

Testing of elastomeric liners used in limb prosthetics: Classification of 15 products by mechanical performance

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Abstract—The mechanical properties of 15 elastomeric liner products used in limb prosthetics were evaluated under compressive, frictional, shear, and tensile loading conditions. All testing was conducted at load levels comparable to interface stress measurements reported on transtibial amputee subjects. For each test configuration, materials were classified into four groups based on the shapes of their response curves. For the 15 liners tested, there were 10 unique classification sets, indicating a wide range of unique materials. In general, silicone gel liners classified within the same groups thus were quite similar to each other. They were of lower compressive, shear, and tensile stiffness than the silicone elastomer products, consistent with their lightly cross-linked, high-fluid content structures. Silicone elastomer products better spanned the response groups than the gel liners, demonstrating a wide range of compressive, shear, and tensile stiffness values. Against a skin-like material, a urethane liner had the highest coefficient of friction of any liner tested, although coefficients of friction values for most of the materials was higher than interface shear:pressure ratios measured on amputee subjects using Pelite liners. The elastomeric liner material property data and response groupings provided here can potentially be useful to prosthetic fitting by providing quantitative information on similarities and differences among products.

Key words: amputee, interface stress, prosthetic suspension.

INTRODUCTION

Elastomeric liners fit snugly on a residual limb, providing support during stance phase and, if equipped with a locking pin, suspension during swing phase. It is rea-

soned that because of their high coefficients of friction (COFs) with skin and low compressive stiffness, elastomeric liners experience minimal displacement relative to residual-limb skin during walking. This low-slip condition helps to maintain total contact and is thought to reduce localized skin tension and shear compared with a conventional closed-cell foam material. The liner is thus more comfortable to the amputee.

A number of different elastomeric liner products are available, and manufacturers and users claim they vary in performance. One would then expect that their material properties differ. However, only two reports comparing elastomeric liner material properties have been published [1,2]. Compressive and shear/friction testing at quite high stress levels was conducted [1,2]—information useful to liner strength and failure characterization. However, mechanical characterization within the more typical working range of the products would also be helpful, as

Abbreviations: ASTM = American Society for Testing and Materials, COF = coefficient of friction, LVDT = linear variable differential transformer, PDMS = polydimethylsiloxane.

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would testing under tensile loading conditions. Of particular use would be to classify materials into groups based on the shapes of their response curves. With this classification, a prosthetist would know in what ways products were similar and different. For example, two materials might exhibit similar compressive responses but vary substantially in their COFs with skin, suggesting that they should not be used interchangeably. The relative assessment among products is of strong use clinically, and that is the thrust of this investigation. In the long term, potentially quantitative differences in material behavior could be correlated with amputee and clinical preferences. The data are also useful toward the development of material models, e.g., finite element models, of potential use in prosthetic engineering design.

This research compared different elastomeric liner products in terms of their compressive stiffness, COFs with a skin-like material, shear stiffness, and tensile stiffness. For each test, we classified materials into four groups based on the shapes of their response curves and

then created a classification table to summarize the similarities and differences among products.

METHODS

Elastomeric liners available commercially were acquired from prosthetics manufacturers. Except for TEC's product, which was a urethane, all other products tested were silicone elastomers, silicone gels, or a combination of the two (**Table 1**). The difference between silicone elastomers and silicone gels is their cross-linking and fluid retention [3]. Silicone elastomers are extensively cross-linked and contain little free polydimethylsiloxane (PDMS) fluid. Silicone gels have lightly cross-linked polysiloxane networks, swollen with PDMS fluid. Since the PDMS fluid is not chemically bound to the network in silicone gels, fluid can bleed out of the gels. In this paper, we based classification of a liner as a silicone elastomer or silicone gel upon manufacturers' product literature.

Table 1.

Liners tested. Thickness values reflect those of 10 samples used for compression testing.

Company (Location)	Product	Material*	Mean Thickness (SD) (mm)
ALPS: St. Petersburg, Florida	EasyLiner ELDT 32-3	Silicone gel w/fabric backing	4.49 (0.03)
	EasyLiner ELDT 32-6	Silicone gel w/fabric backing	5.60 (0.00)
	EasyLiner Super Stretch ELPX32	Silicone gel	6.12 (0.05)
	Clearpro SSA44	Silicone elastomer	2.06 (0.05)
Engineered Silicone Products: Parsippany New Jersey	AEGIS	Silicone elastomer	2.19 (0.06)
	AEGIS Z	Silicone elastomer w/fabric backing	5.10 (0.00)
Fillauer, Inc.: Chattanooga, Tennessee	Silicone Suspension Liner	Silicone elastomer	2.01 (0.03)
Ohio Willow Wood: Mt. Sterling, Ohio	Alpha Liner	Silicone gel w/fabric backing	9.42 (0.09) (front)
Ossur USA, Inc.: Columbia, Maryland	DERMO Liner-9	Gel silicone [†] w/fabric backing	9.29 (0.19)
	DERMO Liner-6	Gel silicone [†] w/fabric backing	5.81 (0.15)
	Iceross Two Color	Silicone elastomer (two layers)	2.27 (0.05)
	Iceross Comfort, Uniform	Silicone elastomer w/fabric backing	5.89 (0.09)
	Iceross Clear	Silicone elastomer	3.36 (0.10)
Silipos: New York, New York	SiloLiner	Silicone gel w/fabric backing	5.21 (0.11)
TEC Interface Systems: Waite Park, Minnesota	Pro 18	Urethane	6.29 (0.03)

*Definition as a silicone gel or silicone elastomer was based on statements in the manufacturers' product literature.

