Calcified Vessel Model Capstone Project

Engineering Calculations Summary

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Top Level Design Summary

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.

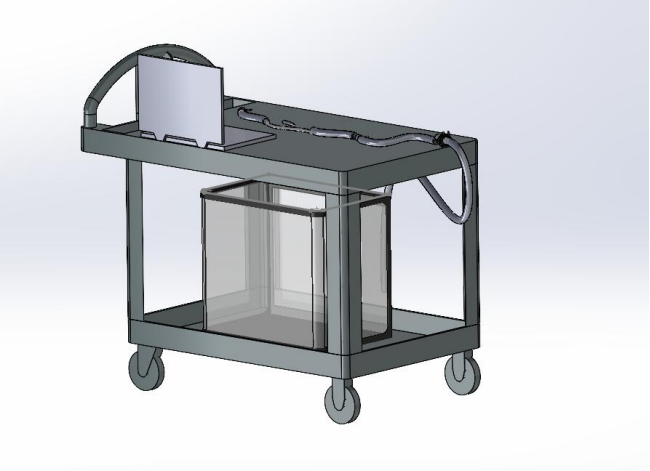
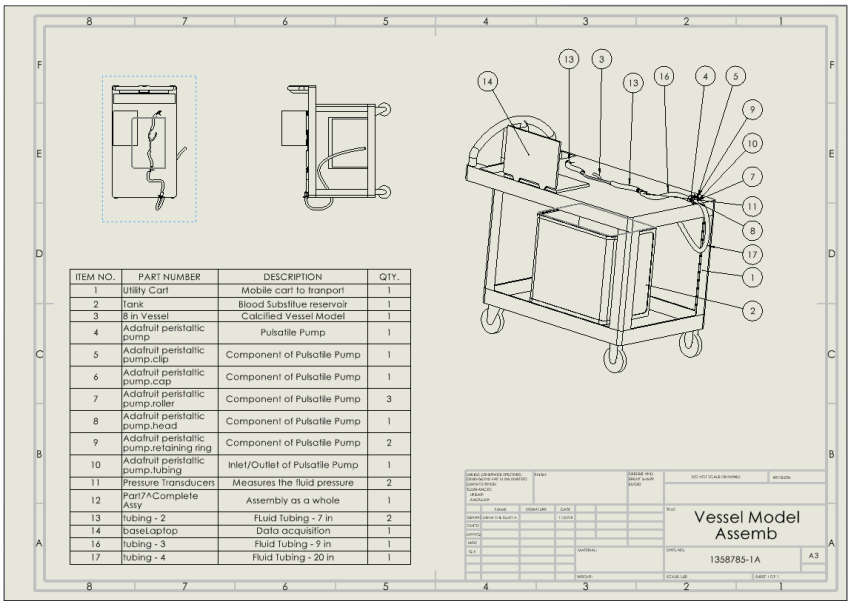


Figure 1 – Final CAD Design for Calcified Vessel Model Assembly

Figure 1 illustrates the team's final CAD design for the calcified vessel model assembly, created using SolidWorks CAD software. Each component and the full assembly were designed by the team, with the corresponding assembly drawing later in this section. The drawing includes balloon pointers to identify individual components. The CAD assembly consists of the calcified lesion model, vessel model, fluid tubing, pump,

pressure transducers, blood substitute reservoir, transportable cart, and data acquisition system. It is important to note that the blood substitute is not represented in the CAD design.



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Utility Cart	Mobile cart to tranport	1
2	Tank	Blood Substitue reservoir	1
3	8 in Vessel	Calcified Vessel Model	1
4	Adafruit peristaltic pump	Pulsatile Pump	1
5	Adafruit peristaltic pump.clip	Component of Pulsatile Pump	1
6	Adafruit peristaltic pump.cap	Component of Pulsatile Pump	1
7	Adafruit peristaltic pump.roller	Component of Pulsatile Pump	3
8	Adafruit peristaltic pump.head	Component of Pulsatile Pump	1
9	Adafruit peristaltic pump.retaining ring	Component of Pulsatile Pump	2
10	Adafruit peristaltic pump.tubing	Inlet/Outlet of Pulsatile Pump	1
11	Pressure Transducers	Measures the fluid pressure	2
12	Part7^Complete Assy	Assembly as a whole	1
13	tubing - 2	Fluid Tubing - 7 in	2
14	baseLaptop	Data acquisition	1
16	tubing - 3	Fluid Tubing - 9 in	1
17	tubing - 4	Fluid Tubing - 20 in	1

Figure 2 – Final CAD Drawing for Calcified Vessel Model Assembly

Figure 2 presents the team's final CAD drawing for the vessel model assembly, developed to seamlessly connect design intent with manufacturing execution. The drawing incorporates balloon indicators for clear component identification and adheres to the industry-standard ASME Y14.5, ensuring consistency and professionalism in documentation. The ballons in the drawing denote specific parts within the team's design. Groupings of these numbers comprise the designs subsystems. The first sub system is the pump. This sub system is comprised of parts 4-10 in figure 2. This sub system will provide accurately simulated blood flow through the model to ensure the simulated use conditions for the intravenous devices will be met. The next sub system is data acquisition which comprised of parts 14 and 11. The data acquisition serves the client by allowing them to monitor the pressure and flow rate of the system while operating the model. The team is striving to transition from the laptop to displaying the sensors data on a digital display on

the model to simplify the operation of the model. The next subsystem is the platform and containment used to hold all other subsystems. Numbers 1-3, 13, 16, 17 are the parts within this subsystem. The cart serves as the platform for all the other components to be mounted on, ensuring the clients will be able to use this model in many different settings, just needing to be plugged in wherever they intend to operate. The tank holds the blood analog, and the tubing guides the blood analog through the entire system. The final and most important subsystem is the vessel and lesion model. This subsystem is comprised of number 3 in figure 2. The vessel model is where the calcified lesion model will sit, and the bulk of the testing will take place at this point. Most of the deliverables given by the client will be met with this section. The vessel model will be 3-D printed from a soft resin that will simulate human artery properties. The lesion model will be 3-D printed from a hard TPU that will match the properties of the calcified lesions encountered within the peripheral artery system.

This section of the memo contains two 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 three subsections which list and define the requirements mentioned previously and display the completed HoQ of this project.

