# Compression Panel Inserts Senior Design Team

# Testing and Standardization of Compression Panels for the Quorum Quatro™ Socket


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May 8, 2022

## Abstract

Typical lower-limb prosthetic sockets are fabricated with a rigid, single piece, custom-fit laminate material. Although this standard procedure is economically favored, the socket cannot be easily adjusted to conform to the volumetric change of the residual limb. Quorum Prosthetics addresses this issue with their Quatro™ technology, a transtibial and transfemoral socket with a BOA dial adjustment system and integrated 3D printed thermoplastic polyurethane (TPU) compression panels. These panels, in unison with the Quatro™ system, give patients control over their comfort by providing easy adjustment of the BOA dial system running through the panels. However, Quorum's initial panel design was limited in its compressive variety, so the need for a range of panel stiffnesses became the primary objective of this project. Rigorous material testing, compression testing, and finite element analysis (FEA) were performed on both dogbone TPU samples and panel prototypes to understand the response and controlling factors of the panel lattices under compression. It quickly became clear that the TPU material properties could not be quantified repeatedly, leading to a number of speed bumps in the design process. However, through mathematical manipulation and scrupulous data analysis, a repeatable FEA simulation and algebraic relationships between material properties and lattice design constraints were created to aid in the design of new panels. Two intermediate panel stiffnesses were produced using these methods, validating their legitimacy, and a detailed design procedure was developed allowing Quorum to continue designing custom panels for their patients.

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## Introduction and Background

It is estimated that approximately 30 million people are in need of prosthetics worldwide [1]. Therefore, it is essential that reliable and comfortable prosthetics are available for those who choose to be fit for one. The average wear time per day was found to be $12.47 \pm 4.34$ hrs in a recent study, and the main reason that users do not wear their prosthetic as long as they wish to is due to comfort issues [2]. The prosthetic is what takes on the weight of the user, however the tissues in the residual limb are not well suited for this type of pressure [3]. Those who use prosthetics should be able to wear their prosthetic as long as they desire and not be restrained by comfort.

The traditional way in which customers are fitted for prosthetics is by custom molding of the user's residual limb. However, this does not take into consideration how a body fluctuates. A limb does not stay the same shape throughout the day and even more changes occur as the week goes on due to fluid fluctuations [3]. People also go through weight gain and loss, so a prosthetic with a custom fit is not always long term sustainable. This inevitably results in return visits for additional custom mold fittings. The projected lifetime cost for a non-computerized lower limb averages over $300,000 [4]. This process is time consuming, expensive, and does not consistently meet the patient's satisfaction of comfort.

The most common suggestions given to prosthetic users to increase their comfort are trying a different socket or liner, thoroughly cleaning their prosthetic, and making adjustments to the prosthetic with their prosthetist [5]. Although these suggestions can temporarily subside the uncomfortable feeling, they do not solve the problem. The motivating factor for this project is to provide customers with a prosthetic socket that is equipped with customizable compression inserts to increase comfort and stability while adapting to users fluctuations daily and in the long term.

There are similar existing projects aiming to create a more comfortable prosthetic for their customers. Bionics for Everyone has developed a smart socket called 'Unhindr'. This is a robotic liner that continuously and automatically adjusts socket pressure by built-in sensors and microfluidic technology. This product also includes a manual override on the user's smartphone to adjust the settings to fit their preferences. Sandia National Laboratories is creating a dynamic prosthetic socket system that will monitor and adjust to the residual limbs volume change. Their idea utilizes bladders controlled by valves and pressurized liquid on the outside of the liner to adjust to changes of the residual limb.

When considering 3D printed compression lattices as an alternative to expensive sensors implemented into the socket itself, there are many examples of related technologies in various industries due to the customizability, accessibility, and fast iterability that they offer. Compression lattices are used in sports as helmet padding for impact absorption, orthopedic shoe inserts for arch support, shoe soles for impact mitigation, and are now utilized to replace traditional inflatable tires[6]–[9]. These lattices display the variety of structures that can be used to produce different levels of compression for different applications. The methods used to produce these products include digital light synthesis (DLS) and fused deposition modeling

(FDM), the latter of which is used commonly with thermoplastic polyurethane (TPU) and is significantly cheaper for rapid prototyping applications [10]. Furthermore, constructing these lattices is relatively easy and inexpensive, as they are simply infill patterns with more negative space than filament. By constraining the lattice density and varying its geometry, the compressibility and pressure distribution of the lattice can be optimized without significantly affecting the required mass of filament [7].

Despite the popularity of additive manufactured (AM) products in prosthetics, there are both ethical and safety concerns to consider while manufacturing and utilizing this technology in a clinical setting. The FDA has classified prosthetic sockets and external components as Class I, 510(k) exempt and medical device good manufacturing process (GMP) exempt, meaning they pose little to no health risk to the patient [11]. However, it is good practice to follow the standards given by the International Organization for Standards (ISO) and American Society for Testing and Materials (ASTM). For this project, the following standards must be adhered to in order to produce a quality testing apparatus and AM product, as well as ensure the safety of the patient:

1. ISO 10328:2016 Prosthetics — Structural Testing of Lower Limb Prostheses – Requirements and Test Methods
2. ISO/TC 168 – Standardization in the field of prosthetics and orthotics, covering such aspects as performance, safety, environmental factors, interchangeability, etc.
3. ISO/ASTM 52910, Standard Guidelines for Design for Additive Manufacturing
4. ASTM F2971, Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing
5. ISO/TC 261 Additive Manufacturing - Standardization in the field of AM concerning processes, test procedures, quality parameters, etc.
6. ASME Y14.5 2018 – Dimensioning and Tolerancing Standard

Considering Quorum's current manufacturing capabilities, TPU is used for the construction of these compression inserts. In the context of sustainability and environmental impact, thermoplastic polymers by design are capable of being reheated and reconfigured after their initial polymerization, giving excellent potential for recyclability. There are also biodegradable biobased TPU substitutes currently available, which will be considered as an alternative to traditional TPU during the budget proposal [12]. Additionally, the cost of a lower limb prosthesis can vary substantially based on user preference, so maintaining a low cost to the consumer will also be sustained throughout this project.

## Problem Statement

Prosthetics, particularly lower limb prosthetics are life changing devices that offer renewed mobility and function for those who have suffered accidents, birth defects, or long term effects of diabetes. There are, however, some issues with these devices that need addressing in order to make them more accessible and convenient for the recipients. The largest issue faced in the current market is the individuality and uniqueness in which prosthetic sockets must be fit. Though the process of custom molding a socket does yield a comfortable and functional fit, this process is both time consuming and expensive. It yields a rigid design that is incapable of growing and changing with the person's residual limb. People gain or lose weight as they age and an amputee's residual limb can change volume up to 10% during the day due to fluid fluctuations [13]. A prosthetic should be able to accommodate these changes, as replacing one is quite expensive. In addition to minute fluctuations in the shape of the residual limb, discomfort is an issue. Only through the patient's sense and experience can comfort be quantified, and due to this, a clinician fitting the prosthetic can only estimate to ensure a comfortable fit. Therefore, adjustability is key to providing a user experience that is not only functional, but pleasant. Finally, there is the issue of tactile feedback to the patient. As this is a mechanical device, it does not interact with the patient's nervous system. It can feel foreign and difficult to understand the position and movement of the prosthetic due to the lack of sensory feedback. In order to make these devices feel more natural and easy to use, there must be some sort of sensory feedback that will allow the user to learn to perceive as natural feedback the way they would with their missing limb. Target customers for a device that would satisfy these problems are the end users and patients that require a prosthetic, such as veterans, those who have suffered amputations as a result of serious accidents or disease, and those afflicted with birth defects such as missing limbs. In addition, this would be beneficial to patients of lower economic status. Due to the fact that a prosthetic has the potential to be a life altering device, these individuals should not have to contend with high costs and an uncomfortable experience, therefore such a device would be an improvement to the market both economically and physically. Stakeholders in this project are companies that produce such products. Creating prosthetics that can change and adjust to a patient will not only eliminate a large portion of the time, expertise, and money involved with custom fitting, but also open up their market to developing regions that do not have the funds or expertise to widely utilize the current procedures.

## Objectives and Goals

The overlying goal of this project was to design accessory inserts that could apply varying compressive forces when placed under load by Quorum's BOA dial system. Currently, Quorum's socket only utilizes one standard panel in their Quatro™ system. An image of a Quatro™ socket can be found in Appendix A.  By designing multiple panels with various lattice properties, patients have the ability to customize the fit of their socket and improve both their comfort and support while their device is in use. While the main purpose of this project was to implement these panels into Quorum's Quatro™ socket, there are other aspects to the project that were addressed. A detailed list of the goals and objectives are shown below in Table 1. The objectives were ranked with a 'priority rating ranging from 1-5, where 5 is the highest priority. The first goal addresses the unique mechanical properties of TPU. Properties of the material are often listed in a wide range, as different filament forms, manufacturing processes, and applications give different results in ultimate strength, elastic modulus, Poisson's ratio , etc. Using the facilities available through the Materials Lab at Colorado State University (CSU), mechanical property data was collected from TPU dogbone samples printed by Sean McClure and Jack Fleischmann.

These comfort inserts would produce quantitative data ranges of pressure, load, force, compressibility, density, etc. Ultimately, the comfort of the patient matters most, however, a numerical range of these properties would aid the prosthetist in the fitting process as well as facilitate testing of the products before they're distributed to the patient. By developing a standardized Finite Element Analysis (FEA) simulation and physical testing procedure, these numerical ranges could be defined and standardized.

The primary goal was to increase the customization in the socket. A patient usually seeks out a prosthetist twice a year to ensure that their prosthetic is still functioning properly and is maintaining optimum fit and comfort [14]. In fact, one study suggests that in the first 160 days alone, the residual limb volume can change anywhere from 17%-35% [13]. Similarly, muscular orientation and topography change as the patient begins to use their prosthetic [15]. This changing volume makes the sizing of a custom socket tricky, as the comfort of the socket is bound to change as the muscle and tissue of the residual limb adapt to the new situation both daily and in the long term. This justified the need for an interchangeable insert that can adjust for volumetric change in the residual limb by adding and subtracting compression and increasing / decreasing pressure distribution to better accommodate the residual limb.

With a prosthesis needing frequent maintenance and alterations, the cost of a prosthetic socket quickly begins to add up, and a patient's health insurance only covers part of the cost. By creating inserts to be implemented into the existing socket, the socket could be immediately adjusted by the user to meet their comfort needs, decreasing the frequency and need for doctor's visits. Similarly, there lies an opportunity to decrease cost during the manufacturing process by optimizing the lattice geometry and other printing practices such as recycling the TPU powder.

***Table 1 : Goals and Objectives***

| Goal | Objective Name | Priority Rating | Method of Measurement | Objective Direction | Target |
|---|---|---|---|---|---|
| **I. Material Testing and Documentation** | *Standardized testing procedure* | **5** | Documentation [visual] | Create and implement | Yes / No |
| | *Write/acquire LabVIEW VI* | **5** | Documentation and successful data acquisition [visual] | Design and implement | Yes / No |
| | *3D print TPU dogbone samples* | **5** | Physical sample [visual] | Design and print | Yes / No |
| **II. Standardized FEA Simulation and Panel Testing Procedure** | *Standardized testing procedure* | **5** | Documentation and physical model [visual] | Create and implement | Yes / No |
| | *Build hardware* | **2** | Physical model [visual] | Design | Yes / No |
| | *Write software* | **2** | Physical model [visual] | Design | Yes / No |
| **III. Improve Customizability** | *Optimize lattice geometry* | **5** | Force and pressure distribution | Optimize | Quantitative lattice beam and deformation relationship |
| | *Optimize lattice thickness* | **5** | Force and pressure distribution | Optimize | Quantitative lattice beam and deformation relationship |
| | *Construct low pressure lattice* | **3** | Customer satisfaction [verbal] | 3D print | Positive feedback |
| | *Construct medium pressure lattice* | **4** | Customer satisfaction [verbal] | 3D print | Positive feedback |
| | *Construct high pressure lattice* | **3** | Customer satisfaction [verbal] | 3D print | Positive feedback |
| **IV. Improve Utility** | *Improve Comfort of Socket* | **5** | Customer satisfaction [verbal] | 3D print | Positive feedback |
| | *Reduce cost of 3D print* | **1** | Volume of print[$mm^3$] | Minimize | 5% decrease |
| | *Less frequent doctors visit* | **1** | Time [days] | Minimize | 1 visit/year |

## Requirements

There were numerous constraints on this system that relate to the ultimate comfort of the prosthetic user, listed below in Table 2. The compression provided by the panel must not deform the socket enough to compromise the comfort of the patient. This would be directly affected by the lattice beam thickness of the 3D printed lattice, which was set to vary between 0.8mm and 1.2mm based on previous findings by Quorum's engineering team, as well as the panel geometry, which was designed to fit within the cutouts on the Quatro™ sockets. As the team's task was to further test and develop an existing design from the Quorum team, the inserts would be composed of a cost effective 3D printed material already utilized by Quorum. This particular blend was Estane 3D TPU M95A-545 provided by Lubrizol. The data sheet provided by Lubrizol is shown below in Appendix E. In terms of material properties, it was determined that the force applied to the samples would be low enough to assume the TPU samples behaved in the linear elastic region when plotted on a stress strain curve. The weight of the compression inserts could not affect the overall comfort or weight of the prosthetic. The insert must have also been able to withstand the force that the residual limb applies to the socket during motion. Numerical values had not been found for these forces as the existing panels had yet to be tested, therefore the constraints were not listed in the table below. The surface area of the panels must have also combined to match the surface area of the original insert and distribute the pressure comfortably across the residual limb.

*Table 2: Summary of Constraints*

| Constraint Name | Method of Measurement | Limitations Consistent with Measurement Method |
|---|---|---|
| Lattice Beam Thickness | [mm] | 0.8mm < x < 1.2mm [16] |
| Linear Elastic Properties | [% strain] | 0-2.5% strain [17] |
| Panel Thickness | [cm] | 2cm < x < 5cm [16] |
| Lattice Height | [mm] | 10mm < h < 30mm [16] |
| Panel Geometry | [length, mm] | Must fit into Quatro™ socket panel cutout [16] |
| Tubing Diameter | [mm] | 4.75mm [16] |
| Feels Comfortable to Patient | [survey] | 1-10 ranking, where 10 is most comfortable |

## Design Summary

Panel models were created in SolidWorks and nTopology to be run through FEA and physical testing. FEA was performed in nTopology to validate results from physical testing. After gathering data from Quorum's original panel designs, a preliminary FEA simulation was run to verify accurate physical results. The settings applied to the preliminary FEA could then be applied to subsequent simulations run on the modeled designs before they were printed to reduce the resources and time required for each iteration. The emphasis on accurate FEA before physical testing was due to the inconsistent material properties of the TPU. TPU does not display properties of typical linear elastic materials. It is well known that plastics under uniaxial load can exhibit viscoelastic behavior with properties such as creep and stress relaxation, permitted by the elastomeric bonds between copolymers in the material. These properties were difficult to incorporate into standard FEA models, and adjustments to input properties like elastic modulus and Poisson's ratio had to be considered. In order to optimize the accuracy of the FEA simulations, preliminary material testing was done on TPU samples printed with Quorum's HP Multi Jet Fusion (MJF) printer. The team modeled dogbone samples based on the dogbone geometries used in previous Materials classes, and printed 18 samples, 3 in each printing direction to assess the effects of printing direction had on material properties. These samples were tensile tested using the Mark-10 tension system in the Materials Lab at Colorado State University, along with extensometers to measure displacement and a data acquisition (DAQ) LabVIEW Visual Interface (VI) provided by Steve Johnson of the Mechanical Engineering Department.

Once the material properties of the TPU had been determined experimentally, a 20mm Body Centered Cubic (BCC) half-cell panel will be modeled in nTopology using geometries from Quorum's current panel design. An FEA compression simulation was conducted on this model utilizing the discovered properties of TPU to determine a bulk output force and stiffness, or a bulk modulus (discussed in more detail in Verification and Validation), of the panel. The Poisson's ratio had a value of .45, and a bulk modulus range of 60 - 100 MPa. A model was printed using Quorum's MJF printer for a physical compression test with the same loading parameters. The output force and the bulk modulus of the FEA simulation and physical test were then compared. The FEA was found to validate the physical testing. With this standardized simulation, lattice geometries and lattie beam thickness were changed and tested in FEA software to produce the aforementioned compressive variety.

Towards the end of semester two, the goal was to provide these panels to Quorum's customers and document their feedback. This step was crucial in the validation of the final design. The quantification of user satisfaction was to be done by a series of surveys given to customers before and after they've used the new panels. The first survey will provide a baseline metric of the comfort and proprioceptive capabilities of their current socket, and the second will evaluate these parameters after the implementation of the panels. In the long term, the cost and frequency of replacing an entire custom fit socket should be compared to the compression panel configuration to verify this model is in fact reducing cost to the customer. These surveys can be found in Appendix C and D. The surveys were created but not given to patients, due to time constraints. The proposed implementation of the survey validation can be found in the future work section.

## Design Decisions

As the team proceeded toward designing new compressive panels, the prototyping phase began. Due to the simplicity and tight constraints of the design, the lattice structure was where most of the design focus was placed. The main shape and function was restricted to perform within the aforementioned goals and objectives. As for testing the prototypes, Quorum offered to 3D print what iterations were created. The new inserts were then compression tested in the Mark-10 tension system utilizing two compression pucks. The results of these iterations are shown below in the Validation and Verification section.

### *Lattice Design*

As the lattice design was the most important factor of these compression panels, options must have been considered carefully. Although the team had the ability to print and test many designs, there was prior decision making to do in order to wisely use time and resources. The main design considerations for the lattice reflected the goals and objectives of the project. These considerations included lattice density, compressive strength, processing complexity, and cost. Lattice density was determined by how much open space was present within the lattice. Compressive strength was tested, so these values would be predictions based on Quorum's current designs. Processing complexity was related to the work required to finish off the print. This included sandblasting the print to remove excess TPU powder. Cost would be an estimate based on the amount of material used. Each of these values were given a weight, based on their significance. Each of the lattice designs were given a score of -1 to 1 for each of the criteria.

| Lattice Structure | | FCC Lattice | BCC Lattice | HCP Lattice | Honeycomb Lattice | Split P TPMS |
|---|---|---|---|---|---|---|
| Lattice Density | 30 | 0 | -1 | 0 | 1 | 1 |
| Compressive Strength | 40 | 0 | 0 | 1 | 1 | 1 |
| Processing Complexity | 20 | 1 | 1 | 1 | 0 | -1 |
| Cost | 10 | 1 | 1 | 1 | 0 | -1 |
| | Totals | 30 | 0 | 70 | 70 | 40 |

***Figure 1: Lattice Structure Decision Matrix***

From Figure 1, it can be seen that the honeycomb or the HCP lattice was hypothesized to be the best route to take. However, this matrix was not determining the final design, as the team had several designs at the conclusion of the project. Lattice density and compressive strength were also criteria that were mentioned to be minimized and maximized, depending on the testing of these lattice parameters. This matrix provided some initial foresight into the prototyping and production phase of this project.

