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Evaluating the effect of manufacturing method on the radial compressive force of the bioresorbable tubes

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ABSTRACT

Bioresorbable stents is going to become the future modality for the treatment of coronary artery disease (CAD). However, the main limitation of the polymeric stent is its poor mechanical properties. For the proper functioning of a stent in the artery; it is required to enhance the radial stiffness of the polymeric stent. Polymeric tube manufacturing is the first and most important step in the stent manufacturing process. Usually, post processing operation which enhances the mechanical properties such as annealing, blowing and die drawing near glass transition are used after tube extrusion. In this study, along with conventional tube extrusion process (SE), a single step biaxial expansion method (BAE) was employed during the tube extrusion. The effect of manufacturing method on the radial compressive strength of the extruded tubes is thereby evaluated. For further determining the tubes radial resistive force, parallel plate crush testing as per ISO 25539-2 was performed and it is observed that tubes extruded by BAE method have better performance during crush testing as compared to the SE tubes of the same material. SEM was used for observing the cross-sectional morphology of the Cryo-fractured surface of fabricated bioresorbable tubes.

1. Introduction

Stents are used to open an occluded artery which gets blocked due to the deposition of the plaque on the artery wall. Bioresorbable stents are used to overcome the drawbacks of drug eluting stents such as late restenosis and permanent presence of the metal even when the requirement of stent is finished [1]. Polylactic acid (PLA) is a widely used material for bioresorbable stents fabrication on commercial scale [2–4]. However, brittle nature of Polylactic acid is not favourable for the stent performance. Thus, though the use of bioresorbable polymers does open a new possibility of providing short term scaffolding to the artery but due to inferior mechanical properties as compared to metallic DES it has limited its use and also the only commercially launched Abbott stent Absorb™ is withdrawn recently [5].

For proper functioning, the stent should have sufficient radial strength so as to resist the applied cyclic arterial radial compressive forces and to provide the necessary support to the lumen. The stent performance depends on the material properties and physical attributes of the tubing utilized for the device formation [6]. Hence, improving the mechanical properties of the polymeric tubes during fabrication process is proposed in this work. Two different methods for the tube fabrication have been employed and compared in this work. To overcome the brittle nature of the Polylactic acid, Polycaprolactone (5 wt%) is blended in twin screw extruder before tube manufacturing.

2. Materials and methods

PLA, Ingeo 4032D grade(density 1.24 g/cc [7] with 6.4 ± 0.3 MFI g/10 min at 210 °C/2.16 Kg, Mn = 90 kg/mol and Mw = 207 kg/mol [8] from NatureworkLLC, USA and PCL, CAPA 6800 was from Perstorp, UK with Mw of 120 kDa and melt flow rate of 3 g/10 min [8].

2.1. Blend formation

For blend formation Co-rotating twin screw extruder TSE (Prism Eurolab 16, Thermo fisher Scientific) was used. Before blend formation, polymer was dried in vacuum oven for 12 h at 50 °C so as to maintain the moisture level below 250 ppm and to prevent the hydrolysis of the polymer during blending.

2.2. Polymeric tubes fabrication

For Tube fabrication, SE and BAE methods were used [9]. Single screw extrude (L/D ratio of 30: 25) has been used [10].

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Fig. 1a) shows the schematic of the BAE method. In brief, in this process a biaxial expansion setup is attached just after the annular die and this BAE setup causes higher radial expansion in the extruded polymeric tube as compared to radial expansion achieved by SE process. Tubes under compression testing are shown in Fig. 1b) and their nomenclatures and dimensions in Table 1.

The extruded tubes ring samples were mechanically characterised by measuring the radial compressive force as per ISO 25539-2 on Instron 5582. The speed of cross head was kept at 1 mm/min. In each group (n-5) samples were tested as shown in Fig. 1c–h) and average is reported.

The tubes were cryo-fractured in liquid nitrogen and SEM micrographs ((Zeiss EVO 50) were taken after gold sputter coating for observing the cross-sectional surface morphology of tubes.

3. Results and discussions

3.1. Radial compressive force of tubes

The tubes were tested for radial compressive force on Instron 5582.

Fig. 2(a–e) shows the compression results of the different polymeric tube samples cut in the form of rings of size 3 mm diameter and 15 mm length under the applied compressive force. It is clear from Fig. 2a) that resistance to the applied compressive load is higher for the PLA-BAE (13.6 ± 1.5 N) samples as compared to PLA-SE (8.16 ± 2.04 N). The same trend is visible for PLCL-5 samples, PLCL-5BAE (7.4 ± 0.63 N) is providing higher resistance to the compressive load as compared to PLCL-5SE (6.06 ± 1.5 N). Thus, change in the fabrication process causes an increased resistance to the applied load and thus leads to higher radial compressive force.

Thus, SE tubes have lower compressive load bearing as compared to the samples of BAE process, both the materials were limited to 40% of strain during testing for maintaining the uniformity in measurement.

This increase in the compressive load bearing capacity and radial force resistance of the biaxially expanded tubular samples can be attributed to the alignment of the polymer chains in the BAE tube fabrication. Higher orientation of the polymer chains in the radial direction provides better compressive force resistance and thus better mechanical properties of the fabricated tubes, which is vital for any stent manufacturing in future.

