Quatro Prosthetic Socket Analysis Senior Design Project

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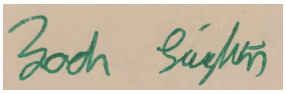
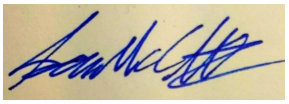
Zach Leighton		303-981-9410	zleighto@rams.colostate.edu
Sean McClure		303-917-3264	smcclure@rams.colostate.edu

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Abstract

The Quatro socket is a revolutionary prosthetic socket created by Quorum Prosthetics with sufficient qualitative data from users stating it is the most comfortable socket they have used compared to traditional sockets. Despite the positive feedback, quantitative data is needed to support the claims that the Quatro socket is a more comfortable socket through collecting data on volume change and pressure distribution. This project consisted of the creation of a process to collect the specified data. The process initially developed included two portions: physical benchtop data collection and a virtual analysis. The benchtop data collection included volume and pressure analyses. The volume analysis was conducted using an air bladder to find the percent volume change the Quatro could experience. This testing found that the Quatro has significant volume change capabilities of ~12.1%, which can compensate for residual limb volume changes and reduce discomfort. Pressure data was to be gathered by placing a Tekscan sensor on a model limb and loading the limb with forces to find the pressure distributions within the socket. The other portion of data collection by virtual analysis was to be executed by creating a virtual model of the socket, inner socket, and residual limb assembly, and then performing a finite element analysis (FEA) on the model. This model could be used to test different force scenarios and accommodate for the patient specificity of the Quatro socket to ensure comfort for each patient. Unfortunately, due to COVID-19 and the University closure, benchtop pressure testing was unable to be conducted and only a simple FEA could be created. An experimental design document was created such that future teams could execute the benchtop pressure and collect that data at a later date. This preliminary data is the foundation for justification of this advanced socket design. The team predicts that the results from the developed methods will provide the data needed that can justify that the Quatro is an improvement to traditional sockets on the market and help Quorum to improve the design.

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Introduction and Background

The field of prosthetics has made significant advancements in recent years but the prosthesis abandonment rate still remains around 25-57%[1]. The main cause of the rejection of a prosthesis is poor socket comfort[2]. Socket comfort can be affected by two major variables, pressure and volume change. High stress throughout the socket over a long period of time can lead to pressure ulcers, skin lesions, or vascular occlusions[1]. Previous research shows that volume change of a residual limb can range from -11% to 7% causing a nonoptimal socket fit[3]. Quorum Prosthetics has enlisted the help of the senior design team to analytically determine comfort through volume change and stress concentrations of their Quatro transfemoral prosthetic socket. The Quatro socket uses three independently adjustable zones, which allow the user to be able to control the volume and compression of the socket on the residual limb. The high adjustability allows for users to put on and take off the socket more easily. This adjustability also allows the users to tighten and loosen the socket depending on their fluctuating limb sizes throughout the day. Though there has been a lot of positive feedback about the Quatro, quantitative data is needed to back up their claim that the Quatro socket is the most comfortable socket available on the market. All prosthetic sockets must submit an application form to the Healthcare Common Procedure Coding System (HCPCS) that is reviewed and used to determine if the product will be granted a code of approval for Medicare/insurance reimbursement. The quantitative data collected by the senior design team is needed to prove that the Quatro socket is significantly different and will be worn longer than a traditional socket, and to get a new HCPCS code of approval for Medicare/insurance reimbursement. Without objective comfort data the device will not be approved by Medicare/insurance and the socket will be too expensive for the average consumer.

The process of determining comfort through volumetric changes and pressure distribution has similar applications for the medical device industry. Devices such as casts and wheelchairs must have a high level of comfort for the consumer to be satisfied. For casts, volumetric change and stress concentrations can be used to measure comfort. A loss in limb volume can result in higher displacements and an enhanced pistoning effect. While, an increase in limb volume can cause higher pressure and shear stress between the skin and the cast[3]. On the other hand, comfort of a wheelchair can be determined through pressure concentrations.

Products already in use to determine volumetric change and stress concentrations bioimpedance analyzers and F-sockets. A commonly used commercial bioimpedance analyzer (Hydra 4200, Xitron Technologies, San Diego, California) uses strip electrodes and a computer analyzer to determine how the volume in a residual limb changes over time[1]. The most used solution for collecting pressure measurements of a residual limb is the piezo-resistive F-Socket System (Tekscan Inc., Boston, MA, USA)[1].The F-socket wraps around the residual limb and allows the user to collect pressure data but not shear stress data. Due to the F-socket system's lack of versatility, cost, and time to be manufactured, the senior design team will be using a different Tekscan product (I-scan system 9830-10 pressure mapping sensor) to ensure the testing is not limited to the dimensions of only one residual limb and costs stay within the budget.

Industries outside of the medical device field also use processes and products to determine the comfort of their products. In a study done by Scott Openshaw at the University of Iowa, seat comfort and discomfort was quantified using objective measurements. To obtain measurements, Openshaw used a Xsensor pressure mapping pad that contained an electrical grid of transducers[4]. This allowed measurements such as average pressure, peak pressure, and contact area to be analyzed. Research has shown that a larger contact area with lower average and peak pressure is optimal for comfort[4].

Another related technology is a volume changing apparatus and storage medium (US6470293B1)[5]. This technology allows the user to rotate the device around two axes of a figure and the volume of the figure will be calculated. Volume change can be calculated by taking two volumetric measurements, one before and one after a volume changing event.

In order to test/apply the process created by the senior design team to determine comfort, a transfemoral amputee with a custom fitted Quatro socket will need to verify the process/results. Informed consent will need to be obtained in order to test the process on patients. Additionally, the HHS "common rule" regulation (45 CFR part 46) for research with human subjects will need to be followed. Measurements of pressure and volume contain uncertainty. Therefore, the ASME B89.7 standard for uncertainty will need to be used.

Problem Statement

A long term comfortable fit for a prosthetic socket is hard to obtain due to changes in volume of residual limb throughout an amputee's day. Quorum prosthetics has developed a patented technology within the Quatro prosthetic socket to allow for easy adjustments of the socket's fit to allow for a more comfortable experience (Figure 1). The socket is designed for transfemoral amputees and it utilizes 3 BOA dials (Boa Technology Inc., Denver CO) to adjust the fit of 4 panels against the residual limb. While Quorum has received plenty of qualitative data from patient testimonials that confirm that this socket is more comfortable than a traditional socket, quantitative data is needed to confirm that the fit and feel of the Quatro is superior. Quantitative data confirming the comfort of the Quatro socket is needed for patients to have the technology covered by Medicare or other insurance. Nearly every device used in the medical industry has an assigned Healthcare Common Procedure Coding System (HCPCS) code for healthcare claims to Medicare or other insurance. Traditional polypropylene prosthetic sockets and prosthetic limb components have a HCPCS code which is used in order to be covered by the patient's insurance. Currently, the Quatro socket does not have an associated HCPCS code. Because the Quatro is more expensive due to a more advanced design, the code for a traditional socket cannot be used to obtain full coverage and its own code must be assigned. Sufficient quantitative data which indicates that the Quatro socket is more comfortable than the

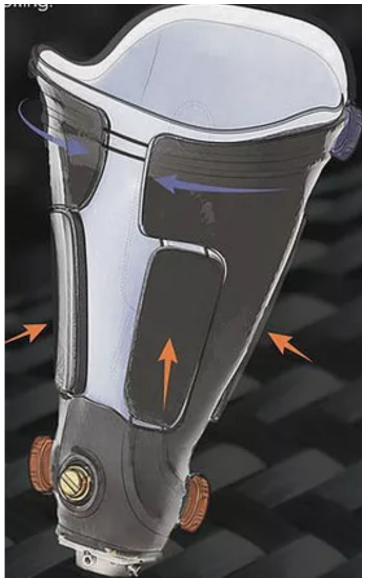

Figure 1: *Quorum Prosthetics - Quatro Socket with arrows showing the areas of adjustment zones*

traditional socket, and therefore more likely to be used for a longer period of time, is needed in order to ensure a HCPCS code can be assigned. Once the Quatro socket has its own code it will be able to be covered by patient's insurance which will make the technology more affordable. Quorum will also be able to distribute their product to more transfemoral amputees. The data produced through this project can also be used by Quorum to advance the design of the Quatro. Therefore, the overarching goal of this project is to present data which exemplifies the improved comfort of the Quatro socket for their users. This data will for the first time allow a direct correlation between pressure, volume change, and comfortability in a prosthetic socket.

Goals and Objectives

The main goal of this project is to quantify comfort of the Quatro prosthetic socket by means of volumetric changes and pressure changes experienced within the socket. While this is the main goal, there are additional goals that are of high importance. As observed in Table 1, the goals and their underlying objectives are listed and ranked from 1 to 5 based on their priority. A "5" indicates a high priority, while "1" indicates a low priority. The first, and main goal is to quantify the comfort of the prosthetic socket. Due to the fact that the main cause of rejection of a prosthesis is poor socket comfort, being able to quantify what comfort really is and what aspects affect comfort of a socket is important[2]. In order to quantify comfort, data on volumetric changes and pressures experienced within the socket will be collected. Quorum believes their tests were unable to capture the entire volumetric range of the Quatro and hope to get data greater than previous tests. Therefore, it is desired to collect data of the total percent volumetric change that exceeds 9.5% (which is what previous tests conducted by Quorum found). The desired output of the pressure testing is the total range of pressure experienced throughout the socket as panel tightness is adjusted.

Along with wanting to quantify prosthetic comfort, another goal is to model an accurate limb/socket interface. This goal was determined due to a request from the Quorum Prosthetics team to create a better virtual model of the socket in order to perform accurate analyses of pressure and load distribution. Within this goal, the objectives include creating a model using the HandyScan Exascan 3D scanner (Creaform Inc.; Levis, QC) and validating the finite element model through a physical experiment.

Another goal of this project is to determine the most common modes of failure of the prosthetic socket. Due to patients likely wearing the prosthesis on a daily basis and relying heavily on the socket's durability, it is important to understand how failure of the prosthesis may occur. The objectives within this goal include completing a failure analysis on the socket through properties of materials used in the socket design and determining possible alternate materials to improve durability.

The final goal of the project is to make the process versatile, meaning it can be replicated between patients. It is important that once the process is created, it must be able to be used for not only the specific Quatro Socket provided to the senior design team, but for other patient's sockets as well. The main objective of this goal is to make the process easily scalable and transferable between patients. If the process was only able to be used for one patient and their

specific socket, then it would not be a beneficial process. That is why the goal of making it versatile is a high priority goal.

Table 1: *Summary of Goals and Objectives*

Goal	Objective Name	Priority Rating	Method of Measurement	Objective Direction	Target
Quantify prosthetic socket comfort	Collect data for volumetric changes within the socket	5	Percent volume change, [%]	quantify	> 9.5%
	Collect data for pressures experienced within the socket	5	Tekscan [Pa]	quantify	Total range
Model limb/socket interface	Create model via 3D scan	5	Accuracy [microns]	maximize	20 microns
	Validate Model	5	Standard deviation	minimize	<1 Std Dev[6]
Determine most common failure modes of prosthetic socket	Complete failure analysis of materials used	5	Von Mises Failure Theory [$\sigma_e > \sigma_y$]	failure	Yes/No
	Determine possible alternate materials to improve durability/ strength	3	Ultimate Strength [MPa]	maximize	To Be Determined
Versatile	Easily scalable and transferable between patients	5	qualitative	N/A	Yes/No

Requirements (Criteria and Constraints)

Due to the research-like nature of this design project, there are limited constraints which are required to be followed. Quorum prosthetics has defined few constraints that are involate of the design which are summarized in Table 2. A need for a detailed pressure and load map on the Quatro socket has been expressed. The socket has been previously tested using a FSocket Clinical (Tekscan Inc., Boston, MA, USA) pressure mapping system (Figure 2). While the FSocket data reports the information advertised, it is not presented in reference to the entire socket. Therefore, a more detailed pressure distribution is required to be implemented in the senior design project (Figure 3). While there is no specified number of nodes for the finite element mesh defined by Quorum, the team aims to have a model which captures the detail of the limb and socket similar to Figure 3 as well as appropriate material properties and boundary conditions.

