Montefiore
THE UNIVERSITY HOSPITAL

EINSTEIN
Albert Einstein College of Medicine

COVER PAGE for ClinicalTrials.gov

Official Title: Percutaneous Interruption of the Coracohumeral Ligament for the Treatment of Frozen Shoulder.

Brief Title: Percutaneous Interruption of the Coracohumeral Ligament for the Treatment of Frozen Shoulder (CHL Tenex)

Sponsor: Albert Einstein College of Medicine

Unique Protocol ID: 2020-11998

ClinicalTrials.gov ID: NCT04549051

Document Date: 2/13/2024

List of Contents:

1. Informed Consent Form
2. Protocol (Redacted Version) * Redacted protocol Includes redaction of personal identifiable information only.

CONSENT FORM

KEY INFORMATION FOR **Percutaneous Interruption of the Coracohumeral Ligament for the treatment of Frozen Shoulder**

We are asking you to choose whether or not to volunteer for a research study about using sonographically guided percutaneous interruption of the coracohumeral ligament for the treatment of frozen shoulder/ refractory adhesive capsulitis. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

We will be cutting a ligament in your shoulder to treat your frozen shoulder. We are predicting that by cutting this ligament there will be an improvement in the shoulder range of motion (ROM) immediately post procedure. Your participation in this research will last about one month from the day of the procedure. At 1 month visit we will again assess your shoulder range of motion

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By being a part of the study, we hope to improve your range of motion in the shoulder, reduce pain, improve in the quality of life, and also reduce the pain medication usage. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This procedure is relatively safe as the area around the shoulder does not have many blood vessels. However, there is a risk of rupture of axillary artery. Potential infection might be caused but since this is minimally invasive procedure, there is only a small incision on the skin. *For a complete description of risks, refer to the Consent Document below.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [redacted]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted]
If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Percutaneous Interruption of the Coracohumeral Ligament for the treatment of Frozen Shoulder**. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is [redacted]

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Why is this study being done?

There are limited treatment options for chronic frozen shoulders. Most of the conservative treatments have a low rate of success. In order to give treatment options for these patients we have conceived a very new procedure which cuts a ligament in your shoulder. We have practiced this procedure in cadavers (dead bodies) with good results. In addition, a similar procedure using a blade was performed in living patients which also showed good results. We believe we have a new superior procedure which might improve the range of motion in patients with frozen shoulders. The goal of this study is to learn if there is improvement in the shoulder range of motion (ROM) immediately post procedure by at least 100%. We will be using a new device called as Tenex for treating refractory adhesive capsulitis.

TENEX OR TX1 Tissue removal system is approved by the U.S. Food and Drug Administration (FDA) to use as a tissue removal system of soft tissues where fragmentation, emulsification and aspiration are desirable in surgical procedures. We will be using this device to perform this new procedure for the first time in frozen shoulders.

Why am I being asked to participate?

You are being asked to participate in this study because you an appropriate non-surgical patient with all the inclusion criteria who can benefit from the procedure. You have met the inclusion criteria like age >18 and <89 years, with diagnosis of Adhesive Capsulitis (AC) of ligament flavum >3mm, under Ultrasound evaluation, decreased shoulder movement, have tried other conventional therapies like steroid, physiotherapy but have not seen any improvement in the shoulder movement. You will be one among the 57 study patients identified by [redacted] as you are non-surgical candidate. This will be conducted at the Hutchinson campus, Montefiore medical center and is a single center study.

How many people will take part in the research study?

You will be one of about 57 people who will be participating in this study.

How long will I take part in this research?

It will take you about one month from the day of the procedure to complete this research study. During this time, we will ask you to make 2 study visits to Hutchinson campus, Montefiore Medical Center. The procedure will last about 45 minutes.

What will happen if I participate in the study?

The Screening Visit will take about 60 minutes. During this visit, we will explain the procedure, risks, and benefits of the procedure. The inclusion and exclusion criteria will be discussed with you. If you aren't eligible, the study doctor will tell you why. At this visit we will screen you and consent you for your participation in the study and to undergo the procedure discussed with you.

