Effect of Dilation on the Mechanical Characterization
of Vascular Prostheses

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Abstract: The purpose of this study has been to investigate the effect of dilation on the some mechanical properties of several types of warp-knitted vascular grafts. The structures of warp knit vascular grafts used in the experiments were reverse locknit, locknit, and Tricot. Various mechanical properties of these grafts were determined using devices developed for the purpose. Clinical data obtained were compared with experimental results of warp knit vascular grafts. The most important mechanical properties are found to be creep extension, bursting strengths, and compliance. Preliminary results indicate that vascular grafts are non-compliant and exhibit creep which is predictive of the long term dilation that has been noted in the clinical results. It is found that there is a positive correlation between experimental data and clinical results for at least the grafts tested.

Introduction

Complications with synthetic fiber fabrics used as vascular grafts are not uncommon. Dilation, aneurysmal failure, anastomotic rupture, bleeding through the interstices and infection are among the most reported complications with vascular grafts [1-7]. The most of such failures have been partially linked to the mechanical mismatch between the graft and the host artery. In particular, compliance mismatch has been implicated as a contributor to aneurysms, rupture of the suture-line and sub-intimal hyperplasia [5-14]. These conditions not only render the graft ineffective, but also threaten the life of the patient. Therefore, a complete evaluation of the properties of vascular grafts is necessary. Compliance, flow behavior, fatigue and creep behaviors are among the first characteristics worthy of consideration. Experimental data should be correlated with clinical data to determine appropriate measures that could identify potentially problematic grafts.

Dilation is the most reported cause of failure cited in the literature [5-14]. Data on fatigue and other appropriate properties of grafts that might explain the dilation phenomenon are either not available or the information is inconclusive. Therefore, the purpose of the paper has been to characterize various mechanical properties of several commercially available graft structures.

Materials and Methods

The Equipment

The static compliance as well as the creep and tubular bursting strength measurements were accomplished on a device built in the laboratory. An outline of the device is given in Figure 1.

This device comprises an air tank, a buffer tank and pressure regulators. The air tank is connected to the buffer tank via a needle valve. As the air from the air tank passes to the buffer tank via a needle valve, it slows down considerably. The air then passes from the buffer tank to the specimen via another needle valve. At the other end of the specimen holder, a release valve is kept closed. The test is started by opening the valve on the regulator attached to the air tank. The air slowly pressurizes the specimen. The settings on the needle valves are kept fixed. Therefore, it takes the same length of time to reach the pressure preset on the regulator. The pressure and displacement are continuously monitored with appropriate transducers, and the data saved via a digital to analog/analog to digital (D/A, A/D) converter installed in a PC and appropriate data acquisition software.

For compliance measurements, the pressure on the regulator is set to the desired level (normally 500 mmHg) and the air tank valve opened. The settings are such that it will take about 15-20 seconds for the pressure to reach 500 mmHg. After 30 seconds, the air supply is shutoff. The pressure and
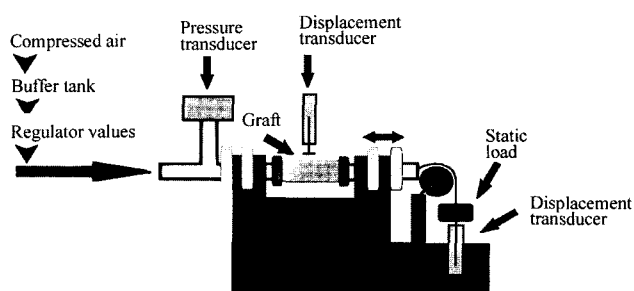

Figure 1. Schematic of the device used for static compliance, bursting and creep tests.

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displacement are continuously recorded throughout the testing cycle.

For bursting strength measurements, the pressure on the regulator is set to the desired level which is anticipated bursting strength, e.g. 1400 kPa, and the air tank valve opened. As soon as the graft fails, the air supply is shutoff. The pressure and displacement are continuously recorded.

This device is also used for the measurement of creep extension. The pressure on the regulator is set to the desired level and the air tank valve opened. After a predetermined length of time, the air supply is shutoff and the release valve opened. The pressure and displacement are continuously monitored.

