Presentation 3
Design Proposal

Calcified Vessel Model Team

ME 476C-002

11/6/2024

NAU NORTHERN ARIZONA UNIVERSITY

Project Description

Client:

W.L. Gore & Associates, Inc.
Medical Division

Project Scope:

The scope of this project is to design, build, and test a replicable (12 count) model of calcified lesions in the Peripheral Arterial System for deployment of peripheral vascular interventional devices under simulated use conditions, using non-biologic materials.

Significance of the Project:

Vascular intervention devices are crucial for treating peripheral arterial disease(s) by restoring blood flow, reducing symptoms, and preventing severe complications through intervention care.

Figure 1 – Gore Logo

Project Description

Peripheral Arterial Disease:
Narrowing of arteries that reduces blood flow to the limbs. Caused by buildup of plaque (fat and cholesterol) on inner arterial walls.

Calcified Lesion:
A buildup of calcium-based mineral deposits in arterial plaque, hardening artery walls.

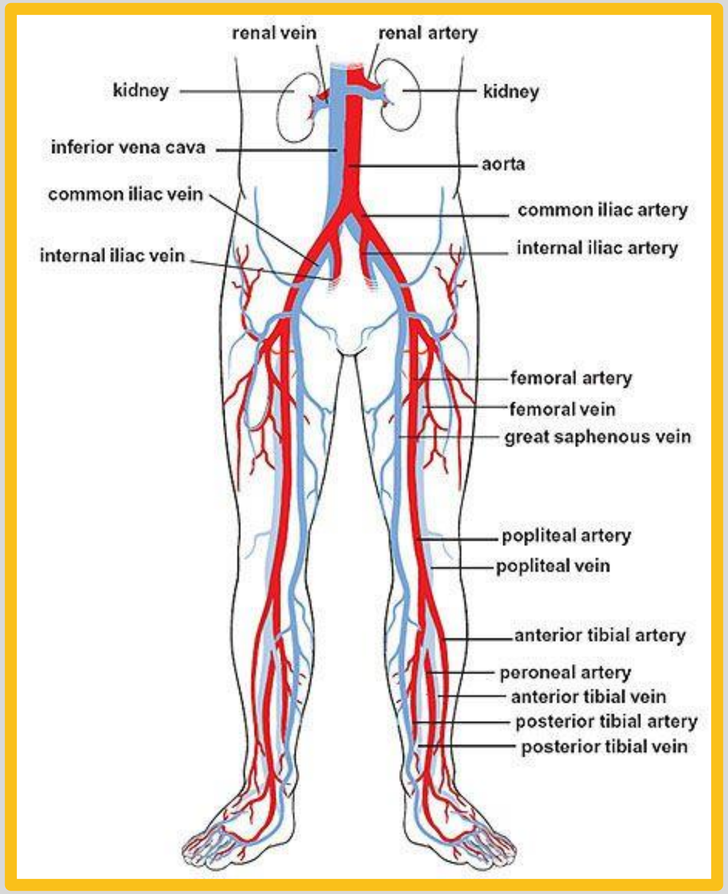

Figure 2 – Peripheral Artery System

Design Requirements

Customer Requirements:

- Replicability
  - Product can be manufactured by Gore
- Models simulated use conditions
  - Accurately models vessel and lesion
- Non-Biological materials
  - Entirely synthetic model
- OSHA/ANSI compliance
  - For safety when operating
- Visualization of deployment
  - For demonstration purposes
- Durability
  - Able to be used for many tests
- Ergonomic for intended use

Engineering Requirements:

- Vessel properties
  - Synthetic vessel to have same elasticity and strength as biological lesion
- Vessel dimensions
  - Synthetic vessel dimensions to fit stent
- Lesion properties
  - Synthetic lesion to have same hardness and adhesion to wall as biological lesion
- Lesion dimensions
  - Accurately represent lesion shape
- Fluid properties
  - Accurately represent blood
- Engineering standard compliance
  - Product must be safe
- Manufacturing cost
  - Under total budget of $3,000

Design Requirements: QFD

System QFD

Project: **Calcified Vessel Model**
Date: 9/11/ 2024

#		1	2	3	4	5	6
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	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 (HS)	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 HS	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

