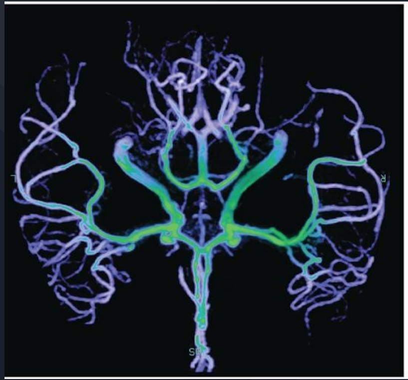
ATI Neurovascular Cast System

Naser Alosaimi
Jalando Edison
Justin McCallin
Matthew Sussman



Mobile In-Vitro Neurovascular Cast System

NORTHERN ARIZONA UNIVERSITY
College of Engineering, Forestry, and Natural Sciences

Project Sponsor:
Dr. Tim Becker

Project Mentor:
Dr. David Trevas

Project Mentor:
Amy Swartz

Client

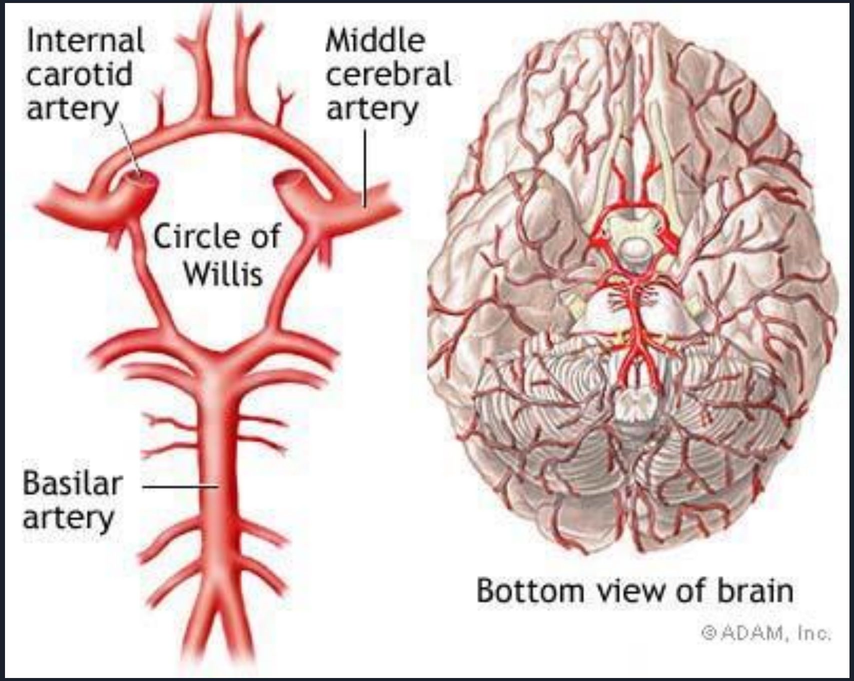
Aneuvas Technologies Inc

- Dr. Tim Becker
- Small start - up company in Flagstaff, AZ.
- Mission to improve human healthcare by developing microcatheter- based medical devices
- Sponsor: W. L. Gore & Associates

Introduction

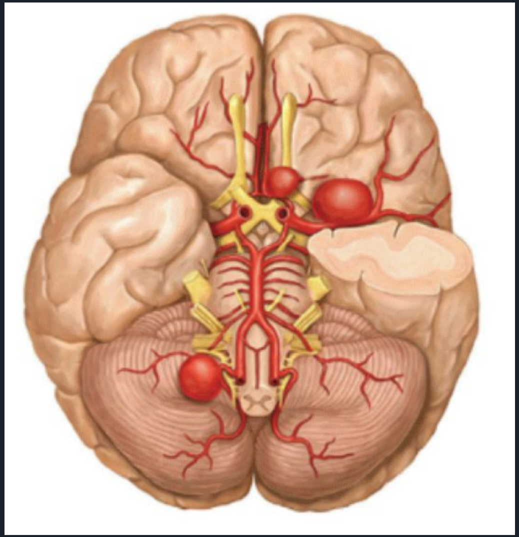
- The task is to design an anatomically correct model of the circle of Willis, a system of arteries that supplies blood to the brain. It will have several aneurysms located in common areas.

