# GORE Calcified Vessel Model Presentation 1

By: Calcified Vessel Model Team

NAU NORTHERN ARIZONA UNIVERSITY

# Roles

**James – Testing Engineer**
- Pump System
- Power Management
- Inlets/Manifolds

**Jamie – Project/Financial Manager**
- 3D Printing expert
- Data Collection
- Pressure/Flow Rates Measurements

**Scott – Manufacturing/CAD Engineer**
- Arterial Design/Manufacturing
- Assembly
- Blood Model

**Gavin – Logistics Manager**
- Data Compiler
- Lesion Expert
- Patient Expert

# 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.

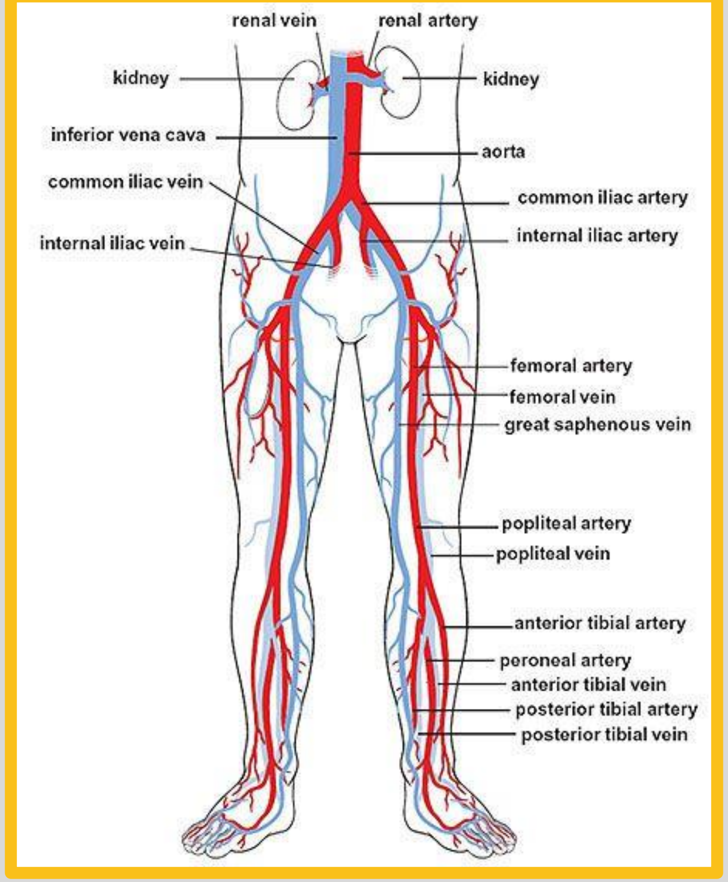



Figure 2 – Peripheral Artery System [1]

# Background & 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

# Background & Benchmarking

| Creative Biolabs 3D Biology | Preclinic Medical Simulation | Vivitro Labs - Simulators |
|---|---|---|

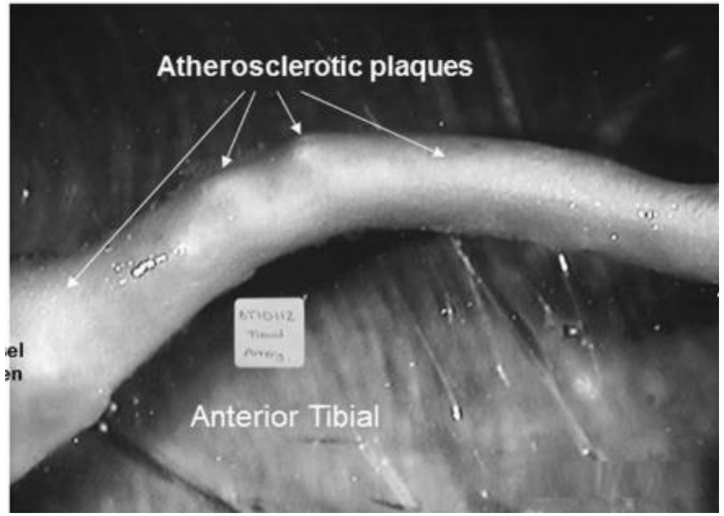



Figure 3. *Atherosclerotic tissue sample* [27]

Figure 4. *Silicone Cardiac Vessels* [28]

Figure 4. *Endovascular Simulator* [29]

# QFD: Requirements

Customer Needs:
- 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

# QFD

## System QFD

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

| # | | Vessel Properties | Vessel Dimensions | Lesion Dimensions | Lesion Properties | Fluid Properties | Engineering Standard Compliance | Manufaturing Cost |
|---|---|---|---|---|---|---|---|---|
| 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 | 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)<br>Opacity (%) | Length (cm)<br>Thickness (mm)<br>Diameter(mm) | Length (mm)<br>Thickness (mm)<br>Angle (deg) | Strength (Pa)<br>Durometer (HS) | Flow rate (mL/s)<br>Dynamic viscosity (Pa*s)<br>Density (kg/m^3) | % | USD | | | | | |
| Technical Requirement Targets | | 11-17 kPa<br>50% | ~30 cm<br>1-2 mm<br>5-9 mm | 5 mm<br>0.5 mm<br>180° | 7 Pa<br>70 HS | 7.2 mL/s<br>0.003-0.006 Pa*s<br>1060 kg/m^3 | 100% | $3000 USD | | | | | |