### *Prototype Testing*

As testing the designs was just as important as the designs themselves, the testing procedure and apparatus was vital to the success of the panels. Several machines have been outlined in the following decision matrix. The criteria these machines were judged with are cost, use complexity, accuracy, and time commitment. This matrix follows the same scoring system as the previous design matrix.

| Prototype Testing | | Custom Tester | Mk-10 Tester | Spring Tester | Instron 6800 |
|---|---|---|---|---|---|
| Cost | 30 | 1 | 1 | 0 | -1 |
| Use Complexity | 10 | 1 | 0 | 1 | -1 |
| Accuracy | 30 | -1 | 0 | 0 | 1 |
| Time Commitment | 30 | 0 | -1 | -1 | -1 |
| | Totals | 10 | 0 | -20 | -40 |

***Figure 2: Prototype Testing Decision Matrix***

From Figure 2, the best option was to build a testing apparatus or to utilize the Mark-10 tester. The largest downside of the custom built model was the accuracy provided, but with solid validation and software testing, it would not have been an issue. The team had acquired materials and performed  preliminary modeling of the final product. However, after conversing with a member of the product development industry and engineer for Avid Product Development, Connor Reddington, it was determined for simplification and repeatability purposes to utilize the Mark-10 tension system available at the Materials Lab.

## Final Concept

### *Geometric Modeling*

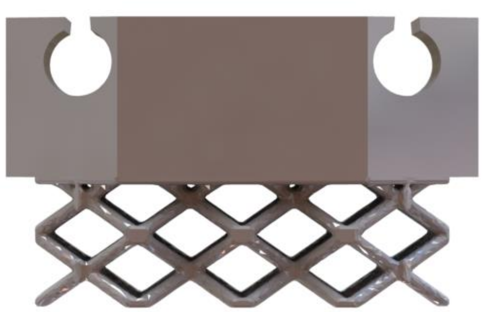


***Figure 3: Quorum Panel Model (Created in nTopology)***

CAD models of Quorum's original panel, shown in Figure 3, were provided as a reference to be recreated in SolidWorks. Initially, the idea was to reduce the file size of the nTopology .STL files and simplify the model for fast iterations in SolidWorks. However, nTopology defined the geometry and volume of the panel first, then the beam thickness of lattice unit cells, and automatically fit the lattice within the volume in a clean and efficient way. In SolidWorks, the geometry of each beam had to be drawn individually and extruded, then those extrusions had to be trimmed in order to create a solid model of the lattice. This method proved to be time consuming and complicated. Three of the attempted iterations in SolidWorks are shown below in Figure 4.

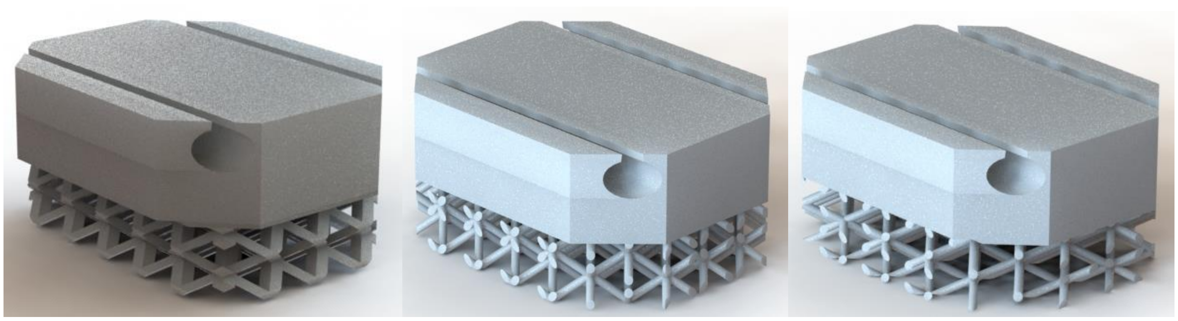


***Figure 4: SolidWorks Iterations of Panel Model and Lattice Geometry***

Considering the time constraints of this project, the team decided to move away from SolidWorks and only use nTopology for panel configuration. This allowed for faster iterations of the lattice unit cell parameters as well as beam thicknesses, and produced more accurate models. Figure 5 below shows some iterations of the final lattice geometries.

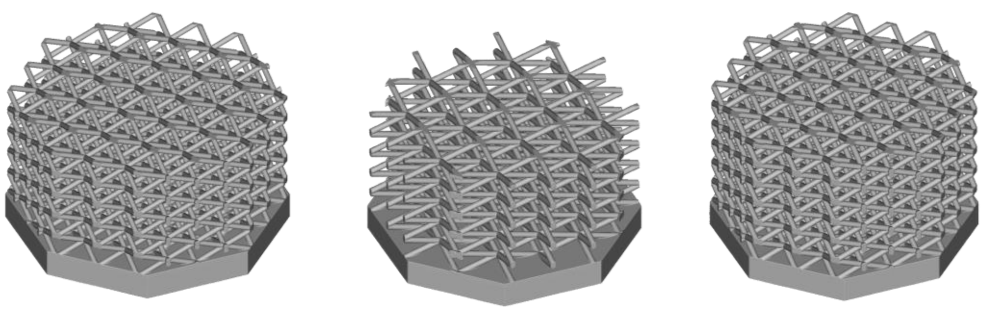


***Figure 5: nTopology Lattice Geometry Models***

## Preliminary/Feasibility Analysis

**FEA Analysis**

One of the necessary tasks of this project was to create an accurate FEA model that could be used to test both current comfort panels as well as future prototypes. Initially, the purpose of the model was to save time, materials, and allow the team to observe the effects of each panel iteration without having to print and physically test them. One problem with this method was that TPU is a unique material and does not consistently exhibit linear-elastic properties. In order to mitigate this, the team again spoke to Connor Reddington, who is familiar with Lubrizol's powdered TPU, as well as performed tensile tests on the TPU dogbone samples in order to observe and learn about its behavior. When a constant strain rate is applied, there are two distinct periods of material behavior that are observed. Initially, the sample behaved fairly linearly. The deformation (elongation due to tensile stress) increased proportionally to the stress. After a certain amount of deformation, however, the rate at which the stress increases drastically slowed, and appeared to level off as the elongation continued to increase until the sample failed. Additionally, a small change to the cross sectional area was observed, which also set this material apart from the more standard engineering materials.

After learning more about this material, it was decided that, for the purpose of FEA and this project, the material would be treated as linearly elastic and tested as such. Though this was not a truly accurate material model, the environment in which the panels were used allowed for the simplification of the material properties. It was also determined that in the setting in which these panels were to be used, the material should stay within its linear behavior region. Due to the angle of the interface between the BOA dial cables and the comfort panels, the true force applied to the panel was much lower than the actual tension in the cable, and as a result created low levels of stress in the part. Therefore, during routine use, the material should never reach the deformation limit in which the stress behavior becomes non-linear.

FEA was a powerful tool that allowed the team  to test new designs with the material properties found during material testing. The initial plan was to utilize Abaqus, as that was what the team was most familiar with. In order to test the usefulness of Abaqus for FEA, initial design files from Quorum were acquired and were run through some simple FEA tasks. However, some problems were encountered with utilizing Abaqus. The files Quorum provided, models of their current panel design, were in a .STL format. There was a significant amount of friction in properly uploading an .STL to Abaqus. The team thought that using SolidWorks in conjunction with Abaqus would help smooth out the process, but SolidWorks also had difficulty loading in the .STL's. A new route was taken in order to actually use FEA.

nTopology was a software that the team had utilized for the modeling and iteration process. nTopology had FEA capabilities, and worked well with the iterative process as the models created would already be loaded into nTopology. With this, FEA was able to be performed as soon as the models were created. The workflow for FEA in nTopology was very similar to Abaqus. It consisted of creating a mesh and boundary conditions. The bottom plate was fixed, and a pressure load was introduced to the top of the panel through a flat plate. Images of the FEA set up process are shown in Figure 6, the boundary conditions are shown on the left and an example FE mesh is seen on the right. The last step before an analysis can be run is to define material properties. Experimenting and testing the material properties in FEA was one major step for verification and validation, and will be explained later in more detail.

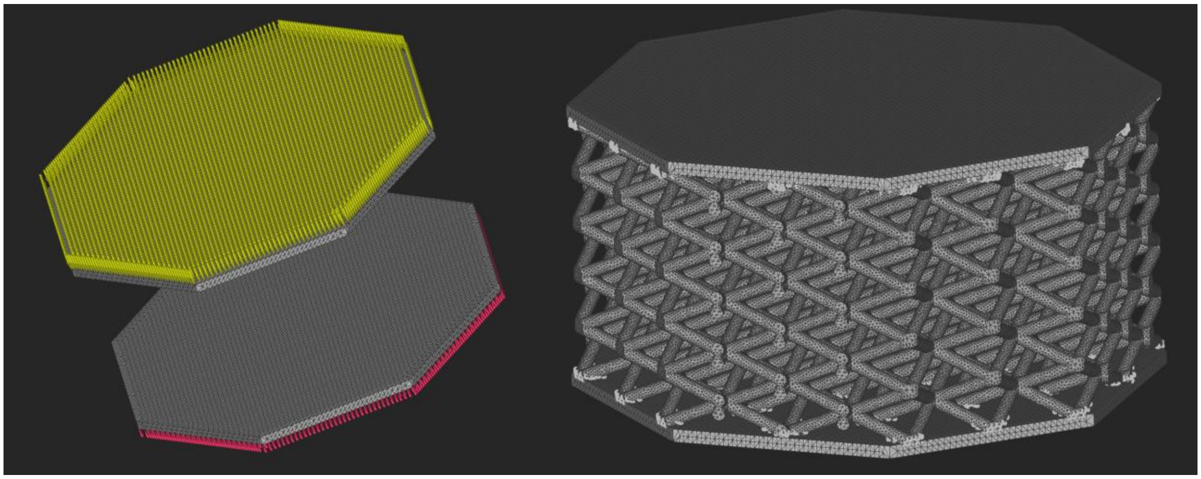


***Figure 6: nTopology FEA Set Up - Boundary Conditions & FE Mesh***

Static analysis was completed with the variables of: elastic modulus, Poisson's ratio, and force applied. Each simulation took approximately one to two minutes of run time. The output for the simulation was displacement data, along with a visualization of the displacement. Figure 7 shows an example of the output given of a static analysis.

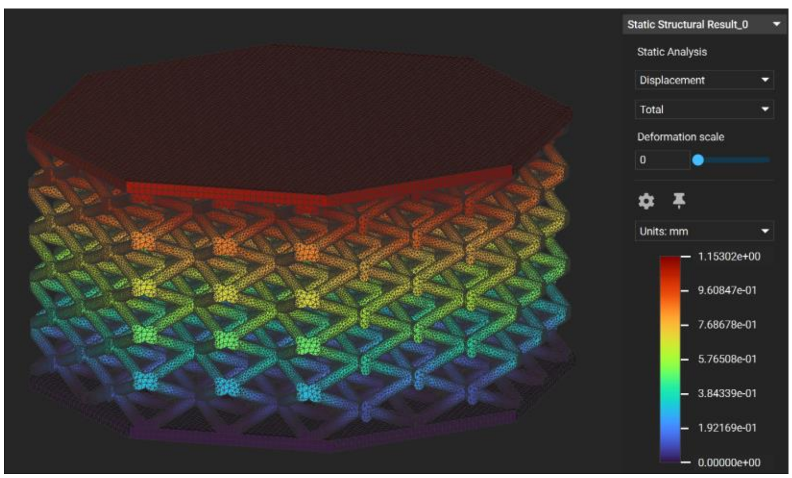



***Figure 7: nTopology FEA Results - Displacement Data & FE Mesh Visualization***

**Material Testing**

Quorum's compression panels have been 3D printed out of TPU at varying print orientations, lattice thicknesses, geometries, etc. Powder based 3D printing is a relatively new manufacturing process that is designed to reuse old filament. The combination of old and new material has a drastic effect on mechanical properties. Lubrizol's TPU blend reported most properties in a wide range of results. With lack of a standardized elastic modulus or a Poisson's ratio value, the team realized quantitative results to present to Quorum would be unattainable by research alone. To combat this, the team had 3 dogbone samples printed in 6 different printing directions to be run through tensile testing. The resulting printed samples and their designated print directions are shown in Figures 8 and 9.


***Figure 8: Completed 3D Printed Dogbone Samples***

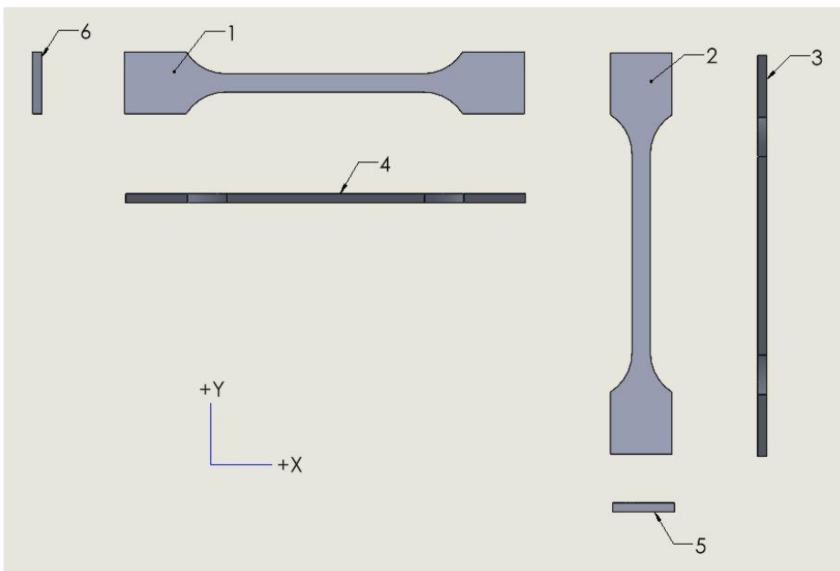



***Figure 9: CAD drawing of dogbone samples in 6 different printing orientations***

In order to assure that the nonlinear properties of TPU were not being incorporated into the material testing, only data from the first 2.5% of the strain range would be used. At this range, only linear elastic properties would be observed. The Mark-10 tension system setup in the CSU Materials Lab is shown in Figure 10.

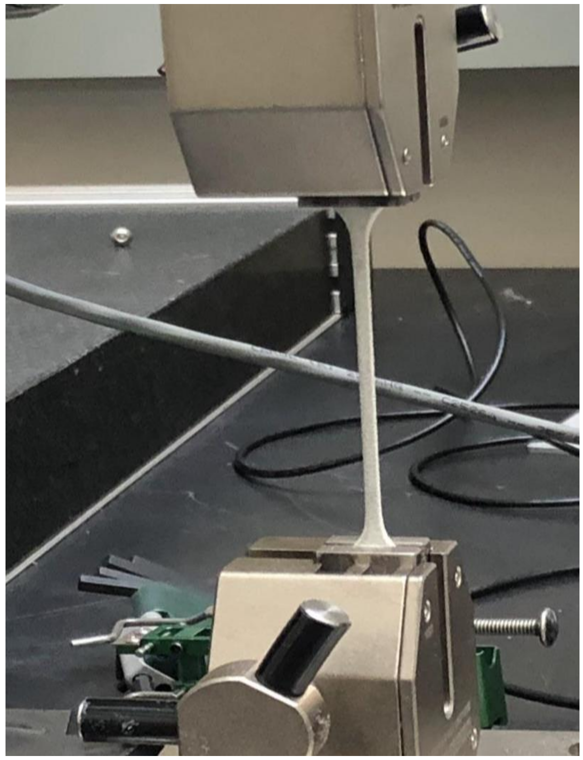


***Figure 10: Preliminary Tensile Testing of Dogbone Samples***

Using the global displacement (d), initial gauge length (L), force (F), and Cross Sectional Area (CSA), the stress ($\sigma$) and strain ($\epsilon$) values were calculated using the Equations 1 and 2, respectively.

1) $$\sigma = F/CSA$$

2) $$\epsilon = \frac{\Delta l}{l}$$

The data from the Mark-10 tensile test was used to create a stress versus strain plot as well as generate an elastic modulus equation (E), Poisson's ratio ($\nu$), and statistical evaluation. These equations are shown in Equations 3 and 4.

3) $$E = \frac{\Delta\sigma}{\Delta\varepsilon}$$

4) $$\nu = -\frac{\varepsilon_{transverse}}{\varepsilon_{axial}}$$

Using Equation 3 above, the elastic modulus was calculated for each sample by finding the slope of the line of best fit applied to the stress versus strain plot. Similarly, the Poisson's ratio for each sample was calculated by using Equation 4 to relate the axial strain, which was calculated from measurements of the initial and final lengths of the sample, to the transverse strain, which was calculated from measurements of the initial and final width of the sample. Using these calculated mechanical property values, a simple FEA simulation could be constructed. If they varied by any significant amount, more testing was performed in order to ascertain which print direction was most reasonable to serve as a realistic material model for the comfort panels.

### *Risk Analysis*

## Failure Modes and Effects Analysis (FMEA)

An in-depth risk analysis was performed to identify the major processes involved in the project that could potentially result in failure and affect the success of the compression panel design. The processes of highest risk included patient comfort and safety, the lattice and geometric properties of the panel, and the custom testing apparatus. Throughout the semester, each of the identified failure modes were ranked on a 1-10 scale on severity, occurrence, and detection consistent with the guidelines listed by the FDA. On this scale, 1 is ranked the lowest and 10 the highest for both severity and occurrence. For detection, the scale is ranked as 1 being the easiest to identify and 10 being the most difficult to identify. Table 3 below highlights the 'Patients Thoughts and Comfort Level' failure process. As the team progressed through further tasks in the spring semester, the 'Actions Taken' column was filled and risk priority numbers (RPN) were updated. If no actions were taken to combat these identified failures, the rightmost updated RPN column matched the leftmost preliminary RPN. The full FMEA table is shown in Appendix B.

