Replicable, Inorganic Calcified Vessel Models

Sponsored by: Gore & Associates – Medical

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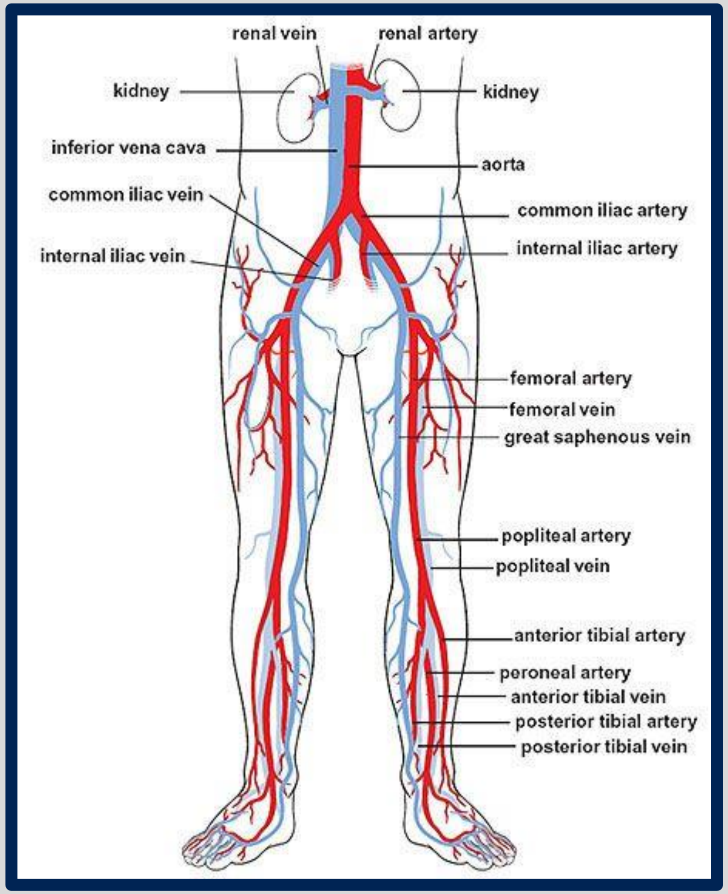
NAU NORTHERN ARIZONA UNIVERSITY

1.1 Project Description

Client:
- W.L. Gore & Associates, Inc. – Medical

Project Scope:
- Design, build, and test a replicable model of calcified lesions in the peripheral arterial system for deployment of vascular interventional devices, under simulated use conditions, using inorganic materials.

Project Significance:
- Accelerate the development of treatments for peripheral arterial disease (PAD) by improving functionality and accessibility of research models



Peripheral Arterial System

1.2 Deliverables

Course Work:

- Project Selection
- QFD House of Quality
- Presentation – 1: Background & Mathematical Modeling
- Report – 1
- Presentation – 2: Concept Generation & Evaluation
- Presentation – 3: Design Proposal
- Report – 2
- Prototyping Demonstration Phase
- Hardware Status Updates; 33%, 67%, & 100%
- Final Presentation & UGRADs

Client Work:

- Minimum 3 varying vessel layouts
- Justified material selection for vessels and lesions
- Final presentation to Gore engineers
- Performance of stent deployment to determine testing effectiveness
- Durability of repeated testing with success
- Ergonomics of intended use

1.3 Success Metrics

- Models are clear, and device deployment is unobstructed
  - Transparency measurement is >50%
- Vessels and lesions are of realistic size, shape, texture, and flexibility
  - Length measurement is >20 cm to allow enough room to deploy devices; diameter measurement is 5-9 mm, wall thickness measurement is 1-2 mm, elastic modulus is 1.5-6.5 MPa as in real femoral arteries
- Lesions are at the proper durometer hardness
  - Hardness measurement is 90 Shore A as in real calcified lesions
- Lesions are adhered to vessels at the proper strength
  - Overlap adhesive strength is 15 MPa as in real cases of peripheral arterial disease
- The models are safe to store and to operate
  - Assessed by compliance to relevant ANSI/OSHA standards
- Pressure transducers and flow rate sensors output accurate data
- 12 models are produced
- Only non-biologic materials are used
- Replicable procurement, manufacturing, and assembly methods are documented
- The entire cost of the project is under the team’s budget of $3,000 + fundraising

2.1 & 2.2 Design Requirements

Customer Requirements:

CR1 – Replicability
- Product can be manufactured by Gore

CR2 – Models simulated use conditions
- Accurately models vessel and lesion

CR3 – Non-biological materials
- Entirely synthetic model

CR4 – OSHA/ANSI compliance
- Safety when manufacturing/operating

CR5 – Visualization of deployment
- For demonstration purposes

CR6 – Durability
- Able to be used for many tests

CR7 – Ergonomic for intended use
- Accessible and convenient to operate

Engineering Requirements:

ER1 – Vessel properties
- Synthetic vessel to have same elasticity and strength as biological lesion

ER2 – Vessel dimensions
- Synthetic vessel dimensions to fit stent

ER3 – Lesion properties
- Synthetic lesion to have same hardness and adhesion to wall as biological lesion

ER4 – Lesion dimensions
- Accurately represent lesion shapes

ER5 – Fluid properties
- Accurately represent blood

ER6 – Engineering standard compliance
- Product must be safe

ER7 – Cost
- Under total budget of $3,000

2.3 House of Quality

System QFD

Project: **Calcified Vessel Model**

Date: 9/11/ 2024

#	Technical Requirement	1	2	3	4	5	6	7
1	Vessel Properties							
2	Vessel Dimensions							
3	Lesion Dimensions		9					
4	Lesion Properties	3	3	6				
5	Fluid Properties	3	3		1			
6	Engineering Standard Compliance							
7	Manufaturing Cost	-3	-3	-1	-1	-1	6	

Customer Needs	Customer Weights	Technical Requirements: Vessel Properties	Vessel Dimensions	Lesion Dimensions	Lesion Properties	Fluid Properties	Engineering Standard Compliance	Manufaturing Cost

Customer Needs	Customer Weights	Technical Requirements: Vessel Properties	Vessel Dimensions	Lesion Dimensions	Lesion Properties	Fluid Properties	Engineering Standard Compliance	Manufaturing Cost	Customer Opinion Survey: 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) Angle (deg)	Strength (Pa) Durometer (HB)	Flow rate (mL/s) Dynamic viscosity (Pa*s) Density (kg/m^3)	%	USD					
Technical Requirement Targets		11-17 kPa 50%	~30 cm 1-2 mm 5-9 mm	5 mm 0.5 mm 180°	7 Pa 70 HB	7.2 mL/s 0.003-0.006 Pa*s 1060 kg/m^3	100%	$3000 USD					

Legend

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

3.1 Benchmarking

Existing Vessel Model Designs

There are many existing simulation models that are designed to simulate the human body. Here we will review three existing designs, devices, and or sub-systems that are potential considerations for our project scope and project solution. These three existing benchmarks have been applied to similar context relevant to our project scope.

Creative Biolabs 3D Biology

- Research Models
- Testing, experimenting and devices for vascular intervention
- Cardiovascular disease

Preclinic Medical Simulation

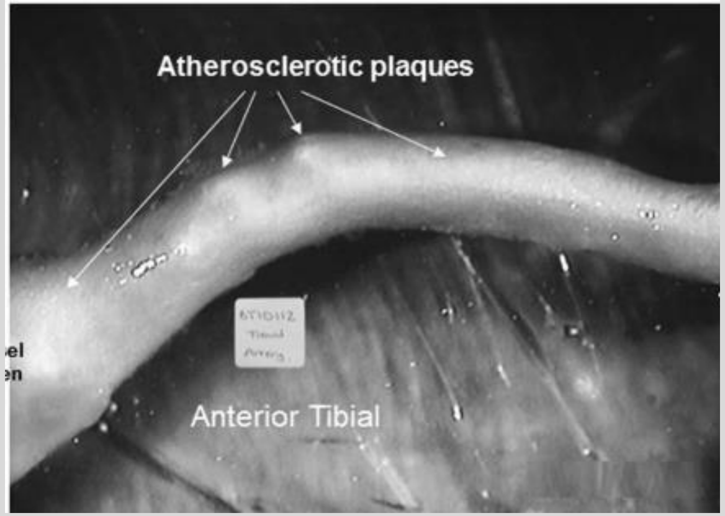
- Numerous models that are specific to certain areas of the arterial system (WB)
- Offers endoscopy simulators
- Models used for training medical professionals

Vivitro Labs – Simulators

- Endovascular simulator
- Deployment accuracy
- Adaptability; easy to reconfigure to different model sizes and connection types

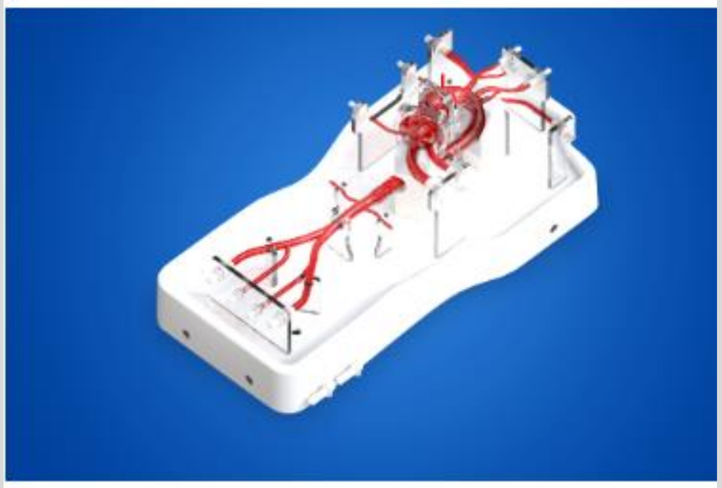
3.1 Benchmarking

Creative Biolabs 3D Biology



Atherosclerotic tissue sample

Preclinic Medical Simulation



Silicone cardiac vessels

Vivitro Labs – Simulators

Endovascular Simulator

3.2 Literature Review

Materials Science and Engineering: An Introduction, 10th Edition [1]	Quantifying Effects of Plaque Structure and Material Properties on Stress Distributions in Human Atherosclerotic Plaques Using 3D FSI Models [6]
Schaum's Outline of Probability and Statistics, 4th Edition [2]	Ultrasound determination of total arterial wall thickness [7]
GORE® VIABAHN® Endoprosthesis [3]	Cardiovascular implants — Endovascular devices (ISO 25539-2:2020) [8]
A new optical coherence tomography-based calcium scoring system to predict stent under expansion [4]	How to design for FFF 3D printing [9]
Carotid Artery Stenting for Calcified Lesions [5]	Product Selection Guide [10]

3.2 Literature Review

Endovascular Today: Stent device guide [11]	Viabahn stent instruction manual [14]
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 [12]	W. L. GORE & ASSOCIATES ENHANCES GORE® VIABAHN® ENDOPROSTHESIS PORTFOLIO WITH LOWER PROFILE DELIVERY [15]
Harrison's Principles of Internal Medicine, 21st edition [13]	OSHA Regulations [16]