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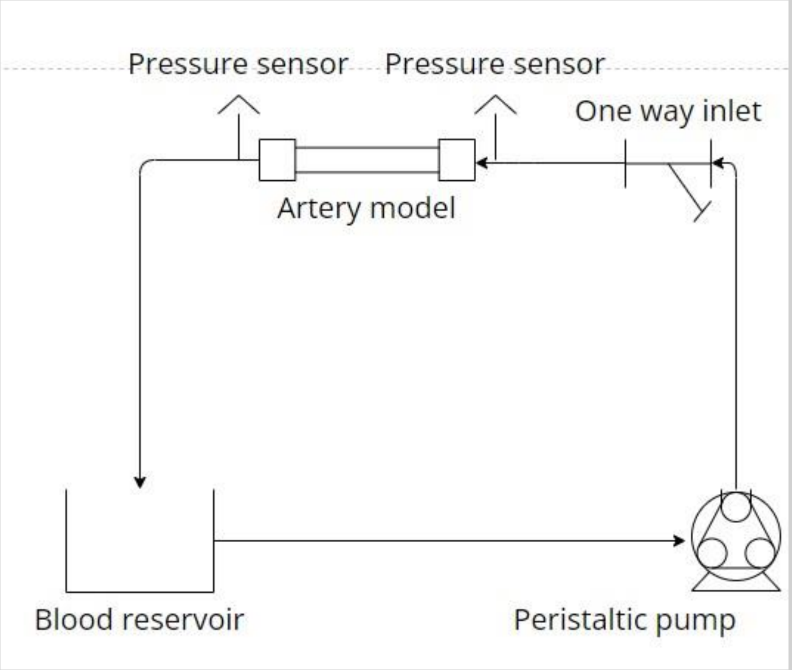
Design Description

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



Pipe Flow Diagram

Hierarchy:

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

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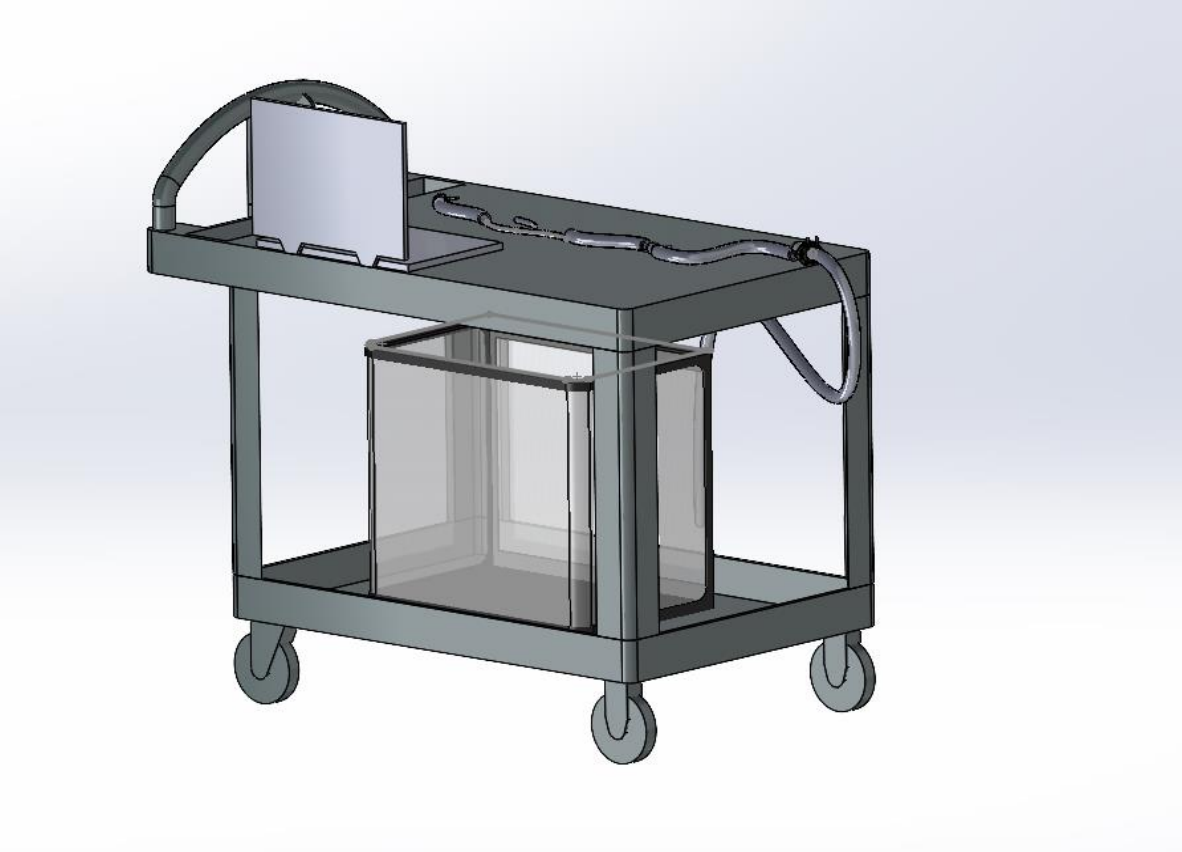
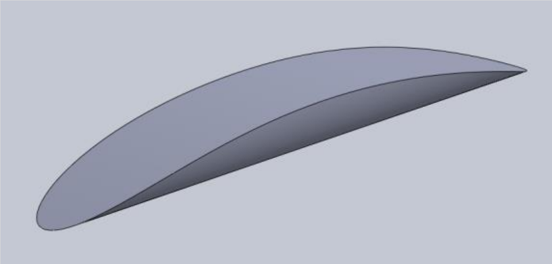
Design Description: Current State of Design





