Mechanical Characterization Testing for Creating an In-Vitro Vessel Model with Properties and Anatomical Structure Similar to Human Neurovascular

Final Report

Team BDL/Aneuvas

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DISCLAIMER

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EXECUTIVE SUMMARY

As endovascular devices become a more widely used method of treating ischemic strokes, research into device capability is becoming more important. Team BDL/Aneuvas is tasked with design, analysis, and 3D printing of a 'plug-and-play' model of the circle of Willis. To run mechanical property tests, smaller sections of the model need to be designed.

Testing the entire circle of Willis model is impractical for collecting mechanical properties, such as shear, compliance, or lubricity. In response to this, smaller subsystems, or sections, are used for testing. For example, a section cut of a tube of the model would allow for compliance and lubricity testing, or an 8mm puck can be tested for shear and compression properties. Subsystem designs are printed using a Stratasys Objet 260 Connex3. Data cumulation is conducted using a Rheometer (Texas Instruments) and Excel analysis. Once data is analyzed, the team compares the data to a previous study conducted by the BDL (Bioengineering Devices Lab), in which researchers collected donor samples of the LCCA and RCCA (Left and Right Common Carotid Artery) and tested the tissue under the same mechanical tests required for this project. Previous material tests have been conducted on single and double (50%-50%) layered 3D prints.

Where this project innovates previous design is in the anatomical similarity of design. The depth of the donor samples averaged to be 1.2mm thick. From the literature review, the human carotid artery consists of three layers: the externa (adventitia), the media (soft tissue), and the intima (slightly rigid tissue). During sample preparation in the donor sample study, the adventitia was removed. In correlation, team BDL/Aneuvas investigated the thickness of the intima and media layers. To create a more anatomically similar model, the team has developed a design of 80%-20% material ratio, in which the media is 0.96mm (80%) and the intima is 0.24mm (20%). For proof of concept, the team focused on Compression and Shear testing using shores 30-50 and 40-60. The shores determine how stiff the material is, with 90 being the highest or stiffest shore. The softer shore makes up 80% of the subsystems.

The sample preparation is crucial to the testing process. First, the pucks are 3D printed and support material is cleaned off them. Then they pucks must soak for a minimum of 4 days prior to being tested. This is because previous studies found that a 4-day soak significantly affected the mechanical properties of the pucks. To have comparable results, this same process was implemented for this project. From the data analyzed during the proof of concept, the team was able to validate the anatomical design decision. In addition, the team found that using these ratios did not produce an averaged shore ratio, which was a concern during hypothesis. For example, the 30-50 pucks did not have the same mechanical property as a pure 40 shore puck. The analysis displayed that the pucks performed closer to the human donors than previous 50%-50% layered and pure material pucks.

After the proof-of-concept results were approved, all six remaining tests were conducted on the samples. The results yielded mechanical properties that are expected for polymers. Polymers are harder than natural tissue, and this was the case for all of the tests. However, the percent difference measured between polymer samples and the donor samples displayed that the layering was effective in producing a polymer load reaction similar to the human vascular load reactions. There are still advancements in future research that are recommended, however the results displayed a trend in the lower percent difference. A greater percent difference would show that the samples are more different than the human vascular results. Some tests such as shear, compression, tension, and hardness tests scored averaged values stronger than human vascular. This is an acceptable measurement due to providing device stability for practical use. These values present the potential for prolonged use for the intended training usage of the model. These results were also compared to current industry materials such as silicone for validation.

ACKNOWLEDGEMENTS

A special thank you is included for the researchers in the Bioengineering Devices Lab (BDL) and the Aneuvas Technologies Inc company for their time and commitment to this project's advancement. Some of the individuals that especially aided in this project are:

Timothy Becker, Ph.D., for material, equipment, and mentoring provided throughout the project.

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Nicholas Norris, B.S., for the original study and publication of material testing as the foundation of this project.

Thank you to everyone who helped make this project possible.

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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 for 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."

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, and 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 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, depending 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.

Responsible for 8% of the customer requirements, samples that are easy to connect is an important factor throughout the project. During certain testing procedures, there will be moments where additional instrumentation will be required. To perform these procedures correctly, the samples and the instrumentation must be compatible and easy to connect to. If they do not connect easily, complications will arise during testing. Therefore, the customer asks for the designs to be connected to specific instrumentation without any hardship. Along with easy connection, layer stiffness is an important requirement from the customer.

Weighting 25%, the customer asked 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 exceptionally 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 remarkably like 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 all tests to be completed without any complications. Therefore, an essential step in making sure the characteristic of material properties of the design is like 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 taken 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 of many engineering requirements that are analyzed 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 (Engineering Requirements) is essential in deciding the size, layer stiffnesses, the weight of the design, material choice, 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 organic tissue.

During specific testing procedures, it requires the samples to be a certain thickness. Therefore, 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.

One of the required tests that will be completed is the compression of the material. Therefore, the following engineering requirement corresponds to the compressive modulus of the material. 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 like organic tissue. On the other hand, the compressive modulus is less of a factor in determining the design's size and whether 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.

To make sure the designed material can withstand similar external influences; the material must withstand a certain range of frequencies. Therefore, 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 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.

The next requirement is analyzed while focusing on external loads, where the amount of transversal strain is important when analyzing whether properties are like organic tissue and determining the retaining of shape. This can be determined through the calculation of Poisson's ratio. The Poisson's ratio provides a 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 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. Organic tissue has a prominent level of compliance, where it can constantly retain its shape under stress. Similarly, the size of the design and the compliancy of the material have 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.

The next requirement is the amount of radial force the material can withstand. 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.

Finally, 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 Functional Decomposition

2.3.1 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 1. The design selected will be printed and run through various mechanical property tests to determine the structure's capabilities.

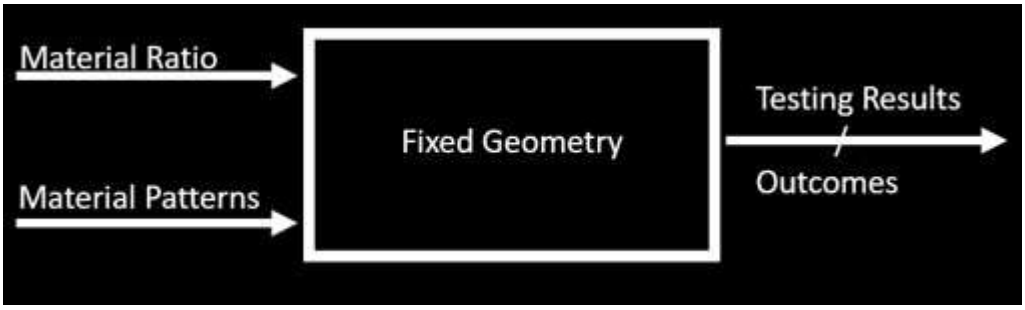


Figure 1: Black Box Model.

2.3.2 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 2. Headed by the project topics, we then break down the design patterns that were generated during brainstorming. For each design concept, there are two material gradients advised by the client to create a proof of concept for changing shore gradients. The previous functional model is included in Appendix A. The model in figure 2 is an updated version that includes the model selected and projected order of tests that will be conducted. This is to better display the progression plan of this project. The proof of concept is also broken down into the ratios tested with which tests were conducted.

