A Computational Tool to Enhance Clinical Selection of Prosthetic Liners for People with Lower Limb Amputation

John Cagle

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Reading Committee:

Joan Sanders, PhD, Chair

Brian Hafner, PhD

Per Reinhall, PhD

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Abstract

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John Cagle

Chair of the Supervisory Committee:
Professor Joan Sanders, PhD
Bioengineering

People with transtibial amputation experience a loss of mobility that results from the removal of propulsive and load bearing anatomy. The more delicate soft tissues of the residual limb are coupled to a hard prosthetic socket, and this results in regular instances of skin breakdown. Soft and flexible prosthetic liners worn between the limb and socket are a common method of reducing these interface stresses. Advances in materials and manufacturing technics over the previous two decades has led to the development of over 70 liner products on the clinical market. The aims of this dissertation were to (1) design a set of benchtop protocols to accurately measure clinical relevant liner characteristics, (2) use the design characteristics to measure a selection of liner products and evaluate assumptions on their use in clinical practice, (3) develop a finite

element model (FEM) that simulates a modern prosthetic design, and (4) use the developed FEM to assess the effect of liner product and socket size. Six protocols were used to assess 24 liner products available on the clinical market. Results showed that liner products demonstrated significant variability, even when products were formulated from a common base polymer (e.g., polyurethane or silicone). This emphasized the need for a tool to facilitate liner selection in a clinical setting. The developed FEM produced results that were reasonable with the context of literature reported interface mechanics, and showed focused stresses in locations that corresponded with incidences of skin breakdown experienced by participants in their as-prescribed prosthesis. Further evaluations showed that a change in liner product could result in 15-25% change in interface stresses, while a 1–2% change in limb volume could correspond to a 15–30% increase in interface stresses.

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Chapter 0. FOREWORD

0.1 INTRODUCTION

Of the seven types of major (non-digit) lower-limb amputations, transtibial is the most common (42%) [1]. Similar to other types of lower limb loss, people with transtibial amputation experience a loss of mobility. This results from a loss of propulsive musculature and the loss of load bearing anatomy such as the plantar padding over the heel. The remaining soft tissues of the residual limb are not designed to sustain ambulatory loads, yet need to be coupled to prosthetic sockets that are typically fabricated from rigid materials such as carbon fiber. This mismatched interface is the basis for regular incidences of skin breakdown, which are a persistent challenge for people with transtibial amputation.

People with transtibial amputation experience about three skin problems each month, and consequently, 25% of patients limit the use of their prosthesis and 28% feel inhibited in social functioning[2]. The most common issues experienced with a month were typically limited to the epidermis and could be categorized as eczema (50%), mechanically induced issues such as blisters or abrasion (43%), or issues from skin occlusion such as pimples or profuse sweating(51%) [3]. More serious issues related to the deeper tissues, such as pressure ulcers (57%), infections (35%), and open wounds (31%) were also experienced by patients at some point[3].

The etiology of many of these issues can be traced to the mechanical coupling of a soft residual limb to a hard prosthetic socket. In recent decades, two major changes in prosthesis design have become widespread in clinical practice. The patellar tendon bearing (PTB) socket design, which originated in the 1950s, has been gradually replaced by modern designs such as the total surface bearing (TSB), vacuum, and pressure cast sockets. These modern designs now account for as much as 82% of clinical prostheses[4]. They serve to reduce focused stresses applied to the limb through wider distribution of ambulatory loads[5]. More specifically, these modern designs remove the heavily contoured patellar tendon bar so there is no longer a single focal point of load transmission.

To further facilitate the goal of improved stress distribution, soft and flexible elastomers have been an increasingly popular interface material used to couple a limb to a socket and are now used in approximately 85% of clinical prostheses[4]. Elastomeric liners contrast with foam (Pelite) liners used in older socket designs not only in material type, but also in implementation. Pelite liners are formed to create a more intimate fit to the prosthesis than the limb, while an elastomeric liner is worn like a sock to create an intimate fit with the limb. The limb-liner coupling is further enhanced by a more adherent contact surface, with some elastomeric liners being sufficiently tacky to support their weight when held inverted.

The outside surface of an elastomeric liner is frequently protected by a fabric backing, because similar to skin, the soft elastomers would otherwise tear when subjected to the mechanical stresses of direct contact with the socket. These features give liner manufacturers three primary material characteristics to optimize: elastomeric stiffness, elastomeric adhesion, and fabric stiffness. The ability to tailor these properties has led to an abundance of selection in the clinical market, with a preliminary study identifying over 70 available liner products[6]. The same study found that only five liner products were in use by 10% or more of surveyed prosthetists, and that 94% of practitioners obtained comparative information directly from manufacturers. The purpose of this dissertation was to investigate the performance of prosthetic liners and to provide objective data to improve clinical practices.

The first chapter of this dissertation focuses on the development of testing protocols to create a foundation for the evaluation and comparison of liner products. The preliminary survey of clinical practices found that, of 22 potential features, prosthetists were most interested in the way in which prosthetic liners transmitted loads to the limb[6]. These features could be defined by typical mechanics of material properties that included compressive elasticity, shear elasticity, tensile elasticity, volumetric elasticity, coefficient of friction, and thermal conductivity. For each material property, fixtures and testing protocols were designed to create accurate and repeatable results for characterizing liner performance within a prosthetic socket.

The second chapter of this dissertation applies these material testing protocols to a selection of clinically available prosthetic liner products. 19 materially unique liner products were selected for testing due to usage by at least 2% of clinical prosthetists[6]. Liner manufacturers were invited to send liner products of interest and novel liner products identified at prosthetic conferences were purchased to compliment this base selection. The selected group of liner products were evaluated using the six material test protocols, and the results were used to evaluate assumptions on liner recommendations and performance in clinical practice. Additionally, a free and online tool was created to provide a way for clinical prosthetists to objectively compare liner products to better meet individual patient needs.

The third chapter of this dissertation focuses on the development of a flexible finite element model (FEM) of a transtibial prosthesis that can evaluate clinically relevant issues, such as the effect of prosthetic liner products. While the six material property tests were able to accurately assess six material properties, each property was measured in isolation. This contrasts with performance inside a prosthesis, where properties contribute simultaneously. FEMs have the capacity to evaluate the effects of multiple properties, albeit with limited accuracy. Therefore, the third study attempted to validate the FEM method by comparing simulated stress distributions to incidences of skin breakdown in participants' as-prescribed prosthesis. To evaluate the consistency of the results, three participants were recruited with characteristic limb shapes of short-conical, long-conical, and cylindrical. In addition to participant specific socket fit, the viability of an ideally designed TSB socket was assessed.

The final chapter of this dissertation applies the developed FEM to two clinical concerns; the effects of different liner products and the effects of limb volume changes. To evaluate the effects of prosthetic liners, four liner products were selected that encompassed the range of measured materials properties. The effects of limb volume changes were evaluated, because management of these fluctuations is the single most common issue reported by people with transtibial amputation[7]. Short term changes that occur over the course or a day and typically result from shifts in extracellular fluid volume[8], while long term changes over months and years typically result from tissue remodeling (e.g., atrophy). These changes create a mismatch between the limb and socket, and increase focused stresses with the socket[9].

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Chapter 1. DEVELOPMENT OF STANDARDIZED MATERIAL TESTING PROTOCOLS FOR PROSTHETIC LINERS

1.1 Abstract

A set of protocols was created to characterize prosthetic liners across six clinically relevant material properties. Properties included compressive elasticity, shear elasticity, tensile elasticity, volumetric elasticity, coefficient of friction, and thermal conductivity. Eighteen prosthetic liners representing the diverse range of commercial products were evaluated to create test procedures that maximized repeatability, minimized error, and provided clinically meaningful results. Shear and tensile elasticity test designs were augmented with finite element analysis to optimize specimen geometries. Results showed that because of the wide range of available liner products, the compressive elasticity and tensile elasticity tests required two test maxima; samples were tested until they met either a strain-based or a stress-based maximum, whichever was reached first. The shear and tensile elasticity tests required that no cyclic conditioning be conducted because of limited endurance of the mounting adhesive with some liner materials. The coefficient of friction test was based on dynamic coefficient of friction, as it proved to be a more reliable measurement than static coefficient of friction. The volumetric elasticity test required that air be released beneath samples in the test chamber before testing. The thermal conductivity test best reflected the clinical environment when thermal grease was omitted and when liner samples were placed under pressure consistent with load bearing conditions. The developed procedures provide a standardized approach for evaluating liner products in the prosthetics industry. Test results can be used to improve clinical selection of liners for individual patients and guide development of new liner products.

1.2 INTRODUCTION

Transtibial amputations are the most common form of major (i.e. non-digit) limb loss, comprising about 42% of all lower-limb amputations[1]. A primary goal in the design of a transtibial prosthesis is to securely connect the socket to the limb to facilitate safe transmission of ambulatory stresses through delicate residual limb tissues[2, 3]. An elastomeric or “gel” liner is often included in the design of the prosthesis to meet this goal. The liner serves to couple the limb to the socket, accommodate changes in limb shape and volume, and distribute concentrated socket stresses. Clinically, a liner must be matched to a patient based on a number of characteristics that include limb shape, tissue quality, socket design, anticipated volume change, and activity level.

Failure to properly match a liner to a patient can lead to a variety of clinical problems. For example, inadequate coupling can result in slipping between the limb and liner, while a soft liner might result in greater displacement between the limb and socket through increased deformation of the liner. These may degrade proprioceptive stability and can lead to gait deviations that are precursors to trips and falls[4, 5]. Miller and colleagues reported that 52.4% of 435 lower-limb amputees reported falling at least once over a 12-month period, and 39.5% reported falling two or more times[6]. Similarly, poor transmission of stresses between the socket and limb can lead to skin issues or breakdown. A survey of 805 lower-limb amputees found that 63.0% of participants experienced skin problems within the prior month, and 82.0% reported problems more than one month prior to the survey[3]. Collectively, these issues can lead to disuse of the prosthesis and reduced participation in desired life activities[7]. Selection of an appropriate prosthetic liner for a patient is therefore vitally important to a user’s health and quality of life.

Prosthetic liners can be made from either a foam or a gel, however, more than 85% of people with transtibial amputation use a suspension system that requires a gel liner[8]. A gel liner consists of an elastomeric polymer base that is commonly reinforced with a fabric backing. Matching a liner to a specific patient can be challenging, as there are presently more than 60 transtibial liner products available on the market, but a paucity of information about their relative performance[9]. Previous studies have examined liner material properties, but the scope of these studies was limited to few products[10, 11], or liners that are no longer available for purchase[12, 13]. In the absence of objective data to compare liner products, practitioners typically rely on information from liner manufacturers' literature or conference brochures[14]. Independent testing of prosthetic liners is needed to enable practitioners to effectively appraise current products and select those most appropriate for their patients.

The purpose of this research was therefore to develop tests to characterize overall elastomeric liner performance. Properties selected for testing were derived from clinically desirable liner characteristics including the ability to distribute ambulatory stresses, suspend the socket on the limb, adhere to a user's skin, accommodate residual limb volume changes, and facilitate transmission of body heat. Tests were designed to obtain quantitative information that could be used to compare and contrast different liner products. Once developed, these standardized tests could be applied to future efforts to evaluate available liners, inform clinical selection processes, and direct liner development efforts.

1.3 METHODS

Six material properties were selected to characterize liner performance – compressive elasticity, shear elasticity, tensile elasticity, coefficient of friction, volumetric elasticity, and thermal conductivity. Compressive and shear elasticity were chosen to determine how a liner distributes ambulatory stresses on the residual limb during the stance phase of gait. Tensile elasticity was chosen to assess a liner's ability to resist stretching during swing phase. Coefficient of friction was selected to measure a liner's adherence to the residual limb. Volumetric elasticity was selected to indicate a liner's ability to accommodate limb volume changes. Lastly, thermal conductivity was selected to quantify a liner's ability to facilitate heat transfer to or from the residual limb. The emphasis of this study was to design the testing equipment and to develop the set of standardized procedures that would be used to measure the selected liner properties. Candidate test variables were evaluated and optimized in order to test liners in conditions similar to those they experience inside a prosthetic socket.

Several industry resources guided development of the liner material property tests. These included testing standards from the American Society for Testing and Materials[15-24] (ASTM, West Conshohocken, Pennsylvania) and material guidelines from Axel Products (Ann Arbor, Michigan), an industry expert in elastomeric testing[15, 22, 25, 26]. Industry test standards served as a basis for design of the test fixtures, selection of initial test parameters (e.g., specimen geometry and conditioning procedures), and consideration of common sources of measurement error. Data from gait and interface stress studies on people with transtibial amputation informed initial test settings[27-33, 10].

Because elastomers are soft materials and the designed tests involved large strain measurements [34, 35], it was important to distinguish engineering and true stresses reported in the industry resources and scientific literature. Engineering stresses are simply the applied load divided by the initial (i.e., pre-stressed) cross-sectional area of a specimen. True stresses account for a specimen's material deformation and change in cross-sectional area under load. While material testing machines (MTM's) typically output engineering stresses, directly measured material responses (e.g., in-socket pressure measurements) and mechanical analyses (e.g., finite element analysis [FEA]) report true stresses. Therefore, MTM-measured engineering stresses were converted to true stresses for all analyses using the large deformation formulation of the Poisson effect for compression [Equation 1.1] and tension [Equation 1.2], where liner materials were assumed to be incompressible (i.e., Poisson's Ratio of 0.5). The difference between the two equations reflects an increasing cross-sectional area for a specimen in compression and a decreasing cross-sectional area for a specimen in tension.

$$Area_{True} = Area_{Initial} \times \left(1 - strain\right)^{-2 \times Ratio_{Poisson}} \tag{1.1}$$

$$Area_{True} = Area_{Initial} \times \left(1 + strain\right)^{-2 \times Ratio_{Poisson}} \tag{1.2}$$

1.3.1 *Instrumentation*

A uniaxial MTM (5944, Instron, Norwood, Massachusetts) with custom fixtures was used to perform the compressive, shear, tensile, and volumetric elasticity tests [Figure 1.1a]. MTM movement was set by an electric ballscrew designed for high displacement rates (up to 30 mm per second). A measurement crosshead that contained a single-axis load cell was mounted to the ballscrew, and moved vertical relative to a base platform. The load cell had a full scale range of 1–500 N and a mean load measurement error of ±0.25 percent of the total applied load (weight of test fixture plus specimen load). Displacement measurement uncertainty was ±0.005 mm. The MTM was calibrated prior to testing and annually thereafter.

A planar friction tester (PFT) (Advanced Friction tester, Hanatek, East Sussex, United Kingdom) was used to evaluate the coefficient of friction (CoF) between elastomer and skin [Figure 1.1b]. Similar to the MTM, the PFT was a single-axis instrument with an electric ballscrew-driven crosshead. However, the direction of crosshead movement was horizontal and the load cell measured the force required to pull a manufacturer-provided specimen sled. An orthopedic-grade soft leather (Cream Cow, WBC Industries, Westfield, New Jersey) was attached to the sled as a surrogate skin material. This material was chosen because it had a non-rigid structure, a surface roughness comparable to skin, and low sample-to-sample variation. Because the PFT was designed to meet the ASTM D1894 test standard[16], adjustments were limited target displacement rate and total measurement distance. The ASTM recommended displacement rate 150 mm/min and distance of 125 mm were maintained, because increasing the displacement rate risked damage to the instrument. To improve the PFT's repeatability, an aluminum spacer was removed from the specimen sled to reduce the nose-down pitch moment that biased load distribution to the leading edge of the leather sample. Repeatability of the CoF test measurement with the specified configuration was ±0.008 across three specimens of the selected leather applied to a single liner product.

A guarded heat flow meter (HFM) (Unitherm 2022, Anter Corp, Pittsburgh, Pennsylvania) was used to measure thermal conductivity [Figure 1.1c]. The HFM included the test instrument, a liquid cooling unit, and a pneumatic pressure supply. Test specimens were compressed with a pneumatic piston between a high-temperature upper plate and low-temperature bottom plate. Plate temperatures were maintained with heating coils on the test instrument and a constant flow from the liquid cooling system, which was typically maintained at 20 deg C below the mean measurement temperature. Dynalene HC-30 (Dynalene Inc, Whitehall, Pennsylvania) was selected among a wide range of coolants because its low freezing point enabled full-scale calibration from 0 to 60 deg C. The core of the HFM was a calorimeter that measured the heat flux between the specimen and the bottom plate. No modifications were made to the HFM. Similar to the PFT, the HFM was designed to meet the ASTM E1530 test standard[24] and the only available adjustments were compressive pressure and mean specimen temperature. Repeatability of the HFM was assessed by creating an instrument calibration profile across a desired temperature range for three manufacturer provided, rigid polymer calibration samples of different thickness with matching thermal conductivities. For the applied calibration, the measurement repeatability was ±0.001 W/m-K across three samples.

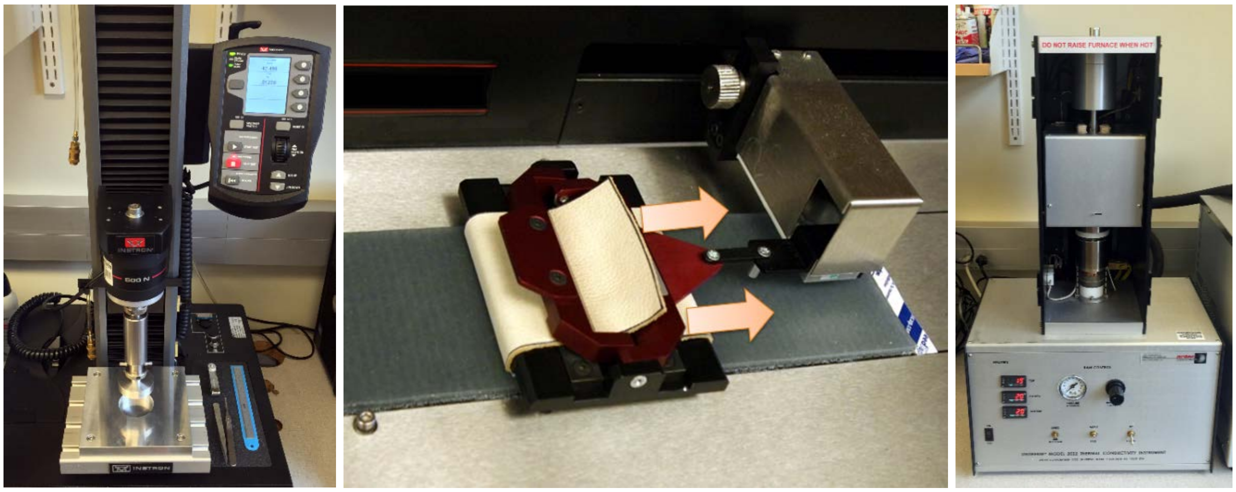

Figure 1.1: Instruments used for material testing. (left) Instron 5944 Material Testing Machine, (middle) Hanatek Advanced Friction Tester, and (right) Anter Unitherm 2022 Thermal Conductivity Tester.

1.3.2 *Materials*

Eighteen new elastomeric liners from six manufacturers were used to create testing procedures and optimize test parameters [Table 1.1]. Liners were fabricated from a range of base polymers, including silicone, urethane, or thermoplastic elastomer (TPE). Evaluations related to each material property test determined test parameters or were used to assess the influence of confounding variables that might contribute to test inconsistencies. A single liner product was used when trying to minimize a confounding variable (e.g., the liner with the greatest CoF was used to evaluate lubricants for the compressive elasticity test). Three or more liner products were used to evaluate the influence of minor variables (e.g., the influence of conductive grease on thermal conductivity was evaluated on three liners with dissimilar fabric thicknesses and densities). All eighteen liners were evaluated when testing highly influential variables, (e.g., the influence of specimen aspect ratio on the compressive elasticity test).

Table 1.1: Liner products evaluated for test protocols

Manufacturer	Product	Base Polymer
Alps	EasyLiner	TPE
Alps	Extreme	TPE
Alps	General Purpose	TPE
Medi	Relax 3C	Silicone
Össur	Comfort	Silicone
Össur	Dermo	Silicone
Össur	Synergy	Silicone
Otto Bock	6Y512 (no fabric)	Urethane
Otto Bock	6Y512 (w/ fabric)	Urethane
Otto Bock	6Y520 (no fabric)	Urethane
Otto Bock	6Y520 (w/ fabric)	Urethane
Otto Bock	6Y75	Urethane
Otto Bock	6Y92	TPE
Prosthetic Design	SealMate	Silicone
WillowWood	Alpha® Classic Max	TPE
WillowWood	Alpha® Classic Original	TPE
WillowWood	Alpha® Hybrid Select	TPE
WillowWood	Alpha® Classic Spirit	TPE

1.3.3 *Testing Environment and Preconditioning*

Definitions of conditioning and preconditioning varied across the scientific literature and industry resources used to inform test development. For this study, the preconditioning refers to thermally conditioning a liner before specimens were extracted from an intact liner, while conditioning refers to mechanically conditioning a specimen immediately before a test was conducted. All liner specimens were thermally preconditioned for a minimum of 24 hours and tested in a temperature controlled room with ambient conditions of 21 ± 1 deg C and a mean humidity of 33% (22% min, 50% max). Liner specimens were also conditioned immediately prior to each material test. The method of conditioning varied by test, but in general, specimens were mechanically stressed until a repeatable response was achieved.

1.3.4 *Specimen Extraction*

Liner specimens were either circular or rectangular in shape, with characteristic dimensions ranging from 10–210 mm. Rectangular specimens were punched with a test-specific steel rule die (Apple Steel Rule Die, Milwaukee, Wisconsin) using a 1.2 kg dead blow hammer (P/N 6051A37, McMaster-Carr, Elmhurst, Illinois). Circular specimens were punched with a hammer-driven gasket and washer punch set (P/N 33785A12, McMaster-Carr, Elmhurst, Illinois). The cutting edge of the punch or die was always placed on the elastomer at the beginning of the cut. Circular specimens were inspected and re-punched if necessary to ensure that circularity was ±0.2 mm from punch size and that vertical edges were visibly square.

1.3.5 *Compressive Elasticity*

The compressive elasticity test was designed to quantify a liner's ability to transmit and distribute concentrated pressures that are known to cause skin breakdown[36] or deep tissue injury[37]. Residual limb volume fluctuations occur in people with transtibial amputation [38] when applied pressures propagating to internal tissues (i.e., arterial blood flow decreases and extracellular fluid is driven out of the interstitial space and back into the capillaries[39]). A liner with a high compressive elasticity will optimize stability by delivering concentrated pressures to desirable load-bearing areas (e.g., patellar tendon). Conversely, a liner with a low compressive elasticity will optimize comfort by distributing pressure over sensitive areas (e.g., fibular head). The compressive elasticity test was designed first because it required consideration of the largest number of test variables and was most comprehensively supported by data in the scientific literature. Test conditions established for the compressive elasticity test were then used to set limits for other material property tests when reference data were unavailable.

Stress/Strain Maximum: ASTM test standards[15, 22] and industry experts[25, 26] have recommended setting strain as a test maximum because of elastomeric strain-conditioning (i.e., the Mullins effect). While clinically applicable liner strains were not available in the literature, limb-socket normal stresses have been frequently reported [10, 27-33]. Therefore, a strain limit that encompassed the reported stress values for clinically available liner products was needed. Studies that evaluated Pelite™ foam liners described mean pressures of 100 kPa with peaks up to 200 kPa[27-32]. These corresponded to a minimum strain limit of 53%, using the reported Pelite modulus of 380 kPa[40]. A more recent study of two elastomeric liners showed lower peak pressures (i.e., mean of 60 kPa and a maximum of 85 kPa)[33]. As a final consideration, a safety limit of 60% strain was imposed to prevent damaging the MTM with thin liners. Accordingly, materials were tested to the lesser of a maximum stress of 250 kPa or maximum strain of 60%. The clinical applicability of these limits was verified by compressing a highly compliant liner specimen to 60% strain and verifying that the corresponding stress was at least 85 kPa, the maximum reported in the literature[33].

Strain Rate: Prosthetic liners, like most elastomers, exhibit a viscoelastic (i.e., strain-rate dependent) stress-strain response[25]. To determine if strain rate affected compressive elasticity, all eighteen liners were tested at strain rates of 150%, 100%, 50%, and 0.5% per second. 150% per second was selected as the fastest strain-rate because it corresponded to the maximum safe operating condition for the MTM.

*Specimen Size**:*** Since prosthetic liners are made from an elastomeric gel with an orthotropic fabric backing, stiffness was expected to vary with specimen aspect ratio[41, 42]. ASTM standards D945[15] and D6147[22] recommend round specimens with diameters between 13.0 and 29.0 mm with a thickness of 6.3 mm to 12.5 mm. To determine the influence of specimen diameter on stress-strain response, 12 mm, 19 mm, and 30 mm specimens from all liners were evaluated. Whenever possible, 6 mm thick liners were evaluated. If 6 mm liners not unavailable, 3 mm liners were tested.

Frictional Effects: Elastomeric liners expand or 'flow' when compressed, and compressive elasticity is ideally measured when specimens are allowed to freely deform. Based on initial maximum stress test results and the assumption of specimen incompressibility, specimen diameter was estimated to increase by 58% at 60% strain. Miller et al[43] reported that frictional effects experienced by a specimen during this expansion artificially increased stress-strain response in a way that was impossible to predict or correct. Potential solutions included switching the test method to biaxial extension (instead of uniaxial compression) or modifying the test setup to minimize friction. Biaxial testing was determined to be unfeasible, as it would require two additional instruments (i.e., a biaxial tester for specimen loading and a digital image correlation system for strain measurement). Therefore, nine lubricants were tested with the liner product with the greatest CoF [Table 1.2]. Each lubricant was tested with two liner specimens that were cyclically compressed for 15 minutes at a displacement rate matching 50% strain per second. The lubricant that best minimized frictional effect was identified as the product that (a) resulted in the most consistent stress-strain response, and (b) produced the lowest measured stress at 60% strain, indicating the smallest artificial increase in material response due to friction.

Table 1.2: Lubricants evaluated for the compressive elasticity test

Manufacturer	Product	Lubricant
C&C Synthetics	Outlast	Synthetic Oil
DuPont	Poly Adhesive	Teflon
Fuchs	Geralyn	Synthetic Oil
HAAS	Automation Oil	Petroleum Oil
PMS	T-9	N/A
Sherwin Williams	Tri-Flow	PTFE
Starrett	M1	N/A
WD-40	3-in-One	Petroleum Oil
WD-40	WD-40	N/A

1.3.6 *Shear Elasticity*

The shear elasticity test was designed to quantify a liner's ability to transmit and distribute concentrated shear stresses. Shear stresses are present at the limb-socket interface when the socket is displaced proximal-distal or anterior-posterior relative to the residual limb. Additionally, shear stresses can be imposed through torsional moments about the long axis of the limb, applied through medial-lateral loading at the foot. As shear stress is a primary contributor to skin breakdown[44, 45], elastomeric liners are often prescribed to distribute and reduce the shear stress experienced in the user's skin. Given the thickness of gel (2–6 mm) relative to fabric (0–1 mm) in an elastomeric liner, the gel is largely responsible for shear distribution. A simple shear test, as opposed to pure or notched shear methods, was selected as it did not require additional equipment to measure specimen deformation. Initial test parameters from the compressive elasticity test were used to define key parameters for the shear elasticity test, including maximum strain and strain rate.

Specimen Size: Simple shear testing is susceptible to measurement errors due to stress concentrations present at the specimen corners. To minimize stress concentrations (and associated errors), ASTM D945[15] recommends a specimen area of 600 mm^2. However, no recommendations for the specimen height or width are specified. It was hypothesized that stress concentrations along the upper and lower edges of the specimen would be the greatest source of measurement error [Figure 1.2]. Therefore, two-dimensional (2D) FEA was conducted to determine the height-to-thickness ratio that minimized the area of stress concentrations. Then, a three-dimensional (3D) FEA specimen was created by extruding the 2D profile and evaluating the optimum width-to-thickness ratio. Once final specimen geometry was obtained, shear accuracy was estimated using eight shear moduli that spanned the range measured during compression testing.

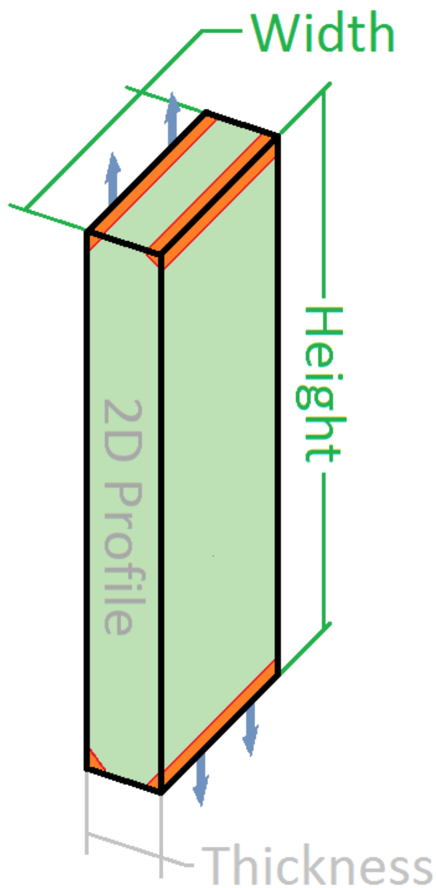

Figure 1.2: Stress concentrations in the shear elasticity test. Stress concentrations (orange) were predicted to be the greatest source of error. Height was optimized first, because adjustments changed the proportional area of influence within the 2D profile. Width was optimized second, because the area of influence was consistent in the extruded profile.

Adhesive Selection: Eight adhesives [Table 1.3] were evaluated to determine their ability to bond a range of prosthetic liner materials (i.e., chemical variations of silicone, urethane, and TPE) to the aluminum test fixture. Adhesives were evaluated by measuring how well each successfully bonded liners to the test fixture over repeated 60% shear strain cycles, without peeling or delaminating.

Table 1.3: Adhesives evaluated for the shear and tensile elasticity tests

Manufacturer	Product	Base Polymer
3M	4XL-EG	Epoxy
3M	Poly Adhesive	Acrylic
FabTech	PLU 90	Urethane
Loctite	E-60HP	Expoy
Loctite	M-11FL	Urethane
Loctite	U-09FL	Urethane
Lord	310A/B	Epoxy
Polymeric Systems	Sili-Thane 803	Silicone

1.3.7 *Tensile Elasticity*

The tensile elasticity test quantifies a liner's ability to stretch axially. A liner experiences axial stretching during swing phase of the gait cycle, when the prosthesis pulls away distally from the residual limb. Tensile elasticity may therefore influence the quality of suspension the liner provides. As published data regarding tensile stresses experienced by prosthetic liners in normal use are unavailable, the test maximum strain was set to the limit established during the compressive elasticity test, while the strain rate was set to the maximum displacement rate of the MTM (30 mm/s or approximately 20% strain per second). The tensile elasticity test limits were matched to the test limits established in compression and shear to follow guidelines[26] that ensure complete material models for mechanical analysis. Since tensile stresses are anticipated to be most prominent in swing phase (when the weight of the prosthesis is suspended by the liner), these limits are expected to exceed peak values that occur in normal use.

Specimen Attachment: The pneumatic specimen grips supplied by the MTM manufacturer produced significant deformations in liner specimens. Therefore, a custom test fixture that used an adhesive bond, rather than clamping force, was designed to affix test specimens [Figure 1.3a]. Adhesive specimen tabs were mounted on a linear slide rail, both to accommodate different specimen thicknesses and to minimize secondary stresses caused by liner deformation during the tensile test. The pneumatic and adhesive specimen attachments were evaluated by comparing instrument strain measured by the MTM to localized strain measured by a digital caliper (CD-8” CSX, Mitutoyo, Aurora, Illinois) across three 10 mm regions centered on a liner specimen. The most suitable attachment method was the one that had the best agreement between instrument and local strains.

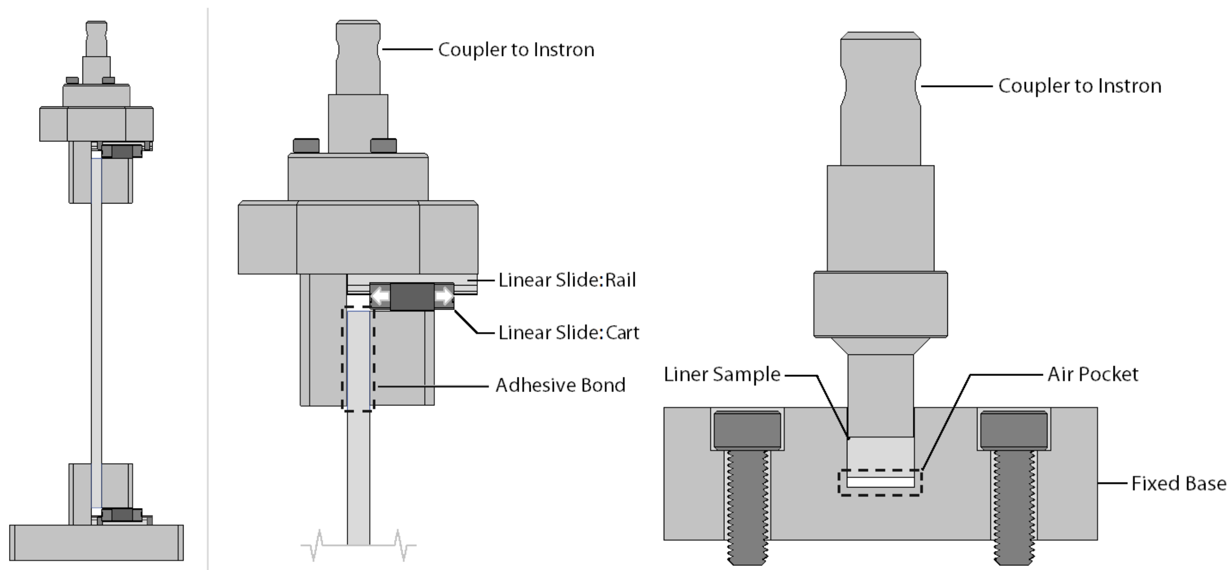

Figure 1.3: Configurations for the tensile elasticity and volumetric elasticity tests. (left) Tensile fixture with adhesive fixation. Left-side specimen mounts were fixed in place, while right-side specimen mounts were attached to a linear slide rail, allowing the specimen to thin while under tension. (right) Bulk test fixture with air pocket. Air pockets were removed by center punching with a large knitting needle, the eye of the needle created a gap that provided a low resistance path to outside of the well.

