ARTIFICIAL LIMBS

Artificial limbs are man-made devices intended to replace amputated or congenitally deformed feet, legs, hands, or arms. The main purpose of an artificial limb is to replace function, to mechanically replace the part of the extremity that no longer exists. Another goal is to provide a cosmetic appearance similar to a normal limb.

The earliest surviving lower limb prosthesis is dated at approximately 300 B.C. Used in the Samnite Wars in Capri, Italy, the prosthesis was made of bronze and wood and was shaped to resemble the thigh, knee, and calf. It functioned to replace the missing extremity on an active lower limb amputee. However, a written report of the use of an artificial limb was documented over 100 years earlier (1). Hegistratus of Elis, a seer who was condemned to death in 424 B.C. by the

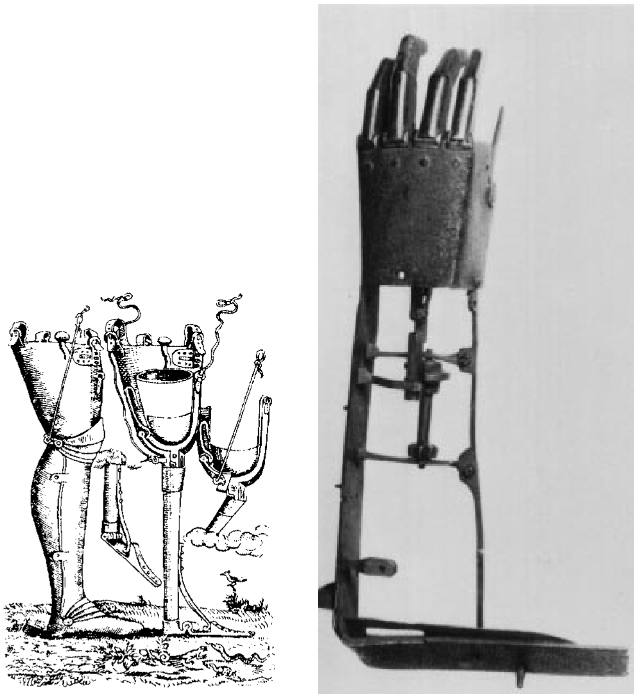

Figure 1. (left) A transfemoral prosthesis invented by Ambroise Pare in the mid-1500s. (From A. Pare: *Oeuvres Completes,* Paris, 1840. From the copy in the National Library of Medicine. From G. T. Sanders, B. J. May, R. Hurd, and J. Milani, *Lower Limb Amputations: A Guide to Rehabilitation,* Philadelphia: F.A. David Company, 1986, with permission.) (right) An iron artificial left hand and arm from approximately 1602. (From M. Vitali, K. P. Robinson, B. G. Andrews, E. E. Harris, and R. G. Redhead, *Amputations and Prostheses,* 2nd ed., London: Bailliere Tindall, 1986, with permission.)

Spartans and tethered by his leg while awaiting execution, amputated his foot to escape. He traveled 30 miles to Tregea. However, in Zaccynthius, he was again captured by the Spartans who this time successfully executed him. Their records indicate that he wore a wooden foot at the time of his death.

Early lower limb prostheses, though bulky and inefficient by today's standards, bear some design features similar to modern-day artificial limbs [Fig. 1(left)]. One of the first reported above-knee prostheses was described by Ambrose Pare in 1564. It utilized fixed equinus (fixed plantarflexion) and a controlled knee lock, features still found in some modern prosthetic designs. In 1696 Verdiun produced a below-knee prosthesis with a leather socket and thigh corset with articulated side steels to hold the prosthesis on and stabilize it with the residual limb, a design similar to that used in the twentieth century. The "Bly" leg, patented in 1858, included a functional ankle. It allowed plantar and dorsiflexion and also lateral motion. In 1860 Marks substituted a hard rubber foot for a wooden foot, creating a more dynamically active prosthetic foot, a concept introduced into a number of commercial products in the latter half of the twentieth century. During the Civil War, Hanger, an amputee in the Confederate army, produced the first articulated prosthetic feet by placing rubber bumpers within solid feet designs.

In the twentieth century, war pushed prosthetic advances further. As a result of a need for fitting World War II veterans, the Veterans' Administration supported development of two new socket designs: the patellar-tendon-bearing socket for below-knee amputees, which was designed to apply much of the weight-bearing load on the durable patellar tendon immediately below the knee cap; and the quadrilateral socket for above-knee amputees, which transferred the majority of the weight-bearing load directly to the ischium and ensured that the position of the prosthetic brim was maintained with respect to the ischium. Advances continued in the 1960s with more frequent use of endoskeletal prostheses, which have a central post through which the force is transferred, as opposed to exoskeletal units, which are hollow with an external frame. Endoskeletal prostheses have the advantages of modularity and weight reduction.

The history of upper limb prosthesis [Fig. 1(right)] also dates back more than 2000 years. The first report of an artificial hand is from the Second Punic War (218 to 202 B.C.), where Marius Sergius, a soldier, lost his right hand during battle and was subsequently fitted with an iron hand (2). The Alt–Ruppin hand discovered in 1800 dates to approximately 1400 and was made of iron with a rigid thumb fixed in opposition. Flexible fingers operating in pairs could be flexed passively and locked into position with a ratchet. Similar to this design was one of the best known artificial hands, that of a German knight, Gotz von Berlichingen who lost his hand at the siege of Landshut in 1509, as described in a poem by Goethe. The fingers could be flexed passively and locked into position with a ratchet.

Prehension, harnessing of the shoulder girdle muscles to allow shoulder motion to control function of the terminal device, was an enhancement introduced to upper limb prostheses in the nineteenth century in Berlin, Germany. Initial systems were reported devised by a Berlin dentist, Peter Ballif (2). However, prehension in those designs was used only for below-elbow amputation. Subsequently in 1844 a Dutchman, Van Peetersen, used the same mechanism to achieve elbow flexion. In 1855 a design that allowed pressure on a lever against the chest to induce elbow flexion was described. The post-Vietnam War era saw the introduction of myoelectric control, a method by which neural signals from the residual limb are used to control externally powered devices, further enhancing the ease of control of upper extremity prostheses.

The scope of amputation provides insight into the populations for whom prostheses must be designed. As of 1984 there were approximately 400,000 amputees in the United States with approximately 60,000 new amputations performed each year (3). Principal reasons for amputation include severe injury, disease (e.g., cancer, diabetes), and congenital defects. Traumatic injury and vascular-related diseases are the principal causes. Approximately 58% of new amputations are on patients between the ages of 21 and 65. Thus there is a significant patient population of young people with amputations, a group likely to conduct strenuous activities when using their prosthetic limbs. For persons over the age of 50, vascular causes are the etiology in 89% of the cases. These individuals typically, but not always, seek a prosthesis that simply allows function or provides a cosmesis.

