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A review of prosthetic interface stress investigations

M. Barbara Silver-Thorn, PhD; John W. Steege, MSME; Dudley S. Childress, PhD
Marquette University, Department of Biomedical Engineering, Milwaukee, WI 53201-1881; Northwestern University, Prosthetics Research Laboratory, Chicago, IL 60611-4496

Abstract—Over the last decade, numerous experimental and numerical analyses have been conducted to investigate the stress distribution between the residual limb and prosthetic socket of persons with lower limb amputation. The objectives of these analyses have been to improve our understanding of the residual limb/prosthetic socket system, to evaluate the influence of prosthetic design parameters and alignment variations on the interface stress distribution, and to evaluate prosthetic fit. The purpose of this paper is to summarize these experimental investigations and identify associated limitations. In addition, this paper presents an overview of various computer models used to investigate the residual limb interface, and discusses the differences and potential ramifications of the various modeling formulations. Finally, the potential and future applications of these experimental and numerical analyses in prosthetic design are presented.

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

INTRODUCTION

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

The soft tissues of the residual limb are not well-suited for load bearing, and the load tolerance of the residual limb depends on the biological and physiological structure of these tissues. Whenever tissues are exposed to excessive or prolonged loading, there is a risk of tissue trauma due to local circulatory deficits and/or abrasion. Thus, for persons with lower limb amputation, where large loads must be borne by the soft tissues, great care is taken in the design of the prosthetic socket to minimize discomfort and possible tissue trauma. Other areas of rehabilitation where soft tissues are exposed to load are subject to similar problems (seat cushion and mattress design for wheelchair and bedridden subjects, orthotic braces, orthopaedic walking casts, and pedorthics for individuals with insensate feet, for example). Nevertheless, although a review paper on interface stress has relevance to many areas, this paper will focus on soft tissue/support systems for persons with amputation.

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

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All terms in italics and followed by an asterisk (*) are defined in the Glossary at the end of this article.

Address all correspondence and requests for reprints to: M. Barbara Silver-Thorn, PhD, Marquette University, Department of Biomedical Engineering, Olin Building, Room 301, P.O. Box 1881, Milwaukee, WI 53201-1881; email: barbara@silver.bien.mu.edu

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

The fitting of a prosthesis is an empirical process. The prosthetist has no quantitative information regarding the load distribution of the soft tissues and must rely on what he/she has been taught and/or has experienced, feedback from the patient, and indirect indications of load (i.e., skin blanching) to gage socket fit. Knowledge of the interface stress distribution between the residual limb and the prosthetic socket would enable objective evaluation of prosthetic fit, and might advance prosthetic socket design through direct application of science and engineering.

It is this desire for quantitative description of prosthetic interface stress distribution that has motivated the experimental and numerical investigations summarized in this paper. The objective of this paper is to provide a summary of past work, to discuss the limitations and potential sources of error of such investigations, and to speculate on work made possible through advances in pressure/force transducer designs and/or computer hardware, computational methods, and computer software.

Experimental Analyses

Several groups have investigated the stress distribution between the residual limb and prosthetic socket for both persons with BK and above-knee (AK) amputation in laboratory and/or clinical settings. Various means of pressure measurement have been used to investigate the effects of prosthetic alignment, relative weight-bearing, muscle contraction, socket liners, and suspension mechanisms on the interface pressure distribution (**Table 1**, 1–27). Most experimental stress measurements have been limited to specific sites around the limb, as measurements can only be obtained at transducer locations. Note that for the purposes of this paper, pressure will be equated with normal stress, and shear will be equated with the tangential stresses. Therefore, complete description of the interface stress distribution includes both pressure and shear.

Direct comparison of the results of these experimental investigations is difficult, as the interface pressure measures are highly dependent on both the means of measurement (i.e., type of transducer) and the calibration method employed. The transducers developed by Sanders (20) and Williams et al. (6) are the only transducers that enable simultaneous measurement of pressure and shear stresses. Ferguson-Pell has reviewed several key factors in transducer use and selection relevant to stress measures between the soft tissues of the body and a support structure (28,29).

The majority of the interface pressure measuring techniques summarized in **Table 1** require fabrication of special sockets. These techniques have limitations in that the mounting of the pressure transducers in the socket requires that ports be tapped/drilled into the socket wall, permanently altering the prosthesis; the transducers are expensive; and the interface pressures are obtained for only a relatively small portion of the interface. In addition, many pneumatic transducers do not have sufficiently quick response to enable pressure measurement during dynamic loading (i.e., gait). Hydraulic sensors may be temperature sensitive and difficult to calibrate. The calibration of all of these transducers is critical to data analysis and interpretation. Transducers designed for hydrostatic/pneumatic applications, but subjected to mechanical load, need to be calibrated appropriately (12,13). Finally, because of the finite thickness of the transducer and/or stiffness incompatibility of the transducer and the interface materials, transducers placed between the residual limb and the prosthetic socket may create stress concentrations that result in measurement anomalies.

Recent commercial developments include systems to measure interface stresses for both seating and prosthetic systems. These systems were designed for routine clinical application, and thus do not require modification of the seat cushion and/or prosthetic socket.

Tekscan, Inc. (Boston, MA) markets several biomedical pressure measurement systems, including systems to analyze tooth pressure (dental occlusion), foot pressure (30), seat pressure, and hospital bed pressures. Each of these systems utilizes a grid-based sensor in which the rows and columns are separated by a polymer whose electrical resistance varies with force. These

Table 1.
Summary of experimental residual lower-limb interface pressure studies reported in the literature.

