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Parametric analysis using the finite element method to investigate prosthetic interface stresses for persons with trans-tibial amputation

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Abstract—A finite element (FE) model of the below-knee residual limb and prosthetic socket was created to investigate the effects of parameter variations on the interface stress distribution during static stance. This model was based upon geometric approximations of anthropometric residual limb geometry. The model was not specific to an individual with amputation, but could be scaled to approximate the limb of a particular subject. Parametric analyses were conducted to investigate the effects of prosthetic socket design and residual limb geometry on the residual limb/prosthetic socket interface stresses. Behavioral trends were illustrated via sensitivity analysis.

The results of the parametric analyses indicate that the residual limb/prosthetic socket interface stresses are affected by variations in both prosthetic design and residual limb geometry. Specifically, the analyses indicate: 1) the residual limb/prosthetic liner interface pressures are relatively insensitive to the socket stiffness; 2) the stiffness of the prosthetic liner influences the interface stress distribution for both the unrectified and patellar-tendon-bearing (PTB) rectified models—the external load state appears to influence the interface pressure distribution, while the prosthetic socket rectification appears to influence the interface shear stress distribution; 3) the interface pressures are very sensitive to the prosthetic rectification; 4) the shape and relative bulk of soft tissue may significantly influence the interface pressure distribution; 5) the interface pressure distribution is also influenced by the residual limb length; and 6) the stiffness/compliance of the residual limb soft tissues may significantly alter the interface pressure distribution.

Key words: *amputation, finite element analysis, pressure, stress.*

INTRODUCTION

Computer models of the lower extremity residual limb have been utilized to investigate the residual limb/prosthetic socket interface stresses; this interface stress distribution consists of both normal stresses (pressures) and tangential stresses (shears). Computer modeling, or numerical analysis, of the residual limb and socket offers several advantages over experimental measurements in the estimation of prosthetic interface stresses. For example, the use of numerical analysis, as opposed to experimental analysis, allows examination of the entire residual limb/prosthetic socket interface. Information regarding the subcutaneous stresses may also be obtained. In addition, prospective socket designs, characterized by material modifications and/or alternative socket rectification schemes, may be investigated prior to socket manufacture. In fact, hypothetical designs that cannot be fabricated due to technological limitations may also be investigated. Finally, the investigation of the effects of various factors on a specific output, such as the interface stress distribution

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via parametric analysis, is only feasible using numerical analysis. Isolated parameter variation is extremely difficult using experimental methods.

Parametric analyses have been conducted to investigate forces and moments exerted on the below-knee (BK) residual limb (1), residual limb/prosthetic socket interface pressures (2,3), and prosthesis design (4). Nissan (1) used a simplified three-dimensional biomechanical model of the short BK residual limb to investigate the effects of load transmission area, tibial geometry, and the role of the fibula on the forces and moments exerted on the residual limb. In contrast, Reynolds (2) and Reynolds and Lord (3) used axisymmetric, two-dimensional finite element (FE) analysis to examine the effects of socket rectification, friction between the residual limb and prosthetic socket, and socket material properties on the BK residual limb/prosthetic socket interface pressures. Quesada and Skinner (4) also conducted FE analysis. Their three-dimensional model of the patellar-tendon-bearing (PTB) prosthesis was used to investigate the influence of prosthetic design parameters (suction and socket stiffness) on the interface pressure distribution.

The purpose of this paper is to present a generic geometric FE model of the residual limb and prosthetic socket, and to summarize the results of parametric analyses conducted to investigate the influence of prosthetic design parameters and residual limb geometry on the interface stress distribution.

METHODS

Introduction to the FE Method

The FE method is a numerical technique that allows investigation of complex structures (defined as having complicated geometry and/or complex material properties). For simple structures, the solution to the problem can often be obtained analytically. For complex structures, however, an exact solution is rarely possible.

The FE method is an approximate solution method whereby a complex structure is discretized, or divided, into a number of regularly shaped pieces, known as elements. Each element is defined by several nodes, or points, the coordinates of which establish the geometry of the structure. The behavior of the complex structure is then approximated as the sum of the respective responses of each of the regularly shaped elements. Due to the rather large number of computations that generally result from the application of the FE method, computers are typically employed to perform these calculations.

FE investigations may include structural (i.e., stress analysis, deformation analysis, fatigue analysis, crack propagation), heat transfer, fluid flow, and/or electromagnetic analysis. In biomedical engineering, structural analyses have been the most common. These investigations have included stress analysis of prosthetic implants, bone remodeling, and current flow through the heart.

FE Model of the BK Residual Limb

A FE model of the BK residual limb and prosthetic socket was created to investigate the effects of parameter variations on the interface stress distribution during static stance. This model was based upon geometric approximations of anthropometric residual limb geometry (geometric model) and was not specific to an individual person with amputation (generic model). Scaling of this "generic geometric" FE model may therefore enable analysis of many individuals with a single model. The painstaking task of digitizing radiographs and the subsequent mesh development for each individual may be avoided.

The MARC FE software, and Mentat pre- and post-processor (MARC Research Analysis Corporation, Palo Alto, CA) was utilized for all FE analyses.

