

Key considerations for finite element modelling of the residuum-prosthetic socket interface

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Conflict of interest

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Abstract

Study Design: Computational modelling

Background: Finite element (FE) modelling has long been proposed to support the design of prosthetics sockets. However, there is minimal detail in the literature to inform practice in developing and interpreting these complex, highly non-linear models.

Objectives: To identify recommendations for best practice in FE modelling of lower limb prosthetics, considering key modelling approaches and inputs.

Methods: This study developed a parametric FE model using MRI data from a transtibial amputee. Sensitivity analyses were performed upon socket loading methods, socket-residuum interface parameters and soft tissue material models from the literature, to quantify their effect on the biomechanical response of the residual limb to a range of parameterised socket designs.

Results: It was found that these variables had a marked impact on the predicted response of the FE model, especially with regards to the interfacial pressure and shear distribution.

Conclusions: All modelling decisions should be justified biomechanically and clinically:

- consider the effects of donning and interface friction to capture the shear stresses
- use representative stiffness hyperelastic material models for soft tissues when using strain to predict injury; and
- interrogate models comparatively, against a clinically-used control
- justification of these modelling decisions within a clinical reference frame.

Clinical Relevance:

Recommendations for future FE models of residual limb-prosthetic socket interface are proposed, to assist researchers in building these models and clinicians in appraising them. Any clinical application of the predictions generated by these models must be rigorously scrutinised.

1. Introduction

The residuum represents a constantly evolving interface for mechanical loading from a prosthetic limb, most commonly through a personalised socket. The shape of the residuum changes over time with oedema, muscle atrophy and stiffening of loaded tissue regions [1]. There are several anatomic and surgical considerations including bone shaping through bevelling, soft tissue coverage and retention of key sensory and vascular structures [2]. Currently, prosthetic limb users often require multiple fittings to achieve an acceptable definitive socket and even then report discomfort which may limit their rehabilitation progress [3]. The need for advanced technology to assist socket design and fitting is well established and recent proposals include the use of sensors, adjustable sockets and numerical simulations [4]. Despite this, there has been limited successful translation from lab to clinic of these advanced technologies.

The finite element analysis (FE) simulation technique is widely used in engineering, for example to determine the distribution of structural deformations or stress. Very particular requirements arise in the robustness of FE models when used to inform clinical practice, and in extracting relevant data [5].

The potential use of FE to simulate the complex residuum-socket interaction is well established. A review of the literature from 2000-2016 [6] discussed how clinical implementation of these tools would enable support for prosthetists in a more evidence-based socket design process whilst identifying opportunities for improving the state of the art in prosthetic limb FEA through applying dynamic loading, advances in imaging and measurements for model validation. Notable studies have considered the effects of different interface parameters [7], material models [8, 9], residuum morphology [9], and explicitly modelling socket donning [10]. One limitation to progress is the lack of published guidance about the effect of model construction decisions and input parameters. To develop such guidance, sensitivity analyses are required [11]. Clarity of reporting and transparency in the modeller's decision making process are also important. As in any scientific publication, methods should be reported in sufficient detail that other researchers may replicate them, and be made aware of the limitations inherent due to simplifications in representing this complex, highly nonlinear system.

This paper presents a parameterised patient-specific FE model of the TTA residual limb and prosthetic socket. Comparative analyses were used to establish the effects of different methods and input variables on the models' predictions. The results were critically appraised within the context of their potential clinical impact, to provide recommendations as informed guidelines for others developing similar models. The aim of such guidelines is to ensure that the decisions made in

developing future FE models are justified as appropriate for their research question, and that future models used to support clinical practice are reliable.