3.2 Literature Review

Biocompatible 3D Printing Resins for Medical Applications [17]	3D Printed Biomedical Devices and their Applications [20]
Research Models for Studying Vascular Calcification [18]	Vascular Corrosion Casting [21]
Comparing Traditional and Contemporary Manufacturing Methods [19]	3D Printed Molds for Injection Molding [22]

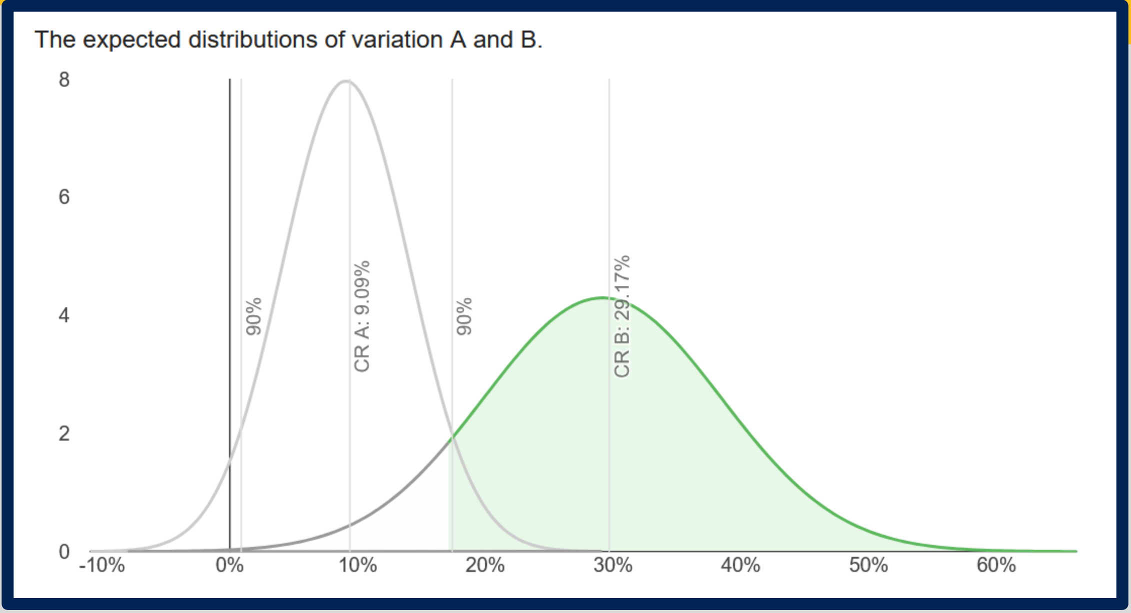
3.2 Literature Review

Endovascular Simulator (vivitrolabs.com) [23]	CRIMSON - An open-source software framework for cardiovascular integrated modelling and simulation [28]
Preclinic Medtech – Medical Simulator [24]	Anatomy, Blood Vessels [29]
Central Versus Peripheral Artery Stiffening and Cardiovascular Risk [25]	Blood Flow in Vessels – Circulation [30]
Cardiovascular Physiology - Chapter 6: The Peripheral Vascular System; McGraw Hill [26]	Tortora's Principles of Anatomy & Physiology [31]
Peripheral Arterial Disease [27]	"Elastic 50A resin V2," Formlabs [X]

3.3 Mathematical Modeling

133 Calcified Lesions

	Thickness >0.5 mm	Thickness ≤0.5 mm
Patients	100	33
Stent expansion <70%	10.0% (10/100)	0.0% (0/33)
	Length >5 mm	**Length ≤5 mm**
Patients	57	43
Stent expansion <70%	17.5% (10/57)	0.0% (0/43)
	Angle >180°	**Angle ≤180°**
Patients	24	33
Stent expansion <70%	29.2% (7/24)	9.1% (3/33)



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

- z-score: 1.9044, p-value: 0.0569
- The significance of the change in experimental success rate is greater than 90%.
- Critical dimensions for stent underexpansion: 0.5 mm thickness, 5 mm length, 180° angle.

3.3 Mathematical Modeling

Equation

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

$$= \frac{1.066 \cdot 62.43 \cdot 0.00235 \cdot 3}{0.8}$$

$$= 0.5864\ lb \cdot \frac{ft}{s}$$

$$= 0.0011\ hp$$

Variables

Sg (blood) = 1.048-1.066
γ (water) = 62.43 lb/ft^3
H (maximum) = 3 ft
Q = 300-400 mL/min → 0.00235 ft^3/s
η ≈ 80%

Conclusion

Required power output for pump is 0.0011 hp, which falls well within the range of commercially-available pumps

3.3 Mathematical Modeling

Define WSS:

Wall shear stress (τ) is the force created by fluid flow and the internal surface of a vessel.

Applying fluid mechanic principles to blood flow in a blood vessel, we can determine appropriate wall thickness of our model.

Considerations:

- Assume laminar flow
- Viscosity of blood (μ) is never fixed
- Shear rate (du/dy) and flow velocity $(V)_{max}$ will need to be calculated as well
- Radius (R)

Calculation:

$(V)_{max} = 0.3$ m/s *typical of a medium-sized artery @ resting conditions
(R) = 0.005 m *reasonable approximation for common
(μ) = 0.0035 Pa*s *common dynamic viscosity value for blood

1. Calculate Shear Rate:

$$du/dy = [2(V)_{max}]/(R)$$
$$du/dy = [2(0.3\ m/s)]\ /\ (0.005m)$$
$$du/dy = 120\ 1/s$$

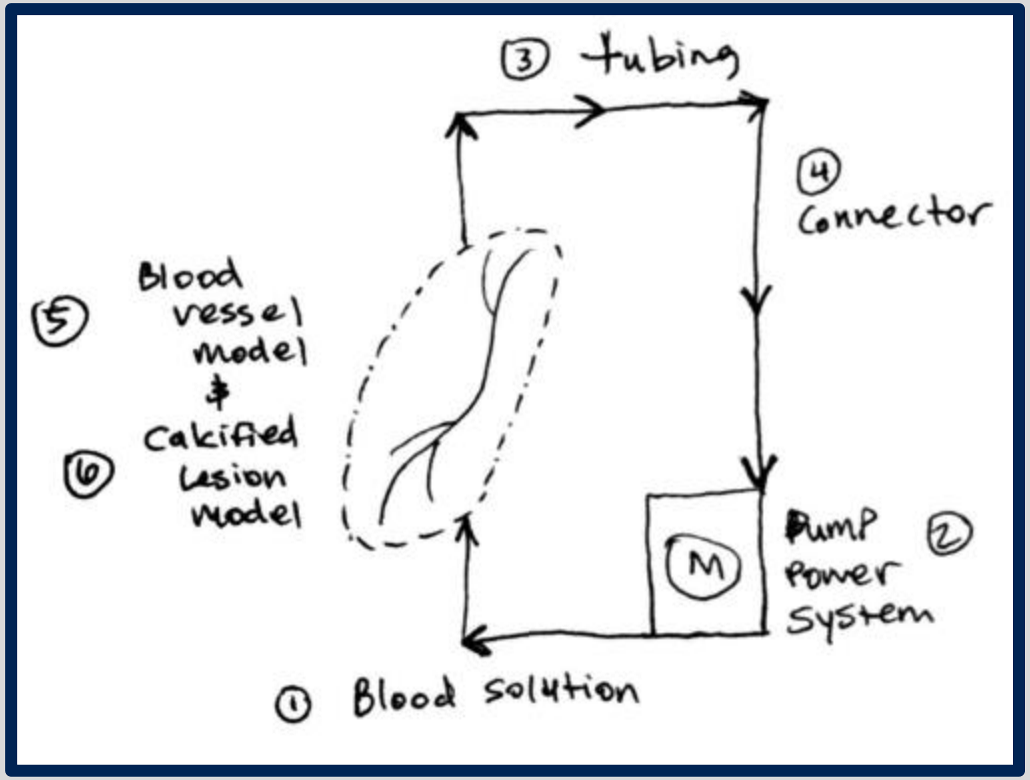
2. Calculate Wall Shear Stress (WSS):

$$\tau = (\mu)(du/dy)$$
$$\tau = (0.0035\ Pa{*}s)\ (120\ 1/s)$$
$$\tau = 0.42\ Pa$$

4.1 Functional Decomposition

System:
Calcified Lesion Vessel Simulation Model

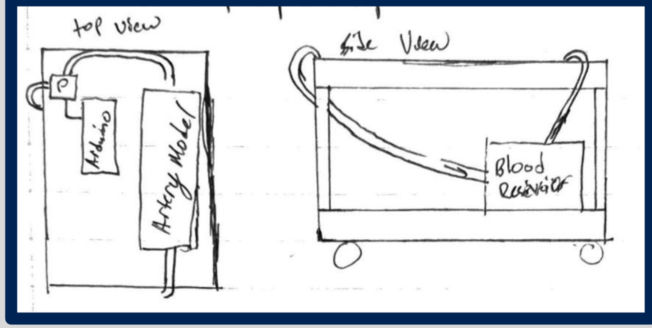
Components:
1. Blood Substitute
   simulates blood
2. Power/Pump System
   produces flow
3. Tubing
   directs flow
4. Connectors
   connects system
5. Blood Vessel Model
   simulates femoral artery
6. Calcified Lesion Model
   simulates calcification



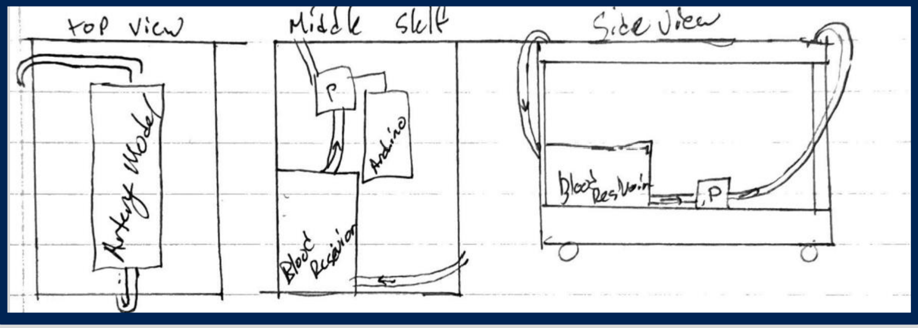
Hierarchy:
- Power/Pump System
  - >Arduino Kit
    - >>Circuitry
  - >Motor
  - >Pulsatile pump
  - >Tubing
  - >Connector
  - >Reservoir
- Calcified Lesion Vessel
  - >Blood Vessel Model
    - >>Femoral artery
  - >Calcified Lesion Model

4.2 Concept Generation

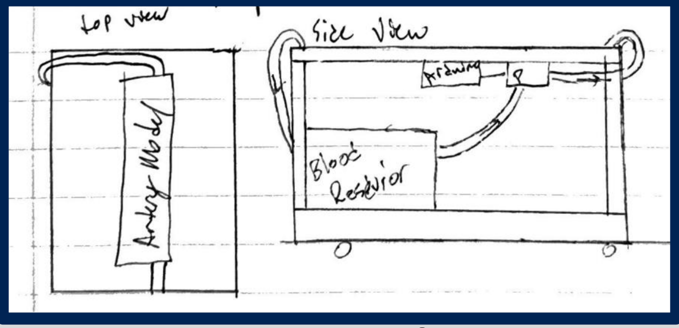
Concepts



Computing and pump on top



Computing and pump on bottom



Computing and pump undermounted

Advantages/ Disadvantages

Computing and pump on top:

+ easy access to the computing and pump systems

+ pump at same level as model

- If failure occurs near pump fluid could get into electronics

Computing and pump on bottom:

+ only the artery model is showing

-If failure occurs at tank or pump fluid can get on electronics

- Pump might not create enough work to get water to the model

Computing and pump undermounted:

+ only artery model is showing

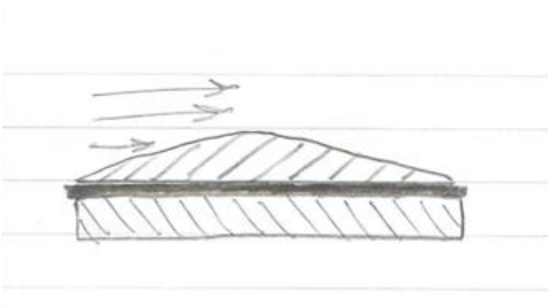
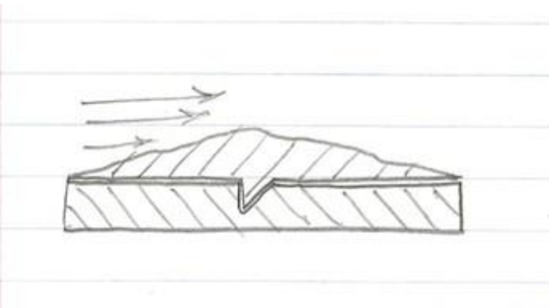
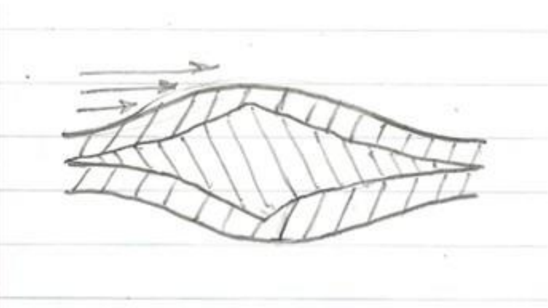
+ electronics are out of the danger zone if failure occurs

-Accessing the electronics and pump system is more difficult

4.2 Concept Generation

Calcified Lesion Material	High-hardness FDM filament	Fired ceramic	Machined steel (1045)
			
Advantages/ Disadvantages	+ Accurate and consistent hardness	+ Most accurate material properties	+ Consistent hardness
	+ High resolution	+ Easy to manufacture	+ High resolution
	+ Complete control of manufacturing process	+ Relatively inexpensive	– Complex manufacturing process
	– Relatively expensive	– Inconsistent hardness	– Relatively low hardness
		– Low resolution	

4.2 Concept Generation

Calcified Lesion Adhesion Method	Adhesive paste	Interlocking mechanism	Embedded
			
Advantages/ Disadvantages	+ Simple manufacturing	+ Simple manufacturing and assembly	+ Simple manufacturing
	+ Complete control over adhesion strength	+ Complete control over adhesion strength	+ No protruding geometries
	+ Accurate to real-world use conditions	– Unidirectional adhesion strength	– Inaccurate to real-world use conditions
	+ No protruding geometries	– Protruding geometries	– No control over adhesion strength
	– Complex assembly	– Low resolution	– Complex assembly

Concept Generation: Blood Solution

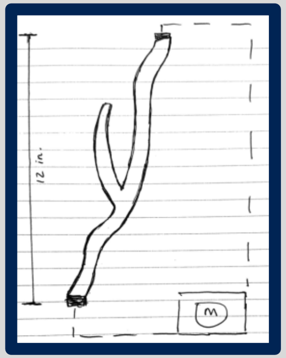
Material	Glycerin	Simulated Blood	Corn Syrup, Water and Flour Mixture
			
Advantages/ Disadvantages	+Transparent +Non-biological materials +No mixing of creating ourselves -More expensive to buy +/- Has safety procedure for use	+Very similar to blood viscosity and flow -Not transparent +Cheaper option to purchase -Has no safety procedures -Limited spec sheet	+Can change the viscosity and flow characteristics -May contain biological materials +Cheapest option +No safety procedure for testing needed -Must be mixed ourselves leaving room for inconsistencies -May harden if left too long

Images and cost estimates provided by www.amazon.com

4.2 Concept Generation

Vessel Design Structure

Femoral Artery (R)

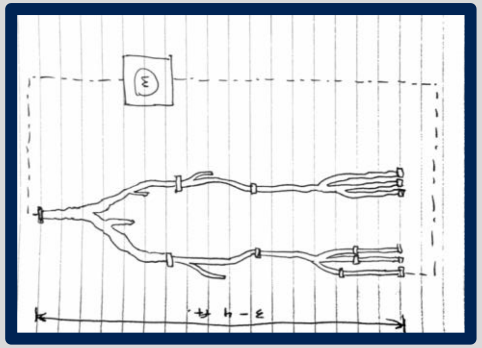


(+/-) Only the right femoral artery in the system

(+) A common vessel site for the occurrence of calcification

(+) With a reduced fluid volume to manage, the system requires less power

Lower Extremity

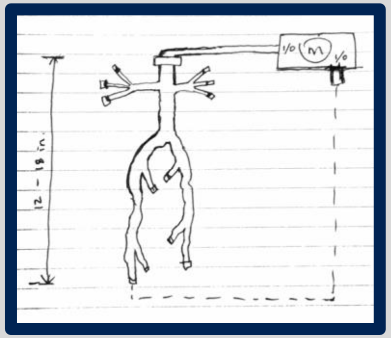


(+) Explore the lower extremity arterial system

(+) Interconnection points for removing and adding vessels

(-) More fluid volume can lead to complications in pump power system

Femoral Artery



(+) Less fluid volume

(+) Less power required to pump

(+) L/R femoral artery

(+/-) Only the femoral artery in the system

Advantages/ Disadvantages

4.2 Concept Generation

Material	Vinyl Tubing (PVC)	3D Printing Filament	Silicone Tubing
			
Advantages/ Disadvantages	(-) Dimensions are general and are limited in thickness size to 3.2mm (-) Only sold in 50 ft rolls (+) Clear and transparent (-) Adhesion compatibility unknown	(+) Design intentions can be met more accurately (+) Hardness: Shore D 76 (-) Will require a 3D printer or 3D printer services (+) Good adhesion compatibility	(+) exceptional pump life for peristaltic pumps (+) Hardness: Shore A 50; soft material but durable (+) sold in various sizes and reasonably priced (-) Not exactly transparent

4.3 Selection Criteria

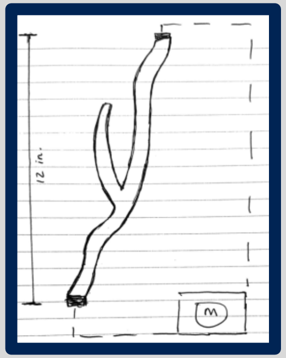
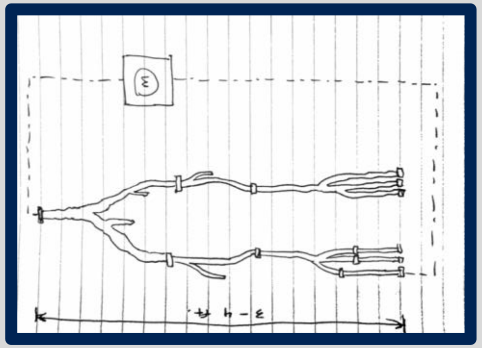
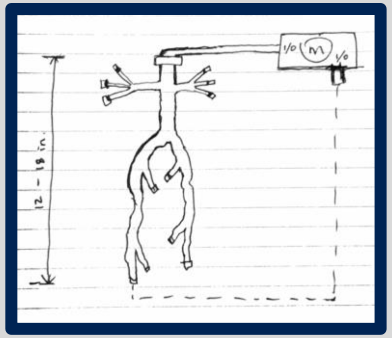
Mechanical Properties of Arterial Calcified Lesions

- Indentation Hardness: 274.8 ± 18.1 HV
  - https://doi.org/10.1177/1758736014520809
- Overlap Adhesive Strength: 15.2 ± 3.6 MPa
  - https://doi.org/10.2319/020807-60
- Scientific studies on mechanical properties of arterial calcified lesions are inapplicable to this project
- Properties are estimated from studies on enamel/dentin, a similar biological mineral
- Exact values are worst-case-scenario maximum values within the realm of possibility

Unit Conversions

- Actual calcified lesions
  HV 274 → Shore 39D
- High-hardness FDM filament
  Shore 90A → Shore 39D
- Fired ceramic
  Mohs 4 → Shore 44D
- Machined steel (1045)
  HB 215 → Shore 33D
- Hardness conversions provided by:
  - https://plantech.com
  - https://www.efunda.com
  - https://www.carbidepot.com

4.3 Selection Criteria

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

4.3 Selection Criteria

Material	Vinyl Tubing (PVC)	3D Printing Filament	Silicone Tubing
			
Customer Needs	Yes & No	Yes	Yes & No
Transparency	Exceptional	Exceptional	Translucent
Life Span	Exceptional	Exceptional	Exceptional

4.4 Concept Selection

Concepts

3D-printed Peristaltic Pump

Peristaltic Pump

Advantages/ Disadvantages

3D-printed Peristaltic Pump:

+ allows for full customization of pump power and flow rate

- Will take several hours of development to create a pump that will meet engineering requirements

Peristaltic Pump:

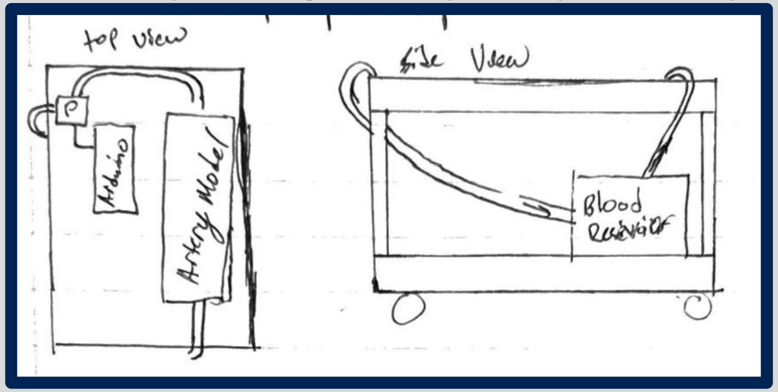
+easy to procure, and meets the flow rate requirement
-might need a higher power output to overcome friction loss in pipes
+ perfect for poof of concept in prototyping

Our decision:
The 3D printable pump would take several modifications to achieve the desired flow rate, therefore a pump that can achieve the flow rate will be purchased for prototyping. If after testing occurs, this pump needs to be changed to better fit engineering requirements, we can do so.

