Lecture # 5

Artificial Limbs I

Transtibial Prosthetics

PROSTHETIC EVALUATION

When evaluating a candidate for transtibial prosthesis, a comprehensive physical examination that includes a detailed history interview is essential. The typical physical examination includes:

- Inspection.
- Palpation.
- Evaluation of muscle performance—manual muscle testing (MMT).
- Active and passive range of motion (ROM) testing—sensory testing.
- Skin integrity assessment.

Each member of the clinical team—therapist, physician, person with amputation, and prosthetist—has information and input that is useful in the rehabilitation process. The best outcome will be the result of a collaborative endeavor involving all the team members. This clinical analysis includes choosing the features that are most appropriate for the individual's current status and their anticipated level of function. The most appropriate prosthesis is the prosthesis that suits the person's individual requirements. One size does not fit all: the ideal prosthesis for one person may be completely useless to another.

Prosthetic design is often a compromise of weight versus function. Adding features that may seldom be used will increase the weight and maintenance requirements of the device. **Increased weight leads to increased energy expenditure and premature fatigue. On the other hand, exclusion of features that the person will need on a regular basis may lead to excessive stresses on the limb, premature component wear or breakdown, and inefficient gait.** The clinical team should agree on the individual's functional goals so that the prosthesis can be designed to meet them.

Generally speaking, persons who undergo transtibial amputations are likely to return to their previous level of function. The Center for Medicare Services created a hierarchical system to classify the functional potential of persons with lower limb amputations. This system, referred to by "K-levels," is summarized in Table 1. Note that each functional level uses the phrase "has the ability or potential" in the description. This highlights the fact that individuals cannot reach their full potential until their prosthesis is provided and rehabilitation has been successful. For certain benefits to be covered under Medicare, the individual must be certified by his or her prosthetist and physician with the appropriate K-level. This is to prevent prescription of prosthesis with costly components that person will not be able to manage or use effectively.

<u>Table (1):</u> Classification of Functional Potential of Patients with Lower-Limb Amputations

K-Level	Classification of Functional Potential of Patients with Lower-Limb Amputations
K0	The patient does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility.
K1	The patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2	The patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
K3	The patient has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

EARLY PROSTHETIC MANAGEMENT

Goals for postoperative management of the transtibial amputee include:

a) Maintain full ROM of the hip and knee.
b) Facilitate rapid healing of the suture line.
c) Maintain or improve cardiovascular and pulmonary conditioning.
d) Enhance static and dynamic balance.
e) Facilitate functional strength in the remaining musculature.

One common complication of transtibial amputation surgery is a loss of full knee extension. Failure to promote full extension of the tibia femoral joint can lead to delays in prosthetic fitting while ROM is restored. If the lack of knee extension remains, a permanent joint contracture can alter the prosthetic fitting process. The clinical team generally encourages rigid dressings that extend well above the knee and hold the knee in full extension. It has been shown that rigid removable dressings (RRDs) provide more favorable outcomes than elastic bandages when used to control postoperative edema and to provide protection to the surgical site. Regardless of the variation of RRD chosen, the goals are the same: the RRD

a) Keeps the knee in full extension to prevent contracture.
b) Protects the limb from exterior trauma.
c) Controls swelling through total contact.

This removable device is worn over at least one layer of cotton sock and is held in place with Velcro straps (Figure 1). It is also fenestrated to allow airflow and release moisture. The device can be worn 23 hours a day and can be removed easily for dressing changes and bathing.