Investigation	Transducer type	Reference
quantification of prosthetic fit	dye-impregnated socks	(1) Meier et al.
	flexible force transducer	(1) Meier et al.
	hydraulic transducer	(2) VanPijkeren et al.
	hydraulic transducer	(3) Isherwood
	diaphragm transducer array	(4) Rae & Cockrell
prosthetic liner effects	diaphragm transducer array	(5) Sonck et al.
alignment variation effects	beam transducer	(6) Appoldt & Bennett
	diaphragm transducer	(6) Appoldt & Bennett
	diaphragm transducer	(7) Pearson et al.
load state variations	diaphragm transducer	(7) Pearson et al.
effects of muscle contraction	diaphragm transducer	(7) Pearson et al.
suspension effects	diaphragm transducer	(8) Burgess and Moore
	diaphragm transducer	(9) Chino et al.
finite element model validation	diaphragm transducer	(10) Steege et al.
		(11) Steege et al.
		(12) Steege & Childress
		(13) Steege & Childress
		(14) Brennan & Childress
		(15) Silver-Thorn
		(16) Silver-Thorn & Childress
		(17) Silver-Thorn et al.
		(18) Torres-Moreno et al.
	diaphragm/beam transducer	(19) Sanders
		(20) Sanders et al.
		(21) Sanders & Daly
		(22) Sanders et al.
		(23) Sanders & Daly
transducer protrusion	diaphragm transducer	(24) Appoldt et al.
dynamic loading	FSR (Tekscan)	(25) Springer & Engsberg
		(26) Engsberg et al.
		(27) Houston et al.

sensors have recently been incorporated into a prosthetic measuring system (26,27,31). None of these prosthetic investigations, however, discuss the calibration of the sensors, their accuracy, or other issues pertaining to their use.

The Socket Fitting System (R.G. Rincoe and Associates, Golden, CO) uses similar technology to enable investigation of prosthetic socket interface pressures (32). This commercial system allows measurement of the interface pressures without damage to the prosthetic socket. Although this system allows examination of a greater portion of the interface during a particular gait trial than prior research investigations, the accuracy and repeatability of these transducers have not been documented. In addition, data acquisition via this system is currently limited to three specific instances in the gait cycle: heel strike, mid-stance, and toe-off.

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Numerical Analyses

In contrast to the experimental techniques, computer models of the residual limb and prosthetic socket have the potential to estimate the interface pressures for the entire residuum, and indeed are not limited to the interface, but also can provide information regarding the subcutaneous stresses. Nola and Vistnes and Daniel et al. have found that initial pathological changes in pressure sore formation occur first in the muscle directly overlying the bone, and then spread outward toward the skin (33,34). Therefore, the subcutaneous stresses may be of importance in evaluating long-term prosthetic success. As current measuring techniques disrupt the very stress distribution that is of interest, these subcutaneous stresses are particularly difficult to measure *in vivo*.

Several groups have used computer models of the residual limb to investigate the residual limb/prosthetic socket interface. Nissan used a simplified three-dimensional (3-D) biomechanical model of the short BK residual limb to investigate the effects of load transmission area, tibial geometry, and the role of the fibula on the forces and moments exerted on the residual limb (35). Winarski et al. attempted to correlate prosthesis loads to interface stresses at the patellar tendon and gastrocnemius areas as a function of the flexion/extension angular alignment for persons with BK amputation (36).

Many investigators have also used finite element (FE) modeling of the residual limb and the prosthetic socket of persons with lower limb amputation to investigate residual limb/prosthetic socket biomechanics, and to estimate the interface pressure distributions. In fact, during the past 10 years, computer models of the residual limb and prosthetic socket have primarily involved FE analysis. For this reason, the FE method and the various formulations that have been utilized in these prosthetic analyses will be reviewed in detail.

Introduction to the FE Method

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

The FE method is an approximate solution method whereby a complex structure is discretized, or divided, into a number of regularly shaped pieces, known as elements. Each element is defined by several nodes, or points, the coordinates of which establish the geometry of the structure. The behavior of the complex structure is then approximated as the sum of the respective responses of each of the regularly shaped elements.

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

Overview of FE Modeling Formulations for the Lower Limb Residual Limb

Complete FE model description requires the geometry, material properties, load state, and boundary conditions of the model (**Figure 1**). As prosthetic FE models have been based on various sources of such information, and various formulations, each of these facets of FE model description will be discussed with respect to past, present, and future models of the residual limb/prosthetic socket system. Many options exist, and the selection of specific formulations is dependent upon and/or influenced by the underlying purpose of the investigation.

Terms identified by asterisks in the following discussion are defined in the Glossary.

