IMPROVING THE NORWOOD PROCEDURE

PROGRESS REPORT

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Group 17

Contents

INTRODUCTION

This report details the progress made by Group 17 in creating a device to enhance pediatric cardiothoracic surgeons' visual field clarity during the Norwood procedure. It specifies updates to the need statement, project scope, design specifications, project logistics, design alternatives, solution analysis, and a chosen solution. There were no updates to the need statement or the project scope. An updated design schedule can be found in Appendix A and an updated design specification table can be found in Appendix B.

The Norwood procedure is the first of three palliative surgeries for infants with Hypoplastic Left Heart Syndrome (HLHS). Having underdeveloped left ventricles, HLHS patients cannot pump adequate amounts of blood to the body. Surgeons perform the Norwood Procedure within the patient's first week of life, repurposing the right ventricle to pump blood to the lungs and the rest of the body. Despite the operation's low frequency, it accounts for 23% of neonatal deaths (Fruitman). The client has indicated a large component of this high death rate is a cluttered operating field and increased operation time. The device aims to address these root issues.

Team Responsibilities

As work has progressed, the group has added and delegated new team responsibilities. The entire group collaborated equally to the progress report. Varun is in charge of uploading updates to the website and has split the literature search work with Akshay. Akshay drafts the weekly reports and amends the design schedule depending on progress. Gerardo designs and implements the tests for the device.

DESIGN ALTERNATIVES AND ANALYSIS

The Pugh charts display ranked alternatives for different characteristics of the device: material type, clamp angle, gap profile, clamping mechanism, and debris removal mechanism.

In each Pugh chart, each design specification is assigned a weight and a score from 0 (not relevant) to 10 (most relevant), indicating its importance to the device characteristic discussed. When the weight of a specification is 0, the scores for all of its alternatives will be 1. The weighted total is calculated by multiplying each score and its corresponding weight for the row and adding the column values together. Table 1 shows the Pugh Matrix for the material type.

Table 1: *Pugh Chart for Solutions with Material Types*

Specification	Weight	Solution and Associated Score			
		Stainless Steel	Titanium	Plastic	Aluminum
Physiological Constraints	0	1	1	1	1
Eliminate Blood Flow	0	1	1	1	1
Debris Removal Flow Rate	0	1	1	1	1
Arterial Integrity	0	1	1	1	1
Weight	7	8	9	3	4
Cost	9	7	5	8	8
Biocompatibility	10	5	10	7*	7*
Maneuverability	0	1	1	1	1
Comfort	0	1	1	1	1
Durability	8	9	10	6	8
Occlusion	0	1	1	1	1
Weighted Total	-	241	248	211	234

**If treated with specialized coating or manufactured with specialized process*

Choosing the proper material will prevent complications during the surgery and make the device more affordable. While surgical tools can be made of many materials, the four options discussed are the most feasible considering the limited budget and production capabilities.

Stainless Steel The stainless steel used in medical-grade equipment is 316L stainless steel, which has chromium alloyed in for corrosion resistance and carbon and nickel for increased strength. Its main advantages are its adequate weight, low cost, and high durability. With a density of 8 $\frac{g}{cm^3}$, its estimated weight would be 80 g, given the client estimation that the device would require 10 cm^3 of material (Matweb). At 80 g, the device would be only 10 g over the upper weight bound given in the design specifications. Its $1.56 per kg cost makes it reasonable to procure (Scrap Monster). As a metal, it is sufficiently durable and will not break down during an operation. A disadvantage is that 316L Stainless Steel may lose its corrosion resistance over time and lose its biocompatibility (AO Foundation).

Titanium Medical-grade titanium (i.e Wexler Titanium AL 2162.2) advantages are suitable weight, biocompatibility, and durability. With a density of $4.5\frac{g}{cm^3}$, the device would weigh approximately 45 g, only 5 g lower than the lower bound of the suitable range (American Elements). Titanium is more corrosion resistant than similar metals, so it is the most biocompatible of the metals considered. Empirical testing shows medical-grade titanium will not yield under repeated load stresses, and a lower modulus of elasticity indicates little rigidity, all showing that it is durable (Kaur). However, it is expensive at $56.38 per kg (Metal Miner).

