

ANALYSIS OF ELASTIC DEFORMATION OF BRAIDED TUBULAR STRUCTURES FOR MEDICAL APPLICATIONS

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Geliş Tarihi : 20.12.2000

ABSTRACT

In this study, self-expanding stents were fabricated and analyzed. These stents are in the form of 3-D tubular braided structures made of polymeric materials. This type of structures is used in medicine to open clogged artheries and veins by exerting radial force. The amount of radial force exerted into the membrane should not give any damage to the veins. Therefore, the geometry of the three dimensional tubular braided fabric is analyzed to give an optimum radial force for medical applications.

Key Words : Braided structures, Medical textiles, Stents, Heat setting

TIBBİ UYGULAMALAR İÇİN BORU ŞEKLİNDEKİ SAÇ ÖRGÜLERİNİN ELASTİK DEFORMASYONUNUN İNCELENMESİ

ÖZET

Bu çalışmada kendinden uzamalı katedırlar üretilip analiz edilmiştir. Katedırlar üç boyutlu saç örgüsü yapısında olup, polimer yada metal malzemeden imal edilirler. Bu tip yapılar tıbbi alanda tıkanmış olan atardamarların açılmasında merkezden dışa dogru bir kuvvet uygulanması prensibine göre kullanılır. Katedır tarafından damar çeperlerine uygulanan kuvvetin damarlara bir zarar vermeyecek miktarda olması zaruridir. Bundan dolayı, bu tür üç boyutlu hortumsal saç örgülerin yapısı tıbbi uygulamalar için optimum radial kuvvet elde edilebilmesi için incelenmiştir.

Anahtar Kelimeler : Saç örgüler, Tıbbi tekstiller, Katedırlar, Isıl işlemler

1. INTRODUCTION

The braiding method is widely used to make tubular structures. Tubular structures (Figure 1) are extensively used in many applications including medical textiles. In medical applications, braided structures, called stents, have been used inside the cylindrical passages of the body. These kinds of stents can be made of either metal or plastic, and usually they are known as self-expanding stents. The self-expanding stent is an implantable intraluminal device which is particularly useful for repairing or serving as a conduit for blood vessels narrowed or occluded by diseases or for the use in other body passageways needing reinforcement (Schmitt, 1992; Paris et all., 1994). For metal stent, the geometrical relations among the variables were given by Jedwab and Clerc (1992).

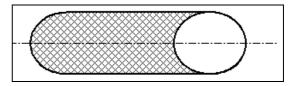


Figure 1. Schematic of braided tubular structure

Although metal stents have some advantages such as being biocompatible, the ratio of self-expansion to the initial diameter is very limited. Therefore, polymeric materials may be preferred. Polymeric materials also have good long-term stability inside the body. The properties of materials used directly affect the behavior of the braided tubular fabric. The main purpose of this work is to investigate the feasibility of producing an ideal tubular braiding structure from polymer. Polyester is used for this purpose because of its biocompatibility and longterm stability (Wahl, 1963).

The literature of braided fabric is relatively scarce although braiding is an old technique. One reason for this may be the limited application of braided fabrics in traditional textiles compared to woven or knitted structures. In technical and industrial applications, braided fabric use is relatively wider.

Several authors studied the mechanical properties and the basic model of braided fabric structures. Ko et all. (1976) provided a mechanical model of the braided fabrics by means of a repeated unit cell. The crimp effects and the calculation of the braid geometry were studied by Goff (1976). The effects of mandrel diameter in fabric braiding were investigated by Du and Popper (1990). The maximum crimp is reported to exist when the braiding angle is 45° and helical length is maximum (Goff, 1976; Du and Popper, 1990; Paris et all., 1994).