This is a double arm randomized study which means there are two groups. One arm will be getting the local anesthetic into the ligament and the other arm we will be using Tenex device plus the local anesthetic to cut into your ligament. All the patients enrolled in this study will undergo the procedure as the patients in local anesthetic group will cross over to Tenex group at the end of 1 month. Both groups will receive the local anesthetic. You will be given quality of life questionnaire (QOL), Visual Analog Scale (VAS) to measure your pain and your shoulder range of motion (ROM) and opioid usage are all collected before and after the procedure. Please note this is a new experimental procedure.

Follow up visit will take 30-45 minutes.
At this visit:
You will be asked to complete the quality of life questionnaire and Visual Analog Scale to measure your pain. Also, your shoulder ROM and opioid usage will be collected.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

As part of this study, we will review your medical records and put the information we collect in our research records.

Information Banking (Future Use and Storage)

Data Stored with Identification Linking Code

We will store information about you in a "bank", which is a library of information from many studies. This information can be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose or treat disease, including genetic research. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy the information in the bank but if the information was already shared with other researchers, we cannot get it back.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility**.**

INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy but will not be used for future studies.

INITIAL YOUR CHOICE BELOW

_____ I consent to be contacted in the future to learn about:
_____ New research protocols that I may wish to join.
_____ General information about research findings.
_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

You will receive a stipend as a $50 gift card for taking part in the one-year follow-up visit.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind other than the mentioned gift card for your specimens and information or for any tests, treatments, products, or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study. The procedural charges are covered by your insurance and there are no additional charges to take part in this study.

What will happen if I am injured because I took part in this study?

Unfunded Research

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems, or injuries you experience during the course of your participation in the study to [redacted].

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.

- If you do not feel well at any time, call your doctor or the research study doctor immediately.

- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.

- You may carry out all your normal daily activities as instructed by your doctor.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers.
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

Information about your participation in this study will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, the information will be available to all your providers who participate in the EMR system. The purpose of this entry is to provide research information that has the potential to impact your medical care.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

The procedure is relatively safe as the area near the CHL is relatively avascular. However, there is a risk a rupture of axillary artery. Care will be taken to ensure this does not happen by clear identification of the axillary artery by using USG.

There is a potential this new procedure may not improve ROM in which case the study will be stopped, and the IRB will be informed immediately as an adverse event.

Potential for infection, although a minimally invasive procedure there will be a small incision on the skin with potential for infection. All care will be taken to perform the procedure in standard universal precautions. Post procedure the incision will be cleaned, and dressing applied. Standard wound care precautions will be given to the patients.

Questionnaire

You can choose not to answer questions that make you feel uncomfortable.

Are there possible benefits to me?

The patients who are being recruited for this study have limited treatment options and have been suffering from frozen shoulder for years.
Possible benefits include.

1. Improvement in shoulder Range of Motion
2. Improvement in Visual Analogue Scale or your pain
3. Improvement in Quality of Life
4. Reduced pain medication usage

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all the standard care and treatment that is appropriate for you.

Your other choices are continuing the conventional treatment like physiotherapy, steroid injections.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and **[**she/he**]** will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study anymore if you injure your shoulder outside the hospital and has to undergo shoulder repair surgery**.** In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks, and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time

Protocol

Title: Percutaneous Interruption of the Coracohumeral Ligament for the treatment of Frozen Shoulder.

Authors: [redacted]

Principal Investigator:

[redacted]
Montefiore Medical Center.

Clinical Study Protocol

Type of study/Study design: Prospective double Arm randomized control trail. Cross over at one month from non-interventional arm (LA) to intervention arm (TENEX).

Background Significance:
Chronic inflammation of the shoulder joint capsule and its associated structures can lead to clinically significant symptoms, including insidious onset of pain, and ultimately restricting range of motion. Although the underlying mechanism for adhesive capsulitis (AC) is not well defined, some studies suggest that fibroblast proliferation and thickening of the coracohumeral ligament (CHL) is a proposed mechanism for which AC and subsequent prolonged immobilization and symptoms present (1, 2, 3). Other studies suggest that it is due to a combination of capsular fibrosis and inflammation within the synovium, and other focus on the fact that thickening of the CHL is responsible for limiting external rotation in patients affected by adhesive capsulitis (1).

