

# Mobile In-Vitro Neurovascular Cast System

## Preliminary Proposal

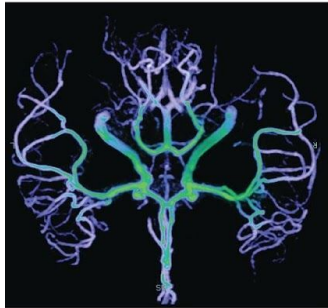
**Naser Alosaimi**

**Matthew Sussman**

**Justin McCallin**

**Jalando Edison**

**2017-2018**



# Mobile In-Vitro Neurovascular Cast System

**NORTHERN  
ARIZONA  
UNIVERSITY** 

College of Engineering,  
Forestry, and  
Natural Sciences

**Project Sponsor:** Anevas Technologies Inc.

**Faculty Advisor:** Dr. Timothy Becker

**Instructor:** Dr. David Trevas

## **DISCLAIMER**

This report was prepared by students as part of a university course requirement. While considerable effort has been put into the project, it is not the work of licensed engineers and has not undergone the extensive verification that is common in the profession. The information, data, conclusions, and content of this report should not be relied on or utilized without thorough, independent testing and verification. University faculty members may have been associated with this project as advisors, sponsors, or course instructors, but as such they are not responsible for the accuracy of results or conclusions.

## EXECUTIVE SUMMARY

The purpose of this project is to design and create an In-vitro Neurovascular cast system with aneurysms to test a treatment for aneurysms which completely closes them using the product labeled PPODA-QT. The cast system will be built using non-biologic materials and must stimulate the size of the Circle of Willis (CW) in the brain and under fluoroscopy testing microcatheter deployment. The design must be an anatomically correct model of the Circle of Willis, a system of arteries that supplies blood to the brain, and it must have several aneurysms located in common areas. The project will allow for testing of a potentially lifesaving treatment with less recovery time. Our sponsor and client for this project is Dr. Timothy Becker and this cast model will be used for his start-up company Aneuvax Technologies, Inc (ATI) to improve human healthcare by using novel microcatheter-based medical devices for the treatment of aneurysms and other vascular defects in the brain. The requirement of this project is to develop, characterize, and justify the vessel shape, diameter, and branching, the vessel friction and elasticity, the cast materials and blood substitutes, and the blood pressure and temperature tolerances. The engineering requirements developed for this project with the help of our client included friction of the inner diameter of the model, the clarity of the material used to make the model, the size of the model has to resemble the size of the CW, the % elongation of the vessels has to resemble that of the CW, contaminant level of the model when the artificial blood is flowing, the cost to manufacture the model which is estimated to be less than \$2000, and the hardness of the model's vessels has to resemble that of the CW. The customer requirements developed for this project includes Portability, Reliability, Durability, Visibility of the model when inserting the microcatheter and artificial flood. The accuracy of the model compared to the actual CW, model must be geometrically realistic to the actual CW, and Reproduction which is the durability and work required to create the model. Through research on prior materials, the team decided to research two possible manufacturing methods: 3D printing and casting. There are three materials that will be used in 3D printing and they are NinjaFlex, Agilus30, and SainSmart, where NinjaFlex has a higher % elongation and each material share a chemical resistance factor and abrasion resistance. Casting manufacturing focuses on a materials made by Star Thermoplastics and testing is underway to find one of their materials that best suits our needs. Testing will be performed using a rheometer which is a device designing to measure the friction of a material. Once testing is complete, prototyping will begin. The first prototype will be created via the 3-D printing method. A second prototype will be creating using a process knowing as dip-coating, where a shape is dipped repeatedly into a liquid causing the liquid to solidify in thin layers over the original shape. Once the prototypes have been generated, testing will occur again to determine the final manufacturing technique and material.

# TABLE OF CONTENTS

## Contents

<b>DISCLAIMER</b>	<b>2</b>
<b>EXECUTIVE SUMMARY</b>	<b>3</b>
<b>TABLE OF CONTENTS</b>	<b>3</b>
<b>BACKGROUND</b>	<b>6</b>
Introduction	6
Project Description	6
Original System	6
Original System Structure	6
Original System Deficiencies	7
<b>REQUIREMENTS</b>	<b>7</b>
Customer Requirements (CRs)	8
Engineering Requirements (ERs)	8
Testing Procedures (TPs)	9
House of Quality (HoQ)	10
<b>EXISTING DESIGNS</b>	<b>10</b>
Design Research	10
System Level	10
Subsystem Level	11
Subsystem #1: Modeling Artery Systems	11
Existing Design #1: Fabrication of aneurysm simulator with a 3D printer	11
Figure. 2 - Fabrication of aneurysm simulator with a 3D printer	12
Existing Design #2: Intracranial Aneurysm Replicator	12
Existing Design #3: Using 3D-Printed Patient-Specific Aneurysm Models in Cadavers	12
Subsystem #2: Designing Realistic Supports	13
Existing Design #1: Realistic Brain and Skull Models	13
Most examples use realistic models for the brain and skull to simulate the support and resistance for the blood vessels. Both must be clear and able to be disassembled. The skull will also need to feature outlets and inlets for the flow of the synthetic blood.	13
Existing Design #2: Vascular Simulations Replicator	13
Subsystem #3: Creating Flow System	13
Existing Design #1: Quick Disconnect Fitting	13

