Title
Modified Suture Anchor for Shoulder Instability Repair

Permalink
https://escholarship.org/uc/item/89r418hp

Author
Sullivan, Meaghan

Publication Date
2016

Peer reviewed|Thesis/dissertation

UNIVERSITY OF CALIFORNIA SAN DIEGO

Modified Suture Anchor for
Shoulder Instability Repair

A thesis submitted in partial satisfaction of the
requirements for the degree Master of Science

in

Bioengineering

by

Meaghan Sullivan

Committee in charge:

Professor Sameer Shah, Chair
Professor Robert Sah, Co-Chair
Professor Karen Christman

2016

The Thesis of Meaghan Sullivan is approved, and it is acceptable in quality and form for publication on microfilm and electronically:

_____

_____

Co-Chair

_____

Chair

University of California San Diego

2016

TABLE OF CONTENTS

LIST OF FIGURES

ABSTRACT OF THESIS

Modified Suture Anchor for
Shoulder Instability Repair

by

Meaghan Sullivan

Master of Science in Bioengineering

University of California San Diego, 2016

Professor Sameer Shah, Chair
Professor Robert Sah, Co-Chair

The shoulder is the most unstable joint in the body.[1] Decreased stability

causes the shoulder to dislocate easily, stretching the joint capsule and

glenohumeral ligaments. This increases the likelihood of redislocation. Recurrent

dislocations can cause the ligaments and joint capsule to pull on the labrum and

x

create a lesion. Once a lesion is formed the joint is chronically unstable, and must be repaired surgically. The standard method of repair is to arthroscopically implant a suture anchor into the bone, which is then used to secure the soft tissue back onto the bone. This reintroduces tension to the capsule and glenohumeral ligaments, therefore restoring stability to the joint. There are several different types of suture anchors currently available on the market: the rigid knotted anchor, the rigid knotless anchor, and the soft anchor.

This study defines the anatomical and mechanical design constraints of shoulder instability repair by researching the injury mechanism, and benefits and downfalls of the current repair methods. Once these design constraints are well defined, two new suture anchor prototype designs are then proposed. Design 1 is a hybrid between a rigid and soft anchor, starting with the design for the current soft anchor, but creating wings from Nitinol, rather than using the sleeve to anchor the device. Design 2 starts with the soft anchor design, but adds a bone barrier to protect the bone from the micro-motion of the anchor.

INTRODUCTION

The shoulder is the most flexible joint in the body, allowing for three degrees of freedom.[1] However, along with increased flexibility, comes decreased stability.[1] Decreased stability causes the shoulder to dislocate easily, accounting for over 50% of major joint dislocations.[2] Once the shoulder has dislocated once, it increases the likelihood of dislocation recurrence. Recurrent dislocations can lead to permanent damage to the anatomy of the shoulder, leading to chronic joint instability.

Shoulder dislocation causes the joint capsule and surrounding ligaments to stretch out and loosen.[3] This loosening explains why redislocation is so common, and how the likelihood of future recurrence increases with each addition dislocation that occurs to the same shoulder.[1] Dislocation is a traumatic event for the joint, putting additional force on the glenohumeral ligaments. The glenohumeral ligaments are attached to the glenoid labrum, which is a circle of fibrocartilaginous tissue attached to the edge of the glenoid fossa, more commonly known as the shoulder socket. When extra force is put on the glenoid labrum it can be torn away from the glenoid fossa, causing permanent damage.[3] A lesion of the glenoid labrum leads to recurrent dislocation that may occur easily, and pain in the affected shoulder.

When the shoulder becomes chronically unstable, surgery must be performed to repair the glenoid tear and restore stability. This issue will not heal

itself. The standard method currently used in practice is to arthroscopically implant a suture anchor into the bone, which is then used to secure the labrum and excess joint capsule tissue back onto the bone.[4] This reintroduces tension to the capsule and glenohumeral ligaments, therefore restoring stability to the joint.[4] Reestablishing contact between the labrum tissue and the bone will also promote natural healing of the lesion.

There are several different types of suture anchors currently available on the market. The suture anchor most commonly used clinically is the rigid anchor, which is available in both knotted and knotless options. The rigid knotted anchor is a small cylindrical piece made out of a biocomposite material. There are threads around the outside of the cylinder to hold the anchor in the bone. This anchor is placed into a drill hole that has been made in the bone, and then sutures attached to the anchor are used to tie the labrum down to the bone.[5] The rigid knotless option uses the same anchor design as the knotted counterpart, however this anchor uses a suture-first method when implanted. By using the suture-first method, it eliminates the need for suture knots, which can irritate the surrounding articular cartilage.

More recently developed, is the soft anchor. This is a small anchor, made of only suture. By creating an anchor of only suture the drill hole for implanting the anchor can be smaller, preserving more of the bone. This anchor contains a suture, with a small polyester sleeve at the middle, which serves as the anchor. When the anchor is input in the bone it must be deployed by pulling rapidly and

tightly on the suture limbs, causing the sleeve to bunch up in the drill hole, securing the component into place.[5]

      This study aims to examine the anatomical and mechanical design constraints of shoulder instability repair by researching the injury mechanism, and benefits and downfalls of the current repair methods. Once these design constraints have been well defined, two new suture anchor prototype designs are then proposed.

CHAPTER 1: INTRODUCTION TO ANATOMY AND CLINICAL PROBLEM

Introduction

In order to design a prototype to repair shoulder instability it is essential to completely understand the anatomy and mechanism by which the injury occurs. All aspects of the anatomy involved in the injury should be taken into consideration in the repair. This will help to prevent the injury from occurring again, after the repair has been completed.

Shoulder Anatomy

Joint Information

The shoulder joint is a synovial, ball and socket joint, made up of the humerus head and scapula. However, the shoulder is unlike other ball and socket joints, where the socket encapsulates the ball. In the shoulder, the socket is relatively small compared to the size of the joint, with only about one-third of the humeral head articulating with the glenoid cavity at a time.[1] This is good for flexibility, allowing the shoulder to have a wide range of motion, however, it is bad for stability.[1]

The shoulder is the most flexible joint in the body, with three degrees of freedom: abduction versus adduction, flexion versus extension, and medial rotation versus lateral rotation.[1] Abduction is when the arm moves away from

the midline of the body, which occurs when the arm is moved outward, and adduction is the opposite, when the arm moves toward the body. Flexion is when the arm moves forward in line with the sagittal plane, and extension is when it moves backwards. Medial rotation is an inward rotation of the arm, and lateral rotation is an external rotation.

The shoulder joint is also considered an articular joint, meaning articular surfaces are covered with a layer of hyaline cartilage. The cartilage on the humeral head is thicker in the middle, and thinner at the periphery, while the cartilage on the glenoid fossa is thicker at the edges and thinner in the middle.[6] These layers of cartilage allow the bones to interact smoothly, decreasing the friction so the bones can move over one another smoothly.

Anatomical components

There are many different anatomical components that come together to make up the shoulder joint. The bones involved in the joint are the humerus, which is the long bone in the upper arm, the clavicle, which is the collarbone, and scapula, which is the shoulder blade. The portions of the bones involved in shoulder joint instability are the head of the humerus, and the glenoid fossa, which is part of the scapula. The humeral head is the ball of the joint, and the glenoid fossa is the socket.

Around the edge of the glenoid fossa, there is a ring of fibrocartilaginous tissue, called the glenoid labrum, that articulates with the scapula.[3] This ring increases the depth of the glenoid cavity by about 50%.[1] The fibrocartilaginous

layer between the bones also provides a suction effect on the humeral head,

which helps to hold the bones together.[1] These two features greatly attribute to

the overall stability of the joint, making the glenoid labrum an important

anatomical component.

The biceps tendon is responsible for attaching the biceps muscle to the

bone of the scapula. The tendon holds the muscle in place; if the tendon were to

tear, the muscle would retract away from the shoulder. It attaches to the scapula

by attaching to the superior portion of the glenoid labrum.[6]

The glenohumeral ligaments are also attached to the glenoid labrum. The

glenohumeral ligaments are three ligaments that attach the glenoid labrum to the
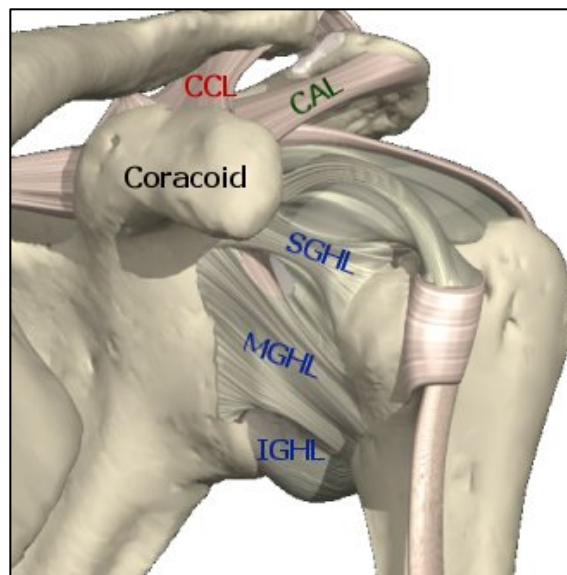
Figure 1: Anterior view of the glenohumeral ligaments connecting the humeral head and the glenoid in a left shoulder. All three glenohumeral ligaments are shown; the superior glenohumeral ligament (SGHL), the middle glenohumeral ligament (MGHL), and the inferior glenohumeral ligament (IGHL).[7]

lesser tubercle of the humerus head, as seen in Figure 1. The three ligaments are

the superior glenohumeral ligament, the middle glenohumeral ligament, and the

inferior glenohumeral ligament. These three ligaments put forces on the glenoid labrum during everyday activities, and also are affected by shoulder dislocation. Other ligaments in the shoulder joint are: the coracohumeral ligament, which connects the coracoid process of the scapula with the greater tubercle of the humerus and prevents the humerus from moving downward, the coracoacromial ligament, which connects the coracoid process of the scapula with the acromion process of the scapula and prevents the humeral head from moving upward, the coracoclavicular ligament, which connects the coracoid process of the scapula with the clavicle and anchors the clavicle inferiorly, the acromioclavicular ligament, which connects the acromion process of the scapula with the clavicle and keeps the clavicle articulating with the scapula, and the transverse humeral ligament, which lies over the biceps tendon and attaches lesser tubercle to greater tubercle of the humerus.[6]

The joint capsule is a membrane that surrounds the joint. The joint capsule attaches to the neck of the humeral head on one side, and to the glenoid labrum on the other, encapsulating the entire should joint inside. The inner layer is lined with a synovial membrane, and filled with synovial fluid, which helps to reduce friction between the layers of articular cartilage and keeps the joint moving smoothly.[6] The outer layer of the joint capsule is a fibrous membrane, which is a continuation of the periosteum of the bone.[6] The joint capsule creates and intracapsular negative pressure, which helps to keep the joint together.[6]

The muscles in the shoulder are the deltoid, the subscapularis, the infrasinatus, the teres minor, the supraspinatus, the pectoralis major, and the biceps. These muscles are important for the movement of the shoulder joint. The muscles are not involved in the mechanism for shoulder dislocation.

Another important aspect of the shoulder anatomy is the bursa. The bursa is a small fluid-filled sac. There are several bursae located throughout the shoulder. The job of the bursa is to protect the tendon from the bone by providing a boundary layer between the two. Over time the bursa can wear away, and once it is gone the tendon will start to wear away.

The blood supply and the nerves in the joint are also important factors to consider when considering shoulder stabilization surgery, because they must be carefully avoided during surgery. The only major arteries to consider are the circumflex humeral, and suprascapular arteries.[6] The glenoid and surrounding aria is a mainly avascular area.[8] The glenoid fossa rim is avascular, which is beneficial during surgery because this is where the anchors are placed in the glenoid, so there is no concern of hitting an artery when placing the anchors.[8] However, this can also be bad for the stabilization repair, because the healing of soft tissue after the repair could be compromised by hypovascularity.[8]

The nerves of concern in the shoulder are the axillary and suprascapular nerves. Damage to the nerves could happen at the time of dislocation, however nerve problems in the shoulder due to dislocation or instability repair are rare.[9] In some cases the drill hole can come in contact with the suprascapular nerve

when drilling in the superior portion of the glenoid, in which cases surgeons must be very careful to not cause any damage to the nerve.[10] This is only a concern in the superior portion of the glenoid.[10]

Shoulder Instability

Anatomical Mechanism

Shoulder dislocation is the first step toward shoulder instability. Dislocation is defined as the ball of the joint coming out of the socket, which for the shoulder means the humerus head comes completely out of the glenoid fossa. The shoulder can also become partially dislocated, called shoulder subluxation, which means the humerus head is partially out of the glenoid fossa, but not all the way out. When the shoulder is dislocated is can cause pain and swelling in the shoulder and is visibly out of place. These symptoms will subside once the dislocation has been reduced, and the humerus head is back in place in the glenoid fossa.[3] The patient will also experience an inability to move the joint while it is dislocated and potentially have a decreased range of motion after the joint initially has been reduced.

Shoulder dislocations account for about 50% of major joint dislocations, occurring in about 23.9 per 100,000 people per year.[2,11] However, this number only represents the number of reported cases per year. It is estimated that the actual number of shoulder dislocation cases is closer to two times the reported value due to individuals reducing the dislocation at home.[11] Of those dislocations

about 95 to 97% are in the anterior direction, with only 2 to 4% in the posterior direction.[12]

First dislocation usually is caused by a traumatic event, such as a fall or sport injury. Shoulder dislocations are highly prevalent in athletes, with 48.3% of dislocations occurring during sports or recreation.[11,13] Athletes are also more likely to experience a dislocation at a younger age than nonathletic individuals.[13] The was no significant difference found based on race, however dislocation occurs almost 3 times more often in males than in females.[11] Shoulder dislocation is highly dependent on age. The most prevalent age group 16 to 20 years old, making up about 54% of the shoulder dislocations that occur each year. Young individuals are at higher risk for dislocation, and dislocations in young patients are more likely to lead to permanent damage.[13]

Once the shoulder has been dislocated once, recurrent dislocations occur much more easily than the first. As recurrent dislocations occur, they do not necessarily need to be caused by a traumatic event. The recurrence rate is also highly dependent on age. The younger the patient is at the first dislocation the more likely they are to experience redislocation, and the more often the dislocations will be.[13] The dislocation recurrence rate can be up to 90% in young patients.[14] Recurrence rates are also dependent an athletic activity, with athletes experiencing more recurrent dislocations and at shorter time intervals than non-athletic individuals of the same age group.[13] The majority of individuals who experience shoulder dislocation also have recurrent dislocations. Of the people

who experience recurrence, most experience more than one additional dislocation. With each dislocation of the shoulder, recurrence becomes increasingly easier to occur.

When the shoulder is dislocated the humeral head is anteroinferior of the glenoid fossa, putting extra force on the glenohumeral ligaments and the joint capsule. This causes the joint capsule and glenohumeral ligaments to loosen and stretch out, which can be seen in Figure 2.[3] The inferior glenohumeral ligament usually experiences the most damage, because of its location: it is in the direct path of the humeral head as it moves in an anteroinferior position during redislocation.[6] The loosened joint capsule and ligaments then allow space for the
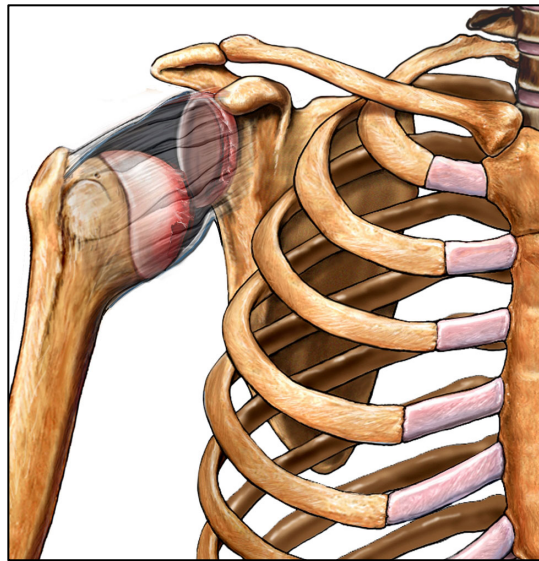
Figure 2: Anterior view of a dislocated right shoulder. The humeral head is dislocated in the anteroinferior direction putting pressure on the glenohumeral ligaments.[15]

shoulder to more easily redislocate.[6] These tissues stretch out more and more with each dislocation, which explains why redislocation usually occurs more than once.

The extra force on the ligaments and joint capsule during dislocation can lead to damage of the glenoid labrum. The glenoid labrum is pulled away from the glenoid fossa, leaving a lesion between the two. This lesion will not heal itself, and leads to further loosening of the joint, causing chronic joint instability. About 27% of reported dislocations eventually lead to the need for instability surgery.[16] This statistic is even higher for the 16 to 20 years age-group, with 38% having to undergo surgery eventually, further proving the detriment of experiencing a dislocation at that age.[16] The clinical symptoms of joint instability include those of typical joint dislocation, with easier recurrence, and a feeling of the joint being loose. Another sign of joint instability is the sulcus sign. The sulcus sign is a depression observed just below the acromion when the arm is pulled in an inferior direction.

Lesion Descriptions

Lesions are specified by their location on the rim of the glenoid fossa. Lesions can occur at all different locations around the rim, however, certain areas are much more likely to be injured than others.

