Balloon-Stent Endovascular Device for the Treatment of Intracranial Aneurysms

Final Report

Team Number: 21Spr02

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DISCLAIMER

This report was prepared by students as part of a university course requirement. While considerable effort has been put into the project, it is not the work of licensed engineers and has not undergone the extensive verification that is common in the profession. The information, data, conclusions, and content of this report should not be relied on or utilized without thorough, independent testing and verification. University faculty members may have been associated with this project as advisors, sponsors, or course instructors, but as such they are not responsible for the accuracy of results or conclusions.

EXECUTIVE SUMMARY

The following report contains the design description, requirements, testing procedures, and risk analysis for the balloon-stent medical device that will be used to treat intracranial, saccular aneurysms. The design consists of a cylindrical balloon surrounding a self-expanding stent; the balloon acts to occlude blood flow into the aneurysm and the stent acts to maintain sufficient blood flow in the parent artery. Our design is constrained by nine customer and engineering requirements that ultimately determine whether our device is successful or not. The testing procedures for this device include analytical and experimental testing.

ACKNOWLEDGEMENTS

The BDL capstone team would like to thank those that assisted us throughout the project. We are grateful for your support, and guidance. This project would not have been possible without the help of the following individuals:

Dr. Timothy Becker – Client and mentor
David Willy- Capstone project mentor
Omid Asgari – Mentor and CFD specialist
Mana Alyami – 3D printing specialist
Nicholas Norris – Rheometer specialist
Neil Jaquez – Machine Solutions Inc.
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TABLE OF CONTENTS

Contents

1 BACKGROUND

1.1 Introduction

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]. Neurosurgeons attempt to reduce the risk of mortality and morbidity by treating unruptured aneurysms through coiling, liquid embolics, flow diverters and flow disruptors. The commonality between the treatments is that they either disrupt blood flow into the aneurysm or maintain normal blood flow in the parent vessel. The purpose of this project is to develop a balloon-stent endovascular device that isolates the aneurysm and provides parent vessel flow while the surgeon operates.

This capstone project is sponsored by the Bioengineering Devices Lab (BDL) directed by Dr. Timothy Becker. The Bioengineering Devices Lab is a translational research lab at Northern Arizona University (NAU) that focuses on developing biomedical devices and biomaterials that help improve the treatment of brain aneurysms. Any accomplishments in the BDL and capstone project bring NAU more recognition and funding for future research. Our client, Timothy Becker, and the graduate students working in the BDL benefit from success in the capstone project because any research conducted is relevant to their projects. Our primary stakeholders, physicians, benefit from this project because it gives them more time to operate increasing the success rate of the surgery. The team recognizes the importance of the project and aims to produce meaningful work that will help our client, stakeholders, and patients.

1.2 Project Description

According to the project proposal, the capstone team is to design, analyze and prototype a novel balloon-stent endovascular medical device. The project description provided by the BDL is found below.

> The scope of this project is to design, model, and analyze (CFD) a prototype endovascular device that improves aneurysm neck protection during embolic device placement, while reducing blood flow obstruction in the parent artery thus minimizing ischemic risk.

The goal for this device is to increase the efficiency of endovascular techniques used to treat intracranial aneurysms. The temporary device should increase the time that physicians have to deliver the treatment of choice to the aneurysm. For the completion of this project, the team assumes that the device must function for a saccular aneurysm located in the internal carotid artery. This assumption is made due to the frequency of aneurysms forming in this area of the brain.

2 REQUIREMENTS

As the purpose of this device is to occlude the aneurysm while maintaining proper blood flow, certain requirements must be met to ensure the device works properly. The following chapter describes the customer and engineering requirements for a functional balloon-stent device.

2.1 Customer Requirements (CRs)

Customer requirements (CRs) are aspects of the design important to the customer, which in this case would be a physician or a medical clinic. The requirements were set based on research and discussion with our client. A list of the CRs are listed in Table 1

Table 1: Customer Requirements

Customer Requirement
1. Must be safe to use on the human body
2. Must prevent occlusion of the parent artery
3. Must prevent embolics from traveling downstream
4. Must have a smooth surface at the neck
5. Must fit in the blood vessel
6. Must block blood flow into aneurysm
7. Must allow surgeons to deploy and maneuver the device
8. Must be within budget
9. Must not cause turbulence in blood flow

2.2 Engineering Requirements (ERs)

The nine customer requirements are then translated to nine engineering requirements (ERs). ERs are technical aspects of the design that would satisfy the customer requirements. Each requirement is testable, and has a target value, tolerance, and relative technical importance. The engineering requirements formulated for the balloon-stent device can be found in Table 2, ranked by RTI.

Table 2: 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	N/A	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	7	28	5	GPa
Friction	8	1	0.5	N/A
Device length	9	20	10	mm
Cost	10	1750	250	USD

2.3 Functional Decomposition

This purpose of this section is to illustrate what the endovascular device must accomplish. This is done by defining the inputs and outputs through a black box model. The functions and sub-functions are illustrated using a functional model. The functional decomposition creates a clear outline that helps generate feasible concepts for the project.

2.3.1 Black Box Model

The purpose of the black box model is to illustrate the inputs and outputs. This helps the team have a good understanding of specific components that the device must have. Figure 1 shows the black box model diagram. The goal for the endovascular device is found in the middle of the box in its simplest form. The material, energy and signal inputs and outputs are shown from top to bottom, respectively. Because the balloon-stent device is meant to be removeable, it is observed that the inputs and outputs are roughly the same.

Figure 1: Black box model

2.3.2 Functional Model

The functional model illustrates the main purpose of the project, sub-functions, and how the sub-functions could potentially be accomplished. The diagram shown in Figure 2 shows the functional model. The team benefits from this diagram as it provides a more detailed description of the project objectives.

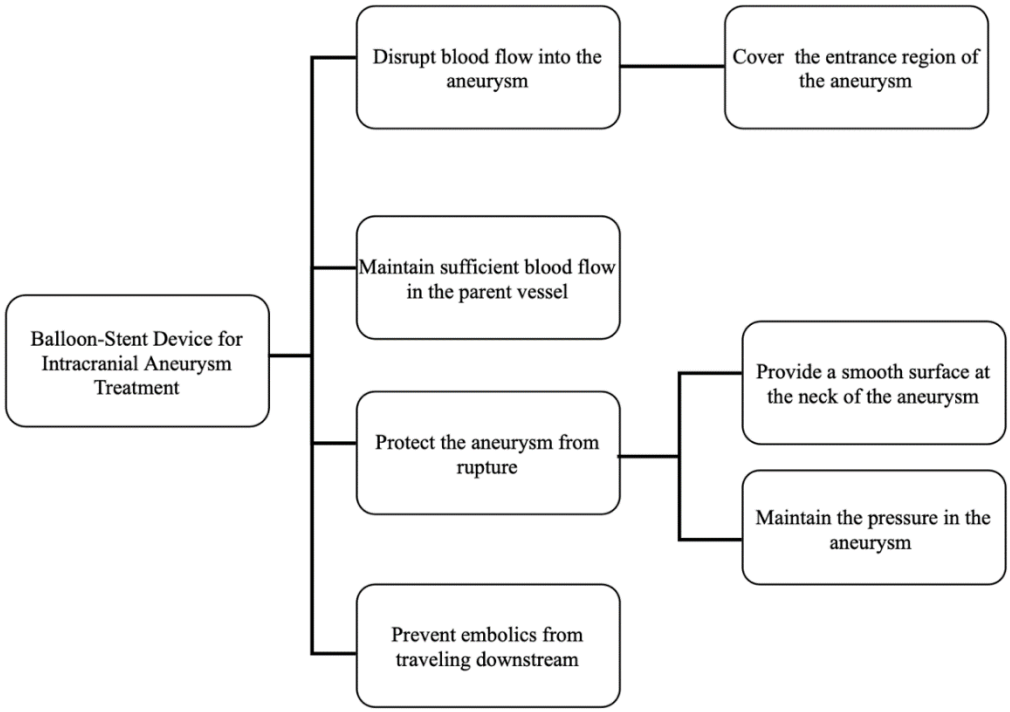


Figure 2: Function decomposition model

2.4 House of Quality (HoQ)

The House of Quality diagram (Figure 3) is a design approach that relates the CRs to ERs; by doing this, we are able to rank the technical importance of each engineering requirement. Observe that the most important ER is the stent radial compression force (N). This is due to the stent radial compression force having a strong correlation to the two highly weighted CNs, a moderate correlation to one highly weighted CN, and weak correlations to two more highly weight CNs. Taking the weights and correlations into account, it is calculated that the stent radial compression force has an Absolute Technical Importance (ATI) of 115, which ranks it first in terms of Relative Technical Importance (RTI). Contrary to this, the least important ER is cost (USD), as it only correlates to one low ranked CR. Each ER is also given a target value with tolerance based on common Circle of Willis artery geometry and other knowledge gained by research. Furthermore, each engineering requirement (except cost) has an associated test procedure that will be explained more later in this document.

