A Review of Structural and Material Properties of Vascular Grafts

B. POURDEYHIMI, PH.D. AND C. TEXT, A.T.I.
Department of Textiles and Consumer Economics
University of Maryland
College Park, MD 20742
U.S.A.

ABSTRACT

A brief review of the textile structures employed in the construction of vascular grafts is followed by a survey of the causes of failure cited in the literature. An attempt is made to determine the structural factors contributing to the failure of vascular grafts, and attention is given to material properties and methods for determining these attributes. Need for further research is emphasized.

INTRODUCTION

The present era of reconstructive arterial surgery using synthetic fabrics extends back to the early 1950s [1,2]. The first arterial prostheses were very primitive, made from industrial fabrics and materials normally intended for use in clothing [3]. The period between 1952, when Voorhees attempted the first reconstructive surgery using Vinyon-N, and 1956 witnessed evaluation of biologic responses of a large variety of synthetic fibers and fabric structures. Among the materials evaluated, Dacron showed the greatest potential as it did not exhibit any significant degrees of biodegradation, loss in strength or adverse reactions [4]. Arterial grafts became commercially available in the United States in 1957. Since 1957, many different types of prostheses with widely differing properties [6] have been introduced commercially. This has been in part due to lack of relevant standards and guidelines. Below, a survey of textile structures employed in vascular grafts is fol-

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lowed by a discussion of factors contributing to their failure and material properties.

Textile Structures Used in Vascular Grafts

The different vascular grafts commercially available are marketed as woven, knitted, velour, and expanded PTFE. From a fabric construction point of view, these may be divided into the major categories of (1) woven, (2) knitted (both warp and weft knitted), with further sub-classification into smooth and velour and (3) nonwoven. The term velour refers to a material with greater exposure of filaments on one or both surfaces through the use of texturized yarns, emphasizing the "filamentous" surface characteristics of the velour grafts.

The commercially available vascular grafts are classified according to their fabric construction and surface characteristics and are shown in Table 1. With the exception of the nonwovens (which are made from polytetrafluoroethylene, P.T.F.E.), all those prostheses shown in Table 1 are constructed from Dacron, Polyethylene terephthalate fibers. However, these prostheses possess significantly different physical properties which are primarily a function of the fabric structure. Nontraditional grafts, primarily experimental in nature, are listed in Table 2. These are discussed separately below.

Woven Vascular Grafts

Early vascular grafts belonged to the woven category. Plain woven vascular grafts account for a significant proportion of the grafts being implanted each year [7]. Woven grafts are dimensionally stable structures. They exhibit high bursting strength, minimum tendency to fatigue and can be fabricated tightly enough to lower permeability to water (and blood). However, they are extremely difficult to handle and suture. Moreover, they are non-compliant and have a tendency to fray at the edges. Figure 1 shows the structure of such a weave.

The smooth walled woven grafts were among the first structures to be studied extensively [8], and were among the first to be introduced commercially. With the exception of Cooley Veri-Soft® that uses bulk texturized yarns, the only difference between the currently produced commercial smooth walled woven grafts is their relative tightness and, therefore, permeability and bursting strength. Woven grafts are today produced as seamless tubes. A number of patents granted between 1958 and 1963 reveal a full description of the weaving process [9–11]. Figure 2 shows the structure of a woven graft.

Table 1. Classification of commercially available vascular grafts.

Woven Vascular Grafts	
Smooth Walled (Plain Weave)	Velour (Plain Weave with Floats)
Meadox Woven Cooley Meadox Woven Meadox Woven Cooley Veri-Soft (Bulk-textured yarns) U.S.C.I. DeBakey Woven	Meadox Woven Double Velour

Weft Knitted Vascular Grafts			
Smooth Walled		Velour	
Single Jersey	Reverse Single Jersey	Single Jersey	Reverse Single Jersey
USCI DeBakey Standard USCI DeBakey Ultralight Weight	Golaski MilliKnit Golaski MicroKnit	USCI Sauvage Filamentous Velour (external velour) USCI Sauvage Filamentous Velour (externally suppported) USCI DeBakey Vascular D (internal velour)	USCI Sauvage Guideline (external velour) Golaski Lopor (external velour)

(continued)

Table 1 (continued).

Warp Knitted Vascular Grafts			
	Velour		
Smooth Walled (Reverse 2 Bar Locknit)	(2 Bar Locknit)	(Reverse 2 Bar Locknit)	(Half Tricot with Inlaid Pile)
Meadox Weavenit Meadox Cooley Graft	USCI Sauvage Bionit (external velour) Meadox Cooley Knitted (double velour) Rhone Poulenc Rhodergon (napped internal velour)	USCI Vascular II (internal velour) USCU DeBakey Graft (double velour)	Meadox Microvel (double velour)

Nonwoven Vascular Grafts (PTFE)
Gore-Tex (P.T.F.E.) Impra Vitagraft

Table 2. Nontraditional vascular grafts.

Compound Grafts			Elastic Grafts					
1960s	Cyanamid 1969	1970s	1950s & 1960s	1966	1970	1974	1978	1983
Catgut & Dacron	PGA & Dacron	Polyglachin & PTFE	Helenaca Dacron	Spandex	Silicone Rubber	Polyurethane	Spandex & Dacron	Pellethane
Anti-Thrombogenic Surfaces								
1970s			1970s & 1980s					
Albumin Coated			Endothelially Seeded			Carbon Coated		

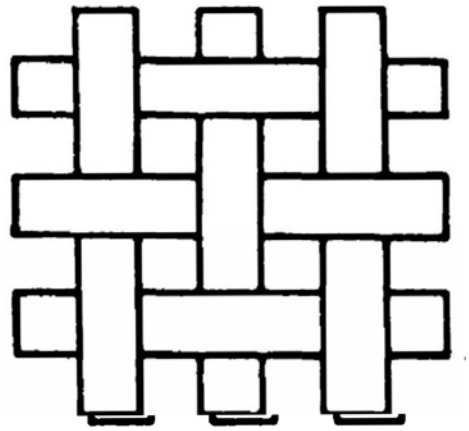

Figure 1. Plain weave structure.

