A Study on The Application of Convoluted PTFE For Arterial Implantation: Mechanical Testing and Properties

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Abstract. Polytetrafluoroethylene (PTFE) is a thermoplastic polymeric material with various applications including aerospace, automotive, biomedical and electrical. PTFE surface is smooth, wear resistant, non-sticky and slippery in nature. Combined with such useful properties, the material conveys various other features such as temperature resistance up to 260ºC, exceptional chemical stability, corrosion resistance, good fatigue strength and sterilisable. This work involved mechanical testing of convoluted PTFE tubes with different thicknesses, diameters and lengths. This included the following tests: volumetric expansion, tensile and elongation, rolling u wear and burst tests by applying real industrial pressures. The mechanical testing showed promising results for the convoluted PTFE tubes which could undergo extreme elongation due to the elastic nature. The % volumetric expansion exceeded the expected values (on average, 3-5% higher than the expected values). The results for the rolling u wear, burst and tensile tests also showed good properties. Based on its mechanical properties, convoluted PTFE seemed to be an appropriate material for replacing damaged/diseased arteries.

Keywords: Convoluted PTFE tubes, mechanical properties, industrial pressures, arterial implantation

1. Introduction

Implant biomaterials have to be biocompatible with human body tissues without causing further damage to the organs and its surroundings. The manufacturing process for the production of synthetic arteries is key for successful implantation. Material selection, design functionality, mechanical and biological properties have to be investigated ensuring these implants are analysed in detail for their approval. The synthetic PTFE is manufactured via free-radical polymerisation of tetrafluoroethylene [1] whereas native arteries consist of muscular and elastic vessels which transport blood around the body via the pulses of the aortic pump [2]. These blood vessels endure high pressures and their thickness vary depending on their location. The arteries contract and relax moving blood forward under systolic and diastolic blood pressures (120 and 80 mmHg, respectively) and various velocities which have a high impact on the arterial walls. The aorta is the leading artery which branches off into several large highways, then into small arteries which are branched off into arterioles and finally into the smallest vessels known as capillaries. The capillaries deliver oxygen and nutrients to the
surrounding tissues and carry away the carbon dioxide and metabolic waste products. It follows therefore that the synthetic artery should withstand pressures of blood transportation, should not be corrosive and must be wear resistant. PTFE is an astonishing polymer with many applications within the medical field. It displays good mechanical and physical properties at temperatures as high as 540°C [1]. It is also an insoluble material in most solvents and is resistant to most acidic and corrosive environments [1] such as human body fluids. Low friction and chemical stability of PTFE are frequently used in industrial handling technology for cleansing procedures [1]. However, PTFE remains with certain disadvantages in surgical procedures mainly due to thrombosis (blood clotting which causes restriction of blood flow in artificial vessels) and anastomosis (tangling of vessels through artificial implantation). Elastic graft failure can also occur over time due to friction leading to wear causing deterioration and complete failure of the grafted vessels.

It can be argued [3, 4, 5, 6] that the most efficient polymeric materials to contribute towards complete arterial grafts are PTFE and expanded PTFE (ePTFE) due to their suitable properties. ePTFE allows extra elongation and increased burst failure modes and such properties are important when dealing with high blood pressures and abnormal flow rates [3]. The tensile loading forces are also increased due to the stretched fibrous nature of the ePTFE structure which allows failure modes to become minimal [3, 4]. However, the biological aspects of ePTFE are yet to be advanced and improved [5]. Thermal factors may not play a key role in implantation, but it is an advantageous property to have. PTFE may not have the elastic properties compared to ePTFE, but can retain its native properties which may be lost during production of ePTFE [6-11]. The reliability aspects of these polymeric materials are high and have life-long application due to their biocompatibility and this alone is a great stepping stone for future vascular implant development.

