Aneuvas 3D Print Testing

Preliminary Proposal

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DISCLAIMER

Conflict of Interest Disclosure

This team is working for Timothy Becker, PhD., through his company Aneuvas Technologies Inc. (ATI). Aneuvas Technologies Inc. and Northern Arizona University have a Conflict-of-Interest agreement that this team is following. The Bioengineering Devices Lab, mentored by Timothy Becker, PhD., will be the location of testing for material samples and data analysis.

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1 BACKGROUND

1.1 Introduction

Endovascular devices are becoming more widely accepted ischemic stroke treatment options in patient healthcare. Current devices must be innovated to quantify the intricate anatomy of the human vascular system. *In vivo* models are limited by local vessel structure and may lack neurovascular anatomy mechanical properties. Standard aneurysm models replicate the structure of the Circle of Willis; however, they may lack the ability to replicate the mechanical properties of human vasculature. The project goal of team BDL/Aneuvas is to research, develop, and mechanically test 3D printed material in relation to the human common carotid artery, such that the material may be able to replicate human vascular properties. The sponsor of this project is Timothy Becker, Ph.D., founder of Aneuvas Technologies inc. Stakeholders include neurosurgeons, model developers, and material engineers. Upon completing the project, the team will be able to statistically qualify a material printing method that will improve the current BDL model to represent human vasculature. Neurosurgeons may benefit through being able to practice procedures on practical models that will respond to instruments such as human vascular would. Model and material engineers may find improvements to the devices they are designed for what materials and methods they currently use due to this team's findings.

1.2 Project Description

The following is the original project description provided by the sponsor:

> "The scope of this project is to analyze, design, build, 3D-print (with anatomical printer), and test a 'plug-and-play' model of blood vessels, such as aneurysms, using non-biologic materials. This system will model the vascular defect as well as allow for the testing of bioengineering devices to repair said defects. The system will support monitoring equipment and tubing attached to the inlets and outlets under static and dynamic loads."

1.3 Original System

NAU's Bioengineering Devices Lab has developed an *in vitro* blood flow and stroke model, which replicates the conditions of the neurovascular system. In prior workings, the *in vitro* model has used innovative 3D printing methods to create a practical model of the Circle of Willis. Now, the model is being developed, in this capstone project, to allow researchers to quantify and characterize the mechanical properties of the material in relation to the common carotid artery. The previous model included a single- or double-layer 3D print of the Circle of Willis. This project will then apply vascular dimensions and the concept of soft and hard tunica media and tunica intima, respectively, to the 3D printed model. The team will test sample' pucks' and 'cylinders' representing cut-outs and lengths of the right common carotid artery to validate material gradients and printing methods as "improvements" to the original design.

1.3.1 Original System Structure

The original model structure is of the Circle of Willis, including the left internal carotid, basilar, and right internal carotid, a basilar bifurcation aneurysm, an anterior communicating aneurysm, and an internal carotid terminus aneurysm, see figure 1. The Circle of Willis model is connected to a' tube connector/interface', connecting the model to a flow system for flow pressure testing.

1.3.2 Original System Operation

At the start of this project, the Circle of Willis model is connected to the flow loop model. Prior mechanical property tests were conducted on 'pucks' and 'cylinders' of 50-50 depths of Agilus and Vero-Clear materials. The completed model experienced flow pressure testing. The flow pressure testing was conducted as part of a master's thesis by Christopher Settanni using pressure transducers, LabView, and a DAQ system. The flow model simulated physiological conditions experienced by the human vascular system, such as pulsatile flow and temperature [1].

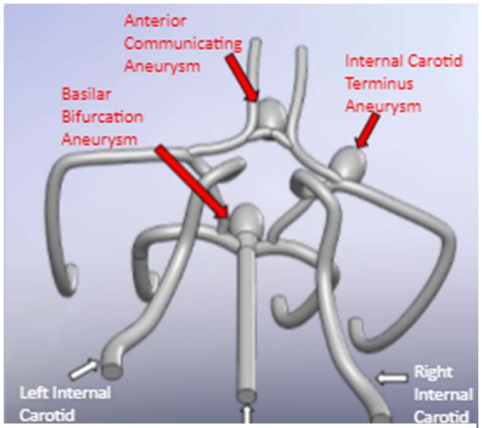


Figure 1 Circle of Willis model designed by Christopher Settanni [1].

1.3.3 Original System Performance

At the time of the project's beginning, no testing of the model itself had been conducted. All material testing was conducted on 3D printed 8mm pucks, tension strips, and cylinders to replicate the properties of the human right common carotid artery (RCCA). In previous studies, the pucks had been printed as a single solid material and as a double layer material. However, the pucks have not been tested for anatomically similar millimeter depths or layers of the RCCA. The previous tests serve as a baseline and guide for all upcoming testing to ensure that the standard operating procedures are relevant and comparable results.

Previous research of the 3D prints is provided in Figure 2 and Figure 3 in Appendix A due to size. Additionally, included are graphical representations of cumulative data relating to this study. This statistical data is thus the foundation of Team Aneuvas's capstone project. Team Aneuvas will be conducting the same tests with 3D printed material of controlled hardness and layer thickness similar to the tunica intima and tunica media of the RCCA. This study will begin by using two very different hardness ratios, i.e., Agilus 30 and Agilus 50, to see if the tests conducted would average the two numbers or determine whether the change affects the property of the print. Then, the team will lower the gap in hardness, i.e., Agilus 30 and 40, and test the samples again. All sets of data will be compared to the previous test results conducted by Nicholas Norris in the cited text to determine if the change in hardness and thickness of the 3D printed walls display change and compare to the properties measured in the RCCA of the three donors. Once completed, the team may adjust the Circle of Willis model to reflect the most favorable change from the material print methods analyzed.

1.3.4 Original System Deficiencies

The original system used 100% for the single-layer and 50-50% depths for the double-layer of Agilus and Vero-Clear. The client would like that we test more anatomically correct ratios of material thickness and shores of hardness. This would determine if using more anatomically correct measurements and hardness will improve the model's function more closely to human vascular. Previous studies revealed that the 3D printed material could come close to the mechanical properties of the human common carotid artery. As a result, we will be testing the biaxial vascular tension of materials, blood vessel compliance, lubricity of the model interior, and the compressive and shear modulus.

2 REQUIREMENTS

The team had scheduled multiple meetings with the client to discuss the project overview and what they wanted to see as results throughout the project. Within the customer (client) requirements, the list will include the size of the testing samples and material thicknesses, different stiffnesses of layered material, the possibility to retain shape. At the same time, forces are being applied to the material, similar properties to that of organic tissue. These customer requirements will then be analyzed and quantified by using the engineering requirements. These engineering requirements will take the customer requirements and convert them into scientific variables relative to the same concept, making it easier to change variables as needed, obtaining solutions to the customer's needs. All of these requirements, customer and engineering alike, will be placed within a House of Quality (HoQ) where each variable can be compared to others supplying information to fully understand which requirements are more important and crucial to the project outcomes than others.

2.1 Customer Requirements (CRs)

The customer requirements are goals that are provided to the team by the client. These requirements provide an overview of what the client is hoping to see from the team's project. Each requirement contains a different relative weight, dependent on how crucial they are to the project's success. These requirements, along with their relative weights, are as follows:

- Size (3%)
- Easy to connect (8%)
- Hard interior/Soft exterior (Layered) (25%)
- Lightweight (3%)
- Material selection (25%)
- Retains shape (8%)
- Similar properties to organic tissue (25%)
- Cost within budget (3%)

The first customer requirement is size. This involves separating areas of the project. Firstly, in the testing process, the testing samples must be printed out in specific sizes, all dependent on the testing procedure. For torsion and compressive tests, the testing sample will be a different size than that of the sample used in the expansion testing procedure. Secondly, the customer requires the team to stick with a rough guideline in the ratio of materials. These thicknesses ratios will have little to no area for interpretation but rather as set numbers that the team must follow when printing samples.

Within the project testing, specific procedures, expansion tests, for example, will require the sample to connected to other instruments. Therefore, if the testing sample can easily connect to the required instruments, then the sample cannot be easily tested. Therefore, the customer requirement of easy to connect is vital to the project, but not as crucial as the following requirement, layer stiffnesses.

Weighting 25%, the customer requirements ask the team to design a product with a medium/hard interior, and a soft exterior is essential within the project procedures. This customer requirement is essential in the testing procedures, allowing the team to perform the necessary tests. The soft exterior and harder interior allow the material to behave normally when forces are applied.

The following customer requirement is the weight of the design. The material that is finally selected must be lightweight. This requirement is closely tied to needing the material to have similar properties to organic tissue. By analyzing the actual organic tissue, there is not a large amount of weight in the design. Therefore, the customer asked the team to design a decently lightweight product.

Being able to retain its shape while under applied forces will allow the design to repeatedly take on those applied forces. Just like that of actual organic tissue, the vessels will constantly be under oscillating forces. Implementing a durable and robust design will ensure that the design can be tested repeatedly until proven successful or as a failure. Similarly, having a design that can retain shape is more durable, robust, and highly reliable. The goal for the team is to create a design that will be durable but also produce the same results no matter how many times the material is tested. Therefore, making sure that the material's compliance is focused upon will satisfy the requirement supplied to the team by the client.

One of the most critical requirements, if not the most important requirement, is making the design contain properties very similar to that of organic tissue. One crucial aspect of creating similar characteristics of organic tissue is creating a safe design to operate. Like that of the organic tissue, the material must remain watertight, allowing for all tests to be completed without any complications. Therefore, an essential step in making sure the characteristic of material properties of the design is similar to the properties of the organic tissue is to make sure that the design is safe to test and operate. The closer the team can bring the properties of the 3-D printed material to that of the properties of actual organic tissue will result in success in the project, satisfying the last customer requirements.

Lastly, a requirement that is important in every project one will participate in, money. Through the testing and design stages of the project, the team must make sure that the budget is not forgotten but rather included in every decision made. This will ensure that the team is designing the best product while still being cost-effective throughout the process.

2.2 Engineering Requirements (ERs)

With each customer requirement, the team must quantify the requirements into variables that can be calculated and altered accordingly. Creating the engineering requirements will allow the team to understand what actions must be made to satisfy the customer requirements stated earlier. Each customer requirement will have corresponding engineering requirement(s) that will help analyze the functionality of the design, relating it to the customer requirements. There are three separate ways to analyze the engineering requirements: target value, maximize value or minimize value. These paths in analyzing the requirements will help justify the values.

The first engineering requirement is the stiffness of the material. This variable can be calculated through the modulus of elasticity. This value describes how well a material elastically deforms under specific stresses. This ER is essential in determining the size, layer stiffnesses, the weight of the design, material selection, and having similar properties to the organic tissue counterpart. Making sure that the design has a hard interior and soft exterior can be directly found by calculating the modulus of elasticity, providing the stiffness of the material layers. Understanding the modulus of elasticity will help decide what materials should be used and what should not be used, all dependent on the characteristic the team needs to obtain similar properties to the organic tissue.

The following engineering requirement pertains to the thickness of the material. This will directly help determine the needed size of the design and the capability of connecting the testing instruments to the design. Therefore, making sure that the thickness of the material is within a specific range will allow testing to flow smoothly and help obtain the best results possible. Minimizing the amount of material the design requires to obtain the goals will help with the efficiency of the material and the cost by requiring less material per product.

The following engineering requirement is the compressive modulus. One of the many tests that the team will perform is a compressive test. This test will help determine if the interior and exterior layers are at the right stiffnesses, the material selection, and whether the design has properties similar to organic tissue. On the other hand, the compressive modulus is less of a factor in determining the design's size and whether or not it is easy to connect to the testing instruments. Maximizing the compressive modulus value will help illustrate how the materials can withstand changes in length under compressive loads.

The next engineering requirement in line is understanding the range of frequency that the material can withstand. Within actual human tissue, the blood vessels are constantly under ranges of frequencies. Therefore, to imitate organic tissue, the team must test whether or not the material can withstand and behave the same way under the targeted frequency range. Similarly, understanding the range of frequencies the material can withstand will help determine whether the shape is retained under those circumstances.