2. Methods

2.1. Generation of the FE model

An FE model was generated from MRI scans obtained through secondary data ethics (ERGO#29927) of a unilateral TTA (MAGNETOM Spectra, Siemens Healthcare GmbH, Germany; 3.0 mm slice thickness, 0.5 mm in-slice resolution, T1-weighted) who provided written, informed consent. The scan was segmented into bones, soft tissue, tendon and meniscus (Scan IP 2017.06, Synopsys Inc., USA). The individual muscles, skin and fat layers were homogenised into a single soft tissue bulk. The patella tendon was modelled as distinct from surrounding tissues due to its importance as a load-tolerant structure, and its high stiffness under tension. Additionally, the quadriceps tendon and meniscus were modelled as preliminary work showed they facilitate a more numerically stable load transfer in the residual limb. The segmentation masks were meshed with quadratic tetrahedral elements and imported into Abaqus 6.14 FEA software (Dassault Systèmes, Vélizy-Villacoublay, France). The prosthetic liner was imported into the model as a separate body and meshed with structured hexahedral elements (Figure 1a). A simplified TSB parametric socket was developed by copying and modifying the external shape of the residual limb (Figure 1b). Four sockets were designed each with a different press-fit along the length of the socket: -2% (over-sized), 0% (matched), 2% (low-press fit) and 4% (high press-fit).

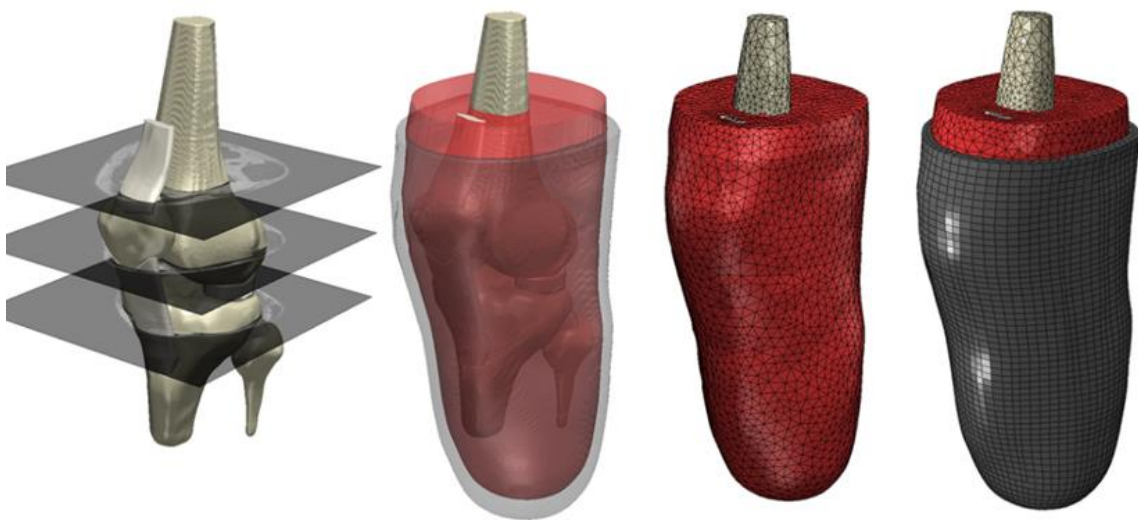


Figure 1: Development of the FE model from the MRI scan, involves the segmentation of the bones, the segmentation of the soft tissue and liner, the generation of the quadratic tetrahedral mesh of the limb and the hexahedral mesh of the liner

2.2. Materials

The tonicity of the soft tissue is an important consideration during the design of the prosthetic socket, and there is substantial variation across the population. To develop a FE model, the soft tissue properties are mapped onto a mathematical material model to replicate the tissue response to loading. Several models can be used to capture the tissues' anisotropic, hyperelastic and viscoelastic material properties. In a number of early FE studies of the residual limb, a linear elastic material model has been assumed for soft tissue, where the elastic modulus is often based upon experimental data from Reynolds 1988 [12]. Alternative material models which capture hyperelastic [13, 14] and viscoelastic [8, 15] effects have since been proposed based upon indenter studies. Substantial work from Gefen and colleagues successfully demonstrated the application of a Mooney-Rivlin model in a TTA FE model enabling the simulation of hyperelasticity in the bulk soft tissues.

