Official Title:	Pecs II Block Versus Surgeon Infiltration for Open Subpectoral Biceps Tenodesis
NCT Number:	NCT04867369
Study Number:	20-01978
Document Type:	Protocol and Statistical Analysis Plan
Date of the Document:	• December 4, 2023

PECS II BLOCK VERSUS SURGEON INFILTRATION FOR OPEN SUBPECTORAL BICEPS TENODESIS

A phase IV, randomized, single-blind, single-center study measuring the effects of Pecs II block with 0.25% bupivacaine versus surgeon infiltration with 0.25% bupivacaine on postoperative pain control and opioid utilization in participants who undergo open subpectoral tenodesis.

Principal Investigator:	**David Furgiuele, MD, FASA** Department of Anesthesiology, Perioperative Care and Pain Med NYU Langone Health NYU Langone Orthopedic Hospital 301 East 17th Street New York, NY 10003 David.Furgiuele@nyulangone.org O: (212) 598-6085
Additional Investigators:	**Mandeep Virk, MD** Department of Orthopedic Surgery NYU Langone Health NYU Langone Orthopedic Hospital 301 East 17th Street New York, NY 10003 Mandeep.Virk@nyulangone.org O: (646) 754-2100 **Thomas Youm, MD** Department of Orthopedic Surgery NYU Langone Health NYU Langone Orthopedic Hospital 301 East 17th Street New York, NY 10003 Thomas.Youm@nyulangone.org 212-348-3636

	Young Kwon, MD, PhD Department of Orthopedic Surgery NYU Langone Health NYU Langone Orthopedic Hospital 333 East 38th Street, 4th floor New York, NY 10003 Young.Kwon@nyulangone.org O: 646-501-7223 **Kirk Campbell, MD** Department of Orthopedic Surgery NYU Langone Health NYU Langone Orthopedic Hospital 301 East 17th Street New York, NY 10003 Kirk.Campbell@nyulangone.org 646-356-9407 **Guillem Gonzalez-Lomas, MD** Department of Orthopedic Surgery NYU Langone Health NYU Langone Orthopedic Hospital 301 East 17th Street New York, NY 10003 Guillem.Gonzalez-Lomas@nyulangone.org O: 646-501-7223
NYULMC Study Number:	*S20-01978*
Study Product:	N/A
ClinicalTrials.gov Number:	*Pending*

Amended Version: 11/22/2023

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), 21 CFR Parts 50, 56, 312, and 812 as applicable, any other applicable US government research regulations, and institutional research policies and procedures. The International Conference on Harmonisation ("ICH") Guideline for Good Clinical Practice ("GCP") (sometimes referred to as "ICH-GCP" or "E6") will be applied only to the extent that it is compatible with FDA and DHHS regulations. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

Table of Contents

List of Abbreviations

ASA	American Society of Anesthesiologist Score
BMI	Body Mass Index
DOS	Day of surgery
VAS	Visual analog scale
AE	Adverse event
SAE	Serious adverse event
IV	Intravenous
ITT	Intention-to-treat
PACU	Post-Anesthesia Care Unit
PEC	Pectoralis nerve block
PO	Taken orally
PRN	Taken as needed
PROMIS	Patient Reported Outcomes Measurement Information System
CI	Confidence interval
SD	Standard deviation; a parameter that characterizes a population distribution
SE	Standard error
ANOVA	Analysis of variance; a linear model
NSAID	Non-steroidal anti-inflammatory drug