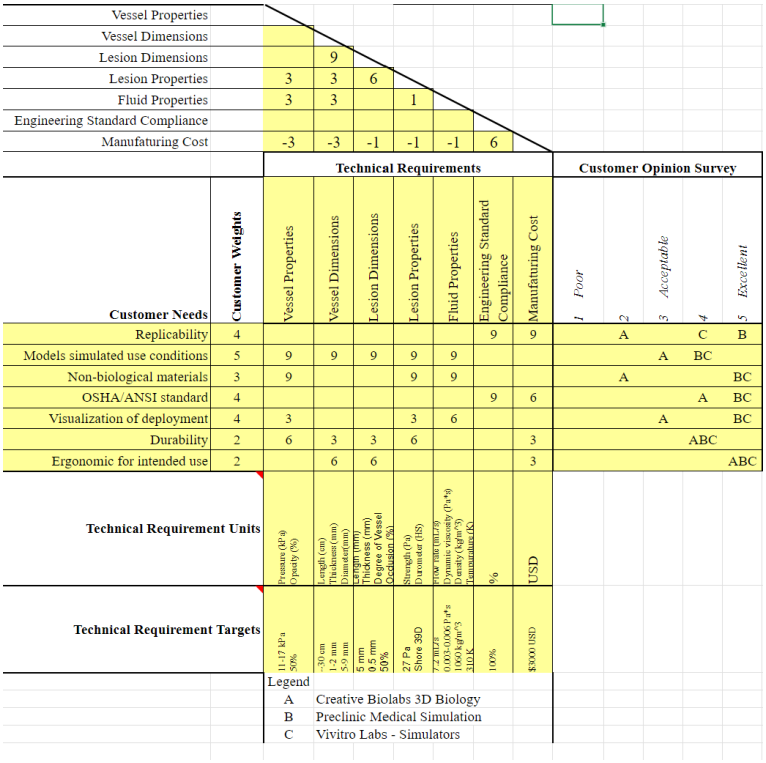


Figure 3 – HoQ deployed for QFD

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

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. 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. 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.

Summary of Standards, Codes, and Regulations

IPC J-STD-001 H Standard Soldering Requirements [1]

This article outlines industry standards for electronic soldering. The actual copy of this standard costs over 200 dollars which exceeds what the team is willing to use from the budget. This article does a great job of outlining the key points of the standard so that the team can ensure that the soldering used in the project will be up to industry standards.

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

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.

How to design for FFF 3D printing [3]

A standard written and published by the Dutch 3D printer manufacturing company Ultimaker regarding designing for additive manufacturing (DfAM) specific to fused filament fabrication (FFF) 3D printing. It covers the most important considerations when designing for an FFF 3D printer, including the performance of printed parts, print success rates, production costs (time and materials), and the speed and efficiency of product development cycles. With this, the team can understand the benefits and limitations of FFF 3D printing, compare build material properties and suggested ideal uses, achieve even finer print details through dual extrusion, and improve their workflow through design modularity. To meet their deadline and budget goals, the team will learn from this standard to maximize their 3D printing output and success.

Product Selection Guide [4]

A standard written and published by the multinational conglomerate company 3M – Industrial Adhesives and Tapes Division regarding product selection of 3M Scotch-Weld Structural Adhesives. It provides a 3-step guide on matching a structural adhesive to a customer's design, performance, and process requirements. With this, the team can select their most difficult-to-bond substrate, determine their key design attribute, and then select the most suitable product family of 3M structural adhesives for their application. This standard also provides a brief guide on generally recommended surface preparation steps for various substrates. With this, the team can ensure maximum adhesive strength and reliability of their adhesive bonds. To meet their deadline and budget goals, the team will learn from this standard to maximize their structural adhesive selection process and their adhesive bonding success.

Medical Device Software – Software Life Cycle Processes (ISO/IEC 62304) [5]

This international standard establishes a comprehensive framework for the development and maintenance of software used in medical devices, focusing on safety and regulatory compliance. It addresses the entire software life cycle, including risk management, design, implementation, verification, and maintenance. This is particularly relevant to this project if software components are integrated into the calcified lesion models for monitoring or control purposes. By following this standard, the team can ensure its models align with all relevant medical device industry requirements and maintain high safety and quality standards.

Standard Specification for Pressure Decay Leak Test Method (ASTM F2070-00(2017)) [6]

This specification defines the pressure decay leak test method for evaluating the integrity of components in medical and industrial applications. It provides detailed

procedures for testing airtightness and detecting potential failures in components. This is essential for this project as it ensures that parts like tubing and vessels used in the calcified lesion models are durable and reliable under simulated conditions. Applying this method will enhance the robustness of calcified vessel model designs and validate the integrity of model subsystems.

Water Meters for Cold Potable Water and Hot Water – Part 2: Test Methods (ISO 4064-2:2014) [7]

This standard outlines the methods for testing the performance of water meters, focusing on accuracy and durability under various conditions. Although designed for water metering, its principles are highly applicable to this project, particularly for fluid dynamics testing in the calcified lesion models. By referencing this standard, the team can ensure that its flow measurement systems meet established industry practices, thereby improving the accuracy and reliability of simulation data.

American Society of Mechanical Engineers' standard - Geometric Dimensioning and Tolerancing [8]

A manufacturing standard source from the American Society of Mechanical Engineers' standards. ASME Y14.5 - 2018 is the most recent version of the geometric dimensioning and tolerancing (GD&T). This standard provides the guidelines and specifications for defining the geometry and allowable variation of manufactured parts. Adhering to this manufacturing standard ensures the manufactured parts achieve proper fit, functionality and interchangeability. This standard will aid in the team's 3D CAD modeling standards. The team will also apply this standard to the CAD drawings for the final CAD design deliverables.

American Society of Mechanical Engineers' standard for Product Def. Additive Manufacturing [9]

A manufacturing standard from the American Society of Mechanical Engineers' that's focused on product definition for additive manufacturing. The standard is ASME Y14.46 - 2022. It provides guidelines and requirements for documenting and communicating the unique characteristics of additive manufacturing processes and products in engineering drawings and models. The team will use this as a standard in 3D printing to ensure reliability in the additive manufacturing process. The standard will also aid the team with ensuring clarity and consistency in the build orientation of the additive manufacturing process.

Summary of Equations and Solutions

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 [10]. 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. [11]

$$P_{pump}=Sg\cdot\gamma\cdot Q\cdot H\eta \quad Ppump=Sg\cdot\gamma\cdot Q\cdot H\eta \qquad (1)$$

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.