Under axial loads, the amount of transversal strain is important when analyzing whether properties are similar to organic tissue and determine the shape-retaining. This can be determined through the calculation of Poisson's ratio. The Poisson's ratio provides the comparison between transverse strain and axial strain. Therefore, understanding Poisson's ratio of the organic tissue will help the team find a design that has a targeted Poisson's ratio.

An engineering requirement that is important in deciding what material is used and whether or not the design retains its shape is calculating the material's compliance. Increasing the value corresponding to the compliancy of the material will help result in a higher quality design. The organic tissue has a high level of compliance, where it can constantly retain its shape under stress. Similarly, the size of the design and the compliancy of the material has a strong relationship in the testing procedures. Therefore, increasing the compliancy of the material will help the material become more like the organic issue counterpart

Within the torsion testing of the materials, one significant aspect that must be analyzed is the angular acceleration of the instrument that will create torsional stress on the material. Previous values corresponding to how the organic tissue reacted to the same tests allow the team to hit the targeted angular acceleration value. The closer the value is to that of the organic tissue, the better. Therefore, the angular acceleration engineering requirement will help determine material selection as well as helping to create the most organic-like material one can design.

In a blood vessel, forces are acting in almost every direction. Therefore, analyzing the amount of radial force the material can withstand will help decide whether the material is close to that of the organic tissue. At a targeted value, the radial force will determine the material selection and the layering process. Though some engineering requirements have a strong relationship with the amount of radial force the material must withstand, the weight of the design is less likely to have a significant impact on the targeted radial force goal.

The last two engineering requirements are the thickness of the layers and the amount of pressure the material can withstand. The layering processes are crucial in almost every customer requirement. It will help determine the soft/hard layering characteristics, material selection, whether the material retains its shape, and lastly, whether it has properties close to that of the organic tissue. Pressure in mmHg is measured and analyzed throughout the test. Material selection and the layering processes are important in ensuring that the target pressure the material must withstand is met. Meeting this target will lead towards one of the most important requirements in the project, the closest properties possible to that of the organic tissue.

2.3 House of Quality (HoQ)

Comparing the customer requirements to the engineering requirements are helpful in order to make sure there is at least one engineering requirement per customer requirement. However, multiple engineering requirements are in place to determine and analyze multiple different customer requirements simultaneously. Similarly, the engineering requirements are compared to the other engineering requirements to see whether or not one variable will affect the results of another critical variable. This can all be analyzed in the House of Quality, as can be seen in Appendix B. As one can see, every engineering requirement has a targeted value or a goal to maximize or minimize that value. The targeted values are the frequency, angular acceleration, radial force, and the pressure the material needs to withstand and that of the Poisson's ratio, where, if met, provides proof in comparing the similar properties to that of the organic tissue. The values that the team wants to maximize in order to meet the customer requirements are the compressive modulus, the compliance, and the layering process. The compressive modulus and the compliance relate to the amount of force the material can withstand and retain its shape and characteristics. Therefore, the higher the value is, the higher quality results the team will see. The last requirement that looks to maximize the value is the layering requirement. With the majority of the project focused on the hard interior and soft exterior and the similarities in properties, the ways the material is layered must be maximized. Lastly, the values that the team wants to minimize to meet the customer requirements are the stiffness characteristic and the overall thickness of the design. Decreasing both of the values will help obtain characteristics similar to the organic tissue, which in turn obtains successful results.

3 DESIGN SPACE RESEARCH

Chapter 3 includes the literature review from each of the team members. This literature review included extensive research into competing systems, neurovascular and the common carotid artery biology, mechanical property testing, and new nomenclature. Aspects of the project progression, such as website development, were also researched. All sections of chapter 3 are summaries of information and the intended application of the researched information to this project.

3.1 Literature Review

3.1.1 Student 1 (Isaac Smith)

3.1.1.1 Project Role

Isaac Smith is a senior mechanical engineering student. He has agreed to be the project lead for this project. The responsibilities of his role are to help coordinate team meetings, review team progression, promote an environment of teamwork and good communication, and manage critical tasks. In addition, he must understand and help in all project categories to ensure uniform progression of the project.

3.1.1.2 Mechanical Testing – Hardness

At the campus of Purdue University, a research study was conducted on the efficiency of teaching students how to conduct hardness testing. This paper was selected because the students tested polymer materials, like the testing that our team would need to conduct. Shore Durometers were used to conduct the tests in an introductory materials course. Round and flat tip durometers were used in this study, and interestingly, the different tip types were tested on materials from different campuses using the same STL experienced differences in hardness reading. "The reason(s) for the differences by type have not yet been explored, but are presumed to be based on how the indentor tip geometry interacts with the variation in molecular bonds generated by each processing method and machine" [2]. This cautions that there can be variations in testing based on indentor tips, which may be a consideration during future testing for this capstone project.

3.1.1.3 Mechanical Testing – Lubricity

The second paper illustrated the exact hardness and lubricity tests our team will be conducting. It was determined that hardness and lubricity tests were destructive tests for the samples, which means that the samples degraded after the tests were conducted. This paper is used to illustrate the lubricity testing our team will be conducting. Lubricity testing is performed by soaking a cylindrical sample in PBS for four days. Then the tube is fitted to a 'lubricity wheel.' A guide catheter is run through the sample up to the rheometer ETC Tension fitting. The guide catheter was fitted with a Y-connector that held a 30cc syringe filled with DI water. The Rheometer then pulls the catheter and measures the resistance experienced. Using the geometry of the angle between the sample and the Rheometer ETC Tension fitting, the lubricity is calculated as the force of friction [3].

3.1.1.4 Vascular Anatomy – Tunica Intima and Media

3.1.1.4.1 Introduction to Vasculature

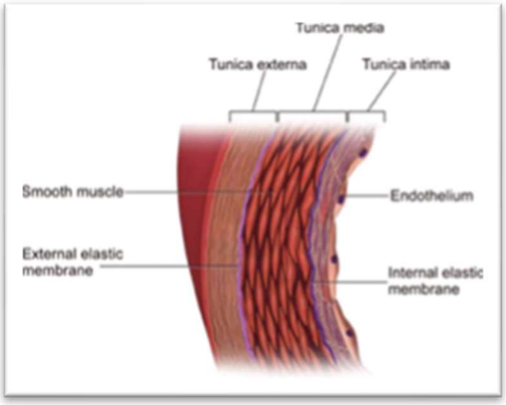


Figure 2 Layers of the RCCA [4].

During the original BDL research on the right common carotid artery (RCCA), the three patient donors had a wall thickness of 1.2mm [4]. This is because, during operation and prep, the lab removed the tunica extrema from the RCCA. Concerning this study, team Aneuvas is evaluating vascular anatomy to create an anatomically sound testing sample and, in final development, a new model. The RCCA is comprised of three main sections: the tunica extrema, media, and intima. Our client described that the extrema are usually a more rigid structure that protects the vasculature; the media is a thicker "soft" muscle. The intima is a slightly more rigid "medium" muscle, see figure 4. The research helped to verify the structure of the RCCA. The literature review intends to evaluate the dimensions of the media and intima and vascular properties and apply them to this project development.

3.1.1.4.2 Research Papers – Thicknesses in Controlled Research Groups

The first literature-reviewed research group evaluated the media-intima thickness of the RCCA using ultrasonography. Ultrasonography is the use of high frequency-energy waved to evaluate tissue. However, the portion of this report that will be focused on is the patients with healthy vasculature – not the coronary artery "case patients." The team found that "the intima-media thickness of the common carotid artery in case of patients and in control patients was, respectively, 0.81±0.25 mm and 0.62±0.18 mm (P=0.001)." [6].

The second research group evaluated used the same ultrasonography evaluation method as the first team. However, the first team used a power base of 5 MHz, and the second team used a base power of 7.5 MHz. Results indicate that "the mean common carotid intima-media thickness was 0.76 mm (SD: 0.19) for women and 0.80 mm (SD: 0.19) for men" [7]. The group did not record the age range of the samples collected. This may account for some of the variations between BDL and other research groups for sample size.

3.1.1.4.3 Relation of Intima and Media to the Project

The vascular structure is an essential aspect that team Aneuvas is trying to replicate in a 3D print and test variable conditions for mechanical property analysis. As such, this team needs to investigate the human RCCA structure in terms of composition and depth of layers. It is possible that there could be variations in depths by different research groups based on how the samples were prepped if disease or deformation such as plaque is present, age of the donor, and the presence of adventitia during measurement or testing. To further point to this possibility of variation, the next group reviewed stated that:

> "Statistical analysis showed significant negative correlations between age and axial inversion stretches for the CCAs (r = −0.67, P = 0.03). A possible explanation for this correlation is that aged arteries show reduced distensibility, since aging causes histostructural changes, such as loss and degeneration of elastin fibers and laminae, and increase of collagenous material and ground substance" [8].

It is important to acknowledge vascular variations because team Aneuvas will need to specify what donor sample conditions we are imitating with 3D printing.

3.1.1.5 Vascular Anatomy – Thickness and Axial Strain of the CCA

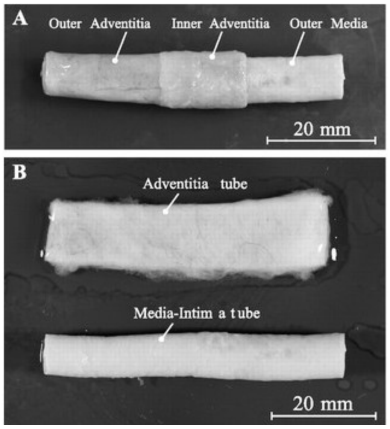


Figure 5 Adventitia and media layers of the CCA [8].

This research group analyzed 11 human donors of the common carotid artery (CCA). The ages ranged from 67 to 86 years old, and any samples that had deformations such as plaque were removed from the study group. Samples were frozen, thawed, and tested within 14 days of being collected. Different from the BDL testing, the adventitia was intact for some tests, such as the radial expansion (BDL removed the adventitia layer); see figure 5 for a visual representation of the CCA in this study. The research group used histology to confirm that adventitia was adequately removed from the media-intima layers.

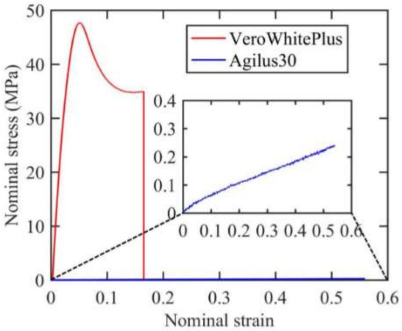
They also compared the testing ability of the adventitia layer alone and the media – intima layer combined. Importantly related, the "unloaded average thicknesses for the intact wall were determined to be 1.17 mm (SD 0.16) for the CCA… and MI composite thickness to be 0.70 mm (SD 0.13) for the CCA" [8]. The MI composite thickness is the thickness of the media and intima combined. The research group found that the MI reacted nonlinearly and stiffened under higher pressure as soft tissue. Remarkably, when preconditioned for the radial expansion test, the CCAs displayed "increasing stretch softening" [8]. A mark for future investigation outside of this project would be to compare BDL radial expansion and compliance tests to this group's method of testing axial expansions. In general, this study relates to the project with removing the adventitia, measurements of the layers, and axial testing of the vessels. It also provides a deeper understanding of the intracity of CCAs and the relevance of this project to modern science. Although the data recorded is not present here, it may be referred to in the future during data analysis.

3.1.2 Student 2 (Luke Nelson)

3.1.2.1 Project Role

Luke Nelson is a senior mechanical engineering student. He has agreed to take on the role of a website design leader. The responsibilities of his role are to create the team website to store all relevant data and updates throughout the project and obtain and organize data, visuals, and reports, placing them accordingly within the website and other locations. Therefore, by accepting the role of the website designer, Luke has also agreed to be the lead data engineer, who will be in charge of data gathering, data presentation, and interpretation. Having insight into each member's roles, the responsibilities include, but are not limited to, assisting the other members if problems arise.

3.1.2.2 Stress/Strain



Combinations of lightweight, strong materials that contain high stiffness levels and can absorb a lot of energy can become crucial in designing material that the team is seeking after. In "Bioinspired Multilayered Cellular Composites with Enhanced Energy Absorption and Shape Recovery," Huan Jiang analyzes the multilayered cellular composites (MCC) that are 3-D printed by comparing them with an often-used material of VeroWhitePlus. As one can see in figure 6, the measured compressive stress-strain curves for Agilus and VeroWhitePlus materials [9]. An MCC is created through the combined use of both Agilus and VeroWhite. Combining the two can alter characteristics, from elasticity and compliance to withstanding higher compressive loads. One can see that incorporating the MCC structure rather than an individual material will help in generating designs that have characteristics closer to that of organic tissue.

