Stump–Socket Interface Conditions

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Introduction

Each year, hundreds of thousands of people undergo a limb amputation. In the US alone, the amputation rate is approximately 84,500 to 114,000 cases per year [1, 2]. There are, in general, two reasons necessitating the surgical removal of a limb: (1) traumatic injury to the point that an extremity cannot be salvaged, for example as experienced in motor vehicle accidents or falls; (2) peripheral vascular disease, e.g. consequent to diabetes or cardiovascular dysfunction. Traumatic injury patients are typically more active and will have a greater number of years as an amputee than dysvascular patients. Thus the performance needs of a prosthesis, a mechanical device intended to replace the missing extremity, are typically more demanding for these individuals.

A prosthesis is made up of a socket that surrounds the residual limb, a terminal device (hand or foot), and an apparatus to connect and adjust the position of the socket relative to the terminal device (Fig. 9.1). Typically the socket is custom-designed for the individual patient while the terminal device and connecting apparatus are purchased commercially. It is recognized in clinical practice that proper design of the socket shape is crucial to the successful clinical performance of a prosthesis. Much of a prosthetist's effort goes into designing and fabricating the prosthetic socket.

Pressure Ulcer Problems Related to Wearing Prostheses

Though both upper-limb and lower-limb prostheses are common, it is lower-limb amputees who most often experience pressure ulcer problems from mechanical irritation with the prosthetic socket. The relatively high loads and their lengthy application times from continual weight bearing and, for the trans-tibial case, the close proximity of the bone to the socket are the reasons. The challenge to a prosthetist is to create a socket that distributes interface stresses in such a way that the prosthetic limb is stably coupled to the bony skeleton yet does not overstress soft tissues. On some patients, this is a seemingly impossible challenge. Stable residual limb–prosthesis mechanical coupling, which will induce a sense of stability to the amputee during gait, requires that high interface stresses be applied. But to avoid skin trauma, interface stresses should be kept low. The skin over the leg

Fig. 9.1. Prosthetic limbs. A trans-tibial prosthesis (*left*) and a trans-femoral prosthesis (*right*) are shown. From Seattle Limb Systems (http://www.soginc.com/SLS) and Ossur Prosthetics (http://www.reykjavikresources.com), respectively

was not intended to tolerate the stresses of weight bearing. Skin there is very different from that on the bottom of the foot, for example.

To design an effective socket, a prosthetist must consider these conflicting design goals and achieve an effective stump–socket interface stress distribution. Using traditional socket design techniques, prosthetists concentrate stresses at load-tolerant areas, for example at the patellar tendon and popliteal fossa on trans-tibial amputees [3, 4] (Fig. 9.2). Loading at the distal third of the residual limb, often a sensitive region, however, is unavoidable. Total contact sockets [5] intended to distribute load uniformly over the stump surface have also been successful and have become increasingly popular in recent years. High distal load-bearing on the bottom of the stump is generally recognized as unfavorable since it can traumatize the soft tissues between the distal end of the bone and bottom of the residual limb. Excessive tissue trauma from distal end-bearing might necessitate surgical revision or amputation to a higher anatomical level. Stresses can be applied in two directions – pressure, which is perpendicular to the skin surface, and shear stress, which is tangential to the skin surface. Both can provide support at the stump–socket interface but above a certain level and duration can induce breakdown.

Skin responds to pressure differently than it does to shear stress. Constant pressure reduces perfusion and can lead to ischemia and tissue necrosis. Just 8 kPa (60 mmHg) pressure is sufficient to occlude skin blood flow [6]. Often, under static loading conditions underlying muscle tissue is affected sooner than skin [7, 8] due to its greater vascularity and metabolic demands. Thus soft-tissue injuries can form in deeper tissue before even being visible on the skin surface.