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

# State-of-the-Art Literature Review

- Viabahn stent instruction manual [1]
  - Provides instructions and insight as to how the stents are to be inserted into the peripheral arteries. This will aid in designing the inlet ports of the model
- Harrison's Principles of Internal Medicine, 21st edition[2]
  - Explains the medical side of the peripheral artery disease. Outlines the cause, and effects of the disease as well as ways to test for the disease. This textbook will provide background information for the project and model
- Comparison of BARD®LIFESTREAM™ covered balloon-expandable stent versus GORE® VIABAHN™ covered self-expandable stent in treatment of aortoiliac obstructive disease: study protocol for a prospective randomized controlled trial (NEONATAL trial) [3]
  - Provides comparison between two products that may be tested within the model. This will aid in creating a functional model that can be used for multiple tests.
- Utilization of Endoluminal Bypass Using the Viabahn Endoprosthesis with Heparin Bioactive Surface Compared With Surgical Femoropopliteal Bypass. [4]
  - Outlines the difference between stent and surgical options for treatment. This provides valuable insight as to why this project is important

# State-of-the-Art Literature Review

- Endovascular Today: Stent device guide[5]
  - Contains dimensions and procedures for multiple different stents that could be used within our model. This will further aid in design decisions within the model.
- 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[6]
  - Explains the interaction between the stent and the artery wall when inserted. The data from this study will aid in creating a model that will interact with the stent correctly
- W. L. GORE & ASSOCIATES ENHANCES GORE® VIABAHN® ENDOPROSTHESIS PORTFOLIO WITH LOWER PROFILE DELIVERY [7]
  - Press release for an improvement to the Gore Viabahn design. Outlines the new lower profile deployment. This provides further knowledge as to how the model will be used for testing.
- OSHA Regulations[8]
  - Provides information on how to keep our project safe when creating and testing the model

# State-of-the-Art Literature Review

- Materials Science and Engineering: An Introduction, 10th Edition [9]
  - Explains the primary types of materials: metals, ceramics, polymers, and composites, as well as the relationships between material structural elements and their properties. It will help guide the characterization and calculation of peripheral arterial calcification (PAC) material properties, such as durometer and adhesion strength.
- Schaum's Outline of Probability and Statistics, 4th Edition [10]
  - Explains the fundamentals of conditional probability and independence, random variables, binominal and normal distributions, sampling distributions, and analysis of variance. It will provide statistical tools for the analysis of medical experiments and the relevant data they provide to designing calcified vessel models.
- GORE® VIABAHN® Endoprosthesis [11]
  - Provides information, instructions, clinical uses, case studies, specifications, and further reading related to Gore Medical's Viabahn endoprosthesis device. It provides an in-depth view of the device to be tested on the calcified vessel model, aiding the understanding of testing conditions which the model must simulate.

# State-of-the-Art Literature Review

- A new optical coherence tomography-based calcium scoring system to predict stent underexpansion [12]
  - A retrospective study using blood vessel imaging technology to create an accurate model of predicting stent underexpansion based on blood vessel calcification levels. It reveals which factors related to blood vessel calcification interfere with stent expansion, and the critical measurements at which they occur.
- Carotid Artery Stenting for Calcified Lesions [13]
  - A correlation study comparing the arc of circumferential vessel occlusion in patients with calcified lesions to the outcomes of balloon expansions in stent placement operations. It reveals a statistical correlation between degree of vessel occlusion and residual stenosis, providing guidelines for necessary balloon expansion pressure during stent placements depending on calcification levels.
- Quantifying Effects of Plaque Structure and Material Properties on Stress Distributions in Human Atherosclerotic Plaques Using 3D FSI Models [14]
  - A computational study using blood vessel imaging technology to create 3D structural and fluid models of calcified plaque in blood vessels for mechanical analysis. It provides mathematical relationships of stress and strain levels in calcified lesions according to plaque material properties and geometries.

# State-of-the-Art Literature Review

- Ultrasound determination of total arterial wall thickness [15]
  - A correlation study using blood vessel imaging technology comparing the ages and peripheral artery disease (PAD) states of test subjects with their artery wall thicknesses. It reveals a statistically significant correlation of the increase in peripheral artery wall thickness in patients 60-69 years old due to PAD.
- Cardiovascular implants — Endovascular devices (ISO 25539-2:2020) [16]
  - A standard written and published by the International Organization for Standardization (ISO) specifying the requirements of vascular stents and delivery systems with regards to their design, manufacturing, and evaluation among ISO member nations. It will provide fundamental technical information on the medical device to be tested in the calcified vessel model, including the rules and regulations they must follow.

