Calcified Vessel Model

Initial Design Report

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DISCLAIMER

This report was prepared by students as part of a university course requirement. While considerable effort has been put into the project, it is not the work of licensed engineers and has not undergone the extensive verification that is common in the profession. The information, data, conclusions, and content of this report should not be relied on or utilized without thorough, independent testing and verification. University faculty members may have been associated with this project as advisors, sponsors, or course instructors, but as such they are not responsible for the accuracy of results or conclusions.

EXECUTIVE SUMMARY

The Calcified Vessel Model is a mechanical engineering capstone project that has been proposed by W.L. Gore & Associates Inc. – Medical and facilitated by Northern Arizona University – College of Engineering, Informatics, and Applied Sciences, for the Fall 2024 and Spring 2025 semesters. The primary objective for the capstone project is to design, build, and test 12 replicable models of calcified lesions within the peripheral arterial system for the purpose of testing peripheral vascular interventional devices intended for the treatment of peripheral artery disease (PAD). The team's goal is to produce these calcified vessel models to mimic real-life anatomical and pathological characteristics of PAD in affected blood vessels, ensuring accurate and effective testing for device deployment. The client stipulated that this goal must be accomplished using only non-biological materials. By utilizing non-biological, three-dimensional printed models, the project addresses cost and reproducibility in device testing and enables better development and delivery of devices for clinical applications. Furthermore, these models could be used as teaching tools for both researchers and medical teams working in vascular interventions.

In the current state of the project, the team has employed several concept evaluation techniques to develop an initial design concept that will be explained thoroughly in this report. The initial design consists of the following sub-systems: the artery model, lesion model, pump system, blood analog, and platform for holding of the model.

The artery model will mimic the shape of the femoral artery, as many cases of PAD occur in this section of the arterial system, and it makes for an effective testing model due to the large diameter of the femoral artery. The analog artery will be 3D printed with a carefully selected semi-translucent flexible filament that best mimics the properties of the femoral artery. The lesion models will also be 3D printed, but they will be printed with a much harder filament that mimics the hardness and other material properties of lesions that are present in PAD. The geometry of these lesion models will vary over the 12 models created to allow for the peripheral vascular interventional devices to be tested on a wide range of lesion shapes. The pump system contains three further subsystems, as the pump system has several functions. The first of these subsystems is the pump, itself. The pump chosen by the team was selected by calculating the power required to achieve the correct properties of blood flow under simulated use conditions. A peristaltic pump that meets these criteria was selected for this purpose. The next of the pump subsystems is the computing and sensing unit. To allow for precise data collection when testing the model, the team will employ pressure transducers at the inlet and exit of the artery model. The data collected by the sensors will be transmitted to and processed by an Arduino module, then printed to an LCD screen for the operator(s) of the model to see. The final pump subsystem is the power supply for the pump. A variable power supply will be used for this purpose. The blood analog that will be pumped through the model must have a similar density and viscosity to real human blood. Following a literature review, the team identified a certain solution of corn syrup, water, and flour which can be used to accurately model properties of human blood well enough for the prototyping phase of the design process. The team will test different ratios of the ingredients until its relevant properties are within an acceptable range. All these sub systems will be contained within a trolly or medical cart that the team will purchase. The artery model will sit on the top of the cart. The pump, computing and sensing unit, and power supply will be mounted on the underside of the top shelf of the cart. The blood analog will be held in a tank that sits on the bottom shelf of the cart.

The next step for the team is to begin prototyping and testing the subsystems listed above to ensure they meet the success metrics of this capstone project. For upcoming deliverables within Mechanical Engineering Design class, the team is required to create at least four prototypes of different subfunctions and test them. To meet this requirement, the team has purchased all their necessary products and will use them to prototype and test the sensing and computing unit, the blood analog, the artery and lesion model, and the pump system with regard to their specific customer and engineering requirements.

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1 BACKGROUND

This section of the report contains three subsections aimed at enhancing the understanding of the background belonging to this capstone project. *Project Description* is a top-level description of the project summarized from the given project outline and meetings the team had with their client. *Deliverables* is a description of the major deliverables, including those of the course and the client. *Success Metrics* is a definition of how the success of the project will be assessed, referencing testing, calculations, and major design requirements.

1.1 Project Description

The calcified vessel model capstone project concerns the designing, building, and testing of 12 replicable models of calcified lesions in the Peripheral Arterial System, using non-biological materials. These models will replicate the conditions under which vascular interventional devices are deployed, offering a precise platform for testing device performance under simulated use conditions. The goal is to create models that mimic real-life anatomical and pathological characteristics, ensuring accurate testing for device development. Peripheral arterial disease (PAD) affects millions globally, often leading to severe complications if untreated. Vascular interventional devices are critical in treating PAD by restoring blood flow and reducing symptoms. This project seeks to enhance the development of these devices by providing affordable and reproducible testing models, facilitating research and design optimization. The project's most significant expenses will be for materials needed to create and test the prototypes. Fundraising efforts include approaching local businesses, launching a GoFundMe campaign, and seeking partnerships with companies or research labs that could benefit from or contribute to the project. These efforts aim to ensure adequate financial backing for the successful production of the calcified vessel models and their associated testing requirements.

1.2 Deliverables

The calcified vessel model capstone project requires that the team meet several deliverables by the end of the project life cycle. The first of those deliverables is a detailed literature review of all credible sources used by the team in their research for this project. A project proposal is to be submitted at the end of the first semester for the client to review and approve the team's proposed design. Furthermore, a final report is to be submitted at the end of the second semester for the client to review the entire body of work the team has produced for this project. All engineering analysis the team performed on relevant technical aspects of the design are to be submitted. A cost estimate to duplicate the entire calcified vessel model is to be submitted, as well as a bill of materials featuring each component used in the design. If applicable, a drawing package and software files are to be submitted, as well. A detailed procedure for repeatable manufacturing of the calcified vessel model is expected to be written and submitted. Receipts of all product purchases and team expenses are expected. Finally, 12 functional models for testing in addition to the original calcified vessel model are to be submitted. Finally, the team will be invited to the offices of Gore & Associates – Medical to present the team's model in-person to the client.

1.3 Success Metrics

In the effort to design, build, and test a replicable model of calcified lesions in the peripheral arterial system for deployment of peripheral vascular intervention devices under simulated use conditions, using non-biological materials, the team has several success metrics with which to judge the overall success of their model. The first such success metric of this project is safety. The model must adhere to all relevant safety standards as defined by ANSI, OSHA, or other applicable organizations. The model will

also be judged by its ability to develop, justify, and characterize a variety of attributes of the calcified lesions present in PAD. These attributes include, but are not limited to, the durometer, adhesion strength, length, thickness, and degree of vessel occlusion. Accurate modeling of these attributes is crucial to the overall effectiveness of the calcified vessel model as a test instrument for peripheral vascular intervention devices. The model will also be judged by its ability to allow visualization of peripheral vascular intervention device deployment. To be an effective model for testing of intervention devices, the operators of this model should be able to see and understand its inner workings as a device interacts with the calcified vessel model. The model will also be judged on the replicability of its manufacturing processes. Because this calcified vessel model is intended for mass-production, the ability to effectively repeat the manufacturing processes involved in its production is crucial to its success. The team should be able to compose a document of these repeatable manufacturing processes that the client is able to follow exactly. Finally, the model will be considered a success if it does not exceed its allotted budget of $3000 provided by the client. The team will likely fundraise an additional 10% of the original budget to contribute towards the project.

Above all, the calcified vessel model capstone project will be considered a success if it upholds the standards of W.L. Gore & Associates products, which are designed to be the highest quality in their class and revolutionary in their effect. As a product, the model should live up to all its promises and address this given technical challenge with an innovative, reliable solution. Further definition of project success metrics is provided in Section 2, as well as in the mathematical modeling of Section 3.3.3, and the selection criteria of Section 4.3.3. Additional success metrics for the model may be developed during this project, especially as the team enters the prototyping and testing phases of the design process.

2 REQUIREMENTS

This section the report contains three subsections to show and explain the quality function deployment (QFD) of this capstone project. The purpose of the QFD is to relate the customer requirements (CRs) to quantifiable engineering requirements (ERs) that will be used to inform the team when making design decisions. The QFD is done via the deployment of a house of quality (HoQ). Within the HoQ exists two rooms; one room shows the correlation between the customer requirements and the engineering requirements, while the other weighs the engineering requirements against each other. The result of a successful QFD is a filled-out HoQ that the team can use when comparing concepts generated in Section 4 of this report. The rest of this section is comprised of the three sections: *Customer Requirements*, *Engineering Requirements*, which each list and define the requirements mentioned previously, and *House of Quality*, which displays the HoQ with all its sections filled out completely.

2.1 Customer Requirements (CRs)

The customer requirements for this project come directly from the client of this capstone project, the W.L. Gore & Associates medical division. The customer requirements list was derived from the initial capstone project outline and from the team's initial client meeting with sponsor mentors.

- Replicability – The calcified vessel model must be easily replicated by purchasing, manufacturing, and assembly procedures available to the client, so that more models can be produced if they are deemed useful in testing endoprosthesis medical devices used in treating peripheral arterial disease (PAD).
- Models simulated use conditions – The calcified vessel model must accurately simulate real-world use conditions for the endoprosthesis medical devices intended to be tested on the model. This requires simulating the conditions of the peripheral arterial system as well as the calcified lesion(s) within that system.
- Non-biological materials – The calcified vessel model must be made entirely from non-biological materials to avoid any additional safety and sanitation risks before, during, and after use.
- OSHA/ANSI Compliance – The model must be safe to manufacture and operate.
- Visualization of deployment – The operator(s) of this calcified vessel model must be able to visualize the deployment of the medical devices undergoing testing on the model, which are used in treatment of PAD.
- Durability – The calcified vessel model should be designed in such a way that it can withstand multiple usage cycles before becoming ineffective for its intended use.
- Ergonomic for intended use – The calcified vessel model must be of a size and shape that allows for the client to use for demonstrative and testing purposes

2.2 Engineering Requirements (ERs)

The engineering requirements for this project were developed by the team to create quantifiable targets that help inform the team when making decisions about the design of the model.

- Vessel properties – The vessel properties include the pressure within the vessel and opacity of the vessel model. The target for pressure within the vessel is 11-17 kPa, and the target for opacity is >50%. This will ensure the vessel has the correct blood pressure and the operator will be able to see the deployment of the stent.

- Vessel dimensions - The dimensions of the vessel must be accurate to the dimensions of the vessel in the body that the stent is designed to be deployed in, as well as accommodate for the stent in its entirety. The targets for this are a length of 30 cm, a wall thickness of 2 mm, and a diameter of 9 mm.
- Lesion properties – The properties important to accurate calcified lesion modeling are the indentation hardness and adhesive strength to the vessel wall. The target property values are 39 on the Shore D scale for hardness, and 27 pascals for adhesive (shear) strength. These values were determined through research and analysis of real-world calcified lesion properties performed by the team (see section 4.3.2 and 4.3.3). Achieving these target values for calcified lesion properties will create a more accurate and useful calcified vessel model.
- Lesion dimensions – The dimensions important to accurate calcified lesion modeling are the length, thickness, and degree of vessel occlusion. The target dimension values are 5 mm for length, 0.5 mm for thickness, and 50% for degree of vessel occlusion. These values were determined through research and analysis of real-world calcified lesion dimensions performed by the team (see section 3.3.2). Achieving these target values for calcified lesion dimensions will create a more accurate and useful calcified vessel model.
- Fluid properties – The blood analog that runs through the artery model must have similar properties to the blood within a patient being treated for this disease. The target values for the fluid properties came from the team's research. The properties measured are flow rate, dynamic viscosity, density, and temperature. The targets for these properties are a flow rate of 400 ml/m, a dynamic viscosity of 0.006 Pa*s, a density of 1060 kg/m^3, and a temperature of 310 K.
- Engineering standard compliance – The engineering standard compliance will be measured by a % deviation from the standards used by the team. The target for this is a 0% deviation, or a 100% compliance, to the applicable standards.
- Manufacturing cost – The cost of manufacturing the overall calcified vessel model and 12 replicable artery models must stay within the $3,000 budget provided by the client. That budget will increase by roughly 10% as the team fundraises more money.