Lesion:
Large
Medium
Small

Vessel:
8 inch
7 inch
6 inch

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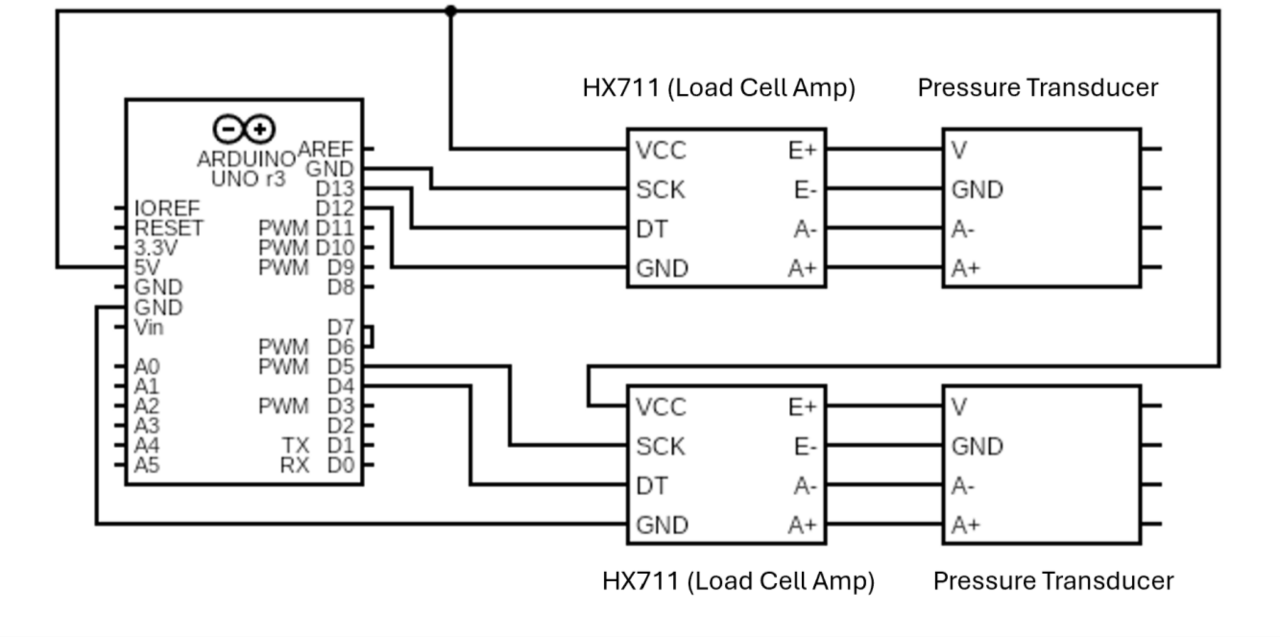
Design Description



Circuit Diagram for Pressure Transducers

Engineering Calculations: Calcified Lesions

- Used engineering calculations to determine which PAD states to model.
- Performed A/B test to determine statistical significance of each factor influencing stent expansion (intended use of model).
- From EuroIntervention study: 133 operations on calcified lesions [13]
    - Calcified lesion thickness, length, and degree of vessel occlusion recorded
    - State of stent expansion recorded
- Concluded that calcified lesion thickness >0.5 mm, length >5 mm, and degree of vessel occlusion >50% are statistically significant predictors of incomplete stent expansion.
- The CVM will represent mild, moderate, and severe PAD states, based on these critical values, to represent its full range of simulated use conditions.

