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The quasi-static response of compliant prosthetic sockets for transtibial amputees using finite element methods

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Abstract

The finite element method (FEM) is a very powerful tool for analyzing the behavior of structures, especially when the geometry and mechanics are too complex to be modeled with analytical methods. This study focuses on the analysis of patellar tendon bearing prosthetic sockets with integrated compliant features designed to relieve contact pressure between the residual limb and socket. We developed a FEM model composed of a socket, liner and residual limb and analyzed it under quasi-static loading conditions derived from experimentally measured ground reaction forces. The geometry of the residual limb, liner and socket were acquired from computed tomography (CT) data of a transtibial amputee. Three different compliant designs were analyzed using FEM to assess the structural integrity of the sockets and their ability to relieve local pressure at the fibula head during normal walking. The compliant features consisted of thin-wall sections and two variations of spiral slots integrated within the socket wall. One version of the spiral slots produced the largest pressure relief, with an average reduction in local interface pressure during single-leg stance (20–80% of the stance phase) from 172 to 66.4 kPa or 65.8% compared to a baseline socket with no compliant features. These results suggest that the integration of local compliant features is an effective method to reduce local contact pressure and improve the functional performance of prosthetic sockets.

Keywords: Amputee; Design; Prosthetic sockets; Compliance; Finite element analysis

1. Introduction

The design and manufacturing of patellar tendon bearing (PTB) prosthetic sockets for transtibial amputees has been improved with the integration of state-of-art freeform fabrication techniques [1]. These techniques allow sockets to be designed within a computer-aided design (CAD) environment directly from digital shape information of the patient's residual limb, which ensures an effective design and the ability to quickly fabricate prototypes by eliminating many of the extensive hand procedures involved in the production of conventional sockets. Furthermore, this approach allows the designer flexibility to incorporate compliant features in the socket walls to enhance socket comfort by relieving high pressures at specific sensitive sites of the residual limb without a corresponding cost penalty in the manufacturing process. However, in order to design efficient compliant features and evaluate their structural and dynamic behavior, appropriate load transfer information between the socket and residual limb is necessary.

Estimating a priori the time history of the interface pressure (defined as the stress normal to the interface surface) magnitude and distribution between the socket and residual limb is a significant challenge in the design of prosthetic devices. A common procedure to estimate the interface pressure is to utilize data measured during clinical trials using an instrumented prosthesis. However, when one of the objectives for improving the socket design is to reduce the interface pressure itself at specific interface sites, then a potentially costly and time-consuming iterative design process is required: an initial prototype needs to be manufactured and instrumented to measure the resulting interface pressure, which in turn is used as the new boundary condition for the subsequent

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redesign, and the process is repeated until the desired results are achieved.

A promising solution for estimating the interface pressure between the residual limb and socket is to use the finite element method (FEM) to model the limb–socket interaction. FEM provides an interface between experimental load measurements, the complex musculoskeletal geometry and material data to quantify the stress distribution on the socket structure. Thus, FEM is a very powerful technique for evaluating the performance of potential socket designs.

The development of a lower extremity FEM model of a transtibial amputee is, however, a challenging task that has been progressing for almost two decades. Comprehensive surveys on early models and approaches have been previously presented [2,3]. Important considerations for using FEM in such applications include: (1) defining the material properties of the soft tissues, which exhibit highly nonlinear and non-uniform behavior; (2) modeling the contact interfaces between the residual limb, socket liner and socket; and (3) modeling the pre-stresses that arise due to wearing the socket. Previous studies analyzing the interface pressure have attempted to address these criteria by modeling the socket either as a rigid and constrained structure or as a uniform thickness shell with a constant stiffness devoid of compliant features [4–9]. However, these previous studies did not focus on the socket structure and its topology, which is important when evaluating the performance of different socket designs from an engineering perspective.