Existing Design #2: Push to Connect Fitting	14
Existing Design #3:Luer Lock Fittings	14
<b>DESIGNS CONSIDERED</b>	<b>15</b>
Design #1: Dip-Coat	15
Design #2: 3-D Printing	16
Design #3: 3-D Printed Frame	16
Design #4: Clear Molded “Brain” Shell	16
Design #5: Paint Material to Core	17
Design #6: Injection Molding	17
Design #7: Compression Molding	17
Design #8: Aluminum Casting	18
Design #9: Sand Casting	18
Design #10: Extrusion	18
Design Description	18
<b>PROPOSED DESIGN – First Semester</b>	<b>20</b>
<b>DESIGN SELECTED – First Semester</b>	<b>20</b>
Rationale for Design Selection	21
<b>CONCLUSIONS</b>	<b>21</b>
<b>REFERENCES</b>	<b>22</b>
<b>APPENDICES</b>	<b>23</b>
Appendix A: House of Quality	23
Appendix B: Individual Analysis	24
Dip-Coat and Factor of Safety Analysis	24
Fluid Flow Analysis	25
Stress Analysis	25
Appendix C: Decision Matrix	26

# 1 BACKGROUND

## 1.1 Introduction

Aneuvus Technologies, Inc (ATI) has tasked our team with creating an anatomically correct model for the Circle of Willis. The objective of the project is to create a means for testing a product created by ATI, PPODA-QT (poly(propylene glycol) diacrylate - pentaerythritol tetrakis(3-mercaptopropionate)). The product is a liquid embolic designed to treat aneurysms by completely filling them when injected by microcatheter. Due to the nature of ATI's testing the model created by our team must include aneurysms in different locations as they would form in the brain.

## 1.2 Project Description

Following is the original project description provided by the sponsor:

Scope of Work:

The scope of this project is to design, build, and test a system for simulating vascular defects and vessel branches, using non-biologic materials and testing microcatheter deployment under fluoroscopy. The system must simulate the vessel size and complexity (tortuosity) of the main brain vessels of the circle of Willis (CW).

Overall Requirements:

1. Develop, justify, and characterize the following attributes (recommended but not limited to):
  - Vessel shape, branching, and diameter
  - Vessel elasticity and vessel/catheter friction
  - Materials (polymer cast materials, blood substitutes, etc.)
  - Blood pressure and temperature tolerances
2. Allow visualization of device deployment (visually clear and compatible with fluoroscopy)

Deliverables:

Literature review, project proposal, final report, engineering analysis, prototype system with resulting data, cost estimate for duplication, bill of materials, detailed procedure for repeatable manufacturing, and all expenses (notify client of intended purchases, or submit receipts for reimbursement within 1-week of purchase).

## 1.3 Original System

The original system was designed by a capstone team last year. They designed the entire Circle, but did so by having a block with hollow vessels. The design also did not include the use of clear vessels and did not include any aneurysms. The system included a flow system which our client has stated will be used in the new system as well.

### 1.3.1 Original System Structure

The previous system consisted of one solid block of polyurethane that was cast around a polyvinyl alcohol core. After the Polyurethane solidified, a hole was drilled into the mold to expose the entrances of the circle of Willis Polyvinyl alcohol print. By placing the model in boiling water, the agitating water dissolved the Polyvinyl alcohol leaving a void with the shape and dimensions of the circle of Willis, Figure 1 shows the completed prototype.



Figure. 1 - Previous Model

The original system operated using the same fluid and pump that our system will use. The holes that were drilled out were then connected to the flow system.

### 1.3.2 Original System Deficiencies

The original system deficiencies included clarity, size, and aneurysms. As seen in Figure 1 the system was not clear, but rather a opaque orange/brown color. The vessels that can be seen also appear to be white rather than clear. The model was almost to scale, though it has been expressed by our client that the vessel diameter was too small in most cases. The final deficiency was the lack of aneurysms modeled, there were none so the system could not be used to test the PPODA-QT.

## 2 REQUIREMENTS

In this chapter of the report, it contains information regarding the design requirements, the customer requirements, and the engineering requirements. Furthermore, the design requirements contain information regarding what the client requires the team to achieve as an end goal. The customer requirements is a list of requirements that are generated from the design requirements and it requires the team to meet with the client themselves in order to generate these and the engineering requirements are based off the customer requirements. This chapter also includes the House of Quality and it is used to indicate the weighted engineering requirements and indicate which is important to the overall goal.

## 2.1 Customer Requirements (CRs)

The customer requirements are requirements generated by the client of the project. And in total the team has seven CR's to focus on and each are presented on a table shown below.

Table. 1 - Customer Requirements

Customer Requirements	Weight (out of 10)
Portability	7
Reliability	9
Durability	7
Visibility	10
Accuracy	5
Geometrically Realistic	10
Reproduction	8

- Portability is how easily the model will be transported from one location to another.
- Reliability is how the model will do what it is required to do and do it repeatedly with little to no issue.
- Durability is how many trails the model can be used before it fails and requires the user to get a new model.
- Visibility is how clear the model is when the artificial blood and the microcatheter is placed inside it.
- Accuracy is how close the model will function when compared the actual Circle of Willis.
- Geometrically Realistic is how the model looks realistically compared to the Circle of Willis.
- Reproduction is the duration and the work required to create the model. The less work and time it takes to make the model the better.

## 2.2 Engineering Requirements (ERs)

The Engineering Requirements are requirements that were developed by the team and it was influenced by the client of the project. Furthermore, there are currently seven engineering requirements that were developed and they are Percentage of Elongation, Friction, Clarity, Size, Contamination Percentage, Cost, and Hardness and they presented in the table below.



Table. 2 - Engineering Requirements

<b>Engineering Requirements</b>	<b>Units</b>	<b>Tolerances</b>	<b>Target Values</b>
Friction	Newtons (N)	±0.5N	0.24N
Clarity	Percentage (%)	±20%	99%
Size	cubed inches (in <sup>3</sup> )	±0.5in <sup>3</sup>	3-4in
% Elongation	Percentage (%)	±10%	%150
Hardness	shore hardness scale (A)	±5A	35A
Contaminant level	Percentage (%)	±25%	99%
Cost	US Dollars (\$)	±200	\$2000

- Friction is the friction of the inside diameter of material used when the microcatheter is placed inside.
- Clarity is how clear the material used to make the model.
- Size is the size of the model and it has to be close to the actual size of the Circle of Willis.
- % Elongation is how far the vessels elongate and it has to be close or equal to the actual elongation of the Circle of Willis.
- Hardness is the hardness of the vessels and it has to be close or equal to the actual hardness of the Circle of Willis.
- Contaminant level is the percentage of the contamination of the model if it dissolves and contaminating the artificial blood when testing the model.
- Cost is how much the whole model will cost to manufacture and the end goal is \$2000.

