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Generic, Geometric Finite Element Analysis of the Transtibial Residual Limb and Prosthetic Socket

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Generic, geometric finite element analysis of the transtibial residual limb and prosthetic socket

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Abstract—Finite element (FE) analysis was used to investigate the stress distribution between the residual limb and prosthetic socket of persons with transtibial amputation (TTA). The purpose of this study was to develop a tool to provide a quantitative estimate of prosthetic interface pressures to improve our understanding of residual limb/prosthetic socket biomechanics and prosthetic fit. FE models of the residual limb and prosthetic socket were created. In contrast to previous FE models of the prosthetic socket/residual limb system, these models were not based on the geometry of a particular individual, but instead were based on a generic, geometric approximation of the residual limb. These models could then be scaled for the limbs of specific individuals. The material properties of the bulk soft tissues of the residual limb were based upon local *in vivo* indentor studies. Significant effort was devoted toward the validation of these generic, geometric FE models; prosthetic interface pressures estimated via the FE model were compared to experimentally determined interface pressures for several persons with TTA in a variety of socket designs and static load/alignment states. The FE normal stresses were of the same order of magnitude as the measured stresses (0–200 kPa); however, significant differences in the stress distribution were observed. Although the generic, geometric FE models do not appear to accurately predict the stress distribution for specific subjects, the models have practical applications in comparative stress distribution studies.

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INTRODUCTION

A prosthesis is often used to restore appearance and functional mobility to individuals following limb amputation. Coupling between the residual limb and the prosthesis is typically achieved by a socket that surrounds the residual limb, and to which the remaining components of the prosthesis are attached. The socket is thus a critical element in a successful prosthesis, as it is the sole means of load transfer between the prosthesis and the residual limb.

The soft tissues of the residual limb are not well-suited for load bearing. Their load tolerance will vary based on their biological and physiological structure, and on the individual. Whenever tissues are exposed to excessive or prolonged loading, there is a risk of tissue trauma (e.g., due to local circulatory deficits, abrasion, and so forth). Thus, for persons with lower limb amputation, where large loads must be borne by the soft tissues, great care is taken in the design of the prosthetic socket to minimize discomfort and possible tissue trauma.

One socket design that has shown success in balancing physiological and load-bearing factors for persons with transtibial amputation (TTA) is the patellar-tendon-bearing (PTB) socket, initially developed at the University of California, Berkeley, in the late 1950s. The basic concept of the PTB socket is to distribute the load over areas of the residual limb in proportion to their abil-

Journal of Rehabilitation Research and Development Vol. 34 No. 2 1997

ity to tolerate load. Load is borne primarily on the patellar tendon (hence the name), medial and lateral flares of the tibia, and popliteal area. The socket precompresses the tissues of the residual limb in these load areas so that forces may be preferentially distributed, and so that movement of the socket relative to the skeleton is minimized. The PTB socket is thus not a replica of the residual limb, but instead includes appropriate shape modifications (i.e., rectifications) so that pressure tolerant areas bear the majority of the load and pressure sensitive areas are largely relieved of load. These shape modifications vary for each patient and prosthesis due to differences in residual limb geometry, tissue stiffness, and pressure tolerances of the tissues.

The fitting of a prosthesis is an empirical process. The prosthetist has no quantitative information regarding the load distribution of the soft tissues and thus must rely on feedback from the patient and indirect indicators, such as skin blanching or reddening, to gage socket fit. Knowledge of the interface stress distribution between the residual limb and the prosthetic socket would enable objective evaluation of prosthetic fit, and may advance prosthetic socket design.

Previous Studies

Several groups have attempted to investigate the interface pressure distribution between the residual limb and the prosthetic socket quantitatively for both persons with TTA and those with transfemoral amputation (TFA) in laboratory and/or clinical settings. This interface stress distribution includes both normal stresses (pressures) and shear stresses. (In this article, the terms normal stress and pressure are used interchangeably; note that positive normal stresses are indicative of compressive loading.) Various means of measurement have been used to investigate the effects of prosthetic alignment, relative weight-bearing, muscle contraction, socket liners, and suspension mechanisms on interface pressure distribution (1). Most experimental stress measurements have been limited to specific sites around the limb, as measurements can only be obtained at transducer locations.

In contrast to these experimental techniques, computer models of the residual limb and prosthetic socket have the potential to estimate interface pressures for the entire residuum, and, indeed, are not limited to the interface, but can also provide information regarding the subcutaneous stresses. Nola and Vistnes (2) and Daniel et al. (3) have found that initial pathological changes in pressure sore formation occur first in the muscle directly overlying the bone, and then spread outward toward the skin. Therefore, the subcutaneous stresses may be of importance in evaluating long-term prosthetic success. The subcutaneous stresses are particularly difficult to measure *in vivo;* current measuring techniques disrupt the very stress distribution that is of interest.

Several groups have used computer models of the lower residual limb to investigate the residual limb/prosthetic socket interface (1). These analyses included three-dimensional (3-D) biomechanical models (4), correlation studies (5), and FE analysis (6–21).

Steege et al. (17–20) were the first to model the residual limb and prosthetic socket system for persons with TTA. In the initial FE analyses (19,20), the range of predicted pressures (0–105 kPa) matched the experimental range (0–130 kPa), but the distribution of the pressures did not correspond well.

Reynolds (12,13) also attempted to predict transtibial prosthetic interface pressures. Initial parametric analyses investigating the effects of friction, material properties, and socket design were conducted for a two-dimensional (2-D), axisymmetric FE approximation of the residual limb. Reynolds then developed and analyzed a 3-D model of the residual limb based on radiographic data. Pressures ranged from 0–200 kPa for the nominal limb model.

Sanders (14,15,22,23) continued the investigations of transtibial interface pressures using both FE analysis of the residual limb and prosthetic socket, and experimental measurement of interface stresses. The work of Sanders differed from previous research in that the stress measurements included both normal (pressure) and shear stress, and the load state for the FE model was dynamic (i.e., gait). The emphasis of this research was the experimental evaluation of interface pressure and shear stress, but some pseudo-static FE modeling was performed for a single person with TTA. The results of these analyses indicated that the model consistently underestimated resultant shear stresses, the model was unable to predict the direction of the shear stresses, and the model demonstrated stress sensitivity to prosthetic alignment not observed during the experimental trials.

Quesada and Skinner (10,11) used FE analysis of a PTB prosthesis to investigate variations in prosthesis design on the interface stress distribution upon heelstrike. These models approximated the bulk soft tissue of the residual limb as parallel (skin) and perpendicular (compressive tissue) linear springs attached to the socket wall. The normal stresses estimated with this model ranged from 0–961 kPa, and the shear stresses from 0–463 kPa. The stresses estimated at the distal anterior end of the residual limb/socket (961 kPa normal stress, 463 kPa shear stress) were considerably higher than those predicted for the remainder of the socket.

