Preliminary Report

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10/5/18

1.0 Background

In hypoplastic left heart syndrome (HLHS), the left heart is underdeveloped in infants after birth (CDC 2016). Thus, infant hearts cannot adequately pump oxygenated blood to the rest of the body. If left untreated, the ailment is fatal because the heart cannot deliver nutrients or oxygen to the rest of the body (Mayo Clinic 2018). According to the National Institute of Health (Fruitman 2000), HLHS occurs in 0.016% to 0.036% of live births but contributes 23% of all neonatal deaths in the U.S. Within the United States, the Norwood Procedure is performed 1000 times annually and its survival rate is approximately 76% (Sano et. al 2009).

Surgeons address the situation by performing a series of three surgical procedures, the Norwood, the Glenn, and the Fontan. The first of the three surgeries is the Norwood procedure, in which the surgeon converts the right ventricle to the main ventricle to pump blood to both the lungs and the body. Furthermore, the surgeon redirects flow from the main arteries to the lung using a shunt, supplying it with blood (Hyperarts 2018). Six months after the Norwood, the Glenn procedure disconnects the shunt and connects the right pulmonary artery to the superior vena cava. The result is half of the deoxygenated blood is piped into the lungs (Hyperarts 2018). Lastly, the Fontan procedure lets all blood flow passively to the lungs by connecting the inferior vena cava and the pulmonary artery.

Currently, there is debris in the operating cavity and a clamp which obscures the view of the surgeon. The solution should eliminate both issues. Clearing the line of sight will decrease operation time and is projected to increase the survival rate. Its users will be pediatric cardiothoracic surgeons and will be placed inside of an infant’s chest to close circulation off during the surgery.

2.0 Need Statement and Scope

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In order to improve patient outcome post surgery, there is a need to improve visual clarity in the operating field for pediatric cardiothoracic surgeons during the Norwood Procedure.

2.2 Scope

In order to improve patient outcome post surgery, there is a need to improve visual clarity in the operating field for pediatric cardiothoracic surgeons during the Norwood Procedure. The proposed solution would not obstruct the surgeon's view of the operating field and remove debris from the operating cavity. A prototype of the device, along with a mechanical drawing and a user manual will be delivered to the client, Dr. Pirooz Eghtesady, by May 2019

3.0 Design Specifications

Based on the client meeting, the group determined several crucial design parameters for the client needs. This included very important considerations such as arterial strength, chest cavity size, and flow rates during surgery. Table 1 shows the client needs with the derived specifications.

Client Need	Design Specification
Know the patient's physiological constraints	Device must handle artery diameters between 6-12 mm, artery thickness between 0.4-0.6 mm and fit into operating incision of 2 cm
Device should close off artery	Max Pressure Device Exerts: 300-450 kPa
Device structure shouldn't be abrasive to tissue	Device should not damage the artery
Device must remove debris during surgery at an adequate rate	Average volumetric flow rate of device must be > 40-60 mL/min and < 100 mmHg of pressure
Device shouldn't be unwieldy to use during surgery	Device weight range: 50-70 grams (the average weight of clamps of similar nature)
Material used should not react with biological tissue	Device should be made of biocompatible material
Easy maneuverability around small artery beds	Device tip (or portions in contact with tissue) should be no wider than 2.8 mm
Device should follow industry standard orientation	Device will be ambidextrous
Device must be functional within the procedure	Device doesn't add more than 10% surgery time

Table 1: List of client needs and corresponding design specifications

From Table 1, the client has asked the group to prioritize meeting the physiological constraints, reaching the specified flow rate, and decreasing the operation time.

4.0 Existing Solutions

In order to reduce visual clutter for small operations, several clamps have been produced. The Cooley Multi-purpose Clamp, shown in Figure 1, bends far enough to remove the clamp handles from field of vision (Sklar Surgical Instruments 2018). However, being multi-purpose, it does not fit the miniature dimensions that are required for the specifications.

Figure 1. A sketch of the Cooley Clamp

The Lees Bronchus Clamp, Figure 2, might be suitable due to its weight distribution and size (Sklar Surgical Instruments 2018). However, the method by which it is placed, may overcomplicate the surgery- i.e. the clamp is difficult to maneuver into the desired location to clamp.