Artificial limbs are classified on the basis of the number of intact joints proximal to the level of amputation. For the lower-limb, amputation levels include partial foot, syme, transtibial (below-knee), knee disarticulation (through-knee), transfemoral (above-knee), and hip-disarticulation (Fig. 2). Those for upper limb include partial hand/wrist disar-

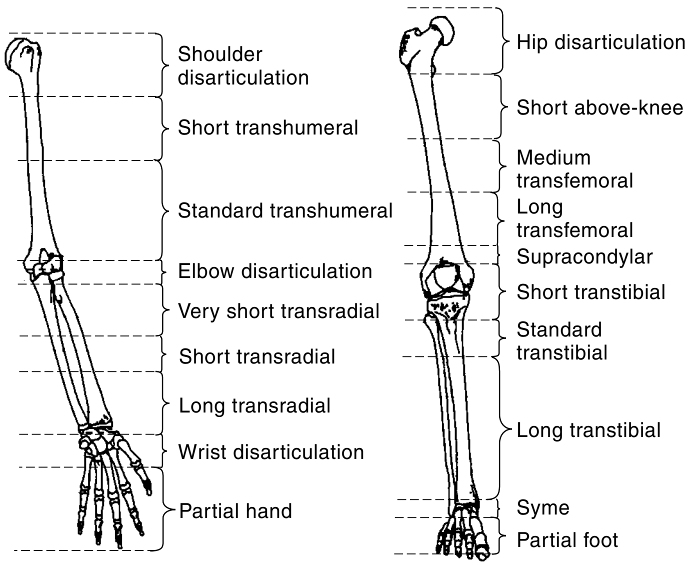

Figure 2. Levels of lower limb and upper limb amputation.

ticulation, transradial (below-elbow), elbow disarticulation (through-elbow), transhumeral (above-elbow), and shoulder disarticulation. In general, a surgeon performing an amputation tries to save as many joints as possible so as to maximize function while still overcoming the etiology that required the amputation.

Most artificial limbs attach to the residual limb via a socket and supplementary apparatus. The socket is usually custom-made for the individual whereas the remaining components, for example the foot or hand, are off-the-shelf items. The inside socket shape is typically not an exact copy of the shape of the residual limb but is instead a modified shape pushed into the residual limb in load-tolerant and supportive regions whereas it is off-loaded in sensitive areas. Supplementary apparatus to hold the prosthesis onto the limb may include straps, sleeves, or cables.

Most artificial limbs are passive devices, that is, they are made of deformable materials and are controlled by the musculature of the residual limb. Energy-storage-and-return, lower limb componentry (feet, ankles), introduced in the 1980s, helped to enhance the efficiency of passive artificial legs. Energy storage components are made of deformable materials that store energy internally when stressed and return that energy as they are unloaded, springing back to their original shape. Active artificial limbs exist, though they are used mainly in upper limb applications, in part, because upper limb prostheses are not subjected to as high levels of load bearing, have lower power requirements, and require finer control than lower limb prostheses.

LOWER LIMB PROSTHETICS

Amputations of the lower limb account for approximately 80% to 85% of all amputations performed annually in the United States. The principal cause is dysvascular disease. Amputation is often the optimal solution for a painful dysvascular limb. Approximately 80% of amputations for dysvascular disease occur in patients with diabetes (4). Other reasons for causes of lower limb amputation include traumatic injury, tumors, and congenital defects.

The primary purpose of a lower limb prosthesis is to provide functional ambulation. Because amputational surgery and prosthetic fitting are geared toward this goal, electronic componentry is used less often than in upper limb applications. Further, research and development efforts focus on creating lightweight, strong, energy-returning components that enhance ambulatory efficiency.

Amputational Surgery

The goals of lower limb amputational surgery are to remove a section of a limb so as to eliminate a pathological state and to create a residual limb that permits functional ambulation when fitted with an appropriately prescribed prosthesis.

In a traumatic injury, often the surgeon must make do with the residual limb tissues that remain, trying to save bone length if the residuum is short but ensuring sufficient viable soft tissue for covering. A very short bone length provides insufficient residual limb surface area for load bearing and stability. A joint with much adherent scar tissue is also difficult to manage because of frequent soft tissue trauma. Thus a joint might be sacrificed in these cases. In a nontraumatic situation (e.g., amputation due to peripheral vascular disease), the surgeon can be more consistent. With the posterior flap surgical technique, skin and soft tissue covering the gastrocnemius and soleus muscles is pulled around the distal end of the tibia and fibula and sutured to the anterior tibial surface. This technique ensures that the well-vascularized posterior tissues cover the distal end of the residual limb (5). Whether amputation is for a traumatic or nontraumatic reason, soft tissues are handled in the gentlest way possible. Vessels are double-ligated and cut at the level of amputation. To avoid painful neuromas, nerves are pulled gently, resected at a sharp angle with a sharp blade proximal to the level of amputation, then released and allowed to retract back into the wound. The anterior-distal tibia is rounded with a file so as to reduce soft tissue trauma over the distal end of the bone. The fibula is typically cut 1 cm proximal to the tibia so as to avoid soft tissue trauma at its distal end. The wound is usually closed in layers, first the fascia, and then the skin. A suction drain is often used postoperatively for one to two days to ensure proper drainage of wound fluid. The wound is covered with wool and plaster of Paris dressing before the early prosthetic fitting begins.

Design of a residual limb to permit functional ambulation represents a challenging biomechanical effort. The aim is to use the remaining structures (e.g., muscles, tendons, bone) to maximal advantage, particularly to overcome anticipated fitting problems of the residual limb in the socket. For example, suspension of the residual limb in the prosthetic socket during the swing phase is enhanced by suturing muscles in slight tension so that the activated muscles cause an enlarged diameter residual limb, helping to hold the prosthesis on the residual limb during the swing phase. A bone bridge, a bony graft inserted between the tibia and fibula, helps to create a more stable residual-limb bony structure.

Types of Prostheses

The nature of the amputation, in part, determines the type of prosthesis. For transtibial amputations, the more common types of prostheses include the total contact, patellar-tendon-bearing (PTB) design in which much of the load is tolerated on the durable patellar tendon distal to the knee cap. PTB sockets are very much the standard for transtibial amputation. The main variations are in the methods of suspension (e.g., y-strap, supracondylar, cuff, supracondylar medial wedge, and neoprene sleeve). A suprapatellar socket design is a variation where the proximal brim goes over the patella and hooks proximally, thus aiding suspension.

Transfemoral socket design is an area of active development. Quadrilateral sockets developed in the early 1950s transfer the majority of load bearing to the ischium. The ischial-containment socket gradually replaced the quadrilateral socket, transferring load to the ischium but distributing more of it to the gluteus, femur, and soft tissues of the residuum. A subsequent variation was to introduce an inner flexible socket that allows some shape adaptability during muscle contraction, improved heat transfer, sensation, and suspension due to greater contact friction. An outer carbon-fiber frame allows considerable weight reduction, and also large window openings in the socket wall allow the flexible socket room to move when adapting to shape. Channel-shaped openings contain and orient active muscle groups.

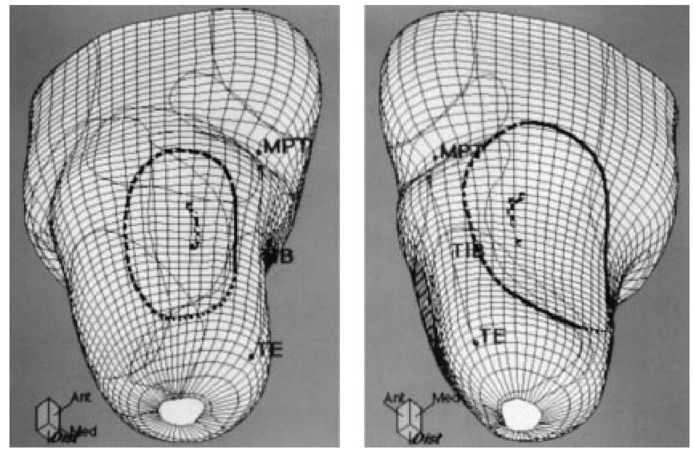

Figure 3. Software used for prosthetic socket shape modification. A transfemoral socket showing rectification regions is shown using ShapeMaker™ software (Seattle Limb Systems, Inc., Poulsbo, WA).

