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Elastic deformation of a tapered vascular prosthesis

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An approximate analysis of the elastic properties of tapered microfibrous polyurethane arterial prostheses is presented by considering a tapered conduit to consist of a series of short cylindrical segments. Using this approach, the relatively simple, non-linear finite deformation models developed for cylindrical arterial specimens may be applied to each segment. A constitutive equation based on a polynomial form of strain energy density function is used in this study. The constitutive constants are determined using experimental data obtained from uniform cylindrical grafts and are used to predict the mechanical response of tapered grafts. The variation in local compliance for linear, tapered grafts of uniform and variable wall thickness is determined. Similarly, the variation in longitudinal strain for tapered grafts subjected to various longitudinal tensions is calculated. The primary purpose of this analysis is to provide data for the design of tapered, compliant vascular grafts. It may also be used to characterize the elastic properties of other non-uniform axi-symmetric elastomeric conduits.

1. Introduction

There are two main arguments usually put forward in support of the claim that small diameter arterial grafts should be designed with elastic properties matched closely to those of the host artery. The first is concerned with the high stress concentrations introduced at the suture line when materials of different mechanical properties are joined together which can lead to anastomotic rupture and the formation of false aneurysms [1]. The second argument relates to the haemodynamic consequences. Differences in elastic properties would give rise to a mismatch in the luminal cross-sectional area resulting in pulse wave reflection [2], flow separation and turbulence [3, 4] near the anastomosis. Pulse wave reflection is accompanied by energy losses and a reduction in the perfusion of the distal tissues. Low and high shear stresses are commonly found in the regions exposed to such haemodynamic disturbances and there is evidence that these sites are predisposed to the development of neo-intimal hyperplasia and thrombosis [5–8]. Intimal hyperplasia leads to a gradual reduction in the lumen of the implant and may result eventually in occlusion.

From mechanical and haemodynamic considerations, it is desirable to match the compliance of the graft to that of the host artery. Recent reports of *in vivo* experiments to compare the performance of rigid and compliant arterial grafts have demonstrated a clear advantage in favour of compliant grafts [9, 10]. Other studies, however, have failed to show a correlation between patency rates and compliance [11].

To design vascular grafts with compliance matched to that of the natural artery, a detailed description of the mechanical properties is required. There have been several papers concerned with the characterization of the static and dynamic elastic properties of elastomeric vascular grafts [12–16]. The mathematical models have only been applied to grafts with uniform cylindrical geometry. Grafts with a tapered lumen have been shown, in *in vitro* experiments, to have hydrodynamic advantages in terms of improved flow stability and high wall shear stresses [17, 18]. Although tapered grafts made of expanded polytetrafluoroethylene (PTFE) have been commercially available for a number of years, there have been no reports dealing with their mechanical properties. The purpose of the paper is to report the results of an investigation into the elastic properties of tapered poly(ether–urethane–urea) (PEUU) grafts. The properties of cylindrical grafts made from the same polymer and having a similar microstructure were described in a previous paper [13]. The experimental data were fitted to a theoretical model based on the existence of a strain energy density function which can be expressed as a polynomial in the principal strains [19]. Equations relating pressure and longitudinal force and strains were derived from which the compliance was to be calculated. There was relatively good agreement between measured and predicted compliance for PEUU grafts of internal diameter 3.4–3.8 mm and wall thickness 0.25–0.55 mm.

In the present study, the tapered graft is assumed to be composed of a series of short cylindrical segments of varying diameter and wall thickness. In order to apply the same constitutive equations to each segment, it is necessary to establish that the constitutive constants are the same irrespective of the graft dimensions. Therefore, one of the aims of this study was to determine whether this was the case for PEUU grafts.