***Table 3: Failure Mode and Effects Analysis at End of Semester 2***

| Process Step/Input | Potential Failure Mode | Potential Failure Effects | SEVERITY (1 - 10) | Potential Causes | OCCURRENCE (1 - 10) | Current Controls | DETECTION (1 - 10) | RPN | Action Recommended | Resp. | Actions Taken | SEVERITY (1 - 10) | OCCURRENCE (1 - 10) | DETECTION (1 - 10) | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| What is the process step, change or feature under investigation? | In what ways could the step, change or feature go wrong? | What is the impact on the customer if this failure is not prevented or corrected? | | What causes the step, change or feature to go wrong? (how could it occur?) | | What controls exist that either prevent or detect the failure? | | | What are the recommended actions for reducing the occurrence of the cause or improving detection? | Who is responsible for making sure the actions are completed? | What actions were completed (and when) with respect to the RPN? | | | | |
| Patient Thoughts and Comfort Level | The patient says the insert is uncomfortable | The patient is uncomfortable | 6 | The lattice provides too much compression | 5 | Varying lattice thickness and geometries | 2 | 60 | Provide patients with numerous insert options | Team | Preliminary Survey finalized 12/12/21 | 6 | 5 | 1 | 30 |
| | | | 6 | The lattice provides too little compression | 5 | Varying lattice thickness and geometries | 2 | 60 | Provide patients with numerous insert options | Team | Preliminary Survey finalized 12/12/21 | 6 | 5 | 1 | 30 |
| | The patient's residual limb is left bruised | The patient is uncomfortable | 6 | The lattice is too thick and the BOA dial gives too much pressure | 5 | Varying lattice thickness and geometries | 2 | 60 | Provide patients with numerous insert options | Team | Preliminary Survey finalized 12/12/21 | 6 | 5 | 1 | 30 |
| | | | 6 | | 5 | BOA dial system allows constant adjustability | 2 | 60 | Provide BOA dial demonstration | Prosthetist/Orthotist | Final survey to be provided (future work) | 6 | 5 | 2 | 60 |
| | The patient's skin is rubbed raw from insert | The patient is uncomfortable | 6 | The inserts move too much in the BOA dial system, resulting in friction | 5 | Varying lattice thickness and geometries | 2 | 60 | Provide patients with numerous insert options | Team | Preliminary Survey finalized 12/12/21 | 6 | 5 | 1 | 30 |
| | | | 6 | | 5 | BOA dial system allows constant adjustability | 2 | 60 | Provide BOA dial demonstration | Prosthetist/Orthotist | Final survey to be provided (future work) | 6 | 5 | 2 | 60 |

## Human Factors Analysis

A human factors analysis was conducted in concurrence with the FMEA. The purpose of this analysis was to identified how human error, from both the amputee as well as the prosthetist, could reduce the overall safety of the compression inserts and the Quatro™ system that they are to be implemented in. By completing this analysis, the team identified potential problems that users could face during the implementation of the product and worked to combat their occurrence before they become an issue.

Figure 11 below illustrates the full human factors analysis for the compression panels. The people in closest contact with the inserts will be both patients and prosthetists already acquainted with the amount of fitting, training, safety, and practice involved with the Quatro™

BOA dial system. However, there is still room for error when used by untrained or under-practiced individuals. Most errors are subject to be performed by the patients as they have the freedom to consistently adjust the BOA dial and switch out compression inserts as they please. The prosthetist has minimal contact with the inserts, but must be familiar with their implementation as well as able to describe in detail the scenarios in which the patients should switch out an insert for a more or less compressive option.

Both patients and prosthetists are subject to skills based, decision based, and perceptual error during the implementation of these inserts. Patients are also subject to both routine and exception violation, where prosthetists are subject to only routine violation. Examples of these errors and violations are listed below.

- *Skills Based Errors*
  Patient - failure to tighten BOA dial properly
  Prosthetist - failure to form socket correctly, failure to check settings of BOA dial system
- *Decision Based Errors*
  Patient - choosing the wrong compression inserts for needs
  Prosthetist - recommending too high or too low of compressibility
- *Perceptual Errors*
  Patient - confusion of symptoms
  Prosthetist - incorrect settings due to inaccurate diagnosis
- *Routine Violations*
  Patient - failure to use socket as specified, consistent over tightening of BOA dial
  Prosthetist - failure to meet training requirement for administering socket
- *Exceptional Violations*
  Patient - use of socket for procedure outside of determined purpose

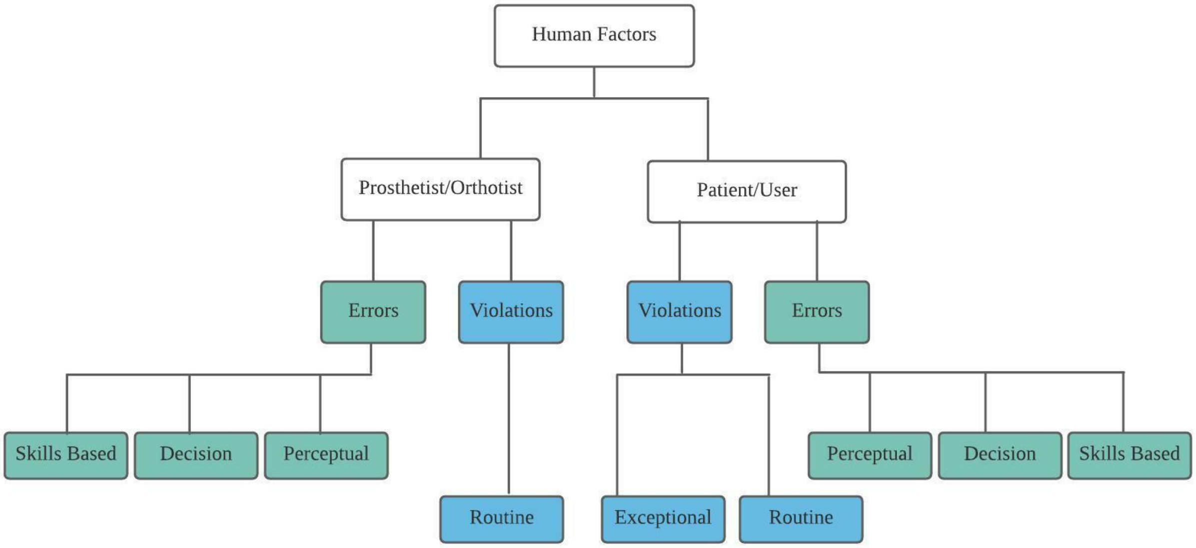



***Figure 11: Human Factors Analysis Flow Chart***

### *Design for X*

One of the most important aspects of the design of the compression panels was reliability. The parts were simple in manufacturing terms, however were to be in constant use, ergo reliability was key. Producing them was quick in terms of time to print, but the design was much more complicated. The lattice structure was the main design that affected the reliability of the panels. Reliability in this case was summarized as the lifespan of the panel. As outlined in a report on designing for reliability, the first step was to test the current designs [5]. This could have been achieved by using standard fatigue and creep testing. A quantitative reliability goal needed to be set for these tests, a target lifespan. If the designs failed, there were several methods to improve the reliability. These methods however ventured quite in-depth and required many resources unavailable to the group. For this reason, the team assessed reliability on a much smaller scale. If there were extra time and resources near the conclusion of the project, it was mentioned as something to be looked into, but was a low priority goal.

Other design aspects such as cost, manufacturability, safety, and usability were considered. However many of these aspects didn't have a large impact on the user or manufacturer due to the simple, low-risk design. Cost was a set value, where the only significant factors  were the amount of printing material and necessary processing post-print. Less material was ideal, but the cost difference was ignored at the scale of which these panels were produced. Safety was an important factor to take into consideration in the design process, but as seen in the FMEA the worst case scenario was some chafing and mild irritation. Manufacturability was developed for the initial design, with MJF printing. This meant that no matter the complexity of the design, it could be made. Tolerancing in this matter was also taken care of, as the tolerances were small and fixed. Usability was intended to be taught to the user, however there were some ideas brainstormed to see improvement in this category in the future. A guide to go with the panels was also thought to be beneficial to some patients. The action of removing / replacing the panel onto the BOA cable proved to be slightly difficult when new to the team. Streamlining this process was a future directive for this product.

### *Primary Components and Budget*

***Table 4: Current Project Budget Detailing Cost per Part, Number of Parts Required, Distributors, and Total Cost Including Tax and Shipping***

| Part | Price Per Unit | # of Units Required | Total Price | Vendor / Part Number |
|---|---|---|---|---|
| Husky 6" Drop Forged C-Clamp | $14.98 | 1 | $14.98 | Home Depot / 97894 |
| 1" 2 Hole Pipe Hanger Strap (4 pack) | $1.73 | 1 | $1.73 | Home Depot / 33544 |
| 2"x 8"x 36" Plain Steel Bar | $9.86 | 1 | $9.86 | Home Depot / 801807 |
| 2" Zinc Plated Mending Plate (4 pack) | $2.88 | 1 | $2.88 | Home Depot /15299 |
| #10 x 3.5" Bugle Head Construction Screws | $9.97 / lb | 1 lb | $9.97 | Home Depot / 312GCS1 |
| 2" x 4" x 8' Pine Pressure Treated Lumber | $11.77 | 2 | $11.77 | Home Depot / 332398 |
| 50 kg Strain Gage Load Cells (4 pack) | $8.95, ($5.99 shipping) | 2 | $23.89 | Amazon / WD1802AX4 |
| Team T-shirts | $52.91 | 5 | $264.55 | CSU Bookstore |
| **Total cost (tax and shipping included):** | | | **$351.10** | |

Above, Table 4 details the money that has been allotted to the team to be spent on parts and required materials. This consisted only of components that were to be used to build the testing apparatus as well as team t-shirts that were worn during final presentations at Engineering Days (E-Days). The parts that were purchased were the 2 by 4 pine beams to create the framework for the testing apparatus, the C-clamp that was to be used as the force applying component, the load cells that were to read output force, and hardware and fixtures such as the wood screws or zinc plated mending plates that were tobe used to assemble the base and framework, as well as affix the C-clamp and sensors to said framework. There were also materials / labor / softwares that weren't included in the budget that the team already had or thought to eventually need in order to complete the project. First of these were SolidWorks 2020 and nTopology, both of which are 3D modeling softwares that were used to create model panels for FEA and 3D printing. In addition, the team attempted to use Abaqus FEA software to test altered panels before printing. Finally, there was the material cost for the TPU that the comfort panels were made of. These softwares / materials incurred no cost pertaining to the project as the team had been granted access through other means. Access to SolidWorks and Abaqus was free to Colorado State University students, and Quorum covered the material costs of TPU, as well as allowed the team access to nTopology from their work stations. With a starting budget of $1000, the team had plenty of funding to account for new designs or emergency purchases.

Near the end of the first semester, it was determined that the creation of a testing apparatus was unnecessary, as the team decided to utilize the Mark-10 system in the Materials Lab to perform both material testing and compression testing. The same Virtual Instrument (VI) was able to be used to record data in the form of stress versus strain and force versus global displacement. This greatly simplified these tasks and reduced both the budget and time spent on testing, as construction and coding of the system were already complete.

## Verification and Validation (Design and Prototype Evaluation)

Once the final design concept was completed, each objective was performed and their results scrutinized under simulated and physical testing conditions. To confirm that the objectives were met within their respective constraints, various validation methods were used and the results documented.

### *I. Material Testing and Documentation*

| Objective | Validation Method |
|---|---|
| Document material properties for TPU | Consult with Steve Johnson and other Mechanical Engineering department members to ensure proper testing methods.<br>Perform mechanical testing on 6 print directions to evaluate the effect of print direction on material properties. |

One of the primary goals of this project was to report accurate material properties for TPU and boundary conditions to be used with FEA to simulate how the comfort panels were to be used in a Quatro™ socket. To do this, the material was first tested in tension in order to calculate and record the material properties required by the program. Once these results were found, they were compared to the results of the FEA simulation to assess its validity and accuracy. The main constraint determining the success of this objective was the assumption that TPU would be operating in a linear elastic region. Because the forces were so minimal on the residual limb when used in the BOA dial system, a strain range of 0-2.5% was sufficient to gather mechanical property data.

| Constraint Name | Method of Measurement | Limitations Consistent with Measurement Method |
|---|---|---|
| Linear Elastic Properties | [% strain] | 0-2.5% strain [17] |

Due to the wide range of the mechanical properties of TPU, the team conducted 3 different rounds of material testing of dogbone samples in tension. Samples were printed in 6 different print directions and data was recorded and analyzed for the linear elastic region of the material.It was assumed, due to the unknowns of the material, that the lattice structures would behave the same in both tension and compression.

The dogbone samples were labeled with their respective print directions and sorted in piles. Because the material was so malleable and inconsistent, the extensometer was not placed on the samples during the testing to avoid notching or bending the samples at the attachment points. The gauge length (the length between the Mark-10 attachment grips) was recorded as well as the initial thickness of the sample. Due to the small size of the samples, the CSA was assumed to be 4.5 $mm^2$ as designed in SolidWorks. The sample was tested at a strain rate of 0.1 mm/sec to reach a certain overall displacement for the first and second rounds of testing and a 2.5% strain reading for the third round. The data was then exported to Microsoft Excel to perform an in-depth analysis.

Using Equations 1 through 4, the stress, strain, and Poisson's ratio were calculated and reported. The data analysis was run from the first non-negative force reading and was completed at the force of the maximum displacement.

After generating results from the first round of testing, it was found that many of the samples had inconsistent data due to human error of non-zeroing of the displacement during some of the samples. Additionally, the overall lateral displacement reading was not recorded after each sample. This meant that not only was there a wide range of elastic modulus values for samples of the same print direction, but also that the Poisson's ratio could not be calculated.

In the second round of tensile testing, the team also took measurements up to a 5mm displacement. The initial and final width of the dogbone samples were recorded at the beginning and then end of each sample run. The elastic modulus was then calculated by running a linear regression through the first 50 non-negative global displacements and their respective stress and strain values. These 50 data points were chosen as they ensured that the elastic modulus would be calculated in a linear region of the stress-strain curve. The average stress-strain curve looked similar to the one shown below in Figure 12. The Poisson's ratio was then calculated. The data reflected Poisson's ratios to be significantly larger than 1. This raised red flags, as this implied that the material stretched more in the transverse direction than in the longitudinal direction. The team had identified that powder TPU was already a unique material and was unsure whether this result was consistent with any reported Poisson's ratio values. Upon further research, it was determined that most TPU samples fall in a Poisson's ratio range of 0.45-0.48 [18].

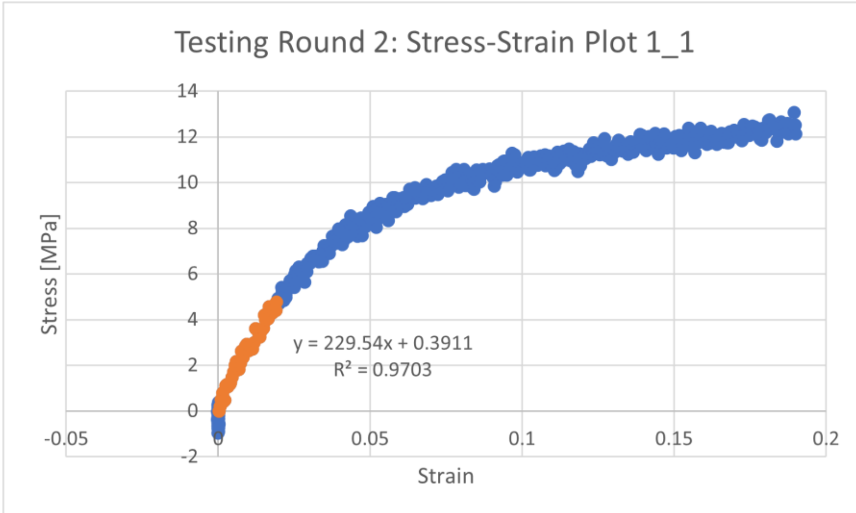



***Figure 12: Material Testing Round 2, Stress-Strain Plot of Print Direction 1, Sample 1***

In an early brainstorming session, it was determined that in the second round of testing the transverse strain measurements were taken at the beginning and end of each test. This meant that after 5 mm of displacement, plastic deformation of TPU was already well underway, and resulted in the transverse strain no longer being measured under the linear elastic assumption. This explained the Poisson's ratios well above 1. Connor Reddington confirmed the team's thinking and suggested to only run samples within a 2.5% strain range. With this knowledge, a third round of tensile testing was determined to be necessary.

In the third round of tensile testing, the team took displacement data only up to 2.5% of the strain range. The gauge length, initial width and final width were measured twice by two different team members, and a total of 18 samples were tested. The same stress-strain plot, elastic modulus, and Poisson's ratio calculations were performed as the second round of testing. The initial and final width were both measured twice by two separate team members due to how tough it was to measure the samples accurately with their rubbery physical properties. It was assumed that the main error in calculation came from inaccurate physical measurements due to human error. Statistical analysis was also performed to remove any outliers from each data set. In Table 5, the results of the third and final round of material testing are shown.

**Table 5 : Results of Third Round of Material Testing of TPU**

| Sample Number | | Linear Regression Eq | R-Squared Value | Average E | Width Initial (mm) | Width Final (mm) | Final Strain Poisson's Ratio | Average Poisson's (Final Strain at Max Displacement) |
|---|---|---|---|---|---|---|---|---|
| 1 | 1 | y = 86.41x + 0.4108 | 0.84 | 78.031 | 3.41 | 3.36 | 0.558815374 | 0.673180988 |
| | 2 | y = 82.454x + 0.3991 | 0.8518 | | 3.42 | 3.37 | 0.5911083589 | |
| | *3 | y = 65.229x + 0.1428 | 0.8441 | | 3.4 | 3.33 | 0.869619231 | |
| 2 | 1 | y = 87.16x + 0.2392 | 0.8702 | 87.99666667 | 3.37 | 3.29 | 0.9096050427 | 0.8498360867 |
| | 2 | y = 88.2x + 0.2358 | 0.8776 | | 3.41 | 3.32 | 1.048754744 | |
| | 3 | y = 87.288x + 0.297 | 0.9032 | | 3.38 | 3.33 | 0.5911484738 | |
| 3 | 1 | y = 93.939x + 0.3885 | 0.9237 | 94.16533333 | 3.32 | 3.3 | 0.2472539971 | 0.447149645 |
| | 2 | y = 94.389x + 0.2827 | 0.8953 | | 3.29 | 3.27 | 0.2440200448 | |
| | 3 | y = 94.168x + 0.1421 | 0.9056 | | 3.32 | 3.25 | 0.8501748931 | |
| 4 | 1 | y = 99.293x + 0.205 | 0.8982 | 97.718 | 3.39 | 3.28 | 1.333513236 | 1.14801928 |
| | 2 | y = 96.837x + 0.4575 | 0.8978 | | 3.37 | 3.33 | 0.4810308491 | |
| | 3 | y = 97.024x + 0.1121 | 0.9369 | | 3.36 | 3.22 | 1.629513753 | |
| 5 | *1 | y = 68.379x + 0.0066 | 0.8162 | 70.875 | 3.15 | 3.09 | 0.7669358612 | 0.7851311495 |
| | *2 | y = 72.01x - 0.021 | 0.8414 | | 3.15 | 3.08 | 0.9246160532 | |
| | *3 | y = 72.236x + 0.0885 | 0.871 | | 3.14 | 3.09 | 0.6638415341 | |
| 6 | *1 | y = 66.293x + 0.1379 | 0.8424 | 63.34333333 | 3.15 | 3.07 | 1.055298986 | 0.7932937076 |
| | *2 | y = 57.031x + 0.2667 | 0.7329 | | 3.13 | 3.08 | 0.8300998178 | |
| | 3 | y = 66.706x + 0.2692 | 0.8641 | | 3.14 | 3.1 | 0.494482319 | |
| * - implies that outliers needed to be removed from the data set and new trendline is provided in the table | | | | | | | | |

As shown in Table 5, the average elastic modulus and Poisson's ratio were calculated for each individual sample and then averaged to provide singular values for each print direction. As shown in Figure 12, the elastic modulus of the first sample of the first print direction of the second round of testing was 229.54 MPa. In Figure 13 below, the results of the third round of testing on the same sample set up was 86.41 MPa. This difference was consistent in all collected third round data. The stress-strain plots from the third round of testing can be found in Appendix F. The elastic moduli ranged from approximately 60 MPa to 100 MPa, which was drastically different from the results generated in the second round of testing. The Poisson's ratio changed drastically with each print direction. According to research referenced by Peter Jung of Lubrizol, TPU has a Poisson's ratio on first loading of 0.45 ± 0.005 [18]. For this reason, the data from print direction 3 was used to guide an initial FEA simulation as it most closely matched the published data that was available. The reason that the mechanical properties ranged so much between print directions and samples was because of the lack of repeatability available in powder based 3D printing as well as the differing print orientations. MJF printers were designed to reclaim powder after a print and reuse it in newer prints. That meant that some powder used in prints had most likely already been inside the printer and processed. Though the powder particles may not have been joined with the adhesive, they were still inside the print and packed tightly together at a high temperature, which could have potentially affected their overall properties. Similarly, the way that each print was oriented while in the print bed affected the mechanical properties. If printed at the traditional x, y,and z axis, the elastic modulus was significantly higher than in the samples 5, and 6, which were printed at offset angles from the traditional axes.

