BDL/Aneuvas 3D Print Testing

Final Proposal

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2021-2022

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DISCLAIMER

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

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.

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 be more efficient, this same process was implemented for this project. The proof-of-concept shear test was conducted on pucks on day 4 of soaking and the compression test was conducted on day 24 of soaking. A future test of compression at 4 days may be conducted to compare 4-day and 24-day data.

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.

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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.

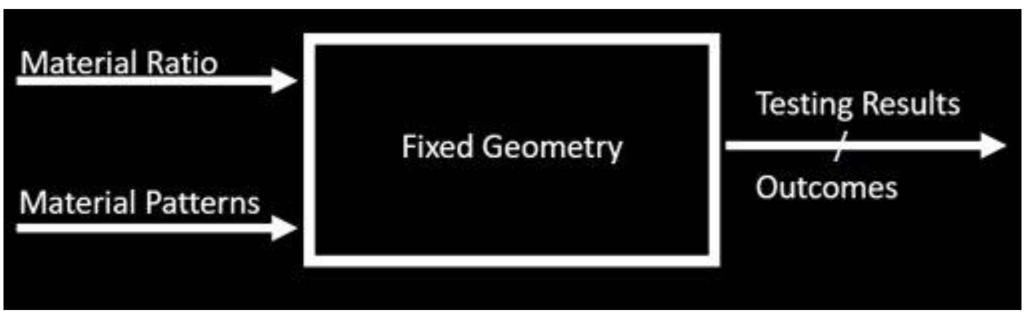


Figure 1 Black Box Model.

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.

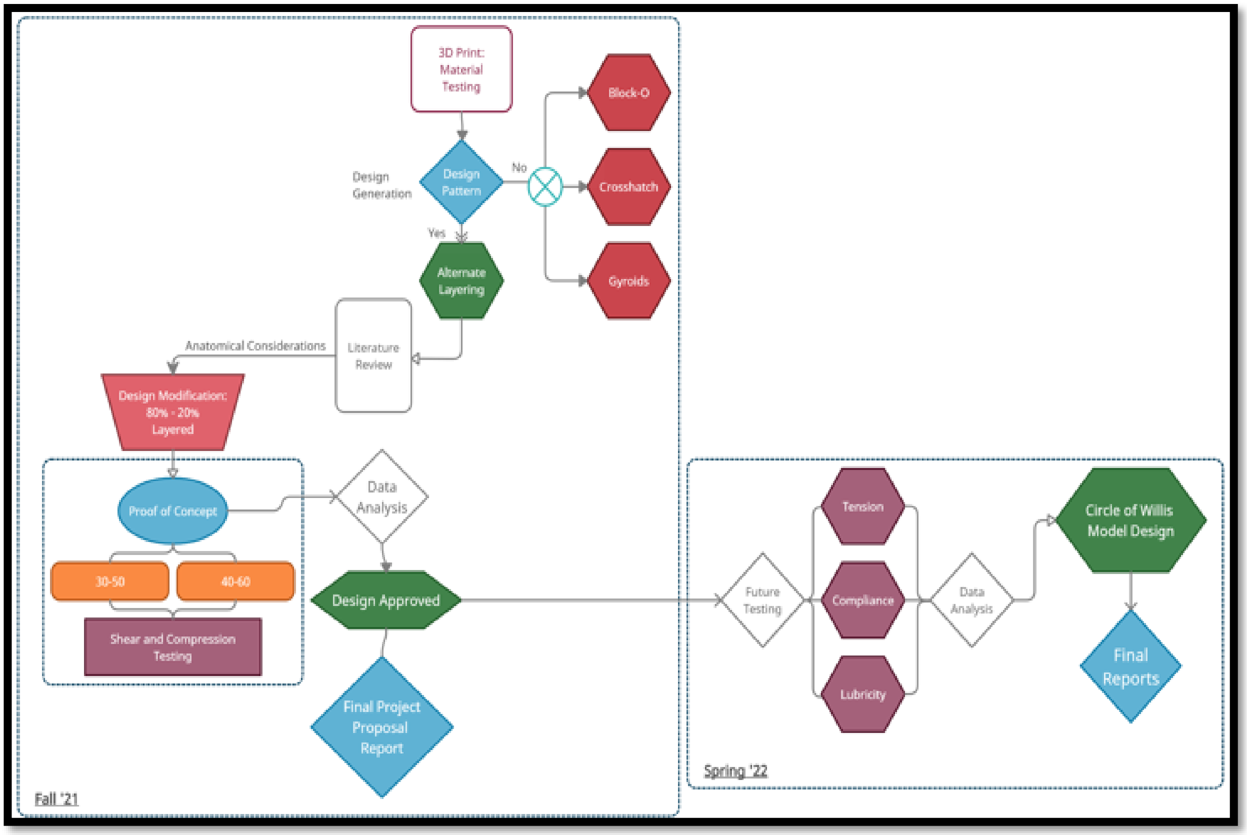


Figure 2 Updated Functional Model.

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.

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 through 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 Testing Procedures (TPs)

There will be five different tests to check various properties of the different samples to ensure that the project is meeting the goals that were set or if there are any changes that need to be made to the design to closer match the properties of human vessels.

3.1 Testing Procedure 1: Lubricity

The lubricity test is to calculate the friction force of the sample. This is one of the more complicated tests that will be performed, mainly due to the precise set-up required.