Plastic Medical plastic boasts low cost and high biocompatibility if manufactured as such; however, it is neither near the adequate weight range nor durable. The price of medical plastic is inexpensive at $1.38 per kg (Beardmore). Along with specialized treatment, plastic has inherent biocompatibility, so it is a safe option to use during surgery (Bigham). The density of plastic is $0.9\frac{g}{cm^3}$, making it too light for the device's needs (Maddah). Plastic has a lower strength than metals; therefore, it has a lower durability.

Aluminum A device made from aluminum may have too little weight, given its $2.7\frac{g}{cm^3}$ density (National Institute of Science & Technology). If manufactured as anodized aluminum, it has inherent biocompatible traits (Sharetts). It is lightweight and can bear high loads, making it durable. Lastly, it is priced at $1.32 per kg, making it less expensive than its metal counterparts (Capital Scrap Metal).

From the prior analysis and Pugh chart, titanium is the best option as it scored high on biocompatibility, durability, and weight, while scoring reasonably on cost.

Clamp angle is another crucial design factor. This angle refers to the bend in the device from the handle's horizontal position that the surgeon holds to the device tip that bends into the chest cavity to hold the artery. Choosing the angle is important to minimize operating field occlusion. Table 2 lists the different angle options.

Table 2: *Pugh Chart for Solutions with Different Clamp Angles*

Specification	Weight	Solution and Associated Score		
		45 degrees	70 degrees	80 degrees
Physiological Constraints	10	8	8	7
Eliminate Blood Flow	0	1	1	1
Debris Removal Flow Rate	0	1	1	1
Arterial Integrity	4	9	8	6
Weight	0	1	1	1
Cost	0	1	1	1
Biocompatibility	0	1	1	1
Maneuverability	9	9	7	6
Comfort	0	1	1	1
Durability	0	1	1	1
Occlusion	10	5	8	9
Weighted Total	–	247	255	238

These three degrees were chosen because they are industry standards, all of which are in compliance with the FDA. In addition, the client has specified that restricting the angles to these three alternatives would ensure ease of prototyping and verification later in the process.

45° bend The biggest advantage of using the 45° clamp would allow for greater maneuverability within the chest cavity because it allows the surgeon to more easily navigate artery beds present in the area of surgery. However, the biggest drawback of this alternative is that it severely occludes the surgeon's view of the chest cavity.

70° bend The 70° clamp angle is a good compromise between the maneuverability of the 45° clamp while also providing significant clarity in the operating view of the surgeon. As the angle increases to 70°, the device will clamp on the artery at a harsher angle increasing the likelihood of arterial damage. The difference from 45° to 70°, however, would be a marginal difference in maintaining arterial integrity, according to the client's empirical experiences.

80° bend The strongest advantage of the 80° clamp is its minimal occlusion of the chest cavity. The sharp bend allows for the handle to remain completely out of the field of view of the surgeon while also clamping down the artery. However, this sharp bend also is a significant flaw in its maneuverability, as it is more difficult for the surgeon to navigate the artery beds.

Based on the Pugh chart and prior research, choosing the 70° angle for the device is optimal. This option balances the physiological constraints and maneuverability necessary for an arterial clamp with the ability to remain out of the surgeon's visual field.

Often with clamps used in infant heart surgeries, blood cannot flow to the lower extremities. Placing a gap in the tip of the device may allow for blood flow to the lower half of the body. After snipping the artery, the surgeon would place a tube inside the artery, which would pump blood down to the lower torso and below. The gap would hold the tube inside of the artery. Table 3 shows the advantages and disadvantages of having a gap profile in the device tip to rectify this issue.