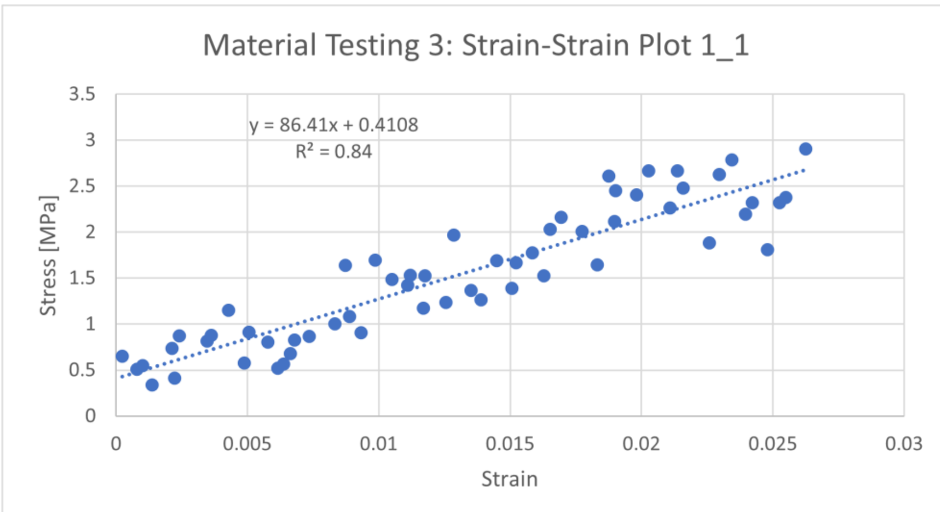



*Figure 13: Material Testing Round 3, Stress-Strain Plot of Print Direction 1, Sample 1*

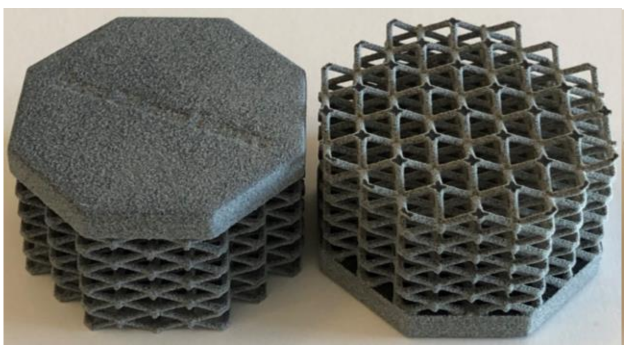
### *II. Develop Standardized FEA Simulation and Panel Testing Procedure*

| Objective | Validation Method |
|---|---|
| Develop Standardized FEA Simulation and Panel Testing Procedure | Utilizing both physical testing and software simulations to test panels for compressive value. |

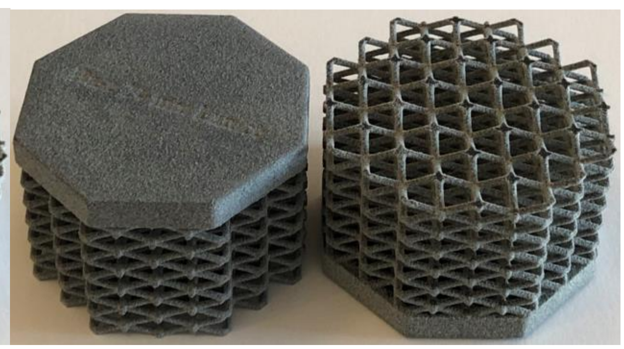
As previously discussed, FEA simulations were to be used to evaluate current panel configurations and design new ones. Once a Poisson's ratio and range of elastic moduli had been established through material testing, a simple FEA simulation was constructed in nTopology of Quorum's base 20 mm thick panel, shown in Figure 3. However, because the elastic modulus ranged from 60 MPa to 100 MPa, accurate simulation results could not be produced. The team decided that physical compression testing on printed panels should be performed to narrow the range of moduli.

| Constraint Name | Method of Measurement | Limitations Consistent with Measurement Method |
|---|---|---|
| Linear Elastic Properties | [% strain] | 0-2.5% strain [17] |

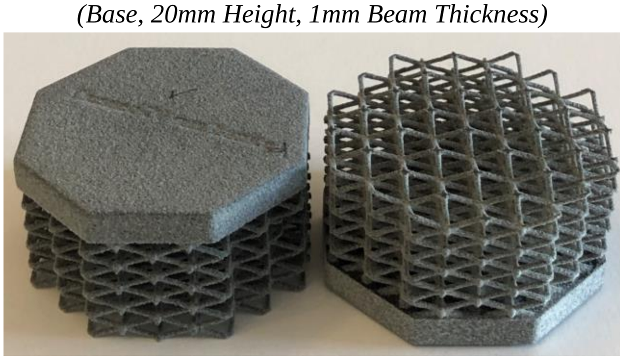
Before the compression tests, 12 panels were printed (2 of each variation) with varying lattice heights, beam thicknesses, unit cell sizes (denoted as UVW count), and lattice structures, as shown below in Figure 14. The BOA tubes were removed from the models as they had no effect on force data as well as increased print time. They would be able to be added back to the model and print at any time after testing.



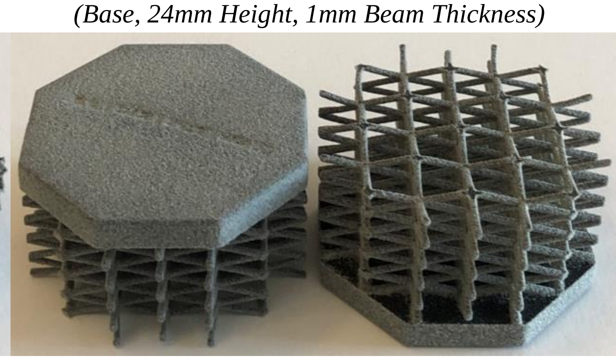
*(Base, 20mm Height, 1mm Beam Thickness)*



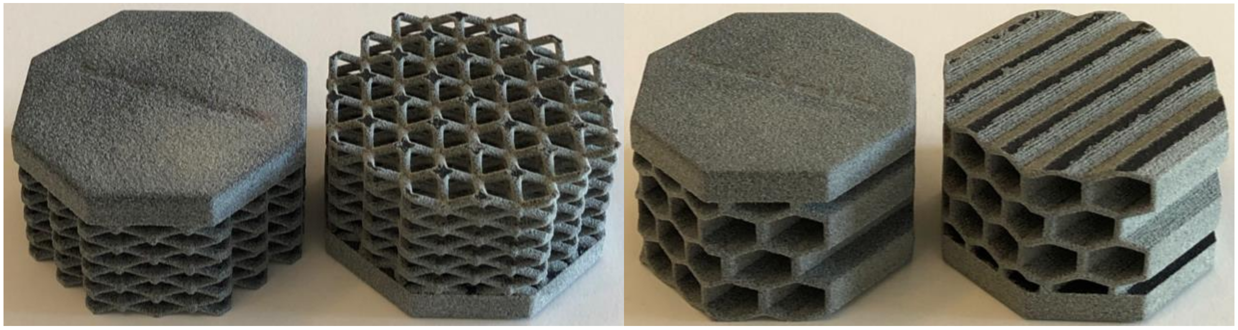
*(Base, 24mm Height, 1mm Beam Thickness)*



*(Thin, 20mm Height, 0.8mm Beam Thickness)*



*(Lower UVW, 20mm Height, 1mm Beam Thickness)*



*(Thick, 20mm Height, 1.2mm Beam Thickness)* *(Hexagonal, 20mm Height)*

***Figure 14: Compression Test Samples***

Using the Mark-10 system, each panel was manually loaded in compression until the lattice could not displace any further. Data was recorded for the force applied to each panel versus the resulting displacement, and was plotted in Excel. Each plot displayed a linear region where the change in applied force was proportional to the change in displacement. The linear region of each plot was fitted with a linear trendline, an arbitrary input force was chosen within this linear region (either 15N or 40N, depending on the range of the data), and the resulting displacement was estimated using the trendline equation. These displacement values represent the physical displacement of each panel variation for a given input force, and are referenced in Appendix G.

In order to narrow the range of moduli from the material testing phase, FEA simulations were created for each panel variation. Using a fixed Poisson's ratio of 0.45, multiple simulations were run on each panel variation with varying moduli from 50-100MPa, and a constant input force was determined by the linear region found in the physical compression tests. The resulting output displacements were recorded and plotted against their corresponding modulus values. A trendline was applied to each displacement versus modulus plot, and it was discovered that the relationship between output displacement and elastic modulus was most similar to a power function, as seen in Figure 15 below.

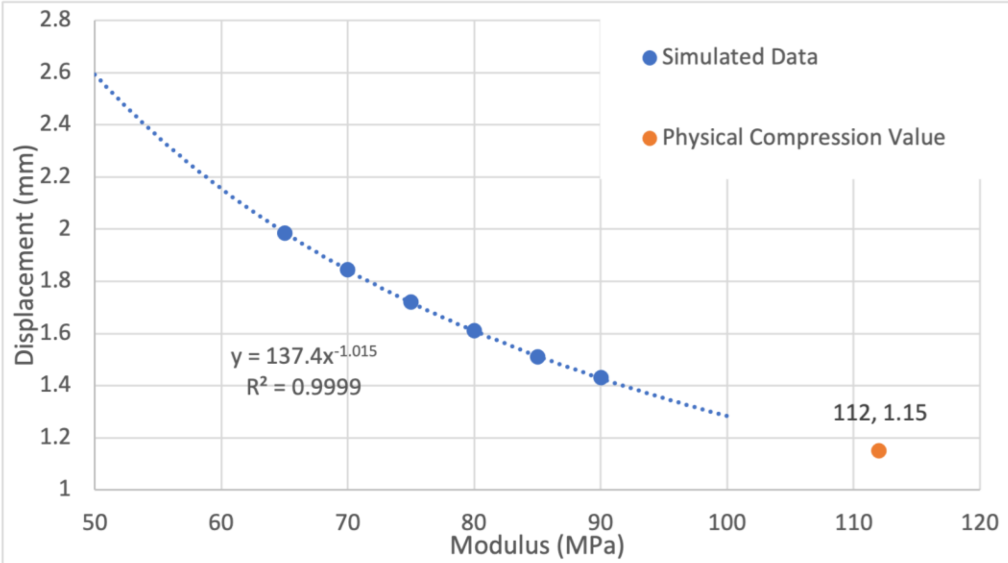


***Figure 15: Base, 20mm Height, 1mm Beam Thickness, Modulus-Displacement Plot***

The physical displacement values found during compression were then input into the power functions, and "physical modulus" values were extrapolated for each panel variation. Before these values were found, the team hypothesized that the moduli of the TPU would be independent of the lattice structure and within the range of moduli found during the material testing phase, between 60 - 100MPa. However, this hypothesis could not be substantiated as the modulus values found in this compression phase now ranged from 41.05 - 148MPa.

The team determined that the difference in "physical moduli" between each panel variation must be related to the lattice configuration as well as the TPU material properties, and chose to pursue a relationship between the design constraints controlling the lattice design and the FEA elastic modulus input parameter. This parameter describing the material as well as the lattice configuration was defined as the "bulk modulus", and is specific to each panel variation.

During the design of the panel variations, only one design constraint was altered per panel (i.e. beam thickness, UVW count, lattice height, etc.) to determine the dependence of lattice geometry on compressive strength. This became useful as the team plotted the bulk modulus values against different design constraints, such as beam thickness, as seen in Figure 16 below.

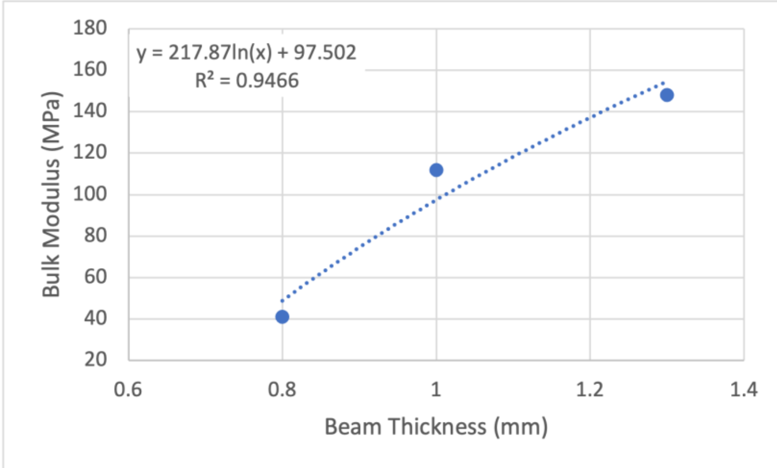



*Figure 16: Bulk Modulus vs. Beam Thickness*

This relationship between the designed beam thickness and the bulk modulus, along with others (Appendix H) became the primary vehicle for producing further designs. To produce more designs with different levels of compressive strength, the group selected two bulk moduli values ⅓ and ⅔ between the smallest and original beam thicknesses: 0.8 mm and 1 mm, respectively. These values were calculated to be 64.7 and 88.35 MPa, and from there, the power trendline equation was used to calculate the corresponding beam thicknesses, shown in Figure 17.

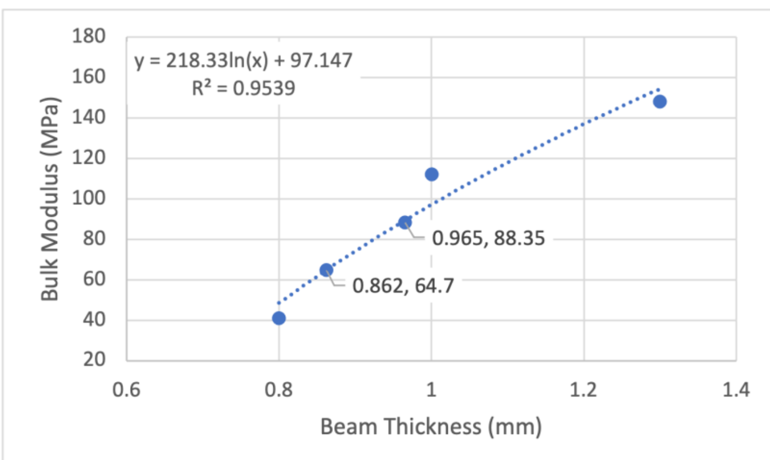



*Figure 17: Bulk Modulus vs. Beam Thickness, New Data*

These new values for beam thickness were then used to design two new panels with correlating levels of compression.

### *III. Improve Customizability*

| Objective | Validation Method |
|---|---|

| | |
|---|---|
| Improve Customizability | Completing several designs that provide a range of compressive values available to the patient. The team can also consult prosthetists for data about which panels are chosen by patients. |

With Quorum's base panel, one of the major goals was to make new designs that allowed a range of options available to the patient. In order to verify this goal, the team wanted printed designs, or at least models. With the modeling capabilities of nTopology, several new designs were made and printed. From the base lattice, several parameters were adjusted: beam thickness, unit cell size, and lattice type. Figure 18 below shows some of the designs created in nTopology.

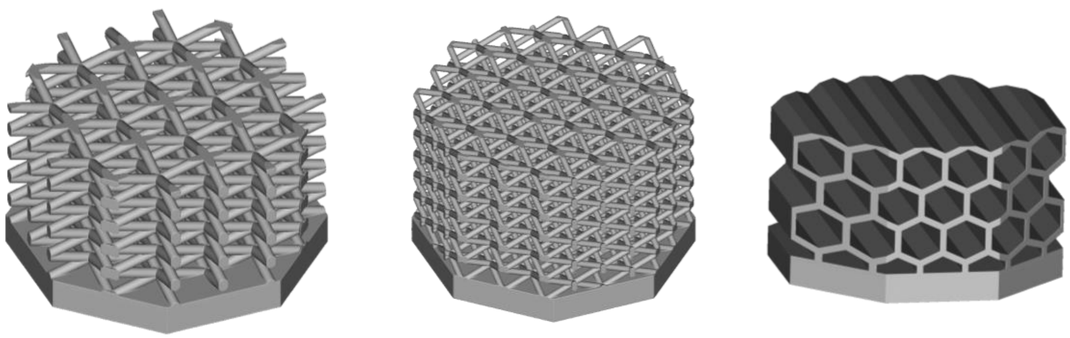


***Figure 18: nTopology Renders of New Lattice Designs.***

| **Constraint Name** | **Method of Measurement** | **Limitations Consistent with Measurement Method** |
|---|---|---|
| Lattice Beam Thickness | [mm] | 0.8mm < x < 1.2mm [16] |
| Panel Thickness | [cm] | 2cm < x < 5cm [1] |
| Panel Geometry | [length, mm] | Must fit into Quatro™ socket panel cutout [1] |
| Tubing Diameter | [mm] | 4.75mm [1] |
| Lattice Height | [mm] | 10mm < h < 30mm [1] |

In nTopology, a lattice was generated by a list of inputs and adjusted within the same list. This made changing one parameter at a time the easiest way to experiment with new designs. The beam thickness was the simplest parameter to change, which allowed the team to create a working relationship between the bulk modulus and the beam thickness. These changes were also limited by the printer's resolution and other constraints, and had to stay within 0.8 mm and 1.2 mm. Adjusting the unit cell size was not as simple. The bounding dimensions of the lattice were determined by the geometry of the base (the octogonal platform the lattice sat on) which was set by Quorum and could not be changed. To keep the base geometry within the constraints, a test base was designed for the prototype lattice structures without the BOA cable tubing to ensure accuracy between physical compression and FEA results. The lattice was trimmed to fit the base, and changing the unit cell size could cause issues with this process. If the unit cell size did not fit well within the base geometry, the edges of the lattice would have been made of unfinished cells. This was avoided, as it could have compromised the structural integrity of the lattice. The design with a larger unit cell size was made by scaling the base cell size up by two, which ensured the lattice would properly fit on the base geometry. For the given BCC lattice, doubling the unit cell was the only adjustment that could have been made to the unit cell size. Some new lattice types were explored as well, such as the hexagonal lattice shown in Figure 18 (right). However, his lattice did not work for Quorum's application due to its substantially large rigidity. Although other lattice types were explored, the issue of unit cells not properly fitting the base geometry persisted. Even with only a few working designs, the team was able to find variables that were easily adjustable. This led the team to the final designs with variable beam thicknesses.