Krouskop (7,8,24) was the first to make use of the FE method as a computer-aided-design (CAD) tool for transfemoral prosthetic sockets. After evaluating the surface geometry of the residual limb through a contact method using two diametrically opposed contracting/retracting probes, ultrasound was used to obtain average local material properties. A generic FE model was then scaled for the surface geometry of the limb, and the local material properties assigned to respective linear elastic 3-D elements. A static loading function, based on measured mean interface pressure profiles of subjects wearing comfortable quadrilateral-brim transfemoral prostheses, was imposed. The FE model was then used to predict the shape of the loaded limb so that the desired pressure profile would be obtained. This rectified socket geometry was then carved on a computer numerically controlled (CNC) milling machine, and the proposed socket subsequently vacuum formed.

Research has also been conducted using FE analysis to study the interface pressure distribution for persons with TFA (9,16,21,25). The models developed by Mak (9), Torres-Moreno (21), and Brennan (25) are similar to the FE models for transtibial residual limbs and sockets mentioned previously. That developed by Seguchi (16), however, was novel. Seguchi avoided characterization of the mechanical properties of bulk soft tissue by modeling only the acrylic socket. As this problem is underdefined, the complementary energy criterion was used to search for the most plausible interface pressure distribution. The FE model was based on transverse computed tomography (CT) scans of the socket, and consisted of thin quadrilateral shell elements. The static response of the socket was investigated for two hypothetical load cases: uniform contact pressure along the entire inner surface of the socket, and weight fully supported at the ischial seat. The clinical value of such a model is questionable, however, as it ignores residual limb geometry and bone/soft tissue interactions. A summary of these FE analyses of residual limb/prosthetic socket systems is presented in **Table 1.**

Regardless of their assumptions and simplifications, computer models of the residual limb and socket offer several advantages over experimental measurements in the estimation of interface pressures. For example, the use of theoretical models allows examination of the *entire* residual limb/prosthetic socket interface and analysis of the subcutaneous stress distribution. 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 current technological limitations (i.e., material constraints) may be investigated. Previously, it has not been possible to perform clinical parametric studies of the prosthetic socket due to difficulties in the repeatability of test procedures, economic limitations, and time constraints; computer models are not subject to these limitations, and thus have the potential for parametric analysis.

In the past, FE analysis has been limited, to some extent, by hardware (i.e., processor speed, memory, disk space) and software (i.e., linear versus nonlinear formulation capabilities, and so forth) developments. Technological advances are now making these limitations a thing of the past.

The validity of all computer models must be assessed and their limitations, which typically vary as a function of model application and/or purpose, must be identified.

Current Study

The aim of the present study was to develop generic, geometric FE models of the transtibial residual limb and prosthetic socket, and to use these models to estimate interface pressures. In contrast to the FE model to be presented in this article, the FE models presented in the literature (**Table 1**) have ranged from relatively simple 2-D axisymmetric approximations (12,13) to 3-D FE models of specific limbs based upon imaging data (6–9,12–15,17–21). The axisymmetric FE models were very general, and results were primarily qualitative. In contrast, the results of the 3-D models were more quantitative, but could not be readily applied or extrapolated to multiple individuals. In addition, the material properties of the soft tissues, while often based on experimental data (i.e., *in vivo* indentor studies), were estimated for a limited number of subjects and small numbers of test sites. Finally, the validation of these FE models, if attempted, was limited.

This study consisted of FE analysis of the transtibial residual limb and prosthetic socket and experimental studies to evaluate the properties of bulk soft tissue in compression, the experimental load state, and the interface pressures for model validation. In contrast to previous studies, the FE model is used to simulate limbs and

Journal of Rehabilitation Research and Development Vol. 34 No. 2 1997

Table 1.
Summary of lower residual limb finite element models.

		Model Validation				FE Model Soft Tissue Properties		
Investigator	**Geometry Source**	**Type**	**#Subjects**	**#Sites**	**#Load States**	**Type**	**#Subjects**	**#Sites**
Steege (17-20)	CT	pressure	1-2 TTA	7	1-2	in vivo indentation	2 TTA	7
Reynolds (12,13)	physical model	pressure	1 TTA	3	2	N/A		
	x-ray	none				in vivo indentation	1 TTA	4
Quesada[1] (10,11)	idealized	none	1 TTA	N/A	N/A	literature	N/A	N/A
Sanders (14,15)	MRI	normal & shear stress	1 TTA	4	pseudo-static approximation of gait trials	literature	N/A	N/A
Krouskop (7,8)	mechanical digitization	none	TFA	N/A	N/A	ultrasonic transducer	9 TFA	4
Seguchi[2] (16)	idealized	circum-ferential strain	1 TFA	2	2	N/A	N/A	N/A
Brennan (25)	CT	pressure	1 TFA	7	1	literature	N/A	N/A
Torres-Moreno (21,26)	MRI	pressure	1 TFA	12	quasi-static approximation of gait trials	in vivo indentation	1 TFA	5
Mak, Liu (9,27)	CT	none	1 TFA	N/A	N/A	in vivo indentation	8 TTA	3
Silver-Thorn (28,29)	idealized CT	pressure	3 TTA	8	9	in vivo indentation	3 TTA	8

FE = finite element; CT = computerized tomography; TTA = transtibial amputation; MRI = magnetic resonance imaging; TFA = transfemoral amputation; [1]transtibial prosthesis model: does not include explicit representation of the residual limb. [2]transfemoral socket model: does not include explicit representation of the residual limb.

sockets for multiple subjects and socket designs. Bulk soft tissue material properties were estimated for each of these subjects, and model validation included experimental analysis of each subject/socket under varying loading conditions.

METHODS

Finite Element Modeling

To investigate the interface pressures between the residual limb and prosthetic socket during stance for persons with TTA, FE models of the limb and socket were developed. The primary assumptions of these models involved approximations of the socket/limb interface, and the material properties of the structures of the residual limb. These simplifying assumptions were:

1. The soft tissues of the residual limb: muscle, tendon, fat, skin, fascia, and so forth, were approximated as a linear elastic, isotropic, homogeneous, nearly incompressible material.
2. As bone is several orders of magnitude stiffer than bulk soft tissue, the femur, tibia, fibula, and patella were represented as a single, fixed internal boundary.
3. As static stance was the only load state considered, the articular cartilage, meniscus, and cruciate ligaments were lumped into the fixed internal boundary.
4. Total contact between the residual limb and prosthetic socket was assumed; this was approximated

experimentally using alginated check sockets during minimal weightbearing.

5. No slip was allowed to occur at the tissue/liner and liner/socket interfaces.

The pre- and postprocessing of all FE modeling were performed using Mentat (MARC Research Analysis Corp.) on a SUN4/360 workstation; FE analysis was performed using the MARC FE code.

Geometry

In contrast to prior residual limb FE analyses, the geometry for these models was not based on magnetic resonance images (MRI), CT scans, or other imaging data. These techniques are costly, and subsequent mesh development for each individual is time consuming. Instead, the internal and external geometry of the residual limb was approximated by standard geometric shapes, the dimensions of which were based on anthropometric data reported in the literature (30–33). A generic, geometric FE model need only be meshed a single time, and may then be scaled to approximate the limbs of specific individuals. Although subtle geometric variations, such as local bone deformity, bone and/or soft tissue atrophy, or hypertrophy are not accommodated, these models can provide a preliminary quantitative means of analysis.