$Sg_{blood}=1.048-1.066 \quad Sgblood=1.048-1.066$

$\gamma_{water}=62.43\ lb/ft^3 \quad \gamma water=62.43\ lb/ft3$

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

$Q=300-400\ mL/min\rightarrow 0.00235\ ft^3/s \quad Q=300-400\ mL/min\rightarrow 0.00235\ ft3/s$

$\eta \approx 80\% \quad \eta \approx 80\%$

After plugging these values into 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.

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 [13].

$$z = \frac{\bar{x} - \mu}{\frac{\sigma}{\sqrt{n}}} \quad (2)$$

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

In formula (2), 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 (3), 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 [13]. 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 4.

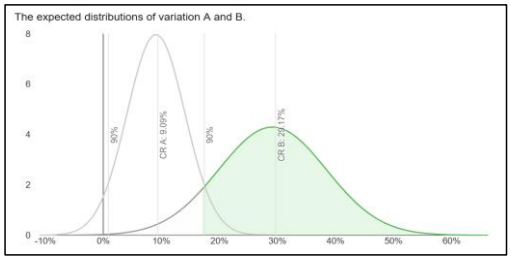


Figure 4 - Two-tailed A/B test for degree of vessel occlusion vs stent under expansion rate

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.

Calcified Lesion Material – Gavin Lazurek

The selection criteria used for concept selection of calcified lesion materials includes the engineering requirements from the QFD of lesion properties. Within this requirement, a material hardness of Shore 39D is desired to accurately model the hardness of calcified lesions.

To calculate the target hardness of a 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, or 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 hydroxyapatite/calcium phosphate deposits within the human body [14]. While reliable medical data on material hardness is unavailable for peripheral arterial calcified plaque, the calcium deposits researched in this medical study are compositionally similar. The hardness of the 3D printer filament, the fired ceramic, and the 304 steel design concepts 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 [15][16][17].

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.

Calcified Lesion Adhesion Method – Gavin Lazurek

The selection criteria used for concept selection of calcified lesion adhesion method include the engineering requirements from the QFD of lesion dimensions. Within lesion properties, an adhesive strength of at least 27 pascals is desired to accurately model the minimum adhesive strength of calcified lesions.

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 (4).

$$P_{min} = F/A \tag{4}$$

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 (5) [18]. 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 (6). The lesion was assumed to be a perfect half-cylinder with a diameter equal to that of the femoral artery inner diameter, as shown in Figure 5. The degree of vessel occlusion variable ultimately cancels out in equation (4), so it is omitted from both equations (5) and (6).

$$F = Q\rho v \quad (5)$$

$$A = \pi dL \quad (6)$$

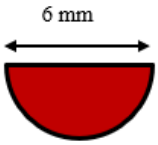


Figure 5 – Calcified plaque in femoral artery cross-section

Through the results of experimental medical studies, the maximum volumetric flow rate of blood in the femoral artery was determined to be 8.183×10^{-6} m^3/s [19], and the inner diameter of the femoral artery was determined to be 6 mm [20]. 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 [21].

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 rounds up to 27 pascals. According to this result, the selected 3M Scotch-Weld Plastic & Rubber Instant Adhesive PR1500, with an overlap shear strength of over 10 MPa [22], will exceed this value for minimum shear adhesive strength between the modeled blood vessel and calcified plaque under simulated use conditions, by a factor of 500,000. This value is in-line with medical research studies of the strength of adhesive bonds to calcium deposits in the human body [23]. Other factors such as substrate compatibility, water resistance, and surface roughness will be more important determiners of success for the adhesive bonds in this application.

SLA Resin Material Properties – Gavin Lazurek

The first section of this analysis determines the elastic modulus of each SLA resin option using information from their technical data sheets. Equation (7) is the simple formula for elastic modulus, *E*, expressed in the SI unit of pascals (Pa).

$$E = \frac{\sigma}{\varepsilon} \tag{7}$$

In this equation, σ represents engineering stress [Pa], and ε represents unitless engineering strain. In each technical data sheet of the SLA resin options, the engineering stress for 50% elongation is given, allowing the elastic modulus of the SLA resin to be derived. For this application, it is assumed that both SLA resin options exhibit elastic behavior at least up to 50% elongation. This is an acceptable assumption to make because both SLA resin options are elastomeric materials with high elongations and high energy returns [24, 25].

Figure 6 depicts a stress-strain curve of a typical artery, as well as the calculation of elastic modulus from the stress-strain curve. Researchers observed two different elastic moduli of typical arteries while in different strain regions, diverging at approximately 6% strain [26]. This analysis assumes that the blood vessel model experiences strain greater than ~6%, so it should replicate the elastic modulus of the high strain region.

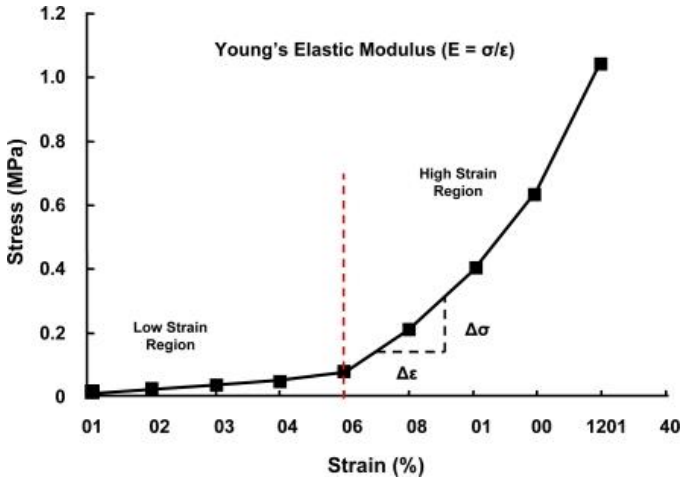


Figure 6 - Stress-Strain Curve of a Typical Artery [5]

The second section of this analysis determines the hoop stress of each SLA resin option as a function of pressure. The blood vessel model is assumed to be a thick-walled cylinder because its wall thickness is greater than one-tenth of its diameter. Equation (8) is the Lamé equation for hoop stress σ_h [Pa] of a thick-walled cylinder [27].

$$\sigma_h = \frac{p_i r_i^2 - p_o r_o^2}{r_o^2 - r_i^2} + \frac{(p_i - p_o) r_o^2 r_i^2}{(r_o^2 - r_i^2) r^2} \tag{8}$$