Material

The materials tested, which were made of 100 % PET yarns, were three different type of warp knit vascular grafts in the structures of reverse locknit, locknit, and tricot. Schematic view of the structures are given Figure 2. The characteristics of the grafts tested were provided in Table 1. The data collected relate to only the 10 mm grafts. All samples were tested in air. Each sample was lined with a latex balloon to prevent air leaking. Attempts were made to use the same balloon throughout the testing in order to eliminate any variations that may have been present in the balloons. It is conceivable that the presence of the balloon may affect the compliance of a graft; however, since these measurements are relative, the presence of the balloon is not expected to change the results significantly. In addition, all samples were held under two constant tensions of 300 and 600 g to also note the influence of pretension on the grafts' behavior.
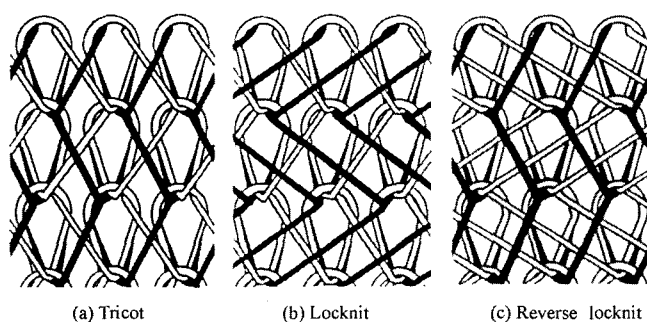

(a) Tricot   (b) Locknit   (c) Reverse locknit

Figure 2. Schematic structures of loop formation in warp knitted vascular grafts.

Table 1. Graft characteristics

Graft structure type	Yarn type	Porosity ($ml/cm^2/min$)	Thickness (mm)	Crimped
Reverse locknit	PET	1600	1.04	Yes
Locknit	PET	1700	-	Yes
Tricot	PET	1900	-	Yes

Compliance

For compliance measurements, the pressure was gradually increased from 0 to about 500 mmHg. However, compliance is only reported for the 'normal' physiological range of 80-120 mmHg.

Compliance (C) is the inverse of the spring constant and is represented by strain over the physiological pressure range which is between 80 and 120 mmHg [6].

$$C = (\Delta V/V)/\Delta P \qquad (1)$$

Where ΔV: change in volume of the graft
V: volume of the vascular graft
ΔP: change in the pressure

Compliance is therefore equal to strain divided by stress [1] and is commonly measured through the use of the dynamic ratio, which describes the incremental increase in vessel volume per unit pressure change during the pulse cycle. Alternatively, when length changes are small when the ends of the grafts are fixed, the measurement may address the change in diameter through the ratio,

$$C = (\Delta D/D)/\Delta P \qquad (2)$$

Where ΔD: change in diameter of the graft
D: diameter of the vascular graft

which describes the change in diameter per unit pressure. Equations (1) and (2) are related to each other as shown in equation (3).

$$(\Delta V/V)/\Delta = 2 \times (\Delta D/D)/\Delta P \qquad (3)$$

Total arterial compliance can also be defined as [18]

$$C = dV/dP \qquad (4)$$

In this study, the arterial compliance (C) was computed using both definitions in equations (3) and (4).

Creep (Static Dilation)

For creep testing, the pressure was set to 115-120 kPa and the test was run for 24 hours. The software was configured so that there would be four stages of data collection. The first stage, which is initial pressurization to the preset level, was acquired at 30 Hz. The second stage, which is creep extension, was recorded at 0.1 Hz. The de-pressurization stage, which is elastic recovery, was recorded at 15 Hz and the relaxation stage, which is creep recovery, was recorded at 1 Hz.

When the vascular grafts are concerned, total creep extension, which is percent dilation, may be defined as the extent of total dilation from the resting position over a time period during which the graft is exposed to a constant pressure. Since the creep is obviously time dependent, longer time periods would yield larger dilations. However, the incremental change in diameter decreases with time. That is, under the laboratory conditions, the most of grafts show their maximum dilation

in the first 24 to 48 hours. This initial period will be useful in determining grafts' potential to dilation.

Burst Strength

Burst strength was evaluated in tubular form with the device described above and in flat form following the ANSI/AAMI VP20 standard test procedures. In tubular form, the pressure was set to 1400 kPa and the test was run until the graft failed. In the flat form, the force necessary to pierce a flat piece of the graft by a probe was measured. Note however, that this test exposes a very small segment of the graft to the probe and may not uncover imperfections, inconsistencies and variations in the material.

Although all grafts are produced as seamless tubes, there still appears a seam where the two warp layers are connected in the warp knitted structures. This seam could effect in its mechanical properties from the body of the graft as during manufacturing, the amount of tension placed on the yarns at the seam may be different from the other threads. The tubular burst strength test would be of interest as it might reveal any differences that exist between the seams and the body of the grafts.