Anterior glenohumeral instability is the most common kind of shoulder instability.[6] There are several different lesions that can cause anterior glenohumeral instability. The Bankart lesion is the most common of all glenohumeral lesions. In a Bankart lesion the anterior joint capsule ruptures, which leads to a displaced labrum. This causes a detachment of the anterior portion of the labrum from the glenoid rim, while leaving the inferior

glenohumeral ligament intact with the labrum. In a bony Bankart lesion, there is

also a fracture in the anterior glenoid bone. A Hill-Sachs lesion can also be

associated with a Bankart lesion. In a Hill-Sachs lesion there is a fracture in the
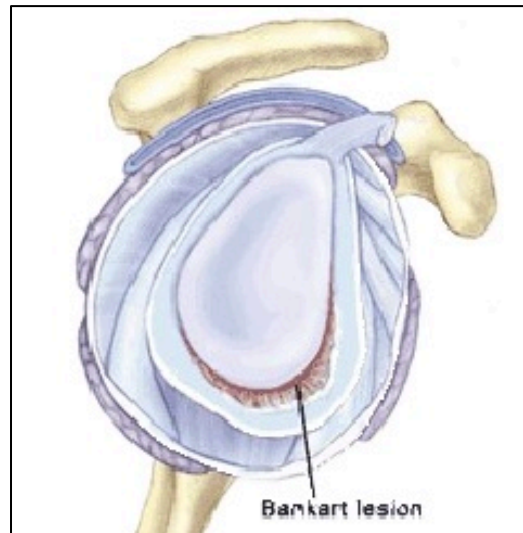
Figure 3: Medial view of a Bankart lesion in a right shoulder.[17]

humeral head caused by compression. The presence of a Hill-Sachs lesion can

contribute to recurring subluxation or dislocation. Another type of lesion that

leads to anterior glenohumeral instability is the anterior labroligamentous

periosteal sleeve avulsion (ALPSA) lesion. This is a tear of the inferior glenoid

ligament from the anterior labrum. In an ALPSA lesion the joint capsule remains

intact. There is also the humeral avulsion of the inferior glenohumeral ligament

(HAGL) lesion. In a HAGL lesion the glenoid ligament tears at its mid-portion, or

is torn from the humeral insertion. This lesion sometimes involves an associated

anterior labral tear, but not in all cases. Lastly, there is the glenolabral articular

disruption (GLAD) lesion. This involves a anterior inferior labral tear, however,

the tear is superficial are usually does not result in shoulder instability.[6]

The shoulder can also experience posterior glenohumeral instability. This can be caused by acute posterior dislocation. Glenohumeral instability is much less common in the posterior direction than the anterior direction, because the posterior glenoid labrum is less likely to experience extreme force. The first kind of posterior glenohumeral instability is the reverse Bankart lesion, which is a posterior labral tear. This is cause by an anteromedial superior humeral head impaction, such as falling on outstretched arms with the arms abducted. There is also the Bennett lesion. The Bennett lesion involves an extra-articular posterior ossification that is associated with posterior labral injury and posterior articular surface rotator cuff damage. This begins with ossification of the posterior band of the inferior glenohumeral ligament, leading to posterior capsular avulsion, which then results in a Bennett lesion. This can be initiated by a posterior subluxation of the shoulder. Posterior glenohumeral instability can also be caused by posterior superior glenoid impingement. This is caused by repetitive impingement of the inferior surface of the rotator cuff, such as in throwing athletes. This puts several structures in the shoulder at risk for injury, including the superior labrum, the rotator cuff tendon, the greater tuberosity of the humeral head, the inferior glenohumeral ligament, the glenoid labrum, and the superior glenoid fossa bone. The repetitive movement causes stretching of the joint capsule and leads to instability in the shoulder, allowing increased angulation in abduction and external rotation.[6]

The shoulder can also experience instability in multiple directions, called multidirectional glenohumeral instability. The most common lesion is the superior labrum from anterior-to-posterior (SLAP) tear. A SLAP tear is a separation between the labrum and the glenoid in the superior portion of the glenoid, close to the biceps tendon anchor. There are several different types of SLAP tears. Type 1 involves a frayed and degenerative superior labrum with normal biceps tendon anchor. Type 2 involves a frayed superior labrum, and detachment of the superior labrum and biceps anchor from the bone. Type 2 often results in a gap between the glenoid bone and the glenoid labrum, where it is attached to the biceps tendon. Type 3 involves a bucket-handle tear of the superior labrum, which is a vertical tear through the superior labrum, which does not extent into the biceps tendon. In type 3 the biceps anchor remains stable and intact. Type 4 also involves a bucket-handle tear, but with type 4 the tear extends into the biceps tendon. SLAP tears are the most common type of multidirectional glenohumeral instability, however this is still far less common than anterior glenohumeral instability, particularly the Bankart lesion. The biceps anchor still remains well attached to the superior labrum in Type 4, but both are detached from the bone.[6] Superior labral tears do not need to be onset by a traumatic event, and are a common occurrence from again. SLAP tears can go undiagnosed and asymptomatic, but show up on a MRI. These asymptomatic SLAP tears should not be repaired, in these cases the effects of surgery are not beneficial for the patient, and it is not worth the risks involved.[18] Multidirectional glenohumeral

instability can also be atraumatic, with no ligament or labral lesions present. In this case the capsular ligaments are redundant, and the labrum is often hypoplastic.[6]

Glenohumeral instability can also be caused by anatomical variances. For example, the Buford complex can cause multidirectional glenohumeral instability. This is a rare congenital impairment, found in only about 1.5% of patients. The Buford complex involves 3 elements: a cord-like middle glenohumeral ligament, rather than the normal sheet-like morphology, a middle glenohumeral ligament that attaches directly to the superior labrum anterior to the biceps tendon, rather than attaching to the anterosuperior labrum, and an absent anterosuperior labrum. All 3 elements must be present for the issue to be defined as a Buford complex. Another anatomical variance is the sublabral foramen. The sublabral foramen is a gap between the labrum and the glenoid rim, typically present in the anterior-superior quadrant. It can range in size from a few millimeters to the entire length of the quadrant. The sublabral foramen is a congenital defect, but it is not a cause of instability. However it can easily be mistaken as a Bankart or SLAP lesion.[6] Since the Bankart lesion accounts for the majority of shoulder instability cases, the focus from this point on will be strictly on this lesion.

Treatment Options

Non-Surgical

Glenohumeral instability is not an issue that will heal itself. Treatment is necessary to restore normal anatomy and prevent recurrent dislocations. Non-

surgical treatment can be used for minor cases of shoulder instability.

Immediately after dislocation the first step is to reduce the dislocation. It is

important to do this as soon as possible because the more time the shoulder

spends out of place, the more the surrounding anatomy will be damaged and

stretched. Once the shoulder has been reduced a sling can be used to immobilize

the shoulder and non-steroidal anti-inflammatory drugs (NSAIDS) can be used to

reduce pain and swelling.[19] NSAIDS only offer short term pain relief for the

patient, and are not a viable long-term solution.

Once the pain and inflammation of the dislocation have gone down it is

important to avoid redislocation.[20] This can be done through activity

modification, by modifying daily activity to avoid those that aggravate symptoms.

This method requires a change in the patient's lifestyle, which is often not an

option, especially for athletes.[19] Physical therapy can also be done to strengthen

the surrounding shoulder muscles and work on controlling the joint. Non-surgical

methods have a poor success rate, only working for about 16% of patients.[20] The

success rate is ever lower, at about 6%, in young patients where the injury is

most common. Non-surgical methods are best if only used to reduce pain

immediately after dislocation, and not used as a long-term solution.

Open Surgery

Open surgery used to be the gold-standard method for repairing shoulder

instability.[4] In this method a surgeon makes in incision in the shoulder to gain

access to the glenoid. Once the glenoid has been accessed a hole is drilled into the

edge of the bone of the glenoid fossa. An anchor is then placed into the drill hole and sutures, attached to the anchor, are used to tie the labrum securely in place.[21] Open surgery has a high success rate with redislocation only observed in 2% of shoulders operated on.[22] However, the incisions made during open surgery cause damage to the soft tissue of the shoulder negatively affecting the range of motion. 31% of patients who undergo open surgery never regain full range of motion of the shoulder.[22]

Arthroscopic Surgery

Arthroscopic surgical techniques for repairing shoulder instability were first introduced in the 1980's.[4] The arthroscopic surgical methods first used had a good initial success rate, but over time that success rate quickly diminished with almost 50% of patients experiencing recurrent dislocations over time.[4] As surgical methods progressed the procedure was made to more closely mirror that of the open surgical procedure.[23] Current methods involve accessing the shoulder joint through cannulas, rather than through an open incision, and then using the same methods as the open surgery to place the anchor and then use sutures to tie down the labrum.[5]

As the methods were improved and better surgical instruments developed the success rate has seen a drastic increase. The current redislocation rate is reported to be about 4%, only slightly higher than that of the open surgery.[24] Of the patients that experienced redislocation, 75% of dislocations had a traumatic onset.[4] Most surgeons report that this value is now even lower the recurrence

rate of open surgery due to recent improvements in surgical technology.

Arthroscopic surgery enabled 86% of patients to return to their pre-injury level

of competition.[4] There is significantly less loss in the range of motion, with loss of

abduction, forward flexion, and internal rotation all at less than 10°.[4] The loss of

external rotation ranged from 0 to 30°, but the average was only 2.4°.[4] There was

no significant difference found in the recurrent instability, loss of external

rotation, or loss of external rotation, between open and arthroscopic

stabilization[24] The benefits of the arthroscopic stabilization are now apparent

and outweigh those of the open method. Arthroscopic surgery is now considered

the standard method used for shoulder stabilization.[4]

Bankart Repair

The goal of the Bankart repair is to restore stability by re-tensioning the

joint capsule and inferior glenohumeral ligament, and re-securing the labrum to

the glenoid.[25] This is done by arthroscopically implanting suture anchors into the

bone about 1 to 2 mm inside of the edge of the glenoid. Anchor location on the

glenoid is described by hours on the clock, with the superior point on the glenoid

being 12 o'clock, and the inferior point being 6 o'clock. In the right shoulder 3

o'clock is on the anterior side of the glenoid, and in the left shoulder 3 o'clock is

on the posterior side of the glenoid. Typically three anchors are used, placed at

the 1:30, 3, and 4:30 o'clock positions in the right shoulder (10:30, 9, and 7:30

o'clock positions in the left shoulder). Anchor placement locations can be seen in

Figures 13 and 14. In some cases 4 anchors are used, which are places at the 1, 2,

3, and 4:30 o'clock positions in the right shoulder (11, 10, 9, and 7:30 o'clock positions in the left shoulder).[26] Anchor placement for different anchor kinds, rigid and soft, are typically the same.

Summary

The anatomical constraints of a shoulder instability repair are to re-secure the labrum to the glenoid, and prevent redislocation, while restoring full range of motion. It is also important to retain as much of the anatomy as possible. This means removing as little bone as possible when drilling holes for the anchors, and using arthroscopic methods to negate the need for an incision.

CHAPTER 2: REVIEW OF CURRENT TECHNOLOGIES

Introduction

The anchors used in shoulder instability repair are an important factor in the long-term success of the surgery. Recurrent shoulder dislocation after surgery is often due to anchor failure. If the anchor success rate can be improved it can greatly improve the overall success rate of the procedure. In order to design a better anchor, first the pros and cons of those currently on the market should be closely examined.

Rigid Anchors

Knotted

Original arthroscopic surgical methods used a transglenoid suture technique introduced by Caspari.[27] However, this technique had a high recurrence rate in long term studies.[28,29] The suture anchor was then developed in attempt to more closely mimic the techniques used in open Bankart surgery.[23] The suture anchor has proven to have a much higher success rate, particularly in long-term studies, than other arthroscopic techniques.[30] The goal of the suture anchor is to stay securely anchored in the bone, and reliably hold down the labrum and joint capsule tissue. The rigid, knotted suture anchor is the oldest suture anchor still used regularly today.

The anchors studied here are the Mitek GRYPHON suture anchor, and the Arthrex SutureTak.[5,31] The knotted anchor is a cylindrical anchor with 6 or 7 treads around the outside. The diameter ranges from 2.0 to 3.7 mm, and width is chosen based on the surgeon's discretion. There are several factors that go into choosing the anchor size, including the load it needs to bear, and the space
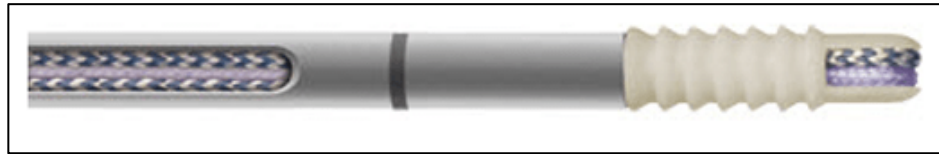
Figure 4: Mitek GRYPHON, rigid knotted suture anchor.[31]

available in the bone, but the ultimate goal is to be able to use as small an anchor as possible. The 2.4mm diameter anchor is used most often.[32] Knotted anchors are typically about 12 mm long.[5] A suture is attached to the anchor, through an eyelet hole either at the end of the anchor, or looped down through the anchor. There can be one or two sutures looped through a single anchor to produce a single-loaded, or double loaded anchor respectively. The anchor is made of a proprietary biocomposite material, and the suture used is a high-strength orthopedic suture, size 1 or 2.

In order for the anchor to be placed, the site must fist be prepared. The cannulas must be places for the surgeon to gain access to the joint. The bone at the anchor sites is then debrided and any articular cartilage is removed to clear a path for the drill. It is important that the bone is debrided, so the labrum will be in contact with healthy tissue when it is anchored down. This will help to promote biological healing of the lesion after repair.[25] Next, the drill holes must

be made. The drill bit is the size of the anchor being used, so typically 2.4 mm.

The drill hole is made at a 40° angle to the surface of the bone. Once the drill hole

has been made the anchor is inserted into the hole. The surgeon does this by

lightly hammering it into place. The treads around the anchor help to keep the

anchor in place in the bone. Once the anchor is securely in the bone the suture

limbs are used to tie the glenoid into place. The surgeon performs capsular
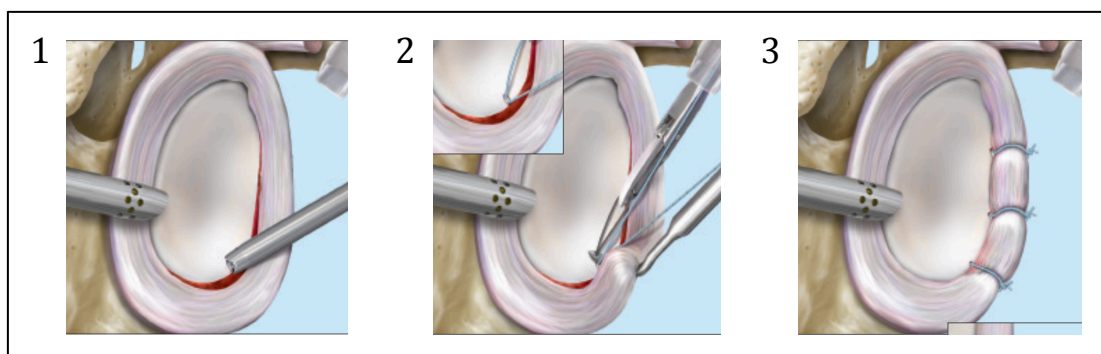
Figure 5: Steps to repairing a Bankart repair with rigid knotted anchors. 1. The drill hole is made in the bone and the anchor is implanted. 2. The sutures are used to secure the soft tissue to the bone. 3. The necessary number of anchors are put in place.[5]

plication when securing down the labrum and also secures down the excess joint

capsule tissue. This helps to tension the joint capsule.[32] By securing down the

labrum this also helps to reintroduce tension to the inferior glenohumeral

ligament, which is attached to the labrum. Once the suture has been tied, a suture

cutter is then used to remove the suture limbs and then the surgical site is closed.

This process is done for however many anchors the surgeon has determined

necessary for the repair.

There are several different ways the knotted anchor can fail. The anchor

can break, the anchor can pull out of the bone, or the suture could fail. Suture

failure includes the knots coming loose, the suture breaking, or the suture tearing

through the soft tissue that it is holding in place. All forms of suture failure are

rare with very few reported cases of each. When the anchor breaks it can either

be the body of the anchor that breaks, or the suture eyelet. The body of the suture

rarely breaks since it is fit well into the drill hole. Eyelet failure and anchor pull

out are the two most common modes of failure for the knotted anchor.[33] There

have been better results seen, with less anchor failure, when the suture is looped

through the anchor, rather than just a small eyelet at the top of the anchor.[33]

When the anchor fails by pullout the entire anchor stays intact, but is pulled out

of the drill hole.

Knotless

The knotted anchor is a reliable method for instability repair, however,

the suture knots involved in the design can irritate the surrounding articular

cartilage.[34] This lead to the development of the knotless rigid anchor. The

Figure 6: Arthrex SutureTak rigid knotless anchor.[5]

knotless anchor is very similar to the knotted anchor; however, the surgical

methods used to implant the anchor are slightly different. The anchor design,

shape, and materials are all the same as that of the knotted anchor, as can be seen

in Figure 6. The difference is in the way that the suture is attached to the anchor

during surgery. The key to the knotless anchor is the suture-first method.

