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Development of weft-knitted and braided polypropylene stents for arterial implant

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Textile biomedical materials have been used for various applications contributing considerably in improving quality of life. The current study aims at improving polypropylene fibre stents which may replace metallic ones. In order to produce the stents, weft-knitting and braiding technologies were used. In the braiding technique, by varying the take-up ratio (using gears with the appropriate number of teeth in the braiding machine), it was possible to manufacture regular braids with angles of 65°, 70° and 75° in order to obtain different covers. In the knitting technique, a circular machine was used and the tightness of the structure was adjusted by varying the loop length and thus the fabric loop density, resulting in variations of the sample diameter. The knitting machine had negative feed, and so loop length variations were achieved by varying the yarn input tension, the stitch cam settings and the fabric take-down tension. The samples were heat set. Yarns were contracted by setting at 130°C and 140°C, and this led to increasing the loop density and the flexural rigidity of the samples. A high cover of the samples resulted in a greater stiffness of the structures. The stents were evaluated by undertaking the tests required for arterial support: rigidity to radial compression, resistance to tensile forces and bending rigidity. The best results were obtained with braided structures. Future work may concentrate in improving the stent design and using new biocompatible fibres.

Keywords: arterial; braid; implant; knit; polypropylene; stent

Introduction

Need has always been the driver of evolution and of the advancement of science. As concerns human beings and their welfare, all energies come together in order to develop efficient solutions (Hongu, Philips, & Takigami, 2005).

Coronary artery diseases (CADs) are caused by arthrosclerosis which is the gradual build-up of plaques inside the blood arteries and vessels. This condition may be treated by implanting stents in the artery through a catheter to compress the plaque and open the artery lumen for efficient flow of blood after the implant. Stents should be designed so that their properties may enable them:

(1) to be carried and placed where required in the artery;
(2) to carry out their mission of support and wall stabilisation so that the artery diameter and geometry enable adequate arterial flow; and
(3) to be compatible with the contacting tissues (San Jose, 1999).

In order to be carried to the place in the artery where the injury is, the stent must be flexible (Palmaz, 1992; Zollikofer, Antonucci, Stuckmann, Mattias, & Salomonowitz, 1992). As the objective of the stent is to keep the artery open and the blood flowing, it must also be elastic so that it may accompany the contraction and expansion of the arteries as the heart beats. The radial expansion force is the resistance of the stent to collapsing during expansion (Roubin, King III, Douglas, Lembo, & Robinson, 1990; Schatz, 1989). This is a determining factor of the capacity of the stent to keep the adequate artery geometry for the blood to flow (Rousseau et al., 1987). The flexibility and the radial elasticity of the stent depend both on the structural design and on the material used. Another important property of the stent is its fluoroscopic visibility which enables its exact detection on the harmed area of the artery. This is related to the material used to make the stent and to its dimensions. Materials such as stainless steel have a low fluoroscopic visibility. However, tantalum has a good fluoroscopic visibility due to its radio opacity (Schatz, 1989). If the stent is too small its fluoroscopic visibility is also poor (Zollikofer et al., 1992). Last but not least the stent must be able to be sterilised to avoid being contaminated by bacteria (de Araujo, Fangueiro, & Hong, 2001).

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Textile endovascular prosthetic devices are defined as the textile biomaterial structures implanted inside arteries to keep their lumen open (Irsale & Adanur, 2006).

A textile stent must therefore meet the following requirements:

(1) lengthwise flexibility;
(2) high radial expansion force;
(3) high elastic recovery after radial expansion;
(4) resistance to corrosion;
(5) good fluoroscopic visibility; and
(6) high biocompatibility (San Jose, 1999).

