# Project 1: W.L. Gore Iliac Bifurcation Aneurysm Model

## Preliminary Report

**Chadrick Jennings**
**Michael Seth Mabes**
**Nicholas Norris**
**Noah Wick**

NORTHERN ARIZONA UNIVERSITY

College of Engineering, Informatics, and Applied Sciences

GORE

**Spring-Fall 2019**

**Project Sponsor: W.L. Gore & Associates**
**Faculty Advisor: Dr. Tim Becker**
**Sponsor Mentor Team: William Reilly, DJ, Edwin, Jason, Jonathan, and Brandon**
**Instructor: David Willy**

# DISCLAIMER

# TABLE OF CONTENTS

## Contents

# 1 BACKGROUND

## 1.1 Introduction

W.L. Gore and Associates has requested that students from Northern Arizona University (NAU) design a replicable model of an aneurysm in the iliac bifurcation and test it. The iliac bifurcation is located below the renal descending abdominal aorta typically in front of lumbar vertebrae 3-5 [1]. This project begins with analyzing the structure of the bifurcation. Then the team will design an aneurysmic model of this structure, and test the materials for compliance within targets set by nature. Finally flow rate and pressure through the model will be tested in order to show success.

The subsequent models of the bifurcation could be used for testing of the deployment of W.L. Gore stents, catheters, and other devices. The overall interest of the stakeholders, besides training and recruiting engineers, is to have a model that will allow for testing of devices that will in turn save lives. The prevalence of aneurysmal disease is increasing in the elderly population with roughly 150,000 new cases every year [2]. W.L. Gore has a mission with all their products, and that is that Gore products will not fail. This is especially important for their medical devices. In order to reach such a lofty goal, Gore will have to test its devices rigorously before releasing them to the public. As research continues into both aneurysmic models of the bifurcation and Gore, it becomes apparent that we are helping to develop life-saving equipment. If an aneurysm bursts in the abdomen there is over an 80% mortality rate [2], so people all over the world will benefit from this model. W.L. Gore and Associates have stakes in this project because they are the sponsors, this starts and ends with Gore. The team's ability to create an accurate aneurysmic model of the iliac bifurcation will directly affect the time it will take to develop devices for that area. This in turn will expedite the creation of stents that can save a life.

## 1.2 Project Description

The original project description provided by the sponsor is as follows:

> "Project 1 - W.L. Gore & Associates Senior Capstone Project Proposal
>
> Spring 2019-Fall 2019
>
> Client - William Reilly
>
> Scope of Work: The scope of this project is to design, build, and test a replicable model of an aneurysm in the iliac bifurcation for deployments of peripheral endovascular interventional devices under simulated use conditions, using non-biologic materials.
>
> Overall Requirements:
>
> 1. Safe per ANSI, OSHA, or other related safety standards.
>
> 2. Design system to mimic anatomical fluid flow conditions (recommended but not limited to):  Flow Rate Pressure
>
> 3. Develop, justify, and characterize the following attributes (recommended but not

limited to):

  - Aneurysm Durometer
  - Aneurysm Compliance
  - Aneurysm Length
  - Aneurysm Thickness
  - Degree of aortic vessel growth (Creep)

4. Allow Visualization of device deployment
5. Document Repeatable Manufacturing Processes
6. Desired but not required:
   - A Graphic User Interface (GUI) outputting the following data to the user (recommended but not limited to):
     - Pressure in the Aneurysm Flow (or leak) rate from the simulated graft to the aneurysm
     - Volume change rate of Aneurysm
     - General Control of the model o Power Off o Flow Rate
   - Desired Engineering Majors:
     - Mechanical
   - Budget: $3,000[1] to cover the cost of:
     - Documentation (reports, presentation boards, etc.)
     - Materials for testing and prototyping
     - Construction of multiple working models.
   - Deliverables:
     - Detailed literature review, project proposal, and final report, all engineering analysis, cost estimate to duplicate, bill of materials, drawing package (if applicable), software files (if applicable), detailed procedure for repeatable manufacturing, all receipts for purchase/expenses, and 12 additional functional models for testing.
   - Onsite Gore Presentation:
     - The team will be invited to visit a W.L. Gore facility and present their project to the technical community at W.L. Gore.

[1] Other resources may be provided as needed/justified" [3]

# 2 REQUIREMENTS

Along with the project description that the client sent the team, a list of basic requirements were presented. These basic demands were the foundation for a list of customer and engineering requirements (CRs and ERs, respectively), that was formed in order to aid in the design process. Furthermore, the CRs and ERs were compared based on relation to determine the relative and technical importance of each. This chapter describes each of the CRs and ERs, as well as describes how they relate to each other in what is known as a House of Quality (HoQ).

## *2.1 Customer Requirements (CRs)*

Developing a list of CRs was the first of many steps in the design process. The team needed to know the basic needs from the client and, therefore, created a list based on the project description sent to them. It can be seen from the list below that all of the CRs relate to the project requirements, each falling under a specific topic. These topics are classified by each numbered item in the project description above. The complete list of Customer Requirements are listed below, each with a description and their ratings (on a 1 to 10 scale, 10 being the most important) created by the team.

1. Safe per ANSI/OSHA: The first project requirement listed in the description is that the model needs to be safe according to any relevant safety standard. Thus, the team developed this CR in order to match the client's need. The team gave this a rating of ten, because they felt that even if the model functions properly, it would be an overall failure if the client can't use the device for regulatory reasons.
2. Easy to Move: This CR was derived from the first one. The team felt that if the overall model was too difficult to move, then it could be considered unsafe for the client. However, it only received a rating of three, because the team determined that if the device is in a location where testing would be conducted, then movement is not entirely necessary.
3. Mimic Anatomical Flow Conditions: The second requirement that the client sent the team was that the model had mimic various anatomical fluid flow conditions, such as flow rate and pressure. The team decided to give this CR a rating of seven, because if the model does not have similar flow conditions, testing can still be done, but results will not be as accurate or useful for the client.
4. Match Aneurysm Mechanical Properties: The third requirement is very similar to the second, in that it requires matching anatomical conditions. The client wanted the team to characterize different mechanical parameters. Therefore, the team decided to develop a model that closely follows those characterizations. The team rated this CR with an eight, because they felt that if the mechanical properties are not suitable, then the device could fail.
5. Match Aneurysm Geometry: This CR is also derived from the third project requirement, by requiring the matching of another anatomical condition. The geometry of the model was important to the team, because it closely relates to the devices that will be tested using the designed model. The team gave this CR a rating of 9, because if the geometry is not similar to anatomical conditions, then the client would not be able to test their devices.
6. Transparent Material: This CR comes from the fourth project requirement given to the

team. The model needs to have a certain degree of transparency so that the client can view their devices as they're being tested. The team gave this a rating of nine, because they felt that if the client's devices could not be seen while testing, the model is a failure.

7. Replicable Manufacturing Process: The fifth project requirement given by the client is that the team needed to document a repeatable manufacturing process. Thus, the team created a CR that directly relates to this deliverable. This CR received a rating of six, because the team determined that since the client may use this model for future use, they would need to be able to recreate it.
8. Displays Pressure: One optional deliverable that the client presented was that of a Graphic User Interface (GUI). The team decided that a GUI would be a very important factor for the model, because it would help determine if the model is functioning as it was designed and if the client's device is implanted successfully. The team gave this CR a rating of five, because the team decided it would be beneficial to the overall model, but the client did not list it as an actual need.
9. Displays Flow Rate: Similar to the CR above, this CR was one that the team decided would enhance the overall model. For similar reasons, it received a rating of five; that is, because it was not explicitly needed by the client, but the team felt it would create a more functional model.
10. Stable Base: Just like the first two CRs, this one was derived from project requirement stating that the model needs to be safe to operate. The team decided that in order to operate safely, the overall design would need to be stable while operating. This CR received a rating of four, because while it provides both safety and ease while operating, it is not as important as the first two safety CRs.
11. Displays Aneurysm Volume Change: This last CR was developed for the same reasons as the eighth and ninth CRs. While it is not entirely critical to the overall model, it provides better functionality for the device, while giving the operator another visual confirmation that the client's device is performing adequately. Therefore, the team gave this CR a rating of three.

## *2.2 Engineering Requirements (ERs)*

From the CRs, the team developed their list of ERs. The ERs are quantifiable requirements that the team can measure, and provide a target for the specifications of the overall model. Each ER has a target value that the team extrapolated from their literature review, and a tolerance that the specification can be within. It is important to note that each target value or tolerance is subject to change as necessary based on new information found in research to come. That being said, all 22 ERs are listed below with their respective target values and tolerances in Table 1.

Table 1: Engineering Requirements with Respective Target Values and Tolerances

| Engineering Requirement | Target Value | Tolerance |
|---|---|---|
| Mean Flow Rate in Left Iliac | 94 (m/s) | ±10 |
| Mean Flow Rate in Right Iliac | 111 (m/s) | ±10 |
| Aortic Pressure (Systolic/Diastolic) | 141/68 mm Hg | ±10/10 |
| Surface Roughness | 0.89 (μm) | ±0.27 |
| Hardness | 40 (Shore A) | ±15 |
| Shear Modulus | 175 (kPa) | ±10 |
| Wall Thickness | 2 (mm) | ±.5 |
| Aneurysm Diameter | 35 (mm) | ±5 |
| Aneurysm Length | 26.7 (mm) | ±3 |
| Creep | 2.9 (mm/yr) | ±1 |
| See-Through Material | Yes/No | n/a |
| Fluid Temperature | 37 (°C) | ±10 |
| Weight of Entire System | 22.68 (kg) | ±2 |
| Total Cost | 2800 ($) | ±200 |
| Diameter of Diastolic Aorta | 19.37 (mm) | ±9 |
| Diameter of Left Iliac | 16.5 (mm) | ±8.5 |
| Diameter of Right Iliac | 16.5 (mm) | ±8.5 |
| Radius of Curvature at Right Junction | 34.57 (mm) | ±5 |
| Radius of Curvature at Left Junction | 50.5 (mm) | ±5 |
| Length from Iliac to Insertion Point | .5 (m) | ±.25 |
| Angle of Right Common Iliac Artery in Coronal Plane | 29 (degrees) | ±5 |
| Angle of Left Common Iliac Artery in Coronal Plane | 14 (degrees) | ±5 |
| Take Off Angle of Iliacs in Sagittal Plane | 15 (degrees) | ±5 |

It can be seen that each ER has a relationship to at least one of the CRs. The ERs can be broken into different categories described by the CRs that they are related to. For example, the flow rates and pressures can be categorized by the third CR listed in the previous section. Likewise, the lengths, radii, diameters, and angles relate to the fifth CR. The initial list of ERs guided the team in their research, determining different points of focus.

The ERs were all attributed a target value based on subsequent research. For example, the geometrical parameters were all developed from one of two sources [1] [4]. Likewise, the tolerances were set based on the various research that the team conducted. Furthermore, a majority of these tolerances were based on the device that the client will be testing with the model [5]. The team felt that this was the best way to justify the tolerances, because the model would be considered a failure if the client could not test their device with it. Also, these tolerances found on the client's website fit within the range found in other research conducted [4]. All of the research conducted will be described in depth in the next chapter.