Customer Requirement	Weight	Engineering Requirement	Balloon diameter- inflated (mm)	Balloon thickness-inflated (mm)	Stent minimum diameter (mm)	Stent radial compression force (N)	Device length (mm)	Young's Modulus (GPa)	Durability (functioning life span)(min)	Friction factor	Fractional Flow Reserve	Cost (USD)
1. Must be safe to use on the human body	5			3		1			9		9	
2. Must prevent occlusion of the parent artery	5		9		9	1		3	1		9	
3. Must prevent embolics from traveling downstream	5		1		1					3		
4. Must have a smooth surface at the neck	2									3		
5. Must fit in the blood vessel	5		3	3	9	9	3				3	
6. Must block blood flow into aneurysm	5				3	3				1		
7. Must allow surgeons to deploy and maneuver the device	5			3			1	3	9	1		
8. Must be within budget	2							3				9
9. Must not cause turbulence in blood flow	5					9						
Absolute Technical Importance (ATI)			65	45	110	115	20	36	95	31	105	18
Relative Technical Importance (RTI)			5	6	2	1	9	7	4	8	3	10
Target ER values			**4**	**0.1**	**3.6**	**3**	**20**	**28**	**15**	**1**	**> 0.75**	**1750**
Tolerances of ERs			± 0.2	± 0.02	± 0.2	± 0.5	± 10	± 5	± 5	± 0.5	-	± 250
Testing Procedure (TP#)			1B	1B	1B	2B	1B	2B	2B	2A	1A	

Figure 3: House of Quality diagram

2.5 Standards, Codes, and Regulations

The standard that we will abide by will be the Human Factors Design Process for Medical Devices standard. This will ensure that the medical device we comply with known safety regulations for the human body.

Table 3: Standards of Practice as Applied to this Project

Standard Number or Code	**Title of Standard**	**How it applies to Project**
ASNI/AAMI HE 74:2001	Human Factors Design Process for Medical Devices	Helps in the design of how the device will interface with the user in a safe manner. Standard will reduce risk and adverse effects caused by materials.

3 DESIGN SPACE RESEARCH

This section contains valuable information found through research. The literature review was helpful in familiarizing with biomedical concepts, and understanding the motivation for this project. The benchmarking helped evaluate the current solutions on the market, including identifying their limitations.

3.1 Literature Review

3.1.1 Daniel Castano

Danny's roles in this project are to be the CAD Engineer, the manufacturing engineer, and the financial manager. Up to this stage of research, he has been focusing primarily on the stent aspect of the design, as he will be designing the CAD model for it.

The first source used was an article titled *Statistics and Facts* from the Brain Aneurysm Foundation website [3]. It is the first source used and was meant to give the unfamiliar student information about aneurysms. This source helped to get a sense of the prevalence of aneurysms, as well as an idea of the factors that affect them. The details contained in this website also aided us in creating our Project Description for our presentations.

The second source used was an article titled *Endovascular Coiling for Brain Aneurysms* from the John Hopkins Medicine website [4]. This source was used to familiarize him with the coiling process for treating aneurysms. Coiling is a procedure in which a surgeon releases an embolic agent into an aneurysm through a catheter. The resulting clot that forms in the aneurysm prevents more blood from flowing in. It is important for us to understand the coiling process, as it will be implemented in tandem with the balloon stent.

The third source used was a peer-reviewed journal article titled *Resuscitative endovascular balloon occlusion of the aorta might be dangerous in patients with severe torso trauma: A propensity score analysis* [5]. In this article, the authors did a study of the effects of Resuscitative endovascular balloon occlusion of the aorta (REBOA) in patients with torso trauma. It was concluded that the use of REBOA in patients with hemodynamically unstable (unstable blood pressure) torso trauma increases the surgery's mortality rate. The reason why this source is important is that it points out a drawback of using occlusion balloons; they pose the risk of ischemia (insufficient blood flow to organs) if the artery is occluded for too long. From what the study points out, occlusion factors vary from person to person, and can change based on details such as torso trauma. With the uncertainty present with this form of treatment, our team finds it best to neglect the occlusion balloon form of treatment and focus on implementing a balloon that allows for the flow of blood.

The fourth source used was a book titled *Flow Diversion of Cerebral Aneurysms* [6]. This book serves as a good source to locate information about multiple forms of flow diversion. The methodology of flow diversion described by this book was implemented when Danny considered the design for his concept variants. Additionally, this book has a useful table that shows the variation of porosity and pore density of stents based on the deployment diameter. This will become useful when we must consider the pore size of our stent.

The fifth source used was a peer-reviewed journal article titled *A Novel, Self-Expanding, Nitinol Stent in Medically Refractory Intracranial Atherosclerotic Stenoses: The Wingspan Study* [7]. This source studied the use of nitinol stents in treating stenosis within patient's arteries. The results reflected a successful decrease of stenosis due to the use of the nitinol stent. This source was important in researching the material that the stent is to be made of, and nitinol will be the chosen material due to its self-expanding properties.

3.1.2 Dallany Segura

The elements for the novel device that the team must develop were determined to be a balloon and a stent. Because these are existing devices, Dallany focused on researching existing endovascular devices and how they operate. A large part of this research was familiarizing with the details of brain aneurysms.

The *FDA Executive Summary- Neurological Devices Panel Meeting* document described the diagnosis and characteristics of brain aneurysms and evaluated the treatment methods to date. Brain aneurysms are

classified based on their morphology, size, and anatomical location. The morphology refers to the type of aneurysm. The most common type of aneurysm is saccular which means that the bulge hangs off the side of the blood vessel. The size of aneurysms is largely dependent on the neck to dome ratio. Aneurysms are classified as small when the dome diameter, d<11 mm, large when 11mm<d<25mm, and giant when d>25mm [8]. The most common location for brain aneurysms is within the Circle of Willis (COW) at the base of the brain. This is because blood vessels of various sizes and flow patterns meet at the COW resulting in a range of pressures. The morphology, size, and anatomical location help the physician determine the treatment for the patient.

The treatment methods evaluated in the document that were most relevant to the capstone project were balloon assisted coiling and stent assisted coiling. Balloon assisted coiling (BAC) consists of inserting a microcatheter that deploys the coils into the aneurysm followed by a balloon catheter that is inflated within the parent artery. In comparison to coiling alone, BAC is meant to have a lower risk of thromboembolic complications [8]. Stent assisted coiling (SAC) entails inserting a self-expanding nitinol in the parent artery to cover the neck of the aneurysm. The SAC method is less likely to result in blood flow returning to the aneurysm dome than coiling [8]. Lastly, studies have shown that SAC has a higher occlusion rate and lower retreatment rate than BAC.

The journal article *The Big Bang theory of intracranial aneurysm rupture: Gazing through the Computational fluid dynamics telescope* provided meaningful information regarding the flow within brain aneurysms. The study analyzed the blood flow of 17 patients using CFD to determine the risk of rupture. The wall shear stress, velocity streamlines, and pressure distribution were found. The wall shear stress and pressure distribution were higher in areas of impingement [9]. The velocity streamlines were useful in determining the areas of impingement and flow pattern.

Hemodynamic Study for New Stent Design with Mesh-Typed Stents in a Cerebral Aneurysm Model using PIV is a conference paper that discusses the method and findings of a study on stent porosity. The flow was observed through four different stent porosities using particle image velocimetry (PIV). The findings were that lower porosity stents decrease the velocity and minimized the flow movement [10].

3.2 Benchmarking

In order to properly understand the benefits and drawbacks presented current endovascular treatment methods, our team benchmarked on both the system and sub system level. The following section highlights the results of our benchmarking research.

3.2.1 System Level Benchmarking

At the system level, there are a couple existing designs for the treatment of aneurysms. The following section describes current treatment methods but are limited to only endovascular treatments. The three designs used to benchmark are the Pipeline Flex [11], the Woven EndoBridge [12], and the Scepter-XC [13].

3.2.1.1 Existing Design #1: Pipeline Flex

The Pipeline Flex (Figure 4) is a device known as a flow diverter. Flow diverters redirect flow away from the aneurysm while a coiling treatment is done. Pipeline flex is meant to be a permanent device that heals itself into the artery with the use of antiplatelet therapy. The device is made up a 48 stranded, braided, cobalt chromium/platinum stent [11]. The main drawback of this device is its inability to properly expand the vessel wall as the stent alone does not provide sufficient radial force. Furthermore, because the stent is porous, there is not complete isolation of the aneurysm. These design flaws were considered when we

created our concepts and emphasized the importance of a balloon and self-expanding stent for proper parent artery flow.

Figure 4: Pipeline Flex within a parent artery

3.2.1.2 Existing Design #2: Woven EndoBridge

The Woven EndoBridge (WEB) (Figure 5) is a device known as a flow disruptor. Flow disruptors are placed within the sac of the aneurysm and aid to disrupt blood from flowing in and to help promote clotting. Like the Pipeline Flex, the WEB is a permanent aneurysm treatment. The primary drawback to this device is its limited use. It can only be used to treat aneurysms with a dome diameter of 3 mm to 10mm with a neck size greater than 4 mm and a dome-to-neck ratio greater than one and less than two [12]. Furthermore, the device is very challenging for the surgeon to maneuver the WEB into the right location; and even when it has been deployed, it can often result in recanalization due to pressure concentrations at the aneurysm neck. Due to the flaws of this design, our team decided it best not to go with a flow disruptor design.

Figure 5: Woven EndoBridge device

3.2.1.3 Existing Design #3: Scepter-XC

The Scepter-XC (Figure 6) is a temporary balloon that is meant to occlude the parent artery for a short amount of time while the aneurysm is treated. The device's balloon is a 4 mm x 11 mm ultra-compliant balloon deployed out of a catheter [13]. The main flaw with this design is that it does not allow for blood flow in the parent artery. The balloon is meant to be inflated and deflated on certain intervals to avoid patient ischemia, but there are different factors that can affect how safe this is such as torso trauma mentioned in [5]. Furthermore, repeated inflation/deflation cycles can cause vessel trauma. The Scepter-XC's ability to stay in place and occlude the artery is due to the balloon providing sufficient radial force. For this reason, our team decided that a hollow balloon that allows for blood flow would be an important component of our balloon-stent.