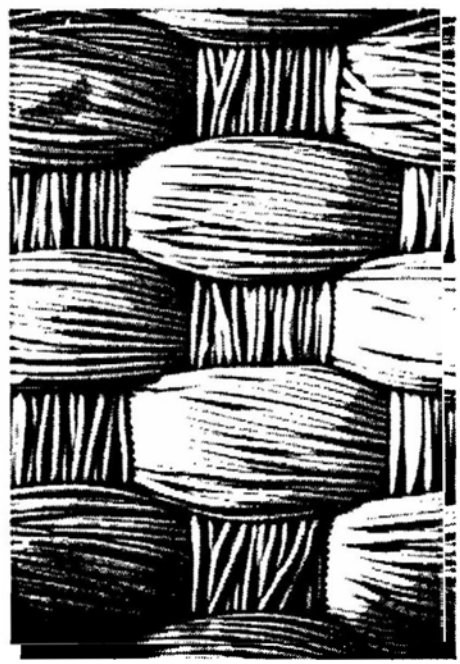

Figure 2. SEM micrograph of Cooley woven.

Figure 3a. SEM micrograph of woven double velour: face.

Figure 3b. SEM micrograph of woven double velour: back.

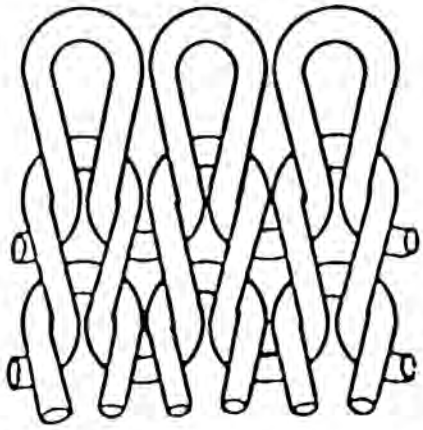

Figure 4a. Single jersey structure: face.

The woven double velour graft introduced recently (see Figure 3) differs from the smooth walled woven grafts in that the employment of an additional set of texturized yarns which are less frequently interlaced than the ground yarns results in a "filamentous" characteristic. Because of the greater exposure of filaments on the surface, the velour graft is softer to handle. Moreover, the velour component allows the reduction of the fabric tightness without adversely affecting the permeability. This type of woven graft has proven superior to the smooth walled vascular grafts in terms of tissue attachment [12]. However, the fact still remains that serious complications may arise in all woven vascular grafts as a result of their stiffness, and a tendency to fray at the edges.

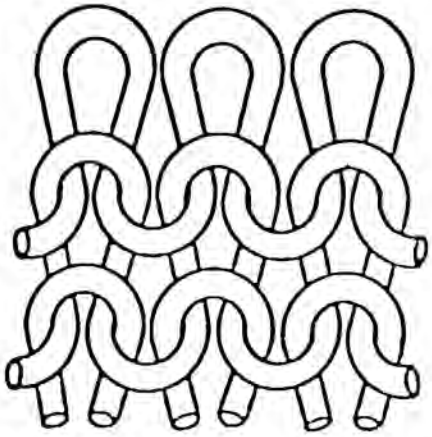

Figure 4b. Single jersey structure: back.

Figure 5a. SEM micrograph of DeBakey standard: face.

Figure 5b. SEM micrograph of DeBakey standard: back.

Knitted Vascular Grafts

Weft Knitted Vascular Grafts

The most popular structure used in the fabrication of vascular grafts is known as single jersey. Single jersey is the simplest weft knitted structure, and very easy to fabricate (see Figure 4). Single jersey grafts are inherently more porous than wovens. The increased porosity (see Figure 5) in this class of grafts results in a greater degree of yarn mobility. In consequence, these grafts are more compliant, easier to handle and suture [13]. This structure provides greater mobility of the yarns in the circumferencial direction than in the longitudinal direction. This anisotropic behaviour somewhat resembles the behaviour of the host artery. However, in cutting, the cut edges curl up, making suturing difficult. Furthermore, the shear stresses at the suture line can result in the "run" of the structure. The term "run" refers to the loss of a series of loops that can propagate throughout the length of the graft. A run is normally initiated by the breakage of a yarn.

The weft knitted velour grafts such as Sauvage Filamentous® are superior in performance to the smooth walled weft knitted grafts. They are easier to suture and handle, and show higher degrees of healability. Moreover, they do not run as easily. This is a feature common to the velour constructions. Sauvage Filamentous is produced by feeding two sets of yarns in a plaiting relationship to each other, one yarn forming the elongated or velour loop and the other forming the main body of the graft. The velour component appears on the inside of the resultant tube. In comparison, the outer surface is relatively smooth (see Figure 6). Subsequently, the fabric is turned inside out to form an external velour graft [14]. The use of bulk texturized yarns has allowed a reduction in porosity (increasing healing porosity) without adversely affecting permeability (bleeding porosity). Furthermore the texturized yarns have served to anchor the fibrin mesh formed at implantation securely, thereby eliminating the danger of delayed hemorrhage, as well as serving as a trellis to assist healing [15–18].

This seems to be one of the more successful concepts judging by the number of single and double velour grafts available on the market. It is worth noting, however, that although in peel tests, it has been shown that the tissue is much more firmly attached to the graft [19], no complete healing has been so far reported in man. However, the use of weaker texturized yarns could increase the chances of such complications as dilatation, rupture, and therefore aneurysms and hemorrhage. A program of life-testing of these prostheses under controlled laboratory conditions is much needed before any solid conclusions are drawn.

Figure 6a. SEM micrograph of Sauvage filamentous: face.

Figure 6b. SEM micrograph of Sauvage filamentous: back.

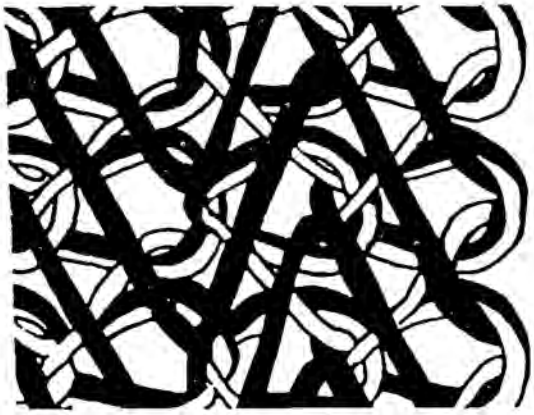

Figure 7. Locknit structure.

The relatively open construction, combined with the relative ease of distortion of the curved knitted loops, result in greater flexibility and compliance, providing better compatibility with the host arteries, at least in the immediate post operative period. However, due to the poor elastic recovery of these structures, the graft's diameter will enlarge in time. This, together with a tendency to run, make this class of grafts a likely candidate for such problems as dilatation, anastomotic aneurysm, rupture, etc.