Figure 2. A sketch of the Lees Bronchus Clamp

Figure 3 depicts the Satinsky Vena Cava Clamp which would fit into the surgical cut and operating space (Sklar Surgical Instruments 2018). However, it clamps tubes vertically. It is not known if this would add an exerted tension to the descending artery that is not desired.

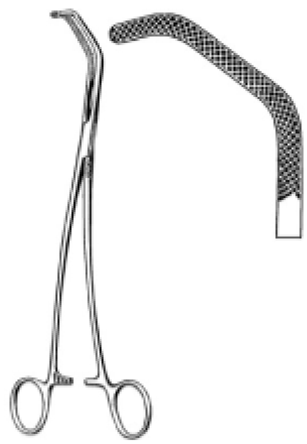

Figure 3. A sketch of the
Satinsky Vena Cava Clamp

The Lambert-Kay Classic Aorta Clamp (Sklar Surgical Instruments 2018) is the closest to the desired solution (figure 4). However, it clamps leaving tubes vertically as well. Nevertheless, this will be the basis for design of the custom clamp. The client has requested an attachment holding the suction pump as well that is not seen in any current design.

Figure 4. A sketch of the

Lambert-Cay Classic Aorta Clamp

An alternative solutions to traditional clamp is an Integral aortic arch infusion clamp catheter (i.e. a balloon clamp) (Bryant et. al 1997). Balloon clamps, as shown in figure 5, bend and slide into arteries while deflated, and inflate to occlude the blood. As the balloon lies on one bendable metal rod, this would work well to reduce the amount that protrudes above the surgery.

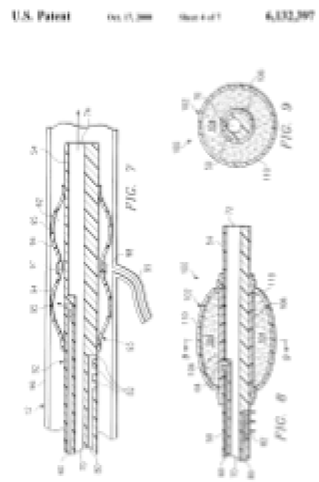

Figure 5. A sketch of the Integral aortic arch infusion clamp catheter

Stents, such as an intracoronary stent, have been used occasional to provide occlusion. These would also hide more during the surgery. However, given that the time frame of use is 2 minutes, these would not work during the Norwood Procedure.

