# A Fastening Device for Rotator Cuff Repair


**A Major Qualifying Project**

**Submitted to the Faculty of the Worcester Polytechnic Institute**

**In partial fulfillment of the requirements for the**

**Degree of Bachelor of Science by:**


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April 24, 2017

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# Abstract

***Current surgical methods for rotator cuff repair involve sutures and bone anchors, which are successful in reattaching the torn tendon but have a 31% re-tear rate. To address this problem, a fastening device was created to reduce the likelihood of re-tear by increasing the surface area of attachment at the surgical site. The device was prototyped using 3D printing technology and underwent mechanical testing. The strength of the device surpassed that of the Mason-Allen suture technique, which is commonly used in rotator cuff repair.***

# Acknowledgements

The team would like to acknowledge Professor Sakthikumar Ambady, PhD, the advisor of this Senior Capstone Design Project as well as Robert Meislin, M.D. of New York University who sponsored this project. Additionally, we would like to extend a special thanks to lab managers Erica Stults, Lisa Wall and Elyse Favreau.

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# Chapter 1: Introduction

Rotator cuff tears are one of the most commonly reported injuries in the country, with the majority of incidents occurring due to old age or overuse (Standring, 2008). The rotator cuff is composed of four tendons that join together to connect to an insertion point in the humeral head (Clark & Harryman, 1992). When a tear occurs, these tendons pull out of the humeral head. Current methods of treating rotator cuff tears are physical therapy, surgery, and cell therapy. Physical therapy is effective in treating the symptoms and pain for less severe tears that can heal properly with minimal interference (Edwards *et al*., 2016). Cell therapy is currently still experimental and involves delivering stem cells to the affected area to prevent the formation of scar tissue and promote tendon healing (Young, 2012). Surgery is a popular option for rotator cuff tears. Rotator cuff surgery involves reattaching the tendon to the humeral head using sutures and bone anchors (Favard, Bacle, & Berhouet, 2007). While this method is effective in fixing the tear, and allowing the tendon to reattach to the insertion point, there is a high re-tear rate after the procedure. When re-tear happens, it is usually more severe than the original tear, making a second surgery necessary (Cummins & Murrell, 2003). Because rotator cuff tears are particularly common and approximately 440,000 repair surgeries took place in the United States in 2010, the goal of this project was  to create a new fastening device that will re-attach tendons while minimizing re-tear (Meislin, 2017).

The hook and loop fastener technique is the inspiration for this project. Just as in commercially used Velcro, the hook and loop system provides multiple attachment points for two materials to connect. Increasing the number of attachment points between the tendon and the device will expand the surface area of the repair site and therefore reduce the amount of stress on the tendon. Decreasing the stress applied to each connection limits the chance of a re-tear to the rotator cuff. This hook and loop design requires two distinct adhesives to attach the device to the soft tendon tissue and the hard bone tissue. When the rotator cuff is being repaired, the tendons in the shoulder must be reattached in a strong, stable, and long lasting way to avoid any further complications post-surgery.

The primary goal for this project was to design and prototype devices that improve rotator cuff repair and reduces re-tear by increasing the surface area of the repair

site. The team did this by choosing appropriate materials and adhesives that are biocompatible, bioresorbable, and have a high tensile strength. After choosing the materials for the device, a fabrication method was chosen for prototyping.

To develop a new fastener system for rotator cuff surgery, the following objectives were established:

- **Reduce the possibility of post-surgery re-tear.**
- **Utilize the hook and loop concept.**
- **Increase the surface area of attachment.**
- **Reduce the possibility of re-tear after rotator cuff repair by increasing the amount of force the repair method can withstand.**
- **Develop a method of attaching the device to the tendon and bone.**
- **Demonstrate use of the device *in vitro.***
- **Make the device usable in minimally-invasive rotator cuff surgery procedures (i.e. mini-open repair).**

The team tested multiple prototypes to determine the strength and usability of the designs. In order for the device to be applicable for use in the body, the team considered FDA regulations during testing. This procedure provided valuable data to aid in refining and producing a device for rotator cuff repair that decreases the risk of re-tear and promotes tendon reattachment by eliminating the need for sutures and adding more attachment points.

# Chapter 2: Literature Review

Shoulder injuries, particularly rotator cuff tears, are among the most common injuries reported in the United States (Edwards *et al*., 2016). Over 4 million rotator cuff injuries were reported in 2010 (Meislin, 2017). The current methods of repair for these injuries have significant disadvantages, including a high possibility of re-tear and the formation of scar tissue. To understand the importance of rotator cuff repair one must consider the mechanics of joints, the components and the complexity of the shoulder, the current repair techniques on the market, potential new techniques, and the manufacturing specifications for these techniques.

## 2.1 Joint Introduction

Joints are the areas of the body at which two or more bones meet, and they allow for movement in the body. The muscles, tendons, and ligaments surrounding joints aid in their function. To understand the mechanics of joints it is important to consider the different types of joints and the components of each.

### 2.1.1 Types of Joints

Joints are classified into 3 categories: fibrous, cartilaginous, or synovial. The joints within the shoulder complex are synovial, which have the highest mobility of the three. Bones within synovial joints do not come in direct contact; the bones are lined with hyaline articular cartilage and the joint contains synovial fluid to reduce friction. Synovial joints can be further categorized based on their shape into plane, hinge, pivot, bicondylar, ellipsoid, saddle, or ball-and-socket (Figure 1). Each joint type allows for different movements and various degrees of freedom. All joints have mobility due to contractions from connected muscles (Standring, 2008).

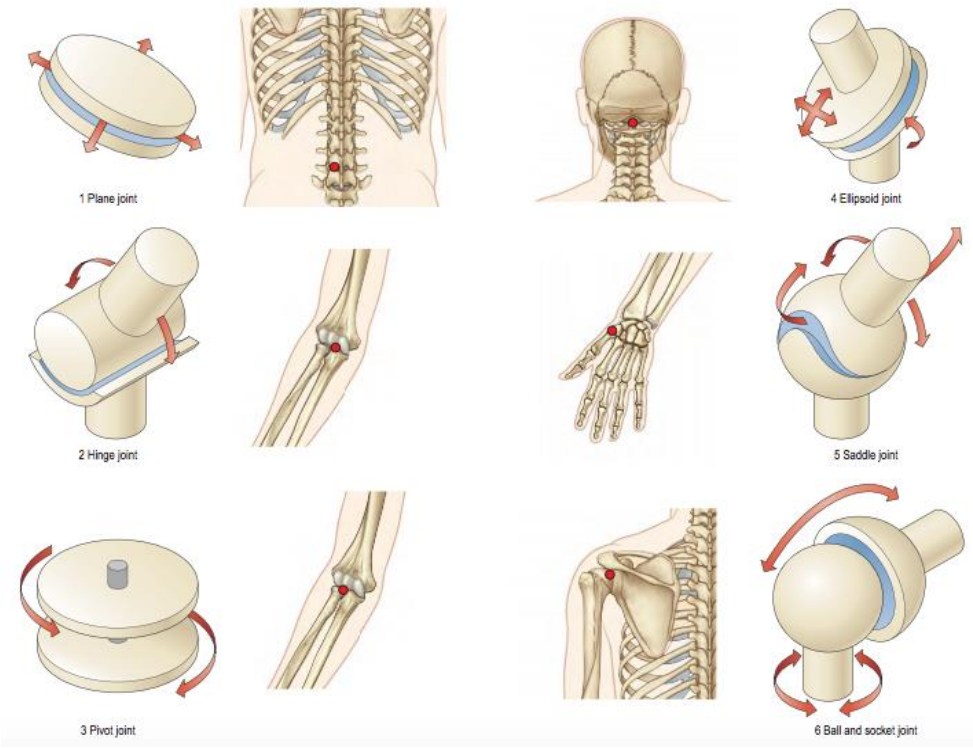



*Figure 1 Types of Synovial Joints with example images (Standring, 2008).*

### 2.1.2 Muscles

The three types of muscles in the body are skeletal, cardiac, and smooth muscle. Skeletal muscles support the skeletal system and aid in its mobility, and are also present within joints. Skeletal muscle is composed of long, striated muscle fibers that can be controlled voluntarily or involuntarily. Skeletal muscles have the ability to contract up to 100 watts per kilogram, which forces the bones of the skeletal system to move (Standring, 2008)

### 2.1.3 Tendons

Muscles are connected to bones by tendons, which are dense connective tissue composed of type I collagen fibers that branch off of muscles and connect to bone. Tendons can stretch 10-15% and have an extremely high tensile strength, but have limited blood supply. Tendons also consume 7.5 times less oxygen compared to skeletal muscle, and therefore have a much lower metabolic rate. This allows tendons to withstand large loads and tension over a long period of time (Vailas, Tipton, Laughlin,

Tcheng, & Matthes, 1978). Tendons allow load to be transferred to and from the skeletal system as provide support to joints (Standring, 2008).

### 2.1.4 Ligaments

Ligaments support joints by connecting bone to bone. Ligaments are also composed of collagen and have similar mechanical properties to tendons. Unlike tendons, which only have fibers adjacent to muscle fibers, ligaments often have collagen fibers in various directions to allow for bone movement over several planes (Standring, 2008). Without the aid of muscles, tendons, and ligaments in joints the body would be unable to move.

## 2.2 The Shoulder Complex

The shoulder is known to be the most mobile but least stable joint complex in the body. The high mobility of the shoulder is due to the three joints that compose it: the sternoclavicular, acromioclavicular, and glenohumeral joints.

### 2.2.1 Sternoclavicular and Acromioclavicular Joints

The sternoclavicular and acromioclavicular joints are located at either end of the clavicle bone. The sternoclavicular joint connects the proximal end of the clavicle and manubrium of the sternum. It is a synovial saddle joint that allows anteroposterior, vertical plane movement, as well as rotation of the clavicle. It is a highly stable joint supported by the costoclavicular, interclavicular, and anterior and posterior sternoclavicular ligaments (Standring, 2008). The components of the sternoclavicular joint are seen in Figure 2.

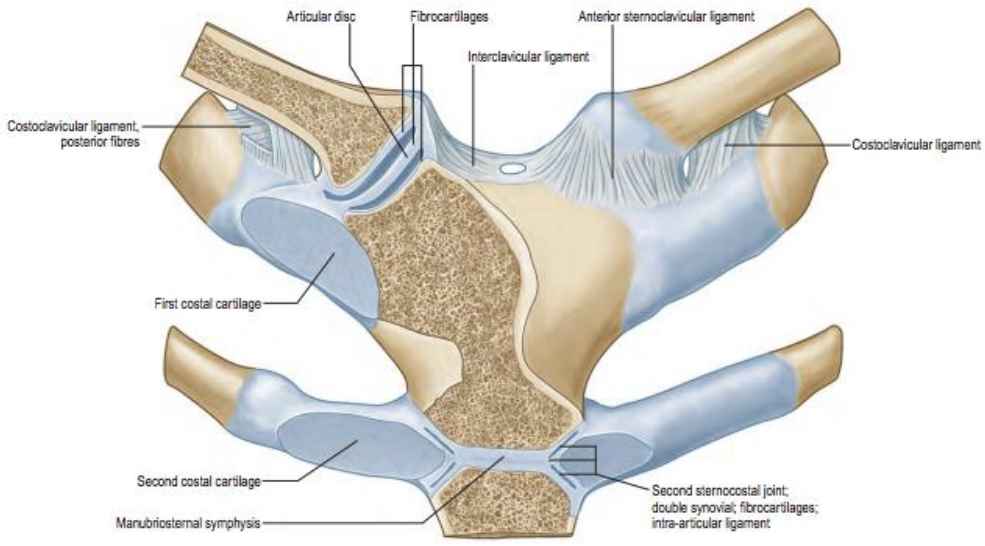



*Figure 2 Diagram of the Sternoclavicular Joint (Standring, 2008).*

The acromioclavicular joint connects the acromial end of the clavicle and the medial acromial margin on the scapula. This joint is a synovial plane joint resulting in anteroposterior gliding and rotation of the acromion. The acromio- and coraco-clavicular ligaments support the acromioclavicular joint. Both joints are not directly moved from the muscles attached to the scapula, but rather allow the clavicle range of motion when muscles of the scapula indirectly move it (Standring, 2008). The components of the acromioclavicular joint are seen in Figure 3.

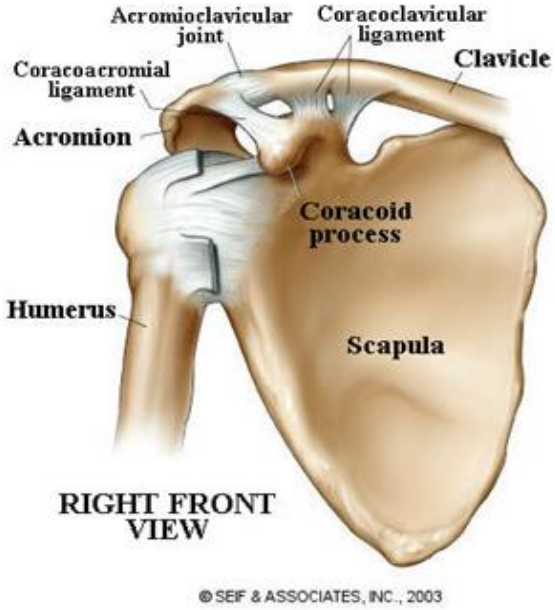



*Figure 3 Diagram of the Acromioclavicular Joint.*

### 2.2.1 Glenohumeral Joint

The glenohumeral joint, otherwise known as the shoulder joint (Figure 4), connects the humeral head with the glenoid fossa of the scapula. The glenohumeral joint is responsible for the extreme mobility of the shoulder because it is a synovial ball-and-socket joint. The ball-and-socket joint allows for three degrees of freedom with flexion, extension, abduction–adduction, circumduction, and medial and lateral rotation movements. There are many muscles that contribute to these movements within the shoulder, but most movements are controlled by the deltoid, pectoralis major, latissimus dorsi, and teres major. The large freedom of movement in this joint also comes with low stability. Five ligaments support the glenohumeral joint: superior glenohumeral, medial glenohumeral, inferior glenohumeral, transverse humeral, and coracohumeral. The long head of the bicep and triceps muscles and the complex of minor muscles called the rotator cuff also protect the joint (Standring, 2008).

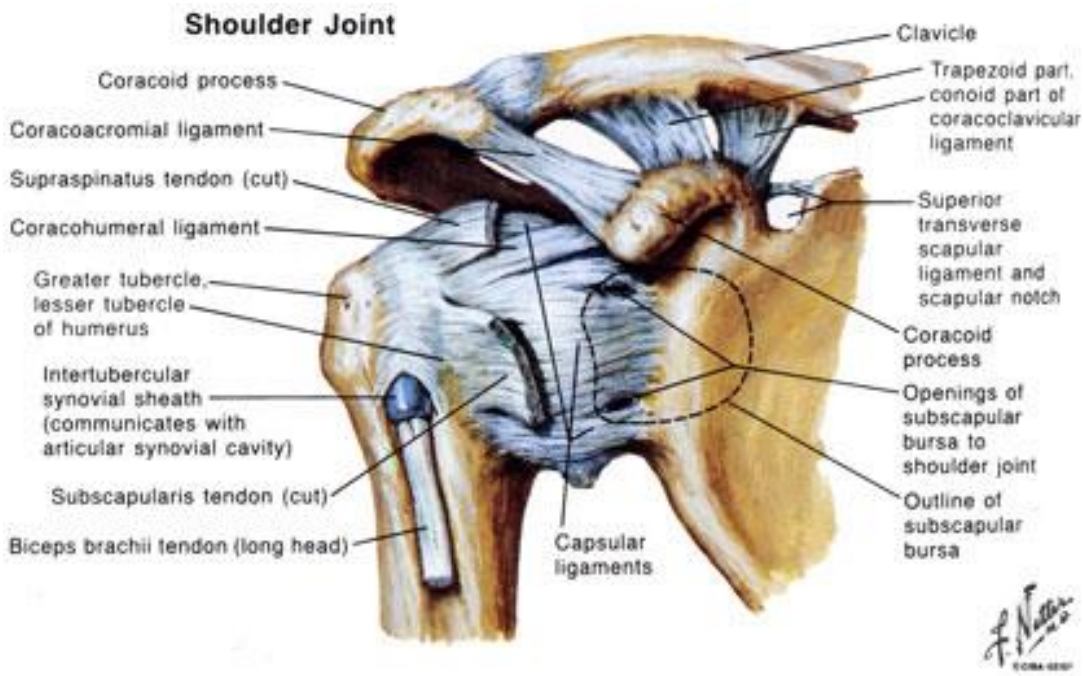



*Figure 4 Diagram of the Glenohumeral Joint.*

### 2.2.1 Rotator Cuff

The rotator cuff is made up of the subscapularis, supraspinatus, infraspinatus, and teres minor tendons (Figure 5). The tendons of the four muscles join together half an inch from their insertion point on the humeral head (Clark & Harryman, 1992). This combination of tendons provides a force that pushes the humerus further into the glenoid

fossa, supporting the unstable glenohumeral joint. The rotator cuff helps to reduce skid, check translation, and increase lateral stability in the joint (Standring, 2008). Without the rotator cuff humans would not be able to properly move the upper portion of the arm (Howell, Imobersteg, Seger, & Marone, 1986).