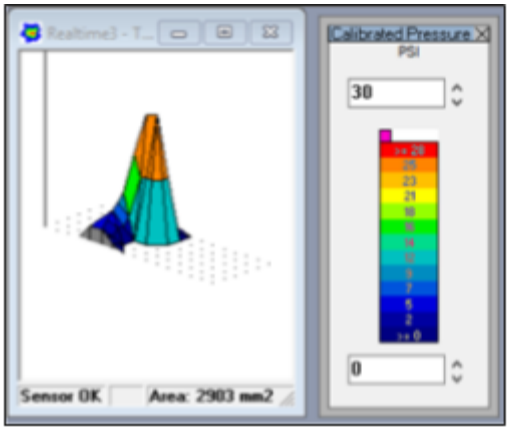

Figure 2: *FSocket (Tekscan) Pressure Distribution*

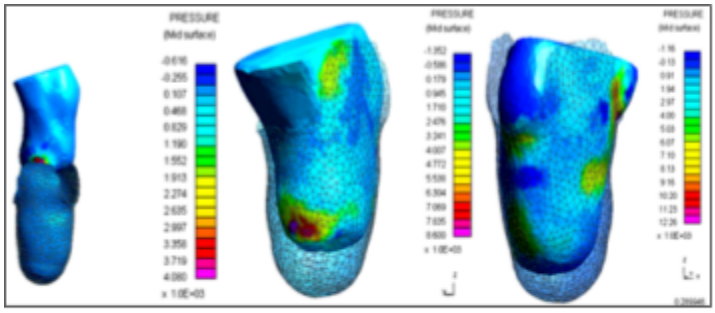

Figure 3: *Suggested Pressure/Load mapping results (Frillici 2008)*

Every Quatro socket is made to fit each patient individually, therefore the process developed to analyze the socket must be able to be transferable between patients. The process developed must not be designed to work only for the socket provided by Quorum. Quorum identified this as a requirement which must be completed. This is reasonable because a socket analysis process that is only applicable to one patient's specific socket is less beneficial to the customer than a process which is more versatile.

When performing a finite element analysis, it is important that the model created is validated through physical data. Therefore, the senior design team is required to conduct a physical experiment to validate the pressure and load mapping data presented in the FEA model. The data collected through benchtop testing will be compared to that shown in the FEA model and will be used to confirm if the properties of the model are accurate, thus validating the model. The experiment will consist of the Quatro socket provided by Quorum, a model residual limb, Tekscan pressure sensor, and a cyclic loading device in the Orthopedic Bone Research Laboratory (OBRL).

Finally, the project is additionally constrained by the budget of $5000 provided by Quorum and limited to be completed within the duration of the senior design course (8 months [September 2019- May 2020]).

Table 2: Summary of Constraints

Constraint Name	Methods of Measurement	Limitations Consistent with Measurement Method
Detailed Pressure and Load Mapping	[Present/Absent]	Present
Transferable Among Various Patients' Sockets	[YES/NO]	YES
Validated Model of Residual Limb and Socket Interface	[Present/Absent]	Present
Cost	[$]	$5000 (project budget given)
Time to complete	[months]	8 months (September 2019-May 2020)

Design Summary

The project consists of a process rather than a product which requires a defined list of tasks rather than a suggested physical design. The process developed by the senior design team includes two portions: benchtop data collection and virtual analysis. Benchtop data collection will include conducting a volume analysis using an air bladder to measure the volume range that the Quatro socket is capable of. Additionally, the data collection will include collecting pressure data using a Tekscan sensor, a model limb constructed from ballistic gel, and a cyclic loading hydraulic machine to simulate the loads associated with walking. Benchtop data may also progress to pressure data within the socket while being worn by a patient (if time permits). The virtual analysis will include volumetric data collection using a virtual 3D model of the Quatro socket. Finite Element Analysis (FEA) will also be conducted to determine a detailed pressure distribution within the socket which can be scaled to apply to various sizes of residual limbs. The virtual model will also be used to conduct a failure analysis which cannot be done in the benchtop phase without breaking a socket. Data collected in the benchtop testing phase will be used to validate the FEA results and ensure that correct boundary conditions were applied and appropriate material properties were used. This was to be conducted using a Smooth-Cast 320 model limb and patient limb. A summary of the process can be seen in Figure 4.

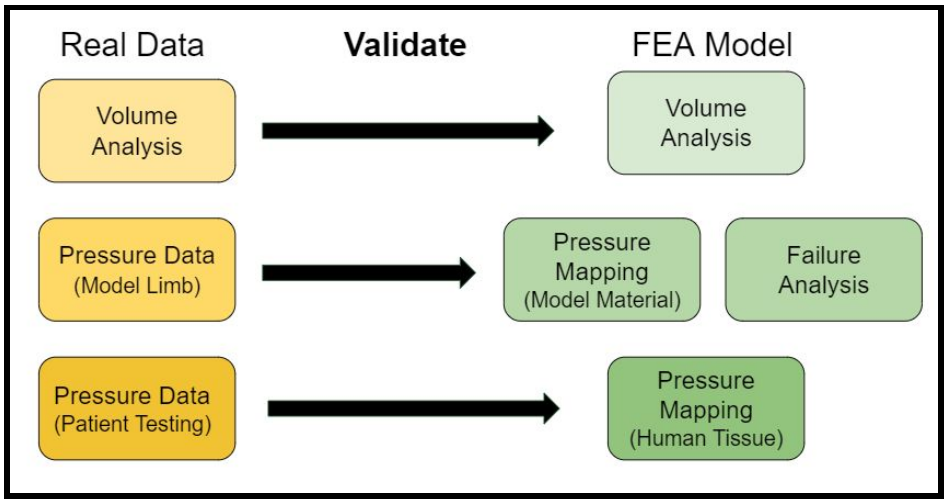

***Figure 4**: Process summary flow chart.*

Design Decisions

When beginning this project, it was known that the main components that needed to be assessed included measuring volume change as the Quatro Socket is adjusted, the pressure/force distribution of the socket on the residual limb, and at what point the socket would fail. These as a whole, would be used by Quorum Prosthetics to determine the quality of the socket, volumetric change capabilities, and quantify comfort. With these components in mind, different design ideas were researched and discussed in order to create a process that was efficient, affordable, versatile, and simple to execute. Several aspects of the process were evaluated, and decision matrices were created in order to determine the best approach for each component of the overall design. To calculate the total values shown in the design decision tables, first the criteria for the decision options were weighted based on relative importance with values 0-100, which in total, had to add up to 100. Then the decision options were either given a 1, 0, or -1, with 1 meaning the criteria was met well, 0 meaning the criteria was met somewhat, and -1 meaning the criteria was not met. After the options were given one of those values, the decision value was multiplied by the weight of the criteria and the column was totaled for each decision option. The option with the highest calculated value was the option chosen for the project. Tables 3 through 6 show the design matrices.

Volume Measurement

As stated in the introduction, one of the major variables that affects socket comfort is volume change, and due to the adjustability of the Quatro Socket, a process to measure the volume change as it is adjusted was necessary. Three different methods of measuring the volume change were discussed and compared. The criteria and decision can be observed in Table 3.

The first method evaluated was the use of a deflated, 8.5 inch diameter rubber air bladder which was to be placed inside of the Quatro socket and filled with air until it began to extend out through the openings in the socket. As the BOA dials are turned to tighten the panels which adjust the volume of the socket, a pressure gauge will measure the pressure of the bladder at different volumes. The ideal gas law will then indicate volume changes via the linear relationship between pressure and volume. The second method evaluated includes filling the waterproof, carbon fiber socket with water, with the initial volume known. Then the BOA dials would be turned to adjust the volume of the socket, and the water displaced would be measured, and the volume change could be determined. The final method included first using an alginate to create a mold of the socket when the BOA dials were completely dialed in, so the socket was as tight as it could be and another mold when the dials were turned so the socket was as loose as it could be. The molds would then be placed in water, and a water displacement test would be performed, and the differences in volume would be recorded.

The table below shows the decision matrix when comparing these different volume measurement methods. The main criteria are a realistic simulation, ease of use, cost, and potential damage to the socket.

***Table 3**: Volume Measurement Method Design Decision Matrix*

Volume Measurement Method		**Bladder**	**Water**	**Alginate**
Realistic Simulation	**60**	1	-1	-1
Ease of Use	**20**	-1	1	1
Cost	**10**	-1	1	0
Damage to Socket	**10**	0	0	-1
	Total	**30**	-30	-50

The decision matrix shows that the use of an **air bladder** is the best method for measuring volume change, while considering the important criteria listed above.

Type of Bladder

Due to the use of an air bladder for measuring volume change being the best method for this process, different types of bladders or bladder-like devices needed to be considered in order to choose the one that would work the best for this process. The three bladders considered included an industrial rubber bladder, a mini soccer ball, and a kick ball.

The table below shows the decision matrix when comparing the different bladders that could be used in the volume change measurement process. The main criteria are ease of use, measurement of total volume that could be obtained, the lead time, cost, and durability of the bladder.

***Table 4**: Type of Bladder Design Decision Matrix*

Type of Bladder		**Industrial Bladder**	**Mini Soccer Ball**	**Kick Ball**
Ease of Use	**25**	-1	0	0
Total Volume	**30**	1	-1	1
Lead Time	**20**	-1	1	1
Cost	**10**	-1	1	1
Durability	**15**	1	-1	0
	Total	-10	-15	**60**

The decision matrix shows that the **kick ball** is the best bladder that could be used in the volume change measurement process, while considering the important criteria listed above.

Program for FEA

Finite element analysis (FEA) will be performed in order to simulate volume and pressure changes experienced in the socket. Because capabilities of FEA programs can vary and the senior design team has limited experience and access to some programs, it is important to compare the possible software with a decision matrix. Two FEA programs considered were ANSYS (ANSYS Inc., Canonsburg, PA., USA) and Abaqus (Dassault Systèmes, Vélizy-Villacoublay, France).

The table below shows the decision matrix when comparing the FEA programs. The main criteria are scalability (which was of great importance considering it is one of the design constraints), experience with the program, solve time, and availability.

***Table 5**: Program for FEA Design Decision Matrix*

Program for FEA		**ANSYS**	**Abaqus**
Scalability	**40**	1	1
Experience	**10**	1	0
Solve Time	**30**	-1	1
Availability	**20**	1	-1
	Total	40	**50**

The decision matrix shows that the **Abaqus** is the better program to be used when performing FEA, while considering the important criteria listed above.

Pressure Measurement Device

For the final design matrix, different pressure measurement devices were considered and evaluated. Because the other main variable that affects socket comfort is pressure, finding a device that can result in detailed pressure information about the socket needed to be determined. The pressure measurement devices were narrowed down to the use of a Tekscan (Tekscan Inc., Boston, MA, USA) and single strain gauges.

The table below shows the decision matrix when comparing the two pressure measurement devices. The main criteria are amount of detail (creates a detailed pressure distribution), ease of use, cost, lead time, and versatility.

***Table 6**: Pressure Measurement Device Design Decision Matrix*

Pressure Measurement Device		**Tekscan**	**Strain Gauges**
Detail	**20**	1	-1
Ease of Use	**20**	1	0
Cost	**15**	-1	0
Lead Time	**15**	0	0
Versatility	**20**	-1	1
	Total	**5**	0

The decision matrix shows that the use of a **Tekscan** is the better device to use when measuring pressure distribution in the socket, while considering the important criteria listed above.

Final Concept

Process Design and Feasibility Analysis

To obtain a geometric model of the socket, 3D scans were performed on the outer socket with (Figure 5) and without the modular panels. High quality 3D scans are important to be able to obtain accurate measurements of the unique geometry of the socket since each socket is unique to the individual patient. The outer surface of the inner socket was scanned separately (Figure 6). The four panels were also scanned individually to allow for the creation of an assembly of the four panels and socket once the parts are all put into the FEA program. The outer socket is composed of carbon fiber that undergoes a wet lay up process over a positive mold created by a cast of the patient's residual limb. This same positive mold is used to make the flexible polyurethane inner socket. These materials will be assigned to their respective 3D models in the finite element model. The 3D scans are composed of a triangulated mesh with faces composed of areas between three vertices of a triangle (Figure 7).