- The purpose of this model is to test an aneurysm treatment which was designed by ATI. The fluid will be delivered via microcatheter, which is inserted into the femoral artery in the inner thigh.



Introduction

What is an aneurysm?



Current Methods of Treatment

Source: Cleveland Clinic, Youtube (https://www.youtube.com/watch?v=rRklkA70O1w)

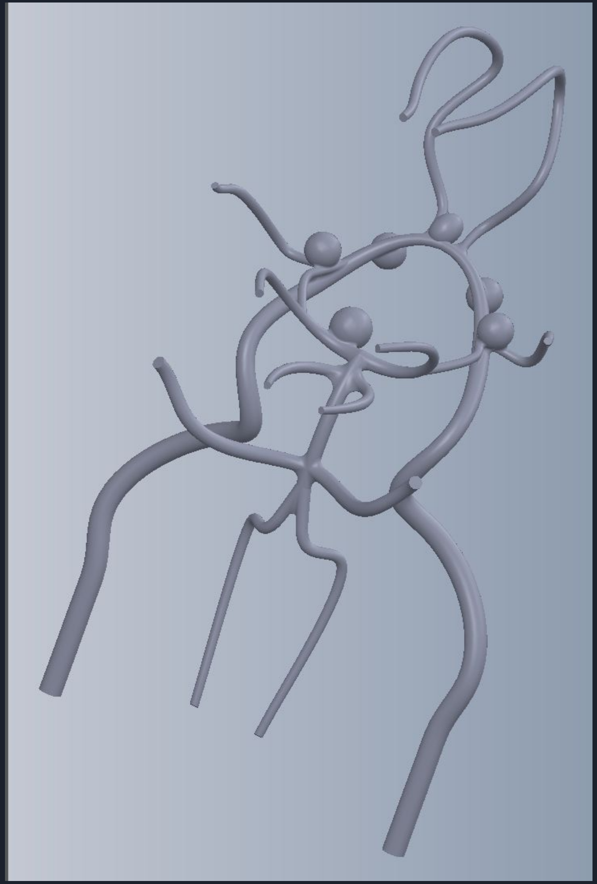
Problem Statement

- The client requests a realistic model of the circle of Willis located in the brain.

- The model is used for testing with aneurysms located in the circle of willis and practice blocking these aneurysms without the need of a human subject.

- With this model the client can help prevent future patients going through major surgery.

- Clear material, low friction, and the material resembles as the circle of Willis.



Customer Requirements

- The customer requirements are requirements generated by the client of the project:
  - Portability
  - Reliability
  - Durability
  - Visibility
  - Accuracy
  - Geometrically Realistic
  - Reproduction

Engineering Requirements

- The Engineering Requirements are requirements that were developed by the team and it was influenced by the client of the project.

Table. 1 - Engineering Requirements

Engineering Requirements	Units	Tolerances	Target Values
Friction (pulling Force)	Newtons (N)	±0.003N	0.015N [2]
Clarity	1 (unclear) -10 (clear)	±2	8
% Elongation	Percentage (%)	±10%	%150
Hardness	shore hardness scale (A)	±5A	35A
Contaminant level	Percentage (%)	±5%	0%
Cost	US Dollars ($)	±200	$2000

Attempted Methods

Dip Coat

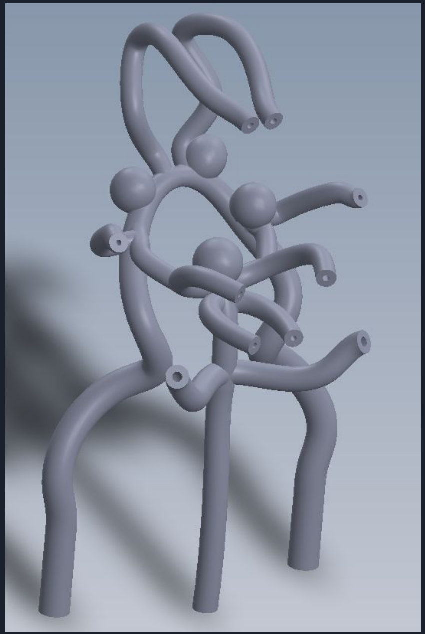
- Create a “core” of the circle of Wills
  - Core is a solid representation of the inside of the tube
  - Core is created using a mold
- Dip Core into molten polymer (melted plastic)
- Allow plastic to solidify
- Remove core from plastic tubes