2. Theory

The mathematical model was based on the model proposed by Vaishnav *et al.* [19]. They adopted a continuum mechanical approach to analyse the two-dimensional elastic behaviour of arteries. By treating the arterial segment as an incompressible orthotropic cylinder, a non-linear theory for large elastic deformation was developed. They assumed a strain energy density function for arterial tissue approximated by the polynomial:

$$W = \mathrm{A}a^2 + \mathrm{B}ab + \mathrm{C}b^2 + \mathrm{D}a^3 + \mathrm{E}a^2b + \mathrm{F}ab^2 + \mathrm{G}b^3 \quad (1)$$

where A, B, . . . , G are the constitutive constants which are determined from experimental data. The Green–St. Venant strains a and b are given below in terms of the graft length L and mid-wall radius R (the mid-wall radius is the external radius minus half the wall thickness). Subscript i indicates the initial undeformed dimensions:

$$a = \frac{1}{2}\left[\left(\frac{R}{R_i}\right)^2 - 1\right], \quad b = \frac{1}{2}\left[\left(\frac{L}{L_i}\right)^2 - 1\right] \quad (2)$$

From the stress–strain relationship for a thin wall cylinder subjected to an internal pressure and a longitudinal extension, the following equations can be derived which relate pressure, P, and longitudinal force, T, with the graft dimensions and the constitutive constants [12].

$$P = \frac{H}{R}[\mathrm{D}a^3 + (4\mathrm{A} + 3\mathrm{D} + 4\mathrm{E}b)a^2 + 2(\mathrm{A} + \mathrm{B}b + \mathrm{E}b + \mathrm{F}b^2)a + (\mathrm{B}b + \mathrm{F}b^2)] \quad (3)$$

$$T = 2\pi RH\left[6\mathrm{G}b^3 + (4\mathrm{C} + 4a\mathrm{F} + 3\mathrm{G})b^2 + 2(a\mathrm{B} + \mathrm{C} + a^2\mathrm{E} + a\mathrm{F})b + \left(a\mathrm{B} + a^2\mathrm{E} - \frac{PR}{2H}\right)\right] \quad (4)$$

Assuming that the material is incompressible, that is, the volume of the material remains constant during deformation, the deformed wall thickness, H, is given by:

$$H = \frac{V}{2\pi LR} \quad (5)$$

where V is the volume of a segment of graft of length L_i, initial mid-wall radius R_i and wall thickness H_i.

Equations 2–5 can only be applied to a tapered graft when it has been demonstrated that the magnitudes of the constitutive constants are a function only of the material and are independent of the graft diameter and wall thickness. An axi-symmetric graft of arbitrary shape may then be assumed to be composed of a series of short cylindrical segments (Fig. 1) and the properties of each segment may then be described by the above equations. Thus, knowing the dimensions of the segments the mechanical response of the graft may be determined.

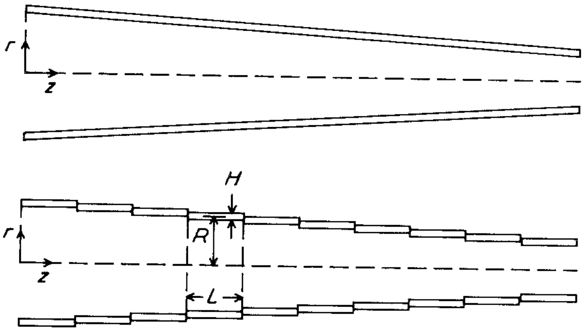

Figure 1 Diagram showing how a linear tapered vascular prosthesis can be approximated by a series of uniform cylindrical segments. The wall thickness may vary along the length of the prosthesis but it is assumed that it is constant within each segment.

3. Materials and methods

3.1. Grafts

Twenty-four graft specimens of internal diameter 3, 4, 5 and 6 mm (6 of each diameter) were manufactured from a proprietary PEUU (Biomer, Ethicon Inc., New Jersey) by electrostatic spinning [20]. Specimens of each diameter were produced with a range of wall thicknesses. Those of 3 and 4 mm diameter had wall thicknesses in the range 0.25 to 0.49 mm. For the 5 and 6 mm diameter grafts, these varied from 0.28 to 0.65 mm. All grafts were produced under identical spinning conditions since it has been shown that the mechanical properties of the electrostatically-spun grafts are dependent on the process parameters [12].