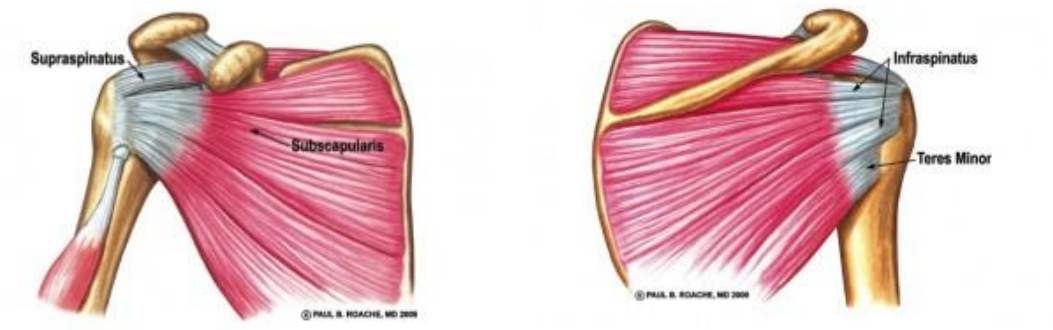



*Figure 5 Anterior and posterior diagrams of the rotator cuff.*

Specialized tissue called enthuses connects the tendon to the bone of the humeral head in the rotator cuff (Lui, Zhang, Chan, & Qin, 2010). This connection is unique because it attaches soft tendon tissue to hard bone tissue. There are two types of attachments that can be made between tendons and bones: direct and indirect (Benjamin *et al*., 2006). The main difference between these two attachments is the lack of periosteum between the tendon and bone in direct attachments (Benjamin *et al*., 2006). The rotator cuff uses direct insertion and is made up of four distinct zones that are used to exchange the body's stresses between the tendons and bones in the rotator cuff. These zones include tendon, uncalcified fibrocartilage, calcified fibrocartilage, and bone (Lui *et al*., 2010). More examples of direct enthuse would include anterior cruciate ligament (Favard *et al*.) attachment, Achilles tendon attachment, and patellar tendon attachment. These attachments each use the same enthuses structure that transitions stresses from the tendon to bone and bone to tendon, similarly to the rotator cuff (Lui *et al*., 2010). An example of indirect connection is the MCL connection to the tibia, which lacks the fibrocartilage interface seen in direct attachments (Benjamin *et al*., 2006). Indirect attachments involve the tendon connecting at an acute angle to the bone, whereas a direct attachment is at a larger angle (Lui *et al*., 2010).

Direct attachment of the tendon to bone is similar to a tree and its roots. The enthuses attaches the entire tendon to its anchor point on the bone. It branches out in

many directions in order to increase the area of attachment and make a stronger connection between the two parts (Benjamin *et al*., 2006). The enthuses is only a small part of the entire mass, leaving the remaining area to continue its normal functioning. The tendon may continue to move as it is pulled because of the strong attachment of the enthuses to the bone of the humeral head. Avascularity is helpful in the mechanical strength of the enthuses but will hinder its healing ability by making it difficult to get blood to the injured area near the site of the tendon to bone attachment (Benjamin *et al*., 2006).

### 2.2.2 Rotator Cuff Tears

Although the rotator cuff is essential in shoulder stabilization, it is prone to injury. Aging or the overuse of the rotator cuff due to activities such as swimming or throwing a baseball can lead to rotator cuff disease, which is the painful inflammation of the rotator cuff. Rotator cuff disease frequently leads to a tear in the tendon complex (Standring, 2008). A rotator cuff tear can also be caused by an acute action (Edwards *et al*., 2016). A rotator cuff tear occurs when the tendons of the rotator cuff rip away from the humeral head, therefore impacting the stability of the Glenohumeral Joint. Rotator cuff tears frequently cause pain over the anterior acromion and restrict shoulder abduction above 60° (Standring, 2008). Many rotator cuff tears, however, can be present without causing pain. These asymptomatic tears often going undetected and are known to worsen or become systematic over time. Yamaguchi *et al*. performed a survey of 45 patients with asymptomatic rotator cuff tears and discovered that 51% of shoulders became symptomatic after an average of 2.8 years (Yamaguchi *et al*., 2001).

Rotator cuff tears are classified as partial or full-thickness tears depending if an entire tendon has ripped from the bone, which is shown in Figure 6. It is estimated that partial thickness tears are more prevalent, but cannot be confirmed because many partial thickness tears can go undetected especially if they are asymptomatic. In a cadaver study of 306 shoulders, Lhor and Uhtroff found that 32% had a partial thickness tear while 19% had a full thickness tear of the supraspinatus tendon (Loehr & Uhthoff, 1987). Tears are most commonly found in the supraspinatus tendon. According to a study performed on 360 shoulders by Kim *et al*., most tears occur near the junction of the supraspinatus and

infraspinatus tendons and begin 15-17 mm posterior to the biceps tendon (Kim *et al*., 2010).

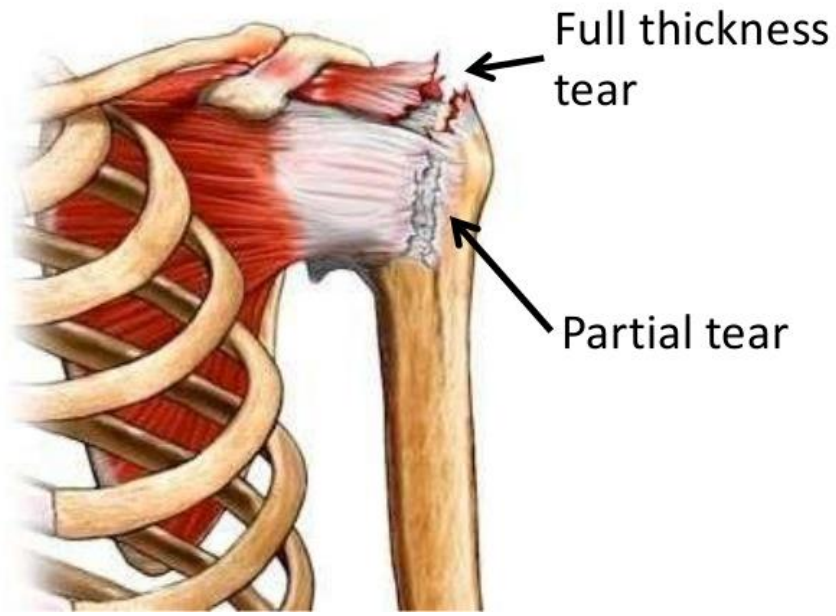



*Figure 6 Rotator cuff full and partial tears (Hanneke van der Weijden, 2013).*

Rotator cuff tears are a common injury, particularly in the elderly population. Over 65% of all shoulder discomfort is related to an issue with the rotator cuff tendons. In the U.S. over 10% of the population over 60 years of age have a rotator cuff tear resulting in 75,000-250,000 repair surgeries each year (Edwards *et al*., 2016). These numbers are predicted to grow in the coming years (Kweon *et al*., 2015). Tendons have poor healing qualities due to limited blood supply and low metabolic rate, making rotator cuff repair difficult (Williams, 1986). After a tendon injury, the affected site heals over the course of three different stages. The first stage involves an inflammatory response where erythrocytes and neutrophils enter the area of the tear. Tenocytes are also sent to the affected area and collagen synthesis is initiated in order to start the healing process. In the second stage of healing, collagen synthesis increases forming repair tissue. During the final stage the tendon is reshaped, repair tissue becomes fibrous, and tenocyte production is high. By the end of this stage, maturation takes place, during which the repair tissue becomes scar tissue. Tenocyte production and vascularity also decline during this stage.

The healing process prior to the maturation stage takes approximately ten weeks and full maturation takes a year to complete (Sharma & Mafffulli, 2006).

## 2.3 Rotator Cuff Repair Techniques

Rotator cuff tears are a common injury and shoulder pain is the third highest musculoskeletal complaint. There are multiple methods of rotator cuff repair (Edwards *et al*., 2016). These treatments range from non-surgical to surgical depending on the severity of the tear. In the event of a rotator cuff injury, the primary approaches taken to heal and/or repair the injury include physical therapy and surgery, but there are new methods being investigated such as cell therapy. Each approach has its advantages and disadvantages. Because of the complexity of the anatomy of the rotator cuff, its poor healing ability, and the range of motions that need to be restored, it is important that the right approach is chosen. Surgical intervention can sometimes exacerbate the injury because sutures and bone anchors can cause trauma to the area and result in scar tissue formation. It is therefore imperative to incorporate less invasive approaches so that the mobility of the rotator cuff is minimized while excessive damage caused by sutures, pins, needles, and other devices used to immobilize the cuff are minimized.

### 2.3.1 Physical Therapy

The foremost treatment option(s) to rotator cuff injuries are non-surgical methods such as rest, ice, and pain medication followed by physical therapy. The goal of physical therapy is not to fix rotator cuff injuries, but rather treat the symptoms and pain (Edwards *et al*., 2016). The target of physical therapy is to strengthen the muscles surrounding the rotator cuff, such as the deltoid and trapezius, to better stabilize the humeral head. When a rotator cuff tear occurs the humeral head is no longer held in its proper location, leading to pain and discomfort (Hawkes *et al*., 2015). A study performed by Kuhn *et al*. showed that physical therapy was an effective treatment method for torn rotator cuffs based on the limited number of patients who elected to have surgery after physical therapy and high patient outcome scores (Kuhn *et al*., 2013). However, Maman and coworkers also discovered in a study on 59 shoulders with rotator cuff tears that 32% of the tears increased in size (Maman *et al*., 2009). Even though physical therapy can relieve minor

joint pains, surgical intervention is currently the golden standard for major injuries that involve tear of the muscle, tendons, and/or ligaments.

### 2.3.2 Surgery

Surgery is popular option for patients with either acute or chronic tears. There are three procedural options available for patients who need surgery: (i) open repair, (ii) all-arthroscopic repair, and (Matsen III) mini-open repair (Ou *et al*., 2016). Each of these options involves using sutures and bone anchors to reattach the tendon to the humeral head. Open repair involves a standard surgical incision over the shoulder so the surgeon can detach the muscle and gain access to the tendon. This process is done for large, complicated tendon tears. A less invasive procedure is the all-arthroscopic repair, which involves inserting a small camera under the surface of the skin to visualize the torn tendon. The surgeon uses thin medical instruments and makes small incisions to access the tendon rather than the large incision involved in open repair. A mini-open repair utilizes the techniques from both the open repair and the all-arthroscopic repair. Arthroscopy is used to repair surrounding damage, for e.g., the removal of bone spurs. The surgeon then reattaches the tendon through a smaller incision in the shoulder (Favard *et al*., 2007).

The goal of surgical repair of the rotator cuff is re-connecting the tendon to the bone at the attachment site, which is essential for healing. Surgeons make an incision to split the seam between the front and middle parts of the deltoid muscle to gain access to the rotator cuff. They remove scar tissue and rough edges of the tendon and humeral head to ensure a smooth pass around the deltoid. In more severe cases, acromioplasty is used to remove part of the bone on the shoulder blade to guarantee smooth movement. In cases where the tendon cannot reach the bone, surgeons will release surrounding tendons and try to reattach healthy tendon to the bone. The case is considered irreparable if the tendon still doesn't reach the bone after this process (Matsen III, 2005).

In order to reattach the tendon, a combination of sutures and bone anchors are used for these repairs. The sutures must be free of tension in order to create close contact between the tendon and the bone. The knots of the sutures are tightened against a device that is used to prevent the knots from damaging bone. After surgery, patients must keep

the injured arm immobile in slight abduction (Favard *et al*., 2007). Figure 7 shows the difference between a torn rotator cuff tendon and the repaired tendon with sutures.

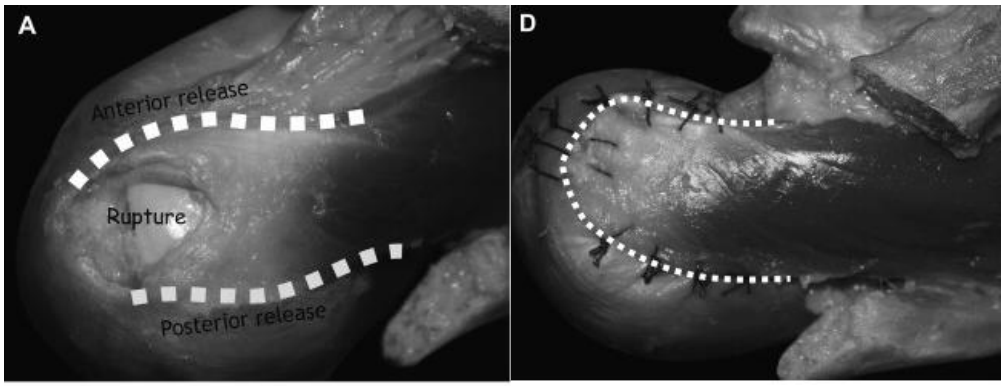



*Figure 7 A Torn Rotator Cuff Tendon and the Repair Completed Using Sutures (Favard et al., 2007).*

While current repair techniques for tendon tears are successful in reattaching tissue, complications arise during the postoperative phase. The re-tear rate after surgery is 30% (Meislin, 2017). The most common type of re-tear involves the tendon pulling through the sutures, indicating a weakness in the tendon-suture interface. Cummins *et al*. found that during revision surgery, the second tear is usually larger than the original tear and the tendon mobility decreases between the two surgeries (Cummins & Murrell, 2003). It is important to have a strong suture material and technique because the tendon itself does not contribute any strength to the repair immediately after the surgery. After approximately three to six weeks of healing time, the tendon provides more tensile strength than the sutures. Suture techniques that involve minimal trauma to the tendon promote closure of the tendon sheath. The tendon sheath is the membrane surrounding the tendon that allows it to stretch and prevents it from adhering to surrounding muscles. Closure of the tendon sheath is essential in the healing process in order to re-establish the connection with the synovial fluid system, which reduces the friction in joints (Ketchum, 1985).

In addition to re-tear, there are other risks involved with rotator-cuff repair surgery. These include infection, injury to nerves and blood vessels, stiffness in the joint, and pain. There is also a chance that there is not enough healthy tendon remaining to repair by surgery. Most of these risks can be addressed by good surgical techniques and proper postoperative care. Patients should not use their shoulder and must keep the

elbow away from the side of the body for three months after surgery. Stress or tension on the repair can lead to failure of the sutures. Patients who underwent surgery also go to physical therapy to help with rehabilitation (Matsen III, 2005).

### 2.3.3 Cell Therapy

The healing process for tendon tears that are repaired using sutures is typically accompanied by fibrosis and scar tissue, making re-tear a higher possibility. A tendon that has undergone repair is thicker, fibrotic, and more prone to tensile stress than an uninjured tendon. Cell therapy is a method of preventing the formation of scar tissue and promoting regeneration of the injured tendon. Cell therapy can be done using mesenchymal stem cells (MSCs), embryonic stem cells (ESCs), tendon-derived cells, or dermal fibroblasts (Young, 2012).

MSCs are useful for tendon cell therapy because they can be used to regenerate connective tissues (Phinney & Prockop, 2007). Previous studies involving MSC therapy with tendons showed that these cells accelerated tendon healing and improved the biomechanical properties of the injured area (Chong, Ang, & Goh, 2007). Allogeneic MSCs can also be cryopreserved, which allows them to be available in high quantities (LeBlanc, 2003). ESCs are pluripotent cells that have a higher tendency to proliferate and can regenerate tendons more efficiently compared to MSCs (Beredjiklian *et al*., 2003). Studies conducted in the past that involved ESCs and tendon repair showed that utilizing these cells with repair techniques improved the size and architecture of the tendon, as well as the fiber patterns of the tissue (Watts, Yeager, Kopyov, & Nixon, 2011). Despite their regeneration capabilities, ESCs pose the risk of causing the formation of teratomas when introduced into the body (Young, 2012).

A study conducted by Bi *et al*. in 2007 led to the discovery of tendon stem/progenitor cells (TSPCs) (Bi, Ehirchiou, & Kilts, 2007). Because these cells are derived directly from the tendon, they are more likely to regenerate injured tendons by differentiating into the specific cells necessary for the healing process. A previous study by Cao *et al*. in 2002 utilized autologous tenocytes in tendon repair in chicken by harvesting these cells and reintroducing them into the same animal to promote healing for flexor digitorum profundus tendon defects. The utilization of these cells caused the repaired tendon to have 83% of normal tendon strength, while repairs that did not contain

tenocytes only had 9% of normal tendon strength (Cao *et al*., 2002). Despite the promise of tendon-derived cells for therapy, there is very little research done on these techniques. Multipotent dermal fibroblasts (DFbs) are commonly used in tissue engineering because they are easy to harvest and reprogram for specific purposes, meaning they can be induced to act in a similar way to tenocytes (Obaid & Connell, 2010). The disadvantage of using these cells is the potential for scar tissue to form in the tendon, which can compromise the biomechanical strength of the healed tendon (Young, 2012).

## 2.4 The Hook and Loop Design

The "hook and loop" design commonly known by the trademark name "Velcro," is a nature inspired fastener. George de Mestral, a Swiss engineer, created the hook and loop design after observing burdock burrs stick to his clothing and dog's fur. He discovered that the burr had rough hooks that wrapped around the loops of his clothing and dog's fur. This attachment method where patches of rough hooks are pressed together with soft loops has proven to be highly effective and is now used in various fields such as the clothing and space industries (Bonser & Vincent, 2007). The hook and loop design is also emerging in the medical field and has been used to create a 3D tissue scaffold by seeding cells onto various layers of hooks and loops then binding them together (Zhang, Montgomery, Davenport-Huyer, Korolj, & Radisic, 2015). The technology has also been developed for wound healing to aid in binding skin (Pierce, 1989). The hook and loop design has great potential for binding torn parts of the body like the rotator cuff. Using the hook and loop design for these repairs will increase the number of fixation points and surface area of the attachment site, therefore decreasing chances for re-tears after surgery (Lo & Burkhart, 2003).