The anchor studied here is the Arthrex SutureTak Knottless, and the

Arthrex PushLock.[5] The surgical method for the knotless anchor starts off the

same way as the knotted. The surgeon access the site through cannulas, then

debrides the area, and articular cartilage cleared. The next step is where the

knotted and knotless differ. Next, the sutures are tied around the glenoid,

preforming capsular plication to take a portion of the joint capsule, before the

anchor is implanted. The sutures are then attached to the anchor outside of the
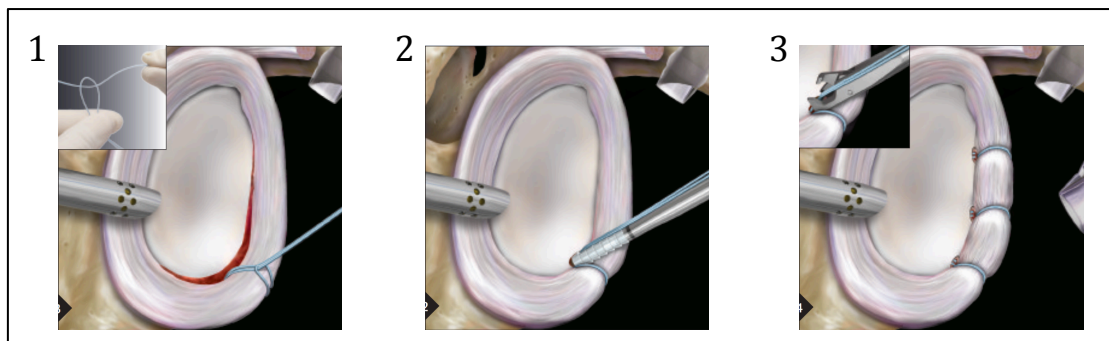
Figure 7: Steps to repairing a Bankart lesion with rigid knotless anchors. 1. The suture is wrapped around the glenoid and a portion of the joint capsule. 2. The drill hole is made and the anchor is implanted, tensioning the suture limbs as it is inserted. 3. The necessary number of anchors are put in place.[5]

body. The anchor is then implanted normally, by drilling a hole for the anchor,

and lightly hammering the anchor into place. By implanting the anchor with the

suture going in first, it eliminates the need for knots. The suture is tensioned as

the anchor is hammered in, tensioning the labrum and joint capsule along with it. Finally the extra suture limbs are removed and the surgical site is closed.

Post-surgery the knotless anchor works the same as the knotted, with the anchor treads holding it into the bone and sutures holding the soft tissue down. The failure methods for the knotless anchor are also similar, however, with this design there is no longer a suture eyelet, so the potential for eyelet failure is eliminated.

Soft

The rigid anchor methods are well-tested and reliable methods for labrum fixation, however their diameters are large for being implanted in small area of bone. Drilling holes into the bone of the glenoid removes bone, and is bad for the overall quality of the bone. Large drill holes increase the risk of bone perforation or crack propagation. The soft anchor has recently been developed in attempt to decrease the amount of bone removed during implantation, by utilizing a smaller drill hole. Another issue with the rigid anchor is that the surgeon must have direct access to the bone, in-line with the drill hole to implant the anchor. Some areas in the glenoid can be difficult to access, so by creating an anchor out of soft material, surgeons can more easily access those hard to reach areas.

The anchors studied here are the Biomet JuggerKnot, and the Smith & Nephew SutureFix ULTRA.[35,36] The suture anchor is an anchor made of only suture. It consists of a suture, with a 2.9 mm sleeve around the middle, which can be seen in Figure 8. This sleeve is the anchor. The suture can be single or double

loaded. The sleeve is made out of braided polyester, and the suture used is the same high-strength orthopedic suture that is used for the rigid anchors.

Figure 8: Smith & Nephew SutureFix Ultra soft anchor. On top is an image of the un-deployed anchor, and the deployed anchor on the bottom.[35]

The surgery for the soft anchor placement starts the same as the rigid anchors, with cannulas implanted and the surgical site prepared through debridement. Next, the hole for the anchor is drilled. The drill hole for the soft anchor is only 1.4mm wide. The drill hole for the soft anchor can be so much smaller than that of the rigid anchors since there is no hard material being
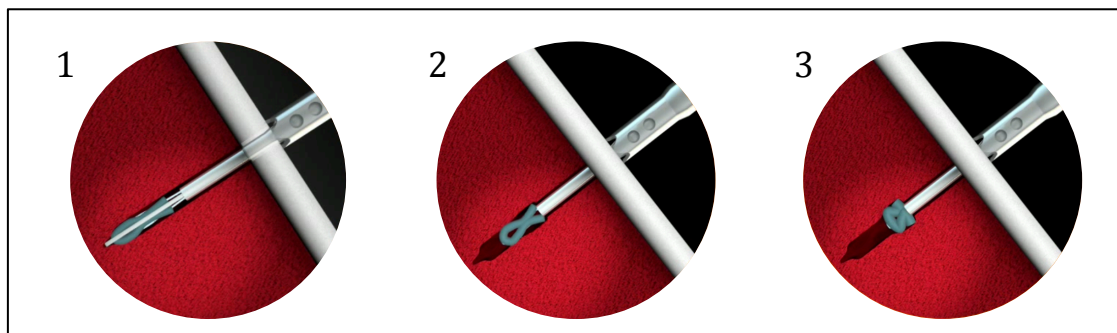
Figure 9: Steps to implant the soft suture. 1. The un-deployed anchor is inserted into the drill hole. 2. The suture limbs are pulled on and the top of the sleeve hits the bottom of the inserter and begins to expand. 3. The sleeve becomes bunched against the bottom of the inserter and the widened diameter anchors the entire thing in the bone.[35]

implanted into the bone. Next the anchor is inserted into the drill hole. This is done using a metal inserter, which is also used to deploy the anchor. The anchor is deployed by pulling quickly and tightly on the suture limbs. When the suture limbs are pulled the polyester sleeve gets caught on the bottom of the metal inserter and expands outward. Some designs also deploy the soft anchor without use of the metal inserter. These designs rely on the sleeve getting caught on the inside of the cortical layer of the bone, and expanding in the same way as those that use the metal inserter. When the sleeve expands into the surrounding trabecular bone it secures the anchor in place. The expanded diameter of the anchor is 6.3± 2.5 mm.[14] Once the anchor has been successfully deployed the sutures are tied around the glenoid, using capsular plication to tension the joint capsule. Knots must be used to secure the soft tissue down in this design. The sutures hold the soft tissue down to the bone in the same manner as with the rigid anchors. Once the knots are tied suture cutters are used to remove the excess suture limbs, then the surgical site is closed.

The mode of failure of the soft anchor is almost exclusively anchor pullout.[32] The strength of the suture is not an issue. The predicted mechanism of anchor pullout is that cyclic loading of the anchor in different directions, as the arm moves in regular daily activity, causes the anchor to move and slip on the bone shelf that was created during anchor deployment. This slipping causes that bone to slowly wear away and eventually allows the anchor to slip out of the drill hole. The soft anchor has not been on the market for a long time, so the actual

mechanism for anchor failure has not yet been published. There are also currently no long-term tests published on the success rate of the anchor. These will be important factors to study once the anchor has been on the market for a longer time.

Experimental Methods

There are several different experimental surgical techniques that have been proposed to improve patient outcome of the stabilization surgery. One method is the labral bridge technique. The goal of this technique is to spread the load experienced by the labrum more evenly across the whole labrum, so it is not just concentrated at certain points where the anchors are attached. It is predicted that providing an even pressure distribution across the length of the glenoid could potentially encourage biological healing of the lesion.[25] The current
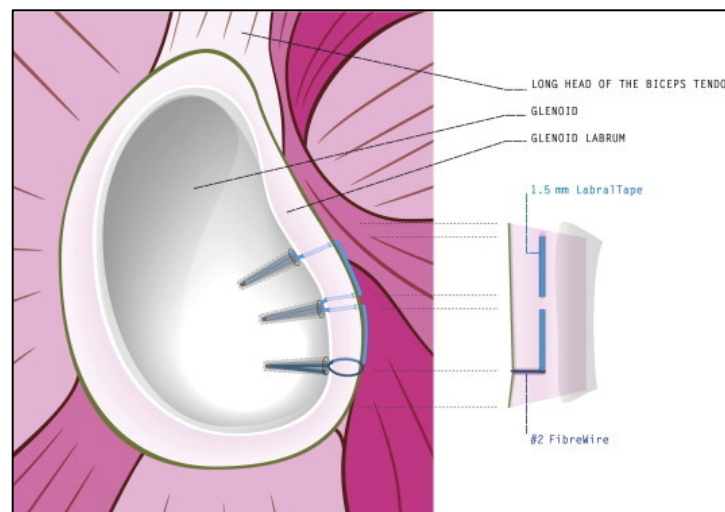
Figure 10: The labral bridge technique, using one labral tape to attach all three anchors and spread the load more evenly across the labrum.[25]

surgical methods only secure the soft tissue down at certain points, where the anchors are located, leaving the area between the anchors unattached to the bone. The labral bridge technique involves using a labral tape to connect all of the anchors being used. Suture anchors are implanted according to the method appropriate for that anchor type, however, before the sutures are tensioned around the soft tissue labral tape is passed through the suture, on top of the labrum. This same labral tape is passed through the suture of all 3 or 4 anchors being used in the repair. The labral tape is first secured into the bone along with the sutures of the first anchor. As the labral tape passes between anchors it is wrapped around the labrum an additional time, also tensioning the joint capsule at the same time. Finally the remaining limb of the labral tape is attached with the last anchor. By wrapping the labral tape around the glenoid an additional time, it helps to secure the tissue between the anchors more closely to the bone. This technique has not been studied over an extended period of time, and there are not long-term results on weather or not this technique reduces the recurrence rate of instability.[25]

Another experimental method proposed is that using fewer anchors is better for the overall outcome of the surgery. This method suggests that instead of using 3 anchors to secure the labrum, just one should be used at a central location. One anchor is able to secure the entire lesion down by using the purse string method when suturing the soft tissue. Instead of just suturing the tissue right above the anchor, the purse string method has each suture limb extend out

in opposite directions along the length of the lesion. Each suture limb is inserted

through the joint capsule and around the labrum at opposite ends of the lesion,

then tied back together in the middle.[37] This method works because when the

"purse strings," or sutures, are pulled there is an increase in the volume of tissue

around the location of the anchor, created by a bunching of soft tissue. This

method relies on this barrier created by the superomedial shift of the

capsulolabral tissue to prevent further dislocation. The short-term results of this
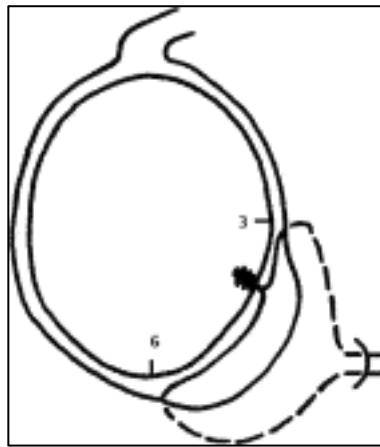
Figure 11: Anchor and suture placement for the purse string technique.[37]

study show a low rate of recurrence, however, there are no long-term studies

done.[37] By relying on the bunched soft tissue, this method changes the

mechanism by which the shoulder prevents dislocation. Normally, the shoulder

prevents dislocation by relying on the tension of the glenoid labrum and

surrounding ligaments. However, with this method, dislocation is prevented by

blocking the path of the humeral head with bunching of soft tissue.[37] It is

predicted that by relying on the soft tissue in this manner will cause the tissue to

wear away. Also, by bunching extra tissue together with sutures, the risk of the

suture tearing through the soft tissue is greatly increased. It is predicted that this method will not succeed in long-term studies. The ability of the lesion to heal biologically is also impeded because by bunching the tissue in this manner the fixation does not secure adequate contact between the glenoid and the labrum.

Anchor Comparison

Now that the design and mechanisms of each anchor type have been laid out, these factors will be compared. This will then be used in designing a new anchor prototype. An anchor prototype should ideally build off of the pros of each anchor type, and try to minimize the overall cons.

The presence of suture knots in the anchor is bad for articular cartilage. The knots can irritate the surrounding articular cartilage, and irritated soft tissue does not promote healing.[34] Rigid anchor offer the option of being knotless, while still maintaining the strength and stability of the knotted counterpart. The soft anchor still contains knots. The current soft anchor design does not allow for the suture-first technique to be used. Because of the way the sutures must be pulled tight for anchor deployment the soft tissue must be secured down using knots.

Preserving as much bone as possible during surgery is important. The smaller the drill hole size is, the better it is for the quality of the bone post-surgery. With a smaller drill hole size more bone is preserved. It is important to preserve as much of the bone as possible to prevent perforation of the glenoid rim, or the creation and propagation of a crack in the bone. Also, with a large drill hole, surgeons must be careful to avoid drill hole intersection, which happens

when the paths of two separate drill holes cross[38]. Drill hole intersection ruins the integrity of all drill holes involved, and potentially the surrounding bone. One of the important benefits of the all suture anchor is that the drill hole size is significantly smaller than that of the rigid anchors. The drill hole size for the soft anchors is 1.4 mm, while that of the rigid anchors is 2.4mm. Smaller drill hole size also enables surgeons to place more anchors in a smaller area, which is useful for difficult repairs

The anchor placement method can also affect the integrity of the surrounding bone. When the anchor is implanted into the bone it can be damaging to the bone. Both anchors cause the size of the drill hole to expand when the anchor is implanted and deployed. The rigid anchor is hammered into the bone when implanted. In this process the rigid piece is forced into the drill hole previously created. This process can be damaging to the surrounding bone. The rigid anchor causes the anchor site to expand to 2.7 mm.[14] The soft anchor widens when deployed. This is how the anchor stabilizes itself in the bone without using any rigid materials; however, this expansion causes the soft anchor to then take up more space in the bone than originally accounted for. The soft anchor expands to have a width of 6.3 ± 2.5 mm.[14]

Another factor to consider is the anchor presence in the bone after surgery. After the surgery is complete it is better to have a smaller anchor presence left in the bone. With less foreign material present, it allows for a greater potential of biological healing to occur at the insertion site.[39] The soft

anchor has a significantly smaller presence in the bone after the insertion is complete. The drill hole for this fixation is only filled with sutures and the polyester sleeve, and the cortical bone only has the sutures going through it. If the bone is able to heal around the sutures in this area it could greatly increase the stability of the anchor, and decrease the likelihood of anchor pullout. The rigid anchor fills the drill hole initially created, not allowing much room for biological healing to occur within the bone.

The soft and flexible nature of the soft anchor can also be beneficial for anchor insertion. A downside of the rigid anchor is that when the anchor is implanted the surgeon must have direct access to the anchor site in line with the drill hole. This can make it difficult to get to the inferior portion of the glenoid, particularly at the 6 o'clock positon.[38] Soft anchors offer a more flexible option, and can make it easier for surgeons to get to those hard to reach locations.

The mode of failure of the anchor is important to consider because when the anchor fails it could potentially cause damage to the shoulder. When the hard anchor fails it is typically by anchor pullout or eyelet failure. When this occurs there is a hard body left in the shoulder. This rigid body is no longer anchored down to the bone, and is able to move freely throughout the shoulder. This could potentially cause damage to the soft tissue in the shoulder. Since the soft anchor is made of just suture and does not contain any rigid pieces the likelihood of soft tissue damage is greatly reduced.

The ultimate load at 2mm displacement determines what load it will take for the labrum to separate from the glenoid by 2mm. This distance is studied because recurrent instability has been clinically found to occur when the separation between the glenoid and the labrum reaches 2mm. In a test performed by Mazzocca on cadaveric shoulders, rigid and soft anchor loads at 2mm displacement were compared. The rigid anchor failed at an ultimate load of 84 ± 19 newtons (N), and the soft anchor failed at an ultimate load of 39 ± 11 N.[32] There was a significant difference between the results observed for the rigid and soft anchor. It would take a much higher load on average to for recurrent instability to occur with the rigid anchor than the soft anchor. A useful next step for this study would be to compare those loads to loads that are experiences physiologically and determine if these results are clinically significant.

Small amount of displacement can happen just from cyclic loading, which occurs when the arms moves during daily activities. Ideally there will be no displacement of the anchor once it is set in the bone. Displacement can cause the anchor to loosen and can lead to recurrent instability and anchor failure. In the soft anchor, displacement occurs through cyclic loading. This displacement is predicted to occur as the bone that the sleeve is anchored against is further compressed, and worn away. The displacement from cyclic loading can be up to 1 to 2 mm, which is significant since at 2mm displacement the shoulder is considered unstable.[14] Also, a major problem with the soft anchors on the market is the formation of cysts in the bone at the site of the anchor. It is predicted that

the displacement of the soft anchor during cyclic loading is irritating the surrounding bone tissue, and causing the formation of these cysts. This is detrimental for the long-term success of the anchor because irritated tissue does not heal well. There is no displacement observed with the rigid anchor during cyclic loading.[14]

The cadaver testing by Mazzocca also tested for the load to failure and the total displacement at failure for the rigid and soft anchors. The load to failure was the ultimate load required to cause the anchor to fail. The total displacement at failure was the amount of displacement between the labrum and the glenoid at the time of failure. There was no significant difference observed in either the load to failure or the total displacement at failure between the soft and the rigid anchor.[32] However, these tests were performed in cadavers and failure was defined as when the anchor failed, usually by pullout or eyelet failure. These tests are not necessary anatomically significant. The results of the ultimate load at 2mm displacement is much more applicable to what is clinically significant.