Table 3: *Pugh Chart for Solutions with Varied Gap Profiles*

Specification	Weight	Solution and Associated Score	
		Gap	No Gap
Physiological Constraints	10	10	10
Eliminate Blood Flow	10	10	8
Debris Removal Flow Rate	0	1	1
Arterial Integrity	5	8	10
Weight	0	1	1
Cost	2	9	10
Biocompatibility	0	1	1
Maneuverability	4	7	10
Comfort	0	1	1
Durability	0	1	1
Occlusion	0	1	1
Weighted Total	–	286	290

Gap The main advantage of a gap profile is its regulation of blood flow in the body. The presence of a gap in the device tip will allow blood flow to the lower body.

No Gap Not implementing the gap has advantages in maintaining arterial integrity, lowering cost, and increasing maneuverability. Clasping the artery in the gap may damage it. Machining the gap into the device may cost slightly more. Maneuvering the device with a gap is more difficult because the gap profile takes up more space and may disturb small artery beds.

Thus, as determined from Table 3, the no gap option is more preferred because of its advantages in arterial integrity, costs, and maneuverability.

The main purpose of device is to restrict blood flow in and out of the heart. Table 4 shows the different clamping mechanisms and styles.

Table 4: *Pugh Chart for Solutions with Varying Clamping Mechanisms*

Specification	Weight	Solution and Associated Score						
		Javid	Alligator	Cooley	Fehland	Balloon	B/S	Gear
Physiological Constraints	10	10	10	10	10	10	10	10
Eliminate Blood Flow	10	10	8	10	8	8	9	10
Debris Removal Flow Rate	0	1	1	1	1	1	1	1
Arterial Integrity	9	9	7	7	9	8	10	10
Weight	3	10	10	10	10	10	10	10
Cost	4	9	7	9	10	5	9	10
Biocompatibility	0	1	1	1	1	1	1	1
Maneuverability	7	8	6	8	9	10	10	9
Comfort	0	1	1	1	1	1	1	11
Durability	5	7	7	10	10	6	9	9
Occlusion	10	7	10	8	9	10	10	9
Weighted Total		508	458	508	534	502	561	558

Javid The Javid-style is the standard clamping mechanism used for most clamps in adult procedures. It bends in gradually to clamp the artery while remaining far from the surgical field of vision. However, for the infant cardiovascular procedure, this long stretch adds both occlusion and issues with maneuverability.

Figure 1: *Javid Design (Medline)*

Alligator The alligator-style clamp uses miniature inlaid levers to create a 90 degree rotation of the top pincer while fixing the position of the bottom pincer. This allows for a thinner shaft than other clamps but, during operations, might prove to have a worse in vivo maneuverability and add time. Thus, while it gets a high score of 10 for occlusion, its maneuverability suffers at 6. Notably as well, the alligator-style clamp has a lower blood flow eliminating capability and arterial integrity. The reason for both lies in the translation of the surgeon's force to the pincer's force. With the fulcrum being higher up on the shaft, less control is given over the pressure exerted on the artery. Too low pressure or too high pressure could result in complications with these specifications.

Figure 2: *Alligator Design (PJ Tool Supply)*

Cooley The Cooley-style mechanism is a hybrid of the Javid and Fehland styles. It uses a kink in the shaft like the Fehland, depicted in Figure 4, but with a much smaller angle. To compensate, the remaining portion of the tip bends gradually to reach the final desired angle. The result of this mismatch is a problem in both occlusion and maneuverability. Due to its sharp turn near the tip, it is also more likely to damage arteries.

Figure 3: *Cooley Design (Sklar)*

Fehland The Fehland-style works like the straight, currently used tool. However, there is a sharp kink in the shaft allowing for horizontal handle force to be translated to a precisely angled tip. Because of this similarity, it scores very high on most specification marks. However, the fulcrum preceding the sharp turn adds a loss of pressure control similar to the alligator-style, resulting in a lower score for eliminating blood flow.