The overall objective of this work was to use FEM to analyze the structural response of four different PTB socket designs. Three of the designs include compliant features integrated within the socket wall to relieve pressure in the area of the fibula head, which is a commonly reported area of discomfort and pain for patients with PTB sockets. The sockets were designed for fabrication with Duraform™ PA (polyamide) material using a solid freeform fabrication technique called selective laser sintering [10]. In addition, the structural behavior of each socket was analyzed to insure safety and effectiveness in relieving pressure to enhance comfort. The specific objectives of this study were to use a FEM model of the residual limb, liner and socket to: (1) evaluate the structural integrity of the sockets by quantifying the stresses throughout the socket walls, (2) assess the resulting deformation in the compliant features and subsequent pressure relief at the fibula head relative to a baseline socket without compliance, and (3) compare the performance of the compliant designs in their ability to relieve pressure.

2. Material and methods

2.1. Overview

To perform the FEM analysis, a baseline finite element model was generated from computed tomography (CT) data acquired from the residual limb of a transtibial amputee patient while wearing a PTB prosthesis and liner. Three geometrically similar prosthetic socket models with additional compliant features integrated within the socket walls were also created. The baseline FEM model was first subjected to a simple downward force of 800 N applied at the knee level to validate the FEM model against contact pressure values reported in the literature. In subsequent analyses, all four models were subjected to quasi-static loading boundary conditions obtained from experimentally measured ground reaction force data. From the FEM results, the structural stresses in the sockets were computed, as well as the contact pressure at the fibula head and the displacement of the compliant features in the sockets. The local deformation in each compliant feature during the quasi-static loading was defined as the displacement at the center of the compliant feature relative to the region of the socket wall immediately surrounding the compliant feature. Comparisons between sockets were made to identify which compliant feature provided the largest pressure relief. Details of the FEM model and analysis are provided below.

2.2. Generation of FEM model from CT data

Previously collected CT data from the amputee patient provided the necessary shape information for the residual limb bones, tissues and inner socket wall. The patient provided informed consent according to the rules and regulations of The University of Texas Health Science Center at San Antonio and The University of Texas at Austin. The patient was a 70-year-old male, 1.82 m tall and weighing 90 kg, diabetic and relatively active. The CT scan was adjusted to produce one image every 2 mm. During the CT scan, the patient was wearing a Pelite liner around his residual limb and a PTB socket that was supported on the bottom using a small force to assure the socket remained in contact during the CT scan. The CT data was converted into separated point clouds for each main surface area (bones, skin and outer liner/inner socket) using Mimics (Materialise[1]). Each point cloud was then processed using Raindrop Geomagic[2] to construct a CAD surface model composed of structured first-order continuous four-sided Non-Uniform Rational B-Splines (NURBS) patches. These surfaces were then organized into solids using Rhinoceros,[3] which were imported into I-deas[4] for meshing and the FEM analysis. The boundaries between the different structure volumes (bone, tissue, liner and socket) were constrained to zero relative displacement between contacting elements. Hence, the contact interface was modeled with zero slipping or displacement between structures. The volumes were then meshed using the I-deas automated mesh generator using 10-node parabolic tetrahedra with the Delaunay mesher option. The resulting meshes were analyzed for

[1] Leuven, Belgium.
[2] Research Triangle Park, NC.
[3] From Robert McNeel & Associates, Seattle, WA.
[4] From EDS, Plano, TX.

distorted or stretched elements, which would likely lead to numerical errors in the FEM analysis. When such elements were identified, they were locally modified to reduce distortion.

The resulting models of the bones (distal femur, patella and remaining fibula and tibia), soft tissues and liner yielded 8625 elements and 14,680 nodes, 19,888 elements and 32,696 nodes, and 10,342 elements and 19,482 nodes, respectively (Fig. 1). Four socket models were then designed from this inner PTB socket shape: one baseline socket with a constant 6 mm wall thickness (Fig. 2A), and three sockets with integrated compliant features. The three compliant features were designed to relieve pressure at the fibula head region (which is the area encompassed by a 90 mm-diameter circle centered at the fibula head): (1) a local thin-wall (1.5 mm) thickness section (Fig. 2B), (2) two concentric and opposed plain 1 mm gap unconstrained spiral slots (Fig. 2C) and (3) constrained spiral slots with an endpoint support to limit maximum displacement and increase stiffness (Fig. 2D). The endpoint support had a support length and width of 119 and 14 mm, respectively (Fig. 3A and 3B). The resulting FEM socket models yielded 6516 elements and 12,657 nodes, 5364 elements and 10,644 nodes, 11,100 elements and 21,528 nodes, and 13,909 elements and 26,773 nodes, respectively.