Lastly, a very important factor to consider is the time the product has been on the market. The rigid anchor has been on the market for quite a while now, while the soft anchor is new to the market. Having more time on the market means a product is well tested. The rigid anchor has been tested under many different circumstances, including many long-term studies. There are no long-term studies published for the soft anchor. Long-term studies are important for this repair because the likelihood of recurrent instability occurring increases

with every year after surgery. Important factors like the recurrence rate of instability, and the anchor performance over time are still not well known for the soft anchor. These factors are necessary information for surgeons and patients to have to make the appropriate decision of which anchor is best for a repair.

Force Body Diagrams

Cadaver Testing

Many tests comparing different aspects of suture anchors are performed on cadavers. These cadavers help to provide useful information about the anchors and their failure mechanisms. However, the testing done on the cadavers does not directly mimic what is happening anatomically. In Mazzocca's cadaver tests the ultimate load at 2 mm displacement, ultimate load at failure, and displacement were compared in a rigid knotted Arthrex SutureTak anchor and a soft Biomet JuggerKnot anchor.[32] This study also compared these factors in anchors implanted in the anterior-inferior (AI) quadrant of the glenoid, with anchors implanted in the posterior-inferior (PI) quadrant.

Anchors were implanted into the glenoid at a 40 degree angle to the glenoid face, which is the angle typically used clinically. Anchors were placed at the edge of the glenoid. Two anchors were place in each quadrant being studies, one 6mm away from the centerline (6 o'clock) and then the next another 6mm away. The sutures were then tied around the glenoid. Capsular plication of exactly 1cm is done at a sagittal angle to the glenoid for each anchor. Before the sutures were tied an extra suture was placed along the edge of the labrum. This

same suture was passed through both anchors in each respective quadrant. This

extra suture is used for the load testing. The experimental set up can be seen in

Figure 12. Cyclic loading was done on the anchors immediately after implanting

to precondition them. 10 cycles of preloading were performed at 0 to 10 N. Once
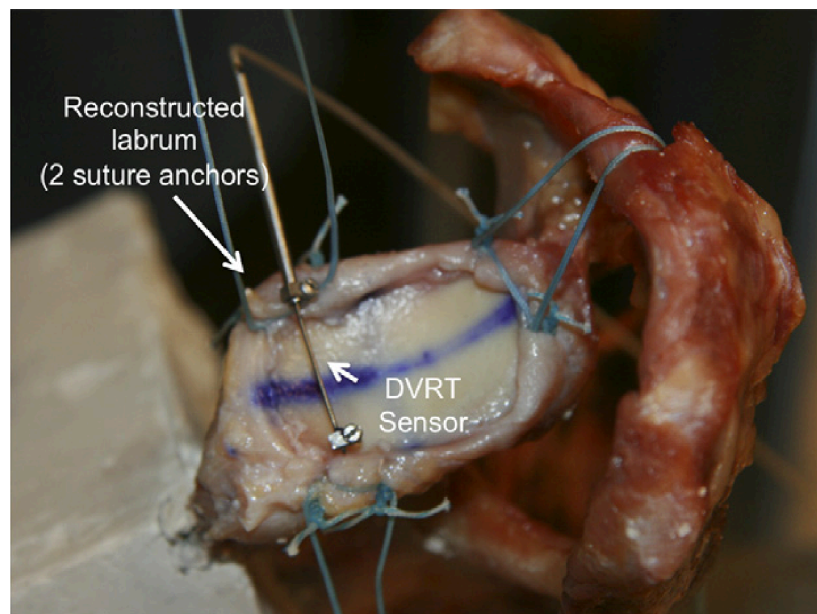
Figure 12: Experimental set up for cadaver testing. The blue line divides the glenoid into anterior and posterior portions, with the inferior side on the left. Anchors are implanted and suture limbs are shown for the test suture.[32]

preloading was complete the sutures were pulled until anchor failure. The

sutures limbs were pulled in the anteroinferior direction for preloading and

testing. The anteroinferior direction was chosen because the shoulder is least

stable in that direction.[32]

Animations of the experimental set up with force body diagrams for both

the AI and PI direction can be seen in Figures 13 and 14 respectively. At the AI

anchor position the direction of force in in line with the anchor, but at the PI

anchor position the direction of force is in the opposite direction. When the force

is in the direction of the anchor the anchor can be pulled out more easily. For the

PI anchor position the anchor will not pull out as easily, however, extra force is

put on the bone above the anchor, which could cause that bone to fracture.
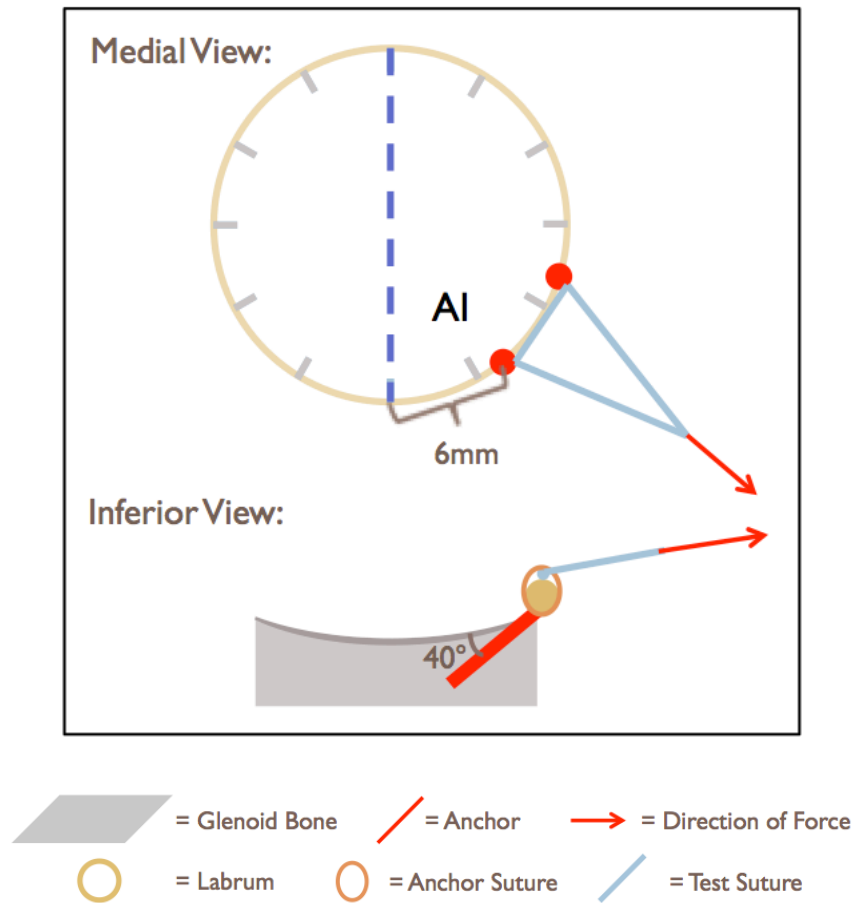
Figure 13: Experimental set up and force body diagram for the AI anchor position. The top image shows the medial view and the bottom shows an inferior view. Positions are given for a right shoulder. The key for the image is shown at the bottom.

The clinically significant result of this experiment is the load at a

displacement of 2mm. This study focused on the differences between anchor

types, however, by examining their data the differences between anchor in the AI

quadrant and the PI quadrant can be compared. The differences observed are not

significant, however, there is an increase observed in the load to 2mm

displacement at the PI position. The results can be seen in Figure 15. This can be
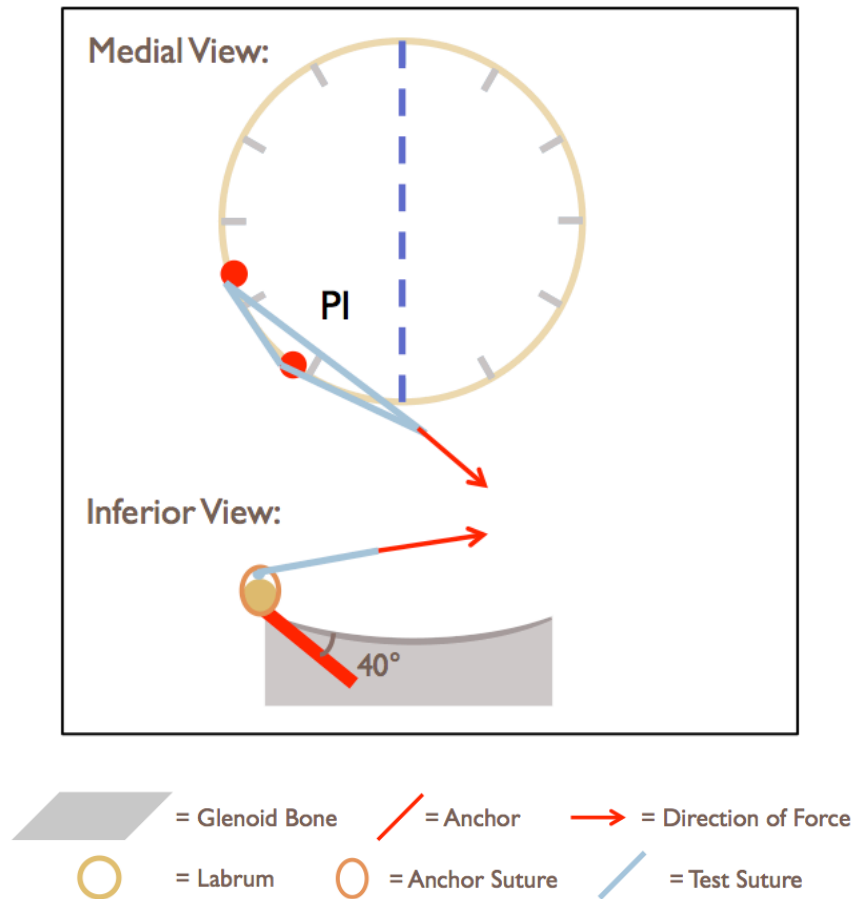
Figure 14: Experimental set up and force body diagram for the PI anchor position. The top image shows the medial view and the bottom shows an inferior view. Positions are given for a right shoulder. The key for the image is shown at the bottom.

explained by the force body diagram of the PI position: at the PI position the

majority of the force is not in the direction of the anchor drill hole, it is against

the bone. This puts torque on the anchor, which could explain why the difference

between the AI and PI position was smaller in the soft anchor. For the rigid

anchor, the entire drill hole is filled with a rigid body, therefore torque is not

allowed to cause much movement of the anchor. However, with the soft anchor,

there is open space left in the drill hole. This open space could allow the anchor

to slip when torque is placed on the anchor, leading to the anchor slipping off of

the shelf of bone it is held against. Other factors must also be considered here,

such as bone quality. The bone in the posterior portion of the glenoid is typically
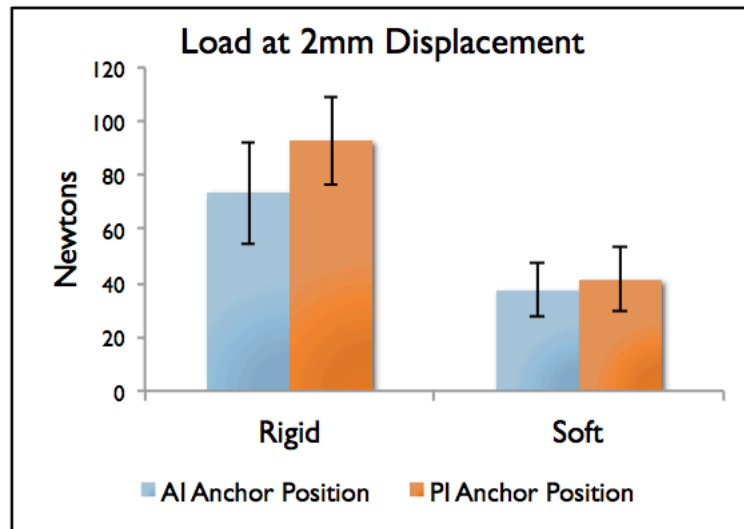
Figure 15: Experimental results of the load at 2mm displacement comparing the AI and PI anchor positions for both the rigid and soft anchors.[32]

more dense than the bone in the anterior side, which could also contribute to a

better anchor outcome.[40]

Anatomical Forces

The forces on the labrum in a live patient after instability repair are not as

clear-cut as those on a labrum during cadaver testing. Forces on the labrum can

come from many different sources. The biceps tendon puts tension on the

superior portion of the glenoid labrum, by holding the biceps muscle in place.

This is not a concern when examining Bankart repairs though, because the lesion

does not extend that far superior. The glenohumeral ligaments are also attached

to the labrum, and then wrap around part of the humeral head to attach to the lesser tubercle. This puts a medial force on the anterior portion of the labrum. Since the glenoid is small in comparison to the humeral head these ligaments also extend in an anteroinferior direction as they wrap around the humeral head.

When the arm is in different positions it can stretch these ligaments and put additional force on the labrum.[41] External rotation of the arm puts the most strain on the glenohumeral ligaments and anterior labrum.[41] When the arm is
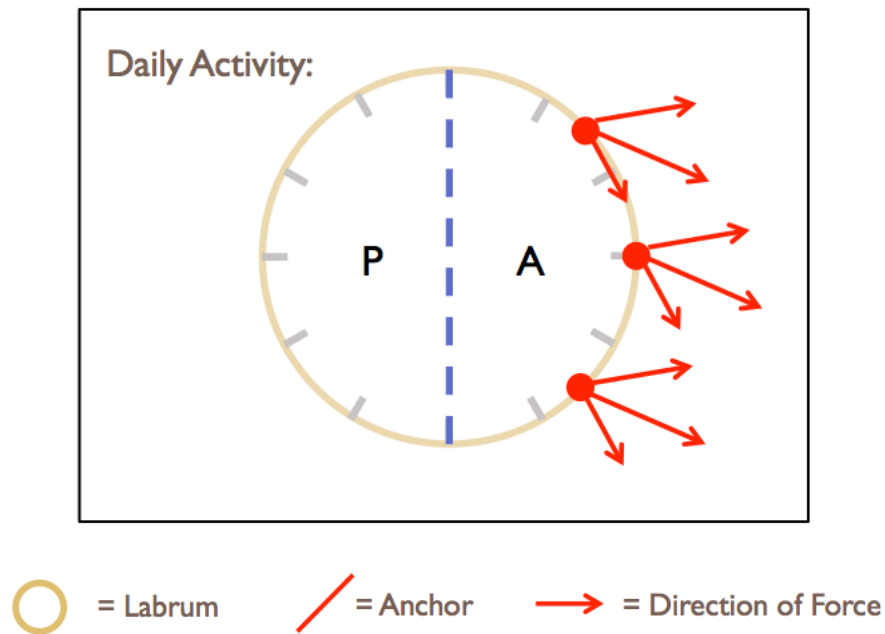
Figure 16: Anchor placement and force body diagram for a Bankart repair during normal daily activity. The medial view of a right shoulder is shown. The key for the image is shown at the bottom.

externally rotated it puts additional force in the medial direction of the labrum. Abduction of the arm may also put additional force on the inferior glenohumeral ligament.[41] The least stable direction of the glenohumeral joint is always the anterior direction, regardless of the position of the arm.[42] The force body diagram

of a Bankart repair in a right shoulder is shown in Figure 16, with the different

directions of force that the labrum experiences during daily activity shown.

Shoulder dislocation puts extreme forces on the ligaments and joint

capsule of the shoulder. When the shoulder dislocates the humeral head moves in

the AI direction. This movement puts pressure on the inferior glenohumeral
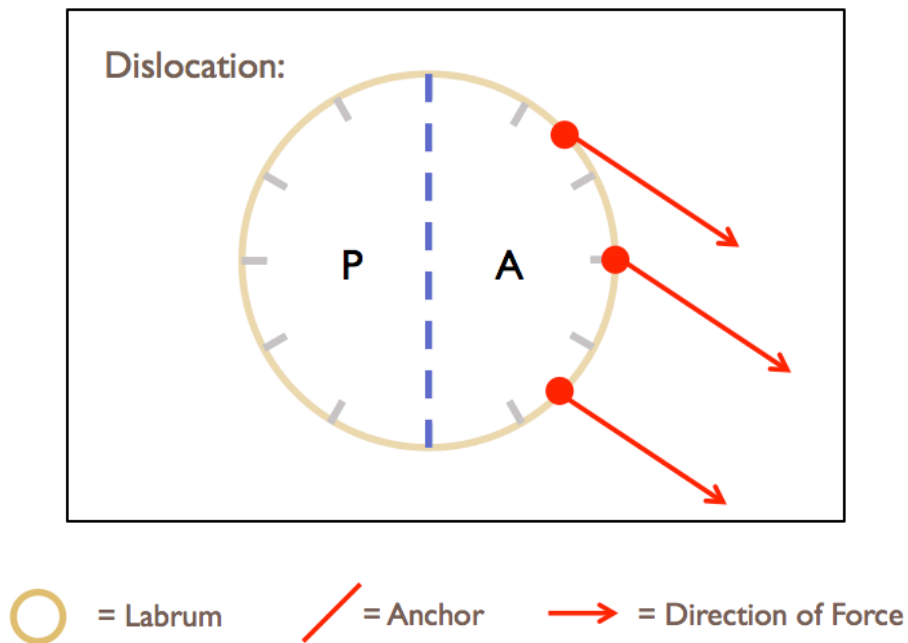
Figure 17: Anchor placement and force body diagram for a Bankart repair during shoulder dislocation. The medial view of a right shoulder is shown. The key for the image is shown at the bottom.

ligament, forcing it to pull on the labrum in the direction that the humeral head is

moving. This is when the most damage is done to the labrum. The force of the

humeral head pushing against the ligaments is much more than the force loaded

on the glenoid during normal daily activity. The force body diagram of a Bankart

repair during dislocation is shown in Figure 17.