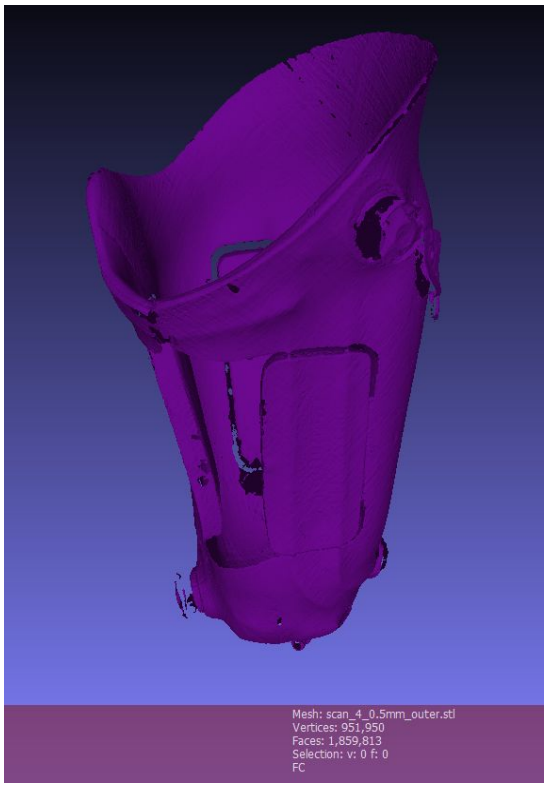

Figure 5: *3D scan of outer socket with modular panels (0.5 mm resolution)*

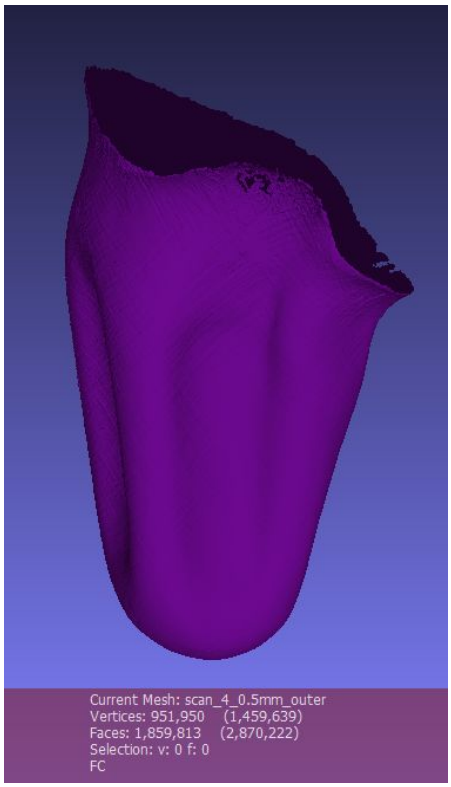

Figure 6: *3D scan of outer surface of inner socket (0.5 mm resolution)*

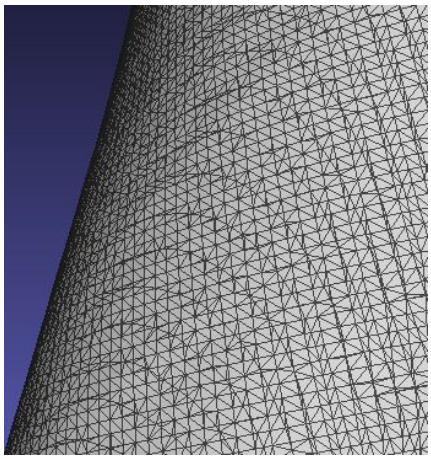

Figure 7: *Close up of the surface mesh (triangular elements) that the 3D scan creates*

The first benchtop experiment of finding the volume change capabilities of the socket is performed utilizing the principles of the ideal gas law. Volumetric change was measured using an air bladder (kick ball), a tire pressure gauge, and an air pump. The air bladder was inserted into the Quatro socket with panels stretched to their loosest setting. Then using the air pump, the bladder was pumped with air to capacity while inside the socket. Figure 8 shows a schematic volumetric change experimental setup. The panels of the socket were tightened against the bladder, and a recording of the internal pressure of the bladder was made when the panels were completely tightened. During these experiments, it was assumed that the number of moles of air molecules and the temperature of the air remains constant. The corresponding volume change of the bladder and therefore socket was then determined using the ideal gas law (equation 1); where 'P' is pressure, 'V' is volume, 'n' is the number of moles of gas, 'R' is the ideal gas constant ($8.314\ \frac{J}{K\ mol}$), 'T' is absolute temperature.

Figure 8: *Volumetric testing set up with the air bladder inside the Quatro socket. Arrows indicate the direction at which the dials were turned.*

$$PV = nRT \qquad \text{(Equation 1)}$$

Throughout the experiments it was assumed that the right side of equation 1 remained constant and therefore an increase in pressure can be linearly related to an equal decrease in volume. It is of interest to record and present the change in volume to the clients, so the change in volume calculated from the change in pressure will be related back to the starting pressure. These values were recorded and reported as a total percent volume change. After executing this process 10 times, the mean volumetric change of the 10 trials was calculated. A detailed procedure of these experiments, along with calculations, raw data, and statistics are included in Appendix A.

The second benchtop experiment to find the pressures experienced within the socket under simulated loading conditions included a series of loading simulations using the Bionix Servohydraulic Test system (MTS Systems, Eden Prairie, MN, USA) from the OBRL. This was going to be done using the specific patients' weight to calculate the force that is needed to simulate scenarios such as standing and walking. These loading cycles are shown in Figure 9. Loading cycles associated with walking and running were determined through literature on ground reaction forces as a percent of body weight[19][20]. The inner socket was used as a mold to create the residual limb model out of Smooth-Cast 320 because this material was easy to manufacture and for the FEA analysis Smooth-Cast 320 mechanical properties are better understood than properties of human tissue. A 9830-10 I-scan pressure mapping sensor from Tekscan (Tekscan Inc., Boston, MA, USA) was going to be used to collect the pressure data. Once the sensor was calibrated, it was going to be placed in the Quatro socket along the panels with the mold of the residual limb, as seen in Figure 10. The MTS system was then going to be

used to simulate the loads from the limb associated with standing, walking, and running to obtain a general pressure distribution within the socket from the Tekscan sensor. The diagram of the Quatro socket experimental setup on the MTS machine can be seen in Figure 11. This same process of pressure data collection was to be repeated using a ballistic gel mold which more accurately models the properties of human tissue. Following this, the same process of pressure data collection was to be conducted with a patient which the provided Quatro socket was created for.

Figure 9: *Suggested loading cycles for pressure testing for standing, walking, and running.*

Due to university closure caused by COVID-19, all physical work on engineering senior design projects was halted in March 2020, so physical pressure data was unable to be produced. To compensate for the lack of benchtop pressure data, a detailed procedure of how to collect the data can be found in Appendix B. This procedure includes calibration instructions, sensor placement, testing set up, and loading scenarios. The Verification and Validation section of this report also explains more of what was to be done on this aspect of the project.

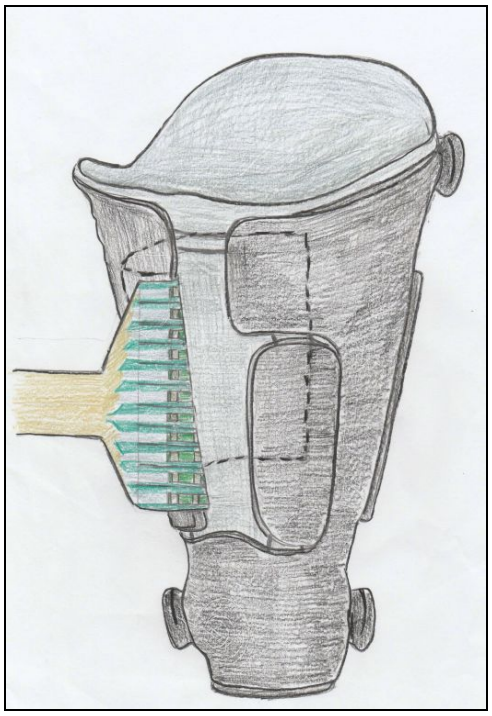

Figure 10: *Illustration of Tekscan placement on Quatro socket for pressure testing*

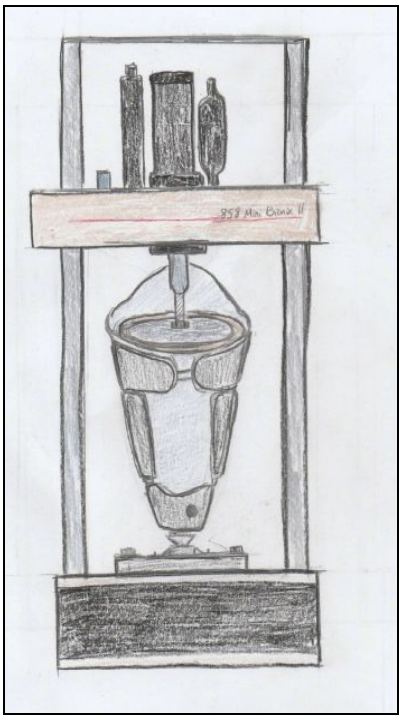

Figure 11: *Illustration of Quatro socket experimental setup on the MTS machine*

The virtual analysis portion of the project was focused on obtaining detailed pressure distribution data within the socket by performing a finite element analysis (FEA). The program called Abaqus (Dessault Systèmes, Vélizy-Villacoublay, France) was used for the FEA. The scan of the socket, obtained as explained previously, was converted into a 3D solid model of the socket in Solidworks (Dassault Systèmes, Vélizy-Villacoublay, France). The 3D scan stl (stereolithography) file cannot be used to create an assembly for FEA and must be converted to a solid prt (part) file via Solidworks' mesh prep wizard and surface wizard functions. When the solid parts have been created, a mesh made up of tetrahedral elements that capture the complex organic geometry of the socket must be created for FEA. The scan of the inner liner of the socket was also used to create a 3D model of the residual limb. An assembly of the socket and residual limb models were constructed and uploaded to Abaqus. A mesh was created using the tetrahedral elements and appropriate material properties for respective aspects of the assembly were assigned. Loading conditions associated with standing were applied to the model, and the model was run to produce pressure data with varying the tightness of the panels.

A finite element model using the Smooth-Cast 320 was simpler to conduct and was more likely to give successful data that aligns with the benchtop testing. The human tissue FEA model will likely be more time consuming due to the process of accurately modeling the complex combination of different soft tissues with different properties within the limb. A summary of models of material properties and associated constants of various soft tissues are outlined in a paper which describes an FEA model of a lower residual limb[16]. Once the model is set up with the appropriate loading of the patient's weight on the limb-socket interface, the material properties are assigned, and the model is validated using benchtop data, a failure mode analysis will be conducted using Abaqus. This failure mode analysis will use the maximum distortional energy theory to determine the locations on the socket in which failure will occur. The failure mode analysis will use the von mises stress associated with each finite element (calculated by Abaqus using the boundary conditions defined) and the yield strength of the socket materials.

The final step in the process consists of validating the results of the finite element analysis using the pressure data collected during benchtop testing. Pressure values from the discrete locations in which the Tekscan sensor is placed on the socket will be compared to the pressure values given by Abaqus on the 3D model. If the pressure values are consistent then the FEA model is known to be valid with accurate boundary conditions and material properties. If these values are not consistent, then the boundary conditions or material properties must be altered to align with the benchtop data.

Again, due to the university campus closure, the computational abilities of the team's personal devices were limited compared to what was available on campus at the OBRL. Therefore, the models created were less complex than what the team thought was ideal, in order for results to be produced remotely. This also affected the validation of the finite element analysis. The Verification and Validation section of this report, again, also explains more of what was to be done on this aspect of the project.

Failure Modes and Risk Analysis

A risk analysis was conducted to identify possible failure modes that would impact the team's designed process and to mitigate them by correcting the process. The team's process risk includes categories such as benchtop data collection, human safety, finite element model validation, and other important design considerations. While designing a method to determine comfort, all risk categories were reviewed and a Risk Priority Number (RPN) was determined prior to the mitigation action. The RPN was then re-evaluated after the mitigation action was taken. The table shown below summarizes potential failures along with their RPN and the actions the senior design team have taken to minimize occurrence. SEV is the severity, or how severe the effect is on the team. OCC is the occurrence, or how frequently the issue is likely to occur. Finally, DET is the detection, or how probable it is to detect the failure mode or its cause. RPN was calculated by multiplying SEV x OCC x DET.

