multiple case studies describing mesh infection. In one retrospective case study of patients who had undergone abdominal sacrocolpopexy, 27% of patients who underwent hysterectomy at the time of sacrocolpopexy became infected requiring mesh removal vs. 1.3% of patients in the same study that had undergone sacrocolpopexy alone [92]. In an additional case series of 19 women who had undergone intravaginal slingplasty with synthetic mesh, six women had infected mesh that had to be removed [93]. In randomized trials comparing native tissue vaginal repair to transvaginal mesh placement using wide-pore [94] polypropylene, the risk of infection appears to be low in some trials and elevated in others [95]; however, many of these studies are small and are not adequately powered to detect differences in infectious morbidity.

Diagnosis of surgical site infection includes pain and tenderness at the operative site and fever. Fever is defined as a temperature of greater than 38 °C on two or more occasions occurring at least 4 h apart [96]. Skin erythema, induration, and/or drainage of purulent or serosanguinous fluid may be visualized on examination. On pelvic exam, there may be pelvic, vaginal cuff, or parametrial tenderness. There may be a leukocytosis on complete blood count [95]. If pelvic abscess is suspected, ultrasound, CT scan, or MRI may be used for diagnosis. Ultrasound is a cost-effective way to image a patient with a suspected abscess. The sensitivity and specificity of pelvic ultrasound to look for pelvic abscess is 81% and 91%, respectively [97]. Computed tomography may be used to diagnose pelvic abscess when the diagnosis by ultrasound is equivocal. However, computed tomography increases exposure to ionizing radiation which may be problematic in younger patients.

Patients with superficial wound cellulitis may be treated with oral therapy. If there is evidence of a wound seroma or hematoma, a small portion of the wound may be opened and/or evacuated. It is important to probe the wound to insure the fascia is intact [98]. It may be necessary to remove staples and sutures in the infected area. Admission is recommended if a patient is febrile, has signs of peritonitis, has failed oral agents, has evidence of a pelvic or intra-abdominal abscess, is unable to tolerate oral intake, or has laboratory evidence of sepsis [95]. Patients requiring admission should receive broad-spectrum parenteral antibiotics. Pelvic abscess may need drainage via opening of the vaginal cuff, CT, or ultrasound-guided drainage [99]. A vaginal cuff abscess may necessitate opening part of or, in some cases, the entire cuff to allow for sufficient drainage. If mesh has been placed, it may need to be removed if directly involved with the infection in order to achieve adequate resolution.

Prevention of wound infection is paramount to the practice of reconstructive pelvic surgery. Good surgical technique, hemostasis, and gentle tissue handling may decrease risk of infection [97]. There have been multiple studies that suggest perioperative cleansing the vagina with saline increases infection rate [100, 101]. Currently, there is no evidence to suggest that cleansing the vagina with any preparation reduces postoperative infection. However, in a retrospective cohort trial of 669 patients who underwent sacral nerve modulation therapy it was found that chlorhexidine washing prior to the procedure may decrease rates of surgical site infections in this population [102].

Table 4.3 Recommended antibiotic prophylaxis by American College of Obstetrics and Gynecology

Procedures	Antibiotic	Dose (single dose)
Hysterectomy, female pelvic reconstructive procedures, procedures involving mesh	Cefazolin[a]	1 or 2 g IV
	Clindamycin plus gentamicin or quinolone or aztreonam	600 mg IV with 1.5 mg/kg or 400 mg IV 1 g IV
	Metronidazole plus gentamicin or quinolone	500 mg IV with 1.5 mg/kg or 400 mg IV

Modified with permission of Wolters Kluwer from ACOG Committee on Practice Bulletins No. 104: antibiotic prophylaxis for gynecologic procedures. Obstet Gynecol. 2009;113(5):1180–9

IV intravenously, *g* grams, *mg* milligrams

[a]Alternatives include cefotetan, cefoxitin, cefurtoxime, or ampicillin–sulbactam

The use of prophylactic antibiotics is an imperative strategy for lowering surgical site infection. Antibiotics should be given within 30 min of incision time to allow for the minimal inhibitory concentrations (MIC) of the drug to be in the skin and tissues at time of incision. Recommendations for prophylactic antibiotic regimens from the AUA and ACOG are listed in Tables 4.2 and 4.3. Cephalosporins are commonly used in pelvic surgery because of their broad antimicrobial spectrum with Cefazolin, the most commonly used agent [87]. Patients who are morbidly obese with BMI greater than 35 should receive increased dosing of antibiotics [88]. Procedures lasting longer than 3 h and blood loss greater than 1500 cc require redosing of antibiotics.

Nerve Injury

Intraoperative nerve injury is a preventable iatrogenic complication. Injury to nerves in the upper and lower extremities, while uncommon, may occur during laparotomy, robotic, laparoscopic, and vaginal procedures. In a prospective cohort study of women who underwent elective gynecologic surgery, the overall incidence of postoperative neuropathy was 1.8% [103]. Brachial plexus injury has a reported incidence of 0.16% [104]. Risk factors for developing nerve injuries during surgery include increased operating room time, patient positioning, and history of smoking [105]. Stretching or direct compression of the nerve results in ischemia, and when prolonged, necrosis can develop [106]. With muscle relaxants given during anesthesia, patients are unable to reposition themselves from nonphysiologic positions, and risk of nerve damage increases. With nerve compression, blood flow to the nerve is decreased, therefore operating room time is a critical factor for nerve injury. The longer a patient is incorrectly positioned, the worse the nerve injury. With the development of robotic surgery, it has been theorized that brachial plexus injuries may become more common [107]. Most robotic procedures require steep Trendelenburg positioning, and depending on the operator, may require longer operating room times. Other risk factors include history of diabetes, alcoholism, and history of herpes zoster [108].

Nerve injuries to the upper extremity mostly occur from overstretching or compression of the brachial plexus or the ulnar nerve. Brachial plexus injury may result in both sensory and/or motor injury. Risk factors for brachial plexus injury include Trendelenburg positioning, longer operating room time, use of shoulder braces, abduction of the arm ≥90°, and unequal shoulder support [103]. Patients with brachial plexus injury may present with numbness of the first, second, and third digits and the radial side of the fourth digit. Patients may experience motor deficits that involve the shoulder, wrist, arm, and hand. In severe cases, patients may experience Erb's palsy or Klumpke's paralysis [106]. Patients with ulnar nerve injury may present with the sensory loss of the lateral hand, with loss of sensation in the fourth and fifth digits.

Management of brachial plexus injury includes physical therapy, analgesics, nonsteroidal anti-inflammatory medications, physical therapy, and neuroleptic medications. Prevention of brachial plexus injury includes utilizing the minimum amount of Trendelenburg positioning, decreasing operating room times as much as possible, avoiding abduction or extension of the upper extremities, and avoiding shoulder braces

[106]. For robotic and laparoscopic surgeries, we recommend padding and tucking the patient's arms to her sides, using a "thumbs up" hand position with the patient's palms facing her thighs to avoid overabduction. To avoid sliding down the operating room table while in Trendelenburg, placing the patient on an egg crate mattress that is taped to the operating room table and then padding the patient's chest with additional foam and tape the foam down to the operating room table can be helpful (Fig. 4.1).

Common lower extremity nerve injuries associated with female pelvic reconstructive medicine include femoral, lateral femoral cutaneous, obturator, sciatic, and common peroneal nerve injuries. Risk factors for lower extremity nerve injuries include ill positioning of the lower extremities using stirrups, lithotomy position, slender patients, smokers, Trendelenburg position, and operating room time greater than 4 h [109]. In laparoscopic and vaginal surgeries, the femoral nerve may be injured due to stretch encountered from the lithotomy position. The lateral cutaneous femoral nerve is one of the most common nerves injured from lithotomy position and injury is caused from compression and stretching under the inguinal ligament, most likely from prolonged flexion of the lower extremities. The obturator nerve may be injured from prolonged flexion of the legs in the lithotomy position. Sciatic nerve injury is less common in the dorsal lithotomy position; however, it may be caused by overflexion of the hip with abduction and external rotation. The common peroneal nerve can be injured via direct pressure on the nerve when legs are touching the pole of the candy cane stirrups—boot stirrups may aid in decreasing risk of injury to this nerve [108].

To prevent lower extremity neuropathies caused by female pelvic reconstructive surgery, it is necessary to utilize correct positioning of the lower extremities. Whenever possible, avoid candy can stirrups as they offer little support and may cause undue hip abduction and external rotation. When positioning the lower extremities in boot stirrups, make sure the heel of the patient's foot fits directly into the boot. Padding the lateral aspect of the knee avoids injury to the peroneal nerve. When placing patient in high lithotomy, the knee should be flexed 90–120°, hip flexion should be less than 60°, and abduction of the thighs should be no greater than 90° (Figs. 4.2 and 4.3). Nerve

Fig. 4.1 Appropriate positioning of patients for laparoscopic or robotic pelvic reconstructive procedures with padding and taping to prevent neurologic injury

Fig. 4.2 Appropriate positioning of the lower extremities for dorsal lithotomy position using candy cane stirrups

Fig. 4.3 Appropriate positioning of the lower extremities for dorsal lithotomy position using boot stirrups

injuries from reconstructive pelvic surgery are minimized when the patient's extremities are positioned correctly.

Injury to the pudendal and other pelvic nerves may occur during specific pelvic reconstructive procedures. In the optimal trial that randomized 374 women with apical vaginal prolapse to either sacrospinous ligament fixation or uterosacral vault suspension, neurologic pain requiring intervention (medications, trigger point injections, or suture release) occurred more frequently after sacrospinous ligament fixation (6.9% vs. 12.4%) and persisted to 4–6 weeks after surgery more often (0.5% vs. 4.3%) [110]. In the TOMUS trial, neurologic complications were noted more frequently in slings performed via the transobturator approach than the retropubic approach (9.7% vs. 5.0%, p = .04); however, most of these were minor and represented transient inner thigh numbness and weakness that resolved by 6 weeks [74]. Of note, four patients (0.7%) had persistent postoperative neurologic symptoms at 24 months after surgery without any difference between the transobturator and retropubic approaches.

Diagnosis of postoperative neuropathy should include a thorough musculoskeletal and neurological exam (Table 4.4). Patient may also experience pain, numbness, and tingling in dermatomes of the nerve routes. EMG and MRI are procedures that may further aid in diagnosis. Treatment includes oral analgesics, nonsteroidal anti-inflammatory medications, low-dose antidepressants, neurologic medications including gabapentin and pregabalin, and physical therapy, especially for prolonged neuropathies. Surgery and steroid injections may be used for severe cases [108].

Table 4.4 Motor and sensory defects associated with lower extremity neuropathy

Nerve	Motor function	Sensation
Femoral	Hip flexion and knee extension	Anterior and medial thigh, medial calf
Lateral femoral cutaneous	N/A	Anterior and lateral thigh
Sciatic	Foot dorsiflexion and eversion	Foot, toes
Obturator	Thigh adduction and internal rotation	Medial aspect of the thigh
Common peroneal	Foot dorsiflexion and eversion	N/A

N/A not applicable

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Anterior Compartment Repair

5

Alana M. Murphy and Courtenay K. Moore

Introduction

The first true surgical anterior colporrhaphy was performed in 1866 by the controversial American gynecologist James Marion Sims [1]. Over the next 50 years, various techniques were used until transvaginal repair of anterior compartment prolapse was popularized by Kelly in the early twentieth century [2]. While this plication technique has generally fallen out of favor for the treatment of stress urinary incontinence (SUI), the same principles are utilized in contemporary anterior compartment repairs.

In addition to a traditional colporrhaphy, the role of various materials to augment anterior compartment repair continues to evolve. While several studies support superior anatomic results with mesh repairs, one must factor in the higher complication rates and the recent FDA rulings, reclassifying transvaginal mesh kits for pelvic organ prolapse (POP) from a class II (moderate risk) to class III (high risk). This chapter will focus on potential complications and prevention of these complications during native tissue anterior repairs (Table 5.1). The specific complications associated with the use of mesh in transvaginal surgery will be discussed in detail in other chapters.

Potential anterior compartment repair complications include intraoperative hemorrhage and blood transfusion, genitourinary tract injury, onset of de novo SUI, and postoperative urinary retention. Given the infrequent nature of these complications, there is a paucity of literature focusing on intraoperative and immediate postoperative complications. In this regard, data on the immediate and shorter term complications must be extracted from studies that focus primarily on long-term anatomical and functional outcomes. Utilization of this data is further complicated by the inclusion of concomitant procedures. Women with high-grade anterior compartment prolapse may require a simultaneous vault procedure to adequately address all aspects of pelvic floor support. While these additional procedures often have complication profiles similar to anterior repairs, the complication rates are often higher. This chapter will focus on the complications, and complication rates only for anterior repairs.

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Table 5.1 Common complications and prevention

Complication	Prevention
Bleeding	Dissection in correct plane
	Avoid retropubic space
Ureteral injury	Cystoscopy with assessment of ureteral patency
Bladder injury	Proper dissection
SUI	Preoperative assessment
Bladder outlet obstruction	Preoperative assessment of voiding function and post-void residual
	Avoidance of Kelly plication sutures

Injury to the Lower Urinary Tract

The incidence of lower urinary tract injuries varies based on the type of vaginal surgery, ranging from 0 to 19.5 per 1000 surgeries performed, with injuries occurring more commonly after reconstructive pelvic and incontinence surgery than other gynecological surgeries [3–5]. While injuries are uncommon, the consequences of unrecognized injuries can significantly increase patient morbidity.

Bladder Injuries

Bladder injury at the time of anterior colporrhaphy is very rare. Gilmour and coworkers conducted a systematic review of the literature from 1966 to 2004 and found the rate of bladder injuries during urogynecologic surgery excluding hysterectomies varied from 12.1/1000 surgeries to 16.3/1000 surgeries when intraoperative cystoscopy was performed [3]. Of those studies that performed intraoperative cystoscopy, 95% of bladder injuries were diagnosed and corrected intraoperatively compared to a 43% detection rate when cystoscopy was not performed, underscoring the importance of intraoperative cystoscopy [4].

While the majority of the studies on bladder injuries during urogynecological surgery include multiple concomitant procedures, several report on the rate of bladder injury after anterior colporrhaphy alone. In a study by Kwon and coworkers of 346 women who underwent traditional anterior colporrhaphy, there were no reported bladder injuries [6].

When comparing the rate of bladder injury among traditional anterior colporrhaphy and transvaginal mesh kits, two randomized controlled studies found there to be no difference in the rate of cystotomy with Weber and coworkers reporting no injuries and Hiltunen reporting 1 in the mesh group [7, 8]. A more recent randomized controlled study by Altman and colleagues found there to be a higher rate of cystotomy in the transvaginal mesh group versus traditional anterior colporrhaphy, 3.5% versus 0.5%. However, this did not reach statistical significance ($p = 0.07$) [9].

Immediate recognition of bladder injury during anterior compartment repairs is essential in reducing postoperative morbidity and potential fistula formation. As cited earlier, intraoperative cystoscopy increases the rate of intraoperative diagnosis and repair. If an intraoperative cystotomy is detected, the injury should be closed in two layers with absorbable sutures. Should the injury be missed, depending on the duration of postoperative catheter drainage and the extent of the injury, the patient is at risk for developing a vesico-vaginal fistula requiring either prolonged catheter drainage or a vesico-vaginal fistula repair.

Ureteral Injuries

Ureteral injuries occur infrequently after routine gynecological procedures (0.5–1.5%), with patients undergoing complex reconstructive procedures for pelvic organ prolapse at an increased risk of ureteral injury [10]. Like bladder injuries, the incidence of ureteral injuries varies depending on the type of urogynecologic surgery, ranging from 2 to 11% [4, 11]. Women with pelvic organ prolapse are at an increased risk of ureteric injury given the anatomic distortion caused by the prolapse itself, with 12–20% of women with symptomatic pelvic organ prolapse having moderate to severe hydronephrosis secondary to chronic obstruction from ureteral kinking [11].

The majority of the studies on ureteral injuries during gynecologic surgery do not separate the rate of injury by procedure. However, a study by Kwon and colleagues looked at the incidence of ureteral injury after anterior colporrhaphy alone [6]. Of the 346 procedures performed, there were seven reported ureteral injuries (2.0%). There was no comment on the POP-Q staging of the women with ureteral injuries. All injuries were recognized at the time of surgery.

Diagnosis of Ureteral Injuries

Intraoperative Diagnosis

If a ureteral injury does occur, the ability to identify the injury at the time of the initial operation is paramount to avoid the permanent damage associated with unrecognized injuries. The single most controllable factor adversely affecting the outcome of ureteral injuries is delayed diagnosis. Studies have shown that intraoperative recognition and repair of ureteral injuries decreases postoperative morbidity, minimizes loss of renal function and need for nephrectomy. Early recognition also decreases the incidence of ureterovaginal fistulas as compared to postoperative diagnosis with delayed repair [12].

If a ureteral injury is suspected during abdominal surgery, direct inspection of the ureter is recommended. However, during vaginal surgery, direct visualization of the ureter is usually not feasible. Therefore, intraoperative cystoscopy has been recommended as a means to identify ureteral injuries during vaginal surgery while obviating the need for an abdominal incision. Prior to cystoscopy, indigo carmine, methylene blue, or fluorescein should be administered allowing for assessment of ureteral patency.

If fluoroscopy is available, another method of assessing ureteral patency is retrograde ureterography. If fluoroscopy is not available, a one-shot excretory urogram can be obtained 10 min after the administration of intravenous contrast material (1 mL/pound of body weight). Fluoroscopically, ureteral injuries present as urinary extravasation or high-grade obstruction.

Delayed Diagnosis

Most ureteral injuries are unsuspected and diagnosed postoperatively [13]. In a study by Meirow and coworkers, the mean delay to diagnosis of patients sustaining ureteral injuries after gynecologic surgery was 5.6 days [14]. Undiagnosed ureteral injuries are associated with significant morbidity, the formation of ureterovaginal fistulas and potential loss of renal function [15]. The majority of patients present with fever, flank pain, continuous incontinence, pyelonephritis, ileus, peritonitis, or anuria. However, 5% of patients remain asymptomatic and are diagnosed at a later date secondary to a nonfunctioning or hydronephrotic kidney [13]. Delayed diagnosis is most often (66–76%) made by CT pyelography, excretory urography, or retrograde ureterography [16].

General Principles of Management

Immediate Intraoperative Management

The management of ureteral injuries depends on the time of diagnosis, location, nature, and extent of the injury. Injuries recognized intraoperatively must be treated immediately. Inadvertent ligation or kinking of the ureter should be treated by suture removal and repeat cystoscopy to ensure ureteral efflux. Typically, if recognized immediately, ureteric damage is minimal as these injuries include other tissue in the ligature [12]. If the extent of the ureteral injury is in question, at minimum, ureteral stent placement is warranted [12]. For more severe injuries, when ureteral viability is unlikely, exploration and direct visualization of the ureter is recommended [17]. The involved ureter should be primarily repaired or resected, debrided, and re-anastomosed over a stent. If the diagnosis of an intraoperative ureteral injury is made during retrograde ureterography, an attempt at retrograde stent placement should be made.

Delayed Management

The type of repair and the timing of delayed-recognition injury repair are controversial. Postoperatively noted suture entrapment can be managed conservatively with immediate attempt at placement of a double-J ureteral stent or nephrostomy tube drainage if the suture is absorbable [18]. However, placement is only possible in 20–50% of patients [16]. In a study by Ghali, only 2 of 21 (19%) iatrogenic ureteral injuries identified postoperatively were able to be stented [16]. When stent placement is possible, as many as 73% of patients will not require open surgery.

If the diagnosis is delayed, the traditional recommendation is that repair of iatrogenic ureteral injuries after urogynecologic surgery should not be undertaken for 3–6 months [19]. However, more recent studies suggest similar outcomes after immediate and delayed repairs [19]. Given that most injuries after vaginal surgery occur to the distal one-third of the ureter, intervention often involves ureteral reimplantation or ureteroneocystostomy. Ureteroneocystostomy is used to repair distal ureteral injuries close to the bladder or in the intramural tunnel.

Hemorrhage

Hemorrhage is a rare complication of anterior compartment repair. During a traditional suture plication repair, proper dissection between the vaginal epithelium and the underlying vaginal muscularis (often called pubocervical fascia) will minimize blood loss and reduce the risk of postoperative hemorrhage. Judicious use of electrocautery during the anterior vaginal wall dissection can also be used to maintain hemostasis. A recent randomized controlled trial by Altman and colleagues included 389 women who underwent isolated anterior compartment repair [9]. Women with stage ≥ 2 prolapse were randomized to a repair using trocar-guided transvaginal mesh ($n = 200$) or a traditional colporrhaphy ($n = 189$). The two treatment groups did not differ significantly in terms of POP-Q stage or previous anterior compartment repairs. The traditional colporrhaphy group had a significantly lower mean estimated blood loss (EBL) (35.4 ± 35.4 mL) compared to the trocar-guided transvaginal mesh group (84.7 ± 163.5 mL, $p<0.001$). The study reported five cases (1.3%) of clinically significant intraoperative blood loss with all five patients having undergone trocar-guided transvaginal mesh placement: four patients (1.0%) had an EBL greater than 500 mL and one patient (0.3%) had an EBL greater than 1000 mL and a subsequent retropubic hematoma. The authors did not provide data on transfusion rates. Due to its focus on anterior compartment repairs without concomitant pelvic floor procedures, the Altman study is a valuable addition to the limited body of literature that addresses the complications of isolated anterior compartment repairs.

Studies that included concomitant pelvic floor procedures also provide data regarding the low incidence of hemorrhage associated with anterior compartment repair [8, 20–22]. Weber and colleagues who performed the very first randomized study of anterior compartment repairs, comparing standard plication, plication with mesh and ultra-lateral anterior colporrhaphy [7]. Subjects were excluded if they underwent any anti-incontinence procedure other than a suburethral plication. Subjects undergoing additional procedures for prolapse were included. Of the 109 women undergoing anterior compartment repair with concomitant pelvic floor procedures, one patient (0.9%) in the standard anterior colporrhaphy group required transfusion rate.

A randomized controlled trial by Hiltunen and colleagues, comparing anterior colporrhaphy with and without tailored mesh, included 201 women with pelvic organ prolapse [8]. Subjects were excluded from the study if they had gynecologic malignancies, apical prolapse mandating apical fixation, SUI, or their main symptomatic compartment was the posterior vaginal wall. Women could be included if they underwent concomitant vaginal hysterectomy, reduction of an enterocele, culdoplasty, or posterior colporrhaphy without mesh. Women were randomized to traditional anterior compartment repair ($n = 97$) or anterior compartment repair reinforced with mesh ($n = 104$). A total of 29 patients (14%) underwent an isolated anterior compartment

repair with no concomitant procedure. There was no difference in rates of previous vaginal surgery or concomitant hysterectomy between groups. All patients had vaginal packing in place for 20 h postoperatively. Although the mean EBL in the traditional repair group (114 ± 109 mL) was less than the mean EBL in the mesh group (190 ± 23 mL), the difference was not statistically significant (p = 0.004). There was no statistically significant difference is clinically significant blood loss (EBL >400 mL) between the groups (3.1% vs. 9.6%, p = 0.07). Two patients in total (1.0%), it was not specified in what group, required blood transfusions.

Careful attention should be paid during dissection of anterior vaginal wall and muscularis to minimize blood loss. Hemostasis can typically be attained using electrocautery. If electrocautery is insufficient, a figure-of-eight stitch with a 2-0 or 3-0 Vicryl suture can be used to over sew a small vessel. When closing the anterior vaginal wall incision, great care should be taken to achieve a secure closure. A tight closure can provide an additional degree of hemostasis by allowing tamponade within the closed anterior compartment.

The low incidence of clinically significant blood loss affects our routine postoperative care pathway. Given that hemorrhage is a rare complication of anterior compartment repair; our practice is to not obtain routine postoperative lab work. If the patient undergoes a pelvic floor reconstruction that includes a concomitant hysterectomy, then we will obtain routine postoperative blood work and admit the patient for overnight observation. A vaginal pack is placed at the completion of the anterior compartment repair and removed after 1 h in the recovery room. If the patient is admitted for observation due to a concomitant pelvic floor procedure, then the vaginal packing is removed in the early morning of postoperative day one. Vaginal packs are commonly used as a means to reduce postoperative hemorrhage, despite the lack of evidence in the literature. An abstract from Thiagamoorthy and colleagues reported the results of a randomized controlled trial assessing the effect of vaginal packing after a vaginal hysterectomy and/or pelvic floor repair [23]. The women were randomized to receive a vaginal pack (n = 86) or no vaginal pack (n = 87). A total of five patients were withdrawn from the no packing group due to intraoperative bleeding. The study demonstrated no significant difference in mean postoperative hemoglobin on the first postoperative day (11.75 g/dL vs. 11.94 g/dL, p = 0.061) and 6 weeks postoperatively (12.55 g/dL vs. 12.49 g/dL, p = 0.884) between the packing and the no packing group. Although the packing group had fewer postoperative hematomas (n = 4) compared to the no packing group (n = 9), the difference was not significant (p = 0.098). Despite the lack of statistical significance, all three clinically significant complications related to bleeding were in the no packing group. One patient returned to the operating room from the recovery room for hemorrhage and two patients required repeat admission for intravenous antibiotics to treat an infected pelvic hematoma. The data presented in the abstract support our continued use of vaginal packing until additional data are available to influence our care pathway.

Hemorrhage recognized in the postoperative setting is rare after an anterior compartment repair. If a patient demonstrates a clinical sign of hemorrhage, such as significant transvaginal bleeding or tachycardia, a vaginal packing should be placed, vital signs closely monitored, and serial hematologic profiles checked until stable values are achieved. As demonstrated in the previously discussed studies, up to 1% of patients will require a transfusion after an anterior compartment repair. In cases of severe hemorrhage that are not responsive to transfusion or are associated with significant hemodynamic instability, angiography with selective embolization should be utilized to control the hemorrhage.

De Novo Stress Urinary Incontinence

De novo stress urinary incontinence (SUI) should be included in the preoperative discussion of potential postoperative complications with greater emphasis in patients with high-grade anterior compartment prolapse. Women with

severe anterior compartment prolapse may not experience SUI due to urethral kinking and SUI may not be detected by the patient or the physician until the prolapse is reduced or surgically repaired [24]. According to the International Continence Society (ICS), SUI with prolapse reduction is defined as SUI observed only after the reduction of coexistent prolapse [25]. Once any degree of urethral kinking is relieved with reduction of the anterior compartment prolapse, the mechanism of de novo SUI is likely multifactorial and may include urethral hyper-suspension or intraoperative damage to the sphincter [26]. In addition to intraoperative factors, reduction of anterior compartment prolapse may unmask compromised periurethral support or frank intrinsic sphincter deficiency [27]. In order to minimize the risk of developing de novo SUI, each patient without subjective and/or objective evidence of SUI should be assessed for SUI with prolapse reduction before undergoing anterior compartment repair for high stage prolapse.

Proper assessment of SUI with prolapse reduction requires adequate reduction of the patient's anterior compartment prolapse. If the office setting, our practice is to perform a stress test after the anterior prolapse is reduced with half of a speculum. If SUI is not demonstrated in the office, the patient may be referred for urodynamic evaluation with prolapse reduction. The most common techniques for prolapse reduction include a vaginal pack, a pessary, and a speculum. No general consensus exists regarding the best method for prolapse reduction. A study conducted by Mattox and Bhatia demonstrated no difference in maximal urethral closure pressure whether a Smith-Hodge pessary, a ring pessary, or half of a Graves speculum was used for prolapse reduction [28]. Visco and colleagues found that rates of SUI with prolapse reduction differed based on method of prolapse reduction, which included a pessary, manual reduction, a forceps, a swab, and a speculum [29]. When interpreting urodynamic results, it is important to remember that each method of prolapse reduction may partially obstruct the urethra and lead to a false-negative SUI assessment.

Controversy continues to surround the management of women with either isolated SUI with prolapse reduction or no evidence of subjective or objective SUI with prolapse reduction. Should these women undergo a concomitant anti-incontinence procedure at the time of anterior compartment repair?

A study done by Chaikin and colleagues on 24 stress-continent women with stage III or IV pelvic organ prolapse (POP) found 14 patients (58.3%) to have SUI with prolapse reduction on preoperative urodynamics and subsequently underwent pubovaginal sling placement with concomitant anterior compartment repair [30]. The remaining ten patients (41.7%) had no SUI with prolapse reduction and underwent isolated anterior compartment repair. Two of the patients (14%) in the pubovaginal sling group had persistent postoperative SUI, while no patient in the group without occult SUI developed de novo SUI at a mean follow-up of 44 months.

Lo and colleagues reported on 79 stress-continent women with stage III or IV POP [31]. The patients were divided into three treatment groups based on the presence or absence of SUI with prolapse reduction on preoperative urodynamics. In group I, 32 patients with SUI with prolapse reduction underwent total vaginal hysterectomy (TVH), anterior/posterior (AP) repair and a mid-urethral sling (MUS). In group IIa, 17 patients with SUI with prolapse reduction underwent TVH and AP repair with no anti-incontinence procedure. In group IIb, 30 patients without SUI with prolapse reduction underwent TVH and AP repair with no anti-incontinence procedure. Postoperatively, group I had three patients (9.4%) with subjective SUI and zero patients with objective SUI. Group IIa had 11 patients (64.7%) with subjective SUI and nine patients (52.9%) with objective SUI on repeat urodynamics. Group IIb had three patients (10.0%) with subjective SUI and zero patients with objective SUI. The data presented by both Chaikin and colleagues and Lo and colleagues suggest that the rate of de novo SUI is low in women with no subjective or SUI with prolapse reduction while women with SUI with prolapse reduction appear to benefit from a concomitant anti-incontinence procedure.

The Colpopexy and Urinary Reduction Efforts (CARE) trial addressed the role of an anti-incontinence procedure at the time of abdominal sacrocolpopexy [32]. A total of 322 women with stage II or greater POP were randomized to abdominal sacrocolpopexy with Burch colposuspension (n = 157) or abdominal sacrocolpopexy alone (control group, n = 165). At 3 months 23.8% of patients in the Burch group and 44.1% of patients in the control group ($p < 0.001$) reported some degree of SUI. When patients with SUI with prolapse reduction were excluded, de novo SUI was reduced from 38.2 to 20.8% in the control group versus the Burch group ($p = 0.007$). A 2 years update of the CARE trial reported that the reduction in de novo SUI was durable with 32.0% of the Burch group and 45.2% of the control group meeting one or more criteria for SUI [33]. The CARE study also supports the utility of preoperative urodynamic testing in reportedly stress-continent women as a valuable tool to enhance preoperative counseling and planning. Examination of the preoperative urodynamic results revealed that 3.7% of women demonstrated urodynamic SUI without prolapse reduction and 6–30% of women demonstrated SUI when their prolapse was reduced (the range of SUI with prolapse reduction rates reflects the use of various methods for reducing prolapse). Regardless of whether or not they underwent Burch colposuspension, patients who demonstrated SUI with prolapse reduction were more likely to have postoperative SUI compared to women without SUI with prolapse reduction [Burch 32% vs. 21% ($p = 0.19$), controls 58% vs. 38% ($p = 0.04$)] [29].

The OPUS trial, outcomes following vaginal prolapse repair and mid-urethral sling, randomly assigned women undergoing vaginal correction of stage or higher anterior prolapse without symptoms of stress incontinence to receive either a mid-urethral sling or sham incisions during surgery [34]. At 3 months, the rate of urinary incontinence was 23.6% in the sling group and 49.4% in the sham group ($p < 0.001$). At 12 months, urinary incontinence was present in 27.3% and 43.0% of patients in the sling and sham groups, respectively ($p = 0.002$). The number of patients required to treat with a sling to prevent one case of SUI at 12 months was 6.3. While sling placement at the time of vaginal surgery for stage or higher POP resulted in lower rates of SUI, it did result in a higher adverse events rate (bladder perforations, urinary tract infection, major bleeding, and incomplete emptying).

Our preference is to perform a concomitant anti-incontinence procedure in patients who demonstrate SUI preoperatively on physical exam or during UDS. Since an anterior compartment repair alters the axis of the anterior vaginal wall and may affect the urethral axis, our practice is to perform an anti-incontinence procedure after the anterior compartment repair. If de novo SUI occurs in previously stress-continent women after anterior compartment repair, we perform an anti-incontinence procedure at a later date.

Iatrogenic Bladder Outlet Obstruction (BOO)/Urinary Retention

Postoperative voiding dysfunction and urinary retention rates following pelvic reconstructive surgery range from 2.5 to 24% with the vast majority of patients undergoing concomitant anterior, posterior, and apical prolapse repairs [35]. Unlike anti-incontinence procedures, very few studies have examined risk factors for iatrogenic BOO after an isolated anterior colporrhaphy.

Hakvoort and colleagues conducted a retrospective study looking at predictors of short-term urinary retention, defined as a post-void residual (PVR) urine volume >200 mL, after vaginal prolapse surgery in 345 women [36]. Patients were excluded if they underwent a colpocleisis, sacrocolpopexy, or had undergone a prior anti-incontinence procedure. Of the 345 patients, transient urinary retention occurred in 100 patients (29%). Catheterization was required after 72 h in 30 patients (8.7%) and after 6 days in four patients (1.1%). In this study population, postoperative urinary retention was temporary with all patients voiding spontaneously with a PVR volume <200 mL by 2 months after surgery. Intraoperative blood loss exceeding 100 mL,

high stage anterior prolapse (grade ≥3 cystocele), and levator or Kelly plication were independent risk factors for postoperative urinary retention.

Wang and coworkers conducted a retrospective cohort study of 294 women undergoing POP repair without an anti-incontinence procedure. A total of 49 women (16.7%) failed their postoperative voiding trial. The women who failed postoperative voiding trials were more likely to have undergone an anterior colporrhaphy ($p = 0.001$) and more likely to have had an elevated preoperative PVR volume (≥150 mL) ($p = 0.001$) [37].

Due to the risk of postoperative voiding dysfunction and urinary retention, all patients undergoing an anterior colporrhaphy should undergo assessment of their voiding function prior to discharge. This voiding assessment is typically a combination of PVR measurement and assessment of a patient's symptoms. If a patient is found to have postoperative urinary retention, mechanical bladder drainage with either an indwelling catheter or intermittent catheterization is required until normal voiding function is achieved. Although there are no robust data to support a postoperative protocol to minimize urinary retention following an anterior colporrhaphy, general recommendations include early ambulation, avoidance, or minimization of constipation and limitation of postoperative narcotic analgesia.

Summary

While complications during anterior compartment repairs are rare, they do occur. Attention to detail and an in depth knowledge of pelvic anatomy can reduce the risk of complications and potential patient morbidity.

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Posterior Compartment Repair

6

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Introduction

Pelvic organ prolapse of the posterior compartment is a herniation of the posterior vaginal wall or anterior rectal wall into the lumen of the vagina. Defects in the posterior compartment may result from nerve (i.e., pudendal nerve) damage or disruption of connective tissue and muscular attachments [1]. Many factors, including childbirth, aging, estrogen withdrawal, chronic abdominal straining, and heavy physical labor, weaken the pelvic floor and its associated support structures. There are also genetic factors that predispose women to this condition. Childbirth, one of the most commonly associated factors contributing to posterior compartment defects, can cause stretching of the prerectal and pararectal fascia with detachment of the prerectal fascia from the perineal body. This allows for the formation of a rectocele. In addition, childbirth damages and weakens the levator musculature and its fascia, attenuating the decussating prerectal levator fibers and the attachment of the levator ani to the central tendon of the perineum. The result is a convex sagging of the levator plate with a loss of the normal, horizontal vaginal axis. The vagina becomes rotated downward and posteriorly, no longer providing horizontal support. These anatomic changes allow downward herniation of the pelvic organs along the new vaginal axis.

Posterior compartment prolapse is not uncommon. A cross-sectional study (Women's Health Initiative Hormone Replacement Therapy Clinical Trial) found that 18.6% of 16,616 women with a uterus had a rectocele on a baseline pelvic examination and 18.3% of 10,727 women who had undergone hysterectomy had a rectocele [2]. Rates of anterior prolapse (cystocele) were higher in both groups at 34.3% and 32.9%, respectively. Isolated posterior compartment defects are relatively unusual and are seen most often in women after severe posterior tears associated with vaginal delivery or in women who have previously undergone correction of the anterior or apical compartment. More frequently, posterior compartment defects are associated with more global pelvic floor dysfunction and

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vaginal prolapse. Management should also consider the role the posterior plate and the genital hiatus may play in preventing recurrent pelvic organ prolapse and restoring sexual function.

Up to 80% of rectoceles seen on physical examination are asymptomatic [3]. In cases of asymptomatic isolated rectoceles, or small rectoceles, with concomitant anterior and/or apical prolapse, surgical intervention should be approached cautiously because of the potential complications that will be discussed later. However, when rectoceles are symptomatic, surgical correction is a reasonable option. Symptoms associated with rectocele include constipation, incomplete rectal emptying, rectal pressure, and vaginal bulge [4]. Some patients will also describe stool being trapped in the rectocele pocket and the need to apply perineal or vaginal pressure in order to facilitate defecation, and this is known as splinting.

Nonsurgical Therapies

Although it is not the intent of this chapter to discuss the evidence behind alternative therapies, these must be considered when trying to avoid surgical complications. This is because if nonsurgical therapies are successful the need for surgery may be obviated.

Observation, or watchful waiting, may be appropriate if the patient has little bother or only minor symptoms from her posterior compartment laxity. A support device such as a pessary can also be considered in a woman with symptoms from pelvic organ prolapse. In the authors' experience, posterior compartment prolapse symptoms can be difficult to treat with these devices. However, if the decision is made to trial a pessary, the process of fitting a pessary in a woman with posterior compartment predominant prolapse should not be anymore difficult than fitting women with anterior or apical prolapse [5]. If a woman derives symptomatic improvement, she can be taught how to remove and clean the pessary, or it can be changed on a regular basis in a physician's office. In either case, routine examination is necessary to ensure that there is no unwanted irritation or granulation tissue development.

Pelvic floor muscle rehabilitation can also be considered as a therapy for posterior compartment prolapse. There is a paucity of data to support its use in preventing progression or improvement of rectocele specific symptoms. However, rectoceles are often not isolated findings. The pelvic floor disorders that may coexist may be effectively addressed with nonsurgical options. For example, pelvic floor exercises are useful in the treatment of stress urinary incontinence. Women with concomitant disorders of the pelvic floor may favor the nonsurgical route for the treatment of the rectocele because of the improvement in the symptoms of other conditions.

In summary, nonsurgical therapies should be discussed with patients in most cases. Given the favorable side effect profile, there is no great downside to attempting these therapies if a woman so desires. They can be used if they help correct the bothersome symptoms. Nonsurgical options are also important in counseling patients who are poor surgical candidates secondary to medical comorbidities.

Surgical Approaches

Rectocele repairs can be approached via the abdominal, transvaginal, and transanal approach. Urologists and Gynecologists most often perform the repair transvaginally [1]. There is no definitive evidence that suggests which surgical approach is best. Based on three randomized controlled trials comparing transvaginal and transanal repair, one analysis concluded that the transvaginal approach has superior subjective and objective outcomes compared to the transanal approach [6]. In contrast, a later literature review comparing the transvaginal to the transanal approach found that there was no significant difference in outcomes [7]. Surgeon's skill, patient's desires, anatomic, and functional outcomes are all important to consider. As importantly, the potential unwanted outcomes, or complications, must be considered. As we are considering potential complications, which vary based on each different surgical approach, some relative indications for the route of repair that is selected should be considered.

The abdominal approach may be indicated in cases where a rectal prolapse is concomitantly noted. The abdominal approach has also become more popular with the widespread use of robotic-assisted laparoscopic surgical platforms. This has led to more publications describing the abdominal approach for rectocele repair [8, 9]. Patients are often selected for an abdominal repair (i.e., robotic-assisted laparoscopic sacrocolpopexy) because of a predominance of apical descent. This should be remembered when reviewing the literature of nonrandomized patients. The studies may include women with some degree of posterior prolapse, but this is often not the predominant defect.

The vaginal approach may be preferred by some surgeons if other transvaginal procedures are needed during the same procedure (i.e., concomitant vaginal hysterectomy with midurethral sling). Further if compromised anal sphincter function exists the surgeon may like to avoid excessive anal dilation from the retractors utilized during the transanal approach to repair this posterior defect. Finally if the defect is a high rectocele it may be difficult to repair through a transanal approach [8, 10]. A Cochrane review in 2010 suggested that for posterior vaginal wall prolapse, the vaginal approach was associated with a lower rate of recurrent rectocele or enterocele or both than the transanal approach (RR 0.24, 95% CI 0.09–0.64) [11]. The review noted a higher postoperative narcotic use and blood loss in this vaginal repair group.

The transanal approach is utilized if there is other perianal or rectal pathology that needs to be treated concurrently such as redundant rectal mucosa, hemorrhoids, etc. A disadvantage of the transrectal approach is that the patient is placed in the prone jackknife position, and it can be difficult to perform a simultaneous perineorrhaphy if needed.

In addition to the approach used, there are other questions that remain. Should a surgeon utilize mesh or graft material? Are traditional repairs vs. site-specific repairs more appropriate? The chapter will address some of the more common complications, and in doing so may help answer some of these questions, or at least inspire future investigation to those questions that remain unanswered. Technique selection and operative plan are always the first step to consider when aiming to minimize and manage complications.

Complications of Posterior Repair

Hemorrhage

Excessive bleeding or hemorrhage is a complication of rectocele repair regardless of the surgical approach. The rectovaginal septum and pararectal fascia are rich in blood vessels. In cases where the tissue is "loose or disrupted," as it often is in cases of posterior prolapse, these vessels have a tendency to retract after they are cut, making identification difficult. This complication should be considered during the preoperative evaluation, intraoperatively, and in the postoperative management of patients. Blood loss to a more mild degree is a relatively unavoidable result when surgical repair is selected. The surgeon's role, however, should be aimed at preventing hemorrhage by attempting to be aware during all phases of patient care.

Preoperative Prevention: Evaluation of Risk Factors and Preoperative Planning of Surgical Approach

Avoidance of excessive bleeding or hemorrhage starts with the preoperative evaluation. A thorough history and physical exam can help identify any bleeding diatheses or hereditary bleeding problems that may require further workup.

Review of patient medication and dietary supplements can identify agents that may contribute to intraoperative and postoperative bleeding. These agents include medications such as aspirin, NSAIDs, clopidogrel, and supplements such as fish oil. Cessation of antiplatelet agents approximately 7 days prior to surgery will reduce the risk of bleeding; however, the surgical team must weigh the risk of bleeding against the potential for adverse outcomes arising from the relative hypercoagulable state that can exist if antiplatelet agents are stopped. In many cases, consultation is recommended where there is question regarding

the safety of stopping antiplatelet agents. For example, one study suggests patients are 2.4 times more likely to experience acute coronary syndrome or death during the first 90 days of discontinuing clopidogrel therapy compared to days 91–180 [12]. This is especially important in patients with coronary artery disease, veno-occlusive disease, and history of cerebral vascular accidents. Care must also be taken with other medications that affect the clotting cascade. Medications such as Coumadin/warfarin, Apixaban, or Argatroban should prompt consultation to decide on appropriate perioperative management. The risk of bleeding must be weighed against the risk of adverse outcomes resulting from stopping these medications, i.e., thrombocclusion [13, 14].

Preoperative lab tests can help identify patients with bleeding diatheses especially if it is suggested by history. Depending on institutional regulations, surgeon's preference, and patient's history, PT/INR/PTT and platelet counts can be evaluated preoperatively. Other test such as bleeding times and clotting factor levels can be evaluated if indicated.

Physical examination is also important in attempting to avoid surgical bleeding complications. Inspection for prior surgical scars, as well as signs of potential vascular abnormalities, should be routine. This information can aid in selection of which approach is most appropriate, as well as the need for other preoperative evaluations. For example, vulvar varicosities (though rare) may lead a surgeon to evaluate the patient with imaging to rule out aberrant vasculature or pelvic congestion syndrome. In a patient with abnormal vasculature, blind passage of trocars (i.e., those found in mesh repairs) should be used with extreme caution [15].

Intraoperative Risk: Avoidance and Identification of Hemorrhage

Meticulous surgical techniques should aim to establish excellent intraoperative hemostatic control. This should also reduce the risk of excessive "oozing" in the postoperative period. Obviously, stopping bleeding by controlling injured vessels is preferred over managing bleeding from uncontrolled vessels. Good visualization can help achieve this goal. This is provided by suction, irrigation, lap pads, and lights. Other general intraoperative considerations (use of electrocautery, suturing technique, etc.) will not be discussed in detail here.

Surgeons have various techniques at their disposal to treat patients with rectoceles. Each technique comes with different expected blood loss and may also have different potential sites of hemorrhage. For example, a double-blind, randomized controlled trial, including women with at least stage 2 symptomatic rectocele, that compared native tissue repair to augmenting the native tissue repair with porcine subintestine submucosal (SIS) graft showed that those who received graft had a significantly greater estimated blood loss (125 mL vs. 100 mL, $p = 0.005$) [16]. This difference does not constitute hemorrhage on one side and no hemorrhage on the other, but it does illustrate a point. We do need to look objectively at new techniques/materials used to ensure that complications (even if rare) do not become more common. This is true even if the alteration to technique (such as in this study) would not seem to impact the complication.

The tactics to avoid or identify hemorrhage also differ depending on surgical approach to posterior compartment repair. Cadaveric studies examining the vascularity in the paravesical and pararectal space near the sacrospinous ligament found a large amount of collateral blood supply and anastomosis with significant anatomical variation of the vasculature. For a vaginal approach at the sacrospinous ligament, the inferior gluteal artery and its coccygeal branch are the most prominent arteries susceptible to injury while the hypogastric and pudendal venous plexi have been reported as the most likely venous sources of significant bleeding [17]. Abdominal approaches to the repair of pelvic organ prolapse routinely required dissection and identification of the sacral promontory. The presacral venous plexus that runs on the anterior aspect of the sacrum can result in significant bleeding that can be difficult to control using conventional measures such as suturing, clipping, or electrocautery. Especially when patients are in the lithotomy position, the

hydrostatic pressure can increase two to three times that of the inferior vena [18]. Intraoperative management of presacral bleeding with the use of hemostatic matrix (FloSeal; Baxter Healthcare Corporation, Fremont, CA) and an absorbable hemostat (Surgicel® Fibrillar; Ethicon, Somerville, NJ) has been advocated by some as first-line treatment for presacral bleeding if it is encountered intraoperatively [19]. More traditionally, things like long periods of compression, sterile thumbtacks, or the use of a fat bolster have been utilized.

In cases where pneumoperitoneum is utilized (i.e., laparoscopy, with or without robotic assistance) some suggest inspection after intra-abdominal pressure has been decreased to physiologic levels to identify any bleeding areas that may be masked by the effects of the positive pressure that pneumoperitoneum provides. The converse of this has also been utilized as a way of controlling bleeding in laparoscopic or robotic-assisted laparoscopic cases. For example, if additional exposure is needed, or other instruments or surgical team are being mobilized, the surgeon may elect to increase the pneumoperitoneum to aid in compressing venous structures and may reduce bleeding for short periods of time. High flow surgical units (SurgiQuest, Milford, CT) can be used if bleeding is anticipated or encountered to allow for more aggressive use of suction laparoscopically or robotically without losing the intra-abdominal pressure needed to visualize bleeding structures.

Another question regarding technique is whether the use of robotic assistance decreases the risk of bleeding compared to pure laparoscopy. A 2011 study compared the minimally invasive abdominal techniques (pure laparoscopic to robotic-assisted laparoscopic) for the repair of a rectocele. The laparoscopic group had a higher intraoperative blood loss compared to the robotic group (mean, 45 ± 91 mL vs. 6 ± 23 mL; p = 0.048); however, this difference may not necessarily be clinically significant [8]. A recent systematic review to evaluate the role of robotic assistance in laparoscopic rectopexy found that robotic rectopexy had no effect on the recurrence rate of rectal prolapse, but did decrease intraoperative blood loss by a weighted mean difference of −0.44 (95% CI −0.71, −0.16) [9]. Devastating complications such as hemorrhage from posterior repair are relatively rare thankfully, but this makes it harder to look at as an endpoint in small-scale studies. The studies are often underpowered to show differences in these types of complications.

Utilizing the vaginal approach for an isolated posterior prolapse repair does not allow for a substantial space for blood to accumulate without the surgeon being aware. In cases where it is difficult to identify the specific site of bleeding, temporary packing can be very useful. It is recommended to direct a vaginal sponge in a posterior-lateral direction toward the ischial spine for a minimum of 10 min [17]. Packing not only allows the patient's innate clotting cascade to begin to work but also allows the surgical staff to obtain equipment necessary to assist in visualization. Lighted retractors (i.e., Miyazaki retractor) (Fig. 6.1a, b) can be quite useful in vaginal surgery if visualization of bleeding is difficult. As mentioned earlier, hemostatic agents such as FloSeal (Baxter Healthcare Corporation, Fremont, CA) can also be quite effective in vaginal surgery if specific sites of bleeding cannot be identified or traditional methods are unsuccessful at stopping bleeding. If suture ligation (i.e., figure of eight sutures) is needed, utilizing a finger in the rectum may reduce the chance that a hemostatic stitch injures the rectal wall and results in another set of postoperative complications. In most cases, these sutures will be delayed absorbable.

Vasoconstrictive agents such as lidocaine with epinephrine or pitressin are used by some surgeons during the vaginal dissection. Vasoconstriction prevents bleeding during the dissection, which can potentially minimize intraoperative blood loss. When the vasoactive substance is mixed with an anesthetic there may be the additional benefit of reduced postoperative pain. The downside of using vasoconstrictive agents is that bleeding vessels may be "hidden" while the epinephrine is active and become problematic when the agent wears off postoperatively. The question of distortion of tissue planes is also raised if a site-specific repair is selected. Surgeon preference is unfortunately all that is available

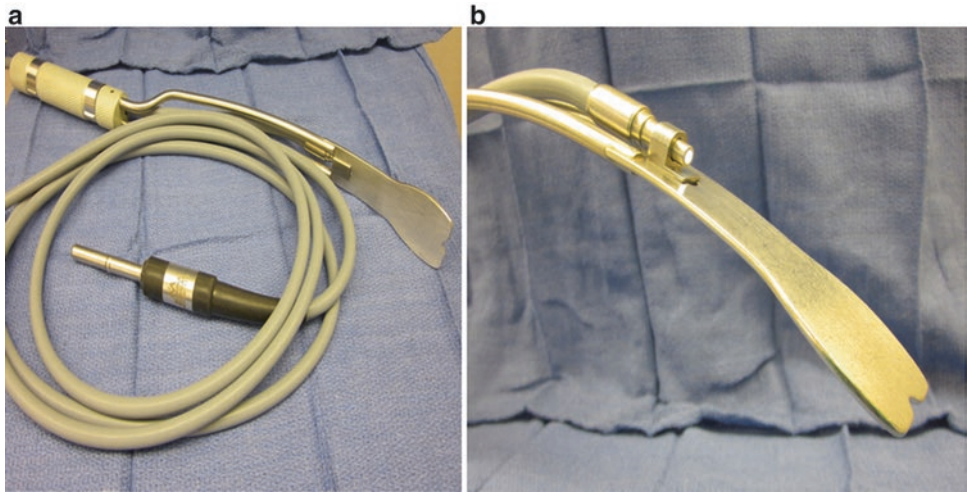

Fig. 6.1 The Miyazaki retractor is shown here (**a**). This retractor has a fiber optic light on the end (**b**) that is useful when the surgeon is working in a narrow space and visualization is poor

upon which to base the decision of the use vasoactive agents.

If extensive dissection is carried out during a vaginal repair, or if there is a high suspicion that postoperative bleeding may occur, we recommend placement of vaginal packing while the patient is still anesthetized. This allows for tighter packing with less discomfort to the patient. The packing can be removed the next morning if patient is staying overnight or in the recovery room prior to discharge if the patient is set to be discharged the same day.

If blind passage of trocars or anchoring sutures—such as those seen in "mesh kits"—are selected for a vaginal repair, it is extremely important to have an intimate knowledge of anatomy, appropriately identify landmarks, and maintain a high suspicion of anatomic variations to minimize the risk of vessel injury. A prospective study looking at outcomes with mesh kits reported the adverse outcomes of mesh-augmented vaginal anterior and posterior repairs. They reported excessive bleeding (defined as ≥500 ml) in 5.1% of patients with prolapse treated with mesh kits [20].

Stapled Transanal Rectal Resection (STARR) can be used for the treatment of internal rectal prolapse, as well as rectocele. Postoperative bleeding is not rare following a stapled hemorrhoidopexy and occurs in about 5% of cases [21]. The bleeding usually occurs at the level of the endorectal suture line. After a stapled rectal resection, reinforcing this staple line with a hand-sewn suture has been suggested to decrease this risk of hemorrhage [22]. Careful inspection is important to identify any bleeding vessel after a STARR procedure.

At least one study compared intraoperative blood loss across rectocele repair techniques. There was less intraoperative blood loss in the STARR group compared to blood loss in the group undergoing standard vaginal rectocele repair (STARR, 43 mL; transvaginal rectocele repair, 108 mL; $p = 0.0015$) [23]. However, the study showed a higher complication rate from the transanal resection group (STARR 61.1% vs. transvaginal rectocele repair 18.9%, $p = 0.0001$). Similarly, meta-analysis in a Cochrane Review in 2013 comparing methods of surgical management of pelvic organ prolapse reported that the transanal approach was associated with significantly lower blood loss (a difference of 79 mL, 95% CI 40–119) compared to the transvaginal repair [11]. Obviously a single outcome such as intraoperative blood loss must not be the only driving factor for selecting an appropriate procedure.

Postoperative Evaluation and Management

It is important to identify postoperative hemorrhage in a timely manner because treatment and resuscitation can prevent other unwanted complications. Education and good communication with recovery room staff are necessary to help identify patients who may require intervention. The standard recovery room protocol in the immediate postoperative period should include monitoring heart rate, blood pressure, urine output, and inspection of surgical incisions or pads. In cases with known bleeding, serial complete blood cell labs with a coagulation panel every 4–6 h is recommended [17].

Patients who are hemodynamically stable but are noted to have excessive oozing from the surgical site should have a vaginal packing placed in order to help tamponade bleeding vessels and minimize the potential space for blood loss. Aside from packing gauze, other compressive devices utilize balloons (i.e., Foley catheters) to allow for appropriate pressure. These maneuvers are not applicable to abdominal repairs, as the potential space is often too large to contain and cannot be effectively compressed. Patients with postoperative hematomas may be monitored expectantly with hemoglobin levels every 6 h and monitoring for signs of infection, or drained.

When conservative measures of fluid resuscitation and packing are not sufficient more invasive measures may be necessary. This is especially true if a patient becomes hemodynamically unstable. Reexploration allows for identification of bleeding vessels and hopefully allows for the surgeon to gain hemostatic control. Reexploration also allows for removal of clot or accumulated blood that if left in situ may prolong recovery. This can be effective; however, one must make this decision to reexplore carefully. Bleeding that has slowed from tamponade, whether intrinsic or iatrogenic, now becomes brisker or uncontrolled after clot evacuation relieves pressure on the vessel or vessels. If during an intra-abdominal reexploration the patient becomes increasingly unstable or coagulopathic and the source of bleeding cannot be identified, the surgeon can consider packing the abdomen with surgical laps until resuscitation can be achieved.

Another option for uncontrolled bleeding is the selective embolization of bleeding vessels. Depending on availability and expertise, superselective embolization may be successfully performed [24, 25]. The time required to transfer a patient to an interventional radiology suite must be evaluated and considered when deciding to utilize embolization. Resuscitation cannot be compromised if this is going to be used to control hemorrhage.

The use of cross-sectional imaging (i.e., CT scan) before reexploration and/or intravascular intervention can be considered; however, it should not be done if this will delay definitive treatment in a hemodynamically unstable patient or if a specific bleeding source is suspected. A flow chart (Fig. 6.2) is provided as a reference for clinicians to use if postoperative bleeding is suspected. Obviously the assessment and management of bleeding complications from posterior compartment repairs must be managed in an individual manner based on clinical scenario and available resources.

Dyspareunia

Sexual function is a complex process that involves many organs and structures of the female pelvis. Further, there is an intricate interaction with the central nervous system, hormonal axis, peripheral nerves, and blood vessels. Women with pelvic organ prolapse may present with varying degrees of sexual dysfunction and the aims of pelvic organ prolapse surgery are to prevent worsening this dysfunction and, hopefully, to restore or improve a woman's sexual function. If there is no dysfunction to start and a woman desires to continue being sexually active, the surgeon should strive to avoid creating a problem. In spite of best efforts, painful intercourse, or dyspareunia, is a potential complication of any pelvic organ prolapse repair and this section will focus on this potential outcome from posterior prolapse repair.

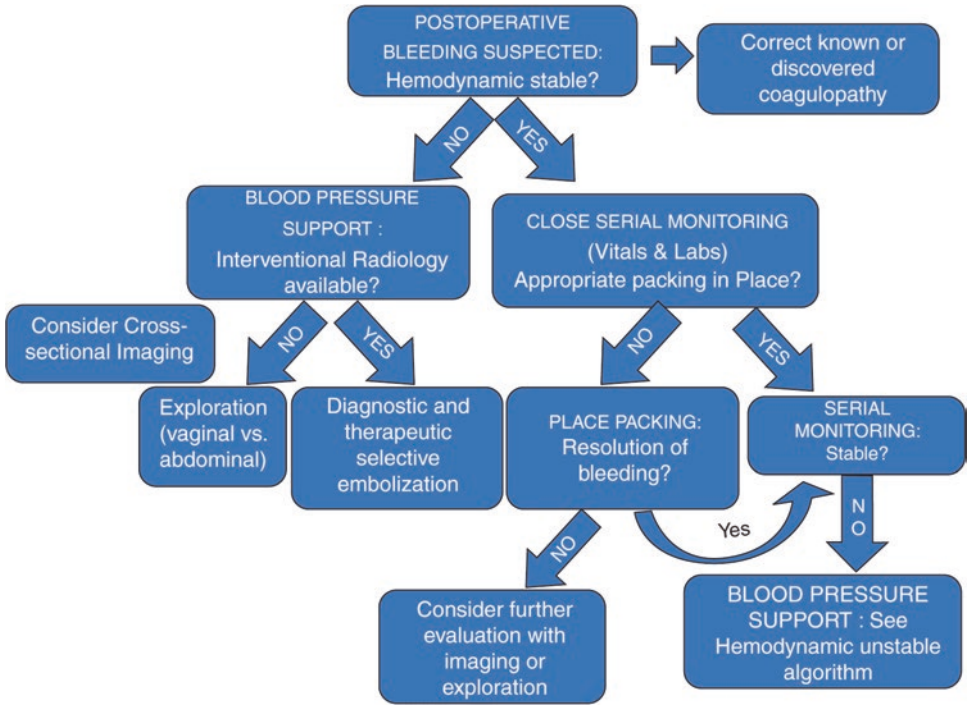

Fig. 6.2 Bleeding flow chart

Preoperative: Evaluation and Counseling

It is very important when taking a history preoperatively to assess if a patient is sexual active, plans on becoming active, and what her current sexual function is. Dyspareunia is reported as a presenting symptom in 29% of women undergoing rectocele repair [26]. Further, dyspareunia is a known potential complication of posterior compartment repair, so the above must be openly discussed preoperatively. There are numerous questionnaires that can be utilized to objectively classify a woman's sexual function both pre- and postoperatively. For example, the Sexual History Form and the Female Sexual Function Index are validated measures [27, 28]. Some questionnaires are for general sexual function and others have been validated specifically in the pelvic organ prolapse population. This preoperative assessment is important to help counsel the patient on the appropriate repair. It is also useful so that there is a baseline to compare postoperative outcomes against if results are not satisfactory.

Women with rectoceles can present with other aspects of sexual dysfunction along with dyspareunia. Out of a selective group of 68 women with sexual dysfunction who were undergoing fascial suture rectocele repairs, 85% were noted to have dyspareunia as a presenting symptom [29]. After the repair at six-month follow-up, the patients showed significant improvement for desire ($p > 0.001$), satisfaction ($p > 0.0001$), and pain ($p > 0.0001$). There were no significant changes for arousal ($p = 0.0897$), lubrication ($p = 1$), or orgasm ($p = 0.0893$). Only one patient experienced de novo dyspareunia. This was attributed to a postoperative infection resulting in excessive scar tissue of the posterior wall of the vagina. A systematic review by Jha and colleagues of 14 articles that assessed sexual function and dyspareunia before and after anterior and/or posterior prolapse repair with native tissue found significant improvements postoperatively in sexual function and dyspareunia [30]. Unfortunately this analysis included all patients who had prolapse repair regardless of whether anterior, posterior, or combined, and no subanalysis limited to posterior

repairs was performed. The authors did note that in studies by Colombo [31], Haase [32], and Dua and colleagues [33], higher rates of dyspareunia were reported in patients who underwent a colpoperineorrhaphy or posterior repair in addition to an anterior repair than in those patients who underwent an isolated anterior repair.

As noted earlier, after prolapse repair there is often an improvement in many of the sexual function domains; however, some studies suggest that posterior repair may have higher rates of postoperative dyspareunia than repair of other compartments of pelvic organ prolapse. One such study looked at a cohort of women who underwent anti-incontinence surgery and concomitant pelvic organ prolapse repair. They divide these women in two groups for comparison: those that had posterior repair and those who did not have a posterior repair. Although both groups had improvements postoperatively in their Pelvic Organ Prolapse-Urinary incontinence Sexual Function Questionnaire (PISQ) score, the women who did not have posterior repairs were noted to have a lower incidence of dyspareunia than those who had posterior repairs [34]. A systematic review of complications after vaginal prolapse repair found that reported rates of dyspareunia varied widely after prolapse repair surgery. Seventy studies were identified with reports of dyspareunia with an average rate of 9.1% and a range of 0–66.7%. These studies were not analyzed based on location of repair; however, five of the papers cited posterior repair as a risk factor for dyspareunia [35].

Dyspareunia rates following transvaginal posterior repair have not been found to vary by type of surgical repair. A meta-analysis showed similar dyspareunia outcome rates for posterior colporrhaphy and for site-specific posterior repairs. Traditional posterior colporrhaphy or midline plication had a reported mean postoperative dyspareunia rate of 18% (range 5–45%) based on analysis of seven studies with a total of 522 patients, and site-specific repair was found to have an identical mean postoperative dyspareunia rate of 18% (range 7–67%) based on analysis of eight studies with a total of 487 patients [6]. Another study compared traditional posterior colporrhaphy to site-specific repairs in a retrospective chart review and again found similar rates of dyspareunia and bowel symptoms, though the site-specific repair had a higher recurrence rate of a symptomatic bulge beyond the hymenal ring (11% vs. 4%, $p = 0.02$) [36].

The surgical approach, whether abdominal, vaginal, or transanal, may affect postoperative dyspareunia rates. In a randomized study comparing transanal and transvaginal rectocele repairs, none of the subjects reported de novo dyspareunia, while 27% reported improvement of sexual function, slightly in favor of the transanal repair [37]. Similar to prior studies, this study also found higher rates of prolapse recurrence with the transanal approach. Though less common, dyspareunia is also seen with the abdominal approach. Sergent and colleagues found that sacrocolpopexy with polyester mesh had a de novo dyschezia rate of 1.7% and dyspareunia rate of 0.8% [38]. Claerhout and coworkers utilized polypropylene mesh in abdominal repairs and found de novo constipation rates of 5% and de novo dyspareunia of 19% with mesh [39]. A comparison of these few small studies is not meant to replace a large randomized study (that would be more appropriately powered to show differences in these domains), but rather to illustrate that different mesh types (i.e. polyester vs. propylene) used abdominally may result in different dyspareunia rates.

Levator plication, another technique to correct posterior compartment defects, is associated with increased rates of dyspareunia. In a prospective study, 93 women who had undergone prolapse repair completed the validated International Consultation on Incontinence modular Questionnaire-Vaginal Symptoms (ICIQ-VS) at 6 and 12 months postoperatively. The study found that the subjective vaginal and sexual matters scores improved less in women who had levator plication sutures during posterior vaginal repair compared to those who did not. Furthermore, the women with levator plication showed a significant increase in postoperative dyspareunia ($p \leq 0.05$) while women who underwent posterior repair only had no change in their incidence of dyspareunia [40]. It is believed that

the de novo dyspareunia that occurs with levatorplasty results from pressure atrophy of the included muscle and the subsequent scarring that takes place [41, 42]. This may not be the complete cause, however, as dyspareunia can be associated with posterior colporrhaphy even if there is no concomitant levatorplasty or synthetic material used.

Intraoperative Considerations: Technique, Mesh, and Surgical Approach

Surgical techniques to decrease risk of dyspareunia are mostly based on expert opinion, as there are no well-designed, randomized controlled trials to assess the impact of different methods of posterior prolapse repair on sexual function and dyspareunia. Sexual function and dyspareunia have not been found to correlate with anatomical success of prolapse repair. One study of sexually active women undergoing posterior repair looked at whether vaginal dimensions at the time of surgery predicted dyspareunia and did not find an effect [42]. However, expert opinion suggests avoiding excessive tightening of the posterior vagina during a rectocele repair. If a concomitant perineal body repair is needed it is also important to avoid excessive tightening of the introitus as this can contribute significantly to sexual dysfunction after surgery. The surgeon's fingers can be used intraoperatively to calibrate the vagina to an appropriate size. Some advocate calibrating the vagina to 2–3 fingerbreadths, which should prevent anatomic difficulties with vaginal penetration in women who are interested in resuming this type of sexual activity [41].

The surgeon may choose to utilize an absorbable mesh, biologic graft, or permanent mesh. The use of mesh to augment posterior repairs is a potential contributor to postoperative dyspareunia. It is important to remember that the mesh may contract after it is placed intraoperatively. Mesh has been shown to contract or retract after placement with some showing up to a 66% decrease in size [43]. To date there is no clear evidence that this gradual decrease in mesh size is associated with dyspareunia, but it is a potential explanation for those who believe that mesh augmentation of the posterior compartment can worsen sexual outcomes. Mesh should be tailored or placed so as to avoid excessive tension to accommodate for such potential tightening. If vaginally placed mesh is anchored in structures such as muscle, the presence of a tight mesh band can lead to pulling on these muscles groups that may result in significant discomfort during intercourse. Mesh exposure and extrusion may also cause sexual complications and will be discussed later in the chapter.

Although mostly based on expert opinion, there are a few areas of surgical technique that should be considered when placing mesh posteriorly. Appropriate thickness of the vaginal flaps and meticulous closure of any vaginal incisions may reduce mesh-related complications. Care must be used to ensure appropriate placement of mesh so that it does not bunch or role in the vagina. This can form areas of inflammatory reactions that can be uncomfortable for women and may also be felt by male partners. Another potential cause of dyspareunia is vaginal narrowing. Vaginal narrowing can occur secondary to excessive trimming of the vaginal wall, which also result in tenuous coverage of any foreign material utilized. For abdominally placed mesh, differences in technique such as the extent of the posterior dissection or the width of the dissection with subsequent mesh fixation have also been proposed as potential factors that might lead to differences in painful intercourse post abdominal sacrocolpopexy.

Sexual function outcomes following vaginally placed biologic grafts have also been considered. Studies have been conflicted regarding whether graft augmentation of posterior repair improves anatomic or functional outcomes [44–46]. Therefore, the decision to utilize a graft or mesh should be weighed against the potential risks, including dyspareunia. Paraiso and colleagues compared posterior colporrhaphy, site-specific repair, and site-specific repair with porcine small intestine submucosa graft in a randomized trial [45]. They found no difference in postoperative sexual function (PISQ-12 and asking "Do you feel pain during intercourse?"). There were also no differences in quality of life measures or

bowel function. Perioperative and postoperative morbidity did not show a difference, albeit the study was underpowered to discern differences in these events. Importantly, however, they reported a lower failure rate with traditional repair techniques compared to the site-specific repair with porcine small intestine submucosa graft for rectoceles. This study suggests that sexual complications do not differ significantly based on repair type, but biologic agents have higher failure rates. A prospective cohort study of 50 women undergoing posterior wall repair and prespinous colpopexy with a biological small intestinal submucosa graft reported statistically significant improvement in vaginal symptoms and sexual matters score at 6 month follow-up [47]. One weakness of this study was that it did not have a control arm, so only limited conclusions can be drawn concerning the use of graft. Of note, this study found that concomitant pelvic surgery did not affect the outcomes of posterior wall repair with prespinous colpopexy and biological graft.

Synthetic permanent mesh is also used in prolapse repair. If the surgeon and patient elect to use a permanent mesh, selecting the appropriate type of mesh is an intraoperative decision that can minimize morbidity. Macroporous, monofilament, polypropylene mesh (type 1) has been found to have the most favorable biocompatibility profile of the synthetic meshes that are currently available. The lack of interstices allows native collagen to grow into the material and the large pore size allow for entry of macrophages and the body's other immune mediators [48]. One study that looked at posterior repair with permanent mesh (composite polyglactin 910-polypropylene) with 3-year follow-up found de novo dyspareunia in 27% of women [49]. The study's long-term follow-up showed no improvement from baseline, preoperative dyspareunia. This was in contrast to previously published short-term results that showed an improvement. When patients with persistent dyspareunia and those with de novo dyspareunia were combined for analysis, the prevalence of dyspareunia was a staggering 60%. The "extrusion" rate was 30% and the recurrence rate was 22%. The repair described in the study avoided a rectovaginal plication and trimming of vaginal wall because these maneuvers (that they avoided) could presumably result in vaginal narrowing, and ultimately dyspareunia. A prospective study of monofilament polypropylene mesh use in posterior repairs reported a similarly high rate of postoperative dyspareunia [50]. At mean follow-up of 17 months a statistically significant increase of dyspareunia from 6% preoperatively to 69% postoperatively was found. In this study, the surgeon dissected laterally to the rectal pillars, performed a plication of the rectovaginal fascial tissues, and secured the mesh. Excess vaginal wall was also trimmed prior to closing the posterior vaginal wall.

Based on the available studies, if a vaginal approach is elected for posterior repair we would caution the use of biological agents or permanent mesh given the high incidence of recurrence and dyspareunia. The International Urogynecological Association Grafts Roundtable that convened in 2005 suggested the following patient factors as relative contraindications for the use of biomaterials in pelvic floor reconstructions: pelvic irradiation; severe urogenital atrophy; immunosuppression; active infection; and comorbidities such as poorly controlled diabetes, morbid obesity, and heavy smoking [51], and we would agree with these relative contraindication for the use of biomaterials in posterior repairs. Further, in 2008 and 2011 the FDA issued Public Health Notifications on the serious complications of transvaginal mesh and subsequently stated that it might reclassify vaginal mesh as a high-risk device requiring clinical study from its status as a moderate-risk device approved in the 510(k) process. It is our opinion that because the data on the use of mesh in the posterior compartment would not support its routine use, as studies have found no significant reduction in recurrence rate with a higher complication rate, we reserve it for the rare case when the rectovaginal septum is completely obliterated.

There are other intraoperative techniques to prevent dyspareunia that may not fit neatly into a category. For example, the use of copious irrigation and perioperative antibiotics is something that routinely happens. These are simple methods

Fig. 6.3 An example of a prescription for vaginal diazepam: "Diazepam 5mg/g Sig. 1 suppository per vagina as needed. Dispense 30." Topical lubricants, vaginal estrogen, and topical local anesthetics have also been described to help lessen or alleviate mild dyspareunia symptoms

to reduce the risk of infection. These techniques are included in this section because of the potential complications that infection can carry. An abscess of a local surgical site infection, for example, may result in excessive scarring and inflammation that potentially lead to painful intercourse.

Postoperative Evaluation and Management of Dyspareunia

In order to identify postoperative dyspareunia, the surgeon should ask specific questions regarding the patient's sexual function. As with preoperative evaluations, standardized questionnaires can be utilized to aid with evaluation. Patient's bother and time from surgery must be considered when discussing potential treatments of this outcome. If a patient elects for therapy for dyspareunia, conservative treatment options exist. Topical lubricants, vaginal estrogen, and even topical local anesthetics have been described to help lessen or alleviate some of the more mild symptoms. Systemic or local anxiolytics such as benzodiazepines have also been utilized to help relax pelvic floor muscles (Fig. 6.3). When palpation on physical examination reveals pain at specific trigger points, injections with local anesthetics and/or steroids can be considered.

Physical therapy with the optional use of vaginal dilators is another method that can help address symptoms. Vaginal dilators are thought to improve dyspareunia by stretching the levator ani muscles and softening or preventing scar formation (Fig. 6.4). A randomized controlled trial of sexually active patients with no preoperative dyspareunia undergoing posterior colporrhaphy was done to determine when vaginal dilators could be safely used during the early postoperative period [52].

Fig. 6.4 Vaginal dilators come in increasing sizes to allow progressive vaginal dilation. Dilators and are thought to improve dyspareunia by stretching the levator ani muscles and softening or preventing scar formation

Patients were randomized to daily vaginal dilator use from postoperative weeks 4–8 or to no dilator use. No difference was found between those using dilators compared to controls with regard to de novo dyspareunia rates, Patient Global Impression of Improvement scores, or Pelvic Organ Prolapse/Urinary Incontinent Sexual Function Questionnaire-12 scores. Of note, in contrast to prior studies that reported improvement in dyspareunia with dilator use [16, 45], this study found no change in overall sexual function from baseline at 6 months. The authors attributed this difference to the relatively low dyspareunia rates at baseline and the lack of standardized definition of dyspareunia across studies.

Careful physical examination is also extremely useful to determine the specific cause of dyspareunia and to identify what will respond best to surgical intervention. Palpation for tight bands of tissue, extrusions, and tender pelvic muscles is an important aspect of the physical exam to identify potential causes of dyspareunia and to direct management of this complication. If a discrete band of tissue is identified on physical exam attached to the vaginal wall and incorporated into the levator ani muscles, operative release of this tissue can help to alleviate symptoms of pain during intercourse. Aside from the release of excessively tight tissue, graft material may be necessary if there is a paucity of local tissue to reconstruct an adequate vaginal lumen. Excessive narrowing of the vaginal introitus or canal may also require surgical intervention.

Other therapies have also been studied for the treatment of dyspareunia. There is level III evidence to support the use of botulinum toxin in the treatment of severe refractory vaginismus. This comes from a study of 24 women where the etiology of vaginismus was not specified in the inclusion criteria. After failing other therapies these women were injected with 150–400 units of onabotulinum toxin type A in three sites on each side of the puborectalis muscle. After a mean follow-up of 12 months none of the patients had recurrent vaginismus, and 75% were able to achieve satisfactory intercourse [53]. More specifically, there are case reports describing the use of botulinum toxin in a postoperative patient who experienced de novo dyspareunia and vaginismus [54, 55].

Rectal Injury

Injuring structures that lie adjacent to or in the surgical field is a potential complication of any surgical intervention. The defect that results in a rectocele is a deficiency of tissue or support between the vagina and rectum. The intimate relationship of the rectum to the rectocele defect makes the rectum a potential source for inadvertent injury.

Preoperative Prevention: Imaging, Bowel Preparation, and Estrogen

Preoperative imaging may be useful during surgical planning; however, there is no standardized method for radiographic rectocele evaluation. It has been reported that 80% of colorectal surgeons use defecography before a rectocele repair compared to only 6% of gynecologists [56]. This variance is due in part to a lack of evidence demonstrating superior outcomes associated with use of preoperative defecography. Defecography provides a two-dimensional view of rectal emptying and is useful to exclude patients with pelvic floor dyssynergia who will not benefit from an

operation. The dynamic nature of the test and use of contrast allows for visualization and identification of the rectocele and any adjacent enterocele, sigmoidocele, or intussusception. Knowledge of associated defects theoretically may aid in avoidance of injury and surgical planning, for example, the addition of a sigmoid resection or sigmoidopexy. A benefit of defecation proctography to dynamic MRI is that it is performed in a position of gravity, which permits study of anatomy and function under conditions that better recreate daily life [57]. However, some studies have shown a lack of utility in obtaining preoperative defecography. In an older study, 74 patients with rectocele and symptoms of obstructed defecation were prospectively enrolled and underwent preoperative defecography in addition to a standardized questionnaire and physical exam [58]. Following a combined transvaginal/transanal rectocele repair they were again evaluated with defecography and, at median follow-up of 58 months, results of the rectocele repair were independently evaluated. Outcome analysis found that clinical success was not influenced by preoperative size of the rectocele, barium trapping, internal intussusception, rectal evacuation, perineal descent, or radiologic evidence of anismus, leading the authors to question the role of defecography in predicting clinical outcomes. Another study retrospectively looked at 170 patients who had undergone defecography and compared detection of prolapse on clinical and radiographic exam [3]. The authors concluded that most radiographic rectoceles and cystoceles are found on physical exam, while correlation is poor between defecography and physical exam in cases of enteroceles and sigmoidoceles.

Depending on surgeon preference, a bowel prep may be used preoperatively for abdominal and transanal posterior repairs. A bowel prep does not necessarily decrease the risk of rectal injury; however, it does decrease the risk of gross contamination if in fact a rectal injury occurs. Some laparoscopic/robotic surgeons have suggested that more complete bowel prep decreases distention secondary to bulky stool or excessive bowel gas that can make dissection more challenging and interfere with visualization. Women with symptomatic rectoceles can have a significant degree of constipation and trapping of stool at baseline. In cases where women have excessive amounts of stool in the rectal vault, intraoperative rectal exam or manipulation can be a more challenging proposition. Patients may benefit from a modified bowel prep. An enema given preoperatively can be an effective way of cleaning out the rectal vault if that is all that is needed preoperatively. Enemas are generally well tolerated and do not dehydrate patients the same way a full bowel prep would.

Preoperative use of estrogen in postmenopausal women can also be considered to thicken the vaginal wall as this may facilitate dissection. Postmenopausal vaginal atrophy may increase the risk of visceral injury due to difficulty identifying proper planes of dissection and thinning of the vaginal wall. A randomized controlled trial found that preoperative estrogen treatment for 2-12 weeks restored vaginal cytology to the premenopausal state [59]. Vaginal wall thickness was not restored, however. Multivariate analysis has shown that local estrogen therapy has no protective effect on vaginal extrusion or exposure after vaginal mesh surgery or after when mesh is used for sacrocolpopexy (level 4) [60]. A more recent double-blind, randomized controlled trial on the role of low-dose estrogens in improving the outcomes of pelvic organ prolapse surgery when used preoperatively reported that epithelial and muscularis thickness was increased 1.8- and 2.7-fold, respectively ($p = 0.002$, $p = 0.088$) by estrogen. The intervention effect was assessed by measuring full-thickness vaginal wall biopsies after 6 weeks of topical estrogen use compared to placebo. In addition to increased wall thickness, the biopsies showed that estrogen use increased the synthesis of mature collagen and decreased degradative enzyme activity. Prior studies had also shown this increase in collagen synthesis with topical estrogen but had not shown a change in the thickness of the vaginal wall. There are no comparative studies to provide evidence regarding the routine use of local or systemic estrogen therapy before or after prolapse surgery using mesh. None of these studies look specifically at the risk reduction with preoperative estrogen on the relatively rarely reported complication of rectal injury.

Intraoperative Avoidance: Positioning and Risk of Rectal Injury

Patient positioning is important to minimize complications during posterior repair. Digital rectal examinations during transvaginal rectocele repair help to avoid or recognize rectal injury during dissection and or suture/trocar placement, and a draping technique that permits this should be utilized. The finger allows the surgeon to ensure that the rectal wall is not violated. Further, after repair the surgeon can perform palpation via rectal exam to identify the presence of suture or mesh material that may have been inadvertently placed through the lumen of the rectum. In a retrospective look at rectal injury during vaginal surgery, Hoffman and coworkers found that over an 11-year period they had a 0.7% injury rate utilizing a vaginal approach for a variety of surgical indications including prolapse [54]. After reviewing the cases they felt that prevention of injury required careful sharp dissection, preliminary dissection on either side of the midline, and occasionally the insertion of a finger into the rectum. They suggest that injection of sodium chloride solution or a dilute vasoconstrictor may also facilitate dissection. The authors of this chapter do not routinely utilize this technique during the posterior dissection because of the potential for distortion of the already thin tissue planes.

If an abdominal approach with laparoscopic or robotic assistance is selected, good basic laparoscopic/robotic technique should be observed. These practices include utilizing an OGT or NGT, and placement of a Foley catheter. Use of these measures is aimed at minimizing risk of injury to hollow viscous organs. We also avoid the use of nitrous oxide to prevent distention of the bowel. Decompression of bowel and bladder is especially important when gaining access to the abdominal cavity and thus these measures are not necessarily aimed at reducing rectal injury. However, intraoperatively they allow for better visualization and can prevent inadvertent injury during dissection.

Mesh prolapse repair kits may require placement via blind trocar passage and this has led some to investigate the risk of rectal injury during posterior mesh kit repair. In one series of mesh prolapse repair kits, with only short-term follow-up, the authors found that they had a 1.1% rectal injury rate [61]. Interestingly, the injured patients sustained the rectal injury during the initial dissection and not from the trocar passage. Both patients had the injury repaired primarily and one did have a posterior mesh placed while the other was converted to a more traditional colporrhaphy. Injury to the rectum has been noted in another series of patients treated with mesh kits where rectal injury was not caused by the initial dissection [62]. In this series of 62 patients, one patient (1.6%) had a rectal injury identified postoperative week one when a rectoscopy was performed for refractory defecatory pain and revealed an arm of the prolapse repair kit mesh traversing the lumen of the rectum. Though there are not much data regarding the safety of placement of mesh after recognizing a rectal injury, but we would in most cases argue against it.

Patients with pelvic organ prolapse can have a significant amount of posterior defects that the surgeon can attempt to address from the abdominal route, whether open, laparoscopic with or without robotic assistance. To achieve this, the dissection is carried down toward the perineal body between the vaginal wall and rectum. In one series of 165 women with vaginal vault prolapse undergoing laparoscopic sacrocolpopexy (using a polypropylene mesh), three sigmoid perforations were noted. These injuries were all in women being treated for rectocele, presumably during the posterior dissection. All injuries were recognized intraoperatively and successfully treated by laparoscopic suture repair [63]. Another series of 124 women undergoing laparoscopic sacrocolpopexy (using multifilament polyethylene terephthalate-polyester) noted two intraoperative rectal injuries (1.6%). One of the rectal injuries was immediately recognized and successfully repaired; the procedure proceeded as planned with uneventful follow-up for this patient. The other intraoperative rectal injury was not recognized, however, and the patient developed a rectovaginal fistula secondary to the occult rectal perforation. This was noted 3 weeks after the surgery, and the fistula was debrided and closed with suture. A transitory colostomy was

concomitantly performed. This patient unfortunately also developed a lumbosacral spondylodiscitis diagnosed at 4 months and required prolonged antibiotic therapy before complete resolution [38].

Identification of Injury

Regardless of approach, recognition of a rectal injury remains paramount in trying to minimize morbidity to the patient. Ideally an injury of the rectum is identified intraoperatively to avoid the sequelae of a delayed diagnosis and to potentially allow for correction of the injury, obviating the need for a repeat operation. If an injury is suspected adequate exposure is needed to investigate the integrity of the rectal wall. Rectal irrigation with saline or betadine may help confirm a small injury. Another technique is to fill the surgical field with irrigation and gently force air into the rectum with a Toomey or bulb syringe. This allows for identification of bubbles if a full thickness injury is present.

If an injury is recognized intraoperatively the surgeon must perform an adequate mobilization of the injured area. The mobilization allows for appropriate exposure so that the injury can be closed in entirety. Mobilization of the rectum away from other tissue is also usually necessary to allow the surgeon to complete the prolapse repair and is critical to a tension-free repair. After mobilization, a two-layer closure should be performed. The first layer uses delayed absorbable sutures to close the rectal mucosal defect (usually in a running fashion). The second layer is an imbricated seromuscular layer and a permanent suture or a delayed absorbable in a Lembert-type fashion has been utilized. It should be noted that during the dissection required to mobilize the injured bowel it is often possible to identify additional tissue (fat, fascia) that can be used to cover the two-layered closure.

The final factor to achieve the best possible outcome from an intraoperative repair of a rectal injury is to give patients appropriate postoperative instructions. It is paramount to ensure that the patient is having soft bowel movements. Also, patients should avoid anything per rectum for approximately 6 weeks. Fecal diversion is usually not necessary. Certainly if the surgeon is unsure of the need for diversion or is not comfortable with the repair, an intraoperative consult can be called.

Delayed Presentation of Unrecognized Rectal Injury

At times, rectal injury may not be recognized until postoperatively. A case report described a patient with ongoing complaints of severe pain radiating down her leg, pelvic pain, dyspareunia, dyschezia, diarrhea, and new onset fecal incontinence after a vaginal mesh placed 5 months prior [64]. On physical exam, mesh was palpable at the vaginal apex and traversing the rectal lumen 6 cm from the anal verge. The authors attributed the rectal injury to inadequate medial retraction of the rectum at the time of sacrospinous ligament fixation. A retrospective study of transanal resections reported a high rate (18%) of postoperative complications [65]. Though these all followed STARR resections, approaches to management can be applied to most rectal injuries. One patient presented with sepsis on postoperative day 1 with fever, hypotension, and retroperitoneal air and was treated with antibiotics. Though rare, a high suspicion must be maintained for perforation following posterior repair. In the study, two patients had abscesses at the level of the anastomosis requiring surgical drainage. Drainage should be considered in all patients who present with fluid collections, which may be caused by abscess or hematoma. If infected, the surgical site should be examined for foreign bodies that may serve as a nidus for infection and inflammation. In the STARR review, a granulomatous staple line led to chronic bleeding in eight patients and resolved after their removal. Any infection should be allowed to cool down before further intervention. In severe cases such as rectovaginal fistula, a diverting colostomy may be required. Identification and management of mesh complications and fistula will be discussed further later.

Rectovaginal Fistula

Cases of rectovaginal fistula have been reported with the use of mesh to augment a posterior colporrhaphy and posterior intravaginal slingplasty

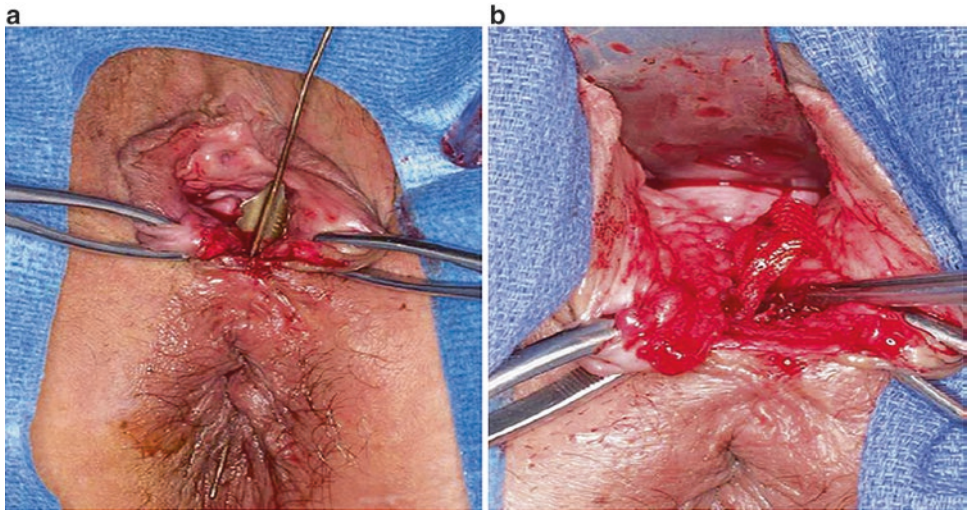

Fig. 6.5 Rectovaginal fistula. (**a**) Rectovaginal fistula demonstrated by a lacrimal duct probe entering the vagina and exiting the anus. (**b**) Posterior intravaginal sling plasty polypropylene mesh protruding though the dissected rectovaginal fistula (Reproduced with permission from Hilger W, Cornella JL. Rectovaginal fistula after posterior intravaginal slingplasty and polypropylene mesh augmented rectocele repair. Int Urogynecol J Pelvic Floor Dysfunct. 2006; 17(1):89–92)

(Fig. 6.5a, b) [66]. Women with rectovaginal fistula may present with foul smelling vaginal discharge, systemic signs of infection, and possibly pelvic or perineal adenopathy. A case series of 10 patients who underwent rectovaginal fistula repairs following prolapse repair with mesh highlighted the morbidity of mesh complications in the posterior compartment [67]. Patients underwent a mean of 4.4 surgeries for definitive fistula repair, with 40% requiring bowel diversion. Five of the patients in the series originally underwent a combined anterior and posterior repair, while three had isolated posterior repairs. On average, patients presented 7.1 months following prolapse repair. Fifty percent of the patients had visible mesh on physical exam, and all but two patients had confirmation of mesh extrusion on proctoscopy or colonoscopy. The authors reported that repairs were most successful when all mesh was removed as noted earlier for handling cases with intrarectal mesh without frank fistula.

It has become standard of care to obtain preoperative imaging in cases of suspected rectovaginal fistulas [68]. Anal endosonography and/or MRI are recommended to better define anal fistula anatomy, aid with planning of surgical approach, and to avoid recurrence of disease. Anal endosonography is often preferred because it is a quick exam, well tolerated by patients, and able to accurately identify the internal opening of the fistula and inter- or transsphincteric fistulas; however, it is highly operator dependent. MRI is recommended for evaluation of patients with recurrent fistula or Crohn's disease because it provides superior image quality, especially if an endoluminal coil is utilized in addition to a surface coil. The endoanal coil enhances spatial resolution, which allows the precise size and location of the internal fistula opening to be visualized, provides information about sphincter integrity, and visualization of both ano- and rectovaginal fistulas. The superior utility of MRI was shown in a prospective trial of 104 patients with suspected fistula [69]. Each patient underwent characterization of their fistula by physical exam, endosonography, and MRI, and the results of these three separate modalities were compared to a reference standard. This study found that

fistula classification was made correctly 61% of the time by clinical exam, 81% by endosonography, and 97% by MRI 97%. Furthermore, it found that MRI has increased sensitivity for detection of horseshoe extensions or abscesses.

Repairs of these fistulas are more involved than repairs of straightforward mesh extrusions. It is imperative to identify and deal with the internal fistula opening, which is usually at the dentate line and can be located through the use of palpation and gentle probes. The injection of air, hydrogen peroxide, or methylene blue may further aid in localization. Because of their complexity, it is recommended to involve a colon and rectal specialist as soon as the rectovaginal fistula is suspected. These repairs often require local tissue flaps, and in more complicated cases diverting colostomy may be considered. If a colon and rectal specialist is not present and intraoperative difficulties are encountered, such as unexpected anatomy, compromised anal canal, or failure to locate the internal opening, the procedure may be abandoned and a draining seton may be employed until a specialist is available to perform a sphincter-saving procedure [70].

Other Complications

Mesh Extrusion or Exposure

Complications with mesh extrusion or exposure are a concern when mesh is used for vaginal prolapse repairs. In 2011, the International Urogynecological Association (IUGA) and International Continence Society (ICS) published a joint terminology and classification scheme to standardize nomenclature for complications of prostheses, including mesh [71]. This advocated replacement of the more general term "erosion" with extrusion, defined as the passage gradually out of a body structure or tissue, and exposure, defined as a condition of displaying, revealing, exhibiting, or making accessible. Adoption of this terminology has not been complete and earlier papers often utilize the older terms leading to imprecision of reported complications.

Risk factors for mesh exposure are similar whether they occur in the vaginal lumen, where it may be discovered on routine pelvic examinations during follow-up, or in the rectum. A 2011 meta-analysis of prolapse repair data found that most graft "erosions," defined in the analysis as exposed graft material in the vagina or surrounding pelvic organs, occur within 1 year of surgery and should be suggested when patients present with dyspareunia, discharge, and/or vaginal pain [35]. This analysis found rectocele repair at the time of vaginal prolapse repair, increasing age, and concomitant hysterectomy to be risk factors for vaginal graft "erosion." In contrast, a more recent systematic review of risk factors for mesh "erosion" found fewer graft "erosions" with increasing age and identified concomitant hysterectomy to be a potential protective factor [72]. This review also identified greater parity, diabetes mellitus, smoking, and premenopausal/ERT as risk factors for mesh "erosions" after female pelvic floor reconstructive surgery. A prospective study looking at outcomes with mesh kits found that the Apogee kit used for posterior repairs had a lower rate of mesh extrusion or exposure than the Perigee kit used for anterior repairs [20]. Like the meta-analysis described earlier, the study identified concomitant hysterectomy as a risk factor for extrusion or exposure along with increased parity, previous native tissue repair, concomitant repair of both compartments, concomitant sling, smoking, and constipation.

Mesh extrusion into the vaginal epithelium can be seen if mesh is used to augment posterior repairs [73]. Care must be used to ensure the appropriate planes of dissection. Improper dissection can potentially lead to thinned vaginal wall that can increase the chance of mesh extrusions when it is used to cover the mesh. Dwyer and coworkers had a 9% overall extrusion rate noted with the use of monofilament polypropylene mesh placed in the anterior and posterior

compartment (and one patient who developed a rectovaginal fistula) [73]. Posterior vaginal mesh extrusion is handled in much the same way that any mesh extrusion is handled as discussed elsewhere in this book. Observation may be warranted if asymptomatic. Topical local estrogen is another conservative approach, and finally, local excision and closure of the vaginal epithelium may be necessary. This may be performed under local anesthesia utilizing an Allis clamp to grasp the exposed mesh prior to sharp excision. In cases of pain secondary to mesh contraction, which may present with prominent bands under the vaginal mucosa, incision may be all that is needed. Lim and coworkers retrospectively noted a 12.9% incidence of vaginal mesh extrusion at 1 year, when a vicryl–prolene mesh was used with posterior colporrhaphy [49]. The authors noted that all of these extrusions were dealt with easily by trimming the area, without the need of mesh removal, in the outpatient setting. In cases when mesh exposure exceeds 5 mm or is compounded, we recommend performing the excision in the operating room.