Results and Discussion

A summary of the clinical data previously published [19] on the same grafts is given in Table 2. As may be noted from these data, specimen with Tricot structure appears to be more

likely to develop problems with dilation in the first 20 to 30 months following implantation. Other specimen with locknit structure appears to demonstrate somewhat a bimodal behavior where in the first 5 to 8 years following implantation, it shows a lower occurrence of high dilation whereas afterwards, the probability increases rapidly. By contrast, the last specimen with reverse locknit structure appears to show a gradual increase in both frequency and magnitude of dilation. However, it too shows a lower probability of dilation in the first 3 to 5 years.

Our earlier results [19] on Weibull distribution of the data revealed that unlike tricot and reverse locknit structures, the specimen with locknit structure demonstrated a bimodal behavior and that for locknit structure, the probability of dilation increased rapidly after about 8 to 10 years. This may be due to premature dilation caused by structural defects or inconsistencies present at the time of implantation. The specimens in tubular form ruptured during bursting reveals that locknit structures rupture consistently at the seam. It was further demonstrated that the specimen with tricot structure showed a lower mean time to dilation than locknit or reverse locknit structures, with locknit structure being the better graft despite its inconsistences.

The present study attempts to develop protocols for evaluating vascular grafts that would tell surgeons which grafts would potentially develop problems associated with dilation.

Static Compliance

Table 3 lists the compliance values obtained under static conditions described above and typical pressure-displacement

Table 2. Descriptive statistics

Locknit					
Variable	Time (months)	Aorta dilation (%)	Left lim dilation (%)	Right lim dilation (%)	Average dilation (%)
Mean	162.71	55.04	55.23	49.28	50.95
Std Dev	52.19	25.51	53.48	16.35	23.77
Reverse locknit					
Mean	68.50	41.21	52.30	54.07	52.14
Std Dev	32.01	16.55	31.26	35.35	23.09
Tricot					
Mean	9.25	48.43	57.79	53.53	52.78
Std Dev	7.88	18.36	16.19	17.72	12.59

Table 3. Compliance results[*]

Graft structure type	Pretension					
	300 g			600 g		
	% Change in volume per mmHg[1]	ml Change in volume per mmHg[2]	% Change in length	% Change in volume per mmHg[1]	ml Change in volume per mmHg[2]	% Change in length
Reverse locknit	4.41×10^{-2}	17.41×10^{-4}	0.176	6.75×10^{-2}	26.71×10^{-4}	0.302
Locknit	9.87×10^{-2}	39.15×10^{-4}	0.097	2.44×10^{-2}	10.38×10^{-4}	0.035
Tricot	12.53×10^{-2}	49.83×10^{-4}	0.304	16.41×10^{-2}	65.47×10^{-4}	0.029

[*]Compliance measured between 80-120 mmHg, [1]measured according to procedures used in reference 11, [2]measured according to procedures used in reference 18.
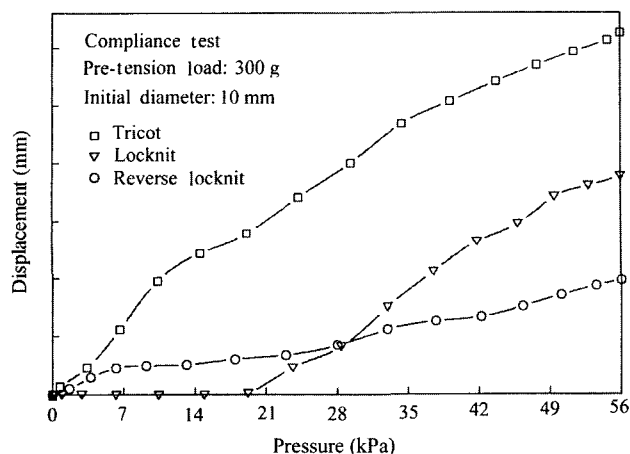
Figure 3. Typical pressure-displacement curves (Compliance).
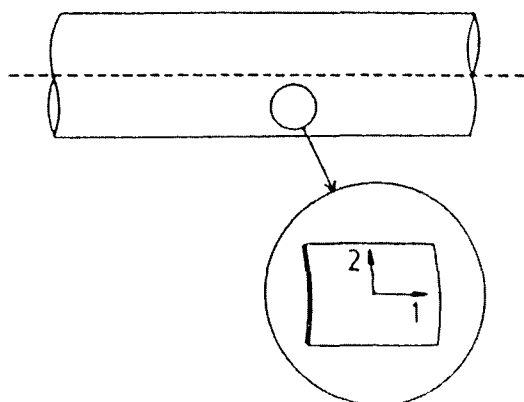

Figure 4. The graft wall viewed as a thin tube made of orthotropic material in a plane state of stress.

curves are given in Figure 3.