Prosthetic Design and Fitting

Fabrication of an artificial limb typically involves three major stages: custom fabrication of the prosthetic socket; selection of off-the-shelf components; and assembly and alignment of the complete prosthesis. Each stage calls for considerable skill and experience from the prosthetist. The prosthetist must take into account the nature of the individual residual limb, the lifestyle of the amputee, and the amputee's physical and financial ability, so as to select the basic socket design and prosthetic components that will return the greatest degree of function to the amputee.

Socket Fabrication. Custom fabrication of the prosthetic socket is divided into four steps: recording the shape of the residual limb, designing the shape of the socket, fabricating the socket liner, and fabricating the socket shell. Together they form the most time-consuming and labor-intensive stage of creating an artificial limb, and thus are the most expensive.

To design a prosthetic socket, first it is necessary to measure the shape of the residual limb so as to have a starting point for design. The most commonly used method for measuring shape is to make a negative mold from a wrap-cast of the residual limb. The prosthetist wraps a plaster of Paris bandage around the residual limb and then applies pressure while the bandage hardens in selective locations where the tissues are more load-tolerant. The pressure is used to distort the cast into a shape desired during actual use of the prosthesis. Use of noncontact scanning methods based on laser or patterned light are becoming more popular and are advantageous because they provide a digital record of the residual limb shape that can subsequently be used for computer-aided design and manufacturing as well as archiving.

Designing the final shape of the prosthetic socket from the plaster cast or a digital image of the residual limb is called socket rectification. The goal of socket rectification is to shield sensitive soft tissues from painful or injurious stresses, while transferring external load to the soft tissues that are more load-tolerant. The exact magnitude and location of the rectifications depend on many factors, including the type of socket design, the presence of scar tissues, the maturity of the residual limb, and the bulk and deformability of the soft tissues. Rectification may also provide for suspension of the socket from the residual limb and for almost complete pressure relief on the distal end. If the socket is being rectified manually, as is commonly the case, the wrap-cast is filled with plaster of Paris paste or similar casting material to produce a positive replica of the residual limb. The prosthetist manually sculpts this replica, shaving away material where directed loading of the soft tissues is required, and adding extra material where the soft tissues need to be shielded from excessive stress. It is common that transparent *check sockets* are made to verify appropriateness of the socket rectifications directly on the amputee's residual limb.

If a digital image is to be modified, rectification is performed with custom software for this purpose (6) (Fig. 3). When the prosthetist has finished rectifying the digital limb, a numerically controlled lathe carves the rectified positive from a blank. Computer-assisted socket rectification is fast, allows rapid fabrication of duplicates, and enables a degree of expertise to be passed to the user of the software. Though computer methods of design and manufacturing have had impact, the technologies are still in their nascent stages. Display and manipulation of three-dimensional shapes on two-dimensional devices have yet to provide the prosthetist with information about the underlying skeletal structure and the deformability (material properties) of the soft tissues as does manual handling of the tissues. This is an important drawback of current computer-aided design methods that needs to be overcome.

Most socket designs for amputations below the knee incorporate a cushioning liner between the residual limb and the socket shell. The socket liner attenuates stress concentrations that occur where the bony skeleton is close to the skin surface and accommodates some of the variation in the shape of the residual limb that occurs over time. Because the liner functions as a glove over the residual limb, the prosthetist typically fabricates it directly onto the rectified positive replica of

Figure 4. Lower limb prosthetic componentry. Two pylons (an aluminum shank and a hydraulic shank), two feet (a SACH foot and a Seattle foot that has been sectioned to show the plastic leaf spring), a heel wedge, and an assembled transradial amputee prosthesis are shown.

the limb, selecting from a number of different elastomeric foams and gels available within the industry. Silicone gel was initially selected as a liner material in transtibial socket design because of its ability to distribute shear stresses. Currently, a number of nonsilicone formulations with similar properties are available. A parallel unrelated development was suction suspension (7), made possible by the newer flexible socket materials that allow a greater degree of contact and thus better interfacial stress distribution. Elastomeric liner sleeves with a distal locking pin in the socket are used. Cushioning liners are not as common in cases where the amputation is above the knee.

The final stage in the custom fabrication of the socket involves forming the load-transmitting structural shell directly over the positive replica with the liner in place. If other components, such as suction valves and inflatable bladders, are incorporated within the socket, then dummies of their shape are also affixed to the positive form. Advances in plastics technologies in recent years have allowed forming lightweight sockets from thermoplastics, such as polyethylene and polypropylene, or from thermoset polyester and epoxy resins reinforced with glass and carbon-fiber fabrics.

Off-the-Shelf Components. The prosthetist selects a number of off-the-shelf components to attach to the socket to form the complete functional artificial limb (Fig. 4). The most important of these are the footpiece at the terminal end and an artificial joint or joints if required. In response to consumer demand from physically active amputees, particularly since World War II, designs have evolved considerably. A wide selection of connecting elements, adapters, and alignment devices to connect the socket and joints to the footpiece are available, as well as a variety of methods of suspension to keep the artificial limb from falling off the residual limb during walking and other activities.

The joints of the normal leg that may need to be replaced in an artificial leg are the ankle, knee joint, and hip joint. Of these, the knee joint has received most design attention. Among its passive functions are locking in extension during standing and flexing as required when seated. Active functions include absorbing shock without buckling, lengthening the limb during stance so as to accelerate the body forward, shortening the limb while it is swinging through the air and then extending it again before the leading foot contacts the ground. Effective designs achieve these functions while satisfying weight, size, and external power restrictions inherent in all artificial limb designs.

Knee joint designs can be conceptually classified based on the way they control rate-dependent aspects of joint flexion. The rotational stiffness (impedance) of the joint must be very high as the leading foot contacts the ground in normal walking or during stumbling. As the knee is flexed further as part of the normal stride, the rotational stiffness needs to decrease so that the rate of rotation matches that of the opposite knee for the current walking speed. Similarly, as the foot is lifted off the ground and swung forward, the knee must first flex and then extend at the same rate as the opposite knee. Thus when the knee is bearing load (the stance phase), it must have two different stiffnesses in flexion, and when it is not bearing load (the swing phase), it must have one rate of flexion and another rate of extension. Each of these rates, in turn, should depend on the walking or running speed selected by the amputee.

The simplest knee mechanisms, often called *constant friction*, use friction within the joint to control the rate of rotation in flexion and extension. In more sophisticated designs, called *stance controlled*, (8), the coefficient of friction is controlled on the basis of the amount of load borne by the leg. Designs based on friction, however, cannot respond to variations in walking speed. In the more complex, popular, and expensive knee mechanisms, pneumatic and hydraulic piston-cylinder combinations allow the designer to tightly control each portion of the walking cycle, producing in many transfemoral amputees a gait that appears entirely natural to all but the highly trained eye. Though these fluid-controlled knees successfully adapt to variations in walking speed, they are essentially tuned to work optimally about a predetermined preferred speed. To allow the active amputee an even greater range of walking and running speeds, designers have recently begun incorporating active controls on the valves that the prosthetist or amputee can set manually. These controls are mediated by microprocessors, and the manual control involves typing instructions via a detachable keypad. Devices are commercially available which sense the walking cadence and adjust the parameters of the hydraulic or pneumatic cylinders accordingly. The next step in development will be to control the valves in real time by microprocessors that use measured rate and direction of rotation as their active inputs.