2.3 House of Quality (HoQ)

Vessel Properties														
Vessel Dimensions														
Lesion Dimensions			9											
Lesion Properties		3	3	6										
Fluid Properties		3	3		1									
Engineering Standard Compliance														
Manufaturing Cost		-3	-3	-1	-1	-1	6							
		Technical Requirements							**Customer Opinion Survey**					
Customer Needs	**Customer Weights**	Vessel Properties	Vessel Dimensions	Lesion Dimensions	Lesion Properties	Fluid Properties	Engineering Standard Compliance	Manufaturing Cost	*1 Poor*	*2*	*3 Acceptable*	*4*	*5 Excellent*	
Replicability	4						9	9		A		C	B	
Models simulated use conditions	5	9	9	9	9	9					A	BC		
Non-biological materials	3	9			9	9				A			BC	
OSHA/ANSI standard	4						9	6				A	BC	
Visualization of deployment	4	3			3	6					A		BC	
Durability	2	6	3	3	6			3				ABC		
Ergonomic for intended use	2		6	6				3					ABC	
Technical Requirement Units		Pressure (kPa) Opacity (%)	Length (cm) Thickness (mm) Diameter (mm)	Length (mm) Thickness (mm) Degree of Vessel Occlusion (%)	Strength (Pa) Durometer (HS)	Flow rate (mL/s) Dynamic viscosity (Pa*s) Density (kg/m^3) Temperature (K)	%	USD						
Technical Requirement Targets		11-17 kPa 50%	~30 cm 1-2 mm 5-9 mm	5 mm 0.5 mm 50%	27 Pa Shore 39D	7.2 mL/s 0.003-0.006 Pa*s 1060 kg/m^3 310 K	100%	$3000 USD						

Legend	
A	Creative Biolabs 3D Biology
B	Preclinic Medical Simulation
C	Vivitro Labs - Simulators

Figure 1 – HoQ deployed for QFD

3 Research Within Your Design Space

This section of the report contains three subsections which aim to provide deep insights into the research performed by the team which aided them in their understanding of the capstone project and influenced their future work. *Benchmarking* identifies and describes three state-of-the-art systems within this design space on the system level, as well as all other subsystem-level benchmarking used. *Literature Review* is an annotated bibliography of references used for this project, providing a brief description of each reference and how it applies to this project. *Mathematical Modeling* is a summary of the equations, engineering tools, and examples used by the team for the design of the project's subsystems.

3.1 Benchmarking

Numerous existing designs of medical testing models aim to accurately simulate aspects of the human body. In this section, there are three designs from three different companies that were analyzed to gain insight into the engineering and applications of artificial vessels and calcified lesions. Each company is currently active in the market and has made their product information available to the public. These companies mainly gain interest from the medical field, and their products have evolved over time to enhance their functionality to these customers. From the team's benchmarking research, it is apparent that all three companies/products share the same goal: to create a product that improves patient outcomes as well as enhance the skills, expertise, and knowledge of surgeons and practitioners.

All research for this section was done through literature review of credible website sources, focused on human body blood vessel simulation models. Through searching, the team was able to find the following three manufacturers with vessel simulation designs that mimic the human body. Each manufacturer provided websites that included their product, their services, and their company purpose. Through this initial benchmarking research, the team gained a clearer understanding of what would go into the design of their client's product. This research gave the team a direction to take their project in. However, the team must conduct this project with a budget in mind, so their design would have to conform strictly to their specific customer needs over other optional considerations.

These three manufactured products operate with one goal: to simulate human blood flow within the desired vessel site to deploy interventional devices. The overview of accurately replicating the human body offers significant benefits for the public. Surgeons and practitioners can use these life-like vessel simulation models to practice stent applications for use on real patients. These products can enhance surgeons' and practitioners' skills in operating medical devices within a diseased vessel, and thus offer patients better medical care. Testing medical devices within these vessel models provides information and data that would be useful for real surgeries.

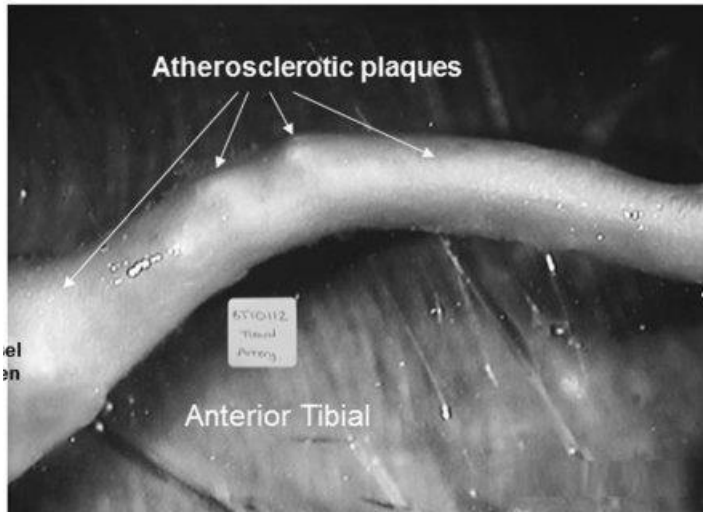


Figure 2 - Atherosclerotic tissue sample [46]

Creative Biolabs 3D Biology [46]

Creative Biolabs is a biotechnology company known for providing specialized services and products. They focus their manufacturing on the 3D biology field, which is crucial for understanding diseases within the human body and the drug intervention exploration for treating these diseases. Creative Biolabs primarily develops 3D biological models that simulate biological functions in the human body. This is important for use in research, drug intervention developments, and medical device testing. Creative Biolabs' 3D models are more realistic testing platforms compared to non-biological models.

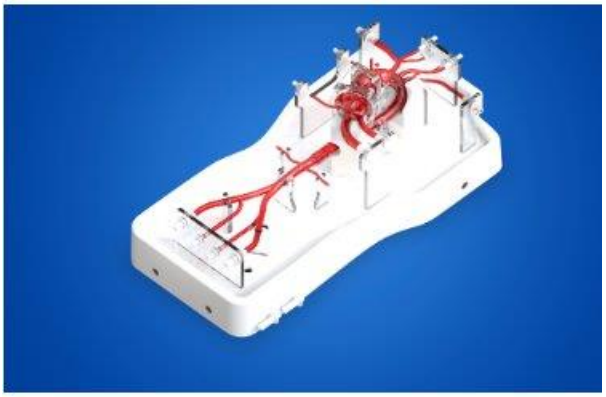


Figure 3 - Silicon Cardiac Vessel Model [44]

Preclinic Medical Simulation [44]

Preclinic Medical Simulation is a manufacturer that specializes in medical simulation models for utilization by medical personnel for training purposes, research, and testing medical devices. This manufacturer does an exceptional job at developing accurate and functionally realistic models that replicate human vessel sites and physiological conditions. This model offers an alternative to using animals for testing medical devices, as no biological material is used in this manufacturer's models. All models are composed of silicone material, which are synthetic polymers made of silicon and oxygen also known as Polysiloxane.

Figure 4 - Endovascular Simulator [33]

Vivitro Labs – Simulators [33]

Vivitro Labs is a manufacturer that specializes in designing and developing advanced cardiovascular testing equipment and simulators used for research, medical testing, and development of intervention devices for cardiovascular diseases. Vivitro Labs focuses on providing precise simulation and testing solutions that replicate the human vessel and arteries along with the physiological conditions of the human body. The process flow of these designs simulates and replicates the dynamic conditions of the heart and vascular system. This allows for realistic testing of medical devices in a controlled setting.

3.2 Literature Review

3.2.1 James Anteau

Viabahn stent instruction manual [47]

An instruction manual from the Gore website that outlines the deployment procedure for their Viabahn stent. This source is created and owned by the client and sponsor for this project. It explains the procedure for use of the stent. It provides crucial information that will inform the design of the inlet port for the stent, as well as the overall dimensions of the model.

Harrison's Principles of Internal Medicine, 21st edition [48]

A medical textbook that contains a chapter on peripheral arterial disease. The chapter discusses the cause, diagnosis, and treatment of this disease. It provides valuable background information about PAD which will help aid the team in preliminary design of the lesions and arteries.

Comparison of BARD®LIFESTREAM™ covered balloon-expandable stent versus GORE® VIABAHN™ covered self-expandable stent in treatment of aortoiliac obstructive disease: study protocol for a prospective randomized controlled trial (NEONATAL trial) [49]

A medical scholarly journal article aimed at providing a comparison of two stents that would potentially be used within the team's final model. It discusses in depth the common failures of both stents as well as their advantages. This will inform the team on how to create lesions or conditions that will prove useful in testing the stents and their failure behaviors.

Endovascular Today: Stent device guide [50]

This website contains a spreadsheet of several different intravenous stents from different medical companies. It contains the dimensions and properties of the stents in a spec sheet format. This will

provide the team with information that will dictate the dimensions of the artery model, and the inlet for the stents.

A computational study of effects of material properties, strain level, and friction coefficient on smart stent behavior and peripheral artery performance during the interaction process [51]

This scholarly journal article contains a computational study of the effects from the interaction between a smart stent and the wall of the artery vessel. As the title states, the article outlines the material properties, strain, and friction coefficient developed when the interaction occurs. This information will inform the team's decisions for material and design of the artery model.

W. L. GORE & ASSOCIATES ENHANCES GORE® VIABAHN® ENDOPROSTHESIS PORTFOLIO WITH LOWER PROFILE DELIVERY [52]

Press release for an improvement to the Gore Viabahn design. This shows the different dimensions and properties of their improved design. This source further deepens the team’s knowledge on the devices that will be used within the model. This furthers the informing for design decisions.

OSHA Regulations [53]

Provides information on how to keep our project safe when creating and testing the model. As one of the customer requirements for this project is compliance with ANSI and OSHA standards the team must review any pertinent codes or standards for this project.

3.2.2 Gavin Lazurek

Materials Science and Engineering: An Introduction, 10th Edition [13]

A textbook on the subject of general and introductory materials science. It explains the primary types of materials: metals, ceramics, polymers, and composites, as well as the relationships between material structural elements and their properties. It will help guide the team in characterizing and calculating peripheral arterial calcification material properties, such as durometer and adhesion strength, which are essential requirements of the project. Furthermore, the textbook may also provide useful information on 3D printing to manufacture calcified lesion models with desired material properties.

Schaum's Outline of Probability and Statistics, 4th Edition [14]

A textbook on the subject of probability and statistics. It explains the fundamentals of conditional probability and independence, random variables, binominal and normal distributions, sampling distributions, and analysis of variance. It will provide statistical tools for the analysis of medical experiments and the relevant data they provide to designing calcified vessel models. For this project, it will be used to determine statistical significance of results from medical experiments regarding angioplasty procedures on peripheral arterial calcifications.

GORE® VIABAHN® Endoprosthesis [15]

A website from the W.L. Gore & Associates, Inc. medical division about their company’s medical device product: the Viabahn endoprosthesis medical device. This source belongs to the sponsor of this team’s capstone project, and they intend to use the team’s calcified vessel model for testing of their Viabahn endoprosthesis. It provides information, instructions, clinical uses, case studies, specifications, and further reading related to Gore Medical's Viabahn stent. This source provides an in-depth view of the Viabahn stent, aiding the team in their understanding of the simulated use conditions which the calcified vessel model should be able to replicate.

A new optical coherence tomography-based calcium scoring system to predict stent underexpansion [16]

A scholarly journal article published in the peer-reviewed medical journal EuroIntervention. It is a retrospective observational study which compares several properties of peripheral arterial calcifications to

the results of angioplasty procedures performed on those calcifications. The study uses blood vessel imaging technology to ascertain precise dimensions of calcifications. Then based on its results, the study proposes a mathematical model which can accurately predict stent underexpansion based on peripheral arterial calcification properties. It reveals which factors related to blood vessel calcification interfere with stent expansion and reveals the critical values at which stent underexpansion becomes likely. This source will help the team make decisions about the dimensions of modeled calcified plaque for effective usage of their calcified vessel model for endoprosthesis testing.

Carotid Artery Stenting for Calcified Lesions [17]

A scholarly journal article published in the official open-access journal Stroke: Vascular and Interventional Neurology of the American Heart Association and the Society of Vascular and Interventional Neurology. It is a correlation study comparing the arc of circumferential vessel occlusion in patients with peripheral arterial calcification to the outcomes of balloon expansions in stent placement operations. It reveals a statistical correlation between degree of vessel occlusion and residual stenosis, providing guidelines for necessary balloon expansion pressure during stent placements depending on calcification levels. This source will assist the team in understanding the common characteristics of heavily calcified arterial plaque and the outward radial pressure they must withstand during angioplasty procedures, which will influence the design of the calcified vessel model.

Quantifying Effects of Plaque Structure and Material Properties on Stress Distributions in Human Atherosclerotic Plaques Using 3D FSI Models [18]

A scholarly journal article published in the Journal of Biomechanical Engineering of the American Society of Mechanical Engineers. It is a computational study that utilizes blood vessel imaging technology to create 3D structural and fluid models of peripheral arterial calcification for mechanical analysis. It provides mathematical relationships of stress and strain levels in calcified lesions according to calcified plaque material properties and geometries. This source will help the team to understand the various stresses that peripheral arterial calcifications must withstand and help them to assess how accurate their calcified vessel model is to real world conditions.