# State-of-the-Art Literature Review

- Biocompatible 3D Printing Resins for Medical Applications [21]
  - Testing research of flexible and nonflexible biocompatible materials and discusses limitations of the resins. This will aid in the design stage and the prototyping in that 3D printing materials and limitations can be part of the testing process and possible variations of the models.
- Research Models for Studying Vascular Calcification [22]
  - Discusses the type of system required to create calcifications and the components within blood that make the calcification build up. This will aid with the ideation of calcification of the model vessels and the materials that most compared to the body to accurately recreate the problem.
- Comparing Traditional and Contemporary Manufacturing Methods [17]
  - Discusses the process of casting resin and the limitations associated. This source also covers the limitations of 3D printing. This source is helpful in the comparison of the restrictions of both processes. We will be able to weight the benefits of each method and decide which limitations apply to our project.
- Vascular Corrosion Casting [23]
  - This article talks about specific silicone rubber casting and its ability to create fine detail aspects efficiently. Understanding this process and prototyping with this silicone rubber will allow us to compare prototypes. This also talked about making a model with multiple ports which will be important for our model as well. A system that allows for multiple components in one model cast.
- 3D Printed Molds for Injection Molding [18]
  - This journal described the process of injection molding which was described as successful process for elastomeric devices. It also talks about the 3D printing process as well as the injection molding. This will be helpful to combine the best components of our designs and think creatively how to manage cost based on materials used.

# State-of-the-Art Literature Review

- Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices [25]
  - This document is the standard for generic biological test methods and safety standards. This suggests that there may be additional testing required for biological devices despite being non-tissue materials. This is important to understand so that when presenting to client they understand the possibility of further testing that could be required.
- Design For Mechanical Measurements Chapter 1 [19]
  - This chapter covers many basics of measurements however the main concept of importance of this chapter is the replication and repetition portion. This is especially important when considering out testing methods. The project entails making 12 models and testing them the same, so the repetition and replication is ideal scenario.
- Design For Mechanical Measurements Chapter 9 [20]
  - This chapter is focused on pressure measurements which is the primary testing procedure for this project. The most helpful aspect of the chapter is the velocity probe section. This details simple procedures, calculations, and purpose of these devices which is essential in determining what system to use for our own procedures.
- 3D Printed Biomedical Devices and their Applications [26]
  - This journal talks about the issues discovered across experiments with 3D printing for medical devices. This pertains to our project as a warning meaning that these are things the team needs to avoid and try to troubleshoot in advance. The other part of the journal specially interesting is the future of 3D printing mainly the materials. These are materials to consider for 3D printing since this was published in 2023 some materials may be available.
- How Cost-Effective is SLA 3D Printing [24]
  - This website is detailing the SLA 3D printing process cost to other manufacturing costs. It also provides information about what SLA printing is and how it compares cost to injection molding or CNC machining. This pertains to our project for the main aspects of 3D printing and Injection molding as these are the two most popular methods for achieving a model like ours.

# State-of-the-Art Literature Review

- Endovascular Simulator creates physiological pulsatile flow and pressures (vivitrolabs.com) [29]
  *Used as a bench-marker; providing some direction in the assembly and design process.*
- Silicone Vessels Simulation Model Manufacturer, Vascular Simulation | Preclinic Medtech (preclinic-sim.com) [28]
  *Used as a bench-marker; providing direction in the assembly and material selection process.*
- CRIMSON: An open-source software framework for cardiovascular integrated modelling and simulation | PLOS Computational Biology [30]
  *Engineering tool used for segmenting vascular structures from medical images. This source will be used as the standard in helping create accurate and detailed simulation modeling for our customer and project.*
- Anatomy, Blood Vessels [31]
  *Used as a textbook chapter from the StatPearls by William D. Tucker; Yingyot Arora; Kunal Mahajan. Help with identifying the peripheral vascular system, includes all the blood vessels that exist outside the heart.*
- Central Versus Peripheral Artery Stiffening and Cardiovascular Risk [32]
  *Used as a peer-reviewed source (journal). This source will help with understanding of the calcification behavior(s) and effects in the peripheral arterial system while linking it back to the entire arterial system.*

# State-of-the-Art Literature Review

- Blood Flow in Vessels – Circulation [33]
  *Used as a peer-reviewed source. This source gives exceptional information on the behavior of the blood flow in vessels. Both peripheral and central systems, we are interested in the peripheral flow characteristics.*
- Cardiovascular Physiology - Chapter 6: The Peripheral Vascular System; McGraw Hill [34]
  *Used as a textbook source. This source will help define the peripheral vascular system that we intend on replicating in our model design.*
- Tortora's Principles of Anatomy & Physiology Textbook [36]
  *Used as a textbook source. This source was used for calculations. Precisely used for the velocity max value.*

# Mathematical Model: Wall Shear Stress

## Define WSS:

Wall shear stress 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 use this calculation to determine appropriate wall thickness of our model.

## Considerations:

- Assuming Laminar Flow
- Viscosity of blood is never a fixed value
- Shear Rate and Flow Velocity $(V)_{max}$ will need to be calculated as well. [35]
- Radius value [36]

## Calculation:

$(V)_{max} = 0.3$ m/s *typical of a medium-sized artery @ resting conditions

$(R) = 0.005$ m *reasonable approximation for common

$(\mu) = 0.0035$ 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):