Biocompatibility is a very important requirement for the successful use of this type of medical device. Any biomedical material must be biocompatible, i.e. it should not influence the organism negatively (it should not be toxic or induce immune responses) and it should not be affected by its surrounding environment when performing a particular task (Anand, 2005; de Araujo et al., 2001). The performance of a textile stent will depend on its interaction with the human cells and fluids. This must be excellent in order to minimise the occurrence of thrombosis (formation of blood clots) and the growth of muscular tissue inside the artery, both leading to the blocking of the artery or restenosis (San Jose, 1999). The parameters used to test biocompatibility include: toxicity, blood clotting, haemolysis, teratogenic, mutagenesis, cancerigenic and infection (Anand, 2005; de Araujo et al., 2001).

Various developments are currently taking place in order to create a stent that minimises the occurrence of restenosis. This is quite a frequent problem with metallic implants, and improvements may occur by applying textile materials over the metallic stent (hybrid stent) or by the application of special substances over the metallic structure (Irsale, 2005). The fibre mostly used for covering metallic stents is polyester. Other advancements have consisted in impregnating the metallic stent with anti blood-clotting substances (San Jose, 1999). The results so far have proven that occurrence of restenosis may be reduced by covering metallic stents with textile fibres. This is the main push for the development of the 100% textile stent.

The most up-to-date stents are therefore textile devices which can be designed with improved properties comparatively to the metallic ones. Both braided and knitted textile stents may be easily compressed, in which case the artery will close and this may ultimately lead to a heart attack, stent migration or other complications (Irsale & Adanur, 2006).

The flexibility of a stent is one of the most important characteristics, as without this property it may not be possible to reach the harmed part of the artery (Palmaz, 1992; Zollikofer et al., 1992). However, to obtain the ideal flexibility of the stent, the radial compression force may be compromised. This latter property refers to the resistance to collapse when the stent expands (Roubin et al., 1990; Schatz, 1989) and defines the stent's capability to maintain the lumen geometry (Rousseau et al., 1987).

Another critical property of the stent is its biocompatibility which has to be very high to minimise the risk of thrombosis or a neointimal proliferative response (San Jose, 1999), as pointed out earlier.

The current study concerns the development of 100% textile stents to replace commercially available metal and hybrid ones. This will be done by prototyping and testing in order to obtain a textile stent which is less evasive to the human body and is of commercial interest.

An interesting fibre to conduct this work would have been polydioxanone (PDS) but it is an expensive fibre and so it was decided to substitute it by polypropylene (PP) which has similar physical properties and has had excellent results in medical applications without any known counter indications. Polypropylene is effective, readily available, versatile and cheap. The use of monofilament will enable a greater stiffness and better results when the stent is subjected to compression, tensile and bending forces as these will be directly directly borne by the yarn (Tan, Bell, Dowling, & Dart, 2003; Wishman & Hagler, 1998).

Experimental

The endovascular implants reported in the literature are made up either of metal or a combination of metal and a textile material.

The present study (Freitas, 2007) concentrates on the development of prototype endovascular stents totally made up of textile materials. The two types of polymeric textile stents developed were made of a tubular narrow structure manufactured either by braiding or knitting.

Materials

The yarns selected were PP monofilaments of the following diameters: 0.15, 0.20 and 0.25 mm. The braided structures were manufactured on a circular braiding machine with 16 spools. A regular braid structure was chosen with varying braid angles of 65°, 70° and 75°. This was achieved by varying the fabric take-up speed relatively to the spools carrier speed by using gears with the appropriate number of teeth. In this way, it was possible to alter the number of picks/cm and hence the tube dimensions and fabric cover or tightness of construction.

The knitted structures were produced on a circular knitting machine with 14 needles. A plain knit structure was chosen and loop length alterations were achieved by varying the yarn input tension, the stitch cam settings and the fabric take-down tension. In this way, it was possible to alter the number of loops/cm^2 and hence the tube dimensions and fabric cover or tightness of construction.

The specifications of the samples – developed after dry relaxation for 24 hours in a standard atmosphere – are shown in Tables 1 and 2. One hundred and sixty-two samples were made, half of which were heat set at 130°C and the other half at 140°C for improving their dimensional stability and this led to fabric shrinkage and increased fabric cover. This was due to an increase in yarn diameter, which resulted in an increase in the number of loops/cm^2 (knitted samples) and in an increase in the braid angle (braded samples). Figure 1 shows some of the samples which were manufactured.