Specimen Size: Similar to the simple shear test method used in the shear elasticity test, uniaxial tensile measurements were prone to stress concentrations at the specimen mount. To limit the effects of stress concentrations, ASTM D412[18] recommends a tensile specimen geometry of 33.0–59.0 mm (L) by 3.0–12.0 mm (W). The recommended geometry was modified for the liner tensile test based on two factors. First, a larger specimen width (i.e., 32.0 mm) was selected to ensure the specimen included a sufficient number of intact fibers in the liner's fabric backing to contribute to tensile elasticity. Second, FEA was used to determine a specimen length that minimized the effects of stress concentrations at the specimen mounts. 3D candidate geometries were then analyzed to assess the effects of width. Once the optimum specimen geometry was selected, eight prospective moduli spanning the range of measured liner products were evaluated in FEA to quantify tensile modulus measurement accuracy.

1.3.8 *Coefficient of Friction*

The CoF test quantifies a liner's ability to adhere to the limb. Liners regularly slip during ambulation, and the resulting abrasion can cause rashes or blisters[3, 46, 47]. CoF is also related to a liner's ability to propagate shear stresses through the skin-liner interface (e.g., a higher CoF will increase the maximum potential shear stress imposed on a limb). Previously reported measurements of the COF between skin and prosthetic liner materials were substantially different: 0.35–0.68[48] and 3.0–6.0[49]. This broad range in measured COF could have been the result of different measurement methods (e.g., torsional friction vs planar friction, measurement area (size), moisture saturation, applied pressure, or displacement rate) or variations in prosthetic liner materials. While some differences were expected between different methods, it was hypothesized that an order of magnitude increase in CoF was characteristic of chemical adherence that could only be the result of different liner materials. Initial tactile evaluation showed that some liners products exhibited sufficient adherence to support their own weight when suspended from human skin. Therefore, three liner samples with different base elastomeric polymers (i.e., urethane, silicone, and TPE) were used to evaluate the instrument's repeatability and assess the protocol's ability to reproduce the range of frictional coefficients reported in the literature.

1.3.9 *Volumetric Elasticity*

The volumetric elasticity test quantifies a liner's stiffness when lateral expansion (i.e., flow) is inhibited. The size and shape of a residual limb changes both over the course of a day[50] and over longer periods of time[39], affecting stress distributions over the entire residual limb. Management of these fluctuations is the single most challenging issue reported by prosthesis users[47]. Additionally, there are several clinical assumptions in the prosthetic industry about the lateral expansion (flow) of different liner materials. For example, it is generally assumed that TPE liners flow more than polyurethane or silicone based liners. The (Poisson's) ratio of lateral expansion, and therefore a liner's tendency to flow, can be estimated through the ratio of volumetric stiffness to compressive stiffness. From an engineering perspective, it is generally assumed that all elastomers are incompressible and little difference is anticipated between liner products. However, it is important to retain this test to provide relevant clinical insight into the common use of prosthetic liners.

Air Pockets: Given the layered composition of elastomeric liners, a consistent, two-phase volumetric compression response was expected. The first phase would be relatively soft and correspond to compression of the fabric backing, the second phase would be stiff and correspond to compression of the elastomer. However, initial volumetric tests were inconsistent, exhibiting noticeably different elastic responses between specimens from the same liner product. It was hypothesized that such a response may have been due to air trapped in the bottom of the testing well [Figure 1.3b]. Two installation methods were therefore compared to determine which method produced a consistent two-phase volumetric response. Specimens in both methods were coated with the lubricant chosen for the compressive elasticity test, and either (a) the specimen was placed into the well inverted with the fabric facing down, or (b) the specimen was installed gel surface down while center-punched with a large knitting needle. The base of the needle was embedded into the specimen to allow trapped air to escape through the eye. When all the air had been expelled, the needle was removed.

1.3.10 *Thermal Conductivity*

The thermal conductivity test quantifies a liner's ability to transmit heat out of the limb. Excessive heat and sweating are common complaints from elastomeric liner users[3, 46]. Elastomers are known to be relatively impermeable to both gases (air) and liquids (sweat). Further, most elastomers are insulating materials that limit conductive heat transfer. A liner with a high thermal conductivity can optimize comfort in a hot environment by moving heat away from a warm limb, while a liner with a low thermal conductivity can optimize comfort in a cold environment by insulating a cold limb. Contact temperatures on the upper and lower surfaces of the liner sample represented the desired experimental set point, since conductive heat transfer is governed by temperature gradients across a medium. The minimum desired contact temperature was 10 deg C while the maximum was 40 deg C, representing the lower[51] and upper[52] safe temperature boundaries for skin contact.

However, the HFM only allowed tests to be designed by setting the mean specimen temperature. Resulting contact temperatures were hard programmed by the instrument's manufacturer to be ±10 deg C offset from the mean specimen temperature. Therefore, to achieve the desired contact temperature range of 10 to 40 deg C, two tests were conducted with mean specimen temperatures of 20 deg C and 30 deg C. The instrument allowed mechanical adjustment of air pressure in a pneumatic piston that compressed the test specimen in 1 psi (7 kPa) increments from 5–60 psi (34-414 kPa). Piston air pressure was set to 10 psi (69 kPa) as a balance between mean sitting pressures of 5 kPa[53] and mean stance phase walking pressures of 100 kPa. It is also worth noting that during the design of the four elasticity tests, peak stresses were of particular interest because of potential skin damage. However, thermal conductivity is a continuous occurrence and therefore the mean socket condition was of the greatest interest.

Test standards[24] often recommend use of thermal grease to eliminate air gaps and improve measurement accuracy. However, the fabric backing on a prosthetic liner presents a mixed volume of solid (fibers) and fluid (air) through which heat must transfer. To determine if thermal grease significantly altered the heat transfer properties of the fabric backing, liner samples were tested both with and without grease applied onto the fabric side of the specimen. Samples were taken from three liner products that represented the range of fabrics used with prosthetic liners. One product had a loosely woven fabric backing that was 1.0 mm thick, one had a tightly-knit and axially-directed weave with aramid fibers that was 0.6 mm thick, and the last had a thin and loosely woven fabric that was less than 0.3 mm thick. Air was not considered a confounding factor if the absence of thermal grease did not decrease measurement repeatability.

1.4 RESULTS

1.4.1 *Compressive Elasticity*

Stress/Strain Maximum: The most compliant liner specimen achieved 85 kPa at 54% strain and 102 kPa at 60% strain [Figure 1.4a]. Therefore, the test limit of 60% strain was considered valid since it produced a stress that exceeded both the maximum measured pressure for elastomeric liners (85 kPa[33]) and the mean measured pressure for Pelite liners (100 kPa[27-32]). Additionally, the least compliant liner evaluated was stiffer than Pelite™, which verified the need for a second test limit of 250 kPa.

Strain Rate: Stress-strain response was nearly identical between 50–150% strain per second [Figure 1.4b]. Toe regions visible below 10% were caused by the MTM accelerating to the target strain rate, and were not representative of the material response. Tangent moduli were calculated over the linear regions of the stress-strain curves (i.e., between 10–35% strain) to facilitate a simple quantitative comparison between test conditions. The resulting tangent moduli were 194 kPa (150% per second), 191 kPa (100% per second), 187 kPa (50% per second), and 156 kPa (0% per second).

Specimen Size: Tangent moduli increased linearly with diameter (R^2=0.9999) but had a non-zero intercept (i.e., the projected modulus at zero diameter was 71 kPa) [Figure 1.4c]. For the specimen diameters evaluated, the resulting tangent moduli in the linear regions of the stress strain curve were 149 kPa (12 mm), 194 kPa (19 mm), and 267 kPa (30 mm).

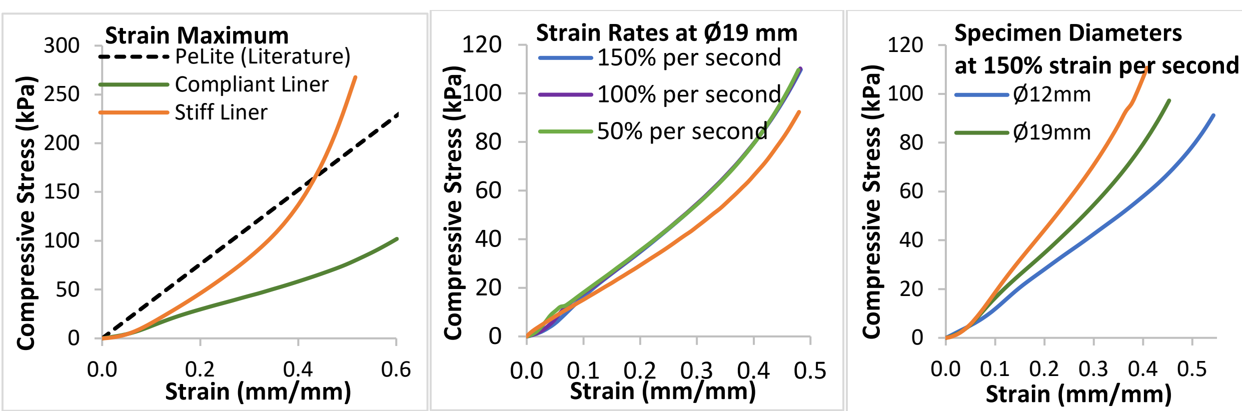

Figure 1.4: Compressive elasticity – parameter assessment. (left) The most compliant liner achieved 102 kPa at 60% strain, while the stiffest liner achieved 200 kPa at 47% strain. Averages for 18 liners specimens evaluating (middle) strain rate and (right) specimen diameter.

Frictional Effects: Of the lubricants evaluated, Outlast Synthetic Oil (C&C Synthetics, Mandeville, Louisiana) was the most effective [Figure 1.5]. Other lubricants exhibited either an inconsistent stress-strain curve or unrepeatable maximum strains for a constant peak stress of 250 kPa during the 15-minute cyclic compression test.

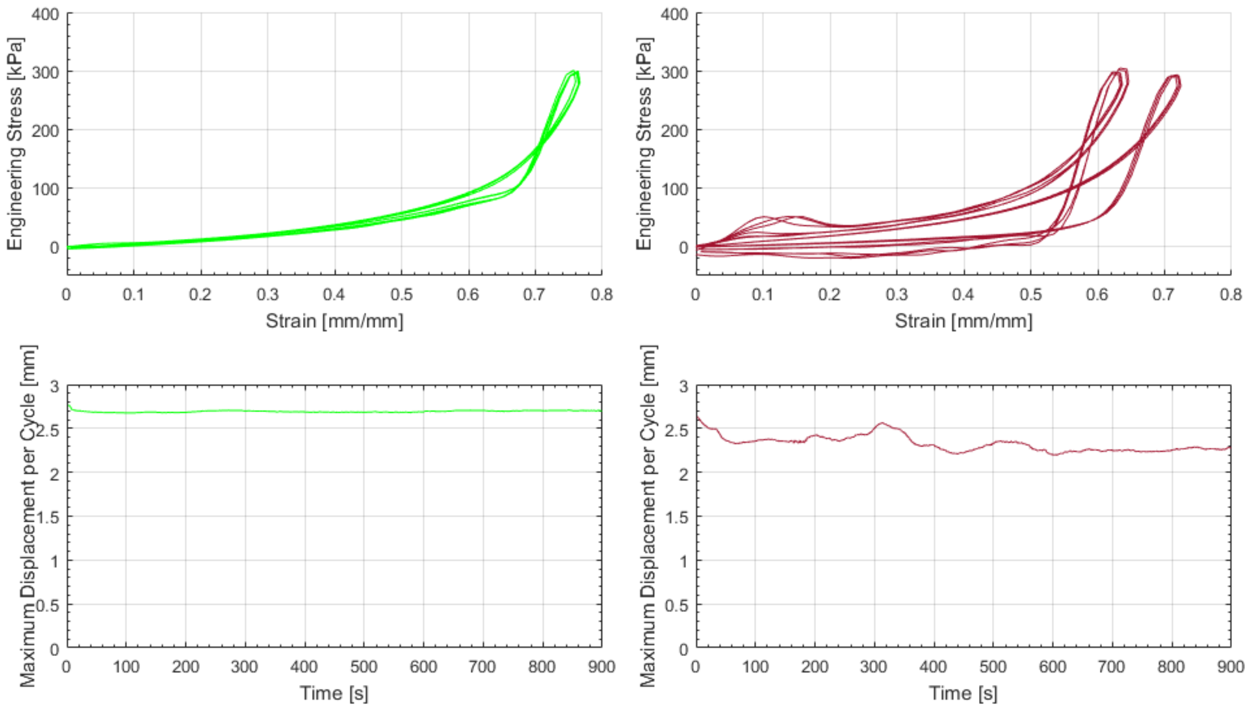

Figure 1.5: Compressive elasticity – lubricant evaluation. Examples from two lubricants tested on the softest liner material (TPE): Outlast Synthetic Oil (left) HAAS Automation Oil (right). Upper plots show overlayed stress-strain curves at nine load cycles and lower plots show displacement over time.

1.4.2 *Shear Elasticity*

Specimen Size: Increasing the height-to-thickness ratio improved measurement accuracy by decreasing the influence of stress concentrations along the upper and lower specimen edges. The absolute size of these concentrations were approximately the same across the tested height-to-thickness ratios, therefore, measurement was improved by increasing the portion of the specimen under a uniform stress [Figure 1.6a]. A height-to-thickness ratio of 20 was found to be optimal; smaller ratios exhibited an increase in net measurement error, while greater ratios showed no meaningful improvement.

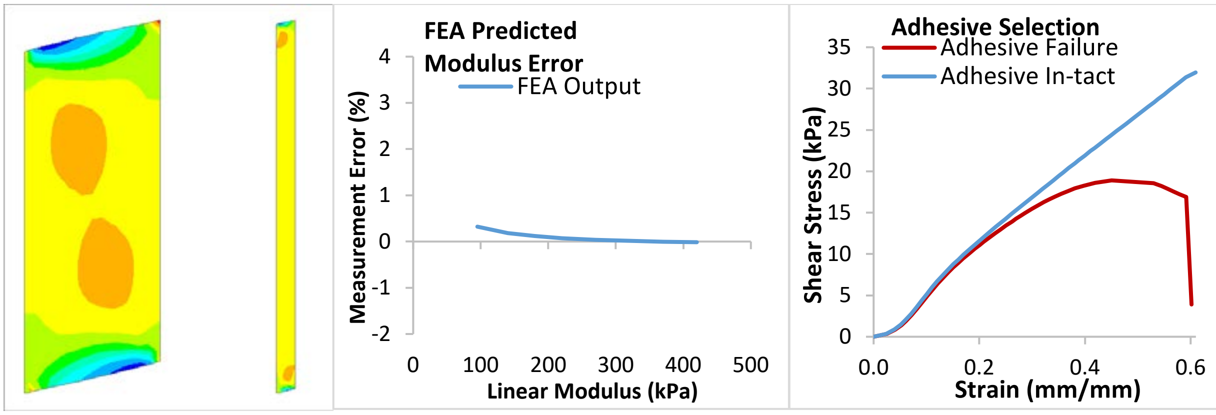

Figure 1.6: Shear elasticity – error assessment. (left) The influence of stress concentrations was minimized as length-to-thickness ratio was increased to 20. (middle) Load measurement error for the chosen specimen size decreased as linear modulus increased. (right) Experimental data showing an adhesive failure that began to peel at 15% strain and delaminated at 55% strain.

FEA indicated that a 6 mm liner with a height-to-thickness ratio of 20 (120 mm) had an optimal width-to-thickness ratio of 5 (30 mm). Over the eight moduli simulated for the optimal specimen geometry, the mean predicted load measurement error was 0.1 ± 0.1 percent. This error was constant over all strains and was non-linearly dependent on simulated modulus [Figure 1.6b].

Adhesive Selection: FabTech 90 (FabTech Systems, Everett, Washington) was found to be the most effective adhesive. FabTech 90 created the strongest bonds with urethane-based elastomeric liners and bonds that were equal or greater in strength with silicone and TPE liners, relative to any of the other adhesives. While FabTech 90 could successfully bond all liners tested through at least five shear cycles, no adhesive was able to bond TPE liners throughout the duration of the 15-minute cyclic test. All failures occurred between the elastomer and the adhesive. Failure modes were evident both in visual inspection of the specimen after testing, and in the resulting stress-strain curves. Edge peeling was characterized by a non-linear (decreasing slope) stress-strain response, while a complete delamination was characterized by a sharp negative slope in the stress-strain response [Figure 1.6c].

1.4.3 *Tensile Elasticity*

Specimen Attachment: The manufacturer-supplied specimen grips demonstrated measurement error that increased with applied strain and an inability to provide sufficient fixation to hold a specimen beyond 45% strain [Figure 1.7a]. The custom adhesive fixture had a mean absolute error of 1.3 ± 2.1 percent and was able to provide fixation from 0 to 100% strain.

Specimen Size: Load measurement error decreased with increasing specimen length [Figure 1.7b]. The absolute specimen length was determined to be more important than length-to-thickness ratio in the tensile test elasticity test because 210 mm was found to be the maximum length of material that could be consistently removed from a liner. For the selected specimen length (210 mm), the FEA-predicted mean load measurement error was 1.2 ± 2.4 percent. Similar to shear, error was independent of strain and dependent on the simulated modulus [Figure 1.7c].

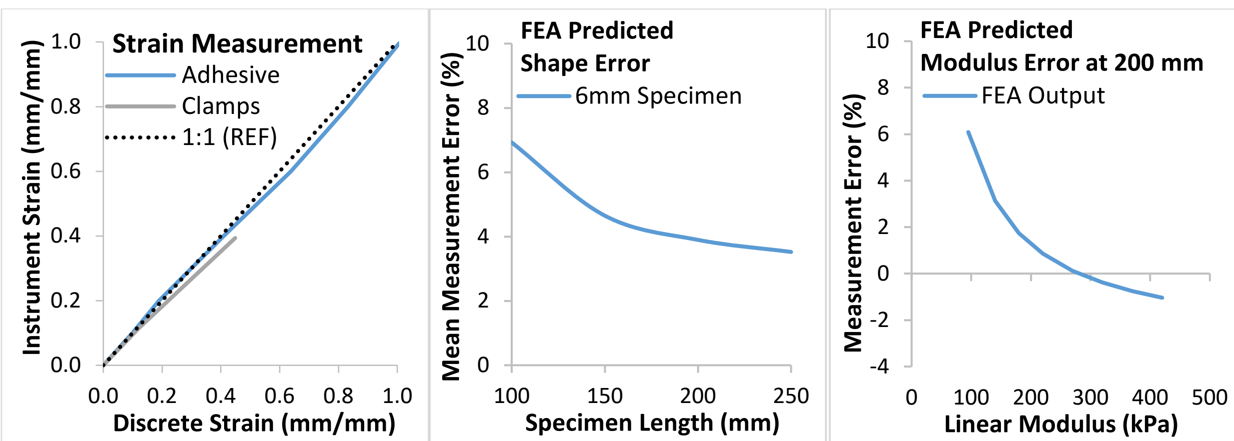

Figure 1.7: Tensile elasticity – error assessment. (left) Adhesively mounted specimens minimized measurement error and increased the achievable maximum strain. (middle) Load measurement error decreased relative to specimen length and (right) decreased with increased specimen stiffness at a length of 200 mm.

1.4.4 *Coefficient of Friction*

Static CoF measurements were less repeatable than dynamic CoF measurements. Comparing two liner samples of the same manufacturer and product, static CoF had a measured standard deviation of 0.75 across six pulls with two pieces of leather [Figure 1.8a]. Dynamic CoF for the same liners had a standard deviation of 0.02 [Figure 1.8b]. Measured dynamic CoFs were distinct across three different liner materials (i.e., urethane, silicone, and TPE) and roughly corresponded to the ranges of CoF reported in the literature[48, 49] [Figure 1.8c].

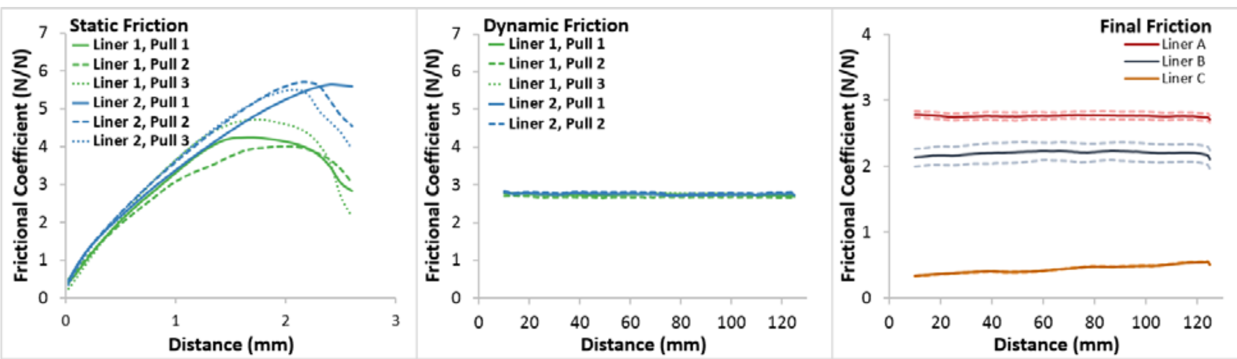

Figure 1.8: Coefficient of friction – static vs dynamic. Single liner model variability for (right) static and (middle) dynamic friction. (left) Mean and standard deviations of three liner models when measuring dynamic friction.

1.4.5 *Volumetric Elasticity*

Air Pockets: Specimens without an air vent showed no clear linear response, while specimens with an air vent exhibited two distinct linear regions in the strain-strain curve [Figure 1.9]. Tangent modulus was evaluated from 200–500 kPa, and the measured modulus of the non-vented specimen (19,400 kPa) was an order of magnitude less than the vented specimen (114,000 kPa). This was evidence of a confounding factor, and indicated trapped air compressing at the bottom of the specimen well for the non-vented specimen (i.e., air has an adiabatic bulk modulus of 133 kPa[54]).

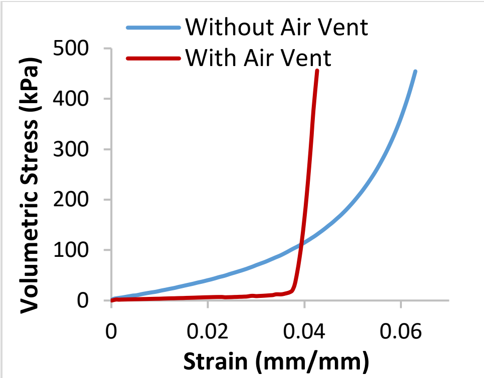

Figure 1.9: Volumetric elasticity – error assessment. Venting specimens during installation significantly reduced the impact of air.

1.4.6 *Thermal Conductivity*

Across the three liner products evaluated, the mean thermal conductivity without grease applied was 0.139 ± 0.002, 0.135 ± 0.002, and 0.173 ± 0.002 W/m-K [Figure 1.10]. Mean thermal conductivities for the same samples after the application of thermal grease were 1.52 ± 0.002, 0.150 ± 0.003, and 0.193 ± 0.002 W/m-K. The weight of thermal grease applied to each liner product was 1.56 ± 0.10, 0.98 ± 0.05, and 1.11 ± 0.02 grams; the addition of grease resulted in a mean increase in thickness of 0.1 ± 0.1 mm.

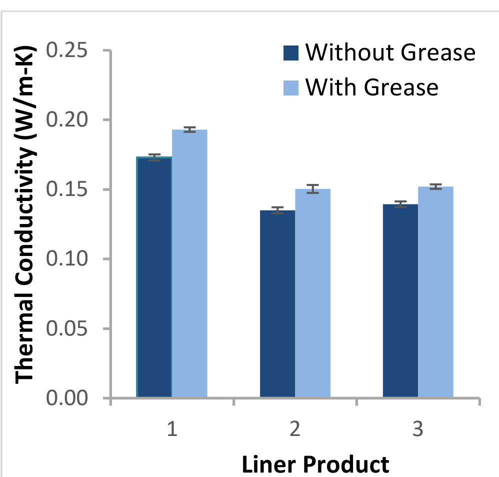

Figure 1.10: Thermal conductivity – error assessment. The absence of thermal grease resulted in a consistent change in thermal conductivity.

1.5 DISCUSSION

The goal of this research was to design a set of standardized material property tests that would facilitate direct comparison of different prosthetic liner products. The unique composition of prosthetic liners (i.e., layered elastomeric gels and fabric backing) required development of novel material tests suited to these materials. Rigorous tests were conducted to define and refine protocols that focused on repeatable results while minimizing measurement error.

To be consistent with material characterization guidelines and to ensure coherent material models for mechanical analysis[26], the final compressive elasticity test protocol was used as a template for the remaining material property tests. Final protocols consist of the same six fundamental steps, with preconditioning and end of test criteria being identical across all properties. Variations in sample geometry, preparation, conditioning, and measurement were specific to each material property test and based on instrument limitations, results of tests conducted for this study, and insights from the literature. The template test (i.e., compressive elasticity) and the variations from it are described below.

1.5.1 *Compressive Elasticity*

Protocol: The compressive elasticity test protocol [Table 1.4] was the template to set test procedures needed to characterize a single liner sample. Three specimens per material property were collected when possible, and this was particularly important for tests with highly impactful factors (such as friction) since multiple samples helped identify invalid tests (e.g., poor lubrication).

Table 1.4: Final test procedure for the measurement of compressive elasticity

Preconditioning	Liner placed in a room controlled at 21 ± 1 deg C for 24 hours
Sample	Three circular specimens 19 mm (D)
Preparation	Specimens and test fixture lubricated (Outlast, C&C Synthetics) prior to installation
Conditioning	Cyclic compression at a constant rate of 100% strain per second to a stress maximum of 250 kPa for a total of 15 minutes
Measurement	Single compression at strain rates of 150% (dynamic) and 0.5% strain per second (quasi-static) Test maximum was 60% strain or 500 kPa (whichever was lesser)
End of Test	Repeat *Measurement* until consistent stress-strain response is achieved

Sample: A 19 mm specimen diameter should be used in the final test protocol. Specimens of three diameters were evaluated for the compressive elasticity test to determine the effect of aspect ratio and optimal specimen size. The observed linear increase in stiffness with increased specimen diameter were likely due to contributions from the fabric backing. As the elastomer flowed and expanded laterally the fabric backing was placed under biaxial tension. Since the primary effect of a change in diameter was a parameter, (opposed to a confounding factor), 19 mm was chosen because it most closely matched the dimensions of sensors used in interface stress measurements reported in the literature[27-33].

Conditioning: Specimens should be cyclically conditioned at 100% strain per second for 15 minutes prior to testing. This timeframe was chosen on the basis of stress relaxation guidelines that indicate steady state is normally achieved 3-4 decades relative to the absolute time from minimum to maximum strain[21, 22]. For example, at 100% strain per second, approximately 0.6 seconds are required to reach the 60% strain limit, and therefore specimen response should reach a steady state after 600-6,000 seconds.

Measurement: Strain-rates of 150% and 0.5% per second should be used for the final test protocols to represent ambulatory (dynamic) and standing (quasi-static) loading conditions. Little difference was observed within the group of strain rates that corresponded to dynamic activity (50–150% per second). The only discernable change in stiffness due to viscoelastic effects was between dynamic and quasi-static responses.

1.5.2 *Shear Elasticity*

Protocol: The shear elasticity test protocol [Table 1.5] differs from the compressive elasticity test protocol in the specifications of sample and conditioning. Compressive and shear elasticity tests were closely related in terms of their final protocols.

Table 1.5: Final test procedure for the measurement of shear elasticity

Preconditioning	Liner placed in a room controlled at 21 ± 1 deg C for 24 hours
Sample	One rectangular specimen 127 mm (H) x 32 mm (W)
Preparation	Specimens bonded to tabs (FabTech 90, FabTech Systems) prior to installation
Conditioning	None - Adhesive could not withstand cyclic conditioning
Measurement	Single shear at strain rates of 150% (dynamic) and 0.5% strain per second (quasi-static) Test maximum was 60% strain
End of Test	Repeat *Measurement* until consistent stress-strain response is achieved

Sample: The specimen length should be 120 mm. FEA determined that specimen size required for an accurate measurement of shear elasticity was larger than expected. While ASTM D945[15] recommended a nominal specimen size of 600 mm^2 for a 12.5 mm thick specimen, results from the present testing indicated that the critical dimension was the specimen length along the displacement axis of the MTM. However, at this length only one shear specimen may be reliably extracted per liner when all other required specimen geometries are considered.

Conditioning: Shear specimens should not be conditioned, as testing revealed that no combination of adhesives could successfully bond all liner products for 15 minutes. Instead, specimens were cyclically conditioned until a repeatable stress-strain response was achieved (typically two cycles).

Measurement: As with compressive elasticity, interface pressures reported in the literature were used to validate the 60% strain limit for the shear elasticity test. MTM measured peak shear stresses in this study were 11 kPa for the softest liner and 50 kPa for the stiffest liner. These were similar to the reported mean and maximum shear stresses of 17 kPa and 59 kPa, respectively[27-32].

1.5.3 *Tensile Elasticity*

Protocol: The tensile elasticity test protocol [Table 1.6] differs from the compressive elasticity test protocol in the specifications of sample, conditioning, and measurement. The motivation for changing the definition of sample conditioning is identical to shear, and is not discussed below.

Table 1.6: Final test procedure for the measurement of tensile elasticity

Preconditioning	Liner placed in a room controlled at 21 ± 1 deg C for 24 hours
Sample	One rectangular specimen 210 mm (H) x 32 mm (W)
Preparation	Specimens bonded to tabs (FabTech 90, FabTech Systems) prior to installation
Conditioning	None - Adhesive could not withstand cyclic conditioning
Measurement	Single pull at displacement rates of 30 mm (dynamic) and 1 mm per second (quasi-static) Test maximum was 60% strain or 500 kPa (whichever was lesser).
End of Test	Repeat *Measurement* until consistent stress-strain response is achieved

Sample: FEA validation for the chosen specimen geometry predicted a mean load measurement error of 1.2%. Experimental results indicated that the lowest measured tangent modulus was approximately 120 k Pa, and this correlated to a measurement error of 4%. While the FEA analysis assumed that liners were comprised of a linear isotropic material, the physical liners were orthotropic layered materials that exhibited a non-linear (i.e., fabric dependent) stiffness. Since the fabric composition and thickness ratio varied by liner product, it was not possible to create a correction factor that would offer a consistent improvement in the measured property across all liners.

Measurement: Similar to the compressive elasticity test, a 500 kPa test maximum should be imposed to provide an alternate upper limit. Some liners had directional fibers intended to stiffen axial elasticity while retaining a low elasticity in radial stretch. As a result, liner products with directional fibers are easy to stretch onto the limb during donning, but stiff and stable during swing phase. Finally, the tensile elasticity test was limited to 30 mm per second (approximately 20% strain per second) because it was the maximum displacement rate of the MTM test head.

1.5.4 *Coefficient of Friction*

Protocol: The CoF test protocol [Table 1.7] varied from the compressive elasticity test protocol in the specifications of sample, conditioning, and measurement. The CoF and thermal conductivity tests are fundamentally different since they measure a single value coefficient rather than a stress-strain response. The available parameters and selected values used to set the specification for measurement are discussed in the methods.

Table 1.7: Final test procedure for the measurement of coefficient of friction

Preconditioning	Liner placed in a room controlled at 21 ± 1 deg C for 24 hours
Sample	(A) One rectangular liner specimen 210 mm (L) x 70 mm (W) (B) Three rectangular leather specimens 63 mm (L) x 63 mm (W)
Preparation	Liner specimens washed with hand soap & warm water then air dried
Conditioning	None
Measurement	Single pull at displacement rate of 150 mm per minute Test maximum was 125 mm.
End of Test	Repeat *Measurement* until three consecutive pulls produce consistent responses

Sample: Leather samples should be tested per liner to reduce the influence of measurement variability. Since CoF measurement variability was relatively high, multiple specimens were desirable for this test. However, specimen size for frictional testing was the largest of the six material property tests, and it was not feasible to obtain more than one per liner.

Conditioning: Conditioning should be a two-step process for each liner. First, to replicate clinical use, liners are washed with hand soap and warm water to remove any debris or residue and then allowed to air dry. Next, each leather sample are conditioned by repeated pulls until three consecutive pulls reported dynamic CoF within 0.05.

1.5.5 *Volumetric Elasticity*

Protocol: The volumetric elasticity test protocol [Table 1.8] varied from the compressive elasticity test in the specifications of preparation, conditioning, and measurement. The (lack-of) conditioning is explained in the measurement definition.

Table 1.8: Final test procedure for the measurement of volumetric elasticity

Preconditioning	Liner placed in a room controlled at 21 ± 1 deg C for 24 hours
Sample	Three circular specimens 10 mm (D)
Preparation	Specimens and test fixture lubricated (Outlast, C&C Synthetics) prior to installation
Conditioning	None
Measurement	Single compressions at a strain rate of 0.1% strain per second Test maximum was 500 kPa.
End of Test	Repeat *Measurement* until consistent stress-strain response is achieved

Preparation: Specimens should be lubricated and center punched with a larger knitting needle during installation to produce the most consistent measurement response. Results indicated that center-punching improved accuracy and repeatability by allowing trapped air to escape. Similar to the compressive elasticity test, lubricating the specimens improved repeatability and facilitated the removal of air pockets

Measurement: Specimens should only be evaluated a quasi-static strain rate (0.1% per second), and conditioned by repeating measurement until a consistent response is achieved. Results showed that a liner specimen's volumetric response could increase from 200–500 kPa in less than 0.3% strain (0.02 mm for a 6 mm thick liner), and therefore a quasi-static strain rate was needed to keep the MTM within safe operating conditions. Since a quasi-static test is not affected by viscoelastic behavior, decade derived (15 minute) cyclic conditioning was not necessary.

1.5.6 *Thermal Conductivity*

Protocol: The thermal conductivity test protocol [Table 1.9] varied from the compressive elasticity test protocol in the specifications of sample, conditioning, and measurement. Similar to the CoF test, the available parameters and selected values used to set the measurement specifications for the thermal conductivity test are discussed in the methods. An important note is that the particular instrument used in this study was only able to set the mean specimen temperatures. Measurements with other instruments should be set to measure the appropriate contact temperature range (10–40 deg C) rather than match the mean specimen temperatures used for the Unitherm 2022 HFM.

Table 1.9: Final test procedure for the measurement of thermal conductivity

Preconditioning	Liner placed in a room controlled at 21 ± 1 deg C for 24 hours
Sample	One circular specimen 51 mm (D)
Preparation	Pneumatic piston pressure set to 69 kPa
Conditioning	Specimens compressed in instrument until constant thickness (15 minutes minimum)
Measurement	Two point thermal conductivity measurement with specimen contact temperatures of 10 and 40 deg C
End of Test	End of *Measurement*

Preparation: Thermal grease should be omitted from specimens during the thermal conductivity test. While thermal grease was recommended by the standard[24], it was omitted to improve clinical applicability. Further, results showed that specimens tested without thermal grease had the same measurement repeatability as those with thermal grease.