In this equation, p_i and p_o represent the pressures of the internal and external cylinder walls, respectively [Pa], r_i and r_o represent the radii of the internal and external cylinder walls, respectively, expressed in the SI unit of meters (m), and r represents the radius at the point of interest within the cylinder wall [m]. Assuming that the external pressure p_o is zero gauge, or atmospheric pressure, equation (8) simplifies to equation (9).

$$\sigma_h = \frac{p_i r_i^2}{r_o^2 - r_i^2} + \frac{p_i r_o^2 r_i^2}{(r_o^2 - r_i^2) r^2} \tag{9}$$

Furthermore, assigning the value of r to the radius of the internal wall r_i, which is the location of maximum hoop stress within an internally pressurized cylinder [27], equation (9) simplifies to equation (10).

$$\sigma_h = \frac{p_i (r_i^2 + r_o^2)}{r_o^2 - r_i^2} \tag{10}$$

This equation gives the maximum hoop stress experienced by the blood vessel model for a given pressure. The internal and external radii of the blood vessel model walls are specified by its geometry. Figure 7 shows a thick-walled cylinder experiencing hoop stress (σ_h) across a differential area on its external wall, as well as the locations of its internal and external wall radii and pressures.

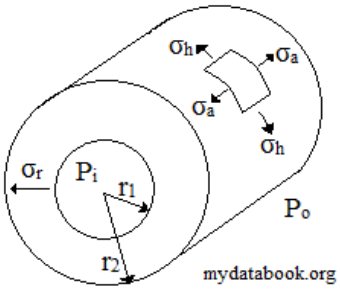


Figure 7 - Thick-Walled Cylinder Experiencing Hoop Stress [27]

The third section of this analysis determines the necessary pressure to increase the radius of the calcified blood vessel model to restore it to the cross-sectional area of an uncalcified blood vessel. Equation (11) is the cross-sectional area A_{vessel} [m^2] of an uncalcified blood vessel. Equation (12) is the cross-sectional area A'_{vessel} [m^2] of an uncalcified blood vessel with an increased radius.

$$A_{vessel} = \pi r_i^2 \tag{11}$$

$$A'_{vessel} = \pi (x r_i)^2 \tag{12}$$

In this equation, the unitless variable *x* represents the factor by which the internal wall radius of the blood vessel model increases.

In Report 1, the team establishes that the maximum degree of vessel occlusion that the calcified vessel model will replicate is 50%. The cross-sectional area of the lesion does not change significantly in response to pressure due to its high hardness. Equation (13) is the cross-sectional area A_{lesion} [m^2] of this corresponding calcified lesion.

$$A_{lesion} = \frac{1}{2} A_{vessel} = \frac{\pi}{2} r_i^2 \tag{13}$$

The increase in radius of the internal wall of the calcified vessel model necessary to restore its unobstructed cross-sectional area to that of an uncalcified blood vessel is found by relating the previous three values in equation (14).

$$A'_{vessel} - A_{lesion} = A_{vessel} \tag{13}$$

In this equation, the left-hand side represents the unobstructed cross-sectional area of a calcified blood vessel with an increased radius, and the right-hand side represents the cross-sectional area of an uncalcified blood vessel.

To calculate the required internal pressure for this application, the maximum hoop stress σ_h calculated in equation (10) is used as the value of engineering stress σ in equation (6). This is possible to do because SLA resins are assumed to have isotropic properties, such that all primary mechanical stresses experienced by the blood vessel model are equally valid for use in equation (7). Unlike fused deposition modeling (FDM) which prints parts with directional material properties, SLA prints parts with uniform material properties due to the nature of its resin curing process [28].

The value of engineering strain is taken to be the change in circumference of the blood vessel model, as hoop stress acts along the circumference of a pipe. Equation (15) is the circumference L [m] of the blood vessel model at the point of maximum hoop stress.

$$L = 2\pi r_i \tag{15}$$

Equation (16) is the change in circumference ΔL [m] of the blood vessel model at the point of maximum hoop stress.

$$\Delta L = 2\pi(xr_i) - 2\pi r_i = 2\pi r_i(x-1) \tag{16}$$

Equation (17) is the unitless engineering strain ε of the blood vessel model at the point of maximum hoop stress.

$$\varepsilon = \frac{\Delta L}{L} = \frac{2\pi r_i(x-1)}{2\pi r_i} = x - 1 \tag{17}$$

Finally, an equation for required internal pressure p_i [Pa] for this application can be derived from equations (7, 10, 17). This derivation is shown in equation (18).

$$E = \frac{\sigma}{\varepsilon} = \frac{\left(\frac{p_i(r_i^2 + r_o^2)}{r_o^2 - r_i^2}\right)}{x - 1} = \frac{p_i(r_i^2 + r_o^2)}{(x-1)(r_o^2 - r_i^2)} \rightarrow p_i = \frac{E(x-1)(r_o^2 - r_i^2)}{(r_i^2 + r_o^2)} \quad (18)$$

Analysis

This analysis begins by calculating the values of internal wall radius increase factor *x* from equation (14) and engineering strain ε from equation (17). This is because these values are only dependent on the geometry of the blood vessel model and do not change between different SLA resin options.

$$\pi(xr_i)^2 - \frac{1}{2}(\pi r_i^2) = \pi r_i^2 \rightarrow x = \sqrt{\frac{3}{2}}$$

$$\varepsilon = \sqrt{\frac{3}{2}} - 1 \approx 0.22$$

With this calculated value for engineering strain, the initial assumptions made for this analysis can be validated. The assumption that the blood vessel model should replicate the elastic modulus of the high strain region is correct, as it experiences engineering strains greater than ~6%, which was previously established as the critical value separating the low strain and high strain regions. Furthermore, the assumption that the blood vessel model exhibits elastic behavior under their simulated use conditions was correct, as it experiences engineering strains less than 50%, which was previously established as being within the range of elastic behavior for both SLA resins.

This remainder of this analysis consists of calculating the values of elastic modulus *E* from equation (7) and required internal pressure p_i from equation (18). The analysis is performed for two different SLA resin options: FormLabs Elastic 50A Resin V2 and FormLabs Flexible 80A Resin. These two were selected due to the conclusions of multiple peer-reviewed medical journal articles that both SLA resin options can accurately replicate the material properties of typical human arteries [29, 30].

From Report 1, the internal femoral arterial wall radius is equal to 3 mm or 0.003 m, and the external femoral arterial wall radius is equal to 4 mm or 0.004 m.