***Table 7**: Failure Modes and Effects Analysis (FMEA)*

Process Step	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Process Controls	DET	RPN	Actions Recommended	Responsibility	Actions Taken	SEV New	OCC New	DET New	RPN NEW
Benchtop data collection	Tekscan sensor breaks	No pressure data / Inaccurate pressure data	8	Mishandling of sensors or sensor failure	4	New sensors used and stored with care	3	**96**	Follow ASTM standards for sensors	Senior design team	Tekscan stored and used according to ASTM	8	2	3	**48**
Benchtop data collection	Incorrect calibration of Tekscan	Inaccurate pressure data	7	Poor calibrations techniques	3	Pre-calibrated sensors purchased	5	**105**	Follow ASTM standards for calibration	Senior design team	Tekscan calibrated and tested prior to being used	7	2	4	**56**
Benchtop data collection	Volume collection method unable to capture full volume range	Inaccurate volumetric data	7	Entire socket not filled / bladder leakage	5	Proper sized bladder used and visual leakage test	2	**70**	Air leakage test to ensure proper seal and fit	Senior design team	Air leakage test and proper sized bladder	7	1	2	**14**
Validated FEA model	Not validated from benchtop data	Does not produce accurate and useful data	9	Incorrect boundary conditions or material properties	7	Research proper applications of boundary conditions and material properties	2	**126**	Additional material testing to ensure correct properties	Senior design team	Individual tests for each material being used	9	3	2	**54**
Validated FEA model	Tekscan placement differs between tests	Benchtop data does not represent FEA model data	6	Inaccurate coordinate loactions	5	Calipers used to measure placement	4	**120**	Coordinate system for benchtop and FEA aligned	Senior design team	Precise coordinate systems created and aligned	6	2	3	**36**

SEV = severity, OCC = occurrence, DET = detection, RPN = risk priority number

Human Factors Analysis and Classification System

In addition to the Failure Modes and Effects Analysis (FMEA), a human factors analysis was conducted for the process. This allows the team to investigate the process, predict possible human errors, and target future training. The team will then be able to identify and determine if these human factors could be reduced within the design of the process. An example of this is to display multiple socket sizing screens in order to limit the possibility that an operator incorrectly sizes the finite element model which would result in inaccurate data. If the team can identify

potential human errors such as this, then it is more beneficial to implement a fix prior to allowing others to go through the process.

A preliminary human factors analysis and classification system (HFACS) was conducted and is shown below (Figure 12). The process will be primarily used by trained prosthetists who have gone through training and the safety protocol of the process. Therefore, they should not have a problem going through the process, and human factors should not impact the process. However, since the process is user friendly and requires minimal contact with a patient, it is likely that an untrained individual will operate part of the process. These individuals must still be looked at within the analysis due to the majority of the risk lying with operators. Patients hold little to none of the risk due to their limited involvement in the process. The only step patients are involved in is the initial measurement of their residual limb.

Skill-based Errors

- Breakdown in visual scan
- Failure to scale model correctly
- Failure to check all settings before starting procedure

Decision Errors

- Failure to use correct residual limb model

Perceptual Errors

- Incorrect settings/scale used based on a faulty measurement
- Failure to set finite element to proper settings

Routine Violations

- Failure to complete process based on specified setting due to previous experience
- Failure to meet training requirements for the process.
- Failure to properly prepare for simulation

Exceptional Violations

- Failure to complete process based on specified setting due to previous experience
- Failure to meet training requirements for the process.
- Failure to properly prepare for simulation

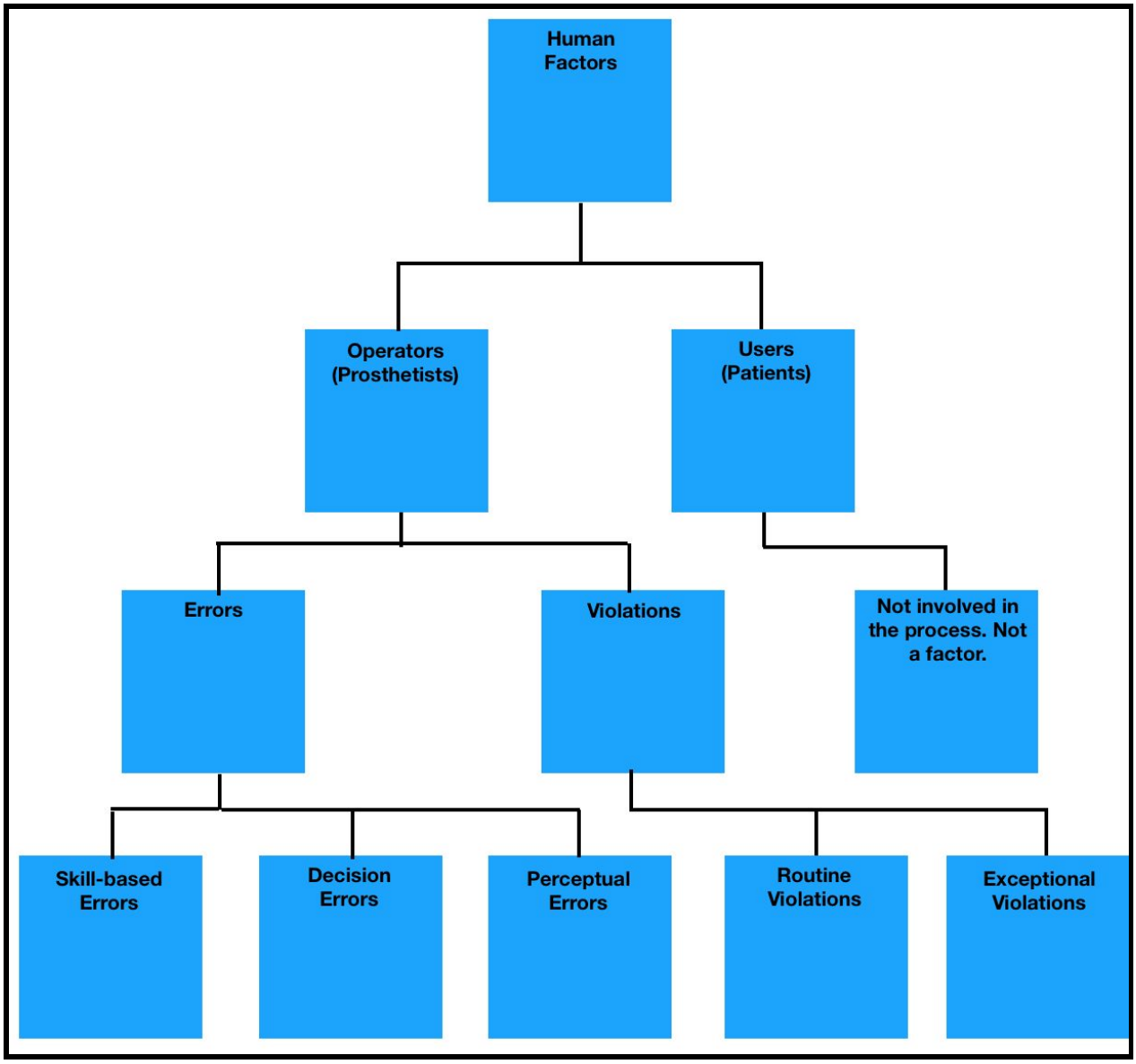

Figure 12: *Human Factors Analysis Chart*

Design for (X)

The Quatro socket testing process was primarily designed for reliability, transferability, and user friendliness. In order to make the process reliable, the finite element models using the smooth cast model limb and patient limb will be validated using the benchtop data. Initially, the finite element model using the smooth cast model limb properties will be validated through the corresponding benchtop data. Validation of the results confirms that appropriate material properties and boundary conditions were used in the finite element analysis. Once the boundary conditions have been confirmed the model will then be altered to include the material properties of human tissue and will be validated through the corresponding benchtop data. This will be done by confirming that pressure data collected with the socket worn by a patient corresponds with the FEA model using human tissue material assignments. This will be conducted if time permits as modeling human tissue material properties in finite element analysis is highly complex. If completed, this will result in two validated models in which one is modeled to simulate an accurate and realistic loading scenario with human tissue material properties. This allows the finite element model to be fully validated and provides the user with accurate and reliable data.

The completed and validated model conducted in Abaqus allows the finite element model to be scaled. Abaqus has the capability to alter the scale of a model. This allows for the model to be transferred between patients of different sizes and types of residual limbs, reliably. A user would then be able to change the finite element model to match a specific patient's residual limb and prosthetic socket. This feature also contributes to the user-friendliness of the process once basic instruction on how to conduct the analysis has been given to the user. The ability to reliably transfer the finite element model between patients is a primary goal of the team’s designed process.

The team's process will be primarily used by prosthetists who likely have little experience using, navigating, and understanding finite element analysis or Abaqus. This lack of experience is why the process was also designed for user friendliness and ease of use. The pressure map, of the prosthetic socket residual limb interface, will be displayed directly on the 3D finite element model of the socket allowing the user to easily identify locations of high and low pressure that affect comfort. Additionally, sizing and selection of the type of residual limb will be simplified by asking the user for key measurements and bone structure of the limb.

Budget

Below is the final budget for the Quorum Prosthetics senior design project. The team's budget is broken up into three sections including benchtop testing, raw materials, and lab fees. Additionally, it is important to note that the group was unable to fabricate and run benchtop data for the pressure analysis. An estimated cost to finish this testing is included in the table below.

Table 8: *Budget Summary*

Quorum Prosthetics Senior Design Budget								
Benchtop Testing			**Raw Materials**			**Lab Fees**		
Item	**Purchase Price**	**Fabrication Cost**	**Item**	**Purchase Price**	**Fabrication Cost**	**Item**	**Purchase Price**	**Fabrication Cost**
Air Bladder + Pump	1 @ $14.00		Balistic gel	1 @ $140.00		I2P	1 @ $50.00	
Tekscan 9830 sensor	1 @ $214.00		Scan spray	1 @ $50.00				
Tekscan software	1 @ $2,687.00							
Pressure Guage	1 @ $9.50							
Category Total	$2,924.50		**Category Total**	$190.00		**Category Total**	$50.00	

Budget Needed to Finish Testing		
Item	**Purchase Price**	**Fabrication Cost**
OBRL computing time	25hrs @ $40.00	
OBRL servo press	10hrs @ $60.00	
Mounting fixtures		1 @ $50
Category Total	$1,600.00	$50.00
Total Future Expenditures	$1,650.00	

Quorum Funds	$5,000
Total Spent	$3,165
Remaining Funds in Budget	$1,835
Estimated Total Future Expenditures	$1,650
Estimated Final Remaining Funds in Budget	$185

Verification and Validation

Once completing the project, the goals and their associated objectives along with the constraints of the project were assessed to see if they were met. Many goals were unable to be met due to the halting of all physical work on Colorado State University engineering senior design projects due to COVID-19. The global pandemic which ensued resulted in a university closure starting in March 2020 and therefore caused difficulty for senior design teams to continue with planned work. Improvisations were made to previous project outlines which are described in detail below. Limitations contributing to goals not being met due to the effects of the pandemic and having to continue senior design work from home are also included.

Goal: Quantify Prosthetic Socket Comfort

Goal	Objective Name	Priority Rating	Method of Measurement	Objective Direction	Target
Quantify prosthetic socket comfort	Collect data for volumetric changes within the socket	5	Percent volume change, [%]	quantify	> 9.5%
	Collect data for pressures experienced within the socket	5	Tekscan [Pa]	quantify	Total range

Objective: Collect data for volumetric changes within the socket

The first objective the team had to complete was to obtain data on the total percent volume change which the Quatro socket is capable of accomodating. The theory behind the process for collecting volumetric change data is outlined in the Final Concept section of this report and the detailed procedure and calculations associated with this objective are outlined in Appendix A.

The results after conducting ten iterations of the volumetric tests included a mean percent volume change of 12.10% with a standard deviation of 0.85% (Figure 13). Raw data from this experiment is presented in Appendix A.

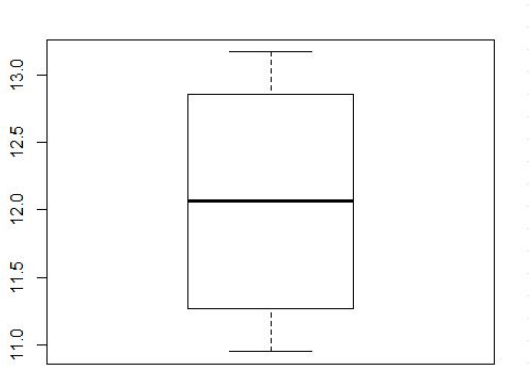

Figure 13: *Boxplot of Volumetric Testing Results*

The objective to collect data on the volumetric changes within the Quatro socket was satisfied because the results obtained from the tests conducted significantly exceeded the target of > 9.5% change in volume (see Table 1).

