

## Mechanical performance of inflatable inserts used in limb prosthetics

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**Abstract**—Inflatable insert products used to overcome residual limb shrinkage were evaluated in a bench test environment under compressive loading conditions. Pressure-loss tests under static loading demonstrated that after inserts were inflated to 43.4 to 45.6 kPa, insert pressures reduced from 0.09%/min to 1.36%/min in the first 5 min and from 0.00%/min to 0.27%/min in the subsequent 55 min. As inserts were inflated, they demonstrated at least two phases in their pressure versus thickness curves: A relatively low-slope portion (Phase I) was followed by a high-slope portion (Phase II). The transition from Phase I to Phase II occurred at more than a 12-mm thickness, a thickness greater than that considered acceptable for practical clinical use (10 mm). This result suggests that in a socket, stress to resist insert expansion is taken by the residual limb and socket more than by the insert itself. Cyclic-loading tests under constrained thickness conditions demonstrated that local stiffness was more sensitive to insert pressure than to constraint spacing (insert thickness). The static and dynamic test results help to explain why some users claim that inserts do not provide equal and consistent support unless inflated to a very high insert pressure. An insert that

allowed adjustment of the location of the Phase I to Phase II transition point in the pressure versus thickness curve might help to overcome these limitations.

**Key words:** *amputee, inflatable inserts, interface stress, limb prosthetics.*

### INTRODUCTION

Inflatable inserts are devices intended to overcome changes in residual-limb shape. With the inserts positioned at the residual-limb and prosthetic socket interface, the user inflates the inserts with air to replace volume lost from residual limb shrinkage. Amputees with residual limbs that undergo substantial diurnal volume fluctuations use these inserts. The air pump or a tube connecting to a pump is typically positioned within a hole in the socket wall, allowing the user access from the outside to inflate the device.

Though inflatable inserts have been available for several years, their use is limited. Some clinicians and users claim that the inserts compress excessively under load. Thus during walking, they do not provide equal and consistent support to the residual limb. If the inserts are inflated to a higher pressure, then the insert deformation

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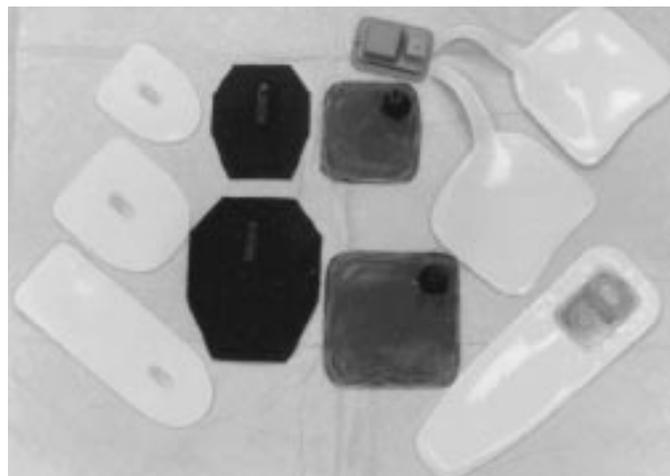
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problem is overcome; however, the inserts are then too big and may distort the localized soft tissues. This distortion can cause discomfort and possibly tissue damage. As a separate issue, some users complain that the inserts leak and do not adequately hold their pressures over time. The inserts are then in need of continual adjustment.

Though potentially these limitations could be overcome by appropriate evaluations and then the insert redesigned based on those results, no mechanical evaluations on inflatable insert products have been reported in the literature. The purpose of this research was to conduct mechanical testing to help evaluate these concerns and provide insight into appropriate design improvements. We conducted tests to quantify insert pressure loss over time, thickness and volume dependence on insert pressure, and insert stiffness under cyclic mechanical-loading conditions.

## METHODS

Inflatable inserts were acquired from four manufacturers: Air Contact System (Otto Bock, Duderstadt, Germany), PNEU-FIT™ (Prosthetic Concepts, Little Rock, AR), Pump It Up!™ (Amputee Treatment Center, Batavia, NY), and Pneumatic Volume Control System (CO-MET, Neustadt a.d. Weinstrasse, Germany) (**Figure 1**). In clinical use, the Air Contact System, PNEU-FIT, and Pneumatic Volume Control System are positioned between the socket and liner, while the Pump It Up! is a bladder positioned between the socket and an interior shell. The interior shell has holes cut in it by the prosthetist, allowing the bladder to protrude into the residual



**Figure 1.**

Inserts tested. Products (in columns from left to right) included the Air Contact System, PNEU-FIT, Pump It Up!, and Pneumatic Volume Control System.

limb at locations where shape change is desired. The Air Contact System, PNEU-FIT, and Pneumatic Volume Control System insert products are available in standard sizes, while the Pump It Up! is custom-shaped by a prosthetist. The sizes and dimensions of the inserts tested in this study are listed in **Table 1**. We tested one insert of each type and size.

For all tests, we used a custom system to set and record insert pressures. The insert, inflation pump, and a pressure sensor (FPG, Sensotec, Columbus, OH) were connected to a three-way stopcock with vinyl tubing (6.35-mm diameter, 1.59-mm wall thickness) (**Figure 2**). Signals from the pressure sensor were sent to a computer data acquisition system (NB-MIO-16 A/D card, National

**Table 1.**

Inserts evaluated.