Three tapered grafts with internal diameter decreasing from 6 mm, at one end, to 3 mm over a length of 25 cm were also fabricated in the same manner and using the same polymer solution. While the wall thicknesses of the cylindrical grafts were uniform, those of the tapered grafts varied linearly with axial position (or diameter), increasing from 0.39 to 0.56 mm with distance into the taper.

The preparation of the test specimens and the experimental procedure have been described in detail previously [13]. Briefly, the grafts were preclotted with gelatin to make them watertight. Segments between 7 and 8 cm in length were mounted, in turn, in a specimen chamber filled with water. The initial undeformed length of the graft specimen was measured by means of a cathetometer. A known longitudinal extension ratio λ_z ($\lambda_z = L/L_i$) was applied to the specimen which was then slowly pressurized by injecting water into the graft lumen using an infusion pump. The infusion rate was set to a level which gave a circumferential strain rate of less than $1.5 \times 10^{-3}\ \mathrm{s}^{-1}$. Thus the pressurization may be considered to be *quasi*-static. The external diameter was recorded continuously with a pulsed infrared diameter gauge [21]. A strain gauge load beam connected to one end of the graft was used to measure the change in longitudinal force during pressurization. Data were collected after three preconditioning cycles over the pressure range 0–26 kPa. For each specimen, measurements were made at four different λ_z in the range 1.04–1.10. After the experiment the specimen was cut longitudinally and its wall thickness was measured at several locations using a micrometer thickness gauge.

In the experiments on cylindrical grafts, pressure and diameter were measured near the centre to avoid edge effects. In the case of the tapered graft, the pressure–diameter relationships were obtained at three axial locations, about 1 cm apart, in the central section. The pulsed infrared gauge measures the average diameter over a finite but adjustable length of the graft. This length was set to about 6 mm for cylindrical and 1 mm for tapered grafts. Prior to the experiment, the positions on the graft surface where the diameter was measured were lightly marked with black ink. At the conclusion of the experiment strips about 1–2 mm wide were obtained from each of these locations. The thickness of each strip was measured and the average of ten or more readings was determined for each position.

4. Results and discussion

The seven material constants (A, B, . . . , G) were determined for each of the 24 cylindrical grafts tested. The procedure has been described previously [12]. Table I shows the average of each of the material constants and the standard error of the mean (SE).

Constants A, B and C have lower standard errors indicating that they vary much less within the grafts tested than D–G. Since the maximum values of a and b are approximately 0.28 and 0.1, respectively, the contribution of the first three terms in the strain energy density function (Equation 1) is relatively more important than the higher order terms. Therefore the errors due to the greater scatter of constants D–G can be expected to be less significant.

Constant A in Equation 1 relates to the contribution of the circumferential strain a to the strain energy density function while C relates to the contribution of the longitudinal strain b. Since C > A, it can be concluded that the cylindrical grafts are stiffer in the longitudinal than in the circumferential direction.

The material constants are similar in magnitude to those of cylindrical Biomer grafts published earlier [13]. The differences in the actual values are attributable to the variation in the properties of the polymer between different batches and changes in the manufacturing process variables.

By substituting the average values of the constants in Equation 3, the pressure–radius relationship is defined for any cylindrical graft of diameter in the range 3–6 mm. From such relationships, the compliance Co (Co is defined as $\Delta D/D\Delta P$, where ΔD is the change in external diameter of a graft subjected to a pressure change ΔP and D is the mean diameter) of a graft of known dimensions can be calculated. Since the pressure–radius relationship is non-linear, Co varies with pressure. The compliances of all the grafts tested (24 specimens, each tested at 4 levels of longitudinal strains, giving a total of 96 separate measurements) were calculated at a mean pressure of 13.3 kPa (100 mmHg) and were compared with the measured values. The agreement between calculated and measured compliances (Co_c and Co_m, respectively) was assessed by determining the mean absolute difference between Co_c and Co_m, expressed as a percentage of Co_m:

$$\varepsilon = \frac{100}{N}\sum(|Co_c - Co_m|)/Co_m$$

where N is the number of paired values. There was fair agreement, with $\varepsilon = 12.8\%$. In the previous study [13], when all the grafts were of the same diameter, ε was 5.38%. The higher ε value obtained in this study is probably a result of the slight variation in the anisotropic properties of different diameter grafts. This can be demonstrated by taking the ratio of the mean values of the constants C/A (a measure of the relative stiffness in the longitudinal and circumferential directions) for grafts of internal diameter 3, 4, 5 and 6 mm. The ratio was found to be a function of graft diameter, and generally decreased inversely with diameter.

It has been shown that the anisotropy of grafts manufactured by electrostatic spinning can be varied by changing the angular velocity of the mandrel on which the graft is formed [12]. It is relatively simple, in the case of cylindrical grafts, to keep the anisotropic properties constant by adjusting the mandrel rotation speed. With tapered grafts, however, it is necessary to adjust this parameter continuously as a function of the local diameter. Since this would necessitate complex control equipment, the anisotropic properties were not controlled. Despite the small variation in anisotropic properties of grafts of various diameters, however, the agreement between predicted and measured compliances was considered to be acceptable.

Another source of error is that which is introduced by the simplifying assumption that the cylindrical grafts have thin walls. This has been discussed by Fung *et al.* [22]. Using their method, the maximum error in the present study was estimated to be about 18%. Although the polyurethane is not perfectly elastic but viscoelastic, it undergoes preconditioning. After a number of loading and unloading cycles have been applied, the response reaches a steady state and becomes stable and reproducible. Preconditioned grafts can be regarded as being *pseudo*-elastic [22], and their response during loading (or unloading) can be defined uniquely. In this study, four preconditioning cycles were applied and only the loading portions of the pressure–diameter–force curves were employed in calculating the material constants.

TABLE I Average material constants and standard error of the mean (SE) from measurements in 24 cylindrical grafts of diameter 3–6 mm and wall thickness 0.25–0.65 mm

	A	B	C	D	E	F	G
				($\times 10^5$ Nm^{-2})			
Mean	3.908	2.793	5.271	− 2.645	− 1.02	− 2.343	− 9.043
SE	0.18	0.21	0.23	0.77	0.87	1.16	0.97

By assuming that the preclotted electrostatically-spun material is incompressible and, knowing the external diameter and length, it enables the wall thickness to be determined. This assumption is usually made when analysing the mechanics of arterial segments and it has been verified for electrostatically-spun prostheses [12].

Using Equations 2, 3 and 5 together with the mean values of the constants in Table I, the compliance of cylindrical grafts of diameter between 3 and 6 mm may be calculated for fixed values of λ_z (or b), by solving for a at the appropriate pressures. Fig. 2 shows how Co varies with wall thickness in grafts of internal diameter 3, 4, 5 and 6 mm. The data were computed for $\lambda_z = 1.06$ ($b = 0.0618$). As expected, grafts of the same diameter become stiffer as the wall thickness increases while those of the same wall thickness become more compliant with increasing diameter. It should be noted that the predicted curves are valid only for graft dimensions (diameter between 3 and 6 mm and wall thickness between 0.25 and 0.65 mm) for which experimental data are available. Since this technique is based essentially on a curve-fitting procedure, extrapolating beyond the above range is not permissible.

Measurements on both uniform and tapered grafts were made over a wide pressure range; from 0 to 26 kPa. The constitutive constants should therefore be valid over this pressure range. In this paper compliance was determined only for a mean pressure of 13.3 kPa since this is the normal mean systemic blood pressure *in vivo*. If required, however, Co can be determined at any mean pressure within the range over which the measurements were made.