### *2.3 House of Quality (HoQ)*

After the CRs were listed and each had their respective weight, and the ERs were listed each with their respective target values and tolerances, a House of Quality (HoQ) was formed. A HoQ places CRs and ERs in a grid system in order to compare them. For example, the column on the far right lists the CRs, while the ERs are listed on the top row. All of the space between the two make up the relationships between each CR and ER. The full HoQ can be seen in Appendix A.

The HoQ was developed in order to determine which requirements were of more importance. Each ER was compared to a CR, and this relationship received either a one, three, or nine based on the importance that the team felt it had. For example, an ER that was directly derived from a CR was most likely given a nine. However, in some cases, an ER that was not derived directly from a CR could either receive a three or a one. This process helped the team through the design process by allowing the team to focus on specific requirements more so than others. For example, the requirement for flow rates would be more of a focus point than the requirement for hardness, because it has higher number of relationships to the CRs. Overall, it can be seen that the more important ERs are those related to flow and mechanical properties, and therefore, will be at the center of design considerations. After the HoQ was finished, the team began researching individual components for the overall design based, which will be the focus of the next chapter.

## 3 DESIGN SPACE RESEARCH

The client and the Project occupies the design spaces of electrical engineering, biomedical engineering, mechanical engineering, and computer engineering. In order to achieve the needs of the client, the four mechanical engineering students had to do extensive independent research in order to understand every aspect of the project. In the sections to follow there will be a literature review of the research that the team has done, its relevance, and what the original document was about. Following the literature review a display of current systems and subsystems will be reviewed in benchmarking, and our current understanding of the project is shown through the functional decomposition of a complete system as we know it.

### *3.1 Literature Review*

In this project the research was split up into between the four team members in order to gather project information more efficiently. Chadrick Jennings has accepted the job of researching sensors and gathering statistics about ages that aneurysm occur, diameters, and locations. Michael Seth Mabes is researching Pumps to simulate anatomical blood flow and the manufacturing process of creating a characterized aneurysm. Nicholas Norris is dedicated to researching GUI interfaces and aneurysm geometry. Noah Wick has the pleasure of researching mechanical features of the vascular system and materials in order to determine a suitable material that can replicate an iliac bifurcation. The team's individual research will all come together to product our first iteration. The specific research is explained by each student in this section and its importance will be related to the project.

### 3.1.1 Chadrick Jennings

Mr. Jennings focused his technical research on statistics and sensors. The team needed to classify a specific age range to target, and acquire relevant data on the average geometry of each age rage. Also, as is stated in the previous chapter, the team decided to incorporate a way of displaying various fluid flow conditions. Therefore, Chadrick researched potential possibilities for fluid flow measurements. Below are the relevant sources found for these technical topics.

I. "In vivo estimation of the contribution of elastin and collagen to the mechanical properties in the human abdominal aorta: effect of age and sex." [6]

The first article that Mr. Jennings found related to his technical research gives information on several mechanical properties, including tensile stress. This data was very helpful in determining an appropriate age range to model after. Also, this source provided the team with other relevant information regarding the overall mechanics of the circulation through the abdominal aorta, and how they change with age.

II. "Theory and Design for Mechanical Measurements" [7]

In order to understand fluid flow concepts, Chadrick used the textbook from his Experimental Methods class. This book lists different ways to measure flow, while also explaining the theory and concepts behind each method. This source has proved useful by guiding Mr. Jennings' research into a few different fluid flow measurements that could work for the model.

III. "MEMS for Biomedical Applications" [8]

Determining which sensor to use for the model became a focus point for Chadrick, as this was one of the main areas for his technical research. He used this source to expand on different types of transducers that can be used. This book is full of information about the classification of sensors, and design considerations that are attributed to each. Also, there are specific details pertaining to certain specific types of sensors, and their biomedical applications. This guided Mr. Jennings towards certain sensors to research for the model.

IV. “Pressure Transducers” [9]

Once Mr. Jennings determined which sensors to begin looking into, he decided to start with pressure sensing technologies. One of the most common forms of pressure measurement in industrial applications is a pressure transducer. This source expands on the working principles, applications, types and styles, and selection criteria of pressure transducers. Also, it has information for pricing that was useful for Chadrick’s benchmarking, which is mentioned in the next section of this chapter.

V. “Types of Fluid Flow Meters” [10]

Along with pressure measurements, the team decided to monitor the flow rate through the model. This presents the need to use some sort of fluid flow meter. This source that Mr. Jennings found explains the principles behind several different types of flow meters, and lists the different applications and benefits of each. This helps determine further research on specific types of flow meters for the model, as well as with further benchmarking.

### 3.1.2 Seth Mabes

#### 3.1.2.1 Pumps

I. “Blood-flow of the inferior mesenteric and internal iliac arteries among patients undergoing open surgery for abdominal aortic aneurysm.” [11]

Pumps will be used to artificially circulate fluid through the iliac bifurcation. The first journal review was used to determine average flow rates through the left and right iliac from 25 different patients. These studies were gathered from patients that were undergoing an aortic aneurysm repair. This information was used to develop target values for the QFD and will allow the team to choose a pump for simulating these flows. Pulsatile pumps will be necessary to simulate the heart's natural flow and through research there are four types of pumps that will be able to obtain the goal of pulsatile flow: piston, peristaltic, and diaphragm.

II. “Flow pumping system for physiological waveforms” [12]

Piston pumps naturally create an oscillatory flow and provide a consistent volume output per beat. “Flow pumping system for physiological waveforms” is an experimental journal that tested the piston pumps ability to match the heart's natural pulsatile flow. The journal explains the process of how this was achieved and tested. The piston pump ended up being able to recreate the heart’s natural flow better than any other pump on the market. The pump needed computer aided software in order to control the pumps speed throughout the stroke at any given point to obtain the desired flow. This aided the group during concept generation to decide if the piston pump is a feasible device for the project.

III. “Dispensing with Piston and Peristaltic Pumps” [13]

This is a web article that compares pistol style pumps against peristaltic pumps. This article states the strengths of each pump and their ability to simulate the proper flow metrics. The article continues to state that piston style pumps are more expensive and complex but offer the best performance, but require regular maintenance. Peristaltic pumps offer perfect flow rate performance but cannot achieve high pressures and will need to be custom built in order to achieve the proper volumetric flow rate. The article explains that several companies are moving to peristaltic pumps due to the maintenance free design and ease of adjustability.

IV. “EFFICIENCY AND POWER REQUIREMENTS OF THE DIAPHRAGM-TYPE ARTIFICIAL HEART.” [14]

Diaphragm pumps are similar to piston but do not require regular maintenance because they do not depend on tight tolerances to operate. “EFFICIENCY AND POWER REQUIREMENTS OF THE DIAPHRAGM-TYPE ARTIFICIAL HEART.” is a research journal that uses a dual bladder pump to artificially replicate the heart's ventricles. The article states that the pumps are not accurate in their volume output has references to state that the heart is also not consistent in its outflow volume. Diaphragm pumps volume output or pressure are not adjustable without exchanging parts.

These articles will all aid in concept generation and selection. The team will need to choose a pump that is cost effective for the given budget and a pump that can replicate the desired flow with ease. Having a pump replicate the anatomical flow of that area is a customer need and will need careful selection.

#### 3.1.2.2 Casting

The iliac bifurcation material will be selected by the team through vigorous research and sleepless nights. Once the material has been selected or generated the next step of the project will be to mold a material into the specific geometry of the bifurcation with a CIAA (common Iliac Artery Aneurysm). A customer need is to develop a replicable manufacturing process for which the material is manipulated. The easiest way to achieve a anatomical replication would be to outsource to a company that specializes in UV 3d printing. This solution was discarded early on for concern of budget and not meeting the replicable manufacturing process of the device. The team decided to make molds and pour the liquid material into the two piece mold to produce the body of the bifurcation.

V. “Sculpture Casting” [15]

This book yields a wide range of information in casting different materials. Chapter 2 is on casting with silicone rubber molds. This method has been incorporated into our concept selection for mold making. This chapter explains different mold release agents to use on the silicone for different types of materials. If the team chooses to use a silicone mold this book will be valuable for its step by step process on how to cure the mold.

Chapter 6 is titled Lost-wax casting. The project material will need to be hollow and a using a wax core is being considered for the core. This book reveals a step by step process on how pack material around a wax mold to pour a metal material to melt out the wax. Other methods explained are casting the wax from a mold and transitioning it to another mold.

Chapters 9 and 10 are about casting sands for metals and finishing the metal after casting. different sand and permanent sands will leave different textures on your material. Aluminum shrinkage can be controlled by the temperature of the sand before pouring the metal. If the team chooses to create aluminum molds from casting this Book will offer great insight in how to make the method repeatable and consistent.

### 3.1.3 Nicholas Norris

Nicholas, the team treasurer, was responsible for the team budget, purchases, and reimbursement; moreover, technical research was done in order to find arterial and aneurysmal geometry, multiple GUI options, and help to establish other target values along the way.

Target Values were researched by the entire team but Nicholas focused on the geometry of the vasculature and aneurysm of the iliac bifurcation along with research on GUI options for the project. Additional resources and their uses are listed last.

#### 3.1.3.1 Aneurysm Geometry

I. “Study of Aortic- Common Iliac Bifurcation and Its Clinical Significance” [1]

This article was about a study of 25 cadavers that were used for dissection and information pertaining to the iliac bifurcation [1]. Data for the diameter of the common Iliacs and diameter of the aorta were taken from this document and averaged against other data to come to target values.

II. “Infrarenal aortic aneurysm structure: Implications for trans-femoral repair” [16]

This article was an analysis of 22 three dimensional scans of aneurysms within the renal arteries moving down the body and including the iliac bifurcation [16]. Dimensional correlations were shown throughout, but the strongest correlation was the diameter vs. length correlation shown below. Length of aneurysm is roughly 1.5625 times the max diameter of the aneurysm according to this graph.

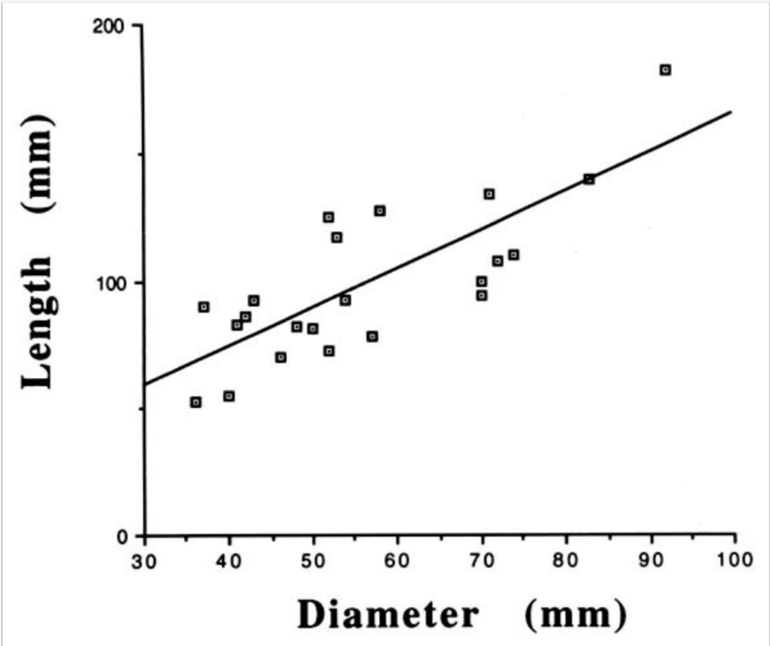

Figure 1. Length Vs. Diameter (r = 0.79) [16]

III. “Abdominal aortic wall thickness and compliance” [17]

This was a near comprehensive study with over 100 patients in which non-invasive methods were used to measure aortic wall thickness, describe the importance of abdominal aortic aneurysm research, and gives reason for aneurysms occurring in the age group they are seen. Elastic fibers decrease and collagen increases after the age of 50, increasing the stiffness of the aorta, thinning the vessel walls, and increasing likelihood of aneurysm [17].

