Cold Shoulderz Final Report

Developing a Stemless Reverse Shoulder Implant

Friday, April 28, 2023

Prepared by:

Team Members

Alexandra Nowzamani – Biomedical Engineering

Ethan Corey – Biomedical Engineering

Will Crittenden – Biomedical Engineering

Valeria Aguilera – Biomedical Engineering

Matthew Mohammed – Mechanical Engineering

Nickolas Wolniewicz – Mechanical Engineering

Faculty Coach:

Dr. Stephen Hugo Arce

Prepared for:

Liaison Engineer:

Mr. Tom Vanasse

Sponsor:

Exactech

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exactech

It is agreed that this final engineering report, dated Friday, December 9, 2022, together with the agreed upon amendments, constitutes the latest contract for work to be performed by the Cold Shoulderz for Exactech.

Name	Major	Signature
William Crittenden	Biomedical Engineering	
Ethan Corey	Biomedical Engineering	
Valeria Aguilera	Biomedical Engineering	
Alexanda Nowzamani	Biomedical Engineering	
Matthew Mohammed	Mechanical Engineering	
Nickolas Wolniewicz	Mechanical Engineering	
Dr. Stephen Arce	Faculty Coach	
Mr. Tom Vanasse	Liaison Engineer	

Executive Summary

The main objective of our project was to develop a new design for a stemless reverse shoulder implant. Originally, in total shoulder arthroplasty (TSA) the only options were anatomical implants that keep the “ball” and “socket” relationship between the humerus and shoulder the same. However, with shoulder designs gradually taking steps to become smaller and shorter, the traditional technique is being changed; with the “ball” and “socket” relationship ultimately being switched. This process is called reverse shoulder arthroplasty (RSA). The overall structure of an RSA allows for the shoulder to use the deltoid muscle rather than the rotator cuff for the overall movement. Along with a different muscle group being utilized, RSA procedures provide patients with better joint stabilization, easier revisions, a decrease of possible fractures, and preservation of bone. These RSA designs, currently only available within the European market, are not yet approved in the United States, leaving a gap for potential designs to be created. Although approved in other countries, there have not been any long-term studies conducted, so this project bears the risk of providing long-term feasibility.

Our group hoped to create a reverse stemless shoulder design and a potential testing mechanism while taking into consideration the current market conditions and similar implants within the market to allow for an improvement of a patient’s range of motion, overall shoulder strength, and elimination of pain. This was accomplished with prototypes and simulations to provide a clear scope on what designs will be most successful. Along with prototyping and simulations, background research will also play a paramount role in giving the team an understandable and comprehensible view on what materials and techniques provide the highest rates of success.

Acknowledgement

We would like to express our appreciation to all those who have supported and contributed to the successful completion of our project. Without their continuous assistance, guidance, and encouragement, this project would not have been possible.

We are grateful to Dr. Arce and Dr. McConomy for their knowledge, guidance, and commitment throughout the entire duration of our project. They directly guided the team throughout the design process by challenging and critiquing our project to continually refine our course of action. This feedback was instrumental in shaping and completing our project.

We extend our thanks to Exactech and specifically Tom Vanasse for his generous support and collaboration with our project. His technical expertise and insight to the industry has enriched our project and helped us gain applicable knowledge and skills.

We are grateful for everyone's constant support and direction during our senior design project. Your contributions have made a tremendous influence on our success, development, and learning.

TABLE OF CONTENTS

LIST OF TERMS AND ABBREVIATIONS

TSA	Total Shoulder Arthroplasty
RSA	Reverse Shoulder Arthroplasty
HA	Hemiarthroplasty.
IDE study	Investigational Device Exemption
AutoCAD	AutoCAD is a commercial computer-aided design (CAD) and drafting software application
RLLs	Radiolucent lines (RLL). Defined as radiolucent intervals (measured in millimeters) between the cement and the bone. A decline in density.
TESS	Total Evolutive Shoulder System

1. Background and Significance

For shoulder complications, a patient may undergo either total shoulder arthroplasty or hemiarthroplasty, in which an implant replaces both the glenoid and the humeral head, or just the humeral head. TSA is a necessary surgery for patients with severe shoulder arthritis or injury, and current TSA implants leave patients with limited shoulder strength and range of motion. Our team's focus is to design a stemless reverse shoulder implant that can successfully be implanted with little to no immune response and a decrease in micromotion.

Figure 1, labeled Prevalence of Shoulder Arthroplasty from 1995 to 2017, shows that each year there is a slow increase in individuals suffering from complications that ultimately require a TSA or HA. With this exponential growth, also comes the need for the development of new and improved implants. With the hope, these new designs will give the patient back similar anatomical functionality.

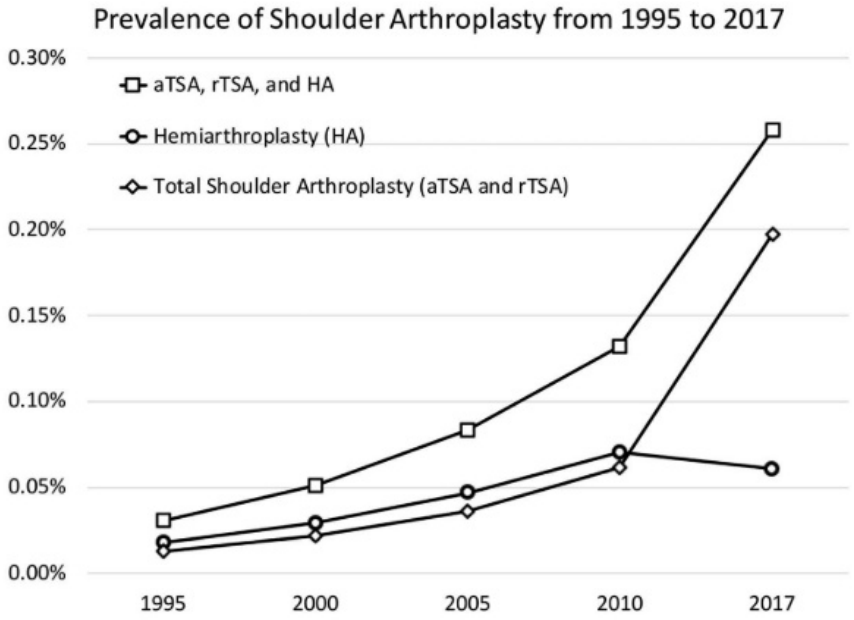

Figure 1: Increase in prevalence of shoulder arthroplasty from 1996 to 2017. aTSA, rTSA, and HA are anatomical TSA, reverse TSA, and hemiarthroplasty respectively. [1]

1.1 Reverse Arthroplasty and Stemless Arthroplasty

Reverse shoulder arthroplasty ultimately changes the relationship between the glenoid and the humerus, with the humerus attaching to the hemispherical structure instead of the glenoid. The notion of RSA implants was to correct the problems anatomical implants were experiencing. Stemless implants not only allow for the humeral cavity to stay more intact, but one study found that "the average operative time was twenty-four minutes less in the stemless cohort compared with the stemmed" [9]. Along with a shorter operation time, the overall surgery was much simpler. With this in mind, one of our team's primary objectives was to perform testing and analysis on Exactech current stemless system; shown in Figure 2 below. Performing testing on these products will lay a foundation for future tests done on our prototypes.