Ultrasound determination of total arterial wall thickness [19]

A scholarly journal article published in the official publication Journal of Vascular Surgery of the Society for Vascular Surgery. It is a correlation study that utilizes blood vessel imaging technology to determine the total wall thickness of various arteries among different test subject groups. The study compares the ages and peripheral artery disease states of test subjects with the total and intima-media thicknesses of their common carotid artery walls. It reveals a statistically significant correlation of the increase in peripheral artery wall thickness in patients 60-69 years old due to peripheral artery disease. The study will inform the team about the expected wall thickness of their modeled blood vessels in their calcified vessel models because of the effects of peripheral artery disease.

Cardiovascular implants — Endovascular devices (ISO 25539-2:2020) [20]

A standard written and published by the International Organization for Standardization (ISO) specifying the requirements of vascular stents and delivery systems with regards to their design, manufacturing, and evaluation among ISO member nations. It provides fundamental technical information on endoprosthesis devices such as Viabahn, including the rules and regulations they must follow. This source will inform the team on how the Viabahn endoprosthesis is to be used in their angioplasty procedures, so that its intended use can be accurately represented in the calcified vessel model.

3.2.3 Jamie Dellwardt

Comparing Traditional and Contemporary Manufacturing Methods [22]

This source highlights the key differences between traditional casting and contemporary 3D printing processes, particularly focusing on the limitations of each. Casting resin, while reliable for producing solid parts, often struggles with complex geometries and fine details. On the other hand, 3D printing excels in precision but can be limited by material properties and layer adhesion. This comparison will help us weigh the benefits of both manufacturing methods, allowing us to assess which constraints—such as cost, precision, and material strength—apply to our project. It is essential to identify which technique offers the most advantages while minimizing limitations in the context of our specific requirements.

3D Printed Molds for Injection Molding [23]

This journal explores the effectiveness of using 3D-printed molds for liquid injection molding, especially for elastomeric devices. The study demonstrates that 3D printing can be a low-cost, rapid prototyping tool that complements traditional injection molding techniques. Combining these processes could be key for our project, as 3D-printed molds can help us quickly iterate designs while injection molding may be used for final production due to its scalability and material versatility. This allows us to strike a balance between rapid prototyping and durable, cost-effective production when considering materials for our calcified lesion models.

Design For Mechanical Measurements Chapter 1 [24]

This chapter delves into the importance of replication and repetition in mechanical testing, which is directly applicable to our project. Since we are producing 12 models to undergo consistent testing, ensuring the same conditions and procedures for each is crucial. This source emphasizes the necessity of maintaining accuracy and repeatability in testing, which aligns with our need to create uniform, reproducible models to validate the effectiveness of vascular intervention devices across multiple trials.

Design For Mechanical Measurements Chapter 9 [25]

Chapter 9 covers pressure measurement techniques, with a specific focus on velocity probes—tools that are vital for measuring fluid flow in vascular systems. This is particularly relevant to our project as the primary testing will involve simulating blood flow and evaluating how well our models mimic real-life hemodynamic conditions. The practical guidance offered on using and calibrating velocity probes will help inform our testing procedures, ensuring that we accurately measure how interventional devices behave under different flow conditions.

Biocompatible 3D Printing Resins for Medical Applications [26]

This article reviews various biocompatible resins used in 3D printing for medical applications, assessing their flexibility, strength, and limitations. Understanding the properties of these materials will aid in the design and prototyping phases of our project, allowing us to select the most suitable materials for our calcified lesion models. Since the models must mimic the characteristics of arterial calcification, choosing resins that balance flexibility and durability while maintaining biocompatibility will be essential for realistic simulations.

Research Models for Studying Vascular Calcification [27]

This source provides detailed information on the biological processes that lead to vascular calcification, offering insight into how calcified lesions form in the arteries. It also outlines the types of systems and environments that promote calcification, which will inform our approach to replicating these conditions in our models. By understanding the key components involved in the calcification process, we can select appropriate materials and techniques to accurately simulate arterial calcifications, making our models more effective for testing vascular intervention devices.

Vascular Corrosion Casting [28]

This article discusses the use of silicone rubber in vascular corrosion casting, which is known for

its ability to create detailed models of vascular systems. This method will be useful for us, particularly in capturing the fine structures within our models of calcified arteries. Additionally, the article highlights the benefits of creating multi-port models, which could be important for testing different access points for vascular devices. Incorporating these casting techniques into our prototyping phase could help ensure our models meet the necessary structural and functional requirements.

How Cost-Effective is SLA 3D Printing [29]

This source compares the costs associated with SLA 3D printing to other manufacturing methods such as CNC machining and injection molding. It details how SLA printing offers a balance between cost-effectiveness and precision, especially for small production runs like ours. Since our project involves building 12 prototypes, SLA printing may provide the most practical solution in terms of both cost and speed for initial model development. This comparison will help guide our choice between using 3D printing for prototyping and switching to other methods, like injection molding, for larger-scale production.

Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices [30]

This document outlines the standard practices for biological testing of materials, which is relevant to our project since we are working with non-biological but medical-grade materials. While our models themselves may not need biological testing, understanding the safety and testing standards for medical devices will be important when presenting our designs to stakeholders. This ensures that they are aware of potential regulatory hurdles and the necessity for further testing should our models transition into devices intended for medical use.

3D Printed Biomedical Devices and their Applications [31]

This review highlights the challenges encountered with 3D-printed biomedical devices, particularly issues like material fragility, inconsistencies in printing quality, and regulatory concerns. These are critical factors for our project to consider, as they represent potential pitfalls we need to avoid when designing and manufacturing our calcified lesion models. Additionally, the journal discusses advancements in 3D printing materials, offering insights into new materials that could enhance the durability and functionality of our models, especially as the technology continues to evolve.

3.2.4 Scott Alex

Endovascular Simulator – Vivitro Labs [33]

Used as a benchmark, providing some direction in the assembly and design process. The source will also give the team an understanding of the flow loop systems that are used in testing and simulation of these vessel simulators. Vivitro Labs is a company that provides scalable and modular test equipment and services to cover fundamental research, early-stage, and V & V design activities. V & V is carried out in parallel with the software/system development process. These V & V activities include but are not limited to traceability analysis, evaluation, review, inspection, assessment, and testing. This source is a great bench-marker for our project.

Silicone Vessels Simulation Model Manufacturer, Vascular Simulation | Preclinic Medtech [32]

Used as a benchmark, providing an example for the overall process flow of the simulation model. This source will provide the team with some potential concepts for the vessel model overview. Silicone Vessels Simulation Model Manufacturer is a company which provides simulation vascular models for medical training, testing and operations. These trainings include virtual surgery simulators to carry out human body teaching, medical operation technology training, surgical training, surgical design and guidance, disease prediction, guide new drug development, new instrument research and development,

and implementing intervention devices, etc. All silicone vessels are printed from patient-specific scans or designs (CT, MRI, 3DRA), literature values, STLs or STPs, with a highly vivid anatomical structure and operational sense, which are matched to human properties. This source is an active benchmarking source for our project scope.

CRIMSON | PLOS Computational Biology [34]

Engineering tool used for segmenting vascular structures from medical images. This source will be used as the standard in helping create accurate and detailed simulation modeling. This source utilizes an open-source software framework for cardiovascular integrated modelling and simulation. There's a lot of useful information in this source for our team to use going forward. Primarily our team will use this source to study and research what it takes to simulate cardiovascular behavior in a vessel model. This will include the pulsatile pump system, the geometric vessel structure of any artery or vessel in the human body. CRIMSON can replicate any vessel structure in the body through their imaging software and tools.

Anatomy, Blood Vessels [35]

A textbook source used for information on the anatomy of blood vessels. The information provided detailed dimensions of the various blood vessels in the human body. Our project scope is focused on the femoral artery and in general the peripheral arterial system. The team will use this source to gain additional information on dimensions of the femoral artery. The source also provides diseased state conditions of the peripheral artery and vessel anatomy.

Central Versus Peripheral Artery Stiffening and Cardiovascular Risk [36]

A scholarly journal known as the American Heart Association and American Stroke Association journals. Originally published on March 19, 2020, by the AHA/ASA journals. This source provides information on the diseased conditions of the peripheral arterial system. There's additional information concerning the mechanisms underlying arterial stiffening that has come from longitudinal studies of arterial stiffness. The team will use this source for insight on the vessel calcification and vessel wall stiffness.

Blood Flow in Vessels - Circulation [37]

A peer-reviewed source from TeachMePhysiology website that provides exceptional information on the behavior of the blood flow in vessels. TeachMePhysiology is a comprehensive, accessible encyclopedia of the physiology of the body. Created by a team of medical field scholars. The information the team is interested in is geared towards peripheral and central arterial systems. The team will use this source for the blood flow behavior in the peripheral arterial system. This source does well in relating blood flow to fluid dynamics. There is an investigation into how blood behaves based on known values such as pressure, viscosity, vessel cross section dimensions, and fluid flow.

Cardiovascular Physiology – Chapter 6: The Peripheral Vascular System; McGraw Hill [38]

A textbook source from the American publishing company McGraw Hill publishing. The textbook is Cardiovascular Physiology, 9e. The information cited and used by the team is from chapter 6 of the textbook, The Peripheral Vascular System. This chapter will aid the team in understanding the basic principles of cardiovascular transport and its role in human homeostasis. The areas of interest in this chapter for the team; Identifies the approximate percentage of the total blood volume that is contained in the various vascular segments, describes differences in the blood flow velocity in the various vascular segments and how these differences are related to their cross-sectional areas.

Tortora's Principles of Anatomy & Physiology Textbook [43]

A textbook source published by John Wiley & Sons, Inc. This source provides a comprehensive overview of human anatomy and physiology. It provides understanding of the structure and function of

the human body, focusing on these two aspects. The book provides detailed illustrations, diagrams and real-world applications for comprehension on any level of competence. The team will use this source to gain insight into the relationship between structure and function of human anatomy, primarily the peripheral arterial system.

3.3 Mathematical Modeling

3.3.1 Pump Power- James Anteau

One of the most important factors in creating a successful calcified vessel model is achieving a realistic flow rate and pressure within the vessel model. From the team's research on the peripheral arterial system, target values for these factors were found. The flow rate in the femoral artery, which was chosen as the subject of this model, varies between 300-400 milliliters per minute []. For the purposes of this mathematical model, the higher end of this range will be used, since the model must be designed for a worst-case scenario. For system pressure, the team researched and found a worst-case blood pressure within a femoral artery of 200 mmHg []. These target values will be achieved via the pump integrated into the calcified vessel model. To be able to select an adequate pump, the power required to achieve the flow rate and pressure targets must be calculated. This is done by using the following equation for pump power. [54]

$$P_{pump} = \frac{Sg \cdot \gamma \cdot Q \cdot H}{\eta} \tag{1}$$

In this equation, Sg is the specific gravity of the fluid used to model blood, γ is the density of water, Q is the desired flow rate, H is the head developed in the system, and η is the efficiency of the pump. The values used in this equation came from additional team research about human blood properties. The values used for these variables are shown below.

$$Sg_{blood} = 1.048 - 1.066$$

$$\gamma_{water} = 62.43\ lb/ft^3$$

$$H_{max} = 3\ ft$$

$$Q = 300 - 400\ mL/\min \rightarrow 0.00235\ ft^3/s$$

$$\eta \approx 80\%$$

After plugging these values into the equation (1), a required power of P = 0.0011 horsepower is found. This value is similar to the power produced by a human heart, which suggests that the team is on the correct path with their calculations. However, this value reflects an ideal scenario in which there is no friction within the arterial system. Once a more accurate calculation for head in the system is performed, a more accurate pressure value will be calculated.

3.3.2 Calcified Lesions - Gavin Lazurek

A statistical analysis was performed on the results of a medical study to characterize disease states of peripheral arterial disease (PAD). The disease presents differently in different patients, so a disease state which is applicable to the intended function of the calcified vessel model was necessary to ascertain. The EuroIntervention study, *A new optical coherence tomography-based calcium scoring system to predict stent under expansion*, proposes that predictive factors of stent under expansion in angioplasty procedures on peripheral arterial plaque include plaque length greater than 5 mm, plaque thickness greater than 0.5 mm, and degree of vessel occlusion greater than 50% [12]. To determine the statistical significance of these claims, a two-tailed A/B test was performed on data collected by the study.