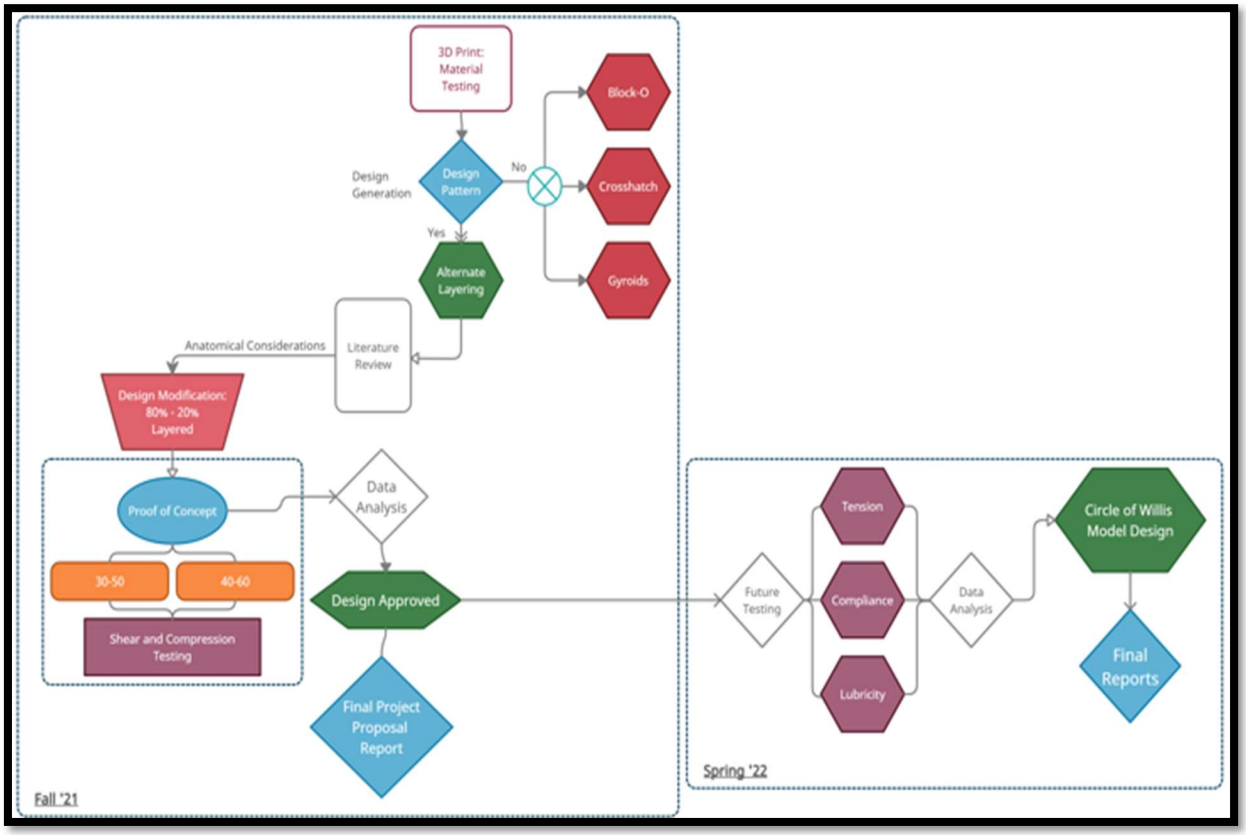
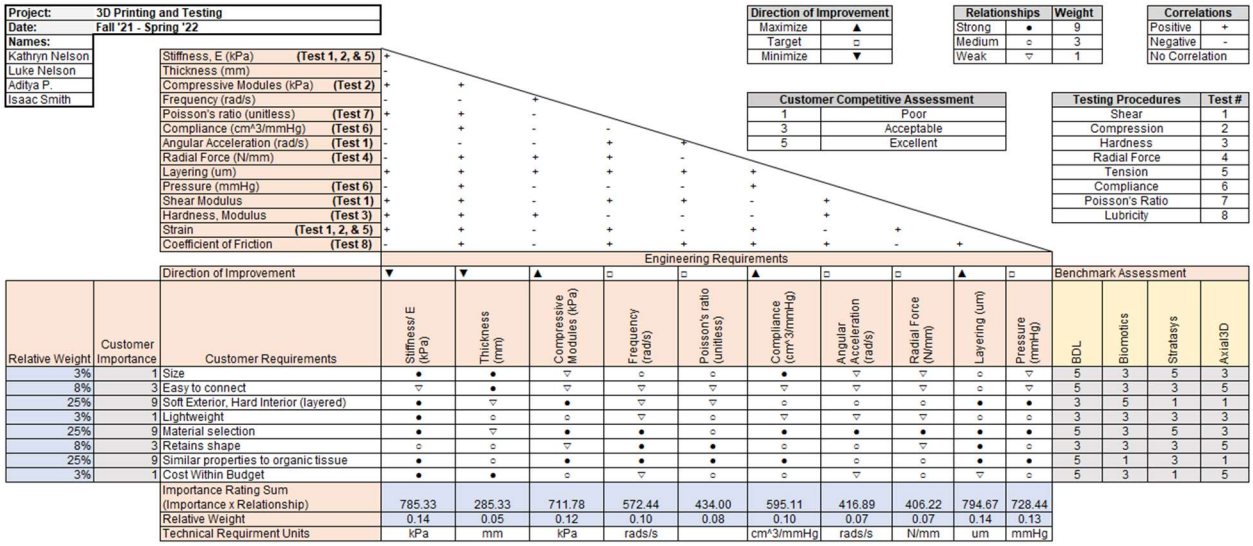


Figure 2: Updated Functional Model.

2.4 House of Quality (HoQ)

Comparing the customer requirements to the engineering requirements is helpful 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 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 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 most 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 values will help obtain characteristics like organic tissue, which in turn obtains successful results.



Project:	3D Printing and Testing
Date:	Fall '21 - Spring '22
Names:	
Kathryn Nelson	
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Direction of Improvement	
Maximize	▲
Target	▫
Minimize	▼

Relationships		Weight
Strong	●	9
Medium	○	3
Weak	▽	1

Correlations	
Positive	+
Negative	-
No Correlation	

Customer Competitive Assessment	
1	Poor
3	Acceptable
5	Excellent

Testing Procedures	Test #
Shear	1
Compression	2
Hardness	3
Radial Force	4
Tension	5
Compliance	6
Poisson's Ratio	7
Lubricity	8

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
8%	3	Easy to connect	▽	●	▽	▽	▽	▽	▽	▽	○	▽	5	3	3	5
25%	9	Soft Exterior, Hard Interior (layered)	●	▽	●	▽	▽	○	○	○	●	●	3	5	1	1
3%	1	Lightweight	●	○	○	▽	○	▽	▽	▽	○	○	3	3	3	3
25%	9	Material selection	●	▽	●	●	○	●	●	●	●	●	5	3	5	3
8%	3	Retains shape	○	○	▽	●	●	○	○	▽	●	○	3	3	3	5
25%	9	Similar properties to organic tissue	●	○	●	●	●	●	○	○	●	●	5	1	3	1
3%	1	Cost Within Budget	●	●	○	▽	○	○	▽	○	▽	○	5	3	1	5
		Importance Rating Sum (Importance x Relationship)	785.33	285.33	711.78	572.44	434.00	595.11	416.89	406.22	794.67	728.44				
		Relative Weight	0.14	0.05	0.12	0.10	0.08	0.10	0.07	0.07	0.14	0.13				
		Technical Requirment Units	kPa	mm	kPa	rads/s		cm^3/mmHg	rads/s	N/mm	um	mmHg				

Figure 3: House of Quality

2.5 Standards, Codes, and Regulations

The standards and codes that relate to this project are provided by the client through the standard operating procedures (SOP) of the client's equipment and testing. In addition, the American Society for Testing and Materials (ASTM) has several standards for polymer mechanical property testing. These standards help to facility testing that is accurate, replicable, and corrective. For example, starting the rheometer is the same for every test, however, the SOP changes between each test such that the way the machine operates changes. Being able to check the machine settings by referencing the SOPs is critical to making sure the test being conducted is the proper test intended. The application of the SOPs also helps to ensure that the data collected is through the same means as data previously collected by BDL. In this manner, we can compare consistent testing methods and results, to show how successful our design/material is responding to each test. See table 1 for the ASTM list and SOP list. The SOP list is combined into one section to lower repetitive inputs.

- Bioengineering Devices Lab: Standard Operating Procedures (BDL: SOPs)
    - BDL has their own testing procedures to follow for rheometer and fluoroscope testing.

- American National Standards Institute (ANSI)
    - AAMI is an accredited standards development organization that utilizes performance-based documents to assess healthcare devices and standards.

- American Society for Testing and Materials (ASTM)
    - ASTM polymer and plastic test techniques. (Multiple standards)

Table 1: Standards of Practice as Applied to this Project

Standard Number or Code	**Title of Standard**	**How it applies to Project**
ANSI/AAMI HE 74:2001	Human Factors Design Process for Medical Devices	Helps in the design of how the device interfaces with the user in a safe manner. The device being designed will be used by personnel in the lab, and the goal is to have a device that neurosurgeons could use to practice operating.
SOP 0.001.00 - 0.014.00	BDL Standard Operating Procedures	Lays out fundamental testing procedures such that the tests can be evaluated accurately and are replicable by other labs. Each test conducted by team BDL/Aneuvas is laid out step-by-step in these procedures. This also helps to prevent misuse of the rheometer and provide relative data. Some of the SOPs in 1-14 may not be needed for testing but apply to equipment use.
ASTM D1621	American Society for Testing and Materials	ASTM compression testing. These standards can be taken into consideration with the BDL SOPs for testing the polymer designs created by our team.
ASTM D1922	American Society for Testing and Materials	Shear strength test standards, which can apply to the shear test conducted during the proof of concept.
ASTM D395	American Society for Testing and Materials	Compression with constant deflection. Similar to how the rheometer is operating within BDL SOPs. Combination of understanding both BDL and ASTM can be applied to project compression testing. This test creates permanent deformation, which the team does not want- so we must watch for it.
ASTM D638, ISO 527	American Society for Testing and Materials	This procedure is for the Poisson's ratio, which is a test that the team may have to conduct in addition to the tests currently requested. The rheometer measures the load and speed of the load, while a camera captures the axial displacement used for Poisson's ratio.

3 DESIGN SPACE RESEARCH

3.1 Literature Review

To gain a better understanding of the goal, each teammate extensively researched different aspects of the project. There was research in mechanical property testing which were used to find the ranges for hardness, lubricity, stress/strain, and shear stress. The study of neurovascular and the common carotid artery biology was used to help figure out how each sample should be shaped in order to perform the proper tests, how many layers should be printed, and the shore hardness of each layer to mimic human vessels. These ranges and descriptions were found by looking into previous studies done by BDL and other labs that looked into the properties of human vasculature. There was also research into the competing systems, which are explained in more detail in the following sections. These were found by looking into the main companies that produced similar products to the one the team is attempting to create and seeing what methods and materials they use to create their models.

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.

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 Methods

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 a process where 2D images will be converted into 3D models.