Conditioning: Specimens should be place at a constant 69 kPa piston pressure until thickness is consistent (typically 15 minutes). Since the HFM requires a static specimen geometry, conditioning by viscoelastic creep is most relevant.

1.6 Clinical Relevance

While the tests in this research focused on elastomeric liners, other materials such as foams (e.g., Pelite) have also been used as an interface material to couple limbs and sockets. Comparing liner materials from the present study to other biological and manufactured materials[40, 55-57] [Figure

1.11], elastomeric liners are seen to span the stiffness range of other common interface materials (i.e., prosthetic socks and foam liners). While foam and elastomeric liners have a similar stiffness, they have nearly opposite Poisson's ratios. The characteristic lateral expansion in compression (commonly called 'flow' the prosthetics industry) of elastomeric liners ensures closer contact with the limb, and may be preferable to the weight savings of lower density foams.

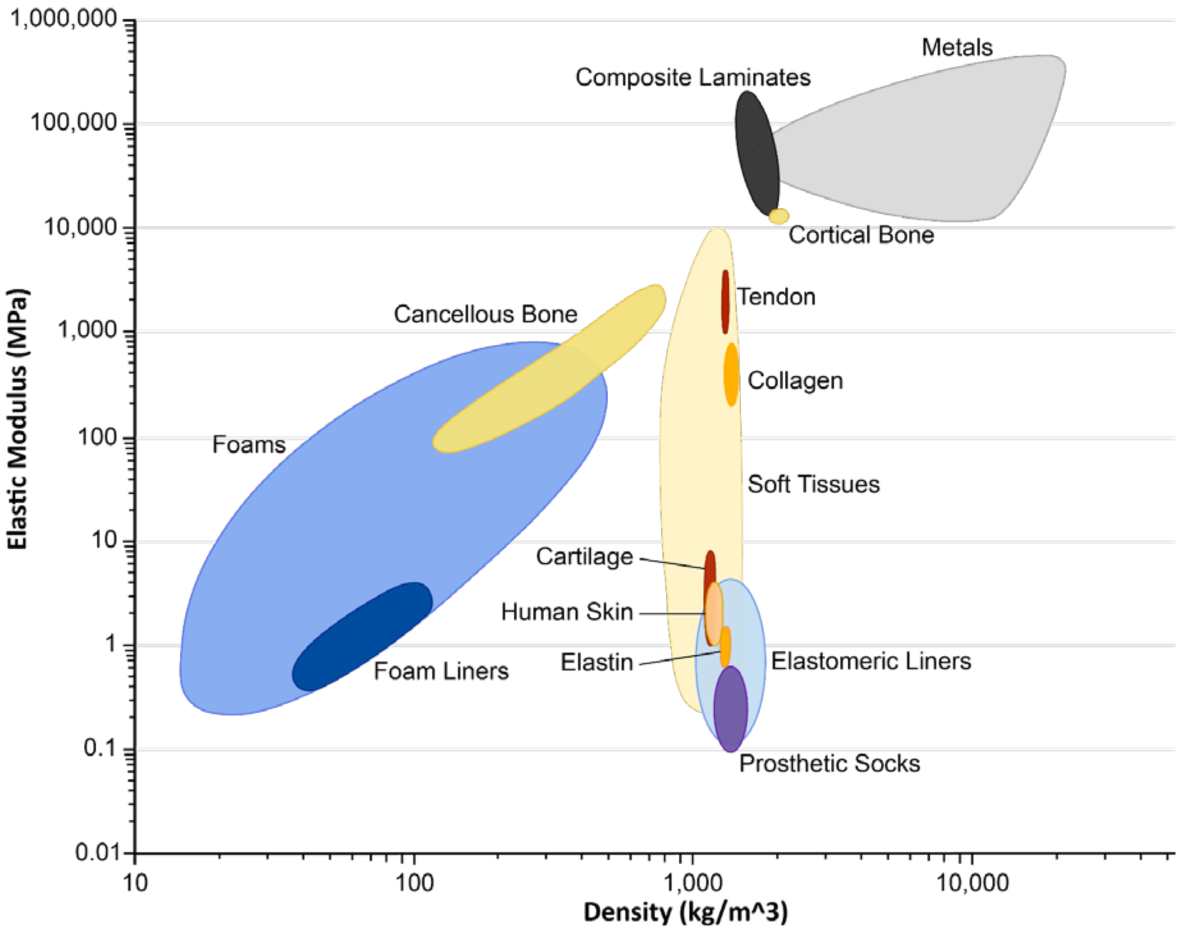

Figure 1.11: Ashby plot of the materials contained in a load bearing prosthesis.

The test protocols developed in this study create a foundation for evidence-based standards of practice, by providing a means to quantitatively characterize and directly compare existing and emerging liner products. Each of the six properties can be associated with one or more characteristics that contribute to a prosthesis user's function, health, or quality of life. Each of the specified test properties typically offers contrasting responses to clinical challenges depending on the magnitude of the measured response (e.g., a high compressive elasticity can enhance stability, while a low compressive elasticity can enhance comfort). This emphasizes the need for practitioners to consider each of these properties when selecting a specific liner product for each individual patient.

1.7 Conclusions

There is a paucity of quantitative data on the mechanical behavior of elastomeric liners used in lower-limb prosthetics. This research produced a set of six, standardized material property tests that allow different liner materials to be objectively characterized and compared. Future research should apply these test methods to a selection of prosthetic liners to provide objective insight into clinical use and facilitate individualized liner selection. Additionally, these tests methods can produce material inputs for mechanical analysis (such as FEA) to provide insight into the compound loading conditions experienced inside a prosthesis.

1.8 Acknowledgements

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Chapter 2. CHARACTERIZATION OF PROSTHETIC LINER PRODUCTS

2.1 Abstract

The purpose of this research was to evaluate commercially available prosthetic liners across six clinically-relevant material properties: compressive elasticity, shear elasticity, tensile elasticity, volumetric elasticity, coefficient of friction, and thermal conductivity. Twenty-four liner products evaluated had base materials of polyurethane (n=5), silicone (n=9), or thermoplastic elastomer (n=10). Across liners, tangent moduli in the linear region of the stress-strain curves ranged from 15–84 kPa for shear elasticity, 96–460 kPa for compressive elasticity, 110–3,450 kPa for tensile elasticity, and 84,000–208,000 kPa for volumetric elasticity. Dynamic coefficient of friction ranged from 0.5–3.1, while thermal conductivity ranged from 0.12–0.18 W/m·K. Fabric backings were found to make a significant impact on the tensile elasticity of certain liner products. Evaluation of existing clinical guidelines found that all elastomeric base materials have an equal tendency to flow, that TPE liners were frequently but not always the softest base material, and that silicone liner products showed the greatest variety in material properties.

2.2 Introduction

Major lower-limb loss is characterized by a loss of mobility that contrasts with a desire to achieve or exceed pre-operational levels of activity[1]. Maintaining limb health is a persistent challenge[2, 3], because the soft tissues of the residual limb are not physiologically suited for bearing ambulatory loads. Patient-specific factors such as limb shape[4], socket design[5], volume fluctuations[6], and suspension method[7] all influence a practitioner’s approach to designing a prosthetic interface. As such, a prosthetist designs a prosthesis to meet a patient's present needs and future goals.

Elastomeric liners have become an increasingly popular part of a modern prosthesis, with recent data suggesting that clinicians select suspension systems that require a gel liner for about 85% of prosthetic patients[8]. With this increase in popularity has come a wide selection of liner products. A recent study on the clinical use of prosthetic liners identified more than 70 liner products on the market[9]. In clinical practice, a recent study found that practitioners generally chose among 2-3 preferred products when selecting liners for patients. An explanation for such limited selection among many available options may be a lack of comparable, objective information about the similarities and differences among liner products. The same study found that only 33% of practitioners surveyed obtained information from scientific journals, while the majority sought information directly from manufacturers (94%) or clinical magazines (65%).

With the proliferation of elastomeric liner products and a lack of comparable performance data, clinical generalizations have materialized in an effort to find practical guidelines that streamline selection. For example, polyurethane liners are generally thought to be the stiffest elastomeric liners while thermoplastic elastomers (TPE) are the softest. A historical study found that fabric backings had no effect on elastic properties[10], although it is known that they increase durability, but newer liner products claim to have enhanced stretch resistance. These outcomes suggest there is a need for scientifically derived metrics that provide insight for common clinical use.

Results of a practitioner survey showed that, of 22 characteristics potentially considered during liner selection, the three most important were durability (91%), patient comfort (87%), and suspension features (78%)[9]. These considerations served as the basis of six materials property tests that were designed to characterize liners' interface with a residual limb[11]. The purpose of this study was to apply these tests to a diverse range of liner products used in contemporary prosthetics practice. The results of these tests can be used to substantiate some of the core assumptions governing the use of prosthetic liners. Further, these metrics could facilitate a more objective comparison so that practitioners can identify the product(s) that best match individual patient needs

2.3 METHODS

Commercially available prosthetic liners were compared across six material property tests. Compressive elasticity and shear elasticity tests were conducted to characterize liners' ability to distribute ambulatory loads during stance phase. Tensile elasticity tests were conducted to measure liners' resistance to axial stretching as would be encountered during swing phase, while the coefficient of friction (CoF) test measured a liner's adherence to a residual limb. Finally, volumetric elasticity and thermal conductivity tests were conducted to assess liners' accommodation to volume fluctuations and limb temperature, two of the most common issues reported by prosthesis users[12, 13]. Development and validation of the liner material property tests are described elsewhere[11]. Brief details of the tests are presented below.

2.3.1 *Instrumentation*

The compressive elasticity, shear elasticity, tensile elasticity, and volumetric elasticity tests were measured with a material testing machine (MTM) (5944, Instron, Norwood, MA). Full scale range of the instrument's load cell was 1–500 N with a mean load measurement error of ±0.25% and a displacement error of ±0.005 mm. Each material property test had a custom fixture that integrated with the MTM.

CoF was measured with a planar friction tester (Advanced Friction Tester, Hanatek, East Sussex, UK). CoF test parameters were predominantly determined by an ASTM testing standard[14], therefore no custom fixtures were fabricated. However, a soft leather (Cream Cow, WBC Industries, Westfield, NJ) was used as a skin surrogate to provide a physiologically consistent contact surface. The final system measured CoF with a repeatability of ±0.008.

Thermal conductivity was measured with a guarded heat flow meter (Unitherm model 2022, Anter Corp, Pittsburgh, PA). Similar to the CoF test, thermal conductivity test parameters were largely determined by an ASTM test standard[15] and no custom fixtures were designed. Repeatability of the instrument was ±0.001 W/m·K.

2.3.2 *Materials*

A recent survey found that of 70 liner products available on the commercial market, only five unique gel-fabric combinations from two manufacturers were in regular use by 10% or more of the surveyed practitioners[9]. For this study, six prosthetic liner manufacturers were invited to donate samples for testing. All samples sent by manufactures were included in the study, but select liners were also purchased to ensure the results of the current research included the 19 unique gel-fabric combinations reported in routine by more than 2% of practitioners[9] as well as novel liners identified at prosthetic conferences.

Liners were divided into sections based on their gel thickness profile [Figure 2.1] and each section was used as a source for test specimens. Liners with uniform gel profiles had a single section while tapered liners had two sections, proximal and distal. If a liner presented different anterior and posterior thickness profiles, test samples were extracted from the anterior region since it is the predominant site of ambulatory loads[16]. Section and specimen thickness was measured with a custom test instrument[17] used in prior studies to measure prosthetic sock thickness[18, 19].

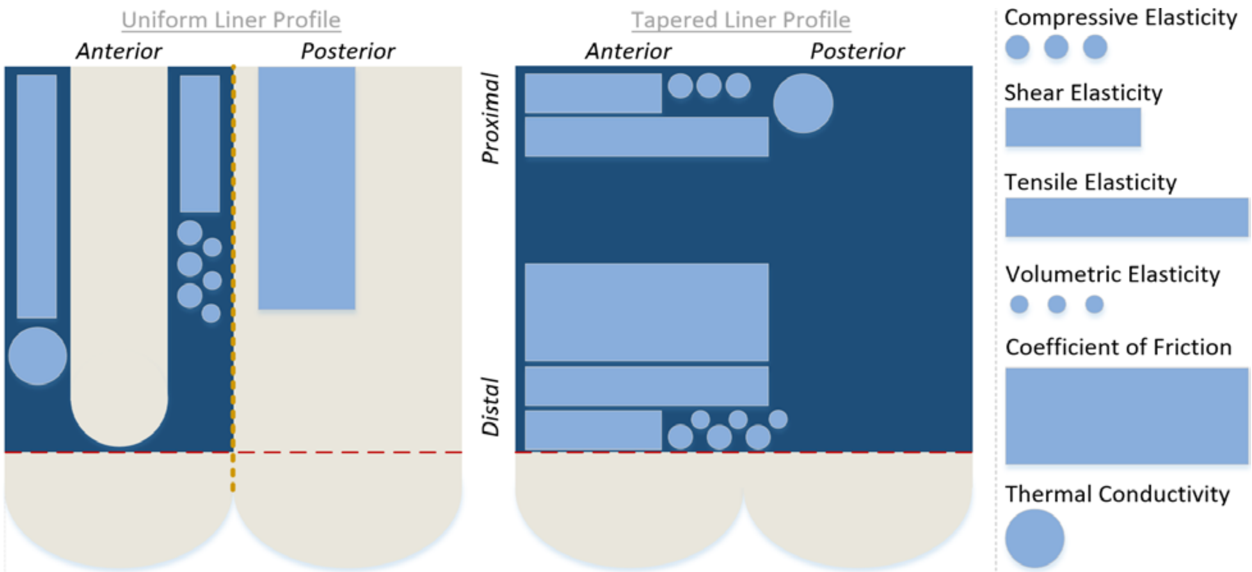

Figure 2.1: Liner sections used for specimen extraction. Test specimens were removed from anterior regions of the liner when possible. (Left) For uniform gel thickness profiles, only a narrow acceptable source region (blue) was available for certain liner products (e.g., WillowWood Hybrid Select), because the mid-anterior region had a different fabric, while distal and posterior regions had different gel thickness (beige). Specimens were pulled from the posterior for the CoF test, because CoF is independent of gel thickness and fabric. (Right) For tapered gel thickness profiles, specimens were oriented along the circumference of the liner to ensure a consistent thickness along the specimens' length. Only one specimen per liner was taken for the volumetric elasticity test and thermal conductivity test, because the differences between sections were expected to be small and the measurements were two of the most time-consuming tests in the suite.

2.3.3 *Preconditioning*

All liner material tests were performed in a temperature controlled room with ambient conditions of 21 ± 1 deg C. Before testing began, each specimen was thermally preconditioned for at least 24 hours.

2.3.4 *Compressive Elasticity*

The compressive elasticity test measured each liner's ability to 'flow' and distribute normal stresses. Normal stresses at the prosthetic interface have been frequently investigated[4, 16, 20-23] and are directly associated with limb health issues such as skin break- down and discomfort in sensitive regions with bony prominences[4]. Subsequently, normal stresses have been used to compare the effectiveness of different socket designs[21] and methods of suspension[24]. The compressive elasticity test characterizes liners' ability to distribute concentrated stresses and facilitate a sense of stability through a firm limb socket-coupling. However, these abilities require opposing stiffness; a soft liner (low compressive elasticity) will facilitate comfort by better distributing peak pressures, while a stiff liner (high compressive elasticity) will deform less and result in less motion between the limb and socket.

The compressive elasticity test evaluated three circular specimens (19 mm [D]) per liner section. Specimens were lubricated (Outlast, C&C Synthetics, Mandeville, LA) and then installed into the MTM. Specimens were cyclically preconditioned for 15 minutes and then re-lubricated before the test measurement. For the measurement of compressive elasticity, specimens were compressed to 60% strain or 250 kPa engineering stress, whichever was greater. Additionally, an upper limit of 500 kPa was imposed for specimens that were particularly stiff. Tests were repeated until specimens produced a consistent stress-strain response. To make the data more comparable to interface stress studies reported in the scientific literature, the measured engineering stress was then converted to true stress under the assumption of material incompressibility. The reported compressive elasticity is the mean stress-strain response across the three specimens averaged at 1% strain increments.

2.3.5 *Shear Elasticity*

The shear elasticity test measured each liner’s ability to propagate and distribute shear stresses. The insight offered by shear elasticity is closely related to a liner's compressive elasticity with two considerations. First, shear stresses are thought to be a leading cause of mechanically induced skin breakdown[12, 25] that can slow or exacerbate wound healing[26, 27]. This makes shear elasticity a particularly important property when selecting liners for people with delicate skin. Second, compression is a combined response of a liner's gel and fabric backing, while shear is exclusively dependent on elastomeric response. It might be possible for a manufacturer to design a liner that has a relatively soft shear elasticity with a relatively stiff compressive elasticity, facilitating load transmission towards normal and away from shear stresses.

The shear elasticity test evaluated one rectangular specimen (127 mm [L] x 32 mm [W]) per liner section. Specimens were bonded to a custom test fixture and sheared to 60% strain. FabTech 90 (FabTech Systems, Everett, WA) was used to bond the majority of the liner specimens, however several TPE and silicone liners showed significantly better bonds with Loctite 409 (Henkel Adhesives, Rocky Hill, CT). Specimens were cyclically sheared until a consistent stress-strain response was achieved (about three cycles). The repeatable response was recorded as the property measurement. Unlike the compressive elasticity test, specimens were not cyclically pre-conditioned for 15 minutes, because no adhesive could successfully bond all liner products for that duration.

2.3.6 *Tensile Elasticity*

The tensile elasticity test measured each liner’s ability to resist (axial) stretching along the length of a limb. Axial stretching is particularly relevant for a pin and lock suspension that rigidly attaches the liner to the base of the socket. During swing phase, the weight of the prosthesis pulls on the pin, and this can result in a slipping movement between the limb and the liner that is commonly called pistoning. Increased tensile elasticity may encourage a closer coupling during occurrences of pistoning when the region of slipping is below the knee and displacements are relatively small. However, increased tensile elasticity may also decrease a liner's ability to conform to the shape of a highly contoured limb or bony prominences.

The tensile elasticity test evaluated one rectangular specimen (210 mm [L] x 32 mm [W]) per liner section. Specimens were bonded to a custom test fixture and then stretched to 60% strain or 500 kPa engineering stress, whichever was less. Similar to the shear elasticity test, specimens were not cyclically conditioned, but instead repeatedly stretched until a consistent stress-strain response was produced. Similar to compression, tensile specimens had a variable cross-sectional area during testing so engineering stress was converted to true stress under the assumption of incompressibility.

2.3.7 *Volumetric Elasticity*

The volumetric elasticity test measured each liner's stiffness when it was not allowed to expand (flow) under compression, a condition experienced by a liner inside a total surface bearing socket. A recent survey found that volume management was the most common problem experienced by persons with a lower limb amputation[13]. A liner with a low volumetric elasticity indicates a liner is more capable of adjusting to limb volume changes of the residual limb, while a high volumetric elasticity indicates a liner is less capable of accommodating volume changes.

The volumetric elasticity test evaluated three circular specimens (10 mm [D]) per liner section. Before installation into the test fixture, specimens were lubricated and then center-punched with a large knitting needle. This puncture provided a path for trapped air to escape during installation and demonstrably improved measurement results[11]. Specimens were repeatedly compressed to 500 kPa until a consistent stress-strain response was achieved. The reported volumetric elasticity was the mean tangent modulus in the linear region of the stress-strain curve (generally between 200 and 500 kPa).

2.3.8 *Coefficient of Friction*

The CoF test measured each liner's ability to adhere to a residual limb. A liner's ability to stick to a residual limb is relevant both in stance and swing phases of gait because all shear stresses are propagated through friction. Since prosthetic sockets are contoured and sloped surfaces, every loading condition is non-orthogonal and therefore dependent on frictional shear stresses. CoF is therefore related to the total amount of shear that a liner is capable of transmitting before slipping, while shear elasticity affects the distribution of localized shear loads.

The CoF test evaluated one rectangular liner specimen (210 mm [L] x 70 mm [W]) and three leather specimens (63 mm [L] x 63 mm [W]) per liner section. Specific to our evaluations, leather samples were installed into the instrument's test sled using the provided magnetic specimen clamps. The leather samples were then pulled across the liner until three consistent measurements were achieved. Each liner's CoF was characterized as the mean dynamic CoF across the three test pulls.

2.3.9 *Thermal Conductivity*

The thermal conductivity test measured each liner's ability to move heat from the limb to the environment. Overheating is one of the most common issues reported by prosthesis users, with as many as 50% experiencing profuse sweating inside their socket[3, 12]. Conversely, the same study reported that 15% of lower limb prosthesis users experience issues with their residual limbs being too cold[3]. A liner with high thermal conductivity will move more heat away from a warm limb. A liner with low thermal conductivity will better insulate a cool limb and may be suitable for low activity or a cold environment.

The thermal conductivity test evaluated one circular specimen (51 mm [D]) per liner section. Specimens were placed into the instrument and compressed with a pneumatic piston pressurized to 69 kPa. Installed specimen thickness was measured with a dial indicator (Model 2416, Mitutoyo, Aurora, IL) immediately after installation and again after 15 minutes to ensure that creep was not impacting the test results. Once conditioned, two thermal set points were measured with a contact temperature range of 10 – 40 deg C. Each liner's reported thermal conductivity was determined as the mean of these two measurements.

2.4 Results

Twenty-three liner products from seven manufacturers were tested [Table 2.1], each with a unique elastomer-fabric combination. Liner base materials consisted of polyurethane (n=4), silicone (n=9), or thermoplastic elastomer (TPE) (n=10). In addition to these commercial liners, a room-temperature-curing silicone (Renew Silicone 10, Smooth-On Inc, Macungie, PA) used for fabricating custom liners was also evaluated. This material provided a reference as a non-fabric backed elastomer with a hardness of Shore 10A, since the Shore hardness scale is commonly used to evaluate the mechanical properties of rubbers and elastomers.

Table 2.1: Liner products subjected to liner material property testing.

	Manufacturer	**Product**	**Base Polymer**	**Elastomer**	**Fabric Backing**	**Profile (Sections)**
1	Alps	EasyLiner	TPE	EasyGel	Tan (anterior)	Uniform(1)
2	Alps	Extreme	TPE	GripGel	Brown	Uniform(1)
3	Alps	General Purpose	TPE	GripGel	Tan	Uniform(1)
4	Alps	Winter's Gel	TPE	WintersGel	Brown	Uniform(1)
5	Freedom Innovations	InceptionGel	TPE	Gel	Endurabond	Uniform(1)
6	Medi	Relax 3C	Silicone	Silicone-Gel	Electromagnetic	Tapered(2)
7	Össur	Comfort	Silicone	Sensil®	Nylon	Uniform(1)
8	Össur	Dermo	Silicone	DermoGel®	Supplex®	Uniform(1)
9	Össur	Original	Silicone	*Unknown*	None	Tapered(2)
10	Össur	Sport	Silicone	DermoSil® & DermoGel®	*Unknown*	Tapered(2)
11	Össur	Synergy	Silicone	DermoSil® & DermoGel®	Supplex®	Uniform(1)
12	Otto Bock	6Y512 (no fabric)	Polyurethane	*Unknown*	*None*	Anatomic(2)
13	Otto Bock	6Y512 (w/ fabric)	Polyurethane	*Unknown*	*Unknown*	Anatomic(2)
14	Otto Bock	6Y520 (no fabric)	Polyurethane	*Unknown*	*None*	Uniform(1)
15	Otto Bock	6Y520 (w/ fabric)	Polyurethane	*Unknown*	*Unknown*	Uniform(1)
16	Otto Bock	6Y75	Silicone	Skeo	*Unknown*	Uniform(1)
17	Otto Bock	6Y92	TPE	*Unknown*	*Unknown*	Tapered(2)
18	Prosthetic Design	SealMate	Silicone	*Unknown*	None	Tapered(2)
19	Renew	Silicone 10	Silicone	Silicone	None	Uniform(1)
20	WillowWood	Alpha®	TPE	ClassicGel	Max	Uniform(1)
21	WillowWood	Alpha®	TPE	ClassicGel	Original	Uniform(1)
22	WillowWood	Alpha®	TPE	ClassicGel	Spirit	Uniform(1)
23	WillowWood	Alpha®	TPE	Hybrid	Select	Uniform(1)
24	WillowWood	Alpha®	Silicone	*Unknown*	Select	Uniform(1)

2.4.1 *Compressive, Shear, and Tensile Elasticity*

The measured elastic property responses increased in order of shear, compressive, tensile, and volumetric elasticity. Across the elastic property tests, liners were designed to be strained to the anticipated extremes seen in clinical use[11]. To create a metric that was applicable to the greatest number of patients, liners were quantified with a single value (tangent modulus) evaluated in the middle of the measured range.

The shear elasticity test was the most linear of these three material property tests, with a consistent tangent modulus from 20–60% strain [Figure 2.2]. The non-linear toe region (from 0–20% strain) showed an inconsistent viscoelastic material response as the MTM accelerated to the test rate of 150% strain per second[11]. In the linear region that constituted the liners' primary material response (from 20–60% strain), TPE liners had a mean stiffness of 23 ± 7 kPa, polyurethane liners had a stiffness of 61 ± 2 kPa, and silicone liners had a stiffness of 68 ± 16 kPa. For the shear elasticity test, little difference was seen between liners with different fabric backings. For example, shear moduli of 26, 26, and 28 kPa were measured across one manufacturer's liners that used the same base elastomer with three distinct backings.

For the compressive elasticity test, the tangent modulus was measured between 10–40% strain [Figure 2.3]. Above 40% strain, the stiffness became non-linear as a response of both the elastomer and fabric backing. TPE liners had a mean stiffness of 132 ± 28 kPa, polyurethane liners had a stiffness of 307 ± 32 kPa, and silicone liners had a stiffness of 300 ± 89 kPa. For the tensile elasticity test, the tangent modulus was defined between 10–40% strain if the liner achieved less than 250 kPa true stress at 60% strain [Figure 2.4]. If a liner reached 250 kPa before 60% strain, then the linear region was defined from 100–250 kPa. The explanation for different linear regions corresponds to primary load transmission shifting from the elastomer to the fabric backing as the stiffness of the fabric backing increased. Tangent moduli in these linear regions were 750 ± 765 kPa for TPE liners, 166 ± 38 kPa for polyurethane liners, and 454 ± 833 kPa for silicone liners.

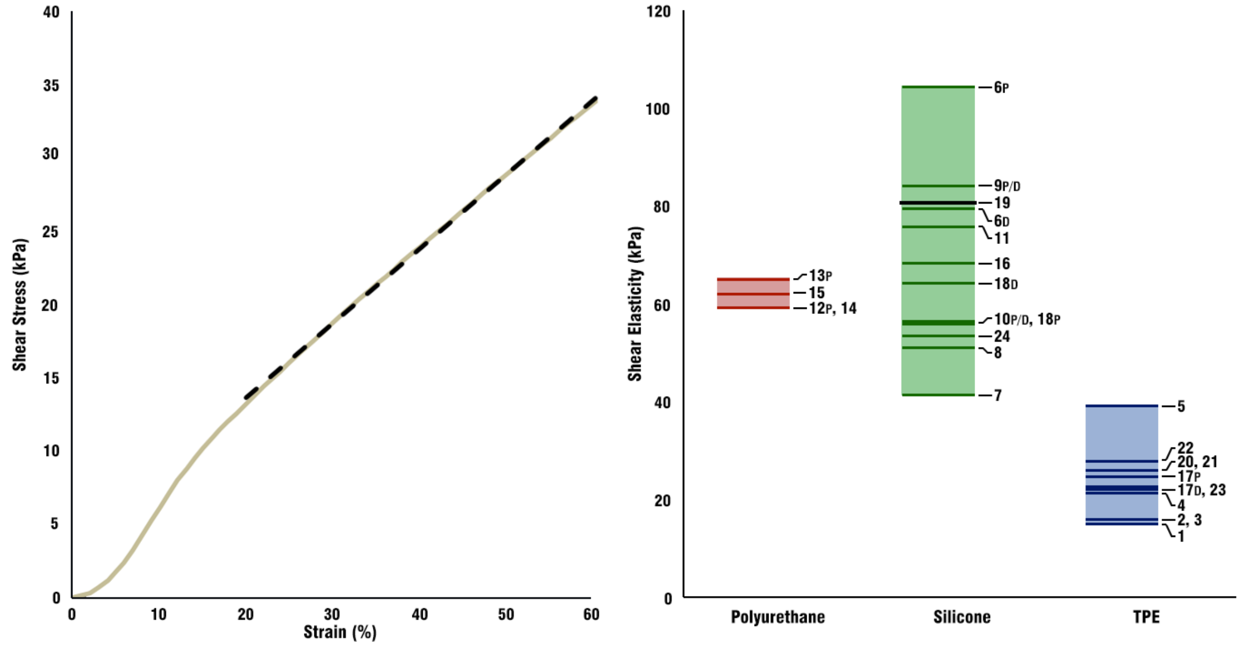

Figure 2.2: Shear elasticity by liner product. Shear elasticity was defined by the tangent modulus from 20–60% strain (left). TPE liner products had the lowest shear elasticity, indicating that TPEs were the softest elastomers of the measured liner products (right).

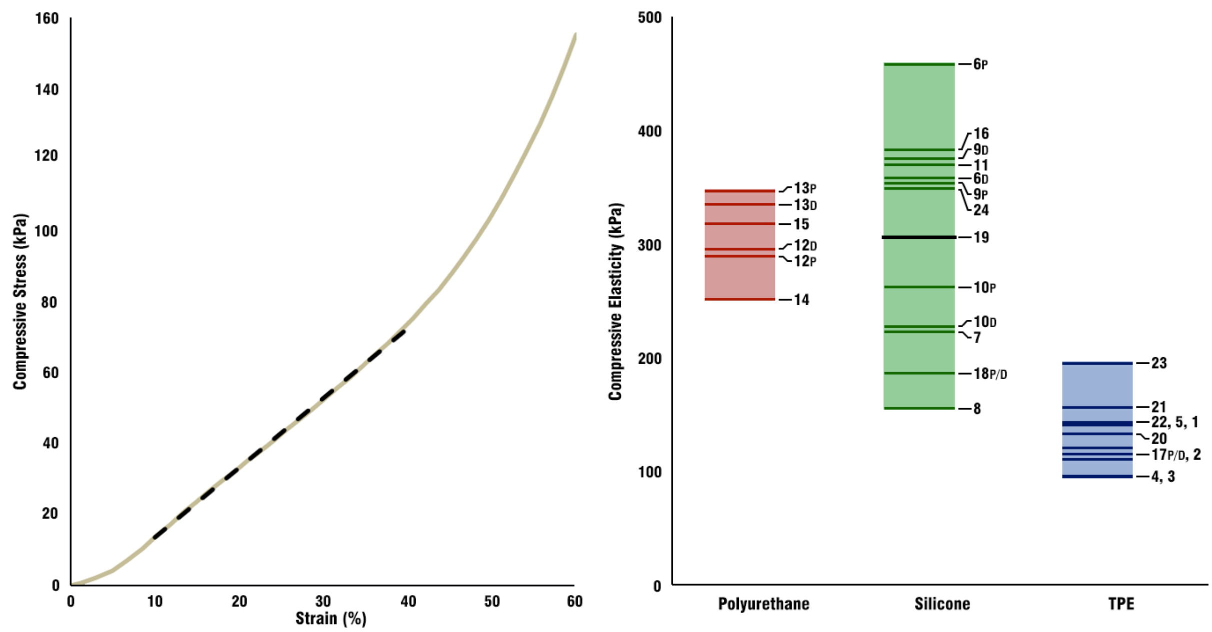

Figure 2.3: Compressive elasticity by liner product. Compressive elasticity was defined by the tangent modulus from 10–40% strain (left). Greater overlap was seen between the base materials compared to the shear elasticity test, indicating that the fabric backing could increase a liner's compressive stiffness (right).

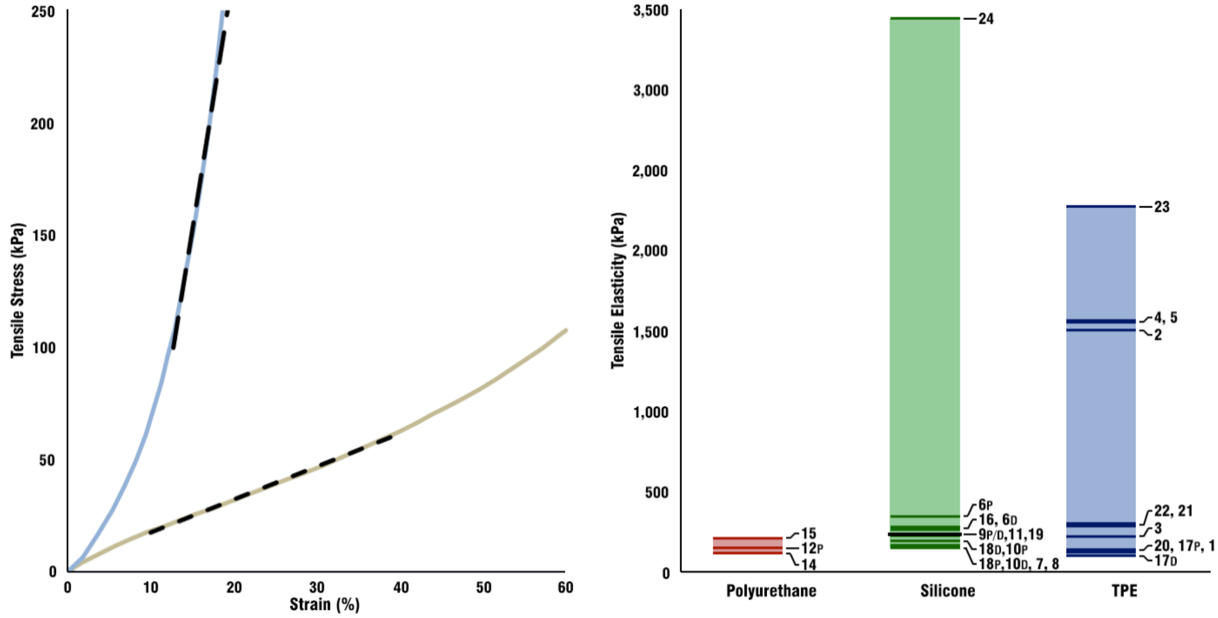

Figure 2.4: Tensile elasticity by liner product. Tensile elasticity was defined by the tangent modulus from 10–40% strain for most liners, but for very stiff liners the tangent modulus was defined from 100–250 kPa (left). The measured moduli showed the greatest overlap for the tensile elasticity test, indicating that the fabric backings made a significant contribution to a liner's stiffness (right).