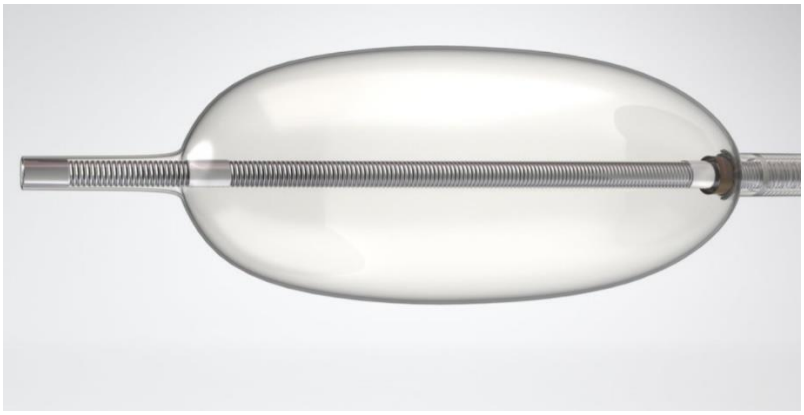


Figure 6: Scepter XC balloon

3.2.2 Subsystem Level Benchmarking

3.2.2.1 Subsystem #1: Cover the entrance region of aneurysm

The first subsystem from our functional decomposition is to cover the entrance region of the aneurysm. This is necessary for the surgeon to successfully embolize the blood in the aneurysm. If blood continues to flow into the aneurysm, a clot cannot form. Furthermore, embolics need to be isolated within the aneurysm so that they do not cause clots elsewhere.

3.2.2.1.1 Existing Design #1: Endovascular Balloon

Existing designs that satisfy this subsystem are conventional endovascular balloons such as the Scepter XC. This balloon would block blood from entering the aneurysm, but it would also prevent blood from flowing in the parent artery.

3.2.2.2 Subsystem #2: Provide smooth surface at neck.

The second subsystem is providing a smooth surface at the neck. This is important so that the embolics heal evenly, as the artery is meant to meant to heal over with. If the surface is not smooth, uneven blood flow can cause recanalization.

3.2.2.2.1 Existing Design #1: Flow Diverters

The existing designs that satisfy this subsystem are flow diverters. Flow diverters are permanent devices that the artery heals over with the use of antiplatelet therapy.

4 CONCEPT GENERATION

The concept generation process consisted of the team brainstorming ideas combining and altering concepts from current existing methods. Using the ideas behind existing methods ensures that the components are safe to use on the human body. This is essential for the scope of this project because there is a time constraint for the project. Attempting to create a completely new medical concept requires a long process that could take years.

4.1 Full System Concepts

The following concepts satisfy the full system. These designs satisfy each subfunction, and they are essentially composed of the hybrids of the existing sub functional designs.

4.1.1 Full System Design #1: Balloon-stent

Figure 7 shows the balloon stent which is composed of a cylindrical balloon surrounding a cylindrical stent. This design would block blood flow into the aneurysm while allowing blood flow in the parent artery. A possible drawback to this design is that it might be difficult to manufacture.

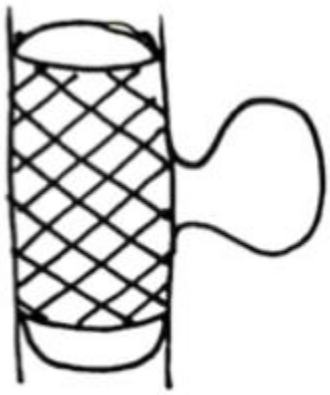


Figure 7: Stent surrounding cylindrical balloon

4.1.2 Full System Design #2: Dual balloon stent

Figure 8 shows the dual balloon stent which is composed of a y-shaped balloon with separate stented channels. This device is similar to Full System Design #1 but is specifically meant to treat bifurcation aneurysms. The flaw to this design is the ease of insertion into the aneurysm area as the orientation can be difficult to maneuver. In addition, this design is redundant of Full System Design #1, which could possibly be used to treat bifurcation aneurysms as well.

Figure 8: Double balloon used for bifurcation

4.2 Subsystem Concepts

This section illustrates promising stent or balloon designs that could be used in the final balloon-stent endovascular device. The primary focus for each subsystem concept is the geometry.

4.2.1 Subsystem #1: Stent with various porosities

As discovered in the literature review, low stent porosity causes low velocity streamlines. This subsystem shows a stent with various porosities. The team found that it could be beneficial to develop a stent that had a lower porosity in the part that corresponded to the neck of the aneurysm to reduce the risk of embolics traveling downstream. Figure 9 shows an image that highlights where the porosity would vary.

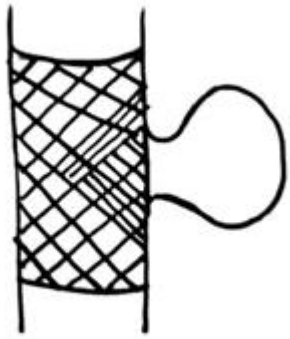


Figure 9: Stent with different porosity levels design

4.2.2 Subsystem #2: Y-shaped balloon

The balloon shown in Figure 10 was specifically meant to benefit bifurcation aneurysms. Bifurcation aneurysms are a type of saccular aneurysms that occur in two or more blood vessels. This concept combined the concept of Y-shaped stents and balloons. This concept provides full coverage and a smooth surface at the aneurysm neck while the physician operates.

Figure 10: Y-shaped assistive balloon design

4.2.3 Subsystem #3: Balloon-inspired plug

The design found in Figure 11 aligns with the concept of a balloon. The idea was to deploy the balloon at the neck of the aneurysm and inflate it to completely isolate the aneurysm from the parent vessel. In simpler terms, the idea is to create a plug for the aneurysm.

Figure 11: Balloon plug design

5 DESIGN SELECTED – First Semester

The following chapter describes the selection process of our final design. Our process involved the qualitative evaluation of our six concept variants to narrow down the top three, followed by a quantitative evaluation of those designs to narrow it down to the final design.

5.1 Technical Selection Criteria

The criteria used for the initial quantitative evaluation of our six concept variants was the customer requirements. To reiterate, the customer requirements are: must be safe on the human body, must prevent occlusion of the parent artery must prevent embolics from travelling downstream, must fit in blood vessel, must block flow into aneurysm, must be maneuverable by surgeons, and must not cause turbulent blood flow. To evaluate how well the concept variants fulfill the CRs, our team implemented a Pugh chart (Figure 12)

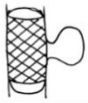
Concept / Criteria	 1	 2	 3	 4	 5	 6
Biocompatible	S	S		S	S	S
Prevents occlusion	+	+		-	-	-
Prevents embolic travel	-	-	D	+	+	-
Protects aneurysm	+	+		-	+	-
Protects parent vessel	S	S	A	-	+	S
Appropriate size	-	S		-	S	S
Isolates aneurysm	S	S	T	S	S	-
User friendly	+	-		-	+	-
Maintains normal blood flow	+	+	U	-	S	-
Cost	-	S		-	+	-
Σ+	**4**	**3**	M	**1**	**5**	**0**
Σ-	**3**	**2**		**7**	**1**	**7**
ΣS	**3**	**5**		**2**	**4**	**3**

Figure 12: Qualitative Pugh Chart

The criteria used to evaluate the remaining designs was the engineering requirements. It should be mentioned that these concepts were evaluated using the engineering requirements from last semester (ME 476C), and a couple of them have been modified since (Table 2). To recap, these engineering requirements were: inflated balloon diameter (mm), deflated balloon diameter (mm), stent minimum diameter (mm), stent wall thickness (mm), device length (mm), Rigidity (unitless), durability (stress-life cycles), friction (unitless), and cost (USD). To evaluate how well the remaining designs correlate to the engineering requirements, our team implemented a decision matrix (Figure 13)

1 = Worst, 10 = Best		Concept 1		Concept 3		Concept 5	
	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Inflated Ballon Diameter	0.0910	9	0.82	9	0.82	9	0.82
Deflated Ballon Diameter	0.1261	7	0.88	7	0.88	4	0.50
Stent Minimum Diameter	0.1541	8	1.23	8	1.23	4	0.62
Stent Wall Thickness	0.1611	8	1.29	8	1.29	4	0.64
Device Length	0.0840	9	0.76	9	0.76	5	0.42
Increase Rigidity	0.1261	7	0.88	9	1.13	2	0.25
Increase Durability	0.1471	3	0.44	5	0.74	5	0.74
Decrease Friction	0.0854	7	0.60	7	0.60	2	0.17
Decrease Cost	0.0252	2	0.05	7	0.18	1	0.03
SUM	1		6.95		7.62		4.19

Figure 13: Quantitative Decision Matrix

5.2 Rationale for Design Selection

The Pugh Chart works qualitatively by scoring better or worst in relation to a datum. The datum chosen was Concept 3, which is similar to the concept described to us by our client, a cylindrical stent within a cylindrical balloon. This was chosen as the datum because it is the design that makes most logical sense and works well with the CRs. However, we still wanted to come up with different, possibly better designs, to evaluate in comparison incase a better one is thought of. Concepts can either be scored better (+), worst (-), or same (S). The scores were then summed up and the results reveal concepts 1, 3 (datum), and 5 as being the top concepts qualitatively.

The decision matrix is used quantitatively by scoring the top concepts on how they fulfill the ERs. The ERs are weighted in the decision matrix based on the absolute technical importance (ATI) values they achieve in the House of Quality diagram (Figure 3).

$$weight_i = \frac{ATI_i}{\sum ATI} \tag{1}$$

The scores each concept receives is weighted accordingly, and the summed up. The results show concepts 1 and 3 having the highest score with scores of 6.95 and 7.62, respectively. From this point on, we will be focusing on the designing for concept 3, the stent within balloon. However, if an issue arises that cause us to switch designs, we will consider concept 1, the stent with varying porosities, as our new design as it is theoretically the next best.

