NORTHERN ARIZONA UNIVERSITY
College of Engineering, Informatics, and Applied Sciences

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Gore Capstone - Iliac Bifurcation Aneurysm Model + Manufacturing Process

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Abstract

The project objective: create an in-vitro model of a Common Iliac Artery Aneurysm (CIAA), a repeatable manufacturing process for multiple models, and a system which replicates anatomical conditions through the model.

The model is designed for endovascular device deployment testing. This model will help determine if a device will successfully exclude an aneurysm under simulated biological conditions. A water clear, flexible polyurethane was selected in order to produce a transparent vascular model that allows for visualization of device deployment. Twelve additional models were produced to verify that the manufacturing process is repeatable. An anatomically accurate CAD model was developed in SolidWorks based on research of human aortic-common iliac bifurcation and aneurysm geometry. Two master models and patterns were printed from the CAD model to define the interior and exterior dimensions of the vascular model (Figure 5). A two part silicone mold was cast from each set of patterns. A wax core was then cast in the inner mold. The core was placed in the outer mold and liquid polyurethane was poured in the mold. Keys were used to hold the wax concentric in the outer mold. After curing, the core was melted out of the polyurethane to reveal a hollow model with a 2.5mm wall thickness. The model was integrated in a system that produces anatomical pulsatile flow and collects pressure and flow data. A touch-screen GUI controls the pump and displays flow rate, and aneurysm pressure. Integration of the electrical components and data acquisition system was completed with an Arduino. The system should provide the ground for a proof of concept for medical devices such as stent grafts.

Design Subsystems

Vascular model

A unique material was developed to produce a translucent model with mechanical properties similar to human arteries. Two-part, room temperature vulcanizing (RTV), flexible clear polyurethane was blended with various ratios of a softening agent to manipulate properties. Material samples of each blend were tested to verify properties.

Fluid circulation

An Arduino Mega board, a DC PWM speed controller, an aquarium submersible water pump, and research of a heart's flow rate per beat was used in order to replicate the pressure, flow rate, and waveform that would be observed in this region of the body. Clear vinyl tubing and fittings were purchased to connect the model to the system.

Sensors

An electronic flow meter and a Deltran pressure transducer was used in order to measure the pressure in the aneurysm and the flow rate of the system.

GUI

A Graphic User Interface (GUI) was built using an Arduino Mega with a TFT touch screen. Pressure and flow rate data from the sensors is displayed on the TFT screen while also allowing the pump to be controlled by the interface. The GUI is able to turn the pump on and off, along with changing the pump from continuous to pulsatile flow. Flow rate and BPM are variable within the GUI.

Manufacturing

Anatomically accurate models were developed using SolidWorks. ABS patterns of the models were printed at NAU's Rapid Lab, then treated with a chemical vapor bath to reduce surface texture. Silicone molds were then constructed from these prints to capture geometry of the vessel. Final models were cast from the liquid RTV polyurethane using these molds.

Design and Iterations

Prototyping revealed opportunities for design improvement. Changes were implemented in the final iteration, which included modified geometry and a pressure transducer port to allow for continuous pressure monitoring in the aneurysm model.

Figure 1: Prototype CIAA and First Iteration of Manufacturing process

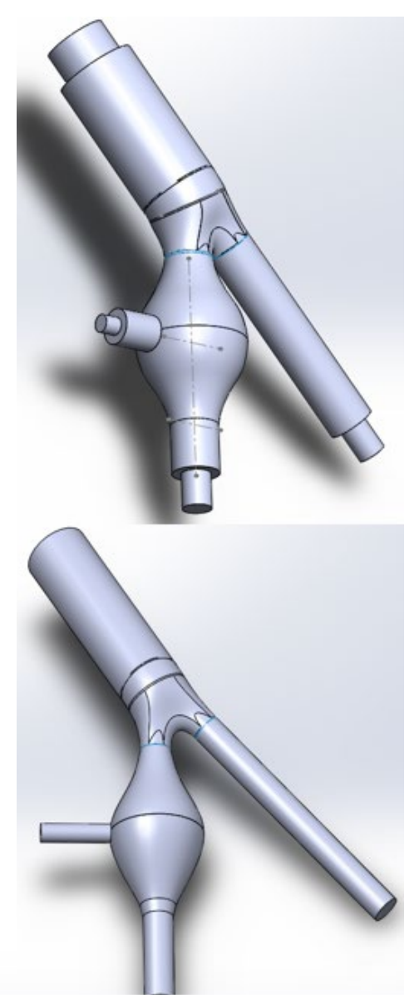

Figure 2: Final CAD Models

Figure 3: Final Model

The final models can be placed within the system in order to mimic pulsatile flow through the model. The GUI is controlled by an arduino that reads and displays pressure and flow rate. The operator can control the flow rate and the type of flow.