It was argued that grafts may be considered as orthotropic structures [1]. Thus, when a graft is pressurized, there are two principal forces acting on the wall in the transverse (hoop or radial) and longitudinal directions as in Figure 4 and the stiffness and compliance can be completely described by four independent elastic constants: the longitudinal and transverse Young's moduli, E_{11} and E_{22}, the in-plane shear modulus, G_{12}, and the major poisson ratio, v_{12}. All grafts have different moduli in the lengthwise and transverse directions. Normally, the lengthwise modulus is much lower than that in the transverse direction because of their crimped configuration. While initially the crimp attributes determine the longitudinal modulus, the true modulus in knitted fabrics is due to their looped structure's resistance to torsion and bending. In consequence, the loops can straighten more easily in the line of the highest stress. When there are significant differences between the longitudinal and transversal moduli, as is normally the case with vascular grafts, upon pressurization, grafts tend to elongate before dilation. However, as the diameter begins to increase, the length will begin to decrease. The amount of

tension placed on the graft will, of course, increase its modulus in the lengthwise direction. This implies that the graft's length will not increase, or increase less, or even contract at higher tensions with concomitant changes in compliance values up to a point where additional tensions will lower compliance. As may be seen from the data presented in Table 3, all grafts showed a lower compliance but higher elongation at 300 g pretension than at 600 g pretension. Reverse locknit and locknit structures do not appear to be different. The behavior for Tricot structure is however, somewhat different. At lower pretensions, it elongates more than its counterparts and shows significantly higher compliance. At 600 g pretension, it contracts and yet continues to show a higher compliance probably because of its inherent weakness.

Overall, yarn mobility appears to be the dominating factor in compliance measurements. Yarn mobility in a given structure is affected by factors such as yarn strength and thickness, texture and finish. Although an increase in porosity implies greater yarn mobility, porosity alone is not a good indicator because differences in other structural parameters particularly yarn bulkiness, fiber crimp and yarn geometry could affect the porosity of a graft. Compliance should be related to the lengthwise and transversal moduli and the amount of tension placed on the graft.

In summary, tricot structure has very significantly lower resistance to extension in both directions than do the other two grafts. It is also evident that the amount of tension placed on the graft will influence the grafts' behavior and that compliance measurement without proper means for controlling the tension will be inadequate.

Bursting Strength

A typical load displacement curve for bursting from our equipment is shown in Figure 5, the data are reported in Table 4. Several important observations can be made. In tubular form, the specimen with reverse locknit structure is the strongest, and the specimen with tricot structure is the weakest. Also note that extension to break for all three grafts
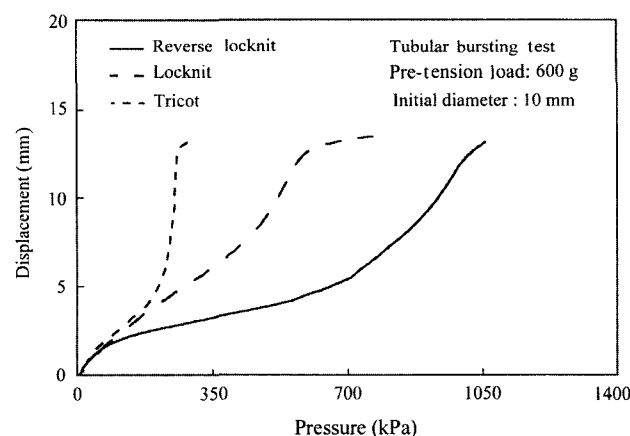

Figure 5. Typical load displacement curve for tubular bursting.

Table 4. Strength results

| Graft type	Test method		
	Tubular bursting test[1]		ANSI/AAMI[2]
	Strength (kPa)	Strain (%)	Strength (kPa)
Reverse locknit	1074.2 ± 7,58	109.4 ± 8.7	502.6 ± 57.22
Locknit	772.9 ± 18.61	130.9 ± 4.0	713.6 ± 26.20
Tricot	288.9 ± 6.20	131.4 ± 1.8	164.0 ± 19.30

[1]Measured in tubular form using equipment developed in the laboratory, [2]measured according to procedures specified in ANSI/AAMI VP20 Standard test method.

is roughly the same. The results for the ANSI/AAMI VP20 standard test method however, are different. The locknit structure appears to be stronger than the reverse locknit structure with the full trikot structure still claiming the lowest burst strength. Two reasons can explain this apparent anomaly. The locknit structure is a smooth graft making it easier to load in the clamps for the ANSI/AAMI VP20 standard test method while the reverse locknit structure is a velour structure making it more difficult to mount. More importantly however, is the fact that in tubular form, the locknit structure consistently ruptured at the seam. While rupture was initiated in the seam for all grafts, in the locknit structure the rupture did not propagate to the body of the graft involving more of the structure. This type of inconsistency will not show up with the ANSI/AAMI VP20 standard test method. A final point worth mentioning is that in both reverse locknit and locknit structures, the main body of the grafts appears to be somewhat intact even after rupture thus indicating that their strength would be significantly higher if it was not for the seam. The tricot structure, however, appears to have become completely ravaged re-emphasizing that it lacks strength and durability.