The purpose of a two-tailed A/B test is to determine whether a change to an experiment produced a statistically significant effect, either an increase or a decrease, in its success rate. The test requires the calculation of a z-score and p-value, using the following formulas [14].

$$z = \frac{\bar{x} - \mu}{\frac{\sigma}{\sqrt{n}}} \tag{2}$$

$$p = P(z < -z_{crit}) + P(z > z_{crit}) \; or \; P(z < -z_{crit}) \tag{3}$$

In the formula (1), a z-score is calculated according to the sample mean, $\bar{x}$, the population mean, μ, the standard deviation, σ, and the sample size, n. In formula (2), the p-value is calculated according to the probability that a z-score is outside the range of a critical z-score, z_{crit}. For example, among patients with less than 50% vessel occlusion, 3 of 33 experienced an incomplete stent expansion, resulting in a sample mean of 0.0909, a standard deviation of 0.2919, and a sample size of 33. Among patients with more than 50% vessel occlusion, 7 of 24 experienced an incomplete stent expansion, resulting in a sample mean of 0.2917, a standard deviation of 0.4643, and a sample size of 24 [12]. The critical z-scores of 1.645 and 1.282, respectively, were found in Appendix C of *Probability and Statistics* according to the parameters of this A/B test [14]. These values were then inputted into an A/B test calculator provided by ABTestGuide.com for analysis, the results of which are shown in Figure 5.

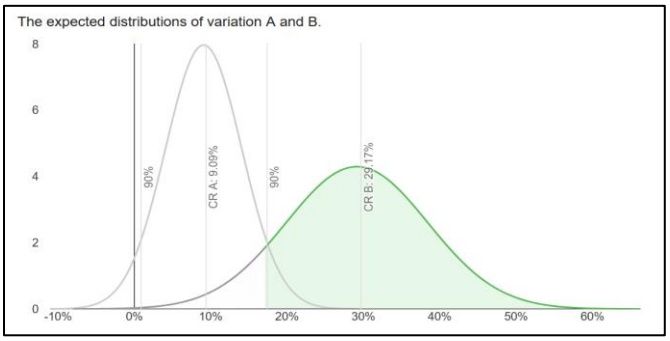


Figure 5 - Two-tailed A/B test for degree of vessel occlusion vs stent under expansion rate

The results of this A/B test show a z-score of 1.9044 and a p-value of 0.0569. This translates to greater than 90% significance regarding the change in experimental success rate. The 90% confidence interval was deemed to be acceptable for the small sample size of the angioplasty procedure data. The factors of plaque length and plaque thickness were both calculated using the same A/B test method and both changes in experimental success rate were found to have greater than 99% significance. Based on these calculations, the calcified vessel model will establish baseline dimensions of modeled calcified plaque as 5 mm in length, 0.5 mm in thickness, and 50% degree of vessel occlusion, as these factors have been determined to be the critical values at predicting stent under expansions in angioplasty procedures. For accurately representing the wide range of disease states of PAD, three calcified plaques will be modeled at dimensions less than, equal to, and greater than these critical values. The usefulness of the calcified vessel model would be greatest if it can accurately represent a best-case scenario, an average scenario, and a worst-case scenario for testing of medical devices across their entire expected range of PAD states.

3.3.3 Cost Analysis - Jamie Dellwardt

This section of the report presents a cost analysis on the production of calcified vessels using two primary methods: 3D printing and injection molding. The analysis is based on specific assumptions and calculations, providing insights into the relative costs of each method. The analysis considers a production of 12 replicable calcified vessels. The following variables and assumptions were used in the calculations:

Product: Calcified vessels

Production Methods: 3D printing and molding

Quantity: 12 units

Variable Costs:

Resin, tubing, syringes, labor, shipping for both methods

Estimated cost savings of $22 per unit for molding compared to 3D printing

Fixed Costs: Pump, tank, cart, blood solution, and other miscellaneous fixed costs

In order to calculate a total cost of each method for our variable costs, the following equations for variable costs were used:

$$C_v = C_m + L + Oh \tag{4}$$

$$pC_v = Resin + Tubing + Syringes + L + Oh \tag{5}$$

The inputs and results of the equations are presented in Table 1, below. These values reflect the estimated costs for producing a single vessel model.

Table 1 - Variable Cost

Method	Resin	Tubing	Syringes	Labor	Shipping	Total
3D Printing	$3.44	$8.91	$65	$22.49	$70	$169.84
Molding	$18.00	$8.91	$65	$0.00	$70	$147.84 (estimated)

After calculating the individual variable cost, the total variable cost (TC_v) for all 12 models was calculated. The totals are presented below.

Table 2 - Total variable cost

Method	TCv
3D Printing	$2,038.08
Molding	$1,774.08

The total variable cost is calculated by taking the individual variable cost multiplied by the number of units. The fixed cost is the sum of all the one-time purchases and the costs no matter the manufacturing processes chosen. The fixed cost for this project is currently estimated to be $323.97. The next significant calculation is for the total cost of the entire 12 models.

$$TC = C_f + TC_v \tag{6}$$

Table 3 - Total Cost for each process

Method	TC
3D Printing	$2,362.05
Molding	$2,098.05

In order to maintain purchasing costs under the project budget, the cost per unit was calculated to ensure there would be enough room to purchase all needed materials for the remaining models. This was done by dividing total cost by the number of units.

Table 4 - Cost per unit for each process

Method	A
3D Printing	$196.84
Molding	$174.84

Based on the calculation results, molding is a more cost-effective method for producing calcified vessels compared to 3D printing. The average cost per unit is lower for molding due to reduced variable costs associated with materials and labor. However, it is important to note that this analysis is based on specific assumptions and calculations. Other factors such as quality, lead time, and production scale should also be considered when making a final decision. Further analysis and evaluation may be necessary to determine the optimal production method for specific requirements and circumstances.

Based on the cost analysis results, it is recommended that the team consider adopting injection molding as the primary production method for calcified vessels. However, further research and analysis should be conducted to evaluate the overall suitability of each method for project-specific requirements such as quality standards and production capacity. Additionally, exploring potential cost-saving strategies within the molding process, such as material optimization or process improvements, could further enhance the economic viability of this method.

3.3.4 Filament Usage – Jamie Dellwardt

In this section, the engineering calculations necessary to determine the filament length required for constructing a calcified vessel model using 3D printing are presented. The calculations begin by determining the solid volume of the vessel, based on its outer diameter and length. Using the formula for the volume of a cylinder:

$$Solid\ Volume = \frac{d^2 \pi l}{4}$$

where $d = 8\ mm$ and $l = 12.4\ mm$, the solid volume was calculated as:

$$Solid\ Volume = \frac{8^2 \pi * 12.4}{4} = 623.29\ mm^3$$

Next, the interior (hollow) volume of the vessel, representing the inner portion, was calculated using the same formula but with the inner diameter $d = 6.2\ mm$:

$$Interior\ Volume = \frac{6.2^2 \pi * 12.4}{4} = 350.60\ mm^3$$

To determine the volume of the material needed to construct the vessel, the interior volume was subtracted from the solid volume, yielding:

$$Volume\ of\ Hollow\ Model = 623.29\ mm^3 - 350.60\ mm^3 = 272.69\ mm^3$$

Finally, to calculate the required filament length, the volume of the hollow model was related to the filament's cross-sectional area using the formula:

$$Volume = Filament\ Length * \left(\frac{Filament\ Diameter}{2}\right)^2 \pi$$

Given the filament diameter $Filament\ Diameter = 1.75\ mm$, solving for the filament length results in:

$$272.69\ mm^3 = Filament\ Length * \left(\frac{1.75}{2}\right)^2 \pi$$

$$Filament\ Length = \ 113.37\ mm\ (or\ 0.11337\ m)$$

In conclusion, the filament length required to fabricate the calcified vessel model is approximately 113.37 millimeters. This calculation ensures that the appropriate amount of material is available for 3D printing the model and is crucial for proper planning and execution of the fabrication process.

3.3.5 Wall Shear Stress – Scott Alex

Wall shear stress in this context is defined as the frictional force exerted by flowing blood on a vessel wall. It represents the tangential force exerted by the blood flow on the endothelial lining of the vessel walls. The wall shear stress calculation is an important biomechanical parameter in blood vessels. This stress significantly influences the evolution of atherosclerosis in the arterial and vessel system. Wall shear stress calculation in blood vessels helps indicate atherosclerosis development and progression to calcification in the blood vessel [34]. Though calcification is not the same as atherosclerosis, it commonly occurs and develops in parallel together [33]. Calcification in the arterial system is a buildup of calcium deposits that, over time, leads to development of calcified plaque adhered to the wall of the vessels. Atherosclerosis is fatty deposit buildup in the arterial system also known as plaque in the arterial system. Wall shear stress, calcification, and atherosclerosis are all related factors.

Applying fluid mechanic principles to blood flow in a blood vessel we can use this wall shear stress calculation to determine appropriate wall thickness of our model. Below will be the teams model calculation for wall shear stress. Blood flow is the important parameter in this calculation, so the team will do extensive research into blood modeling for the process. The team aims to construct a blood substitute that is almost a match to the dynamic viscosity of human blood. This will ensure the vessel model to be accurate to the human body function. This calculation will use dimensions that are common to the femoral artery, as the team will be focusing on this particular artery for the calcified vessel model.

Calculation considerations:
1. Assume laminar flow
2. Viscosity (μ) of blood/blood substitute is complex
3. Shear rate also needs to be calculated [36]
4. Flow velocity (V_{max}) is used for arteries with peripheral arterial disease (PAD)
5. Radius value (R) [37]

Known values:

$$V_{max} = 0.3\ m/s$$
$$R = 0.005\ m$$
$$\mu = 0.0035\ Pa \cdot s$$

Calculate shear rate:

$$\frac{du}{dy} = \frac{2V_{max}}{R} \quad (7)$$

$$\frac{du}{dy} = \frac{2(0.3\ m/s)}{0.005\ m}$$
$$\frac{du}{dy} = 120\ s^{-1}$$

Calculate wall shear stress (WSS):

$$\tau = \mu \cdot \frac{du}{dy} \tag{8}$$

$$\tau = (0.0035\ Pa \cdot s) \cdot (120\ s^{-1})$$
$$\tau = 0.42\ Pa$$

The results of this calculation show that the wall shear stress calculation for the blood vessel dimensions (femoral artery dimensions) is equal to the value of 0.42 pascals. This is a small value; it represents the shear force exerted by the blood substitute on the model vessel wall under the given conditions. The team will need to consider this value when selecting filament material for the 3D print of the model to withstand the pressure and flow of the blood substitute. The model blood vessel wall thickness will match the femoral artery thickness at 1 to 2 mm, so the material will need to withstand this stress value. If the team does not consider this stress value, there could be potential aneurysm formation or vessel wall failure, which are not desired simulated use conditions for this model.

4 Design Concepts

This section of the report contains four subsections which aim to offer insight into the design process of the project across several key stages of transforming the project requirements into a viable, cohesive solution. *Functional Decomposition* breaks down the overall system into their essential physical components and their associated functions. *Concept Generation* explores design concepts with various approaches for fulfilling the design requirements provided in the QFD, resulting in many potential subsystem solutions. *Selection Criteria* shows how these design concepts are evaluated against selection criteria derived from the project's customer and engineering requirements, quantifiable through calculations and/or part specifications. *Concept Selection* discusses and shows the selection process through a variety of tools. A CAD of the current state of the overall design and pipe flow diagram are provided at the end of this section.

4.1 Functional Decomposition

The team created a physical decomposition of the calcified vessel model to aid in the concept generation stage of the design process. The overall calcified vessel model can be broken down into several subsystems and components. Each subsystem and component will serve a role in replicating the desired physiological conditions in human patients. This decomposition covers both the physical process, and the functional aspects required for the calcified vessel model and its purpose of facilitating medical testing and research studies for the deployment of arterial intervention devices.

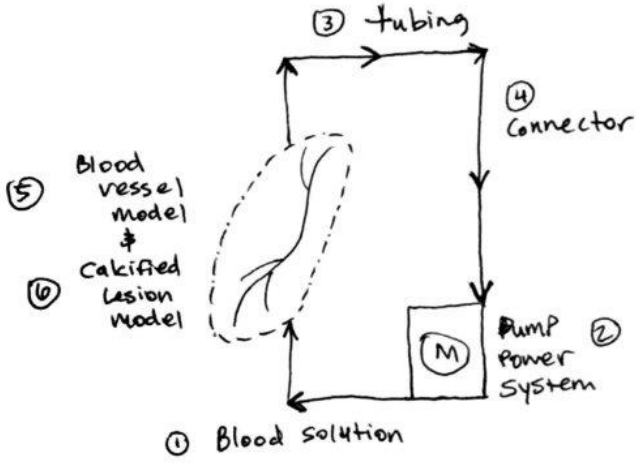


Figure 6 - Process flow of calcified vessel model

System:
Calcified Vessel Simulation Model

Components:

1. Blood Substitute
   simulates blood
2. Power/Pump
   produces flow
3. Tubing
   directs flow
4. Connectors
   joins system
5. Blood Vessel Model
   simulates femoral artery
6. Calcified Lesion Model
   simulates calcification

The team created a hierarchy chart for a better visual of the components and the subsystems involved in this calcified vessel model design. The intention behind this chart is to aid in design considerations for the entire project. The chart will list the physical components and the subsystems within each component. Paired with the above decomposition, this chart will delve deeper into the design and connect the required parts needed for this calcified vessel model to successfully simulate human physiological conditions. The hierarchy chart is as follows.