3.1.1 Testing Procedure 1: Objective

Before the test can proceed, a table must be placed perpendicular to the rheometer with a plastic container containing a 3D printed wheel placed some distance away, the desired distance of the container changes depending on the sample, and a clamp on the clamped to the other end of the table. A syringe filled with water will be used as a weight and will freely hang off the clamp when the wire is tied to it. A tube-shaped sample is secured to the wheel and surgical wire is connected to the rheometer, through the sample and connected to a syringe, creating two triangle shapes. Once everything is set up, the test can begin. The rheometer will gently pull on the wire and measure the amount of resistance the wire is experiencing while moving, allowing the friction of the interior of the sample to be found. By finding the friction property of the sample, it can be compared to the friction property of the human vessels to see if there are any similarities or if any changes need to be made to help the sample values get closer to the human values.

3.1.2 Testing Procedure 1: Resources Required

The equipment required to perform this test is the rheometer, table, plastic container filled with saline, a 3D printed wheel, clamp, surgical wire, syringe filled with water, 3D printed sample, and personal protective equipment (PPE). The program used to measure the friction force is the “Vessel Friction-tension” program that is preloaded into the rheometer. And while this test can be performed by one person, having multiple people help can ensure that the test is running accordingly by double checking the set up and watching to see if anything goes wrong.

3.1.3 Testing Procedure 1: Schedule

Since this test involves a tedious set up, multiple samples, and each sample having to be tested four times, there is a critical requirement needed for this test. This procedure will be split up into two separate testing days, roughly eight hours each, and these days will most likely take place within the first couple weeks of the semester.

3.2 Testing Procedure 2: Compliance

The compliance test is used to measure how much change in volumetric pressure the sample can handle before causing permanent deformation.

3.2.1 Testing Procedure 2: Objective

To perform this test a tube-shaped sample will be secured a pressure transducer and syringe, one on either side. The sample will be filled with thick liquid until there is no air left inside and placed under the fluoroscope. Slowly fill the sample with more liquid until the pressure gage reads 80mmHg, take a picture with the fluoroscope and then increase the pressure by 40mmHg, take another picture. Repeat this step until the pressure has reached 280mmHg. Send the images taken during this process to the rheometer in the lab. This helps see how much the sample can swell from internal pressure. By doing this procedure, the compliance properties of the sample can be compared to the properties of the human vessel and necessary changes can be made.

3.2.2 Testing Procedure 2: Resources Required

The equipment required to perform this test is a fluoroscope, thick liquid (typically Conray), syringe, pressure transducer, laptop suture to attach syringe and pressure transducer to the sample, 3D printed sample, rheometer, and PPE. The program that will be used for this procedure is LabView NI 9237, the program on the laptop to measure the internal pressure in the sample. This test requires multiple people to perform, one filling the sample, one watching the laptop, and one to capture the photos.

3.2.3 Testing Procedure 2: Schedule

This is another test that the team plans to complete earlier in the semester. There will be two hours of testing since there will be three samples to test and each sample will be tested once. It will be completed earlier due to the time needed to complete the analysis of the data found from the test.

3.3 Testing Procedure 2: Tension

This procedure measures the tensile strength of the sample.

3.3.1 Testing Procedure 2: Objective

To perform this test, a rectangular sample is secured in the rheometer and pulled until it experiences an axial force of 100mHg. The procedure is done again but this time the sample will experience an axial force of 160mmHg. Measuring the tension properties of the samples informs the team on how close the prototypes are to the properties of human vessels.

3.3.2 Testing Procedure 2: Resources Required

The equipment required to perform this test are the rheometer with the "tension fixture" and ETC tension attachments and the 3D printed sample. The program used to measure the tensile force is the "Vessel Dynamic Pull Elastic Modulus" preloaded rheometer program. This procedure can be completed by one person.

3.3.3 Testing Procedure 2: Schedule

Due to the simplicity of this test, it can be completed in one day, roughly taking two hours since there are two samples, and each being tested four times. This will be one of the last tests that the team plans to perform, most likely happening a month or two into the semester.

3.4 Testing Procedure 2: Shear

This test will measure the shear modulus of the sample.

3.4.1 Testing Procedure 2: Objective

To perform this test, a small piece of sandpaper will be placed into the rheometer and a disk sample will be placed on top of it. The rheometer will then apply a continuous oscillating force or direct shear to the sample. By measuring the shear modulus of the sample, it can be compared to the shear properties of human vessels and changes can be made accordingly.

3.4.2 Testing Procedure 2: Resources Required

The equipment needed to perform this test is the rheometer with 8mm parallel plate and immersion cup, sandpaper, and 3D printed sample. The program used to measure the shear modulus is the "Vessel Dynamic Shear Modulus" preloaded rheometer program. This test can be performed by one person.

3.4.3 Testing Procedure 2: Schedule

This testing procedure has already been completed by the team, however, if the design experiences changes in the future, then further testing will happen. This would happen a month or two into the semester. If so, then this will take one day for eight hours to test eight samples, each sample getting tested eight times.

3.5 Testing Procedure 2: Compression

This test measures the elastic modulus of the sample.

3.5.1 Testing Procedure 2: Objective

To perform this test, a small piece of sandpaper will be placed into the rheometer and a disk sample will be placed on top of it. The rheometer will then apply an axial force of 0.9-1.4 N onto the sample, measuring how resistant the sample is to the force. By measuring the elastic modulus of the sample, it can be compared to the shear properties of human vessels and changes can be made accordingly.