Specifically, the bony structures of the residual limb were approximated as spheres, triangular prisms, and cylinders: the femoral condyles, tibial tubercle, and fibular head as spheres; the tibia and fibula as triangular prisms; and the femoral shaft as a cylinder. As shown in **Figure 1,** the external or surface geometry of the limb was approximated by an elliptical cylinder proximal to the knee joint, a tapered elliptical cylinder distal to the knee joint, and an elliptical dome at the distal end of the limb (28). Note that the limb model included 5° of knee flexion to approximate typical prosthetic alignment, and the tibio-femoral angle was 170°.

The prosthetic liner, an optional soft insert encasing the residual limb, was modeled as a 6-mm layer surrounding the soft tissues; the prosthetic socket was modeled as a 3-mm layer surrounding the prosthetic liner. The prosthetic liner/socket trimlines (i.e., the proximal borders of the liner and socket) were based on typical PTB socket design.

Transverse slices of the approximated residual limb and socket geometry were taken at 1 cm increments. This information was then digitized and built into a 3-D mesh

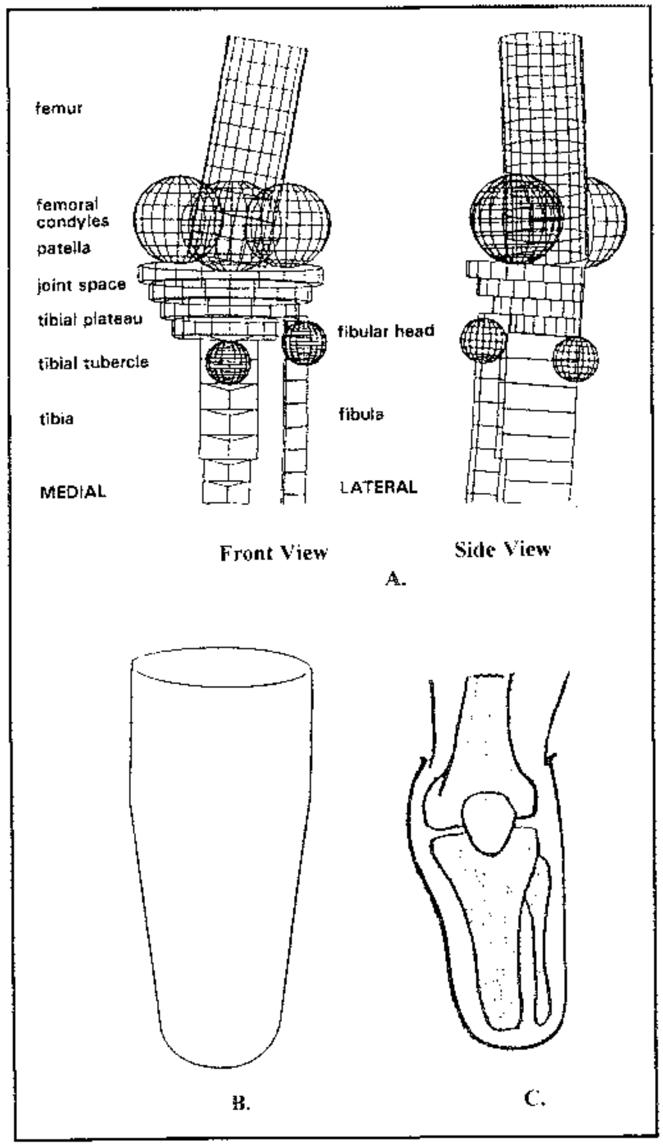

Figure 1.
Generic, geometric approximation of (a) internal and (b) surface structures of the transtibial residual limb; a diagram of the "actual" limb geometry is shown (c) for comparison.

of 8-noded isoparametric brick elements. The mesh consisted of 1,688 elements and 2,221 nodes (**Figure 2**) and was nonuniform, with finer mesh density in areas of minimal tissue thickness (e.g., anterior tibial crest region) and in areas where stress gradients were expected to be high (e.g., patellar tendon area). On average, the mesh consisted of 80–100 elements for each of 20 transverse levels. Models using higher order elements (i.e., 20-node quadratic isoparametric brick elements) and coarse and more

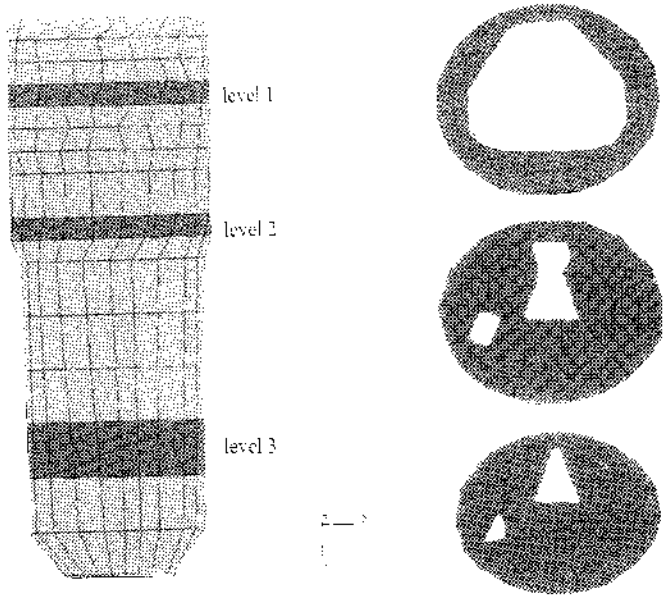

Figure 2.
Finite element mesh of the residual limb tissues: anterior view of entire residual limb (left) and transverse view at three specific levels (right).

refined meshes of linear elements, 1,000 and 4,000 elements, respectively, were analyzed to evaluate the adequacy of the FE mesh. These analyses indicated that the 2,000-element mesh of linear elements was sufficiently accurate for stress output.

Scaling

For each test subject, the generic, geometric FE model was scaled to account for individual differences in residual limb geometry. The scaling method involved direct measurement of the anteroposterior and mediolateral dimensions of the residual limb at three levels: proximal (approximately 10 cm proximal to the level of the tibial plateau), the tibial plateau level, and distal (approximately at the level of the distal end of the tibia). These dimensions were used to scale the hard (i.e., fixed boundary) and soft tissues of the modeled limb and smoothly taper the approximated limb surface between these levels (28). The length of the limb, from the level of the tibial plateau to the distal end, and the distal tissue thickness were used to complete the scaling of the FE model.