The role of the normal human foot–ankle complex in walking is similar in many respects to that outlined for the knee joint. As the foot contacts the ground, the ankle joint acts as a shock absorber until the foot is planted flat on the ground. As load is transferred to the foot, it must adapt to any unevenness of the terrain so as to provide a stable base on which to bear load and from which to accelerate the body forward. Finally, as the amputee prepares to take the next step, the ankle joint actively extends, contributing to the accelerating force. In addition to these dynamic requirements, there is often a cosmetic requirement that the footpiece easily fit within a shoe or other routine footwear.

Despite this conceptual similarity of function between the foot and the knee, the approach to artificial ankle and footpiece design is markedly different from that of the knee joint. Whereas the knee joint relies on very intricate and complex linkage systems, in general, the footpiece is a single-unit composite of different metallic or polymeric materials without any moving parts. Because the footpiece is at the end of a swinging pendulum, its weight takes on enormous significance. There is also less space available at the end of the leg for a linkage-based, ankle-joint design. Finally, the location of the foot–ankle contacting just centimeters above the ground makes mechanisms prone to damage and wear from water, dust, and other contaminants.

For about three decades between the 1950s and the 1980s, the footpiece of choice was a relatively simple design called the solid ankle cushioned heel (SACH) foot. The basic design incorporates a curved wooden keel, modeled after a shoe last, and a foam heel bumper surrounded by an elastomeric sheath. The cushioned heel absorbs energy as the heel contacts the ground, the elastomeric sheath allows a small amount of adaptability to the terrain, and the curved keel allows the amputee to roll forward on the foot in a manner that simulates ankle flexion. Notably there is no active push-off as the foot leaves the ground at the end of the stance phase. Sophistication of this basic design includes a choice of stiffness for the heel, a choice of heel heights to match different shoe designs, and an injection-molded sheath that includes toes and other cosmetic features. A conceptual variant of the SACH foot that was popular in Europe is the single-axis foot. It incorporates a uniaxial joint at the ankle level and has a slightly different location for the heel bumper. Some multiaxial feet were also developed, but weight and durability issues limited their widespread acceptance.

With the advent of injection-molded plastics, the wooden keel in the SACH foot began to be replaced with plastic keels. A favorable feature of this material is that the torsional and bending stiffness of the keel can be controlled, allowing for greater shock absorption and adaptability to uneven terrain. A number of different keels designs evolved in this class of energy-absorbing feet, though the most notable of these was the stationary ankle flexible endoskeleton (SAFE) foot. With the departure from the solid keel of the SACH design, it was only a matter of time before designers realized that the energy stored in the distortion of the keel could be returned to assist in the push-off phase of stance. The Seattle foot, developed in the mid-1980s (9) led the trend towards these energy-storing, energy-returning, or dynamic elastic response feet, as they have been variously called. There remains a great deal of debate whether these feet actually assist in the push-off phase, but that does not detract from the design philosophy which is dynamic as opposed to passive. As with the knee joint, however, a design that attempts to provide rate control of rotation performs best at a predetermined speed and can be awkward to use at other speeds.

Assembly and Alignment of Components and Socket. The final stage in fabricating the prosthesis entails assembling and aligning the socket shell and the off-the-shelf components into a functional limb. The orientation of the socket with respect to the footpiece is set on the workshop bench following the general recommendations of the design selected. Finer adjustments to the alignment are made through adjustment screws incorporated into the components, after observing the amputee standing or walking on the artificial limb. The goals of the alignment process are to produce a symmetric, smooth, and cosmetically acceptable walking pattern that demands a limited amount of energy from the amputee, and does not produce discomfort or pain. Comments from the amputee on the ease of walking and other aspects can be highly relevant in the alignment process, particularly for an amputee who has received several prostheses during his or her lifetime and thus has much experience. The assessment of the amputee's walking pattern is commonly called clinical gait analysis.

In its most basic form, clinical gait analysis consists of careful observation by a highly trained observer and interpretation based on an understanding of the biomechanics of amputee walking. The use of video recording and slow-motion replay can be of considerable assistance to novices as they build up their expertise. However, an understanding of prosthetic biomechanics is still required to correlate the abnormalities in the gait with specific misalignments and socket deficiencies. It is also possible to quantify and then evaluate an individual's gait pattern for prosthetic alignment or computational evaluation, though this is generally done only for research purposes because of the complexity of data acquisition, analysis, and interpretation.

Such quantification of gait involves recording the three-dimensional motion of the entire body with respect to time (kinematics), the forces transmitted through the limbs to the floor (kinetics), and the intensity and duration of muscle activity in the various groups that control the prosthetic limb (dynamic electromyography). Then these data are compared with known or expected patterns. The kinematic portion of the analysis involves recreating a segmented stick-figure model of the subject by tracking passive (reflective) or active (infrared emitting) markers on the subject with multiple video cameras. Software extracts the markers from the images, triangulates their positions, and then extracts relevant parameters of translational and rotational velocities and accelerations (10). Kinetic data can be added to the analysis if force transducers (called force plates) are positioned flush with the floor in the path of the walking amputee. Based on the kinematic analysis, the kinetic data can be transformed into coordinate systems relative to specific segments or joints of the limb. Surface electrodes affixed to the skin above important muscle groups can pick up signals of gross muscle activity. This last component of information can be potentially very valuable, because it can help distinguish ineffective muscular performance from a misaligned prosthesis.

There is room for affordable and portable technologies to enhance the research tools described with alternatives better suited to the clinical environment for ease-of setup, use, and interpretation. Lightweight load cells that can be positioned within a prosthesis have been developed, as have versatile data capture systems, allowing data collection over many sequential steps and in nonlaboratory environments (different surface terrains, different inclinations). Software to interpret and apply such data to fitting (e.g., suggest appropriate alignments), however, is only in its formative stages of development.

The design of the hip joint has remained essentially the same through most of the latter half of this century, in part, because of the low demand for it. At this amputational level the energy requirement for an amputee to walk is so great that a high level of functionality is not commonly restored.

UPPER LIMB PROSTHETICS

Amputation of the upper limb accounts for an estimated 12,000 surgical procedures a year in the United States and 15% to 20% of all amputations of major extremities. The most prevalent cause of upper extremity loss is trauma. Over 90% of all upper limb amputations result from major tissue damage from fractures, burns (electrical, chemical, or thermal), frostbite, and machinery accidents (11).

Amputation of the upper limb often has a long-term impact on the patient's life. Although lower limb amputations occur primarily in elderly dysvascular persons, the majority of upper limb amputations occur in young men between 20 and 40 years of age. Further, the upper limb has increased anatomical complexity and a need for finer control, making effective prosthetic design more challenging.

Because of the low benefit-to-effort ratio of upper limb prosthetics, more than 50% of all upper limb amputees choose to forego prosthetics of any kind (12). Reasons for rejecting the prosthetic device include effective adaptation to a life with one hand, poor training or lack of skill in using the prosthetic device, and public perception of the prosthetic device. For those amputees who elect to use a prosthetic device, the choice of components varies considerably based on the level of amputation, the type of action required, the size and strength of the residual limb, and the desire to use body-controlled or electric components.

