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Technical note

How does vacuum forming affect Pelite mechanical properties?

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Abstract
Pelite® is a polyethylene closed cell foam commonly used as an interface material in prosthetics. Both normal and vacuum-formed Pelite were tested under compression and under shear loading. For shear testing, the results were not significantly different for normal and vacuum-formed Pelite. For normal Pelite, the slope of the stress-strain curve was 1.17MPa (±0.14) while for vacuum-formed Pelite it was 1.24MPa (±0.22). Compressive results, however, were significantly different. Below 80kPa of applied compression, the slope of the stress-strain curve for normal Pelite was 0.99MPa (±0.11) while for vacuum formed Pelite it was 0.72MPa (±0.12). Between 80kPa and 200kPa of applied compression, the slope of the stress-strain curve for normal Pelite was 0.45MPa (±0.03) while for vacuum formed Pelite it was 0.55MPa (±0.05). Reasons for the differences and their significance to interface mechanics and computer-aided prosthesis design are discussed.

Introduction

An amputee using a lower-limb prosthesis typically wears a cushioning liner between the stump and the prosthetic socket. Pelite, which is an expanded closed cell polyethylene foam made up of units of hydrocarbon chains, is commonly used for this purpose. Typically used in 3mm or 5mm thickness, Pelite is well suited for use with recently developed computer aided design/computer aided manufacturing (CAD CAM) prosthetic socket fabrication systems (Davies and Russell, 1979). It deforms plastically under heat and pressure to conform to the inside socket shape.

Clinical experience suggests that Pelite is altered by the vacuum forming process. A qualitative description is that it becomes thinner and more rigid. The change is important because the liner has less of a cushioning effect on the stump, i.e. the distribution of the normal and shear forces between the stump and socket is altered. In addition, inconsistencies in mechanical properties in different regions of the liner occur, and this further affects performance. At bony prominences, which require the socket to be curved to relieve interface stress, the Pelite becomes more thin and rigid than the surrounding regions of the liner.

In current clinical practice, the changes in Pelite thickness and stiffness as a result of vacuum forming are usually not planned or desirable. A prosthetist will typically overcome them by altering the liner after vacuum forming, for example placing an additional backing material on the outside of the liner. Alternatively more layers of Pelite could be added before vacuum forming to regions anticipated to become too thin.

In this technical note, changes in Pelite mechanical properties as a result of vacuum-forming are investigated. The purpose is to provide the initial work to determine quantitatively how the changes in Pelite mechanical properties from vacuum forming alter interface stresses. Finite element model

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analysis of the stump, liner, and socket will be conducted subsequent to the investigations described here to evaluate interface stress sensitivity to the measured Pelite liner mechanical property changes. If important interface stress changes are found then subsequent work will investigate techniques to overcome the detrimental effects of vacuum-forming and instead alter the liner properties in a favourable way. In other words, we would like to control liner properties during fabrication so that favourable stump prosthetic socket interface stresses as opposed to unfavourable ones are created.

There are a limited number of studies in the rehabilitation literature investigating mechanical properties of interface materials. Most of them have been conducted on shoe insert materials which are similar to the prosthetic materials of interest here, however the stress levels in those studies were higher than those encountered by amputees using prosthetic limbs. Four studies are of relevance to the work in this technical note. Campbell *et al.* (1982) found that under compression some closed-cell foam interface materials had a three part load-deformation curve: a high initial slope, a moderate intermediate slope, then a high final slope. He called those materials "moderately deformable" and suggested they represented the best class of interface materials because the slope changes were gradual. Materials that have only two distinctly different slopes, low and high, are less optimal, and Campbell called those "very stiff" or "highly deformable" materials, depending on their moduli. Loading history effects on Pelite mechanical properties were also investigated. Campbell *et al.* (1984) found that after release from seven days of sustained loading at 50% strain, 1.6mm thick Pelite suffered 25% elastic strain, i.e. was only 75% of its original thickness. After repetitive loading of 250,000 cycles at 294kPa, approximately 25% elastic strain was found. But in another study where 5mm thick Pelite was loaded at 392kPa for 10,000 cycles at 1Hz, the elastic strain was only 2% (Brodsky *et al.*, 1988). Thus the results suggest elastic strain is dependant on the number of cycles and initial thickness. Kuncir *et al.* (1990) suggested there are relationships between cell dimensions, uniformity, and reticulation and proposed such relationships are of tremendous clinical relevance because these properties strongly affect the distribution of stress and the time dependent recovery characteristics of the materials. A more complete description of the theory of closed cell foams where quantitative relationships are described is presented by Gibson and Ashby (1988).