The objectives for this work were to test convoluted PTFE tubes in certain conditions which the hose may encounter in the biological environment of the human body after implantation. The standard PTFE specimens were, therefore, mechanically tested under industrial conditions and various parameters such as volumetric expansion, tensile and elongation, rolling u-wear and burst properties were evaluated and compared to other polymeric hoses to conclude which polymer could be associated with vascular implants and for future development of vascular prostheses.

2. Methodology
The convoluted PTFE samples were supplied by Aflex Hose Limited (Halifax, UK), with dimensions given in Table 1.

| Table 1. PTFE Smoothbore standard limits (Aflex Hose Limited., 2018). |
|---------------------------------|
| Bore Size (Nominal) | Bore Size (Actual) | PTFE Tube Wall Thickness | Braid Outside Diameter | Minimum Bend Radius | Maximum Working Pressure | Weight per Unit Length | ePart Number |
|---------------------|-------------------|--------------------------|------------------------|---------------------|--------------------------|------------------------|--------------|
| Half | 7/8 | 1.00 | 0.005 | 31.25 | 80 | 126 | 288 |
| 3/4 | 0.75 | 0.005 | 31.25 | 80 | 126 | 288 |
| 1/2 | 0.50 | 0.005 | 31.25 | 80 | 126 | 288 |
| 1/4 | 0.38 | 0.005 | 31.25 | 80 | 126 | 288 |
| 1/8 | 0.25 | 0.005 | 31.25 | 80 | 126 | 288 |

2.1. Volumetric Expansion Test
This test determined the % volumetric expansion for each PTFE tube using the hydraulic volumetric expansion test stand BPDV for flexible hoses according to the normal test pressures set by ISO6801 –
ASTM D380. Three samples of convoluted tubes at 1m lengths, actual bore size (diameters) of 0.25, 0.375 and 0.75 inch (=6.35, 9.53 and 19.05 mm, respectively, see Table 1) and tube wall thickness of 0.025, 0.025 and 0.03 inch (=0.63, 0.63 and 0.76 mm, respectively, see Table 1) were tested. The following steps were implemented for each volumetric expansion test:

1. An initial hydrostatic test was completed to determine the hose has no defects and does not leak.
2. A flow of water passed through the entire system and up to the graduated scale until all air had been expelled out of the system, this is achieved through the switching of the valves.
3. The graduated scale was filled to approximately a quarter and completely shut off.
4. The secondary valve was closed off to restrict any further flow of water.
5. The tube was pressurised to 4 bars.
6. The initial valve was shut off to restrict any further flow.
7. The pressurised tube was allowed to rest for 30 seconds.
8. The secondary valve opened to release the pressure into the graduated scale, and given 30 seconds to completely relax and to give the additional volume.
9. Steps 1-8 were repeated for each sample of PTFE tube.

The following formula was used to calculate the % volumetric expansion:

\[
\% \text{ volumetric expansion} = \frac{1000 \beta}{X} \times 100
\]

Where:
- \( X = \pi r^2 L \)
- \( \pi = 3.142 \)
- \( r = \) The nominal internal radius of the tube in mm
- \( L = \) The free length of the tube in mm
- \( \beta = \) The expansion in ml (\( V_2 - V_1 \))
- \( X = \) The volume of the tube bore in mm\(^3\)

2.2. Tensile Testing
Three samples of convoluted PTFE tubes with nominal length of 40 mm each and three bore size at 0.25, 0.375 and 0.75 inch were cut and tested in tension using a standard tensile test machine (LS series, Lloyd's Instruments) at a crosshead speed of 5 mm/minute.

2.3. Rolling-U Wear Test
This test was carried out in order to test the cyclic wear resistance of each tube. The tubes were aimed to achieve a minimum of 100,000 cycles without failure according to BSEN 16643. This test was completed by using 1m length samples of each tube (same bore size and thickness used in this work) connected at each end whilst bent in an inverted ‘U’ shape, i.e. a mechanism which would move in an upward and downward motion whilst the tube was pressurised.