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. Therefore, creating Biomodics as an initial benchmark will allow the team to continue towards their project goal of biomimicry and compatibility.

4 CONCEPT GENERATION

Based on client's requirements and our black box model, we developed a design that fits all the criterions that were specified. We primarily focused on having a design that will help obtain the characteristics of an organic tissue. Based on our benchmarking and literature reviews, we pinpointed the structure of the arterial wall of the human common carotid artery (CCA) and implemented that in our design using the same thickness for each layer. Common carotid arteries have three layers as highlighted by figure 3. Common carotid arteries have three layers as highlighted by figure 4. The extrema, which is the much more rigid part of the wall is neglected in the design as in the final in-vitro model does not implement that layer to see into the design much more clearly. This design will be implemented with both ratios of hardness values we will be testing. These two shore ratios are 30-50 and 40-60 (Aglilus30 and VeroClear).

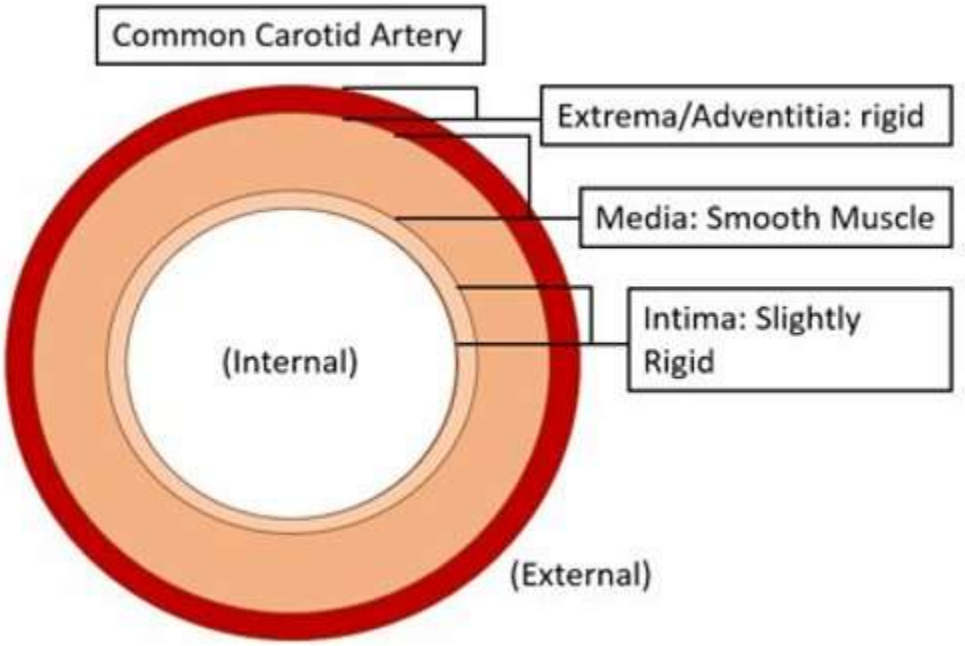

Figure 4: Structure of common carotid artery wall

5 DESIGN SELECTED – First Semester

We found that our final design is formed from the alternative design that we presented in our analysis from ME476C, the layered design of the samples that enables us to come close to a soft tissue and help us have the same characteristics as a human artery. The design we selected was used in our decision matrix table and the Pugh chart and ranked on top of both tables because it was weighted superior over most of the alternatives by being the most beneficial in almost every criterion.

5.1 Design Description

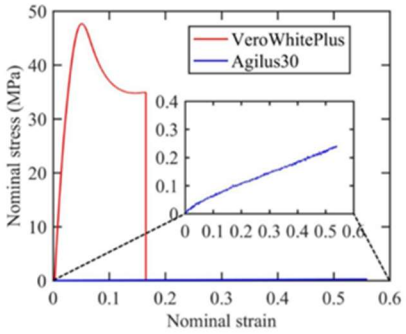

Figure 5: Agilus30 and Vero Clear.

We started finding our final design by looking at our customer requirements and ways to mimic the human artery in physical properties, our client, wanted the design to match much closer to an actual common carotid artery geometry, which does not contain more than three significant layers in its arterial wall. The design did not change due to construction malfunctions as there are no attachments to our design. We are analyzing different layered designs to determine the best possible material to use for the devices in our client's lab. The changes can only come from better research, testing or feedback from the client. We took the clients' feedback into consideration and proposed a design to, this was the layered design with two distinct layers that match the similarities of an organic blood vessel. Below we will describe the final design in detail and how we reached our final design. We will be using Agilus30 and Vero-Clear as our materials as they have two distinct shore/hardness values; if we analyze figure to the left, we can see that these materials, when used in a combination, can yield favorable material properties [9].

5.2 Final Design

After realizing that the client wanted a design that is a bit closer to one of their requirements, which was to mimic the properties of an organic tissue, we decided to implement their feedback into our design prototype. To satisfy this requirement, we used the same type of sphere used in organic tissues, which is the tunica intima and tunica media. Although actual vessel geometry has another layer, tunica externa – which acts as a support for the two internal layers [3], we will be focusing more on mimicking the inner layers as the operating system that we will be using our prototype does not have the outer layer in its design. Our design, as seen in Figure 6 & 8, can be seen to replicate human vascular layers. The layers make a depth of 1.2 mm with the intima layer having a 0.26mm height and the media layer having a 0.94mm height. After these layers have been printed, these layers cannot be differentiated with the naked eye, therefore, to access both layers, a small nub is placed on the side of the bigger layer (media) to ID each layer separately. In the future, we will also have shaped pucks for a better analysis in the five tests we will perform.

5.3 Samples as Prototypes

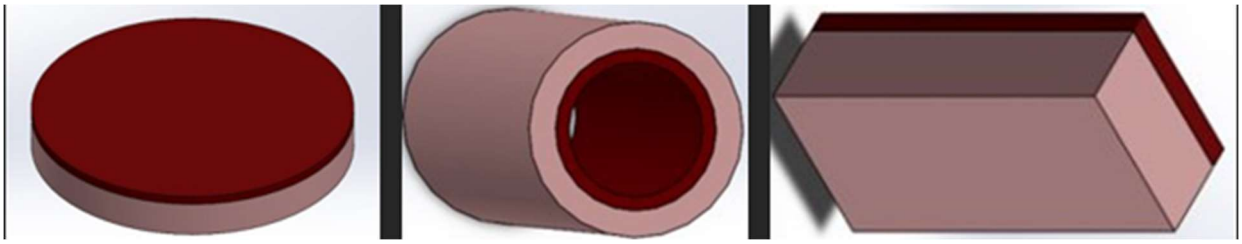

Figure 6: Simple Puck (left), Cylindrical Sample (middle), Tension Sample (right)

As you can see in the figure above, these are the three sample designs we used to test on and validate our final anatomically correct two layered design. The simple puck on the left was used for tests such as compression, shear, hardness, and Poisson's ratio. The cylindrical sample highlighted in the middle was used for radial force, compliance, and lubricity. The rectangular sample on the right was used just for tension. We believe that changes in the sample geometry will not affect the results as we will use the same concept as our final design with implementing the 80% Media layer and the 20% Intima layers into the sample.

5.4 Justification

After getting the approval from our client that our design matches their requirement of mimicking an organic tissue, we began printing and testing our samples. We will use 3D printing as our source of manufacturing using Agilius30 and VeroClear as our polymers. In the original system a single-layer of Agilus30 and Vero-Clear was laid at 100% depth and a double-layer at 50-50% depth. To ensure anatomically correct results, the client wants us to test the material thickness and hardness shore ratios. In our system we used two different shore ratios: 40-60 ratio and 30-50 ratio. Since Aglilus30 has a 30shore hardness, to get higher hardness's, we mixed it with VeroClear to get the different hardness values. We then printed four samples of each ratio for better data collection and tested it on the Rheometer. We have performed the shear tests completely and have used it to justify our design. If we see the shear and compression charts which compare it to donor tissue in Appendix A: - Shear and Compression, the shear and compression values for both ratios are significantly greater than the donor tissue that we are comparing to, but they are almost half the values of previous studies using a 50-50 ratio and Agilus40 (mixed with VeroClear to get that hardness value). This shows us that we are closer to the donor mechanical properties than previous studies and therefore validating our design to be a feasible design for the system. We now have proof that changing the ratios of the polymers can influence its mechanical properties and can even come close to the human tissue properties.

6 Project Management – Second Semester

6.1 Gantt Chart

This semester was filled with testing days and printing samples and analysis. The team aided in all the different components and helped a smooth operation throughout the semester. We implemented three additional tests on top of the five proposed by our client last semester. We kicked off this semester by contacting our client, Dr. Becker, to start off a plan for our testing and analyzing the data for our project. Since our project revolves around a more of a design of experiments-based system, we were asked by our client to do eight individual tests for different samples with different hardness values. So, the test days were implemented in the Gantt Chart (Appendix H), and it will primarily be on Saturdays with an additional day of testing on Monday to finish collecting data and compiling them together for visual representations. The beginning will be compromised of solely testing and wish to finish all of the eight tests by hopefully the beginning of March to get started on designing a system with our material. We will also use the tests in our project as our individual analysis assignments to help us boost our knowledge into the different variables to manipulate our material efficiently. Our major goal for this semester is to have a working model that can act and behave like a blood vessel around spring break. The specific date will be discussed more through roughly as we moved forward, we could be behind schedule as might have to move some dates around for finalization of the system by spring break but that is one of the goals that the team is determined to achieve. Overall, we will have a major testing phase in the beginning as we have nothing to manufacture, which will give us more time to analyze the data midway through and hopefully with a few tweaks get a working system running by spring break to get it approved by the client and add additional capabilities to our device.