AC coined frozen shoulder by Codman in 1934 [2), has an estimated prevalence of 2-3% in the general population, with ages 40-70 affected most commonly, and predominantly women. While the precise etiology remains undefined, it can be secondary to trauma or an idiopathic etiology and has been found to have an incidence as high as 20% in diabetic patients, with worse functional outcomes when compared to non-diabetic patients. Hypothyroidism and cerebrovascular disease have also been shown to be associated with an increased risk of developing AC (4). AC is typically a clinical diagnosis. However, both magnetic resonance and ultrasonography have consistently shown thickening of the CHL (1). Several studies have compared arthrographic evidence of findings in adhesive capsulitis, and many reported a thickening of the CHL in cases of frozen shoulder as compared to control subjects (2). In a study implementing shear-wave elastography (SWE), the CHL in patients diagnosed with adhesive capsulitis was thicker and stiffer (4).

Interventions aimed at improving AC and CHL damage, clinical symptomatology, as well as histopathological findings range from rest and physical therapy, local injections and hydrodilation, to advanced surgical interventions (4, 5). These surgical options include manipulation under anesthesia (MUA) and arthroscopic capsulotomy. MUA is an aggressive mobilization of the joint in an effort to lyse adhesions and to stretch the contracted glenohumeral capsule. Despite potential benefits, MUA has been associated with superior labral anterior and posterior (SLAP) lesions, bankart lesions, capsular tears, hemarthrosis, and even humeral or glenoid fractures (4). Arthroscopic capsulotomy allows for direct visualization of the CHL and confirmation of the diagnosis of AC, and several studies have shown improvement in pain relief as well as range of motion (4). However, patients who did not benefit from this intervention were women, typically over the age of 50, with a past medical history of diabetes mellitus. CHL resection has also been described as a potential treatment option for AC (6, 7), with current therapy limited to a surgical approach. Management of refractory disease through arthroscopic capsular release has been shown to improve pain and increase range-of-motion (8, 9, 4). A sequela of arthroscopic surgery is postoperative persistent AC, which some surgeons attempt to prophylactically prevent with adequate postoperative pain control so that the patient can participate in a physical therapy program. The potential limitations of current conservative management and

sequelae of surgical approaches have prompted additional novel therapies. International have researchers developed an ultrasound guided technique with a scalpel incision of the CHL to address this need. Scalpel use is not the standard of care for interventional musculoskeletal pain treatments and our team decided to improve this limitation. Blades and scalpels limit US visibility, thus marginalizing the safety of the procedure. Our team used a percutaneous, ultrasound visible, needle shaped, tissue cutting device to lesion the CHL while improving upon the potential safety concerns. The tool, TENEX®, is widely used by Pain physicians to perform percutaneous tenotomies and has been described in the management of various tendinous pathologies (10, 11, 12, 13, 14, 15).; this device was selected because the gross architectural similarities of tendon and ligament suggest that the CHL could be modified by this tool. Our novel procedure was performed on cadavers to provide proof of concept

The authors performed cadaveric dissection in 8 cadaveric shoulders with the hypothesis that sonographically guided percutaneous dissection will result in sectioning of the coracohumeral ligament. In this study we found that complete sectioning was reproducibly achieved in 7 minutes with approximately 250 passes of the device. This was the desired outcome for improving the shoulder ROM (16). This shows proof of concept and we want to perform this procedure in living subjects for validation. If the results are positive patients can have an outpatient procedure in the interventional pain clinic with desirable results. This cadaveric technique study has already been submitted to Pain Medicine journal for publication.

In addition to the above proof of concept above this procedure was performed in living subjects. A peer reviewed paper was submitted based on data from these subjects. 7 patients were selected for the publication as these patients had follow-ups as requested by the reviewer. In these patients the average improvement in external rotation was 40 degrees and the average abduction improvement was 31 degrees. All patients retained this improvement in shoulder ROM at follow-up visits. Of note, one patients follow-up visit was 116 after the procedure and her improvement in ROM was 60 and 110 in external rotation and abduction respectively. Given these outcomes the authors decided to do a prospective RCT.