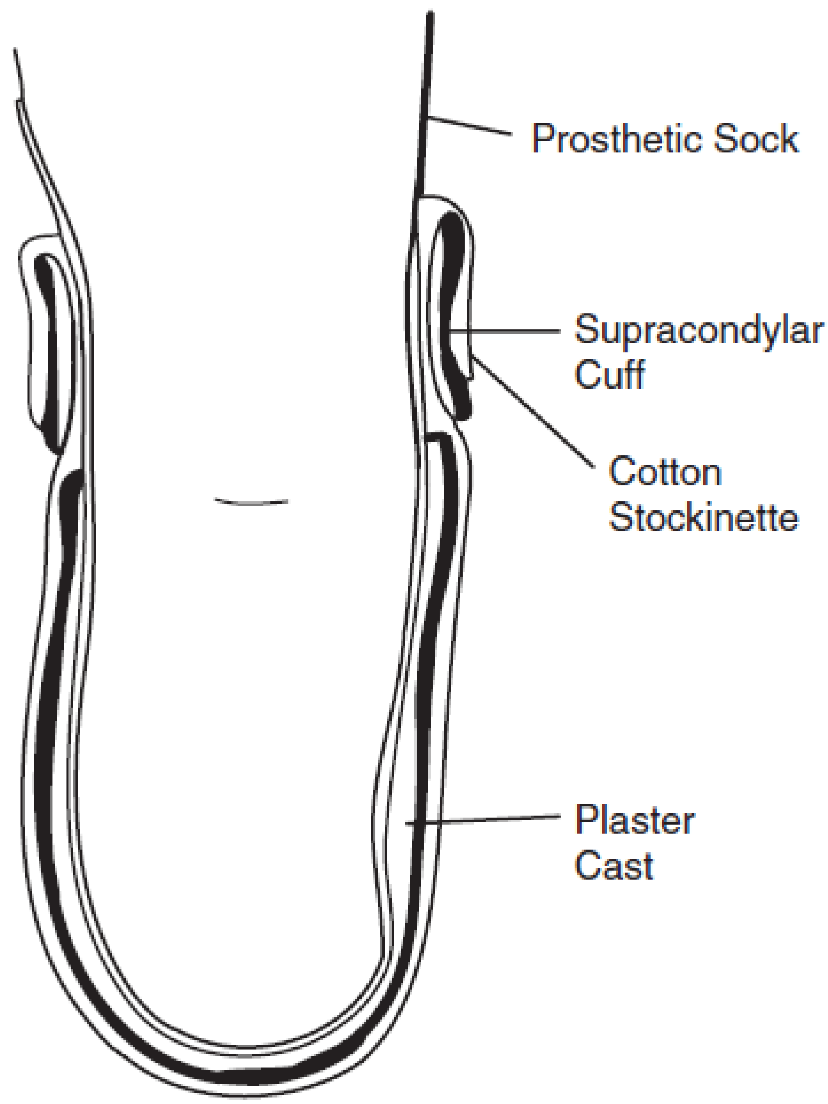


Figure 1: Cross sectional diagram of a Rigid dressing for transtibial amputation. Cotton stockinette is placed over the residual limb, and padding is placed over vulnerable areas (i.e., suture line, bony prominences). The residual limb is then wrapped with several layers of plaster-of-Paris impregnated gauze. Rigid dressings can be used until the suture line closes. They have been shown to reduce postoperative complications and accelerate the rehabilitation process.

PROSTHETIC PRESCRIPTION

A prosthetic prescription is a detailed description of all the features of the completed prosthesis:

a) Socket design.
b) Skin-socket interface.
c) Suspension strategy.
d) Additional modular components (For transtibial prostheses, the components are limited to feet, shock absorbers, torque absorbers, and dynamic pylons).

The socket is the interface between the residual limb and the prosthesis; all the forces from the ground during gait are transferred to the limb through the socket. All the forces from the limb needed to control the motion of the prosthesis are transferred to the prosthesis through the socket. Much care and time should be spent on socket design and fitting, as a less than ideal fit can quickly lead to pain, injury, and lack of function. **The socket design, interface, and suspension need to be considered together as their functions are often interrelated and interdependent upon one another**. Forethought regarding how those three design elements intermingle will increase the probability of producing a comfortable and functional prosthesis for the individual.