Mesh can also extrude into the rectal lumen, where it is less likely to be visualized or palpated during a routine postoperative speculum examination of the vagina. A digital rectal exam should thus be considered part of the postoperative physical exam, especially if a posterior repair was performed. There are case reports and prolapse repair series that describe a small, but real, number of women who develop mesh extrusions, exposure, or misplacements into the rectum recognized postoperatively [74–76]. Successful diagnosis of mesh extrusion into the rectum requires a high index of suspicion. Women may present with rectal bleeding, change in bowel habit, or worsening dyspareunia several months after posterior prolapse repair with mesh. Physical examination is often all that is needed to confirm suspicion of a mesh complication but more involved testing with a rigid sigmoidoscope may also be necessary. Figure 6.6a, b shows an example of mesh seen by an endoscope in the rectal wall. We know from the trauma literature on penetrating rectal injuries that rigid sigmoidoscopy is much more sensitive than digital rectal exam for uncovering rectal injury. This is a different population with a different mechanism of injury; however, if suspicion is high that a rectal injury occurred (or developed), digital rectal exam alone may not be adequate [77].

For cases of transvaginal excision of synthetic mesh with involvement of the rectum, the basic idea is to remove as much (if not all) of the mesh as possible and to repair any violations of the rectum. Data on surgical techniques and outcomes of mesh excision are limited to small retrospective studies. Based on the extent of the injury and comfort of the surgeon these procedures can be done in conjunction with a colorectal surgeon. A posterior midline vaginal incision is probably most common as it allows for complete exposure. The vaginal epithelium should then be dissected from the fibromuscularis laterally. The mesh should be identified and it is useful to facilitate the initial dissection by grasping it with an instrument such as an Allis clamp. Ideally the distal edge of the mesh is now identified and freed sharply. At this point the mesh should be dissected off of the rectovaginal septum in a cephalad direction. The use of a finger in the rectum can help the surgeon appreciate the appropriate depth of dissection as well as the area(s) of rectal violation. Furthermore, the rectal exam can identify the location of the anal sphincter. Awareness of this location allows us to avoid unnecessary sphincter injury. The mesh should be removed laterally to the pelvic sidewalls to as great an extent as possible, assuming this does not worsen the extent of the injury or potentially prevent adequate tissue to repair. This is often aided by incising the mesh down the middle allowing for dissection above and below the synthetic mesh, freeing it completely. In many cases, mesh can become incorporated into the rectal submucosa or placed through the rectal mucosa, and in order to remove it, it may be necessary to resect a full-thickness portion of the anterior rectal wall. The defect should be closed in at least two layers in a watertight fashion. A proc-

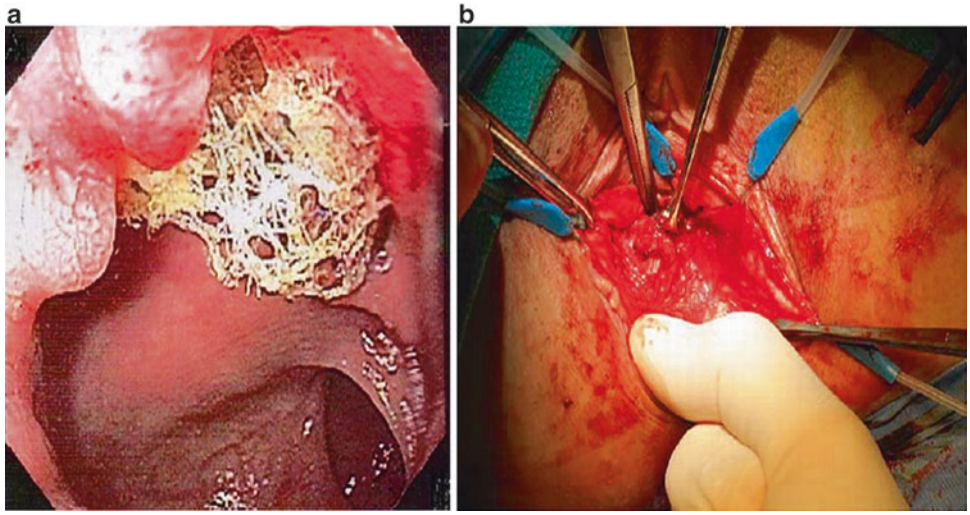

Fig. 6.6 Posterior mesh complication. (**a**) View during a sigmoidoscopy of an eroded (or misplaced) mesh visualized in the lumen of the rectal wall. (**b**) An intraoperative photo of the mesh removal via a transvaginal approach. The surgeon's finger is placed in the rectum to aid in the removal of the mesh. (Reproduced with permission from Hurtado EA, Bailey HR, Reeves K. Rectal Erosion of Synthetic Mesh Used in Posterior Colporrhaphy Requiring Surgical Removal. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(12):1499–1501)

toscope or other means of irrigating the rectum (i.e., a catheter) should be used to ensure that the closure is adequate. After the mesh removal and defect repair, a rectocele may be present and this should be closed without synthetic material. The vaginal epithelium is then closed.

Bladder Injury

Bladder injury is an uncommon complication during posterior prolapse repair. A series of patients with mesh prolapse repair kits had a 1.6% intraoperative bladder injury rate [61]. The authors noted that these injuries were secondary to the trocar placement and not dissection. Another series discussed earlier of 124 patients who underwent laparoscopic sacrocolpopexy noted three bladder injuries (2.4%) [63].

If mesh is discovered in the lumen of the bowel or bladder, attempts to treat the mesh complication can be done endoscopically. This is usually done by cutting the exposed mesh and allowing the mucosa or urothelium to heal over the excised arm of the mesh. However, if this is unsuccessful, not possible, or if a more definitive approach is desired, a mesh excision with repair of the adjacent involved organ is warranted. This can be done by a transabdominal or transvaginal approach depending on the approach of original mesh placement, the site of the mesh complication, the surgeons skill set, and the potential need for concomitant procedures.

Summary

See Fig. 6.7 for a summary of the main complications of posterior compartment repair.

	Hemorrhage	Dyspareunia	Rectal Injury
Preoperative	Identify bleeding diathesis ○ Hereditary risk ○ Medication	Assess Function/Dysfunction ○ Degree of sexually activity ○ Future plans for sexual activity ○ Sexual Function questionnaires	Imaging in select cases ○ dynamic MRI ○ defecating proctogram Consider bowel prep (modified or full) Preoperative estrogen
Intraoperative	Maintain proper visualization Awareness of vasculature ○ Inferior gluteal artery + coccygeal branch, hypogastric and pudental venous plexi- *Vaginal approach* ○ Presacral venus plexus- *Abdominal approach* Reinforce staple line with hand-sewn suture- *STARR Approach* Utilize compression, packing, hemostatic matrix, absorbable hemostat, pneumoperitoneum	Avoid levator plication if possible Avoid excessive tightening of the posterior vagina and the introitus- calibrate often Consider relative contraindications to mesh use. However if utilizing mesh: ○ Place without excess tension, bunching or rolling ○ Accommodate for contracture ○ Avoid anchoring in muscle ○ Minimize trimming of vagina Reduce infection with irrigation and perioperative antibiotics	Position patient to permit digital rectal examination Identify injury early if able ○ Inspect posterior dissection, utilize irrigation and/or air ○ Palpate via rectal exam for suture or mesh If injury recognized and primary repair viable adhere to basic principles ○ Mobilize area ○ Irrigation ○ Two-layer closure: 1st running delayed absorbable, 2nd imbricating Lembert permanent or delayed absorbable suture
Postoperative	Recovery Room Protocol ○ HR, BP, UOP, inspection of incision ○ CBC, coagulation panel q4-6 hrs with known bleed ○ Vaginal packing If Bleeding Suspected ○ Hematoma- Hgb q6hrs ○ Cross-sectional imaging ○ Reexploration –or– IR Selective Embolization	Use Sexual Function questionnaires to identify dysfunction Conservative Measures ○ Topical lubricants, vaginal estrogen, topical anesthetics, anxiolytics ○ Physical therapy, vaginal dilators Interventions ○ Trigger-point injections ○ Botulinum toxin for vaginismus ○ Surgical release of tissue bands ○ Reconstruction for narrowing	Postoperative instructions ○ Bowel regimen, soft stool ○ 6 wks nothing per rectum Delayed Presentation of Injury ○ Palpate for foreign body(s) ○ Maintain high suspicion for perforation ○ Drain abscess or hematoma if found Additional Evaluation of Fistula ○ Anal endosonography or MRI ○ Colorectal specialist, draining seton, identify internal opening

This chart contains an assortment of tips and suggestions and is not meant to imply standard of care. Utilizing these thechniques does not in all cases reduce the risk of complications or improve outcome as the data remains limited.

Fig. 6.7 Summary of the main complications of posterior compartment repair

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Uterosacral Ligament Suspension

7

Kamran P. Sajadi and Sandip Vasavada

Introduction

Uterosacral ligament vaginal vault suspension (USVVS) is one of the most common native-tissue transvaginal apical suspensions and offers a minimally invasive alternative to sacrocolpopexy in select patients. Nonetheless, as with any major surgical procedure, there are complications specific to this approach. Complications common among all reconstructive pelvic surgeries—including urinary tract infection, wound infection, venous thrombosis, and position-related neuropraxias—are discussed elsewhere. We focus on major complications related to USVVS including hemorrhage, ureteral injury or obstruction, bowel injury, and peripheral nerve injuries specific to this approach.

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Hemorrhage

The incidence of hemorrhage requiring blood transfusion during USVVS is 1.3–1.6% [1, 2]. Prompt attention to bleeding is necessary because this procedure is intraperitoneal, and therefore it can be difficult to control by tamponade alone. When bleeding is encountered during USVVS, it is important to remember that the most common sources may be the uterine vessels if a concomitant vaginal hysterectomy was performed. For this reason, leaving long suture tags on the pedicles for easy retrieval and examination can be invaluable. The distal uterosacral ligament lies close to the uterine vessels, close to the ureter, and is the weakest part of the ligament, and therefore targeting suspension sutures towards the middle or proximal uterosacral ligament is the best approach. Minor to moderate bleeding from placement of the uterosacral ligament suture can be controlled by applying tension to the suture until the end of the operation, at which point it can be tied down to stop the bleeding.

Ureteral Injury and Obstruction

Ureteral obstruction from USVVS usually results from kinking of the ureter during plication of the uterosacral ligament to the vaginal cuff and, less commonly, direct ureteral suture injury. The distal

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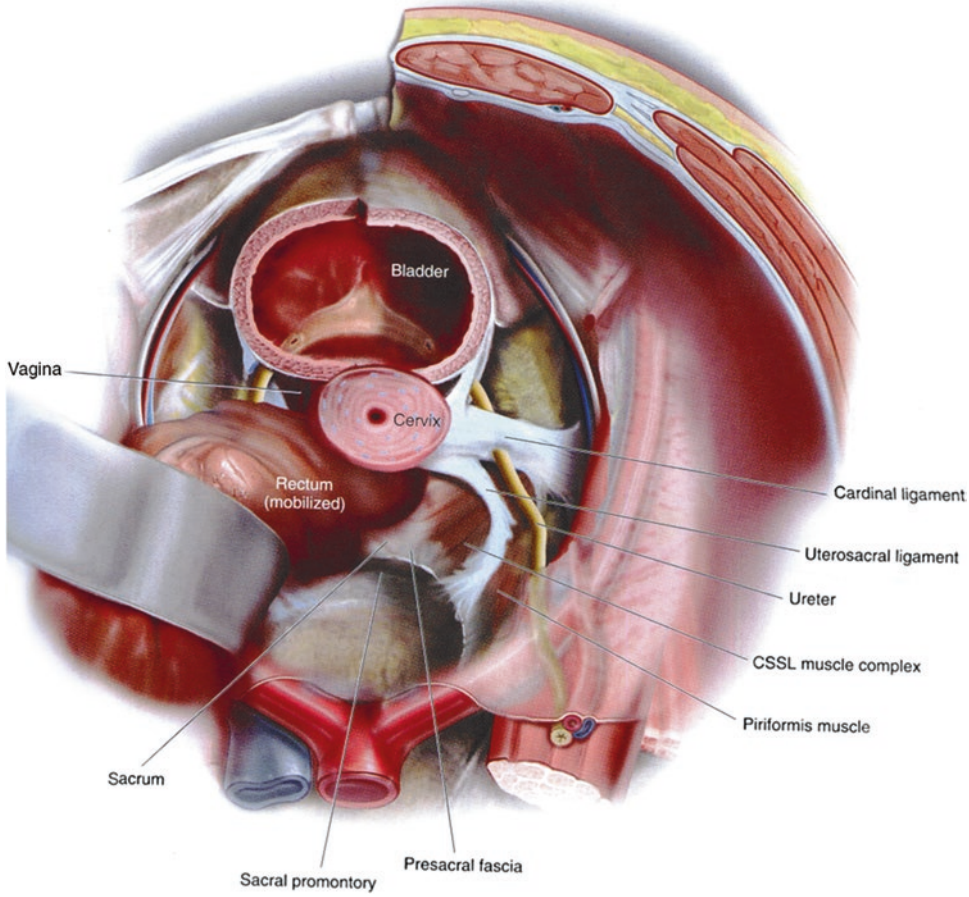

Fig. 7.1 Abdominal view illustrating the relationship between the ureter and the uterosacral ligament. Proceeding cephalad, the uterosacral ligament proceeds medially while the ureter proceeds laterally. Vault suspension to the proximal third therefore has the lowest rate of ureteral obstruction. (Used with permission of Elsevier from Vaginal Repair of Vaginal Vault Prolapse. In: Baggish MS, Karram MM: Atlas of pelvic anatomy and gynecologic surgery, 3rd ed. PhiladlephiaA: Elsevier-Saunders; 2011;709)

uterosacral ligament is intimately involved with the cardinal ligament—which contains the uterine vessels—and lies in close proximity to the ureter. Anatomic studies of the ligament demonstrate that the middle and proximal segments may be ideal for use in apical suspension, with the mean ± SD distance from the ureter 0.9 ± 0.4 cm distally, 2.3 ± 0.9 cm in the middle segment, and 4.1 ± 0.6 cm proximally (Fig. 7.1) [3]. Ureteral kinking is minimized by placing sutures from lateral to medial, which is away from the ureter [4]. Patient demographics and the number and type of suture used have not been shown to predict ureteral kinking [1, 5], but the use of a suture placement device may be protective against ureteral obstruction [5]. Obstruction can occur in up to 11% of procedures [6], but the incidence is markedly reduced by performing cystoscopy at the conclusion of the procedure. With intraoperative cystoscopy, the contemporary incidence of intraoperative ureteral kinking is 3.2–4.5% [1, 7], and postoperatively identified (i.e., not detected by intraoperative cystoscopy) ureteral obstruction is 0.5% [1]. Historically, indigo carmine is injected intravenously, and cystoscopy is performed to visualize efflux of dye from each ureter. If a strong ureteral jet is seen from both sides after the vault suspension has been completed, then ureteral obstruction is

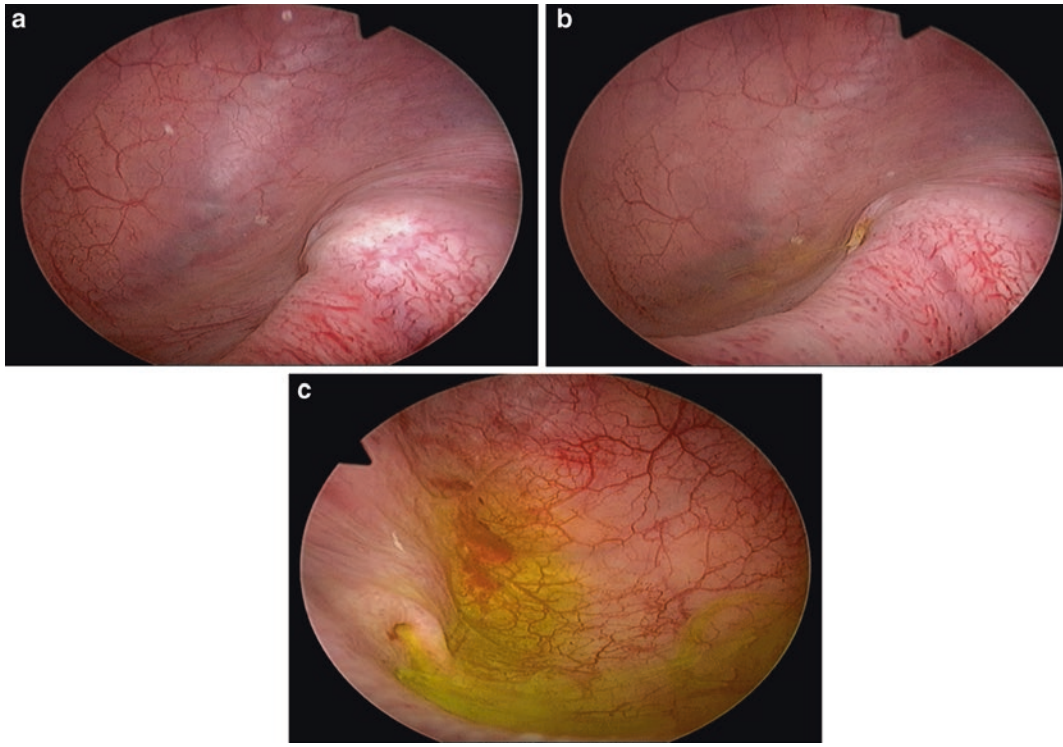

Fig. 7.2 (**a**) Cystoscopic view of the right ureteral orifice. (**b**) Following IV administration of sodium fluorescein, brisk efflux of neon-yellow urine occurs, indicating ureteral patency. (**c**) Within minutes of administration, efflux from the contralateral ureteral begins to discolor the entire bladder contents

unlikely. In the United States, indigo carmine has limited availability, but a few alternatives exist [8]. In our experience, methylene blue takes too long to be excreted once administered and has risks of drug interactions with several classes of drugs patients may be taking. Preoperative oral phenazopyridine can be administered; however, this requires preoperative planning. We prefer to use sodium fluorescein (10% solution, 0.25 – 1 mL IV), which produces rapid excretion of a bright, neon-yellow efflux that is easy to visualize (Fig. 7.2c) [9]. Anecdotally, one should readily visualize the ureteric orifices first before sodium fluorescein administration as the cystoscopic field will quickly become opacified with the neon-yellow efflux and make further identification of the ureteric orifices challenging. A study of hysterectomies showed that cystoscopy is cost-effective when the rate of injury is at least 2% [10], and intraoperative as opposed to postoperative diagnosis of ureteral obstruction substantially reduces morbidity [11].

Ureteral Obstruction: Intraoperative Presentation

When there is no efflux from one or both sides, it is important to have a clear plan and algorithm in place for diagnosis and management (Fig. 7.3). First, consider the patient scenario. Reevaluate the patient's history to consider if she has had a prior nephrectomy or ureteral reimplant; in the latter case, the ureter may efflux from a different position. If the patient has had any previous abdominal imaging, it can be helpful in identifying the occasional case of a prior nephrectomy or congenital absence of the ipsilateral kidney.

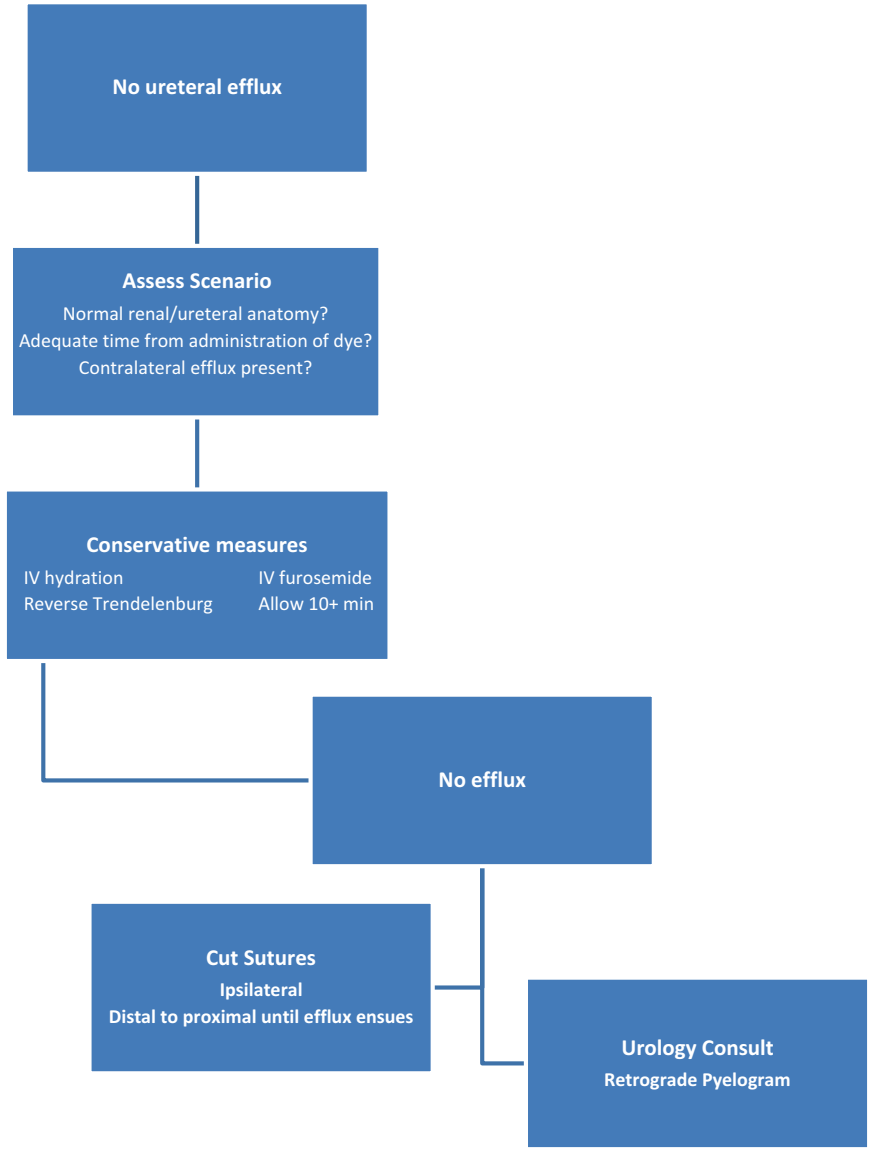

Fig. 7.3 Algorithm for evaluation and management when ureteral efflux is not seen cystoscopically following USVVS

In addition, confirm the time of administration of sodium fluoroscein with the anesthesiologist or nurse, as early delivery may mean that all dye has been excreted. Many different maneuvers have been attempted to promote more rapid excretion of the dye. Most commonly, ensuring adequate hydration by the anesthetist and/or administrating a diuretic such as furosemide may promote more rapid renal excretion of sodium fluoroscein. Resuming a level position or reverse Trendelenburg to encourage gravitational drainage has also been performed although these reports are anecdotal. Once sufficient time has passed to confirm a lack of excretion from one or both sides, there are a few ways to proceed. One option is to cut the more distal (i.e., more lateral) uterosacral plication suture (the uterosacral ligament is closest to the ureter distally) out of the vaginal cuff, and observe if efflux then occurs. With an assistant, it is possible to cut this suture while the cystoscope is still in place. If this suture was the cause, brisk efflux will usually

immediately ensue and most pelvic reconstructive surgeons would not attempt to replace the suture in this situation because replacing or not replacing those sutures does not seem to affect the rate of prolapse recurrence [1]. If efflux does not ensue, remove the remaining sutures on that side, one at a time, proceeding from the most lateral and caudad to the most medial and cranial. It is important to remember, however, that if a concomitant anterior colporrhaphy was performed, that procedure also carries a risk of ureteral obstruction, and it may be prudent to remove those sutures although the rate of ureteral kinking with USVVS is higher than from anterior colporrhaphy [5].

Occasionally, there will still be a lack of efflux even after removal of all potentially offending sutures. If the patient lacks preoperative upper urinary tract imaging or sufficient historical reason to explain the lack of efflux, urologic consultation is indicated. The most common obstacle to performing retrograde ureterography in such cases is that these patients are often not positioned appropriately on the bed or on an appropriate operative table for pelvic fluoroscopy. Therefore, many urologists will attempt blind passage of a wire or ureteral catheter into the ureter to assure patency. If this is done, a flexible tipped, soft hydrophilic wire should be used, and even then there is risk of converting a ureteral kink or obstruction into a ureteral perforation. Making the extra effort to obtain a C-arm and repositioning the patient can significantly improve patient safety. With retrograde ureteropyelography, the urologist can accurately assess the patency of the ureter and make a decision whether or not a stent should be placed. If there is a suspicion of injury and a stent can be passed, it should be left in place for a minimum of 4–6 weeks [11].

Ureteral Obstruction: Postoperative Presentation

Ureteral injury is a potential complication of uterosacral colpopexy even when intraoperative cystoscopy reveals bilateral ureteral efflux. The so-called delayed obstruction may occur due to excessive scarring between the uterosacral plication and the distal ureter, due to compromise of the ureteral blood supply or perhaps because of inadequate intraoperative examination for efflux. Ureteral obstruction presents in the acute postoperative period with flank pain, nausea, and vomiting, and potentially fever. The diagnosis should be confirmed with imaging, and the study of choice in patients with normal renal function is CT Urography (CTU, see Fig. 7.4c). The severity of hydronephrosis, site of ureteral obstruction, presence and location of any extravasation, presence or size of a potential urinoma, and the status of the contralateral kidney can all be assessed with a CTU. Once identified, in the acute postoperative period (up to 7 days), cutting the offending colpopexy sutures may be sufficient to relieve the obstruction. It is usually ideal to perform this in the operating room for several reasons. Aside from patient comfort, under anesthesia cystoscopy and retrograde ureteropyelography can be performed at the same time to confirm patency of the ureter following removal of the suture(s). In addition, given the potential for ureteral edema and the severity of the obstruction, many urologists would choose to place an indwelling ureteral stent after relief of the obstruction. With further delay in presentation or failure to unobstruct in this manner, open abdominal or laparoscopic ureterolysis and reimplant are often necessary although transvaginal ureterolysis and retrograde stenting has also been reported [12]. In a meta-analysis of USVVS, there was a 1.8% rate of ureteral obstruction, of which 2/3 resolved with suture removal, and the remainder required ureteral reimplantation [2].

Bowel Injury

Despite the intraperitoneal nature of the operation, bowel injury is rare with USVVS and is reported in less than 1% of cases [1, 2]. Small bowel obstruction (SBO) is very rare and was first reported in a series in 2007 [13]. Three patients presented with significant nausea and vomiting on postoperative days 1–14 and were found to have possible SBO [13]. After failing conservative management, all subsequently

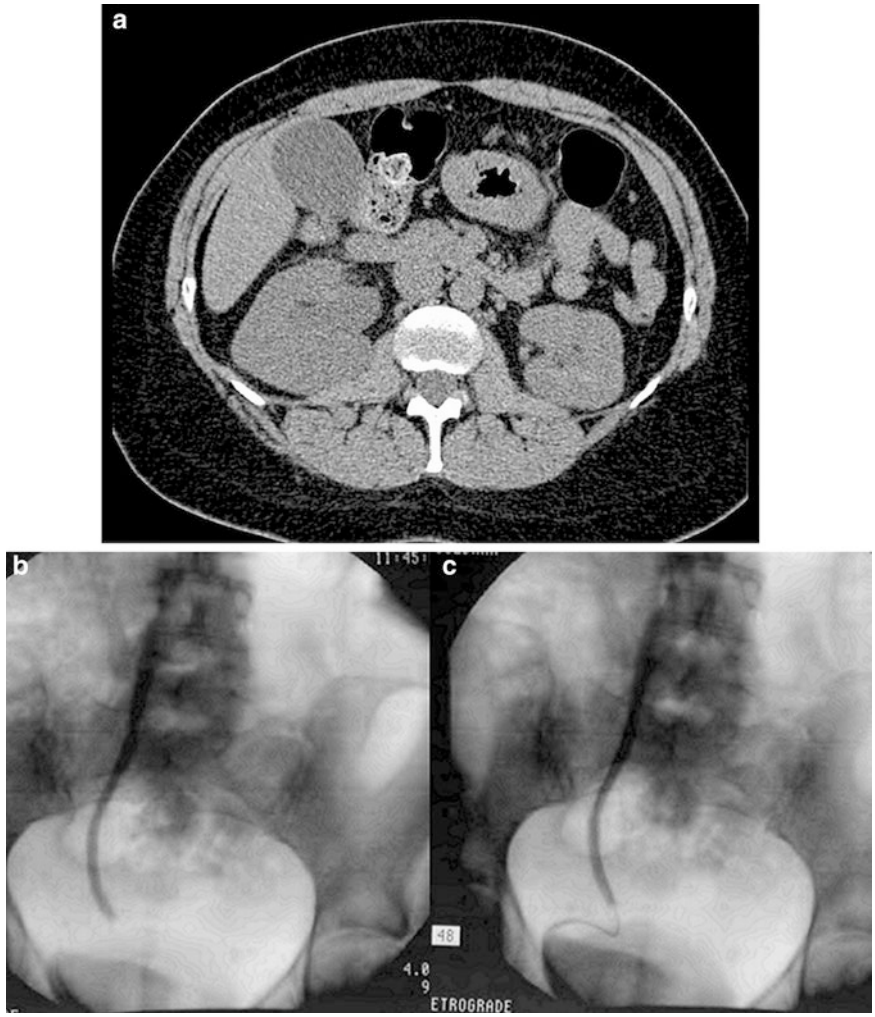

Fig. 7.4 (**a**) A woman with postoperative suspicion of ureteral injury is found to have right hydronephrosis on a CT. (**b**) Right retrograde ureterography demonstrates medial deviation of the distal ureter, and the distal ureter is not opacified. (**c**) A wire was successfully passed, over which a stent was then placed. (Courtesy of Howard Goldman, MD, Cleveland Clinic, OH)

underwent laparoscopy, and the source of the obstruction was adhesions in two of the patients, and a polypropylene suture in the third. One of the patients requiring significant adhesiolysis and underwent small bowel resection and enteroenterostomy due to enterotomies during dissection. SBO is more likely with known abdominal and pelvic adhesions or history of endometriosis [1]. Careful attention to surgical technique helps maintain a very low rate of SBO or bowel low. When exposing the uterosacral ligaments, packing of the bowel with tagged, counted laparotomy sponges is usually necessary. The peritoneum should be carefully inspected for abdominal adhesions, the sponges advanced slowly and gently to avoid enterotomies, and gentle retraction on the sponges to minimize trauma. Similarly, these packs should be removed slowly and carefully, and counted, after placing suspension sutures. If performing culdoplasty, care in closing the peritoneum can avoid capturing bowel in the closure and keeping the patient in the Trendelenberg position during this maneuver.

Evisceration

Small bowel evisceration has been reported following vaginal hysterectomy [14, 15]. Evisceration is a surgical emergency, and although some have had success through a transvaginal route alone, usually a transabdominal route is helpful to assess the viability of the small bowel involved [16].

Neurologic and Pain Complications

The intraperitoneal nature of this operation makes direct visualization of retroperitoneal vasculature and nerves difficult, and therefore a thorough anatomic understanding is necessary.

Assessing the position of the ischial spine allows avoidance of the pudendal nerve, which is usually sufficiently far from the uterosacral ligaments [17]. The sacral nerve routes are closer and more susceptible to injury during USVVS. A cadaveric study demonstrated that by tenting the uterosacral ligaments distally and ventrally using an Allis clamp before suture placement, the sacral nerve roots can be avoided [17]. Although tension on the ligament is also distributed to the ureter, this effect is seen most dramatically distally and can be avoided by proximal suture placement [3]. The sacral nerve roots as well as the intrapelvic portion of the sciatic nerve are vulnerable to entrapment during uterosacral suspension, which can explain postoperative pain in some patients [18]. Sensory neuropathies in the S1–S4 distribution have been reported in 1.1–3.8% of patients, but weakness has also been reported [1, 19, 20]. Pain tends to present in the acute postoperative period, in the distribution of the S1 through S4 nerve roots, with a sharp, stabbing pain in the buttock, perineum, and or lower extremity in a dermatomal distribution [19, 21, 22]. Nerve entrapment pain is more common on the right side, which is thought to be due to a predominance of right-handed surgeons, or a relative protective effect of the rectosigmoid junction on the left [17, 19, 21]. Medical management consists of nonsteroidal anti-inflammatories, narcotic pain management, and/or neuromodulating agents such as gabapentin or amitriptyline, and adjuncts can include physical therapy [21]. When conservative measures fail, removal of the ipsilateral sutures is indicated and often causes precipitous relief [21]. Similarly, when pain is severe and abruptly presents upon awakening from surgery or in the recovery room, the sutures on the side of pain should be removed promptly in the operating room [22]. With the appropriate management, neurologic symptoms usually resolve within 12 weeks [1, 19, 21, 22].

Summary

USVVS is a minimally invasive prolapse repair that carries specific risks. Minimize the risk of ureteral kinking by suture placement proximal on the ligament, from lateral to medial, but cystoscopy should be performed regardless to confirm ureteral patency. Less than 2% of cases require blood transfusion, and most minor bleeding resolves with tying suspension sutures. SBO occurs <1% of the time, usually due to adhesive disease. Manual tenting of the ligament can help avoid injury to sacral nerve roots. The incidence of postoperative neuropathies is <4%, and most resolve with conservative measures or suture removal.

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Sacrospinous Ligament Suspension

8

Elodi Dielubanza and Javier Pizarro-Berdichevsky

Introduction

Apical prolapse presents an important challenge to reconstructive surgeons. Recognition and proper management of apical prolapse is imperative in minimizing the risk of recurrent symptoms in women with multi-compartment disease. Abdominal sacrocolpoexy, uterosacral vault suspension, iliococcygeus vault suspension, and sacrospinous ligament fixation (SSLF) are well-accepted techniques for the treatment of apical prolapse. Despite the wide availability of traditional and robotic-assisted laparoscopic techniques to minimize the morbidity of transabdominal repair, transvaginal approaches predominate surgical correction of pelvic organ prolapse. More than 80 % of surgeries for pelvic organ prolapse are performed in this manner [1]. Uterosacral vault suspension, iliococcygeus fixation, and SSLF are viable choices due to ease of access, lower morbidity, recovery and hospital stay, and applicability across a wide range of age, health status, and surgical history, compared to transabdominal approaches.

Sacrospinous ligament fixation is an extraperitoneal technique that can be utilized with the uterus in situ or post-hysterectomy. Fixation can be performed unilaterally or bilaterally, via either an anterior or posterior approach. The advantages of SSLF include the preservation of vaginal length and width and extraperitoneal nature of the procedure, which minimizes risk of direct bowel injury and enhances the efficacy of hemostatic maneuvers in the setting of significant bleeding. The main disadvantages of the approach include the technical complexity of identifying the ligament and the posterior deviation of the vaginal axis, which may contribute to recurrence of anterior prolapse and dyspareunia. Common practice is to perform a unilateral, right-sided fixation via a posterior approach. Unilateral fixation offers comparable efficacy to bilateral, and right-sided procedures reduce the risk of indirect bowel injury by alleviating the need to retract the sigmoid colon to visualize the left ligament.

The overall rate of complications associated with SSLF reported in the literature ranges from 2.3 to 16.7 % though serious complications comprise only a small fraction of these [2]. Intraoperative and postoperative complications can often be avoided with understanding of relevant anatomy

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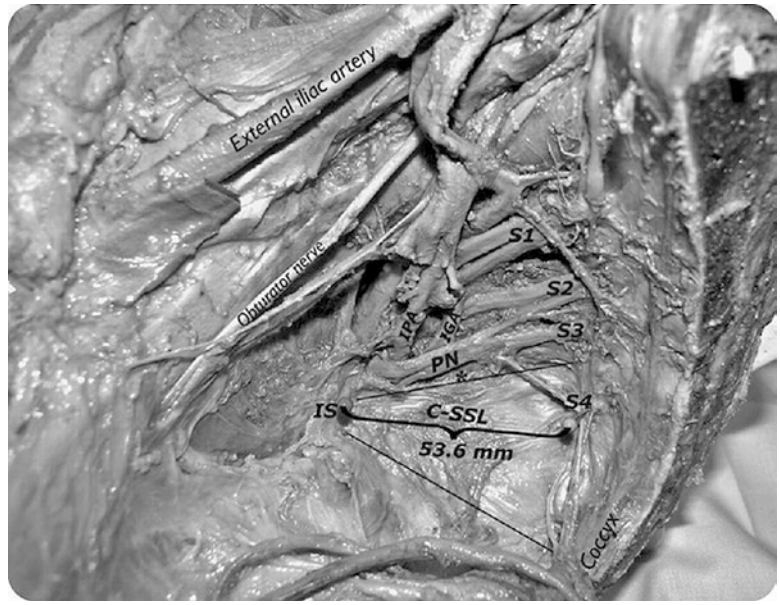

Fig. 8.1 Sagittal cadaveric dissection demonstrating the relationship of the coccygeus-sacrospinous ligament (C-SSL) to the sacral nerve roots and pudendal nerve (PN). Important vascular structures include the internal pudendal artery (IPA) and the more medial inferior gluteal artery (IGA). (Used with permission of Roshanravan SM, Wieslander CK, Schaffer JI, Corton MM. Neurovascular anatomy of the sacrospinous ligament region in female cadavers: implications in sacrospinous ligament fixation. Am J Obstet Gynecol. 2007;197:660.e1–6)

and meticulous dissection and suspension suture placement (see Fig.8.1).

Hemorrhage

The anatomic location of the sacrospinous ligament confers a greater risk of bleeding with SSLF compared to other transvaginal procedures. The sacrospinous ligament runs from the ischial spine to sacrum, forming the inferior border of the greater sciatic foramen. The piriformis muscle, superior and inferior gluteal vessels, and internal pudendal vessels run through this foramen. The gluteal vessels and sciatic nerve are near to the proximal aspect of the ligament, while the pudendal neurovascular bundle runs immediately inferior and medial to the distal aspect. In spite of the close proximity to several major vascular structures, the majority of cases reported in the literature are associated with moderate blood loss. In five RCTs comparing SSLF with other procedures for vault prolapse, the mean blood loss for SSLF was 126–448 mL [2–4]. The reported rate of transfusion is 2–3 % [2, 4, 5]. The best first step in minimizing the risk of clinically significant blood loss is establishing the optimal plane of dissection, as significant blood loss can occur in the setting of an aberrant plane of dissection. Utilizing a vasoconstrictive agent for hydrodissection helps to delineate the optimal plane between the vaginal epithelium and muscularis and offers hemostasis during dissection to aid optimal visualization and avoidance of inadvertent injury to adjacent structures. When significant bleeding is noted during dissection, this is often secondary to interruption of small venous plexuses in the vagina. In this situation, vaginal packing can be performed and held in place for 5 min for tamponade. The extraperitoneal location of the dissection should allow for significant slowing of the hemorrhage with this maneuver. Thereafter, the packing can be systematically removed to facilitate cauterization or placement of hemostatic sutures or clips as needed. Correction of the plane of dissection should be undertaken as soon as adequate hemostasis is obtained.

Optimization of suspension suture placement is also imperative to avoiding significant bleeding. To avoid vascular injury, suspension sutures should be placed in the medial aspect of the ligament, approximately 2 cm medial to the ischial spine, at a depth that only includes the ligament, as many vessels run deep to the underlying iliococcygeus muscle. Suture placement can be

carried out with direct visualization or palpation of the ligament, utilizing a needle driver or a suture passing device (i.e., Capio device, Deschamps ligature carrier, Miya hook ligature carrier). In retrospective and prospective series comparing complications associated with traditional direct vision suspension suture placement vs. placement with palpation and use of a suture passing device, there were no differences in rate of transfusion or postoperative hematoma [6, 7]. Selection of approach should be based on surgeon comfort and experience.

When significant bleeding is encountered with suture placement, optimizing visualization is paramount to achieving timely vascular control. Handheld retractors should be utilized to establish proper exposure of the bleeding vessels and adjacent structures and facilitate careful placement of hemostatic sutures and clips. It is important to note that the posterior approach allows for better exposure in this setting than the anterior approach. If visualization remains poor after maximizing exposure with retractors, due to brisk blood loss, firm vaginal packing can be a very effective step to slow blood loss and allow for gradual inspection of the surgical field. Additionally, application of topical hemostatic agents (i.e., fibrin sealants, thrombin, gel matrix) can also be helpful in establishing hemostasis and improving visualization. It is important to keep anesthesia providers informed as to the magnitude of blood loss so that laboratory testing and volume resuscitation can occur in a timely manner.

If adequate hemostasis cannot be obtained vaginally and major vascular injury is suspected, thoughtful consideration should be given to selective embolization with interventional radiology. Vessels can be controlled in this manner without risk to adjacent neural structures.

Urinary Tract Injury

SSLF itself is not commonly associated with urinary tract injury; however, concomitant surgery (i.e., hysterectomy, anterior or posterior repair, mid urethral sling) is performed in 59–91 % of patients and can confer increased risk [2–4, 6, 8, 9].

In an early systematic review of 17 studies of SSLF outcomes, inclusive of 1080 patients, the rate of cystotomy or bladder laceration was 0.3 % [5]. Several large contemporary series, describing a variety of approaches, have reported no cystotomy unless SSLF is performed with concomitant synthetic mid urethral sling [4, 6, 8, 10, 11]. Ureteral injury is similarly rare. There were no ureteral injuries observed in an RCT of 208 women receiving sacrospinous hysteropexy vs. vaginal hysterectomy with uterosacral ligament fixation [3]. Similarly, no ureteral injuries were observed among 240 women undergoing suspension suture placement under direct visualization or by palpation [6].

The course of the ligament is posterior to the course of the ureter; thus, the placement of fixation sutures should not result in ureteral kinking or occlusion. Intuitively, the risk of bladder injury can be minimized with the choice of approach. The anterior approach requires dissection of the ipsilateral paravaginal space as well as mobilization of the bladder away from the vaginal apex and thus confers the greatest risk of injury. The posterior approach confines dissection to the rectovaginal space and dramatically minimizes the risk of injury. Maintaining the proper plane of dissection can minimize the risk of urinary tract injury with an anterior approach. Excessively deep dissection can result in bleeding and poor visualization, increasing the risk of inadvertent cystotomy.

Cystoscopy is a prudent adjunct to SSLF performed via an anterior approach or with multi-compartment procedures as it adds minimal morbidity and helps to indentify injuries that are unlikely to be apparent without such evaluation. Bladder injuries should be closed in two layers with absorbable suture. When sluggish or absent ureteral jets are found, removal or revision of sacrospinous fixation sutures is unlikely to result in improvement. If hysterectomy has been performed, retrograde pyelography or ureteral cannulation with guide wire should be performed. In the setting of concomitant anterior repair, plication sutures should be removed and the patient reassessed for return of ureteral efflux.

Pain

Pain is one of the most commonly reported complications of SSLF. The reported rate of ipsilateral buttock, perineal, and/or posterior thigh pain is 6–15 % in the literature. Fortunately, most pain is self-limited and resolves in the early and intermediate postoperative period. Overall, 84–100 % of these cases resolved with supportive care and oral analgesia within 6 months of surgery, most within 12 weeks. Nerve block or other injection of analgesic agents or surgery to remove suspension sutures were required in 0–8.7 % and 0–13 % of cases of pain, respectively [3, 8, 11–13]. There are rare reports of foot drop, most of which resolved spontaneously or with release of the suspension sutures. Pollack and coworkers reported a case of foot drop that persisted at long-term follow-up despite suspension suture removal [6].

Given the close anatomic association of the ligament with several neural structures, the prevalence of pain complications comes as no surprise. The risk to the sciatic nerve at the proximal aspect of the ligament and the pudendal nerve in the distal aspect is well appreciated. Reconstructive dogma is that the medial one-third of the ligament is a virtual "nerve-free zone" and proper suspension suture placement in this region should minimize risk of neural injury and pain complications. However, several anatomic and histological studies have shown nerves to the coccygeus and levator ani muscles course over the mid portion of ligament, nerve fibers run through the substance of the ligament, and that the proximal portion of the pudendal nerve can be in close proximity to the mid portion of the ligament [14–16].

These findings suggest that even with optimal placement pain complications remain a salient risk. Be that as it may, careful placement of the suspension suture is the best and most reliable way to avoid pain complications. Completing adequate dissection, confining sutures to the medial third of the ligament approximately 2 cm from the ischial spine, and avoiding incorporation of adjacent soft tissue are vital steps.

Pollak and coworkers found that the chosen approach for fixation suture placement, direct visualization vs. palpation, impacts the rate of postoperative pain complications. In a retrospective review of 240 women, placement of sutures in the ligament by palpation and a use of a Deschamps ligature holder resulted in 10% rate of nerve injury compared to none with suture passage under direct visualization or with palpation and utilization of a Miya hook ($p = 0.002$) [6]. However, this finding has not been corroborated with randomized control trial.

When significant pain is present after surgery, it is important to recognize symptoms that suggest nerve entrapment. Perineal, vulvar, or gluteal pain that is persistent, unrelieved by pain medication and is worsened with sitting is suggestive of pudendal nerve entrapment. Posterior leg pain and foot drop are suggestive of sciatic entrapment. In cases where entrapment is strongly suspected, consideration should be given to timely surgical release or revision of ipsilateral suspension sutures. In all other cases, it is reasonable to pursue a trial of conservative management with medical therapy and/or physical therapy to allow for spontaneous resolution.

Bowel Injury

Compared to uterosacral vault suspension and abdominal sacrocolpopexy, SSLF is associated with a lower risk of visceral injury due to its extraperitoneal location. However, the dissection of the pararectal space utilized to reveal the sacrospinous ligament confers modest risk for rectal injury. Two systematic reviews in the literature report rectal injury rates of 0–1.4 % [5, 9]. A RCT of sacrospinous hysteropexy observed no injuries in a cohort of 105 women [3]. Maintaining the proper plane of dissection and avoidance of undue traction on the rectum while exposing the ligament are the two key maneuvers essential to avoiding injury. Hydrodissection helps to identify the correct plane between the vaginal mucosa and muscularis and facilitates efficient blunt dissection after initial sharp dissection. Prior posterior

repair may impair the efficiency of hydrodissection, so special attention should be given to reoperative fields. Gentle placement of a gloved finger in the rectum can aid in adherence to the correct plane.

Once the plane between the vagina and rectum is fully dissected, the ischial spine is palpated and the rectum is retracted medially. Retractors utilized to expose the ligament should be placed with care to avoid undue traction and laceration. Unilateral, right-sided ligament fixation minimizes risk of rectal injury, as it avoids the need to retract the rectosigmoid junction for visualization of the left ligament. When the suspension suture is placed, it is important to avoid inadvertent incorporation of the rectal wall. This is more likely when retraction is insufficient and sutures are being placed by palpation rather than under direct vision. Careful visual and digital examination should help to confirm proper suture placement. Sutures that incorporate rectum should be removed and replaced. Before apical sutures are placed, the rectal wall should be carefully examined to exclude injury. All injuries should be repaired primarily in 2–3 layers of absorbable sutures by the reconstructive surgeon or a general surgery colleague, depending on the surgeon's level of comfort and the degree of injury.

Summary

SSLF is a safe and effective transvaginal approach to apical prolapse. However, the anatomic location of the ligament in close proximity to numerous vascular and neural structures mandates firm knowledge of pertinent landmarks and meticulous technique in order to minimize complications.

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Abdominal Sacrocolpopexy

9

Michelle Koski, Erin Dougher, Barry Hallner Jr, and Jack Christian Winters

Introduction

With the aging of our population, pelvic organ prolapse is an increasingly common condition that negatively affects patient quality of life. Vaginal vault prolapse has been reported to occur in as many as 18.2% of all women with prolapse [1], and many would suggest that vaginal vault prolapse is a component of most high-grade anterior compartment descensus. Several repairs exist that reconstitute support to the vaginal vault, and certainly there is no single procedure that is optimal for all patients. However, abdominal sacral colpopexy is considered the gold standard approach in patients with recurrent or vault prolapse [2]. Abdominal sacral colpopexy (ASC) offers an effective and durable repair for vaginal vault prolapse [3]. It maximizes functional vaginal length and approximates the normal vaginal axis [4]. Patient selection for ASC should be considered for patients with failed prior vaginal repairs, isolated high-grade apical prolapse, patients who desire to maintain sexual function, patients with chronic pain, or when there is concern for chronic intra-abdominal pressure [5, 6]. The procedure may be performed open, laparoscopic, or robotically assisted. There have not been many robust studies to compare the different approaches to ASC. The laparoscopic and robotically assisted route is discussed in a separate chapter. The few studies that do compare the routes do suggest either route of repair is clinically equivalent [2]. Constantini and colleagues performed a randomized controlled trial of 61 patients who underwent laparoscopic sacrocolpopexy (LSC) vs. ASC. For the duration of 41.7 months, cure rate was 100% with no significant difference in point C/D post repair, no vault prolapse recurrence, and no statistical difference in complications. Although not clinically significant, anterior compartment descensus after LSC was higher especially during uterine preservation, and increased posterior compartment descensus was found in ASC [2].

In our experience, the key components of the operation include utilization of a permanent, type I macroporous mesh, secure suture fixation of the graft to the sacral promontory and

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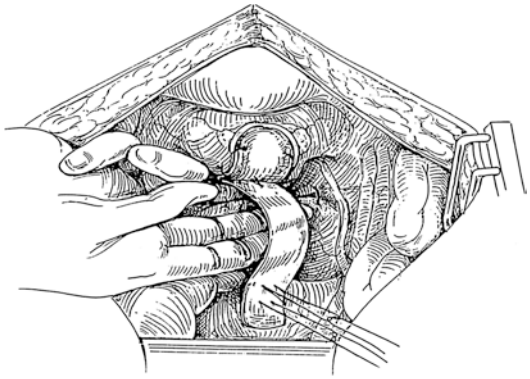

Fig. 9.1 Type 1 macroporous mesh is sutured to the sacral promontory and the vaginal cuff

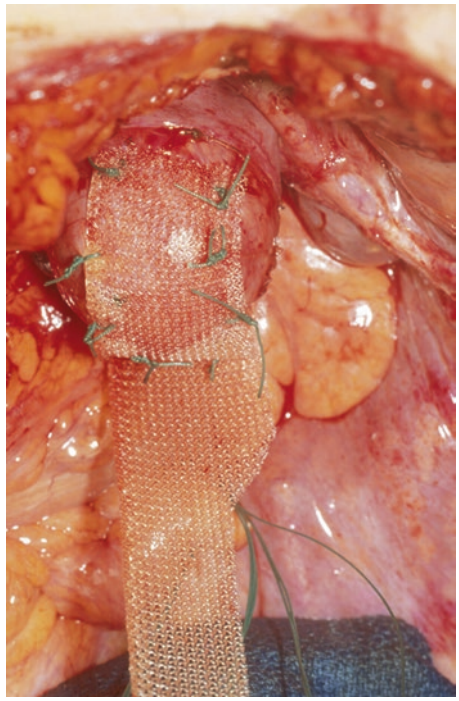

Fig. 9.2 The mesh graft is affixed to the apex of the vagina with multiple sutures for even tension distribution

vaginal cuff (Fig. 9.1), complete enterocele reduction and culdoplasty, and the addition of concomitant anti-incontinence procedures as indicated [5]. We affix the vaginal portion of the graft with multiple sutures to distribute the tension evenly over the vaginal apex (Fig. 9.2) and avoid excessive tension between the apex

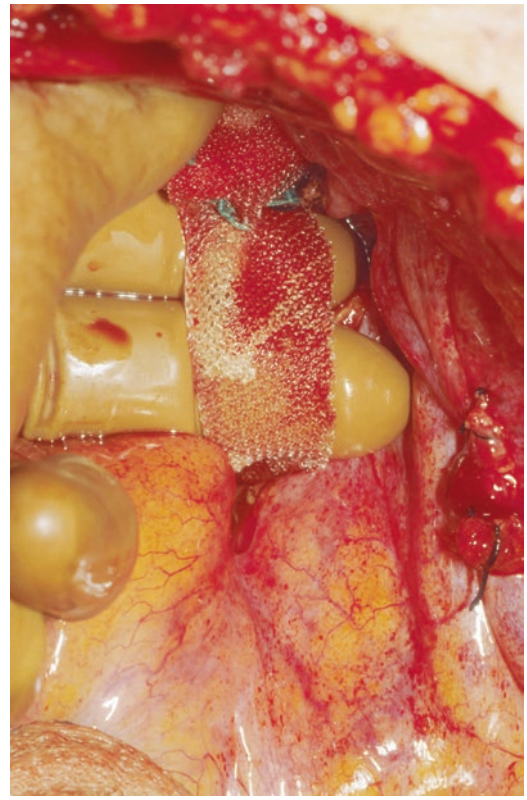

Fig. 9.3 Intraoperative view: graft in final position. A space of two fingerbreadths between the graft and the rectum prevents compression of the rectum under the graft. Incised peritoneum will be closed over graft

and sacrum (Fig. 9.3). We routinely close the peritoneum over the mesh. In this chapter, we will address the recognition and management of complications potentially associated with this method of the repair.

Intraoperative Complications

In a large meta-review by Nygaard and colleagues [3], intraoperative complications included hemorrhage or transfusion (0.18–16.9%), cystotomy (0.4–15.8%), enterotomy or proctotomy (0.4–2.5%), and ureteral injury (0.8–1.9%). When compared with the minimally invasive approach open ASC does involve a longer hospital stay, increased blood loss, and complications associated with those factors [7].

Hemorrhage

Presacral hemorrhage incurred during the dissection of the sacral promontory is one of the most feared complications of ASC, as well as one of the more commonly reported in the literature [3]. Bleeding from the presacral space may be large volume because the bleeding vessels may retract into the sacrum. Historically, in the 1970s, the operation was described with fixation of the mesh graft to the level of S3–S4 below the sacral promontory in an attempt to create a more natural vaginal axis [8]. After a life-threatening hemorrhage at this site, Sutton advocated for fixation higher on the sacral promontory at the S1–S2 level [9]. This site allows better visualization of the middle sacral artery and the slight difference in vaginal axis has not resulted in negative outcomes. Careful dissection at the sacral promontory should be used to avoid laceration of the unseen presacral vessels. Excessive blunt dissection should be avoided to prevent shearing of the presacral veins. Monopolar cautery should be used precisely, and diathermy cautery may be helpful as well. If uncontrollable bleeding is incurred which is not amenable to direct cautery, it may be managed with stainless steel thumbtacks [10], bone wax, or a figure of eight stitch [11]. It is important to be aware of the left common iliac vein, as this structure is frequently located more medial than the artery and can be injured during exposure of the promontory.

Cystotomy, Enterotomy, and Ureteral Injury

Injury to the bladder or bowel may occur during dissection or inadvertently. Care should be taken at all points of bladder dissection to maintain a full thickness dissection and avoid cystotomy. Additionally, we try to avoid excessive cautery in the dissection of the bladder from the vagina. If a bladder injury is detected, it should be closed in two layers with absorbable suture and an adequately sized urethral catheter should be left for bladder drainage. At this point, it would be at the discretion of the surgeon whether to proceed with mesh attachment to the vaginal apex. Mesh should not be placed adjacent to or in proximity to the cystotomy as it might predispose to erosion of mesh into the bladder or fistula formation [12]. If vesical injury is missed, patients may present with fever, pain secondary to urinoma or urinary ascites.

Enterotomy with any fecal or enteric soilage precludes placement of mesh. The bowel injury should be repaired and the case concluded. If enterotomy is missed, patients with unrecognized bowel injuries often present 1–2 days postoperatively and may lack the typical signs of peritonitis. Patients may present with low-grade fever and leukopenia with a left shift. The clinician should maintain a high index of suspicion and order a computed tomography (CT) scan in these patients.

The ureters should be identified early on in the case to avoid injury from dissection or entrapment or kinking in the culdoplasty sutures. To insure patency of the ureter, we perform cystoscopy after the conclusion of the case with D50 for clear visualization of the effluxing urine.

Postoperative Complications

Postoperative complications in a comprehensive review included urinary tract infection (2.5–25.9%), wound infection or separation (0.4–19.8%), ileus (1.1–9.3%), deep venous thrombosis or pulmonary embolism (0.4–5.0%), small bowel obstruction (SBO) (0.6–8.6%), and incisional hernia requiring repair (0.4–15%). Additionally, mesh erosion was noted at an overall rate of 3.4% in the 2178 patients reviewed in this meta-analysis [3].

Vaginal Mesh Erosion

Key signs and symptoms of vaginal mesh erosion include persistent pain, discharge, and occasionally dyspareunia for the woman and/or her partner. Suture erosions are typically asymptomatic [13, 14]. A comprehensive review of ASC quoted an overall mesh erosion rate of 3.4% [3] although rates of erosion quoted in the literature vary [13, 15–17].

While mesh erosions after ASC typically occur 4–24 months after surgery [13, 15], they may also present several years later [18]. Because of this, determining an accurate erosion rate in series is complicated by length of follow-up. Additionally, mesh type, surgical technique, and modifiable factors may affect the rate of erosion. Predicting mesh erosion can be difficult. Retrospective cohorts have found that mesh exposure is greater in ASC in patients with advanced stage (three or more) prolapse, when performed with concomitant hysterectomy, and patients who have had three or more vaginal procedures [19].

Mesh type appears to affect erosion rates based on comparison of the literature although there have been no standardized trials comparing different materials. In the Nygaard meta-analysis, polypropylene carried an erosion rate of 0.5% in comparison to 3.1% for polyethylene terephthalate (Mersilene®; Ethicon/Johnson & Johnson, Somerville, NJ, USA), 3.4% for polytetrafluoroethylene (Gore-Tex®; W.L. Gore, Flagstaff, AZ, USA), 5.0% for polyethylene (Phillips Sumika, Polypropylene Co., Houston, TX, USA), and 5.5% for Teflon® (E.I. DuPont de Nemours and Co., Wilmington, DE, USA) [3]. No conclusions were made in this review regarding whether certain mesh types predispose to erosion because in this setting they could not control for other variables (method of graft placement, concurrent hysterectomy, etc.). However, certainly, particular mesh materials are more at risk for erosion. Govier and colleagues found a 23.8% graft complication rate (mesh erosion or infection) in a retrospective review of 21 patients who underwent ASC using a silicone-coated polyethylene preformed graft [16]. A subanalysis of the Colpopexy and Urinary Reduction Efforts (CARE) study found a nearly fourfold increased risk of mesh erosion if Gore-Tex mesh was used compared to non-Gore-Tex mesh, which reached statistical significance and altered their use of Gore-Tex mesh [17].

The recent concern about synthetic mesh has increased the appeal of biologic materials, but they are not without complication. Allograft fascia lata has been described as a biologic alternative to mesh. Increased risk of abdominal hernias after harvesting of the abdominal fascia has been reported [20]. This material precludes the risk of mesh erosion. However, reports of failures associated with attenuation or absence of the fascia lata graft in reoperation [21, 22], presumably secondary to autolysis, have led to decreased use of this material. A retrospective cohort study comparing polypropylene mesh to Pelvicol® (CR Bard, Murray Hill, NJ, USA) and autologous fascia found a higher rate of failures as well as erosions and other graft-related complications in the Pelvicol group (although it should be noted that Pelvicol was used more frequently in patients undergoing concomitant hysterectomy) [23]. Similar findings of high rates of graft-related complications and unacceptable failure rates were found with porcine grafts [24]. In a randomized trial of 100 women who underwent ASC and were randomized to cadaveric fascia lata vs. polypropolene mesh with a 5-year follow-up, anatomic success was considered greater in the mesh group (93% vs. 62%) and there was no difference in success of patient symptom improvement (97% vs. 90%) [20].

A modifiable risk factor for erosion after ASC identified by the CARE trial analysis was tobacco use [17]. In their group of 322 patients, smoking was associated with a fivefold increased risk of erosion. A retrospective study of 499 patients undergoing ASC found a nonsignificant trend of smokers requiring more than one surgery for effective treatment of vaginal mesh erosion [25]. The dominant theory is that microvascular vasospasm with associated hypoxia may lead to poor wound healing and vaginal mesh erosion in smokers [18].

Approach and technique affect mesh erosion rates. If graft or suture is introduced through the vagina in sacral colpoperineopexy, erosion rates are increased. In a retrospective review of 273 patients, there was no statistically significant difference in mesh erosion rates for patients undergoing ASC (3.2%) or purely abdominal sacral colpoperineopexy (4.5%). In patients undergoing sacral colpoperineopexy with vaginal introduction of mesh or sutures, the erosion rates increased to 16% (vaginal placement of sutures) and 40% (vaginal mesh),

which maintained statistical significance on multivariate analysis. These patients exhibited a shorter time to mesh erosion as well, with median time to erosion 15.6 months for ASC, 12.4 months for abdominal sacral colpoperineopexy, 9.0 months in the suture group ($P < 0.005$), and 4.1 months in the vaginal mesh group ($P < 0.0001$) [26].

The role of concomitant hysterectomy in mesh erosion after ASC has been debated. In the CARE subanalysis [18], concurrent abdominal hysterectomy was performed in 26% of the patients, who incurred a 14% risk of erosion as compared to 4% in women who had undergone prior hysterectomy. This represented a fivefold increased risk of erosion. Culligan and colleagues found a statistically significant increase in erosion rates in patients undergoing concomitant hysterectomy in a retrospective review of 245 patients (27.3% erosion in those undergoing hysterectomy, 1.3% erosion without hysterectomy) [27]. A retrospective review of 313 patients found a statistically significant fivefold risk of mesh erosion in women on estrogen with concomitant hysterectomy [28]. Of note, they found no significant difference in erosion rates in those undergoing concurrent hysterectomy in the non-estrogen group, or in the overall group as well. These data imply that either estrogen or hysterectomy may increase erosion rates. In our experience, it seems hysterectomy would be the most likely risk factor. In contrast, in a retrospective review of 124 patients undergoing ASC (60 with hysterectomy and 64 without), Brizzolara and Pillai-Allen found a low overall mesh erosion rate of 0.8% and no significant difference in mesh erosions in the hysterectomy group [15]. They attributed their success to two-layer closure of the cuff, careful handling of tissues, and use of antibiotic irrigation [15]. Based on these findings, if a small vaginal laceration is encountered during colpopexy, we close the laceration in two layers as described in the previous study. In reviewing outcomes of colpopexy following hysterectomy, the significance of the CARE subanalysis, as opposed to retrospective reviews, is that it was prospectively designed to capture complications, including mesh and suture erosions, at regular study intervals in the first 2 years. The CARE trial has since extended its analysis and has found the complication of mesh extrusion continues long-term up to 10.5% at 7 years [29].

In cases of mesh erosion after combined hysterectomy and ASC, the erosion site is usually at the cuff. This may be secondary to potential vaginal bacterial contamination of the mesh from the opened vagina during hysterectomy. Alternatively, poor healing may occur at the cuff secondary to a devascularizing effect of cuff closure combined with mesh vaginal attachment sutures [18]. Some authors advocate supra-cervical hysterectomy as an alternative to total hysterectomy at the time of ASC [16]. Currently, the practice of concomitant hysterectomy and ASC remains controversial.

In cases of erosion of Type I mesh (Dacron®; Marlex®; Prolene® [Ethicon, Johnson & Johnson, Somerville, NJ, USA]), treatment with antibiotics and trimming and covering of the mesh is sufficient [14]. Because of the macroporous nature of the mesh, it is expected that macrophages will pass, making complete removal of the graft unnecessary. Additionally, eroded Type III mesh (combinations of multifilament and macroporous components: Teflon, Mersilene) may be treated with partial removal and reclosure of vaginal flaps [14]. However, infected Type II mesh (microporous material: Gore-Tex) must almost always be removed completely, as its microporous nature creates a bacterial sanctuary where access to antibiotics and the immune response is reduced [14, 18].

Conservative therapy with observation and topical estrogen may be initially attempted in small mesh erosions of type I or III mesh (<1 cm). Local excision of mesh is utilized as first line therapy as well, or in cases of failed conservative therapy. In a series of vaginal erosions of Ethibond® (Ethicon, Somerville, NJ, USA) suture and Marlex and Mersilene mesh, patients presented at an average of 14 months postoperatively (range 4–24). All patients were initially treated with vaginal estrogen and 8 weeks of pelvic rest. Two patients with suture erosions resolved with this regimen, but all five patients with mesh erosion required surgical intervention and were successfully treated with vaginal mesh excision and

flap advancement [13]. In another series, local surgical excision of exposed mesh carried a reported efficacy rate of 50% [25]. If the upper portion of the mesh is infected, it must be removed [18]. In the CARE subanalysis, 6% of patients experienced mesh/suture erosion. Most of the women with mesh erosion (13/17) underwent at least one surgery for partial or total mesh removal. Two patients completely resolved, six had persistent problems, and five were lost to follow-up [18]. Of the four women who elected observation, none experienced resolution [18].

Well-circumscribed areas of mesh extrusion may be approached vaginally. We excise only the exposed area with an additional margin of 1–2 cm; not all of the mesh needs to be excised. Surgical exposure of apical mesh extrusions in the post-sacrocolpopexy patient is more challenging than in distal vaginal extrusions. When the apex is well supported, it may be difficult to pull the apex into the forefront of the surgical field. We use a Lone Star® retractor (Cooper Surgical, Trumbull, CT, USA) with sharp hooks placed proximal to the mesh to expose as well as possible. Hydrodissection may be utilized around the area of the extrusion. We grasp the edge of the vaginal margin and dissect laterally between the vaginal margin and the mesh with Metzenbaum scissors to create vaginal flaps that extend about 2 cm circumferentially. If the edge of the mesh is available, we grasp that edge and begin our dissection underneath the mesh. If an edge is not accessible, we incise the mesh and isolate each resultant edge in an Allis clamp. Oftentimes, the mesh will peel off the underlying tissue with a combination of blunt and sharp dissection. We keep the scissor tips pointing toward the mesh. Once the mesh has been separated back to the edges of the initial dissection we inspect the quality of the edges of our vaginal margins. If there is any question about the quality of the tissue, we will excise or debride the edges. Finally, we reapproximate the vaginal flaps with absorbable suture in a tension-free closure with no mesh under the suture line. Other authors have advocated a partial colpocleisis type approach [25]. If the initial extrusion is extensive or if prior vaginal approaches have failed, an abdominal approach may be attempted. Abdominal excisions are associated with higher blood loss, longer hospitalization, and additional morbidity [25].

In all cases, the approach to extrusions is vaginal unless there is other intra-abdominal pathology warranting correction. In an abdominal approach, extensive scarring and adhesions will be encountered. A full bowel preparation is recommended and vaginal localization can be assisted with the use of an EEA sizer and or a Lucite vaginal stent. Partial removal of offending mesh is acceptable unless gross infection is present. The vaginal defect should be repaired in two layers using absorbable sutures. In cases of poor tissue quality, a biologic interposition over the vaginal cuff or omentum may be utilized to assist in cuff healing.

Erosion of Mesh into Bladder or Bowel

Patients with mesh erosion into the bladder after ASC may present with hematuria, irritative voiding symptoms, recurrent urinary tract infections, or chronic bladder stones. Diagnosis of this problem hinges on a high index of suspicion and a low threshold to perform cystoscopy. Maintaining a full thickness of the bladder without cystotomy during dissection, or alternatively, minimizing bladder mobilization may help in avoiding this complication.

Patsner reported a case of erosion of polypropylene mesh and Prolene suture into the bladder base presenting 4 months after ASC who was treated with open excision after two failed cystoscopic attempts [30]. Shepherd and coworkers performed a retrospective cohort study over 10 years looking at the mesh/suture erosion rate based on type of suture. Mesh suture exposure rate was found to vary with type of suture, 3.7% with Ethibond and 0% with PDS [31]. Yamamoto and coworkers report a vesicovaginal fistula after abdominal hysterectomy and ASC which occurred adjacent to the edge of the mesh and required abdominal repair [9]. In our experience, we have not had a mesh or suture erosion into the bladder secondary to ASC (Fig. 9.4). To reduce

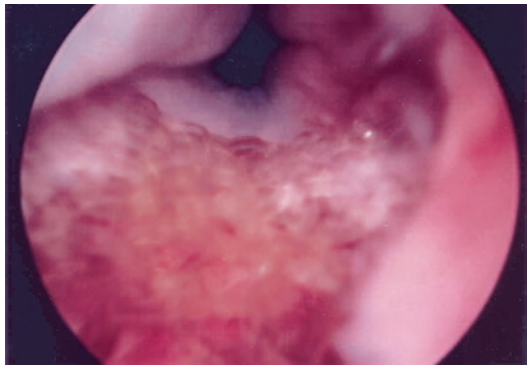

Fig. 9.4 Cystoscopic view of mesh erosion into the bladder

risk of suture erosion into the bladder, we now use PDS suture to fixate the graft to the vagina. Depending on the site of erosion and the amount of mesh, a cystoscopic approach may be attempted. If this fails or is precluded by position or mesh volume, an open cystorrhaphy may be necessary. If the mesh is near the ureteral orifice, the surgeon should consider a retrograde pyelogram or a ureteral stent to delineate the ureter. In a retrospective review of intravesical mesh management cases (from various causes), Frenkl and coworkers concluded that, in their experience, sutures were managed most successfully with endoscopic techniques, where mesh was best managed with cystorrhaphy [32].

There have been only three reported incidences of mesh erosion into the bowel. In a rare report of mesh erosion into the sigmoid colon 8 years after ASC, the patient was noted to have stool in her vagina and was ultimately treated with sigmoid colon resection with a low colorectal reanastamosis and omental J-flap placement [33]. Kenton and coworkers described a Gore-Tex graft erosion into the rectum with spontaneous passage of the graft 7 years post-ASC without fistula formation [34]. Hopkins and Rooney describe a small bowel fistula secondary to adhesion of a loop of terminal ileum to an exposed mesh that had been "minimally retroperitonealized" [35]. Based on this, they advocate retroperitonealization of the mesh as a way to prevent adhesion of bowel. Most early descriptions of sacrocolpopexy describe closing the peritoneum over the graft. Other authors question the utility of this step. In a small study of 35 women, 3 had postoperative bowel obstructions, all resulting from intestine trapped under the mesh, despite careful retroperitonealization [36]. Due to the low incidence of bowel mesh erosions, it is unlikely that this question will be addressed in a standardized fashion. In order to prevent these complications, we would advise meticulous placement of the mesh with careful attention to ensure an adequate space between the mesh and the sigmoid colon. We routinely close the peritoneum over the mesh.

Ileus and Small Bowel Obstruction

The reported incidence of postoperative ileus is a median 3.6% (range 1.1–9.3%) of patients and reoperation for SBO is a median 1.1% (range 0.6–8.6%) after ASC in meta-analysis [3]. This review comprised mostly retrospective reports. The findings from a sub-analysis of the CARE trial supported these findings in the framework of a large prospective trial [37]. Of their 322 patients, 5.9% had postoperative gastrointestinal conditions resulting in reoperation, prolonged hospitalization, or readmission. Four patients (1.2%) required reoperation and all were found to have small bowel entrapment in, or adhesion to, the abdominal wall incision (Fig. 9.5). Overall, the rate of SBO was 1.9–2.5% and the rate of ileus was 2.2–2.8%. Age was found to have a significant association with ileus [37]. A recent retrospective cohort of 589 subjects who underwent ASC were found to have a 5% risk of post op ileus/small bowel obstruction, the patients in this group were found to have more previous abdominal surgeries. It is possible that this added risk with an abdominal incision increases the complexity of the case and risk of ileus/SBO [38].

Recurrence

Recurrent vaginal vault prolapse after ASC with permanent mesh is rare. The extended CARE trial suggested the probability of failure (ana-

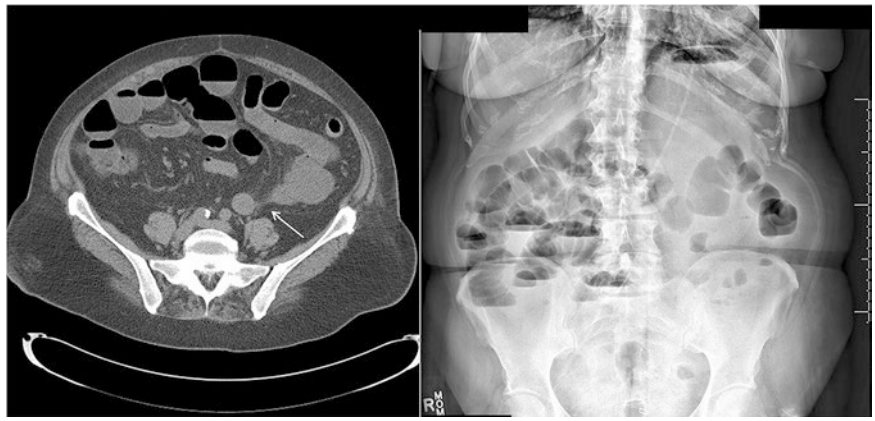

Fig. 9.5 Radiographic images of a patient with partial small bowel obstruction after abdominal sacral colpopexy. The CT scan (*right*) shows distended loops of bowel with a transition point marked with an *arrow*

tomic or symptomatic) can range from 0.34 to 0.48 up to 7 years after POP repair with a steadily increasing failure rate after 2 years [29]. Baessler and colleagues proposed that rare cases of symptomatic apical recurrence are usually secondary to detachment of the mesh from the vagina and that separation of the mesh from the sacrum is much less common [15]. If the mesh is still secured to the sacrum, they describe attaching a new mesh to it, which is then sutured to the vagina. They warn against removal of the original mesh due to the high risk of hazard to the ureter and bowel in a potentially difficult dissection. Addison and colleagues reiterate this in their series of recurrences, all resulting from disruption of the mesh from the vaginal apex (one of these cases secondary to a dissection of an enterocele beneath the mesh, causing disruption) [39]. They advocate performing a meticulous culdoplasty with permanent sutures and attachment of the mesh to the vaginal vault with multiple permanent sutures placed through the entire thickness of the vagina over a broad area as methods to help prevent recurrence [39].

Unmasking of Occult Stress Incontinence

We routinely assess for occult SUI preoperatively with either urodynamics or cough stress test with the prolapse reduced. Rates of urodynamic SUI with prolapse reduction have been reported ranging from 25 to 100% in symptomatically continent women using various methods of reduction [40]. Patients undergoing ASC are at significant risk for developing bothersome stress urinary incontinence, even in the absence of preoperative symptoms. In a prospective, controlled trial of 322 previously stress-continent women, 23.8% who underwent Burch colposuspension at the time of ASC showed postoperative SUI compared to 44.1% who underwent ASC alone. Those in the ASC alone group were also more likely to report bothersome SUI symptoms as compared to the Burch group (24.5% vs. 6.1%) [41]. Women who demonstrated preoperative SUI with prolapse reduction were more likely to report postoperative SUI, regardless of concurrent colposuspension (controls 58% vs. 38% ($P = 0.04$) and Burch 32% vs. 21% ($P = 0.19$)) [40]. In this study, the majority of women who did not leak with prolapse reduction did not leak after prolapse surgery (60%). In addition, women who did have a Burch procedure still experienced an approximately 30% rate of recurrent SUI. It is equally important not to over tension the vagina, as a retrospective cohort analyzed by LeClaire and colleagues found that the abdominal approach and change in point Aa of >3 cm led to increased risk of SUI after sacrocolpopexy [42]. Based on these findings, we use urodynamics to counsel our patients and identify who might best benefit from concurrent anti-incontinence procedures,

but we also inform our patients that a negative test does not preclude postoperative incontinence. We prefer midurethral sling concurrently in patients undergoing ASC with symptomatic or occult SUI detected on screening. If women have significant obstructive symptoms on urodynamics with the prolapse reduced, we will perform ASC without sling. If a woman has no occult SUI or symptoms of SUI, patients choose whether or not to undergo concomitant sling. Our bias is to not place a sling at that time. If patients develop SUI after ASC alone, a midurethral sling can be placed at a later date with minimal difficulty.

Osteomyelitis and Spondylodiscitis

Osteomyelitis after ASC is rare and is generally heralded by persistent new low back pain. Weidner and colleagues described two cases of lumbosacral osteomyelitis after ASC, both treated successfully and definitively with prolonged parenteral antibiotic therapy guided by aspirated cultures and neither requiring mesh removal [43]. One patient presented with unremitting severe low back pain 5 years after ASC, and the second patient presented 2 months postoperatively. Both sacral fixations were performed with TiCron® (Davis and Geck, Wayne, NJ, USA) suture. Both were diagnosed on MRI, which is the most sensitive method for detecting osteomyelitis and defining the extent of the infection. Plain films and bone scan may be diagnostic, but are less sensitive than MRI. The authors suggest maintaining a higher level of suspicion for osteomyelitis in patients with a history of degenerative disc disease [43], as patients with degenerative disc disease are predisposed to infection due to disruption of the vertebral endplate and neovascularization of disc spaces, which allows bacteria into a normally avascular space [44]. In the rheumatologic literature, Cailleux and colleagues reported on five cases of sacral osteomyelitis after ASC (of a retrospective review of 45 patients with sacral osteomyelitis) [45]. Initial symptoms occurred at an average of 38 days postoperatively. In three of the patients, the same bacterial species was identified in urine cultures 1–4 days postoperatively as in the biopsy of the infected bone.

Since these initial series, there have been more reports, usually in the form of case report. Nosseir and coworkers reported a case secondary to titanium tacks that resolved with parenteral antibiotics [46]. Muffly and coworkers reported a case of osteomyelitis and infected mesh with a sinus tract after robotic hysterectomy with ASC which required discectomy, sacral debridement, and mesh removal [47]. Another case of sacral osteomyelitis with concomitant mesh erosion and sinus formation required mesh removal and tract resection [48]. Taylor and coworkers described a case that presented with vaginal erosion of mesh and osteomyelitis with progressive neurologic symptoms requiring a decompressive laminectomy [49]. Dalawi reported two cases of pyogenic discitis in patient in which the graft was fixated to the anterior longitudinal ligament; in one patient stainless steel screws were used and the other patient the graft was fixated with titanium tacks to the ligament [50]. Both patients presented with persistent lower back pain.

We advocate empiric routine preoperative IV antibiotics and meticulous surgical technique with mesh and other permanent implants. We also advocate not using tacks or screws to fixate the graft to the ligament and using new monofilament suture to fixate the graft to the anterior longitudinal ligament that has not been used to fixate the graft to vagina. It is also likely important to make an effort to just pass the suture through the ligament and not into the actual disc or bone. Patients with degenerative disc disease may be at increased risk of osteomyelitis and should be treated with care as well as a higher index of suspicion postoperatively. MRI should be used to rule out osteomyelitis in the carefully selected patient, and if possible, CT-guided aspiration and culture should be performed to guide antibiotic therapy. Isolated osteomyelitis may respond to prolonged antibiotics alone. In cases that fail antibiotics or in patients with mesh erosion, infection, or sinus tracts, surgery may be required. The surgeon should maintain a low threshold to consult infectious disease, orthopedics, and/or neurosurgery as indicated by the patient's presentation.

Conclusion

Sacrocolpopexy is a well-established standard of care procedure for the surgical correction of vaginal vault prolapse. It has become minimally invasive with the robotic and laparoscopic approach. In many ways, it is now a more comparable alternative to vaginal apical repair operations. Complications occur at a low incidence [3]. For the vast majority of patients, this procedure provides a gratifying outcome which is durable and anatomic. A thorough knowledge of anatomy, graft biology, and potential complications is optimal in order to assure this procedure may be performed as safely and efficiently as possible.

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Robotic/Laparoscopic Female Pelvic Reconstructive Surgery

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Introduction

As the life expectancy of our population continues to increase, so does the prevalence of medical conditions associated with advancements of age. Pelvic organ prolapse (POP) is a common condition associated with aging, menopause and prior pregnancy, and delivery. Surgical repair of POP is currently the most common type of inpatient procedure performed in women older than 70 years [1], and there is no doubt that the incidence of procedures for this condition will continue to increase. As we attempt to improve patient awareness of POP and options in treatment of symptomatic prolapse, we in turn strive to optimize surgical treatment techniques.

The abdominal sacrocolpopexy is regarded as the "gold standard" procedure for correcting defects of the vaginal vault [2] and for some patients, this open, abdominal technique continues to be an appropriate choice for prolapse repair. In many patients, however, minimally invasive routes of this and other gynecologic procedures are preferred [3, 4], and offer advantages both for the patient and the surgeon. Minimally invasive sacrocolpopexy has been compared with the abdominal approach in various studies and has proven to be as efficacious and safe, with the added benefit of decreased morbidity [5–7]. More recently, two level 1 studies have been published comparing abdominal sacrocolpopexy with a minimally invasive approach. Both trials reveal comparative outcomes between the groups and illustrate that the minimally invasive approach is associated with decreased morbidity, less blood loss, shorter length of stay, and overall decreased recovery time [8, 9]. These data support the use of minimally invasive surgical approaches to sacrocolpopexy and other POP procedures.

With minimally invasive surgery comes a unique set of perioperative considerations, counseling topics and both intraoperative and postoperative complications. Surgeons should be aware of these unique components of minimally invasive surgery and should understand ways to minimize potential obstacles wherever possible. This chapter aims to highlight the potential perioperative complications unique to minimally invasive female pelvic surgery and to discuss how to effectively handle these problems, should they arise.

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Preoperative Considerations

When determining surgical candidacy for minimally invasive reconstructive pelvic surgery, the surgeon must gather critical information during the office evaluation. It is imperative to focus the history and physical exam around factors that could increase the risk of complications unique to minimally invasive surgery. When considering a laparoscopic or robotic approach, the medical history should include questions about the patient's exercise tolerance, smoking history, presence of cardiopulmonary or chronic renal conditions, and history of prior pelvic surgeries. The surgeon should have a good understanding of the hemodynamic and metabolic effects of intra-abdominal CO_2 insufflation on individuals with these conditions. Potential contraindications to laparoscopic or robotic surgery such as increase in intracranial pressure or baseline hypovolemic state should be contemplated, especially when the operative time may be prolonged. Patients with pulmonary compromise should be particularly counseled on possible conversion to laparotomy if the degree of physiologic strain, such as impairment of pulmonary functional residual capacity, becomes intolerable to the patient during surgery [10]. It is well documented that patients benefit from smoking cessation prior to surgery and encouraging patients to stop smoking within 8 weeks of surgery can be beneficial. Studies demonstrate improvements in respiratory function and lower risks of postoperative atelectasis and aspiration pneumonia, known results of the inability to tolerate pneumoperitoneum or steep Trendelenberg positioning [11]. While research indicates that pulmonary complications after laparoscopy may be lower than those associated with laparotomy, surgeons should be aware of the specific risks in patients with cardiopulmonary comorbidities, such as COPD. Pulmonary complication risk is also found to correlate positively with older age and longer operative time [12]. This should be taken into consideration when deciding route of pelvic reconstructive surgery.

The physical exam should include assessment of abdominal scars and the presence of any abdominal hernias, particularly if a patient has had multiple prior abdominal surgeries. This will allow for anticipation of potential difficulties with port placement and pelvic adhesive disease when planning a minimally invasive surgical approach. Particular attention should be paid to umbilical hernia as the umbilicus is often utilized as a port site during minimally invasive surgery. Additionally, a bimanual pelvic evaluation to assess uterine mobility and size is necessary. One should attempt to palpate the width of the lower uterine segment (LUS) at its junction with the cervix and assess degree of movement of this segment toward the contralateral pelvic sidewall. In general, lateral mobility of 2 cm or more on each side predicts adequate access to uterine vessels laparoscopically. The presence of obstructing fibroids or pelvic adhesions should also be considered, as these characteristics can limit uterine mobility and preclude successful minimally invasive pelvic surgery. Placing cephalad pressure on the LUS and attempting to elevate the uterus out of the lower pelvis can help with understanding of circumferential space that is present. This technique may be inhibited by patient body habitus. At times, pelvic imaging may be necessary to adequately assess uterine size and other pelvic pathology that may make laparoscopy more difficult.

Obesity itself should not preclude minimally invasive surgery; however, it can make a laparoscopic or robotic approach to pelvic surgery more challenging due to impact of this condition on both respiratory and gastrointestinal mechanics. Obese patients, particularly with a BMI >40, are prone to poor gas exchange and delayed gastric emptying, increasing risk of impaired respiratory function and aspiration during and after surgery. Obesity also is commonly associated with increased central adiposity, which can preclude optimal patient positioning, trocar placement and visualization intraoperatively [13, 14]. It is imperative to consider these risk factors when counseling patients on minimally invasive surgery and extra time should be allotted perioperatively to ensure optimization of patient positioning.

The surgeon should inquire about any known anomalies of pelvic anatomy. Anatomic variances such as a horseshoe kidney, transplant kidney, or

any sacral anomalies could make the minimally invasive sacrocolpopexy more difficult or contraindicated. Knowledge of these potential structural alterations should prompt adequate imaging to obtain a clearer understanding of any variations or abnormalities in pelvic anatomy. Surgeons can then plan for any required modifications in instrument placement or surgical technique when performing pelvic surgery.

Screening for stress incontinence is pertinent when performing any prolapse procedure and if present, discussion of a possible concomitant anti-incontinence procedure is needed. The surgeon should take into account the risks and benefits of added operative time with concomitant procedures, and potential complications this could pose. Conversely, without the presence of stress incontinence, there still should be a discussion regarding the possibility of de novo stress incontinence post-prolapse repair. Ideally, patients should be screened for occult stress incontinence with prolapse reduction preoperatively to allow for proper counseling and surgical planning. Management of expectations is critical and patients should be made aware that mid-urethral sling placement at the time of minimally invasive sacrocolpopexy may be associated with lower incontinence cure rates, when compared to sling surgery alone [15].

Traditionally, preoperative mechanical bowel preparation (MBP) has been used as a way to enhance visualization of the surgical field and improve intraoperative bowel handling. In theory, this practice leads to a decreased incidence of bowel injury and lowers minimally invasive operative times. More specifically, bowel preparation can facilitate sacral visualization during minimally invasive sacrocolpopexy. Recently, there has been evidence in the literature refuting the necessity of mechanical bowel preparation in minimally invasive surgery in gynecology [16, 17]. In a recent systematic review of high-quality trials across surgical specialties, there were no or few benefits of MBP or rectal enemas and no negative effects on perioperative outcomes were reported [18]. These data should prompt surgeons to contemplate the risk and benefit of MBP when performing minimally invasive prolapse surgery. In surgical procedures where this practice seems beneficial, preparations using Magnesium Citrate or Miralax combined with 64 oz. of Gatorade appear to be the best tolerated [17].

Patient Positioning and Surgical Setup

Intraoperatively, there are many techniques that can be adopted to allow a surgeon to decrease risk for complications when performing minimally invasive pelvic reconstructive surgery. It is critical to maintain constant communication between the anesthesia and surgical teams when choosing the most appropriate operating room set up, as each case may require adaptations to the arrangement of room layout, instrument choice, and other ergonomic considerations. For both laparoscopic and robotic-assisted prolapse repair, proper patient positioning is imperative to sustain optimal surgical exposure and prevent neuromuscular compromise. One obvious concern with these surgical techniques is cephalad sliding of the patient on the operating table during steep Trendelenburg positioning. This can result in skin breakdown and neuropathic injuries, as well as incisional extensions and formation of hernias through port sites due to the overstretching caused by incidental changes in patient position. Nerve injury is increased in obese patients, who most commonly suffer from ulnar and sciatic neuropathies [14]. The surgeon should ensure proper corporeal padding of both upper and lower extremities. The knees should be flexed at a maximum angle of 60° when patients are placed in dorsal lithotomy position. Any greater flexion increases the risk for femoral nerve compression. Arms should be tucked at the patient's side and all pressure points should be adequately protected. Leaving the arms extended or the use of shoulder blocks can increase the risk of brachial plexus injury and these practices should be avoided [19]. Recent evidence illustrates that use of anti-skid materials such as egg crates, surgical beanbags, or gel pads minimizes risk of shifting and therefore decreases potential for nerve stretch injuries, even in patients with a BMI >30 [20].

After the anti-skid material is placed on the operating table, the patient should be placed directly on this material without intervening bedsheets. This direct contact allows for optimal drag coefficient to keep the patient from slipping and is very effective for steep Trenedelenburg positioning during pelvic reconstructive surgery.

The risk of facial trauma and corneal abrasions should also be considered, especially when performing robotic surgery. The patient's face can be in close proximity to the robotic camera system and instruments, especially when port sites are placed superior to the umbilicus or when using a 30° down scope in steep Trendelenburg position. At these instances, the robotic camera system may only be a few centimeters away from the face and facemasks or adhesive eye shields should be used to protect from facial trauma. Direct trauma is known to be the cause of up to 20% of corneal abrasions, and most are thought to be due to lagopthalmos or failure of complete eyelid closure [21]. To protect this perioperative complication, the eyes can be taped closed after induction of anesthesia. It is important to consider these potential adverse events and discuss ways to minimize risk with the anesthesia team.

Whether performing laparoscopy or robotic-assisted pelvic surgery, the utilization of Trendelenburg positioning is traditionally noted to be essential to achieve adequate exposure. Compared with traditional laparoscopy, robotic surgery has been associated with the use of more pronounced Trendelenburg positioning. Although there is no consensus in the medical literature as to the appropriate amount of Trendelenburg used in pelvic surgery, experts have routinely called for "steep" Trendelenburg positioning, usually categorized as 25°–45°. While this has long been the routine positioning of patients undergoing robotic pelvic surgery, recent data have suggested that gynecologic surgeries can be effectively performed without use of this steep angle positioning, which is often times associated with increased morbidity, especially in the elderly or obese populations. In a recent article by Ghomi and coworkers, 20 women underwent robotic-assisted gynecologic surgery for benign disease. The procedures included total and supracervical hysterectomy as well as sacrocolpopexy. Surgeons were blinded to the degree of Trendelenburg used; however, they were instructed to choose the degree of positioning which would allow them to obtain adequate exposure of the surgical field. Degree of Trendelenburg was measured at the end of each case and results revealed the mean Trendelenburg position used was 16.4° and no patient was placed further than 24°. There were no incidences of conversion, no perioperative complications and average BMI was 28.5, while median console time was 87.5 min [22]. Though the only study of its kind, these data defy the practice of routine adherence to steep Trendelenburg positioning if not absolutely necessary and surgeons should take care to individualize patient positioning for each case in order to minimize complications associated with a considerable degree of Trendelenburg placement. Extra caution should be taken in any patient with retinal disease or prior retinal surgery, as Trendelenburg positioning has been associated with retinal complications in some reports.

Having a clear understanding of abdominal wall anatomy is crucial for proper port site placement, in order to avoid vessel injury during this portion of the case. Both robotic and laparoscopic ports are generally placed in a W configuration, a minimum length of 10 cm apart, to allow for adequate space and optimal utilization of all ports and to minimize arm collisions. To optimize visualization of the sacral promontory, the camera port should be placed above the umbilicus if the distance from the umbilicus to the pubic symphysis is less than 15 cm. The use of a 30° (up) robotic camera to place the four additional ports is oftentimes helpful to adequately evaluate the pelvis for any intrusive adhesions and also to position ports properly and ensure avoidance of epigastric vessels. Port site bleeding is noted to occur at an incidence of about 0.7% [23], and the origin is most commonly due to perforation of the inferior epigastric artery. If perforation does occur, it is best to leave the offending trocar in place to denote the location of the injured vessel. If each end of the transected vessel can be identified, cauterization of both ends using bipolar cautery should be

attempted. If this is not successful, the method of tamponade using a foley catheter can be used. A size 10 or 12 French Foley catheter should be introduced through the 5-mm trocar and inflated with approximately 10–15 mL of sterile water. The trocar is removed only once the balloon has been inflated, and then traction should be applied to allow the balloon to tamponade the port site [24]. Clamping the catheter on steady traction with use of an umbilical clamp or hemostat is helpful and this can be left in position postoperatively if necessary, until hemostasis is achieved. If neither of these methods will stop port site bleeding, interrupted 0-vicryl sutures can be placed into the abdominal wall using a CT or CT-1 needle. One suture should be placed at each side of the trocar site and tied externally. These sutures can be removed after 12–24 h of observation, and the trocar should be left in place during this time.

The use of an 8-mm accessory port is our preference, as the literature reveals a smaller accessory port results in less postoperative pain and decreased risk of port site hernias when compared to larger accessory ports. In a survey conducted by the American Association of Gynecologic Laparoscopists, port site hernias were found to occur in port sites 10 mm or larger in 86% of cases, while those 8 mm or smaller were associated with only 3% of port site hernias reported [25]. More recently, Paraiso and coworkers discussed the notion of lower postoperative pain with use of smaller ports when comparing postoperative pain scores in patients undergoing robotic and laparoscopic prolapse surgery. Those undergoing laparoscopy endured fewer and smaller trocar incision sites, which correlated with lower postoperative pain scores [26]. Given this, we routinely use the smallest size ports necessary when performing minimally invasive pelvic organ prolapse surgery. For robotic sacrocolpopexy, once ports are placed and the robot docked, introduction of robotic instruments should be done under camera visualization in a 3, 2, 1 consecutive order to increase efficiency; it can be difficult to rotate the camera to visualize placement of arms 2 and 3 if arm 1 has already been placed. Lastly, each arm's range of motion should be thoroughly assessed to minimize arm collisions during robotic pelvic surgery. Many of these technical issues have been overcome with the new da Vinci Xi® (Intuitive Surgical, Sunnyvale, CA, USA) robot, which has a much smaller and lighter weight camera and slimmer arms, allowing more range of motion and fewer problems with clashing.

