Presentation 2
Concept Generation and Evaluation

Calcified Vessel Model Team

ME 476C-002

10/9/2024

NAU NORTHERN ARIZONA UNIVERSITY

Project Description

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

Figure 1 – Gore Logo [1]

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.

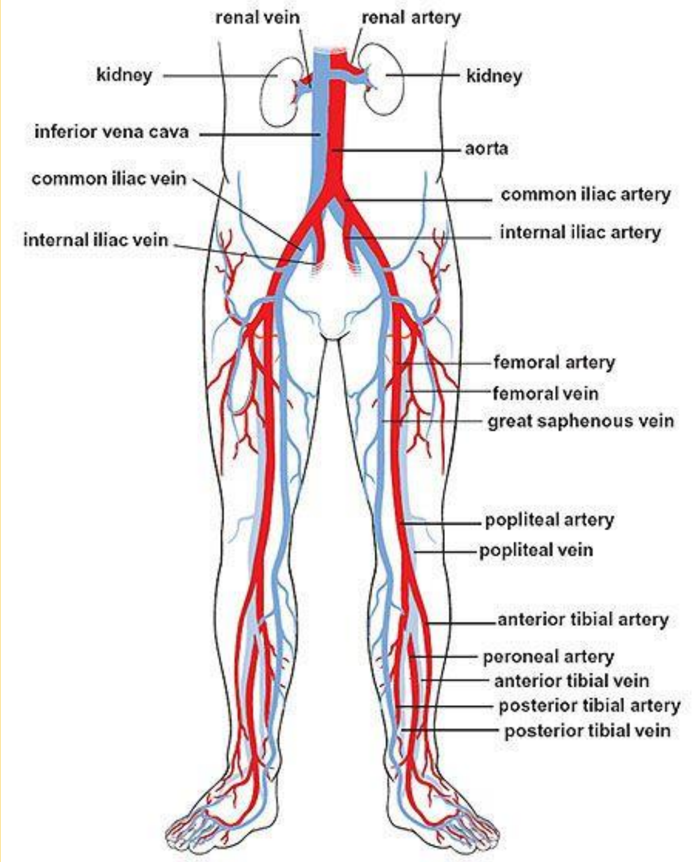
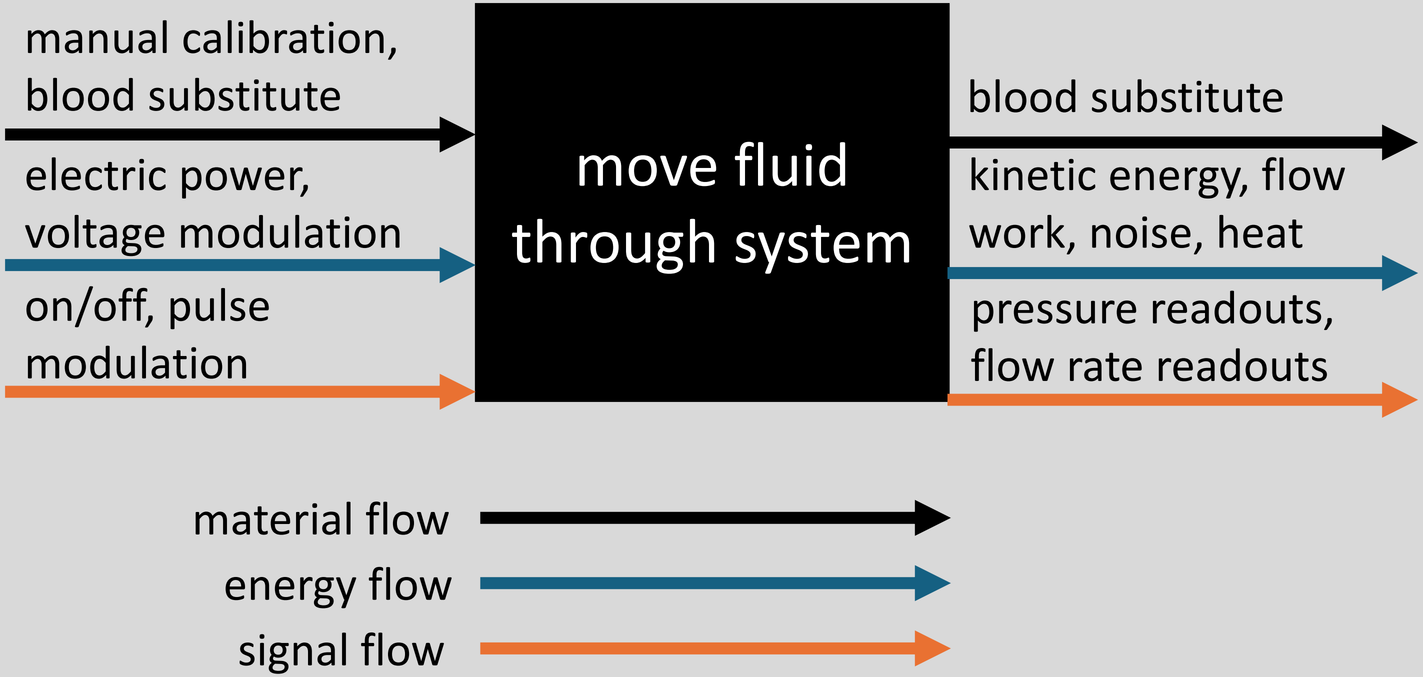


Figure 2 – Peripheral Artery System [1]