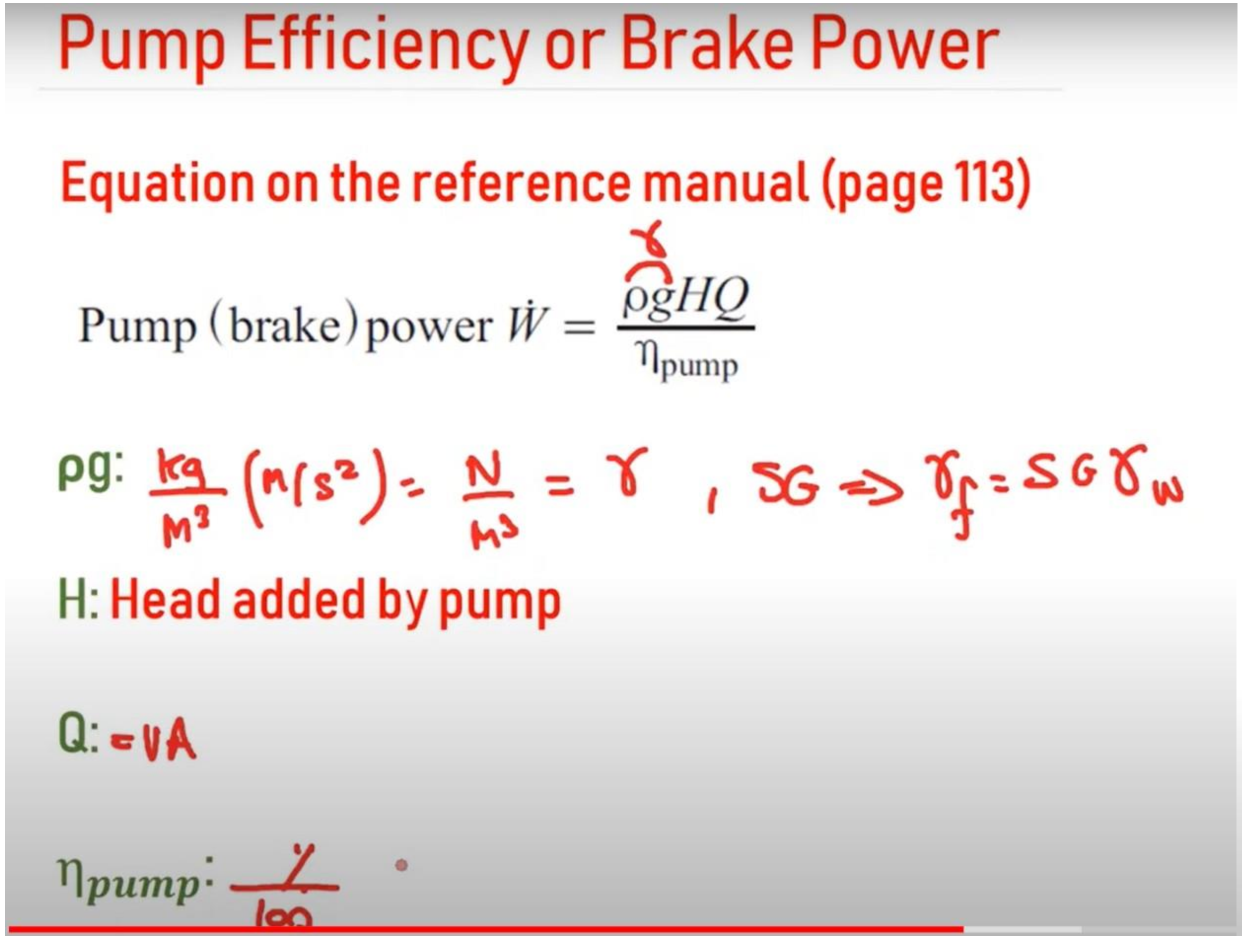
$\tau = (\mu)(du/dy)$

$\tau = (0.0035\ Pa*s)\ (120\ 1/s)$

$\tau = 0.42$ Pa

Figure 6. WSS Calculation [38]

# Mathematical Model: Pump Power




Online example:
Outlines the equation as well as the units needed within the equation