Test methods

The stents were evaluated by undertaking the tests required for arterial support, i.e. rigidity to radial compression, resistance to tensile forces and bending rigidity. All tests were performed on the samples after heat setting at 130°C and 140°C.

Radial compression test

Figure 2(a) shows the set-up for the radial compression test which took place in a Radial Compression Tester (Dayuan, model Y6061, Laizhou Electron Instrument Co. Ltd.). In this test, samples of a length of 6 cm are placed in a plate which is lifted against a finger with a sensor. A compression force is applied to the middle of the sample tube and L′ is recorded. This is repeated for three consecutive times at 5 seconds intervals. The force applied must compress the tube to half of its diameter. The test procedure was undertaken in three samples for each fabric code. The elastic recovery ER (%) to compression is calculated by using the following equation:

$$\mathrm{ER}(\%) = \frac{L_1 - L_0 - L'}{L_1 - L_0} \times 100 \quad (1)$$

where ER = elastic recovery (%); L = initial distance (cm) between the sensor and half the diameter of the stent which is placed on the plate before lifting; L_0 =

Table 1. Dimensional properties of the plain knit structures after dry relaxation.

Fabric code	Yarn diameter (mm)	Yarn linear density (tex)	Fabric tube diameter (mm)	Stitch density (loops/cm^2)	Courses/cm	Wales/cm	Loop length (cm)
15Ja	0.15	17.22	7.82	33.06	5.80	5.70	0.18
15Jb	0.15	17.22	7.69	34.80	6.00	5.80	0.17
15Jc	0.15	17.22	7.31	42.70	7.00	6.10	0.16
20Jd	0.20	28.51	10.37	17.20	4.00	4.30	0.23
20Je	0.20	28.51	10.62	15.96	3.80	4.20	0.24
20Jf	0.20	28.51	11.43	15.96	4.00	3.90	0.26
25Jg	0.25	42.83	10.62	16.80	4.00	4.20	0.24
25Jh	0.25	42.83	10.87	18.45	4.50	4.10	0.24
25Ji	0.25	42.83	9.10	20.58	4.20	4.90	0.20

Table 2. Dimensional properties of the braid structures after dry relaxation.

Fabric code	Yarn diameter (mm)	Yarn linear density (tex)	Fabric tube diameter (mm)	Picks density (picks/cm)	Braid angle (°)
15R65	0.15	17.22	7.02	09.70	65
15R70	0.15	17.22	7.20	12.20	70
15R75	0.15	17.22	7.24	17.30	75
20R65	0.20	28.51	7.16	07.40	65
20R70	0.20	28.51	7.03	10.00	70
20R75	0.20	28.51	7.37	14.90	75
25R65	0.25	42.83	7.42	09.20	65
25R70	0.25	42.83	7.47	11.40	70
25R75	0.25	42.83	7.23	12.10	75

Figure 1. Samples manufactured (knitted in the foreground and braided in the back).

intial distance (cm) between the sensor and the surface of the stent before the plate moves upwards; L' = final distance (cm) between the sensor and the surface of the stent – L_0.

Bending test at 90°

Figure 2(b) shows the set-up for the bending test. The samples were bent at 90° as shown in the figure and the initial diameter (D) (diameter before bending) in a relaxed state is compared with the diameter during bending at 90° (d). The relation $d/D \times 100$ is expressed in (%) and shows the percentage of the diameter which is not obstructed by this action. The accepted minimum value of resistance to this bending action to avoid the stent from collapsing is 75%. For each fabric code, three different samples were tested.

Tensile test

Figure 2(c) shows the set-up for the tensile test which took place in a Tensile Tester (model HD026N+, Hong Da, Nantong Hongda Experiment Instruments Co. Ltd.). In this test, samples of a length of 10 cm were clamped between the jaws of the tester at a gauge length of 6 cm. The test was performed at a speed of 100 mm/minute until rupture occurred. Both load (N) and elongation at break (mm) were recorded. For each fabric code, three different samples were tested.

