

Hongjun Yang,
*Weilin Xu,
**Chenxi Ouyang,
*Fei Zhou,
*Weigang Cui,
*Changhai Yi

College of Textiles,
Donghua University,
Shanghai 201620, China

*Hubei Key Laboratory
for New Textile Materials and Applications,
Wuhan University of Science and Engineering,
Wuhan 430073, China

**Department of Vascular Surgery,
Union Hospital,
Tongji Medical College
of Huazhong University of Science & Technology,
Wuhan 430022, China

Circumferential Compliance of Small Diameter Polyurethane Vascular Grafts Reinforced with Elastic Tubular Fabric

Abstract

Small diameter vascular grafts were fabricated from pure Polyurethane (PU), as well as PU reinforced with a weft-knitted tubular fabric. Textured polyester and Spandex blend yarns were used for knitting on a purpose-built weft-knitting machine. The circumferential compliance properties of the reinforced composite vascular grafts were compared with those of the tubular fabric itself and the pure PU vascular grafts. The elasticity and strength of the reinforced vascular grafts were improved in the radius compared with the tubular fabric. The strength of the reinforced vascular grafts was 5 - 10 times that of the pure PU vascular grafts. Expanding the tubular fabric to increase the inner diameter of the reinforced vascular graft increased the graft's strength and initial modulus, but the difference was reduced as the PU content was increased. For grafts of the same inner diameter, increasing the PU content increased the thickness and strength of the graft wall, which led to a general increase in the strength and initial modulus of the composite vascular grafts. The new composite vascular grafts combine the good elasticity and blood-proof properties of PU with the strength and stability of weft-knitted fabrics.

Key words: polyurethane, tubular fabric, vascular graft, textile composite graft, weft-knitted fabric, circumferential tensile strength.

rious clinical problem in spite of continuous improvements in graft development, vascular surgery and follow-up medical treatment of the recipient [14]. Polyurethane has been used to solve the thrombus problem due to its excellent elasticity and biocompatibility, and its microporous structure can be successfully fabricated in the wall using different methods [15 - 22]. The porosity of commercially available polyester (Dacron) knitted vascular grafts can be reduced by coating or sealing them with a novel ionic urethane to improve their blood-proof property. The mechanical properties of coated vascular grafts have been found to be comparable with, or superior to, a pre-coated Dacron substrate [23 - 33].

Natural vascular vessels are actually not made of one uniform material. Sonoda et al [34] studied a dog's artery and proposed a design concept for a coaxial double tubular graft, with one material in the vascular wall acting as a high elastic material and the other as a low elastic material. This design concept allows the development of grafts that are microporous and elastomeric, coaxial or triple-tubular using different types of materials that have complementary properties. For instance, polyester filament is strong but has poor elasticity, whereas polyurethane has good elasticity but is relatively weak. Combining these two types of materials may overcome the disadvantages associated with using one type of material on its own.

In this study, we developed composite PU vascular grafts reinforced with a weft-knitted elastic structure and examined the tensile properties of the composite grafts. The weft-knitted tubular fabrics were made on a purpose-built weft-knitting machine, and textured polyester/spandex yarns were used for knitting. The compliance properties in the radius of composite vascular grafts of different inner diameters, reinforced with the same elastic weft-knitted tubular fabrics, were also compared in this study.

Experimental

Materials

Polyurethane (PU) with a solid content of 30% was purchased from the Chemical Industry Co. Ltd., Yantai, China. N, N-dimethyl formamide (DMF) of analytical grade was obtained from the Shanghai

Introduction

Vascular grafts are special tubes that serve as artificial replacements for damaged blood vessels. While large diameter vascular grafts (larger than 8 mm in the inner diameter) are already commercially available, mainly produced from polyester knitted or woven fabrics [1 - 4], or expanded PTFE [5 - 10], a considerable challenge remains with respect to the development and application of small diameter vascular grafts (SDVG). Recently, electrospun nanofibres have been used in small diameter vascular grafts with special microporous structures [11 - 13]. However, graft thrombosis is still a se-