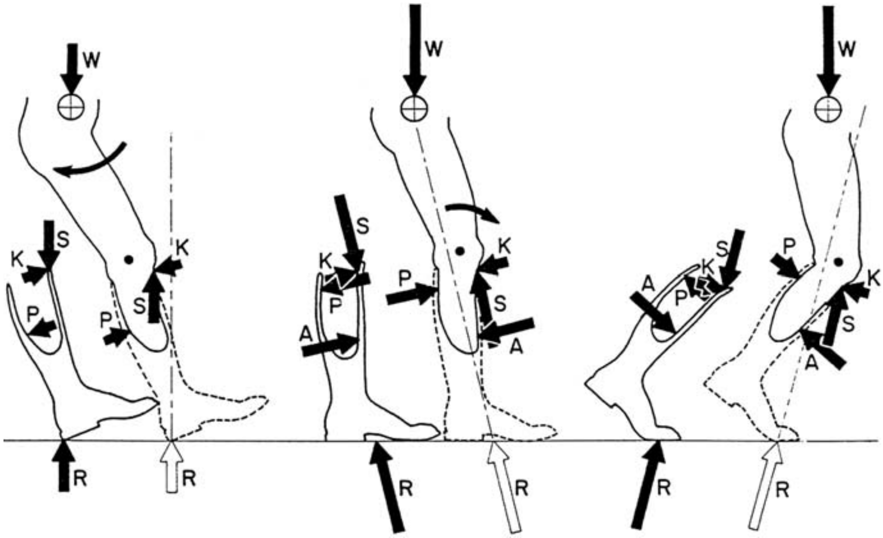

Fig. 9.2. Interface loading during gait. With a patellar-tendon-bearing prosthesis, pressures and shear stresses are concentrated at the patellar tendon bar and at the popliteal fossa. Anterior distal and posterior distal loading, however, are unavoidable. *Left panel* is during heel contact, *center panel* is during mid-stance, and *right panel* is during push-off. From: Radcliffe CW, Foort J. The patellar-tendon-bearing below-knee prosthesis. The Regents of the University of California, 1961

Skin response when shear stress is added is much dependent upon how the shear stress is applied. If shear is applied with slip between the supporting surface and the skin, then it is termed "friction". Friction can lead to blister formation, with blister fluid collecting below the granular layer and above the basal cell layer of the epidermis [9, 10]. Heat built up between the two sliding surfaces may be an important contributor to blister formation. At locations where the epidermis is very thin, an epidermal abrasion will form instead of a blister. For shear stress application without slip between the supporting surface and the skin, often termed "tangential shear," the applied force is distributed through a greater volume of tissue, thus reducing local stress concentrations and reducing the risk of injury. Heat build-up is also reduced. Skin can thus tolerate greater stresses if tangential shear is applied rather than friction [11].

Studies have been conducted attempting to quantify relationships between interface stresses and breakdown. An inverse relationship between pressure and duration in the development of a pressure ulcer was initially proposed in 1942 [7] and later studied further by a number of investigators [8, 12–18]. The results demonstrate a second-order relationship between the threshold pressure for ulcer formation and the duration of pressure application. The threshold pressure decreases quickly as duration is increased. Furthermore, soft tissue can tolerate moderately high load levels provided they are applied intermittently and not continuously. Other studies show that at a sufficiently high level of shear, shear stress will reduce the pressure necessary to cause blood flow occlusion by about one half [19]. Thus in this sense adding shear stresses is unfavorable. However, cyclic shear stresses, as occur on the stump during ambulation with a prosthetic limb, presumably allow release during each step, thus reducing the duration of occlusion and the associated detrimental effects of shear. Under frictional loading where there is slip between the support surface and skin, often unavoidable in prosthetics, quantitative evaluations demonstrate that it is more favorable to apply low frictional loads for a long time than to apply high frictional loads for a short time [20]. Therefore, concentrated frictional stresses should be avoided, and low stresses applied often are a more favorable alternative. Small amounts of fluid added to the interface, as might occur during sweating for example, will increase shear stresses. If the interface is extremely wet (flooded), however, the shear stress will decrease [21]. Thus sweat can alter the original stress distribution designed by the prosthetist. The effects of sweat at the skin–support interface are discussed in more detail in a separate chapter (Chap. 8).