Figure 4: *Fehland Design (Midwest MD)*

Balloon The balloon-style mechanism is a relatively new version of clamp technology. It is positioned with in the artery and inflates, similar to a balloon catheter. However, using a metal shell, it can fully prevent blood flow and essentially clamp the artery. The problems with the balloon-style lie in its testing. Naturally, by resisting with sharp metal plates from within, it is more likely to damage arterial walls and then allow blood flow. Due to its high reliance on advanced miniature machinery, the clamp becomes expensive and more likely to break. Thus, in its current form, it is not ideal for procedural use.

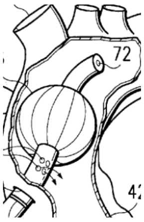

Figure 5: *Balloon Design (Davis et. al)*

B/S (i.e. Ball-and-Socket) The ball-and-socket mechanism is a design entirely removed from modern day clamps. Rather than relying on a fulcrum to translate handle force to forceps force, it would use a flexible metal wire much like the forceps on an endoscopy camera. The premise behind this design choice is to allow full rotation and revolution of the upper half of the clamp. This is achieved using the ball and socket mechanism that allows 180° motion in the x and y plane and 360° rotation in the z plane. Here, the x and y axes are perpendicular to the pincers while the z axis is parallel to it. Due to the removed translation in force, the blood flow eliminated may be lower than the perfect clamp. However, the product suits the given specifications with the highest weighted total of 561.

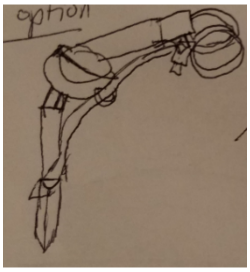

Figure 6: *Ball-and-Socket Design*

Gear The gear mechanism in theory would be the currently used vascular clamp with a slight modification: the shafts would have a snap and gear allowing for 90° of rotation in the y axis. The gears would be placed on the two shafts above the current fulcrum and perpendicular in the direction to it while remaining on the xy plane. This design would provide more occlusion than the ball-and-socket style but compensate with a greater comfort, cost, and blood flow elimination due to its facsimile in mechanics to the standard vascular clamp.

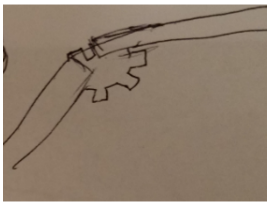

Figure 7: *Gear Design*

Given its notable advantages in maneuverability, minimizing occlusion, and highest weighted total from Table 4, the best clamping mechanism is the ball-and-socket.

To clear the operating field, it is necessary to have a debris removal mechanism. Table 5 shows the various options for debris removal.

Table 5: *Pugh Chart for Varying Debris Removal Mechanisms*

Specification	Weight	Solution and Associated Score		
		Tea Basket	Bardic	Diffusion-Tip
Physiological Constraints	10	10	10	10
Eliminate Blood Flow	0	1	1	1
Debris Removal Flow Rate	10	9	10	8
Arterial Integrity	3	10	6	9
Weight	2	10	10	10
Cost	6	10	10	7
Biocompatibility	0	1	1	1
Maneuverability	8	9	8	10
Comfort	0	1	1	1
Durability	8	9	7	10
Occlusion	0	1	1	1
Weighted Total		444	418	402

Tea Basket The tea basket style of cardiotomy suction tips provides small sifting holes followed by rigid divets in the tip. This allows for the filtering of blood from flesh tissue. The side effect is that many holes can be blocked by the tissue, reducing the debris flow rate. However, it does allow for a more compact tip end, greatly increasing its maneuverability and durability.

Figure 8: *Tea Basket Design (Punjabi)*

Bardic The Bardic style suction tip looks similar to a fountain pen tip. The size of this hole allows for a great debris removal rate. However, its size greatly reduces maneuverability. Also, the hole allows for tissue to clog the tip, placing a strong penalty on its durability.