SOCKET DESIGNS

Early transtibial prostheses were fashioned by hollowing out a block of wood and attaching metal single-axis knee joints and a leather thigh corset. The sockets were referred to as “plugfit” sockets because they were open-ended and the limb fit into the socket like a plug fits in a drain. The attached thigh corsets took advantage of the conical shape of the thigh to transfer weight proximally and transmit mediolateral forces to and from the limb. Although many persons with amputation were quite functional with this system, the lack of contact on the distal end of the residual limb often led to painful edema in that area. Additionally, the joints and corset added bulk and weight to the prosthesis and unnecessarily restricted knee motion.

Patellar Tendon-Bearing Socket

This design (Figure 2) has been used successfully over the past five decades to strategically load the limb in areas that are more pressure tolerant, namely the patellar tendon and medial tibial flare, and relieve the tissue over bony prominences like the tibial crest and head of the fibula. In most cases, this eliminated the need for proximal weight bearing.

The main goal of the PTB socket design was to increase the surface area on the residuum that is available for weight bearing so as to eliminate the need for the knee joints and thigh corset. The PTB socket was described as "total contact," which meant that there were supposed to be no voids or air pockets between the limb and socket. This design allowed weight bearing to occur in any area that capable of supporting a load.

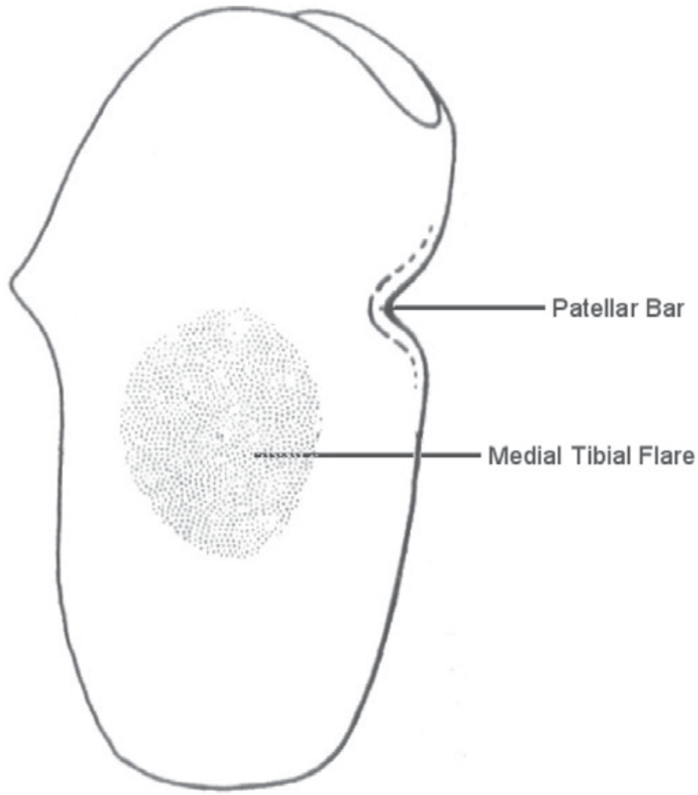


Figure 2: The patellar tendon bar and medial tibial flare are the major weight-bearing areas of the PTB socket; this total-contact socket design has been used for more than 60 years for a comfortable prosthetic fit person with transtibial amputation.

Total Surface-Bearing Socket

The total surface-bearing (TSB) socket strives to further distribute the weight-bearing load over the entire surface of the limb, even in areas that had been traditionally considered to be pressure intolerant. Strategic compression of soft tissue and relief for bony prominences are the tools used to direct more force into areas of the limb that can tolerate it, and less force into areas that are prone to skin breakdown. The intent in designing a TSB socket is to distribute uniform pressure over the entire surface of the limb. It is expected however, that during a typical step while walking, the pressure in any given location will change from a negative pressure during swing phase to high pressure in stance that, if sustained, would cause tissue damage. Because the forces on the limb change quite dramatically throughout the gait cycle, that dynamic pattern must be anticipated so as to use those forces to design the reliefs for pressure-intolerant areas; larger forces means more tissue compression, which require larger reliefs. The other factor to consider is the density and structure of the tissues comprising the limb. Tissue properties vary widely, and there are temporal effects too; muscle tissue, for example, behaves one way while relaxed and very differently while contracting. Once they are accommodated, the relative locations of these tissues within the socket must be preserved; this not only provides a good environment for the tissues, but also allows accurate control of the prosthesis.