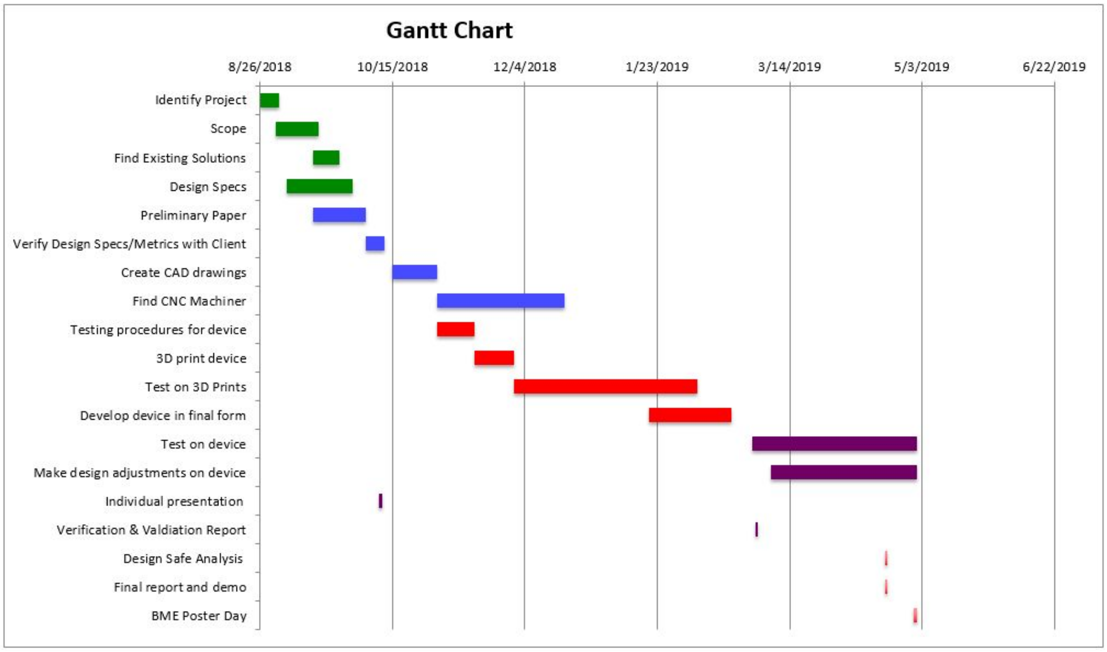

Figure 6. The Gantt Chart for the group detailing deadlines and timelines

Figure 6 displays a Gantt Chart. During first semester, the group aims to create online designs and 3D print physical models. The goals of the group second semester entail creating the finished device, creating testing procedures, testing the device, and making adjustments on the device.

Team Responsibilities

Varun Lahoti	Gerardo Molina	Akshay Thontakudi
1. Client contact 2. Finding CNC Machine 3. Presentation 1	1. CAD drawings 2. Recording test results 3. Presentation 3	1. Patent literature/search 2. Creating testing procedures 3. Presentation 2

Table 2 shows the team responsibilities segmented by group members

Cited Patents and Resources:

"US6277126B1 - Heated Vascular Occlusion Coil Development System." *Google Patents*, Google, patents.google.com/patent/US6277126B1/en?q=vascular%2Bocclusion&oq=vascular%2Bocclusion.

"US20090297582A1 - Vascular Occlusion Devices and Methods." *Google Patents*, Google, patents.google.com/patent/US20090297582A1/en?q=vascular%2Bocclusion&oq=radiopaque%2Bfluids%2Bvascular%2Bocclusion.

"US4969458A - Intracoronary Stent and Method of Simultaneous Angioplasty and Stent Implant." *Google Patents*, Google, patents.google.com/patent/US4969458A/en?q=vascular%2Bocclusion&oq=vascular%2Bocclusion.

"US5423829A - Electrolytically Severable Joint for Endovascular Embolic Devices." *Google Patents*, Google, patents.google.com/patent/US5423829A/en?q=vascular%2Bocclusion&oq=vascular%2Bocclusion.

"US5645564A - Microfabricated Therapeutic Actuator Mechanisms." *Google Patents*, Google, patents.google.com/patent/US5645564A/en?q=vascular%2Bocclusion&oq=vascular%2Bocclusion.

"Suction Tube Yankauer Vented." *BettyMills.com: Cleaning, Sanitary & Medical Supplies.*, www.bettymills.com/suction-tube-yankauer-vented-16-66203?utm_source=cpc-strat&utm_medium=cpc&utm_campaign=parts&utm_keyword=MON62034000&utm_content=Medical&gclid=Cj0KCQjwi8fdBRCVARIsAEkDvnIZNFk2bI7LFIQGtkf_jynmz6du2txuKwE3YjJiFo2G3R7PmDg9TCQaAq34EALw_wcB_.

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Questions:

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Sklar Surgical Instruments. (2018). Cooley Multi-Purpose Clamp - Clamps - Cardiovascular Instruments. Retrieved October 4, 2018, from https://www.sklarcorp.com/cardiovascular/cardiovascular-clamps/6-1-2-cooley-multi-purpose-clamp-45d.html

Sklar Surgical Instruments. (2018). Bronchus Clamps - Cardiovascular Instruments. Retrieved October 4, 2018, from https://www.sklarcorp.com/cardiovascular/bronchus-clamps.html

Sklar Surgical Instruments. (2018). Satinsky Vena Cava Clamp - 9-1/2" - Clamps - Cardiovascular Instruments. Retrieved October 4, 2018, from https://www.sklarcorp.com/cardiovascular/cardiovascular-clamps/9-1-2-satinsky-vena-cava-clamp.html

Sklar Surgical Instruments. (2018). Lambert-Kay Clamp - 8" - Clamps - Cardiovascular Instruments. Retrieved October 3, 2018, from https://www.sklarcorp.com/cardiovascular/cardiovascular-clamps/8-lambert-kay-clamp.html

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