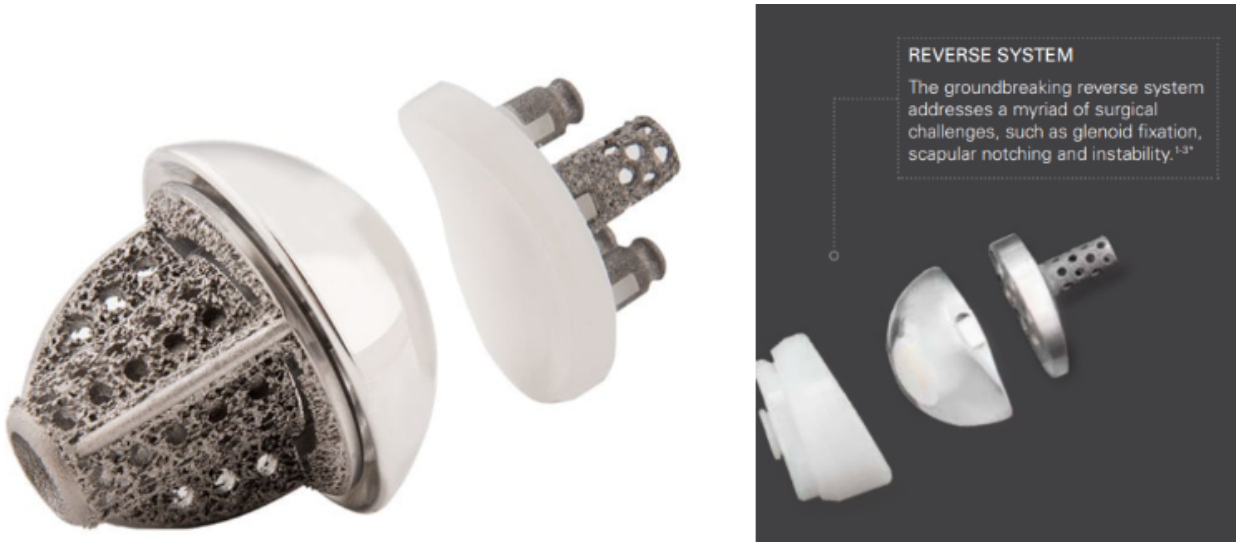

Figure 2: Current Exactech Models

1.2 Inlay versus Onlay

The main distinction between inlay versus onlay is the way the humeral tray sits. In an inlay design, the humeral tray is seated/placed within the metaphysis, whereas in an onlay design, the humeral tray sits on the metaphysis. There have been multiple studies conducted that have dismissed that one option is better than the other: with little to no clinical differences in relation to an improvement in range of motion [8]. There was, however, a higher incidence rate of scapular notching in an inlay style and scapular spine fracture in the onlay style. Scapular notching occurs when there is erosion at the glenoid neck, this is caused by the tray's constant contact with the bone when the arm is in a downward position. In the onlay style, it was observed an increase in scapular spine fracture.

1.3 Surgery, Recovery, and Revisions

In relation to shoulder replacement surgery, stemless options are becoming increasingly more popular, and one can say that the stemless replacement design is driven by the desire to create a product that preserves bone, has easier revisions, decreases possible fractures, and reduces operating times. Even when compared to stemmed implants, even when having similar outcome results, there has been a decrease of fifteen minutes in operating rooms when performing a stemless surgery.

1.4 Impact

The prevalence of TSA in the United States has slowly increased over time and as life expectancies slowly trend upward and incident/accident rates stay stagnant, the demand will only continue to grow. This can be supported as it was recorded that in 2017 that approximately "823,361 patients were living in the United States with a shoulder replacement" [6]. The total shoulder replacement market size was valued at 2.24 billion USD and was projected to grow 7.6% from 2022 to 2027 [7]. This project can help aid in the growth of a new category of TSA

implants, allowing and aiding research that could help many patients to receive a potentially better shoulder implant.

1.5 Competitive Landscape

The overall market for this product is large as of 207, with more than 800,000 individuals in the United States undergoing some type of TSA [6]. This project on stemless RSA seeks to solve the same shoulder problems that multiple types of existing implants already solve; however, its purpose was to design an implant that surpasses the current products and improves both surgical outcomes and the quality of life of the patients beyond what is currently on the market. As mentioned prior, there are already existing RSA products some of which include FX Solutions Easytech Revered Stemless system, Lima Corporate's SMR Stemless Reverse, Zimmer Biomet's Nano Stemless Shoulder Reverse, and Affinis Short Stemmed Total Shoulder Prosthesis.

The FX Solutions Easytech Reversed Stemless system is a reversed stemless design that features "peripheral fixation of the humeral component that is designed to be more bone sparing as compared to the traditional stemmed devices and its unique-to-market design for improved fixation to withstand the forces of reverse total shoulder arthroplasty" [5]. This product has been in use within the European market since 2015. This innovator has become a leader in the shoulder replacement market in France and is pushing to expand their market into the United States. Quickly, FX Solutions has quickly modified to the requirements of the United States Market and has already started obtaining 510(k) clearance to continue forwards with products, designs, and models.

Lima Corporate's SMR Stemless Reverse is another product with the intended idea for the total replacement of the shoulder joint. The U.S. Food and Drug Administration just gave the approval to allow Lima Corporate's SMR 140-degree Reverse Humeral Body to start a "randomized, multicenter comparative clinical trial" on 17 December 2020 [4]. This study is designed to compare and evaluate the safety and effectiveness of the SMR Reverse Stemless to the SMR Reverse Shoulder System [4]. This study that this device is undergoing is an IDE study which ultimately allows for a device to be tested in a clinical setting to collect pertinent data to determine quality and safety.

The Nano Stemless Shoulder Reverse, created and manufactured by Zimmer Biomet, is another product that just underwent an IDE study. Within this study, 116 prostheses were used and found to be beneficial in bone preservation. Along with bone preservation, this prosthesis demonstrated that it allows for an increase in movement and a decrease in pain. When observing the functionality of this specific implant it was found that after two years it has a 92.2% survivorship with only 9 of the 116 experiencing problems and complications [3]. Zimmer Biomet also advertises its simplicity within the surgical setting. Instrumentation and surgical procedures play a vital role in the success of an implant. If the procedure is long, tedious, and involves a lot of steps, a patient may stray away. Detailed in Zimmer Biomet the instrumentation is designed for surgeons to facilitate ease and allow for smooth flow.

Affinis Short Stemmed Total Shoulder Prosthesis manufactured by Mathys Affinis is yet another stemless option currently within the European market. The purpose of the study, outlined on PubMed, was to observe the "survivorship…and radiological outcomes of Affinis short prosthesis" [2]. Of the 141 prostheses implanted, five underwent revision surgery, three ended in rotator cuff failure, one implant resulted in infection, and one was reported to have malposition.

The survivorship of this specific implant was 95.4% when measured and observed at five and nine years. Radiological outcomes were observed for 99 of the 141 prostheses implanted and the results included: “humeral RLLs in one case, glenoid RLLs in 15 cases, and radiological rotator cuff failure in 22 cases” [2]. RLLs are crucial in TSA studies as they provide insight on certain observed regions that may or may not have a decrease in density. This decrease in density is important to understand as the bone cavity is ultimately what stabilizes and holds the implant in place. With a decrease in density, outcomes such as micromotion and fractures could occur, leading to revisions.

1.6 Technical, Economic, and Regulatory Hurdles

There are many hurdles that need to be crossed for the successful implementation and creation of this design. One of the largest includes the economic aspect of product design. Every surgery, procedure, or product, whether large or small, is costly. The implant created needs to be economical, otherwise, patients experiencing situations that require TSA or RSAs will not be able to afford the product. For this reason, our group cannot choose any materials or manufacturing methods that could come costly. For manufacturing, it would be insightful to use a method or machinery technique that Exactech has adopted to allow for the removal of initial investment and research.

With any design, all aspects must adhere to and comply with the standards set by the International Organization of Standardization. One specific standard that this project will follow closely is ISO 3485:2016, which regulates specific requirements for quality management. On top of quality management, this standard also regulates risks, legal compliance, and efficiency of the product. Within this standard, there is also importance set on the insurance of repeatability and consistency.

This type of device also needs to follow ISO 10993 standards and FDA regulations under title 21, chapter 1, subchapter H: medical devices to be approved before any patient testing and after further testing, being placed on the market. On top of the intense biocompatibility and sterilization testing, there also needs to be rigorous mechanical testing to ensure that the implant can withstand forces, stress, and strain without harm to the patient.