Product (manufacturer)	Model	Material	Approximate dimensions (deflated)
Air Contact System (ACS) (Otto Bock)	Small	Polyvinyl chloride	80 mm × 60 mm × 0.6 mm
	Medium	Polyvinyl chloride	100 mm × 80 mm × 0.6 mm
	Large	Polyvinyl chloride	170 mm × 60 mm × 0.6 mm
PNEU-FIT (PF) (Prosthetic Concepts)	Small	Dacron, rubber	80 mm × 70 mm × 1.6 mm
	Large	Dacron, rubber	110 mm × 90 mm × 1.6 mm
Pump It Up! (PIU) (Amputee Treatment Ctr)	Small	Natural rubber	70 mm × 70 mm × 1.7 mm
	Medium	Natural rubber	90 mm × 90 mm × 1.7 mm
Pneumatic Volume Control (PVC) System (CO-MET)	Anterior knee disartic, small	Polyurethane	220 mm × 70 mm × 0.8 mm
		Polyurethane	Two 100-mm × 90-mm × 0.8-mm chambers

Instruments, Austin, TX; Power Macintosh 7100/66, Apple, Cupertino, CA) under LabView (ver. 4.0, National Instruments) control. All testing was conducted at a 22 °C room temperature.

### Pressure Loss Under Static Loading

During testing, each insert was constrained between two 19-cm by 19-cm aluminum plates, spaced 10.0 mm apart. The basis for using this constraint was that if left unconstrained, the inserts could not all achieve the 43-kPa minimum pressure required for the test and still maintain a usable shape. Further, the constrained condition was considered to better reflect clinical use of the

inserts than the unconstrained condition. Inserts were positioned between the plates and then inflated with a squeeze-ball pump provided by PNEU-FIT. (This pump was very similar to that provided by Pump It Up! and Air Contact System.) The Pneumatic Volume Control System inserts were modified to bypass their onboard pump and instead use the hand-held pump. Each insert was inflated to a maximal pressure deemed practical clinically (between 43 and 46 kPa).

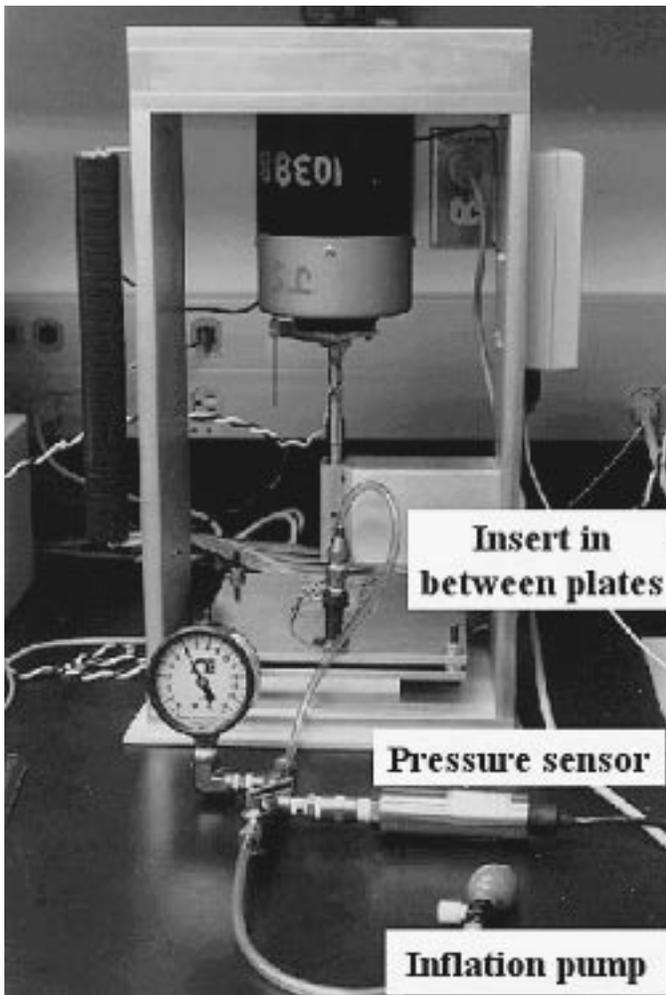
After the inserts were inflated, we closed the stopcock to remove the pressure to the pump and eliminate pump leakage from the system. This practice allowed pressure-loss evaluation exclusively for the insert material and the valve-to-bladder fitting. Insert pressure was assessed at 1-min intervals over the 60-min test period.

To remove system leakage effects from the data, we positioned a solid plug in place of the insert in the testing system and pressurized the system to the 43- to 46-kPa pressure. The system leakage over a 60-min time interval was 0.45 percent of the initial pressure. The system leakage versus time data were subtracted from the 60-min insert pressure loss versus time data to determine pressure loss exclusively from insert material deformation, insert leakage, and valve-to-bladder connection leakage.

Pressure versus time data were separated into two parts: the first 5 min and the subsequent 55 min. Pressure loss for each of the two intervals was determined. We selected these intervals for analysis because they were considered of most interest to clinical use—soon after donning (5 min) when the amputee might consider making minor adjustments and after a reasonable period of continuous use (60 min). The pressure losses over time did not affect the pressure-volume or pressure-thickness test results presented in the subsequent paragraphs.

### Pressure-Volume and Pressure-Thickness

To assess volume change for different inflation pressures, we oriented a deflated insert vertically and placed it in a 2-L widemouth Erlenmeyer flask. The flask was filled with water, and a rubber stopper (No. 13) with two holes was used to seal the top. The vertical orientation of the insert helped to ensure equal total hydrostatic pressure on opposite faces. The insert inflation hose extended through one hole in the stopper. Through the other hole, an exit hose extended to a water-filled graduated cylinder that served as a fine volume change indicator. Pressure and water height were measured for at least 11 inflation pressures between 0 kPa and the maximal inflation pressure. Since the inserts were unconstrained, some inserts



**Figure 2.** Testing apparatus. Insert pressure was assessed with the use of a commercial pressure transducer (foreground). For cyclic-loading tests, a shaker motor was used to apply controlled cyclic displacements to an insert position between two parallel aluminum plates (background).