To fully accommodate the dynamic tissue loading that occurs in a prosthetic socket, the prosthetist must consider both the shear and the normal forces on the limb. Shear forces run parallel to the limb surface and are best mitigated through the use a socket interface. Interface materials, such as socks, sheaths, flexible liners, and gel liners, offer a continuum of shear reduction on the skin surface. The best materials to minimize shear are those found in gel liners. Normal forces are those that are applied perpendicular to the surface of the limb. The socket walls should be contoured according to the type of tissue in the area and the anticipated loading patterns. Because there is no way to reduce the force on the limb without restricting the inidividual's activities, the best way to reduce pressure is to distribute the forces over as broad a surface as possible. The actual forces on the limb are a combination of shear and normal forces that occur together in various proportions.

Throughout the gait cycle the forces and moments on the socket and limb change continuously. There is a flexion moment during loading response, a varus moment throughout mid-stance, an extension moment in terminal stance, and a flexion moment again in pre-swing (Figure 3). The forces on the limb range from a compressive force of 1.2 times body weight in stance, to a distractive force slightly higher than the weight of the prosthesis in swing phase. well-fitting prosthesis must provide tolerable pressure distribution in all of those varied loading conditions. Soft tissue, muscle tissue, and bone contours must each be accounted for in a specific way to achieve a good fit. Soft tissue can tolerate moderate compression so the prosthetist will precompress that tissue in the socket. Muscles can tolerate mild compression but should be encouraged to contract with each step so less precompression should be applied. The shape of muscle tissue changes when it contracts. Flexible materials can be used over muscle bellies that allow for the geometric variability. Finally, bony prominences must be given extra volume within the socket so that when the tissue around them compresses during loading, the pressure will not exceed the tolerable limit.