3.1.2.3 Biomaterial Engineering

As the world of technology constantly sees advancements, the world of engineering has been able to coexist within the world of medicine and biology. With the growing advancements in technology, that same technology has improved and even saved lives. The article "Biomaterial for Vascular Tissue Engineering" by Swathi Ravi and Elliot Chaikof explains the research that has been conducted in the generation of protein polymers that mimic native structural proteins and adopt the characteristics of the arterial wall. The authors continue by stating that the challenges of creating the ideal tissue-engineered vascular substitute are plentiful. However, significant progress and advancements have been made to understand the importance of biomaterials' mechanical and biological requirements [10]. Understanding more about the world of biomaterials and how they are used to create solutions to medical complications will help the team understand the concepts within the project. Through this research and collaboration among vascular professionals, material scientists, and biomedical engineers, existing complications in the creation and perfection of an arterial substitute will unquestionably be surpassed.

3.1.2.4 Data Acquisition (DAQ)

In any experiment or project, one might undergo, the produced data will determine whether or not the experiment processes were correctly done. Therefore, to make sure all data is collected correctly, proper procedures and systems must be used to provide that certainty. Data Acquisition (DAQ) is a process that involves collecting information and measurement to understand physical phenomena using sensors, measurement devices, and a computer [11]. DAQ systems are highly versatile, allowing for multiple measurements to be conducted simultaneously. By testing with a DAQ system, the team is able to factor in multiple other potential variables that might affect the results of the project. These variables could include but are not limited to temperature, humidity, vibration, calibration errors. [11]. Therefore, understanding how DAQ systems work and performing DAQ processes accurately will allow anyone to obtain the most accurate results they may want.

3.1.2.5 Professional Web Design

As the website designer in the team, an important aspect of the role is to make sure that all data obtained is gathered and displayed professionally and adequately for any individual to examine. Therefore, continuing the research into making the most professional and effective website will allow the team to continue their research with no complications along the way. Much information can be included within the website, from short biographies and research documents to navigation techniques and design processes. Even though the team's website will not be as complete as some professional websites in the world, there are a few basic tips that should be used in building and maintaining a website. These tips include being consistent with the information, graphic elements, colors. [12]. Similarly, one major tip that many do not follow is that if one doubts whether to include a piece of information, one should often stick with a more straightforward, cleaner design [12]. By understanding these tips and many others, one can make sure that a website conveys all the information correctly in a clean and precise way.

3.1.2.6 Circle of Willis

A broad understanding of the anatomical world of aneurysms is vital in understanding the project results and possible changes. Within the Circle of Willis, there are Intracranial aneurysms (IAs), which are acquired abnormal vascular dilations that occur in roughly 4% of the general population, characterized by damage localized to the arterial wall, having lost in the internal elastic lamina and alteration of the middle layer [13]. Cerebral aneurysms cause dangerous complications where its rupture and severe hemorrhage result in a morbidity and mortality rate greater than 50% [13]. The study conducted by Dan Zimelewicz Oberman evaluates certain variables concerning brain aneurysms, classifying if patients had a ruptured or unruptured aneurysm in the anterior communicating artery (AcomA) and the posterior communicating artery (PcomA) and which area is associated more with the rupture. Within the results, Oberman explains that 352 patients were diagnosed with an IA. However, only 132 of them were determined to have an aneurysm that is located in either the AcomA or PcomA [13]. Continuing, Oberman states that the median age of the patients within the study was roughly 62 years old, displaying a statistically significant association between the age of the patient and a ruptured aneurysm, where only 52 of the patients had ruptured aneurysms [13]. The study concludes that variations in the anterior complex of the Circle of Willis, in addition to playing a role in the development of cerebral aneurysm, may contribute to their rupture, especially those from AcomA aneurysms.

3.1.3 Student 3 (Kathryn Nelson)

3.1.3.1 Project Role

Kathryn Nelson is a senior mechanical engineering student. She agreed to take on the role of research and financial leader. The responsibilities of her role are to keep up to date with any new products or research that might assist in the development of the project, oversee all purchases, the main contact with Front office for budget management, monitor and record all purchases for budget tracking, and update the Bill of Materials.

3.1.3.2 Fused Deposition Modeling Printers

We will be using a Stratasys Objet 260 Connex3 or a PolyJet printer for this project. PolyJet, and many other models like it, is a fused disposition modeling printer (FDM), meaning that it prints layer by layer, with layers as thin as 10 to 200 micrometers or 10E-6 meters [14]. These printers can switch between materials, such as various thermoplastics and biomaterials, in the middle of printing without any outside interference and can mix materials by itself as well [14]. This type of printer is prevalent when it comes to creating models replicating areas in the brain because of its ability to create such small models with varying properties like those of vessels.

3.1.3.3 3-D Modeling Patients

One common use is creating scaled models of a patient's brain that neurosurgeons can use to practice before surgery. The patient gets a computed tomography (CT) scan of their brain to get a model, creating multiple 2D images of the affected and surrounding area, which are then turned into 3D models that can be printed out [15]. These models allow neurosurgeons to better understand the situation before going into surgery, which decreases surgery time and increases the success rate of the procedure [15]. Since the surgery to cure an aneurysm can be dangerous to the patient if there is little understanding of the path to take, creating these models with materials that replicate the properties of veins is proven to increase the safety and or assist with future patients with similar cases. Creating these models can also assist in further research in neurosurgery since there are accurate models of various brain vessels that can be studied to improve current procedures.

3.1.3.4 Commonly Used Materials

The materials commonly used for these types of projects are VeroClear and Agilus30. VeroClear is a hard plastic-like material used to create a hardened exterior to prevent deformation of the models and mimic the resistance to expansion that brain vessels would have during tests [16]. Agilus30 is a rubber-like material used to mimic the lubricity of the brain vessel while also providing some elasticity to the models [16]. While these materials can be used on their own for specific models, they can also be mixed with different ratios to provide various properties to match veins in different parts of the body. These materials can also be used to replicate different types of diseases that can affect vessels, which can better understand how to handle curing those diseases properly.

3.1.3.5 Vascular Anatomy

To better understand the area that we are focusing on, we investigated the vascular anatomy of the brain. The brain is made up of a plethora of nerves and arteries, each with its physical properties [17]. The system that will be focused on is the arterial and capillary system which contain internal carotid arteries that enter the skull, carry 80% of the total blood to the brain, and create a circle surrounding the base called the circle of Willis [17]. The capillaries in this system contain 50-60% of the total blood volume, and their walls are made up of a single layer of cells that vary in properties depending on the type of vessel [17]. The arteries in this system can suffer from pressure differences caused by various factors (disease, surgery, etc.), affecting their radius and lubricity [17]. These changes can cause strokes, harming the patient, or cause lasting damage to the patient's vessels leading to other complications.

3.1.3.6 Circle of Willis

To shrink the focus for the project, we decided to research the circle of Willis further. The circle of Willis is a network of various arteries that surround the base of the brain to help provide circulation between the brain and brain tissue [18]. As of right now, there are three types of patterns that the circle can have: no variation, one posterior communicating artery with hypoplasia (little cell growth) or aplasia (no cell growth), or both posterior communicating arteries with hypoplasia or aplasia [18]. These patterns affect the remaining arteries and change the path neurosurgeons take during surgery which could affect the patient's safety. Understanding these circles and the effect of each pattern can help ensure that neurosurgeons are prepared for their patient's specific needs.

3.1.4 Student 4 (Aditya Ponugupaty)

In this project, Aditya has been assigned to be the test manager for the semester. His primary function is to plan, coordinate, test, and gather the data for the team to use. Since the project relies heavily on data acquisition, data quality must not be misconstrued; that way, when a design proposal is developed, it matches our data.

3.1.4.1 Rheology testing

As a test engineer, my primary objective is to get good data to use to make a good model. The Rheometer, which we will be using for most of our tests, if not all, calculates the stress, strain, and strain rate of a specimen. Since the specimen we are testing is a complex mixture of soft polymers, we need to consider the possibility of error, which would entail not getting the valid stress-strain values. The article that the team will be using will help us navigate through any challenges we face when collecting the data. Sometimes when measuring the shear stress of our sample, we can misinterpret the data by looking at the wrong experimentally accessible window, i.e., the window of the data interval, and see that data aligns with our assumptions. This might not actually be the case as the data before the interval and after can be read to see the strain reactions to the sample [19]. To avoid this, I will be using the figures and data discrepancies highlighted in my research, such as stress-strain assumptions, the factor of safety equations for different mechanical tests, and general rheometer troubleshooting, which are all highlighted in the article [19]

3.1.4.2 Wall Shear Stress and its effects on developing an aneurysm

In order to understand the scope of the project, we have to understand the causes of the problem we are trying to solve. Aneurysms in the circle of Willis, a group of arteries in the lower side of the brain, is what the project is based on, so we had to find what is causing the aneurysms in that area. This article was used to determine the effects of wall shear stress on the artery's relation to the occlusion of an aneurysm. The paper talks in detail about how in the arterial wall, frictional forces may have led to aneurysm formation due to high amounts of wall shear stress and hypertension [20]. It then says that high shear stress can be a factor in determining where the aneurysm can be developed. They measure the flow rate and determine the shear stress on the walls in each vessel in the circle of Willis and determine critical areas with higher shear stress, and tied it with data of general aneurysm formation positions [20]. This correlation proves that higher shear stress in some vessels will yield to the formation of aneurysms.

3.1.4.3 Mechanical Properties of a Common Carotid Artery (CCA)

Now that we have established the cause of the project, we then look at the available data. Since we are making a model that emulates a CCA, we have to look at the elastic and mechanical properties to compare our data. This article shows us identified variables such as pressure, Intima-Media thickness (IMT), and elastic modulus [21]. This will help us in various ways as; if we need to measure using a different set of variables or need a formula for a particular test, we can refer back to this article and look at how they approached the problem. We can also compare our data points to the one in the article and determine if we are on the right track or not. This will be a crucial aid when it comes to testing.

3.1.4.4 Wall Tension in Cerebral Artery Aneurysms

Not much is known about how to assess wall tension in cerebral aneurysms computationally. The testing mechanics we are using, which is the Rheometer, can only base properties by stress over strain. But the Rheometer cannot determine the tension in an artery with a legion, such as an aneurysm [22]. This article will help us guide through the design where we have to develop the aneurysm model. This can help us determine the maximum tension a model can handle with our given material properties. The article provides advanced isogeometric fluid-structure analysis to determine the tension of the aneurysm with its structural dimensions [22]. This has never been done before and is a novel method. We can use these formulas and create another variable for our material and see if our tension values exceed typical values.

3.1.4.5 Carotid Artery Diameter and its effects on compliance

As a group, we have extensively researched the mechanical properties of the common carotid artery and its physical properties. Much of this data has been extensively researched using different methods to acquire them, but it is different for compliance data. This is highlighted in the article that we use for compliance data:

> "Vascular compliance in the human carotid artery has not by far been evaluated to the same extent. Previous investigations were performed either on exposed vessels, on materials that were not sex-matched, or with inclusion of subjects in a limited age range." [23]

This makes it difficult to compare our data to existing ones as some of the research could be done with poorly run systems or unhealthy test subjects, as previously mentioned. The article that we will be using sets out to evaluate 119 healthy subjects and measure their change in arterial diameter, pressure strain elastic modulus (Ep), and stiffness (p) were calculated and used as the inverse estimate of compliance [23]. The results show a linear decrease in compliance in male and female subjects [23]. This data can give us a good benchmark to compare our values and also use their existing data to determine a better fit for our vessel.

3.2 Benchmarking

Benchmarking was conducted on three companies that work in either 3D printing or bio-related 3D printing. The baseline is the BDL owned PolyJet 3D printer sold by Stratasys. Relevant problems for this benchmarking session include types of material used, printing methods of different companies, and goals of companies working in the medical devices field for 3D printing. These attributes relate directly to the project proposal of finding a new method of printing materials that can produce a model capable of simulating human vasculature. This evaluation is based on the studies conducted by BDL, before the start of this project, on human donors for the right common carotid artery.