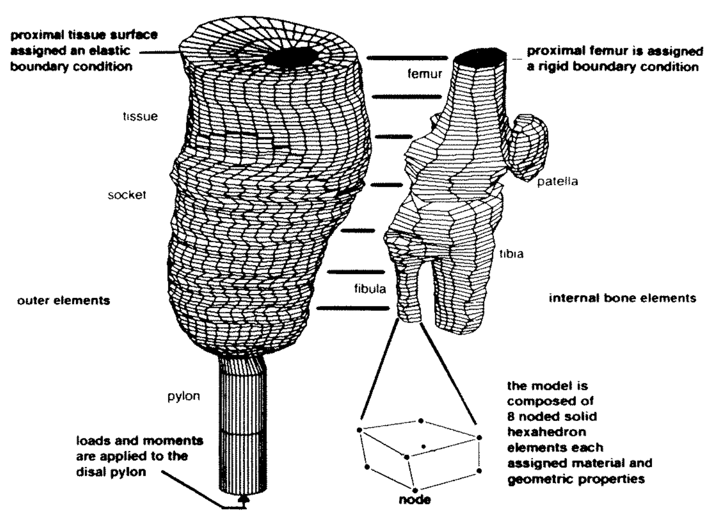

Figure 1.
Sample FE model of a BK residual limb and prosthetic socket, illustrating key parameters in the model: limb geometry as defined by the nodal coordinates and the element connectivity, material property description for all elements, boundary conditions and loading.

Model Geometry

Type of Analysis. FE analysis of the lower residual limb has generally involved either two-dimensional (2-D, *axisymmetric**) or 3-D models. Although neither the BK nor AK residual limbs are axisymmetric, 2-D modeling enables preliminary analysis that may indicate the relative importance of certain modeling parameters. However, 2-D analysis has limited applicability in furthering prosthetic socket design, as the axisymmetric geometry approximation limits application of realistic prosthetic socket rectifications. More complex 3-D analyses usually follow 2-D analysis. These models typically require additional memory and computer run-time due to the more complex representation of limb geometry and the increased number of *degrees of freedom**, but 3-D analysis enables more accurate representation of residual limb geometry and prosthetic socket shape.

Whether performing 2- or 3-D analysis, care must be taken to avoid *warped** and *skewed* elements**, and high *aspect ratios**, all of which may contribute to computational errors in the analyses. Both linear and higher order elements have been used in these FE models.

Source of Geometric Data

Data describing the geometry of the residual limb have been based on the literature and non-contact and/or contact methods such that either surface geometry only, or surface and internal (i.e., bone) geometry was obtained.

Literature-based anthropometric data is generic and not individually specific. Such data can be scaled for particular individuals. This data source will likely miss subtle variations in residual limb geometry that may have a significant role in prosthetic fit. Thus, anthropometric models may be most appropriate for parametric studies and/or qualitative analysis.

Non-contact methods of shape sensing have included traditional computer-aided design, computer-aided manufacture (CAD-CAM) optical surface methods (laser scanners and Moire contours) as well as volumetric imaging methods: X-ray, computed axial tomography (CAT or CT scans), magnetic resonance imaging (MRI), and ultrasonic methods as shown in **Table 2** (37–46). These volumetric imaging techniques, which quantify both the internal and surface geometry of the residual limb, have been the primary non-contact method used in FE limb models. Ultrasound, CT, and especially MRI data allow identification of individual structures within the soft tissue bulk, and may enable more complex representation of residual limb soft tissues.

Imaging data, however, may also be subject to several limitations.

1. Imaging data is subject specific, and thus must be obtained and digitized for each individual. Thus, imaging techniques, and the subsequent digitization required for model incorporation, may be more time-consuming and expensive than other approaches.
2. CT and X-ray techniques expose the subject to ionizing radiation.
3. X-ray data is 2-D (planar projection of 3-D data); a minimum of two views are necessary for 3-D approximation of limb geometry. 3-D extrapolation of this data may be subject to large errors.
4. Identification of the prosthetic socket/residual limb/bone boundaries in X-ray, CT, and/or MRI scans may require sophisticated image processing techniques.
5. Many of these imaging techniques require that the patient be supine or prone during data acquisition. As a result, the tissue geometry obtained may be dependent upon body position within the gravitational field.

In contrast to these non-contact methods, contact methods are an atypical source of FE geometry for residual limb models, but they are the most common shape-sensing techniques used in CAD-CAM in prosthetics today. In general, contact methods of shape sensing are susceptible to errors due to soft tissue deformation associated with casting and/or caliper measurements. These methods include: mechanical digitization of a prosthetic wrap cast (UCL CASD, Seattle ShapeMaker), reference model selection, and scaling based upon antero-posterior and medial-lateral measurements via calipers and circumferential measurements using a tape measure (MERU, University of British Columbia).

Material Properties

The material properties of all of the structures included in the FE model must be estimated and assigned to the respective elements. The source of these estimates has been the literature, materials testing, and/or *in vivo* or *in vitro* studies. In general, these materials have been modeled as linear and nonlinear elastic *isotropic** materials. In addition, both small and

Table 2.

Summary of residual limb and/or prosthetic socket models reported in the literature.