Warp Knitted Vascular Grafts

Warp knitted fabrics are extremely versatile in the sense that they can be especially designed to resemble woven or weft knitted fabrics in terms of mechanical performance.

Figure 8. Reverse locknit structure.

Figure 9a. SEM micrograph of Cooley double velour: face.

Figure 9b. SEM micrograph of Cooley double velour: back.

The most popular structures in the construction of warp knitted vascular grafts are the locknit and reverse locknit [20,21]. (Loop diagrams are given in Figures 7 and 8.) These structures are relatively dimensionally stable and exhibit a higher compliance in the circumferential direction than in the longitudinal direction. Their compliance is greater than that of woven grafts but lower than that of weft knitted grafts. They do not run, unravel, curl up or fray at the edges. The velour structures of locknit and reverse locknit are achieved normally through incorporation of an extra set of texturized yarns fed under very little tension and at higher rates than the ground (nontexturized) yarns. Because of the difference in the feeding rate, the texturized yarns are more exposed on the surface, giving the graft a filamentous characteristic (see Figure 9).

Meadox Microvel® appears to use a half tricot structure wherein the texturized yarns are inlaid. It is worth noting, however, that the patent specification refers to the use of locknit of tricot structures [22]. Half tricot is inherently very porous resulting in a superior velour characteristic, but is dimensionally unstable, and has a tendency to tear along the wales of the graft.

Although warp knitted grafts offer certain advantages over woven and weft knitted grafts, problems still persist. These are discussed below.

Nonwoven Vascular Grafts

Unlike the other prostheses, Gore-Tex, Impra, and Vitagraft are constructed from polytetrafluoroethylene (P.T.F.E., or Teflon). Further, these are the only grafts that may be classed as nonwoven. It should be noted, however, that both Dacron and Teflon vascular patch grafts of the nonwoven category are also commercially available. These are, however, beyond the scope of this survey and are not therefore discussed.

In 1972, Soyer et al. [23] were among the first to report the use of Gore-Tex as a venous prosthesis in pigs. Previously, the material was primarily used as industrial chemical tubing. There are numerous patents on the production techniques of Gore-Tex material. They all however, share one common feature, namely that the material is processed initially as a film and subsequently stretched to produce a microporous structure (see Figure 10) from the non-porous film; the degree of porosity being related to stretching [24–29]. Initially, Gore-Tex was relatively weak. To improve upon this, the material was later reinforced with a thin open mesh attached to the exterior of the tube. Im-

Figure 10. SEM micrograph of Gore-Tex.

pra, on the other hand, has always been a one-piece design. Vitagraft is said to have two distinct layers. The thin inner layer has typically internodal spacing and less axial orientation. The outer macroporous layer is much thicker [30].

Gore-Tex, Impra and Vitagraft have found applications mostly in small caliber arterial and venous replacements where loss of patency is of prime concern. The slightly superior performance is related primarily to the polymer type. Teflon is the most chemically inert of all polymeric materials [31], with a surface energy of 18 ergs/cm^2. However, in terms of mechanical properties, these grafts are relatively weak and non-compliant. None of the structures mentioned above match the properties of the arteries they are called upon to replace. In consequence, complications associated with the use of these prostheses arise often.

POST-MANUFACTURING TREATMENTS

Upon removal from the knitting machines or looms, the tubular fabrics undergo special treatments before being packaged. These include compaction, crimping and sterilization.

Compaction is necessitated by the fact that the permeability of the grafts (those of knitted especially) is initially too great. Compaction is thus, carried out under controlled conditions to reduce the porosity to acceptable levels. This is accomplished by either thermal or chemical treatments, which reverse the changes effected during heat drawing of fibers.

The changes in the molecular arrangement, orientation and crystallinity [6] may be accompanied by significant decreases in strength. Furthermore, it has been found that the internal changes in the fibers may affect the healing performance of the prostheses [32]. Nonetheless, however, the compaction is essential in loosely knitted grafts.

Early in the history of vascular grafts, one major problem in all early grafts was lack of compression resistance and kinking upon bending. The kinking was a major problem especially at joints having an extensive range of movement as for example in the hip joint between the legs and the primary body trunk. The problem was solved by Sterling Edwards and James Tapp who introduced a method of crimping in 1955 [33]. Crimping is a process of permanently setting pleats or corrogations in the structure. Subsequent techniques that have become universal are due to R. E. Roberts [34] for mold crimping and E. E. Starks [35] for the thread winding process. An explanation of these techniques can be found elsewhere [36].

Crimped grafts have a greater bulk and luminal friction and kink resistance [37]. However, research has shown that the luminal corrugations fill rapidly with fibrin and cellular materials [38,39]. Comparative studies on the patency of crimped and non-crimped vascular prostheses have shown that crimping may result in delayed healing, and a thicker inner lining that increases the risk of occlusion [40,41]. This is of particular concern in the small caliber arteries for below the knee implantations. Although kink resistance is vital, a higher probability of thrombosis is not at all desirable. To overcome kinking without crimping, the concept of externally supported (EXS) vascular prostheses was recently introduced. Kink resistance is achieved by wrapping a monofilament polypropylene in areas of flexion and heat-fusing it onto the external surface, leaving grafts smooth internally, with an inner-flow surface that would be expected to show improved patency—despite a possible reduction in compliance [42]. The crimped configuration is not at all desirable and certainly not necessary in areas where kink-resistance is not crucial.

Postmanufacturing sterilization is essential for freeing the prostheses of microorganisms that could lead to graft infection.

The different types of sterilization processes may involve the use of

dry or moist heat, chemical agents or irradiation [6], the last being by far the most popular so far as graft manufacturers are concerned. The first two procedures are common to hospitals where resterilization may be necessary. Obviously, these treatments may lead to significant changes through chain scission, cross-linking, oxidation, etc. The clinical significance of such changes have not been yet established and there appears to be a need for identifying the significance of such changes.