Results and discussion

Radial compression properties

The results for the radial compression tests for both knitted and braided samples are shown in Table 3. The best results were obtained for the braided fabrics with a marginal increase for those heat set at 140°C. The best performer was sample 25R75 which was braided with an angle of 75°, using a 0.25 mm diameter monofilament PP yarn, heat set at 140°C. It was noticed that as the fabric cover increases the resilience of the structures also increases (de Araujo & Melo e Castro, 1987; San Jose, 1999).

Bending properties

The results for the bending tests at 90° for both knitted and braided samples are shown in Table 4. The best results were obtained for the braided fabrics with the effect of the heat setting temperature producing small and unclear differences. The best performer was sample 25R75 which was braided with an angle of 75°, using a

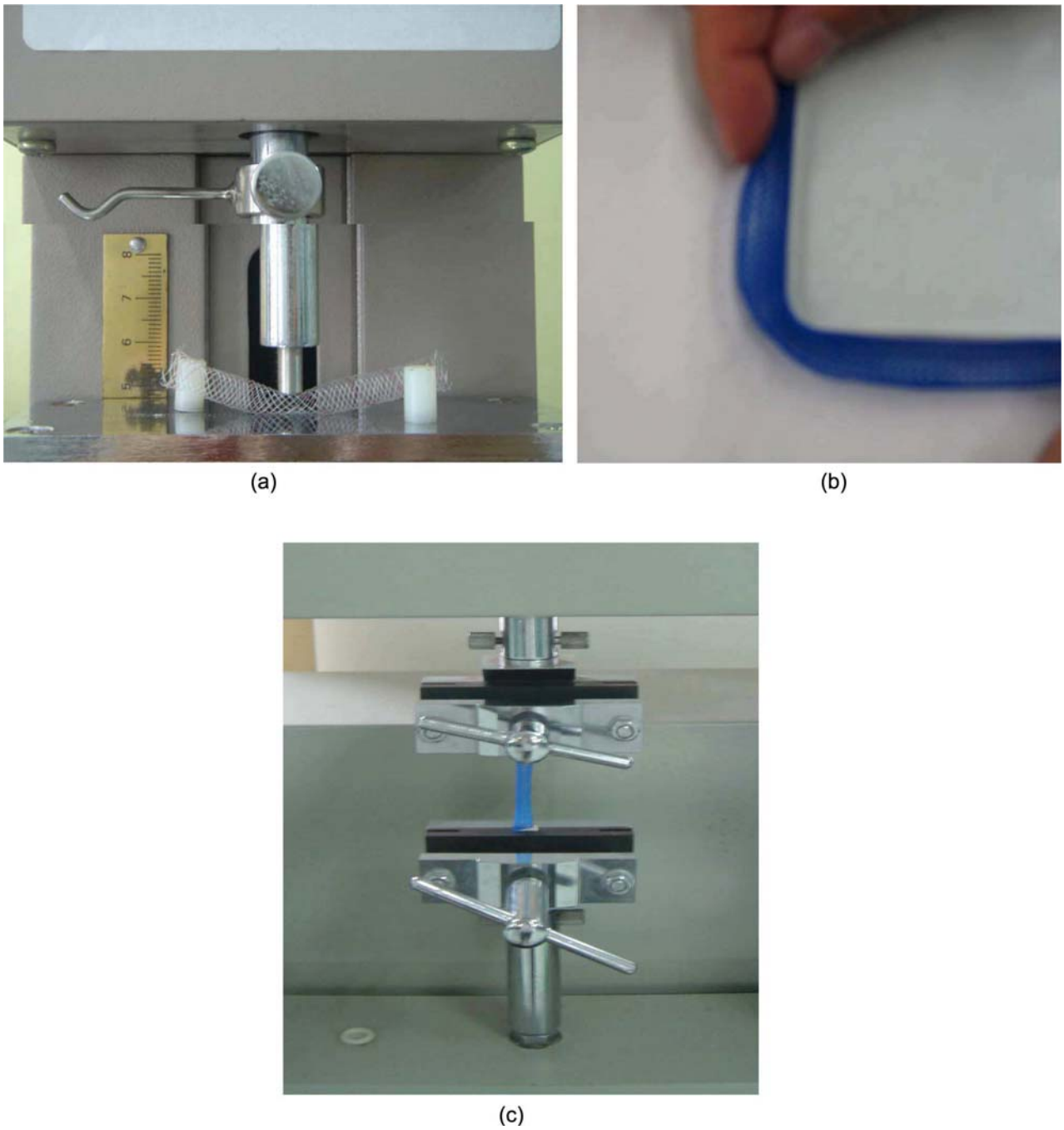

Figure 2. Stents under test: (a) radial compression test; (b) bending test at 90°; (c) tensile test.

0.25 mm diameter monofilament PP yarn, heat set at 140°C.

It was noticed that as the fabric cover increases the resilience of the structures also increases (de Araujo & Melo e Castro, 1987; San Jose, 1999).

Tensile properties

After the values obtained for elastic recovery in the radial compression test and the bending test, it was clear that the samples heat set at 140°C showed the best results. For this reason, only the tensile properties of the samples heat set at 140°C were studied. The results for the tensile tests for the knitted samples are shown in Figure 3 and for the braided samples in Figure 4.