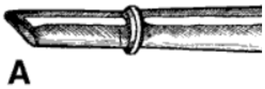

Figure 9: *Bardic Design (Gravelee et. al)*

Diffusion Tip The diffusion tip is a complicated geometric shape with large holes, but placed intricately in arches with a weighted midpoint juncture. This unique design allows for great maneuverability and durability. However, it suffers from the negatives of both the bardic and the tea basket style resulting in the worst debris removal of the three. The intricate shape also results in a greater cost than the other two designs.

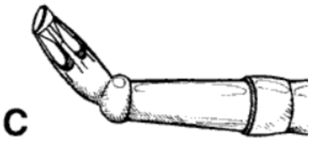

Figure 10: *Diffusion Tip Design (Gravelee et. al)*

Given its advantages in maintaining arterial integrity, debris removal flow rate, and maneuverability, the tea basket is best option for debris removal.

OPTIMAL SOLUTION

Taking the highest weighted totals from each Pugh Chart yields the optimal solution of the device. The device must be: made from medical-grade titanium, have no gap profile, use a ball-and-socket clamping mechanism, and have a tea basket debris removal mechanism.

It should be noted that because the ball-and-socket mechanism has an adjustable handle that there will be no fixed angle. Thus, the analysis from Table 2 is not applicable to the optimal design.

Medical-grade titanium will provide the best biocompatibility, durability, and weight distribution for the device. No gap profile will increase maneuverability and contribute a lower machining cost. The ball-and-socket clamping mechanism is an innovative option to almost entirely eliminate operating field occlusion and maintain arterial integrity. Lastly, the tea basket debris removal mechanism results in an adequate debris removal flow rate and exceptional durability and maneuverability.

The next steps for the team entail creating CAD files for the ball-and-socket mechanism and devising a way to minimize space when attaching the debris removal mechanism to the rest of the device.

PROPOSED BUDGET

Table 6: *Budget*

Item	Quantity	Unit Price ($/quantity)	Price ($)	Description
Titanium	1 block	$67.03/block	67.03	Material that will be used to create the device. Medical-grade titanium can only be purchased in blocks (TMS Titanium)
CNC Machiner	2 hours	$175/hour	350	Machining needed to make device. Estimate for labor given by Prof Klaesner
Pressure transducer	1	0	0	Prof Widder will provide testing equipment
Tubing	4	0	0	Prof Widder will provide tubing
Blood-Mimicking Fluid	1 bottle	19.63	19.63	Used during testing (Adorama)
Total Cost			436.66	

Table 6 shows the estimated budget for the project. The specific request for money will be clarified in Appendix C.

REFERENCES

Fruitman, D. S. (2000, May). Hypoplastic left heart syndrome: Prognosis and management options. Retrieved October 3, 2018, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2817797/

Matweb. (n.d.). Medical Grade Stainless Steel 316LVM. Retrieved November 26, 2018, from http://www.matweb.com/search/datasheet_print.aspx?matguid=29a84d10fada4e4fa3ebe3986e52d848

Scrap Monster. (2018). 316 SS Solid Scrap Price $US / Lb United States, North America, Stainless Steel Prices. Retrieved November 26, 2018, from https://www.scrapmonster.com/scrap-prices/north-american-stainless-steel/316-ss-solid-scraps/334/1/1

AO Foundation, AO Trauma. (n.d.). Handout Implant Materials. Retrieved November 26, 2018, from https://aotrauma.aofoundation.org/Structure/education/educational-programs/operating-room-personnel/Documents/Handout_Implant materials.pdf

American Elements. (2018). Medical Grade Titanium. Retrieved November 26, 2018, from https://www.americanelements.com/medical-grade-titanium-7440-32-6

Kaur, K. (2017, August 01). Stainless Steel and Titanium in Surgical Implants. Retrieved November 26, 2018, from https://www.azom.com/article.aspx?ArticleID=7156

MetalMiner. (2018). MetalMiner Prices: Titanium Prices. Retrieved November 26, 2018, from https://agmetalminer.com/metal-prices/titanium/