After the first round of printing new designs, some feedback was given by the prosthetists. The base 20 mm height, 1 mm beam thickness lattice was the stiffest they wanted the panels to go. This provided some challenge to creating new designs. It was much simpler to increase the stiffness of the panels than it was to decrease. Decreasing the stiffness of the panels could be achieved by decreasing the beam thickness and increasing the unit cell size. The beam thickness could not go much lower than the 1 mm thickness of the base design, due to the fragility of the beams at that thickness and the resolution of the printer. This gave the team a small range to work within: 0.8 mm to 1 mm. However, the bulk modulus could be adjusted enough within this range.

Final designs of 0.862 mm and 0.965 mm beam thicknesses proved to be much softer than the 1 mm beam thickness. Many people were asked to handle these panels, and everyone was able to discern a difference in the stiffness of each. With this final test, the team achieved the original goal of creating designs that allowed patients to choose from several options.

### *IV. Improve Utility*

| Objective | Validation Method |
|---|---|
| Improve Utility | Talk to Quorum clinicians and customers through a two-part survey to compare the overall cost of the socket with the panels to a traditional socket, the frequency of socket adjustment appointments, and the difference in material and manufacturing costs. |

Another form of validation that the team utilized was a survey. An initial and end survey was intended to be sent to Quorum's customers. The initial survey would have asked about their current socket and what kind of adjustments they make on the daily. This would have allowed the team to understand their current comfort levels, how long they were able to wear their socket, and if they experienced any pain. There were several questions acknowledging the user's stability and proprioception due to their importance to the user's comfort. The end survey would have then been given to Quorum's customers after they had been able to use the new compression inserts for some time. Similar questions would have been asked considering their comfort, stability, proprioception, and the adjustments that they made using their new inserts.

| Constraint Name | Method of Measurement | Limitations Consistent with Measurement Method |
|---|---|---|
| Feels Comfortable to Patient | 1-10 ranking, where 10 is most comfortable | Survey data will be analyzed to determine the overall comfort felt by the patient. |

The initial and end surveys would have allowed the team to validate the project on a customer based level. Unfortunately, due to time and health restrictions, these surveys were not able to be sent out to customers. This will be addressed in the future work section. The completed initial survey and final survey are provided in Appendix C and D.

## Contextual Considerations

The Access Prosthetics article states that there are more than 1 million limb amputations globally which can be equated to approximately one amputation every 30 seconds [19]. These statistics are able to show how the teams' work in conjunction with Quorum Prosthetics to create a more customer oriented lower limb socket will have a positive societal impact. By creating the Quatro™ socket, the user is able to have a more adaptable and customizable approach to fit their comfort needs. This may help in reducing the amount of times the user would need to be fitted for a new socket and in turn reduce costs. The development of this socket would benefit the physician in having several recommendations and options for increasing or decreasing the compression within the user. The user will be able to benefit from the Quatro™ socket by being able to wear their prosthetic longer than they usually do because of the increased comfort that their socket provides. The user will also benefit from the customizability aspect of changing the inserts of their socket to meet their specific comfort levels.

The Quatro™ socket will have a decreased environmental impact when compared to current techniques used to create sockets. The significant reduction in environmental impact is due to the socket and inserts created by 3D printing. This means that the socket and inserts are additive manufacturing rather than the usual subtractive manufacturing technique in creating prosthetic sockets. The additive manufacturing procedure follows principle 5 of The Principle of Green Engineering, Output-Pulled Versus Input-Pushed. This principle states that the system components should minimize the amount of resources consumed for inputs to become the desired output [20]. By using additive manufacturing the materials wasted are reduced. Another way in which the design is more environmentally friendly is because of the decreased amount of times users will need to be fitted for a new socket. When the user has to be fitted for sockets more frequently they are consuming more materials and energy for manufacturing. This includes creating more waste when the socket is no longer able to be used and needs to be disposed of.

Regulations and standards are important aspects with a new and/or improved design. The Quatro™ socket and the compression inserts are classified as a Class I device due to the non-invasive and non-life sustaining component to these devices. Prosthetics pose little to no health risk to the user and therefore are 510(k) exempt and medical device good manufacturing process (GMP) exempt [21]. There are procedures and standards that do need to be followed in regards to the International Organization for Standards (ISO) and American Society for testing and materials (ASTM). For this particular project there are significant procedures that the team will abide by stated in the introduction relating to ISO, ASTM, and ASME standards.

The senior design team innovating the compression panel inserts project is working with the project sponsors Quorum Prosthetics, all intellectual property belongs to Quorum Prosthetics. The work completed will continue to stay with Quorum Prosthetics where it will be further developed. When the compression panel inserts go onto the market, the burden and the reward will fall on Quorum Prosthetics. There is a current patent for Quorum's Quatro™ socket as well as a patent pending for Quorum's comfort cells.

## Discussion

In order to create new customizable panel designs that interface with the Quatro™ socket, the team had three major goals: material test TPU to gather material properties, create a FEA simulation that could be used to rapidly test the stiffness of new panel prototypes, and finally to create a series of new panel structures that would differ in stiffness and ultimately allow for a greater degree of patient customization and comfort. Each of these goals came with its own set of data and results achieved through experimentation.

In the first semester, the team approached the testing phase with plans to construct a unique compression testing apparatus. However, in the preliminary thoughts of 'testing phase', material testing was not considered as the team fallaciously assumed the material properties of TPU to be less complicated. The components were purchased to build a testing apparatus to compress samples with the thought that Quorum could keep the testing apparatus once the project had concluded. Before construction, it was determined that the apparatus would not be easily repeatable in procedure and the team lacked the coding knowledge to confidently build a fixture from scratch. Additionally, when the unique properties of TPU were discovered in research, the Mark-10 system in CSU's Materials Lab appeared to be the best way to proceed. Material testing was performed on dogbone samples of TPU and compression testing on existing and new panel designs. With the assumption that TPU was linearly elastic under small strains, the tension testing yielded a range of elastic moduli from 60 to 100 MPa, and a wide range of Poisson ratios from 0.24 to well over 1.0.

The next round of results came from FEA using nTopology. A basic simulation was created with Quorum's standard base 20 mm height, 1 mm beam thickness panel as the model. The bottom of the lattice was fixed in place and the solid top was subjected to a uniform pressure. The elastic moduli values obtained during material testing were used as a bounding range for the FEA input parameter. Due to the wide range of experimental Poisson ratio values, a referenced value of 0.45 was used to minimize any further material testing and allow the team to move on to more important objectives. By using several different elastic moduli and the compression testing data that was gathered through physical compression testing, the team was able to refine the simulation through iteration until it accurately matched the physical behavior of the lattice in compression. This simulation was then sent to Quorum to design and evaluate new panel designs rapidly before printing.

Following this result, new panel designs were created by varying the beam thickness, unit cell size, and lattice structure. These new designs were simulated in FEA, printed by Quorum, and compression tested to validate the FEA results. Using the data from these simulations and experiments, a bulk modulus was defined for each unique lattice design. The team decided reporting this bulk modulus was more relevant than an elastic modulus because it could be input into nTopology for different lattice designs without complicating the mechanics of the simulation. TPU’s properties also change with print orientation and a variety of other factors, and conducting further material testing on TPU would not allow the team to proceed towards the expected goals within the scope of the project. The bulk modulus was not a material property, but rather a combination of properties representative of the lattice structure, material and print characteristics, and other factors affecting the compressive strength of the panel. It is best described as a design parameter specific to Quorum’s design process that can also be used as a comparative measure of the level of compression a new design will exhibit.

The final result of this project was a series of working relationships between the bulk modulus of the lattice structures and different design constraints. To do this, values for beam thickness, mass, volume of TPU, and volume fraction were gathered from an analysis of the CAD models in nTopology. This data was then plotted against the bulk modulus of each panel (Appendix H). Each of these relationships can be used to achieve a desired bulk modulus by varying one of the constraints listed. An example of this can be seen in Figure 19 below.

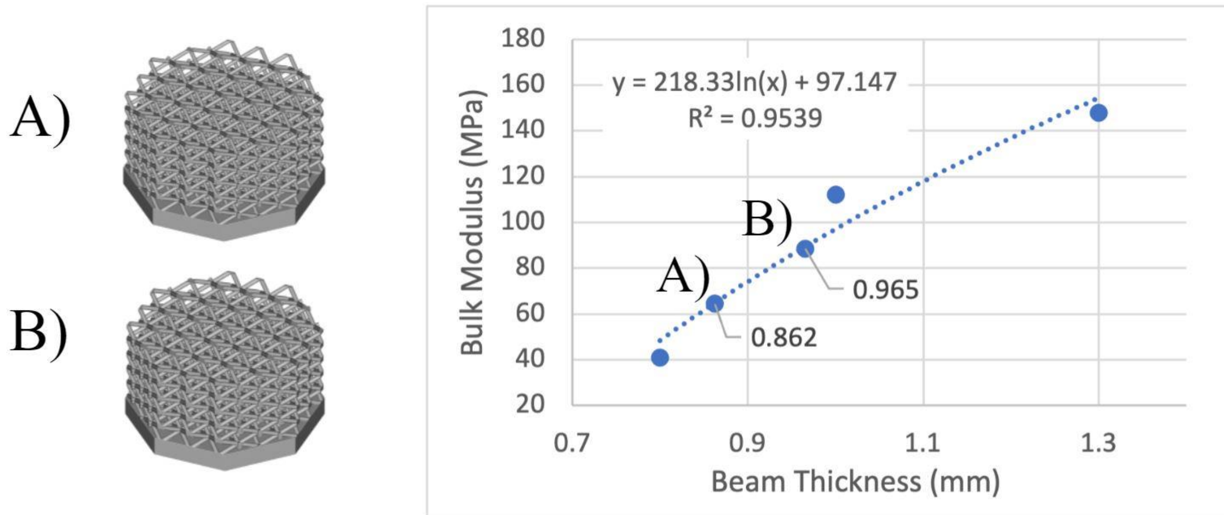



***Figure 19: Graph of Bulk Modulus versus Beam Thickness, Two New Panels with Stiffnesses at 33% (A) and 66% (B) of the Desired Stiffness Range***

These mathematical relationships were created by performing a simple regression to find a trendline that could then be used to alter the represented variable in order to achieve a desired stiffness. It is important to note that these relationships were based on a very limited sample size, and more data points from different panel designs would be beneficial to improve accuracy. In the example shown in Figure 19, bulk modulus and beam thickness are plotted and a regression was performed to determine their mathematical relationship. A logarithmic regression yielded an equation with the highest $R^2$ value. The range of bulk modulus values used in the design of panels A and B was between Quorum's standard 1 mm beam thickness, which had a bulk modulus of approximately 114 MPa, and the thinnest panel printed, deemed to be too fragile for effective use, at a bulk modulus of approximately 41 MPa. As a proof of concept, panels A and B were designed using this relationship to be 33% and 66% of the bulk modulus range, respectively. These were calculated using the Equations below:

$$Desired\ modulus = \frac{114MPa\ *\ \%_{desired}}{100}$$

$$New\ beam\ thickness = e^{\left[\frac{Desired\ modulus}{218.33} + 97.147\right]}$$

Doing this at 33% and 66% resulted in beam thicknesses of 0.862 mm (panel A) and 0.965 mm (panel B). These values were changed in nTopology, then sent to Quorum for printing. Though no compressive testing was performed, these new beam thicknesses did produce a tactile difference in stiffness both to the team and to others who handled the panels. This showed that these relationships could be used to quickly adjust a patient's panels to fit their desired level of compression, and ultimately improve the overall comfortability and usability of the Quatro™ socket.

## What We Achieved / Learned

Over the course of this project there were several issues and learning experiences that arose. The largest contributor to these issues was the material testing phase, for a number of reasons. Many of the issues stemmed from the strange behavior of the TPU used in these parts. Tensile testing, as the team performed, was a process designed for linearly elastic materials such as metals, and as such would not yield the same results as a material that does not behave in such a way. There was a small elastic region that can be observed in the TPU at the beginning of the tests, which was the data the team chose to use as a starting point for FEA simulation. However, this was not a good general representation of material properties, which resulted in significant simulation refinement of the properties used through iteration. It was eventually determined that the precision of the material values was somewhat inconsequential due to the nature of the device. A patient in need of a stiffer or softer panel would most likely have little opinion of what the bulk modulus of the panel was, but would rather prefer to feel a difference in comfort. Therefore the comparison and relationship was far more important than the actual numerical value. Due to this, it was decided that the range of material properties calculated were to be used as a starting point to create a simulation accurate enough to reflect the difference in stiffness of the panels.

Another important realization that arose due to material testing was the fact that print direction had a noticeable impact on material properties. These parts were created with a powder based printer at 6 different orientations, all yielding different values for both elastic modulus and Poisson's ratio. This was important to observe because it could have had an effect on the strength and durability of these panels depending on the orientation in which they were printed. In addition to this, a large portion of the TPU powder used was recycled from previous prints. Cycling through the machine before use in an actual print may have led to changes in material properties and was an area of interest. The team did not explore this particular aspect of the material over the course of this project, however it is an area to look into in future work.

Finally, there were several sources of error involved with material testing that needed to be overcome. During the first round, the team neglected to measure the initial and final widths of the dogbone samples, which is critical data for the calculation of Poisson's ratio. This led to another round of material testing in which these measurements were taken at the beginning and end of the tests. The data, however, indicated that the usable linear region was only found at or under approximately 2.5% strain, and the final width measurements were taken long after that had been surpassed. Due to this error, material tests were performed once more, this time halting the test at the 2.5% threshold, where the final width measurement was taken. It was this round of testing that led to the values used to continue the project with FEA. In addition to these errors, it must be noted that there was a certain degree of error involved with width measurement. This was performed by hand with calipers, which can cause problems when working with a small and easily deformable sample. This may seem inconsequential, but when one was dealing with the difference between 3.15 mm and 3.08 mm, it does matter and can have a noticeable effect on calculations.

Another learning experience came from the FEA simulation. After several issues with using Abaqus with the panel CAD files, it was determined that it would be more beneficial to the team to use nTopology, as it would be more compatible with the part. This required learning unfamiliar software, as nTopology, specifically simulation set up, is quite different from traditional finite element analysis software. Another realization that came about after simulating and compression testing several new panel designs was that the bulk modulus of the panels was a far more useful metric. Trying to find an accurate modulus that would adequately simulate different structures was ultimately fruitless, as that value did not take into account A, the odd behavior of the material, and B, the full stress state of the beams in the lattice, which could be experiencing bending, shearing, and tensile stresses. The bulk modulus, however, is far more powerful as a comparative tool. It can be likened to a spring constant that describes the relative stiffness of a spring; it can give a patient a good idea of what has changed with the new parts they are using.

Finally, the team learned a lot about teamwork and the division of labor that goes into a group project. Throughout the 9 months of work, one team member remained out of state due to COVID-19. Though subjected to remote work, she was still able to organize team meetings and attend major events while significantly contributing to the workload. Similarly, all team members were involved in extracurricular activities and employment opportunities. Each team member had different school schedules, work commitments, and homework assignments to juggle around. The team was able to communicate as a full team at least once a week, with other meetings occurring several times a week between smaller groups working on similar aspects of the project. The team learned how to navigate in a hybrid environment and divide tasks up evenly. In the evolving workplace environment, the team is excited to use these new skills as they enter the workforce.

## Future Work / Considerations

Though the team was able to cover a great deal in the scope of the developed goals and objectives, there is always room for improvement and future work. The team was able to determine the quantitative relationship between the bulk modulus and the lattice beam thickness and created two new panel designs to Quorum. Though these panels had a difference in diameter less than 1 mm, there was an apparent physical difference in the feel of the panel. In future work, it would be beneficial to find more relationships between the bulk modulus and other design constraints in Quorum’s designs. For example, changing the lattice structure, changing the panel geometry, or altering the panel height. Then once iterations are made for several constraints, the panels could be grouped together and provided to patients in the form of a panel kit. This kit would contain a few inserts, each with abilities explained to them by their doctor, that they can then use with their socket as needed.

The team was limited to the use of Lubrizol’s TPU blend. It would be advantageous to look into alternative powder based materials that are compatible with an MJF printer as well as other post-processing methods. Some panels that were tested in compression at larger UVW's or with slightly altered geometries were found to be too weak and the lattice would begin to fall apart, or were easily damaged while in transport. Though the lattice may be too weak when made from TPU material, the team is curious to find out whether another material would solve the issue or a protective coating would make the lattices last longer under normal wear and tear.

Addressing wear and tear, the team received several questions about the fatigue rate and cyclical testing results of the current panel designs. From the information shared to the team by Quorum, the panels wearing out didn't seem to occur or if they did were rare. However, when defining new relationships between bulk modulus and other constraints, it would be interesting to see the effect that they had on cyclic testing. The panels could lose their compressive strength overtime and become less effective, or since the forces are so small, they might compress the same throughout their entire service life. Testing would be necessary to clarify this. It would provide patients and their prosthetists a timeline to not only replace the panels, but schedule appointments and check-ins.

Lastly, it was mentioned that the team had intentions of providing a survey to current Quorum patients to highlight some information about their current prosthetic setups. Using the feedback from this survey, the team planned to iterate a design that would address the most common thoughts. A final survey was also created to gather information on the effectiveness of the new panel designs and for further validation of the physically felt compressive difference between the designs. Due to COVID and timeline constraints, the team was unable to send out these surveys, but think that would be a great place to start another senior design team or a useful resource for Quorum to utilize should they choose to implement the new designs and new prototyping process the team developed for them.