3.5.2 Testing Procedure 2: Resources Required

The equipment needed to perform this test is the rheometer with 8mm parallel plate and immersion cup, sandpaper, and 3D printed sample. The program used to measure the shear modulus is the "Vessel Dynamic Elastic Modulus" preloaded rheometer program. This test can be performed by one person.

3.5.3 Testing Procedure 2: Schedule

This testing procedure has already been completed by the team, however, if the design experiences changes in the future, then further testing will happen. This would happen a month or two into the semester. If so, then this will take one day for five hours to test eight samples, each sample getting tested four times.

4 Risk Analysis and Mitigation (Kathryn)

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 D.

4.1 Critical Failures

4.1.1 Potential Critical Failure 1: Tearing the Sample

During certain procedures, such as the tension test, there is a chance of the sample tearing due to experiencing a greater axial force of 2 N. This would destroy the sample and any data collected from it will be inaccurate. To avoid damaging the sample, the team will work slowly during the testing and watch to see how much force the sample is experiencing and immediately stop testing if the experienced force exceeds the appropriate amount.

4.1.2 Potential Critical Failure 2: Excessive Force

During certain procedures, such as shear and compression tests, there is a chance of the sample experiencing an excessive force greater than 2 N. This would cause the sample to be permanently deformed and any data collected from the sample inaccurate. To avoid this, the team will work slowly during the testing and watch to see how much force the sample is experiencing and immediately stop testing if the experienced force exceeds the appropriate amount.

4.1.3 Potential Critical Failure 3: Excessive Shear

During the shear test, there is a change that the sample could experience a twisting force greater than 1.5 N. This could cause the meshing between the layers to come loose and separate, potentially causing the sample to fall apart, and any data found from the sample to become unusable. To avoid this, the team watch to see how much force the sample is experiencing and immediately stop testing if the experienced force exceeds the appropriate amount

4.1.4 Potential Critical Failure 4: Catheter cutting

During the lubricity test, there is a chance that the sample could experience a force greater than 1.5 N. This could cause damage to the sample and render the data collected from that test inaccurate and unusable. It's possible that the catheter will move too quickly and cut the material. To avoid this, the team will ensure that the set up for this test is correct and watch to see how much force the sample is experiencing, immediately stopping testing if the experienced force exceeds the proper amount

4.1.5 Potential Critical Failure 5: Improper Cleaning

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. To prevent this from happening, the team plans to check the dispensers before printing to see if they were cleaned and clean them if they seem dirty and clean them after every print to prevent mixing for future prints.

4.1.6 Potential Critical Failure 6: Compliance Rupture

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. This would affect the data collected from the test and potentially damage the sample. To prevent this, the stitch will be placed behind the bard hook and the sample will be closely monitored to ensure that the bard does not slip or the knot on the stitch comes undone.

4.1.7 Potential Critical Failure 7: Circle of Willis, Thin wall sag

If the walls are too thin on the circle of Willis, there is potential for the internal structure to collapse under its own weight. If this happens, then the team will have failed to produce a viable model per the customer requirements. To prevent this, the team will use similar dimensions of existing models to ensure that structural integrity is kept. In addition, the team can enhance the lengths of sections and areas where the internal stricture connects to the outer case. This will help to stabilize the structure.

4.1.8 Potential Critical Failure 8: Cleaning Tear

Cleaning the designs after printing is necessary to produce accurate data. The 3D printer automatically prints support material inside and outside of designs to stabilize the structure while it prints. While removing this support material, it is possible that the team can scratch or tear the prints due to how tiny they are (1.2mm thick). If this happens, a new print will need to be made and the process restarted. If this is not noticed until during testing, the test may produce data that is obscure. To prevent this the team plans to be slow and meticulous during the removal phase and to lightly wash the same in water prior to the soaking process.

4.1.9 Potential Critical Failure 9: Error in printing mesh

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. To avoid this issue, each sample will be looked over thoroughly before testing to ensure that proper meshing has occurred and discard any samples that seem to have improper meshing.

4.1.10 Potential Critical Failure 10: Circle of Willis model rupture

When creating the circle of Willis model, there is 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, and resulting in inaccurate data. To avoid this, each sample mush be thoroughly tested to ensure that the full model would withstand the induced pressure.

4.2 Risks and Trade-offs Analysis

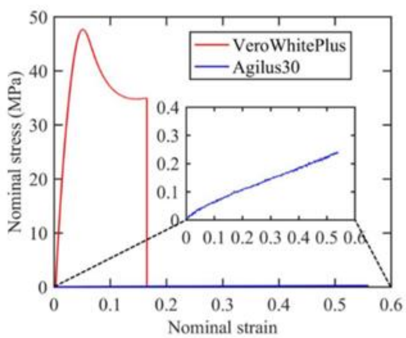
While some of the failures are due to human error during testing, there are some that relate to each other. For example, if there is an error in meshing, and it goes unnoticed, the samples have a higher chance of becoming damaged or deformed during testing, making the collected data inaccurate and unusable. Same idea goes for if the printer isn't 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 don't 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. Luckily, mitigating any of the failures wouldn't negatively affect the mitigation of other failures.