The data on volumetric change was collected prior to the university closure due to COVID-19. Therefore this objective was unaffected by the restrictions on physical work. Even if this had not yet been completed prior to the university closure, all of the materials and equipment necessary for performing these tests were available off campus and could be conducted from home.

While there were no issues in completing this objective that were associated with COVID-19, the team experienced issues in the testing procedure resulting in the BOA dials to break while tightening the panels. This was an inconvenience for the team but it provided information on the failure modes of the socket. While one would initially assume that failure of the Quatro would first occur at the cord which is tightened by the dials, the discovery that the dials are the first site of failure was important insight for the team on failure modes.

Objective: Collect data for pressures experienced within the socket

Due to the COVID-19 restrictions on physical work and testing of various aspects of the project, the team was unable to collect pressure data through the planned experimental designs. Though this came at an unfortunate time during the project, the team was on the verge of conducting these benchtop tests of the socket limb interface. The team had acquired the necessary materials and were in the process of fabricating fixtures for the mating of the MTS machine, model limb, and socket. The sensors were equilibrated and were in the process of being calibrated for the various testing scenarios.

The experimental design for this objective is outlined in a standalone document found in Appendix B. This was created to thoroughly illustrate the planned testing to obtain pressure data and to allow for the testing to be conducted at a later date by future students. While this objective was not met because of COVID-19, the senior design team made an effort to demonstrate the work that was done in planning the detailed testing process and depict what would have happened had the university closure not occured.

Goal: Model Limb-Socket Interface

Goal	Objective Name	Priority Rating	Method of Measurement	Objective Direction	Target
Model limb/socket interface	Create model via 3D scan	5	Accuracy [microns]	maximize	20 microns
	Validate Model	5	Standard deviation	minimize	<1 Std Dev[6]

Objective: Create model via 3D scan

The next objective that had to be completed by the team was creating a virtual model of the Quatro socket via 3D scanning. This 3D model was important to create in order for the finite element analysis to be performed. The Final Concept section of the report details how a 3D scanner was used to create the virtual model. This objective was able to be completed and a scan of the outer and inner surface of the socket were created, as well as the inner socket liner. The scan was created within the target resolution of 20 microns as the 3D scanner used was capable of capturing this resolution.

An image of a scan of the socket can be seen in Figure 14. These scans were successfully uploaded to Solidworks in order to make a 3D solid model of the socket as well as a 3D model of the residual limb. The models created from these scans were then able to be uploaded into Abaqus to perform the finite element analysis.

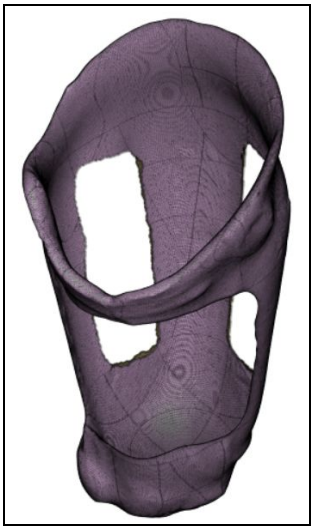

Figure 14: *3D scan of Quatro socket created*

Objective: Validate model

The objective to create a fully validated finite element model was not fully completed due to the COVID-19 university closure. This objective was supposed to use the 3D solid model of the Quatro socket within an Abaqus simulation. However, the senior design team no longer had access to the OBRL's supercomputer and Abaqus license. This required that the team use the academic Abaqus license which limited the number of nodes that could be used to 250,000. The 3D scan contained well over 250,000 nodes. Therefore, the scan could not be used and an alternate model of the socket needed to be made with less detail. Additionally the university closure limited the team to the less powerful computational ability of their personal computers which were not capable of producing FEA results as fast as the computers available at the OBRL.

The final socket used to perform the finite element analysis was created by making a shell from an obj file of the patient's scanned residual limb. This ensured perfect contact between the socket and the residual limb. Material properties, boundary conditions, and loading conditions were assigned based on a walking gait cycle and can be seen in Figure 15. The final results of the finite element analysis can be seen in Figure 16.

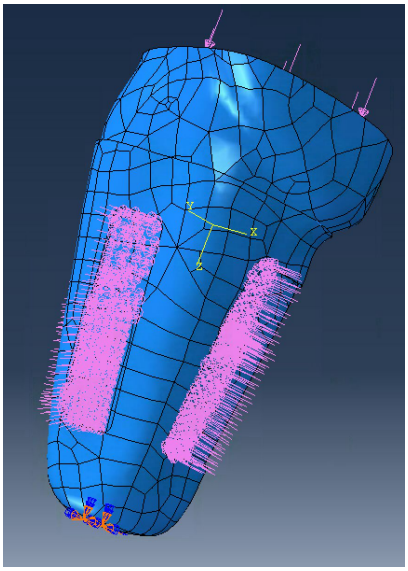

Figure 15: *Loading Conditions*

In order to validate this model, benchtop data is needed to compare pressures and validate that the finite model results are within 1 standard deviation of the benchtop data. Due to COVID-19, benchtop data was not able to be collected. Therefore, the final model is not validated and the objective was not met.

In the future, a more sophisticated finite element model can be created using the 3D scans and more nodes. This new model can then be validated after the benchtop data is performed. If the results are within 1 standard deviation of each other the model can be said to be validated. However, if they are not with 1 standard deviation the finite element model needs to be altered such that the pressure data agrees.

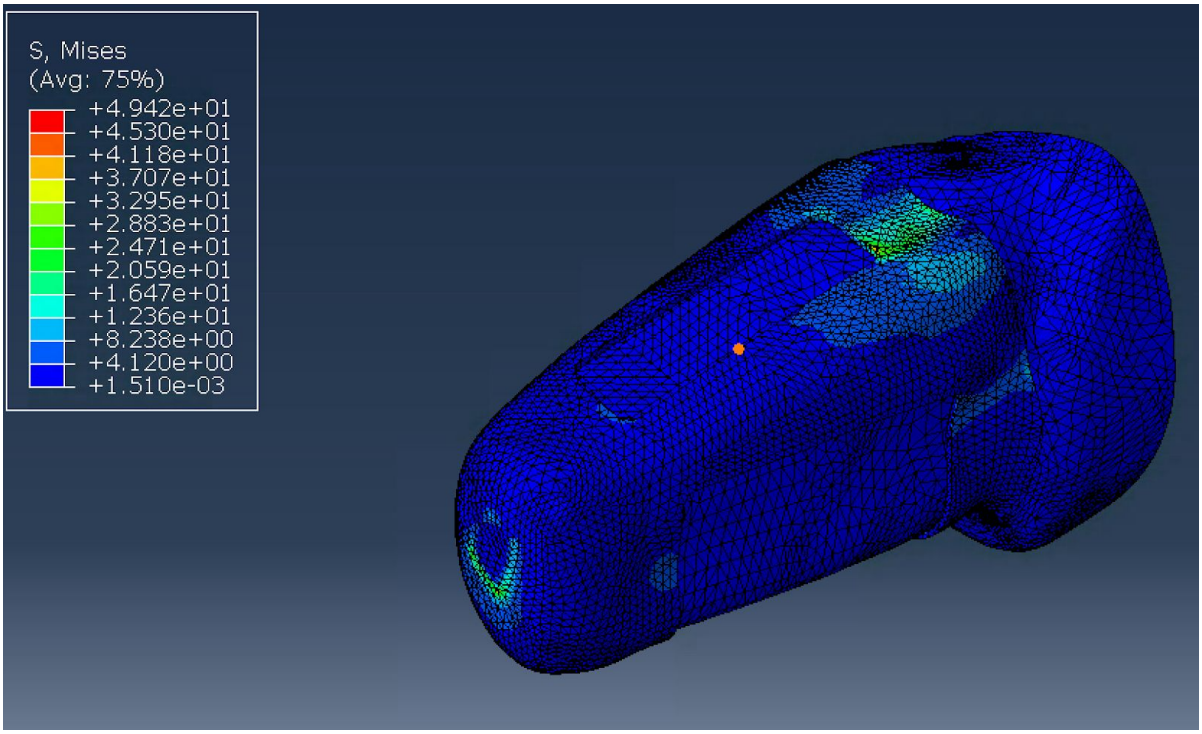

Figure 16: *Final result of FEA*

Goal: Determine Most Common Failure Modes of Prosthetic Socket

Goal	Objective Name	Priority Rating	Method of Measurement	Objective Direction	Target
Determine most common failure modes of prosthetic socket	Complete failure analysis of materials used	5	Von Mises Failure Theory [$\sigma_e > \sigma_y$]	failure	Yes/No
	Determine possible alternate materials to improve durability/ strength	3	Ultimate Strength [MPa]	maximize	To Be Determined

Objective: Complete failure analysis of materials used

This objective aimed to determine what part of the Quatro socket would break first and at what loading condition this would take place at. Completing this objective would provide information on the locations of these high concentrated stresses. This objective relied on having a fully validated FEA model to analyze. Since no validation was able to take place, no failure analysis was conducted and the objective was not met. Running a failure analysis on an unvalidated FEA would provide inaccurate data.

In the future, a fully validated FEA will be completed and a full failure analysis will be able to be conducted. If the equivalent von mises stress calculated in Abaqus is greater than the materials yield stress it acts on, failure will occur. The locations of these stresses can be automatically determined within the Abaqus finite element software. This information can then be used in the next objective to find alternate materials to improve the durability/strength of the socket.

Objective: Determine possible alternate materials to improve durability/strength

This objectictive's completion relied heavily on the results from the previous objective of failure analysis of the materials used. Because that objective was unable to be completed due to the setback in verifying finite element model from the university closure, this objective was unable to be completed as well.

The completion of the previous objective would provide information on where the most concentrated stresses are experienced in the socket and therefore which material was likely to cause initial failure. With that information, the team would likely have to conduct an analysis of various materials and compare their material properties to the existing materials causing failure.

Cost and characteristics of manufacturability of the materials must be looked into as well. This comparison would determine the best new material to improve the overall strength and quality of the socket.

Quorum suggested that the most common failure mode would be associated with the cables which are run through the panels and tightened by the BOA dials. However, through volumetric testing, the senior design team found that failure was experienced at the BOA dial and not the cables (see Figure 17). It appeared that the hole at the plastic center of the BOA dial where the end of the cable anchors experienced too much stress and collapsed. This resulted in the BOA dial being unable to properly maintain tension of the cable and allowed the panels to loosen.

Figure 17: *Failure of BOA dial at center plastic spool from volume testing.*

Based on this observation, the team recommends investigating a design of a new and similar dial made with a metal center (without violating any patents owned by BOA on the design of the dial) if no convenient solutions using stronger materials exist on the market.

Goal: Create Versatile Model

Goal	Objective Name	Priority Rating	Method of Measurement	Objective Direction	Target
Versatile	Easily scalable and transferable between patients	5	qualitative	N/A	Yes/No

Objective: Easily scalable and transferable between patients

This objective aimed to have a validated FEA model that could be applied to each individual patient. We were not able to validate the simplified FEA model through benchtop testing due to the closures. Therefore this objective was unable to be met as well.

When the FEA model can be validated the model can then be adjusted in Abaqus to mimic a second patients prosthetic socket that was provided to the team that had a much different size, shape, and design. This socket would then be analyzed with the same methods as the first socket and run through a FEA simulation using the same constraints, boundary conditions, and appropriate loading scenarios for the individual patient. If the model could be made and validated for this second individual it would verify that the model could be used with any

individual patient. Once this is verified, alternative designs of each model made specific to each patient, could be analyzed using the FEA methods established in this project in order to optimize the design of each socket.

Constraints:

Five main constraints were established by the sponsors and team that were involate of the project and design. This section addresses each constraint and explains whether it was satisfied or not satisfied during the course of this project.