## 2.5 Biocompatible Adhesives

Creating a device using the hook and loop design to improve rotator cuff tear repair will also require the use of biocompatible adhesives. Adhesives alone such as cyanoacrylate glue have been tested for tissue tear repair, but it was found that the glue-to-glue interface was the first area to fail under stress (Powell, Trail, & Noble, 1989). A device using the hook and loop design will eliminate this glue-to-glue interface

and allow for different adhesives to be used on the soft tissue tendon and hard tissue bone interfaces. There are a wide variety of adhesives on the market for medical purposes, but different applications require different properties. This project requires durable adhesives that are biocompatible, biodegradable, and can withstand wet environments. To make the bioengineered Velcro successful in reattaching the tendon to bone, the product needs two separate adhesives: one for soft tissue and one for hard tissue.

### 2.5.1 Adhesives for soft tissue

Collagen, fibrin, and gelatin are three components commonly used for soft tissue adhesives. Collagen-based adhesives adhere to wound sites by adsorbing blood and coagulation products. They have previously been used as surgical sutures, wound dressings, and hemostatic glue. Two collagen-based adhesives currently on the market are FloSeal and Proceed, both of which are made with bovine collagen and thrombin. Collagen-based adhesives have the advantage of being completely biodegradable because they are directly derived from a substance that is already present in the body. On the other hand, these adhesives have the tendency to swell with tissue compression, which can cause complications with the repair site (Duarte, Coelho, Bordado, Cidade, & Gil, 2012).

Fibrin adhesives consist of fibrinogen and thrombin. When combined, these two components crosslink in a way that mimics blood clotting. Fibrin adhesives are used for a variety of purposes, including cardiovascular surgery, neurosurgery, and cosmetic surgery. These adhesives are typically used in conjunction with sutures and staples due to their reduced biomechanical strength in wet conditions (Duarte *et al*., 2012). EVICEL Fibrin Sealant and TISSEEL Fibrin Sealant are used for hemostasis during surgery when standard surgical techniques are ineffective. Although fibrin adhesives are the most popular adhesives on the market and have the most possible applications, they come with a risk of infection because their components are obtained through human blood (Mo, Iwata, Matsuda, & Ikada, 2000).

Gelatin-based adhesives can be used for a variety of applications involving soft tissue, particularly for bonding tissue and repairing leaks. Gelatin cross-linked with calcium independent microbial transglutaminase (mTG) creates a gel that can bind with wet tissue and has a higher adhesive strength than fibrin adhesives. Tests conducted *in*

*vivo* using gelatin-mTG adhesive showed that the gel adhered to tissue in under five minutes and can serve as a hemostatic sealant without the use of sutures (Duarte *et al*., 2012). A study conducted by Mo *et al*. (2000) involved creating a gelatin adhesive using polysaccharides. The resulting gel formed three seconds faster and had almost double the bonding strength compared to a fibrin adhesive (Mo *et al*., 2000). Gelatin-based adhesives show promise for the medical world; however, the disadvantage associated with these adhesives is the lack of research and experience behind them (Duarte *et al*., 2012).

Cyanoacrylate based adhesives are strong, fast acting adhesives commonly used for wound closure. Vet bond is an example of a cyanoacrylate based soft tissue adhesive currently on the market and is used for wound closure in animals. According to the manufacturer, 3M, the glue is composed of N-butyl cyanoacrylate, Hydroquinone, and blue dye which is used for better visibility during application. The adhesive polymerizes within seconds of application. The disadvantage of this glue is that it is only approved for external use. A study conducted by Sabol *et al*. found similar wound tensile strength for sutured and glued wounds at 7 and 22 days in Sprague Dawley rats. However, the glued wounds showed increased granulation tissue formation (Sabol *et al*., 2010).

### 2.5.2 Adhesives for hard tissue

A magnesium-based bone adhesive can be used specifically for tendon-to-bone healing. The insertion site for tendon-to-bone interactions tends to heal poorly with injuries that involve detachment of the tendon. When analyzing the effect of using a magnesium-based bone adhesive to reattach the flexor tendon in dogs, it was found that the initial tensile strength of the repair was greater than that of a non-magnesium-based repair. After 21 days, however, biomechanical properties showed signs of decreasing, which can create potential problems during the healing process (Thomopoulus *et al*., 2009).

Cyanoacrylate adhesives are also commonly used in the medical and dental fields for procedures that involve working with hard tissues such as bone and teeth. In a study conducted by Neto *et al*. (2008), different types of cyanoacrylate adhesives were tested for biocompatibility using rats. The results of the study showed that alpha-cyanoacrylate

had the highest biocompatibility because it caused the least amount of irritation and inflammation in the rats compared to cyanoacrylate ester and n-butyl cyanoacrylate (Neto, Mello, Moretti, Robazza, & Pereira, 2008). Bone cement is also often used in orthopedic surgery for fixation purposes. Benthien *et al*. (2004) compared the effects of bone cement to cyanoacrylate glue using human fibroblasts and osteoblasts *in vitro*. Analysis of the bone cement showed that fibroblasts were able to grow around the cement without adhering to it, and there was a normal level of apoptosis. The cyanoacrylate glue caused a high rate of apoptosis in the study, showing that bone cement exceeds cyanoacrylate glue in terms of biocompatibility (Benthien, Russlies, & Behrens, 2004).

UV Glue is a type of hard tissue adhesive that cures with the application of UV light. The glue cures in approximately 90 seconds with 400-500 nm UV, which is much faster than the curing time of bone cement currently used by many surgeons (Endres *et al*., 2008). Endres *et al*. describes a new technique to utilize an amphiphilic bone bonding agent (similar to Dentin) as an interlayer between the hydrophobic bone cement (PMMA) and hydrophilic bone surface to create a stronger connection. PMMA cannot build adhesion forces with bone because of the difference in hydrophilicity. The bonding agent has hydrophilic hydroxyl and carboxyl functional groups and hydrophobic MMA monomers so it can adhere to both surfaces as a hybrid layer. The R-COOH groups bond chemically with the calcium ions in bone and the R-OH groups form a water-insoluble bond with amino groups. When UV light is applied, the MMA molecules crosslink and form a coating for bone cement to adhere to. Table 1 compares the bond strength of bonding agents. The amphiphilic bone bonding agent discussed by Endres *et al*. exhibits the highest bond strength.

*Table 1 Comparison of bone bonding agents (Endres et al., 2008)*

| nature of bonding agent | bonding agent | bonding partner 1 | bonding partner 2 | average bond strength [MPa] |
|---|---|---|---|---|
| amphiphilic bone bonding agent | self-made amphiphilic bone bonding agent | bovine bone | modified PMMA cement light- and selfcuring | 8,49 ± 1,72 |
| dentin bonding agents | Etch & Prime ® | porcine bone | Tetric® colour A2 (Vivadent) | 4,05 ± 1,53 |
| | Excite® | porcine bone | Tetric® colour A2 (Vivadent) | 2,96 ± 1,34 |
| | Clearfil New Bond | porcine bone | Tetric® colour A2 (Vivadent) | 8,00 ± 1,36 |
| | | porcine bone | porcine bone | 6,39 ± 2,05 |
| tissue adhesives | Histoacryl® | porcine bone | Tetric® colour A2 (Vivadent) | 5,22 ± 2,00 |
| | | porcine bone | porcine bone | 1,95 ± 0,49 |
| | Cyano Veneer® | porcine bone | Tetric® colour A2 (Vivadent) | 4,56 ± 0,76 |

The study also tested the bond strength in wet conditions over time which showed a small decrease from 8.1MPa to 7.5MPa over 42 days. Furthermore, the strength of a plate attached with the bonding agent and bone cement was compared to the strength of a plate attached with only bone cement. The sample with the bonding agent significantly outperformed the sample without the bonding agent with a strength of about 8.5 and 0.2 MPa respectively. In addition to bonding agents, commercial biocompatible UV glue such as Loctite and Masterbond can also be used (Endres *et al*., 2008).

A natural biocompatible adhesive is derived from barnacles. Barnacles are crustaceans with a strong mechanism for underwater adhesion. This adhesion system of barnacles is commonly known as cement and is created from a multi-protein complex (Kamino, 2013). The cement is fibrous, viscoelastic, and can have an elastic modulus of up to 1.2 GPa depending on the type of cement (Zheden, Klepal, Gorb, & Kovalev, 2015). The strength of the cement attachment is attributed to its insolubility in water, which gives it potential in biomedical applications. A visual representation of the attachment of a barnacle to a foreign substratum, or bedrock, is presented in Figure 8.

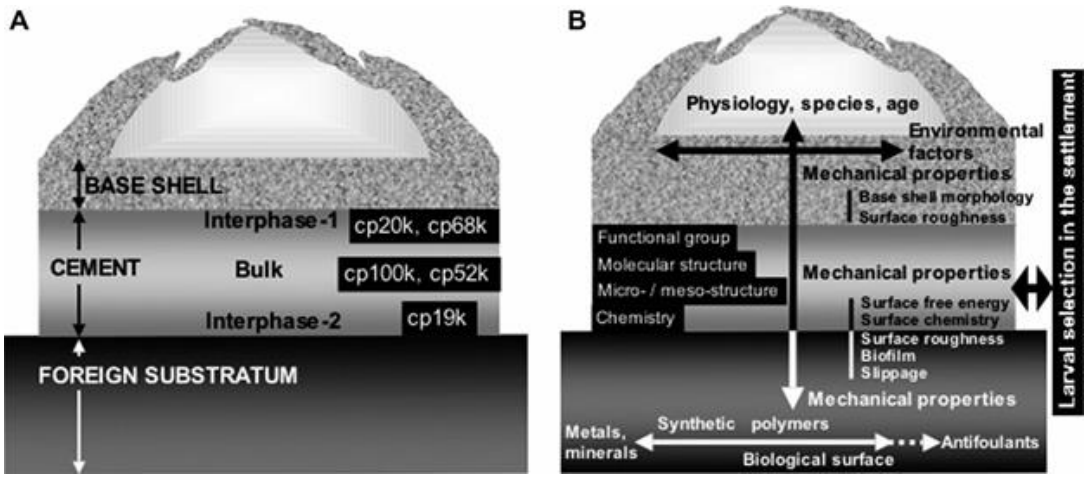



*Figure 8 Cross-sectional view of a barnacle attached to a foreign substratum (Kamino, 2013)*

As explained in Figure 8, the cement adhesive is made of Interphase-1, Bulk, and Interphase-2 sections. There are multiple types of barnacle adhesives; *Lepas anatifera* is one type of adhesives that is made of the elements Na, Mg, C, Cl, S, Al, Si, K, and Fe. Additionally, 90% of this adhesive is made up of proteins made from these elements (Jonker *et al*., 2015). The specific proteins are (cp) 100, cp68, cp52, cp20, and cp19 k (Kamino, 2013).

Mussels are known for their ability to attach to hard, wet surfaces by secreting adhesive proteins that have a high percentage of the amino acid 3,4-dihydroxy-L-phenylalanine (DOPA). Adhesives that contain DOPA show high adhesion strength; the largest force required to detach DOPA from a surface was recorded at approximately 800 pN (Waite, Anderson, Jewhurst, & Sun, 2005). A limitation that currently exists with many medical adhesives is the poor adhesive properties in wet environments, specifically bodily fluids. Several natural and synthetic adhesives have been created using DOPA to bypass this limitation (Lee, Lee, & Messersmith, 2007). Brubaker *et al*. created synthetic adhesive hydrogels using DOPA that were then implanted into mice. The adhesive showed minimal inflammation and the adhesive-tissue interface was secure for up to one year (Brubaker, Kissler, Wang, Kaufman, & Messersmith, 2010).

## 2.6 Manufacturing

Throughout the design process of a fastening system for rotator cuff tears, manufacturing methods must be considered. It is important to understand how to create a model with the ideal mechanical properties, what materials will best fit the application,

and what sterilization methods are appropriate for these materials for the desired purpose.

### 2.6.1 Rapid Prototyping

Rapid prototyping is being used increasingly in the design world to create inexpensive and accurate models that can be put through testing. Of late, 3D printing has come to the fore as a useful technology for rapid prototyping. More recently advances in materials and properties in 3D printed objects have also lead to the use of 3D printed parts in wide ranging applications such as the automotive, medical, and aerospace industries.

Fused Deposition Modeling (FDM) printing refers to the process by which heated thermoplastic is extruded through a tip to form a 3D object layer by layer (Griffey, 2014). FDM printing is known for strength and durability, but has limited resolution and creates parts with ridges from the layers of plastic due to the additive nature of the method. The resolution of a FDM printer can be improved by decreasing the layer resolution or the height of each layer. The Monoprice 3D printer available for this project uses FDM technology. The Monoprice printer is a dual extrusion printer, meaning it can print two different materials during one print. The Monoprice has a nozzle diameter of 0.44mm, layer resolution of +/- 0.10mm, a heated build plate, and has a build volume of 225 x 145 x 150 mm. The printer also uses Replicator G software to slice STL files and translate them into gcode, which can be read by the printer.

PolyJet 3D printing is a more recent advance in 3D printing. This technology uses a liquid photopolymer that can be cured using a UV light layer by layer to create a 3D part. PolyJet printing has a much higher resolution than FDM that allows the creation of finer structures. The photopolymer, however, is not as durable as thermoplastics printed from FDM machines and materials for PolyJet printers are much more limited than FDM (Ionita *et al*., 2014).

Stereolithography (Zheden *et al*.) is also a 3D printing method that uses UV light to cure liquid resin. In SLA printing the build tray is first dipped into a bath of resin then a layer is cured by a UV laser before the tray is dipped into the resin again. SLA printer lasers either use the mask-based or direct focused beam-writing methods to only cure the outline of the part. SLA parts have a high resolution, but have low strength, creep

performance, stiffness, environmental instability, and require extensive post processing after printing (Bártolo, 2011). Two printing methods with more ideal part properties have developed from SLA printing. Digital light processing (DLP) works similarly to SLA, but uses an arc lamp, with a liquid crystal display panel or a deformable mirror device to cure the resin resulting in a faster print and a shallower bath of resin. DLP parts have similar properties as SLA parts. Continuous Liquid Interface Production (CLIP) or carbon printing is an extremely new 3D printing method developed by Carbon 3D. CLIP parts have outstanding mechanical properties, resolution, and surface finish comparable to injection molding. CLIP parts are created by curing resin by a UV light projected through oxygen permeable glass. The unique difference in CLIP is that the part always remains in the liquid bath of resin eliminating the negative effects of building a part by layers. CLIP is also a much faster process than SLA. CLIP printing would be ideal for this project, but due to budget constraints it will not be possible to use a Carbon 3D printer.

Aside from finding the proper method of 3D printing rapid prototyping also requires the use of digital software to electronically model the part. Computer aided design software such as SolidWorks allow users to create a design from scratch and download the file into an STL file that can be converted to a printer. A limitation of SolidWorks for this application is the large number of intricate hook and loop hair-like structures that will have to be modeled. PhD Students at Massachusetts Institute of Technology have created software, Cillia, which can easily model thousands of hair-like structures with a resolution up to 100 microns. The software allows the user to specify the angle, height, thickness, and density of the hairs and can place hairs on curved surfaces using the triangles created within an STL file (Ou *et al*., 2016). This software is not yet available on the market, but should be considered for the future of this project.

### 2.6.2 Materials

Several different characteristics of a material must be considered before being selected for a design. For this project, it is important for a material to be biocompatible, biodegradable, non-toxic, and flexible, as well as have a high tensile strength and good manufacturing properties. The chart below shows the properties of various biodegradable materials.

*Table 2 Mechanical Properties of Biodegradable Materials (Jamshidian, Tehrany, Imran, Jacquot, & Desobry, 2010)*

| | $T_g$(°C) | Tm (°C) | Tensile strength (MPa) | Tensile modulus (Mpa) | Elongation at break (%) |
|---|---|---|---|---|---|
| LDPE | −100 | 98 to 115 | 8 to 20 | 300 to 500 | 100 to 1000 |
| PCL | −60 | 59 to 64 | 4 to 28 | 390 to 470 | 700 to 1000 |
| Starch | – | 110 to 115 | 35 to 80 | 600 to 850 | 580 to 820 |
| PBAT | −30 | 110 to 115 | 34 to 40 | – | 500 to 800 |
| PTMAT | −30 | 108 to 110 | 22 | 100 | 700 |
| PS | 70 to 115 | 100 | 34 to 50 | 2300 to 3300 | 1.2 to 2.5 |
| Cellulose | – | – | 55 to 120 | 3000 to 5000 | 18 to 55 |
| PLA | 40 to 70 | 130 to 180 | 48 to 53 | 3500 | 30 to 240 |
| PHB | 0 | 140 to 180 | 25 to 40 | 3500 | 5 to 8 |
| PHA | −30 to 10 | 70 to 170 | 18 to 24 | 700 to 1800 | 3 to 25 |
| PHB-PHV | 0 to 30 | 100 to 190 | 25 to 30 | 600 to 1000 | 7 to 15 |
| PVA | 58 to 85 | 180 to 230 | 28 to 46 | 380 to 530 | – |
| Cellulose acetate | – | 115 | 10 | 460 | 13 to 15 |
| PET | 73 to 80 | 245 to 265 | 48 to 72 | 200 to 4100 | 30 to 300 |
| PGA | 35 to 40 | 225 to 230 | 890 | 7000 to 8400 | 30 |
| PEA | −20 | 125 to 190 | 25 | 180 to 220 | 400 |

Although all of these materials are biodegradable, some materials are more qualified for this project due to additional properties.