It is difficult to develop a stemless reverse shoulder implant since it must not dislodge or loosen under the same forces that a stemmed implant is expected to withstand but with far less surface area in contact with the patient’s bone. Figure 2 shows an example of the forces that would be exerted on the shoulder in daily life, by simply lifting a coffee pot up and down exerting up to 105 percent of the patient’s body weight [1]. We tried to measure these properties through tests for lever out and shear which involves “implanting” a prototype device into a bone substitute (with similar properties to bone) and applying a force to determine the force required for the implant to dislodge. The implant must also be simple enough for a surgeon to use without excessive training or instruction, allowing for a short instruction manual to be sufficient for a surgeon to learn how to proficiently implant or revise the device.

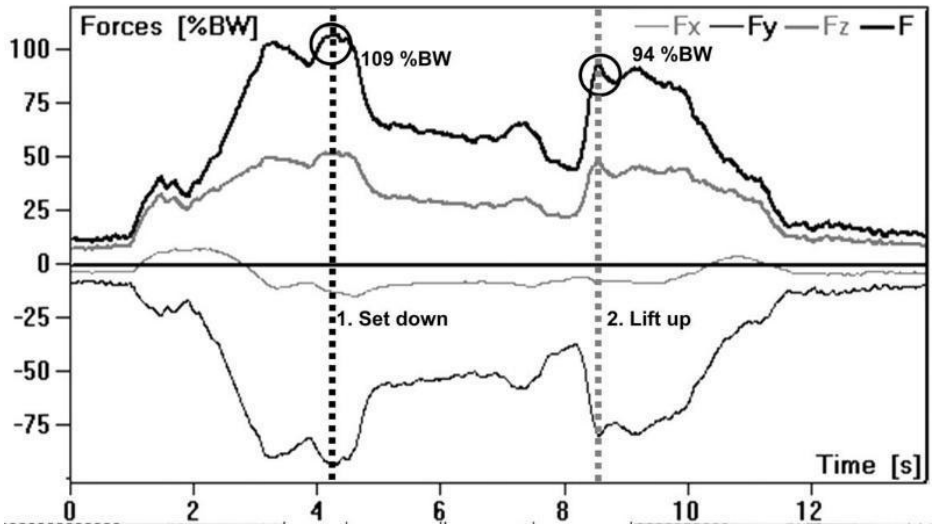

Figure 3: Force components and the resultant force on the humeral component of an implant over a 14-second period; measured as the patient lifted and set down a coffee pot. [1]

1.7 Mechanics

One of the most important aspects of our team's design was the retention of properties throughout the time of use, i.e. no fracturing, breaking, and having the implant stay in place. Understanding the mechanics behind the stresses that the implant and the bone experience helped accomplish these goals. We accounted for daily and possible extreme forces that the body undergoes to determine the cyclic and maximum loading that the device will be under. For this, the following equations were used.

$$\Sigma F = 0$$
$$\tau = \frac{F}{A}$$
$$M = F * r$$
$$\Sigma M = 0$$

The sum of all forces equals 0 in static systems, where F is force applied, τ is shear stress, A is the cross-sectional area, M is the moment, and r is the radius. Using these equations force balances can be made and the forces on the implant can be determined appropriately. The forces were analyzed with respect to the forces applied on the arm as it is extended carrying the normal maximum a person would be carrying in day-to-day life. Another important factor to take into consideration was bone's natural material properties and the relationship bone has with the material of the implant. It was ensured that both these materials are working in unity. The main test we performed on our implants included a novel examination of the lever-out force.

1.8 Stakeholders

When the question is posed of who the main stakeholders are within a specific scientific or medical field, patient users are usually the first and only to come to mind. Surprisingly though, users can entail countless other types of individuals and groups. These can include, but

are not limited to doctors, nurses, researchers, engineers, and investors. Stakeholders also can include anyone who is impacted by the manufactured device and design; these can include both relatives and caregivers. With TSA surgeries becoming more and more common to the public the importance of typed stakeholders has grown of increasing importance.

Doctors and nurses play a key role through all steps of the operation. Gathering background health, obtaining vitals, and having a clear picture of the fundamental parts of the surgery are the steps doctors and nurses must take before, after, and during shoulder replacement surgery. Patients, like doctors and nurses, are another key part of the system. Without patients, there would be no surgery and ultimately after surgery, patients assume the role of a doctor when they are home and starting to recover. Engineers and researchers are another key stakeholder. Engineers help create the design and product. With a background in both education and experience, engineers provide insight into what and how the product should function. Both mechanical and biomedical engineers help doctors, nurses, and other parties understand the mechanical and biological relationship. Engineers ultimately pair and work with researchers to properly test and analyze products to ensure functionality and effectiveness.

2. Product Definition

2.1 Explain Customer Requirements

This implant was designed to reduce the stress placed on the patient and improve their quality of life through the restoration of function. To restore functionality to the best of our ability, we tried to develop an implant that gives the maximum range of motion and drastically decreases the pain that the patient feels, and the implant should not fail under normal stresses while still being affordable. Certain customer requirements that they may not think about directly affect the surgeon doing the implantation, these are considerations such as reducing the number of revisions required, making any necessary revisions easier for the surgeon, and causing less damage to the original material.

2.2 Design inputs

User Need	Design Input	Qualitative Goal or Range
Range of motion	Cup and head shape	Allows lift of arm from side to horizontal
Lower revision rate/easier revision surgery (for patient)	Biocompatible/Easy to clean material choice	No post surgery infection or rejection due to the implant
	Size/Anchoring method	Bone removal limited to humeral head
Easier revision surgery (for surgeon)	Structure of implant (what devices fit with it)	Must work with current stemless implant removal devices/must allow use of an osteotome.
No Pain	Implant shape and mechanism of movement	must function mechanically perfectly with no damage to surrounding tissue
No mech. Failure	shape choice of head and cup, material choice, manufacturing method choice	cannot experience mechanical failure (breakdown or fracture of implant component(s)) under at least 130% of user's body weight
No micromotion	structure of the section that contacts the patient's bone	Cannot further damage bone at all due to minor movement of patient for 3 weeks post-op
No exorbitant costs	material choice, manufacturing	Should manufacture with existing exactech capabilities, likely choose a cobalt or titanium alloy for metal components

Figure 4: Table of user needs and the portion of the design that affects the need and our goal for the device.

2.3 House of Quality Table

The house of quality below in Figure 5 shows the relation between multiple design requirements as well as their relation to the user needs that the implant must fulfill.