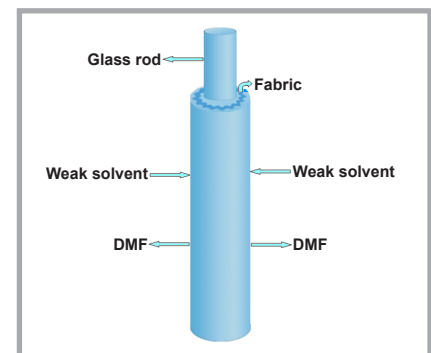


Figure 1. Scheme showing a glass mandrel covered with a tubular fabric immersed in a PU/DMF solution.

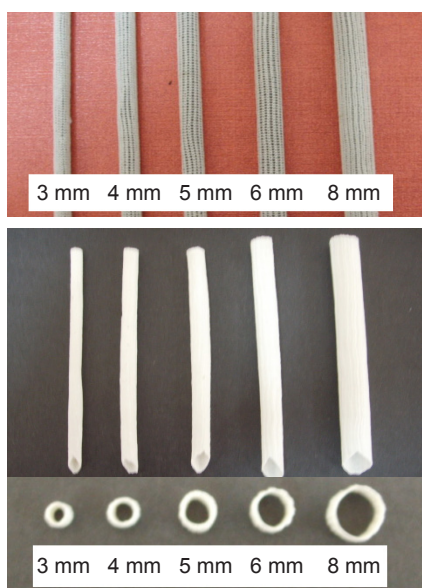


Figure 2. Longitudinal and cross-sectional views of knitted tubular fabric on glass mandrels of various diameter, as well as composite PU vascular grafts reinforced with the same weft-knitted tubular fabric.

Advanced Chemical Industry Factory, Shanghai, China.

Textured yarns (90D/37F) of polyester/spandex blend (polyester: 75D/36F; Spandex: 30D/1F) were supplied by the Yilian knitting Co., Ltd, China. The strain at break, tenacity at break and initial modulus of the textured yarns were 25.8%, 4.8 cN/dtex and 2.15 cN/dtex, respectively. The blend yarns were knitted into a tubular fabric on a special purpose-built weft knitting machine, with 12 needles and a gauge of 14. The tubular fabrics were about 2 - 3 mm in width and could easily be dressed onto a 4 mm (diameter) round glass mandrel due to their excellent elasticity.

Sample preparation

A certain amount of polyurethane (PU) and DMF were fully mixed together in a clean beaker and stirred in a rockered flask until a transparent and homogeneous solution was obtained. The flask was vacuumed to remove any bubbles in the PU solution. In this experiment, a homogeneous solution containing 10% PU was prepared.

Pure PU vascular grafts were prepared based on a reported method [35]. To prepare the composite vascular grafts, the weft-knitted tubular fabrics were first dressed onto glass mandrels of different diameter (from 4 mm to 8 mm). The mandrels were then immersed in the prepared

PU/DMF solution for 30 minutes to allow the PU to fully impregnate the fabrics. The impregnated fabric/mandrel assemblies were then passed through a coating mould with an appropriate alignment device to ensure uniform coating thickness on each mandrel. They were then quickly placed in a coagulating bath for about 2 to 3 h to form porous PU vascular grafts on the mandrels and subsequently soaked in distilled water twice (120 min/soak). **Figure 1** (see page 89) depicts the fabrication process for the vascular graft in the coagulation solution. The microporous and reinforced PU vascular grafts were dried in a hot-air circulating oven at 60 °C for 2 h before further testing. The dipping (coating) times were determined according to the different contents of polyurethane in the solutions. In this way, reinforced small-diameter tubular fabric vascular grafts with different inner diameters were fabricated. Glass mandrels covered with the tubular fabrics of different diameter, from 3 mm to 8 mm, are shown in **Figure 2**. As the mandrel diameter increased, the fabric became more open. The final samples fabricated with different diameters are depicted in **Figure 2**.