4.1. Tapered grafts

The validity of the assumption that the tapered graft is composed of a series of short cylindrical segments depends on the diameter and wall thickness for each segment being relatively constant. In order to optimize the signal-to-noise ratio and sensitivity of the infrared diameter gauge, it was necessary to measure external diameter over a finite length of the graft. The output from the infrared gauge represented, therefore, the average diameter over this segment. A length of 1 mm was selected as a good compromise between the need to minimize the segment length and to increase signal-to-noise ratio. For a typical tapered graft employed in this study, the difference in diameter over this length was 24 μm, representing only about 0.4% of the actual diameter.

Assuming that a tapered graft is composed of a series of short cylindrical segments, the variation in local compliance can be calculated for tapered grafts of constant wall thickness. This is depicted in Fig. 3 for four grafts of internal diameter varying from 6 to 3 mm and having a wall thickness of 0.25, 3, 4, or 5 mm. It shows that Co increases with internal diameter. Moreover, the variation is almost linear when the wall thickness is ≥ 0.4 mm.

For a tapered graft to have a constant compliance, the wall thickness should vary along its length. It should have a thicker wall at the wide end and become progressively thinner towards the narrow end. The actual wall thickness distribution for such a graft can be determined using Equations 2, 3 and 5. Fig. 4

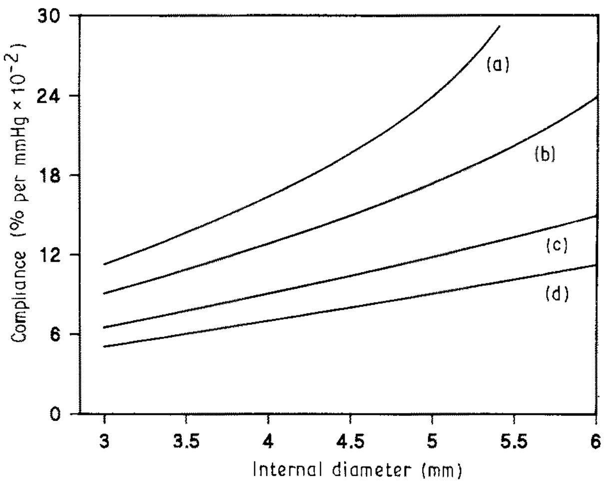

Figure 3 Predicted compliance variation with local internal diameter for tapered grafts of constant wall thicknesses between 0.25 and 0.5 mm: (a) 0.25; (b) 0.3; (c) 0.4; (d) 0.5 mm.

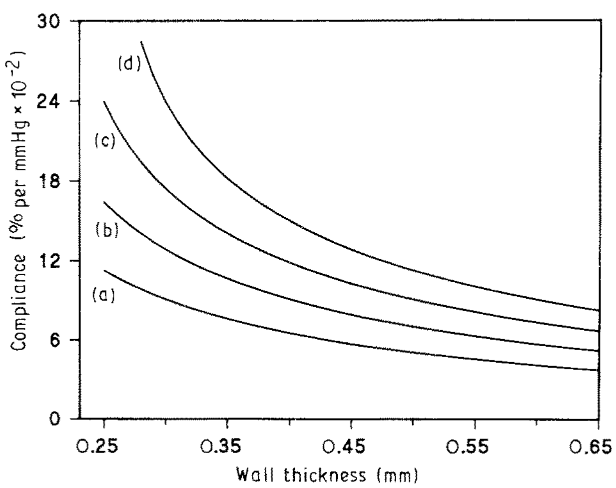

Figure 2 Relationship between compliance and wall thickness for cylindrical grafts of internal diameter between 3 and 6 mm calculated from Equations 2, 3 and 5; (a) 3.0; (b) 4.0; (c) 5.0; (d) 6.0 mm.