NON-TRADITIONAL GRAFTS

Compound Grafts

The concept of a "compound Vascular Graft" was first proposed in the late 1950s and early 1960s by Adam Wesolowski [18,57]. Noting that formation of a thin layer of fibrin within the prostheses shortly after implantation impeded the flow of tissue from the outer capsule, Wesolowski reasoned that high levels of porosity facilitating full-wall healing, would appear to be a most important determining factor in the ultimate long-term fate of arterial prostheses. On the other hand, however, minimization of bleeding through the interstices of the graft at implantation would require a tightly fabricated structure. To satisfy these two requirements, Wesolowski proposed fabrication of a compound prosthesis composed of non-absorbable (e.g., Dacron) and resorbable (e.g., catgut) yarns, so that during healing, the resorbable components would be replaced by tissue. Grafts evaluated included mesh fabrics coated with collagen, plain woven fabrics incorporating Dacron and catgut and plain woven and knitted (single Jersey) fabrics making use of a compound yarn consisting of 30–70 denier Dacron wrapped around a core of catgut.

The third class of grafts evaluated were the most successful of the compound grafts tested. The catgut component, however, had not been totally resorbed by the time of healing of the inner capsule. Being unable to control the degradation rate of the catgut, the idea was thus abandoned. Although the project did not succeed in promoting a new novel design, it led to a better understanding of the tissue material interactions, providing sound guidelines for researchers. It is worth noting that in recent years, the introduction of synthetic absorbable (biodegradable) fibers such as Poly-Glycolic-Acid (PGA), Poly-Lactic-Acid (PLA) and Poly-Diaxonen (PDS) has revived the concept of compound grafts. In 1969, American Cyanamid obtained patents on the

use of PGA fibers for vascular prostheses of the single Jersey type [43]. In 1972, Ruderman [44] developed and examined a partially biodegradable vascular prosthesis using PLA in a plain-woven graft. More recently, Bowald, Busch, and Eriksson [45] used two separate tubes, one microporous tube of PTFE and one mesh tube of polyglactin suture material, the mesh having been inserted into the FTFE tube. Although apparently the inner surface was covered by "endothelialized tissue," there was much evidence of cell regeneration. Although the concept of compound vascular grafts has not proven successful, it has busied researchers on both sides of the Atlantic.

Elastic Grafts

Experiments with "elastic" (compliant) arterial prostheses extend back to 1956, when Whillsey [46] reported favourable results for "elastic nylon tubes" of braided helenaca yarn. Helenaca Dacron yarn was fabricated in longitudinally elastic woven grafts in 1958 [47,48], and again in 1965 [49]. In 1966, Wagner et al., experimented with a knitted (single jersey) compliant graft composed wholly of Spandex (Lycra®) [50]. The graft failed within 6 weeks due to aneurysmal dilation. However, later experiments [51] with Lycra as abdominal patch grafts showed satisfactory incorporation of the prosthesis by host tissue. In 1974, Kardos developed a four-ply laminated tube made from segmented polyetherurethane [52]. This has been the only real attempt at matching the anisotropic stiffness of the host arteries.

In 1978, Norman Rosenberg reported briefly on an early experience with a composite graft of Dacron-Lycra [53]. In 1983 an update on a "3-year study of the graft in the dog" was given [54]. This was a woven graft composed of Darcon warp and Lycra weft. The 3-year follow-up had not indicated evidences of degeneration of the Lycra component and had not shown any evidence of aneurysmal dilatation. It is important to note that Rosenberg's graft lacks longitudinal compliance. Fraying is frequent and attempts to heat seal or even chemically seal the edges may not be particularly successful.

Finally a non-woven compliant graft was developed in Canada in 1983 [55]. This is a spun bonded graft made up of Pellethane® (Polyurethane). The novel feature of the graft lies in the fact that fibers once extruded are wound on a rotating mandrill at desired angles of orientation, and result in the formation of stable, kink resistant porous tubes; the anisotropic behaviors of the tube being dependent on the processing variables. This seems to be an extension of a similar process patented by Raymond Lightwood of Birmingham, England in 1970, in which a

porous tube was produced by winding extruded silicone rubber thread onto a mandrel [56].

Although it is widely believed that compliance is not an important consideration and not crucial to the long-term survival of these prostheses, we do believe that a match in mechanical properties is crucial to the short-term and possibly long-term survival of such prostheses. Judging from the literature, it is apparent that some researchers are beginning to work in that direction.

Anti-Thrombogenic Grafts

Anti-thrombogenic surfaces are designed to interfere with the natural healing processes thereby eliminating the build-up of cellular deposits. There are two clear trends that have received attention by various researchers. These include the artificial intima approach, and anti-thrombogenic coating approach. Some of the more important work in this area is reviewed below.

Production of artificial intima, including the concepts of molecular engineering at blood-solid interfaces, have not been proven applicable to cardiovascular prostheses [57]. Most emphasis has, therefore, been placed on the prevention of thrombus formation on synthetic vascular surfaces by true endothelial cell linings [58]. Synthetic microfiber surfaces composed of polypropylene and polyester, prelined with autologous endothelial cells implanted in calves have shown no thrombus build-up, platelet deposition or any adverse reactions where the cultured cell lining has remained intact. It is believed that true endothelial cells can be easily harvested, grown in tissue culture and attached to artificial surfaces. Reimplanted in the circulation, these cells would then prevent thrombus generation. However, it appears that much work needs to be done before this concept may be exploited commercially.

The other trend in this area relates to the attempts at albumin coating of the prostheses. It has been shown that albumin coated materials can be endothelialized [59–66]. This concept has apparently been successful in that it has recently been commercialized, the added advantage being the elimination of the need for preclotting.

The other approach that has proven successful in devices such as hemodialysis shunts is the heparin release mechanism. Experimental results have shown that heparin bonded rubber buttons would remain free of thrombus up to 18 months. Although this technique seems to be of value in for example, shunts, it has not found application in synthetic vascular grafts [67,68].

The bonding of heparin to graphite by Gott in 1963 introduced the family of carbons to the list of biocompatible materials [69–71]. Although many different types of carbon, for example, Vitreous carbon, acetylene black amongst others [72–76], have proven to be quite biocompatible and thromboresistant, the one that has received much attention is the pyrolytic carbon. Pyrolytic carbon, an isotropic turbostatic carbon, has been used as a coating material by a vapor-deposition process in which the carbon is deposited from a hydrocarbon-containing gaseous environment onto a suitable substrate in a fluidized bed [77]. The pyrolysis reaction is controlled by such process variables as deposition temperature, contact time, and composition of pyrolyzing gas. Obviously, both the high temperature isotropically deposited (HTI) carbon and the low temperature isotropically deposited (LTI) carbon requiring deposition temperatures of above 2000 C°, and about 1500 C° respectively, would not be suitable for coating vascular grafts. However, the recent development of the ultra-low temperature isotropically deposited (ULTI) carbon which requires deposition temperatures of less than 100 C° [78], may be deposited on fabrics. Experimental results in dogs have shown excellent patency [79]. Similar results of excellent thrombogenicity have been observed for LTI carbon tested in heart valves [80,81]. There is much evidence that carbon coated Dacron grafts may find applications in small caliber arterial grafting. However, although thrombogenic, the material would become even more rigid and problems such as dilatation and suture line deterioration, may result in prosthesis failure. Judging by the number of patents on various methods of carbon coating of vascular grafts, it appears that there is much continued interest in this concept [82–87]. However, excepting the employment of autogenous veins and arteries (and to a limited extent the heparin bonding techniques) no effective endothelial substitutes have yet been developed. The prevention of thrombosis, therefore, continues to be dependent largely on maintaining a sufficient velocity of flow through the prostheses in an attempt to keep the mural accumulation of fibrin to minimum.