IV. “Advances in determining abdominal aortic aneurysm size and growth” [2]

This article was a study of different methods of imaging that has been used to analyze aneurysm size and growth. Overall it showed that present imaging systems are more accurate and have improved surgical success [2]. This article provided significance for our project along with some size information for confirmation.

3.1.3.2 GUI Options

V. *Programming Arduino: getting started with sketches*, 2nd ed. [18]

This book is a beginner’s guide for arduino. It is an excellent resource when wiring sensors to the Raspberry Pi as it provides basic rules and tips to protect equipment. It also gave information about arduino that pushed benchmarking in a different direction.

VI. National Instruments Website “What is LabVIEW” [19]

This is a general website for nation instruments [19]. From this website, LabVIEW data acquisition (DAQ) equipment can be seen. This website was used in order to learn more about LabVIEW, budgeting, and specifications for comparison to other GUI options.

VII. Raspberry Pi Foundation [20]

The Raspberry Pi Foundation is an entire community that is constantly developing code, projects, and forums about Raspberry Pi and Python coding. “Getting Started with GUIs” is a page on raspberrypi.org [20] and is an excellent starting point for creating a GUI using Python.

3.1.3.3 Additional Research for Group Aid

VIII. “Reservoir Pressure Analysis of Aortic Blood Pressure – an in vivo study at five locations in humans” [21]

This article was an invasive study of 40 patients already undergoing coronary catheterization [21]. The average pressure waveforms were used to set targets for our model and pump systems.

IX. “Biaxial mechanical properties of the human thoracic and abdominal aorta, common carotid, subclavian, renal and common iliac arteries” [22]

This article pointed out the lack of a comprehensive study of large and medium sized arteries, and the mechanical properties of both diseased and healthy artery walls [22]. This article helped to confirm information found by Noah.

X. *Fox and McDonald’s Introduction to Fluid Mechanics,* 9th ed. [23]

This is the fluid mechanics textbook that had been used by the group for our fluids classes. It provides formulas for pipe flow that will be used for the project as well as information about laminar and turbulent flows which will be important for analysis of arterial and aneurysmal flows respectively.

### 3.1.4 Noah Wick’s Research

The initial focus of Noah’s research was geometric anatomy of the iliac bifurcation to determine geometric parameters and target values for the model. Geometry was determined through research of the human anatomy. Tolerances for these values were based on specifications for the devices to be tested within the model. After geometry was determined, materials were researched to select the optimal material for the model. During this research, it was found that materials for the model must be compatible with mold materials should molding and casting be used for manufacturing. This resulted in some overlap between research of materials and manufacturing methods. Close collaboration with Seth, who researched manufacturing methods, and individual research of molding and casting helped direct the focus of materials research.

I. “Geometric anatomy of the aortic-common iliac bifurcation” [4]

This article studies the aortic-iliac bifurcation to ascertain geometric parameters of the region. The authors used tools including calipers and scales to measure and document various lengths, diameters, and angles of the aortic and iliac arteries on cadavers during autopsy. the purpose of this research was to provide useful data for further study of atherogenesis. The article provides a detailed figure of the aortic-iliac bifurcation and includes average values for geometric dimensions of this region. This information has been useful for setting target values and will be utilized to dimension the physical model of the bifurcation.

II. "Review on rubbers in medicine: Natural, silicone and polyurethane rubbers, Plastics, Rubber and Composites" [24]

Generally describes three different elastomers and their mechanical properties, benefits and drawbacks, and medical applications. This article provided an overview of potential materials for the design to determine whether they were feasible for use with this design. This helped the team narrow down materials selection for the physical model to either polyurethane or silicone.

III. "Mechanical characterization of polyurethane elastomer for biomedical applications" [25]

This a study on mechanical properties and behavior of ether based polyurethane elastomer, specifically with reference to building mock arteries. This article documents a comprehensive study of mechanical properties of ether-based polyurethane that includes changes with varying temperature, humidity, and loading conditions. The authors reported that mechanical behavior of this material is highly dependent on temperature and humidity. The article also describes the benefits of polyurethane over silicon in medical applications. This work provided justification for materials selection and provided values for modulus of elasticity to characterize the model.

IV. Gore Medical [5]

The project goal is to produce suitable a model for testing the client's devices. To meet this goal, the model must be compatible with devices currently produced by the client. Therefore, it was necessary to determine specifications for these devices to ensure compatibility. Specifications for the device to be tested in the model were found on the Gore website, which will continue to be used as a reference throughout the project [5]. These specs were used to set target values for geometric parameters in the QFD.

V. BJB Enterprises [26]

BJB Enterprises is a source for high quality casting and mold making materials. This company is a potential source for materials that meet the project requirements. They offer several materials with a wide variety of mechanical properties to fit customer specs for many applications. Product sheets with properties of each material are available on the website. The website also contains tutorials with detailed step-by-step instructions on how to make molds and cast objects using their products. This website has been and will continue to be a valuable resource for the project whether or not materials are sourced through the company.

## 3.2 Benchmarking

A rough diagram of a complete system was first sketched to identify all components involved.

After this top-level system concept was understood by the team, individual components were then organized into two major subsystems, fluid circulation and data acquisition.  The fluid circulation subsystem contains all the required components for the project and includes the pump, pump controller, tubing with aneurysm model, and working fluid.  The data acquisition subsystem contains the optional desired components to improve on the basic design and includes data acquisition software, sensors, and a graphical user interface (GUI).  Components of each major subsystem were identified as individual subsystems.  Benchmarking of the overall system and individual subsystems was divided among the group to complete this process within time constraints.  Subsystems were selected by team members based upon their interests and SOTA literature review findings.  Each team member took a unique approach to benchmarking.  Details and results of individual benchmarking studies are described below.

## 3.2.1 System Level Benchmarking

A web search was performed to locate existing products with potential for complete system benchmarking.  Through trial and error, the keywords “vascular simulators” were found to return results that included suitable products for complete system benchmarking.  Three systems were found that contain all the necessary components for the project.  Each of these three complete systems are listed and described in detail below.

### *3.2.1.1 Existing Design #1: Vivitro Labs Endovascular Simulator*

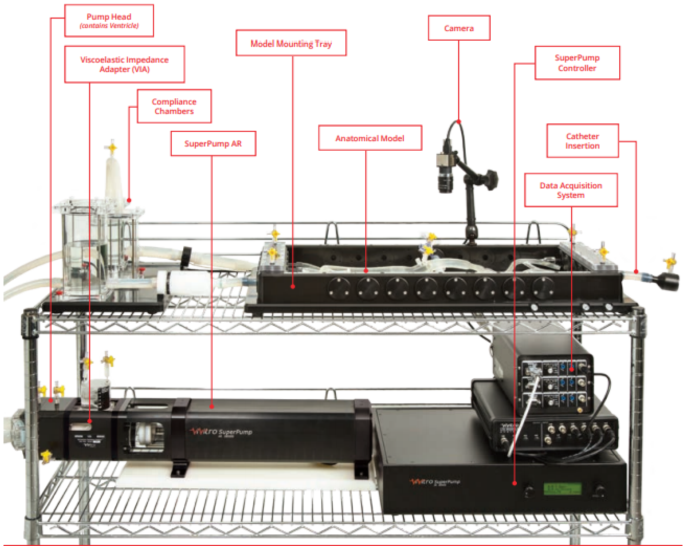

Figure 1. Complete System [27]

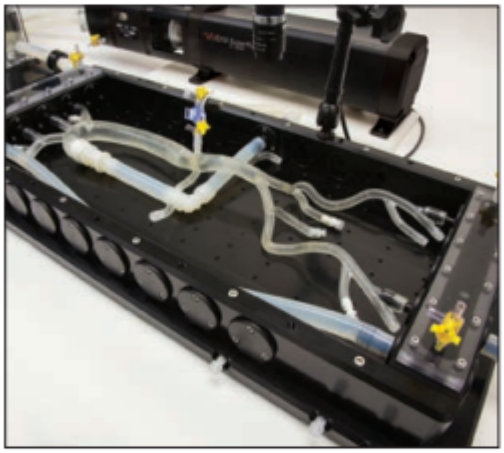

Figure 2. Part of Complete System [27]

The first complete system benchmarked was the Vivitro Labs Endovascular simulator.  This system contains all the necessary components for the project, shown in Figure 1.  A vascular model, pump that produces pulsatile flow, pump head with valves to produce circulatory flow, pump controller, tray with anatomical model, compliance assembly, heating system, and a data acquisition system that measures pressure and flow at any point in the system are all included.

The system can be setup in multiple configurations on a bench or cart. This product has the ideal layout for our model. Figure 2 shows the open tray that contains the vascular model will provide a good reference by which to begin designing a secure frame for our model. The catheter insertion port is being studied to understand how to design a leak- resistant entry point. The pump can be purchased separately and is being considered for our system. Pricing information is currently being obtained to determine if this is feasible.

### *3.2.1.2 Existing Design #2: Vascular Simulations Replicator Pro*

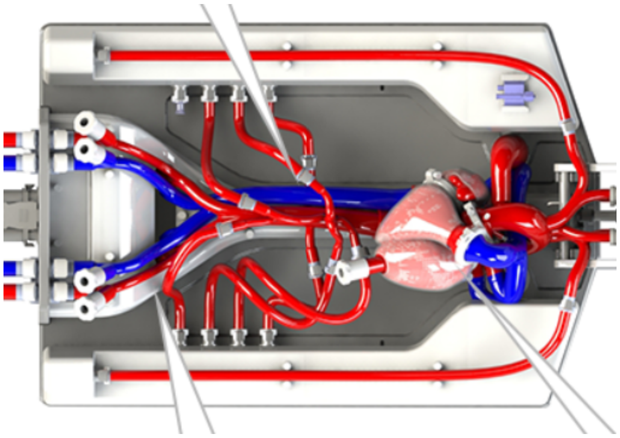

Figure 3. Silicon vasculature [28]

Figure 4. Multiple insertion points [28]

The Vascular Simulations Replicator Pro is a second complete system that meets all project requirements. It also includes a functioning aortic valve, which is beyond the scope of the project. In addition to providing all the necessary components shown in figure 3, the “Reflex” silicon anatomical model included with this system is matches the physiological range of compliance. The system also includes multiple catheter entry ports shown in figure 4. This design will also be studied to determine how to design leak proof insertion ports and incorporate multiple ports.