Intraoperative Complications

During robotic sacrocolpopexy, it is our preference to begin with the dissection of the sacral promontory, in order to complete the more difficult portion of the surgery first. The 30° (down) camera is preferred by some surgeons, allowing for better visualization of the sacral promontory. This portion of the procedure requires adequate retraction of the sigmoid colon toward the left pelvic sidewall, in order to maintain optimal visualization of the sacral promontory. Prior to mobilization, however, the surgeon should thoroughly survey the abdomen and maneuver the small intestine into the upper abdomen if steep Trendelenburg positioning has not already accomplished this. Bowel injury during pelvic surgery, although occurring in only about 0.5% of cases, most commonly occurs in the small bowel at the time of intra-abdominal access (55%) and delay in identification of a bowel injury can result in mortality in an average of 3% of cases [27]. For this reason, it is imperative to be mindful of this complication and take extra time to evaluate for any potential injury during abdominal entry. If a puncture injury of the bowel is identified, a step-by-step inspection of the entire bowel is recommended to ensure no additional injuries are present. The most common cause of non-entry-related bowel injury is usually due to thermal defects, and these are more likely to go unnoticed.

Small serosal or muscularis defects should be repaired using 3-0 delayed absorbable sutures in a two layer, imbricating technique [28]. Recently, barbed suture has also been used for repair of bowel and bladder injuries with good results. This has been described with use of a single layer of 3-0 barbed suture for seromuscular injuries,

while two layers of 3-0 barbed suture are used for full thickness defects. Additionally, some surgeons will use one layer of barbed suture for repair, followed by a second layer of continuous or interrupted delayed absorbable suture [29]. During small bowel repair, sutures should be placed perpendicular to the long axis of the intestine to prevent stricture formation. Conversely, large bowel enterotomies should be repaired with care to avoid any tension on the tissue. Given the larger lumen at this level, stricture formation is less likely; however, any suture tension at the level of the rectosigmoid colon could compromise the integrity of the repair. Although some injuries can be repaired laparoscopically, a number of bowel injuries may require laparotomy [27]. It is important to confer with colleagues intraoperatively at the time injuries are identified, as resection and temporary diversion may be required in some cases.

Avoidance of the above complications can be maximized with proper patient positioning in Trendelenburg, proper mobilization techniques and use of blunt tools for assistance. The small bowel should always be reflected first so that the large bowel can then secure hold of the small bowel out of the pelvis. Use of fan retractors may also prove helpful in laparoscopic procedures. In the obese patient, there may be redundant rectosigmoid colon, requiring cephalad mobilization and/or retraction. Scheib and coworkers has described use of an accessory stitch placed through the epiploic appendices and subsequent suspension of the colon to the anterior abdominal wall or left upper quadrant to remove the bowel from the operative field. Endoloops can also be used in a similar fashion and can be drawn out through ports and secured temporarily [14, 30].

Another significant complication of laparoscopic prolapse surgery, namely, sacrocolpopexy, is that of presacral hemorrhage. Although rare, this complication can be life threatening, and it is imperative to identify the middle and lateral sacral as well as common iliac vessels, the most common sites of hemorrhage in sacrocolpopexy. Although robotic sacrocolpopexy has been associated with lower overall blood loss when compared to both abdominal and laparoscopic approaches, a recent meta-analysis reported a 0.4% incidence of intraoperative vascular complications, namely, left iliac venotomy, with both laparoscopic and robotic approaches to sacrocolpopexy [31–33]. With this in mind, the surgeon should make it a priority to properly identify the sacral promontory as a landmark, which is best identified just below the bifurcation of the common iliac arteries. The assistant surgeon should be utilized to help with tactile feedback during this process. When incising the peritoneum overlying the promontory, one should be cognizant of the variability of the vascular pattern of the presacral space. There can be significant variability in the location of both sacral and iliac vessels, particularly on the left side of the anterior longitudinal ligament of the sacrum [34]. Many surgeons prefer to expose the ligament and vessels thoroughly in a layer-by-layer fashion, in order to minimize injury. The left common iliac vein has a highly variable course and can be difficult to identify as it often appears flat and white due to the effects of the pneumoperitoneum.

If presacral vascular injury is encountered, it has been well documented that conventional hemostatic measures oftentimes have proven to be futile, and this is likely due to the increase in hydrostatic pressure when in lithotomy position, as well as the fixed nature of the venous plexus to the sacral periosteum. When the hemorrhage is identified, it is important to communicate effectively with the patient side team and immediately apply direct pressure to the area with the nearest blunt robotic instrument. A RAY-TEK or cottonoid sponge can be passed into the field by the side surgeon, and this can also be used to apply direct pressure for a minimum of 5 min. If the bleeding persists, topical hemostatic agents should be considered. Germanos and coworkers described three cases of presacral hemorrhage which were successfully managed using a combination of a hemostatic matrix (Floseal®; Baxter, Hayward, CA, US), which should be directly applied over the area of bleeding, followed by application of an absorbable hemostat (Surgicel® Fibrillar; Ethicon, Somerville, NJ, US) that is applied over the top as a pad [35]. Topical hemostatic agent use should be accompanied by temporary pressure applied with gauze to secure the hemostatic matrix. Laparoscopic tacks or clips

can also be placed and should be readily available in anticipation of vascular injury. Another method described in the literature utilizes absorbable hemostat material (Surgicel®), which is then secured in placed using laparoscopic fasteners. These fasteners are then anchored to the sacrum to apply targeted pressure to the bleeding area [36]. These techniques can only be utilized for relatively small sacral vessels. In the case of a common iliac venous injury, formal repair is critical to stop hemorrhage.

When these minimally invasive approaches fail, the surgeon should be prepared to convert to an open procedure. If a robotic approach is underway, the team should have an "emergency undock" protocol in place. The surgical and anesthesia teams should always be in constant communication regarding extent of blood loss and potential need for transfusion protocols to be activated. While preparing for conversion to laparotomy, pressure using a gauze, cottonoid, or blunt instrument must be maintained to prevent further hemorrhage. This can be accomplished with a robotic arm followed by a laparoscopic instrument through an accessory port when the robot is being undocked. Blood products should be ordered and brought to the operating room. Vascular instruments should be prepared and intraoperative vascular surgery consultation requested.

Urinary tract injury, although rare, is a conceivable complication of minimally invasive prolapse surgery, and many genitourinary injuries go unrecognized at time of the procedure. Minimally invasive sacrocolpopexy has been associated with intraoperative bladder injury rate of 0.4–3.3% and up to 10% in patients with post-hysterectomy vaginal vault prolapsed [32, 37]. While some of this could be due to the learning curve associated with newer robotic-assisted techniques, it is important to recognize the possibility of bladder injury and to be prepared to identify and attend to this complication, should it occur. Ureteral injury does appear to occur less frequently, and there is a paucity of literature to determine exact ureteral injury rate during laparoscopic prolapse repair specifically. That being said, laparoscopic hysterectomy has been most recently associated with a ureteral injury incidence of 0.02–0.54%, and incidence does not significantly differ between subtotal and total hysterectomy [38, 39].

In order to minimize risk of genitourinary injury, the surgeon should develop a command of the anatomy and knowledge of the most common sites of injury. Additionally, preoperative risk stratification and intraoperative assessment of ureteral and bladder integrity is essential in preparing for and preventing urinary tract complications. It is imperative to address patient-specific risk factors, such as prior pelvic surgical history and anomalous anatomy. History of three or more previous cesarean sections comes with a cystotomy rate of 20% in the setting of laparoscopic hysterectomy [40]. With regard to type of injury, the dome of the bladder is most commonly involved in injury during total hysterectomy while the most common sites of ureteral injury occur in close proximity to the uterine artery or at the pelvic brim, near the infundibulopelvic ligament. Identification of the vesicovaginal junction is crucial to avoiding bladder injury. The placement of a sponge stick or end-to-end anastomosis (EEA) sizer vaginally can help with mobilization of the vagina and detection of the plane between the vagina and bladder. This dissection should be bloodless and areolar tissue should be easily identified. If bleeding is encountered, the surgeon should suspect compromise of bladder wall integrity. Bladder insufflation can also prove helpful during this time to ensure proper dissection. If bladder injury occurs, a double layer closure should be performed with 2-0 or 3-0 absorbable sutures after dissection is complete. Bladder repair can also be successfully performed with barbed suture or a combination of the two types [29]. Subsequently, a retrograde fill of the bladder should be performed to ensure adequate closure. We recommend indwelling catheter placement for 5–14 days, depending on size and location of the defect.

Transperitoneal identification of the ureter can usually be performed at the level of the pelvic brim, and the ureter can be coursed from this point. This technique should be routinely performed whenever possible to decrease risk of ureteral injury; however, in patients with aberrant anatomy or those who have had multiple abdominal surgeries, this may be difficult. In these instances, use of

prophylactic ureteral catheterization may reduce the risk of injury during high-risk procedures although routine use is debated, and this practice should not take the place of meticulous surgical technique [41]. Additionally, the use of ureteral stents can be limited when a robotic technique is employed, due to lack of tactile feedback. Recently, Siddighi and coworkers [42] described the use of indocyanine green (ICG) to identify ureters intraoperatively. Prior to the start of surgery, 25 mg of ICG was dissolved in 10 mL of sterile water and injected into each ureter through a 6-French ureteral catheter. The ICG injection resulted in reversible staining of ureters through protein binding for the entirety of each of ten gynecologic surgeries. There were no adverse events described at the time of the operation or up to 2 months postoperatively and cost was approximated at $100 per 25 mg of ICG. This technique can be utilized in anticipation of abnormal anatomy or high-risk prolapse cases when performing robotic-assisted prolapse repair; this technique should be considered as part of one's armamentarium when treating patients with risk factors for urinary tract injury, such as those with diagnoses of endometriosis, multiple abdominal surgeries, ectopic ureter insertion, or duplication of urinary collecting system. If ureteral injury is identified intraoperatively, the ureter should be adequately mobilized and the injured segment is excised prior to ureteroureterostomy using 4-0 absorbable sutures. Intracorporeal placement of a JJ stent can then be performed. Good success rates of this repair have been described using robotic techniques [43]; however, ureteral repair may require laparotomy at times, as well as consultation with other subspecialty services.

Lastly, vaginotomy has been quoted as a fairly common complication of minimally invasive POP repair and has been associated with an incidence from 0.4% up to that of 24% in robotic assisted sacrocolpopexy with patients who had post-hysterectomy vaginal vault prolapsed [32, 33]. The presence of this complication has been associated with postoperative vaginal mesh exposure, and for this reason it is of utmost importance to take precautions when performing vaginal dissection [44]. To minimize vaginotomy risk, an EEA sizer or vaginal stent can be placed in the vagina and elevated cephalad either anteriorly or posteriorly by the assistant. This allows the surgeon at the console to delineate vesicovaginal and rectovaginal planes appropriately when performing the vaginal dissection. In cases of post-hysterectomy vaginal vault prolapse, it is important to also be mindful of the cuff closure site, as this is usually the area of thinnest peritoneum. Dissection in this area should be only performed after a clear plane has been identified, as vaginotomy is more likely to occur here [45]. It is our preference to leave the peritoneum intact whenever possible and we routinely forego dissection of the posterior peritoneum off of the cervical stump when performing supra-cervical hysterectomy robotically. We prefer to maintain the peritoneal integrity here to reduce risk of mesh extrusion as it is felt additional dissection in this area is not significantly helpful. In cases where vaginotomy does occur, it is imperative to reinforce this area with a second imbricating layer of suture. Additionally, mesh should not be placed directly over any vaginotomy site. We routinely continue to perform supracervical hysterectomy with sacrocolpopexy rather than total hysterectomy to further minimize mesh exposure or extrusion risk. This is done unless the patient has known cervical pathology or some other medical indication requiring removal of the cervix. We prefer Gor-Tex® (Gore Medical, Flagstaff, AZ, USA) sutures for anterior and posterior mesh fixation, as their monofilament structure makes vaginal extrusion less likely.

Postoperative Complications

Although overall morbidity remains lower and recovery time is usually shorter in the setting of comparable success rates with an open approach, postoperative complications do occur with minimally invasive sacrocolpopexy [6, 8, 9, 32, 37, 46]. It is important to recognize those that occur most often, so that one may anticipate these setbacks and tend to them in a timely fashion.

Postoperative surgical site infection (SSI) is found to occur at a rate of approximately 2–4% during minimally invasive hysterectomy and sacrocolpopexy procedures, and this complication is associated independently with intra-/postoperative

blood transfusion and longer operative time [37, 47]. These characteristics are likely representative of longer, more complicated surgeries. Possible reasons for wound infections could include failure to redose antibiotics during longer cases, prolonged tissue and or trocar manipulation, increased risk of violation of sterile technique and larger potential for thermal or glycemic disregulation. The surgeon should always be mindful of the time and discuss potential need for redosing of antibiotics with the anesthesia team. Antimicrobial prophylaxis guidelines should be reviewed. Most often, cephalosporins are used for minimally invasive POP repair. In general, redosing should occur after 4 h or with >1500 mL blood loss. Additionally, patients over 120 kg should receive 3 g initially instead of the standard 2 g dosing. OR assistants should also assist with periodic evaluation of trocar sites or need for repositioning to decrease tissue damage during the case that could lead to SSI postoperatively [48]. If wound infection does occur, antibiotics to cover Gram-positive organisms should be initiated, as these organisms are most commonly associated with SSI in those individuals undergoing gynecologic/urogynecologic procedures [49, 50]. Any area of erythema around the surgical site should be clearly demarcated. Although the routine use of preoperative antiseptic scrubs has been debated, there is evidence to show that this technique reduces rate of antibiotic resistant SSI, and use may be considered in patients with predisposing risk factors to wound infection [50–52].

Another postoperative complication to be aware of is that of venous thromboembolism, which is thought to come with a risk of approximately 14% in gynecologic surgery for benign disease [53]. Although there is no consensus on VTE prophylaxis for patients undergoing pelvic reconstructive surgeries, it should be noted that many of these patients are defined as "high risk" solely on the basis of age >60 years which comes with a general VTE risk of 20–40% [54]. Both the AUA and ACOG recommend the use of anticoagulation in "high-risk" populations undergoing high-risk surgeries such as vaginal wall repairs and sacrocolpopexy [55, 56]. Given the average age of the patient undergoing POP repair, strong consideration should be given to these recommendations and benefit of heparin intraoperatively should be weighed against individual bleeding risk. That being said, the use of pneumatic compression devices should be employed routinely, independent of other anticoagulation, unless the patient has a contraindication to this. If a VTE is suspected, the patient's pretest probability should be calculated and diagnostic tests should be performed. Davis [57] provides a concise review of clinical models used for diagnosis and treatment of VTE in gynecologic surgery. These algorithms can be helpful when choosing treatment method and duration for patients.

Bowel complications after minimally invasive sacrocolpopexy can range from very painful constipation to bowel obstruction secondary to adherence of intestines to exposed abdominal mesh. While bowel obstruction rates are rare, ranging from 0.4 to 1.7% [37], overall rates of bowel dysfunction far surpass this, with an incidence rate of 5–14% in a recent meta-analysis of robotic-assisted sacrocolpopexy. The most common types of dysfunction cited were dyschezia, obstructed defecation and outlet constipation [31]. Recent studies suggest that having concomitant posterior prolapse repair does not increase bowel dysfunction rates, and these symptoms may be related to surgical technique of sacrocolpopexy [58]. It is imperative to place the mesh as flat as possible against the sacral promontory and to avoid attachment to the levator ani musculature in order to decrease anorectal dysfunction postoperatively. Extensive dissection in the rectovaginal septum should be avoided to reduce the risk of rectal denervation injury. Additionally, management of expectations is important in this area. Patients should understand that average time to first bowel movement (BM) is estimated at 3 days after prolapse surgery, and a recent RCT revealed no difference in average time to BM with a more rigorous bowel regimen. Additionally, bowel movements were comparatively painful in both groups and those with higher incidence of postoperative narcotic intake had higher postoperative pain scores associated with bowel movements [59]. These data are compelling and clearly more research in this area is indicated. Since there is no consensus in the literature for bowel dysfunction reduction, we use various techniques to attempt to mitigate this postoperative issue. In order to

reduce narcotic use, which is a known contributor to constipation, we implement the use of Toradol 30 mg every 6 h as a standing regimen with narcotics only for breakthrough pain. When transitioning to PO regimen, patients are encouraged to use 800 mg Ibuprofen or 1 g of Tylenol every 8 h. Additionally, patients are started on twice daily stool softeners and a powder laxative 1–2 times daily postoperatively and encouraged to continue this regimen until BMs are regulated.

Nausea and emesis should always provoke the question of ileus or small bowel obstruction postoperatively. Many times, this can be managed conservatively with clear liquid diet or nasogastric tube. At times, obstruction persists, requiring reoperation, and the decision about this intervention should be made on a case-by-case basis. Surgical technique may again contribute to an obstruction of the bowel, and debate exists about whether obstruction is, in most instances, directly related to mesh placement or exposure. In a recent review, surgeons found similar obstruction rates with and without re-peritonealization of sacrocolpopexy mesh [60]. Conversely, one case series demonstrated two cases of delayed obstruction to be directly attributable to the barbed suture used to re-peritonealize the sacrocolpopexy mesh [61]. These are important cases to consider. At our institution, we do utilize barbed suture to routinely re-peritonealize sacrocolpopexy mesh; however, we make sure to cinch tissue after each throw of suture to reduce barbed suture exposure, and we routinely cut suture ends flush with peritoneal tissue to decrease the risk of this complication.

Various other mesh complications can also arise, including pelvic pain or dyspareunia, mesh infection, and mesh extrusion. Patients should be extensively counseled on the possibility of these mesh-related complications and the low but present risk of need for reoperation due to mesh complications, which was found to occur at a rate of 2.9% in a recent review article [62]. Mesh extrusion rates associated with minimally invasive sacrocolpopexy hover around 2–3% [33, 37] and are shown to be higher with silicone-coated polyester and polytetraflouroethylene mesh materials [62]. For this reason, use of these mesh types is not recommended. We routinely perform supracervical hysterectomy with minimally invasive sacrocolpopexy to avoid higher rates of mesh extrusion [62], unless there is a medical indication to remove the cervix at the time of prolapse repair. Although pain and dyspareunia are found to be less with sacrocolpopexy when compared to vaginal prolapse repairs, these issues still do occur. If pain occurs in the absence of mesh extrusion and conservative measures such as analgesics, local hormone therapies or local anti-inflammatory injections fail, reoperation to remove the mesh may be necessary. When evaluating these patients, differential diagnosis should include bowel or bladder mesh erosion, suture erosion, lumbosacral discitis, and osteomyelitis. Possible diagnostic tests should include and not be limited to cystoscopy, colonoscopy, CT scan, and MRI. There are case reports to support the utility of these tools when evaluating post-sacrocolpopexy pain [63].

While extremely rare, back and/or buttock pain accompanied by acute signs of infection could denote pyogenic spondylitis. This class of lumbosacral infections requires immediate attention and can be life threatening. It is imperative to avoid the L5-S1 disc and to localize the sacral promontory and avoid the sacral nerve, which is most commonly found approximately 3 cm from the upper surface of the sacrum and 1.5 cm from the midline [64]. Sutures should be placed at or below the sacral promontory to avoid the disc space and when this is not possible, surgeons should be mindful of the 1–2 mm thickness of the anterior longitudinal ligament and place sutures no deeper than this to avoid the disc itself [65]. This complication may often require reoperation and removal of mesh and suture, followed by a prolonged course of broad-spectrum antibiotics.

Lastly, de novo stress urinary incontinence can occur following sacrocolpopexy in the minimally invasive setting and the need for further intervention with mid-urethral sling placement in these patients can far exceed 10% [31]. We routinely perform clinical evaluation to assess for occult SUI if the patient does not identify with this symptom profile. Furthermore, we have implemented a “shared decision-making” model into our practice, when considering concomitant

anti-incontinence procedures in this setting. It is crucial to assess anterior and apical support vaginally at the time of sacrocolpopexy mesh fixation, to ensure that overcorrection of the anterior compartment has not occurred. If there appears to be tension on the tissues of the anterior vaginal wall or splaying of the urethral meatus, adjustment may need to be considered.

Overall, sacrocolpopexy, whether done via laparoscopic or robotic route, is an extremely safe and effective form of pelvic organ prolapse repair. These modes of surgery are rapidly becoming the new gold standard, as minimally invasive techniques are found to be more appealing to both patient and surgeon; minimally invasive sacrocolpopexy has comparable profiles of safety and feasibility, parameters that will only continue to improve with enhancement of surgeon efficiency. It is crucial, however, to acknowledge the unique set of complications that may accompany minimally invasive approaches to sacrocolpopexy, so that we may be equipped to avoid surgical pitfalls and optimally prepared to treat complex situations, should they occur. Surgeon understanding of the complications associated with minimally invasive sacrocolpopexy provides for consensus to develop best practices, which can help to decrease the incidence of these complications and increase overall patient satisfaction associated with these procedures.

Summary

Table 10.1 offers an excellent summary for avoiding complications of minimally invasive female Pelvic organ prolapse repair.

Table 10.1 Avoiding complications of minimally invasive female pelvic organ prolapse repair

Preoperative considerations	
Patient history and physical exam	• Thorough assessment of tolerance of abdominal insufflation/Trendelenberg positioning
	– Smoking history, exercise tolerance, obesity
	– Cardiopulmonary/renal disease
	– Increased ICP
	– Hypovolemic state
	• Abdominal survey for scars, hernias, and understanding of prior pelvic surgeries, anatomical variants
	• Uterine mobility, adnexal mass
	– Lateral mobility ≥2 cm for uterine vessel access
	• Gentle preoperative bowel prep only when deemed necessary (surgeon preference)
	– Mg Citrate, Miralax
Patient positioning and surgical setup	• Proper use of corporeal padding
	• Joint flexion at maximum angle of 30°
	• Anti-skid materials to decrease risk of nerve injury
	– Pink pad, egg crate, surgical beanbag
	• Facial padding, eye taping to reduce facial injury
	– Direct facial trauma responsible for 20% of corneal abrasions
	• Be mindful of degree of Trendelenberg positioning absolutely necessary
	– Less steep degree may decrease morbidity without negative effects on surgical time, visibility (Ghomi et al.)
	• 30° camera for optimal sacral visualization
	– If distance from umbilicus to pubic symphysis <15 cm, camera port should be supra-umbilical
	• Direct visualization and abdominal survey during trocar insertion
	– Port site bleeding most commonly from perforation of inferior epigastric artery
	– 55% of bowel perforations occur during intra-abdominal access
	• Use of 8-mm or 5-mm accessory port to decrease hernia risk

(continued)

Table 10.1 (continued)

Intraoperative complications	
	• Port site bleeding
	– Attempt to cauterize injured vessel with offending trocar in place
	– Tamponade can be attempted using a 12-Fr foley catheter through trocar
	– Sutures can be placed at each side of trocar site and tied externally with removal after 24–48 h
	• Bowel injury
	– Use of fan retractors, accessory stitch, Endoloop to retract bowel effectively
	– If injury detected vicryl or barbed suture can be used for repair
	– Repair should be performed in two layers with sutures placed on the long axis of intestine to prevent stricture
	• Presacral hemorrhage
	– Middle and lateral sacral vessels should be well delineated
	– Assess for variability of sacral/iliac vessels, particularly on the left side of anterior longitudinal ligament
	– Apply direct pressure with a RAYTEK or cottonoid as first line treatment
	– Hemostatic agents (Floseal, Surgicel) and laparoscopic vessel fasteners should be readily available
	• Urinary tract injury/vaginotomy
	– Use of EEA sizers or vaginal stents to allow for proper visualization of vesicovaginal junction
	– Dissection of this junction should be bloodless if correct plane has been identified
	– 25 mg ICG in 10 mL sterile h20 can be injected into ureters prior to RASC for ureteral identification
	– Bladder/vaginal injury should be repaired in a double, imbricating layer using vicryl or barbed suture
	– Mesh should not be placed directly over vaginotomy site, should one occur
Postoperative issues	
	• Surgical site infection
	– Cephalosporins should be redosed intraoperatively after 4 h or with >1500 mL blood loss
	– Patients >120 kg should receive a 3 g initial dose instead of standard 2 g dosing
	– Postoperative antibiotics for wound infection should be targeted at Gram-positive bacteria
	• VTE
	– LMWH should be considered in patients >60 yo, as they are deemed “high risk” with VTE risk 20–40%
	• Bowel complications
	– Dyschezia, obstructed defecation, and outlet constipation are the most common types of post-op bowel dysfunction and patients should not expect a bowel movement within the first 3 days after surgery
	– Extensive dissection of rectovaginal septum should be avoided to reduce bowel denervation
	• Mesh complications
	– Mesh should be placed as flat as possible and against sacral promontory to decrease anorectal dysfunction
	– Supracervical hysterectomy is preferred to reduce mesh extrusion rates
	– Use of lightweight type I mesh to reduce risk of graft infection
	• De novo SUI
	– Vaginal examination should be performed intraoperatively to assess for anterior/apical overcorrection which could lead to new onset stress urinary incontinence

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Colpocleisis

11

Umar R. Karaman and Alexander Gomelsky

Introduction

The proportion of the US population aged 60 years or over is expected to increase from 20.7 to 26.1% over the next 15 years [1]. This represents an increase from approximately 66 million to nearly 93 million people. As pelvic organ prolapse (POP) occurs in an estimated 37% of women over the age of 80, the demand for pelvic floor services is expected to increase by 45% over the next 30 years [2, 3]. Currently, more than 200,000 surgeries are performed annually to address POP, and repairs of apical defects comprise a significant percentage of these surgeries [4, 5]. All of these statistics underscore the importance of effective, durable, and safe methods of surgically treating POP in elderly women.

There are two major categories of surgical approaches. The focus of reconstructive surgery is to augment and restore vaginal support mechanisms with the goal of vaginal preservation. On the other hand, obliterative surgery eliminates the potential space of the vagina, without compartment-specific reinforcement of the supportive connective tissue layers. With the latter approach, the vaginal cavity is significantly reduced, essentially eliminating the possibility of vaginal coitus. Thus, the chosen surgical approach depends on both, desired anatomic and functional outcome, as well as the possibility for future sexual activity.

Colpocleisis is a minimally invasive, obliterative procedure that may be performed with or without uterine preservation. While these procedures typically boast a high anatomic success rate, adverse sequelae are possible as with any surgical intervention. This chapter will focus on optimizing perioperative outcomes and minimizing postoperative complications in women undergoing colpocleisis.

History

Denuding and closing a significant portion of the prolapsed vagina were both initially described by Gerardin in 1823 and performed by Neugebauer in 1867 [6, 7]. This procedure, also referred to as colpectomy or total colpocleisis, is performed on a woman with significant POP following hysterectomy (Figs. 11.1, 11.2, 11.3, and 11.4). In 1877, LeFort described his technique of uterine-sparing, partial colpocleisis that entailed denuding the

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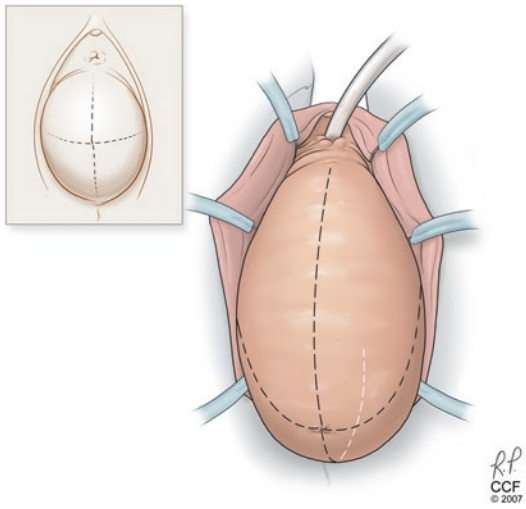

Fig. 11.1 Incisions in the vaginal epithelium are mapped out in a woman with post-hysterectomy vaginal prolapse. Note that the vertical incision stops at least 1.5 cm proximal to the bladder neck. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2007–2016. All Rights Reserved)

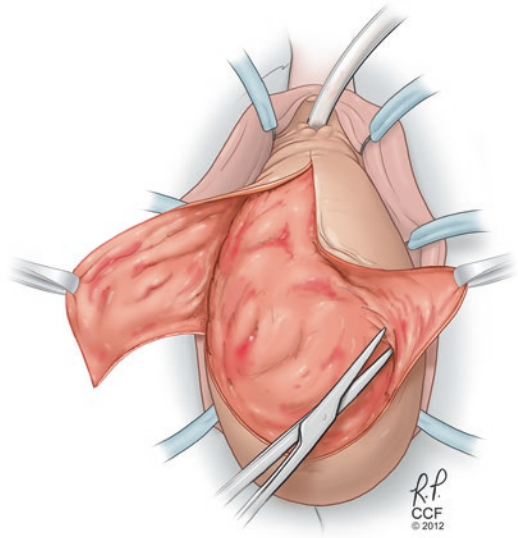

Fig. 11.2 The vaginal epithelium is dissected off the underlying pubocervical fascia, rectovaginal fascia, and any enterocele sac. Care is taken to keep a "thin" plane of dissection so as to minimize the possibility of injury to the bladder, rectum, or ureters. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2007–2016. All Rights Reserved)

middle portion of the anterior and posterior vaginal wall mucosa and then suturing them together allowing for lateral draining channels [8]. Both

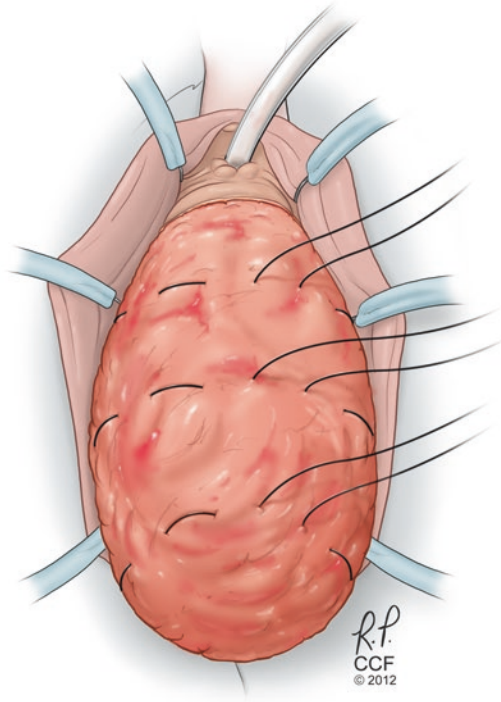

Fig. 11.3 Sequential purse-string delayed absorbable sutures are placed beginning at the apex. The prolapsing segment is reduced as the sutures are tied down. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2007–2016. All Rights Reserved)

techniques have been traditionally reserved for older women that do not desire future vaginal coitus. Likewise, the minimally invasive approach and shorter operative times may be appealing for treating those women who may be poor surgical candidates for reconstructive procedures owing to their medical comorbidities.

Preoperative Considerations

As the focus of this chapter is the discussion of perioperative complications, it is beyond our scope to describe, in detail, the nuances of each surgical technique. However, it is important to note that preoperative counseling and perioperative management unequivocally aid in decreasing the rates of postoperative adverse sequelae. Prior to undergoing a partial colpocleisis, it is recommended that women should have their upper genital tract evaluated with either transvaginal ultrasound or endo-

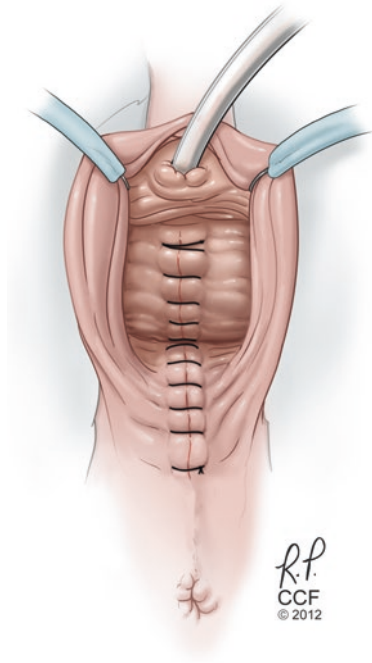

Fig. 11.4 After the pubocervical and rectovaginal fasciae are sutured together, excess vaginal epithelium is removed and the incision is closed with delayed absorbable sutures. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2007–2016. All Rights Reserved)

metrial biopsy. Papanicolaou smear must be performed prior to surgery to assess for abnormal pathology. Women who require upper genital tract surveillance, such as those with preinvasive conditions of the cervix or endometrium, should be considered for other forms of repair.

If overt stress urinary incontinence (SUI) is present, consideration should be given to a concomitant anti-incontinence procedure. However, women with significant POP may be subjectively continent because the bladder base descent may mechanically kink and dynamically compress the urethra [9]. In these cases, the SUI uncovered only after POP reduction is called occult SUI and its incidence in the literature fluctuates significantly from 6 to 80% [10–15]. The wide range reflects the lack of universal criteria for the diagnosis of occult SUI and the multitude of techniques described for POP reduction [11]. A recent multi-institutional study from the Netherlands found that women with occult SUI had a higher risk of reporting SUI after POP surgery compared with women without occult SUI [16]. Adding a midurethral sling (MUS) to POP surgery reduced the risk of postoperative SUI and the need for its treatment in women with occult SUI. Of women with occult SUI undergoing POP-only surgery, 13% needed additional MUS. Hence, preoperative evaluation with POP reduction should merit strong consideration.

Upper urinary tract evaluation is another preoperative consideration. In one retrospective study of 121 women with POP, the overall incidence of hydronephrosis was 20.6% [17]. The incidence of hydronephrosis in patients with severe vault POP was 7.1 and 22.4% in women with severe uterovaginal POP. The incidence of renal impairment was 3.3%. Of interest, 64% of the 25 patients with hydronephrosis had complete resolution after treatment while 20% had residual but smaller degrees of hydronephrosis. Preoperative renal ultrasonography and postoperative surveillance may be considered.

As the majority of postoperative morbidity is related most closely to surgical stress on the elderly, a medical and cardiac, clearance may be necessary. This will often dictate the method of intraoperative anesthesia, and these surgeries have been performed under both regional and local anesthesia with success [18, 19]. The ultimate choice of anesthesia is at the discretion of the surgeon, anesthesiologist, and patient. As the incidence of rectal and small bowel injury is very low, preoperative bowel regimen may be omitted, but should be considered in women with a history of significant constipation or multiple previous vaginal surgeries [20, 21].

Finally, preoperative counseling and a thorough discussion of risks and benefits, as well as options to colpocleisis, should be undertaken. Although long-term anatomic cure rates of colpocleisis typically exceed 90%, intraoperative and postoperative complications do occur [22]. Additionally, if an anti-incontinence procedure is performed in the same setting, the risks of this surgery should be included in the informed consent process. Furthermore, approximately 10% of women experience regret after undergoing colpocleisis and should be counseled appropriately regarding the loss of vaginal depth [23].

Prophylactic intravenous antibiotics are given within an hour of surgical "cut" time (first or second-generation cephalosporin, gentamycin and clindamycin, or a fluoroquinolone) [24]. As rates of deep vein thrombosis (DVT) approach 15% for benign pelvic surgery, a prophylactic strategy should be employed in each surgery [25]. Intermittent pneumatic compression (IPC) devices are applied prior to induction of anesthesia. Also, as age >60 years alone places women undergoing colpocleisis into the high-risk category for DVT, consideration should be given to combination therapy with IPC plus low-dose unfractionated heparin (LDUH) or low molecular weight heparin (LMWH), unless the bleeding risk is considered unacceptably high. The presence of additional risk factors, such as smoking, obesity, immobility, estrogen-containing oral contraception or hormone replacement therapy, or heart or respiratory failure, places the woman into the highest risk category and LDUH or LMWH is strongly recommended [25]. If required, pubic hair is clipped in the operating room to minimize skin trauma. We prefer to keep an indwelling urethral catheter to continuous drainage during the surgery. A Scott/Lone Star retractor may be of assistance in obtaining exposure. Finally, general tenets, such as cautious intraoperative hydration, minimization of blood loss, meticulous hemostasis, and consideration for transfusion to minimize anemia and cardiac compromise, are imperative adjuncts to any surgical procedure in the elderly population [22].

Intraoperative Considerations

While each surgeon performing these procedures on a regular basis has their own routine to optimize anatomic outcomes and minimize adverse sequelae, we propose several general tenets that are germane to any colpocleisis protocol. First, while the "deep" plane of dissection into the true vesicovaginal space may be preferred for the placement of interposition grafts or transvaginal mesh, we keep our plane of dissection superficial to the pubocervical and rectovaginal fasciae. This lessens the possibility of injury to pelvic viscera, urethra, or ureters, as the latter may be rotated forward significantly from significant anterior compartment prolapse. Second, intraoperative stenting with temporary urethral catheters may potentially lessen the chance of ureteral injury, and definitely assist in recognizing such an injury, should it occur. Also, we perform intraoperative cystoscopy with each colpocleisis surgery, regardless of concomitant anti-incontinence procedure. This step assists in identifying any bladder injury and has a sensitivity and specificity for identifying ureteral obstruction of 94.4% and 99.5%, respectively [26]. Rare false negative cases may occur with partial obstruction. Third, as recommended by Fitzgerald and coworkers, we typically preserve at least 1.5 cm of the anterior vaginal epithelium proximal to the urethrovesical junction [22]. The purpose is to avoid downward traction on the urethra when it is approximated to the posterior vaginal muscularis. Fourth, a concomitant MUS may be placed through a separate 1 cm suburethral incision to minimize migration towards the bladder neck. If the patient opts for an autologous rectus fascia pubovaginal sling, a single incision is used for the sling and colpocleisis. The sling is anchored to the underlying pubocervical fascia to keep it from dislodging. Regardless of sling choice, sling tensioning is performed after all of the POP surgery has been performed. Finally, a levator myorrhaphy or perineorrhaphy (our choice) is performed to decrease the size of the genital hiatus and minimize POP recurrence [22].

Anatomic and Subjective Outcomes

In a PubMed review of available literature (1996–2004), FitzGerald and coworkers cited "success" rates of 91–100% [22]. The authors note that the early literature is fraught with poor characterization of preoperative symptoms and inconsistent postoperative follow-up. Outcomes of more recent studies by Zebede and coworkers and Koski and colleagues support the low anatomic recurrence rates of colpocleisis [27, 28].

Colpocleisis for POP is also associated with high subjective success rates. A recent prospec-

tive study assessed quality of life (QoL) in women >65 years of age undergoing obliterative and reconstructive procedures and found significant postoperative QoL improvement without an increase in depression or body image [29]. Vij and colleagues performed a longitudinal study involving 34 women who underwent colpocleisis with a median follow-up of 3 years and demonstrated that 91% of women would recommend colpocleisis to a relative or friend [30]. Likewise, in von Pechmann's series, telephone follow-up revealed that 90.3% of patients achieved subjective cure and were either satisfied or very satisfied with how surgery resolved their POP [31].

Intraoperative Complications

Intraoperative complications can be divided into hemorrhage and injuries to surrounding structures. Zebede and colleagues cited intraoperative complications in 1.6% of their patient population [27]. These included bowel injury and hematoma during concomitant suprapubic catheter placement in two patients, two small bladder punctures during trocar passage for MUS placement, and one uterine injury during hysteroscopic resection of a mass. Of interest, the added complication rate appears to be strongly associated with concomitant surgery, and specifically hysterectomy [22]. Outcomes of two studies, in particular, both revealed low rates of intraoperative complications; however, mean operative times, estimated blood loss, postoperative transfusion rates, and length of hospital discharge were significantly higher in the groups undergoing concomitant hysterectomy [21, 31].

Ureteral injury and obstruction has been estimated to occur in 0.3–11% of all types of pelvic reconstructive procedures [32, 33], while the rate of ureteral obstruction during colpocleisis, specifically, is approximately 4% [26]. Ureteral obstruction is hypothesized to occur from kinking at the trigonal level secondary to anterior vaginal wall distortion. Intraoperative identification of obstruction and injury is imperative to prevent long-term complications requiring complex ureteral reconstruction. As vaginal surgery does not allow easy identification of the ureters, cystoscopy after administration of intravenous dye can confirm ureteral and bladder integrity [26]. If an obstruction is suspected, removal of the offending suture intraoperatively will relieve the ureteral obstruction in about 90% of cases, whereas other patients may require a ureteral stent for 2 weeks to allow resolution of the intramural ureteral edema with no residual kinking seen on postoperative imaging [26, 31].

Conversion to laparotomy is a rare event and has been associated with concomitant hysterectomy [31]. Whereas vascular injury secondary to a bleeding ovarian vessel at time of concomitant adnexectomy was reported in one patient, the second laparotomy was due to rupture of a diverticular abscess upon entry into the pouch of Douglas. Furthermore, a proctotomy was identified on a third patient and was repaired without incident [31].

Perioperative and Early Postoperative Complications

While the elderly are at higher risk for complications during vaginal surgery, those women undergoing colpocleisis may experience fewer overall complications. A recent retrospective analysis of 264,340 women from the Nationwide Inpatient Sample found that the overall in-hospital mortality risk was 0.04% after POP surgery [34]. When compared with women <60 years of age, the odds ratio of mortality in women >80 years of age was 13.6. The overall complication rate was 14.4% with 20% of women >80 years of age having one or more complications. Those octogenarians who underwent obliterative procedures were less likely to suffer a complication as compared to those receiving reconstructive procedures (17% vs. 24.7%).

A retrospective, multi-institutional study involving 145 medical centers reviewed over 4700 colpocleisis procedures dating from 2002 to 2012 and cited overall complication rates of 6.82% [35]. Despite 53% of the procedures being performed in octogenarians, the intensive care unit (ICU) admission rate was only 2.8% and there were seven deaths for a mortality rate of

0.15%. Readmissions were uncommon, with an overall 30-day readmission rate of 4.2%. Higher volume centers had lower ICU admission rates and shorter length of stay.

In another retrospective review of colpocleisis procedures from the American College of Surgeons NSQIP database, Catanzarite and colleagues cited an 8.1% overall complication rate within 30 days [36]. The most common complication was UTI in 6.4% and only 2.1% required a return to the operating room within 30 days. Concomitant sling placement did not increase the 30-day complication rates. In another study of 245 women, postoperative UTI occurred in 34.7% [21].

In Fitzgerald's review, cardiac, thromboembolic, pulmonary, and cerebrovascular postoperative complications occurred in 5% of patients [22]. However, in the studies performed since 1980, the complication rate due to performing surgery on the elderly has decreased to 2%. Complications related to colpocleisis, including transfusion and pyelonephritis, occurred at a rate of 4% and were associated with concomitant hysterectomy as previously mentioned.

Late Postoperative Complications

Pyometra, pyocolpos, or pelvic abscess can occur on occasion despite the creation of adequate vaginal channels during a partial colpocleisis [37–39]. Meticulous hemostasis cannot be overemphasized. Use of a Bakri balloon has been proposed for dilation of the tunnels in cases of persistent hematocolpos [40]. Gynecologic malignancies are rare after colpocleisis, with fewer than 15 reported in the literature [41].

The impact of colpocleisis on urinary storage and emptying symptoms warrants discussion. Urinary retention is rare, with one patient in a large series requiring the use of an indwelling catheter at 3 months after surgery [20]. No surgery was performed for postoperative voiding difficulty and no patient underwent sling incision or urethrolysis. In a more recent study, Koski and coworkers likewise reported that no patients had urinary retention after surgery that required chronic catheterization or reoperation [28].

As mentioned previously, women with overt SUI should be strongly considered for a concomitant anti-incontinence procedure, while an evaluation with POP reduction should be considered for those women who are subjectively stress-continent. De novo postoperative SUI has been postulated to occur due to either the unmasking of occult SUI after POP correction or excessive downward traction on the urethra during approximation to the posterior vaginal muscularis [22]. Whereas early authors attempted modifying the LeFort technique by altering the anterior edge of the colpectomy away from the urethral meatus [42, 43], more recent series combine colpocleisis with anti-incontinence procedures [22]. The type of procedures has included suburethral plications, transvaginal bladder neck suspensions, and slings placed at the bladder neck or midurethra [22]. There are no prospective studies comparing one concomitant anti-incontinence procedure with another and operative choice remains at the experience and discretion of the surgeon.

Interestingly, postoperative SUI may yet occur in women who have a concomitant anti-incontinence surgery. In one series of 140 patients, bothersome SUI 1 year after colpocleisis was 13% in women who had undergone a concomitant anti-incontinence procedure and 14% in women who only had colpocleisis [20]. New onset bothersome SUI was not common, occurring in only in 4% of patients who had an anti-incontinence procedure and in 3% who did not. Of the women that did not seek correction of SUI in the series by Koski and coworkers, four had persistent SUI and one developed de novo SUI [28]. In another retrospective study, eight out of 30 women without preoperative SUI developed new-onset SUI after surgery [44]. These findings suggest that the relationship between SUI and POP is an inconsistent one and that, despite treatment of occult SUI, overt SUI may still occur after POP repair. Our ability to properly characterize SUI in the presence of significant POP is further questioned.

Significant POP is also related to other urinary storage symptoms and urgency urinary incontinence. In the study by Fitzgerald and coworkers,

lower urinary tract symptoms improved at the 3-month follow-up and improvement was maintained at 1 year [20]. Fifteen percent of patients at 1 year described bothersome urge compared to 41% at baseline. The most common complaint on postoperative UDI-6 was frequency and urgency, and these complaints were present preoperatively [28]. In this study, there was no evidence of postoperative de novo urgency. These findings are corroborated by further significant postoperative improvement in mean IIQ-7 and UDI-6 scores [23]. Thus, while not guaranteed to eliminate all preoperative storage symptoms, colpocleisis, in general, has a beneficial effect.

The impact of bowel function has been infrequently reported in colpocleisis studies; however, what has been reported indicates a postoperative improvement in these symptoms [22]. Fitzgerald and coworkers reported significant improvement on the Colorectal Anal Distress Inventory (CRADI) and Colorectal Anal Impact Questionnaire at 3 and 12 months after surgery [20]. Additionally, Vij and colleagues reported low postoperative CRADI scores after colpocleisis [30]. Two to five years following colpocleisis, there were no new adverse bowel symptoms reported, with improvement of fecal incontinence in two of nine women and no change in fecal urgency.

Despite appropriate informed consent discussion, the loss of vaginal sexual function following colpocleisis may be associated with regret. One year after surgery, 94% of patients in Fitzgerald's cohort were either satisfied or very satisfied with their decision to have vaginal closure [20]. Two percent felt their body looked worse, whereas 10% of women reported improved sexual function following surgery, 3% reported worsening function, and 87% stated it had remained the same. Overall, the regret rate, when reported, ranged from 0% in the Reisnauer's study to 12.9% in the study by von Pechmann and colleagues [31, 45]. In von Pechmann's study, however, four of the eight women expressing some degree of regret after colpocleisis stated they would undergo surgery again, while only one definitely would not [31].

Conclusions

Colpocleisis is an effective and minimally invasive method to manage significant POP in the elderly woman who no longer desires vaginal coitus. Intraoperative complications are infrequent and may be minimized by careful dissection and meticulous hemostasis. Morbidity is lower in women undergoing partial colpocleisis. Bothersome urinary, colorectal, and pelvic symptoms are typically alleviated after surgery and the anatomic recurrence rates are low. Although subjective satisfaction is high, some women may still experience a sense of regret over a vaginal obliterative procedure. Informed consent remains of utmost importance when discussing this procedure as it has significant implications on a woman's personal life. Proper patient selection and thorough preoperative work-up cannot be overemphasized.

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Mesh Prolapse Repair

12

Farzeen Firoozi and Howard B. Goldman

Introduction

The lifetime risk of requiring pelvic surgery for vaginal prolapse or incontinence for a woman in the United States is 11 %, with a risk for reoperation of 29 % [1]. Traditional vaginal repairs for prolapse using only the patient's native tissues have had reported rates of recurrence ranging from 10 to 50 % depending on the compartment repaired [2]. In the last 10 years, there have been advancements in pelvic floor reconstructive surgery to create repairs that are reproducible with improved subjective and objective outcomes.

Initial attempts were made to augment transvaginal repairs using biologic grafts or absorbable synthetic mesh. In terms of anterior vaginal wall augmented repairs, Meschia and colleagues compared outcomes of anterior colporraphy with and without a porcine dermis onlay graft (Pelvicol™ [Bard Medical, Covington, GA]). The objective failure rate at 1 year, determined by pelvic exam, was 20 % in the anterior colporraphy group versus 7 % in the porcine dermis onlay group [3]. In 2005, Gandhi and colleagues reported their experience with the use of solvent dehydrated cadaveric fascia lata (Tutoplast® [RTI Biologics, Inc., Alachua, FL]) in augmenting anterior vaginal wall repairs. Outcomes of anterior colporraphy with or without the cadaveric fascia lata were compared. The authors reported no difference in the objective and subjective outcomes between the two groups at 13 months follow-up [4]. In addition, Weber and coworkers failed to show any difference in cure rates between Vicryl mesh repairs versus traditional anterior repairs [5].

The first trial to compare mesh versus nonmesh repairs in the management of posterior wall vaginal prolapse was published by Sand and coworkers in 2001. In this study, absorbable Vicryl mesh was used for the augmented repair arm. The authors found virtually no difference in rectocele recurrence rates between the two groups [6]. In 2006, Paraiso and coworkers compared posterior colporraphy, site-specific repair and site-specific repair with porcine small intestine submucosal onlay graft for rectocele repair. From an objective standpoint, there was a higher recurrence rate of rectocele in the graft onlay group versus the posterior colporraphy group. When comparing all three groups, there was no difference in subjective report of prolapse symptoms [7]. As a result of these types of studies, the

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use of biologic grafts or absorbable synthetic mesh had been largely abandoned as an alternative for augmenting traditional vaginal repairs of anterior and posterior compartment prolapse.

In terms of apical prolapse, the gold standard has been the abdominal sacrocolpopexy utilizing mesh attached to the vaginal wall. Success rates for managing apical prolapse repairs using mesh via an abdominal route range between 85 and 100 % [2]. The safety of this approach has been well established in numerous studies reported over the last several decades [8].

The use of transvaginal mesh was adapted initially on a large scale after the introduction of synthetic slings for the treatment of urinary incontinence [9]. The safety of synthetic mesh slings has been well established over the last 15 years. The use of synthetic mesh slings for urinary incontinence has shown significant efficacy, durability, and safety and led the way for innovation towards transvaginal mesh prolapse repairs. This was an intuitive step on the progression of improved transvaginal repairs, especially since biologic and absorbable synthetic mesh trials in the past had failed to demonstrate superiority to traditional repairs. The newly designed synthetic mesh kit procedures were first approved by the Food and Drug Administration (FDA) in 2003. Since their introduction over 8 years ago, a multitude of mesh kit procedures have become available on the commercial market. Although each is designed slightly differently the common goal has been to establish a new transvaginal repair that would prove safe, with improved efficacy and durability when compared to traditional repairs.

Hiltunen and colleagues reported a significant difference in anterior wall recurrence rates between their traditional repairs versus their nonabsorbable mesh augmented repairs, 38.7 % and 6.7 %, respectively [10]. Nguyen and Burchette in 2008 found in their randomized controlled trial that the traditional repair arm had a recurrence rate of 45 %, versus 13 % in the nonabsorbable mesh augmentation group [11]. In 2011, a randomized controlled trial of transvaginal mesh kit repair versus traditional colporraphy for anterior vaginal wall prolapse was published in the New England Journal of Medicine by Altman and colleagues. The overall rate of objective success, based on pelvic organ prolapse quantification (POP-Q) stages, was significantly higher in the mesh group (60 %) compared to the traditional colporraphy group (35 %) [12]. The purported benefit in most of these studies was the objective superiority of repairs involving nonabsorbable mesh augmentation. In addition, many of these studies showed trends towards improvements in subjective outcomes in those with mesh but these findings were not significant at the time points evaluated.

The use of synthetic mesh in transvaginal prolapse repairs has not been without controversy. At the heart of the controversy lies the concern that complications related to mesh use outweigh the benefit of augmenting repairs with synthetic mesh. The main issues are the risks of pain, dyspareunia, and mesh extrusion or perforation requiring corrective surgery. Adding significant legitimacy to this side of the debate was the initial white paper published by the FDA in 2008 regarding the use of transvaginal mesh for both incontinence and prolapse surgery. The overall tone of the report was in keeping with the main concerns, namely, the risk for intra- and postoperative complications. The recommendations included the proper counseling of patients as to the potential risks of mesh use in incontinence and prolapse surgery. A recent update in July 2011 further expressed the concern for use of synthetic mesh for prolapse surgery, but very clearly separated the use of mesh for urinary incontinence—somewhat of an acknowledgement to the arguments made by many experts that the safety of synthetic mesh slings had been well established over almost two decades of study.

There are two general theories that explain the occurrence of mesh complications. The first is that synthetic mesh implanted in the vagina is simply prone to causing pain, extrusion, or perforation. The other theory is that it is generally a problem with appropriate surgical technique that accounts for mesh complications [13]. We will discuss this portion of the debate in our next section. Regardless, while the use of synthetic mesh has shown some utility in augmenting traditional transvaginal repairs of prolapse a very

real aspect of these repairs are the potential intra- and postoperative complications related to use of mesh. In this chapter, we will review techniques for avoiding complications, recognizing technical issues intraoperatively, and managing complications postoperatively.

Avoiding Complications of Transvaginal Mesh Repairs

Preoperative Considerations

Preoperative preparation of patients for transvaginal mesh repairs begins with optimization of vaginal tissue. We recommend the initiation of vaginal estrogen supplementation 4–6 weeks preoperatively to improve perioperative tissue quality. There are currently many options on the market including Premarin® cream (Pfizer, New York, NY), Estrace® cream (Allergan, Parsippany, NJ), Vagifem® (Novo Nordisk, Plainsboro, NJ), and E-string® (Pfizer, New York, NY). The continued use of local hormone replacement postoperatively is recommended to maintain tissue quality and to facilitate tissue healing.

Certain patient populations with impaired wound healing or damaged vaginal skin may be at greater risk for mesh extrusion. Patients who have had pelvic radiotherapy, those on steroids and possibly smokers are examples of these types of patients. Very careful consideration of risk profiles and an acknowledgement of increased rates of extrusion should be undertaken before surgery is performed in this population.

Intraoperative Considerations

A cornerstone of transvaginal mesh repair is developing the proper plane of dissection. Probably, the best way to accomplish this is with copious hydrodissection of the vaginal wall to aid in the actual sharp and blunt dissection that follows. The vaginal wall incision is made through the viscerofascial layer to the potential space (filled with a gelatinous fluid after hydrodissection) between the fascial layer (either pubocervical or prerectal) and the underlying viscera. This plane is much deeper than the typical superficial plane external to the viscerofascial layer used for a traditional repair. If the superficial plane is inadvertently utilized for mesh placement, vaginal wall necrosis and ulceration or extrusion may ensue. In addition to vaginal wall extrusion, the risk for vaginal/pelvic pain and dyspareunia are increased by dissection and mesh placement in too superficial a plane.

Once dissection is complete, hemostasis is of utmost importance. Initial postoperative pain following transvaginal mesh repairs can be secondary to perioperative bleeding. This is typically in the form of a hematoma, which can exert pressure on the vaginal tissues eliciting pain. In addition to pain, hematomas can also delay healing and promote wound separation. Wound separation in the setting of mesh use may result in extrusion of the synthetic material. For these reasons, it is paramount that adequate hemostasis is achieved at the completion of the case and a tight vaginal pack is typically placed overnight as well.

Dissection should be adequate to allow the mesh to lay flat over the defect both side to side and proximal to distal. When a trocar-based system is used one must take care to make the lateral dissection wide enough to allow the arms to be spread as they pass through that area to avoid bunching of the mesh. Bunching and buckling of the mesh can predispose to pain and extrusion.

Similar to placement of synthetic mesh slings, the mesh placed during transvaginal repair is meant to be placed without tension. The main reason for this surgical tenet is the avoidance of postoperative vaginal/pelvic pain. Whether a trocar or trocarless kit is used, there should be no tension after completion of mesh placement. This can be done by loosening the arms if they are present and making a releasing incision in the body of the mesh if necessary. Again, the goal is placement of a tension-free system.

Prior to closure, the practice of vaginal wall trimming (common to traditional repairs) needs to be avoided in transvaginal mesh repairs. Only excoriated areas should be removed and only in a very judicious fashion. The reasoning behind

minimization of vaginal wall trimming relates to the competency of the wound. A wound under tension has the increased risk of developing a possible separation or compromised coverage of the underlying mesh predisposing to extrusion of the synthetic graft.

Postoperative Considerations

A Foley catheter and vaginal packing are typically left indwelling at the completion of the case. The vaginal packing serves to tamponade the vagina and reduces the risk of postoperatively bleeding and can be removed within 24 h after surgery.

Intraoperative Complications

With correct dissection, bleeding involving the vaginal wall or the tissue remaining deep to this dissection plane should be minimal during transvaginal mesh repairs. If bleeding does occur on either the vaginal wall or plane of mesh placement, hemostasis can typically be achieved with electrocautery. If bleeding persists, absorbable suture placed in figure of eight interrupted fashion can be used as a further means of hemostasis. Bleeding can also occur with passage of external trocars or internal trocars with both anterior and posterior approaches. The first maneuver should be direct compression at the site of bleeding. If bleeding persists, optimal exposure of the site of bleeding is paramount. Typically, the source of bleeding is an aberrant vessel which cannot be managed with compression alone. Once further dissection is performed and exposure of the bleeding vessel is achieved, judicious placement of small clips may be performed to halt further bleeding. Some surgeons use hemostatic agents such as Floseal if there is venous oozing in a deep area where it is difficult to see. If significant bleeding cannot be controlled packing followed by embolization must be considered.

Another potential intraoperative complication of transvaginal mesh repair is injury to other pelvic organs including the bladder or rectum. If bladder injury occurs, multilayer closure of the cystotomy should be performed with absorbable suture. A Foley catheter should be left indwelling for approximately 10 days prior to cystogram for confirmation of bladder healing. If a rectal injury is encountered, consultation with general or colorectal surgery is recommended. The ultimate decision of primary repair of rectal injury versus repair with diversion is at the discretion of the consultant surgeon. With either bladder or rectal injury, placement of mesh at the same setting is discouraged. The main concern for mesh placement would be a risk for mesh perforation of the organ given compromised tissue healing and infection after an injury.

Evaluation of Mesh Complications

History

There is a litany of complaints that patients can present with after transvaginal mesh repair. In this chapter, we will concentrate on patients who present with mesh extrusions and perforations. In 2010, the ICS and IUGA created a classification system to help promote a universal language that could be used by all pelvic floor surgeons in order to aid with reporting of mesh complications. The new classification system uses three components to describe complications related to the use of prosthesis/grafts, which include the category (C), time (T), and site (S). The C includes the anatomical site which the graft/prosthesis complication involves and identifies degree of exposure. More severe complications would involve increasing migration/protrusion into surrounding anatomical structures, opening into surrounding organs, and systemic compromise. The T for the complication is when it is clinically diagnosed. There are three time periods used: intraoperative to 48 h, 48 h to 6 months, and over 6 months. The S selection of this division incorporates the current sites, where the graft/prosthesis complications have been noted.

The first step in taking a history from a patient involves documenting the presenting complaint, which can include dyspareunia, prolonged vaginal discharge, severe incontinence, rectal dis-

charge, recurrent prolapse, urinary tract infection, defecatory dyfunction, and thigh drainage or infection. Vaginal pain and pelvic pain are also presenting complaints, which are covered in another chapter.

A complete review of systems should be performed, specifically those symptoms which have occurred since the time of surgery. If the original case was performed by another surgeon, the preoperative records, operative reports, and any other hospital reports should be reviewed. Any intraoperative issues—such as bleeding or injury to pelvic organs or problems that occurred postoperatively such as prolonged bladder catheterization, blood transfusion, or need for reoperation—should be closely reviewed. These issues tend to signify a complicated postoperative course, which may relate to the complication at hand. Finally, a detailed history of events that followed surgery is useful in any future medical or surgical management of mesh complications. Good documentation of one's findings is critical as these cases may end up under medicolegal review.

Physical Exam

The focused physical exam involves a complete genitourinary exam. This includes a thorough pelvic exam with a pelvic speculum with internal or external light source. Before the speculum exam, careful initial palpation can be performed to elicit any areas of pain. These areas can be associated with folded over mesh, contracted mesh, or taut arms of the mesh if present. Care should be taken to evaluate each vaginal compartment in mapping out all areas of pain. Often it is easier to palpate extruded mesh than to see it, and thus a very careful palpation of the entire vaginal surface should be performed.

In terms of the speculum pelvic exam, systematic evaluation of the entire vagina should be carried out. Any areas of mesh extrusion should be documented. If a patient complains of pain over the mesh—the specific sites of pain should be mapped out. Other important findings such as fistulae should be evaluated closely. Other urologic testing such as cystoscopy to rule our mesh perforation, cystogram or a colored dye test to confirm the presence of fistula, and urodynamics for bladder dysfunction may also be performed based on presenting symptoms. Those patients who present with rectal bleeding or discharge should be evaluated with proctoscopy.

Management of Mesh Complications

Mesh Extrusion

Complications from transvaginal mesh repairs may present days to years after initial surgery. Vaginal mesh extrusion typically occurs as a result of wound separation, infection, or vaginal atrophy. Typically, mesh extrusion noted in the immediate postoperative period, usually within 6 weeks, is a result of wound separation. If the wound does not appear infected, additional attempt at wound closure may be offered under local anesthesia with or without sedation. If the wound appears infected, a short course of antibiotics may rectify the issue, with close observation to ensure closure of the wound. Vaginal estrogens should be applied during this time. If the infection persists, then excision of the exposed area is recommended.

Vaginal mesh extrusion noted more than 6 weeks after surgery may be due to technical error, local infection, vaginal atrophy, or wound separation secondary to hematoma. Initial conservative therapy with local estrogen may be offered in order to avoid reoperation. If conservative therapy fails, partial or complete mesh excision should be pursued. Typically, only the areas of mesh that are involved in an extrusion need to be excised—much of the uninvolved mesh can usually be safely left behind. Some very small extrusions can be excised under local anesthesia in the office by just cutting the exposed portion and allowing the vaginal skin to heal over the area. Many patients with point tenderness can be treated in a similar fashion with just those areas causing tenderness excised—though this is typically done under a deeper anesthetic in the operating room. In such cases, one must carefully

map out the areas of pain preoperatively as there will be no extruded mesh to guide you at the time of operation.

Surgical Technique for Excision of Mesh Extrusion

Under either intravenous sedation or general anesthesia, the patient is placed in the dorsal lithotomy position, and the vagina and lower abdomen are prepped and draped in standard fashion. One percent lidocaine with 1:200,000 epinephrine is used to infiltrate under the vaginal skin around the site of the extrusion. Bilateral vaginal flaps are created extending at least 2 cm lateral to the visible mesh. One centimeter of skin immediately around the mesh is usually discarded. The mesh is then incised in the midline and dissected off of the bladder or rectum in either direction at least 1–2 cm lateral to where the skin will be closed. It is critical to gently separate the mesh from the underlying bladder or rectum. Typically, sharp or blunt dissection using Kittners, working the underlying tissue off of the mesh, prevents inadvertent injury to the underlying organ. The bottom line is that all the tissue should be left behind and only the mesh removed. Once the lateral extent of the mesh is dissected, the mesh is excised. The vaginal wall is then closed in a single layer with absorbable suture. A vaginal packing is placed and removed later in the recovery room.

Mesh Perforation

Once mesh perforation of the bladder or rectum has been diagnosed, mapping of the areas of perforation must be documented. Mesh perforation of the bladder is typically seen at the bladder base or lateral bladder walls, where mesh arms can sometimes be found (Fig. 12.1a–h). If the mesh has been in the bladder for an extended period of time, calcification of the synthetic material may occur. We have described the purely transvaginal excision of bladder and rectal mesh perforation as safe and efficacious [14] and feel that often the easiest way to remove the mesh is via the same route it was placed.

Surgical Technique for Excision of Mesh Perforation of the Bladder

Under general anesthesia, the patient is placed in the dorsal lithotomy position, and the vagina and abdomen are prepped and draped in standard fashion. Retrograde pyelograms may be performed to rule out ureteral involvement. If no ureteral involvement is noted, temporary bilateral open-ended ureteral stents are inserted. One percent lidocaine with 1:200,000 epinephrine mixture is infiltrated under the vaginal skin and an inverted U-shaped incision is made. The vaginal wall is dissected to create an inverted U-flap, which serves as the final layer of closure for the repair [in cases where there is a vesico-vaginal fistula (VVF) closer to the vaginal apex a true (noninverted) U-flap is created with the bottom of the U at the VVF site] (Fig. 12.1a). Dissection of the vaginal skin is performed laterally from the U-flap towards the pelvic sidewall (Fig. 12.1b). When only a small area of mesh has eroded into the bladder, the remainder may be found relatively superficially under the vaginal wall. If a substantial volume of mesh has eroded into the bladder, the mesh may not be as easy to find and the detrusor muscle may need to be incised vertically in the area of the mesh (which can be determined with cystoscopic guidance) until one comes across it. A right angle clamp can be used to mobilize the mesh off the bladder in the midline (Fig. 12.1c). An incision is made in the midline of the mesh after which the lumen of the bladder is visible (Fig. 12.1d). Any remaining overlying tissues (superficial to the mesh) are bluntly and sharply dissected. By grasping on the midline (incised edge) of the mesh and pulling laterally, the bladder wall underneath the mesh is carefully peeled off using both sharp and blunt dissection. If there is a fistula present, it can be seen in its entirety at this point (Fig. 12.1e). The mesh is incised as far laterally as feasible and removed (Fig. 12.1f). The ureteral catheters can be both palpated and visualized. The mucosal layer is re-approximated using 3-0 absorbable suture taking care to stay medial to the ureteral catheters. The detrusor layer is then closed in two layers using 2-0 vicryl suture (Fig. 12.1g). The anterior vaginal wall is closed with 2-0 vicryl

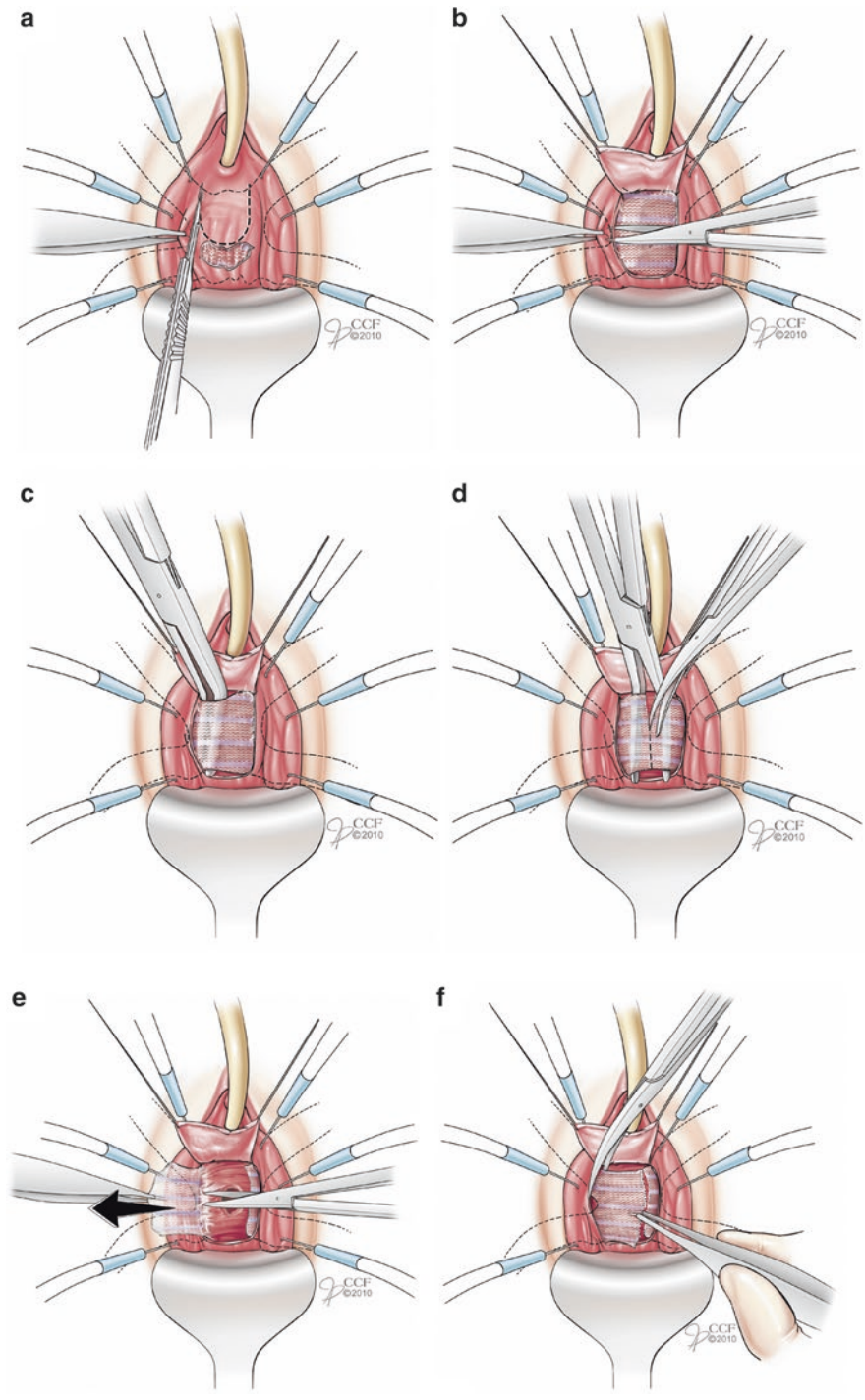

Fig. 12.1 (**a**–**h**) Excision of transvaginal mesh. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2010–2016. All Rights Reserved)

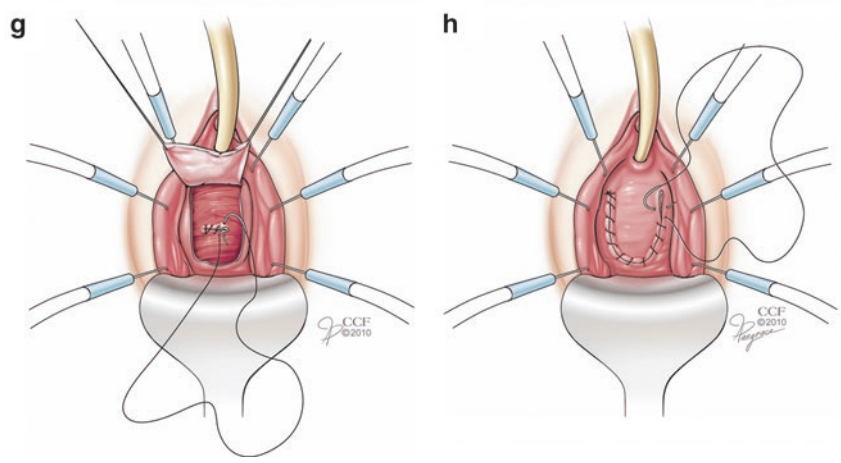

Fig. 12.1 (continued)

suture (Fig. 12.1h). Although not mandatory, the open-ended ureteral stents can be replaced with JJ ureteral stents to prevent any potential ureteral obstruction from inflammation and edema involving the bladder. A vaginal packing is placed and an 18 French Foley catheter is left per urethra.

Another option for removal of mesh perforation of the bladder would be a transabdominal approach. A Pfannenstiel incision is made in the lower abdomen. The incision is carried down to the level of the rectus fascia using electrocautery. The rectus fascia is incised transversely and the space of Retzius is entered. The bladder is filled via the indwelling Foley catheter to aid in identification. The bladder is then bivalved with a vertical incision using electrocautery. The mesh can now be visualized. The incision is carried down to the mesh. Bladder flaps are now created lateral to the body of the mesh. The mesh is then excised. The vaginal wall is closed using 2-0 absorbable suture. A portion of omentum may be mobilized and placed as an interposition graft between the vagina and bladder. The bladder is then closed in two layers with 2-0 absorbable suture. A vaginal packing is placed and an 18 French Foley catheter is left per urethra.

Surgical Technique for Excision of Mesh Perforation of the Rectum

Under general endotracheal anesthesia, the patient is placed in the jackknife position, the perineum and buttocks are prepped and the rectum is cleaned with betadine irrigation. A Hill Ferguson retractor is placed to aid in visualization (Fig. 12.2). Mucosal flaps are developed around the exposed mesh. The mesh is then dissected off of the underlying rectal wall and excised. The mucosal flaps are closed with vicryl suture.

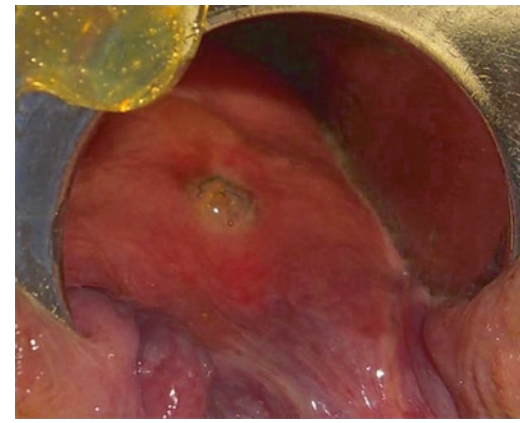

Fig. 12.2 Mesh perforation into rectum

Palpable Tender Mesh Arm in Fornix of Vagina

Occasionally, a patient will note pain near the fornix and one can palpate a tense arm of mesh at that spot. In such cases, division of the mesh arm may ameliorate the patient's symptoms. Under IV sedation and local or general anesthesia palpate the arm of interest, inject lidocaine with epinephrine in the vaginal wall overlying it, incise

through the vaginal skin at that site, identify and dissect out the mesh arm and then cut it and close the vaginal skin.

Conclusion

The use of synthetic mesh for the management of pelvic organ prolapse has been debated for the past few years. At the heart of the controversy lies the concern that complications related to mesh use outweigh the benefit of augmenting repairs with mesh. Although studies have shown objective benefit to augmenting transvaginal repairs, particularly in the anterior compartment, with mesh, there is still concern about potential complications [12, 15]. On the other hand, many believe that the issue is not mesh itself but to a large degree the surgical techniques used by many [13]. While all would agree that complications can occur, there are published case series in the literature of transvaginal mesh repairs performed in the hands of experts with very low complication rates. Furthermore, most complications after transvaginal mesh repairs have been shown to be manageable with resolution of most presenting complaints [16]. The authors have their own extensive experience in the management of mesh complications secondary to the use of commercially available kits. In our experience, these complications were able to be successfully managed transvaginally with minimal morbidity [17]. We do believe that all who perform transvaginal mesh repairs should be equipped with the surgical skills to manage the potential complications of this surgery.

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Retropubic Bladder Neck Suspensions

13

Susanne Taege and Elizabeth R. Mueller

Introduction

Open abdominal retropubic procedures for urinary incontinence were widely performed in the United States starting in the 1950s until the turn of the century when the use of transvaginal synthetic slings gained in popularity [1]. That said, data regarding the success and complications of retropubic suspensions were mostly expert opinion, case series or underpowered randomized trials until the early 2000s when two large randomized trials comparing the Burch urethropexy to suburethral slings were published [2, 3]. Since that time, little has been added to the literature regarding open retropubic suspensions [4]. This chapter will review the retropubic procedures for incontinence and the diagnosis and management of complications that arise from retropubic urethropexy procedures.

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Overview of Retropubic Procedures for Incontinence

Retropubic urethropexy procedures generally include the Marshall Marchetti Krantz (MMK), the Burch colposuspension, and the paravaginal defect repair. First described by Marshall in 1949, the MMK procedure [5] suspends sutures placed on each side of the bladder neck to the posterior aspect of the pubic bone. This is thought to stabilize the bladder neck and allow abdominal pressures that are being transmitted to the bladder to be equally transmitted to the proximal bladder neck, maintaining continence during stress activities.

The Burch urethropexy was described by John Burch in 1961 as being born out of necessity when the sutures he was trying to place during an MMK kept pulling out of the pubic bone periosteum [6]. After utilizing the arcus tendineus and Cooper's ligament as the point of fixation, he chose the latter based on its consistent presence and inherent strength.

First described by White in 1909 as a procedure for anterior vaginal prolapse repair, the paravaginal defect repair was popularized for female stress incontinence when the authors reported that reattaching the detached and retracted levator ani fascia to the arcus tendineus resulted in a greater than 90% cure rate [7]. It does not have acceptable success rates to justify its use as a stress incontinence procedure at this time.

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Current Clinical Urology, DOI 10.1007/978-3-319-49855-3_13

Key Surgical Techniques in Avoiding Complications

All of the open abdominal retropubic procedures require the patient to be prepped and draped in dorsal lithotomy so that the primary surgeon can have their nondominant hand in the vagina for definition of anatomy and counter-traction. A Foley catheter is passed into the urethra and is used to identify the bladder neck. An adequate Pfannenstiel or Cherney incision is made to ensure adequate exposure during dissection of the retropubic space. The apt surgeon should make good use of the assistant to provide counter-traction during the dissection. The venous plexus that can be seen in the vaginal wall should be avoided as much as possible since these vessels can be the source of a significant amount of blood loss when sheared during dissection or suture placement.

The goal of both the MMK and the Burch cystourethropexy is to elevate the vagina to a minimally retropubic position. Care should be taken when tying the sutures as not to cause constriction of the bladder neck and urethra, leading to postoperative urinary obstruction. Numerous authors have described laparoscopic approaches to the Burch colposuspension [8–10]. While the dissection of the retroperitoneal space is similar, various materials have been used to attach the vaginal wall to Cooper's ligament including sutures, staples, spiral metal tacks, and mesh. Although these materials lend well to the laparoscopic approach, they can be a source of foreign body complications.

Surgical Success

In the 5th edition of the International Consultation on Incontinence, published in 2013, Dmochowski and colleagues [11] reviewed all of the literature available on current incontinence procedures. While the authors discussed the open Burch procedure as a comparator to the midurethral sling, the fascial sling, and the laparoscopic Burch, it was not individually commented on. This clearly demonstrates the declining use of the procedure by contemporary surgeons. The authors concluded, based on level 1 evidence, that the retropubic transvaginal tape (TVT) is more effective than open retropubic Burch colposuspension. In addition, the operative time, hospital stay, and time to resume normal daily activity are shorter with TVT. The authors also state that laparoscopic Burch colposuspension is not recommended for routine treatment but may be considered by expert surgeons in patients undergoing concurrent laparoscopic surgery for other reasons. In contrast, the American Urological Society 2009 Guidelines for Surgical Management of Stress Urinary Incontinence state that open retropubic and laparoscopic suspension along with injectables, midurethral slings, and pubovaginal slings, although not equivalent, may be considered for the uncomplicated women with stress incontinence [12].

Complications

Burch Colposuspension

Two large randomized trials comparing the open Burch colposuspension to tension-free vaginal tape and to the fascial sling were published in 2002 and 2007, respectively [2, 3]. The studies randomized 475 women to Burch colposuspension thus providing a solid basis for understanding complications that arise when a large number of surgeons are performing the procedure. Ward and colleagues [13] enrolled women from 14 urogynecology and urology centers in the United Kingdom. Women were randomized to the open Burch colposuspension or the tension-free midurethral sling. Exclusion criteria included current need for, or previous history of, surgery for pelvic organ prolapse (POP). One hundred and forty six women underwent the Burch urethropexy. Women in the Ward–Hilton study had the following intraoperative and postoperative complications reported at 6 months: urinary tract infection (32%), de novo detrusor overactivity on urodynamics (11%), wound infection (7%), voiding disorder (7%), bladder injury (2%), deep vein thrombosis (2%), and incisional hernia (2%).

Although overall blood loss was higher for the colposuspension, there were no reports of vascular injury or retropubic hematoma in this series. The need for patient catheterization decreased over time, but remained substantial with 8% of women requiring catheterization after 6 months. Interestingly, there was no statistically significant difference in rates of catheterization and voiding dysfunction compared to TVT.

In 2004, the authors [2] reported the 2-year follow-up data. Of the 146 women randomized to Burch urethropexy, 5 (3.4%) underwent surgery for stress incontinence, 7 (4.8%) surgery for POP, and 5 (3.4%) had an incisional hernia repair. At 2 years, 4 (2.7%) women continued to catheterize and 3 (2.1%) continued to have symptoms of UTI. On physical exam, the number of women with vault/cervical prolapse increased from 21% preoperatively to 63% at 24 months; 18% of the women with POP were symptomatic. Over the same 2-year time period, vault/cervical prolapse rates increased from 16 to 29% in the TVT arm. In summary, when compared to TVT, Burch colposuspension at 24 months resulted in higher rates of enterocele, voiding dysfunction, and need for catheterization and a 4% lower rate of UTI.

In the Stress Incontinence Surgical Efficacy Trial (SISTEr) [14] involving nine surgical centers in the United States, women were randomized to an open Burch colposuspension or autologous rectus fascial sling. A total of 329 women received a Burch colposuspension; however, 48% of the women had concomitant procedures for pelvic organ prolapse. The following adverse events were reported in women who underwent the Burch colposuspension: cystitis (50%), new-onset urge incontinence (3%), incidental cystotomy (3%), surgical wound complications requiring surgery (2.4%), voiding dysfunction > 6 weeks (2%), recurrent cystitis leading to diagnostic cystoscopy (1.5%), bleeding (1%), ureteral injury (1%), incidental vaginotomy (0.5%), ureteral vaginal fistula (0.5%), erosion of suture into the bladder (0.5%), and pyelonephritis (0.5%). In summary, compared to a rectus fascial sling, a Burch colposuspension resulted in lower rates of success for stress incontinence and lower rates of cystitis, urge incontinence, and voiding dysfunction.

Marshall–Marchetti–Kranz Procedure

Complications related to the MMK procedure are similar to those mentioned for the Burch colposuspension. In a 1988 review of the literature, Mainprize and Drutz [15] summarized the occurrence of postoperative complications in 2712 patients as follows: wound complications (5.5%), urinary tract infection (3.9%), osteitis pubis (2.5%), direct injury to the urinary tract (1.6%), and ureteral injury (0.1%). Of course, these data are limited and, with the exception of osteitis pubis, direct comparisons to the Burch data obtained in a randomized trial would not be advised.

Approach to Specific Complications

Intraoperative Complications

Intraoperative Hemorrhage

Intraoperative risk of hemorrhage can be minimized by assuring adequate exposure of the retroperitoneal space which includes proper lighting, retraction, and appropriate length of skin incision. There are numerous vessels that run alongside the bladder and within the vaginal wall. Vaginal wall vessels that are visible can usually be avoided when placing the sutures and if punctured will often stop bleeding once the sutures are tied into place. When brisk bleeding does occur, direct pressure held for 5 min is often sufficient. Attempts to use metal clips often result in additional shearing of vaginal wall vessels. When packing is insufficient, hemostatic agents may be necessary.

Urinary Tract Injury

The placement of lateral sutures at the level of the bladder neck and midurethra can result in ureteral entrapment and proximal urethral injury. A cystourethroscopy should be performed after the Burch suspension is completed to check ureteral

patency and look for a foreign body. The detection of brisk ureteral efflux can be aided by giving the patient oral Phenazopyridine just prior to being taken to the operating room.

Postoperative Complications

Urinary Tract Infections

Women who undergo surgical treatment for stress incontinence will most often develop symptoms that are consistent with or mistaken for a urinary tract infection. The rates are highest in the first 6 months but do remain between 2 and 9% 24 months after surgery [3, 13]. As a result, it is sensible to require that women with a history of urinary tract infections be free of infection prior to undergoing surgery. Women with symptoms of urinary tract infection (urgency, frequency, burning with urination) would benefit by having urine cultures obtained prior to antibiotic treatment to allow for more specific antibiotic treatment but also to document when the symptoms occur with negative cultures. Nonbacterial etiologies include lower urinary tract inflammation, urethral irritation, and irritative voiding symptoms associated with urethral obstruction.

Possible etiologies of recurrent or persistent UTI included incomplete emptying, bacterial colonization from instrumentation and a foreign body in the urinary tract (Fig. 13.1a, b). Women who require catheterization (intermittent or indwelling) should be placed on "treatment" doses of antibiotics once they have stopped using catheters since bacterial colonization occurs often within days of catheter use. Data from the SISTEr trial demonstrate that cystitis rates are highest in the first 6 weeks after surgery [14]. When compared to self-voiders with a cystitis rate of 6%, women who have intermittent or indwelling catheters have higher (23% and 13%, respectively) rates of cystitis. In addition, women who undergo voiding trials with post-void residual measurements are often catheterized 2–3 times prior to being discharged thus increasing their risk of colonizing the urinary tract.

When UTIs also present with systemic signs such as fever, chills, and flank pain, upper tract imaging is warranted. The specific imaging depends on the question that needs to be answered. For example, women presenting with febrile UTI and flank pain following an isolated retropubic urethropexy, the imaging question may be "does this patient have ureteral reflux or obstruction" and a voiding cystourethrogram and renal ultrasound can be ordered. For patients with concomitant prolapse repair, upper tract imaging to assess ureteral patency and cystoscopy to rule out bladder foreign body or cystotomy would be indicated.

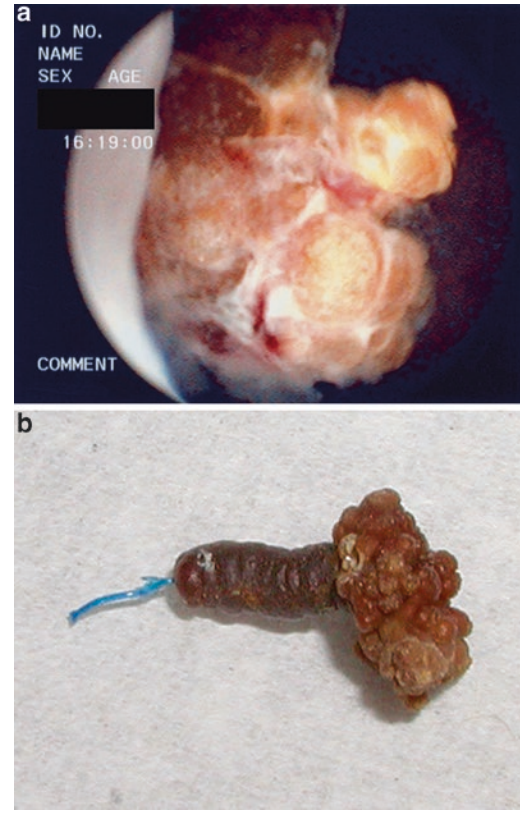

Fig. 13.1 (**a**) Cystoscopic view of a stone at the bladder neck in a patient with pelvic pain and UTIs following a Burch procedure. (**b**) Prolene suture and stone following surgical removal. (Photographs courtesy of Howard Goldman, MD, Cleveland Clinic, OH)

Urgency Incontinence

In the Ward–Hilton study, 91% of women reported symptoms of bothersome urgency incontinence prior to Burch urethropexy that

decreased post-procedure to 34% at 6 months and 2 years. On urodynamic testing, the number of women who developed unstable detrusor contractions increased from 1% pre-op to 10% 6 months following a Burch colposuspension. Similarly, persistent urgency incontinence was found in 18% of women enrolled in the Burch arm of the SISTEr trial and new-onset urgency incontinence remained low at 3%.

Possible etiologies of de novo urgency incontinence include UTI, obstructive voiding, and the presence of a foreign body in the lower urinary tract. In women whose symptoms persist after 6 weeks and post-void residuals are normal, conservative treatment for urgency incontinence can be considered including anticholinergics and behavior modifications. A woman who is not responsive or whose symptoms appear severe might benefit from a cystoscopic examination to rule out the presence of a foreign body in the lower urinary tract. Women, who have undergone a laparoscopic Burch procedure and have evidence of a foreign body in the bladder, may have undergone the procedure using metal helical "tackers" to suspend the bladder neck (Fig. 13.2). These are often placed or migrate into the bladder causing symptoms. If operative notes are not available, then an anterior/posterior and lateral plain x-ray will allow visualization of the offending material.

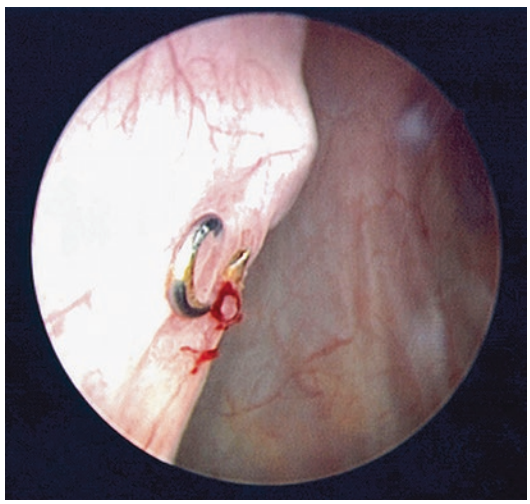

Fig. 13.2 Cystoscopic view of a metal tacker placed during a laparoscopic Burch colposuspension. (Photograph courtesy of Howard Goldman, MD, Cleveland Clinic, OH)

Uterine or Vaginal Vault Prolapse

In his initial description of the surgical procedure, Burch reports the surgical complication of uterine or vaginal vault prolapse. As described previously, 18% of women developed symptomatic prolapse, and 4.8% underwent surgical correction over the 24 months of the Ward–Hilton study [13]. This is believed to be due to the anterior orientation of the vaginal apex. As a result, all women undergoing surgical correction of stress incontinence should have a complete physical exam including the evaluation of vaginal topography ideally in the standing-straining position. Women, who demonstrate apical or uterine descent of greater than 3 cm from optimal position with Valsalva effort, would more likely benefit from a synthetic or autologous suburethral sling since they have not been shown to increase the risk of POP. When a patient is undergoing treatment of POP following an incontinence procedure, care should be taken to not "over-correct" the apical support since this may result in incontinence.

Voiding Dysfunction

Rates of voiding dysfunction following retropubic suspensions vary based on the definitions used, duration of the studies, and whether women with preexisting voiding dysfunction were excluded from enrollment. The Ward–Hilton study [13] defined a woman as having a voiding dysfunction when two of the three measurements were found on 6-month postoperative urodynamic studies (UDS): peak flow < 15 mL/s, maximum voiding pressure > 50 cm H_2O, and residual volume > 100 mL. Of the women who underwent postoperative UDS, 7% were diagnosed with a voiding dysfunction. Thirty-three percent of women required catheterization (suprapubic, urethral, or intermittent) a week after surgery and this continued to diminish over time to 13% at 1 month, 8% at 6 months, and 2.7% at 24 months. There were no reports of surgical intervention for voiding dysfunction.

The SISTEr trial also had a gradual return to self-voiding in women undergoing the Burch procedure. While only 56% of women passed their first voiding trial, the authors reported low rates (2%) of voiding dysfunction > 6 weeks after surgery and no surgical revisions for voiding dysfunction in the 329 women who had undergone Burch procedure. As the series above demonstrate, most voiding dysfunction resolves by 6 weeks and can be treated conservatively with intermittent or indwelling catheterization. In addition, many patients may benefit by undergoing pelvic therapy specifically aimed at pelvic floor relaxation techniques [16].

When obstructive voiding symptoms persist, patients may benefit from filling cystometry and pressure-flow studies to determine if the etiology is obstructive or due to decreased detrusor function. In centers with fluoroscopy, imaging can be helpful. A cystoscopy at the same time would rule out suture placement in the urethra (although this is a rare phenomenon). The etiology is typically obstructive from sutures pulling the bladder neck; sutures placed distally resulting in urethral kinking or scarring of the bladder neck to the back of the pubic bone.

Women who clearly demonstrate obstruction on UDS should be considered for an urethrolysis. In women who have physical exam findings of an indentation of the anterior vaginal wall where sutures have been placed, we consider a transvaginal urethrolysis. A midline vaginal incision is made ~ midurethra and carried to the level of the bladder neck. The dissection continues using sharp and blunt dissection as if making the sling tunnels for a rectus fascial sling. Tissue that is adherent to pubic bone is swept lateral to medial using the surgeon's index finger. Since it is customary in our practice to use a permanent suture, we can palpate the suture as it travels from the proximal urethra and bladder neck to its attachment on the pubic bone (MMK) or Cooper's ligament (Burch). A scissors is then guided to the level of the sutures behind the pubic bone by the surgeon's index finger and the sutures are transected on each side.

In woman who are clearly obstructed and have failed a transvaginal urethrolysis or who do not have a palpable indentation at the level of the bladder neck, a retropubic urethrolysis can be performed. A Pfannenstiel incision is made and carried to the level of the fascia which is incised two centimeters proximal to the back of the pubic bone. As when placing the sutures, the surgeon's nondominant hand is placed into the vagina to assist in locating the sutures that are transected. If the anterior bladder remains fixed to the back of the pubic bone, then this is carefully dissected until the bladder neck and urethra are sufficiently freed to restore a normal degree of mobility.

Anger and colleagues reported on a retrospective review of 16 women who had symptoms of overactive bladder and/or obstruction following a Burch urethropexy [17]. The study consisted of seven women who had a vaginal approach and nine who underwent the retropubic approach. The groups were not equivalent since 43% in the vaginal group and 55% of the women in the retropubic group performed self-catheterization. Success rates for a return to normal voiding were 66% with the vaginal approach and 100% with retropubic. The authors also reported that overactive symptoms were improved in the retropubic group compared to the transvaginal. They hypothesize that the inability to transect the most proximal sutures through the transvaginal route might result in the lower rates of symptom improvement. That said, many surgeons would agree that the transvaginal approach is less morbid and might be worth attempting as first-line treatment.

Osteitis Pubis

Osteitis pubis is an inflammatory disease of the pubic symphysis and its surrounding attachments. It occurs in 1–2.5% of MMK procedures but can also occur in any procedure that is in the retropubic space (Fig. 13.3a, b). Symptoms include pubic pain that may be localized to the pubis or radiate to the lower abdomen and thigh. Often patients adopt a limp and wide-based gait. The diagnosis can be aided by the use of MRI which can distinguish between osteitis pubis and pelvic osteomyelitis [18]. Medical management includes rest, ice, nonsteroidal anti-inflammatory drugs, physical therapy, and the use of steroids.

