

TEXTILE PROSTHESES FOR VASCULAR APPLICATIONS

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Abstract

Strain energy method and Castigliano's theorem were applied for modeling. Agreement between the values of Young's modulus of textile stents derived by the strain energy method to those of the experimental is good. Braid structural parameters, i.e., length and width of each diamond trellis, total number of diamond trellises, length of fabric braided in one carrier rotation, and braid inclination angle are formulated. Load-strain curves were obtained by strip testing of textile stents on Instron. The objective of the empirical model was to formulate, quantify, and predict compression force of textile stents. The empirical model is able to predict the compression force of textile stents from any two of the known manufacturing variables. Blood flow with the stent is characterized using ANSYS.

Goal

The objective of this project is to develop a new class of implantable endoluminal prosthesis for biomedical applications based on advanced textile technology. The most likely

initial application will be in the field of arterial circulation. As a result of this project, applications of textiles in medical technology will be expanded.

Introduction

The current study suggests the application of polyester monofilament braided structures to be used as stents, hence called textile stents. Prototypes of textile stents and bifurcated textile stents were manufactured with textile machinery [1]. Manufacturing variables namely braid angle, braid diameter, and heatset time showed statistically significant effect on the compression force of textile stents [2]. Strong correlation (*adjusted* $R^2 = 0.9999$) was observed between radial and *in vitro* (unidirectional) compressions of textile stents [3]. The objective is to predict the Young's modulus of textile stents by strain energy method. In the current study, strain energy method and Castigliano's theorem [4] were applied for modeling. The equations needed to predict the Young's modulus by strain energy method were divided into three parts: determination of structural geometry, definition of the strain energy function, and equations derived by strain energy method [5, 6]. The strain energy equations were derived from those of the plain weave [7]. Strain energy method is being used by textile researchers to understand various facets of the performance of fiber assemblies [8], fibrous composite materials [9], yarns [10], plain weave fabrics [11], and hybrid fabrics [12]. Previous braid models developed by Heirigs and Schwartz [13] and Zang *et al.* [14] provided useful guidelines in understanding the structure and properties of braids.

Young's Modulus

The Young's modulus of the textile stent was determined by the strain energy method. The resulting equation is

$$E_l = \frac{x^3 (\cos^2 \theta_1) + y^3 (\cos^2 \theta_2)}{\frac{x^3 y^3}{12B} \sin^2 \theta_1 \cos^2 \theta_2}$$

where $x = A_1PA_2$, $y = C_1PC_2$ (Figure 1)

θ_1, θ_2 : respective braid inclination angles

B: flexural rigidity of monofilaments

To calculate Young's modulus, flexural rigidity of monofilaments is necessary. Flexural rigidity is calculated by the approach proposed by Ucar [15]. Ten monofilament samples were tested for flexural rigidity. All the necessary calculations were performed with the Maple[®] software. The values of Young's modulus calculated by the strain energy (mechanical) model were compared to those obtained by strip testing (ASTM[®] D 5035-95) of textile stents on the Instron.