						Geometry		Loading		Material Properties													Max PRS
										Bone			o Soft Tissue • skin/fat x muscle + cartilage					o Socket • liner x pylon					
Reference	Kind	#	VLD	Code	Size	type	SRC	type	SRC	type	E MPa	v		type	E KPa	v	SRC		type	E MPa	v	SRC	KPa
Steege (11-13)	ANL	1-BK	PRS	SAPIV	1282 ND 1017 EL	3D SD	CT	STC	FP	8 ND HX	n/s	n/s	o	8 ND HX	60	n/s	IND	•	ES	.38	n/a	EXP	90
(13,14)	ANL	2-BK	PRS	GIFTS MARC	1976 ND 1578 EL	3D SD	CT	STC	FP	8 ND HX	1.6	.28	o +	8 ND HX 8 ND HX	60 790	.49 .49	IND LIT	•	8 ND HX	.38	n/s	EXP	300
(13,14)	FND	IDL	NO	MARC	120 EL	3D LD	IDL	STC	IDL	8 ND HX	1.6	.28	o	9 ND IN	NL	NL	LIT	•	EF	.38	n/a	EXP	40
(57)	FND	IDL	NO	MARC	13362 ND 11676 EL	3D SD	CT / LIT	QSI	LIT	8 ND HX	10 - 1500	.28	o +	8 ND CD 8 ND CD	2.6 - 96 100	.499 .499	LIT IDL	o x	8 ND HX 8 ND HX	1-2100 7000	.28 .28	LIT LIT	200
Reynolds (53)	FND	IDL	PRS	PAFEC	970 EL	AX	IDL	DSP	CAD/ IDL	DSP BC	n/a	n/a	o	20 ND AX	170	.45	IND	o	SLIP, RGD & DSP BC	n/a	n/a	CAD	370
(53,54)	PRM	1-BK	NO	PAFEC	1458 ND 972 EL 3500 DF	3D SD	XRY & MDG	DSP	CAD/ IDL	RGD BC	n/a	n/a	o	8 ND HX	50 - 145	.45	IND	o	DSP BC	n/a	n/a	CAD	287
Silver-Thorn (16,17)	FND	3-BK	PRS	MARC	2221 ND 1688 EL	3D SD	CT / LIT	DSP STC	CAD FP	RGD BC	n/a	n/a	0	8 ND HX	.6 - 176	.45	IND/ LIT	o •	8 ND HX 8 ND HX	1500 .38	.30 .45	IND LIT	276
(59)	PRM	3-BK	PRS	MARC	2400 ND 2000 EL	3D SD	LIT/ IDL	STC	FP	RGD BC	n/a	n/a	o	8 ND CD	20 - 180	.45 - .499	LIT	o •	8 ND HX 8 ND HX	5-45K .1-1.1	.30 .45	LIT LIT	1700
Quesada (58)	PRM	IDL	NO	SAP80	636 ND 655 EL	3D SD	MDG	STC HS	IDL/ LIT	n/a	n/a	n/a	o	2 ND ES	247 - 2490	n/a	LIT	o	4 ND SH	14000	.13	LIT	463 - 961
Sanders (20,24)	ANL	1-BK	PRS & SHR	ANSYS	795 ND 840 EL	3D SD	MRI	QSI	SG	RGD BC	n/a	n/a	o x	8 ND HX 8 ND HX	3.5-6.9 131	.49 .49	LIT LIT	o • x	4 ND QD 8 ND HX beam	n/s 1.8 n/s	n/s .39 n/s	n/s EXP n/s	90
Krouskop (61)	FND	1-AK	NO	ANSYS	287 EL	3D SD	LIT	LIT/ USD	IDL	8 ND HX	n/s	n/s	o	8 ND HX	n/s	n/s	USD	o	not modeled	n/a	n/a	n/a	n/a
(62)	CAD	3-AK	CAD	ANSYS	n/s	3D SD	MDG	PRS	IDL	RGD BC	n/a	n/a	o	8 ND HX	53 - 141	n/s	USD	o	PRS BC	n/a	n/a	IDL	n/a
(63)	CAD	2-AK	CAD	ANSYS	~ 720 EL	3D SD	MDG	PRS	IDL	RGD BC	n/a	n/a	o	8 ND HX	5 - 10	n/s	USD	o	PRS BC	n/a	n/a	IDL	n/a
Seguchi (65)	ANL	1-AK	SG	ANSYS -PC	683 ND 694 EL	3D SD	CT	STC	IDL	n/a	n/a	n/a		n/a	n/a	n/a	n/a	o	4 ND SH	n/s	n/s	LIT	n/a
Brennan (15)	PRM	1-AK	PRS	MARC	3458 ND 2673 EL	3D SD	CT / IDL	STC	IDL	8 ND HX	1.6	.28	o	8 ND CD	60	.49	LIT	o	DSP BC	n/a	n/a	CAD	150
Torres-Moreno (19,49)	ANL	1-AK	PRS	ABA- QUS	1962 ND 2628 EL 7884 DF	3D LD	MRI	DSP & PRS	EXP	HX	n/s	n/s	o x	6 ND IN 6 ND IN	27-146 n/s	.4999	IND	o	DSP BC	n/a	n/a	n/s	97
Mak (64)	FND	1-AK	NO	NISA II	60 AX 960 EL	AX 3D	IDL CT	n/s	n/s	RGD BC	n/a	n/a	o	4 ND AX 8 ND HX	n/s	n/s	n/s	o	RGD BC	n/a	n/a	n/s	n/s
Vannah (47,48)	FND	IDL	NO	MARC	108AX	AX	IDL	DSP	IDL	RGD BC	n/a	n/a	o	4 ND IN	20.7	.45 - .50	IND	o	not modeled	n/a	n/a	n/a	n/a

KEY: AK=above-knee amputee, ANL=analytical, AX=axisymmetric model, BC=boundary condition, BK=below-knee amputee, CAD=computer aided design, CD=constant dilitation, CT=computer aided tomography, DF=degrees of freedom, DSP=displacement, E=Young's modulus, EF=elastic foundation, ES=elastic spring elements, EXP=experimental methods, FND=fundamental, FP=force plate, HS=heel strike, HX=solid hexahedron element, IDL=idealized, IN=incompressible, IND=indentor tests, LD=large displacement, LIT=literature, MDG=mechanical digitization, MRI=magnetic resonance imaging, ND=node, NL=nonlinear, PRM=parametric, PRS=pressure, QD=quadrilateral, QSI=quasi-static, RGD=rigid, SD=small deformations, SG=strain gage, SHL=shell element, SHR=shear, SLIP=slip allowed at interface, STC=static load, USD=ultrasounic method, v=Poisson's ratio, XRY=X-ray, n/a=not applicable, n/s=not stated.

