Protocol Outline

Protocol Title: Restoring the anatomic tension relationship of the long head of the biceps during tenodesis
IRB #: 212671
Protocol Version: 6
Protocol Date: August 13, 2024
Principal Investigator: Dane Salazar, MD and Nickolas Garbis, MD
Research Team: Robert Burnham Jr., MD, Katherine Baur, BS, Tyler Morad, BS, Amy Wozniak, MS, Amanda Spevacek, BA, Hassan Farooq, Marissa VanDeVeer, Joshua Anderson, MS, Krishin Shivdasani MPH, Andrew Chen MD, Amir Boubekri MD, Michael Scheidt MD, Thomas Stanila BS

Abstract

The long head of the biceps can be a source of anterior shoulder pain that is primarily due to inflammation or instability of the long head of the biceps (LHB) tendon . Patients that fail non-operative management become candidates for biceps tenotomy and tenodesis. Currently, there is no universal protocol or gold standard for how the LHB tendon is tensioned. At our institution, the LHB is tensioned based on individual surgeon feel for the correct tensioning. The purpose of this study is to conduct a randomized, single-blinded prospective study comparing patients of the current regimen of bicep tensioning vs. utilizing a standardized method of anatomically tensioning the LHB tendon. The primary aim of assessing change in the American Shoulder and Elbow Surgeon (ASES) scores from baseline to post-surgery between the control and intervention groups will be assessed using a student's t-test. In addition, longitudinal mixed effects models will be used to estimate changes in ASES scores, over all time-points using a random effect for surgeon. Other relevant patient characteristics such as age, sex, and Charlson score will be included to explore the adjusted relationship of the intervention and outcomes over time. A secondary aim of this study is to collect specific measurements of the myotendinous junction of the LHB tendon to potentially establish if any characteristics predispose patients to developing pathology of the LHB tendon.

I. Background and Significance/Preliminary Studies

Pathology involving the long head of the biceps (LHB) tendon is an established source of upper extremity pain. Biceps tendon pathology is often associated with other primary shoulder pathologies including subacromial impingement, rotator cuff tears, or stenosis of the bicipital groove. The histological findings of the extra-articular portion of the LHB tendon indicate that it undergoes a chronic, degenerative process much like other tendinopathies of the body, such as de Quervain's tenosynovitis of the wrist.

Management of bicipital tendinopathy, such as tendonitis, is generally treated with conservative measures first, which consists of activity modification, non-steroidal anti-inflammatory drugs, and corticosteroid injections. If the patient fails these modalities of treatment, then surgical intervention is considered [7]. There are

multiple ways to perform the procedure and different techniques to perform the tenodesis. The procedure involves performing a tenotomy (cutting) the LHB at the junction between the tendon and the supraglenoid tubercle (origin of the biceps tendon). Tenodesis (or re-attachment of the tendon at a different site) is performed at some location within the intertubercular groove, but outside of the shoulder joint, using one of many forms of fixation either with an open or an arthroscopic approach. Post-operatively, some patients report persistent shoulder pain, biceps muscle fatigue, and bicipital groove tenderness. Scores on the American Shoulder & Elbow Surgeons (ASES), a functional validated scale, are often used to measure these outcomes.

Clinically, it may be important to consider the site of tenodesis in order to restore tension similar to that of normal physiological function. To date, there is no gold standard for the site and level of tenodesis [1, 3, 4, 6]. The current method for fixation (tenodesis) of the LHB tendon after tenotomy is based on surgeon feel for appropriate tensioning within the bicipital groove. We hypothesize that anatomic tensioning of the LHB during tenodesis will provide improved patient outcomes in the form of reducing anterior shoulder pain, bicipital fatigue, bicipital groove tenderness, and ASES scores.

Additionally, there are no current population studies on the anatomy of the LHB tendon and myotendinous junction. Specifically, detail regarding the myotendinous junction transitional zone has not been described [2, 4, 5], nor whether certain anatomical aspects of LHB tendon and myotendinous junction affect the rate of pathology of the LHB. This research project serves as a means to discover if these anatomical differences have clinical significance by obtaining measurements at the myotendinous junction of the LHB.

II. Study Aims

The main purpose of this study is to determine the clinical impact of restoring the anatomic-tension relationship of the long head of the biceps (LHB) when performing a biceps tenotomy and tenodesis. Specifically, we will investigate whether anatomic tensioning will improve functional outcome scores and decrease postoperative complications. We hypothesize that through a standardized method of anatomically tensioning the LHB tendon during tenodesis, patient outcomes will improve.