The failure mechanism of the suture anchors in patients with recurrent

instability after surgery is not well documented. This information would be

useful to know, not just the failure mechanism, but also which anchor location is failing most often.

Comparison

There are some major differences between the way a labrum is loaded anatomically and the way it is loaded during cadaver testing. A few simple changes could greatly increase the clinical significance of the results of cadaver testing. In a Bankart repair the anchor are spread out evenly across the glenoid, not just in a localized area. Having the anchors more spread out means they are responsible for securing more of the labrum and each is under a greater load. Also, the cyclic loading for the cadaver testing is done in just one direction. In the body, cyclic loading occurs in many different directions as the shoulder moves around during normal activity, not just one consistent direction. The movement in different directions could be what leads to the cyst formation at the site of the anchor. Cyclic loading experimentally should vary directions in the anterior, inferior, and medial directions to better match what is happening anatomically.

Summary

Current anchor designs and failure methods can provide a lot of insight into the different aspects that must be taken into consideration in a suture anchor design. The success of the suture anchor can define the overall success of the entire repair. It is necessary that a design not only is strong enough to bear a high ultimate load, but also that it can handle the cyclic loads of daily activity.

CHAPTER 3: PROTOTYPE DESIGNS

Introduction

Now that the anatomical and mechanical constraints are understood a prototype can be created. A new design should aim to overcome the downfalls of past designs, while being careful to not forgo any of the benefits already established.

Design Criteria

Anatomical Constraints

A suture anchor must abide by certain constraints in order to successfully be implanted in the bone. It must also be able to achieve an adequate level of stabilization in order to be successful. A constricting anatomical constraint of the suture anchor design is the size of the anatomy in the shoulder joint. The bone of the glenoid fossa is small, with the maximum width averaging at 39 ± 3.5 mm, and the height at 29 ± 3.2mm. Also, the labrum is only about 4 mm thick.[43,44] It is also important to avoid the blood supply and nerves in the shoulder when conducting surgery. The suprascapular nerve can sometimes be in the region of the drill holes when placing anchors in the superior portion of the glenoid.[10] These factors make it important that the drill hole is as thin, and short as possible, so the minimum amount of bone is removed. Space is also a concern when the surgery is being performed, because some areas on the glenoid can be

difficult to access. The anchor must be easy to implant and deploy so it can be easily implanted, even in the hard-to-reach areas.

It is also important to preserve the quality of the anatomy. If the tissue is irritated it does not heal well. In the bone anchor micro motion can cause irritation, which can lead to cyst formation in the bone. The bone around the edge of the drill hole is also affected by the anchor deployment method. When the anchor is deployed it should do as little damage to the surrounding bone as possible. Minimizing the anchor deployment width can help preserve that bone. In the soft tissue it is important to promote natural healing. Spreading the load of the anchors as evenly as possible across the entire labrum can help with this. It is also important to establish as much contact as possible between the soft tissue and the bone. Biological healing is predicted to occur along where there is good bone to soft tissue contact.[25] The anchor can also cause tissue irritation if the body rejects the material used. All materials used must be biocompatible.

The initial quality of the bone at the time of implantation can affect the outcome of the surgery. The bone consists of two layers; the outside, cortical bone, which is stronger and more dense, and the inside trabecular bone, which is more porous.[45] The porous trabecular layer of the bone allows the anchor to easily deploy in it, while the rigid cortical layer helps to provide a strong anchoring point in the bone. The quality of the bone also decreases with age. As the quality of the bone decreases so does the density, which could affect how well the anchor stays in the bone.

It is essential that the repair securely reattaches the labrum to the bone, and prevents redislocation. To do this the repair must prevent the glenoid from re-tearing, and re-tension the glenohumeral ligaments and joint capsule all to keep the humeral head in place. The repair should also aim to restore the full range of motion by minimizing scar tissue and using arthroscopic surgical methods.

Mechanical Constraints

Mechanically the anchor must be able to sustain a load, and still hold the repair steady without allowing for any displacement or micro motion. A suture anchor must be able to bear a load of at least 40 N at 2mm of displacement, and an ultimate load of about 150 N to be able to compare with current technology. Anchor failure needs to be avoided as much as possible, by preventing anchor pullout or breakage.

The anchor must also be able to handle forces in different directions. Cyclic forces on the anchor from daily activity can be in the anterior, inferior, and medial directions. The anchor should be able to handle this cyclic loading without becoming displaced, which could lead to instability. Another reason it is important the anchor can handle loads in all directions is that as position of the anchor around the glenoid changes, the direction of the extreme force the shoulder experiences during displacement changes relative to the anchor.

Many shoulder instability surgeries are performed on young patients, with he average age at 25 years.[13] Since the anchors are being implanted into the

shoulders so early it is crucial that they have a long life span. The anchors need to stay stable, and can't loosen or fall out over time, so there is no need for repeat surgery. Also, the material that the anchor is made of must not wear over time. If the material wears it will degrade the integrity of the anchor, and the worn parts can be harmful to the shoulder.

It is also important that the anchor is simple to manufacture and deploy. If an anchor design is too complicated it can become expensive or difficult to mass-produce. Also, if the anchor is difficult to deploy it increases the likelihood of something going wrong during the surgery. Surgeons aim to keep the patient open on the table for as little time as possible, so by maintaining a simple deployment method they can quickly and easily implant the anchor with confidence.

Design 1

Concept of Design

The inspiration for this design originates from trying to maintain the pros of the current designs, while eliminating some of the cons. One pro to maintain is the small drill hole size associated with the soft anchor. The glenoid bone is small so it is best to preserve as much of the bone as possible. To do this it is also beneficial to minimize the size of the deployed anchor. The design should also maintain a simple, yet reliable deployment method. The deployment method cannot be too complicated because that would complicate the surgery.

A con to eliminate include anchor failure. Anchor pullout is the primary form of anchor failure. If the pullout rate of the anchor can be decreased, the overall success rate of the surgery can be improved. It is predicted that micro-motion of the soft anchor in the bone causes the sleeve of the anchor to rub against the bone, causing irritation. This irritation can lead to the formation of cysts inside the bone. When there are cysts in the bone at the anchor site the bone is not allowed to heal properly, which could allow the anchor to more easily slip out of the bone. Therefore, if this micro-motion can be reduced, the rate of anchor pullout could also be reduced.

Inspiration for the anchor also comes from different anchors that are currently on the market. One anchor is the Piton developed by Tornier. The piton is a rigid suture anchor that is used to secure soft tissue down to the bone in various sites in the body. The Piton can be used for glenoid lesions; however, its
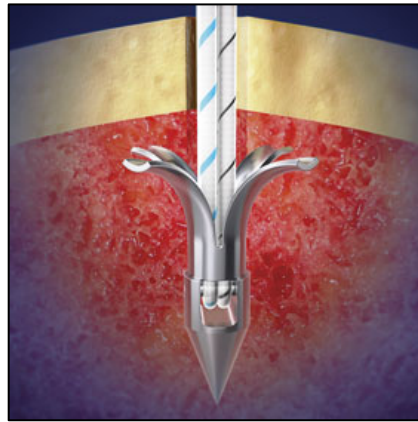
Figure 18: Tornier Piton suture anchor.[46]

wide deployed diameter makes it unideal for this location. The Piton anchors into the bone with several rigid, metal wings, which spread outward and upward

when the suture limbs are pulled upward. The prototype design will also use similar wings, which spread outward and upward when the anchor is deployed.

This prototype design is very similar to that of the current soft anchor design. The soft anchor relies on the sleeve to spread outward at deployment and hold the anchor in place in the bone. For this prototype design a similar design is used, however, instead of using a soft, all-suture sleeve, rigid wings are used. By using rigid wings instead of just the soft sleeve it decreases the ability of the anchor to experience micromotion in the drill hole, because the anchor cannot
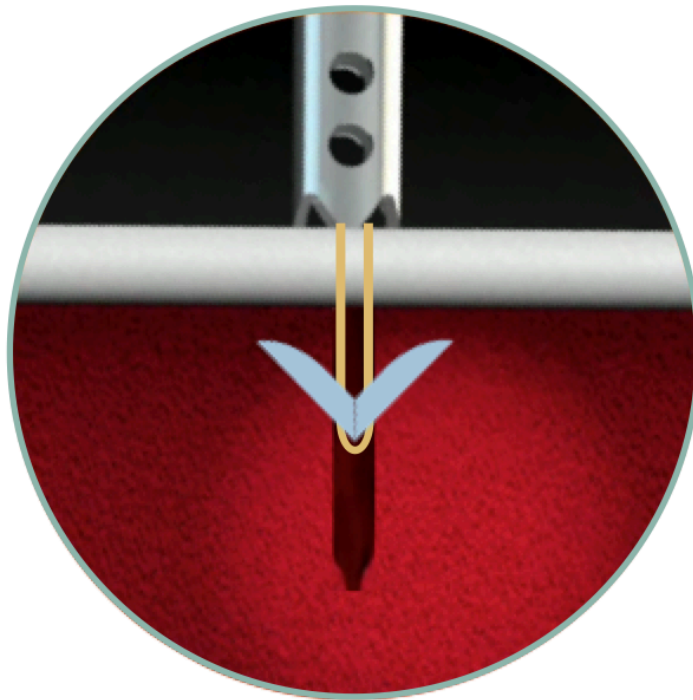
Figure 19: Prototype design 1 implanted in bone.

deform. A benefit of the soft anchor is its small size. Therefore, instead of adding an additional component to the anchor, the sleeve is just replaced with rigid wings. This enables the anchor to maintain its small size. By just using a kind of

rigid sleeve in place of the soft sleeve the current deployment method can also be easily modified for this anchor.[35] This anchor design can also be considered similar to that of a Toggle Bolt, which is a kind of anchor used for walls. This anchor works by having two wings that are folded in at insertion, but then widen once the anchor is fully in the drill hole, holding the entire thing in place.

There are three components involved in this design: the suture, wings, and inserter. The suture is anchored into the bone then the limbs are used to secure the soft tissue down to the bone in the same fashion that is used with the anchors currently on the market. Suture knots must be used to secure the soft tissue down for this design. There are two wings incorporated in the design. The wings are strung onto the suture to keep the suture in place in the bone. The wings are responsible for anchoring the device into the bone. Since the goal is to maintain the small size of the soft anchor, instead of adding an additional component to the anchor, this design just makes the sleeve of the soft anchor out of a rigid material. The inserter is a hollow cylinder of material that is also used to access the suture limbs during surgery. The inserter is used to implant the device into the bone and then deploy the anchor.

The method for implanting this anchor begins with the same steps as the current suture anchors. First the glenoid must be accessed through cannulas, and the articular cartilage cleared from the bone at the site of the drill hole. Once the cartilage is cleared and the bone debrided the drill hole is made. The drill hole is 1.4mm in diameter. Then the anchor can be placed into the drill hole. The

inserter is used to push the anchor into the drill hole. There is a flat piece of metal at the center of the inserter, which holds the suture at the very bottom of the anchor. This keeps everything in-line when the anchor is being inserted. Once the anchor has been inserted this center piece is pulled back up through the inserter,
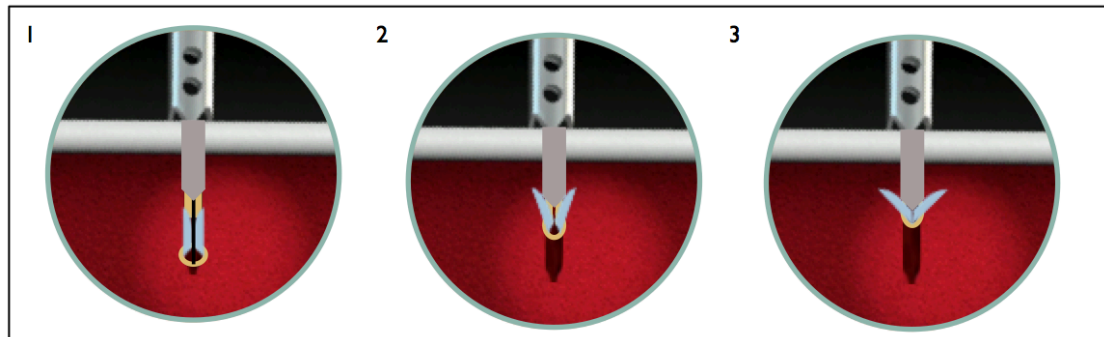
Figure 20: Deployment of design 1. 1. The un-deployed anchor is inserted into the drill hole. 2. The suture limbs are pulled on and the top of the wings hit the bottom of the inserter and begin to expand. 3. Deployment stops when the sides of the wings are flush with the inserter and the bottom of the wings are flush with each other.
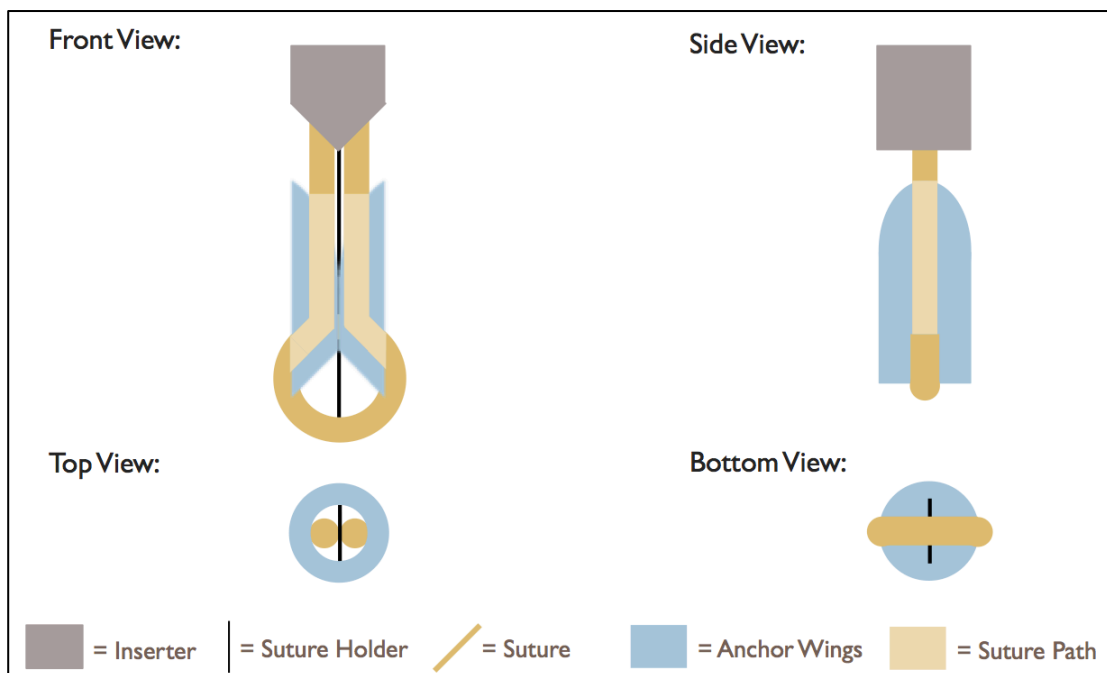
Figure 21: Un-deployed prototype design from different views. Key is at bottom of image.

leaving everything in place, including the rest of the inserter. This completes the insertion of the anchor, next the anchor must be deployed.

To deploy the anchor the suture limbs are pulled on with a quick, hard pull. This will pull the entire anchor up, causing it to hit the bottom of the inserter. When the top of the wings hit the bottom of the inserter the angle of the inserter and curve of the wings will cause the wings to spread outward and into the surrounding trabecular bone, as seen in Figure 20. This will continue until the
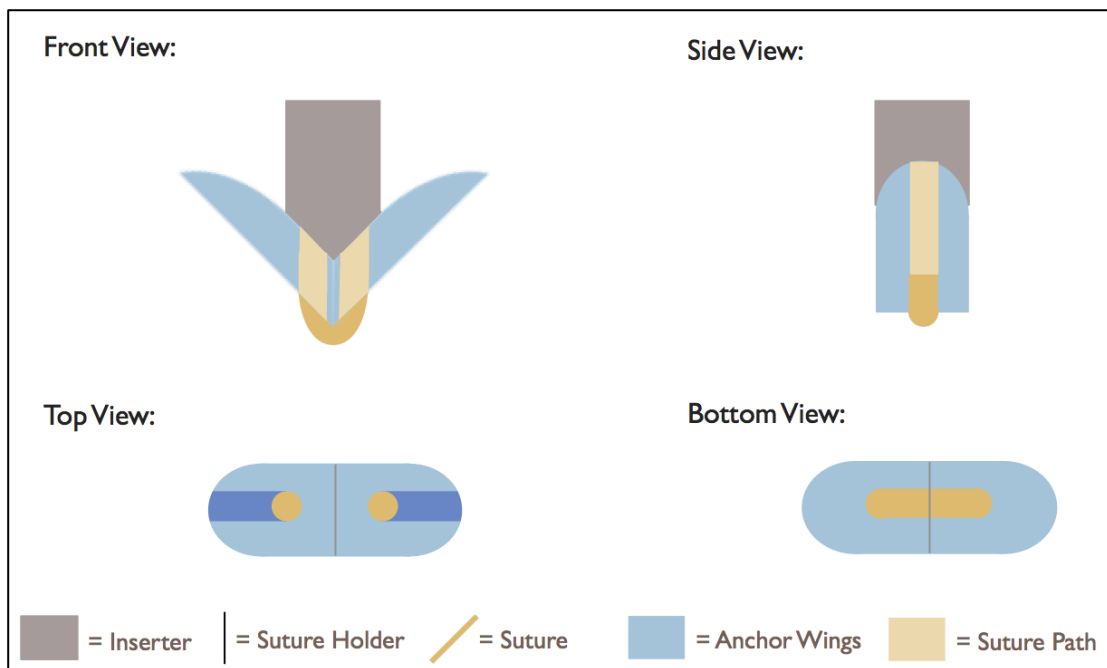
Figure 22: Deployed prototype design from different views. Key is at bottom of image.

sides of the wings are flush with the bottom of the inserter and the bottom of the wings are flush with each other, causing the deployment to stop at the desired deployment angle. Once deployment is complete the inserter is removed and the suture limbs are used to tie down the glenoid and a section of the joint capsule to re-tension the joint. This is done for the desired number of anchors needed,

which is determined by the surgeon. The same number of anchor is used with this anchor design as with those currently on the market. Once all anchor are in place the surgical site is closed and the procedure is complete.