Elastic 50A Resin V2

From the FormLabs Elastic 50A Resin V2 technical data sheet, its stress at 50% elongation is equal to 0.90 MPa or 900,000 Pa [24].

$$E = \frac{900{,}000\ Pa}{0.50} = 1{,}800{,}000\ Pa$$

$$p_i = \frac{(1{,}800{,}000\ Pa)\left(\sqrt{\frac{3}{2}} - 1\right)(0.004\ m^2 - 0.003\ m^2)}{(0.003\ m^2 + 0.004\ m^2)} = 356{,}000\ Pa$$

Flexible 80A Resin

From the FormLabs Flexible 80A Resin technical data sheet, its stress at 50% elongation is equal to 2.6 MPa or 2,600,000 Pa [25].

$$E = \frac{2{,}600{,}000\ Pa}{0.50} = 5{,}200{,}000\ Pa$$

$$p_i = \frac{(5{,}200{,}000\ Pa)\left(\sqrt{\frac{3}{2}} - 1\right)(0.004\ m^2 - 0.003\ m^2)}{(0.003\ m^2 + 0.004\ m^2)} = 1{,}030{,}000\ Pa$$

The Elastic 50A Resin V2 was determined to have an elastic modulus of 1.8 MPa and a required internal pressure of 356 kPa. The Flexible 80 A Resin was determined to have an elastic modulus of 5.2 MPa and a required internal pressure of 1030 kPa. These calculated values will be interpreted in the next section of this report and used to make recommendations regarding the selection of SLA resin options for use in manufacturing the blood vessel model.

Results

The results of this analysis reveal several important insights into the simulated use conditions of this application. First, the unobstructed area of the blood vessel model was determined to be 0.0000283 m^2, or 28.3 mm^2. Additionally, the factor by which the internal wall radius of the blood vessel mode must increase to restore its unobstructed cross-sectional area x was determined to be equal to $\sqrt{(3/2)}$, or approximately 1.22. This value will be useful for the client, as it provides a target goal for the radius of their vascular interventional devices to restore full blood flow within the blood vessel model. It is also

important for the proceeding calculations on both SLA resin options which utilize this variable in their governing equations.

From analysis of the technical data sheets of each SLA resin option, the elastic modulus of the Elastic 50A Resin V2 was determined to be 1,800,000 Pa or 1.8 MPa, and the elastic modulus of the Flexible 80A Resin was determined to be 5,200,000 Pa, or 5.2 MPa. These calculated values allow both SLA resin options to be directly compared to typical human femoral arteries to assess their abilities to accurately replicate their material properties. A research study has determined that the elastic modulus of a typical human artery while in the high strain region is approximately 2-6 MPa [26]. For an SLA resin to be considered viable for use in this application, its elastic modulus should fall within this range of values. The elastic modulus of the Elastic 50A Resin V2 falls slightly outside this range of values, but it may be considered within an allowable tolerance due to the low resolution of the experimental data. The elastic modulus of the Flexible 80A Resin falls firmly within this range of values. These results indicate that either SLA resin option can accurately replicate the elastic modulus of the calcified vessel model's simulated use conditions, suggesting that both are viable options for use in this application.

From derivations of the equation for elastic modulus, the Lamé equation for hoop stress, and the equations for cross-sectional area of the blood vessel model, an equation for the required internal pressure of the blood vessel model at the calcified lesion to restore its unobstructed blood flow was obtained. The required internal pressure for the Elastic 50A Resin V2 was determined to be 356,000 Pa or 356 kPa, and the required internal pressure for the Flexible 80A Resin was determined to be 1,030,000 Pa or 1,030 kPa. These calculated values of required internal pressure for each SLA resin option are well below their corresponding yield limits, resulting in factors of safety of approximately 2.53. These values will be useful for the client because they provide target goals for the pressures of the client's vascular interventional devices to restore full blood flow within the blood vessel model.

The calculated required pressure values of both SLA resin options can be directly compared to the minimum and maximum internal pressures of the calcified vessel model's simulated use conditions. The minimum value is taken to be the maximum internal pressure of a human femoral artery due to blood flow, which the team established in Report 1 is equal to 180 mmHg, equivalent to approximately 24.0 kPa. The maximum value is taken to be the maximum safe operating pressure of angioplasty balloons, which a research study has determined is equal to 16 standard atmospheres [31], equivalent to approximately 1620 kPa. For an SLA resin to be considered viable for use in this

application, its required internal pressure must fall within this range of values, which both SLA resin options do. These results indicate that either SLA resin option can accurately replicate the required internal pressures of the calcified vessel model's simulated use conditions, suggesting that both are viable options for use in this application. Table 1 concisely summarizes the important results of this analysis.

Table 1 - Elastic Moduli and Required Internal Pressures of SLA Resin Options

Resin Option	Elastic Modulus [MPa]	Required Internal Pressure [kPa]
Minimum Target	~2	24.0
Elastic 50A Resin V2	1.8	356
Flexible 80A Resin	5.2	1030
Maximum Target	~6	1620

Thermocouple Uncertainty – Jamie Dellwardt

To ensure the accuracy and reliability of the sensors integrated into the arterial model, several assumptions were made to guide the calculations. These assumptions address both the physical behavior of the system and the performance of the sensors, providing the foundation for quantifying uncertainties and validating the model.

For thermocouples, the system is assumed to be well-insulated, minimizing ambient heat transfer and isolating temperature changes to those directly influencing the blood analog. The viscosity (μ) of the blood analog, a key factor in flow behavior, is temperature-dependent and modeled using Equation 19, Sutherland's law [33]

$$\mu = \mu_0 \left(\frac{T}{T_0}\right)^{\frac{3}{2}} \left(\frac{T_0+C}{T+C}\right) \tag{19}$$

where:

- μ_0: Reference viscosity (Pa·s)

- T: Measured temperature (K)

- T_0: Reference temperature (K)

- C: Sutherland's constant (K)

This equation describes how viscosity changes with temperature, impacting the overall flow dynamics within the model. Thermocouple uncertainties, quantified using the Root Mean Sum of Squares (RMSS) method [34], include contributions from calibration ($U_{calibration}$), sensitivity ($U_{sensitivity}$), and response time ($U_{response}$). The total uncertainty is performed with Equation 20.

$$U_T = \sqrt{(U_{calibration})^2 + \left(U_{sensitivity}\right)^2 + \left(U_{response}\right)^2} \quad (20)$$

Each variable represents a specific source of potential error that can impact the accuracy of temperature measurements.