### **2.3 Testing Procedures (TPs)**

To ensure the team's cast system meets the engineering requirements, Testing Procedures (TP) will be conducted. The follow lists how each of the TPs will be performed.

#### **% Elongation**

Elongation is important in accurately creating aneurysm on the Circle of Willis and the material should have a high elongation to avoid material failure. Each material the team selected has material properties given, specifically the elongation at break measurement percentages. We can verify these numbers using an Instron testing device from the university's Multifunctional Materials and Adaptive Systems Lab.

#### **Friction**

Using the DHR-2 Hybrid Rheometer from our client's lab, the team will mold a tube from our tested material and inserting a microcatheter into our modeled vessel. Following rheometer testing guidelines,

we will measure the friction between the two material in which the least friction material will be the selected in the tests conducted.

### **Clarity**

Testing clarity will be qualitative in that the material should be clear enough to see the microcatheter once it's inserted into our model. The client will express his preference once several models are created and a microcatheter is visible while inside the Circle of Willis.

### **Size**

The model has to be anatomically accurate to the Circle of Willis and this is achieved by researching existing data for the dimensions. From there, a micrometer will be used to measure the diameter, length, and wall thickness of our model and compare to the data gathered. Designed aneurysms will be measured for length and diameter to keep within average sizes found in the brain.

### **Contaminants**

The team is working along side another group that has the same client and their goal is to ensure they account for the particles are accounted for and few if any foreign particles are released into the vessels in the brain. This is extremely important as it can lead to strokes for the patient, and they hope to achieve this through several methods but fluoroscopy is an mentioned solution.

## **2.4 House of Quality (HoQ)**

The House of Quality is a template that allows the team to process ideas and help with planning what is needed next. Furthermore, the House of Quality contains two main sections and they are Customer Requirements and Engineering Requirements. To explain, the Customer Requirements are requirements where the team meet with the client and discuss what is needed to be done as an overall goal. Meeting with the client benefited us because we could identify currently seven Customer Requirements and they are Portability, Reliability, Durability, Visibility, Accuracy, Geometrically Realistic, and Reproduction. The next main section is the Engineering Requirement and it contains specific information regarding the project which is Mobile In-Vitro Neurovascular Cast System and they are Percent of Elongation, Friction, Cost, Hardness, Clarity, Size, and Contamination Percentage. The House of Quality currently awaits the client's approval and it is displayed in Appendix A.

## **3 EXISTING DESIGNS**

### **3.1 Design Research**

Many different sources were used to research and evaluate design alternatives. Several are company websites. These companies produce things such as intracranial aneurysm surgery simulators and analyzing their methods to see what will and won't work for this project has been very valuable. In addition, journal articles have been cited. These often contain newer, more experimental methods and information. Biology and anatomy textbooks are also a valuable resource. Lastly, the group interviewed a surgeon to gain more hands-on information on human anatomy and surgery processes.

## 3.2 System Level

There are several design subsystems that required us to research and come up with different options. The focus is on the arteries in the Circle of Willis region. It must be highly realistic and transparent. It must also be able to be fabricated in a cost-efficient manner. The surrounding systems are just as important: the support system and surrounding materials must be realistic. Lastly, a system to allow for the required flow must be designed and implemented.



The black box model, pictured above, shows the flows of the major inputs and outputs. A black box model is useful to visualize the essential elements of a design.

## 3.3 Subsystem Level

### 3.3.1 Subsystem #1: Modeling Artery Systems

The most important subsystem is the blood vessel system. It will also be the most difficult to execute in a way that creates highly realistic models. There are several existing models similar to what we want; each with good and bad design features.

#### 3.3.1.1 Existing Design #1: Fabrication of aneurysm simulator with a 3D printer

This article from a scientific journal [1] describes the process of creating a synthetic skull, brain, and artery system [1]. Their purpose is to create a model for use in training surgeons [1]. To create the artery system, they first 3D print a negative (interior) of the system [1]. They then paint the 3D print in liquid silicone and allow it to harden. Lastly, the 3D print is dissolved. This process is different than others because they do not print a model of the aneurysm, they leave an area thin so that an aneurysm develops naturally [1].

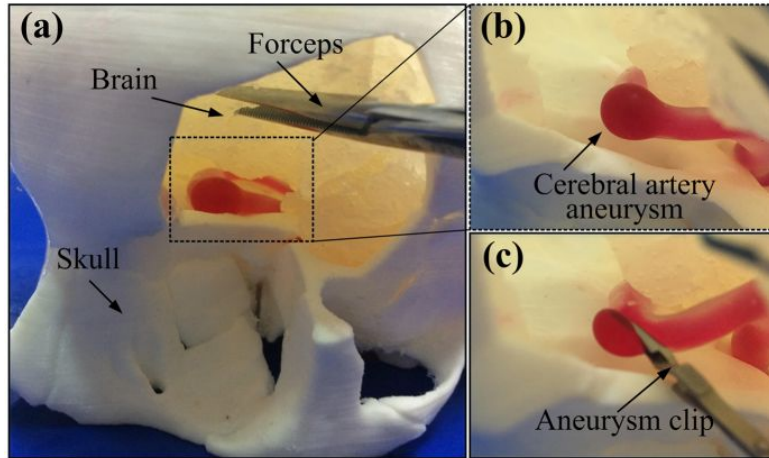


Figure. 2 - Fabrication of aneurysm simulator with a 3D printer

### 3.3.1.2 Existing Design #2: Intracranial Aneurysm Replicator

The Replicator from Vascular Simulations is highly realistic. It uses their proprietary synthetic blood warmed to body temperature and has realistic flow [2]. The artery system is suspended in a gel designed to mimic the elasticity of the brain. The blood vessels are made out of a soft silicone [2]. However, silicone as the material for the arteries was specifically ruled out by the customer; due to it being too soft and having high friction.