### *3.2.1.3 Existing Design #3: TrandoMed Endovascular Simulation*

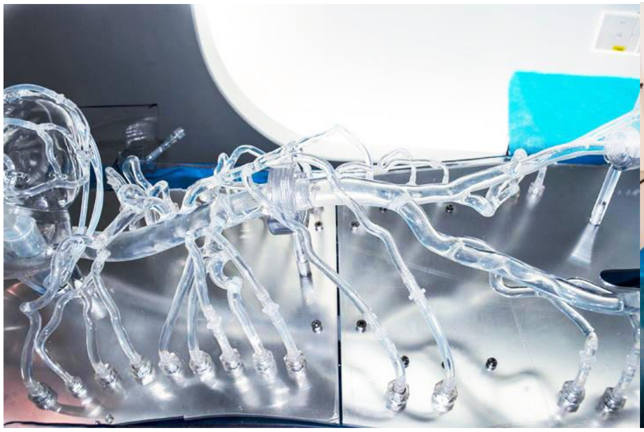

Figure 5. Vasculature [29]

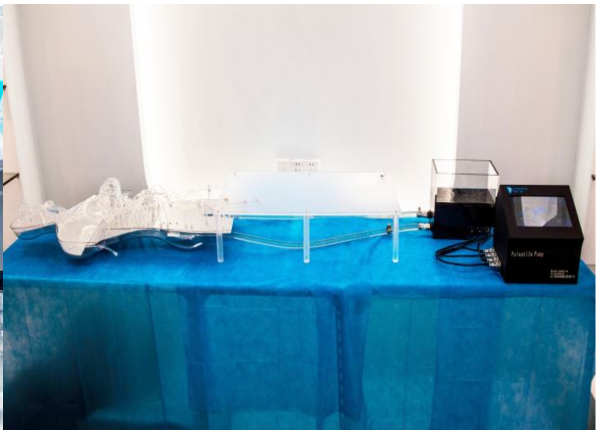

Figure 6. Complete system [29]

The TrandoMed endovascular simulation, shown above in figures 5 and 6, is a complete system manufactured in Zhejiang, China. Vessels in this system are composed of a proprietary silicone blend and are reconstructed from actual CT scan or MRI data. This system is also designed for medical device deployment training using catheters or guidewire. It contains an adjustable pump system capable of reproducing physiological conditions including blood pressure, temperature, and flow rate. Four complete vessel systems or custom ordered systems are available. This product inspired the team to seek MRI images for reference to create the most realistic iliac bifurcation model possible.

### 3.2.2 Subsystem Level Benchmarking

Subsystems where divided among the group in accordance to the literature review done by that group member. Chadrick's research focused on sensors and so he benchmarked sensors. This was the same for all members: Nicholas benchmarked GUI options, Seth benchmarked pumps, and Noah benchmarked materials. Casting methods was researched by Seth but no benchmarking is on these methods as the materials will sway the casting method one way or the other.

#### *3.2.2.1 Subsystem #1: Sensors*

It was decided by the team that the model should have a fluid flow condition monitoring system that would be used to display pressure and flow rate within the model. There are many different types of sensors on the market that are used to measure these values, so the team decided to benchmark with existing designs in order to aid in the concept generation and selection process. The sensor benchmarking is based on flow meters (the first three existing designs), and pressure transducers (the second three existing designs). Based on this benchmarking, the team will decide which sensors will be best to use for their initial concept. Below, these benchmarks are described in detail.

##### 3.2.2.1.1 Existing Design #1: Adafruit Liquid Flow Meter

This first design is a flow meter that can be used with liquids. It is a pinwheel flow meter, meaning that it allows the liquid to flow over a turbine, measuring the rotational speed, which can me converted to the linear speed of the fluid. This linear speed would be used to determine flow rate. This design requires careful calibration, and would not provide very accurate results. However, the cost is desirable, and it would work as a basic flow measurement device. It has threads for connection at the inlet and outlet, which could be used to attach to the model. It has a maximum water pressure of two MPa, which is well in the range that the model will be in.

##### 3.2.2.1.2 Existing Design #2: STEMiNC Ultrasonic Flow Sensor

This flow sensor uses ultrasound technologies in order to measure the velocity of a moving fluid. It provides a much larger accuracy than the pinwheel turbine, as long as it calibrated and configured correctly. The price is also comparable to that of the previous design, however, the team would need to buy two sensors in order to operate the system.

##### 3.2.2.1.3 Existing Design #3: Dwyer Series SFI-800 Sight Flow Indicator and Transmitter

This design is another pinwheel flow meter. It has very similar specifications to that of the first design mentioned above. This model has a much better accuracy, but has a significantly higher price. It can operate within the specifications of fluid flow that the team is trying to achieve, including temperature and pressure.

#### 3.2.2.1.4 Existing Design #4: AUTEX Pressure Transducer

The next step in sensor benchmarking was to benchmark with different pressure sensing technologies. This first design is a pressure transducer made with a stainless steel body, and is compatible with water. It can operate with pressures up to 150 psi, which is well above the expected pressure for the model. It can also operate at the expected temperature for the model. This transducer has a very competitive price, and could be beneficial to the team and the model.

#### 3.2.2.1.5 Existing Design #5: Dwyer Series 628CR Pressure Transmitter

This pressure sensor is very similar to the previous sensor, but it is a transmitter instead of a transducer. This means that the signal that it outputs is measured in milliamps instead of millivolts. This does not affect the usefulness, however, and can be accommodated for. This sensor has a higher price, but comes with a higher accuracy in the pressure readings. It operates within all of the fluid flow conditions that the model is expected to have, so this sensor is a viable option.

#### 3.2.2.1.6 Existing Design #6: Barksdale Series 600 OEM Pressure Transducer

This last pressure sensor is very similar to the second one mentioned above. It has a comparable accuracy and operates under the same conditions. However, this product was designed to withstand more cycles in a harsher environment. This increases the price significantly, which is not desirable. With the higher price and similar specifications, this transducer is not the team's first choice for a pressure sensor.

### *3.2.2.2 Subsystem #2: Pumps*

It was requested by the client that the team's device must match anatomical flow rates through the iliac bifurcation and the CIAA. This need will be met by choosing or developing a pulsatile pump that can produce the necessary parameters. These pumps need to be sufficient in its ability to deliver fluid (of density 1060 kg/m^3) at 111 ml/s, with a volume of 70 ml/beat, and a pressure of 141 mmHg. These parameters will be the minimum desired specifications if a pump is reviewed it will have these qualifications and its accessories will be reviewed.

#### 3.2.2.2.1 Existing Design #1: Peristaltic pump

The first pump is a peristaltic pump called the Masterflex L/S Compact Variable-Speed Pump. As described in the name it is a variable speed pump that can load two output hoses of the same diameter and synchronize their flow. This system can load hoses into the pump so that the pump can be removed from the system without teardown. Speed control ranges from 1.6 to 239 mL/min and is adjusted by a potentiometer. The dial type adjuster does not allow for accurate flow selection and pressure regulation is dependent on the size of the chosen tubing which will also change the flow rate. The pump is able to reverse and pause direction with the flip of a switch and has a max flow toggle switch for draining and priming. This pump has a price of 915.00 USD and is designed around medical applications.

#### 3.2.2.2.2 Existing Design #2: Piston Pump

The Vivitro Superpump is a pulsatile piston pump that is designed for artificial circulatory use. The pump has several accessories that attach to the outlet of the pump in order to simulate multiple areas of the vasculature. The pump works on a wide range of speeds (0-200

BMP), stroke lengths to change the volumetric flow rate (0-180 mL) and the pump can change its velocity wave platform. The pump controller has a digital display to accurately control the pump. If more precise pump control is necessary the system comes with its own software where the data collected from the pump can be displayed graphically in real time.

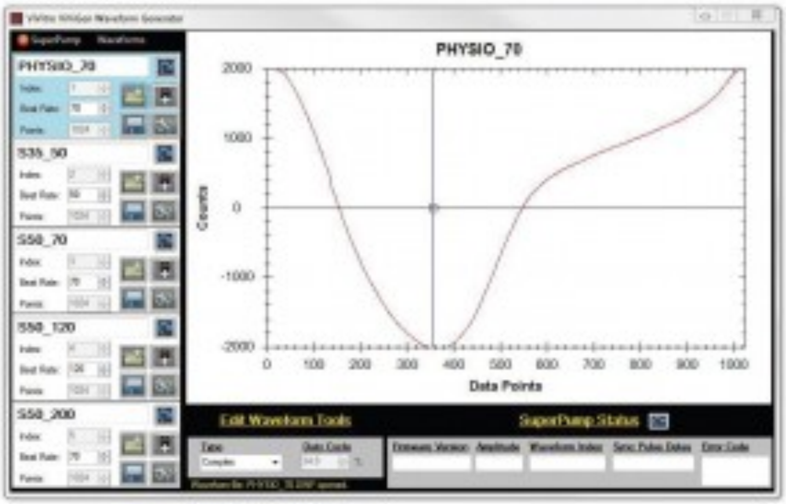

Figure 7. Data Collection from Pump Software [30]

#### 3.2.2.2.3 Existing Design #3: PD-1100

BDC Laboratories is a company that produces testing equipment for ventricular systems. Along with their systems they sell 3 different types of piston pumps. Pumps that are specifically designed for testing artificial heart valves and pumps for testing stents and grafts. The third pump that is company sells is a fully adjustable pump to perform at a wide range of applications. This pump is called the PD-1100 and it is able to operate at: 2-240 BPM, 0-25 L/min, max stroke volume of 300 mL, max pressure of 200 mmHg, and either Sinusoidal or arbitrary waveforms. This system also comes with its own software data collection.

### *3.2.2.3 Subsystem #3: Graphical User Interface for Display of Pressure and Flow Rate*

This subsystem was requested but not required from the client. In order to display active changes in the aneurysm pressure, flow rate, and volumetric change a GUI will be needed. There are many options for a GUI but Arduino, LabView, and Raspberry Pi were focused on for this project. Below is a description of the possible existing designs and equipment for each.

#### 3.2.2.3.1 Existing Design #1: Arduino - The microcontroller

Arduino is a very powerful tool that can interface seamlessly with computers and sensors in order to achieve different desired goals. Specifically, it is for microcontroller based projects [18]. This means that achieving a true GUI can be a little more difficult in the code than other options.

Arduino is by far most affordable option as LCD displays can be purchased on Amazon from three to fifty dollars [31]. Programming the microcontroller would require research and practice but could be done within the budget. LCD displays can be attached to an arduino and be programmed to display time variable data as time goes on [31]. Arduino GUIs are an option for this project still.