The two main issues and the only two issues we encountered in the progress of our Gantt chart timeline came during the last test we did – compliance and in the final few weeks of the manufacturing phase of the project. We were on track for all the tests expect for the compliance test which we had to redo as we did not follow the SOP on the first try. This was solved by redoing the test over spring break which saved us time and did not make us too delayed. The other main issue we faced was the 3D printer malfunctioning when the final design was printed. Careful troubleshooting was done to properly reassess the device and the design was printed a week later but this did not hinder our productively.

6.2 Purchasing Plan

The team was given a budget of $1000 to design and test our product. In order to print and test the deigns that were chosen, materials and equipment had to be bought by the team. Due to generosity of the client, all the materials and equipment needed were made available to the team by BDL. The rheometer was rented at $15 per hour and the cost of the materials and print of those materials changed with the size of each print. There are three materials used for printing; Angilus30 which is $0.75 per gram, VeroClear which is $0.70 per gram, and the support material which is $0.60 per gram. Throughout both semesters, there were roughly 35 samples printed (260 grams), two final models (576 grams), and performed a total of 25 hours on the rheometer. The fluoroscope used for the compliance test did not require any renting from the team. A BOM for a full model is shown below and the entire budget can be seen Appendix F.

Table 2: Bill of Materials for Full Model

Material	Cost ($/gram)	Quantity Used (g)	Indv. Total ($)
Agilus 30	0.75	12	9
VeroClear	0.70	184	128.80
Support	0.60	128	76.80
		Total	214.6

In the beginning of budgeting, the team underestimated the cost of the materials as well as how many samples would need to be printed. This underestimation is in part to the team not fully considering the amount of samples that might need to be reprinted and the cost of the materials changing multiple times and the final cost not being known until three weeks before the end of the project. At the end of the first semester, it was estimated that a full model would cost rough $62, but when it came to actually print a full model, it was found that it costs roughly $200 to print. Luckily, there was a large amount of the budget remaining after rental and sample printing to make up for the large difference in estimated and actual cost, but it did leave the team with little money remaining in case the models printed were to break. By the end of the project, there were about $80 left of the team's budget. Some things the team could have done better is communicate more with the client to finalize the cost of the materials and to overestimate the amount of material/samples needed rather than underestimate. By doing that, the team would have been more prepared for the large cost of the full models as well as the additional costs of the extra samples and models.

6.3 Manufacturing Plan

The design fit the criteria of our customer requirements and engineering requirements; we also validated our design by our eight tests we performed. The final hardness value we decided was the 30-50 Shore values using Aglius30 and VeroClear (Photopolymers). The system for 3D printed our samples will use SolidWorks, GrabCAD print (Boston, MA), VeroClear and Aglilus30 for materials and Northern Arizona University's (NAU) Objet260 Connex3 3D-printer (Stratasys, Eden Prarie, MN). GrabCAD enables us to select different hardness values and mix the materials while the 3D printer will ensure fast and safe printing of our design while UC-curing the materials.

The BOM is included in Table 2. All items and equipment were donated by Aneuvas Technologies inc. and the Bioengineering Devices Lab. The final Bom is a cost estimate to break even for creating a single model by a student team. The main change in the BOM from previous semesters is the cost of material was higher than the initial estimate(s). Outside of this, no changes were made.

7 Final Hardware

7.1 Final Hardware Images and Descriptions

The final hardware is a 3D printed model that has been cleaned and integrated into the flow system provided by BDL. The blue frame at the center of figure 7 is the base of the Circle of Willis, which attaches to the flow model. The Circle of Willis itself is within this frame. Figure 7 Is used to display that the printed model is functional within the flow system. Several pressure transducers are attached to the inlets and outlets of the aneurysm model to validate that the model can withstand pulsatile flow.

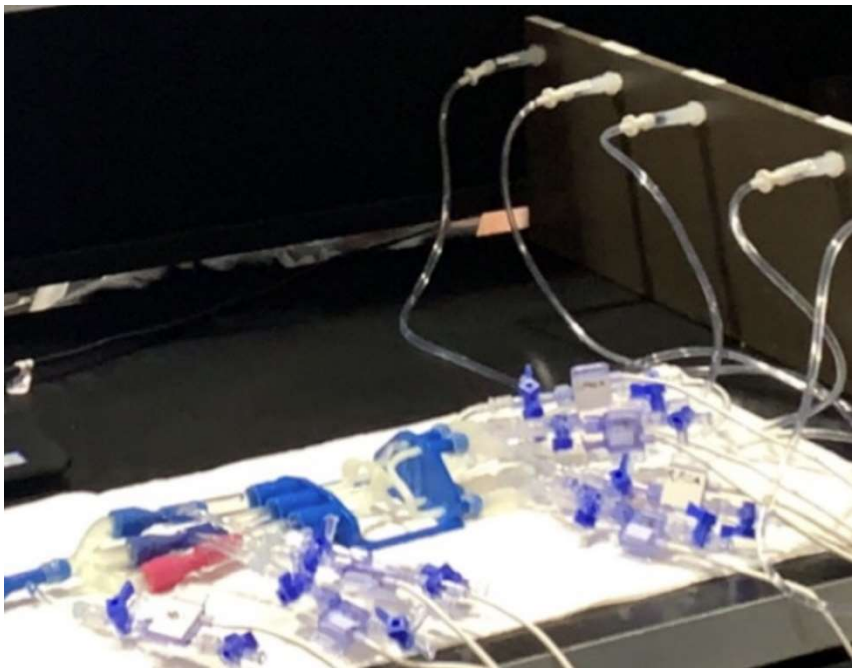

Figure 7: Final Hardware System.

7.2 Design Changes in Second Semester

7.2.1 Design Iteration 1: Change in [subsystem/component] discussion

The original design is a single layered circle of Willis model that has an average wall thickness of 1mm. For this semester, a second layer was integrated into the original model, while maintaining the original wall thickness. The change in wall thickness produces a more anatomically correct model due to the natural layering of the vascular in the human body. Figure 8 displays the Circle of Willis model that has been altered as a CAD image. The intima, inner layer, is red-orange to better display the layering. The bottom of the image is the left side of the circle off Willis with the media, outer, layer as transparent to display the inner tubing.

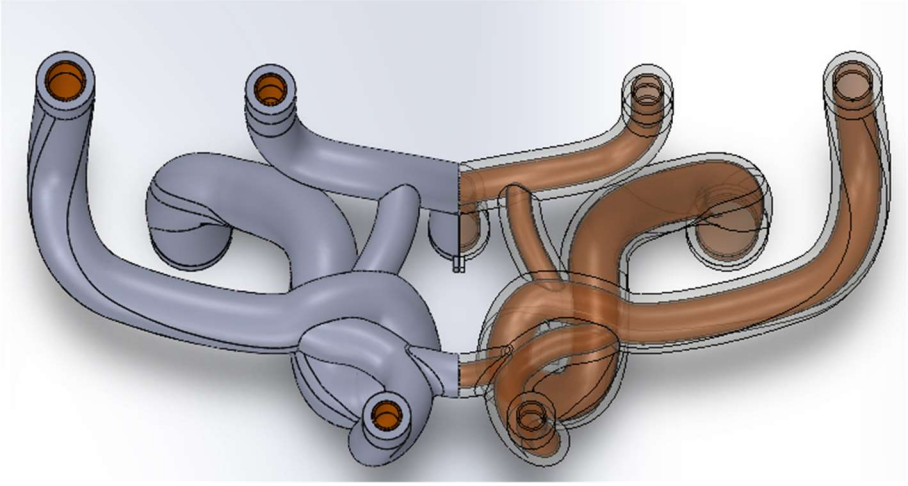

Figure 8: Improved Circle of Willis CAD

7.3 Challenges Bested

The Stratasys printer experienced complications where the resin yielded more than expected. This caused the UV light to come in contact with the resin, resulting in the resin burning and sticking to the light. This resulted in 400 grams of resin being lost, spilling throughout the printer, concluding in a massive, 6-hour, clean up. Several phone calls to Stratasys, head optimization, UV calibrations, and hours of frustration populated the process to fix the printer. The original model also had a fault in the dimensions and resulted in a weak outlet structure which in turn caused two models to break during cleaning. As a result, the CAD was completely revamped, and the weak section was reinforced with a filet as an extra precaution. The sample testing itself went relatively well. The primary challenge was preparation and equipment setup, which often resulted in longer testing times. The team also needed to re-test the compliance samples and the compression disks due to some analytical errors found later. Most of these challenges only meant extra time in the lab, extra cleaning time, and attempts to plan equipment use ahead of time, all of which were dealt with speed and efficiency so that the team could continue on with little to no other future complications.