To determine the effect of soft tissue stiffness on the biomechanical response of the residual limb, five material models were obtained from various literature sources [12, 14, 16], in addition to two intermediate values (Table 1). For each stiffness, its elastic or hyperelastic equivalent was calculated [17]:

$$E_{eqv} = \frac{18C}{3 + CD}, v_{eqv} = \frac{3 - 2CD}{6 + 2CD} \quad (1)$$

$$C_{eqv} = \frac{E}{4(1 + v)}, D_{eqv} = \frac{6(1 - 2v)}{E} \quad (2)$$

where E is the elastic modulus, v is the Poisson's ratio, and C and D are the hyperelastic constitutive model parameters. Average flaccid muscle was selected as the baseline model. The material properties of the other structures of the model were obtained from the literature (Table 1).

Table 1: Material properties of FE model structures

Structure	E, MPa	ν	C, kPa	D, MPa^{-1}
Bone [18]	12000	0.3	-	-
Tendon [19]	400	0.49	-	-
Meniscus [20]	59	0.49	-	-
Liner [21]	-	-	37.6	0.54
Socket [22]	1500	0.3	-	-
Soft tissue – soft flaccid [14]	0.01375	0.495	2.300	4.360
Soft tissue – average flaccid [14]	0.02540	0.495	4.250	2.360
Soft tissue – stiff flaccid [14]	0.03708	0.495	6.200	1.620
Soft tissue – contracted [16]	0.04829	0.495	8.075	1.243
Soft tissue – intermediate a	0.10000	0.495	16.722	0.600
Soft tissue – intermediate b	0.15000	0.495	25.084	0.400
Soft tissue – classical linear [12]	0.20000	0.495	33.400	0.300

2.3. Socket donning and loading

Socket donning applies pre-stresses to the residuum tissues. Simulating this process presents a complex, nonlinear problem for the FE model in order to reconcile the difference in shape between the limb and the press-fit socket. For modelling simplicity and computational stability, most studies have used a simplified ‘overclosure’ method where the external surface nodes of the residual limb are displaced until they contact the internal surface of the socket [22]. Lacroix and Ramírez Patiño 2011 compared the relative differences between overclosure and explicitly donning the socket in transfemoral models. They found that donning introduced longitudinal shear stresses at the interface periphery, which were not captured by radial overclosure [10]. For this study, two alternative model loading methods were tested (Figure 2):

- 1) overclosure: removal of radial interference between residuum and socket at a range of initial limb-socket tip distances, and
- 2) explicit donning: removal of limited radial interference at a range of initial limb-socket tip distances, followed by translation of the socket proximally until a 5mm residuum-socket tip gap remained.

Following the removal of this interference, the socket was loaded, either in a uniaxial 400 N load case, or in a quasi-static load point from gait corresponding to heel-strike, mid-stance and toe-off were defined from studies of 6 axis load data within the literature (Figure 2). Three datasets were

defined from two studies within the literature, normalised to body weight (Figure 2b). As per Cagle *et al* [7], only forces and moments in the sagittal plane were modelled, which are the dominant forces during gait. The F_y and F_z forces and the moment M_x were applied across a circular region of nodes at the base of the socket, representing the connection of the socket pylon, according to the directions in Figure 2a. Throughout all stages of model loading, the proximal surfaces of the femur and quadriceps tendon were fixed in all directions.