All structural materials used in the analysis were assumed to be linearly elastic, homogeneous and isotropic. For the bones and socket (fabricated with Duraform™ PA[5]), the Young's moduli were 15 GPa [4] and 1.6 GPa (obtained from tensile tests performed on SLS fabricated specimens following ASTM Standard D638-03), and Poisson's ratio was 0.3 and 0.39, respectively. For the Pelite liner, the Young's modulus was 380 kPa and Poisson's ratio was 0.39 [6]. The Young's modulus for the soft tissues was assumed to be 200 kPa [5]. However, to account for the pre-stresses in the socket and stiffening soft tissues that occur during load bearing conditions [11,12], the Young's modulus value was increased to 250 kPa in the patellar-tendon region where the pre-stresses are the highest [4].

2.3. Boundary conditions

Initially, the load values for the boundary conditions in the baseline socket were modeled as a simple downward vertical force of 800 N to validate the FEM analysis against pressure data found in the literature. In all subsequent analyses, the loading conditions were quasi-static approximations using experimentally measured three-dimensional ground reaction forces and moments using a force platform while the patient walked at his self-selected speed. The forces and moments were transferred from the laboratory reference frame to the reference frame fixed at the top surface of the bones (Fig. 4). Six points of ground reaction force data were used as loading conditions in the analyses of all sockets. Each point came from the ground reaction force data at 0% (heel strike), 15, 35, 55, 78 and 100% (toe off) of the stance phase, respectively. A zero displacement constraint was specified on the bottom of the socket, where the prosthesis pylon is normally attached.

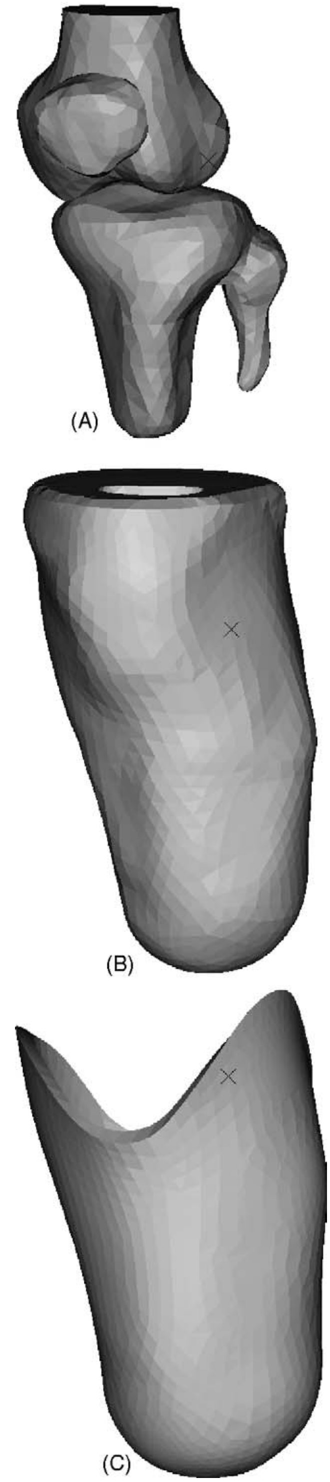

Fig. 1. FEM model of (A) bones, (B) soft tissues and (C) liner.

[5] 3D Systems, Valencia, CA.