Another purpose of this study is to provide further information referencing the longitudinal anatomy of the LHB, specifically at the myotendinous junction transition zone. There are multiple measurements that are unique to each individual. The measurements that we will analyze are the length from the supraglenoid tubercle to both the proximal and distal extents of the myotendinous junction. From these two measurements, we can calculate the total length of the myotendinous junction from beginning of muscle fibers to the end of tendinous fibers. We will also measure the width and circumference of the myotendinous junction.

To date, these particular measurements have never been done before in an in vivo fashion. Our hope is that this analysis of the LHB myotendinous junction will identify any relationships with pathology at the LHB tendon.

III. Administrative Organization

a. The following sites will be utilized for this study: Loyola Center for Health at Burr Ridge, Loyola Center for Health at Oakbrook Terrace, Loyola Outpatient Center in Maywood
    i. These locations will be where Dr. Salazar and Garbis will have their initial clinical encounter with these patients. During these encounters, they will be approached about the research project if they are eligible based on inclusion/exclusion criteria.
b. The surgical encounters will occur at Loyola Ambulatory Surgery Center in Maywood, Russo Operating Center at Loyola Main campus, and Gottlieb Memorial Hospital

IV. Study Design

a. Experimental Design: Patients that meet the inclusion/exclusion criteria will be eligible for participation in the study. The design will be a single blinded format where the surgeon will be aware of what treatment the patient will receive (Control vs. Intervention). The patient will not be informed of what arm of treatment they were selected for. Block randomization will be utilized to place an equal number of patients into both groups.
b. Study Population: Patients undergoing arthroscopic shoulder surgery with long head of the biceps tendon pathology.
c. Sample size determination and power analyses:
   Based on previous studies, it is assumed that the pre-ASES score for all patients undergoing biceps tenodesis is approximately 45. At 1 year post surgery, the standard of care group will increase to 85 (Mean difference = 40, STD=18). It is hypothesized that the treatment group with anatomical fixation will increase to approximately 93 (Mean difference = 48, STD=18).

   The necessary sample size was calculated using 80% power of rejecting the null hypothesis (that there is no difference in change in ASES scores between the two groups of interest), when the population mean difference in ASES is $\Delta 1 - \Delta 2 = 48 - 40 = 8$, with a standard deviation of 18, and with a significance level (alpha) of 0.05. This power and sample size calculation was computed using a two-sided two-sample equal-variance t-test.

   To achieve this power, at least 81 patients will need to be enrolled in each group. Patients will only be randomized once to this study. If a patient has a repeat surgery, that case will not be eligible for randomization.

d. Study outcomes/endpoints
    i. Study endpoint will be decided based on the power analysis that was calculated by the research team biostatistician.
    ii. Data collected:
        1. Demographics: Name, MRN, age, sex, hand dominance, ethnicity, profession, BMI

2. Clinical Factors: Indication for surgery, procedures performed, past medical history of upper extremity pathology
3. Medical History: Myocardial infarction, congestive heart failure, peripheral vascular disease, transient ischemic attack or cerebrovascular accident, dementia, chronic obstructive pulmonary disease, connective tissue disease, peptic ulcer disease, liver disease, diabetes, hemiplegia, chronic kidney disease, solid tumor, leukemia, lymphoma
4. Measurements: (in mm)
    a. Supraglenoid tubercle to end of myotendinous junction (most distal tendinous fibers)
    b. Supraglenoid tubercle to start of myotendinous junction (most proximal muscle fiber)
    c. The width of the long head of the biceps tendon at the mid portion of the myotendinous junction

V. Study Procedures

a. Subject selection procedures
    i. Sampling plan
        1. Inclusion criteria:
            a. Patients at least 18 years of age undergoing arthroscopic shoulder surgery
            b. Operations that occur at Loyola University Medical Center (Maywood, IL), Loyola Ambulatory Surgery Center (Maywood, IL), or Gottlieb Memorial Hospital
        2. Exclusion criteria:
            a. Previous shoulder surgery involving the long head of the biceps tendon
            b. Younger than 18 years old
            c. Current pregnancy
                i. As per standard protocol with all surgeries, a urine pregnancy test is performed prior to surgery. If positive, the surgery will be cancelled and the patient will be excluded from the research study.
    ii. Recruitment procedures
        1. Where will recruitment occur?
            a. During the patient's initial clinical visit, qualifying patients will be identified by Dr. Garbis or Dr. Salazar and will be approached for voluntary study participation. At that time, they will be given a written document for informed consent. The clinician will go over the consent and the patient will have the opportunity to ask any questions. If they agree to be in the study, then informed consent will be

obtained then. If they wish to read over the consent further and make a decision later, then they will be approached on the day of surgery by a member of the research team. If they decide against the research study, then they will continue to receive the standard of care as per usual.