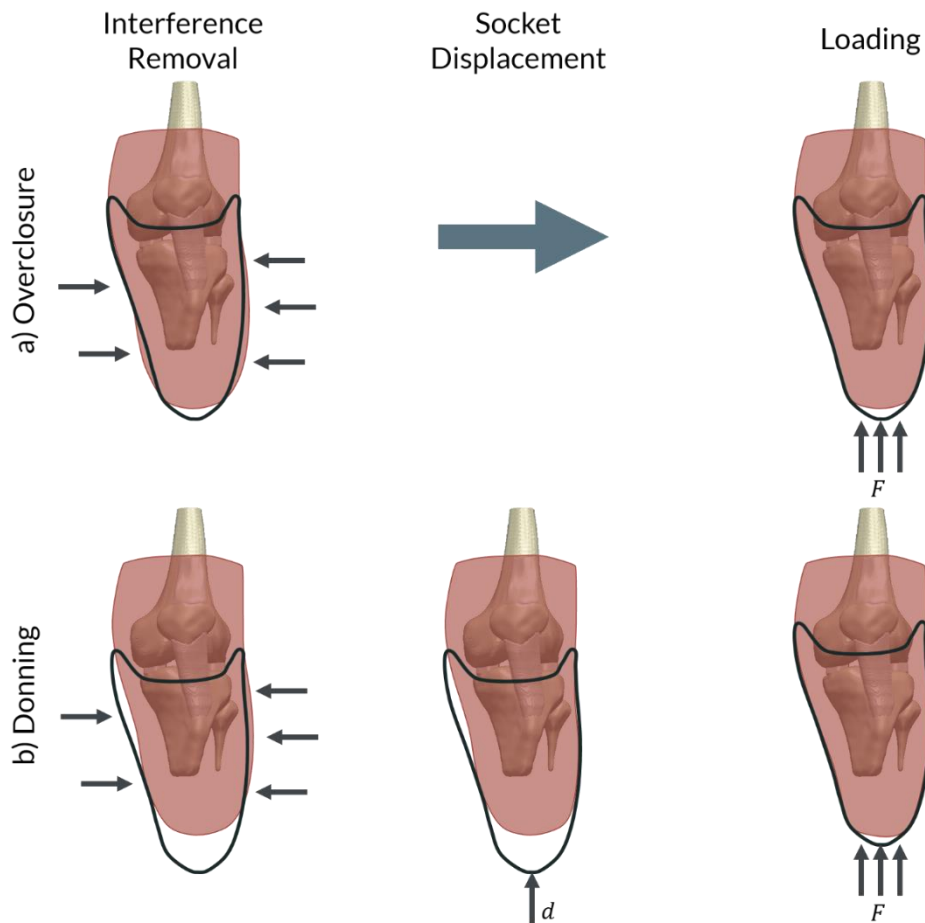


Figure 2: Comparison of the two socket donning methods. a) The overclosure method removes radial interference and then loads the socket while b) the explicit donning method introduces a socket displacement step.

2.4. Interface properties

The large pressure gradients and frictional sliding at the residuum-socket interface require sophisticated automated contact analysis within the FE solver [23]. Experimental studies have aimed to quantify the interface properties between these bodies, specifically the static coefficient of friction (COF), in order to predict the shear stress generated under a given pressure [24]. Cagle *et al* [7] studied the effect of varying the COF at the liner-skin interface between 0.5 and fully bonded but did not investigate the effects of varying the socket-liner COF, instead keeping it constant at 0.5.

In the present study, a static COF at the liner-socket interface in a Coulomb slip-stick model was considered. A baseline value of COF=0.5 was chosen from the literature [7] and was varied in increments of 0.1 between 0.3 and 0.7 under double leg stance loading. The residuum-liner surface was fully bonded, representing a sticky gel liner.

2.5. Model results parameters

The model was interrogated by reading the 95th percentile pressure and shear stresses on the liner surface over 30 and 60 mm circular zones around residuum distal tip and tibial tuberosity landmarks respectively, which are associated with socket fit and comfort [25]. The 95th percentile compressive strain in the soft tissue interior near the residual tibia's distal tip was used as an indicator of deep tissue injury risk [26].

3. Results

3.1. Effect of socket donning and COF on interface pressure and shear

Substantial differences in pressure and shear were observed between the two model loading methods, notably at the residuum tip. Inclusion of socket donning increase proximal interface shear (22 kPa in donning vs 4 kPa in overclosure, which stabilised the construct, thus protecting the residuum tip from such elevated pressure (0 kPa in donning vs 41 kPa in overclosure).

This effect of increased longitudinal shear on the residuum tip pressure was also observed with an increase in the socket-liner COF. Comparing between COF values of 0.3 and 0.7 for the 2% socket, the peripheral shear was predicted to increase from 12 kPa to 21 kPa accompanied by a subsequent drop in residuum tip pressure from 14 kPa to 0 kPa.