*large displacement** formulations have been attempted. Such complexity may be required for soft tissues and/or prosthetic materials that undergo significant deformation under load. Variations in FE material property description will be discussed with respect to the specific structures/materials commonly included in residual limb/prosthetic socket models.

Prosthetic Socket and Liner

The prosthetic socket is typically composed of a relatively stiff material, such as polypropylene or polyester, and is approximately 3 to 6 mm thick. The prosthetic socket has been explicitly modeled as:

- elements
- elastic foundations or springs
- a rigid kinematic boundary.

Modeling the prosthetic socket as elements requires material property description. For example, if the prosthetic socket is assumed to be a linearly elastic isotropic *homogeneous** material, material property description includes specification of *Young's modulus** and *Poisson's ratio**. Elastic foundations and springs require material property description in terms of force/area or force/length, respectively. The use of elastic foundations and springs reduces the number of unknowns in the model (i.e., there are fewer elements/nodes), but is limited in that the stress distribution in the prosthetic socket cannot be calculated. In addition, application of various prosthetic rectification schemes may be difficult to simulate. Finally, the prosthetic socket has been modeled as a rigid boundary via prescribed nodal displacements. This formulation allows application of prosthetic rectification schemes, but again neglects internal socket stresses.

The FE model may also include a soft liner, which has been similarly modeled as elements, elastic foundations, and/or linear springs.

Bone (Hard Tissue)

The bony structures of the residual limb also need to be incorporated in the FE model. In general, bone has been modeled in one of two ways, either as elements with properties estimated by literature values cited for compact and/or cancellous bone, or as a fixed internal boundary, since bone is several orders of magnitude stiffer than soft tissue. By representing the bony structures of the residual limb with elements, FE analysis can be used to obtain estimates of bony stresses, motion of the bony structures with respect to one another, and bone motion within the soft tissue bulk. The latter formulation, a kinematic boundary, is less informative but results in a model with fewer degrees of freedom, thus requiring less computer memory.

Soft Tissue

The soft tissue (muscle, skin, fat, ligaments, and tendons) of the residual limb is neither homogeneous nor isotropic. However, incorporation of homogeneous and isotropic material property assumptions greatly reduces the complexity of the model. Consequently, although many of the investigators in this field have speculated that precise representation of the tissue properties is critical to model accuracy, the soft tissue has typically been assumed to be an elastic, isotropic, homogeneous material (14,16,17,19,47). Properties of soft tissue have been estimated from literature data, or experimentally evaluated using *in vivo* indentor studies of the residual limb (11,16,47–54).

The use of ultrasound, CT, or especially MRI data provides the capability of explicitly modeling the individual structures of fat, muscle, and skin. However, if the model is to include such detail, these structures must be identified as specific elements, and the material properties of these respective elements must be estimated and assigned. Current models have yet to include these structural complexities to any great degree.

An additional complexity of bulk soft tissue is that it is believed to behave as a nearly *incompressible** material. This near incompressibility has been approximated by several methods:

1. linear elastic formulations with Poisson's ratio, ν, approaching 0.5
2. constant *dilatation** formulations in which soft tissue is assumed to be incompressible on an element basis
3. nonlinear *elastomeric** formulations that utilize various forms of the strain energy equation (Mooney or Jamus-Green-Simpson formulations).

The first of these formulations, a linear elastic representation of bulk soft tissue, may result in artificially stiff behavior due to limits of displacement method FE analysis. To avoid this anomaly, reduced integration elements may be used (55). The constant dilatation formulation requires the introduction of a pressure parameter which is equivalent to hydrostatic pressure in the limit of incompressibility (55). This additional parameter, which can be thought of as a Lagrange multiplier, is incorporated as an additional node per element. Therefore, this method results in increased complexity of the FE model, and requires additional computer memory due to the increase in the number of degrees of freedom per element. The elastomeric formulations, defined by the strain energy equation, involve functions of the strain invariants. This method has seen limited use in FE limb models, as the constant coefficients in the strain energy equations are not known, and the relationship between these coefficients and the elastic moduli is not explicit (14,47,48). Most FE limb models have incorporated linear elastic formulations, $0.45<v<0.49$, due to the simplicity of this formulation.

A final complexity of bulk soft tissue is its viscoelasticity and dependence on load history. Bulk soft tissue, like its individual components, is believed to be a viscoelastic material. Thus, its behavior, or response to loading, is dependent on the load rate and the preconditioning of the tissue. Bulk soft tissue is expected to demonstrate hysteresis upon loading/unloading, and exhibit stress relaxation and creep. The preconditioning of such tissues illustrates the dependence of the tissues' current loading response to prior loading. As yet, these phenomena have not been incorporated in residual limb FE models.

Load State

The load state of these FE residual limb models has been either static or pseudo-static. In general, prior analyses have concentrated on static loading, or stance, and pseudo-static approximations of gait. These load states have typically been based on data obtained from force plates or other force transducers during studies of amputee gait and/or balance, subject to alignment variations. The loading has been applied to the elements/nodes of the bone, although models which represent the bony structures of the residual limb as a fixed boundary have applied load to the distal nodes of the prosthetic socket.