Why it failed

- Melted plastic too viscous
- Mold material failed to solidify properly

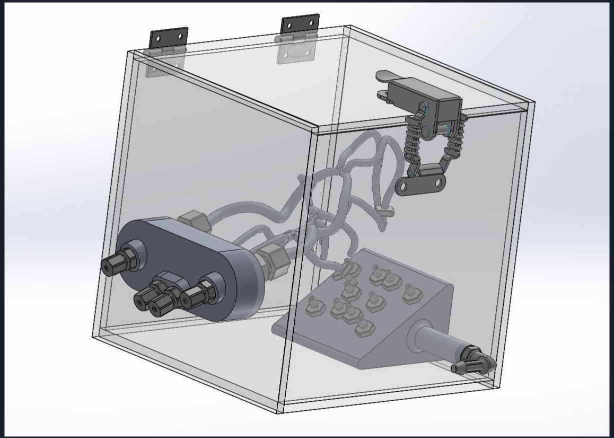
Final Design

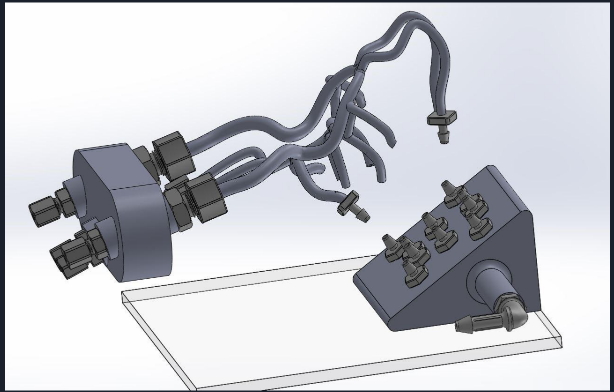
- The circle of Willis is a model of the actual system of arteries in the brain
- Circle of Willis Model will be 3D printed by ProtoLabs using their material
  - Digital Photopolymer Clear 30A
- Case system will be made using high clarity cast acrylic
- Flow system previously in use will be utilized



Circle of Willis-Case- Flow system Connection

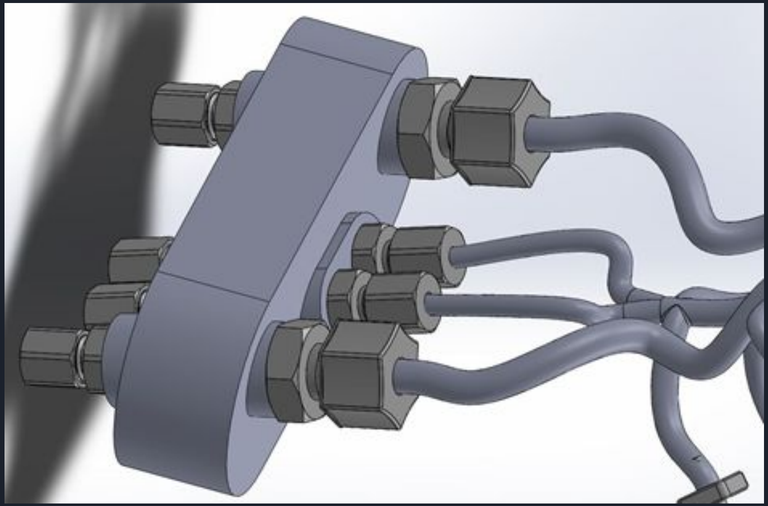
- The flow system has three main parts the pump, the inlet adapter, and the exit manifold
  - The pump simulates blood flow and warms the fluid to body temperature
  - The inlet adapter uses compression fittings to maintain the inner diameter
  - The outlet manifold connects all the flows and sends the fluid back to the pump
- The inlet adapter and outlet manifold are connected to the case with inlet and outlet ports drilled out of the case.
- The circle of Willis model connects directly to the inlet adapter and outlet manifold.