Beardmore, R. (2006). Plastics Costs. Retrieved November 26, 2018, from http://www.roymech.co.uk/Useful_Tables/Matter/Costs_Plastics.html

Bigham, K. (2017). Biocompatibility of Plastics. Retrieved November 26, 2018, from https://www.zeusinc.com/wp-content/uploads/2014/03/RESINATE-SE-Biocompatibility-of-Plastics.pdf

Maddah, H. A. (2016). Polypropylene as a Promising Plastic : A Review. American Journal of Polymer Science, 6(1), 1âĂŞ11. https://doi.org/10.5923/j.ajps.20160601.01

National Institute of Science and Technology. (n.d.). Composition of ALUMINUM:. Retrieved November 26, 2018, from https://physics.nist.gov/cgi-bin/Star/compos.pl?matno=013

Sharretts Plating Company. (2018, April 25). Guide to Biocompatibility and Design for Medical Industry. Retrieved November 26, 2018, from https://www.sharrettsplating.com/blog/biocompatibility-design-considerations/

Capital Scrap Metal LLC. (2017). Price of Scrap Metal | Highest Price Guarantee. Retrieved November 26, 2018, from https://www.capitalscrapmetal.com/prices/

Medline. (2018). Javid-Carotid Artery Clamps. Retrieved November 27, 2018, from https://www.medline.com/product/Javid-Carotid-Artery-Clamps/Artery-Clamps/Z05-PF09252

Midwest MD. (2018). FEHLAND INSTESTINAL CLAMP, JAW LENGTH 3 1/4" (8.2 CM), 10" (25.4 CM). Retrieved November 27, 2018, from http://midwestmd.net/5157-76

Sklar. (2018). Cooley Anastomosis Clamp - 6-1/2" - Clamps - Cardiovascular Instruments. Retrieved November 27, 2018, from https://www.sklarcorp.com/cardiovascular/cardiovascular-clamps/6-1-2-cooley-anastomosis-clamp.html

PJ Tool Supply. (2018). Alligator Clamp, 3 1/2" (Ear Polypus). Retrieved November 27, 2018, from https://www.amazon.com/PJ-Tool-Supply-Alligator-Polypus/dp/B003YMIL4I Amazon Published

Davis, A., Lloyd, W., Draper, C., Suresh, M., Hernon, D., Bryant, R. C. (1997). U.S. Patent No. US6068608A. Washington, DC: U.S. Patent and Trademark Office.

Punjabi, P. P., Taylor, K. M. (2013). The science and practice of cardiopulmonary bypass: From cross circulation to ECMO and SIRS. Global Cardiology Science and Practice, 2013(3), 32. https://doi.org/10.5339/gcsp.2013.32

Gravlee, G. P., Davis, R., Kurusz, M., Utley, J. (2000). Cardiopulmonary bypass: Principles and practice (2nd ed.). Retrieved November 28, 2018, from http://tele.med.ru/book/cardiac_anesthesia/text/gr/gr_bookinfo.htm CHAPTER 5: CIRCUITRY AND CANNULATION TECHNIQUES

TMS Titanium. (2018). Online Titanium Products. Retrieved November 27, 2018, from https://store.tmstitanium.com/products/1347/titanium-sheet-plate/6-4-grade-5/2.000-thick-8.000-wide-1.100-long

Adorama. (2018). Sirchie Synthetic Blood for Classroom Instruction, 8oz, Chemically Similar. Retrieved November 27, 2018, from https://www.adorama.com/sisynb8.html?gclid=Cj0KCQiA8_PfBRC3ARIsAOzJ2uohBjXTRv39w_hjQn-zFgX4oqCXSYdI-dm4w497gQ7Ky5N-4SVSLFgaAncJEALw_wcB