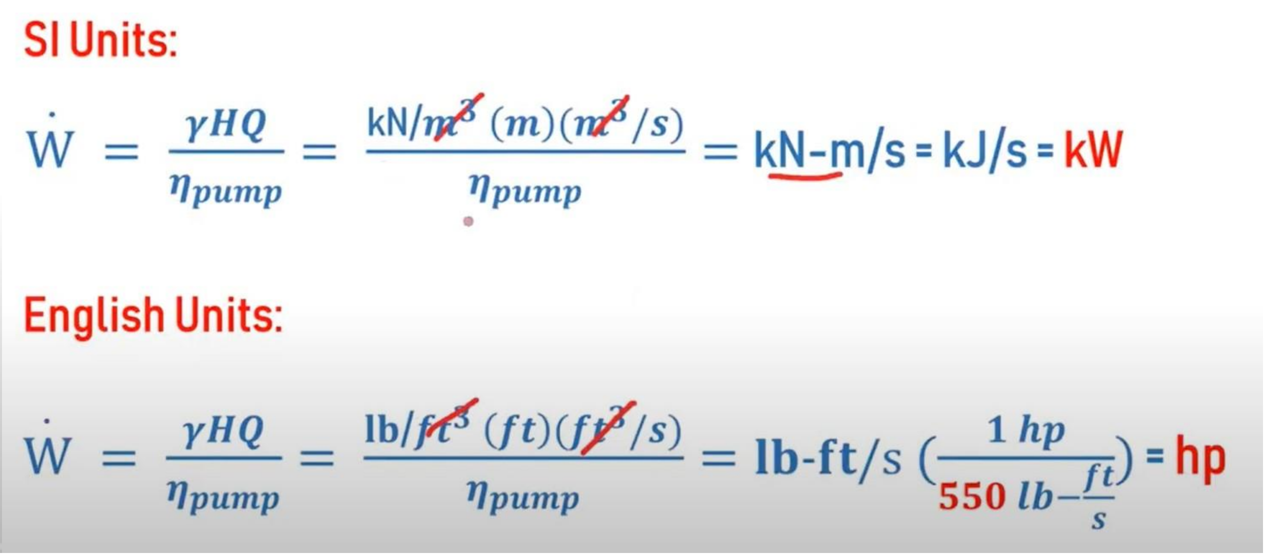



Figure 7. pump power calculation

# Mathematical Model: Pump Power

## Equation

$$P(pump) = \frac{Sg*\gamma*Q*H}{\eta}$$

$$P = \frac{1.066*62.43*0.00235*3}{0.8} = 0.5864\ lb - \frac{ft}{s}$$

$$P = 0.5864\ lb - \frac{ft}{s} * \left(\frac{1\ hp}{550\ lb - \frac{ft}{s}}\right) =$$

$$P = 0.0011hp$$

## Variables

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

## Conclusion

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

# Mathematical Model: Cost Analysis

Online Example:

Amid the conversion of raw materials it purchased into finished goods ready to be sold to its customers, the manufacturer incurred a total of $500,000 in fixed costs.

- Total Number of Units Produced (Q) = 25,000
- Total Fixed Costs = $500,000

Moreover, the variable cost per unit of production is $4.00, so the total variable costs incurred over the course of the fiscal year were $100,000.

- Variable Cost Per Unit = $4.00
- Total Variable Costs = $4.00 × 25,000 = $100,000

The sum of the manufacturer's fixed and variable costs, i.e. the total cost of production, comes out to $600,000.

- Total Cost of Production (TC) = $500,000 + $100,000 = $600,000

In the final step of our exercise, the total cost of production is divided by the total quantity of units produced to arrive at an average cost of $24.00.

- Average Cost Per Unit = $600,000 ÷ 25,000 = $24.00

Total Number of Units Produced (Q) = 25,000
Total Fixed Costs = $500,000

Variable Cost Per Unit = $4.00
Total Variable Costs = $4.00 x 25,000 = $100,000

Total Cost of Production (TC) = $500,000 + $100,000 = $600,000

Average Cost Per Unit = $600,000 / 25,000 = $24.00

Equation found from WallStreet Prep [16]

# Mathematical Model: Cost Analysis

## Equation

$$Q * C_v = TC_v$$

$$TC = C_f + TC_v$$

$$A = \frac{TC}{Q}$$

## Calculation

Q = 12 units
$C_v$ = material cost, labor cost, shipping
Resin, tubing, syringes, labor at $15/hr, average of $10 shipping fee
$C_f$ = fixed cost
Pump, tank, cart, blood solution

$$Q = 12$$

$$C_v = \$3.44 + \$8.91 + \$65 + \$22.49 + \$60 + \$10$$
$$C_v = \$169.84$$

$$C_f = \$71 + \$26.24 + \$9.98 + \$150 + \$66.75$$
$$C_f = \$323.97$$

$$TC_v = C_v * Q = 169.84 * 12 = \$2038.08$$

$$TC = C_f + TC_v = 2038.08 + 323.97 = \$2{,}362.05$$

$$A = \frac{TC}{Q} = \frac{2362.05}{12} = \$196.84$$

## Variables

Q - Total Number of Units Produced
Cv – Variable Cost
TCv- Total Variable Cost
TC- Total Cost
Cf- Fixed Cost
A- Average Cost per Unit

This calculation applies to both 3D printing and molding because the same materials are purchased just in various quantities. So, there will be slight alterations to variable cost if molding is chosen direction (would be roughly $22 cheaper per unit)

# Mathematical Model: Disease States

<u>Question</u>

- How to characterize peripheral arterial calcification disease states?
- Peripheral arterial disease presents differently in different patients.
- Characterizations must be relevant to their effects on vascular stents.

<u>Methods</u>

- Perform A/B test to determine statistical significance of each incomplete stent expansion factor.
- From EuroIntervention study: 133 operations on calcified lesions [14]
  - Calcified lesion thickness, length, and degree of vessel occlusion recorded
  - Stent expansion completion recorded

# Characterization of Disease States

<u>Equations</u>

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

$$p = P(z < -z_{crit}) + P(z > z_{crit})$$

[11]

<u>Variables</u>

$\bar{x}$- sample mean

μ- mean

σ- standard deviation

n- sample size

$z_{crit}$- critical z-score

<u>Example</u>

<50% occlusion:

μ = 3/33 = 0.0909

σ = 0.2919

n = 33

$z_{crit}$ = 1.645

>50% occlusion:

μ = 7/24 = 0.2917

σ = 0.4643

n = 24

$z_{crit}$ = -1.282

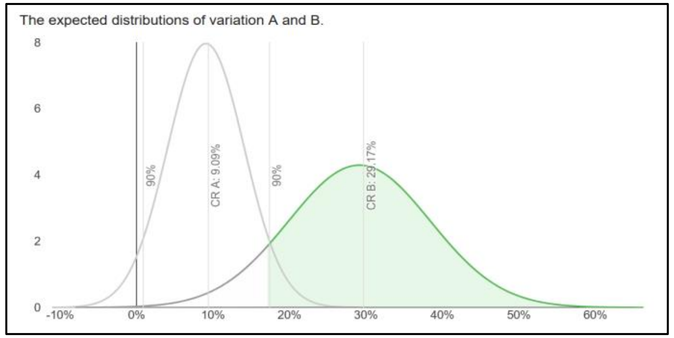



Fig. 8 – two-tailed t-test for degree of vessel occlusion vs incomplete stent expansion rate (per 180°) [18]

<u>Results</u>

p value – 0.0569

z-score – 1.9044

Significance: >90%

# Characterization of Disease States

## Conclusions

- Calcified lesion thickness >0.5 mm, length >5 mm, and degree of vessel occlusion >50% are statistically significant predictors of incomplete stent expansion.
- These factors can be effectively used to characterize PAC disease states.