Detailed pressure and load mapping

This constraint is dependent on the association of the benchtop data and FEA model. Since benchtop data was unable to be collected due to the COVID-19 university closure, there was no data to be mapped out onto a 3D model of the limb and socket assembly. Therefore the constraint was not met. During collection of the benchtop data the placement of the sensors on the socket or limb were going to be traced out and transferred onto the 3D model. The Tekscan software has the capabilities of isolating the particular area of the sensor that is of interest for analysis. Using this feature in conjunction with the software's ability to save the data as an ASCII object file, should provide the ability to import the data into Abaqus or some other software that can display the 3D model of the socket and limb assembly. With some coordinate manipulation the pressure data from Tekscan should be able to be overlayed onto the 3D model of the system. This would provide the visualization of the detailed pressure map that was requested by the client.

Validated model of residual limb and socket interface

The constraint of completing a fully validated finite model of the residual limb and socket interface was not able to be met because the benchtop data was not collected due to the COVID-19 university closure. With benchtop data available, the team would have been able to compare and analyze the pressure maps from the benchtop data and the FEA. Multiple locations of pressure from the benchtop data would be taken and compared directly to the same locations on the FEA model. To ensure the same locations are being analyzed, detailed measurement would have taken place. As previously mentioned, the data would need to be within 1 standard deviation of each other to be considered validated. If not within this range material properties, boundary conditions, contact, and loading conditions would need to be altered. The process of checking the standard deviation then altering the FEA would go on until the constraint is completed. Once completed, the model can be easily transferred between patients.

Transferable among various patients' sockets

The constraint that the model would be transferable among patients could not be met because a validated model was not created due the COVID-19 university closure.In the future there should be multiple patients' sockets that should go through the same procedures for pressure testing and FEA. The plan for this project was to scale the validated model of the original patient's limb and socket to match that of a second patient's limb and socket. The corresponding FEA simulation

tailored to the new patient would then be run. In order to confirm that the model was successfully transferred to the new patient, the benchtop testing procedures of the new patient's socket and model limb would be run to match the tailored FEA simulation. If the results from the simulation and benchtop testing were also within a single standard deviation of each other, as are the standards to validate the original model, then the new model for that individual patient can be validated. This process of repeating the experimental design on a different patient model will validate that the model can be transferable between patients without having to perform the benchtop procedures on each individual socket.

Cost

The cost constraint of this project was $5,000, which was the given budget of the project. As observed in the budget section shown previously (Table 8) the budget summary indicates that the constraint was satisfied and the team did not go over the established budget. The remainder of the budget can be used by future design teams to further the development of this project.

Time to Complete Project

The time constraint applied to this project was that it had to be completed within the time frame of the two semesters of senior design (~8 months). This would have been met if all of the desired goals were completed by April 24th (E-days). However, due to the unforseen circumstances of COVID-19 halting all physical work on senior design projects at Colorado State University, several goals were unable to be completed and therefore the constraint of time to complete the project was not met. Due to this issue, the team decided to outline the procedure that is to be conducted in the future once testing is able to be resumed when proper safety guidelines surrounding COVID-19 are in place or the risk of the virus is low enough by university standards. The procedure for the future physical testing is outlined in Appendix B of this document and hopefully can be completed by future senior design teams.

The failure for all of the goals outlined by the team at the beginning of the project to be completed within the two semesters of senior design affects the usability of this project. As the data is important for Quorum to further the design of the Quatro socket, the delay in having the data provided will cause delays in Quorum’s future work on the Quatro socket and delays in developing goals for future senior design teams. The team provided Quorum with the data which had been collected on volumetric testing and FEA results, as well as the outline of the pressure testing to be conducted in the future. This was done in hopes to provide the customer with useful data for the development of their product.

Contextual Considerations

Consideration for Public Health and Safety

The result of this senior design project is not a product, rather a process which allows for useful data to be collected to analyze a prosthetic socket. The process developed could be reused by Quorum Prosthetics or by future students in senior design to collect additional data. Because of this, it is important that those who could potentially execute this process take precautions to avoid injury when interacting with potentially harmful materials, such as smooth cast ingredients, and working with machinery capable of transmitting substantial forces, such as the MTS machine. Additionally injury can occur when machining a smooth cast mold and when assembling the pressure testing setup. If this project is continued in the future by collecting pressure data with a patient wearing the Quatro socket, there is potential for the process developed to have health and safety concerns for that user. The only foreseen concern that exists is injury from walking or running due to the data collection setup. However, it is not foreseen that this process developed could have an impact on the health and safety of the general public. There only exists concerns on the future conductors of this process and potential testing subjects. This is because this process will likely not be released due to Quorum Prosthetic's ownership of the intellectual property of this project and therefore will limit the users to future senior design teams and Quorum Prosthetic's employees.

Regulatory and Engineering Standards Considerations

The outcome of this senior design project is not a product that could be taken to market, rather a process developed to test and produce data on prosthetic sockets. Therefore regulatory standards pertaining to manufacturing and distributing a medical grade device do not apply for this project. However, to ensure proper engineering methods are in place, engineering standards relating to testing must be considered for this project in the case that this process is expanded and used on a wider scale. Standards pertaining to calibration and testing (ISO/ IEC 17025) must be followed to ensure that the results produced in this process are valid. Additionally because the MTS machine applies a force to the testing apparatus in this procedure, the standard practice for force verification of testing machines (ASTM E4-20) should be considered. However, this process is likely not to be conducted on a large scale and is only to create validated FEA models which can be scaled to apply to any patient. This means that the physical testing and associated standards will likely not apply.

Environmental, Global, and Societal Impacts

The process developed to analyze the Quatro socket is not expected to be executed by a large number of users or at a high frequency. The most waste experienced in this process was due to broken parts. Additionally, no hazardous materials are used in the socket analysis process. Due to these aspects of the process, there is little concern of significant negative environmental impact due to waste.

While this process will likely be predominantly used by Quorum for the Quatro Socket, the process has potential to be expanded to evaluate the comfort and design of traditional prosthetic sockets. Because a majority of the world's amputees are citizens of developing countries, the analysis developed for this project could be used to determine the comfort of sockets in these areas of the world. This would ensure that the prosthetics given to patients are as comfortable as possible to increase the sockets' use. No cultural issues are foreseen to arise from the prosthetic socket analysis developed.

The data produced by this process is hoped to be used by Quorum to improve the design of the Quatro socket and obtain a health insurance code to be used by Medicaid and insurance companies. If the data produced from the testing is able to aid Quorum in obtaining this code for the Quatro socket, the socket will be more affordable and therefore be able to be obtained by more amputees in need of its useful technology.

Economic and Intellectual Property Considerations

As mentioned in the previous section, the data produced from the senior design project is to be used by Quorum to hopefully obtain a health insurance code for the Quatro socket. Therefore an economic impact of this project is the potential decrease of out of pocket cost for future users of the socket in the case of the code being assigned to the Quatro.

Other economic considerations to be made is the cost that was involved in conducting the project and future costs associated with continuing the project and repeating the process on further iterations of the socket. The total cost of conducting the project to date was $3,165 out of the total budget of $5000 provided. However, future costs that are foreseen for next year's senior design team include charges by the OBRL for use of the MTS machine and computers. While this is dependent on hours which the lab will be used by the team, estimates of this cost consisted of 25 hours of computing time at a rate of $40/hr and 10 hours of using the MTS at a rate of $60/hr for a total of $1600 as seen in the Budget section of this report. The sensors and software for pressure testing were already purchased and a model of the limb was already created. Costs could be incurred in the case of damage to the pressure sensor and an additional sensor needing to be purchased. The lab charges would also likely apply to any testing done on future iterations of the Quatro socket.

Quorum prosthetics owns the intellectual property associated with this project. The equipment, sensors, and software used by the senior design team to execute and outline the process of analyzing the Quatro socket are able to be obtained by anyone and the process could be conducted on any prosthetic socket design. However, due to the intellectual property being under ownership of a private company, the outlined process will not be available to the public and will not be open source.

Discussion

Physical work on all senior design projects at Colorado State University was halted in March 2020 for the remainder of the semester due to the increasing severity of the COVID-19 pandemic. As a result, there was work that was planned for this senior design project which was not completed. For the project, plans for conducting benchtop pressure testing on the MTS machine were unable to be followed through. While the finite element analysis of the Quatro socket via Abaqus was still able to be conducted by the team through remote access, the computing power was extremely limited compared to what was available at the OBRL. The limited number of nodes on the academic license of Abaqus and the long computing time on personal computers caused the FEA model to be less detailed than was intended and less variations of models were able to be run. Despite the drawbacks due to the university closure, the team was still able to accomplish a significant amount of work.

One of the needs most emphasized by Quorum was to capture the full volumetric range that the Quatro socket is capable of. Quorum requested this because they believed their own volumetric tests were insufficient in that they were not capturing the full volume range of the Quatro and therefore wanted another method to be conducted by the senior design team. These previous tests conducted by the sponsor gave a volumetric range of 9.5%. The volumetric testing which was conducted by the team was successful in that it presented a higher volumetric range than what was found by Quorum. The air bladder tests to determine a percent volume change through pressure measurements and calculations using the ideal gas law gave an average result of 12.10% with a standard deviation of 0.85%. The bladder volume tests indicating a higher volumetric range than what was previously found by Quorum suggests that the method used by the senior design team was more effective and that the goal to collect data on the percent volume change of the Quatro socket was met. The data also provides support to Quorum's claim that the Quatro is capable of providing volumetric adjustments for users as their limbs experience changes in size over time.

While the finite element model that was created by the senior design team was less detailed than desired, the team was still successful in being able to produce finite element results. A 3D scan was able to be converted to a solid model and constructed into an assembly consisting of a socket, model limb, and adjustable panels. Issues relating to boundary conditions were troubleshooted and appropriate material properties of the socket and model limb were applied to the model in Abaqus. The team hoped to have more detailed and varying inputs for the finite element model with varying panel tightness and for situations simulating walking and running but the limited computing power of the team's personal computers along with the limited number of nodes in the software version available made this not possible. However, the files and information exists for improved finite element models to be run in the future.

Along with meeting the objectives mentioned above, the team was also successful in satisfying the objectives pertaining to creating a model via 3D scan and the constraint of budget. The limitations due to the sudden stop of physical work resulted in the objectives and constraints pertaining to collecting physical data for pressures experienced within the socket, validating the FEA, conducting a full failure analysis, transferring the model between patients, and time to

complete the project to not be satisfied this semester. While the team was able to produce results, work still needs to be conducted by future senior design teams. Benchtop pressure testing which was not able to be completed needs to be conducted following the instructions outlined by the team in Appendix B of this document. The pressure data produced by the benchtop test will be used to validate the pressure indicated by the FEA results. Variations in the test data from the FEA data could indicate issues with the setup of the finite element model's boundary conditions or material property assignments. Future teams will also need to increase the sophistication of the finite element model using a version of Abaqus without limited nodes and using computers capable of producing FEA results at a higher rate. The files already created can be used by future teams and be altered to produce results with more detail and accuracy. Additionally FEA results which include varying panel tightness and loads related to walking and running will need to be produced as well as results from a traditional static prosthetic socket. Completing this model with high detail will allow for results which can aid in improving the design of the Quatro and allow for optimization of patient specific fittings which will reduce the lead time and improve product lifespan.

Once a more sophisticated and validated FEA model has been created, a failure analysis must be conducted using the model to determine when the Quatro socket will break. Once these basic tasks have been met the team can focus on increasing the sophistication of the process further by conducting benchtop testing and creating a finite element model using a ballistic gel mold of the residual limb. This can be further improved by collecting pressure data using a patient wearing the socket and creating a finite element model using material properties of human tissue.

Additionally, Quorum has been hoping to improve the production of the Quatro socket through 3D printing. They have expressed to the team that they have an interest in applying this testing procedure using the newer 3D printed socket to determine failure modes with the new material. This would require an updated finite element model and benchtop pressure data using the 3D printed Quatro.

Throughout this project the team gained valuable experience in having to quickly adapt to extreme limitations while still having to produce meaningful results. The data produced by the senior design team in this project, while limited due to the university closure, will provide the needed data that can justify that this design is an improvement on traditional sockets on the market and provide a baseline for comparison to future design iterations of the Quatro socket. The team hopes that the work which was unable to be completed during this semester will be able to be continued by future senior design teams to help Quorum further improve the design and increase the accessibility of the revolutionary Quatro socket.