Engineering Calculations: Calcified Lesions

Minimum adhesion strength due to blood flow:

$$P_{min} = F/A$$

$$F = (1/2)Q\rho v \text{ [2]}$$
$$A = (1/2)\pi dL$$

$$Q = 8.183 \times 10^{-6}\, m^3/s \text{ [3]}$$
$$\rho = 1060\, kg/m^3 \text{ [4]}$$
$$v = 0.2894\, m/s$$
$$d = 0.006\, m \text{ [5]}$$
$$L = 0.050\, m$$

- Assume maximum volumetric flow rate of blood in femoral artery
- Assume calcified lesion is perfect half-cylinder of 6 mm diameter and 5 mm length
- Assume calcified lesion does not significantly obstruct blood flow

$$P_{min} = 26.63\, Pa$$

Engineering Calculations: Calcified Lesions

Part specifications for material hardness:

- 3D printer filament (TPU)
  - Shore 90A ≈ Shore 39D [6]
- Fired Ceramic
  - Mohs 4 ≈ Shore 44D [7]
- Steel (304)
  - HB 215 ≈ Shore 33D [8]
- Target
  - HV 274 ≈ Shore 39D [9]

Conversions provided by

- plantech.com
- www.efunda.com
- www.carbidepot.com

3D printer filament was selected as the lesion material, in part because it offers the most accurate hardness to the target value.

Engineering Calculations: Blood Vessel

Yield Strength

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

-Mechanical Properties – Femoral Artery [20]

d = 7 to 8 mm (outer diameter)

r = 3.5 to 4 mm (radius)

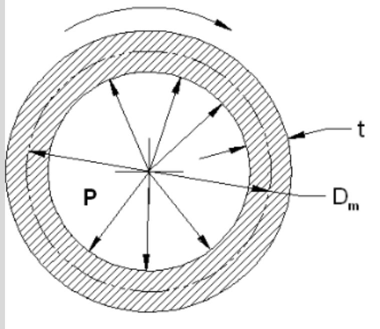
p = 200 mmHg (peripheral arterial diseased)

t = 1 mm (wall thickness)

Yield strength of filament: 0.8MPa = 800kPa
We will design our vessel to not exceed the hoop stress value of 93.45kPa for this will ensure no plastic deformation of the vessel.

- Hoop Stress (Circumferential) [22]

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



D_m = O.d. - t = 8mm – 1mm = 7mm

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

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

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Engineering Calculation: Filament

Volume:

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

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

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

Filament Required:

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

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

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

New Calculations Coming Up

Uncertainty

Differential Pressure

Flow Rate

Product Name Calcified Vessel Model		Development Team James Anteau, Gavin Lazurek, Jamie Dellwardt, Scott Alex	Page No 1 of 1
System Name			FMEA Number 1
Subsystem Name			Date 11/6/2024
Component Name			