3.2.1 System-Level Benchmarking

3.2.1.1 Existing Design #1: Biomodics

A company like Biomodics, where they look towards developing the future medical devices for the health sector, provides an intriguing interest in the benchmarking process. Biomodics works thoroughly with supercritical fluid processing and functional surfaces and materials for drug delivery [24]. Biomodics has a strong patent portfolio of new material technologies. These material technologies have seen success in working with the human body. Therefore, by looking to design a material that works well with organic human tissue, Biomodics will be thoroughly studied and examined in the benchmarking process.

3.2.1.2 Existing Design #2: Stratasys

Stratasys is one of the leaders of the 3-D printing world. Stratasys printing is seen in many industries, including aerospace, automotive, dental, consumer products, medical, and railway industries [25]. From their research, they have simulated everything from soft tissue and muscles to cartilage and bone in a single print job. Similarly, they have been able to incorporate transparent materials to get an unobstructed view of hidden tissues and blood vessels [26]. Seeing advancements that Stratasys has made in the 3-D printer world and the 3-D material made them a perfect existing design for the team to benchmark and study.

3.2.1.3 Existing Design #3: Axial 3D

The work done by Axial 3D has supplied aid for surgeons in multiple health sectors. Today, many 2D imaging processes can complicate pre-operative planning, leading to many complex surgeries being misdiagnosed or mixed-planned. Nevertheless, through these same 3D images, Axial 3D makes conceptualized complex three-dimensional anatomical structures, which provides aid to even the most experienced surgeons [27]. Axial 3D combines the world of 3D printing and medicine, a crucial company to research in the study during the benchmarking process. Axial's models are similar to the design ideas that the team is hoping to achieve by the project's end.

3.2.2 Subsystem Level Benchmarking

3.2.2.1 Subsystem #1: 3D Printing Method

3D Printing methods, in general, are the overarching idea behind our project. This creates a necessity to compare what BDL is doing for printing (as a baseline and what technology is available to us) to what other companies are doing. Each of the significant system-level companies that are analyzed all has similar 3D printing processes. However, it is hard to say what method is "best" without researching what is currently on the market and what current model deficiencies are with respect to the project.

3.2.2.1.1 Existing Design #1: MRI Scan/Imaging

Making models patient-specific is a design that will most likely be met within the term limit of the project. However, it is an important concept to grasp to understand the entire project. Being able to scan the focused human organ will allow each 3D model to be printed with characteristics related to the corresponding organ and make sure that each model is designed to be identical to the organ/system being analyzed. The use of MRI scans and imaging allows the expert to understand what is happening beneath the individual's skin without having to be cut open. Therefore, this provides a different meaning behind the project. By design material that will act as similar as possible to the actual human tissue will allow for more pre-operative planning, surgical simulations, intrateam discussions, and, finally, reduce the time and cost of surgery [27].

3.2.2.1.2 Existing Design #2: PolyJet

Different kinds of PolyJet material are used, all dependent on the characteristics that the designer wants to imitate. In this project, the team is working a lot with Agilus PolyJet material. Like what Stratasys uses in their products, Agilus is used mainly due to its highly rubber-like characteristics. This material has a high tear-resistance and can withstand repeated flexing and bending [28]. The team is looking to further Agilus use in the project through these characteristics, utilizing its exceptional durable properties.

3.2.2.1.3 Existing Design #3: Polymer Networks

Polymer Networks are essential in the biocompatibility and the biomimicry of our design. One of the significant variables of the projects is the altering of the polymer network. Each change in the network will directly change the characteristics and functionality of the material. Therefore, understanding polymer networks used in similar circumstances will help the team find the successful design there are aiming after.

3.2.2.2 Subsystem #2: Modeling Method

For modeling methods, different companies use a variety of tools to create their 3D printed models. We will be using PolyJet materials; however, there is potential that a "better" material is on the market, in development, or in current models that could be improved. Some companies emphasize the model structure accuracy but become deficient in the mechanical properties concerning the model application. For example, a vascular model of an intracranial aneurysm may be structurally relevant for a neurosurgeon to practice. However, the model walls may not respond the same to a catheter as a human vessel would. Thus, current modeling methods must be benchmarked to create a subjective, more anatomical, and mechanically accurate model.

3.2.2.2.1 Existing Design #1: MRI Scan/Imaging

One modeling method that has seen major advancements is that of modeling based on the images or scans that have been provided. This will allow each model to be unique, dependent only on each image. This method provides the most intellectual understanding. However, it also provides the most accurate results. These scans will provide 2D images that will be converted into 3D models through this process.

3.2.2.2.2 Existing Design #2: Basic CAD with a .STL File

The modeling method that the team is working with as of now is creating basic CAD models and printing the 3D model through the use of STL files. Though this requires less intellectual understanding than MRI scanning and imaging, it still provides a high level of accuracy, dependent on the designer. Therefore, the team understands that to obtain the most accurate information, the CAD models that will be used must be thoroughly examined and must contain important details throughout the model.

3.2.2.2.3 Existing Design #3: Vascular/Biologic Approach

The vascular/biologic approach is the modeling method that requires the highest intellectual understanding of the anatomical world is that of the vascular/biologic approach. This approach bases all understanding of the knowledge of the human body and the vascular system. After obtaining this information, then it will be converted into models that can be used to 3D print. This approach contains pros and cons, where it contains a high level of the anatomical areas of the project but contains less understanding in the 3D printing design aspect. Therefore, to see the best results, one must have a high intellectual understanding of every aspect of the project.

3.2.2.3 Subsystem #3: Biological Approaches

Lastly, the biological approach to creating models is different for competing companies. How the company incorporates human biology into its models will help inform and guide our team to produce a functional model. The implications of different company methods may require additional research and brainstorm for developmental processes. For instance, the technology available may be a limiting factor to our model innovation, or a competing method may be more developed and capable than the currently available processing. Evaluating these attributes helps the team to understand the market and the project relevance better.

3.2.2.3.1 Existing Design #1: Aim of Axial 3D: Cranial vasculature

The company, Axial 3D, takes MRI scans and uses many images to develop a 3D image. From this 3D image, engineers can create a printed, 3D model of accurate vasculature of a patient for a surgeon to practice on. This is an exciting approach compared to the current BDL method of using a biological approach (standard human anatomy) to model a Circle of Willis model.

3.2.2.3.2 Existing Design #2: Aim of Stratasys: Developing Practical Medical Models

Stratasys prides itself in being able to print client-provided models to a high degree of accuracy. However, they also use a form of normal human anatomy to create comprehensive surgical models.

3.2.2.3.3 Existing Design #3: Aim of Biomodics: Device Complications

Biomodics aims to improve biocompatibility. This importance in compatibility will allow the company to handle many different areas of medical complications, anywhere from surgical infections to drug delivery and analysis. Therefore, the team shows interest in Biomodics' research due to their continued advancement in the design, focusing highly on biocompatibility and biomimicry. Understanding and furthering advancing this research is the aim of the team. Therefore, creating Biomodics as an initial benchmark will allow the team to continue towards their project goal of biomimicry and compatibility.

3.3 Functional Decomposition

3.3.1 Black Box Model

The Black Box Model is a design tool to help the project concept generation process. This model helps to provide insight into the functions that go into a developed model solution to the project problem. For the 3D printing project, the black-box model is slightly unconventionally used. However, the black box model in this manipulation served to help the team realize what topics to focus on and break down the design process. The inlet functions are material ratio and material patterns. For a 3D printing project with precision in the micron units, altering the material ratio is a relatively easy technological capability. However, controlling the ratio or gradients of material is what the team aims to do to produce a model that is replicable of human vascular. This data is based on the right common carotid artery (RCCA) and can produce similar mechanical properties to the human donor samples analyzed by BDL in prior research. The team then brainstormed patterns of the material. One hypothesis was that by altering the pattern of the material printed by using different shores of hardness, the team might find data that would have either a higher standard deviation from the human samples or that the properties of varying shores would be averaged. This study will not be conducted based on the design generation and selection. Due to this project being an analytically heavy project, the outlet of the black-box model is "testing results/outcomes," see figure 7. The design selected will be printed and ran through various mechanical property tests to determine the structure's capabilities.

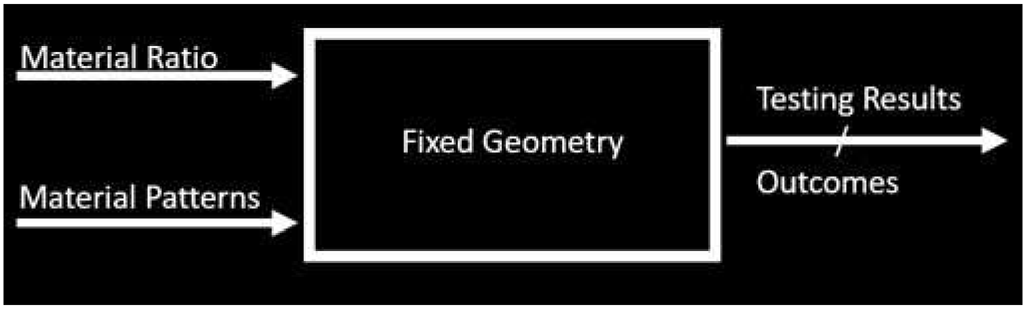


Figure 7 Black Box Model.

3.3.2 Functional Model/Work-Process Diagram/Hierarchical Task Analysis

The functional model helped the team break down variations of the 3D designs generated and gradients of material shores that could be used, see figure 8. Headed by the project topics, we then break down the design patterns that were generated during brainstorming. The arrows indicate which design the team selected, which two designs were runners up, and the final design that was a no. For each design concept, there are two material gradients advised by the client to create a proof of concept for changing shore gradients. This model helps the team visually break down the gradients being used per design and record what gradients will be tested. There are a wide variety of combinations of gradients available, so this is the order chosen.