[†]"Gel silicone" is a term used by this manufacturer. Content and structure are not described in product literature.

Compression Testing

Ten short cylinder specimens of 11.1 mm diameter were prepared for each material. So that specimens were cylindrical-shaped and not hourglass-shaped, they were punched in a constrained environment. A 16 mm diameter sample was put within a 16 mm thru-hole in a piece of polycarbonate and then punched with a No. 13 steel punch. The punch was held with an alignment guide so that it was oriented perpendicular to the sample. Samples of 11.1 mm diameter were thus generated.

We conducted compression testing using a custom-designed system similar to that described in detail elsewhere [4] (**Figure 1(a)**). A shaker motor delivered a compressive force up to 29 N through U-joints, a linear bearing, and a load cell (31/1426-04, Sensotec, Columbus, Ohio, 0 to 44.5 N range) to a 25.4 mm diameter plunger. Before testing began, the plunger face was carefully aligned with the bottom plate face so that the faces were parallel with each other. We measured compression of the material (axial displacement of the motor axis) using a linear variable differential transformer (LVDT) (MHR-500, Schaevitz, Pemsauken, New Jersey, 0 to 12.7 mm range), with the bore mounted to the frame of the system and the core mounted to the motor faceplate.

The mean test sample diameter:thickness ratio (2.8:1.0) was similar to that from ASTM (American Society for Testing and Materials) standard test number D3574-91 Test C, "Standard Test Methods for Flexible Cellular Materials: Compressive Force Test." The samples were not confined laterally as they were in previous elastomeric liner studies [1], since it was of interest to measure unconfined compression rather than confined compression. Covey et al. selected laterally confined compression to investigate the effect of "strain-rate" and the so-called "flow-constraint" on the compressive behavior [1]. The present tests were not intended to investigate strain-rate. They were intended to provide empirical descriptions as well as to help build material models, e.g., finite element models, that have predictive ability. One important point to determine in material modeling is whether the materials behave similarly in tension and compression; thus both uniaxial tension tests and compression tests were performed.

Preliminary testing demonstrated minimal permanent deformation or change in the shapes of load-deformation curves over a 60 min time interval. Thickness of all materials changed less than 0.8 percent. Therefore, all subsequent testing was conducted for a 10 min interval.

Friction at the surfaces was demonstrated sufficiently low to not significantly affect the stiffness data; tests with a thin lubricant at the surfaces showed results consistent to those without any lubricant, within the resolution limits of the instrument. The loading rate was 1 Hz. The maximal-applied stress levels in the 10 trials for a material were in the range of maximal interface pressures measured on lower-limb amputees [5] (~200 kPa). Low stiffness materials, however, could not be stressed to this level because the maximum force capability of the motor was insufficient near the ends of its displacement range. The system was run under displacement control with a proportional gain controller written and implemented in LabView (v. 4.1, National Instruments, Austin, Texas) with data acquisition boards (PCIMIO-16XE-50, PCI-1200, National Instruments, Austin, Texas) on a computer (8500/180, Apple, Cupertino, California). With this system, the resolution in the stress and strain data were 0.29 kPa and 0.0007 mm/mm, respectively. Data were collected for 2 s at 60 s intervals, starting with data collection 60 s after loading was initiated. The sampling rate was 45 Hz.

In the analysis of collected data, compressive stress was assumed equal to the measured force divided by the area of the unloaded specimen surface (96.7 mm²). Strain was calculated as the measured displacement divided by the initial sample thickness. Data for each sample were least-squares fit. The curve fit for the loading portion defined the stress-strain equation for each material as $\sigma = (A * \epsilon) + B * (\epsilon - C)^D$, where σ is the stress; ϵ is the strain; and A , B , C , and D are constants determined from curve fit optimization. The first term was required because some materials experienced quite large displacements under low force. A power series was used for the second term because it fit the data better than the alternatives considered (linear, exponential growth, logarithmic growth). Median values of curve-fit parameters were computed, and outliers were dropped by visual inspection. Less than 6 percent of the data were dropped as outliers. Residual error was computed as the difference between the experimental stress and that predicted by the equation. The (Pearson's Product Moment) correlation coefficient between the experimental stress and the predicted stress was also computed as a measure of the quality of fit.