For a linear model, superposition is valid. Therefore, the analysis of various load states for linear models may be approximated as the sum of prior analyses of simplified load components. For example, the initial stress state due to prosthetic socket rectification may be summed with the results of static loading.

Dynamic analysis introduces many additional parameters, such as time-load increments and numerical integration methods, that may greatly complicate the analysis and influence model stability. Such analysis may also necessitate the inclusion of *viscoelastic** phenomenon. Currently, all dynamic loading has consisted of pseudo-static analysis, which may be approximated as a series of superposed load steps.

Boundary Conditions

The boundary conditions of the reported residual limb models range from simple to complex. The simplest formulations assume total contact between the bone/soft tissue, soft tissue/prosthetic liner, and prosthetic liner/socket interfaces. More complex formulations allow time-varying boundary conditions.

The preceding section on prosthetic sockets indicated that the socket interface has been approximated as an elastic foundation or as elastic springs. These investigations of the residual limb/prosthetic socket interface only report normal stresses (pressures) at the interface, and ignore, due to the total contact condition, the shear stresses. While deformation of the limb is allowed along the socket wall, slip cannot be computed with these FE models (i.e., the models assume infinite friction).

In addition, tensile normal stresses may develop at the residual limb surface in the FE models. As tension cannot exist to any great extent between a limb and a socket, the existence of tension in FE models may be counter-intuitive. Therefore, attempts have been made to reduce these tensile stresses through various iterative means.

Finally, more complicated formulations, which model the structures as deformable and rigid bodies, allow the influence of contact and slip/friction to be investigated. However, such formulations increase the complexity of the model, as every increment must be analyzed to determine whether contact has been made, or broken, between the respective bodies. The ability of commercial FE software to perform 3-D contact analysis is a relatively recent development, and residual limb models are only now being developed that incorporate this method of analysis.

Specific Residual Limb FEMs

A number of investigations of the residual limb/prosthetic socket system have been carried out using FE analysis methods, and these approaches are reviewed in the following paragraphs. Special attention is given to the FE formulation parameters, and the potential effects these parameters have on model output. The formulation parameters of the respective models are summarized in **Table 2.**

Steege et al. were the first to model the residual limb and prosthetic socket system for persons with BK amputation (11,12). Their work included both FE analysis of the residual limb and prosthetic socket, and experimental verification of local interface pressures for two individuals with BK amputation. The internal and external geometry of the residual limbs was based on transverse CT scans of the residual limb and unrectified prosthetic socket. The soft tissue was assumed to be a homogeneous, linearly elastic, isotropic material, and the value of Young's modulus (E=60 kPa) was based on the mean results of *in vivo* indentor studies of the soft tissues of the residual limb at several locations. The material properties of the bone, cartilage, and patellar tendon were based on the literature. The load state for these analyses and for the pressure measurements was static double support stance. In the initial FE analyses, the range of estimated pressures was 0–105 kPa. More recently, Steege et al. have reported using FE analysis to design BK prosthetic sockets, as well as performing quasi-static analysis based upon dynamic gait data (56,57)

Reynolds (53) and Reynolds and Lord (54) also attempted to estimate BK prosthetic interface pressures. Initial parametric analyses, investigating the effects of friction, material properties, and socket design, were conducted for a 2-D, axisymmetric FE approximation of the BK residual limb. Verification of the interface pressure estimates was performed using a physical model of this axisymmetric approximation of the residual limb. These analyses were of limited clinical value, since the actual geometry of the residual limb was poorly represented, and the imposed socket rectification schemes were highly artificial. Reynolds then developed and analyzed a 3-D model of the BK residual limb based on radiographic data. The properties of the bulk soft tissue were assumed to be linear, with local Young's moduli based on *in vivo* indentor tests at four sites on the residual limb (50–145 kPa). Analyses were performed for various socket rectification schemes and for various material property approximations of bulk soft tissue for static, double support loading. Pressures ranged from 0 to 200 kPa for the nominal limb model. No verification/validation of the 3-D model was performed.

Sanders (20) and Sanders and Daly (22,24) investigated BK interface pressures using both 3-D linear FE analysis of the residual limb and prosthetic socket, and experimental measurement of interface stresses. Sanders' work differed from previous research in that: 1) stress measurements included both normal (pressure) and shear stress, 2) the load state for the FE model was dynamic (i.e., quasi-static representations of gait), 3) the residual limb geometry was based upon MR images, and 4) the FE model approximated bulk soft tissue as a combination of skin/fat and muscle.

Quesada and Skinner used FE analysis of a PTB prosthesis to investigate variations in prosthesis design on the interface stress distribution at heel strike (58). These models approximated the bulk soft tissue of the residual limb as parallel (skin) and perpendicular (compressive tissue) linear springs attached to the socket wall. The normal stresses estimated with this model ranged from 0 to 961 kPa; the shear stresses ranged from 0 to 463 kPa. The stresses estimated at the distal anterior end of the residual limb/socket (961 kPa normal stress, 463 kPa shear stress) were considerably higher than the stresses predicted for the remainder of the limb/socket. No verification of the model has been reported.