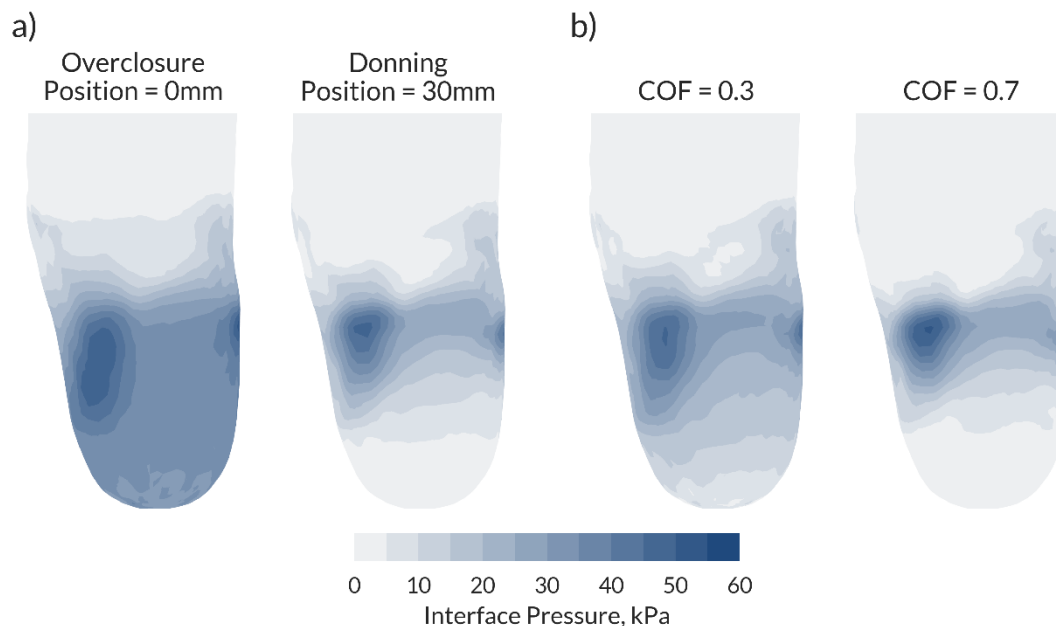


Figure 3: Interface pressure predictions under stance loading for different socket press-fitting methods and interface COF parameters: a) overclosure method with 0mm initial distance compared to 30mm initial distance in donning for the 3% distal socket design. b) Effect of changing the COF from 0.3 to 0.7 on the predicted pressure distribution for the 2% socket. Limb view rotated by 35° around the vertical axis from the anterior coronal plane.

3.2. Loading conditions

Substantial differences were predicted between the quasi-static load cases of heel-strike, mid-stance and toe-off. Tibial tuberosity pressure was predicted to be highest at heel-strike or mid-stance, while tissue strain was highest during toe-off loading. Differences in pressure distribution were also observed between socket designs. The tightest 4% socket was predicted to reduce residuum tip pressure and therefore soft tissue strain in this region. However, it also generated high values of fibula head and tibial tuberosity pressure. The toe-off loading case was predicted to generate high levels of pressure over the patella tendon in all socket design cases (Figure 4).