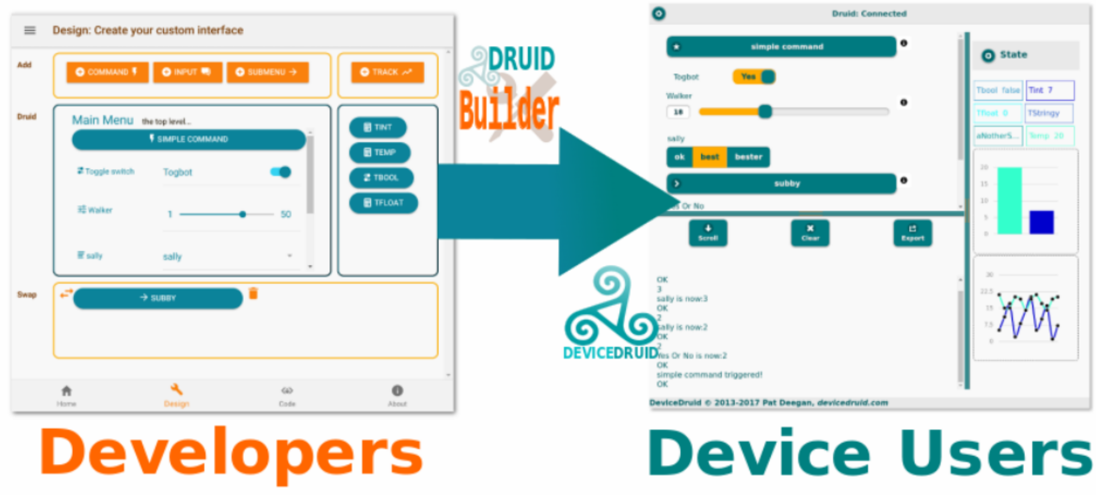

Figure 8. Example GUI created using Device Druid [32]

Arduino has the potential to display the requested data on LCD screens, but, it can also connect directly to a computer and simply transfer data to the GUI on that computer. Since the arduino community is so vast, there are other options for creating a GUI with Arduino. Online software developed by Pat Deegan can help to program the GUI for the computer and Arduino [32]. Arduino is tentatively the best option at this time because of resources like Device Druid.

### 3.2.2.3.2 Existing Design #2: Raspberry Pi

Raspberry Pis are considered pocket computers [20] and can be used for endless projects because of their ability to complete even the most complex of tasks. Running on Python the Raspberry Pi would be a learning experience as this language is not familiar to any group member. It is possible to run the arduino on the Raspberry Pi in order to have a take away GUI that will work for the client without need of downloading software and setting up the code on each computer.

The existing GUIs for Raspberry Pis are either a mixture of a microcontroller and Raspberry Pi or just Raspberry Pi.

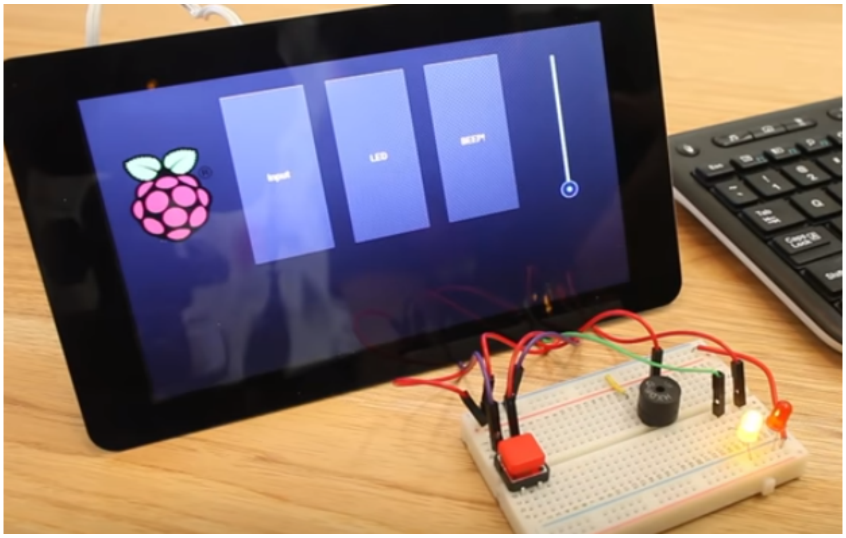

Figure 9. Example GUI using only a Raspberry Pi [20]

A Raspberry Pi would be able to create a GUI for our client. Raspberry Pi does not have a built in way to receive digital signals and would have to have an analog to digital converter to allow the pressure sensor to work properly. Overall if the group can complete the project with an Arduino then it can also interface a Raspberry Pi to make a complete GUI that can travel with the device.

#### 3.2.2.3.3 Existing Design #3: LabView GUI

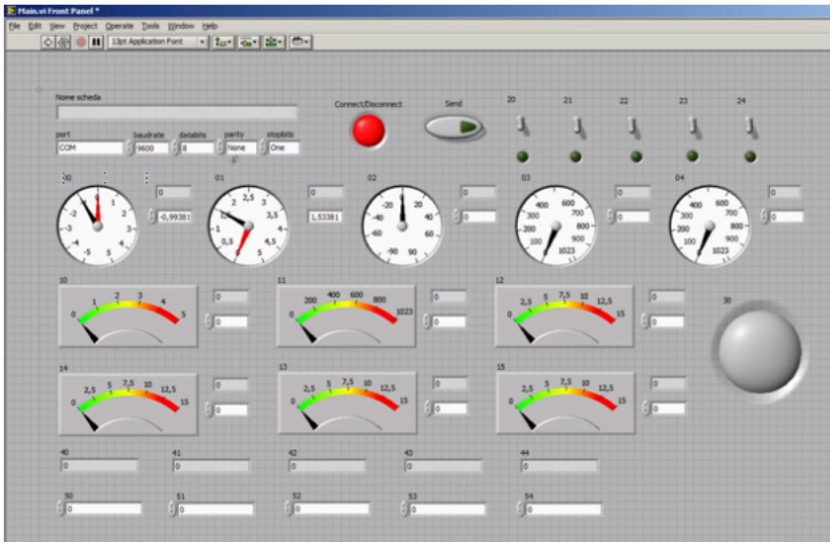

Figure 10. LabView GUI [19]

Above, Figure 10. shows a GUI created on LabView. This software by National Instruments, has been created for engineering data acquisition (DAQ) [19]. LabView is the easiest, fastest, most accurate, and most expensive option researched to create a GUI. The sensors have the highest accuracy and seamless connection to the device. The software comes with purchase of a DAQ. The software is easy to use and a simple GUI with pressure, flow rate, temperature, and volumetric change would be easy to create and navigate. This is easily the preferred method of creating a GUI; however, it is very expensive in comparison to other GUI options.

## *3.3 Functional Decomposition*

Functional decomposition was performed to determine the overall function and sub-functions of the design. To develop a black box model, the project description was reviewed and carefully dissected to analyze each requirement and identify the overall function.  After a satisfactory black box model was created, the project description was again reviewed to decompose the main function into sub-functions. In addition, benchmarking, which occurred concurrently with functional decomposition, revealed components necessary for a complete system.  Functions of these components were used to define sub-functions for the functional model.  Development of the black box model and functional model are described in detail below.

### 3.3.1 Black Box Model

The verb-object statement describing the overall function of this design was first described as “model aneurysm.” After further discussion and review of project requirements, the team determined this statement did not describe the entire function, which in addition to mimicking material properties and geometry of the aortic-iliac bifurcation and aneurysm, also includes mimicking anatomical conditions including flow rate and pressure through the model. As a result, the final overall function was defined as “model aneurysmal condition,” to include the overall condition in the human body.

Material, energy, and signal flows were identified as follows:

Materials inputs include hand, fluid, endovascular interventional device (device), and catheter. For the model to operate, the working fluid must first be inserted by hand to create the anatomical blood flow condition. The hand then inserts a catheter which deploys the device into the model. Outputs include catheter and hand. The catheter is removed while the device and fluid remain in the model. Energy inputs include human energy and electrical energy. Human energy is necessary to insert the catheter and device. Electrical energy is necessary to power a pump to circulate the fluid. Energy outputs include kinetic energy of the circulating fluid and heat energy from the pump. The on/off switch acts as an input signal to initiate fluid circulation. Output signals include sound from the pump, indicating its operation, heat from the pump, and a visual signal of the device and catheter location through the transparent material. The black box model is shown below in Figure 11.

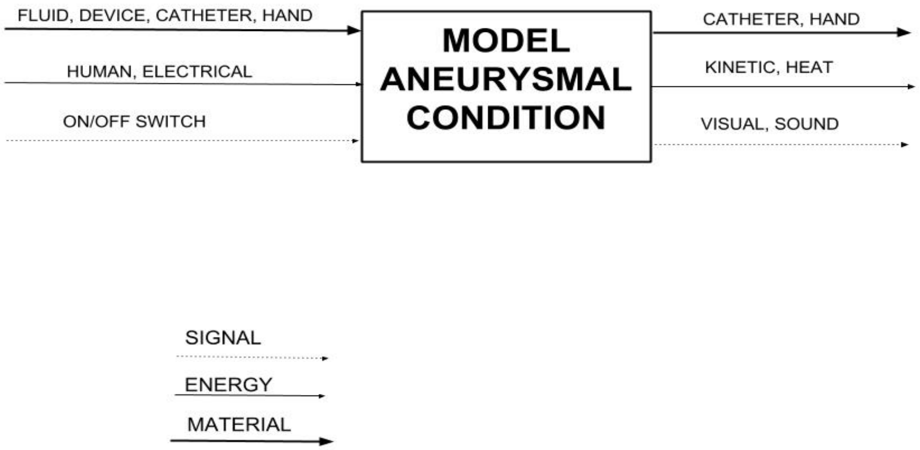

Figure 11. Black Box Model

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

The team analyzed the individual components identified for benchmarking to determine each of their basic functions. These basic functions were defined as the design's sub-functions. Sub-functions were systematically arranged and related to one another through material, energy, and signal flows defined in the black box model. The functional model shown in the figure 12 below was the product of this analysis. This model includes only the required functions listed in the project description. The optional functions required for the data acquisition system will be analyzed and added or an additional functional model created if data acquisition is added later.

One important sub-function of the design is fluid circulation, which is necessary to mimic blood flow through the iliac bifurcation and aneurysm. Electrical energy must be imported and converted to mechanical energy to perform this action. This indicates the need for an electric pump capable of moving fluid similar to the action of the human heart. A second important sub-function is device containment, which relates to catheter insertion, device deployment, and catheter removal. These actions are performed by hand, which requires human energy. The design must contain the device securely enough to prevent migration and leakage around the interface between the device and synthetic artery. This indicates the geometry of the physical model must match that of the human anatomy very closely in the region near the device, and mechanical properties of the material must be such that a water tight seal can occur at this interface. Further discussion of this function chain also uncovered the importance of designing an entry point that will resist leakage of the circulating fluid after the catheter and device are inserted.