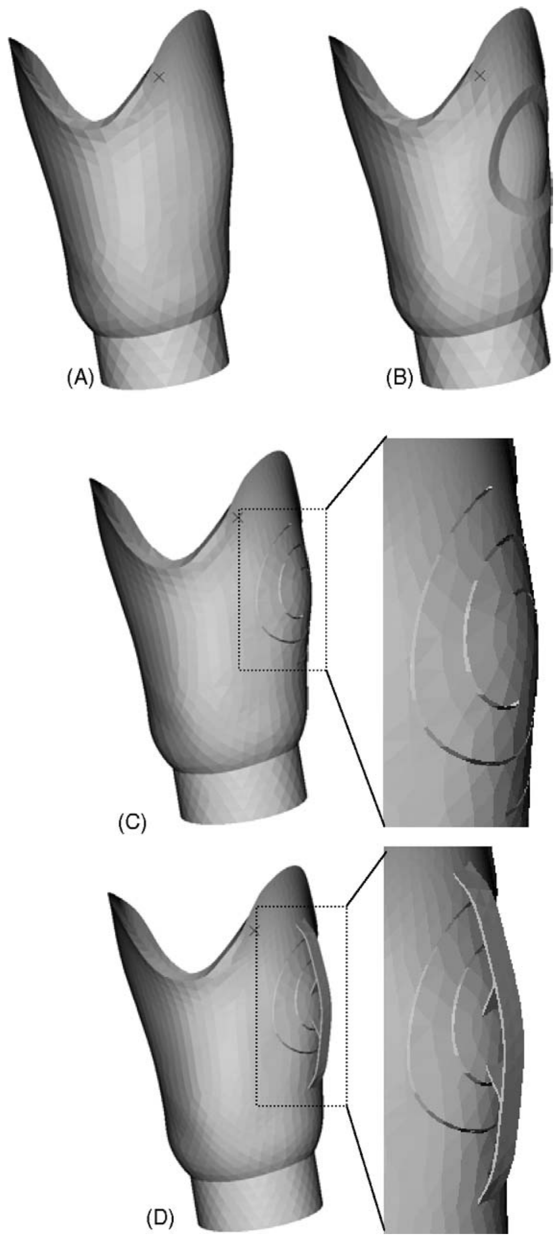

Fig. 2. FEM models of the four different socket designs simulated: (A) baseline socket with no compliant features, (B) socket with thin-wall compliance, (C) socket with unconstrained spiral slots, and (D) socket with constrained spiral slots.

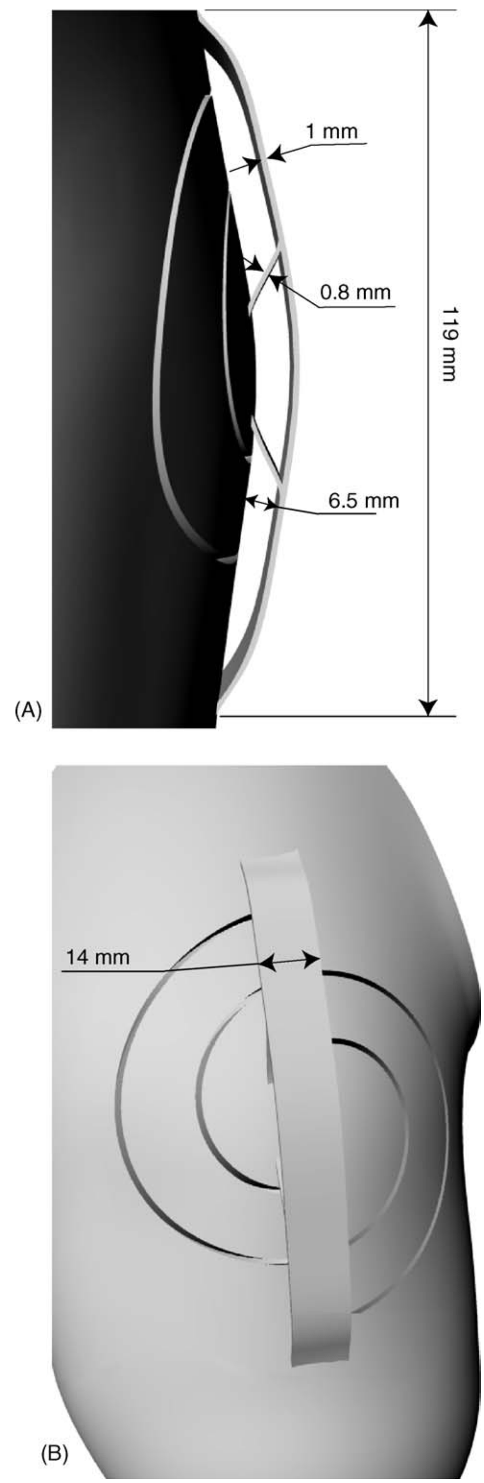

Fig. 3. Dimensions of the compliant support (from Fig. 2D): (A) side view and (B) frontal view.