A point of clinical interest might be how well the material test data can be applied to liner products of different elastomeric thickness (e.g., how does the data for a measured 6 mm liner compared to that of a prospective 3 mm liner). This can be answered to some extent by looking at the five liner products with tapered thickness profiles (no. 6, 9, 10, 17, and 18). Four of the liner products had a consistent fabric profile from proximal to distal end, while one product (no.6) had a second, inner layer of fabric that made proximal-distal specimens inconsistent.

For the five liners with comparable proximal and distal specimens, the mean change in stiffness was 2.65 kPa for the shear elasticity test, 15.5 kPa for the compressive elasticity test, and 22.0 kPa for the tensile elasticity test. This compared to a total stiffness range of 89 kPa for shear elasticity, 362 kPa for compressive elasticity, and 3,326 kPa for tensile elasticity. Therefore, while the change in stiffness against different specimen thickness was not insignificant, it was relatively small compared to the total change seen across the range of liner products.

Another point of clinical interest might be the contribution of fabric backings, and if they are able to increase tensile elasticity (as claimed by some manufacturers). Results showed that fabric backings can be selectively used to substantially increase a liner's tensile elasticity (>200%), and this can have secondary effects of increasing a liner's compressive elasticity (<50%). Only one liner product evaluated had fabric backed and non-fabric backed variations (no. 14 and 15). However, there were two other groups of liner products that used a single base elastomer with the option for one of several fabric backings (liner no. 2 and 3, as well as liner no. 20–22). Within these two groups, the range in shear elasticity (elastomeric stiffness) was 1.9 kPa, while the range in tensile elasticity was 1,390. Even more striking was a group of three TPE liner from the same manufacturer, no. 20, 21, and 23 [Figure 2.5]. Within this group, the range in shear elasticity was 4 kPa while the range in tensile elasticity was 2,130 kPa.

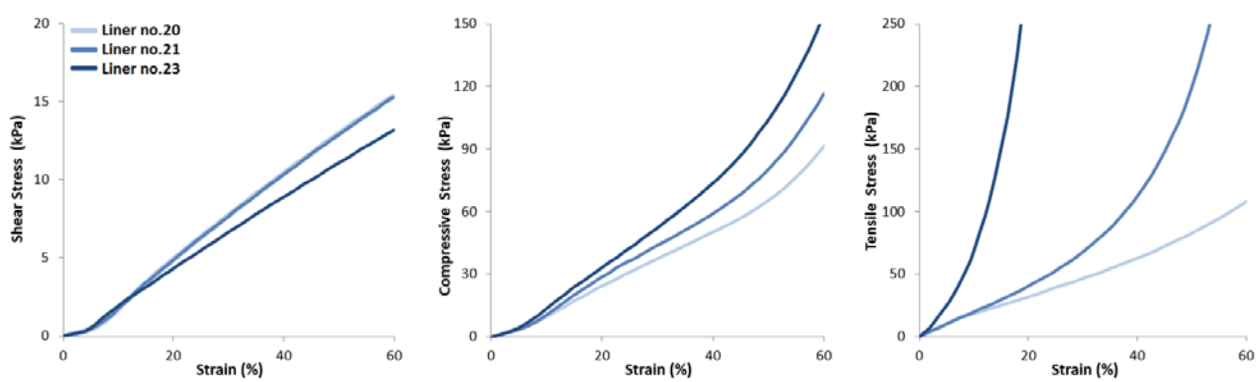

Figure 2.5: Contribution of the fabric backing. Results from three TPE liners from the same manufacturer demonstrate how increasing stiffness of the fabric backing correspondingly increases the liner's response in compression and tension.

2.4.2 *Volumetric Elasticity*

The volumetric elasticity test exhibited the greatest stiffness of the material property tests and had generally small variability with the exception of three liner products with a common base silicone elastomer [Figure 2.6]. Similar to the compressive, shear, and tensile elasticity tests, volumetric elasticity was quantified in the linear region of the stress-strain curve. However, the incompressible nature of elastomers meant that the linear region occurred at very low strains (1–5%) and this corresponded to a stress range of 200–500 kPa. While the stresses are outside the range of normal use, no other single-value metric could be used to quantify the results. Tangent moduli in the linear regions were 111,000 ± 25,000 kPa for TPE liners, 146,000 ± 39,000 kPa for polyurethane liners, and 86,000 ± 62,000 kPa for silicone liners. The magnitude of the values indicates that little performance difference is anticipated within the current selection of prosthetic liners.

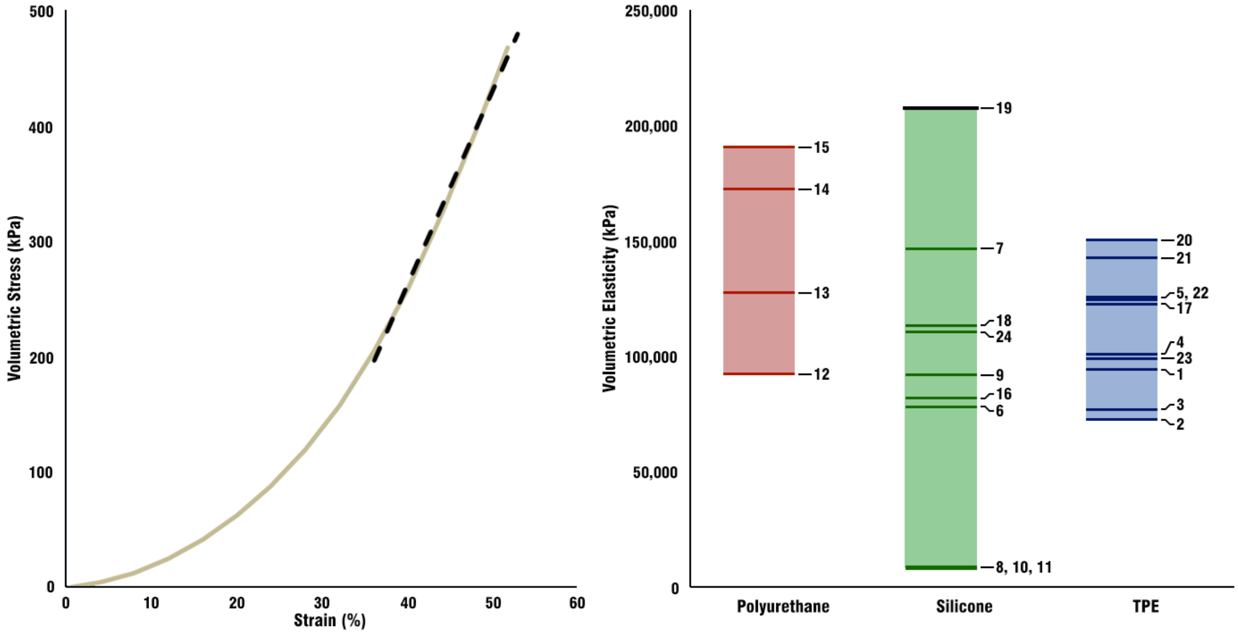

Figure 2.6: Volumetric elasticity by liner product. Volumetric elasticity was defined by the tangent modulus from 200–500 kPa (left). While there was a broad range in measured volumetric elasticities, even the lowest values were sufficient to produce a functionally incompressible material response (right).

2.4.3 *Coefficient of Friction*

The CoF results exhibited the greatest variety in elastomeric contribution across the six material property tests [Figure 2.7a], with the most adherent liners having a coefficient six times greater than the least adherent liners. Polyurethane had the most consistent response and the lowest range of dynamic CoF, 0.4–0.7. Silicone liners ranged from 1.4–3.1 while TPE liners ranged from 0.8 to greater than 3. The dynamic CoF could not be measured for all TPE liners, because several had static CoFs that were approaching the load limit of the instrument's load cell.

2.4.4 *Thermal Conductivity*

Thermal conductivity showed the least variability of the six material properties [Figure 2.7b], with the most conductive liners transmitting only 60% more heat than the most insulating.

Thermal conductivity of polyurethane liners ranged from 0.14–0.17 W/m·K, silicone liners ranged from 0.12–0.18 W/m·K, and TPE liners ranged from 0.12–0.14 W/m·K.

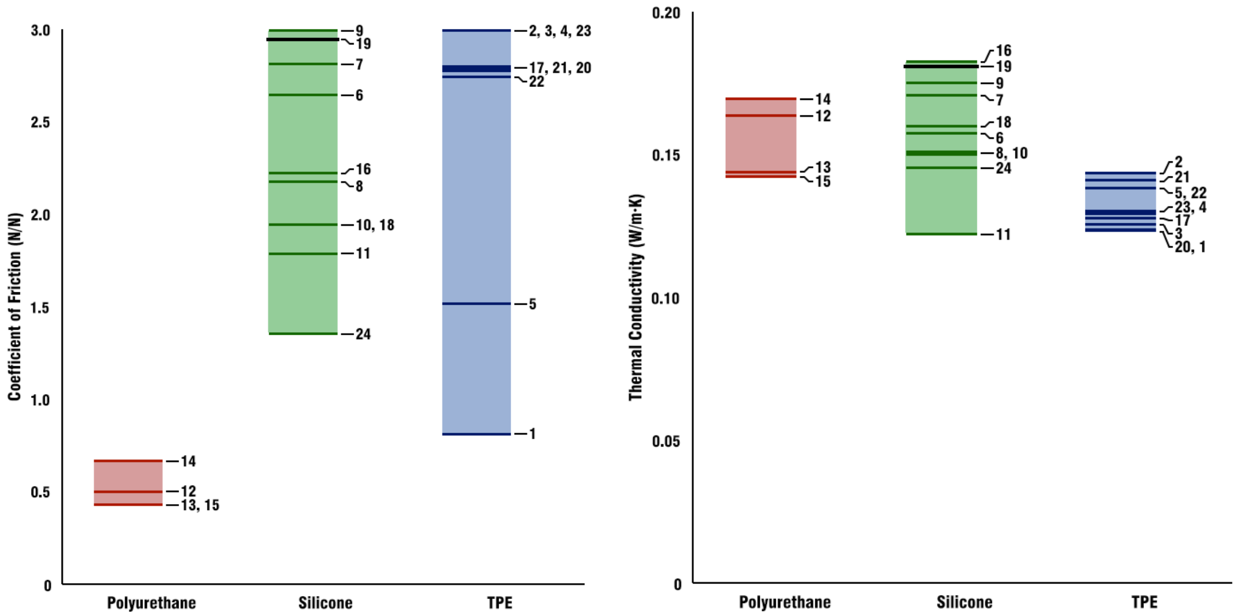

Figure 2.7: Coefficient of friction and thermal conductivity by liner product. CoF was the lowest for polyurethane liners while silicone and TPE liners varied (left). Thermal conductivity showed the least variability of the material properties; the most conductive liner transmitted just 60% more heat than the most insulating liner (right).

2.5 Discussion

Twenty-four liner products were evaluated across six material property tests. Single value quantifications have been obtained for each test to enable an objective comparison between liner products. Beyond the comparison of liner products, results from the compressive, shear, and tensile elasticity tests can offer insight into the contributions of the elastomer and fabric backing. Additionally, the isolated elastomeric response can be used to assess performance advantages between the three base elastomeric materials. These evaluations may offer insight into clinical assumptions and performance gaps in current liner products.

The term “flow” is commonly used in the prosthetics industry to describe an elastomeric liner’s ability to spread and distribute focused pressures. This concept is true when Pelite liners are compared to elastomeric liners. Pelite is a polyethylene foam, and most foams do not expand when compressed[28]. Elastomers are typically incompressible and will expand when compressed to maintain a constant volume (e.g., the more an elastomer is compressed from its initial thickness, the more it will expand). In addition to the major differences between Pelite and elastomeric liners’ tendency to flow, it is generally accepted that there are differences between different base elastomers (e.g., TPE liners are thought to flow the most). This concept is partially true; the Poisson’s ratios seen in this study (0.493–0.499) indicate that all liner products tested are functionally incompressible and have an equivalent tendency to flow from a material perspective. A silicone liner will flow just as much as a TPE liner, so long as they have an equivalent compressive elasticity (liners no. 8 and 21 for example). However, differences between liner products are expected in a clinical environment, because a softer liner will tend to compress more under than same ambulatory stress, and this will result in a greater amount of flow.

It is often presumed that TPE liners are the softest of the three base liner materials, flowing more in compression and stretching more in tension. This concept is generally true with a few insights gained from the selective contribution of fabric backings. While TPE liners were measured as the softest liners in the compressive elasticity and shear elasticity tests, a liner’s tensile elasticity will depend on the stiffer material between the elastomer and fabric backing. For example, across all liner products TPEs were the softest elastomers as measured by the shear elasticity test. However, four of the five liner products with a tensile elasticity greater than 1,000 kPa were TPE based. This is because of stiff fabric backings that support the majority of transmitted tensile (stretch) loads.

It is typically believed that polyurethane liners are stiffer than silicone liners, however results showed that no definitive generalization can be made about the stiffness of polyurethane liners compared to silicone liners. A recent study noted that only one of twelve liner manufacturers use polyurethane, while silicone and TPE liner products are more prolific[9]. Because of the limited number of available polyurethane liners, the stiffness range is much narrower. Across the elastic material tests, polyurethane properties are roughly comparable to the median of the measured silicone liner range. It should also be noted that both silicone and polyurethane elastomers are chemically tailorable polymers, and in other industries both are used to create elastomers with a much wider range in stiffness than those used in prosthetics.

It is generally accepted that elastomeric liners are hot to wear because they are insulating, and this study confirmed previous findings. The measured range of thermal conductivities (0.12–0.18 W/m·K) was similar to Klute et al (0.11–0.27 W/m·K)[29], with prosthetic liner materials being even less conductive than commonly used thermal insulators (e.g., pure fiberglass is 1.0–1.5 W/m·K). While Pelite liners are equivalently poor conductors[29], elastomeric liners are in intimate contact with the residual limb while Pelite liners are form fit to a socket. The characteristic gap between the pelite liner and limb enables convection to cool the limb, while elastomeric liners are effectively limited to conductive heat transfer and warmer as a result.

2.6 Clinical Relevance

Patient goals are specific to an individual, and the optimization of one response (e.g., comfort) typically comes at the cost of another (e.g., stability). Therefore, it is generally not possible to find a single optimal liner that suits all patients. Instead, specific needs should be considered on a case-by-case basis. To facilitate a more comparative method of liner selection, data produced in this study were integrated into a free online tool called the Prosthetic Liner Assistant (www.LinerAssist.org). Material property test results (i.e., single value quantifications) from the current research have been added to a custom-sortable, visual database. This enables users to evaluate liners that are similar to an existing (patient's) liner, and find candidate liners that may improve on a feature deemed important by the patient or clinician. The underlying quantitative data used to build the Prosthetic Liner Assistant can be found in Appendix A.

2.7 Conclusions

Prosthetic liners are an increasingly popular component of a complete prosthesis. Results from this study can be used to offer clinical insight into the variability of liner products, and identify performance gaps that liner manufactures may use to guide the development of novel liner products. Future research should focus on identifying how these properties interact within a prosthesis, and if guidelines can be established as a starting point for liner recommendations based on patient and limb characteristics.

2.8 Acknowledgements

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2.10 APPENDIX A: SINGLE VALUE RESULTS FROM MATERIAL PROPERTY TESTS

Liner Code	Section Thickness *mm*	Compressive Elasticity *kPa*	Shear Elasticity *kPa*	Tensile Elasticity *kPa*	Volumetric Elasticity *kPa*	Poisson's Ratio *mm/mm*	Coefficient of Friction *N/N*	Thermal Conductivity *W/m·K*
1	4.00	141	15.2	124	94,700	0.4998	0.81	0.124
2	3.90	111	16.0	1,510	73,000	0.4997	>3.0	0.144
3	3.75	96	16.0	225	77,000	0.4998	>3.0	0.126
4	5.24	96	21.4	1,560	101,000	0.4998	>3.0	0.130
5	5.87	144	39.3	1,554	126,000	0.4998	1.52	0.139
6	3.12 (prox) 5.96 (dist)	458 (prox) 359 (dist)	104.6 (prox) 79.6 (dist)	353 (prox) 268 (dist)	78,300	0.4991	2.65	0.158
7	5.88	224	41.5	158	147,000	0.4997	2.82	0.171
8	6.19	156	51.2	154	8,360	0.4969	2.18	0.151
9	2.11 (prox) 3.81 (dist)	354 (prox) 375 (dist)	84.3 (prox) 84.2 (dist)	232 (prox) 244 (dist)	92,400	0.4993	3.07	0.175
10	2.92 (prox) 3.62 (dist)	263 (prox) 228 (dist)	56.7 (prox) 56.8 (dist)	194 (prox) 173 (dist)	8,785	0.4953	1.95	0.150
11	3.04	370	76.0	241	8,740	0.4929	1.79	0.122
12	2.79 (prox) 4.45 (dist)	290 (prox) 296 (dist)	59.3 (prox) n/a* (dist)	157 (prox) n/a* (dist)	92,600	0.4995	0.51	0.164
13	3.59 (prox) 5.15 (dist)	347 (prox) 336 (dist)	65.2 (prox) n/a* (dist)	n/a**	128,000	0.4996	0.44	0.145
14	4.56	252	59.3	124	173,000	0.4998	0.67	0.170
15	5.26	318	62.2	216	191,000	0.4997	0.44	0.143
16	3.15	384	68.5	286	82,500	0.4992	2.23	0.183
17	4.49 (prox) 6.57 (dist)	121 (prox) 116 (dist)	24.9 (prox) 22.8 (dist)	136 (prox) 110 (dist)	123,000	0.4998	2.80	0.128
18	2.99 (prox) 6.34 (dist)	186 (prox) 187 (dist)	56.1 (prox) 64.4 (dist)	170 (prox) 199 (dist)	113,500	0.4997	1.95	0.160
19	5.70	307	81.0	237	208,000	0.4998	2.95	0.181
20	6.84	134	26.2	145	151,000	0.4999	2.78	0.124
21	6.33	157	26.1	294	143,000	0.4998	2.79	0.141
22	6.39	144	28.0	309	125,000	0.4998	2.75	0.138
23	6.14	196	22.2	2,280	99,500	0.4997	>3.0	0.130
24	4.36	349	53.6	3,450	111,000	0.4995	1.36	0.146

*Liner has an anatomic thickness profile, which made it impossible to collect distal specimens of uniform thickness

** Fabric backing is present, but was not bonded to the elastomer above mid-patellar-tendon. Property is best approximated by liner no.12

Chapter 3. DEVELOPMENT OF A COMPUTATIONAL TOOL TO ASSESS THE TRANSTIBIAL LIMB-SOCKET INTERFACE

3.1 ABSTRACT

The purpose of this research was to create a transtibial finite element model of a contemporary prosthesis with novel simulation features that included two frictional interactions (limb-liner and liner-socket), an elastomeric liner, and complete socket geometry. To make the results more broadly applicable, MRI scans from three people with characteristic, transtibial limb shapes (ie, short-conical, long-conical, and cylindrical) were acquired. Each limb-socket model was evaluated with two load profiles to identify locations of focused stresses. The FEM identified five total locations where peak stresses matched locations of mechanically induced skin issues experienced by participants over the nine months prior to being scanned. The peak contact pressure across all simulations was 98 kPa and the maximum resultant shear stress was 50 kPa, showing reasonable agreement with reported interface stress measurements. Finally, the load distribution potential of a modern socket design (i.e. total surface bearing) was assessed to determine if an idealized socket with uniform interface stresses was practically achievable.

3.2 INTRODUCTION

People with major lower limb loss have a goal to meet or even exceed activity levels prior to amputation[1]. Achieving this goal is a challenge for every person with transtibial amputation, because the soft tissues of the residual limb are poorly suited to transmit ambulatory loads. Soft tissues are coupled to a rigid socket, and this often leads to mechanically induced skin breakdown[2, 3]. As a result, investigation of the limb-socket interface has been a focal point of numerous studies that have measured ambulatory loads[4-6], limb-socket displacement[7, 8] and stresses transmitted to the soft tissues of the residual limb[9-11].

In-socket measurements of skin contact stresses have proved challenging in prior studies. Precision three-axis load cells require holes to be drilled in the socket and require the fabrication of custom prostheses[9]. Low-profile sensors fit within the socket,[10, 11] but can frequently measure only pressure and at a reduced accuracy. As a complement to empirical measurements, finite element models (FEM) have been used to evaluate stresses that are physically impossible or too expensive to measure experimentally, such as internal stresses of the soft tissues[12, 13] or the effects of different socket stiffness[14, 15].

However, nearly all FEMs reported in the literature are based on an older socket design (patellar tendon bearing) with a foam (Pelite^{TM}) liner, if any liner is included[13-21]. Recent data suggests that only 18% of sockets in clinical practice are patellar tendon bearing[22], while the majority of modern socket designs seek to decrease peak pressures by better distributing loads throughout the socket. This is the key principle underlying the total surface bearing socket, which is intended to distribute a patient's weight as a uniform pressure over the entire residual limb. This design philosophy has been made possible by elastomeric (gel) liners, which are now a part of as many as 85% of clinical prostheses[22]. The most notable feature of elastomeric liners are their incompressible, non-linear material response[23], and tendency to expand or 'flow' under compressive stresses. This response is thought to directly contribute to the ability to distribute peak pressures between the limb and socket.

These changes in prosthesis design have brought a fundamental shift in the implementation of the prosthetic liner; a Pelite liner is in intimate contact with the socket wall while an elastomeric liner is in intimate contact with the residual limb. This is best evidenced by the use of prosthetic socks, which accommodate shape differences between the limb and socket[24, 25]. Prosthetic socks are worn between the limb and liner when using a Pelite liner, and between the liner and socket when using an elastomeric liner. This reflects a shift in the primary slipping interface from limb-liner to liner-socket, or potentially both. As a result, some of the fundamental assumptions made in previous FEMs are not valid for a modern prosthesis. For example, the socket geometry should not be omitted in favor of a fixed boundary condition applied to the outer nodes of the liner.

The goal of this research was to create a flexible FEM that captured the complete geometry of a modern transtibial limb-socket interaction. This model was designed to provide insight into common clinical issues, such as the difference between different liner products[26] and the effects of limb volume fluctuations[27]. For the current research a single clinical hypothesis will be tested: the ideal design of a total surface bearing socket is impossible for a transtibial prosthesis, because the forward position of the tibia will bias stresses to be greater on the anterior aspect of the limb.

3.3 METHODS

A FEM that simulated the coupling between a residual limb and prosthetic socket was designed and optimized to measure the interface between the skin and prosthetic liner. To make the model more broadly applicable, three participants were recruited for the study with distinct characteristic limb shapes (ie, short-conical, long-conical, and cylindrical). New prosthetic sockets were fabricated for each participant to standardize the liner interface to a 6 mm uniform profile, and to make the sockets compatible with magnetic resonance imaging (MRI).

3.3.1 *Socket Design and Imaging Method*

Two imaging methods were available, MRI and x-ray computed tomography (CT). MRI was selected because of the desire to obtain accurate geometries of load bearing soft tissues (e.g., the patellar tendon). The enhanced spatial resolution of CT imaging was less important, because one of the most important criteria for a stable limb-socket FEM is smooth geometric features[28].

Many materials used in a modern socket have magnetic susceptibility and produce artifacts (e.g., aluminum) or are incompatible and unsafe (e.g., steel) [29] with MRI scanning. Therefore, a custom socket was designed to provide MRI compatibility and optimize scan quality. To eliminate major imaging artifacts, all metallic components were removed for the study socket design and replaced with MRI-compatible alternatives. The locking-pin and umbrella required in a pin-and-lock suspension were omitted in favor of a sleeve type suspension, and a polymer socket base was designed using additive fabrication (Objet RGD840, Stratasys, Eden Prairie, Minnesota).

For the study sockets, all participants were converted to a single liner product with a 6 mm uniform profile. This profile was selected because one of the core goals of the FEM was to investigate the impact of different liner material properties, and more data exists for 6 mm liners than any other size [23]. Before a specific liner product could be selected, the MRI visibility for elastomeric liner products had to be evaluated. While there are over 70 prosthetic liners available[26], each product is typically made from one of three base polymers: silicone, urethane, or thermoplastic elastomer (TPE) [30]. In a preliminary search, a selection of five candidate liner products of a uniform thickness profile were evaluated [Table 3.1], and all but the polyurethane liner produced a visible MRI signature [Figure 3.1]. For their study socket, all participants were converted to a single liner product (Dermo, Össur, Reykjavik, Iceland) of a 6 mm uniform profile. This liner product was selected because it has a true uniform profile (anterior and posterior), is commonly used by people with transtibial amputation[26], and had material properties comparable with other common liner products [23]. Further, the Dermo liner had a distal gel-thickness (14.3 mm) that was similar to other common liner products that were not available in a 6 mm uniform profile. The use of a cushion liner meant that the size and rigidity of the liners' polymeric distal caps did not need to be considered.

Table 3.1: Candidate liner products evaluated for MRI signal strength

Liner	Manufacturer	Product	Elastomer
1	Otto Bock	6Y75	Silicone
2	Otto Bock	6Y520	Urethane
3	Össur	Dermo	Silicone
4	Alps	WinterGel	TPE
5	Alps	General Purpose	TPE

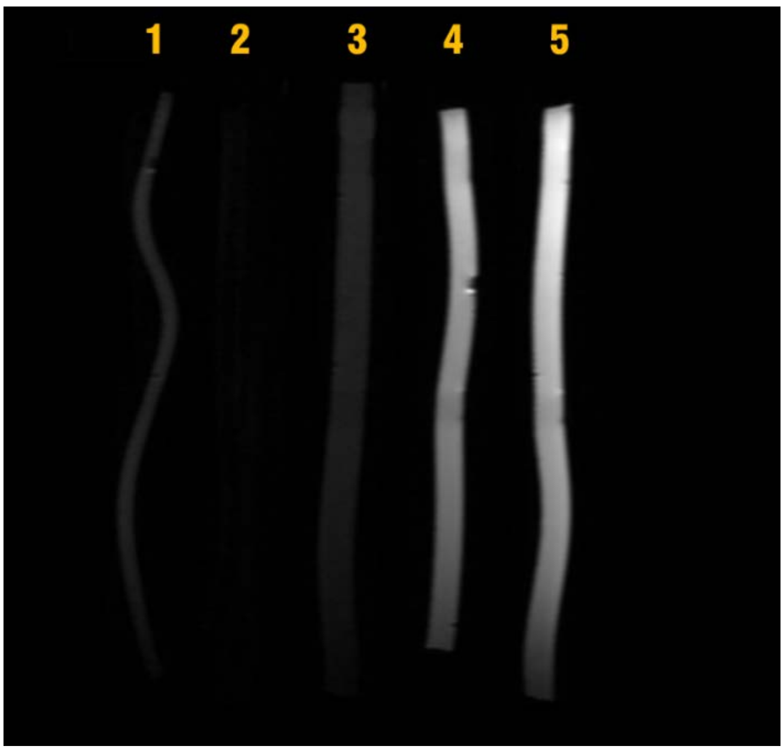

Figure 3.1: MRI signal strength of prosthetic liners. TPE liners showed the greatest signal strength, while the polyurethane liner was nearly invisible.

Modern prosthetic sockets are typically woven composites laminated with carbon fiber, a material that is partially incompatible with MRI. While recent studies have shown that carbon fiber implants produce minimal artifacts[31], this is because carbon fiber demonstrates significant radio frequency shielding that inhibits the stimulus and receive signals of an MRI scanner[32].

Therefore, a limb inside a carbon fiber socket would produce virtually no image.

Study sockets were fabricated with an epoxy-acrylic resin (EAR1, Paceline, Matthews, North Carolina) and weave made from a polymeric fiber (Synthex™, Fabtech Systems, Everett, Washington). Preliminary MRI scans showed the laminate had no RF shielding properties but was invisible to MRI. In an effort to make the sockets visible, several additives were mixed with the resin during lamination; gadolinium (III) chloride, mineral oil, polyethylene (powder), and Triton X-100. Each additive contained long alkane chains that are similar to those found in lipids and fatty acids, as targeted by the scanning profile selected for the limb-socket imaging. However, no additive tested was able to produce a MRI signature without significantly degrading the quality of the composite. For the study images [Figure 3.2], the socket was identified as a negative space (similar to cortical bone) existing between the prosthetic liner and suspension sleeve. To identify the inner socket wall in the distal gap between the liner and socket, the bottom of the socket was coated in a layer of ultrasound coupling gel (Aquasonic 100, Parker Labs Inc, Fairfield, New Jersey) that produced a strong MR signature.

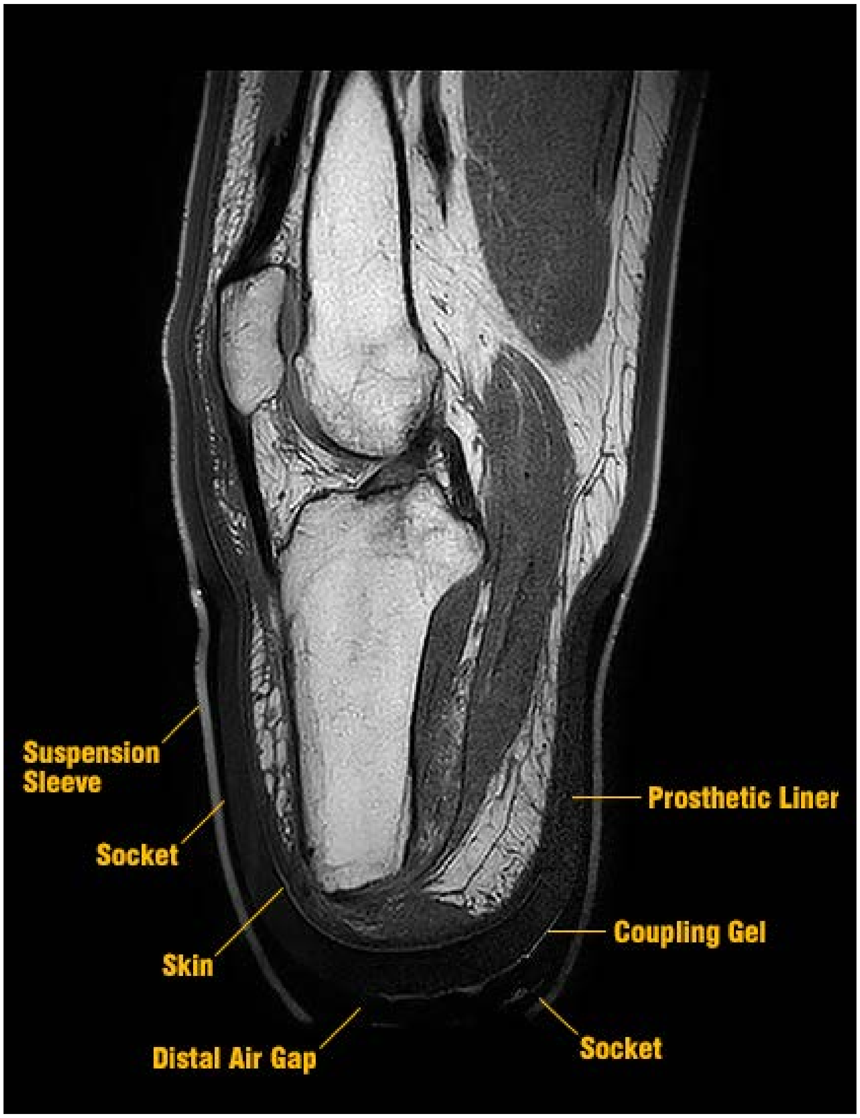

Figure 3.2: Study MRI image. The socket, distal air gap, and skin are not visible, these features were identified by contact edges with the prosthetic liner, suspension sleeve, and coupling gel.

3.3.2 *Participant Recruitment and Limb-Socket Imaging*

Three people with transtibial amputation were recruited, with characteristic limb shapes identified as short-conical, long-conical, and cylindrical. Three sessions were needed to capture each participant's limb-socket geometry: (1) collect participant metrics, (2) fit candidate study sockets to determine the final study socket, and (3) image participant with the final study socket. A research prosthetist performed a socket fit or assessed socket fit in every session; it was therefore important to have an early and consistent start time across all sessions to account for daily limb volume fluctuations[33, 27]. Participants were included in the study if they (a) had no orthopedic bolts or plates below the waist. If any bolts or plates were present above the waist, then the material was verified to be MRI compatible (e.g., titanium), (b) normally wore an elastomeric liner with a uniform thickness profile (e.g., 3 mm or 6 mm), (c) needed less than 1.8 mm (~5 ply) of prosthetic socks to achieve a comfortable fit in their prescribed prosthesis, and (d) were at least 24 months' post amputation.

The first session was used to collect a description of participants' as-prescribed prosthesis, and included five groups of data. (1) Participants' liner product and size in their as-prescribed prosthesis as well as (2) the thickness of prosthetic socks required to achieve a comfortable fit[36]. (3) To estimate the donned thickness (including stretch) of participants' as-prescribed prosthetic liner, limb circumferences were measured at the mid patellar tendon (MPT) and distal tibia (DT) of the bare limb and limb with liner donned. (4) To create a base shape for the candidate study sockets, the prescribed sockets were captured using a coordinate measuring machine (Platinum Arm, Faro Technologies, Lake Mary, Florida) [37]. (5) a Prosthesis Evaluation Questionnaire (PEQ) [34] and Socket Comfort Score(SCS) [35] were completed for participants' as-prescribed prosthesis to establish a point of comparison for the study sockets.

The prescribed socket was modified for the study socket to include a 6 mm uniform liner and to create a fit characterized by a comfortable fit with no sock required. The geometry for the study sockets was defined as a surface-normal, uniform offset to the participants' prescribed prosthesis[38] that accounted for the removal of prosthetic socks, the thinning of the prosthetic liner as it was stretched during the donning process, and any change in thickness between their prescribed liner and the selected study liner. The number of variables made it impossible to accurately predict a single offset that would result in a well-fitting socket. Therefore, two sockets were fabricated for the second session with uniform offsets determined by:

Socket A: The mean difference between the change in effective radii of the MPT and DT

Socket B: The thickness assessed by a research prosthetist as appropriate

During the second session the study liner and sockets were fit to the participants, with the research prosthetist blinded to the individual socket sizes. Sockets were fit on a fitting stool with a long and slender probe to check for gaps between the limb and socket, following the same method used in clinical practice to evaluate fit of prosthetic check sockets. A socket was considered appropriately fit if no gaps were present and if the participants answered “yes” when queried if they would feel comfortable wearing the socket for an entire day. If one of the sockets was appropriately fit without the use of socks, it was declared the final study socket and the participant proceeded to the third session for imaging. If neither could be appropriately fit without the use of socks, one or two additional sockets were fabricated using the fit data from the first group of study sockets and the second session was repeated on a different day.