b. If the patient wished to read the informed consent further at the clinical visit prior to making a decision, then they will be approached on the day of surgery by a member of the research. Once again, the entirety of the research project will be explained to the patient. If they wish to proceed, then written consent will be obtained. If they decide NOT to participate in the study, then they will continue on to surgery and receive the standard of care.

2. Who will obtain consent?
    a. If obtained at the initial clinical visit, then it will be obtained by Dr. Garbis or Dr. Salazar.
    b. If obtained on day of surgery, then a member of the research team will obtain the written consent.
3. What recruitment materials will be provided to the potential participant (brochures/information sheets/video presentation)?
    a. At the patient's initial clinical visit, they will be given a copy of the informed consent that details specifics of the research study that we are conducting. It will be translated into a health comprehension level deemed appropriate by the IRB committee (7^{th} grade).

iii. Screening procedures
1. What procedures are required for screening?
    a. At the initial outpatient office visit, qualifying patients will be further screened using the aforementioned inclusion/exclusion criteria. At that time, Dr. Garbis or Dr. Salazar will speak with the patient about the research study to its entirety, which will include the potential benefits, risks and alternatives.
2. What is the screening schedule (number of visits, length of visits)?
    a. Patient will be screened during their initial outpatient office visit.
    b. Those patients that express interest will again be approached on the day of surgery. On this day, a member of the research team will explain to the patient, for the second time, the research project.
3. Which screening tests/procedures are part of standard care and which are for research purposes only?

a. A member of the research team will be at the office visit to obtain an ASES score prior to surgery and will contact patients via phone at 2 weeks, 6 weeks, 3 months, and 6 months and one year after surgery.
b. Standard of Care: Aspects of the physical examination including range of motion, strength, neurovascular status, and shoulder/elbow specific testing will be recorded by the surgeon in the chart per standard history and physical documentation.
    i. A member of the research team will gather this information via chart review.
c. Research Specific: On the day of surgery, a member of the research team will ask the patient a short series of questions in order to calculate an American Shoulder & Elbow Surgeon (ASES) score as their preoperative score. The member of the research team administering the questionnaire will not be blinded. A specific description of the ASES questionnaire is detailed later in the protocol. This questionnaire will again be tested at the patient's 6 month follow up.

4. What happens with screen failures (including any data gathered during screening)?
    a. Those patients that are not eligible based on the inclusion/exclusion criteria, will not be included in the study.
    b. The risk of patients incorrectly being included in the study despite screening the inclusion/exclusion criteria is essentially zero.
        i. All female patients are screened day of surgery with a pregnancy test.
        ii. Age of patient is obtained & confirmed at all clinical encounters.
        iii. History of prior surgery is obtained and verified at initial clinical visit.

b. Randomization procedures
    i. Surgeon block randomization scheme will be used. This will be 1-1 stratified for Dr. Salazar and Dr. Garbis.
    ii. Each surgeon will receive a stratified block randomization list provided by the department of Biostatistics and will be used for patients in chronological order for the surgical start time. Both surgeon schedules are accommodating of this because they are in the operating room on different days of the week.
    iii. Prior to the start of the surgery, the surgeon will be notified by a member of the research team if the patient will be part of the control group or the anatomic fixation group.

c. Study Intervention
    i. Control Group: The control group patient will undergo biceps tenotomy and tenodesis based on surgeon feel on appropriate tensioning of the tendon (Current practice).
        1. Of note, there is no universal method or gold standard on how the long head of the biceps should be tensioned during bicep tenodesis.
    ii. Intervention Group: Patients that are randomized to the intervention group will undergo biceps tenodesis in a standardized, step-by-step protocol as outlined below
d. Surgical Procedure Overview
    i. The initial indication for tenodesis is at the surgeon's discretion, but after that decision is made, then the Control vs. intervention is determined based on our randomization scheme.
    ii. Per current surgeon protocol, all patients will receive a single injected pre-operative nerve block and standard post-operative pain regimen.
    iii. As with every shoulder arthroscopy, a diagnostic scope of the shoulder will be performed, which will include evaluation of the intra-articular portion of the long head of the biceps tendon. If there is any instability or tendinopathy, then the surgeon will decide if biceps tenotomy and tenodesis is indicated.
    iv. Surgical Steps: Biceps Tenotomy & Tenodesis