Figure 4: Final System Design

Manufacturing Process and Validation

The client for this project requested that a repeatable manufacturing process be developed and documented. The team's manufacturing process requires three main steps: CAD model development, Silicone mold construction and Polyurethane and wax casting.

CAD and 3D Printing

1.Create an acceptable anatomically accurate CAD model from research on CIAAs and arteries (Figure 2).

2.Print masters and patterns for interior and exterior geometries from either PLA or ABS (ABS prints shown in Figure 5).

3.Vapor treat prints to smooth, seal, and strengthen surfaces. Acetone for ABS (Results of the Acetone bath in Figure 6). Ethyl Acetate for PLA.

4.Paint and prime prints for mold making.

Silicone Mold Construction

1.Build walls around the pattern, mix and pour silicone to a specified height.

2.Remove pattern from mold, place master in mold, build walls and pour again.

3.Part the silicone mold at the midline (easily seen by eye) and remove the master to reveal the inner mold cavity. (Interior and Exterior molds: Figure 7)

Polyurethane and Wax Casting

1.A 10% CNC to 90% Paraffin wax mixture was created and poured into the interior mold to create a wax key (center of Figure 7).

2.Wax key is smoothed and placed in exterior mold. Mix, degas, and pour innovative 3-part polyurethane mixture to create a 15 Shore A Hardness model.

3.Degas entire mold (Figure 8). Let Cure for 2 days.

4.Split mold halve, remove model, and remove the wax to reveal a final model.

Rheometer Testing

Four tests were replicated for polyurethane samples (each containing different amounts of thinner). Puck samples were 8mm in diameter and strip samples were 4x1x2cm. Characterization was done in order to select a more biomimetic model for realistic deployment of devices.

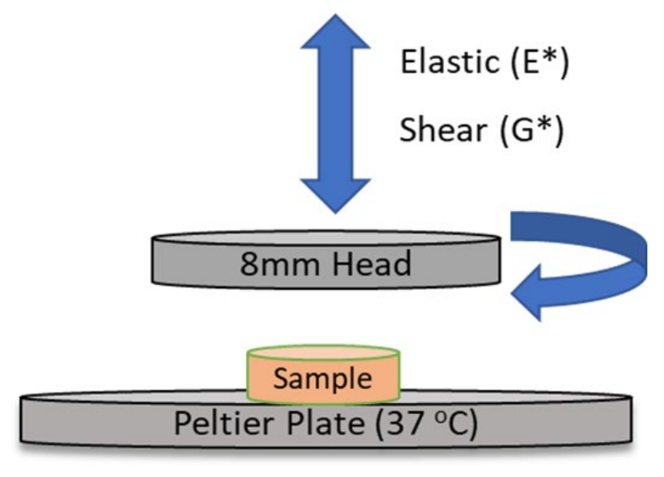

Figure 9. Puck Sample Elastic and Shear Modulus Test [1]

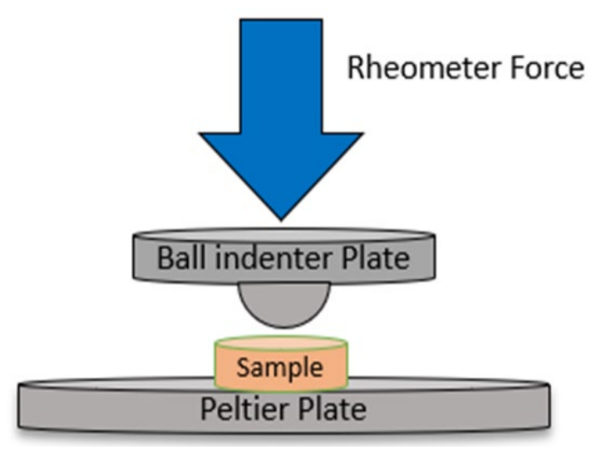

Figure 14. Exponential weakening occurs from 75% to 100% thinner.