3. Results

3.1. FEM results: socket stress, pressure and deformation

The application of the downward vertical load of 800 N in the baseline socket produced a maximum pressure of 250, 109 and 205 kPa in the patellar tendon, popliteal depression and medial tibia regions, respectively (Fig. 5). During the FEM simulations using the quasi-static loading condition that emulated the stance phase in walking, the peak structural stresses in the baseline socket was 14.1 MPa, which occurred near 35% of the stance phase at the front of the socket near the intersection between the cylindrical base and the bottom of the socket (Fig. 6). In the compliant sockets, the peak stresses also occurred near 35% of the stance phase, with the largest values occurring in the compliant features where the deformations were the largest. For the socket with a thin-

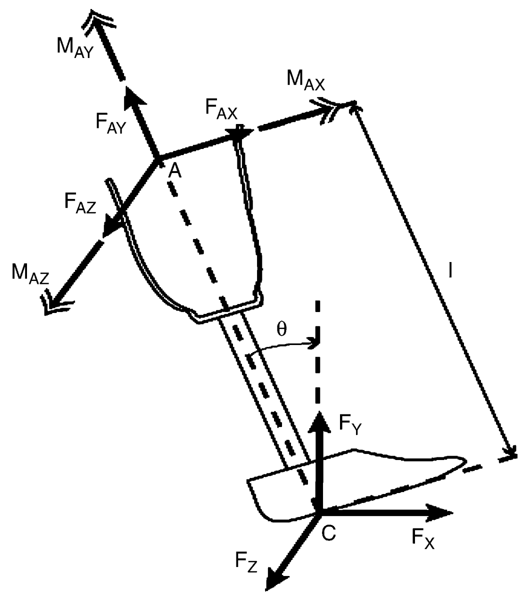

Fig. 4. Free-body diagram of a prosthetic leg in the sagittal plane (x–y).

wall region, the largest structural stress was 16.9 MPa near the anterior most portion of the thin region (Fig. 7); for the unconstrained spiral slots, 44 MPa concentrated at the most distal region of the slots (Fig. 8); and for the constrained spiral slots, 35 MPa also at the most distal region of the slots (Fig. 9).

The peak pressure on the fibula head occurred near 75% of stance for all designs (e.g., Fig. 10A). For the baseline socket, the maximum pressure was 172 kPa; for the thin-wall design, 135 kPa; for the unconstrained spiral slots, 66.4 kPa; and for the constrained spiral slots, 78.5 kPa. The average pressure relief provided by the compliant sockets relative to

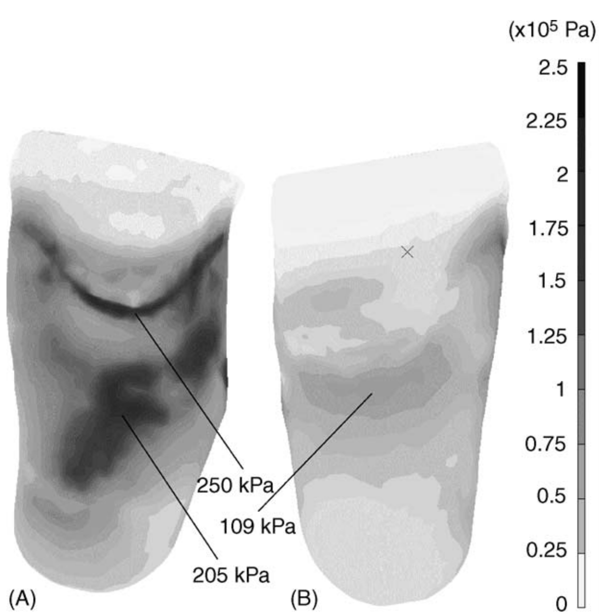

Fig. 5. Pressure on the residual limb using the baseline socket undergoing a downward vertical load of 800 N: (A) anterior and (B) posterior views.