4.4 Concept Selection

Top level design:

Computing and pump on top

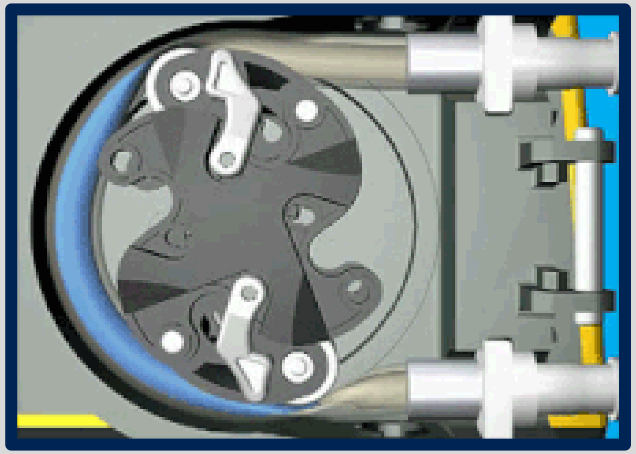


- Keeps computing unit and electronics out of the areas where fluid would rest if failure occurs
- Placing the pump atop the cart reduces the overall head in the system

Pump selection:

Peristaltic pump

- Pumps fluid without it contacting any machinery
- Precise flow rate is achievable through correct motor control



A peristaltic pump with integrated RPM control was chosen to reduce the complication of motor control.

4.4 Concept Selection

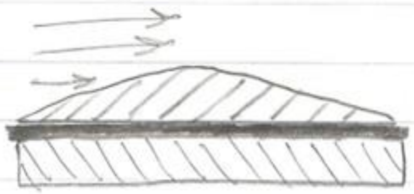
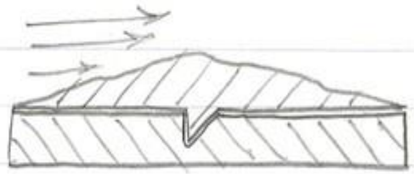
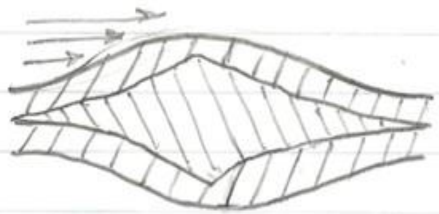
Table – Calcified Lesion Material Concept Selection

Material	**High-hardness FDM filament**	**Fired ceramic**	**Machined steel (1045)**
Target			
Hardness: Shore 39D	Shore 39D	Shore 44D	Shore 33D
Resolution: <0.01 mm	0.1 mm	1 mm	0.01 mm
Cost: $0.00	$40/kg + manufacturing	$7/kg + manufacturing	$14/kg + manufacturing

High-hardness FDM filament was chosen as lesion material due to its replicability, accurate modeling of simulated use conditions, high resolution, and desirable lesion properties (see design requirements).

4.4 Concept Selection

Table – Calcified Lesion Adhesion Method Concept Generation

Adhesion Method	Adhesive paste	Interlocking mechanism	Embedded
Target			
Adhesion Strength: 15 MPa	~15 MPa	~15 MPa	Yield strength of vessel model
Dimensions: 0 mm	0 mm	1 mm	0 mm
Cost: $0.00	$0.40/mL	~$0.00	~$0.00

Adhesive paste was chosen as adhesion method due to its accurate modeling of simulated use conditions, lack of protruding geometries, and desirable adhesion strength (see design requirements).

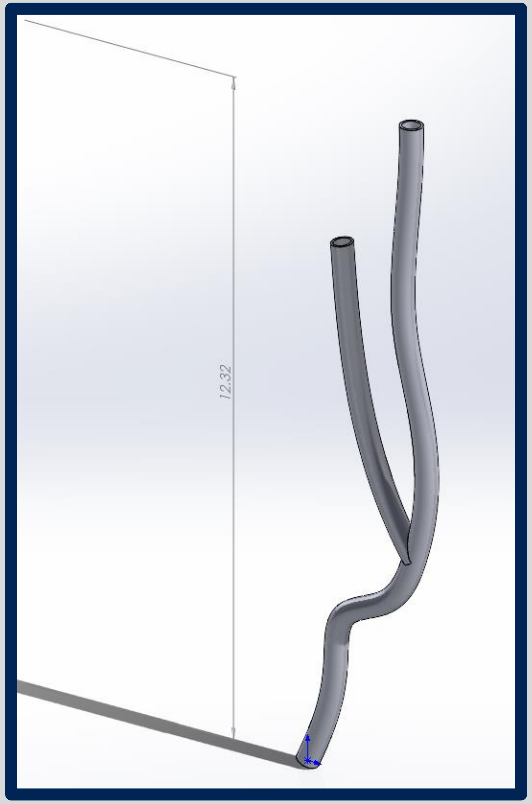
4.4 Concept Selection

Initial Selection

Specifications (CAD):
- Density = 0.04 lbs/in.^{3}
- Mass = 0.03 lbs
- Volume = 0.74 in.^{3}
- Surface Area = 37.74 in.^{2}

Comparison:
- Best at meeting customer needs
- Most cost effective
- Least at generating waste
- Best at avoiding constraints

Femoral Artery (Right)



4.4 Concept Selection

Final Selection

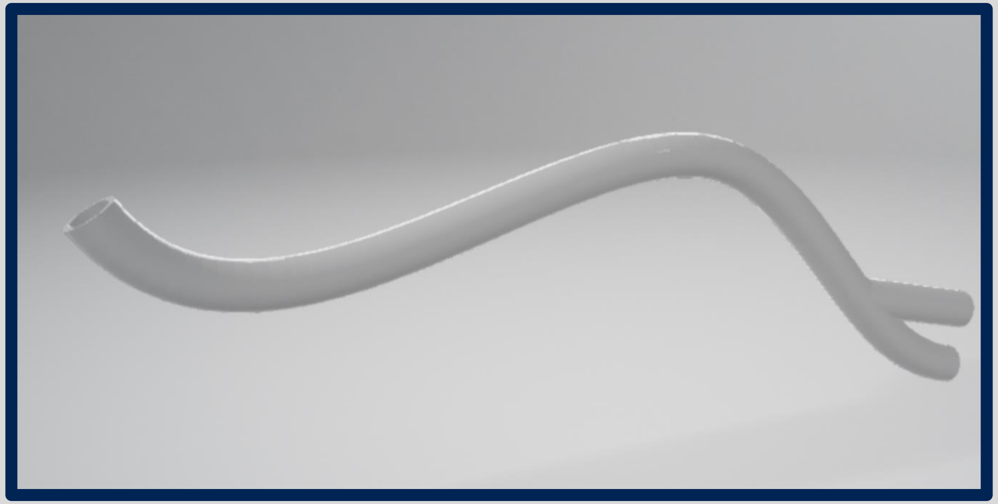
Specifications (CAD):

- Density = 0.04 lbs/in.^{3}
- Mass = 0.038 lbs
- Volume = 0.67 in.^{3}
- Surface Area = 33.54 in.^{2}

Comparison:

- Exceptional at meeting customer needs
- Fair at cost per unit (12 units)
- More at generating waste
- Branch closer to inlet/outlet (meets CRs)

Femoral Artery (Right)



4.4 Concept Selection

Initial Selection

Specifications

- PETG Filament; produces a clear product
- Diameter = 1.75 mm (common)
- $24.99/kg
- Hydrophobic (moisture-resistant)
- Strong adhesion factors
- Print temperature = 230 – 260 °C
- Tensile at yield = 0.8 MPa

Comparison

- Adequate control of vessel dimensions
- Less waste involved
- Fair adhesion factors for lesion

Hatchbox Transparent Filament

4.4 Concept Selection

Final Selection

Specifications

- Shore Hardness: 55A
- Ultimate Tensile Strength: 3.4 MPa
- Stress @ 50% Elongation: 0.9 MPa
- Stress @ 100% Elongation: 1.7 MPa
- Elongation @ Break: 160%
- Tear Strength: 12.3 kN/m

Comparison:

- More control of vessel dimensions
- More waste involved
- Better adhesion factors for lesion
- Resin printer required
- Exceptional material for medical models
- $199.00 per Liter

Elastic 50A Resin V2

4.4 Concept Selection

Blood Analog

Glycerin: Final Design Blood Analog

Density: 1.26 g/mL
Cost: $60
Viscosity: 934 cP

Final Design:

- Quantity with limited error in manufacturing
- Procedure for testing
- Much closer to blood specifications
- Available in desired quantity for reasonable price

Corn syrup Solution: Prototype Blood Analog

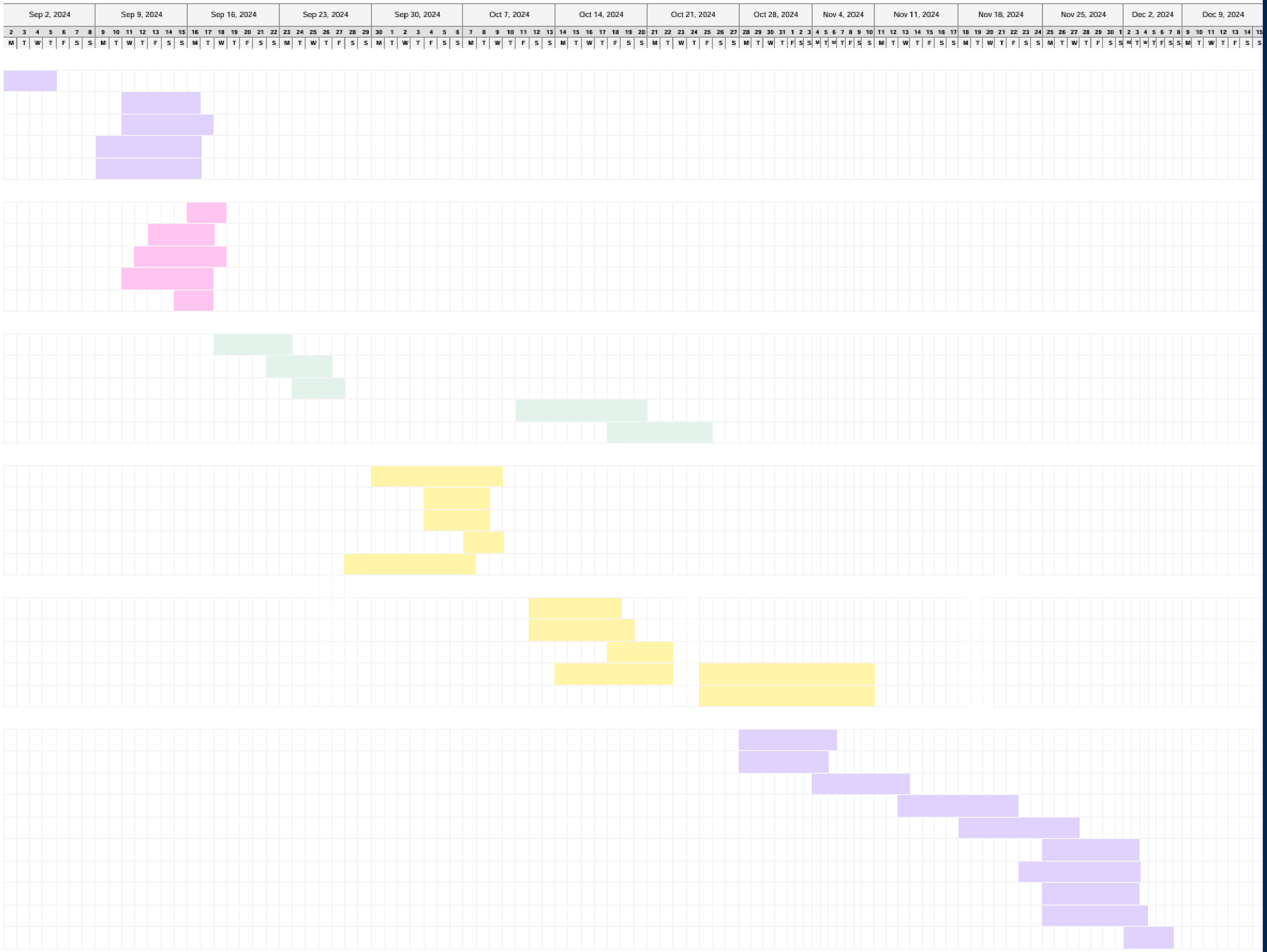
Density: 1.37 g/mL
Cost: $10
Viscosity: Similar, but depends on composition