        *Bolded steps are deviation from current, standard surgeon protocol

        1. Positioning of the patient will be in the standard beach chair position
        2. During the diagnostic arthroscopic shoulder scope, the long head of the biceps is inspected for any instability or tendinopathy, which would be an indication to perform tenotomy at the junction of the supraglenoid tubercle with arthroscopic scissors
            a. If Control group: Bicep tenotomy will occur now
        3. The patient will undergo all other indicated arthroscopic portions of the case (i.e. rotator cuff repair, subacromial decompression, rotator interval release, etc.)
        4. At the conclusion of the arthroscopic portion of the case, the patient's arm will be placed with the elbow at 90 degrees of flexion and neutral forearm rotation. ***The trochar in the anterior shoulder portal and the arthroscope in the posterior shoulder portal will be left in the glenohumeral joint momentarily. The arthroscopic light will be shut off temporarily. Both will be secured to the shoulder using sterile ioban to maintain a good water seal & ensure that both are kept in the correct position for tenotomy later***
        5. The standard mini-open subpectoral approach will be made along the anterior axillary fold
        6. Full thickness skin flaps are developed down to muscular fascia

7. The biceps fascia is opened and the pectoralis major tendon is retracted superiorly
8. ***The myotendinous junction of the long head of the biceps tendon and its location within the intertubercular groove will be marked using electrocautery***
9. ***The surgeon will then turn back to the glenohumeral joint, remove the ioban, turn the arthroscope back on, then perform the biceps tenotomy. All instrumentation will be removed from the glenohumeral joint at this time***
10. ***The surgeon will then turn to the mini-open subpectoral incision that was previously made and the long head of the biceps tendon will be retrieved***
11. **A ruler will be used to measure the entire length of the long head of biceps tendon from origin to end of tendon fibers, origin to beginning of tendon fibers, and width of the tendon**
12. **The arthroscopy camera will be used to take pictures of the biceps tendon at the myotendinous junction next to a ruler for scale**
    a. Per standard protocol, these arthroscopic pictures will be inserted into the electronic medical record. This data will be retrospectively collected by a member of the research team.
13. The tendon is tagged with a running, locking number 2 fiberwire suture at the mid substance of the myotendinous junction ***using the previously made electrocautery marks to set the tension***
14. The tendon is shortened
15. The sutures from the biceps are passed through the Arthrex cortical button
16. The pectoralis major tendon is retracted and 2 centimeters proximal to the distal insertion a unicortical bone tunnel is drilled in the bicipital groove with a 3.2 millimeter drill
17. The wound is irrigated and the biceps button is threaded into this tunnel and then flipped. The suture is tensioned, securing the biceps against the groove
18. The skin is closed in the usual fashion

e. Study Assessments and Activities
    i. If indicated, patients will undergo biceps tenodesis, as described above
        1. Standard protocol for Dr. Salazar and Dr. Garbis is for patients to follow up at 2 weeks, 6 weeks, 3 months, and 6 months after surgery.
            a. A member of the research team will be at the office visit to obtain an ASES score prior to surgery and will contact patients via phone at 2 weeks, 6 weeks, 3 months, and 6 months and one year after surgery.

b. A member of the research team will retrospectively collect history and physical examination data using Dr. Salazar or Dr. Garbis' notes (Complications, Range of motion, strength, special shoulder or elbow physical exam tests).

2. Once the patient has completed their 6 month follow up appointment, all identifiable data from that patient will be deleted from all research records.