5.3 Prototype – Semester 1

The first prototype of the balloon-stent was printed using the high-resolution photopolymer 3D printer in the Bioengineering Devices Laboratory (BDL). Two assemblies were printed, one scaled up in size 4:1 and another true to the sizes specified in the SolidWorks model. The following Figure 1 contains an isometric exploded view of the 4:1 scaled prototype. The balloon (color white) is made of Agilus30 photopolymer, while the stent (color blue) is made of a slightly stiffer VeroCyan photopolymer. As the prototypes print, they are being encased in a water-soluble support material which must be cleaned off.

This prototype serves as a proof of concept. The final prototype incorporates a scaled up, functioning, woven, nitinol stent, and a modified, 3D printed balloon. While the new balloon prototype can be slightly inflated, it is not a functioning, polyurethane balloon.

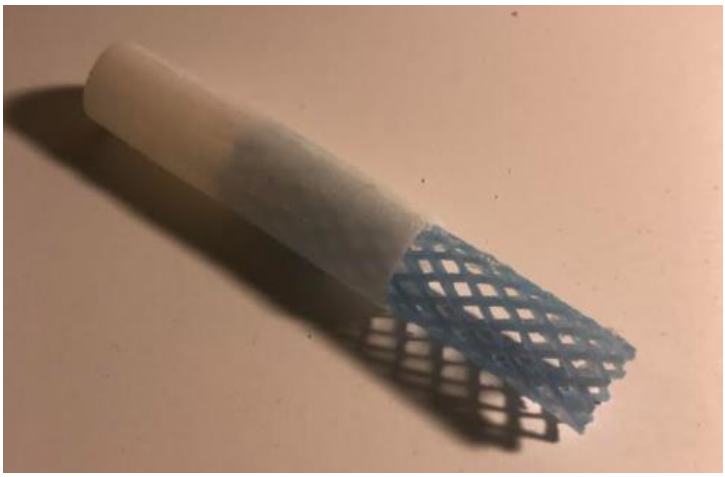


Figure 14: Isometric exploded view of the 4:1 scaled prototype.

6 IMPLEMENTATION – Second Semester

During the second semester the overall design for the balloon-stent stayed the same. The main differences existed in the details of the stent and the balloon, otherwise, the cylindrical stent encased in a cylindrical balloon design remained the same. In terms of the stent, the cylindrical grid design incorporated in last semester's prototype has since been changed to a woven, alternating diamond design (Appendix A). This design increases the flexibility and length capabilities of the stent. Since the design is woven, each connection point is in tact via a weave rather than a solid connection, thus increasing the flexibility. This also allows the stent to compress and stretch as the woven portions are free to move away from each other. In order to make the woven stent, the nitinol was woven around a still jig (Appendix A) consisting of rows of radial pins. Once woven, the stent is heat treated (annealed) to a temperature of 500°C for an hour, then quenched to reset the nitinol's shape memory. Once this is complete, the pegs can be removed from the jig so that the stent can be taken off. Now that the stent has been heat treated, elastic deformation can be reversed by heating the stent to its activation temperature of 35°C. The balloon design shape remained as a cylinder, but due to the complexity of the manufacturing process expected (dip molding), the balloon model was 3D printed with Adulus 30 photopolymer for demonstration purposes. The CAD was adjusted to have an entry for the microcatheter lumen, fileted edges, and a greater thickness to improve the 3D print. The final prototype can be found in Figure 15.

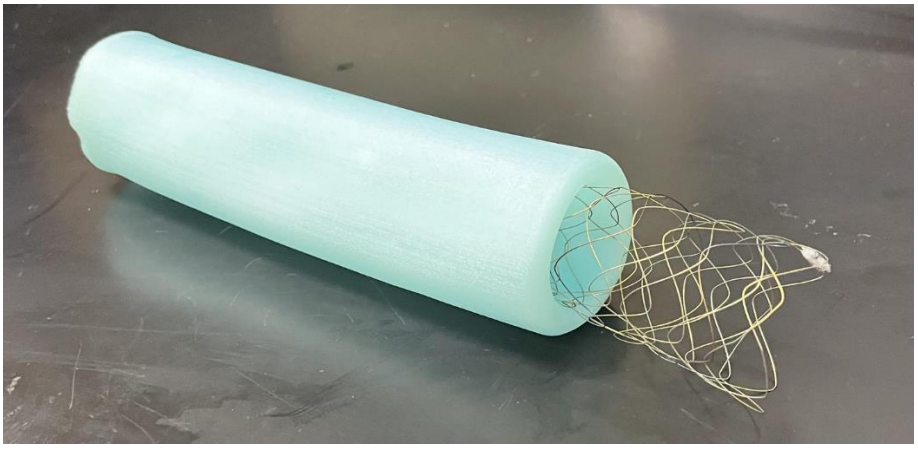


Figure 15: Isometric exploded view of the 7.33:1 final prototype

7 RISK ANALYSIS AND MITIGATION

This section will discuss the risk analysis of the device. Establishing potential failures methods helps the team prevent failure of the device before it occurs. In specific to this capstone project, the medical device directly affects patients' health and physicians' liability. The success of the device depends on the physicians' faith in the device.

7.1 Potential Failures Identified First Semester

To date, the team has considered three subcomponents of the device to evaluate. The components in consideration include the: balloon, stent, and microcatheter. While the design components only consist of the balloon and the stent, the microcatheter enables the placement of the device.

7.1.1 Potential Critical Failure 1: Stress corrosion on the balloon

Shear force caused by blood can possible cause the corrosion of the balloon-stent, however it is unlikely that this could occur during the 15-minute surgery.

7.1.2 Potential Critical Failure 2: Over inflation of the balloon

Over inflation of the balloon can cause it to rupture, which in turn caused the failure of the surgery and the possible release of embolics into the blood stream. This risk can be mitigated with automated balloon inflating as to make sure the maximum inflation point is not reached.

7.1.3 Potential Critical Failure 3: Low cycle fatigue on the balloon-stent

Caused by the balloon-stent being over-used, will likely not be an issue if a new balloon-stent is used after each operation.

7.2 Potential Failures Identified This Semester

7.2.1 Potential Critical Failure 1: Kinking in the stent

Kinking in the stent causes permanent deformation that may cause the stent to collapse. This potential critical failure poses a threat to the patient and the physician. If the stent does not behave as expected, the risk of morbidity and mortality is increased for the patient due to the lack of oxygen supplied to the brain. If kinking occurs due to the physician using the device incorrectly, they could potentially face lawsuits in the case of extreme situations where the patient is harmed.

7.3 Risk Mitigation

The risk mitigation process followed for this semester involved not deforming the stent too much or exposing it to the activation temperature too often prior to testing the compression strength. The team wanted to make sure that the data collected was consistent and not affected by a kinking defect.

8 ER Proofs

This section discusses the process of evaluating each engineering requirement for the balloon-stent device. The results of the experimental and analytical methods used are explained and related to the requirements to determine the validity of the device.

8.1 ER Proof #1 – Stent Radial Compression Force

8.1.1 ER #1: Radial compressive strength - Target = 3 ± 0.5 N

The radial compression force is an important aspect of the design. Since the stent serves to provide addition scaffolding to maximize the inner diameter of the balloon-stent, it must be able to exert enough radial force. Additionally, the radial force should increase as a function of temperature due to the nitinol's urge to return to its memorized state. Target value is obtained from relevant literature regarding stent flat plate compression [3].

8.1.2 Testing Procedure

To test the radial compression strength of the stent we conducted a flat plate compression test using a rheometer in the Bioengineering Devices Laboratory. The stent prototype (diameter of 26 mm, scaled up by a factor of 7.33) was submerged in a bath of three different temperatures to see how the self-expansion affects the force. The diameter was slowly compressed at a rate of 100 μm/s until a gap of 2 mm remained between the compression plate and the bottom surface. It should be mentioned that the industry standard radial strength tests for stents are conducted using a specialized radial strength tester [4] that applies force along the entire circumference of the stent, which we unfortunately do not have access to. However, we can expect to obtain values comparable to this using the flat plate compression method at a high deformation. Furthermore, by using the rheometer we can examine the effects that temperature has on radial compression strength.

8.1.3 Testing Results

Figure 16 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°C) condition, the maximum force exerted by the stent (compressed to gap of 2 mm) was 2.79 N. For the activation temperature condition (35°C), the maximum force exerted by the stent was 3.08 N. For the higher temperature condition (45°C), the maximum force exerted by the stent was 4.56 N. Within a temperature difference 10°C above the activation temperature, the strength of the stent increased by 67.5%. Since the stent would be deployed in the body, the nitinol used in the actual product would have an activation temperature at body heat (~37°C). The data shows that at activation temperature, the radial compression strength is 3.08 N, which falls within the target value tolerance range.