The geometry of braided fabric is characterized by many variables including yarn-bending stiffness. In this work, the radial force of the braided tube is considered in relation to the diameter of the monofilament yarns. The relations among braid angle, helical length, braid diameter, and elastic radial force are developed. Braided tubular structures that are to be used as stents should have a high elastic radial force. The braided tube used in this work is represented as a number of interlaced helical springs that behave so as to impose an outward radial force on the surrounding cylindrical passage as shown in Figure 2. When an axial tensile (or a radial compressive force) is applied, the stent extends in axial direction and its diameter decreases. When the axial tensile (or radial compressive force) is removed, and an axial force which is opposite to the initial tensile force, restores the force balance while radial expansion takes place. The magnitude of this radial force is affected by several variables, which are analyzed below.

2. BRAIDED STENT GEOMETRY

The geometrical structure of a braided tube before and after the application of load is shown in Figure 2 and 4. Outward radial forces are created by tubular structure expansion. The initial average and external tube diameter is related to the mandrel diameter and the yarn diameter (Figure 3).

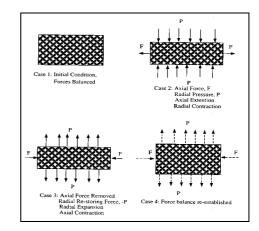


Figure 2. Structural changes in a stent under the influence of forces

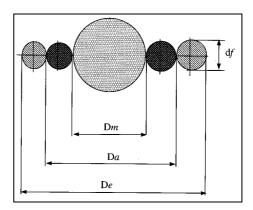


Figure 3. Cross-section of mandrel and yarn

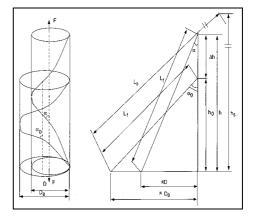


Figure 4. Geometry of braided tube before and after application of axial load

$$D_a = D_m + 2d_f = D_e - 2d_f \tag{1}$$

where Da is the average stent diameter, D_m is the mandrel diameter, D_e is the maximum external diameter, representing the outer border of the stent, and d_f is the filament diameter. Structural geometry

effects of tube expansion are depicted in Figure 4. The initial length of filament twist is given by:

$$h_{o} = \frac{\pi D_{a}}{\tan \alpha_{o}}$$
(2)

where α_o is the initial braid angle. The number of coils, n_c , is given by:

$$n_{c} = \frac{h_{s}}{h_{o}}$$
(3)

where h_s is the total length of the braided stent. The length of one filament per turn is given by:

$$L_{f} = \frac{\pi D_{a}}{\sin \alpha_{o}} .$$
(4)

After axial extension of the tube, this relationship becomes

$$L_{\rm f} = \frac{\pi D}{\sin \alpha} \tag{5}$$

where D and α are the new stent average diameter and braid angle, respectively. Under the action of an axial load F, the length of the braided tube increases as its diameter decreases. Coil length remains constant before and after applying load F. This assumption is true given that there is no extension in the filament length. Therefore, the new diameter of the stent is given by :

$$D = D_a \frac{\sin \alpha}{\sin \alpha_0}$$
(6)

Extension in stent length, Δh , is given by

$$\Delta h = \frac{\pi D_a}{\sin \alpha_o} (\cos \alpha - \cos \alpha_o) \tag{7}$$

and the length of one twist after applying the load is given by:

$$\mathbf{h} = \mathbf{h}_0 + \Delta \mathbf{h} \tag{8}$$

After applying the force F, the total stent length is given by :

$$h_s = n_c (h + \Delta h) \tag{9}$$

The total filament length, L_t , employed in the stent is given by:

