Adaptive Stent for Congenital Pulmonary Artery Stenosis

Axel Delakowski, Hannah Morgan, Calvin Okulicz, Kristen Zozulia

Department of Biomedical Engineering The College of New Jersey, Ewing NJ

TCNJ THE COLLEGE OF NEW JERSEY

Abstract

Branch pulmonary artery stenosis (BPAS), narrowing of the right and left pulmonary arteries (RPA and LPA respectively), is a common congenital heart disease, occurring in 1 in 10,000 births.[1] This condition can develop as a part of other congenital heart diseases and as a complication of their treatment.[2] BPAS is also seen in genetic syndromes such as Williams Syndrome, Alagille Syndrome, and Noonan Syndrome.[3] Current treatment methods include balloon angioplasty and stenting with balloon-expandable stents. In the case of stenting, multiple redilation procedures are often necessary to maintain patency as the patient grows. These recurring dilations pose a safety risk to pediatric patients. A novel stent that self-expands, concomitant with vessel growth, will eliminate the need for additional redilation procedures after initial implantation. The proposed design is composed of nitinol with non-linear serpentine-like spring elements that allow for non-linear expansion in the vessel. Finite element analysis (FEA) ensures the stent can support the vessel safely without failure. Computational fluid dynamics (CFD) results compare normal fluid velocities and wall shear stresses occurring in the LPA and RPA to those expected following stent implantation in order to minimize risk factors for thrombosis and hemolysis, and flow-loop testing ensures low rates of hemolysis and thrombus formation in the stent.

Introduction

Children born with congenital pulmonary artery stenosis undergo stent implantation at a very young age. These stents usually require multiple expansional procedures as the patient grows. With these procedures comes an increase in risk for each redilation. The Adaptive Stent aims to expand alongside the child during their development to reduce the need for such procedures. Redilation procedures not only pose a health risk, but also have critical social implications by increasing time spent away from school and impacting families financially due to medical costs. The Adaptive Stent aims to circumvent these procedures to greatly improve the quality of life within children affected by this disorder. The stent must be adequately tested under FDA and ISO protocols and guidelines to ensure that the device is safe and effective inside the body, especially as a Class III device.

Design Inputs

The Adaptive Stent must be able to mechanically support the affected vessel without imparting high stresses vessel wall, maintain flow without significantly increasing thrombosis and hemolysis risk, and must be biocompatible to minimize adverse tissue and systemic responses from the patient. Most importantly, the stent must be able to accomplish all of these at every functional diameter and be able to be delivered via conventional catheterization techniques. The range of functional diameters was determined to be 7 – 11 mm to encompass the range of vessel anatomy of a developing child, and the stent must also be able to be crimped to 3 mm in diameter to be inserted into the catheter for delivery. For mechanical support, the vessel wall must not be experienced to more than 4 MPa of stress, and the stent must not see any permanent structural changes at any diameter. To ensure the stent has minimal thrombosis and hemolysis risk, the affected area after implantation must have shear stresses between 14 and 27 dynes/cm^2 across 70% of the area to approximate normal physiological conditions. Lastly, to ensure the stent does not cause any immune responses to the device, the device must have passing scores on the cytotoxicity and hemolytic index.

Design Solution

Figure 1: The final stent design chosen by the team to meet the described design inputs. This model was used in all computational simulations and 3D printed version was used in flow-loop testing. The model above represents the fully expanded 11 mm diameter version of the design.

The above design features a non-linear serpentine spring design which allows for non-linear expansion of the stent. The non-linearity in the spring allows the device to produce the adequate amount of force across all functional diameters. The stent is designed at the full diameter of 11 mm intended to provide the expansion force across all intended diameters. In addition to its non-linearity, the stent is constructed with an “open-cell” inspired construction which allows for the larger expansions necessary for success in the patient. Previous designs included a “closed-cell” design utilizing biodegradable polymers as well as a locking mechanism design, but this design was selected due to its simplistic design and manufacturability.

Testing

Tests were performed to verify that the stent can mechanically support the vessel, be able to compress to be able to be delivered by catheterization and can bend over varying pulmonary artery curvatures. Both computational and benchtop tests are performed to test the stents affect on blood flow, specifically if it results in hemolysis or promotes thrombosis.