(Pump It Up!, Pneumatic Volume Control System) could not achieve the 43- to 46-kPa range and maintain a reasonable size. Since data collected with this protocol were not affected by insert pressure loss over time, no correction for pressure loss was necessary.

We assessed thickness changes for different inflation pressures for each insert using a height gauge (NDS-8" M, Mitutoyo America Corporation, Aurora, IL) on a flat tabletop. The highest point was found by gradually lowering the arm and sweeping across the surface until interference was achieved (~0.25-mm resolution). Thickness measurements were recorded for at least 15 different inflation pressures between 0 kPa and the maximum inflation pressure for each of the nine inserts (maximum pressures were the same as those from the pressure-volume tests).

Pressure versus volume and pressure versus thickness data were segmented into a maximum of three linear portions and best fits established for each section. Volume and thickness at the intersections of the segments and the slopes of each segment were determined.

### Cyclic Compression

We compressed each insert in a custom-designed testing device, similar to that used previously to assess prosthetic liner materials (1). Force was applied with a shaker motor (ET126, Labworks, Costa Mesa, CA) through U-joints and a linear bearing to a plunger (**Figure 2**). Maximum motor axis displacement was 5 mm and maximum motor force was ~23 N. Displacement was measured with a linear variable differential transformer (LVDT) (MHR-500, Schaevitz, Pensauken, NJ), with the core connected to the face of the motor, and the bore attached to the frame of the system. Force on the plunger was measured with the use of a 44.5-N load cell (31/1426-04, Sensotec) positioned just above the plunger. Signals from the load cell were conditioned with a two-pole Butterworth low-pass filter with a cutoff frequency of 1,000 Hz to eliminate radio frequency noise. The system was operated under displacement control with the use of a virtual instrument written in LabView. Sinusoidal displacements were applied to the insert at 1 Hz while the system recorded at a 45-Hz sampling rate the force from the load cell, displacement from the LVDT, and pressure from the insert pressure sensor.

Because the surface area that was loaded, and thus the stress calculation, was highly sensitive to curvature changes at the edge of the insert as it was inflated, only a 81.9-mm<sup>2</sup> surface area was loaded with the plunger. We

positioned the insert between two 19-cm by 19-cm aluminum parallel plates (**Figure 2**). The top plate included a 10.80-mm diameter clearance hole to allow the plunger (10.21-mm diameter) to pass through and load the surface of the insert. The maximum force applied (~23 N) induced a normal stress comparable to the high end of that measured at the residual limb/prosthetic socket interface on amputee subjects walking with patellar-tendon-bearing prostheses (2), under the assumption that the force was uniformly distributed on the bottom of the plunger. At each of the two plate-separation distances (5.0 mm, 10.0 mm), we tested three insert pressures (low: 13.5 to 18.0 kPa, medium: 27.9 to 31.6 kPa, high: 41.2 to 45.6 kPa). Two plate separation distances were tested so as to assess influence of prestrain on the results. In clinical use, prestrain would exist. At the outset of each run, the plunger was adjusted so that the "0" position was flush with the inside surface of the top plate. To ensure that unrecovered material strain from initial expansion of the insert did not alter the results, we left samples in the device for 10 min before initial insert pressure was recorded and cyclic loading was initiated. Load versus displacement data were fit with a third-order polynomial for the loading segment.

We performed two different tests using the compression testing system: (1) A 10-min test with 2 s of data collection at 1-min intervals was run to establish the shapes of the stress-strain curves under short-term loading. All nine inserts were tested. (2) A 60-min test with 2 s of data collection at 10-min intervals provided insight into changes in properties over time. Only the Air Contact System large, PNEU-FIT small, Pump It Up! medium, and Pneumatic Volume Control System knee were tested for the 60-min interval and only at the medium insert pressure.

## RESULTS

### Pressure Loss Under Static Loading

All insert initial pressures were between 43.4 and 45.6 kPa. Pressure-loss rates varied by insert (**Table 2**), ranging from 0.00 percent/min to 1.36 percent/min.

For all inserts tested, pressure losses were higher for the first 5 min compared with the subsequent 55 min (**Table 2**, cols. 4 and 6). The Pneumatic Volume Control System inserts showed greater pressure losses than the other products, both in the first 5-min interval and subsequent 55-min interval. On further inspection (soapy water

**Table 2.**  
Insert pressure losses under static loading.

Mfr	Size	0 to 5 min		6 to 60 min	
		%*	%/min	%	%/min
Air Contact System	Small	1.09	0.22	1.02	0.02
	Medium	0.47	0.09	0.43	0.01
	Large	0.47	0.09	0.10	0.00
PNEU-FIT	Small	2.79	0.56	12.84	0.23
	Large	1.43	0.29	1.23	0.02
Pump It Up!	Small	2.47	0.49	1.99	0.04
	Medium	1.91	0.38	2.16	0.04
PVC System	Knee	6.78	1.36	7.37	0.13
	Anterior	5.05	1.01	14.76	0.27