While there is no doubt that interface stresses induce breakdown, it is important to recognize that soft tissues have the capability to remodel and adapt to repetitive stresses. Thus the threshold for inducing injury can be altered through practice. Clinical experience, for example, shows the effectiveness of a mobilization program for an individual with spinal cord injury who has undergone myocutaneous flap surgery to treat a pressure ulcer [22–24]. A 3-week period of pressure relief is followed by short periods of weight bearing in bed. Subsequently, range of motion is increased so as to apply tensile forces to the area, and then a sitting program is initiated, increasing weight bearing duration over time. Tissue tolerance should slowly improve. For an amputee patient with adherent scar tissue on the stump, lubricated tissue massage might be used to improve deep tissue mobilization.

Despite the relevance of soft tissue adaptation to mechanical stress, skin adaptation at the cellular and molecular level is a minimally investigated area of research [25]. A study on pigs showed that after a 1-month period of combined pressure and shear loading on the hind limb, collagen fibrils, the major load-bearing components in skin, were 20.4% larger in diameter than fibrils from unstressed control skin [26]. Similar results were obtained using an in vitro skin organ culture model [27], suggesting that the adaptation process can occur without blood flow being present. In tendon release studies, collagen fibers disaggregated and the density of nonsulfated proteoglycans increased when tension was released [28, 29]. When the tendons were repaired and tension restored, collagen fibers reappeared, the density of nonsulfated proteoglycans decreased, and the density of sulfated proteoglycans increased. Epidermal proliferation and thickening in response to repetitive mechanical loading has also been demonstrated [30, 31]. Thus distinct structural adaptations to repetitive mechanical stress have been shown.

Further investigation into the bioprocesses of adaptation is needed if the adaptive capabilities of soft tissue are to be used to maximal advantage in clinical prosthetic treatment. Molecular-based therapies might be pursued to facilitate adaptation in cases where it is impeded or lacking. A hypothesis of the detailed bioprocesses involved in skin adaptation has been suggested [32] but is currently unproven.

Given that tissue response, whether breakdown or adaptation, is so sensitive to the applied stresses, an important need in prosthetics is to quantify the magnitudes and directions of stresses applied at the stump–socket interface and to identify the prosthesis design features to which they are most sensitive. Such knowledge could enhance treatment as well as prosthetic componentry design.

Interface Stress Measurement

Interface pressures and shear stresses during ambulation with a prosthetic limb have been studied by a number of investigators using a variety of instruments (see Fig. 9.3 for an example system). Strain-gauge transducers [33–48], fluid-filled sensors [49, 50], pneumatic sensors [51–53], printed circuit sheets [54–57], and a field coil and magnet transducer [58] have been used. Only Sanders' and Williams' transducers measured both pressure and shear stress simultaneously. Results show interface pressures to approximately 415 kPa and resultant shear stresses to approximately 65 kPa [57, 59, 60]. As a reference, peak pressures on the foot during walking typically range from 700 to 870 kPa pressure [61, 62], and peak shear stresses from 24 to 70 kPa [63]. 95 kPa of suction applied for 17 min can produce a skin blister [64]. 53 kPa of frictional shear for 40 rubs on a human limb can induce a blister [20]. Thus it is of little surprise that amputees experience breakdown on their residual limbs; the stresses induced are relatively high.

Of relevance to prosthetic design is what happens to interface stresses when features of the prosthesis or amputee subject are changed. The most studied prosthesis design parameter is alignment of the prosthetic components [35, 38, 65–68]. Typically changes in peak interface stresses or interface stresses at the first peak in the axial force curve are analyzed. Results from testing trans-tibial amputee subjects, in general, show that interface stress changes at anterior sites for misaligned compared with aligned prostheses are greater than those at posterior sites [35, 66, 67]. This is a reasonable result given the much thinner layer of soft tissue over bone on anterior trans-tibial stump surfaces compared with posterior surfaces. For translational and angular misalignments that were substantial but deemed clinically safe for lab testing, pressure changes at a site up to 40 kPa [65, 68], 16 kPa [67], and 81 kPa [66] have been reported. If transducers were inserted between the limb and socket instead of flush with the interface, however, much higher pressure changes were measured: 266 kPa [35] and 147 kPa [38]. Sensor protrusion into the skin, however, may have caused erroneously high measurements in these latter studies [69, 70].