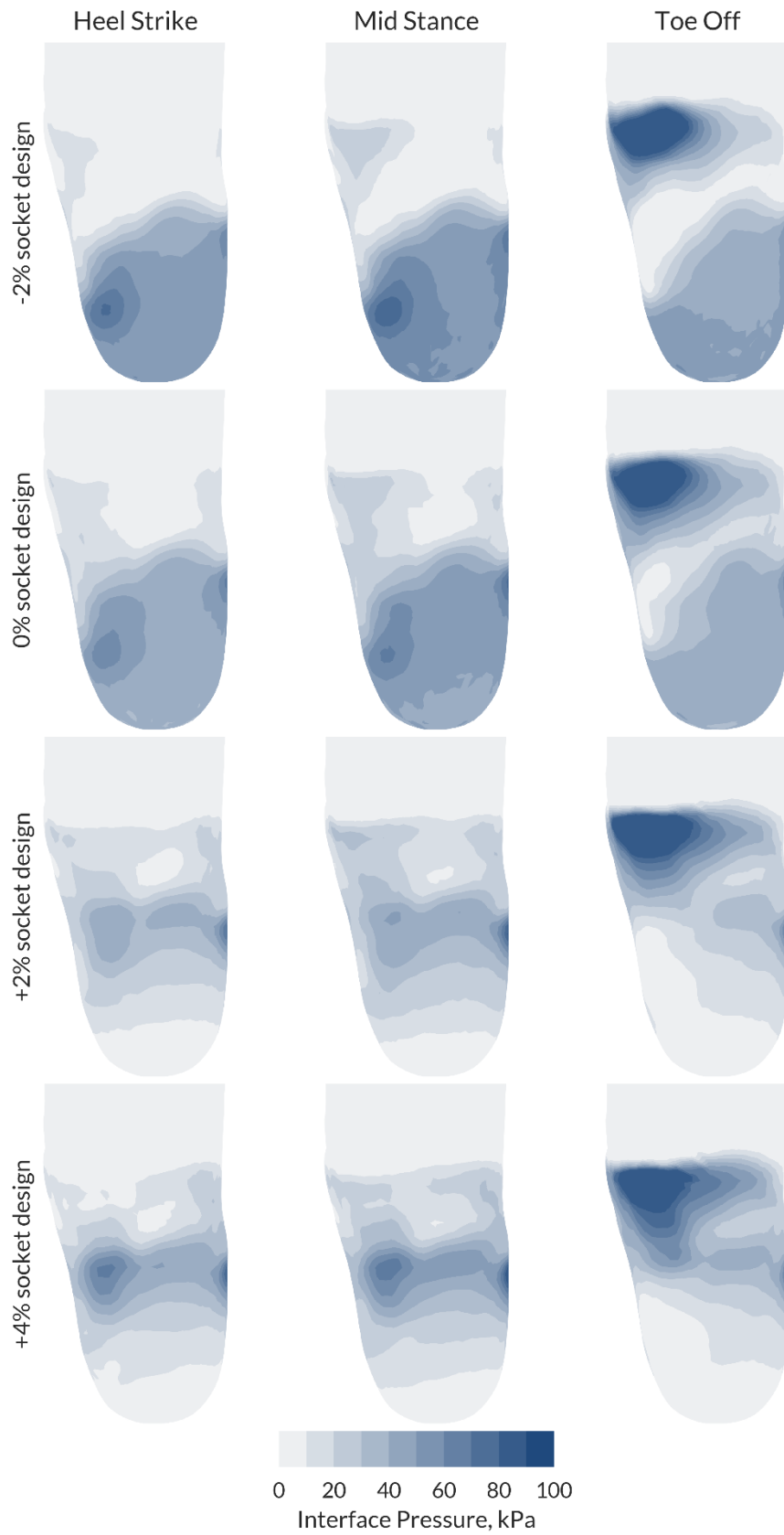


Figure 4: Full field pressure data for the four socket designs during heel strike, mid stance and toe off. Limb rotated by 35° around the vertical axis from the anterior coronal plane.

3.3. Soft tissue material model

Soft tissue strain was evaluated at heel strike (i.e. a high strain condition) to observe the expected differences between the linear and hyperelastic models (Figure 5). However, negligible differences were noted between linear and hyperelastic models of equivalent initial stiffness. The most notable difference between the linear and hyperelastic models was the increased numerical stability of the hyperelastic models. More flexible FE models are typically more likely to fail to ‘converge’ or reach a solution under full load. The lowest soft tissue stiffness achieving numerical convergence at 100% loading was 100 kPa for the linear model and 25.4 kPa for the hyperelastic model. Increasing the soft tissue stiffness resulted in a reduction of the compressive strain around the distal tibia. For the 0%, line-to-line socket, the lowest modulus tissue resulted in a predicted strain of 99% compared to 14% for the stiffest tissue of 200 kPa.