\*% of initial pressure (43.4 to 45.6 kPa)

on the insert), leakage was found to occur at the check valve at the top of the pump apparatus for both inserts. To determine if the problem was simply a matter of two defective products, we tested two additional inserts (BK large left, AK combo). Results showed comparable or greater pressure-loss magnitudes as a percentage of initial pressures as well as pressure-loss rates: for the BK large left, 6.86 percent and 1.37 percent/min for the first 5 min and 27.21 percent and 0.49 percent/min for 6 to 60 min; for the AK combo, 7.17 percent and 1.43 percent/min for the first 5 min and 34.35 percent and 0.62 percent/min for 6 to 60 min. Thus leakage appears to be a property of products from this manufacturer. The small PNEU-FIT showed substantial leakage at the valve-to-bladder connection. However, the large PNEU-FIT did not show this result. Requests from the manufacturer for additional inserts were not granted; thus it was not possible to determine if the small PNEU-FIT's poorer performance was simply a matter of a single defective product or a typical result. Further leakage evaluation is needed on a larger sample size of PNEU-FIT products. Since other results presented in the following paragraphs (pressure-volume, pressure-thickness, cyclic-compression results) are independent of insert leakage, analysis and interpretation of those data are not affected by insert leakage. For the other inserts, pressure-loss rates among products from the same manufacturer were comparable.

To determine if pressure loss was due to unrecovered material strain from initial loading, we reinflated four of the inserts (Air Contact System medium, PNEU-FIT large, Pump It Up! medium, and Pneumatic Volume Control System knee small) 5 min after initial inflation.

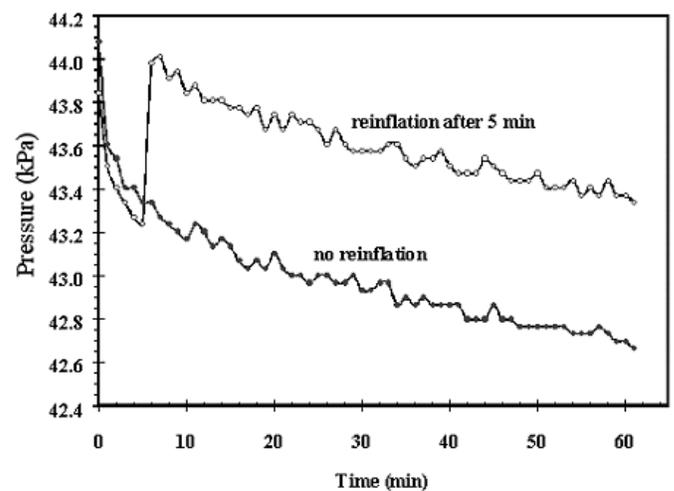
Results showed reduced pressure loss during the first 5 min after inserts were reinflated. Results for the PNEU-FIT large insert (**Figure 3**) are typical. While the 6- to 60-min pressure losses were comparable to those listed in **Table 2**, after inserts were reinflated, pressure losses for the 5-min interval were substantially reduced.

### Pressure-Volume

All inserts showed a low-slope initial portion (Phase I) followed by a steeper-slope secondary portion (Phase II) (**Figure 4; Table 3**, cols. 5 and 6). The Pump It Up! inserts showed a third segment (Phase III) of lower slope than the slope in Phase II. For inserts from the same manufacturer, the location of the transition from Phase I to Phase II depended on the size of the insert, being further from the origin for larger inserts (**Table 3**, col. 3). In general, for products from the same manufacturer, the Phase II slopes (**Table 3**, col. 6) decreased with increased insert volume. Slopes were much higher for the PNEU-FIT than for the other products, the only product that had ribbing across it to control thickness. Slopes were lowest for the Pump It Up!, the only product with membranes made entirely of natural rubber.