For the third session, the selected participants were imaged with the final study socket. Immediately before scanning, participants donned the socket on a fitting stool without the use of socks. Participants were asked if they would feel comfortable wearing the final socket for an entire day, and then filled out PEQ-Utility and SCS questionnaires. It is important to note that PEQ requests the participants to reflect on the quality of their prosthesis over the previous two to four weeks, while study sockets had only been donned for a few minutes. The objective was to establish that the final study socket fit was a plausible representation of the fit achieved with the participants’ as-prescribed socket.

Geometries of the residual limb, prosthetic liner, and socket were then imaged with a 3.0 tesla MRI scanner (Ingenia CX, Phillips Healthcare, Andover, Maine). Three image series were acquired for each participant: socket doffed, socket partially donned, and socket fully donned. A partially donned state was achieved by participants bearing approximately half of their weight on the fitting stool, and answering “no” when asked if they felt their socket was fully donned. A fully donned state was achieved by participants bearing all of their body weight on the fitting stool, and answering “yes” when asked if they felt their socket was fully donned. After participants achieved the desired fit, the suspension sleeve was rolled on in a manner that best preserved the current socket state. Participants were then moved to a supine position on the scanning bed with their socket braced to achieve a knee angle of 10–15°, similar to the weight acceptance portion of stance phase (9–12°) reported for trans-tibial amputees[39].

3.3.3 *FEM Creation*

Geometries for the FEM were taken from the partially donned imaging series, because it represented the best approximation of the two non-linear materials present in the limb-socket interface: the prosthetic liner and soft tissues. Soft tissues (e.g., dermis) present a two-stage non-linear response, with a small and linear initial modulus (~5 kPa) [40] until an age dependent strain limit (30–60%) [41], after which the stiffness becomes non-linear with tangent moduli as high as 30 MPa. This two-stage material response is not possible to simulate using any standard material model. A prosthetic liner has a non-linear material response that has been characterized over the applicable range of normal prosthetic use [23] and can be adequately represented with a hyperelastic material model. The partially donned state provided the best balance of allowing the soft tissues to deform in the low-modulus region to fit the general socket shape while also limiting pre-stresses on the prosthetic liner. Therefore, a FEM created from a socket doffed image series would provide too stiff a soft tissue response as the limb deformed to fit the socket, while a FEM created from a fully donned image series would omit meaningful stresses from regions where the liner was compressed locally [Figure 3.3].

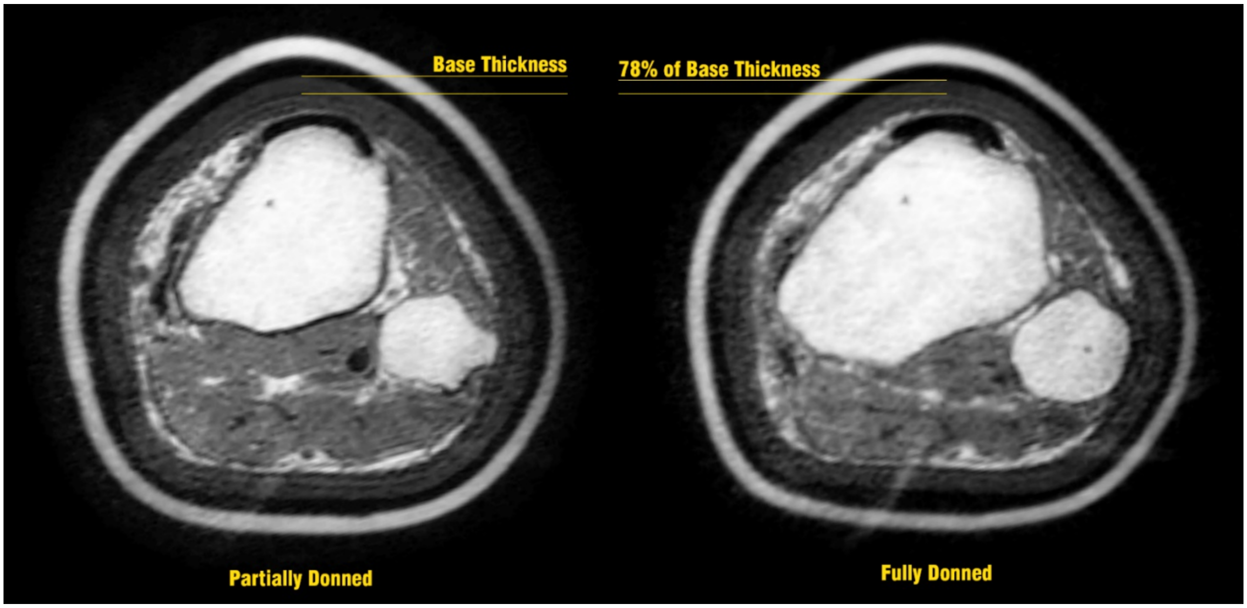

Figure 3.3: FEM source scan. The partially donned state was selected for the source geometry rather than the fully donned state, because the liner compressed locally inside the socket in a manner that could not be corrected in the FEM.

Building the FEMs was a four-step process. Slice images were imported into a parametric modeling program (Inventor 2016, Autodesk, San Rafael, CA), and fit with bounding splines [Figure 3.4]. Spline profiles were then imported into a 3D scan data processor (Geomagic Design X, 3D Systems, Rock Hill, South Carolina) to be lofted and smoothed. Limb-socket assemblies were meshed in a pre-processor (Hyperworks 14, Altair Engineering, Troy, Michigan) [Figure 3.5] and then imported into the FEM simulation software (Abaqus 6.16, Dassault Systèmes, Vèlizy-Villacoublay, France).

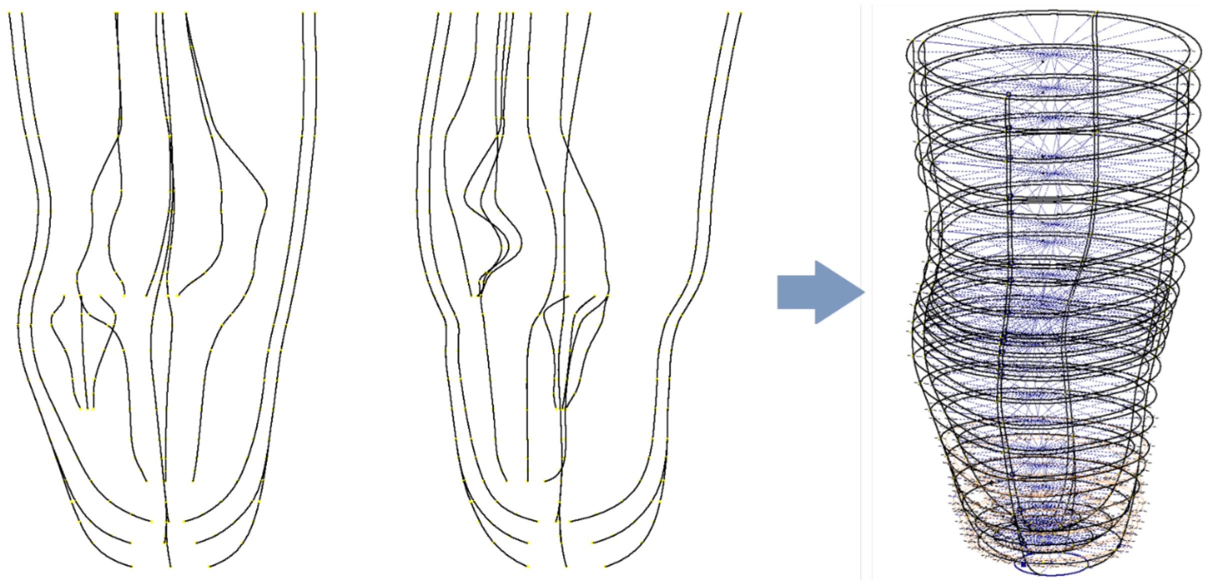

Figure 3.4: Splined limb-socket geometry. Proximal-distal guide splines were created first (left), followed by transverse bounding splines (right)

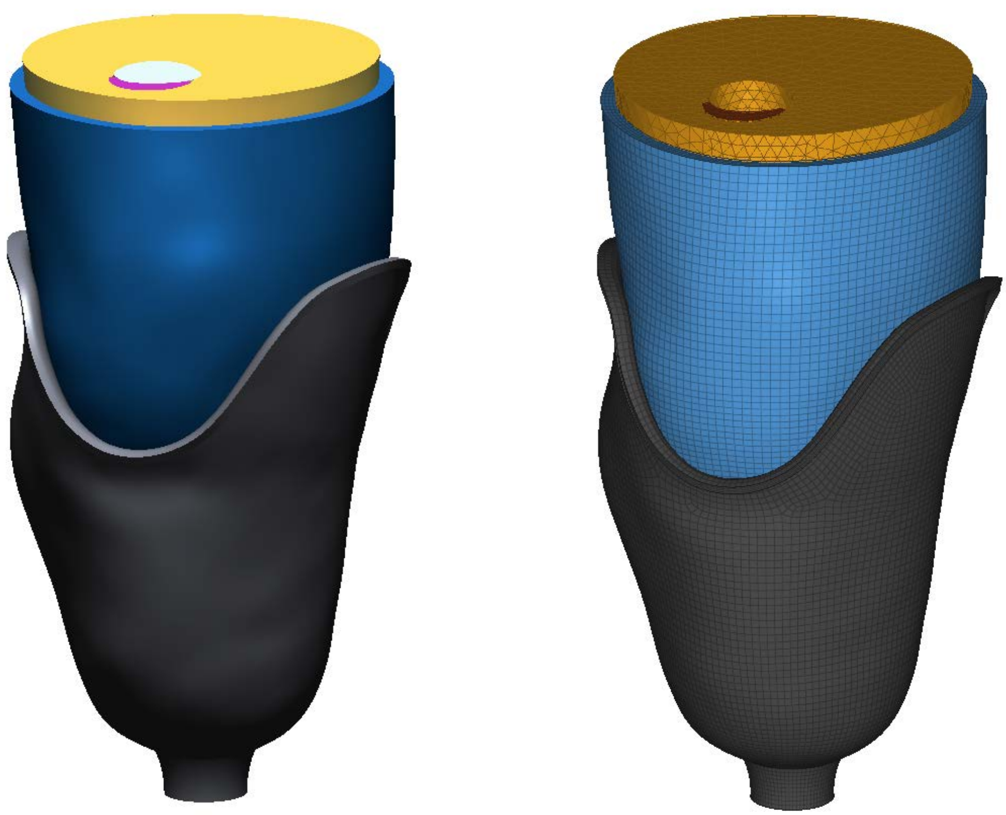

Figure 3.5: Meshed limb-socket geometry. Socket assemblies were lofted and smoothed in Geomagic Design X (left), meshed in Hypermesh (right), and then imported into Abaqus for simulation.

The design focus for the FEM was the ability to assess the skin-liner interface in a variety of loading scenarios. Of particular note was two major frictional contact interactions were present, the skin-liner(elastomer) and socket-liner(fabric) interfaces. Simulating both contacts as frictional was a novel feature that was also a core requirement to appropriately model a modern prosthesis. The skin-liner(elastomer) interface was of greatest interest, but values reported for the coefficient of friction (CoF) [42] indicated that slipping would be biased towards the socket-liner(fabric) interface. To optimize the FEM for soft tissue contact interfaces[43], reduced integration 8-node hexahedral elements were used to mesh the socket (type C3D8R) and liner (type C3D8RH), with the liner elements also having a hybrid formulation that better emulated incompressibility. Both the socket and liner were meshed with four elements through the thickness to overcome issues with reduced shear stress distribution and artificial increases in bending stiffness associated with 8-node hexahedral elements. Two groups of soft tissues were modeled, the patellar tendon and accumulated (remaining) soft tissues. A preliminary model showed that it was not possible to further segregate the tissues without introducing significant convergence problems. For the same reason, solid bone models were omitted and the soft tissue-bone attachment was implemented as a fixed boundary condition. All soft tissues were modeled with modified 10-node tetrahedral elements (type C3D10M). Nodal spacing at the contact surfaces was approximately 2.5 mm (e.g., the length of an element with mid-side nodes was 5 mm); this was found to be the best compromise between element shape quality and geometric accuracy.

3.3.4 *FEM Parameter Optimization*

The cylindrical limb-socket model was used to evaluate key parameters associated with convergence stability. The parallel loading surfaces on the anterior and posterior aspects were predicted to be least conducive to distributed load profiles and therefore the most challenging to simulate. From these evaluations the following simulation parameters were defined.

The Abaqus General Contact algorithm was used, but the only active contacts were the skin-liner and liner-socket pairs. Both the General Contact (default) and Contact Pair (individual) algorithms decreased stability and increased solution time, and no change was seen in the simulation results.

Separate CoF's were used for the skin-liner and liner-socket interface. CoFs greater than 3.0 have been reported in amputee[42] and benchtop measurements[23], however, the FEM would only converge with a maximum CoF of 2.0. A set of preliminary simulations evaluated two liner elasticities, the softest and stiffest measured[23], with CoF's of 0.5, 1.0, 1.5, 2.0, and infinite (bonded) for the skin-liner interface. Results showed that a CoF of 2.0 approximated a bonded contact, with converging stress, strain, and slipping [Figure 3.6]. This indicated a simulated CoF of 2.0 was a suitable representation for any liner with a CoF greater than 2.0.

A hyperelastic material model was used for the prosthetic liner, with the material coefficients determined by a standalone application (Hyperfit, Brno University, Brno, Czech Republic). Preliminary simulations showed that Mooney-Rivlin and Yeoh constitutive models demonstrated the best combination of stability and accuracy. For the study liner product, the root mean square error of the model fit was 0.4 kPa for Mooney-Rivlin and 0.2 kPa for Yeoh in compression, and 2.1 kPa for Mooney-Rivlin and 2.1 kPa for Yeoh in tension. For all simulations the study liner was modeled with the Yeoh constitutive model [Table 3.2].

When performing a simulation of an incompressible material, FEM solvers typically recommend a maximum Poisson's ratio of 0.495. Historical limb-socket models have recommended values of 0.45[28] to 0.49[44]. For a hyperelastic material model the Poisson's ratio is not set directly, instead the coefficient D1 is used, which is inversely related to the material's

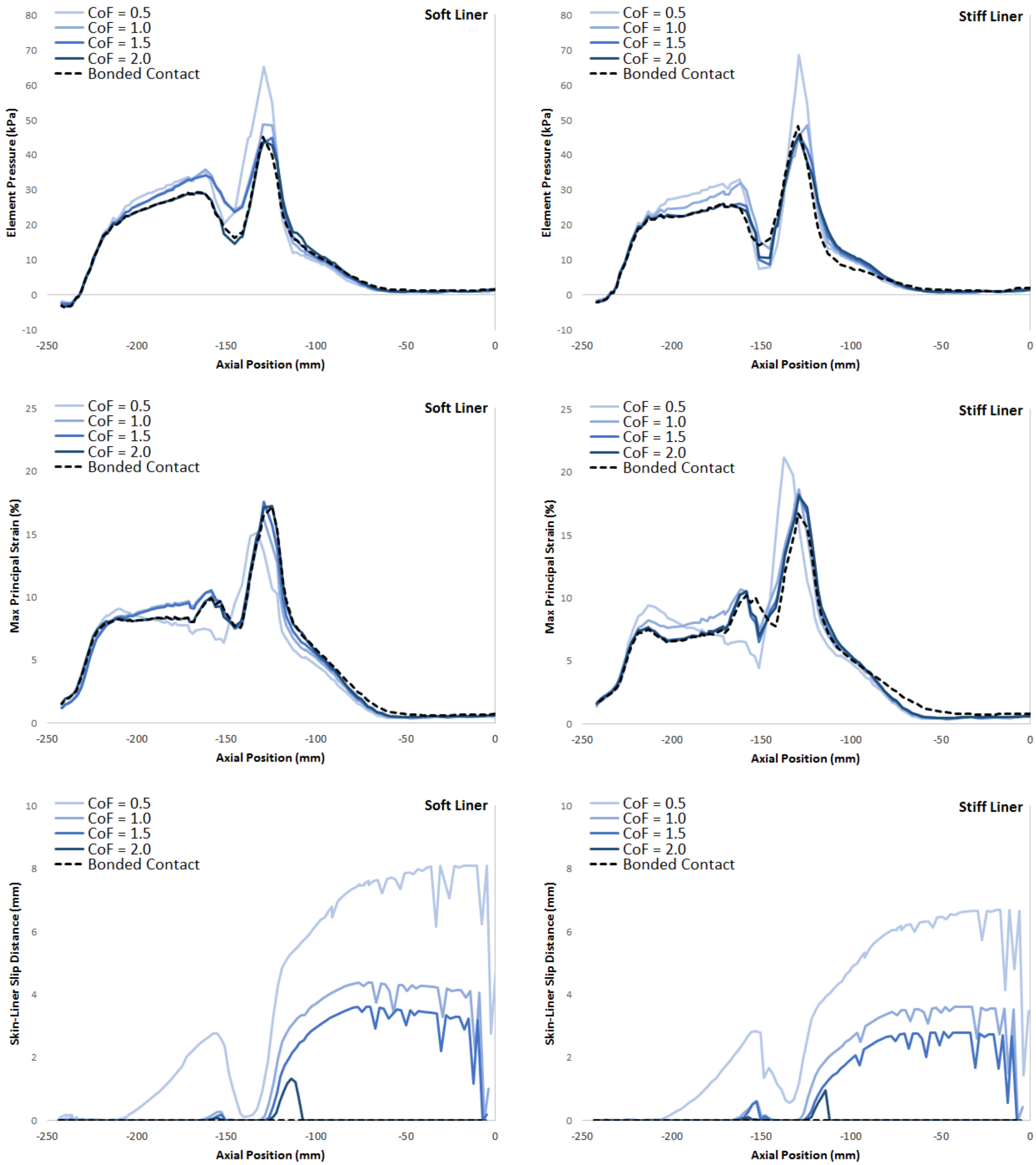

Figure 3.6: FEM – effects of coefficient of friction. Slipping between the skin and liner became minimal as the CoF reached 2.0.

bulk modulus. To simulate material incompressibility of the prosthetic liner, D1 was set to 3.0e-06, which approximates a Poisson's ratio of 0.48. The selected value provided the best convergence stability with the closest possible representation of material incompressibility.

Table 3.2: Hyperelastic coefficients for the prosthetic liner

Yeoh Coefficients	
Össur Dermo	
C10	2.014E+04
C20	-1.541E+03
C30	4.094E+02
D1	3.00E-06

It was not possible to simulate the soft tissues with a hyperelastic material model because of convergence stability. Instead, a linear modulus was selected based on historical studies of the dermis [40, 41]. Interpreting data from soft tissue compression over the anteromedial aspect of the tibia [Figure 3.7], suggests an estimated stiffness range of 150–220 kPa. This study and value was of particular interest, because stiffness is dependent on applied load and 50 kPa is a common magnitude of stress exerted on residual limbs[9, 10]. A more recent study measured a soft tissue stiffness of 300–350 kPa over the anterior tibia, with applied pressures as high as 600 kPa [19]. Model stability was evaluated at these four stiffness values; 300 kPa and 350 kPa were found to be significantly more stable than 150 or 220 kPa. Therefore, the accumulated soft tissues were simulated with a modulus of 300 kPa and a Poisson's ratio of 0.45 across all simulations.

The stiffness of the patellar tendon has been reported as low as 260 kPa[45] and as high as 2.0 GPa[46]. The differences in reported values are likely due to differences in testing methods interacting with the orthotropic material composition of the tendon. In-vivo measurements of a relaxed tendon in out-of-plane compression[45] would be expected to produce a significantly lower modulus than an ex-vivo in-plane tensile measurement[46]. Since the quadriceps are active during stance phase and the patellar tendon was anticipated to be under tension, a stiffness of 150 MPa was selected as a compromise between the reported values.

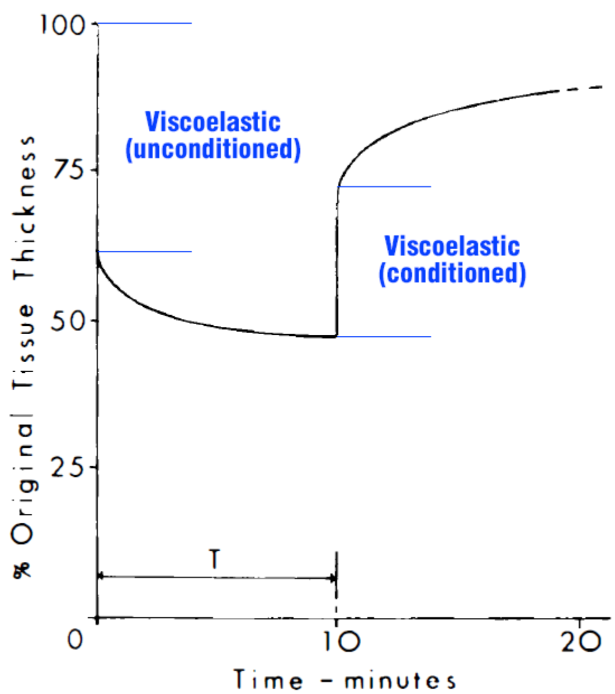

Figure 3.7: Estimated soft tissue elasticity. Adapted from Daly (1982). The approximate soft tissue modulus including viscoelastic effects can be estimated from the initial compression and recovery of a 50 kPa load.

Carbon fiber was modeled as a linear elastic material with a stiffness of 19 GPa and a Poisson's ratio of 0.1, a manufacturer reported value for the ±45° woven fabric matching the type and orientation of carbon fiber used in prosthetic sockets[47].

3.3.5 *FEM Validation*

Once parameters had been set, all three limb-socket models were evaluated with two loading profiles to ensure that observed trends were consistent across multiple inputs. Loads were applied distally, and no constraints were placed on the sockets' resulting displacements or rotations. The first loading profile (uniaxial) was a vertical load equal to 110% of the participants' body weight.

A vertical load was chosen, because it most closely represented the loads applied to the study sockets as they were being fit by the prosthetist and assessed by the participants. The magnitude was selected because it matched reported peak ground reaction forces that encompassed stable and unstable ambulators [5]. The second loading profile (compound) contained a vertical load, shear load, and sagittal moment that simulated heel-strike to first peak of stance phase [Figure 3.8]. This load profile was adapted from a measurement by Neumann (2013) that used a pylon mounted, six-axis load cell to estimate socket stresses [48]. The selected profile was compared to 16 data sets that contained three axis (or greater) load measurements at the first peak of the gait cycle [48, 6, 49, 50] and found to be a median representation of reported ambulatory loads[Figure 3.9].

Once the FEM outputs were shown to be consistent under multiple loading conditions, the results were compared to incidences of mechanical issues of skin-breakdown experienced by participants over the nine months prior to imaging. The etiology of each instance was assessed by a research prosthetist to verify it was mechanically induced. Accuracy of the FEM was assessed by comparing locations of skin-breakdown to locations of high pressure and shear stresses across both load profiles.

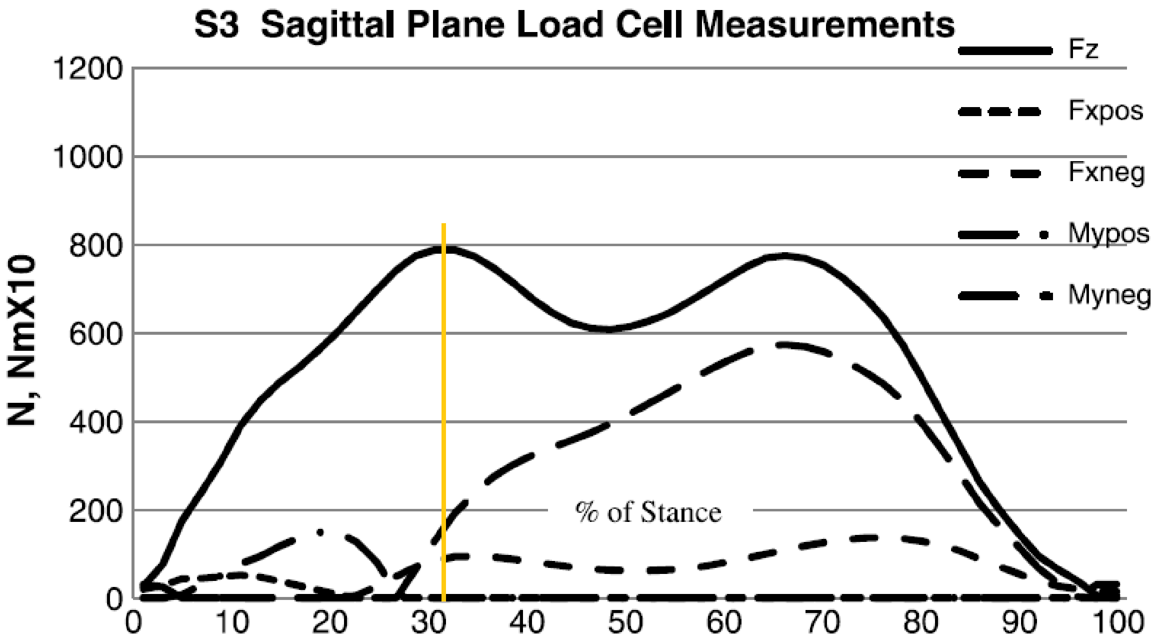

Figure 3.8: FEM – Compound load profile. Adapted from Neumann (2013). The compound load profile began at heel-strike (0% of stance), and ended at first peak.

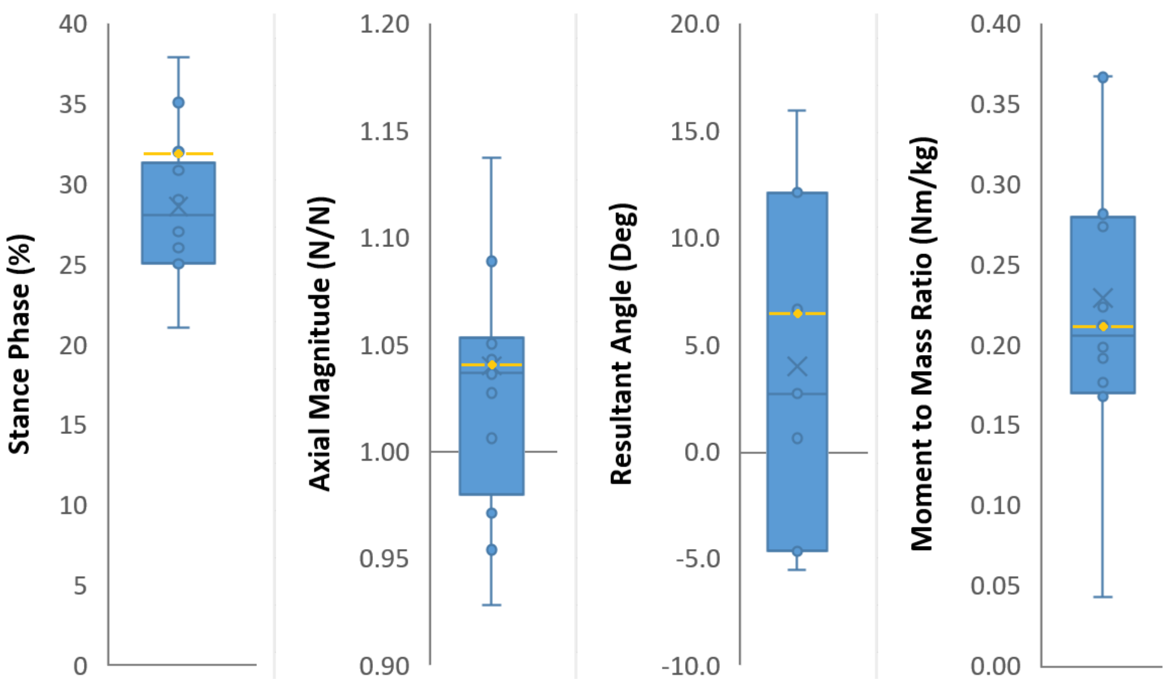

Figure 3.9: Measured loads at first peak of the gait cycle. The selected profile was compared against 16 datasets from the literature to ensure it was a reasonable representation of median loads experienced by people with transtibial amputation.

3.4 RESULTS

Three people with transtibial amputation were recruited to evaluate a novel method of creating a transtibial limb-socket FEM [Table 3.3]. As a first step in validating the FEMs, the fit of the final study sockets was compared to the as-prescribed prosthesis using participant feedback. Two surveys (SCS and PEQ) were completed, however, scores for only three questions were used (below) since the study sockets were not connected to a prosthesis and could not be used to ambulate. Responses to these three questions indicated the two sockets were comparable to each other; on average the study sockets scored 1.7 points higher on the SCS and 3.8 points higher on the selected PEQ-Utility questions [Figure 3.10]. The slight elevation in scores for the study sockets is most likely due to their brief evaluation period.

- (SCS) On a 0–10 scale, if 0 represents the most uncomfortable socket you can imagine, and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb at the moment.
- (PEQ-Utility) Rate the fit of your prosthesis [0–100]
- (PEQ-Utility) Rate your comfort while standing when using your prosthesis [0–100]

Table 3.3: Participant data

	Participant		
	1	2	3
Limb Shape	short-conical	long-conical	cylindrical
Height	185 cm	180 cm	178 cm
Weight	91.4 kg	83.7 kg	87.3 kg
K-Level	3	3	3
Time since amputation	42 years	38 years	9.5 years
Limb Length	13.2 cm	19.0 cm	15.1 cm
MPT circumference	34.4 cm	30.5 cm	31.1 cm
DT circumference	26.0 cm	19.3 cm	26.0 cm
As-prescribed liner	WillowWood Silicone	WillowWood Hybrid Select	Össur Synergy
Number of sessions over previous 9 months	11	9	18
Incidences of skin issues	2	1	2

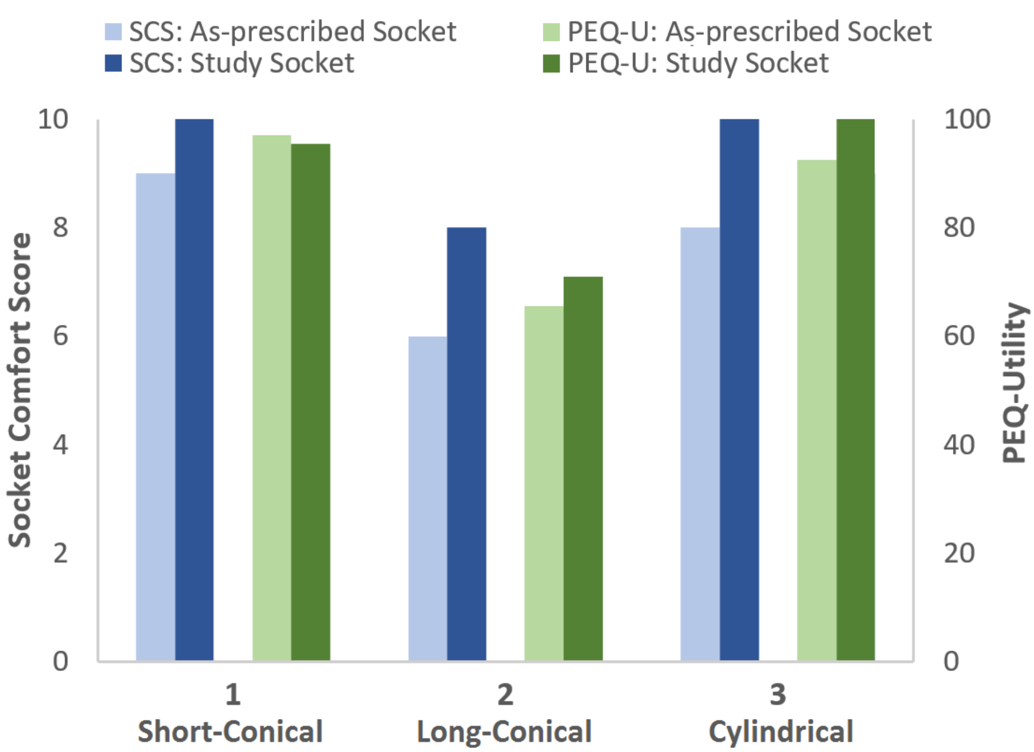

Figure 3.10: Study sockets – participant evaluation. Both the SCS and select questions from the PEQ-Utility showed that the final study sockets were a reasonable representation of participants' as-prescribed sockets.

As a second step in validating the FEMs, two load profiles were compared across all three limb geometries to ensure the simulation outputs were consistent. One of the core differences between the two load profiles was that the compound profile had a greater total energy input into the simulation. In the simulation results, this was exhibited predominantly through an increase in stresses over the anterior aspect of the limbs [Figure 3.11]. The medial, lateral, and posterior aspects of the limb showed a trend of decreasing contact stresses with the compound load profile, however the changes were small (2.8 kPa mean, 6.4 kPa max) compared to those on the anterior aspect (7.2 kPa mean, 24.2 kPa max). The mean limb-socket displacement was 8.0 ± 0.8 mm; no limb geometry or load profile resulted in contact stresses applied to the distal end of the limb. Since each limb geometry showed a consistent response to the two load profiles, the FEMs as a group were considered repeatable enough compare with observed instances of skin health problems. Specific results for participants are presented in order of one-three-two in an effort to make the observed results more easily comparable.