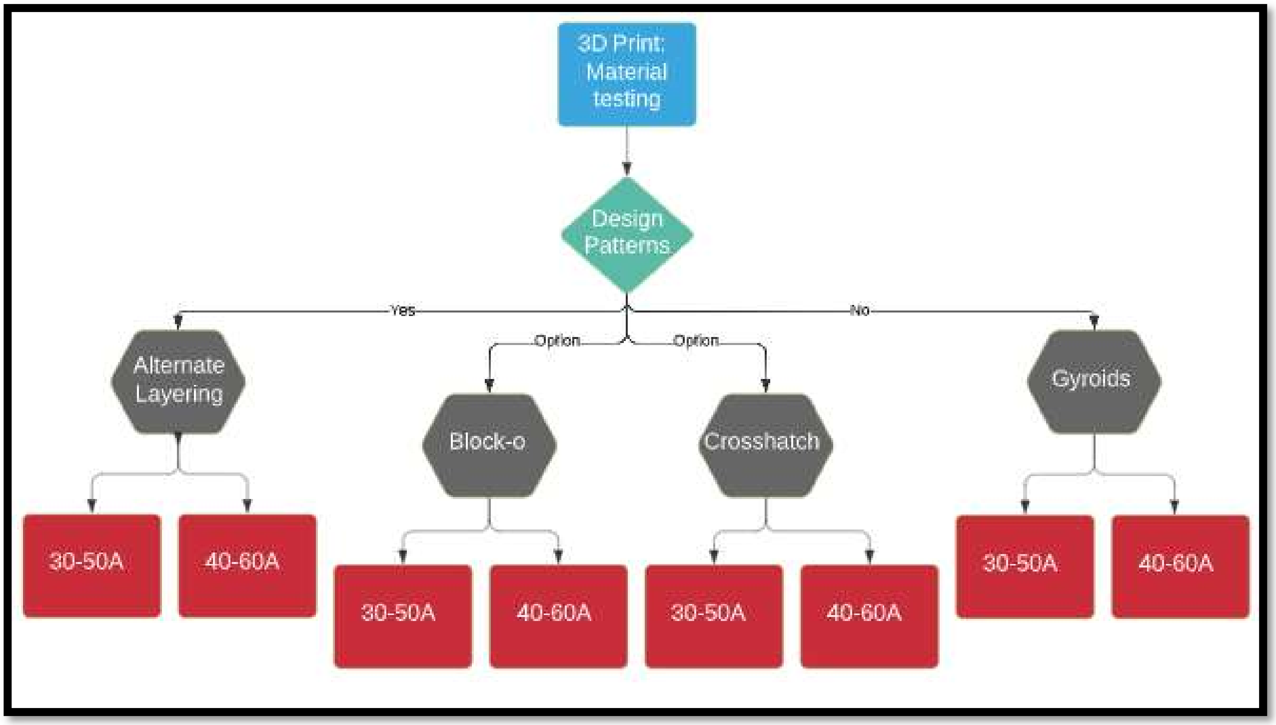


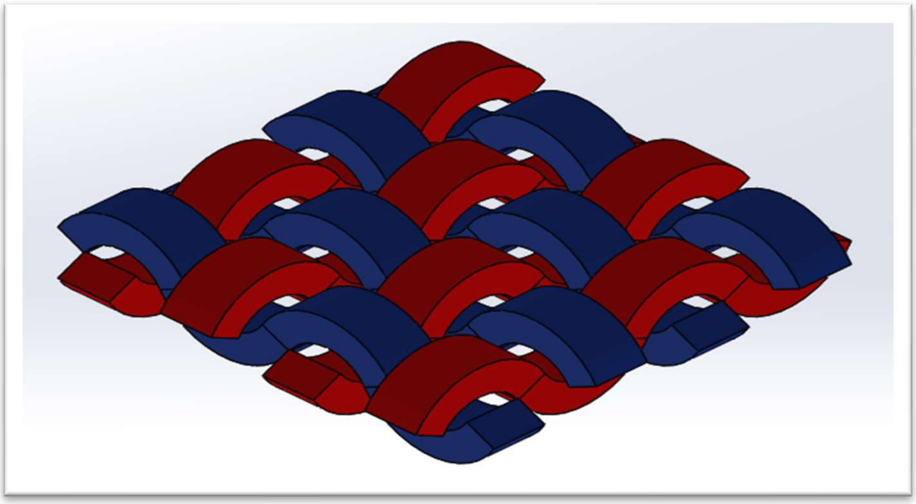
Figure 8 Functional Model.

4 CONCEPT GENERATION

After talking more with Dr. Becker and brainstorming potential solutions that fulfill the client's requirements, each teammate came up with a design. Some designs build off current designs used for this type of research, while others look at more complex patterns. Each design considered the difficulty of printing, how the materials could be layered and how that layering could affect the model's properties, and how closely it replicates the human vessels.

4.1 Full System Design #1: Crosshatch

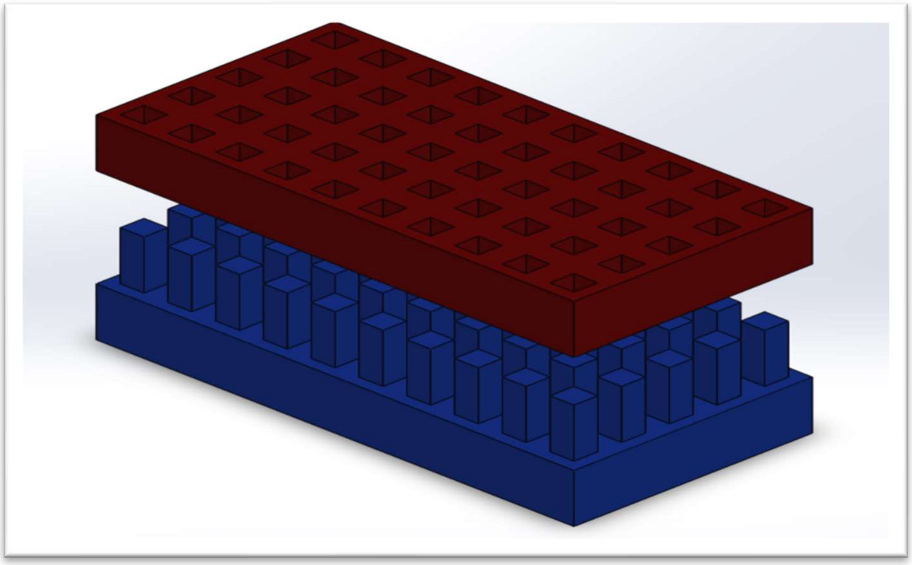
This design focused on a crosshatched pattern design where each material would be weaved into each other. This design would provide a mix of hard and soft materials and provide great flexibility or compliance to the model. However, the weaving pattern will cause complications when printing, creating many air pockets that could affect future testing and not allow for multiple layers since all the materials are woven into a single layer. This design was also one of the more complex designs, but it does not mimic the natural occurring layering method.



4.1.1 Figure [9]: Crosshatch design

4.2 Full System Design #2: Alternate Layering (Block-o)

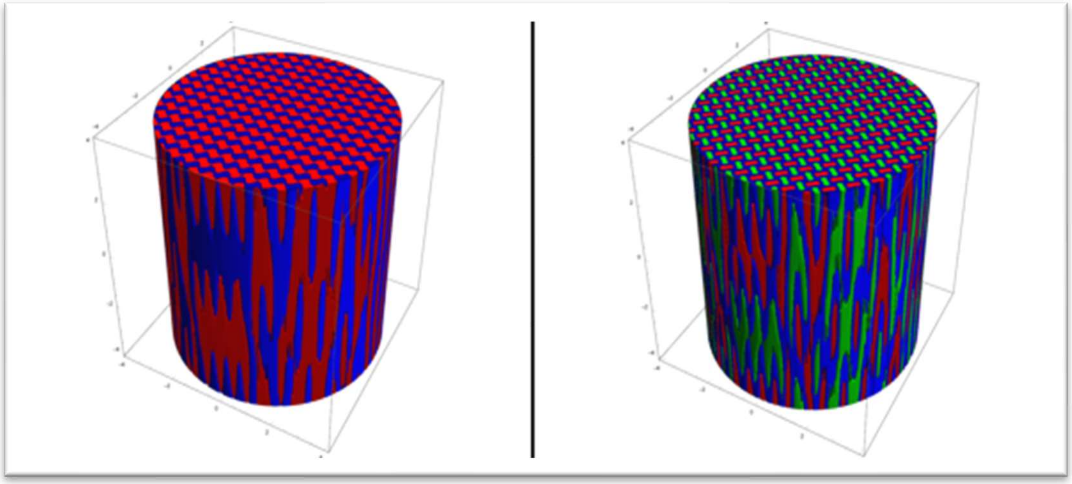
This design mimics a build block design where the top layer of material would have multiple evenly spaced holes, and the bottom layer will have pegs that fit into those holes. Due to the hole-peg nature of the design, the secures together, and the type of layering allowed each layer to have its hardness level. Some issues with this design are that the pegs could cause issues with printing since everything has to line up nicely, or there will be air pockets, and that it will be challenging to add more than two layers to the design.



4.2.1 Figure [10]: Alternate Layering

4.3 Full System Design #3: Gyroids

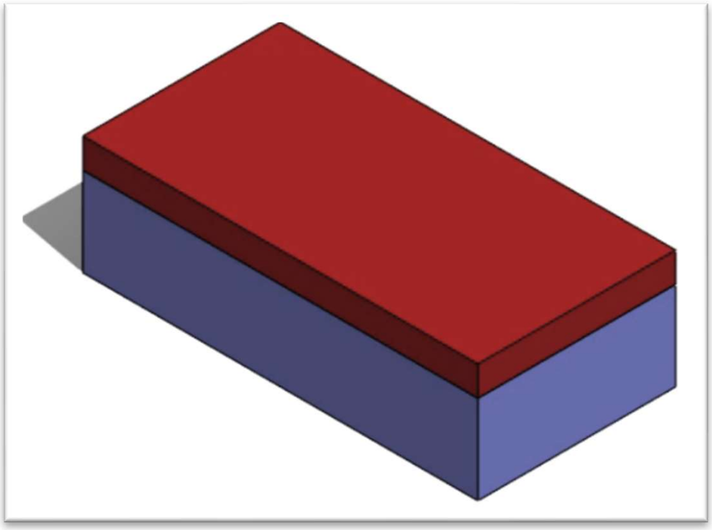
This design uses sinusoidal patterns to interweave materials together. This pattern allows the model to have more complex properties and allows for multiple materials to be used in a single layer. Some issues are that this design would provide many complications when printing since the design is so complicated. Also, it does not allow for diversity of hardness levels within the model since there can only be a single layer and does not have much compliance.



4.3.1 Figure [11]: Gyroids

4.4 Full System Design #4: Alternating Shores

This design focused on simple layering materials with a varying hardness on top of one another. The materials are printed with a simple layering method, no mimicking patterns or creating pegs and holes, with the bottom layer taking up most of the model. In this design, the layers will be meshed to create tight bonds, leading to no air pockets and requiring much support when printing. While this is a simple design, it does have a similar type of layering to the organic tissue and allows for a transition between soft and hard materials. This transition will allow the model to have close to the desired compliance needed during testing.



4.4.1 Figure [12] : Alternating Shores

4.5 Subsystems Concept

4.5.1 Subsystem #1: Pattern

The pattern the layers are printed in could affect the print time, the integrity of the layers. The printing is in a UV Cured material. So, when changing the pattern of the material through different shore hardness, there is potential to change the overall material's properties when tested. There is also potential that the pattern would be subjectively averaged when tested, which means that a mixed pattern of 30A and 40A may average to an ordinary 35A. This is going to be a testing application through testing 30A and 50A. If shores are too average, then changing gradients would become obsolete unless an in-between of two materials not commonly manufactured is desired.

4.5.1.1 Design #1: Mesh Print

Mesh print involves UV-cured printing. The layers are printed so closely together that they are essentially meshed, creating no air pockets. The lack of air pockets mimics the water tightness of human vessels and ensures that the liquid used during the compliance test stays within the tube. This type of printing also allows for an easy gradient to be created between layers, assisting in the transition from soft to hard materials. The simplicity of this type of printing means that there will be less time to print the models, which allows for multiple types of models to be printed in a shorter amount of time. However, this type of printing does not allow for more complex designs and expands upon current printing techniques.

4.5.1.2 Design #2: Overlapping Layers

Overlapping layers involves creating strings of each material essentially and weaving them together, creating a sheet. This print type creates a sturdy model that allows for a more complex way of mixing materials within layers. However, due to the weaving pattern's nature, there will be too many air pockets within the layers, which causes issues with the compliancy tests, doesn't match the same water tightness as human vessels, and makes it difficult to examine each material. This type of printing also increases the print time of the models due to the complexity of the design and could cause complications of unintentional mixing while printing.

4.5.1.3 Design #3: Equation Driven Patterns

Equation-driven patterns involve using standard equations to creates the mix of materials within layers. Since the equation remains the same for every layer, models are easy to replicate for future projects. This type of printing also avoids air pockets, creating the model's wall with a watertight seal, mimicking the same property as human vessels. However, due to the complexity of this design, it would not be easy to analyze each layer's effectiveness without averaging all the data. Due to the way the materials are mixed, the models would become too rigid to mimic the softness of human vessels. While the models for this type of printing would be easy to replicate, the printing portion itself would be complicated, increasing print times and causing potential complications with dispensing the materials.

4.6 Subsystem #2: Layering

The type of layering of a model can influence the model's properties. Each model is roughly 1.2 mm in thickness.

4.6.1.1 Design #1: Simple layering (1-3 layers)

With simple layering, each layer is the same thickness, and all would have the same hardness level. This design allows for any desired number of layers to be printed within the model and allows for quick tests to be done since print time would reduce. Some cons to this type of layering are that because it is so simple and does not allow for more than one material to be used, the data found from these tests would not be of much use, and there is not any variety of hard/softness levels within the model. Since each layer is roughly the same thickness, the models would not match the layering of human vessels.

4.6.1.2 Design #2: Thickness Relative to the Vascular Anatomy

This design would be trying to mimic the same thickness to vascular anatomy. There will be two layers; the first layer will take up roughly 80% of the thickness to mimic the media section of vessels. This layer will also be printed using a softer material, while the thinner layer will be printed with a more rigid material. This design does exclude the extrema layer of the vessel since that layer only provides support and has little to no effect on the testing that will be performed [4]. The pros of this layering design are that the thickness of the two layers is relative to vascular anatomy, which will help provide accurate data during the tests. Some cons to this design are that this type of design has not been tested in previous research, so there is a possibility of this design suffering from minor changes tests continue.