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# Appendix:

## Appendix A: Quatro™ Socket Image

## Appendix B: Failure Modes and Effects Analysis

**FMEA**

Process/Product Name: Compression Inserts for Quorum's Quatro Socket

Prepared By: Maren Baur

Responsible: Compression Inserts Senior Design Team

FMEA Date (Orig.): 2-Nov (Rev.): 1- 11/30/21; 2- 12/8/21; 3 - 4/11/22

| Process Step/Input | Potential Failure Mode | Potential Failure Effects | SEVERITY (1 - 10) | Potential Causes | OCCURRENCE (1 - 10) | Current Controls | DETECTION (1 - 10) | RPN | Action Recommended | Resp. | Actions Taken | SEVERITY (1 - 10) | OCCURRENCE (1 - 10) | DETECTION (1 - 10) | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| What is the process step, change or feature under investigation? | In what ways could the step, change or feature go wrong? | What is the impact on the customer if this failure is not prevented or corrected? | | What causes the step, change or feature to go wrong? (how could it occur?) | | What controls exist that either prevent or detect the failure? | | | What are the recommended actions for reducing the occurrence of the cause or improving detection? | Who is responsible for making sure the actions are completed? | What actions were completed (and when) with respect to the RPN? | | | | |
| Patient Thoughts and Comfort Level | The patient says the insert is uncomfortable | The patient is uncomfortable | 6 | The lattice provides too much compression | 5 | Varying lattice thickness and geometries | 2 | 60 | Provide patients with numerous insert options | Team | Preliminary Survey finalized 12/12/21 | 6 | 5 | 1 | 30 |
| | | | 6 | The lattice provides too little compression | 5 | Varying lattice thickness and geometries | 2 | 60 | Provide patients with numerous insert options | Team | Preliminary Survey finalized 12/12/21 | 6 | 5 | 1 | 30 |
| | The patient's residual limb is left bruised | The patient is uncomfortable | 6 | The lattice is too thick and the BOA dial gives too much pressure | 5 | Varying lattice thickness and geometries | 2 | 60 | Provide patients with numerous insert options | Team | Preliminary Survey finalized 12/12/21 | 6 | 5 | 1 | 30 |
| | | | 6 | | 5 | BOA dial system allows constant adjustability | 2 | 60 | Provide BOA dial demonstration | Prosthetist/Orthotist | Final survey to be provided (future work) | 6 | 5 | 2 | 60 |
| | The patient's skin is rubbed raw from insert | The patient is uncomfortable | 6 | The inserts move too much in the BOA dial system, resulting in friction | 5 | Varying lattice thickness and geometries | 2 | 60 | Provide patients with numerous insert options | Team | Preliminary Survey finalized 12/12/21 | 6 | 5 | 1 | 30 |
| | | | 6 | | 5 | BOA dial system allows constant adjustability | 2 | 60 | Provide BOA dial demonstration | Prosthetist/Orthotist | Final survey to be provided (future work) | 6 | 5 | 2 | 60 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Overall Appearance of the Prosthetic | The insert causes the socket to be bulky | The patient won't want to wear their socket | 4 | The insert is too thick | 3 | Thickness varying polygon that the lattice is attached to | 1 | 12 | Ensure base of panel is designed as thin as possible without adverse affect on strength | Team | FEA simulation set up 4/1/22 | 4 | 1 | 3 | 12 |
| | | The patient has to alter their clothing to ensure the socket fits | 3 | The insert is too thick | 3 | Visual verification that the insert is extended | 1 | 9 | Ensure base of panel is designed as thin as possible without adverse affect on strength | Team | FEA simulation set up 4/1/22 | 3 | 3 | 1 | 9 |
| The Lattice Geometry | The lattice tears | The patient is uncomfortable | 3 | The patient tears lattice while placing the insert | 5 | Visual verification that the lattice is in tact | 4 | 60 | Provide patient with replacement panels (multiple of each in the set) | Team | Multiple suggested inserts 4/4/22 | 3 | 5 | 4 | 60 |
| | | | 3 | Part of the lattice is torn off by catching on socket liner | 5 | Visual verification that the insert is uniformly shaped | 4 | 60 | Provide patient with replacement panels (multiple of each in the set) | Team | Multiple suggested inserts 4/4/22 | 3 | 5 | 4 | 60 |
| | | The patient has to replace their insert | 3 | The patient tears lattice while placing the insert | 5 | Visual verification that the lattice is in tact | 4 | 60 | Provide patient with replacement panels (multiple of each in the set) | Team | Multiple suggested inserts 4/4/22 | 3 | 5 | 4 | 60 |
| | | | 3 | Part of the lattice is torn off by catching on socket liner | 5 | Visual verification that the insert is uniformly shaped | 4 | 60 | Provide patient with replacement panels (multiple of each in the set) | Team | Multiple suggested inserts 4/4/22 | 3 | 5 | 4 | 60 |
| | The lattice breaks due to cyclic failure | The patient is uncomfortable | 6 | The insert is worn out due to continuous activity | 5 | The lattice does not return to normal shape when outside of BOA dial system | 1 | 30 | Provide patient with replacement panels (multiple of each in the set) | Team | Multiple suggested inserts 4/4/22 | 6 | 5 | 1 | 30 |
| | | The patient has to replace their insert | 6 | The inserts is worn out due to continuous activity | 5 | The lattice does not return to normal shape when outside of BOA dial system | 1 | 30 | Provide patient with replacement panels (multiple of each in the set) | Team | Multiple suggested inserts 4/4/22 | 6 | 5 | 1 | 30 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| The Rigidity of the Socket | The BOA dials break | The socket cannot adjust | 7 | Internal failure of BOA dial parts due to fatigue or high stress from high cable tension | 3 | The socket is made of plastic material that will remain strong | 2 | 42 | BOA dial testing during socket fitting | Prosthetist/Orthotist | Final survey to be provided (future work) | 7 | 3 | 2 | 42 |
| | The inserts cause the socket to fold in on the patient's residual limb | The socket cannot safely support the patient | 7 | Socket walls were printed too thin leading to material failure under stress | 3 | Rigid exterior socket of the Quatro should keep the socket from concaving | 2 | 42 | BOA dial testing during socket fitting | Prosthetist/Orthotist | final survey to be provided (future work) | 7 | 3 | 2 | 42 |
| Interchangability of the inserts | The inserts are hard to remove | The patient does not switch the inserts | 3 | Printed BOA dial thread opening diameter doesn't meet tolerances | 6 | Standardized BOA cable hole size and tolerance | 2 | 36 | Increasing hole tolerancing | Team | final survey to be provided (future work) | 3 | 6 | 2 | 36 |
| Testing Apparatus | The apparatus breaks/malfunctions | The wooden supports/frame break | 8 | The apparatus falls | 2 | The testing apparatus will remain on the ground | 1 | 16 | Keeping the apparatus on the ground | Team | Use of Mark-10 Tension System | 3 | 2 | 1 | 6 |
| | | | 8 | The fasteners holding the apparatus together fail | 2 | Visual confirmation that the fixture is ready to be tested with | 1 | 16 | Checklist to verify the apparatus is ready for testing before every test | Team | Use of Mark-10 Tension System | 3 | 2 | 1 | 6 |
| | | | 8 | A team member leans on apparatus during insert transfer | 2 | Team members will remain aware of their surroundings near the apparatus | 1 | 16 | Team members will not go near the apparatus during testing | Team | Use of Mark-10 Tension System | 3 | 2 | 1 | 6 |
| | | The measurement system placement changes | 8 | The notch/fastener holding the measurement system fails | 3 | Visual confirmation that the fixture is ready to be tested with | 3 | 72 | Checklist to verify the apparatus is ready for testing before every test | Team | Use of Mark-10 Tension System | 3 | 3 | 3 | 27 |
| | | | 8 | The apparatus is bumped and the measurement system is knock from it's normal postition | 2 | Team members will remain aware of their surroundings near the apparatus | 4 | 64 | Team members will not go near the apparatus during testing | Team | Use of Mark-10 Tension System | 3 | 2 | 4 | 24 |
| | The sensors do not work | The DAQ module does not record usable sensor data | 8 | The team cannot read the data well in the serial output of Arduino | 5 | Datasheets of the acquired load sensors and drivers | 1 | 40 | Testing in the Materials lab with various DAQ modules | Team | Conversation with Steve Johnson 12/8/21 | 8 | 2 | 1 | 16 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | The sensors move from their location | 8 | The sensors are not properly held down by an adhesive on the apparatus | 2 | Visual confirmation that the fixture is ready to be tested with | 3 | 48 | Checklist to verify the apparatus is ready for testing before every test | Team | Use of Mark-10 Tension System | 3 | 2 | 3 | 18 |
| | | | 8 | The load cells are bumped out of place by a team member | 2 | Visual confirmation that the fixture is ready to be tested with | 4 | 64 | Checklist to verify the apparatus is ready for testing before every test | Team | Use of Mark-10 Tension System | 3 | 2 | 4 | 24 |
| | | | 8 | The load cells are bumped out of place during the repositioning of the apparatus | 4 | Visual confirmation that the fixture is ready to be tested with | 4 | 128 | Checklist to verify the apparatus is ready for testing before every test | Team | Use of Mark-10 Tension System | 3 | 4 | 4 | 48 |
| | The tension testing method fails | The force applied remains unknown | 8 | The distance covered by each BOA dial turn isn't consistent | 3 | BOA dial data sheets | 7 | 168 | Hand measuring the distance moved by hand for verification | Team | Use of Mark-10 Tension System | 3 | 3 | 7 | 63 |

## Appendix C: Initial Survey

# Quorum - CSU Senior Design Team Survey

Please take a few moments to answer these questions regarding the comfort of your current socket. The first three questions will allow the design team to compare initial and end surveys while staying anonymous.

* Required

1. What day is your birthday? (i.e. 08)

_______________________

2. What is the first letter of your name?

_______________________

3. How many siblings do you have?

_______________________

4. What socket are you currently using? (i.e. Quatro, standard, etc.) *

_______________________

5. Do you use an Above Knee or Below Knee socket? *

*Mark only one oval.*

- ◯ Above Knee
- ◯ Below Knee

6. Which picture below most closely resembles your current prosthetic set up? *

*Mark only one oval.*

- ◯ Comfort Cells - images needed
- ◯ Original Quatro Panels - images needed
- ◯ 3-Panel Lattice - images needed
- ◯ New TPU socket insert - images needed

7. On average, how many hours per day do you spend wearing your socket? *

*Mark only one oval.*

- 1-3 hours
- 3-6 hours
- 6-9 hours
- 9-12 hours
- 12+ hours

8. What reasons typically cause you to take your socket off? *

________________________________

9. How would you rank the comfort of your socket? *

*Mark only one oval.*

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Unbearable | | | | | | | | | | | Enjoyable to Wear |

10. If applicable, where are the most common pain-points in your socket? *

*Check all that apply.*

- Front-side (anterior)
- Back-side (posterior)
- Outside (lateral)
- Inside (medial)
- Bottom (distal end)

11. How stable do you feel in your prosthetic? *

*Mark only one oval.*

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Unstable | | | | | | | | | | | Nicely Balanced |

12. Approximately how many times a day do you adjust your socket with the BOA dials or another method if you are not using BOA dials? *

_______________

13. How often do you replace your socket and why? *

_______________

14. How would you gage your spatial awareness of your prosthesis? *

*Mark only one oval.*

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| No spacial awareness | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | Good spacial awareness |

15. Is where you imagine your foot in space accurate with where it physically is in space? *

*Mark only one oval.*

⬭ Yes
⬭ No

16. Do you consistently have to look down to know where to place your foot when you step? *

*Mark only one oval.*

⬭ Yes
⬭ No

17. Do you have any general feedback/comments about your socket? Anything you like/dislike or could otherwise be improved?

_______________
_______________
_______________
_______________
_______________

# Appendix D: End Survey

## Quorum - CSU Senior Design Team End Survey

Please take a few moments to answer these questions regarding the comfort of your current socket. The first three question will allow the design team to compare initial and end surveys while staying anonymous.

* Required

1. What day is your birthday? (i.e. 08) *

2. What is the first letter of your name? *

3. How many siblings do you have? *

4. With the new inserts how many hours per day did you spend wearing your socket on average? *

   *Mark only one oval.*

   - 1-3 hours
   - 3-6 hours
   - 6-9 hours
   - 9-12 hours
   - 12+ hours

5. How would you rank the comfort of the socket with the new inserts? *

   *Mark only one oval.*

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Unbearable | | | | | | | | | | | Enjoyable to Wear |

6. How stable do you feel in the prosthetic with the new inserts? *

*Mark only one oval.*

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Unstable | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | Nicely Balanced |

7. Approximately how many times a day did you adjust your socket with the BOA dials? *

______________________

8. Approximately how many times did you switch out the different inserts in a single day? *

______________________

9. Did you use the higher compression inserts or lower compression inserts more often and why? *

______________________

10. How would you gage your spatial awareness of your prosthesis with the new inserts? *

*Mark only one oval.*

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| No spatial awareness | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | ⬭ | Perfect spatial awareness |

11. Is where you imagine your foot in space accurate with where it physically is in space? *

*Mark only one oval.*

⬭ Yes

⬭ No

12. Do you consistently have to look down to know where to place your foot when you step? *

*Mark only one oval.*

- ◯ Yes
- ◯ No

13. Do you have any general feedback/comments about the new inserts? Anything you like/dislike or could otherwise be improved? *

# Appendix E: Lubrizol Estane 3D TPU M95A-545 Datasheet

Lubrizol

## ESTANE® 3D TPU M95A-545 OR UV

**Technical Data Sheet**

**Type:** Polyether Thermoplastic Polyurethane (TPU)

**Uses:** HP Multi-Jet Fusion (MJF)

**Base Resin Information:**

| Physical Properties | Value (Metric) | Unit | Test Method |
|---|---|---|---|
| Specific Gravity | 1.17 | | ASTM D-792 |
| Melting Temperature (by DSC) | 200 | °C | Lubrizol DSC |

- Testing samples were injection molded to 80 mils or 2 mm thickness.
- Prior to testing, samples were conditioned at 23°C for 48 hours.
- Listed values are "typical (average) values" and should not/cannot be applied for specification purposes and do not constitute any agreed contractual specification/quality of ESTANE® 3D TPU M95A-545 OR UV.

**Multi-Jet Fusion Printed Part Information:**

- ESTANE® 3D TPU M95A is certified for skin sensitization and cytotoxicity.

| Physical Properties | Value (Metric) | Unit | Test Method |
|---|---|---|---|
| Vicat Softening Temperature | 161 | °C | ASTM D-1525 (10N) |
| Ross Flex Test at 23°C | No Crack | | 60° for 150,000 cycles |
| Ross Flex Test at -6°C | No Crack | | 60° for 150,000 cycles |

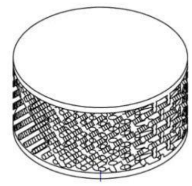
| Mechanical Properties | Full Print Bed Build | Half Print Bed Build | Unit | Test Method |
|---|---|---|---|---|
| | 100% Fresh Powder (Generation 5) | | | |
| Specific Gravity | 1.10 - 1.15 | | | ASTM D-792 |
| **Properties in X** | | | | |
| Hardness (5 sec) | 93 ± 3 | | Shore A | ASTM D-2240 |
| Abrasion Volume Loss | 100 (140) | 80 (100) | $mm^3$ | DIN-53516 / ISO-4649 |
| Tensile Strength | 17 (11) | 18 (14) | MPa | DIN-53504 / ISO-37 |
| Elongation at Break | 400 (180) | 430 (340) | % | DIN-53504 / ISO-37 |
| Tear Strength (Die C) | 80 (80) | 95 (96) | KN/m | ASTM D-624 |
| Flexural Modulus | 85 | | MPa | ASTM D-790 |
| **Properties in Z** | | | | |
| Hardness (5 sec) | 93 ± 3 | | Shore A | ASTM D-2240 |
| Abrasion Volume Loss | 90 (120) | 80 (100) | $mm^3$ | DIN-53516 / ISO-4649 |
| Tensile Strength | 8 (5) | 8 (6) | MPa | DIN-53504 / ISO-37 |
| Elongation at Break | 90 (30) | 110 (70) | % | DIN-53504 / ISO-37 |
| Tear Strength (Die C) | 35 (33) | 45 (44) | KN/m | ASTM D-624 |

| Dimensional Properties | | | |
|---|---|---|---|
| Dimensional Accuracy in XY | +/- 1.0 | mm | |

- Skin sensitization and cytotoxicity of printed parts were certified as per ISO10993-5 and -10
- Listed values are "typical (average) values" and should not/cannot be applied for specification purposes and do not constitute any agreed contractual specification/quality of ESTANE® 3D TPU M95A-545 OR UV.
- Listed values were printed with using HP 4200 Multi-Jet Fusion printer and print bed density was approximately 7 %.
- Generation 5 values were obtained when 80% recycled and 20% fresh powder blend was used in full bed and half bed printing cycles with 7% print bed density.
- Tensile specimens were printed in Type 2 per ISO-37 or S2 per DIN-53504.
- Dimensional properties were measured with the dimensions ranged from 3 to 100 mm.

### Application Example: MJF Printed Lattice Structure

| Design Characteristics | Value | Unit |
|---|---|---|
| Outside Diameter | 50 | mm |
| Lattice element diameter | 1.5 | mm |
| Center to Center distance | 4 | mm |
| Solid plate thickness | 2 | mm |



- This geometry is designed to provide physical properties of general lattice structure (as shown).

| Physical Properties of Printed Part | 80% Reclaimed / 20% Virgin Powder Blend | | Test Method |
|---|---|---|---|
| | Value | Unit | |
| **Properties in XY** | | | |
| Vertical Resiliency | 52 | % | ASTM D-2632 |
| Swing-arm Resiliency | 55 | % | DIN-53512 |
| Compression Set at Room Temp | 18 | % | 50% Deflection for 6 hrs |
| Compression Set at 50 °C | 30 | % | 50% Deflection for 6 hrs |
| **Properties in Z** | | | |
| Vertical Resiliency | 53 | % | ASTM D-2632 |
| Swing-arm Resiliency | 57 | % | DIN 53512 |
| Compression Set at Room Temp | 17 | % | 50% Deflection for 6 hrs |
| Compression Set at 50 °C | 19 | % | 50% Deflection for 6 hrs |

- Properties of lattice parts may vary depending on part design.
- These values should only be taken as exemplary properties of lattice structure printed by ESTANE® 3D TPU M95A-545 OR UV, should not/cannot be applied for specification purposes and do not constitute any agreed contractual specification/quality of ESTANE® 3D TPU M95A-545 OR UV.

### Reclaimed Powder Information:

- Standard refresh rate of ESTANE® 3D TPU M95A-545 OR UV is 80% reclaimed and 20% virgin.
- As the powder blend is reclaimed for more printing cycles, the yellowness of the powder blend increases.
- The print mode assumes a high reclaim rate as the blend has been tested up to 10$^{th}$ generation.

- Powder yellowness values can vary significantly depending on measurement location, print bed density and part types.

**Powder Caking Information:**

• ESTANE® 3D TPU M95A-545 OR UV is specially developed to provide EASY and COLD unpacking.
• This feature may provide decreased stress to an operator during powder cleaning and unpacking process.
• The powder caking properties are shown below.