Interestingly, three studies showed that compensation for an alignment change in a positive direction was not simply the reverse of the compensa-

Fig. 9.3. Example of interface stress measurement system. With this system pressures and shear stresses are monitored at 13 socket sites during standing or walking. The transducers and mounts are small and lightweight (< 25 g) so as to minimize weight addition to the prosthesis

tion for the alignment change in the negative direction [35, 66, 67]. At most sites, subjects adjusted their gaits to maximize or minimize interface pressures at the clinically-deemed optimal alignment instead of at the modified alignments. This result points to the importance of an amputee's ability to compensate to prosthesis changes. Subjects adjusted their gaits to accommodate the modifications, in part by the interface conditions they sensed, and those adaptations were not predictable. Variability (standard deviation/mean) did not increase for steps at misaligned compared with aligned settings [66, 67], a result similar to that reported by Jones [71] in analysis of pylon force and moment data.

Effects of changes in socket design and componentry on interface pressures have also been studied [46, 50, 53, 54, 56]. However, most of these reports were in-depth case studies investigating the performance of one particular feature. Generalizations about socket design could not be made. Krouskop [53], however, conducted pressure studies on 18 trans-femoral subjects and noted consistent differences in the pressure distributions between quadrilateral and normal-shape, normal-alignment (NSNA) sockets.

The NSNA had distal loading around the distal femur, while the quadrilateral socket did not.

With advances in materials technology, novel interface liners have been created that can potentially help to improve interface stress distributions. Closed-cell foams are used extensively in the industry. They are typically polyethylene, urethane, or silicone-based. Liners made of polyethylene foams such as Pelite or Plastezote are easily fabricated since these are relatively moldable materials. They also are easily modified later if necessary, using grinding or heat. However, an important weakness is that they deform over time in an unpredictable way, thus altering the original interface shape. More recently, elastomeric liners have become increasingly popular. They are typically made from urethane, silicone elastomers, silicone gels, or an elastomer/gel combination. Elastomeric liners fit snugly on a residual limb, providing direct support during stance phase and, if equipped with a locking pin, suspension during swing phase. They are intended to maintain total contact with the residual limb, thus reducing localized skin tension and shear compared with a conventional closed-cell foam material. This environment should be more comfortable for the amputee. Importantly, because different products have different mechanical properties [72–74], a wide range of liners to meet a range of clinical needs are available. This variety is helpful to prosthetic fitting.

Though the stress changes induced by prosthesis or liner modifications can be relevant to fit, to date the most important feature shown to induce changes in interface stress loading is time. While for short leg-off times (minutes) interface stress changes have been measured at approximately 10%, for sessions more than 3 weeks apart differences can be higher than 50% [46, 60, 65, 66, 67]. In one study even 5-h intervals showed appreciable changes [75]. In this later study, the absolute magnitude pressure difference for 5-h intervals was comparable to that between sessions 5 weeks apart. Thus diurnal changes, not just long-term changes, can be appreciable. Limb shape changes are the most likely sources of interface stress fluctuations, and would be expected to have a strong impact given how sensitive fit is clinically to socket shape.

Problems with Changes in Stump Shape Over Time

Changes in residual limb shape occur for a number of reasons and to varying degrees, depending on the patient's activities, weight, amputation procedure, health, and other factors. Part of the challenge in prosthetic fitting is to accommodate these shape changes.

Differences in the time courses of the two types of changes, diurnal and long-term, must be recognized. Diurnal changes are cyclic, occurring over a 24-h period. In general, residual limbs shrink from the morning to the evening. The change is likely due to extracellular fluid movement, as this mechanism of transport is relatively slow compared with the blood [76, 77]. The pumping effect the socket has on residual limb soft tissues during ambulation may help drive out fluid from within the interstitial spaces over the course of a day [78]. Fluid flow entering the interstitial spaces from the vasculature is low because the prosthetic socket acts as a rigid container to prevent limb expansion, thus preventing an increase in the blood–interstitial fluid pressure difference. The result is an overall dehydration of soft tissues. At night, with no socket to constrain the tissues and the dynamic pumping effect removed, the blood–interstitial fluid pressure difference increases, interstitial fluid returns, and the limb swells back to a larger size.