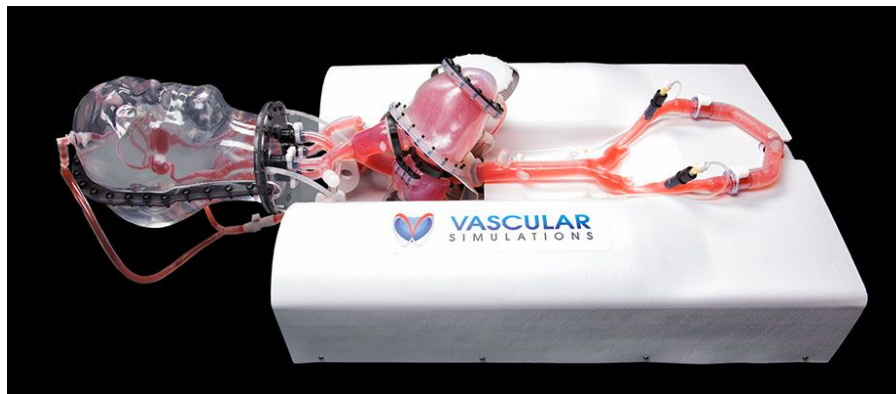


Figure. 3 – Intracranial Aneurysm Replicator

### 3.3.1.3 Existing Design #3: Using 3D-Printed Patient-Specific Aneurysm Models in Cadavers

This research paper researches whether or not the process of using 3D-printed patient-specific aneurysm models in cadavers is a viable practice [3]. The goal is to simulate the specific case a surgeon is working on to increase results for the actual surgery. The authors of the paper conclude that this process could be extremely valuable as a training method in difficult cases. The 3D printed aneurysm is done out of a rubber-like material called tangoBlackPlus [3]. The material is available in clear and may be a good alternative to our current 3D print material: NinjaFlex.

### **3.3.2 Subsystem #2: Designing Realistic Supports**

In the the skull, the arteries are supported differently in different regions, depending on anatomy. In some locations, it is only supported by the brain. In others, it passes through the skull; which means that the vessel is fairly rigid in that region. Our goal is to simulate these differences as closely as is feasible.

#### **3.3.2.1 Existing Design #1: Realistic Brain and Skull Models**

Most examples use realistic models for the brain and skull to simulate the support and resistance for the blood vessels. Both must be clear and able to be disassembled. The skull will also need to feature outlets and inlets for the flow of the synthetic blood.

#### **3.3.2.2 Existing Design #2: Vascular Simulations Replicator**

Mentioned previously, the Vascular Simulations Replicator uses a clear gel in place of an anatomically correct brain model. The gel simulates the resistance and support given by the brain [2]. The advantages of this would be not needing to design and fabricate a brain model. In addition, the fluid is clear and provides good visibility. A disadvantage is dealing with the gel when you need to open and close the system.

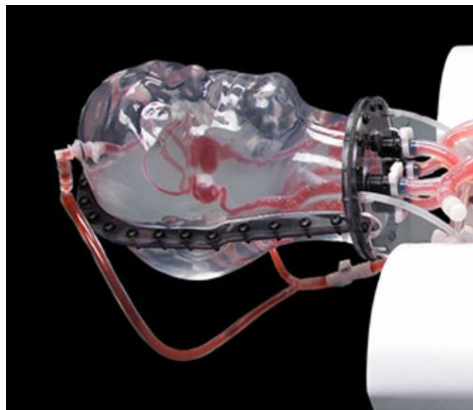


Figure. 4 – Close view of Intracranial Aneurysm Replicator

### **3.3.3 Subsystem #3: Creating Flow System**

The model will have a synthetic, blood-like fluid flowing similarly to actual conditions. This includes flow rates, viscosity, and temperature. The blood vessels will allow for this flow, but additional systems must be implemented to create a flow loop with removable connections. In addition, these connections must not interfere with the path of the microcatheter.

#### **3.3.3.1 Existing Design #1: Quick Disconnect Fitting**

The fastest type of tube connector is a quick disconnect fitting. However, the connectors are usually not rated to the relatively high pressure that we may deal with. In addition, the interior has several parts which may interfere with the operation of the microcatheter.



Figure. 5 – Quick Disconnect Fitting

### 3.3.3.2 Existing Design #2: Push to Connect Fitting

Push to connect fittings are also relatively easy to use. However, they are also able to withstand higher pressures and are more reliable. But, just like the quick disconnect, they have internal parts that would get in the way of operation. It may however be possible to modify one of these connectors to suit our needs.

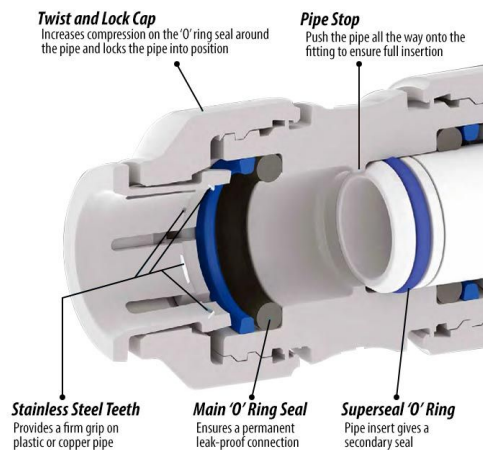


Figure. 6 – Push to Connect Fitting

### 3.3.3.3 Existing Design #3: Luer Lock Fittings

The best option may be using Luer locks. These locks are frequently used along with syringes in medical applications. They use simple threads to make the connection. Because of the lack of any mechanical seals and moving parts, it will be easier to control the inner diameters of the connections and make modifications if necessary.



