Gore: Calcified Vessel Project

Midpoint Report

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1 Introduction

For this project the team was tasked with creating a safety compliant and customizable calcified vessel model for W.L. Gore & Associates. The model will be used to better understand how lesions affect blood flow and how endoprostheses function as they are deployed in calcified vessels of varying disease levels. This design is important to W.L. Gore & Associates because they want to have the ability to test and study the deployment of their endoprosthesis in an environment that is as similar as possible to a real life situation. Currently, Gore only possesses healthy models to test their stents in. Studying the deployment of their stents in a diseased model, with varying levels of disease, will be very useful for future product development.

1.1 Background

Cholesterol in the blood attaches to fat, calcium, and other substances found in blood and can begin to accumulate on the arterial wall. Over time this plaque can build up and effectively cause the artery to narrow and constrict the blood flow [1]. The calcification of an artery is referred to as atherosclerosis, and at first does not cause any health issues, but over time can have serious and life-threatening implications such as stroke or heart attack. The cause of atherosclerosis is not entirely understood, but several risk-factors that lead to this disease have been identified. There are many lifestyle choices that can affect one's likelihood of developing atherosclerosis, the main ones being diet, exercise, stress, excessive alcohol consumption, and smoking [1], [2].

Medication can be prescribed to help control cholesterol levels, but in severe cases an invasive procedure is necessary [3]. The two procedures used to treat atherosclerosis are bypass surgery and stenting. Bypass surgery is when a surgeon removes a healthy blood vessel from the body and uses that to create a new path for blood to flow. Stenting is the process of inserting a catheter into the patient's artery and using an x-ray device to track the catheter to the diseased area of the artery. A stent, a metal mesh that retains its shape, is then deployed in the constricted region of the artery. With the use of a small balloon on the catheter, the stent is expanded inside the artery. The catheter is removed and blood can now flow more easily through the previously constricted artery [3], [4].

1.2 Project Description

W.L. Gore & Associates currently only possess healthy blood vessels to test and study the deployment of their endoprosthesis. Creating a diseased vessel, with the ability to increase/decrease the severity of the diseased occlusion, is a worthwhile endeavor when trying to study the deployment of their stents.

The following is the original project description provided by the sponsor:

> "The scope of this project is to design, build, and test a replicable model of calcified lesions in the Peripheral Arterial System for deployment of peripheral vascular interventional devices under simulated use conditions, using non-biologic materials."

2 REQUIREMENTS

The following requirements were created using the project description given by W.L. Gore & Associates. Each customer requirement (CR) is a general requirement that the final product must meet. After being weighted based on significance to the final design, each CR is quantified through the use of engineering requirements (ER). These ERs feature specific target and tolerance values that control the measurable quantities for the final design.

2.1 Customer Requirements (CRs)

Each of the following four CRs feature a weighted value based on their importance in relationship to the final design. The CRs are directly related to the original project description presented by W.L. Gore & Associates. Each CR is related to a broad topic associated with the final design.

2.1.1 Industry Safety Standards (50)

ANSI and OSHA standards need to be met and adhered to for all aspects of the design. By following these guidelines, the model will be safe and convenient to use, as no extra precautions need to be taken when using the device. The device will need to be able to function at temperatures and pressures commonly seen in the human body without any concern for the user's physical safety. Absolutely no biological materials can be used that pose any risk of infection or contamination to the user or the workplace. Creating the model should involve minimal risk that can be controlled when the proper precautions are taken.

2.1.2 Manufacturability/Reproducible (80)

The calcified vessel model will need to be easily reproducible in a lab environment with minimal manufacturing equipment. Multiple models will need to be created efficiently and economically. The manufacturing process of the vessel will need to be extensively documented and easily repeated by another independent party. The need for multiple models that are easily reproduced is considered a very high priority so this CR is given a weighted value of 50.

2.1.3 Visualization (50)

The model must be transparent. A better analysis of peripheral vascular devices and their behavior within the body can be conducted if the user can easily see what is happening when the device is deployed. The material used to create the model must have a high transparency that does not distort the view into the vessel in any way.

2.1.4 Simulates Calcified Lesion (70)

In order for the devices to be properly evaluated, the test conditions need to simulate the human body. Vascular intervention devices commonly use materials designed to react at temperatures seen in the human body, making the temperature of the model a crucial aspect for proper deployment. The arterial compliance and calcification representation must behave similar to the human body under conditions seen in the human body (i.e. temperature and blood pressure) to ensure an accurate model.

2.2 Engineering Requirements (ERs)

The following ERs were created to attain measurable target values for each of the four CRs. Each ER features a target value along with an acceptable tolerance value based on academic research. Table 1 features each ER and their respective target and tolerance values.

2.2.1 Vessel must be transparent

Vessel transparency will allow the user to see the deployment of interventional devices. The vessel must have a transparency that approaches 100% (vessel must be see-through).

2.2.2 Operates at body temperature

This requirement has been designated a low technical effort (LTE). It has been given this value because the materials proposed in the design will function in the range of temperatures seen by the human body. The target value for this requirement is 98 ± 10°F [5].

2.2.3 Lesion durometer

Lesion durometer indicates the hardness of the calcified lesion using the Shore hardness scale. Through calculations using the stress versus strain curve of a calcified lesion [6] the shore hardness of a calcified lesion was determined. The target hardness for the lesion is 85 ± 10 on the Type A Shore hardness scale.

2.2.4 Lesion adhesion strength

The ability of the lesion to stay fixed to the inside of the vessel will be evaluated using the lesion adhesion strength. The adhesion strength target is to replicate the levels of adhesion seen inside of the human body.

2.2.5 Lesion length

The length of the lesion will be measured from end to end and will be completely contained in the vessel. The lesion length target is 6 ± 5 inches [7], [8].

2.2.6 Vessel diameter (inside)

Proper representation of the vessel diameter is needed to ensure interventional devices deploy properly in the vessel. The target diameter for the vessel is .35 ± .08 inches [9].

2.2.7 Degree of vessel occlusion

The degree of vessel occlusion must represent the degree at which interventional devices are used by surgeons. The target value for the percent of vessel occlusion is 75 ± 20% [10].

2.2.8 Lesion thickness

The lesion thickness will designate the shape of the lesion as well as the vessel occlusion. This value is based on percent occlusion and vessel diameter. The target range for the lesion thickness is .25 ± .08 inches [9], [10].

2.2.9 Cost

The customer has provided a budget that must cover all project costs. The cost of all prototypes, report materials and final products must not exceed $3,000.00 [11].

2.2.10 Operates at blood pressure

This requirement has been designated an LTE. It has been given this value because the materials proposed in the design will function in the range of pressures seen by the human body. The target range for this requirement is 2.7 ± 1.3 psig [12].

2.2.11 Meets ANSI standards

The product must meet applicable ANSI safety and testing standards.

2.2.12 Meets OSHA standards

The product must meet applicable OSHA safety standards.

A summary of all of the Engineering Requirement values is presented in Table 1 below.