Material Properties

The material properties of the structures in this model (bone, cartilage, prosthetic socket, and liner) were based on the literature and indentor studies of the bulk soft tissue. The mechanical properties of bone and articular cartilage in compression have been studied in some detail over the past 25 years. However, as stated previously, the femur, tibia, fibula, and patella (as well as the articular cartilage and ligaments of the knee) were modeled as a fixed boundary, as bone is several orders of magnitude stiffer than soft tissue. In contrast to bone and cartilage, little information regarding the mechanical properties of bulk soft tissue in compression is available. *In vivo* indentor studies estimates of bulk soft tissue moduli for various regions of the lower limbs for both persons with TTA (12,13,19,20,27) and those with TFA (7,8,26) ranged from 20 to 220 kPa. These moduli were observed to vary with test site location and also between individuals. The current study, therefore, included soft tissue testing for each of three subjects, at eight local test areas (lateral tibial flare, fibular head, medial tibial flare, medial femoral condyle, patellar tendon, pretibial, distal anterior tibia, and popliteal areas).

To obtain estimates of bulk soft tissue moduli, the generic geometric FE models were scaled for each subject, as described previously. The linear FE model (unrectified socket) was systematically subjected to unit normal displacements at nodes approximating the location of each of the eight test sites. Analysis yielded the corre-

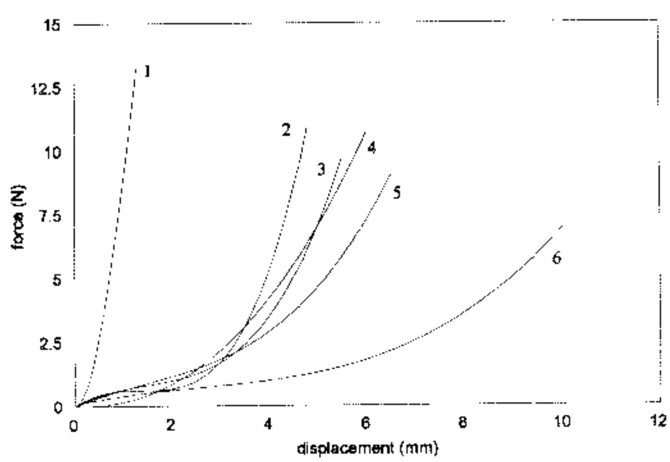

Figure 3.
Representative force-displacement data for a single subject with TTA: 1) distal anterior tibia, 2) medial femoral condyle, 3) medial tibial flare, 4) patella tendon, 5) pretibial, and 6) popliteal areas. Each curve is based upon a third order polynomial fit of 15–20 preconditioned loading curves obtained during the *in vivo* indentor studies (28).

sponding nodal reaction force. At each test site, the local soft tissue modulus was evaluated based on comparison of FE reaction force/prescribed displacement and the force-displacement curve obtained during the *in vivo* indentor studies. As the local force-displacement curves were often nonlinear (**Figure 3**), with the material becoming increasingly stiff at large displacements, the portion of the curve used for material property selection was based on the magnitude of the local prosthetic socket rectification imposed in the respective PTB rectified FE models. (For the unrectified socket models, the initial linear region of the force-displacement curves was utilized for modulus evaluation.) Moduli for the intermediate regions of the residual limb (i.e., those regions where neither interface pressure measurement nor indentor tests were performed) were interpolated to smooth the modulus distribution. The estimated moduli ranged from 0.6 to 110 kPa for the unrectified socket models (average modulus, 40 kPa); increased moduli for the popliteal (6 kPa to 27 kPa), patellar tendon (74 kPa to 258 kPa) and medial tibial flare (27 kPa to 162 kPa) regions were evaluated for the PTB rectified socket models. The value for Poisson's ratio, ν, was assumed to be 0.45 (12–15,17–20), that is, the bulk soft tissue was assumed to be a nearly incompressible material.

The material properties of the socket itself were somewhat difficult to determine, as a typical transtibial prosthetic socket is a composite: polyester and synthetic resin with carbon, cotton, or nylon fibers. As such, the material properties of the socket may vary from one facility to another, and from one socket to another. Based on the material properties of reinforced polyester woven cloth, Young's modulus assigned a value of 1500 MPa ($\nu = 0.3$). For the soft socket models, the Pelite liner was approximated by a Young's modulus of 380 kPa ($\nu = 0.45$), based on material testing studies performed by Steege et al. (17–20) and Reynolds (12,13).

Boundary Conditions and Loading

In addition to geometry and material properties, FE model description also requires information regarding the model boundary conditions. The soft tissues of the residual limb extending beyond the proximal brimlines of the socket were approximated as a free surface. An elastic foundation at the proximal end of the limb model was applied to account for the tissues of the thigh that were not explicitly modeled. The PTB socket rectification was implemented by studying the rectification template from the University College London (UCL) Computer-Aided-Socket-Design (CASD) system (**Figure 4**). This template identifies the nine areas of a transtibial socket that are most commonly rectified. In the generic, geometric FE model, the socket node numbers corresponding to these nine rectification areas were noted, and radial nodal displacements ranging from 2 to 9 mm, corresponding to the respective prosthetic socket rectification scheme, were applied (28).

The experimental load state was limited to static stance with the load supported equally by both the prosthetic and physiologic legs (double support): the weight supported solely by the prosthetic leg (single support): and the weight supported by the physiologic limb only (prestress state). The forces and moments measured at the feet via force platforms were transferred to the FE model. This external load was applied distally to the prosthetic socket; proximal application to the femur was not an option as the femur was not represented by elements, but was modeled as a fixed boundary.

These individualized FE models (i.e., application of the scaling algorithm and assignment of subject-specific material properties) were then analyzed for the respective experimental load states to estimate normal and shear interface stresses. As tension cannot exist to any great extent between the residual limb and the prosthetic socket, existence of tension in FE models was counter-intuitive. Therefore, any tensile normal stresses that developed at the residual limb surface in the FE models were removed through an iterative process: equal and

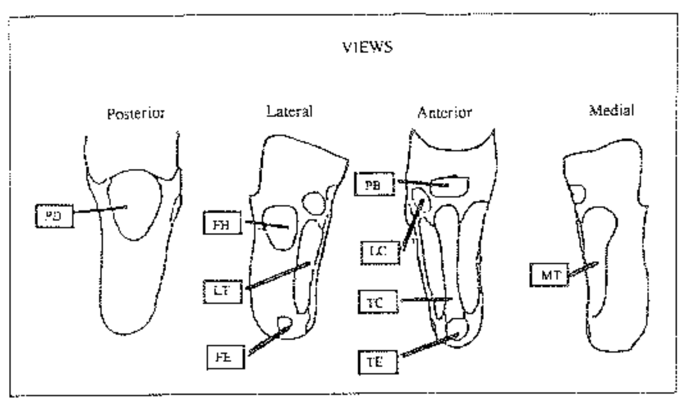

Figure 4.
Sample rectification template for the UCL CASD system: each area represents regions of the transtibial PTB prosthetic socket design that typically undergo shape modifications or rectification. PD = popliteal depression; FH = fibular head; LT = lateral tibial flare; FE = fibular end; PB = patellar tendon bar; LC = lateral femoral condyle; TC = tibial crest; TE = tibial end; MT = medial tibial flare.

opposite compressive stresses were applied to redistribute the load so that tensile normal stresses at the interface were negligible.