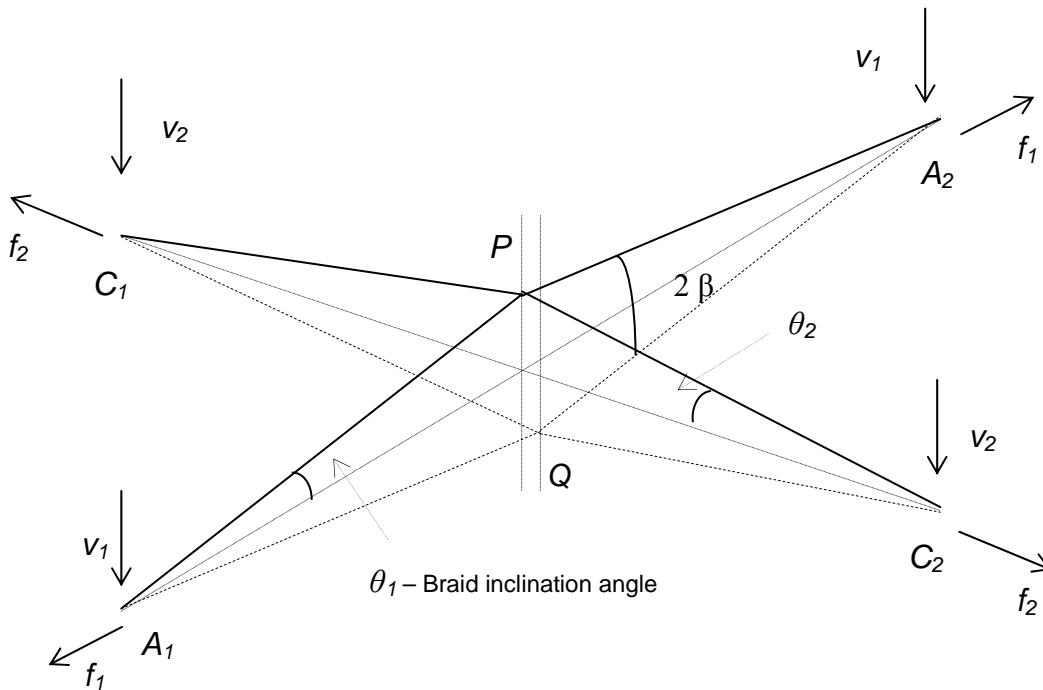


Figure 1 Monofilaments intersection as a unit of the braided structure.

Figure 2 shows the comparison of Young's moduli values. In the Figure, 60° braid angle and 60 minutes heatset textile stents were compared for their Young's modulus. The comparison showed good correlation (adjusted $R^2 = 0.7955$).

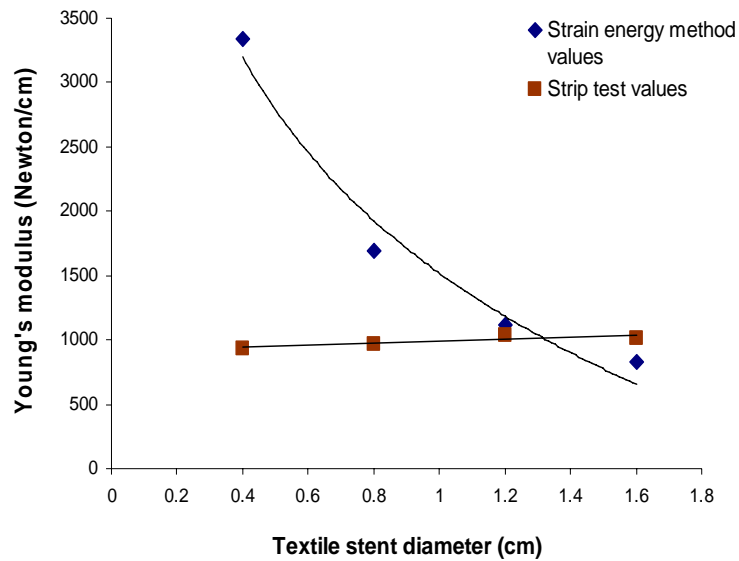


Figure 2 Comparison of Young's moduli

The strain energy (mechanical) model was based on energy stored in the system during deformation. The Young's modulus of textile stents was determined from the geometry of the structure and flexural rigidity of monofilaments. It gave similar values for textile stents of different braid angles. Also, textile stents being compared were heatset, but there was no heatset factor in the strain energy model. It was assumed that monofilaments were rigidly joined at the point of their intersection.

Figure 3 shows the load-strain curves of the textile stents. The initial region of the load-strain curve is defined as 'decrimping strain', where monofilaments were just slipping within the structure. Once the decrimping was over, textile stent started elongating. Higher diameter textile stents showed higher decrimping strain. 'Decrimping strain' was a distinguishing characteristic of the textile stents. Self-expanding textile stents need to be crimped while placing on the catheter.