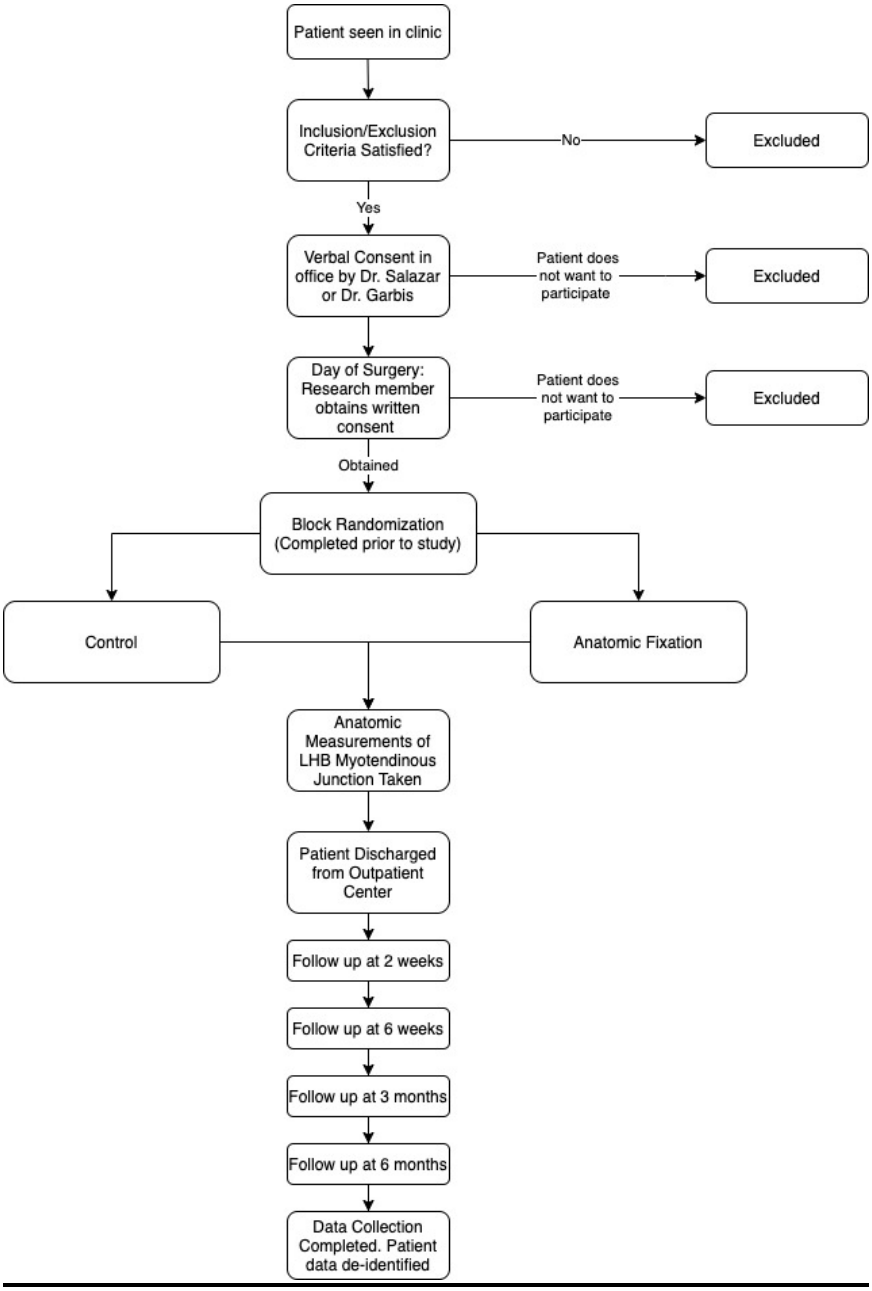
ii. Description of American Shoulder and Elbow Surgeons Score (ASES)

The ASES form was created by the Society of the American Shoulder and Elbow Surgeons to help standardize outcome measures by both combining a physician-rated and patient rated section. The total maximum score (and best outcome) is 100. Half of the score is weighted for pain and the other half for function. The final pain score is calculated by subtracting the visual analog scale from 10 and multiplying by 5. For the functional portion, each of the 10 separate questions are on a scale from 0 to 3. The functional portion total is then multiplied by 5/3 to make it a total of 50 points. In summary, 50 points come from the visual analog scale and the other 50 come from the functional portion, which equals a possible total of 100.

1. What is your usual work/occupation?
2. Usual sport/leisure activity?
3. Do you have pain at night? Y/N
4. Do you take pain killers such as paracetamol (acetaminophen), diclofenac, or ibuprofen? Y/N
5. Do you take strong pain killers such as codeine, tramadol, or morphine? Y/N
6. How many pills do you take on an average day? Quantity
7. Intensity of pain? 0 to 10 (10 being the worst)
8. Is it difficult to put on a coat? Unable to do, very difficult to do, somewhat difficult, not difficult
9. Is it difficult for you to sleep on the affected side? Unable to do, very difficult to do, somewhat difficult, not difficult
10. Is it difficult for you to wash your back/do up bra? Unable to do, very difficult to do, somewhat difficult, not difficult
11. Is it difficult for you to manage toileting? Unable to do, very difficult to do, somewhat difficult, not difficult
12. Is it difficult for you to comb your hair? Unable to do, very difficult to do, somewhat difficult, not difficult
13. Is it difficult for you to reach a high shelf? Unable to do, very difficult to do, somewhat difficult, not difficult