Despite recognition of the importance of liner properties and relationships between cell structure and liner properties, the effects of vacuum forming, a technique commonly used in prosthetics to fabricate a socket liner, on Pelite foam structure or mechanical properties has not been investigated. The purpose of this study was to compare normal and vacuum formed Pelite. Mechanical performance of normal and vacuum formed Pelite under compressive loading and under shear loading was evaluated. Loading magnitudes in the ranges of recent interface stress measurements on trans-tibial amputees (Sanders *et al.*, 1993) were used. Subsequently, beyond the scope of this technical note, effects of the different properties on interface stresses will be investigated using a finite element model.

Methods

Specimens

For testing of normal Pelite, sheets of 5 mm thickness of Pelite were obtained from a distributor (Durr-Fillauer Orthopaedic, Incorporated; Chattanooga, TN). For vacuum formed testing, flat specimens were constructed by fabricating parallel pipe plaster/cornstarch casts using computer aided software (Shapemaker©, Prosthetics Research Study, Seattle, Washington). Socket vacuum forming was conducted using a number 2 Pelite truncated cone with end pads. An oven temperature of 220°C and a vacuum pressure of 98kPa were used. Vacuum formed sheet thickness was 2.79mm (±0.27). Normal specimen thickness was 4.95mm (±0.21).

For compression testing, 2.54cm diameter disks were cut using a punch press. Specimens were taken from the central 80% of the width and length of a sheet to avoid thickness changes at the corners. For shear testing, 9.0mm x 9.0mm specimens were cut using a custom designed device that held two scalpel blades parallel during cutting. Specimens were square to within ±0.07mm tolerance. Specimens were taken from the central 80% of the width and length of a sheet. For compression testing, five normal and five vacuum formed specimens were used. For shear testing, ten normal and ten vacuum-formed specimens were used.

To gain insight into structural differences between normal and vacuum formed Pelite, thin cross-sectional slices cut perpendicular to the surface were prepared and examined using a light microscope. A qualitative assessment of the structure was conducted.

Compression testing

Compression testing was performed using an Instron™ (Canton, MA) testing machine with a 2000N load cell. Displacement was measured with a Schaevitz™ (Pennsauken, NJ) linear velocity displacement transducer (LVDT) (DC-D 500) with the bore attached to the base and the core attached to the crosshead. A single trial was performed to pre-condition the specimen. A strain rate of 0.5cm/min and a maximal stress of 200kPa were used. Subsequently, data were collected during two consecutive tests of loading and unloading at a strain rate of 0.5cm/min with 60 seconds between the tests. Data acquisition was performed with an A/D board (Data Translation DT2801A, Marlboro, MA) and a personal computer at a sampling rate of 1Hz.

Only a single specimen at a time was placed between the platens during testing. Though stacks of specimens would reduce edge effects, stacks of Pelite were not used here because it was desirable to test the materials in the same configuration as they would be when in a prosthetic socket. Thus testing of stacks of materials is considered an area of further research; differences with data here might provide further insight into foam mechanics.

Shear testing

Testing was performed to provide insight into Pelite response under shear loading, information that combined with the compression data above might expand insight into mechanics of the closed cell foam when loaded at the stump-socket interface. Using the apparatus shown in Figure 1, two specimens at a time were tested under shear loading. The crosspiece mass was 19.2 grams. Care was taken to ensure that the aluminum slats were parallel to each other so

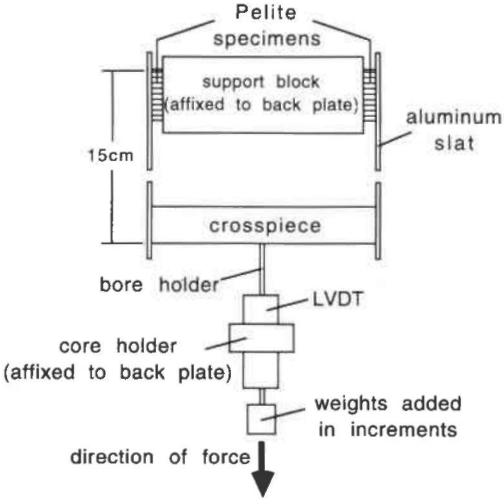

Fig 1. Two 9.0mm x 9.0mm specimens were tested under shear loading as shown.

that the Pelite was not pre-stressed in torsion before the weights were added. After a single pre-conditioning trial, two consecutive tests of loading and unloading were performed with 60 seconds between the tests. Loads to 575 grams were applied in 10 steps. Approximately 5 seconds elapsed after each load addition before a measurement was recorded.

Force and deflection measurements were converted to stress and strain data respectively. The initial dimensions of the normal and vacuum formed Pelite specimens were used for the area term in the stress calculations and for the initial thickness in the strain calculations.