8 Testing

8.1 Testing Plan

There are eight testes that will be conducted by the Team BDL/Aneuvas in accordance with the initial project proposal and standard operating procedures (SOPs) used by BDL. The SOPs help to ensure the quality and replicability of tests being conducted. The customer requirements and engineering requirements (CR/ERs) are in accordance with the client meetings, House of Quality, and design analysis conducted Fall 2021. The SOPs are multi-page procedures provided by BDL and are being summarized below.

Many of the tests performed meets several of our clients' requirements such as the specimen retaining its shape after testing (CR-6), using the right material to make the specimen our clients wanted (CR-5), and becoming closer to being like organic tissue (CR-7). However, each test is used to look for specific mechanical characteristics of the samples to ensure that that data found is within the range provided the human donor samples found in previous research.

The shear test is used to find the shear modulus (ER-11) of the materials and the compression tests is used to find the compressive modulus (ER-3) of the samples. Both of these tests are also used to find the frequency (ER-4). These tests have the same set up in the rheometer, where a disk is placed into the rheometer and a continuous oscillating force (shear), or a constant axial force (compression) are applied to the sample. The lubricity test is used to find the coefficient of friction (ER-14) of the inner layer of the sample and is found by running a weighted wire through a cylindrical sample with the help of the rheometer and measure how much resistance the wire experiences. The compliance test is used to figure out the compliance (ER-6) of the sample and the amount of internal pressure (ER-10) the sample can handle before rupturing. This is done by filling a cylindrical sample with fluid until it reaches a desire pressure, incrementally increasing the pressure, snapping an image of the sample with a fluoroscope at each increment, and analyzing how much the sample expanded with the pressure increase. The tension test is used to find the young’s modulus (ER-1) and angular acceleration (ER-7) of the sample and is found by using the rheometer to pull a rectangular sample axially and measuring how restraint it is to the pull. The hardness test is used to find the hardness modulus (ER-12) and strain percentage (ER-13) of the sample and is done by taking a puck sample and, using the rheometer, compress a metal ball into the sample until destruction. The Poisson’s ratio test is used to find the Poisson’s ratio (ER-5) of the sample and is performed the same way as the compression test but instead of a solid bottom, the sample is placed on a glass plate with a camera place underneath. The team then analyzes the video to measure how far the puck expanded radially when compressed. The radial force test is used to find the radial force (ER-8) of a cylindrical sample and is done by compressing the sample to 50% of its diameter height. All of the data collected from each test is then compared to the data collected from the human donors. This will show the team is the chosen ratios produce vales close to or within the range of the human donors, or if there need to be any changes to the design.

8.2 Testing Results (8 Mechanical Properties Tests)

Based on the results of our testing procedures and comparing it to the previous design which was iterated by the bioengineering devices lab (BDL), we believe the 30-50 variation of hardness values in the intima and media met all of our client’s requirements and also was closer to mimicking human vasculature mechanical properties. Below, we highlight our results and how we our results compared to the donor samples and pervious designs mechanical properties.

8.2.1 T1- Shear Modulus

Table 3: Shear Modulus compared to donors

4 Day Soak						
	30-50		40-60		50% Layered	
	% diff.	p value	% diff.	p value	% diff.	p value
Shear moduli						
Donor 1	555.65	<0.001	635.62	<0.001	-823	< 0.001
Donor 2	2330.02	<0.001	2626.36	<0.001	-2850	< 0.001
Donor 3	1990.33	<0.001	2245.25	<0.001	-1650	< 0.001
Avg	1625.33	<0.001	1835.75	<0.001	-1774.33	< 0.001

The shear test for both our shore ratios was compared to the donor samples data which was gathered by the bioengineering devices lab (BDL). The 30-50 shore ratio came out to be 1625.33% and the 40-60 came out have an average difference of 1835.75%. Our design shows significant shear resistance when compared to the donor samples. This is different from the previous design which showed it was less resistant from the donor samples. Further analysis from the lab needs to be conducted in order to determine these mixed results. The shear modulus did not meet the client's range but was acceptable as the design fit the customer requirements.

8.2.2 T2 – Compression

Table 4: Compression compared to donors

4 Day Soak						
	30-50		40-60		50% Layered	
	% diff.	p value	% diff.	p value	% diff.	p value
Compressive moduli						
Donor 1	-22.30	<0.001	-23.59	<0.001	*-22.5*	*< 0.001*
Donor 2	-76.71	<0.001	-77.10	<0.001	-336	< 0.001
Donor 3	-82.82	<0.001	-83.10	<0.001	-310	< 0.001
Avg	-60.60	<0.001	-61.26	<0.001	-222.83	< 0.001

Compressive moduli for our two variations of shore ratios when compared to the donor samples came out to have an average difference of -60.6% and -61.26% for 30-50 and 40-60 respectively. The negative difference states that our design was less compressive than the donor samples. These percent differences were significantly lesser than the previous design though as that had a difference of -222.83%. The elastic modulus did not meet the client's requirements but was shown to be statistically significant when compared to the previous model.

8.2.3 T3 – Hardness

Table 5: Hardness compared to Donors

4 Day Soak						
	30-50		40-60		50% Layered	
	% diff.	p value	% diff.	p value	% diff.	p value
Hardness Moduli						
Donor 1	-99.455	<0.001	289.5	0.58538	2.44	0.796
Donor 2	-98.994	<0.001	260.51	0.00013	-100	0.002
Donor 3	-99.155	<0.001	649.55	0.001177	-112	0.009
Avg	-99.202	<0.001	399.55	0.1956	-69.853	0.269

Hardness values were out of range for both our variations with a difference of -99.2% and 399.5% for 30-50 and 40-60 respectively. Our design was much softer than the donors and also the pervious design which had an average difference of -69.8%. Although this is a softer material, we can meet some of the client's requirements such as retaining its shape and that it is similar to the properties to human tissue.

8.2.4 T4 – Poisson's Ratio

Table 6: Poisson's ratio compared to donors

4 Day Soak						
	30-50		40-60		50% Layered	
	% diff.	p value	% diff.	p value	% diff.	p value
Poisson's Ratio						
Donor 1	-31.51	0.016712	-28.88	0.024648	-15.6	0.356
Donor 2	-50.52	<0.001	-48.62	<0.001	16.5	0.128
Donor 3	-38.21	0.001303	-35.84	0.002055	-4.32	0.774
Avg	-40.08	0.009007	-37.78	0.013351	-1.14	0.419

Our Poisson's values did not exactly meet the required range that was asked by us from our client. The client asked us to have a ratio 0.30-0.50 Poisson's ratio, but we came out to be around 0.21-0.32. Our average differences when compared to donors were -40% and -37% for 30-50 and 40-60 respectively. Although it does not meet the engineering requirements, we can still maintain shape much better in our design, so the client accepted these ranges for our design.

8.2.5 T5 – Radial Force

Table 7: Radial Force compared to donors

4 Day Soak						
	30-50		40-60		50% Layered	
	% diff.	p value	% diff.	p value	% diff.	p value
Radial force						
Donor 1	473.45	<0.001	383.04	<0.001	-318	0.001
Donor 2	1301.5	<0.001	1080.54	<0.001	-11500	< 0.001
Donor 3	269.03	<0.001	210.85	<0.001	-169	0.02
Avg	681.33	<0.001	558.15	<0.001	-3995.7	0.0105

Our design was much more resistant to radial deformation than the previous design. The average difference, when compared to donor samples, came out to be 681.3% and 558% for 30-50 and 40-60 respectively. Pervious design was less resistant to radial deformation as it had an average difference of -3995% when compared to donors.

8.2.6 T6 – Tension

Table 8: Tension compared to donors

4 Day Soak						
	30-50		40-60		50% Layered	
	% diff.	p value	% diff.	p value	% diff.	p value
Tensile Moduli at 160mmHg						
Donor 1	10.01	<0.001	13.85	<0.001	-47.4	< 0.001
Donor 2	322.15	<0.001	336.87	<0.001	-418	< 0.001
Donor 3	170.04	<0.001	179.45	<0.001	-266	< 0.001
Avg	167.4	<0.001	176.7	<0.001	-243.8	< 0.001

Our design tensile modulus shows us that for both variations of shore ratios, we had a much more resistive design when compared to donors. The average difference came out to be 167% and 176% for 30-50 and 40-60 when compared to the donors. While previous design was less resistive which an average difference of -243.8%. The tensile modulus did meet the target range however and was deemed to be statistically significant.

8.2.7 T7 – Compliance

Table 9: Compliance compared to donors

4 Day Soak						
	30-50		40-60		50% Layered	
	% diff.	p value	% diff.	p value	% diff.	p value
Compliance						
Donor 1	-55.76	<0.001	-70.03	<0.001	-202	< 0.001
Donor 2	-90.18	<0.001	-93.35	<0.001	*27.3*	*0.07*
Donor 3	-70.32	<0.001	-79.89	<0.001	-102	0.002
Avg	-72.08	<0.001	-81.09	<0.001	-92.233	0.036

Our final compliance values met the client's requirements and also have a much lower difference when compared to the donor samples than previous designs. the 30-50 and the 40-60 have an average difference of -72% and -81% respectively. Our design was less compliant than the donors but when we see that the pervious design had an average difference of -92% we can see that our data has statistical significance and is getting closer to mimicking the compliance levels of human vasculature.