Test method

The compliance of the vascular grafts in the radius direction was tested using the method shown in **Figure 3**. The width of the vascular graft was 5 mm; the diameter and thickness of the sample varied according to the diameter of the mandrel and the different coating times. The graft thickness and internal diameter were determined according to Standard ISO 7198: 1998. Tensile tests of the samples were performed on an Instron 5566 Universal Testing Machine. The width of the specimen was 10 mm and the strain rate 100 mm/min. Each group was tested 5 times, and the results were averaged. The circumferential tensile strength of each sample was determined as follows:

$$\text{Circumferential tensile strength} = \frac{T_{\max}}{2L}$$

Where T_{\max} is the maximum load, and L is the width of the specimen.

Results and discussion

Determination of the circumferential tensile strength of the pure PU vascular grafts

Pure PU grafts were prepared with different coating times in the PU solution, which was then followed by coagulation. Different tubular vascular grafts with dif-

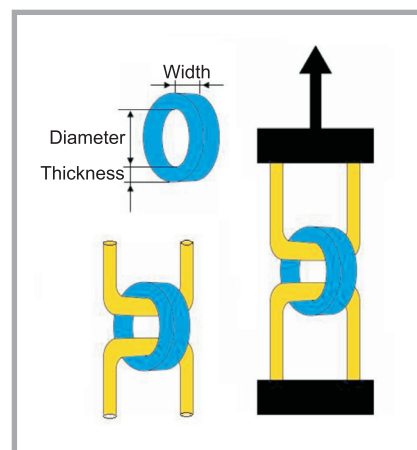


Figure 3. Method of determining the circumferential tensile strength of vascular grafts.

ferent coating times in the coagulation solution showed various thicknesses and mechanical properties. With increasing coating times the wall thickness of the PU vascular graft increased, which increased both the strength and elongation of the PU vascular grafts in the radius direction (**Figure 4**, see page 88). However, despite their excellent elasticity and blood-proof property, pure PU tubular vascular grafts are not suitable for clinical applications. The main problems we encountered were (a) large holes appearing near the sutures because of the low shear resistance when the wall of the pure PP vascular graft was thin, and modification of the polyurethane to improve its shear resistance usually leads to reduced elasticity; (b) the self-supporting property of the tubular PU graft was not satisfactory, especially when the wall thickness was thin; the vascular graft often collapsed into a flat ribbon shape.

Comparison of the vascular grafts made from PU and reinforced elastic fabric PU

As mentioned above, pure PU vascular grafts usually show low strength but excellent extension and flexibility, and their blood-proof property is better than that of weft knitted or woven vascular grafts because their microporous distribution and porous size can be controlled. Knitted tubular fabric shows excellent mechanical properties, especially when the fabric is knitted from polyester and spandex blend yarn. What is more, the elastic property can be greatly improved, but their holes are usually larger than what we hope for. The strength and elongation of pure PU vascular grafts with an inner diameter of 4 mm is shown in **Figure 5** (see page 88). Test results for the weft knitted tubular

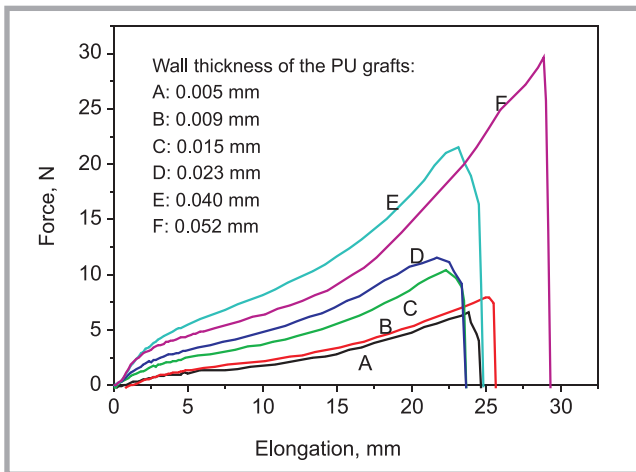


Figure 4. Circumferential tensile strength of pure PU vascular grafts of 4 mm inner diameter and different wall thickness.