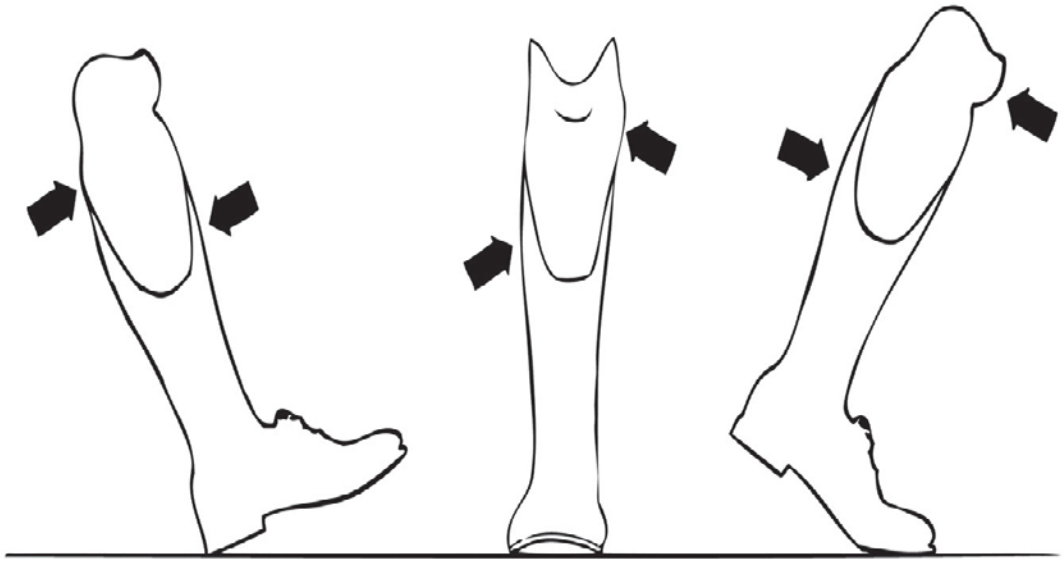


Figure 3: The magnitude and direction of the forces on the socket change throughout stance phase, concentrating pressure in predictable areas. At initial contact and loading response there is an anterior force at the proximal posterior knee and distal anterior residual limb. At midstance weight bearing forces create proximal-medial and distal-lateral pressures. At the end of stance phase the anterior force moves to the proximal anterior knee and distal-posterior residual limb.

INTERFACE MATERIALS

The material that separates the limb from the socket is referred to as an interface. Interfaces play an important role in lower limb prosthetics. Interfaces can offer shock absorption, they can mimic soft tissue to provide an extra layer of cushioning for those who are bony, and they can help to mitigate shear forces on the limb. Interfaces influence the hygiene, ease of donning, and maintenance requirements of the prosthesis as well.

Hard Socket

Early prostheses were made from hard materials like wood, which did not offer much cushioning. Persons with amputation used layers of cotton or wool socks to provide a soft interface between their limb and the hard socket. There are several advantages to this system: the socket is relatively thin, so the it is easily concealed under clothing; a clean sock can be used each day, or changed times throughout the day if needed; the number and ply of socks can be adjusted to accommodate for limb volume fluctuation during the day; and the socket itself is very durable. Because there are no compressible surfaces, the fit is reliable; it will not become "packed down" in high pressure areas. It is nonporous, easy to clean, and relatively maintenance free. It also does a fair job of eliminating shear as the coefficient of friction between the socks and socket is relatively low compared to that between the socks and skin. This type of socket is most challenging to fit and is not recommended for mature limbs that have lost much of their soft-tissue protection over bony prominences. It is also more difficult to adjust than other socket styles.

Socks and Sheaths

Prosthetic socks can be made from various combinations of cotton, nylon, wool, Lycra, polyester, and spandex. Some manufacturers have recently started using silver fibers in their socks as well to enhance the antimicrobial properties of their socks and sheaths (Figure 4). The prosthetic sock provides shock absorption, decreases the shear forces on the limb, and wicks away moisture. To further decrease friction, a nylon sheath is often recommended as the initial layer and the thicker socks would be donned over the sheath. The sock also provides the individual with a method to control socket fit; as the residual limb matures and shrinks, additional sock ply may be required to restore the fit and comfort of the socket.

Figure 4: Prosthetic sheaths are very thin stocking-like garments worn between the skin and prosthetic sock or socket liner. They are used to reduce friction, disperse moisture, and control bacterial growth.

Soft Inserts

Closed cell foam, used because they do not absorb moisture, can be molded over a model of the limb to create a soft insert. This insert lines the entire socket and terminates just proximal to the socket trim lines. For increased protection, a distal end-pad, which is an extra layer of soft material at the bottom of the insert, can be used to cushion the distal end of the tibia.

Flexible Inner Socket

If PTB theory is to direct weight bearing into specific areas of the limb and away from others, then the flexible inner socket is the incarnation of that idea. With this system, an inner socket is made over a model of the limb from a flexible material that will stretch upon the application of force. Then a rigid frame is built around the inner socket, corresponding to areas of the residual limb where weight bearing is desirable. The result is a socket that flexes away from forces in non– pressure-tolerant areas, but remains rigid in the force-tolerant areas. Because flexible sockets in rigid frames can eliminate compressive forces in any specific area, this system is useful for persons with particularly bony residual limbs and those with severe localized sensitivity. They are not recommended for residual limbs with adherent scarring, however, because pressure differentials created by the frame tend to amplify the shear forces on the limb.