Black Box Model



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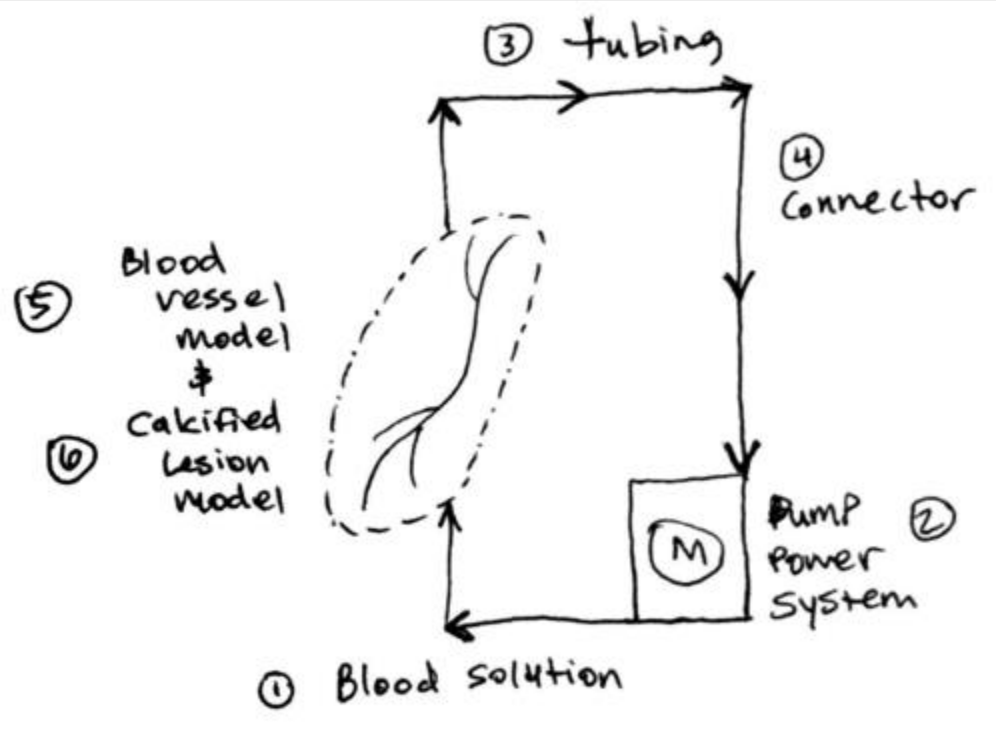
Physical Decomposition

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

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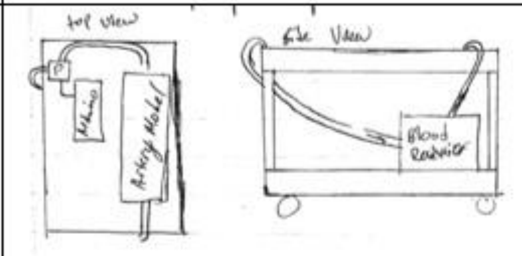
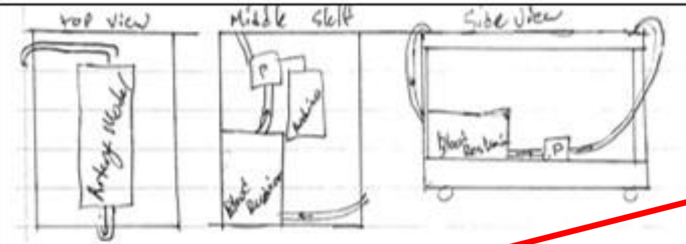
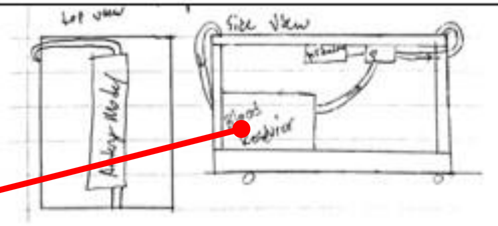
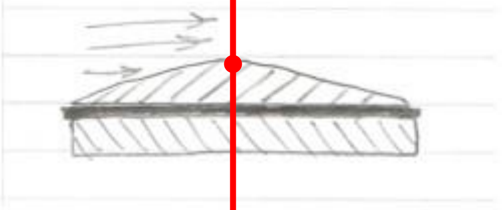
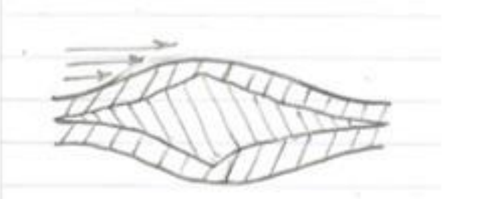
Morphological Matrix

Subsystem	Concept 1	Concept 2	Concept 3
Top Level design			
Lesion Material			
Lesion Adhesion			

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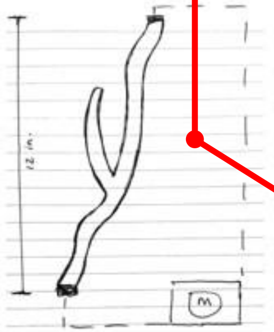
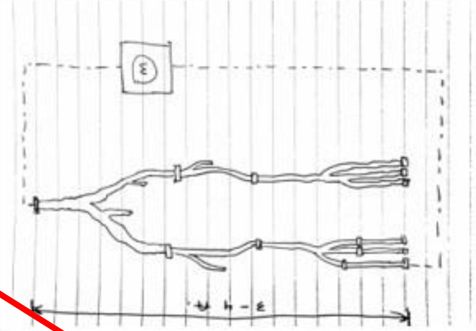
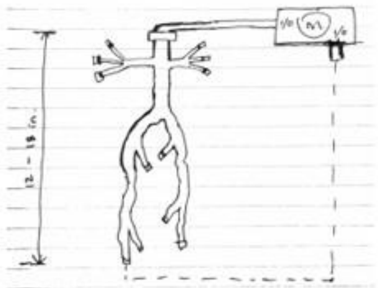
Images provided by www.amazon.com