14. Is it difficult for you to lift 10 pounds above your shoulder? Unable to do, very difficult to do, somewhat difficult, not difficult
15. Is it difficult for you to throw a ball overhand? Unable to do, very difficult to do, somewhat difficult, not difficult
16. Is it difficult for you to do your usual work? Unable to do, very difficult to do, somewhat difficult, not difficult
17. Is it difficult for you to do your usual sport/leisure activity? Unable to do, very difficult to do, somewhat difficult, not difficult

iii. Provide a schedule of all study assessments and subject activities, including a tabular representation or timeline as applicable -



VI. Safety Monitoring Plan

a. Definition of adverse events, serious adverse events

i. All surgical interventions are accompanied by a risk of blood loss, infection, and damage to surrounding structures. Patients will be advised that post-op pain and stiffness is expected and normal. If this surgery is not successful, there may be need for additional surgeries. If the patient undergoes rotator cuff repair in addition to biceps tenotomy and tenodesis, there are risks that the rotator cuff repairs may fail to heal or even retear. Symptomatic retears may require further operative intervention. Scar tissue accumulation may also require further operations. All of these risks are routine risks associated with arthroscopic biceps tenotomy and

tenodesis with or without rotator cuff repair. The only known possible risk specific to this research study will be an additional 1-2 minutes under anesthesia for those selected for the intervention group. This risk is considered low with minimal risk to the patient. There is minimal risk of loss of patient confidentiality. All data will be recorded and stored in the password protected Loyola R: drive, then will be de-identified prior to data analysis.

b. What procedures will be used to monitor subject safety?
    i. As with all patient interactions, safety will be prioritized by all participants involved in caring for the patient. Our research project does not incur any increased safety concerns. However, due to the nature of research, participants in our study will inherently receive more attention because of increased interactions with members of the research team. If any concerns, suggestions, or questions arise during our research project, they will immediately be brought to the attention of the principal investigators of the study.
c. Who (list names) will identify, document, and report adverse events?
    i. Adverse event identification will be the responsibility of each member of the research team, specifically, Dr. Dane Salazar and Dr. Nickolas Garbis. These events will be reported promptly to the IRB office.
d. What are the stopping rules with regard to efficacy and safety?
    i. All patients involved in the study will be allowed to withdraw at any time. Consent may be revoked at any time prior to completion of the study, which is expected to be a duration of one year. All members of the research team will be held responsible for notifying the sponsors of the study (Dr. Salazar & Dr. Garbis) if patient safety is compromised.

VII. Plan for patient identifiers and information

a. Plan to protect patient identifiers for improper use and disclosure
    i. All patient health information (PHI), demographics and sensitive data will be kept on the Loyola provided secure server in an assigned password protected folder located on the R: drive. All paper records, if any, will be kept in a locked cabinet in the offices of the principal investigator.
b. Removal of patient identifiers and record retention
    i. Upon completion of the study, electronically stored patient identifiers will be deleted from the R: drive and any paper records will be disposed of using Loyola Medical Center approved shred bins for such purpose.
c. Individuals with access to protected health information
    i. Only research team members listed on the protocol will be granted access.
d. Summary of the use of the data
    i. Data will be collected in a prospective manner, statistically analyzed and formatted for presentation at regional or national surgical meetings and/or publication in peer reviewed surgical/medical journals.

VIII. Statistical Analysis Plan

The primary aim of assessing change in the ASES score from baseline to post-surgery between the control and intervention groups will be assessed using a student's t-test, as indicated in the study design.

In addition, longitudinal mixed effects models will be used to estimate changes in ASES scores, over all time-points using a random effect for surgeon. Other relevant patient characteristics such as age, sex, and Charlson score will be included to explore the adjusted relationship of the intervention and outcomes over time.

IX. Literature Cited

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Document ID #: 212671ar4.011724
Version Date: 01/17/2024

IRB NUMBER: 212671021920

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES CAMPUS
MAYWOOD, ILLINOIS
DEPARTMENT OF ORTHOPAEDIC SURGERY

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Restoring the anatomic tension relationship in long head of the biceps tenodesis

THE APPROVAL FOR THIS PROJECT EXPIRES ON 01/17/2025.

