Balloon-Stent Aneurysm Treatment Device

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Abstract

The following poster details the design process for the Balloon-Stent, a next generation, endovascular aneurysm treatment device. This temporary device aims to improve aneurysm neck protection during embolic placement, while maintaining sufficient blood flow in the parent artery, thus minimizing ischemic risk. While the Balloon-Stent is deployed, the surgeon will be able to treat the aneurysm with the desired treatment method.

Some important requirements for the Balloon-Stent are that the stent must be self-expandable, the balloon must inflate to occlude blood flow into aneurysm, and the fractional flow reserve (FFR) must be 0.75 or greater to maintain sufficient blood flow.

Through physical testing, analytical analysis, and CFD, it was found that the compression force of the stent at activation temperature is 3.08 N and increased by 67.5% within a 10℃ increase, and that the FFR is 0.91.

Background

Brain aneurysms can be defined as an abnormal bulge on blood vessels within the cranium. Intracranial aneurysms affect approximately 2-3% of the general population [1]. The main concern with brain aneurysms is that they are prone to rupture which results in hemorrhage into the subarachnoid space. The mortality rate due to aneurysm rupture is 20-40%, where 50% of survivors face other health complications such as permanent brain damage [2]. Physicians attempt to reduce the risk of mortality and morbidity by treating unruptured aneurysms using methods like surgical clipping or endovascular techniques. Endovascular treatment methods are often preferred because they are less invasive than clipping which results in more favorable outcomes. Some common endovascular techniques include coiling, liquid embolics, flow diverters and flow disruptors. In each case, physicians use a system to deliver the treatment to the affected area which then disrupts the blood flow in the aneurysm.

Requirements

The scope of this capstone project is to model, analyze, and prototype a novel Balloon-Stent hybrid endovascular device. The design consists of a self-expanding, woven stent that fits within a cylindrical balloon. The balloon is meant to occlude the aneurysm while the stent provides additional scaffolding. This device is designed for saccular aneurysms, although it could possibly be used to treat some bifurcation aneurysms with simple geometries. Table 1 shows the engineering requirements, target values, and tolerances ranked by relative technical importance (RTI). These values are considered assuming the device will be deployed in the internal carotid artery (4 mm ID), which is prone to saccular aneurysms [3].

Table 1: Engineering Requirements

Engineering Requirement	RTI	Target Value	Tolerance (±)	Units
Stent radial compression force	1	3	0.5	N
Stent minimum diameter	2	3.6	0.2	mm
Fractional Flow Reserve (FFR)	3	0.75	0.5	N/A
Durability	4	15	5	min
Balloon diameter- inflated	5	4	0.2	mm
Balloon thickness- inflated	6	0.1	0.02	mm
Rigidity, Young's Modulus	6	28	5	GPa
Friction	7	1	0.5	N/A
Device length	8	20	10	mm
Cost	9	1750	250	USD

Methodology

Manufacturing:
The self-expanding stent is made of nitinol, a nickel-titanium allow with shape memory properties. The nitinol is woven around a jig using an alternating diamond weave pattern then annealed at 500℃ [4] to reset the shape memory. Once the memory is reset, the stent can be elastically deformed and returned to its memorized state when heated above its activation temperature (35℃).
The key purposes of the balloon are to occlude the blood flow into the aneurysm, and to provide a smooth surface at the neck of the aneurysm to support cell regeneration. Considering the state-of-the-art balloons, a polyurethane balloon is the appropriate as it is most likely to fulfill its purposes, and has the ability of covering minimal radial space within the vessel due to its high compliance. The desired manufacturing process for the envisioned balloon consists of dip molding in order to achieve its cylindrical shape. For demonstration purposes, a balloon model is 3D printed with a photopolymer.

Testing:
The radial compression force is tested using a flat plate compression test with a rheometer. The stent was submerged in a bath of three different temperatures to see how the self-expansion affects the force. The diameter was slowly compressed until a gap of 2 mm remained between the compression plate and the bottom surface. Results of this test can be found in Figure 1. A computational CFD analysis using *SimVascular* is done to test FFR.

Results

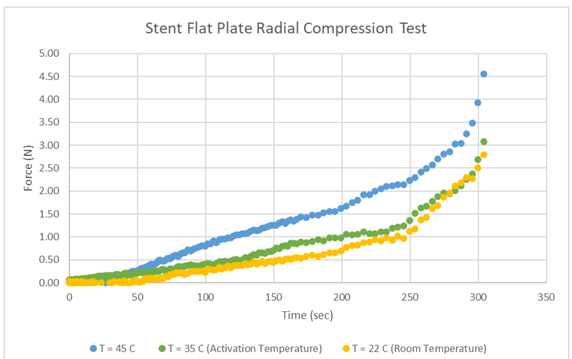

Figure 1: Stent flat plate radial strength test for stent at different temperatures. Plate gradually compresses stent until a gap of 2mm remains.