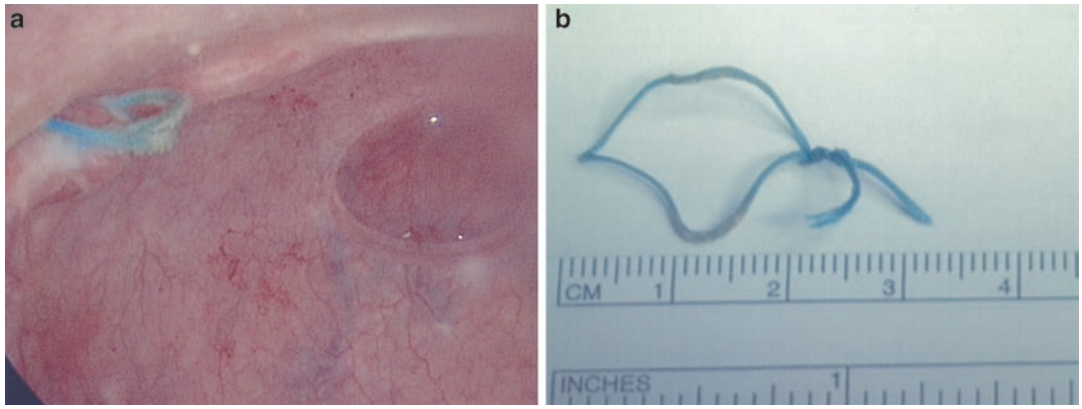

Fig. 13.3 (**a**) Cystoscopic view of suture in the right lateral wall of the bladder placed during open Burch colposuspension 3 years prior. Early postoperative course complicated by osteitis pubis requiring removal of the left-sided suspension sutures. (**b**) Removal of the right bladder wall suture resulted in resolution of suprapubic pain at rest and ambulation. (Photographs courtesy of Howard Goldman, MD, Cleveland Clinic, OH)

Patients who are refractory to medical management may benefit by surgical removal of the offending sutures (Fig. 13.3a, b).

Summary

With the advent of synthetic midurethral slings, the retropubic suspensions are often referred to as a procedure of historical interest. However, as we continue to see product liability issues surrounding transvaginally placed surgical mesh, there remains a role for this procedure in the armamentarium of the well-versed pelvic surgeon. It is important to understand potential complications, principles to prevention, and their management strategies.

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14 Pain Related to Transvaginal Mesh Placed for Stress Urinary Incontinence and Pelvic Organ Prolapse

Ashley B. King and Howard B. Goldman

Introduction

Since the Food and Drug Administration (FDA) released the safety communication regarding transvaginal mesh used for prolapse repair, the focus on complications related to transvaginal mesh has been heightened [1]. In 2011, the FDA reported that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare." The focus of this safety communication was on transvaginal mesh for pelvic organ prolapse repair (TVM/POP), not for stress incontinence (SUI).

In response, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) published their position statement on mesh used for prolapse repair. ACOG and AUGS recommended that patients are counseled appropriately regarding risks and alternatives, and the surgeons have proper training on the specific devices implanted. They also stress the importance of proper data collection on outcomes [2]. The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) and AUGS also released a position statement in support of synthetic midurethral slings [3].

Various complications can occur after transvaginal mesh placed for either stress incontinence or pelvic prolapse; however, this chapter will focus on persistent pain after mesh placement for stress urinary incontinence and pelvic prolapse, including vaginal pain, dyspareunia, suprapubic pain, and thigh pain.

Classification of Complications

IUGA and ICS developed a new classification system for complications related to grafts used in female pelvic surgery. The classification system is outlined in Fig. 14.1. Category 1 includes cases where there is no exposure of mesh in the vagina, but the mesh is prominent because of folding or wrinkling or there is mesh contracture or shrinkage. Mesh exposure in the vagina is further characterized and differentiated from perforation of viscera. Complaints of pain are divided into pain provoked by vaginal exam alone, pain during sexual activity, pain during physical activity, and spontaneous pain [4].

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- General Description
  - Vaginal: no separation
  - Vaginal: ≤ 1cm exposure
  - Vaginal: larger >1 cm, or any extrusion
  - Urinary Tract: compromise or perforation
  - Rectal or Bowel: compromise or perforation
  - Skin and/or Musculoskeletal: complications including discharge, pain, lump or sinus tract formation
  - Patient: compromise including hematoma or systemic compromise

- Category
  - Asymptomatic
  - Symptomatic
  - Infection
  - Abscess

- Time (clinically diagnosed)
  - T1: Intraoperative to 48 hours
  - T2: 48 hours to 2 months
  - T3: 2 months to 12 months
  - T4: over 12 months

- Site
  - S1: Vaginal: area of suture line
  - S2: Vaginal: away from area of suture line
  - S3: Trocar passage (excluding intra-abdominal)
  - S4: Other skin or musculoskeletal site
  - S5: Intra-abdominal

- Subclassification of Pain
  - Asymptomatic or no pain
  - Provoked pain only (during vaginal examination)
  - Pain during intercourse
  - Pain during physical activities
  - Spontaneous pain

Fig. 14.1 IUGA/ICS joint terminology and classification of the complications related directly to the insertion of prostheses. (Reprinted with permission of John Wiley and Sons from Haylen BT, Freeman RM, Swift ST, et al. An international urogynecological association (IUGA)/international continence society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Neurourology and Urodynamics 2011 Jan;30(1):2–12)

Evaluation of Patient

Evaluation of a patient with vaginal, suprapubic, or thigh pain after transvaginal mesh placement starts with a thorough history and physical exam. During the history, it is important to determine if the patient had any chronic pain prior to mesh placement as this is important in counseling about success after any mesh removal. Obtaining details regarding the original surgery as well as any prior excisions is important. Reviewing the prior operative notes, if they can be obtained, is critical. Descriptive information regarding location of pain, type of pain, and any alleviating or aggravating factors should be well documented.

On physical exam, a thorough abdominal exam, vaginal exam, and thigh exam as indicated is important. Assessing for any pain or tenderness along the expected trajectory of any mesh placed should be done with palpation. Often exposures are best detected with finger palpation although visualization can be helpful also. The levator muscles should also be palpated to try to differentiate levator spasm from pain related to the mesh, although the former could develop in reaction to the latter. Rectal exam should be performed to assess tone and evaluate for pain or mesh perfora-

tion. Cystoscopy may be utilized to rule out bladder or urethral perforation. Urodynamics may be indicated depending on the other presenting symptoms; however, if mesh excision is planned for pain, then urodynamics may not be indicated.

Vaginal Pain and Dyspareunia

Synthetic Midurethral Slings

Vaginal exposure, vaginal pain, dyspareunia, and sexual function outcomes after midurethral sling placement are extremely intertwined and difficult to tease out in the literature. Overall rates of exposure after sling placement range from 1.7 to 12.1% [5, 6]. The most recent Cochrane review reports an overall exposure rate of 2.09% [7]. The 5-year data from the TOMUS trial showed no difference in exposure rate between retropubic and transobturator slings [5].

Dyspareunia rates range from 4.3% in larger reviews [6] to 14.5% in smaller series [8]. One finding after TOT sling that has been reported is paraurethral banding. Some have thought that this could lead to worsening pain and dyspareunia; however, this has not been supported in the literature [9–11].

Sexual function generally improves after sling placement, although this can be related to improved coital incontinence [12]. However, de novo dyspareunia and urgency incontinence negatively impact sexual function [12, 13]. Some studies have shown similar improvement in sexual function after both retropubic and transobturator slings; however, the 5-year data from the TOMUS trial shows greater improvement in sexual function after transobturator sling [5, 13].

Transvaginal Mesh for Pelvic Organ Prolapse Repair

Rates of vaginal exposure after TVM/POP vary; however, in the Cochrane Review from 2011, the overall mesh vaginal exposure rate was 10% [14] but has been quoted as high as 20% in some series [15]. Vaginal exposure does not always correlate with dyspareunia or vaginal pain. Bontje and colleagues reported their series of 84 patients who underwent a Prolift® (Ethicon, Somerville, NJ, USA) graft. None of the patients with dyspareunia had a mesh exposure [16]. Other studies have also found that dyspareunia was more common in patients without mesh exposure [15]. De novo dyspareunia rates after TVM/POP vary, ranging from 2.5 to 16.7% [17, 18]. According to the Cochrane Review, there is no difference in dyspareunia rates between suture-based repairs and TVM/POP [19].

The effect of TVM/POP on overall sexual function is controversial. Altman and colleagues reported on a series of 261 patients who underwent an anterior, posterior or total Prolift mesh prolapse repair. Of the 105 who were sexually active prior to the procedure, overall sexual function declined; however, dyspareunia rates were not significantly changed. The decline in sexual function was related to more behavioral or emotional domains. The authors also found that anatomic success did not correlate with improved sexual function [20]. Others have found no effect on sexual function [21].

Risk Factors

Vaginal pain and dyspareunia after transvaginal mesh placement can be related to mesh exposure or may present without any mesh exposure. Separating this causality in the literature is difficult. However, risk factors for mesh exposure include increased blood loss intraoperatively [22], lower BMI [22], and smoking [23]. Sirls and colleagues performed a retrospective review of 335 women who underwent mesh augmented prolapse repair to assess for risk factors for mesh exposure. Overall exposure rate was 8.1% with median time to detection of exposure of 96 days. Lower BMI and increased blood loss were associated with mesh exposure but no other risk factors were identified including age, smoking history, menopause, diabetes, steroids, past surgery, or prolapse stage [22].

There has been an assumption that postmenopausal status would lead to worsening pain after mesh placement. The literature on this is limited; however, Long and colleagues examined the effect of menopausal status on changes in sexual function after mesh augmented prolapse repair. Contrary to the expected outcome, they found that sexual function worsened in the premenopausal group compared to the postmenopausal group and that anatomic success was not correlated with improvements in sexual function. However, it should be noted that there was a significant minority of patients in the postmenopausal group on estrogen replacement. In addition, although most of the total patients were postmenopausal, only 30% of the postmenopausal group was sexually active and completed follow-up compared to 89% of the premenopausal group [24].

Another concern brought up in the FDA communication was regarding the role that mesh contraction plays. Some have found that mesh length in the patients who reported vaginal pain and de novo OAB was significantly decreased by about 1 cm compared to patients without these complaints [25]. However, it is important to remember that several series including the most recent Cochrane review found no difference in dyspareunia rates after mesh or native tissue prolapse repair [19, 26]. Other studies have shown more dyspareunia after mesh augmented prolapse repair compared to native tissue repair. Anger and coworkers utilized a 5% random sample of Medicare beneficiaries who underwent prolapse repairs with and without mesh from 2007 to 2008. These were compared to patient who underwent prolapse repair without mesh from 1998 to 2000. They found that failures within 1 year requiring reoperation were higher in the nonmesh group; however, the mesh group was more likely to report dyspareunia and pelvic pain [27].

Prevention

While nothing can completely prevent complications from occurring, a number of strategies can help minimize the risk of pain after mesh surgery. Dissection must be carried out in the proper plane. If the dissection is too superficial, then the patient is at increased risk of exposure and potentially for vaginal pain. The mesh should be placed to avoid any tension on the mesh body or arms. Good hemostasis is also important as hematoma formation and drainage can lead to wound separation and exposure. Knowledge of the anatomic borders and staying within them is vital.

Treatment

Treatment depends somewhat on whether there is vaginal pain and dyspareunia (or partner-related pain) with or without a vaginal exposure. However, overall treatment options include medical management, physical therapy, and surgical intervention.

To treat vaginal pain and dyspareunia without vaginal exposure, NSAIDS, pain medications, neuroleptics, and muscle relaxants can be utilized alone or with pelvic floor physical therapy. Botulinum toxin A has been used to improve pain related to levator spasms; however, insurance coverage can be difficult in some cases as it is not an FDA-approved treatment for pelvic pain. Local anesthetic can also be injected to relieve pain. Pudendal nerve blocks can be performed in patients with pudendal neuralgia.

If a patient fails more conservative treatment options, then mesh excision can be performed. Typically in the face of pain and vaginal exposure, excision is favored; however, topical estrogen cream and other more conservative treatments can be attempted depending on the size of exposure and degree of pain.

Technique for Mesh Excision

Typical mesh excision can be performed transvaginally as previously described [28] although in the case of ureteral involvement or bladder perforation transabdominal repair may be necessary. Typically, if the excision is done for pain then a wider excision is performed than for vaginal exposure alone; however, the focus of dissec-

tion should be on the areas that cause pain with palpation as determined on physical exam. Further details of transvaginal mesh removal are contained in another chapter.

Outcomes of Surgical Excision

Resolution rates of vaginal pain and dyspareunia vary in the literature. Many series quote a resolution rate around 50%; however, this varies from 13 to 100% resolution [29–32]. The series, which showed resolution of dyspareunia in only 13% after mesh excision, found on multivariant analysis that complete excision, de novo overactive bladder symptoms after initial placement and obesity correlated with improvement in symptoms. Patient who developed de novo OAB symptoms after the original surgery did show improvement of these symptoms. As far as the relationship between obesity and improved symptoms, the authors proposed a possible role of elevated estrogen from peripheral conversion in the adipose tissue as leading to improved healing [31]. One series found that patients who had mesh exposure were more likely to have improvements in pain after excision but the difference was not statistically significant. The authors also found that a history of chronic pain led to a higher risk of worsening or unchanged symptoms [33].

Recurrence of SUI after excision for pain ranges from 24 to 37.8% [34, 35]. Recurrence of prolapse occurs in 5–29% with higher rates of recurrence after complete excision [36]. Some series report low complications rates after transvaginal excision; however, others report slightly higher complication rates. Tijdink and coworkers performed a retrospective series of 73 patients who underwent mesh excision. Overall, intraoperative and postoperative complication rates were 5% and 16%, respectively. Intraoperative complications included three bowel injuries and one case of bilateral ureteral injury which was diagnosed postoperatively with anuria. The patient underwent bilateral ureteral reimplantation after diagnosis [36]. Counseling the patient is very important, including possible lack of improvement in pain, possibly worsening symptoms, recurrent incontinence, or prolapse depending on type and degree of mesh excised, visceral injury, significant bleeding, ureteral injury requiring abdominal surgery, and fistula formation.

Suprapubic Pain

Risk Factors

Fisher and coworkers performed anatomic dissection to illustrate possible nerve injuries that are at risk with TVT placement. The ilioinguinal and iliohypogastric nerves can be injured if the trocar is passed too laterally. The ilioinguinal nerve is involved in sensation to the skin over the pubic symphysis, groin, labia, and inner thigh. The iliohypogastric has similar sensory function over the pubic symphysis and groin. The pudendal nerve has branches under the pubic bone and if one passes the trocar scraping the edge of the pubic bone (often done to avoid bladder injury), these branches can be involved. Injury to the pudendal branches can lead to localized pain or perineal pain [37]. In addition, obturator neuralgia has been reported from a lateral passage of TVT trocar [38]. Therefore, it appears that suprapubic pain after retropubic sling placement can be reduced by proper passage of the trocars.

Treatment

Overall, rates of persistent suprapubic pain after sling placement appear low around 2.3% [39]. However, when pain persists, treatment options include NSAIDS, pain medications, and neuroleptics. Local anesthetic injection can be utilized. If a patient fails more conservative treatment options, then mesh excision can be performed. If there is concurrent vaginal pain, a vaginal excision alone may be considered first. However, if this does not relieve the suprapubic pain or if there is isolated suprapubic pain, then excision of the suprapubic arms can be performed either open or laparoscopically [38, 40].

Technique for Suprapubic Dissection

Suprapubic dissection can be performed open, laparoscopically or robotically. If performed open, the dissection is extraperitoneal; however, if done laparoscopically or robotically, either an extraperitoneal or intraperitoneally approach can be done.

Open excision can be done through an infraumbilical or Pfannenstiel incision. The rectus muscles are split, and the space of Retzius is developed. The mesh arm is localized by palpation and visualization in the expected location of passage. The arm can then be dissected off the pubic bone down through the endopelvic fascia and then in the opposite direction out to the level of the skin. Bladder injury should be avoided; however, if a bladder injury occurs during dissection, it can be repaired from this approach.

For a laparoscopic or robotic-assisted approach, a midline periumbilical camera port can be placed as well as two working ports, each about 8 cm lateral and 2 cm caudal to the midline port. Additional assistant ports can also be utilized. The approach is similar to the open technique; however, with an intraperitoneal approach, the space of Retzius must be exposed. This is done by incising the peritoneum above the pubic symphysis and then dividing the median umbilical ligaments and the urachus. The bladder can then be dropped down to obtain adequate exposure. To perform the surgery via an extraperitoneal approach, balloon dilation must be done first to develop the space of Retzius.

An alternative approach can be done if a vaginal dissection is performed concomitantly. The vaginal arms can be dissected through the endopelvic fascia. Then with an instrument on the mesh, the tip of the instrument can be advanced around the pubic bone towards the prior suprapubic incision. Next, through a smaller suprapubic incision, the tip of the instrument can be found and the mesh can be dissected free. Cystoscopy is prudent after excision to rule out any bladder injury.

Thigh Pain

Transobturator Sling

The risk of persistent thigh pain is higher after transobturator slings compared to retropubic slings. In the TOMUS trial, at the 12-month follow-up, neurologic symptoms were higher in the transobturator group compared to the retropubic group (9.4% vs. 4.0%) [41]. At 5-year follow-up, two women in the transobturator group reported persistent thigh pain [22]. Others have reported rates of persistent thigh pain at 5 years of 32.8% [42].

Risk Factors

Two main factors that may contribute to the development of persistent thigh pain are patient positioning at time of sling placement and technique of transobturator sling placement. Two cadaver studies have emphasized the importance of proper patient positioning to increase the distance between mesh placement and the branches of the obturator nerve. Hinoul and coworkers showed in a cadaveric study that the exit site of the TVT-O is variable and affected by the positioning of the legs during trocar placement. They recommended hyperflexion to maximize trocar distance from the obturator nerve branches [43].

Hubka and coworkers also analyzed the effect of leg position during TVT-O procedure on proximity to the branches of the obturator nerve in both properly positioned and malpositioned cadavers. The malpositioned bodies were placed with the legs at 30° to the horizontal plane versus the properly positioned bodies with legs at 90° to the horizontal plane. All the legs were abducted 30° to the sagittal plane. In the malpositioned group of both formalin-embalmed bodies and fresh frozen bodies, the mean distance from all the branches of the obturator nerve was less than 1 cm, and there was direct contact with the nerve noted three times in this group of 19 bodies. In the properly positioned fresh frozen bodies, the mean distance from the obturator nerve was over 2 cm and no direct contact with the nerve was noted [44].

Others have looked at the impact of body mass index on risk of persistent pain after transobturator mesh placement. Cadish and colleagues performed a retrospective study of all patients who underwent TVT-O sling placement. A total of 219 TVT-O slings were reviewed. The overall rate of postoperative thigh or hip pain was 15.5% with an average follow-up of 1.6 months. There was equal incidence of right sided, left sided, and bilateral groin pain. The rate of postoperative groin pain was higher in normal size women versus obese patients (21.0% vs. 10.3%). The authors propose several explanations for these findings, including increased adipose tissue serving as a barrier to surrounding nerves or possible increased attention during positioning by the care team in obese patients. However, the study is limited by the retrospective nature that lacked a direct, standardized routine assessment of postoperative groin pain [45]. This study and the cadaver studies discussed above all focused on the TVT-O, presumably because one has less control over the exit site with "inside-out" slings than "outside-in" slings.

Treatment

As discussion in the previous sections, treatment options for thigh pain include NSAIDS, pain medications, and local anesthetic injection. If a patient fails more conservative treatment options, then mesh excision can be performed. Vaginal dissection can be attempted initially to see if that alone relieves thigh pain. However, if pain persists or if there is isolated thigh pain, then thigh dissection can be performed to remove the thigh portion of the mesh.

Technique for Thigh Dissection

The technique of thigh dissection can be performed in a similar fashion as described by Wolter and colleagues and King and colleagues [46, 47]. If a vaginal mesh excision is planned concomitantly, then vaginal dissection can be performed first. The vaginal portion should be left intact to use as an aid in the thigh dissection. For the thigh dissection, an incision is marked 1–2 cm lateral to the inferior pubic ramus. The incision is approximately 6–8 cm in length (Fig. 14.2). After incision, dissection is carried down to the gracilis muscle, which is then cut as close to the inferior pubic ramus as possible (Fig. 14.3). The remaining muscle layers are cut and then reflected in a similar fashion, including the adductor brevis and obturator externus. Occasionally, the mesh is found more easily and then can be traced to the obturator membrane without dividing all the muscle layers. However, typically localizing the mesh arm can be difficult and is aided by knowledge of the typical route of passage, visualization of any scar from initial groin incision, close inspection for mesh fibers and palpation. The mesh arm can be located in an aberrant location, complicating dissection. (Fig. 14.4) Once the sling has been identified, it is dissected to the obturator membrane. The arm should be freed from the inferior pubic ramus if possible. The dead space is closed and the skin incision is closed after placing a bulb suction drain.

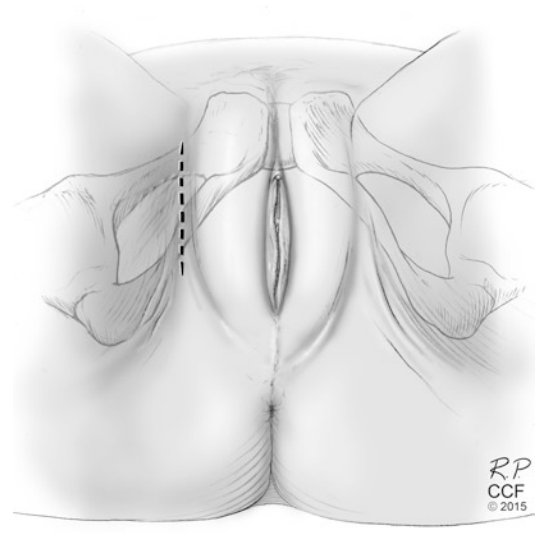

Fig. 14.2 Incision for thigh dissection to remove TOT tape. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2015–2016. All Rights Reserved)

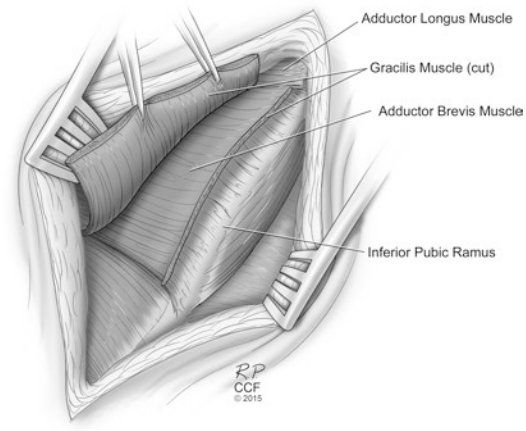

Fig. 14.3 Gracilis muscle has been cut to reveal Adductor Brevis Muscle below. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2015–2016. All Rights Reserved)

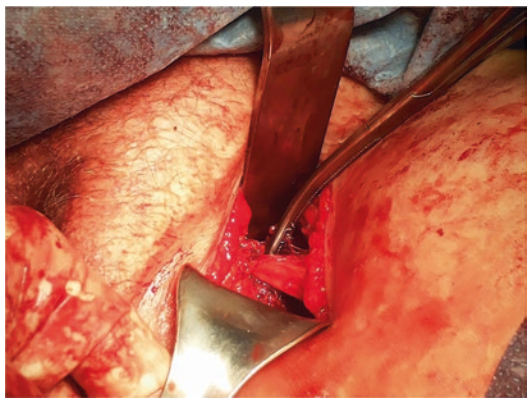

Fig. 14.4 Thigh portion of mesh above the adductor longus tendon. Surgical clamp is grasping portion of mesh

Outcomes

The data are limited; however, some series have shown improvement with conservative management including local anesthetic and nerve blocks [48, 49]. In addition, there are two series of eight patients each who underwent thigh dissection with improvement in pain after mesh excision. Rigaud and colleagues found that at a mean follow-up of 6.4 months pain scores improved from 7 (±1.7) to 3.5 (±3.3). There was a trend towards greater improvement in the TOT group who underwent thigh dissection compared to patients who underwent transvaginal excision alone. No complications were noted [50].

Reynolds and colleagues performed a multicenter, retrospective study of eight patients who had undergone thigh dissection to remove transobturator mesh arms from either transobturator slings or mesh placed for pelvic organ prolapse repair. With an average follow-up of 6 months, five patients reported cure [51]. Overall, the data are very limited regarding thigh dissection and likely should be limited to centers with experience performing this procedure [47].

Conclusion

While the majority of patients do not have pain after mesh-based procedures, pelvic floor surgeons must be equipped to deal with this when it arises. In the patients who do suffer from persistent vaginal pain, dyspareunia, suprapubic pain, or thigh pain, there is significant associated morbidity. As pelvic floor surgeons, the goal is to be able to counsel our patients appropriately regarding either mesh placement or mesh excisions and to have the technical expertise to try to help relieve pain as best we can.

Dunn and coworkers interviewed 84 women treated for mesh-related complications. The authors identified three different experiences that characterized these women. One was “cascading health problems” where the women were very hopeless and overwhelmed by multiple health problems. Other women were “settling for a new normal,” while others had suffered complications but had undergone surgery or medical intervention which allowed them to return to their previous state of health [52]. This emphasizes the significant mental toll that can occur from mesh-related complications especially related to pain. Our objective is to minimize any pain caused from anti-incontinence and prolapse repair surgery.

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Autologous Fascial Slings

15

Paholo G. Barboglio Romo
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Introduction

The autologous fascia pubovaginal sling (PVS) was popularized in 1978 by McGuire and Lytton to address stress urinary incontinence (SUI) caused by low urethral closing pressure and or fixed (immobile) urethra that may be scarred from prior surgical interventions [1]. Indications for PVS procedures were gradually expanded to address uncomplicated stress urinary incontinence as well [2]. With the introduction of the synthetic mid-urethral synthetic sling (MUSS), the use of autologous PVS procedures has declined. However, the procedure remains an excellent anti-incontinence surgery and can still be considered as a first-line anti-incontinence treatment in women who want to avoid synthetic material. In addition, autologous tissue slings are commonly utilized in complex cases (e.g., urethral diverticulum, urethrovaginal fistula, prior failure to MUSS, history of radiation, or severe intrinsic sphincter deficiency). Rectus abdominis fascia and fascia lata are the most common materials employed for PVS. Rectus fascia is used most commonly, but fascia lata may be appropriate for those with extensive abdominal scarring from prior operative procedures.

The aim of this chapter is to describe the complications from autologous PVS (a-PVS) and their management. Complications were classified according to the American Urological Association (AUA) Guideline for the surgical management of female stress urinary incontinence (Tables 15.1 and 15.2) [3]. Table 15.2 displays available randomized control trials (RCT) that include complication outcomes.

Immediate Post-Op Complications and Intraoperative Adverse Events

Genitourinary Complications

Bladder injury can be sustained when developing the space of Retzius and dissecting the bladder off the pubis, especially in the presence of scarring from prior anti-incontinence procedures. Inadvertent bladder injuries can be minimized by dissecting directly on the pubis, just lateral to the insertion of the rectus muscle bodies. Sharp dissection may be required to develop this retropubic space especially when there is scarring. Bladder injuries which occur during the retropubic dissection should be identified and repaired, as these injuries tend to be large.

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Table 15.1 Adverse events from surgical management of female stress urinary incontinence

Perioperative genitourinary
• Bladder and urethral injury
Gastrointestinal (GI)
• Bowel injury
Vascular
• Bleeding complication (with and without surgical intervention)
• Deep venous thrombosis
Neurological
• Nerve injury
• Chronic pelvic pain
Delayed genitourinary
• Urethral erosion
• Voiding dysfunction
Infectious
• Urinary tract infection (UTI)
Wound complications

Bladder injury can also occur when instruments are introduced into the retropubic space to deliver the sling sutures from the vaginal incision to the abdominal incision. We typically use a long, curved clamp with a fairly sharp tip (Crawford clamp) for this maneuver. At the time of passage, the clamp is kept in direct continuity with the back of the pubis at all times, and a finger is positioned within the ipsilateral aspect of the vaginal incision, adjacent to the urethra. This allows for direct tactile control as the instrument tip is passed through the endopelvic fascia, and minimized the degree of "blind" passage. As recommended by the AUA Guidelines, we perform cystoscopy after passage of the instruments to rule out injury to the urinary tract [3]. Use of a 70° lens allows for a thorough evaluation of the entire bladder and urethra with minimal angling of the cystoscope. If a clamp is noted to be in the bladder, it is withdrawn and repositioned, and repeat cystoscopy is performed. Injuries from clamp passage do not require formal repair although it may be prudent to maintain bladder drainage with a Foley catheter for a few days postoperatively.

Bladder injuries can be missed and present at a later date with voiding symptoms (Fig. 15.1). A retrospective review of delayed genitourinary injuries after sling surgeries identified two autologous rectus fascia sling bladder erosions encountered in the bladder dome. Both patients presented with urge incontinence and were diagnosed at 4 and 9 days after surgery. The slings were removed cystoscopically, and the patients did well with adequate continence outcomes [15].

Injuries to the urethra or bladder neck injuries can occur if the vaginal dissection is too deep into the periurethral fascia or if the retropubic space is dissected too medially. In these occasions, primary repair with a two layer closure is recommended. Urethral injury can also be sustained at the time of the transvaginal urethral dissection, especially in patients with a history of prior vaginal surgery. In these circumstances the urethra is closed and the autologous sling then provides another layer to the repair. If the urethral injury is large or the tissue quality is poor, a Martius flap can be interposed between the urethra and the sling (Fig. 15.2).

Vascular Complications

Bleeding

It is not uncommon to encounter venous bleeding from the vaginal epithelium during the vaginal portion of the procedure. For this reason, we will typically harvest the sling from the rectus fascia prior to proceeding with the vaginal dissection. Vaginal bleeding can be minimized by entering the correct surgical plane superficial to the periurethral fascia. Vasoconstrictor agents are also commonly injected into the vaginal wall to facilitate the dissection before making the incision, but we are aware of no data which demonstrate that this maneuver reduces the amount of bleeding. Most vaginal bleeding stops after the sling is placed and the incision is closed. Therefore, the most effective maneuver to stop vaginal bleeding is to expeditiously proceed with the procedure rather than attempt to identify and cauterize or ligate bleeding sources. In rare cases with brisk venous bleeding, placement of absorbable figure-of-eight sutures through the vaginal mucosa at the vaginal forces can help to control bleeding. A vaginal gauze pack is typi-

Table 15.2 Autologous pubovaginal sling (a-PVS) complication rates

Author (year)	Demirci (2001) [4]	Maher (2005) [5]	Wadie (2005) [6]	Bai (2005) [7]	Kondo (2006) [8]	Guerrero (2007) [9]		Albo (2007) [10]	Sharifiaghdas (2008) [11]	Tcherniakovsky (2009) [12]	Amaro (2009) [13]	Khan (2014) [14]
Follow-up	12 months	12 months	6 months	12 months	24 months	42 months (mean)		24 months	6 months	12 months	36 months	10 years
Comparison	a-PVS vs. Burch	a-PVS vs. Bulking (Macropla.)	a-PVS vs. MUSS (TVT)	Burch vs. a-PVS vs. MUSS (TVT)	a-PVS vs. MUSS (TVT)	a-PVS (20 cm) vs. a-PVS (8 cm) on string		Burch vs. a-PVS	a-PVS vs. MUSS (TVT)	a-PVS vs. MUSS	a-PVS vs. MUSS	a-PVS vs. Pelvicol vs. MUSS (TVT)
Arms (comparison)	a-PVS	a-PVS	a-PVS	a-PVS	a-PVS	a-PVS (20 cm)	a-PVS (8 cm)	a-PVS	a-PVS	a-PVS	a-PVS	a-PVS
N	23	22	25	28	29	81	84	326	36	20	21	61/79
Mean Op time (min)	61	60	70	NR	87	62	54	125	80	60	70	50
Mean EBL (ml)	NR	200	NR	NR	NR	274	230	184	NR	NR	NR	NR
Serious Adverse Events	NR	NR	NR	NR	NR	NR	NR	42 (13 %)	NR	NR	NR	NR
Bladder injury	NR	NR	1 (4 %)	NR	7 (24 %)	NR	NR	2 (0.6 %)	2 (5.6 %)	1 (5 %)	1 (5 %)	NR
Urethral injury	NR	NR	NR	NR	0	NR	NR	NR	NR	NR	NR	NR
Suture erosion into the bladder	NR	NR	NR	NR	NR	NR	NR	0	NR	NR	NR	NR
Urethral sling erosion	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0
Wound serious AE (intervention)	NR	NR	NR	NR	NR	NR	NR	11 (3.4 %)	NR	6 (30 %)	NR	NR
Bleeding — intervention	NR	NR	NR	NR	NR	NR	NR	1 (0.3 %)	NR	NR	NR	NR
Urethrolysis or sling lysis	NR	NR	NR	NR	4 (14 %)	1 (1 %)	4 (5 %)	20 (6 %)	2 (5.6 %)	NR	NR	2 (3 %)

(continued)

Table 15.2 (continued)

Author (year)	Demirci (2001) [4]	Maher (2005) [5]	Wadie (2005) [6]	Bai (2005) [7]	Kondo (2006) [8]	Guerrero (2007) [9]		Albo (2007) [10]	Sharifiaghdas (2008) [11]	Tcherniakovsky (2009) [12]	Amaro (2009) [13]	Khan (2014) [14]
All Adverse Events (AE)	NR	NR	NR	NR	11	NR	NR	206 (63 %)	NR	12 (60 %)	NR	NR
Wound adverse event (non-intervention)	NR	NR	NR	NR	NR	NR	NR	71 (22 %)	NR	1 (0.05 %)	NR	NR
UTI	1	3	NR	NR	NR	10 (12 %)	6 (7 %)	299 (92 %)	NR	NR	NR	NR
Bleeding	NR	NR	NR	NR	NR	NR	NR	8 (2.4 %)	1 (2.7 %)	NR	NR	NR
Pain associated from surgery	4	NR	7	NR	NR	52/78 (67 %)	42/82 (51 %)	2 (6.1 %)	NR	NR	NR	2 (3.3 %)
Voiding Dysfunction	NR	4 (18.2 %)	7 (28 %)	2 (7.1 %)	NR	19/81 (23 %)	17/84 (20 %)	46 (14 %)	11 (30.5 %)	NR	NR	NR
De novo urgency	NR	1	NR	NR	3	6/81 (7 %)	2/84 (2 %)	11 (3 %)	8 (22 %)	NR	40 %	0

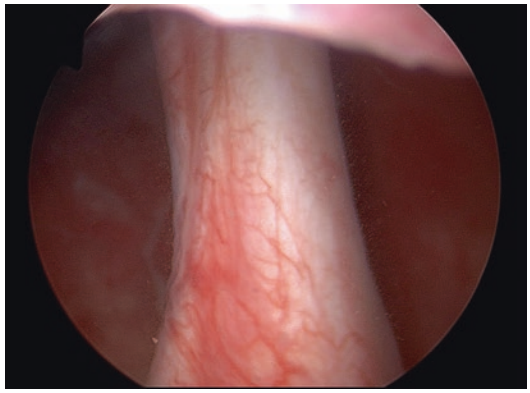

Fig. 15.1 Cystoscopic view of autologous fascia perforation at the 2 o'clock position from the bladder dome that was diagnosed 3 months after surgery on a patient with irritative urinary symptoms (de novo urgency)

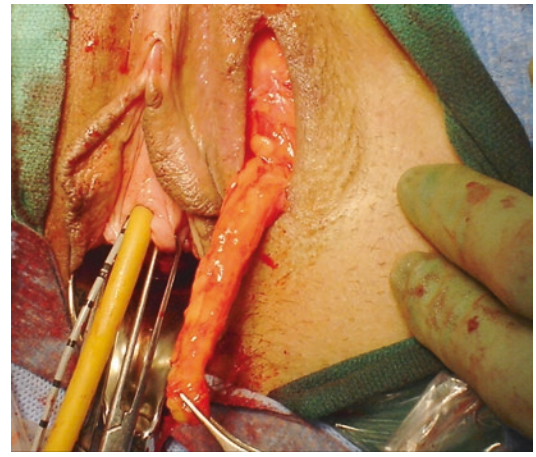

Fig. 15.2 Adipose tissue labial (Martius) flap with an inferior pedicle

cally placed postoperatively and is left in place overnight to maintain pressure and prevent bothersome oozing from the incision. Using these maneuvers, the reported blood transfusion rate is approximately 2 % [10, 16] although these rates include concomitant procedures and likely overestimate the transfusion rate for a-PVS performed in isolation.

Clinically significant bleeding that does not respond to conservative measures may need to be addressed surgically, but this is rare. In patients with evidence of persistent postoperative bleeding, CT scan of the pelvis or pelvic ultrasound can help to identify the presence of a pelvic or retroperitoneal hematoma and may help to determine the bleeding source (Fig. 15.3).

If the bleeding source is retropubic, the prior Pfannenstiel incision and rectus fascia are opened and the hematoma is evaluated. After irrigation, bleeding sites are identified and addressed. The peritoneum can be opened if necessary to examine the iliac vessels. Another alternative is to consider angiography and embolization when the patient is hemodynamically stable, and it is unclear whether there is active bleeding. Elard and colleagues reported a case where they were able to control bleeding from an inferior vesical artery with selective embolization [17].

Deep Venous Thrombosis

The estimated incidence of deep venous thrombosis (DVT) after any type of vaginal sling procedure is 0.35 % [16]. DVT prophylaxis should be based on the overall risk assessment for the patient. For low risk patients, sequential compression devices alone are considered acceptable, while higher risk patients may require the addition of chemoprophylaxis (heparin or enoxaparin) [18].

Gastrointestinal Complications

Bowel Injury

Bowel injury can occur while mobilizing the superior leaf of the rectus fascia during the abdominal dissection. If there is a large amount of scarring in this area due to previous surgery, we favor using scissors rather than electrocautery for this dissection. If the peritoneum is entered, it is closed after the fascia is adequately mobilized. Bowel injury can also occur during retropubic passage of the clamp, especially if there has been prior pelvic surgery and the peritoneum extends deep into the pelvis. In rare cases, entry into the peritoneum may be necessary to clearly identify the anatomy and ensure that the clamps can be passed safely.

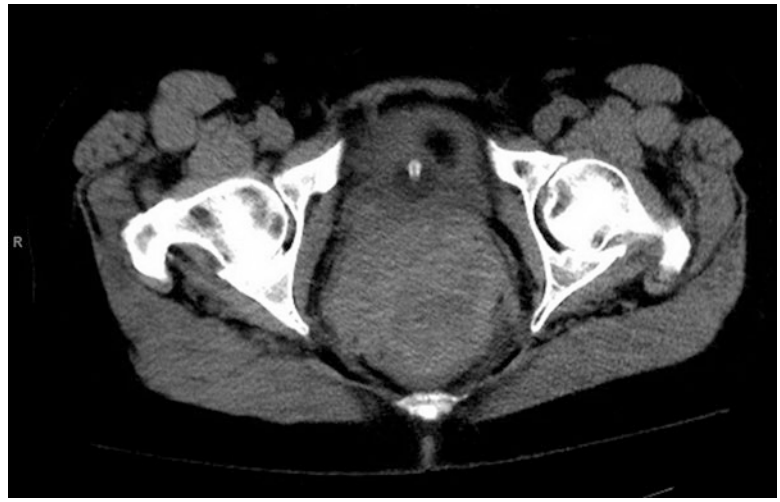

Fig. 15.3 CT scan shows a retroperitoneal hematoma likely associated with retropubic dissection or instrument passage

Table 15.3 Types of nerve injury during pubovaginal sling

Nerve	Motor	Sensation	Cause	Treatment
Femoral	Knee extension	Front and inner sides of the thigh, shin, and arch of the foot	Retroperitoneal hematoma positioning injury, direct pressure at the time of the surgery	Consider going back if large hematoma and significant symptoms, physical therapy
Ilioinguinal	None	Mons pubis, labia majora	Direct injury, supra/para-vesical hematoma, pressure from retractors	Consider evacuate supravesical hematoma or explore in the early post-op. Nerve could be caught during fascia closure or less commonly by the string/sling. Physical therapy and consider trigger point injections
Genitofemoral	None	Upper anterior thigh (femoral branch)	Retroperitoneal hematoma, injury when passing positioning or passing instrument	Consider evacuate retroperitoneal hematoma, physical therapy
Lateral femoral cutaneous	None	Lateral thigh	When harvesting fascia lata, extrinsic compression over the groin area	Physical therapy
Obturator	Thigh adduction	Medial thigh	Direct injury in the retroperitoneal tunnel or retroperitoneal hematoma	Consider release the sling in the first 24 h if no major hematoma and significant neuropraxia, physical therapy

Neurological Complications

Nerve Injury

Significant pain, dysesthesia, or evidence of motor dysfunction in the immediate postoperative period suggests a nerve injury. These are most commonly associated with prolonged surgical procedures and are therefore more likely if the a-PVS is performed concomitantly with other surgeries. Table 15.3 describes the most common nerve injuries that are encountered during pelvic surgery [19]. The obturator nerve can be injured when passing the instrument in the retropubic space. Patients with obturator nerve injuries will typically report hip pain and/or weakness during hip adduction. Depending on the type of injury, adduction of her

thigh could be absent or simply impaired. These symptoms can usually be managed conservatively with pain control and physical therapy, but severe and intractable pain may require surgical exploration and removal or repositioning of the sling.

Chronic Pain

Chronic pain in the groin or the pelvic area after a-PVS is not commonly reported in the literature, and we are aware of no reports where a sling was removed or urethrolysis was performed to address isolated pain symptoms after a-PVS. It is common for patients to report unilateral discomfort on one side of the Pfannenstiel incision which can persist for weeks. We surmise that this may be due to irritation from the dissection or from the sling sutures.

Postoperative Complications (24 h–90 Days)

Genitourinary

Urethral Erosion

There are isolated reports in the literature of urethral "erosions" following autologous PVS placement, but most of these occurred after a traumatic catheterization or other event, suggesting that catheter trauma rather than erosion was the etiology [20, 21]. Other reports occurred in the early postoperative period, suggesting intraoperative urethral injury may have occurred [22, 23]. The vast majority of these injuries can be managed conservatively with urethral catheterization to permit wound healing.

Urinary Retention

Postoperative storage and/or voiding symptoms are very common after a-PVS and patients should be counseled appropriately so they have realistic expectations. The average duration of urinary retention after a-PVS is 8 days [24]. Therefore, all patients are told that intermittent self-catheterization (ISC) will be required after sling placement. We utilize preoperative ISC teaching selectively (e.g., for those who express concerns, obese patients). If a patient is unable to catheterize herself, it is frequently possible to identify a family member or caregiver who can do the catheterizations. The majority of patients are taught ISC postoperatively before they are discharged from the hospital. ISC should be performed as frequently as necessary in order to maintain bladder volumes of less than 500 mL. Patients are instructed to stop catheterization when residual bladder volumes are less than 150 mL. If ISC is not possible, we favor placement of a suprapubic tube at the time of a-PVS to allow for postoperative voiding trials.

As a routine, patients are informed that catheterization may be required for as long as 3 months after a-PVS placement [24]. In those with persistent urinary retention, the decision to offer urethrolysis is individualized, depending on the trajectory of symptoms and patient preferences. If surgery is performed early (at 4–6 weeks), it is often possible to isolate and divide the autologous sling. An inverted U-shaped incision is favored to facilitate closure with a vaginal epithelium flap. With a urethral catheter in place, the sling is identified in the midline as it courses across the urethra. The sling is then separated from the urethra and divided [25]. For surgeries performed at 3 months, the sling may be inconspicuous, and a urethrolysis of the lateral periurethral tissues is usually performed.

Voiding Dysfunction

"Voiding dysfunction" refers to the presence of new or persistent lower urinary tract symptoms after sling placement. Voiding dysfunction appears to occur more commonly after a-PVS than after retropubic suspensions [10] or synthetic mid-urethra slings [26] and will frequently improve or resolve with time. In those with persistent symptoms (longer than 3 months), the clinical evaluation focuses on determining whether the symptoms are caused by bladder outlet obstruction from the sling. If the clinical impression is that obstruction is present, then urethrolysis would be indicated. Conversely, if the sling is not the reason for the symptoms, then treatments focused on the bladder would be appropriate. Therefore, a careful history is critical to determine the temporal association between the symptoms and the sling surgery. Pelvic

examination should be performed but is rarely very helpful. Measurement of the post-void residual measurement is important to assess bladder emptying. In patients with a low residual volume who have symptoms that are predominantly related to urine storage (e.g., urgency, frequency), a trial of an antimuscarinic medication may be indicated. Conversely, patients who have to strain to urinate and who have severe de novo urgency incontinence may be candidates for urethrolysis. In patients with voiding dysfunction after sling placement, we frequently utilize videourodynamics to aid in our decision-making. There are no uniform validated criteria to diagnose female bladder outlet obstruction and high detrusor contraction with low flow values is rather not specific. When using urodynamics, we diagnose obstruction based on the presence of a sustained detrusor contraction accompanied by a low or absent flow, augmented with the use fluoroscopic imaging to diagnose and localize the obstruction as proposed by Nitti and coworkers [27], as captured in Fig. 15.4.

Urethrolysis

Urethrolysis can be performed from a retropubic [28], infrapubic (suprameatal) [29], or vaginal approach [30] and reported success rates vary from 65 to 93 %. In our practice, a transvaginal approach is performed through an inverted U incision in the anterior vaginal wall, with dissection proceeding medial to lateral until identifying the sling as described by McGuire [30]. Allis clamps are placed in each lateral border of the sling and dissection is carried up to the endopelvic fascia. The sling is divided at this level without getting into the retropubic space after the urethra is been cleared with the passage of a right angle instrument as described above. If no release is observed at the time of lysis of the sling or the PVS cannot be identified, then a circumferential urethrolysis is recommended. This procedure starts with a standard transvaginal urethrolysis in which the lateral urethral attachments and scar are sharply divided with scissors. This dissection should be conducted along the medial aspect of the ischiopubic ramus in order to prevent injury to the urinary tract. Following the lateral dissection, further dissection is conducted anteriorly, between the urethra and the overlying pubis. Staying just under the pubis maintains the dissection at the level of the mid-urethra and prevents injury to the bladder. Once the circumferential dissection is complete (Fig. 15.5), we wrap a Martius flap around the urethra to prevent postoperative scarring. A crede maneuver as described by Amunsden can help when there is a question about the necessity of further urethrolysis [21].

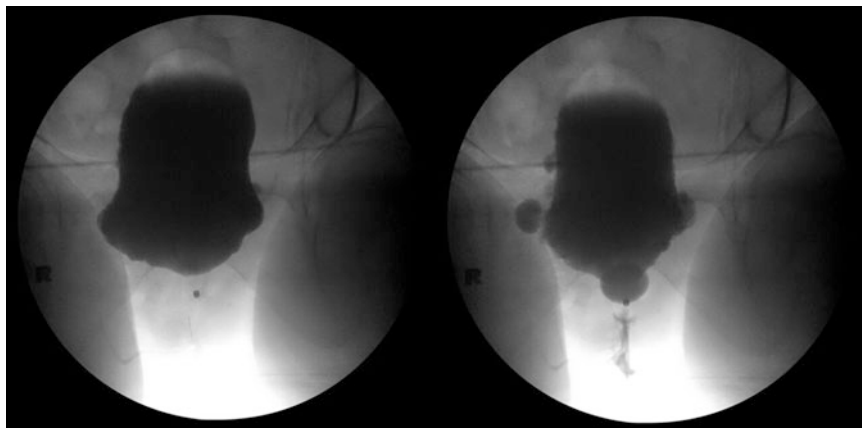

Fig. 15.4 Fluoroscopic images during filling (*left*) and voiding (*right*). Note the very prominent dilation of the bladder neck and urethra during voiding to the level of the obstruction

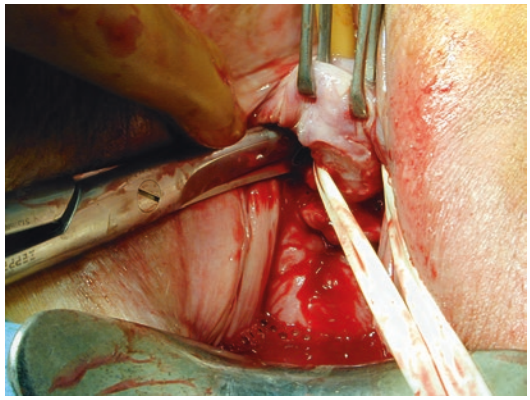

Fig. 15.5 A Penrose is utilized to facilitate traction and circumferential dissection of the urethra

Infection

Urinary Tract Infection

As noted above, many patients experience lower urinary tract symptoms following sling placement as part of the normal recovery process. As a result, it is very common for patients to be diagnosed with presumed urinary tract infections in the postoperative period. The UTI rates reported in the literature vary widely, depending on whether a urine culture is required to make the diagnosis. The SISTEr trial reported an incidence of 299 UTI events in 326 women who underwent a-PVS, but a positive urine culture was not required for diagnosis which may have led to overdiagnosis of UTI [10]. In our practice, patients who report UTI symptoms after a sling are requested to submit a urine specimen for culture. While awaiting the culture results, empiric antimicrobial treatment can be started for those patients with an acute change in their symptoms.

Wound Complications

Since the peritoneum is not entered during a-PVS surgery, abdominal wound complications tend to be straightforward and fairly easy to manage with standard wound care principles. Intraoperative subcutaneous drain placement is not routinely performed, as there is no evidence that it reduces postoperative complications. If the abdominal wound needs to be opened to treat a hematoma, seroma, or abscess, care should be taken to avoid cutting the sling sutures, as this may compromise the efficacy of the surgery. The vaginal infection rate following a-PVS is surprisingly low and such infections can typically be managed with antibiotics. If vaginal exploration is required to remove or drain infected tissue, the incision can be left open if needed, and the exposed tissue will re-epithelialize.

Conclusion

The autologous pubovaginal sling is an effective treatment for women with complex stress urinary incontinence and for those who wish to avoid the use of synthetic materials. Significant perioperative complications are rare. Transient urinary retention occurs very frequently following the surgery; patients should be made aware of this before surgery, and a clear plan should be implemented to manage this postoperatively. Lower urinary tract symptoms are also common postoperatively, and these usually resolve with time. Evaluation of persistent postoperative urinary symptoms is focused on determining if urinary obstruction is present. If so, this should be treated with urethrolysis.

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Synthetic Midurethral Slings: Urinary Tract Sequelae

16

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Introduction

Female stress urinary incontinence (SUI) is estimated to affect half of all adult women [1]. Despite the pervasiveness of SUI, surgical treatment options were historically limited to invasive therapies such as pubovaginal slings, suspension-type procedures, or retropubic urethropexies until the development of the midurethral sling (MUS) [2]. The MUS is currently considered by many to be the standard of care for the treatment of SUI due to the minimal morbidity, rapid convalescence, short operative time, and long-term efficacy [3]. The American Urological Association (AUA) Guideline for the surgical management of SUI supports this change in practice, as estimated cured/dry rates in patients without concomitant prolapse treatment range from 81 to 84 %. These rates are comparable to autologous fascial slings and Burch suspensions showing equivalent efficacy for the surgical treatment of SUI [4].

Complications from MUS surgery unique to the use of polypropylene mesh may occur including chronic pelvic pain, dyspareunia, and mesh exposure, which are the most common, as well as mesh contracture, neuromuscular injury, and/or organ perforation (see Chap. 17). In addition, there can be significant urinary tract sequelae such as urinary tract injury, de novo urgency and/or urgency urinary incontinence (UUI), urinary obstruction, and/or urinary tract infection (UTI). As a result of these complications and the ensuing morbidity, it is imperative that providers have a high index of suspicion for intraoperative and postoperative complications.

Preventing Urinary Tract MUS Complications

Complications can be minimized by adhering to fundamental surgical practices during the MUS insertion. These include appropriate knowledge of pelvic and vaginal anatomy; careful vaginal dissection and hemostasis; diligence during the passage of the sling trocars to avoid injury or perforation to the bladder, urethra, vaginal tissue, or groin structures; appropriate tensioning (i.e., "tension-free") during sling deployment; and, prudence for identifying intraoperative

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complications. According to the standards in the AUA Guidelines, intraoperative cystoscopy should always be performed at the time of sling placement. The AUA Guidelines also state that an MUS should not be placed in the presence of a urethrotomy [4].

Diagnosing Mesh-Related Urinary Tract Sequelae

To evaluate a patient with a potential mesh-related urinary tract complication, the clinical evaluation should begin with a detailed clinical history. Providers should maintain a high index of suspicion as mesh-related complications can be subtle and difficult to identify. Patients should be assessed for voiding dysfunction, hematuria, urinary incontinence, and recurrent UTIs, as well as vaginal discharge or bleeding, pelvic/groin pain, dyspareunia, or hispareunia (painful intercourse secondary to a mesh exposure that is reported by the male partner) [5]. Standardized questionnaires can also be utilized to assess baseline symptomatology and monitor improvement throughout subsequent therapies. A complete surgical history—including the clinical time course of symptom presentation and information about previous treatments—should also be obtained. Acquiring the previous operative records is paramount to confirm the type of mesh and previous surgical approach.

A physical exam, including a thorough abdominal and pelvic exam, should be performed. Attention should be directed at identifying vaginal discharge or bleeding, scar tissue contraction or banding, reproducible areas of tenderness or discomfort, granulation tissue, or foreign body exposure. At times, an exam under anesthesia may be required to ensure a complete examination, especially if significant pain or difficult body habitus are present. A urinalysis should be obtained to assess for hematuria and/or UTI, with urine culture, if indicated. Measuring post-void residual (PVR) urine volumes can identify incomplete emptying or urinary retention.

Cystourethroscopy should always be performed if there is any suspicion for a mesh-related complication. This can identify a mesh perforation within the urethra or bladder. Urodynamics (UDS) should be performed for patients who present with voiding dysfunction, which may identify iatrogenic bladder outlet obstruction (BOO) or de novo or persistent detrusor overactivity. Videourodynamics (VUDS) may also be helpful to identify urethral narrowing or kinking and associated proximal urethral dilation at the level of the MUS during a sustained detrusor contraction [6, 7].

While imaging has not been routinely employed in this setting, translabial ultrasonography has been utilized to aid in both preoperative and intraoperative identification of the sling. Staack and colleagues compared the clinical versus definitive operative findings of 51 women undergoing surgical MUS excision. The study was able to accurately locate the position of the mesh sling and identify the type (retropubic vs. transobturator) [8].

Managing Urinary Tract MUS Complications

Intraoperative

Urinary Tract Injury

The lower urinary tract (LUT) is at risk for injury during any portion of the MUS procedure, and, if unrecognized, can have significant ramifications. Specifically, passage of the MUS trocars may cause injury to the bladder, urethra, or bladder neck. The urethra can also be injured during the vaginal dissection. Though rare, ureteral injury can occur with passage of the MUS trocar near the trigone or with the vaginal dissection. Patients with an unrecognized LUT injury can develop mesh perforations in the urethra or bladder, urethrovaginal or vesicovaginal fistulae, gross hematuria, bladder stones, pelvic pain, and recurrent UTIs. As such, it is paramount that these injuries be identified intraoperatively. The rate of urinary tract injury with a trocar at the time of surgery ranges from 2.7 to 23.8 % [9].

To assess for LUT injury, intraoperative cystoscopy should always be performed with 70°

and 30° lenses after trocar passage and with the trocars in place. The bladder should be fully filled to achieve complete expansion. The bladder as well as the bladder neck and urethra should be carefully inspected along the trocar course. Urethroscopy can be difficult in women due to short urethral length, but diligence is required as urethral perforation can be subtle and poorly visualized. Ureteral patency should also be documented by identifying efflux of clear urine, and, if there is concern for injury, a retrograde pyelogram should be performed: a JJ stent should be placed if extravasation occurs.

In an attempt to prevent LUT injuries, the MUS trocars should only be passed after the bladder is fully drained. A rigid urethral guide can be used to gently deflect the urethra to the contralateral side while the ipsilateral trocar is passed through the paraurethral space. If a bladder injury does occur during trocar placement, the offending trocar should be removed and repassed (Fig. 16.1). A Foley catheter may be left in place if there is concern for a large bladder defect, but a small trocar puncture site typically closes without difficulty and prolonged catheterization is unnecessary. As aforementioned, if a urethral injury occurs either during the vaginal dissection or with passage of the MUS trocar, mesh sling placement should be aborted [4]. The urethral defect should be closed primarily and an indwelling Foley catheter is left in place for healing.

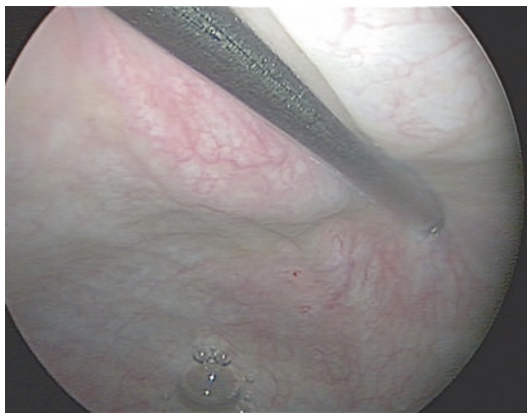

Fig. 16.1 Cystoscopic view of MUS trocar passed through the bladder wall. The offending trocar should be carefully withdrawn and repassed

Postoperative

Urinary Tract Infection

Approximately 4–15 % of women undergoing sling placement will report one or more UTIs [4]. Patients with typical symptoms of a UTI such as frequency, urgency, and/or hematuria should be evaluated with a urine culture. Those with severe, recurrent, or persistent symptoms may warrant a more thorough investigation including blood cultures, cross-sectional imaging, PVR, UDS, or cystoscopy when clinically appropriate. Abscesses, urinary obstruction, foreign bodies, sling perforation, or stones should all be included in the differential [10].

The AUA best practice policy statement on urologic surgery antimicrobial prophylaxis recommends 24 h of therapy for vaginal surgery [11]. However, a recent randomized controlled trial (RCT) of 149 patients by Jackson and colleagues evaluated the benefit of adding a 3-day antibiotic course postoperatively for patients undergoing vaginal surgery for SUI. Patients were randomized to a 3-day postoperative placebo ($n = 75$) or nitrofurantoin (100 mg two times a day) ($n = 74$). Overall, 37 (24.8 %) women were diagnosed with a UTI within the 6-week postoperative study period. The incidence was significantly lower in the treatment arm (17.6 %) compared to placebo (32 %), ($p = 0.04$) [12]. This may suggest a potential benefit to a short course of postoperative antibiotic prophylaxis but further studies are warranted. A recent study by Gehrich and colleagues used the National Surgical Quality Improvement Program (NSQIP) to review data collected on 9851 patients who underwent an MUS. Of these, 3.4 % developed a UTI, suggesting that the incidence of postoperative UTIs remains constant [13].

Lower Urinary Tract Dysfunction

Lower urinary tract dysfunction or overactive bladder (OAB) can occur after placement of an MUS in patients without any previous OAB symptomatology. De novo urge incontinence or UUI is often transient and may resolve spontaneously. In such cases, patients should be counseled and reassured. However, persistent symptoms

requiring intervention can occur in a quarter of patients [14]. The rate of de novo urge incontinence was previously estimated at 6 % [4]. In a series of 463 patients, Holgren and colleagues reported de novo urgency in 14.5 % of patients undergoing an MUS. Older age and parity were identified as significant risk factors for developing de novo urgency [15]. Lee and colleagues also evaluated risk factors for developing de novo urgency or UUI. The study identified 358 women with SUI or mixed urinary incontinence who underwent a MUS. De novo urgency occurred in 27.7 % of patients and de novo UUI occurred in 13.7 %. Intrinsic sphincteric deficiency, previous surgery for SUI or pelvic organ prolapse (POP), colposuspension, and/or preexisting detrusor overactivity increased the risk of postoperative urgency or UUI [16].

Reversible causes of de novo urgency/UUI should be evaluated and treated accordingly. A recent review by Abraham and Vasavada cited that de novo urgency occurs in 6 % of patients and modifiable causes include postoperative UTI (7.4–14.7 %), bladder outlet obstruction (BOO) (1.9–19.7 %), and perforation of the urinary tract (0.5–5 %), with 0–28 % of cases occurring due to idiopathic etiologies [17]. Conversely, it has been also been proposed that a MUS can actually improve OAB symptoms. A study by Segal and coworkers retrospectively reviewed 98 MUS patients and found that approximately 57 % of patients with OAB demonstrated resolution of their symptoms, while only 4.3 % reported de novo OAB [18].

Treatment options for post-MUS urgency or UUI are similar to those for uncomplicated OAB and first include behavioral modification such as bladder training, bladder control strategies, pelvic floor muscle training, and/or fluid management. According to the updated AUA Guidelines for OAB, this may be combined with antimuscarinics or beta-3 agonists as options for second-line therapy, and onabotulinumtoxinA, sacral neuromodulation, or peripheral tibial nerve stimulation (PTNS) for refractory OAB [19]. Of note, a recent study by Serati and coworkers found that in the setting of de novo OAB after a MUS, solifenacin had significantly lower efficacy compared to controls [20]. OnabotulinumtoxinA, however, showed similar efficacy in a prospective study of 102 women comparing those with idiopathic OAB (n = 53) to women with de novo OAB post-MUS (n = 49) in a study by Miotla and colleagues [21].

Bladder Outlet Obstruction

Bladder outlet obstruction can present in a variety of ways and, as a result, the true incidence is difficult to accurately assess. The rate of urinary retention (catheter dependency for at least 28 days) is estimated to occur after 1–10 % of MUS [4, 22]. Additionally, patients may also complain of de novo frequency and urgency, UUI, hesitancy, straining to void, weak stream, incomplete emptying, dysuria, or recurrent UTIs. Pressure-flow UDS and a PVR may be used to assess BOO. Currently, however, there is no consistent index value for BOO in women and the absence of "high pressure, low flow" on UDS does not rule out iatrogenic obstruction [23, 24].

Treatment options for BOO vary widely according to individual patient factors, sling type, and patient or surgeon preference. Surgical intervention is often necessary including: sling loosening, sling incision, sling excision, or urethrolysis (infrapubic, retropubic, or transvaginal) [25]. Nonsurgical therapies may be offered for transient obstruction such as self-intermittent catheterization (SIC) or indwelling catheterization [22]. Often times, residual edema after the procedure can lead to urinary retention. Spontaneous voiding should occur within 1 week, and 66–100 % of temporary voiding dysfunction resolves by 6 weeks [14, 26].

If the patient cannot void at that time, loosening the sling has been reported in the literature. Advocates of this technique recommend making a small vaginal incision along the previous suture line. A right-angle clamp is then placed behind the sling and steady downward traction is applied to gently loosen the MUS [27]. Care must be taken to avoid urethral injury when passing the clamp between the overtensioned MUS and the periurethral fascia. This has been described in an office setting under a local anesthetic, but maxi-

mizing vaginal exposure in the operating room can be advantageous.

If the obstructing sling is well incorporated into the vaginal tissue, a sling incision can also be performed [28]. Once a vaginal incision is made over the previous suture line, the rough tissue overlying the MUS can typically be palpated. A cystoscope or urethral sound may be inserted into the urethra with upward traction to assist with identification of the MUS. The overlying granular tissue can be visualized or a tight, band-like structure can be identified. A right-angle clamp is then carefully inserted behind the sling and spread gently open (Fig. 16.2). Once the right-angle clamp is completely behind the sling, a scalpel is used to incise the MUS complex. This should be done with extreme caution to prevent urethral injury. The cut edges of the sling will then retract due to the tension release, and the suburethral portion of the sling may then also be excised to prevent erosion [10].

When the clinical presentation is especially delayed, a formal sling excision should be performed. This technique is best employed with an inverted, U-shaped anterior vaginal wall flap, with the base located at the bladder neck and the apex at the urethra. This incision maximizes exposure for the lateral dissection along the pubocervical fascia. If the MUS complex is identifiable at this juncture, the sling may be transected. The dissection is then carried as lateral as possible along the sling to safely remove the maximum amount of mesh (Fig. 16.3). This should be done judiciously as there can be significant bleeding and/or organ injury within the transobturator or retropubic spaces.

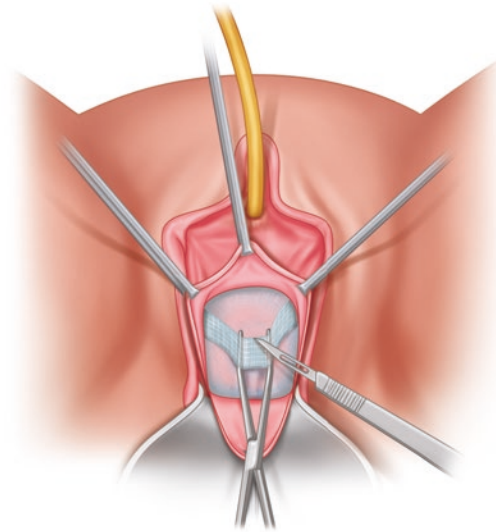

Fig. 16.2 Isolation of the MUS complex with a right-angle clamp

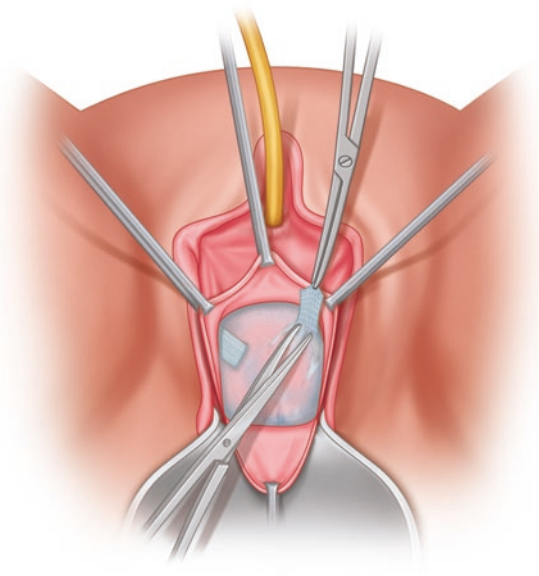

Fig. 16.3 After the MUS is transected, the mesh arms are isolated and the dissection is carried laterally to remove the maximum amount of mesh that is safely possible

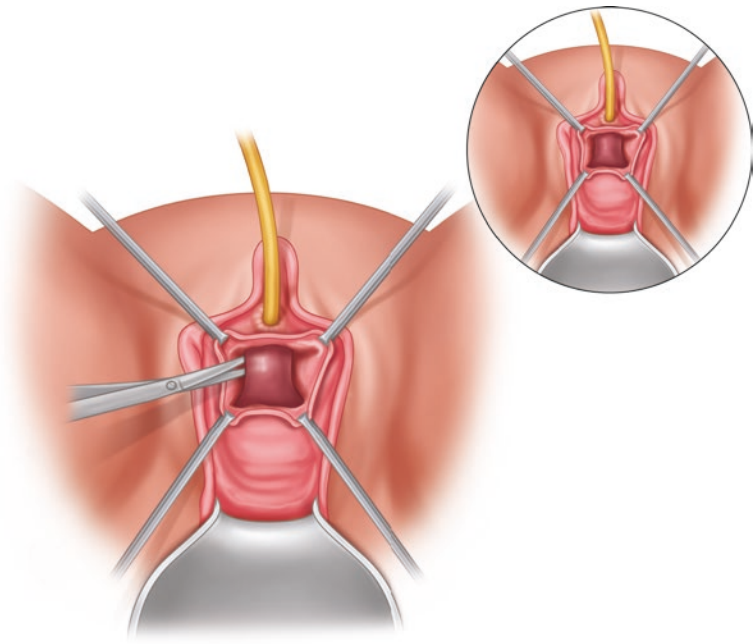

Fig. 16.4 Transvaginal approach for urethrolysis

If the sling is not easily identifiable, the endopelvic fascia may be perforated with Metzenbaum scissors to enter the retropubic space. Using a combination of blunt and sharp dissection, the sling can often be identified laterally and then transected and excised. In such cases, a partial or total urethrolysis may also be required. With careful, blunt dissection, the urethra is freed from its attachments anteriorly to the pubic bone and proximally to the bladder neck (Fig. 16.4).

If adequate vesicourethral mobility cannot be achieved, a sling excision and urethrolysis can be performed from a retropubic approach [10]. This can allow for complete removal of the retropubic mesh arms. A low midline or Pfannenstiel incision is made, and the space of Retzius is adequately developed. Any retropubic and prevesical adhesions are sharply incised and all visible sling material is transected and removed (Fig. 16.5). Observation of free flowing urine by Crede maneuver can confirm a complete urethrolysis. In the original description, an omental pedicle flap is interposed between the urethra and the pubic bone to prevent readherence [10].

In the setting of a MUS, cure rates for urethrolysis are variable as much of the initial data are extrapolated from pubovaginal slings (Table 16.1). The earlier literature for suspension procedures and bladder neck slings suggests that the rate of recurrent SUI is low. However, a recent study of 107 MUS patients evaluated the rate of recurrent SUI after surgical intervention for BOO. In the 107 patients, recurrent SUI occurred in 49 %: significant bother was reported in 83 %, leading 14 % of the women to undergo a subsequent anti-incontinence procedure [44].

It has been postulated that delayed surgical intervention of BOO may not necessarily improve micturition, and long-standing obstruction of the urethra can have an irreversible impact. In fact, persistent voiding dysfunction after urethrolysis has been reported in the literature. In a series by Starkman and coworkers, approximately 50 % of patients reported persistent OAB symptoms following urethrolysis. The study evaluated 40 patients with obstructive urinary symptoms, 36 of whom reported OAB symptomatology at presentation. After urethrolysis, 56 % reported refractory OAB and were continued on antimuscarinics postoperatively, with eight ultimately undergoing sacral neuromodulation [33, 46]. As such, prompt diagnosis of BOO and early intervention is imperative.

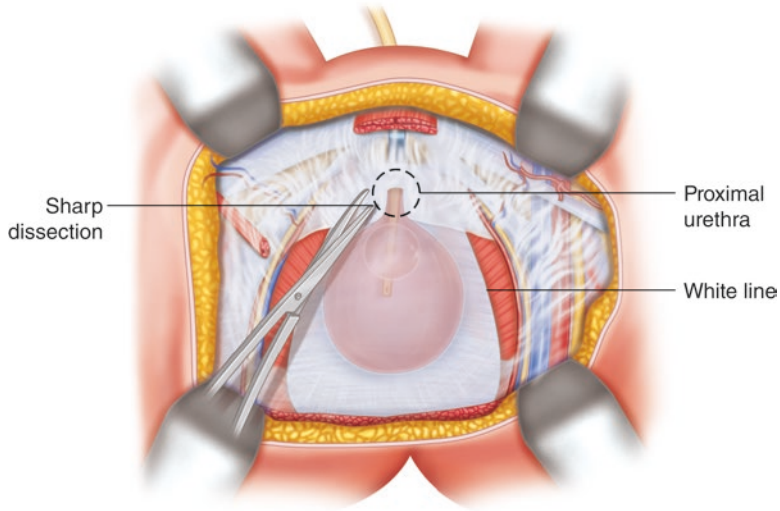

Fig. 16.5 Retropubic approach for urethrolysis

Mesh Perforation and Urinary Fistula

Pelvic surgeons should always maintain a high index of suspicion for LUT mesh perforation (Fig. 16.6), as it can present with variable symptomatology. In a retrospective review by Osborn and coworkers, 27 patients were identified to have a postoperative MUS perforation (bladder perforation $n = 12$, urethral perforation $n = 15$). Of these, 11/27 (41 %) presented with irritative voiding symptoms, 7/11 (26 %) with incontinence, 4/11 (15 %) with vaginal pain, and 2/11 (7 %) with either recurrent UTIs or dyspareunia [47]. The true incidence of mesh perforations is unknown but it is estimated to be 0.7–5 % for retropubic slings and 0–0.5 % for transobturator slings [17, 47]. It is also unclear whether a mesh perforation results from a missed LUT injury at the time of the procedure or from progressive erosion of mesh over time [10]. Various etiologies leading to mesh exposure include extensive vaginal dissection resulting in devascularization of the urethra, sling tension, missed trocar injury at the time of MUS placement, traumatic catheterization or dilation, or compromised urethral vascularity such as from estrogen deficiency [10].

Mesh perforation typically mandates surgical excision; however, this may be performed in a variety of approaches. For a small, isolated mesh segment within the urinary tract, endoscopic management has been described with scissors, holmium laser, or transurethral resection [48, 49]. However, most mesh perforations require a transvaginal and/or abdominal exploration and excision, closure of the urinary tract, and postoperative urinary drainage.

For a urethral or bladder neck mesh perforation, a transvaginal mesh excision is performed. Prior to incision, complete cystourethroscopy verifies the location of the urinary tract mesh. Then, similar to a vaginal mesh excision, an inverted, U-shaped anterior vaginal wall flap is created to maximize exposure. The pubocervical fascia is dissected laterally, and the endopelvic fascia is perforated with Metzenbaum scissors. A cystoscope or urethral sound may be inserted into the urethra to assist with identification of the MUS. Once the sling is identified, the mesh is carefully transected and removed from within the urethra or bladder neck. The bladder and/or urethral mucosa is then repaired with a fine, absorbable suture in a running fashion. The vaginal incision should be closed in several layers, if possible, with an absorbable suture. Depending on the location of the defect within the urinary tract, an interposition graft—such as a Martius, vaginal, or omental flap—can be employed. An indwelling catheter is left in place for prolonged urinary drainage.

An abdominal mesh excision maximizes exposure for a mesh perforation within the bladder dome, wall(s), or trigone. A low midline or Pfannenstiel incision is made, and the space of

Table 16.1 Results of delayed surgical intervention for BOO after anti-incontinence procedures

Investigators	Patients (*n*)	Initial anti-incontinence procedure	Surgical approach	Mean time to intervention (months)	Overall success (%)	Recurrent SUI (%)
Webster and Kreder [29]	15	SP	RP lysis	8	93	13
Scarpero et al. [26]	24	PVS, SP	RP lysis	9	92	18
Petrou and Young [30]	12	MUS, PVS	RP lysis	19	83	18
Petrou et al. [31]	32	PVS, SP	SM lysis	–	67	3
Carr and Webster [32]	54	PVS, SP	RP lysis 65 %	15	78	14
			TV lysis 28 %			
			SM lysis 7 %			
Starkman et al. [33]	40	PVS	TV lysis 90 %	22	82	15
			RP lysis 10 %			
Anger et al. [34]	16	SP	TV lysis 44 %	11	78	11
			RP lysis 56 %	14	43	14
Austin et al. [35]	18	PVS, SP	TV lysis	>6	69	6
Amundsen et al. [36]	32	MUS, PVS	TV lysis 75 %	10	94	13
			TV SI 25 %			
Carey et al. [37]	23	MUS, PVS, SP	TV lysis	14	87	13
Foster and McGuire [38]	48	PVS, SP	TV lysis	26	65	0
Nitti and Raz [39]	42	PVS, SP	TV lysis	54	71	0
Cross et al. [40]	39	PVS, SP	TV lysis	11	72	3
Goldman et al. [41]	32	PVS, SP	TV lysis	14	84	19
McCrery et al. [42]	55	MUS, PVS, SP	TV lysis	34	87	16
Nitti et al. [43]	19	MUS, PVS	TV SI	11	84	17
Abraham et al. [44]	107	MUS:		22	24	49
		TOT 43 %	TV SI 21 %			
		RP 57 %	TV SE 79 %			
Yoost et al. [45]	39	MUS	TV SI	29	63	28

Lysis urethrolysis, *MUS* synthetic midurethral sling, *PVS* pubovaginal (bladder neck) sling, *RP* retropubic, *SE* sling excision, *SI* midline sling incision, *SM* suprameatal, *SP* suspension-type procedures, *TOT* transobturator, *TV* transvaginal

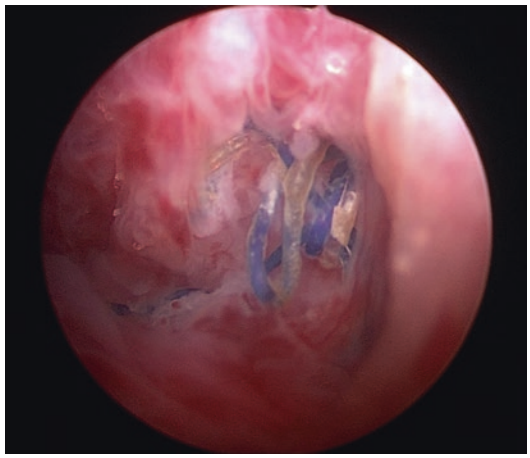

Fig. 16.6 Cystoscopic view of MUS perforation within the urethra

Retzius is adequately developed. A cystotomy may be required to visualize and adequately remove the mesh arm(s) from the bladder mucosa. Care should be taken to observe ureteral efflux as a ureteral neocystotomy may also be required. Once the mesh is completely excised, the cystotomy is repaired with an absorbable suture and closed in multiple layers. Again, prolonged urinary drainage with an indwelling catheter is necessary for healing. A concomitant transvaginal excision may also be required to remove the suburethral component of the sling.

Shah and coworkers described a series of 21 patients with mesh perforation after MUS who underwent a transvaginal or transvaginal/transabdominal mesh excision, urinary tract recon-

struction, and concomitant pubovaginal sling with autologous rectus fascia. Of these, 100 % had complete resolution of their presenting symptoms. All of the patients with mesh perforations of the bladder were continent and 10/14 (71.5 %) with urethral perforations were continent postoperatively [50].

Unrecognized or untreated mesh perforations can lead to fistula formation; fistulae can also develop after attempts to treat prior mesh complications. Blaivas and Mekel reported a series of 10 women who presented with urinary fistulae after MUS placement. Patients presented with SUI (70 %), unaware incontinence (50 %), OAB (40 %), pelvic pain (30 %), and voiding symptoms (20 %). Of these 7/10 underwent a successful fistula repair. A urinary diversion was performed in one patient, while the other 9/10 underwent primary repair with an interposition graft (Martius flap, omental flap, bladder wall flap, or autologous sling) [51]. In this series, the majority of patients had a successful repair, but results can be quite variable.

Long-Term Sequelae

Unfortunately, despite multiple attempts at surgical revision, complications from MUS can be quite morbid. Blaivas and colleagues reported a retrospective review of 47 women with a surgical history of at least one operation to correct MUS complications [52]. With a mean follow-up of 3 years, 72 % of patients had a successful outcome after the first procedure. Of the 13 patients with treatment failure, 9 patients underwent a total of 14 salvage operations. Another study by Hansen and colleagues evaluated 111 patients with vaginal mesh complications. Of these, 37 % were MUS patients (mean 2.4 years prior) presenting to the tertiary care facility for further intervention. Results from the administered, validated questionnaire showed patients commonly reported problems with their "emotional health" or "feeling frustrated" suggesting that these sequelae can significantly impact a patient's quality of life [53]. As such, prior to any procedure for the management of an MUS complication, preoperative counseling should include a thorough discussion of realistic outcomes.

What Every Woman Should Be Told

The Current State of the MUS

The plethora of MUS complications, in addition to those reported from transvaginal mesh (TVM) use in the treatment of POP, led the Food and Drug Administration (FDA) to issue a Public Health Notification in 2008 to inform patients of adverse events related to the use of mesh placed in the urogynecology setting. In 2011, the FDA released a Safety Communication, which reported complications with TVM for POP, but did not include TVM for SUI. Subsequently, in 2013, the FDA updated their recommendations regarding the use of TVM for SUI asserting that the currently marketed, multi-incision, polypropylene MUS are safe and effective with a positive risk-to-benefit profile [54].

Similarly, The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), and the American Urogynecologic Society (AUGS) issued a joint position statement in 2014 strongly supporting the use of polypropylene mesh for the treatment of SUI, maintaining that the MUS procedure is safe, effective, and remains the standard of care for the treatment of SUI [55]. Additionally, the AUA position statement on the use of vaginal mesh for the surgical treatment of SUI states that the restriction of the use of synthetic multi-incision MUS would be a disservice to women who choose surgical correction of SUI [56]. It is noteworthy that patients who present without complaints of mesh-related symptomatology and report no mesh-related complications should not undergo surgical revision unless bothersome symptoms develop [54].

Nevertheless, there has been a plethora of litigation surrounding the placement of mesh for POP and SUI. Legal action has been taken against hospitals, surgeons, and mesh manufacturers [57]. Consequently, it is imperative that physicians provide and document clear, unambiguous informed consent that includes specific mesh-related risks when discussing any procedure involving mesh. The AUA, SUFU, and International Urogynecological Association

(IUGA) all have issued detailed guidelines for consenting patients [55, 56, 58]. Additionally, the FDA published their own guidelines for obtaining informed consent for mesh-related procedures stating: providers should inform patients that (1) implantation of surgical mesh is permanent, and that some complications associated with mesh may require additional surgery that may or may not correct the complication; and (2) there is potential for serious mesh-related complications that can have an effect on quality of life, including dyspareunia, scarring, and vaginal wall narrowing [54]. The FDA strongly advises that providers explicitly state to patients that mesh will be used in surgery and recommends that written information about the specific mesh product be given to the patient.

Conclusions

Urinary tract complications after MUS are not rare. The MUS should be inserted according to the standard guidelines by an experienced surgeon to reduce the incidence of complications. However, if a patient reports persistent or worsening lower urinary tract symptoms, providers should have a high index of suspicion for mesh-related urinary tract sequelae. Unfortunately, these complications such as de novo OAB, BOO, mesh perforation, and fistula formation are not always reversible and can be quite debilitating for patients. Despite the MUS complication profile, the FDA, AUA, SUFU, AUGS, and IUGA all continue to support the MUS for the surgical treatment of SUI.

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Synthetic Midurethral Slings: Exposure and Perforation

17

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Abbreviations

BMI	Body mass index
FSFI	Female Sexual Function Index
IUGA/ICS	International Urogynecological Association/International Continence Society
MUS	Midurethral sling
PFPT	Pelvic floor physical therapy
RCT	Randomized clinical trial
RP	Retropubic
SIS	Single-incision sling
SUI	Stress urinary incontinence
TO	Transobturator
TOMUS	Trial of midurethral slings
TUR	Transurethral resection
TVT	Transvaginal tape

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Introduction

Urinary incontinence is a quality of life condition, and the potential complications of surgical treatment are important to consider due to their impact on surgical decision-making. Since its description by Ulmsten and Petros in 1995, the mesh midurethral sling (MUS) has revolutionized the treatment of stress urinary incontinence (SUI) [1]. Outcomes are excellent, with reported long-term success rates of 43–92% for transobturator and 51–88% for retropubic slings [2]. In the US there has been a near doubling of SUI surgical procedures between 1979 and 1997, and this same trend continued into 2009 [3]. The excellent results, prompt return to normal activities, and low complication rates (Table 17.1) have quickly pushed MUS to the forefront of surgical procedures chosen for SUI treatment. However, sling procedures can result in immediate surgical injury to the vaginal wall, urethra, bladder, or surrounding organs, and the use of mesh introduces the concept of delayed mesh-related complications, like vaginal wall exposure and adjacent organ perforation.

IUGA/ICS published a consensus on mesh complications terminology in 2011 [4]. The generic term of "erosion" should be avoided, as it implies a wearing away by friction or pressure, and it does not represent the clinical presentations encountered. IUGA/ICS instead suggested use of the term *exposure* to represent vaginal mesh that is

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Table 17.1 Reported vaginal wall exposure rates and mesh perforation rates of mesh midurethral sling surgery

	Retropubic	Transobturator	Single incision
Vaginal wall mesh exposure	1.5% [2]	0.4% [2]	Higher than "inside-to-out" TO slings; RR 3.75, 95% CI 1.42 to 9.86 [5]
Bladder injury	2.7–3.9% [2]	0.4% [2]	0.8% [6]
Urethral injury	0.2–0.3% [2]	0.2–0.3% [2]	<4% [5]
Bowel injury	0–0.04% [2]	0% [2]	0.8% [6]

visible or palpable through the separated mucosa at the original vaginal incision site, whereas the term *extrusion* was suggested to represent the delayed process whereby mesh gradually passes through the vaginal wall. However, these definitions were suggested after many reports were already published in the literature, and the events of mesh exposure vs. extrusion can be difficult to distinguish. Therefore, *in this chapter we will use the term mesh exposure to describe mesh that is visible or palpable through the vaginal wall mucosa, whether at the incision site or elsewhere, at any time point. Mesh perforation will describe a delayed event where mesh has entered an adjacent hollow organ, either the urinary tract (urethra or bladder) or the bowel. Trocar injury will refer to the recognized passage of the sling trocar through the vaginal wall, or into the urethra, bladder, or bowel at the time of sling placement.*

The astute reader must be careful to distinguish between the two different types of publications reporting on MUS complications. One group of studies and meta-analyses report complications from index surgeries, and a second group of publications reports symptoms identified in patients referred to a regional center for management of complications. The former are felt to represent "real-world" complication rates, whereas the latter are affected by selection bias, because patients referred to these institutions have more complicated sling problems requiring expert management.

Midurethral Sling Surgery Uses Less Vaginal Dissection

All MUS procedures, including retropubic (RP), transobturator (TO), or single-incision slings (SIS), are "tension free." They provide support under the hypermobile urethra only during times of increased abdominal pressure, leading to "dynamic kinking" of the urethra which prevents leakage of urine. The transvaginal tape (TVT) was the first midurethral sling [1], and it requires a less extensive dissection than the traditional fascial pubovaginal sling. The traditional pubovaginal sling dissection requires a wide vaginal incision and subsequent periurethral mobilization to permit passage of the surgeon's finger (not just a narrow trocar) into the retropubic space. This allows for controlled guidance of the sling passage needle from the suprapubic incision onto the surgeon's finger as it is passed behind the pubic bone and delivered through the vaginal incision. Precise control of the needle minimizes the chance of inadvertent bladder injury. In contrast, the TVT is a trocar-based device that places a piece of mesh tape retropubically through a limited vaginal incision and exits through a small suprapubic skin incision. The vaginal-to-suprapubic trocar passage is also called the "bottom-up" approach. The TVT procedure introduced "blind" passage of the trocar through the retropubic space, as it is not passed directly on the surgeon's finger. This blind passage resulted in increased bladder and bowel injury, and by 2001, these complications helped to promote the development of the TO sling. The TO sling follows a lateral vector, the natural curve of the vaginal wall, to pass the sling through the obturator fossa, which allows it to avoid the blind retropubic pass [7]. With subsequent development of the "top-down" retropubic sling in 2001 and then the "inside-out" transobturator sling in 2003, four different methods of placing a MUS were available (RP: "bottom-up" and "top-down"; TO: "inside-out" and "outside-in"), each with its own benefits and complication profiles, secondary to their different vectors of passage.

The SIS sling was FDA approved in 2006. It was designed to have the benefits of lateral vector passage, like a TO sling, but to avoid passage through the adductor muscle complex of the thigh, which is associated with rare pain complications.

This chapter will review MUS complications and their management, with a specific emphasis on two main concepts:

1. Mesh exposure, defined as exposed mesh visible or palpable through the full-thickness vaginal wall at either the incision site or a separate site. These may be early or delayed.
2. Mesh perforation, very early presentation may represent a technical error of sling trocar placement through the urethra, bladder, or bowel, and when delayed, it may represent more patient-specific tissue healing factors. While these complications are uncommon overall, a clear understanding of the sling-specific and patient-specific risk factors and the utility of prompt diagnosis and appropriate treatment are critical for the pelvic reconstructive surgeon.

Mesh Exposure

Mesh exposure, defined as exposed mesh visible or palpable through the full-thickness vaginal wall, is rare after midurethral sling, occurring in 0–4.4% of patients [8–15]. Mesh exposure occurs secondary to a combination of patient and technical factors. Patient factors include body habitus, poor tissue ingrowth, and poor wound healing. Technical factors include folding or wrinkling of the sling, sling tension, sling material properties, and iatrogenic vaginal wall injury [13, 16]. While increasing age is not a risk factor for mesh exposure [17], younger age is a risk factor for the need for surgical intervention for vaginal mesh exposure, with women 18–39 years old at the highest risk [18]. Younger women may be more sexually active, experience vaginal spotting, dyspareunia, or partner dyspareunia, which prompts evaluation and secondary surgery [18].

Synthetic slings behave differently than autologous, allograft, and xenograft slings. The polypropylene mesh sling is a permanent foreign body that may expose the patient to long-term complications. Biomechanical properties of the sling material play a crucial role in vaginal mesh exposure. Although various materials have been used for sling surgery, the literature strongly supports the use of the Amid Classification Type I mesh, a macroporous weaved monofilament polypropylene mesh [19]. Type I mesh has a large pore size that allows for tissue ingrowth and incorporation into the surrounding tissue, which minimizes sling encapsulation and infection [20, 21]. Historical use of nontype I mesh products, with their smaller pore size, resulted in poor tissue incorporation into the mesh, more encapsulation, and subsequently higher rates of vaginal mesh infection and exposure. Examples include ObTape® (Mentor Corp, Santa Barbara, CA, USA) and Uratape® (Mentor Corp, Santa Barbara, CA, USA), with reported mesh exposure rates of 19% and 12%, respectively [16, 22].

Mesh Exposure Reflects the RP and TO Vectors of Placement

Vector differences when passing the RP and TO sling trocars are directly related to the different rates and locations of vaginal wall mesh exposure. The increased incidence of mesh exposure with TO slings reflects the "smile" sling vector traveling from the midurethra, coursing laterally along the anterior vaginal wall, and passing toward the obturator foramen. At the lateral vaginal sulcus there is a potential for thinning of the vaginal wall, either due to individual patient anatomy or to surgeon dissection, and this may lead to mesh exposure. The RP sling has a "U" vector, which travels underneath the urethra, then directly behind the pubic bone. It does not travel laterally along the anterior vaginal wall. RP slings have a lower rate of mesh exposure than TO slings because passage of the RP sling avoids the lateral vaginal sulci [23, 24]. Mesh exposure

after a RP sling most commonly occurs in the midline at the incision site.

Both RP and TO slings have two different entry points and trajectories: either from the vaginal incision to the outside skin ("bottom-up" RP sling and "inside-out" TO sling) or from the outside skin to the vaginal incision ("top-down" RP sling and "outside-in" TO sling). Because each courses laterally, both TO approaches still carry the risk of vaginal perforation at the lateral vaginal sulcus. In 341 women who underwent TO sling, Abdel-Fattah and colleagues reported an increased risk of vaginal wall mesh exposure with the "outside-in" technique. Only 3 of 20 lateral sulcus injuries occurred after "inside-out" TO slings versus 17 of 20 after "outside-in" TO slings ($p = 0.001$) [25]. Similar results were noted by But in 2008 [26]. The reason for the increased exposure rate with the "outside-in" approach may be due to the additional dissection required to allow a finger to receive the TO trocar at the pubic bone. It may also be secondary to the relative lack of three-dimensional orientation when receiving the sling trocar entering from the groin crease. This is in contrast with the "inside-out" technique, in which the surgeon places the trocar in a precise and controlled position under direct vision relative to the vaginal wall and urethra.

The single-incision sling—or "mini-sling"—follows the same vector as the TO sling; however, due to its shorter length, it only reaches to the obturator internus membrane. Because it has a similar lateral vector of passage along the anterior vaginal wall as the TO sling, SIS have a rate of mesh exposure of 1.3% (95% CI 0.8–1.9), comparable to the TO sling [27].

In a 2014 meta-analysis, the rate of vaginal wall perforation by TO sling was 2.8% (95% CI 2.2–3.5%), whereas the rate of vaginal wall perforation by the RP sling was 0.73% (95% CI 0.40–1.2%) [27]. The Trial of Midurethral Slings (TOMUS), a high-quality multicenter RCT of 597 women, reported that the recognized vaginal wall trocar or perforation rate at the time of surgery was 4.4% with TO sling and 2% with RP sling, and the mesh exposure rates on follow-up were 1.3% with TO sling and 0.7% with RP sling [15].

Surgical Tips to Minimize the Risk of Vaginal Wall Mesh Exposure

Optimal vaginal wall thickness during dissection is essential to avoid urethral or vaginal wall thinning and to minimize vaginal wall trocar perforation. Hydrodissection is performed prior to incision with 10 cc of saline at the midurethra, and hydrodissection may be performed laterally to the vaginal sulcus for the TO sling. This hydrodissection creates a submucosal space that can facilitate the creation of the optimal plane. We place the vaginal wall over the midurethra on tension using a toothed forceps to help the 18-gauge injection needle find a surgical plane at an appropriate depth. Early vaginal wall blanching means the injection is too superficial, and lack of an obvious injection bleb means the hydrodissection is too deep. Direct visualization and palpation of the sling trocar trajectory during all phases of passage are critical to inform the surgeon of vaginal wall thickness.

If inadvertent perforation of the lateral vaginal mucosa is noted, a new deeper access for the sling trocar is created using Metzenbaum scissors, and the sling trocar is repassed into the new path with thicker vaginal wall coverage. The vaginal wall perforation should be closed with an absorbable suture. In TOMUS, perforation of the vaginal epithelium managed by operative repair and replacement of the sling led to no short- or long-term complications at 2 years [15].

Another potential risk factor for mesh exposure is postoperative formation of a vaginal wall hematoma. The hematoma may either cause incisional pressure, resulting in reopening of the incision, or it may cause mucosal separation with mesh exposure as the hematoma liquefies and drains. Good mucosal closure may minimize delayed mucosal separation, and if the vaginal dissection has caused more bleeding than normal, some surgeons will try to minimize the vaginal wall hematoma by placing a vaginal pack that is removed in the recovery room after 1–2 h.

See Box 17.1 for key points for prevention and management of vaginal wall perforation.

Box 17.1 Key Points: Prevention and Management of Vaginal Wall Perforation

- Prevention
  - Adequate hydrodissection
    - Transobturator sling, hydrodissection laterally to sulcus
  - Confirm vaginal wall thickness by palpation
- Management
  - Identification is key
  - Remove trocar, create deeper plane, beware of urethra, replace trocar
  - Close vaginal wall injury with 3–0 Vicryl

Clinical Presentation of Vaginal Wall Mesh Exposure

Vaginal wall mesh exposure may be early or delayed and has a variety of presentations. A patient may be asymptomatic, with the sling visible or palpable only on physical examination. The symptomatic patient may have vaginal spotting or discharge, vaginal pain, dyspareunia, and/or partner dyspareunia. Because symptoms can be nonspecific, one must have a high index of suspicion with any postoperative sling patient.