Expandable Wall Socket

When the limb is amputated at or below the ankle, the resulting long residual limb present an interesting challenge to the prosthetist. The proximal trim lines of the prosthesis can be lowered to a more distal position on the limb because there is a long lever arm for prosthetic control during ambulation. However the distal residual limbs is larger in diameter than they are in the more proximally because the malleoli are still present. The prosthetist can accommodate for a larger distal size by creating a removable wall in the socket that is replaced after the prosthesis is donned, by using a specially designed soft liner, or by creating an expandable wall socket. The expandable wall socket is made from an elasticized material that stretches enough for the individual to push his or her limb through in weight bearing, and tightens up over the malleoli to provide suspension. This socket is too flexible to attach a foot to, so a rigid frame is made over the flexible socket with a small space between them in which the expansion can occur. This is a self-suspending socket that can be very comfortable for the person. It is difficult to fabricate this style socket, and it is even more difficult to make adjustments to the fit once it is fabricated.

Gel Liner

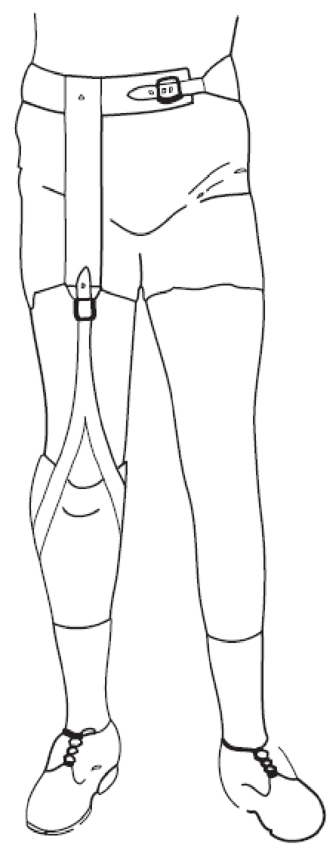
The term gel liner is loosely used in the field to describe a liner that is made from a material that exhibits gel-like properties. There are three basic varieties of these liners: (a) silicone elastomers, which are highly cross-linked at the molecular level; (b) silicone gels that have a relatively low amount of crosslinking; and (c) urethanes. The properties of these materials vary and are relevant to the prosthetist and person with amputation because they directly affect the forces that are transmitted through them to the residual limb. Gel liners are a key component of TSB sockets. Gel liners are designed to be worn directly on the skin or over a thin liner referred to as “liner liners.” Liner liners are thin nylon sheaths with silver fibers that are meant to be worn between the skin and gel liner to prevent skin irritation caused by the warm moist environment of the gel.

SUSPENSION

Another important consideration when designing a prosthesis is the method by which the prosthesis is held to the limb; this is referred to as the "suspension." When prosthesis is suspended perfectly, there is no relative motion between the socket and the limb. When motion occurs because of a faulty or inadequate suspension system, the limb is subjected to an entirely different loading pattern. This motion is referred to as "pistoning" as it bears some resemblance to the motion of a piston in the cylinder of an internal combustion engine. Pistoning can lead to pain, skin breakdown, and reduced control of the prosthesis. Great care should be taken to minimize motion within the socket. There are several strategies for suspension, they can be used individually as the primary mode of suspension or more than one technique can be used simultaneously to provide auxiliary suspension.

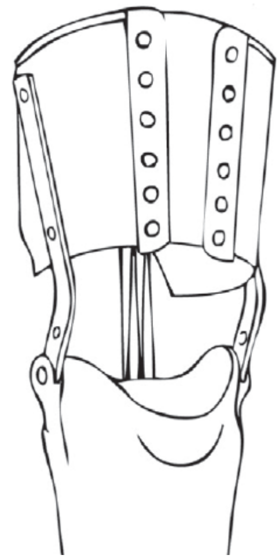
Waist Belt

A waist belt connected by an elastic strap to the thigh corset was used to suspend early transtibial sockets. Waist belt and inverted Y-strap suspends the prosthesis through tension in the elastic strap between the belt and Y-strap. The strap is fitted to allow hip and knee flexion during swing phase. The elastic recoil of the strap during swing phase assists swing limb advancement of the prosthesis.