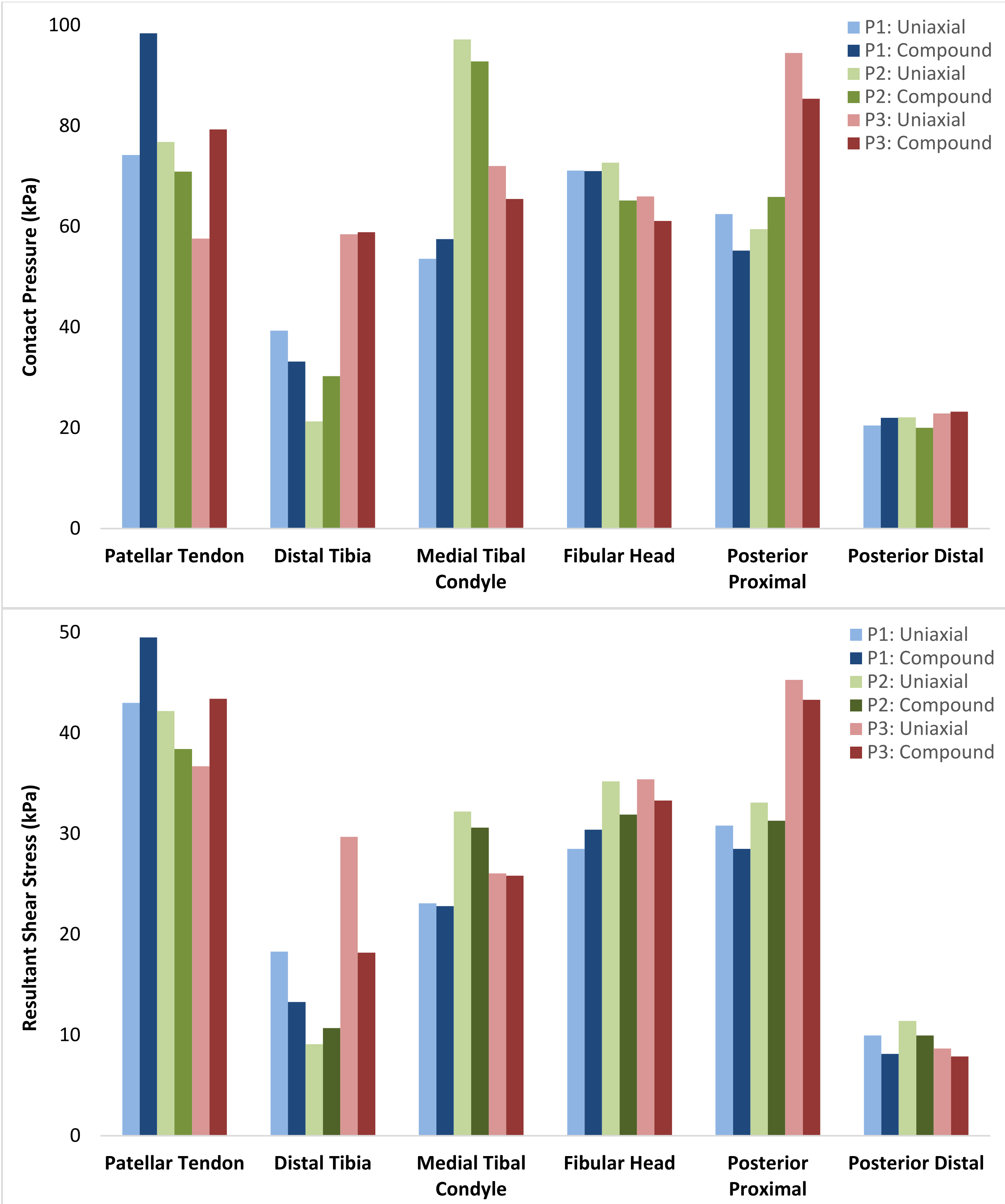

Figure 3.11: FEM interface stresses by location. Contact pressures (a) and resultant shear stresses (b) were typically higher in the anterior and lower in the posterior for the compound load profile load profile.

Participant one (short-conical limb) had the highest rated prescribed prosthesis as indicated by the PEQ and SCS, and this was generally reflected in the FEM. The output of both load profiles showed a load distribution that most closely resembled a total surface bearing socket [Figure 3.12], a modern method of socket design that decreases peak stresses by distributing ambulatory loads to all surfaces within a socket. However, the contours of the soft tissues and locations of bones means there will always be areas of increased stress concentrations on the limb. Participant one showed focused stresses between the patellar tendon and fibular head, with the compound load profile exhibiting the highest stresses observed across all simulations. Contact pressures increased over the entire anterior-proximal region of the socket (98 kPa max), while resultant shear stresses became more focused over the brim (50 kPa max). Posterior pressures were distributed over the proximal region of the socket (62 kPa max), with focused resultant shear stresses along the brim (31 kPa max) [Figure 3.13].

Over a nine-month period, participant one had two observed instances of skin breakdown. The first instance was mechanically induced, and occurred over the patellar tendon and lateral aspect of the limb [Figure 3.14a]. This issue persisted for over a month, with wounds over the fibula being the last to heal [Figure 3.14b]. The second incidence of skin breakdown was a fungal infection on the posterior aspect, and was not likely a result of contact stresses [Figure 3.15a]. However, the distributed stresses seen in the posterior proximal region of the FEM did correlate with exacerbated skin damage [Figure 3.15b]. The results of both load profiles showed good correlation with the observed instances of skin break-down, however, the compound load profile better matched the first instance while the uniaxial simulation better matched the second instance.

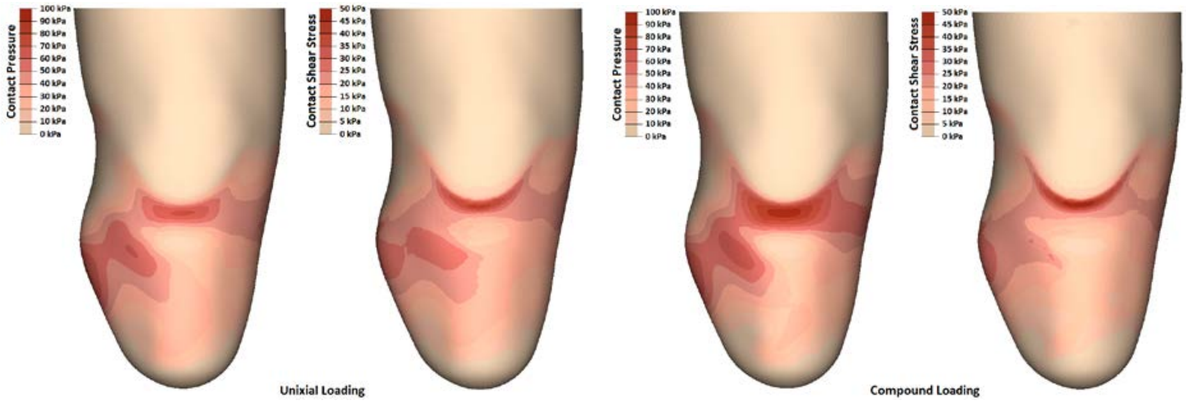

Figure 3.12: Participant one – anterior stresses. **S**tresses for the compound load profile showed increased contact pressures across the anterior-proximal socket region, and focused shear stresses over the patellar tendon.

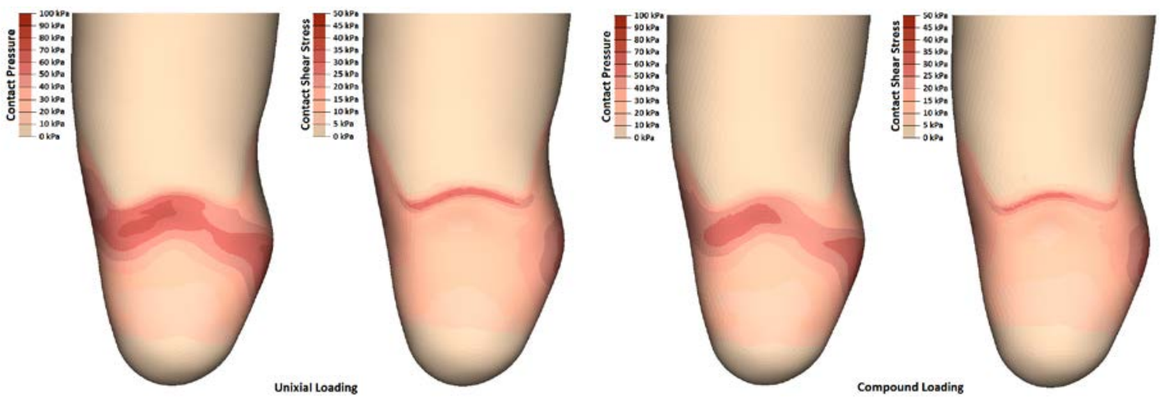

Figure 3.13: Participant one – posterior stresses. Stresses for the compound load profile showed a consistent stress distribution, but with a decrease in the magnitude of contact pressures and resultant shear stresses.

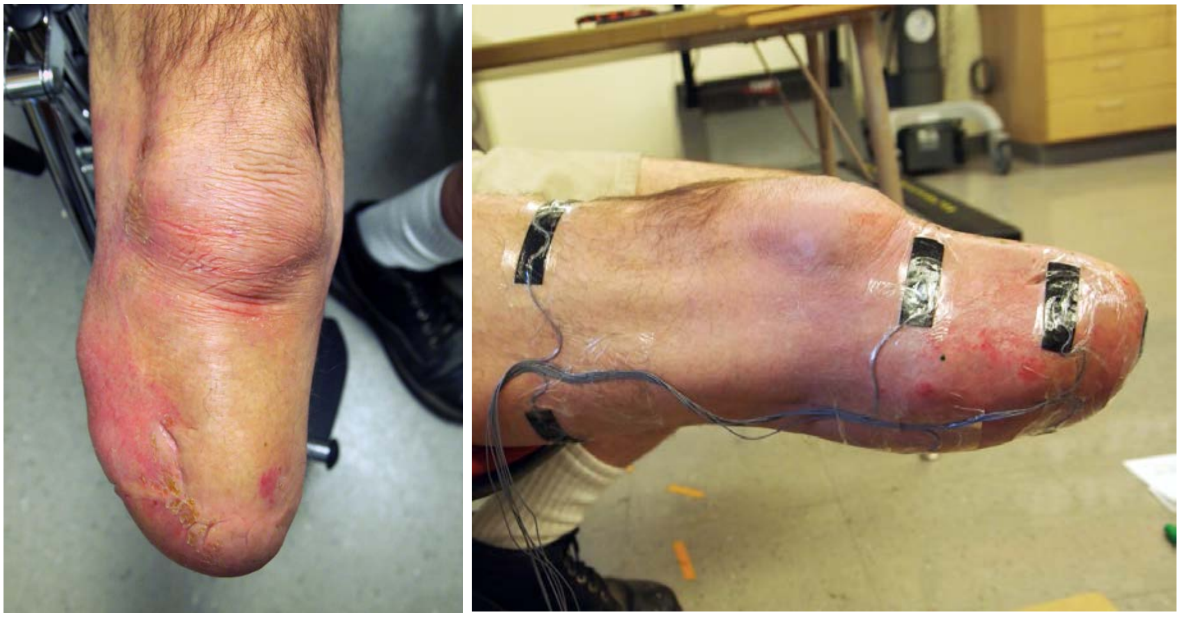

Figure 3.14: Participant one – first skin issue. Participant one had an instance of mechanically induced skin break down that covered the patellar tendon and lateral aspect of his limb (a). The issue persisted for over a month in the fibular region(b).

Figure 3.15: Participant one – second skin issue. Participant one also had an instance of a fungal infection on the posterior-proximal region of his limb that was exacerbated by mechanical stresses.

Participant three (cylindrical limb) had the second highest rated prescribed prosthesis as indicated by the PEQ and SCS, but within two months of completing the study, the participant requested that his prosthetist fabricate a new socket. This outcome was anticipated in the FEM, and demonstrated by discontinuous contact over desirable loading regions (e.g., flat face of the tibia) on the anterior aspect of the limb with focused stresses occurring over proximal and distal socket contours [Figure 3.16]. Stresses on the distal tibia were the highest of the three limb-socket geometries (59 kPa max) and were present below the tibial bevel, a region that is poor at sustaining focused ambulatory loads. The posterior aspect exhibited the highest stresses [Figure 3.17] with contact pressures (95 max) and resultant shear stresses (45 kPa) greater or equal to those seen over the patellar tendon.

Participant three had two mechanically induced limb health issues observed over a nine-month period. The first was an instance of skin break-down over the distal tibia [Figure 3.18a] that persisted for over a month [Figure 3.18b]. The location of both the initial and persistent wound were best represented by the uniaxial load profile. The second observed instance was a persistent sore spot along the posterior brim [Figure 3.19a] that never developed into a wound, but did tear the participant's prosthetic liner [Figure 3.19b]. Unlike participant one, the posterior issue experienced by participant three was better described as edge loading. This trend was observed in the FEM output through higher peak stresses over a smaller area along the socket brim. Both load profiles exhibited this type of stress distribution, and the peak stresses in the region were distinct compared to the other limb geometries.

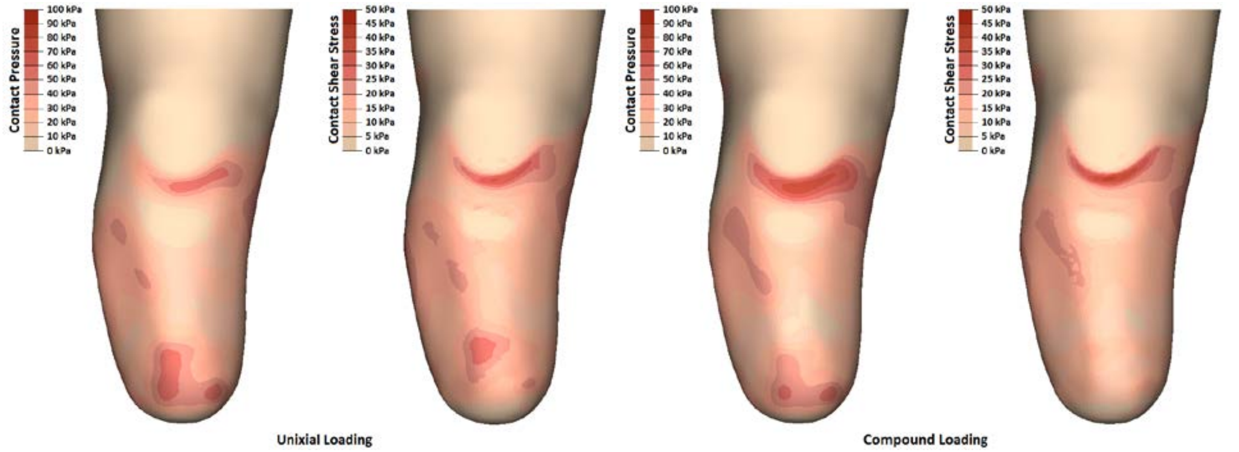

Figure 3.16: Participant three – anterior stresses. Stresses for the compound load profile showed a general increase in contact pressures and resultant shear stresses over the anterior-proximal region. The size of stress distributions over the anterior-distal region were decreased, but only the magnitude of the resultant shear stress decreased while peak pressure over the distal tibia was consistent.

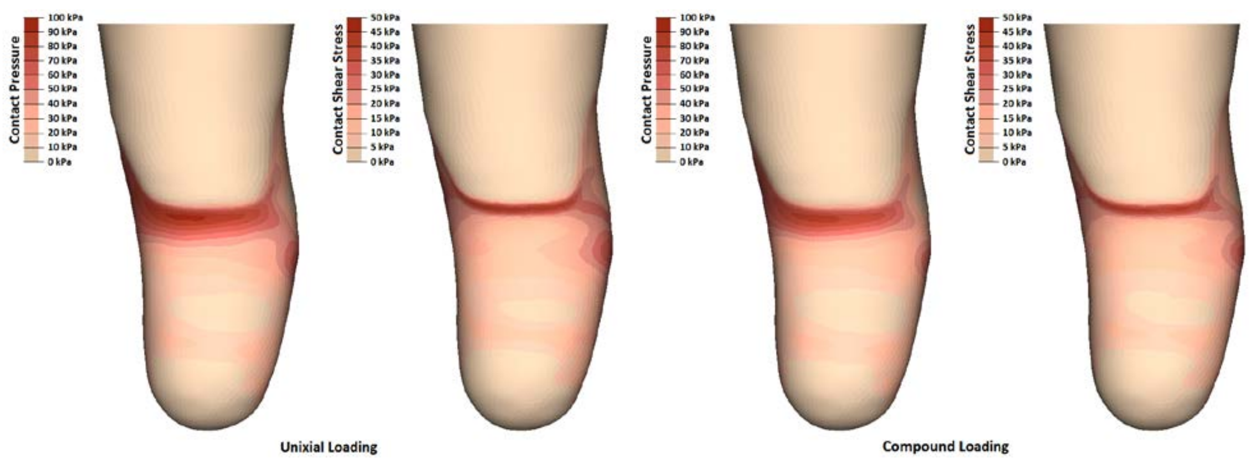

Figure 3.17: Participant three – posterior stresses. Stresses for the compound load profile showed a consistent stress distribution, but with a decrease in the magnitude of contact pressures and resultant shear stresses.

Figure 3.18: Participant three – first skin issue. Participant three experienced an instance of mechanically induced skin breakdown over his distal tibia (a) that persisted for over a month on the distal-lateral aspect (b).

Figure 3.19: Participant three – second skin issue. Participant three also experienced edge loading issues from the posterior brim (a) that were significant enough to tear the fabric backing of his prosthetic liner (b).

Participant two (long-conical) had the lowest rated as-prescribed prosthesis, and the SCS score of 6 was representative of a socket that likely needed adjustment[35]. This trend was reflected in the FEM as a proximally biased load distribution with limited contact stresses over the entire distal aspect of the limb [Figure 3.20]. Two regions showed distinct contact stresses compared the other limb geometries; participant two had the lowest contact pressures over the distal tibia (30 kPa max), and the highest contact pressures over the medial tibial condyle (98 kPa). This peak load distribution wrapped around to the limb, where radiant stresses constituted the highest posterior contact pressures (66 kPa max) and resultant shear stresses (33 kPa max) [Figure 3.21]. Throughout the rest of the socket, peak contact stresses were intermediate compared to the two other limb geometries.

Participant two had one mechanically induced limb health issue observed repeatedly over a nine-month period, but no instance of skin break-down was reported. After removing his socket, the distal end of his limb was red and purple in color [Figure 3.22], returning to normal after approximately ten minutes. A research prosthetist identified this issue as a lack of distal end bearing, with the purple (oxygen depleted) tissue being a precursor to verrucous hyperplasia. While no skin issues were observed over the medial tibial condyle, it is worth noting that only the contact pressures were high; the resultant shear stresses were comparable to other locations inside the socket. This may have contributed to the socket’s lack of comfort, while skin breakdown was belayed without a sufficient magnitude of compound stresses that are associated with soft tissue damage.

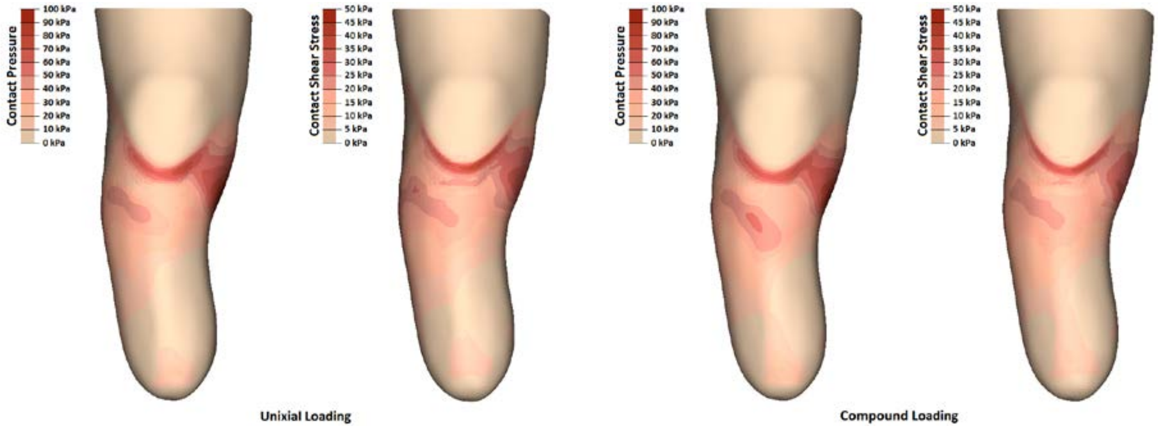

Figure 3.20: Participant two – anterior stresses. Stresses for the compound load profile showed an increase in contact pressures and resultant shear over the body of the tibia, and was the only participant to show decreased stresses over the patellar tendon.

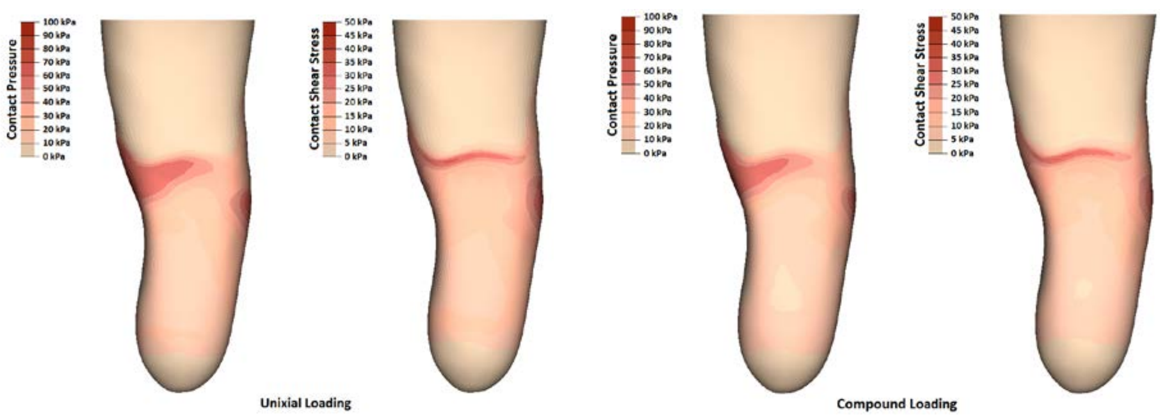

Figure 3.21: Participant two – posterior stresses. Stresses for the compound load profile showed a general decrease in contact pressures and resultant shear stresses over the posterior aspect. Unlike participants' one and three, the peak contact pressures appeared to originate from contours on the medial aspect.

Figure 3.22: Participant two – first skin issue. Participant two only experienced one mechanical issue on the distal end of his limb. The purple hue indicated oxygen depleted tissues caused by a proximal biased load distribution with a lack of distal end bearing. During swing phase it was anticipated that the socket was pulling on the distal end of the similar to a suction cup.

3.5 Discussion

This research presented a novel method of creating a transtibial limb-socket FEM. While the FEM output showed a good correlation between the locations of peak simulated contact stresses and locations of mechanical issues within as-prescribed prosthesis, it is necessary to compare the simulation output with measurements of interface mechanics. Across the literature, both the magnitude and locations of peak reported stresses vary considerably. At the first peak of stance phase, the range in reported values was as low as 60 kPa (over the anterior aspect)[10] to as high as 300 kPa (over the fibular head)[11]. While the results from this study are closest to the former (as well as using the same liner product), further assessment is merited to narrow the range of stresses that are considered reasonable.

Recent interface stress measurements frequently make use of thin load transducers that fit between the skin and prosthetic liner. These transducers only report pressure and sacrifice accuracy for portability[51]. Sanders et al performed a series of studies that employed socket mounted, 3-axis load cells that measured a mean first peak pressure of 94 kPa and a peak shear stress of 11 kPa across 10 subjects in five studies[52-56]. A sixth study with eight participants reported a mean first peak pressure of 99 kPa and mean a shear stress of 11 kPa[9]. While these results are quite consistent, this group of historical studies were conducted with patellar tendon bearing sockets (compared to total surface bearing sockets), and the liner materials were Pelite™ rather than elastomeric.

The peak pressures reported in the current study may therefore be considered reasonable, i.e., they are lower than those reported by Sanders et al, but this is expected to some extent since the purpose of both a total surface bearing socket and an elastomeric liner are to better distribute ambulatory loads. However, the mean shear response may be less reasonable. The maximum value of 50 kPa for the current FEM is similar to the maximum value of 45 kPa [53] reported in the literature, but shear magnitudes at every major anatomic location were higher than the reported mean value of 11 kPa. From a material perspective this may be expected to some extent, the incompressible elastomeric liner is spreading (flowing) as it is compressed and this may be facilitating a more distributed load transmission through shear stress that further reduces contact pressures. It may also be partially explained as a limitation of the FEM, e.g., the soft tissues are simulated in pre-stressed state and unable to deform in the two-stage, non-linear manner demonstrated by Daly [40]. The inability of the soft tissue geometry to deform in a low stress state may facilitate better (i.e. continuous) coupling interaction between the limb and socket with the tendency to transmit a greater portion of the load through shear.

Finally, the current FEM simulated the complete distal end of the limb-socket interface, including the thickening of the prosthetic liner from 6 to 14 mm, as well as the distal gap between the liner and socket. It was anticipated that the limb-socket displacements of the current research would be greater and more plausible than the 1 mm displacements reported in historical FEMs[16, 13]. Tucker et al and Darter et al measured 12–18 mm of limb-socket displacement depending on the method of suspension[7, 8]. Darter found that approximately 60% of this displacement occurred during initial weight acceptance (0–20% body weight) independent of suspension method[8]. The remaining 40% (5–7 mm) occurred during the final 80% of load bearing. This range better matched the results of the current FEMs (7–9 mm) and is likely explained by the absence of a simulated swing phase (i.e., the socket was not pulled away from the limb in the FEM).

3.6 Clinical Relevance

This study offers insight into several techniques used in clinical practice, particularly limitations of a total surface bearing socket design. The name "total surface bearing" reflects the goal of achieving an equal load distribution across the entire surface of the residual limb. However, in this study only participant one had a limb shape that enabled true total surface bearing. Participants two and three both had overhanging surfaces preventing the transfer of vertical loads [Figure 3.23]. In spite of this, the peak stresses were about the same across all limb geometries. Each limb had a specific point of peak stress that was greater than all other stresses in the socket. This contrasts with the traditional view of using desirable pressure points that combine to provide vertical loading and horizontal stability. For example, a limb supported on the patellar tendon is generally thought to need a load-bearing support on the posterior-proximal (popliteal) region of the limb. However, results from all three simulated limb geometries showed there was no counter balance location of similar stress magnitude for any of the primary loading points. This may be a consequence of peak stresses occurring in regions close in proximity to bony prominences, where there is not sufficient thickness of the soft tissue and elastomeric liner to distribute loads.

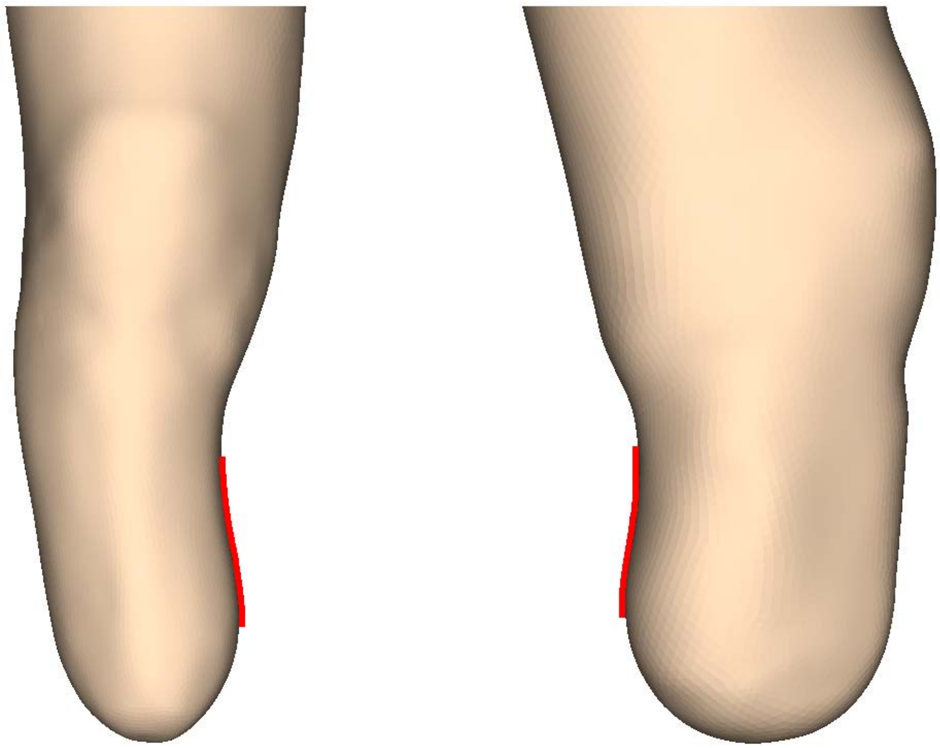

Figure 3.23: Overhanging contact surfaces. Participant two (left) had an overhanging surface on the medial surface of his limb, while participant three (right) had an overhanging surface on the posterior aspect that prevented meaningful load transfer.

This research used incidences of skin breakdown to assess the locational accuracy of the finite element model, which also provided preliminary data that illustrated a potential to predict soft tissue damage. The soft tissue breakdown explored in this model was limited to relatively well fitting sockets with superficial wounds, which were most likely to be related to skin stresses and abrasion. Deep tissue injuries could be explored in future studies, though the study design might need to be adjusted to account for poorly fitting sockets. Additionally, research has shown that deep tissue injury is related to cellular strains[57, 58] rather than interface contact pressures. Given the highly non-linear mechanical response of soft tissues, damage is better predicted in a FEM through strain-energy[58].

3.7 CONCLUSIONS

This research produced a method for creating a transtibial FEM that simulates modern prosthesis design. Novel features that improve the flexibility the analysis question include a hyperelastic material model and a complete socket geometry on the proximal and distal end. Future research should make use of the existing FEM features to evaluate clinically relevant issues such as the effects of different liner products and changes in residual limb volume. Further development of the FEM could include a more robust model that is better able to simulate the complete gait cycle. The addition of a suspension element could enable the simulation of a complete gait cycle that included swing phase. This might give a better approximation of slipping within the socket since a greater total limb-socket displacement would be anticipated, and it might offer insight into the effectiveness of increased tensile properties of a prosthetic liner. Separately, the preliminary results indicated that a CoF of 2.0 or greater had approximately the same interface as a bonded contact and 70% of measured liner products have a CoF greater than 2.0[23]. The use of a bonded contacts would enable more complex geometry to be simulated, which might enable the evaluation of prosthetic socks or pads within the socket.

3.8 ACKNOWLEDGMENTS

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Chapter 4. EFFECTS OF LIMB VOLUME FLUCTUATIONS AND LINER PRODUCTS ON INTERFACE MECHANICS

4.1 INTRODUCTION

The finite element model (FEM) presented in chapter three of this dissertation was designed to answer several clinical questions. This chapter applies this model to address two questions related to the effects of limb volume fluctuations and prosthetic liner product. The effects of limb volume fluctuations were simulated as degrading socket fit without the use of prosthetic socks. The evaluation of prosthetic liners is a common theme across this dissertation, and the ability to simulate different liner products was a goal of this FEM. For this evaluation, a representative set of liner products were simulated across all three limbs to determine the range of interface stresses.

4.2 EFFECTS OF SOCKET SIZE: −3% TO +3%

4.2.1 *Methods*

Volume fluctuations of the residual limb are the most common issue experienced by people with transtibial amputation[1]. Fluctuations can occur over the course of the day as extracellular fluid is transported in and out of the limb. Larger changes in volume can occur over months and years as the soft tissues adapt to weight changes, physical conditioning, or atrophy[2]. These changes lead to shape mismatches between the soft tissues of the residual limb and the prosthetic socket, which can lead to instances of skin break-down. FEMs can provide estimates into the effects of limb volume change on interface stresses experienced by the residual limb that would be otherwise challenging to obtain through physical measurement.

Three transtibial FEMs were used to simulate limb volume change and predict the changes in interface stresses. For this study, volume changes were effected through the size of the socket rather than the size of the limb. This was because the soft tissue-bone contact was modeled as a fixed boundary condition in the FEM, so any volume change applied to the limb would induce artificial stresses.

The FEM included the limb, socket, and prosthetic liner, but did not include prosthetic socks. Therefore, the maximum volume change evaluated was that of greatest volume discrepancy anticipated between a limb and socket that might be encountered without the use of prosthetic socks. The three most commonly used sock sizes are 1, 3, and 5-ply[3, 4], so the absence of a 5-ply sock was selected as worst plausible condition. The 1.5–1.8 mm thickness of a 5-ply sock[4, 5] was roughly equivalent to a 3% volume offset. To evaluate the effect of volume change, three limb socket FEMs were simulated from −3% to +3% in 1% increments using the uniaxial load profile established in the FEM validation.

4.2.2 *Hypotheses and Outcomes*

A socket that is too small for the limb behaves like a bad total surface bearing socket:

- Mostly true, there were minimal changes in mean pressure from 0% to −1%, with significant increases in mean pressure from −1% to −3% [Figures 4.1–4.3]. Conversely, there were significant decreases in mean shear from 0% to −1%, with minimal changes from −1% to −3%. These trends were consistent across all three participants. Additionally, limb-socket displacement decreased by 5.8 mm at a −3% socket size.

A socket that is too large behaves like a bad patellar tendon bearing socket:

- True across all three participants [Figures 4.1–4.3]. As socket size increased, stresses became more localized, resulting in increased peak pressure and peak shear. Additionally, limb-socket displacement increased almost linearly as socket volume increased (+3.4 mm at +1% and +9.6 mm at +3%).

The (final) study socket was the best fitting socket:

- Since limb-socket displacement and shear stresses decreased as socket size was decreased (two seemingly desirable outcomes), this hypothesis was best evaluated through the minimum in both the mean limb contact pressure [Figures 4.1–4.3] as well as location specific [Figures 4.4–4.6] contact pressures.
- *Participant 1*: True, the 0% socket produced the minimum pressure at 5 of 6 locations.
- *Participant 2*: The −1% socket was roughly equivalent to the 0% socket. The 0% socket had lower stresses over the fibular head and distal tibia, while the −1% socket had lower stresses over the medial tibial condyle and patellar tendon. The sensitivity of the fibular head and distal tibia might explain the participant's preference for the 0% fit during the socket fitting (from previous chapter).
- *Participant 3*: The 0% socket showed minimum pressure at only three locations, and this made its fit quality difficult to distinguish from the −1% socket. The participant's as-prescribed (daily use) socket was too large in the proximal region, and the socket's radius over the distal tibia was too tight. These issues combined to make the distal tibia an existing site of skin breakdown for this participant. It was therefore surmised that a −1% fit would be an improvement if a pressure relief were built in for the distal tibia.

