Large Bioresorbable Stents for Congenital Heart Disease
Welch TR¹, Wright, J.¹

Introduction: Poly-L-Lactide (PLLA) has been investigated as an implantable biodegradable material that has more recently been investigated for biodegradable stents. An ideal bioresorbable stent would successfully treat congenital heart disease such as aortic stenosis and then disappear. Prior work was performed on a Ø3mm PLLA stent design to examine localized yielding regions of the stent. The goal of this research is to design a Ø10mmx18mm stent 3D model and analyze the stent with Finite Element Analysis and experimental techniques for biodegradable stents used in congenital heart disease.

Materials and Methods: PLLA fibers were hot melt extruded and drawn to a 6:1 ratio for 0.25±0.01 diameter. Tensile testing of these fibers were performed on an Instron 5565. These fibers were then wound into a stent configuration. PLLA stents were analyzed by expanding at incremental balloon pressures from 0 to 8 atm. The stent size of Ø10mm x 18mm was then modeled in Solidworks 2016 and imported into Abaqus 6.13 (Dassault Systemes Simulia Corp. Providence, RI). A mesh of 252,204 elements was used for the stent model and 38,400 for the balloon model. A frictionless rigid cylinder balloon was used to analyze the expansion of the stent to a 10mm balloon diameter and a second step to simulate the stent relaxation after removal of the balloon. A nonlinear model is used imposing von Mises isotropic strain hardening yielding criterion using the material properties and stress-strain curve from the PLLA fibers. Stent hoop strength testing was performed on an Instron RX 550/650.

Results and Discussion: The mechanical properties of the 0.25 thick PLLA fibers showed Young’s Modulus of 5380±26 MPa with the ultimate tensile strength 476±16 MPa and fail strain 44±26%. These material properties were used with large deformation to simulate the stent expansion and springback analysis. The stent showed localized regions of material yielding causing the stent to permanently deform into a cylindrical position. Stent validation was performed by analyzing the elastic recoil and shortening of the stent through expansion. The experimental results showed a 1.5±0.5% elastic recoil and no shortening of the stent. Stent radial testing showed a hoop strength of 0.29±0.06 N/mm.

Conclusion: A Ø10mm x 18mm bioresorbable stent has been successfully designed for congenital heart disease. Initial studies were performed on a 3 coil platform and analyzed for iliac vessels using finite element analysis. This design was modified to a 6 coil platform to successfully create a bioresorbable stent with localized plastic yielding similar to predictions in a 3 coil platform. Hoop strength testing shows the PLLA stent having a high radial hoop strength. Further studies were investigated with this approach fabricating this PLLA stent design to a 12mm diameter and compared against a metal CP Stent™ showing significantly higher radial hoop strength.

Disclosure Statement: This stent design is covered by patent US 9,155,640 B2.

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