 $L_t = n_c n_f L_f \tag{10}$

Where n_f is the number of filaments. The surface area of the braided tube is πDL . Although enclosed area of the structure is normally defined as the product of total filament length and filament diameter, the cover is reduced by the area of each intersection. This intersection area is given by (Jedwab and Clerc, 1992):

$$\frac{d_{\rm f}^2}{\sin(2\alpha)} \tag{11}$$

The number of intersections N_I in a given braided tube is found by dividing the stent into transverse slices such that each slice contains $n_f / 2$ intersections. The axial distance L_a is given by:

$$L_a = \frac{2\pi D \tan \alpha}{n_f} \,. \tag{12}$$

From Equation 11, the total area of the intersection is given by:

$$A_{\text{total}} = \frac{N_{\text{i}}d_{\text{f}}^2}{\sin(2\alpha)}$$
(13)

The percent cover factor, CF, of the braided tube is given by (Jedwab and Clerc, 1992):

$$CF = \frac{\left\lfloor L_t d_f - \left(\frac{N_i d_f^2}{\sin(2\alpha)}\right) \right\rfloor}{\pi DL} \times 100$$
(14)

Cover factor is an important factor in application of stents for support of the arthery walls to prevent bulging. In traditional textile engineering, cover factor of the fabric is a standard design parameter. The cover factor is a parameter which defines the density of the fabric, as it treats the braided fabrics as two dimensional object. Therefore, the initial development of the design uses cover factor as a primary parameter.

3. MECHANICAL PROPERTIES OF THE BRAIDED TUBE

A braided tubular structure can be considered as an open coiled helical spring with ends free to rotate. In this case the following equation can be used to determine the axial load on a braided tube (Wahl, 1963; Dieter, 1976; Jedwab and Clerc, 1992).

$$F = 2n_{f} \left[\frac{GI_{p} \sin \alpha}{C_{3}} \left(\frac{2 \cos \alpha}{C_{3}} - C_{1} \right) - \frac{EI}{\tan \alpha C_{3}} \left(\frac{2 \sin \alpha}{C_{3}} - C_{2} \right) \right] (15)$$

$$C_{1} = \frac{\cos(2\alpha_{o})}{D_{a}}, C_{2} = \frac{2 \sin^{2}(\alpha_{o})}{D_{a}}, \text{ and } C_{3} = \frac{D_{a}}{\sin(\alpha_{o})}$$

Where C_1 , C_2 and C_3 are constants depending on the initial average braided diameter, D_a , and braid angle, α_o . I and I_p are the moment and polar moment of inertia of the fiber, respectively. G is the modulus of rigidity, and E is the modulus of elasticity of braided tubes. The moment of the inertia and the rigidity modular are given by (Gere and Timoshenko, 1984):

$$I = \frac{1}{2}\pi r^4 l\rho \tag{16}$$

$$G = \frac{E}{2(1+\upsilon)} \tag{17}$$

Where r is the radius of the fiber, l is the length of the fiber, ρ is the density of the material, and v is Poisson's ratio. The relationship shows that E, G, and v are not independent elastic properties of materials. Defining the value of Poisson's ratio, v, between zero and 0.50, the value of the rigidity modulus, G, ranges from 0.33E to 0.50E. The radial load of the braided fabric is dependent upon the bending rigidity of fibers.

When a load, F, is applied to a braided fabric, the fabric diameter decreases while its length increases. To extend the length of a braided fabric by an incremental value of dh, a certain amount of energy, dW, must be applied to the braided fabric. The same amount of dimensional rearrangement occurs with a radial pressure, P, at a diameter change dD. The integrals of both longitudinal and radial change yield the amount of energy required for the dimensional change. This situation can be simply demonstrated as follows:

$$dW = \int_{L_s}^{L} Fdh$$
 (18)

$$dW = \int_{D_a}^{D} P dD$$
(19)

The deflection, dh, is the result of the radial pressure P applied to an idealized wall at the braided fabric perimeter. When an axial tensile or radial compressive force, acts on the braided tube, the length of the tube increases as the value of the tensile force or radial pressure increases. The diameter decreases as the braiding angle, α , decreases. Figure 2 illustrates four cases as follows:

Case 1 :at the initial condition, the braided tube is stable, and the total force acting to the tube is zero.