Geometry

As stated previously, the geometry of both the residual limb and prosthetic socket in this model has been approximated by standard geometric shapes, the size and selection of which were based on available anthropometric data (5–7). The femur was modeled as a cylindrical shaft, with the femoral condyles approximated by spheres. The joint space, cartilage, and cruciate ligaments of the knee were lumped into a tapered elliptical cylinder. The tibial plateau was modeled as a tapered elliptical cylinder, with the tibial shaft represented by a tapered triangular prism; the tibial tubercle was represented as an embedded sphere. The fibula was modeled as a triangular prism of constant cross section, with the fibular head approximated by an embedded sphere. Finally, the patella was represented as a rounded rectangle. This model of the bone and cartilage of the BK residual limb is illustrated in **Figure 1.**

Due to muscular atrophy, the shape of the residual limb is generally somewhat conical. As such, the external surface of the modeled soft tissue was approxi-

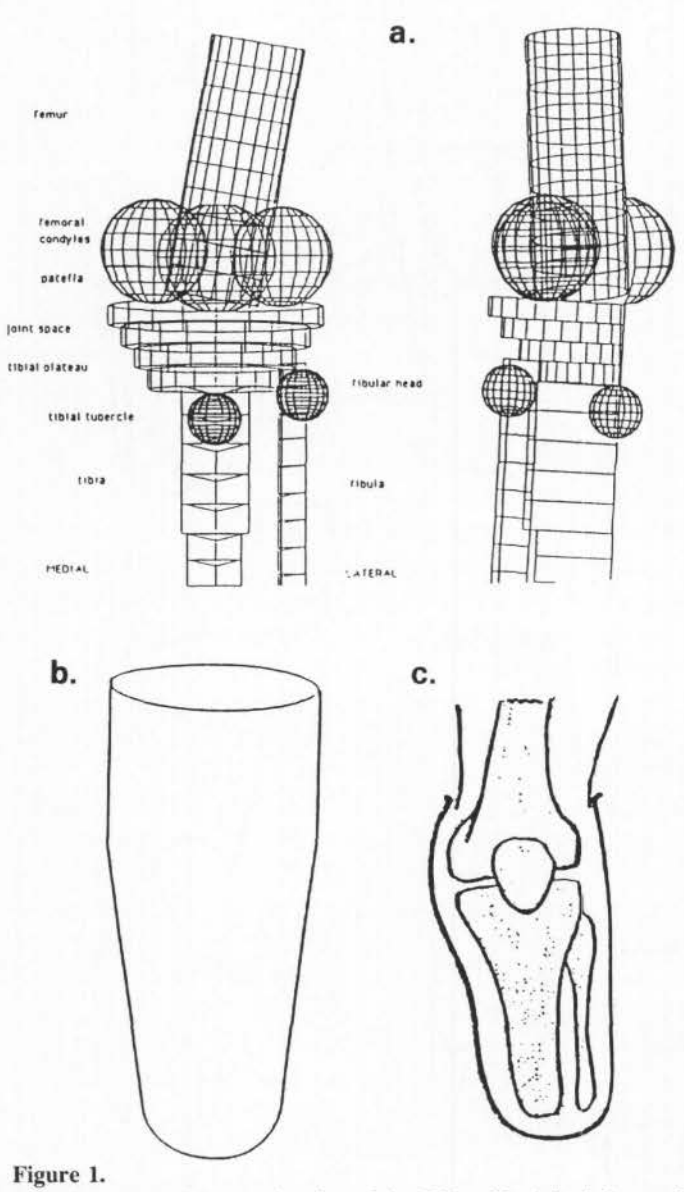

Figure 1.
Generic, geometric approximation of the BK residual limb: internal frontal and sagittal planes (a); surface structures (b); a diagram of the "actual" BK residual limb geometry is shown for comparison (c). Note that the model included 5° of knee flexion to approximate typical prosthetic alignment; the tibio-femoral angle was 170°.

mated by an elliptical cylinder above the knee, which was gradually tapered below the knee. The soft tissues of the distal end were represented by an elliptical dome (**Figure 1**).

This modeled tissue was encased in a 6 mm layer representing a soft prosthetic liner, and was further surrounded by a 3 mm layer representing a prosthetic socket. Each of these structures was cut away over the anterior and posterior aspects of the femur, and the level of the proximal brimlines was consistent with typical socket fabrication guidelines.

Transverse slices of this lower limb CAD model were taken at 1 cm increments. The information was then digitized and built into a three-dimensional mesh of 8-node linear, isoparametric, hexahedron elements. The FE mesh was nonuniform; areas of minimal tissue thickness, or areas where stress gradients were expected to be high, were subjected to greater mesh refinement. On average, the mesh consisted of 80–100 elements per transverse level; the nominal model contained 20 transverse levels and consisted of 1,688 elements and 2,221 nodes. To evaluate the accuracy of the FE mesh, models using higher order elements and more refined meshes of linear elements were created and analyzed. The nominal limb mesh was found to be sufficient for stress analysis. Extensive optimization of the mesh was performed to minimize the bandwidth of the model, reducing both the model run-time and the memory requirements; the semi-bandwidth of the nominal FE model was 210.

Material Properties

FE model description requires that the material properties of all modeled structures be quantified. For the generic geometric limb model, these structures include the residual limb tissues and the prosthetic liner and socket.

The mechanical properties of bone and articular cartilage in compression have been studied in some detail over the past 20 years. However, as bone is several orders of magnitude stiffer than bulk soft tissue, and only static stance was modeled, the femur, tibia, fibula, and patella (as well as the articular cartilage of the knee joint) were modeled as a fixed internal boundary. This approximation significantly reduced the number of degrees of freedom in the model.

In contrast to bone and cartilage, little information regarding the mechanical properties of bulk soft tissue in compression is available. *In vivo* indentor studies, conducted on various regions of the calf for both persons with BK amputation and nondisabled subjects estimated bulk soft tissue moduli ranging from 20 to 220 kPa (2,8–11). These moduli were observed to vary with test site location and also between subjects. For this model, the soft tissue, assumed to be a linear, elastic, isotropic, nearly incompressible, homogeneous material, was assigned a Young's modulus of 60 kPa (Poisson's ratio, v, equal to 0.45). Constant dilatation formulations, in which bulk soft tissue was modeled as an incompressible material on an element basis, were also analyzed (v=0.499). However, these formulations resulted in artificially high stresses due to prosthetic socket rectification (13). The results of the constant dilatation analyses will not be presented in this paper.