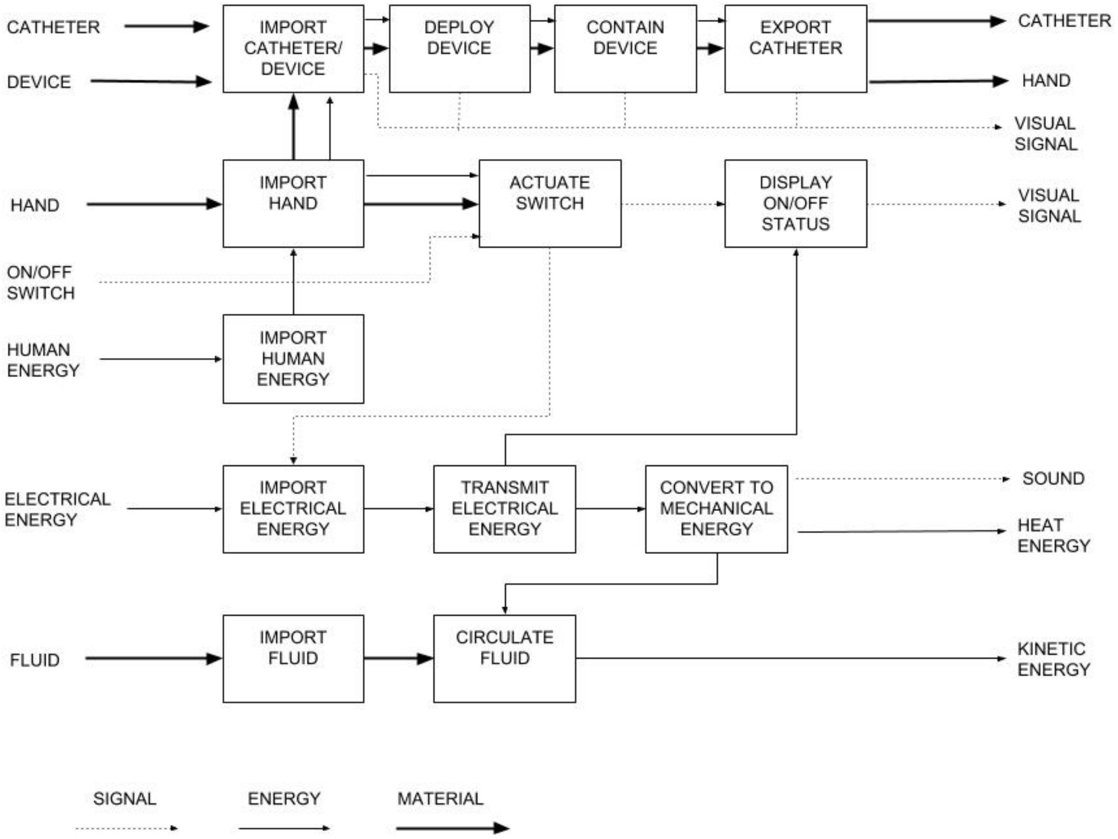

Figure 12. Functional Model

# 4 CONCEPT GENERATION

## *4.1 Full System Concepts*

Three full system concepts are described below. These concepts have been generated using different combinations of subsystem concepts. Detailed descriptions of each subsystem concept with benefits and drawbacks of each follow this section.

### 4.1.1 Full System Design #1: Fundamental system (Base)

This design contains the following components:

-30 shore A silicone model

-Silicon mold for wax core

-Low melt wax core

-Aluminum outer mold

-Custom built pulsatile pump

-Room temperature DI water

This design will be the lowest cost option. The model would be cast from 30 shore A silicone using an aluminum mold. 60 shore A silicone mold would be created to cast a low melt wax core to shape the inside of the model. A pulsatile pump would be custom built to move the fluid. Deionized water would be used for the working fluid. No heating element would be supplied to heat the fluid.

### 4.1.2 Full System Design #2: System with Temp Control and (DLX)

The deluxe design contains these components:

-Polyurethane model

-Silicon mold for wax core

-Low melt wax core

-Silicon outer mold

-Off the shelf pulsatile pump

-Temperature Control

-DI water for working fluid

This design is a balance of cost and effort. It contains a model cast from 45 shore A polyurethane. The outer mold and wax core mold would both be composed of 45 shore A silicone. A complete pulsatile pump would be purchased off-the-shelf to produce physiological pressure and flow conditions. A heating element would be included to heat the fluid within the range of human blood temperature. Deionized water would be used for the working fluid in the system.

### 4.1.3 Full System Design #3: Complete System with Temp Control, Realistic Fluid, and GUI (SR4)

The SR4 design package contains the following components

-40 shore A silicone model

-Silicon inner and outer molds

-low melt wax core

-Off the shelf pulsatile pump

-DAQ with GUI

-Temperature Control

-Blood mimicking fluid

This complete system consists of all the required and optional components for the design. The model will be cast from 40 shore A silicone. Both inner and outer molds would be created from 45 shore A silicone. The low melt wax core would be used to shape the inside of the model. An off the shelf pulsatile pump would provide physiological pressure and flow conditions. Fluid with a similar viscosity and to blood would be circulated by the pump and heated to human blood temperature. Dwyer Series pressure transmitter and SFI 800 sight flow indicator and transmitter would provide pressure and flow data to a labquest data acquisition system which will output to a graphical user interface.

## 4.2 Subsystem Concepts

Subsystem concepts were generated in accordance to research and benchmarking so once again each piece was taken on by the group members just as before; however, Seth also handled casting methods in this section on top of pumps.

### 4.2.1 Subsystem #1: Sensor Configuration

There are two main ways that the pressure sensors can be configured. Each method provides an adequate pressure reading, while not significantly interfering with the model. It is important to note that each configuration would only require one flow meter before the aneurysm, with no real significance in its placement, because flow rate can be assumed relatively constant throughout the modeled aorta. Both configurations are described below.

#### *4.2.1.1 Design #1: Two Pressure Transducers Surrounding Aneurysm*

One configuration in which the pressure sensors can be set is right before and right after the aneurysm in the model. This way, a pressure difference can be measured which can determine an estimated pressure inside of the aneurysm. This method would be desirable because it would maintain the complete geometry of the aneurysm. However, this configuration would require two transducers to be purchased.

#### *4.2.1.2 Design #2: One Pressure Transducer at Aneurysm*

Another configuration for the sensors is having only one transducer, located in the middle of the aneurysm. This setup will allow a pressure measurement to be made directly, rather than taking the difference between two points. This would create the need to create a tapping on the wall of the aneurysm, which could potentially alter the geometry and flow rate, which can skew the results. Nevertheless, this method would require only one transducer and, therefore, is more cost effective.

### 4.2.2 Subsystem #2: Materials

#### *4.2.2.1 Platinum-Based Silicone*

Two-part room temperature thermosetting platinum based silicone is being considered for the design due to its elastomeric properties and thermal stability. Silicon has low toxicity, antiadhesive properties, and low modulus, making it an ideal candidate for the vascular model [4]. Shore A hardness of 15-40 can be achieved with the translucent silicones being considered [26]. Although translucent, the silicon model may not be as clear as polyurethane.

4.2.2.1.1 30 Shore A Platinum Silicone

The 30 shore A translucent silicone has tensile strength of 700 psi, 400% elongation, and a tear strength of 65 pli. The mixed viscosity in the liquid state before setting is 45000 cps, and the work time is 30 min. [26] The lower viscosity will be easier to cast with than harder silicones. Although the lower tear strength and % elongation may be less desirable, this softer material may provide a better seal at the interface between the model and device. 30 Shore A hardness was also recommended by the team's faculty advisor. Thermal stability gives silicone an advantage in performing consistently under different temperature and humidity conditions.

4.2.2.1.2 40 Shore A Platinum Silicone

The 40 shore A silicone has tensile strength of 865 psi, 540% elongation, and a tear strength of 95 pli. The mixed viscosity in the liquid state before setting is 65000 cps, and the work time is 40-45 min. [26] Although the higher viscosity may be slightly more difficult to cast with than 30 shore A silicon, the longer work time may offset this. Higher tear strength and % elongation will yield a stronger model than 30 shore A silicon, but harder material may not seal as well at the interface.

#### 4.2.2.2 Water Clear Polyurethane Elastomer

The 45 shore A polyurethane has tensile strength of 390 psi, 300% elongation, and a tear strength of 43 pli. The mixed viscosity in the liquid state before setting is 910 cps, and the work time is 20 min [26]. This low viscosity liquid may be the easiest option for pouring into a mold. This material is the most transparent of those considered and will provide the best viewing of the catheter and device during insertion and deployment. This polyurethane is compatible with platinum silicone molds, is easy to cast with and releases easily after curing [26]. Polyurethanes are also superior to silicones in abrasion and flex-fatigue life. They are highly sensitive to environmental changes, and soften significantly with increasing temperature and humidity. [24] This could be advantageous in providing a rigid model that maintains its geometry but softens under testing conditions to provide a better seal. The cost of this material is slightly higher than silicones listed above.

### 4.2.3 Subsystem #3: Casting Methods

Casting the material will involve the team creating a CAD model and 3D printing that model. The 3D Print will be the foundation for several types of mold making and will need to be as precise as possible. Not only will shrinkage of the print be a critical point but the print will need to be costed and sanded to a smooth finish. Once the desired 3D print has been completed it will be time to choose a method for making the mold. Methods that have been explored and considered are aluminum casting, silicone casting, and clay packing.

#### 4.2.3.1 Design #1: Aluminum

There are multiple ways that the team could achieve an aluminum mold. One of the team members has an aluminum foundry and has experience in casting. This method would yield a cost effective mold that would have a sandblasted looking finish across the inner surface. The mold would be aesthetically pleasing and would be an excellent prop for presentations. The strength would exceed the number of castings that this project requires and would have a long shelf life in case the project needed to be repeated in later years.

The 3D print would be made in two negative molds and then packed with petrobond sand. The sand would be removed from the mold and placed in a squared out box of more and this would leave a negative sand shell for aluminum to be poured on top of. This process would have to be repeated for each side of the mold. Silica sand would be the other option of creating this cast. Silica sand would be mixed with resin and poured into the negative and set to dry. This would create a solid mold of half of the model on a flat plane this would then have the aluminum poured over the back of the silica sand and could be reused to make multiple molds. This technique leaves the aluminums surface much more rough compared to the petrobond [15].

Pros:

1. Strength
2. Multiple casting potential
3. Long life span
4. Impressive presentation prop
5. Cheap

Cons:

1. building time will take away from other project deliverables
2. Sandblasted texture may cause poor translucence
3. Casting shrinkage would make precise geometry difficult
4. may take several attempts

#### *4.2.3.2 Design #2: Silicone*

Silicone molding is commonly used for casting chocolate candies and other cool temperature pours. Silicone molds are able to be reused multiple times depending on the material casted. Several companies sell compliant silicon mold and cast materials. Silicone can be casted in several values of hardness, ranging from shore A 15-60 [26]. Silicone has release characteristics that would allow it to release other silicones, resins, and polyurethanes. A release agent would still be used in order to extend the life of the mold. Silicone oxidizes slowly over a long period of time and this would reduce the shelf life of the mold.

The 3D print would be placed in a Plexiglas box and the two part liquid silicone mix would be slowly poured over the print, after it was degassed. The silicone would then be carefully cut away from the 3D print to yield two silicone shells. A pour hole would be cut out the top of the mold so that the material could be poured into the mold. This method would produce a smooth surface finish that would be aesthetically pleasing and would increase its translucent characteristics.

Pros:

1. Cheap compared to outsourcing a CNC mold
2. Smooth surface finish
3. Reusable

Cons:

1. Make take several attempts
2. Messy
3. Shelf life

#### *4.2.3.3 Design #3: Inner core*

The previous casting methods have all been focused on how to create the exterior of the mold. This material needs to be hollow which will involve either a second mold or some removable material for the core. The difficulty of having a removable core is the bifurcation. The bifurcation will make it so we cannot have a solid inner core. One option for a solid inner core would be to make the core like Legos. The three pieces will lock into one another and be able to be detached in order to pull them out of the material. The other consideration will be a melt-able or dissolvable material.