Amputational Surgery

The percentages of amputees who use prostheses vary by amputational level: partial hand/wrist disarticulation (12%), transradial (57%), elbow disarticulation (3%), transhumeral (23%), and shoulder disarticulation (5%). The level of amputation is often chosen to retain as much limb length as possible while ensuring effective wound healing.

Partial hand amputations (including the loss of digits) account for the majority of upper limb amputations. An important aspect of partial hand amputation is to retain the functional capability of the thumb, providing apposition so as to retain grasping capability. Wrist flexion and extension are also maintained, as are forearm pronation and supination, functions which can then be transferred to the prosthesis. Adequate palmar skin must be available for this level of amputation, as the tactile palmar skin is used to cover the stump and to provide the grasping surface.

Wrist disarticulation is typically performed when the thumb or fingers are lost. It is also performed as secondary surgery after partial hand amputation when functional apposition is not achieved. Wrist disarticulation offers the advantages of allowing full forearm pronation and supination, retaining an oval or rectangular residual limb that is a better holding shape in a socket and a more load-tolerant distal end because the distal ends of the radius and ulna are more load-tolerant surfaces. However, it can be difficult to fit a prosthetic device to the longer limb, thus a surgeon might choose a transradial amputation instead.

Unlike the corresponding transtibial amputation, in transradial amputation both bones in the residual limb are transected to the same level to provide the largest amount of pronation/supination possible. As the length of the limb decreases, so too does the available degree of pronation/supination. Thus a long residual limb is preferred. Even if the residuum of the forearm is too small to attach an adequate transradial prosthesis, retention of the elbow is still highly desirable as a power source for body-powered cables.

Although loss of a single upper limb is damaging, the loss of the second can be devastating. The sense of touch and proprioception provided by the hand is vitally important in daily living. The Krukenberg procedure provides an alternative for bilateral upper limb amputees (13). In this procedure, the radius, ulna, and associated muscles are separated, creating a prehensile organ capable of sensation and the capability to grasp objects. Because of the unsightly appearance of this technique, it is often reserved for bilateral amputees, blind amputees, and amputees in foreign countries where modern prosthetic devices are unavailable.

An elbow disarticulation provides many of the same advantages as a knee disarticulation in lower limb amputees. The flared end of the residual limb at the condyles of the humerus provides suspension of the prosthetic socket and allows transmission of humeral rotation to the prosthetic device, alleviating the need for a separate component. The longer limb length is more advantageous as a moment arm and, like the wrist, the residual end provides a more load-tolerant residual limb. However, it can be difficult to fit a prosthesis, and the standard body-operated prosthesis for this type of residuum requires external locking hinges which often damage the amputee's clothing.

The long transhumeral amputation provides good power for body-controlled systems. Additionally, this level provides excellent sites for obtaining the signals used with a myoelectric terminal device, which controls an active device based on neural signals measured with surface or implanted electrodes, and provides the prosthetist with more options in location and access to components than the short transhumeral amputation. The short transhumeral amputation still provides adequate control of body-powered devices but lacks the appropriate power often needed to run such devices.

Transhumeral amputations shorter than 30% of the original length may be considered shoulder disarticulations for all practical purposes. The shape of the shoulder is maintained by the soft tissue, providing a more natural looking contour. The amputee, however, has little to no excursion available for flexion, extension, or abduction of the prosthesis. Thus the use of a prosthesis is difficult.

Prosthetic Design and Fitting

Unlike lower limb sockets, the upper limb socket is not a weight-bearing device. Despite this difference, the need for a close yet comfortable fit is necessary for proper fitting. During the fitting process, the prosthetist pays close attention to the distribution of pressure, especially over bony areas such as the epicondyles and olecranon. The socket design consists of a double wall, the first to provide contact with the limb, and the second to provide an outer, cosmetic, stable shell.

The distal area of the socket must provide adequate relief so that lifting with the forearm does not cause extreme pressure on the soft tissue between the radius and the socket wall. If the terminal device is body-powered, a sock should be worn on top of the residual limb to help reduce the pressure at the edges of the socket. However, myoelectric terminal devices require contact with the skin directly. Hence a sock cannot be worn.

To avoid rubbing and restriction of shoulder motion, transhumeral sockets are generally fitted to those patients with between 30% and 90% of the humerus remaining. Using such a device, forearm flexion to 90% and abduction to 30% should be possible (14).

The components of the prosthetic system include the terminal device, wrist unit, elbow unit, shoulder harness, and control system. Because of the large number of manufacturers and components, special attention must be given to the compatibility of all devices in the system, particularly electric components that may have special requirements.

Terminal Devices. Terminal devices can be divided in two categories, passive and prehensile (or active). The prehensile device is also divided into two categories, body-powered and externally powered.

The passive terminal device is the most prescribed form of terminal device. The passive hand is often simply used as a cosmetic device, although many passive devices have been designed for recreational activities, such as fishing, bowling, baseball, archery, and golf, though they require no motion or are passively positioned by the amputee. A passive hand is formed from a lightweight foam with central wires in the fingers covered with a cosmetic glove made from polyvinyl chloride or silicone rubber to provide a skinlike appearance.

In a body-powered prosthesis, the amputee provides all of the energy to run the device. The body-powered terminal device is often designated by the opening or closing method. Generally, the device is characterized as either voluntary opening (VO) or voluntary closing (VC). In each case, the amputee applies a force by way of a control cable to provide the voluntary motion, and a spring or rubber band acts to return the device to its rest state. The force applied in grasping an object by the terminal device is determined by the spring force of the closing device for the VO and by the strength of the amputee in the VC. Such systems have the advantage of offering the patient sensory information based on the degree of motion of the controlling harness and shoulder position.

The body-powered prehensile device can be one of two forms, a hook or hand. Quick release couplings allow easy interchange between them. The hook provides a more functional advantage as it provides superior prehension and visual feedback to close the control loop, especially when grasping small objects. The hook is most often designed in a *split* fashion where one finger is stationary and the other is driven by the control cable to provide lateral prehension. The hook prosthesis is also less expensive, more reliable, and far more sturdy than its hand counterpart.

The body-powered hand device offers the advantage of cosmetic appearance over the rather obvious hook prosthesis. Rather than providing lateral prehension like the hook, the hand provides a palmar grasp, usually with a pinching motion between the thumb and the first and second fingers. Because of the increased complexity of the hand terminal device, friction in the joints is high and the overall efficiency (and pinch force) is low. Other disadvantages include limited functionality, reduced reliability, and ease of damage to the plastic glove often worn over the hand.

Externally or electric-powered prehensile devices use motors to bring opposing surfaces into contact to grasp an object. Currently no hand devices exist which offer the independent action of each finger in the device, although an electric hook device is available with independent motors to control each hook for greater flexibility and power. The externally powered prosthesis offers the advantage of improved appearance, improved output-to-input force ratio, range of motion, and a lesser degree of harnessing than a body-powered prosthesis. Like body-powered devices, their components are usually interchangeable, depending on the associated task. The electric devices typically run on a 6 V motor, providing grip strengths as high as 120 N (15) and closing times as fast as 0.8 s (16).