Long-term shape changes are different than diurnal. They occur over weeks or months, and typically are not easily reversible. They are probably due to soft-tissue remodeling, and can be caused by a variety of factors, including limb maturation, large weight changes, muscle atrophy, and changes in the patient's vascular condition. Thus the mechanisms of diurnal and long-term shape changes are quite different, and one would expect the way they change residual limb shape to be quite different as well.

Experimental research suggests shape changes are distributed differently for diurnal variation than for long intervals [75]. In eight trans-tibial amputees, diurnal changes tended to induce a relatively uniform shrinkage over the residual limb surface. Six-month changes tended to be localized. Variance of the change in cross-sectional area down the length of the residual limb for 6-month intervals was on average 2.8 times higher than that for diurnal intervals. The differences are important because they suggest that different treatment methods might be needed to accommodate diurnal vs. long-term differences.

There are a limited number of methods to accommodate residual limb shape change. Adding/removing stump socks, filling/deflating inflatable inserts, modifying the inside socket shape, and using elastic stockinet shrinkers are examples. The former three methods add material inside the socket to replace departed tissue. Limited data collected on trans-tibial amputee subjects suggests that adding/removing stump socks of uniform thickness does not return interface stresses back to their original values before shrinkage occurred [79]. This result well illustrates one reason why prosthetic fitting is so difficult. A prosthetist must design a limb that will distribute interface stresses properly despite substantial changes in limb shape.

Most air-inflatable insert products are problematic because they tend to perform well at only a single volume level as opposed to a range of levels [80]. Thus they lack versatility. Use of liquid-filled inserts might help to overcome this problem since liquid is relatively incompressible. Whatever route is used to address this challenge, a successful approach will likely need to have some means for allowing subtle volume changes over the course of a day, preferably without the patient needing to manually make the adjustments.

Though progress is being made in interface liners and treatments for shape change, part of the challenge is that it is difficult to conduct controlled testing where just one variable, e.g. the type of liner, is changed. Other features that depend on liner performance, including the patient's stump shape, might change as well. Therefore, the quality of a design is difficult to assess quantitatively, and enhancements and improvements are slow. If an additional means to test different designs that did not have these limitations could be developed, then progress would likely proceed more quickly. Clinical testing could then be used to test only the most promising treatments. Computer modeling is one possible option.

Computer Models for the Design of Stump Sockets

Computer models have been used to try to predict interface stresses for different prosthesis designs and residual limb conditions. Several reviews exist on the topic [81–83]. An advantage of computer models over direct interface stress measurement is that they allow different sockets to be tested without subjecting an amputee's residual limb to potentially detrimental interface stress patterns. In concept, optimization strategies could be developed to interface with the computer models to design an optimal socket for each individual amputee early on in fitting.

Finite-element modeling has been the most common computer modeling method used to try to predict stresses at the stump–socket interface [44, 48, 68, 84–104]. The concept of finite-element modeling is to describe the residual limb and proposed socket design computationally as collections of small blocks or elements. Use of these small simple shapes to characterize the complex residual limb and socket makes the analysis computationally feasible. The stiffness and other material properties of the residual limb and socket, information typically derived from mechanical testing experiments, need to be specified for the analysis to be carried out. Then the mechanical interaction of each element with its neighboring elements is analyzed, based on loads applied in the computer model to the prosthesis or to the proximal residual limb reflective of standing, walking, or some other activity of interest. The computational analysis corresponds to a minimization of the potential energy in the system. The result is a complete description of the stress distribution throughout the residual limb and socket (Fig. 9.4).