Images of the un-deployed and deployed anchor can be seen in Figures 21 and 22 respectively. The light yellow color represents the path that the suture takes through the inside of the wings.

Design Specifications

The suture used is a high strength orthopedic suture, size #1. This is the same suture used in current suture anchor designs. The strength has proved to be more that enough to not risk the suture breaking. This design can be single or double-loaded. Suture size #1 has a diameter of 0.4mm.

The inserter is made out of surgical stainless steel, and is only single-use. They must be disposed of after each anchor is in place. There are two pieces to the inserter. The outer piece is a hollow cylinder with the bottom angled to match

Front View: Side View:

θ
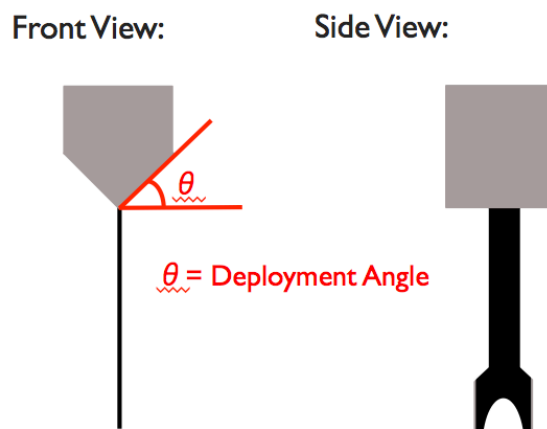
θ = Deployment Angle

Figure 23: Inserter seen from the front (left) and side (right). The middle piece is shown in black, with the outer piece in gray.

the angle of deployment. The bottom is angled to a point at the center, made from cutting two sides; one for each of the wings. The outer diameter of this piece is 1.4mm, to match the size of the drill hole used. The inner diameter must be greater, or equal to 0.8mm, to allow space for both of the suture limbs to pass through. The other component of the inserter is a flat piece of metal, also surgical stainless steel, which is pass through the center of the outer piece. This inner piece is in place to hold the anchor together and prevent early deployment before, and during insertion. This piece is thinner at the top, then widens at the bottom, with a portion of the bottom cut out to make a path for the suture to pass through. It is important that this piece does not wrap all the way around the suture, because it must leave the suture in place when it is removed during deployment. Images of both pieces of the inserter can be seen in Figure 23.

There are two wings used for this design. Two wings were chosen because the wings are held in place by being strung on the suture limbs. There are two suture limbs, and each can only hold one wing. If more wings were incorporated into the design it would greatly complicate the geometry of the design. Also, space is constraining, by only using two wings the small drill hole diameter of the soft anchor can be maintained. If more wings are added, with a more complicated geometry, it is likely that the diameter of the anchor would need to be increased. The shape of the wing can be seen in Figure 24. The wing is curved at the top. The shape of this curve is determined by the radius of deployment of the leading point of the anchor. This is done to minimize bone loss, by only removing bone
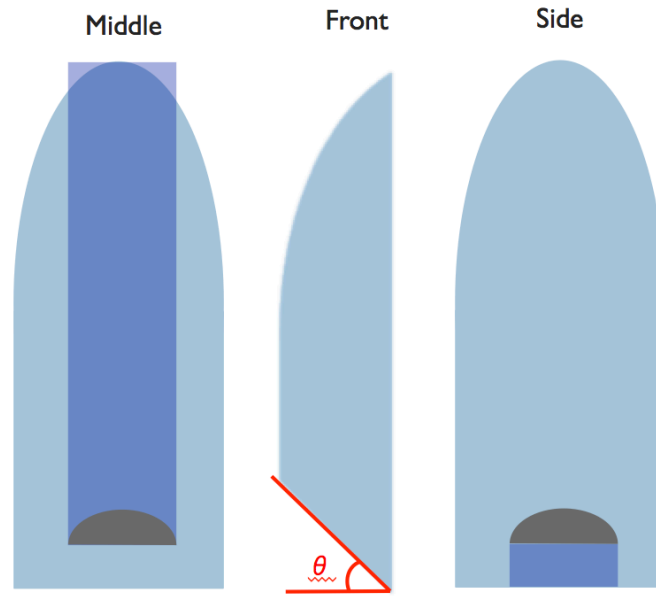
Figure 24: Wing shape from various views. Dark gray represents the hold that the suture passes through, and dark blue is the indentation made for the suture to pass through.

that is in the space that will be occupied by the wing after deployment. This is

also important, because the bone surrounding the wing is necessary to hold the

wing in place. If this bone is removed during deployment then the wing will not

have anything to hold it in place. Each wing is 0.7mm by 1.4mm. This maintains a

constant diameter of 1.4mm. The wing is 3.5mm tall.

The angle at the bottom of the wings matches the angle of deployment.

This ensures that the deployment of the anchor stops at the correct angle. The

angle of deployment is 45°. When the wings are deployed at a 45° angle, the

height and width of each wing is 2.5mm. This leads to an overall deployed width

of the anchor of 5mm.

There is a path for the suture to pass through each of the wings. This path

can be seen in Figure 24. At the top the suture is passed through the middle of the

two wings. The suture path is 0.4mm deep, but 0.8mm wide. This is done to

maintain a constant depth of the wing around the outside, of 0.3mm. When the suture is then 0.3mm from the bottom of the anchor the path for each suture limb splits, with one limb going through one wing. The path goes through the wing, following the angle of deployment, staying 0.3mm in from the bottom of the anchor. This path goes through to the other side of the wing, allowing the suture to be strung completely through. The suture then goes towards the middle of the anchor, where it is then strung through the other wing. There is a small notch at the bottom-outside of the anchor. This notch is used to keep the suture in place as it passes from one wing to the other, and prevent it from slipping out of place. The notch is the same width as the suture path, with is 0.4mm, however, it is only 0.1mm deep.

The drill hole for this anchor is 11mm. This accounts for the space needed to insert, and then deploy the anchor. When the anchor is deployed the bottom of the anchor is at the bottom of the inserter, therefore the wings expand upward. So the drill hole depth must account for the 3.5mm height of the un-deployed wings, plus the 2.5mm height of the deployed wings. Also, it is important that the wings are deployed strictly in the trabecular region of the bone. The cortical region of the bone is about 3mm thick, so the top of the deployed anchor must remain 3mm below the top of the bone. This leads to an overall drill depth of 11mm.

The wings are made of a porous, superelastic nitnol. Nitinol is a nickel titanium alloy, which is commonly used for biological implants and ideal for

orthopedics use.[47] This material is chosen because it can be small but rigid. Nitinol can be used to create the wings with small dimensions, without compromising the strength of the wings. The pores in the structure will allow for bone ingrowth, creating a bone-implant composite, which is found to have properties superior to those of just Nitinol.[48] Nitinol has been found to have a higher bone-to-implant surface contact area than that of pure Titanium. The bone ingrowth and high contact area will help to make the area between the wing and the surrounding bone continuous, which could also help improve the pullout strength of the structure. Nitinol also has good outcomes in the long-term, since it is a Titanium-based alloy and Titanium and Titanium-based alloys are not expected to produce surface corrosion in the body.[47]
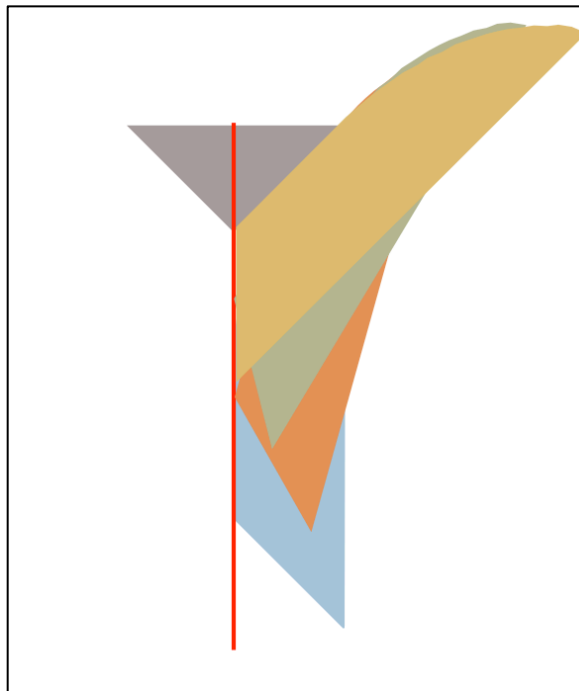
Figure 25: Deployment path of proposed design.

The deployment angle and wings length were determined by examining the deployment path. The deployment path for the proposed design can be seen in Figure 25. It can be seen that no bone is removed above the deployed wing. If the angle of deployment is made to have be shallower, meaning the anchor has to travel a longer path to be deployed, this causes the bone above the deployed anchor to be removed. This would destabilize the deployed anchor. A steeper angle is not chosen because with a steeper angle there is less bone above the
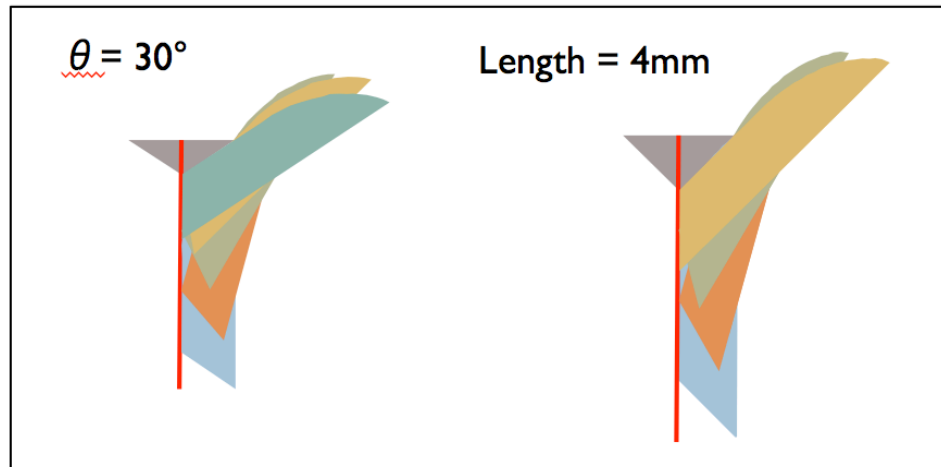
Figure 26: Deployment path for a deployment angle of 30° (left) and a wing length of 4mm (right).

anchor, and if there is less bone above the anchor the force that the anchor must withstand is more concentrated. Also, with a steeper angle the path of the wing deployment would be close to the drill hole path and that could ruin the integrity of the bone holding the anchor into place, decreasing its ability to withstand a load. The bone above the path of deployment is also removed if the wing length is increased. The maximum wing length is chosen without risking removing any of the bone above the deployment path. This is done because longer wings will

extend to an overall wider deployed diameter, making the anchor more stable. The deployment path for a shallower angle and longer wing length are shown in Figure 26.

The estimated load to failure for this anchor design is 132 N. The failure is defined as the load required to obtain 2mm displacement between the labrum and the glenoid bone; the point at which the shoulder become unstable again. This value was found by calculating the compressive strength of the bone in 2mm above the anchor. The compressive strength of the cortical bone in the glenoid is 67 MPa.[48] The bone in the trabecular region is much weaker than that in the cortical region. In the first 1mm of the trabecular bone the pullout strength is about 75% of that of the cortical bone, at about 50 MPa. After the first 1mm the strength decreases to be about 30% of that of the cortical bone, which is about 20 MPa.[48]

For this prototype design the force is being put on the bottom of the anchor, which would be pulled through the trabecular region. The bottom of the anchor is 2.5mm below the cortical region, so the portion of the bone that the anchor would be pulled through has a compressive strength of 20 MPa. The surface area of the bone was found by calculating the area as seen by the top view. This was used instead of the actual area of bone that the anchor comes in contact with because it is the area that the anchor would have to pull through when it is displaced. The area of the drill hole was subtracted from the surface area because the bone has been removed from this region. The surface area is

6.62×10^{-6} m^2. The surface area is then multiplied by the compressive strength to find the estimated load to failure of 132 N. This is much higher than the load at 2mm displacement for the current anchors, with the rigid having an ultimate load of 84 ± 19 N, and the soft with a load of 39 ± 11 N.[32]

A possible miscalculation with this estimation is that it is calculated for the trabecular region. If the wings maintain their angle at the 45° deployment angle, then the top of the anchor will be pulled through trabecular bone, which is much stronger than the trabecular bone. However, it is predicted that the strength of the cortical bone will cause the wings to bend before they are pulled through the cortical bone. Also, for this approximation it was assumed that the surface of the deployed wings was flat, however, the actual shape of the wings is curved upward when deployed, and the wings are at an angle. These factors could affect the mechanism by which the anchor fails, and therefore change the pullout strength.

Pros and Cons

Some advantages of this design include its size and stability. This design maintains the small drill hole diameter that is used for the soft anchor, while making the depth of the drill hole even shorter. The rigid wings should minimize micro-motion of the anchor in the bone, and therefore decrease any irritation inside the drill hole. By incorporating a rigid portion into the design the ultimate load at 2mm displacement could potentially be increased from that which is found for the soft anchor, making the anchor less likely to displace in the bone.

A disadvantage of this design is that by re-introducing rigid pieces back into the design, the risk of damage to the surrounding tissue if the anchor fails is back. Also, this anchor has a wide deployed diameter compared to that of the current rigid anchors. Since this anchor needs the inserter in place for it to be deployed, curved guides cannot be used to put it in place. This means that it will still be difficult for surgeons to implant this anchor in the hard-to-reach areas, such as the 6 o'clock glenoid location. This design also does not allow for the use of the suture-first technique and suture knots still need to be used.

The competitive advantage of this anchor over the suture anchors that are currently on the market is that is incorporated benefits from both the soft and rigid anchors. It maintains the small drill hole of the soft anchor, but fills the deployed anchor space with a rigid piece, to decrease micro-motion. Also, even through the wings must deploy outward, the deployed diameter is still less than that of the soft anchor. The rigid wings should increase the strength and stability of the anchor overall. Also the drill hole size is the smallest of all of the designs currently seen.

Design 2

Concept of Design

The inspiration for this design also aims to maintain several of the important pros of the anchor on the market, while eliminating some of the cons. This designs aims to maintain the small drill hole diameter of the soft anchor, and provide an anchor that is easy to manufacture and deploy. It is important that the

anchor is simple to manufacture because, if the design is too complicated it can quickly cause the price of the product to increase. If the deployment method is too complicated it can either cause the anchor to not properly deploy in the bone during surgery, and then the anchor wouldn't hold in place in the bone. Also, a difficult deployment method could take extra time, and surgeons want to keep the shoulder open for surgery for as little time as possible.

This anchor design also aims to decrease the likelihood of the anchor failing. The main form of failure for the soft anchor is anchor pull out. The predicted mechanism of anchor pull out is that micro-motions occur due to the soft nature of the anchor, causing the bone to become irritated and not heal properly. When the bone does not heal properly this allows for the anchor to wear away at the bone shelf that it sits on and eventually slips out of the drill hole. Also, the shelf the bone normally sits on is just made of bone. This allows the anchor to slip against the bone and displace. If a sturdier shelf can be used in place of the bone, this could decrease the displacement observed and ensure that the anchor hold the tension necessary for repair.