Morphological Matrix

Final Design

Prototype Only

Subsystem	Concept 1	Concept 2	Concept 3
Vessel Structure			
Vessel Material			
Blood Solution			

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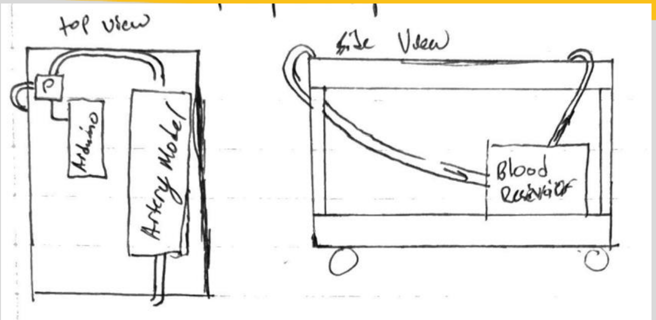
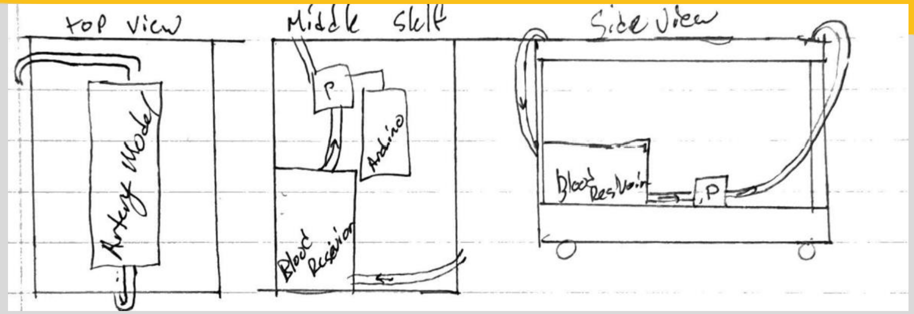
Images provided by www.amazon.com

Concept Generation: Top level Design

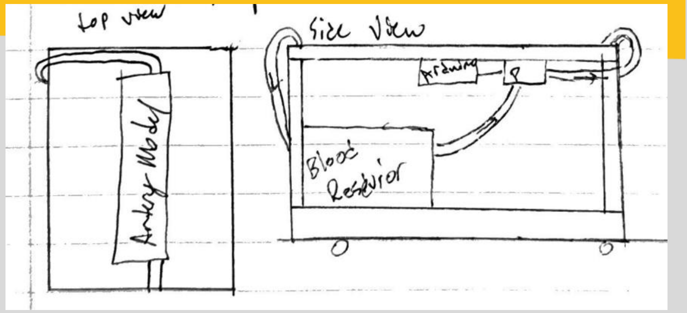
Concepts



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

Concept Generation/Evaluation: Pump

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 prototypeing

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.

Concept Generation/Evaluation: Computing

Concepts

Arduino

+ allows for circuits to be created easily

+easily accessible through the school to be able to prototype

-manufacturing of a way to hold all parts is needed

Raspberry pie

+ allows for circuits to be created easily

- Creating the code is more difficult

-manufacturing of a way to hold all parts is needed

Advantages/ Disadvantages

Our decision:
Since both will meet the customer needs we will use the easier of the 2 concepts We will use the Arduino since supplies and learning material are readily available.

Concept Generation: Calcified Lesions

Material

Advantages/ Disadvantages

High-Hardness 3D Printer Filament [1]

+ Accurate and consistent hardness
+ High resolution
+ Complete control of manufacturing process
– Relatively expensive

Fired Ceramic [2]

+ Most accurate material properties
+ Easy to manufacture
+ Relatively inexpensive
– Inconsistent hardness
– Low resolution

Machined Steel [3]

+ Consistent hardness
+ High resolution
– Complex manufacturing process
– Relatively low hardness

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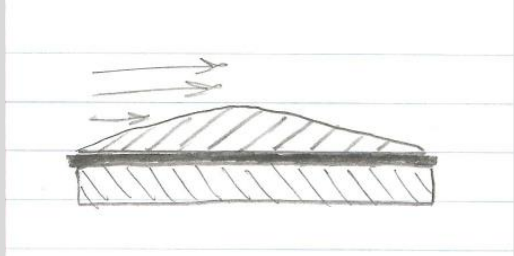
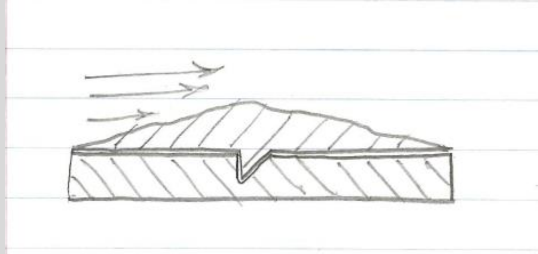
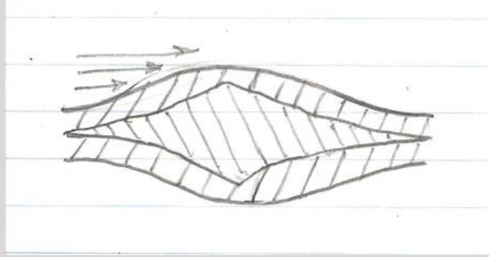
Images and cost estimates provided by www.amazon.com

Concept Generation: Calcified Lesions

	Adhesive Paste	Interlocking Mechanism	Embedded
Adhesion Method			
Advantages/ Disadvantages	+ Complete control over adhesion strength + No protruding geometries + Accurate to real-world use conditions + No additional manufacturing complexity – Additional assembly complexity	+ Complete control over adhesion strength + No additional manufacturing/ assembly complexity – Unidirectional adhesion strength – Protruding geometries	+ No protruding geometries + No additional manufacturing complexity – Additional assembly complexity – Adhesion strength determined by vessel wall strength – Inaccurate to real-world use conditions