Once all data for all liners were collected, the materials were classified into four groups for this test as well as for the friction, shear, and tensile tests described in the following paragraphs. Delineation of the groups was

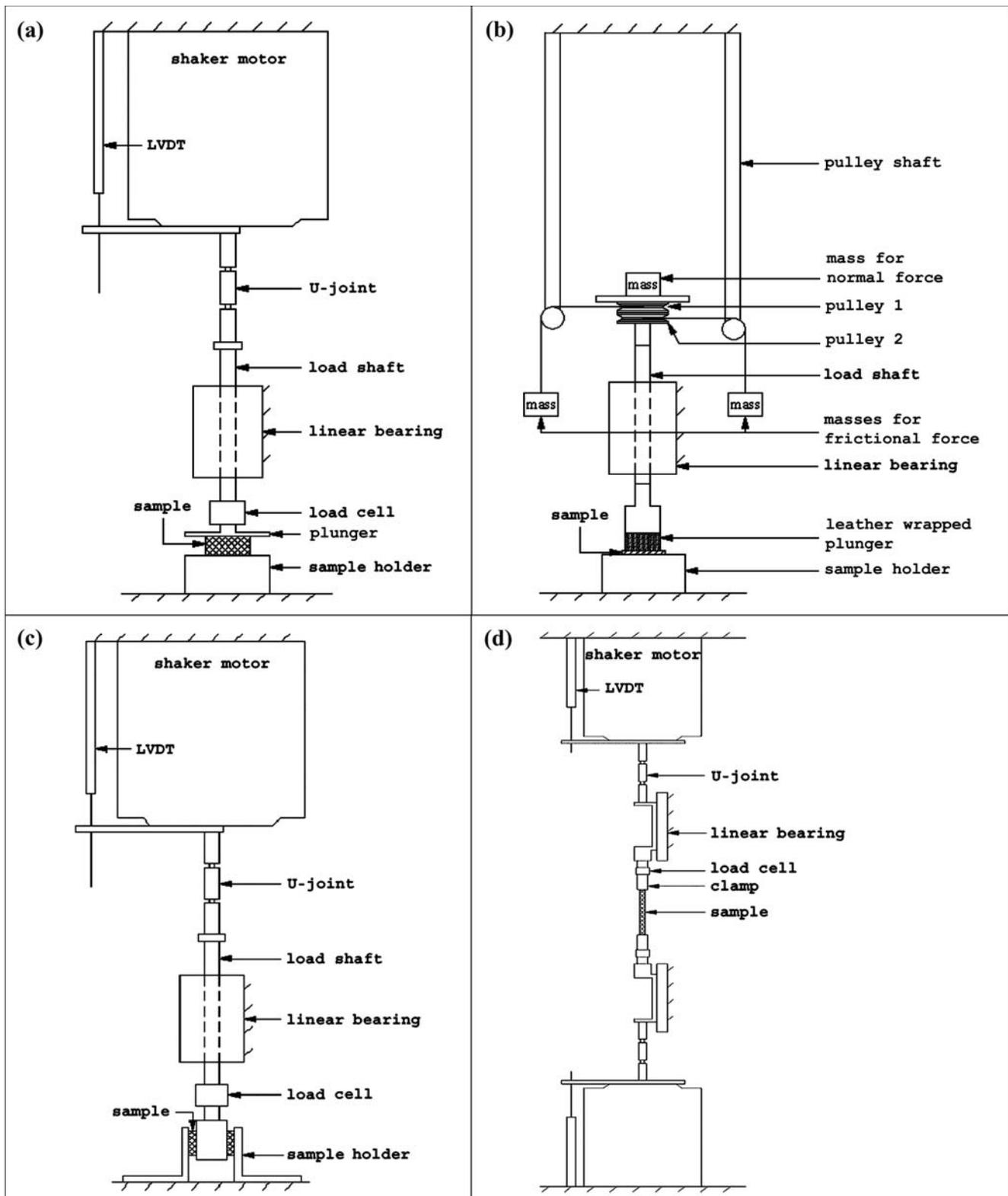


Figure 1.

Test systems. Schematic illustrations showing the configurations used for mechanical testing under (a) compression, (b) friction, (c) shear, and (d) tension. LVDT = linear variable differential transformer.

based on visual inspection of the response curves and on consideration of the shape features of greatest clinical interest. Thus the bounds of the groups are as defined in the figures discussed in the Results section of this paper.

Frictional Coefficient Testing

We evaluated the coefficient of static friction between each liner material and a skin-like material (leather) using a custom-designed jig (**Figure 1(b)**). Use of a consistent material (the smooth side of the leather) allowed results among different materials to be compared. Leather was selected because its properties were more skin-like than the alternatives considered—silicone rubbers or closed-cell foams. Compressive and shear loads were delivered through a vertically oriented loading rod and leather-covered annular ring (8 mm inner diameter; 14 mm outer diameter) to the elastomeric liner material sample. In preliminary testing when full thickness samples of the liners were used, excessive deformation and bunching of the liner material against the leather ring proved problematic, causing an inconsistent measurement. Because only the surface interaction of the materials with the leather-covered pad was of interest, thin samples of the liners were prepared. A rotary cutter was used to prepare 1.75 mm-thick samples of outer dimensions 3.8×3.8 cm. We placed a thin epoxy layer on the bottom of each sample to create a stiff bottom surface.