Prototyping:

- Cost effective
- Simple to make
- Extreme case of blood thickness
- Limited mess/procedure for use

Cost estimates provided by www.amazon.com

TASK	ASSIGNED TO	PROGRESS	START	END
Research				
Role Definition	All	100%	9/2/24	9/5/24
Mathematical Model	All	100%	9/11/24	9/16/24
Benchmarking	Scott and Gavin	100%	9/11/24	9/17/24
Technical Roles	All	100%	9/9/24	9/16/24
Literature Review	All	100%	9/9/24	9/16/24
Presentation - 1				
Schedule	Jamie and Scott	100%	9/16/24	9/18/24
Budget	Jamie	100%	9/13/24	9/17/24
Slides	All	100%	9/12/24	9/18/24
QFD	Gavin and James	100%	9/11/24	9/17/24
Benchmarking	Scott and Gavin	100%	9/15/24	9/17/24
Analysis & Report - 1				
Materials Research	All	100%	9/18/24	9/23/24
Cost Analysis	All	100%	9/22/24	9/26/24
Integrating with Des	All	100%	9/24/24	9/27/24
Report - 1	All	100%	10/11/24	10/20/24
Website Check #1	All	100%	10/18/24	10/25/24
Prototyping & Presentation - 2				
Presentation - 2 Cor	All	100%	9/30/24	10/9/24
Engineering Calcula	All	100%	10/4/24	10/8/24
Concept Generation	All	100%	10/4/24	10/8/24
Integrating all Conc	All	100%	10/7/24	10/9/24
Conceptual Design	All	100%	9/28/24	10/7/24
Test Ideas	All	100%	10/11/24	10/16/24
Gather Feedback (E	All	100%	10/12/24	10/18/24
Refine Process	All	100%	10/12/24	10/19/24
Optimize Design	All	100%	10/18/24	10/23/24
CAD Desigining	Gavin and Scott	100%	10/14/24	11/10/24
Prototype - 3D Printi	Jaime	100%	10/24/24	11/10/24
Final Deliverables				
Presentation - 3	All	100%	10/28/24	11/6/24
FMEA	All	100%	10/28/24	11/5/24
1st Prototype Demo	All	100%	11/4/24	11/13/24
Individual Analysis	All	100%	11/13/24	11/22/24
Report - 2	All	100%	11/18/24	11/27/24
Final BOM	Jaime	100%	11/25/24	12/3/24
Final CAD - Vessel	Scott	100%	11/23/24	12/3/24
Final CAD - Lesion I	Gavin	100%	11/25/24	12/3/24
2nd Prototype Demc	All	100%	11/25/24	12/4/24
Website Check #2	All	100%	12/2/24	12/7/24



Gore Calcified Vessel Team – Gantt Chart Fall Semester 2024

TASK	ASSIGNED TO	PROGRESS	START	END
Kickoff 486C Capstone				
Kickoff Meeting	All	100%	1/13/25	1/15/25
Project Management	All	100%	1/14/25	1/17/25
Eng. Model Summary	All	100%	1/17/25	1/23/25
Self-Learning/Individual Anal	All	100%	1/17/25	1/30/25
Team/Staff Meetings	All	100%	1/20/25	2/13/25
Hardware Status Update #1	All	100%	1/16/25	2/13/25
HSU #1 - 3D Printing Vessel	Jaime	100%	1/20/25	1/31/25
HSU #1 - Purchasing Materi	Jaime	100%	1/14/25	1/20/25
HSU #1 - CAD Changes/Up	Gavin & Scott	100%	1/13/25	1/19/25
HSU #1 - Assemble Parts/S	All	100%	1/16/25	2/13/25
HSU #1 - Instrumentation &	James	100%	1/23/25	1/30/25
67% Hardware Built				
Website Check #1	All	100%	2/14/25	2/27/25
Hardware Status Update #2	All	100%	2/27/25	3/6/25
HSU #2 - Prinitg Vessel/Le	Jamie	100%	2/14/25	2/26/25
HSU #2 - Purchasing Plan (1	All	100%	2/13/25	2/25/25
HSU #2 - Assemble (67%)	All	100%	2/13/25	2/25/25
HSU #2 - Instrumentation &	James	100%	2/18/25	2/25/25
Techinical Data Package	Gavin & Scott	100%	2/13/25	2/25/25
Team/Staff Meetings	All	100%	2/13/25	3/13/25
Spring Break (Team Reflecti	All	100%	3/10/25	3/14/25
100% Hardware Built				
Initiate Testing Plan	All	100%	2/28/25	3/10/25
UGRADs Registration	All	100%	3/1/25	3/6/25
Finalize Testing Plan	All	100%	3/10/25	3/21/25
Draft of Poster	All	100%	3/14/25	3/28/25
Hardware Status Update #3	All	100%	3/3/25	3/25/25
HSU #3 - Final Resin Prints	All	100%	3/3/25	3/25/25
HSU #3 - Assemble (100%)	All	100%	3/7/25	3/25/25
HSU #3 - Instrumentation &	James	100%	3/17/25	3/25/25
Initiate Testing Results	All	100%	3/31/25	4/9/25
Final Poster & PPT	All	100%	3/31/25	4/11/25
Final CAD Packet	All	100%	4/4/25	4/13/25
Final Deliverables				
Final Product Demo	All	100%	4/12/25	4/16/25
Final Testing Results	All	100%	4/14/25	4/16/25
Final Report	All	80%	4/16/25	4/18/25
Final Website Check	All	88%	4/17/25	4/19/25
Ops & Assembly Manual	All	67%	4/27/25	4/30/25
Client Handoff	All	75%	4/30/25	5/2/25
UGRADs Symposium	All	90%	4/23/25	4/25/25
GORE Presentation				
Client Presentation	All	80%	4/30/25	5/2/25

Gore Calcified Vessel Team – Gantt Chart Spring Semester 2025

5.1 Schedule

Fall Semester 2024 Schedule

Presentation – 1 (Research)

- Literature Review
- Benchmarking
- QFD

Presentation – 2

- Concept Generation, Evaluation and Selection
- CAD Modeling

Design Report – 1

Presentation – 3 (Design Proposal)

Prototyping Phase

- Prototyping Demonstrations 1 and 2

Design Report – 2

Spring Semester 2025 Schedule

Hardware Status Update - 1

- 33% build
- 85% purchased

Hardware Status Update - 2

- 67% build
- 100 % purchased

Hardware Status Update – 3

- 100 % build

Final Testing

Final Product Demonstration

Final Design Report

Gore Presentation

5.2 Budget

Item	Quantity	Price/Per	Total	Purchased/Mai	Vendor	Lead Time
Pump	1	$ 28.43	$ 28.43	Purchased	Amazon	3 Days
Variable Power Supply	1	$ 54.03	$ 54.03	Purchased	Amazon	3 Days
85A Filament	1	$ 56.15	$ 56.15	Purchased	Amazon	3 Days
SainSmart TPU	1	$ 53.78	$ 53.78	Purchased	Amazon	3 Days
Tubing	2	$ 7.63	$ 15.26	Purchased	Home Depot	1 Day
Cart/Platform	1	$ 94.50	$ 94.50	Purchased	Harbor Freight	1 Day
Tank	1	$ 46.39	$ 46.39	Purchased	PetSmart	1 Day
Arduino	1	$ 45.00	$ 45.00	Purchased	Amazon	2 Weeks
Lession Adhesive	2	$ 5.19	$ 10.37	Purchased	Amazon	3 Days
One way Inlet	1	$ 9.86	$ 9.86	Purchased	Amazon	2 Weeks
Artery Stand	1	$ 16.38	$ 16.38	Manufactured	In House	1 Week
Blood Analog	1	$ 36.30	$ 36.30	Purchased	3B Scientific	3 Weeks
Syringes	1	$ 16.37	$ 16.37	Purchased	Amazon	2 Weeks
50A Resin	1	$ 200.00	$ 200.00	Purchased	Amazon	2 Weeks
Pressure Transducer	1	$ 275.75	$ 275.75	Purchased	Utah Medical	3 Weeks
2pc Microcontroller	2	$ 20.62	$ 41.24	Purchased	Amazon	2 Weeks
Flow Sensor	2	$ 10.36	$ 20.72	Purchased	Amazon	2 Weeks
55D TPE Filament	1	$ 25.99	$ 25.99	Purchased	Amazon	2 Weeks
40D TPU	1	$ 56.15	$ 56.15	Purchased	Amazon	3 Weeks
Vessels	12	-	-	Manufactured	In House	On going
LCD Screen	1	$ 11.99	$ 11.99	Purchased	Amazon	1 Week
Dupont Wire	1	$ 6.98	$ 6.98	Purchased	Amazon	1 Week
Battery Holder	2	$ 8.28	$ 16.56	Purchased	Amazon	1 Week
Breadboards	1	$ 8.79	$ 8.79	Purchased	Amazon	1 Week
AnyCubic Photon Mono 5S Pro	2	$ 102.00	$ 204.00	Purchased	Amazon	1 Week
Arduinos	4	$ 16.99	$ 67.96	Purchased	Amazon	1 Week
Elastic 50A Resin V2	5	$ 217.17	$ 1,085.84	Purchased	FormLabs	2 Weeks
Super FLex Resin	2	$ 54.67	$ 109.33	Purchased	Amazon	1 Week
Hose Fittings 1/4"	6	$ 2.91	$ 17.44	Purcahsed	Amazon	1 Week
Hose Fittings 3/16" to 1/4"	10	$ 1.53	$ 15.27	Purchased	Amazon	1 Week
Hose Fittings 3/16"	10	$ 1.05	$ 10.47	Purchased	Amazon	1 Week
Blood Analog	1	$ 30.51	$ 30.51	Purchased	Amazon	1 Week