## Recommendations

- To represent the entire range of PAC disease states, several calcified vessel models should be made which feature none of these factors, some factors, and all factors.

# Schedule – Gantt Chart

**Gantt Chart:**

- A project management tool.
- Utilize Gantt Chart to help with production throughout the life span of our project.
- The Gantt Chart aids in clearly assessing task responsibilities with deadlines for project progress to be maintained.
- We can redefine our Gantt Chart to be utilized as a "Can-Build" chart as well.

Figure 9. Time Management [37]

# Schedule – Gantt Chart

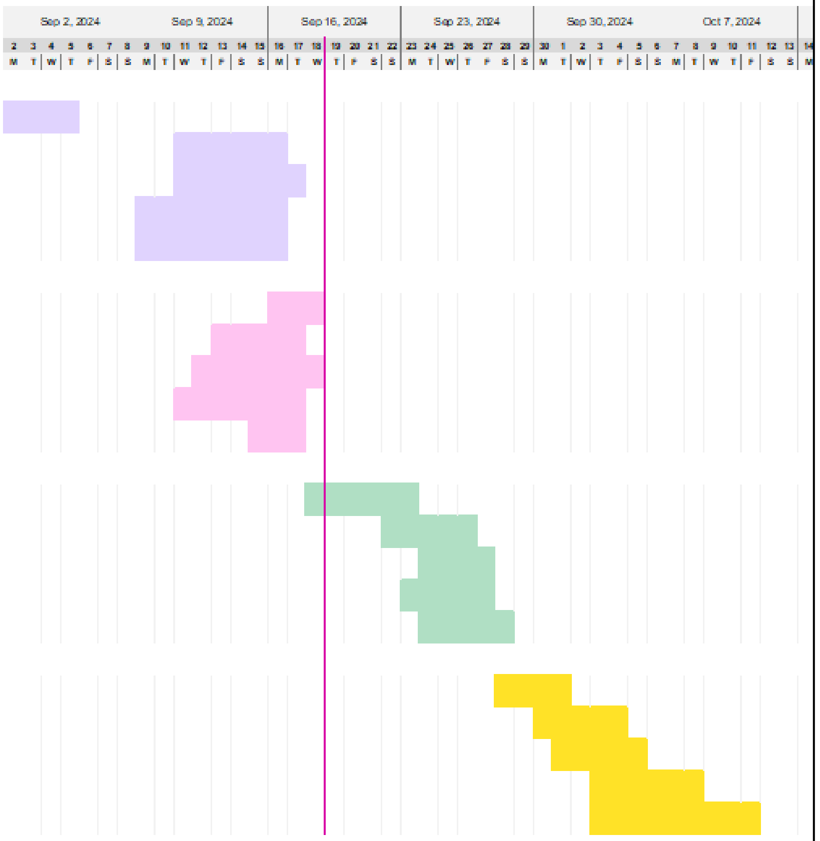
## GORE Calcified Vessel

Jamie Dellwardt   Project lead

Project start: **Mon, 9/2/2024**

Display week: **1**

| 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** | | | | |
| 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 | | 0% | 9/18/24 | 9/23/24 |
| Mechanical Characteristics | | 0% | 9/22/24 | 9/26/24 |
| Seek Material Availability | | 0% | 9/24/24 | 9/27/24 |
| Cost Analysis | | 0% | 9/23/24 | 9/27/24 |
| Integrating with Design | | 0% | 9/24/24 | 9/28/24 |
| **Protyping** | | | | |
| Conceptual Design | | 0% | 9/28/24 | 10/1/24 |
| Test Ideas/Assemble Ideas | | 0% | 9/30/24 | 10/4/24 |
| Gather Feedback (Data) | | 0% | 10/1/24 | 10/5/24 |
| Refine Process | | 0% | 10/3/24 | 10/8/24 |
| Optimize Design | | 0% | 10/3/24 | 10/11/24 |



# Budget

| | | | | |
|---|---|---|---|---|
| Income | $3,000 | | | |
| Fundraising | $300 | | | |
| | | | | |
| Item | Cost | Details | Purchased Date | Received |
| Resin | $65 | Flexible resin | | |
| Resin | $22.49 | 3D printer resin | | |
| Pump | $9.98 | mini water pump | | |
| Plastic tubing | $8.91 | 12 meters | | |
| Pump tank | $26.24 | Fish tank? | | |
| Syringes | $3.44 | medical dosing syringe | | |
| Utility Cart | $71 | Hold the model | | |
| Filament | $50.00 | per liter | | |
| Prototype 1 | $196.84 | All materials required | | |
| Prototype 2 | $196.84 | All materials required | | |
| Final Model | | Split up above in individual costs | | |
| | | | | |
| Total Spent | $651 | | | |
| | | | | |
| Total Remaining | $2,649 | | | |

Most cost expected right now is ordering materials to start building prototypes and testing procedures.