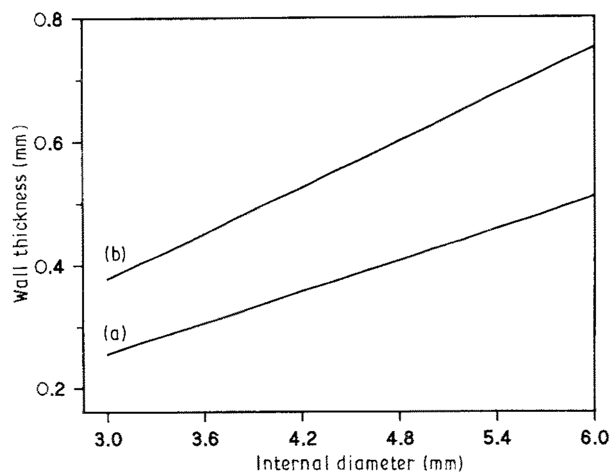

Figure 4 Plot of wall thickness variation as a function of local internal diameter in two tapered grafts of constant compliance: (a) 0.11; (b) 0.077% per mmHg.

shows the wall thickness variation as a function of local diameter for two tapered grafts of constant Co of 0.077 and 0.11% per mmHg. These values correspond to the lower and upper bounds of compliance variation of the human femoral artery and saphenous vein. It is shown that the wall thickness should increase with diameter. For these two specific Co values, the thickness distribution is seen to be linear.

It was not possible to verify the above results experimentally since grafts of the desired wall thickness distribution could not be produced on the unmodified electrostatic spinning rig. The wall thickness of the available tapered grafts increased inversely with diameter. The compliance was therefore expected to decrease with distance into the taper. The wall thickness distribution for one of the grafts tested (Graft # T26) is shown in Fig. 5a. The thickness was obtained at the three measuring points, namely at the centre and at 1 cm on either side. The mean value and ± 1 standard deviation (denoted as the error bars) are plotted against the local internal diameter. The linear least squares fit to the data is also plotted on the same figure as the continuous line. Fig. 5b shows a plot of the measured compliance data at the three points on the graft specimen. The longitudinal strain applied to the graft segment corresponded to an overall λ_z of 1.06. The predicted compliance can be obtained at each point by substituting the local radius and wall thickness values in Equations 2, 3 and 5. By repeating the calculations for increments in diameter of 0.02 mm, between 5.0 and 5.3 mm, the compliance distribution can be determined. This is shown on Fig. 5b as the continuous curve. There was relatively good agreement, although the measured values were greater than predicted by between 7.4 and 9.5%. Similar measurements were made in three graft specimens subjected to λ_z between 1.04 and 1.10. The mean percentage difference, ε, between predicted and measured compliances for 17 measurements was 11.25% $\pm$ 4.33 (SD). This compares favourably with the ε value of 12.8% obtained for the cylindrical grafts.

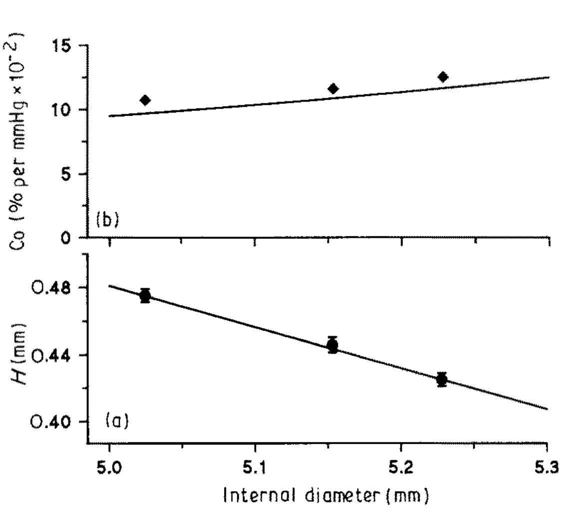

Figure 5 (a) Bottom graph; showing the wall thickness distribution of tapered graft (T26). (●) represent mean values with error bars indicating one standard deviation. The straight line represents the least squares fit to the mean thickness data. (b) Top graph; comparing the measured compliance (◆) with calculated compliance distribution (———).