Table 1 - Summary of Engineering Requirement Values

Requirement	Units	Target	Tolerance	Range
Transparent	%	100	-20	80-100
Lesion Durometer	Shore A	85	± 10	75-95
Lesion Adhesion	N/m	20	± 15	5-71
Lesion Length	cm	15	± 1	3-27
Vessel Diameter	mm	7	± 1	4-12
Lesion Thickness	mm	6	± 1	4-6
Degree of Occlusion	%	75	± 10	50-95
Vessel Length	cm	+10 per side	± 1	15-40
Cost	$	3000	N/A	<3000
ANSI Standards	N/A	Meets All	N/A	N/A
OSHA Standards	N/A	Meets all	N/A	N/A
Body Temperature (LTE)	°C	37	± 12	25-49
Blood Pressure (LTE)	mPa	19	± 9	10-28

2.3 Testing Procedures (TPs)

The following testing procedures highlight how each attribute of the design has been tested to ensure that they fall into the ranges detailed in the engineering requirements. ASTM testing standards are used where applicable, while more simplistic testing methods are used for most tests.

2.3.1 Testing Procedure 1

Using procedures outlined in ASTM-D2240, the durometer of a material is determined by applying a load on the surface via an indenter. The indentation is evaluated and the hardness of the material is determined [13].

2.3.2 Testing Procedure 2

The adhesion strength of the lesion to the vessel is evaluated using ASTM-D6862. This procedure will pull the vessel at a 90 degree angle relative to the lesion using a tensile force. The strength of the adhesion between the parts is evaluated based on the force required to separate them [14].

2.3.3 Testing Procedure 3

To certify the model meets this requirement, an analog measurement of length has been conducted. This test is completed using a high resolution ruler. To ensure the model is not being altered during measurement, only the natural length has been evaluated.

2.3.4 Testing Procedure 4

In order to analyze dimensions less than 20 mm an image measuring application, ImageJ has been used to evaluate area and thickness. Pictures are taken of each dimension and evaluated using the software, which uses pixels to determine relative size [15].

2.3.5 Testing procedure 5

The degree of vessel occlusion is evaluated numerically based on average cross sectional area of the occlusion, given by the ImageJ application, divided by the cross sectional area of the vessel, also gathered from the ImageJ application.

2.3.6 Testing procedure 6

The transparency of the model is evaluated using a visual test. A single line of 10 pt. times new roman font, printed on white printer paper, will be place inside the vessel, both with and without the occlusion. If the evaluator is able to read the text through the vessel then the model meets the transparency requirement.

2.4 Design Links (DLs)

The following design links explain how each of the engineering requirements will be met through the construction of the proposed design model found in Section 5.2. The number associated with each design link correspond to the design link number in the house of quality.

2.4.1 Lesion Durometer – Design Link 1

The lesion durometer refers to the hardness of the calcified region of the model. The calcium that forms in a lesion is predominantly calcium phosphate (hydroxyapatite) and is formed in a way similar to bone formation or bone repair [16]. A material has been selected that accurately mimics the hardness values of an SFA calcification. Thorough testing will ensure through a statistical analysis that the hardness value of the selected material is appropriate.

2.4.2 Lesion Adhesion Strength - Design Link 2

Lesion adhesion strength is defined as the force required to disrupt the bond between the arterial vessel and the calcified occlusion within the vessel. It is dangerous in many cases for a calcified buildup to break free from a vessel and travel to a different area of the body. In order to create a model that accurately represents calcified lesions in the human body, the adhesion strength of the model lesion must fall into the range of strengths seen in the human body.

Through academic research it was determined that the lesion strength needs to withstand a maximum shear stress of six Pascal's [17]. A bonding agent will be selected that accurately mimics the adhesion strength values of SFA calcification to the SFA. Thorough testing will ensure through a statistical analysis that the adhesion strength value of the selected material is appropriate.

2.4.3 Lesion Length - Design Link 3

When a vessel calcifies, a certain length of the vessel changes in physical characteristics, which is known as the lesion length. In order to create a model that accurately represents calcified lesions in the human body, the length of the model lesion must fall into the range of lengths seen in the human body. Through academic research, it was determined that the lesion should be an average of 6 inches in length [18]. In order to best represent the variability seen in human subjects, a range of ±5 inches has been implemented [19]. The lesion length is a direct reflection of the model length. The model length is set to the target value of 15 cm.

2.4.4 Lesion Thickness - Design Link 4

When a vessel calcifies, the calcified lesion will achieve a certain thickness based on how long the lesion has been forming and the length of the lesion. In order to create a model that accurately represents calcified lesions in the human body, the thickness of the model lesion must fall into the range of thicknesses seen in the human body. The lesion thickness has a target value of 6 mm. The lesion thickness is determined by the depth of the 3D printed model, which has a depth of 6 mm.

2.4.5 Degree of Occlusion - Design Link 5

In order to meet the design requirements, a varying degree of vessel occlusion must be manufacturable to accurately model possible diseased arteries. In order to find the proper level of occlusion, research was conducted and it was found that a stent would be placed in the body with a level of occlusion between 55-95% of lumen reduction [20]. Lumen refers to the inner most walls of the artery, which blood travels through. It is the reduction of the lumen vessel (inner diameter) that is the focus of this test [21]. A target value of 75% occlusion has been accomplished through the construction of the 3D printed mold combined with the known specifications from the silicone tubing manufacturer.

2.4.6 Vessel Diameter - Design Link 6

The vessel diameter relates to the inner and outer diameter of an artery or vessel within the human body. Accurately mimicking the inner diameter of the femoral artery is of more importance than mimicking the outer diameter. Through academic research it was found that the average diameter for a femoral artery is 7 mm [22]. In order to best represent the variability seen in human subjects, a range of ± 1 mm has been implemented. The diameter of the vessel is constant, as it has been procured through a silicone tubing manufacturer. Routine measurement of the acquired vessel has ensured that it still meets the design requirements.

2.4.7 Vessel Length - Design Link 7

In order to fully encompass the desired lesion length, the artificial vessel is 10 cm longer on either side of the lesion to allow for installation of the model into the testing system. Accounting for the length of the lesion, each artificial silicone vessel has a length of 35 cm.

2.4.8 Visualization of Deployment Device - Design link 8

In order to meet the transparency requirement, the material used to create the vessel is clear. The level of transparency must approach 100%. This is important because the user must be able to see the deployment of the device in order to better analyze its performance. The silicone tubing provided has a high transparency and can be clearly and easily seen through without special equipment.

2.4.9 Repeatable Manufacturing Processes - Design Link 9

In order for this design to be practical in industry it must be easily produced, as each calcified model is to be used just once to study the deployment of a particular device. Documentation has been provided to the client which describes the vessel and lesion creation guidelines, allowing for the creation of a customized lesion.

2.5 House of Quality (HoQ)

The house of quality is used to highlight the customer requirements and their relationship to the prescribed engineering requirements. The target and tolerance values for engineering requirements are also noted in the house of quality. See Appendix B for the house of quality spreadsheet.

3 EXISTING DESIGNS

There are a multitude of existing designs related to accurately simulating the human body. In particular, three designs from three different companies were analyzed to create an understanding of what has already been engineered and used in relationship to artificial vessels and calcifications. All three companies have made their products available to the market, and have used their products to better the lives of patients as well as practitioner experience and understanding.

3.1 Design Research

To begin researching similar devices that replicate the human body and its characteristics, web-based research of existing designs was conducted. The results of this research are shown below. Research methods for these manufacturers and designs was obtained through the use of web-based search engines and the Cline Library Ebscohost database. All three manufacturers were contacted via email and telephone in order to more accurately understand the intricacies of their specific products.