Although growing in popularity, these devices have some disadvantages. The electric devices are more expensive and complicated than body-powered devices, necessitating continual maintenance. Also, such devices operate more slowly than similar body-powered devices. In recent studies, patients using both forms of terminal device took about twice as long to perform similar tasks with the electric device (17). The cosmetic glove typically worn over the electric prosthesis, like the body-powered equivalent, is often damaged but also often hinders operation of the electric device.

Wrist. Commercially available prosthetic wrist units provide two functions: attachment of a terminal device and positioning for the terminal device. Wrist units can augment an amputee's ability to supinate/pronate the forearm by rotating the terminal device. Wrist units are generally only passive devices, using friction to hold the terminal device in place. Any adjustment to the position must be accomplished by prepositioning the device with the opposing hand. The units are easily locked in one position, though mechanisms to allow for quick release and change of position are available. Electric wrist rotators are beginning to be used in more advanced systems. These units offer additional independent control but suffer from added weight and low torque.

Elbow. Both body-powered and electric-powered elbows are available (Fig. 5). Although most body-powered, transradial sockets require harnessing, self-suspension sockets provide freedom from harnessing or cables when used with electric terminal devices. Such a system is particularly useful with short or very short transradial amputations and an electric terminal device.

The elbow unit simulates rotation at the elbow through a turntable device located in the transhumeral prosthesis and allows flexion through hinges mounted internally or externally to the lateral sides of the prosthesis. The force for arm flexion derived from a cable system is similar to the voluntary opening terminal device. The two systems are often combined in a single tension line to provide flexion of the elbow when the elbow is unlocked and opening of the terminal device when the elbow is locked. Like the wrist unit, this device offers several locking positions (usually seven to eleven discrete positions of flexion). The elbow forearm lift-assisted units are often friction-held or spring-balanced to remove some of the weight of the forearm from the residual limb and reduce the

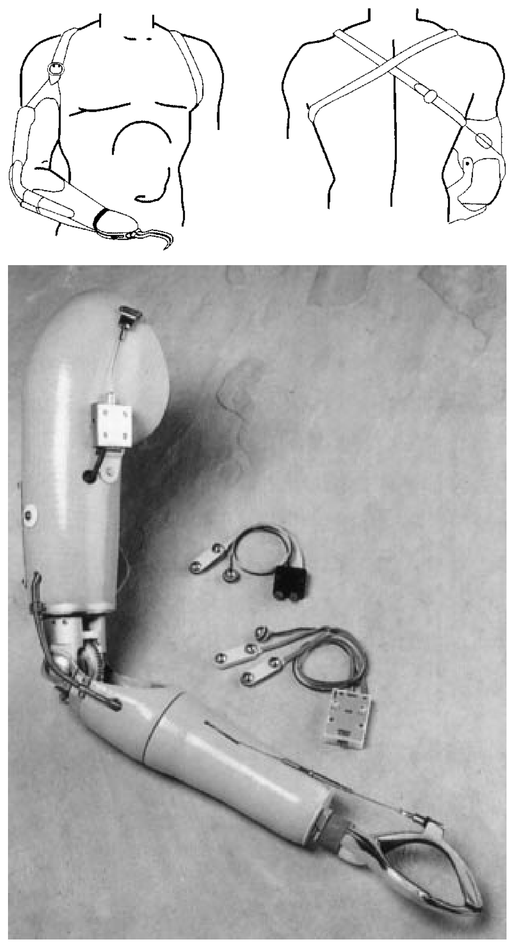

Figure 5. Upper limb prostheses. (upper) Figure eight method for harnessing an upper extremity transradial prosthesis (From N. Berger, Upper limb prosthetic systems, in *Atlas of Limb Prosthetics, Surgical and Prosthetic Principles,* American Academy of Orthopaedic Surgeons, St. Louis, MO: C. V. Mosby Company, 1981, with permission.) (lower) A NY electric elbow with prehensile actuator (From Hosmer Dorrance Corporation, The NY elbow system, Electric Components, 1997, with permission.)

force necessary for flexion. If more than 90% of the humerus remains, then internally locking elbows are not possible, and externally mounted hinges must be used. Electric-powered elbows incorporate either myoelectric signals or switch controls and are often used in conjunction with myoelectric devices. Because of high cost, high weight, and low reliability, electric elbows are rarely used, and instead a hybrid system is used consisting of a myoelectric terminal device and a standard body-driven elbow unit to provide separation of control.

Shoulder Harness. To provide power for the body-controlled components, a control harness is often used. One of the best methods for providing motion is glenohumeral (shoulder) flexion, provided enough humeral length remains. Between approximately 180 N and 270 N of force is generated by the average adult in shoulder flexion (17), providing adequate power for flexing elbows and/or opening terminal devices. Another method of providing force for operating the prosthetic control system is shoulder elevation and depression, capturing scapular motion. Although it provides a relatively large amount of force, it requires an anchor point, usually at the waist, to accomplish the task. This motion is often used for locking and unlocking elbow units in transhumeral or higher levels of amputations. Other actions, such as scapular abduction and chest expansion, are often used to accomplish these tasks if other motions are unavailable.

The harness system is dictated by the level of amputation. Transradial amputees most often use the figure-eight harness [Fig. 5(upper)], whereas transhumeral amputees require a more complex harness with an additional support strap. The transhumeral harness uses one strap to keep the prosthesis suspended from the residual limb and a single control cable to operate the terminal device. The transhumeral harness utilizes an elbow-lock cable strap to operate the elbow unit in much the same manner as the figure-eight harness used for the terminal device.

Myoelectric Control Systems

Although not a new technology, myoelectric control in prosthetic systems, has been at the forefront of research for many years. Myoelectric control is a relatively simple concept. When a neural signal is transmitted from the brain via the spinal cord, which in an intact individual would produce muscle contraction, this signal can be detected by electrodes inserted under the skin or applied to the skin surface. These signals can be used to control specific devices.

The myoelectric system consists of five main components, the signal source (muscle activation), the electrodes, the controller, the power source (battery), and the prosthetic device. Analysis of the electromyographic (EMG) waveform demonstrates that the majority of the energy in the signal lies in the 30 to 300 Hz frequency range and that the maximum peak-to-peak amplitude of the signal ranges from a few microvolts to several millivolts (18). Correlation between the activation and the properties of the signal can be determined and a method of control obtained. It is important to note that this method of control is suitable for atrophied, partially innervated, and remnants of muscles often seen in the residual limb.

The surface electrodes, typically made of gold or stainless steel with a surface area of less than 1 cm^2 or less, provide one of the most problematic areas in myoelectric systems. The skin is a natural electrical insulator and often distorts the myoelectric signal. Future areas of research may include percutaneous conductors, myoacoustic receptors, or implanted telemetry systems to overcome this problem. Another common difficulty is that relative movement between the electrode and skin creates noise that is often greater than the myoelectric signal. To alleviate this problem, the electrodes are set at a fixed distance (2 to 3 mm) from the skin surface with a conductive cream or gel filling the intermittent gap. However, the amplitude of the myoelectric signal degrades rapidy as the distance between the source and the electrode increases. Further, at these greater distances, as other local active muscles contract, they produce *crosstalk* in the signal, causing erroneous control.