The material properties of the prosthetic socket were based on that of polypropylene; an initial value for Young's modulus of 1000 MPa (v=0.3) was assumed. A value of 0.38 MPa for Young's modulus (v=0.49) was used to model the soft prosthetic liner, based upon materials testing of Pelite performed by Steege et al. (8). Sanders (12) also conducted materials testing of Pelite and estimated Young's modulus as 1.7 MPa (v=0.39).

Boundary Conditions

The final information needed to complete FE model description concerns the boundary conditions and the load state. The modeled soft tissues of the residual limb extending beyond the socket brimlines were approximated by a free surface. An elastic foundation (E_{found}=60 kPa) was applied to the proximal surface of the model. Thus, contact between the residual limb and the rest of the body, while not explicitly modeled, was not ignored.

For persons with BK amputation, the shape of the prosthetic socket does not generally mirror that of the residual limb. Instead shape modifications, or rectifications, are imposed on the prosthetic socket such that the socket preferentially distributes the load to the tissues which are best suited to handle load. The PTB rectification scheme, the most common BK socket design, was implemented in the model by studying the rectification template from the University College London (UCL) computer aided socket design (CASD) system (**Figure 2**). This template identifies the nine areas of a BK socket that are most commonly rectified: patellar tendon bar (PB), lateral tibial flare (LT), medial tibial flare (MT), popliteal depression (PD), anterior tibial crest (TC), tibial end (TE), lateral femoral condyle (LC), fibular head (FH) and fibular end (FE). In the generic geometric FE model, the socket and liner node numbers corresponding to these nine rectification areas were noted, and radial nodal displacements were applied such that all nodes within the respective rectification area were subjected to the same displacement.

The load state was assumed to be "double support" stance of a person with BK amputation. The specific loading, based on the results of Steege et al. (8), was applied to the distal end of the prosthetic socket, as

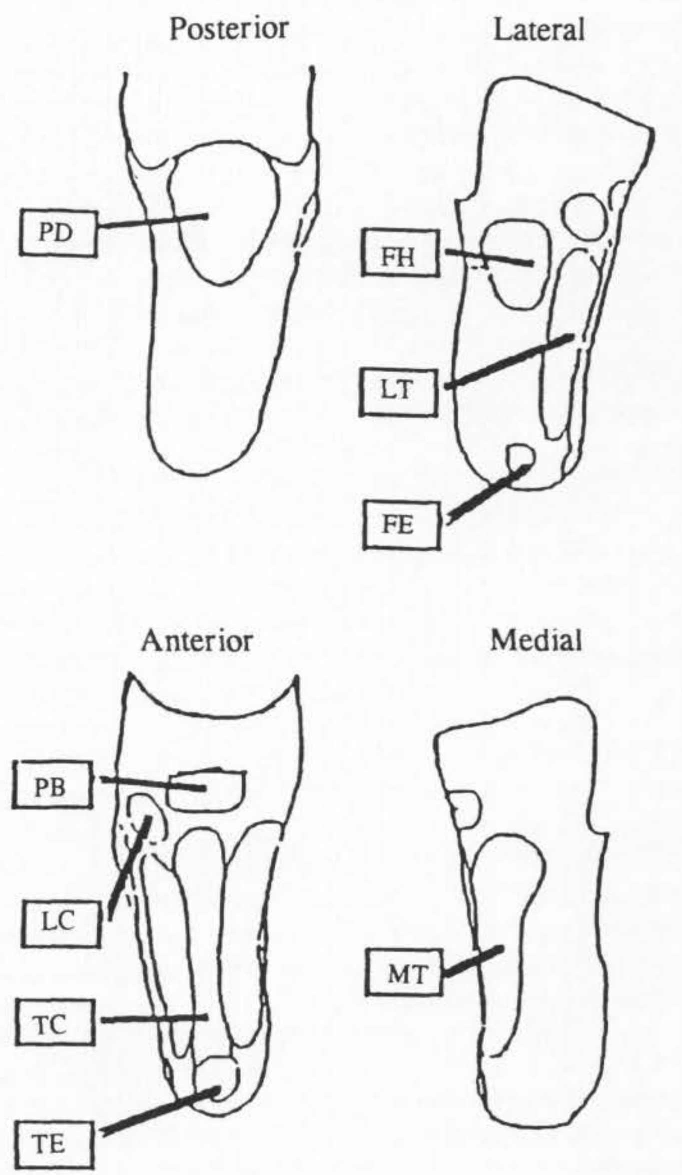

Figure 2.
Sample rectification template from the University College London (UCL) computer-aided socket design (CASD) system. Each area (PD=popliteal depression, FH=fibular head, LT=lateral tibial flare, FE=fibular end, PB=patellar tendon bar, LC=lateral femoral condyle, TC=anterior tibial crest, TE=tibial end, MT=medial tibial flare) represents regions of the BK PTB prosthetic socket design that are typically rectified.

the femur was not represented by elements but was modeled as a fixed boundary. This load state was as follows:

flexion moment:	10.9 N-m	(8.0 ft-lb_f)
varus moment:	13.9 N-m	(10.3 ft-lb_f)
external rotation:	1.2 N-m	(0.9 ft-lb_f)
vertical load:	287.0 N	(64.4 lb_f)

Parametric Analysis

Parametric analysis of the FE model may be used to provide insight into residual limb/prosthetic socket interface biomechanics. Such analyses are only feasible using numerical methods. Analyses were conducted for a "generic" person with BK amputation, during static stance, for both unrectified (null modification) and PTB rectified socket designs. As the PTB socket models include tissue loading due to both prosthetic socket rectification and the external load state, the unrectified socket models allowed isolated investigation of loading effects.