The knitted structures produced with the thicker yarn have a greater stiffness. For the same yarn diameter the shorter loop length resulted in the stiffer structure.

The braided structures produced with the thicker yarn have a greater stiffness. For the same yarn

Table 3. Elastic recovery properties to radial compression of knitted and braided structures after heat setting at 130°C and 140°C.

Fabric code: knit	15Ja	15Jb	15Jc	20Jd	20Je	20Jf	25Jg	25Jh	25Ji
ER (%): 130°C	46.98	63.54	68.67	57.94	59.87	63.33	58.76	72.41	71.08
ER (%): 140°C	70.25	68.58	70.54	65.11	62.5	66.48	81.87	83.20	86.32
Fabric code: braid	15R65	15R70	15R75	20R65	20R70	20R75	25R65	25R70	25R75
ER (%): 130°C	85.63	88.96	90.14	91.26	91.35	92.50	92.82	93.84	94.07
ER (%): 140°C	86.14	90.76	90.85	91.58	92.23	93.35	93.49	94.58	95.27

Table 4. Recovery of the diameter of the stents after bending at 90°.

Knitted		Braided	
Fabric code	*d*/*D* (%)	Fabric code	*d*/*D* (%)
15Ja-130	62.5	15R65-130	89.4
15Ja-140	69.2	15R65-140	88.1
15Jb-130	65.2	15R70-130	87.1
15Jb-140	69.1	15R70-140	95.7
15Jc-130	70.9	15R75-130	92.1
15Jc-140	70.4	15R75-140	91.1
20Jd-130	74.0	20R65-130	94.7
20Jd-140	76.9	20R65-140	96.2
20Je-130	71.0	20R70-130	92.5
20Je-140	74.4	20R70-140	93.6
20Jf-130	74.0	20R75-130	96.1
20Jf-140	79.0	20R75-140	92.4
25Jg-130	81.5	25R65-130	94.5
25Jg-140	82.0	25R65-140	96.8
25Jh-130	79.4	25R70-130	98.6
25Jh-140	83.0	25R70-140	94.1
25Ji-130	80.0	25R75-130	97.9
25Ji-140	82.4	25R75-140	98.3

diameter, the higher the braid angle the stiffer the structure. The braided structures were considerably stiffer than the knitted structures and therefore better performers. The stiffer structure was the sample code 25R75-140 which was braided with an angle of 75°, using a 0.25 mm diameter monofilament PP yarn, heat set at 140°C.