5 DESIGN SELECTED – First Semester

We found that our final design is formed from the alternative design that we presented in our analysis, the layered design of the samples that enables us to come close to a soft tissue. 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

We started finding our final design by looking at our design concept variants, which had four distinct geometrical patterns we can design. These four were used in the decision matrix and Pugh chart to determine the best possible design which met our customer requirements and fulfilled our engineering requirements also. Based on the decision matrix and Pugh charts results, we determined the 4-layer alternative shores design was appropriate for goal of the project. We had planned an implementation and planned to perform tests on the design. After proposing the design to our client, they wanted the design to match much closer to an actual blood vessel geometry, which does not contain four significant layers in its properties. 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 an alternative design to our first proposed design to our client, this was the layered design with two distinct layers that match the similarities of an organic blood vessel. Below we will describe each design in detail and how we reached our final design. We will be using Agilus30 and Vero-Clear as our materials; if we analyze figure to the left, we can see that these materials, when used in a combination, can yield favorable material properties [9].



5.1.1 Alternative Shores (4 layers)

Having conducted our analysis during the preliminary stage of the project, the decision matrix has concluded that an alternate shores design is the optimal solution to meet all our customers' needs. One area where it didn't fulfil the criteria was how close it comes to mimicking the organic tissue, but we decided that since all the other requirements were met with a high margin of safety, the design would work for the end goal. The concept of multiple layers of different firmness is key to the success of this concept. This produces a mesh with a softer outer shell and an interior of medium firmness that resembles tissue. A total height of 1.2mm is achieved with four layers of 0.3mm each. As a result of our client's recommendation, it was designed and developed to look and feel like a vessel. The decision to design and develop it in this manner met all the client's requirements. There will be no air pockets between the layers because the layers are meshed, and this will help us achieve a better bond between them. Overall, it has been found to meet all our requirements and will serve as a reliable baseline for future usage. A further advantage we have is that we have two layers with different firm values of their own. We are hoping that, with this design, we will be able to create a system that mimics the organic tissue/Common Carotid Artery (CCA) tissue. This design can be seen in Appendix C: Design Description.

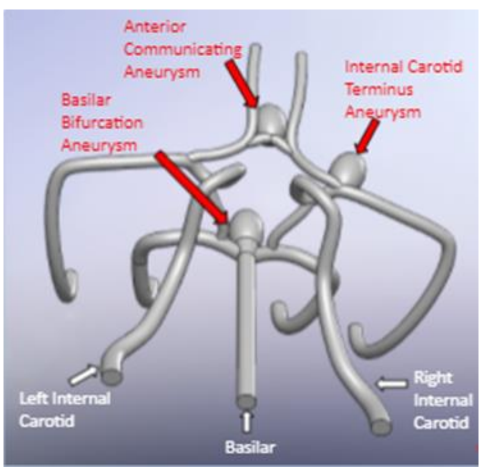
5.1.2 Layered Design (2 layers)

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 doesn't have the outer layer in its design. Our design, as seen in appendix C: design description, 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.

5.1.3 Justification of Final Prototype

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 4 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 E: Data Analysis - 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 have an effect on its mechanical properties and can even come close to the human tissue properties. We will know more information in the beginning of next semester on how to change the values when the other tests have been performed and compared to human tissue.

5.2 Implementation Plan



Our design prototype yielded results better than we expected after comparing it to donor tissue data. We have derived that changing the ratios of hardness's in each layer of the sample yielded a much closer complexion modulus to that of a donor common carotid artery. We will now print new samples with different geometries as highlighted in the earlier sections and use those for our tests which will be conducted in the next semester. We will soak the printed samples in PBS for at least four days to get a much softer material to test on. After examining each sample using the five tests which are: biaxial vascular tension of materials blood vessel compliance, lubricity of the model interior, and the compressive and shear modulus; we will use the design and implement it to the original system, which is the circle of Willis as seen on the side. This system will be used to research and medical practice to gain knowledge on new devices and practice novel medical procedures.

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. Exploded view of our printed samples (pucks only since we did not need any cylinders for shear testing) can be seen in Appendix C.

The system we will be using for testing is the NAU's HR-2 hybrid rheometer (TA Instruments, New Castle, DE), which focuses on the strain rate of the material in the context of each test. This will be the main testing machine but we will also use BV Pulsera C-Arm fluoroscope (Philips, Eindhoven, Netherlands) for compliance testing and images. TRIOS is the software provided with the Rheometer to implement different tests and gather the data. The plan for next semester is to test and analyze all the different mechanical properties using the five stress-strain tests given to us by our client and compare it to donor vessel data. We will be going back and forth with our client to determine the next steps for a bigger scope or a change in design with the data we have gathered. We have listed our outline for next semester in Appendix F using our Gantt chart.

All the necessary equipment supported testing has been through NAU's Bioengineering Devices Laboratory which is run by Timothy A. Becker Ph.D. We would like to acknowledge and thank him for his financial and infrastructure backing of the project. Our bill of materials has been mostly for the polymers provided by the BDL laboratory and renting out equipment for data collection and printing of the samples. As you can see, equipment renting has been taken up majority of our expenditure and that cannot be changed nor can we find different rates as it is fixed. Other areas are the cost of our polymers which isn't substantial for now as they are small samples, the cost of the prints will be much greater next semester when we have to print the original system using our specifications. Out of the budget ($1000) we have about $919.60 remaining for the end of this semester.