2.4. Burst Test
This test was performed to record the pressures that each tube could withstand before failing. Each tube was pressurised until failure. This test applies constant increase in pressure inside the hose assembly until failure occurs. In this test a minimum of four times the MAWP (maximum allowable working pressure) is required for each hose to pass the burst test.

3. Results and Discussion
The calculated % volumetric expansions for the convoluted PTFE specimens are given in Tables 2, 3 and 4 for 0.25, 0.375 and 0.75 inch diameter tubes, respectively. On average, these results exceeded
the expected values by 3-5% [1, 10, 11]. The tensile testing results are shown graphically in Figures 1, 2 and 3. All three samples showed consistency with fracture forces at ~ 90N, 165N and 185N for the 0.25, 0.375 and 0.75 inch samples, respectively. The convoluted PTFE tubes also showed consistent % elongation in the range 120-150% for different hose size (see Table 5) and within the accepted limits due to the elastic nature of this material [1, 10, 11]. The burst test results are given in Table 6 with burst pressures in the range 18-34 bar and within the expected range [1, 10, 11]. The rolling-wear test results are given in Table 7 for all three bore size and did not show any failure and exceeding the expected 1000,000 cycles.

| Test Sample 1 (4 bar) | Start Water Level (ml) | Finish Water Level (ml) | Change in water level (ml) | Volumetric Expansion (%) | Average VE (%) |
|----------------------|------------------------|-------------------------|----------------------------|--------------------------|----------------|
|                      | 20                     | 18.5                    | 1.5                        | 1.9                      | 2.2            |
| Test Sample 2 (6 bar)| 20                     | 18.45                   | 1.55                       | 1.9                      | 2.2            |
| Test Sample 3 (8 bar)| 20                     | 18.55                   | 1.45                       | 1.9                      | 2.2            |

Table 2. % Volumetric Expansion for Size: 0.25”

| Test Sample 1 (4 bar) | Start Water Level (ml) | Finish Water Level (ml) | Change in water level (ml) | Volumetric Expansion (%) | Average VE (%) |
|----------------------|------------------------|-------------------------|----------------------------|--------------------------|----------------|
|                      | 20.1                   | 18.55                   | 1.45                       | 2.9                      | 3.27           |
| Test Sample 2 (6 bar)| 20.1                   | 18.45                   | 1.55                       | 3.3                      | 3.27           |
| Test Sample 3 (8 bar)| 20.1                   | 18.3                    | 1.7                        | 3.6                      | 3.27           |

Table 3. % Volumetric Expansion for Size: 0.375”

| Test Sample 1 (4 bar) | Start Water Level (ml) | Finish Water Level (ml) | Change in water level (ml) | Volumetric Expansion (%) | Average VE (%) |
|----------------------|------------------------|-------------------------|----------------------------|--------------------------|----------------|
|                      | 20                     | 18.15                   | 1.85                       | 3.8                      | 4.23           |
| Test Sample 2 (6 bar)| 20                     | 18.10                   | 1.9                        | 4.1                      | 4.23           |
| Test Sample 3 (8 bar)| 20                     | 18                      | 2                          | 4.8                      | 4.23           |

Table 4. % Volumetric Expansion for Size: 0.75”
Figure 1. Graph of applied force versus extension length for the 0.25inch test piece.

Figure 2. Graph of applied force versus extension length for the 0.375inch test piece

Figure 3. Graph of applied force versus extension length for the 0.75inch test piece
Table 5. Calculated % elongation values for different hose size

| Hose Size | Sample No. | %Elongation |
|-----------|------------|-------------|
| 1/4"      | 1          | 128         |
|           | 2          | 146         |
|           | 3          | 124         |
| 3/8"      | 1          | 130         |
|           | 2          | 129         |
|           | 3          | 130         |
| 3/4"      | 1          | 140         |
|           | 2          | 139         |
|           | 3          | 126         |

Table 6. Burst test results for different hose size.