Overall, the braided structures had better mechanical properties, i.e. higher stiffness, than the knitted ones and this was due to their structure being made up of straight yarns rather than loops. The tightness of construction increased the stiffness in all cases as more fibre per unit area is available to resist the loads.

It was observed that as the yarn diameter increased the thickness of the fabrics (stent wall) also increased. This may explain the increase in the stiffness of the stents with yarn diameter due to an increase in the thickness of the stent wall.

Conclusions

The use of 100% PP monofilament yarns for the manufacture of stents was particularly successful when the braiding technology was used.

Braided stents have shown good dimensional stability and they provide great resistance to radial compression, recovering almost 100% of their initial form.

Regarding tensile and bending properties, braided stents have shown to be stiffer than knitted ones. However, they have shown to be sufficiently flexible to give the necessary form to the arteries. CAD's treatment with surgery should be easier with these stents.

The stents with the higher cover showed the best results in both knitted and braided structures. It may be concluded that this property is most relevant for design purposes, when the objective is to supply sufficient rigidity for the best performance of the vascular endoprostheses, bearing in mind that some degree of openness of the structure is needed for the transfer of blood proteins through the arteries.

The best values of cover were achieved by increasing the heat setting temperature to 140°C. This increased the density of the structures. The samples produced with the thicker yarn diameter (diameter = 0.25 mm) were considered the best samples, particularly sample 25R75-140, which could be the most efficient in the treatment of diseases associated with the arterial system.

The present study was conducted for stents of approximately 6 mm in diameter and it is only applicable in cases where that gauge is required. Therefore, it is not possible to conclude that this type of stent may be applicable in all cases. Other studies will have to be conducted for the various gauges needed for other arteries.

In order to compare the properties and performance of textile stents with those of other types, such as metallic ones, the same working conditions and the same dimensional and physical parameters need to be evaluated and compared.

This study shows the behaviour of two distinct textile structures, opening new directions for future works in this area of biomedical textiles.