3.2 Current Manufacturers

Replicating the human body accurately has several advantages when the need to test medical devices arises. Visualizing the deployment of a stent will allow the engineer to understand if a device requires further design to function as intended. Deploying a stent in an actual patient is never simple, and having a system, such as United Biologics or Vascular Simulations, which replicates arterial geography allows the engineer to determine if their stent can be guided to any diseased location in the body with relative ease. The study of plaque buildup and its inherent material properties, is necessary when deploying stents into that environment. Stent structural requirements may be modified, after testing deployment in a life-like model, in order to more accurately handle the harsh environment of a diseased vessel.

3.2.1 Vascular Simulations

Vascular Simulations is a New York based company that replicates the cranial, aortic, and abdominal blood vessels of patients in need of endovascular procedure. This is possible with the use of a 3D rotational angiogram, CT angiogram, or MR angiogram that scans the exact vasculature of the patient. The completed vascular replica is made of a hollow silicone structure that mimics the patient's vessel walls, and is able to have fluids pumped through it.

Vascular Simulations utilizes pulsatory flow in their models to better replicate the in-vivo environment that practitioners work in. When using pulsatory flow the silicone walls expand and contract with the variance in fluid pressure, mimicking actual blood vessel behavior. A sample vessel is shown in Figure 1 below.

This system provides the interventionalist a near-exact vessel structure to use when practicing the endovascular procedure. Providing intravenous practice to the interventionalist greatly decreases risk to patient health during the procedure.

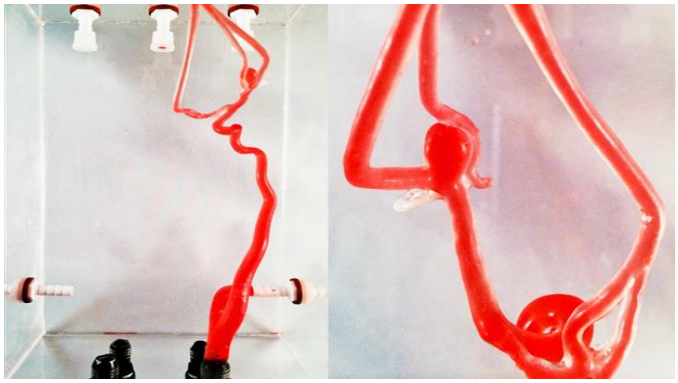

Figure 1 – Vascular Simulations' Model [23]

3.2.2 United Biologics Inc.

A researcher and manufacturer of vascular simulations is United Biologics Inc. The company is engaged in designing silicone replications of human vasculature shown in Figure 2. Although most of their products are a model of the common pathologies of the human body, there have been physicians and engineers that have requested and received custom vessels to accurately replicate specific patient scenarios. In the company's words, "Our silicone vessels are designed to demonstrate, facilitate and challenge the development and training of endovascular medical devices" [24].

These devices contain a core model which can be purchased, and then a wide variety of attachments can be added. To simulate the real world, a surgery would require moving through the iliac artery to deploy the endovascular medical device. This "core" could be used in multiple tests, and the only change would be to the femoral artery line. This would add to a higher level of precision in testing and a more controllable environment for stent deployment.

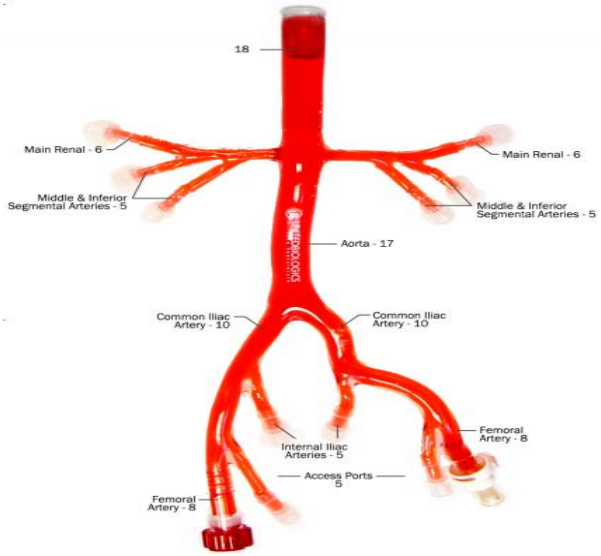

Figure 2 – United Biologics' Vascular Model [27]

3.2.3 BoneSim Laboratories

BoneSim Laboratories is a small Michigan based company that produces calcified lesion models [25]. They produce models that vary in lesion density, vessel wall thickness, vessel diameter, lumen position and lumen diameter as seen in Figure 3. The models do not have designation to which vessel they represent within the human body. BoneSim's products can be ordered in both large quantities and single units. This company was researched through a website search engine, through email correspondence, and through telephone communication with the president of the company.

Figure 3- BoneSim's calcified vessel models [18]

3.3 System Components

When designing a system to replicate the human body, many subsystems are important. The necessary requirements pertaining to this design are:

- Arterial vessel similarity
- Calcified lesion similarity

These requirements are met through the use of silicone tubing, which can either be manufactured in house through the use of a molding process or they can be bought through an artificial vessel manufacturer directly. The calcified lesion will be replicated through the use of a 3D printer, by either printing a mold in which a material is poured or by directly printing the calcified lesion.

3.3.1 Silicone Vessels

Silicone is an elastomeric polymer whose elasticity and surface texture accommodate for vessel-like flow. Silicone vessel walls are commonly used for their artery-like properties, as arteries within the human body are not rigid, and are able to expand and contract due to the pulsatory flow and body movement. Silicone's high elasticity allows for optimal reproduction of this pulsatile expansion and contraction. It also accurately represents the structural characteristics of arteries in terms of radial strength and elasticity.

3.3.1.1 Vascular Simulations Vessels

Vascular Simulations utilizes silicone vessel walls in their synthetic vasculature to mimic the risks that a patient will face when endovascular procedures are conducted. Some of their products are exact replicas of the patient's vasculature, showing that silicone is a viable option for vessel material due to its manufacturability and its mechanical properties. Some of their designs include a gel that surrounds the silicone vessels. This replicates the external pressure that vessels experience in the body, but does not restrict the expansion of the silicone during flow.

3.3.1.2 United Biologics Vessels

United Biologics uses a customizable core model with peripheral attachments to accurately reproduce the human arterial geography. Due to its vessel-like properties, silicone is used in all of their core models. These models are 3D printed and are extremely precise, manufactured to the specifications shown in Figure 4. The 3D printed silicone is able to meet the many specifications of United Biologics' design requirements, and is highly customizable. This allows for many applications that require specific properties.

Silicone Properties	
Durometer: Shore A	37-39
Elongation: %	340
Tear Resistance: N/mm (ppi)	21 (120)
Elastic Modulus: N/mm^2 (psi)	3.1-3.4 (450-500)
Tensile Strength: N/mm^2 (psi)	6.3 (920)
Specific Gravity:	1.08
Color: Transparent	with red tint
Refractive Index:	1.41

Figure 4 - Silicone Properties

3.3.1.3 BoneSim Laboratories Vessels

Although there is no manufacturer's information given on the material of the tubing used to represent the vessel, it appears to be latex based on the amber color. Several inner diameters are offered, ranging from 3mm to 12mm, and all models are 100mm in length [26].