### *Polylactic Acid: PLA*

Polylactide (Vepari & Kaplan), a commonly used polymer in medical implants, is created by the synthesis of lactic acid (Yang, Wu, Yang, & Yang, 2008). PLA is considered to be an environmentally friendly material because it is derived from renewable resources (Lasprilla, Martinez, Lunelli, Jardini, & Maciel Filho, 2012). PLA degrades in the body through hydrolysis then is metabolized by cells (Jamshidian *et al.*, 2010). In a previous study conducted by de Tayrac and coworkers on the degradation rate and biocompatibility of PLA, it was found that the molecular weight of PLA scaffolds begins to decrease at 6 weeks due to polymer chain scission. Despite the loss of molecular weight, however, the study also showed that the tensile strength of the scaffold started to decrease after 8 months. Additionally, while gamma-ray sterilization made the

PLA scaffold more sensitive to degradation, ETO sterilization did not have an effect (de Tayrac *et al*., 2008).

As seen on the chart, PLA has a high mechanical strength of 48-53 MPa and a melting point above body temperature at 130-180 °C. The disadvantages of PLA it is relatively stiff due to the tensile modulus of 3500 MPa and is not highly flexible due to the low elongation at break value. PLA also has a low toxicity and is considered to be visually appealing compared to other materials (Jamshidian *et al*., 2010). Any inflammation caused by PLA implants only targets local tissues, so the reaction is not systemic. The severity of inflammation reactions depend on the rate of degradation of the PLA implant; an implant with a high degradation rate causes more adverse effects because there is an accumulation of degradation products in the surrounding tissue that the body then has to eliminate (Ramot, Zada, Domb, & Nyska, 2016). PLA is available in the Monoprice printer but not the PolyJet printer.

### *Polycaprolactone: PCL*

Poly (ε-caprolactone) (PCL) is also used in medical implants, but has slightly different properties than PLA. Unlike PLA, PCL has higher flexibility, due to its high elongation at break value, and is much less stiff when compared to PLA. PCL is also nontoxic when placed within the body (Kai, Hirota, Hua, & Inoue, 2008). PCL was not available for the Monoprice printer or the PolyJet Printer. A major drawback from PCL is its lower tensile strength of 4-28 MPa. The tensile strength of the material for this application is one of the most important properties to ensure the device can hold the ruptured tendon to the humeral head. The combination of PLA and PCL would create a material with ideal properties for this project, but these two materials do not adhere well together (Gardella, Calabrese, & Monticelli, 2014).

### *Polyglycolic Acid: PGA*

Polyglycolic acid (PGA) is a commonly used biocompatible material used to make sutures (Gentile, Chiono, Carmagnola, & Hatton, 2014). Table 1 shows that PGA has an extremely high tensile strength. However, PGA is extremely brittle and less flexible than PLA and cannot be printed from the Monoprice 3D printer. PGA also degrades quicker than PLA, but a hybrid of the two plastics, PLGA, has been created. The degradation of PLGA can be controlled easier and has the ideal mechanical

properties from each material (Gentile *et al*., 2014). Although PLGA has beneficial properties, it also cannot be extruded from the Monoprice 3D printer.

### *Silk*

Silk, which is composed of silk fibroin and globular protein, is a natural biomaterial that has considerable mechanical strength (Melke, Midha, Ghogh, Ito, & Hofmann, 2016). Silk is organized in β-sheet structures that allow for tight packing of the proteins (Vepari & Kaplan, 2007). There are a variety of organisms that have the ability to produce silk, including the *Bombyx mori* insect, otherwise known as the silkworm. The majority of studies on silk as a biomaterial have utilized *B. mori* silk because it is the most common type of silk used in textiles (Melke *et al*., 2016). Along with its mechanical properties, which are shown in Table 3, silk is also biocompatible, has controlled degradability, and is morphologically flexible.

*Table 3 The mechanical properties of different varieties of silk (Vepari & Kaplan, 2007).*

| Source of Biomaterial | Modulus (GPa) | UTS (MPa) | Strain (%) at break |
|---|---|---|---|
| *B. mori* silk (with sericin) | 5–12 | 500 | 19 |
| *B. mori* silk (without sericin) | 15–17 | 610–690 | 4–16 |
| *B. mori* silk | 10 | 740 | 20 |
| *N. clavipes* silk | 11–13 | 875–972 | 17–18 |
| Collagen | 0.0018–0.046 | 0.9–7.4 | 24–68 |
| Crosslinked collagen | 0.4–0.8 | 47–72 | 12–16 |
| Polylactic acid | 1.2–3.0 | 28–50 | 2–6 |

There are a variety of ways to process silk scaffolds, including electrospinning, creating hydrogels, and 3D printing. Electrospinning produces silk fibers that can be layered to form scaffolds. Hydrogels are ideal for cell delivery and tissue engineering because they can be injected into the body. 3D printing using silk allows for the creation of scaffolds that have customizable properties and internal architecture. Silk scaffolds derived from aqueous solutions have the ability to degrade completely between 2-6 months (Melke *et al*., 2016).

### *MED610*

MED610 is a biocompatible photopolymer that is ideal for prolonged contact with the skin. This material has been approved for cytotoxicity, genotoxicity, delayed type hypersensitivity, irritation, and UPS Class VI Plastic. MED610 is rigid with a modulus of elasticity of 2000-3000MPa, a tensile strength of 50-65MPa, and is not degradable. Additionally, this material is available to the team and is compatible with the high resolution PolyJet 3D Printer (Forcast3D).

## 2.6.3 Sterilization

The device created must eventually be implanted into the body, so it is crucial to sterilize the device to destroy any bacteria that may cause harm to a patient. Most sterilization methods use steam, radiation, chemicals, or heat (Athanasiou, Niederauer, & Agrawal, 1996). It is important to consider the material when choosing a sterilization technique because all methods are not compatible with certain materials. This section will focus on PLA, as it is the material with the most advantages for this project. The most effective sterilization techniques for PLA are ethylene oxide (EO), γ-radiation, ultraviolet (Ramot *et al*.) radiation, and $NO_2$ (Valente *et al*., 2016). EO sterilization is cost effective and can be performed at a low temperature, but can cause physical morphology, change the toxicity, and leave gas residue on the PLA. γ-radiation can penetrate further into a material without leaving harmful gas residues, but can alter mechanical properties and the color of PLA. UV radiation is low cost and has high antimicrobial properties, but can alter the molecular weight and chemical properties of PLA (Valente *et al*., 2016). $NO_2$ sterilization can be performed at room temperature, leaves no carcinogenic or toxic, residues on the material, is non-flammable, and takes approximately three hours to perform (Goulet, 2015).

It is also important to consider FDA standards for sterilization. The FDA has categorized sterilization methods into two established categories and a novel category. The FDA has already approved established methods, while novel methods require additional approval. EO and γ-radiation are considered established methods, while UV radiation is a novel method (FDA, 2016). $NO_2$ sterilization was recently approved 501(k) clearance from the FDA categorizing it as an established method. Each of these

sterilization methods has advantages and disadvantages that must be considered when testing the final device.

# Chapter 3: Project Strategy

## 3.1 Initial Client Statement

At the start of the project, the team received the following client statement:

*"Currently, tendon tears in the shoulder are typically repaired with suture anchors placed in the bone. Sutures are then passed through the torn tendon and tied down to the bone. This created a 'spot welding' approach. The hook and loop structure of the commercially available 'velcro' adhesive is the basis for the project; in this case to create a biological absorbable solution. This project is therefore intended to adopt this technology to develop an easy 'fastener' system for use in various surgical applications. You are expected to create at least one functioning prototype for at least one of the many possible surgical applications for the device. At the end of the project, you should be able to demonstrate the utility of the device in the application area(s) chosen at the beginning of the project. Ideally, you should demonstrate the use of the device in an appropriate 'model system.' Sufficient numbers of prototypes should be tested (for statistical significance) to calculate the stress-strain curve and 'strain-to-failure.' The students should follow the engineering standards guidelines in the design process and the analysis of the materials and the device with particular focus on the materials property and FDA regulations for an implantable device.*

*Research/Design Considerations:*

1. *Use of a commercially available 3D printer for developing the prototype(s)*
2. *Design multiple 'Velcro' patterns*
3. *Use appropriate biomaterial for printing the prototype*
4. *Make stress/strain measurements to determine the maximum forces the prototypes can withstand*
5. *Incorporate appropriate 'Engineering standards' in your design process*

6. *Use appropriate statistical method(s) for data analysis*
7. *Demonstrate the utility of your prototype using an appropriate model system"*

Based on this statement, the primary goal of the project is to develop a fastener system using the hook and loop technology of Velcro for various surgical techniques. Reviewing the client statement allowed the team to create an outline of research topics that were necessary for the design process. The team also assessed which concepts were significant to the product and created a list of objectives as a guide for the remainder of the project.

## 3.2 Design Requirements

The design requirements for this project include the objectives, functions, constraints, and specifications. Design requirements play an important role in shaping the design process and creating guidelines for the team. This chapter will discuss the details of these elements and how the team decided which aspects were significant to the project.

### 3.2.1 Objectives

The team created a list of objectives based on the client statement that would satisfy the wants of the client while also making the device functional. The objectives are listed in the objective tree in Figure 9.

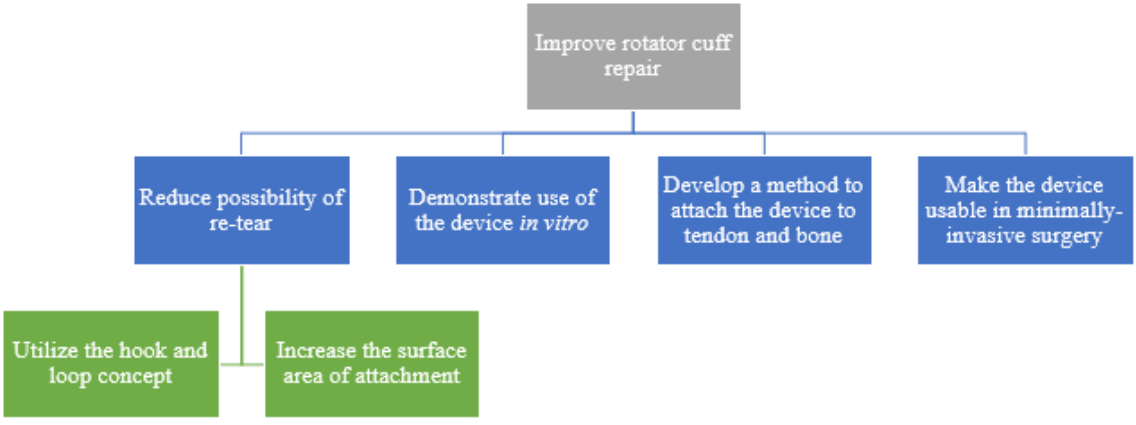



*Figure 9 Objective tree*

Figure 9 shows that the main objective for this project is to improve rotator cuff repair. Several objectives were created to guide the team in achieving this goal, which include reducing re-tear, demonstrating use of the device *in vitro*, developing a method to attach the device, and making the device usable in minimally invasive surgeries. To reduce re-tear, the team created two additional objectives, which include utilizing the hook and loop concept and increasing the surface area of attachment.

### 3.2.2 Constraints

To supplement the objectives, the team created a list of constraints to set limitations and guidelines for the project. The constraints are divided into two categories: device-specific constraints and project-specific constraints. Table 4 lists the constraints established by the team.

*Table 4 Device- and project- specific constraints*

| **Device-specific** | **Project-specific** |
|---|---|
| ● *Safety*: the device must be biocompatible and non-toxic so the patient is not harmed during or after the surgery. Biocompatibility is also necessary to ensure that the product can pass through clinical trials and become marketable.<br>● *Size*: the device must be able to fit within the rotator cuff without causing discomfort to the patient while also having a large enough surface area to make attachment successful.<br>● *Equipment*: the team is limited to the supplies and machinery in the laboratory designated for the project. | ● *Time*: as part of the MQP, the final design and prototype must be completed by the end of the academic year, which is April 2017.<br>● *Budget*: according to the MQP guidelines, the team has a budget of $1000. |

### 3.2.3 Functions

The team created a list of functions for the device that would satisfy the objectives while staying within the limitations of the constraints. Deciding on the functions for the device allowed the team to consider design specifications that would make the functions feasible. The device must:

- Ensure reattachment of the torn tendon to soft tissue and/or hard tissue
- Promote proper tendon healing
- Degrade as the tear heals

The primary goals for this project are to improve rotator cuff tears by creating a device that will successfully reattach the tendon to either the humeral head or the remaining tendon, depending on the nature of the tear. The device must promote proper tendon healing by establishing a biological connection between the two pieces of tissue; the device should not hinder the healing process by preventing the tear from fully closing. To guarantee that this connection is established, the device must degrade as the tear heals.

### 3.2.4 Specifications

The team created a list of specifications to quantify the functions established for the device. Specifications give the team direction for choosing appropriate materials, manufacturing processes, and testing methods. The specifications for this device include:

- *Strength:* the device must be able to withstand >398 N of shear force and 200N of tensile force. Mason-Allen sutures, which are a common type of suture used during surgical repair, can withstand a force of approximately 398 N (Baums *et al*., 2010). The project sponsor, Dr. Robert Meislin, an orthopedic surgeon, stated that 200N was an appropriate threshold for tensile strength for rotator cuff surgeries. To achieve the goal of improving rotator cuff repair, the device must withstand forces larger than 398 N in shear force and 200N in tensile force(Baums *et al*., 2010). This will also reduce the possibility of re-tear. This concept is discussed further in section 4.2.
- *Resorbability:* the device must be able to retain its strength for at least 6 months and fully degrade by approximately one year. It takes 10 weeks for the tendon to begin the maturation phase of healing, and this phase can last for a year. Having a

one year lifespan for the device gives the tendon enough time to completely reattach to the appropriate tissue.

- *Dimensions*: the device should not exceed the width of the supraspinatus tendon, which is approximately 25 mm (Ruotolo, Fow, & Nottage, 2004). If the device exceeds this size, it could cause discomfort to the patient and create complications for the surgeon. Additionally, the device should not exceed to promote tendon healing. If the device exceeds this thickness, the tendon will not reattach to the bone and healing time will be significantly reduced.

## 3.3 Revised Client Statement

After the team discussed the project with the client and established a better understanding of the primary objectives for the device, a revised client statement was created that highlighted the goal for this project:

> "Develop a device for rotator cuff repair that decreases the risk of re-tear and promotes tendon reattachment by increasing the surface area of attachment."

With this revised client statement, the team hypothesized that by increasing the overall number of attachment points at the repair site, the likelihood of post-surgery re-tear would decrease. A larger number of attachment points creates a larger surface area of attachment, therefore decreasing the amount of stress on the tendon.

## 3.4 Management Approach

The duration of this project, based on the nature of the MQP, is from August-April 2017. The team created a Gantt chart, shown in Table 5, to schedule each aspect of the project accordingly and ensure that it is completed by the end of the academic year.

*Table 5 Gantt chart*

| **Task** | **A-term (8/25/16-10/13/16)** | **B-term (10/25/16-12/15/16)** | **C-term (1/12/17-3/3/17)** | **D-term (3/13/17-5/2/17)** |
|---|---|---|---|---|
| Research | | | | |
| Writing | | | | |
| Establishing objectives and constraints | | | | |
| Preliminary designs | | | | |
| Material Selection | | | | |
| Prototype fabrication | | | | |
| Finalize testing methods | | | | |
| Finalization of designs | | | | |
| Submit patent application | | | | |
| Design testing | | | | |
| Adhesive testing | | | | |
| Data analysis | | | | |
| Final design selection | | | | |
| Prototype finalization | | | | |
| Present at bioengineering conference | | | | |
| Report editing/finalization | | | | |
| Presentation preparation | | | | |

# Chapter 4: Design Process

## 4.1 Needs Analysis

To effectively prioritize the goals and objectives, the team has determined two categories: "needs" and "wants." A need item is necessary for the success of the device. A want item is beneficial to the device but is not necessary and may not be possible given the constraints. The objectives were analyzed in the decision matrix in Table 6.

*Table 6 Decision Matrix for Objectives*

| Objectives | Increase surface area of attachment | Utilize hook and loop concept | Reduce re-tear | Develop an attachment method for tendon and bone | Demonstrate device use *in vitro* | Make device usable in minimally-invasive surgeries | Total |
|---|---|---|---|---|---|---|---|
| Increase surface area of attachment | **X** | 1 | 0 | 1 | 0.5 | 1 | 3.5 |
| Utilize hook and loop concept | 0 | **X** | 0 | 0 | 0 | 0.5 | 0.5 |
| Reduce re-tear | 1 | 1 | **X** | 1 | 0.5 | 1 | 4.5 |
| Develop an attachment method for tendon and bone | 0 | 1 | 0 | **X** | 0.5 | 1 | 2.5 |
| Demonstrate device use *in vitro* | 0.5 | 1 | 0.5 | 0.5 | **X** | 1 | 3.5 |
| Make device usable in minimally-invasive surgeries | 0 | 0.5 | 0 | 0 | 0 | **X** | 0.5 |

From this matrix, the team determined the needs and wants for the device are as follows:
Needs:

- Reduce re-tear by ensuring that the device can withstand >398 N in shear force and >200N in tensile force, as specified in section 3.2.4
- Increase surface area of attachment by creating a device with >8 attachment points, which is the largest number of attachment points for sutures that the team has found in research (Mazzocca, Millett, Guanche, Santangelo, & Arciero, 2005)
- Demonstrate device use *in vitro*

These objectives were ranked the highest from the decision matrix and deemed the most important. The team will prioritize these specific objectives when designing and prototyping devices.
Wants:

- Develop an attachment method for tendon and bone
- Utilize hook and loop concept
- Make device usable in minimally invasive surgery

These objectives were ranked the lowest from the decision matrix because they are not as important to the end result as the other objectives. The team hopes to incorporate the wants into the final design, but will not prioritize them at the cost of more important needs.