Physical Components:

Blood Vessel Structure
- >femoral artery model
- >branching vessels (optional)
- >calcification model
  - >>lesion material
  - >>lesion adhesion
  - >>lesion variations

Materials
- >vessel material
- >calcified lesion material
- >blood substitute material

Fluid Flow Process
- >pump system
  - >>pulsatile frequency
  - >>steady frequency
- >plumbing tubing

Metrology

>data acquisition software/computer
>>pressure sensors
>>flow meters
>>feedback loop

Model Support Structure

>transportable cart
>resting mounts

4.2 Concept Generation

4.2.1 Top-Level Design

For the overall design of the model, three concepts were generated with varying locations of each sub-function component within the calcified vessel model. The top-level design is crucial to the success of the project, as it is what the team will use to plan the mounting of parts needed to achieve the project goals. It consists of a medical cart with a top and a bottom shelf, upon which an artery model, an Arduino module, a blood analog reservoir, and a pump are mounted in various locations.

The first design concept places the computing and pump module on the top shelf of the medical cart, while the artery model, and the blood analog tank are on the below shelf.

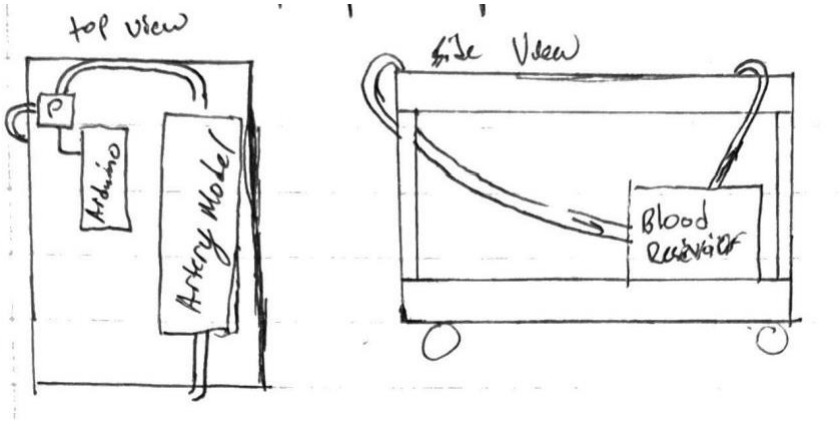


Figure 7 – Top-level design concept 1

This concept has the benefit of easy access to the electronics and the pump for any necessary maintenance and/or upgrades. However, this position for the electronics places them in the way of potential fluid spillage if a structural failure were to occur within the artery model. If this occurred, the electronic units would be permanently broken, and the team would need to replace them. Though the electronics are in danger, the pump will be in an advantageous position that reduces the head which the pump must overcome to create flow within the model. This is advantageous because it allows for the team to use a more cost-effective pump, since its necessary power will be lower than in other locations.

The second design concept features a top-level design in which the pump and electronics are placed on the lower shelf of the cart with the blood analog tank, leaving the artery model as the only component on the upper shelf of the cart.

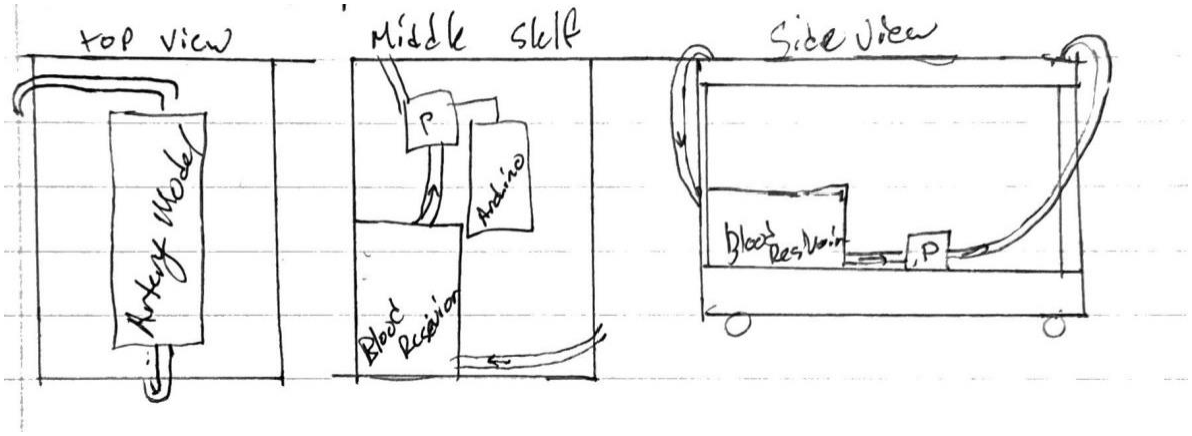


Figure 8 – Top-level design concept 2

This design has the advantage of featuring only the artery model on the top cart shelf, leading to a better user experience as defined in the customer need for ergonomics. However, there are several disadvantages to this design. The first of these disadvantages is the fact that the pump and electronics are in danger of fluid spillage, since they will be placed next to the blood analog reservoir. If any aspect of the tank were to fail, the electronics will be permanently broken. On top of this, the head for the pump to overcome is the greatest of the three concepts.

The final design concept for the top-level design is a mixture of the first two. This concept has the pump and electronics be undermounted on the top shelf of the cart. The artery model is placed by itself on the top of the cart, and the blood analog tank is placed on the bottom shelf, like the other two concepts.

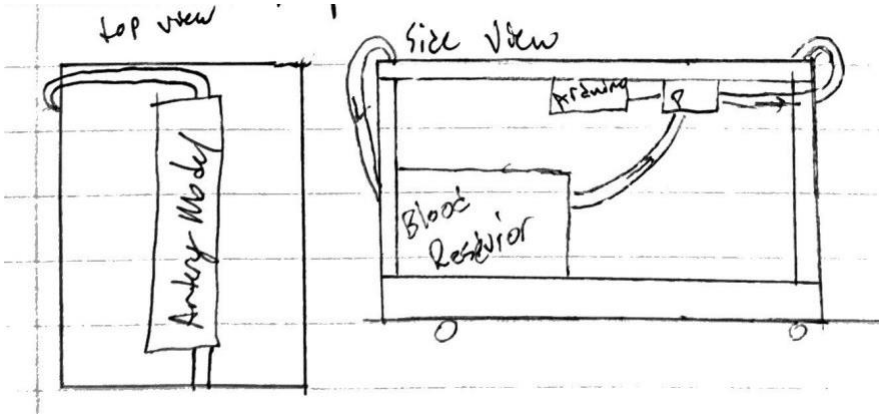


Figure 9 – Top-level design concept 3

With the position of the pump being undermounted on the top of the cart, this concept has the advantage of featuring only the artery model being atop the cart, while also minimizing the head for the pump to overcome. Additionally, the pump and electronics are in a position such that the risk of fluid spillages damaging them is minimized, since they are not resting on the same surface as any of the other components which circulate the blood analog.

4.2.2 Calcified Lesion Material

Three design concepts were generated for the subfunction regarding the material of the modeled calcified lesion. The lesion material is crucial to the success of the calcified vessel model because some material properties of the lesion were specified in the project outline and reflected in the customer requirements and engineering requirements.

The first concept is a high-hardness 3D printer filament, shown below, which would use additive manufacturing via a 3D printer to form it to the correct geometric specifications of a calcified lesion.

Figure 10 – High-hardness 3D printer filament

The 3D printer filament concept has the benefit of maintaining a consistent hardness across production runs, as its vendors guarantee consistency in the material properties of their products. Furthermore, the hardness of the filament can be accurately chosen due to the wide selection and precise hardness specifications of 3D printer filaments available on the market. The 3D printer filament concept also has the benefit of a high resolution, as 3D printers maintain sub-millimeter precision. It would also guarantee the capstone team complete control of their manufacturing process, resulting in faster lead times and the ability to make rapid design changes. However, the 3D printer filament concept was found to be relatively expensive compared to other design concepts within this subfunction [1].

The next concept is a fired ceramic, shown below, which would be modeled out of mid-high fire clay to the shape of a calcified lesion and fired in a kiln until the part is hard, dry, and nonporous.

Figure 11 – Fired ceramic

The fired ceramic concept is beneficial for its material properties similar to real calcified plaque (which is primarily made of ceramic materials) that go beyond the specific material properties requested by the client. The fired ceramic concept also benefits from a relatively easy manufacturing process, relying on ancient technology such as molds and kilns. Fired ceramic is also the least expensive of the design concepts within this subfunction. However, the fired ceramic concept lends itself to inconsistent hardnesses across production runs, as the heat and application of the kiln cannot be precisely controlled. In addition, this concept cannot offer high resolutions, as mid-high fire clay is a malleable material and is susceptible to warping during the firing process [2].

The final concept is a high-hardness steel, shown below, which would use subtractive manufacturing via a CNC machine to form it to the correct geometric specifications of a calcified lesion.

Figure 12 – High-hardness steel

The high-hardness steel concept has the benefit of consistent hardness across production runs, as the composition and manufacturing of steel is kept consistent by its producers, and its hardness remains the same after machining. The steel concept also benefits from a very high resolution, as CNC machining can achieve sub-millimeter precision. However, the steel concept suffers from a complex manufacturing process due to the nature of CNC machining. This may result in longer lead times and the inability to make rapid design changes. Furthermore, the hardness of steel is limited by the capabilities of CNC machines, so the desired hardness of a calcified lesion may only be offered by steels which are too hard for CNC machines to cut [3].

Product images were provided by www.amazon.com.

4.2.3 Calcified Lesion Adhesion Method

Three design concepts were generated for the subfunction regarding the adhesion method of the modeled calcified lesion to the modeled blood vessel. The adhesion method is crucial to the success of the calcified vessel model, as some adhesive properties of the lesion were specified in the project outline and reflected in the customer requirements and engineering requirements.

The first such concept is an adhesive paste or tape, shown below, which would be applied between the modeled lesion and vessel and allowed to set until its maximum adhesive strength is reached.

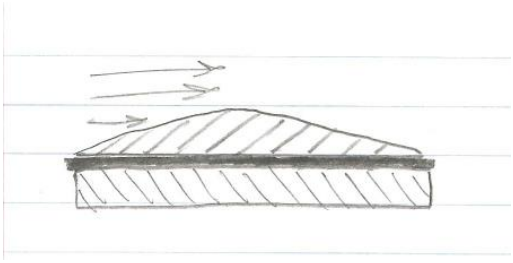


Figure 13 – Adhesive paste or tape

With the adhesive paste or tape concept, the adhesive strength can be accurately chosen due to the wide selection and precise adhesive strength ratings of adhesive pastes and tapes available on the market. The concept also has the benefit of requiring no additional manufacturing complexity. The paste or tape should be ready for application as purchased, and the lesion and vessel require no additional geometric features. However, the adhesive paste or tape concept suffers from requiring additional assembly complexity, as the process of applying the paste or tape to the vessel and lesion can be complicated and/or difficult. It may also require a substantial amount of time for the adhesive to set until its maximum adhesive strength is reached, resulting in delays before prototyping and testing.

The next concept is an interlocking mechanism between the calcified lesion and blood vessel, shown below, which would resist separation forces between the two parts and be comprised of a protruding feature on one part and an intruding feature on the other.

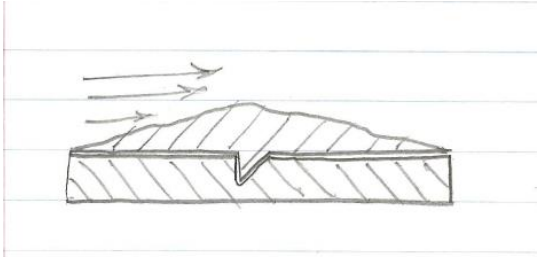


Figure 14 – Interlocking mechanism

With the interlocking mechanism concept, the adhesive strength can be accurately controlled through careful manipulation of the part geometries to generate the desired forces between them. The concept also has the benefit of requiring little additional assembly complexity. The two parts should be able to snap into place and hold themselves together once assembled. However, the interlocking mechanism concept suffers from requiring additional manufacturing complexity, as small protruding and intruding geometries on the two parts may be difficult for the chosen manufacturing method to generate. In addition, the adhesion strength which the concept can model is limited in application. An interlocking mechanism may only be able to model shear adhesion strength and not normal stress, and the model could not be rotated if it relies on gravity to model adhesion strength.