4.6.1.3 Design #3: Different Hardness of Layers

The different hardness of layers design focuses on each layer having a slightly higher hardness than the previous. Each layer will have an equal thickness, and this design could have as many layers as desired. This design allows for materials to be mixed in particular layers which provides a transition between hard and soft materials. The multiple layers of different materials can mimic the different hardness levels that vessels have, which could be used to help provide somewhat accurate results to natural vessels. However, since each layer has the same thickness, this does not replicate the layering in vessels, and models with this design will not provide the desired results.

4.7 Subsystem #3: Material

The type of materials used and the ratios of those materials can affect the properties of the model.

4.7.1.1 Design #1: Agilus 30 & 50 Combination

This mixture of materials involves mixing Agilus 30 and 50. The higher the number, the higher the hardness levels, so Agilus 50 would have a higher shore than Agilus 30. The outer layer would be Agilus 30, while the inner layer is made of Agilus 50. Having a more rigid interior is more anatomically correct and provides a more lubricious surface. This will also help provide structural stability to the structure. During compliance tests, the sample does not rupture and is hypothesized to display similar qualities of the human RCCA. 50A may be too rigid to provide vascular-like responses. However, it is used to validate combining different shores in specific thicknesses to determine a change in overall material properties.

4.7.1.2 Design #2: Agilus 40 & 60 Combination

This mixture involves combining Agilus 40 and 60. The outer layer would be Agilus 40, while the inner layer would be made of Agilus 60. The slightly harder 40 shore on the exterior causes the model to be more lubricious than the Agilus 30, displaying similar properties to human vessels. While having the interior have a high hardness level provides needed structure to the model during compliancy tests. It is possible that the material could be too rigid to mimic the flexibility of human vessels and affect the results from the lubricity test. There is a possibility with the mix of Agilus 40 & 60 that the results would simply be the average of the two numbers, making the results the same as using Agilus 50 instead of producing different data. If that is true, then there is no need to switch to Agilus 60.

4.7.1.3 Design #3: Pure VeroClear vs. Pure Agilus

This design focuses on using the pure version of either material when creating the layers. Pure Agilus is exceptionally soft, which provides the needed flexibility for specific tests, but this material is highly fragile. This material would most likely tear during most of the tests performed, such as busting during the compliance test, providing inadequate data. Pure VeroClear is highly rigid, with no flexibility, and provides a sturdy layer, but due to that lack of malleability, it would also result in inadequate data. A model created with these materials would not mimic human vascular's softness/hardness levels and would prove to be a waste of the budget.

5 DESIGNS SELECTED – First Semester

In this section, we will analyze the different concepts that the team has generated and the analysis for streamlining our requirements into the final design. The team brainstormed on all the different possibilities and created four different solutions highlighted in section 4.0. This was done by reviewing our research on the subject and getting approval from the client. The team then used different problem-solving tools to decompose the requirements into smaller subsections (sub-functions) to fulfill and solutions (concept variants). Then a decision matrix was created to analyze the concept variants and narrow it down to our final design.

5.1 Technical Selection Criteria

After creating four distinct geometries for our concept variants, we decided to use the decision matrix to analyze our concept variants using the criterion developed in the QFD (Quality Functional Decomposition). A weight is assigned to each criterion and is totaled to 1. Typically, the decision matrix only has one type of alternative and is compared to the criterion and assigned a value; these values are then totaled up and ranked between all the alternative concepts and are given a high rank to low rank. In our case, we are asked by the client to see if there are any differences in the material properties if the ratios (shore) change in our design. Therefore, we included two different shore values of the materials for all concept variants and will compare them to the criterion. These criteria are soft exterior, medium interior, lightweight, compliance, equivalent properties to organic tissue. These designs are then given a value the group thought appropriately and then multiplied to the weighted criteria. This is shown in the decision matrix in the appendix. C

5.1.1 Alternate Shores

Based on our analysis, the decision matrix has concluded that alternate shores geometry is the best design that fits all our engineering requirements. It meets all our criteria and does so with high margins. A vital part of this concept is that the layers have different firmness; this creates a mesh with a softer outer shell and a medium firmness interior that mimics tissue. We have two layers of varying height and make up a height of 1.2mm. Our client recommended that we make it look like a vessel in shape and feel; this matched all the demands the client wanted. The layers have meshed so that there will be no air pockets, and that will help us with a tighter bond between the layers. Overall, it matches all our criteria and will be a good baseline for us to use. We also have the advantage of having two different layers with two different firmness values on their own. When meshed, it would make a system of mimicking an artery, which we hope to achieve with this design.

5.2 The Rationale for Design Selection

5.2.1 Decision matrix evaluation

If we see in the decision matrix below in appendix C, the design with the alternating shores ranks 1 when compared to all the other designs. The design matched all our criteria with top points and helped it rank the highest, and it was helpful that the device was compatible with the higher-ranked criteriums and fulfilled what the client wanted. The design ranks first in our decision matrix due to its high ratings in Soft Exterior, Compliance, and Similar Properties to Organic Tissue. The weight of these criteria shows us how important they are to the client and overall design evaluation; Soft Exterior is considered 20% of the total importance while Compliance and Similar Properties to Organic Tissue are weighted as 15% and 35% respectively in importance. However, some of the design's capabilities fall short of other highly weighted criteria; such disadvantages came out to be its firmness on the interior (medium firmness interior) and lightweight.

5.2.2 Technical Analysis

Dividing our mechanical properties into two different correlations helped us analyze each component thoroughly and in a manner that would help us validate our design alternatives. We will analyze compliance values and how similar it is to organic tissue. These were selected as the two primary analyses as they ranked the highest in weight percentage.

5.2.2.1 Compliance

Compliance is an essential aspect of making our model responsively like human tissue. A pressure transducer and a 10cc syringe filled with Conray are connected to a tube of 3D printed material to measure compliance. The material is inflated with Conray to specific pressures the human body would experience, and images are captured with a fluoroscope. The internal walls/diameters are visible in the image and measured to find the vessel's compliance at a set pressure. The goal is to print a cylindrical tube that outward expands under pressure to the same degree as human RCCAs would; see Appendix A for donor valued compliance data.

5.2.2.2 Similar to organic tissue

The material printed will be tested for its mechanical properties, which will then be compared to human RCCA mechanical properties. For the height in our sample, we have two sublayers meshed to make a whole layer. The actual carotid arteries are three layers: Tunica intima, Tunica media, and Tunica extrema [30]. From a purely physical and design specifications standpoint, we are adverse the extrema part of the layer. With the recent changes from the data collected, it will not be printed on the Circle of Willis design we would make at the end of the capstone year. This omission of the tunica extrema is because the BDL team removed the adventitia and tunica extrema from the RCCAs (Right Common Carotid Artery) before their testing. As a result of this, we need to make models that are similarly layered to compare the data sets. For the intima and media thickness (IMT), we can take the measurements from the age range 41-86 as that is around the time most aneurysms begin to show up; So, the media values are 0.95mm (P25+P50) and intima 0.61mm [30]. This is close to our geometry, an overall depth of 1.2mm, dividing the two layers by 80% media and 20% intima. So, our values are close in media – 80% of 1.2 = 0.96mm. and the intima has a difference from 0.61 in actual RCCAs (Right Common Carotid Artery) to 20% of 1.2mm = 0.24mm [30].

6 REFERENCES

[1] C. Settanni, "In Vitro Neurovascular Model Development for Liquid Embolic Implant Simulation," *Google*. [Online]. Available: https://docs.google.com/presentation/d/14mdgqx2 XWuA98fz6Ufh07s_CHWN_O8-w/edit#slide=id.p9. [Accessed: 10-Oct-2021].

[2] W. D. Vian and N. L. Denton, "ASEE IL-IN Section Conference," in *https://docs.lib.purdue.edu/aseeil-insectionconference?utm_source=docs.lib.purdue.edu%2Faseeil-insectionconference%2F2018%2Ftech%2F3&utm_medium=PDF&utm_campaign=PDFCoverPages*, 2018.

[3] H. Weidmann, H. Williams, C. D. Mack, S. C. H. Li, and H. J. Medbury, “Figure 1. Structure of the vascular wall (adapted from Wikipedia)....," *ResearchGate*, 01-Aug-2018. [Online]. Available: https://www.researchgate.net/figure/Structure-of-the-vascular-wall-Adapted-from-Wikipedia-Disposition-of-the-three_fig1_286948064. [Accessed: 10-Oct-2021].

[4] N. G. Norris, W. C. Merritt, and T. A. Becker, "Application of nondestructive mechanical characterization testing for creating in vitro vessel models with material properties similar to human neurovasculature," *Journal of biomedical materials research. Part A*, 17-Sep-2021. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/34617389/. [Accessed: 13-Oct-2021].

[5] M. L. Eigenbrodt, R. Sukhija, K. M. Rose, R. E. Tracy, D. J. Couper, G. W. Evans, Z. Bursac, and J. L. Mehta, "Common carotid artery wall thickness and external diameter as predictors of prevalent and incident cardiac events in a large population study," *Cardiovascular ultrasound*, 09-Mar-2007. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1831763/. [Accessed: 12-Oct-2021].

[6] E. M. da Rosa, C. Kramer, and I. Castro, "Association between coronary artery atherosclerosis and the intima-media thickness of the common carotid artery measured on ultrasonography," *Arquivos Brasileiros de Cardiologia*, 01-Jun-2003. [Online]. Available: https://www.scielo.br/j/abc/a/Vr7N44sDSfSdHTxMmskwmSd/?lang=en. [Accessed: 14-Oct-2021].

[7] S. Rosfors, Stefan Rosfors From the Department of Clinical Physiology (SR, S. Hallerstam, Staffan Hallerstam From the Department of Clinical Physiology (SR, K. Jensen-Urstad, Kerstin Jensen-Urstad From the Department of Clinical Physiology (SR, M. Zetterling, Maria Zetterling From the Department of Clinical Physiology (SR, C. Carlström, Christian Carlström From the Department of Clinical Physiology (SR, and C. to S. Rosfors, "Relationship between Intima-media thickness in the common carotid artery and atherosclerosis in the carotid bifurcation," *Stroke*, 01-Jul-1998. [Online]. Available: https://www.ahajournals.org/doi/full/10.1161/01.STR.29.7.1378. [Accessed: 14-Oct-2021].

[8] G. Sommer, I. of Biomechanics, P. Regitnig, I. of Pathology, L. Költringer, G. A. Holzapfel, Address for reprint requests and other correspondence: G. A. Holzapfel, A. V. Kamenskiy, and F. M. Callaghan, "Biaxial mechanical properties of intact and layer-dissected human carotid arteries at physiological and supraphysiological loadings," *American Journal of Physiology-Heart and Circulatory Physiology*, 01-Mar-2010. [Online]. Available: https://journals.physiology.org/doi/full/10.1152/ajpheart.00378.2009#F10. [Accessed: 14-Oct-2021].

[9] H. Jiang, L. Le Barbenchon, B. Bednarcyk, F. Scarpa and Y. Chen, "Bioinspired multilayered cellular composites with enhanced energy absorption and shape recovery", Additive Manufacturing, vol. 36, p. 101430, 2020. Available: 10.1016/j.addma.2020.101430 [Accessed 10 September 2021].

[10] S. Ravi and E. Chaikof, "Biomaterials for vascular tissue engineering", Regenerative Medicine, vol. 5, no. 1, pp. 107-120, 2010. Available: 10.2217/rme.09.77 [Accessed 12 October 2021].

[11] Omega Engineering Inc., "A Complete Guide to Data Acquisition (DAQ) Systems", https://www.omega.com/en-us/, 2021. [Online]. Available: https://www.omega.com/en-us/resources/daq-systems. [Accessed: 12- Oct- 2021].

[12] R. Terman, "Personal Academic Webpages: How-To's and Tips for a Better Site | Townsend Center for the Humanities", Townsendcenter.berkeley.edu, 2021. [Online]. Available: https://townsendcenter.berkeley.edu/blog/personal-academic-webpages-how-tos-and-tips-better-site. [Accessed: 12- Oct- 2021].