The results from finite-element models are potentially very attractive and useful to prosthetists. With this tool a prosthetist can determine the interface stress loading patterns as well as stresses within different residual limb soft tissues for a number of different socket designs before ever actually putting a prosthesis on the patient. However, prosthetic computer models are still in their nascent stages, and they are not yet accurate or rapid enough for clinical use. Part of what makes these models so difficult to develop is that it is computationally very difficult to describe movement between a residual limb and prosthetic socket (pistoning). Some progress has been made using gap [68, 103] or automated contact elements [104]. Further, accurately specifying the material properties of the residual limb for each individual amputee is very challenging. Some instruments for assessment have been developed and used in clinical research [105–107]. Much progress has been made in

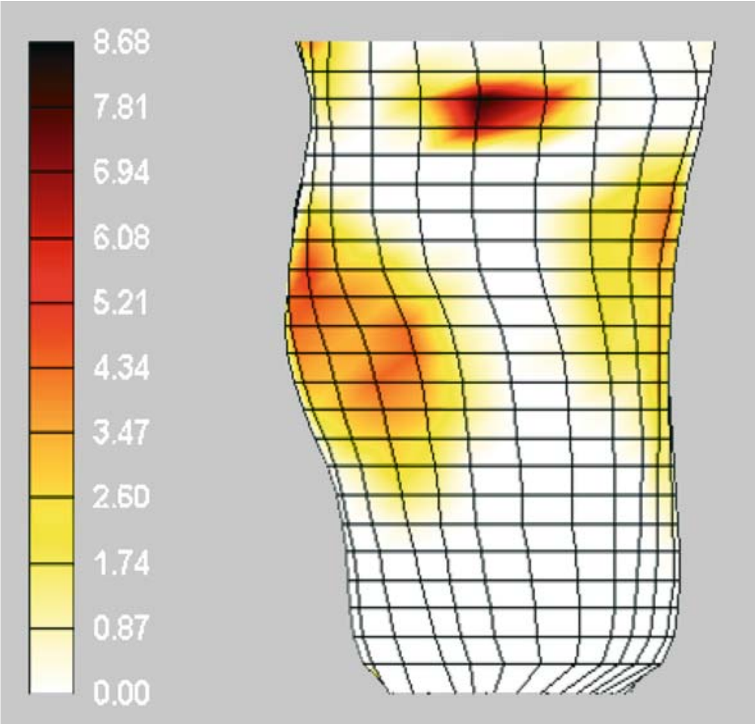

Fig. 9.4. Residual limb finite element model. Donning pressures are predicted for a trans-tibial residual limb in a patellar-tendon-bearing socket. Pressures are concentrated at the patellar tendon and tibial flares, as expected. Units are kPa

the measurement of both the socket and the residual limb shape [108]. Several imaging methods have been used, though the use of video cameras with optical or laser light sources are currently the most common [109–118]. Mesh-generation strategies to create the models quickly and easily have also been developed [119]. Thus considerable progress in finite-element modeling of residual limbs has been made since it was first attempted in 1985 [84], though quality of the models to a level acceptable for clinical practice is still in the future. Once the models are developed a range of features could be tested to establish how they affect interface stress loading, including diurnal and long-term shape change and treatments for stabilization, amputation procedure, and fluid inserts.

Future Perspectives

It is important to recognize that though interface stresses are a crucial feature of prosthetic fit and performance, ultimately it is the response of soft tissues to the stresses that determines breakdown. Several measurements related to tissue quality are possible, including transcutaneous oxygen tension [120, 121], laser Doppler flowmetry [122, 123], and thermal recovery time [124–126]. Transcutaneous oxygen tension is the partial pressure of oxygen in tissue and is typically used to determine level of amputation. Electrodes containing photoelectric sensors capable of distinguishing the wavelengths of oxygenated versus reduced hemoglobin are positioned on the skin to take the measurement. Laser Doppler flowmetry, a technique for assessing flow or perfusion in the microcirculation, is similarly used to determine amputation level. Here the Doppler effect is assessed using a low-power laser directed at the moving blood particulates. Thermal recovery time is a method under development intended to predict the risk of skin breakdown. It is the time after release of a moderate load that is required for the skin temperature difference between the stressed site and a control site to reach either a maximum or a constant value. In a population of nursing home patients, thermal recovery time was shown to correlate strongly with the risk of developing pressure ulcers, with risk defined using data on ulceration occurrence over a 1-month follow-up period [125]. The method was also used in a separate investigation to demonstrate that diabetic patients with autonomic neuropathy had an impaired thermal recovery time after pressure relief compared with normal control subjects [126]. Use of thermal recovery time or a feature from some other imaging modality may possibly quantify breakdown risk at different locations on a stump before a definitive prosthesis is designed. Such instrumentation would be very advantageous to prosthetic fitting.