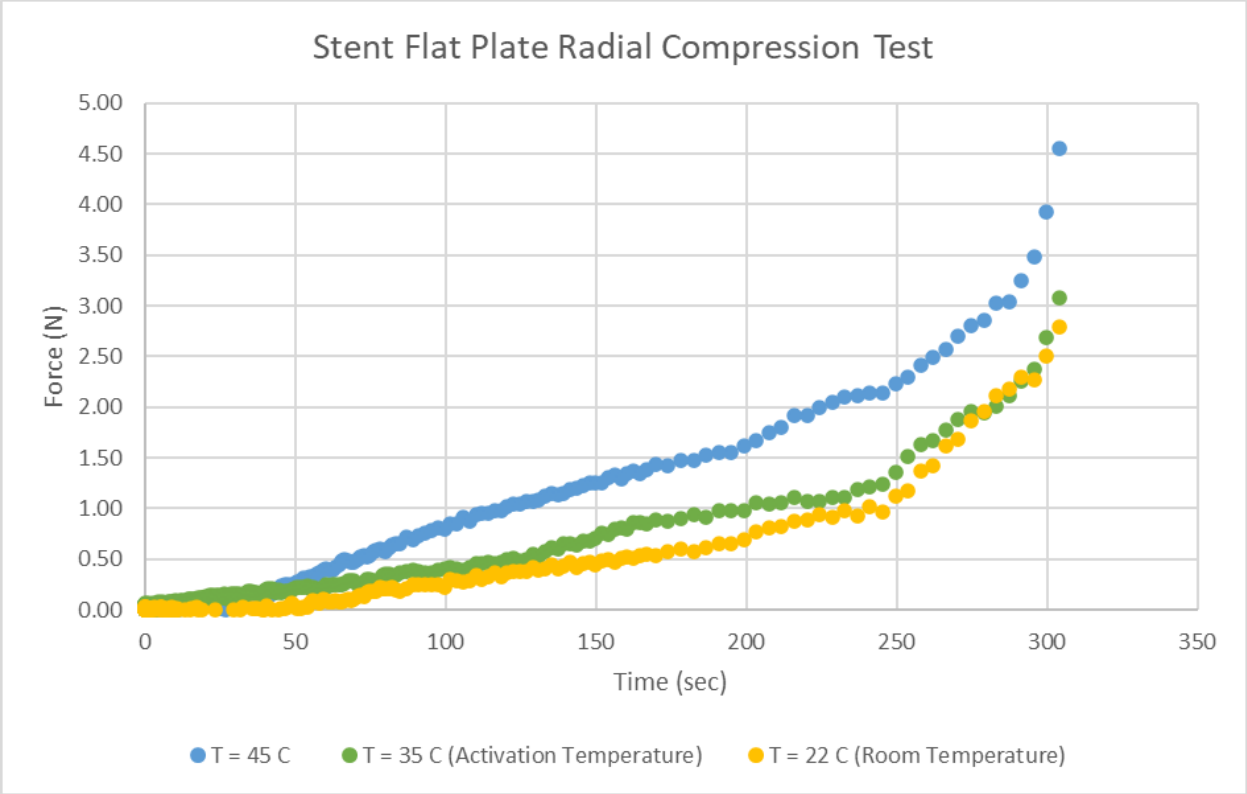


Figure 16: Results of the stent flat plate radial compression test. Data taken until a clearance of 2 mm is reached.

8.2 ER Proof #2 – Stent minimum outer diameter (relaxed)

8.2.1 ER #2: Relaxed diameter of stent - Target = 3.6 ± 0.3 mm

The minimum outer diameter of the stent corresponds to the diameter when the stent is in its relaxed state prior to being at activation temperature. This value is important because it must be small enough to fit within the balloon's inner diameter but large enough so that it fits snugly and is able to transfer force to the inner walls of the balloon. The target value is calculated based on the geometry of the device.

8.2.2 Testing Procedure

To test whether this engineering requirement is satisfied, the diameter of the stent prototype is measured using calipers. The measurement is then adjusted to correspond to the actual scale of the device.

8.2.3 Testing Results

Figure 17 shows an image of the stent prototype's relaxed diameter being measured with calipers. The measurement obtained is 26.39 mm, which translates to 3.60 mm if the prototype was to scale, thus satisfying the engineering requirement's target value.

Figure 17: caliper measurement of stent prototype diameter.

8.3 ER Proof #3 – Fractional Flow Reserve (FFR)

8.3.1 ER #3: Fractional Flow Reserve- Target ≥ 0.75

The FFR is the ratio comparing the blood flow through an area of stenosis to the normal blood vessel. The device must allow a minimum of 75% of the normal blood flow to pass through it in order to reduce the risks of ischemia [9]. The FFR also ensures that the patient receives enough oxygen in the brain reducing the risk of mortality and morbidity. This engineering requirement is important because it proves that the device is safe to use.

8.3.2 Analytical Procedure

A Computational Fluid Dynamics (CFD) was performed, using *SimVascular*, on a simple CAD model to determine the pressure across the balloon-stent device. This was accomplished by creating a mesh of 0.03 mm globally, and 0.01 mm in the focal area. The smaller mesh size is intended to produce more accurate results. The meshes are shown in figure 18 and figure 19. Once the meshing was completed, a simulation job was run for 60,000 time-steps to approximate a solution using Navier-Stokes equations. According to the *SimVascular* simulation guide, the nonlinear residual should be smaller than 0.001 to ensure that the solution is accurate. This was verified by examining the data shown in figure 20, where the first column shows the time-step and the third column shows the value of the nonlinear residual. The results were then converted to the last, and most accurate cycle, from time-steps 40,000 to 60,000. The meshed model and converted results were exported to *ParaView* to analyze the solution. The pressures of blood flow with respect to time were then exported to Excel to calculate the FFR using equation 2, where P is the average pressure.

$$FFR = \frac{P_{distal}}{P_{proximal}} \quad (2)$$

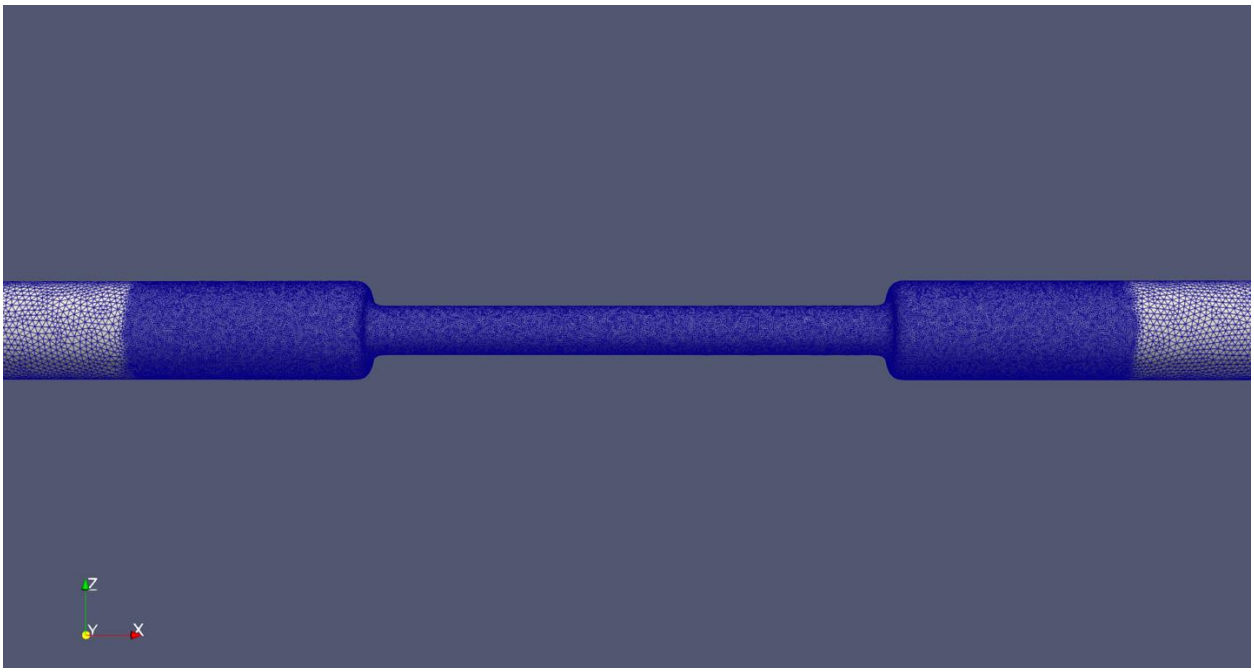


Figure 18: Mesh variation along a simple model representing stenosis.

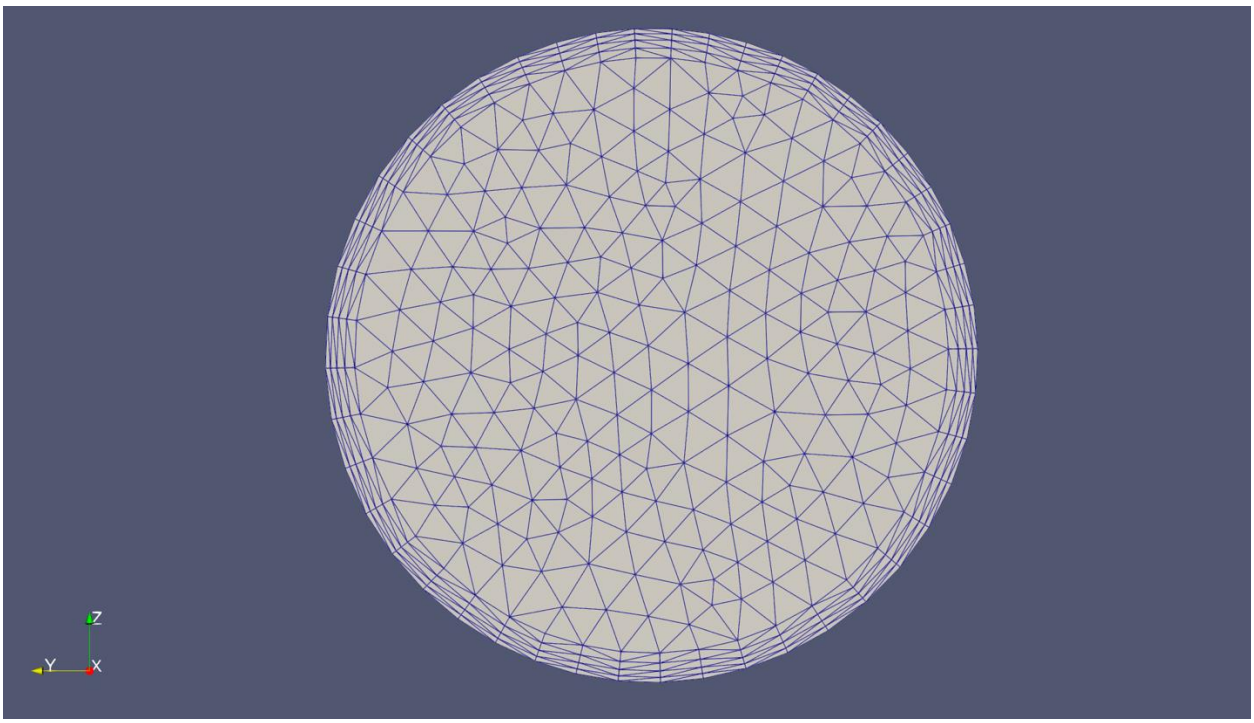


Figure 19: Sectional mesh including four boundary layers.