[13] D. Zimelewicz Oberman et al., "Morphologic Variations in the Circle of Willis as a Risk Factor for Aneurysm Rupture in the Anterior and Posterior Communicating Arteries", World Neurosurgery, vol. 154, pp. e155-e162, 2021. Available: 10.1016/j.wneu.2021.06.151.

[14] S. Esmaeili et al., "An artificial blood vessel fabricated by 3D printing for pharmaceutical application," Nanomed. J, vol. 6, no. 3, pp. 183–194, 2019, doi: 10.22038/nmj.2019.06.00005.

[15] Jannin, P. and Morandi, X., 2007. Surgical models for computer-assisted neurosurgery. NeuroImage, 37(3), pp.783-791.

[16] A. Dell, F. Wegner, E. Aderhold, T. M. Buzug, and T. Friedrich, "Stenosis simulation of femoral arteries using an adaptive 3D-printed actuator," pp. 1–2, 2021, doi: 10.18416/AMMM.2021.2109576.

[17] N. Agarwal and R. O. Carare, "Cerebral Vessels: An Overview of Anatomy, Physiology, and Role in the Drainage of Fluids and Solutes," Front. Neurol., vol. 11, no. January, pp. 1–8, 2021, doi: 10.3389/fneur.2020.611485.

[18] J. D. Jones, P. Castanho, P. Bazira, and K. Sanders, "Anatomical variations of the circle of Willis and their prevalence, with a focus on the posterior communicating artery: A literature review and meta-analysis," Clin. Anat., vol. 34, no. 7, pp. 978–990, 2021, doi: 10.1002/ca.23662.

[19] Ewoldt R.H., Johnston M.T., Caretta LM (2015) Experimental Challenges of Shear Rheology: How to Avoid Bad Data. In: Spagnolie S. (eds) Complex Fluids in Biological Systems. Biological and Medical Physics, Biomedical Engineering. Springer, New York, NY. https://doi.org/10.1007/978-1-4939-2065-5_6

[20] S.-W. Nam, S. Choi, Y. Cheong, Y.-H. Kim, and H.-K. Park, "Evaluation of aneurysm-associated wall shear stress related to morphological variations of circle of willis using a microfluidic device," *Journal of Biomechanics*, vol. 48, no. 2, pp. 348–353, 2015.

[21] Alexandre Franquet, Stéphane Avril, Rodolphe Le Riche, Pierre Badel, Fabien Schneider, et al.. Identification of the in vivo elastic properties of common carotid arteries from MRI: a study on subjects with and without atherosclerosis.. Journal of the Mechanical Behavior of Biological Materials, 2013, 27 (11), pp.184-203. ff10.1016/j.jmbbm.2013.03.016ff. ffhal-00805128f

[22] J. G. Isaksen, Y. Bazilevs, T. Kvamsdal, Y. Zhang, J. H. Kaspersen, K. Waterloo, B. Romner, and T. Ingebrigtsen, "Determination of wall tension in cerebral artery aneurysms by numerical simulation," *Stroke*, vol. 39, no. 12, pp. 3172–3178, 25-09-2008.

[23] F. Hansen, P. Mangell, B. Sonesson, and T. Länne, "Diameter and compliance in the human common carotid artery — variations with age and sex," *Ultrasound in Medicine & Biology*, vol. 21, no. 1, pp. 1–9, 1995.

[24] Biomodics, "Biomodics - Improving interaction between medical devices and biological material", *Biomodics.com*, 2021. [Online]. Available: https://www.biomodics.com/. [Accessed: 14- Oct- 2021].

[25] Stratasys Ltd., "Stratasys: 3D Printing & Additive Manufacturing", *Stratasys*, 2021. [Online]. Available: https://www.stratasys.com/. [Accessed: 14- Oct- 2021].

[26] Stratasys Ltd., "Personalized Patient Care with 3D Printed Models | Stratasys", *Stratasys*, 2021. [Online]. Available: https://www.stratasys.com/medical/personalized-patient-care-3d-printed-models. [Accessed: 14- Oct- 2021].

[27] Axial 3D, "Neurosurgery", *Axial3D*, 2021. [Online]. Available: https://axial3d.com/solutions/physicians/neurosurgery. [Accessed: 14- Oct- 2021].

[28] Stratasys Ltd., "Agilus 30: A Flexible Photopolymer 3D Printing Material | Stratasys", *Stratasys*, 2021. [Online]. Available:

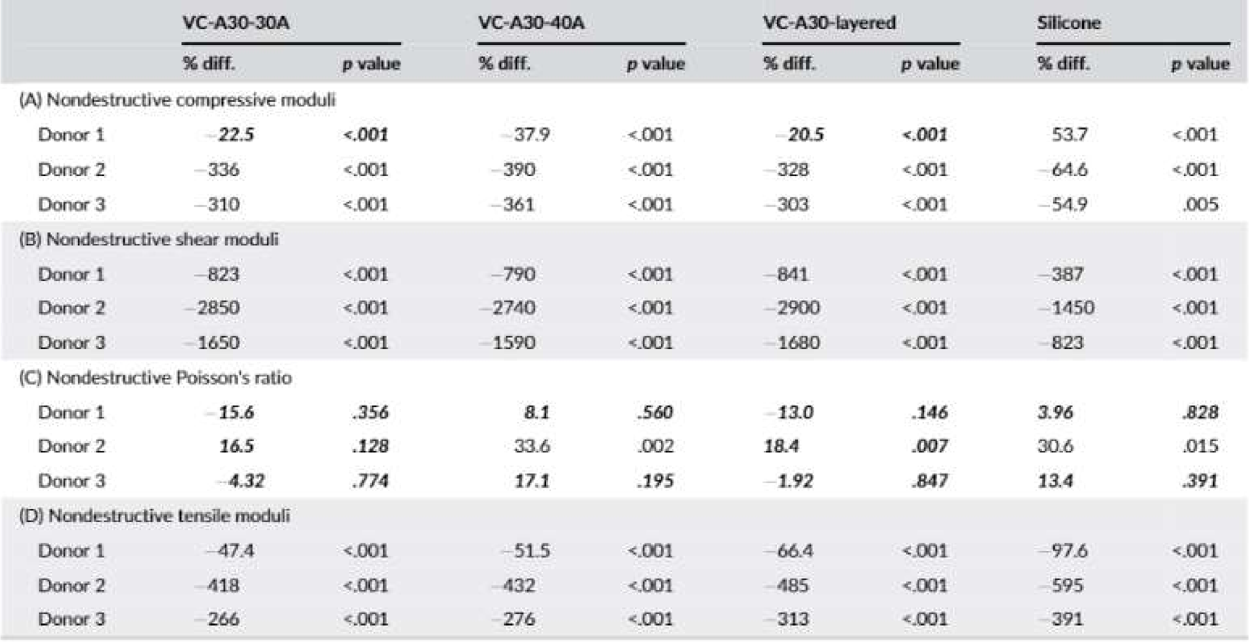
https://www.stratasys.com/materials/search/agilus30#imageCarousel. [Accessed: 14- Oct- 2021].

[29] Biomodics, "Biomodics - Improving interaction between medical devices and biological material", *Biomodics.com*, 2021. [Online]. Available: https://www.biomodics.com/#vd_solution. [Accessed: 14- Oct- 2021].

[30] F. Hansen, P. Mangell, B. Sonesson, and T. Länne, "Diameter and compliance in the human common carotid artery — variations with age and sex," *Ultrasound in Medicine & Biology*, vol. 21, no. 1, pp. 1–9, 1995. https://123sonography.com/assessment-intima-media-thickness-imt . [Accessed: 15- Oct- 2021].

7 APPENDICES

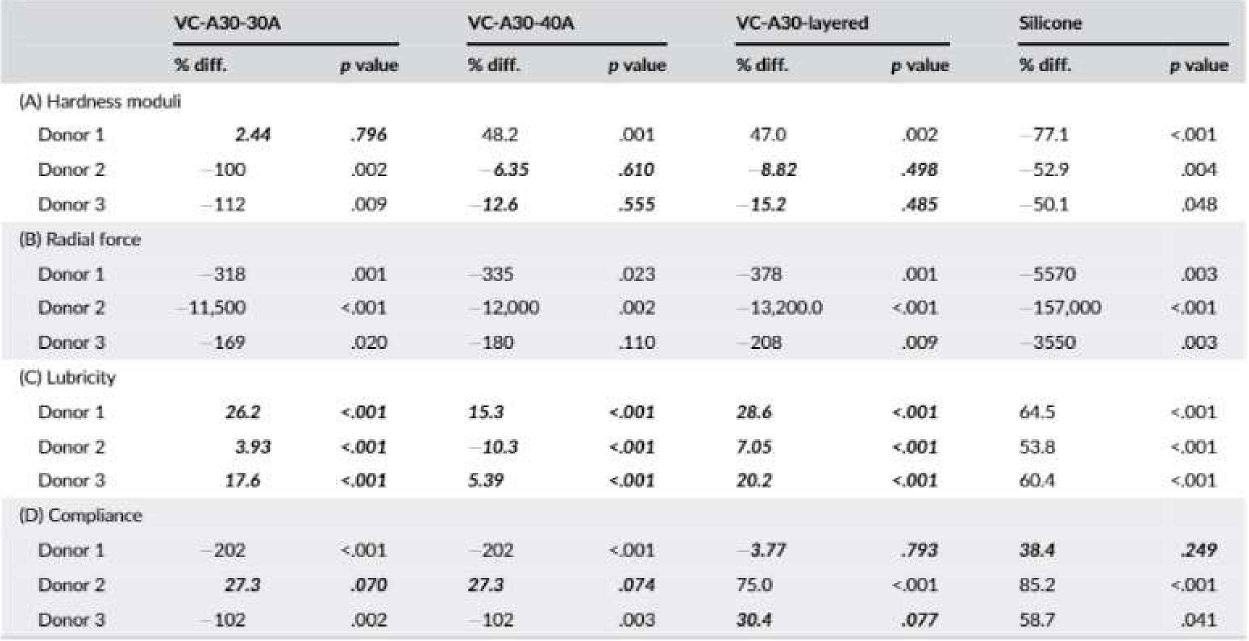
7.1 Appendix A: Original System Performance Tables



	VC-A30-30A		VC-A30-40A		VC-A30-layered		Silicone	
	% diff.	*p* value	% diff.	*p* value	% diff.	*p* value	% diff.	*p* value
(A) Nondestructive compressive moduli								
Donor 1	***−22.5***	***<.001***	−37.9	<.001	***−20.5***	***<.001***	53.7	<.001
Donor 2	−336	<.001	−390	<.001	−328	<.001	−64.6	<.001
Donor 3	−310	<.001	−361	<.001	−303	<.001	−54.9	.005
(B) Nondestructive shear moduli								
Donor 1	−823	<.001	−790	<.001	−841	<.001	−387	<.001
Donor 2	−2850	<.001	−2740	<.001	−2900	<.001	−1450	<.001
Donor 3	−1650	<.001	−1590	<.001	−1680	<.001	−823	<.001
(C) Nondestructive Poisson's ratio								
Donor 1	***−15.6***	***.356***	***8.1***	***.560***	***−13.0***	***.146***	***3.96***	***.828***
Donor 2	***16.5***	***.128***	33.6	.002	***18.4***	***.007***	30.6	.015
Donor 3	***−4.32***	***.774***	***17.1***	***.195***	***−1.92***	***.847***	***13.4***	***.391***
(D) Nondestructive tensile moduli								
Donor 1	−47.4	<.001	−51.5	<.001	−66.4	<.001	−97.6	<.001
Donor 2	−418	<.001	−432	<.001	−485	<.001	−595	<.001
Donor 3	−266	<.001	−276	<.001	−313	<.001	−391	<.001

Note: Values in bold/italics represent significant results and/or % diff. less than 30%.