Results

Safety data

N	Age	Sex	Procedure date	Medical Complications	Surgical Complications	Follow-up 3 month	Note
1	58	M	7/30/18	NA	NA	NA	Pt never followed-up. PT/OT notes says full ROM achieved
2	72	F	8/27/18	0	0	Yes	No complications
3	72	F	8/22/18	0	0	Yes	2 and 3 are same patient with procedure on both shoulders
4	85	F	1/7/19	0	0	Yes	No complications
5	71	F	10/16/19	0	0	Yes	No complications
6	47	F	10/16/19	0	0	Yes	No complications
7	87	F	8/14/19	NA	NA	NA	Multiple FU calls made. Pt finally FU 5 months later “very satisfied with results”
8	79	F	8/28/19	0	0	Yes	No complications
9	65	F	11/13/19	0	0	NA	Did not FU with pain. Gen Med visit does not say shoulder pain
10	44	F	11/20/19	0	0	Yes	No complications
11	76	F	11/20/19	0	0	Yes	No complications
12	73	F	1/10/20	0	0	Yes	No complications

13	77	M	1/13/20	0	0	Yes	Pt has CRPS of arm. C/O pain. CHL is a ligament and should be unrelated to nerves
14	84	F	1/13/30	0	0	Yes	Pt seen in other dept. Does not mention shoulder pain in notes
15	80	F	3/18/20	NA	0	NA	COVID not seen
16	49	F	7/27/20	0	0	Yes	No complications
17	49	F	9/16/20	0	0	Yes	No complications

Patients in whom goniometry was done

Patient	1	2	3	4	5	6	7
Sex	Female	Female	Female	Female	Female	Female	Female
Age	83	70	70	69	70	46	78
Laterality	Left	Right	Left	Right	Right	Left	Left
Target tissue	CHL	CHL	CHL	CHL	CHL	CHL	CHL
Procedure time, min	6	5.5	4	7	5.4	7	7
Passes	300	200	200	300	300	300	300
Pre procedure							
Ext rotation, degrees	20	50	15	10	15	30	50
Abduction, degrees	40	50	50	80	60	60	95
Post procedure							
Ext rotation (% change in degrees)	50 (150)	60 (20)	60 (300)	60 (500)	70 (367)	80 (167)	90 (80)
Abduction (% change in degrees)	90 (125)	80 (60)	110 (120)	90 (12.5)	70 (16.6)	80 (33)	130 (37)
Follow-up							
Days between procedure to follow-up	24	111	116	15	36	36	50
Ext rotation (% change in degrees)	70 (250)	75 (50)	23 (50)	60 (500)	80 (433)	70 (133)	80 (60)
Abduction (% change in degrees)	85 (113)	75 (50)	75 (50)	80 (0)	85 (42)	90 (50)	90 (-5.3)

Given the significance of CHL hypertrophy in AC, the authors believe lesioning this pathologic ligament will result in significant improvement for patients suffering from AC. Our cadaveric technical analysis added to the clinical safety trail by the This study aims to use sonographically guided percutaneous sectioning of coracohumeral ligament for the treatment of AC. This novel technique is minimally invasive, and we present our findings with proof of concept for a clinical technical treatment of the CHL in patients with frozen shoulder. The patients we will be recruiting will

be subjects who have failed the conservative treatment and are not surgical candidates. We will explain the risks and the procedure and take informed consent.

Study Objective:

The objective of this study is to use sonographically guided percutaneous interruption of the Coracohumeral ligament for the treatment of refractory Adhesive Capsulitis. We have already performed this procedure in cadavers and will validate the cadaveric findings in human subjects.

Study Design:

Patient will be identified by the Co-PI ([redacted]) for screening. He will then determine whether the patient is an appropriate non-surgical candidate. If the subject is an appropriate non-surgical candidate, he/she will be then referred to the PI ([redacted] will then screen the patient for participation in the study. He will then inform the research staff, who will approach the patient in the clinic for possible participation in the study.