Parameter Variations

Material and geometric variations of the residual limb and socket were imposed upon a reference model to investigate the effects on the residual limb/prosthetic socket interface stress distribution. Parametric studies were conducted on prosthetic socket design parameters (socket stiffness, liner stiffness, and socket rectification) and on residual limb parameters (surface limb shape or taper, residual limb length, and bulk soft tissue stiffness). For each of these parameters, analysis was performed for the reference model (set of nominal parameter values, P_0), for a value three times the nominal parameter value ($3\ P_0$) and for a value one-third the nominal parameter value ($1/3\ P_0$).

Sensitivity Analysis

The results of the aforementioned analyses may be plotted as a direct comparison of the local interface stress versus parameter value. An alternative method of presenting these results is via "sensitivity analysis."

Sensitivity is defined as the ratio of the relative change in behavior to the relative change in parameter. If we define the parameters of interest, P, as the respective socket design or the residual limb parameter, and the behavior variables, B, as the interface stress, then the sensitivity can be defined as:

$$sensitivity = \frac{(B_2-B_1)/B_0}{(P_2-P_1)/P_0}$$

where the subscript $_0$ refers to the reference model, and the subscripts $_1$ and $_2$ refer to the model variations.

Validation of FE Models

To assess model performance and to evaluate the limitations of the model, experimental verification of the FE model was performed (13). The results are briefly summarized in the Appendix.

RESULTS AND DISCUSSION

The results of the parametric analyses, namely the sensitivity of the interface stress distribution to variations in prosthetic design parameters (socket and liner stiffness, patellar tendon, and popliteal rectification) and residual limb parameters (limb taper, residual limb length, and bulk soft tissue stiffness), are presented in **Figures 3–8.** The selected regions of interest were based on pressure tolerant areas (medial and lateral tibial flares, patellar tendon, medial tibial plateau, and posterior popliteal) and pressure sensitive regions (fibular head, fibular end, tibial crest, and hamstring insertion) of the BK residual limb. Note that the interface stress distribution includes both normal stress and shear stresses. As only the normal stresses were experimentally verified, and clinically meaningful directions for the shear stresses are unknown, this paper will primarily present the interface normal stress results. The shear stress magnitude results will only be presented for a select case.

Socket Design Parameter Variations

Influence of Prosthetic Socket and Liner Stiffness

The stiffnesses (i.e., Young's modulus) of the prosthetic socket and liner were varied to observe their respective influence on the interface shear and normal stress distribution. Such an analysis is an investigation of prospective alternative prosthetic socket and liner materials, regardless of whether such materials currently exist. The sensitivities corresponding to these analyses are plotted in **Figures 3** and **4,** for both an unrectified (i.e., null socket design) and a PTB rectified socket. Recall that as the PTB socket models include tissue loading due to both prosthetic socket rectification and the external load state, the unrectified socket models allow isolated investigation of loading effects. Thus the variation in the stress sensitivities between these two socket designs reflects the influence of prosthetic socket rectification on the interface behavior. As stated previously, although the interface shear magnitude was readily available for all of the respective FE models, this is the sole instance where such results will be presented. The shear magnitudes are particularly interesting for this parametric analysis, and the results illustrate how such interface shear magnitudes might be interpreted.

For the unrectified socket models, the normal stress appears to be fairly insensitive to the socket stiffness, and on a local level, moderately to highly sensitive to

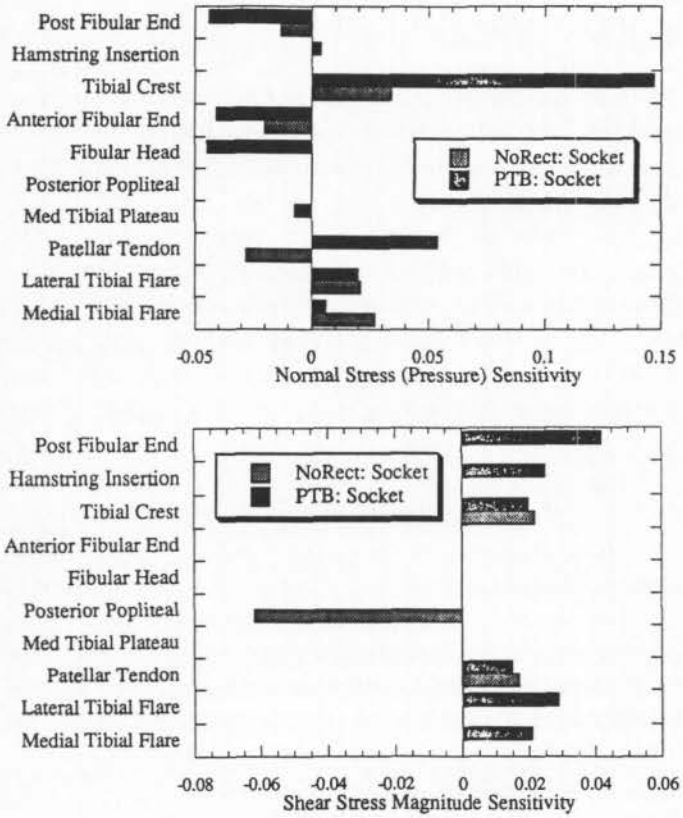

Figure 3.
Pressure (top) and shear magnitude (bottom) sensitivity in response to changes in the stiffness of the prosthetic socket for both unrectified (NoRect) and PTB rectified (PTB) sockets.