In making the assumption that the material is homogeneous, it is implied that the stresses and strains are uniform throughout the specimen. This assumption is justified in a uniform cylindrical graft of constant wall thickness. Whether or not this is the case for a tapered graft will now be examined. Consider a tapered graft specimen of uniform wall thickness subjected to a constant intraluminal pressure and longitudinal strain. The longitudinal force measured at the ends of the graft is T. We now assume that the graft is composed of a number of cylindrical segments the diameter of which vary in increments. From equilibrium consideration, the longitudinal force in each cylindrical segment is also T. Since the cross-sectional area of the wall increases with diameter, the longitudinal stress (and strain) is clearly not uniform over the length of the segment. The longitudinal extension ratio λ_z will vary continuously over the length, being greatest at the narrow end of the graft and least at the wide end. Hence Co cannot be computed for fixed λ_z in a tapered graft in which the wall cross-sectional area vary significantly. It is possible, however, to calculate the compliance distribution for fixed T as shown below.

The variation in λ_z in the tapered graft was determined for a given intraluminal pressure and longitudinal force by solving Equations 3 and 4 simultaneously for a and b (using an iterative procedure based on the Levenberg–Marquardt method, MathCad, Mathsoft Inc.). This was determined for the grafts of constant compliance with wall thickness profiles shown in Fig. 4. The results are presented in Fig. 6 for constant longitudinal force, T, of 0.2, 0.35 and 0.5 N. To simplify the computation, λ_z distribution was determined for $P = 0$, although the procedure can be repeated at other pressures. As expected, λ_z is found to increase as the diameter (and wall cross-sectional area) decreases. Moreover, the variation was markedly more non-linear as the longitudinal force (T) and the compliance increased. A similar result was obtained for a tapered graft of constant wall thickness of 0.4 mm. The relationship between λ_z and local internal diameter is shown as the solid lines on Fig. 7. The dashed curves represent the λ_z variation for one of the tested grafts (wall thickness profile is shown in Fig. 5a). Since the wall cross-sectional area of this, and all other tested grafts, was relatively constant, λ_z did not vary appreciably with local diameter. Thus, for these grafts the compliance distribution can be calculated for fixed values of λ_z using Equations 2, 3 and 5. In other tapered grafts, the compliance distribution should be computed for a fixed longitudinal force by solving Equations 3 and 4 simultaneously for a and b at the appropriate transmural pressures. In this case, the λ_z distribution is also obtained.

Wave reflection at the junctions (proximal and distal anastomoses) between a graft and an artery will occur unless the impedances are matched. If wave reflection is significant, the transmitted energy across the junctions is reduced, i.e., energy is lost [23]. The characteristic impedance of a conduit is a function of internal diameter area and compliance. Since both diameter and compliance vary along the arterial tree

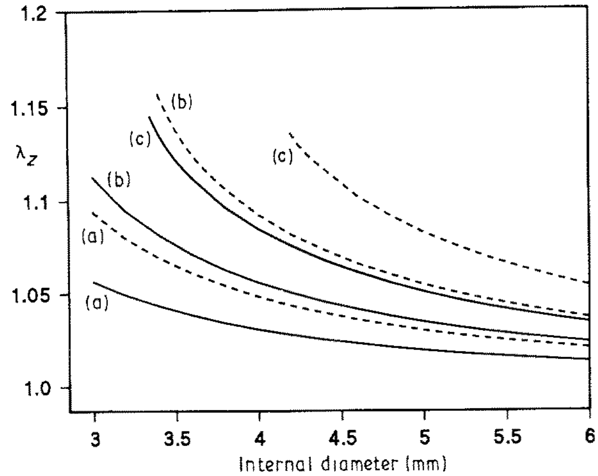

Figure 6 Distribution of longitudinal extension ratio λ_z in tapered grafts of uniform compliance subjected to constant T of between 0.2 to 0.5 newton: (a) 0.2; (b) 0.35; (c) 0.5 N. λ_z increases non-linearly with distance into the taper, i.e., as wall cross-sectional area decreases: (———) 0.077; (– – –) 0.11% per mmHg.