The research staff will then explain the procedure, risks and possible benefits of the procedure. PI ([redacted]) will also explain the procedure as he will be performing the procedure. After informed consent is taken the patient will then be enrolled in the study. They will then undergo the procedure. Of note, this procedure will only be performed on Wednesdays when [redacted] is physically present on the same floor of the Hutchinson campus. He will not be in any other surgery when the patient is undergoing the procedure with [redacted] will thus be available for any assistance.

This is a study where patients will be randomized to two groups. One group will receive Local anesthetic and Tenex. The second group will receive local anesthetic only. The second group will be given the option of crossing over to local anesthetic and Tenex group at 1-month visit. Please note Local anesthetic is standard of care for diagnostic purposes. Both groups will be receiving the same anesthetic.

Subjects shoulder ROM, QOL, VAS and opioid usage will be assessed before and after the procedure in both the groups. These parameters will also be evaluated at the 1-month visits.

Other relevant data will be collected through chart review. This includes patient medical, surgical history, medication history, other health conditions, demographics and exercise/physiotherapy sessions.

Primary outcomes: Improvement in shoulder range of motion (ROM) (external rotation) immediately post procedure by at least 100%

Secondary outcomes:
Sustained ROM at 1-month visit compared to pre-procedure ROM
Opioid use before after and at 1-month visit
VAS scale for an expected difference of 3 points
Quality of life questionnaire before procedure, after procedure and at 1-month visit.
Bilateral shoulder ROM improvements in subjects with bilateral procedure

Target Population: 57 adult patients will be enrolled in the Montefiore Hutchinson campus.

Power Analysis:

Assume 30% of patients in the local anesthetic group will have at least a 100% improvement in range of motion one-month post treatment. With a sample size of 32 patients in the Tenex group and 16 patients in the local

anesthetic group, the study will have 81.9% power to detect a difference of 45% in patients with at least a 100% improvement in range of motion between the Tenex group and local anesthetic group one-month post treatment using a two-sided Fisher's exact test at a 0.05 significance level.

Assume an attrition rate of 15%, 57 patients will be enrolled and randomized in a 2:1 ratio to receive either Tenex or local anesthetics.

Randomization

Block randomization was done using SPSS software by the in house statistician. Randomization is noted at the end of the document for all our patients. Please note randomization is 2:1 Tenex:LA. LA will cross over to Tenex at 1 month if the subjects desire.

Inclusion:

1. Adults >18 and <89 years
2. Established Diagnosis of Adhesive capsulitis (AC)
   - Ligament Flavum >3mm, diagnosed by US evaluation
   - decreased shoulder ROM in external rotation and abduction (50% of unaffected side) (17)
3. Patients who have tried other conventional therapies like steroid treatments, surgical treatments, physiotherapy with little (defined by less than 20 degrees improvement in shoulder ROM – external rotation) to no improvement in the shoulder ROM

Exclusion:

1. Patients with AC but showing improvement in shoulder ROM progressively (defined by improvement in ROM > 200 external rotation or 20 degrees per week when undergoing physiotherapy)
2. Patients who are currently pregnant
3. less than 18 years old and older than 89 years old

Patient recruitment:

Patients will be identified by the PI/Co-PI and will be consented, screened and enrolled into the study by the approved research staff at the Montefiore Hutchison campus.

Informed consent:

All the subjects will be consented before enrolling into the study. A detailed informed consent is taken by the approved research staff who will explain the study in detail with regards to risks and benefits. The patient can refuse to be a part of the study at any point even after signing the consent.

Benefits:

The patients who are being recruited for this study have limited treatment options and have been suffering from frozen shoulder for years

Possible benefits include

1. Improvement in shoulder ROM
2. Improvement in VAS
3. Improvement in QOL
4. Reduced pain medication usage

Risks:

The procedure is relatively safe as the area near the CHL is relatively avascular. However, there is a risk a rupture of axillary artery. Care will be taken to ensure this does not happen by clear identification of the axillary artery by using USG.

There is a potential this procedure may not improve ROM in which case the study will be stopped, and the IRB will be informed immediately as an adverse event.

Potential for infection, although a minimally invasive procedure there will be a small incision on the skin with potential for infection. All care will be taken to perform the procedure in standard universal precautions. Post procedure the incision will be cleaned, and dressing applied. Standard wound care precautions will be given to the patients.