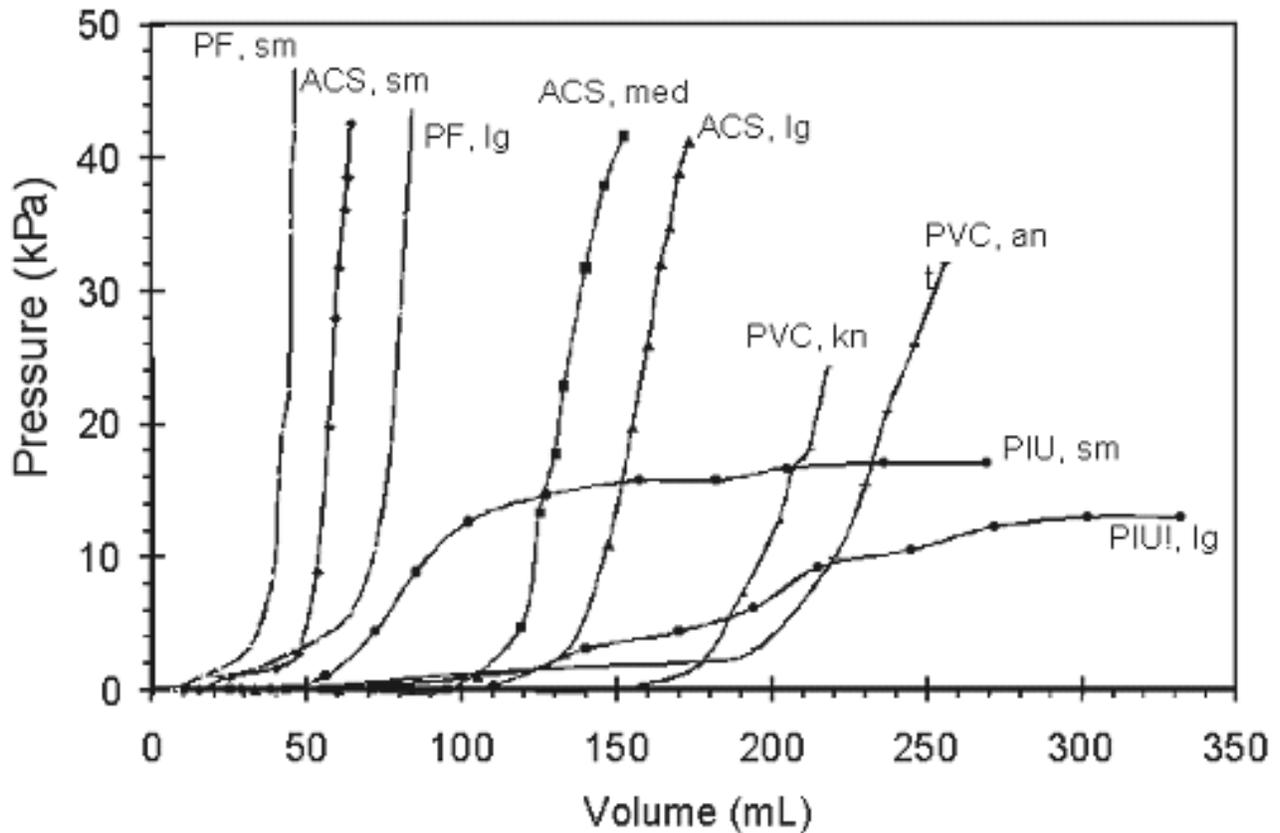
### Pressure-Thickness

Pressure versus thickness curves also showed a low-slope initial portion (Phase I) followed by a steeper-slope secondary portion (Phase II) (**Figure 6**). However, inserts



**Figure 3.**

Pressure loss over time. Pressure loss was highest during the first 5 min after initial inflation (solid circles). However, when the insert was reinflated after 5 min, the pressure loss for the subsequent 5 min was minimal (open circles). Results are for PNEU-FIT large.



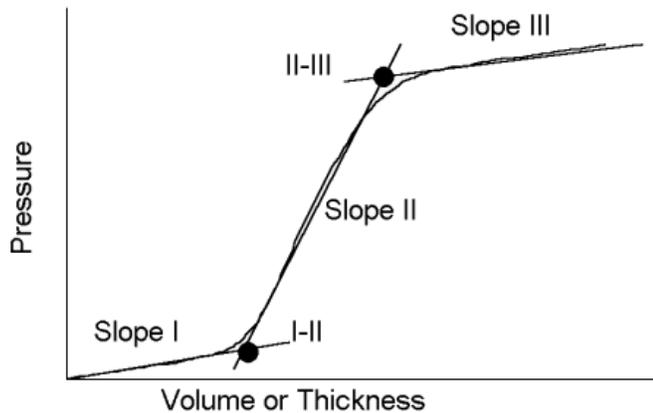
**Figure 4.**

Pressure-volume results. All inserts showed low initial slope portions followed by steeper secondary slope regions. PF=PNEU-FIT; ACS=Air Contact System; PVC=Pneumatic Volume Control System; PIU!=Pump It Up!; sm=small; med=medium; lg=large; kn=knee disartic. small; ant=anterior.

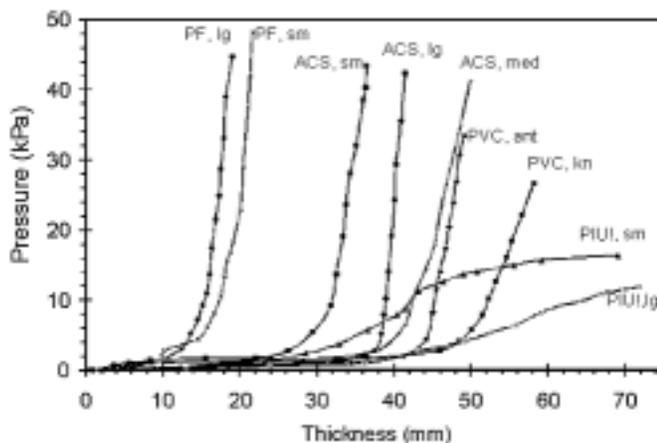
**Table 3.**

Pressure-volume (PV) and pressure-thickness (PT) results.  $V_{\text{infl}}$ : volume at inflection point,  $t_{\text{infl}}$ : thickness at inflection point, Phase I slope: initial linear portion, Phase II slope: secondary linear portion, Phase III slope: tertiary linear portion (if applicable). The slopes and inflection points are defined as shown in **Figure 5**.

Mfr	Size	P vs V					P vs t				
		$V_{\text{infl}}$ (ml)		Slope (kPa/ml)			$t_{\text{infl}}$ (mm)		Slope (kPa/mm)		
		I-II	II-III	I	II	III	I-II	II-III	I	II	III
Air Contact System	Small	51.02	—	0.07	3.06	—	30.99	—	0.09	7.12	—
	Medium	113.81	—	0.00	1.15	—	40.93	—	0.07	4.14	—
	Large	139.30	—	0.02	1.20	—	38.23	—	0.04	12.55	—
PNEU—FIT	Small	39.49	—	0.14	5.83	—	15.53	19.92	0.35	3.69	5.36
	Large	73.63	—	0.09	3.58	—	12.45	15.80	0.28	2.38	10.53
Pump It Up!	Small	52.72	109.35	0.00	0.26	0.02	30.02	48.68	0.06	0.65	0.14
	Medium	109.25	241.26	0.00	0.08	0.03	39.98	67.87	0.03	0.36	0.20
PVC System	Anterior	208.84	—	0.02	0.62	—	43.84	—	0.03	6.02	—
	Knee	174.14	—	0.00	0.51	—	49.70	—	0.05	2.82	—