Two 1.9 cm diameter pulleys (U-PNB-2/12, Small Parts, Miami Lakes, Florida) were attached to the upper section of the loading rod to deliver torsion to the leather-liner interface. The application of torsion and axial loads caused compressive and shear forces to be delivered from the leather ring to the elastomeric liner.

To conduct a test, we applied a normal force of 2.63, 5.58, 10.48, or 20.29 N using a weight on top of the upper assembly. A 20.29 N normal force corresponded to a 195.8 kPa, compressive stress, under the assumption that the load was uniformly distributed. Testing was conducted on three samples for each material. We carefully centered the weight so as to avoid inducing a bending moment on the rod, which would have induced friction in the bearing and altered the force delivered. Torsion was increased incrementally (using equal weights on the two moment arms) with the increments corresponding to 0.45 N shear force at the leather-liner interface. Shear forces up to 14.87 N were delivered to the leather-liner interface. The threshold force at which slip occurred was recorded. Repetitive testing of preliminary samples of all

materials demonstrated highly repeatable results. The mean and standard deviation (SD) curves were calculated for each material. For each level of normal force, the shear forces at which slip occurred were averaged for all samples and a curve calculated: $(S = E * N^F)$, where S is frictional shear force, N is normal force, and E and F are constants determined from curve-fit optimization. A power decay equation was used because it fit the data better than alternatives considered (linear, logarithmic decay, exponential decay). COF was computed from the local slope of this equation. The correlation coefficient between the experimental shear force and the predicted shear force was also computed as a measure of the quality of fit.

Shear Testing

We conducted shear testing using a modification of the compression testing apparatus (**Figure 1(c)**). The shaker motor delivered cyclic shear forces at 1 Hz to two samples (1.52×1.52 cm) simultaneously through a custom frame. The frame kept the applied load parallel with the same surfaces, thus ensuring that exclusively shear forces were delivered to the samples. Three pairs of samples were tested for each material. Motor axial force was measured with the load cell in line with the sample, and displacement was measured with the LVDT mounted to the motor faceplate and system housing. Because of a limited displacement range of the motor, shear stresses to only 30 kPa were possible. This range, however, does cover resultant shears reported with no liner on amputee subjects and thus was considered acceptable [5]. Stresses were delivered for 10 min, with data recorded at 60 s intervals, starting 60 s after load was initiated. For the loading portion of each data sequence, the slope of the best-fit straight line relating shear stress to shear strain (in a least-squares sense) was computed and then averaged. The correlation coefficient between the experimental shear stress and the predicted shear stress was also computed as a measure of the quality of fit.

Tensile Testing

Dumbbell-shaped test samples were prepared consistent with ASTM standard test number D412-98a-Die C, “Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension.” Three samples were tested for each material. Liners fabricated with a fabric backing (**Table 1**) were tested both with and without the backing. Samples were held at the ends with stainless steel clamps that applied a consistent force

across the ends despite thinning of the samples during stretching. The clamps attached to a displacement-controlled testing apparatus, described in detail elsewhere [6]. Briefly, two shaker motors applied a sinusoidal (1 Hz) tensile load while motor axis displacements were measured with LVDTs. Forces were recorded with a load cell (31/1434-02, Sensotec, Columbus, Ohio) in line with the motor axes (**Figure 1(d)**). The system was a closed-loop proportional-integral-derivative (PID) controller implemented in LabView (v. 5.1). The test was run for a 10 min interval, with data collected every 60 s, beginning 60 s after loading was initiated. Data were processed in the same manner as for the shear tests.

RESULTS

Results for EasyLiner ELDT 32-3 and 32-6 were similar and fell within the same classification groups for the different tests; thus only data for ELDT 32-6 are reported here. DERMO Liner-6 and DERMO Liner-9 results fell within the same classification groups; thus only data for DERMO Liner-6 are reported here.

Curve fit data for all tests are shown in **Table 2**. All correlation coefficients for all tests were greater than 0.97, except for Clearpro under shear testing, which had a correlation coefficient of 0.84.

Compression Testing

Compression testing results showed two types of responses: (1) a first phase of large strain at low stress, followed by a second phase of increased stiffness (Groups C1, C2, and C3), and (2) a gradual increase in stiffness over the loading range with a maximal strain of 50 to 60 percent (Group C4) (**Figure 2**). The second group consisted only of silicone gel materials (ELDT 32, Super Stretch, Alpha Liner, and SiloLiner).

The C1, C2, and C3 responses varied in terms of their first-phase strains and their second-phase stiffness. Materials in C1 had relatively high first-phase strains and high second-phase stiffness. C2 materials had low first-phase strains and moderate second-phase stiffness. C3 materials had moderate first-phase strains and low second-phase stiffness. Thus the silicone elastomer products, which were in all three groups (C1, C2, and C3) varied over a wide range of responses, while the silicone gels fell within only one narrow group (C4). The only urethane tested was a C2 material.