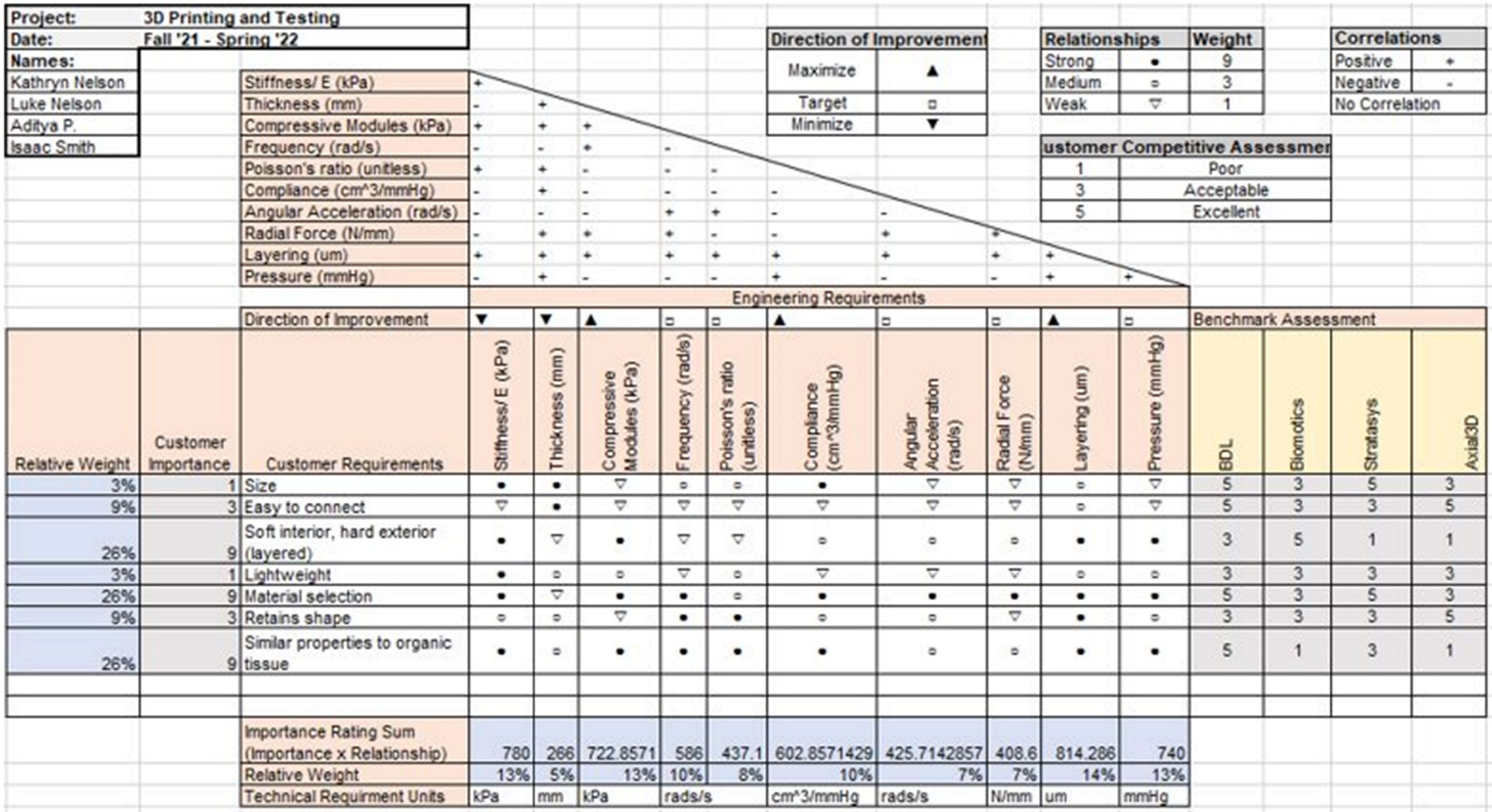
Figure 2 Table display of polymer vs. donor mechanical properties by testing method [2].



	VC-A30-30A		VC-A30-40A		VC-A30-layered		Silicone	
	% diff.	*p* value	% diff.	*p* value	% diff.	*p* value	% diff.	*p* value
(A) Hardness moduli								
Donor 1	***2.44***	***.796***	48.2	.001	47.0	.002	−77.1	<.001
Donor 2	−100	.002	***−6.35***	***.610***	***−8.82***	***.498***	−52.9	.004
Donor 3	−112	.009	***−12.6***	***.555***	***−15.2***	***.485***	−50.1	.048
(B) Radial force								
Donor 1	−318	.001	−335	.023	−378	.001	−5570	.003
Donor 2	−11,500	<.001	−12,000	.002	−13,200.0	<.001	−157,000	<.001
Donor 3	−169	.020	−180	.110	−208	.009	−3550	.003
(C) Lubricity								
Donor 1	***26.2***	***<.001***	***15.3***	***<.001***	***28.6***	***<.001***	64.5	<.001
Donor 2	***3.93***	***<.001***	***−10.3***	***<.001***	***7.05***	***<.001***	53.8	<.001
Donor 3	***17.6***	***<.001***	***5.39***	***<.001***	***20.2***	***<.001***	60.4	<.001
(D) Compliance								
Donor 1	−202	<.001	−202	<.001	***−3.77***	***.793***	***38.4***	***.249***
Donor 2	***27.3***	***.070***	***27.3***	***.074***	75.0	<.001	85.2	<.001
Donor 3	−102	.002	−102	.003	***30.4***	***.077***	58.7	.041

Figure 3 Table display of polymer vs. donor mechanical properties by testing method [2].

7.2 Appendix B: HOQ



Project:	**3D Printing and Testing**
Date:	**Fall '21 - Spring '22**
Names:	
Kathryn Nelson	
Luke Nelson	
Aditya P.	
Isaac Smith	

Direction of Improvement	
Maximize	▲
Target	□
Minimize	▼

Relationships		**Weight**
Strong	●	9
Medium	○	3
Weak	▽	1

Correlations	
Positive	+
Negative	-
No Correlation	

ustomer Competitive Assessmer	
1	Poor
3	Acceptable
5	Excellent

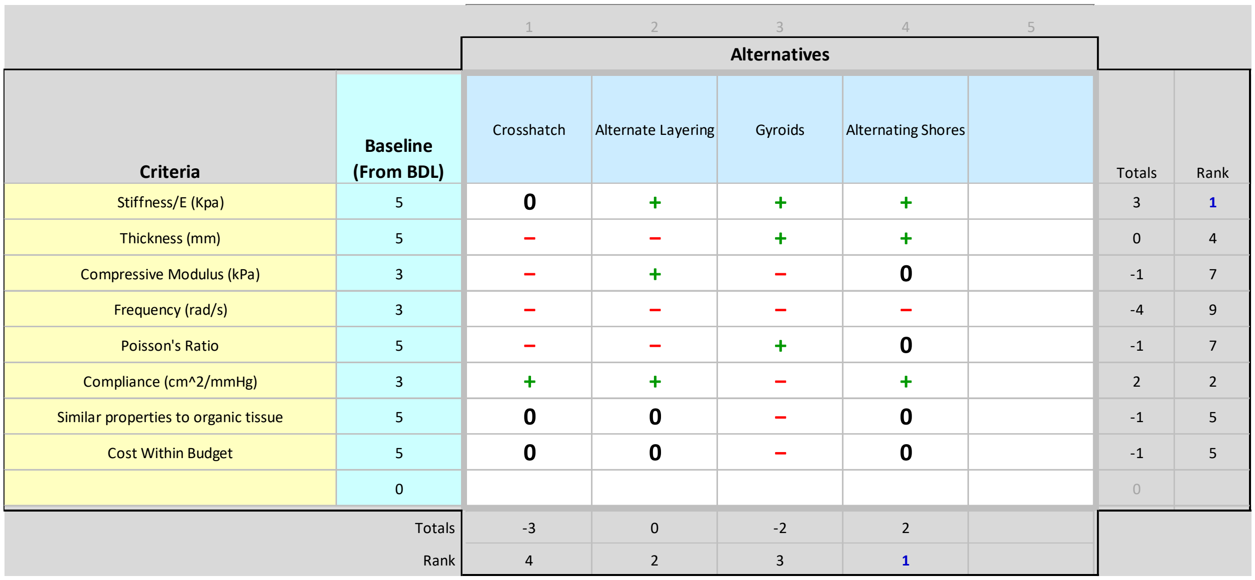
Stiffness/ E (kPa)	+									
Thickness (mm)	-	+								
Compressive Modules (kPa)	+	+	+							
Frequency (rad/s)	-	-	+	-						
Poisson's ratio (unitless)	+	+	-	-	-					
Compliance (cm^3/mmHg)	-	+	-	-	-	-				
Angular Acceleration (rad/s)	-	-	-	+	+	-	-			
Radial Force (N/mm)	-	+	+	+	-	-	+	+		
Layering (um)	+	+	+	+	+	+	+	+	+	
Pressure (mmHg)	-	+	-	-	-	+	-	-	+	+

			Engineering Requirements										Benchmark Assessment			
		Direction of Improvement	▼	▼	▲	□	□	▲	□	□	▲	□				
Relative Weight	Customer Importance	Customer Requirements	Stiffness/ E (kPa)	Thickness (mm)	Compressive Modules (kPa)	Frequency (rad/s)	Poisson's ratio (unitless)	Compliance (cm^3/mmHg)	Angular Acceleration (rad/s)	Radial Force (N/mm)	Layering (um)	Pressure (mmHg)	BDL	Biomotics	Stratasys	Axial3D
3%	1	Size	●	●	▽	○	○	●	▽	▽	○	▽	5	3	5	3
9%	3	Easy to connect	▽	●	▽	▽	▽	▽	▽	▽	○	▽	5	3	3	5
26%	9	Soft interior, hard exterior (layered)	●	▽	●	▽	▽	○	○	○	●	●	3	5	1	1
3%	1	Lightweight	●	○	○	▽	○	▽	▽	▽	○	○	3	3	3	3
26%	9	Material selection	●	▽	●	●	○	●	●	●	●	●	5	3	5	3
9%	3	Retains shape	○	○	▽	●	●	○	○	▽	●	○	3	3	3	5
26%	9	Similar properties to organic tissue	●	○	●	●	●	●	○	○	●	●	5	1	3	1
		Importance Rating Sum (Importance x Relationship)	780	266	722.8571	586	437.1	602.8571429	425.7142857	408.6	814.286	740				
		Relative Weight	13%	5%	13%	10%	8%	10%	7%	7%	14%	13%				
		Technical Requirment Units	kPa	mm	kPa	rads/s		cm^3/mmHg	rads/s	N/mm	um	mmHg				

7.3 Appendix C: Decision Matrix

Decision Matrix		Alternatives															
		Cross-Hatch				Alternate Layering (Lego)				Gyroids				Alternating Shores			
Criteria	Weight	A30-A50		A30-A60		A30-A50		A30-A60		A30-A50		A30-A60		A30-A50		A30-A60	
Soft Exterioir	0.2	60	12	40	8	80	16	60	12	40	8	20	4	100	20	60	12
Medium Interior	0.2	20	4	60	12	20	4	60	12	80	16	80	16	20	4	60	12
Lightweight	0.1	20	2	60	6	20	2	60	6	20	2	60	6	20	2	60	6
Compliance	0.15	100	15	80	12	100	15	80	a	60	9	40	6	100	15	80	12
Similar Properties to Organic Tissue	0.35	60	21	40	14	100	35	60	21	60	21	40	14	100	35	60	21
Totals	1	|	54	|	52	|	72	|	51	|	56	|	46	|	76	|	63
Rank	-	|	5	|	6	|	2	|	7	|	4	|	8	|	1	|	3

7.4 Appendix D: Pugh Chart



		1	2	3	4	5		
		Alternatives						
Criteria	**Baseline (From BDL)**	Crosshatch	Alternate Layering	Gyroids	Alternating Shores		Totals	Rank
Stiffness/E (Kpa)	5	**0**	+	+	+		3	1
Thickness (mm)	5	−	−	+	+		0	4
Compressive Modulus (kPa)	3	−	+	−	**0**		-1	7
Frequency (rad/s)	3	−	−	−	−		-4	9
Poisson's Ratio	5	−	−	+	**0**		-1	7
Compliance (cm^2/mmHg)	3	+	+	−	+		2	2
Similar properties to organic tissue	5	**0**	**0**	−	**0**		-1	5
Cost Within Budget	5	**0**	**0**	−	**0**		-1	5
	0						0	
	Totals	-3	0	-2	2			
	Rank	4	2	3	1			