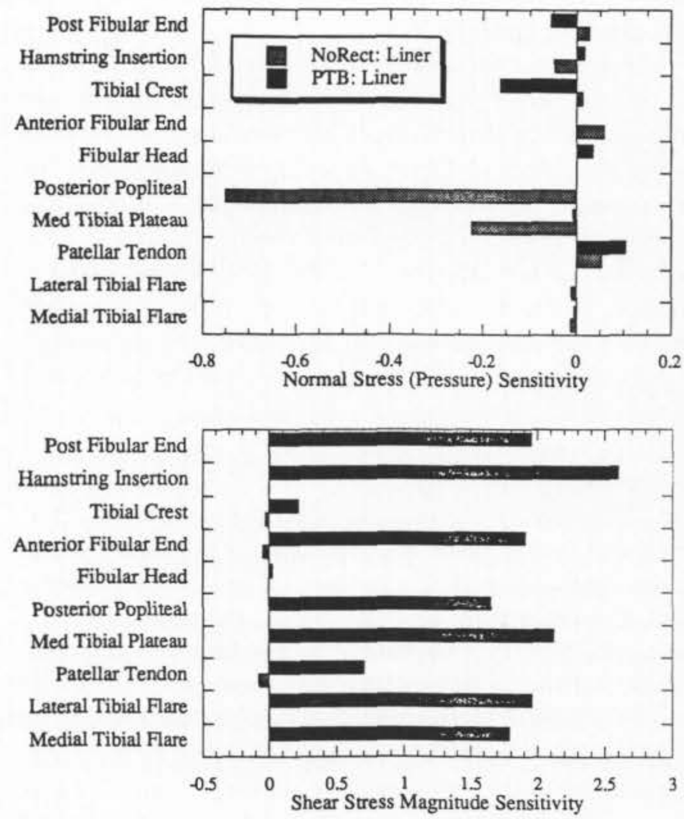

Figure 4.
Pressure and shear magnitude sensitivity in response to changes in the stiffness of the prosthetic liner for both unrectified (NoRect) and PTB rectified (PTB) sockets.

prosthetic liner stiffness. For example, these sensitivity plots indicate that increased socket stiffness may result in increased pressure over the tibial crest and tibial flares, and decreased pressure over the patellar tendon and fibular end. In contrast, increased liner stiffness may result in significantly decreased pressure in the posterior popliteal and medial tibial plateau regions. The interface shear stress magnitude for the unrectified socket models appears to be relatively insensitive to the stiffness of both the prosthetic socket and liner.

For the PTB rectified socket models, the interface pressure distribution is moderately sensitive to both the prosthetic socket and liner material properties. Increased socket stiffness may result in increased pressure over the tibial crest and patellar tendon, and decreased pressure over the fibular head and end. Increased liner stiffness may result in increased pressure in the patellar tendon region, and decreased pressure over the tibial crest.

The sensitivity of the interface shear stress to these prosthetic design parameters (socket and liner stiffness) for the PTB rectified socket models is very interesting. Although the shear stress magnitude appears to be fairly insensitive to the prosthetic socket stiffness, it is very sensitive to the prosthetic liner stiffness. As the stiffness of the prosthetic liner is increased, the shear magnitudes increase. Therefore, more compliant (less stiff) liners would be advantageous, as this would minimally affect the interface pressures (increased pressure over the posterior popliteal and medial tibial plateau regions both of which are pressure-tolerant regions of the BK residual limb), but may significantly reduce the interface shears.

Comparison of the sensitivity analyses for the unrectified and PTB rectified sockets indicate that, in general, the interface stress distribution is much more sensitive to prosthetic liner material properties than to the prosthetic socket material properties. Variations in the liner stiffness for the unrectified socket models indicate that the load state primarily affects the interface pressure distribution. Similar variations in liner stiffness for the PTB rectified socket models indicate that prosthetic socket rectification primarily influences the shear stress distribution.

Influence of Prosthetic Rectification

Two primary areas of rectification involved in the PTB design are the patellar tendon and popliteal depression regions, both of which correspond to pressure tolerant regions of the limb. The influence of the magnitude of the rectification in these areas on the interface stresses was investigated for static double support stance.

The interface pressure distribution demonstrated local sensitivity to variations in the magnitude of both the patellar tendon and popliteal rectifications. **Figure 5** indicates that increased patellar tendon rectification may result in increased pressure in the areas of the patellar tendon and tibial crest and decreased pressure over the fibular end. Thus, although increased patellar tendon rectification may result in a minimal increase in pressure relief for the fibular end, it may also create increased pressure over the tibial crest, a pressure sensitive region of the residual limb. The increased pressure over the tibial crest, however, is likely due to a modeling anomaly which enforces total contact between the residual limb and prosthetic liner/socket. The clinical utility of this model for investigation of prosthetic socket rectification is thus in question unless contact between the residual limb and prosthetic liner/socket can be disrupted.

In contrast to patellar tendon rectification, increased rectification posteriorly, in the area of the popliteal depression, results in increased pressure over the medial tibial plateau, posterior popliteal and hamstring insertion areas, and decreased pressure over the fibular head. Thus, although increased popliteal rectification results in greater pressure relief for the fibular head during double support stance, it may also result in increased pressure over the hamstring insertion area, a pressure sensitive region of the limb. As with the patellar tendon rectification analyses, these analyses are also subject to the total contact constraint between the residual limb and prosthetic liner/socket. This constraint needs to be relaxed to more thoroughly assess the residual limb/prosthetic socket interface mechanics.