"Apparent moduli" were calculated from compression testing results. The term "apparent" is used so as not to confuse the results with true moduli, which is a parameter measured from accepted standards testing procedures. For soft closed cell foams such as Pelite, standards have not as yet been approved thus means of obtaining true moduli are not yet specified. For shear testing results, the slopes of the stress-strain curves are presented. Again, no standard shear test has been approved for soft closed cell foams, thus "apparent shear modulus" is the terminology used here.

Results

Compression testing results for normal Pelite were different from results for vacuum formed Pelite. Typical stress-strain plots are shown in

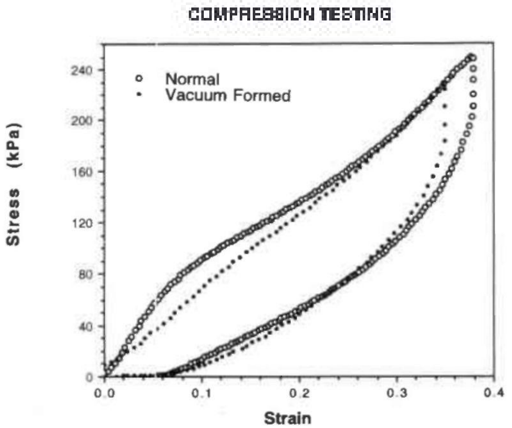

Fig 2. Typical compression testing results for normal and vacuum formed Pelite.

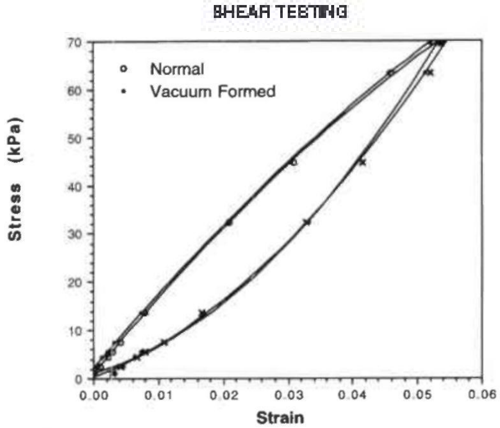

Fig 3. Typical shear testing results for normal and vacuum formed Pelite.

Figure 2. Two apparent moduli, which were linear least square fits to the data, were calculated for each trial, one for the range 0kPa to 80kPa and one for the range 80kPa to 200kPa. The basis for selection of 80kPa as the division point was this was the stress of the greatest slope change in the curves. Only the loading phase of each trial was considered in this analysis. Normal Pelite apparent modulus averaged 0.99 (±0.11) MPa at stresses between 0Kpa and 80kPa while it was 0.45 (±0.03) MPa at stresses between 80kPa and 200kPa. Vacuum formed Pelite apparent modulus was 0.72 (±0.12) MPa at stresses less than 80kPa while it was 0.55 (±0.05) MPa at stresses between 80kPa and 200kPa (Table 1). The differences between normal and vacuum formed were significant ($p<0.01$) for both the 0kPa to 80kPa range and the 80kPa to 200kPa range. Elastic strains after the second and third trials were minimal.

Shear test results were not significantly different for normal and vacuum formed specimens (Fig. 3). Apparent shear moduli were 1.17 (±0.14) MPa and 1.24 (±0.22) MPa respectively. Linear least square fits to the data were used to calculate the slopes. Elastic strains after the second and third trials were minimal.

Examination with a microscope showed that normal and vacuum formed Pelite had different structures. Cells on the surfaces of vacuum formed specimens were collapsed while those in the mid-region of the cross-section were circular or elliptical with their major axes parallel with the surface. Thus there was a "skin" of compressed cells on the top and bottom surfaces. Normal Pelite, however, showed rounded cells throughout with minimal or no "skins" on the surfaces.

Discussion

In previous research, maximal stance phase interfaces stresses on tibial flare, lateral, and posterior regions on trans-tibial amputees ranged from 46kPa to 205kPa for normal stress and 9kPa to 54kPa for shear stress (Sanders *et al.*, 1993). On trans-femoral amputees normal stresses ranged from -6kPa to 345kPa (Appoldt *et al.*, 1968). Thus results presented in this technical note show that within those ranges normal and vacuum formed Pelite demonstrated different mechanical properties.

The differences can be explained by alterations in the cellular structure. Vacuum formed Pelite as evidenced by its elliptical cell structure in the central region lost the integrity

Table 1: Thicknesses and mechanical properties for normal and vacuum formed Pelite.