Symptoms may begin within a few weeks to a few months after the procedure. Osborn and colleagues found that patients who had mesh exposure presented at a median of 6 months from the time of their initial surgery [28]. The most common symptom was vaginal bleeding (20/50 women), reported as intermittent spotting increasing after intercourse. Vaginal discharge was reported in 3/50, 18/50 had dyspareunia, and 20/50 women had vaginal pain. Kokanali reported the most common presenting symptom of vaginal wall mesh exposure was the patient feeling the mesh on self-examination [29]. In the authors' experience, when patients report vaginal pain or dyspareunia, we are also concerned that the sling may be too tight and are careful to evaluate for evidence of pelvic floor muscle dysfunction/spasm.

According to a 2013 review of 188,454 index patients who underwent midurethral sling placement, the risk of surgical removal or revision due to mesh exposure increases throughout the first 4 years after surgery, from 1.3% at 1 year to 2.1% at 4 years postoperatively. After that time, the rate of surgical intervention for mesh exposure remains around 2.5% [18]. These findings are consistent with the 5-year results from the Trial of Midurethral Slings (TOMUS), which reported a 1.7% rate of mesh exposure [30].

The RP MUS has been extensively studied, with average follow-up greater than 10 years in several publications. These studies inform the clinician that there is a continued, but small, risk for vaginal mesh exposure. In the Nordic study, only one of 46 women who did not have mesh exposure at 7 years and returned for the 17-year physical examination had mesh exposure [31]. Similarly, Svenningsen reported 0.6% mesh exposure rate at mean follow-up of almost 11 years [32]. The longest published TO sling follow-up study reported 2/61 women had vaginal mesh exposure at 5 years, and, importantly, both were recognized on the 1 year exam [33].

Clinical Evaluation of Mesh Exposure

A thorough pelvic examination is typically adequate to diagnose vaginal mesh exposure. Careful visual inspection of the entire anterior vaginal wall and the lateral sulcus should be methodically performed, making special note of the location of the vaginal wall incision. The urethra should then be methodically palpated, beginning in the midline and extending laterally to each sulcus, feeling for a lateral exposure. Careful examination of the lateral vaginal fornices is particularly important after a TO or SIS. Mesh may not readily be visualized but may only be palpated as a grainy, superficial structure, sometimes with a sharp edge.

Inspection and palpation of the suprapubic and bilateral lower quadrants and each groin crease should also be performed, looking for any evidence of early or delayed wound issues, such as tenderness, inflammatory changes, drainage,

or a potential fistula tract. In the patient who is difficult to examine, vaginoscopy with a cystoscope, with manual compression of the labia to permit filling of the vagina, may allow visualization of mesh exposure, though this technique is more commonly used to look for proximal vaginal wall mesh exposure after prolapse surgery.

Management of Vaginal Wall Mesh Exposure

Once exposed vaginal mesh is recognized, there are multiple appropriate treatment strategies based on the patient's quality of life and expectations. If the patient is asymptomatic, particularly if she is not sexually active, observation may be appropriate. While addition of vaginal estrogen is commonplace, a paucity of literature exists demonstrating the efficacy of estrogen replacement therapy for complete regrowth of the vaginal epithelium over the exposed mesh. In 2009 Higgins and colleagues evaluated the effect of vaginal estrogen in an ovariectomized rabbit vagina model with mesh implantation. Estrogen supplementation did show some beneficial effects, including reversal of vaginal atrophy and increased deposition of collagen into the mesh [34]. In the authors' experience, vaginal estrogen can make the mucosa more vascular and healthy, as well as reduce the size of the exposure, but *very rarely* will it result in complete coverage of the mesh exposure.

Type I mesh allows for excellent tissue ingrowth and typically remains uninfected even when exposed. Thus, exposed mesh that is well incorporated can be left intact and re-covered with vaginal epithelium with minimal risk of infection. However, if the mesh has folds, wrinkles, or any ridges, excision and revision may be necessary to reduce the risk of repeat exposure. Some older nontype I mesh slings may be found free floating without any tissue incorporation (Fig. 17.1) and sometimes with obvious infection. These slings need to be excised until healthy tissue is seen investing and surrounding the sling. In the authors' practice, complete sling removal is not commonly needed unless the sling is clearly not incorporated into the tissue, suggesting possible infection, which is an unusual finding with type I mesh. More extensive mesh removal along the course of the vaginal wall may be considered if the initial attempt at mesh trimming and vaginal mucosal flap coverage has failed. However, extensive retropubic, obturator, or groin dissection to remove all portions of the sling is typically unnecessary. In the case reports of these extensive procedures, very specific indications were present.

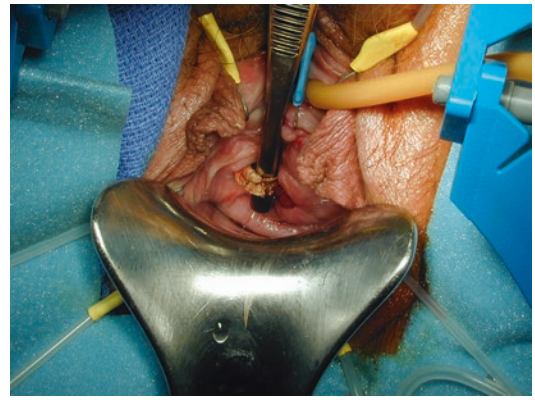

Fig. 17.1 Midurethral sling mesh exposure through vaginal wall. Note this nontype I mesh is not well incorporated and is free floating with calcifications. The mesh will need to be resected back to where it is well incorporated into the tissue

If a patient is symptomatic from her mesh exposure, operative intervention is reasonable. Location of the procedure—whether in the office or in the operating room—is dependent on surgeon experience, the patient's tolerance, and the size and location of the exposure. Myers and coworkers successfully managed small exposures less than 5 mm via an office-based excision, while exposures 6 mm to 1 cm were managed in the operating room [35]. Small midline exposures may be managed in the office by experienced surgeons. Local anesthetic is infiltrated around the exposure, and an incision is made from the mesh exposure into the surrounding healthy tissue. If significant inflammatory or granulation tissue is present, an elliptical excision of the granulated vaginal mucosal edge may be needed to expose healthy tissue that can then be mobilized. Once the extent of the exposure is clarified, and healthy

vaginal wall exposed, dissection superficial to the mesh but under the vaginal mucosa helps to create mobile vaginal wall flaps to provide tension-free coverage of the exposed mesh. The Finnish nationwide review reported that 10/1455 MUS procedures had mesh exposure [9]. Three of these patients were managed without surgical intervention, four patients had the mesh re-covered with mobilized vaginal mucosa, and two patients required partial mesh excision. In this cohort, continence was maintained in all patients, regardless of the management.

Mesh excision can improve sexual function. In Kuhn and coworkers, the sexual function in women with MUS mesh exposure was evaluated pre- and postoperatively with the Female Sexual Function Index [FSFI] [36]. Of 21 exposures, 18 had mesh re-coverage with vaginal mucosa. Two patients had recurrent exposure, one had repeat vaginal closure, and the other had partial sling excision and vaginal closure. Importantly, FSFI domains of desire, arousal, lubrication, satisfaction, and pain improved significantly.

The authors recommend leaving well-incorporated exposed mesh in situ and covering it with vaginal epithelium. An absorbable suture, such as a 3–0 VICRYL® (Ethicon, Somerville, NJ, USA), is used to close the mobilized vaginal wall in a tension-free manner. The patient should abstain from intercourse or tampon use for several weeks to permit healing. If the patient has a large exposure (>1 cm), exposure at the lateral vaginal sulcus, or if surgeon comfort dictates, we prefer surgical management in the operating room with better retraction and exposure. Removal of a portion of the sling can be performed if indicated. The patient should be counseled on the risks and benefits of removing or covering only the exposed mesh versus excision of a larger section of the sling. It is important to recognize that removal of a large section of the sling does risk injury to the urethra and recurrence of stress incontinence. If a large section of a RP sling is to be removed, the sling can be incised and dissected lateral to the urethra behind the pubic bone. Chasing the RP sling into the retropubic space is done only with bladder or other adjacent organ injury that demands a more aggressive approach. Because it requires extensive dissection behind the pubic bone, which is difficult to perform vaginally, complete removal of a RP sling from the retropubic space usually requires a concurrent open or laparoscopic/robotic approach. Similarly, the TO sling can be traced laterally behind the pubic bone to its path through the obturator internus muscle. Removing the TO sling from the obturator fossa or groin crease/adductor muscles should only be done in the rare patient who has significant symptoms such as pelvic floor muscle or adductor muscle pain. Dissection past the obturator internus from the vaginal approach can be difficult and may be associated with bleeding that is difficult to control. Therefore, if complete removal is indicated, a groin crease or medial thigh counter incision may be needed. SIS sling removal is similar to the vaginal approach of TO sling removal.

See Box 17.2 for key points for management of vaginal mesh exposure.

Box 17.2 Key Points: Management of Vaginal Mesh Exposure

- Asymptomatic and not sexually active: consider observation
- Symptomatic
  - Exam
    - Confirm location
    - Identify all exposed mesh
  - Surgical intervention
    - Resection
      - Remove inflamed mucosa surrounding exposed mesh
      - Remove wrinkled, folded, or prominent mesh
      - Remove “free-floating” poorly incorporated mesh
    - Closure
      - Mobilize vaginal wall to allow tension-free closure
      - Close with 3–0 SAS

Mesh Perforation: Adjacent Organs

Bladder

Bladder Injury Is Higher with the RP Sling

Bladder perforation is more common with RP slings due to the blind pass and trajectory of the retropubic trocar behind the pubic bone. Most current literature describes bladder trocar injury at the time of the index surgery. A 2015 meta-analysis reported a 3.2% rate of bladder perforation with RP sling, significantly higher than the TO sling rate of 0.2% (OR 5.72, CI 2.94–11.12, $p < 0.0001$) [37]. The TOMUS trial, which consisted of high volume fellowship-trained surgeons practicing at teaching institutions, reported a 5% rate of bladder perforation and 1% urethral perforation rate with the RP sling compared to 0% bladder and 0% urethral perforation with the TO sling [15]. The rate of bladder or urethral trocar injury with TO surgery in other randomized studies is reported between 0 and 1.3% [15, 38]. Interestingly, Tamussino reported 9/10 bladder injuries occurred with the "outside-in" TO trocar technique [39].

Several risk factors are associated with bladder perforation. First, as with any procedure, there is a learning curve, so proper training and surgeon experience are important. Stav and coworkers reported that 32/34 (94%) bladder perforations were by surgeons who had performed fewer than 50 slings ($p < 0.0001$). All but one of these perforations was by a RP sling, and the route of trocar insertion ("top-down" or "bottom-up") did not affect risk [40]. History of prior abdominal or pelvic surgery that may scar the retropubic space can increase the risk of bladder perforation, including colposuspension, cesarean section, or prior anti-incontinence surgery. Diabetes mellitus is a medical comorbidity that may increase the risk of bladder perforation. Chen noted an increased risk of mesh perforation into the bladder in diabetic patients, possibly related to their poor wound healing abilities [41]. Interestingly several series have reported decreased rates of bladder perforations with RP slings in patients with BMI > 30 kg/m^2 [40, 42, 43]. The protective mechanism may be that the retropubic fat pushes the bladder away from the pubic bone, shielding the bladder from the trocar.

Prevention of Bladder Injury

To minimize risk of bladder perforation, the bladder must have an indwelling foley catheter and be empty prior to sling placement. Ulmsten's original paper on the RP sling describes hydrodissection behind the pubic bone by injecting 60–70 cc of local anesthesia through a spinal needle suprapubically on the left and right sides [1]. When placing a RP sling we will inject 20 cc of saline through a spinal needle behind the pubic bone on both the right and left side to hydrodissect the retropubic space and help push the bladder away from the pubic bone. Careful technique is then required to pass the curved trocar directly behind the bone, keeping the tip of the trocar directly against the bone as a guide, regardless if the approach chosen is "top-down" or "bottom-up."

Finding a Bladder Injury

The AUA states that cystoscopy should be considered a standard component of any surgical implantation of a sling [44]. Intraoperative bladder perforation is most reliably recognized with cystoscopy. If bladder injury is recognized at the time of cystoscopy, management consists of trocar replacement and repeat cystoscopy to confirm the proper location. When using a rigid cystoscope it is important to use a 70° lens and have a reasonably full bladder to reduce the risk of a bladder fold that may hide a bladder injury. Of note, Cetinel and coworkers reported normal cystoscopy in two patients with bladder perforation. In those cases, the trocars were removed and cystoscopy fluid began to leak from the suprapubic incisions [45]. In the series by Zyczynski et al., patients who sustained trocar bladder injury that was recognized cystoscopically at the time of retropubic MUS underwent sling removal and replacement at the time of the index surgery. They found that trocar injury was not associated with overall success, voiding dysfunction, recurrent urinary tract infection, or urge urinary incontinence [46]. No study has shown a link between

recognized bladder trocar injury and postoperative bleeding, hematoma, or subsequent mesh perforation into the bladder or urethra. Thus, in patients with inadvertent bladder perforation, which is recognized and corrected at the index surgery, both the surgeon and the patient can be reassured that there are no long-term sequelae.

Management of Mesh Perforation of the Bladder

Patients who present at a later date with a bladder perforation most commonly sustained an unrecognized trocar perforation at the time of index surgery. They may present at any time after the index surgery with a variable symptomatology, including irritative voiding symptoms, recurrent urinary tract infection, bladder stones, or hematuria. Unlike asymptomatic vaginal wall mesh exposure, mesh perforation of the bladder should not be observed. As with any other foreign body in the bladder, the mesh can encrust, leading to stone formation (Fig. 17.2).

Small areas of bladder mesh may be managed with endoscopic techniques, including endoscopic scissors, TUR, and holmium laser ablation. However, a separate abdominal, laparoscopic, or robotic approach to the retropubic space is often necessary to completely remove all mesh. Oh and coworkers reported successful deep TUR of transvesical mesh, with excision into the perivesical fat, in 13/14 patients with an 18-month follow-up [47]. Holmium laser excision of transvesical mesh has been reported by several authors [48, 49]. We would consider endoscopic removal of mesh only in cases with a small amount of mesh in the bladder and prefer open surgical removal for a definitive single operation.

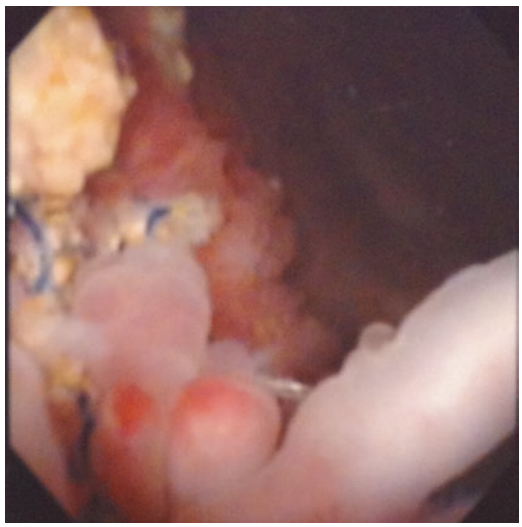

Fig. 17.2 Cystoscopic view of midurethral sling mesh perforation just inside the bladder, below the trigone (though ureteral orifices not seen in photo), with stones that have encrusted the mesh

The open approach for removing mesh perforating the bladder can be vaginal or abdominal (either open, laparoscopic, or robotic). Mesh perforating the bladder below the trigone is often accessible via a transvaginal approach. Supratrigonal perforations may require an abdominal approach. Cystoscopy is important to assess the proximity of the ureteral orifices to the perforation and to help guide the surgical approach. If the mesh perforation incorporates the ureteral orifice, or is within 5–10 mm, the patient may need an abdominal approach as well as a ureteral reimplant. During abdominal approach for mesh perforation, it may be necessary to open the bladder for exposure and to assure complete mesh removal (Fig. 17.3). This approach also permits placement of additional tissue for coverage, such as omentum, per the surgeon's discretion.

When using a vaginal approach, an inverted U-shaped incision exposes the urethra, bladder neck, and floor to permit removal all of the mesh within or near the bladder, which is the primary surgical goal. The mesh is identified and traced to the site of the bladder perforation. Complete sling removal will require a cystotomy, but usually the entire sling does not need to be removed. After careful closure of the cystotomy, the surgeon may use a Martius or other flap for additional coverage. Another advantage of the inverted U-shaped incision is that closure avoids overlapping suture lines, helping to minimize the risk of vesicovaginal fistula.

See Box 17.3 for key points for management of bladder trocar injury.

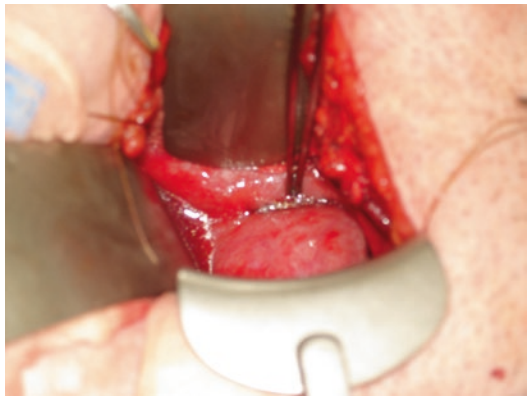

Fig. 17.3 Abdominal approach to supratrigonal mesh perforation of the bladder. The bladder has been opened for exposure. Careful evaluation of the ureteral orifices is required

Box 17.3 Key Points: Management of Bladder Trocar Injury

- Prevention
  - Confirm empty bladder
  - Hydrodissection of retropubic space
  - Careful technique to hug pubic bone with RP trocar
- Identification
  - Careful cystourethroscopy
    - Look for hematuria/clot
    - Fill bladder completely—folds can hide mesh
- Management
  - Immediate recognition
    - Remove, replace trocar
    - Repeat cystoscopy to confirm placement
    - Foley per surgeon discretion
  - Delayed recognition
    - Location/access guides approach
      - Above trigone/through trigone
        - Evaluate proximity to ureteral orifices
        - May require combined vaginal/abdominal approach
          - Ureteral reimplantation?
      - Below the trigone
        - Vaginal approach with inverted U-shaped incision
        - Follow mesh into bladder/cystotomy
        - Widely resect mesh
        - Close cystotomy

Urethra

Urethral Injury Is Less Common But Can Be More Complex

Urethral injuries are uncommon, occurring in 0.2–0.3% of MUS surgeries [40, 50]. The urethra can be injured during dissection or trocar placement, or delayed mesh perforation can occur secondary to technical factors or tissue characteristics. Patient factors that increase the risk of urethral perforation include previous surgery with scarring, any condition causing poor vascularity, including a history of radiation, estrogen deficiency, or urethral atrophy. Technical factors predisposing to delayed urethral perforation include over tensioning of the sling, dissecting too deeply into the urethral wall, of placement of the sling trocar partially through the urethral wall at the time of surgery. Importantly, urethral dilation postoperatively to loosen an obstructive sling is not only ineffective at relieving obstruction but has also been reported to cause urethral perforation [7].

Prevention of Urethral Injury

The same surgical technique described to minimize vaginal wall mesh exposure also protects against urethral injury. The bladder is emptied with an indwelling foley catheter. Midurethral hydrodissection is performed with 10 cc of saline. For the TO sling, hydrodissection also can be performed laterally to the vaginal sulcus. A toothed forceps is used to tension the vaginal wall over the midurethra, permitting easy entry of the 18-gauge injection needle into the proper surgical plane at an appropriate depth. Early vaginal wall blanching means the injection is too superficial; lack of an injection bleb indicates the hydrodissection is too deep. Hydrodissection

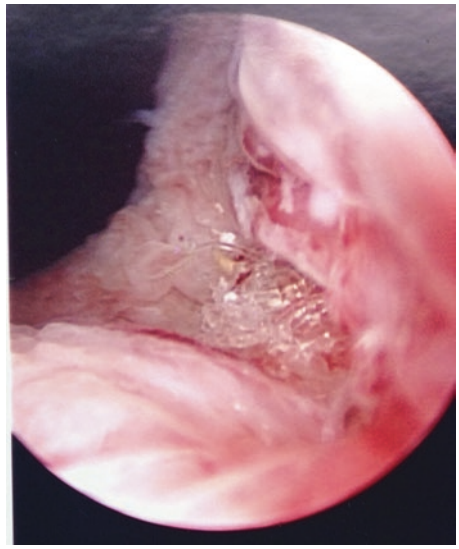

Fig. 17.4 Cystoscopic view of midurethral sling mesh at the proximal urethra. This location is amenable to open transvaginal excision with primary urethral repair

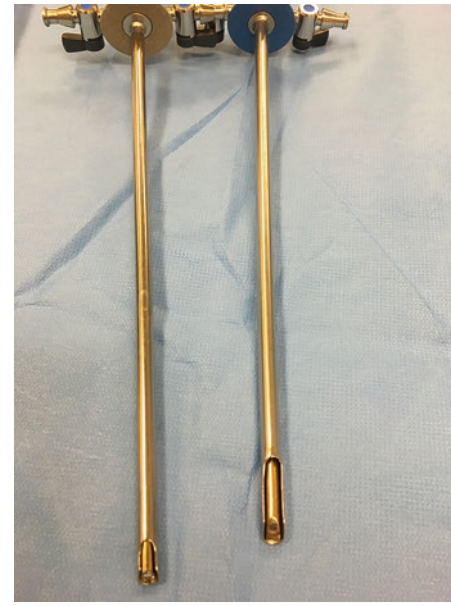

Fig. 17.5 Short-beaked 17-French "female" cystoscope sheath, seen on the left, compared to standard rigid cystoscope sheath on the right. The short "beak" allows fluid flow closer to the lens, allowing excellent distension and careful inspection of the shorter female urethra

creates a submucosal plane that helps to find proper vaginal wall thickness and avoids urethral thinning or injury. Direct visualization and palpation of the sling trocar trajectory with frequent palpation of the urethra (via palpation of the indwelling urethral catheter) informs the surgeon of proper urethral wall thickness during all phases of trocar passage.

Finding a Urethral Injury

Urethral mesh perforation is diagnosed with cystourethroscopy (Fig. 17.4). Flexible cystoscopy or the short-beaked 17-French "female" rigid cystoscope sheath is used (Fig. 17.5). The shorter length of this rigid cystoscope sheath permits fluid flow and urethral distention very close to the lens, which allows the surgeon to more carefully inspect the shorter female urethra. Unlike bladder or vaginal injury at the time of the initial surgery, if urethral injury is recognized at the time of index surgery, proper management includes sling removal and urethral repair. The primary surgeon must also decide at that time whether to proceed with concomitant sling placement. Depending on the extent of injury and patient characteristics, it may be appropriate to abort the surgery and to allow for complete healing prior to another SUI procedure.

Delayed urethral mesh perforation may present with a variety of nonspecific voiding symptoms. Sergouniotis reported that 77% of patients presented with de novo urgency [51], whereas Velemir reported the most common presenting symptom was obstructed voiding [52]. Other less specific symptoms that may indicate urethral injury include recurrent urinary tract infection, urinary retention, recurrent incontinence or hematuria. Less commonly the patient presents with continuous incontinence, indicating an urethrovaginal fistula. Timing of presentation is variable. Amundsen reported the diagnosis is typically made within 1 year of surgery, with a mean time from surgery to symptoms of 9 months [53], whereas, in Hammad and colleagues, 30% of the urethral injuries were diagnosed more than 1 year after index surgery [54].

Management of Urethral Mesh Perforation

Management options for delayed urethral perforation include a variety of endoscopic techniques or open transvaginal excision. The authors prefer transvaginal surgical excision as a first-line treatment. However, the literature also supports

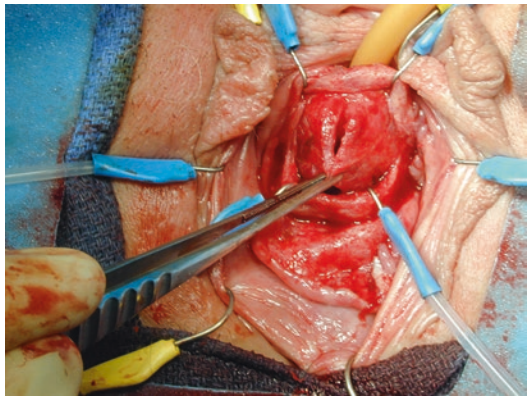

Fig. 17.6 Urethrotomy after urethral perforation and mesh removal. Forceps are approximating the longitudinal urethral wall opening that will be closed vertically, the periurethral fascia (retracted by blue stays) will be closed transversely, followed by closure of the vaginal wall U-shaped incision, seen lying at the 6-o'clock position. This multilayered closure with nonoverlapping suture lines will minimize the risk of urethrovaginal fistula

endoscopic management as the initial step for a small urethral mesh perforation. Successful endoscopic removal of urethral mesh is not definitive and does not ensure that all mesh is removed. There may be a risk of recurrent urethral mesh perforation that will require additional procedures for removal.

Reported endoscopic techniques include using hysteroscopic scissors through a cystoscope [55], electrosurgical resection, and use of the holmium laser. Jo and colleagues compared transurethral electrosurgical resection to holmium laser in patients with urethral and bladder mesh perforations and saw higher success rates after TUR, but TUR was also associated with subsequent vesicovaginal fistula development [56]. If endoscopic treatment fails, the next step in management of urethral mesh perforation is a transvaginal approach and mesh excision with urethral repair.

An inverted U-shaped incision via an open transvaginal approach provides excellent exposure to the urethra and bladder neck. The goal is to completely remove the mesh from the area of the urethral injury and subsequent repair. Layered closure should avoid overlapping suture lines, minimizing the risk of urethrovaginal fistula (Fig. 17.6). The RP sling is grasped and dissected back behind the pubic bone until it enters the retropubic space. A TO sling should be followed laterally where it courses under the pubic rami. The mesh arms traveling behind the pubic bone or through the obturator foramen are not removed unless there are other special circumstances, such as poorly incorporated mesh suggesting infection. Prior to closure of the vaginal incision, a Martius flap may be used for additional coverage, based on the surgeon's discretion, followed by indwelling urethral catheter drainage for 7–14 days. Some surgeons will place a fascial sling in the same setting to manage potential recurrent SUI.

Box 17.4 Key Points: Management of Delayed Urethral Perforation

- Diagnosis
  - Cystoscopy with short-beaked cystoscope sheath
- Treatment
  - Inverted U-shaped incision
  - Remove mesh from urethra, resect mesh from urethra/bladder location
  - Close urethra with 3–0 or 4–0 SAS
  - Consider use of Martius flap
  - Foley catheter x 7–14 days +/− VCUG

Women with delayed urethral perforation should be counseled extensively on the increased risk of persistent SUI after urethral repair. In Colhoun and colleagues, 4/5 patients reported persistent SUI at a mean of 54 months postoperatively. 2/5 underwent pelvic floor physical therapy (PFPT), 1/5 underwent pubovaginal sling placement, 1/5 underwent both PFPT and pubovaginal sling placement, and 1 remained incontinent and declined any additional intervention [57].

See Box 17.4 for key points for management of delayed urethral perforation.

Bowel

Sling Perforation of the Bowel

Bowel injury during midurethral sling placement is exceedingly rare, reported in 0–0.04% of cases [30, 58, 59]. All reported bowel injuries have occurred after the RP sling, which is intuitive,

considering that the TO sling avoids the pelvic compartment. Typically, bowel injuries occur in patients with a history of prior abdominal or pelvic surgery and adhesions of the bowel to the pelvis. Most commonly the patient presents within hours to several days after surgery with abdominal pain, nausea, vomiting, decreased urine output, other signs of peritonitis, and possibly passage of bowel contents through the suprapubic trocar sites. However, patients can have significantly delayed and atypical presentations. Some patients may not have signs or symptoms of peritonitis at presentation [60], and Elliott reported an asymptomatic patient whose bowel injury was found incidentally [61]. Chelvaratnam and Phillips both describe patients who presented years after their RP sling. One report describes a patient with symptoms of diarrhea and right-sided abdominal pain who was found to have the RP sling perforated into the ascending colon [62]. Another patient presented with a de novo small bowel obstruction whose laparotomy showed that the sling had penetrated the peritoneum and caused inflammation near the terminal ileum, leading to local adhesions and bowel obstruction [63]. Bowel injury in the patient with peritoneal signs may be confirmed with free infra-diaphragmatic air on plain abdominal x-ray. In a patient with a less clear or more insidious clinical course, CT scan of the abdomen and pelvis is appropriate.

Treatment consists of abdominal exploration to remove the mesh and perform bowel repair. While Meschia and Elliott both report laparoscopic management, others prefer laparotomy to evaluate and repair the bowel, irrigate the abdomen, and evacuate spilled bowel contents. The mesh is localized and excised back to the retroperitoneal space, with closure of the peritoneal defect. The injured bowel may require resection and primary repair as per the surgeon's judgment. The patient is managed hemodynamically and placed on broad-spectrum antibiotics.

To prevent potential bowel injury, de Almeida recommend preoperative CT in high-risk patients to permit localization of the bowel and to evaluate for any pelvic adhesions, or one can choose to place a TO instead to avoid the pelvis and any bowel injury [60]. Overall the risk of bowel injury remains low but is an important consideration when choosing which sling procedure to perform in a given patient.

Box 17.5 Key Points for Prevention of Bowel Injury

- Risk factors: prior abdominal or pelvic surgery
- Consider CT abdomen/pelvis
- Surgical technique
  - Choose another approach—TO or SIS instead of RP
  - Hydrodissection of retropubic space
  - Careful technique to hug pubic bone with RP trocar

See Box 17.5 for key points for prevention of bowel injury.

Conclusion

Midurethral mesh slings are the gold standard treatment for surgical management of female stress urinary incontinence. The complications are acceptably low, but the surgeon must be properly trained and maintain a surgical volume to remain competent. MUS surgeons must practice surgical techniques that minimize these complications, and importantly, be able to recognize and manage or refer complications of vaginal wall mesh exposure and adjacent organ injury when encountered.

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Mini-Slings: Unique Issues

18

Dina A. Bastawros and Michael J. Kennelly

Abbreviations

MUS	Midurethral slings
RCT	Randomized control trial
RPS	Retropubic slings
SIMS	Single-incision mini-slings
SUI	Stress urinary incontinence
TOT	Transobturator tape
TVT	Transvaginal tape
UI	Urge incontinence

Editor's Note: At editorial time the TVT-Secur, MiniArc and AJUST slings are no longer being marketed. The landscape and availability of mini-slings is currently shifting given the current medicolegal climate, industry changes, and FDA requirements that mini-slings undergo further clinical testing. However, these "discontinued" products have been placed in many patients, and, thus, it is important for the reconstructive surgeon to be familiar with them all as they may see patients who have had these slings, and in some cases, complications related to these products.

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Introduction

Over the years, synthetic midurethral slings (MUS) have shown to be effective and minimally invasive treatments for stress urinary incontinence (SUI). There have been many studies exploring the efficacy and outcomes of both the retropubic and transobturator approaches, with positive outcomes, making it the most widely used treatment for SUI. However, in recent years, the advent of the single-incision mini-sling (SIMS) poses as an alternative minimally invasive treatment for SUI that may potentially be done in an ambulatory office setting.

The designs of these third-generation synthetic slings are aimed to provide fewer complications. SIMS are shorter in length, usually around 8–10 cm long, as opposed to the 40 cm that most MUS are. Additionally, these slings only require a single vaginal incision. SIMS are anchored just beyond the vagina, thus avoiding blind passage through the retropubic and obturator spaces [1]. Table 18.1 summarizes the various characteristics of SIMS currently available on the market. This chapter will focus on the unique issues associated with single-incision mini-slings.

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Table 18.1 Characteristics of Single-Incision Mini-Slings

	ALTIS™	AJUST™	MiniArc™	MiniArc Precise™	Needleless®	Ophira™	Solyx™ SIS System	TVT-Secur™
Manufacturer	Coloplast (Humlebaek, Denmark)	Bard (Covington, GA)	Astora Women's Health (Eden Prairie, MN)	Astora Women's Health (Eden Prairie, MN)	Neomedic International (Terrasa, Spain)	Promedon (Córdoba, Argentina)	Boston Scientific (Natick, MA)	Ethicon (Somerville, NJ)
Year introduced	2012	2009	2007	2010	2007	2012	2008	2006
Trajectory	Transobturator	Transobturator	Transobturator	Transobturator	Transobturator	Transobturator	Transobturator	Transobturator or retropubic
Fixation point	Obturator membrane	Obturator membrane	Obturator internus muscle	Obturator internus muscle	Obturator internus muscle fascia	Obturator internus muscle	Obturator internus muscle	Obturator internus muscle ("hammock") or urogenital diaphragm ("U")
Fixation tips	Polypropylene anchor	Permanent self-fixating polypropylene anchors	Permanent self-fixating tips	Permanent self-fixating tips that are tapered and reinforced	Pocket positioning. No anchor tips	Multipoint fishbone-like polypropylene tips	Permanent polypropylene carriers	Absorbable 2 cm fixating tips coated with PDS™ and Vicryl™
Tensioning method	Two-way adjustability	Bidirectional independent adjustment	Optional redocking feature	Only by advancement, prior to device release	Bilateral and bidirectional	Only by advancement, prior to device release	Only by advancement, prior to device release	Only by advancement, prior to device release
Intraoperative tightening	Yes (and loosening)	Yes (and loosening)	Yes (optional redocking feature)	Yes (optional redocking feature)	No	No	No	No
Mesh size (cm)	1.1 × 7.75	1.2 × 5	1.1 × 8.5	1.1 × 8.5	1.4 × 12	0.9 × 10.2	9	1.1 × 8
Needle	Two needle introducers	One needle driver and flexible stylet	One needle and driver	One needle and driver	None	One needle and driver	One needle and driver	Two needles and driver
Needle diameter (mm)	–	5	2.3	2.3	–	2.2	3.81	8
Needle disengagement	One step	One step	One step	One step	–	One step	One step	Two step
Midline mark	No	Yes	Yes	Yes	Yes	Yes	No	No
Pull out force (lb)	–	6.56	5.5	5.75	1.9	–	4.64	1.9
Available on the market	Yes	Yes	No—discontinued 4/2016	No—discontinued 4/2016	Yes	Yes	Yes	No—discontinued in 2012

Preoperative Considerations

Many studies and reports indicate that millions of women suffer from SUI, negatively contributing to their quality of life [1–3]. Often, many women with severe SUI have failed conservative measures, including pelvic floor physical therapy, lifestyle modifications, behavioral therapies, and timed voiding [3]. Patients who failed the aforementioned measures and who desire surgical intervention are often appropriate candidates for synthetic sling procedures, including the single-incision mini-sling.

There have been several different types of single-incision mini-slings available on the market (Table 18.1, Figs. 18.1, 18.2, 18.3, 18.4, 18.5, 18.6, and 18.7). Studies exploring the efficacy of the TVT-Secur™ (Ethicon Women's Health and Urology, Somerville, New Jersey, USA) (Fig. 18.1), a third-generation mini-sling, had significantly lower cure rates as perceived by patients compared to retropubic approaches [3]. Of note, TVT-Secur™ is no longer on the market due to voluntary cessation of production by Ethicon. The MiniArc™ Precise Single Incision Sling System (Astora Women's Health, L.L.C., Eden Prairie, Minnesota, USA) (Fig. 18.2) has been shown in a previous study to offer similar cure rates as the transobturator sling approach [4]. (Editor's Note: MiniArc™ is no longer marketed as Astora Women's Health has gone out of business.) Currently, we have 2 years of data on the MiniArc™ sling by Moore and colleagues and Kennelly and colleagues showing comparable outcomes to MUS, with similar subjective and objective improvement rates at 2 years. However,

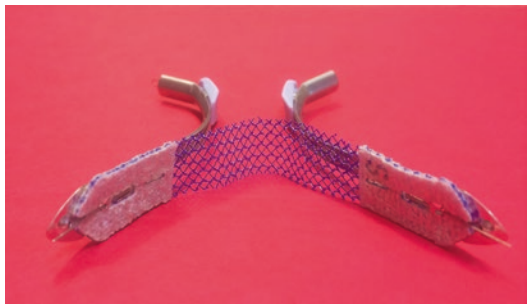

Fig. 18.1 TVT-Secur™. The TVT-Secur's 8.0 × 1.1-cm polypropylene mesh with 2-cm absorbable fixation tips can be placed in either the "U" retropubic trajectory position or the "hammock" transobturator trajectory position (manufactured by Ethicon, Inc., Somerville, New Jersey, USA)

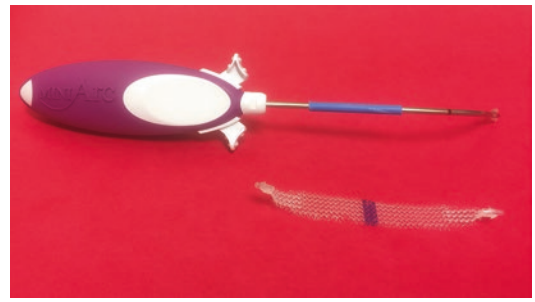

Fig. 18.2 MiniArc Precise™. The MiniArc Precise's 1.1 × 8.5-cm macroporous polypropylene mesh fused to self-fixating tips is placed with a 2.3 mm needle (manufactured by Astora Women's Health, L.L.C., Eden Prairie, Minnesota, USA)

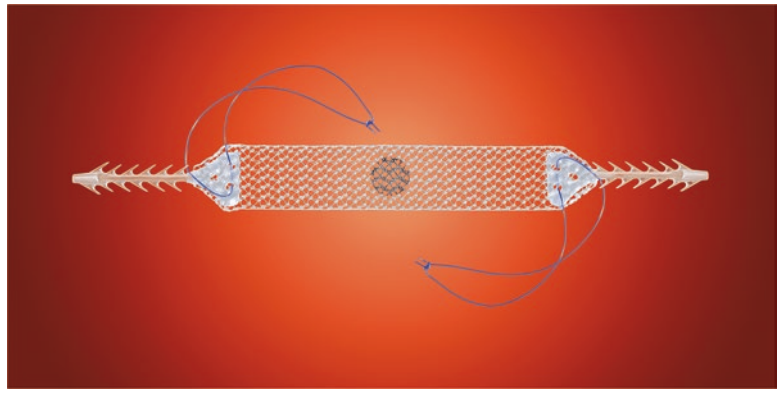

Fig. 18.3 Ophira® Mini Sling. The Ophira Mini Sling System's 0.9 × 10.2-cm polypropylene mesh uses several self-fixating tips placed in the obturator internus membrane with a 2.2 cm needle (manufactured by and image provided courtesy of, Promedon, Cordoba, Argentina)

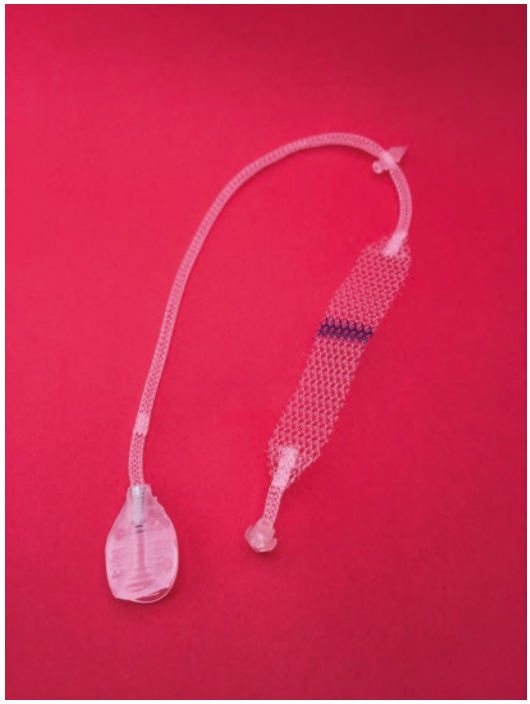

Fig. 18.4 Ajust™ Adjustable Single-Incision Sling. The Ajust 1.2 × 5-cm polypropylene mesh is placed through the obturator membrane with self-fixating anchors. Postinsertion adjustments can be made by loosening or tightening the mesh relative to the fixed anchors (manufactured by C.R. Bard, Inc., Covington, Georgia, USA)

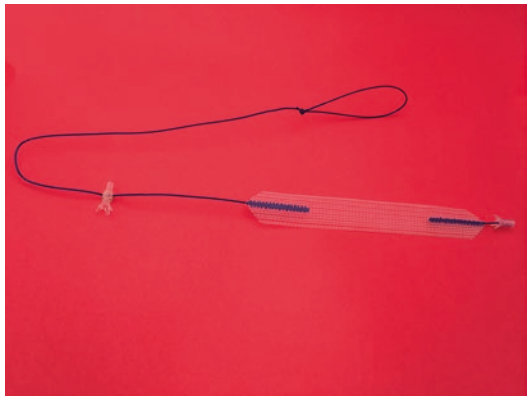

Fig. 18.5 Altis® The Altis's 1.1 × 7.75-cm polypropylene mesh is placed through the obturator membrane with self-fixating anchors. Postinsertion adjustments can be made relative to the fixed anchor (manufactured by Coloplast, Minneapolis, Minnesota, USA)

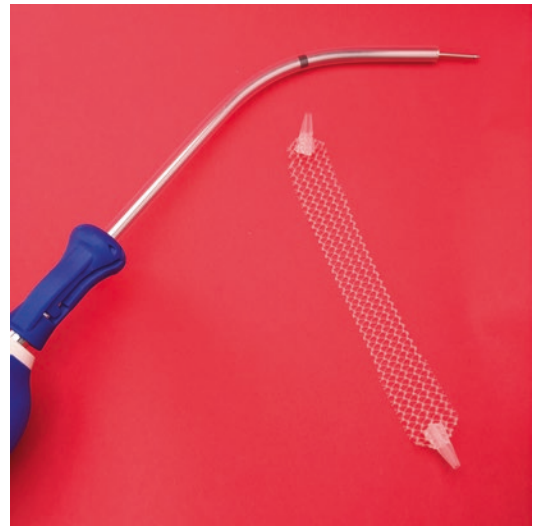

Fig. 18.6 Solyx™ Single Incision System. The Solyx's 9.0 cm polypropylene mesh with fused carrier barbs is placed in the obturator internus muscle with a snap-fit delivery device (manufactured by Boston Scientific Corporation, Natick, Massachusetts, USA)

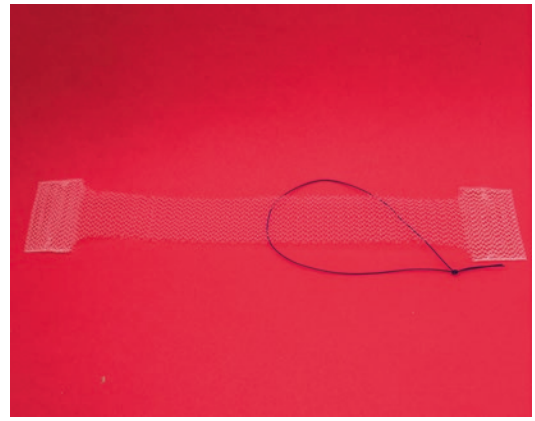

Fig. 18.7 Needleless® System. The Needleless 1.4 × 12-cm polypropylene mesh is placed in the obturator internus fascia without any anchor tips (manufactured by Neomedic International, Terrassa, Spain)

there are no long-term data studying the safety and efficacy of SIMS beyond that period [5, 6].

Despite the emerging studies on single-incision mini-slings, the ideal patient is yet to be determined [7]. SIMS have not been on the market as long as other traditional slings, thus it has

been only studied in classic SUI patients. SIMS, however, may not be the best option for patients with severe cases of SUI. A study exploring the Ophira™ Mini Sling System (Promedon, Cordoba, Argentina) (Fig. 18.3), which anchors to the obturator internus muscles on the same plane as the tendinous arc, demonstrated the likely ideal candidate for the Ophira™ Mini Sling System are patients who have never had prior incontinence surgery [8]. Per this study, the best cure rates were witnessed in the cohort without prior surgery (89.6 %), as compared to the cohort with prior incontinence procedures (67.9 %) [8].

Women with conditions that may impair wound healing are not ideal candidates for MUS. This may also hold true for SIMS candidates. Women with a history of tobacco use, diabetes, pelvic radiation therapy or have any other risk factor that may affect surgical recovery are at increased risk for mesh erosions and exposure [9].

Similar to retropubic and transobturator midurethral slings, SIMS have very similar contraindications to placement. Current pregnancy is an absolute contraindication to sling procedures. Women who are of reproductive age should be counseled and certain that they have completed childbearing prior to undergoing incontinence procedures, as pregnancy and delivery disrupt the pelvic floor support [9]. Other contraindications to midurethral synthetic slings include previous or concurrent urethral surgery or injury (e.g., urethrovaginal fistula repair), hypersensitivity or allergy to mesh material, poor vaginal epithelium, any pelvic radiation, urethral diverticulum, and resting severe intrinsic sphincter deficiency (with or without urethral hypermobility) [10].

Urethral hypermobility is another facet that must be closely inspected. Slings are theorized to fulfill their purpose by acting as a 1 cm wide catching net that provides resistance beneath the urethra, leading to compression of the urethra between the sling and the pubic symphysis when intra-abdominal force is present. With this mechanism of action in mind, sling placement should theoretically be more effective in women with hypermobility of the urethra, compared to women with fixed urethras [8, 9, 11]. Typically, preoperative testing showing a maximum Q-tip mobility less than 30° indicates a fixed urethra, thus leading to a 1.9-fold increased risk of sling failure to treat SUI [9, 12].

Akin to MUS candidates, those women that are being considered for a single-incision mini-sling need to also be evaluated for mixed urinary incontinence. It is imperative to treat the urge component prior to SIMS placement. This may be done conservatively or with anticholinergic medications. In some cases, once the urge component is treated, the need for surgical treatment of SUI may be eliminated.

Some studies may suggest that age may also be a factor when deciding on SIMS. The study examining the Ophira™ Mini Sling System, as mentioned earlier, suggests that elderly patients may not benefit as much from this system compared to the younger patient. In this study, women over 60 years old were categorized as elderly. These women had a subjective cure rate of 80.6 %, which was acceptable to the authors [8]. However, many other studies concluded that patients greater than 70 years old resulted in decreased success rates, likely due to poorer tissue integrity [8, 9, 13].

Obesity is a well-studied risk factor for SUI [5]. Moore and colleagues suggests that the MiniArc™ has comparable cure rates in both obese (defined as body mass index greater than 30 kg/m^2) and nonobese patients. This study introduces 2 years of data from a multicenter, prospective trial that demonstrates no difference in improvement rates or complication rates. Although no ideal patient has been defined for SIMS, this study suggests that obesity is likely not an exclusionary trait.

Perioperative Considerations

Single-incision mini-slings were developed with the aim of reducing intraoperative and postoperative complications that may be seen with retropubic and transobturator approaches. These include complications such as retropubic hematoma, groin pain, bladder perforation, infection, bowel perforation, and injury to nerves and vessels [14].

The aim of SIMS is to provide a minimally invasive sling that reduces risk, operative time, postoperative complications, and recovery.

Currently available SIMS are typically placed through a single 1.5 cm anterior vaginal incision at the midurethra in a transobturator direction. The obturator internus muscles or obturator membrane is the fixation point for the transobturator direction SIMS, without passing through the structures within the obturator foramen. Some other SIMS models may also be placed in a retropubic direction with the urogenital diaphragm serving as the fixation point [1, 7, 15].

Single-incision mini-slings may be placed in the operating room under general anesthesia, which comes with its own inherent risks. However, unlike the MUS, SIMS may also be implanted in the office under local anesthesia. Across various studies, operating time for mini-slings ranged anywhere from 7 to 16 min, demonstrating it to be a quick and easy procedure [16, 17]. Local anesthesia, typically lidocaine, is used with this approach. Care must be taken to ensure that the target fixation tissue is not over-infiltrated with local anesthesia, thus negatively affecting the pullout force. The Ophira Mini Sling™ study by Palma reports three patients with lidocaine hydrochloride toxicity, for which they were treated conservatively [8]. No additional studies were encountered that reproduced this adverse effect.

A key intraoperative point with several single-incision mini-slings that anchor in the obturator internus muscle is the inability to confirm tissue placement. During sharp tissue dissection, special care should be taken to avoid penetrating the urogenital diaphragm, obturator internus muscles, and the obturator membrane, as this may decrease the holding ability of the sling anchors. Fixation to tissue with good integrity cannot always be confirmed intraoperatively or tested for integrity. It is theorized that this may be contributory to early failures of single-incision mini-slings, which will be further discussed later in the chapter. Barber and colleagues discuss a high proportion of device malfunction or technical difficulties (8.8 %) with the TVT-Secur™ observed during implantation that ultimately resulted in using a second mini-sling device or alternate sling [2]. Additionally, the MiniArc™ and other SIMS have the reduced capabilities of correction after the self-fixating tips have been deployed in the tissue, leading to possibly ineffective slings.

The AJUST™ Adjustable Single-Incision Sling (C.R. Bard, Inc., Covington, Georgia, USA; Editor's note: The AJUST™ sling no longer marketed) (Fig. 18.4) and ALTIS™ (Coloplast, Minneapolis, Minnesota, USA) (Fig. 18.5) were developed to address the concerns of incorrect anchor placement. With these systems, the anchors are placed through the obturator membrane, rather than surrounding obturator internus muscle or connective tissue [7]. Postinsertion adjustment of the mesh (tightening or loosening) can be performed to achieve optimal placement [7].

There have been documented reports of vaginal wall perforations with the placement of SIMS. Studies have demonstrated this occurrence to be as high as 2 % [11]. In order to avoid this, Taner and coworkers described using the surgeon's index finger as a guide for the delivery trocar through the vaginal incision for the Ophira™ Mini Sling System. Once the surgeon feels the needle at the vaginal fornix, the needle was then directed toward the obturator internus muscle to set up the anchors for deployment [16].

Single-incision mini-slings are purported to reduce the risk of bladder perforation and injury. Although less likely, bladder perforations may still occur with single-incision mini-slings. These patients will typically present with a variety of mild symptoms, including irritable bladder symptoms, SUI, and reduced urine flow. Zivanovic and coworkers describe three case reports in which perforation of the bladder was noted with the TVT-Secur™ [18]. These injuries were noted to be at the base, anterior bladder wall, and lateral walls. Based on their reports, Zivanovic and coworkers recommend routine intraoperative cystoscopy with a 70-degree cystoscope after mini-sling procedures [18]. The manufacturers of TVT-Secur™ also recommend that cystoscopy be performed at the discretion of the surgeon [18]. A Spanish study evaluating the complications of the TVT-Secur™ versus the MiniArc™ also reported one bladder perforation that was treated conservatively with catheteriza-

tion [19]. Coskun and coworkers reported two women with extensive urethral mesh erosions in their study. These women did not undergo intraoperative cystoscopy, suggesting that cystoscopy should be performed after every procedure [20]. However, the risk of bladder injury compared to retropubic sling approaches is theorized to be minimal. Once a bladder perforation is recognized, the sling should not be placed in the same location and alignment in order to avoid further injury [14, 20].

Bleeding and hematomas are known to be a rare, but potentially a life-threatening complication of retropubic slings. Thus, SIMS were developed in an effort to reduce this risk. However, case reports show that single-incision mini-slings are not immune to this complication. O'Boyle and coworkers describe a case report that describes a woman that underwent placement of a TVT-Secur ™ mini-sling, resulting in serious bleeding injury to the corona mortis vessel and internal obturator muscle [21]. Palomba and coworkers presented a study examining three different SIMS systems. This report noted two cases of intraoperative hemorrhage within the TVT-Secur™ group [17]. Most hematomas are a result of venous bleeding. However, arterial bleeds will become more apparent during surgery due to rapid hematoma expansion and a patient that is quickly decompensating. A case reported in the literature by Jung and coworkers describes an internal pudendal artery injury, necessitating interventional radiology to embolize the artery to achieve hemostasis [11, 22]. Intentional bladder distension and vaginal packing are excellent tools for a tamponade effect and are recommended to aid in achieving hemostasis.

Postoperative Considerations

Single-incision mini-slings have been developed and marketed as a feasible and minimally invasive solution for SUI. However, as a third-generation synthetic sling, there are not much in the way of long-term data regarding efficacy and safety of slings in this class. Further research with longitudinal follow-up and prospective studies will continue to add more information regarding the safety and utility of SIMS as a treatment option for SUI.

Failure to Correct SUI

Many early studies comparing single-incision mini-slings initially report conflicting evidence regarding improvement of symptoms in the short and long term, compared to retropubic and transobturator approaches. Basu and Duckett implemented one of the first prospective randomized trials comparing the MiniArc™ single-incision mini-sling (American Medical Systems, Minnetonka, Minnesota, USA) with another sling, the Advantage TVT™ (Boston Scientific, Natick, Massachusetts, USA). In this study, both subjective and objective failure rates at 6 weeks and 6 months were significantly higher (Odds Ratio 9.49 and 8.14, respectively) than in the RPS cohort. From this study, 9 of the 37 patients randomized to the MiniArc™ group subsequently underwent reoperation and placement of a retropubic sling. All the patients in the cohort were cured of their persistent SUI [23]. In a recent meta-analysis by Abdel-Fattah and coworkers, it also demonstrated that single-incision mini-slings are associated with lower objective and patient-reported cure rates in the short-term period [24]. These findings have also been observed in other studies, such as another meta-analysis by Schimpf and colleagues that suggests traditional synthetic midurethral slings significantly maximized cure rates in comparison to single-incision mini-slings [25]. Similarly, the meta-analysis also showed higher reoperation rates for SUI, due to greater severity of SUI [24].

One explanation for the high failure rate is that the anchors of SIMS may not be as strong as more traditional slings, which traverse through more tissue. Prior studies also demonstrated that the obturator internus muscles and the obturator fascia are weak points for anchor fixation for the SIMS. Therefore, the MiniArc™ anchors, for example, should include the fascia, muscle, and membrane in order to ensure higher retention forces [23, 26].

Prior anti-incontinence surgeries were also found to be associated with a higher failure rate to correct SUI. Palma and colleagues demonstrated that this factor was significant in its association with failure. Their Ophira™ study found that the success rate was considerably lower (67.9 %) compared to naïve patients (no prior anti-incontinence surgeries), who had a cure rate of 89.6 % [8]. However, this factor does not seem to be unique to SIMS. A prospective study by Rezapour and Ulmsten evaluated women with recurrent SUI and RPS as a treatment approach. This study demonstrated a cure rate as high as 82 % [27]. Many other studies exploring the success rates of RPS and TOT in women with recurrent SUI reported significantly lower success rates, ranging from 62 to 74 % [8, 28–33]. Long-term studies and data are still needed in order to consider mini-slings as an equivalent option to traditional synthetic midurethral slings.

Recurrence of SUI

There are not many published reports on long-term data regarding the efficacy and cure rates of single-incision mini-slings. Many of the studies looking at the cure rates of SIMS report subjective and objective short-term results as high as 85–91 % across the different types of mini-slings. For example, Kennelly and colleagues study is one of the many studies that describe satisfactory objective success rates, with this particular study's data illustrating an 84.5 % success rate with a negative cough stress test [6]. However, like the other midurethral sling systems, SIMS are not completely immune to complications of recurrent SUI.

Midurethral slings (both RPS and TOT) can be tightened after placement into host tissue. Additionally, these slings also exhibit further retraction, which contributes to the treatment mechanism for SUI. SIMS do not exhibit these characteristics. Upon placement, SIMS typically cannot be adjusted or tightened (except for the AJUST™ and ALTIS™). Therefore, these mini-slings are usually placed very close against the periurethral tissue. This mechanism is thought to decrease postoperative voiding dysfunction and necessity for catheterization. Any change that occurs after SIMS placement is likely the sling loosening over time. As such, some women may begin to experience recurrence of SUI. Basu and Duckett report that their studies showed that mini-slings have higher rates of recurrent or persistent SUI in comparison to RPS [23]. There are no published reports regarding the true incidence of this complication.

De Novo Urge Incontinence

Many patients often present with a picture of mixed urinary incontinence. It has always been advised to treat urge incontinence (UI) prior to stress incontinence in order to prevent worsening UI symptoms. Basu and Duckett described approximately 5 % of mini-slings can result in worsening UI [17]. Other studies report de novo UI in SIMS patients to be as high as 1.5–15.6 % [20]. Comparatively, RPS have been cited in the literature to have approximately 0.8–25.9 % of patients undergoing the procedure experience de novo UI [34].

De novo urge incontinence may be triggered by various characteristics of the mini-sling. Taner and colleagues hypothesize that de novo urge incontinence may actually be due to the position of the mini-sling [16]. SIMS must be positioned under the urethra, nearly abutting it. It is thought that this close proximity of the mesh to the urethra may cause an irritation that leads to UI [16]. Another hypothesis of de novo UI associated with SIMS may be due to its material composition. Mini-slings are made of synthetic, nonabsorbable, and hydrophobic polypropylene mesh. Likely, the mesh irritates the surrounding tissue, leading to de novo UI [16]. Studies looking at the TVT-Secur™ indicate that this no longer marketed mini-sling system actually has a higher de novo UI rate (as much as 10 %) compared to the rate of 4 % found with RPS and TOT systems [11].

Many studies, however, show that there is likely not a difference between the rates of de

novo UI between SIMS and MUS. RPS and TOT slings have approximately a 4 % rate of de novo UI. Mostafa and colleagues suggest no difference in rates of worsening UI or de novo UI between mini-slings and midurethral slings [20, 35]. De Ridder and coworkers also echo this finding after comparing the MiniArc™ to the TOT [17, 36]. Patients that present with de novo UI as a result of SIMS or MUS can be treated with anticholinergic medications with high rates of success.

Voiding Dysfunction

Urinary retention and bladder outlet obstruction are common risks that clinicians must be cognizant of when placing and positioning MUS and SIMS. Retropubic and transobturator approaches boast a "tension-free" configuration. If these MUS are placed too tightly, obstruction is likely. Unlike the MUS, SIMS should be nearly abutting the urethra in order to work effectively. If loosened, the likelihood of failure or persistent SUI is very high. Urinary retention and bladder obstruction, however, still remain as serious complications that must be considered and discussed with patients interested in SIMS.

There are many ways to treat voiding dysfunction postoperatively. Taner and coworkers describe observation with spontaneous resolution in one of their study subjects experiencing voiding difficulties [16]. Urinary catheterization for a period of 24 h has also shown to be effective in relieving urinary retention.

Studies have shown that bladder outlet obstruction rates following SIMS range from 0 to 8 %, depending on the definition used for obstruction [20]. This is likely due to mesh that is excessively tight. Bladder outlet obstruction with SIMS may be treated in different ways. Self-catheterization or a Foley catheter may be used temporarily until spontaneous voiding resumes. Sling release or transvaginal urethrolysis should be considered in patients where spontaneous voiding does not resume [37]. These techniques are rapid and minimally invasive.

Mesh Exposure and Erosion

Polypropylene mesh is a synthetic, hydrophobic, inert, and macroporous material that is very popular for use in MUS and SIMS. This mesh is designed to minimize risk of exposure and erosion while ensuring strong urethral support [38]. Mesh exposure is defined as exposed material that has eroded through vaginal epithelium [39]. Mesh erosion is defined as the presence of material that is present in the lower genitourinary tract, such as the lumen of the urethra or bladder [39].

Mesh exposures and erosions are hypothesized to occur due to excessive tension on the slings or poor suturing techniques [39]. Additional factors that may contribute to mesh exposure and erosions include mesh characteristics, such as pore size and filament construction [39]. Type II and III mesh are multifilamentous, and thus allow bacterial passage and adherence to graft tissue, increasing the risk of infection [39]. Type II, III, and IV mesh all have small pore sizes, which ultimately prevent leukocytes, macrophages, and fibroblasts from passing through to counter any invading bacteria [39]. Type I mesh is macroporous and monofilamentous, which is what is most often used today with consistent success [39].

Patient-related characteristics also serve as a risk factor for mesh exposure and erosions. Host factors that increase risk of mesh exposure include extremes of age (greater than 70 years old), estrogen deficiency with severe genital atrophy, diabetes, prior scarring or pelvic irradiation, tobacco use, early postoperative sexual activity, poor wound healing, infection and chronic steroid use [40]. Any unrecognized urethral or vesical injury may contribute to higher rates of erosions [39]. If there are additional surgical procedures at the time of mesh placement, such as a hysterectomy, the risk of exposure and erosion is slightly higher [39, 40].

Vaginal exposure may be precipitated by infection, poor tissue vascularity, or poor incorporation of the mesh into host tissue. This exposure may be located at the incision midline or the lateral part of the anterior vaginal wall. Exposures

along the midline suggest impairment in wound healing whereas lateral exposures suggest vaginal wall perforations or injury that went unrecognized at the time of sling placement. Studies have shown that it takes more than 90 days for complete integration of the mesh into host tissue [16]. Complications of mesh are becoming increasingly significant, and rates of mesh exposure and erosion are very important to consider. Literature shows the rate of SIMS mesh exposure is 2.4 %, which is near equivalent to rates of mesh exposure for RPS at 1 year [11]. The TVT-Secur™ was known to have higher mesh extrusion rates in comparison to MUS [11].

Women with vaginal mesh exposure may present with multiple symptoms or may be completely asymptomatic. Common complaints of mesh exposure include vaginal bleeding or discharge, pain, dyspareunia, and partner dyspareunia [39]. A thorough pelvic exam is indicated to identify mesh exposure. Sometimes, a pelvic exam under anesthesia may be necessary in order to fully identify mesh exposure sites in the event there is high clinical suspicion without any evidence on office examination [39].

Mesh exposure may be treated conservatively or surgically, depending on the type of mesh. Patients should abstain from sexual activity during the healing period, which is approximately 6–8 weeks [39]. Topical estrogen has been shown to be a valid treatment option as well [39]. If the conservative measures fail or the patient wants definitive management, mesh exposure may be treated by ambulatory excision of mesh in the exposed area while under general anesthesia.

Patients with mesh erosions may present with de novo SUI, urgency, hematuria, urinary tract infection, or obstruction [39]. Regardless of mesh type, eroded areas of mesh need to be excised completely [39].

A meta-analysis by Abdel-Fattah and coworkers found more urethral erosions associated with SIMS in comparison to MUS. This was thought to occur due to the surgeon learning curve and lack of cystoscopy after procedure completion [24]. Urethral erosions can be treated using a holmium laser to remove the mesh that eroded into the urethra [20] though multiple treatments are often required. Alternatively, urethral erosions can be treated via urethrolysis with mesh removal, debridement, and primary closure of the urethra [39]. Bladder erosions may be removed cystoscopically [39]. though again multiple treatments may be necessary. When utilizing minimally invasive methods of removing intravesical or intraurethral mesh it is critical to get deep to the mucosa during the removal to ensure no fragments remain that are exposed. During the repairs for mesh erosion and exposure, cystoscopy should be performed in order to ensure no additional mesh erosions are found in the urethra and bladder.

Dyspareunia and Pain

Pain and dyspareunia are recognized postoperative complications that can occur with MUS. Pain may be experienced in the groin, vagina, pelvis, lower abdomen, and urethra. The TOT, when placed using the inside-to-outside approach, tends to incur higher rates of groin pain, as high as 16 % [36, 40]. SIMS were designed to be the solution to reduce postoperative pain. Randomized control trials (RCT) have shown the MiniArc™, a SIMS, has less pain and quicker recovery time than the Monarc™ (Astora Women's Health, L.L.C., Eden Prairie, Minnesota, USA), which is a TOT. Additional RCTs comparing the TVT-Secur™ with the TVT-O™, a transobturator sling, also demonstrated less groin pain with the TVT-Secur™. Both sling systems are placed in the obturator internus muscle [1, 41, 42]. The rates of thigh and groin pain and leg neuropathy with the SIMS range from 0 to 3.3 %, which is much lower than the initial 24.4 % rate of pain, followed by a 3.7 % risk of pain in the long term [43, 44].

Dyspareunia related to SIMS has been reported to occur in approximately 3–8 % of SIMS patients [20]. It is thought to occur due to tissue fibrosis, mesh exposure, mesh infection, or mesh shrinkage. The sexual partner of the patient may also experience dyspareunia. This is particularly true for patients who have exposed vaginal mesh. Removal of exposed mesh is the treatment of choice for this complication.

Conclusion

Single-incision mini-slings (SIMS) are currently being designed and refined to meet the growing needs of SUI patients. The introduction of SIMS propels continued research and innovation to further develop an answer to SUI that decreases complications associated with MUS and anesthesia, postoperative pain, and carves a path to quicker recovery. However, there is a paucity of long-term information regarding the ideal patient profile, efficacy, and safety of SIMS. Research efforts continue in order to evaluate this missing data. Regardless of the technique employed, the surgeon should be aware of the right diagnosis and the best anti-incontinence treatment option for patients suffering from SUI.

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Female Urethral Reconstructive Surgery

19

Rajveer S. Purohit and Jerry G. Blaivas

Introduction

Female urethral reconstruction is an uncommon surgery for urethral strictures, urethral diverticula, or urethral tissue loss (e.g., fistulas). Consequently, there are significantly less data regarding outcomes and prevention of complications compared to male urethral reconstruction. However, from available sources and anecdotal experience conclusions can be drawn. Complications can be minimized with careful preoperative assessment and focus on principles of surgical technique and approach. Intraoperative complications include hemorrhage and bladder or ureteral injury. Early postoperative complications include infection, flap or graft necrosis, and late complications include stricture or fistula recurrence, sphincteric incontinence, urethral obstruction, and overactive bladder. In addition, complications of ancillary procedures such as a Martius flap or buccal graft may occur.

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Preoperative Assessment

Many complications related to urethral reconstructive surgery are preventable because the elective nature of most of these surgeries permits careful preoperative surgical planning. Minimizing the risk of complications begins with a focused, but detailed history, physical examination of the urethral defect and vagina, assessment of urethral sphincter and detrusor function, exclusion of concomitant urethral obstruction, vesicovaginal or ureterovaginal fistula, and ureteral obstruction. Almost all patients who require urethral reconstruction have had prior surgery, so it is important to either obtain the operative reports or discuss the surgery with the previous surgeon. It is particularly important to determine if a foreign body such as mesh is in or near the wound. One of our patients failed a urethral reconstruction because of retained mesh at the site of an urethrovaginal fistula. Neither the patient nor the surgeon even knew that a mesh sling had been done previously. This unfortunate case emphasizes the need for obtaining an accurate surgical history.

Preoperative physical examination should be performed with a comfortably full bladder. Particular attention should be paid to the health of the vaginal tissue. In patients with vaginal atrophy and postradiation changes, preoperative estrogen cream may improve the quality of vaginal tissue. A careful speculum examination of the

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entire vaginal wall should assess the presence of sling erosion. Granulation tissue, drainage from a sinus tract and fistula are tell-tale signs of erosion.

In cases of urethral damage from previous vaginal or urethral surgery, the vaginal tissue is often scarred, fibrotic, and ischemic. The extent of urethral tissue loss, the integrity of the vaginal tissue, adequacy of the vasculature, and the need for advancement, lateral or pedicle skin flaps, should be assessed preoperatively (Figs. 19.1 and 19.2). Bimanual pelvic exam should focus on the presence of urethral masses or pelvic organ prolapse. When incontinence is observed from the urethral meatus, and a fistula suspected, the examination should be repeated with a finger occluding the meatus to observe leakage from the fistula itself.

Videourodynamics may show urethral obstruction, sphincteric incontinence, low bladder compliance, impaired detrusor contractility, or detrusor overactivity secondary to urethral damage. The voiding cystourethrogram (VCUG) is a critical component in preoperative evaluation of the diseased urethra. In patients with urethral obstruction, the VCUG demonstrates the site, and for those with strictures, its length and location in relation to the bladder neck. If the urethral stricture is located in the distal third of the urethra or at the meatus, imaging typically reveals ballooning of the bladder neck on voiding (Fig. 19.3). In addition, residual diverticular contrast after void-

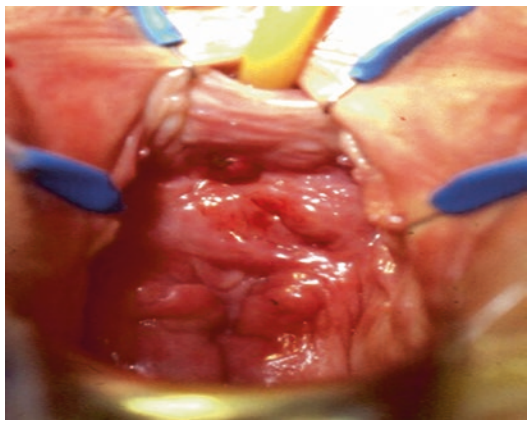

Fig. 19.1 Inspection of the anterior vaginal wall in a woman with a seemingly straightforward urethrovaginal fistula. She underwent a simple repair with vaginal wall flaps and a Martius flap, but the fistula recurred within 3 weeks. At secondary repair, a mesh sling was encountered and excised. Neither the patient nor the surgeon knew that mesh had been used in a prior anti-incontinence operation (Figure Copyrighted © J.G. Blaivas, M.D.)

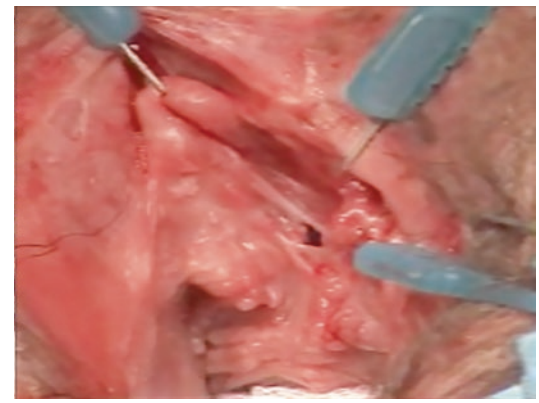

Fig. 19.2 Inspection of the anterior vaginal wall in a woman who had previously undergone an extensive urethral reconstruction after excision of a sterile periurethral abscess that formed after injection of calcium hydroxylapatite (Coaptite) for sphincteric incontinence refractory to two mesh slings. Despite the obvious stricture, she had severe sphincteric incontinence as well. At the time of surgery, after incising the stricture, the proximal urethra was only about 2 cm in length, just barely large enough to accept an autologous fascial sling (Figure Copyrighted © J.G. Blaivas, M.D.)

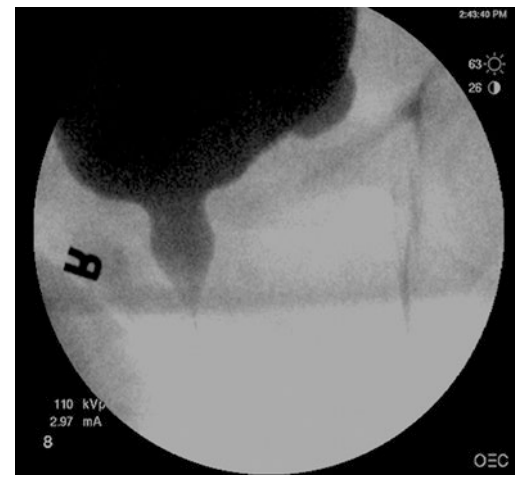

Fig. 19.3 Voiding cystourethrogram in this patient confirms a distal urethral stricture. There is almost no possibility of sphincteric injury during reconstructive surgery that is limited to the distal urethra, so either a ventral or dorsal approach may be considered (Figure Copyrighted © J.G. Blaivas, M.D.)

ing may help provide details about the anatomy of the diverticula to aid in surgical planning.

Other imaging techniques like MRI and delayed CT with contrast may be useful to distinguish abscess, cyst, tumor, and urethral diverticulum in patients with periurethral masses, to assess foreign bodies, and to rule out additional injury to the urinary tract following pelvic trauma.

Cystourethroscopy will confirm a urethral stricture, the presence of a foreign body, including suture or sling material, and evaluate the extent of the fistula. It can also evaluate the remainder of the urethra, particularly the length, viability of the proximal urethra.

Principles of the Surgical Technique

The choice of surgical technique is dictated by a number of factors including (1) the experience and expertise of the surgeon, (2) the desires of the patient, (3) the patient's age and comorbidities, (4) lower urinary tract and renal function, (5) the presence of concomitant conditions such as pelvic organ prolapse or abdominal or pelvic disease requiring surgical correction, (6) prior abdominal and pelvic surgical procedures, and (7) sexual function:

1. *The surgeon*: Urethral reconstruction ranges from simple ventral incision and meatotomy for distal urethral strictures to full-length dorsal buccal grafts for longer strictures to neourethral reconstruction with local vaginal wall flaps reinforced with Martius flaps and occasionally, gracilis, thigh, or rectus flaps. Few of these procedures are learned in residency or fellowship; most of the expertise is garnered over decades of experience in tertiary referral centers. In our judgment, the most demanding part of the expertise is decision making both before and during the surgery. With the exception of proximal dorsal buccal mucosal grafts for strictures, ventral bladder neck reconstruction and complex urethral diverticula, the technical aspects of the surgery are usually straightforward. With these caveats in mind, it is up to the individual surgeon to decide whether he or she possesses the requisite surgical expertise for each individual patient. In some instances, referral to a reconstructive expert is prudent.
2. *The patient*: For practical purposes, the damaged urethra presents one or more of three potential problems—incontinence, urethral obstruction, and pelvic pain. Surgical treatment of incontinence and pain is entirely elective; whereas, untreated urethral obstruction may portend urinary retention or upper tract damage and even renal failure. Further, the success rate for treating urethral obstruction and sphincteric incontinence is very high—over 90 %, while the success rate for pelvic pain and overactive bladder is far less. Keeping these facts in mind, it is important that the patient be apprised of the pros and cons of surgical intervention and that the decision about how to proceed is based on realistic expectations for success, failure, and complications.
3. *Patient age and comorbidities*: Age and comorbidities are factors insofar as the patient's life expectancy and ability to withstand the morbidity of surgery that could last as long as 4–6 h should be taken into account, although excessive blood loss during surgery is rare. The decision to undergo elective surgery is based on a complex calculus involving factors such as the bother to the patient, risk of complications if no surgery is pursued versus the likelihood of success and duration of recovery based on the patient's preoperative age and comorbidities. For example, in an elderly patient with minimal bother from a urethrovaginal fistula and difficulty with ambulation, the improvement in quality of life may not be worth the risks of surgery and morbidity of recovery to the patient.
4. *Urinary tract function*: It is axiomatic that lower urinary tract function is an essential component of decision making in planning surgery. As a general rule, we believe it is most prudent to treat sphincteric incontinence as part of the reconstructive procedure, although some surgeons prefer a staged operation. Low bladder compliance and detrusor overactivity often improve after successful

surgery, so they are not addressed at the same time except in rare circumstances when due to multiple surgeries or radiation. In these instances, urinary diversion rather than urethral reconstruction might be considered (Fig. 19.4).

5. *Concomitant conditions*: When concomitant conditions such as vesicovaginal fistula, urethral diverticulum and localized urethral cancer are present, the decision about how to proceed should be made on a case by case basis taking particular care to assess the potential impact on flap or graft survival if more than one procedure is done at a time. *Prior surgery*: It is important to know what prior pelvic surgeries the patient has undergone, particularly if mesh has been used for prior repairs. As a general rule, as much mesh as can be safely removed should be taken; when that is not feasible, it is important that all mesh be at least removed from the urethra and bladder when there has been erosion. In patients complaining of pain, it is best to remove all mesh from the affected side whenever possible, but this can be extremely challenging in patients who have undergone TOT repairs.
6. *Sexual function*: It is essential that the patient's desires about postoperative sexuality be discussed and incorporated into surgical planning and informed consent. The literature about sexual complications of urethral reconstructions is rudimentary at best, but dyspareunia can occur after any of these operations. When maintaining sexual function is a factor, special attention must be paid to insuring adequate vaginal size of at least two loose finger breaths to a depth of at least 8 cm.

Surgical Techniques

Before proceeding with the vaginal incision, it is critical to choose the site and shape of the initial incision for the urethral reconstruction. We have previously described several methods of urethral reconstruction for stricture, and in the majority of the cases, the repair can be accomplished with a single transvaginal operation [1].

All surgical approaches follow the same rules: fine sharp dissection is preferable and homeostasis is maintained. Sharp dissection permits the development of correct planes and excision of the dense fibrotic tissue and may prevent inadvertent injury to the bladder or sphincter. The urethra should be opened proximal enough to clearly see the extent of the urethral stricture when present. If the edges of the stricture are uncertain, we place progressively larger bougie-a-boule sounds into the urethra past the area of suspected stricture. As the sound is pulled back it will catch on the stricture. The urethrotomy is extended until the bougies can be withdrawn without resistance. In addition to aiding visualization, attention to homeostasis may prevent hematoma and breakdown of the sutures lines. When excessive bleeding is encountered, pressure should be applied until the bleeding stops or bleeding vessels individually clamped and sutured or coagulated. Frantic efforts to control hemorrhage without clearly identifying the bleeding vessels may lead to unnecessary injury to adjacent organs.

In preparing for vaginal surgery, the patient is placed in a dorsal lithotomy position with the least degree of Trendelenburg that is necessary for adequate exposure. Draping should permit access to the vagina as well as abdominal area (when concomitant surgery is planned). At the onset of surgery, the bladder is drained via a transurethral catheter and palpation of the balloon allows identification of the bladder neck. If suprapubic cystotomy, pubovaginal sling, or rectus muscle graft is planned, these should be done prior to the vaginal reconstructive surgery to avoid subsequent damage to the reconstruction during dissection for these procedures. For pubovaginal slings, though, the sutures should not be tied until the reconstruction has been completed so that tension can be judged.

In cases of minimal urethral disruption, such as small urethrovaginal fistula or diverticulum, the defect can be circumscribed and closed over a catheter with tension-free, interrupted sutures of 3–4:O chromic catgut. An inverted U anterior vaginal wall flap is usually adequate for closure, but sometimes a lateral vaginal flap may be more appropriate.

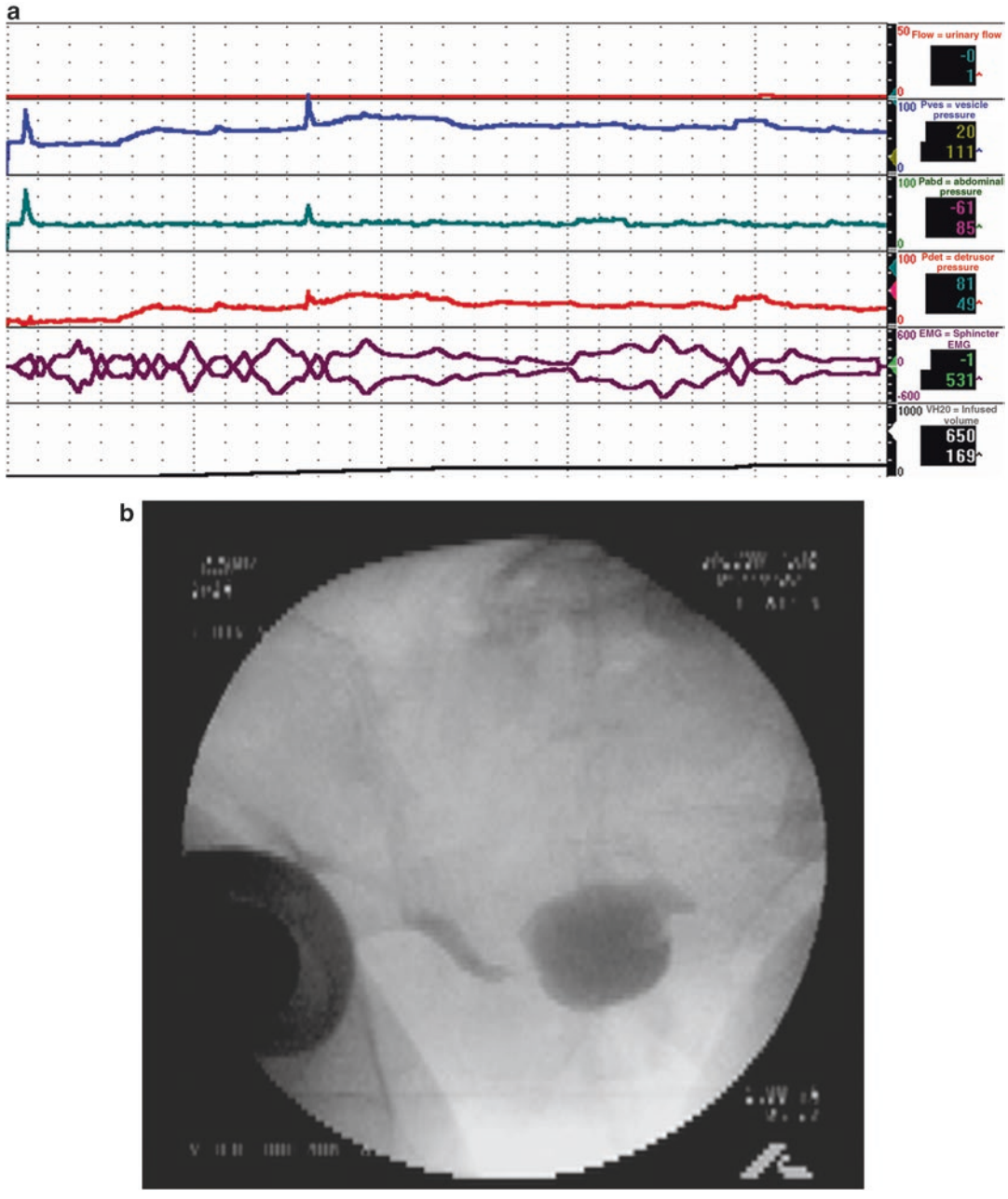

Fig. 19.4 Videourodynamic study in a 72-year-old woman who underwent anterior prolapse repair and TVT sling complicated by colovesical and urethrovaginal fistula. She subsequently underwent unsuccessful attempts at surgical repair of these defects and presented with refractory urge incontinence as well as sphincteric incontinence and colovesical fistula. She had arthritis that precluded self-catheterization through the urethra. Because of the findings described below, she underwent continent urinary diversion instead of another attempt at lower urinary tract reconstruction. (**a**) Urodynamic tracing demonstrates severe low bladder compliance (2 mL/cm H_2O) at a bladder volume of only 50 mL. Note that each time infusion is stopped, detrusor pressure falls. (**b**) Cystogram reveals a tiny bladder with right vesicoureteral reflux. The colovesical fistula and sphincteric incontinence was not visualized (**a**, **b**: Copyrighted © J.G. Blaivas, M.D.)

If urethral injury is extensive and sufficient vaginal wall tissue exists, vaginal wall flaps may be considered. Flap-based urethroplasty techniques have been demonstrated to be effective and improve the outcome in the urethrovaginal fistulas and are the treatment of choice for most female urethral strictures that are distal to the sphincter mechanism [2–4]. In one such technique, the anterior vaginal wall can be mobilized and a rectangular incision around the urethral defect is made. A lateral vaginal wall flap is advanced, rolled over the catheter, and sutured to the contralateral side, without tension, to form the entire posterior urethral wall. However, if the extent of urethral injury and lack of vaginal tissue preclude simple repair, use of an advancement flap may be required. Another choice is to create a labia minora flap. An oval-shaped incision is made in an adjacent hair-free portion of the labia minora and carried through the underlying tissue and a pedicle is raised on a posterior- or anterior-based blood supply. This island flap is tunneled beneath the vaginal wall, rotated, and sutured over the catheter, so the vaginal epithelial surface creates the inner wall of the urethra. Rarely, it is not possible to close the defect in the vaginal wall primarily and in such instances, it is possible to create a labia majora flap to cover the wound. We have only needed a gracilis flap on one occasion and have never used any other major kind of flap (rectus, Singapore, etc.), but of course, those are available if needed [1].

Urethral damage associated with erosion of synthetic material poses unique considerations and the repairs can be even more challenging [5]. Most authors agree that eroded synthetic slings require complete removal of the sling from the urethra and bladder. The literature on the surgical management of erosions suggests midline anterior vaginal wall incision at the erosion site, bilateral dissection into the retropubic space, and removal of the entire synthetic sling including sutures, and when possible, bone anchors if they were used [6]. In our experience, especially with transobturator techniques, attempting to remove the entire sling leads to difficult and morbid surgery and should probably be reserved for those who failed at first attempt. Once the sling has been excised, the urethra can usually be repaired primarily. If this is not feasible, any of the techniques described above may be considered.

For patients with distal urethral strictures, ventral urethroplasty using vaginal and labial skin flaps is, in our judgment, the least morbid technique. This approach is utilized in patients with mid-to-distal urethral strictures and an intact bladder neck and urinary sphincter mechanism. However, ventral urethrotomy risks urethral sphincter damage and de novo urinary incontinence when the stricture involves the proximal urethra or when sphincteric incontinence was present preoperatively. In cases of documented preoperative sphincteric incontinence, the dorsal approach offers easier access to the bladder neck and permits an easier concomitant anti-incontinence procedure.

Unlike the dorsal approach, ventral urethroplasty may redirect the urethra and the urinary stream anteriorly or posteriorly. When the urethra is too short, a vaginally directed urinary stream that causes post-void dribbling may occur. In some patients, there has been spontaneous resolution; in others, reconstructive surgery to lengthen the urethra may be required [7]. If the urethra is too long, there may be an excessive arc to the stream and the patient may actually void over the toilet bowl. This is easily corrected with a ventral meatotomy.

Vaginal tissue from the labia minor has be reported as a free inlay graft with minimal short-term complications [8]. Several groups have proposed a dorsal onlay urethroplasty using buccal mucosa graft [9, 10], labia minora skin graft [11], or vestibular flap [12]. The dorsal technique has several advantages, but requires different surgical expertise, utilizing many of the surgical principles derived from urethral reconstruction in men. A surgical plane is developed between the urethra and overlying clitoral cavernous tissue. Care should be taken during the dissection of the dorsal urethra to avoid injury to the clitoral bulb, body or crura, and the clitoral neurovascular bundle and minimize excessive bleeding. The clitoro-urethrovaginal complex is supplied by pudendal neurovascular bundles which arise from pelvic

side walls and bifurcate into clitoral and perineal divisions. The clitoral neurovascular bundle ascends along the ischiopubic ramus and adjacent clitoral crura on both sides, runs under the surface of the symphysis pubis in the midline, and then travels along the cephaled surface of the clitoral body towards the glans (Fig. 19.5). The nerves of the clitoral neurovascular bundle are not large enough to be seen on the MRI. However, the histological dissections show that they accompany the vessels [13].

From a practical standpoint, it is fairly straightforward to avoid these structures during the dissection by confining the dissection to the dorsal urethra. We are not aware of any reports of injury to the clitoral structures, nor have there been any reports of orgasmic changes. Our experience corroborates these findings.

Not infrequently during the dissection troublesome bleeding is encountered, but we caution against blind coagulation or suture ligature. All that is usually necessary is to place a gauze pack between the dorsal urethra and pubis, extending into the retropubic space for compression. Positioning the graft on the dorsal surface preserves intact ventral midurethra and provides a better vascular bed for a graft. In our judgment, doing so minimizes the likelihood of requiring an incontinence procedure. However, unlike the ventral approach, dorsal dissection is infrequently performed in pelvic reconstructive surgery, and for most surgeons, the anatomy is not

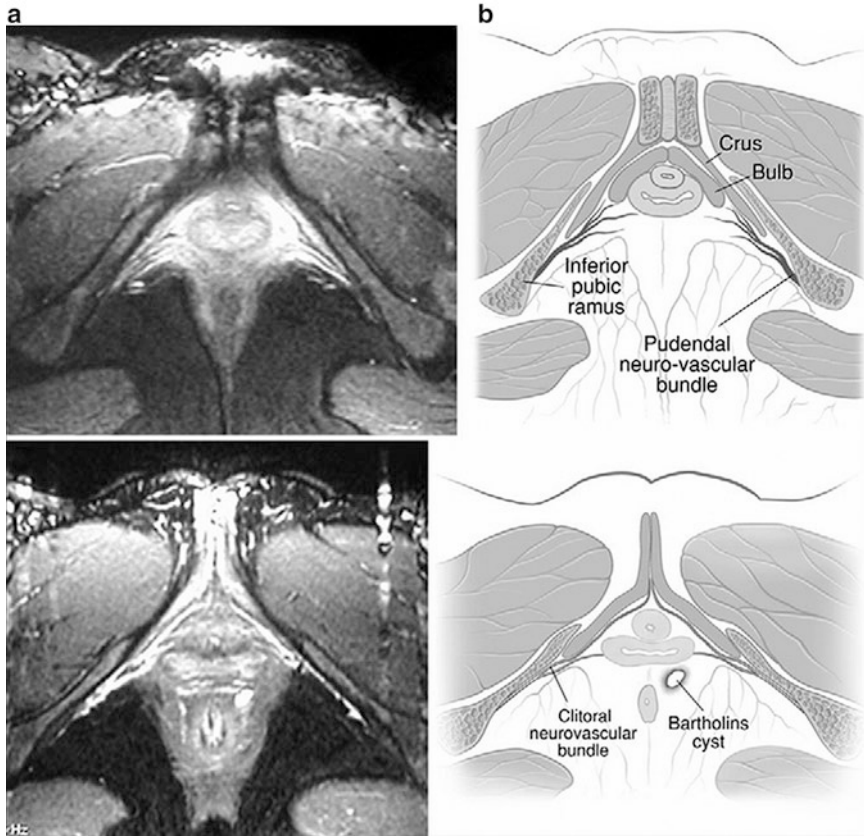

Fig. 19.5 (**a**) MRI of the clitoris in the axial section as seen on the left shows divisions of the pudendal neurovascular bundle, which arises from the pelvic side wall and bifurcates into perineal and clitoral neurovascular bundle. Vascular component of the bundle and cavernous tissue are bright white due to fat saturation technique. Muscles and bone appear as dark structures. (**b**) On the right is an artist's rendition of the images (Used with permission of John Wiley and Sons, Inc., from Rehder P, Glodny B, Pichler R, Exeli L, Kerschbaumer A, Mitterberger MJ. Dorsal urethroplasty with labia minora skin graft for female urethral strictures. BJU international. 2010;106(8):1211–4)

well known. Further, most pelvic surgeons are unfamiliar with the techniques of graft reconstruction that are done much more commonly in men.

Use of a Graft and Potential Complications

One of the challenges of urethral reconstruction is achieving a long and stricture-free lumen that allows nonobstructive voiding and maintains continence. Due to the variable etiology of the urethral pathology, local tissue may not be available for the urethral repair. In cases of extensive posttraumatic or postsurgical urethral fibrosis, congenital malformations, and recurrent urethral strictures, reconstructing the urethra with a free graft provides an alternative to a vaginal flap or bladder flap.

Various graft urethroplasty techniques have been proposed in small series. These techniques can be complicated and require knowledge and experience with processing and tissue transfer.

Buccal mucosa grafts are commonly used in male urethral reconstructive surgery and have been shown to be successful in construction of the neourethra in female pediatric patients [14]. The buccal mucosa graft has been applied to female urethral strictures using both dorsal and ventral approaches [7, 9, 10, 15].

In our experience, buccal mucosa graft is an option in patients with previously failed reconstructive surgery and urethral stricture recurrence. It is also our treatment of choice for proximal urethral strictures in women who do not have a current or past history of sphincteric incontinence because we believe that there is no need for anti-incontinence surgery when the dorsal approach is used. Buccal mucosa has several advantages, is easy to harvest, is resilient to infection, and is already accustomed to a wet environment. Properties like elasticity and thick epithelium make it easy to handle [16]. It has the ability to supplement the native urethral plate to form a conduit that closely resembles a normal functioning urethra with low risk of sacculation and diverticulum formation. In addition, buccal grafts have a panlaminar vascular plexus which eases graft take to the recipient bed. In animal studies, extensive neovascularization in the subepithelial layer was evident 3 weeks after surgery, followed by inflammation and minimal fibrosis at 6 weeks [17]. Supple urethral coaptation can be accomplished by buccal mucosa graft and may play a role in achieving continence after urethral reconstruction [14]. The graft is harvested from the buccal mucosa inferior to Stensen's duct which is identified adjacent to the second upper molar. The graft typically measures between 2 and 2.5 cm wide and 2–5 cm in length depending on the amount of tissue needed. The graft is defatted and sutured to the urethrostomy. To maximize outcomes after free grafts, ensuring adequate vascularity of the donor bed is necessary. All fibrotic tissue has to be excised and the graft must be anastomosed to the recipient bed using monofilament absorbable sutures. In order to allow possible postoperative shrinkage of graft, it should be trimmed to larger size than urethral defect or stricture.

Complications associated with harvesting buccal mucosa graft are rare and have not been reported in any female case series. In male reconstructive surgery, complications reported include donor site wound pain, swelling, damage to Stensen's duct, postoperative perioral numbness, and infection. Wound contraction can also occur which manifests as a sensation of tightness when the mouth is opened. According to data from male case series, 59 % of patients developed short-term numbness after surgery, which persisted in 16 % beyond 1 year [18]. Complications of buccal grafts are uncommon; however, the possibility of a mental nerve neuropathy is unique to buccal graft surgery [19]. Injury to Stensen's duct is extremely rare and can be avoided by marking the buccal mucosa and careful closure of the donor site. When it is difficult to perform closure, some surgeons prefer to leave the harvest site open. One randomized study found that while there were no long-term differences, primary closure of the buccal mucosal graft bed decreased postoperative pain and improved oral intake [20]. If buccal mucosa graft is used ventrally and adequate periurethral tissue does not exist for cover-

age of the graft, it may be advisable to use well-vascularized tissue flaps to provide an adequate blood supply and prevent fistula formation. However, to our knowledge tissue flaps have not been utilized in dorsal approach.

Sharma has described the use of dorsal onlay lingual graft urethroplasty in 15 women with urethral stricture [21]. Lingual mucosa, harvested from lateral and ventral surfaces of the tongue, has similar tissue characteristics as buccal mucosa thick epithelium, high content of elastic fibers, thin lamina propria, and rich vascularization [22]. There were no functional limitations or intraoral complications at 1-year follow-up. Advantages reported of harvesting lingual mucosa graft instead of buccal mucosa graft are avoidance of injury to parotid gland duct and facial nerve without risk of the mouth deviation or lip retraction [21].