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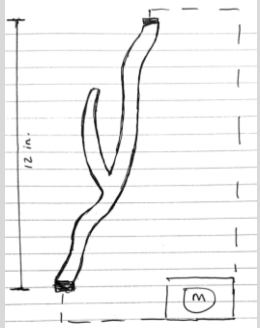
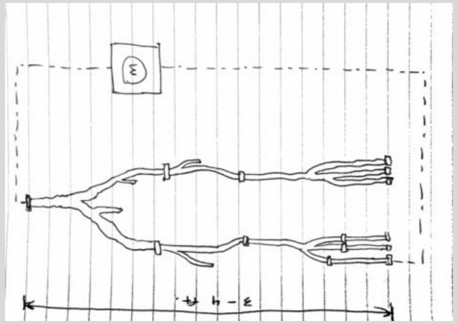
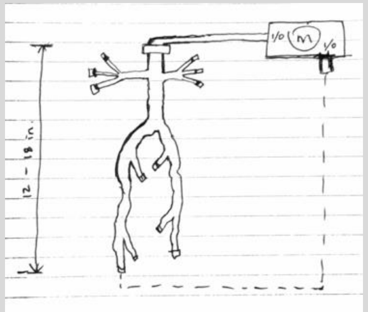
Concept Generation: Blood Vessel Structure

Vessel Design Structure	Femoral Artery (R)	Lower Extremity	Femoral Artery
			
Advantages/ Disadvantages	(+/-) 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	(+) Explore the lower extremity arterial system (+) Interconnection points for removing and adding vessels (-) More fluid volume can lead to complications in pump power system	(+) Less fluid volume (+) Less power required to pump (+) L/R femoral artery (+/-) Only the femoral artery in the system

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Concept Generation: Blood Vessel Structure

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

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

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Images and cost estimates provided by www.amazon.com

Concept Generation: Blood Solution

Material / **Advantages/ Disadvantages**

Doppler Ultrasound Gel

+Readily available

+Cheap to purchase

-Gel does not have fluid properties

-Non-transparent

-Higher viscosity than needed

Red Blood Cell Surrogates

+Very realistic for model

-Biological materials

-Not realistic for attaining

-Typically, from healthy patients not sick ones

PEG 200 Polyethylene Mixture

+Available for purchase

+Closely relates to blood properties

-More expensive than other options

-Not available in large quantities that are required

-Long list of procedure for use and safety requirements

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Images and cost estimates provided by www.amazon.com

Engineering Calculation: Pump Placement

Pump power = $\dot{W} = \rho Q g H_p$, [22] Where $H_p = \left(\frac{p}{\rho g} + \frac{V}{2g} + z\right)_{discharge} - \left(\frac{p}{\rho g} + \frac{V}{2g} + z\right)_{suction}$

then

$$\dot{W} = \rho Q g[\left(\frac{p}{\rho g} + \frac{V}{2g} + z\right)_{discharge} - \left(\frac{p}{\rho g} + \frac{V}{2g} + z\right)_{suction}]$$

When assumption is applied

$$\dot{W} = \rho Q g(\frac{p}{\rho g} + \Delta z)$$

So the head on the pump is dictated by the pressure and the height between pump and the vessel model

We can reduce the total head and therefore the power required by the pump by putting the pump at the same level as the model

Variables:

ρ = 1060 $\frac{kg}{m^3}$

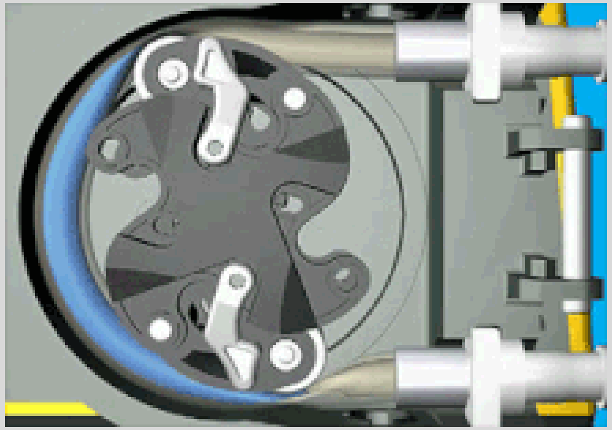
Q = 400$\frac{ml}{min}$ = 6.66*10^{-6} $\frac{m^3}{s}$

g = 9.81$\frac{m}{s^2}$

p=200mmHg = 27kPa

Assumptions:

- Velocity is same at inlet and exit
- No major or minor losses in pipe flow



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Engineering Calculations: Calcified Lesions

Part specifications for material hardness:

- High-hardness 3D printer filament
  - Shore 90A ≈ Shore 39D [1]
- Fired Ceramic
  - Mohs 4 ≈ Shore 44D [2]
- Machined Steel (1045)
  - HB 215 ≈ Shore 33D [3]
- Target
  - HV 274 ≈ Shore 39D [9]

Conversions provided by

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

Engineering Calculations: Calcified Lesions

Minimum adhesion strength due to blood flow:

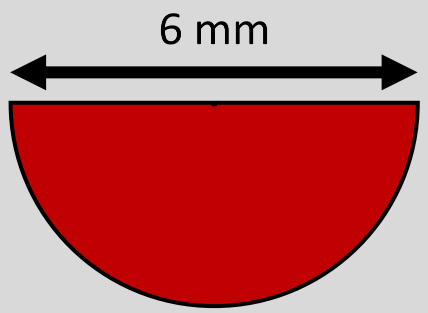
$$P_{min} = F/A$$

$$F = (1/2)Q\rho v \text{ [4]}$$
$$A = (1/2)\pi dL$$

$$Q = 8.183 \times 10^{-6}\, m^3/s \text{ [5]}$$
$$\rho = 1060\, kg/m^3 \text{ [6]}$$
$$v = 0.2894\, m/s$$
$$d = 0.006\, m \text{ [7]}$$
$$L = 0.050\, m$$