- Case 2 :then, tensile force, F, or radial pressure, P, acts to the structure. Because of the effect of forces, the structure attains a smaller diameter and increased length.
- Case 3 :when the braided tube is released, the structure begins to return its initial position because of the stored energy.
- Case 4 : at the final stage, the diameter increases as the length decreases until the structure reestablishes force balance as in the initial state.

For a braided fabric compression by a radial amount of dD / 2, Equation 18 and 19 may be rewritten as follows:

$$dW = \frac{P\pi DLdD}{2}.$$
 (20)

Then,

$$P = \frac{2F}{\pi DL} \frac{dh}{dD}.$$
 (21)

Since D is an explicit function of α ,

$$\frac{\mathrm{d}\alpha}{\mathrm{d}D} = -\frac{1}{\mathrm{C}_3 \cos\alpha} \tag{22}$$

The radial pressure, P, is given by (Jedwab and Clerc, 1992):

$$P = -\frac{2Fn_c}{DL}\tan\alpha.$$
 (23)

The magnitude of radial force is influenced by the radial stiffness of the structure. The value of the radial stiffness is a function of the number of filaments used in the braided tube, the tube diameter, and the braid angle. The properties of material such as modulus of the fiber etc., also affect the value of the radial stiffness.

4. EXPERIMENTAL

4.1. Materials

Different diameter polyester monofilament yarns were used to make tubular structures. The properties of the monofilaments are shown in Table 1. The samples were braided using 16 and 32 head braiding machines. The 32 head-braiding machine was used for 0.303-mm diameter polyester monofilaments. The mechanical and geometrical properties of the braided tubes produced are given in Table 2. It was assumed that the braid tube retains constant volume when subjected to a load; therefore, the value of the

rigidity modulus is only one-third of its modulus because the Poisson's ratio is 0.5 for constant volume deformation. The reason for heat setting is to remove internal stresses in the fabric and obtain a more stable and predictable structure. In general, heat setting is done to improve the mechanical properties of fabric structures including elastic modulus, rigidity modulus, and yield strength. Three different heat setting temperatures and heat setting times were used in the experiment. Specimens were subjected to 350, 400, 450 °F temperature levels. Heat setting times were 10, 20, 30 minutes for each level of temperature. Totally, three replicates were produced for each level of combinations. Figure 5 shows some tubular braided stents that were manufactured.

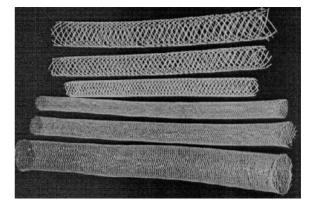


Figure 5. Some braided tubular structures manufactured for experiment

Table 1. Mechanical Properties of Monofilaments Used in the Stents

Type of Monoflament	Linear Density (Denier)	Tenacity (g/denier)	Modulus (g/denier)
Polyester (0.3-mm)	855	4.12	52.23
Polyester (0.9-mm)	2475	3.98	34.7

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Table 2. Mechanical and Geol	neurcai Fio	bernes of bra	alueu Siluc	luies				
Tube Diameter	22	2.3	27	7.0	33	3.4	4	2.3
Number of Filaments	16	32	16	32	16	32	16	32
Rigidity Modulus, G (MN/m ²)	0.27	0.16	1.16	0.33	2.52	0.37	2.96	(
Young's Modulus, E (MN/m ²)	0.82	0.35	3.49	0.98	7.55	1.12	8.89	1
Initial Braid Angle, α (Degree)	45.4	26.6	49.3	62.6	58.0	66.3	59.1	- 69

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Table 2 Mechanical and Geometrical Properties of Braided Structures

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4.2. Testing

Specimen Length (mm)

The heat-set specimens were tested using an Instron material-testing machine. For the radial pressure measurement, a compression test method was used. Samples were placed on the compression cell and a compressive force was applied until the distance between the two compression plates was reduced to 10 mm as shown in Figure 6. This method was repeated for every mandrel diameter, heat setting temperature, filament diameter, heat setting time, and number of filaments used in the braided tube. At each measurement point on the braided tube, the compression force was measured with a load cell, which is connected to the computer with a Data Acquisition (DAQ) Card.