3.3.2 Calcified Lesions

A calcified lesion is a clump of plaque found within a blood vessel, which has adhered to the vessel. The buildup is initially soft, but after a period of time, the plaque will become rigid. This is when the calcification of the arterial plaque occurs. Mimicking the calcification will be done through the use of either dental stone or hydroxyapatite. Testing will be completed to compare each materials properties to the researched properties of SFA calcifications.

3.3.2.1 BoneSim Laboratories Lesions

BoneSim uses reconstituted bovine bone and a synthetic binder that can be altered to create varying densities of the lesion [26]. The different densities are used to represent the varying levels of hardness found in calcified lesions. BoneSim offers three levels of occlusion, characterized by the lesion lumen size as well as three different lumen positions, offset from the center.

4 DESIGNS CONSIDERED

Based on the products and systems studied during the existing design stage, the following brainstormed ideas were discussed and analyzed. The brainstorming methods focused on a traditional brainstorming session in which team members verbally communicated ideas to each other, with a single note taker. A method in which a ball was thrown from team member to team member, focusing on the repetition of previous ideas and the creation of new ideas was also used.

The focus of the brainstorming session revolved around accurately replicating the occlusion within the artery, as this particular aspect of the project has very few applications outside of this design. Another focus was centered on successfully implanting the created occlusion into the artificial artery.

4.1 Buildup through Flow

This bio-inspired design idea revolved around the use of a liquid filled with particulates, which would slowly build up a calcification within a vessel represented by a stock piece of silicone tubing. The tube may need to be altered to accelerate the buildup of the calcification. This idea is similar to how coral reefs are created in nature. A gravity fed system would flow liquid through the artificial vessel and the process would be repeated until the desired calcification was achieved.

Pros:

- Replicates natural buildup
- Cheap
- Easy to manufacture

Cons:

- Time to manufacture
- Not consistent in calcification characteristics
- Would require modification to inside of silicone tube

4.2 Diseased Pig Vein

This bio-inspired design would focus on the use of diseased pig vasculature. Portions of the pig arteries would be removed from the corpse and used in the experimental procedure. Varying levels of disease could be present, depending on the pig used.

Pros:

- Natural
- No manufacturing

Cons:

- Uses biological materials
- Not consistent in calcification characteristics
- Sloppy and unhealthy

4.3 Vertical Centrifugal System

This design would use a system that rotates the vessel, a stock piece of silicone tubing, at a high rate of speed to distribute the material inside the model. The material used to replicate the lesion would be injected from the top in a liquid form. The lesion size could be changed by the amount of material injected into the vessel. This would require a small mechanical set-up to spin the vessel as material was injected.

Pros:

- Replicates round lesion
- Easy to manufacture
- Short manufacture time

Cons:

- Only simulates round lesions
- Material has to be liquefied
- Difficult to normalize

4.4 Petroleum based Product

This design would use a petroleum based product to represent the calcification. The product would have properties such that it melted at a lower temperature than the silicone tubing used to replicate the vessel but remained solid at body temperature. This would allow the vessel to be reused with various degrees of occlusion. The petroleum product would be injected into the vessel using a syringe.

Pros:

- Reusable vessel
- Low cost
- Easy to manufacture

Cons:

- Would simulate lesions well
- Difficult to normalize occlusion
- Intervention device may become lodged inside vessel

4.5 Smashed Fired Clay

This design would utilize broken pottery pummeled into a fine powder. This powder would then be placed into the silicone vessel using a liquid adhesive such as super glue. The vessel used in this model would be a stock piece of silicone tubing.

Pros:

- Low cost

Cons:

- Difficult to normalize occlusion
- Difficult to pulverize clay sufficiently
- Injection of adhesive would be difficult

4.6 Sand

This design idea focuses on the use of sand to create the occlusion within an “off the shelf” silicone tube. Sand would be injected into the vessel through the use of a syringe, and it would be bonded to itself through the use of a chemical binder similar to a sand casting process.

Pros:

- Low cost
- Moderately easy to manufacture

Cons:

- Difficult to normalize occlusion
- Bonding agent may fail during testing

4.7 3D Printing

This design would use a 3D printer to print an occlusion out of various materials, depending on the desired lesion durometer. The 3D printer could also be utilized to print a mold, in which a material is poured into the printed mold. Limitations on lesion size are based solely on the precision of the available 3D printer. The printed occlusion would be placed into a silicone tube using some sort of adhesive.

Pros:

- Extreme precision in occlusion representation
- Easy to adjust for various requirements

- Easy to reproduce occlusions

- Material limitation
- 3D printer limitation

Cons:

4.8 Spray Can Texture

This design idea would use a texture, sprayed out of a pressurized can (similar to a drywall texture) to create the occlusion. The can nozzle would simply be placed inside the silicone tube, which represents the artificial vessel, and discharged. The properties of the spray and the material would ensure that it stuck to the inside of the vessel.

Pros:

- Easy to manufacture
- Low cost
- Short manufacturing time

Cons:

- Difficult to normalize occlusion
- Spray velocity may be too high for vessel
- Lots of wasted product

4.9 Balloon in Tube

This design idea revolves around using a silicone tube to represent the vessel and then deploying a blown up balloon inside of the tube. This balloon would represent the occlusion within the artery. It would have the ability to be inflated to various sizes/pressures to offer a variety in occlusion characteristics.

Pros:

- Offers variety in occlusion characteristics
- Low cost

Cons:

- Simplistic approach
- Balloon sizing may be difficult
- Adhesion characteristics would be insufficient

4.10 Two Concentric Tubes

This design would use two silicone tubes placed inside of each other. The outer tube, which would represent the artificial vessel, would have an inner diameter matching the outer diameter of the inside tube, which would represent the occlusion. This sizing would create the necessary adhesion strength between the vessel and occlusion.

Pros:

- Easy to manufacture
- Low cost
- Occlusion variability

Cons:

- Vessel properties are diminished
- Simplistic approach
- Poor representation of calcification

4.11 Synthetic Plaque

This design would focus on the deployment of a premanufactured synthetic plaque into a silicone vessel. The synthetic plaque would have characteristics that accurately mimic the plaque found within the human body. The synthetic plaque would be injected into the vessel to achieve the desired level of occlusion.

Pros:

- Represents plaque very well
- Easy to manufacture

Cons:

- High cost
- Does not represent calcification well
- Simplistic approach

4.12 Gum

This design idea uses preprocessed chewing gum to represent the occlusion within an artery. Silicone tubing would be used as artificial vessels, which is where the chewing gum would be inserted. Insertion of the chewing gum into the artificial vessel would be difficult, though its inherent characteristics may act as a glue to hold it to the inside of the vessel.

Pros:

- Easy to create occlusion

Cons:

- Simplistic approach
- Difficult to normalize occlusion

5 DESIGN SELECTED

5.1 Rationale for Design Selection

Through the use of group brainstorming sessions, the team came up with twenty different ideas to construct both the vessel and the occlusion. These twenty ideas were not restricted to plausibility or overall effectiveness. Initial prototyping ideas came from these twenty ideas, as many are easy to construct and cheap to produce. After creating the twenty ideas, a Pugh Chart (Appendix A) was used to narrow the ideas down to a more usable number of effective ideas. A datum idea was chosen, and then the other nineteen ideas were compared to it, simply using pluses or minuses to compare each idea. The three ideas that compared most favorably to the datum were chosen to be analyzed and compared further.