For pressure transducers, the flow is assumed to remain laminar throughout the system, with a Reynolds number (Re < 2300) due to the high viscosity of the blood analog. This ensures the applicability of the Hagen-Poiseuille equation [35], Equation 21, for flow resistance

$$R = \frac{8\mu L}{\pi r^4} \quad (21)$$

where:

- R: Resistance to flow (Pa·s/m^3)

- μ: Viscosity of the blood analog (Pa·s)

- L: Length of the arterial segment (m)

- r: Radius of the vessel (m)

The calculated flow resistance, the flow rate (Q) is determined by Equation 22

$$Q = \frac{\Delta P}{R} \quad (22)$$

where:

- Q: Flow rate (m^3/s)

- ΔP: Pressure drop across the lesion (Pa)

Pressure transducer uncertainties are similarly evaluated using Equation 23, the RMSS method

$$U_P = \sqrt{(U_{calibration})^2 + \left(U_{sensitivity}\right)^2 + (U_{environmental})^2} \quad (23)$$

where each term represents the contributions of calibration accuracy, sensor sensitivity, and environmental factors to the total measurement error.

These assumptions, equations, and variable definitions provide the basis for analyzing the sensors' performance and quantifying their uncertainties. By addressing potential errors and their impacts, the model ensures reliable data collection, enabling accurate replication of physiological conditions and effective testing of vascular devices.

Calculations

Given:

- $\Delta P = 10\ mmHg = 10\ x\ 133.32\ Pa = 1333.2\ Pa$

- $\mu = 3.5\ x\ 10^{-3}\ Pa * s$ (blood analog viscosity)

- $L = 0.1\ m$ (length of the lesion)

- $r = 0.005\ m$ (radius of the vessel)

$$R = \frac{8\mu L}{\pi r^4} = \frac{8(3.5 * 10^{-3})(0.1)}{\pi(0.005)^4}$$

$$R = \frac{2.8 * 10^{-3}}{\pi * 6.25 * 10^{-8}} = \frac{2.8 * 10^{-3}}{1.9635 * 10^{-7}} = 1.426 * 10^4 \frac{Pa * s}{m^3}$$

$$Q = \frac{\Delta P}{R} = \frac{1333.2}{1.426 * 10^4} = 9.35 * 10^{-2} \frac{cm^3}{s}$$

To demonstrate the uncertainty analysis using the Root Mean Square Sum (RMSS) method, let's calculate the total uncertainties for both a thermocouple measuring temperature and a pressure transducer measuring pressure.

Thermocouple Uncertainty Analysis

The total uncertainty (U_T) is determined using equation 20 which results in

$$U_T = \sqrt{0.0525} \approx 0.23\ ℃$$

Pressure Transducer Uncertainty Analysis

The total uncertainty (U_P) for the pressure transducer is similarly calculated using equation 20 again resulting in

$$U_P = \sqrt{5.6} \approx 2.37\ mmHg$$

Interpretation

The thermocouple uncertainty (±0.23°C) ensures that temperature readings are sufficiently accurate to monitor viscosity changes in the blood analog, which are critical for modeling flow dynamics. Similarly, the pressure transducer (±2.37mmHg) is acceptable within the range of expected physiological pressure drops. These uncertainties are low enough to ensure reliable and meaningful data collection during testing. Both results demonstrate that the sensors are appropriately selected and calibrated to provide accurate measurements, minimizing error and ensuring that the arterial model performs as intended. These calculated uncertainties also guide sensor placement and validate that the data generated is suitable for evaluating the performance of vascular intervention devices.

In addition to sensor performance, the calculated flow rate of $Q = 9.35 * 10^{-2}\ \frac{cm^3}{s}$ represents the volumetric flow through the arterial model under the specified conditions. This serves as a benchmark for assessing whether the model realistically simulates physiological flow rates. Deviations in flow rate caused by variations in pressure drop (ΔP) or changes in vessel geometry, such as those introduced by calcified lesions or deployed devices, provide valuable insights into how these factors influence blood flow. For example, a significant decrease in Q may indicate excessive resistance introduced by the lesion or suboptimal device performance. Conversely, a higher-than-expected Q could suggest the model is failing to accurately replicate the restrictive characteristics of calcified lesions.

Together, these analyses ensure that the arterial model serves as a robust platform for evaluating and optimizing the design of interventional devices. By reducing flow disruptions and pressure gradients caused by calcified lesions, the model provides actionable data to improve device functionality and efficacy. This detailed interpretation of both sensor uncertainties and flow rates confirms the reliability and accuracy of the

system, ensuring that it meets the project's objectives for replicating realistic physiological conditions.

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.

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 all 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 2, below. These values reflect the estimated costs for producing a single vessel model.

Table 2 - 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 3 - 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 4 - 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 5 - 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.

Differential Pressure – Scott Alex

This section of the report presents an analysis of differential pressure within the vessel. The analysis will focus on the femoral artery vessel site. The team seeks to gain further understanding of the mechanics of blood flow with individuals with vascular diseases such as peripheral arterial disease (PAD). Differential pressure readings in the femoral artery are used to distinguish the presence and severity of PAD. This is done through identifying significant pressure drops between different levels of the leg, indicating potential stenosis or narrowing due to calcification in that vessel area. In the femoral artery location, blood flows away from the heart so that would be in the down direction carrying oxygenated rich blood to the lower extremities. The blood would flow freely above the femoral artery and when reaching the femoral artery, there would be resistance to flow if there is stenosis or calcification present. Essentially this will result in a pressure drop over the femoral artery location. This pressure drop reading will determine the severity of the PAD in the vessel location. Pressure gradient is often employed to describe differential pressure as well. For this analysis we will distinguish differential pressure as pressure drop, this reading is what we are interested in. Differential pressure plays a crucial role in producing blood flow and driving the blood through the circulatory system in the body. Along with the pressure gradient or differential pressure, there are other factors that influence blood flow throughout the circulatory system. These other factors include the vessel dimensions/geometry, the vessel wall properties, and induced abnormalities within the vessel due to disease like calcification lesions. This analysis aims to align with the

team's broader scope, this involves modeling a calcified vessel. Essentially, this analysis will account for the differential pressure accurate to an individual with PAD or diseased state vessel.