Analyses included representative trials for each alignment (neutral, plantarflexion, and dorsiflexion) for the double support load state of each prosthetic test socket for a total of 21 analyses. The ability of the FE models to estimate the interface pressures was assessed based on comparison of experimental and FE interface pressures.

Generic, Geometric Approximation of Residual Limb Geometry

To investigate the validity of the generic, geometric approximation of residual limb geometry used in the FE models, two additional FE models based on alternative geometry were created for a single subject. The first used digitization of the undeformed wrap cast to define the surface geometry, while the bony geometry remained approximated by generic, geometric shapes. Residual limb geometry for the second model was based on transverse CT scans of the residual limb and hard, unrectified socket. This digitization therefore included both the internal and external geometry of the residual limb, as well as detail regarding the relative position of the bone within the soft tissue bulk. All three models, generic/geometric, surface digitized, and CT digitized, had approximately the same mesh distribution.

The ability of these two alternative formulations to estimate transtibial residual limb/prosthetic socket interface pressures was assessed and compared to the generic, geometric FE model results. This information was then used to assess the limitations of the generic, geometric approximation of residual limb geometry in modeling the residual limb/prosthetic socket system.

Experimental Methodology

To evaluate the ability of a scaled generic, geometric FE model to estimate residual limb/prosthetic socket interface pressures, experimental studies were conducted to evaluate local soft tissue properties of the residual limb for FE model description, to measure local interface pressures for model validation, and to measure the load state at the prosthetic foot and the position of the socket with respect to the center of pressure to enable transformation of the load state to the prosthetic socket in the FE models. Experimental trials were conducted for three subjects (persons with unilateral TTA wearing definitive prostheses who had no prior history of dermatological problems and demonstrated sufficient endurance and stability to stand for 45 min without tiring) wearing a variety of prosthetic socket designs. Informed consent was obtained from each subject prior to his/her participation in the study. For each socket design, measurements were taken for three trials for each of three static load states: double support, single support, and prestress state detailed above. In addition to this variation in the load state, variations in prosthetic alignment were also investigated.

Test Prostheses

The first step in the experimental methodology was the fabrication of endoskeletal test prostheses. Two to three different sockets/prostheses were manufactured for each of the subjects. The first experimental socket was a hard (no liner) unrectified socket, forming an approximate replica of the residual limb shape and fabricated from an undeformed wrap cast of the residual limb. This socket was used to assess the tissue properties of the residual limb and to quantify interface pressures for a "null" socket design. The remaining test sockets were PTB rectified sockets created with the UCL CASD system and fabricated with and without a Pelite liner. The rectification scheme was the same for both: the only variable was the presence/absence of the liner. The interface pressures measured with these sockets were used solely for validation of the FE model.

The manufacture of the test sockets required that the prosthetist take an undeformed wrap cast of the residual limb of each subject. The wrap cast was subsequently digitized with a 3-D cast digitizer (Prosthetic Research Study, Seattle, WA), and a plaster positive of it was carved using a CNC milling machine. A transparent check socket was then vacuum-formed over the plaster positive. To ensure that total contact was achieved between the residual limb and prosthetic socket, as is assumed in the FE models, a quick-setting paste (alginate) was used to fill any gaps that existed between the residual limb and prosthetic socket. The alginated check socket was then promptly filled with plaster to form a new plaster positive that was an approximate replica of the unloaded residual limb. The hard, unrectified experimental sockets were laminated over these replicas, and modified so that eight test ports (for the mounting of the tissue indentor and the pressure transducers) were located in their walls. To quantify socket fit as a function of interface pressure, the eight test sites chosen represented key areas involved in prosthetic socket rectification (see **Figure 4**). The sites of interest were: medial femoral condyle, patellar tendon, medial tibial flare, lateral tibial flare, fibular head, popliteal, pretibial, and distal anterior tibia areas.

Fabrication of the PTB rectified sockets was similar to that for the unrectified sockets, except that the initial socket design obtained from the digitized wrap cast was modified (i.e., rectified) using the UCL CASD system. The fit of the corresponding check socket was evaluated by the prosthetist, and design modifications were made via the UCL software. Once a satisfactory design had been achieved, the check socket was again filled with alginate to ensure total contact. The PTB rectified socket was then laminated over the resulting plaster positive, and Pelite liner; test ports were similarly positioned in the socket wall.

To complete the experimental prostheses, each test socket was attached to a pylon via a socket adapter with pyramid and a tube clamp adapter that allowed alignment variations. Another tube clamp adapter and modular SACH foot adapter linked the pylon distally to a SACH foot. The prosthetist then aligned the limb using conventional static and dynamic alignment techniques.

Soft Tissue Studies

In vivo indentor studies of the soft tissues of the residual limb of each subject were performed to estimate the bulk soft tissue properties for the FE models. A manually actuated, plunger-type load-displacement testing device consisting of a small load cell (range= 0.0–44.4 N) and a linear variable differential transformer (LVDT: range=+6.25 mm) with a 6.35-mm diameter, flat-tipped indentor was used for all tissue testing (28). This device allowed simultaneous measurement of indentor excursion and the corresponding reaction force.

The plunger device was threaded into each of the eight test ports in a hard, unrectified test socket so that its tip was approximately flush with the interior surface of the socket. The subject stood in the experimental prosthesis and imposed minimal weightbearing to ensure that the limb was properly seated within the test socket. This protocol helped to ensure that the displacements measured via the LVDT reflected soft tissue displacement and did not include rigid body motion of the internal bony structures. Force/displacement curves were obtained by cyclically plunging and retracting the indentor into the soft tissues of the residual limb (28).

Experimental Load State

The load state for use in the FE model was obtained by having the subject don the test prosthesis and stand on two AMTI (Advanced Mechanical Technology, Inc., Newton, MA) force plates, with one foot on each plate. The force plates measured the 3-D forces and moments, as well as the center of pressure (COP). The data was displayed on two oscilloscopes to provide vertical force feedback so that a comfortable position could be consistently obtained.

To impose this experimental load state on the FE model, the orientation of the residual limb/prosthetic socket system with respect to the COP of the force plates was needed. A Cartesian Optoelectronic Dynamic Anthropometer 3 Movement Monitoring System (CODA-3) scanner (Charnwood Dynamics, Barrow-on-Soar, Leics., England) measured the 3-D position of three retroreflective markers on the socket surface, thereby enabling evaluation of socket position relative to the previously determined position of the force platforms. In addition, the spatial location of three of the eight test sites on the socket was used to develop a coordinate transformation matrix between the experimental setup and the corresponding three nodes in the FE model.

Three trials of double and single support stance were conducted while wearing the unrectified and PTB rectified sockets. For the PTB rectified sockets, an additional three trials were conducted with minimal weightbearing on the prosthetic leg (just enough to maintain proper socket placement) to evaluate prestresses on the tissues due to PTB socket rectification. To obtain a variety of load states, the same protocol was repeated for both maximum plantarflexion and maximum dorsiflexion of the prosthetic foot.