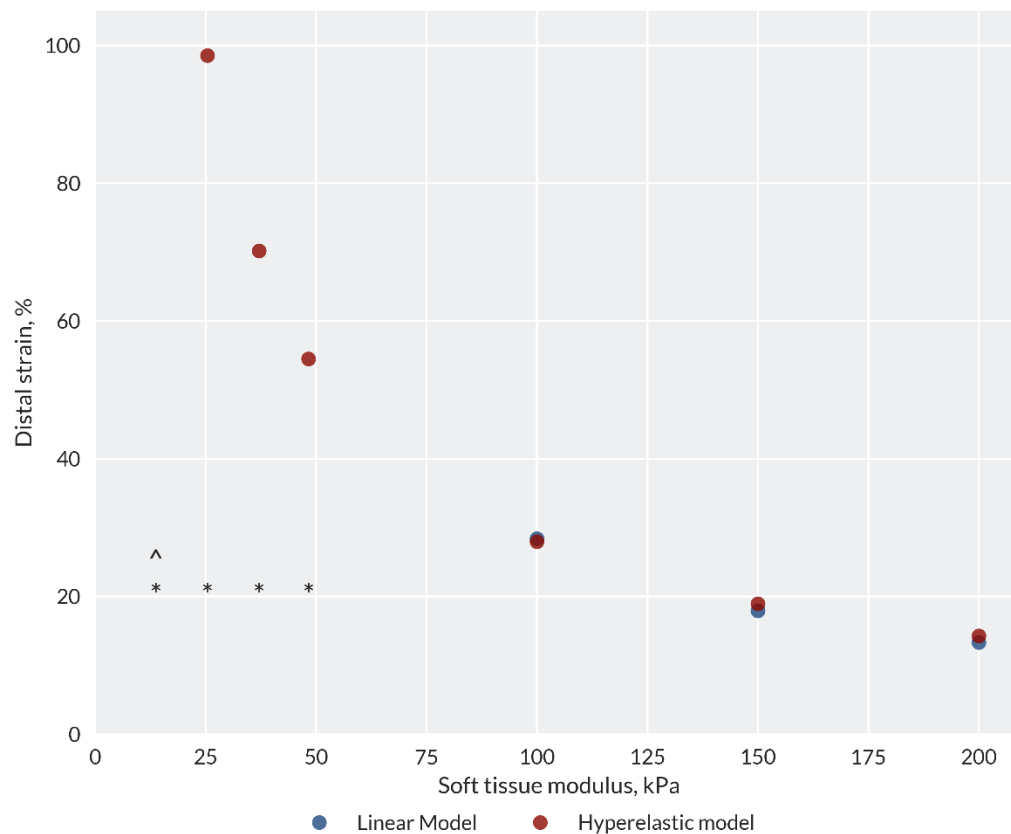


Figure 5: Distal soft tissue strain for linear and hyperelastic soft tissue material models of different moduli. The model was evaluated under heel-strike loading with a 0% press-fit socket design. * indicates that the linear model did not converge, whilst ^ indicates the hyperelastic model did not converge.

4. Discussion

The aim of this study was to critically appraise different methods and input variables for developing FE models of the transtibial amputated leg and prosthetic socket. The motivation was to provide informed guidelines for future model developments, and to assist clinicians in appraising the FE research they read in the literature. This sensitivity analysis tested a large range of inputs, in addition to different socket designs and loading scenarios representative of gait. The predicted pressures and shears under stance loading were 50 kPa and 20 kPa respectively, with peak pressure at toe-off loading of 180 kPa, comparable to previous computational models [7] and experimental pressure and shear sensor data [27, 28].

4.1. Effect of shear generated at residuum socket interface

A key finding is the importance of shear stresses generated at the residuum-socket interface which was influenced by the loading method and interfacial properties. Explicitly modelling donning was predicted to introduce shear stresses which resulted in reduced pressure over the residuum tip. The pure overclosure method did not generate any peripheral shear stresses, thereby causing elevated pressure at residuum tip once stance loading was applied. These predictions are consistent with the benchmark report by Lacroix and Ramírez Patiño [10]. The present study predicted a similar effect in a TTA model, and went on to add stance loading to the donned sockets, showing the relative contributions of these load cases.

The longitudinal shear stresses were also influenced by the residuum-socket interfacial properties, where higher friction resulted in reduced residuum tip pressure. The increase in longitudinal shear stresses with COF is also consistent with previous studies of the liner-skin interface [7]. Prosthetists aim to achieve limited socket-residuum shear load transfer to protect the residuum distal tip from excessive end-bearing, whilst avoiding excessive shear which may increase the risk of skin breakdown [29]. As such, accounting for the different sources of shear loading in these models is of particular importance for clinical translation.