The myoelectric controller controls the power to the motor. It typically consist of three separate components, an amplifier, a signal processor, and a logic unit. An adjustable amplifier increases the myoelectric signal amplitude to a suitable

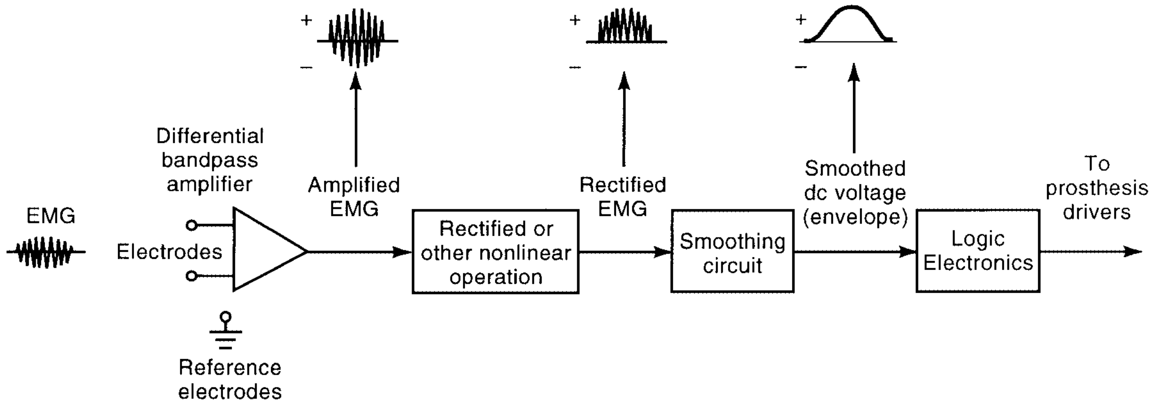

Figure 6. Myoelectric signal (EMG) processing in a typical myoelectric control system (From D.S. Childress, Control of limb prostheses, in *Atlas of Limb Prosthetics,* American Academy of Orthopaedic Surgeons, St. Louis, MO: Mosby Yearbook, Inc., 1992, with permission.)

level (gain of typically 10,000 to 100,000). A differential amplifier, including a common electrode and two active electrodes for each channel, is most often used to accentuate the myoelectric signal interpreted by the logic unit and also to reduce amplification of noise.

A signal processor overcomes noise inherent in the myoelectric signal and sends a more meaningful control waveform (19) (Fig. 6). Typically, the mean absolute value of the signal is used. Tests have, however, shown that the *amount* of myoelectric signal becomes more accurate as the average signal is sampled over a longer time, creating a delay. A typical delay of 0.2 s is used in modern myoelectric prosthetic control systems.

The battery provides power to the motor for the terminal device (or electrical component). Most electric prosthetic devices are powered by secondary cell (rechargeable) batteries, such as nickel-cadmium, although some utilize primary cell (nonrechargeable) batteries when necessary. The battery typically provides between 6 V and 12 V to the motor. Although the majority of the electric systems operate at 6 V, some systems are designed to operate at multiple voltage levels in case primary cell batteries are needed to run the unit.

Because one prosthetic device rarely meets the needs of any amputee, electronic prosthetic systems are designed to be modular, providing the amputee with the ability to interchange components based on desire or need. In theory, almost any electric device can be controlled through a myoelectric signal, provided the voltage requirements of each device are consistent with the other components in the system.

CURRENT RESEARCH

Interfacial Mechanics

In recent years much research effort in prosthetics has concentrated on better understanding how mechanical stresses are distributed at the interface of a residual limb and prosthetic socket, particularly in lower limb prosthetic applications which involve high load bearing. A better understanding of interfacial mechanics and how design features of the residual limb and prosthesis affect them will help prosthetists create artificial limbs that reduce the risk of skin breakdown while maintaining stability.

A number of pressure-sensing instruments and a limited number of pressure/shear stress measurement devices have been used to quantify interfacial stresses (20). Such measurements are difficult to acquire because of sensor size and mass restrictions in the confined interfacial environment and a need to limit alterations of the natural interface. Nevertheless, some insight has been achieved and interfacial stress sensitivity to different parameters has been assessed. An interesting finding consistent with clinical experience is that diurnal and long-term changes in residual limb shape and/or material properties cause substantial changes in interfacial stress distributions. Residual limb shape changes are an important challenge for prosthesis users, and establishing relationships between interfacial stresses and shape change is an important goal for researchers interested in interfacial mechanics.

One tool with potential to enhance understanding of the effects of residual limb shape changes and other features on interfacial mechanics that does not suffer from the measurement problems of interfacial stress transducers is scientific computing. At present, computer-aided methods of fabricating sockets are largely limited to measuring the residual limb shape and carving the rectified positive replica. The application of engineering design principles based on modeling the geometry and material behavior under anticipated loading could considerably enhance socket rectification.

Modeling the interaction between the prosthetic socket and the residual limb is currently being carried out in research laboratories. The three inputs required for such models are (1) the geometry of the residual limb and prosthetic socket, including the individual geometries of the bones, the soft tissues, the socket liner, and the socket shell; (2) the material characterization of each geometric component; and (3) the external dynamic load experienced by the socket, plus other external constraints, such as suspension, friction, and suction. The reference against which the predictive ability of the models is assessed is the experimentally measured contact stresses between the prosthetic socket and residual limb. Finite element methods of structural analysis are commonly used in the models because of the complex geometries involved and the very nonlinear behavior of the component materials, especially the soft

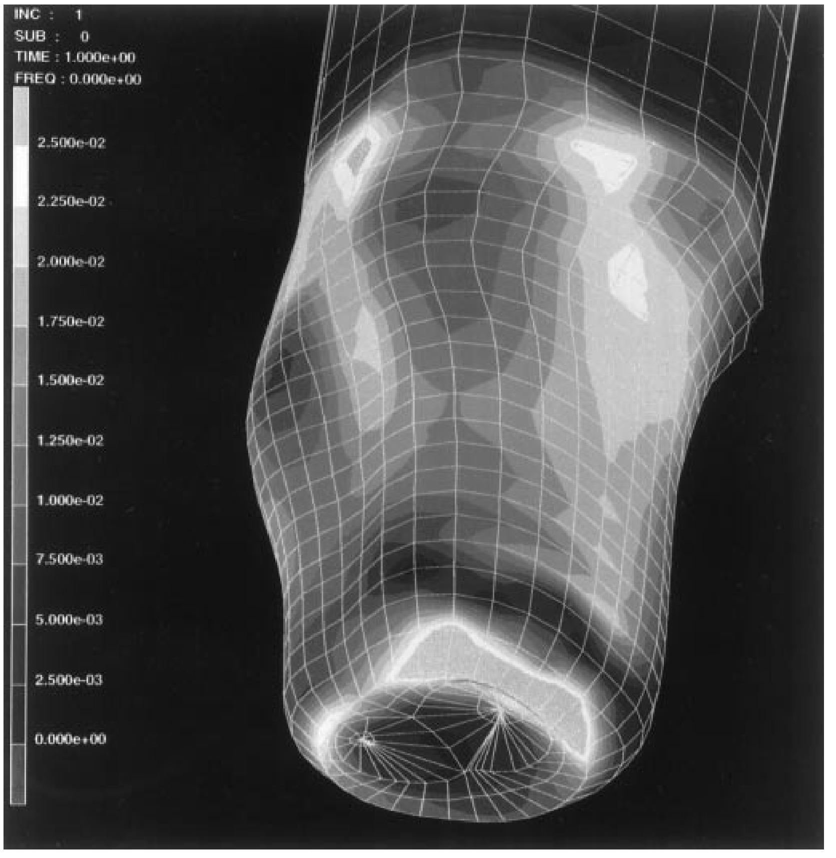

Figure 7. Finite element model prediction of resultant shear stress magnitudes (in MPa) on the surface of a residual limb. An axial load equal to body weight was applied and homogeneous, linear, isotropic material properties were assumed for all materials.

tissues (Fig. 7). Finite element models potentially can predict interfacial pressures and shear stresses for proposed socket designs, information that could then be used to optimize socket design features.