Interface Pressure Measures

The pressure measurement system consisted of miniature Kulite piezoresistive metal diaphragm transducers (model XTM-190, Kulite Semiconductors, Leonia, NJ) with an approximate sensitivity of 170 mV/MPa hydrostatic pressure, and a maximum pressure reading of 350 kPa (50 psi). These transducers weigh approximately 8 grams, and are 3.76 mm in diameter (28,34). The variability in interface pressure varied as a function of subject, test site location, and loading/alignment configuration; typical standard deviations in interface pressure at a given test site for a given subject/load/alignment were 3 kPa.

Journal of Rehabilitation Research and Development Vol. 34 No. 2 1997

RESULTS

Experimental Data

Normal stresses (pressures) and the experimental load state were measured for three subjects during stance in several different prostheses. Three trials were conducted for each of three prosthetic alignments (neutral, dorsiflexion, and plantarflexion) and for each of three different load states (prestress, double, and single support). The experimental pressures were measured in areas that, based on the principles of PTB socket design, should bear significant load (patellar tendon, popliteal areas) and relatively minimal load (fibular head and distal anterior tibia regions). A representative sample of the measured interface pressures for a single subject during double support stance is presented in **Figure 5.** Variations in the interface pressure distribution occur locally for each subject, and also appear to be influenced by prosthetic socket design and prosthetic alignment.

Finite Element Models

The results of the FE models and the corresponding experimental validation are contrasted with numerical and experimental analyses reported in the literature for persons with TTA wearing neutrally aligned PTB prostheses during double support stance (**Table 2**). Comparisons are approximate, as details regarding socket design and test site location in previous studies are incomplete. Differences may be attributed, in part, to differences in experimental protocol, particularly variations in the means of measuring pressure, and also variations in the numerical models.

Results of the FE analyses for double support stance for a single subject are illustrated in **Figure 6;** these FE results correspond to the experimental data shown in **Figure 5.**

Pressure Estimation Ability

The results of the individually scaled FE models,

Table 2.
Comparison of local interface pressure results from the generic, geometric FE model and the corresponding FE model validation (average of three subjects) to both numerical and experimental analyses reported in the literature. All analyses involve persons with TTA wearing PTB rectified sockets (static loading only, neutral alignment).

Limb Area	Generic Geometric FE Model Pressures (kPa)	Experimental Validation (kPa)	Literature Pressures (kPa)	Analysis Type	Reference
lateral tibial flare	10	88	12	numerical	(19)
			30	experimental	(36)
			39	experimental	(35)
			48	experimental	(19)
			110	numerical	(12)
medial tibial flare	41	40	5	experimental	(36)
			25	numerical	(19)
			34	experimental	(35)
			71	numerical	(12)
medial femoral condyle	20	99	5	numerical	(19)
			7	experimental	(35)
			47	experimental	(19)
patellar tendon	105	84	40	experimental	(36)
			48	experimental	(19)
			64	experimental	(35)
			83	numerical	(19)
			200	numerical	(12)
popliteal area	41	74	0	experimental	(19)
			11	numerical	(19)
			43	experimental	(35)
			120	numerical	(12)

FE = finite element; TTA = transtibial amputation; PTB = patellar-bearing-tendon.

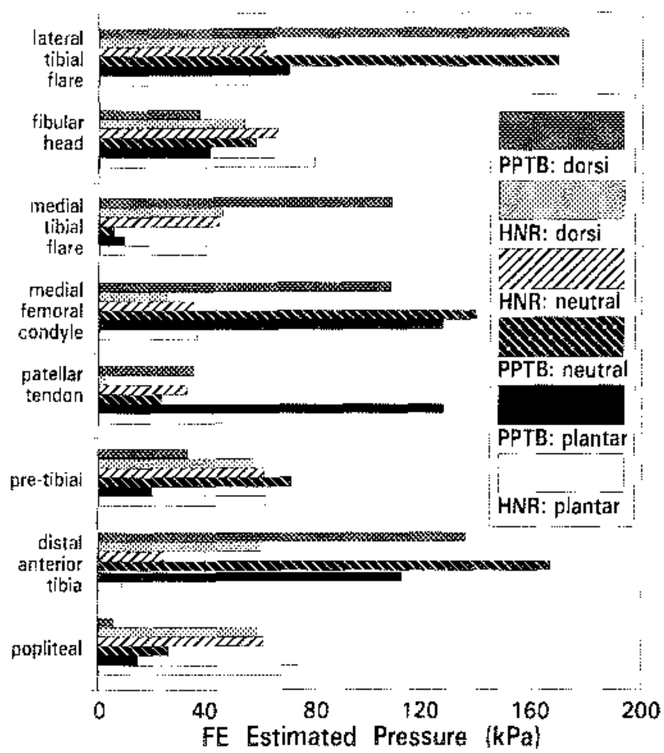

Figure 5.
Summary of interface pressures measured for a single subject in a variety of prosthetic socket designs (HNR=hard, unrectified socket; PPTB=Pelite-lined, PTB rectified socket) and prosthetic alignments (dorsi=dorsiflexed foot; neutral=neutral alignment; plantar=plantar-flexed foot). All measurements are representative trials of double support stance.

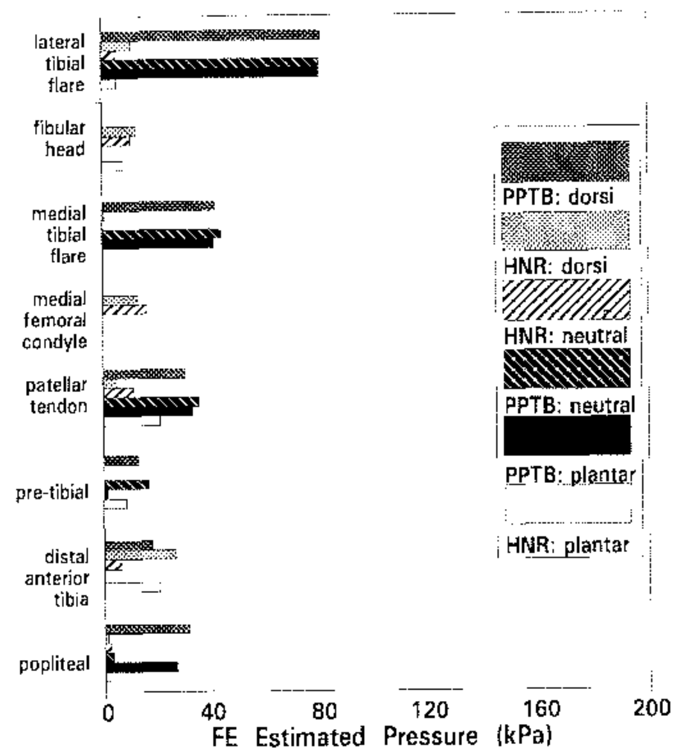

Figure 6.
Interface pressures estimated by the scaled, generic, geometric finite element model for the subject and experimental conditions reported in **Figure 4**, in double support stance (HNR=hard, unrectified socket; PPTB=Pelite-lined, PTB rectified socket).

namely the interface pressures or normal stresses, were compared to those measured during the experimental trials; the corresponding pressure estimation errors are summarized in **Table 3.** This table illustrates that, with the exception of the hard, PTB rectified socket models, the FE models typically underestimated (i.e., negative pressure estimation errors) the interface pressures in both the pressure-tolerant and pressure-sensitive regions of the transtibial residual limb. These errors were not normalized as the experimentally determined interface pressures included small, near-zero values.