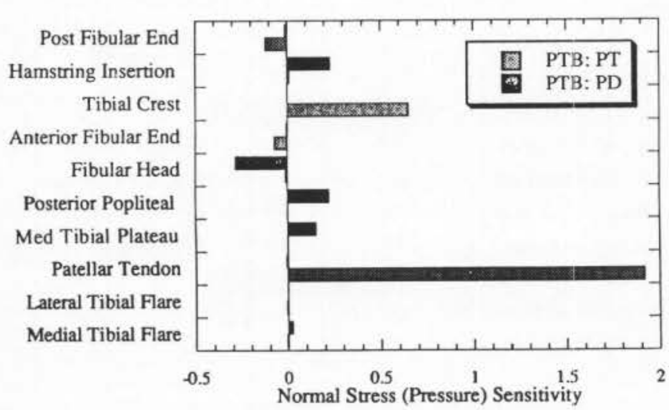

Figure 5.
Pressure sensitivity in response to variations in the prosthetic rectification scheme, namely rectification in the patellar tendon (PT) and popliteal (PD) regions.

The influence of various prosthetic rectification schemes on the interface stress distribution will likely vary for alternative load states (i.e., other than double support stance). For double support stance, the interface pressure distribution appears to be more sensitive to patellar tendon rectification than popliteal rectification. Regardless of the model limitations due to the total contact assumption, this section illustrates how a FE model of the residual limb and prosthetic socket might be used to evaluate prospective designs. To improve the clinical utility of the FE model, the model needs to incorporate contact analysis so that gaps between the residual limb and the prosthetic liner/socket might be incorporated.

Residual Limb Geometry Variations

Influence of Residual Limb Soft Tissue Bulk

The analyses involving soft tissue bulk investigate the influence of the taper (shape) of the residual limb on the interface stress distributions. BK residual limbs are generally somewhat conical, although some may be cylindrical, or even bulbous. A more tapered limb may reflect, to some degree, greater atrophy of the soft tissues. In contrast, a less tapered, cylindrical limb may reflect edema of the limb soft tissues. In this paper, regardless of the cause of the variations in residual limb taper, limb taper corresponds to relative bulk or thickness of soft tissue.

The variations in residual limb taper were implemented in two fashions: local and global taper. Local taper reflects local variations in soft tissue bulk. These local increases/decreases in tissue bulk were limited to those areas without bony prominences, areas which would be more likely to be affected by edema and/or atrophy. In contrast, global taper reflects variations in soft tissue bulk throughout the lower extremity: all soft tissues of the limb, whether relatively thick or relatively thin over bony prominences, were modified equally.

Note that changes in residual limb taper affect both the residual limb volume and the residual limb/prosthetic socket contact area.

The results of the investigations of soft tissue bulk are illustrated in **Figure 6.** Increased global taper (i.e., limb atrophy) resulted in isolated changes in the interface normal stresses: decreased pressure in the regions of the fibular head, tibial crest, and patellar tendon. At first glance, these results may seem counter-intuitive, as a more tapered limb may be expected to slip further into the socket, thus increasing the pressures at the bony prominences. However, the model assumes a total contact, intimately fitting socket, and thus indirectly illustrates the importance of maintaining proper fit to minimize the incidence of excess pressures. If the results are studied in terms of relative limb contact area, greater clinical significance can perhaps be inferred. For a more tapered limb, there is greater contact area proximally than distally. As pressure is inversely proportional to area, the pressures would therefore be expected to decrease proximally and increase distally.

In contrast to the global taper analyses, increases in local taper primarily resulted in increased pressure over the tibial crest area, since variations in local taper correspond to changes in bulk soft tissue thickness over only the fleshy areas of the residual limb. In general, the model appears to be more sensitive to global variations than to local taper. As the global taper method is the more aggressive of the two approaches, such results are not surprising. However, local taper variations seemingly reflect limb volume changes such as edema and/or atrophy more realistically.

Influence of Residual Limb Length

The effect of the residual limb length on the interface stress distribution during double support stance was also investigated. An increase in residual limb length corresponds to an increase in the overall surface area available for load transfer. Thus, the average pressure on the residual limb would be expected to decrease with increased residual limb length. This increase in overall limb surface area also corresponds to an increase in local rectification area for the tibial crest, the posterior popliteal, and the medial and lateral tibial flares. The increased rectification area for the posterior popliteal and medial/lateral tibial flares should enable greater pressure relief for the rest of the limb. However, the greater relief provided by these regions may be offset, in part, by the increased relief over the extended tibial crest region.

As illustrated in **Figure 7,** the normal stress distribution was sensitive to variations in residual limb length. An increase in residual limb length in the FE models resulted in increased pressure over all regions of the residual limb except the lateral tibial flare, patellar tendon, and tibial crest. Therefore, although the average pressure of the bulk soft tissue was expected to decrease with increased limb length, decreased pressure was only observed for the tibial crest, patellar tendon, and lateral tibial flare regions. The clinical significance of these results is somewhat difficult to assess. In general, one wants to maximize the residual limb length to maximize the surface area available for load transfer, particularly

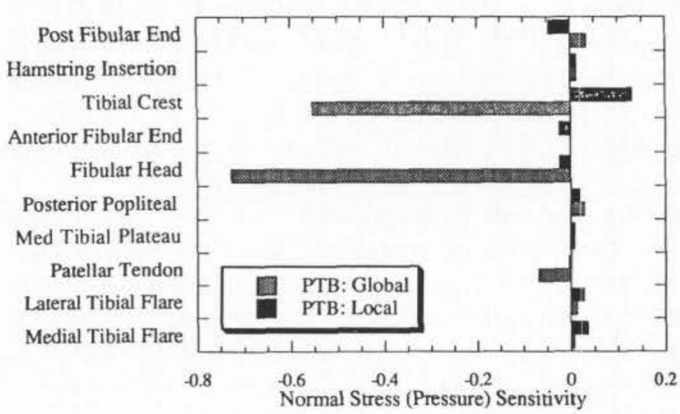

Figure 6.
Pressure sensitivity in response to changes in residual limb bulk or taper for a PTB rectified socket model. Variations in both local and global taper are presented.