The analysis accounted for assumptions that were related to the femoral artery vessel site and differential pressure. Differential pressure in this analysis can also be described as the difference in pressure between two specific points without the consideration of the distance between the two points. Pressure gradient refers to the rate of change in pressure over a distance. Ultimately, pressure gradient defines how quickly pressure changes across a space, considering the distance or space. We can assume that the stenosis of the femoral artery will have an impact on the differential pressure but what impact it has is unknown for now. We assume this because stenosis, the narrowing of the artery due to calcification, essentially reduces the patency of the artery or the radius of the artery. We can assume that because stenosis reduces the radius of the artery this results in increased resistance to flow pressure. Resulting in a pressure drop. We are interested in this pressure drop reading. This is all tied back to PAD patients because of the narrowing of arteries within PAD patients. We can assume our boundary conditions are the length of the femoral artery. This is the pressure at the inlet and outlet of the femoral artery location. In arteries, blood flows away from the heart carrying oxygenated-rich blood to the rest of the body. So, this determines the inlet to be the top of the femoral artery and the outlet to be at the bottom of the femoral artery. We can assume initially or prior to the femoral artery location that there is laminar flow of the blood. Meaning that the blood flow is without turbulence and moving in parallel layers with the center of the vessel being the location of the highest fluid velocity.

Poiseuille's Law utilized for Pressure Drop. [36]

$$\Delta P = \frac{8\mu LQ}{\pi r^4}$$

Where:

ΔP = Pressure drop across the femoral artery measured in pascal

μ = Dynamic viscosity measured in pascal seconds

L = Length of femoral artery location measured in meters

Q = Volumetric flow rate measured in meters cubed per seconds

r = Radius of the femoral artery, diseased state, measured in meters

Properties of a PAD patient: [37]

$$\mu = 0.0035\ Pa \cdot s$$

$$L = 0.35\ m$$

$$Q = 2.53 \times 10^{-6}\ \frac{m^3}{s}$$

$$r = 0.003\ m$$

Substituting the values and calculating the pressure drop of the PAD patient:

$$\Delta P\ =\ \frac{8(0.0035\ Pa \cdot s)(0.35\ m)\left(2.53 \times 10^{-6}\ \frac{m^3}{s}\right)}{\pi(0.003\ m)^4}$$

$$\Delta P\ =\ 97.43\ Pa$$

Properties of a healthy patient: [37]

$$\mu = 0.0035\ Pa \cdot s$$

$$L = 0.35\ m$$

$$Q = 2.53 \times 10^{-6}\ \frac{m^3}{s}$$

$$r\ =\ 0.005\ m$$

Substituting the values and calculating the pressure drop of the healthy patient:

$$\Delta P = \frac{8(0.0035\ Pa \cdot s)(0.35\ m)\left(2.53 \times 10^{-6}\ \frac{m^3}{s}\right)}{\pi(0.005\ m)^4}$$

$$\Delta P = 12.63\ Pa$$

The results from this analysis prove that a significant pressure drop over the femoral artery location results in peripheral arterial disease within a patient. The analysis considered all assumptions and took into consideration a healthy patient's pressure drop over the same location as well. The difference was the parameters of the healthy state individual. The radius and volumetric flow were different due to area and shrinkage/expansion of radius in the patient. This was done to provide a comparison to the diseased-state individual. The narrowing of the artery shows to have impact on the pressure of the fluid and in return this results in the heart having to work harder. Often patients with PAD express concerns of heart palpitations occurring at random or when exerting energy outside the normal day to day functions. This is due to the narrowing of the peripheral arteries, in this case the femoral artery. When the pressure drop is significant the human body responds with an increased heart rate to pump faster and must make of for the pressure lost.

The mathematical modeling of differential pressure in the femoral artery demonstrates the significant burden that PAD patients deal with due to the calcification lesion and narrowing of the artery. The results show an increase in the pressure gradient across the femoral artery. This model is employed for early detection of PAD to reduce the physiological stress on the cardiovascular system. Through calculations it provides a foundation for incorporating real-world clinical data into simulations to assess the impact of treatment options. Treatment options or interventions like stents, vessel bypass operations, and or pharmacological interventions. The goal is to provide normal flow and normal pressure of the dynamic blood fluid to a patient with PAD.

Wall Shear Stress – Scott Alex

This section of the report presents an analysis of wall shear stress. 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
4. Flow velocity (V_{max}) is used for arteries with peripheral arterial disease (PAD)
5. Radius value (R) [38]

Known Values [38]:

$$V_{max} = 0.3\ \frac{m}{s}$$

$$R = 0.005\ m$$

$$\mu = 0.0035\ Pa \cdot s$$

Calculate Shear Rate:

$$\frac{du}{dy} = \frac{2V_{max}}{R}$$

$$\frac{du}{dy} = \frac{2\left(0.3\ \frac{m}{s}\right)}{0.005\ m}$$

$$\frac{du}{dy} = 120\ s^{-1}$$

Calculate Wall Shear Stress (WSS):

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

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

$$\tau = 0.42\ Pa$$

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.

Table 6 - Minimum Factors of Safety

Part	Load case scenario	Material	Method of calculating FOS	Minimum FOS
Pump	Full power for 30 min of operation	Plastic, Silicone, Motor	Hand calculation from spec sheet	Not calculated yet
Tubing	27.0 kPa internal pressure	Polyethylene	Hand calculation	33.20

Vessel walls	356 kPa internal pressure (angioplasty balloon)	FormLabs Elastic 50A Resin V2	Hand calculation	2.53
Lesion adhesion	27 Pa wall shear stress (blood analog flow)	3M Scotch-Weld Plastic & Rubber Instant Adhesive PR1500	Hand calculation	$>5\times10^{6}$

The first factor of safety shown in Table 6 above will show if the pump will be able to operate for the duration of a normal stent deployment operation without overheating. There are no specs on an acceptable run time for the current pump being used by the team, so to do this calculation a thermal analysis will be conducted for the pump and its motor as part of the next individual analysis assignment.

The tubing factor of safety presented in Table 6 shows a very large margin of safety. The factor of safety value being 33.20 indicates that the tubing will not be a cause for failure concern. The team is applying a pressure of 27.0 kPa to the tubing and system. The Everbilt brand that manufactures polyethylene tubing has a maximum pressure yield of 896.32 kPa for that material [10]. Using a hand calculation method for the factor of safety, the results indicate the team is exercising safety measures for tubing selection.