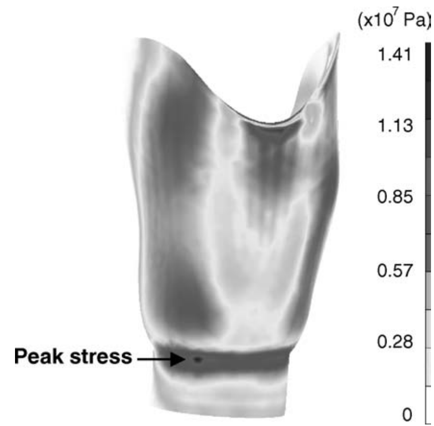

Fig. 6. FEM results displaying the structural stresses on the baseline socket at 35% of stance where the largest stresses were encountered. Units are in Pa.

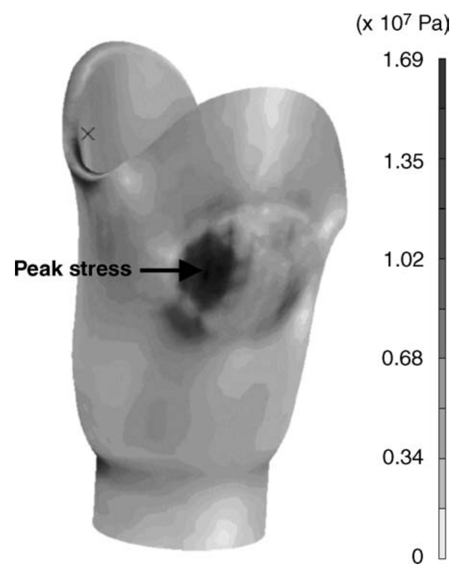

Fig. 7. FEM results displaying the structural stresses on the compliant socket with a thin-wall feature at 35% of stance where the largest stresses were encountered. Units are in Pa.

the baseline socket throughout single-leg stance (i.e., 20–80% stance phase) was 27.4% for the thin-wall design, 65.8% for the unconstrained spiral slots and 58.5% for the constrained spiral slots. The largest deformations occurred near 35% of stance (Fig. 10B), with the deformation in the thin-wall socket at 1.34 mm; unconstrained with spiral slots at 3.73 mm; and constrained spiral slots at 3.55 mm.

4. Discussion

The overall objective of this work was to use FEM to analyze the structural response of four different PTB socket designs, three of which included compliant features integrated within the socket wall. The ability of FEM to simulate before manufacturing a prototype the structural response of a socket design provides an effective means to optimize

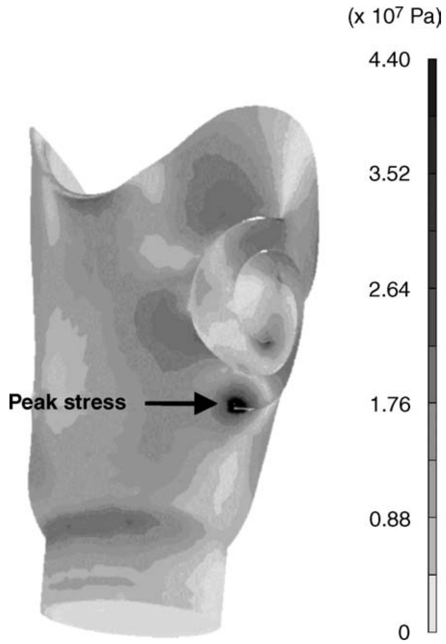

Fig. 8. FEM results displaying the structural stresses on the compliant socket with unconstrained spiral slots at 35% of stance where the largest stresses were encountered. Units are in Pa.