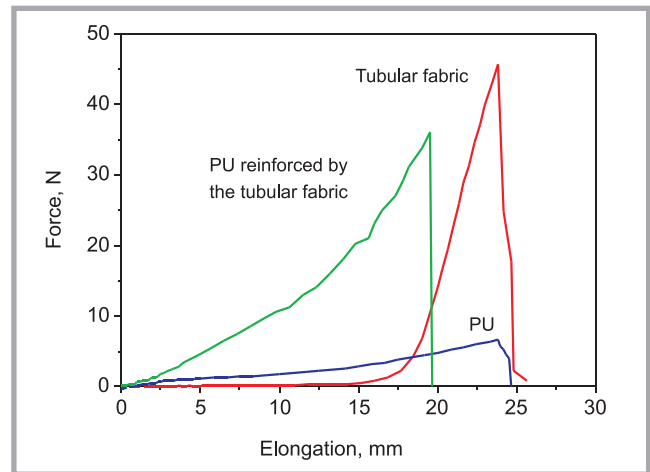


Figure 5. Circumferential tensile strength of tubular fabric, pure PU and a composite PU vascular graft reinforced with tubular fabric.

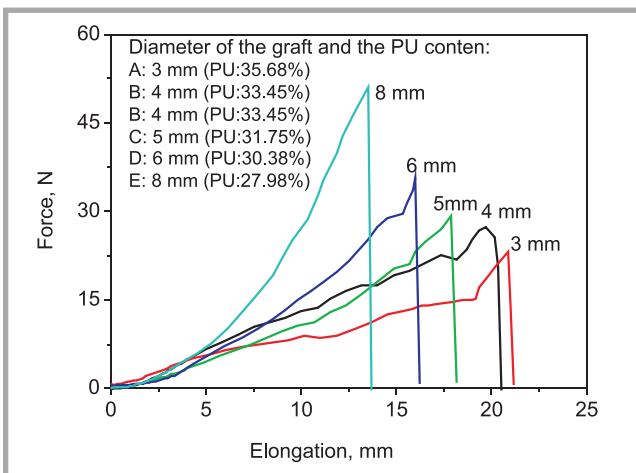


Figure 6. Circumferential tensile strength of vascular grafts of various diameter reinforced with the fabric and coated with a layer of PU.

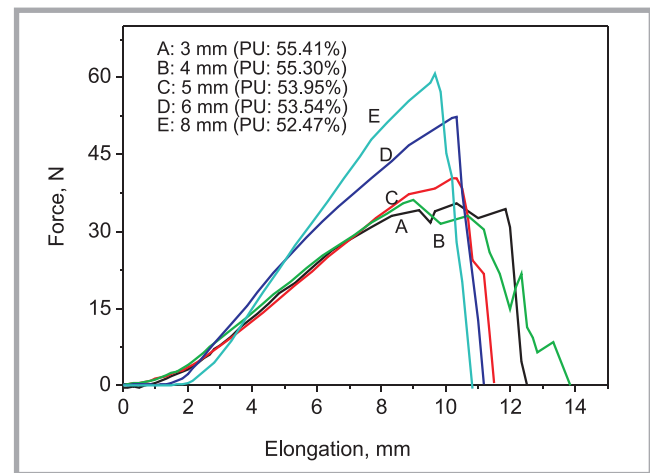


Figure 8. A mandrel coated with weft knitted elastic tubular fabric 3 times.

fabric are also shown in the figure; their mechanical properties are very different in the radius direction, and the strength of tubular fabric is almost 8 times that of a pure PU graft. However, the initial modulus of tubular fabric is lower

than that of a pure PU graft. The composite PU vascular graft reinforced by tubular fabric showed relatively higher strength than the pure PU graft and tubular fabric, which is depicted in **Figure 5**. Meanwhile, a relatively high elongation

remained due to their elasticity. Most importantly, their dimensional stability was greatly improved. The weft knitted tubular fabric often collapsed into a flat ribbon shape; the pure PU vascular graft with a thin wall thickness also showed this tendency. A steady round shape in the circumference is very important for a vascular graft.