Intraoperative Complications

Intraoperative complications during urethral reconstructive surgery are rare based on our review of the literature. One case of intraoperative hemorrhage has been reported in early series by Elkins on 20 women who underwent repair of a vesicovaginal fistula involving the urethra with the anterior bladder flap technique and Martius flap. During total urethral reconstruction, a patient developed hemorrhage in the space of Retzius and required postoperative blood transfusion [23]. However, there is no surgery that spares the patient from potential risk of other anesthetic complications or injury to adjacent organs such as bladder, ureter, or rectum. For bleeding that occurs during the dissection for creating vaginal flaps, we believe it is best to simply apply pressure with a pack unless there is an obvious bleeding vessel that can be coagulated or ligated. Bleeding that occurs from the retropubic space after entry from the vagina is best handled with the same approach. If bleeding seems excessive, we advise against trying to explore from the vaginal wound; rather, one or two 4 × 4 sponges or a lap pad should be inserted into the retropubic space through the vagina to tamponade the bleeding while other parts of the operation are continued. In thousands of reconstructive surgeries, we have never found it necessary to explore the retropubic space from above to control bleeding. Another potential source of excessive bleeding is during the dissection for the Martius flap that is discussed in "Complications of Ancillary Procedures" section. It is possible to injure the distal ureter during a dissection for urethral reconstruction, but we have never seen this nor has it been reported. On two occasions, though, the ureter has been transected or avulsed in the course of removing mesh to which the ureter was adherent. One should be alert to the possibility of this complication whenever the dissection extends to the vicinity of the ureter or when traction is exerted on retropubic mesh. For that reason, it is always prudent to administer intravenous dye and check for ureteral patency by observing efflux of blue urine from each ureteral orifice through a cystoscope. If there is preoperative suspicion of ureteral involvement with mesh, ureteral stent placement prior to commencing surgery is helpful. If intraoperative concern exists about ureteral injury, retrograde pyelography should be done and a ureteral stent left in place if there appears to be an injury. In cases of avulsion or transaction of the ureter, immediate ureteroneocystotomy should be done.

Early Complications

All types of urethral reconstructive surgery share common complications like infection, flap necrosis, urinary retention, and postoperative bleeding, yet the overall incidence of major complications such as bleeding is very low. Complications related to the ancillary procedures like graft, flap, or sling placement are discussed below.

One of the earliest, but rare, complications of urethral reconstruction is wound infection and flap necrosis. Unrecognized infection may lead to the disruption of the suture lines, flap necrosis, and fistula formation; however, we could find no reports on this and none has ever occurred in our series.

Sharma and colleagues in a case series of 15 patients, who underwent dorsal onlay lingual mucosal graft urethroplasty for urethral stricture, reported one case of wound infection requiring antibiotics. The patient subsequently developed submeatal stenosis treated with monthly dilation [21].

Another potential complication is inadvertent traction on the urethral catheter that occurred in one elderly patient in our series completely disrupting the repair. To prevent that, we routinely suture the Foley catheter to the anterior abdominal wall with a gentle loop in order to minimize tension on the urethra. Failure to maintain a correct position of the catheter may result in necrosis of the urethra. The urethral wound and the catheter should be checked frequently during postoperative care to ensure that there is no pressure on the suture line. Additionally, adequate bladder drainage should be maintained until the patient voids at 3 weeks postoperatively and VCUG does not show extravasation.

Another complication that may be encountered in the early postoperative period is urinary retention, but there are no reports of this in the literature that we reviewed and none has occurred in our series. If urinary retention were to occur, first check for meatal stenosis, and if present, a gentle attempt at urethral dilation should be done. If there is no obvious meatal stenosis, we recommend a gentle attempt at placement of a small Foley catheter followed by trial of voiding after about 2 weeks. If placement of the catheter is unsuccessful, a suprapubic catheter should be placed. If the patient fails the second voiding trial, we recommend cystoscopy, and if there is no obvious cause of obstruction, videourodynamics should be done. If urethral stricture is diagnosed, it should be dilated. Recurrent strictures may require repeat reconstruction.

Late Complications

Because of the relatively small number of case series reported in the literature, available data cannot provide a consensus for management of various complications of urethral reconstructive surgery. In general, when urethral reconstruction is properly performed, it is associated with high long-term anatomic success rate and low complication rates. However, functional complications including overactive bladder and stress incontinence have been reported.

Postoperative Sphincteric Incontinence

Postoperative stress urinary incontinence is a result of unrecognized sphincteric incontinence before the procedure or a consequence of injury to the sphincter during dissection. In proximal urethral injuries, postoperative incontinence rates may range between 44 and 80 % unless a concomitant anti-incontinence surgery is performed [24]. In the majority of studies, the criteria for incontinence following the reconstructive surgery are not specified leading to a likely underestimation of incidence.

In our previously published series of 74 patients who underwent vaginal flap urethroplasty, 62 women with preoperative incontinence underwent concomitant fascial pubovaginal sling placement. Successful anatomical repair was achieved in 93 % patients and 87 % considered themselves cured or improved with respect to incontinence. All patients with persistent postoperative stress incontinence were successfully treated by secondary procedures [1].

In our most recent case series of nine women who underwent urethral stricture repair, five concomitant fascial slings were performed synchronously due to sphincteric incontinence. Postoperatively no urinary incontinence was reported. Success or failure of anatomical repair and incontinence was assessed subjectively and objectively by validated questionnaires, physical examination, voiding diaries, and 24 h pad tests. There was no recurrence at 1 year but two women had stricture recurrence at 5.5 and 6 years, respectively [25].

In patients undergoing urethral reconstruction following mesh sling surgery, some authors suggest that extensive scarring may preclude the successful repair and recommend a staged proce-

dure to correct the incontinence [6]. Amundsen and colleagues reported persistent stress incontinence in two of three cases following synthetic sling removal, repair of the urethra, and Martius flap placement. All were treated with a second stage pubovaginal sling placement and injection of transurethral collagen. Interestingly, none of the patients after excision of the non-synthetic sling required further anti-incontinence procedures. Clemens and colleagues reported five cases of recurrent postoperative stress incontinence in six patients who underwent removal of an eroded sling from the urethra or vaginal mucosa [26]. In our view, documented preoperative sphincteric incontinence and compromised integrity of the sphincter during reconstruction are sufficient reasons to perform concomitant pubovaginal sling at the time of urethral reconstruction. First, harvesting of the fascial graft and placement of the sling around the urethra should be done, then the urethral reconstruction should be completed and, when necessary, a Martius flap is interposed between the reconstructed urethra followed by tensioning and tying the sling in place [27] (Fig. 19.6a–c).

When sphincteric incontinence develops after urethral reconstruction, treatment should be tailored to the patient. Of course any treatment at all is elective and some patients are not bothered enough to want to consider further treatment. In our judgment, the patient should be evaluated just as would be done if she had not had prior urethral reconstruction and, for us, that means a bladder questionnaire, diary, exam, uroflow, assessment of post-void residual urine, videourodynamics, and cystoscopy. As a general rule, though, we defer this evaluation until about 3 months from the reconstructive surgery. If recurrent sphincteric incontinence is documented, we recommend a biologic sling, and prefer autologous fascia. Ideally, the sling should be placed at a virgin site at the bladder neck, or the mid or proximal urethra,

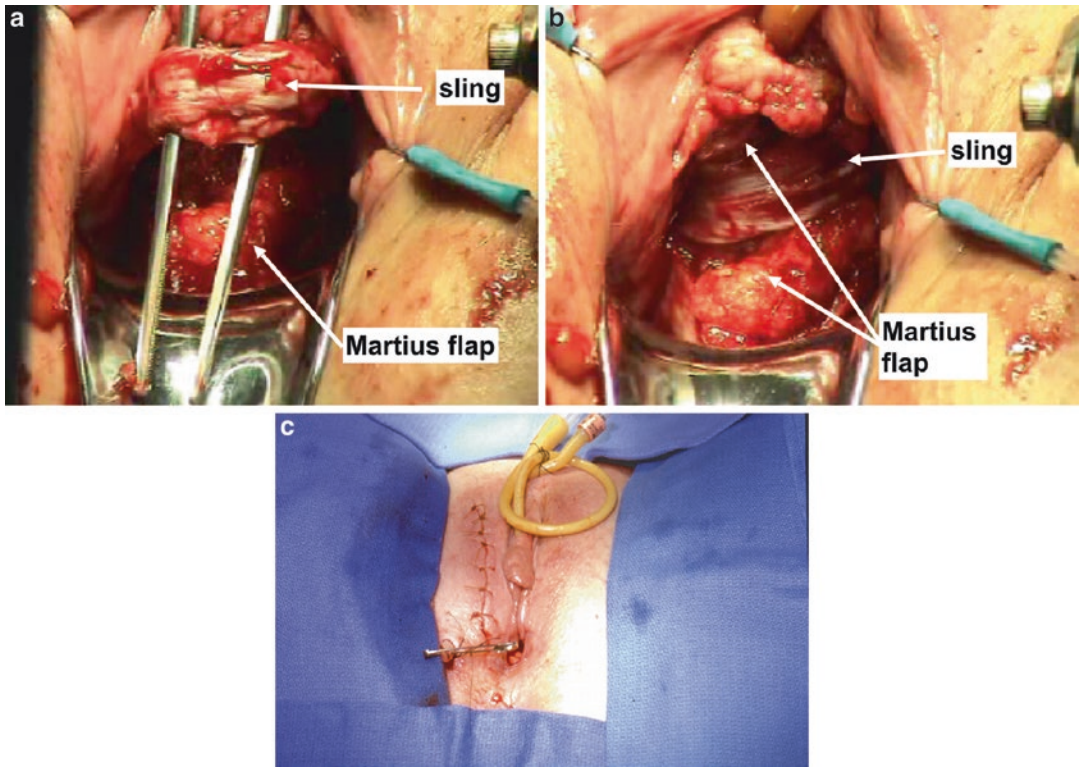

Fig. 19.6 (**a**, **b**) After mobilization of the Martius flap, it is placed between the reconstructed urethra and the autologous fascial sling. (**c**) The completed repair with the Foley catheter sutured in place to prevent downward traction that could disrupt the wound (**c**: Copyrighted © J.G. Blaivas, M.D.)

proximal to the site of the reconstruction. If the entire mid and proximal urethra has been reconstructed, it is possible to place the sling at the reconstructed urethra, but special care should be taken to not injure the urethra during the surgery. To this end, we recommend that the plane of dissection around the urethra be accomplished sharply under direct vision with a scissor staying in a very superficial plane just beneath the vaginal epithelium. If there is any difficulty extending the dissection into the retropubic space, it should be opened from abdominal side and completed under direct vision. Depending on the nature of the prior reconstruction and the characteristics of the urethra, a Martius flap may be considered as well, placing it between the sling and reconstructed urethra. We believe a synthetic sling is contraindicated in these circumstances.

Overactive Bladder

Persistent or de novo overactive bladder symptoms can be problematic postoperatively. In our series of 74 women after urethral reconstruction, 16 % of patients had severe urinary urgency or urge incontinence postoperatively, including those who underwent concomitant autologous pubovaginal sling placement [1]. The series by Onol and colleagues reports 2 cases of persistent urge incontinence in 17 women who underwent urethral stricture repair [7]. Similarly, Gormley counted 2 cases of persistent urge incontinence and 1 de novo urge incontinence among 12 women who had repair for urethral stricture [3].

The assessment of OAB symptoms should commence within days to weeks after their occurrence to look for remediable causes such as urinary tract infection, urethral obstruction, and incomplete bladder emptying:

Urinary tract infection should be treated with culture-specific antibiotics and urethral obstruction and incomplete emptying ruled out by uroflow and measurement of post-void residual urine. Women who preoperatively have a long standing history of obstruction and high detrusor voiding pressure will often maintain a "normal" maximum flow rate but can still be significantly obstructed. One clue for recurrence of obstruction to consider in the uroflow is a flattening of the flow curve, even if maximum flow is normal. If obstructive symptoms persist after these conditions have been treated or excluded, empiric treatment can be tried, but if they prove unsuccessful after a month or so, we recommend cystoscopy and urodynamics to look for obstruction, foreign body, and stones. Patients with refractory OAB after 3 months or so, who underwent sling surgery as part of the reconstruction, are candidates for empiric sling incision or urethrolysis even if they appear unobstructed, but in our series this has not been necessary

Urethral Stricture

Strictures have occurred after dorsal labia minora skin graft urethroplasty [11], dorsal lingual mucosa graft urethroplasty [21], ventral buccal mucosa graft urethroplasty [15], and all were distal to the initial reconstruction. In the first case, the patient reported recurrent urinary tract infections and lower urinary tract symptoms at 9 months after surgery. Meatal stenosis was diagnosed and treated with meatotomy, and she was asymptomatic thereafter [11]. In another series, two patients presented with obstructive voiding symptoms at 3 months and lower urinary tract symptoms at 5 months follow-up [15, 21]. Both were found to have submeatal stenosis requiring urethral dilations that resulted in complete resolution of symptoms at 12 months follow-up.

In our experience, late stricture recurrence of 5 years or more after surgery is possible. In two women from our recent case series who underwent vaginal flap urethroplasty, urethral stricture recurrence was noted at 5 and 6 years. Subsequently, both patients underwent successful urethral repair using dorsal buccal mucosa graft and were stricture free at 12 and 15 months follow-up [25]. Both of these patients developed the recurrent stricture at the time of menopause, so it is possible that hormonal influences played a role in their genesis. To prevent recurrent strictures, we recommend that peri-menopausal and menopausal women be treated with topical estrogens. In a report by Gormley who described follow-up on 12 patients after vaginal flap urethroplasty for

female stricture disease, one patient underwent repeat dilation 3 weeks after procedure due to narrowing of the bladder neck and another required cystoscopy with catheter insertion in the OR 58 months postoperatively [3].

Although most studies report good short-term success, long-term follow-up of every patient is recommended to avoid complications of unrecognized urethral stricture recurrence.

Unfortunately, current data are too sparse to determine what factors predispose a patient to stricture recurrence. We hypothesize that failure to expose and incise the proximal extent of the stricture during surgery, ischemic changes, and wound contracture might possibly lead to stricture recurrence.

Sexual Dysfunction

One of the possible adverse effects of urethral reconstruction is sexual dysfunction. From a theoretical standpoint, this is of particular concern after the dorsal dissection between the clitoris and urethra that is done for dorsal buccal mucosal graft urethroplasty which could damage the corporal bodies or nerves. To date, though, we are unaware of any reports of this complication after reconstructive surgery and in many other cases using the same incision for take-down of Marshall–Marchietti–Krantz or Burch procedures for urethral obstruction. We have not published these data, but have specifically queried all of our patients who underwent this surgery about changes in sexual function, including orgasm and pain and none have suffered any negative sequelae.

Complications of Ancillary Procedures

As discussed, after reconstruction of the severely damaged urethra, it is sometimes advisable to perform a concomitant pubovaginal sling and interpose a vascularized pedicle flap over the repair site. When an anti-incontinence procedure is deemed necessary, in the vast majority of cases, a Martius flap incorporating a labia majora fat pad can be successfully used. Other flaps include rectus abdominus muscle and gracilis myocutaneous flaps have never been necessary in our experience. Flaps improve vascularity of periurethral tissue bed, enhance granulation, separate the suture lines, and promote graft survival.

For construction of a Martius flaps, a vertical incision is made over the labia majora and is carried down through Scarpa's fascia. The fat pad is mobilized with attention to preserve the ventral blood supply from the external pudendal artery or dorsal from internal pudendal artery. We almost always base the flap on the internal pudendal artery. To minimize blood loss, it is important to incise Scarpa's fascia and dissect between it and the fat pad to create a flap. The fat pad is tunneled underneath the vaginal epithelium and sewn in place over the suture lines of the reconstructed urethra. To the inexperienced surgeon, the plane between Scarpa's fascia and the skin looks like a better plane. However, there are multiple, broad, flat veins from which bleeding is difficult to control, so that plane should be avoided.

If a Martius flap is used, a Penrose drain is traditionally left in for 24–48 h. The overall incidence of the complications attributable to Martius flap is low. In data by Elkins and coworkers on 35 women who underwent vesicovaginal and rectovaginal fistula repair with a Martius graft, two had blood loss of more than 350 mL from the harvest site, three experienced cellulitis, and two dyspareunia due to narrowing of the vagina. However, in two circumstances of cellulitis and vaginal narrowing, closure of the vaginal mucosa over the flap was not possible and it was left to heal by secondary intention [2].

In our cumulative experience with urethral reconstructive surgery between 1983 and 2011, 1 of 70 women who underwent vaginal flap repair with concomitant Martius graft required incision and drainage of a labial hematoma.

Serious hemorrhage can be prevented by careful dissection of the plane of fibroadipose tissue with avoidance of deep muscle tissue and attainment of meticulous hemostasis. Other complications of the labial flap may include an undesirable cosmetic effect, asymmetry, and impaired sensation at the harvest site [28].

Urinary retention, obstruction, urgency, and urge incontinence are well-known complications after pubovaginal sling. The most recent AUA panel data report 8 % urinary retention rate after pubovaginal fascial sling placement without concurrent repair of prolapse. The rates of de novo urge incontinence and postoperative urge incontinence in patients with preexisting incontinence were 9 % and 33 %, respectively [29]. In our retrospective review of more than 500 women who underwent pubovaginal fascial sling procedure for stress incontinence, de novo urge incontinence occurred in 3 % patients. Other complications such as wound infections, incisional hernia, or long-term urethral obstruction requiring surgery or intermittent catheterization each occurred in 1 % of patients [30].

Conclusions

Urethral reconstruction in women is an uncommon surgery and as such complications are not well described in the literature. Complications can be minimized by a thorough preoperative work-up and preoperative planning of the surgical approach. Intraoperative complications include hemorrhage and ureteral injury, though both are rare. Perioperative and postoperative complications include complications specific to graft or flap site, recurrence, incontinence, urethral obstruction, or detrusor overactivity. In our experience, these complications are unusual and can be treated successfully. Because of the possibility of late recurrence of stricture, long-term follow-up is mandatory.

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Urethral Diverticulectomy

20

Lindsey Cox, Alienor S. Gilchrist, and Eric S. Rovner

Introduction

Urethral diverticulum (UD) is a rare condition and diagnosis can be challenging to the clinician [1]. Once the correct diagnosis is made, transvaginal surgical excision is the mainstay of definitive treatment [2]. Although options for the surgical treatment of urethral diverticula include marsupialization, which would be appropriate for some lesions with a distal ostium, this review will focus on complications from the transvaginal approach for mid- and proximal urethral diverticulum excision, as has been previously described [3]. A full discussion of urethral diverticulectomy surgical technique is beyond the scope of this chapter, but specific points will be discussed where appropriate.

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Prevention of Complications

Although most complications of urethral diverticulectomy are treatable and reversible, it is optimal to prevent or minimize adverse outcomes. Prevention of complications begins in the preoperative period, during the diagnostic evaluation and work-up. The typical evaluation of patients with a suspected UD consists of a history, physical examination, cystourethroscopy, and appropriate imaging, including voiding cystourethrograpy and magnetic resonance imaging as clinically indicated. For patients with lower urinary tract symptoms or incontinence, videourodynamic studies may be utilized to evaluate for the presence of stress incontinence, detrusor overactivity, bladder outlet obstruction, and specifically for the presence of a closed, competent bladder neck at rest. Patients with stress incontinence or an incompetent bladder neck can be offered concomitant placement of an autologous fascial sling at the time of UD excision. Urine cytology, when positive, can assist in making the correct diagnosis of malignancy; however, negative cytology does not rule out malignancy. In all cases, UD specimens should be sent for permanent pathologic evaluation following excision to evaluate for malignant tissue. Preoperative urine cultures are obtained to appropriately tailor preoperative antibiotics and decrease the risks of perioperative and postoperative infection. The differential diagnosis of

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periurethral masses (Table 20.1) is extensive and includes Skene's gland cyst or abscess (Fig. 20.1), vaginal leiomyoma [4], and primary urethral malignancy. Therefore, the importance of a correct diagnosis prior to undertaking surgical excision cannot be overemphasized.

Preoperative topical estrogen replacement in those with postmenopausal vaginal atrophy can be helpful in improving tissue quality.

Table 20.1 Differential diagnosis of periurethral masses

Leiomyoma
Skene's gland abnormalities
Gartner's duct abnormalities
Vaginal wall cysts
Urethral mucosal prolapse
Urethral caruncle
Periurethral bulking agents
Malignancy
Endometriosis

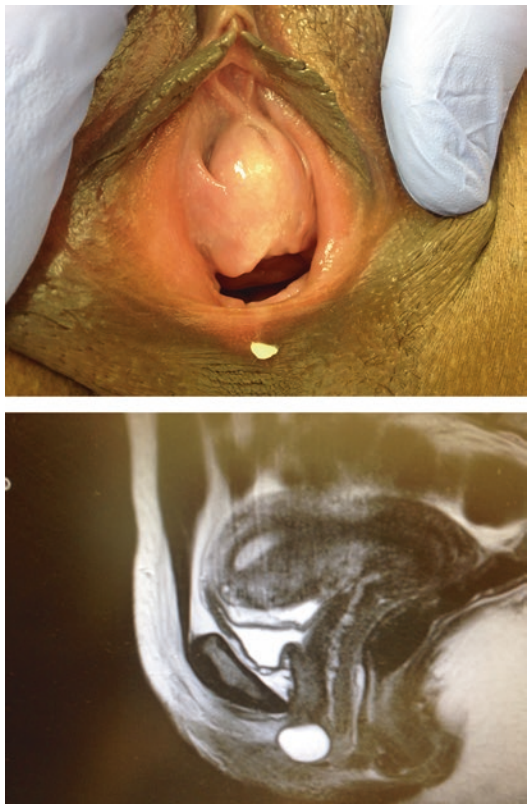

Fig. 20.1 Skene's gland abscess clinically (*top*) and on MRI (*bottom)*

Intraoperative Complications

Intraoperative complications related to anterior compartment vaginal surgery have been previously described and include, but are not limited to, bleeding and injury to the urinary tract.

Bleeding

The risk of bleeding during surgery can be minimized, but not entirely eliminated by good operative technique. Multiple blood vessels traverse the deep pelvis including large venous channels in the retropubic space. Named vessels in the obturator fossa along the pelvic sidewall, including branches of the internal iliac, and those vessels within the vascular pedicle of the bladder are at risk for injury, particularly during passage of trocars or needles for concomitant pubovaginal sling. Major vascular injury can quickly lead to life-threatening hemorrhage if not recognized intraoperatively and may result in large retropubic hematomas postoperatively [5, 6]. Bleeding during the harvest of a concomitant Martius flap is usually easily visualized and controlled with a combination of cautery, suture ligature, and direct compression. Labial hematomas have been reported with postoperative bleeding [7].

Bleeding during UD surgery can be problematic. The initial dissection of the vaginal flap from the underlying periurethral fascia should be associated with minimal bleeding. Bleeding encountered during this early dissection may indicate an excessively deep and incorrect surgical plane. In this circumstance, immediate recognition and reevaluation is necessary to avoid inadvertent entry into the urethral diverticulum or urinary tract and to minimize bleeding. Following identification of this situation, dissection should proceed in the proper surgical plane; in reoperative surgery, however, this may be difficult to identify.

Another common site of bleeding during transvaginal UD surgery occurs when traversing the endopelvic fascia for placement of a pubovaginal sling. Entry into the retropubic space

from the transvaginal side or placement of the suprapubic needles or trocars from the abdominal side may be associated with copious bleeding as the endopelvic fascia is perforated. If the bleeding continues and is brisk, the vagina can be packed. It can be very helpful to manually elevate the anterior vaginal wall and compress it anteriorly against the posterior symphysis pubis for several minutes using the surgeon's hand, sponge stick, or a retractor. These maneuvers will effectively tamponade bleeding in the retropubic space. Packing and compression will result in adequate control in the majority of cases; if not, the surgeon should expeditiously complete the procedure, close the incisions, and pack the vagina [8]. Additionally, absorbable sutures can be placed through and through the vaginal wall in the lateral fornices of the anterior vagina to ligate vessels that cannot be visualized in the operative field. Brisk bleeding that does not respond to manual compression for an extended period of time may suggest a major vessel injury and mandates retropubic exploration.

Urinary Tract Injury

Urethra

The Foley catheter is usually seen following complete excision of UD at the location of the entry of the ostium into the urethra. The urethra can be reconstructed over as small as a 14F Foley catheter without long-term risk of urethral stricture, and should be closed in a watertight fashion with absorbable suture [9]. The closure should be tension free. Uncommonly, a UD may extend circumferentially around the urethra and require transection of the involved portion of the urethra and complex reconstruction [10, 11].

Ureter

Ureteral injury during UD surgery is rare, but may occur with a large or proximal UD extending beyond the bladder neck and posterior to the bladder trigone. In these instances, cystoscopic placement of ureteric catheters prior to the dissection may aid in ureteral identification. Virtually all of these injuries can be identified by intraoperative cystoscopy. The administration of intravenous vital dyes such as indigo carmine permits obvious visualization of ureteral efflux confirming ureteral patency. With limited availability of indigo carmine, preoperative oral phenazopyridine, 50% dextrose solution for bladder filling, or intraoperative intravenous 10% fluorescein can be used as alternatives [12, 13]. Suspected ureteral injuries are confirmed by retrograde pyeloureterography. Ureteral transection requires ureteroneocystostomy. Inadvertent ureteral obstruction by sutures can also be recognized with cystoscopic confirmation of ureteral patency. If obstruction is suspected, offending sutures can be identified and removed, and placement of a temporary indwelling ureteral stent should be considered.

Bladder

Intraoperative bladder injury may occur during dissection of a large UD extending proximal to the bladder neck and inferior to the bladder (Fig. 20.2), or alternatively, may occur with passage of a ligature carrier through the retropubic space if placing a pubovaginal sling.

Injury to the bladder during UD excision is diagnosed intraoperatively by careful endoscopic examination of the bladder and bladder neck with a 70° lens or a flexible cystoscope with retroflexion following UD dissection and/or

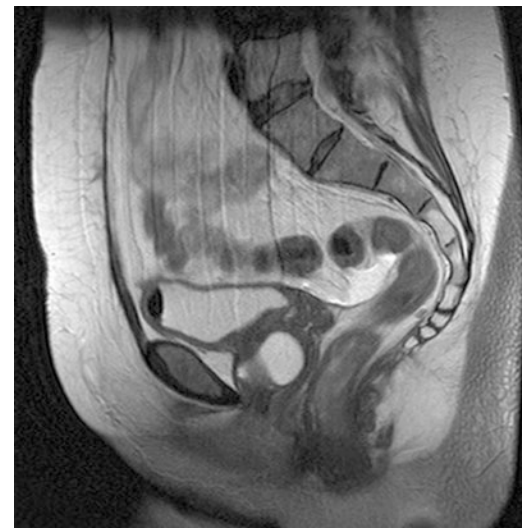

Fig. 20.2 Urethral diverticulum extending below trigone

passage of the ligature carrier. The bladder should be filled and then examined to ensure that a small injury does not go unrecognized in a fold of the bladder wall.

To avoid injury during ligature carrier passage, the urethra should be clearly palpated, the bladder drained, and the pelvic anatomy well delineated. If a bladder injury is noted intraoperatively, the ligature carrier should be removed and reinserted. Bladder perforation from a ligature carrier usually does not require primary closure.

Injury to the bladder floor during UD dissection requires cystoscopic examination to assess the extent of the injury and intravenous dyes should be administered to confirm ureteral integrity. Small cystotomies may be closed in layers with absorbable sutures transvaginally. More extensive injuries involving the trigone or more proximal bladder may require transabdominal repair. Postoperative drainage of the bladder with a Foley catheter will help avoid urinoma, fistula formation, and pelvic abscess.

Postoperative Complications

Careful adherence to the principles of transvaginal urethral diverticulectomy should minimize postoperative complications (Table 20.2). Nevertheless, complications may arise (Table 20.3). One small series suggested that large diverticula (>4 cm) or those associated with a lateral or horseshoe configuration may be associated with a greater likelihood of postoperative complications and risk factors for failure or poor functional outcome included horseshoe or circumferential configuration or a previous (failed) surgical intervention [14]. Large or more complex UD typically require greater dissection and more involved reconstruction.

Early Postoperative Complications

Raup and coworkers described 30 day complications of diverticulectomy in the multi-institutional cohort derived from the National Surgical Quality Improvement Program user files. They found that out of 2.3 million cases in the database, there were 122 female urethral diverticulectomy cases reported between 2007 and 2012. Minor complications occurred in 3.3 % of cases, with urinary tract infection being most common (four patients), and one each of superficial wound infection and hemorrhage requiring transfusion [15]. Nickles and coworkers report a series of 43 patients who underwent urethral diverticulectomy with UTI rates of 3/11 (27 %) for complex UD, and 1/32 (3 %) for simple UD [16]. In a series of 38 patients undergoing autologous rectus fascial pubovagninal sling and UD repair, Enemchukuwu and coworkers report a 5 % (2/38) rate of wound infection, presumably at the harvest site [17].

Table 20.2 Principles of transvaginal urethral diverticulectomy

Mobilization of a well-vascularized anterior vaginal wall flap(s)
Preservation of the periurethral fascia as a separate layer
Identification and excision of the neck of the UD or ostium
Removal of entire UD wall or sac (epithelium)
Watertight urethral closure
Multilayered, nonoverlapping closure with absorbable suture
Closure of dead space
Preservation or creation of continence

Data from Rovner ES. Bladder and Female Urethral Diverticula. In: Wein AJ, Kavoussi L, Novick A, Partin A, Peters C, eds. Campbell-Walsh Urology. 10th ed. Philadelphia: Elsevier Saunders; 2012

Table 20.3 Complications of transvaginal urethral diverticulectomy

Complication (% range of reported incidence)
Urinary incontinence (1.7–16.1 %)
Urethrovaginal fistula (0.9–8.3 %)
Urethral stricture (0–5.2 %)
Recurrent UD (1–25 %)
Recurrent UTI (0–31.3 %)
Other
Hypospadias/distal urethral necrosis
Bladder or ureteral injury
Vaginal scarring or narrowing: dyspareunia, etc.

Data from Dmochowski R. Surgery for vesicovaginal fistula, urethrovaginal fistula, and urethral diverticulum. In: Walsh P, Retik A, Vaughn Jr. E, Wein A, eds. Campbell's Urology. 8th ed. Philadelphia: WB Saunders; 2002

Incontinence

Stress Urinary Incontinence

Patients with preoperative symptomatic stress urinary incontinence (SUI) in association with UD can be offered simultaneous anti-incontinence surgery. Preoperative videourodynamics may be helpful in evaluating the anatomy of the UD, assessing the competence of the bladder neck, and confirming the diagnosis of SUI. In patients with SUI and UD, Ganabathi and others have described excellent results with concomitant needle bladder neck suspension [9, 18], although such needle suspensions are rarely done in contemporary practice. More recently, pubovaginal autologous fascial slings have been utilized in patients with UD and SUI with satisfactory outcomes [1, 17, 19, 20]. The role of synthetic midurethral slings, however, has not been well defined in this population and current AUA guidelines recommend against using synthetic material in this setting [21]. Placement of synthetic material adjacent to a fresh suture line following diverticulectomy in the setting of potentially infected urine may place the patient at higher risk for subsequent urethral erosion and vaginal extrusion of the sling material as well as urethrovaginal fistula formation and foreign body granuloma formation [21].

Significant postoperative de novo SUI may occur in between 7 and 16 % of individuals undergoing urethral diverticulectomy surgery without a concomitant anti-incontinence surgery [7, 22, 23]. However, Lee and colleagues noted at least minor de novo SUI in 49 % of patients following urethral diverticulectomy, the majority of which was minor and did not require additional therapy [24]. Only 10 % of these individuals underwent a subsequent SUI operation. Risk factors for de novo SUI may include the size of the diverticulum (>30 mm) and more proximal location [23]. Ljungqvist and colleagues correlated de novo SUI with wide diverticulum excision in addition to size and location [7]. Popat and Zimmern [25] reported long-term follow-up for 12 women with horseshoe diverticula who underwent diverticulectomy using a urethral preservation technique. Four patients had stress incontinence preoperatively, two had residual stress incontinence, one went on to have treatment with collagen injection [25]. Nickles and coworkers report de novo SUI in 1/11 (9.1 %) after complex UD repair and 1/32 simple UD repairs, noting a significantly higher rate of concomitant PV sling with complex repair [16]. De novo SUI may arise from the extensive suburethral or circumferential dissection required for a large UD, and the more proximal UD location may compromise the urethral sphincter and bladder neck anatomical support and/or the sphincter mechanism [23]. Alternatively, large UD at the bladder neck may cause obstruction [26] and occult SUI may be unmasked after removing the obstructing UD [27].

Management of de novo postoperative SUI is undertaken after allowing postsurgical inflammation to subside. Autologous pubovaginal sling is a reasonable option in this setting. Synthetic materials such as midurethral polypropylene slings must be used judiciously in this setting, however, as safety data are lacking. Repeat preoperative imaging may be helpful in excluding a recurrent or persistent UD, or urethrovaginal fistula prior to surgery for incontinence [7].

Urinary Urgency and Urgency Incontinence

Stav and colleagues reported rates of urgency-frequency symptoms decreased significantly postoperatively from 60 to 16 % and noted complete resolution of urgency incontinence [23]. Other series, however, have demonstrated rates of postoperative urgency of 54 % [28] and de novo urgency incontinence in 36 % of patients [7] including the recent series by Nickles and coworkers which showed urgency urinary incontinence in 3/11(27.3 %) patients undergoing complex diverticulectomy and 6/32 (24 %) of patients undergoing simple UD repair [16]. Preoperative counseling should include a discussion of new onset storage symptoms. These symptoms may be managed expectantly postoperatively; nonetheless, continued symptoms postoperatively may herald UD persistence, UD recurrence or de novo urethral obstruction. Importantly, urinary incontinence following UD

excision should be evaluated to rule out the presence of urethrovaginal or vesicovaginal fistula.

Urethrovaginal Fistula

A urethrovaginal fistula located distal to the sphincteric mechanism (Fig. 20.3) should not be associated with symptoms other than perhaps a split urinary stream and/or vaginal voiding. As such, an asymptomatic distal urethrovaginal fistula may not require repair although some patients may request repair. A proximal urethrovaginal fistula located at the bladder neck, or at the midurethra in patients with an incompetent bladder neck will likely result in considerable symptomatic urinary leakage (Fig. 20.4). Fistula repair in these symptomatic cases can be undertaken transvaginally with consideration for the use of an adjuvant tissue flap such as a Martius flap to provide a well-vascularized additional tissue layer. The timing of urethrovaginal fistula repair relative to the initial diverticulectomy is controversial, but should allow for tissue inflammation to subside. Meticulous attention to surgical technique, good hemostasis, avoidance of infection, preservation of the periurethral fascia, and a well-vascularized anterior vaginal wall flap, combined with a multilayered closure and nonoverlapping suture lines, should minimize the potential for postoperative urethrovaginal fistula formation [27]. Urethrovaginal fistula rates in two recent publications combining diverticulectomy series showed 7/580 or 1.2 % rate of fistula [29] and of the 42 studies with 1928 patients mentioning fistula outcomes, 38 fistulas were described, but the data were too heterogeneous to combine, giving a range of 1–8 % [30].

Recurrent Symptoms

While complete resolution of obstructive and irritative urinary symptoms after UD excision may occur [23, 30], some patients will have persistence or recurrence of their preoperative symptoms postoperatively. Ljungqvist and colleagues noted reoperation (but not necessarily extent of the primary operation) was the greatest clinical factor associated with residual symptoms postoperatively [7]. These symptoms may be a result of surgery itself, and if so, may resolve over time. Such symptoms should be carefully investigated, as recurrent UD, new UD, or urethral stricture should be high on the differential diagnosis.

Recurrent Urethral Diverticulum

Recurrence of UD may be due to incomplete removal of the epithelialized UD sac, failure to recognize a second ostium, inadequate closure of the urethra, failure to close residual dead space, excessive tension on the repair, infection, or other technical factors [27, 31]. Lee noted recurrent urethral diverticulum in 8/85 patients at follow-up of between 2 and 15 years from the initial UD resection [32], while Ljungqvist and colleagues reported recurrence in 11/68 patients over a 26-year follow-up [7] The risk of recurrence of UD following transvaginal excision may be related to the complexity of the anatomical

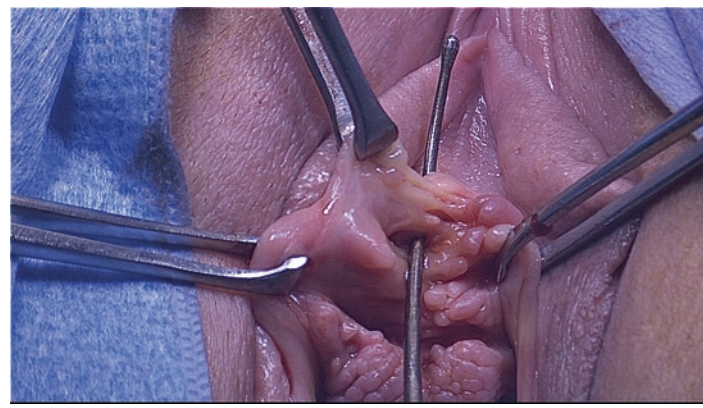

Fig. 20.3 Distal urethrovaginal fistula

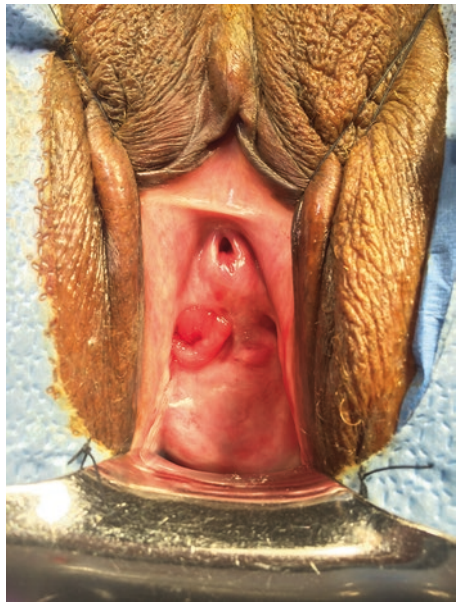

Fig. 20.4 Midurethral urethrovaginal fistula

configuration. Han and coworkers reported no recurrent UD in 17 patients with simple UD, but of the 10 patients with circumferential UD, recurrence was noted in 6 (60 %) [22]. Notably in this series, secondary procedures were not as successful in completely removing the UD. Ockrim and coworkers similarly cured all 19 patients presenting with simple urethral diverticula on the first attempt, but the 11 patients with complex anatomical configurations required a total of 17 procedures for success [26]. Ingber reported a 10 % reoperation rate for UD recurrence which was associated with proximal UD location, multiplicity, and prior urethral vaginal surgery [28]. Nickles reported one recurrent complex UD out of 11, and no recurrences in 32 simple UD [16]. Popat reported one recurrence in 12 patients with horsehoe UD [25]. In a series of 38 patients undergoing UD repair with rectus sheath pubovaginal sling, there were 2 UD recurrences [17]. Recurrent UD after failed prior surgeries may lead to more complex, circumferential involvement [10]. Repeat urethral diverticulectomy surgery can be challenging due to altered anatomy, scarring, and the difficulty in identifying the proper anatomic planes. Prevention of recurrence, especially in reoperative UDs, includes the use of a Martius flap, while MRI remains invaluable in surgical planning to ensure complete excision [26, 33]. Complications such as fistula and recurrence of the UD are more common in reoperative cases [7].

Urethral Stricture

Urethral strictures are rare following UD excision; Rovner and Wein noted urethral stricture in 1/44 patients and Ljungvqist in 1/27 patients [7, 10]. Stricture may result from closing the urethra too tightly or reconstructing it over too small a sound/catheter or in one instance, postoperative catheter dislodgement [10]. Additionally, poorly vascularized periurethral tissues could result in ischemia and stricture formation postoperatively. A Martius flap should be considered intraoperatively if urethral reconstruction is complex to provide a healthy graft and assist in stricture prevention. A urethral stricture may be managed postoperatively with urethral dilation. Rarely is open reconstruction with urethroplasty necessary.

Recurrent Urinary Tract Infections

Frequent UTIs may persist following UD excision and may be due to recurrence of the diverticulum or other etiologies. Ingber and coworkers found 23 % of patients reported having three or more infections in the last year of follow-up after urethral diverticulectomy [28]. In a series of 30 patients, Ockrim found the incidence of recurrent UTIs decreased from 17 to 3 % [27]. Bodner-Adler report in their systematic review of the literature that 7–31 % of patients have recurrent UTIs after diverticulectomy [30]. Recurrent UTI work-up can be undertaken once recurrent UD has been excluded.

Pain

Urethral pain and/or severe pelvic pain was significantly relieved or resolved in all patients following diverticulectomy in one series [10]. Romanzi found resolution of preoperative urethral pain in all but two patients postoperatively [1]. Nonetheless, urethral pain may persist

despite surgical intervention. Ockrim and coworkers reported persistent pain in two patients, despite repeat diverticulectomy including extensive dissection of the urethra [26]. Persistent postoperative urethral and pelvic pain, in the absence of UD recurrence, may be secondary to postsurgical changes, chronic inflammation of the periurethral tissues from the prior UD, pelvic floor muscle disorders, or may be multifactorial in etiology and may ultimately require a multimodal treatment approach.

Dyspareunia

Dyspareunia is one of the classic presenting symptoms of UD. In two larger series of UD patients with preoperative dyspareunia rates of 54 % and 56 %, rates dropped to 10 % and 8 %, respectively [23, 26]. Persistent or de novo dyspareunia postoperatively may result from postsurgical changes, including vaginal scarring and narrowing, especially in patients undergoing reoperative surgery. Vaginal narrowing can be prevented by harvesting a wide-based vaginal flap, thereby avoiding subsequent devascularization and contracture. Romanzi and coworkers reported dyspareunia resulting from the Martius flap and labial point tenderness on the harvest side [1]. Patients should be counseled appropriately regarding possible postoperative persistence of this symptom and be well informed of the possible sequelae of the Martius flap harvest. Similar to persistent urethral and pelvic pain, postoperative management of dyspareunia may require a multimodal approach.

Hypospadias/Distal Urethral Necrosis

Distal urethral tissue loss and hypospadias are possible complications of the Spence-Duckett marsupialization procedure. Changes in the distal urethra can cause spraying stream or vaginal voiding.

Malignant Lesions

Malignant and benign neoplasms may be found in urethral diverticula at the time of permanent pathologic specimen. Approximately 10 % of urethral diverticulectomy specimens may demonstrate histopathological abnormalities including metaplasia, dysplasia, or frank carcinoma, which require long-term follow-up or additional therapy [34]. The most common malignant pathology in UD is adenocarcinoma, followed by transitional cell and squamous cell carcinomas [34, 35]. In contrast, the most common histologic type of primary urethral carcinoma is squamous cell carcinoma. Nonexcisional therapy of UD such as marsupialization or endoscopic incision can be combined with a biopsy to rule out malignancy [36]. It has not been conclusively demonstrated that any particular preoperative imaging modality such as ultrasound or MRI can reliably and prospectively diagnose a small malignancy arising in a UD [37]. There is no consensus on proper treatment in cases where a malignancy is found in a diverticulectomy specimen, and recurrence rates are high with local treatment alone [35]. When considering curative therapy, it is unclear whether extensive surgery including cystourethrectomy with or without adjuvant external beam radiotherapy is superior to local excision followed by radiotherapy [38]. However, pelvic exenteration may offer the highest likelihood of prolonged disease-free interval [39].

Stones

Calculi within UD are not uncommon and may be diagnosed in 4–10 % of cases [1, 40, 41] and are most likely due to urinary stasis and/or infection. This may be suspected by physical exam findings or noted incidentally on preoperative imaging. The presence of a stone will not significantly alter the evaluation or surgical approach, and it can be removed with the UD specimen at the time of surgery.

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Vesicovaginal and Urethrovaginal Fistula Repair

21

Michael Ingber and Raymond R. Rackley

Introduction

A fistula represents an abnormal connection between two body parts. In the case of a urogenital fistula, an abnormal communication between the urinary tract and the vagina develops that causes urine to leak into the vagina via a route other than the urethral meatus. Vesicovaginal fistulae represent the most common type of fistula encountered by pelvic surgeons today. In developed countries, the more common etiologies include pelvic surgeries for hysterectomy, incontinence, or pelvic reconstructive procedures [1]. In developing countries, pregnancy-related complications from obstructed labor result in ischemic injury to the bladder and vagina and can lead to very large fistulae that can be difficult to treat [2] (Table 21.1).

Regardless of the etiology, repair of vesicovaginal fistulae can be technically challenging, and complications can occur even when performed by expert surgeons. Patients with fistulae, by their nature, often have significant comorbidities that make them more prone to having complications. Furthermore, not only do tissue ischemia, inflammation, and devitalized tissue cause fistulae, but they also can be a limiting factor in proper management and cure. Controversies continue to exist with respect to the proper timing of treatment, route and method of surgery, and use of any adjuvant flaps. Nevertheless, several steps may be performed in order to minimize such perioperative issues. Herein, we describe complications related to vesicovaginal and urethrovaginal fistulae and ways to prevent adverse outcomes from surgical repair.

Preoperative Considerations

Timing of Repair

Obstetrical fistulae typically have significant tissue ischemia due to prolonged pressure from the fetal head on the bladder wall. Furthermore, fistulae from radiation damage may have surrounding ischemic tissue which may take several months to a year to stabilize. As such, most experts agree that waiting several months to fix such fistulae increases likelihood of

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Table 21.1 Causes of urogenital fistulae

Congenital
Acquired
Iatrogenic
Postoperative
Hysterectomy
Abdominal
Transvaginal
Laparoscopic
Incontinence procedures
Transvaginal slings
Retropubic
Laparoscopic
Prolapse procedures
Anterior colporrhaphy
Mesh kits
Sacrospinous/uterosacral fixation
Sacral colpopexy
Urethral diverticulectomy
Endoscopic procedures
Bowel and vascular surgeries
Radiation injury
Noniatrogenic
Pelvic malignancy
Obstructed labor
Trauma
Sexual injury
Infection
Foreign body

success (Fig. 21.1) [3]. However, when to fix an iatrogenic fistula has been a subject of controversy for many years [4]. Each case should be managed individually, as both early repair and delayed repair may be successful in the appropriate circumstance [5–8]. In general, fistulae which are recognized in the immediate postoperative period can be immediately repaired. Delaying in cases of immediate recognition only causes additional psychological suffering, given the significant amount of leakage that patients will experience while waiting for repair. In cases where tissue edema and inflammation prevent successful repair, a waiting period of several weeks to months may be appropriate.

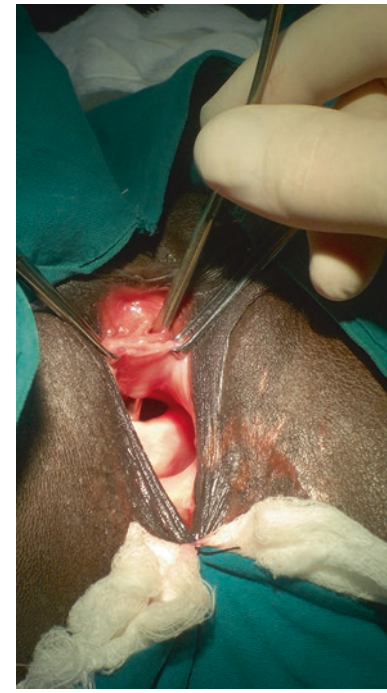

Fig. 21.1 Obstetric vesicovaginal fistulae are typically larger, due to prolonged tissue ischemia

Diagnostic Studies

Determining the location of a fistula in cases of severe vaginal urinary leakage is often the most challenging part of an incontinence evaluation. While voiding cystourethrograms and plain cystograms can often demonstrate the presence of a fistula, they often fail to demonstrate the exact location of vesicovaginal fistulae, as well as the presence of multiple fistulae (Fig. 21.2). Additionally, ureteral injury can be present in up to 12% of cases of vesicovaginal fistulae, and recognition of this preoperatively is essential [9]. CT urography has largely replaced intravenous pyelography as a diagnostic modality of choice when evaluating upper tract damage or fistula. Cystoscopy is an essential component in the evaluation of any woman with unexplained or continuous incontinence. Typically, cystoscopy can show a fistulous tract, or at least suggest fistula due to severe inflammatory changes (Fig. 21.3). Retrograde pyelogram at the time of

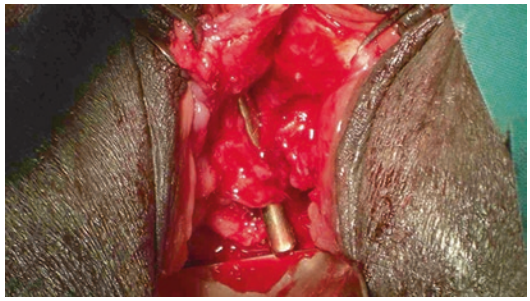

Fig. 21.2 Performing a careful examination is essential, as many patients have multiple fistulae which should all be addressed simultaneously during surgical repair. This patient had both a vesicovaginal and a urethrovaginal fistula

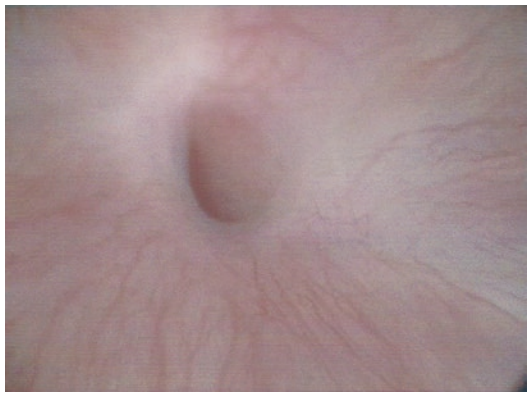

Fig. 21.3 Cystoscopic examination will often show a fistulous tract, or area of inflammation suspicious for vesicovaginal fistula

cystoscopy can usually demonstrate ureteral extravasation of contrast (Fig. 21.4). Alternatively, CT urography can show locations of urinary extravasation and often be diagnostic of ureterovaginal fistula (Fig. 21.5).

Approaches to Fistula Repair

Determining which route to perform fistula repair is of utmost importance in order to prevent untoward complications. Most fistula experts agree that the first attempt at repair is the most important surgery which can provide the surgeon with the best opportunity to definitively repair the defect. Therefore, the first attempt should be the route which the surgeon feels most comfortable with. There are some benefits, however, to choosing specific methods based on the type of fistula.

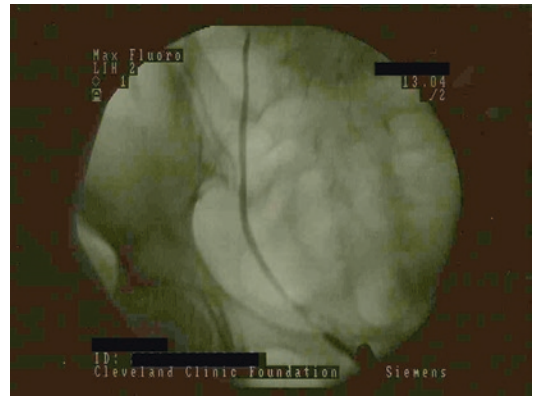

Fig. 21.4 Retrograde pyelogram demonstrating ureteral extravasation of contrast into vagina. With ureterovaginal fistulae, early ureteral stenting may avert need for ureteral reimplantation

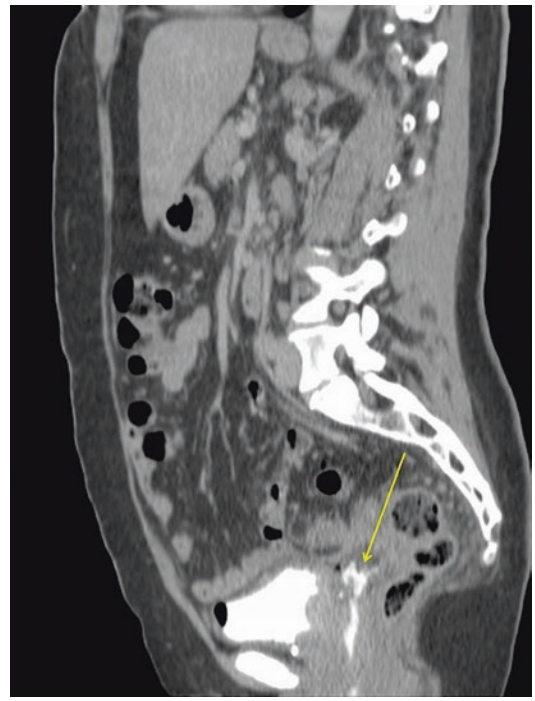

Fig. 21.5 CT urography can be an excellent imaging modality when evaluating for the presence of fistula. Here, a communication can be seen (*arrow*) between the distal ureter and vagina

Open Abdominal Repair

The abdominal route may be preferred in women who have poor vaginal access, ischemic tissue from radiation, or those in whom a laparoscopic approach is contraindicated. Women with multiple fistulae including other organs (i.e., enterovaginal fistulae) are often better served with an open abdominal approach. Large, well-vascularized adjuvant tissue flaps are a major advantage available with open abdominal approaches and may decrease recurrence risk in such cases. Complications related to open repair include wound infection, incisional hernia, and increased bleeding risk.

Transvaginal Repair

Choosing a transvaginal route and avoiding intraperitoneal access is often a preferred method in most fistulae, provided that the surgeon has access to the site. Specifically, for distally located fistulae, the transvaginal route is recommended, as fistula repair can be performed in an outpatient setting. Some practitioners prefer the Latzko partial colpocleisis to repair apical fistulae, as this method has rather high success rates [10–12]. Most women handle postoperative pain well with the transvaginal route. Complications specific to the transvaginal route include vaginal shortening and vaginal stenosis which may lead to dyspareunia.

Laparoscopic and Robotic-Assisted Laparoscopic Repair

Several authors have described laparoscopic and robotic-assisted laparoscopic repair of vesicovaginal fistulae [13, 14]. The advantage of utilizing robotic technology is the ability to have excellent magnified views of the repair, along with the ability to suture for those surgeons not experienced in laparoscopic suturing techniques. Robotic and laparoscopic repairs are often a preferred route in apical fistulae that are unable to be reached vaginally, as they provide superior visualization to defects in this area when compared to the open route. One potential disadvantage that could lead to increased risk for recurrence is the difficulty in obtaining an interposed omental flap although peritoneal flaps are typically easy to obtain during laparoscopic repair.

In a recent report, authors compared intraoperative data and outcomes of 12 robotic-assisted repairs to 20 open surgical repairs [15]. All subjects in the robotic group and 90% of those in the open cohort were managed successfully. Not surprising, mean blood loss was significantly less in the robotic group (88 mL vs. 170 mL, $p < 0.05$). Mean hospital stay was also shorter in the robotic group (3.1 vs. 5.6 days, $p < 0.05$). Another single-institution experience noted a mean operative time of 214 min, and a median length of stay of 1 day [16]. In the authors' experience, laparoscopic and robotic-assisted repaired patients can typically be discharged home after a 23 h stay. Neither group had a significant difference in complication rate. Complications relevant to laparoscopic repair include port-site hernias, bowel injury, and adjacent organ injury.

Intraoperative Considerations

Because of the already present poor tissue conditions that led to development of a fistula in the first place, intraoperative complications can be relatively common during fistula surgery.

Complications During Dissection

Many fistulae are surrounded by significant inflammation, which can lead to excessive bleeding and poor visualization intraoperatively. Careful dissection is of utmost importance when performing repair, as the surgeon must obtain several layers of closure to prevent recurrence. Complications may occur if the initial dissection of the vaginal epithelium is too deep, and additional layers of closure are unattainable. Excess bleeding may result when improper tissue planes are entered. In cases where flaps are too thin for a good watertight closure, adjuvant tissue flaps uti-

lizing omentum (in abdominal repair) or a Martius flap (in vaginal repair) are crucial.

The authors do not routinely excise the entire fistula tract. Nevertheless, in cases of prior malignancy or in postradiation fistulae, one should obtain a biopsy to ensure that there is no malignancy at the site of the fistula. Any nonviable tissue should always be removed in order to obtain better healing. Avoidance of cautery is important, as excess cautery can compromise blood supply to tissue flaps and jeopardize healing. Hence, significant bleeding should be controlled with interrupted suture.

Complications related to adjacent organ injury are relatively uncommon. If the ureters are close to the repair, they should be stented initially. Ureteral injury may be a result of cautery injury or sharp dissection and should be recognized immediately. A small ureteral defect may be repaired primarily. However, extensive cautery injury, or full transection, typically requires reimplantation in order to prevent ureteral leak or stricture formation. Injury to the bowel may occur during transperitoneal repair, either immediately from dissection injury, or 1–2 weeks following repair due to cautery injury. Patients with prior pelvic radiation may have more inflammation, resulting in additional adhesions, and can be more prone to such injuries.

Closure

Choosing the proper suture is extremely important in minimizing complications. Closure of the bladder or urethral defect should be performed with absorbable suture such as 3-0 polygalactin or 3-0 chromic. If knots are tied on the intravesical side, a patient may be predisposed to developing calcifications or infections due to delayed absorption when exposed to urine. Nonabsorbable suture should never be used during fistula repair, as permanent suture material can lead to infections and stone formation within the bladder (Fig. 21.6). Additional layers such as a pubocervical fascial layer should also be closed with absorbable suture so that suture lines are nonoverlapping. Once fully closed, the repair should be tested for water-tightness by instilling saline. Any sites of leakage along the suture line should be oversewn with additional suture to ensure complete closure.

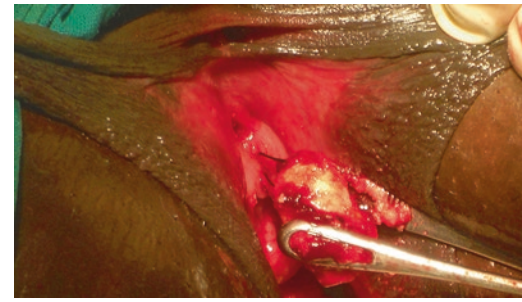

Fig. 21.6 Permanent sutures should never be used during fistula repair. Similarly, absorbable suture knots should be tied external to the bladder mucosa, in order to prevent fistula recurrence and stone formation, as in this patient

Adjuvant Flaps

Providing an additional layer of coverage should be considered when a three-layer closure is not able to be performed, or when tissue quality may compromise proper healing. Interposed tissue flaps should be secured with absorbable suture at least 1–2 cm beyond the site of repair. Complications related to harvesting flaps are relatively minimal and are typically limited to bleeding from the site of where the flap was obtained. One study evaluated eight women who underwent Martius flap surgery and questioned subjects on appearance of the harvest site and any postoperative complications [17]. Three (38%) women felt the appearance of the flap site was different from the contralateral labia. At 1 year after the procedure, one patient (13%) complained of dyspareunia, three (38%) patients had intermittent discomfort in the harvest area, and five patients (62%) complained of permanently decreased sensation or numbness at the harvest site. Another study evaluating mostly obstetrical urethrovaginal and vesicovaginal fistulae, however, showed decreased incidence of dyspareunia as well as recurrence after Martius interposition [18].

Omental flaps are an excellent source of adjuvant tissue during transabdominal repair and can

occasionally be accessible during transvaginal repair in posthysterectomy vesicovaginal fistulae. The blood supply to omental flaps is based upon the right or left gastroepiploic artery, although the right gastroepiploic is both larger and more caudal, allowing for better reach distally during intra-abdominal fistula repair. Regardless, tissue interposition should be determined based on the quality of repair. All patients should be counseled about potential use of flaps and the complications specific to the site of tissue interposition.

Postoperative Complications

Not unexpectedly, the most common complication encountered after vesicovaginal and urethrovaginal fistula repair is recurrence of the fistula. With a complete preoperative workup, attention to basic fistula principles, and careful surgical repair, recurrence rates can be minimal. Should a recurrence occur, management can be via any route.

To a woman suffering from continuous incontinence from a fistula, persistence of urinary incontinence despite a properly repaired fistula can be devastating. Stress incontinence may occur after both transvaginal and transabdominal fistula repair if the dissection disrupts the ligamentous support of the urethra or the sphincteric mechanism. In several series, the rate of stress incontinence after fistula repair ranges from 4 to 33% after surgery and are likely higher in obstetrical fistula [19, 20]. Risk factors of stress incontinence after fistula surgery include involvement of the urethra, small bladder capacity, large fistula, and need for extensive vaginal reconstruction [21]. In women with vesicovaginal fistula and concomitant stress incontinence, a simple midurethral sling may be performed provided that the urethral dissection is well away from any fistula repair. However, in the setting of any periurethral dissection during fistula repair, it is the authors' preference that any therapy for stress incontinence wait until after total healing occurs after fistula surgery.

Urinary tract infection is a relatively common complication of fistula repair postoperatively, as instrumentation of the urinary bladder itself can predispose a woman to infection. Studies evaluating antibiotic use during and after fistula repair are limited to obstetric fistula. In a review of single-dose gentamicin vs. extended postoperative antibiotics during 722 obstetric fistula repairs in Ethiopia, Muleta and colleagues showed no difference in rates of postoperative infection [22]. Regardless of postoperative antibiotic use, sterilization of the urine prior to repair is of utmost importance, as preoperative urinary tract infection may increase the likelihood of fistula recurrence [23]. The authors occasionally use a low-dose antibiotic such as nitrofurantoin while patients await repair not only to prevent perioperative urinary tract infection, but also to decrease tissue edema and inflammation which allows for easier repair.

Urinary urgency may occur after any vaginal surgery which involves dissection around the urethra and the bladder. Rates of postoperative urinary urgency are difficult to determine due to the few studies that have used urinary urgency as an outcome. However, in one small study evaluating 20 genitourinary fistulae, seven (35%) developed urinary urgency postoperatively. Because de novo urgency can be an irritative complication, it should be discussed preoperatively with patients. It is the authors' preference to offer patients anticholinergic therapy during the healing phase when catheters are present to minimize uninhibited detrusor contractions. Rarely, patients may have persistent urinary urgency even several months after repair. When such a complication occurs, urodynamic investigation to ensure no evidence for bladder outlet obstruction is essential. Long-term treatment of the urgency may be required in some patients.

Vaginal shortening is more common with apical fistulae when the Latzko partial colpocleisis is utilized. However, when done appropriately, only 1–2 cm of vaginal length is compromised, and this should not be an issue. Typically, women can remain sexually active without major problems with dyspareunia even when significant vaginal shortening occurs [24]. Nevertheless, vaginal shortening should be mentioned when counseling women who are sexually active, as women may

recognize the change in anatomy with deep penetration of their partner.

Urethrovaginal Fistula

While vesicovaginal fistulae are relatively common, there is a paucity of information on the repair of urethrovaginal fistula. In developed countries, urethrovaginal fistulae are most commonly a result of previous vaginal surgery. Symptoms are variable as are techniques for repair. Like vesicovaginal fistula, complications specific to urethrovaginal fistula most commonly involve recurrence, with 10% of primary repairs recurring in a recent series [25]. Knowing the location and number of the fistulae are extremely important.

Because of the proximity to the urethral sphincter, patients with urethrovaginal fistula that occur within the proximal and/or middle urethra are prone to development or worsening of stress urinary incontinence after repair (Fig. 21.7). In the aforementioned study, of 71 subjects undergoing repair, 37 (52.1%) developed stress incontinence after repair [25]. Some surgeons advocate the use of autologous fascia in order to correct stress incontinence during urethrovaginal fistula repair [26, 27], but the author typically prefers to wait until any fistula repair is complete. Once several months of healing has occurred, if the incontinence remains, it may be assessed, and a synthetic or autologous sling may be placed if necessary.

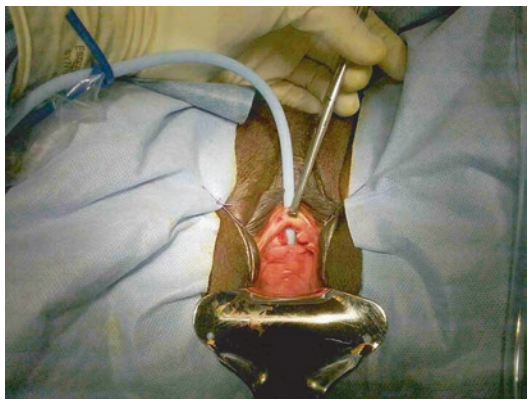

Fig. 21.7 Urethrovaginal fistula can affect the external sphincter and simple repair of the defect may still result in chronic incontinence. This patient required autologous fascial sling to correct the resulting stress incontinence after fistula repair (Courtesy of Howard B. Goldman, MD)

Like vesicovaginal fistula repair, reoperation after urethrovaginal fistula repair is relatively common. In a recent study with long-term follow-up, Lee and Zimmern published their results of 18 women who underwent urethrovaginal fistula repair [28]. At a mean follow-up of 52 months (range 9–142), success rate overall was 95%. Reoperation in this group was 33%, with three women requiring periurethral bulking agent injection, two requiring excision of additional mesh, and one requiring urethral dilation.

Conclusion

Vesicovaginal and urethrovaginal fistulae are conditions which require extensive preoperative planning, experience-driven intraoperative judgment, and close outpatient follow-up. When basic principles of fistula repair are followed, complications may be minimized, and subsequently, chances of a successful repair can be maximized.

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Transvaginal Bladder Neck Closure

22

David A. Ginsberg

Indications

The primary indication for an adult woman to undergo a transvaginal bladder neck closure (BNC) is an eroded and destroyed bladder neck/urethra secondary to a chronic, indwelling catheter. While the indication for the initial catheter placement may be varied, the chain of events leading to this scenario is usually quite similar. The catheter is usually placed for refractory urinary incontinence or retention, usually of neurogenic etiology but not necessarily.

The common clinical scenario that results in an incompetent, eroded urethra is initiated with the simple decision to manage a patient with an indwelling catheter. With long-term catheter use female patients may experience urethral erosion, which often leads to urinary leakage around the catheter. This initial erosive reaction is often further exacerbated by the caregivers' decision to use a larger catheter size and inflate the balloon with larger volumes of water. The hope is that this will minimize leakage around the catheter; however, this often results in further urethral erosion. Erosion can be so severe that catheters cannot be maintained in the bladder and spontaneously fall out. In addition, a poorly secured catheter that is repeatedly pulled out can also contribute to urethral injury. If severe enough, the urethra becomes overly patulous and a urethral indwelling catheter cannot be maintained. The urethra can be wide enough and short enough that one or two fingers can be inserted directly into the bladder [1]. In addition, the erosion can be severe enough that when a finger is inserted into the urethra, the undersurface of the pubic symphysis is directly palpated as there is no remaining urethral tissue anteriorly. Because of the length of the urethra, this is rarely an issue in the male patient; the analogous reaction in the male to long-term catheter usage would be a traumatic hypospadias.

For these women, there are few options besides use of pads/diapers. There is no female version of a condom catheter, and many of these patients are not interested in or physically able to undergo lower urinary reconstruction due to their disability. Placement of a suprapubic catheter (SP) is a simple option for these patients, and by itself, may be sufficient to control leakage of urine per the eroded urethra [2]. However, depending on the degree of the erosion and damage to the urethral sphincteric mechanism, leakage may still occur per the urethra despite continuous drainage per the SP tube. For these patients who wish to continue with SP drainage further options include placement of an obstructing sling or BNC. A potential advantage of sling

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placement is that it does not permanently close the bladder neck; however, these outlets are often so damaged that there is not an adequate amount of urethral tissue to allow for sling placement. Approaches for BNC include transvaginal and transabdominal. The transabdominal approach is often done in conjunction with some type of LUT reconstruction, is more invasive than a vaginal procedure, and has been reported to have a lower rate of post-op leak/fistula formation. The alternative is a transvaginal approach which is often done in conjunction with SP tube placement and is less invasive, but may be a more challenging procedure for surgeons less experienced with vaginal surgery [3].

Complications

There is essentially one primary complication associated with BNC which is continued leakage and formation of a vesicovaginal fistula (VVF) between the attempted closure site and anterior vaginal wall. The reported fistula rates after initial BNC range between 0 and 100% and are summarized in Table 22.1. The various surgical techniques described are fairly similar and are based on several essential principals: (1) complete mobilization of the urethra/bladder neck off the supporting pelvic ligaments; (2) resection of necrotic tissue down to healthy, viable tissue before closure is attempted; (3) multilayered closure; (4) mobilization of a large anterior vaginal wall flap to advance over the BNC.

Depending on the degree of erosion, it is possible that BNC may occur in close proximity to the ureteral orifices. It is important that the ureteral orifices are identified prior to BNC to minimize risk of damage. Certainly, there is a theoretical risk of ureteral injury at the time of transvaginal BNC though that has not been previously described in the literature.

The remainder of this chapter will focus on perioperative steps to minimize the risk of fistula formation after transvaginal BNC as well as how to manage the problem if a fistula does occur. These steps are summarized in Table 22.2.

Preoperative

There is unfortunately little that can be done preoperatively to enhance the postoperative success in these patients. One important decision the surgeon should make is whether or not to perform BNC at all, and if so, via which approach. Levy and colleagues reviewed their experience with 12 patients, all of whom underwent BNC for urethral injury secondary to long-term indwelling catheters [3]. The first four patients all underwent a primary transvaginal approach. Of those, two succeeded and the other two failed a total of five transvaginal attempts to close the bladder neck, resulting in a success rate of 50%. Both of these patients

Table 22.1 Bladder neck closure fistula rate, transvaginal approach

References	Patients	Fistula rate (%)
Zimmern et al. [1]	6	0
Nielsen and Bruskewitz [11]	5	20
Eckford et al. [12]	50	22
Levy et al. [3]	4	50
Andrews and Shah [2]	8	50
Stoffel and McGuire [13]	8	87.5
Ginger et al. [4]	2	100
Rovner et al. [6]	11	9
Willis et al. [5]	35	14

Table 22.2 Perioperative steps to minimize complication risk after transvaginal bladder neck closure

Pre-op factors	• Appropriate patient selection
	• Surgeon expertise
	• Optimization of nutritional status
Intra-op factors	• Complete mobilization of the urethra/bladder neck off supporting pelvic ligaments
	• Resection of necrotic tissue down to healthy, viable tissue
	• Multilayered closure
	• Mobilization and advancement of anterior vaginal wall flap over the bladder neck closure
Post-op factors	• Optimize bladder drainage
	• Minimize detrusor overactivity

ultimately underwent successful BNC with a combined abdominal and vaginal approach. The next ten patients (eight new patients and the two that had failed the prior transvaginal attempts) underwent combined abdominal and vaginal approach with 100% success. The authors' recommendation at the time was that a purely transvaginal approach may not be optimal if the operating surgeon does not have extensive experience performing transvaginal surgery. This manuscript was published in 1994 and one would hope that urologic surgeons have become more comfortable with transvaginal surgery. However, if that is not the case, then use of an abdominal approach should be considered. There are few studies that evaluated outcomes using multiple approaches. Ginger and colleagues revealed a 11% leakage rate in 26 patients undergoing a transabdominal BNC compared to a 100% leakage rate in the two patients in their study that underwent transvaginal BNC [4]. Willis and colleagues reviewed their experience with both approaches in 64 patients (35 transvaginal, 29 retropubic) and noted residual urethral leakage in five patients in both the transvaginal (5/35–14.3%) and retropubic (5/29–17.2%) cohorts [5].

Poor nutrition is one issue that can be addressed preoperatively. Rovner and colleagues correctly state that many of these patients often have multiple medical comorbidities and poor nutritional status at baseline [6]. Poor nutrition has been shown to impact wound healing, increase susceptibility to infection, and place the patient at increased risk for pulmonary complications, prolonged hospitalization, and mortality [7]. However, preoperative nutritional supplementation appears to only be valuable in severely malnourished patients; in all other patients, surgery does not need to be delayed [8].

Intraoperative

To minimize risk of postoperative failure and leak, there are several surgical steps that should be emphasized. Initially, two incisions are made. One is made circumferentially around the external urethra meatus. The other incision, along the anterior vaginal wall, allows for the dissection of a wide, anterior vaginal wall flap when beginning the procedure. This flap is advanced once the BNC is complete past the area of repair, thus minimizing the presence of overlapping suture lines. Prior to closing the bladder neck, appropriate mobilization is necessary. This includes transection of the urethra completely off the pubourethral ligament dorsally and the urethropelvic ligaments and remaining attachments laterally. Optimal mobility of the bladder neck is extremely important. Without mobility the closure of the bladder neck itself is very challenging. Prior to closing the urethra/bladder neck, all necrotic tissue should be resected down to viable tissue. This often results in resecting all if not the entire urethra. Adequate mobility allows the surgeon to pull the bladder neck out with stays; thus making the actual closure of the bladder neck less challenging. In addition, with adequate mobility of the closed bladder neck, the repair itself can be mobilized anteriorly away from the vaginal wall closure. After closing the bladder neck in two layers, I will tag the sutures involved with the repair. The needle attached to those BNC sutures can then be brought through the undersurface of the pubic symphysis or even the anterior abdominal wall. This results in mobilization of the suture line of the BNC anterior, away from the vaginal wall closure. Theoretically, this will help minimize fistula formation if the initial repair is not watertight. This maneuver cannot be done if adequate mobility of the bladder neck has not been obtained.

Closure of the bladder neck with multiple layers is certainly an important step and several techniques have been described. Zimmern and coworkers used an initial vertical and anterior–posterior layer followed by a second layer placed transversely in perivesical fascia and detrusor muscle superficially [1]. Rovner and coworkers described a modification of this technique using a posterior urethral flap (Fig. 22.1a–f). Once the bladder neck has been fully mobilized, the dorsal urethra is bivalved into the anterior bladder wall for 2–3 cm. The bivalved posterior urethral flap is then rotated cephalad and secured to the anterior bladder wall. That suture line is subsequently

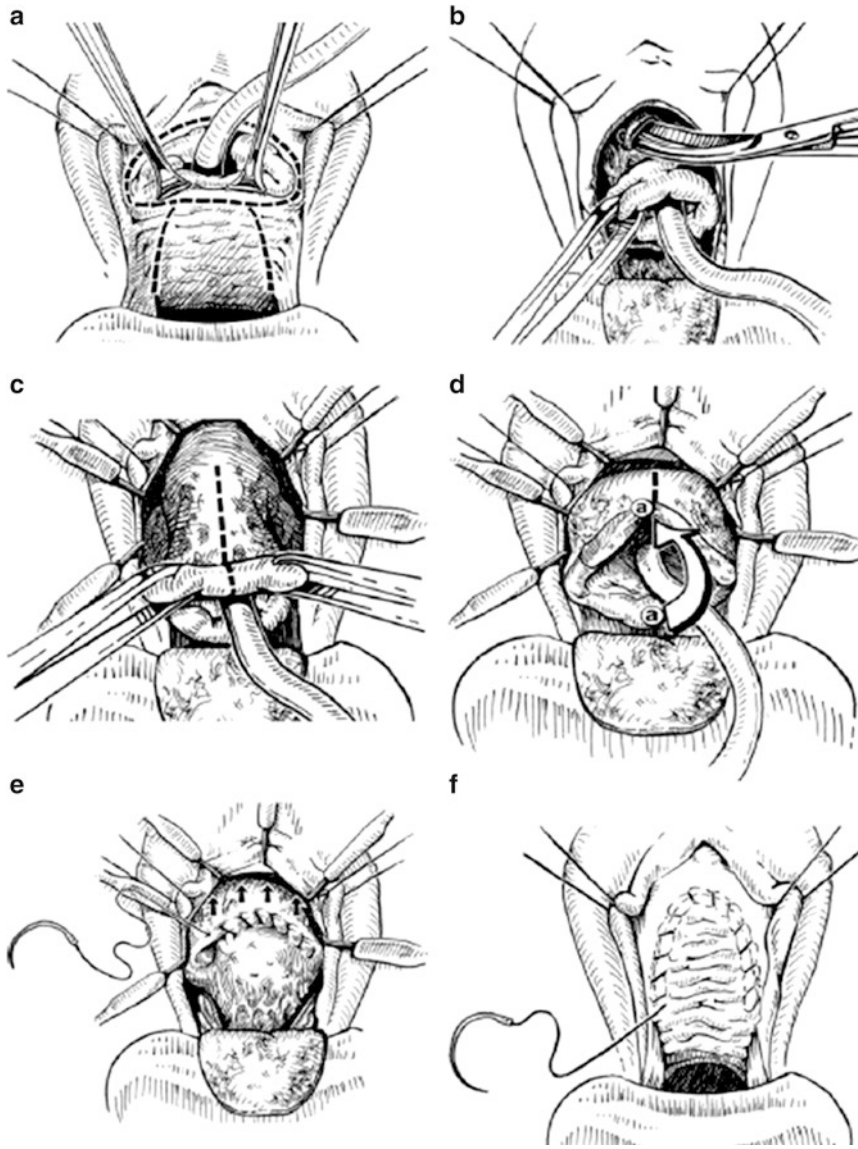

Fig. 22.1 (**a**) Incision made circumferentially around urethra with arms extending proximally to develop anterior vaginal wall flap. (**b**) Urethra is freed from its attachments as the urethropelvic and pubourethral ligaments are divided. (**c**) Dorsal urethra bivalved up to bladder neck. (**d**) Ventral urethra flap rotated up to edge of bivalved urethra. (**e**) Closure of bladder beck. With rotation of flap in a cephalad direction, the suture line rotates under the symphysis pubis. (**f**) Anterior vaginal wall advanced and vaginal wall closed with no overlapping suture lines

rotated upwards to the retropubic space, behind the pubic symphysis [6]. It should be noted that use of an adjuvant flap or graft placement is not usually required for primary repairs; these techniques are more commonly seen for patients requiring redo surgery for postoperative fistula after failure of primary BNC [4].

Postoperative

Without appropriate post-operative management even the best of repairs will break down, resulting in formation of a VVF. The importance of optimal post-operative drainage in these patients can-

not be overemphasized. Ginger and coworkers noted a significant association between poor post-operative catheter care and persistent leakage [4]. A total of 29 patients in their series underwent retropubic BNC, with eight of these patients continuing to have persistent urinary leakage postoperatively. This was directly attributable to catheter mismanagement in seven of the eight patients. An appropriately sized suprapubic tube should be placed, secured, and optimally drained post-operatively to help ensure healing of the suture line along the closed bladder neck.

In addition to poor drainage, residual detrusor overactivity can negatively impact the healing process. Even with a catheter in place allowing for continuous bladder drainage, patients can have residual detrusor overactivity. The bladder's natural response to a detrusor contraction is relaxation of the bladder neck and a spontaneous void. If the bladder neck has been surgically closed, this only leads to increased pressure on the suture line and greater risk of post-operative failure. Anticholinergics are thus an important part of the post-operative management of these patients and should be started immediately post-operatively. Theoretically, peri-operative injection of botulinum toxin A into the detrusor muscle could be done at the time of BNC with the hope that minimization of post-operative detrusor overactivity would improve the likelihood of a successful repair [9].

Fistula Diagnosis

The diagnosis of a post-BNC fistula is fairly straightforward and can be done either radiographically or on examination. A leak at the closure site may be suggested at the postoperative visit if the patient complains of continued urinary leakage vaginally. However, a lack of leakage does not necessarily mean that the BNC has adequately healed. All patients should have a cystogram 2–3 weeks postoperatively to adequately assess the quality of the repair. If a residual leak is noted, then catheter drainage should be continued. The theory with a posthysterectomy VVF is that prolonged catheter drainage can be successful and lead to closure if the patient is dry with the catheter in place and is unlikely to succeed if the patient continues to leak per the fistula site despite continuous catheter drainage. This has not been evaluated in post-BNC leaks, but it is likely that the theory and healing process is similar—if urine continues to leak through a hole (i.e., the fistula site), then that hole will not heal.

If the cystogram is equivocal or if a patient returns complaining of leakage despite a previously noted negative cystogram, then direct examination may be helpful in identifying a fistula. As opposed to most posthysterectomy fistulae, which tend to be deep towards the vaginal vault and can be challenging to identify on examination, these fistulae are not deep in the vault and are often easy to see on examination. A simple technique to easily evaluate for a leak is to perform a pelvic examination while an assistant fills the bladder through the suprapubic tube with normal saline colored with a dye such as methylene blue or indigo carmine. If a leak is present, it will be readily apparent when the blue-tinged fluid is noted leaking through the fistula site in the vagina. If the patient is concerned a leak is present but cannot come to the office for immediate evaluation, another option would be for her to do a Pyridium (phenazopyridine) pad test at home. A pad that turns orange after taking Pyridium post-BNC is strongly suggestive of the presence of a fistula.

Fistula Management

If a VVF develops between the vagina and bladder neck closure site despite appropriate surgical technique and perioperative care, then several options are available. An attempt to maximize drainage with supravesical diversion using bilateral nephrostomy tubes could be attempted. This has primarily been used in the postoperative setting in patients with a urine leak at the ureteroileal anastamosis site after urinary diversion. With a mature fistula tract, it is unlikely this will allow for closure of the fistula though this may theoretically help close a leak early in the postoperative period.

Once the fistula tract has matured, the patient is destined to undergo further surgery if repair is desired. Prior to undertaking repair it is important to realize that all fistulas do not have to be repaired. At times, patients may have a fistula on cystogram but are dry when the catheter is left to drainage. If this is the case and the patient is content, then further intervention is generally unnecessary.

For experienced vaginal surgeons, a second attempt at a transvaginal BNC could be considered. The technique is essentially the same as was attempted with the initial attempt at closure. However, use of an adjuvant flap or graft is highly recommended in a redo procedure, especially if one was not used in the initial procedure. If a graft/flap was used with the initial attempt at BNC, it is possible that it could be identified intraoperatively and reused if healthy.

For those surgeons not experienced with transvaginal surgery, an abdominal approach should be considered after a failed prior attempt at BNC. If an abdominal BNC is performed, an omental flap can be harvested and placed at the closure site to add an extra layer of repair [10]. If further evaluation finds that the bladder is not salvageable or the BNC cannot be done, then the surgeon and patient should also be prepared for possible cystectomy and either continent or incontinent diversion to the skin. This is certainly a much larger undertaking than BNC and, if it is thought that this might be a possibility, appropriate preoperative preparation is required including patient counseling, stoma site marking, and obtaining an adequate informed consent.

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Bladder Augmentation

23

Sender Herschorn and Blayne K. Welk

Abbreviation

CIC Clean intermittent catheterization

Introduction

Bladder augmentation with an ileal patch was first described by Von Mickulicz in 1899 [1]. Different gastrointestinal segments were subsequently reported—colon by Lemoine in 1912 [2], sigmoid by Bisgard in 1943 [3], cecum by Couvelaire in 1950 [4], and stomach by Leong in 1978 [5]. In 1950, Couvelaire began performing augmentation cystoplasty to treat contracted bladders resulting from tuberculosis and the technique started to gain acceptance [4]. Other attempts using organic tissues such as peritoneum, omentum, human dura, skin, pericardium, placenta, gallbladder, free fascial grafts, and preserved bladder tissue were unsuccessful as were efforts using synthetic materials [6]. In 1959, Goodwin described the modern operative technique of using a detubularized ileal patch [7].

Bladder augmentation is often done in conjunction with other surgical procedures, such as creation of a continent stoma, or bladder outlet procedures to reduce urinary incontinence. This chapter will outline the indications and techniques of bladder augmentation and focus on short- and long-term complications and their management.

Indications

In 1977, Smith and colleagues [8] reviewed augmentation cystoplasty and suggested that the procedure was "a successful long-term solution for patients with small contracted bladders of almost any etiology." Table 23.1 lists the current indications.

Congenital Conditions

Myelodysplasia, a form of spinal dysraphism, may lead to neurogenic bladder dysfunction. Approximately 1/3 of patients have sphincter dyssynergia, and the urodynamic pattern often changes as the child ages [9]. The failure of conservative or medical therapy to adequately treat urinary incontinence, high detrusor leak point

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Table 23.1 Indications for augmentation cystoplasty (usually with associated symptoms of urinary incontinence, high detrusor pressures, or renal dysfunction refractory to other management options)

	Indication
Congenital	Myelodysplasia
	Posterior urethral valves
	Exstrophy/epispadias complex
Acquired neurogenic bladder	Spinal cord injury
	Multiple sclerosis
Acquired non-neurogenic bladder	Overactive bladder
Infectious	Tuberculosis
	Schistosomiasis
Inflammatory	Radiation cystitis
	(Interstitial cystitis)
Iatrogenic	Intraoperative loss of bladder wall
	Urinary undiversion

pressures, and renal dysfunction are indications for bladder augmentation. It was estimated that approximately 5% [10] to 30% [11] of patients with spina bifida may undergo an augmentation cystoplasty. However, there has been a 25% in numbers of pediatric patients who have undergone cystoplasty in the 2000s for various reasons [12]. Augmentation is often combined with other procedures such as a catheterizable abdominal stoma and bladder neck procedure or sling to increase urinary outlet resistance.

Posterior urethral valves in males can lead to bladder dysfunction and renal failure. Augmentation cystoplasty may be required prior to renal transplantation [13–17]. Patients with exstrophy/epispadias complex also require bladder augmentation when staged functional reconstruction is unsuccessful [18–22].

Other congenital anomalies that may lead to the need for bladder augmentation include sacral agenesis, cloacal exstrophy, imperforate anus, and persistent urogenital sinus [22, 23].

Acquired Neurogenic Bladder

Spinal cord injury can lead to severe detrusor overactivity, poor bladder compliance, and decreased capacity over time. The changes are frequently related to the level of injury. Suprasacral spinal cord lesions often lead to detrusor overactivity with sphincter dyssynergia. This antagonistic dysfunction of the bladder and the outlet can impair detrusor compliance, and over time lead to reduced bladder capacity [24]. Sacral spinal cord lesions often lead to detrusor areflexia with a fixed, nonrelaxing sphincter. Generally, the bladder has normal compliance; however, over time, decreased compliance and reduced capacity can develop [24].

Bladder augmentation may be indicated if incontinence, high detrusor leak point pressures, severe autonomic dysreflexia, or renal dysfunction occur due to failure of the bladder to store urine at a low pressure. Usually, augmentation is considered when other measures such as behavioral modifications, anticholinergics, intravesical botulinum toxin, or rarely anterior nerve root stimulation are ineffective [25–28].

Multiple sclerosis is another cause of neurogenic bladder dysfunction that may result in detrusor overactivity with sphincter dyssynergia [29]. Bladder dysfunction can worsen over time, and progressive neuromuscular deterioration can make intermittent self-catheterization difficult [30]. Medical therapy with anticholinergics and intravesical botulinum toxin are usually the preferred treatment. However, occasional cases may be amenable to augmentation cystoplasty [31].

Overactive Bladder

Overactive bladder is a syndrome or symptom complex of urinary urgency with or without urgency incontinence, urinary frequency, and nocturia [32]. Bladder augmentation is a treatment of last resort for refractory symptoms associated with detrusor overactivity that cannot be controlled with behavioral therapy, anticholinergics, intravesical botulinum toxin, or sacral/peripheral neuromodulation [33]. The number of cystoplasty procedures for OAB has fallen in the UK in the years 2000–2010 possibly secondary to the advent of botulinum toxin and sacral neuromodulation [34].

Infection

Genitourinary tuberculosis occurs in 10–20% of patients with pulmonary tuberculosis [35]. Tuberculous infection causes swelling and inflammation, and bladder wall thickening. Tubercles may form within the mucosa, coalesce, and ulcerate. The most common site is around the orifices, which can become obstructed. The disease can progress and severely reduce bladder capacity [30]. Tuberculosis, once a common indication for augmentation [36], is now a rarity due to better therapies and decreased incidence in the developed world [37, 38].

Schistosomiasis, an endemic parasitic infection found primarily in the Middle East and Africa, may cause bladder wall fibrosis due to granulomatous inflammation [39]. Reduced bladder capacity may be improved by augmentation [40].

Inflammatory Causes

Radiation changes may follow external beam radiation therapy for treatment of pelvic malignancy. Acute cystitis symptoms usually resolve within a few months; however, occasionally, bladder wall fibrosis may occur and reduce bladder capacity and impair function [41]. Patient comorbidities and further oncologic treatment may limit augmentation in this group [42].

Bladder augmentation has been used as treatment for interstitial cystitis in patients with contracted small capacity bladders [43]. However, augmentation has shown only modest success as treatment for pain associated with interstitial cystitis [30, 44]. Its use in this population is controversial [30, 45–47].

Iatrogenic

Augmentation cystoplasty may be necessary in patients with significant loss of the bladder wall due to surgical resection. This may be from the resection of locally advanced non-urologic cancer or benign bladder resections. For patients with previous urinary diversion who did not undergo a cystectomy, redirecting the ureters to an augmentation cystoplasty may be a reasonable method of undiversion in some patients [48].

Contraindications

Serious bowel dysfunction, such as inflammatory bowel disease or after radiotherapy, in which removal of a segment will compromise absorption is a contraindication to augmentation. In patients with short gut syndrome ileum and colon should not be used although stomach may be an alternative. The presence of bladder pathology that would preclude its use is a contraindication. Another contraindication is when a patient is unwilling or unable to do clean intermittent catheterization (CIC), performed either by himself/herself or a caregiver [49].

Poor baseline renal function may predispose patients to severe electrolyte abnormalities and worsening renal function and is a relative contraindication [49, 50]. However, in patients with continuing renal dysfunction as a direct result of bladder dysfunction, augmentation may be appropriate and can slow the decline in renal function [49, 51].

Surgical Considerations

Preoperative workup usually involves renal and bladder imaging (to assess renal anatomy, obstruction, and the presence of stone disease), video-urodynamics (with special attention to the appearance of the bladder neck in order to assess the need for concomitant bladder neck or incontinence surgery), cystoscopy (to assess lower urinary tract anatomy), urine culture, complete blood count, renal function, and electrolyte levels. A history of bowel disease or surgery may require preoperative bowel imaging studies or colonoscopy. A full preoperative bowel preparation is generally used. Recently, questions have been raised regarding its safety and necessity [52, 53]. However, a large study of 8442 patients undergoing elective colorectal surgery from

National Surgical Quality Improvement Program (NSQIP) database, with 3822 patients (45.3%) with preoperative oral antibiotics and mechanical bowel preparation and 2296 (27.2%) without either, showed that these intervention resulted in a significantly lower postoperative incidence of surgical site infection, anastomotic leak, and ileus [54].

The bladder is usually exposed through a lower midline abdominal incision, and the bowel segment is assessed for its suitability for use. The surgeon assesses the ease of moving the segment down to the bladder combined with the possible nutritional and metabolic consequences that will be discussed below. The bowel segment is usually detubularized to maximize the surface area (and therefore the resulting bladder volume), and reduce bowel contractions and postoperative detrusor pressure [55].

Ileum is often the preferred segment due to its familiarity among urologists, low complication rate, and tolerable metabolic profile [30, 50]. It may result in lower postoperative maximal detrusor pressures and may reduce uninhibited contractions more effectively than sigmoid [56]. A 20–40 cm segment is selected (depending on the need), at least 20 cm proximal to the ileocecal valve. It is detubularized and used in various configurations for augmentation (Figs. 23.1a, b and 23.2) [57].

Sigmoid is an alternative and has been reported to have a lower rate of bowel obstruction [58, 59]. A 15–20 cm detubularized segment can be used.

Another alternative is cecum and ascending colon that can be mobilized up to the hepatic flexure. Cecum can be detubularized and used alone or in conjunction with a 15–30 cm segment of detubularized ileum to form the augment. Ileum or appendix can be used as a continent catheterizable channel with the ileocecal valve (or intravesical tunneling of the appendix) providing the continence mechanism. The ileal segment can also be used as a bladder "chimney" to reach resected or obstructed ureters for reimplantation if necessary.

Stomach is rarely used and jejunum should probably be avoided because of associated metabolic complications such as hyperchloremic, hyperkalemic metabolic acidosis, and hyponatremia that have been reported with conduits [60].

Alternative procedures for bladder augmentation include ureterocystoplasty (which is an option in patients with megaureter and an ipsilateral nonfunctional kidney [61, 62]) and autoaugmentation. Autoaugmentation involves performing a detrusor myectomy to create a large, low-pressure bladder diverticulum. Autoaugmentation avoids the complications associated with bowel; however, it has poor long-term efficacy [63–67]. This was analyzed in a recent review of alternatives to enterocystoplasty [68].

Once the bowel segment has been selected, the bladder is usually opened with a sagittal incision to bivalve it ("clam" cystoplasty [69]). An alternative is a wide U-shaped anterior or posterior incision that effectively creates a large flap for a wide anastomosis [70]. Supratrigonal bladder excision [71] can also be done. The ureteric orifices are identified to avoid injury. The bowel segment is sutured to the bladder with a wide anastomosis to ensure good drainage of the augmentation. A pelvic drain, suprapubic tube, and Foley catheter may be placed for the postoperative period.

Reports of completely intraperitoneal laparoscopic, robotic-assisted and single port augmentation cystoplasties in both adults and children have been published. These procedures require advanced laparoscopic skills and are not yet widely used [72–75].