The final concept is an embedded calcified lesion within the wall of the blood vessel, shown below, which would model adhesion strength by being completely enclosed within the surrounding wall, as is found in certain disease states of PAD.

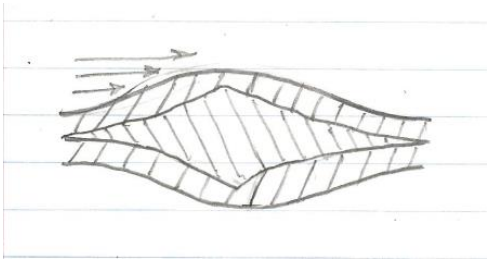


Figure 15 – Embedded lesion

The embedded lesion concept benefits from requiring little additional manufacturing complexity. There are no protruding or intruding geometries present on either part, so both can be manufactured according to their original specifications. In addition, the concept does not require the application of adhesives. However, the embedded lesion concept suffers from the inability to accurately control the adhesive strength of the lesion, as that is entirely determined by the yield strength of the modeled blood vessel wall enclosing it. Furthermore, the concept introduces additional assembly complexity because enclosing the lesion within the vessel wall may present a difficult engineering challenge. The concept is also inaccurate to the scope of the calcified vessel model, as embedded lesions are most common in lower-leg arteries, while the model will represent the femoral artery located in the upper-leg [13].

4.2.4 Blood Analog

In developing a calcified vessel model, selecting a suitable blood analog to accurately model human blood is critical to the overall success of the project. Various options for this sub-function were considered, with each offering distinct advantages and disadvantages, as well as the potential for visual documentation of each solution or mixture. These options are listed as follows.

Figure 16 - Glycerin

Glycerin stands out as a top option due to its high transparency and non-biological nature, allowing researchers to directly observe internal processes such as blood flow and interactions with

calcified lesions in real time. This feature is particularly beneficial for assessing the efficacy of vascular intervention devices, as it enables the visualization of flow patterns and potential areas of turbulence. However, its higher cost compared to other alternatives—often due to its purity and expensive manufacturing processes—can be a limiting factor for budget-conscious projects. Additionally, while glycerin is generally safe to use, it requires specific safety protocols during handling, such as the use of personal protective equipment (PPE) to mitigate risks of skin and eye irritation.

Figure 17 - Simulated blood

Simulated blood closely mimics the viscosity and flow characteristics of real blood, making it suitable for various experimental conditions where fluid dynamics are crucial. Its formulation incorporates components that replicate the cellular makeup of blood, enhancing its realism in flow studies. However, its opaqueness restricts visibility, complicating direct observation and making it difficult to visualize interactions of vascular devices with the model. Furthermore, the absence of standardized safety guidelines for simulated blood further complicates its use, as researchers must conduct their own risk assessments, which may introduce variability into experimental setups.

Figure 18 - Corn syrup, water, and flour mixture

A mixture of corn syrup, water, and flour presents a highly customizable and cost-effective solution, allowing researchers to adjust the proportions of components to create tailored viscosity and flow properties that can simulate different physiological conditions. This adaptability can be particularly useful in mimicking pathological states, such as for an increased blood viscosity associated with certain diseases. However, this method requires significant preparation and mixing time, which can add logistical challenges and delay experiments. Additionally, the mixture may harden over time, leading to potential inconsistencies in viscosity and flow characteristics that could compromise the reliability of test results.

Figure 19 - Doppler ultrasound gel

Doppler ultrasound gel is easily accessible and relatively inexpensive, which is generally advantageous for initial testing or for budget-restrictive projects. Its formulation provides a smooth texture that can reduce friction in flow models, which is beneficial for certain applications. However, its higher viscosity compared to blood can impede fluid movement and limit its effectiveness in accurately replicating blood flow dynamics within the model. Furthermore, the gel's opaqueness hinders internal observations, which is essential for understanding flow patterns and device interactions with the model.

Figure 20 - Red blood cell surrogate

Red blood cell surrogates provide a highly realistic representation of blood's rheological properties, closely mimicking the behavior of real red blood cells in a flow environment. This realism can significantly enhance the predictive accuracy of the model regarding how vascular devices interact with human blood. However, these surrogates may not accurately reflect the properties of blood in individuals with specific health conditions, such as anemia or sickle cell disease, limiting their applicability across a wide range of scenarios. Furthermore, ethical considerations surrounding the use of biological materials can complicate sourcing and increase the number of regulatory hurdles.

Figure 21 - PEG 200 polyethylene

Lastly, the PEG 200 polyethylene mixture closely resembles blood properties, offering the potential for excellent simulation of blood behavior, particularly in terms of shear-thinning properties and viscosity. However, it tends to be more expensive than other alternatives, which may pose budgetary constraints, especially in larger-scale studies. Its limited availability can also be a challenge, as not all laboratories have ready access to this material. Additionally, the use of PEG requires adherence to complex safety protocols, including potential toxicity evaluations, which can introduce further logistical challenges for researchers.

Ultimately, the optimal blood solution will depend on carefully weighing these factors—desired realism, cost, availability, and ethical considerations—necessitating further research and experimentation to determine the most suitable option for the model. This comprehensive analysis underscores the importance of aligning the choice of blood solution with the specific goals and requirements of the calcified vessel model project.

4.2.5 Blood Vessel Design

Several design concepts were generated for the overall design of the blood vessel used in the calcified vessel model. The chosen design of the blood vessel is crucial to satisfying the client's needs for this project. There were three leading concepts that adhered the best to the relevant customer needs and engineering requirements. With these diverse concept generations, the team can better understand which designs meet their goals and filter out designs that don't meet the customer requirements and engineering requirements. The following will review each concept generation and evaluate how each one may or may not address the key goals of the calcified vessel model.

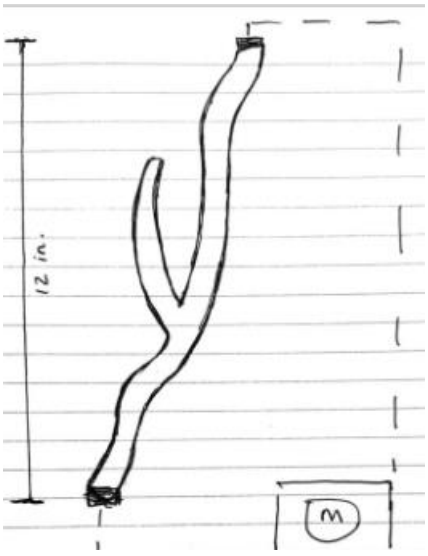


Figure 22 - Femoral artery (R)

The first generated design concept for the blood vessel design is the right side of the femoral artery. This design only features the femoral artery on the right side of the human body. The femoral artery is a common vessel site for calcifications in the peripheral arterial system. With this design, there will be less fluid volume to manage, and thus less power requirement to move the fluid through the system, compared to other concepts. The dimensions for the femoral artery will be more manageable as well. Furthermore, the cost to manufacture twelve units of this design is expected to fall within the allocated project budget. It will relatively be 12 to 18 inches in length, and less than 0.4 inches in vessel diameter. It will have two or three vessel branches off the main vessel to match the real femoral artery. The relatively small size of this vessel design concept will aid in the pump system, as the relative lack of complex geometry in the vessel design boosts the efficiency of the process flow.

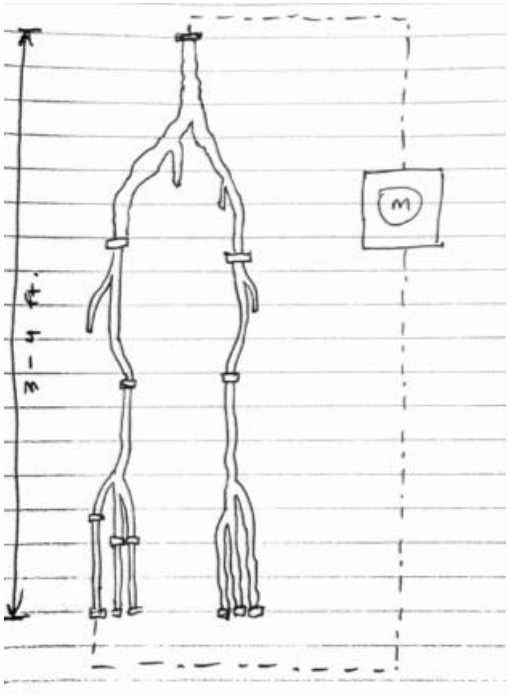


Figure 23 - Lower extremities

The second generated design concept for the blood vessel design is the lower extremities design. This design features the main arterial system of the lower extremities. The system spans from the hips to the feet. The lower extremities of the peripheral arterial system are common vessel ranges for calcifications. Unfortunately, the cost to manufacture twelve units of this design is expected to fall outside the allocated project budget. This design will require a greater fluid volume to manage, which could lead to complications in the process flow. More fluid volume requires more power to move the fluid through the system. This design is relatively large with a length of 3 feet, and complex with various vessel diameters throughout the model. The model will be broken up into sections of vessels with fittings and connectors used to assemble the model; the model will not be manufactured as one part. The large size of this model requires more power from the pump system. The complex geometry of the vessel design could also create issues within the pump flow.

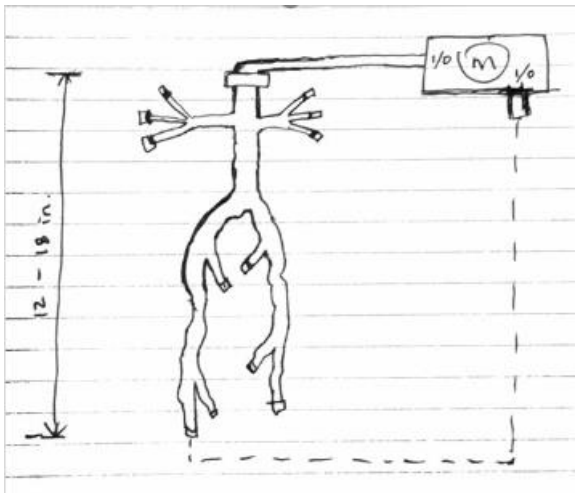


Figure 24 - Femoral artery (R & L)

The third generated design concept for the blood vessel design is the right and left sides of the femoral artery. This design features both the femoral arteries on the right and left sides of the human body. As mentioned before, the femoral artery is a common vessel site for calcifications in the peripheral arterial system. The fluid volume for this design would fall in the middle of the two previous concepts but would still be considered manageable in terms of the required power to move the fluid through the system. The cost to manufacture twelve units of this design is expected to fall within the allocated project budget. The size of the model will be 12 to 18 inches in length and less than 0.4 inches in vessel diameter. The design will match the real femoral arteries. The relatively small size of this vessel design concept will aid in the pump system, as it does not require a large fluid volume and the geometry of the vessel design is not complex compared to other concepts.

4.3 Selection Criteria

4.3.1 James Anteau

The selection criteria for the top-level design includes the customer requirement of ergonomic for intended use, as well as the engineering requirement of power required for the pump to overcome the head of the system, from the project QFD. From the calculations in Section 3.3.1 of this report, it is known that the closer in elevation the pump is to the artery model within the design, the lower the head of the system will be. Additionally, to achieve the ergonomics the client wishes for, only the artery model should sit on the upper shelf of the medical cart. The final design will likely be different from the one chosen for prototyping, because testing the project subsystems will lead to further development of an optimized design. The difference in cost for the three concepts in this section will be negligible since the components are the same, with only their layout differing.

4.3.2 Calcified Lesion Material

The selection criteria used for concept selection of calcified lesion materials include three engineering requirements from the QFD: lesion properties, lesion dimensions, and cost. Within lesion properties, a material hardness of Shore 39D is desired to accurately model the hardness of calcified lesions. Within lesion dimensions, a resolution of as small as possible is desired to accurately manufacture the subtle geometric features of calcified lesions. And for cost, a purchasing and manufacturing cost as close to $0 as possible is desired to keep the project under its allotted budget.

To calculate the hardness of the calcified lesion and compare it to those of the design concepts, their material hardnesses need to be identified and converted to a common unit of measurement. The project outline requested that calcified lesion hardness be expressed in durometer, which follows the Shore D scale, so all hardness values identified would be converted to their Shore D equivalent. Calcified lesion hardness was identified to be ~274 on the Vickers hardness scale, based on experimental testing of similar hydroxyapatite/calcium phosphate deposits within the human body [9]. The hardness of the 3D printer filament, the fired ceramic, and the 304 steel were identified to be 90 on the Shore A scale, 4 on the Mohs hardness scale, and 215 on the Brinell hardness scale, respectively, based on available specification sheets for each material [1][2][3].