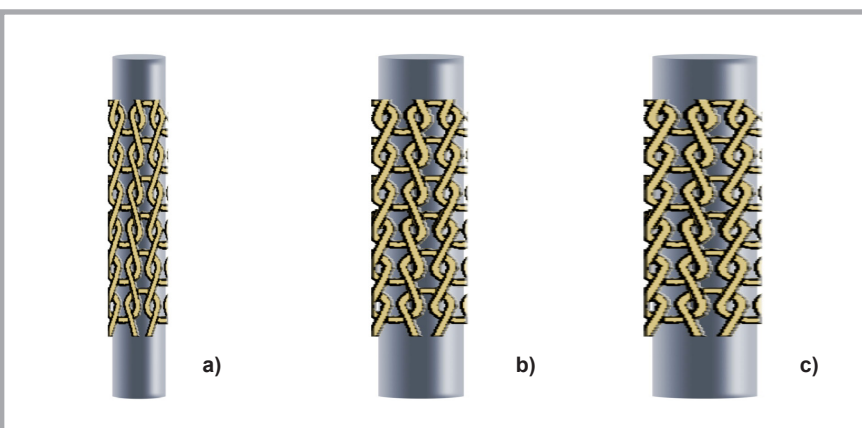


Figure 7. Circumferential tensile strength of vascular grafts of various diameter reinforced with the fabric and coated with 3 layers of PU; a) Small diameter, b) Medial diameter, c) Large diameter.

Determination of the circumferential tensile strength of vascular grafts with various diameters reinforced by the same tubular fabric

The same tubular fabrics were dressed onto glass mandrels of different diameter to produce reinforced PU vascular grafts in the solution, the tensile curves of which are shown in **Figure 6**. Because the fabrics were the same, increasing the mandrel diameter increased the fabric openness, as shown in **Figure 2**. This would increase the strength and initial modulus of the reinforced vascular

Table 1. Results showing the effect of coating times on the properties of composite vascular grafts of 4 mm inner diameter.

Times of coating	Thickness of wall	PU content, %	Breaking extension, mm	Circumferential tensile strength, N/mm	Initial modulus, N/mm
1	0.20	33.45	20.83	1.16	4.035
2	0.25	46.65	14.83	1.55	3.395
3	0.26	55.30	10.33	1.66	4.430
4	0.27	63.05	10.83	2.02	5.398
5	0.29	65.04	9.50	2.11	5.649
6	0.30	70.18	9.67	2.52	6.927

grafts in the radius direction, especially when the mandrel diameter was large (i.e. 8 mm), which was because the yarn in the loop gradually transferred from the longitudinal direction to the circumferential direction when the tubular fabric was enlarged to be more open, which is shown in **Figure 7**, thus more yarn was transferred to the circumferential direction, and the strength increased.

With increasing coating times, the strength of the composite grafts increased, but the differences caused by the variable mandrel diameters were reduced (**Figure 8**). **Table 1** lists the results for how the coating times affect the graft wall thickness, PU content, and tensile properties of composite grafts of 4 mm inner diameter.

Conclusions

New composite vascular grafts of small diameter, from 3 mm to 8 mm, were developed by reinforcing Polyurethane (PU) with weft-knitted Polyester/Spandex fabrics. These composite grafts combine the good elasticity and blood-proof properties of PU with the strength and stability of a weft-knitted structure. The tensile test results in the radius direction show that reinforced vascular grafts are much stronger than pure PU grafts and reinforcing fabric itself. Weft-knitted polyester/Spandex tubular fabrics are quite elastic and can be easily expanded to fabricate composite grafts of larger inner diameter, the strength of which increases as the fabric structure becomes more open, due to the loop transferring in the fabric. But the difference caused by different inner diameters is reduced when the PU content in the composite grafts is increased. For grafts of the same inner diameter, increasing the PU content increases the thickness and strength of the graft wall, which improves the strength and initial modulus of composite vascular grafts.

Acknowledgment

This study was supported by 973 project (No. 2009CB526402) of China and the National Natural Science Foundation of China (No. 50873079).

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Received 28.02.2008 Reviewed 17.06.2009