Tensile tests were done according to ASTM test method D1775 ASTM (Anon., 1993). Braided tubes were placed in the Instron machine under no tension. Then, they were secured at both ends in the machine and stretched in the axial direction. Longitudinal force at four set points was directly obtained from the Instron using computer interface. The tensile load was applied until the diameter of the braided fabric decreased to 10 mm. Fabric extension was measured and automatically recorded by the tensile tester.

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32 0.53 1.59

69.6

254

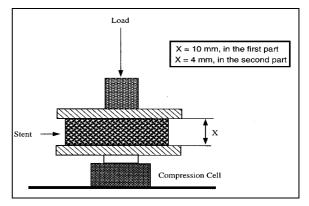


Figure 6. Schematic of compression test

5. RESULTS AND DISCUSSION

Figure 7 shows the axial tensile force as a function of stent length for several structures. As the stent length increases, the axial tensile force also increases as expected. The curves get steeper at higher stent length because more force is needed to overcome the structural resistance to extension. In other words, the longitudinal stiffness of the stent increases as the stent is stretched more. The agreement between the experimental and theoretical results is satisfactory. Equation (15) was used to calculate the theoretical data.

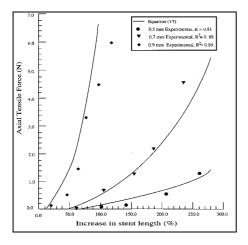


Figure 7. Theoretical and experimental axial tensile force versus stent length for various filament diameters

Figure 8 shows the relationship between radial pressure exerted by the stent as a function of stent diameter. As the stent diameter is decreased, the radial pressure increases. The radial pressure stiffness (slope of the curve) decreases with increasing stent diameter.

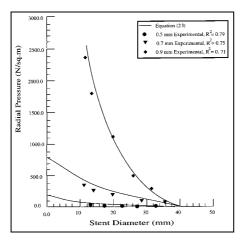


Figure 8. Theoretical and experimental radial pressure versus stent diameter for Various filament diameters

Experimental data for variation of stent diameter with stent elongation are shown in Figure 9. Assuming that the volume of the stent is constant, any increase in the stent length results in a decrease in the stent diameter. Figure 10 shows the comparison of theoretical and experimental data for a stent that is made of 0.5 mm diameter monofilament. Theoretical data is calculated using Equation (6).

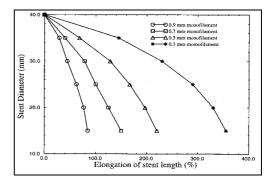


Figure 9. Variation of stent diameter with stent elongation

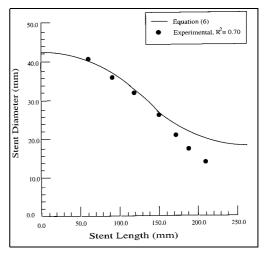


Figure 10. Comparison of theoretical and experimental data for stent length and diameter

Cover factor of stent is important for a good support of the vein walls. Braided structures are generally open structures compared to other fabric forming techniques. Figure 11 shows the experimental and theoretical percent fabric coverage as a function of stent diameter. Equation (14) was used to determine the theoretical values. As shown in the figure there is a point in each curve where the area covered by the yarns is minimum. This corresponds to the case where the yarns on the braided fabric intersect each other at or close to 90°. As the braid angle deviates from 90°, the stent diameter increases or decreases depending on the loading conditions. The extremes of these two cases are called 'jamming' conditions in which the cover factor is maximum. As expected, larger filament diameters give higher fabric coverage.