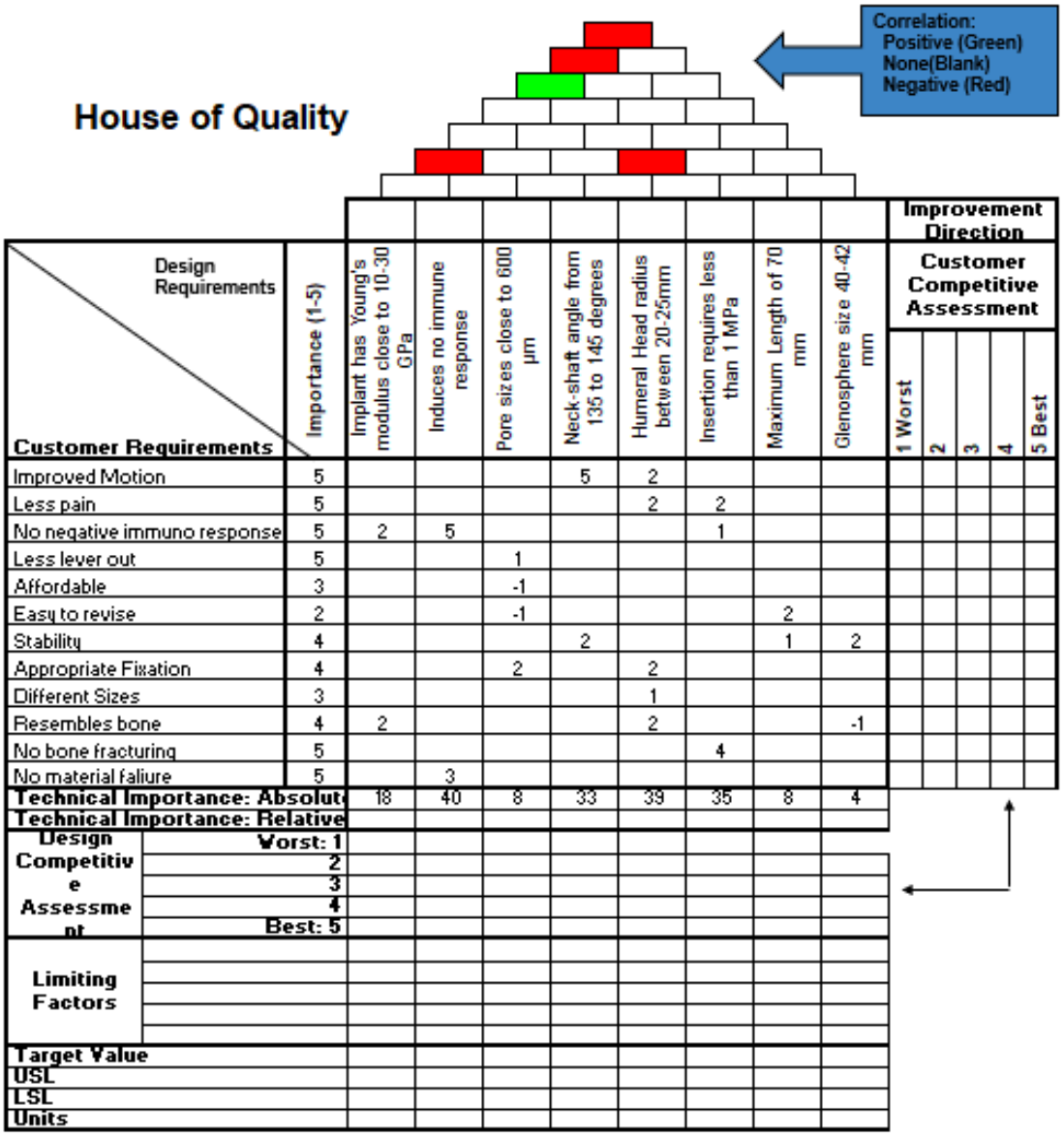

Figure 5: A house of quality showing how each design input affects the properties of the implant

2.4 Concept Selection

We had 6 concepts for humeral anchors that we tested to decide which will be made into a better prototype. We decided to focus on the humeral anchor instead of other parts of the implant due to it being the most likely to be affected by a change to reverse arthroplasty. The concepts consisted of an Exactech-like model that uses the existing Exactech shape for the anchor, a twist/screw shape that acts similarly to a screw, the anchor-like that functions similarly to a wall anchor and deforms to remain in place, a ridge/wedge shape that is shaped with ridges to prevent lever out, an expanding shape that expands after implantation, and a T shaped fin that uses a similar design to the Exactech-like model but with the fins having a “T” shape when

viewed from above. Figure 6 below shows a Pugh chart that we made to compare the models with respect to the roles that the anchor needs to fill.

Pugh Chart

Cold Shoulderz Pugh Chart

Needs\Designs	Importance from 1-3 Weight	Existing Exactech	Twist/Screw shape	How it fills the need from 1-5 1 = not at all, 3 = average, 5 = excellently Anchor-like	Ridged	Expanding	T-Shaped Fin
Prevents lever out	3	3	5	5	4	4	5
Prevents micromotion	2	3	2	3	3	5	4
No device fracture/failure	3	5	4	4	3	1	3
No bone fracture	3	4	3	2	3	1	3
Easy revision	2	4	3	1	2	5	3
Immune response	2	5	2	3	2	2	4
Ease of implantation	1	5	3	3	4	3	4
Totals:	-	65	53	50	48	45	59

Figure 6: A pugh chart for analysis of the different model ideas.

2.5 Current Design

From the above Pugh Chart, only the Exactech model was chosen as our main prototype. It was used as a canvas. For that reason, different modifications to the current Exactech model were performed to determine optimal implant design. The current Exactech-like model can be seen in Figure 7.

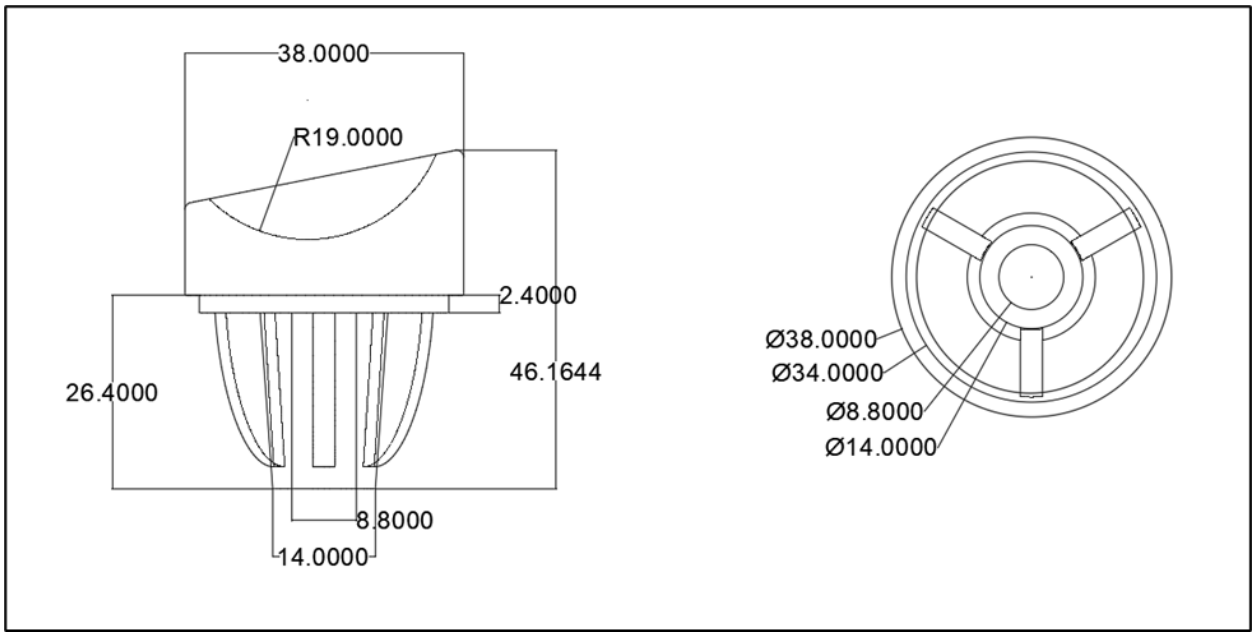

Figure 7: The dimensions of the existing Exactech model to be used for testing

Considering that our tests were solely for the anchor section's properties, we printed the models with the tray attached so that any attachment issues do not affect our test results as mechanical failure is not what we intend to test. The final design included a separately attached tray. Furthermore, more adjustments were made to the Exactech-like model, which can be seen in Figure 7, to change the number of fins and determine the best anchoring mechanisms.

2.6 Prototyped Models

A printed anchor that is one of the 5 models tested can be seen below, in Figure 8. The other designs can be seen in Figure 9. We used a Lulzbot TAZ Pro 3D printer and a Formlabs Form 3B+ Resin Printer available to us in the biomedical engineering instrumentation lab to print our models. The models will be printed using Pro PLA filament and Formlabs Tough 1500 resin.