| Hose Size | Sample No. | Burst (bar) |
|-----------|------------|-------------|
| 1/4"      | 1          | 31          |
|           | 2          | 33.2        |
|           | 3          | 32.7        |
| 3/8"      | 1          | 25.8        |
|           | 2          | 24.9        |
|           | 3          | 25.4        |
| 3/4"      | 1          | 19.7        |
|           | 2          | 19.6        |
|           | 3          | 18.9        |

Table 7. Rolling U wear test results for different hose size

| Hose Size | Sample No. | Rolling U (Cycles) |
|-----------|------------|--------------------|
| 1/4"      | 1          | 146523             |
|           | 2          | 156744             |
|           | 3          | 145685             |
| 3/8"      | 1          | 154496             |
|           | 2          | 155845             |
|           | 3          | 145628             |
| 3/4"      | 1          | 139878             |
|           | 2          | 140564             |
|           | 3          | 147596             |

The volumetric expansion test measures various types of pressures and flows through the PTFE tubes with high and low (blood) pressures commonly encountered within the human body. The convoluted PTFE tubes showed they can withstand high pressures and amongst synthetic polymers, PTFE has shown excellent flexibility and expansion characteristics [1, 7, 11]. The tubes have a rigid outer lining and able to bend easily and become more flexible. This can be a good vascular substitute as flexibility will play a main factor allowing the tube to move freely and in contact with its surrounding tissues and organs.

Compared to ePTFE, polyurethane and polyethylene terephthalate, PTFE meets all the correct requirements for vascular implantation [3, 6, 7,10]. The diameter of the capillary is notably smaller.
compared to the diameter of an arteriole, and there are vastly more capillaries in the body than there are other forms of blood vessels. Vasodilation and vasoconstriction of the arterioles have key roles in controlling the blood pressure compared to the other blood vessels. The bore sizes of the tubes tested in this work are not the specific size of arteries, arterioles and veins, however, the results obtained met the expectations. The aorta is one of the largest blood vessels in the human body and withstands extreme pressures as it is the closest vessel to the aortic pump. The pressures and forces of the blood flow will be much higher compared to the flow in the vessels further away from the heart. Our results suggest that the 0.75” tube has an average expansion rate of 4.4% which is much higher compared to those for the 0.25” or 0.375” tubes [see Tables 1, 2, and 3]. To be noted is that the natural blood found in the biological system is more compressible than water due to the presence of plasma protein and haemoglobin molecules.

On average, the calculated % elongations for the 0.25, 0.375 and 0.75 inch tubes were at 100%, 137% and 175%, respectively, and fracture occurred after maximum tensile forces of about 90N, 165N and 185N, respectively, leading to tensile strengths of about 10, 7.5 and 3.0 MN/m2 for the 0.25, 0.375 and 0.75inch diameter tubes, respectively. The results gained from the tensile tests were similar to those reported by others [1, 7, 11, 12] and as the bore size of the PTFE tubes increased the failure/fracture forces also increased. This property is ideal for arterial graft implants as blood pressures are always fluctuating at random and the material will need to meet such changes in diameter so as there is no failure which can lead to further complications.

The PTFE tubes showed clearly that they can withstand a minimum of 100,000 cycles (via rolling-u wear tests) without failure which proved that this material is highly wear resistant. However, in the rolling-u wear experiments the tubes did not come into any contact with other surfaces and the real blood vessels are most likely to make some form of contact with other organs inside the human body and thus for further future work the rolling-u wear test should be conducted in contact with a surface of a tissue-like biomaterial to mimic the human body. To be noted is the fact that such vessels will be surrounded with blood and other fluids which act as lubricants, hence, wear may be very minimal for the PTFE tubes due to lubrication. Also, compared to ePTFE, the standard PTFE has higher elasticity [1, 3, 12], thus elongating much further than that of ePTFE, hence in body environments the standard PTFE is a more suitable choice of material.

4. Conclusions

The mechanical testing results obtained in this work were promising and seemed appropriate for arterial implantation of convoluted PTFE tubes. Further future work regarding biological tests to investigate cell-convoluted PTFE surface interactions would be useful.

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