**Figure 5.** Definitions for slopes and inflection points for data in **Table 3**.



**Figure 6.** Pressure-thickness results. The steep secondary slope regions for all inserts occurred beyond a 10-mm thickness level. PF=PNEU-FIT; ACS=Air Contact System; PVC=Pneumatic Volume Control System; PIU!=Pump It Up!; sm=small; med=medium; lg=large; kn=knee disartic. small; ant=anterior.

with a smaller surface area did not necessarily transition at a lower thickness. The Phase I slopes (**Table 3**, col. 10) were higher for the PNEU-FIT than for the other products. In the Phase II portions, the thickness change over the reasonably large pressure range was only 3 to 9 mm for all products except the Pump It Up! The Pump It Up! showed an 18- to 28-mm range for Phase II and an additional 4- to 20-mm range for Phase III. The PNEU-FIT results were separated into three phases because of their slow Phase I to Phase II transition regions. The PNEU-FIT Phase III slopes were much higher than the Phase II slopes for the other products.

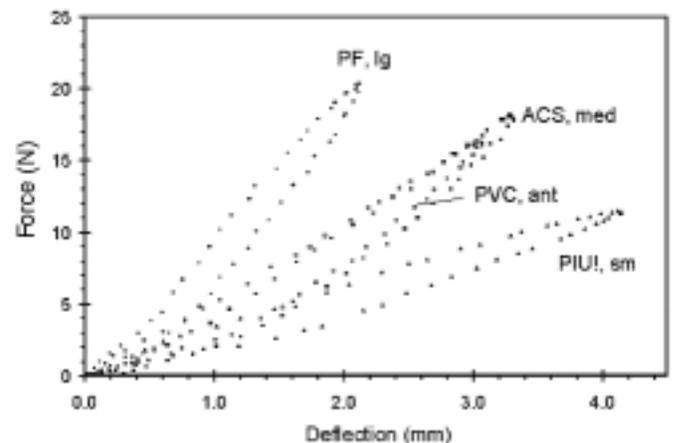
Results for both the pressure-volume and pressure-thickness tests are plotted with an unconventional practice, the dependent variable (volume, thickness) on the horizontal axis. We did this to ensure consistency with other plots in this paper: load on the vertical axis and deformation on the horizontal axis.

### Cyclic Compression

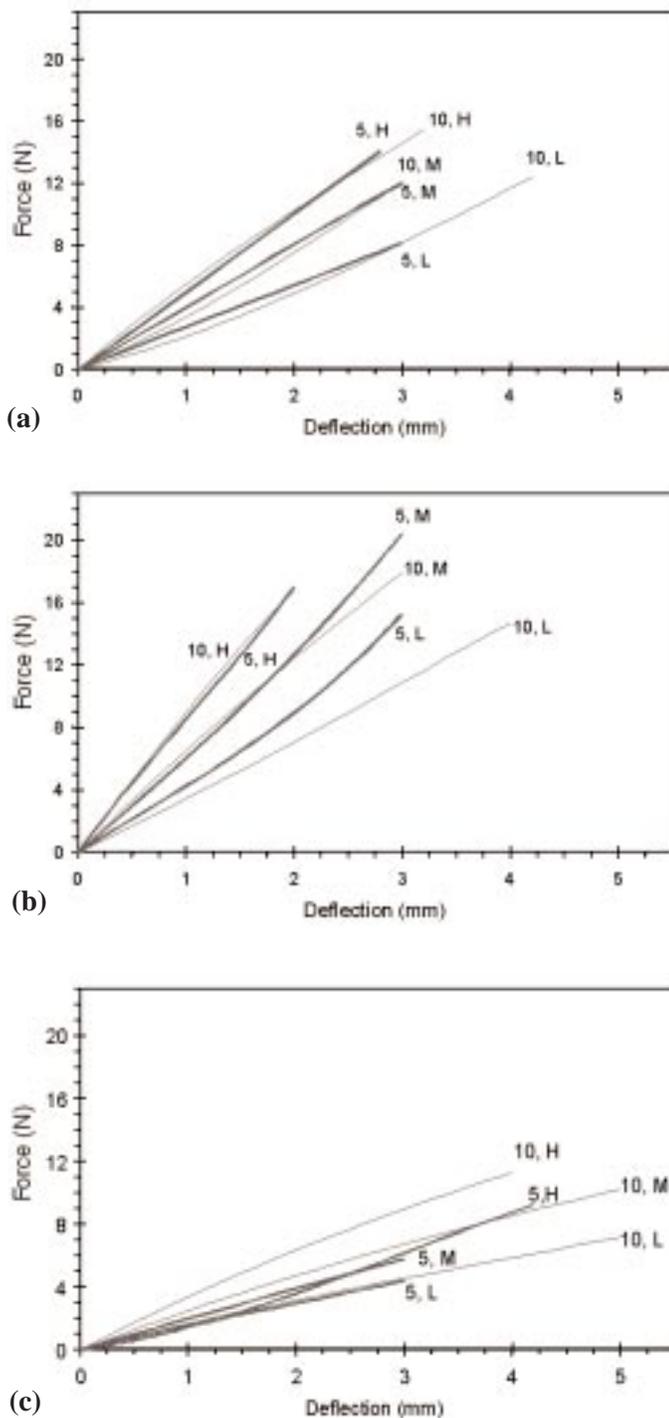
The inserts showed nonlinear force-deflection curves and reasonably large hysteresis (**Figure 7**). The hysteresis is expected because of viscoelastic effects in the bladder material. However, slopes varied among products, being highest for the PNEU-FIT and lowest for the Pump It Up! All curve fits had R-squared values of greater than 0.99.