We added compressive stiffness data for soft tissue over the posterior calf of normal subjects to **Figure 2** using material parameter data from Vannah and Childress [7]. If a material with Vannah and Childress's parameters were used in our compression tests on short cylindrical specimens, the behavior would have been as shown in

Table 2.

Curve fit data for all tests. All strains are engineering strains. σ is in units of kPa; ε is in units of mm/mm.

Liner	Compression* $\sigma = (A * \varepsilon) + B*(\varepsilon - C)^D$				Friction $Sh = E * N^F$		Shear $\sigma = G * \varepsilon$	Tension $\sigma = H * \varepsilon$
	A	B	C	D	E	F	G	H
ELDT 32-6	46.96	540.31	0.05	2.12	1.47	0.60	23.28	76.09
Super Stretch	107.06	410.24	0.21	1.59	0.97	0.79	21.19	30.41
Alpha Liner	108.17	223.94	0.12	1.51	0.88	0.55	26.49	50.05
SiloLiner	6.47	834.13	0.01	2.69	1.12	0.47	19.29	40.77
DERMO-6	52.38	837.11	0.09	1.59	0.72	0.53	52.86	56.28
Iceross Comfort	44.85	624.89	0.06	1.57	0.78	0.63	41.55	55.86
Iceross Clear	34.17	1,404.34	0.24	1.00	1.97	0.45	124.54	194.53
Iceross Two Color	44.10	1,105.75	0.27	0.87	1.26	0.66	125.92	118.76
Clearpro	27.19	1,816.59	0.24	1.06	1.28	0.61	90.54	131.39
Fillauer Silicone	0.00	3.3e5	0.10	5.79	1.49	0.51	170.70	248.56
AEGIS	58.41	2,081.74	0.24	1.07	2.06	0.42	175.20	205.01
AEGIS Z	79.44	1,059.04	0.09	1.47	1.40	0.61	43.99	87.88
TEC Pro 18	69.98	657.12	0.08	1.08	4.20	0.43	82.73	88.06

*For $\varepsilon < C$, $\sigma = A * \varepsilon$; for $\varepsilon \geq C$, $\sigma = (A * \varepsilon) + B*(\varepsilon - C)^D$

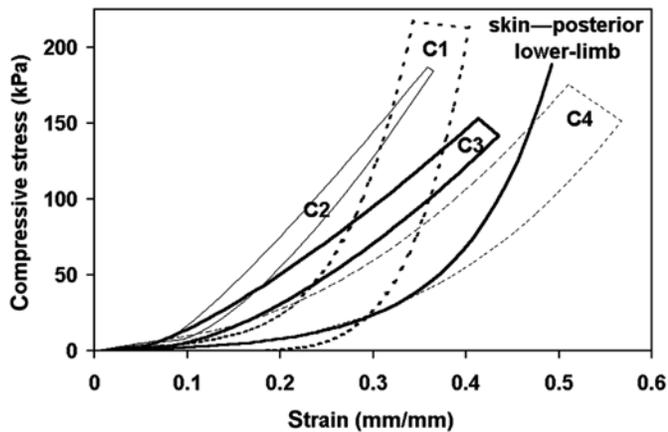


Figure 2. Compression testing results. Data fell into four groups, C1 to C4 (see **Table 3** for liner identification by group). Compression testing results from posterior soft tissue of a normal subject (from Vannah and Childress [7]) are also shown.

Figure 2. Most of the curve falls within the C4 group. In a different study, compression testing over the anterior medial surface of the tibia on normal subjects showed up to 28 percent strain at 50 kPa pressure within seconds after load initiation [8]. This result falls within the responses for C1, C2, and C3 materials. Thus posterior soft tissue best matched C4 materials, while anterior soft tissue best matched C1, C2, and C3 materials.

Friction Testing

The TEC Pro 18 material in Group F1 had the highest COF of any material tested (**Figure 3**). The TEC liner was the only urethane tested.

The other COF groups (F2, F3, and F4) did not match with liner material content. Both silicone elastomers and silicone gels had liners in different groups. F2 and F3 responses were similar to each other, but F2 materials were more linear over the range and had higher mean COF values. F4 materials had the lowest COF values.

Shear Testing

Shear testing data showed highly linear responses for all materials tested, with stiffness ranging from 19 kPa to 175 kPa (**Figure 4**, **Table 2**). All silicone gels had relatively low shear stiffness (Group S4), consistent with their lightly cross-linked structure, whereas the silicone elastomers had higher stiffness (Groups S1, S2, and S3), consistent with their greater cross-linking density. The urethane was in the middle of the range (Group S2).