In order to narrow the final design from the group brainstorming sessions to a single idea, a decision matrix was used. The decision matrix analyzed the three designs from section 4. Table 2 shows the decision matrix and the associated criteria and weights that were calculated based on each design.

Table 2 - Decision Matrix

Requirement	Weight	Buildup through flow	3-D printing	Two concentric tubes
Feasibility	7	42	56	49
Normalize	4	8	40	40
Accurate Representation of Plaque	5	40	35	15
Cost	2	16	14	14
Time to Manufacture	3	3	24	27
Repeatability	4	24	40	40
Total	25	133	209	185

The selected manufacturing method used to create the model of the artery and plaque was by 3D printing. The arterial vessel will be simulated by standard tubing and the focus of the project and manufacturing will be on the lesion. The limiting factor for 3D printing is the material and the tip size of the 3D printer. If the 3D printer cannot model the calcification's mechanical properties with a given material then a mold will have to be created. If a mold needs to be created it will be printed from an easy to manufacture plastic.

The most common material to print in is thermoplastics and among these are Polylactic Acid (PLA), Acrylonitrile Butadiene Styrene (ABS) and PolyAmide (PA). PLA is typically made from a petroleum based plastic and can be easily manipulated. PLA melts at 130 °F which would make it a low cost material to manipulate. The primary issue with using plastics for the modeling of plaque is that a calcified lesion has a large variation in hardness. According to a study "The majority of calcified samples showed durometer values of 0.7 ± 2.2GPa" [27]. This research also noted that as the occlusion increases in size, the durometer of the calcification increases. This large range of potential hardness values makes it difficult to use any single material to model all occlusions. Current production in the NAU manufacturing facility is limited to plastics; however, a graduate student is currently working on a metal adaptation system. The most probable material to make the lesion out of is ceramics, which is not an option for direct 3D printing at the moment. Future research in thermoplastics will shed light on possible materials to use for the occlusions.

Due to the plastic mechanical property limitation, an accurate mold made by a 3D printer could then be manufactured such that the material set in the mold would more accurately simulate the lesion. Again, this lesion simulating material will most likely be ceramic. Specifically, Alumina Silicate Refractory, which is typically associated with bricks for housing. However, the material is very similar to plaque from a property view point. This material could be easily molded into small plaque replicating tubes for testing. If there is a way to 3D print the lesions directly, it would be preferred; however, a mold seems much more practical currently.

No matter what specific manufacturing process is selected, the end products will be similar to Figures 5 and 6. The first figure shows a smooth, or ideal lesion whose level of occlusion linearly increases until only 60% of regular blood flow would travel through this system. This level was selected because several medical journals note that the majority of patients can live with 60% blood flow without knowing and without seeing symptoms of occlusion [20]. Figure 6 shows an extremely rough section of plaque. This lesion is most constricted at only 30% blood flow, but also provides several rough texture areas. The average restriction in this system was limited to approximately 45% of regular blood flow.

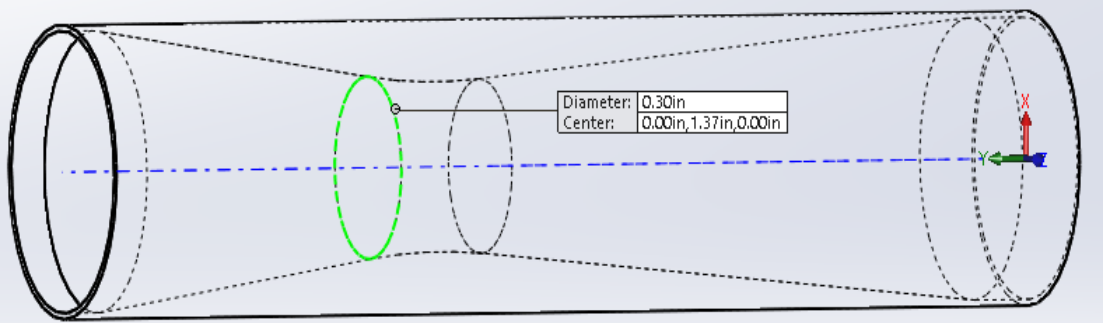

Figure 5 - Initial Ideal Lesion Smoothness

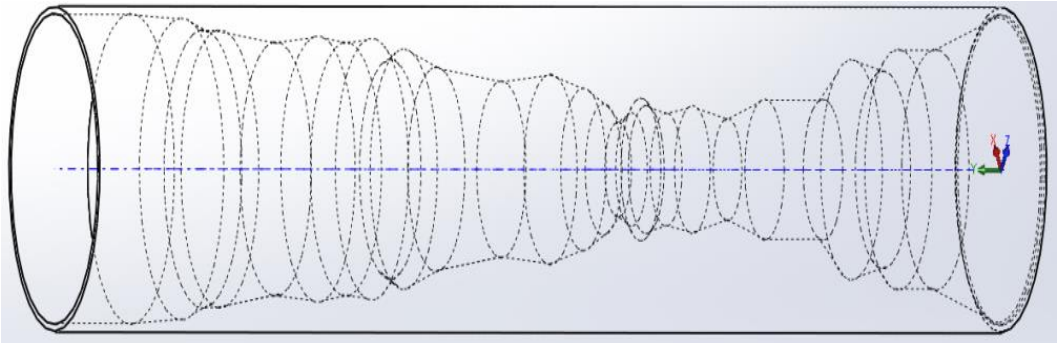

Figure 6 - Initial Extreme Lesion Roughness

5.2 Design Description

5.2.1 Engineering Calculations

In accordance with the engineering requirements and Table 1, the following final design has been modeled in Solidworks. The dimensions of the lesion represent the target values from Table 1. The lesion will be adhered to the vessel tubing using an adhesive. The length of the lesion will be 150mm. The diameter of the lesion will be 7mm to match the inside diameter of the vessel.