Protocol Summary

Title	Pecs II Block versus Surgeon Infiltration for Open Subpectoral Biceps Tenodesis
Brief Summary	A phase IV, randomized, single-blind, single-center study measuring the effects of Pecs II block with 0.25% bupivacaine versus surgeon infiltration with 0.25% bupivacaine on postoperative pain control and opioid utilization in participants who undergo open subpectoral tenodesis.
Phase	Clinical study phase IV
Objectives	To determine if Pecs II block is superior to surgical infiltration in reduction of axillary pain after open subpectoral bicep tenodesis, especially in terms of duration.
Methodology	Phase IV, randomized, single-blind, single-center study
Endpoint	**Primary Endpoint:** Opioid utilization for the first 24 hours after surgery, including during surgery, calculated as oxycodone equivalent. **Secondary Endpoints:** Patient reported VAS scores in PACU Patient reported VAS scores on POD 1 and POD 3 Reaction to surgical subpectoral incision (signs include patient movement, tachycardia, etc.) Skin assessment of sensation in PACU (axilla, distal to surgical dressing)
Study Duration	The study will continue until 80 subjects are enrolled per arm, to allow for potential dropout and increased power.
Participant Duration	Each participant will be enrolled on DOS and complete their final follow up on postoperative day three.
Duration of IP administration	Once during surgery
Population	80 patients per study arm scheduled for open biceps tenodesis
Study Sites	NYU Langone Orthopedic Hospital and NYU Ambulatory Surgery Center at 38th street
Number of participants	160
Description of Study Agent/Procedure	Patients in both groups will receive an interscalene nerve block with 20 mL 0.5% bupivacaine. Subjects in the Pecs II block group will receive a Pecs II fascial plane block with 20 mL 0.25% bupivacaine. The Surgical infiltration group patients will receive local infiltration of 0.25% bupivacaine by the surgeon, up to 15 mL.
Reference Therapy	Reference is Interscalene block with 0.5% bupivacaine and surgical infiltration with bupivacaine 0.25%
Key Procedures	Interscalene block with 0.5% bupivacaine, Pecs II block with 0.25% bupivacaine, local surgical infiltration with 0.25% bupivacaine
Statistical Analysis	Continuous and categorical baseline characteristics will be compared using Hedges standardized difference. Outcomes will be assessed using an intention-to-treat (ITT) methodology. Normally distributed data will be compared using t tests while non-normally distributed continuous outcomes will be assessed using the Mann-Whitney U test.

Key Roles

Principal Investigator:

David Furgiuele, MD, FASA
Professor of Anesthesiology
Department of Anesthesiology, Perioperative care and Pain Medicine
NYU Langone Orthopedic Hospital
NYU Langone Health
301 East 17th street
New York, NY 10003
David.Furgiuele@nyulangone.org
212-598-6085

Co-Investigator:

Mandeep Virk, MD
Department of Orthopedic Surgery
NYU Langone Orthopedic Hospital
NYU Langone Health
301 East 17th street
New York, NY 10003
Mandeep.Virk@nyulangone.org
O:(646) 754- 2100

1 Background and Specific Aims

Biceps tendinopathy can range from inflammatory to degenerative pathology and can often contribute to anterior shoulder pain.[1] This pain is generally located at the anteromedial aspect of the shoulder in the area of the intertubercular groove.[2] Surgical treatment by biceps tenodesis can help increase strength and decrease pain in patients that have failed non-operative management. Although there are many variations to the surgical approach, one approach that has been shown effective is the open subpectoral biceps tenodesis.[3]

For arthroscopic and open shoulder surgeries, assuming there are no contra-indications, anesthesiologists at our institution most often perform interscalene brachial plexus blocks along with IV sedation. The brachial plexus provides innervation to most of the shoulder joint and adjacent soft tissue. Nerves that require blockade to achieve effective analgesia include the subscapular, axillary, lateral pectoral, and suprascapular nerves.[4,5] These nerves are anesthetized with the interscalene brachial plexus block which targets the C5-6 nerve roots and spares the inferior trunk of the brachial plexus. When an open subpectoral biceps tenodesis is being performed, either alone or with shoulder arthroscopy, a vertical incision is made along the anteromedial aspect of the arm centered over the pectoralis major tendon.[5,6] Unfortunately, this area of the upper arm is not anesthetized by the interscalene brachial plexus block.