Figure.7 – Luer Lock Fitting

## 4 DESIGNS CONSIDERED

The designs considered relate not to the geometry of the Circle of Willis, but rather to the manufacturing process and the display method. The designs must be able to accurately replicate the Circle and support the completed model in realistic ways.

### 4.1 Design #1: Dip-Coat

The dip-coat manufacturing process would require a core to be created, most likely 3-D printed but it can also be cast of soft flexible materials. Once the core has been printed, it will be dipped repeatedly into a bowl of a clear molten polymer. The dip-coat process will be repeated until the desired thickness is achieved. The polymers that are being considered for the melting process are designed by Star Thermoplastics. Below, Table 3 shows the Star Thermoplastic polymers being considered. One of the design requirements is to keep the shore hardness within 30-40A so we will be considering only the materials that meet this criteria.

Table. 3 - List of available StarMed TPE's [6]

StarMed® TPE 9000 Series	Hardness Shore A	Specific Gravity g/cc	Tensile Strength psi	300% Modulus psi	Elongation %	Tear Strength pli
StarMed® 9007-0000	7 A	0.88	266	65	713	35
StarMed® 9015-0000	15 A	0.89	857	99	973	170
StarMed® 9025-0000	26 A	0.90	823	197	553	154
StarMed® 9030-0000	29 A	0.90	1,100	149	675	235
StarMed® 9035-0007	34 A	0.89	1,444	215	753	512
StarMed® 9040-0000	40 A	0.89	925	323	598	304
StarMed® 9040-0007	43 A	0.92	1,651	311	995	450
StarMed® 9045-0000	44 A	0.89	747	577	593	363
StarMed® 9030-1000	28 A	0.89	729	261	604	200
StarMed® 9045-1000	46 A	0.89	710	413	556	295
StarMed® 9045-1001	45 A	0.90	976	281	616	142
StarMed® 9055-1007	54 A	0.89	1,484	388	815	325

Pros:

- Clear
- Easily repeated
- Multiple can be produced at once

Cons:

- Core will not be reusable
- Time consuming to get large thickness
- Wall thickness will be hard to keep constant

## **4.2 Design #2: 3-D Printing**

3-D printing the vasculature is a one step process that simply needs the materials and a CAD drawing. The Material that would be used is Agilus30 as it has a shore hardness within the range of 30-40A and is offered in clear. This material and manufacturing process will require the model to be professionally printed to ensure the highest possible resolution and surface finish.

Pros:

- High Precision
- Easy to replicate

Cons:

- Expensive
- Time consuming

## **4.3 Design #3: 3-D Printed Frame**

3-D printing a frame would allow for the vasculature to be held securely in place while keeping them visible to the naked eye. The frame would hold the Circle from below and there would be clips holding the vessels placed periodically. The clips could be fine tuned to either hold the vessels tight or loosely depending on the level of movement desired. The frame would be mounted to a table or cart to ensure that the model does not move unintentionally.

Pros:

- Easy to produce
- Easy to modify

Cons:

- Could overly hinder the movement of the vessels

## **4.4 Design #4: Clear Molded “Brain” Shell**

A clear molded brain shell would allow the vessels to be supported similar to how they would be in the human head. The shell would consist of two parts, an inner and an outer. The inner part would be the “brain” which is essentially simulating the pressure the brain applies to the vessels. The outer part is the



equivalent of the skull, and again simulates the pressure applied by the human skull.

Pros:

- Even pressure across all vessels
- Clear

Cons:

- Difficult to replace Circle of Willis model
- Difficult to design and manufacture

#### **4.5 Design #5: Paint Material to Core**

This design can be used with the design for the 3-D printed core, but can also be used with other materials. The design would require a core to be either molded or printed, once the core has been created the vasculature material will be applied with a paint brush until the desired thickness is achieved. This method will work best with the Star Thermoplastics options considered above.

Pros:

- Easy to reproduce
- High Precision

Cons:

- Core is not reusable
- Lengthy process to get wall thickness
- Multiple paint brushes may be required
- Chance for contamination by paint brush

##### **4.5.1 Design #6: Injection Molding**

This design would require a professional company to manufacture the mold, core, and model. Once the mold and core are created, the molten polymer can be injected. The polymer would most likely remain the Star Thermoplastics options considered above.

Pros:

- Quick reproduction
- Accurate reproduction

Cons:

- Highly expensive
- Complicated Geometries may be hard to achieve
- Large order must be placed

##### **4.5.2 Design #7: Compression Molding**

This design would again require a professional company to produce the model for us. For this process the model would need to be manufactured in two halves, once the halves are made they will be joined with heat or adhesive.

Pros:

- Quick reproduction

- Accurate reproduction

Cons:

- Highly Expensive
- Large order must be placed

### **4.5.3 Design #8: Aluminum Casting**

For this design an aluminum mold would be machined in the NAU machine shop, this mold would then have our molten polymer poured into it creating our model. There would either need to be a core or it would be produced in two halves and joined with heat.

Pros:

- Accurate reproduction
- Consistent surface finish

Cons:

- Complicated
- Expensive

### **4.5.4 Design #9: Sand Casting**

A core would be 3-D printed and then used to create the sand molds. The sand molds would then be filled with the molten polymer. As with the aluminum casting, there would either need to be a core or the two halves would be joined with heat.

Pros:

- Cheap to reproduce
- Consistent Outer Diameter

Cons:

- Poor surface finish
- High chance of contamination

### **4.5.5 Design #10: Extrusion**

To extrude the model, would again require a professional company to manufacture it. Extrusions require simple geometry with constant diameters, so the model would be produced in separate parts and joined later. The process would make long sections of the same parts which would then be shipped to us where we will cut those long parts into their final size. Once the parts have been properly sized, the models will be assembled by hand using heat.