One way inlet valve	6	$ 10.91	$ 10.91	Purchased	Amazon	1 Week
One way inlet valve	5	$ 20.73	$ 20.73	Purchased	Amazon	1 Week
Platform for cart	1	$ 10.00	$ 10.00	Purchased	Amazon	1 Week
Electronics Housing	1	$10	$10	Manufacturing	In House	2 Weeks
Force Gauge	1	$ 36.98	$ 36.98	Purcahsed	Amazon	2 Days
Durometer	1	$ 29.99	$ 29.99	Purcahsed	Amazon	2 Days
Cleaning supplies	1	$ 30.00	$ 30.00	Purchased	Walmart	1 Day
4PCS Breadboards Kit 2PCS	1	$ 12.32	$ 12.32	Purcahsed	Amazon	2 Days
Hosyond 3pcs I2C LCD Display	1	$ 7.56	$ 7.56	Purcahsed	Amazon	2 Days
ELEGOO 120pcs Dupont Wire	1	$ 3.41	$ 3.41	Purcahsed	Amazon	2 Days
Gikfun 9v Battery Holder ON/Off	1	$ 60.30	$ 60.30	Purcahsed	Amazon	2 Days
Filament	3	$ 20.00	$ 60.00	Purcahsed	Amazon	2 Days
Tile Cock	1	$ 10.00	$ 10.00	Purcahsed	Amazon	2 Days
Screws	8	$ 2.00	$ 16.00	Purcahsed	Amazon	2 Days
Towels	2	$ 20.00	$ 20.00	Purcahsed	Walmart	1 Day
Funnel	1	$ 12.00	$ 12.00	Purcahsed	Walmart	1 Day
Wash and Cure Station	1	$ 86.79	$ 86.79	Purcahsed	Amazon	1 Week
Isopropynol Alcohol	3	$ 22.12	$ 66.36	Purcahsed	Walmart	1 Day
Glycerin	1	$ 37.82	$ 37.82	Purcahsed	Amazon	1 Week
Leur Connectors	5	$ 13.12	$ 13.12	Purcahsed	Amazon	2 Days
Peristaltic Pump	1	$ 53.28	$ 53.28	Purcahsed	Amazon	1 Week
Gloves	30	$ 1.02	$ 30.54	Purcahsed	Amazon	1 Week
Callippers	1	$ 21.92	$ 21.92	Purcahsed	Amazon	2 Days
Miscellaneous parts	-	$ 11.00	$ 11.00	Purcahsed	All over	-

Client Budget	$ 3,000.00
Fundraising	$800
Total	$ 3,800.00
Remaining	$ 441.16

5.3 Bill of Materials (BOM)

Item	Quantity	Price/Per	Total	Purchased/Manufactured	Vendor	Lead Time
Artery Stand	12	$ 1.37	$ 16.38	Manufactured	In House	1 Week
Blood Analog	2	$ 18.15	$ 36.30	Purchased/Manufactured	3B Scientific	3 Weeks
Vessels	12	-	-	Manufactured	In House	1 Week
Platform for cart	1	$ 10.00	$ 10.00	Purchased/Manufactured	Amazon	1 Week
Electronics Housing	1	$10	$10	Manufacturing	In House	2 Weeks
Electronics System	1	-	-	Manufactured	In House	3 Weeks
Tubing System	1	-	-	Manufactured	In House	1 Week
Pressure Transducer Wiring	2	-	-	Manufactured	In House	1 Week
More vessel Designs	2	-	-	Manufacturing	In House	2 Weeks
Housing Updates	1	-	-	Manufacturing	In House	2 Weeks
Additional stands	1	-	-	Manufacturing	In House	2 Weeks

For one unit: each of these would need to be included

6.1 Failure Modes

Connector Decoupling:

- Happens when pressure exceeds operating limits in the system
- Potential causes - clogged tubing, closed outlet valve, or too high of a flow rate.
- Mitigation includes a correct and detailed operation manual along with ensuring the outlet valve is open before use.

Vessel Rupture

- Caused by 3D print defects in vessel
- Potential causes – Stent balloon inflation pressure, similar pressure accumulation to the connector issue
- Mitigation includes visual inspection of each vessel before installing into the system as well as same precautions for previous failure mode

6.2 Initial Prototyping

Lesion/Vessel Model Prototype

Question:

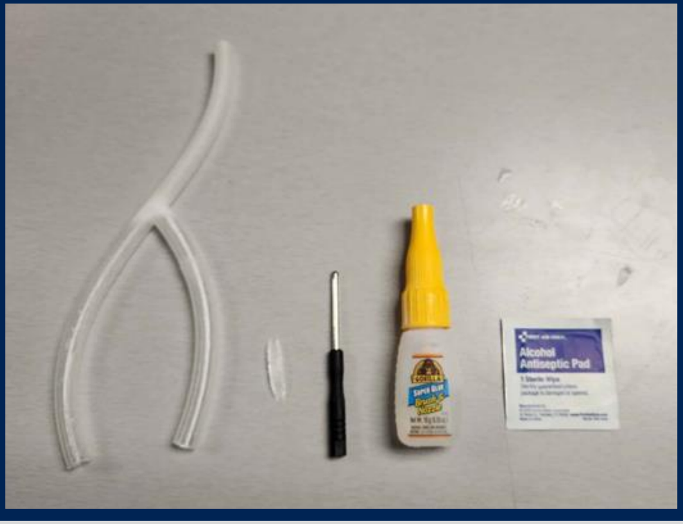
- Do FDM-printed vessel models meet design requirements for wall thickness, diameter, surface quality, and flexibility?
- Can they form successful adhesive bonds to lesion models under simulated use conditions?

Answer:

- Vessel models printed with TPU filament have accurate dimensions and surface quality but are not as flexible or as watertight as real arteries.
- The adhesive bond was successful but had gaps in adhesion and weakened with water exposure.

Recommendation:

- Use SLA printing with flexible resin to meet design requirements.
- Use waterproof cyanoacrylate superglue optimized for plastic substrates, with high viscosity for gap-filling.



Adhesive Application Materials

Model of Lesion Adhered to Vessel

6.2 Initial Prototyping

Arduino and Sensor Prototype

Question:

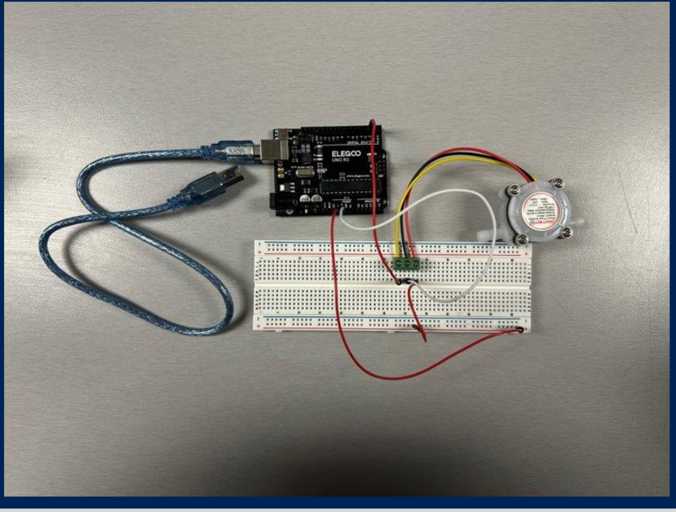
- Will the chosen sensors be able to read accurate data from the system?

Answer:

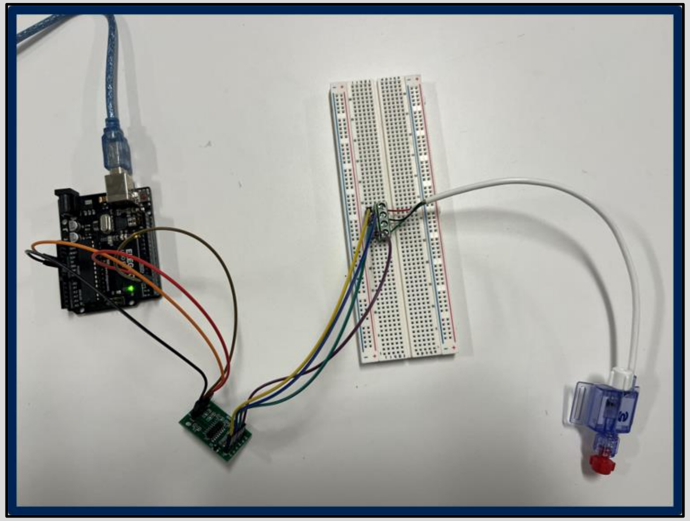
- The Arduino computing module coupled with the sensors collected accurate and meaningful data from the system. One issue is this prototype requires a laptop to see the date

Recommendation:

- Implement these sensors into the system with the addition of LCD displays to print the data to. This will remove the need for the data acquisition laptop.



Flow Sensor circuit



Pressure Transducer Circuit

6.3 Other Engineering Calculations

SLA Resin Material Properties

- Hoop strain to restore unoccluded vessel area (50% degree of vessel occlusion):

$$\varepsilon_h = \frac{2\pi \cdot \Delta r_1}{2\pi \cdot r_1} = \frac{\Delta r_1}{r_1} = \frac{0.674\ mm}{3\ mm} \approx 0.225$$

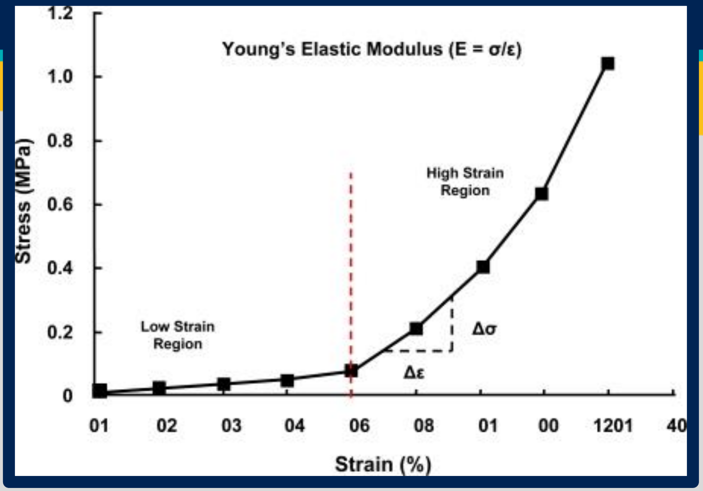
- Maximum hoop stress of internally-pressurized thick-walled cylinder (external pressure is zero gauge):

$$\sigma_h = \frac{P_i(r_1^2 + r_2^2)}{r_2^2 - r_1^2} = \frac{P_i\left((3\ mm)^2 + (4\ mm)^2\right)}{(4\ mm)^2 - (3\ mm)^2} = 3.57P_i$$

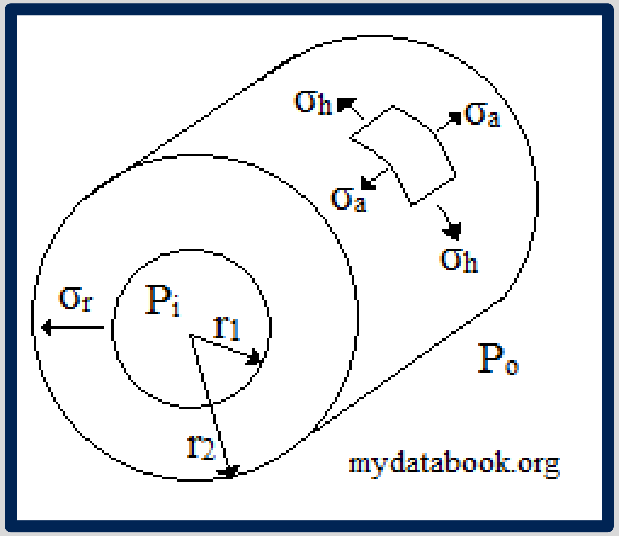
- Elastic modulus of FormLabs Elastic 50A Resin V2: 1,800 kPa

$$E = \frac{\sigma_h}{\varepsilon_h} \rightarrow 1{,}800\ kPa = \frac{3.57P_i}{0.225} \rightarrow P_i = 113\ kPa$$

- Elastic modulus falls within acceptable range of real artery elastic moduli of 1,500-6,500 kPa
- Internal pressure falls within operational limits of 24 kPa due to blood pressure and 1620 kPa due to maximum pressure of angioplasty balloons



Stress-Strain Curve of an Artery



Internally-Pressurized Thick-Walled Cylinder

6.3 Other Engineering Calculations

Volume of Filament:

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

$$Interior\ Volume = \frac{d^2\pi L}{4} = \frac{6^2 * \pi * 12.4}{4} = 350.601\ mm^3$$

$$Volume\ of\ Hollow\ model = Solid\ Volume - Inner\ Volume = 623.29\ - 350.601 = 272.69\ mm^3$$

Length of Filament Required:

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

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

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

6.3 Other Engineering Calculations

Yield Strength

The stress level where the blood vessel wall begins to deform plastically (no return).