The rising parts of the force-deflection curves showed greater sensitivity to insert pressure than to plate spacing (constrained thickness) (**Figure 8**), particularly for the low and medium insert pressures for Air Contact System, Pump It Up!, and Pneumatic Volume Control System, and the medium and high insert pressures for PNEU-FIT. Thus in clinical use, if the thickness is changed for the ranges investigated here by altering the residual limb to socket distance, the local mechanical response is not severely affected.

For the 60-min cyclic-loading tests, the shapes of force-deflection curves at 10 min were very similar to



**Figure 7.** Force-deflection results—raw data. Data at 10-min mark from cyclic-loading tests on four inserts are shown. Inserts were tested at a 10.0-mm plate spacing and high (41.2 to 45.6 kPa) insert pressure. PF=PNEU-FIT; ACS=Air Contact System; PVC=Pneumatic Volume Control System; PIU!=Pump It Up!; sm=small; med=medium; lg=large; ant=anterior.



**Figure 8.**

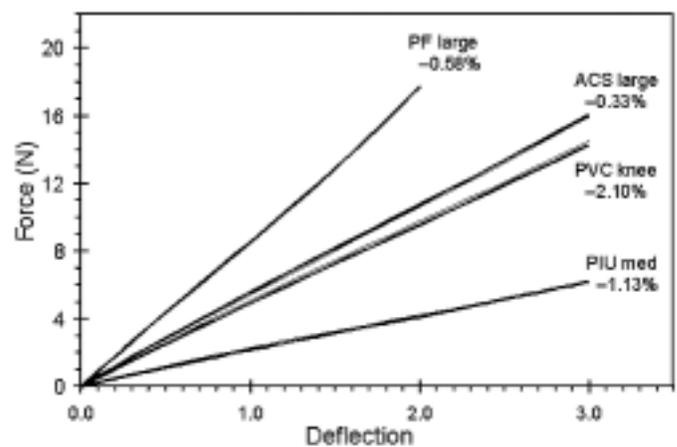
Force-deflection results-fit data. Results from cyclic-loading tests (loading portion only) for four inserts are shown: (a) Air Contact System, large; (b) PNEU-FIT, small; (c) Pump It Up!, medium; and (d) Pneumatic Control System, knee. 5 (thick line)=plate spacing of 5.0 mm, 10 (thin line)=plate spacing of 10.0 mm, L=low insert pressure (13.5 to 18.0 kPa), M=medium insert pressure (27.9 to 31.6 kPa), and H=high insert pressure (41.2 to 45.6 kPa).

those at 60 min (**Figure 9**). Thus the loss in insert pressure shown to occur over a 60-min interval (**Table 2**) did not substantially alter the force-deflection data. However, different products had different slopes. PNEU-FIT products had the highest slopes and the Pump It Up! products had the lowest slopes.

## DISCUSSION

Because the pressure-loss rates (percent/min) from the static tests were higher for the first 5 min than for the next 55 min for all materials (**Table 2**), all materials likely experienced some unrecovered strain after initial loading. The materials stretched in response to the initial pressure. Because 60-min cyclic-loading tests at medium insert pressures (27.9 to 31.6 kPa) showed minimal force-deflection curve differences in the comparison between 10 min and 60 min (**Figure 9**), it is reasonable to conclude that pressure losses were significant only at high pressures and only very soon after inflation. Because pressure losses were reduced after inserts were reinflated (**Figure 3**), it is likely that material creep was a major source of the initial 5-min pressure loss. Thus in clinical practice, users need to reinflate inserts after the first few minutes of use if it is desirable to reach initial high pressures.

The pressure versus volume data (**Figure 4**) showed that the inserts expanded under minimal resistance during



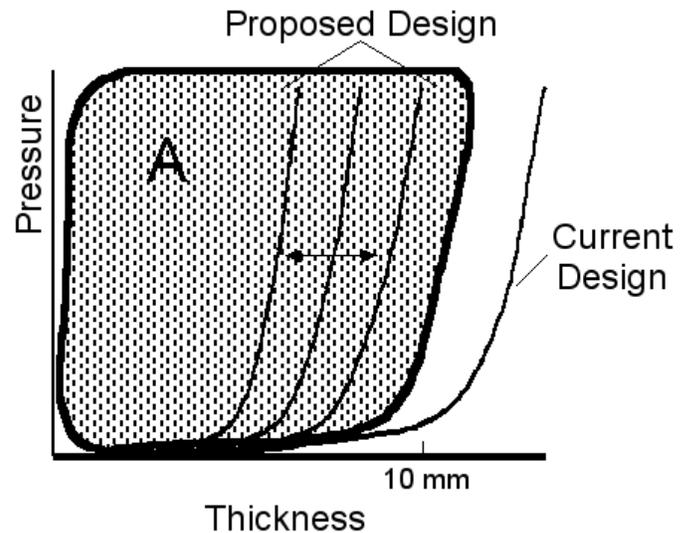
**Figure 9.**

Time effects. Comparison of 10-min (thin line) and 60-min data (thick line) from cyclic-loading tests (loading portion only) from four inserts tested at a 10.0-mm plate spacing and medium insert pressure (27.9 to 31.6 kPa). Numbers are maximal differences between 10-min and 60-min results as a percentage of full-scale output.

the initial Phase I parts of the curves. However, the inserts offered sufficient resistance to provide support when they hit the Phase I to Phase II transition points. According to the size and design of the insert, the volume at that I to II threshold varied. The PNEU-FIT product had a lower threshold transition point than the other products, presumably because the ribbing across it limited its increase in volume. The Pump It Up! product was unique in that it showed a three-phase curve, consistent with that from tensile testing of natural rubber (3), its membrane material. The Pump It Up! insert was the only product to achieve a relatively moderate pressure-volume slope at high insert volumes.