It is quite clear that despite all efforts, the vascular grafts of today are not significantly different from those of the 1950s and 1960s. Although many of these structures have performed somewhat satisfactorily as medium or large arterial grafts, they have failed as small caliber arterial replacements. This has led to the concentration of efforts on the development of suitable small caliber grafts at the cost of overlooking problems in existing grafts. It is this topic that is investigated below.

GRAFT FAILURE

Well documented cases of graft failure reported in the literature are rare. Furthermore, in a majority of cases, sufficient details about the type of grafts have not been provided. In the absence of such details, a comprehensive assessment of these prostheses is difficult. Recently, however, we reported on the major trend in graft failure. It is not intended to restate these findings, but rather to draw attention to structural parameters responsible for graft failure.

The trends are quite clear, and vary depending on the size and location of the implants. Generally speaking, in small caliber grafts (<6 mm in diameter), the main cause of graft failure has been associated with the loss of patency, and occlusion [45–73]. In medium to large caliber grafts, however, the four most reported significant complications have been associated with (1) dilation, (2) suture-line failure, (3) structural defects, and (4) bleeding and infection [88–121]. Specific details are given elsewhere [122].

Small Caliber Grafts

Blood flow has a direct influence on the blood vessel properties as it interacts with the artery both chemically and physically. It determines the initiation, propagation and fate of thrombus, and ultimately the blood vessel or the implant. Formation of thrombus has been mostly related to damaging shear stress on the wall resulting in the loosening of endothelial cells from their subendothelial attachment. Blood platelets subsequently adhere to the exposed wall, giving rise to coagulation reactions [123–135]. The role of fluid flow in artery/implant systems is dependent on the mechanical behaviour (compliance) and the surface characteristics of the system used. Commercially available vascular grafts are essentially non-compliant tubes whose elastic moduli can be about ten times (more or less depending on the structure) greater than that of natural arteries they are called upon to replace. Depending on the location, and thus the velocity of the flow, these differences in rigidity may create strains near the suture line and separate flow regions in the vessel, yielding turbulent flow and additional shear stresses on the wall. This may give rise to endothelial cell damage.

Loss of patency is a serious complication in smaller grafts, and it is commonly believed that synthetic grafts available today can not compete with saphenous veins in the replacement of blood vessels below the knee [126]. Patency rates for saphenous veins are compared with those of Dacron and PTFE grafts in Table 3. The slight superiority of

*Table 3. Cumulative patency rates (%).**

Period (Years)	Material		
	Dacron**	P.T.F.E.†	Saphenous Vein
1	72	75	91
2	56	61	74
3	43	51	80
4	41	47	78
5	38	44	76

* The rates are the mean of reported patency rates [138–166].
** These rates related to Dacron type grafts.
† These rates related to Gore-Tex and Impra grafts.

PTFE over Dacron grafts is primarily due to nature and properties of the polymer. PTFE grafts are also non-compliant.

It has been suggested that minimalization of compliance mismatch between the host artery and synthetic substitutes will improve graft patency. While this may be true of the immediate post-implantation period, the tissue in growth results in a reduction of the implant compliance. Therefore, the control of stiffness constants as a function of time may be perhaps a more important consideration.

Medium and Large Caliber Grafts

Table 4 summarizes the failure data on the medium to large arterial grafts. Dilation is by far the most often cited cause of graft failure. Suture-line failure and structural defects, together, also form a significant percentage of the causes of failure. Bleeding and infection by contrast, do not seem to be as significant. These, however, relate mostly to the immediate post-implantation period.

Dilatation is an inherent feature to a greater or lesser degree of all existing vascular grafts, even though it may not lead to graft failure.

Table 4. A summary of failure data on arterial grafts.

Cause of failure	Frequency of failure	Mean time to failure (months)	Range of time to failure (months)	Period with highest probability of failure (months)
Dilation	147	35	0–110	30–40
Suture-line failure	56	42	0–120	30–50
Defects	76	53	0–170	40–60
Bleeding & Infection	30	13	0–80	0–10

Dilatation stems from poor fatigue resistance of these structures, and may be minimized by the incorporation of elastomeric yarns. The fatigue properties of grafts are discussed in a later section. Of interest is that more than 90% of the reported graft failures due to dilation had exhibited between 10 to 30 percent increases in diameter. Most knitted grafts, especially those belonging to the weft knitted category, can exhibit dilations of the same magnitudes in the immediate post implantation period [122].

Suture-line failure is also cited as a major cause of failure. Failure at the suture line normally results in blood leakage; consequently, an anastomotic aneurysm will evolve [127]. Suture-line failure may be due to the failure of the implant close to the suture line, the fracture of the suturing material, or the failure of the host artery. Irrespective of the mode of failure, the most significant cause of suture line deterioration is perhaps the stresses that mainly arise from the mismatch in compliance of the host artery and the prosthetic vascular graft. It will be recalled that vascular grafts are essentially nondistensible, while the host artery may show a diameter change in excess of 10 per cent over the cardiac cycle pressure [128]. Further, the probability of graft failure increases with time not only because of tissue ingrowth (and the associated decrease in compliance), but also because of the weakening of the suture material and/or the graft as a result of reaction with body fluids. Graft failure as a result of suture-line deterioration has been most often reported between thirty and fifty months of implantation.