Part # and Functions	Potential Failure Mode	Potential Effect(s) of Failure	Severity (S)	Potential Causes and Mechanisms of Failure	Occurance (O)	Current Design Controls Test	Detection (D)	RPN	Recommended Action
Power supply	Power Surge	Pump motor failure	10	Power supply failure	1	Thoroughly test the power supply	1	10	Select new power supply if first is faulty
	Shortage due to fluids	Fry electronics	10	Failure in other systems	3	Test system with protection of electronics	2	60	Ensure the layout of trhe final design minimizes the risk of fluids comeing in contact with this circuit
Pump	Airlock	Loss of pump function	7	Air trapped in piping system	5	Test system and priming procedure multiple times to see if an airlock occurs	3	105	Redesign pump priming system
	Motor failure	Loss of pump funtion, and potential perminant failure	7	Surge from power supply	1	Test system to see if power can excede limit	4	28	Install breaker into system
	Pressure variation from inproper voltage	Inaccurate pressure or tubing failure	4	Incorrect input from power source	1	Test operations of model	5	20	Create detailed instructions so the user can avoid this error
Connector tubing	Decoupling	Flow will stop and fluid will spray from the failure point	10	Tubing could decouple from pressure	3	Test the system above the expected pressure range	2	60	Rethink coupling choice
Vessel stand	Manufacturing issue	Vessel model will be unstable	6	3D printing defects	1	Test visually while system is operating	1	6	Evaluate for improvements and refine design
Vessel model	3D print error	Vessel model will not hold the fluid pressure	10	3D printing defects	1	Test visually with a water flow system prior to implementing into the blood substitute system	1	10	Omptimize for a watertight design adding fillets and chamfers at corners to reduce stress concentration in those areas
						Test visually with a water flow system			Use post processing

	Rupture from pressure	Vessel model will leak and not hold pressure	10	3D printing defects	1	to ensure an air tight seal is present.	1	10	methods like sealant material and allow for adequate curing times
Pressure sensors	Uncertain readings	Uncertainty is outside acceptable range	2	Human, calibaration, device malfunction, reading	3	Test with calculations	1	6	Have a preddicted value range before testing to make sure number is reasonable
	Pressure range exceeded	Sensor will break, potential fluid	7	Pump failure could lead to this failure.	2	Test pressure sensors with the presure range used	3	42	Select new pressure transducers if necesary
Arduino module	Soldering defects	The load cell amplifier chip will not work	5	Frying the chip while soldering is quite common	5	Test the sensor and chips after soldering.	1	25	Make sure to test for functionlity of the sensors before installation.
	Exceeds current capabilities	Arduino unit will be fried and unusable	5	If input power for Arduino exceeds its opperating range	2	Test operations of model	5	50	Ensure the re are safety measures in place to keep this from occuring
Flow sensor	Uncertain readings	Uncertainty is outside acceptable range	2	Human, calibaration, device malfunction, reading	3	Test with calculations	1	6	Have a preddicted value range before testing to make sure number is reasonable
	Unintentional build up	Flow sensor will not work	4	Sediment in blood mixture	3	Test the blood solution for any large particles before use.	1	12	Strain blood solution before use
Blood tank	Hose decoupling from tank	Fluid would pourout of tank onto the cart	9	Hose not secured correctly to the tank	3	basic teasting of the system will show the failure	1	27	Rethink coupling choice
Lesion model	Separation from vessel model	Ejection of lesion model, partial obstruction of fluid flow	6	Low substrate surface energy, improper surface preparation	3	Testing an adhered lesion can withstand its maximum expected shear force	2	36	Select an adhesive compatible with substrates; improve surface preparation procedures
Cart	Breaking	Damage electronics and model if it collapses	5	Joints disconnect, wheels break, water damage	1	Inspect cart before use	1	5	Inspect cart before use, build ourselves
	Water Compromised	Ruin electronics	6	Water overflow, disconnected tubing, leak in vessel	3	Test other systems	1	18	Keep electronics in safety box, inspect all components before each test

Design Validation: Testing Procedures

Calcified Lesion Dimensions:

- Distance and angle measurements – length, thickness, degree of vessel occlusion
  - Calipers, protractor

Calcified Lesion Properties:

- Durometer hardness test – hardness
  - Shore A durometer; ASTM D2240 [10]
- Overlap shear strength test – adhesion strength
  - Universal testing machine & software, load cell, side-action grips; ASTM D1002 [11] (unrealistic with this budget)
  - May need to rely on product's technical data sheet

Design Validation: Testing Procedures

Fluid Properties:

- Density - divide mass by volume
  - Scale and volumetric flask
- Viscosity – ball drop test
  - Graduated cylinder and timer. The tame for the ball to drop through the fluid is run through an equation to find the viscosity
- Pressure and flow rate
  - This data is collected by sensors within the model, so testing will involve running the system to see what the pressure and flow rate will be and adjusting the pump accordingly

Design Validation: Testing Procedures

Overall Model Testing:

- Pressure transducers
  - Placed on either end of the vessel model to determine the pressure drop
- Flow sensors:
  - Connected to inlet and outlet of the vessel ranges to measure the flow change with the lesion inserted in the vessel
  - The flow sensor will be measuring flow rates directly from the pump and then during testing will be measuring outlet of vessel for differential calculations
- Thermocouple
  - Temperature will be monitored through a thermocouple. This ensures that viscosity remains consistent

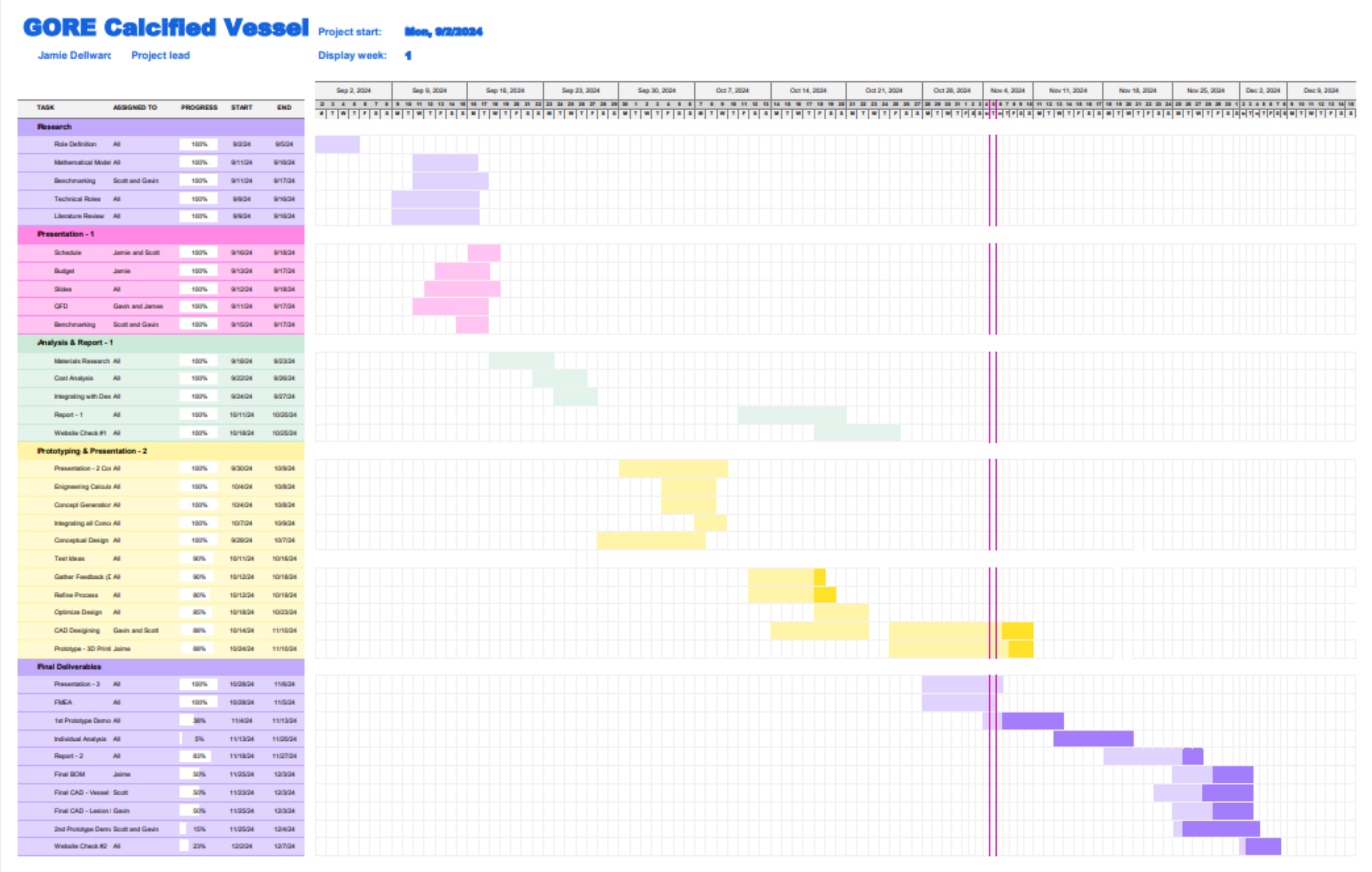
Schedule: Gantt Chart

Forecast:

- Final Deliverables
    1. 1st Demo
    2. Report – 2
    3. 2nd Demo
    4. Final Design

Currently:

- ON schedule



BOM and Budget

Bill of Materials

Item	Quantity	Cost
40D TPU	1	56.15
Peristaltic Pump	1	28.43
Power Supply	1	54.03
Arduino	1	45
SainSmart TPU	1	53.78
2pc Microcontroller	5	41.24
55D TPE Filament	1	25.99
Anycubic Photon Mono M5s Pro	1	299
Resin	1	20.36
Flow Sensor	2	20.72
Pressure Transducers	25	275.75
Utility Cart	1	94.5
90A Filament	1	30.56
UV Curing Light	1	23.39
Pump	1	28.43
Variable Power Supply	1	54.03
85A Filament	1	56.15
SainSmart TPU	2	53.78
Tubing	2	15.26
Tank	1	46.39
Lession Adhesive	1	10.37
One way Inlet	1	9.86
Artery Stand	1	16.38
Blood Analog	1	36.3
Syringes	100	16.37
	Total Cost	1412.22

Budget

Item	Quantity	Price/Per	Total (w/tax)	Ordered	Received	Remaining Budget
40D TPU	1	-	56.15		?	2943.85
Peristaltic Pump	1	-	28.43			2915.42
Power Supply	1	-	54.03			2861.39
Arduino	1	-	45			2816.39
SainSmart TPU	1	-	53.78			2762.61
2pc Microcontroller	5	-	41.24			2721.37
55D TPE Filament	1	-	25.99			2695.38
Anycubic Photon Mono M5s Pro	1	-	299			2396.38
Resin	1	-	20.36			2376.02
Flow Sensor	2	-	20.72			2355.3
Pressure Transducers	25	-	275.75			2079.55
Utility Cart			94.45			1985.1
90A Filament	1	-	30.56			1954.54
UV Curing Light	1	-	23.39			1931.15

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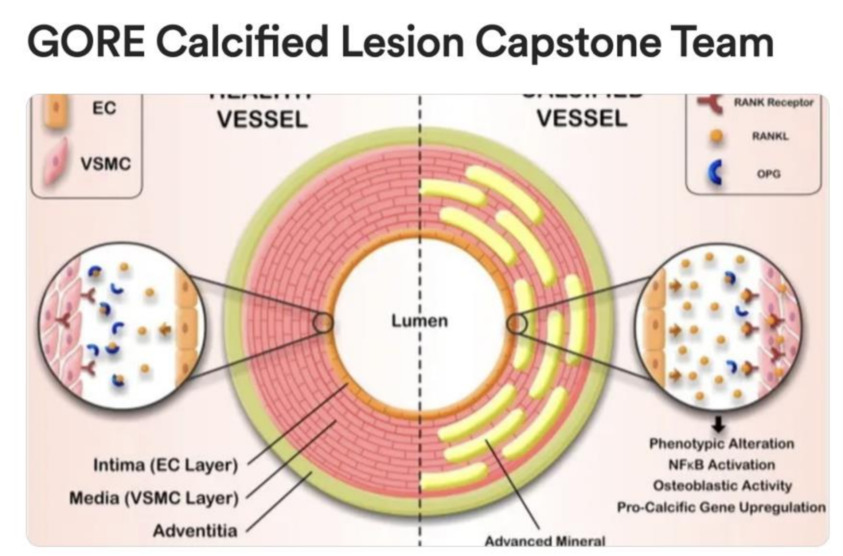
Cost estimates provided by www.amazon.com

Fundraising

Donors

Donor Name	Amount	Total Fundraised
Tori Dellwardt	$ 20	$ 20
Annonymous	$ 100	$ 120
Patrick Anteau	$ 100	$ 220
Michael J Anteau	$ 25	$ 245
Gary Lazurek Jr	$ 55	$ 300
Annonymous	$ 150	$ 450
Gary Lazurek	$ 50	$ 500
Lissette and Travis Rogers	$ 100	$ 600
Daniel Serpas	$ 100	$ 700
Marllette Owen	$ 100	$ 800

GoFundMe



Scan to donate

Cost estimates provided by www.amazon.com

Thank You!

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