Requirement	Target	Tolerance	Actua l	
Wall thickness(mm)	2.3	±0.6	2.53	±0.3
Aneurysm Diameter (mm)	30	±5	30.27	±0.55
Aneurysm Length (mm)	46.87	±4.1	43.7	±1.48
Left Iliac Diameter (mm)	12.36	±2.35	12.55	±0.37
Right iliac Diameter (mm)	12.71	±2.94	12.78	±.65
Left common iliac length (mm)	58.14	±20.01	60.79	±1.72
Right common iliac length (mm)	60.86	±18.89	62.91	±1.78

Manufacturing Process validation

Twenty two polyurethane models were produced in total. Six of these models were randomly selected for testing. The following parameters were tested to validate the manufacturing process and ensure models were within tolerances. Test procedures are described below.

- Creep: A sample was placed in the hybrid rheometer under constant force for a prescribed duration, and creep was measured.
- Compliance: The model was connected to a sphygmomanometer and pumped to anatomical pressure. Compliance was calculated from the resulting diameter change.
- Aneurysm Length: Length was measured using a digital caliper.
- Aneurysm Diameter: Diameter was measured with a digital caliper.
- Hardness: Hardness was measured with a shore A durometer.
- Translucence: A guidewire was inserted in the model to verify visualization.
- Elastic Modulus: Elastic Modulus was measured with hybrid rheometer using the procedure outlined.
- Right common iliac length: Right iliac length was measured with a digital caliper.
- Left common iliac length: Left iliac length was measured with a digital caliper.
- Pressure transuducers were used along with a pitot tube to measure velocity and calculate flow rate. A flow meter was used to verify this calculation.

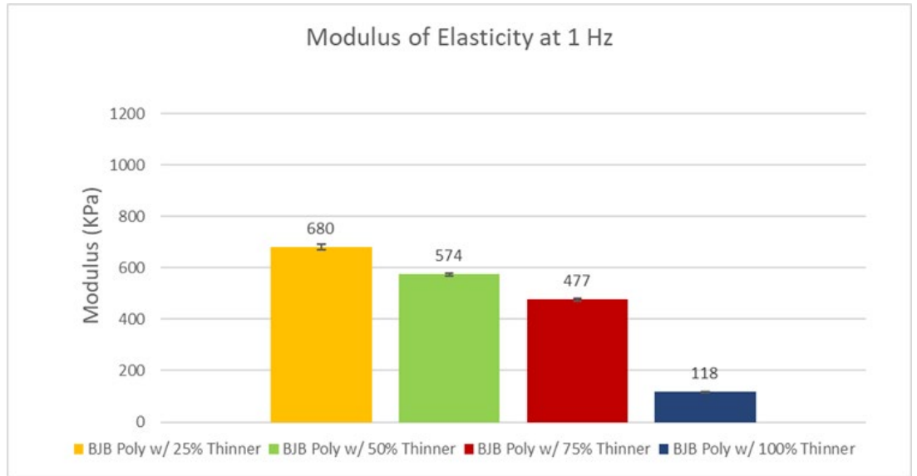

Figure 10. Puck Sample Hardness Test [1]

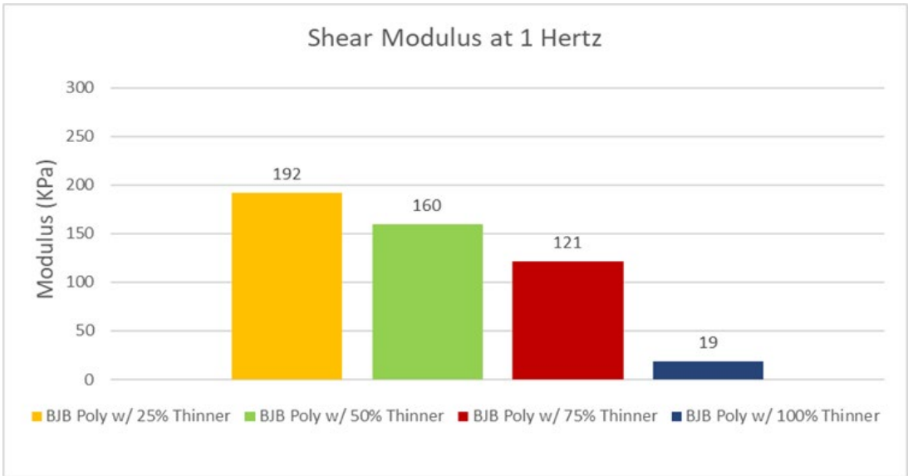

Figure 15. Shear validated the weakening and 75% was chosen.