So far as failure due to defects is concerned, the incidence of early graft failure is indeed very low and most cases have been reported between 40 and 60 months of implantation. We have concluded that such defects are in all probability, not macroscopic. Thus quality control measures fail to identify potential hazards. On the other hand, the chemical and mechanical compaction procedures used to reduce the grafts porosity, crimping, sterilization, and resterilization together with the handling of the material during implantation could all be potential causes of defect generation. These are relatively more difficult to control. It would be advisable, however, to reduce the number of chemical, mechanical and thermal treatments necessary, by employing newer structures and methods of manufacturing.

Failure due to bleeding and infection are rarely reported in the literature. This is perhaps why they form only a small percentage of failure cases studied. Bleeding occurs at the suture line in woven grafts while it occurs through the interstices of knitted grafts immediately following implantation. The latter is by far more serious and could result in hemorrhage. This may be due to the graft's excessive porosity and/or

improper preclotting prior to implantation. These two factors are interrelated in the sense that in highly porous grafts preclotting can prove to be very difficult and ineffective. The newer grafts that are albumin coated do not require preclotting and could eliminate this problem altogether. Infection is also rarely reported in the literature. This is not material dependent, and would be expected to occur very early in the life of the implant. Development of infection resistant grafts through drug delivery systems is beginning to receive some continued attention [129–133] and will hopefully reduce the occurence of graft failure. Some reports, however, relate graft failure to bleeding or infection very late in the life of the implant. Bleeding was not the cause, but the outcome of graft failure, and infection was probably a host reaction to the material.

In closing, it is worth stating that in many of the reported cases of graft failure, only one complication has been mentioned as the unique cause of graft failure. It is quite probable, however, that one complication may have resulted in or arisen from other complications. This emphasizes the need for identifying the cause or causes of failure when reporting on clinical experiences on implanted grafts.

Material Properties

Currently, the commercial vascular grafts make use of Dacron, or Teflon, materials. In fact, the type of structures employed is somewhat governed by the materials used. Dacron is a relatively strong fiber, and very easy to fabricate into fabrics (both knitted and woven). Teflon, on the other hand is a somewhat weak fiber and although it may be knitted or woven into a graft, early experiments have shown the Dacron to be far superior. Grafts made up of Teflon, therefore, do not employ fibers and are completely different in their structure. These two categories are treated separately below.

The PET grafts exhibit widely differing physical properties. As explained previously, this is primarily due to the fabric structures employed and possibly the post-manufacturing processes that follow. A summary of some of the physical properties are shown in Table 5.

PTFE grafts are limited in number, but do show significant differences in their properties. Furthermore, they are normally weaker than PET grafts and are relatively thicker. These are also noncompliant grafts, and the reason for a relatively better patency is related to the material type. A short summary of the physical properties is given in Reference [30].

Prior to the recent AAMI guidelines and test methods, there were no

Table 5. Physical properties of commercial vascular grafts.

Name	Structure		Manufacturer	Thickness (mm)	Volume Fraction (%)	Water Porosity ml/min/cm²	Bursting Strength kg/cm²
	Type	Name					
Cooley Woven	Woven	Plain Weave	Meadox	0.25	59	130	55.1
Cooley Verisoft	Woven	Plain Weave	Meadox	0.25	60	520	29.8
DeBakey Woven	Woven	Plain Weave	USCI	0.25	50	350	52.9
Woven Double Velour	Woven	Plain Weave with Floats	Meadox				
DeBakey Standard	Weft Knitted	Single Jersey	USCI	0.49	34	2,600	32.0
MilliKnit	Weft Knitted	Reverse Single Jersey	Golaski	0.36	33	5,800	18.6
MicroKnit	Weft Knitted	Reverse Single Jersey	Golaski	0.21	40	3,340	14.9
Sauvage Filamentous	Weft Knitted	Reverse Single Jersey	USCI	0.58	30	3,600	18.9
Cooley Double Velour	Warp Knitted	Locknit	Meadox	0.69	30	1,700	12.4
Microvel	Warp Knitted	Half tricot w/ Inlaid Yarn	Meadox	0.90	18	2,500	10.2
WeaveKnit	Warp Knitted	Reverse Locknit	Meadox	0.35	36	3,000	15.9
Cooley Knitted	Warp Knitted	Reverse Locknit	Meadox	0.55	31	2,400	29.1

rational test methods for the evaluation of the various physical properties of vascular grafts. The recent guidelines by AAMI are certainly a step in the right direction, although much more work is needed. Various test methods are discussed below.

Strength Testing

Many types of strength tests have been employed. The simple tension test using strips of fabrics has been used with limited success. Tension tests can be successfully applied to woven grafts, nonwoven grafts, and possibly some warp knitted grafts. However, weft knitted grafts can not be reliably tested using this method. (It will be recalled that weft knitted grafts account for more than 50% of the structures available.) Weft knitted grafts tend to stretch extensively and contract laterally. Subsequent necking in the center of the specimen makes the result unpredictable and unreliable. Tension tests may only be useful in determining the degree of anisotropy in the materials. Another method which has been extensively used is the split bar method. A tubular specimen of a fixed length is pulled over two pins which are subsequently pulled apart. This test could easily be done on an Instron, although simpler fixtures have been used [134]. This test method is not suitable for knitted grafts at all as it can easily cause a "run" in the structure. Perhaps the most appropriate test method involves pressurizing a tubular specimen [135]. Due to the inherent porosity of specimens, a thin latex tube is used to line the grafts. This test is particularly suitable for knitted grafts. Woven grafts are more difficult to accommodate as they require substantially higher pressures. It should be noted that the results can be influenced by sample size and dimensions. Also care should also be exercised in clamping the ends of the specimen. This test method results in biaxially loading the specimen and would not normally cause premature failure. Other burst strength measurement methods requiring flat specimens are not appropriate simply because the tubes do not normally produce large enough samples.

Fatigue Testing

As was discussed earlier, dilation appears to be the most frequent reported cause of graft failure. Dilation referring to the enlargement of the diameter is brought about as a result of pulsating stresses. It has been shown that dilation clinically occurs in two stages. We have concluded elsewhere that the early or immediate dilation is due primarily

to the fabric structures employed while late or delayed dilation is due to fiber fatigue [122].