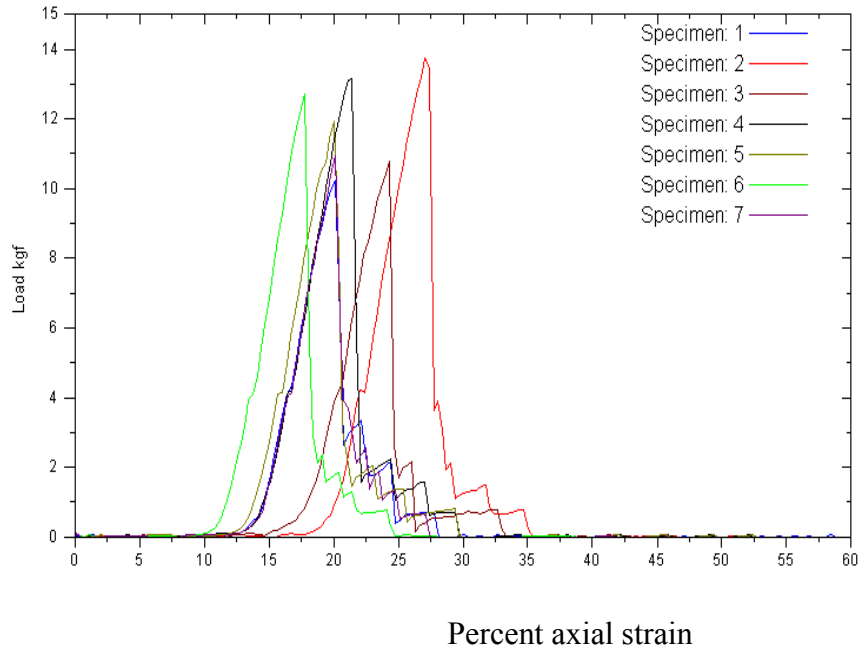


Figure 3. Load-strain curves (4 mm diameter textile stents).

Compression Force

The strain energy (mechanical) model could not quantify compression related parameters. The objective of the empirical model was to formulate, quantify, and predict the compression force of textile stents. The empirical model is able to predict compression force of textile stents from any two of the known manufacturing variables. This can become an innovative approach to formulate, quantify, as well as predict a material property from the available pool of parent data. The parent compression force data used in the empirical model were obtained by the novel compression testing of textile stents on Instron [16]. The compression force of textile stents is plotted against the heatset time in Figure 4.

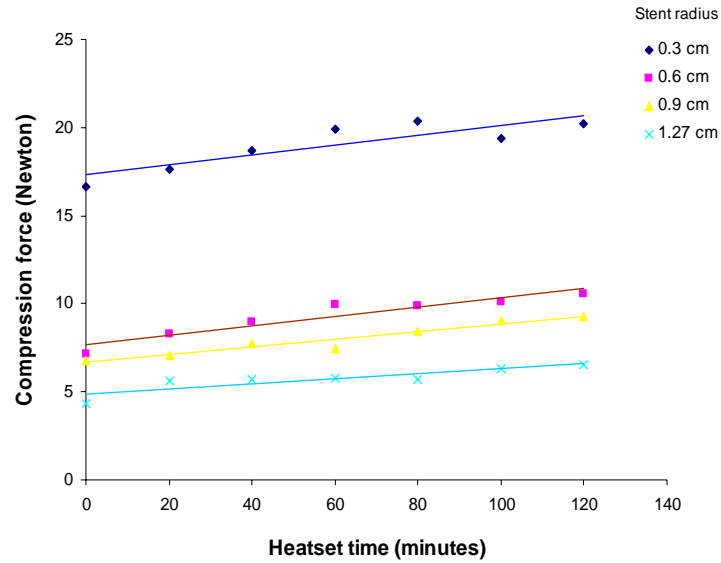


Figure 4. Trends for 60 degree braid angle textile stents.

Blood Flow Characterization: Analysis of Stent Geometry and Exit Velocity with ANSYS®

Textile stent geometry and blood flow were represented by monofilament size (denier) and blood input velocity, respectively. Five artery diameters, three monofilament sizes and three respective blood input velocities were selected for simulation experimentation. Simulation (*Fig. 5*) was done in two-dimensional module of ANSYS® Flotran. ANSYS® is a simulation driven, finite element based design development software.

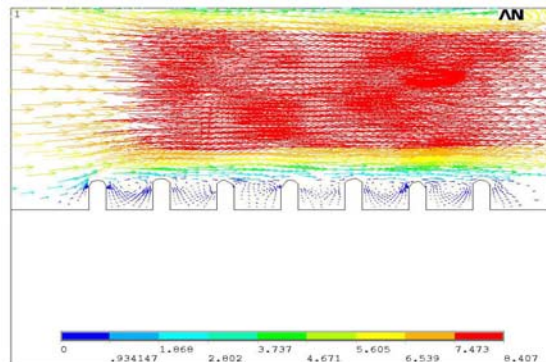


Fig. 5 Blood flow variations due to textile stent

Blood flow characterization was helpful in understanding accumulation of plaque after stent implantation known as restenosis. Implantation of textile stent produced blood flow variations. These flow variations increase ‘residing time’ of blood particles and enhance the deposition of platelets (also called as thrombocytes) in the textile stented artery segment during the acute stages of implantation and post-implantation as well.