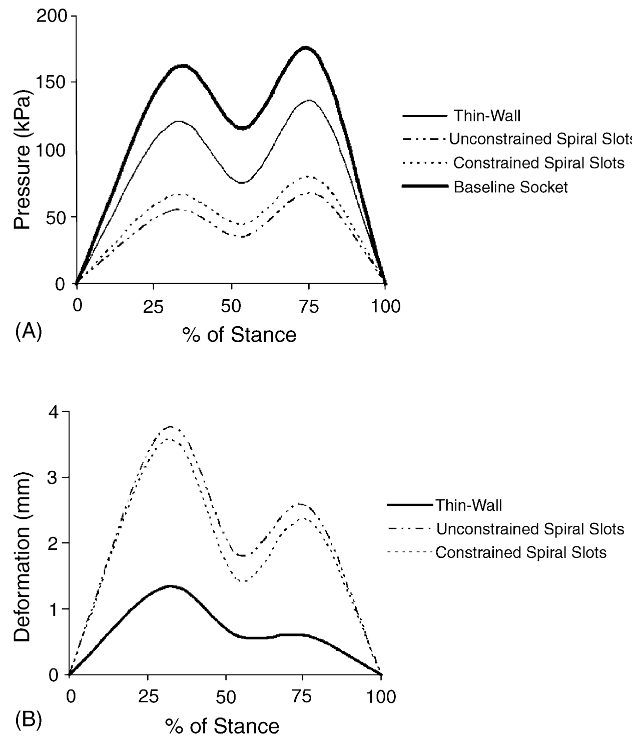

Fig. 10. Comparison of resulting FEM values for (A) pressure at fibula head and (B) local deformation at the compliant feature for the three different socket designs simulated.

the solution within the CAD environment, without the need for time-consuming and costly intermediate prototypes and experimental measurements. However, providing realistic boundary conditions is critical to the accuracy of FEM analyses. As such, a model of the residual limb was incorporated into the analysis. This allowed an improved representation of the interface stresses between the residual limb and the socket. As a result, the work presented here provides an important advancement in the structural analysis of different socket designs, with the long-term goal of enhancing their performance to improve the comfort and quality of life for amputees. Moreover, the use of CT image data allowed us to generate a very detailed subject-specific model of the residual limb, liner and socket.

The FEM analysis showed that the ability to relieve contact pressure at the specific site of the fibula head using spiral slots was considerably greater than that of the socket with the thin-wall compliance (Fig. 10A). Conversely, the socket designed with the unconstrained spiral slots produces a stress concentration value that approached the tensile strength of the Duraform^{TM} PA material (44 MPa). Thus, the design with the constrained spiral slots, although providing a slightly lower level of compliance, ensured the structural integrity of the socket was preserved.

An important aspect of any FEM analysis is model validation. This was achieved in the present study through a comparison between the model and experimental measurements obtained during a downward vertical 800 N load. The FEM analysis produced an overall contact pressure distribution on the skin and peak pressure values that compared well with experimental measurements (Fig. 5) [2]. Specifically, the computed contact pressures at the patellar tendon (250 kPa) and the popliteal depression (109 kPa) were within the previously reported range of 380–200 and 175–80 kPa,

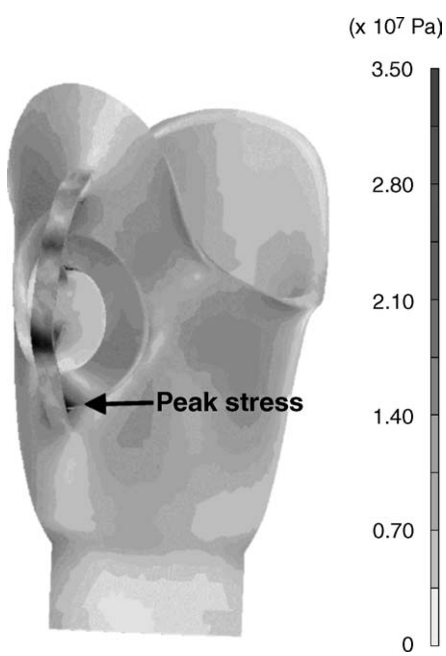

Fig. 9. FEM results displaying the structural stresses on the compliant socket with constrained spiral slots at 35% of stance where the largest stresses were encountered. Units are in Pa.

respectively, in published FEM-based [4–6,8,9] and experimental [13,14] analyses.