Type of Pelite	Thickness (mm)	Compressive Apparent Modulus (MPa) [0 to 80kPa]	Compressive Apparent Modulus (MPa) [80 to 200kPa]	Shear Apparent Modulus (MPa) [0 to 70kPa]
Normal	4.95 (±0.21)	0.99 (±0.11)	0.45 (±0.03)	1.17 (±0.14)
Vacuum formed	2.79 (±0.27)	0.72 (±0.12)	0.55 (±0.05)	1.24 (±0.22)

of vertically oriented structural elements within the foam, resulting in reduced resistance at low loads. Thus the lower part (0kPa to 80kPa) of the compression testing stress-strain curve for vacuum formed Pelite had a lower apparent modulus than that for normal Pelite. At higher loads, however, the cells were collapsed thus loads were transferred across the cell walls. Thus at high loads (80kPa to 200kPa) the apparent modulus was higher than for normal Pelite. Shear testing results provide further insight into cell response to stress. The lack of a significant difference in apparent shear moduli for normal and vacuum formed Pelite but the presence of a difference in structure suggests that vacuum formed cells responded differently than normal cells. Vacuum formed Pelite had "skins" of collapsed cells on the top and bottom surfaces, and presumably those regions underwent minimal lateral deformation. The lack of deformation in the skins, however, was compensated for by excessive deformation in the elliptical cells, thus under shear loading the elliptical cells deformed more easily than the normal cells. This interpretation is consistent with the interpretation of compressive testing results described above. The vacuum formed Pelite had a weaker cell structure. To evaluate the above suggested hypotheses, cellular structural modelling, similar to that suggested by Kuncir *et al.* (1990) for body support interface materials and more formally described by Gibson and Ashby (1988) for foams in general, should be conducted.

The findings presented here are consistent with results presented in the literature. Campell *et al.* (1982) suggested that the slope differences for different regions of the stress-strain curves are of clinical relevance. Thus changes in the slopes of normal vs. vacuum formed Pelite might explain the clinically observed performance differences for normal vs. vacuum formed Pelite. In addition, literature results suggest that for a short number of load cycles (less than 10,000 cycles), elastic deformation is minimal, a finding supported by results presented here. Reports from the literature do suggest, however, that long-term loading does affect Pelite mechanical properties, thus further research should consider long-term loading effects on the results.

If subsequent investigation using finite element analysis demonstrates that stump-socket interface stresses are highly sensitive to Pelite mechanical property changes encountered during vacuum forming, then an exciting concept is introduced to prosthetics. During liner fabrication, control of Pelite local properties might possibly be used to control interface stress distributions. This could be accomplished in a practical manner by altering the cell dimensions in the closed cell Pelite foam, possibly using local thermal control. Thus liners would be custom designed to the needs of the individual patient. The concept of variable mechanical property liners is currently practised clinically, but the methods are time consuming and impractical. A prosthetist typically cuts out a region of the liner and replaces it with a new material that is of more appropriate mechanical properties for that skin region. For example, nylon reinforced silicone is commonly placed at very sensitive soft tissue sites. However, clinical results are not necessarily always beneficial, in part because the edges at the interface of the two linear materials is a source of subsequent skin irritation. In addition, the fabrication processes are extremely time consuming. A liner that was continuous but with local changes in mechanical properties, for example a liner with locally variable micro-cell sizes, would be more optimal.

Acknowledgements

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REFERENCES

APPOLDT FA, BENNETT L, CONTINI R (1968). Stump-socket pressure in lower extremity prostheses. *J Biomech* **1**, 247-257.

BRODSKY JW, KOUROSH S, STILLS M, MOONEY V (1988). Objective evaluation of insert material for diabetic and athletic footwear. *Foot Ankle* **9**, 111-116.

Campbell GJ, McLure M, Newell EN (1984). Compressive behaviour after simulated service conditions of some foamed materials intended as orthotic shoe insoles. *J Rehabil Res Dev* **21,** 57-65.

Campbell GJ, Newell EN, McLure M (1982). Compression testing of foamed plastics and rubbers for use at orthotic shoe insoles. *Prosthet Orthot Int* **6,** 48-52.

Davies RM, Russell D (1979). Vacuum formed thermoplastic sockets for prostheses. In: Disability./ edited by Kenedi RM, Paul JP, Hughes J. – London: MacMillan Press Ltd. p385-390.

Gibson LJ, Ashby MF (1988). Cellular solids: structure and properties. – Oxford: Pergamon Press.

Kuncir EJ, Wirta RW, Golbranson FL (1990). Load-bearing characteristics of polyethylene foam: an examination of structural and compression properties. *J Rehabil Res Dev* **27,** 229-238.

Sanders JE, Daly CH, Burgess EM (1993). Clinical measurement of normal and shear stresses on a trans-tibial stump: characteristics of waveform shapes during walking. *Prosthet Orthot Int* **17,** 38-48.