## 4.2 Conceptual Design

When narrowing down the concept of the design, the feasibility of each aspect was considered. Multiple comparisons were done to make decisions on how the team's design should come together. Ideally, the material of the design needs to be biocompatible, non-toxic, and bioresorbable to be used in the body. The material should degrade after at least one year to be certain that the tendon has formed a biological attachment to either the humeral head or damaged tendon. The material needs to have a high strength greater than 398 N in shear force and greater than 200 N in tensile force to

ensure reattachment of the tendon and prevent the device from failing after surgery as well as surpass the strength of current repair methods. Because of the wet environment of the body, the device should be able to maintain its strength within these conditions. Additionally, the material should be flexible to properly fit to the tendon and humeral head and have a similar stiffness as an intact rotator cuff tendon in the range of 108.3 +/- 16.9 (McKeown, Beattie, Murrell, & Lam, 2016). Table 7 shows the process followed to decide what material to use. The advantages and disadvantages of each will be considered when deciding on the materials.

*Table 7 Advantages and disadvantages of materials (all information cited in Chapter 2)*

| **Material** | **Advantages** | **Disadvantages** |
|---|---|---|
| **PLA** | -Maintains its tensile strength up to 8 months in the body<br>-Degradation time= >1 year<br>-Low toxicity<br>-High mechanical strength (48-53 MPa)<br>-Biocompatible | -Stiffness (tensile modulus is 3500 MPa and the elongation at break is 30-240%) |
| **PCL** | -Flexible (tensile modulus is 390-470 MPa and elongation at break is 700-1000%)<br>-Nontoxic<br>-Biocompatible<br>-Degradation time= 1-2 years | -Low tensile strength (4-28 MPa) |
| **PGA** | -Biocompatible<br>-High tensile strength (890 MPa) | -Brittle (tensile modulus is 7000-8400 MPa and elongation at break is 30%)<br>-Degradation time= 2-3 months |
| **Silk** | -High tensile strength (between 500-740 GPa for *B. mori* silk)<br>-Morphologic flexibility<br>-Biocompatible<br>-Modifiable degradation time based on silk fibroin protein concentration | -Not easily accessible |
| **MED610** | -High tensile strength (50-65MPa)<br>-Biocompatible<br>-Available on PolyJet printer | -Rigid (elastic modulus =2000-3000MPa)<br>-Not degradable |

The next design considerations are the hard and soft tissue adhesives to be used in the product. The adhesive materials must have the same requirements as the design material. Similar advantages and disadvantages charts were created to decide the most feasible option for each adhesive. Tables 8 and 9 show the advantages and disadvantages of soft and hard tissue, respectively.

*Table 8 Advantages and disadvantages of soft tissue adhesives (all information cited in Chapter 2)*

| Soft Tissue Adhesive | Advantages | Disadvantages |
|---|---|---|
| **Collagen based** | Completely degradable | Tendency to swell with tissue compression |
| **Fibrin** | Most popular adhesive on the market | Low strength in wet conditions |
| **Gelatin** | Can adhere to tissue in under 5 minutes | Still in early developmental stages |
| **Cyanoacrylate based** | High strength<br>Commercially available | Not approved for *use in vivo* |

*Table 9 Advantages and disadvantages of hard tissue adhesives (all information cited in Chapter 2)*

| Hard Tissue Adhesive | Advantages | Disadvantages |
|---|---|---|
| **Magnesium based** | Used in tendon-to-bone healing already | Biomechanical properties decrease over time |
| **Cyanoacrylate** | Commonly used with bone and teeth | Causes high rate of apoptosis |
| **Bone Cement** | Biocompatible | Cement may loosen over time |
| **UV Glue** | Biocompatible and short curing time | Required specialized equipment |
| **Barnacle Adhesive** | Strongest biological adhesive that can withstand wet environments | Not available on the market |

The concept map that the team followed for research is shown in Figure 10.

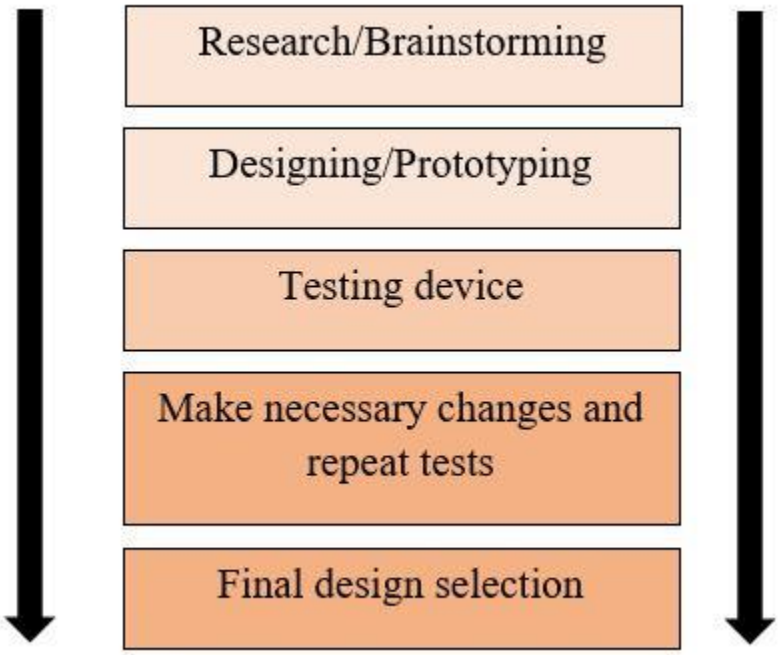



*Figure 10 Concept Map*

Testing the design prototypes and adhesives alone is essential to understanding the limits of each component separately before they are combined. The ultimate strength, elongation, and stiffness requirements for the fastening device and the ultimate strength of the adhesive were determined by researching the mechanical properties of the current repair methods on the market.

Appendix A shows the ultimate shear strength, cyclic elongation, stiffness, and failure points of various repair methods. The tests summarized in Appendix A were performed on force measurement systems where the humerus was attached to one end of the testing device and distal end of the tendon was attached to the other end. Based on the information in Appendix A, the Mason-Allen double row sutures were able to withstand the most shear force at 398 N. This value of 398 N was set as the minimum requirement for shear testing of the device. Additionally, 200 N was set as the minimum requirement for tensile testing based on recommendations from the project sponsor, Dr. Robert Meislin, MD of New York University.

In addition to considering the results summarized in Appendix A, the testing methods for this project were based on the protocol outlined in the reports. Creating a testing method similar to the research on current repair methods allowed the team to easily compare results collected with the values in the tables.

## 4.3 Alternative Designs

In addition to the hook and loop variations of Velcro, there are other types of fastening systems that can be utilized. This section will discuss several hook and loop models, rod-style attachment points, and barbed fixation points.

### 4.3.1 Hooks and Loops

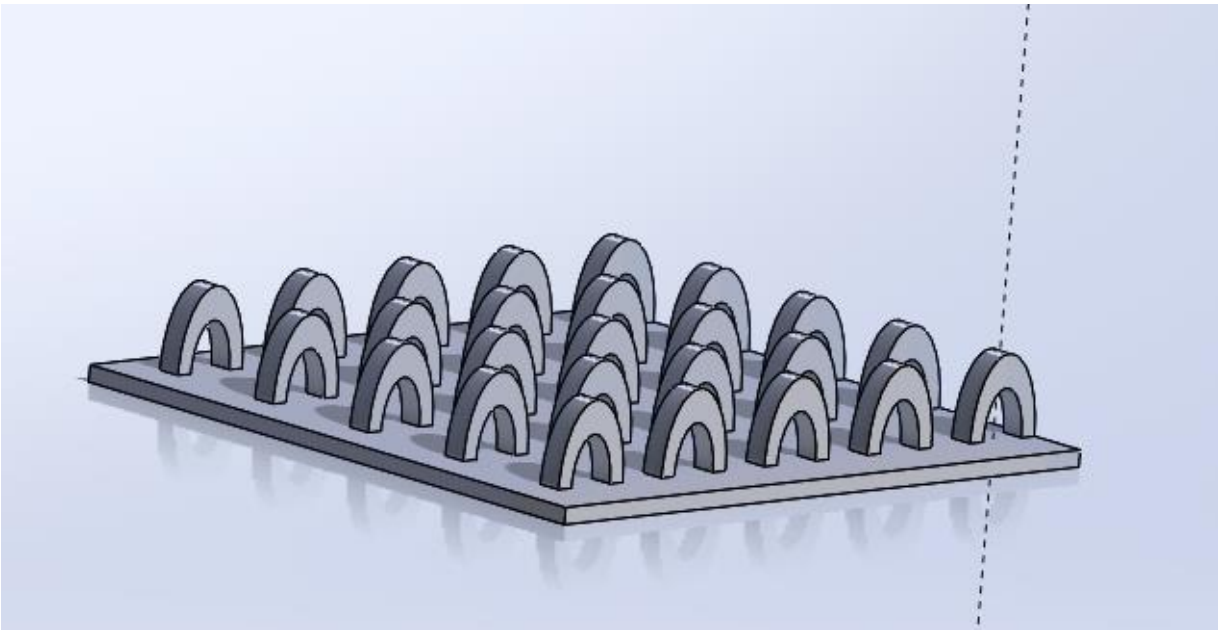
The hook and loop concept is the idea that originated from the initial client statement and served as the foundation for further conceptual designs. The idea of a hook and loop device was inspired by commercial Velcro. This design idea involves two panels: one panel has a set of hooks and the other side has a set of loops. When the two panels are pressed together, they attach because the hooks are threaded through the loops. To repair a rotator cuff tear, one of the panels would be attached to the end of the supraspinatus tendon and the other panel would be attached to either the humeral head or the damaged tendon, depending on the nature of the tear. Soft tissue and hard tissue adhesives would be utilized to attach the panels to the appropriate areas. Utilizing hooks and loops adds more attachment points to the repair site, which therefore minimizes the amount of stress put on the tendon. The device would degrade as the tear heals to ensure that a biological attachment is re-established.

Tables 10 and 11 show the CAD models and brief descriptions of the loop designs.

*Table 10 Example and description of the thin loop design*

<table>
<tr><td colspan="2">Design: Thin, flexible loops<br>  <br>(Photo: Thomas Northcut)</td></tr>
<tr><td colspan="2">Description:<br>This model involves many hair-like loops that can freely attach to hooks. The loops are made from a flexible material that allows multiple loops to attach to one hook.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>Flexible loops have a greater resistance to snapping off.</li><li>Thin loops allow for a higher concentration of attachment points in one area</li><li>The thin loops do not require extensive force to attach to hooks.</li><li>The flexible hooks allow for a better biological attachment by reducing the amount of overall thickness of the design.</li><li>The hook and loop design can be easily pulled apart and reattached.</li></ul></td><td><ul><li>These loops cannot be manufactured with a biocompatible and biodegradable material to the scale and precision needed.</li></ul></td></tr>
</table>

*Table 11 CAD model and description of the thick loop design*

<table>
<tr><td colspan="2">Design: Rigid loops<br>  </td></tr>
<tr><td colspan="2">Description:<br>This model involves more structured loops made from a rigid material. Each loop attaches to one hook.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>The one-to-one hook to loop attachment creates a tight snap fit.</li><li>The hook and loop design can be easily pulled apart and reattached.</li></ul></td><td><ul><li>When 3D printed, the rigid loops snap off easily.</li><li>The 3D printers available for this project do not have a high enough resolution to print clean loops.</li><li>The rigid loops are difficult to align with the hooks.</li><li>The rigid loops are larger and therefore do not have as many attachment points.</li></ul></td></tr>
</table>

Tables 12-14 show the CAD models and brief descriptions of the hook designs.

*Table 12 CAD model and description of the loose hook design*

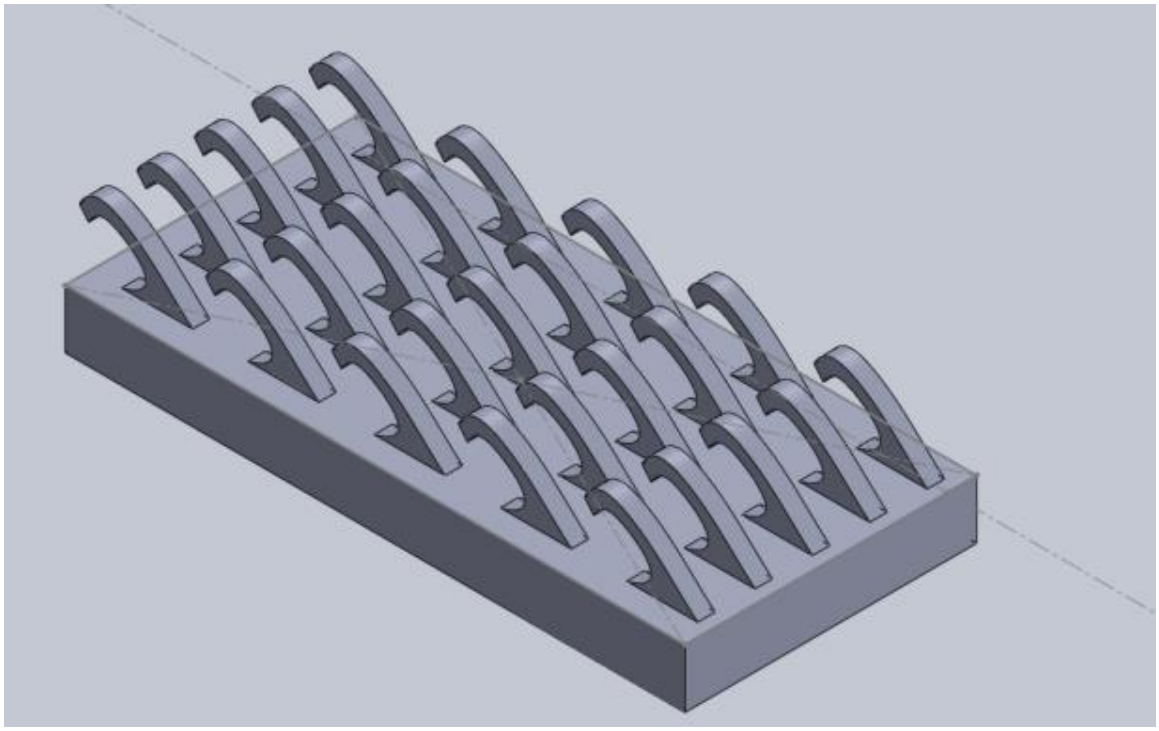
<table>
<tr><td colspan="2">Design: Loose hooks<br>  </td></tr>
<tr><td colspan="2">Description:<br>These hooks are designed to be used with thin, flexible loops, and are designed so multiple loops can attach to each hook.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>The hooks have a larger base because they are designed to attach to multiple flexible loops, preventing the hooks from snapping off as easily.</li><li>The hook and loop design can be easily pulled apart and reattached.</li></ul></td><td><ul><li>Flexible loops cannot be created with the available machinery and materials so the loose hooks do not have an interlocking counterpart.</li><li>The hooks snap off easily when 3D printed.</li></ul></td></tr>
</table>

*Table 13 CAD model and description of the tight hook design*

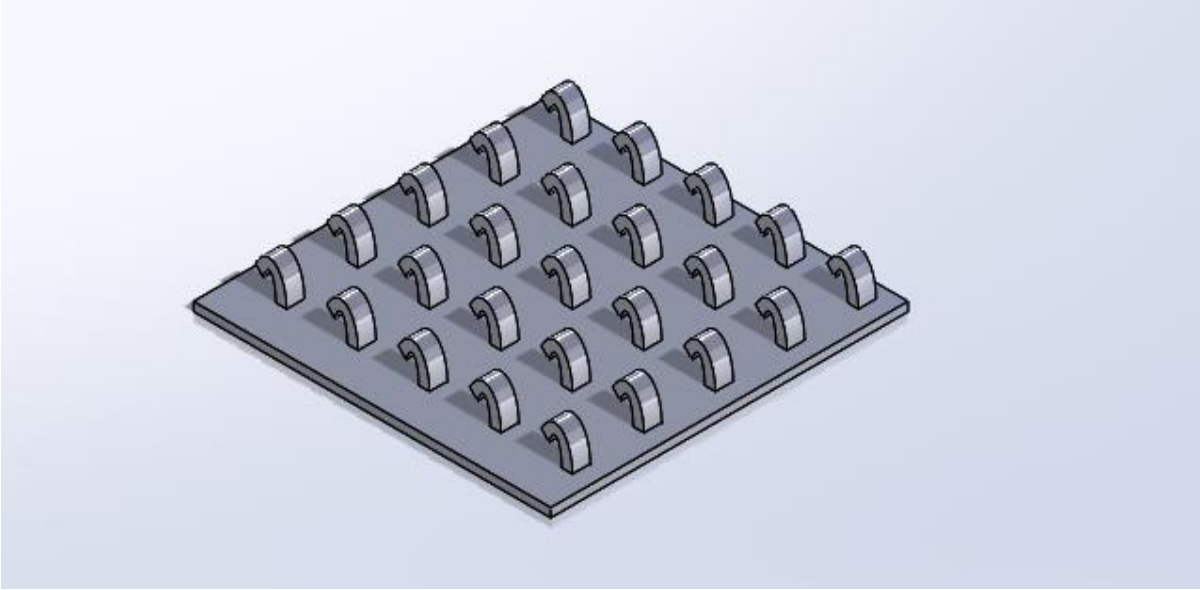
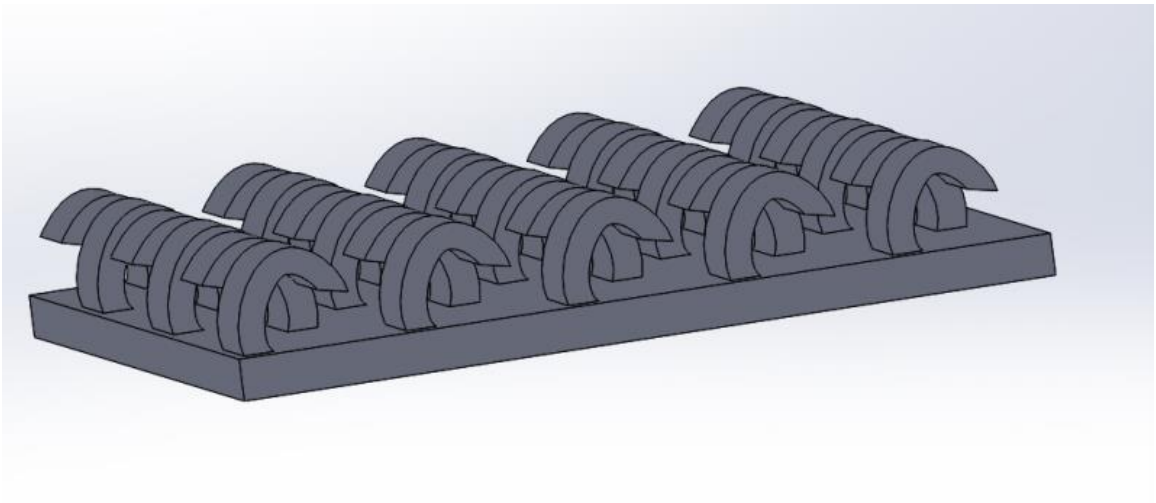
<table>
<tr><td colspan="2">Design: Tight hooks<br>  </td></tr>
<tr><td colspan="2">Description:<br>These hooks are meant to be used with rigid loops, and are designed so one loop will attach to each hook.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>Tighter hooks secure a strong bond with the loops to prevent detachment.</li><li>Feasible to print.</li><li>The hook and loop design can be easily pulled apart and reattached.</li></ul></td><td><ul><li>Must thread loops through hooks which is difficult to do instead of pressing the two pieces together.</li><li>The hooks snap off easily when 3D printed.</li></ul></td></tr>
</table>