Generic, Geometric Approximation of Residual Limb Geometry

The pressure estimation errors resulting from the FE models incorporating alternative representations of residual limb geometry were compared to the corresponding pressure estimation errors for the generic, geometric FE model for the same subject are shown in **Figure 7.** These results indicate that the magnitude of the pressure estimation errors for each of these geometric approximations are comparable.

DISCUSSION

Based on comparison of **Figures 5** and **6**, the variation in interface pressures due to prosthetic alignment is less pronounced in the FE analyses than in the experimental studies. These results differ from Sanders (14,15,22) who observed stress sensitivity to prosthetic alignment in her FE model that was inconsistent with her experimental results. Both the FE model and the experimental data indicate interface pressure sensitivity to prosthetic socket design, including the rectification scheme and the presence/absence of a prosthetic liner, and test site location. The sensitivity of the generic geometric FE model to variations in prosthetic socket design

Journal of Rehabilitation Research and Development Vol. 34 No. 2 1997

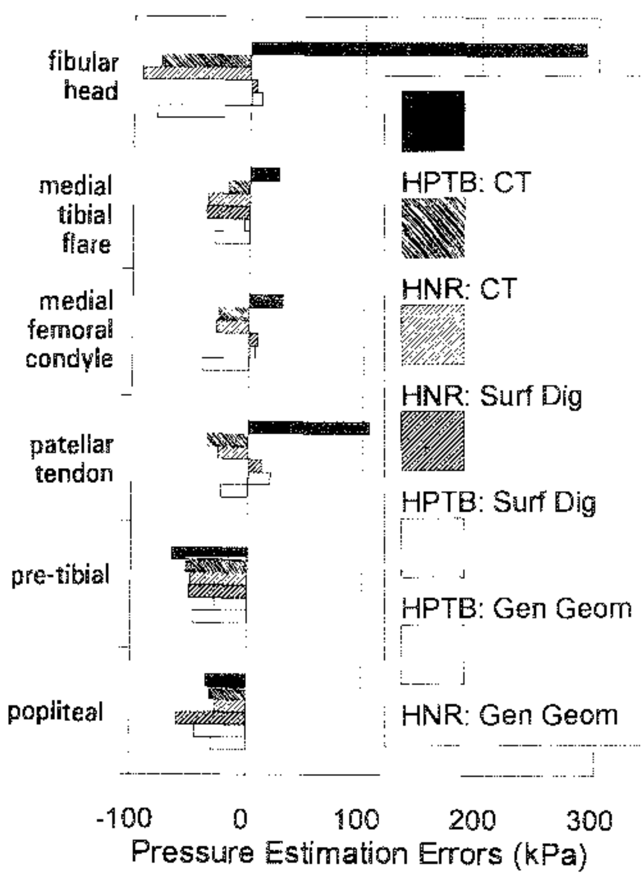

Figure 7.
Summary of pressure estimation errors for the residual limb finite element models for a single subject for models that incorporate different approximations of residual limb geometry: generic/geometric (Gen Geom); surface digitized external limb geometry (Surf Dig); and radiographic data (CT). Two different socket designs were investigated: a hard, unrectified socket (HNR) and a hard, PTB rectified socket (HPTB).

and limb geometry has been presented elsewhere (37,38). As illustrated in **Table 2,** these experimental and FE pressures are consistent with values for transtibial residual limb/PTB rectified sockets previously reported in the literature.

If the FE models were consistently able to estimate the interface pressure distribution, the FE pressure and the experimental pressure would be equivalent, and the pressure estimation errors would be negligible. However, as illustrated in **Table 3,** the FE models appear to both over- and underestimate the normal stresses. For the hard unrectified socket, the FE models typically underestimated the experimental pressures for all investigated regions except the distal anterior tibial region. The Pelite-lined PTB rectified socket models overestimated the interface stresses at the patellar tendon area of the residual limb; the model underestimated pressures for all other investigated regions. Finally, the hard PTB rectified socket models overestimated pressures for the fibular head, medial tibial flare, medial femoral condyle, and patellar tendon regions. In general, the magnitude of these average pressure estimation errors are significant compared to the mean experimental pressures.

There are several sources that may have contributed to the pressure estimation errors, all of which are associated with the simplifying assumptions incorporated in the FE models. These include the approximation of bulk soft tissue as a linear elastic, homogeneous, isotropic, nearly incompressible material; the use of linear, small displacement models to represent the loaded residual limb; the approximate location of the experimental test sites in the FE model; the inadequate representation of the socket/liner and liner/soft tissue interfaces; the failure to explicitly model the socket donning procedure; and errors in the generic, geometric approximation of residual limb geometry.

In the generic geometric FE models, bulk soft tissue was assumed to be a linear elastic, homogeneous, isotropic, nearly incompressible material. However, this simplifying assumption is inaccurate. Bulk soft tissue is composed of many different tissues, including skin, muscle, fat, and tendons, all of which have different microscopic structures. Therefore, bulk soft tissue is not homogeneous. In addition, the orientation of these microstructures (i.e., collagen fibers, elastin, and so forth) tend to indicate that bulk soft tissue is also not isotropic. The representative force-displacement curves illustrated in **Figure 3** obtained during *in vivo* indentation of the lower limb indicate that bulk soft tissue is also nonlinear. Finally, the validity of the nearly incompressible material approximation of bulk soft tissue cannot be easily assessed; however, based upon the predominance of fluid in it, near incompressibility is likely an adequate assumption. The difficulty arises in the approximation of this near incompressibility in FE models. Various formulations of near incompressibility in the MARC FE software include a constant dilatation approach in which incompressibility is enforced on an element level, various values of Poisson's ratio (0.45–0.499) that may result in artificially stiff behavior (28), and nonlinear elastomeric formulations that utilize strain energy equations that enforce incompressibility through the third strain invariant. The limitations of the linear, elastic, homogeneous, isotropic, nearly incompressible approximation of bulk soft tissue are likely to significantly influence the per-

Table 3.
Summary of average FE and experimental pressures and mean pressure estimation errors for three persons with TTA during double support stance. The summary data for the hard unrectified and Pelite-lined PTB rectified socket models represent averages of three subjects for three alignment trials. The data for the hard PTB rectified socket are mean results for a single subject for three alignment trials.