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Flow Charts and other Diagrams

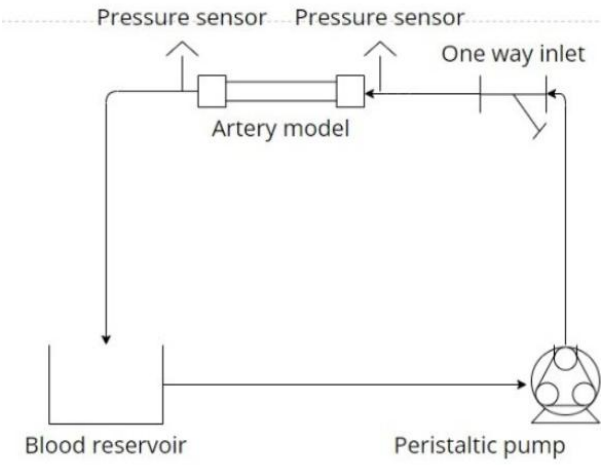

Figure 6 – Pipe Flow Diagram

Figure 6 contains a pipe flow diagram showing the path the fluid takes through the model. The diagram shows the sensors and electronics that it will encounter as it passes through the system. The purpose of this diagram is to allow for the team and the client to better visualize the system and the purpose of specific components, such as the pressure sensors and stent inlet. Below a circuit diagram for the pressure transducers is provided in Figure 7. This circuit diagram shows how the sensors are wired to a load cell amplifier chip, then plugged into the Arduino microcomputer. This setup will allow for the team to display the data collected from the system onto an LCD display for the user to see.

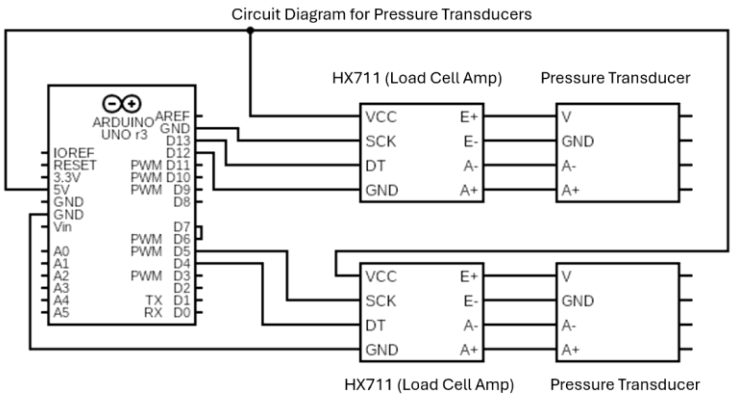

Figure 7 – Circuit Diagram for Pressure Transducers

Figure 7 contains a circuit diagram for pressure transducers. The circuit consists of two pressure transducers, accompanied by two load cell amplifiers, and an Arduino wiring board. The circuit is powered by a power source which is not pictured in the circuit diagram. The load cell amplifier is used to amplify the signal from the load cell (pressure transducer). Typically, the signal from the load cell is feeble or a low strength signal and by adding the load cell amplifier it strengthens the signal. The pressure transducer, also known as a pressure transmitter, converts a pressure reading into an electrical signal that is measured and displayed on the data acquisition.

Moving Forward

As the team progresses in their project, several areas require further work and refinement to ensure the calcified vessel model meets all customer, client, and project requirements. The pressure transducers require additional calibration to improve accuracy and consistency in measuring pressure drops across the vessel model. The team is also transitioning from a laptop-based data display to a dedicated digital display on the model to simplify client usage and enhance ergonomic operation. A thermal analysis of the pump is necessary to confirm its ability to sustain full-power operation for 30 minutes without overheating. Additionally, the Factor of Safety (FOS) analysis for the pump and its motor has not yet been completed. This analysis will help determine the pump's reliability and operational safety during extended use, ensuring it meets the requirements of a typical stent deployment operation.

Similarly, while both SLA resin options (Elastic 50A Resin V2 and Flexible 80A Resin) meet most requirements for replicating human artery properties, further validation of their elastic moduli under simulated use conditions will confirm their suitability. Additional testing is needed to optimize the vessel wall thickness to withstand the angioplasty balloon's internal pressure of 356 kPa. Although the current factor of safety of 2.53 for both resins appear adequate, refinements may be required to optimize durability. Cost analysis indicates that injection molding is the most cost-effective production method, but further research into reducing variable costs, such as alternative materials or process improvements, could enhance financial feasibility. The blood analog also requires further refinement to ensure its viscosity, density, and temperature accurately replicate human blood properties, as these parameters significantly impact pressure and wall shear stress calculations.

The adhesive strength of the calcified lesions exceeds the minimum requirement of 27 Pa by a substantial margin, but experimental validation is necessary to ensure its durability under repeated use. Wall shear stress (0.42 Pa) and differential pressure (97.43 Pa for PAD patients vs. 12.63 Pa for healthy individuals) have been calculated based on modeling and assumptions, but these values must be experimentally verified to confirm the model accurately simulates diseased and healthy states. Filament usage calculations for 3D printing indicate that 113.37 mm of filament is required per vessel model, but consistency across all 12 models must be confirmed. Additionally, injection molding processes should be validated for scalability while maintaining quality standards.

Per the engineering requirements outlined in the team’s QFD, another critical vessel model property is the vessel model opacity. Considering the 50% opacity target the team selects a 40D TPU 3D printing filament that is transparent in color. The transparent property of the filament attempts to meet the 50% opacity target. The team can test opacity requirements by either visual inspection or following ASTM D1003, the standard test method in measuring luminous transmittance of transparent plastics [39]. The method for visual inspection involves subjective assessment by an observer. The vessel is viewed against a standardized test object with high contrast to evaluate its transparency. The method for ASTM D1003 transmittance measurement involves measuring the amount of light that passes through the 3D printed vessel model material. The model is placed between a light source and a detector. The detector measures the intensity of light before and after passing through the material. The instrument used for transmittance measurement is a transmittance meter or a spectrophotometer. Despite the associated costs to the team's budget, there are cost-effective alternatives available for this test. One such option is to utilize a handheld light transmission meter, such as the Qualtech QPI-115A or Linshang LS116. A final alternative to achieve this opacity requirement would be to get the team’s clients involved and present them with the team’s product for visual inspection and interpretation.

The Quality Function Deployment (QFD) analysis have been essential for aligning customer requirements with engineering targets. However, as the design evolves, periodic updates are necessary to account for any changes in priorities or constraints. Finally, physical testing of the vessel model must align with simulations of flow rate, pressure, and structural integrity to validate its performance. This includes replicating scenarios such as stent deployment and failure testing to ensure compliance with ISO 25539-2:2020 standards for endovascular devices. By addressing these areas systematically, including completing the FOS analysis for the pump, the team will ensure a robust, cost-effective, and reproducible calcified vessel model that meets all project objectives and facilitates advancements in vascular device testing.

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