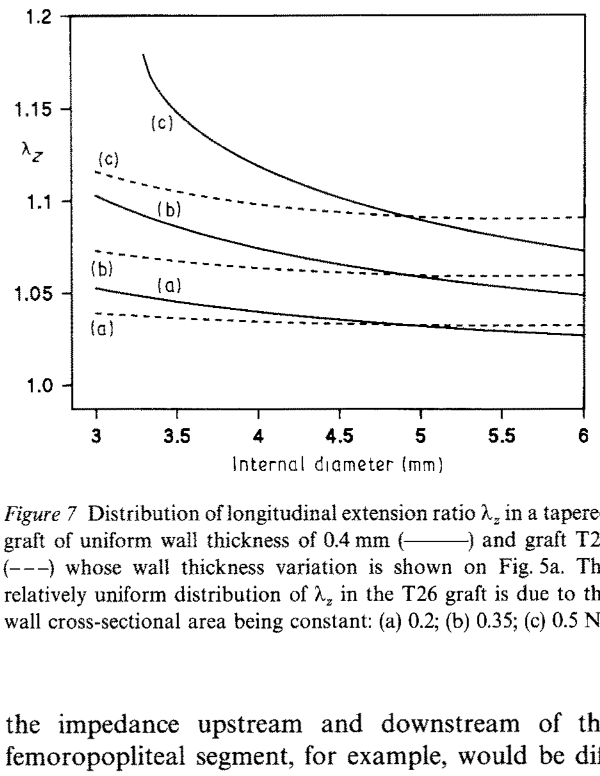

Figure 7 Distribution of longitudinal extension ratio λ_z in a tapered graft of uniform wall thickness of 0.4 mm (———) and graft T26 (– – –) whose wall thickness variation is shown on Fig. 5a. The relatively uniform distribution of λ_z in the T26 graft is due to the wall cross-sectional area being constant: (a) 0.2; (b) 0.35; (c) 0.5 N.

the impedance upstream and downstream of the femoropopliteal segment, for example, would be different. It is possible with the data provided in this paper to design tapered grafts with impedances at the inlet and outlet matched to those of both the femoral and popliteal arteries. This cannot be achieved easily with a cylindrical graft.

Only the elastic properties were considered in this study since the experiments were carried out under *quasi*-static loading conditions. We have previously shown that electrostatically-spun PEUU grafts are viscoelastic and their mechanical properties are a function of the rate of pressurization [13]. The dynamic compliance in 4 mm diameter cylindrical grafts was determined in response to sinusoidal pressures over a physiologically relevant frequency range. The ratio of dynamic to static compliance was found to be linearly related to the logarithm of frequency. Moreover, the dynamic properties were not influenced by λ_z and wall thickness. Therefore, the dynamic compliance of a graft at a given frequency can be predicted if the quasi-static compliance is known. The measurements were carried out only on the 4 mm diameter grafts and it remains to be shown whether the dynamic behaviour is also independent of diameter. If this can be demonstrated, a similar approach can be used to predict the dynamic compliance of tapered PEUU grafts.

In conclusion, the design and development of compliant vascular grafts is greatly facilitated by the availability of relatively simple expressions relating mechanical behaviour with applied loads. The advantage of the method described here is that it is based on a general constitutive equation. Once the constitutive constants for a particular material have been determined they may then be used to predict the mechanical response for any combination of transmural pressure and longitudinal force. It is also possible to investigate the elastic properties of tapered grafts if it is assumed that they are composed of short cylindrical segments. This method may be applied to other elastomeric vascular grafts provided that the materials can be considered to be homogeneous and the constitutive constants are independent of the graft dimensions. Only linear tapered grafts have been considered here but this approach can easily be applied to other axi-symmetric conduits which satisfy the condition that each short segment approximate to a uniform cylinder.

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