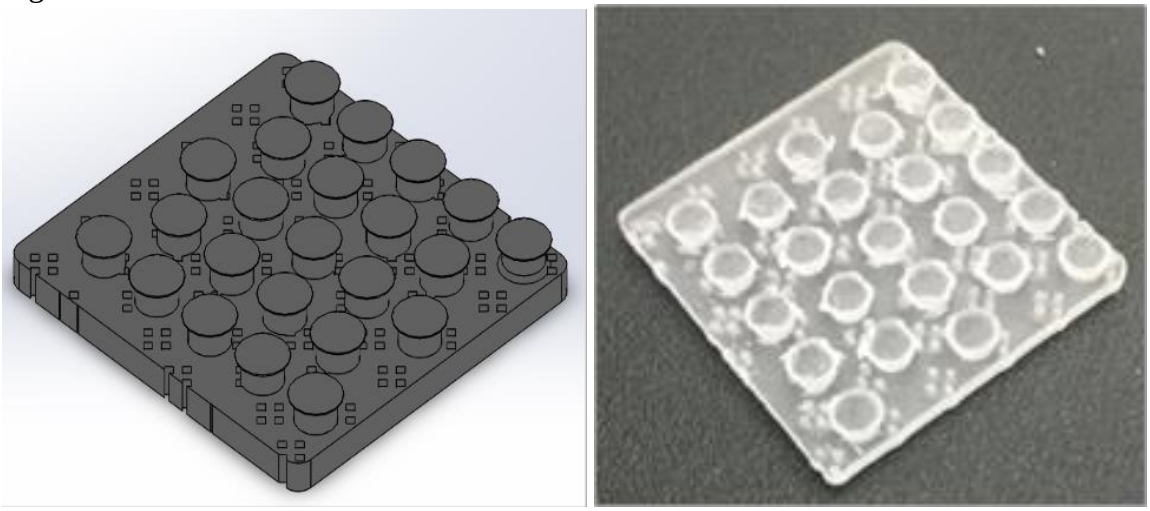
*Table 14 CAD model and description of the alternating hook design*

<table>
<tr><td colspan="2">Design: Alternating hooks<br>  </td></tr>
<tr><td colspan="2">Description:<br>These hooks are designed to be used with the thin, flexible loops. The hooks are placed in alternative directions.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>The multi directional hooks allow for shear strength in both directions.</li><li>The alternating hooks allow for twice the attachment points.</li></ul></td><td><ul><li>The thin, flexible loops that are meant to attach to this design are not feasible to 3D print with the available machinery and materials.</li></ul></td></tr>
</table>

### 4.3.2 Rods

The rod-shaped design is an alternative type of attachment method similar to the hook and loop design. In this design, both pieces have rods that connect by attaching through the space in between the rods in an alternating pattern. Table 15 shows the rod design as well as its advantages and disadvantages.

*Table 15 CAD model and description of the thick rod design*

<table>
<tr><td colspan="2">Design: Rods<br>  </td></tr>
<tr><td colspan="2">Description:<br>The attachment points in this model are rods with a thick cylindrical base and a semi-spherical head. This model involves two pieces of rod attachment points that connect through the spaces in between the rods.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>The lip on the top of the attachment points prevents the rods from pulling apart.</li><li>This design is strong in shear force because the rods push against each other.</li></ul></td><td><ul><li>The rods may break off or loosen over time after multiple attachments.</li><li>The rods must be aligned correctly for maximum strength.</li><li>Difficult to attach</li></ul></td></tr>
</table>

### 4.3.3 Barbed clamp

Going beyond the concept of Velcro, the idea of utilizing a barbed clamp to attach the device to the tendon was also considered. These structures were influenced by a honey bee's barbed stinger; when the bee inserts the stinger into the skin, the barbs

prevent it from being removed. Having a large concentration of fixation points also increases the surface area of attachment, which lowers the amount of stress on the tendon. However, this method is similar to sutures in that the attachment points must puncture the tendon in order to establish the connection. Two pieces of the barbed attachment points would puncture the tendon and clamp together through insertion points embedded in the base. The tendon would sit in between the two pieces and the barbed attachment points would hold the tissue in place. After conducting research on the idea of using barbed attachment points for this device, a similar product was found. Quill™ sutures, shown in Figure 11, are modified sutures that have been used in rotator cuff repair. The barbs eliminate knot tying and show the potential for the possibility of using barbed fixation points for rotator cuff repair specifically.

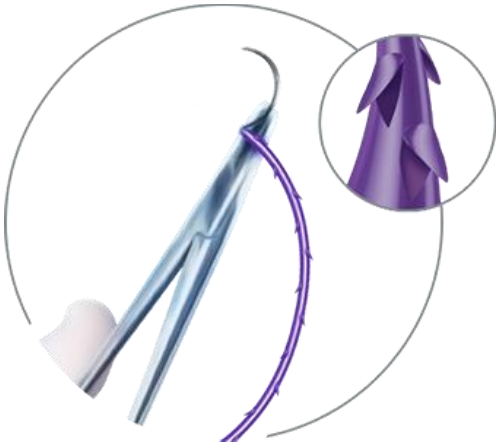
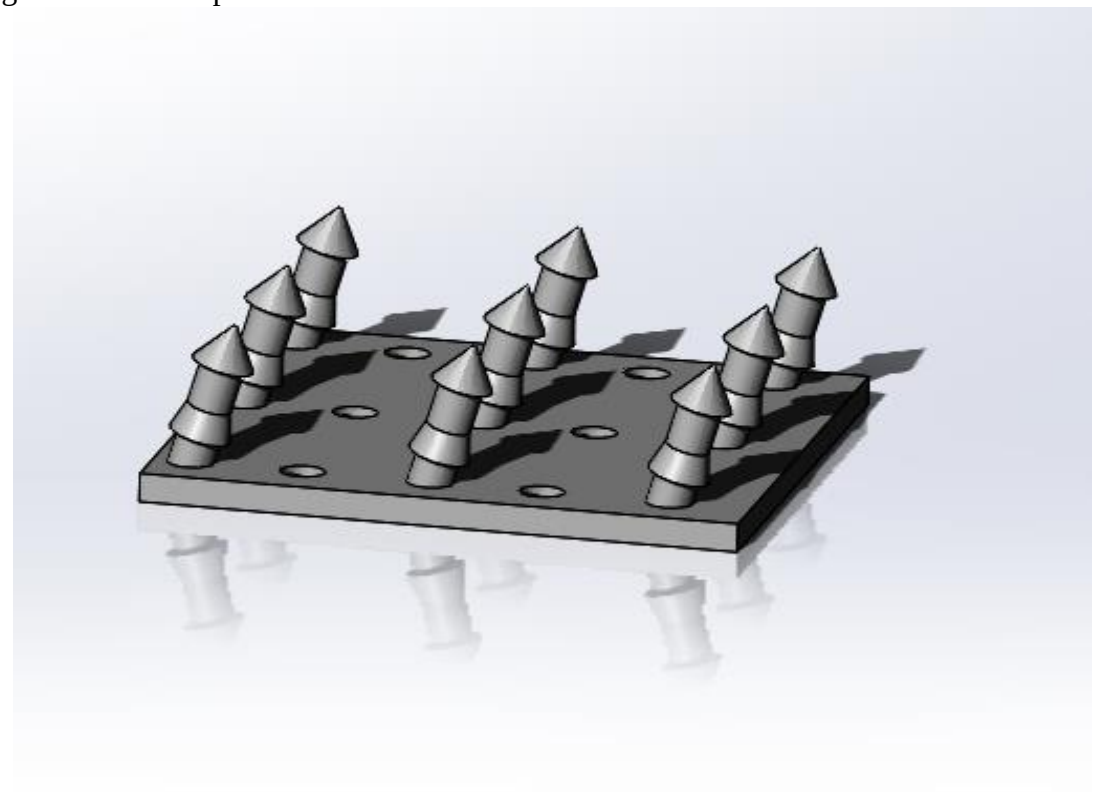


*Figure 11 Close-up picture of barbed structure (Quill™)*

Table 16 shows the CAD model and a description of the barbed fixation point model.

*Table 16 CAD model and description of the barbed fixation point design*

<table>
<tr><td colspan="2">Design: Barbed clamp<br>  </td></tr>
<tr><td colspan="2">Description:<br>In this model, barbed rods are designed to puncture through both sections of a torn tendon to interlock and clamp the ripped tendon together.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>The clamp design does not require any additional adhesives.</li><li>This design promotes tissue healing because there is no barrier between the torn tendon.</li><li>The angle of the clamps decreases the pressure on the device when shear stress is applied.</li></ul></td><td><ul><li>The clamp design punctures the tendon.</li><li>The design requires needles or must be sharp enough to puncture the tendon.</li><li>This design is not reversible.</li><li>The surgeons must align the clamps for proper attachment.</li></ul></td></tr>
</table>

### 4.3.4 Slot designs

Using the idea of insertion points built into the base that the barbed clamp design utilized, two different slot designs were created. The attachment points have a lipped top that allows them to enter the insertion point and secure into place. Table 17 shows the Press-fit design, and Table 18 shows the Keyhole design.

*Table 17 CAD model and description of the Press-fit design*

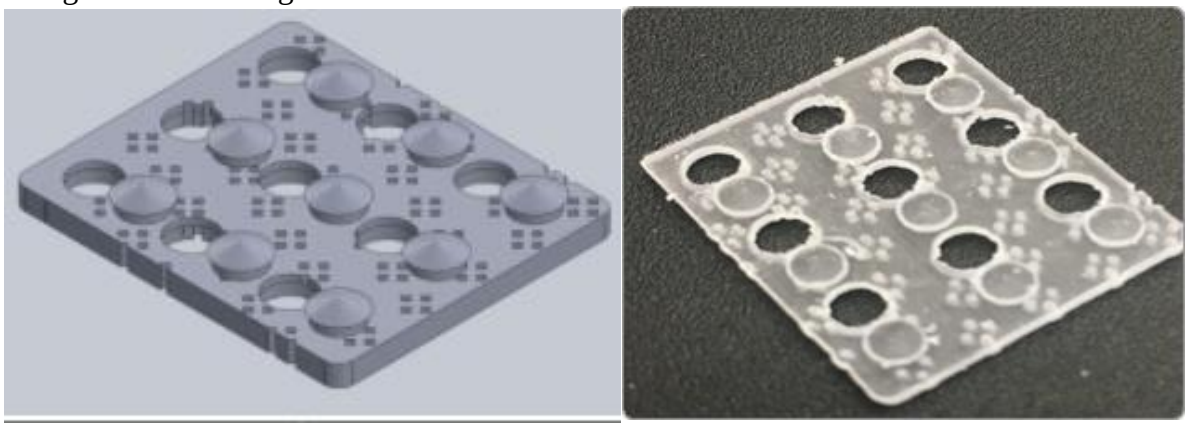
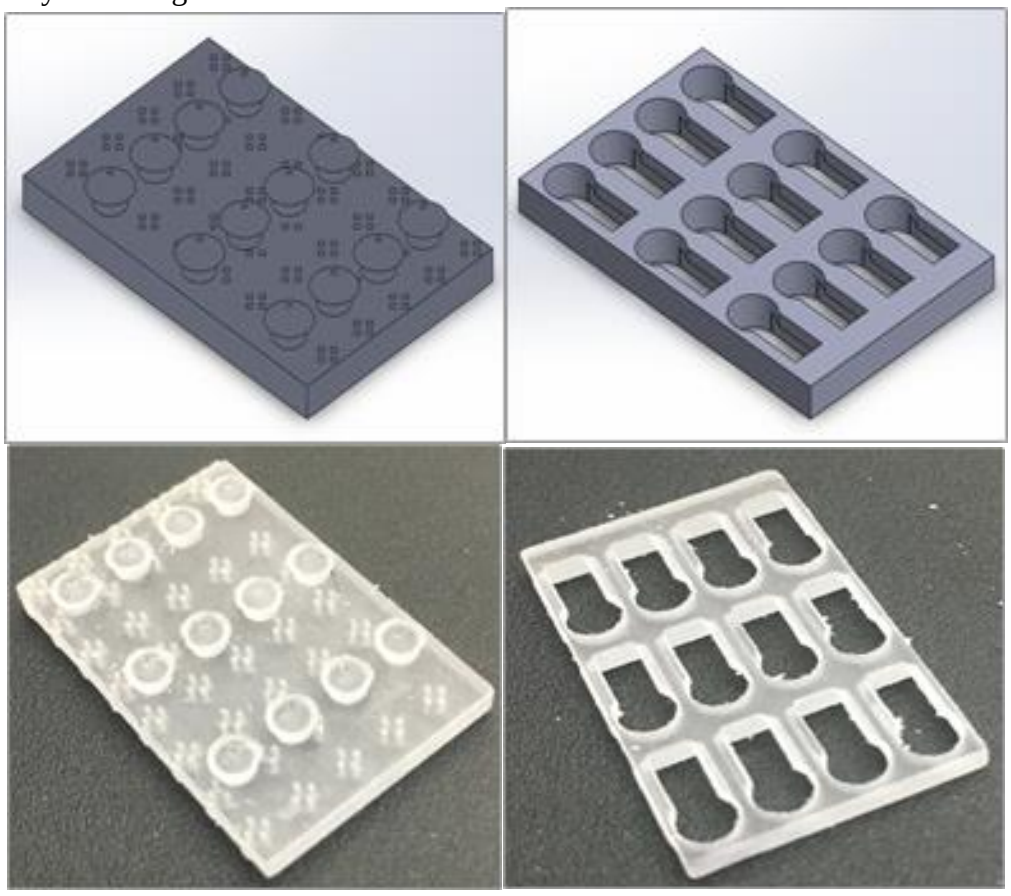
<table>
<tr><td colspan="2">Design: Press-fit design<br>  </td></tr>
<tr><td colspan="2">Description:<br>This model has a short, cylindrical base with a conical lipped top that insert into a corresponding hole.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>The lip on the protrusions prevents the design from pulling apart.</li><li>The protrusions through the base increases the shear strength of the design.</li><li>The design is easy to attach.</li><li>The mesh base allows for cell proliferation and tissue interaction.</li></ul></td><td><ul><li>The surgeon must align the two pieces for proper attachment.</li></ul></td></tr>
</table>

*Table 18 CAD model and description of the Keyhole design*

<table>
<tr><td colspan="2">Design: Keyhole design<br>  </td></tr>
<tr><td colspan="2">Description:<br>This model has rod protrusions with a lip that are inserted into a larger hole then slid into the smaller keyhole for attachment. When this design is attached to the tendon or bone, it must be oriented so that the tendon pulls in the direction of the rectangular extension.</td></tr>
<tr><td>Advantages</td><td>Disadvantages</td></tr>
<tr><td><ul><li>Easier to align than the press fit design as the hole is larger than the head that enters through.</li><li>The tight fit keyhole allows for the rod protrusions to stay in place.</li><li>The snap fit increases shear strength in the direction of the keyhole</li></ul></td><td><ul><li>If a shear force is applied in the opposite direction, the rods can potentially slip out of the key hole.</li><li>The thickness is over 5mm, limiting tendon regrowth.</li></ul></td></tr>
</table>

## 4.4 Final Designs for Testing

After several prototype iterations and initial mechanical testing on the Instron two final designs and a final material were chosen. Prototypes of these designs created with the final material were further tested on the Instron to determine a single final design.