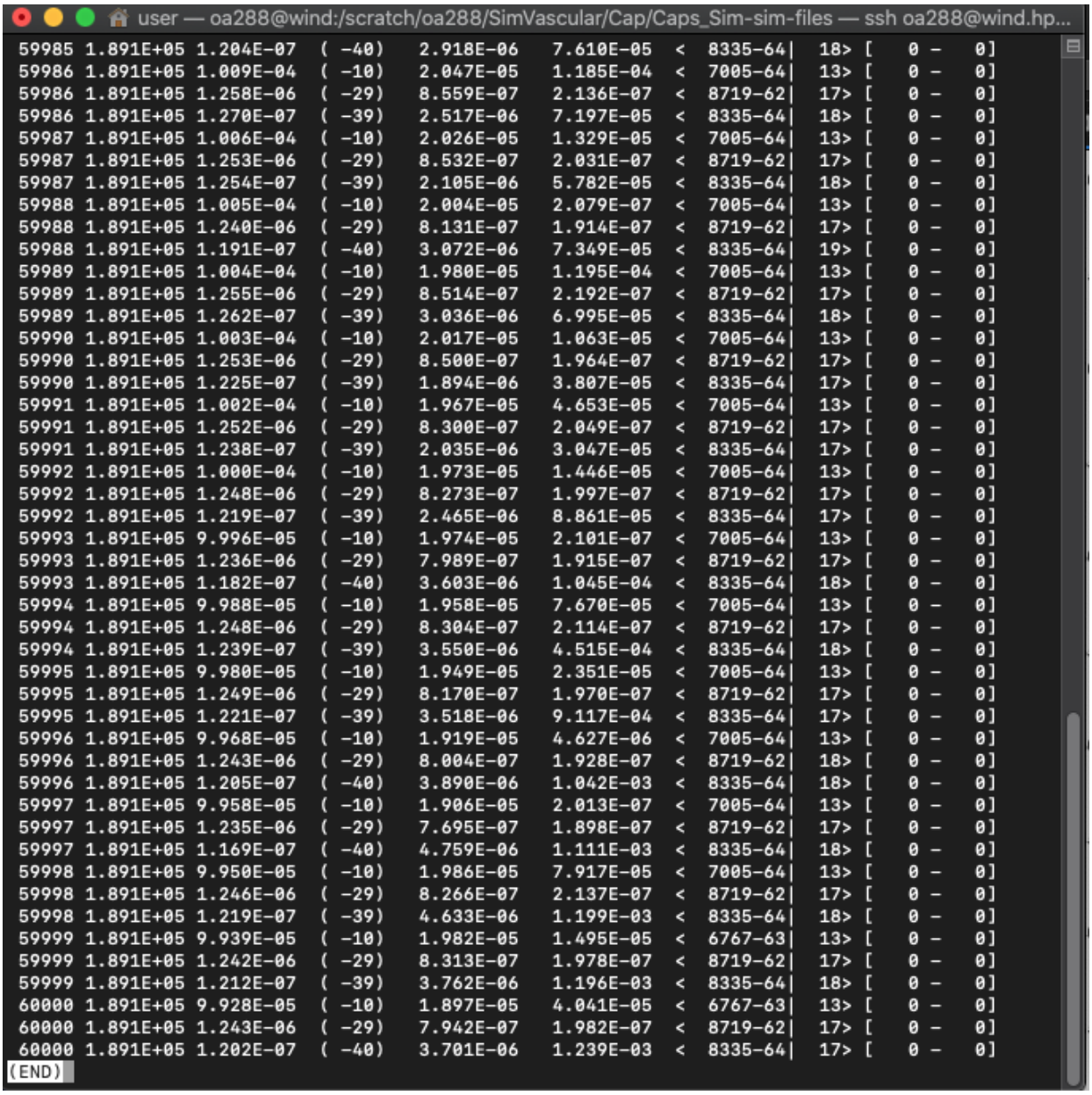


Figure 20: Simulation details used to verify the accuracy of the solution.

8.3.3 Analytical Results

Through the CFD procedure mentioned previously, the pressure across the model was determined. Table 4 shows the average pressures at the inlet, center, and the outlet of the model.

Table 4: Resulting pressure throughout the model from CFD approach.

Average Pressure (mmHg)		
Inlet	Center	Outlet
90.71	92.55	99.53

From these inlet and outlet pressures, the FFR was calculated using equation 1, and resulted in 0.91 which satisfies the FFR requirement as it is greater than 0.75. However, there are limitations to this approach as the viscosity of the blood, microcatheter interference, and pulsatile flow are not accounted for. Figure 21 provides a better visualization of the pressure results obtained from the CFD.

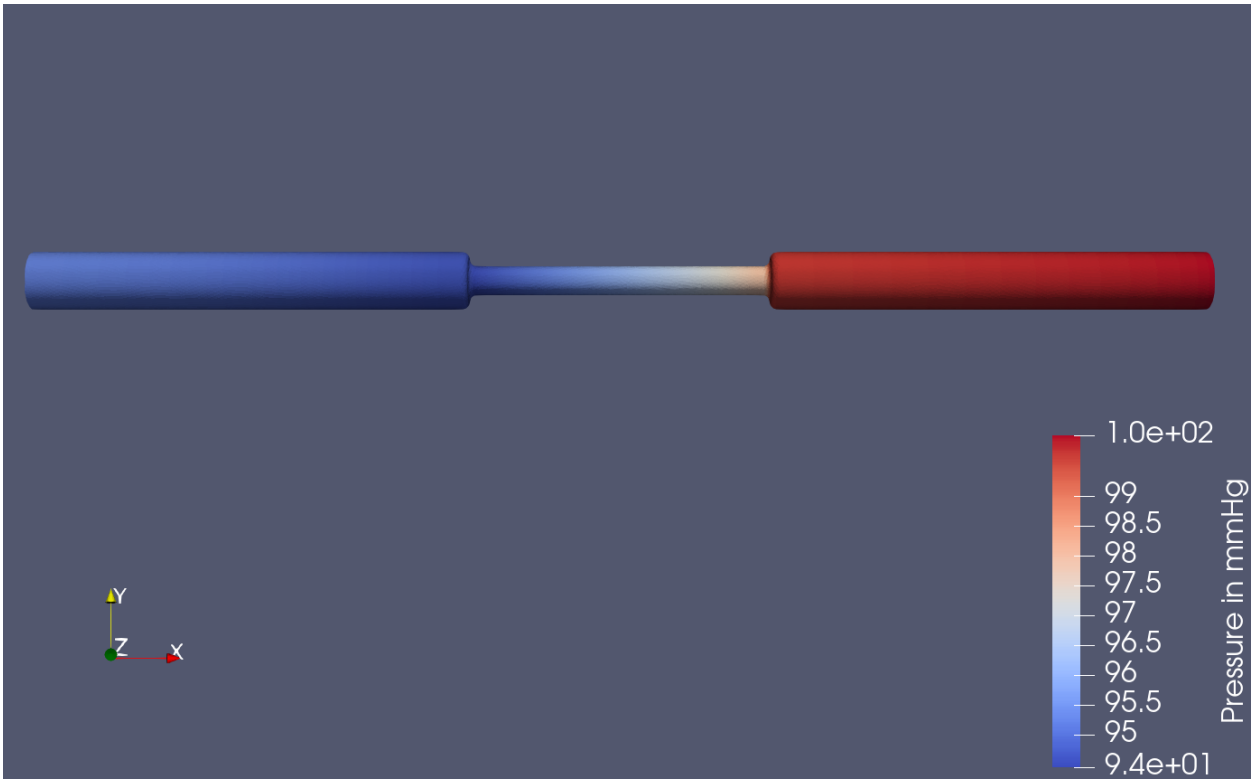


Figure 21: Pressure, in mmHg, across the model.

8.4 ER Proof #4 – Durability

8.4.1 ER #4: Functioning lifespan – Target= 15 ± 5 min

The functional durability of the balloon-stent device must be sufficient to withstand the approximate time frame of an endovascular aneurysm surgery, which is approximately 15 minutes. The durability of the device would be constrained to one use per device, as each operation would implement a new balloon-stent.