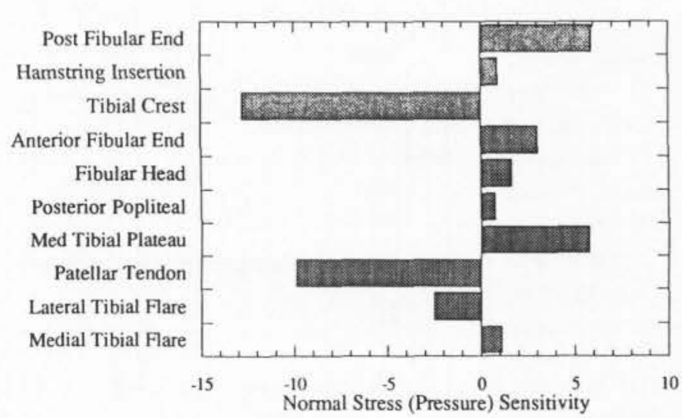

Figure 7.
Pressure sensitivity in response to variations in residual limb length for a PTB rectified socket model.

for the pressure-tolerant areas involved in prosthetic socket rectification. Longer residual limbs for persons with BK amputation also result in a longer lever arm to facilitate knee flexion and extension.

Influence of Bulk Soft Tissue Stiffness

The interface normal and shear stresses are also influenced by the stiffness of the bulk soft tissue, and the bulk soft tissue incompressibility approximation. As illustrated in **Figure 8,** these effects are magnified by the rectification process. The implementation of prosthetic rectification, via prescribed displacement of the socket and liner nodes, pre-stresses the limb tissues. Therefore, it is not surprising that the interface stress distribution for the PTB socket models is sensitive to the bulk soft tissue material property formulations. Note that the results reported in this paper correspond to nearly incompressible representations of bulk soft tissue (v=0.45). Constant dilatation formulations, which enforce incompressibility on an element level, resulted in artificially high pre-stresses in response to prosthetic socket rectification (13).

For the unrectified socket models, increased tissue stiffness results in increased pressure over the medial tibial plateau and posterior popliteal areas. In contrast, for the PTB rectified socket models, increased tissue stiffness results in increased pressure over all areas except the tibial crest and fibular end. As the PTB socket design concept relies on local compression of the residual limb soft tissues (via prescribed nodal displacements), it is not surprising that the interface normal stresses are more sensitive to the stiffness of the bulk

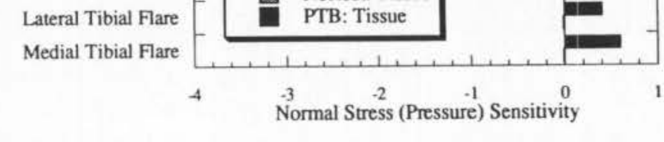

Figure 8.
Pressure sensitivity in response to changes in the stiffness of the soft tissue for both unrectified (NoRect) and PTB rectified (PTB) socket models.

soft tissue for this socket design. In general, it is noted that prosthetic rectification over bulk soft tissues of increased stiffness may result in a more secure fit. Therefore, a residual limb composed of relatively stiff tissues may require less prosthetic socket rectification to distribute the load and secure the socket on the limb.

The generic geometric model assumed that the properties of the soft tissues are uniform throughout the limb. While this is admittedly not true (soft tissue stiffness is likely influenced by limb physiology/anatomy, age, edema, and/or muscle tone), the sensitivity of the interface stresses to variations in soft tissue stiffness is independent of the initial modulus (i.e., reference modulus) for a linear model. Thus the results of these parametric analyses may be extrapolated or expanded to local variations in the tissue stiffness.

CONCLUSIONS

Parametric analysis via computer models of the residual limb provides an opportunity for investigation of residual limb/prosthetic socket interface stresses, subject to variations in prosthetic design and residual limb geometry, that cannot be investigated by experimental means. Such analyses are largely qualitative, describing behavioral trends rather than specific local interface stress values.

The results of the parametric analyses of the generic geometric FE model of the BK residual limb and prosthetic socket indicate that the residual limb/prosthetic socket interface stresses are affected by variations in both prosthetic design and residual limb geometry. For static double support stance, the results are summarized below.

1. For an unrectified socket design, the residual limb/prosthetic liner interface pressures are relatively insensitive to the socket stiffness. The implementation of a PTB rectification scheme resulted in local variations in the interface pressures and increased sensitivity to prosthetic socket stiffness. For example, increased socket stiffness contributed to increased pressure over the medial tibial flare, lateral tibial flare, and tibial crest, and decreased pressure over the fibular end and patellar tendon, without significantly influencing the shear magnitudes. Therefore, the use of semi-rigid sockets (i.e., local variation in prosthetic socket stiffness) may enable "sculpting" of the interface pressure distribution, in addition to

that traditionally achieved by prosthetic socket rectification. However, it can also be noted that the interface stress distribution appears to be much more sensitive to the prosthetic liner material properties than the prosthetic socket properties.