Follow-up

Close follow-up is necessary in the immediate postoperative period until indwelling catheters are removed and the patient adjusts to CIC and bladder irrigation. The augmentation usually enlarges with time. Long-term follow-up consists of renal imaging, renal function tests, electrolyte measurements (to test for metabolic derangements), and complete blood count (to detect pernicious anemia). Some authors have advocated screening cystoscopy 5–10 years after augmentation to assess for bladder cancer;

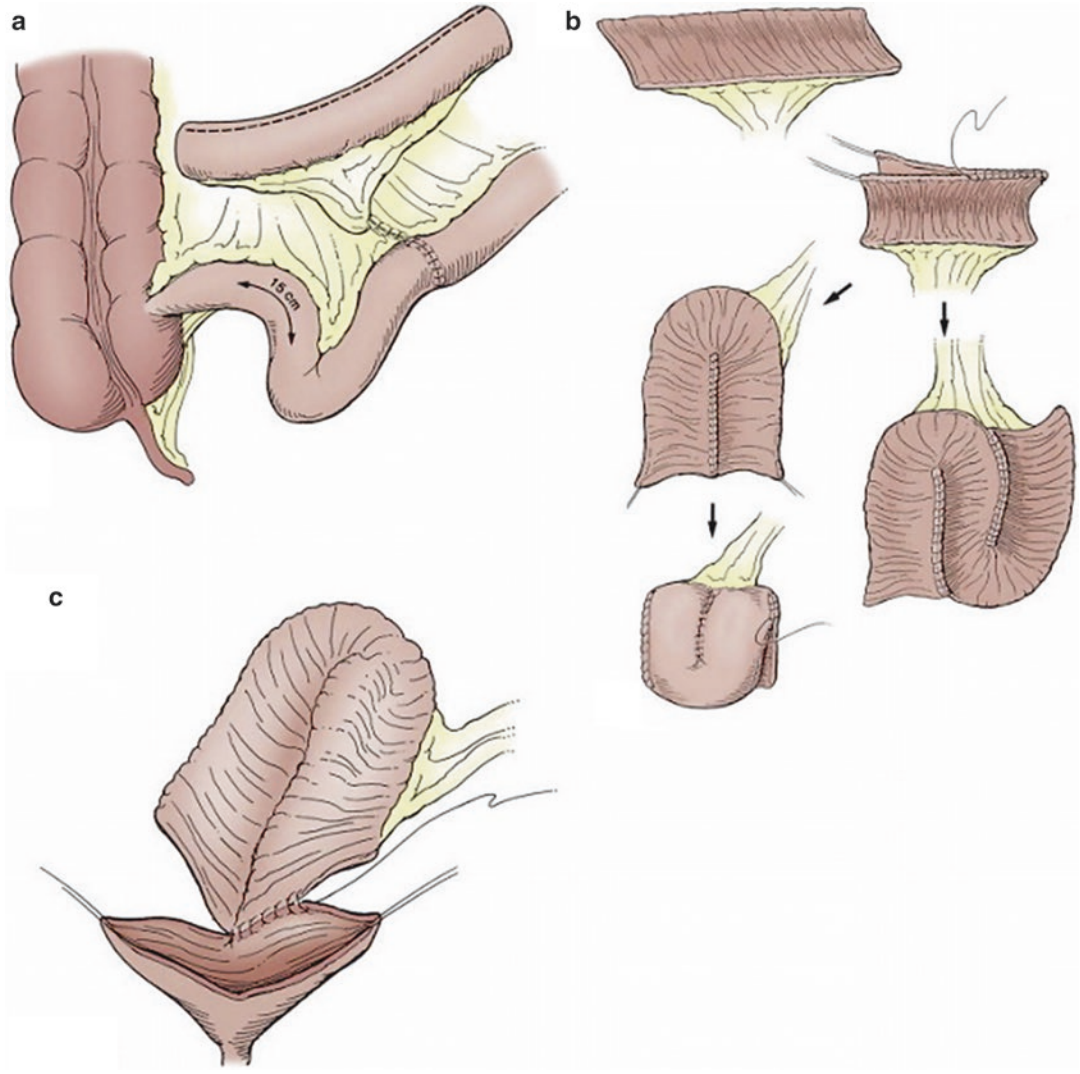

Fig. 23.1 (**a**) Ileocystoplasty. A 20- to 40-cm segment of ileum at least 15 cm from the ileocecal valve is removed and opened on its antimesenteric border. Ileoileostomy reconstitutes the bowel. (**b**) The opened ileal segment should be reconfigured. This can be done in a U, S, or W configuration. It can be further folded as a cup patch. (**c**) The reconfigured ileal segment is anastomosed widely to the native bladder. (Used with permission of Elsevier from Adams MC, Joseph DB. Urinary Tract Reconstruction in Children. In Campbell-Walsh Urology, Vol. 4 (eds: Wein A, Kavoussi LR, Novick AC, Partin AW, Peters CA). Philadelphia: Saunders Elsevier; 2007: 3656–3702)

however, this is controversial [76, 77]. Urodynamics may be done if there is a change in symptoms, onset of new hydronephrosis, or worsening renal function.

The overall complication rates in various series range from 3 to 41% depending on the duration of follow-up and completeness of reporting [78, 79].

Early Postoperative Complications

With any major abdominal surgery there are associated cardiovascular, respiratory, and gastrointestinal complications. Postoperative mortality rates have been reported between 0 and 3.2% [49, 78, 80–87] and were generally the result of postoperative myocardial infarction

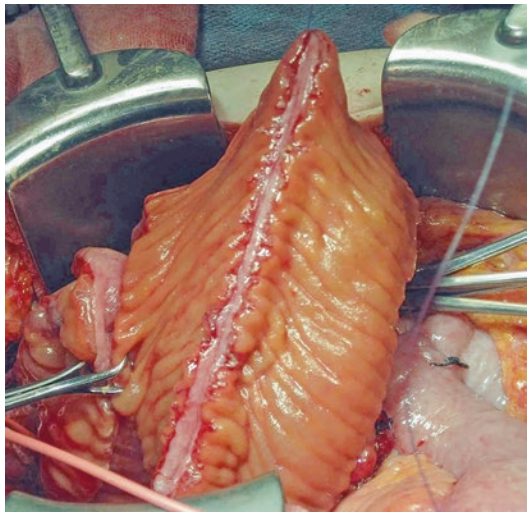

Fig. 23.2 A 40 cm length of ileum is shown. The segment has been isolated from the GI tract and reconfigured. The antimesenteric border was incised and the bowel segment was detubularized into an inverted U-shaped. It will be anastomosed to the bladder

(0–2.7%) and pulmonary embolus/deep vein thrombosis (0–7%) [39]. There have been a small number of reports of other severe complications, such as major bleeding requiring reoperation [39] and necrosis of the bowel segment [8, 87].

Small bowel obstruction requiring operative intervention may occur in 3–6% of patients, and approximately 5–6% of patients may develop a wound infection or dehiscence [49]. Anastomotic leak from the bladder occurs in 2–4% of patients. Postoperative ileus is common, and prolonged ileus occurs in approximately 5% of patients [49]. Severe postoperative complications are less frequent in contemporary case series [49].

Continence and Urodynamic Outcomes

Several groups have reported long-term functional outcomes in adult and pediatric populations. Blavias and colleagues [70] reported on 65 adult patients who underwent augmentation cystoplasty (primarily with an ileocecal segment) with or without creation of an abdominal stoma (and included an additional 11 patients who had a continent diversion). At a mean follow-up of 5 years, 70% considered themselves cured, and 18% considered themselves improved. Failures consisted almost exclusively of interstitial cystitis patients. Mean bladder capacity increased from 166 to 572 mL, and mean maximal detrusor pressure fell from 53 to 14 cmH_2O. Flood and coworkers [42] reported on 122 augmentation cystoplasties (67% ileocystoplasty, 30% ileocecocystoplasty) with a mean follow-up of 3 years. They had a primarily adult population. They reported similar urodynamic improvements, a 75% cure rate, and a 20% improvement rate in incontinence.

Quek and Ginsberg [88] reported durability of the urodynamic improvements and 96% patient satisfaction among 24 patients with a mean follow-up of 8 years (range 4–13).

Herschorn and Hewitt [78] preformed a cross-sectional survey of 59 adults who underwent augmentation cystoplasty (usually with additional simultaneous reconstructive procedures) at a median follow-up of 6 years. Sixty-seven percent of patients reported complete continence, and 30% reported only mild incontinence (requiring on average 1–2 pads per day). Almost all patients were very satisfied with their urologic management.

Results in the pediatric populations are similar although the majority of patients require additional reconstructive procedures such as ureteral reimplantation, bladder neck procedures, and creation of catheterizable channels. Lopez Pereira and coworkers reported on 29 children with a mean follow-up of 11 years [89]. Mean postoperative bladder capacity increased from 90 to 521 mL, and mean maximal detrusor pressure fell from 45 to 10 cmH_2O. Shekarriz and coworkers reported a 95% continence rate among 133 pediatric patients at a mean follow-up of 5 years [58].

A number of authors have compared the outcomes of ileum, ileocecal, and sigmoid segments and have not shown any consistent advantages of any segment in terms of urinary continence or renal function [87, 90–92]. Urodynamically demonstrated contractions might persist postoperatively with colonic segments [56, 93].

Long-Term Consequences

The possible long-term consequences of augmentation are listed in Table 23.2 and discussed below. Complications requiring intervention may occur years after the original surgery [78, 79]. This underscores the necessity of long-term follow-up.

Growth Retardation and Decreased Bone Mineral Density

Small case series by Mundy and Nurse [94] and Wagstaff and coworkers [95] were the first to suggest there is a decrease in linear growth in children after augmentation cystoplasty. Since then, several additional studies have been published, of which 2 suggested there is approximately a 15% decrease in linear growth after augmentation and 6 which did not demonstrate a significant change to linear growth [96, 97]. There is also contradictory evidence as to whether decreased bone mineral density or osteopenia is a result of the augmentation [97]. In a case series of 24 children followed for an average of 9 years after augmentation, Hafez and coworkers reported a 20% incidence of significant osteopenia [98]. The osteopenia is likely a result of buffering of the acidosis by the skeletal system, which leads to changes in bone mineralization [99]. Correction of this acidosis may improve bone density [100]. Other mechanisms of osteopenia include reduced renal tubular reabsorption of calcium and intestinal malabsorption of calcium [101]. In a recent study, Haas and colleagues demonstrated that bone mineral density was significantly related to ambulatory status and secondarily to neurological level rather than to the presence or absence of augmentation cystoplasty [102]. The long-term impact of the osteopenia and how it affects children as adults is still unknown [97].

Management includes appropriate screening and treatment of postoperative metabolic acidosis. Patients with renal failure are more likely to have uncompensated acidosis and should be followed closely and treated for this complication. Some authors have advocated bone mineral density measurements after augmentation [98].

Electrolyte Abnormalities

The expected pattern of metabolic abnormality is dependent on the segment of bowel used in the augmentation cystoplasty. Other factors that influence the severity of the electrolyte imbalance include the surface area of the augmentation, urine pH, and the urine contact time [101].

Ileum and Colon

With an ileal or colonic augmentation, the classic electrolyte pattern is hyperchloremic metabolic acidosis. The symptoms associated with metabolic acidosis are fatigue, anorexia, weight loss, and polydipsia. There are several possible mechanisms: frequent pyelonephritis may lead to distal tubular acidification defect, urea in the urine may be metabolized by intestinal flora to ammonium which is then absorbed by the bowel, loss of bicarbonate from the bowel that lead to metabolic acidosis, or chloride that is actively transported from the bowel into the urine leads to reabsorption of ammonium or hydrogen ions [103]. The most likely mechanism is ammonium substitution for sodium in a sodium-hydrogen ion antiport; this antiport is coupled with a bicarbonate-chloride exchanger, leading to a net reabsorption of hydrogen ions, ammonium, and chloride [104]. Hypokalemia can occur during treatment of an acidosis, which unmasks low total body potassium, or as a result of renal potassium wasting (seen more frequently with colonic segments) [104, 105]. Associated hypocalcemia and hypomagnesemia (usually restricted to patients with renal insufficiency and more commonly seen in colonic augmentations) may be due to reduced renal reabsorption due to a high level of sulfate that is reabsorbed from the bowel, or due to chronic acidosis causing calcium mobilization and subsequent activation of parathyroid hormone [105, 106].

Normal renal function can often compensate for this acidosis; the majority of patients will have a measurable abnormality [107]; however,

Table 23.2 Long-term consequences of augmentation cystoplasty and potential management strategies

	Description	Management
Growth retardation and osteopenia	• Conflicting evidence on the presence of linear growth reduction	• Consider monitoring bone mineral density
	• Chronic acidosis may lead to osteopenia	• Treat acidosis
Electrolyte abnormalities	• Hyperchloremic, metabolic acidosis ± hypokalemia	• Chloride restriction, bicarbonate, niacin, chlorpromazine
Ileum/colon	• Hypochloremic, hypokalemia, metabolic alkalosis ± hematuria–dysuria syndrome	• IV fluids, potassium supplementation, histamine antagonists, proton pump inhibitors
Stomach		
Renal insufficiency	• May occur as a result of complications associated with augmentation cystoplasty, especially in patients with poor preoperative renal function	• Postoperative monitoring of renal function
Vitamin B12 deficiency	• Due to ileal resection	• Postoperative monitoring of complete blood count
		• B12 supplementation
Bladder Cancer	• Increased risk of aggressive bladder cancer among patients with neurogenic bladder; controversial if the augmentation is an independent risk factor	• Aggressive investigation of hematuria, frequent urinary infections, or penile/scrotal discharge
Bladder perforation	• Consider in any patient with peritonitis, septic shock, abdominal pain and distension, nausea and vomiting, fever, referred shoulder pain, or intraperitoneal fluid	• In stable patients, a trial of conservative therapy may be attempted.
		• Standard treatment is laparotomy for surgical repair
		• Prevention with education of patient to comply with IC
Stone disease	• Due to metabolic alterations, poor bladder emptying, mucus, and chronic infection	• Endoscopic, percutaneous, or open surgical procedure
		• Increased fluid intake and dietary modifications
		• Bladder irrigation
Mucus	• Produced by the bowel segment	• Bladder irrigation
		• Acetylcysteine/urea irrigations
Urinary tract infection	• Asymptomatic bacteriuria is common	• Antibiotic therapy for symptomatic infections
	• Symptomatic urinary infection require treatment	• Antibiotic prophylaxis or intravesical irrigations for frequent symptomatic infections
		• Bladder irrigation
Bowel dysfunction	• Due to alterations to bile acid metabolism; often exacerbates underlying neurogenic bowel or irritable bowel syndrome	• Low fat diet
		• Antidiarrheal medication
		• Bile acid binders (cholestyramine)
Voiding dysfunction	• Incomplete emptying or inability to void	• CIC is commonly required postoperatively
	• Incontinence may be due to an incompetent outlet	• Surgical treatment of incontinence is common
Pregnancy		• Vaginal delivery preferable
		• Urologic assistance is helpful during elective cesarean sections

it will only be clinically relevant in approximately 10–20% of patients [49, 108]. The absorptive properties of the bowel may be attenuated with time due to mucosal atrophy [109, 110]. Treatment of the acidosis is usually considered once the base excess falls below −2.5 mmol/L [105, 108]. Therapy consists of dietary chloride restriction, bicarbonate supplementation (sodium bicarbonate, potassium citrate), and maximal urinary drainage [106]. Niacin or chlorpromazine inhibits active chloride transportation in the intestine and may be useful especially when the solute load of bicarbonate therapy is undesirable [98].

Stomach

In a gastric augment, the classic electrolyte pattern is hypochloremic, hypokalemic, and metabolic alkalosis. Associated clinical symptoms include pelvic pain, fatigue, mental status changes, seizures, or cardiac arrhythmias [105]. Treatment of the electrolyte disturbance involves maximal bladder drainage, normal saline fluid resuscitation, and potassium replacement when necessary [105, 111]. Long-term therapy with potassium chloride may be required [105]. Acid secretion can be suppressed with histamine antagonists or proton pump inhibitors [105].

Hematuria–dysuria syndrome is characterized by excess acid secretion causing peptic ulcer disease, hematuria and dysuria; it occurs in up to 25% of patients, and treatment with a proton pump inhibitor is required intermittently or continuously in a small proportion of patients [112].

Hyperammonemia

The liver is responsible for metabolizing ammonium (absorbed from an augmentation cystoplasty) into urea. Impaired hepatic function or sepsis can lead to the inability of the liver to cope with the hyperammonemia; symptomatically, this presents as ammoniagenic encephalopathy [106]. Treatment is maximal urinary drainage, low protein diet, ammonium binders (such as lactulose or neomycin), and in severe cases intravenous arginine glutamate [105].

Renal Insufficiency

Deterioration of renal function may occur in 0–15% of patients after augmentation [49]. It is unknown whether this is a direct result of the augmentation or due to associated complications [113]. Renal insufficiency occurs independent of the bowel segment selected [114, 115]. The etiology of renal dysfunction may be urinary stone disease, bacteriuria, high detrusor pressures, vesicoureteral reflux, unrecognized obstruction, and lack of compliance with catheterization [114]. One study suggests approximately 5% of patients will have renal dysfunction after augmentation without a clear etiology [114]. Some authors have demonstrated that baseline renal function is a significant predictor of renal deterioration after augmentation cystoplasty, with an increased risk when creatinine clearance is <40 mL/min [8, 49, 116, 117]. Other studies in children and adults with baseline renal dysfunction did not appear to demonstrate that they have accelerated renal failure after augmentation cystoplasty [51, 78].

In a recent review of 80 patients treated at the Mayo Clinic with ileocystoplasty and simultaneous bladder neck outlet procedure after a median follow-up of 14 years (range, 8–45 years), Husmann reported upper tract deterioration in 40% (32/80) of the patients. Development of ≥ stage 3 chronic renal failure occurred in 38% (12/32) of the patients with scarring, i.e., 15% (12/80) of the total patients. Prior to the development of the renal scarring, 69% (22/32) of the patients had been noncompliant with intermittent catheterization. He attributed the new onset renal deterioration largely to patient noncompliance with medical directive [118].

Although there is no published consensus on the order of performing augmentation cystoplasty and renal transplant, there are no significant differences between pretransplant and posttransplant AC. It therefore seems reasonable to perform the AC before a kidney is transplanted to avoid damage to the graft from the hostile bladder [17]. Graft survival and function after AC also appear to be similar to those in children with normal bladders [17].

Postoperatively, patients should have renal imaging and serum creatinine measurements to screen for renal insufficiency [106]. Serum creatinine can be difficult to interpret in this population, due to a low muscle mass in neurogenic patients, and increased reabsorption of urine creatinine by the ileum. Nuclear renograms may be better for definitive measurement.

Vitamin B12 Deficiency

Vitamin B12 is bound to intrinsic factor in the duodenum which allows is to be absorbed in the terminal ileum. With ileocystoplasty, the most distal 15 cm of the ileum should be preserved to prevent this complication [106]. Vitamin B12 deficiency may cause megaloblastic anemia and neurologic changes [106]. In nutritionally normal individuals, it takes up to 3 years for the liver's store of B12 to be depleted and the resulting deficiency to manifest. The incidence of B12 deficiency related to ileal resection is 3–20% [106, 119].

This complication may be treated prophylactically with B12 supplementation if more than 50 cm of ileum is used for the bladder augmentation [120]. Otherwise, patients should have complete blood counts in follow-up to screen for pernicious anemia.

Malignancy

Bladder cancer has been reported in young patients after augmentation [79, 121, 122]. It has also been reported that spinal cord injury patients and spina bifida patients develop bladder cancer at a young age (40–50 years), have an increased risk of locally advanced disease, an increased number of adenocarcinomas and squamous cell carcinomas, and a short median survival after diagnosis [77, 123]. In a matched cohort study from a registry of patients with bladder dysfunction due to neurologic abnormalities, exstrophy, and posterior urethral valves, Higuchi and colleagues did not find a significant difference in the incidence of bladder cancer among patients with augmentation cystoplasty (using ileum or colon) compared to patients managed with intermittent catheterization [76]. The authors did demonstrate that the incidence of bladder cancer was higher in both groups with congenital bladder anomalies independent of augmentation status when compared to the SEER database. Possible reasons for a higher rate of bladder cancer in patients with neurogenic bladder may be reduced intracellular antioxidant activity (leading to increased rates of DNA mutation) [124], impaired DNA repair in the bowel due to the hyperosmolar urine [125], and immunosuppressant use in patients after renal transplantation [76]. However, patients who have undergone a gastric augmentation may have a higher cancer risk compared to other bowel segments [76]. In a subsequent report, Rove and Higuchi presented more case series to illustrate that congenital bladder anomalies alone are a risk factor for malignancy [126]. Current screening tests such as cystoscopy and cytology are not cost effective and have not diagnosed the cancers.

In a recent systematic review of 57 articles involving malignancy and AC, Biardeau and colleagues [127] concluded that AC is associated with a risk of malignancy. In spite of its limitations, annual cystoscopy surveillance is the only validated tool available for diagnosis. It should be started 10 years after surgery and accompanied by clinical examination and surveillance imaging [127].

Urologists should have a particular awareness of the potential for aggressive bladder cancer in this population whether or not they have had an AC. Symptoms such as hematuria, frequent urinary infections or penile/scrotal discharge need to be aggressively investigated; visual changes in the bladder due to the augmentation, recent infections, or catheterization can make cystoscopy challenging, and biopsy or CT should be considered if there is any uncertainty [123].

Bladder Perforation

Bladder perforation is a potentially life-threatening complication that occurs in approximately 6–13% of patients [23, 128–132].

Patients with neurogenic bladders, those with competent bladder necks, those without a catheterizable channel and those who abuse alcohol appear to be at an increased risk [23, 49, 133, 134]. Perforation can occur at any time postoperatively, even years after surgery. It can present with fever, abdominal pain, and distension with intraperitoneal extravasation of urine, nausea and vomiting, referred shoulder pain, peritonitis, and septic shock [58, 130]. Because of neurologic abnormalities of these patients, the presenting symptoms are often nonspecific. Diagnosis can be made with a CT cystogram; standard fluoroscopic cystography has a 10–20% false negative rate [58, 129, 135]. CT or US can demonstrate intraperitoneal fluid which is an important sign that bladder perforation has occurred [136]. Due to the augmentation, extraperitoneal ruptures are rare [137]. The area of perforation is usually at the bowel-bladder anastomosis or within the weaker bowel wall [129]. The etiology of bladder perforation is thought to be from traumatic catheterization, acute over distension, increased intravesical pressure, chronic overdistension (from CIC noncompliance), or infection leading to localized areas of ischemia and necrosis [135, 138].

The treatment of patients with large perforations and clinical instability usually is laparotomy for surgical repair. In patients that are stable (usually with a small perforation), a trial of conservative therapy (Foley catheter and antibiotics) may be considered [138, 139]. Mortality is high in patients with clinical instability on presentation and those with a delayed diagnosis; overall mortality has been estimated at up to 25% [128, 140, 141]. If clinical suspicion is high, and imaging is negative, the patient should still be treated as a possible bladder perforation [49]. There is a 25% rate of recurrence of bladder perforation after the initial episode [23, 135, 142].

In a recent review of long-term complications of AC in spins bifida patients, Husmann underscored the need for patient education regarding compliance with IC and refraining from high risk behavior such as alcohol abuse [118].

Stone Disease

Patients are at increased risk for bladder and upper tract calculi and urinary stones have been reported in 9–15% of patients after augmentation [49, 78, 143–145] and in some series as high as 50% [146]. Many of the risk factors for stones are present in patients that undergo augmentation and may not be directly related to the surgical procedure [147]. Patients with a continent catheterizable channel (which may not drain the bladder completely), those using urethral CIC (compared to those voiding spontaneous) and patients with urease splitting bacteriuria are at increased risk [49, 144]. Possible reasons for stone formation include chronic bacteriuria (a significant risk factor in multivariable analysis [148]), intravesical foreign bodies, elevated post-void residuals, and mucus secretion from the bowel segment [149]. Similar to a typical stone forming population, dietary choices and inadequate fluid intake increase the risk of stone disease [150]. Metabolic changes, such as hypercalciuria and hypocitraturia secondary to metabolic acidosis, water loss through the cystoplasty bowel segment, and mild enteric hyperoxaluria (from the bowel resection or antibiotic-related deficiency of oxalobacter formigenes) can predispose these patients to stone formation [146, 150, 151]. Most stones are struvite due to frequent bacteriuria or calcium oxalate; they are usually mixed with calcium phosphate due to the alkaline urine [146, 150, 152].

Treatment of stones includes endoscopic, percutaneous, or open surgical procedures depending on the stone size, location, and patient factors [49, 143].

Prevention of bladder stones consists of bladder irrigation, which may [153] or may not [154] be preventive, increased fluid intake, decreased salt, purine, and oxalate intake and medical therapy directed by 24 hr. urine and stone analysis. Husmann showed that bladder irrigation 250 mL of saline daily significantly reduced the incidence of recurrent stone formation compared to bladder irrigations of either 60 mL ($P < 0.0002$) or 120 mL ($P = 0.0152$) by the seventh year following the initial stone extraction [118].

Mucus

Ileal and colonic segments used in augmentations continue to produce mucus. Up to 40 g of mucus can be produced daily, and this continues over time despite villous atrophy [155]. Colonic bowel segments produce more mucus than ileal segments [143]. The mucus is thought to help reduce malignant changes [156]; however, it has been implicated as a causative factor in urinary tract infections, stone formation, poor bladder emptying, and bladder perforation [49].

Problematic mucus secretion can be treated with daily bladder irrigations. These can be augmented with acetylcysteine or urea irrigations which help dissolve mucus [157] or oral ranitidine which may help to reduce mucus production [158].

Urinary Tract Infection

Asymptomatic bacteriuria is nearly universal among augmentation enterocystoplasty patients and usually does not require treatment except in cases of urease splitting organisms (such as Proteus and Klebsiella) [159]. Studies in ileal conduits have shown that bacteria freely adhere to bowel mucosa and do not incite an inflammatory reaction [160]. This chronic bacteriuria has been cited as a risk factor for stone disease, incontinence, and bladder cancer [49, 161]. The most common organism is Escherichia Coli [162].

Symptomatic urinary tract infection which occurs in 5–40% of patients [49, 87, 91] requires antibiotic treatment. Risk factors are similar to asymptomatic bacteriuria and include urinary stasis, mucus production, and intermittent catheterization [39]. Symptoms may be nonspecific if bladder sensation is absent and include incontinence, abdominal pain, hematuria, new onset foul smelling urine and lethargy.

Management of urinary tract infection consists of appropriate antibiotic therapy. In patients with frequent symptomatic infections despite oral antibiotic prophylaxis, intravesical irrigation with antibiotics may reduce symptomatic infections [163]. In a small pilot study of 15 patients after ileocystoplasty cranberry extract reduced asymptomatic bacteriuria [164].

In a recent report of long-term complications from >300 AC in spina bifida patients, Husmann reported that the use of high volume 240 mL bladder irrigations, compared with lower volume irrigations, were found to significantly decrease the incidence of bacterial colonization of the bladder as determined by the yearly surveillance urine cultures. High volume irrigations also significantly decreased the incidence of symptomatic UTI over a 10-year time span [118]. This relatively simple maneuver of high volume irrigations appears to provide long-term benefits.

Bowel Dysfunction

Bowel dysfunction after bowel resection for augmentation or diversion occurs in approximately 20–50% of patients [78, 165, 166]. The most common symptom is diarrhea seen in about 25% of patients; however, potentially more distressing symptoms of fecal urgency and incontinence and nocturnal bowel movements are also common [165]. Bowel dysfunction is more common among patients with a neurologic diagnosis as a result of associated neurogenic bowel dysfunction and among patients with previous radiation or bowel resections [165, 166]. Approximately 30% of patients with irritable bowel syndrome have detrusor overactivity; this may be due to an intrinsic disorder of smooth muscle calcium metabolism [166].

Specific surgical factors may contribute to postoperative changes in bowel function that lead to diarrhea. Bile acids, generated in the liver and secreted into the small intestine, are necessary for fat absorption. Bile acids are reabsorbed in the distal ileum, enter the liver, and participate in the feedback mechanism for regeneration. Resection of long sections of the terminal ileum can lead to bile acid malabsorption. Bile acids entering the colon may cause diarrhea by inducing water and salt secretion and by promoting motility [167]. Ileal resection of more than 100 cm results in severe bile acid malabsorption that cannot be compensated for by increased hepatic synthesis.

In such cases, steatorrhea results from impaired micelle formation due to decreased luminal concentrations of conjugated bile acids. In shorter ileal resections, bile acid malabsorption can usually be compensated for by an increase in hepatic synthesis and malabsorbed bile acids cause the diarrhea rather than steatorrhea [168, 169]. Resection of the ileocecal valve leads to bacterial colonization of the distal ileum that destroys the bile acids. The lack of bile acids, which leads to unabsorbed fatty acids in the large bowel stimulates the colon to secrete more water and mucus, increase motility and prompt defecation [170].

Treatment of this complication involves a low fat diet and antidiarrheal medications. Bile acid-related diarrhea can be diagnosed with a selenium homocholic acid taurine test. A therapeutic trial of bile acid binders such as cholestyramine [170] may be helpful.

Voiding Dysfunction and Incontinence

The interposition of bowel into the bladder usually prevents the efficient detrusor contractions that are necessary for voiding [171]. The urethral outlet resistance may be high due to neurologic disease or concomitant surgery to treat incontinence. Some patients are able to void spontaneously with abdominal straining.

If the patient is unable to void or has complications from incomplete emptying, he/she will need to use CIC to empty their bladder. This is necessary in 25–100% of neurogenic patients and a lower proportion of neurologically intact patients [49].

Continence rates range from 60 to 100% [78, 88]. Nocturnal incontinence can occur due to failure of the urethral sphincter to respond to contractions of the augmented bowel and increased urine output due to water loss from the augmented bowel segment. Daytime incontinence can be due to stress incontinence, detrusor overactivity, or from phasic contractions of the augmented bowel segment [172, 173]. These phasic contractions are usually <40 cmH_2O and occur at higher volumes [88].

Treatment of incontinence in these patients includes behavioral modification (such as more frequent CIC), anticholinergics, and surgical procedures such as midurethral slings, bladder neck slings or bladder neck reconstruction, and artificial urinary sphincters [49, 174]. Occasionally, repeat augmentation is necessary [145].

Pregnancy

Pregnancy after augmentation cystoplasty is becoming more common [135]. Complications such as premature labor, urinary tract infection, renal dysfunction, and urinary tract obstruction are more prevalent in this population [175]. Patients usually require antibiotic treatment of bacteriuria as screening urinalysis for infection or proteinuria is not accurate due to mucus from the augmentation cystoplasty [176].

Vaginal delivery is preferable [176, 177]; however, there is controversy as to whether cesarean section is necessary for patients with artificial sphincters and bladder neck procedures [49, 176]. If an elective cesarean section is scheduled for other reasons, urologic assistance during the surgery, and a high segment section may help avoid damage to the bladder augmentation [49, 176]. The bowel segment can survive inadvertent damage to the vascular pedicle; however, this may lead to eventual contraction of the bowel segment [178].

Conclusion

Bladder augmentation with intestine has been successfully used to treat various conditions that result in small capacity bladders. The surgical technique involves detubularization and reconfiguration of a segment of bowel (usually the ileum or colon) to create a patch. A successful clinical outcome is dependent upon creating a large capacity, low-pressure reservoir to store urine; additional procedures to aid in catheterization or continence are often necessary. Potential complications have been well described and are usually reported in case series. Medical and sur-

gical treatments of complications are similarly well elucidated although some are still controversial. Since complications may occur at any time after surgery prolonged and possibly life-long follow-up and monitoring are essential.

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Anal Sphincteroplasty

24

Lauren Wilson and Brooke Gurland

Introduction

Direct sphincter trauma or neuropathic injuries from vaginal deliveries are the principal causative factors in the development of fecal incontinence in women less than 40 years old [1]. In patients of any age, reasons for fecal incontinence in addition to obstetric injuries include conditions that predispose the patient to diarrhea, neurologic conditions, chronic medical conditions such as diabetes, obesity, and COPD, iatrogenic injuries from anorectal operations, trauma, and anatomic conditions including rectal prolapse and congenital abnormalities [2]. In many cases, there may be an occult sphincter or pelvic floor defect from an obstetric injury that becomes clinically relevant when present in combination with other conditions [1].

Treatment options for the incontinent patient include nonoperative interventions such as medications to improve stool consistency and biofeedback, procedures including injection of bulking agents and controlled delivery of radio frequency energy (Secca), and operative interventions including anal sphincteroplasty, sacral nerve stimulation (SNS), artificial bowel sphincter, posterior anal repair, dynamic graciloplasty, transobturator posterior anal sling (TOPAS) procedure, and Fenix™ (Torax Medical, Shoreview, MN, USA) or magnetic sphincter augmentation.

Historically, anal sphincteroplasty has been the preferred surgical treatment for the symptomatic patient with an anatomically disrupted external anal sphincter (EAS) muscle. Short-term results report improved bowel continence as high as 90% [3] with decreasing continence (0–73%) in long-term follow-up studies [4–8]. Recent studies evaluating suture choice and augmentation with synthetic materials explore ways to improve longevity of the repair [9, 10].

Over the past 20 years, SNS has been utilized as a treatment modality with good results for patients with fecal incontinence with or without an anal sphincter defect, but requires an implantable device and the potential for future procedures for device maintenance. The artificial bowel sphincter, a silastic band surgically placed around the lower rectum, has been shown to improve bowel control but with high complication rates. Infection rates are reported up to 34% in multicenter studies, with device erosion and malfunction being other common complications. Approximately 50% of patients undergoing reconstruction with an artificial bowel sphincter will require explantation of

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the device due to infection or erosion, but those who do have successful implantation, have good results with respect to control of continence [11, 12]. At the present time, the artificial bowel sphincter is not being manufactured for implantation in the United States. Posterior anal repair is described for neuropathic incontinence. Studies on postanal repair have variable results with some studies showing improvement in up to 68% of patients [13]. Mackey and colleagues, however, reported that only 26% of patients have minimal incontinence with 74% of patients having moderate to severe incontinence. Of note, in this study, quality of life and satisfaction scores were high despite high rates of incontinence [14]. Dynamic graciloplasty is a complex procedure that involves gracilious muscle transposition and stimulation with an implantable stimulator. This requires expertise, it is associated with a high morbidity [15], and it is expensive [16, 17]. This procedure is not an option in the United States since the stimulator used for muscle contraction is not commercially available. The transobturator posterior anal sling (TOPAS) procedure shows good results with respect to continence and safety [18]. Mellgren and colleagues in a multicenter trial demonstrated that at 1 year almost 70% of patients had more than a 50% decrease in incontinent episodes per week and 19% were completely continent. Side effects were mainly pain though 15% had infections. There were no organ perforations, extrusions, or erosions [19]. While this study demonstrates success and the device is FDA approved, at the present time the device is not being manufactured. Mesh litigation has made companies hesitant to provide mesh devices for implantation in the pelvis. Finally, magnetic sphincter augmentation, FENIX™ is currently being evaluated and is showing promising early results for improving continence with a low complication profile [20, 21].

Unlike many of the alternatives mentioned, anal sphincteroplasty does not require expensive devices or postoperative maintenance necessary with implantable devices and remains an important treatment modality to treat patients with fecal incontinence with a disrupted anal sphincter who do not want an implantable device or who live in communities in which postoperative maintenance is not available. Furthermore, anal sphincteroplasty plays an important role in the management of other anorectal pathology, specifically rectovaginal fistula. Sphincteroplasty can also be performed in conjunction with other pelvic organ prolapse and urinary incontinence procedures without additional morbidity and potentially some improvement in continence [22]. The complications associated with anal sphincteroplasty are minor and include wound complications, UTI, chronic pain or discomfort, and recurrence of fecal incontinence. Major complications are rare. This chapter will address the prevention of complications and further management should a complication occur.

Patient Evaluation

Preventing failure of the procedure and occurrence of complications begins with appropriate patient selection and improving modifiable conditions. A comprehensive history and physical exam is imperative to appropriate patient selection. The following considerations are important when evaluating a patient with fecal incontinence for sphincteroplasty:

1. *Bowel habits:* Loose or watery stools may result in fecal incontinence. Bulking agents such as fiber and antidiarrheals to thicken and decrease frequency of bowel movements remain first-line therapies and must be used in conjunction with operative interventions. Sphincteroplasty will not be effective in patients with loose and irregular stools. Markland and colleagues compared psyllium to loperamide for treatment of fecal incontinence. Both medications were effective for improving fecal incontinence and quality of life, but loperamide had more side effects, specifically constipation [23].
2. *Age of the patient:* Aging tissues are less likely to recover and maintain good quality over time. Several retrospective analyses suggest that older women have anorectal function that deteriorates over time [6, 24]. Advancing age may

be associated with other pelvic floor defects including increased fibrosis and collagen deposition [25]. Several studies suggest poor continence outcomes in older patients [5, 6, 26, 27], while other studies have found that age does not affect outcomes [3, 28, 29]. Each case should individually take into consideration factors such as tissue quality and anal muscle contractility rather than biologic age alone.

3. *Obesity and other medical conditions:* A high body mass index has been associated with poorer outcomes after sphincteroplasty [24, 30]. Obese women may have other factors that can contribute to the incontinence such as excessive pelvic floor descent and diabetes. Control of diabetes and minimizing immunosuppression will decrease infectious and local wound healing complications.
4. *Severity of symptoms:* Patients should be counseled preoperatively regarding realistic postsurgical expectations. Nikiteas and colleagues found that patients with severe symptoms undergoing primary repair reported the best outcomes [24]. Measures of success in studies of sphincter repair are not standardized but include some measure of gas and stool incontinence as well as patient quality of life and satisfaction scores. In contrast, most studies of sacral nerve stimulation use a more standardized measure of success of the procedure if there is an improvement of more than 50% in occurrence of incontinent episodes per week [31]. It is rare for a previously incontinent patient to experience complete continence following sphincteroplasty or any other continence procedure, i.e., some degree of gas and stool incontinence should be expected. Importantly, many women consider their operation a success while reporting high rates of fecal incontinence [5].
5. *Local physical findings:* Lax anal sphincter muscles or a patulous anus may be associated with mucosal or full thickness rectal prolapse. Decreased or no anal sphincter contractility noted on physical examination is a poor prognostic sign for sphincter repair as it represents a poorly functioning anal sphincter. Patients should be asked about symptoms of other pelvic organs problems including urinary incontinence and pelvic organ prolapse. Physical exam should also include a vaginal exam in the female patient assessing for pelvic organ prolapse. This can be performed by the colorectal surgeon or in conjunction with a gynecologist or urologist if comanagement of multiple problems is anticipated based on history.
6. *Anal physiologic testing* includes endoanal ultrasound and anal manometry. Low-squeeze pressure on anal manometry in conjunction with an anterior sphincter defect on endoanal ultrasound is the primary indication for sphincteroplasty. Other sonographic findings may include a variegated appearance of the EAS-indicating atrophic muscles, a very thin internal anal sphincter (IAS), and size estimate of the defect of the EAS muscle. Pudendal nerve terminal latencies (PNTML) have also been used to evaluate the neurologic function of the anal sphincters, but the significance of prolonged PNTML are debated. Gilliand and coworkers in the largest series evaluating the role of PNTML, found that bilateral normal PNTMLs were the only factor predictive of long-term success of anterior overlapping sphincteroplasty [32].

Preoperative Management

In addition to appropriate patient selection, setting realistic postoperative continence expectations, and optimizing stool consistency and other comorbid conditions, preoperative management includes mechanical bowel preparation and administration of a single dose of intravenous antibiotics administered prior to the surgery. Some groups advocate using a full bowel prep while others use enemas in the preop area.

Fecal diversion prior to sphincteroplasty has not been shown to improve outcomes and is not recommended. Hasegawa and colleagues [33] demonstrated equivalent sphincter related outcomes between groups randomized to sphincteroplasty with or without diverting stoma. Patients in the stoma group suffered stoma-related complications.

Operative Management

Operative Technique and Results

Depending on surgeon preference, sphincter repair can be performed in lithotomy or prone position. After the perineum is prepped and draped, an anterior 120° curvilinear incision is made along the perineum to allow dissection and mobilization of the sphincter muscle and scar. It is important to preserve all scar tissue in order to anchor the sutures.

A number of techniques have been described for sphincteroplasty and the choice is operator dependent. Repair techniques include end-to-end apposition versus overlapping repair, choice of suture material, and augmentation of the repair with a biologic material. The data to support these options are limited but can affect the complication profile and thus should be considered by the surgeon prior to repair.

Primary repair of obstetric anal sphincter trauma is typically carried out by gynecologists around the time of delivery. Several randomized studies of end-to-end versus overlapping sphincter repairs have shown conflicting results with studies showing no difference, better outcomes with overlapping repair, and better outcomes with end-to-end repair [34]. Secondary repairs are carried out months to years after the injury and are most frequently performed by colorectal surgeons though occasionally by gynecologists.

Both end-to-end repair and overlapping sphincteroplasty for secondary repairs have been described in the literature though the majority of large series employ the overlapping technique. There is only one randomized controlled trial comparing these two techniques for secondary sphincter repairs for incontinence. Tjandra and coworkers [35] studied 23 patients with fecal incontinence caused by obstetric injuries, 12 underwent direct repair, and 11 overlapping sphincter repair. At a median follow-up of 18 months, the functional results were significantly improved in both groups irrespective of the technique with improvement in continence in 75% and 73%, respectively.

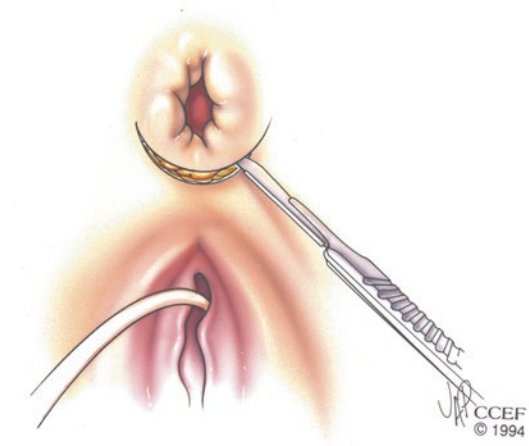

Fig. 24.1 A transverse incision along the perineum. Note the patient is positioned in the prone position with the anus superior and vagina inferior (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 1994–2016. All Rights Reserved)

End-to-end repair is performed by isolating the IAS from EAS and repairing these separately. Overlapping sphincteroplasty, can be performed *en bloc* thus avoiding separating the internal and external sphincters though many series describe isolating the internal and external sphincters with repair of the internal sphincter and overlap of the external sphincter, as well as anterior levatorplasty [26, 36]. Mattress sutures are used to approximate the sphincter (Figs. 24.1, 24.2, and 24.3).

There is a paucity of information on the choice of suture material. Parnell and coworkers [10] investigated the use of permanent versus absorbable sutures in overlapping anal sphincteroplasty specifically related to loss of solid stool and severity of incontinence symptoms. Four surgeons performed the overlapping technique with no separation of the IAS and EAS. Each surgeon used their preferred suture material. Permanent suture types included Gore-Tex® (Gore Medical, Neward, DE, USA), Nurolon® (Ethicon, Somerville, NJ, USA), and Ethibond® (Ethicon, Somerville, NJ, USA), while absorbable sutures were Vicryl and PDS. Forty patients were included in the study with 20 in the permanent suture group and 20 in the absorbable group. The primary endpoint was loss of solid stool greater

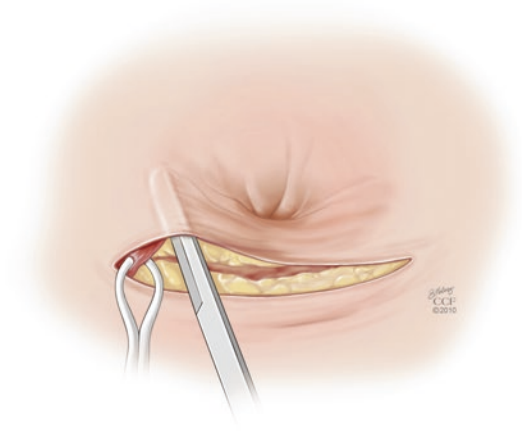

Fig. 24.2 The external sphincter is identified and grasped with the Allis clamp (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 1994–2016. All Rights Reserved)

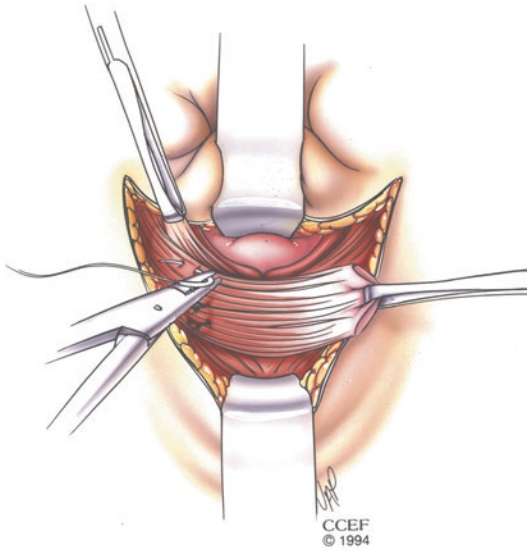

Fig. 24.3 The external sphincter is overlapped and sutured into place (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 1994–2016. All Rights Reserved)

than 1–3 times per month. The groups had similar rates of overall incontinence to solid stool, but the use of permanent suture was associated with decreased severity of fecal incontinence and fewer social limitations. Complications of wound separation and wound infection occurred equally in both groups. Three suture erosions occurred in the permanent suture group and one in the absorbable group, all of which were managed in the clinic. Studies of suture type in sphincteroplasty and posterior repair or sacrospinous ligament suspension have indicated higher rates of infection with braided permanent sutures. This study suggests that permanent monofilament sutures may reduce the risk of infection associated with braided permanent sutures.

Once the sphincter repair is complete, the edges of the wound are approximated in a V shape or longitudinally with interrupted 3.0 Vicryl mattress sutures. The center of the wound can be left open, a small drain inserted, or the wound can be closed.

Postoperative Management

Postoperative management requires keeping the stools soft, the area clean, and pain tolerable. At our institution, patients are kept overnight and discharged the following morning. There is no consensus on the routine administration of postoperative oral antibiotics at discharge. The patient is discharged on stool softeners with the goal of keeping the stool soft to avoid straining. The patient should be counseled to avoid liquid stools.

Warm soaks in a bathtub or sitz bath for 5–10 min help with pain relief by promoting relaxation of the pelvic floor muscles. Other surgeons instruct patients to avoid submerging the incision but rather directing a handheld shower or peri-bottle at the wound to facilitate hygiene and gently debride the perineum. Nonsteroidal

medications are encouraged over narcotics for pain relief to avoid the constipating side effects associated with narcotics.

Postoperative Complications

Complications that can occur in the early postoperative period include hematoma or seroma formation. These can be treated by opening the wound and evacuating the contents. Antibiotics with Gram positive, Gram negative, and anaerobic coverage are selectively prescribed in the setting of wound cellulitis.

Late complications include abscess formation, fistulas, and wound dehiscence. Abscesses and fistulas require additional operative interventions including debridement and in rare cases a stoma, while wound breakdown usually heals secondarily and rarely requires secondary suturing. In addition to prolonged healing and additional procedures for drainage, poor continence outcomes are more common in those patients with deep wound infections [26].

The patient's main complaint after surgery is pain from the perineal wound. Table 24.1 reports complications after sphincteroplasty. Among the studies analyzed, the overall complication rate ranged from 8 to 31%.

Long-Term Outcomes

Early symptom improvement is noted after sphincteroplasty [3, 36, 38, 39]; however, long-term follow-up reveals a decline in continence and increasing fecal accidents [4]. There is a deterioration of fecal continence over time with return to baseline by 10 years [5–7]. Johnson and coworkers reported improved results in 55% of patients but excellent results in just 9% of patients after 8.6 years [40]. Halverson and Hull reported 14% of patients totally continent after 5 years and 41% continent to liquid and solid stools [39], but among the same cohort at 10 years, no patients were totally continent and no patient was continent to liquid and solid stool [6]. Similarly, Buie and coworkers reported 23% total continence at 3 years and 39% with continence to liquid and solid stool [38]. The same cohort of patients, showed worsened continence rates at 10 years with only 6% with total continence and 16% incontinent to gas only [5]. The outcomes are reported using different endpoints making comparisons between study groups difficult. Table 24.2 summarizes studies with long-term follow-up.

For patients with recurrent fecal incontinence after sphincteroplasty, reevaluation and repeat repair can be considered. The rate of success of the repeat sphincter repair is the same as that after a primary repair [37] and hence should be considered for selected patients with failed primary repairs.

Conclusion

Despite criticism regarding long-term functional results, sphincteroplasty is a viable option for women with sphincter trauma and associated fecal incontinence. Improvement in continence after sphincteroplasty is noted but it is not to the level that it was before the sphincter injury and declines over time. Complication rates are low and this procedure can be offered with limited morbidity. While SNS is increasingly used in the United States and worldwide, anal sphincteroplasty remains an important procedure for colorectal surgeons to be familiar with as it is a good option for patients who do not want or cannot have an implantable device and can also be combined with other procedures for treatment of fecal incontinence, pelvic organ prolapse, and rectovaginal fistula.

Acknowledgments The authors gratefully acknowledge the contribution of Patricia C. Alves-Ferreira, PT, who coauthored the prior edition of this chapter.

Table 24.1 Complications after sphincteroplasty

References	*N*	Age at time of surgery, mean (ranges)	Repair	Complications
Gibbs and Hooks (1993) [8]	36	47 (20–74)	OSR	11/36 patients (31%)
				Temporary voiding issues: 5
				UTI: 3
				Anal stenosis: 3
				Colostomy for wound sepsis: 2
				Congestive heart failure: 1
				Perianal sinus tract: 1
Buie et al. (2001) [38]	191	36 (20–74)	OSR	12/191 patients (8%)
				Urinary retention: 6
				Hemorrhage not requiring transfusion: 2
				Abscess: 2
				UTI: 1
				Fecal impaction: 1
Halverson and Hull (2002) [39]	44	38.5 (22–80)[a]	OSR	4/44 patients (9%): Wound infection
Grey et al. (2007) [36]	85	46 (22–80)	OSR	26/85 patients (31%)
				Wound infection: 11
				UTI: 5
				Hematoma: 3
				Urinary retention: 2
				Pain: 2
				Fecal impaction: 2
				Pneumonia: 1
Oom et al. (2009) [26]	160	58 (30–85)[a]	OSR	39/160 patients (23%)
				Wound infection: 35
				21/35 Abscesses requiring further surgery with fistula formation in 15
				Ileus: 2
				DVT: 1
				Lung embolism: 1
Johnson et al. (2010) [40]	33	36 (22–75)[a]	OSR	6/33 patients (18%): Wound infection
Lehto et al. (2013) [41]	56	51 (30–79)	OSR or end-to-end if overlap not possible	10/56 patients (26%): Postop superficial wound rupture and/or wound infection treated with antibiotics
Lamblin et al. (2014) [4]	20	46 (31–62)	OSR	5/20 patients (25%)
				Skin hematoma (no drainage): 1
				Delayed skin healing: 1
				Severe pain: 3 (2 resolved spontaneously in 1 week, 1 pudendal neuropathy)

OSR overlapping sphincter repair, *UTI* urinary tract infection
[a]Results reported as median

Table 24.2 Long-term outcomes after sphincteroplasty

References	*N*	Age at time of surgery, mean (ranges)	Repair	FU months, mean (ranges)	Outcomes, good/excellent *N* (%)
Gibbs and Hooks (1993) [8]	33	47 (20–74)	OSR	43 (4–114)	Good/Excellent (73%)
					10/33 Reliable control of liquid and solid stool
					14/33 Occasional loss of liquid stool or gas
Karoui et al. (2000) [7]	74	52.9 (21–85)	OSR	40	21/74(28%) Totally continent
					17/74 (23%) Incontinent to gas
					36/74 (49%) Incontinent to feces
Malouf et al. (2000) [42]	46	43 (26–67)	OSR	77 (60–96)	23/46 (50%) Either no or monthly or less frequent urge fecal incontinence
					4 continent to solid and liquid stool
					No patient fully continent
Buie et al. (2001) [38]	158	36 (20–74)	OSR	43 (6–120)	97/158 (61%) Excellent or good results
					36/158 (23%) Completely continent
					61/158 (39%) Gas incontinence or mild stain
					42/158 (26%) Pad or incontinence less than once per month
					19/158 (12%) Incontinence greater than once per month
Halverson and Hull [39]	44	38.5 (22–80)a	OSR	62.5 (47–141)[a]	6/44 (14%) Completely continent
					18/44 (41%) Continent to liquid and solid stool
					16/44 (36%) Best possible quality of life score
Gutierrez et al. (2004) [5]	130	37	OSR	120 (84–192)	8/130 (6%) Completely continent
					21/130 (16%) Incontinent to gas only
					25/130 (19%) Soiling
					74/130 (57%) Incontinent of solid stool
Grey et al. (2007) [36]	47	46 (22–80)	OSR	60+	28/47 (60%) Improved continence
					17/47 (36%) Initially improved, but since deteriorated
					2/47 (4%) Unchanged
Zutshi et al. (2009) [6]	31	44 (22–80)	OSR	129 (113–208)	No patients completely continent
					No patients continent to liquid and solid stool
Oom et al. (2009) [26]	120	58 (30–85)[a, b]	OSR	111 (12–207)	44 (37%) Excellent or good outcomes
					7/120 (6%) Excellent outcomes
					37/120 (31%) Good outcomes
					28/120 (23%) Moderate outcomes
					48 (40%) Poor outcome—less than 50% reduction of incontinent episodes and not satisfied with their situation
Johnson et al. (2010) [40]	33	36 (22–75)[a]	OSR	103 (62–162)[a]	19 (58%) Excellent or good outcomes
					3/33 (9%) Fully continent
					16/33 (49%) Improved
					14/33 (42%) Incontinence unchanged or worse

OSR overlapping sphincter repair
[a]Results reported as median
[b]Age at follow-up

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Cosmetic Gynecologic Surgery

25

Dani Zoorob and Mickey Karram

Introduction

Whether called cosmeto-gynecology or genitoplasty, the desire for enhancement of the genitalia is becoming more prevalent. As this field grows and is more in demand, surgeons have devised various techniques in the hopes of generating better outcomes. In the recent past, there has been a tremendous amount of direct to consumer marketing of these modalities by individual surgeons, promising improved sexual function. The objective of this chapter will be to briefly discuss these various techniques for cosmetic gynecologic repairs as well as to best avoid and manage potential complications. See Table 25.1 for a summary of Suggested Complication Avoidance Tips in Cosmetic Gynecologic Surgery.

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Labioplasty

Labia Minora

Labioplasty, also known as labial rejuvenation, is a term typically used to indicate surgical enhancement of the labia minora.

History

The documented origin of labioplasty dates back to the Pharaos in Egypt [1]. This practice, although modified, has persisted in the African continent with variations as minor as modification of the labia minora up to extensive resection of all external female genital organs including labia majora and minora as well as the clitoris.

Amongst the earliest modern medical references discussing labioplasty is that of Hodgkinson and Hait [2] where they discuss the functional and aesthetic standpoints. Over the years, multiple procedures by Alter [3], Rouzier [4], Choi [5], and others were devised with varied outcomes and complications inherent to the different techniques used. Although less commonly used, the term labioplasty may encompass the augmentation or reduction of the labia majora.

Indications and Techniques

A common nonaesthetic indication for labioplasty is dyspareunia, which usually occurs in women with labial hypertrophy due to the labia being pulled on significantly during intercourse.

H.B. Goldman (ed.), *Complications of Female Incontinence and Pelvic Reconstructive Surgery*, Current Clinical Urology, DOI 10.1007/978-3-319-49855-3_25

Table 25.1 Suggested complication avoidance tips in cosmetic gynecologic surgery

Labia minora	Simple resection
	– Delineate area to be resected prior to both initiating the incision and infiltration with anesthetic
	– Use interrupted not running sutures at skin edges
	– Avoid excessive resection of tissue keeping in mind that the base of the labia minora is wider than the edge
	Wedge resection
	– Direct the majority of the resection specifically to the hypertrophied region
	– Initiate the suture line as close to the labial base as possible
	De-epithelialization technique
	– Attempt symmetrical de-epithelialization on both sides of the labia to ensure symmetry
	– Ensure performing elliptical shaped de-epithelialization zones along the long axis of the labia minora
	Defect correction techniques (YV flaps)
	– Avoid excessive tension/traction on the suture line
	– Use the least cautery possible
	– Ensure maintaining adequate blood supply/perfusion
Labia majora	– If incisions are required, plan the incision sites close to the labia minora so as to reduce scar visibility
	– Consider elliptical incisions to allow for a natural crease appearance
Vagina	– Avoid fascial involvement (resulting in site-specific defects) during rugae formation when using lasers.
	– Monitor for excessive tissue heating during laser and monopolar cautery use
Clitoris	– Ensure avoidance of resection of clitoral tissue (unless clitoral reduction is being performed)
	– Use interrupted sutures when closing an incision
	– Inspect the incision within 3–7 days postoperatively to assess for potential contracture formation
Non-site-specific	– Ensure adequate hemostasis at the end of the procedure
	– Judiciously limit the use of cautery and other forms of energy to avoid potential structure and fibrotic band formation
	– Assess the surgical site within the first week
	– Ensure patients do not have a keloid history or reaction to suture types being used
	– Advise cessation of blood thinners, NSAIDs, Vitamin E, and Fish oil containing products prior to the procedure (exact duration is based on physician preference)

Other indications include vulvar irritation and discomfort with the use of underclothes or during ambulation or exercise. Some patients report an inimical impact on hygiene, especially when menstruating. The negative psychological impact of the "unnatural" or abnormally appearing labia, even if subjective, is also a frequent reason to consult a physician.

When performing a labioplasty, the essential goals should include the reduction of the hypertrophied labia minora with maintenance of the neurovascular supply, preservation of the introitus, optimal color/texture match, and minimal invasiveness [6, 7].

While many systems to stage the severity of this condition exist, there is still no consensus on how best to define and classify labial hypertrophy. One system divides the classification into three stages: none (no edges protruding beyond the labia majora), mild (1–3 cm beyond the labia majora edges), severe (>3 cm). Another system described by Felicio [8] divides labial hypertrophy into four stages: I (<2 cm), II (2–4 cm), III (4–6 cm), IV (>6 cm). Franco and Franco [9] describe a similar classification. However, Rouzier [4] considered that the normal maximal length of the labia minora should not exceed 4 cm, whereas Radman [10] considers it to be 5 cm (Fig. 25.1).

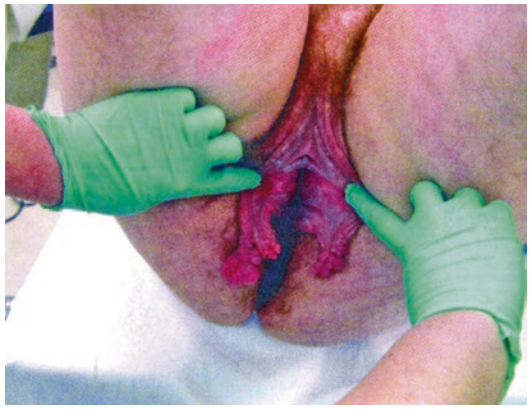

Fig. 25.1 Massive hypertrophy of the labia minora in a young woman with cerebral palsy

A myriad of surgical techniques have been reported in the literature, including simple resection, wedge resection with modification of excisions, VY and Z-plasties, and de-epithelialization (Figs. 25.2a–c and 25.3a–c).

In *simple resection*, the excess or protuberant labial tissue is removed using scissors, a scalpel, or even a laser, in an elliptical or straight line [11]. The edges are thereafter reapproximated with sutures, preferably simple interrupted, to ensure appropriate healing while maintaining the new contour. Depending on the defect or abnormality, the resection is preferably made while preserving a regular labia minora edge. Some surgeons suggest a remnant minimal labia minora depth of 1 cm [2, 12]. A novel technique called "*Lazy S*" reported by Warren is reported to assist in reducing the likelihood of contractures and phimosis of the labia minora [13]. This technique involves marking the area to be resected in an S shape—rather than an ellipse or straight line—prior to infiltration with local anesthetic and then resecting along the broadly wavy tract. It is reported that once healing occurs, the wavy line would take a relaxed appearance with little tension at the periphery of the tissue, giving a more "natural" and aesthetic look.

Another technique is *wedge resection*, which is reported to reduce hypersensitivity and contour irregularities upon healing. The wedge system targets the most hypertrophied region in the labia minora and resects it all the way to its base in a V or wedge form. This in turn allows for a smaller exposed healing area; however, depending on the resection required, it might be deep enough that it reaches the proximity of the labia majora. Multiple variants of this procedure have been devised including Z-plasty and VY and the Matarasso modification/*Star wedge resection* [6]. The initial description of the technique involved a V-shaped wedge resection of the area with the most excess tissue identifiable [3]. Maas and Hage reported the wedge technique to strictly involve a W-shaped resection margin in the labia minora with no involvement of the clitoral dorsal hood, prepuce, or fourchette [12]. The advantage of this technique (also known as the Zig-Zag technique) was reported to be the lower likelihood of dyspareunia and introital obliteration. This technique is reported by some to induce loss of the pigmentation along the border of the labia minora despite the more natural contour being generated. In 2008, Alter published the extended central wedge technique, a modification of his previous wedge resection, producing a more aesthetic look, with the possibility of resection of excess tissue in the clitoral hood [14]. This was based on the follow-up of previously operated patients. Among the modifications was one reported by Munhoz and colleagues where the wedge is resected from the inferior aspect of the labia minora and a superior pedicle flap is developed [15]. This is reported to provide a better aesthetic look due to a more homogenous tinting of the labia.

In 2000, a technique was devised by Choi and Kim so as to maximally help preserve tint, texture, sensation, and the neurovascular supply to the labia minora [5]. This technique involved the central *de-epithelialization* of both labia minora on both sides with suturing of the new edges together.

In 2011, Alter described the use of *YV advancement flaps* for the reconstruction of either absent, abruptly terminated, distorted, or scalloped labial edges [16]. Being the closest match to labial tissue, clitoral hood tissue is mobilized in such a manner as to release two parallel folds—including the Dartos fascia and blood

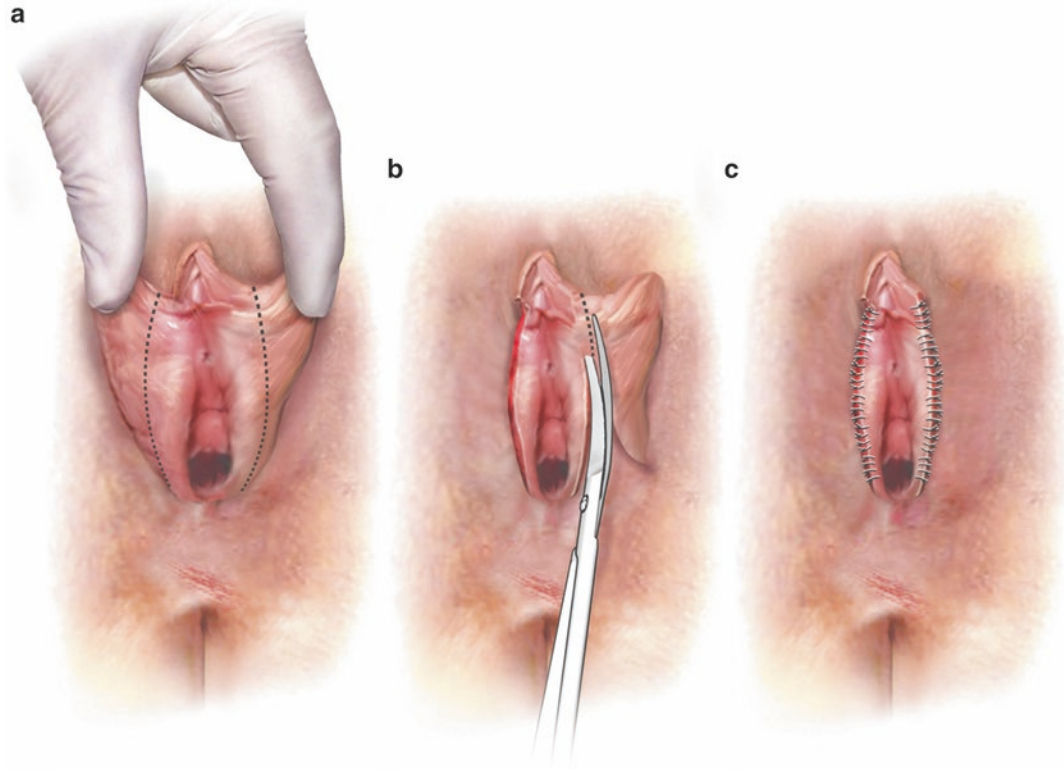

Fig. 25.2 The technique for simple excision of enlarged or hypertrophied labial skin. (**a**) Excess skin to be removed is marked. (**b**) Skin is excised. (**c**) Interrupted sutures reapproximate the edges of the labia

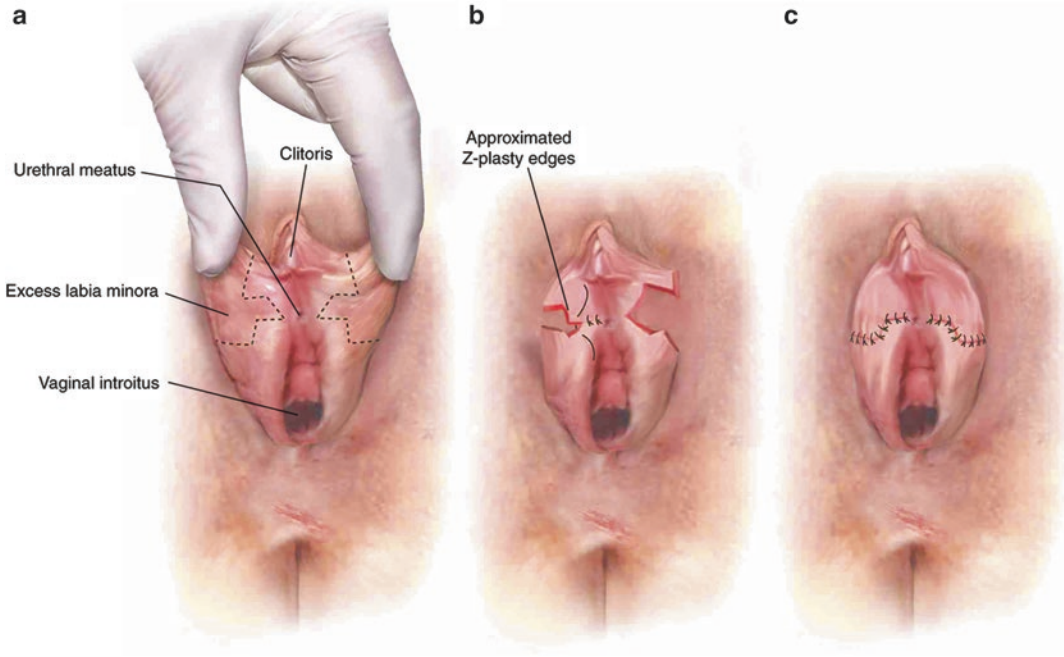

Fig. 25.3 Technique for Z-plasty. (**a**) Skin is to be excised. (**b**) Skin is excised and to be reapproximated transversely with fine interrupted sutures. (**c**) Completed repair

supply—from around the clitoris and rotating them on each side to form the labia minora.

Composite reduction refers to labial reduction as well as enhancement of the clitoral hood. Described first by Gress in 2013, it allows for uniform reduction of the labia and the tissues covering the clitoris [17]. The study, which consisted of 812 patients, reported high patient satisfaction and an increase in patient excitability in 35% of patient undergoing the correction of clitoral protrusion.

Labia Majora

Many conditions affect the labia majora fat content including weight gain and weight loss. This is notable especially when weight loss is significant. Knowing that they can be molded as needed, grafts of fat pads and fat injections can be used to improve the atrophied look [18, 19]. Felicio reported up to a maximum of 60 mL of fat can be injected into each labia majora per session, while requiring a drain if more is to be implanted or a continuation of the procedure is performed 6 months later [20]. Labia minora injections are also possible. Labia majora augmentation is reported to assist in increased comfort and sexual satisfaction, possibly due to acting as a shock absorber and possibly due to increased fullness and firmness of the labial tissues. Regarding hypertrophied labia majora, reduction of fat or skin may be indicated. As such, the option of resection of skin in an elliptical or S-shaped incision is advised, if performed. The closer the final incisional edge is to the labia minora, the more inconspicuous the scar is [21]. Miklos and Moore reported use of a semilunar incision on the medial border of the labia majora [22]. The possibility of lipoplasty could assist in avoiding large incisions and shorten the recovery period and reduce postoperative pain; however, the need for repeat or touch-up surgery may be required.

Labioplasty Complications

A variety of complications have been reported with labioplasty surgery. As a multitude of different techniques and modifications have been described, it is essential that the surgeon undertaking these procedures be familiar with the anatomy of the external genitalia and its surrounding structures.

Infection

The perineal area seems less susceptible to infection compared to other regions of the body but the potential for abscess formation does exist, and it is mandatory to follow the universal guidelines for surgical site cleansing prior to initiating surgery. Although no definitive recommendations for labioplasty have been set by any society, routine administration of surgical antibiotic prophylaxis is advisable.

Surgical Site Breakdown

The possibility of contractures, tissue breakdown along the suture line, flap necrosis, edge necrosis, irregular resorption, phimosis of the clitoral hood, new onset of dyspareunia, loss of sensation or hyperalgesia may occur in the resection areas.

Close care following surgery whether immediately postoperatively or a few weeks out is mandatory. No set criteria are available in the literature denoting particular postoperative wound care. However, it is advisable that postoperative patients avoid trauma to the surgical site and observe pelvic rest, such as by avoiding intercourse and use of tampons and sexual toys, for a minimum of 4–6 weeks so as to ensure adequate healing. Felicio reports that ice packs and NSAIDs are ideal for postoperative edema and swelling [20]. He also recommends ensuring that labioplasty is not concurrently performed with perineoplasty due to the intense swelling resulting in prolonged discomfort persisting up to 6 months. In addition to discomfort, the likelihood of suture-line breakdown is much higher with swelling. Thus, staging the enhancement

procedure would be advisable for both patient care and outcome.

Generalized flap degeneration or necrosis is more commonly seen in patients with sutures that have been placed tightly across the edges or when there is excessive traction on the attached tissue or flaps. It is crucial that when a flap is to be mobilized, the surgeon needs to ensure the persistence of the blood supply to allow the flap to survive as well as incorporate appropriately into the transposition site. Distal flap necrosis and subsequent gap formation in the labia may ensue if the vascular supply is not preserved. Additionally, in YV advancement flaps, the devascularization due to extensive undermining or extreme skinning prior to mobilization particularly endangers the survival of the transposed flap. Thus, ensuring minimal vessel distortion when mobilizing tissue with the least possible rotation/torque applied allows for better tissue survival. The development of a wound dehiscence is particularly ominous in esthetic surgery.

Bleeding

Hemorrhage and the possibility of hematomas may be encountered based on the vessels severed. Arterial blood vessels usually require active control by cautery or suture ligation, whereas venous bleeders may need less aggressive management including pressure applied to the area involved or simple application of hemostatic agents.

The acute worsening of pain postoperatively may indicate the expansion of a hematoma, particularly in highly vascularized areas such as the labia majora. In addition to the psychological impact on a patient, the formation of a hematoma could potentially require drainage as well as prolonged courses of antibiotics, and ultimately exploration to control the bleeding vessel. This can be attempted initially by freeing the suture line and then evacuating the hematoma. Since not all hematomas are associated with arterial bleeding, the use of fibrin clotting agents could be useful at times when persistent minimal venous oozing is noted. While multiple agents exist, there are no studies identifying the benefit of one compared to. another in the setting of labial hematomas.

Dyspareunia

Postoperative dyspareunia is known to occur more with wedge excisions as well as simple resection of labial tissue due to the newly formed exposed labial edge. Multiple studies have been done to assess the innervation in hypertrophied labia compared to normal sized ones with no evidence of variability demonstarted relative to size [23–25]. However, postoperative hyperalgesia has been noted to occur, especially with associated infection, severe inflammation, or when severe edema ensues postoperatively. If swelling occurs and the tissue perfusion is impacted, the possibility of labial retraction and contracture (called phimosis if involving the clitoral hood) may occur as the healing process continues. This contracture may in turn cause severe dyspareunia that may require reoperation if resulting in inability to achieve penetration.

Suture Granulomas and Scarring

Compared to simple interrupted sutures, the use of running locked sutures at the edges may predispose to a rugged or irregular labial edge due to localized necrosis or skin retraction. This in turn may result in contracture formation. The use of simple interrupted sutures is preferred in simple excision procedures. The various studies available in the literature report no suture material to be superior to another. When using absorbable sutures, the use of vicryl and monocryl would be ideal, although the use of chromic sutures also has good reported outcomes [5]. Use of nonabsorbable sutures is theoretically associated with the least reaction at the suture site with possibly better cosmesis; however, it is less convenient to use due to the discomfort endured by the patient upon removal of the sutures. To ensure better outcomes, it is advisable to inquire preoperatively about any history of vicryl-associated suture granulomas. The removal of any permanent sutures should be carried out within 1 week of surgery to assist in healing while ensuring the pressure on the incision site is lower since the edema will have partially receded by then. When left too long, the sutures can potentially develop epithelialized tracts, and this may have an unsightly appearance.

Simple amputation of the protuberant labium is reported to generate a stiff and weakly healed edge along which irritation and potential retraction could occur [12]. The stiff edge formation is mostly due to extensive local fibrosis developing when healing. A technique called "Lazy S" is reported to assist in reducing the likelihood of contractures and phimosis [13]. This technique involves marking the area to be resected in an S shape. With healing, the wavy line takes a relaxed appearance with little tension at the margin. The homogenous or gradual labial pigmentary changes need to be preserved in order to ensure aesthetic outcomes. The sudden change from dark pigmented folds to lightly pigmented labial folds is not advisable. The de-epithelialization and zig-zag techniques preserve this best.

Postoperative Labial Asymmetry

A complication that has been reported is the inability to perceive the length of labial tissue necessary to be resected once they have been infiltrated with local anesthetic. The distortion incurred intraoperatively by the solution injected could render the margins irregular and not easily identifiable, and thus it is imperative to mark the area for excision prior to any local injection. This helps prevent over-resection and provides the appropriate aesthetic result. It would be prudent that the delineation be done immediately preoperatively while the patient is awake, as well as preferably initially in the office during the surgical scheduling appointment so the appropriate change in labial size that is medically advisable compared to the patient's expectations can be determined.

Vaginoplasty

Vaginoplasty refers to modifications in the vagina to incur visual, sexual, or functional improvement. Its indications remain vague but usually include the desire for enhancement of vaginal aesthetics and improvement and augmentation of the sexual experience. Ostrzenski considers it a transformation involving both anatomy and function to allow for heightened sensation in intercourse [26]. Typically, aesthetic vaginoplasty is primarily a perineoplasty. It involves restoring the normal visual anatomy of the region of the perineum and posterior fourchette.

At all times, the vaginal canal should have a perpendicular relationship relative to the perineum. Having had an episiotomy or laceration during parturition, some women may have had inadequate repairs and end up with an introitus that has a large membranous portion covering the posterior fourchette. This membrane often causes dyspareunia due to friction and stretching. This is usually due to an iatrogenic malapproximation of overlying skin, and at times musculature, resulting in the perineum not having sufficient support and thus dyspareunia develops due to significant stretching and pulling of the thinned-out portion of this vulvo-vaginal structure (Fig. 25.4). The "membrane" itself does not have any physiologic purpose, and thus it is advisable to have the "membrane" resected when restoring normal anatomy to the perineum.

Moving deeper into the vagina, the presence of significantly redundant tissue inside, whether following any surgical procedure or even if present naturally, could be reported as unappealing to the sexual partner. In rejuvenation and vaginoplasties, this may be considered as a potential repair site, where excess rugae may be excised, cauterized, or lasered. Certain areas to be tar-

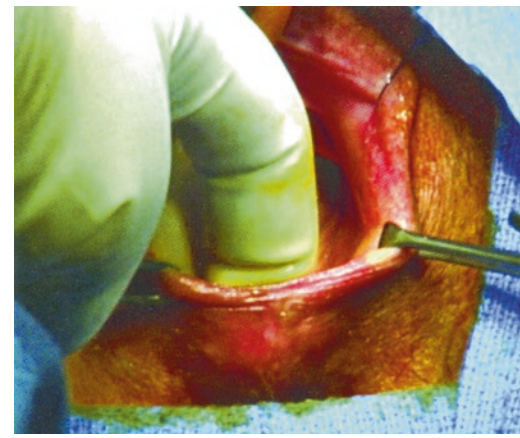

Fig. 25.4 The skin of the labia minora has been previously sewn across the midline, most likely at the time of the repair of a midline episiotomy

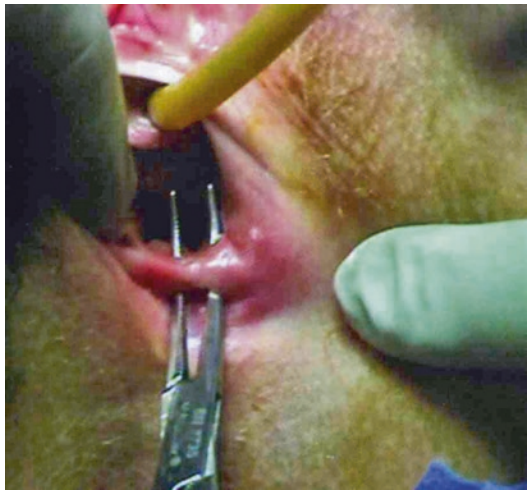

Fig. 25.5 Band of perineal scar tissue in a young patient following the repair of a perineal laceration

geted while resurfacing are episiotomy skin/mucosal tags or laceration repair sites, areas of a previous colporrhaphy where dog-ears/tags have developed, as well as possible breakdowns in the repairs.

Another form of rejuvenation, called mucosal tightening/lateral colporrhaphy, involves excision of a wedge of vaginal mucosa after which the raw edges are sutured together. A case series showed a 95% improvement in "vaginal tightness" sensation after such a procedure [27].

At times, band-like adhesions may be noted extending across the vagina due to varied resorption and healing after any kind of repair (Fig. 25.5). Sometimes, strictures may be seen across the vagina. Severing these adhesion bands may be accomplished by using cautery that is allowed to go deep into the vaginal wall—releasing the adhesion at its base if possible.

This typically allows for restoration of the normal vaginal caliber. Healing in such cases may require secondary intention closure rather than surgical mucosal overlay. Recent studies have aimed at the regeneration of vaginal rugae to effect augmentation of sensory-coital pleasure. Loss of this rugation may occur with age as estrogen production dwindles, as well as in areas with site-specific defects. Studies have also shown that the anterior vaginal wall has denser innervation relative to the posterior wall particularly distally [28–30]. Attempts at regenerating rugae using linear laser stratification with vaporization up to the vaginal fascia was noted to improve sexual satisfaction in a prospective observational study but in only 20% of the test subjects [26].

Typically occurring postpartum, many women develop a widened genital hiatus as well as vaginal laxity. Prior to surgical repair aimed at tightening of the vagina itself, pelvic floor rehabilitation should be initiated to ensure adequate muscular toning of the vagina. In general, only a perineoplasty is required for tightening the genital hiatus but some may consider doing a posterior colporrhaphy (Fig. 25.6a–f). Studies done to assess dyspareunia following colporrhaphy show that it is less frequent if perineorrhaphy involving the levators is avoided.

Complications of Vaginoplasty

Depending on the procedure used for vaginoplasty, a myriad of complications may occur.

Laser and Cautery-Related Complications

If the laser is used to create rugae, the avoidance of damage to the fascial layers is important. Currently, there are no recommendations for the depth of vaporization, but it is best to avoid reaching the glistening fascial layer so as to avoid iatrogenic development of site-specific defects. The laser vaporization, if not used judiciously, may incur damage to any of the underlying tissues including the bowel, bladder, and urethra. Furthermore, it is advisable to avoid prolonged tissue exposure—of the same spot—to avoid peripheral damage by heat conduction. As with the laser and due to significant peripheral heating of adjacent tissues, caution is advised with extensive use of monopolar cautery. In procedures of resurfacing where the extra rugae or skin tags in the vagina are removed, it is best to brush rather than attempt to cut or shave the rugae. The brushing technique, as its name implies, involves rapid and superficial back and forth cautery tip motion. This modality will result in removal of only the

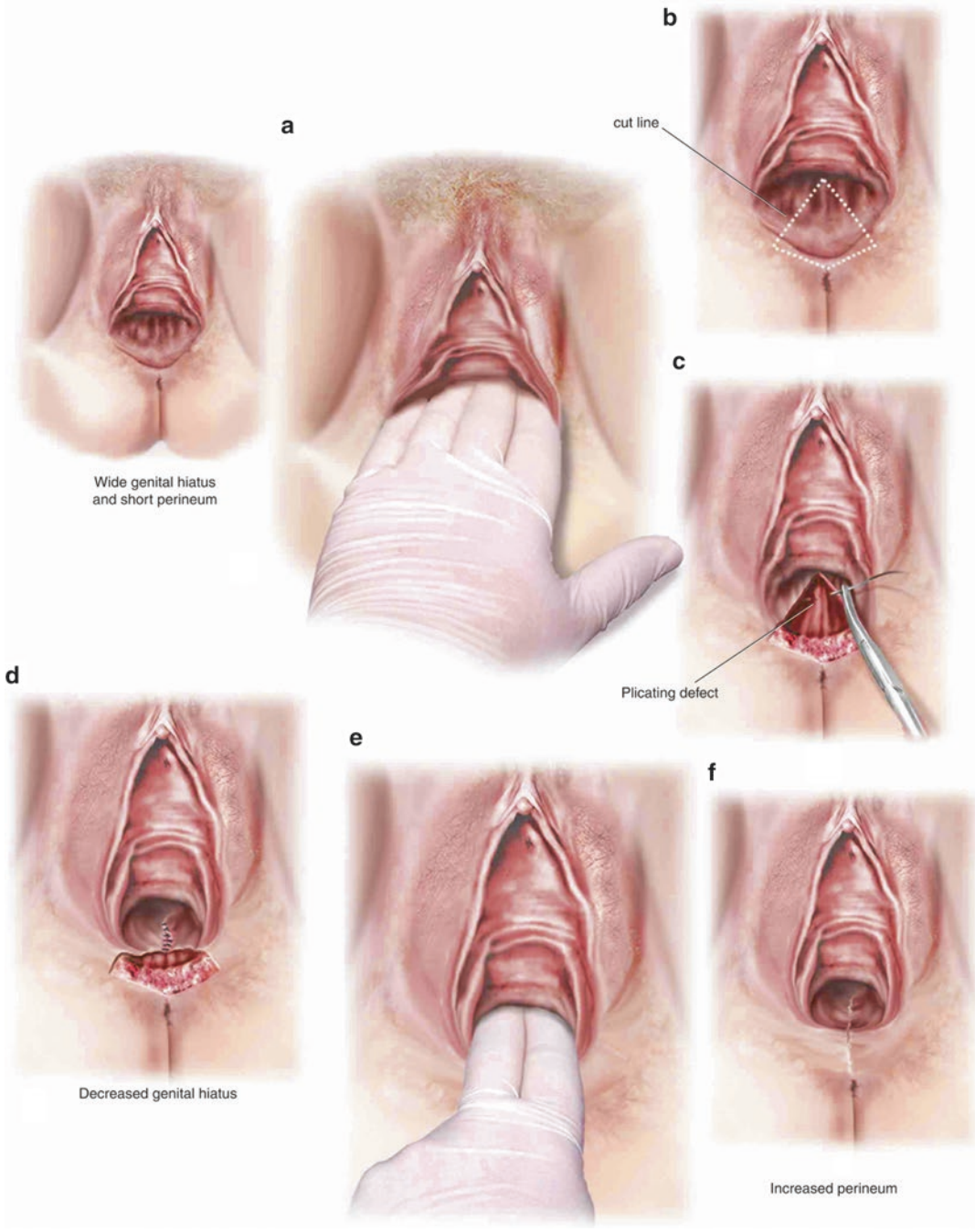

Fig. 25.6 The technique of vaginoplasty and reconstruction with the sole aim of tightening the vaginal introitus. (**a**) Note the wide genital hiatus, which easily allows the insertion of four fingers. (**b**) A diamond-shaped piece of tissue to be excised is marked. (**c**) The tissue has been removed, and deep stitches are taken through the perirectal fascia and levitator muscles to build up the posterior vaginal wall. Great care is taken to avoid the creation of a posterior vaginal wall ridge. (**d**) The upper portion of the posterior vaginal wall is closed in preparation for perineal reconstruction. (**e**) After perineal reconstruction, the introitus allows the insertion of only two fingers. (**f**) Completed repair; note the perpendicular relationship between the posterior vaginal wall and the perineum

necessary tissue particularly since the extent of the cautery is well visualized and controlled. If the cautery tip is placed on the vaginal mucosal tag and activated continuously until the tag shrivels, the underlying tissue may be damaged by the excessive heat generated at the tag site and accordingly may result in a potential area of necrosis that could impact the integrity of the vaginal walls. This in turn may predispose one to a vesicovaginal or rectovaginal fistula. If reporting new onset fluid leakage or foul odor on intercourse following vaginal resurfacing, then a detailed pelvic exam with assessment for fistulas should ensue. Furthermore, it is important to inform the patient of the significant discharge that will develop after surgery, which could last for weeks as sloughing occurs. Pain should be absent to minimal with this type of procedure and the patient should recover rapidly. If the patient develops worsening pain or if pain develops days after surgery, then the likelihood of damage to an adjacent structure is higher. The development of fever is unlikely unless an infection has occurred. The use of the cautery to create relaxing incisions when vaginal strictures exist is highly successful in resolving the constrictions as long as bleeding is controlled and vessels are avoided. Being familiar with the vascular anatomy of the vagina prior to any surgery is crucial. It is advisable to use simple interrupted sutures to control hemorrhage of actively bleeding tissues since cautery may sometimes make further suturing difficult, especially if retraction of the vessel occurs with unsuccessful cautery. The sutures applied should preferably be placed perpendicular to the band that was released so as to maintain the newly developed caliber. The use of any form of energy in the vagina increases the risk of stricture and fibrotic band formation, even if the initial surgery was for the release of strictures.

Persistent Postoperative Dyspareunia

The vaginal innervation is densest anteriorly and distally. If colporrhaphy is primarily performed for rejuvenation and not defect repair, then the risk of dyspareunia is lower; however, it is lowest when a perineoplasty is not performed. Severe superficial dyspareunia has been reported when the perineoplasty involves levator muscle plication, and it classically occurs when the introitus is tightened significantly. The pain is usually muscular related and not neurogenic in nature, but the dyspareunia can be quite significant at times, resulting in abstinence instead of enhancement of the sexual experience.

High-Tone Pelvic Floor Dysfunction

The use of Botox for alleviation of Levator ani spasm has been reported in the literature with notable results [31]. It has been described for the rejuvenation process as well; however, the associated complications, although rarely encountered, can potentially last for a few months until the medication wears off. Judicious injection could help avoid the development of retroperitoneal hematomas and internal bleeding, pelvic muscle dyssynergia, urinary and fecal incontinence and obstruction, pelvic abscess formation, permanent neural damage, leg and pelvic weakness, and new onset of referred pain. Careful assessment and application of Botox is necessary while ensuring an injection is not placed too deep.

Site-Specific Augmentation Complications

To increase sensation to both partners, injections of fat or fillers into the vagina, and even grafts, have been described. The placement of grafts is potentially associated with erosions and dyspareunia as well as bowel and bladder perforation. Despite it being typically injected into the labia majora in vaginal rejuvenation, some have used fat to create ring formations within the vagina itself with the hope of providing an enhanced sexual experience. The complication that may ensue is severe edema that could potentially impact urination as well as abscess formation and vaginal mucosal wall breakdown with ulcer formation—with the breakdown developing immediately postoperatively or potentially during intercourse. Another potentially injectable and often topical form of treatment for vaginal rejuvenation is

mesotherapy, which uses herbs and chemicals to induce lipolysis or change tissue consistency and thus theoretically enhance vaginal sensation. Since these compounds have not been tested adequately for vaginal use, they are better avoided as they may create irritative and potentially damaging effects resulting in sclerosis and significant sloughing of the epithelium causing pain and copious discharge.

Clitoroplasty

The first well-documented 'corrective' clitoral surgery, which described a clitoridectomy, dates back to 1934 [32]. Studies in the mid- to late-1960s ascertained the need and importance of the clitoris in the sexual experience, and thus clitoral 'enhancement' was suggested.

Clitoroplasty can involve the increased exposure of clitoral tissue which may augment sexual enjoyment. It may also involve the removal of tissues to assist in an enhanced visual genital appearance, especially when combined with labioplasty and possibly vaginoplasty. Furthermore, clitoroplasty may involve the repositioning and resizing of the clitoris especially in women with evidence of hypertrophy—particularly if afflicted with hyperandrogenism.

Various techniques have been described to surgically manage clitoromegaly. One technique involves resecting the excess tissue from the clitoral hood, reapproximating the edges with concurrent reduction in the clitoral size by resecting part of its corpora and then attaching it to the periosteum [33].

With the increasing desire for enhancing sexual pleasure, techniques for exposing the clitoris have been devised. Clitoral unhooding involves resection of tissue covering the clitoral tip, at times circumferentially, thus exposing it more, much like circumcision in males. A similar procedure is the reduction of the clitoral hood, which involves repositioning of the tissues overlying the clitoris with the help of sutures rather than actual tissue resection. This usually allows for increased stimulation during intercourse and accordingly heightened sexual pleasure.

Complications of Clitoroplasty

Hemorrhage and Necrosis of the Clitoris

When reducing, advancing, or repositioning the clitoris, the likelihood of severing of the vascular supply is high. Undiagnosed, this could result in withering and death of the reattached clitoral tip. Partial resection of the clitoris, which is often done in certain types of female genital mutilation (sometimes misleadingly called "circumcision"), usually have a marked negative impact on intercourse and is associated with significant blood loss at the time of the procedure. The blood supply to the labia minora as well as the clitoris arises from the posterior labial, perineal, and dorsal clitoral branches of the internal pudendal artery. The neurovascular bundle lies at the dorsal side of the clitoris, covered with fatty tissue padding and with the suspensory ligament of the clitoris lying beneath it. Ensuring appropriate dissection durign surgery is crucial to avoiding complications.

New-Onset Clitoral Pain

When reduction of the clitoris involves resection or repositioning of the clitoris, it is crucial to safeguard the neurovascular connection between the tip of the clitoris and the body [34]. The interruption of the neural pathway could render the clitoris insensitive and its contribution to the sexual experience rendered absent. Thus, nerve-sparing techniques have been devised and their use is advised.

The posterior labial and perineal branches of the pudendal nerve (S2–S4) predominantly supply sensation to the labia minora with the clitoris receiving additional autonomic innervation from the hypogastric and pelvic plexuses. Anecdotally with clitoral repositioning procedures, the entity of persistent postoperative pain generated at the periosteal clitoral insertion site as well as throughout the clitoris occurring with arousal has been reported.

Contractures Around the Clitoris

Contracture of the incision line may result in phimosis and theoretically strangulation of the clito-

ral tip especially if multiple gynecoplasty procedures are done simultaneously. Due to the edema that develops postoperatively, it is advisable to avoid using a running suture line and use widely spaced interrupted sutures instead.

In cases of clitoral reduction, development of contractures along the suture lines as well as long standing pain are risks the patient needs to know about preoperatively; these develop more often in association with infection and hematomas. In clitoral unhooding, the amount of tissue excised as well as the closure techniques are crucial. The complete exposure of the clitoris causing hypersensitivity could become bothersome due to the continuous friction with the patient's clothes. Furthermore, the appearance of the clitoris, if excessively unhooded, might be unsightly.

Conclusion

As women become more aware of the their genital appearance in comparison to what is publicized as normal or ideal, more women turn to surgical alternatives for cosmetic or perceived sexual enhancement. This is an evolving field with different techniques continuously being developed to achieve both better outcomes and reduced risks. Since gynecoplasty aims at improving the quality of life, it is crucial that the enhancements are what the patient desires and are within the limits of safe surgical practice. Patients who are considering such procedures should be fully aware of the various potential complications discussed in this chapter.

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Martius Labial Fat Pad Construction

26

Dominic Lee, Sunshine Murray, and Philippe E. Zimmern

Introduction

The Martius labial fat pad (MLFP) is a pedicle graft of fatty tissue from the labia majora, which can be used as an interposition layer during a variety of vaginal procedures. First described by Martius [1], the procedure is fairly simple and quick, allowing the surgeon to harvest a well-vascularized fat pad of variable length (typically 8–12 cm) and transfer it where needed to enhance the repair of complex or recurrent urethral or vesical pathology. However, as with any surgical technique, complications can occur including hematoma, infection, pain or numbness, sexual dysfunction, and labial distortion. We aim to describe these complications as well as provide what information is available from the literature and our own experience on how to avoid them and manage them when necessary. To this end, we will also briefly cover the indications and technique for this versatile procedure.

Indications

The MLFP is quite versatile and therefore has been used as an adjunct in many complex vaginal reconstructive surgeries to improve outcomes (Table 26.1). It can be used as an additional tissue interposition layer in closure of vesico- or urethrovaginal fistulas (VVF/UVF) and may be most important in those fistulas associated with radiation and/or recurrent fistulas that have failed to close after prior attempt at repair [2–6]. Recently, we published our long-term outcomes with a mean follow-up duration of 55 months (range 6–198) from a prospective database on a series of non-radiated VVF patients. Of the 66 women in our cohort, the majority of the patients had tissue interposition, with Martius fat graft being the most common graft utilized. We reported a 97% fistula closure rate and only one of the two patients with fistula recurrence did not have tissue interposition at the time of initial repair [7].

In regard to the repair of UVF, we do favor tissue interposition and reported a 95% anatomical success for closure of UVF due to near exclusive use of tissue interposition in our series.