4.2.3 *Results*

Mean change from 0% to +3% socket size across three limbs:

Change in peak contact pressure:	43.0 ± 6.0 kPa	(49.5 ± 10.4 %)
Change in peak resultant shear:	24.4 ± 1.3 kPa	(56.1 ± 2.8 %)
Change in mean contact pressure:	23.0 ± 4.5 kPa	(39.6 ± 6.9 %)
Change in mean resultant shear:	10.1 ± 1.4 kPa	(36.5 ± 3.6 %)
Change in socket displacement:	9.6 ± 0.8 mm	(122.6 ± 21.7 %)
Change in net load transmission (normal/shear):	0.08 ± 0.03 %Body Weight	

Mean change from 0% to +1% socket size across three limbs:

Change in peak contact pressure:	14.5 ± 4.0 kPa	(16.9 ± 6.2 %)
Change in peak resultant shear:	8.2 ± 0.6 kPa	(18.9 ± 1.3 %)
Change in mean contact pressure:	8.4 ± 1.6 kPa	(14.3 ± 2.1 %)
Change in mean resultant shear:	4.6 ± 0.5 kPa	(16.5 ± 0.8 %)
Change in socket displacement:	3.4 ± 0.4 mm	(43.5 ± 9.8 %)
Change in net load transmission (normal/shear):	0.03 ± 0.01 %Body Weight	

Mean change from 0% to −1% socket size across three limbs:

Change in peak contact pressure:	-2.6 ± 5.9 kPa	(-2.2 ± 7.0 %)
Change in peak resultant shear:	-11.1 ± 1.8 kPa	(-25.6 ± 3.8 %)
Change in mean contact pressure:	1.9 ± 2.7 kPa	(3.5 ± 4.9 %)
Change in mean resultant shear:	-5.5 ± 1.4 kPa	(-19.7 ± 4.4 %)
Change in socket displacement:	-2.4 ± 0.5 mm	(-30.9 ± 10.2 %)
Change in net load transmission (normal/shear):	0.03 ± 0.03 %Body Weight	

Mean change from 0% to −3% socket size across three limbs:

Change in peak contact pressure:	31.1 ± 7.5 kPa	(36.6 ± 13.6 %)
Change in peak resultant shear:	-11.8 ± 2.6 kPa	(-27.0 ± 5.2 %)
Change in mean contact pressure:	28.9 ± 2.4 kPa	(50.1 ± 5.9 %)
Change in mean resultant shear:	-5.7 ± 1.7 kPa	(-20.4 ± 4.6 %)
Change in socket displacement:	-5.8 ± 0.8 mm	(-73.2 ± 12.4 %)
Change in net load transmission (normal/shear):	0.20 ± 0.06 %Body Weight	

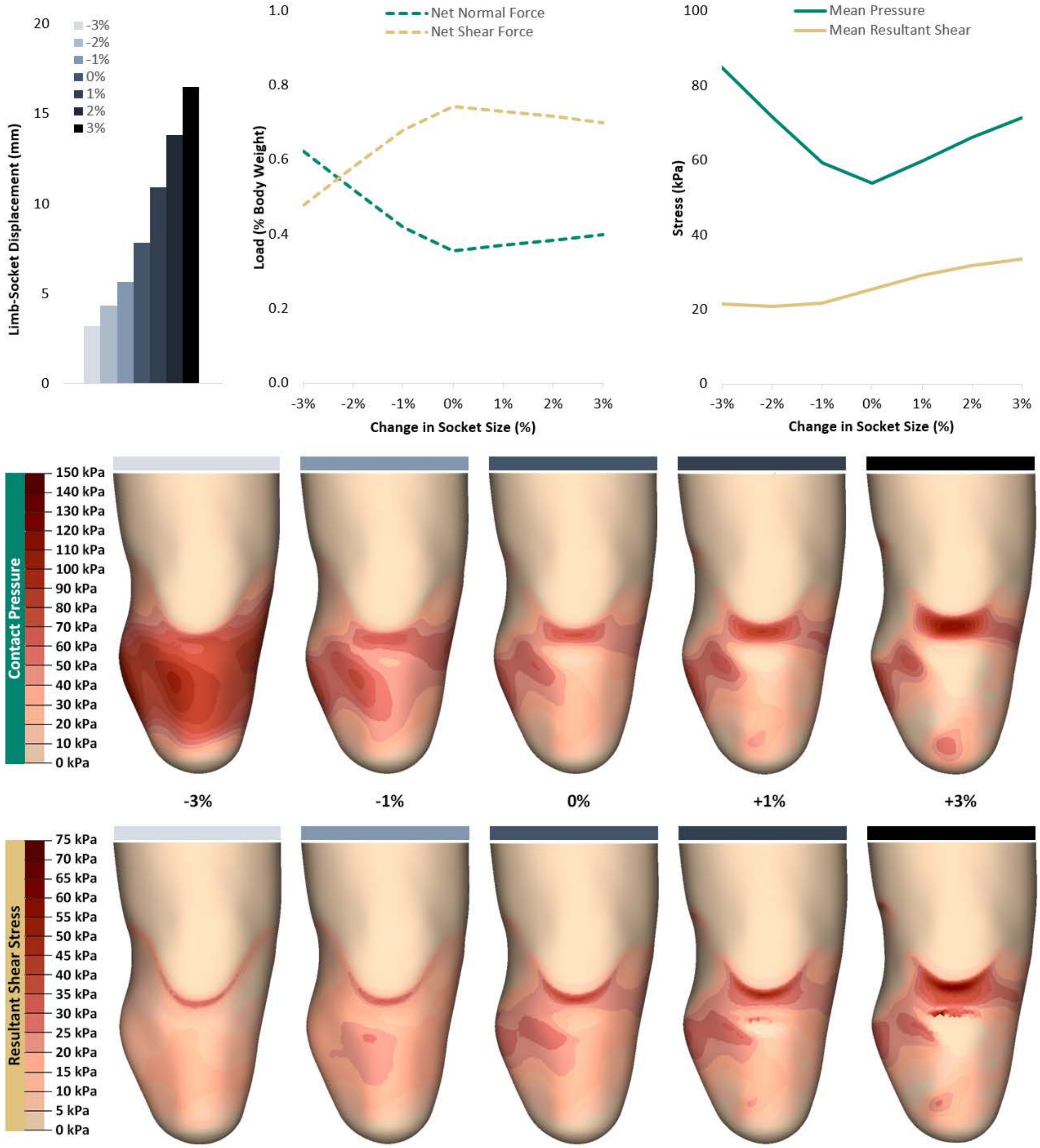

Figure 4.1: Participant one – FEM output from −3% to +3% socket sizes

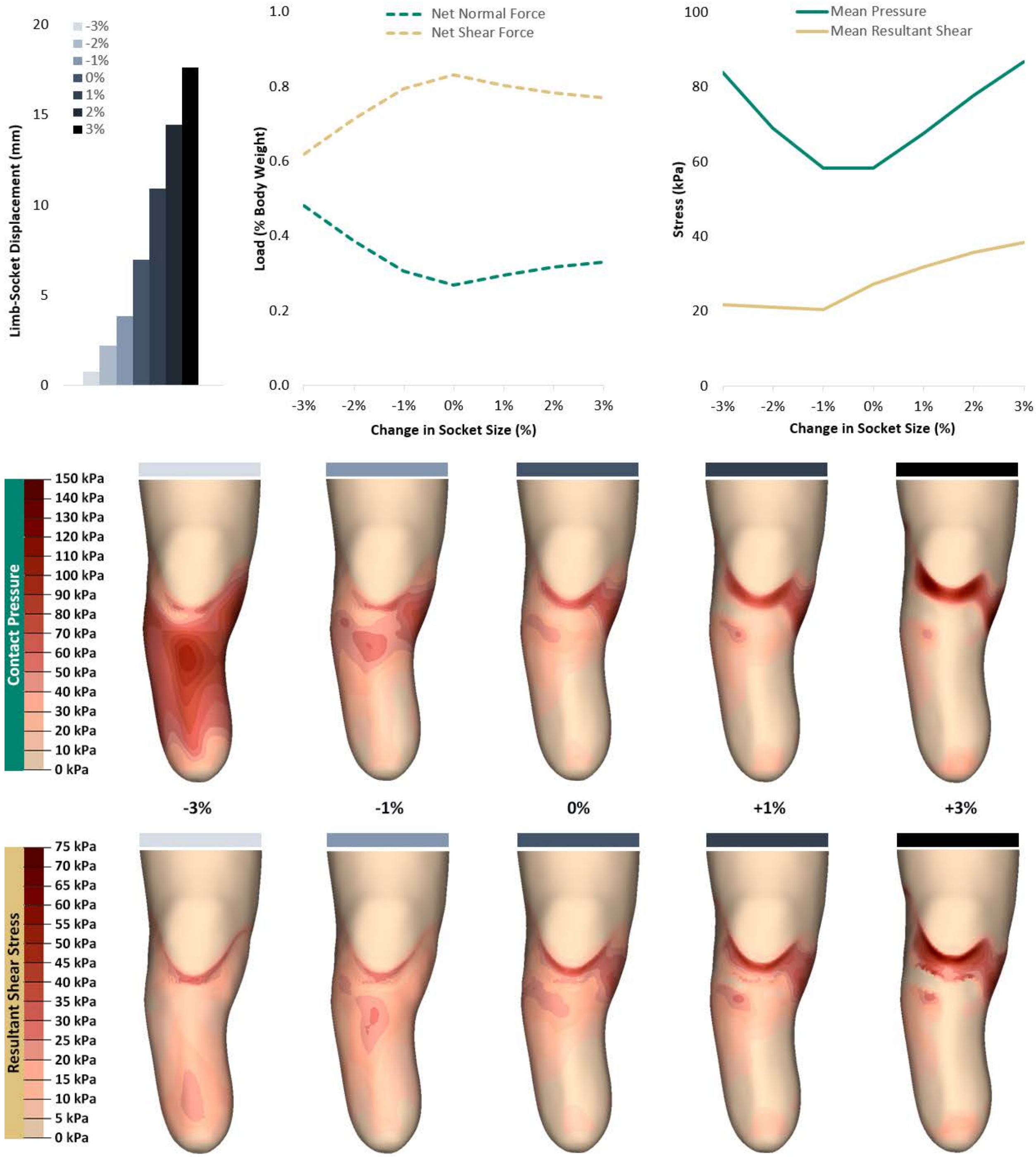

Figure 4.2: Participant two – FEM output from −3% to +3% socket sizes

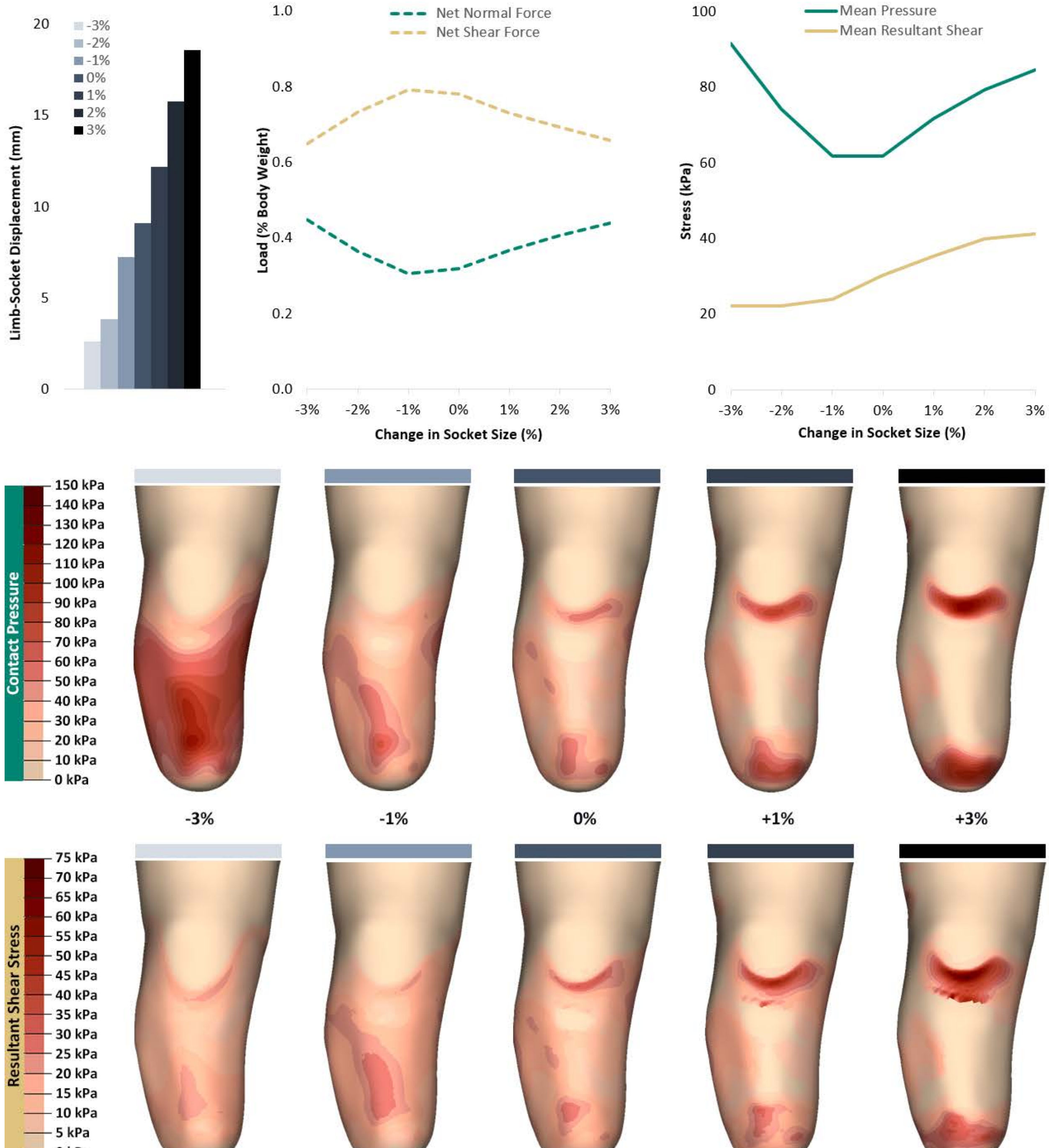

Figure 4.3: Participant three – FEM output from −3% to +3% socket sizes

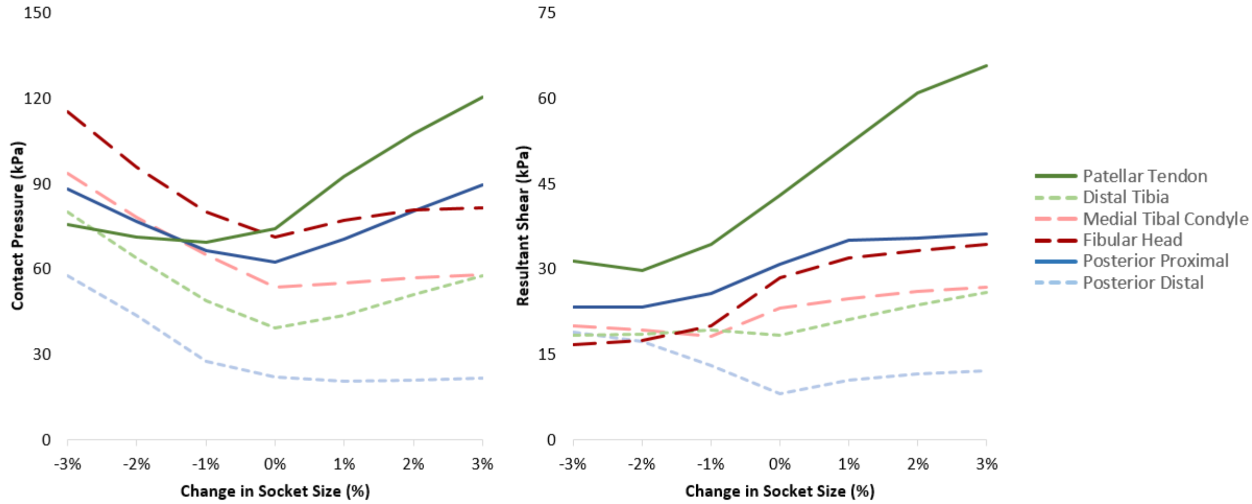

Figure 4.4: Participant one – stresses by location from −3% to +3% socket sizes

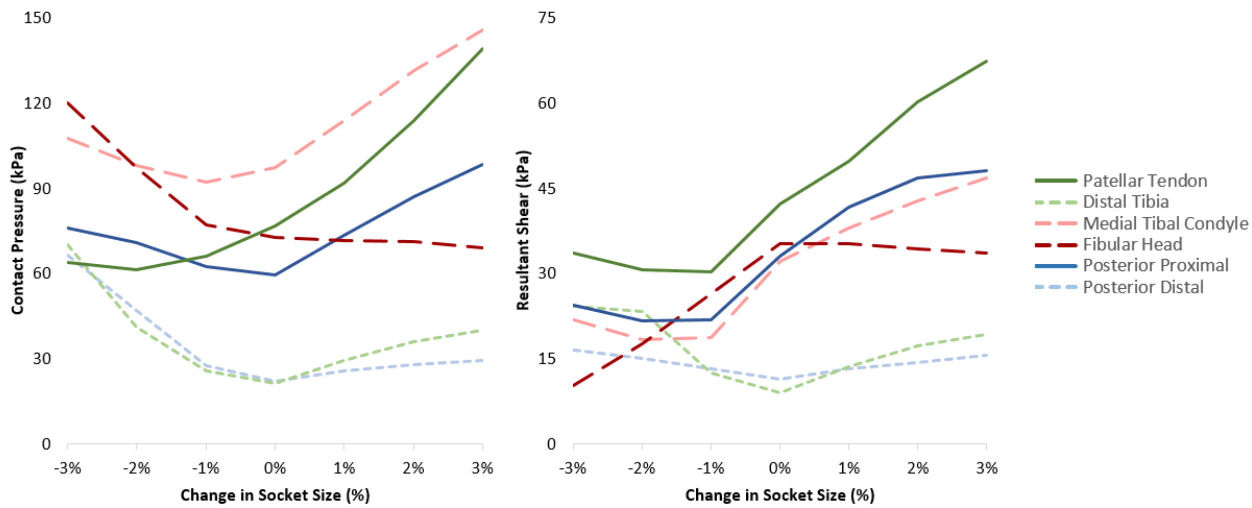

Figure 4.5: Participant two – stresses by location from −3% to +3% socket sizes

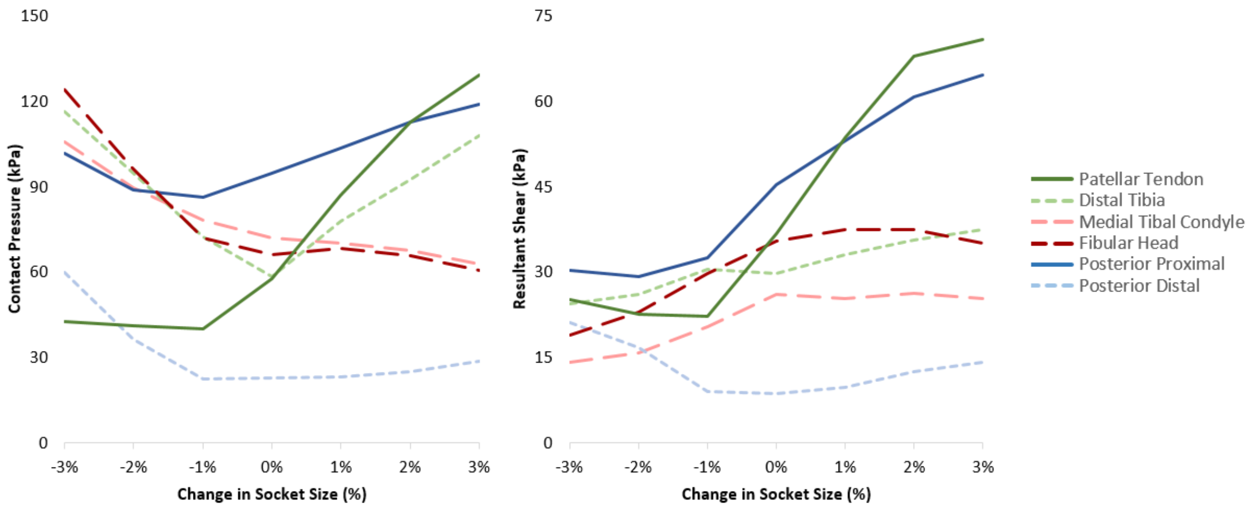

Figure 4.6: Participant three – stresses by location from −3% to +3% socket sizes

4.3 Effect of Liner Material: Five Representative Products

4.3.1 *Methods*

Mechanically induced skin breakdown is a common occurrence for people with transtibial amputation. 50% of patients experience light wounds monthly (e.g., blisters, abrasion, callousing) and 57% of patients experience deep wounds (e.g., pressure ulcers or infection) on their limbs at some point[6-8]. This is primarily a result of the soft tissues of the residual limb coupling with a hard prosthetic socket. To help reduce the occurrence and severity of skin breakdown, elastomeric liners are commonly used as an interface material to reduce contact stresses and slipping along the surface of the skin.

A recent study evaluated twenty-four liner products across six material properties that included compressive elasticity, shear elasticity, tensile elasticity, volumetric elasticity, coefficient of friction, and thermal conductivity. Each property was measured in isolation, but they all interact a prosthetic socket. While the previous study evaluated distinct material properties, their combined response inside a prosthesis and the influence on clinically relevant metrics (e.g., applied contact stresses) is unclear. The previously developed FEM was specifically designed to provide insight into this question.

Four liner products that encompassed the range of available liner products were selected, and are concisely described as either hard or soft and either sticky or slick (e.g., hard-sticky) [Figure 4.7]. The fifth liner product, medium-sticky, was included because it was the liner used during the creation of the FEM and served as a reference to determine if the changes between soft-sticky and hard-sticky were linear. Since the FEM could only simulate a maximum CoF of 2.0, and the FEM validation study showed that limb-liner slipping was non-existent at a CoF of 2.0, any liner with a CoF greater than 2.0 was labeled as sticky. Tensile elasticity was not included in the selection process, because a preliminary model of the stance phase loading implemented in this FEM showed that compressive and shear stresses were predominant and the tensile stiffness had little effect on the simulation output. Similarly, the volumetric elasticity of a liner was not included in the selection process, because the reported Poisson's ratio across all liner products was greater than 0.493 while the FEM was most stable with a Poisson's ratio of 0.48.

Once selected, hyperelastic material models were created for all five liner products using both Mooney-Rivlin[9] and Yeoh[10] constitutive models. The two constitutive model were compared per liner product to determine the most stable material formulation. For the liner comparison, the five selected liner products were simulated for all three participants using the uniaxial load profile established in the FEM validation. To ensure that the results were not specific to a selected load profile, participant one's limb-socket model was also simulated with the compound load profile that included axial load, shear load, and a bending moment about the sagittal plane.

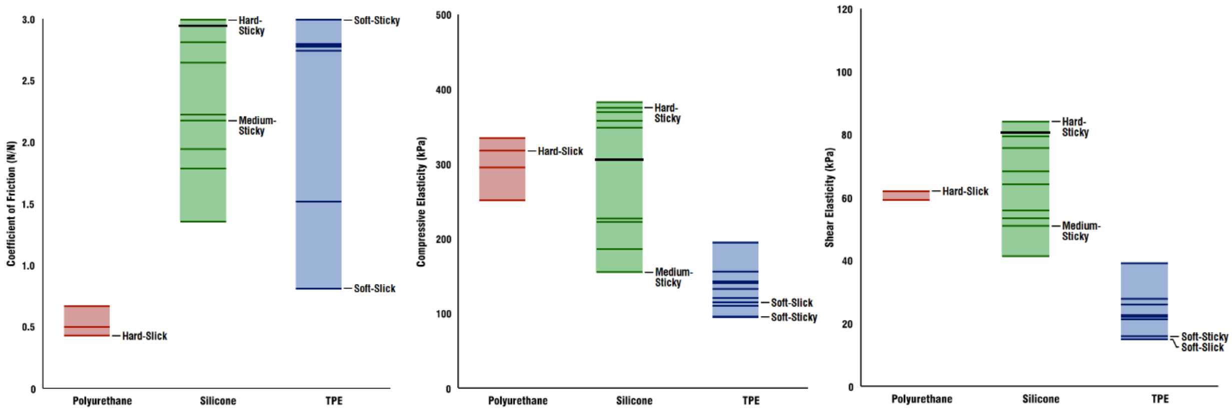

Figure 4.7: Liner product selection for FEM. Coefficient of friction (left), compressive elasticity (middle), and shear elasticity (right) for the selected liner products. For tapered liner products, only the distal elasticities were considered since the proximally measured specimens were located outside of the socket.

4.3.2 *Hypotheses and Outcomes*

The soft-slick liner will result in the greatest limb-socket displacement and the greatest skin-liner slip

- True across all four simulations [Figures 4.8–4.11]

The hard-sticky liner will result in the least limb-socket displacement

- True across all four simulations [Figures 4.8–4.11]

The hard-slick liner will result in the greatest skin-liner slip

- True across all four simulations [Figures 4.16–4.17]

The hard-slick liner will result in the greatest peak pressure and peak shear stresses

- This hypothesis is true when tested at individual locations [Figures 4.12–4.15], however there are significant changes in single location values that can affect whole limb evaluations [4.8–4.11]. Of particular note for participant one, the soft-slick liner had close to or the highest peak pressures across both load profiles.

- *Participant 1-compound*: The hard-slick liner had the second highest for peak pressure behind the soft-slick liner (6 of 6 locations). The hard-slick liner had the highest peak shear stresses in 3 of 6 locations, but the lowest peak shear at the point of greatest shear stress (patellar tendon)
- *Participant 1-uniaxial*: The hard-slick liner had the highest peak pressure in 4 of 6 locations, but was roughly equivalent to the soft-slick liner across the whole limb. Had the highest peak shear stresses in 4 of 6 locations, but the lowest shear stress in 1 of 6 locations.
- *Participant 2-uniaxial*: The hard-slick liner had the highest peak pressure and shear in 5 of 6 locations
- *Participant 3-uniaxial*: The hard-slick liner had the highest peak pressure and shear in 5 of 6 locations

The soft-sticky liner will result in the lowest peak pressure and peak shear stresses

- This hypothesis was almost never true when evaluated with mean and peak values [Figures 4.8–4.11]. The medium-sticky liner generally produced the lowest mean pressure while the hard-sticky liner generally produced the lowest peak pressures. The soft-slick liner generally produced the lowest mean and peak resultant shear stresses.
- Individual locations exhibited a variety of responses [Figures 4.12–4.15] and the only clear trends were associated with shear stresses. The soft-sticky liner consistently produced low resultant shear stresses at bony prominences (e.g., fibular head and medial tibial condyle), while the soft-slick liner consistently showed low resultant shear stresses along the socket brim (e.g., patellar tendon and posterior proximal). Other trends were

apparent (e.g., the hard-sticky liner consistently had low pressures over the patellar tendon), but there was not a clear clinical association.

4.3.3 *Results*

Mean changes across all four limb-socket simulations (best liner to worst liner):

Change in peak contact pressure:	13.5 ± 3.8 kPa (15.5 ± 5.2 %)
Change in peak resultant shear:	9.0 ± 2.7 kPa (23.5 ± 7.1 %)
Change in mean contact pressure:	9.6 ± 1.8 kPa (16.9 ± 2.2 %)
Change in mean resultant shear:	4.0 ± 1.8 kPa (14.9 ± 6.5 %)
Change in socket displacement:	1.6 ± 0.2 mm (21.9 ± 2.8 %)
Change in net load transmission (normal/shear):	0.05 ± 0.01 % Body Weight

4.3.4 *Clinical Relevance*

The hard-slick liner consistently demonstrated the greatest pressure, shear, and skin-liner slip, and this might raise the question of why it would ever be used in clinical practice. Liner manufacturers recommend this type of liner for patients with excess loose skin, because it helps constrain movement without applying focused stresses to the skin. This type of benefit goes beyond the capacity of this FEM to simulate, because it was designed with participants who did not have excessive loose skin. It is therefore quite possible that this type of liner is beneficial for the intended application.

The soft-slick liner consistently demonstrated the lowest peak shear stresses with the greatest limb-socket displacements of the five liner products simulated. Since shear stresses have been shown to slow wound healing [11, 12], this may indicate that the soft-slick liner optimizes limb health at the expense of a loose limb-socket coupling.

The three sticky liners produced the lowest contact pressures across the three limbs, although no single liner was consistently lowest. The soft-sticky liner tended to decrease mean shear stress but increase peak shear stress. In contrast, the hard-sticky liner tended to increase mean shear stress and decrease peak shear stress. These results indicate sticky liners are likely a preferable starting point for most patients, but the final selection is dependent on the individual person. This may explain why 70% of the liner products evaluated in chapter two could be classified as sticky liners.