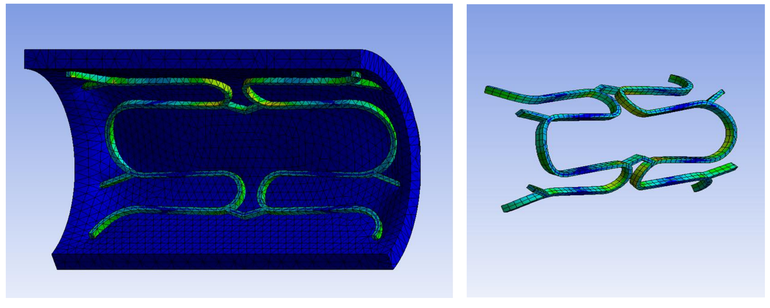

Figure 2: FEA analysis of the stresses in the vessel wall and the stent resulting from compression

The stresses the stent imparts on the vessel were all within the allowable range. The stresses on the stent itself were within range at all diameters except at 3 mm, the diameter required for delivery via catheterization. There was found to be permanent structural change at 3 mm. During the bending test, although the stent met the specification the stent no longer retained its structural integrity (Figure 3).

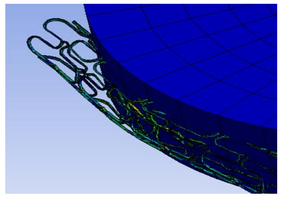

Figure 3: FEA analysis setup for bending test

The shear stresses imparted on the stent were outside the specified range of 16- 25 dynes/cm^2. The average shear stresses were approximately 60-80 dynes/cm^2 (Figure 4). Additionally, the stresses imparted on the vessel by the stent were also analyzed (Figure 5). Additionally, there were areas of recirculation around the connectors (Figure 6). Although these areas of recirculation are relatively small, they can still be areas of platelet trapping which promotes thrombosis. Using a power law model for hemolysis, the percent of hemolysis was found to be 0.05%, less than the 2% allowable maximum.

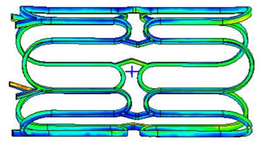

Figure 4: Shear stresses on one cell of the stent (cooler colors indicate low shear stresses)

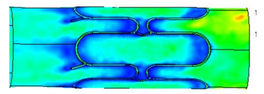

Figure 5: Wall shear stress on the vessel

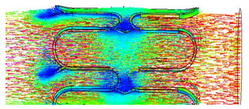

Figure 6: Fluid velocity vectors. Recirculation, negative velocity, in the blue areas.

Conclusions

Overall, the Adaptive Stent does not cause damage in the vessel and has acceptable stress in the stent at any of the functional diameters, but further testing is needed to ensure that the stent maintains targeted stiffness and radial force needed. The Adaptive Stent was found to have permanent structural change when compressed down to 3 mm in diameter for catheterization. CFD testing illustrates that the stresses imparted are greater than the physiological values. However, there was minimal hemolysis with the stent. More testing will be done on multiple cells of the stent. At this moment, fluid benchtop testing is still being completed but the mechanical results suggest a slight redesign is needed to reduce the stress exhibited by the stent at its connecting pieces to allow for full compression of the device.

References

1. Tonelli, A. R., Ahmed, et al. (2015). Peripheral Pulmonary Artery Stenosis as a Cause of Pulmonary Hypertension in Adults. Pulm. Circl., 5, 204-210.
2. Trivedi, K. R., et al. (2003). Interventional strategies in the management of peripheral pulmonary artery stenosis. J. Interv. Cardiol., 16(2), 171-188.
3. Pierpont, M. E., Basson, et al. (2007). Genetic basis for congenital heart defects: current knowledge: a scientific statement from the American Heart Association Congenital Cardiac Defects Committee, Council on Cardiovascular Disease in the Young: endorsed by the American Academy of Pediatrics. Circl., 115(23), 3015-3038.

Acknowledgements

We would like to thank the Department of Biomedical Engineering, School of Engineering, and especially Dr. Constance Hall for their constant guidance and aid during the project.