8.2.8 T8 – Lubricity

Table 10: Lubricity compared to donors

4 Day Soak						
	30-50		40-60		50% Layered	
	% diff.	p value	% diff.	p value	% diff.	p value
Lubricity						
Donor 1	27.33	<0.001	27.39	<0.001	26.2	< 0.001
Donor 2	33.39	<0.001	33.45	<0.001	3.93	< 0.001
Donor 3	31.33	<0.001	31.39	<0.001	17.6	< 0.001
Avg	30.68	<0.001	30.74	<0.001	15.91	< 0.001

Our design when compared to the donor samples came out to be less lubricious than pervious design. We have an average difference of 30.68% and 30.74% for 30-50 and 40-60 respectively while the previous design came out to be 15.91%.

9 RISK ANALYSIS AND MITIGATION

To ensure that the samples and models that are created for this project are going to meet the goals set, potential failures must be discussed. These failures can happen during testing or after the final model has been created. How the failures could occur, the effect of the failure, and how to mitigate the failure will be discussed. The FMEA (Failure Mode and Effect Analysis) is included in Appendix G.

9.1 Potential Failures Identified First Semester

The main failures of last semester were mainly due to improper testing of the samples. During certain procedures, such as the tension, shear, and compression tests, there is a chance of the sample tearing due to experiencing a greater axial force of 2 N or if the sample experiments a twisting force of greater than 1.5 N, all of which would destroy the sample. During the lubricity test, it is possible that the catheter will move too quickly and cut the sample, rendering it useless. During the compliance test, the team must induce up to 240 mmHg pressure on the vessel. It is possible for the vessel to rupture, the stitch to tear, or the barb hook to come undone while loading. All of these failures will render the sample no longer usable and discredit any data collected during the failure.

Another area of failure is with the printing and cleaning of the samples and models. During the printing process, there is a possibility of the meshing between the layers being incomplete. This would mean that there would be holes between the layers, resulting in an un-watertight mesh or incorrect ratio. This could result in testing data being inaccurate, especially for the compliance tests. After each print, printer and material dispensers must be cleaned to ensure that there is no unintentional mixing of materials. If mixing does occur, the sample's properties are affected and could cause the samples to have different properties, either too soft or rigid, and potential become easier to deform during testing and provide inaccurate data.

The last area of failure is with the final model of the circle of Willis. If the walls are too thin on the circle of Willis, there is potential for the internal structure to collapse under its own weight. There is also a potential for the walls of the model to be too thin and unable to withstand the proper induced pressure by the pump. This would result in the model rupturing and leaking, destroying the model. If this happens, then the team will have failed to produce a viable model per the customer requirements.

Table 11: Potential Failures for First Semester

Part # and Functions	Potential Failure Mode	Potential Effect(s) of Failure	Potential Causes and Mechanisms of Failure	RPN
samples	Excessive Force	deforms sample	Prevents pucks from testing properly	56
0	Tearing	rips sample	Prevents pucks from testing properly	16
0	Error in meshing	creates holes in model	Improper complicane testing	8
0	Excessive Shear	Seperates layers in sample	Improper Shear Testing	8
0	Catheter Cutting	Splits sample	Improper Friction Testing	16
0	Compliance Rupture	Damages sample	Improper Friction Testing	16
0	Cleaning Tear	Splits sample	Improper cleaning of samples	96
Printer	Improper Cleaning	Unintentional Mixing	Not cleaning the printer before every print	70
Circle of Wilis	Thin Wall Sag	Weak Supports	Thin walls of the model, improper printing	16
0	Model Rupture	Destroys Model	improper printing, extreme internal pressure	24

9.2 Potential Failures Identified This Semester

New failures were identified in the second semester of testing. The main failure was with the printing of the models. The printer had a malfunction when printing one of the models and caused 300 grams of material to leak from the printer and produced a deformed, half-finished model. There was also another malfunction where the printer printed one of the outlets as a solid piece instead of hollow. While

the model produced was still able to function, there was an issue with the flow field inside the model causing some outlets the experience more internal pressure than planned. There was another failure found where the outlets of the model were weak and broke easily during cleaning. In order to counteract that, filets were added to the CAD model to reinforce these thinner areas of the model.

9.3 Risk Mitigation

To ensure that none of the testing failures occur, the team performed each test carefully and ensured that the sample was not experiencing an excessive amount of force that could cause permanent deformation to the sample and to immediately stop the test if that were to happen. While some of the failures are due to human error during testing, there are some that relate to each other. For example, if there is an error in meshing, and it goes unnoticed, the samples have a higher chance of becoming damaged or deformed during testing, making the collected data inaccurate and unusable. Same idea goes for if the printer is not thoroughly cleaned before printing, the samples would be affected, and the data found would be useless. Another example would be when the team is ensuring that they do not ruin the samples during the clean process, they are also checking to see if the layers are meshed properly and seeing if there is any noticeable unintentional mixing of materials. When it comes to the printer malfunctioning, the team plans to thoroughly clean the printer before printing and to watch the print to be able to stop the print if the failure were to occur again. Luckily, mitigating any of the failures would not negatively affect the mitigation of other failures.

10 LOOKING FORWARD

10.1 Future Testing Procedures

Some of the most important processes an individual and/or team can follow is to make sure that the testing procedures stay the same. By using the same testing procedures for future designs will prove that the tests are reliable. The extent to which the results can be reproduced when the procedures are repeated in the same conditions will help further the reliability of the results. Therefore, there will be no changes in the testing procedures

10.2 Future Iterations

Using the results from this research will help in the determination of the future designs, which will finally see a hopeful conclusion. Future work may include using ratios of 30-40 and 40-50 shore hardness with the same 80-20% layering method. Advancements have been made in the journey towards perfect similarities. Once completed, a new model could be designed to be more anatomically correct physically and mechanically. Additionally, future work may also include adding an adventitia layer to the samples, allowing for an identical representation of the human vasculature. However, another set of donor testing would need to be conducted due to the removal of adventitia in the first study, which will result in a prolonged testing timeframe.

11 CONCLUSIONS

Team BDL/Aneuvas is tasked with designing and testing a new material layering method in comparison to human tissue data previously collected by BDL. Mechanical tests that are to be conducted are tension, shear, compression, lubricity, and compliance, radial force, and Poisson's ratio. This report included various class deliverables such as the Black box model, House of Quality, the FMEA, etc... As well as noted, developments throughout the last two semesters, such as project design, the functional model, implementations of planning/testing, delivering the final model, and accumulated reports.

In conclusion, during proof-of-concept testing, the anatomical similarity design displayed more favorable mechanical properties than previous BDL tests. In response, complete testing and analysis was conducted. Results found that the premise of anatomical layering and matching shore hardness produces more favorable results for creating anatomical models. Future work and testing will likely build onto this premise in adjust the shores, matching layer depths, and even new studies with the adventitia and a replicated third layer.

11.1 Reflection

In regard to public health and safety, the potential of this model being used by medical professionals allows for advanced training prior to operation. The model could be fine tuned to a patient's anatomy so that the medical staff can experience how the vascular will actually respond during several common procedures such as thrombectomies, aneurysm treatments, stent placements, catheter training, and even balloon catheter placement. Having a model that responds the same way would benefit several agencies wanting to test out their own devices or treatment options in an invitro model as well. Globally, this is a universal model with practical application potential in a number of fields of study and practical use. These factors are the most important considerations for proper design, implementation, and testing of our model and samples. We ensure the safety of our design through the durability exhibited in several tests such as shear and compliance. In addition, our design does not pose any health or safety hazards. No environmental hazards are exhibited through the use of common PolyJet materials that can be easily disposed of through standard disposal services.

11.2 Resource Wishlist

Redoing this project, it would be really cool to have an additional polymer material to test. Having varying shores of VeroClear and Agilus creates a lot of possibility but having another either PolyJet or similar polymer that is compatible with the printer would be helpful for creating diversity in the analysis.

11.3 Project Applicability

This project has helped to prepare us for our future careers through many of the deliverables for both the class and the client. Learning to manage time effectively was the biggest application as a team we had to work through. Coordinating the project meetings, equipment usage, and team availability with classes being considered was a very applicable skill to learn. In the real world, life happens, employees may have conflicting projects, schedules, or understanding of projects when contributing or designating time to work on something. Professionalism for presentations, client meetings, and ultimately the UGRADS Symposium will help with conferences and meetings with future employers or companies. Being able to conduct analytical research may also apply directly to manufacturing in the sense of quality assurance. This project involves medical device and biological understanding/research, which some members of the team plan to continue in creating medical devices for some companies. Conducting research alone is a skill that some people do not have access to, and this project allows for a deeper understanding behind why research, devices, FDA regulations, and peer reviews are so important. Test validations and repeatable processes are also a very important aspect of design verification and peer review. If another lab cannot implement the same process using the same or similar equipment, that can be a cause for concern.