Fundraising plan right now is to go to local businesses and set up GoFundMe. Possibly also reach out to larger companies or research labs that may be interested in this model.

# Thank You!

# References

[1] Gore, *Instructions for use for: Gore Viabahn Endoprosthesis*, 1st ed., vol. 1. W.L. Gore & Associates, 2016. Accessed: Sep. 18, 2024. [Online]. Available: https://eifu-render.goremedical.com/PDFPrint.aspx?DocId=33

[2] M. Creager and J. Loscalzo, *Harrison's Principles of Internal Medicine*, 21st ed. McGraw-Hill Education, 2022, p. Arterial diseases of the extremities. Accessed: Sep. 18, 2024. [Online]. Available: https://accessmedicine-mhmedical-com.libproxy.nau.edu/content.aspx?sectionid=265454926&bookid=3095#266382434

[3] Qi, Y., Wang, J., Zhao, J. *et al.* Comparison of BARD®LIFESTREAM™ covered balloon-expandable stent versus GORE® VIABAHN™ covered self-expandable stent in treatment of aortoiliac obstructive disease: study protocol for a prospective randomized controlled trial (NEONATAL trial). *Trials* **23**, 392 (2022). https://doi.org/10.1186/s13063-022-06332-7

[4] Walraven, Laurens & Velandia Sánchez, Camilo & Iqbal, Kashfa & Zeebregts, Clark & Holewijn, Suzanne & Reijnen, Michel. (2024). Impact on Hospital Resource Utilization of Endoluminal Bypass Using the Viabahn Endoprosthesis with Heparin Bioactive Surface Compared With Surgical Femoropopliteal Bypass. Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists. 15266028241245602. 10.1177/15266028241245602. https://www.researchgate.net/publication/379691816_Impact_on_Hospital_Resource_Utilization_of_Endoluminal_Bypass_Using_the_Viabahn_Endoprosthesis_with_Heparin_Bioactive_Surface_Compared_With_Surgical_Femoropopliteal_Bypass

[5]S.-E. Stent, "Self-Expanding Stent Grafts - Endovascular Today," *Endovascular Today*, 2024. https://evtoday.com/device-guide/us/self-expanding-stent-grafts (accessed Sep. 18, 2024)

[6] F. Nematzadeh, "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," *Journal of intelligent material systems and structures*, vol. 33, no. 5, pp. 703–714, 2022, Accessed: Sep. 18, 2024. [Online]. Available: https://illiad.nau.edu/illiad/illiad.dll?Action=10&Form=75&Value=780137

[7] W. L. GORE & ASSOCIATES, "W. L. GORE & ASSOCIATES ENHANCES GORE® VIABAHN® ENDOPROSTHESIS PORTFOLIO WITH LOWER PROFILE DELIVERY," W. L. GORE & ASSOCIATES, Sep. 2021. Accessed: Sep. 18, 2024. [Online]. Available: https://www.goremedical.com/resource/21104751-en

[8]United States Department of Labor, "Regulations (Standards - 29 CFR) | Occupational Safety and Health Administration," *Osha.gov*, 2019. https://www.osha.gov/laws-regs/regulations/standardnumber/1910

[9] Genie Prep, "Pump Power Formula (FE Exam Review)," *YouTube*, Sep. 06, 2019. https://www.youtube.com/watch?v=RCZh8l19x0g (accessed Sep. 18, 2024).

# References


[10] W. D. Callister and D. G. Rethwisch, *Materials science and engineering: an introduction*, 10th ed. Hoboken, Nj: Wiley, 2018.

[11] M. R. Spiegel, J. J. Schiller, and R Alu Srinivasan, *Probability and statistics*. New York: Mcgraw-Hill, 2013.

[12] "GORE® VIABAHN® Endoprosthesis," *Gore Medical*. https://www.goremedical.com/products/viabahn

[13] A. Fujino *et al.*, "A new optical coherence tomography-based calcium scoring system to predict stent underexpansion," *Eurointervention*, vol. 13, no. 18, pp. 2182–2189, Apr. 2018, doi: https://doi.org/10.4244/eij-d-17-00962.

[14] M. Tsutsumi *et al.*, "Carotid Artery Stenting for Calcified Lesions," *American journal of neuroradiology*, vol. 29, no. 8, pp. 1590–1593, May 2008, doi: https://doi.org/10.3174/ajnr.a1126.

[15] D. Tang *et al.*, "Quantifying Effects of Plaque Structure and Material Properties on Stress Distributions in Human Atherosclerotic Plaques Using 3D FSI Models," *Journal of Biomechanical Engineering*, vol. 127, no. 7, pp. 1185–1194, Jul. 2005, doi: https://doi.org/10.1115/1.2073668.

[16] T. C. Hodges *et al.*, "Ultrasound determination of total arterial wall thickness," *Journal of Vascular Surgery*, vol. 19, no. 4, pp. 745–753, Apr. 1994, doi: https://doi.org/10.1016/S0741-5214(94)70051-6.

[17] International Organization for Standardization, Cardiovascular implants — Endovascular devices (ISO 25539-2:2020). 2020.