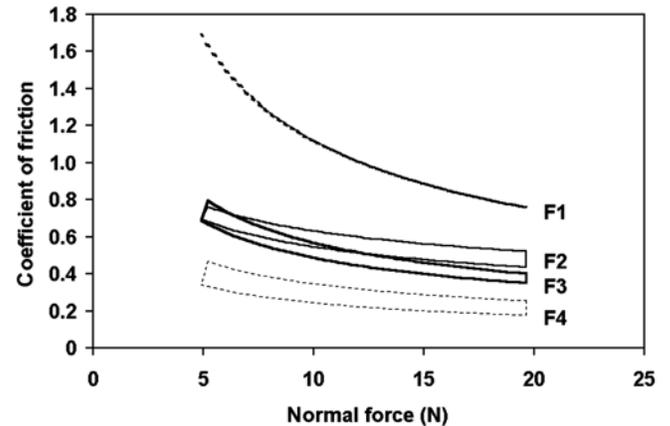


Figure 3. Frictional testing results. Data fell into four groups, F1 to F4 (see **Table 3** for liner identification by group).

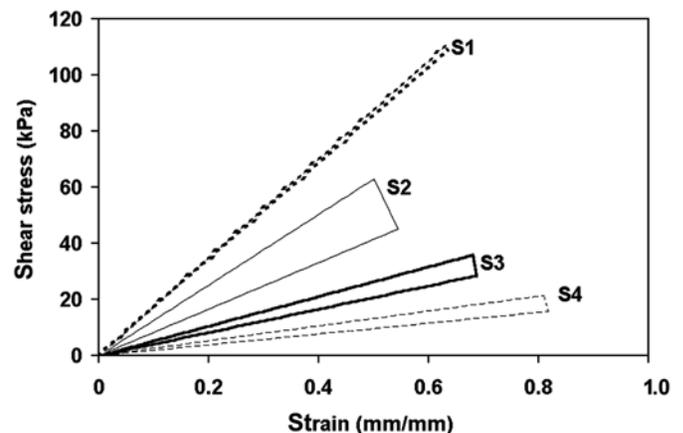


Figure 4. Shear testing results. Data fell into four groups, S1 to S4 (see **Table 3** for liner identification by group).

Tensile Testing

Tensile testing results showed highly linear responses for all materials tested, with stiffness ranging from 30 kPa to 249 kPa (**Figure 5**, **Table 2**). Similar to the compression and shear test data, the silicone gels had the lowest stiffness of all materials (Group T4), consistent with their makeups. Silicone elastomer properties, however, extended over the T1 to T4 range. The urethane had a T4 stiffness value. Tensile testing of skin from Daly and Odlund showed results similar to the T4 materials (**Figure 5**) [9]. Results for liners with fabric backings were comparable to those with the fabric backings removed. Data were classified into the same groups in the two specimen configurations for each product tested.

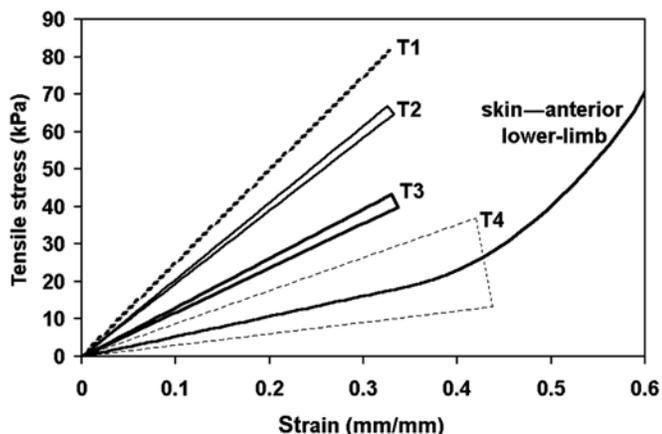


Figure 5. Tensile testing results. Data fell into four groups, T1 to T4 (see **Table 3** for liner identification by group). Tensile testing results from cadaveric skin (from Daly and Odlund [9]) are also shown.

DISCUSSION

Elastomeric liner material property data can potentially be useful to prosthetic fitting by providing quantitative information on differences among products. In concept, if a prosthetist knew what properties he or she desired in a liner, he or she could go to the characterization table included here (**Table 3**) and select a liner. For

example, the ELDT 32, Super Stretch, Alpha Liner, and Silo Liner all have comparable compressive, shear, and tensile stiffness properties, although different COFs. Thus in deciding among these materials, a prosthetist might use COF as part of the basis for selection. The material property data help to reduce the trial and error of learning about different liners' mechanical performances.

Toward interpretation of the collected data, two important features of this investigation must be noted. First, all liner products tested were new. Degradation and changes in properties over time (longer than a 1 h interval) were not considered. Thus no conclusions can be drawn about durability. Durability was, however, a topic of previous investigations [1,2]. Second, testing was conducted under interface loading conditions reflecting those measured at a number of interface locations during walking but not at the patellar-tendon [5]. Thus stresses applied during testing here were lower than patellar-tendon stresses or those experienced during running. High activity, such as running, could induce sweating that could further alter mechanical response. Thus toward clinical interpretation of the data, these features of the study design should be recognized.