Solid core materials will need to be manufactured to exact geometry and be able to connect without the material leaking into the connection points. For this reason the team will be using a melt out material. A second mold will need to be created in order to cast such a material. This cast will need to be as smooth as possible to resemble the inside of an artery. Casting wax for the core would give the team an ability to remove the core and have a smooth surface. [15]

Pros:
1. Smooth
2. Easily removable
3. Replicable process

Cons:
1. Messy
2. Material will need to withstand melt out temperature

### 4.2.4 Subsystem #4: Graphic user interface options.

Functional decomposition was done for the minimum requirements; moreover, a GUI was not on that list. The project team has set a goal to include a GUI. In order to display on and off positions a switch would suffice. The client requested a GUI that will display on and off, volumetric change in the aneurysm, pressure of aneurysm, and the flow rate through the model. Volumetric change in the aneurysm will be considered in later reports given that a working GUI is created to display the other three requests first.

In order to fulfill this request Nicholas began research on GUI options that would be applicable to the project. Three options were found and focused on: LabVIEW, Raspberry Pi, and Arduino.

#### *4.2.4.1 Design #1: LabView*

LabView can easily create the requested GUI. The DAQ system used in LabVIEW is what makes the software so expensive. A sufficient DAQ for this project is shown in Figure 13. below. Using this we could make an appropriate GUI on a laptop and have the software accessible to the client.

Figure 13. USB DAQ [31]

**Pros**

1. Easy to use software
2. Configure and calibrate most sensors using in software prompts
3. High level of accuracy can be established with little effort
4. Multiple device inputs are built in and ready

**Cons**

1. This is the most expensive option. A single GUI with National Instruments would be 5 or more times more expensive than one from an arduino.
2. Must have a computer for working GUI.

#### *4.2.4.2 Design #2: Raspberry Pi*

A Raspberry Pi would be able to make a GUI that would be either have an LED display or a more complex graphic screen. The PI requires a wireless keyboard, mouse, HDMI screen, appropriate programming, sensors, and a few more electronic pieces to make a complete unit. This would be a carry away unit that could provide the desired GUI on the fly.

**Pros**

1. Raspberry Pi foundation is a community of programmers that open source code and can help with questions on forums.
2. Affordable computer and graphical interface possibilities.
3. Complete GUI that can be taken by client.
4. Interface with microcontroller if required.

**Cons**

1. Learning a new programming language python
2. Lots of start-up electronics required before programming can begin
3. Digital pins so an analog to digital converter (ADC) will be required

#### *4.2.4.3 Design #3: Arduino*

An arduino would require a computer for the GUI. The program could be uploaded via a USB to any computer and executed to provide the requested GUI. Each sensor can be interfaced to the arduino analog pins and calibrated through the free programming supported by arduino.

**Pros**

1. Most affordable option for a GUI
2. Open source community with example code and free help
3. Can be calibrated and interfaced with almost any sensor
4. Analog and digital pin receivers so ADC not required

**Cons**

1. Does not have as much function as a Raspberry Pi.
2. Must be paired with a computer for GUI to work.

### 4.2.5 Pumps

Pumps will be key for completing our project to meet our client's needs. The pump will be used to create an anatomical pressure and flow rates of the fluid through the system. There are several pumps on the market that work with differing methods. The scope of this project is not to build a pump to achieve this flow so, the team will be looking to purchase a pump. This section will be covering the different type of pumps and not any specific brand in order to choose which style meets our criteria best.

#### *4.2.5.1 Peristaltic*

Peristaltic pump work by squeezing a flexible hose to push the fluid through the system. These pumps are usually built to deliver a set volume of fluid per beat. For the team budget it may not be feasible to purchase a peristaltic pump that would have an adjustable volume therefore, the pro and cons list will be based on a non-adjustable volume pump. These pumps are used for this type of application because of their ability to self-prime and to provide a precise amount of fluid per cycle [13].

Pros:
1. Cheap
2. Easily maintained
3. Adjustable Cycles per minute
4. Precise volume output
5. Pulsatile flow

Cons:
1. Non-Adjustable volume
2. low pressure application

3. May be built to hold one size of hose
4. Cannot control wave platform

#### *4.2.5.2 Piston*

Piston style pumps are the best at replicating the hearts anatomical flow. These pumps are expensive and require regular maintenance. This maintenance requires the system to be drained of its fluid in order to remove the pump from the system. The main reason these pumps are more commonly used is that they are adjustable for volume, pressure, and cycles. These pumps are also of few that can create a sinusoidal flow in the system to match a hearts flow [12].
Pros:

1. Adjustability
2. Anatomical replication
3. Pulsatile flow
4. Sinusoidal pressure

Cons:

1. Expensive
2. Difficult maintenance

#### *4.2.5.3 Continuous Flow*

Continuous flow pumps are usually centrifugal or axial type pumps. These pumps are starting to be used in the field of artificial medical application. These pumps are adjusted by the speed of the of the flow and pressure by the diameter increase or decrease of the output hose. These pumps can be pulsatile with computer monitoring by regulating the motors speed in a sinusoidal waveform [33]. This is not impossible to achieve for the team but may take more time than is desirable when compared to purchasing a pump that already provided a pulsatile and sinusoidal flow.

Pros:

1. Cheap
2. Reddit available
3. Meets anatomical flow is computer aided

Cons:

1. difficult to set up pulsatile flow

# 5 DESIGN SELECTED – First Semester

The design selected is a design that the team currently agrees will achieve the goal of the project. The overview of the project is to select a material, a pump, fluid, and manufacturing method. The Project is expected to grow after these selections can be proven to function to the team specifications. The next Phase of the project the team will add a GUI and sensors to the system. These sensors will be able to prove that our system is meeting our requirement in real time.

## 5.1 Technical Selection Criteria

The QFD [Appendix A] lays out the projects engineering requirement and target values along with their tolerances. These target values are the results of weeks of individual research and the team's ability to gather and order the data accordingly. Each concept generation was developed with these target values in mind. If a concept could not meet these requirements the concept was discarded and a new concept was developed. The requirement will be broken down for each of the subsystem concepts and related to the customer need that they meet.

### 5.1.1 Sensors

The sensors that will be chosen must be able to handle the conditions that the model will be operating at. For example, the team has decided that the model will maintain a temperature of 37 °C, so the sensors must be able to withstand this temperature. Likewise, the sensors must be able to operate at a pressure between 68 and 141 mmHg, and a flow rate between 94 and 111 mL/s. Also, these sensors must be able to operate with water, or a similar fluid, as the working medium, otherwise the model will fail. Additionally, it is desired by the team that these sensors output an analog signal, and can be connected to any DAQ and GUI. Lastly, it is desired that the cost of these sensors not exceed five percent of the total budget per individual sensor. If sensor were to satisfy each of these criteria, it would likely be chosen.

### 5.1.2 Materials

Properties of the material selected for the model including surface roughness, hardness, and shear modulus must relate to those of the arteries to replicate physiological conditions as stated in the project requirements. These engineering requirement targets were initially selected through research of mechanical properties of human anatomy.  Research was performed to identify suitable materials to meet these requirements.  It was found that since the arterial walls have complex structure and exhibit complex mechanical behavior, it is extremely difficult to match all material properties of the human anatomy [25].  Further research of vascular models constructed from non-biological materials was used to define reasonable target values and tolerances for materials to ensure the model will perform well.

### 5.1.3 Casting

Casting of the material will affect the geometry of the model and the method will need to be selected to reduce deformation and increase consistency. The bifurcations geometry is dependent on: surface roughness, wall thickness, aneurysm length, aneurysm diameter, diameter of distal aorta, diameter of left iliac, diameter of right iliac, radius of curvature of each junction, distance from bifurcation to femoral insertion point, and angles of the Iliacs. These Geometric quantities will be carefully included when producing the CAD model. The job of the casting material will be to accurately contour the 3D print without major changes to the surface of the material. These engineering requirements were developed from the customer need to match the anatomical geometry of the bifurcation and aneurysm.

Casting incorporated into concept generation to meet the client requirement for a replicable manufacturing process. If a method did not yield accuracy or consistency in each cast the concept was discarded. The engineering requirement that related to this customer need was cost. It is desired to keep the cost low which results in discarding the option of having each of the models UV 3D printed.

### 5.1.4 GUI

GUI options were examined for ease of use and compatibility with sensors. In order to quantify ease of use Nicholas took note of each member's familiarity with the GUI software. Sensors send signals in analog or digital; therefore, the GUI build was analyzed for both inputs. Raspberry Pi needs an ADC in order to receive analog signal and it is the least familiar programming language for the entire group, so it was at the bottom of the list for selection. Arduino is the second best as it is able to receive both analog and digital inputs but only one group member is familiar with the microcontroller. LabView was the best option as its software is familiar to half the team, it receives both kinds of input signal, and calibration of sensors is a built in function; however, the DAQ is very expensive. In order to stay within budget, the team will plan on using Arduino for the GUI.

### 5.1.5 Pumps

The client requested that the system is to be able to replicate anatomical flow conditions. These flow conditions are met through pump choice and manipulation of a pump. The engineering requirements that were created for this customer need are mean flow rates of the Iliacs and the aortic pressure. There is not a engineering requirement to describe the pulsatile flow because the heart does not meet any quantifiable function. The flow and pressure targets were previously mentioned in section 3.2.2.2, 5.1.1, and can also be found in the QDF in appendix A.

## 5.2 Rationale for Design Selection

45 Shore A clear polyurethane is currently the preferred material for the model. It is compatible with any of the silicones being considered for molding and has a much lower viscosity (910 cps in its liquid state), which will make it easier to work with than silicone. It also has the highest transparency of the materials considered [26]. Polyurethane has a tear strength, abrasion, and flex fatigue life superior to silicone [25]. Hardness and tensile strength fall within tolerances for the design. This material softens with increasing temperature and moisture, which should result in a good seal at the interface between the device and model [25]. Samples of this material and the silicones being considered are currently in shipping and will be tested and compared before final material selection.

45 Shore A room temperature curing platinum-based silicon is currently the preferred material for the molds. This material came highly recommended over other silicones from the potential source due to its ease of use and compatibility with the polyurethane selected for the design [26]. Although the cost is slightly higher than the aluminum being considered, it will produce a model with a smoother surface. Samples of this and other silicones are also being shipped for testing.

Arduino is currently the preferred GUI for the system. This is due to the fact that the GUI can be made using DeviceDruid and the assistive software can even aid in calibration of the sensors. Although LabView is capable of interfacing and performing data collection, the cost outweighs the benefits of the DAQ. Arduino is as compatible as a LabView DAQ. It will take more work to get the GUI as user friendly as a LabView GUI, but the price of an Arduino justifies the effort.

The best possible pump that the team could use is a piston style pump. The team reached out to a company to request pricing for a superior piston pump that was designed to simulate the heart's natural rhythm. This pump was priced at 25,000 USD with a 5% discount for academic purposes.

The teams max budget sits at a comfortable 3,000 UDS. This pump was the absolute leader in heart simulation so, the team will continue to try to find piston style pumps in order to deliver the best performance to our client. In the event that a piston style pump cannot be found the team will resort to peristaltic pumps which are cheaper and more readily available.

The team is excited to gather materials to start characterizing and testing.