However, in order to create a computationally feasible FEM model, various material, model and loading approximations were necessary that warrant discussion. First, the soft tissue and liner possess nonlinear, viscoelastic characteristics, which would increase exponentially the computational complexity of the FEM model. In addition, there is little data available in the literature to support the use of specific parameters for the soft tissues. As a result, we used linear approximations as was done in previous studies [4–9]. Previous studies have proposed a Mooney–Rivlin formulation for these materials [15,16]. However, further studies are still needed to establish the range in which the parameters in such a formulation may vary across patients. The implementation and sensitivity of such a material formulation remain as an area for future work. Finally, the effect of pre-stresses on the tissue material characteristics was represented by locally increasing the Young's moduli in the patellar-tendon region where the pre-stresses are highest [4]. Future work will be directed at quantifying the level of tissue stiffening. However, the model validation showed that the values used in the analysis were reasonable approximations.

The contact between the soft tissues and liner, and between the liner and socket, were modeled assuming no sliding or gaps occur. Since the present study focuses on the stance phase of gait, the gapless assumption was considered reasonable considering this is the region of the gait cycle with the highest loads. As for the no sliding assumption, previous work has shown that the use of automated contact elements in FEM analysis of transtibial amputees with a "no slipping" model underestimates the mean normal contact stress by 16% and overestimates the mean shear stress by a factor of two when compared to a model with frictional slip (using a coefficient of friction of 0.675) [9]. Although the shear stresses are important in the clinical study of socket–limb interface mechanics, that was not the focus of the present work that concentrated on the structural behavior of the socket and the effects of compliant features on normal contact stresses. Thus, the present no-slip model was considered adequate for this study.

The quasi-static approximation for the loading in the boundary conditions in the present study also requires discussion. An approximation model to account for the dynamic effects (i.e., centripetal and Coriolis forces) in the ground reaction force load formulation was recently proposed [5], which showed that the main vertical load is not significantly influenced by the dynamic effects during the stance phase. In addition, the horizontal force would be increased by a maximum amount of 19%. Since the horizontal component of the force accounts for only a small portion of the total force, it would have little effect on the normal contact stresses. However, the applied moment at the knee joint due to the horizontal force was shown to increase up to 27%, which would be enough to decrease the normal stresses by 50% at the patellar tendon and increase it by 14% at the popliteal depression. Since the same loading profile was applied to all four socket models analyzed and each had a similar structural response, differences between the socket models under dynamic loading conditions would also expected to be similar. Future work will be directed at integrating a dynamic model of the loading conditions at the FEM model boundaries to assess the sensitivity of the results.

A final consideration is with regards to the use of CT data, which required exposing the patient to low levels of CT radiation. Unless the patient is already scheduled to undergo a CT scan for other clinical purposes (as was the case in the present study), alternative methods for acquiring the necessary imaging data may be considered. One alternative would be to use magnetic resonance imaging (MRI) data, which does not expose the patient to harmful radiation. However, MRI data is not always readily available and can have prohibitive costs. Another alternative would be to use cylindrical and conical solid primitives to approximate the bone structures [16]. However, these estimations are quite general and do not accurately represent the residual limb geometry, which greatly effects the resulting pressure distributions. Another alternative would be to store within a CAD environment a set of possible geometric variants of the bone topologies acquired from existing CT or MRI data. Appropriate scaling could then be used to match as close as possible direct measurements of the residual limb surface. Future work will be directed at assessing this possibility.

The FEM analysis proved effective in analyzing design variants of a transtibial amputee socket to ensure the socket's structural integrity. The results showed that integrating local compliant features within the socket wall can be an effective method for relieving contact pressure between the residual limb and socket that may improve the comfort and quality of life for amputees. A continuation of this study will use the present framework to develop sockets for a number of amputees to assess their performance through objective analysis and subjective feedback.

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