This Semester	
Current Amount Spent	
Initial Instruments Prep.	$16.85
Newest Sample Mat.	$1.65
Total	$18.50
Potential Spending for Rest of Term	
Possible Printed Models	$61.90
Total Spent:	
With models	$80.40
No Models	$18.50
Leftover:	
With Models	$919.60
No Models	$981.50

Next Semester	
Potential Prints	
3 Full Models	$185.70
10 Samples	$185
Additions	
Equipment Rent	$300
Total Spent:	
With Models	$751.10
No Models	$503.50
Leftover:	
With Models	$248.90
No Models	$496.50

6 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. Additionally, a radial force test may be asked for by the client next semester. 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 semester, such as project design, the functional model, and implementations of planning/testing.

In conclusion, during proof-of-concept testing, the anatomical similarity design displayed more favorable mechanical properties than previous BDL tests. In response, future testing will be conducted using this ratio to create a complete report of 80%-20% ratio designs and the final circle of Willis model will be developed in a shore ratio of 80%-20% that most closely replicates the human tissue mechanical properties. Included in Appendix E are the shear and compression proof-of-concept analysis graphs.

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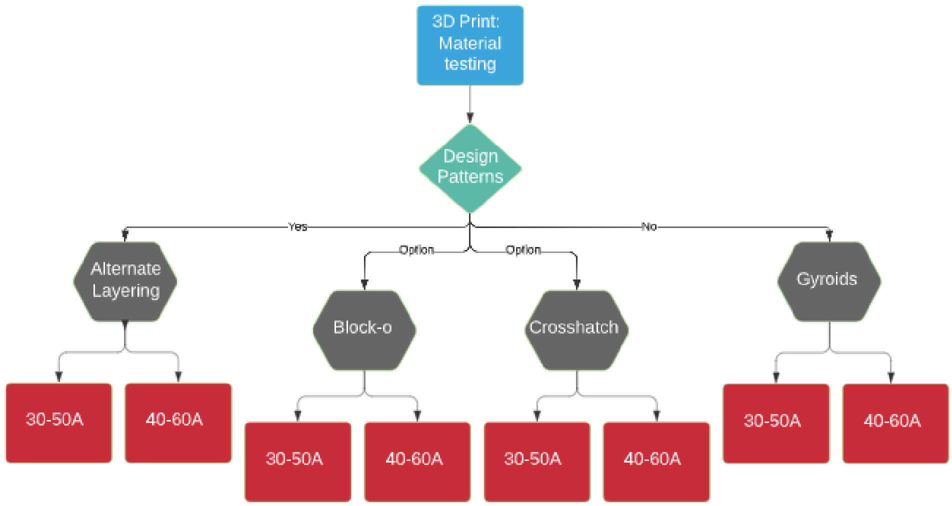
8 APPENDICES

8.1 Appendix A: Previous Functional Model



8.2 Appendix B: House of Quality

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

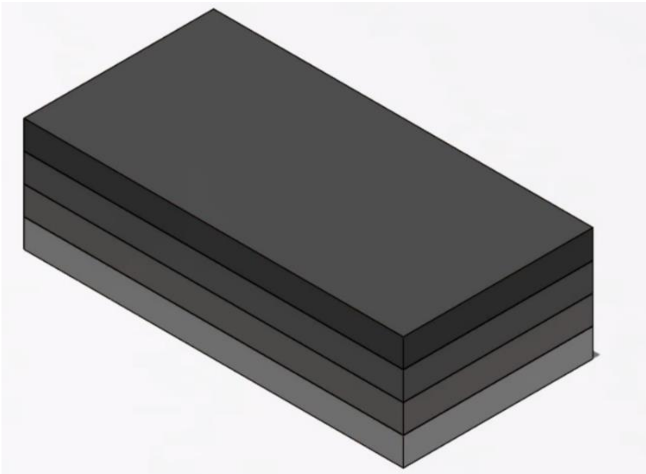
Correlations	
Positive	+
Negative	-
No Correlation	

ustomer Competitive Assessmer	
1	Poor
3	Acceptable
5	Excellent

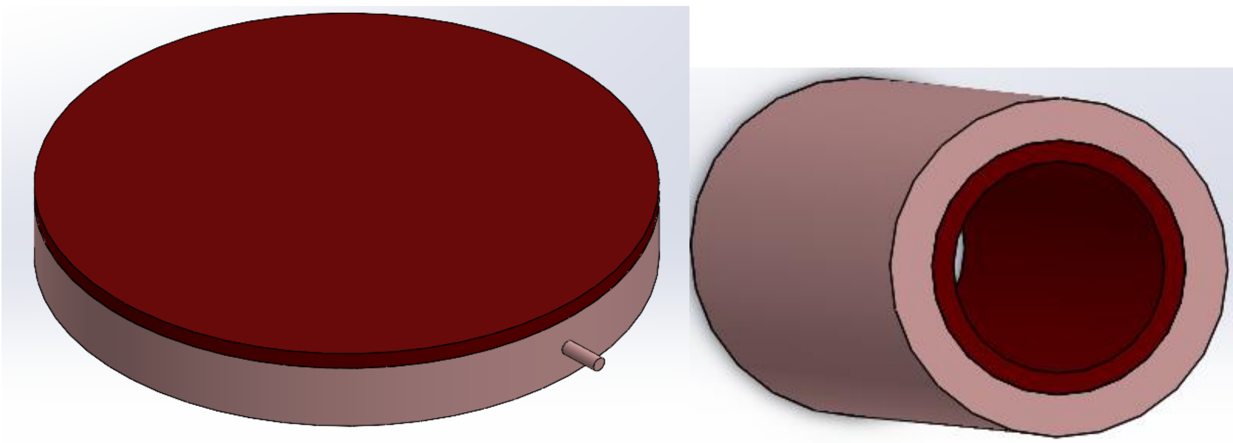
	Stiffness/ E (kPa)	Thickness (mm)	Compressive Modules (kPa)	Frequency (rad/s)	Poisson's ratio (unitless)	Compliance (cm^3/mmHg)	Angular Acceleration (rad/s)	Radial Force (N/mm)	Layering (um)	Pressure (mmHg)
Stiffness/ E (kPa)	+									
Thickness (mm)	-	+								
Compressive Modules (kPa)	+	+	+					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