A number of hurdles must be crossed to achieve such a clinical goal. At present magnetic resonance imaging and computed tomography offer ways to visualize the subsurface structures. Both of these are cumbersome and expensive. Some investigators have shown that ultrasound can be used to build a picture of the residual limb's internal and external geometries (21). Such a technology may be viable within a prosthetic production facility. Electromechanical indentation devices to assess the soft tissue material behavior have been developed in many research labs and have also been used in arrays for wheelchair cushion design. The most challenging aspect of the design is predicting the stress pattern resulting from a particular design and activity level. Finite element analysis for nonlinear material properties and interfacial frictional behavior is still very much in its early development. Further, current finite element models treat all the muscles as though they were a uniform material when in fact muscles are fibers contained within specific sheaths and have corrections to the skeletal system at specific places; in addition, they may also stiffen when they are active. These features need to be taken into account in the models. Though software tools exist for finite element analyses, the computational cost limits their use to the most high-end engineering workstations and supercomputers. None of these challenges, however, is insurmountable.

Advanced Upper Limb Control Methods

Much of the advanced work in upper limb prosthetics is governed by problems associated with myoelectric prostheses. Although such devices provide a more cosmetic look, improved function, and freedom from harnessing, they still suffer from substantial drawbacks. Two important issues include the need for multifunctional control systems and electronic and sensory feedback in the prosthesis.

Multifunctional Control Systems. The standard myoelectric control system is characterized by the number of host sites required for the electrodes and the number of control states available to the muscle. Currently, both single and dual sites are available per action (i.e., flexion/extension or open/close).

The one-site, one-state control [Fig. 8(a)] offers control of the device through electrodes placed on a single muscle. Activation of the muscle activates the device (usually open), and then springs or rubber bands return the device to the rest position. Two-site, one-state [Fig. 8(b)] control uses two such devices to control both the open and close motion of the device. Activation of one opens the device and activation of the other closes it. This method of myoelectric control is used most often. The one-site, three-state control (Fig. 8(c) allows the user to change control between open and close based on the magnitude of the myoelectric signal. This method uses two threshold levels to determine the close and open states. A time delay in the control allows the user to transfer directly from off to close if so desired.

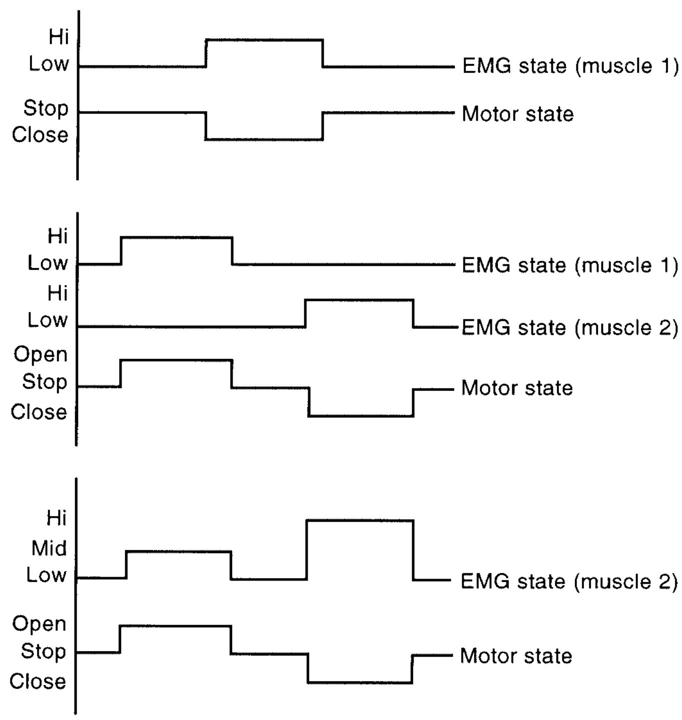

Figure 8. Typical control options for myoelectric prosthetic systems. (a) one-site, one-state; (b) two-site, two-state; (c) one-site, three-state.

Advanced control systems now under development utilize two muscles in much the same method as the two-site, two-state control but with a greater degree of multifunctional motion. *Proportional control* or procontrol is used in some systems to allow the rate and magnitude of the myoelectric signal to provide additional movement. In this system, the rate of motion of the device (elbow, wrist, or terminal device) is proportional to the magnitude of the EMG signal rather than the binary (threshold) on-off/constant-velocity motion of other devices. The harder the control muscles are flexed, the faster the motion of the device. Additionally, the rate of muscle activation provides additional multistate control. Holding the arm in a single position causes the elbow to lock in position, switching control to the hand or wrist. A quick coactivation of both control muscles allows the user to return to the elbow-control mode, thereby affording a full range of motion to the amputee with limited control sites.

Other systems use enhanced feedback features to provide improved control over each component. A vibration sensor and appropriately designed controller is used in some systems to help control the grasp of the terminal device. This multistate control allows the user to control both the position and force of the hand with two muscles. In this case, the device is a voluntary opening hand, where tension in the extensor opens the hand proportionally to the magnitude of EMG signal. When a sensor in the hand comes in contact with the object, movement is stopped. Tension in the flexor muscles activates the HOLD state and an automatic force grip is activated. The automatic force control detects movement of the object from the sensor and adjusts to prevent slippage. While in HOLD mode, the user can override the control in a SQUEEZE mode to apply additional force to the object or can initiate a RELEASE mode to return to the original position of contact. Such a system offers more control than a conventional myoelectric controller but requires more gradients in the EMG signal than typical two-site, two-state devices (22).

Electronic and Sensory Feedback. The two types of feedback important in prosthetic control are electronic feedback, the feedback provided to the electronic control system, and sensory feedback, the feedback provided directly to the amputee. Electronic feedback provides feedback to enhance the function of the prosthetic device, such as position, joint angle, joint torque, and velocity. Such measurements are provided by force and angle transducers in the device. Such feedback ultimately enhances control of the prosthetic device.

Sensory feedback or proprioception is critically valuable to the amputee. Without such feedback, the terminal device may provide too much or too little force, thereby damaging or dropping a grasped object. In the past, researchers have used inflatable bags to provide pressure on the residual limb, which corresponds to the grip force of the terminal device. The most popular of the current methods of proprioception includes electrical stimulation and vibration. One problem with such methods is the limited amount of feedback provided. Most patients can differentiate among only approximately five levels of stimulus, limiting the value of the feedback information transferred in this manner. Additionally, the feedback provided by electrical stimulation can cause interference or crosstalk with the sensitive myoelectric system. Further advances in sensory perception are possible using direct communication with peripheral nerves (23), but research is still continuing in this area.

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ARTIFICIAL NEURAL NETWORKS. See NEURAL ARCHITECTURE IN 3-D; NEURAL NETS BASED ON BIOLOGY.

ASSEMBLERS FOR PROGRAMS. See PROGRAM ASSEMBLERS.

ASSEMBLY LANGUAGES. See INSTRUCTION SETS.

ASSEMBLY, SURFACE MOUNT. See SURFACE MOUNT TECHNOLOGY.