Joints and Corset

The joints and corset feature provides suspension as well as a weight bearing element if the thigh corset is properly fitted over the femoral condyles. Thigh corset with knee joints is used when the residual limb is not capable of supporting the full weight of the patient



Cuff Strap

A cuff strap is a flexible leather cuff that attaches to the medial and lateral walls of the socket at the same point that orthotic knee joints would attach. The cuff strap suspension uses the proximal aspect of the patella as well as the femoral condyles to achieve suspension of the prosthesis on the residual limb.

Sleeve

One of the most versatile means of suspending a prosthesis is with a knee sleeve. A suspension sleeve provides suspension through two biomechanical principles: friction and vacuum. Sleeves provide a cosmetic, low profile, versatile means of suspension. Sleeves use friction against the shell of the prosthetic socket distally and the wearer's skin proximally to suspend the prosthesis on the residual limb.

Suction

Modern sleeves are referred to as “sealing sleeves” because they are made from nonporous materials that seal the proximal end of the socket against the skin so that no air can flow into, or out from, the socket. This creates a suction suspension.

Locking Liners

The first references to locking liners involve the use of a rollon silicon liner, referred to as an “Icelandic roll-on suction socket” (Iceross). These roll-on gel liners are compliant enough to contour nicely to the shape of the residual limb and include a threaded hole at the distal end. This hole serves as a point of attachment for the suspension hardware.

IMPRESSION TECHNIQUES

The first step in creating a well-fitting socket is capturing an accurate impression of the residual limb. This can be done in a variety of ways ranging from plaster bandages to noncontact optical scanners. Each technique has its own set of advantages and disadvantages and there is no one best method for every limb. Capturing a static impression of the limb is quite simple and any method will suffice if done properly. The challenging task is to capture the dynamic nature of the biological tissue by compressing the soft tissues during the process to simulate the conditions that will be on the limb during weight-bearing.

Hand Casting

During hand casting, the limb is gently wrapped with a plaster bandage and the prosthetist pushes in key weight-bearing areas while the plaster is setting up.

Pressure Casting

Another way to precompress the tissue is to use a pressurizing technique. This involves placing the limb into a vacuum or pressure chamber while the plaster is setting up.

Optical Scanning

Optical scanners can be used to capture the three-dimensional external shape of the limb to within 1 mm of accuracy. They are quite useful in situations when casting is impossible or impractical such as immediately following surgery or with bulbous limbs that cannot be removed from a plaster cast without cutting or distorting the cast.

ALIGNMENT

Alignment refers to the spatial orientation of the prosthetic socket relative to the foot. This alignment will influence the magnitude and direction of the ground reaction force throughout the gait cycle. There are four goals in prosthetic alignment:

1) Facilitating heel strike at initial contact.
2) Providing adequate single limb stability during stance phase.
3) Creating smooth forward progression (rollover) during the transition from early to late stance phase.
4) Insuring adequate swing phase toe clearance.

These goals are reached through dynamic alignment of the prosthesis, during which the person walks on a prosthesis that is fitted with an adjustable device that allows for alignment changes in all three planes. Prosthetic alignment can also be used in conjunction with socket fit to address pressure issues within the socket. Because of this socket fitting and dynamic alignment must occur simultaneously.

Bench Alignment

The first step in the alignment of a transtibial prosthesis is to position the socket in what is known as "bench alignment." This is the alignment that serves as the starting point for the dynamic alignment process.

Height

Once the prosthesis is bench aligned, the person dons the prosthesis, and stands with equal weight bearing on both lower extremities. The first measurement examines the length of the prosthesis. The goal is to achieve relatively equal leg length, comparing the intact and prosthetic limbs.