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13 APPENDICES

13.1 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

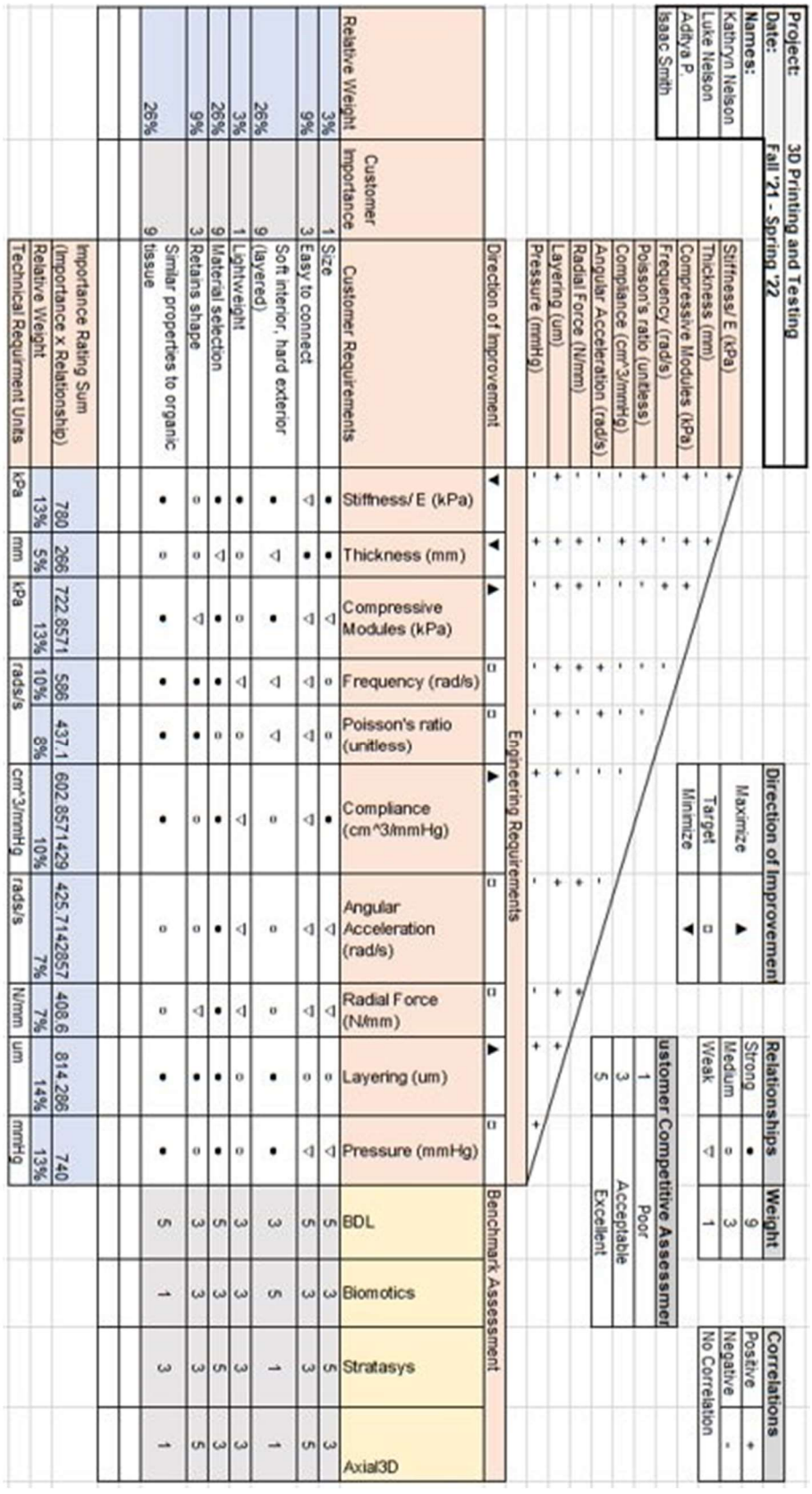
Note: Values in bold/italics represent significant results and/or % diff. less than 30%.

Figure 1 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 2 Table display of polymer vs. donor mechanical properties by testing method [2].

13.2 Appendix B: Original House of Quality



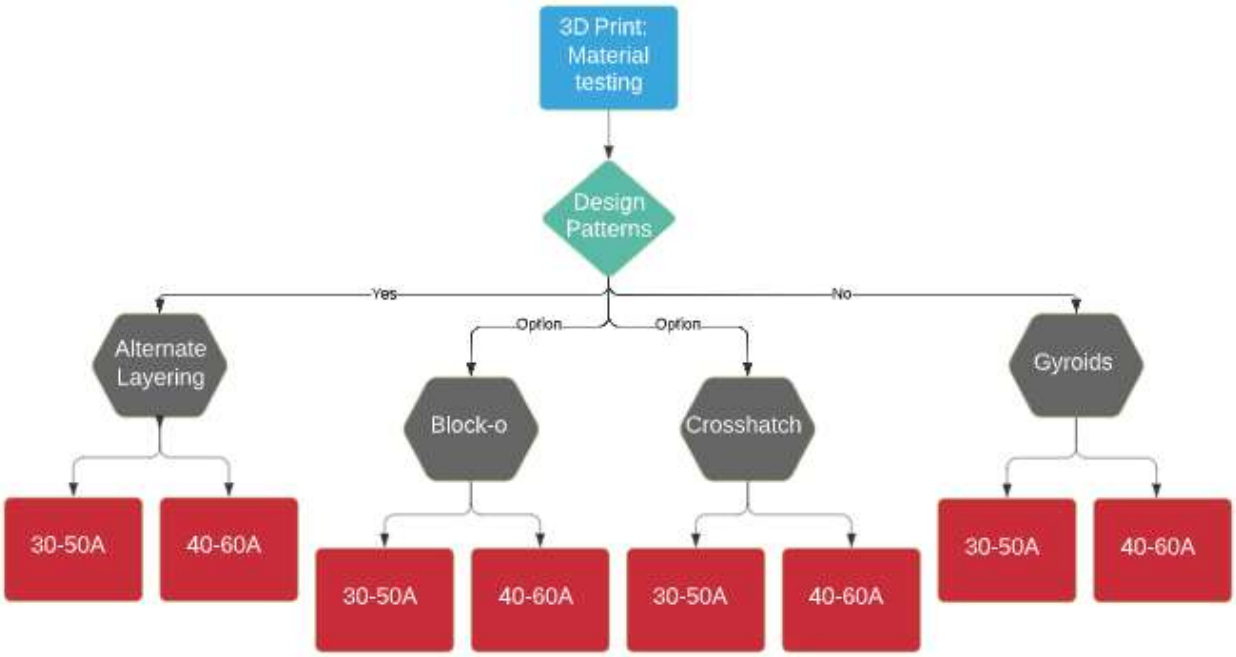
13.3 Appendix C: Decision Matrix

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	40	80	60	40	20	4	100	20	60	12	
Medium Interior	0.2	20	60	20	60	80	80	16	20	4	60	12	
Lightweight	0.1	20	60	20	60	20	60	6	20	2	60	6	
Compliance	0.15	100	80	100	80	60	40	6	100	15	80	12	
Similar Properties to Organic Tissue	0.35	60	40	100	60	60	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				