Using hardness conversion tables and calculators provided by www.plantech.com, www.efunda.com, and www.carbidedepot.com, the identified hardness values of the three materials were converted to their Shore D equivalents. The target hardness of the calcified lesion was calculated as Shore 39D, while the hardnesses of the 3D printer filament, fired ceramic, and 304 steel were calculated as Shore 39D, Shore 44D, and Shore 33D, respectively. These conversions allow for direct comparison of hardnesses between the target value and the design concepts, and design concepts will be evaluated on the proximity of their hardness value to that of the target hardness value.

4.3.3 Calcified Lesion Adhesion Method

The selection criteria used for concept selection of calcified lesion adhesion method include three engineering requirements from the QFD: lesion properties, lesion dimensions, and cost. Within lesion properties, an adhesive strength of at least 3 pascals is desired to accurately model the minimum adhesive strength of calcified lesions. Within lesion dimensions, dimensions of protruding or intruding geometries as close to zero as possible are desired to most accurately model real-world calcified lesions. And for cost, a purchasing and manufacturing cost as close to $0 as possible is desired to keep the project under its allotted budget.

To calculate the minimum adhesive strength of calcified lesions, a fluid mechanics force analysis was performed on the system including the blood vessel, blood flowing through the vessel, and calcified lesion inside the vessel. The minimum shear adhesive strength required due to blood flow, P_{min}, is equal to the force of the blood flow on the cross-sectional area of the lesion, F, divided by the contact area between the lesion and vessel, A. This is represented by equation (3).

$$P_{min} = F/A \tag{9}$$

The force of the blood flow on the cross-sectional area of the lesion, F, is the product of the lesion's degree of vessel occlusion, the blood volumetric flow rate (Q), the blood density (ρ), and the blood velocity (v), represented by equation (10) [4]. The blood volumetric flow rate was assumed to be its maximum recorded value within the femoral artery. The contact area between the lesion and vessel is the product of the lesion's degree of vessel occlusion, pi, the artery's inner diameter (d), and the lesion length (L), represented by equation (11). The lesion was assumed to be a perfect half-cylinder with a diameter equal to that of the femoral artery inner diameter. These are represented by the equations (4) and (5), respectively. The degree of vessel occlusion variable cancels out in equation (9), so it is omitted from equations (10) and (11).

$$F = Q\rho v \tag{10}$$

$$A = \pi dL \tag{11}$$

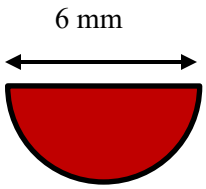


Figure 25 – Calcified plaque in femoral artery cross-section

Through the results of medical experimental studies, the maximum volumetric flow rate of blood in the femoral artery was determined to be 8.183×10^{-6} m^3/s [5], and the inner diameter of the femoral artery was determined to be 6 mm [7]. With these values, the velocity of blood in the femoral artery can be derived as 0.2894 m/s. The lesion length was taken to be 5 mm, which was established as the baseline length of calcified plaque for PAD in Section 3.3.2. The average density of human blood was taken to be 1060 kg/m^3 [6].

When these values are inputted into the above equations, the minimum shear adhesive strength required due to blood flow is found to be 26.63 pascals, which is rounded up to 27 pascals. Based on this result, all calcified lesion adhesion method design concepts will be evaluated on their ability to meet and exceed this value for minimum shear adhesive strength between the modeled blood vessel and calcified plaque under simulated use conditions.

4.3.4 Blood Analog

When selecting a proper blood analog for calcified vessel modeling, several critical selection criteria must be considered to optimize model performance. The foremost criterion is density, as it is the primary factor that influences fluid dynamics within the model. The density selection must be in line with physiological conditions so that fluid in the model behaves more or less like blood. This would be beneficial in the assessment of device performance in vivo; for accurate results, the model must obtain the exact density which significantly relates to device efficacy.

Cost is another vital consideration, especially for research projects with scant provisions in terms of funding. The appropriate concept shall allow performance and cheapness to go hand in hand, thereby enabling the extensive testing and experimentation that the project normally requires without the detrimental concern of achieving high costs. This is crucial information in ensuring that different choices remain in line with resource allocation.

Viscosity is critical for the correct simulation of blood flow behavior. Viscosity is the one test where a chosen model should be modeled to closely and accurately represent blood in terms of various shear and pseudo shear rates. This is necessary, especially in assessing the interaction of intervention devices with the fluid, as the flow patterns and, in turn, the device performance may vary significantly with the change in viscosity. The final target viscosity stands at around 10 cp. Solubility plays a significant role in the compatibility of the blood solution with other materials used in the model. A solution with appropriate solubility characteristics can facilitate interactions between different components, enhancing the model's fidelity. This compatibility is crucial for accurately representing biological conditions and ensuring that the model behaves as expected.

Manufacturing considerations also come into play in blood solution selection. How easy it is to manufacture, and the availability of the chosen solution could tremendously impact the modeling process. Solutions such as these that insert little to no sacrifice regarding the setup time and effort will allow researchers to spend more of their energy on experimentation and analysis, thus streamlining the entire operation.

Being transparent is an important parameter for observation and analysis since one could easily observe flow dynamics and interaction in the model. Only if the fluid is transparent can one visualize the mode of flow in the channel and assess the behavior of the vascular devices. It is also helpful for troubleshooting and various subsequent model iterations to gain additional understanding of the model.

In conclusion, density, cost, viscosity, solubility, ease of manufacturing, and transparency are all very significant criteria in choosing the most appropriate blood solution for the calcified vessel model. With these takings into account, much care will ensure that the solution chosen will replicate blood flow adequately, allowing for more reliable data and insight into the practice of vascular interventions.

4.3.5 Blood Vessel Design

The outlined criteria for concept selection of the vessel design considers the QFD requirements of replicability, vessel properties, modeling of simulated use conditions, and cost. First, the design must be replicable. This includes providing a technical data package which includes the CAD model and CAD drawing (dwg) of the design to the client for their effective replication of the design. The design must be simple to manufacture and assemble, while also matching human vessel dimensions and simulating human vessel functions.

The vessel properties of the design are constructed and designed to the customer needs. The opacity property of the vessel design must be close to a value of zero. A value of zero opacity results in complete visual transparency. The vessel design is required to be see-through because the customer must be able to visualize the deployment of their intervention devices within the vessel model.

The vessel model will be required to hold a fluid pressure, as the model is a closed-loop system. A pulsatile pump will provide the system with a constant pulsatile pressure that the vessel will need to be able to withstand. The blood analog pressure will simulate that of the arteries within an individual who has peripheral artery disease. The blood analog pressure the team aims to design for is 200 mmHg systolic pressure, which is converted to Pascals by multiplying the mmHg value by 133.3, resulting in approximately 26.7 kPa. An analysis of the blood substitute pressure and yield strength of the vessel model was done to ensure there would be no potential plastic deformation of the vessel model.

The design of the calcified vessel model must model simulated use conditions. This is in context to real blood vessels with PAD, and the actual flow rates, pressures, and shear stresses found within them. The pump system that the team is implementing will replicate the actual heart with a pulsatile pump. This pump will operate on a cadence close to the pumping of an actual heart. This is a customer need, because the vessel model will be used for testing deployment of arterial intervention devices in real patients. Thus, the calcified vessel model will need to simulate the pump mechanisms found in arteries with PAD.

The cost of manufacturing the vessel model will be important to the overall success of the project. The project has an allocated budget of $3000, and with that, the team must consider the most cost-effective solutions to the customer and engineering requirements. A balance of quality, functionality and cost reduction throughout the project will be needed to achieve this objective. The scope of the project is to manufacture twelve of these units, so the team will consider vessel design concepts which offer cost reductions in services, required tools, and materials needed for prototyping and production.

4.4 Concept Selection

4.4.1 Top-level design

To select the concept of top-level design a simple, weighing of the advantages and disadvantages for each design is considered. This selection is subject to change as the project progresses, since testing will lead to further development of the design. The first concept leads to the lowest head in the system out

of the three concepts because the pump is on plane with the artery model. Although it has the least head, this concept does not lead to the best ergonomics since the top of the model will have more components than necessary. Additionally, the electronics are in a location where there is a risk of fluid ruining them. The second concept fixes the ergonomics issue; however, it has the greatest head out of the three designs. This design also puts the electronics in harm's way since they are next to the blood analog tank. The third concept combines the best aspect of both previous, as well as keeping the pump out of the way of potential fluid from failure. This design leaves only the artery model atop the cart and has minimal head since the pump is near the same level as the artery model. With the advantages and disadvantages listed above, the top-level design concept that best fits the deliverables of the project is the third concept shown in Figure 9 in Section 4.2.1 of this report.

4.4.2 Calcified Lesion Material

The design concepts for calcified lesion materials were selected based on evaluation by a specification table. This specification table is shown below in Table 1. It compares each design concept across the project's engineering requirements of lesion hardness, resolution, and cost. Designs were judged on the proximity of their values within these three criteria to their corresponding target values. Criteria considered more important to the overall success of the project were weighted more heavily in the selection process, as shown on the project QFD.

Table 5 – Calcified lesion material specification table

Material -	**3D Printer Filament**	**Fired Ceramic**	**Steel**
Target			
Hardness: Shore 39D	Shore 39D	Shore 44D	Shore 33D
Resolution: ~0.01 mm	0.1 mm [10]	~1 mm	0.01 mm [11]
Cost: $0	$40/kg + manufacturing	$7/kg + manufacturing	$14/kg + manufacturing

Design concepts could not be compared to benchmarked designs because none feature modeled calcified lesions. Modeling arterial calcified lesions is a novel feature within nonbiological blood vessel models, and so the generated design concepts could only be compared to each other.

According to the project's customer requirements, 3D printer filament and fired ceramic best model simulated use conditions, 3D printer filament and steel are the most replicable, and steel is the most durable. According to engineering requirements, 3D printer filament most accurately and consistently models lesion hardness, 3D printer filament and steel offer the highest resolution, and fired ceramic is best in terms of lowest material costs.

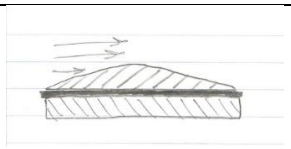
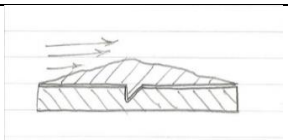
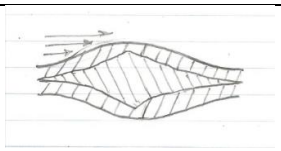
Ultimately, the 3D printer filament design concept was chosen as the calcified lesion material due to its high scores in the criteria of replicability, accurate modeling of simulated use conditions, high resolution, and desired lesion hardness. The material cost of filament was the highest of all design concepts, but the manufacturing costs of the other design concepts were estimated to be even greater. Overall, the 3D printer filament design concept scored highest within the highest-weighted relevant customer and engineering requirements, and thus is considered the best calcified lesion material concept for contributing to the success of the calcified vessel model.

Product images cost estimates were provided by www.amazon.com.

4.4.3 Calcified Lesion Adhesion Method

The design concepts for calcified lesion adhesion method were selected based on evaluation by a specification table. This specification table is shown below in Table 2. It compares each design concept across the project's engineering requirements of lesion adhesive strength, dimensions, and cost. Designs were judged on the proximity of their values within these three criteria to their corresponding target values. Criteria considered more important to the overall success of the project were weighted more heavily in the selection process, as shown on the QFD.

Table 6 – Calcified lesion adhesion method specification table

Adhesion Method -	**Adhesive Paste/Tape**	**Interlocking Mechanism**	**Embedded Lesion**
Target			
Adhesive Strength: >3 Pa	>27 Pa	>27 Pa	(Yield strength of vessel wall)
Dimensions: ~0 mm	0 mm	~1 mm [19]	~0 mm
Cost: $0	$0.72/mL of paste or $1.90/m of tape	Negligible	Negligible

Design concepts could not be compared to benchmarked designs because none feature modeled calcified lesions. Modeling arterial calcified lesions is a novel feature within nonbiological blood vessel models, and so the generated design concepts could only be compared to each other.

According to customer requirements, the adhesive paste/tape best models simulated use conditions, the interlocking mechanism is the most replicable, and the embedded lesion is the most durable. According to engineering requirements, the adhesive paste/tape and the interlocking mechanism most accurately and consistently model lesion adhesive strength (embedded lesion adhesive strength cannot be controlled), the adhesive paste/tape and embedded lesion have no protruding/intruding dimensions, and the interlocking mechanism and the embedded lesion are best in terms of lowest additional material costs.

Ultimately, the adhesive paste/tape was chosen as the calcified lesion adhesion method due to its high scores in the criteria of accurate modeling of simulated use conditions, lack of protruding/intruding dimensions, and desirable adhesive strength. The material cost of adhesive paste/tape was the highest of all design concepts, but its total cost was considered relatively small compared to the total budget. Overall, the adhesive paste/tape design concept scored highest within the highest-weighted relevant customer and engineering requirements, and thus is considered the best calcified lesion adhesion method concept for contributing to the success of the calcified vessel model.