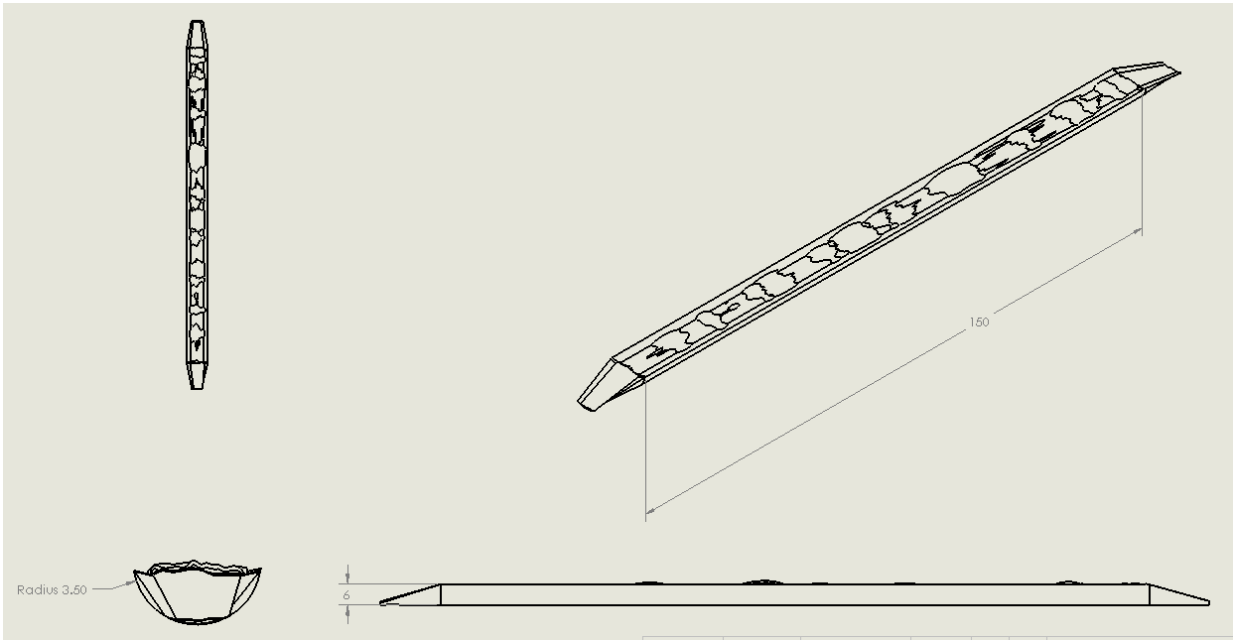

Figure 7 - Final Design: Dimensions

5.2.2 Modeled Drawings

The selected design is a 3D printed lesion, which includes all design requirements. This model has an open top so that the deployment of the interventional device can be seen through the transparent vessel as it is activated. The lesion is opaque, therefore it cannot be a solid cylinder and still fulfill the transparency requirement. The rough surface represents a calcified lesion's tendency to have non-uniform build up. Having a rough surface better replicates life like qualities as well as allows a change in occlusion percentage.

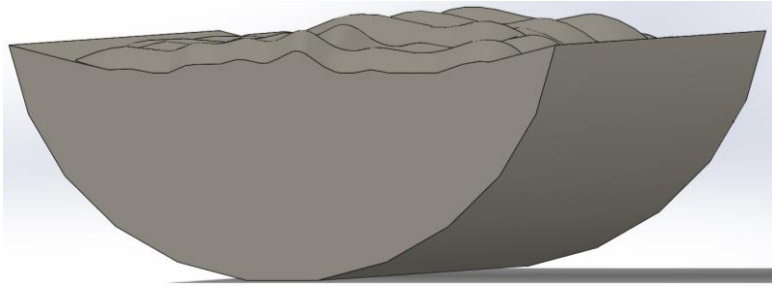

Figure 8 - Final Design: Lesion Cross-section

The lesion will be inserted into the mock vessel manually. Prior to insertion the lesion will have a bonding agent attached to the semi-circular side so that is accurately mimics life like adhesion. When the lesion is inserted, there will be an extra 10 cm of mock vessel on each side of the lesion to allow for connection to a testing system and for laminar flow to form. The lesion will also have an increasing cross sectional area to help maintain laminar flow.

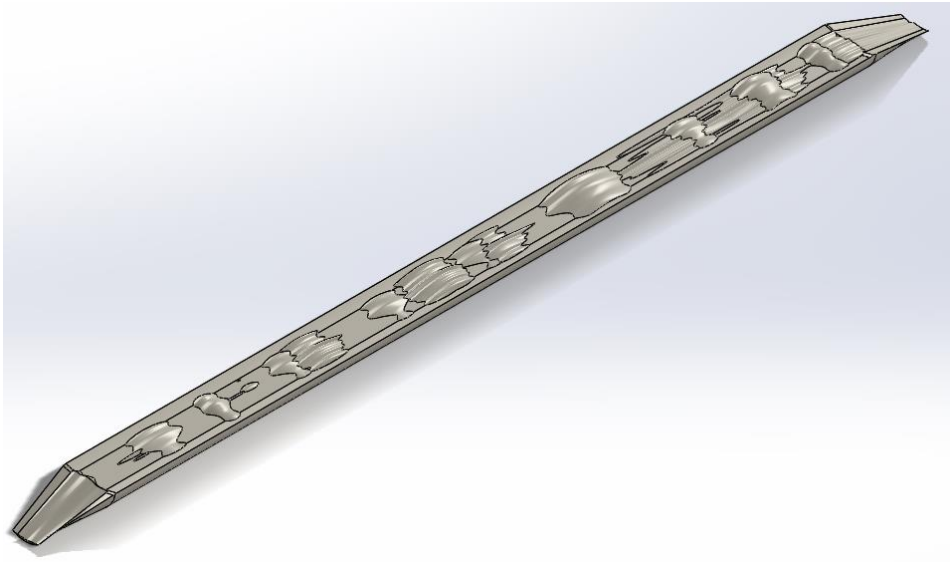

Figure 9 - Final Design: Lesion Overview

5.2.3 Prototypes

In order to construct a Works like Prototype, small silicone tubes were used to represent the vessel and a wooden dowel was placed inside to represent the occlusion. Creating this model helped the team understand the difficulties in placing the occlusion inside the small vessel. It was evident that the lesion must have smooth edges to ease the placement of it inside the vessel. Additionally, an assisting tool like small thin tongs may be necessary to place the lesion a full 10cm from the mock vessel ends.

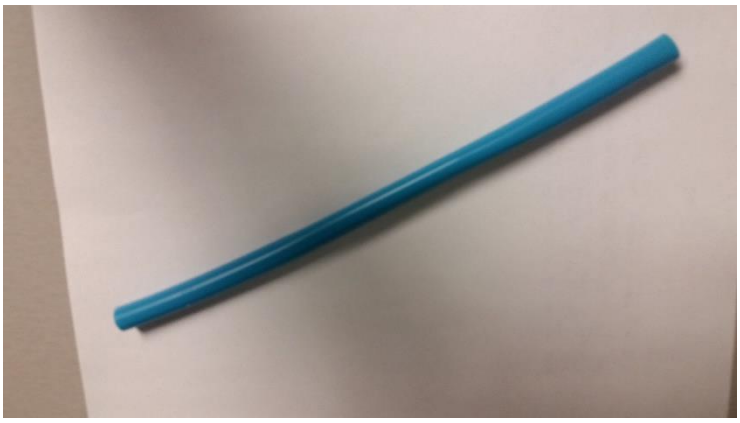

Figure 10 - Works like Prototype

In order to construct the Looks like Prototype, a large diameter clear tube was purchased and used. Foam insulation was inserted into the tube to represent the occlusion. A semi-cylindrical occlusion was chosen over a full cylinder occlusion to allow for visualization of the deployment device. Also, determining the degree of vessel occlusion through the use of the app ImageJ is easier with this semi-cylindrical occlusion. The Looks like Prototype foam was glued to the tubing, however the super glue dried before it could bond the two surfaces. Other glues did not hold the foam firmly in place, so this prototype showed that a very specific bonding agent must be chosen.