13.4 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			

13.5 Appendix E: Previous Functional Model



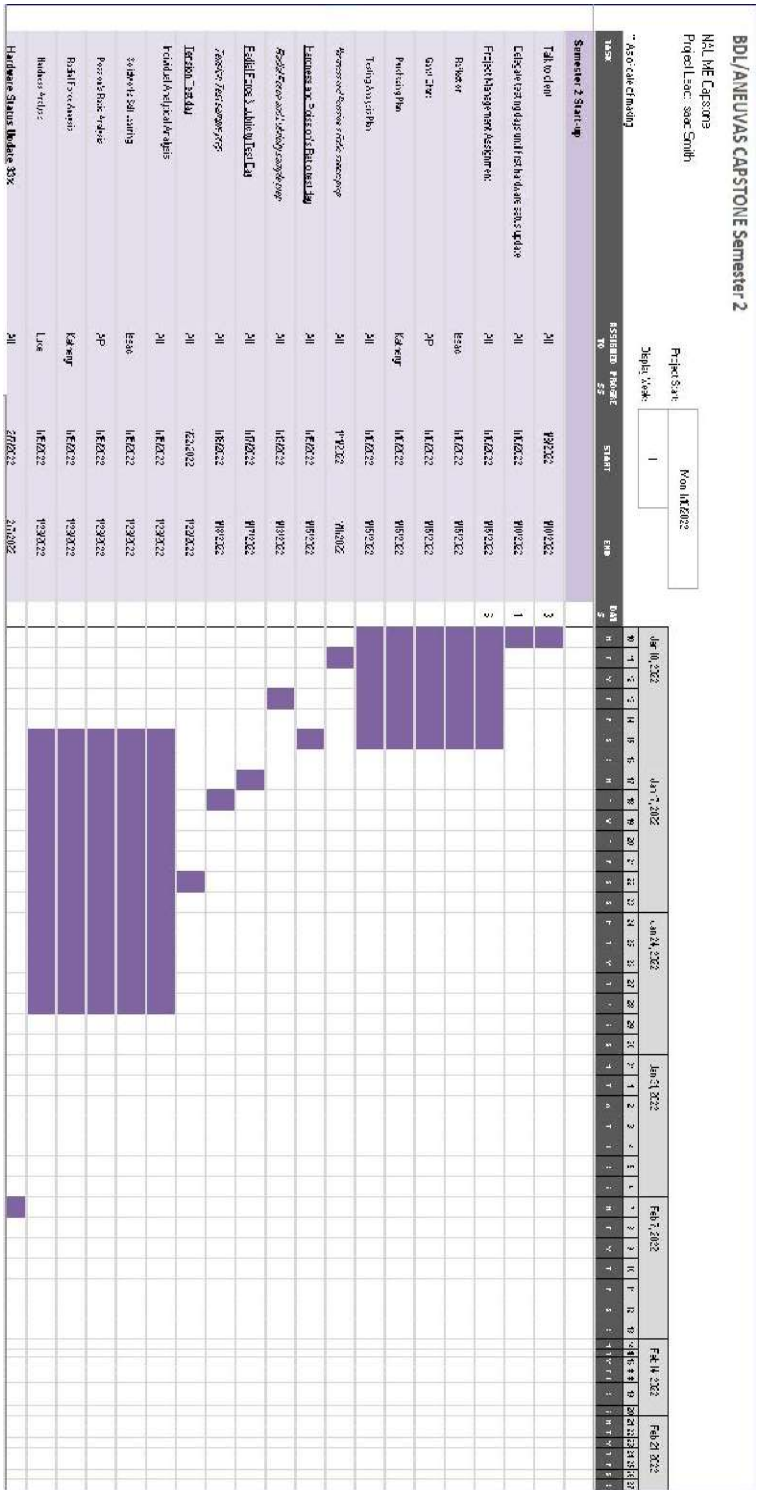
13.6 Appendix F: Budget for Project

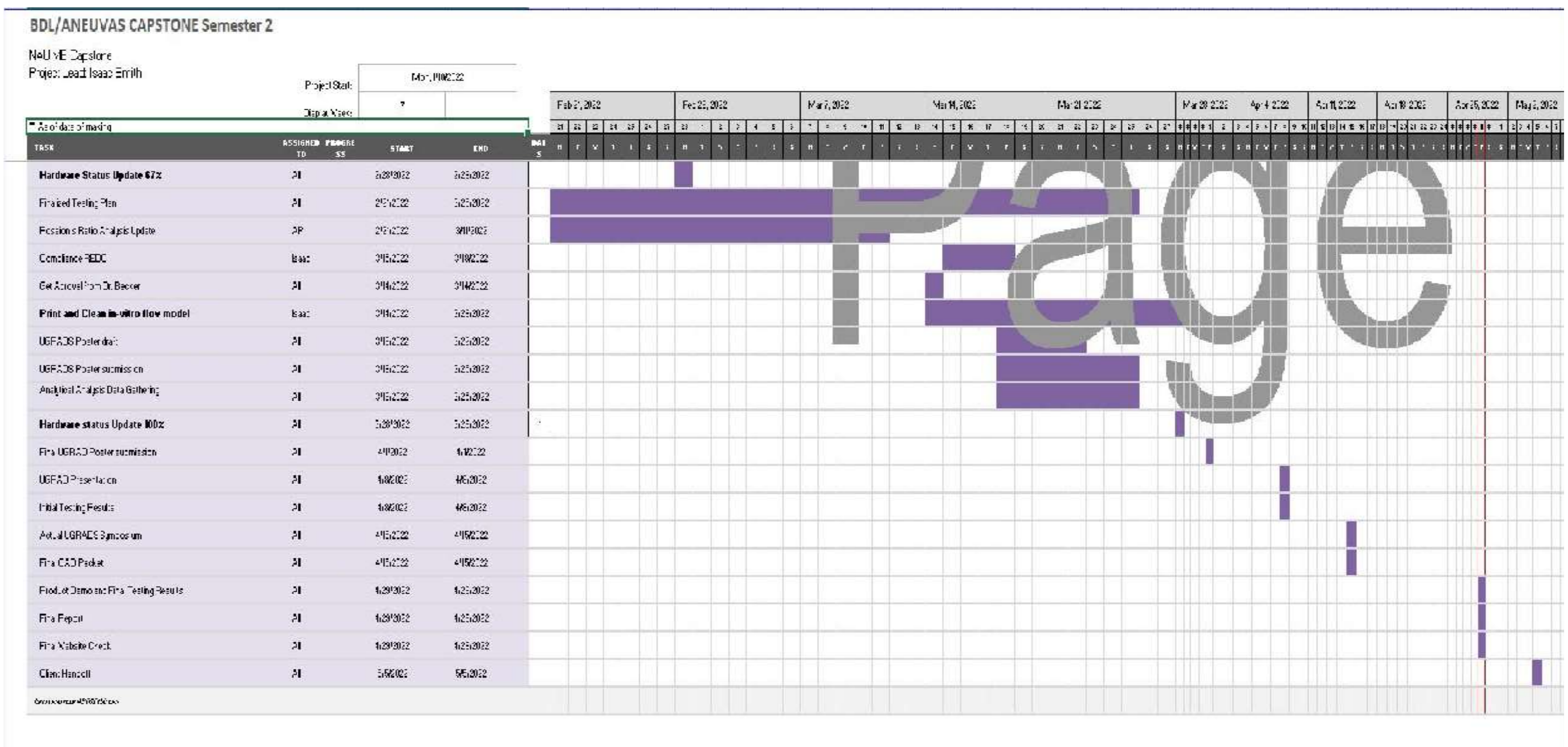
				TIME OF RHEOMETER		MATERIALS			OTHER				BALANCE
TASK	DESCRIPTION	START DATE	END DATE	HR	$/HR	AGILUS (g)	$/PER GRAM (A)	VEROCLEAR (g)	$/PER GRAM (V)	SUPPORT (g)	$/PER GRAM (S)	SPENT	REMAINING
PROTOTYPES	Tests Performed	-	-	-	15	-	0.75	-	0.7	-	0.6	$1,000.00	$1,000.00
FALL '21	Samples for Practice (all shapes)	2-Oct	2-Oct	0.0	15	30.0	0.75	0.0	0.7	60.0	0.6	$58.50	$941.50
FALL '21	Shear test (pucks)	24-Oct	24-Oct	8.0	15	2.0	0.75	2.0	0.7	5.0	0.6	$125.90	$815.60
FALL '21	Compression test (pucks)	13-Nov	13-Nov	5.0	15	0.0	0.75	0.0	0.7	0.0	0.6	$75.00	$740.60
SPRING '22	Poissons and Hardness test (pucks)	15-Jan	15-Jan	4.0	15	3.0	0.75	2.0	0.7	11.0	0.6	$70.25	$670.35
SPRING '22	Radial Force and Lubricity test (cylinders)	17-Jan	17-Jan	3.0	15	11.0	0.75	5.0	0.7	44.0	0.6	$83.15	$587.20
SPRING '22	Tension test (rectangle)	22-Jan	22-Jan	3.0	15	3.0	0.75	2.0	0.7	10.0	0.6	$54.55	$532.55
SPRING '22	Compliance test (cylinder)	19-Feb	19-Feb	0.0	15	11.0	0.75	5.0	0.7	44.0	0.6	$38.15	$494.40
SPRING '22	Compression test pt.2 (puck)	19-Feb	19-Feb	2.0	15	2.0	0.75	2.0	0.7	6.0	0.6	$36.50	$457.90
SPRING '22	Model	16-Mar	16-Mar	0.0	15	12.0	0.75	148.0	0.7	128.0	0.6	$189.40	$268.50
SPRING '22	Model	17-Mar	17-Mar	0.0	15	12.0	0.75	148.0	0.7	128.0	0.6	$189.40	$79.10
SUBTOTAL				25.0	$375.00	86.0	$64.50	314.0	$219.80	436.0	$261.60	$720.90	$79.10

13.7 Appendix G: FMEA (1st Semester)

Part # and Functions	Potential Failure Mode	Potential Effect(s) of Failure	Potential Causes and Mechanisms of Failure	RPN
samples	Excessive Force	deforms sample	Prevents pucks from testing properly	56
0	Tearing	rips sample	Prevents pucks from testing properly	16
0	Error in meshing	creates holes in model	Improper complicane testing	8
0	Excessive Shear	Seperates layers in sample	Improper Shear Testing	8
0	Catheter Cutting	Splits sample	Improper Friction Testing	16
0	Compliance Rupture	Damages sample	Improper Friction Testing	16
0	Cleaning Tear	Splits sample	Improper cleaning of samples	96
Printer	Improper Cleaning	Unintentional Mixing	Not cleaning the printer before every print	70
Circle of Wilis	Thin Wall Sag	Weak Supports	Thin walls of the model, improper printing	16
0	Model Rupture	Destroys Model	improper printing, extreme internal pressure	24

13.8 Appendix H: Gantt Chart




BDL/ANEUVAS CAPSTONE Semester 2
Project Start:
Display Week:
TASK
ASSIGNED TO
START
END
Hardware Status Update 67%
Finalized Testing Plan
Compliance FEDC
Print and Clean in-vitro flow model
UGRADS Poster draft
Analytical Analysis Data Gathering
Hardware status Update 100%
UGRAD Presentation
Initial Testing Results
Actual UGRADS Symposium
Final CAD Packet
Final Report
Client Handoff