Mechanical Properties – Femoral Artery

d = 7 to 8 mm (outer diameter)

r = 3.5 to 4 mm (radius)

p = 200 mmHg (w/ peripheral arterial disease)

t = 1 mm (wall thickness)

Yield strength of filament: 0.8 MPa = 800 kPa;
We will design our vessel to not exceed the hoop stress value of 93.45kPa to ensure zero plastic deformation of the vessel.

Hoop Stress (Circumferential)

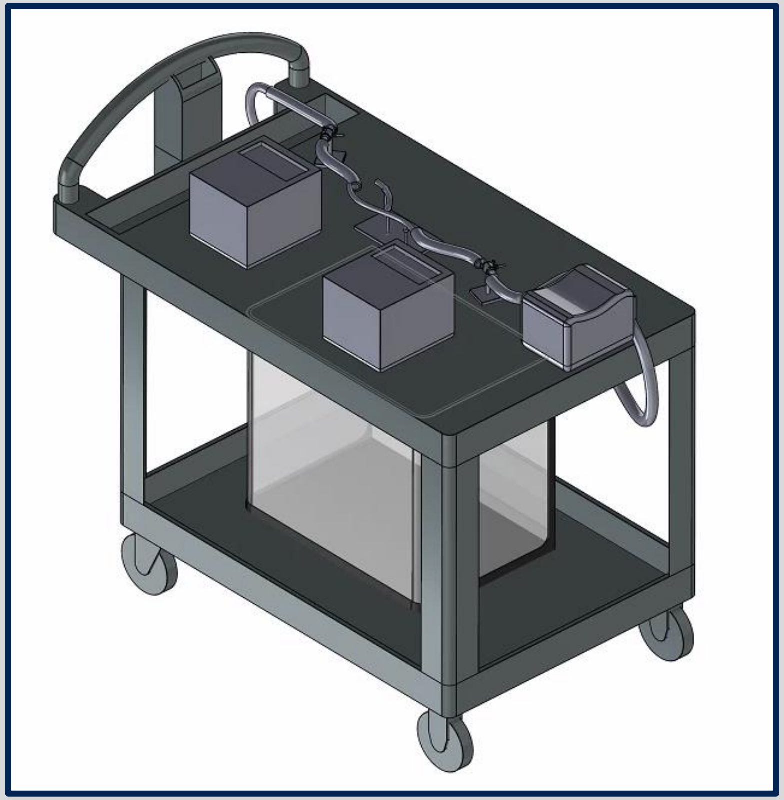
p = internal pressure
t = wall thickness
r = inside radius
D_m = mean diameter
σ = hoop stress

D_m = d - t = 8mm – 1mm = 7mm

σ = p*D_m /(2*t)
σ = [(26.7kPa)*(0.007m)] /(2*0.001m)

σ = 93,450 Pa or 93.45kPa
$(\sigma)_{axial}$ = 46,725 Pa or 46.73 kPa

7.1 Design Summary

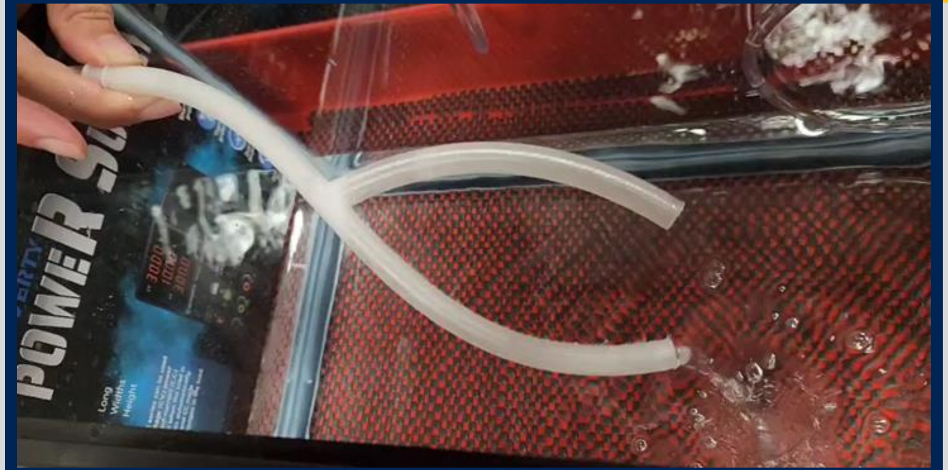


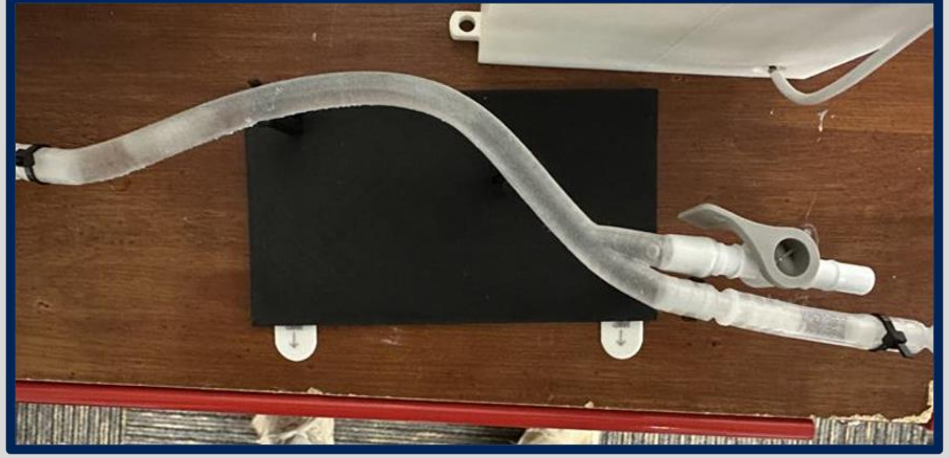
Final CAD – Complete Assembly

Final Product – Complete Assembly

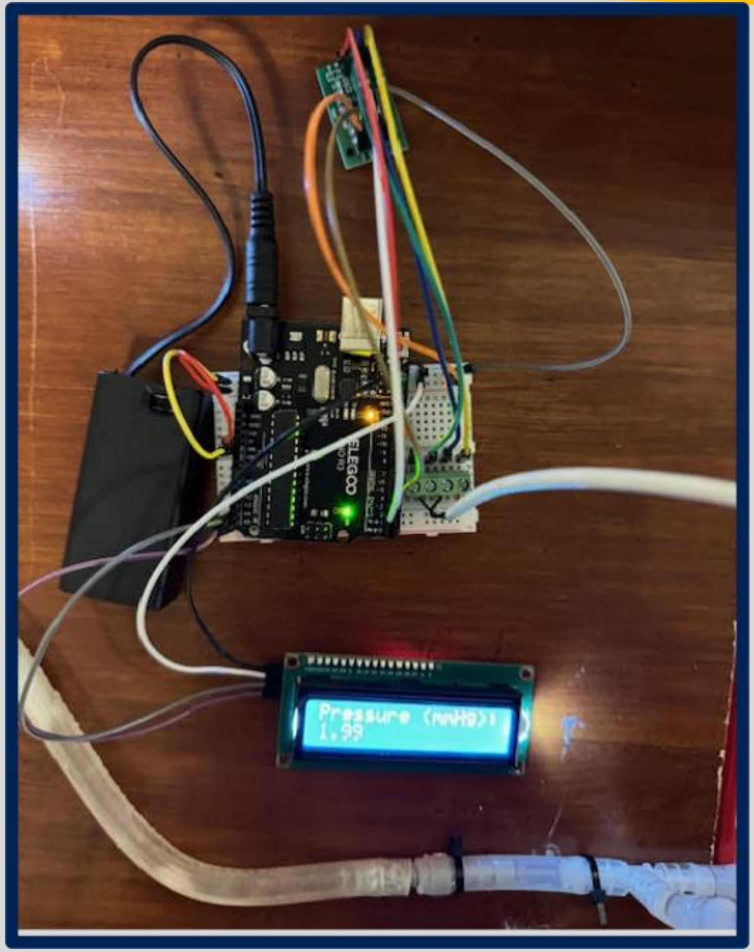
7.1 Design Summary

- A vessel model is SLA printed from FormLabs Elastic 50A Resin V2 is connected to plastic tubing to pressure transducers and flow sensor
- A lesion model is FDM printed from 90A TPU filament, and is adhered to a prepared surface inside the vessel model using 3M Scotch-Weld PR1500 cyanoacrylate adhesive
- Vessel is translucent to see the lesion model as well as device deployments
- Vessel is raised to a constant level with printed (PLA) stands
- Peristaltic pump delivers blood analog through the vessel for simulated use conditions





7.1 Design Summary



Pressure Transducer Circuit

- Two pressure transducers are connected to the system to monitor flow conditions
- An Arduino computing module and LCD screen are coupled to each sensor to show the user the data
- All the circuitry and electronics are housed within a box to avoid any water leaking onto them
- The sensors have been calibrated to ensure the user displays accurate data while operating

Pressure Transducer Display

Top Level Testing

Experiment/Test	Relevant DRs	Testing Equipment Needed	Other Resources
EXP1 – Measurement Test	CR2 – Models Simulated Use Conditions ER2 – Vessel Dimensions ER4 – Lesion Dimensions	Caliper Protractor	Vessel & lesion model samples
EXP2 – Hardness Test	CR2 – Models Simulated Use Conditions ER3 – Lesion Properties	Digital Durometer	Lesion model sample
EXP3 – Adhesion Strength Test	CR2 – Models Simulated Use Conditions ER3 – Lesion Properties	Digital Force Gauge	Testing stand Vessel & lesion model samples Adhesive
EXP4 – Fluid Flow Rate Test	CR2 – Models Simulated Use Conditions ER5 – Fluid Properties	Stopwatch Graduated cylinder	Pump and flow rate sensor
EXP5 – Fluid Pressure Test	CR2 – Models Simulated Use Conditions ER1– Vessel Properties	Pressure Transducer Blood Pressure Kit (Balloon, analog gauge)	Vessel model

