Balloon-Stent Endovascular Device for the Treatment of Intracranial Aneurysms

Preliminary Proposal

Team Number: 21Spr02

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2021

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DISCLAIMER

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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 [7]. 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 (BDL) 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.

2 REQUIREMENTS

As the purpose of this device is to treat 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 surgeon or a medical clinic. The requirements were set based on research and discussion with our client. The most important CRs are weighted the highest, and for the balloon-stent these are: must be safe on the human body, must prevent occlusion of the parent artery (to avoid brain ischemia), must prevent embolics from travelling downstream (can cause clotting outside of aneurysm), must fit in blood vessel, must block flow into aneurysm (to allow surgeon to embolize blood in aneurysm), must be maneuverable by surgeons, and must not cause turbulent blood flow (can cause clots in the parent artery). These CRs were weighted on a scale of 1 to 5 as a 5. While this is a large number of requirements weighted as a 5, they are all critical to the success of the surgery and safety of the patient. Additional, less crucial, requirements are: must have a smooth surface at the neck of the aneurysm, and must be within budget. All the nine CRs and their respective weights can be found on the House of Quality diagram in Figure 1.

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. The requirements formulated for the balloon-stent device are: 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). These ERs can also be found on Figure 1.

2.3 House of Quality (HoQ)

The House of Quality diagram (Figure 1) is a design approach that relates CRs to each ER; by doing this, we are able to rank the technical importance of each engineering requirement. Observe that the most important ER is the stent wall thickness (mm). This is due to the stent wall thickness 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 wall thickness 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.

Customer Requirement	**Weight**	**Engineering Requirement**	Balloon diameter- inflated (mm)	Balloon diameter- deflated (mm)	Stent minimum diameter (mm)	Stent wall thickness (mm)	Device length (mm)	Rigidity, Young's Modulus (unitless)	Durability (functioning life span)(min)	Friction (unitless)	Cost (USD)
1. Must be safe to use on the human body	5					1			9		
2. Must prevent occlusion of the parent artery	5		9		9	1		9	3		
3. Must prevent embolics from traveling downstream	5		1		1					9	
4. Must have a smooth surface at the neck	2									3	
5. Must fit in the blood vessel	5		3	9	9	9	3				
6. Must block blood flow into aneurysm	5				3	3				1	
7. Must allow surgeons to deploy and maneuver the device	5			9			9	9	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	90	110	115	60	90	105	61	18
Relative Technical Importance (RTI)			5	4	2	1	7	4	3	6	8
Target ER values			**3**	**0.4**	**1**	**0.05**	**25**	**200**	**15**	**3**	**2000**
Tolerances of ERs			**± 2**	± 0.2	(+) 5	(+) 0.3	± 10	± 20	± 5	± 1	± 1000
Testing Procedure (TP#)	N/A										

Figure 1: House of Quality

3 DESIGN SPACE RESEARCH

To get us familiar with the details of endovascular surgery and aneurysm treatments, which are biology heavy subjects, we had to conduct research. The following chapter highlights relevant sources used in our research, as well as the benchmarking process we used.

3.1 Literature Review

This section summarizes the information gained through independent research of each team member. The research helped the team gain a better understanding of the diagnosis of brain aneurysms, flow within and around the aneurysms, and existing devices used in treatment. The findings were used in the benchmarking and concept generation process.

3.1.1 Student 1 (Danny 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 [13]. 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 [12]. 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* [8]. 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* [9]. 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* [1]. 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 Student 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 [6]. 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 [6]. 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 [6]. 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 [3]. 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 [4].

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 [10], the Woven EndoBridge [5], and the Scepter-XC [11].

3.2.1.1 Existing Design #1: Pipeline Flex

The Pipeline Flex (Figure 2) 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 [10]. 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 2: Pipeline Flex within a parent artery

3.2.1.2 Existing Design #2: Woven EndoBridge

The Woven EndoBridge (WEB) (Figure 3) 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 [5]. 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 3: Woven EndoBridge device

3.2.1.3 Existing Design #3: Scepter-XC

The Scepter-XC (Figure 4) 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 [11]. 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 [8]. 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.