Plain woven fabrics have a comparatively high initial modulus and exhibit little or no hysteresis at low levels of stress. However, both warp and weft knitted structures are quite different in the relative value of the initial extension and initial modulus. Due to their looped structure, knitted fabrics have very little resistance to extension which is mainly due to the resistance of parts of the structure to bending and torsion. In consequence, the loops can straighten relatively easily in the line of the highest stress. The large hysteresis observed in knitted fabrics is not due to yarn hysteresis but rather due to the straightening of the loops and the frictional restraints at the contact points. The yarns would find greater mobility with increased porosity, resulting in a 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 seems inevitable that some degree of permanent deformation (enlargement of the diameter) will develop. This may be further aggravated by the fatiguing of the yarns. The extent to which dilatation may occur is also a function of the applied stress. It follows, therefore, that in hypertensive patients dilations could become an even more serious problem in a relatively shorter time, as witnessed by Nunn, Freeman and Hudgins [116].

The only test method used for the determination of immediate dilation involves balloon testing of grafts at a static pressure for one minute while being held at both ends at a constant tension estimated to be similar to that applied at the time of surgery [96]. This method is very sensitive to the tension applied at the time of testing. There appears to be no consensus regarding the extent of this tension; values are therefore selected arbitrarily. Obviously higher longitudinal tensions would restrict the extent of immediate dilation in the hoop direction.

This method of testing does not test for delayed dilation which appears to be a more significant problem. Indeed it has been shown that while early or immediate dilation may reach 50 percent, delayed dilation could be as high as 150 percent [117]. The delayed dilation occurring mostly between 30 and 60 months of the implants' lifetime is primarily due to fiber elongation and fatigue. This may be further aggravated by the fact that PET undergoes changes in presence of body fluids. A reduction in molecular weight and rearrangement of crystals together with the associated loss in strength could indeed accelerate yarn fatigue.

At present there are no standard test methods available for long-term

fatigue testing of arterial grafts. However, various researchers have devised their own techniques for carrying out this task. The most appropriate method involves cyclic loading of tubular segments lined with a latex material. There is very little data available, and it appears that these tests are run at physiological pressures and frequencies for several months and the samples are then tested for residual strength using the split bar method. Yarn samples are also extracted from samples and tested for residual strength [134]. No conclusive results however, have yet been presented. Various grafts (e.g. knitted) are grouped together and no comparison is allowed among the samples.

We are at present conducting a thorough investigation of the fatigue properties of vascular grafts. A pump has been designed and built that is capable of fatigue testing of tubular specimens. The pump is capable of running at both normal (1 Hz), and accelerated rates (up to 30 Hz). The pump can generate signals of any form or shape, and is a strong tool for simulation studies. The system comprises a purpose built servo-actuator, a high volume pump, a power driven amplifier, and is controlled with an IBM minicomputer through an A/D-D/A converter. The input and output of the pump is controlled through a negative feedback circuit.

Preliminary results indicate that residual strength is not perhaps the appropriate criterion for the evaluation of fatigue resistance of grafts. Even after several months of being subjected to fatigue, the grafts exhibit relatively high strengths. A 20% reduction in strength of a knitted graft after 6 months does not necessarily indicate that the lifetime will be about 30 months. The behavior of fabrics in fatigue is much more complex and involved. Further, a graft, even after losing 20% of its original strength, may be significantly stronger than other grafts, or indeed the host tissue. It should also be pointed out that residual strength measurements made on extracted yarns of these grafts are very inconclusive. The yarns lose some strength after being woven or knitted into a fabric. Exactly how much strength the yarns lose, is not known and is a function of the manufacturing practices. Furthermore, the mere process of yarn extraction can be severe enough to result in a significant strength loss. What is perhaps the most important aspect of fatigue testing that needs to be studied extensively, is the degree of permanent deformation in the material. A graft may retain more than 80–90% of its original strength even after dilating 50% or more. While the strength loss may not necessarily lead to graft failure, clinical experience has shown that dilation will. If samples are to be tested in an attempt to rank their survival rates, then accelerated fatigue testing at pressures much above the physiological pressures need to be per-

formed. We will publish our results on the fatigue testing of vascular grafts as soon as they are completed.

Compliance Measurements

The concept of elastic compliance is defined in various ways in the literature. The most common definition arises from the load-displacement curves obtained in a tension test, where the compliance is simply the constant of proportionality C in the formula

$$U = CP \tag{1}$$

where U is the specimen displacement and P is the load. The units of compliance in Equation (1) are meter/newton. The compliance therefore, represents the inverse of the spring constant of the material. It ought to be noted that compliance is a parameter that should be defined as a function of the direction in which the tensile test is performed. Unlike isotropic materials where the number of elastic constants (stiffness or compliance) necessary to completely describe the mechanical behavior are restricted to two, in arterial grafts where the materials are anisotropic (and viscoelastic), the number of elastic constants necessary could be as high as 21 if the material is completely nonsymmetric. We have argued elsewhere that perhaps a good approximation would consist in assuming that the wall material is orthotropic, possessing three planes of symmetry perpendicular to each other. Under this assumption, and in a plane state of stress, the number of independent elastic constants is reduced to four.

The viscoelastic nature of the materials implies that, at any time, there is a phase difference between the force and the resulting deformation. There would be a need for methods to characterize this phase difference in vascular grafts.

Grafts have also been tested through internal pressurization, and bursting, where a biaxial stress state is achieved. Since a circular cylindrical geometry is involved, the effective radial dilation is commonly measured through the use of the dynamic ratio,

$$(\Delta V/V)/\Delta P$$

which describes the percentage increase in vessel volume per unit pressure change during the pulse cycle. Alternatively, the measurement may address the change in diameter through the ratio,

$$(\Delta d/d)/\Delta P$$

which describes the change in diameter per unit pressure change. The equipment we have developed for fatigue testing of vascular grafts is being used to measure both these ratios. The displacement of the graft is recorded using a video system. The frames are then digitized and measurements made. The advantage of the system lies in the fact that numerous measurements can be made along the length of the graft, and that through time lapse photography, time dependence of compliance can be investigated. These results will be published subsequently.

Suture Retention

This area has not received as much attention in the literature. This is rather unfortunate in that suture line failure is a major reported cause of graft failure. As explained previously, the failure could be due to failure of the graft, the suturing material or the host artery. The failure of the graft at the suture line is normally initiated by either yarn breakage or yarn slippage. Yarn breakage is normally more common in knitted grafts. A yarn break evolves easily into a "run" or a "rent" which could propagate along the total length of the graft. In half-tricot grafts, a yarn breakage could quickly propagate causing complete splitting of the graft. Yarn slippage, on the other hand, is common in woven grafts. Heat sealing of edges is normal practice, but may not prove completely successful especially if the graft has been cut on the bias. This problem could be perhaps remedied by employing weave structures that are more resistant to fraying.