- Assume maximum volumetric flow rate for blood
- Assume 50% occlusion, 6 mm diameter, and 5 mm length for calcified lesion

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



Femoral Artery Cross-Section

Engineering Calculations: Blood Vessel

Yield Strength

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

-Mechanical Properties – Femoral Artery [22]

d = 7 to 8 mm (outer diameter)

r = 3.5 to 4 mm (radius)

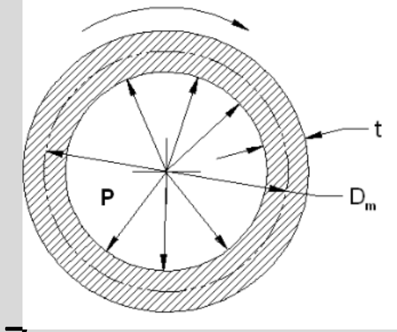
p = 200 mmHg (femoral arterial diseased)

t = 1 mm (wall thickness)

Yield strength of filament: 0.8MPa
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) [23]

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:

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

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

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

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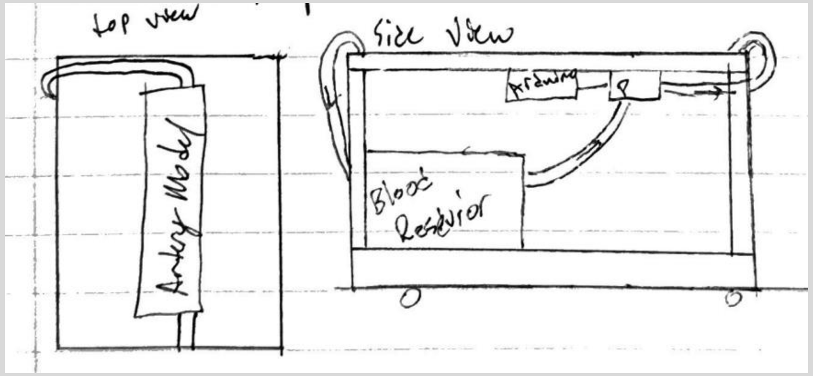
Concept Evaluation: Top Level Design and Pump

Top level design:

Computing and pump undermounted

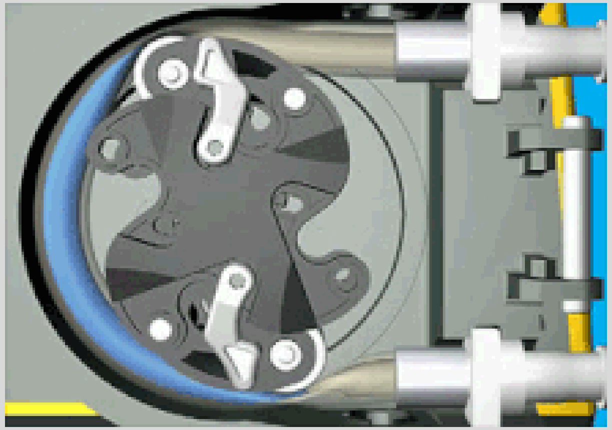


- Keeps computing unit and electronics out of the areas where fluid would rest if failure occurs
- Pump placement will be dependent on pump specs, calculations, and testing

Pump selection:

Peristaltic pump

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



To start prototyping, a pump capable of 400ml/min flow rate will be purchased. After a proof-of-concept alternate pumps might be selected to better match blood flow properties

Concept Evaluation: Calcified Lesions

Material	**High-Hardness 3D Printer Filament** [1]	**Fired Ceramic** [2]	**High-Hardness Machined Steel** [3]
<u>Target</u>			
Hardness: Shore 39D [9]	Shore 39D	Shore 44D	Shore 33D
Resolution: ~0.01 mm	0.1 mm [10]	~1 mm	0.01 mm [11]
Cost: <$1	$40/kg + manufacturing	$7/kg + manufacturing	$14/kg + manufacturing

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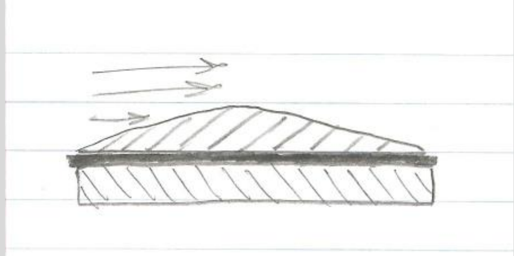
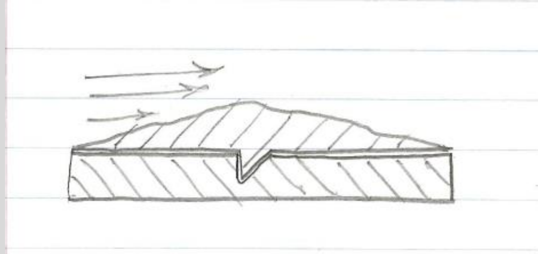
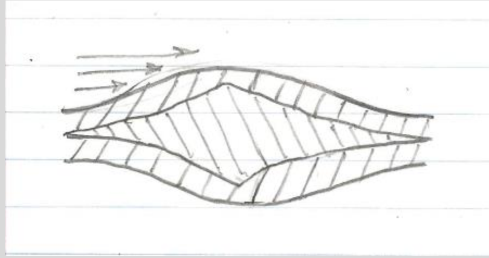
Images and cost estimates provided by www.amazon.com

Concept Evaluation: Calcified Lesions

- Modeling arterial calcified lesions is a novel feature not found in benchmarked designs. According to customer requirements, filament and ceramic best model simulated use conditions, filament and steel are the most replicable, and steel is the most durable.
- According to engineering requirements, filament most accurately and consistently models lesion hardness, filament and steel offer the highest resolution, and ceramic carries the lowest cost.
- Filament was chosen as lesion material due to its replicability, accurate modeling of simulated use conditions, high resolution, and desirable lesion properties, which were among the highest-weighted customer and engineering requirements.