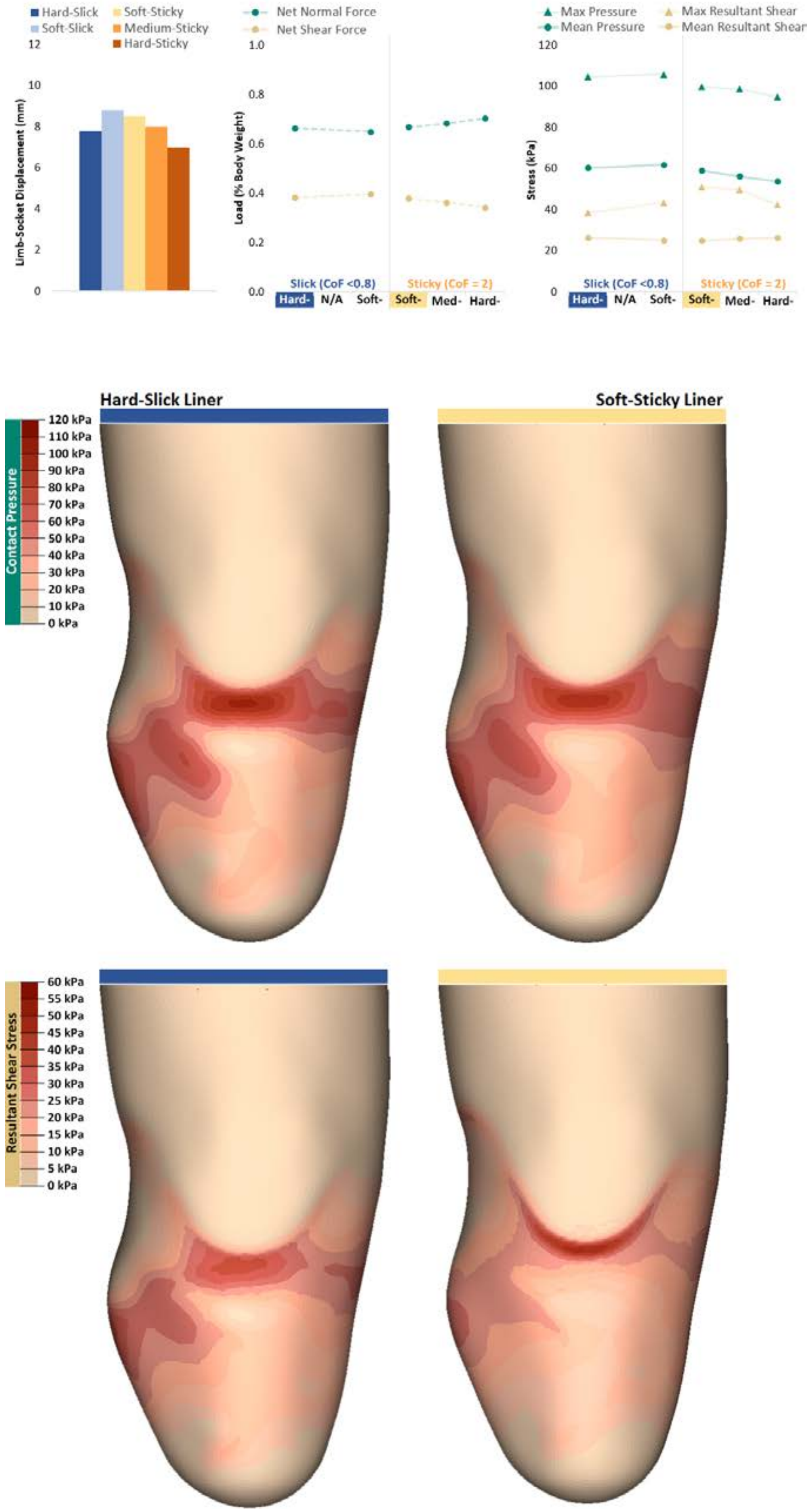

Figure 4.8: Participant one (compound) – FEM output by liner product

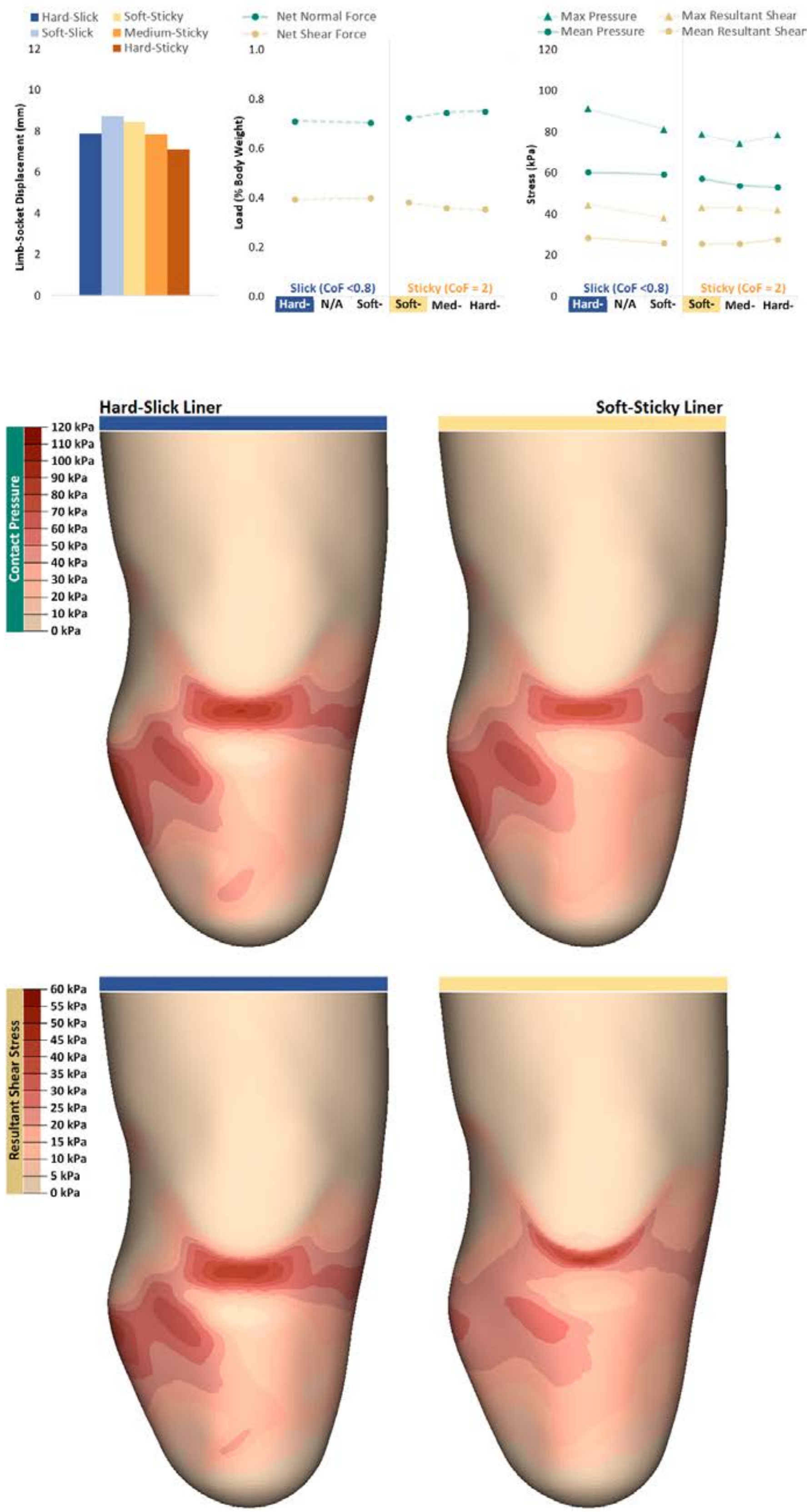

Figure 4.9: Participant one (uniaxial) – FEM output by liner product

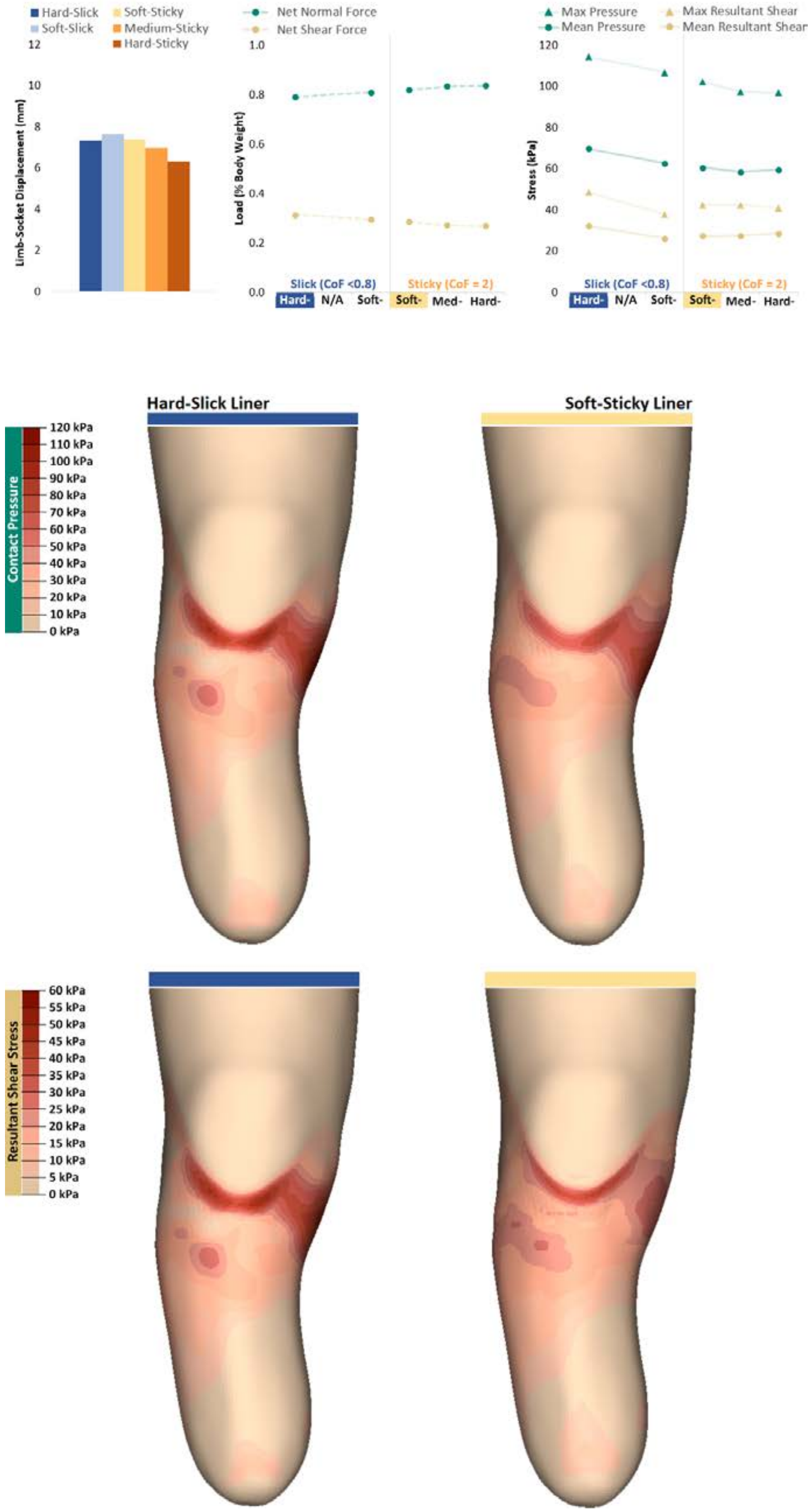

Figure 4.10: Participant two (uniaxial) – FEM output by liner product

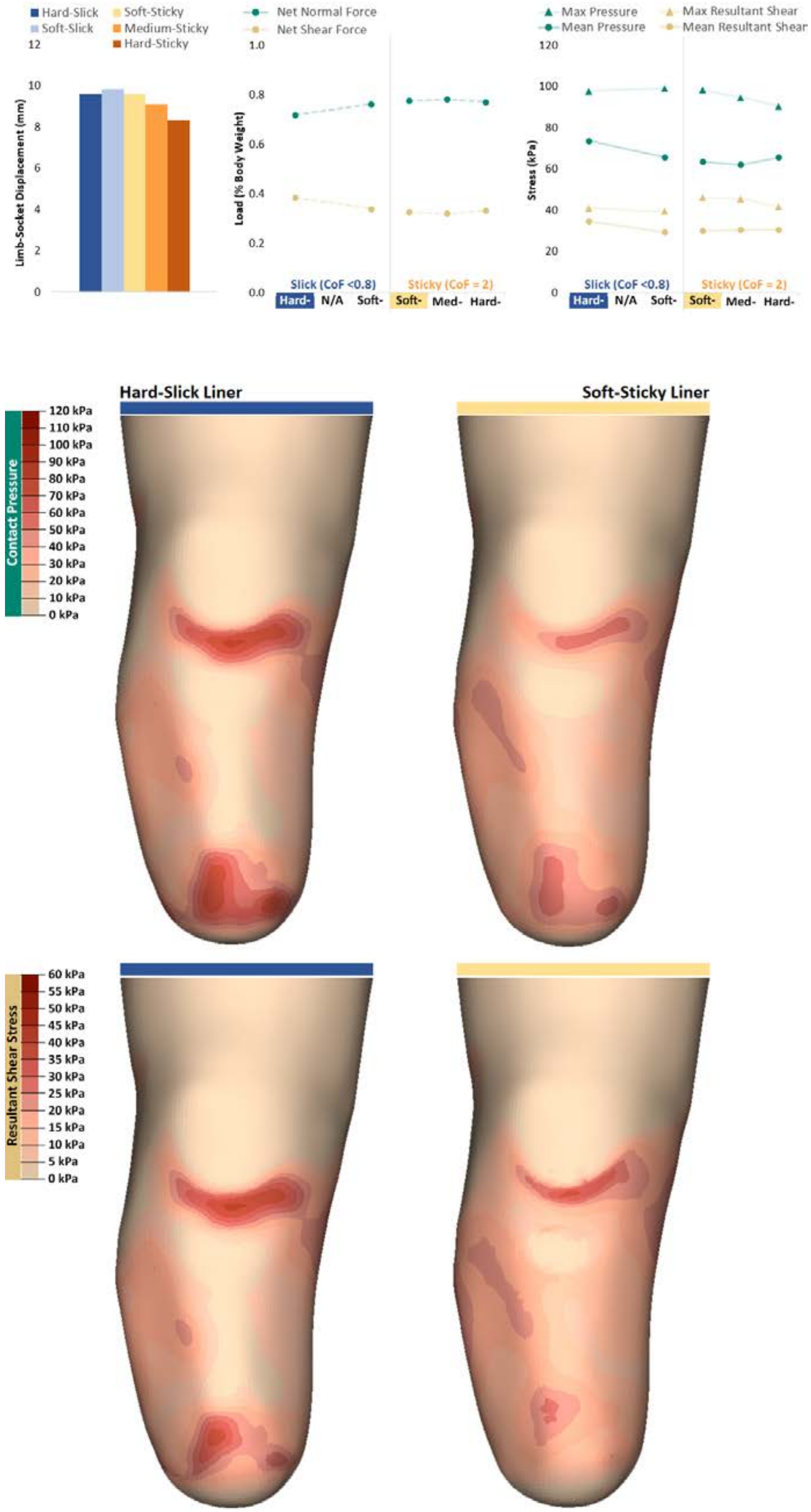

Figure 4.11: Participant three (uniaxial) – FEM output by liner product

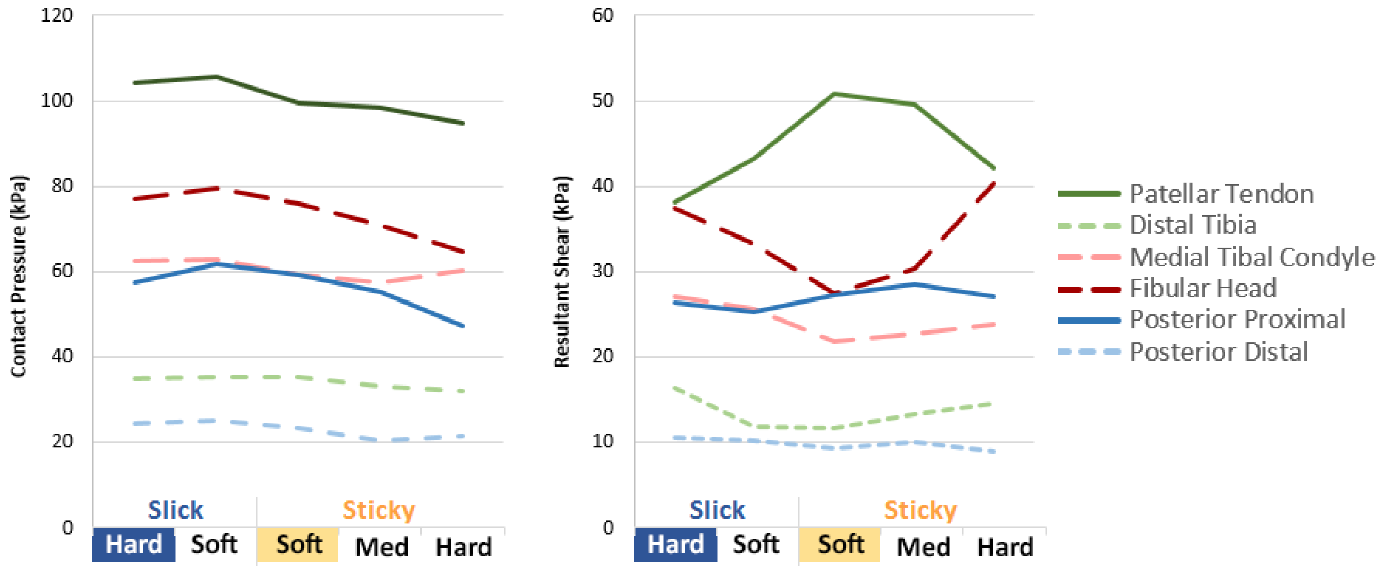

Figure 4.12: Participant one (compound) – stresses by location by liner product

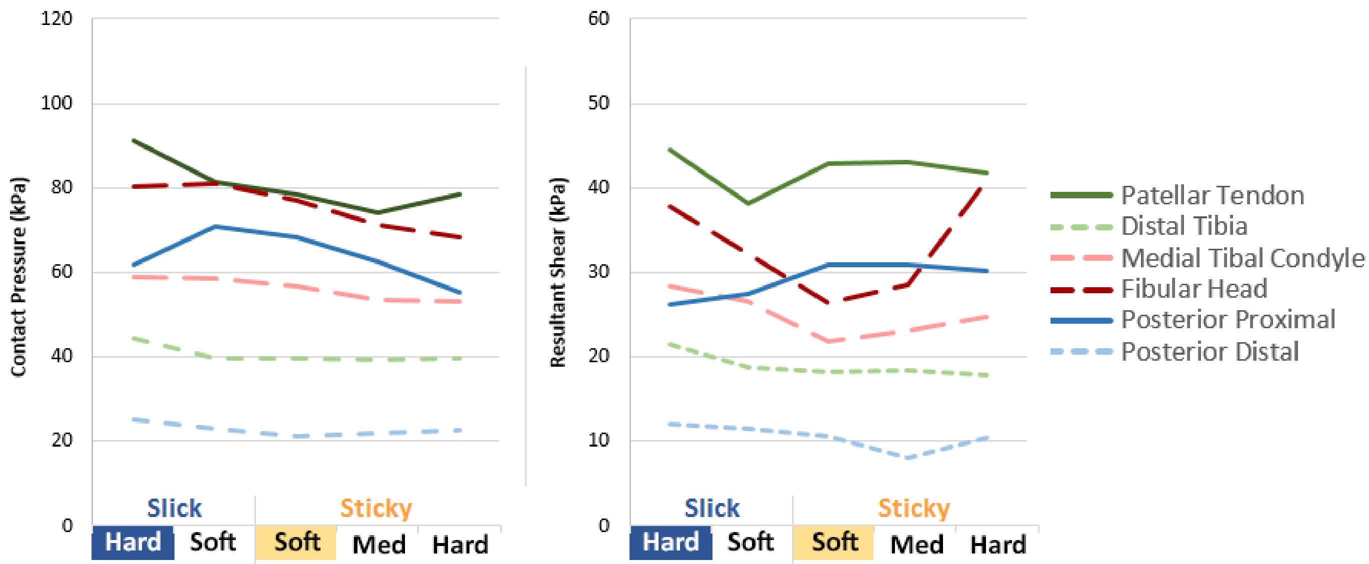

Figure 4.13: Participant one (uniaxial) – stresses by location by liner product

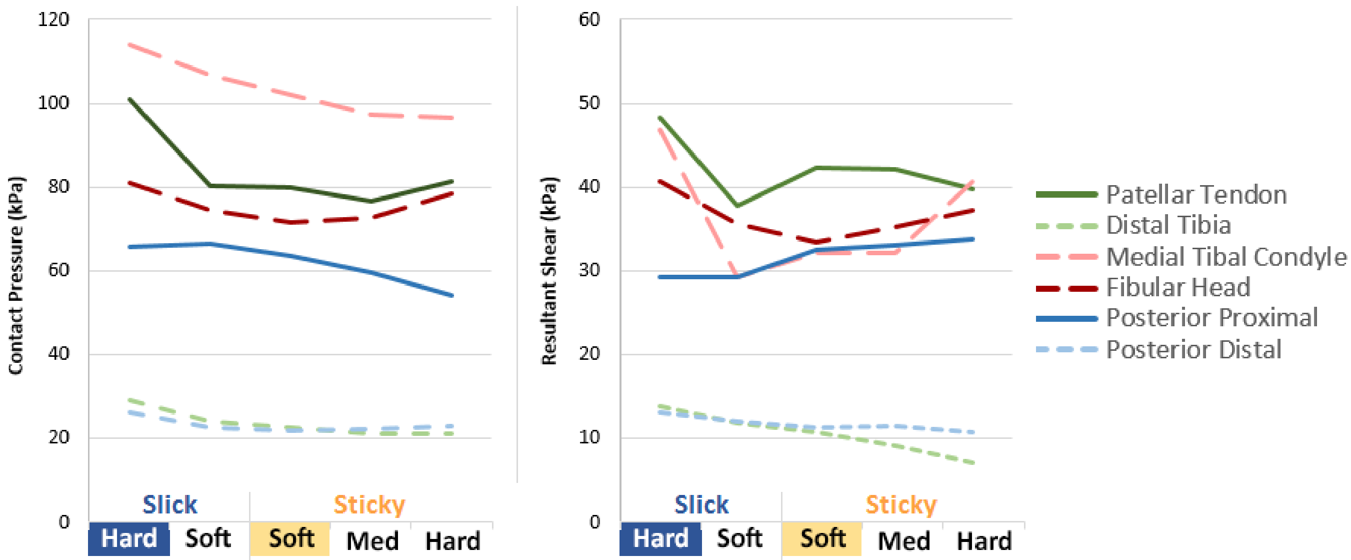

Figure 4.14: Participant two (uniaxial) – stresses by location by liner product

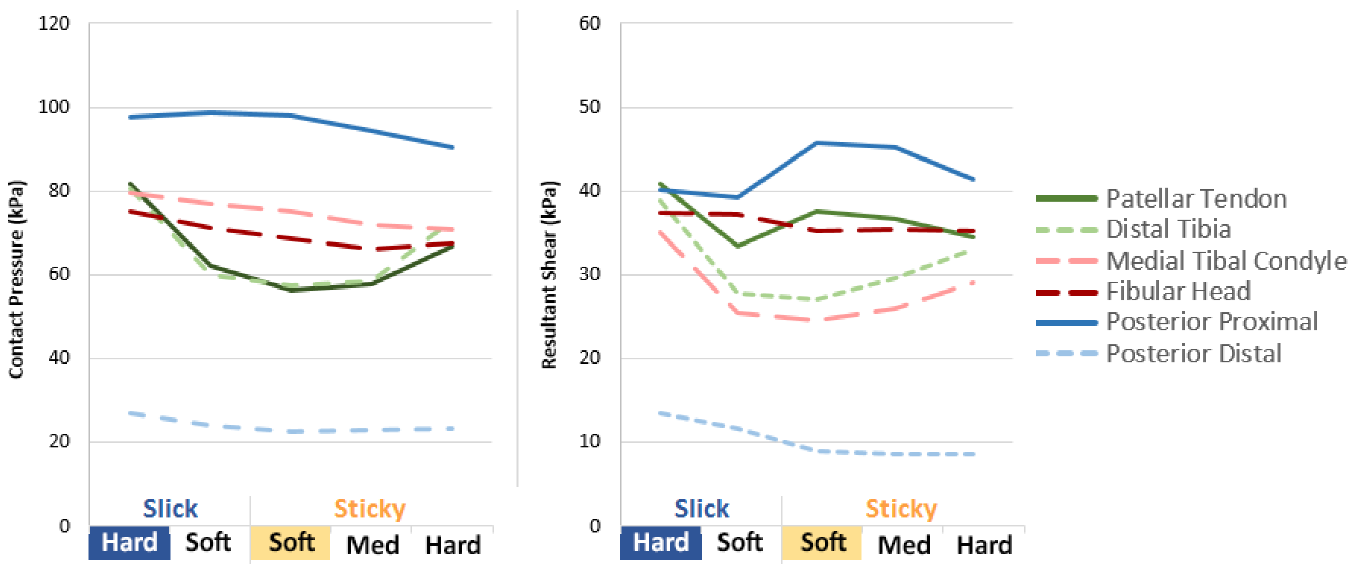

Figure 4.15: Participant three (uniaxial) – stresses by location by liner product

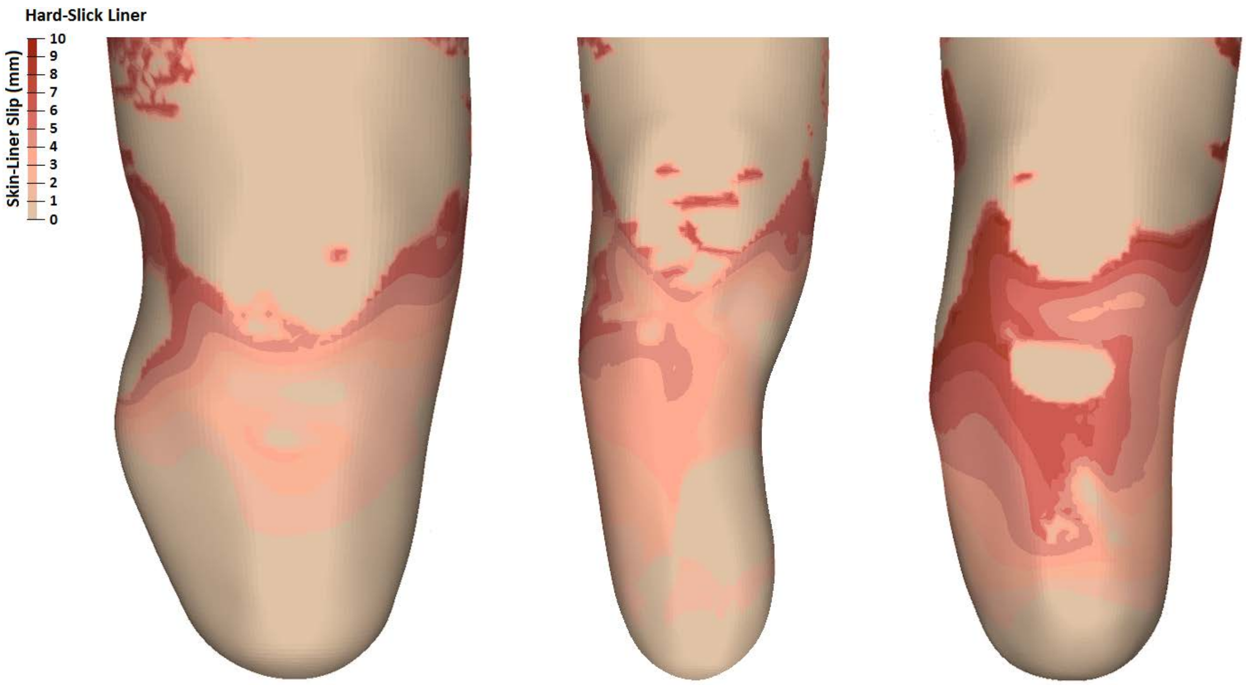

Figure 4.16: Skin-liner slip distance for the hard-slick liner product. The hard-slick liner resulted in the greatest slip, which occurred inside and outside the socket

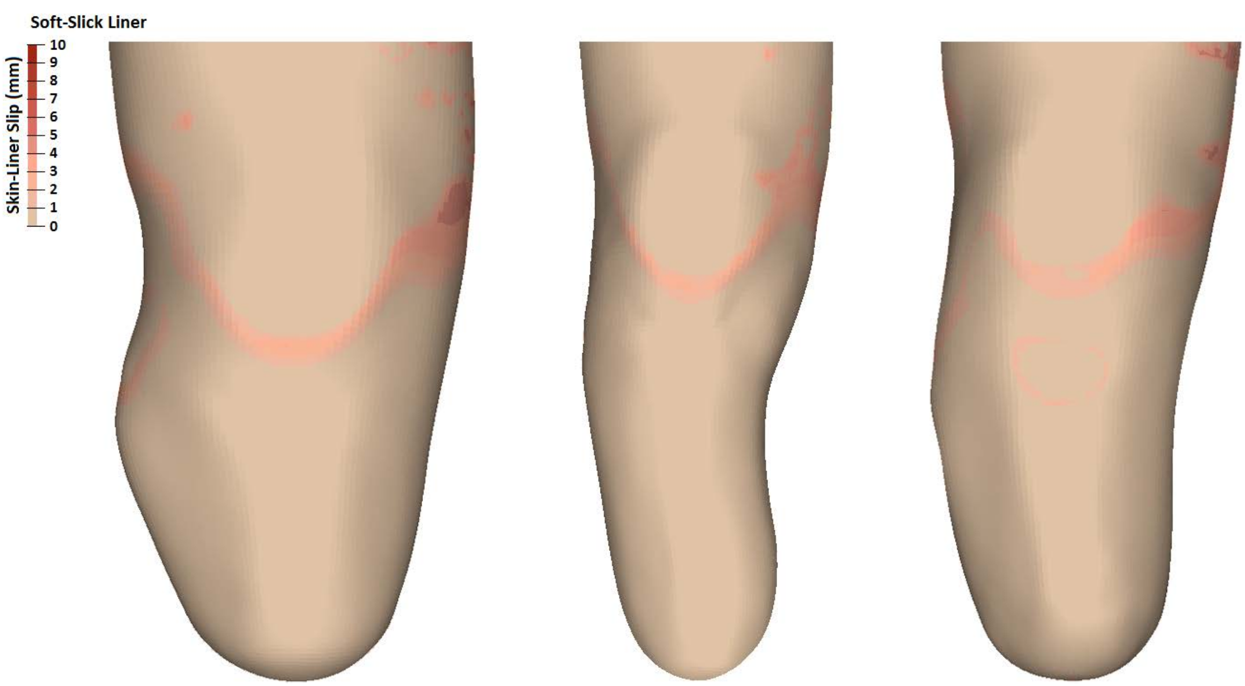

Figure 4.17: Skin-liner slip distance for the soft-slick liner product. The soft-slick liner was the only other liner product to produce slip, which occurred primarily on the brim of the socket.

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Chapter 5. CONCLUSIONS

5.1 RESEARCH SUMMARY

The research presented in this dissertation provides insight into the interface between a residual limb and prosthetic socket. A common point of focus across the four chapters was the objective evaluation of prosthetic liners with the end goal of creating a foundational knowledge base to improve clinical practice. This effort started with the measurement of liner performance, and the first chapter of this dissertation concentrated on the design of test protocols that produced accurate and repeatable measurements. The design of these protocols highlighted the number of confounding variables when measuring elastomer materials that are soft, non-linear, and incompressible. The developed protocols can be used to measure liner products with quantitative results that enable both clinical comparisons and mechanical analysis (FEM).

The second chapter in this dissertation evaluated 24 liner products across the six material property tests. The results from these tests were used to evaluate several core assumptions about the use of prosthetic liners in clinical practice. Most notably, liner properties were more specific to a product than may have been assumed in clinical practice. It was not typically possible to make generalizations about performance by the elastomeric base material; e.g., polyurethane liners were not always stiffer than silicone liners, and thermoplastic elastomer (TPE) liners did not flow more than polyurethane or silicone liners. Additionally, some of the contemporary materials used for fabric backings were shown to increase a liner’s compressive elasticity by up to 50% and significantly increase a liner’s tensile elasticity more than 200%. The variety in performance characteristics, and the inability to make generalizations about liner products performance by material, emphasizes the need for a quantitative method of comparison. A free and online tool called the Prosthetic Liner Assistant (PLA) (www.LinerAssist.org) was created to enable practitioners to identify liner products that meet patient specific needs.

The third chapter in this dissertation focused on the development and validation of a novel flexible finite element model (FEM). This was the first limb-socket FEM that evaluated a modern socket design with an elastomeric liner, and showed good agreement with measured limb-socket interface measurements reported in the literature. Further, the FEM results correlated with the locations of skin breakdown experienced by participants in their as-prescribed sockets. From a clinical perspective, the research investigated the viability of an ideal total surface bearing socket (TSB) and determined that it was not possible to have a uniformly distributed contact pressure over the load bearing region on the residual limb. This was in part because of focused stresses that occurred over thin layers of tissues covering bony features, and also because of overhanging contact surfaces that could not transmit compressive loads.

The final chapter in this dissertation applied the developed FEM to two clinical questions. Evaluation of limb volume fluctuations showed that a 1–2% change in socket size resulted in a 15–30% increase in interface stresses. A socket that was too small (enlarged limb) fit similarly to a poor TSB socket with elevated contact pressures over the whole limb. A socket that was too large (reduced limb) fit similarly to a poor patellar tendon bearing socket with focused contact pressures and resultant shear stresses. The evaluation of liner products showed that slick liners, with coefficients of friction (CoF) less than one were suited for achieving specific issues, while the differences between sticky liners were subtle and would likely require patient feedback. A soft and slick liner optimized comfort with the lowest resultant shear stresses, but potentially sacrificed stability with the greatest limb-socket displacement. A hard and slick liner resulted in the greatest contact pressures and resultant shear stresses, and this may explain why liner manufacturers recommend it use for patients with loose skin. Sticky liners, with CoFs greater than 2.0, resulted in the lowest contact pressures and reasonably low resultant shear stresses. While contact pressures and resultant shear stresses were generally low, no liner product was consistently lowest across the three participants. This indicated that the optimal stiffness for a sticky liner is patient-specific, and may explain why 70% of the liner products measured in chapter two could be classified as sticky.

5.2 Future Directions

The efforts to assess liner performance in this research started with the most objective and repeatable form of assessment, benchtop measurement. Future efforts would be ideally directed to improve clinical application and integration. From a clinical perspective, a prosthetist attempts to facilitate a patient’s ambulatory goals by finding a balance between a rigidly coupled prosthesis that instills a sense of stability and comfortable prosthesis that maintains a healthy limb. Clinical application could therefore be improved by associating benchtop measured material properties with patient outcome in a clinical setting. For example, it is not clear if increased adherence or increased tensile elasticity minimizes pistoning between the limb and socket. Further, it is not presently clear what combination of compressive elasticity, shear elasticity, and CoF are best suited for a limb with excessive scar tissue or for a bony limb with loose skin. Providing insight to these questions would add greatly to the clinical impact of this research.

Clinical integration could be improved through two avenues, practitioner training and an improved clinical interface. Appropriate use of the PLA requires a basic understanding of the mechanics of materials, a subject that is typically not taught to prosthetists in training. A dedicated course, such as a certified training module through the American Academy of Orthotists and Prosthetists, would likely improve use of the PLA. However, widespread use of the PLA is not anticipated unless the information it contains is presented in a format that minimizes practitioner effort. Clinical software packages such as OPIE (www.opiesoftware.com) allow practitioners to filter available products by fit and record the components selected for each patient. The increased personalization of patient care requires a practitioner to make more frequent decisions with a greater variety in results. This type of software helps to manage selection by enabling practitioners to only compare products that are compatible with a patient's prosthesis and quickly recall what has or has not worked. For a highly personalized process such as liner selection, clinical use would be anticipated to improve if the PLA database was integrated with OPIE or a similar software package.

Future research using the FEM could explore further clinical questions using the existing model or develop additional features to assess different socket scenarios. The existing model could be readily adapted to provide insight into different socket materials or to further address the issue of skin breakdown. For example, frictionally induced issues are commonly reported issues among people with transtibial amputation, and include abrasion (24%), blisters (30%), and calluses (23%) [1]. It would be anticipated that frictionally induced skin breakdown depends on more than slipping distance between the skin and liner, as reported in chapter four. Slipping that occurs under a greater pressure or stickier liner should be more damaging than slipping under lower pressures or with a slick liner. A potential metric to assess abrasion is frictional work[2], which can be directly calculated using the nodal output of the existing FEM [Figure 5.1].

Deep tissue injury occurs less frequently than skin breakdown[1, 3], and as the name suggests, is more dependent on internal stresses than contact pressures[4, 5]. Further, deep tissue injury should be more closely associated with a poorly fitting socket, while the existing FEM was based on reasonably well fitting sockets. A potential expansion to the existing FEM would be the inclusion of prosthetic socks, since the quantity of prosthetic socks is a clinical standard for adjusting fit[6, 7] and the basis for defining a poorly fitting socket that needs to be replaced. During chapter three, it was found that the simulated skin interface for a liner with a CoF of 2.0 or greater was nearly identical to a bonded contact. Additionally, 70% of the liner products tested on the clinical market had a CoF greater than 2.0. Therefore, the existing contact model could be simplified such that the skin-liner interface was bonded rather than frictional. This would exclude the evaluation of four liner products that are cumulatively in use by up to 20% of practitioners[8], but would potentially allow the evaluation of poorly fitting sockets with the addition of prosthetic socks. In contrast to the existing model that was optimized for skin interface, this model would be optimized to evaluate deep tissue stresses and movements (displacements and rotations) of the limb within the socket.

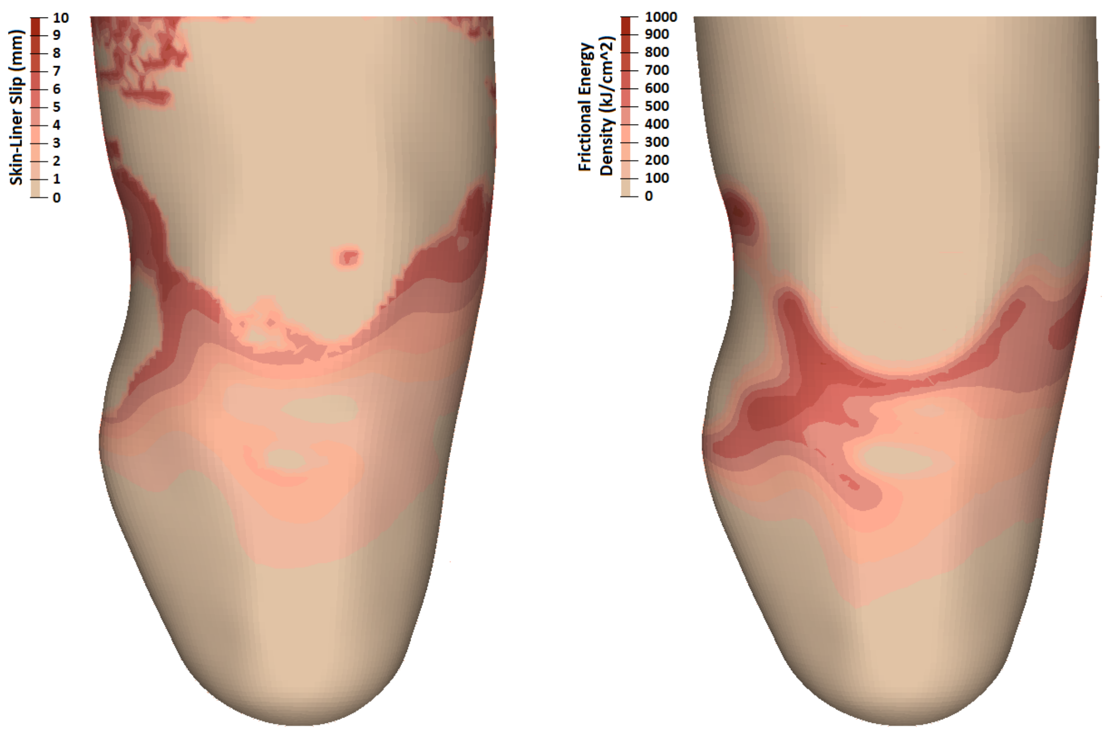

Figure 5.1: Skin-liner slip vs frictional work. The work performed by friction (right) may be better than resultant slip (left), because it takes into account slip distance, pressure, and coefficient of friction.

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VITA

JOHN C. CAGLE

Department of Bioengineering
Box 355061
3720 15th Ave NE
Seattle, WA 98195

Office Tel: (206) 221-5873
Email: jcagle@uw.edu

EDUCATION

Ph.D. in Bioengineering, University of Washington, Seattle, WA. December, 2016. Research interests: prosthetic interface mechanics, imaging, mechanics of materials.

Bachelor of Science, Mechanical Engineering, University of Denver, Denver, CO. June, 2006.

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