Silver-Thorn (16) and Silver-Thorn and Childress (17,59) created a FE model of the BK residual limb and prosthetic socket to investigate the effects of parameter variations on the interface pressure distribution during static stance. The geometry of both the residual limb and prosthetic socket in this model were approximated by standard geometric shapes, the size and selection of which were based on available anthropometric data. The femur, tibia, fibula, and patella, as well as the articular cartilage of the knee joint, were modeled as a fixed internal boundary. For the parametric studies, the soft tissue, assumed to be isotropic, linearly elastic, and homogeneous, was assigned a Young's modulus of 60 kPa (Poisson's ratio=0.45). The prosthetic socket and liner were modeled as elements, the material properties of which were based on the literature. The load state "double support" stance, was applied to the distal end of the socket. Parametric analyses were performed to investigate the effects of variations in: 1) the material properties of the residual limb, prosthetic liner, and prosthetic socket; 2) the internal and external geometry of the residual limb; and 3) the prosthetic socket rectification scheme. Analyses were conducted for a person with BK amputation for both unrectified and PTB rectified socket designs. The ability of this generic geometric FE model to estimate prosthetic interface pressures was evaluated based upon comparison of the FE interface pressures (individually scaled models) to that measured for three people with BK amputation in a variety of socket designs and static load/alignment states (16,17,56).

Krouskop et al. were the first to make use of the FE method as a CAD tool for AK prosthetic sockets (60–62). After evaluating the surface geometry of the residual limb through a contact method using two diametrically opposed contracting/retracting probes, ultrasound was used to obtain average local material properties. A generic FE model was then scaled appropriately for the subject's surface geometry, and the local material properties were assigned to respective linear elastic 3-D elements. A static loading function, based on average interface pressure profiles measured for subjects wearing comfortable quadrilateral-brim AK prostheses was imposed. The FE model was then used to predict the shape of the loaded limb such that the desired pressure profile would be obtained. This rectified socket geometry was then carved on a computer numerically carved (CNC) milling machine, and the proposed socket was subsequently vacuum formed. Krouskop reported the successful fitting of two persons with AK amputation using this methodology.

Research has also been conducted using FE analysis to study the interface pressure distribution for persons with AK amputation. The models developed by Brennan and Childress (15), Torres-Moreno et al. (19), and Mak et al. (63) are similar to the FE models for BK residual limbs and sockets mentioned previously. The model developed by Seguchi et al. was novel (64). Seguchi avoided characterization of the mechanical properties of bulk soft tissue by modeling only the acrylic socket. As this problem is underdefined, the complementary energy criterion was used to search for the most plausible interface pressure distribution. The FE model was based on transverse CT scans of the socket, and consisted of thin quadrilateral shell elements. The static response of the socket was investigated for two hypothetical load cases: 1) uniform contact pressure along the interior surface of the socket, and 2) weight fully supported at the ischial seat. Experimental verification of both the model and the method consisted of circumferential strain measurements during point loading on the anterior and posterior walls of the socket. The clinical value of such a model is questionable, however, as the model ignores residual limb geometry and bone-soft tissue interactions.

SUMMARY

Many of the interface pressure measurement techniques involve research applications and methodologies that are not appropriate for routine clinical use. However, the development of commercial systems using thin force sensitive resistive materials to measure interface pressures/stresses for both seating systems and prosthetic sockets may provide a diagnostic tool that can be readily incorporated into prosthetic fitting. These systems have clinical potential and may facilitate creation of prosthetic pressure databases such that interface pressures, whether measured in research settings, clinical settings, or estimated with computer models, may be properly interpreted.

We believe that the two greatest limitations in current modeling efforts involve the representation of tissue properties across the entire limb and the interface condition between the residual limb and prosthesis. The ability of current FE models to estimate prosthetic interface stresses, while in some cases performing reasonably well, has not been highly accurate on the whole. Nevertheless, the methodology has distinct promise and potential, and the trend is toward improved accuracy. Advances in FE software, enabling nonlinear elastomeric formulations of bulk soft tissue, contact analysis, and dynamic analysis may help to address some of the current limitations of the models. In addition, the advances in computer hardware make application of these modeling complexities feasible. Thus, the tools needed to advance the FE models are available, and continued progress appears likely. Corresponding advances in the pressure transducer technology will help to validate the computer models, and also facilitate interpretation of the results of the analyses.

Applications and Utility of Prosthetic Interface Stress Studies

Clinical measurement of the prosthetic interface pressures has the potential to provide quantitative, objective information to assist in the evaluation of prosthetic fit. In addition, the effects of prosthetic alignment and componentry on the interface stress distribution can be determined. Routine use of such systems/devices will help to establish a database so that the significance of the results might be established and assist in the interpretation of the results.

Regardless of the assumptions and the simplifications of various computer models, numerical analysis of the residual limb and socket offer several advantages over experimental measurements in the estimation of prosthetic interface pressures. For example, the use of computer models, as opposed to experimental analysis, allows examination of the entire residual limb/prosthetic socket interface. In addition, prospective socket designs, characterized by material modifications and/or alternative socket rectification schemes may be investigated prior to socket manufacture. In fact, hypothetical designs that cannot be fabricated due to current technological limitations (i.e., material constraints) may be investigated. Note that computer models necessitate experimental verification to establish model validity.

Currently, it is not possible to perform clinical parametric studies of the prosthetic socket due to difficulties in the repeatability of test procedures, cost, and time constraints. Computer models are not subject to these limitations, and provide the potential for extensive parametric analysis.