An extension of the pressure versus volume data, the pressure versus thickness data provide insight into the clinical criticism that inserts often do not provide equal and consistent support to the residual limb and that if they are inflated to a higher pressure to overcome this problem, then the inserts are too big and may distort the localized soft tissues. The thickness during the Phase II portions of the curves (12 to 58 mm) is beyond that for practical clinical use (<10 mm). Most prosthetists would make a new socket if a 10-mm or more thickness were needed. The liner would be too distorted to function properly. Further, stresses would be concentrated only in the area over the insert, a relatively small area compared to the surface area of the residual limb that changed shape and needed insert support. Because the thickness during the Phase II portions of the curves is beyond 10 mm, when inflated within a socket, inserts encounter resistance by the residual limb and socket surrounding the insert before sufficient tension is generated in the insert membrane material itself. Rather than the insert supporting the residual limb as desired, the residual limb is supporting the insert. In other words, the insert is serving as a compressible unit that is softer than the residual limb. This response is very important because blood flow occlusion in human skin occurs at a relatively low pressure (~8 kPa) (4). When the insert thickness is <10 mm, the tissues rather than the membranes of the insert experience high stresses in their effort to control insert thickness. The inserts are operating in region A (**Figure 10**) of the pressure-thickness curve.

The cyclic-loading data extend this interpretation. The low dependence of the shape of the force-deflection curves on plate-separation distance shows that the mechanical response was dependent on the local environment around the plunger. Both the tensile stiffness of the membrane material and the underlying insert pressure



**Figure 10.**

Modified insert design. Inserts operate in region A. An improved design would allow adjustment of high-slope portion within region A.

determined the local stiffness measured. When insert thickness was restricted by the plates (as a residual limb would restrict insert thickness in a socket), local stiffness was highly dependent on insert pressure. Thus the underlying pressure provided a reasonable amount of the resistance to the load; the tensile stiffness of the membrane was relevant, but it did not dominate to the point that response was relatively independent of underlying pressure. Since the inserts were not stretched to the Phase II regions, the tensions in the insert membranes were not as high as what would be needed for them to dominate constraint of the inserts. They still could elongate and did so in the cyclic-loading tests. Thus during ambulation, because the insert membranes are not in their high state of tension, the inserts can be highly susceptible to localized deformation, inducing a sense of instability during ambulation, as noted clinically.

An improved insert design would exhibit a I to II transition point at a reasonably low thickness (<10 mm) so that membrane tension rather than residual limb compression would provide the resistance to a thickness increase (**Figure 10**). We selected a thickness of 10 mm here based on clinical experience that a thickness greater than 10 mm requires socket replacement. The PNEU-FIT product is a step toward achieving this design in that it has ribbings across it to restrict insert expansion. Thickness at the transition point was relatively low (12 to 16 mm) compared to the other products (30 to 50 mm). Further, the PNEU-FIT insert is very stiff when inflated,

thus providing a good stiff support. However, a limitation of the proposed design is that though the insert would perform well at the volume and thickness within the designed Phase II region, that range is very narrow. Thus the product would have minimal adjustability. It would perform well and provide good residual-limb support at that volume and thickness, but it would be poor in terms of accommodating a wide range of volumes and thickness. A better design could shift the I to II transition point easily and conveniently (**Figure 1**), while still maintaining a high Phase II slope. A means to control and adjust the distance between the top and bottom membrane of the insert, a manually adjustable mechanism for example, would be one method of achieving this versatility. The thickness and thus volume could be adjusted according to the need. Another alternative would be to use a viscous fluid rather than air as the medium, making the thickness independent of insert pressure.

The Pump It Up! product exemplifies another approach to achieving insert volume and thickness adjustment. This product differs from the others in that it takes advantage of the three-phase response of rubber to create a region where a moderate increase in pressure achieves a large increase in insert volume (Phase III). It is unclear from the testing conducted here, however, if the Phase III portion of the curve is reached during clinical use, i.e., if the membrane constrains the insert instead of the residual limb constraining the insert. The Pump It Up! insert, unlike the other products, is positioned between the socket and an inner shell, protruding through holes in the inner shell to effect a volume change of the socket. Thus the tension in the membrane is dependent on the prestresses in the material achieved with the fabrication and assembly procedure. If Phase III tensions were achieved and the pressure thresholds of that region (transition II to III) were high enough to provide sufficient residual-limb support, then an effective means for adjusting volume is achieved. It would be important, however, to ensure that the insert membrane, not the residual limb, did indeed constrain insert thickness.

## CONCLUSIONS

The pressure-loss, pressure-volume, pressure-thickness, and cyclic-loading data presented here provide insight into links between mechanical response and insert clinical performance. Results indicate—

1. Insert pressure-loss rates were higher in the first 5 min after inflation compared with the next 55 min, indicating that if a user seeks to re achieve an initial high inflation pressure, the insert should be reinflated after a few minutes. The pressure-loss rates varied considerably among products.
2. For sizes practical for clinical use (<10-mm thickness), inserts encounter resistance from the residual limb and socket before insert membrane tension can provide much support. Since blood flow occlusion occurs at a relatively low pressure (8 kPa) (4), tissue damage can easily occur.
3. Insert designs that allowed adjustment of the location of the steep-slope portion of the pressure-thickness curve within a clinically useful range (<10 mm) would help to overcome limitations.

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