Concept Evaluation: Calcified Lesions

Adhesion Method	**Adhesive Paste**	**Interlocking Mechanism**	**Embedded**
Target			
Adhesion Strength: >27 Pa	>27 Pa	>27 Pa	[Yield strength of vessel wall]
Dimensions: ~0 mm	~0 mm	~1 mm [12]	~0 mm
Cost: <$1	$0.40/mL	negligible	negligible

Cost estimates provided by www.amazon.com

Concept Evaluation: Calcified Lesions

- Modeling arterial calcified lesions is a novel feature not found in benchmarked designs. According to customer requirements, paste best models simulated use conditions, mechanism is the most replicable, and embedded is the most durable.
- According to engineering requirements, paste and mechanism most accurately and consistently model lesion adhesion strength, paste and embedded require no protruding geometries, and mechanism and embedded require negligible additional cost.
- Paste was chosen as adhesion method due to its accurate modeling of simulated use conditions, lack of protruding geometries, and desirable adhesion strength, which were among the highest-weighted customer and engineering requirements.

Concept Evaluation: Blood Vessel Structure

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

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Concept Evaluation: Blood Vessel Structure

<u>Specifications [25] :</u>

- PETG Filament; produces a clear product
- Diameter = 1.75 mm (common)
- $24.99/kg
- Hydrophobic (moisture-resistant)
- Strong adhesion factors
- Print temperature = 230 – 260 deg. C
- Tensile at yield = 0.8 MPa [24]

<u>Comparison:</u>

- More control of vessel dimensions
- Less waste involved
- Better adhesion factors for lesion

Hatchbox Transparent Filament

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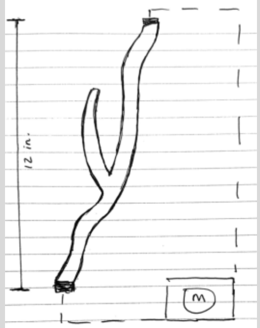
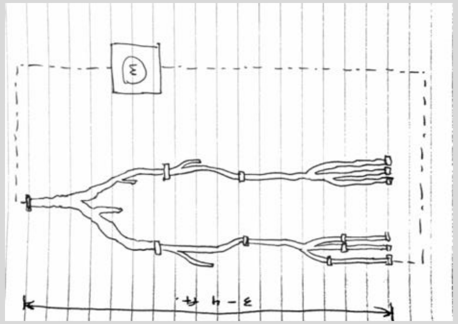
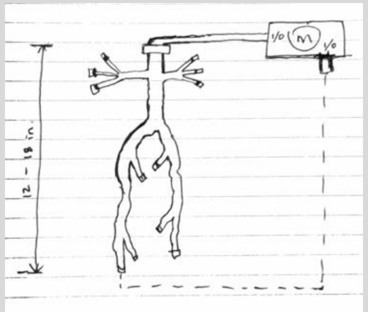
Concept Evaluation: Blood Vessel Structure

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

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Concept Evaluation: Blood Vessel Structure

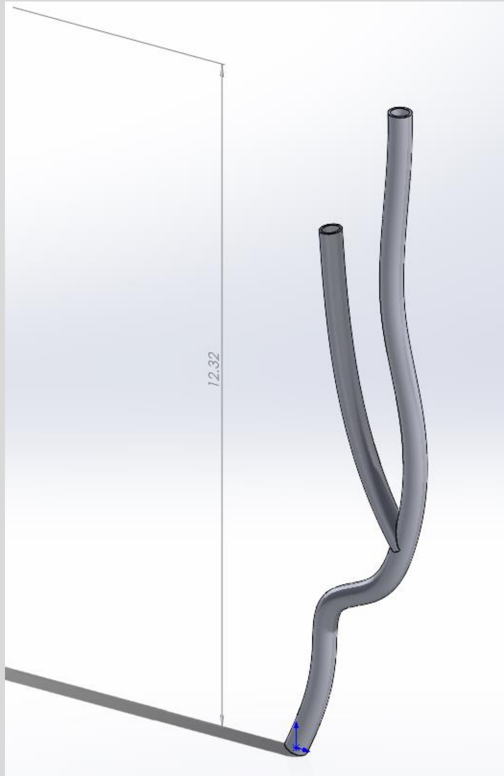
Specifications (CAD):

- 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)



Concept Evaluation: Blood Solution

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

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Cost estimates provided by www.amazon.com