# 6 REFERENCES

[1] A. Deswal, B. K. Tamang, A. Bala, “Study of Aortic- Common Iliac Bifurcation and Its Clinical Significance,” *Journal of Clinical & Diagnostic Research*, vol. 8, no. 7, July, 2014. [10.7860/JCDR/2014/8767.4559]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4149059/. [Accessed Feb. 25, 2019].

[2] N. Kontopodis, Et al., “Advances in determining abdominal aortic aneurysm size and growth,” *World Journal of Radiology*, vol. 8, no. 2, February 2016. [doi: 10.4329/wjr.v8.i2.148]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4770177/. [Accessed Feb. 26, 2019]

[3] W. Reilly. “Project 1 - W.L. Gore & Associates Senior Capstone Project Proposal,” Project Description (January, 2019)

[4] P. Shah, H. Scarton, And M. Tsapogas, “Geometric anatomy of the aortic-common iliac bifurcation,” *Journal of Anatomy*, vol. 26, no.3, pp. 451-458, Aug 1978.

[5] W. L. Gore & Associates (2019) goremedical.com [Online]. Available: https://www.goremedical.com/products/excluder/specifications [Accessed Mar. 3,2019]

[6] H. Astrand, Et al., “In vivo estimation of the contribution of elastin and collagen to the mechanical properties in the human abdominal aorta: effect of age and sex,” *Journal of Applied Physiology*, January 2011. [doi: 10.1152/japplphysiol.00579.2010] Available: https://www.physiology.org/doi/full/10.1152/japplphysiol.00579.2010. [Accessed Feb. 28, 2019].

[7] R. S. Figliola, D. E. Beasley, *Theory and Design for Mechanical Measurements*. Hoboken: John Wiley and Sons, Inc, 2011.

[8] Shekhar Bhansali and Abhay Vasudev, *MEMS for biomedical applications*, Oxford : Woodhead Pub., 2012. [E-book] Available: https://www-sciencedirect-com.libproxy.nau.edu/book/9780857091291/mems-for-biomedical-applications. [Accessed Feb. 28, 2019].

[9] OMEGA engineering, “What is a Pressure Transducer?,” *OMEGA engineering,* 2003 - 2019. [Online] Available: https://www.omega.com/prodinfo/pressure-transducers.html. [Accessed Feb. 28, 2019].

[10] Engineering ToolBox, *Types of Fluid Flow Meters*. 2003, [online] Available: https://www.engineeringtoolbox.com/flow-meters-d_493.html [Accessed Feb. 28, 2019].

[11] Björck and Bergqvist (2006). Blood-flow of the inferior mesenteric and internal iliac arteries among patients undergoing open surgery for abdominal aortic aneurysm. Vasa, [online] 35(1), pp.11-14. Available at: https://www.ncbi.nlm.nih.gov/pubmed/16535963./ [Accessed 3 Mar. 2019].

[12] Tsai, W. and Savaş, Ö. (2010). Flow pumping system for physiological waveforms. Medical & Biological Engineering & Computing, [online] 48(2), pp.197-201. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2807595./ [Accessed 3 Mar. 2019].

[13] LAMBERT, P. (2019). [online] Available at: http://www.pharmtech.com/dispensing-biopharmaceuticals-piston-and-peristaltic-pumps [Accessed 3 Mar. 2019].

[14] Donovan FM Jr, e. (2019). Efficiency and power requirements of the diaphragm-type artificial heart. - PubMed - NCBI. [online] Ncbi.nlm.nih.gov. Available at: https://www.ncbi.nlm.nih.gov/pubmed/4815813 [Accessed 3 Mar. 2019].

[15] Kowal, D. (2014). Sculpture casting. New york: crown publishers, inc., pp.24-36, 83-127, 150-188.

[16] T. Chuter, Et al., "Infrarenal aortic aneurysm structure: Implications for transfemoral repair," *Journal of Vascular Surgery*, vol. 20, no. 1, July, 1994. [doi: 10.1016/0741-5214(94)90174-0]. Available: https://www.jvascsurg.org/article/0741-5214(94)90174-0/fulltext. [Accessed Feb. 25 2019].

[17] Karel van de Vosse, "Abdominal aortic wall thickness and compliance," University of Technology Eindhoven, Eindhoven, Netherlands, BMT Number. BMTE 08.47, Sept. 2008. Available: http://www.mate.tue.nl/mate/pdfs/9872.pdf. [Accessed Feb. 25, 2019].

[18] S. Monk, *Programming Arduino: getting started with sketches*, 2nd ed., New York, NY: McGraw-Hill, 2016.

[19] National Instruments, "What is LabVIEW," *National Instruments*, 2019. [Online]. Available: http://www.ni.com/en-us/shop/labview.html. [Accessed Feb. 26, 2019]

[20] Raspberry Pi Foundation, "Getting started with GUIs," *Raspberry Pi Foundation,* [Online]. Available: https://projects.raspberrypi.org/en/projects/getting-started-with-guis/2. [Accessed Feb. 26, 2019]

[21] O. Narayan, Et al. "Reservoir Pressure Analysis of Aortic Blood Pressure – an in vivo study at five locations in humans," *Europe PMC Funders Group*, vol. 35, no. 10, October, 2017. [doi:10.1097/HJH.0000000000001424]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5581543/pdf/emss-73076.pdf. [Accessed Feb. 25, 2019].

[22] A. V. Kamenskly, Et al., "Biaxial mechanical properties of the human thoracic and abdominal aorta, common carotid, subclavian, renal and common iliac arteries," *Biomechanics and modeling in mechanobiology*, vol. 13, no. 6, November, 2014. [doi: 10.1007/s10237-014-0576-6]. Available: https://www.ncbi.nlm.nih.gov/pubmed/24710603. [Accessed Feb. 25, 2019]

[23] P. J. Pritchard, J. W. Mitchell, and J. C. Leylegian, *Fox and McDonald's Introduction to Fluid Mechanics,* 9th ed., Hoboken, NJ: John Wiley & Sons, Inc.,2015

[24] A. Rahimi and A. Mashak, Review on rubbers in medicine: Natural, silicone and polyurethane rubbers, Plastics, Rubber and Composites, v 42, n 6, p 223-230, July 2013.

[25] V. Kanyanta and A. Ivankovic, "Mechanical characterisation of polyurethane elastomer for biomedical applications," Journal of the Mechanical Behavior of Biomedical Materials, vol. 3, no. 1, Jan., pp. 51-62, 2010.

[26] BJB Enterprises (2019) bjbenterprises.com [Online]. Available: https://bjbenterprises.com [Accessed Mar. 3,2019]

[27] Vivitrolabs inc. (2019) Vivitrolabs.com [Online]. Available: https://vivitrolabs.com/product/endovascular-ev-simulator/. [Accessed Feb.1,2019]

[28] Vascular Simulations (2019) vascularsimulations.com [Online]. Available: https://vascularsimulations.com/. [Accessed Mar. 3,2019]

[29] Trando Med (2019) trando-med.com [Online]. Available: https://www.trando-med.com . [Accessed Mar. 3,2019]

[30] Biomedical Device Consultants & Laboratories LLC. (2019). Pulsatile Pump Systems. [online] Available at: http://www.bdclabs.com/testing-equipment/pulsatile-pump-systems/ [Accessed 3 Mar. 2019].

[31] Amazon.com. (2019). *Amazon.com: Online Shopping for Electronics, Apparel, Computers, Books, DVDs & more*. [online] Available at: https://www.amazon.com/ref=nav_logo. [Accessed Feb. 28, 2019].

[32] Pat Deegan, *Device Druid.* Devcedruid.com, 2017. [Online]. Available: https://devicedruid.com/. [Accessed Feb. 28, 2019]

[33] Ising, M., Sobieski, M., Slaughter, M., Koenig, S. and Giridharan, G. (2015). Feasibility of Pump Speed Modulation for Restoring Vascular Pulsatility with Rotary Blood Pumps. ASAIO Journal, 61(5), pp.526-532.

# 7 APPENDICES

## 7.1 Appendix A: House of Quality

| Customer Requirement | 1. Safe per ANSI/OSHA | 2. Easy to Move | 3. Mimic Anatomical Flow Conditions | 4. Match Aneurysm Mechanical Properties | 5. Match Aneurysm Geometry | 6. Transparent Material | 7. Replicable Manufacturing Process | 8. Displays Pressure | 9. Displays Flow Rate | 10. Stable Base | 11. Displays Aneurysm Volume Change | Absolute Technical Importance (ATI) | Relative Technical Importance (RTI) | Target ER values | Tolerances of Ers | Testing Procedure (TP#) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Weight** | 10 | 3 | 7 | 8 | 9 | 9 | 6 | 5 | 5 | 4 | 3 | | | | | |
| **Engineering Requirement** | | | | | | | | | | | | | | | | |
| Mean Flow Rate in left iliac (ml/s) | | | | | | | | | | | | | | 94 | | |
| Mean Flow Rate in right iliac (ml/s) | 1 | | 9 | | | | | | 9 | 3 | | | | 111 | | |
| Aortic Pressure sys/dias (mmHg) | 3 | | 9 | | | | | 9 | | | | | | 141/68 | | |
| Surface Roughness (micrometers) | | | | | | | | | | | | | | | | |
| Hardness (shore OO) | | | | 9 | | | | | | | | | | 41 | | |
| Shear Modulus (kPa) | 1 | | | 9 | | | | | | | | | | 175 | | |
| Wall thickness | 1 | 1 | 1 | | 9 | | | | | | | | | 2 | | |
| Aneurysm Diameter | | | | 9 | | | | | | | | | | 35 | | |
| Aneurysm Length (mm) | | | | 9 | 9 | | | | | | | | | 27 | 4.1 | |
| Creep (mm/year) | | | | 9 | | | | | | | | | | 2.9 | | |
| See-Through Model (binary) | | | | | | 9 | | | | | | | | Y/N | n/a | |
| Fluid Temperature (C) | 1 | | 1 | 1 | | | | 1 | 1 | | | | | 37 | | |
| Weight of entire system (kg) | 1 | 9 | | | | | | | | 3 | | | | 23 | | |
| Total Cost ($) | | 1 | 3 | 3 | | 1 | 3 | 3 | 3 | 1 | 3 | | | ### | 200 | |
| Diameter of distal Aorta | | | 9 | 3 | | | | | | | | | | 25.5 | 6.5 | |
| Diameter of Left Iliac | | | 9 | 3 | | | | | | | | | | 16.5 | 8.5 | |
| Diameter of right iliac | | | 9 | 3 | | | | | | | | | | 16.5 | 8.5 | |
| Radius of Curvature at Right Junction (mm) | | | 3 | 3 | | | | | | | | | | 34.6 | | |
| Radius of Curvature at Left Junction (mm) | | | 3 | 3 | | | | | | | | | | 51 | | |
| Length from iliac to catheter insertion point | | | 3 | 3 | | | | | | | | | | | | |
| Take Off Angle of Right common iliac in coronal pla | | | 3 | 3 | | | | | | | | | | 23 | | |
| Take Off Angle of Left common iliac in coronal plan | | | 3 | 3 | | | | | | | | | | 14 | | |
| Take off angle of Iliacs in saggital plane (degrees) | | | | | | | | | | | | | | 15 | | |