### 4.4.1 Design Selection

The final designs for testing were selected based on the top three needs of the project: increase the surface area of the attachment, ability to demonstrate the use of the device *in vitro*, and have a greater strength than the current gold standard of repair (398 N). All preliminary designs had a similar surface area in contact with the tendon (approximately 400 $mm^2$). The requirement to demonstrate use *in vitro* was met if a successful prototype was created. The shear strength was measured by pulling the device apart using an Instron. If the shear strength of the device surpassed 398 N the design was considered successful. Table 19 outlines each design's success based on the ability to prototype and the preliminary shear testing results.

*Table 19 Comparison of initial designs*

| | Ability to Prototype | Preliminary Shear Testing Results |
|---|---|---|
| Hook and loop | No | N/A |
| Rods | Yes | >150 N |
| Barbed Clamp | Yes | N/A |
| Press-fit | Yes | >500 N |
| Keyhole | Yes | > 900 N |

Table 19 shows that the Press-fit and Keyhole designs were the only two designs able to be successfully prototyped and have a shear strength greater than 398 N. All iterations of the hook and loop design could not be successfully prototyped on a 3D printer with the desired dimensions and therefore were not tested. The barbed clamp

design was not pursued for testing because after speaking with Dr. Robert Meislin MD, NYU, it was determined that the design would be too difficult for physicians to use. The rods design did withstand a significant shear force load, but did not surpass 398 N, so it was not selected as a final design. Based on this initial analysis of designs the Press-fit and Keyhole designs were chosen for final testing. Both designs were also created with a mesh backing to increase regrowth in the tendon and were tested in unison with the original designs.

### 4.4.2 Material Selection

The final material selection was also based on the success of prototyping. Originally, all prototypes were created with PLA on the Monoprice printer, but were brittle and had a low resolution. The second round of prototypes were made on the Stratasys FDM printer with acrylonitrile butadiene styrene (ABS) and had a higher resolution, but were still brittle particularly on the thin features. ABS is also not a biocompatible material, so it is not feasible for this application. The final round of initial prototypes were developed using a PolyJet printer with MED610 material. These prototypes were strong and could withstand shear forces of over 900 N and had the highest resolution compared to PLA and ABS, but still did not have optimal flexibility. Table 20 shows an overview of the properties observed when prototyping with each material. Green represents that the material was suitable for the project, yellow represents mediocre quality, and red represents poor quality.

*Table 20 Comparison of prototyping materials*

| | Resolution | Strength | Flexibility | Biocompatible | Bioresorbable |
|---|---|---|---|---|---|
| PLA | | | | | |
| ABS | | | | | |
| MED610 | | | | | |

PLA is the ideal material for *in vivo* use due to its bioresorbability. However, MED610 was chosen as the final material for prototyping due to its availability on a high-resolution printer, strength, and biocompatibility.

# Chapter 5: Testing and Results

Once the preliminary testing stage was completed, the Press-fit and Keyhole designs underwent tensile, shear, and cyclic testing to determine the maximum and average force at failure. A total of six trials of each test were conducted for each design over four lots of prototypes to account for variability with the 3D printer. Soft tissue adhesive testing using Vetbond was conducted to determine the feasibility of attaching the device to the tendon using adhesives. The results of these tests along with the usability of each design were the primary factors that led to the final design choice.

## 5.1 Testing Methodology

This section outlines the procedures for tensile, shear, and cyclic testing for the Keyhole and Press-fit designs using an Instron 5544 machine.

### 5.1.1 Material Selection

For tensile testing, a rod extension with dimensions of 7 mm x 10 mm x 15mm was built onto the back of each half of the designs. The rod extension was secured in the grips of the Instron so each half of the design sat flush against the base of the grips, ensuring that only the strength of the attachment points was tested. Figure 13 shows a schematic of a tensile testing prototype in the Instron.

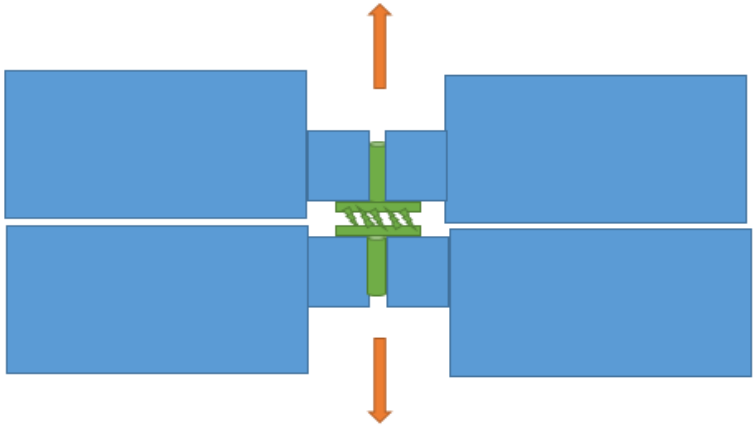


*Figure 12 Diagram of a prototype with the rod extension undergoing tensile testing. The blue figure represents the Instron grips and the green figure represents the prototype with the extension.*

For shear testing, the base of the designs was extended 10 mm past the attachment points on one side of the device. Similarly, the Instron grips held the extended base in place during testing so the first row of attachment points sat flush against the base of the grips. Figure 13 shows a schematic of a shear testing prototype in the Instron.

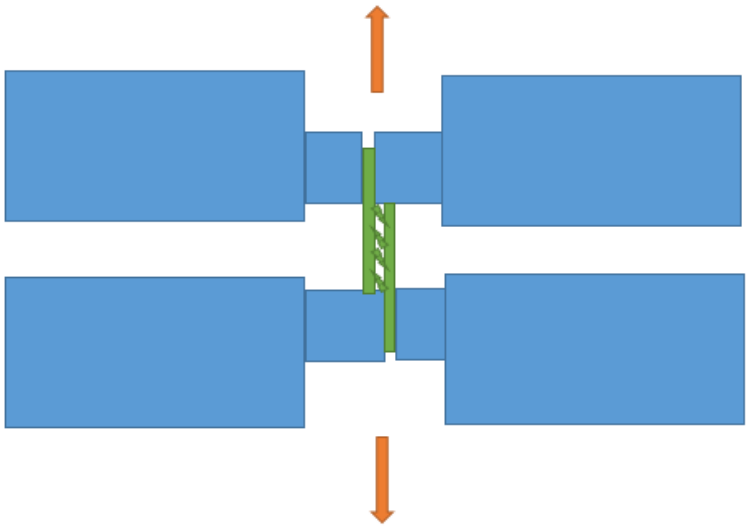


*Figure 13 Diagram of a prototype with the base extension undergoing shear testing. The blue figure represents the Instron grips and the green figure represents the prototype with the extension.*

Each of the designs underwent six trials of tensile and shear testing and the force was recorded against the gap formation of the device. The parameters for tensile and shear testing are shown in Table 21.

*Table 21 Testing parameters for the tensile and shear strength*

| | |
|---|---|
| **Preload** | 10 N for 30 seconds |
| **Test** | Pull apart at a rate of 1 mm/s to failure |

### 5.1.2 Cyclic Testing

Cyclic testing was done in the shear direction because the device will primarily experience repetitive shear forces when placed in the rotator cuff. Testing prototypes had the same base extension as the prototypes used in shear testing. The parameters for cyclic testing is shown in Table 22.

*Table 22 Cyclic testing parameters for the shear strength*

| | |
|---|---|
| **Preload** | 10 N for 30 seconds |
| **Precycling** | 200 cycles between 10 N and 100 N at a rate of 100 N/s |
| **Test** | Pull apart at a rate of 1 mm/s to failure |

### 5.1.3 Statistical Analysis Method

Statistical analysis of the data was performed to investigate the variability between each sample and the significance of results between each design. Each test used the maximum force values from each trial. The standard deviation between each sample for each test was calculated using the following formula in Excel.

$$SD = \sqrt{\frac{\sum(x-\bar{X})^2}{(n-1)}} \quad (1)$$

The difference of results between the two designs was determined by a paired two sample mean t-test. The t-test determined if there was a significant difference between the maximum forces of the designs. A confidence interval of 95% was used, so if the p-value calculated was greater than 0.05, the results were proven to not have a significant difference.

## 5.2 Data Collection

Bluehill software was used in collaboration with the Instron 5544 to record the time of the test, gap formation of the device, and the force placed on the device for each trial. The force at failure was taken from each trial to find the maximum force and average force for each design.

### 5.2.1 Press-fit Design Data

Table 23 shows the average force, maximum force, and standard deviation for the tensile, shear, and cyclic tests for the Press-fit design.

*Table 23 Press-fit results*

| | **Tensile (N)** | **Shear (N)** | **Cyclic (N)** |
|---|---|---|---|
| Average Force ± SD | 227 ± 54.06 | 477 ± 98.22 | 542 ± 154.10 |
| Maximum Force | 294 | 668 | 703 |

The corresponding graphs for the Press-fit data are shown in Figure 14. Each graph shows the gap formation against the force applied to the device for all six trials.

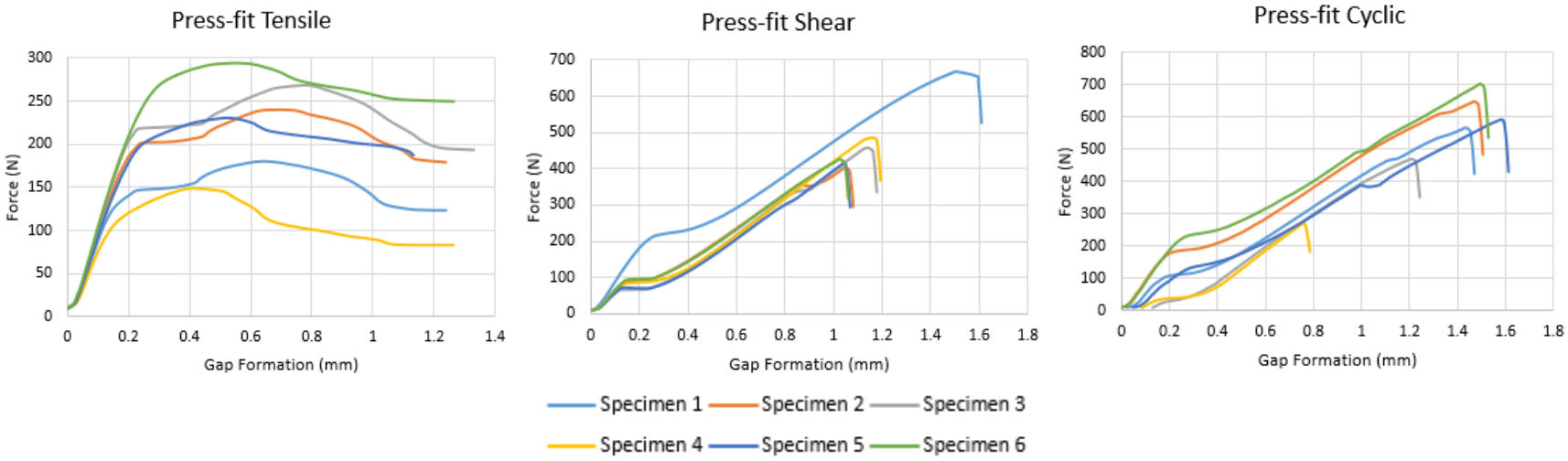



*Figure 14 Gap formation vs. force graphs for the tensile, shear, and cyclic Press-fit test.*

### 5.2.2 Keyhole Design Data

Table 24 shows the tensile, shear, and cyclic results for each trial for the Press-fit design, as well as the average and maximum forces.

*Table 24 Keyhole results*

| | **Tensile (N)** | **Shear (N)** | **Cyclic (N)** |
|---|---|---|---|
| Average Force ± SD | 241 ± 42.78 | 512 ± 55.88 | 602 ± 149.70 |
| Maximum Force | 297 | 586 | 795 |

The corresponding graphs for the Keyhole data are shown in Figure 15.

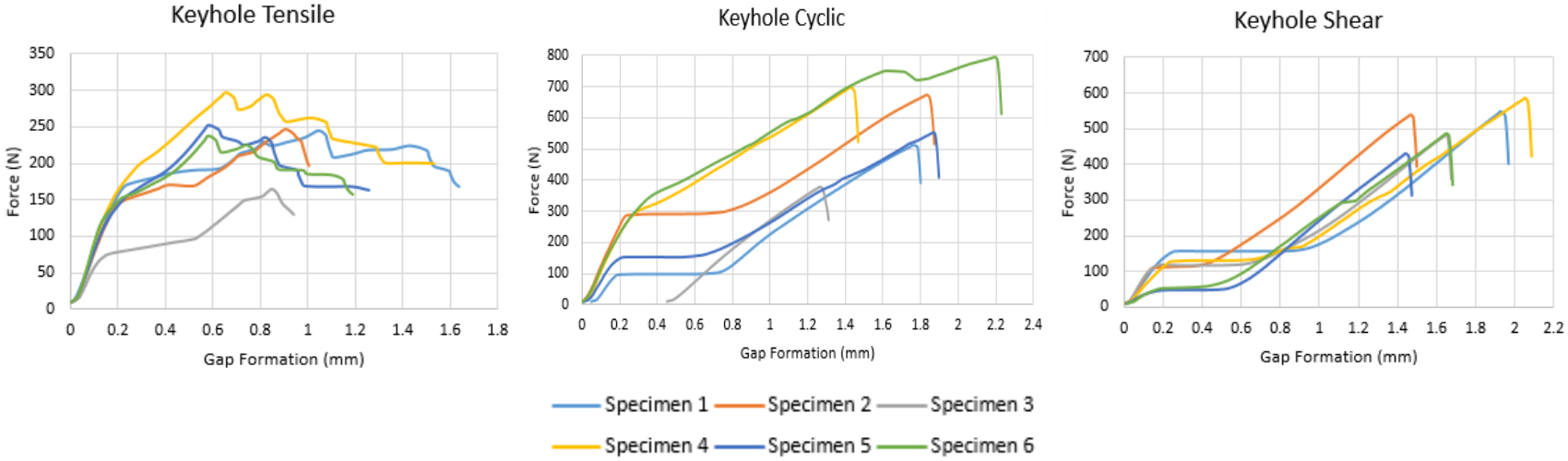



*Figure 15 Gap formation vs. force graphs for the tensile, shear, and cyclic Keyhole tests.*

### 5.2.3 T-test Results

The results from the t-tests are displayed in Table 25. The results show that there is no statistical significance in the strengths of the two designs because the p-values were greater than 0.05.

*Table 25 Results from t-test*

| | **Tensile** | **Shear** | **Cyclic** |
|---|---|---|---|
| Two tail p-value | 0.719 | 0.368 | 0.480 |

## 5.2 Adhesive Testing

An adhesive feasibility test was conducted using the cyanoacrylate soft tissue adhesive Vetbond. The goal of this testing was to determine the strength of the adhesive interface between the tendon and the device. Spare prototypes of the designs with the shear testing extension were attached to bovine tendon samples using Vetbond and allowed to cure for approximately one minute. The tendon was then wrapped in gauze to prevent slipping and clamped into the grips of the Instron, with the testing extension of the device clamped at the other end, as shown in Figure 16.

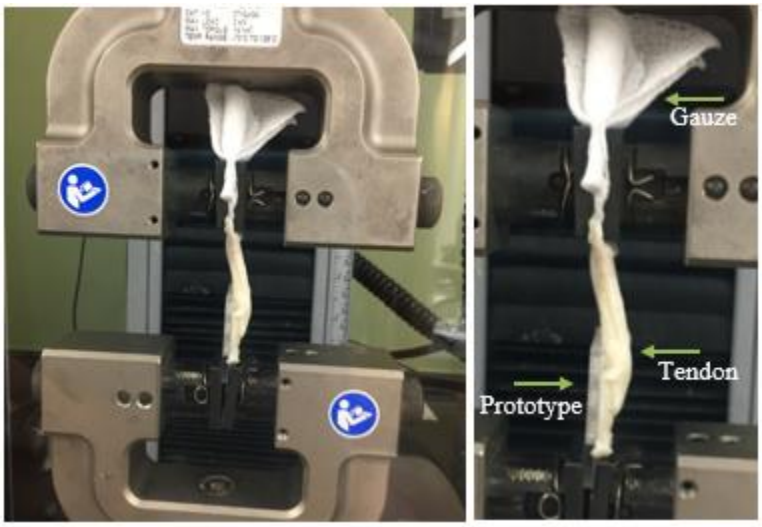



*Figure 16 The tendon and prototype loaded in the Instron.*

The shear strength of the adhesive was tested using the same parameters for the shear test shown in Table 21. The average and maximum forces of five trials are shown in Table 26.

*Table 26 Adhesive testing results*

| | |
|---|---|
| Average Force | 60 N |
| Maximum Force | 101 N |

# Chapter 6: Discussion

The results discussed in Chapter 5 along with several observations allowed the team to select a final design. This data proves that most of the feasible objectives set forth in this project were met.

## 6.1 Final Design Selection

The final design was selected from the Press-fit and Keyhole designs. The choice was made based on the following functions: usability, thickness, stability of attachment, tensile strength, shear strength, cyclic strength, and method of failure. Table 27 summarizes how well each design met every function. The green cells indicate that the design met the function and red cells indicate that the design did not.

*Table 27 Summary of final design selection*

| | **Keyhole** | **Press-fit** |
|---|---|---|
| Usability | Good | Good |
| Thickness | 5 mm | 3 mm |
| Stability of attachment | Poor | Good |
| Mean tensile strength | 241 N | 227 N |
| Mean shear strength | 512 N | 477 N |
| Mean cyclic strength | 602 N | 543 N |
| Method of failure | Attachment points break off | Testing extension breaks off |

Table 27 shows that the Press-fit design met every function, while the Keyhole design did not meet three functions. Although the Keyhole design did have greater average tensile, shear and cyclic strength, the results from the t-test showed no statistical significance, $p>0.05$, between the mean strengths of each test for the two designs. The Press-fit design did have greater variability between samples for each test shown by the larger standard deviations, but this could be due to difficulty with aligning the Instron for several Press-fit tests.