Top Level Testing

Experiment/Test	Relevant DRs	Testing Equipment Needed	Other Resources
EXP6 – Fluid Viscosity Test	CR2 – Models Simulated Use Conditions ER5 – Fluid Properties	Meterstick High speed camera Stopwatch Scale Graduated cylinder	Ball Testing fluid
EXP7 – Additive Manufacturing Test	CR1 – Replicability	Resin 3D printer	Possibly another model printer
EXP8 – Visual Inspection Test	CR3 – Non-Biological Materials CR4 – OSHA/ANSI Compliant CR5 – Visualization of Deployment ER6 – Engineering Standard Compliant ER7 – Manufacturing Cost	N/A	N/A
EXP9 – Product Demonstration Test	CR6 – Durability CR7 – Ergonomic for Intended Use	N/A	Power supply Fluid supply Testing room

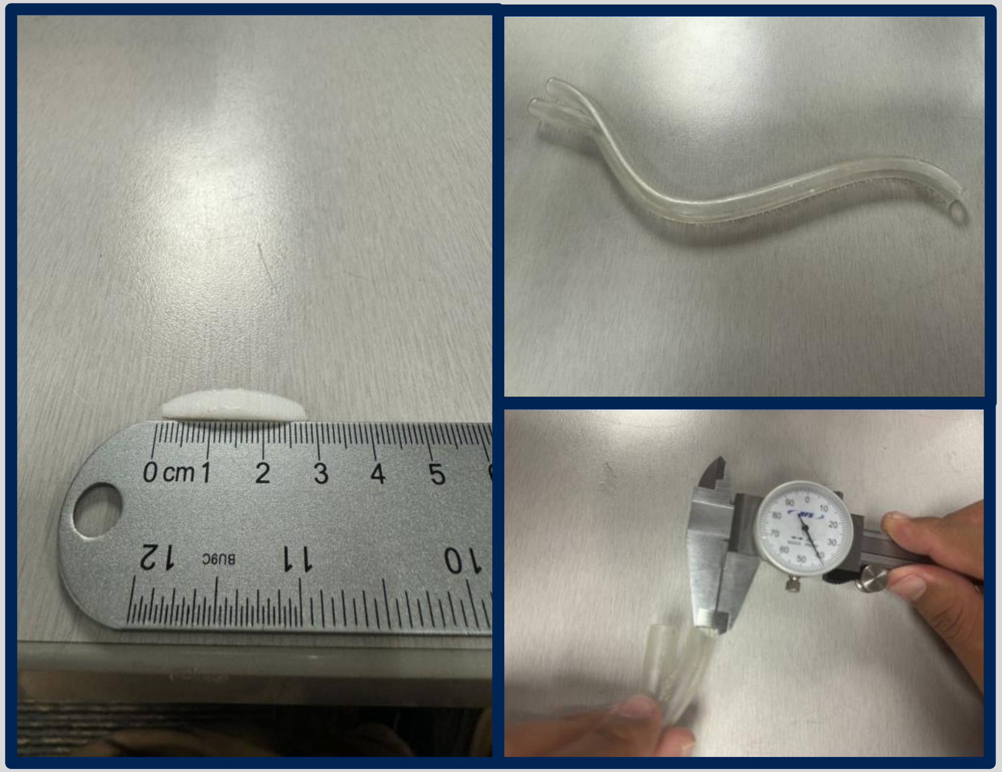
8.2 Testing Plan

Measurement Test
This test will answer whether the final product accurately models the dimensions of the vessel site and calcified lesions.

- CR2 – Models Simulated Use Conditions
- ER2 – Vessel Dimensions
- ER4 – Lesion Dimensions

Equipment: caliper, ruler, and protractor
Measurement: vessel and lesion dimensions

Testing Procedure:
A team member will use the dial caliper to measure length, wall thickness, and diameter of vessel model, and the length and thickness of the lesion model.



Measurement Testing

8.2 Testing Plan

Lesion Measurement Test

Results:

Target:

3 cm length

3 mm thickness

50% occlusion

Actual:

2.8 cm length

3.3 mm thickness

45% occlusion

Vessel Measurement Test

Results:

Target:

>20 cm length

1 mm wall thickness

8 mm diameter

Actual:

21.2 cm length

1.04 mm wall thickness

7.81 mm diameter

8.2 Testing Plan

- Testing the fluid flow properties within the system
- CR2 – Simulates use conditions ER5 – Fluid properties
- Graduated cylinder and stopwatch for flow rate
- Pre calibrated pressure gauge to validate fluid pressure

Flow Test Procedure

- Run the system and allow for flow to develop
- Aim the outlet into the graduated cylinder
- Time how long it takes to fill the cylinder
- Repeat 3 times and take average
- Divide the volume by the average tie to get the volumetric flow rate

Fluid Flow and Pressure Test Materials

Pressure Test Procedure

- Connect the bulb to tubing leading to 3-way connector
- Connect pressure transducer to one other end and pressure gauge to the third end
- Use balloon to pressurize tubing and pressure transducer
- Record the gauge value and the transducer value
- Get a series of points at varying pressures
- Get calibration curve values and adjust code to match
- Test again at minimum 3 values to confirm calibrated

Testing Plans

Fluid Flow and Pressure Test Materials

Flow Rate Test

Results:

Target:

500 ml/min

Actual:

483 ml/min

Pressure Test

Results:

Target:

180 mmHg

Actual:

174 mmHg

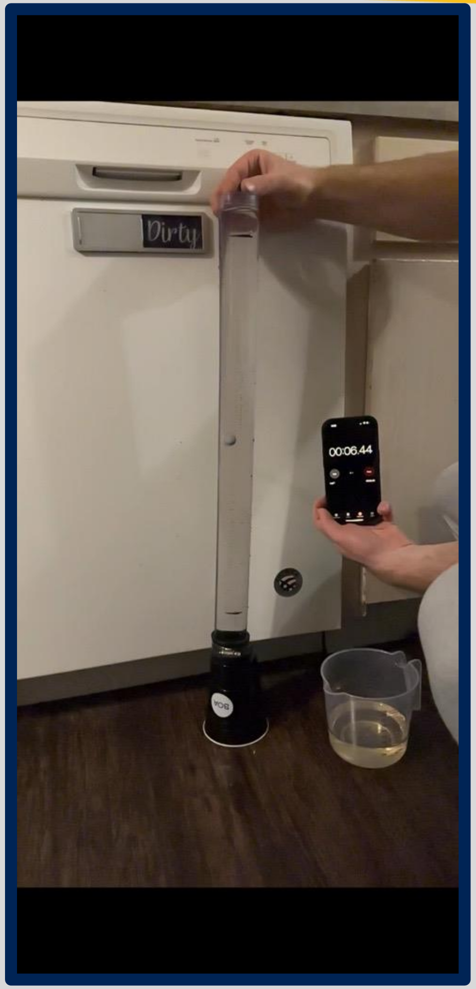
Pressure Transducer 1

	analog (mmHg)	measured (mmHg)
1	0	0.66
2	100	98.4
3	120	119.4
4	140	139.1
5	160	158.7
6	180	178.5
7	200	196.7

Pressure Transducer 2

	analog (mmHg)	measured (mmHg)
1	0	1.55
2	100	99.8
3	120	119.2
4	140	139.27
5	160	158.3
6	180	177.86
7	200	198.7

8.2 Testing Plan



Viscosity Test

- Testing the fluid properties
- CR2 – Simulates use conditions ER5 – Fluid properties
- Ball drop test designed for the expected viscosity range

Materials:

- Tube full of the fluid
- Sphere to drop through the fluid
- Stopwatch to time the descent
- Slow-motion camera to assist in timing

$$Viscosity = \frac{2(\rho_b - \rho_f)gr^2}{9v}$$

Results:

A mixture of 54% glycerin and 46% water yields a viscosity of 4.5 centipoise

Procedure:

- Mark 50 cm on the tube
- Determine density of the sphere and fluid
- Fill tube with the fluid
- Hold a stopwatch in view of the camera
- Drop the ball while filming with the slow-motion camera
- Analyze the video to get the most accurate time
- Repeat three times and take the average time
- Use the average time in the equation to the left to obtain the fluid viscosity

8.2 Testing Plan

Hardness Test

Summary

- Use digital durometer to measure indentation hardness of lesion model

Procedure

- Press durometer probe into lesion model with 10 N of force, wait 1 second, record display value, repeat twice at different locations, calculate average hardness value

Results

- 91 Shore A measured
- 90 Shore A expected

Adhesion Strength Test

Summary

- Use digital force gauge, vessel and lesion models, and adhesive to measure overlap strength of adhesive bond

Procedure

- Apply adhesive to 5x5 mm square on model, press models together, allow to cure, attach force gauge, pull slowly until adhesive failure occurs, repeat twice, calculate average peak force value

Results

- 5.7 MPa measured
- 13.8 MPa expected

8.3 Finalized Specification

Customer Requirement	CR Met? (✓ or ✗)	Client Acceptable? (✓ or ✗)
CR1 – Replicability	✓	✓
CR2 – Models Simulated Use Conditions	✓	✓
CR3 – Non-Biological Materials	✓	✓
CR4 – OSHA/ANSI Compliant	✓	✓
CR5 – Visualization of Deployment	✓	✓
CR6 – Durability	✓	✓
CR7 – Ergonomic for Intended Use	✓	✓

8.3 Finalized Specification

Engineering Requirement	Target	Tolerance	Measured/Calculated Value	ER Met? (✓ or ✗)	Client Accceptable? (✓ or ✗)
ER1 – Vessel Properties	11-17 kPa pressure	zero	15.3 kPa	✓	✓
	>50% opacity	zero	79% opacity	✓	✓
ER2 – Vessel Dimensions	>20 cm length	zero	21.2 cm length	✓	✓
	1 mm wall thickness	±5%	1.04 mm wall thickness	✓	✓
	8 mm diameter	±5%	7.81 mm diameter	✓	✓
ER3 – Lesion Properties	90HA durometer hardness	±6HA	91HA	✓	✓
	15.2 MPa overlap adhesive shear strength	±3.6 MPa	5.7 MPa	✗	✓
ER4 – Lesion Dimensions	3 cm length	±10%	2.8 cm	✓	✓
	3 mm thickness	±10%	3.3 mm	✓	✓
	50% vessel occlusion	±10%	45%	✓	✓
ER5 – Fluid Properties	500 mL/min flow rate	±5%	483 mL/min	✓	✓
	3.5-5.5 cP viscosity	±5%	4.48 cP	✓	✓
	180 mmHg pressure	±5%	174 mmHg	✓	✓
	1060 kg/m^3 density	±5%	1128 kg/m^3	✗	✓
ER6 – Engineering Standard Compliant	100%	zero	100%	✓	✓
ER7 – Manufacturing Cost	<$3,800	zero	$3,600	✓	✓

8.3.1 Product Demo

9.1 Future Work

- Iterate upon the vessel design to model more complex designs
- Design and manufacture models of specific medical scenarios
- Streamline the electronics and display outputs into one circuit
- Iterate upon the blood model to achieve more accurate fluid properties while maintaining translucency
- Communicate with clients earlier and more frequently about vessel design and troubleshooting tools to effectively print complex geometries
- Next steps include handing the product over to client with instructions and all versions of model
- Present to Gore engineers to discuss process and the discoveries made within the project
- Practice the implementation of the devices and model

Thank You!