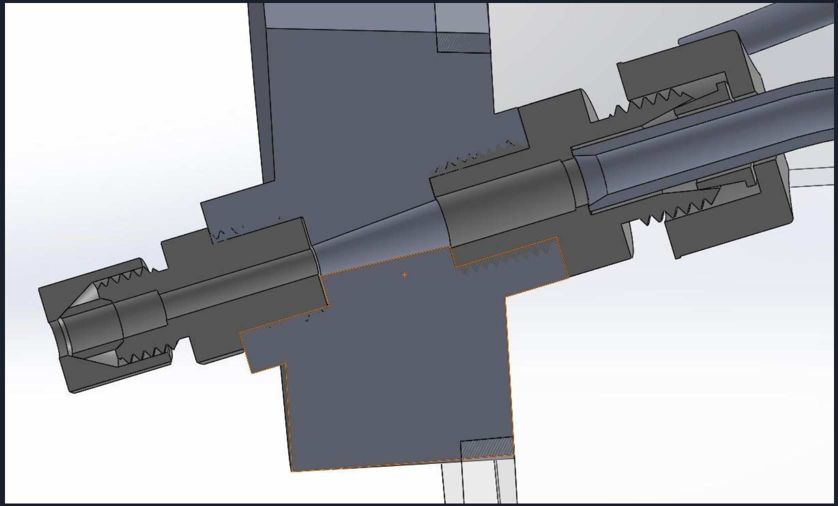




Circle of Willis-Case-Flow System Connection

- The Inlet adapter has a taper to ensure smooth transition by microcatheter
- Compression fit connectors used maintain constant inner diameter





Hardware Review - Friction (Pulling Force)

- Testing was done using the Rheometer to get the friction.
- Friction testing for the materials was taken by taking the average of each trial.
- Each materials went through approximately 20 trials to ensure accuracy of results

Hardware Review - Friction (Pulling Force)

Material	Pulling Force [N]	SD
ProtoLabs 30A	0.3294	±0.0412
ProtoLabs 40A	0.3351	±0.0470
Blood Vessel	0.015 [2]	±0.003

- Data shows that the material does not meet the engineering requirements
- Data was approved by the client because there was testing involved that contains friction forces within the ranges [3].

Hardware Review - Clarity

- Clarity is not related to the realistic look of the blood vessel but it helps with the accuracy of the trails.
- Clarity is based on how clear is the model when conducting trails.
- Testing for the clarity is done by using a microcatheter and seeing if it is clear inside the model.
- The client can see the microcatheter and the liquid embolic (treatment) which is used to seal the Aneurysm
- The clarity meets the engineering requirements
    - Client classifies clarity as a 6 out of 10

Hardware Review - Elongation

- Elongation is how far can the material elongate before breaking.
- Elongation matters because the material needs to be elastic to handle the microcatheter.
- The elongation of the selected material is higher than the engineering requirement.
- The elongation percentage was received from the material properties [4].

PROPERTIES:

Digital Material Properties	ASTM Standard	Unit of Measure	30
Tensile Tear Strength	D-624	Kg/cm	5.0-7.0
Elongation at Break	D-412	%	220-270

Hardware Review - Hardness

- Hardness is a material's ability to resist changing its original form permanently
- The material used was rated a shore hardness of 30A from the supplier's material properties information
- It's important for the material to have the target hardness to avoid changes in the flow within the model and providing inaccurate data
- The hardness falls within the tolerances of the engineering requirement target value [4]