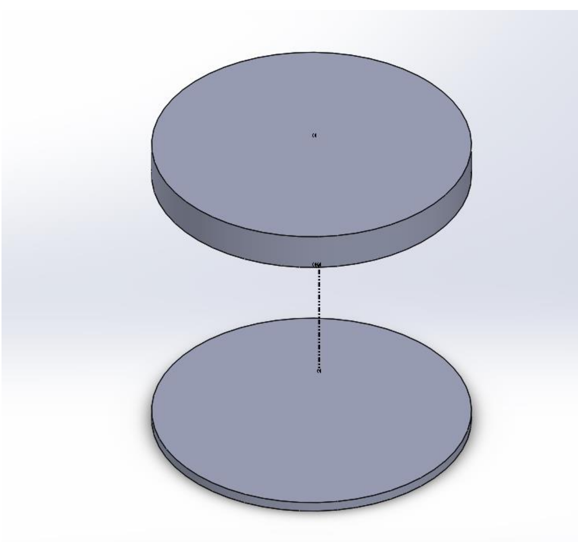
8.3 Appendix C: Design Description



Alternate Shores Design



Final Prototype – Layered Human tissue design for various testing types.



Exploded view of puck samples

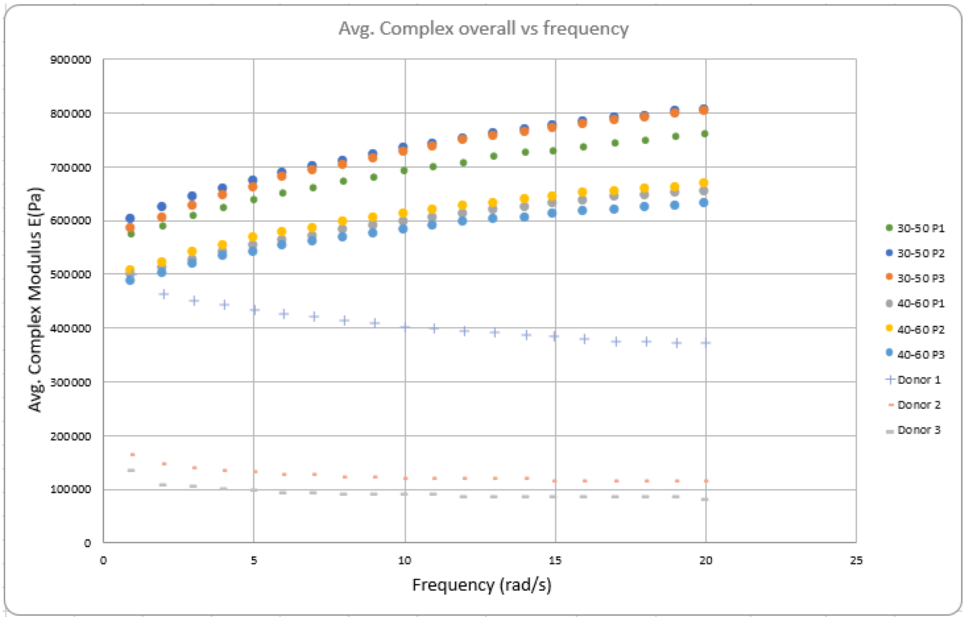
CAD drawing for puck samples

8.4 Appendix D: FMEA (updated)

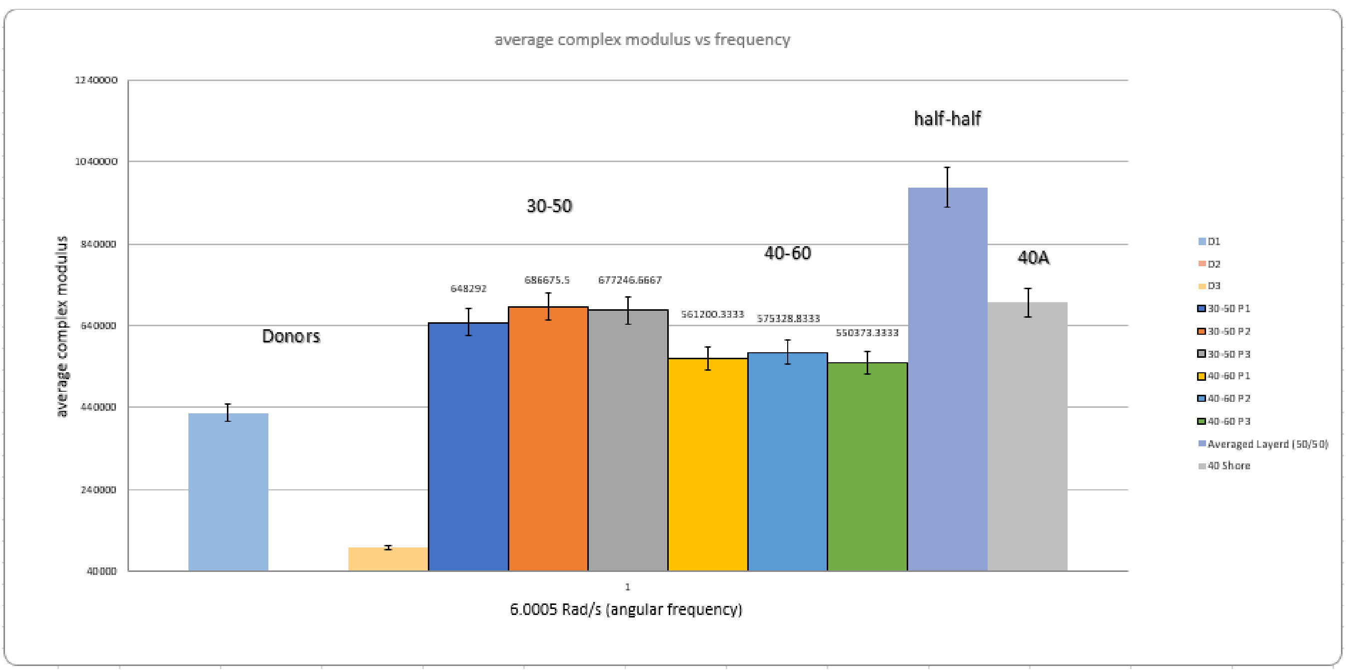