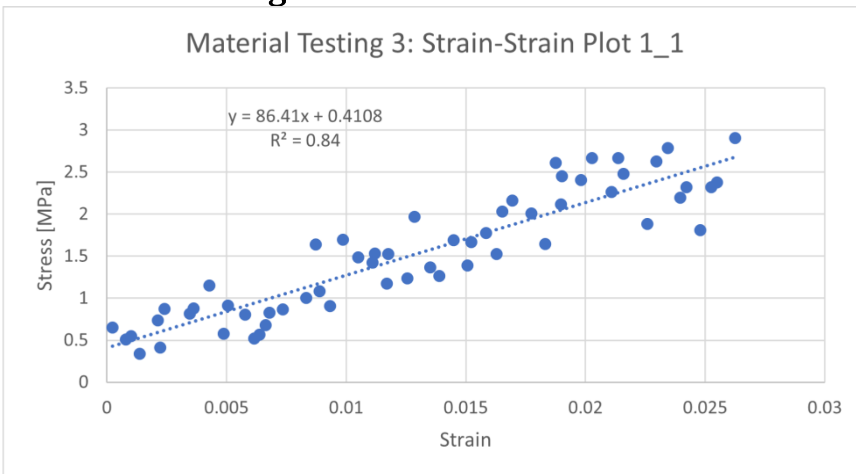
| Powder Caking Properties | ESTANE® M95A | Test Method |
|---|---|---|
| Maximum Stress at Break | 9.14 kPa | Lubrizol |
| Strain at Break | 4.4 mm | Lubrizol |

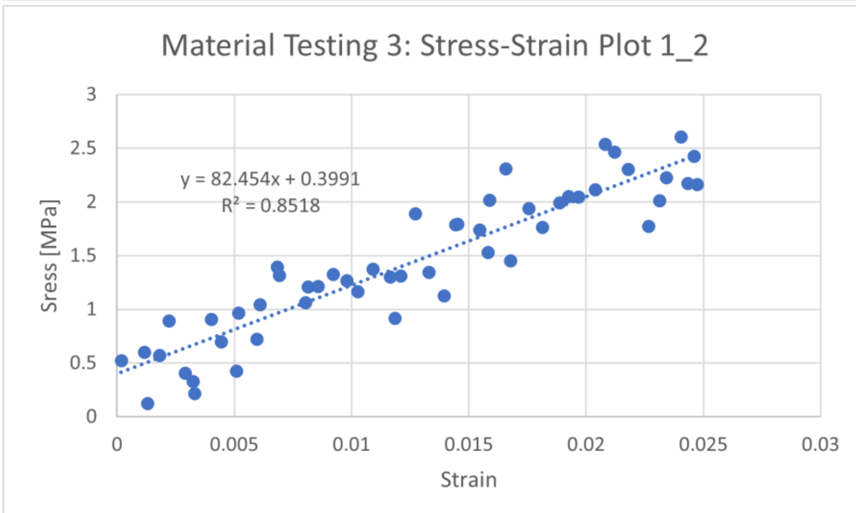
- Samples were oven aged at 140°C for 18.5 hours and cooled down to 23°C prior to testing.
- Listed values were measured according to Lubrizol's internal test method.
- Listed values are "typical (average) values" and should not/cannot be applied for specification purposes and do not constitute any agreed contractual specification/quality of ESTANE® 3D TPU M95A-545 OR UV.

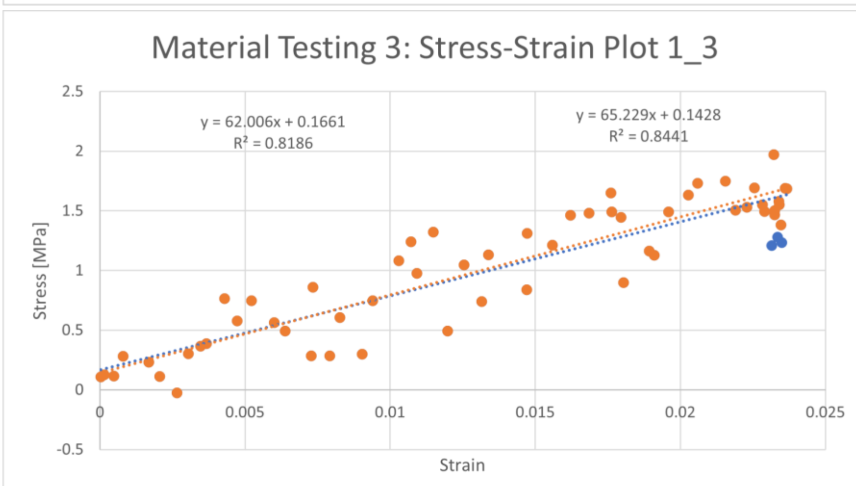
**Supply Form and Standard Packaging**

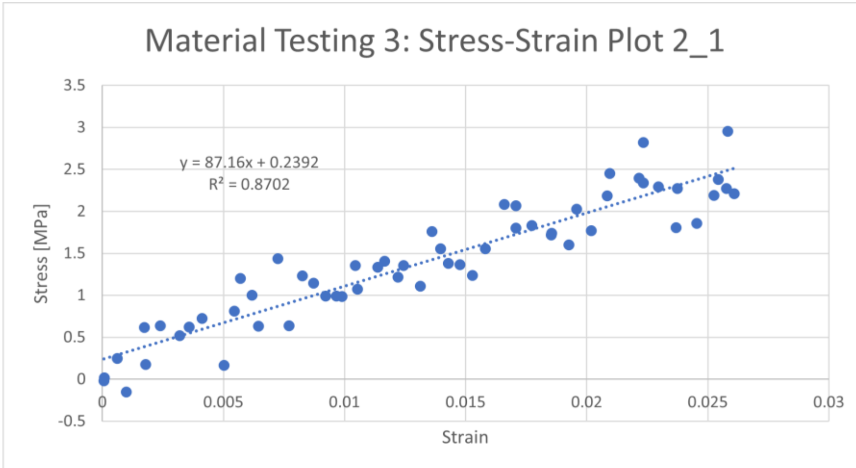
• **ESTANE® 3D TPU M95A-545 OR UV** is supplied in powder form and packaged in 30 liter/300 liter HP certified packaging and 480 kg Lubrizol packaging.

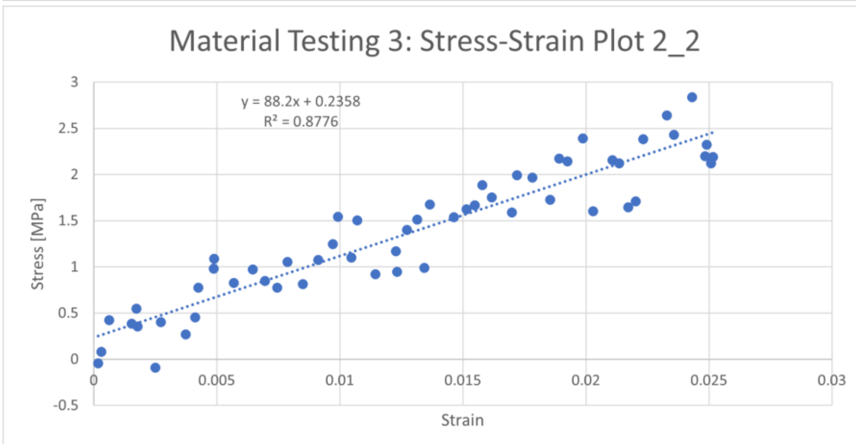
# Appendix F: Material Testing Round 3 Results

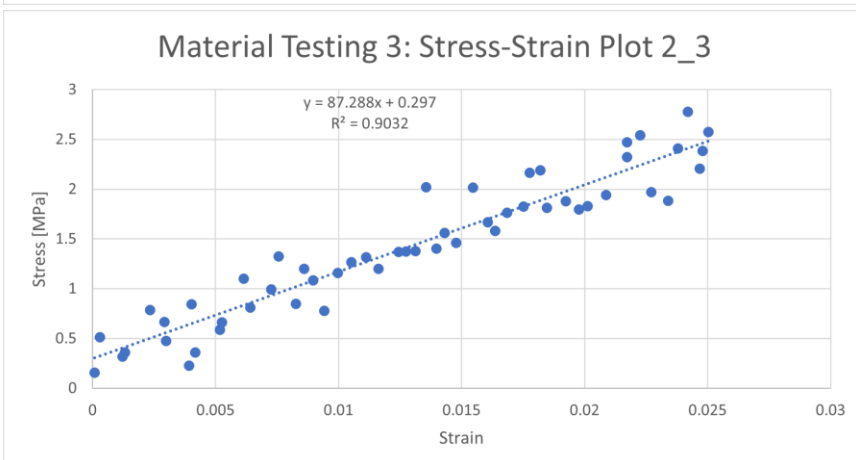


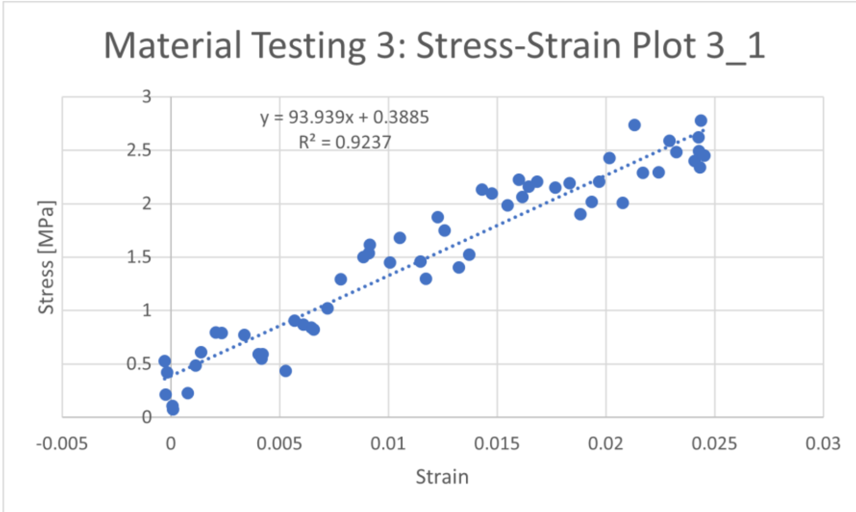



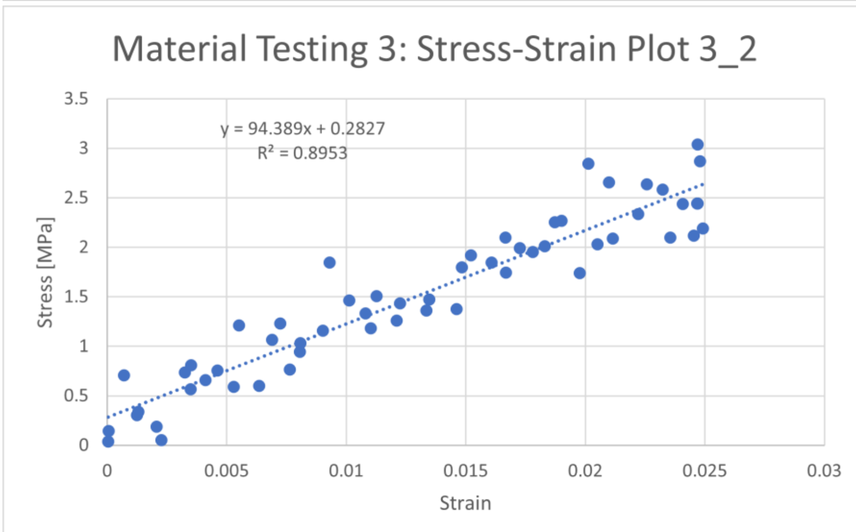



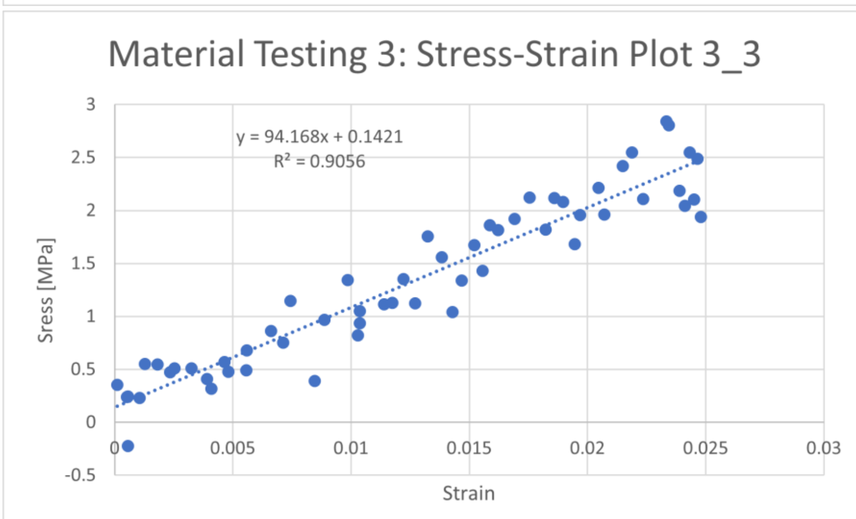

Material Testing 3: Stress-Strain Plot 2_1
y = 87.16x + 0.2392
R² = 0.8702
Stress [MPa]
Strain
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
0
0.005
0.01
0.015
0.02
0.025
0.03

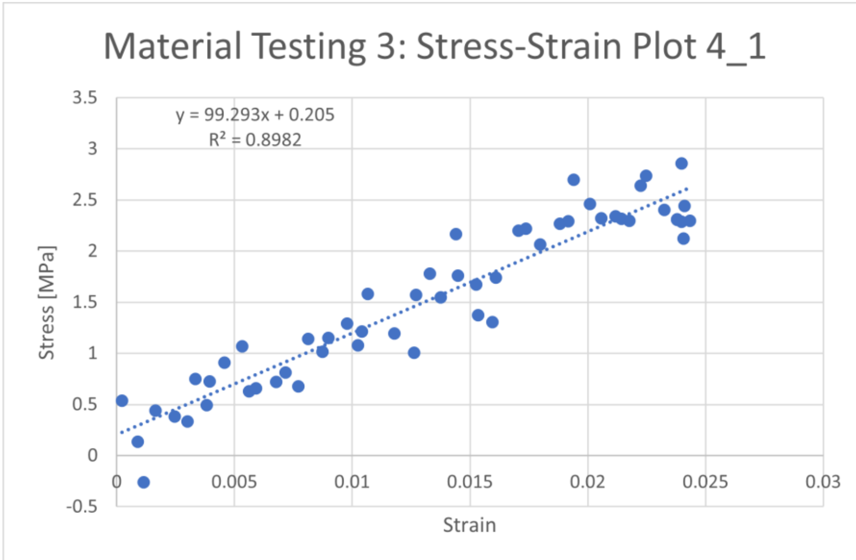

Material Testing 3: Stress-Strain Plot 2_2
y = 88.2x + 0.2358
R² = 0.8776
Stress [MPa]
Strain
3
2.5
2
1.5
1
0.5
0
-0.5
0
0.005
0.01
0.015
0.02
0.025
0.03

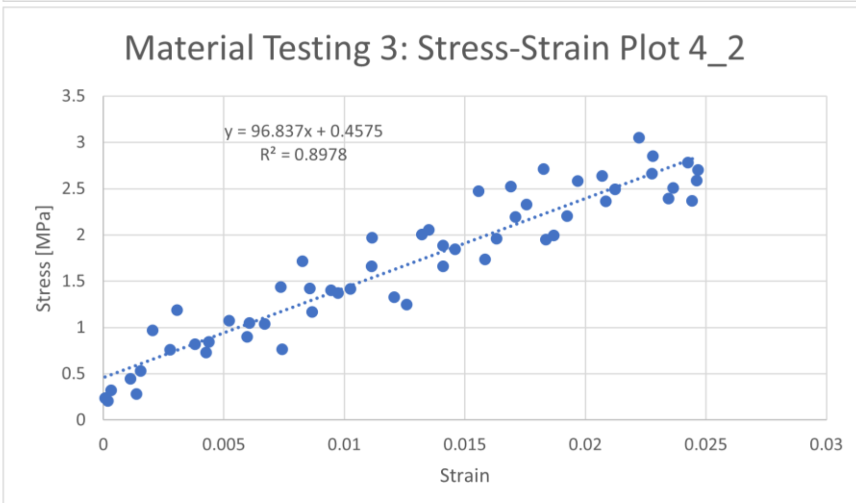

Material Testing 3: Stress-Strain Plot 2_3
y = 87.288x + 0.297
R² = 0.9032
Stress [MPa]
Strain
3
2.5
2
1.5
1
0.5
0
0
0.005
0.01
0.015
0.02
0.025
0.03

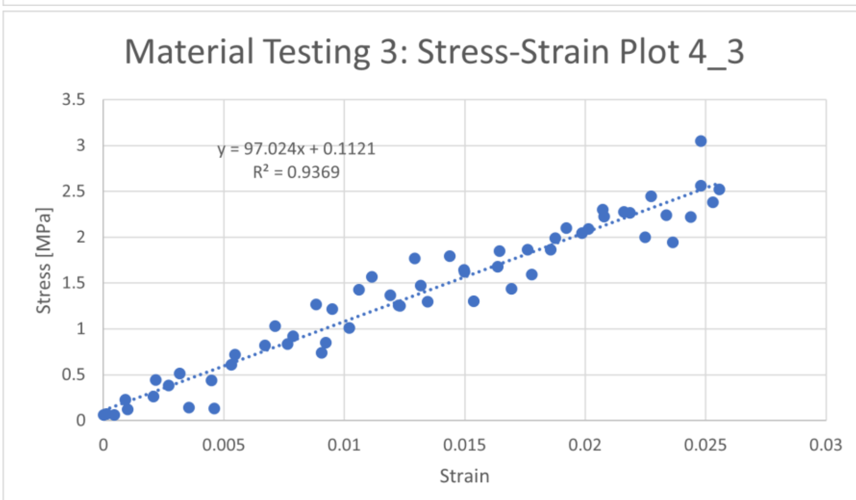

Material Testing 3: Stress-Strain Plot 3_1
y = 93.939x + 0.3885
R² = 0.9237
Stress [MPa]
Strain
3
2.5
2
1.5
1
0.5
0
-0.005
0
0.005
0.01
0.015
0.02
0.025
0.03