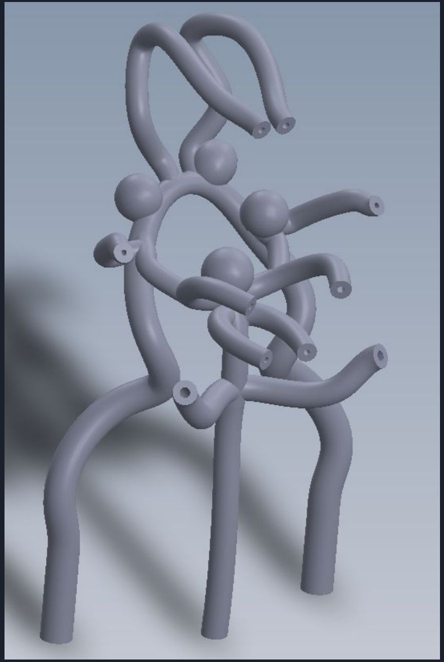
Shore Hardness	D-2240	Scale A	30-35
Tensile Strengnth	D-412	MPa	2.4-3.1

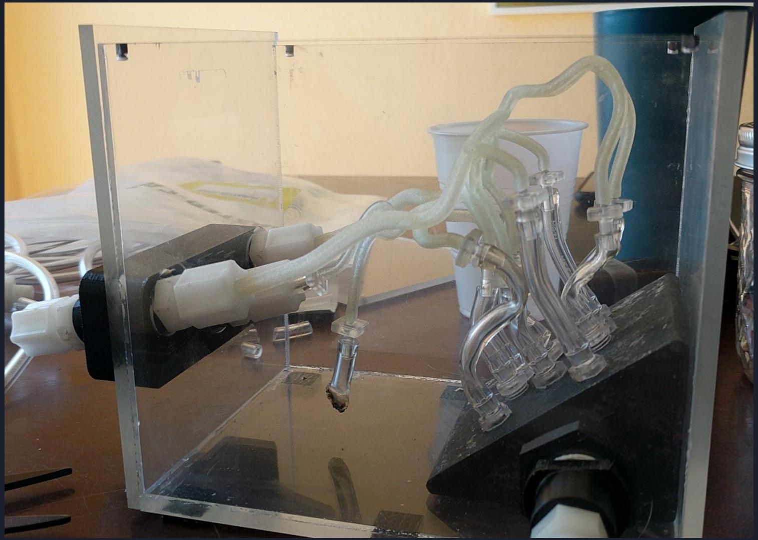
Contamination Level Measurement Method

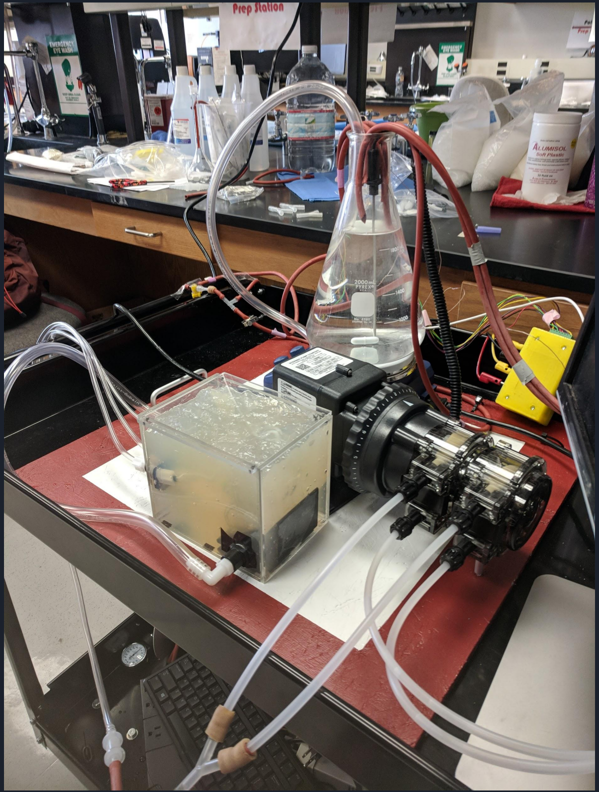
- Connect model to the flow system
  - The flow system has an in-line filter designed to capture contaminates
- Pump activated and allowed to cycle “blood” for 5 minutes
- Pump is turned off and the in-line filters are removed
- Contaminate particles are counted, measured, and characterized
  - Particles are measured and characterized following USP 788 [5]
  - Any particles larger than 10µm are considered [5]

Testing has not yet been performed as the particle characterization method was being developed by another capstone team.