	Hard Unrectified Socket			Pelite Lined PTB Rectified Socket			Hard PTB Rectified Socket		
Limb Area	Avg FE Pressure	Avg Expl Pressure	Avg ERROR	Avg FE Pressure	Avg Expl Pressure	Avg ERROR	Avg FE Pressure	Avg Expl Pressure	Avg ERROR
lateral tibial flare	6.4±3.0	58.0±3.4	−51.5±3.7	60.1±21.9	82.9±75.8	−22.8±60.2	11.0±0.3	19.3±3.2	−7.0±2.6
fibular head	5.1±4.4	63.2±20.7	−49.42±26.7	1.5±26.2	59.4±17.3	58.0±15.9	9.6±6.6	4.5±4.1	2.8±4.6
medial tibial flare	3.6±4.3	46.5±16.7	−44.0±20.9	47.8±20.5	71.3±86.6	−23.5±95.8	26.1±2.6	16.6±3.2	11.2±3.5
medial femoral condyle	5.2±6.0	38.2±14.8	−30.5±18.3	0.0±13.6	93.3±49.7	−93.3±49.7	0.9±1.2	−2.4±1.1	3.8±2.4
patellar tendon	15.4±10.3	28.7±16.6	10.7±16.8	105.0±82.7	98.1±55.3	6.9±62.3	46.5±9.7	9.8±4.2	36.9±3.8
pre-tibial	2.5±6.9	56.4±5.0	−66.8±28.1	33.9±42.1	65.3±50.9	−60.3±52.9	27.5±0.5	n/a	n/a
distal anterior tibia	191.0±370.0	26.6±32.3	53.4±242.6	1.9±5.6	87.7±75.6	−85.8±74.5	12.8±18.1	22.7±12.3	−11.0±1.0
popliteal	1.4±6.5	45.5±16.0	−47.7±29.9	27.3±13.4	73.0±78.8	−45.7±78.7	6.2±0.2	22.8±6.1	−13.3±3.2

FE = finite element; TTA = transtibial amputation; PTB = patellar tendon bearing; Avg = average; Expl = experimental; ERROR = $P_{fe}-P_{exp}$ where P_{fe} = pressure predicted by FE model; P_{exp} = pressure measured experimentally; ERROR <0, the FE model underestimates the pressure; ERROR >0, FE model overestimates the pressure. All data are in kPa.

formance of the FE model. Attempts to reflect more accurately the mechanical properties of bulk tissue in future models will improve FE model performance.

In addition to the limitation of the bulk soft tissue material formulations, the FE model uses a linear, small displacement formulation to approximate the loaded residual limb. Incorporation of large displacement/large strain formulations to more accurately reflect the response of bulk soft tissue to prosthetic loading and, more importantly, to prosthetic socket rectification may be necessary.

As described in the experimental protocol, the estimation of the location of the experimental test sites in the FE model are used to generate the transformation matrix used to convert the experimental load state measured at the prosthetic foot to an FE model load condition at the distal prosthetic socket. Errors in the estimation of these test site locations will therefore cause errors in the calculation of the model load state. Thus, differences in the experimental load state due to changes in prosthetic alignment may not be adequately represented, resulting in heightened or diminished model sensitivity to prosthetic alignment.

In addition to the aforementioned model limitations, the FE model also inadequately represents the socket/liner and liner/soft tissue interfaces. These interfaces may be more accurately approximated via nonlinear contact analysis in which contact between the socket and liner (and/or liner and soft tissue) may occur or be disrupted. Such an analysis would also enable the influence of friction/slip at the interface to be explicitly modeled. Similarly, the failure of the FE models to explicitly simulate the socket donning procedure (i.e., via contact analysis) may influence the initial stress state of the residual limb tissues.

Finally, errors in the generic, geometric approximation of residual limb geometry, including the scaling procedure, the placement of the interior, bony boundary within the soft tissue bulk, and the inadequate representation of the surface limb geometry, may contribute to pressure estimation errors. As one of the primary differences in this research was the approximation of the residual limb geometry with generic, geometric structures, errors due to the approximation of that geometry were investigated. Although these analyses were limited to a single subject, preliminary results indicate that limitations of the generic, geometric approximation of residual limb geometry were minimal, as evidenced by the similar pressure estimation errors resulting from FE models with the same mesh distribution using either surface digitized limb geometry or volume digitized limb geometry obtained from transverse CT scans. Thus, the errors due to this geometric approximation were either small compared to other sources of error, or were well masked by other sources of error. Further investigation to examine the respective influence of the positioning of the bony structures, the adequacy of the scaling algorithm, and the simplification of the limb surface geometry needs to be conducted.

Although the generic, geometric FE models of the residual limb and prosthetic socket do not appear to accurately estimate the interface pressure distribution for specific subjects, the model does have practical applications in comparative stress analysis. Parametric analyses investigating the effects of various socket parameters (e.g., liner stiffness, socket stiffness, socket rectification scheme) on the interface stress distribution can be investigated. Such general information may contribute significantly to improved understanding of residual limb/prosthetic socket mechanics.

CONCLUSIONS

A generic, geometric FE model was developed to investigate interface pressures between the residual limb and prosthetic socket for persons with TTA. The model differed from previous limb models in that the geometry was not based on conventional imaging techniques, but instead used standard geometric shapes approximating anthropometric data. This model was individualized by incorporating the material properties of the limbs of the respective subjects (based on *in vivo* indentor studies), subject-specific scaling, and the respective custom prosthetic socket design. The results of these models, namely the interface stress distribution, were compared to experimentally measured local interface pressures. In general, comparison of the FE and experimental results indicate:

1. The variation in interface pressures due to prosthetic alignment is less pronounced in the FE analyses than in the experimental studies. However, both the FE model and the experimental data indicate interface pressure sensitivity to prosthetic socket design and limb location.
2. The FE models appear to both over- and underestimate the interface normal stresses; these pressure estimation errors vary in both the magnitude and the distribution.
3. Many of the simplifying assumptions incorporated in the FE models may have contributed to the pressure estimation errors. These potential sources of error include: the approximation of bulk soft tissue as a linear elastic, homogeneous, isotropic, nearly incompressible material; the use of linear, small displacement models to represent the loaded residual limb; the approximate location of the experimental test sites in the FE model; the inadequate representation of the socket/liner and liner/soft tissue interfaces; the failure to explicitly model the socket donning procedure; and errors in the generic, geometric approximation of residual limb geometry.
4. Additional FE models that incorporate contact analysis and nonlinear bulk soft tissue properties are needed to more accurately represent the residual limb/prosthetic socket system.

Note that these are preliminary investigations. Ultimately, if FE analysis is to have a role in prosthetic socket design, the model must also be valid for dynamic loading. In dynamic loading, the interface boundary condition is more complicated, and the role of shear, friction, and slip will likely be more significant. Before such complexities are introduced, however, more thorough understanding of the behavior and limitations of residual limb FE models subject to static loading is necessary.

Finally, although the generic, geometric FE models of the residual limb and prosthetic socket do not appear to accurately estimate the interface pressure distribution for specific subjects, the model does have practical applications in comparative stress analysis. Parametric analyses investigating the effects of various parameters related to limb geometry and/or socket design on the interface stress distribution can be conducted. Such general information may contribute significantly to improved understanding of residual limb/prosthetic socket mechanics.

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