It is also common that the implant failure may be due to the fracture of the suturing material. The loss in strength due to the mechanical fatigue of suture materials, combined with the biodegradative role played by tissue fluids and enzymes, may weaken the suture materials to such an extent that they would not be able to withstand the stresses at the suture line.

A final cause of suture line failure is the tearing of sutures out of the host arterial wall. This is primarily due to the progression of the disease or aseptic necrosis of the suture line, resulting perhaps from devascularization of the host artery at the time of surgical dissection. This may be further aggravated by excessive tensions applied at the time of surgery. In this regard, longitudinal compliance would be desirable.

Suture line deterioration is not a straightforward and easy problem. Obviously, the structure has much to do with suture retention. Equally, the distance at which the sutures are placed from the edge can markedly influence the suture retaining strength of the material. Unfortu-

nately, however, there are no appropriate test methods available today for determining this property. The only test method used by various researchers involves pulling a single suture material passed through the wall of a graft until rupture or to a given load [55]. The results obtained using this test method exhibit a high degree of scatter. Further, the values obtained are not indicative of the true suture retaining strengths of the materials. In graft/artery assemblies where a number of sutures are placed, the stresses are shared by sutures, and excessive shear strains are not present as is the case with samples tested under this test method. A more realistic test method would be to adapt the procedure used for fatigue testing of sutures [136]. This method involves suturing tubular samples which are then internally pressurized. Obviously, much work is needed, and there is a need for understanding and improving suture retention.

Porosity Testing

The pioneering work of Adam Weslowski in the early 1960s led to the many concepts later developed commercially [18,57]. In one of his earliest experiences with experimental grafts, an endeavour was made to quantitatively measure the degree of porosity in grafts as it was then and even now believed that porosity is directly related to tissue ingrowth and healing. The test method employed for measuring graft porosity comprised a chamber, and a holder for clamping small samples beneath the chamber. The chamber was filled with water to reach a static pressure of 120 mm Hg; the water level was kept constant by constantly resupplying the water. The method measured the rate of water flow through fabric grafts. Subsequent methods used by industry and researchers are simple modifications of the same concept [137]. However, this method does not reveal the true porosity of the materials. Especially, with the use of texturized yarns, the grafts possess increased bulk, which in turn results in the reduction of the water porosity; clinical researchers have differentiated between the two, naming the true porosity "healing porosity." In fact, for most comparative studies, it is more appropriate to use the values of true porosity rather than water porosity. True porosity is termed volume fraction and can be obtained using the following relationship where θ is volume fraction, μ is fiber density (1.38 g/cm^3 for polyester), and μF is the fabric density. Fabric density can easily be measured, and does not require purpose built equipment.

$$\theta = \mu_f/\mu_F$$

Ease of Suturing

Ease of suturing is not directly related to the performance of the material *in vivo*. It however, influences the surgeon's decision in selecting a graft. A graft which is easy to suture, and handle, may not necessarily be the right choice. Some weft knitted grafts are inherently very porous and easy to suture and handle but are not stable structures.

Ease of suturing and handling are normally rated subjectively. Ease of suturing is clearly an important factor in the surgeon's preference of knitted grafts. It is not surprising that ease of suturing is considered to be one of the criteria required of an ideal vascular graft. Based on the definition that suturability relates to the amount of force required to puncture a graft using a surgical needle, we recently developed a simple testing procedure [13]. The method involves clamping a flat piece of material in a specimen holder, placing the assembly on a compression cell, and puncturing the material using a surgical needle [135]. Results of such a test are shown in Table 6. The needles used were taper point surgical needles obtained from Miltex Instrument Company in sizes 5, 10, 15, and 20. The diameters measured approximately 1.0, 0.9, 0.7 and 0.6 mm respectively. It may be seen from Table 6, that the grafts tested vary considerably in their resistance to needle penetration; knitted grafts are generally superior to the woven grafts. The porosity of the grafts is the key to the force of suturing. Water porosity has a direct correlation with suturability only in smooth grafts; volume fraction would be a better parameter to relate suturability to.

It ought to be noted that the desirability of ease of suturing should not be interpreted as absolute desirability of excessive degrees of porosity. An increase in porosity for a given structure leads to higher degrees

Table 6. Force of suturing.

Name	Force of Suturing (g)				Water Porosity ml/min/cm²	Volume Fraction (%)
	Needle Size 20	Needle Size 15	Needle Size 10	Needle Size 5		
Cooley Woven	185	270	460	720	130	59
DeBakey Woven	150	240	440	570	350	50
Woven Double Velour	100	200	350	410	250	40
Cooley Knitted	90	180	300	400	2,400	29.1
Sauvage Filamentous	80	140	240	310	3,600	18.9
Weavenit	50	100	180	215	3,000	15.9
Cooley Double Velour	30	38	46	88	1,700	12.4

of dilation and possible difficulty in preclotting, despite possible improvements in compliance (in the case of knitted grafts especially). The advantages of having an improved suturability should be weighed against the disadvantages reflected in a reduction in other properties. The most challenging task would be to develop an ideal vascular graft that will have all the desired properties of healing, compliance, ease of suturing, fatigue resistance, etc.

CONCLUSION

In conclusion, an endeavor was made to present a critical review of the structural and material properties of vascular grafts and the test methods for the evaluation of their physical properties. Although there has been a very significant degree of research activity concentrated on the development of an "ideal" vascular graft over the past three decades, today's vascular prostheses are not particularly different from those introduced in the late 1950s and early 1960s. The trends observed in graft failure in the literature clearly point out the problems associated with certain structures employed in the construction of vascular grafts. Dilation and suture-line failure are the two most major cited causes of graft failure. However, very little has been done to overcome these problems. There appears to be an urgent need for identifying potentially hazardous structures that might lead to graft failure, and proper testing procedures for the evaluation of long-term behavior of grafts under strict laboratory conditions are much needed in order to understand the structural and material relationships to graft failure. It appears that there is some interest in the development of rational standards, guidelines, and procedures by various organizations such as the AAMI and ASTM, and we can hopefully look forward to a more interesting era in the history of vascular grafts.

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ABOUT THE AUTHOR

Dr. Pourdeyhimi is an Assistant Professor in the Department of Textiles and Consumer Economics at the University of Maryland. He holds a Ph.D. in Textiles from the University of Leeds, U.K., and is an associate and licentiate member of the Textile Institute, U.K. He is also a member of the Fiber Society, and Committee F4, ASTM.