8.4.2 Testing Procedure

Since our prototype does not incorporate a functioning polyurethane balloon, the stent will be the focus of this durability test. However, we can assume that a medical grade, polyurethane balloon would be able to function for the targeted period of time. The testing procedure for this requirement involves measuring the total time that the stent is subjected to the radial compression force used to test ER #1. Since the radial compression force deforms the stent significantly (from 26 mm to 2 mm), we assume that the stent experiences sufficient force to accurately assess whether it can withstand the targeted functioning lifespan.

8.4.3 Testing Results

Referring back to Figure 1, it can be observed that the total time for each test was approximately 300 seconds, or five minutes. Considering that the stent was subjected to three of these tests, the stent was able to function of approximately 15 minutes, which meets the targeted value. This would be the stent's minimum functioning lifespan, as it was not tested until failure.

8.5 ER Proof #5 – Inflated balloon diameter

8.5.1 ER #5: Inflated diameter of balloon - Target = 4 ± 0.2 mm

The inflated balloon diameter corresponds to its outer diameter if it were inflated. The target value is set assuming the aneurysm is located in an artery of 4 mm. While we want the balloon to expand to the diameter of the artery, we do not want it to cause any vessel trauma, therefore the tolerance is set to be comparatively small.

8.5.2 Testing Procedure

To test whether this engineering requirement is satisfied, the diameter of the balloon prototype is measured using calipers. The balloon prototype is 3D printed at the geometry as if it were inflated. The measurement is then adjusted to correspond to the actual scale of the device.

8.5.3 Testing Results

Figure 22 shows an image of the balloon prototype's diameter being measured with calipers. The measurement obtained is 31.73 mm, which translates to 4.32 mm if the prototype was to scale. This value slightly exceeds the targeted tolerance, therefor the engineering requirement is not quite met. Future versions of the balloon will have adjusted geometry so that this requirement can be satisfied.

Figure 22: Caliper measurement of balloon prototype diameter.

8.6 ER Proof #6 – Inflated balloon thickness

8.6.1 ER #6: Inflated thickness of balloon - Target = 0.1 ± 0.02 mm

The wall thickness of the balloon is relevant as there are space constraints foreseen due to the size of the blood vessels within the cranium. To cover minimal radial space, the balloon should be as thin as the polyurethane allows. However, the balloon should not be so thin that it would damage the compliance of the balloon. In the case that the balloon ruptures, the main concern would be that the polyurethane travels into different areas of the body which would cause the patient to experience further complications.

8.6.2 Testing Procedure

To test whether this engineering requirement is satisfied, the thickness of the balloon prototype is measured using calipers. The balloon prototype is 3D printed at the geometry as if it were inflated. The measurement is then adjusted to correspond to the actual scale of the device.

8.6.3 Testing Results

Figure 23 shows an image of the balloon prototype's wall thickness being measured with calipers. The measurement obtained is 2.74 mm, which translates to 0.37 mm if the prototype was to scale. This value slightly exceeds the targeted tolerance, therefor the engineering requirement is not quite met. Future versions of the balloon will have adjusted geometry so that this requirement can be satisfied.

Figure 23: Caliper measurement of balloon prototype wall thickness.

8.7 ER Proof #7 – Young's Modulus of Stent

8.7.1 ER #7: Modulus of Elasticity - Target = 28 ± 5 GPa

The modulus of elasticity of the stent material, nitinol, needs to be sufficient to withstand any forces that might cause the material to experience plastic deformation. This is particularly important when the stent is to be deployed by the microcatheter, as it needs to return to its original shape/diameter to function properly. The modulus of elasticity for a typical nitinol alloy is 28 GPa [5], which makes that the target value. Since the nitinol was heat treated at 500°C, it was shifted to the martensite range, making the modulus of elasticity slightly increase. While this martensite modulus could not be measured as it would ruin the stent, it was still able to withstand the compression testes without experiencing any plastic deformation. Further analysis would be required to determine which exact modulus would allow the stent to transition to and from the microcatheter without risk of failure.

8.8 ER Proof #8 – Friction

8.8.1 ER #8: Coefficient of friction of balloon - Target = 1 ± 0.5

The engineering requirement for friction relies on the coefficient of friction, μ, of the balloon and the pressure at which the balloon is inflated. The balloon must exert enough normal force, N, on the vessel wall to keep the device in place while withstanding the oncoming flow of blood. Target value is based on common friction factors of polyurethane materials.

8.8.2 Analytical Procedure

Since the balloon prototype is non-functioning, an analytical analysis is conducted instead. While we still don't know the exact friction factor of the polyurethane material the balloon would be made of, we do know a range of friction factors for that material [6]. Similarly, we do not know the exact pressure the balloon would be inflated to, but we do know a range of pressures common for medical balloons [7]. This analytical analysis aims to determine the force of friction (Equation 3) for different friction factors and pressures. By analyzing this, we can determine how the friction factor affects the force of friction and decide which pressure would be sufficient considering the target value of 1. This analysis was conducted on MATLAB and the full code can be found in the Appendix.

$$f = \mu N \tag{3}$$

8.8.3 Analytical Results

Figure 24 shows the plotted results of this analytical analysis. The plot represents how the frictional force changes as a function of the balloon pressure for different coefficients of friction. It can be observed these plots follow a positive, linear trend, with higher friction factors resulting in more frictional force.
The magnitude of frictional force must exceed the arterial force of blood flow for the device to stay in place. Say, for example, a patient has a common mean arterial blood pressure of 80 mmHg [8]. This would mean that blood is exerting 0.40 N of force against the thickness of the balloon. If the balloon's coefficient of friction equals its targeted value of 1, then the device should have no problem staying in place. At the minimum pressure value of 30 psi, the balloon exerts a frictional force of 51.98 N, which exceeds the value of force due to the arterial pressure. This tells us that a polyurethane balloon with a friction factor of 1 inflated at 30 psi can withstand the flow of blood.

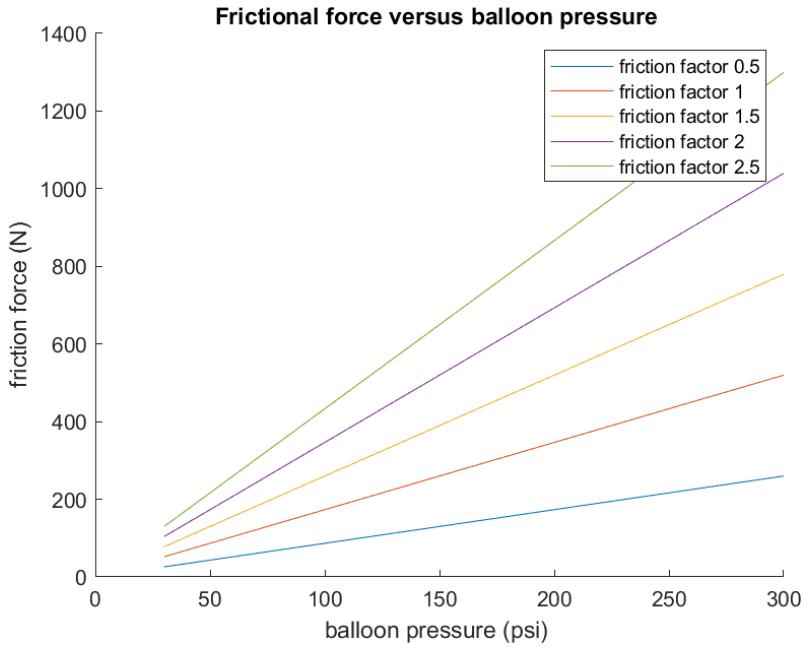


Figure 24: Analytical results for frictional force as a function of pressure for various coefficients of friction.

8.9 ER Proof #9 – Device Length

8.9.1 ER #9: Total length of device - Target = 20 ± 10 mm

The targeted value of the length of the device comes directly from the client proposal, which is stated to be 20 mm. This device length would allow the surgeon to deploy the balloon-stent with ease in the case of a typical aneurysm and would be long enough to completely occlude blood flow into the aneurysm, while still maintain an FPR > 0.75. The tolerance stated considers multiple aneurysm neck sizes. An aneurysm with a large next might need a longer balloon-stent to completely prevent blood from flowing inside it. Similarly, an aneurysm with a small neck would not need as long of a device. Additionally, a longer device could also accommodate for non-ideal or bifurcation aneurysm shapes.

8.9.2 Testing Procedure

To test whether this engineering requirement is satisfied, the length of the balloon-stent prototype is measured using calipers. The measurement is then adjusted to correspond to the actual scale of the device.

8.9.3 Testing Results

Figure 25 shows an image of the balloon prototype's diameter being measured with calipers. The measurement obtained is 146.15 mm, which translates to 19.93 mm if the prototype was to scale, thus satisfying the engineering requirement's target value.

Figure 25: Caliper measurement of balloon-stent prototype length.

8.10 ER Proof #10 – Cost

8.10.1 ER #10: Cost under $2000 - Target = $1,750 ± 250

The targeted value for the cost comes from the client specified budget of this project. Since the team is to keep costs under $2,000, a targeted budget of $1,750 with a tolerance of ± $250 is specified for our cost engineering requirement to ensure that the budget is not accidentally exceeded. Our final state of the budget reflects a total amount of $350.13 spent, resulting in a remaining budget of $1399.87 if subtracted form the target value, thus satisfying the requirement.

9 LOOKING FORWARD

Over the course of this project we have designed, analyzed, and testing important aspects of the balloon stent. However, since the final prototype is not functional, additional work must be done so that the device can function in an in-vitro blood flow environment, then FDA approved and put on the market. Future iterations of this design will require a modified manufacturing process to make the balloon-stent at it's designed scale. This process, particularly for weaving the stent, is likely to require a computer automated method in order to achieve a fine enough mesh size. In terms of the balloon, its design will need to be produced by a medical balloon manufacturer so that it can be compatible with the stent.