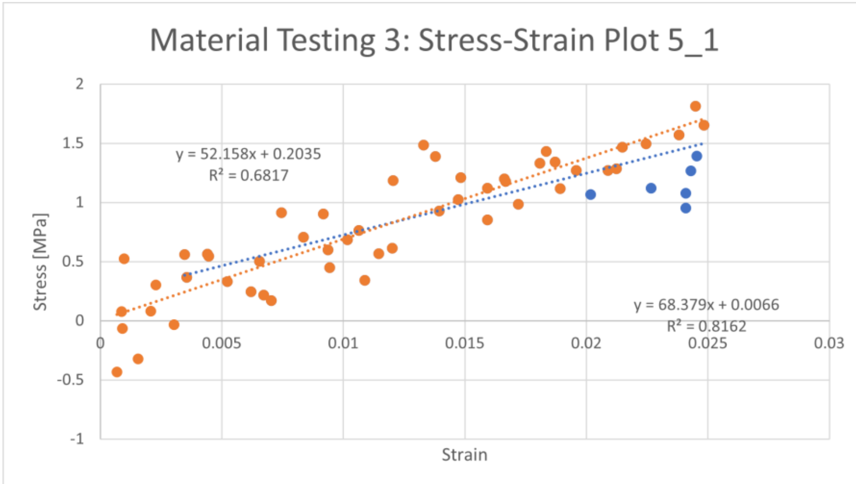

Material Testing 3: Stress-Strain Plot 3_2
y = 94.389x + 0.2827
R² = 0.8953
Stress [MPa]
Strain
3.5
3
2.5
2
1.5
1
0.5
0
0
0.005
0.01
0.015
0.02
0.025
0.03

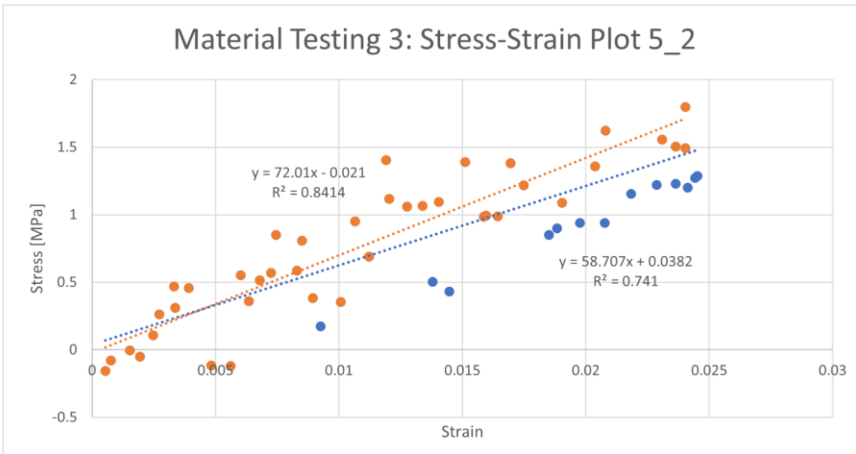

Material Testing 3: Stress-Strain Plot 3_3
y = 94.168x + 0.1421
R² = 0.9056
Sress [MPa]
Strain
3
2.5
2
1.5
1
0.5
0
-0.5
0
0.005
0.01
0.015
0.02
0.025
0.03

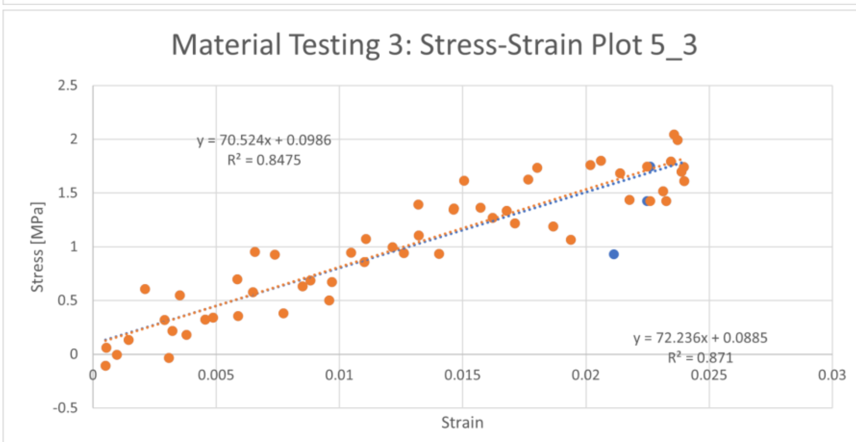

Material Testing 3: Stress-Strain Plot 4_1
y = 99.293x + 0.205
R² = 0.8982
Stress [MPa]
Strain
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
0
0.005
0.01
0.015
0.02
0.025
0.03

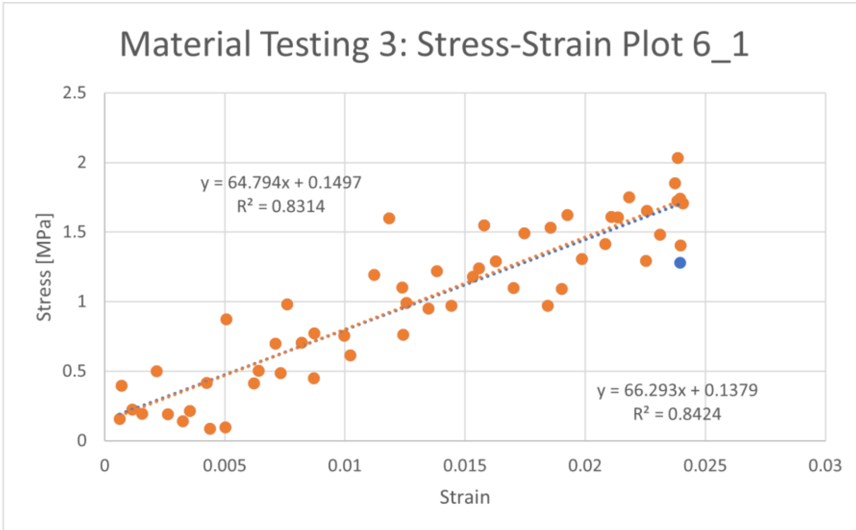

Material Testing 3: Stress-Strain Plot 4_2
y = 96.837x + 0.4575
R² = 0.8978
Stress [MPa]
Strain
3.5
3
2.5
2
1.5
1
0.5
0
0
0.005
0.01
0.015
0.02
0.025
0.03

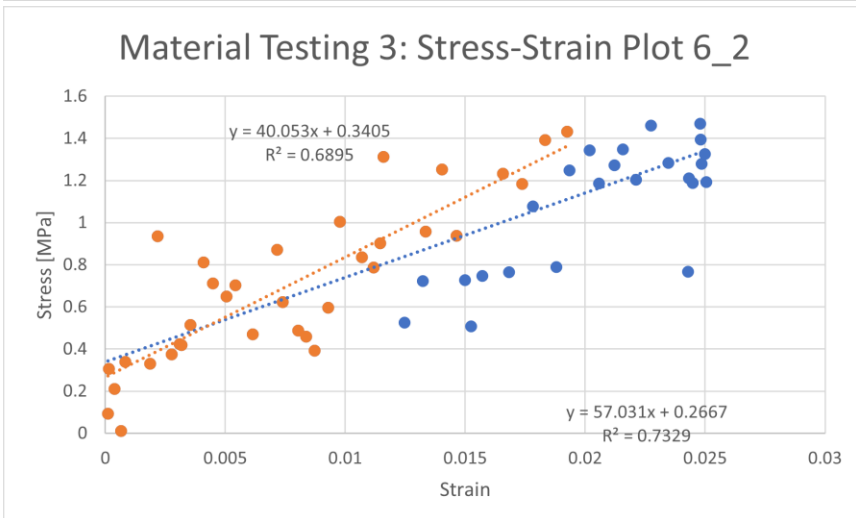

Material Testing 3: Stress-Strain Plot 4_3
y = 97.024x + 0.1121
R² = 0.9369
Stress [MPa]
Strain
3.5
3
2.5
2
1.5
1
0.5
0
0
0.005
0.01
0.015
0.02
0.025
0.03

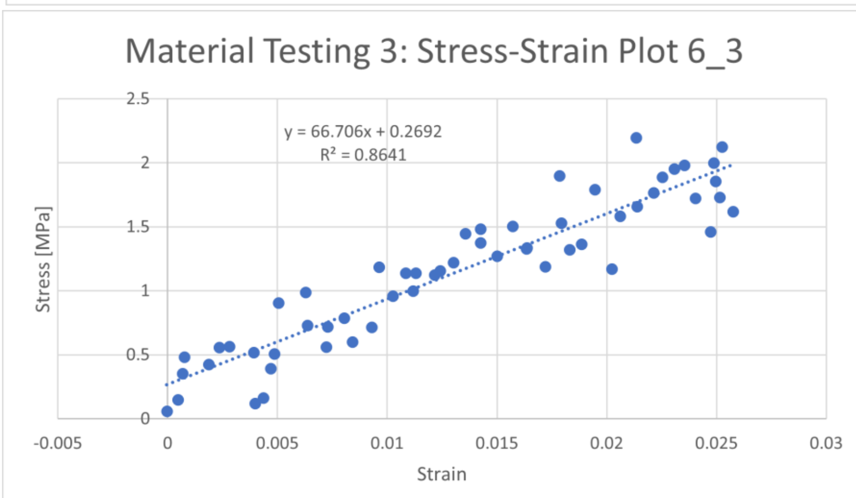

Material Testing 3: Stress-Strain Plot 5_1
y = 52.158x + 0.2035
R² = 0.6817
y = 68.379x + 0.0066
R² = 0.8162
Stress [MPa]
Strain


Material Testing 3: Stress-Strain Plot 5_2
y = 72.01x - 0.021
R² = 0.8414
y = 58.707x + 0.0382
R² = 0.741
Stress [MPa]
Strain


Material Testing 3: Stress-Strain Plot 5_3
y = 70.524x + 0.0986
R² = 0.8475
y = 72.236x + 0.0885
R² = 0.871
Stress [MPa]
Strain

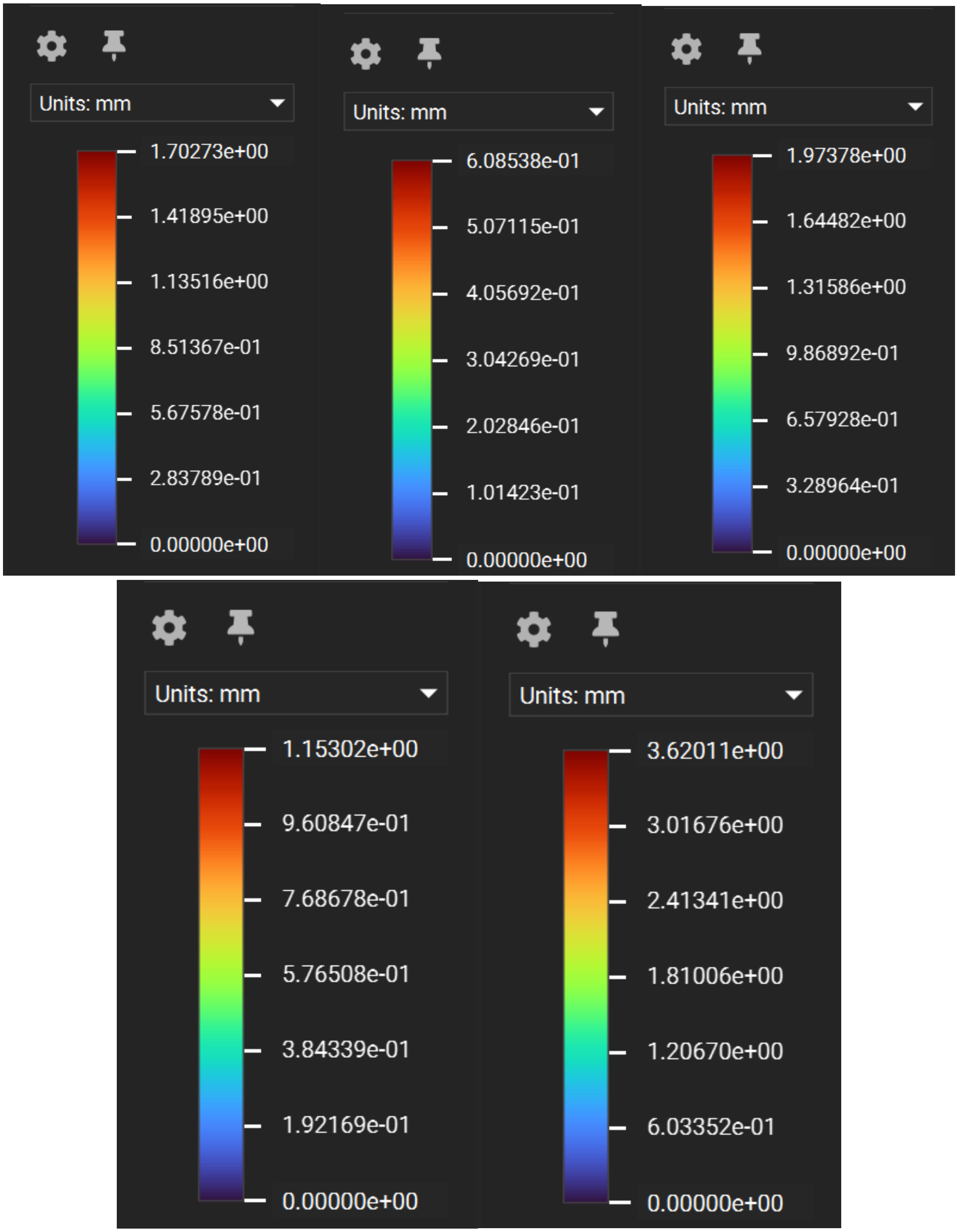

Material Testing 3: Stress-Strain Plot 6_1
y = 64.794x + 0.1497
R² = 0.8314
y = 66.293x + 0.1379
R² = 0.8424
Stress [MPa]
Strain
0
0.5
1
1.5
2
2.5
0.005
0.01
0.015
0.02
0.025
0.03


Material Testing 3: Stress-Strain Plot 6_2
y = 40.053x + 0.3405
R² = 0.6895
y = 57.031x + 0.2667
R² = 0.7329
Stress [MPa]
Strain
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
0.005
0.01
0.015
0.02
0.025
0.03


Material Testing 3: Stress-Strain Plot 6_3
y = 66.706x + 0.2692
R² = 0.8641
Stress [MPa]
Strain
0
0.5
1
1.5
2
2.5
-0.005
0.005
0.01
0.015
0.02
0.025
0.03

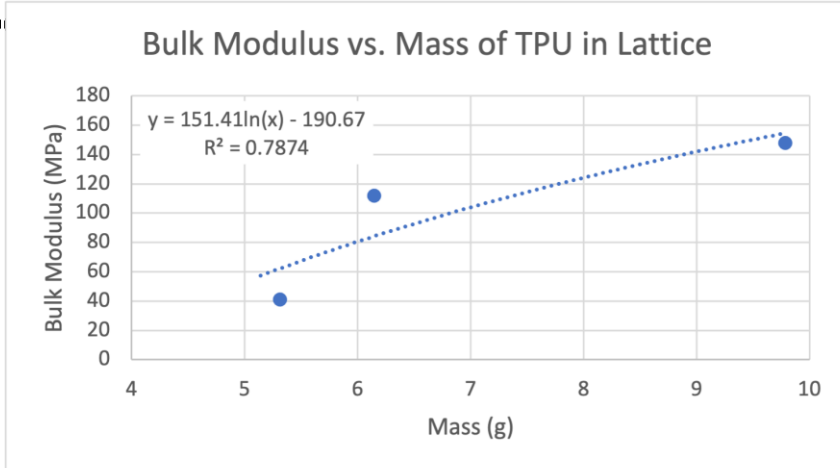
,

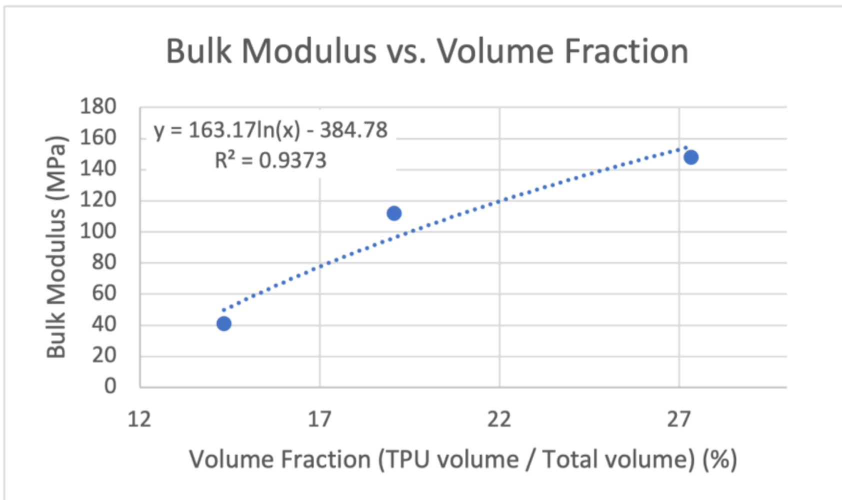
## Appendix G: FEA Displacement Results

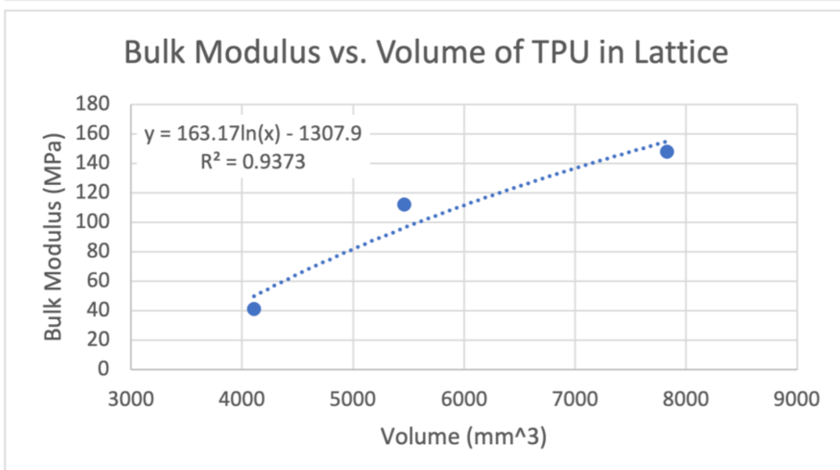



*FEA Displacement Results: Displacements for the Base, Thickened, Thinned, Hexagonal, and 24mm Lattices at a Force of 40 N Respectively*

## App ships


Bulk Modulus vs. Mass of TPU in Lattice
y = 151.41ln(x) - 190.67
R² = 0.7874
Bulk Modulus (MPa)
180
160
140
120
100
80
60
40
20
0
4
5
6
7
8
9
10
Mass (g)


Bulk Modulus vs. Volume Fraction
y = 163.17ln(x) - 384.78
R² = 0.9373
Bulk Modulus (MPa)
180
160
140
120
100
80
60
40
20
0
12
17
22
27
Volume Fraction (TPU volume / Total volume) (%)


Bulk Modulus vs. Volume of TPU in Lattice
y = 163.17ln(x) - 1307.9
R² = 0.9373
Bulk Modulus (MPa)
180
160
140
120
100
80
60
40
20
0
3000
4000
5000
6000
7000
8000
9000
Volume (mm^3)