Compressive stiffness results were consistent with liner content. All Group C4 materials were silicone gels, which had relatively nonbiphasic stress-strain curves, had

Table 3. Liner classification table. Materials were classified into one of four groups for each test, with groups defined as shown in **Figures 2 to 5**.

Liner	Compressive Stiffness				Coefficient of Friction				Shear Stiffness				Tensile Stiffness			
	Hi		Lo		Hi		Lo		Hi		Lo		Hi		Lo	
	C1	C2	C3	C4	F1	F2	F3	F4	S1	S2	S3	S4	T1	T2	T3	T4
Gels																
ELDT 32 (3,6)	—	—	—	x	—	x	—	—	—	—	—	x	—	—	—	x
Super Stretch	—	—	—	x	—	x	—	—	—	—	—	x	—	—	—	x
Alpha Liner	—	—	—	x	—	—	—	x	—	—	—	x	—	—	—	x
SiloLiner	—	—	—	x	—	—	—	x	—	—	—	x	—	—	—	x
Elastomers																
DERMO Liner (6,9)	—	—	x	—	—	—	—	x	—	—	x	—	—	—	—	x
IceroSS Comfort	—	—	x	—	—	—	—	x	—	—	x	—	—	—	—	x
IceroSS Clear	x	—	—	—	—	—	x	—	—	x	—	—	—	x	—	—
IceroSS Two Color	x	—	—	—	—	x	—	—	—	x	—	—	—	—	x	—
Clearpro	x	—	—	—	—	—	x	—	—	x	—	—	—	—	x	—
Fillauer Silicone	x	—	—	—	—	—	x	—	—	x	—	—	—	x	—	—
AEGIS	x	—	—	—	—	—	x	—	—	x	—	—	—	—	x	—
AEGIS Z	—	x	—	—	—	x	—	—	—	—	—	x	—	—	—	x
Urethane																
TEC Pro 18	—	x	—	—	x	—	—	—	—	—	x	—	—	—	—	x

experienced the highest strains, and had the lowest stiffness of all materials tested. Silicone gels are lightly cross-linked and bleed fluid upon compression. All C1, C2, and C3 materials, except for the TEC Pro 18, were silicone elastomers, which are highly cross-linked. The silicone elastomers showed a range of properties, varying both in the strain experienced in the first phase low-stiffness portions of their stress-strain curves, and in the stiffness of the second phases. Physically, upon compressive loading as experienced at the residual-limb prosthetic-socket interface, silicone elastomers deform to align their polymer chains perpendicular to the load direction and then stiffen as the aligned polymer takes the load.

A prosthetist needs to select an appropriate liner material based on the patient's needs. Of the four groups, the C4 gels most closely match the material properties of posterior calf soft tissue (as Vannah and Childress have reported [7]); thus if the prosthetist's goal is to achieve this match, then these materials would be most appropriate. Such properties would likely be needed for bony residual limbs or over bony sites so as to reduce stress concentrations. For a residual limb with excessive soft tissue though, C4s would be expected to facilitate instability because of so much deformation within the liner material; C1, C2, or C3 materials would likely be better matched. C1, C2, and C3 curves better match the compressive properties of skin over the anterior tibial surface [8]. The longer the low-deformation portion of the curve, as in C1 materials, the more the material will compress before it takes load. But note that all C1 materials were relatively thin (**Table 1**); thus in an absolute deformation sense, their first phase compressions were not that much different than the C2 or C3 materials compressions. A prosthetist needs to consider what material response he or she wants when selecting a liner. Of relevance here is that the prosthetics industry provides a range of compressive stiffness products; thus the prosthetist has a wide choice with regard to compressive stiffness.

The range of compressive stiffness values measured here is comparable to that of closed-cell-foam liner materials characterized previously [4]. However, the elastomeric liners tested here recovered much better after each load cycle than did the closed-cell foams. The closed-cell-foam liners were reduced in thickness up to 83 percent 1 h after 1 h compression tests. Thus at least for short-term use of elastomeric liners, a prosthetist does not need to plan ahead in socket design so as to anticipate permanent deformation. This feature would be expected to make fit-

ting with elastomeric liners more consistent than fitting with closed-cell foams. The data here do not support the concept of a flow phenomenon over time, but the time interval tested was rather short (maximum of 1 h).

High COF materials stick better to skin than low COF materials. Thus F4 materials would have a greater tendency to slip and to piston than would the F1 material. However, note that all materials tested with the exception of F4s were above the typical resultant shear:pressure ratio measured during stance phase in interface stress studies on transtibial amputee subjects using Pelite liners [10]. Values there ranged from 0.02 to 0.50. Thus F2 and F3 materials might not slip during clinical use; they just do not have the margin of safety of the F1 material as far as preventing slip. In general, closed-cell foams had higher COFs with skin (0.60 to 0.89 range) than did the elastomeric liners with leather assessed here [4]. For all materials tested here, COFs decreased with increasing normal force. Thus as interface pressures increase, such as during the weight-acceptance phase of gait, COFs would be expected to go down.