Study reimbursement: None

Statistical analysis:
Differences in VAS, opioid use, and QOL scores before and after the procedure will be compared using paired t-tests or Wilcoxon singed-rank tests.

Assume 30% of patients in the local anesthetic group will have at least a 100% improvement in range of motion one-month post treatment. With a sample size of 32 patients in the Tenex group and 16 patients in the local anesthetic group, the study will have 81.9% power to detect a difference of 45% in patients with at least a 100% improvement in range of motion between the Tenex group and local anesthetic group one-month post treatment using a two-sided Fisher's exact test at a 0.05 significance level.

Assume an attrition rate of 15%, 57 patients will be enrolled and randomized in a 2:1 ratio to receive either Tenex or local anesthetics.

Data analysis:
Simple descriptive statistics will be used in analysis of the data. The main primary outcome is the improvement in shoulder ROM and we expect to improve the ROM by at least 100 percent in external rotation. Differences in VAS, pain medication use, and QOL scores before and after the procedure will be compared using paired t-tests or Wilcoxon singed-rank tests.

Data Safety
The PI will give assurances of data safety as well as the timely report of any breach. The data will be stored on a password protected encrypted computer which is located in a locked room with access only to the PI and the research staff. The data reported will be deidentified and any chances of identifying information will be minimized. In addition, the data will be stored on an password protected excel file on the above password protected computers. The identifiers will be destroyed at the end of the study i.e., 3 years from the start of the study.

Subject Safety
In addition to following the inclusion/exclusion criteria, [redacted] will be available on the day of the procedure. He will not be scrubbed in to any other case and will be available for immediate back up in case of a medical or surgical complication on the day of the Tenex procedure. Please note he will also be in the same building.

DSMB and DSMP
Data safety monitoring board will be managed by Dr. Amaresh Vydyanathan, Dr. Pramod Voleti and Dr. Michael D Hossack. All the three above Physicians are independent researchers and practicing clinicians with expertise in managing chronic pain at Montefiore. They are not associated with the study. Dr. Voleti and Dr. Hossack practice in Orthopedics and Dr. Vydyanathan practices Anesthesiology and pain medicine.

Any adverse events will be immediately reported to them in addition to IRB. They will regularly conduct data monitoring and safety visit every 6 months. In addition, they will assure the safety of research participants and continued relevance of the study question.

DSMP SCHEDULE

1. Adverse events reportable in 48 hours.

2. Safety monitoring every 6 months.
3. Independently report any safety concerns to IRB immediately at any point of the study.
4. They can stop the study if >40% of the study subjects have no improvement in ROM or worsening of ROM at 1-month visit
5. Study withdrawal criteria - worsening of the ROM>40 degrees from baseline in external rotation

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Randomization schedule

Obs	ID	Block	Treatment
1	3515	1	B
2	4598	1	A
3	4849	1	A
4	387	2	A
5	3463	2	A
6	7924	2	B
7	209	3	A
8	4438	3	B
9	6993	3	A
10	1355	4	A
11	2866	4	B
12	5693	4	A
13	1119	5	A
14	4594	5	B
15	6735	5	A
16	1154	6	A
17	1269	6	B
18	3982	6	A
19	1136	7	A
20	3623	7	A
21	3720	7	B
22	5357	8	B

Obs	ID	Block	Treatment
23	7033	8	A
24	8664	8	A
25	159	9	B
26	3267	9	A
27	4521	9	A
28	821	10	A
29	1228	10	A
30	3677	10	B
31	2123	11	A
32	4903	11	A
33	9499	11	B
34	1095	12	B
35	1333	12	A
36	8586	12	A
37	1143	13	B
38	5573	13	A
39	8400	13	A
40	4149	14	B
41	8490	14	A
42	8980	14	A
43	187	15	A
44	5888	15	A
45	5961	15	B
46	700	16	A
47	3577	16	A
48	4446	16	B
49	1727	17	A
50	2434	17	A
51	9304	17	B
52	2244	18	B
53	2758	18	A
54	4147	18	A
55	2169	19	A

Obs	ID	Block	Treatment
56	3367	19	A
57	4305	19	B

A: Tenex

B: local anesthetic