Inspiration for this anchor was also obtained by looking at the anchors previously studied here, and also some other tissue anchors and sutures. One suture type that was studied is the barbed suture. The barbed suture was developed to replace the need for suture knots in soft tissue repairs. The design starts with regular suture, but then cuts are made into the side, as seen in Figure 27. These cuts create barbs, which stick out of the sides of the suture. The barbs

can be in various directions or one, and of varying sizes, which are determined by

the desired use. The barbs stick into the surrounding tissue, holding the suture in

place, without needing to use suture knots.
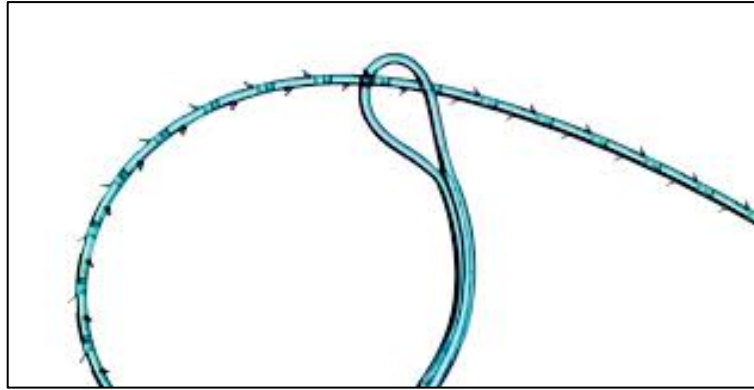
Figure 27: Barbed suture with barbs all facing one direction.[49]

The MedShape Morphix suture anchor was also studied. This is a rigid

suture anchor used to secure soft tissue down to the bone in various sites in the

body. Similar to the Piton, this anchor can be used for glenoid lesions; however,
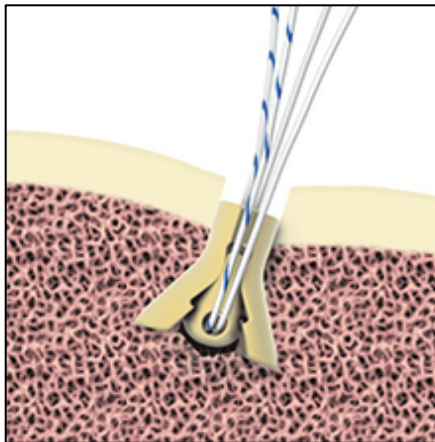
Figure 28: MedShape Morphix suture anchor deployed in bone.[50]

its wide deployed diameter makes it unideal for this location. This anchor starts

with a small tear-shaped bead that is implanted into the drill hole. Next two

wings are pushed into the drill hole and spread outward when the hit the top of

the bead. The deployed anchor can be seen in Figure 28. The suture is only directly attached to the small bead initially implanted, but the widened diameter of the wings holds the whole device in place in the bone.

This prototype design builds off of the current soft anchor design. This design proposes starting with the current soft anchor design, but adding an additional component, the bone barrier, that creates a carrier between the anchor sleeve and the bone. The idea with this anchor is not to try to eliminate the micro-motion of the anchor, but instead create a barrier between the anchor and the bone so the bone does not feel the micro-motion. A benefit of the soft anchor is the small size, so ideally this will be maintained. This design adds an additional component to the whole structure, but it is not a load bearing structure, therefore this bone barrier only needs to be a thin layer.
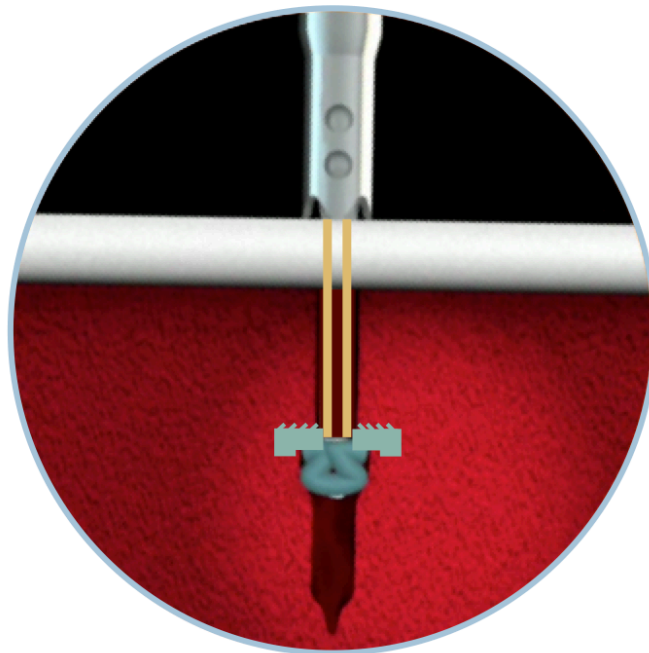
Figure 29: Prototype design 2 implanted in bone.

The novel component of this design is the bone barrier. The bone barrier is a thin piece of metal that is deployed above the sleeve of the soft anchor to create a shield between the micro-motions of the sleeve and the bone tissue. There are barbs incorporated on the shield that deploy into the bone, away from the anchor sleeve. These barbs help to hold the bone barrier in place on the bone. The barrier should not be attached to the anchor sleeve because when the sleeve moves the barrier should remain steady.

The implantation method of this anchor design is the same as that of the current soft anchor. First the site is accessed and area prepared, and then the drill hole is made. The drill hole is 1.4mm in diameter, and 12 mm long, matching that of the current soft anchor. The anchor is placed in the drill hole where is it then ready to be deployed. The flat piece of metal at the center of the inserter is then
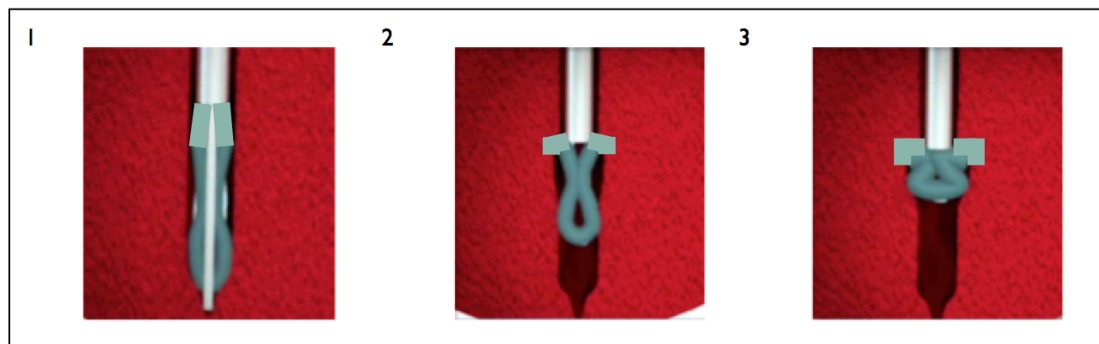
Figure 30: Deployment of design 2. 1. The un-deployed anchor is inserted into the drill hole. 2. The suture limbs are pulled on and the top of the sleeve reaches the bottom of the inserter and begin to expand, pushing the bone barrier outward. 3. Deployment stops when the sleeve is completely bunched against the inserter and the bone barrier is extended outward.

removed. When the anchor is inserted the bone barrier extends down past the top of the sleeve. The anchor is deployed with a quick, hard pull on the suture limbs. When the top of the sleeve extends outward it pushes the bone barrier
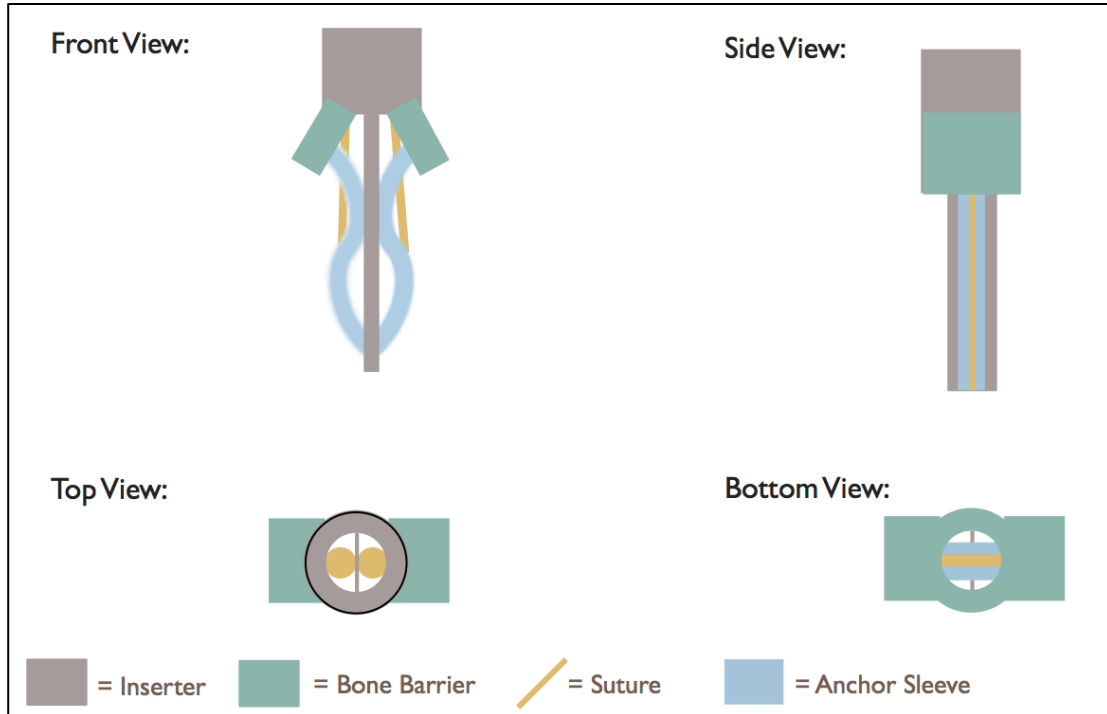
Figure 31: Un-deployed prototype design from different views. Key is at bottom of image.

along with it. The bone barrier is made out of a very thin material, allowing it to easily fold around the top of the sleeve, and extend outward with it. Deployment stops when the sleeve is completely bunched up in the bone, and the bone barrier has been extended outward. Once deployment is complete the inserter is removed and the suture limbs are used to tie down the glenoid and a section of the joint capsule to re-tension the joint. This is done for the desired number of anchors needed, which is determined by the surgeon. The same number of anchor is used with this anchor design as with those currently on the market. Once all anchor are in place the surgical site is closed and the procedure is complete. Images of the un-deployed and deployed anchor can be seen in Figures 31 and 32 respectively.
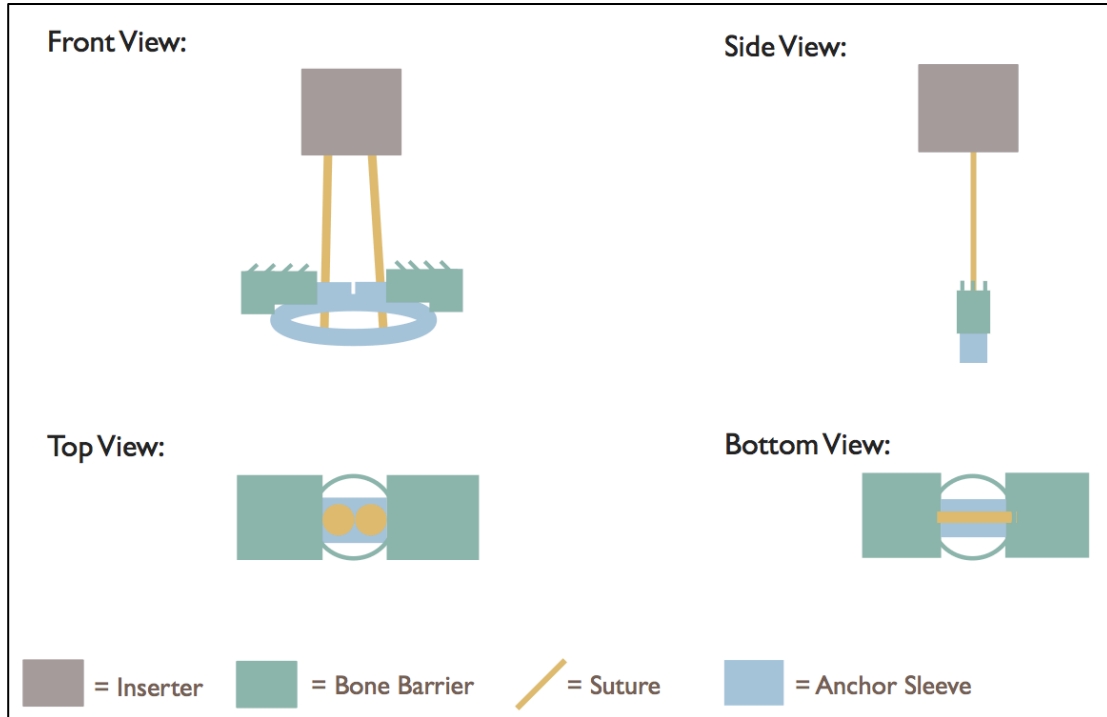
Figure 32: Deployed prototype design from different views. Key is at bottom of image.

Design Specifications

The suture used is a high strength orthopedic suture, size #1. This is the same suture used in current suture anchor designs. The strength has proved to be more that enough to not risk the suture breaking. This design can be single or double-loaded. Suture size #1 has a diameter of 0.4mm. The sleeve is made from braided polyester. The average deployed diameter of the sleeve is 6.4mm.

The inserter is made out of surgical stainless steel, and is only single-use. They must be disposed of after each anchor is in place. There are two pieces to the inserter. The outer piece is a hollow cylinder. Unlike with the first prototype design, the bottom of the inserter is flat for this design. The outer diameter of this piece is 1.4mm, to match the size of the drill hole used. The inner diameter must

be greater, or equal to 0.8mm, to allow space for both of the suture limbs to pass through. The other component of the inserter is a flat piece of metal, also surgical stainless steel, which is pass through the center of the outer piece. This inner piece is in place to hold the anchor together and prevent early deployment before, and during insertion. This piece is thinner at the top, then widens at the bottom, with a portion of the bottom cut out to make a path for the suture to pass through. It is important that this piece does not wrap all the way around the suture, because it must leave the suture in place when it is removed during deployment.

The bone barrier starts as a cylinder made from a thin metal material. Two slits are made on opposite side of the cylinder starting 2.5mm from the top of the
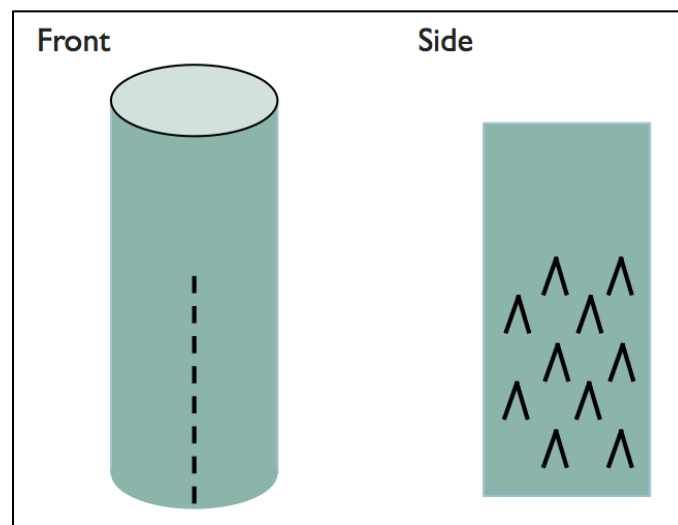
**Figure 33: Bone barrier from front and side views. The front view shows where the slit is made to create the two separate side of the bone barrier. Barbs are shown on the side view of the bone barrier.**

cylinder and extending down to the bottom. The entire cylinder is 6mm long with a diameter of 1.4mm. These two slits separate the two sides of the bone barrier;

one will go over each side of the anchor sleeve. The top connected portion will go at the bottom of the inserter, with the wings extending over the ends of the sleeve initially. The connected portion is important to keep each side of the bone barrier connected to the entire device at insertion. This portion remains connected after deployment and helps the bone barrier to remain steady and un-moving in the bone. There are also barbs punched into each of the sleeves. All barbs point upward in the un-deployed anchor. The barbs are triangular in shape and are 0.25mm tall and 0.25mm wide. The height is determined by a study performed with barbed sutures that determined the ideal barb height and depth for different tissues. It was determined that for tougher tissues shorter barbs work better.[51] The width of 0.25mm was chosen to maintain a strong barb that will not just deform under force, without making it too wide for the pores of the bones in the trabecular region. The barbs will be at a 30° to the sleeve. This angle was determined to be ideal for barb strength.[51]

The bone barrier is made from body temperature Nitinol, at a thickness of 0.018mm. Nitinol has special shape memory properties that allow it to return to its original shape after being deformed when it is heated to a certain temperature. This temperature varies depending on the composition of the Nitinol. With body temperature Nitinol the material must first be annealed at its initial shape. The shape it is annealed at is the shape it will remember. Then when the material is cool it can be deformed. After the shape has been deformed it can then return to its initial shape by heating it to body temperature.[52] This is how

the barbs on the bone barrier will be deployed. When the bone barrier is

manufactured barbs will be punched into it and the barbs will be made to point

outward. The material will be annealed with the barbs out like this. After it has

been annealed the barbs can then be pushed down, so the bone barrier lies flat. It

is helpful for the barrier to lie flat to minimize the size of the anchor during

insertion, and to ensure that the barbs do not get caught to any tissue in the body

before it is deployed. Once the anchor is implanted and deployed the body heat

will cause the barbs to go back to their initial position, pointing outward into the

bone. The bone barrier must be held at a temperature below body temperature

after the barbs have been pressed down or it will cause the barbs to deploy

early.[52] The Nitinol will need to completely heat to body temperature for the

barbs to deploy, so the barbs will not extend immediately after the anchor is

inserted in the body. The time it will take for the anchor to heat to body

temperature will allow for the anchor to be fully deployed before the barbs

deploy. The Nitinol used for this design is a single flat layer of material, however,

by incorporating the barbs into the design, the same advantages will apply to this

structure as apply to the porous material used for Design 1. The deployed width

of the anchor is the same as that of the soft anchor, averaging at about 6.4mm

wide.