The three functions that the Keyhole design did not meet were thickness, stability of attachment, and method of failure, which are significant factors in this application. The large thickness of 5mm for the Keyhole design will likely block tendon regrowth, which is crucial to this device because it is biodegradable and is meant to be a temporary fastener while the tendon heals. The Keyhole design had poor attachment stability because the rods slide freely in the slots compared to the Press-fit design that stayed in place once assembled. The Keyhole sliding was an issue because it could irritate other tissues or have a greater chance of breaking apart. The Keyhole design failed by the small rod attachment points breaking off, which was deemed dangerous because small foreign objects within the body can result in an elevated immune response. In comparison, the Press-fit design failed at the testing extension suggesting that it could withstand higher loads when attached to the tendon. Overall, the Press-fit design was chosen as the final design because the data demonstrated that it met every crucial function for this application.

## 6.2 Evaluating Objectives

The Press-fit design meets most of the feasible objectives set at the start of this project. The objectives outlined in Chapter 3 were:

- Utilize the hook and loop concept.
- Increase the surface area of attachment.
- Reduce the possibility of re-tear after rotator cuff repair by increasing the amount of force the repair method can withstand.
- Demonstrate use of the device *in vitro*.
- Develop a method of attaching the device to the tendon and bone.
- Make the device usable in minimally-invasive rotator cuff surgery procedures (i.e. mini-open repair).

Due to limitations with prototyping capabilities, the design was not able to mimic the hook and loop concept, but instead was developed from the idea of interlocking components that can be re-attached multiple times. The Press-fit design increased the surface area of the attachment as it is roughly 20mm x 23mm in dimensions. The tensile,

shear, and cyclic testing results show that the design reduces the possibility of re-tear and that the use of the device can be demonstrated *in vitro*. The average tensile load that the design withheld was 227N. This value is above the goal of 200N determined necessary by the project sponsor Dr. Robert, Meislin, an orthopedic surgeon. The average shear strength of 477N and cyclic strength of 543N both surpass the maximum load, 398N, of the gold standard, Mason-Allen sutures. These high strength values suggest that the Press-fit device is more effective than the current standard for rotator cuff tear repair on the market.

The remaining two objectives, developing an attachment method and making the device usable in minimally-invasive surgery, were determined to be out of the scope of this project and unable to be met due to time constraints and other limitation. Extensive research was done on methods to attach the device to tendon and bone and are described in Chapter 8.

## 6.3 Limitations

There are several limitations that this project faced. One major limitation was the resolution of available 3D printers and materials. The original hook and loop design had to be dropped because there was no printer available with a high enough resolution. The materials within the available printers were also limited. Ideally the final material would have been PLA, but the resolution of the FDM printers that could use PLA was not accurate enough for the designs. This project also faced limitations with surgical adhesives. Several adhesives were not on the market or could only be obtained by trained surgeons. The most significant limitations for this project were time and budget. The project was restricted to one year and a budget of $1000. There are many areas where this project could have been expanded, such as attaching the device to tendon and to bone, testing the device on a simulated use model and *in vivo*, and optimizing the device to be used in minimally invasive surgeries. Although this project faced many limitations, it could meet many of the feasible objectives. The future recommendations discussed in Chapter 8 expand upon the limitations and describe how several technologies could have been incorporated into the project if they were available.

# Chapter 7: Design Validation

To validate the final design, the impact of the device and engineering standards were considered. When developing a new device, it is important to understand the effect it will have on people and the environment. Following engineering standards when designing and testing products ensures that the device can be marketed.

## 7.1 Impact of Device

This section outlines the ethics, health and safety risks, manufacturability, and sustainability of the device.

### 7.1.1 Ethical Concerns

As further testing is conducted using this device, it will need to go through animal and human testing before being cleared by the Federal Drug and Food Administration for surgical use. This calls into question the ethics behind these testing procedures. Proper guidelines for animal and human testing would be followed to ensure the maximum comfort for all subjects. An International Review Board approval would be obtained and all animal and human welfare regulations would be followed.

### 7.1.2 Health and Safety Issues

The product will influence the health and personal safety of people by minimizing their risk of rotator cuff tendon re-tear. The Press-fit device can withstand more force than current methods, reducing the patient's chances of being exposed to the trauma of additional surgery if their tendon is re-torn. This design also avoids the use of suturing in the repair, likely resulting in less damage to the tendon and an easier recovery for the patient. The material used in this device is biocompatible and biodegradable, limiting the possibility of a cytotoxic response to the implantation of this device and positively affecting the safety of the patient.

### 7.1.3 Manufacturability

The device was prototyped using 3D printing techniques based on SolidWorks models. Designing the device in SolidWorks allowed for changes to be made based on testing results throughout the prototyping process. Although 3D printing is optimal for prototyping, it is not economical or efficient for large quantities. Ideally, the final product would be manufactured using injection molding to fabricate bulk quantities at a low cost. Following sterilization and packaging, the device can be used in a surgical procedure.

### 7.1.4 Sustainability

The use of 3D printing while prototyping reduces the effect on the surrounding biological or ecological environment. Analysis of the sustainability of 3D printing has shown that it leads to cost reduction, energy saving, and reduced carbon dioxide emissions {Gebler, 2014 #133}. The biodegradability of the device also contributes to its sustainability. There will be no waste left from the device because it fully degrades naturally through hydrolysis within the body.

## 7.2 Engineering Standards

The following engineering standards were considered when developing the device:

### 7.2.1 - Medical Devices - Quality Management Systems (ISO 13485)

This standard details requirements for companies to provide consistent medical device products that meet quality and regulatory specifications. This includes the design and development stage of a medical device, which is the aspect that this project is focused on.

### 7.2.2 - Sterility (ISO 11737-2:2009)

This standard describes the requirements for sterility tests on medical devices to validate the process. A sterile medical device is defined as one that does not contain viable microorganisms. The sterility of a device population is determined by the probability of the existence of a microorganism present on the device after sterilization.

### 7.2.3 - Biological Evaluation and Biocompatibility Testing of Medical Devices (ISO 10993-1)

This standard identifies the necessary tests for biological evaluation of medical devices based on the duration of contact with the body. These tests would be crucial for the device as it will stay in the body for approximately one year before degrading.

### 7.2.4 - Endotoxic and Pyrogens (ISO 10993-11:Systemic Effects)

This standard discusses the process of evaluating the toxicity of medical devices on organs and tissues that are not in contact with the device. The team's device will be present in the body for approximately one year, so testing the potential toxicity is essential to the success of the implant.

### 7.2.5 - Long term implantation (ASTM F981-04(16))

This standard tests the tissue response to biomaterials implanted in the body against control materials which have been previously been approved to have an acceptable degree of cellular reaction. The device will be made from PLA which is a common biomaterial.

### 7.2.6 - Standard Test Method for Uniaxial Fatigue Properties of Plastics (ASTM D7791)

This standard describes fatigue tests on plastics to determine the effects of fatigue resistance, surface condition, processing, and stress. The device will be made from PLA, a plastic that should go through these fatigue tests before implantation.

# Chapter 8: Recommendations and Conclusion

Although the device met many objectives, the team has recommendations for prototyping, attachment methods, and testing to continue the project.

## 8.1 Recommendations

The design process was restricted by many limitations including time, resources, and finances. The recommendations fell under the following three categories: prototyping, attachment methods, and testing. Additional prototyping options for the design include Cilllia software and silk fibers. The Cilllia software, created by students at MIT, enables the creation of 3D printed hair-like structures that can act as attachment points when pressed together (Ou *et al*., 2016). The thin feature capability of this software would allow for the development of the original hook and loop concept. 3D printed silk fibers were also considered in the design process. Silk is a strong, biocompatible material that has greater flexibility than the current prototyping material, MED610 and the ideal final material PLA. The flexibility of a silk device could potentially allow it to be inserted through a minimally invasive arthroscopic surgery, reducing the harm to the patient.

Recommended areas for further research into attachment methods include the use of a barnacle glue adhesive, CT-3 adhesive, TissueGlu, or a clamp through the tendon design. Barnacle glue, a natural adhesive that utilizes barnacle proteins can be used as a hard tissue adhesive to attach one half of the device to the bone. A major advantage of this adhesive is its high strength in aqueous environments. Another possible adhesive that has the potential to be used along with the Press-fit device is CT-3, a bioadhesive created by Histogenics. This bioadhesive is currently used along with the product NeoCart, which is a cartilage repair implant created by Histogenics. The bioadhesive is made from methylated collagen, activated polyethylene glycol and a salt buffering solution that acts as a curing component. The glue is biodegradable, nontoxic, and stronger than commonly used fibrin glue {Gridley, 2014 #134}. This adhesive is not currently available on the market but is a promising option for a soft tissue adhesive to use with this device. Another option is TissueGlu, a strong soft tissue adhesive but only available to certified

board surgeons. According to the manufacturers, Cohera Medical, this is the only FDA approved, high strength surgical adhesive for internal use. TissuGlu is used to hold tissues in place following abdominoplasty while also aiding in healing. A small drop of the adhesive can hold around ten pounds of force, making it ten times the strength of fibrin glue. Overall, TissuGlu remains soft and flexible while creating a tight bond before absorbing into the body, making it a great option for this application. The Press-fit design can also be modified to clamp the tendon between the two sides of the device and eliminate the need for adhesives. In this design, the attachment points are extended so they can puncture through the tendon and attach to the corresponding holes on the other side of the device. The team attempted to create and test a prototype for this design but was unsuccessful due to a lack of time. The design required the creation of multiple holes in the tendon to accommodate the attachment points because they were not sharp enough to puncture through on their own. Further iterations will be necessary to create an optimal prototype for this application.

Due to time, budget, and resources limitations there are several tests that could be performed to further analyze the Press-fit device. The reattachment strength of the device would be a useful area to investigate. Evaluating the strength of the device after it has been pulled apart and refastened several times would provide valuable information to physicians who may need to reattach the device during surgery due to misalignment. Investigating the impact of larger mesh holes on the strength of the device would also be beneficial for further optimizing the design. Currently, the mesh holes on the base of the Press-fit design do not impact the strength of the device, but their small size may restrict cell proliferation and tendon healing through the device. A test evaluating the effect of several different mesh hole sizes on the strength of the device will determine the ideal mesh hole size optimizing strength and tendon healing.

## 8.2 Conclusion

The primary goal of this project was to reduce the likelihood of rotator cuff re-tear by increasing the total surface area of attachment at the surgical site. Through research, prototyping and testing, a final design was chosen that can withstand over 398 N in the shear direction and 200 N in the tensile direction. These values ensure that the device

surpasses the strength of the gold standard for rotator cuff repair, the Mason-Allen sutures. The results of cyclic testing also show that 200 cycles have little effect on the overall strength of the design. The dimensions of the device are small enough to prevent the device from interfering with healing while also maintaining a stable attachment. These factors suggest that this device has the potential to reduce re-tear compared to sutures when implanted in the body.

The development of this successful rotator cuff repair device has the potential to have a significant impact on the population as there was over 4 million rotator cuff injuries and 440,000 repair surgeries in the United States in 2010 alone. When only considering successful surgeries, 31% resulted in re-tear of the rotator cuff demonstrating need for our device. The current market for surgical rotator cuff repair is $622 million with $550 million dedicated to sutures and suture anchors (Meislin, 2017). The Press-fit device eliminates the need for sutures and suture anchors indicating its large market potential. The design can also be extended to additional tissue tear applications. Overall, this patented design concept has enormous potential to excel in the market and improve the lives of many.

# Appendix

## Appendix A: Summary of Current Repair Methods

| Subject | Tendon | Repair Method | Ultimate Strength (N) | Cyclic Elongation | Stiffness (N/mm) | Failure Point |
|---|---|---|---|---|---|---|
| Human (Esquivel, Duncan, Dobrasevic, Marsh, & Lemos, 2015) | supraspinatus | single-row repair with simple stitch | 309.5 ± 129.8 | N/A | 3.6 ± 9.0 | -60% suture tore through the tissue<br>-20% at anchor,<br>-20% tissue tore through the anchors |
| | | single-row repair with modified Mason- Allen | 378.4 ± 154.4 | N/A | 17.9 ± 10.7 | -60% at the tissue<br>-20% at the anchor<br>-20% suture broke |
| | | double-row Mason-Allen | 361.0 ± 56.8 | N/A | 15.1 ± 4.4 | -100% suture tore through the tissue |
| | | double-row cross bridge | 350.7 ± 126.0 | N/A | 20.5 ± 6.9 | -80% tissue tore<br>-20% at the anchor |
| | | double-row suture bridge | 333.0 ± 114.4 | N/A | 18.5 ± 6.3 | -40% suture tore through tissue<br>-40% at the anchor<br>-20% suture broke |
| Human (Virk *et al*., 2016) | supraspinatus | suture bridge (TOE-SB) double-row (DR) near the musculotendinous junction | 311.6 +/- 30.7 | Anterior:14.8 +/- 4.5%<br>Posterior: 16.9 +/-5.4 % | 66.2 +/- 4.4 | -33% Failure at the medial row construct in cyclic testing<br>-22%Failure at the medial row construct in failure testing<br>-33% Suture cut through the tendon in failure testing<br>-11% Anchor pull out from bone in failure testing |
| | | suture bridge (TOE-SB) double-row (DR) 10mm lateral to the musculotendinous junction | 388.3 +/- 40.6 | Anterior: 11.1+/- 3.9 %<br>Posterior: 14.3 +/- 4.8 % | 78.9 +/- 8.9 | -67% Suture cut through the tendon in failure testing<br>-11% Suture pull out from anchor in failure<br>testing<br>-22% Anchor pull out from bone in failure testing |
| Sheep (McKeown *et al*., 2016) | infraspinatus | Sutures alone | 147.2 +/- 7.4 | N/A | 15.4 +/- 3.7 | -100% sutures cutting through tendon |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | PTFE BARD patch (20mm x50mm) | 225.3 +/- 19.2 | N/A | 10.3 +/- 2.8 | -50% suture pulled out of anchor<br>-33% sutures pulling through at the patch to tendon<br>-17% sutures cutting through the tendon in a button-hole manner |
| | | ePtFe Gore-Tex patch (20mm x50mm) | 176.9 +/- 10.6 | N/A | 10.4 +/- 3.7 | -50% sutures cutting through the tendon in a button-hole manner<br>-50% sutures pulling through at the patch to tendon |
| Sheep (Baums *et al*., 2010) | infraspinatus | Mason Allen with 2 rows of Ethibond Sutures | 293.4 +/- 16.1 | N/A | 127.4 +/- 6.9 | -25% tore at tendon-muscle junction, repair intact<br>-12.5% suture anchor system tilted and suture tore at bony ridge<br>-25% torn suture at eyelet<br>-37.5% torn sutures |
| | | Mason Allen with 2 rows of HiFi Sutures | 397.7 +/- 7.4 | N/A | 162 +/- 7.3 | -50% tendon tore at tendon-muscle junction, repair intact<br>-25% suture anchor system tilted and suture tore at bony ridge<br>-12.5% torn suture<br>-12.5% sutures cutting tendon, sutures intact |
| | | Mason Allen with single row of Ethibond Sutures | 254.6 +/- 42.4 | N/A | 115+/- 16.7 | -37.5% sutures cutting tendon, sutures intact<br>- 12.5% torn suture at eyelet<br>-37.5% torn sutures<br>-12.5% suture anchor system tilted and suture tore at bony ridge |
| | | Mason Allen with single row of HiFi Sutures | 155.7 +/- 31.1 | N/A | 84.4 +/- 19.9 | -12.5% suture anchor system tilted<br>-12.5% torn sutures<br>-75% sutures cutting tendon, sutures intact |
| Pig (Hinse, Ménard, Rouleau, Canet, & Beauchamp, 2016) | infraspinatus | transosseous with 2 mm braided tape suture | 147 ± 63 | Bare Footprint Area:<br>57 ± 41% | N/A | - 100% in tendon |
| | | transosseous with multi-strand No. 2 sutures | 91 ± 51 | Bare Footprint Area:<br>81 ± 34% | N/A | - 100% in tendon |
| | | double row suture bridge with suture anchors loaded with No. 2 braided sutures | 175 ± 82 | Bare Footprint Area:<br>26 ± 27% | N/A | - 100% in tendon |

## Appendix B: Press-fit Results

| | **Tensile (N)** | **Shear (N)** | **Cyclic (N)** |
|---|---|---|---|
| Trial 1 | 180 | 668 | 567 |
| Trial 2 | 240 | 405 | 649 |
| Trial 3 | 268 | 458 | 470 |
| Trial 4 | 149 | 486 | 272 |
| Trial 5 | 231 | 416 | 593 |
| Trial 6 | 294 | 426 | 703 |
| Average Force | 227 | 477 | 542 |
| Maximum Force | 294 | 668 | 703 |

## Appendix C: Keyhole Results

| | **Tensile (N)** | **Shear (N)** | **Cyclic (N)** |
|---|---|---|---|
| Trial 1 | 245 | 548 | 513 |
| Trial 2 | 247 | 539 | 674 |
| Trial 3 | 165 | 483 | 379 |
| Trial 4 | 297 | 586 | 699 |
| Trial 5 | 252 | 431 | 553 |
| Trial 6 | 238 | 487 | 795 |
| Average Force | 241 | 512 | 602 |
| Maximum Force | 297 | 586 | 795 |

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