Figure 11 - Looks like Prototype

6 IMPLEMENTATION

For the calcified vessel project, various resources in and out of campus to ensure that what is being built is both anatomically accurate and feasible. Starting with the team's sponsor, W.L. Gore and Associates, engineers from the company have been instrumental in putting the team on the right path in terms of engineering requirements and research topics. The mentorship team is also providing various diameters of silicone tubing for prototyping purposes. Dr. Becker has also been a point of contact for his knowledge in biomedical engineering. His guidance has helped team members make engineering sense of the medical verbiage and provided his own considerations on calcified vessel project that has helped refine research. Material and manufacturing for proof of concept is being provided by Dr. Oman in the form of a 3D printer and the modeling material. For the time being there is no need for traditional manufacturing tools, but should those resources ever be necessary many members of the team have access to the machine shop in building 98C.

6.1 Manufacturing

The manufacturing approach for this project consists of a 3D printed two-piece mold, in which a calcification replication material is placed into. The calcification replication material (dental stone) is mixed by hand and placed into the mold by hand. The mold is sprayed with a dry lubricant which eases the removal of the delicate calcification. The mold is then overfilled with the wet dental stone, then clamped shut. The excess dental stone is squeezed out of the mold through runners designed into the mold. The top half of the mold is removed after twenty seconds, well before the dental stone has cured. After eight to ten minutes (depending on mixture ratios) the calcification is removed from the bottom half of the mold.

A schedule (See Appendix C) has been created which outlines the milestones, meetings, and deliverables for the project. The semester began with research and the selection of a material to be used for the occlusion. As the materials are selected the team will work on to the construction and testing of the initial mold and make adjustments as necessary. The initial materials tested were dental stone, mortar, and hydroxyapatite. After the initial materials testing was completed, it was determined that the dental stone yielded the most consistent and useful properties in relationship to the ER's. After the final materials are selected and tested the team will begin a statistical analysis of 100 samples. The final deliverables will then be prepared, including the UGRADS presentation as well as a presentation at a W.L. Gore facility. The team is currently on schedule to complete all tasks.

Table 4 - Bill of Materials

Application	Item	Use	Source	Cost
Lesion	3D Printed Models	Proof of concept of lesion and mold shape	MakerBot, Dr. Oman	-
	Calcium Hydroxyapatite	Lesion material	Amazon	$15.46
	Dental Stone	Lesion material	Amazon	$37.46
	Tile Grout	Lesion material	Amazon	$12.88

	BoneSim	Lesion material	BoneSim, yahoo	$190.50
Vessel	Silicone tubing		W. L. Gore & Associates	-
Equipment	Ruler	Replicable	Amazon	$40.00
	Shore Durometer Tester	Test vessel and lesion hardness	Amazon	$39.95
	Digital Caliper	Lesion and mold measurements	Amazon	$39.97
Total Cost				**$376.22**
Remaining Budget*				**$2,610.18**

* Includes cost of previously acquired materials (Table 6 located in Appendix D)

6.2 DOE

The following variables will be considered during the manufacturing process:

- Water to powder ratio
- Percentage of Calcium Hydroxyapatite in Dental Stone

Based on the output hardness value, each of the two variables will be altered to understand if they have an impact on the final hardness value of each specimen. Iterations in the specimen creation will continue to be made until a sufficient hardness value is found. After the hardness is set, the team will move onto finding an appropriate adhesive between the lesion and the vessel.

6.2.1 Initial Testing Results

Four batches of material samples were created for initial hardness testing. Each batch consists of ten 2.5 cm discs with an average thickness of 1.2 cm. The fourth batch was unable to be successfully tested due to the material being too difficult to manufacture. Table 5 represents the results of initial testing of the material samples.

Table 5 - Design of Experiment (Material)

Factor		Average Hardness Value (Shore A)	Comments
A	B		
Low	Low	97.15	Easiest to work with right away
High	Low	95.55	Takes longer to dry than Low Low
Low	High	96.05	More brittle, difficult to handle and work with
High	High	N/A	Mixture was unworkable due to prolonged set time

A = Water to powder mixture ratio, B = Percentage Calcium Hydroxyapatite

For factor A the low value was assigned to 45ml of water to 100g of dental stone powder, with the high value assigned to 50ml of water to 100g of dental stone powder. For factor B the low value is associated with no calcium hydroxyapatite (CA) and the high value is associated with 1g of CA to 100g of dental stone powder.

The hardness values were acquired using a handheld Shore A durometer tester. An

average hardness value was calculated based on the ten samples in each batch, gathered 3 days after each batch was created. Based on instrument uncertainty, human error, and the small difference percentage between the three calculated averages it cannot be determined that the combination of the two factors have any influence on the specimens final hardness value.

Based on the gathered hardness values, a new material or mixture of materials needs to be created and tested. The gathered hardness values are one to two units outside of the acceptable range, based on the house of quality values. Higher water to powder ratios will be experimented with to determine if significantly higher ratios have an effect on lowering the hardness values. Experimentation with the mixing procedure will be implemented to determine if this aspect of the process effects the final hardness values. Mechanical mixing is the primary focus, with the hopes of introducing more air into the mixture, therefore lowering the hardness values.

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8 APPENDICES

8.1 Appendix A

Table 1 - Pugh Chart

Design Criteria	Weight	Buildup through flow	Using tree sap to model calcification	Diseased Pig Vein	Sugar and salt buildup with evaporating water	Centrifugal system(similar to cotton candy machines)	Petroleum based product with high solidifying temp.	Using Human Body Parts	Radioactive hamster feces used as calcification	Fill the vessel with Gore-Tex	Gelatin used to create occlusion	Fired clay as calcification material	Sand as occlusion material	3D Printing	Spray can texture (i.e. drywall spackle)	Wood chips as occlusion material	Rust, Oxidized Metal	Tubular balloon to mimic occlision	Concentric tubes	Synthetic plaque or occlusion material	Gum as occlusion material
Feasibility	70	+	+	-	+	-	|	-	-	+	S	-	-	+	-	+	-	+	+	-	+
Ability to Normalize	40	-	S	-	-	-	D	-	-	+	S	+	-	+	S	-	-	+	+	S	-
Accurate representation of body	50	+	+	+	-	+	|	+	-	-	S	+	+	+	-	-	-	-	-	+	-
Cost	20	+	-	-	+	-	A	-	-	-	S	+	+	-	+	+	+	+	+	-	+
Time to Manufacture	30	-	+	+	-	+	|	-	-	+	+	-	+	-	+	-	-	+	+	+	+
Repeatability	40	+	S	+	-	-	T	-	-	-	S	+	-	+	S	-	-	+	+	S	S
Meets industry safety standards	60	+	+	-	+	+	|	-	-	+	S	+	+	+	S	+	-	+	+	+	S
Total Weighted Score	Σ+	5	4	3	3	3	U	1	0	4	1	5	4	5	2	3	1	6	6	3	3
	Σ-	2	1	4	4	4	|	6	7	3	0	2	3	2	2	4	6	1	1	2	2
	ΣS	0	2	0	0	0	M	0	0	0	6	0	0	0	3	0	0	0	0	2	2