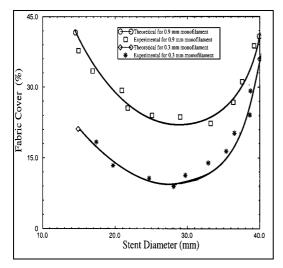


Figure 11. Effect of stent diameter on fabric cover

The results showed that the radial force and tensile force depend on the diameter of the braided tube and number of filaments used in the fabric. The stiffness of materials affects the value of the force obtained from the braided fabric as well as the static of the tube structure. The stability of the tube is high when its diameter is small. As the diameter of the braided tube increases, its stability decreases.

The tensile force increases sharply from the diameter 22.3-mm to 33.4-mm; however, this increase is very small or sometimes negative from 33.4-mm to 42.9-mm. The crimp angle influences the value of this increase for the heat-set specimens. For specimens that are not heat-set the cause of this could be unstable structure of the braided tube due to high stiffness. When minimum crimp is obtained from the tube, the value of the tensile force approaches maximum. Frictional force resists the tensile force more at high crimp level.

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The heat setting temperature and heat setting time did not have a significant effect on the tensile or compression force in the heat setting and testing range that were used. The effect of heat setting temperature and time are shown in Figures 12 and 13 for the tensile tests and in Figure 14 and 15 for the compression tests, respectively. In general, heat setting is done to improve the mechanical properties thermoplastic industrial fabric structures of including elastic modulus, rigidity modulus, and yield strength. The reason heat setting did not make a big difference in the braided tubular structures in the present work is due to the structure of the stents. They have, by design, very open and loose structures, i.e., the fabric cover factor is very low. As a result, the structures respond to the tensile and compressive forces by undergoing a purely geometrical deformation rather than showing a structural or material resistance. Since the structures are very open, heat-setting effects could not be seen. Another reason for the indifference to heat setting was the testing range. During both tensile and compressive testing, the structures were never loaded to the extent that the maximum geometrical deformation reached after which the stent would start showing structural and material resistance. Heat setting, however, increased the stability and handling of the stents.

The experimental design was intended as split-plot format. The effects of time, heat setting time, number of filaments, and diameter of the braided tube were analyzed. All factors were fixed. In the compression test, there were five or six replicates, while two or three replicates were used in the tensile test for each level of combination.

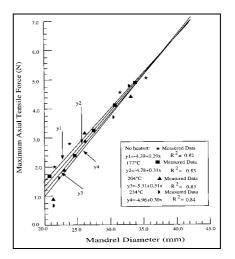


Figure 12. Effect of heat set temperature on tensile force (16 monofilaments, heat set time 30 min.)

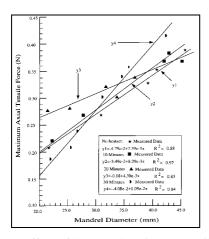


Figure 13. Effect of heat set duration on tensile force (32 yarns, heat set temperature 234 °C)

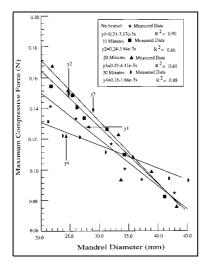


Figure 14. Effect of heat set duration on compressive force (32 yarns, heat set temperature 234 °C)

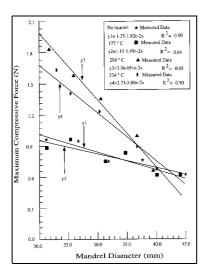


Figure 15. Effect of heat set temperature on compressive force (16 monofilaments, heat set time 30 min.)

To calculate F-null values, residual analysis (Montgomery, 1991) technique was used. SAS statistical package program was employed to analyze the data observed from the heat setting experiment. Some specimens were not subject to heat setting to serve as control. The number of filaments present and the diameter of the tube were significant at the 1% confidence interval both for tensile and compressive forces.