4.2. Comparative Analysis of Parameterised Socket Designs

The modelled loading conditions produced substantially different interface pressure predictions. Peak pressures were observed at the patella tendon during the toe-off load case. The socket design had a greater effect upon the peak pressure location under heel-strike loading. Tighter sockets (2% and 4% press-fit) loaded the tibial tuberosity and fibula head, whereas looser sockets (exact fit or 2% oversized) demonstrated predicted end-bearing throughout heel-strike, mid-stance and toe-off, and elevated pressure at the distal anterior tibia.

4.3. Effect of soft tissue stiffness and elasticity models upon predicted strain

Variation of the soft tissue stiffness caused substantial differences in the predicted strain (Figure 5). There was minimal difference in the strains predicted for equivalent linear- and hyperelastic models, however the hyperelastic models were more computationally 'stable' – they produced solutions under considerably higher loads. Increasing the soft tissue stiffness increased the stability of the model solution, as a stiffer material will distort less. This effect has been observed previously, and one study selected a 300 kPa modulus linear model on the basis of its numerical stability [7] although this is considerably stiffer than indicated by experimental tests [6]. FE models have been proposed as tools to predict soft tissue damage based upon strain thresholds [30], reported between 40 and 60% [26, 31]. Based on the presented results, prediction of soft tissue damage risk would be heavily influenced by the material stiffness selected. Clinical assessment of soft tissue damage risk should therefore be based upon carefully selected, representative soft tissue material properties, and these would need to be patient specific.

4.4. Limitations

There are a number of acknowledged limitations to this study. Considering the model itself, simplifications were made in light of model use for comparative analysis of socket designs. The soft tissue, fat and skin layers were all consolidated into a single body, apart from the two tendons, and no sliding was allowed at the knee. This is in contrast to previous studies which have segmented MRI scans of multiple participants into tissue, fat, skin and scar layers [9]. A further increase in the fidelity of the model geometry can be captured using diffusion-tensor MRI [32]. Such models would likely facilitate a more realistic transfer of load than one in which the soft tissues are homogenised. Continual advances in medical imaging will present opportunities for future models to capture the complex individual structures of the residuum. For the four socket designs presented, no experimental data were collected, thereby preventing full model validation. Instead, the predicted pressure response of the residuum was corroborated by comparison to experimental measurement data from the literature.

4.5. Clinical Relevance

Any clinically-implemented modelling technologies must provide sufficiently accurate and reliable results. This study demonstrates that model development method and selected input parameters will have a substantial and potentially significant effect on the biomechanical response of the limb. The relationship between peripheral shear stresses and residuum tip pressure is one such effect, due to the risks associated with residuum end-bearing [33]. An inaccurate prediction of the residuum pressure due to an inaccurate model would likely result in a poor fit for the prosthetic user and, in extreme cases, development of pressure ulcers from adverse pressure and shear gradients [29]. Of

greater concern is underestimation of tissue strains, as this may lead to a failure to predict deep tissue injury, which may be undetected in high-risk individuals with insensate residua.

High-quality input data from experimental studies, in addition to good practice in model development, is necessary for reliable FE modelling. Many studies have already sought to characterise patient anatomy [34], gait analysis [35], soft tissue material models [13] and interface properties [24]. More recently, a framework has been presented to incorporate this population variability, to enhance this evidence base whilst maintaining low requirements of computational resources, FE training and experience [34]. Such methods have applications for lower limb prosthetics to move away from single-case research studies, and move towards clinical application enabling prosthetists to access rapid, comparative predictions of a wide range of socket designs.

4.6. Recommendations

It is recommended that future studies in the field should:

- simulate the effects of donning, with appropriate interface friction properties, to initiate the shear stresses that would be neglected using simplified loading methods;
- ideally employ a comparative approach in analysing different socket designs under a representative range of loading conditions;
- use hyperelastic material models to increase computational stability, with appropriate soft tissue stiffness, especially when using soft tissue strain to predict damage risk; and
- clearly justify their modelling decisions and research questions within a clinical reference frame.

Finally, as there is not yet a full consensus regarding the data required for model generation, continued effort to add to the evidence base of soft tissue properties, gait analysis and patient anatomy would benefit the community.

Conflict of interest

There is no potential conflict of interest. The authors did not receive and will not receive any direct or indirect benefits from third parties for the performance of this study.

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