The anteromedial aspect of the upper arm is typically innervated by the medial brachial cutaneous nerve and the medial pectoral nerve, which arise from the inferior trunk of the brachial plexus, along with the intercostobrachial nerve, which originates from the T2 nerve root. In order to anesthetize this area, one can consider utilizing the Pecs II block. The Pectoralis nerve blocks (Pecs) were initially intended for breast surgeries; however, they have also become a popular substitute for paravertebral blocks and thoracic epidurals following thoracic and abdominal wall surgeries.[7] The Pecs I block consists of an injection of local anesthesia between the pectoralis major and minor

muscles. This is intended to block the medial and lateral pectoral nerves. The Pecs II block consists of an additional fascial injection between the pectoralis minor muscle and the serratus anterior muscle, and anesthetizes the upper intercostal nerves. Reynolds previously demonstrated that the Pecs II block is beneficial in decreasing postoperative axillary pain during an open biceps tenodesis compared to no block.[4] However, patients in that study received general anesthesia for the surgery. The alternative to performing a Pecs II block would be surgical infiltration of local anesthesia at and around the incision site. Prior to this study, our institution relied heavily on this alternative to adequately provide analgesia to the anteromedial upper arm and decrease postoperative axillary pain.

To date, there are few studies on surgical infiltration for open biceps tenodesis. Based on the success of the Pecs II block for open bicep tenodesis demonstrated by Reynolds, we propose this randomized controlled study comparing a Pecs II block versus surgical infiltration for this procedure. We hope to elucidate which technique will provide better pain control after open subpectoral bicep tenodesis surgery.

1.1 Specific Aims

This study will aim to compare Pecs II block versus surgical infiltration for axillary pain in patients undergoing arthroscopic shoulder surgery with an open subpectoral bicep tenodesis.

AIM 1: To determine if Pecs II block is superior to surgical infiltration in reduction of axillary pain after open subpectoral bicep tenodesis, especially in terms of duration.

1.2 Statistical Hypothesis

We hypothesize that patients who receive a Pecs II block will have lower postoperative opioid consumption over the first 24 hours (measured in oxycodone equivalents) compared to those who receive surgical infiltration of local anesthetic. Furthermore, the Pecs II block patient group will have reduced adverse effects associated with opioids such as constipation, nausea, pruritis ileus. Failing to reject the null would signify that the Pecs II block has no clinically relevant difference on post-operative opioid consumption outcomes in Open Subpectoral Biceps Tenodesis as compared to surgical infiltration of local anesthetic.

1.3 Objectives and Purpose

The goal of this study is to compare the postoperative pain control using a Pecs II block with 0.25% bupivacaine to the standard of care of local surgeon infiltration with 0.25% bupivacaine following open subpectoral biceps tenodesis, particularly in terms of duration of pain control and adjunctive postoperative analgesic consumption. The primary objective will be to compare opioid utilization between the two arms within the first 24 hours after surgery, including intraoperatively, as measured by oxycodone equivalents. Our secondary objectives are measuring patient reported pain scores in PACU and at 24 hours, reaction to surgical incision, and skin assessment of sensation in the PACU.

2 Study Design and Endpoints

Arm 1: Experimental	Arm 2: Control
Sample Size: 80	**Sample Size:**80
Medication: 20ml 0.5% bupivacaine for ISB + 20ml 0.25 % bupivacaine for Pecs II	**Medication:** 20ml 0.5% bupivacaine for ISB + 15ml 0.25% bupivacaine for surgical infiltration

2.1 Description of Study Design

RECRUITMENT PHASE/CONSENTING PHASE:
Surgeons will inform eligible patients of the study during their pre-surgical visit in their office. If the patient is agreeable, a member of the research team will provide further details and ask the patient to participate on day of surgery. Patients will be made acquainted with the study before DOS during pre-surgical appointments. On DOS when they arrive 1.5/2 hours before surgery we (study team members) will consent them and provide ample time to discuss and review any questions or concerns they may have.

BASELINE ASSESSMENTS:
Subjects will complete a baseline global health and pain assessment.