2. The stiffness of the prosthetic liner influences the interface stress distribution for both the unrectified and PTB rectified models. The external load state appears to influence the interface pressure distribution, while the prosthetic socket rectification appears to influence the interface shear stress distribution. Variable durometer liners may be useful for massaging the interface stresses such that a comfortable stress distribution may be obtained. Specifically, more compliant liners for the PTB rectified socket design may be advantageous, as their use may significantly reduce the interface shear stresses.
3. As expected, the interface pressures are very sensitive to the prosthetic rectification scheme. Modification of two primary rectification areas, the patellar tendon and popliteal regions, may significantly influence the pressures experienced at other areas of the residual limb. Systematic variation of the prosthetic rectification scheme may be useful in illustrating the potential effects of all regional rectifications. These analyses require significantly less work/time than would be required if such variations were implemented via CAD-CAM and check sockets. Thus, parametric analysis can be a useful instructional tool. However, accurate simulation of the residual limb and prosthetic liner/socket interface is critical: ignoring potential gaps in the interface that may arise due to loading and/or socket rectification may contribute to modeling anomalies.
4. The shape and relative bulk of soft tissue may also significantly influence the interface pressure distribution. The maintenance of proper fit, however, minimizes potential stress concentrations, particularly near bony prominences, that may develop. In general, a more tapered limb has less tissue and the contact surface area is decreased distally. Therefore, a more tapered limb may exhibit decreased pressures proximally and increased pressures distally.
5. The interface pressure distribution is also influenced by the residual limb length. As pressure is inversely proportional to the surface area, increases in residual limb length corresponding to increases in local contact area and increases in the pressure tolerant rectification areas generally result in decreased pressures. The residual limb length should therefore be maximized, while ensuring that the resulting limb shape is biomechanically suitable for prosthetic use.
6. The stiffness/compliance of the residual limb soft tissues may also significantly alter the interface pressure distribution. Such variations may occur due to edema, muscle contraction, scarring, and so forth. Less prosthetic socket rectification may be required to transfer load and secure the socket on the residual limb for limbs with relatively stiff soft tissues. Note that parametric analysis of the effect of soft tissue stiffness on the interface stress distribution may be confounded by the incompressibility, linearity, elasticity (as opposed to viscoelasticity), and isotropic approximations/assumptions.

Relatively simple FE models of the residual limb and prosthetic socket, such as those presented in this paper, may not estimate residual limb interface stresses with high precision. However, these models provide a very useful tool for improving our understanding of residual limb/prosthetic socket interface mechanics, the influence of various design parameters, and the effects of individual limb variations on the interface stresses. Thus parametric analysis may be considered a potentially powerful educational and instructional tool.

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APPENDIX

To validate the generic geometric FE model, local interface pressures were measured at seven of the following sites (medial femoral condyle, patellar tendon, medial tibial flare, lateral tibial flare, fibular head, popliteal, pre-tibial, and distal anterior tibial regions of the residual limb), using miniature diaphragm pressure transducers (Kulite Semiconductors, Leonia, NJ). The experimental load state was simultaneously evaluated. Trials were conducted for three persons with BK amputation during stance, for several static load states (weight supported primarily on the physiological limb, weight supported equally on the physiologic and prosthetic limbs, and weight supported primarily on the prosthetic limb) in three different alignments: neutral, extreme dorsiflexion, and extreme plantarflexion. Both unrectified and PTB rectified sockets were incorporated into experimental test prostheses.

The generic geometric FE model was scaled for the respective subject, individual estimates of bulk soft tissue properties based on *in vivo* indentor studies were applied, and the respective socket design was imposed on the model. The load state, as measured experimentally via force platforms, was applied to the model, and the model was analyzed.

The results of the individually scaled FE models, namely the interface pressures, were compared to those measured during the experimental trials (13). For the unrectified sockets, the FE models consistently underestimated the experimental pressures; the FE pressures ranged from 0 to 25 kPa while the experimental pressures ranged from 0 to 95 kPa. For the PTB rectified sockets, the FE model both under- and overestimated the interface pressures. The FE pressures ranged from 0 to 200 kPa; the corresponding measured pressures also ranged from 0 to 200 kPa. The results of these FE models are contrasted with numerical and experimental analyses reported in the literature in **Table 1** (2,8,13–15).

Although the FE model appears to have its limitations as a local pressure predictor, these results do not indicate that the FE method is not a viable tool for prosthetic interface investigations. The results merely suggest that the FE models must be refined or modified, perhaps including nonlinear representations of bulk soft tissue properties and more accurate representations of the prosthetic interface, to improve model performance. In addition, although the generic geometric FE models of the residual limb and prosthetic socket do not appear to estimate the interface pressure distribution with high accuracy for specific subjects, the model does have practical applications in comparative stress analysis.

Table 1.
Comparison of local interface pressure results.

Location	FE Model (kPa)	Literature (kPa)	Analysis Type	Ref
Medial tibial flare	41	40	EXP	(13)
		25	NUM	(8)
		71	NUM	(2)
		34	EXP	(14)
		5	EXP	(15)
Lateral tibial flare	10	88	EXP	(13)
		12	NUM	(8)
		48	EXP	(8)
		110	NUM	(2)
		39	EXP	(14)
		30	EXP	(15)
Pantellar tendon	105	84	EXP	(13)
		83	NUM	(8)
		48	EXP	(8)
		200	NUM	(2)
		64	EXP	(14)
		40	EXP	(15)
Medial tibial condyle	20	99	EXP	(13)
		5	NUM	(8)
		47	EXP	(8)
		7	EXP	(14)
Popliteal area	14	74	EXP	(13)
		11	NUM	(8)
		0	EXP	(8)
		120	NUM	(2)
		43	EXP	(14)

Results from the generic geometric FE model (average of 3 subjects) compared to both numerical and experimental analyses reported in the literature. All analysis involved persons with below-knee amputation wearing PTB rectified sockets (static loading only). EXP=Experimental; NUM=Numerical; Ref=Reference.