Part # and Functions	Potential Failure Mode	Potential Effect(s) of Failure	Potential Causes and Mechanisms of Failure	RPN
samples	Excessive Force	deforms sample	Prevents pucks from testing properly	56
0	Tearing	rips sample	Prevents pucks from testing properly	16
0	Error in meshing	creates holes in model	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

8.5 Appendix E: Data Analysis - Shear and Compression

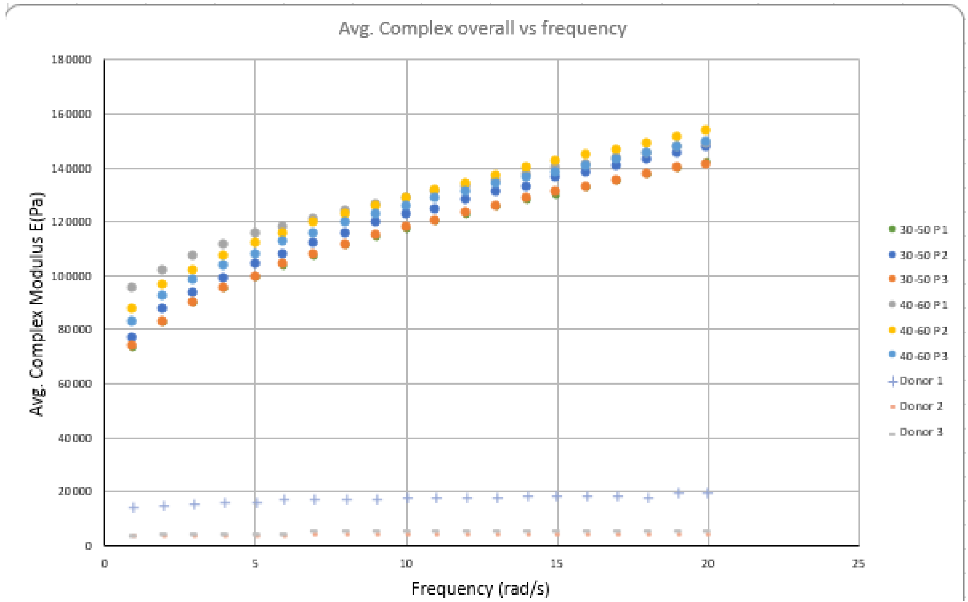
Compression:



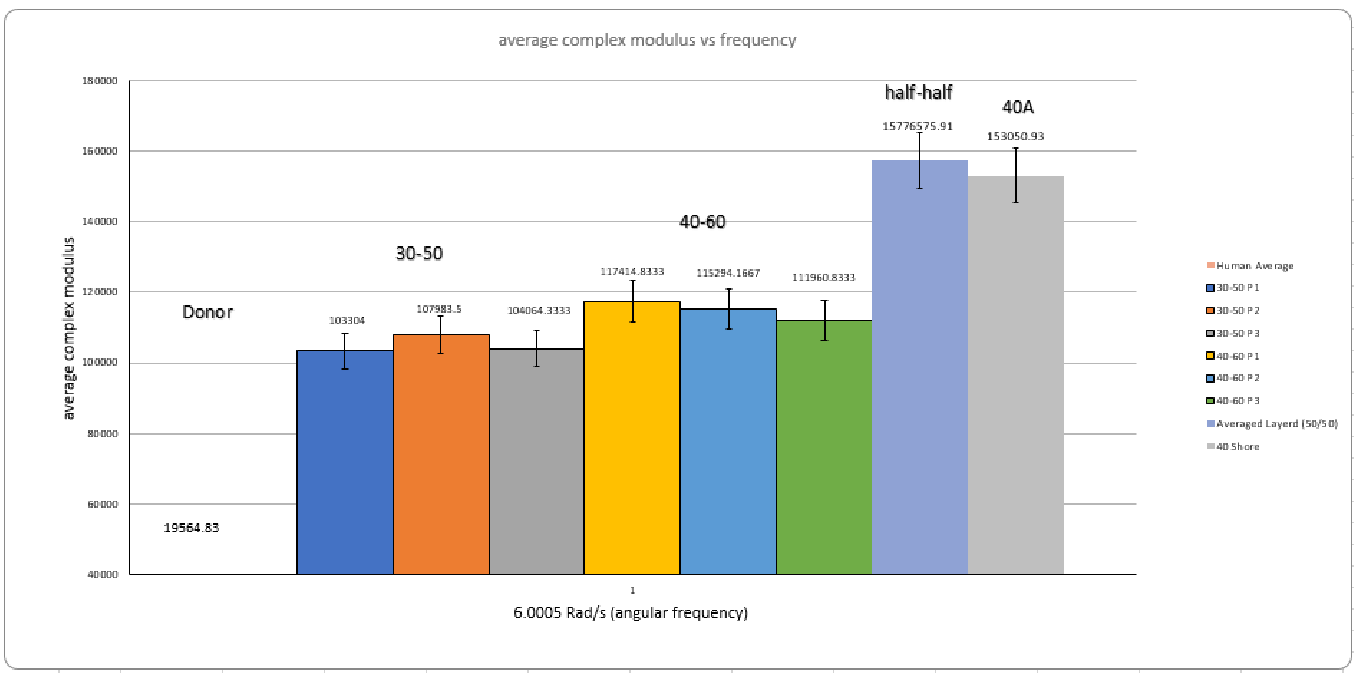
All data with Donor relation.



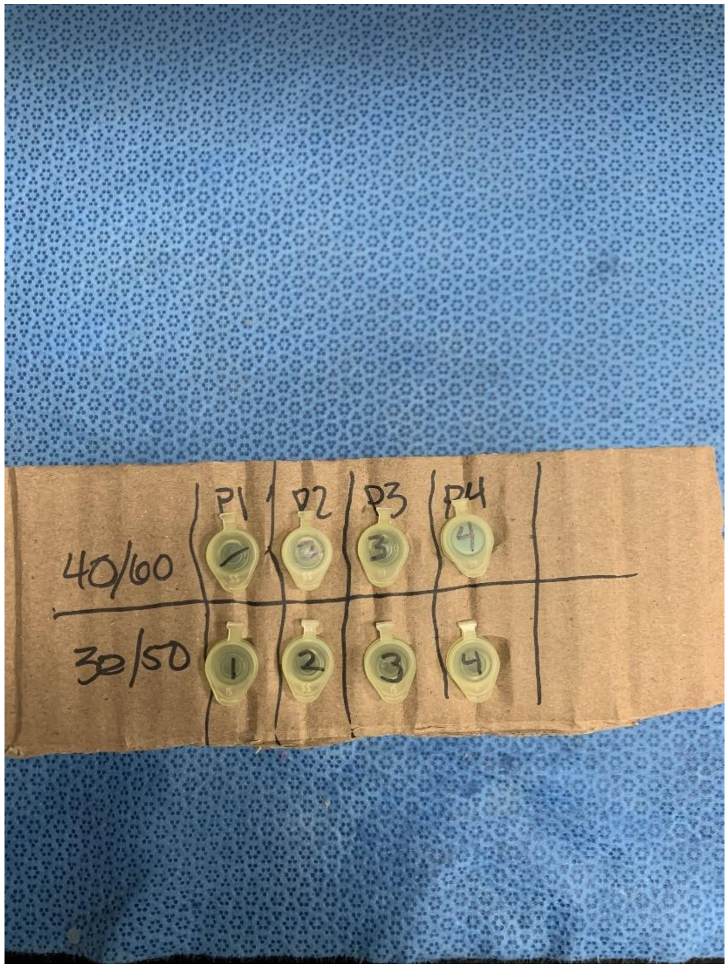
Shear Data:



All data with Donor relations.



8.6 Appendix F: Pucks in PBS soak



Carboard is used as a cheap and eco-friendly holder for the pucks while they soak.

8.7 *Appendix G: Future Plan*

BDL/ANEUVAS CAPSTONE Semester 2

NAU ME Capstone
Project Lead: Isaac Smith

Project Start: Mon, 1/10/2022
Display Week: 1

** As of date of making

TASK	ASSIGNED TO	PROGRESS	START	END	DAYS
Semester 2 Start-up					
Talk to client	All		1/14/2022	1/14/2022	1
Post Mortem of Final report from S1	All		1/14/2022	1/14/2022	1
Delegate testing days and start on final design	AP		1/14/2022	1/14/2022	1
Project Update and First report delegation	Issac		1/14/2022	??	#####
Website Updates	Luke		1/14/2022	1/14/2022	1
Finalize BOM for testing with client	Katheryn		1/21/2022	1/21/2022	1
Individual Analytical Analysis	All		1/10/2022	2/1/2022	23
Midpoint Presentation and Report	All		2/1/2022	??	#####
Testing days	Issac, AP		Multiple Days: TBD	Multiple Days: TBD	#####
Test data analysis	Luke,Katheryn		Dependent on above	Dependent on above	#####
Final Product and Design Summary	All		4/1/2022	4/15/2022	15
Final Report	All		4/15/22	5/6/22	22