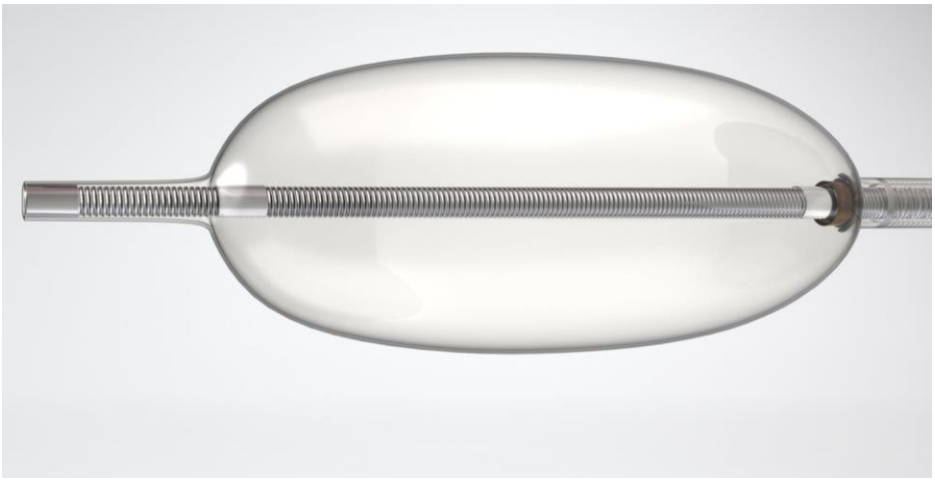


Figure 4: Scepter XC balloon

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.

3.3 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.

3.3.1 Black Box Model

The purpose of the black 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 5 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 5: Black box diagram

3.3.2 Functional Model/Work-Process Diagram/Hierarchical Task Analysis

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 6 shows the functional model. The team benefits from this diagram as it provides a more detailed description of the project objectives.

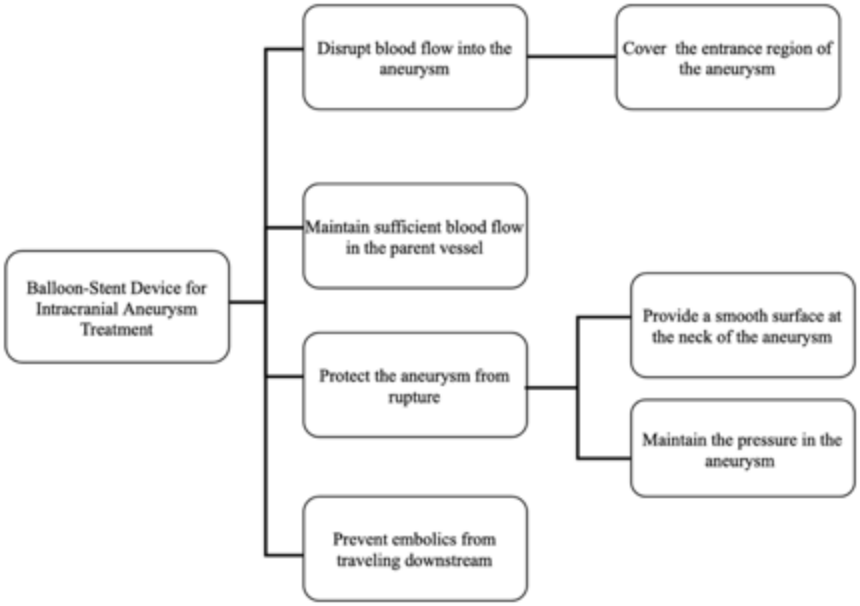


Figure 6: Function decomposition diagram

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 both essentially composed of the hybrids of the existing sub functional existing 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.

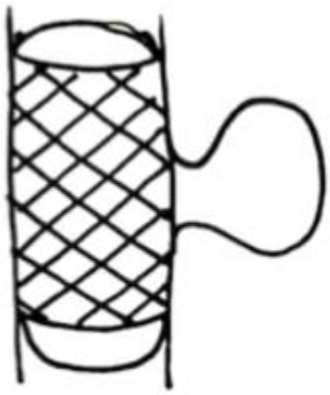


Figure 7:

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:

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.

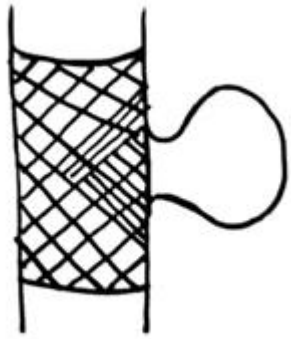


Figure 9: Stent with different porosity levels design

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 DESIGNS SELECTED

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 CNs, our team implemented a Pugh chart (Figure 12)

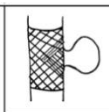
Concept / Criteria	 1	 2	 3	 4	 5	 6
Biocompatible	S	S		S	S	S
Prevents occlusion	+	+		-	-	-
Prevents embolic travel	-	-	D	+	+	-
Protects aneurysm	+	+		-	+	-
Protects parent vessel	S	S	A	-	+	S
Appropriate size	-	S		-	S	S
Isolates aneurysm	S	S	T	S	S	-
User friendly	+	-		-	+	-
Maintains normal blood flow	+	+	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. To reiterate, these engineering requirements are: 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 CNs. 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 (Figure 1).

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

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.

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