The adhesion of platelets and other blood particles to the artery wall of the textile stented region generally leads to restenosis. Statistical analysis showed statistically significant effect of blood input velocity on exit velocity. Monofilament denier also showed statistically significant effect on exit velocity for artery diameters except 1.6 and 2.5 cm.

Our research establishes guidelines for commercial manufacturing of textile stents by prototype manufacturing, testing, as well as modeling of textile stents. We showed that, braid angle, braid diameter and heat set time of textile stents had statistically significant effects on their compression force. Our novel compression test showed strong correlation between actual (radial) and novel test (unidirectional) compression. Values of Young’s modulus calculated by the energy model showed a moderate correlation to those obtained by strip testing of textile stents on Instron machine. Blood flow characterization was helpful in understanding accumulation of plaque after stent implantation known as restenosis. Therefore, we think that textile stents have potential to replace the commercially available metal stents. We are also planning to implant textile stents in animal arteries to analyze their performance.

Conclusions

The strain energy method and Castigliano’s theorem were applied for modeling to determine modulus. Agreement between the values of Young’s modulus of textile stents derived by the strain energy method to those of the experimental was good (*adjusted R*²= 0.7955). Braid structural parameters, i.e., length and width of each diamond trellis, total number of diamond trellises, length of fabric braided in one carrier rotation, and braid inclination angle were formulated. Load-strain curves were obtained by strip testing of textile stents on Instron. The objective of the empirical model was to formulate, quantify, and predict compression force of

textile stents. The empirical model is able to predict compression force of textile stents from any two of the known manufacturing variables. The blood flow was characterized using finite element analysis.

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Patent Disclosure:

1. Adanur, S., and Irsale, S., “Polymeric Textile Prostheses for Vascular Surgery Applications”, Auburn University Technology Disclosure, 25 July 2005.

Publications:

1. Irsale, S., and Adanur, S., “Blood Flow Characterization of Polymeric Textile Stents”, submitted to the Journal of Industrial Textiles, 1 August 2006, 17 pages.
2. Adanur, S., and Irsale, S., “Modeling Polymeric Textile Stents: Predicting Young’s Modulus and Compression Force”, submitted to the Journal of Industrial Textiles, 1 August 2006, 23 pages.
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Oral Presentations:

1. *Irsale, S.*, and Adanur, S., “Exporing Textile Stents: Prototyping and Modeling”, Fiber Society Spring 2005 Conference, May 25-27, 2005, St. Gallen, Switzerland.
2. *Irsale, S.*, and Adanur, S., “Compression Force Modeling of Braided Textile Stents”, SECTAM XXII, 22nd Southeastern Conference on Theoretical and Applied Mechanics, August 15-17, 2004, Tuskegee, AL.
3. *Irsale, S.*, and Adanur, S., “Monofilament Yarns in Braided Vascular Prostheses”, TechTextil Symposium North America, Atlanta, GA, March 30-April 1, 2004.
4. Irsale, S., “Prototype Manufacturing of Textile Stents”, Auburn University Graduate Research Forum, Auburn, AL, (March 4, 2004).
5. Irsale, S., “Textile Prosthesis for Vascular Applications”, Six State Graduate Student Consortium- Florida State University, Tallahassee- FL, (April 15, 2004).

Industrial Contacts:

Sonobond Ultrasonics, Sonitek Corporation, Dukane Intelligent Assembly Solutions, Branson Ultrasonics Corp., and various medical technology companies.

Since the Inception of the Project:

Graduate students involved in the project: 3
No. of undergraduate students involved in the project: 4
No. of thesis completed: 2
No. of oral presentations: 5
No. of poster sessions: 5
No. of publications: 6
No. of notices of invention: 1

Project Web Address:

<http://www.eng.auburn.edu/department/te/ntc/2006/F03AE02.pdf>

For Further Information:

1. S. Adanur and S. Irsale, *Design and Characterization of Polymeric Stents*, J. Industrial Textiles, 35(3), 189-200 (2006).
2. S. Irsale, *Textile Prosthesis for Vascular Applications*, MS Thesis, Auburn University (2004).
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5. S. Adanur, and S. Irsale, *Polymeric Textile Prosthesis for Vascular Surgery Applications*, United States Provisional Patent Application # 60/701,927.

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