The analyses of variance tables for the tensile and compression test are shown in Table 3 and 4 respectively. Analysis of variance showed that the diameter of the braided tube and the number of the filaments used in the tube have significant effect for both compressive and tensile forces. The heat setting temperature is significant for the tensile force, but it does not have any effect in the compression force. Since the main effect of temperature is insignificant, two-way interactions containing the temperature are also insignificant. The rest of the two-way interactions show a significant effect. Three-way interactions are not significant with the exception of time-number-of-mono-filament-diameter for the tensile force.

Table 3. Analysis of Variance Table (ANOVA) for Compression Tests

Sources	<u>D</u> F	Sum of	Mean	F Values	$\underline{Pr} \ge \underline{F}$
	_	Squares	Squares		
TOTAL	71	18.953299	-	-	•
TEMP	2	0.279211	0.139606	3.80	0.0525
TIME	2	0.018036	0.009018	0.25	0.7859
TEMP*TIME	4	0.516689	0.129172	3.52	0.0402
FIL	1	11.608168	11.608168	316.37	0.0001
TEMP*FIL	2	0.208078	0.104039	2.84	0.0981
TIME*FIL	2	0.022103	0.011051	0.30	0.7454
TEMP*TIME*FIL	4	0.547739	0.136935	3.73	0.0339
DIAM	3	1.679271	0.559757	15.26	0.0002
TEMP*DIAM	6	0.515700	0.085950	2.34	0.0988
TIME*DIAM	6	0.441508	0.073585	2.01	0.1436
FIL*DIAM	3	1.260126	0.420042	11.45	0.0008
TEMP*TIME*DIAM	[]2	0.421533	0.035128	0.96	0.5295
TEMP*FIL*DIAM	6	0.547544	0.091257	2.49	0.0845
TIME*FIL*DIAM	6	0.447286	0.074548	2.03	0.1394
ERROR	12	0.440306	0.036692		-

Table 4. Analysis of Variance Table (ANOVA) for Tensile Tests

Sources	<u>DF</u> *	Sum of	Mean	<u>F</u> Values	<u>Pr≥</u> F
		Squares	Squares		
TOTAL	71	565.615202		-	·
TEMP	2	0.05221	0.02611	2.69	0.1084
TIME	2	0.29429	0.14714	15.16	0.0005
TEMP*TIME	4	0.06862	0.01716	1.77	0.2002
FIL	1	300.98311	300.98311	31006.99	0.0001
TEMP*FIL	2	0.02013	0.01007	1.04	0.3842
TIME*FIL	2	0.25907	0.12954	13.34	0.0009
TEMP*TIME*FIL	4	0.05552	0.01388	1.43	0.2833
DIAM	3	135.04879	45.01626	4637.53	0.0001
TEMP*DIAM	6	0.14974	0.02496	2.57	0.0773
TIME*DIAM	6	1.34020	0.22337	23.01	0.0001
FIL*DIAM	3	125.61464	41.87155	4313.57	0.0001
TEMP*TIME*DIAM	112	0.12642	0.01054	1.09	0.4448
TEMP*FIL*DIAM	6	0.13280	0.02213	2.28	0.1057
TIME*FIL*DIAM	6	1.35319	0.22553	23.23	0.0001
ERROR	12	0.116472	0.009706	•	-
	um of S	quares DF = 1	Degree of Freedor	n	

6. CONCLUSIONS

Several tubular braided structures were manufactured which could potentially be used in medical applications. The stent structures were analyzed both experimentally and theoretically to investigate the relationships among the polymeric stent structural parameters that are critical in end-use applications.

The results showed that the diameter of the braided tube and the number of filaments with its diameter have significant effect on the force measured from the braided tube. The stent diameter decreases with increasing the stent length. As the stent diameter is increased, the axial tensile force increases and radial pressure decreases. Heat setting temperature and duration did not have a significant effect on the mechanical properties of the stents made of thermoplastic polymeric materials.

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