Replicable, Inorganic Calcified Vessel Models to Simulate Peripheral Arterial Disease

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Abstract

This project aimed to accelerate the development of treatments for peripheral arterial disease (PAD) by improving the functionality and accessibility of research models. Currently, researchers use organic models which are difficult to procure, inconsistent, and have substantial ethical considerations.

This project involved designing, building, and testing a replicable model of calcified lesions in the peripheral arterial system for deployment of vascular interventional devices, under simulated use conditions, and using inorganic materials.

Data was gathered from medical research studies on PAD to establish target values of blood vessel, calcified lesion, and blood flow properties and dimensions in the common femoral artery (a common location of calcified lesions). These target values informed development of analytic models and construction of prototypes for this product. Analysis of data collected from product tests verified that the experimental results aligned with the theoretical results.

The team's solution provides a replicable calcified vessel model that accurately simulates the mechanical and structural properties of PAD, using inorganic materials. The design requirements of this project match what is expected by analytic models based on current PAD research studies. The project is compliant with all applicable engineering standards and was completed under budget. These results offer potential to advance PAD treatment research by reducing the required time and cost of device testing.

Requirements

Engineering Requirements	Customer Requirements
ER1 – Vessel Model Properties Pressure within the vessel and opacity of the vessel model. **CR2, CR5, CR6**	**CR1 – Replicability** Ability to replicate the purchasing, manufacturing, and assembling. **ER6, ER7**
ER2 – Vessel Model Dimensions Accurate vessel model length, wall thickness, and diameter to femoral arteries. **CR2, CR7**	**CR2 – Simulated Use Conditions** Accurate simulations of real-world use conditions to endoprosthesis device applications. **ER1-ER5**
ER3 – Lesion Model Properties Accurate lesion model indentation hardness and adhesive strength to vessel wall. **CR2, CR6**	**CR3 – Non-Biological Materials** Composed of entirely inorganic material.
ER4 – Lesion Model Dimensions Accurate length, thickness, and degree of occlusion to calcified lesions. **CR2, CR7**	**CR4 – OSHA/ANSI Compliance** Fully safe to manufacture, assemble, and operate. **ER6, ER7**
ER5 – Blood Model Properties Accurate flow rate, pressure, density, and temperature to blood. **CR2 , CR5**	**CR5 – Deployment Visualization** Allows operators to visualize deployment of devices. **ER1, ER5**
ER6 – Engineering Standards Fully compliant with applicable engineering standards. **CR1, CR4**	**CR6 – Durability** Able to withstand multiple use cycles consistently. **ER1, ER3**
ER7 – Cost Total cost is under budget. **CR1, CR4**	**CR7 – Ergonomics** Of a size and shape that allows for effective demonstrations and tests. **ER2, ER4**

Methods

- Vessel models printed on an AnyCubic Photon Mono M5s Pro Resin 3D Printer using FormLabs Elastic 50A Resin V2, Figure 1 (top left)
- Calcified lesion models printed on an Ender 3V KE 3D Printer using 90A TPU filament
- All models were sliced in Cura for both SLA and FDM processes
- Lesion models adhered to vessel models using 3M Scotch-Weld Plastic & Rubber Instant Adhesive
- Vessel and lesion model dimensions verified by length measurements with a dial caliper, Figure 1 (bottom right)
- Lesion model hardness verified by measurements with digital durometer, Figure 1 (bottom left)
- Adhesive overlap shear strength verified by measurements with digital force gauge for overlap shear test on adhered models, Figure 1 (center)
- Fluid properties verified by performing a ball drop viscosity test, and by calibrating sensors to determine flow rate and pressure within system, Figure 1 (top right)

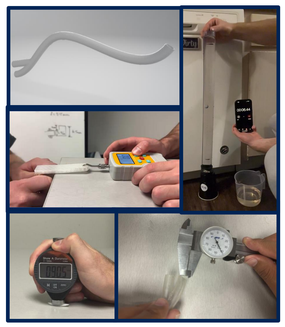

Figure 1: Model Verification

Results

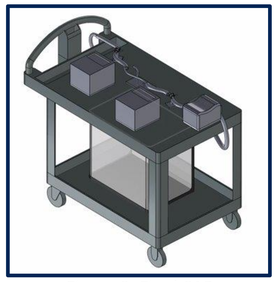

Figure 2: Final CAD

Figure 3: Final Product

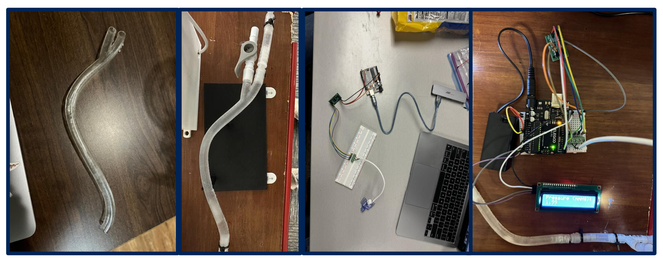

Figure 4: Prototyping

Table 1: Engineering Requirements Summary Table

Engineering Requirement	Target; Tolerance	Measured/Calculated Value
Vessel Properties	11-17 kPa, >50% opacity	15.3 kPa, 79% opacity
Vessel Dimensions	20-30 cm × 1-2 mm × 7-9 mm	21.2 cm × 1.04 mm × 7.81 mm
Lesion Properties	Shore 32-47D, 11.6-18.8 MPa	Shore 39D, 5.7 MPa
Lesion Dimensions	0.5-3.0 cm × 0.5-3.0 mm × 8-50% occlusion	2.8 cm × 3.3 mm × 45% occlusion
Fluid Properties	500 mL/min, 6 mPa·s, 1,060 kg/m^3, 310 K; 5%	483 mL/min, 6 mPa·s, 1,128 kg/m^3, 310 K
Eng. Standard Compliance	100% compliance	100%
Cost	<$3,800.00	$3587.87

Conclusion

- Developed a replicable, non-biologic model for simulating calcified lesions in the peripheral arterial system for vascular interventional device testing.
- Enhancing treatment outcomes for PAD patients by accurately modeling PAD which allows for researchers to optimize interventional device design and performance leading to better treatment options. The project provides a realistic, standardized testing environment for peripheral vascular interventional devices, ensuring their effectiveness and safety before clinical use.
- The client confirmed that the team's final product accurately simulates real-life conditions, enabling effective testing of their Viabahn endoprosthesis devices.
- Using non-biological materials is an ethical choice in this project, as it eliminates the need for animal or cadaveric testing, reducing ethical concerns while providing a cost-effective and repeatable solution.
- Some researchers argue that non-biological materials cannot fully replicate the complex biomechanical properties of human arterial systems due to their layered structure and composition, but advances in materials science and engineering allow for high-fidelity synthetic models that closely mimic key arterial properties, providing an ethical, cost-effective, and reproducible alternative for device testing and optimization.
- Future research possibilities include integrating advanced imaging and simulation techniques, like fluoroscopy, to evaluate vascular interventional devices and their interactions within the calcified vessel models.
- Adapt and/or design the model to simulate different types of vascular diseases, such as soft plaque, deep vein thrombosis, or aneurysms, for broader device testing applications.

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