The advantage of a high COF material is that by sticking to the skin, it helps to reduce localized shear stress concentrations in the soft tissues. High COF materials would be expected to be important around adherent tissue or weak skin sites (areas highly susceptible to breakdown from high stress concentrations). The TEC product (F1) clearly had the highest COF of any material and was the only urethane tested. In a previous study [2], a urethane was shown to have a higher COF than silicone, Bock-Lite, or Pedilin.

Note that all liners tested here except the TEC product were roll-ons, although TEC does now market a roll-on liner of a similar material. Thus the liners will experience some compressive prestress upon donning. This prestress could lower initial COFs, since COFs decrease with increased normal force, as shown in **Figure 3**. Also, depending on the match of the liner shape to the residual-limb shape, local areas might be more prestressed than others, affecting the uniformity of the COF. Liners that are better matched to the residual-limb shape would be expected to have a more uniform mechanical response.

Interestingly, COF data do not classify into groups consistent with liner makeup as do compressive stiffness data. Thus one could reasonably conclude that manufacturing processes control COF more than liner material contents do.

A material with a low shear stiffness will give to allow the residual limb to move deeper into the socket upon weight-bearing, while one with a high shear stiffness will not. It would be expected that high shear stiffness liners are more appropriate for residual limbs with excessive soft tissue, and low shear stiffness liners more appropriate for bony residual limbs. As with compression test data, shear stress data showed that silicone gels had lower stiffness than silicone elastomers, consistent with differences in their content and structure. Note that for liners with a fabric backing, the maximum shear stress at the residual-limb prosthetic-socket interface is affected by the COF on the fabric side. Slip at the liner-socket interface for liners with fabric backings would be expected to lower the shear stress delivered to the skin.

Tensile properties of the liners are important toward suspension. A high tensile stiffness material will provide good suspension during swing phase, provided the COF is adequately high so that slip between the liner and skin does not occur. A low tensile stiffness liner will contribute to pistoning during swing phase. The silicone gels had relatively low tensile stiffness. However, tensile stiffness for silicone elastomers spanned the T1 to T4 range. Note that some manufacturers recommend casting with the liner in tension. This tension would stretch the liner and put it under greater tension during use, potentially altering its stress-strain curve from that shown in **Figure 5** and increasing the stiffness.

Several of the liner products had fabric backings on their external surfaces in contact with the socket. The results here showed that the backings' effects on liner tensile stiffness were minimal. The backings, however, might improve the failure characteristics of the liner, i.e., increase the tension at which failure occurs, but testing at higher stresses would be needed to verify this expectation.

Because the compression and tension data are dissimilar (**Figures 2** and **5**), using one stress-strain curve to describe both compressive and tensile behavior in prosthetic finite element models is not appropriate. Frictional effects, Poisson effects, and possibly near incompressibility would need to be considered separately for socket donning (best represented by tensile testing) and stance phase (best represented by compressive testing).

What is the best liner? In our opinion, an ideal liner for a bony residual limb would be soft and sticky and thus would have a low compressive stiffness and a high COF. A low shear stiffness is desirable so that there is some give upon weight bearing. The tensile stiffness

should be high so that there is minimal loss of suspension if a suspension liner is used. For a residual limb with excessive soft tissue, however, an ideal liner would be stiff and sticky and thus would have a high compressive stiffness and a high COF. Shear stiffness should be midrange so that there is not a sense of loss of stability upon weight bearing. Tensile stiffness again should be high so as to facilitate suspension. As shown in **Table 3**, no liner meets what we consider the ideal criteria for either the bony or excessive soft-tissue case. It would be virtually impossible to do so without introducing a high degree of orthotropy, using oriented reinforcement, for example. Such a goal, however, would be a challenging design and manufacturing effort. Alternative liners could be created with regional differences in stiffness and COF properties, differences on the anterior versus posterior surface for example. Such possibilities represent a challenge to the prosthetics manufacturing industry.

CONCLUSION

The liners were not all similar to each other in terms of their mechanical responses. For the 15 liners tested, we identified 10 unique classification sets (**Table 3**).

Compressive, shear, and tensile stiffness differences for silicone gel versus silicone elastomer liners in general followed the structure and content differences of these two classes of materials. Silicone gels are lightly cross-linked and bleed upon loading. Silicone elastomers are highly cross-linking and retain their fluid under stress. In general, gels had lower compressive, shear, and tensile stiffness than did silicone elastomers. Material responses for gels were quite similar to each other. Those for silicone elastomers varied over a much wider range.

COF data did not follow the silicone gel/silicone elastomer distinction. Both material types had different COFs for different liner products, suggesting that COF is more controlled by manufacturing than by content for the silicones. The only urethane liner tested had a substantially higher COF than any other material tested.

The prosthetics industry provides a wide range of liner products that vary in material properties; thus a prosthetist has a wide choice of selections. The elastomeric liner material property data presented here are potentially useful to prosthetic fitting by providing quantitative information on similarities and differences among products.

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