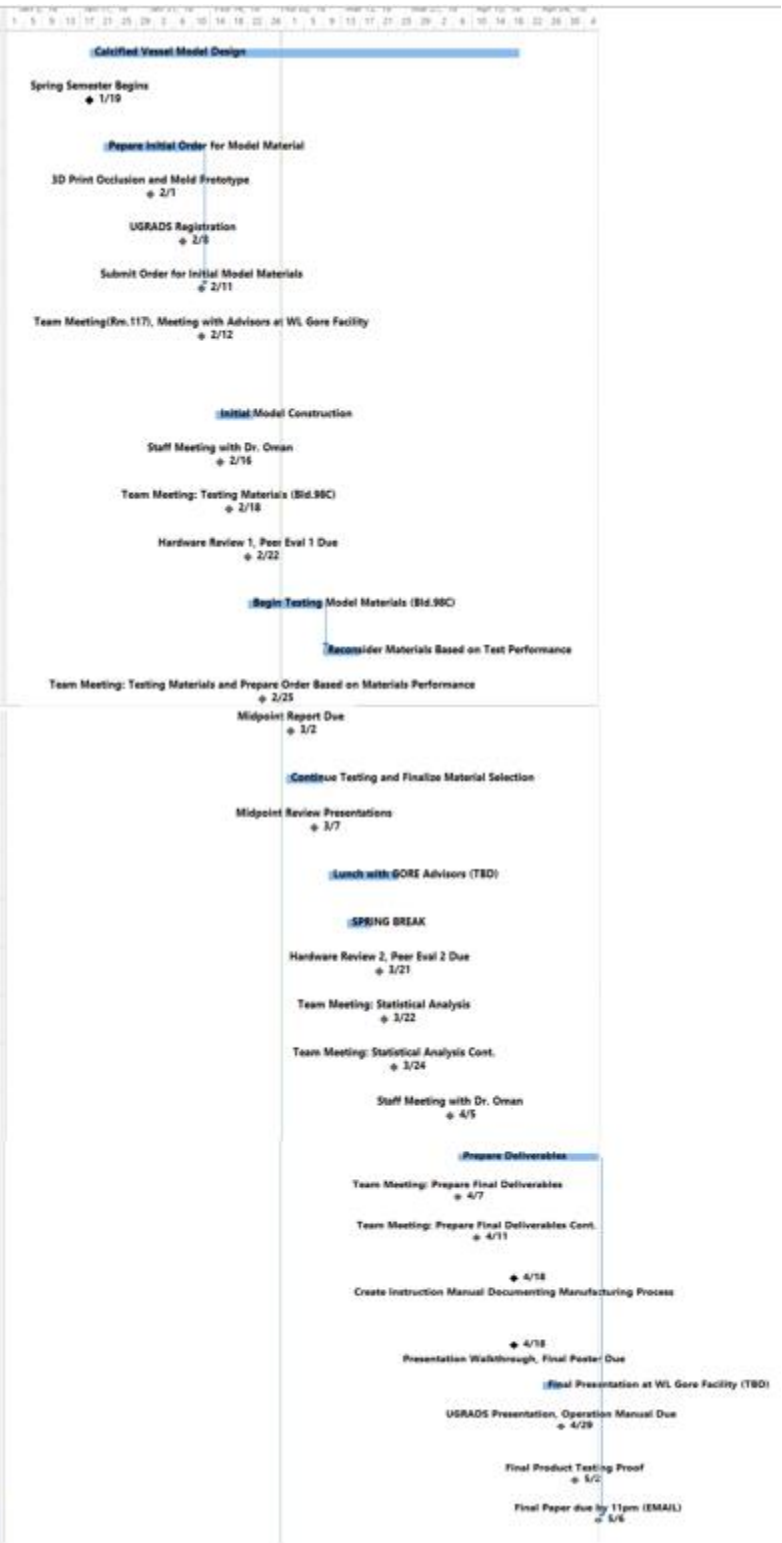
8.2 Appendix B

Please see the attached 11”x17” house of quality.

8.3 Appendix C

GANTT CHART

	Task Mode	Task Name	Start	Finish
1		Calcified Vessel Model Design	Tue 1/19/16	Tue 4/19/16
2		Spring Semester Begins	Tue 1/19/16	Tue 1/19/16
3		Pepare Initial Order for Model Material	Fri 1/22/16	Thu 2/11/16
4		3D Print Occlusion and Mold Prototype	Mon 2/1/16	Mon 2/1/16
5		UGRADS Registration	Mon 2/8/16	Mon 2/8/16
6		Submit Order for Initial Model Materials	Thu 2/11/16	Thu 2/11/16
7		Team Meeting(Rm.117), Meeting with Advisors at WL Gore Facility	Fri 2/12/16	Fri 2/12/16
8		Initial Model Construction	Mon 2/15/16	Mon 2/22/16
9		Staff Meeting with Dr. Oman	Tue 2/16/16	Tue 2/16/16
10		Team Meeting: Testing Materials (Bld.98C)	Thu 2/18/16	Thu 2/18/16
11		Hardware Review 1, Peer Eval 1 Due	Mon 2/22/16	Mon 2/22/16
12		Begin Testing Model Materials (Bld.98C)	Mon 2/22/16	Tue 3/8/16
13		Reconsider Materials Based on Test Performance	Wed 3/9/16	Wed 3/16/16
14		Team Meeting: Testing Materials and Prepare Order Based on Materials Performance	Thu 2/25/16	Thu 2/25/16
15		Midpoint Report Due	Wed 3/2/16	Wed 3/2/16
16		Continue Testing and Finalize Material Selection	Tue 3/1/16	Tue 3/8/16
17		Midpoint Review Presentations	Mon 3/7/16	Mon 3/7/16
18		Lunch with GORE Advisors (TBD)	Thu 3/10/16	Thu 3/24/16
19		SPRING BREAK	Mon 3/14/16	Fri 3/18/16
20		Hardware Review 2, Peer Eval 2 Due	Mon 3/21/16	Mon 3/21/16
21		Team Meeting: Statistical Analysis	Tue 3/22/16	Tue 3/22/16
22		Team Meeting: Statistical Analysis Cont.	Thu 3/24/16	Thu 3/24/16
23		Staff Meeting with Dr. Oman	Tue 4/5/16	Tue 4/5/16
24		Prepare Deliverables	Thu 4/7/16	Fri 5/6/16
25		Team Meeting: Prepare Final Deliverables	Thu 4/7/16	Thu 4/7/16
26		Team Meeting: Prepare Final Deliverables Cont.	Mon 4/11/16	Mon 4/11/16
27		Create Instruction Manual Documenting Manufacturing Process	Mon 4/11/16	Mon 4/18/16
28		Presentation Walkthrough, Final Poster Due	Mon 4/18/16	Mon 4/18/16
29		Final Presentation at WL Gore Facility (TBD)	Mon 4/25/16	Thu 4/28/16
30		UGRADS Presentation, Operation Manual Due	Fri 4/29/16	Fri 4/29/16
31		Final Product Testing Proof	Mon 5/2/16	Mon 5/2/16
32		Final Paper due by 11pm (EMAIL)	Fri 5/6/16	Fri 5/6/16



8.4 Appendix D

Table 6 – Previously Acquired Materials

Item	Use	Source	Cost
1.5’’ Rubber Tubing	Visual vessel proof of concept	Home Depot	$5.95
1’’ Hard Foam	Visual lesion proof of concept	Home Depot	$3.95
.5’’ Silicone Tube	Purpose vessel proof of concept	Home Depot	$1.75
Wood Dowel	Purpose lesion proof of concept	Home Depot	$1.95
Total Cost			**$13.60**