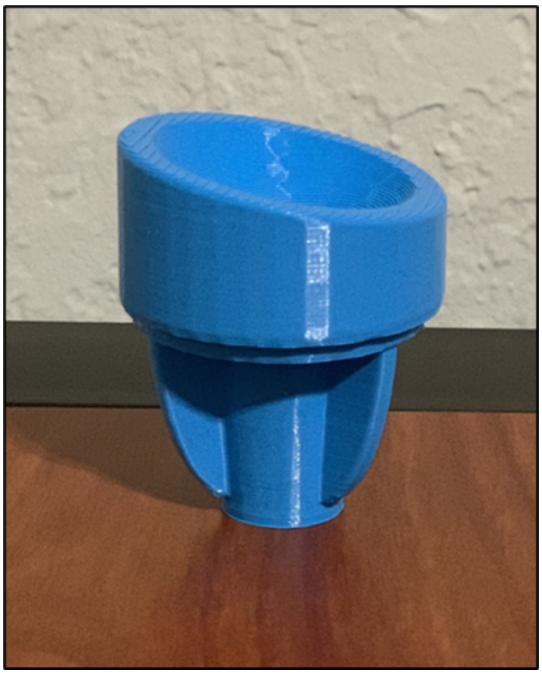

Figure 8: The exactech-like model that has been modeled in CAD and printed using the Lulzbot TAZ Pro 3D printer and is made out of Pro PLA filament.

We have developed 5 base prototypes to test, we varied the fin count from 2 to 6 anchor fins with the fins spaced equidistant from each other. In later testing, we altered the alignment of the fins for the 2 and 3 fin models with respect to the tray. This was done by rotating the initial model (one fin perpendicular to the applied force, 3 o'clock) by 90 degrees clockwise, and 90 degrees counterclockwise. This led to one fin pointing toward the applied force and one pointing away from the applied force (12 o'clock and 6 o'clock respectively).

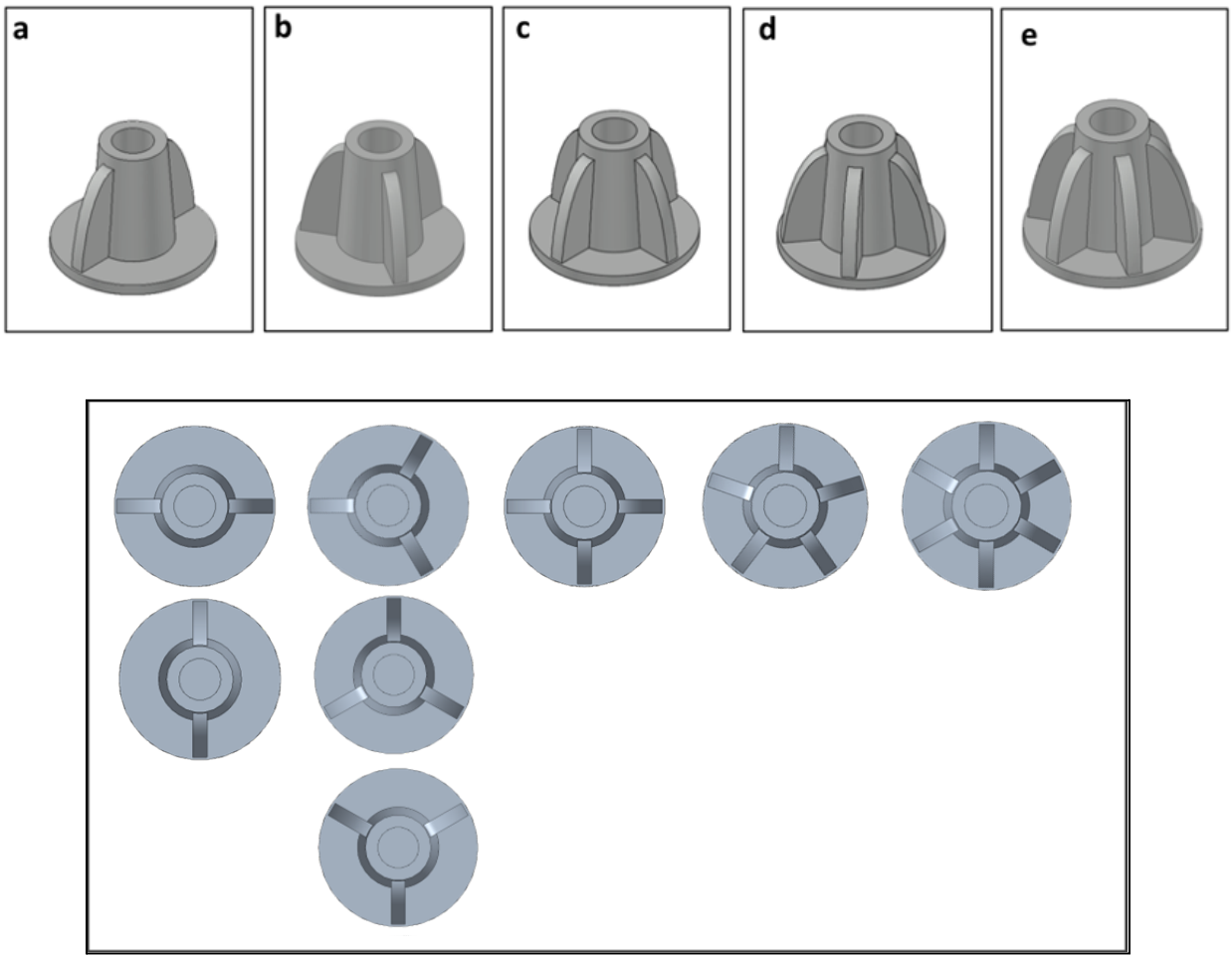

Figure 9: The humeral anchor designs tested from the top (bottom frame) and side views (a-e).

3. Discussion

3.1 Prototyping and Testing

After we printed all the prototypes, testing was carried out starting with preliminary tests in extruded polystyrene insulation, with a 10 kg force gauge, and our Pro PLA anchors. Once this was completed we proceeded to test with bone blocks of varying porosity 10 and 15 PCF (pounds per cubic foot), a Shimpo FGE-50XY Digital Force Gauge, and a Shimpo FGS-100H Manual Hand Wheel Operated Test Stand. This data was recorded with iPhone cameras and documented to make insightful correlations in terms of designs and their efficiency. The spring prototyping and testing plan can be seen in the following Gantt chart.

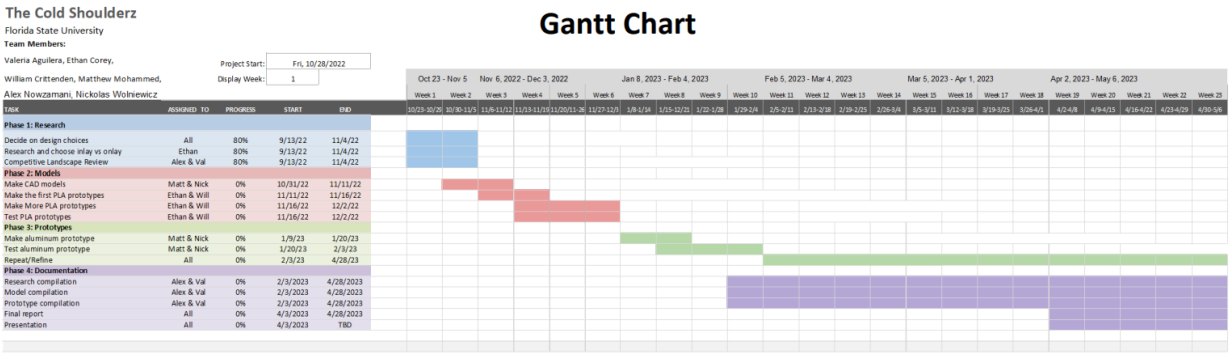

Figure 10: The Gantt chart previously made, a larger version is available in the appendix.