The direct attachment of a prosthesis to the bony skeleton is a treatment strategy that has been pursued for over 50 years [127]. The concept is to surgically implant a strong biocompatible post within the medullary cavity of a femur or tibia that projects out through the skin. A prosthetic pylon, foot, and, in the trans-femoral case, a knee are then attached to this implant. During weight bearing, ground-reaction forces are transmitted directly to the bony skeleton. An advantage of this method of prosthesis attachment over the traditional prosthetic socket is that soft tissue loading is minimal. Thus skin breakdown problems from contact with a prosthetic socket are non-existent.

Interestingly, mechanical failure at the bone–implant interface has not proven particularly problematic in either animal [128, 129] or human [130–132] studies of direct skeletal attachment. In some patients, the bone–implant interface has proven stronger than either the bone or the prosthesis itself. There is, however, an important limitation with the treatment. The difficulty is that the skin–implant interface is a major source of bacterial penetration and migration. Achieving an effective seal between the skin and the implant is very difficult. Exit site problems are similar to those experienced by peritoneal dialysis patients, prosthetic urethra wearers, and individuals with indwelling blood access devices [133]. Epidermal cells tend to migrate on the implant rather than attach directly to it. Not only can bacteria migrate through spaces at the cell–implant interface, epidermal cells can migrate down and attempt to "grow out" the implant. The result is a site that is, to some degree, perpetually irritated. In some cases the site will be stable for a lengthy period, while in other cases it worsens and an infection develops. Once the bone–implant interface is infected, the implant typically must be removed. Thus direct skeletal attachment is an area of active research and has shown some promising results, but there are still important challenges to be overcome.

Summary

Wearing a prosthesis puts high demands on soft tissues covering the residual limb, particularly for active lower-limb amputees. A prosthetist must use clinical experience, knowledge gained from research studies on tissue response to stress, the capability of the skin to adapt, and individual tissue quality assessment to design an effective prosthesis for an amputee. If stresses at the stump–socket interface are not properly distributed, the amputee can experience blister, cyst, or ulcer formation on the residual limb, conditions that in severe cases worsen and lead to further disability.

Prosthetic interface mechanics studies have provided insight into how amputee and prosthesis characteristics alter interface stresses. Those studies highlight the importance of a person's adaptive capabilities to accommodate prosthesis modifications. An amputee uses, in part, pressure and shear sensation at the stump–socket interface to alter walking style so as to adjust to changing conditions. Results from interface stress studies suggest that while changes in prosthetic alignment, walking speed, and componentry can be accommodated for, changes in the residual limb over time, particularly stump shape and volume, are very difficult to manage. A challenge to prosthetists, amputees, bioengineers, and others in the prosthetics community is to develop effective treatments to overcome shape and volume changes and stabilize fit.

Computer models may eventually contribute towards improvement in the speed and quality of individual socket design for amputee patients. Much progress has been made in computer modeling towards limb geometry and mechanical property characterization, and towards interface specifications. However, until models are shown to accurately predict interface pressures and shear stresses, the capability to use finite element modeling in prosthetic socket design is a goal for the future.

Direct skeletal attachment of a prosthesis to the bony skeleton has been performed on a limited number of amputee patients and may represent a viable means of avoiding the stump–socket interface challenge altogether. However, another interface, the skin–implant interface, is proving problematic in direct skeletal attachment efforts. The interface, once again, will be our challenge.

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