[18] "A/B-Test Calculator - Power & Significance - ABTestGuide.com," *abtestguide.com*. https://abtestguide.com/calc/

# References

[16] *Average Cost (Per Unit Cost)*. (2024, September 17). Wall Street Prep. https://www.wallstreetprep.com/knowledge/average-cost/

[17] Casilang, M. (n.d.). *Comparing Traditional and Contemporary Manufacturing Methods*. Jameco Electronics. https://www.jameco.com/Jameco/workshop/ProductNews/casting-3d-printing-compare-contrast.html

[18] Chung, P., Heller, J. A., Etemadi, M., Ottoson, P. E., Liu, J. A., Rand, L., & Roy, S. (2014). Rapid and Low-cost Prototyping of Medical Devices Using 3D Printed Molds for Liquid Injection Molding. *Journal of Visualized Experiments*, *88*. https://doi.org/10.3791/51745

[19] Figliola, R. S., & Beasley, D. E. (2019a). *Theory and design for mechanical measurements* (pp. 1–33). Wiley.

[20] Figliola, R. S., & Beasley, D. E. (2019b). *Theory and design for mechanical measurements* (pp. 315–354). Wiley.

[21] Guttridge, C., Shannon, A., O'Sullivan, A., O'Sullivan, K. J., & O'Sullivan, L. W. (2022). Biocompatible 3D printing resins for medical applications: A review of marketed intended use, biocompatibility certification, and post-processing guidance. *Annals of 3D Printed Medicine*, *5,* 100044. https://doi.org/10.1016/j.stlm.2021.100044

[22] Herrmann, J., Babic, M., Tölle, M., Markus, & Schuchardt, M. (2020). Research Models for Studying Vascular Calcification. *International Journal of Molecular Sciences*, *21*(6), 2204–2204. https://doi.org/10.3390/ijms21062204

[23] Hossler, F. E. (2003). Vascular Corrosion Casting. *Microscopy Today*, *11*(4), 46–47. https://doi.org/10.1017/s1551929500053098

[24] *How Cost-Effective is SLA 3D Printing Compared to Other Manufacturing Methods? - ZONGHENG3D*. (n.d.). Https://Www.zongheng3d.com/. https://www.zongheng3d.com/how-cost-effective-is-sla-3d-printing-compared-to-other-manufacturing-methods/

[25] International, A. (2016, December 27). *compass*. Compass.astm.org. https://compass.astm.org/document/?contentCode=ASTM%7CF0748-16%7Cen-US&proxycl=https%3A%2F%2Fsecure.astm.org&fromLogin=true

[26] Mamo, H. B., Adamiak, M., & Kunwar, A. (2023). 3D printed biomedical devices and their applications: A review on state-of-the-art technologies, existing challenges, and future perspectives. *Journal of the Mechanical Behavior of Biomedical Materials*, *143*, 105930. https://doi.org/10.1016/j.jmbbm.2023.105930

# References


[27] *Burke, S.K.; et al. Decellularization of human internal mammary artery: biomechanical properties and histopathological evaluation. Journal of Cardiovasc Pharmacol. 2014, 64(6): 530-536.*

[28] "Heart Surgery Surgeon Simulator Manufacturer, Heart Disease Prediction Model | Preclinic Medtech," *Preclinic Medtech (Shanghai) Co., Ltd.* , 2024. https://www.preclinic-sim.com/products/silicone-cardiac-vessels/ (accessed Sep. 18, 2024).

[29] "Endovascular Simulator," *ViVitro Labs*. https://vivitrolabs.com/product/endovascular-ev-simulator/

[30] C. J. Arthurs *et al.*, "CRIMSON: An open-source software framework for cardiovascular integrated modelling and simulation," *PLOS Computational Biology*, vol. 17, no. 5, p. e1008881, May 2021, doi: https://doi.org/10.1371/journal.pcbi.1008881.

[31] W. D. Tucker, "Anatomy, Blood Vessels," *Nih.gov*, Aug. 08, 2023. https://www.ncbi.nlm.nih.gov/books/NBK470401/

[32] S. Yu and C. M. McEniery, "Central Versus Peripheral Artery Stiffening and Cardiovascular Risk," *Arteriosclerosis, Thrombosis, and Vascular Biology*, vol. 40, no. 5, pp. 1028–1033, May 2020, doi: https://doi.org/10.1161/atvbaha.120.313128.

[33] "Blood Flow in Vessels - Circulation," *TeachMePhysiology*. https://teachmephysiology.com/cardiovascular-system/circulation/blood-flow-in-vessels/

[34] "The Peripheral Vascular System," *McGraw Hill Medical*, 2024. https://accesscardiology.mhmedical.com/content.aspx?bookid=2432&sectionid=190800825 (accessed Sep. 18, 2024).

[35] J. E. Hall and M. E. Hall, *Guyton and Hall textbook of medical physiology*, 14th ed. Philadelphia, Pa: Elsevier, 2021.

[36] G. J. Tortora and B. H. Derrickson, *Tortora's Principles of Anatomy & Physiology Textbook*, 15th ed. Wiley, 2017.

[37] *Clipground.com*, 2024. https://clipground.com/images/conceptual-clipart-18.jpg (accessed Sep. 18, 2024).

[38] G. A. Truskey, Fan Yuan, and D. F. Katz, *Solutions manual to accompany Transport phenomena in biological systems*. Upper Saddle River, N.J.: Pearson/Prentice Hall, 2004.