      The estimated load to 2mm displacement for this anchor design 575 N.

This value was calculated with the same method used for the estimated load to

2mm displacement for Design 1. For this design, when the anchor is deployed it is

only about 0.5mm below the cortical bone layer. This means that for the anchor

to displace by 2mm it must be pulled through the cortical layer, therefore the

compressive strength of the cortical bone in the glenoid is used. The compressive

strength of the cortical bone is 67 MPa.[48] The surface area of the anchor,

subtracting the area of the drill hole, is 8.96×10^{-6} m². The surface area is then

multiplied by the compressive strength to find the estimated load to failure of

575 N. This is a significantly higher load than any of the competition can

withstand. The rigid anchor has an ultimate load at 2mm displacement of 84 ± 19

N, and the soft has a load of 39 ± 11 N.[32]

A potential error with these calculations is that this estimate assumes that

the anchor will maintain a constant surface area as it is being displaced. The

sleeve of the anchor is made from a soft material, and the bone barrier is very

thin and can easily be deformed. This deformation would make the anchor easier

to displace and would lower the ultimate strength needed to obtain 2mm of

displacement.

Pros and Cons

This prototype design maintains the small drill hole size of the soft anchor.

By introducing the bone barrier to the design the contact area between the bone

and the sleeve is decreased, which could potentially decrease the irritation of the

bone tissue and promote more natural healing. However, this design incorporates

a small piece of rigid material, which could cause damage to the surrounding

tissue in the shoulder if it came loose from the anchor. Also, this design still

requires the anchor to widen when deployed, and requires suture knots to hold down the soft tissue. These factors could be harmful to the quality of the surrounding tissue. This design relies on the presence of the inserter for the anchor to be deployed, therefore getting to the hard-to-reach areas during surgery will still be difficult. This design could also potentially be expensive. Nitinol can be an expensive material, and specifying the shape memory abilities to an exact temperature range requires precision. This precision and detail in the material could be expensive.

The competitive advantage of this design over those currently on the market is that by adding a small additional component to the design it could greatly improve the ability of the bone to heal, and healthier bone is more likely to prevent anchor pullout. Also this anchor is small, maintaining the small drill hole of the soft anchor, and it is easy to manufacture since it is only adding a component to a design already on the market.

Future Work

Design 1

In the future, the designs can be refined to be more successful through careful testing. For design one, the wing length and deployment angle should be optimized through force testing. The idea wing angle and length should be found by testing for the ideal wing length that will bear a high enough load, while remaining as small as possible. Another alteration that would benefit the outcome of the anchor would be to create an interlocking hinge between the two

wings, at the bottom point, where the wings are always in contact. The suture holds both of the wings together, and if equal force is put on both of the suture limbs during deployment both wings should deploy together, creating no issues. However, if the wings were to slip against each other and one deployed before the other it could prevent the anchor from completely deploying.

The wing properties can also be experimented with. If the wings were made to be more flexible then they could bend during deployment. This would reduce the risk of extra bone being removed during deployment because the anchors could bend to follow the path of the leading edge. Doing this could allow other deployment angles or wing length to be a reasonable option. Also, different wing surface textures could produce better outcomes for the material reaction with the surrounding bone tissue.

The number of wings could be increased. Adding additional wings to the design could increase the ultimate load of the anchor. Additional wings would cause the design to go from a line of stability to a plane of stability. This could improve the overall strength of the anchor. However, by doing this the geometry would become much more complicated and the anchor could potentially take up more space.

Design 2

Properties of design two that would benefit from experimental testing are the bone barrier length and the barb pattern. It is important that the length of the bone barrier is not too long, so it does not get in the way of deployment, or too

short, so it does not properly protect the bone. The ideal length must be determined for adequate bone protection. It is also necessary that the length used works for all soft anchors, not just those that deploy at the average width. For the barb pattern, more barbs are better. The poor size of the bone in the trabecular region of the glenoid is large, so there is more open space than bone in the trabecular region, so increasing the number of barbs used increases the likelihood that an adequate amount will properly attach to the bone.[40]. Also, the bone barrier will not be under tension, so it is okay if the tensile strength is decreased by the presence of the barbs. However, with too many barbs there is the risk of the bone barrier cracking. The ideal relationship between number of barbs, and risk of breaking should be determined.

For design two other deployment options should also be considered with the goal of eliminating the need for the inserter. With the current proposed design the inserter is necessary for the deployment of the anchor. Since the inserter is needed it is still difficult for surgeons to get to the hard-to-reach areas of the glenoid. If altering the deployment method could eliminate the need for the inserter, it could make it easier for surgeons to access more of the glenoid.

Other Ideas

Starting with the current proposed prototype ideas, first the design should be compared to determine with is better. Once one option has been determined as the better, and more viable option for the market, more future work can be done from there. One method is to determine if other surgical techniques could

benefit the outcome of the design. For example, using experimental surgical methods such as the labral bridge technique could promote more biological healing at the repair site. The anchor should also be tested then used for all surgical sites around the perimeter of the glenoid. The anchor proposed could also potentially be modified for other surgical sites in the body, such as the hip or for rotator cuff repairs.

Another idea for a suture anchor prototype is to add barbs to the sleeve of the soft anchor. By adding barbs directly to the sleeve of the soft anchor it would help keep the anchor in place in the bone, therefore decreasing micro-motions. The problem with this design idea is the necessary size of the barbs is about 0.8mm, which is larger than the size of the suture used. Other methods for incorporating the barbs into the design either make the sleeve too rigid, which would prevent the sleeve from properly deploying, or make the sleeve too wide, adding too much to the overall diameter of the anchor. If an appropriate method could be determined to integrate the barbs onto the sleeve this would be a viable option.

Bone growth factors are used in place of bone grafts in spinal fusion surgeries.[53] Previously a bone graft had to be taken from the pelvis, but now, a sponge is containing bone growth factor is placed at the site. This growth factor promotes bone growth more reliable and quickly than bone graft methods.[53] Incorporating this bone growth factor into anchor designs could help encourage biological healing of the bone at a much more rapid pace than what is currently

seen. After the anchor is deployed and inserter removed put a small piece of sponge with the growth factor on it into the bone. This will promote bone growth at the top of the drill hole. If bone grows back here and closes over the hole, anchor pull out would be much more difficult. This could increase the pull out strength of the anchor.

The problem with this design is that it could make the design much more expensive. Growth factors are expensive to obtain, and using them would decrease the shelf life of the product. This would also make storage and mass production of the product more difficult. This idea is currently unrealistic, however, if bone growth factors can be modified in the future to overcome some of these obstacles using them could become a reasonable option.

REFERENCES

1.   The Noted Anatomist. *Glenohumeral joint: Structure and actions*.
        (youtube.com, 2015).

2.   Sherman, S. C. Shoulder dislocation and reduction. *UpToDate* (2016).

3.   AnatomyZone. *Shoulder Joint - Glenohumeral Joint - 3D Anatomy Tutorial*.
        (youtube.com, 2012).

4.   Marquardt, B., Witt, K.-A., Liem, D., Steinbeck, J. & Pötzl, W. Arthroscopic
        Bankart repair in traumatic anterior shoulder instability using a suture
        anchor technique. *Arthroscopy* **22,** 931–936 (2006).

5.   SutureTak. *Arthrex* Educational Resources (2016). Available at:
        http://www.arthrex.com/shoulder/suturetak. (Accessed: 16th December
        2015)

6.   AnatomyTV. *Primal Pictures* (2016). Available at: http://anatomy.tv/.
        (Accessed: 24th January 2016)

7.   Glenohumeral Ligament Image. Surgical Anatomy of the Shoulder

8.   Abrassart, S., Stern, R., Hoffmeyer, P. Arterial supply of the glenoid: An
        anatomic study. *J. Shoulder Elb. Surg.* **15,** 232–238 (2006).

9.   Brand, R., J Visser, C. P., J E M Coene, L. N. & J Tavy, D. L. The incidence of
        nerve injury in anterior dislocation of the shoulder and its influence on
        functional recovery A PROSPECTIVE CLINICAL AND EMG STUDY. *J Bone Jt.
        Surg [Br]* **8181,** 679–85 (1999).

10.   Koh, K. H., Park, W. H., Lim, T. K. & Yoo, J. C. Medial perforation of the
        glenoid neck following SLAP repair places the suprascapular nerve at risk:
        A cadaveric study. *J. Shoulder Elb. Surg.* **20,** 245–250 (2011).

11.   Zacchilli, M. A. & Owens, B. D. Epidemiology of shoulder dislocations
        presenting to emergency departments in the United States. *J. Bone Joint
        Surg. Am.* **92,** 542–9 (2010).

12.   Lam, A. C., Shih, R. D. & Kang, C. Luxatio Erecta Complicated By Anterior
        Shoulder Dislocation During Reduction. *West. J. Emerg. Med.* **28,** (2010).

13.   Rhee, Y. G., Cho, N. S. & Cho, S. H. Traumatic anterior dislocation of the
        shoulder: factors affecting the progress of the traumatic anterior

dislocation. *Clin. Orthop. Surg.* **1,** 188–193 (2009).

14. Pfeiffer, F. M., Smith, M. J., Cook, J. L. & Kuroki, K. The histologic and biomechanical response of two commercially available small glenoid anchors for use in labral repairs. *J. Shoulder Elb. Surg.* **23,** 1156–1161 (2014).

15. Shoulder Dislocation Image. *Houghton Legal* Medical Demonstrative Evidence (2016).

16. Hovelius, L. Olafsson, A., Sandstrom, B. Nonoperative treatment of primary anterior shoulder dislocation in patients forty years of age and younger. a prospective twenty-five-year follow-up. *J. Bone Joint Surg. Am.* **90,** 945–52 (2008).

17. Bankart Lesion Image. *Advanced Assessment of Upper Extremity Injuries* Shoulder Injuries (2009).

18. Schwartzberg, R. Reuss, B., Burkhart, B. High Prevalence of Superior Labral Tears Diagnosed by MRI in Middle-Aged Patients With Asymptomatic Shoulders. *Orthop. J. Sport. Med.* **4,** 1–7 (2016).

19. Chronic Shoulder Instability. *American Shoulder and Elbow Surgeons* OrthoInfo (2013). Available at: http://orthoinfo.aaos.org/topic.cfm?topic=a00529. (Accessed: 18th April 2016)

20. Non-surgical Management of the Unstable Shoulder. *Orthopaedic Research Institute Department of Orthopaedic Surgery & Sports Medicine, St. George Hospital Campus, University of New South Wales, Sydney Australia* Shoulder (2013). Available at: http://www.ori.org.au/shoulder/conservative.html. (Accessed: 5th May 2016)

21. SHCCvideo. *Open Bankart for Anterior Glenohumeral Instability - Dr. Tokish*. (youtube.com, 2015).

22. Rowe, C. R., Patel, D. & Southmayd, W. W. The Bankart procedure: a long-term end-result study. *J. Bone Joint Surg. Am.* **60,** 1–16 (1978).

23. Wolf, E. M., Wilk, R. M. & Richmond, J. C. Arthroscopic Bankart repair using suture anchors. *Oper. Tech. Orthop.* **1,** 184–191 (1991).

24. Kim, S.-H., Ha, K., Kim, S. Bankart repair in traumatic anterior shoulder instability. *Arthrosc. J. Arthrosc. Relat. Surg.* **18,** 755–763 (2002).

25. Ostermann, R. C., Hofbauer, M., Platzer, P. & Moen, T. C. The 'Labral Bridge':

A Novel Technique for Arthroscopic Anatomic Knotless Bankart Repair. *Arthrosc. Tech.* **4,** e91–e95 (2015).

26. Hayashida, K., Yoneda, M., Mizuno, N., Fukushima, S. & Nakagawa, S. Arthroscopic Bankart Repair With Knotless Suture Anchor for Traumatic Anterior Shoulder Instability: Results of Short-Term Follow-Up. *Arthrosc. - J. Arthrosc. Relat. Surg.* **22,** 620–626 (2006).

27. Yoneda, M., Hayashida, K., Izawa, K., Shimada, K. & Shino, K. A simple and secure anchoring system for Caspari's transglenoid multiple suture technique using a biodegradable poly-l-lactic acid button. *Arthroscopy* **12,** 293–9 (1996).

28. Söderlund, T., Mattila, V. M., Visuri, T. I. & Pihlajamäki, H. K. Long-term outcome of a transglenoid suture technique for anterior shoulder instability in young adults. *J Bone Jt. Surg [Br]* **90,** 189–93 (2008).

29. Kim, S.-J. Is the transglenoid suture technique recommendable for recurrent shoulder dislocation? A minimum 5-year follow-up in 59 non-athletic shoulders. doi:10.1007/s00167-009-0748-6

30. H van Oostveen, D. P., A Schild, F. J., van Haeff, M. J. & F Saris, D. B. Suture Anchors Are Superior to Transglenoid Sutures in Arthroscopic Shoulder Stabilization. doi:10.1016/j.arthro.2006.07.006

31. GRYPHON Suture Anchor. *DePuy Synthes* Shoulder Reconstruction Products Available at: https://www.depuysynthes.com/hcp/shoulder/products/qs/GRYPHON-Suture-Anchor. (Accessed: 10th May 2016)

32. Mazzocca, A., Choweniec, D., Cote, M. Biomechanical evaluation of classic solid and novel all-soft suture anchors for glenoid labral repair. *Arthrosc. - J. Arthrosc. Relat. Surg.* **28,** 642–648 (2012).

33. Ruiz-Suarez, M., Aziz-Jacobo, J. & Barber, F. A. Cyclic load testing and ultimate failure strength of suture anchors in the acetabular rim. *Arthroscopy* **26,** 762–768 (2010).

34. Oh, J. H., Lee, H. K., Kim, J. Y., Kim, S. H. & Gong, H. S. Clinical and radiologic outcomes of arthroscopic glenoid labrum repair with the BioKnotless suture anchor. *Am. J. Sports Med.* **37,** c (2009).

35. Arthroscopic Shoulder Instability Repair Using the SUTUREFIX ULTRA Suture Anchor and SUTUREFIX ULTRA Instrumentation System.

36. JuggerKnot Soft Anchor. *Biomet Sports Medine* (2014). Available at:

http://www.catalogodelasalud.com/documenta/contenido/112608/Jugge rKnot-1.4mm.pdf. (Accessed: 15th May 2016)

37.   Witney-Lagen, C., Perera, N., Rubin, S. & Venkateswaran, B. Fewer anchors achieves successful arthroscopic shoulder stabilization surgery: 114 patients with 4 years of follow-up. *J. Shoulder Elb. Surg.* **23,** 382–387 (2014).

38.   JuggerKnot Long Soft Anchor. Biomet (2016).

39.   Agrawal, V. & Pietrzak, W. S. Triple labrum tears repaired with the JuggerKnot™ soft anchor: Technique and results. *Int. J. Shoulder Surg.* **9,** 81–9 (2015).

40.   Li, X., Williams, P., Curry, E. Trabecular Bone Microarchitecture and Characteristics in Different Regions of the Glenoid. doi:10.3928/01477447-20150305-52

41.   Drury, N. J., Ellis, B. J., Weiss, J. a, McMahon, P. J. & Debski, R. E. The impact of glenoid labrum thickness and modulus on labrum and glenohumeral capsule function. *J. Biomech. Eng.* **132,** 121003 (2010).

42.   Halder, A. M., Kuhl, S. G., Zobitz, M. E., Larson, D. & An, K. N. Effects of the glenoid labrum and glenohumeral abduction on stability of the shoulder joint through concavity-compression : an in vitro study. *J. Bone Joint Surg. Am.* **83-A,** 1062–9 (2001).

43.   Knipe, H. Glenoid Labrum. (2008). Available at: http://radiopaedia.org/articles/glenoid-labrum.

44.   Iannotti, J. P., Gabriel, J. P., Schneck, S. L., Evans, B. G. & Misra, S. The normal glenohumeral relationships. An anatomical study of one hundred and forty shoulders. *J. Bone Joint Surg. Am.* **74,** 491–500 (1992).

45.   Lee, S., Porter, M., Wasko, S. Potential Bone Replacement Materials Prepared by Two Methods.

46.   Piton Image. *Tornier Piton* Features & Benefits (2015).

47.   Shabalovskaya, S. a. Surface, corrosion and biocompatibility aspects of Nitinol as an implant material. *Biomed. Mater. Eng.* **12,** 69–109 (2002).

48.   Frich, L. H., Jensen, N.C., Odgaard, A. Pedersen, C. M., Sojbjierg, J. O., Dalstra, M. Bone strength and material properties of the glenoid. *J. Shoulder Elbow Surg.* **6,** 97–104

49.   Barbed Suture Image. *Covidien Medtronic* Wound Closures: Barbed Suture (2016).

50.   Morphix Image. *MedShape Morphix* Morphix Suture Anchor System (2013).

51.   Ingle, N. P., King, M. W. & Zikry, M. A. Finite element analysis of barbed sutures in skin and tendon tissues. *J. Biomech.* **43,** 879–886 (2010).

52.   Nitinol Specification Guidlines. Johnson Matthey Medical Components (2016).

53.   Accelerated Bone Healing. *Emory Healthcare* Orthopedics & Spine (2016). Available at: http://www.emoryhealthcare.org/medicaladvances/orthopaedics-etma/accelerated-bone-healing.html. (Accessed: 13th May 2016)