Final Product



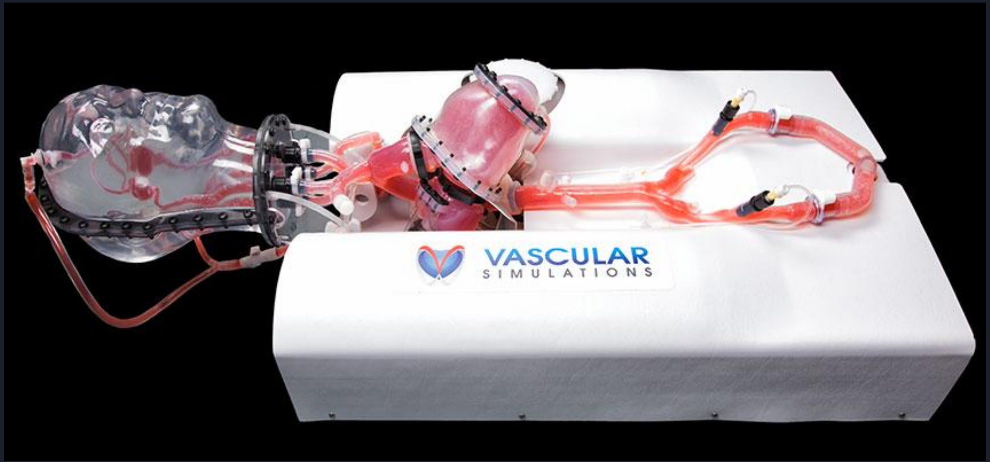




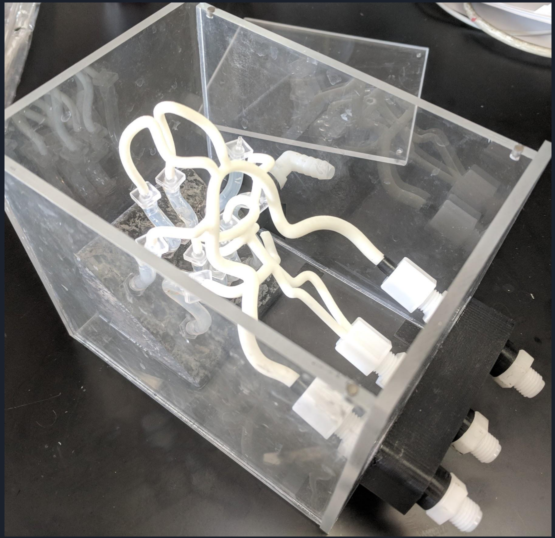
Matt, 4/27/2018, Mobile In-Vitro Neurovascular Cast

Advantages Over Other Products

- Custom circle of Willis model to customers exact specifications
- Material realistically replicates artery movement and flexibility
- Easy maintenance and model replacement
- Three different entrances for catheters
- Better visibility



The Replicator from Vascular Simulations



Matt, 4/27/2018, Mobile In-Vitro Neurovascular Cast

Conclusions

- Most engineering requirements were met except for:
  - Friction
  - Contamination level
- The team achieved the project goals and the client was satisfied with the final project
- Next steps
  - Test for contamination levels
  - Introduce and begin testing aneurysm treatment

References

[1] https://www.youtube.com/watch?v=rRklkA70O1w

[2] https://www.researchgate.net/publication/223539627_Contact_and_friction_

between_catheter_ and_blood_vessel

[3] https://illiad.nau.edu/illiad/illiad.dll?Action=10&Form=75&Value=658338

[4] https://www.protolabs.com/media/856667/polyjet-material-spec-data-sheet-02.pdf

[5] https://www.mddionline.com/analyzing-particulate-matter-medical-devices

Questions