9.1 Future Testing Procedures

The following sub sections contain future testing procedures for the balloon-stent. These tests could not be implemented this semester as they exceed the capabilities of the testing resources provided to us. Additionally, some testing can only be conducted once the balloon stent is completely functioning.

9.1.1 Testing Procedure 1: Industry Standard Stent Radial Force

9.1.1.1 Testing Procedure 1: Objective

The objective of this test would be to implement the industry standard radial test on the stent prototype. This test would be conducted using the MSI RX550/650 radial expansion force gage [14]. Testing will be done at different temperatures with varying mesh sizes to inform the design of an optimal stent. The optimal stent would exert just enough radial force on the inner diameter of the balloon the maintain sufficient blood flow, while not applying too much radial force to cause vessel trauma.

9.1.1.2 Testing Procedure 1: Resources Required

This test will require the use of the MSI RX550/650 radial expansion force gage. If the BDL were to purchase this device, it could serve as a valuable piece of equipment to test radial strength. Otherwise, one could collaborate with Machine Solutions Inc., the manufacture of the MSI RX550/650, to use their equipment to run tests on the stents, as they are located in Flagstaff, Arizona.

9.1.1.3 Testing Procedure 1: Schedule

This testing could take place as soon as next semester, assuming that a future capstone group can continue where we left off. It can begin as soon as multiple stents are produced using jigs with different amounts of pegs to vary the mesh size. This might require some time, but once an appropriate jig is manufactured, it should not take long to weave the nitinol around it if the scaling is large enough. The anticipated date for this testing could be as early as March 2021, and is likely to occupy at most one day of testing per stent variation.

9.2 Future Work

One of the main hurdles that must be faced to produce a functioning balloon stent is manufacturing the device to scale. This would allow it to be implemented in an in-vitro aneurysm model, where the deployment process can be perfected to then potentially be implemented in clinical trials. In terms of the stent, the jig should be modified so that it can be manufactured by a high precision, automated program. The modified jig should consist of vertical beams with rows of pegs arranged in a circle, rather than a solid cylinder with rows of pegs. This would allow the stent to be easily woven, as the cylinder is not obstructing the nitinol when it has to pass under the row above it. Once the weave is complete, it can be heat treated, and the vertical pegs can be easily removed to free the stent from the jig. The future work for

the balloon involves prototyping a polyurethane balloon through a dip molding manufacturing process. This would allow us to observe the behavior of the material. Additionally, testing on the balloon and system would help evaluate the validity of the design even further.

10 CONCLUSIONS

The purpose of this capstone project was to design, analyze, and prototype a balloon-stent device that would assist physicians upon the delivery of endovascular treatment for intracranial aneurysms. The design of the device was accomplished by following the iterative engineering design process. First, the team gathered research to identify the problem, and current state-of-the-art devices. Then, the customer and engineering requirements were set to have a clear understanding of the capabilities of the device. The design process involved generating potential solutions to the problem, and evaluating the concepts with the requirements. The optimal solution was the balloon-stent design where a self-expanding, nitinol stent would be encapsulated by a cylindrical, polyurethane balloon. The balloon component, which served for demonstration purposes, was prototyped by 3D printing a scaled-up model with an Adulus 30 photopolymer. The scaled stent prototype consisted of hand weaving nitinol around a jig, and then heat treating it. The validity of the balloon-stent device was analyzed using experimental and numerical methods. Through experiment, it was found that the stent would exert greater forces when heated to or above the activation temperature. This proves that the stent is self-expanding, and would serve its main purpose of scaffolding. Through analytical methods, it was found that the necessary blood flow was maintained in the parent artery. While the team was able to accomplish the project requirements, the quality of the product was not as expected. The limitations of the balloon-stent device mostly occurred due to the lack of knowledge in the biomedical field, lack of resources, and time constraints.

10.1 Reflection

The balloon-stent device intends to improve quality of life through innovation. The device demonstrates the consideration of public health because it is meant to be used to treat unruptured, intracranial aneurysms which reduces the risk of morbidity and mortality. The team prioritized safety by establishing requirements to protect patients, and by using existing materials that have been deemed biocompatible. Additionally, this device aims to improve the efficiency of minimally-invasive endovascular procedures that are more cost efficient than surgical treatments. Encouraging endovascular methods helps those that struggle to receive proper healthcare due to their economic status.

The main contributor to the project success was communication and respect among team members. The team was able to communicate effectively to address ownership of sections in assignments, make team decisions, and collaborate. Upon communicating, team members were active listeners, and treated each other with respect. This made it possible to focus on the work that had to be accomplished rather than solving team issues.

11 REFERENCES

[1] “Www.scopus.com.” [Online]. Available: https://www.scopus.com/record/display.uri?eid=2-s2.0-0022011065&origin=recordpage. [Accessed: 01-Dec-2021].

[2] A. Manhas et al., "Comprehensive Overview of Contemporary Management Strategies for Cerebral Aneurysms," in *World Neurosurgery*, Oct. 2015. [Online].

[3] “Statistics and Facts,” *Brain Aneurysm Foundation*, 17-Nov-2020. [Online]. Available: https://bafound.org/about-brain-aneurysms/brain-aneurysm-basics/brain-aneurysm-statistics-and-facts/. [Accessed: 05-Feb-2021].

[4] S. Kieffer, “Endovascular Coiling for Brain Aneurysms: Treatment: Johns Hopkins Aneurysm Center,” *Treatment | Johns Hopkins Aneurysm Center*, 08-Dec-2017. [Online]. Available: https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/aneurysm/treatment/aneurysm_endovascular_coiling.html. [Accessed: 01-Mar-2021].

[5] J. Inoue, A. Shiraishi, A. Yoshiyuki, K. Haruta, H. Matsui, and Y. Otomo, “Resuscitative endovascular balloon occlusion of the aorta might be dangerous in patients with severe torso trauma,” *Journal of Trauma and Acute Care Surgery*, vol. 80, no. 4, pp. 559–567, 2016.

[6] M. S. Park, P. Taussky, F. C. Albuquerque, and C. G. McDougall, *Flow diversion of cerebral aneurysms*. New York: Thieme, 2018.

[7] A. Bose, M. Hartmann, H. Henkes, H. M. Liu, M. Teng, and I. Szikora, “A Novel, Self-Expanding, Nitinol Stent in Medically Refractory Intracranial Atherosclerotic Stenoses : The Wingspan Study,” *Stroke*, vol. 38, no. 5, Nov. 2006.

[8] “FDA Executive Summary General Issues: Meeting to Discuss the Evaluation of Safety and Effectiveness of Endovascular Medical Devices Intended to Treat Intracranial Aneurysms,” *FDA.gov*. [Online]. Available: https://www.fda.gov/media/111329/download.

[9] B. J. Sudhir, G. Menon, J. B. Reddy, T. Jayachandran, H. K. Jha, and C. Kesavadas, “The Big Bang Theory of Intracranial Aneurysm Rupture: Gazing Through the Computational Fluid Dynamics Telescope,” *2018 International Conference on Intelligent Informatics and Biomedical Sciences (ICIIBMS)*, 2018.

[10] C.-ho Yu, S. Shida, K. Mmatsumoto, D.-J. Kim, and M. Ohta, “EXPERIMENTAL HEMODYNAMIC STUDY WITH SEVERAL STENTS IN CEREBRAL ANEURYSM MODEL USING PIV,” *Nano-Biomedical Engineering 2012*, Oct. 2012.

[11] Medtronic, “Pipeline Flex - Aneurysm Treatment Products,” *Medtronic*. [Online]. Available: https://www.medtronic.com/us-en/healthcare-

professionals/products/neurological/aneurysm-treatment/pipeline.html. [Accessed: 28-Feb-2021].

[12] Center for Devices and Radiological Health, "Woven EndoBridge (WEB) Aneurysm Embolization System - P170032," *U.S. Food and Drug Administration*, 28-Jan-2019. [Online]. Available: https://www.fda.gov/medical-devices/recently-approved-devices/woven-endobridge-web-aneurysm-embolization-system-p170032. [Accessed: 28-Feb-2021].

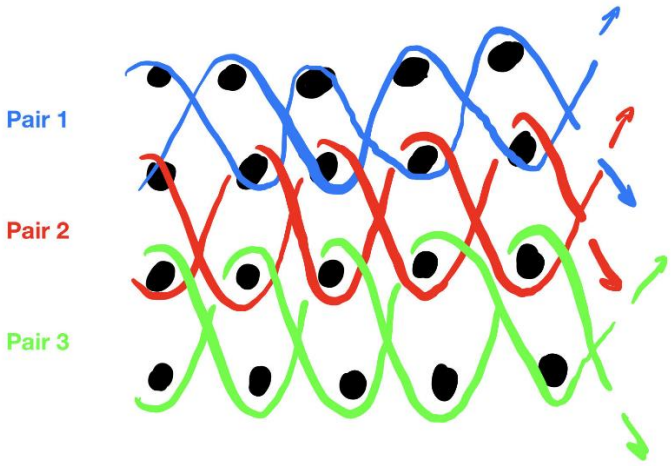
[13] "MicroVention," *Microvention*. [Online]. Available: https://www.microvention.com/product/scepter. [Accessed: 01-Mar-2021].

[14] M. S. I. Equipment, "Balloon stent catheter - dry radial force testing equipment," *MSI*, 05-Jun-2020. [Online]. Available: https://msi.equipment/product/rx550rx650/. [Accessed: 15-Nov-2021].

12 APPENDICES

12.1 Appendix A: - Stent Weave Details

Weave pattern-



Jig –

Stent –