Conclusion and Future Work

Thirteen anatomically accurate iliac bifurcation models were manufactured using a unique blend of clear flexible polyurethane. Iteration of CAD models produced realistic geometry in the final models. Chemical vapor treatment produced a smooth surface on the patterns which transferred to the molds and final models. Material testing and experimentation produced a model with suitable mechanical properties for the application. A data acquisition system was successfully designed to collect data using an Arduino, flow meter, and pressure transducer. The required data was displayed on a graphical user interface. The Arduino program effectively controlled the pump to produce selectable pulsatile and constant flow on demand from the touch screen. System flow rate was validated using concomitant methods. Aneurysm model geometry was validated using 6 random samples. Translucence was validated using a guidewire to verify visualization. Shore A hardness of the final models was 15.5 +/-1. Percent change of the mock vessel when pressurized was 2.3-5.0% at 80 mmHg and 2.8-5.6% at 120 mmHg.

Future work would include further material experimentation to produce pressurized curing. Longer aortic and iliac arteries would be incorporated in the design to accommodate fittings and increase the healthy tissue landing zone.

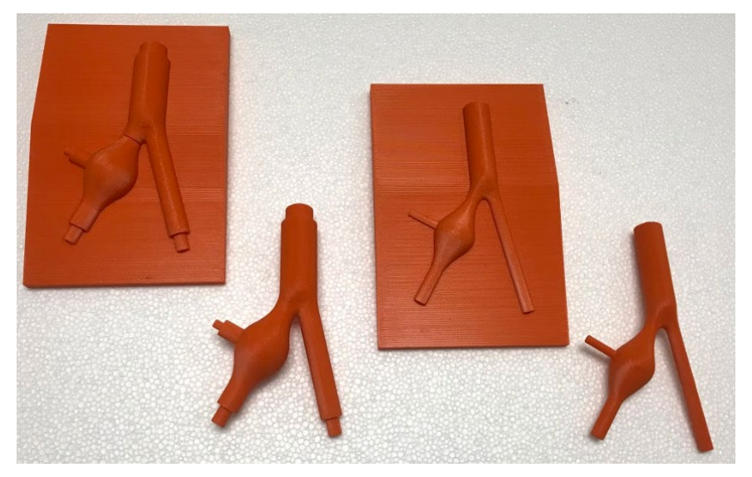

Figure 5. ABS Masters and Patterns.

Figure 6. Vapor Bath Result

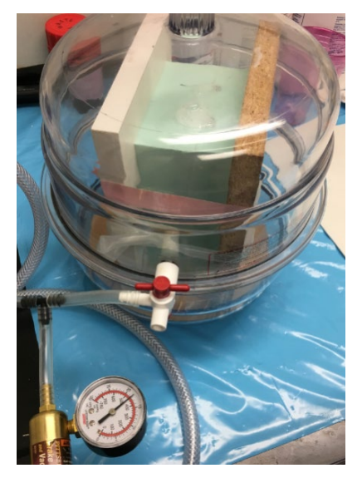

Figure 5. Vacuum Chamber

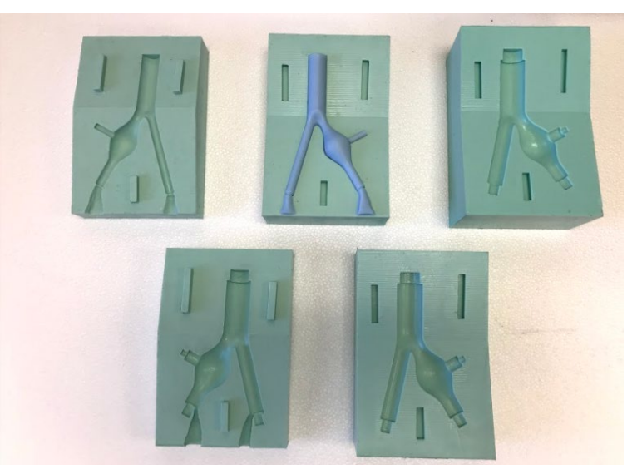

Figure 5. Silicone Molds

References

[1] Norris N, Settanni C, Merrit W, Smith I, Becker T. In Vitro Vascular Model Material Characterization. Journal of NuroIntroventional Surgery Issue 11

[2]

Acknowledgements

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