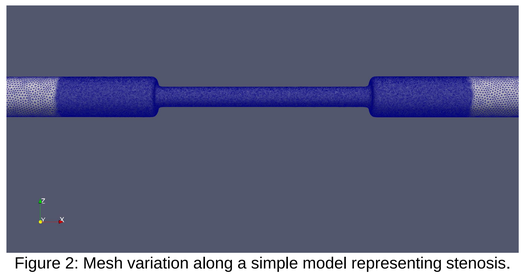

Figure 2: Mesh variation along a simple model representing stenosis.

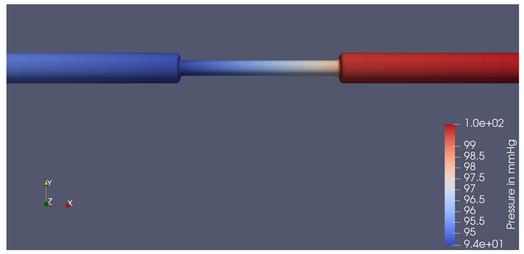

Figure 3: Pressure (mmHg) throughout the model obtained from CFD.

Figure 1 shows the results of the flat plate radial strength test. It can be observed that once the activation temperature is reached, the stent begins to exert a greater force. A higher temperature means that the stent will exert more force in attempt to revert to its memorized position. For the room temperature (22℃) condition, the maximum force exerted by the stent (compressed to gap of 2 mm) was 2.79 N. For the activation temperature condition (35℃), the maximum force exerted by the stent was 3.08 N. For the higher temperature condition (45℃), the maximum force exerted by the stent was 4.56 N. Within a temperature difference 10℃ above the activation temperature, the strength of the stent increased by 67.5%

Since the balloon is expected to form into the stent mesh, a simple cylindrical model is used to complete the CFD. The model resembles the expected stenosis when the device is in place. Figure 2 shows the mesh variations along the model. The global mesh size is 0.03, and the area of interest has a mesh size of 0.01 to produce more accurate results. Figure 3 shows the pressure of the blood flow along the model. The average pressure, in mmHg, at the inlet, center, and outlet are 90.71, 92.55, and 99.53, respectively. From these values, the FFR is calculated, using equation 1, and results in 0.91 which satisfies the FFR requirement.

$$FFR = \frac{P_{distal}}{P_{proximal}} \qquad \text{eq. 1}$$

Final Prototype

Figure 4 shows the final prototype of the Balloon-Stent device, scaled up by a factor of 7.22. The stent prototype has a mesh size of approximately 8 mm, which would translate to a mesh size of 1.09 mm at its true scale. The mesh size can be reduced by increasing the number of pegs on the jig. The balloon protype was printed using an Adulus 30 photopolymer. Future work for this design involves collaborating with stent and balloon manufacturers to produce a function, to scale version of this design.

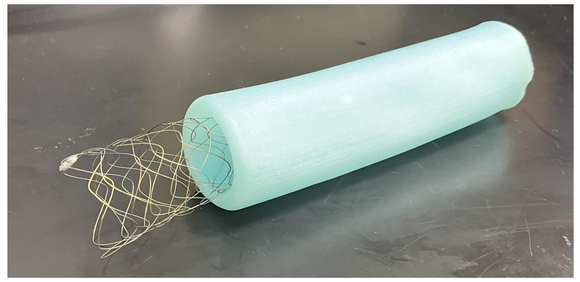

Figure 4: Final prototype of the Balloon-Stent (exploded view)

Conclusion

The Balloon-Stent design shows a high potential to become a successful saccular aneurysm treatment device. Through the course of this project, the Balloon-Stent has been prototyped, modeled, and analyzed to validate its requirements. The balloon prototype was created using a precision, Adulus 30 3D printer. The stent prototype was created by weaving nitinol around a steel jig and annealing for an hour at 500℃. The flat plate radial compression test conducted on the stent demonstrates its self-expanding capabilities. The force measured at activation temperature with maximum deformation was 3.08 N. A CFD analysis was conducted to model the stenosis and determine whether the minimum FFR requirement of >0.75 is satisfied. The results of the CFD reflect an FFR of 0.91, thus satisfying the requirement. However, this model does not take into account the added geometry of the microcatheter. Other limitations to the results stem from the behavior of blood including pulsatile flow, and blood viscosity. Future iterations of this CFD analysis will take that into account. With this design, surgeons can treat aneurysms, and worry little about the patient suffering ischemia, embolics escaping the aneurysm, or the device getting dislodged. This design shows a bright future for minimally-invasive endovascular aneurysm treatments.

References

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Acknowledgements

Sponsor: Bioengineering Devices Laboratory
Client: Dr. Timothy Becker
Faculty Mentor: David Willy
Consultants:
Omid Asgari, graduate student
Mana Alyami, graduate student
Nicholas Norris, graduate student
Neil Jaquez, Machine Solutions Inc.
Devon Martindale, POBA Medical