Creep (Dilation)

An interesting difference between the grafts and the natural arteries lies in their stress-strain behavior. Natural blood vessels show an increasingly lower incremental diameter change as a function of pressure. That is, their modulus increases with pressure at least within the physiological pressure range. Structural reasons for this behavior have been discussed elsewhere [1,2]. Synthetic grafts, on the other hand, exhibit a relatively constant incremental change as a function of pressure.

Another important property of grafts is that they are viscoelastic and exhibit hysteresis, which is indicative of plastic deformation. For vascular grafts, the plastic deformation results in the dilation of the graft over a period of time. As noted in earlier publications [1,2,6,7], the large hysteresis observed in knitted fabrics is initially due to the straightening of the loops and the frictional restraints at the contact points. Once the structure has fully opened, any further dilation will be due to yarn hysteresis. Normally, vascular grafts do not differ significantly in their choice of structure but differ in their selection of yarn thickness, bulkiness, and the overall grafts porosity [15].
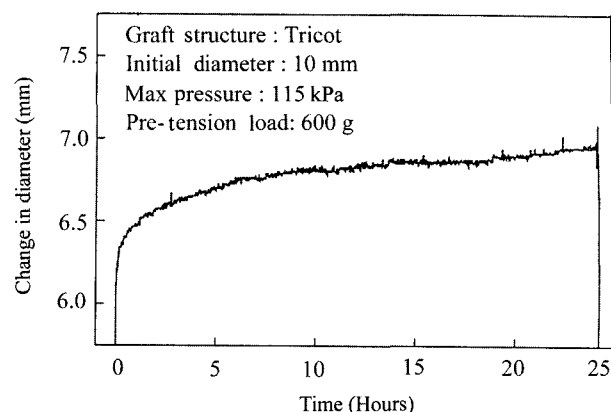
Figure 6. Typical creep curve.

Table 5. Creep (static dilation) results

Graft type	Change in diameter dilation[1] (%)	Change in diameter dilation[2] (mm)	Constant pressure (kPa)
Reverse locknit	30.2	3.02	120
Locknit	32.1	3.21	120
Tricot	9.9	6.99	115

[1]Diameter measured after 24 hours, [2]diameter measured from the resting position.

Under these circumstances, all grafts are viscoelastic and therefore, a higher compliance implies greater yarn mobility and therefore larger hysteresis. In the arterial system where the graft is subjected to a static pressure as well as to the repeated stress of pulsation, it is inevitable that some permanent deformation will develop. This may be further aggravated by the fatiguing of the fibers. The extent to which dilation may occur is also a function of the applied stress. It will follow, therefore, that in hypertensive patients, dilation could become a serious problem in a relatively short time.

Figure 6 shows a typical creep curve, and the data are presented in Table 5. The values shown in Table 5 relate to total dilation, total increase in diameter and the pressure applied over 24 hours. The pressures selected are obviously greater than those that the grafts are subjected to *in vivo*. The reason for selecting the higher pressure is simply that it will be easier to distinguish between different grafts. Lower pressures will require significantly longer times to reach the same levels of dilation.

From the data presented, it is quite clear that the grafts tested undergo creep. However, the specimen with tricot structure has undergone twice the dilation of other grafts. It will be recalled that the specimen with tricot structure showed the highest compliance and the lowest burst strength among the grafts tested. The specimens with reverse locknit and locknit structures were not significantly different in their compliance and burst strength and are essentially the same in their dilation

behavior. It is interesting that clinical data confirms that tricot structure is more of a potential problem early in the life of the graft than the other two grafts.

Conclusions

These preliminary results indicate that vascular grafts vary greatly in their characteristics and that simple *in vitro* test methods are capable of ranking vascular grafts in their tendency to dilate. It was also demonstrated that compliance values are dependent on the tension placed on the grafts, that there is a correlation between yarn mobility which can interpreted as compliance, strength and dilation behaviors.

This study has shown the desirability and the need for further evaluation of these samples as well as other samples, especially long-term studies which would provide a better understanding of factors which may affect dilation. Attention must be paid to coordinated clinical and experimental studies to further investigate the relationship between structure, dilation, and failure.

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