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Table 26.1 Indications for Martius fat pad graft

• Fistula (vesico-vaginal/urethrovaginal/ano-rectal vaginal)
• Iatrogenic bladder injury
• Urethral diverticulectomy
• Mesh (prolapse/mid-urethral sling) erosion
• Urethrolysis
• Vaginal/neovaginal reconstruction
• Bladder neck augmentation for artificial urinary sphincter
• Bladder neck closure

We used mainly autologous fascia as it allows us not only to cover the urethrotomy closure defect but also to prevent secondary SUI associated with intrinsic sphincter defect induced by the UVF. However, in our series, three patients had both a rectus fascia and MLFP interposition with good results. In the context of UVF, a Martius graft may not necessarily be ideal given the bulkiness of the graft and the limited stretching of the vaginal flap to close over it. Nevertheless in the case where vaginal mucosa is deficient for primary closure, a Martius graft with an island of skin can be utilized to breach the defect and allow for tension-free closure [8].

The versatility of the MLFP graft is evident also in the closure of ano- and rectovaginal fistulas [9, 10] as well as in the transvaginal repair of bladder injury during vaginal hysterectomy to prevent fistula formation [11]. Martius flap can be used in transvaginal bladder neck closures as well as urethral diverticulectomy and can also be useful in transvaginal artificial urinary sphincter placement although most authors recommend a retropubic approach for placement of cuffs. Another rare indication is in the post-cystectomy patient with a peritoneo-vaginal fistula [12] or neobladder-vaginal fistula [13]. It can also be used in construction of a neovagina after pelvic exenteration or other rare cases requiring vaginal construction or reconstruction [14]. The most common indication in our practice is as an adjunct to urethrolysis to prevent re-scarring to the back of the pubic symphysis [15–17]. In recent times, the use of synthetic mesh products for prolapse and stress incontinence surgery has seen an escalation in the incidence of mesh erosion and extrusion. Often mesh excision is required and the Martius graft has been utilized with reasonable success as an interposition/buffer layer against fistula formation and/or for the closure of a large defect for healing [18, 19]. Recently, following groin exploration to excise a TOT arm in a woman with additional one-sided vaginal pain and dyspareunia, we used the MLFP as an interposition graft alongside the vaginal wall to create a buffer and decrease pain related with sexual activity on that one side.

Technique

An 8–10 cm long vertical incision is made over the labia majora from the level of the mons pubis down towards the level of the fourchette. This is a typical incision for a high vault vesico-vaginal fistula because the length of the fat pad must be sufficient to reach the vaginal apex. When the procedure is indicated for urethral or bladder neck pathology, the incision can be shorter and may start midway over the labia majora, still extending down to the level of the posterior fourchette. The side, left or right, depends on the location of the pathology being repaired, and at times should be done from the side opposite to where the fat pad will ultimately be placed because of the need for it to cross over.

The labia majora incision is deepened to the level of the labial fat pad. The fat pad can be gently grasped with a Babcock clamp and mobilized on an inferior pedicle providing a postero-inferior blood supply to the graft based on branches from the internal pudendal artery. To facilitate the dissection of the flap, the skin edges can be held retracted by the hooks of a Lonestar retractor. To avoid medial labial skin distortion or retraction after the fat pad harvest has been completed, we recommend leaving some fat medially beneath the labial skin and carrying the fat pad dissection slightly obliquely and away from the inner labial folds. Once a sufficient length has been dissected laterally and medially, the flap is gradually divided superiorly. Large veins can supply the apex of the flap coming from the mons pubis, and

they may require careful ligature to avoid retraction and a secondary labial hematoma. Next, the Martius fat pad graft dissection continues by detaching the fat pad posteriorly off the underlying ischiocavernosus and bulbocavernosus muscles, taking care once again to leave a broad base inferiorly to protect the blood supply.

Historically, the MLFP included the bulbocavernosus muscle vascularized by the labial artery, a branch of the internal pudendal artery, as well as the fat pad of the labia majora vascularized by the obturator artery and the internal and external pudendal arteries. Currently, most specialists use the labial fat pad without excising the bulbocavernosus muscle. However, in situations involving a vaginal wall defect after extensive mesh removal or large vesico-vaginal fistulae, the labial fat pad graft can be harvested with a segment of skin to close both defects.

Following complete mobilization of the fat pad, a figure of eight absorbable suture can be placed at the extremity of the flap to help with its tunneling alongside the vaginal wall later on. The fat pad graft can be harvested ahead of any upcoming steps in the repair, which can involve significant bleeding. By doing so, the fat pad is ready for use and can help decreasing the overall blood loss, thus reducing the likelihood for blood transfusion. The fat pad can be wrapped in moist gauze until its use later on. Once the fistula repair or other procedure for which the fat pad graft was selected is completed, a tunnel should be created alongside the lateral vaginal wall towards the destination of the flap. This tunnel is created with long Metzenbaum scissors and/or a ring forceps. The tunnel should be widened to accept at least two fingers in order to prevent compression of the blood supply of the fat pad, which could compromise its survival. The suture at the extremity of the fat pad can then be grasped at the end of a right angle clamp or long Kelly clamp, which can be slid through the pre-established tunnel alongside the vagina. The suture can be retrieved easily on the vaginal side and pulled out to direct the fat pad into its tunnel and ultimately into position over the intended area of coverage. The pedicle graft once passed through the tunnel can be secured in place with a few absorbable sutures over the suture line, which it is intended to protect.

Although the dissection of the tunnel can sometimes provoke bleeding, once the fat pad is in place the bleeding will typically decrease or stop. However, to avoid a secondary labial hematoma, it is recommended to place a labial drain (small Penrose or #7 Jackson-Pratt). The incision is closed in two layers, a running subcutaneous deep absorbable suture over the drain, and then interrupted absorbable sutures on the skin. In case of a secondary infection or hematoma, some of these interrupted sutures at the lower extremity of the skin incision closure can be easily removed to facilitate a drain placement. In the absence of bleeding, swelling, or infection, the labial drain can be removed within 24–48 h postoperatively. A step-by-step video demonstration of our surgical technique has recently been published to aid clinicians in understanding the key points in the operative process [19].

Complications

Hematoma or Seroma

As is the case with most surgical procedures, there is a risk of bleeding and hematoma formation. The fat pad is mobilized on an inferior pedicle based on branches of the internal pudendal vessels as discussed earlier. One of the benefits of this graft as a tissue interposition is its vascularity, but this also contributes to the risk of bleeding and hematoma formation. Thus, maintaining and ensuring achievement of hemostasis at the site of harvest as well as on the pedicle graft itself is of utmost importance in preventing hematoma formation. In addition to meticulous hemostasis at the time of surgery, the use of a drain (Penrose or Jackson-Pratt) postoperatively may also decrease the likelihood of hematoma formation. Although incidence of hematoma is not reported in the literature, Songne and coworkers [10] described a seroma formation in 3 of 14 patients (21%) undergoing repair of anovaginal or rectovaginal fistulas with Martius

interposition. A recent abstract by Hussain and coworkers reported one (2%) labial hematoma in a series of 55 women with MLFP performed for various indications [20].

In our experience, maintaining careful hemostasis at the site of harvest as well as on the pedicle graft itself is of utmost importance in preventing hematoma formation. In addition, the use of a drain (Penrose or Jackson-Pratt) postoperatively may also decrease the likelihood of hematoma or seroma formation. Typically, seromas and hematomas when they occur will resolve on their own over time without any intervention. Recently, we published our long-term outcomes (mean follow-up duration of 7 years) in 97 women who had MLFP and no hematoma or seroma was encountered in our series [21].

Infection

Although the incidence of wound infection for a Martius fat pad graft is not well studied or reported, the risk of such a complication appears to be relatively small. McNevin and coworkers [9] reported one (6%) superficial labial wound breakdown among 16 patients undergoing repair of complex rectovaginal fistulas with the use of Martius as tissue interposition whereas Songne and coworkers [10] reported no wound infections in their retrospective series of 14 patients. Just as with hematoma and seroma, the use of a drain postoperatively may decrease the risk of infection as may appropriate perioperative antibiotic usage. This has been a very rare occurrence in our practice over the past 25 years. Yeast infection can also easily develop in the groin or over the incision and should be treated by the use of antifungal ointment or oral medications. This can sometimes be prevented by the preoperative treatment of infections present prior to surgery and by keeping the groin and perineum clean and dry postoperatively. However, if either becomes infected as would be indicated by erythema surrounding and/or purulent drainage from the incision, then prompt drainage is indicated.

Pain and/or Numbness

Pain in the immediate postoperative period is expected and typically lasts a few days until the drain is removed and the swelling decreases. Ice packs are recommended initially. Loose underwear or garments allow for avoidance of direct skin contact and irritation. Likewise, a urethral Foley catheter when necessary is taped to the leg opposite the involved labia, or, when not critically needed, it is removed early on, trusting a suprapubic tube for bladder drainage. Following showering or bathing, direct contact with a towel can be avoided by using a blow dryer.

Chronic pain at the harvest site appears to be a rare complication of the procedure and might be a result of nerve injury during the harvesting. Intermittent discomfort and labial sensitivity was found in a retrospective review by Petrou and coworkers [15], in 3 of 8 women undergoing a Martius flap at the time of suprameatal urethrolysis for bladder outlet obstruction up to 1 year postoperatively. However, 5 (62%) reported self-perceived decreased sensation or numbness at the harvest site. A few other reports had similar findings, including Webster and colleagues [17], where 2/12 (17%) women undergoing Martius flap in combination with urethrolysis reported decreased sensation at the site of harvest, and Carey and colleagues [16], where 2/23 (9%) reported transient labial numbness. However, Carr and Webster reported on four women who underwent full-thickness cutaneous Martius flap for vaginal reconstruction [22], and all patients reported reduced sensation at the harvest site, suggesting that when a skin island of the labia majora is harvested with the fatty pedicle flap the incidence of decreased sensation may be increased. In our long-term outcome series, 79/97 women (81%) had normal labial sensation, with 5 (5%) reporting pain and 13 (14%) had numbness [21]. It is difficult to ascertain whether sensory changes are a direct result of the Martius harvest rather than the urethrolysis performed, as there are an abundance of sensory nerves surrounding the clitoris that may have been injured.

Sexual Dysfunction

Sexual dysfunction secondary to a Martius fat pad graft appears related to the labial pain and/or numbness, as well as sometimes to skin retraction medially. Sexual function typically resumes within 2–3 months after the original procedure once the labial and vaginal incisions are completely healed. Sexual dysfunction is uncommon even in series reporting initial pain and/or numbness. For example, Petrou and colleagues [15] noted 38% of pain at the harvest site and 62% with decreased sensation or numbness at 1 year, yet only one of eight patients (12.5%) reported sexual dysfunction due to pain. Elkins and colleagues [6] in a retrospective review of patients undergoing Martius flap along with vesico- and rectovaginal fistula repairs reported a 25% incidence of dyspareunia.

Since the Martius flap is used in complex vaginal surgery where scarring can be expected and this scarring could potentially lead to a high rate of secondary dyspareunia, it has been suggested that its use will lead to lesser scarring and therefore possibly less vaginal discomfort or dyspareunia. In fact, in one series by Rangnekar and colleagues [5], 38 patients underwent successful urinary-vaginal fistula repair (20 with Martius and 18 without). No patients undergoing repair with Martius reported dyspareunia postoperatively, whereas 6 (33%) of those repaired without Martius did. The authors proposed that the increased blood supply and lymphatic drainage afforded by the flap interposition might have lessened vaginal scarring thereby leading to the lower rates of dyspareunia. Recently, we used the validated female sexual function index (FSFI) questionnaire to objectively evaluate whether sexual dysfunction was a significant finding in MLFP patients. We categorized our patients into three groups; VVF (20), bladder outlet obstruction (60), and others (17: bladder neck closure, urethral diverticulum, excision of duplicate urethra). A third reported sexual activity in our series, most with satisfactory sexual function and minimal pain on FSFI questionnaire between all three surgical groups [21]. Given the lack of preoperative baseline data, it is difficult to ascertain whether MLFP itself can contribute to postoperative sexual dysfunction as opposed to the presenting conditions that warranted operative management. This clinical issue warrants further research.

Labial Distortion

Due to the removal of underlying fatty tissue from the labia majora on one side, labial distortion can raise cosmetic concerns. A few reports comment on the incidence of this complication, but all are retrospective reviews and the numbers reported are quite variable. McNevin and colleagues [9] reported no complaints related to cosmesis among 16 patients undergoing Martius in combination with low rectovaginal fistula repair. However, in eight women who underwent Martius in combination with suprameatal urethrolysis, Petrou and colleagues [15] reported 2 (25%) felt the harvest site appeared no different from preoperative appearance, 2 (25%) that it was almost normal, and 1 (12%) noted it was markedly different. The remaining three patients (38%) had never examined the harvest site. In our long-term series, nine women (7%) reported distortion of the labia majora. Although most were minor and non-bothersome, one case of symptomatic labial distortion was managed with fat injection with good cosmetic outcome and satisfactory return to sexual activity afterwards [21]. In an attempt to prevent or limit this secondary distortion due to labial skin healing and outward retraction at the superior medial edge of the labia majora, we have changed our practice to a more lateral incision over the bulge of the labia majora. In addition, we purposely leave fat medially over the inner portion of the labia majora. The surgical outcome of this technique is shown with intraoperative and postoperative images in Fig. 26.1a, b and the surgical video [19]. In addition, an in situ technique for Martius harvesting has been described by Rutman and colleagues [23], which avoids a labial incision entirely by dissecting a tunnel under the vaginal wall and harvesting the pedicle graft through the vaginal incision. Although potentially useful, no reports on these

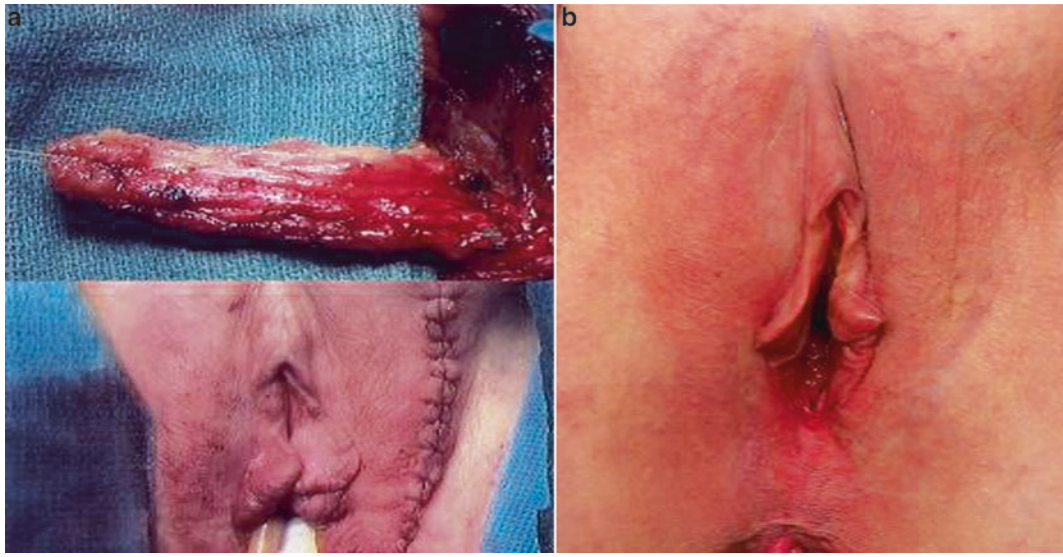

Fig. 26.1 Martius fat pad harvested through an incision on the lateral side of the labial bulge. Fat was left medially to avoid any postoperative distortion or retraction (**a**). Same patient seen 1 year later. The incision is barely visible and there is no asymmetry (**b**)

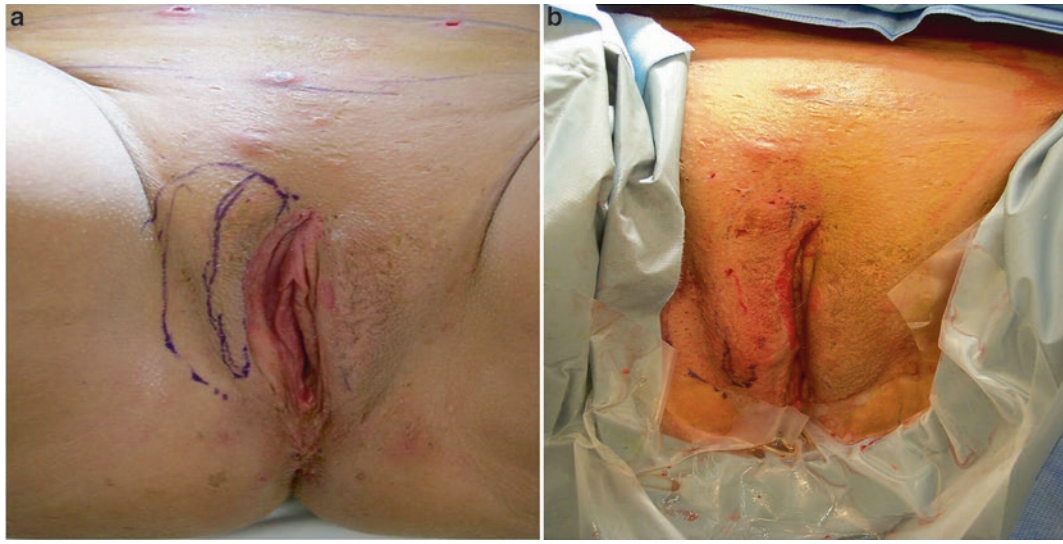

Fig. 26.2 Pre- (**a**) and postoperative (**b**) images of a patient with labial distortion after a Martius who underwent autologous fat injection into the right labia majora for cosmetic repair

technical variants regarding cosmetic outcomes can be found in the literature thus far.

In case of symptomatic labial distortion, a labial fat injection to remodel the labia can be considered. In a single patient (pre- and postoperative views seen in Fig. 26.2a, b), autologous fat was harvested and injected with good cosmetic and functional outcomes.

Conclusions

The Martius labial fat pad is a pedicle graft which can be used as an additional layer of tissue interposition when needed in complex vaginal reconstructive cases. It is relatively simple to harvest and use, but does have a few known associated complications, including hematoma or seroma formation, wound infection, pain or numbness at the site of harvest, sexual dysfunction, and labial distortion. The true incidence of these complications is not well documented, but is estimated to be low overall based on the limited evidence found in the literature, as well as our recently reported series with long-term follow-up. Solutions to avoid these complications and/or management after the fact are predominantly based on the authors' experience with very little discussion of such techniques in the literature. Overall, the Martius labial fat pad graft is a relatively safe adjunct to complex vaginal reconstruction which can improve rates of successful outcome in some difficult situations.

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27 Periurethral Bulking Agent Injection in the Treatment of Female Stress Urinary Incontinence

Deborah J. Lightner, John J. Knoedler, and Brian J. Linder

Introduction

Urinary incontinence is a highly prevalent condition, affecting up to 40 % of women in United States in some estimates [1]. Among these women, pure stress urinary incontinence is the most common form of incontinence reported, representing roughly one-third of cases [2]. In fact, it is estimated that by age 80 roughly 14 % of women will undergo a surgical procedure for correction of stress urinary incontinence [3].

When clinically evaluating stress urinary incontinence, patients have historically been categorized by the hypothesized mechanism of their leakage. That is, whether they have poor anatomic support of the urethra and bladder neck, manifesting as urethral hypermobility, or a failure of the urethra to generate adequate closure pressures, as seen in intrinsic sphincter deficiency. Previously, this delineation was used for surgical decision-making, with urethral bulking agents being reserved for cases of intrinsic sphincter deficiency [4]. However, further studies expanded the role for urethral bulking agents, demonstrating equivalent outcomes in the setting of urethral hypermobility and sphincteric deficiency, though admittedly, most contemporary clinical applications of bulking agents continues to be in cases of sphincteric deficiency [5–7].

While urethral bulking may be utilized in patients with stress incontinence of either type, secondary to low long-term efficacy they are not frequently chosen as first-line therapy. Notably, bulking agents are an option in the most recent AUA Guidelines for management of the index female patient with stress incontinence, with the caveat of lower efficacy [8]. Though not an ideal primary procedure for many patients, the overall use of urethral bulking agents is relatively common, representing roughly 16 % of all procedures performed annually for female stress urinary incontinence in the United States [9]. This is likely due to their use in the select group of patients who are willing to accept the lower efficacy of bulking agents, given the decreased potential morbidity. Additionally, bulking agents are frequently used in a few specific cohorts of patients, such as: those who have failed multiple previous anti-incontinence surgeries [10, 11], the elderly [12, 13], those who cannot discontinue their anticoagulation, those who have not completed childbirth [14], and those with an increased risk from anesthesia, as it can be performed with local anesthesia in an office setting or under limited sedation. Furthermore, given the aging US population, use of anti-incontinence procedures,

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including periurethral bulking agent injections which are at times preferentially used in the elderly and infirm, may increase in the future [3].

Additionally, more unique applications of urethral bulking agents have also been reported in some challenging clinical scenarios, including cases with altered anatomy from prior therapies. For instance, bulking agent injection has been described in women with incontinence following radical cystectomy with orthotopic neobladder formation [15, 16], after partial urethrectomy for vulvar malignancy [17], following vesicovaginal fistula repair [18], and in women that have had prior pelvic radiation [19]. Likewise, bulking agents have been used to augment continence of a catheterizable stoma [20]. It should be noted that use of bulking agents in these less common settings are not well studied, with evidence limited to case reports, and thus there may be additional risks to consider. For instance, in one series evaluating bulking agent injection after orthotopic neobladder, neobladder-vaginal fistula formation was identified in both patients treated [21]. It is also worth noting that bulking agents are used for soft tissue augmentation in other specialties, including plastic surgery, dermatology, and otolaryngology. For example, there has been interest in the use of bulking agents for managing fecal incontinence [22] and gastric reflux [23].

Available Agents

Since originally reported in 1938, with periurethral injection of sodium morrhuate, a sclerosing agent synthesized from cod liver oil [24], the agents used for urethral bulking for stress urinary incontinence have evolved. The currently available commercial agents are potentially more durable [25], generally safe [26], induce minimal local inflammatory reaction, and have a low prevalence of significant adverse events.

The discussion herein will concentrate on the currently available FDA-approved bulking agents for periurethral use: calcium hydroxylapatite (Coaptite™, Boston Scientific Corporation, Marlborough MA, USA), pyrolytic carbon-coated zirconium beads (Durasphere® EXP, Coloplast Corporation, Minneapolis, MN, USA), and vulcanized silicone microimplant (Macroplastique®, Cogentix Medical Inc., Minnetonka, MN, USA). Each material purportedly forms a scaffold which promotes secondary tissue infiltration with variable degrees of inflammatory reaction [27, 28] rather than encapsulation [29], which risks agent extrusion [30].

The discontinuation of several older injected materials, including tetrafluoroethylene, autologous fat, and ethylene vinyl alcohol copolymer resulted from concerns regarding safety, as well as limited efficacy [30–33]. As such, these agents should not be used. Additionally, off-label use of other soft tissue bulking agents will be discussed to decry the practice.

Given these caveats of experience, the evaluation of future bulking agents such as autologous muscle derived cells [34, 35], cartilage [36], polyacrylamide hydrogel [37] (Bulkamid®, currently undergoing multicenter studies and is approved in Europe, Contura International A/S, Soeborg, Denmark), and Porcine dermal implant [38] (Permacol™, Covidien plc, Dublin, Ireland) should be subject to the same high degree of scrutiny regarding unique complications related to the material as previous soft tissue bulking agents.

Of note, the complications seen in one surgical discipline generally mirror the experience of bulking agents in other subspecialties. For example, polytetrafluoroethylene has been associated with granuloma formation in multiple specialties [33, 39–41] Likewise, local migration with radiopaque carbon-coated zirconium beads has been reported in the colorectal literature [42], although without clinical consequences. Thus, when evaluating new injectable agents, complications reported in other specialties should be considered, as similar adverse events may be encountered in alternative applications.

Of note, one of the most widely studied urethral bulking agents, glutaraldehyde cross-linked collagen (Contigen, Bard™, Covington, GA, USA), was discontinued in 2011 secondary to lack of a primary supplier of the bovine product and not because of lack of efficacy or safety concerns.

Complications

Complications from periurethral bulking agent injection will be divided into groupings of local or systemic, and early or delayed in presentation. It should be noted that the currently available bulking agents have a low overall complication rate, with most complications being related to transient voiding dysfunction and with major adverse events being rare and limited to case reports.

Early Onset Local Complications

Early onset local complications following periurethral bulking agent injection are the most common adverse event encountered. In 5–10 % of patients, transient urinary retention from periurethral edema, de novo urinary urgency, urge-incontinence, dysuria, an uncomplicated urinary tract infection secondary to instrumentation, or transient hematuria from the transmucosal injection can occur. When postoperative urinary retention occurs, we prefer the use of a small (10 or 12 French) catheter for either intermittent catheterization or, if not feasible, a short period of indwelling catheterization until resolution of this infrequent complication. Anecdotally, given concern for possible deformation of the injected bulking agents causing decreased efficacy, using the smallest catheter, for the shortest duration, is likely optimal. Other manifestations of voiding dysfunction such as dysuria, hematuria and de-novo urinary urgency typically resolve with conservative management [25, 43].

In patients with either persistent urinary retention or persistent de-novo urinary urgency/urge incontinence, the less common possibility of over-bulking leading to obstruction should be considered. When encountered, this can be treated early with endoscopic unroofing/drainage or simple aspiration with most agents [44, 45]. Notably, a transurethral approach is favored due to the theoretical risk of iatrogenic urethrovaginal fistula from transvaginal excision, those this has not been reported. Notably, with aspiration or incision and drainage of the injected agent, recurrence of the patient's stress urinary incontinence may occur [44, 45].

One additional acute local complication is periurethral bleeding. While this is typically minimal and resolves with conservative therapy, more severe hematoma formation has been reported in patients on therapeutic anti-coagulation [46, 47]. Likewise, while rare in our practice, we have encountered clinically significant periurethral hematomas in the setting of bulking agent injection in two patients on therapeutic anti-coagulation (Fig. 27.1). Cases of large periurethral hematoma formation in this setting typically present with acute urinary retention from bladder neck obstruction. Management in these cases ranges from conservative therapy with bladder drainage and observation to hospital admission for transfusion with blood products [46, 47]. Notably, a case of urethrovaginal fistula formation, potentially secondary to periurethral hematoma formation, has been reported [47].

Late Onset Local Complications

Late onset local complications appear to be partially independent of the material used, in so far that such complications are rare and are, at least, theoretically possible with each of the

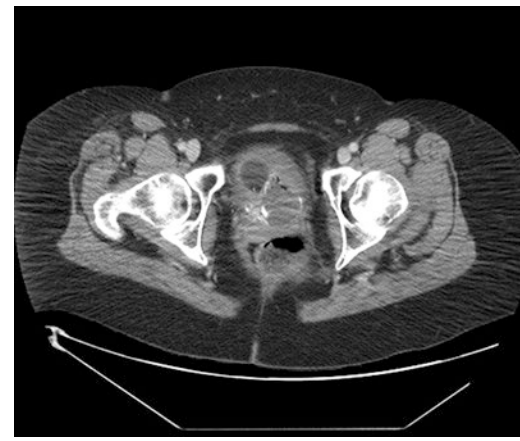

Fig. 27.1 Pelvic CT imaging demonstrates a large periurethral hematoma in a patient on warfarin presenting for pelvic pain and acute urinary retention following transurethral bulking agent injection. The hematoma is seen displacing the bladder neck and Foley catheter laterally

FDA-approved agents. This implies that some of these adverse events may be characteristic of the procedure and location, and less likely resultant of the material. Delayed local complications of periurethral bulking agents include: pseudo-abscess/sterile abscess formation, urethral diverticulum formation and misdiagnosed anterior vaginal wall masses.

Pseudo-Abscess/Sterile Abscess

A periurethral collection variously described as a pseudocyst [48], pseudo-abscess [32] or a non-communicating diverticulum [49] appears to reflect the same underlying process. Notably, the mechanism underlying pseudo-abscess formation is unknown, with hypothesized etiologies including exaggerated host response, infection, or obstruction of periurethral glands. Historically, pseudo-abscess formation was thought to be secondary to delayed hypersensitivity to the bovine dermal product (collagen) [50]; however, repeated skin tests did not show conversion. Furthermore, pseudo-abscesses have been reported with a variety of different injectable agents [44, 45, 51, 52]; thus pseudo-abscess formation may be related to periurethral application, as opposed to simply the specific material utilized. It is worth noting, that while possible with all periurethral injectables, some agents (not approved for periurethral injection) had an unacceptably high rate of local reaction. For instance, dextranomer hyaluronic acid is an agent particularly associated with granuloma [53, 54] and/or pseudo-abscess formation [55].

Clinically, pseudo-abscesses typically present with a palpable well circumscribed anterior vaginal wall mass and potentially de-novo obstructive or irritative voiding symptoms. The mass is variably tender on examination. Several authors have reported that these collections may be infected [56], although many series note sterile culture results [44, 45]. Pelvic imaging in these cases can be clinically useful in ruling out other pathologies [57].

With regard to management, aspiration alone may lead to recurrence of the pseudo-abscess, whereas transurethral unroofing of these periurethral masses is invariably associated with reoccurrence of their presenting symptom of stress urinary incontinence [44, 45]. In these cases, the periurethral pseudocyst is thick-walled, containing cystic or loculated cavities which may or may not communicate with the urethral lumen. The contained fluid is usually non-odiferous viscous appearing fluid, with negative Gram stains and cultures. With larger cavities—not easily accessible via the urethra or with associated loculations—transvaginal unroofing/excision may be needed. Notably, while concerns regarding chronic inflammation and subsequent dysplastic changes have been noted, no cases have been associated with malignant or pre-malignant changes on evaluations occurring up to 19 months postinjection [58].

Notably, if spontaneous drainage of a pseudo-abscess occurs, alternative clinical presentations may arise. For instance, pseudo-abscess formation and subsequent drainage of the submucosal space into the true urethral lumen is the presumptive mechanism for pseudo-diverticulum formation after bulking injection [49, 59]. Likewise, spontaneous pseudo-abscess drainage has been suggested as a rare cause of urethrovaginal fistula formation [60]. Similar phenomena have also been described without pseudo-abscess formation [21, 47]. In these cases, it is possible that the submucosal injection may reduce blood supply to the thin overlying mucosal, as with presumably any injection into a closed space, leading to erosion and fistula formation [21, 47].

Clinical Example: Pseudo-Abscess Formation

An otherwise healthy female with mixed urinary incontinence opted for primary management of her stress component with an injectable bulking agent; bovine glutaraldehyde-cross-linked collagen. After a negative skin test for bovine collagen allergy, a periurethral injection of a total of 5 cm^3 was performed uneventfully. Six weeks later, she complained of terminal dysuria, with her symptoms progressing to obstructive symptoms with straining to void, increasing urethral discomfort and dysuria. Her physical examination demonstrated a large tender, non-expressible periurethral fluctuance. Urinalysis and urine culture were both negative for infection. Imaging demonstrated a large fluid collection periurethrally (Fig. 27.2). Given the size and location, the pseudo-abscess

was vaginally drained through an inverted-U incision, taking care to preserve the periurethral fascia (Fig. 27.3a, b). A simple longitudinal incision was made directly into the pseudo-abscess, in order to establish complete drainage. The pseudo-abscess fluid here was typical: non-odiferous viscous toothpaste-appearing fluid compresses adjacent tissues, with negative Gram stains and cultures, even for fastidious organisms. The high pressures on the surrounding tissues are putatively the cause of the urethral pain, and reoccurrence of the pain should precipitate an evaluation for recurrence of the pseudo-abscess.

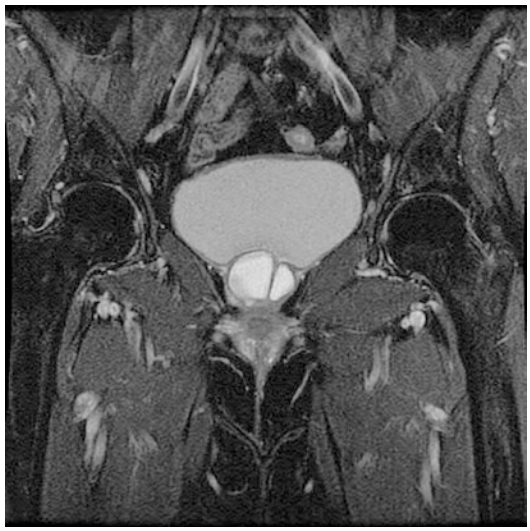

Fig. 27.2 Pelvic imaging demonstrates a large periurethral fluid collection. Collagen pseudo-abscesses can be challenging to diagnose on unenhanced CT imaging; however, the avascular fluid collection becomes readily apparent after administration of contrast agents. Also, the pseudo-abscess is typically considerably larger than the injected total bulking agent volume

Other Late Onset Local Complications

Urethral prolapse has also been reported in case reports with several agents of both current and historic interest [61–64]. The hypothesized mechanism of this complication includes distal particle migration and/or separation of the supporting periurethral tissue. Treatment is local excision in symptomatic cases. Notably, following local excision, many patients will have recurrent stress incontinence.

An additional late local complication is delayed onset urinary retention. As noted above, persistent urinary retention after urethral bulking injection may develop secondary to overbulking, necessitating aspiration or unroofing, though this is uncommon [44, 45, 65, 66]. However, in the elderly, we have encountered the late development of urinary

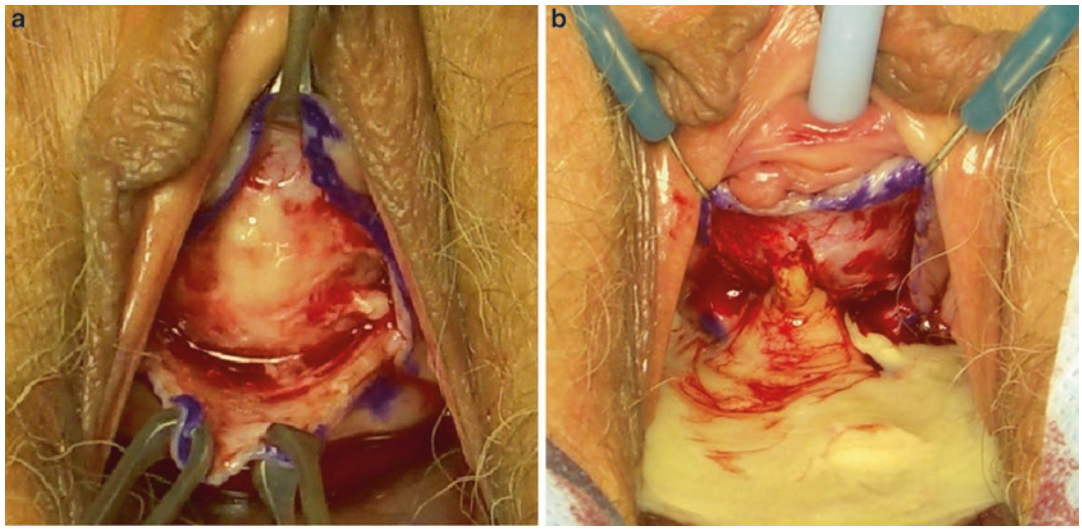

Fig. 27.3 (**a**) An inverted-U incision for transvaginal drainage of a pseudo-abscess assures a watertight secondary closure minimizing the risk of fistula formation; (**b**) the pseudo-abscess should be expressed and drained completely; loculations can occur and should be adequately drained to prevent recurrence (from Lightner DJ and Knoedler JJ "Complications of Soft Tissue Bulking Agents Used in the treatment of Urinary Leakage", in Complicaitons of Female Incontinence and Pelvic Reconstructive Surgery. Howard B Goldman, Editor. Spinger Science+Business Media, LLC, 2013.)

retention due to progressive loss of detrusor power, without intervening outlet obstruction or other complication of the outlet. These rare patients require treatment as clinically indicated for their detrusor failure and the bulking agent itself does not require other management.

One final local sequela to consider after periurethral bulking injection is that of misdiagnosis of a pelvic mass. In some cases where an accurate history is not available, asymptomatic patients may undergo additional work-up or procedures for a periurethral or bladder mass, which is in fact secondary to their prior urethral bulking procedure. Notably, in this setting, imaging can be definitive and potentially prevent additional interventions in asymptomatic cases [57].

Early Onset Systemic Complications

Early onset systemic complications, using the current FDA-approved agents, are exceedingly rare. The most commonly discussed systemic consideration is particle migration. Theoretically, any injected agent, injected at any pressure in juxtaposition to lymphatics or vessels, could be potentially migratory or embolic. Notably, use of bulking agents with a size greater than 80 μm [40] reduces, but does not eliminate this risk [67, 68]. However, there have been no reports of symptomatic emboli from the currently available agents, which is in contradistinction to older agents, such as autologous fat where a pulmonary embolus was reported [32]. However, asymptomatic particle migration, presumptively into lymphatics and submucosal tissues, was observed with a radio-opaque agent [67]. Likewise, silicone particle migration was reported in a canine model [68]. The clinical significance of these migrations are unknown.

Late Onset Systemic Complications

There are no chronic systemic complications of soft tissue bulking agents reported, in large part because of the care taken to ensure that these agents are non-immunogenic, hypoallergenic, and biocompatible [29]. Historically, delayed hypersensitivity with arthralgias secondary to periurethral collagen injection in a patient with negative skin test has been reported [69]. It has been reported that the potential for this type of hypersensitivity reaction is possible due to antibody stimulation from the collagen injection [70].

A Word of Caution

It is important to note that the complications above are related to the current FDA-approved periurethral bulking agents. It worth emphasizing that agents producing high-grade complications such as obstruction from the granulomata (as in polytetrafluoroethylene) or clinically significant embolic phenomenon (as in autologous fat) [32] should not be used. Likewise, agents with a higher prevalence of adverse reactions (as in urethral erosion or even urethrocutaneous fistula with ethylene vinyl alcohol copolymer) [30, 71], or pseudo-abscess formation (with dextranomer-hyaluronic acid) [55] should not be used, as has occurred "off-label."

Conclusions

In summary, the judicious use of the currently FDA-approved bulking agents, (Coaptite, Durasphere, and Macroplastique) in the treatment of female stress incontinence is associated with a low prevalence of local complications, the most serious of which are pseudo-abscess formation and/or outlet obstruction. The treatment of these two complications is typically associated with the reoccurrence of the urinary incontinence. The reader is cautioned that other bulking agents may not have the same clinical safety profile particularly when applied periurethrally; specifically off-label use of other soft tissue bulking agents is discouraged.

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Sacral Neuromodulation

28

Steven W. Siegel

Introduction

Sacral Neuromodulation (SNM) has become a standard of care for certain types of voiding dysfunctions and fecal incontinence. Since its initial approval by the FDA for urinary urge incontinence and frequency/urgency in 1997, there have been many refinements of the tools and techniques which have directly contributed to better surgical and functional outcomes, less patient morbidity and reoperation, and greater worldwide adoption of techniques [1]. Still, there is further need for refinement, and the therapy as it exits today can become simpler, safer, and more dependable. In this chapter, I will give my personal insight into practical solutions using current devices that can lead to prevention of immediate and long-term complications, and methods I have used successfully to evaluate and remedy problems which can potentially arise.

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Infection Prevention

The rate of device explantation for infection was 3.3% in the largest multicenter prospective trial using current devices and techniques [2]. No specific protocol for infection control was used, so the rates are likely to represent a broader "real-world" experience with most implanters. Do you know exactly what your own current infection rate is? Does your hospital? I suspect that if the "exact" standard is used, the answer is probably a "no." Yet I will bet your hospital knows its exact infection rate for orthopedic implants for the previous year. This is an issue of great importance to them due to the volume of procedures and quality measures. Why should our concern be any less, and why should our precautions be any different? Ask your institution what measures are being taken to reduce infections for total joint procedures, and consider following them to a "T" for interstim implants. Here is what we do for first or second stage and combined procedures:

At home:

Hibiclens® (Mölnlycke Health Care US, LLC, Norcross GA, USA) shower night before and morning of procedure

In Pre-op:

Wipe area of surgery with 2% Chlorhexidine gluconate cloth in pre-op (Fig. 28.1)

Cefazolin pre-op if not serious PCN allergy, Vancomycin if allergy or specific concern for MRSA

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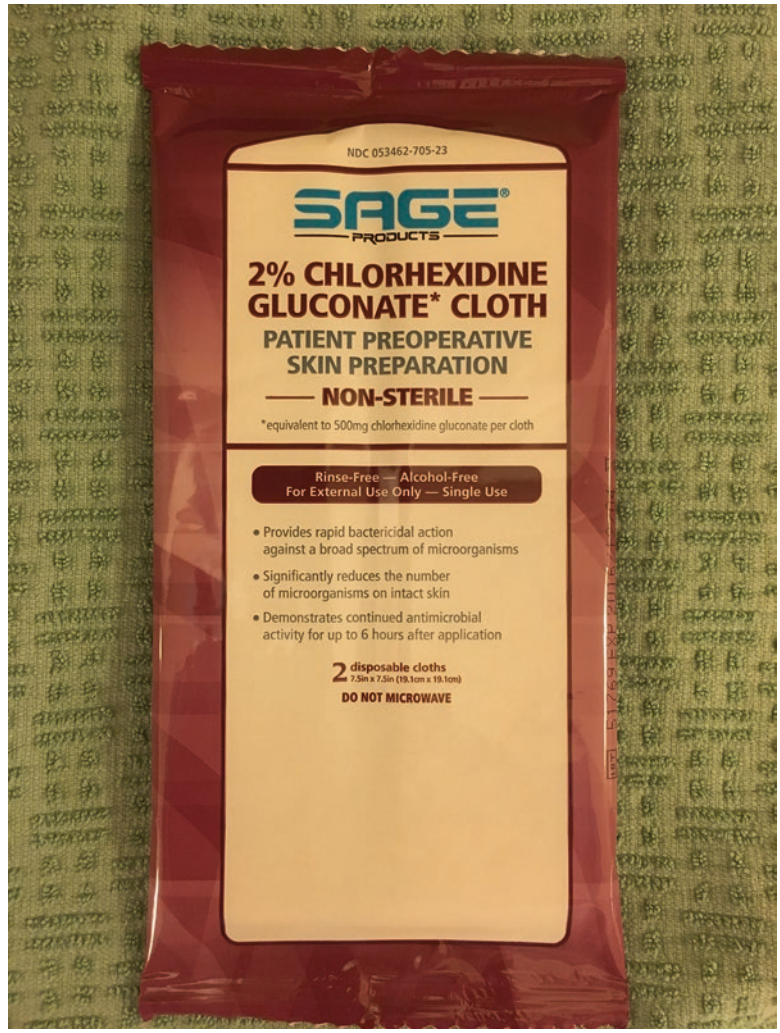

Fig. 28.1 2% Chlorhexidine gluconate cloth (Sage Products, Cary, IL, USA) for wiping area in pre-op

Intra-op:

Alcohol wipe of skin, allow to dry, 3M™ (Minneapolis, MN, USA) DuraPrep™, 3M™ (Minneapolis, MN, USA) Ioban™ dressing, antibiotic irrigation

Post-op:

Five days of oral antibiotic

There are also steps to be taken with draping which may decrease infection rate. It is not necessary to tape the buttocks apart and observe the anus for motor responses, even if that is the way you have always done it. A 3M™ Ioban™ drape covering the buttocks and pre-sacral area is adequate for visualization and may improve sterility (Fig. 28.2).

During implantable pulse generator (IPG) placement, pocket size, depth, and hemostasis are all issues that can impact infection rate and other local complications. Make sure the device is at least 2 cm beneath the skin, and creation of the pocket should use cautery and minimize blunt dissection to avoid bleeding. The pocket should be parallel to the skin and just the right size for the device to prevent flipping or undue pressure on the incision. Consider marking the pocket site with patient cooperation in pre-op for an unusual body habitus or specific patient concern such as need to wear a utility belt for work.

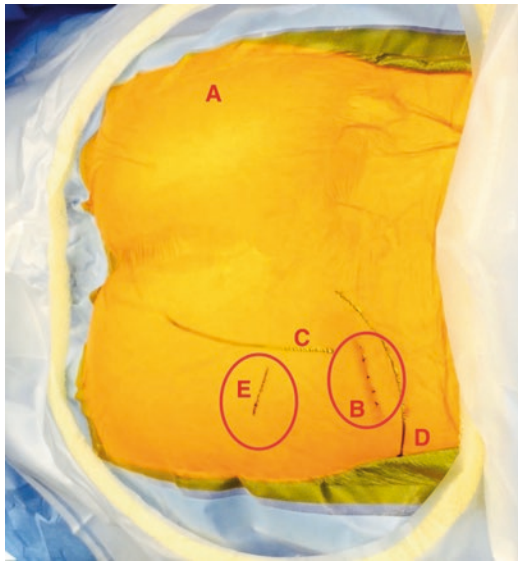

Fig. 28.2 After wiping the skin with alcohol, allowing to dry, then prepping with DuraPrep™ (3M, Minneapolis, MN, USA), an Ioban™ drape (3M, Minneapolis, MN, USA) is used to cover the skin in the operative field. Care is taken to make it smooth, and the intergluteal fold is pulled apart and then allowed to return to its natural position so that the drape will dip down and allow ready visualization of the bellows. A 3M™ (Minneapolis, MN, USA) Steri-Drape™ Cesarean-Section Sheet and Pouch with Ioban™ is an excellent alternative as it has the proper opening size and orientation and a large fluid dam to collect irrigation fluids

Infection Management

If there is any question about wound infection when converting a first stage procedure to a full implant, it is prudent to have a low threshold for removing the lead and waiting for it to heal fully before proceeding with a full implant at a later date. If there is an obvious acute infection, or persistent or recurrent draining sinus weeks or months after implant, the entire implanted system should be removed. Usually the lead extracts very easily from the pocket due to surrounding inflammation, and a separate pre-sacral incision can be avoided. I have never seen a subsequent problem arising from the lead site using this strategy, though I suppose it could happen. I have been asked many times if both components must be removed, or if a salvage procedure may be tried such as with penile prosthesis. I do not know for sure, but it seems both of these strategies are likely to fail. It is not that hard to replace a lead, and the potential benefit of leaving it in place does not seem like it would outweigh the obvious risk. It is also my practice to excise any pseudo capsule to speed up formation of granulation tissue. I do not attempt to close the wound, but allow to heal by secondary intention, and to encourage the use of a wound vacuum system whenever feasible. I generally wait for a minimum of 3 months before considering reimplant when indicated.

Lack of or Declining Efficacy

The best possible surgical technique is unlikely to make a difference in efficacy if the procedure is performed on a poor candidate. My suggestion is to stick with FDA-approved indications, and make sure diaries are used to demonstrate sufficient objective benefit in the relevant symptom categories. The change in symptoms should be obvious and dramatic, and patients should never be pushed into a full implant. Even adhering to these suggestions, there may be a hierarchy in terms of which patients are likely to do best and require the least amount of reprogramming or revisions. It appears that the therapy is most robust for the fecal incontinence indication. I base this statement on the experience of colorectal surgeons in the USA, who are, as a group, the newest to the therapy and the least experienced, yet their success rate approaches 90% [3], and also on some examples of lead placements I have seen which were adequate for FI control but not for urinary complaints (Fig. 28.3). After FI, OAB wet is the most robust indication, while OAB dry and OAB with pelvic pain are successively harder indications requiring the most precision in lead placement. NOUR is in its own separate category due to the difficulty in identifying an ideal candidate. It seems the more "motor" the problem is, the easier it is to achieve success with less rigorous technique, and the more "sensory" the disorder, the more critical lead placement

is, even perhaps to the point of needing alternate nerve targets (pudendal) and requiring electrodiagnosis (EMG) to place the lead next to the nerve. While still unproven, I think "optimal lead placement and response pattern" (Figs. 28.4 and 28.5) is necessary to achieve the best clinical result, especially in the more challenging conditions [4]. If precision is not used, it is more likely that the potential role for pudendal lead placement, bilateral stimulation, or an alternative therapy such as intravesical botulinum toxin will be falsely elevated.

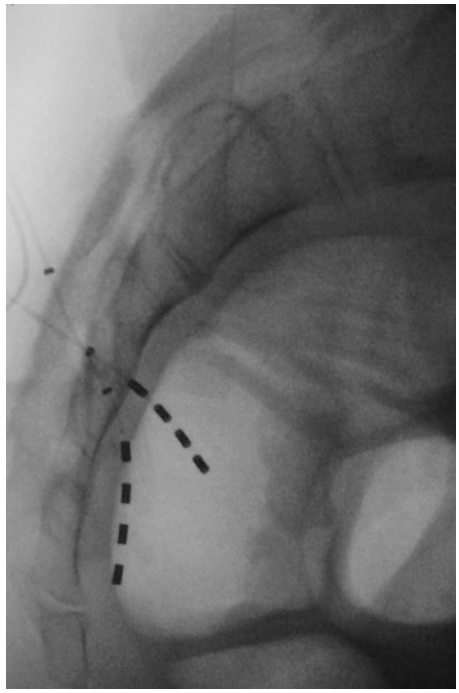

Fig. 28.3 This is a fluoro image taken of a lead placed in a patient for mixed urinary and fecal incontinence. The lead is in S4, enters very lateral to the medial foraminal edge, and has the wrong depth and orientation in the lateral view. Somehow, the FI symptoms were improved, but the UI symptoms were not. A subsequent revision to a more ideal lead position resulted in improvement of both conditions

Lead migration can also be an explanation for declining efficacy (Fig. 28.6a, b). I attempt to place a curve in the tunnel between the lead insertion site and the connection site when doing a staged procedure, in order to provide some "slack" which may prevent outward migration from pulling on the lead from pressure on the IPG or buttocks for normal movement. Inward migration is more of a problem overall, in part related to tine design, which resists only outward extraction. The most common scenarios for inward migration is in thin patients, where a "knuckle" occurs at the pre-sacral site (Fig. 28.7a–c). In addition to the presence of a knuckle being undesirable from a patient comfort standpoint, it can also lead to inward migration of the lead when the knuckle is pressed against a hard surface, such as a chair, before the lead has fully healed into place. Care must be taken to make a large enough incision to place a Sen inside the incision, and lift up on the Sen while tracking back towards the insertion site and deeply over to the IPG.

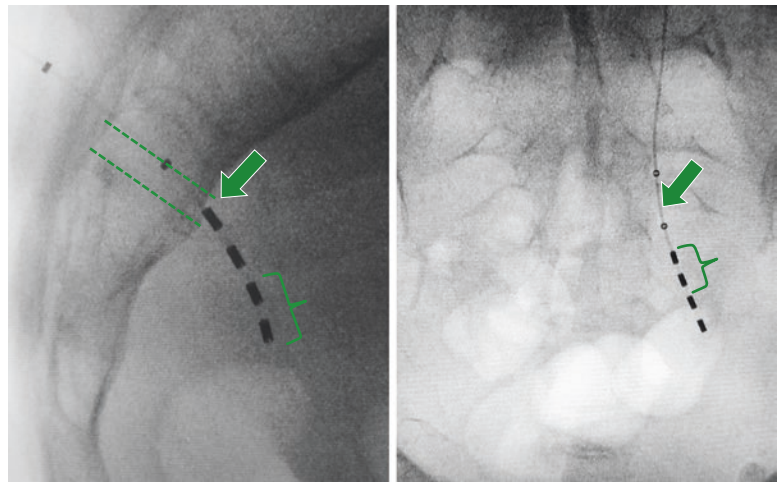

Fig. 28.4 Optimal lead placement. Lateral View: Parallels fusion plane, enters above hillock, curves down; Distal contacts appear closer than proximal. AP View: Starts next to medial edge of foramen, curves out; proximal contacts appear closer than distal

Revision for Declining Efficacy

Once reprogramming options to improve efficacy have been exhausted, it is reasonable to consider lead revision. This is particularly true in cases where a prior peripheral nerve evaluation (PNE) demonstrated better symptomatic control than the permanent implant, which implies a "flub" in placing the permanent lead. AP and lateral x-rays can be helpful in determining if there are obvious areas where lead position could be improved. Furthermore, sensory responses may also suggest a goal. If there is too much stimulation down the leg or in the foot, it implies the lead needs to be directed more caudad from the prior position, and if the stimulation is all in the rectum, it needs to be more cephalad in orientation. If thresholds are high, it suggests the lead must be too inferior or lateral when entering the foramen. In the case of a successful PNE, with obvious problems identified with permanent lead placement, it is reasonable to correct the problems during revision and to connect to the IPG in a single stage revision. If the response to the original trial is questionable in retrospect ("the doctor told me this would be good for me"), it may be appropriate to perform a staged trial with the new lead, and to connect after diaries confirm symptom control. If further improvement is not demonstrated, it may then be appropriate to remove all implanted devices. There is no sufficient evidence that bilateral stimulation holds a further advantage (Fig. 28.8a, b).

- Motor thresholds ≤ 2 on all 4 contacts
- Bellows first, then toe shortly after:
  - Too much foot correlates with leg sensation
  - Toe correlates with genital sensation
  - No toe correlates with rectal sensation
- Sensation is comfortable and in genital area: No radiation into leg or butt check.

Fig. 28.5 Optimal responses to lead placement

Pain at IPG Site

Mechanical pain at the IPG site can in part be minimized by making sure the pocket size, depth, and orientation parallel to the skin are appropriate at the time of surgery. A "flippy" device results from a too large pocket, and can lead to lead damage from repeated turning (Fig. 28.9). Also the position of the IPG incision is important. It should be below the posterior superior iliac crest and lateral to the lateral sacral edge. It should not be over either of these

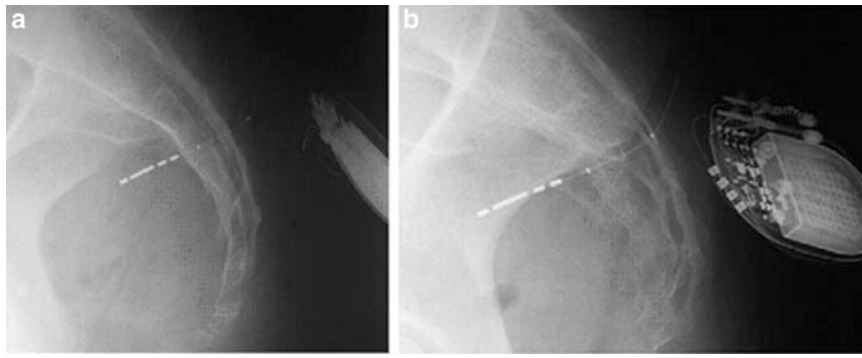

Fig. 28.6 Example of anterior migration: (**a**) Post IPG; (**b**) Anterior migration. This figure, from the literature, was used to describe the problem of anterior lead migration. Note how thin the patient is, which is the typical scenario where this complication is a concern. Also note to poor position of the lead, and the likely consequence of lead migration resulting in movement of contact 3 (the only likely electrode to be of clinical benefit) which could predictably result in decreased efficacy and inability to correct with reprogramming. (Reprinted with permission from Deng DY, Gulati M, Rutman M, Raz S, Rodriguez LV. Failure of Sacral Nerve Stimulation Due to Migration of Tined Lead. J Urol. 2006 Jun;175(6):2182–5)

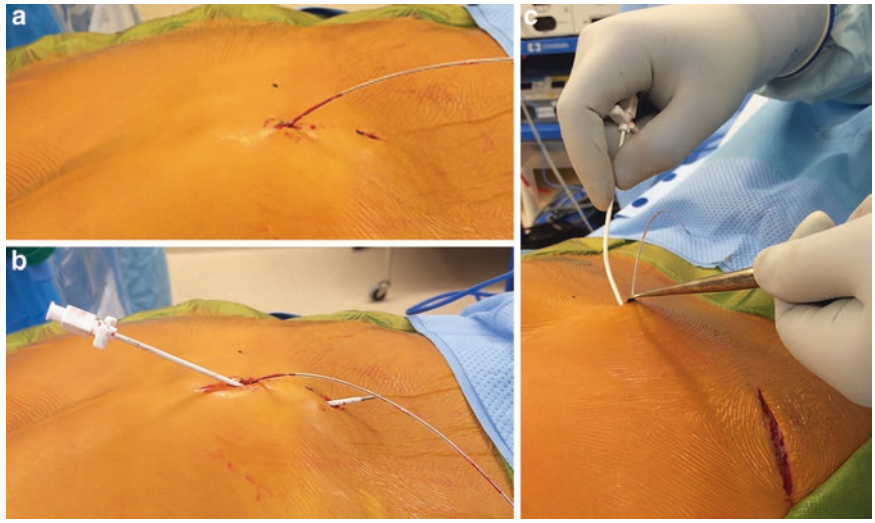

Fig. 28.7 Steps that can be taken to reduce the chance of lead knuckling in a thin patient. On the left (**a**, **b**), a "skipping incision" was made above the lead insertion site, and the lead introducer sheath was bent to allow the lead to be flattened at the facial level, and then curved over to the IPG site from the upper incision. On the right (**c**), care was taken to make a large enough pre-sacral incision to insert a Sen, which in turn is lifted upward to release the skin while the lead is tunneled deeply from the fascial site over to the IPG incision

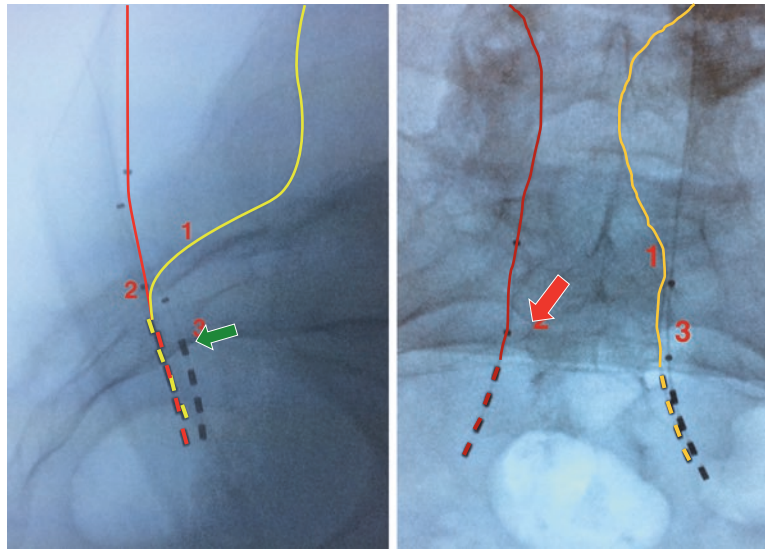

Fig. 28.8 (**a**, **b**) These are images from a patient who has been successfully treated with interstim for over 22 years. She has had three leads and four IPGs over that period of time. The original lead (*yellow*) was placed blindly under general anesthesia using a cut down to the sacrum and periosteal bone anchor. Note how the lead course hugs the posterior surface of the sacrum in the lateral view, and there are no imbedded markers. This lead worked well with an Interstim I battery and a replacement for many years. She was revised to a new lead (*red*) and Interstim II battery by another physician in her hometown. The original lead was not removed because of its deep fixation. The new system provided benefit, but did not feel as comfortable and did not control the symptoms as completely as the original lead even after multiple reprogrammings. When the third battery was depleted, her physician told her it should be replaced reusing the *red* lead, because her results were good enough, and out of concern a new lead might not be able to be placed on the original side. As can be seen, there was plenty of room for the final lead. It is in a much more ideal position than the previous ones. The patient immediately felt stimulation vaginally and comfortably (she called it "home again") and her symptoms are now controlled better than ever after over 20 years of therapy

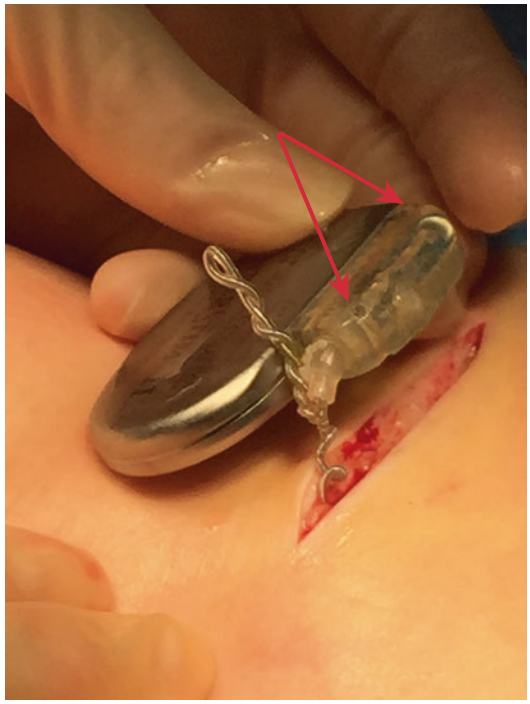

Fig. 28.9 This was the patient's second revision for the same problem. The first time she "twiddled" the device which she found to be very loose in the subcutaneous soft tissue. Her surgeon repaired by placing the IPG in the same pocket and attempted to close off the extra space using absorbable sutures without excising the pseudo capsule. When the problem recurred, the patient was accused of twiddling again, which she adamantly denied. Along with a new lead, the device was revised to a higher than usual position (above the waist line) in a new, appropriately sized pocket, and was sutured to the exposed lumbodorsal fascia with prolenes through the premade apertures (see *arrows*) on either side of the plastic header. There were no further complications or recriminations

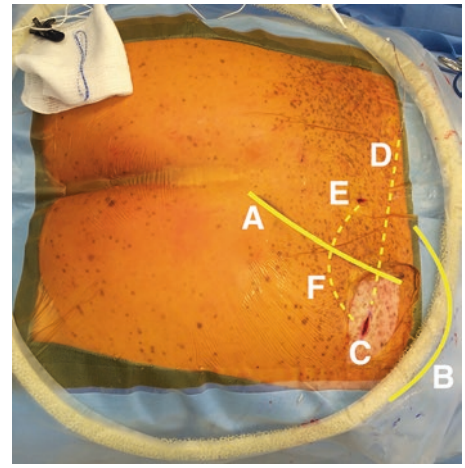

Fig. 28.10 In this setup for a staged lead implant, A represents the lateral sacral edge and B is the posterior superior iliac crest. C is the site of the future IPG incision, should the trial be successful. The lead extension D is tunneled directly in line with this incision, at a slant to avoid tracking back to the lead insertion site, and the connection hub will be positioned just under lateral edge of the future incision site. Only a small incision is needed for the connector site during this stage. Any excess lead is looped out of the way in the inferior subcutaneous tissue. Note how the tunneler goes from the pre-sacral site E to the connecting incision F with a curve, allowing some slack in the lead to prevent mechanical dislodgement. The lead extension should be placed before the bend is made

boney structures (Figs. 28.10 and 28.11). If pain depends on if the device is on or off, there can be a problem due to feedback in the IPG because the set screw is over an active electrode. Care should be taken to make sure the device is programmed in a bipolar mode if there is pain during stimulation at the IPG site. Conservative management of IPG site pain includes reprogramming, use of lidocaine patches over device, tricyclics, and rarely trigger point injection. If repositioning is required, make sure it is positioned off any boney prominence. If using the same pocket, a strategy I have employed is to use the old pseudo capsule floor as a surgical

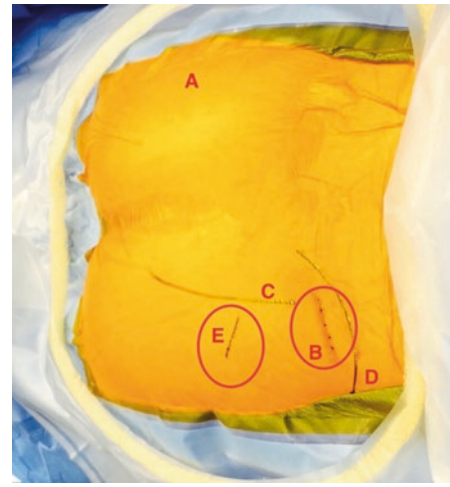

Fig. 28.11 This is the patient's second revision for the same problem. Her original IPG (superior) was too superficial and uncomfortable. Her surgeon used the same pocket and made it deeper, and used sutures to anchor the device in place. You can see that in this thin patient, the original IPG crossed both the lateral edge of the sacrum and the PSIC. It needed to be repositioned lower, deeper, and more lateral to resolve the concern

layer. I create a sub-pocket deeper in the subcutaneous tissue below it. Then I use the capsule floor as a layer for closure, taking wide bites to partially obliterate it, and then excising the remaining portion of pseudo capsule before closing the dead space in the overlying subcutaneous tissue. Attempts to close down the pseudo capsule space with sutures instead of obliterating are more likely to be unsuccessful, and may result in the device squirting back into the old space like a bar of soap. Another option is to place the device in the abdomen, using a longer extension to come over the hip, but this position was originally responsible for more pain at the IPG site, ultimately leading to the preference for placing in the upper buttocks in 1997. There are holes in the IPGs for suture placement, and they may be used to anchor the device to fascia in order to prevent flipping or twiddling. It is usually not helpful to anchor to fat. Placement of the IPG on the opposite side may also be helpful for some situations, but the lead must be disconnected and re-tunneled from the pre-sacral site in order to do so.

MRI Concerns

The current devices are MRI conditionally safe for MRI of the head, as long as interstim II devices with intact leads are in use. It is critical to turn the devices off, and to make sure a 1.5 T lateral bore magnet and a "send and receive coil" are being used to limit the field of energy. I cannot understand the reason why these rules should not apply to other geographically distinct areas such as extremities, as long as the send and receive coil is used. One of our local radiology groups has been doing them for this situation, after obtaining appropriate patient consent, for years now without incident. Patients should be warned of the concern related to MRI, and every effort should be made to find an alternative form of imaging when appropriate. Patients with retained lead fragments may not be safe for any type of MRI, since it is the lead which heats up during MRI, and the IPG acts as a heat sink to dissipate energy.

Tined Lead Retention

Although the tined lead can easily be pulled from the connector site after a failed staged trial, it may be harder to extract in this fashion if it has been in place for months or years. If the lead fractures during extraction, it may become harder or impossible to remove the remaining portions. These concerns should be discussed with the patient carefully prior to removal. The ideal method is to remove the lead by making a separate incision over the original pre-sacral point of insertion, and to dissect down along the lead until the tines may be seen. It is often helpful to reinsert a stylet, which may have been used for placement of a new lead before extraction of the old. Care should be taken if electrocautery is used to dissect along the lead since a breach in insulation can lead to stimulation of the nerve with electrocautery. Others have described use of a fascial or ureteral dilator in order to aid in dissection down the course of the lead. Once one of the tines is seen, the lead can be clamped distally and slow, steady traction on the lead in the opposite direction of original insertion should be used. Even under these circumstances, the lead may fracture. If so, it is usually in a specific fashion due to how the lead was assembled. A "ghost" lead remains (Fig. 28.12a–c) where no filament is left behind, and only the plastic housing with four contacts remains. In this circumstance, it may be difficult to remove the remaining portion of the lead without a sacral laminectomy, and the risk of nerve damage would seem to be less in leaving the lead in place. The filament is necessary in order to act as an antenna for MRI energy, so without it, it is unlikely the contacts will heat during MRI, and it is my understanding the study is safe in this situation, as opposed to one in which a length of lead a filament remains. In those cases, it is usually possible to identify the remaining lead position in the pre-sacral soft tissue using fluoro, and dissect down to it and extract.

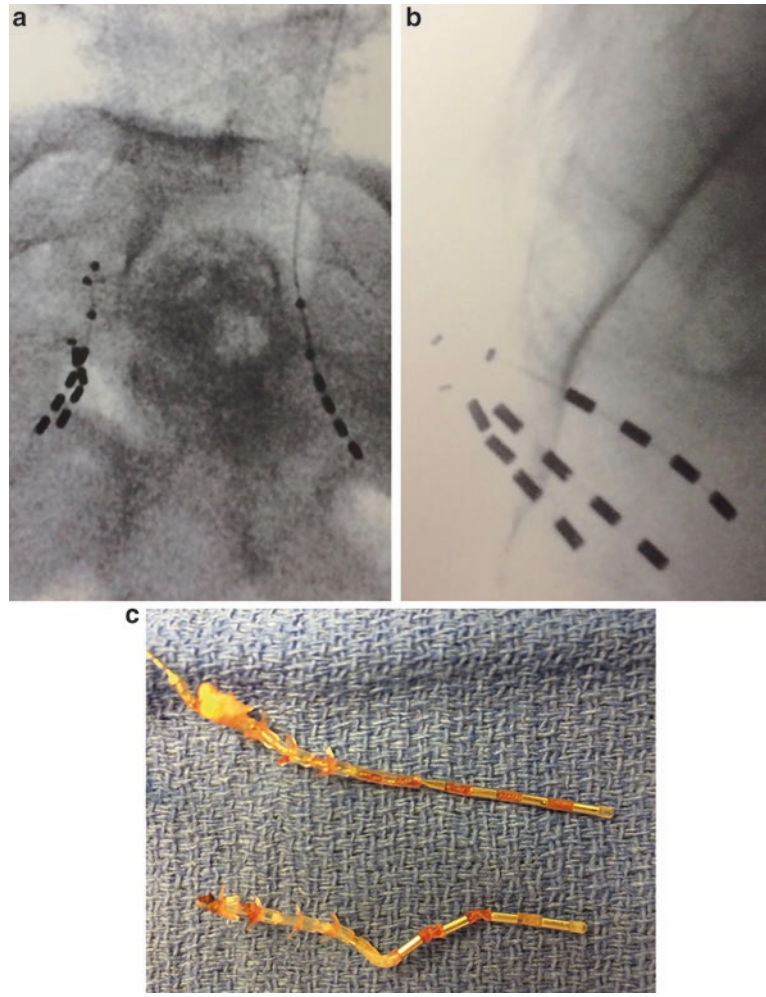

Fig. 28.12 (**a**–**c**) This patient had two prior leads which did not work well for symptom control. One of them had broken off. The new lead is on the left side and is much higher in the foramen than either of the prior right sided leads. On the lateral x-ray, note that there is a filament posterior to the sacral edge associated with the middle lead. This was extracted from above using fluoro to locate. The original fractured and crimpled lead fragment had no filament running through it ("ghost lead"). Luckily, the tip of the retained plastic case of this lead was discovered while removing its ipsilateral partner, and it was also fully extracted

Pregnancy

There is no evidence that use of SNM during pregnancy is risky, but evidence to the contrary has not been sufficiently documented [5]. Therefore, patient should be warned that the device should be turned off if possible. The first trimester is the most critical. It might make sense to consider an alternative such as intravesical Botox in a patient who is planning to become pregnant. Otherwise, the device should be turned off as soon as possible after pregnancy, and kept off for as long as possible. It is possible that increased risk may result if the device is turned off, specifically in the case of patients who have been successfully implanted for retention, and who have symptoms return without stimulation. They are at increased risk for UTI and the associated risks related to pregnancy. It is possible that the device may function differently after pregnancy, possibly due to movement of the electrode or change in the underlying status of the patient. While I do not know this to be true for certain, it is my opinion that patients with high tone pelvic floor muscle dysfunction who have had symptoms successfully controlled with interstim would be better off having pre-emptive anesthesia (spinal or epidural) and a scheduled C-section, instead of active labor.

Table 28.1 Best practices for avoiding or managing complications

Problem	Remedy
Infection prevention	Hibiclens® (Mölnlycke Health Care US, LLC, Norcross GA, USA) shower p.m. before/a.m. of surgery
	2% Chlorhexidine gluconate cloth in pre-op
	Cefazolin or Vancomycin IV if allergic
	EtOH skin wipe, Duraprep™ (3M, Minneapolis, MN, USA), Ioban™ (3M, Minneapolis, MN, USA) intra-op
Managing infection	Remove all devices, capsule, wound vac
Lack of or declining efficacy	Proper patient selection, objective documentation of symptoms, "optimal lead placement," avoid lead knuckle which can be related to antegrade migration, reprogramming, revision
Revision for declining efficacy	PNE successful but implant not ⇒ direct revision. PNE questionable ⇒ staged revision. AP and Lateral XR of original lead ⇒new lead more caudal if too much foot, cephlad if only rectal sensation
Pain at IPG site	"Right-sized" pocket, lateral to sacral edge, inferior to PSIC, at least 2 cm deep and parallel to skin surface. Bipolar programming can help with feedback in IPG
MRI concerns	Find suitable alternative. Safe for head or extremity if 1.5 T lateral bore magnet with send/receive coil. Extra concern about lead fragments. May be necessary to remove IPG and lead if no alternative
Tined lead retention	Use pre-sacral incision to remove in opposite direction of original placement. Use stylet to stiffen. "Ghost lead" fragment with filament removed may be safe
Pregnancy	Turn off before first trimester if possible. Consider bridging with BoNT before planned conception. Turn off if possible. Some risks may increase (UTI) by turning off. Consider scheduled c-section under spinal do avoid spinal cord windup

Staying Out of Trouble in the First Place

The key to success with therapy is to select appropriate patients and to use best practices in order to optimize lead position and the number of contacts that give appropriate responses at low thresholds (Table 28.1). The pattern of and timing of responses may be critical in order to predict comfortable sensation of stimulation after implant. Placement of the IPG with care can minimize local complications afterward. Care should be taken to avoid infection by using up-to-date antibiotic protocols and patient preparation. Trials should be of adequate length to allow for objective documentation of symptom control using diaries.

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Botulinum Toxin Injection

29

Melissa R. Kaufman

Introduction

Few therapies have so galvanized management of a urologic condition as that witnessed over the past decade regarding use of onabotulinumtoxinA (BoNT-A) for bladder dysfunction. The range of clinical applications in the urologic realm, coupled with relative ease of administration, has revolutionized therapeutic options for several prevalent conditions. Although injection of BoNT-A is generally considered low risk, there remain a number of critical considerations with regard to contraindications and adverse events which must be carefully weighed prior to including BoNT-A in a patient's treatment algorithm. Herein, we discuss common urologic applications and the associated potential sequela of utilization of BoNT-A in the urinary tract.

History of Botulinum Toxin

Botulinum neurotoxin (BoNT) is produced by the Gram-positive obligate anaerobe *Clostridium botulinum*, initially isolated in 1897 by van Ermengem [1]. Despite the weighty role of BoNT in the manifestations of food-borne botulism, decades of innovative research have exploited the toxin's properties revealing a multitude of clinical applications which impact a variety of debilitating conditions. In addition to the urologic indications outlined below, BoNT is routinely employed for treatment of chronic migraines, pain, head and neck dystonia, hyperhidrosis, and anal fissures in addition to the commonly recognized cosmetic applications [2].

BoNT induces flaccid muscle paralysis by inhibiting release of the neurotransmitter acetylcholine from the presynaptic nerve terminal at the neuromuscular junction. In the lower urinary tract, effects are principally mediated at the parasympathetic presynaptic nerve terminal [3]. Generally considered the most potent neurotoxin recognized, and classified by the Centers for Disease Control and Prevention as a Category A bioweapons threat, it has been postulated that a mere 1 g of appropriately dispersed purified BoNT could be lethal to a million people [4, 5].

C. botulinum produces seven antigenically distinct serotypes of BoNT, each with multiple subtypes; however, only types A and B are currently employed clinically [6]. Expansive discussion of the molecular mechanism of action and pharmacology of BoNT is outside the scope of this review and extensively detailed in other publications [7]. However, several salient aspects are critical to understand applications, limitations, and complications for urologic utilization. The

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most commonly utilized serotype, type A, is a 150 kDa polypeptide with several domains imparting distinct function. As mentioned above, end-organ lower urinary tract manifestations are mediated by BoNT-A at the parasympathetic presynaptic nerve terminal. BoNT-A directly cleaves synaptosomal-associated protein (SNAP-25), required for fusion of synaptic vesicles at the cellular membrane, thus specifically preventing release of neurotransmitters into the synaptic cleft [8]. However, despite our classic concepts of BoNTs impact on the neuromuscular junction, emerging robust data implicate a diversity of alternative mechanisms of action to account for the clinical effects demonstrated in the lower urinary tract [9]. BoNT-A inhibits release of an assortment of neurotransmitters (acetylcholine, ATP, substance P), in addition to downregulating purinergic and capsaicin receptors on afferent neurons with potential culmination in a central desensitization [10]. Indeed, many of the alternative targets of BoNT-A have been previously implicated to contribute to the pathophysiology of detrusor overactivity and the overactive bladder (OAB) symptom complex. BoNT-A binds with high affinity to synaptic vesicle protein 2 (SV2), expressed predominantly in the parasympathetic fibers of the human bladder and additionally present in approximately half of the sensory fibers [11]. Clinical effect of BoNT-A likely integrates both efferent, parasympathetic pathways and afferent, nociceptive pathways. Also critical for understanding clinical utility, and potential complications, is that BoNT produces a reversible chemical denervation with recovery due to axonal sprouting and formation of novel synaptic connections [12]. Clinical results are not typically completely manifested for several weeks following injection and duration of response is variable depending on indication, dosage, and patient symptomatology.

Clinical Applications in Urology

Use of BoNT in lower urinary tract disorders was pioneered by Dykstra and colleagues in 1988 for treatment of detrusor-external sphincter dyssynergia (DSD) [13]. Currently, BoNT-A is utilized predominantly for the Federal Drug Administration (FDA)-approved indications of neurogenic detrusor overactivity (NDO) and refractory overactive bladder (OAB) [14, 15]. Additional applications have been extensively investigated for benign prostatic hyperplasia (BPH), interstitial cystitis/bladder pain syndrome (IC/BPS), radiation cystitis, urethral stricture disease, detrusor underactivity, and myofascial pelvic pain with variable clinical results. Full synopsis of the current data regarding each of the urologic applications is outside the scope of this chapter and expertly detailed in several meta-analyses and reviews [16–18]. Potential complications associated with the commonly employed on-label usage are generally applicable to investigational applications. For the purposes of this discussion, adverse event (AE) is defined by the FDA as an "untoward medical occurrence associated with the use of a drug in human, whether or not considered drug related" [19].

Hypersensitivities and Absolute Contraindications

Remarkably, there are few definitive contraindications to administration of BoNT-A for lower urinary tract applications. Several relative contraindications should be carefully weighed but remain at the clinician's discretion. The primary absolute contraindication to BoNT-A administration is a known hypersensitivity to the toxin. Immediate hypersensitivity reactions have been reported including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea. A solitary fatal case of anaphylaxis was reported with lidocaine as the diluent, and thus the causal agent for the reaction remains unidentified [20]. Systematic review of efficacy and safety for NDO revealed no reported anaphylactic reactions for detrusor injection in the neurogenic population in the published literature [21].

For bladder indications, a more consequential absolute contraindication includes the presence of active urinary infection at the time of injection. Clinical trials for both NDO and OAB indications excluded patients reporting more than two

urinary tract infections (UTI) in the past 6 months or those taking chronic antibiotics for UTI treatment [14, 15]. Careful vigilance in assessing active infection must be undertaken by the treating physician as, particularly for the neurogenic population, atypical UTI symptoms may manifest. As will be discussed in a following section, UTI was the primary AE documented in multiple clinical trials. Therefore, embarking on detrusor injection in the setting of active infection significantly increases the global risk to the patient for adverse outcomes, including potential progression to urosepsis.

Special Populations

Although not an absolute contraindication, exceptional caution must be employed for patients with diagnoses of preexisting peripheral motor neuron diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders such as myasthenia gravis or Lambert–Eaton syndrome. Such patients may demonstrate increased risk of generalized effects following BoNT injection such as weakness, diplopia, ptosis, dysphonia, dysarthria, dysphagia, and respiratory compromise. Careful deliberation in collaboration with the treating neurologist should be undertaken prior to embarking on detrusor injections for this patient population as the risks often outweigh the potential benefits. Likewise, in spinal cord injury and MS patients with restrictive lung disease treated for NDO, at least 15% reduction in Forced Vital Capacity (FVC) was noted in BoNT-A treatment arms compared to placebo [20]. Therefore, exceptional caution and monitoring is mandated in patients with concomitant pulmonary pathology and neurologic disease in the periprocedural period.

Spinal cord injury patients additionally display elevated risk for autonomic dysreflexia (AD) with intradetrusor injection of BoNT-A as compared to placebo (1.5% versus 0.4%) [14]. This data suggest it may be prudent to forgo clinic injection and consider monitored anesthesia care for patients with known or potential issues with AD desiring BoNT-A injection.

BoNT-A is considered by the FDA as Pregnancy Category C, indicating there are no adequate and well-controlled studies conducted in pregnant women to determine safety [20]. In animal models, intramuscular injection resulted in reductions in fetal body weight and skeletal ossification. During the critical phases of organogenesis in rats and rabbits at doses which extrapolate to the maximum recommended human dose of 400 Units, daily injections revealed significant maternal toxicity, abortions, early deliveries, and even maternal death was observed. However, a single dose at three different periods resulted in no AEs on fetal development. Overall, it is recommended to only employ BoNT-A during pregnancy if the benefit significantly outweighs the risk. Likewise, it remains unknown if BoNT-A is secreted in breast milk, so caution should be exercised when administering to nursing mothers.

Note that the FDA-approved indications include only dosage regimens and applications for adults >18 years of age. Utilization of BoNT-A for bladder applications in the pediatric population, although widely investigated for decades and generally reported safe and effective, remains off-label.

For geriatric patients undergoing 100 Unit BoNT-A injections for OAB indications, AEs such as UTI and urinary retention were demonstrated to be markedly more common in patients 75 years or age or older compared to younger patients. Rates of UTI for patients ≥75 years receiving BoNT-A was 38% (placebo 19%) compared to 30% for patients 65–74 years old and 21% for patients ≤65 years of age [15]. In general, caution is recommended for dose selection in the geriatric population with preferential initiation at low dose ranges to accommodate for the amplified frequency of decreased hepatic, renal, or cardiac function in addition to concomitant diseases and pharmaceuticals.

Potential Drug Interactions

Significant possible drug interactions critical to consider include avoidance of co-administration of BoNT-A with aminoglycosides or curare-like

compounds which may interfere with neuromuscular transmission and potentiate toxin effects [22]. Therefore, broadly employed periprocedural urologic antimicrobial medications such as gentamicin must be carefully eliminated from the treatment pathway for patients surrounding BoNT-A injections. For patients treated for NDO or OAB, concurrent usage of anticholinergics may potentiate systemic antimuscarinic effects and risk of urinary retention. Additionally, patients concurrently utilizing muscle relaxants may experience exaggeration of weakness following administration of BoNT-A.

Toxin Preparation Equivalence

Commercially available BoNT-A preparations in the United States include Botox® (onabotulinumtoxinA, Allergan Pharmaceuticals, Dublin, Ireland), Dysport® (abobotulinumtoxinA, Ipson Biopharm, Basking Ridge, NJ, USA), and Xeomin® (incobotulinumtoxinA, Merz Pharmaceuticals, Frankfurt, Germany). A single type B BoNT preparation is additionally available, Myobloc® (rimabotulinumtoxinB, Solstice Neurosciences, Inc., Louisville, KY, USA). Presently, only onabotulinumtoxin A possesses FDA approval for urinary tract indications. With substantial differences in dosing, efficacy, and safety profiles, these BoNT preparations should not be considered interchangeable. Indeed, significant inconsistencies were revealed between studies determining dose equivalency and therefore no standardized data exist to provide robust clinical guidance for interchange of toxin preparations for intradetrusor applications [23].

Injection Technique and Local Complications

BoNT-A is administered via intradetrusor injection under local, regional, or general anesthesia using a rigid or flexible cystoscope, frequently in a clinic setting. While no protocol regarding the location and number of injections is universally accepted, general best practices for injection have been previously described [24]. Prior to injection, 30 mL of 2% lidocaine are instilled into the bladder and allowed to dwell for 30–60 min to provide local anesthesia. For FDA-approved indications, 100 Units of BoNT-A is diluted in 10 mL preservative-free saline (OAB) or 200 Units is diluted in 30 mL preservative-free saline (NDO) and commonly injected in a grid pattern on the posterior bladder wall in 0.5 mL increments for OAB and 1 mL increments for NDO separated by a distance of 1–1.5 cm. Dilution modification is commonly employed in clinical practice to provide 10 Units per mL allowing reproducible 1 mL injection volumes for both indications. Injection depth is optimized at 2 mm which, in most instances, allows spread of BoNT-A deep to the mucosal layers and directly into the detrusor. Injections to the bladder dome are generally avoided to prevent perforation and extravesical injection. The trigone has additionally been circumvented as an injection site due to a theoretical risk of vesicoureteral reflux, detailed in a following section.

Transient adverse events associated with the act of injection, rather than BoNT-A itself, include dysuria, pain, hematuria, bacteriuria, and elevation of post-void residual (PVR). Of note, most mild AEs occurred within the first week following injection. Occasionally, needle or anxiety-related events, such as vasovagal responses, may occur at the time of injection and should be treated per the clinician's standard of care. Additional AEs reported at low frequencies included nausea, depression, muscle spasm, constipation, de novo incontinence, generalized or localized muscle weakness, insomnia, dizziness, diarrhea, influenza, hypertension, headache, back pain, mycotic infection, multiple sclerosis (MS) relapse, pain, fever, and de novo autonomic dysreflexia.

Systemic Complications

As mentioned previously, BoNT is often considered the most potent biological toxin recognized, thus potential AEs from administration are theoretically profound [25]. Although generally

considered a focal therapy on local peripheral nerves, a black box warning accompanies the prescribing information for BoNT-A highlighting the prospect for systemic spread. Doses of BoNT-A are represented by mouse units (U), with one unit of toxin representing the dose necessary for mortality following intraperitoneal injection in 50% of a group of female mice. In humans, an extrapolated lethal dose of BoNT-A would range from 2000 to 3000 Units [26]. Although incidence of such systemic events remains exceedingly rare, the clinician must employ a high index of suspicion for such sequela [27]. New onset symptoms such as focal or generalized muscle weakness, hoarseness or dysphonia, dysarthria, de novo or worsening urinary incontinence, difficulty with breathing or swallowing, and impaired vision are potential indications of regional or systemic toxin spread [28–30]. Reports of progression to respiratory depression and death have thus far been limited to children receiving elevated doses for skeletal muscle spasticity [31]. Meta-analysis of long-term efficacy and safety of 2309 patients encompassing 36 studies reported overall risk of mild or moderate AEs in patients receiving BoNT-A to be 25% compared to 15% in controls [31]. The only AE occurring more significantly in the BoNT-A group was focal weakness, again highlighting the potential for infrequent, yet significant, AEs. Similar literature reviews for both OAB and NDO demonstrated the exceptional rarity of systemic events [21, 32, 33].

Urinary Tract Infection and Urinary Retention

The most prevalent AEs noted with BoNT-A injections for both OAB and NDO include urinary tract infection and urinary retention, complications which are frequently interrelated. Confounding analysis of these common sequela of BoNT-A injection are inconsistent application of definitions for urinary infection, retention, and thresholds for initiation of catheterization. Additionally, the duration and frequency of intermittent catheterization is not standardized or well documented in the available literature.

Meta-analysis of four randomized controlled trials (RCTs) for OAB encompassing 1263 patients reported rates of UTI in the BoNT-A treatment arm as 19.7% compared to 6% of controls [33]. Initial data for OAB indications demonstrated 18% rates of UTI with 100 Unit injection [15]. For patients with diabetes, UTI rates were substantially elevated to 31% in the BoNT-A arm compared to 12% with placebo. When defined as symptomatic retention with PVR between 200 and 350 mL or PVR ≥350 mL, urinary retention in the BoNT-A group was reported at 6%. However, with more stringent criteria encompassing practical clinical scenarios, a well-designed trial utilized limits of 200 mL to define retention and 43% of patients met criteria, with 75% of BoNT-A treatment arm patients requiring antibiotic therapy for UTI [34]. Retrospective analysis of a single institution clinical practice revealed rates of urinary retention, defined as the need for catheterization, of 35% [35]. The comorbidity of infection and retention was demonstrated in the pivotal RCT with UTI documented in patients experiencing PVR ≥200 mL at 44% compared to 23% in those with PVR ≤200 mL [15]. Meta-analysis of available RCTs reporting PVR demonstrate injection of BoNT-A significantly increased PVR versus placebo (32.8% versus 2.0%), with initiation of intermittent catheterization of 8.4% in the treatment arms [33].

For NDO patients with either spinal cord injury (SCI) or MS, UTI was dramatically increased in the 200 Unit BoNT-A arm at 49% compared to 18% of controls [14]. Of patients who were spontaneously voiding prior to injection, 47% were initiated on catheterization during the course of the analysis for all causes compared to 22% of placebo patients. No defined PVR for initiation of intermittent catheterization was employed in the protocol. MS patients demonstrated significant dose-dependent increases in PVR with retention rates at 200 Units BoNT-A of 29% compared to 5% of placebo controls, with concomitant large discrepancies in UTI reported at 50% in the treatment arm versus 28% of controls.

Overall, urinary retention remains a dominant driving force for patient selection for BoNT-A injection and a major clinical concern following

the procedure. Appropriate counseling regarding a realistic risk for retention and requirement for duration of intermittent catheterization is mandated for the physician performing BoNT-A injection for patients currently spontaneously voiding. Assessment of the patient's, or caregiver's, willingness and the ability to perform intermittent catheterization is imperative prior to performing BoNT-A injection.

Likewise, insuring the absence of active infection at the time of injection and closely monitoring for signs of infection following the BoNT-A procedure are critical. Many clinicians advocate preprocedural urine culture accompanied by pretreatment with culture-specific antibiotics for high-risk patients, such as those with chronic bacteriuria secondary to intermittent catheterization.

Hematuria

While primarily related to the act of detrusor injection, transient hematuria is common following BoNT-A injection. However, complications resultant from persistent bleeding may be significant. Primarily, it is imperative to insure patients are appropriately discontinued from anticoagulant therapy prior to injection. Clinical judgment with regard to the risk/benefit ratio of the timing of reinitiating anticoagulant therapy following injection should be an individualized decision for each patient. A number of patients with neurogenic bladder may display significant fibrosis and even friable bladder mucosa. If greater than anticipated bleeding is encountered during the procedure, consideration for placement of an indwelling catheter for several days which would allow bladder irrigation may be prudent. Indwelling catheter placement may be particularly beneficial for patients reliant on self-catheterization to reduce the risk of further mucosal trauma and clot retention which are complex situations to manage with smaller caliber single-use catheters. Exceedingly infrequently is there need to employ electrocautery for fulguration of active bleeding following BoNT-A injection.

Vesicoureteral Reflux

With collective evidence of BoNT-A's influence on sensory pathways, there has manifested a concomitant increased focus on trigonal and suburothelial injections. The trigone of the bladder is particularly rich in sensory receptors which may enhance response to BoNT-A for a variety of indications. Injections to the trigone have traditionally been avoided out of concern for potential provocation of vesicoureteral reflux (VUR). Despite this apprehension, several studies have demonstrated trigonal injections to be safe and effective without evidence of resultant VUR [36, 37]. Indeed, recent meta-analysis comparing trigonal and extratrigonal injection technique in patients with NDO and OAB revealed no significant differences with regard to adverse effects or short-term efficacy, suggesting that patient-specific factors and dosing dominate response to BoNT-A rather than injection location [38].

Administration for Multiple Indications

Significant numbers of patients receive BoNT for multiple indications, most frequently in neurogenic patients for extremity spasticity in addition to detrusor overactivity. The maximum cumulative dose for treatment of adult patients is currently recommended to not exceed 400 Units in a 3-month interval [20]. These dosage limits were increased from 360 to 400 Units in January 2016. Such dosage restrictions are promoted due to risk of seroconversion owing to BoNT-A antibody formation, rather than to address systemic toxicity, discussed at length in the following section. A retrospective cohort study of patients undergoing high dosage injections of BoNT-A for multiple indications demonstrated only transient adverse events, even with a median dose administration of 800 Units within the 3-month window [27]. As indications for BoNT-A injection are expanded, careful documentation regarding dosage utilization is critical and may often dictate a multidisciplinary coordination of effort to accomplish the patient's goals for therapy.

Refractory Patients

Defining the cohort of patients who are initial or eventual nonresponders for treatment is a multifaceted process as the majority of studies only include patients who by definition demonstrated a primary response to treatment [39]. For patients treated with repeat or high-dose injections, concerns exist regarding the immunogenicity of BoNT-A and eventual decrease in clinical response due to seroconversion and antibody formation. Early data with patients administered long-term therapy with BoNT-A identified nonresponders who subsequently underwent antibody testing with a mouse protection assay (MPA) [40]. In this group, only 18% of patients tested positive for antibody formation. Notably, many of these patients began therapy as early as 1985 when the formulation for BoNT-A was composed with a higher protein content. Following a decrease in the protein content in 1997 from 25 to 5 ng/100 Units, the rate of antibody formation was reduced from 9.5 to 0% [41]. In a meta-analysis designed to assess for the presence of neutralizing antibodies with the MPA, the highest rate demonstrated was 1.3% in patients treated for cervical dystonia [42]. Multiple modalities for antibody testing are available; however, these are not widely employed due to cost and logistical constraints. Recent analysis of long-term data for an extension trial of NDO patients included 240 patients followed for at least 4 years [43]. Rates of seroconversion as assessed by the MPA in the group receiving either 200 Units or 300 Units of BoNT-A was 2.1%, with the rate of those injected solely with 200 Units at only 1.5%. More critically, it remains unclear from several investigations if clinical response is consistently compromised in patients who develop neutralizing antibodies against BoNT-A for bladder applications [44].

Histologic Changes

Concern exists for potentiation of detrusor fibrosis following multiple applications of BoNT-A injection. Examination of the histological and ultrastructural impact of BoNT revealed minimal effect with regard to neuronal architecture and in fact demonstrated reduction in bladder wall fibrosis compared to untreated controls [45, 46]. Further analyses have confirmed that BoNT-A injections do not induce substantial inflammation, fibrosis, or dysplasia in the urothelium or suburothelium in patients treated for either NDO or OAB [47].

Conclusion

Overall, for FDA-approved bladder indications, BoNT-A is generally safe and well tolerated with transient and self-limiting side effects. The substantial incidence of urinary retention and UTI mandate vigilance for identification of these complications and promotion of appropriate counseling such that patient outcomes closely match expectations. Potential concern for dosage limitations with BoNT-A treatment will amplify in the future as patients meet criteria for multiple indications due to continuously expanding applications. Clinicians should remain vigilant to reduce both expected sequela of BoNT-A injections and potential systemic manifestations, despite the rarity of such severe events.

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