Pros:

- Consistent surface finish

Cons:

- Time consuming
- Expensive
- Inaccurate

## 5 Design Selected

### 5.1 Rationale for Design Selection

Using the customer requirements and the results of the decision matrix shown in Table 4, it was originally determined to select the NinjaFlex material for our design. Testing revealed that this material is unsuitable for use with our design due to high difficulty with printing. Looking to simplify the manufacturing procedure it was decided to outsource the 3D printing to a professional company. Once that was decided, there was one clear option for materials, Agilus 30. This material was close enough to the Ninjaflex that it did not require additional matrixing. While the 3D printing process was decided in the decision matrix to be the design option that should be pursued, it was also decided to attempt the dip-coat process and perform tests to see which material/process was superior for the customer. Also seen in the Table 4 is that the 3D printed frame was the best selection to hold the cast as it is in use. The team will be moving forward with prototypes for each of the three designs and will continue to adjust as the client needs evolve.

Table. 4 - Design Decision Matrix

Design Criteria	Criteria Weig	Dip-Coat	Weighted	3-D Print Mod	Weighted	3-D Print Fra	Weighted	Molded Shell	Weighted
Reliability	9	8	72	9	81	10	90	8	72
Durability	7	9	63	9	63	7	49	10	70
Visibility	10	10	100	7	70	8	80	9	90
Accuracy	5	5	25	9	45	9	45	7	35
Geometrically Real	9	10	90	10	90	8	72	9	81
Reproduction	8	6	48	8	64	10	80	6	48
Cost	3	7	21	7	21	10	30	6	18
Low Friction	8	6	48	7	56	0	0	0	0
Contaminant	4	8	32	8	32	0	0	0	0
Elongation	7	10	70	10	70	0	0	0	0
<b>Total</b>			<b>569</b>		<b>592</b>		<b>446</b>		<b>414</b>

### 5.2 Design Description

The design consists of the entirety of the Circle of Willis (CW) as well as the vessels that branch into the brain. The vessels that branch into the brain will be used for the return flow, and the major supply arteries will be used as inlet flow. The vessels will be connected to the flow system using Luer locks that have the same inner diameter as our vessels. The vessels will be made of a clear polymer, either Agilus30 or StarMed 9030-000. Two processes will be used for prototyping, 3D printing and dip-coating, these processes are detailed below in the proposed design section. Along with the model, a support frame will also be present to help the model maintain its shape when in use.

Analyses were performed on this design to guard against failure, the analysis are listed in Appendix B. The factor of safety analysis was performed using data from the stress analysis, and shows that with a wall thickness of .15 mm all of our materials have a factor of safety of at least 20. The high factor of safety may not be needed, so after testing the wall thickness may be reduced.

Figure 9 shows a drawing detailing the overall dimensions of the Solidworks model. Dimensions of specific regions are primarily based on a scientific paper that measured a large number of specific arteries and compiled the data into averages [7]. Geometry is based on various MRI's and a 3D model created by a doctor in the field [8]. The model is currently being reviewed by a neurosurgeon to confirm accuracy. This model will be used to create both the 3D print and the inner mold.