3.2 Computational Methods

COMSOL was used to simulate a finite element analysis model of an implant when experiencing a shear stress force ranging from 0 N to 500 N. The shear stress is applied from the left to right direction. The results are displayed in N/m^2 units. This is represented in Fig. below.

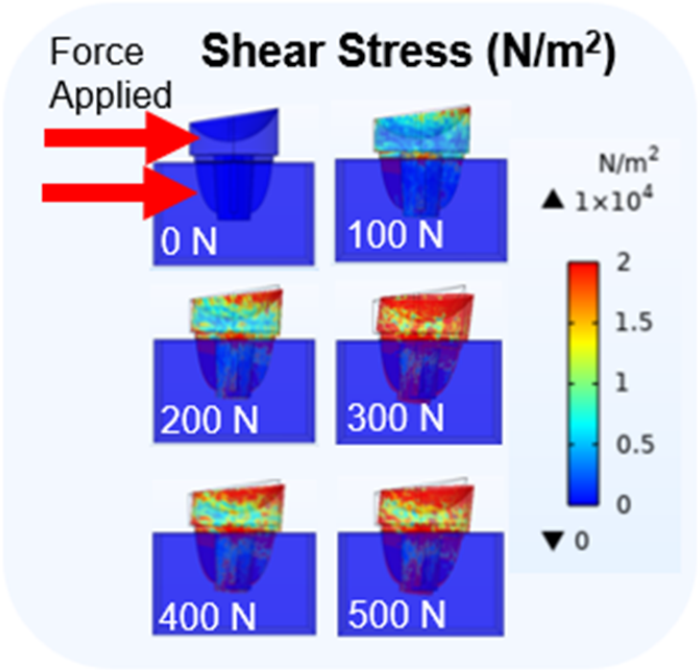

Figure 11: COMSOL model showing shear stress acting on the implant.

3.3 Physical Methods

The first phase of testing was done by placing the PLA implants in sections of insulated foam sheets. To simulate leveling out, we placed the hook of a 10 kg spring scale right below the

liner tray of the implant and pulled the scale along a wooden block to calculate the force it took to lever out the implant while keeping the scale horizontal. Exactech's three-fin design produced the greatest resistance to the lever-out force (N). Tests the peak force required to completely shear the implant out of the bone block. Performed by directly applying a force on the glenosphere tray vertically. Tests the peak force needed to dislodge the implant from the bone block through a pulling motion. Performed by applying a vertical pulling force with a metal hook attached to the glenosphere tray.

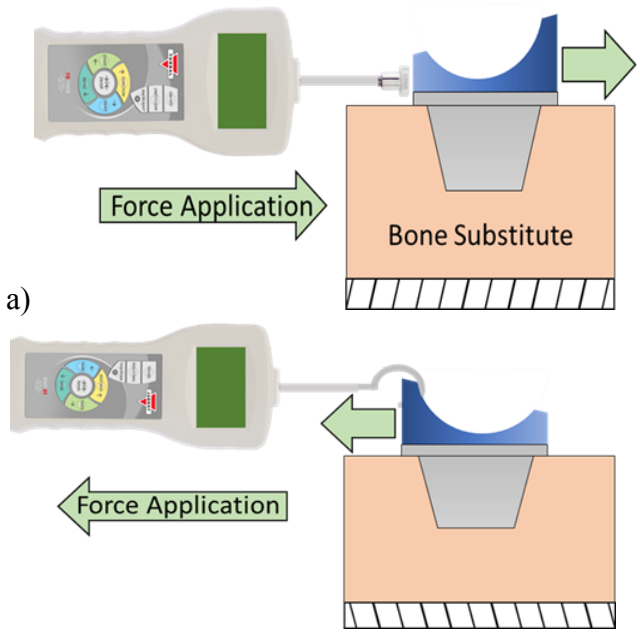

Figure 12: Representation of Testing Methods for Implant. (a) Shear Testing in 15 PCF Bone Block. (b) Lever-Out Testing in 15 PCF Bone Block.

3.4 Testing Results and Implications

The results of the preliminary test showed no significant data except for the six-fin model vs the Exactech model. This can be seen in figure 13. Trials were performed twenty times for each design. The p value for the six-fin model to the Exactech model was 0.0170258. For phase II of testing, the shear test for the six different fin variations showed a linear relationship of ~0, with datasets not being significantly different from each other. Trials were performed three times for each design. The shear test for the different orientations of the three-fin model showed the orientation with the fin lined up to the high end of the glenosphere tray at the 12 o'clock position to be the most effective. The correlation was that the inclusion of fins in the design perpendicular to the force acting upon the implant produced the greatest values. The results from phase II can be seen in figures 14 through 16.

Applying a compressive force to the walls of the bone block increased the peak force values the implants could withstand before failure. This compressive force keeps the implant more secure in the bone block before dislodging. The 15 PCF bone blocks were more susceptible to fractures forming during the implantation process as opposed to the softer 10 PCF bone blocks because they were more brittle. When the fins were orientated perpendicular to the applied force, the peak force performance was higher. When a fin was oriented in the rotational path of the cage, the maximum withstanding force was lower. The study was limited by the number of bone blocks available as additional trials are needed to produce more accurate results. The three-fin orientation with the fin lined up to the high end of the glenosphere tray at the 12 o'clock position proved to be the most effective. This orientation had the greatest force-withstanding value for shear testing with a respective value of 630 N. Future designs can incorporate an orientation with fins perpendicular to the opposing force. This implant design has the potential to improve resistance to the forces peculiar to reverse stemless shoulder implants.

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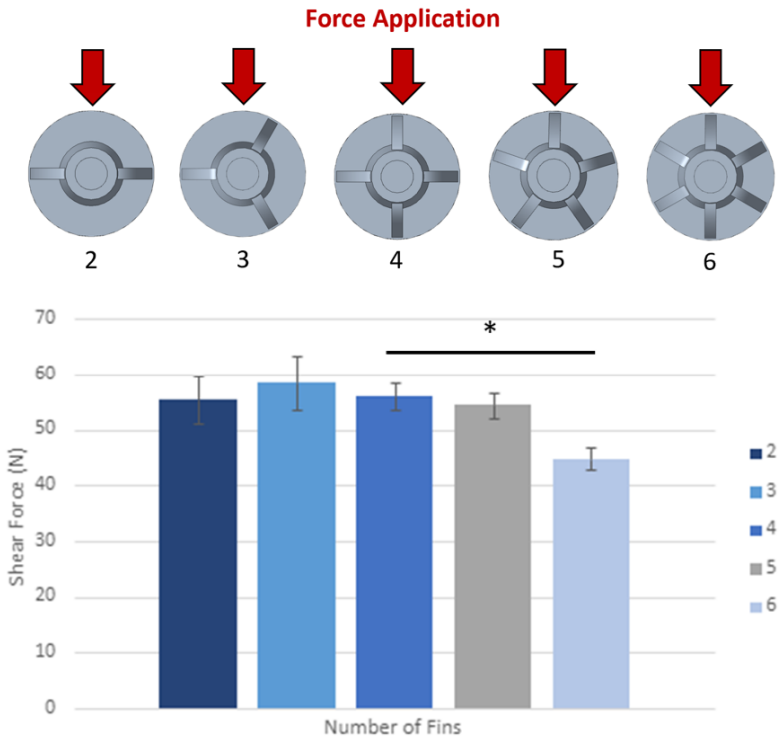

Figure 13. Phase I (Preliminary) Lever out data. Models and force applications are shown on the top.