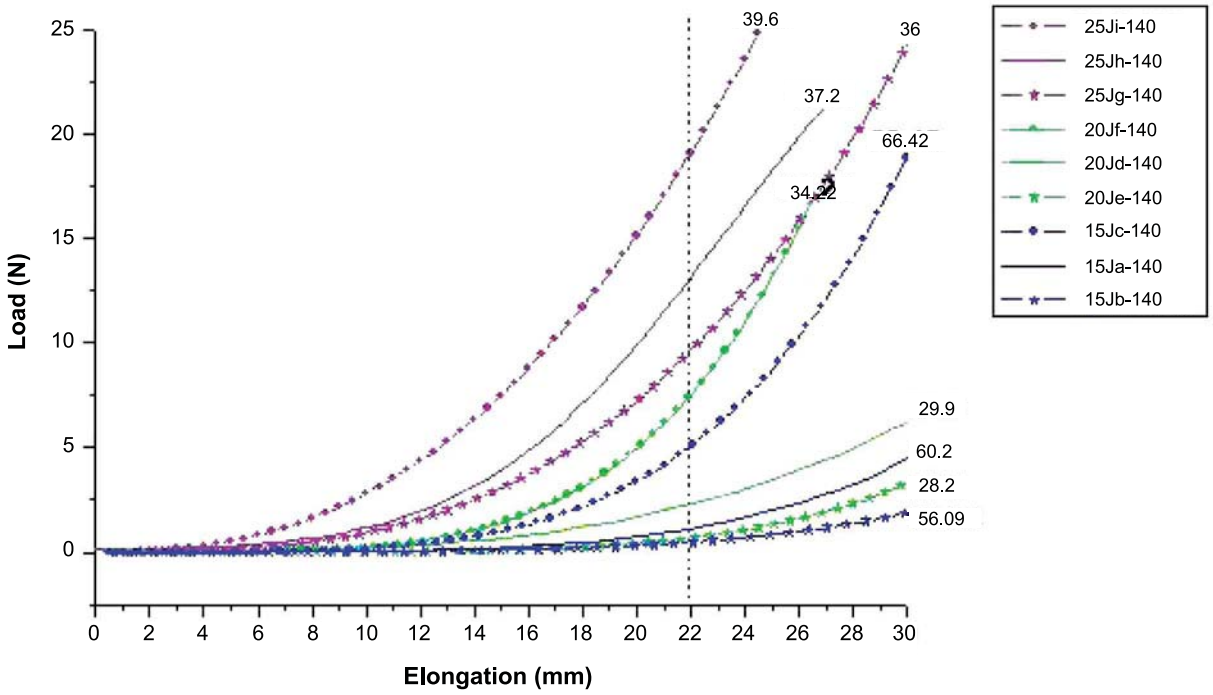

Figure 3. Initial part of the load-elongation curves of the knitted samples heat set at 140°C (vertical line helps to visualise and compare loads at a 22 mm elongation).

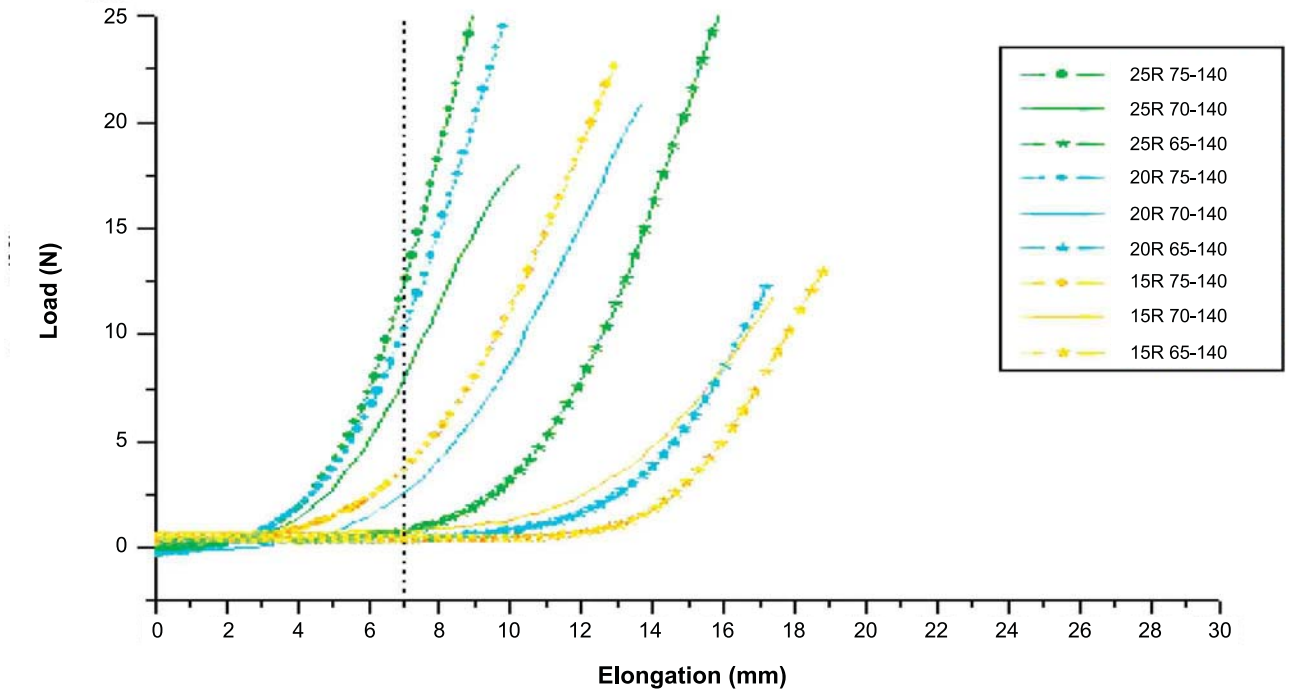

Figure 4. Initial part of the load-elongation curves of the braided samples heat set at 140°C (vertical line helps to visualise and compare loads at a 7 mm elongation).

Future work may concentrate in improving the stent design and using new biocompatible fibres.

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