Concept Evaluation: Blood Solution

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: Prototyping Blood Analog

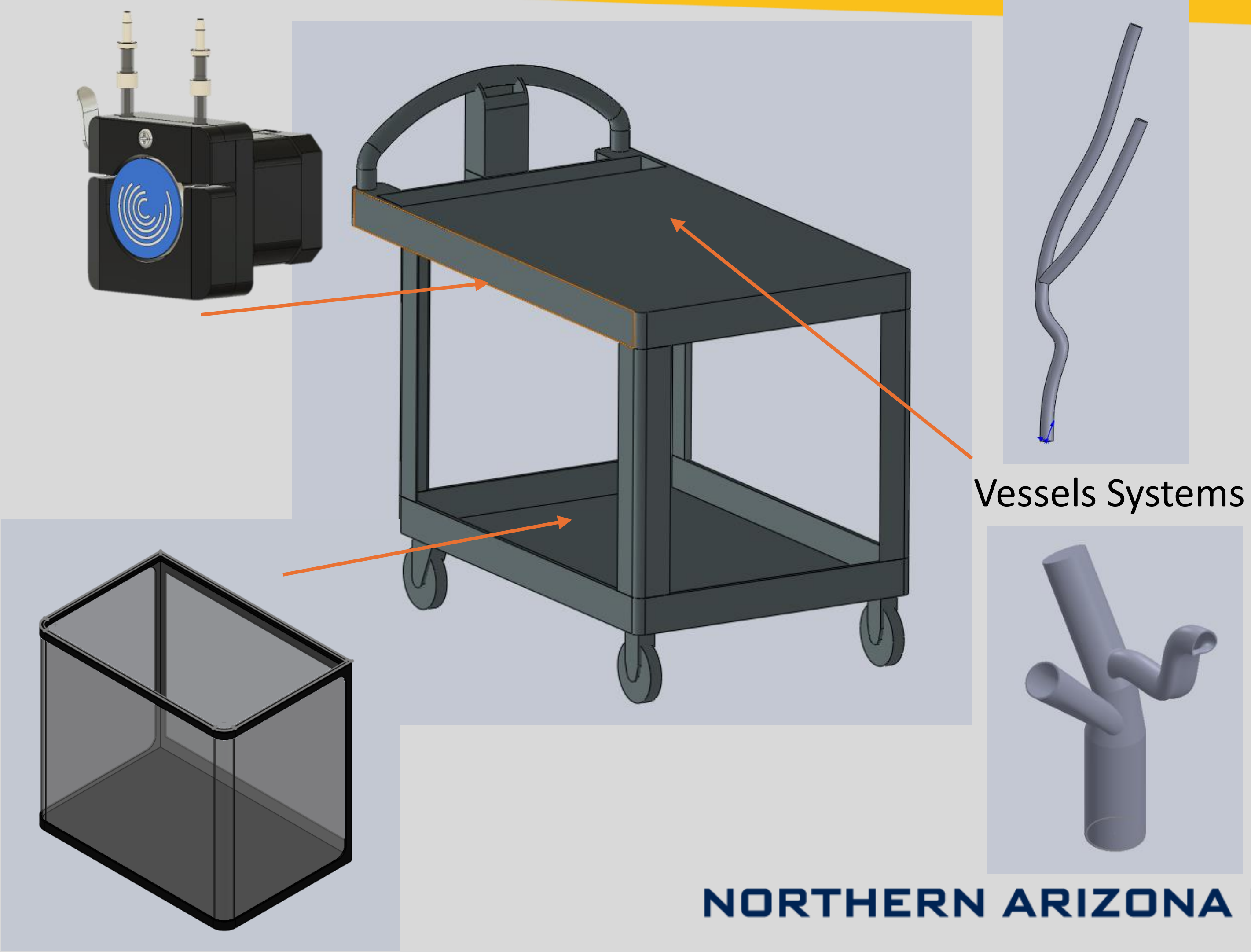
Density: 1.37 g/mL
Cost: $10
Viscosity: Similar but depends on the solution made

Prototyping:

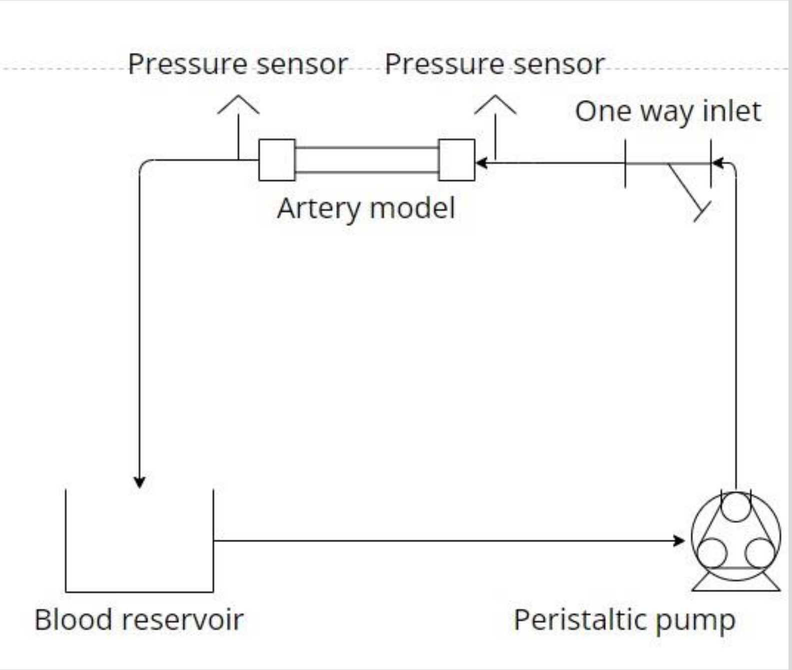
- Cost effective
- Simple to make
- Extreme case of blood thickness
- Limited mess/procedure for use

Cost estimates provided by www.amazon.com

Current State of Design



Pipe Flow Diagram:



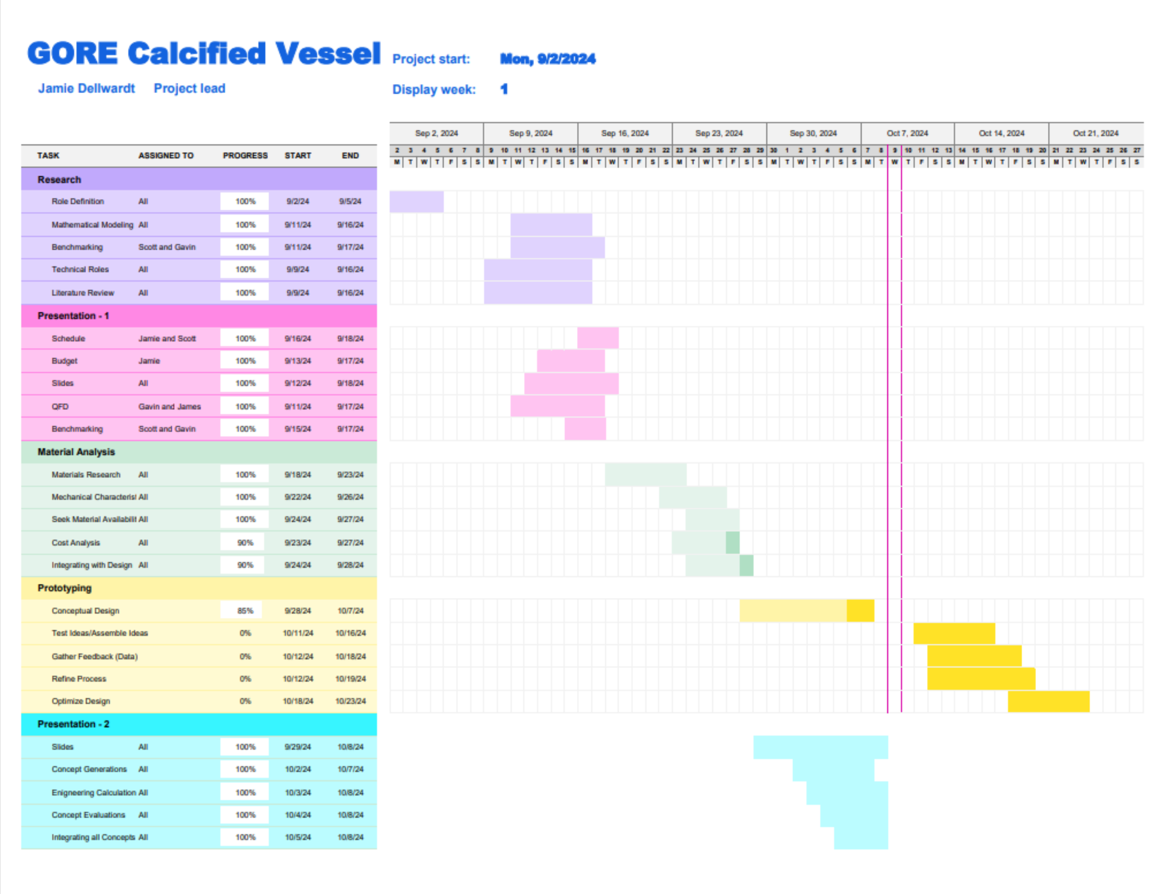
Schedule – Gantt Chart

Forecast:

- Prototyping phase
- Report 1

Currently:

- ON schedule
- Need to begin prototyping
- Sub-concepts together to gear production towards final design



TASK	ASSIGNED TO	PROGRESS	START	END
Research				
Role Definition	All	100%	9/2/24	9/5/24
Mathematical Modeling	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
Material Analysis				
Materials Research	All	100%	9/18/24	9/23/24
Mechanical Characterisi	All	100%	9/22/24	9/26/24
Seek Material Availabilit	All	100%	9/24/24	9/27/24
Cost Analysis	All	90%	9/23/24	9/27/24
Integrating with Design	All	90%	9/24/24	9/28/24
Prototyping				
Conceptual Design		85%	9/28/24	10/7/24
Test Ideas/Assemble Ideas		0%	10/11/24	10/16/24
Gather Feedback (Data)		0%	10/12/24	10/18/24
Refine Process		0%	10/12/24	10/19/24
Optimize Design		0%	10/18/24	10/23/24
Presentation - 2				
Slides	All	100%	9/29/24	10/8/24
Concept Generations	All	100%	10/2/24	10/7/24
Enigneering Calculation	All	100%	10/3/24	10/8/24
Concept Evaluations	All	100%	10/4/24	10/8/24
Integrating all Concepts	All	100%	10/5/24	10/8/24

NORTHERN ARIZONA UNIVERSITY

BOM and Budget

Bill of Materials

Item	Quantity	Cost Per Unit	Total Cost	% of Unit Cost
Pump	1	$26.04	$28.43	6%
Variable Power Supply	1	$49.49	$54.03	12%
85A Filament	1	$51.43	$56.15	12%
SainSmart TPU	2	$24.63	$53.78	12%
Tubing	2	$6.99	$15.26	3%
Cart/Platform	1	$71.00	$77.52	17%
Tank	1	$42.49	$46.39	10%
Sensing Unit	1	$29.59	$32.31	7%
Lession Adhesive	1	$9.50	$10.37	2%
One way Inlet	1	$9.03	$9.86	2%
Artery Stand	1	$15.00	$16.38	4%
Blood Analog	1	$33.25	$36.30	8%
Syringes	100	$14.99	$16.37	4%
		Total Cost	**$453.15**	

Budget

GORE Calcified		**Income**	**$3,000**	
Item	**Quantity**	**Cost Per Unit**	**Total Cost**	**Notes**
85A TPU Filament	1	$51.43	$56.15	Purchased
Peristaltic Pump	1	$26.04	$28.43	Purchased
Variable Power Supply	1	$49.49	$54.03	Purchased
SainSmart TPU	2	$24.63	$53.78	Purchased
Pump tank	1	$26.24	$28.65	
Syringes (100 count)	1	$14.99	$16.37	
Utility Cart	1	$71.00	$77.52	
Plastic tubing (12 m)	2	$6.99	$15.26	
Sensing Unit	1	$29.59	$32.31	
Lession Adhesive	1	$9.50	$10.37	
One way Inlet	1	$9.03	$9.86	
Artery Stand	1	$15.00	$16.38	
Blood Analog	1	$33.25	$36.30	
		Spent	$192.40	
		Total Predicted	$435.41	
		Total Budget Remaining		**$2,564.59**

Cost estimates provided by www.amazon.com

Thank You!

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