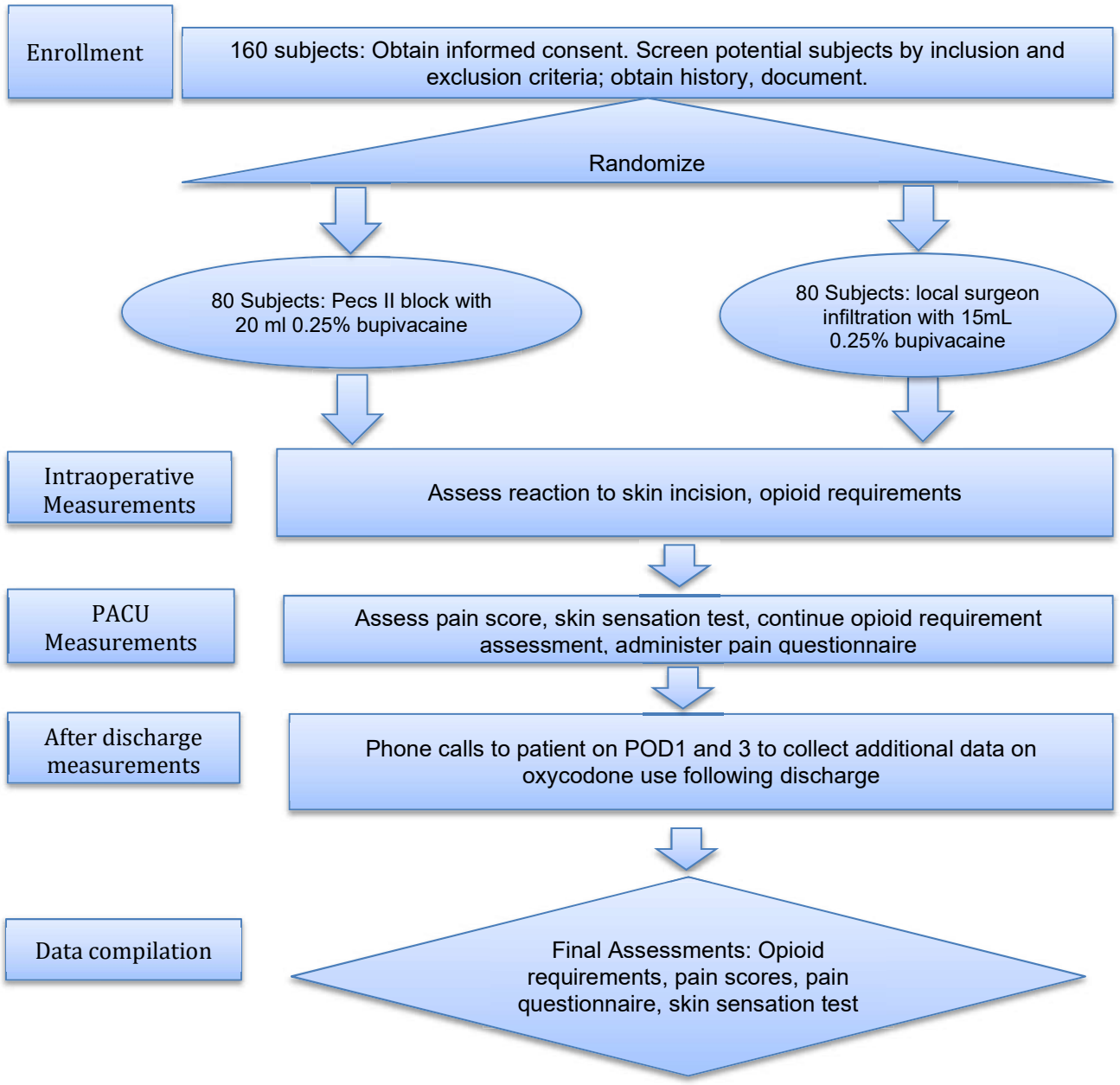
RANDOMIZATION PHASE:
Subjects scheduled to undergo open subpectoral biceps tenodesis will be randomized to either Pecs II block with bupivacaine 0.25% or subpectoral surgical skin infiltration with bupivacaine 0.25%. A randomization scheme will be created prior to start of study enrollment using the randomizer.org website to generate the assignment. Block randomization is commonly used in clinical trial design to reduce bias and achieve balance in the allocation of participants to treatment arms throughout the course of the study. Randomized block design allows us to account for variables so that observed differences are largely due to true differences between treatments and not to the variable. The greatest variable affecting the PECS study is surgical technique and it could possibly vary throughout the duration of the study. We will create blocks of four patients and in each block, two patients will be assigned to the PECS II group, and two to the infiltration group. Thus, patients in both groups with be evenly spread from the beginning to the end of the study period.