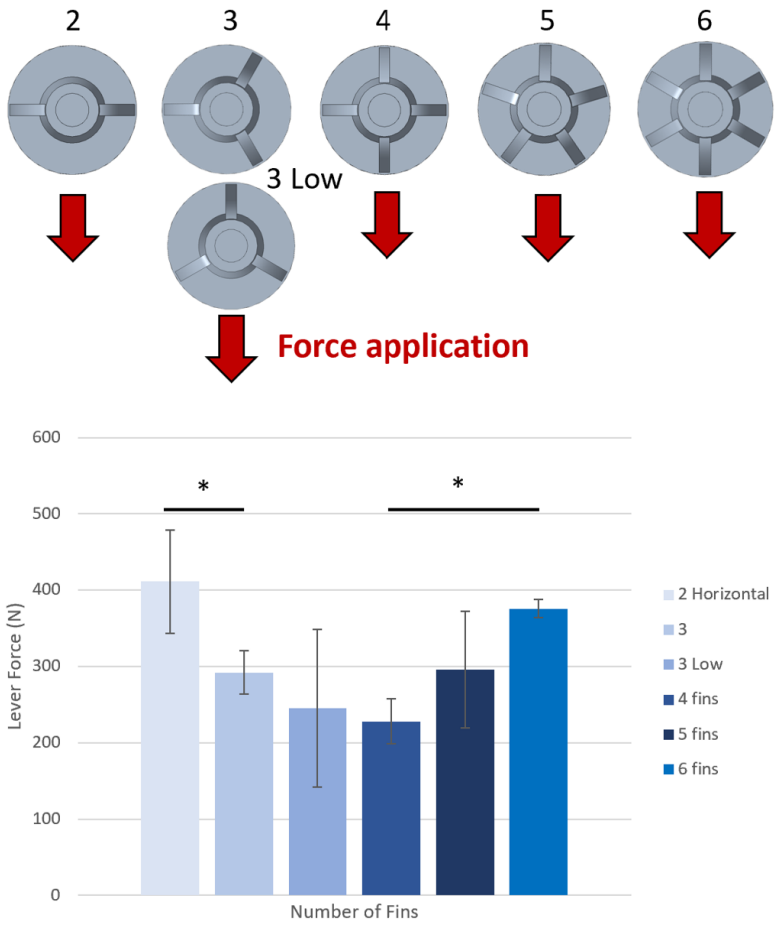

Figure 14. Phase II Lever out data. Models and force applications are shown on the top.

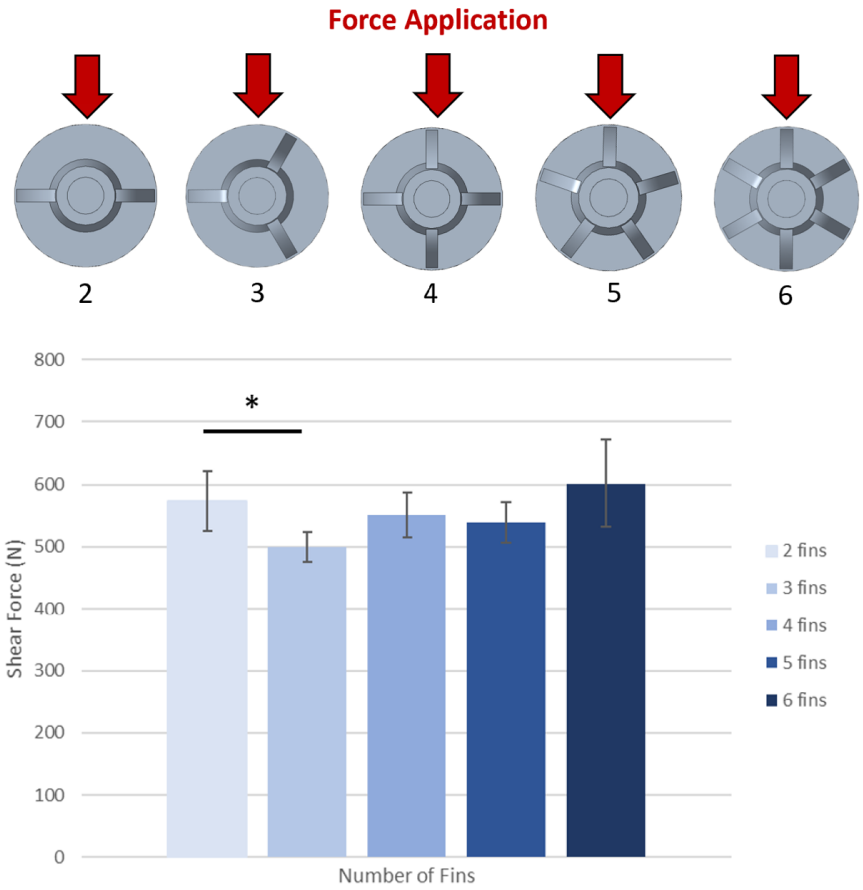

Figure 15. Phase II Shear out data. Models and directions of the applied force can be seen on the top.

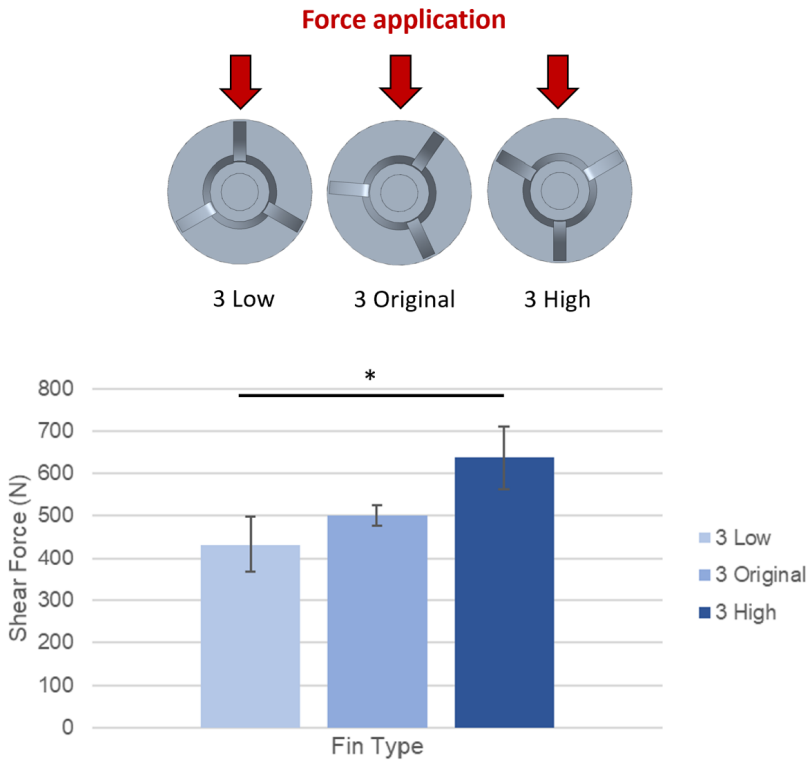

Figure 16. Phase II Testing for Three-Fin Variation Shear Out Forces. Models and direction of forces can be seen above.

3.5 Relevant Standards and Guidance

There are many standards related to this project. In regards to biocompatibility, some of the standards that are going to be followed are ISO 10993. Some of the specific standards include, but are not limited to, ISO 10993-10, ISO 10993-4, and ISO 10993-5. When it comes to sterilization for the device, some of the standards followed will be ISO 11137-1, 10 CFR 37, USP <161>, USP <85><85>, and ANSI/AAMI ST72.

Some relevant standards that guided the methodology of our testing were the standards for bench performance testing. Those standards include ASTM F1378-6.2, ASTM 2028-17, and ASTM 2003-02. Those standards can and will be used to determine the implant's performance and whether it was successful or not.

3.6 FDA Strategy

This implant is a class 2 device. This means that, according to the FDA, it has a medium to high risk. For that reason, the pathway for this implant has to do with doing a 510(k) submission. If it passes the 510(k), then the implant will be FDA-cleared and can be marketed. The time it takes for the FDA to process and determine the outcome of most class 2 devices is close to 3-6 months. Furthermore, the implant will be given a 510(k) number to register the device. In order for the implant to be cleared, it needs to be substantially equivalent to a predicate device that was already cleared by the FDA.