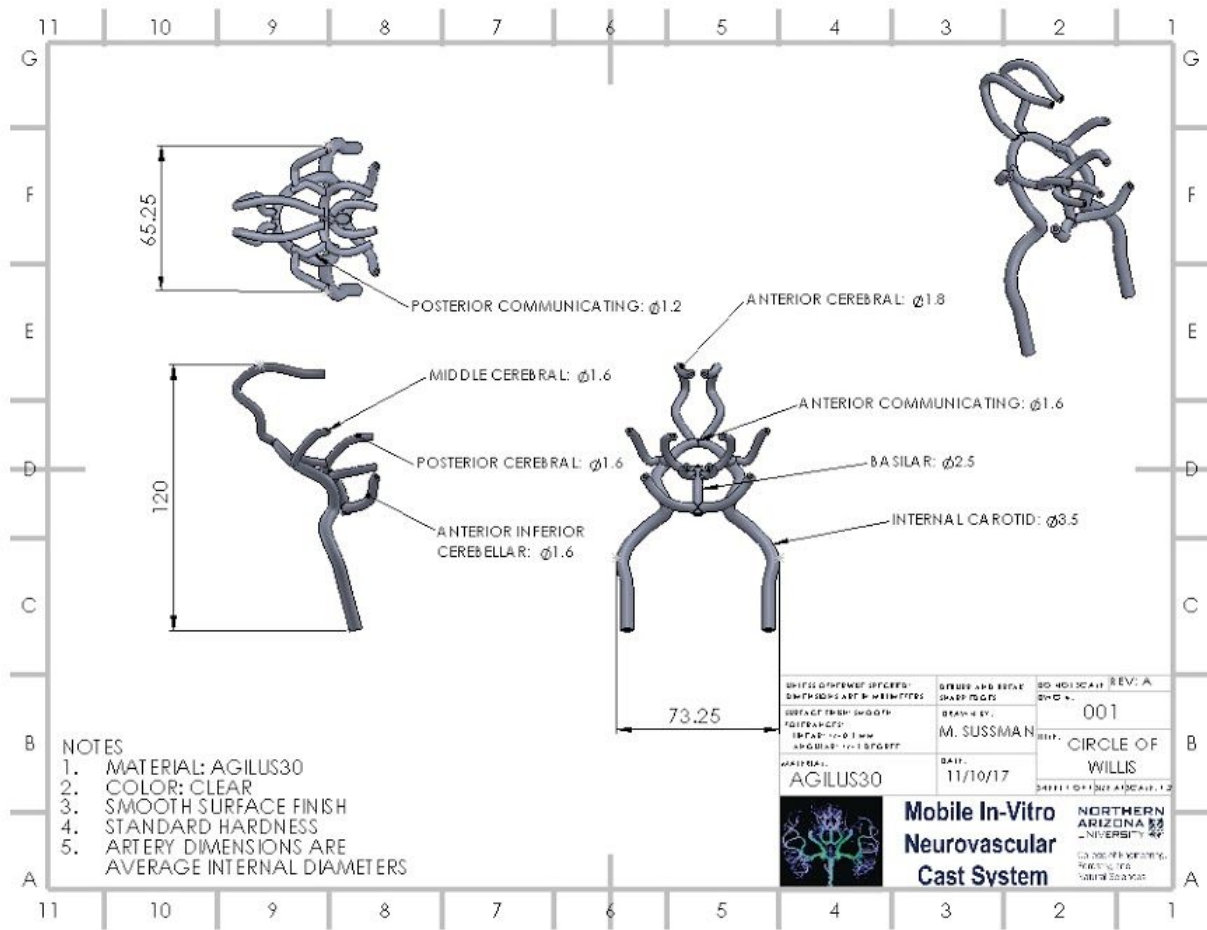


Figure 9: Solidworks drawing showing different views and overall dimensions of Circle of Willis model

## 6 PROPOSED DESIGN

Currently there are two proposed designs that will be implemented, the first is using a dip-coat manufacturing process and the second is using a 3-D printing process. The dip-coat process will be performed in house by our team, while the 3-D print process will be outsourced.

Before any prototypes will be made, the CAD model will be checked by a neurosurgeon for geometric accuracy. Once the model has been approved, aneurysms will be added to the most common locations. Those locations include any point where bifurcation occurs, and the carotid arteries. At least five aneurysms will be added to the model to allow for multiple tests to be run with the PPODA-QT.

To create the model using the dip-coat process a core to which the molten plastic will adhere is needed. The prototype core will be 3-D printed by the Rapid Lab using ABS, it will be a closed hollow core. The core must be hollow as it will be crushed after the molten plastic has solidified. Once the core is crushed the model will be flushed with water to remove the ABS particulates. The prototype model will be made

of Star Thermoplastic’s StarMed 9030-0000, pending testing via the rheometer for friction coefficients. To melt the polymer pellets, we will be purchasing a countertop convection oven which can reach the temperatures needed. ABS has a lower melting temperature than StarMed 9030-0000 so it is entirely possible that the core will melt during the dip-coat process. If the ABS core fails, a silicone core will be used. With silicone and StarMed 9030-0000 being elastic in nature the core should be easily removed by pulling it out. The first prototype will be completed early in the spring semester, testing of the material properties must be completed by the end of the fall semester.

The 3-D print process is a one step process where the model will be sent to a professional print company. The material that will be used is Agilus30, and estimate to have the first prototype made is \$79. This prototype will be completed before the start of the spring semester.

Next semester, both prototypes must be completed no later than February 1st so testing with each model can commence. Once testing has been completed, the best of the two designs will be selected and the manufacturing process for that design will be fine-tuned.

Table. 5 - Bill of Materials for the 3D Printed Circle of Willis Model

	<b>Part #</b>	<b>Description</b>	<b>Quantity</b>	<b>Vendor</b>
<b>1</b>	001	Circle of Willis model	1	Xometry
<b>2</b>	002	Brain mount left half	1	Rapidlab
<b>3</b>	003	Brain mount right half	1	Rapidlab
<b>4</b>	51525K144	Luer lock female	14	McMaster
<b>5</b>	51525K294	Luer lock male	14	McMaster
<b>6</b>	5233K93	PVC Clear Tubing, 5/32" ID	25 ft	McMaster

## 7 CONCLUSIONS

In conclusion, the team has discussed the background of this project and explained the project description which is the Mobile In-Vitro Neurovascular Cast System. In addition, the team can meet with their client and discuss with them in order to identify and analyze the Customer Requirements and the Engineering Requirements. With this information the team could construct a House of Quality and with it we were able to discuss which Costumer/Engineering Requirement requires more attention and which requires more time being invested on. With these requirements the team could research existing designs related to the project itself and collect relevant sources that will aid us in future design work. After that, the team created and discussed a black box model and a functional decomposition chart that is used to depict the important functions of what the project must accomplish. with this information the team can discuss the advantages and disadvantages of each of the designs considered and describe it with respect to the requirements displayed in the House of Quality. The team now can discuss other areas that require improvement such as research and discussing with the clients in detail regarding any questions that we may have.



## 8 REFERENCES

- [1] Y. Liu, Q. Gao, S. Du, Z. C. Chen, J. Z. Fu, B. Chen, Z. J. Liu, and Y. He, "Fabrication of cerebral aneurysm simulator with a desktop 3D printer," *Scientific Reports*, 2017. [Online]. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5434791/>. [Accessed: 07-Oct-2017].
- [2] Vascular Simulations Replicator – Custom Silicone Vessels, Endovascular Simulator, Silicone Arteries, Vascular Replicas, Mock Silicone Vessels. [Online]. Available: <http://www.vascularsimulations.com/Replicator>. [Accessed: 07-Oct-2017].
- [3] A. Benet, J. Plata-Bello, A. A. Abila, G. Acevedo-Bolton, D. Saloner, and M. T. Lawton, "Implantation of 3D-Printed Patient-Specific Aneurysm Models into Cadaveric Specimens: A New Training Paradigm to Allow for Improvements in Cerebrovascular Surgery and Research," *BioMed Research International*, 2015. [Online]. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4619899/>. [Accessed: 07-Oct-2017].
- [4] "NinjaFlex 85A TPU Flexible 3D Printing Filament," *NinjaTek*. [Online]. Available: <https://ninjatek.com/products/filaments/ninjaflex/>. [Accessed: 07-Oct-2017].
- [5] "PolyJet Materials Data Sheet," USglobalimages. [Online]. Available: [http://usglobalimages.stratasys.com/Main/Files/Material\\_Spec\\_Sheets/MSS\\_PJ\\_PJMaterialsDataSheet.pdf?v=635785205440671440](http://usglobalimages.stratasys.com/Main/Files/Material_Spec_Sheets/MSS_PJ_PJMaterialsDataSheet.pdf?v=635785205440671440). [Accessed:07-Oct-2017].
- [6] starthermoplastics.com. [Online]. Available: <http://www.starthermoplastics.com/our-products/starmed/>. [Accessed: 07-Oct-2017].
- [7] S. Kamath, "Observations on the length and diameter of vessels forming the circle of Willis," *Department of Anatomy, St John's Medical College*, vol. 133, no. 3, pp. 419-423, 1880.
- [8] "Circle of Willis: Arteries of Brain [ANIMATED] by Doctor Jana - 3D model", *Sketchfab*, 2017. [Online]. Available: <https://sketchfab.com/models/25e3f5851d5044ffb333bd852a86f238>. [Accessed: 11-Nov- 2017].