Also, Fig. 2a) shows brittle behaviour of the PLA tubular samples during the compression testing which is an inherent property of PLA and limits its use in medical world. Fig. 2b) of PLCL-5 SE and BAE shows a ductile material behaviour during compressive loading. Thus, by addition of 5 wt% of PCL in PLA, brittle behaviour of the PLA changes to a ductile phenomenon and its toughness increases. Also, with the incorporation of PCL there is no major reduction in the compressive load bearing capacity of the PLCL5 blend as the two curves are comparable with each other and similar results were also observed by Ostafinska et al. [11]. Thus, by adding PCL and using the biaxial extrusion method for the tubular stent fabrication the material properties desirable for a stent can be enhanced. Fig. 2d)–e) shows an average radial compressive force comparison of PLA-SE and PLA-BAE and PLCL-5SE and PLCL-5BAE, respectively.

The increase in the radial compressive resistive force is significantly higher for BAE tubular samples as compared with SE

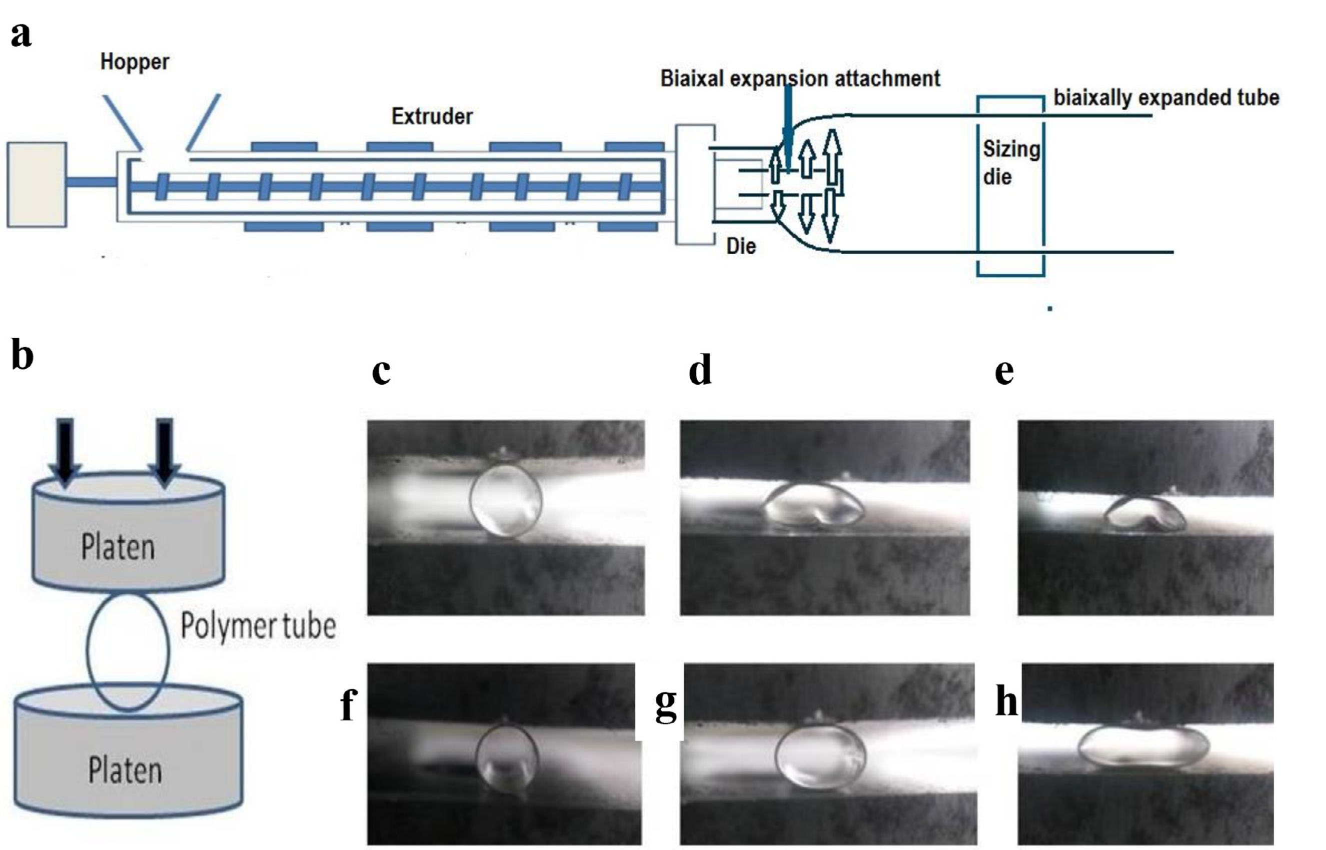

Fig. 1. a) Schematic of biaxial expansion setup developed in-house. b) Schematic of Compression test of polymeric tube, c) Actual testing of PLA tube and its deformation during compression testing (0% deformation). d) PLA tube at 30% deformation. e) PLA tube at 40% deformation (fracture occur). f-h)PLCL-5tube deformation f) 0%, g) 30% and h) 50% deformation (No fracture).