3.7 Reimbursement Strategy

The reimbursement strategy deals with assuring that all steps in the reimbursement decision process are successful. This includes the coverage, coding, and payment. In order to ensure that the implant is covered, there needs to be evidence from comparative clinical trials to present the implant's effectiveness in improving the health of the patients. When it comes to codes, current procedural terminology (CPT) and International Classification of Diseases, 11th revision (ICD-11) codes can be used. Lastly, in terms of payment, Medicare pays for the procedure that uses the device, not for the device itself. It might be beneficial to provide substantial clinical improvements for using this implant versus other implants in the market. If this is the case, Medicare might provide special 'provisions' and give an extra payment to cover the implant. Some of the CPT codes for shoulder arthroplasty can be seen in the following figure.

CPT Code	Code Description
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement [e.g., total shoulder])
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component

Figure 17: Current CPT codes for shoulder arthroplasty.

3.8 Possible Clinical Studies

Because the implant has the same materials as other FDA-cleared devices, it does not need to undergo clinical studies to be cleared by the FDA. The implant can be marketed as long as it is substantially equivalent to the predicate device. Having said this, clinical studies can be carried out after the implant is in the market. This can show its performance in comparison to other implants in the market from other companies. This can be beneficial as it can give Exactech a comparative advantage and can be used in advertising and marketing.

3.9 Intellectual Property Considerations

In terms of intellectual property, the implant will need to be exclusive to Exactech. In order to protect the implant, a design patent can be granted by the U.S. Patent and Trademark Office. This will give property rights to Exactech. Furthermore, depending on the market the implant will be sold on, it might be in Exactech's best interest to patent the design in the European Patent Office (EPO) as well. Other than that, because there are no other stemless implants for reverse shoulder arthroplasty in the United States, the probability of this implant committing an infraction of other patented inventions is almost nonexistent.

3.10 Safety, Intended Use and Labeling Info

Safety

The safety of this implant can be shown by the standards and guidelines it follows. As stated previously, the implant will follow all biocompatibility and sterilization standards, which include ISO 10993-10, ISO 10993-4, ISO 10993-5, ISO 11137-1, 10 CFR 37, USP <161>, USP <85><85>, and ANSI/AAMI ST72. Furthermore, the cytotoxicity standards followed are ISO 10993-5, ISO 10993-1, and ISO 10933-12. The assessment of carcinogenicity will follow the guidelines within ISO 10933-10 in conjunction with ISO 10933-1 and ISO 10933-18. Lastly, in terms of hemocompatibility, ISO 10993-4 will be followed. All these standards will ensure the safety of the implant in terms of sterilization, cytotoxicity, hemocompatibility, and carcinogenicity, which are the main concerns for implants used in reverse shoulder arthroplasty.

Intended Use

The implant is intended for use in reverse shoulder arthroplasty for pain reduction and improved arm motion for adult patients. It is meant to be used in adult individuals with degenerative diseases of the glenohumeral joint and an irreparable rotator cuff. It can also be used for a failed glenohumeral joint replacement that led to the loss of rotator cuff function, in which reverse shoulder arthroplasty is the preferred method of treatment.

Labeling Information

When it comes to labeling, it will comply with ISO 6018:1987. Each package containing the implant will have the name, registered trademark, address of the manufacturer, and a description of the contents, which can include names, dimensions, and materials. In addition, indications of use will be given as well as the statement "Sterile unless package damaged." The labeling will also include the implant's sterilization process, the recommended method of opening and handling the package to ensure sterility, and the expiration date or date the implant was manufactured, according to ISO 2014.

3.11 Ethical considerations

The ethical concerns in relation to implantable devices have to do with end of life issues, mental or personal identity changes, or supernatural enhancements to the human body. When it comes to the end of life, the implant does not raise any concerns. The same can be said about mental and personality changes. Lastly, because the implant has to do with restoration of movement, it does not supernaturally enhance the body. It tries to restore the body to normal functioning while reducing pain. Overall, this project will closely follow the BMES Code of Ethics. This means that this project will seek to enhance the standard of care for patients needing reverse shoulder arthroplasty, adhere to biomedical regulations, and promote accessibility, affordability, and availability to biomedical technologies.

4. Conclusion

4.1 Reflection and Recommendations

Before testing began we hypothesized that the number of fins would've had the most significant impact on the amount of stress the implant models would take. After testing each design, the data gathered showed that the number of fins was not statistically significant, however, fin placement had a major effect on the test results. This occurrence is a great example that not everything goes according to plan, however, everything that happens has a lesson to learn leading us closer to our goals. For future testing, it is recommended that more tests are conducted to increase data resolution as the test number for this study was limited due to materials and the time constraints of the project. These future tests should also be done with models made out of a metal alloy with some form of a surface coating and be done with a force meter that allows for digital data collection, this will give more accurate results to the system in place when the anchor is implanted into the humeral head with bone growth and give better resolution about the forces and displacement of the implant. The bone blocks used for these tests should be properly secured to prevent unwanted fractures during implantation and testing.

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APPENDIX

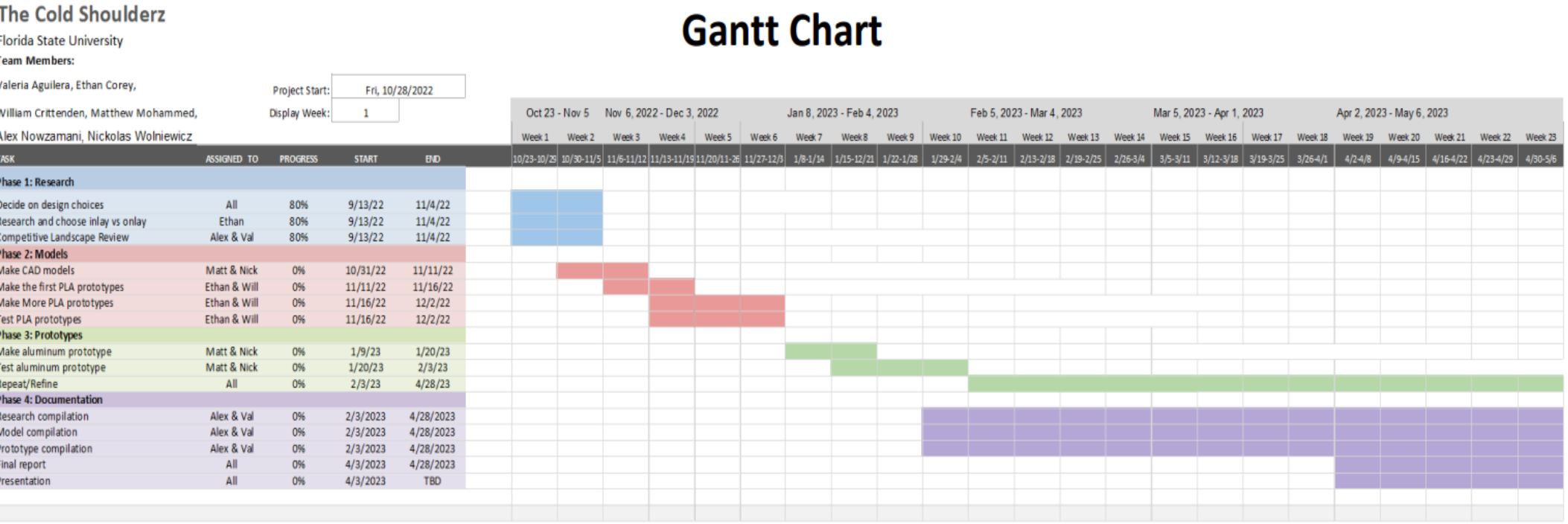

Figure 9: a Gantt chart containing our tentative schedule for the project from earlier this semester