# 9 APPENDICES

## 9.1 Appendix A: House of Quality

House of Quality (HoQ)

Customer Requirement	Weight	Engineering Requirement	% Elongation	Friction	Clarity	Size	Contaminant	Cost	Hardness
Portability	7	-	-	-	-	6	3	-	-
Reliability	9	6	6	6	6	-	6	-	3
Durability	7	9	6	6	-	3	6	-	6
Visibility	10	-	-	-	9	-	-	-	-
Accuracy	5	6	9	9	9	3	6	3	3
Geometricly Realistic	10	-	6	3	9	-	6	-	-
Reproduction	8	6	-	-	-	3	-	9	3
<b>Units</b>		<b>% Elongation</b>	<b>N</b>	<b>% clarity</b>	<b>in^3</b>	<b>%contamination free</b>	<b>\$</b>	<b>shore</b>	
<b>Absolute Technical Importance (ATI)</b>		161	174	216	183	147	141	108	
<b>Relative Technical Importance (RTI)</b>		4	3	1	2	5	6	7	
<b>Target ER values</b>		150%	0.24N	99%	3-4 inches	99%	\$2,000	35A	
<b>Tolerances of ERs</b>		±10%	±0.5	±20%	±0.5inches	±25%	±\$200	±5	

Team member 1: Naser Alosaimi, NA, October 27th 2017
Team member 2: Matt Sussman, MS, October 27th 2017
Team member 3: Justin McCallin, JM, October 27th 2017
Team member 4: Jalandro Edison, JE, October 27th 2017

Importance	Rating
9	Excellent
6	Immediate
3	Poor

Approved by Dr. Becker



## 9.2 Appendix B

### 9.2.1 Dip-Coat and Factor of Safety Analysis

$$T = c_1(\eta U_0 / \rho g)^{.5} \quad \text{Thickness Eq}$$

$U_0 = 0.1 \text{ mm/s}$   
 $c_1 = 0.8 \text{ 1/mm}$   
 $g = 9810 \text{ mm/s}^2$

$$n = S_{UT} / \sigma \quad \text{Factor of Safety Eq}$$

Where:  
 $T = 0.15 \text{ mm}$   
 $\sigma = 111.0536 \text{ Kpa}$

#### **StarClear 1035-0000**

$\eta = 9.6 \text{ Pa}\cdot\text{s}$   
 $\rho = 890000000 \text{ kg/mm}^3$   
 $S_{ut} = 3213 \text{ Kpa}$

$T = 0.00026 \text{ mm}$  Thickness of one dip  
 $n = 28.93198$  Factor of Safety

#### **StarMed 9040-0000**

$\eta = 14 \text{ Pa}\cdot\text{s}$   
 $\rho = 890000000 \text{ kg/mm}^3$   
 $S_{ut} = 6378 \text{ Kpa}$

$T = 0.000314 \text{ mm}$  Thickness of one dip  
 $n = 57.43173$  Factor of Safety

#### **StarMed 9030-0000**

$\eta = 9.1 \text{ Pa}\cdot\text{s}$   
 $\rho = 900000000 \text{ kg/mm}^3$   
 $S_{ut} = 7584 \text{ Kpa}$

$T = 0.000252 \text{ mm}$  Thickness of one dip  
 $n = 68.29135$  Factor of Safety

#### **Star TPE 57050**

$\eta = 10.5 \text{ Pa}\cdot\text{s}$   
 $\rho = 890000000 \text{ kg/mm}^3$   
 $S_{ut} = 5990 \text{ Kpa}$

$T = 0.000272 \text{ mm}$  Thickness of one dip  
 $n = 53.93792$  Factor of Safety

#### **Agilus30**

$S_{ut} = 2400 \text{ Kpa}$

$n = 21.61119$  Factor of Safety

## 9.2.2 Fluid Flow Analysis

Flow Analysis			
	L (cm)	1.37	given
	D(cm)	0.49	given
	Re	7277.227723	Calculated
	$\Delta P$ (Pa)	4.1662E-08	Calculated
	m (1/s)	0.8	Assumed
	n (1/s)	0.966	(Retrieved from figure 2)
	$\frac{du}{dy}$ (1/s)	1.4901E-08	given
	$\tau$ (N/cm <sup>2</sup> )	98	(Retrieved from figure 2)
	V (cm/s)	150	given
	density (kg/m <sup>3</sup> )	1000	given
	$8V/D$	2448.979592	Calculated
	$\mu$ (cmPa *s)	10.1	(retrieved from figure 3)
$Re = (\rho * V * D) / \mu$			
$\Delta P = (L/D) * (du/dy)$			

## 9.2.3 Stress Analysis

	Diameter (mm)	Wall thickness (mm)	Hoop Stress $\sigma^t$ (kPa)
ACA-A1	2.33	0.25	105.61424
ACA-A2	2.4	0.25	108.7872
MCA	2.86	0.35	92.59862857
PCA-P1	2.13	0.3	80.4572
PCA-P2	2.1	0.3	79.324
ACoA	1.47	0.15	111.0536
PCoA	1.45	0.15	109.5426667
P(mmHg)=	170	max	
P(kPa)=	22.664	converted	