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Appendix A: Volumetric Testing Procedure, Calculations, Results, and Statistics

Procedure

Materials used:

- Larger Quatro socket provided by Quorum Prosthetics + inner liner
- One 8.5” diameter rubber kickball
- Kickball pump and needle
- Tachikara DIGI-GUAGE Digital Air Pressure Gauge
- Marker

1. Make sure the inner liner is properly placed in the socket, observe for any damage to the panels, and make sure the BOA dials appear to tighten the cables and allow for cables to loosen properly as well.
2. Unlock all 3 BOA dials on Quatro to allow for cables to loosen.
3. Pull out all 4 panels as far as possible and such that each panel sits equal distance from the socket.
4. Place the deflated kickball into the socket such that the surface of the ball is in contact with the whole length of all 4 panels and such that any folds in the kickball are not in contact with the panels but the open space on the socket that is between the two shorter panels. Additionally make sure the kickball’s inflation hole is facing out the top of the socket.
5. Use the kickball pump to fill the ball with air as full as possible. The kickball should extend out the spaces for the panel but not touch the panels. (Schematic of this setup is illustrated in Figure 8 in this document)
6. Mark a spot where the bladder meets the socket’s inner surface with a marker to make sure the kickball does not move as panels are tightened.
7. Insert the pressure gauge into the kickball and record an initial pressure reading.
8. Lock all the BOA dials.
9. Begin tightening the panels by turning the two lower BOA dials simultaneously. Turn both dials equal amounts with both hands. Someone may have to hold the socket upright while another person is turning the dials. The person holding the socket up must be watching the pressure on the gauge to make sure it is going up as the dials are tightening the panels.

IF THE PRESSURE REMAINS CONSTANT OR DECREASES WHILE THE DIALS ARE TIGHTENING THE PANELS THIS LIKELY MEANS A BOA DIAL IS BROKEN AND IS NOT KEEPING TENSION IN THE CORDS. STOP THE TRIAL AND REMOVE THE DIALS FROM THE SOCKET TO INSPECT FOR ANY DAMAGE AND REPLACE IF NECESSARY. (This damage can also be identified if it is difficult for the panels to be pulled out fully in step 3).

Continue turning the dials until the panels cannot be tightened further- the panels should be flush or nearly flush with the side of the socket. Make sure the line marked on the kickball has not moved. Also make sure to not pull out the dials turning them (this will release the tension in the cable and cause the panels to loosen).

This process may be more difficult as the dials are further tightened. If tightening the panels become increasingly difficult physically do not continue with bare hands- place a rag over the dials or use gloves- using excessive force to tighten the panels with bare hands can result in blistering of the hands

10. Once the panels are tight as possible turn the upper dial which adjusts the superior circumference of the socket.
11. When all of the dials are turned as much as possible record a final pressure reading, unlock all the dials and deflate the kickball. Check for signs of damage to the cable, the dials, the panel, or the kickball.
12. Repeat for 10 trials.

Calculations

The calculations to convert the pressure data points collected to a percent volume change were conducted in Microsoft Excel (Microsoft Corporation, Redmond WA). The equation to convert the pressure data to a percent change in volume was determined as follows (reasoning behind these equations is outlined in the Final Concept section of this report):

Variables:
Initial Pressure: P_1
Initial Volume: V_1
Final Pressure: P_2
Final Volume: V_2

Boyle's Law: $P_1V_1 = P_2V_2$

$$\Rightarrow V_2 = \frac{P_1}{P_2}V_1$$

$\%\Delta V$: $\%\Delta V = \frac{V_2 - V_1}{V_1} \bullet 100\%$

$$\Rightarrow \%\Delta V = \frac{\frac{P_1}{P_2}V_1 - V_1}{V_1} \bullet 100\%$$

$$\Rightarrow \%\Delta V = \frac{V_1(\frac{P_1}{P_2} - 1)}{V_1} \bullet 100\%$$

$$\Rightarrow \%\Delta V = (\frac{P_1}{P_2} - 1) \bullet 100\% \qquad \text{(Equation 2)}$$

Equation 2 was used for the Excel code to convert all final and initial pressure reading into a percent change in volume for each trial.

Results

The results of the 10 trial's final and initial pressure reading and calculated percent volume change in Excel are shown below (Table 9):

Table 9: *Results from volumetric testing procedure.*

Test #:	Absolute Initial Pressure (psi)	Absolute Final Pressure (psi)	% Change in Volume
1	12.2015	13.9515	-12.54345411
2	12.2015	13.7015	-10.94770646
3	12.2015	13.7515	-11.27149765
4	12.2015	13.8015	-11.5929428
5	12.2015	13.8015	-11.5929428
6	12.2015	13.7515	-11.27149765
7	12.2015	14.0015	-12.85576545
8	12.2015	13.9515	-12.54345411
9	12.2015	14.0515	-13.16585418
10	12.2015	14.1015	-13.47374393

Statistics

The data from the results were input into the statistical program R Studio (RStudio Inc, Boston MA) to obtain data on mean and standard deviation and to produce a boxplot (Figure 13) of the data. The brief R code including the results of mean, variance, and standard deviation are below.

```
> deltav= c(12.54,10.95,11.27,11.59,11.59,11.27,12.86,12.54,13.17,13.17)
> mean(deltav)
[1] 12.095
> var(deltav)
[1] 0.7194278
> sd(deltav)
[1] 0.8481909
> boxplot(deltav)
```

Appendix B: Pressure Testing Procedure

Pressure Testing on the MTS Machine with the Tekscan on the Quatro Socket

Table of Contents

Introduction

Poor socket comfort is the main cause of the rejection of a prosthesis. One of the variables that affects socket comfort is pressure. Those who experience high stress throughout the socket over long periods of time can result in pressure, ulcers, skin lesions, or vascular occlusions. With these issues in mind, the team at Quorum Prosthetics designed the Quatro socket so that it is adjustable and can be tightened and loosened to fit the patient's residual limb comfortably throughout the day. In order to quantify comfort of the Quatro socket, pressure experienced on the residual limb while wearing the Quatro socket needs to be analyzed.

In order to test and quantify pressure experienced on the residual limb prosthetic socket, a series of loading tests will be performed. Testing will be performed on a static socket and the Quatro socket in order to compare the pressure differences. This document is meant to outline the procedure to collect this data.

Materials and Methods

How to Calibrate the Tekscan

(Techniques used to calibrate the sensors followed the Tekscan documentation provided in the software package; *I-Scan Manual,* and C*alibration & Equilibration Guide.* It is recommended to follow this general outline of procedures, but the unique practices to this application are outlined below.)

Materials Needed

- 9830-10 Iscan-System Tekscan Sensor
- Tekscan dongle
- Computer with Tekscan software (I-Scan 7.65)
- Air Compressor w/ air hose and variable pressure valve (outlet pressure dial)
- TruBlu Pneumatic Equilibrator (in OBRL)
- Tape

Methods

The TruBlu Pneumatic Equilibrator is a device which is useful for calibrating pressure sensors (Figure 1). The device contains an air bladder, between two parallel plates, which can be filled to a specified pressure which is ideal for calibration. Before beginning calibration make sure the bolts on the edges of the equilibrator are well tightened.

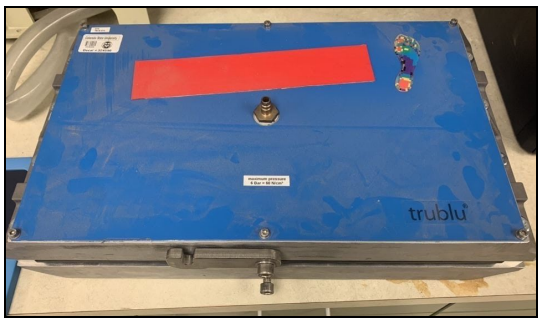

Figure 1: TruBlu Equilibrator

Place the sensor on the tray with the dongle attachment portion extending out of the notch as seen in Figure 2. Apply a few pieces of tape to the corners of the sensor, ensuring the tape does not contact any sensels, to prevent movement from occurring during calibration. Slide the tray into the equilibrator and close the front hook. Attach the air hose to the quick-connect on the top of the equilibrator (Figure 3). Attach the hose to the compressor and ensure that the compressor has power and the outlet valve is completely closed such that there is no air filling the TruBlu device.

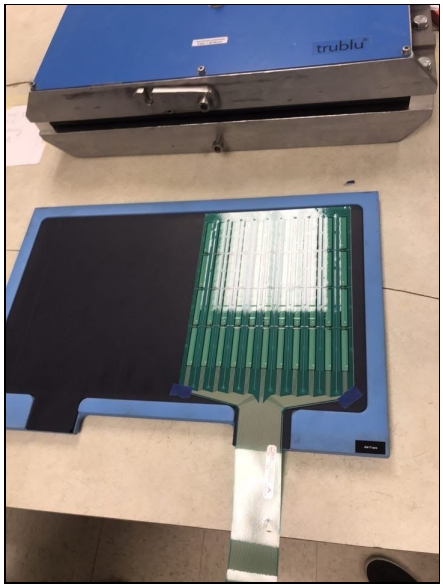

Figure 2: Sensor on Tray Placement

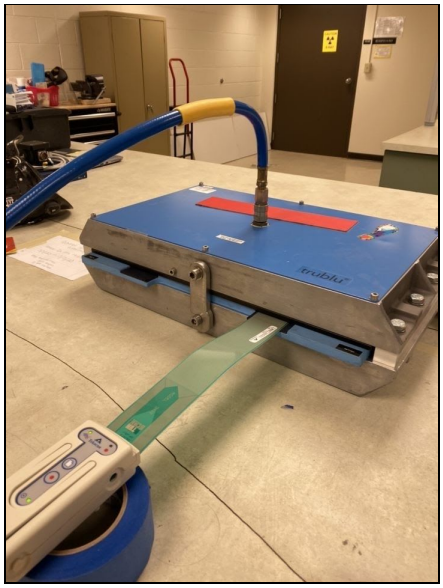

Figure 3: Hose attachment on TruBlu Equilibrator

Equilibration (a.k.a. Normalization)

Multi-Load Equilibration was utilized to prepare the sensor prior to calibration. This is outlined and explained in the Tekscan Documentation. The pressures at each of the four points of equilibration that should be used for this sensor and application are 30, 40, 50, and 60psi.

Some things to consider during equilibration:

1. **DO NOT FILL THE TRUBLU BLADDER WITH MORE THAN 6 BAR (87PSI) OF PRESSURE!** To be safe, limit pressure to 70psi.
2. Hold the pressure at each equilibration point constant for 2-5 minutes prior to recording the equilibration point. This will account for any compliance in the system.
3. This process, as stated in the guide, may need to be repeated prior to each experiment to account for the uneven repetitive loading of the sensor. So use specific names for equilibration files.

4. It is important to keep the sensor and handle aligned during equilibration such that the neck of the sensor does not flex, bend, twist, etc. This will ensure an accurate equilibration over the entire surface of the sensor.

If there is any confusion on the calibration methods within the Tekscan program, the *I-Scan Manual* can be referenced for Software (page 77) and Calibration (page 113) sections as well as the previously mentioned guide.

Calibration (2-Point Power Law Calibration)

It is appropriate to use a 2-point calibration in this type of application where the loads can vary a considerable amount during experiments. The recommended points are at 20% and 80% of the maximum test load. This will be unique to each scenario of experiments. Note that calibration can be done prior to the experiments and a calibration file can be saved for each scenario. This calibration file can be applied to the data either during collection or after. The max load applied to the sensor should be estimated for each type of experiment and the sensor calibrated accordingly.

Using the MTS machine these estimated forces can be applied to the sensor in a stable and accurate manner. Similar to the method of equilibration, it is important to set up the sensor such that it will not get damaged and it is between two clean flat parallel surfaces that will apply this known force. It may be of interest to use similar shapes and materials to the actual quatro socket panels that will be used in the actual experiments.

The Bionix Servohydraulic Test System at the OBRL (pictured below in Figure 4) will be used to perform these series of tests.

How to Set Up the Quatro Socket and Model Limb in the MTS Machine

Materials Needed

- 858 Mini Bionix.II MTS machine
- Aluminum stock (for base plate fixture)
- 2 ½”-20 bolts (for securing base plate)
- Quatro socket/model limb assembly
- 2 ½”-20 bolts (for attaching to MTS machine)
- Custom Steel plate (6’’ diameter, ¼” thick) to fit top of model limb

Methods

1. Secure base plate onto the bottom of the 858 Mini Bionix.II MTS on left and right sides with two ½ 20 bolts.
2. With the bottom attachment secured on the Quatro socket, twist the Quatro socket onto the base attachment until secured.
3. Screw the ½ 20 bolt into the lever arm of the MTS machine
4. Place a ½ 20 nut onto the bottom of the bolt. Then place the 6in diameter steel washer onto the bolt, and then secure the washer with another ½ 20 nut on the bottom.