Participant Information

About this research study
Scientists do research to answer important questions which might help change or improve the way we do things in the future. You are being asked to participate in a research study.

Taking part in this research study is voluntary
You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the Loyola university health system.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Overview and Key Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. **Why am I being asked to take part in this research study?**
   We are asking you to take part in this research study because you are having an arthroscopic shoulder surgery (using a scope with a camera to see the inside of your shoulder).

2. **Why is this research being done?**

   There are two reasons for why this research is being done. The first reason is to better study the anatomy of a tendon that we will encounter during your surgery. The second reason is to help develop a better step-by-step process of performing a specific portion of your surgery. We want to develop a more thorough surgical routine to potentially help patients after surgery so that they have less pain and weakness.

3. **What will happen to me during the study?**
   You will undergo shoulder surgery like normal. During your surgery, we will take pictures of your biceps tendon as part of our study. In addition, you will be randomly selected (50/50 chance) to have your surgery done in a more detailed, step-by-step process. Neither you nor your doctor will be able to choose your treatment. You will not be told which treatment you had.

4. **How long will I participate?**
   Your participation in this study will last one year following your surgical procedure. You will be asked to complete your normal clinical visits after surgery. These clinic visits are the standard for any patient that undergoes this procedure and are not unique to this research project. The only additional time required in participating in this study is that you will receive a phone call and be asked a series of 17 questions These phone calls will occur prior to surgery, at your 2 weeks, 6 weeks, 3 months, and 6 months and one year by a member of the research team, which should take less than two minutes of your time.

5. **Will I benefit from the study?**
   We do not know if you will benefit from participating in this study. For more information, please see Benefit section below.

6. **What are the risks?**
   If you are selected to be in the intervention group of this study, you will be under anesthesia for approximately 1-2 additional minutes to allow the surgeon to perform the procedure. For additional risks please refer to the risks and discomfort section.

7. **Do I have other options besides taking part in this study?**
   Participation in research is completely voluntary. If you choose to not participate, you will receive your doctor's usual treatment for your problem.

8. **Will I be paid to participate?**
   You will not receive any payment for taking part in this study.

9. **Will it cost me anything to participate?**
   There is no cost to you for taking part in this study.

End of Overview and Key Information

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

PURPOSE OF RESEARCH: You are being asked to participate in this study because you are having arthroscopic shoulder surgery (a scope with a camera to look inside your shoulder joint)

The purpose of this study is to investigate whether a more thorough, step-by-step process to perform a portion of your surgery will result in decreased complications after surgery. In addition, we are studying a specific portion of your biceps tendon that has not been studied before.

The study is being conducted Dr. Dane Salazar and Dr. Nickolas Garbis.

Approximately 164 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will be asked to do the following things:

All participants in the study will have pictures taken of their biceps tendon during the procedure using a shoulder scope. Those images will be securely stored in the electronic health record, then studied by a member of the research team.

You will be assigned by lottery to be in either group 1 or group 2.

> Group 1: The control group. This is the group that will have no change to the surgical procedure. This surgery would be the same as someone who did not participate in the study. You would still have biceps tenotomy (cutting of the biceps tendon) and tenodesis (the tendon is fixed at a different location on the bone). When placing the tendon at a different location on the bone, the surgeon will go by feel of what is not too tight or not too loose when performing this procedure.
>
> OR
>
> Group 2: The intervention group. This group will have a standardized, step by step process to perform a portion of your surgery. The specific portion that will be affected is called biceps tenotomy and tenodesis. What this means is that the biceps will be cut (tenotomy), then we will place the tendon at a different location on the bone (tenodesis). When placing the tendon at a different location on the bone, the surgeon will use markings on the tendon and bone to make sure that the tendon is put back in its natural/anatomical location. If chosen to be in this group, then your surgery will be lengthened by about 1-2 minutes.

Neither you nor your doctor can choose the group you will be in. You will not be told which group you were in. Your doctor can tell you when the study is completed which may not be for some time.

All patients undergoing surgery will be asked to return for follow up visits at 2 weeks, 6 weeks, 3 months, 6 months and one year after surgery. These are regularly scheduled follow up visits, regardless of participation in this research study. Prior to your visit you will recive a telephone questionnaire and be asked a short questionnaire about pain, quality of life,. This will take approximately 2 minutes of your time for each visit.

If during your participation in the research project new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

RISKS/DISCOMFORTS: The surgical procedure you are assigned to receive may not be as effective or may be associated with more problems than the other surgical procedure in this study that you did not receive.