APPENDIX A: DESIGN SCHEDULE

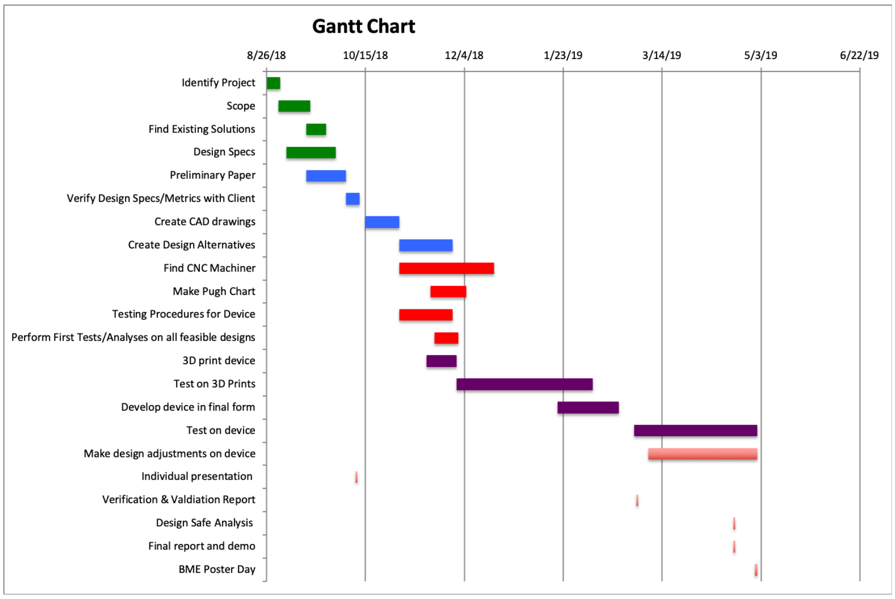

Figure 11: *Updated Gantt Chart showing more a detailed timeline for Group 17*

APPENDIX B: UPDATED DESIGN SPECIFICATIONS

***Table 7:** Modified Specifications used to Prototype Device*

Specification	Metric	Description
Physiological Constraints	Arterial – diameter: 6-12 mm – thickness: 0.4-0.6 mm Incision diameter: 2 cm	Device must suit artery diameters and thickness and fit into operating incision
Eliminate Blood Flow	300-450 kPa	Maximum pressure of the device should be in the range listed in the left column
Debris Removal Flow Rate	40-60 $\frac{ml}{min}$	Device should achieve listed flow rate to match rate of debris generation, and maintain pressure < 1.4 kPa to prevent tears in heart tissue
Arterial Integrity	N/A	Device must not damage or be abrasive to arteries
Weight	50-70 grams	The weight range balances strength and wieldiness
Cost	≤$1000	Cannot cost >$5000 to create as per client request
Biocompatibility	N/A	The device should not react with bodily tissue or corrode
Maneuverability	Device tip width: ≤2.8 mm	Must be able to move around small artery beds
Installation time	≤10% of operation time	Device will not increase operating time more than 10%
Comfort	Handle Diameter/Device thickness: 15-20 mm	Device should be comfortable to grasp and have ambidextrous functionality
Durability	10 years	The device should last at least 10 years
Occlusion	20% of operating field	The device should not occlude more than 20% of the surgeon's operating field

Highlighted in gray in Table 4 are three new design specifications: comfort, durability, and occlusion, which were added after further discussion with the team and client. The design must be easy to use during surgery, stay functional for 10 years, and occlude a maximum of 20% of the operating field.

APPENDIX C: BUDGETARY REQUEST

The team will be requesting funds for the blood-mimicking fluid only, which costs $19.63. Proper testing of a surgical environment will require a fluid that is similar to blood. Thus, the team requests the department for money to purchase this fluid.

The University has testing equipment (e.g. pressure transducer and tubing) readily available. Furthermore, the team will create the prototype using 3-D printing, which can be done for free in Professor Widder's lab. Thus, the team will not purchase any medical-grade titanium or place orders for CNC machining. The only expense will be blood-mimicking fluid.