Figure 5 shows a visualization of the top setup with the model limb and the MTS machine and Figure 6 shows a visualization of the overall final set up of the Quatro socket/model limb/MTS machine experimental setup for pressure testing.

Figure 4: *Bionix Servohydraulic Test System*

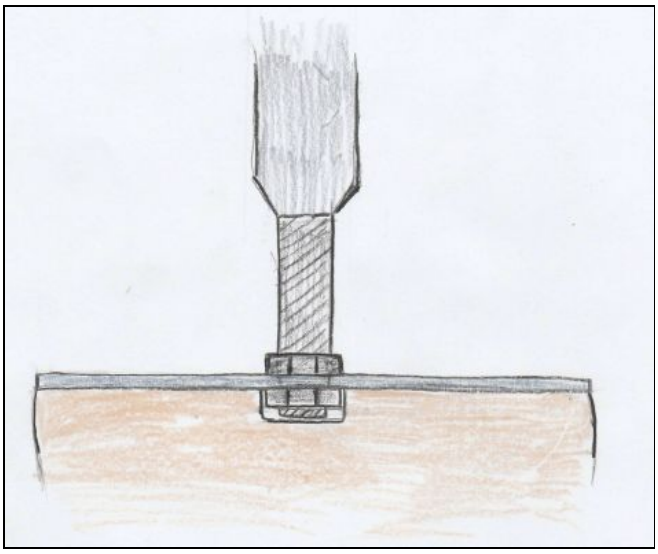

Figure 5: *Top Attachment of MTS Machine into Model Limb*

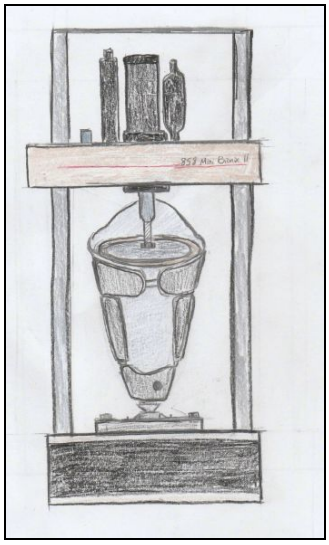

Figure 6: *Quatro Setup in MTS Machine*

How to Place the Tekscan in the Socket

Materials Needed

- Quatro Socket
- Quatro Socket flexible inner liner.
- Model Limb
- Static Socket
- 9830-10 I-scan System Tekscan Sensors
- Double sided tape
- Tekscan dongle

Methods

One to two 9830-10 I-scan system Tekscan sensors should be properly equilibrated and calibrated before being positioned inside the socket (see how to calibrate Tekscan in the calibration portion of this guide or reference the Tekscan guide).

The Quatro socket consists of 4 adjustable panels (two shorter and two longer in vertical length) and an adjustable superior circumference. Between the two shorter panels and below the strings for the adjustable circumference there is a medial opening in the socket. Before inserting the inner liner of the socket and the model limb, the Tekscan sensors should be secured on the inner surface of the Quatro socket.

The most important data to collect is the area around the adjustable panels. Therefore the center of the sensor should be lined up with the center of the longer panels to ensure data from the entire area of all the panels are captured by the Tekscan.

Insert the 9830-10 Tekscan sensor through the medial opening in the socket and wrap the sensor around the circumference of the socket such that the dongle attachment of the sensor is outside the socket (see Figure 7). If the sensor does not easily fit through the opening without bending, creasing or crumpling, place it inside through the top opening and feed the dongle attachment through the medial opening instead. If sensiles cover the entire circumference then only one sensor is needed. However, if one sensor is not sufficient then a second sensor should be inserted on the other side of the opening and wrapped around the circumference as well. In this case, ensure that the center of the sensor is still lined up with the center of the longer panels but have the end of the sensors secured at the midway point of the socket between the two longer panels. Also still make sure that the entire circumference of the socket is covered with sensiles. To ensure this, either cut the top portion of the sensors that do not have sensiles and have the ends of the sensors meet in the socket, or, overlap the two sensors such that the last sensiles meet. In the case of using two sensors some sensiles may not be inside the socket, this is okay. When placing the sensors make sure the sensiles face the inside of the socket and secure them into the socket with double sided tape (if there is still 3D-scan spray on the socket this may need to be cleaned in order for the tape to stick). The most important thing when securing the sensors into the socket is to ***make sure to not crease or crumple the sensors.*** This will ruin the sensors! Please be gentle.

The dongle attachments should be extending out through the medial opening. Once the sensors are placed gently insert the inner liner and the model limb into the socket as well.

When placing the sensor in the static socket, there are no panels and therefore no openings between panels. Due to this, the sensors will have to be secured vertically within the socket and the dongle attachments will extend out the top. In this case the sensors will likely not be long enough to extend down the entire length of the socket. The sensors can be placed in the static socket to attempt to cover the entire circumference. This may not be possible but it is less of a concern since the static socket does not have adjustable panels. When placing the sensors make sure the sensiles face the inside of the socket and secure them into the socket with double sided tape (if there is still 3D-scan spray on the socket this may need to be cleaned in order for the tape to stick). The most important thing when securing the sensors into the socket is to ***make sure to not crease or crumple the sensors.*** This will ruin the sensors! Please be gentle.

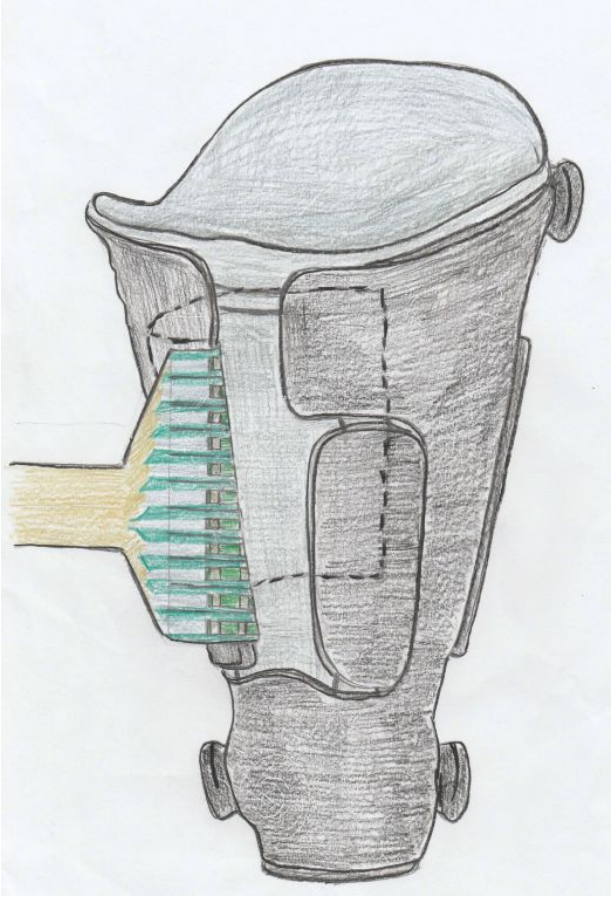

Figure 7: Tekscan Sensor Placement on Quatro Socket/Model Limb Interface

Pressure Testing Procedure on the MTS Machine

Materials Needed

- 858 Mini Bionix.II MTS machine
- Properly set up Quatro Socket and Model Limb in the MTS Machine
- Properly placed and calibrated Tekscan in the sockets

Methods

For testing, there will be one test with three different trials when finding pressure within the static socket (static, walking, and running). For the Quatro socket, three tests (one for each setting of the BOA dials) with three trails (static, walking, and running) in each test will be performed to find the pressure experienced.

Once the static socket has been set up in the MTS machine with the Tekscan placed as previously mentioned, pressure data collection can begin. To simulate a static motion, initially

load the residual limb to a force of 255N. Then, with a vertical delta of 20mm/min, load the residual limb to 355N (~½ body weight of the patient). With the same vertical delta, unload the limb to 255N. This simulates one cycle of loading. Run 20 cycles of loading and only take data on the 20th cycle. Data being collected should include force (N) from MTS @ 100Hz, contact area from Tekscan, and pressure from Tekscan.

To simulate walking, initially load the residual limb to a force of 680N. Then, with a vertical delta of 20mm/min, load the residual limb to 780N (~1.1 body weight of the patient). With the same vertical delta, unload the limb to 680N. This simulates one cycle of loading. Run 20 cycles of loading and only take data on the 20th cycle. Data being collected should include force (N) from MTS @ 100Hz, contact area from Tekscan, and pressure from Tekscan.

To simulate a running, initially load the residual limb to a force of 1320N. Then, with a vertical delta of 20mm/min, load the residual limb to 1420N (~2.5 body weight of the patient). With the same vertical delta, unload the limb to 1320N. This simulates one cycle of loading. Run 20 cycles of loading and only take data on the 20th cycle. Data being collected should include force (N) from MTS @ 100Hz, contact area from Tekscan, and pressure from Tekscan.

Following the testing of the static socket, set up of the Quatro socket and model should be completed. The previous static motion, walking simulation, and running simulations should be repeated for the Quatro socket set up. Three iterations of each scenario should be repeated with the following dial settings: loose, fully tight, and normal. The loose setting should be set up such that the panels are fully let out and then tightened such that the panels just barely contact the model limb; this setting should be used for all three scenarios first. The next setting that should be used is the completely tightened model. This should be done by tightening the dials from the loose setting as much as possible while recording how many turns of the dial have been completed to reach the tightest setting. After running each simulation at this setting the dials should be set back to the loose setting before adjusting to the normal setting. The normal setting will be set such that the number of turns of the dials will be half the amount of turns it took to reach the tightest setting.

Discussion

This data would give the team the ability to quantitatively compare a static socket to the Quatro socket. Theorized, the data would show that the pressure within the static socket is more uneven than the pressure distribution in the Quatro with the dials adjusted. This data can then be related to the comfort of the two sockets. The theorized data would suggest that the Quatro socket is more comfortable than the static socket due to the Quatro asserting more even pressure on the

residual limb. By showing the Quatro is more comfortable via quantitative data, Quorum will have the ability to prove the effectiveness of their design with qualitative and quantitative data.

The data collected from this procedure will allow the finite element model of the Quatro socket to be validated. Therefore, allowing the FEA to be easily transferable between patients. A validated FEA will also allow the materials being used for the socket to be assessed. A failure analysis would show locations most likely to fail under high loading conditions. Locations of high pressure can be redesigned to further enhance the compatibility of the Quatro prosthetic socket.

Potential Pitfalls

Because this procedure was unable to be executed by the team, there are likely to be some problems that may occur when implementing it. The team has identified possible pitfalls, however there is always the chance that an issue that was not foreseen could occur.

The first potential issue that could happen could be that the setup and placement of the Tekscan in the Quatro socket does not result in the ideal pressure map. The team thought that this setup would result in the Tekscan being as flat as it could be, without causing any folds or wrinkles, but since this was not actually physically tested, there is a chance for wrinkles to occur. This is why careful handling of the Tekscan is very important. The placement may not be as smooth as it could be, so adjustments may need to be made, such as extra securement of the Tekscan to the Quatro or liner, may need to be taken into consideration.

Another issue that could occur could be failure or breaking of the dials as they are turned. If the dials break, it is likely the hole at the plastic center of the BOA dial, where the end of the cable is anchored and allows the cable to wrap around the spool of the dial, experienced too much stress and collapsed. If this occurs, replacement BOA dials can be purchased and replaced fairly easily.

A final potential issue that could occur during pressure testing could be the failure of some of the fixtures. For example, the washer that serves as the interface between the MTS actuator and the model limb, could be bent and the pressure distribution may be skewed. Another possible fixture failure that is possible is the adapter between the bottom of the socket and the base plate fixturing could shift, flex or the bolt could be bent under the forces applied during testing. This could have adverse effects on the force and pressures experienced in the system. The goal of this experimental design is to focus on pure axial forces and it is important that the alignment of the force and model and socket assembly is held to a relatively tight tolerance.