These advantages of numerical analysis might also be utilized to enhance the education and training of prosthetists. Graphical results, still or animated, generated from computer models investigating prosthetic alignment and socket shape may be incorporated into prosthetic training software. Such software would allow the prosthetist to visualize the stresses resulting from his/her design efforts.

Future Trends

The recent availability of commercial systems to measure and record prosthetic interface pressures (and possibly shears) should provide additional objectivity when evaluating prosthetic fit. However, these systems and their respective transducers must be thoroughly characterized so that results for various individuals and systems may be interpreted appropriately. These devices may make it possible to create databases of interface pressures (and shears) experienced during amputee stance/gait. Such information will be useful in evaluating prosthetic fit, and in designing prosthetic sockets, whether the design involves CAD-CAM or conventional techniques.

FE analysis of the lower residual limb and prosthetic socket system will likely continue in the future. The FE method has proven itself as an extremely useful general engineering tool, and while its application to limb prosthetics has not been as straightforward as initially hoped, the FE method holds promise for parametric analysis of prosthetic systems. These computer models offer distinct advantages over experimental measurements, in that stress information can be obtained for the entire prosthetic interface, and that the subcutaneous stress distribution may also be investigated. In addition, parametric analysis, aimed at improving the understanding of the residual limb prosthetic system, is only feasible via computer analysis.

FE models have potential applicability in CAD of prosthetic sockets. Current prosthetic CAD systems allow the prosthetist to replicate on the computer what he has always done with his hands, that is, change geometry in an attempt to control force distribution in the residual limb. We foresee the FE technique being incorporated as the "engine" of future CAD (or perhaps more appropriately computer aided engineering: CAE) programs. Similar to current methods, prosthetists will use the computer mouse to identify areas on a graphical rendering of a residual limb. Instead of making shape changes to the surface of the limb, they will prescribe pressure tolerance information to the model. This optimal load information will be the input to the FE-based CAE design program; the output will be the computed shape of the new socket. In this manner, the prosthetic design will be based directly on the control parameter, namely force or pressure.

Finally, future developments in CAD of prosthetic sockets are also likely to be influenced by alternative shape sensing methodology, such as ultrasound, cast digitizers, and spiral CT scanning, that will enable timely evaluation of residual limb geometry and/or material properties.

Future FE models will likely vary from those summarized in this paper. Advances in computer technology (faster processors and larger memory) allow analysis of larger, more complex models. In addition, developments in FE software enable incorporation of nonlinear material properties, contact analysis, and true dynamic analysis. The development of commercial or custom software to process imaging data and automate FE mesh generation, similar to packages for custom prosthetic hip design, should decrease the time needed to create these models. The incorporation of these features will likely have a significant impact on the performance of residual limb/prosthetic socket models, and the future utility of such models in prosthetic design.

GLOSSARY

Aspect Ratio. Ratio of the longest to shortest element dimensions; to minimize computational errors, one generally wants element aspect ratios less than 3 for linear elements and less than 10 for quadratic elements.

Axisymmetric Model. Structure to be modeled is a body of revolution; the model geometry, material properties, and boundary conditions can be modeled in cylindrical coordinates (r,Θ,z), and are such that all are independent of Θ. Such criteria enable 3-D structures/problems to be analyzed in 2-D, thereby reducing the complexity of the model.

Degrees of Freedom. Number of nodal displacements and rotations allowed in a particular problem. For example, for 2-D problems, each node can move in the x- and y-directions; thus, there are two degrees of freedom per node.

Dilatation. Volume change; for constant dilatation problems, no volume change is allowed (i.e., structures are incompressible). The constant dilatation constraint is enforced on an element basis via an additional node.

Elastomer. "Rubberlike" polymeric material that can sustain very large elastic deformations; the behavior is usually approximated by various formulations of the strain energy equation.

Element. There are many types of element formulations, including linear elements in which the element sides remain straight and higher order elements in which the element sides may be curved. The order of the element affects the element shape and the corresponding element strain and stress. Examples of linear elements include 3-node triangles and 4-node quadrilaterals (2-D) and 4-node tetrahedrons and 8-node bricks (3-D). Quadratic elements include 6-node triangles and 8-node quadrilaterals (2-D) and 10-node tetrahedrons and 20-node bricks (3-D).

Homogeneous. Material which is uniform in structure or composition.

Incompressible. Material whose volume cannot be reduced due to loading.

Isotropic. Material whose elastic properties are identical in all directions.

Large Displacement. For a large displacement formulation, the dependence of the stress-strain relationship upon the current state of strain (or displacement) is explicitly modeled. This formulation is synonymous with nonlinear geometric modeling.

Linear FE Model. In linear FE models, the element material properties and model geometry are linear. In contrast, nonlinear FE analysis may include nonlinear material properties, geometry (buckling and/or large displacement) and/or boundary conditions.

Poisson's Ratio (ν). Ratio of the transverse to longitudinal strain under uniaxial tension.

Skewness. Variation of element vertex angles from 90° for quadrilaterals or from 60° for triangular elements. To minimize computational errors, one wants to minimize excess skewness or element distortion.

Viscoelasticity. The behavior of a viscoelastic material is a function of the load rate. Viscoelastic materials exhibit hysteresis, stress relaxation, and/or creep.

Warpage. Relevant to 3-D analysis when a node on a single face of a solid (or plate or shell element) deviates from a single plane. To minimize computational errors, excess warpage or element distortion should be minimized.

Young's Modulus (E). Measure of material property stiffness. Young's modulus is the slope of the linear portion of the stress-strain curve for elastic materials.

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