Product cost estimates were provided by www.amazon.com.

4.4.4 Blood Analog

Material:	Glycerin	Simulated Blood	Corn Syrup, Water, Flour Mix
			
Specification Requirements:			
Density	1.26 g/mL	1.043-1.060 g/mL	Corn syrup- 1.37 g/mL (adjusted with water)
Cost	$60	$33	$10
Viscosity	934 cP	N/A but states similar	Made to ideal
Solubility	High	Soluable	Good
Transparency	Yes	No	Yes mostly
Manufacturing	Pre-made	Pre-made	Mix ourselves

Figure 26 - Concept Selection Criteria

In the quest for an optimal blood analog for the calcified vessel model, three leading candidates were thoroughly evaluated based on established criteria: glycerin, corn syrup-water-flour mixture, and simulated blood. Each option was scrutinized for its strengths and weaknesses concerning their density, cost, viscosity, solubility, ease of manufacturing, and transparency.

Glycerin is a transparent, non-biological substance known for its low toxicity and wide availability. One of its most significant advantages is its density, which is relatively close to that of human blood, allowing for an accurate simulation of physiological conditions within the model. This similarity is crucial when assessing the performance of vascular devices, as any discrepancies in density could lead to inaccurate conclusions about device effectiveness. Glycerin's transparency also facilitates direct observation of fluid dynamics within the model, enabling researchers to visualize interactions between the blood analog and the vascular devices in real time. This visibility is invaluable for troubleshooting and refining experimental setups, as it allows for immediate identification of anomalies in fluid behavior. However, glycerin does have a higher price compared to other options, which could strain the project budget. Additionally, while Glycerin is relatively safe to handle, it does necessitate adherence to established safety protocols, which, while manageable, add a layer of complexity to its use.

The corn syrup-water-flour mixture represents a more cost-effective and customizable alternative. The team can easily modify the proportions of these ingredients to adjust the viscosity and flow characteristics of the solution, tailoring it to meet specific experimental needs. This adaptability is particularly advantageous for experiments that require precise control over fluid properties. However, the preparation of this mixture can be time-consuming, as it involves careful mixing and ensuring the right consistency. Additionally, the mixture's stability poses concerns; it may harden over time, which could compromise its accuracy and consistency in simulating blood flow. This variability could lead to challenges during experimentation, requiring researchers to constantly monitor and adjust the solution.

Simulated blood is engineered to closely mimic the viscosity and flow properties of real blood, making it an attractive option for accurately representing biological conditions. This close resemblance helps in providing reliable data when evaluating the performance of vascular devices. However, a significant drawback of simulated blood is its opacity, which hinders visibility during experiments and complicates the observation of internal processes. This limitation could restrict the ability to analyze interactions effectively, making it difficult to troubleshoot issues or validate findings. Furthermore, the absence of standardized safety guidelines for handling simulated blood means that researchers must undertake their own safety assessments, introducing an element of uncertainty and potential risk.

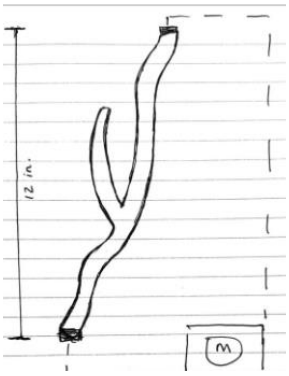
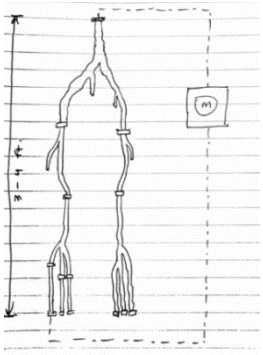
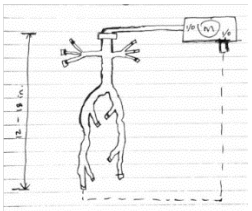
After careful consideration of the three options, glycerin emerged as the most suitable blood

solution for the calcified vessel model. Its transparency and density closely match those of blood, providing a robust platform for accurately simulating blood flow and facilitating direct visualization of vascular device interactions. Despite its higher cost and the need for safety precautions, glycerin's benefits significantly outweigh its drawbacks. The ability to observe fluid dynamics in real time enhances the understanding of how devices function within the vascular system, contributing to the project's objective of optimizing vascular interventions and improving patient outcomes. Glycerin's non-biological nature also reduces contamination risk and ethical concerns, making it a practical choice. While other options such as simulated blood and corn syrup mixtures have merits like lower cost and customizable properties, their lack of transparency and consistency renders them less effective for direct observation and analysis. Glycerin strikes a balance between transparency, ease of use, and safety, ensuring the collection of reliable, reproducible data essential for advancing research and development in the field of vascular care.

4.4.5 Blood Vessel Design

The blood vessel design concepts were selected based on evaluation of the QFD and applying its customer needs and engineering requirements to each design concept. To help in the evaluation process, a table is used to visualize the best design based on qualitative comparisons to selection criteria. The criteria used in the table are related to the QFD, either engineering requirements or customer requirements. Yes and/or no answers of whether each concept effectively meets a certain criterion are used in the table to provide direction to the best concept. The best concept will be cost-effective, simple to manufacture for cost purposes and model simulated use-conditions.

Table 7 – Blood vessel design concept evaluation

Vessel Design Structure	**Femoral Artery (R)**	**Lower Extremity**	**Femoral Artery**
			
Customer Needs	Yes	No	Yes & No
Time Constraint	No	Yes	Yes & No
Material Constraint	No	Yes	No
Budget Constraint	No	Yes	No
Achievable	Yes	No	Yes & No

The results presented in this table assisted the team in the selection process, ultimately directing the project towards the right-side (only) femoral artery design. This design meets key criteria, including cost effectiveness, replicability, and realistic simulation used conditions. Additionally, it presents no significant constraints in terms of design or manufacturability. These results suggest minimal production challenges in the future. With consistent progress and active team engagement, there is great opportunity to successfully produce this model, and the project's subsystem lead times can be worked in parallel to one another. Given the project's seven-month life cycle, it is important the team select a design that is feasible to produce and aligns with the client's requirements.

4.4.6 Final Design CAD and Flow Diagram

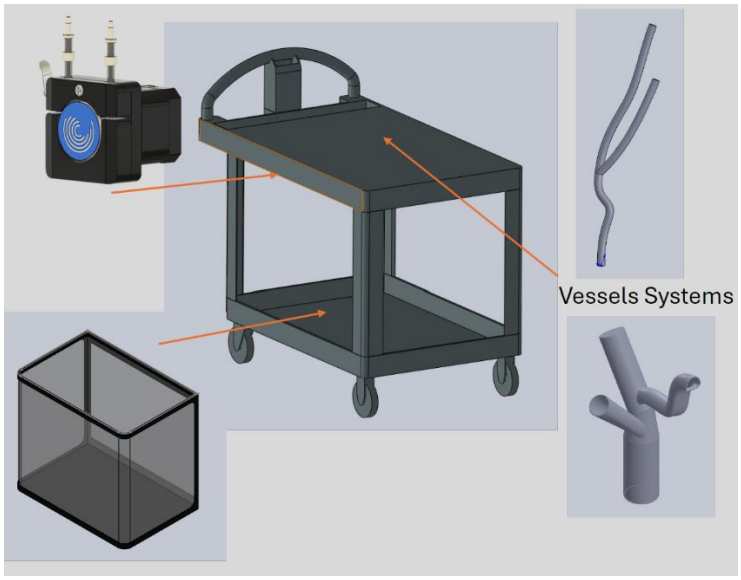


Figure 27 – Current state of design

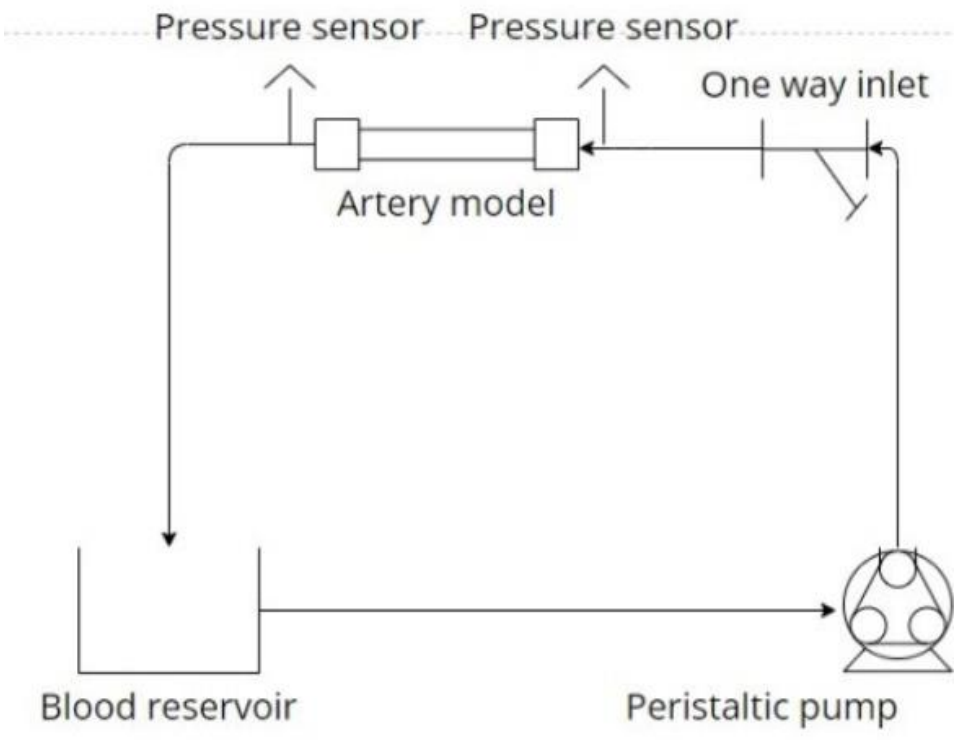


Figure 28 – Pipe flow diagram

5 CONCLUSIONS

The W.L. Gore & Associates Calcified Vessel Model capstone project aims to develop a realistic simulation of a calcified vessel experiencing peripheral arterial disease (PAD) for the purpose of medical device testing and research. The primary project goal is to replicate the properties of a human femoral artery with varying levels of calcified lesion buildup, as these are the simulated use conditions for which the client desires to test and evaluate their medical devices. The team's client, W. L. Gore & Associates – Medical, will be evaluating their peripheral vascular interventional device, the Viabahn endoprosthesis, with the team's vessel model. Critical requirements for the successful completion of this project include accurately simulating vessel dimensions and anatomy of the right femoral artery, replicating the compliance of vessel walls, mimicking the hardness and adhesion of calcifications to vessel walls, and producing realistic blood flow dynamics. The calcified vessel model will also need to accommodate pressure and/or flow rate sensor integration for precise measurements of model behavior and relevant data collection. The model should also be compatible with other common medical devices intended to treat PAD.

Throughout this half of the semester, the team took a fundamental approach to the concept generation, concept evaluation, and development of the calcified vessel model. Essential engineering requirements were converted into measurable selection criteria, including the following: vessel dimensions, material properties, flow characteristics, and metrology capabilities. Mathematical models were conducted to ensure that the final design meets physiological conditions for vessel compliance, blood analog flow rates, lesion adhesion, lesion material, vessel material, vessel pressure, and vessel stress forces. Material selection for model components was based on accurately replicating the physiological behaviors of human vessel properties, such as elasticity of the vessel walls and hardness of the calcified lesion.

The final design concept selected consists of a right-side femoral artery model structure with branching vessels that end in short lengths, with a calcification site of varying hardness distributed along the main artery. The model will be equipped with a blood analog fluid system capable of steady flow and pulsatile flow. This system ensures realistic circulation simulation of the vessel model, and circulation through the calcified lesion area. Material selections for the vessel and calcification are within an allowable range of human blood vessel properties. The team aims to produce varying types of calcification lesion models to cover a range of diseased states. These varying levels of calcification will enhance the model and provide a greater range span for medical research on these medical devices. The metrology integration utilizes sensors and flow meters for collecting and displaying relevant data of the system, providing useful information for the operator(s) of the model.

The final selected design concept tentatively meets all project customer and engineering requirements at this stage of the design process. If this design concept for a calcified vessel model is successful, it will serve as a platform for testing and evaluating the performance and deployment of peripheral arterial interventional devices, contributing to their continued development and efficacy in real surgical procedures for the treatment of PAD. Moving forward in this project, the team will focus on refining the vessel and calcification models' anatomies, adding features within the metrology system to collect additional data, and enhancing simulation accuracy through prototype iterations and modifications.

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