While participating in this study, you may experience the following risks, side effect and/or discomforts:

As per all surgical interventions, there is a risk of blood loss, infection, and damage to surrounding structures. Post-op pain and stiffness is expected and normal. If this surgery is not successful, there may be need for additional surgeries. If you undergo a rotator cuff repair in addition to biceps tenotomy and tenodesis, there are risks that the rotator cuff repairs may fail to heal or even re-tear. Symptomatic re-tears may require further operative intervention. Scar tissue accumulation may also require further operations. All of these risks are routine risks associated with arthroscopic biceps tenotomy and tenodesis with or without rotator cuff repair.

There may be other side effects that we cannot predict or are currently unknown.

BENEFITS: We do not know if you will benefit from participating in this study. The information we learn may help others.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center.

Your doctor has discussed other options with you along with their risks and benefits.

FINANCIAL INFORMATION: Taking part in this study may or may not cost your insurance company more than the cost of getting treatment without being in this study. Some health plan insurers will not pay the costs for people taking part in studies. Check with your health plan insurer to find out what they will pay for. Depending on your health insurance coverage, there may be out-of-pocket costs for you like co-payment of the standard visits, co-insurance, or deductibles. You will be responsible for these expenses.

RESEARCH RELATED INJURY:
In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds

available from Loyola University Medical Center, Gottlieb Memorial Hospital, Loyola University Health System or Loyola University of Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and how you do from you and your Loyola University Medical Center or Gottlieb Memorial Hospital medical records. The information will be collected by the study physician(s), the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University of Chicago the research sponsor; data collection and study verification agencies; and/or government regulatory agencies such as the Food and Drug Administration.

The information we will collect and send includes:

__X__ DEMOGRAPHIC INFORMATION (e.g., name, address, phone number)

__X__ MEDICAL RECORD (including, but not limited to, history and physical exam notes, progress notes, consultation reports, laboratory test results, AND/OR operative reports)

__X__ PHOTOGRAPHS, VIDEOTAPES, OR DIGITAL OR OTHER RADIOGRAPHIC IMAGES (PHOTOGRAPHS OF YOUR BICEPS TENDON)

We will collect and provide this information about you for as long as you are in the study. We anticipate that duration to be approximately one to two years

Once the information is disclosed outside of Loyola University Medical Center or Gottlieb Memorial Hospital, it may no longer be protected by federal privacy laws.

De-identified data from this study may be shared with others for research purposes. We will remove or code any personal information that could identify you before data are shared with other researchers to ensure that no one will be able to identify you from the information we share, however this cannot be guaranteed. Once identifying information is removed, the information and samples cannot be withdrawn from further use. You will not be asked to sign an additional consent for this use.

It is possible that the research team, research nurses, data collection and/or study verification agencies, data administrators or staff, or the Food and Drug Administration will come to Loyola University Medical Center or Gottlieb Memorial Hospital and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information Loyola University of Chicago is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

This authorization does not expire.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at Loyola University Medical Center or Gottlieb Memorial Hospital, as applicable, unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by Loyola University of Chicago and the sponsor.

As per normal protocol, we will have you follow up with Dr. Salazar or Garbis at regularly scheduled visits that are at 2 weeks, 6 weeks, and 6 months after your surgery.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Amanda Spevacek (Research Coordinator) or give it to the study staff. Your withdrawal from the study will not have any effect on any actions by Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago taken before the attached form is received by Loyola University of Chicago.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the sponsors, Dr. Salazar or Dr. Garbis, may terminate the study at any time with or without your consent.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at Robert.Burnham@lumc.edu

_____Date:____/_____/____
Signature

Dr. Dane Salazar or Dr. Nickolas Garbis, the principal investigators for this study, or their associates will be available to answer any questions you may have. Robert Burnham (Orthopaedic resident) can be reached at: Robert.Burnham@lumc.edu

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Campus, at 708-216-2633 or Cynthia Tom-Klebba, MA, CIP, Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

PROJECT TITLE: Restoring the anatomic tension relationship in long head of the biceps tenodesis

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Restoring the anatomic tension relationship in long head of the biceps tenodesis", at Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable. I also revoke my consent to release information I provided to Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable, that allowed use and disclosure of my medical information as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS

SIGNED ORIGINALLY). I understand that this revocation does not apply to any action Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable, have taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Amanda Spevacek, Research Coordinator
Loyola University of Chicago
2160 South First Avenue
Maywood, Illinois 60153