Dynamic Alignment

During the dynamic analysis, the prosthetist will ask the individual to walk in a safe environment, typically within the parallel bars, and observe the motion of the prosthesis throughout the gait cycle. Adjustments are made to minimize gait deviations and create a smooth and stable gait pattern. The prosthetist will attempt to create an energy efficient stride by minimizing the horizontal and vertical excursion of the center of mass. Goals for the optimal alignment are stance stability, swing clearance, equal step length, and energy efficiency.

Electronic Alignment

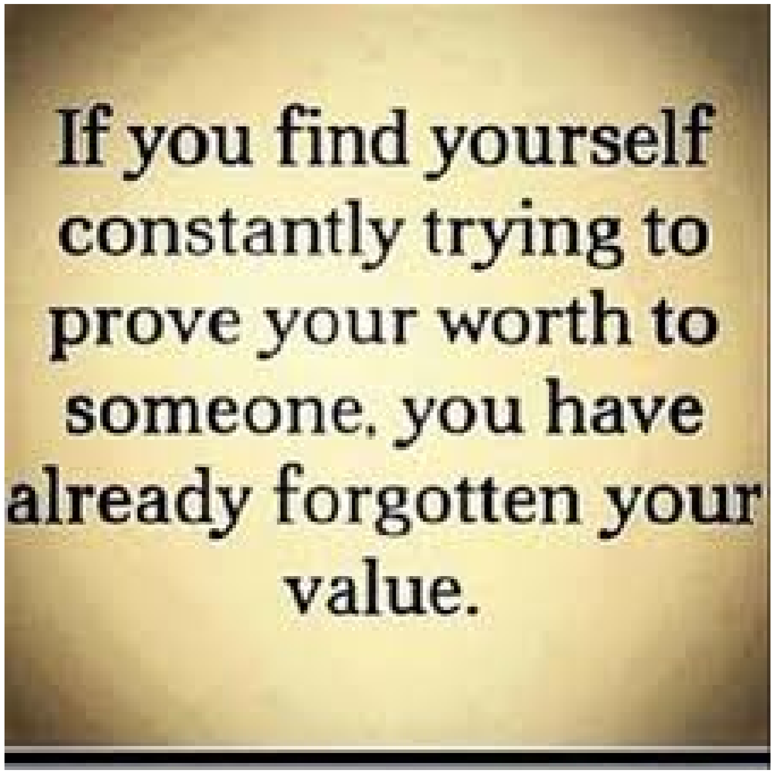
Electronic sensors imbedded in the prosthetic components are capable of transmitting real-time gait data to a nearby computer. The computer processes these data and superimposes a graph of the actual forces and moments for one complete gait cycle over a set of “normal” data.

ADDITIONAL FEATURES

There is an assortment of modular components that can be added to a prosthesis between the socket and the foot to enhance certain features and function of the prosthesis. These include shock absorbers, torque absorbers, and dynamic pylons. The downside of such components are that they weight and require sufficient clearance between the socket and foot. They may limit foot choices for that reason and are typically used in cases where excessive shock is expected or when an acceptable gait pattern is not attainable with existing feet alone. Care should be taken to mount these components as proximal as possible on the prosthesis to minimize the inertial effects of the additional weight during swing phase.

GAIT DEVIATIONS

Gait deviations can be caused by improper socket fit, misalignment of the prosthesis or by weakness or other musculoskeletal pathologies of the individual. Careful evaluation is essential to determine the cause of the deviations and what can be done to correct them. Variations in limb volume or shoe type can introduce deviations in a prosthetic wearer's gait that had not been exhibited before. It can be very productive to ask the person if there have been any changes in their routine recently. Changes in diet, medications, shrinker wear, or activity level can all effect limb volume. If a shoe with a higher or lower heel is placed on the prosthesis it will change the orientation of the socket to the ground. Unless there is a component that will accommodate the new heel height, the patent's gait will be adversely affected.


If you find yourself
constantly trying to
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someone, you have
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