A research coordinator will place the randomization results in sealed opaque envelopes prior to recruitment. Each subject enrolled in the study will be assigned a number and the sealed envelope assigning the subject to the PECS II versus surgical infiltration arm will be opened on the day of surgery after the patient has signed consent agreeing to participate in the study.

TREATMENT PHASE:
Patients in both groups will receive an interscalene nerve block with 20 mL 0.5% bupivacaine. Subjects in the Pecs II block group will receive 20mL 0.25% bupivacaine; 20ml will be injected between pectoralis minor and serratus anterior muscles. The subpectoral surgical skin infiltration group will receive 15mL bupivacaine 0.25% by the surgeon. These medications will be obtained from the operating room omnicell. Neither the anesthesiologist nor surgeon will be blinded to the patient's group assignment, as they are the ones administering the treatment. All other stakeholders (patient, other caregivers, and research staff collecting the data) will be blinded to the patient's group assignment.

POST-OPERATIVE PHASE:
After initial recruitment, subjects' pain will be assessed via visual analog scale (VAS) by nursing staff during the post-operative period as per standard of care. The VAS pain scores are collected and documented in the patient's electronic medical record. Additionally, a standardized regimen of pain medication will be given to all subjects who are enrolled. The pain medications given to patients are standard of care medications and vary based on pain level. This is determined by the clinical staff caring for each patient. While the patient is in the PACU, an authorized research member will visit the patient and obtain a pain score using the Numeric Rating Scale (NRS) and McGill Pain Scale. Skin testing in the axilla will be done in PACU prior to discharge to evaluate the presence or absence of sensation in that area. Data on PACU opioid use documented in EPIC will be collected. On POD1 and POD 3, a phone call to the patient will be made to collect additional data on oxycodone use at home as well as an NRS score at 24 and 72 hours after surgery.

2.2 Schematic of Study Design



3 Study Enrollment and Withdrawal

The researchers will approach patients scheduled for shoulder arthroscopy with open biceps tenodesis who are eligible for participation in the study. Anesthesiology attendings, fellows, residents, and authorized researchers will consent and enroll patients pre-operatively.

3.1 Inclusion Criteria

1. Patients between 18 and 75 years of age
2. Patients undergoing shoulder arthroscopy with open subpectoral biceps tenodesis

3.2 Exclusion Criteria

1. Patients younger than 18 and older than 75;
2. Patients with a history of chronic pain that have used opioids for pain management for 3 months or longer;
3. Patients who are allergic to oxycodone;
4. Patients with diagnosed or self-reported cognitive dysfunction;
5. Patients with a history of neurologic disorder that can interfere with pain sensation;
6. Patients with a history of drug or recorded alcohol abuse;
7. Patients who are unable to understand or follow instructions;
8. Patients with severe liver disease, renal insufficiency, congestive heart failure, and/or significant heart disease;
9. Patients with an allergy or contraindication to any of the medications used in the study, or patients with a contraindication to any study procedures;
10. Patients with a BMI over 45;
11. Any patient that the investigators feel cannot comply with all study related procedures;
12. NYU Langone Health students, residents, faculty or staff members.

3.3 Vulnerable Subjects

No vulnerable populations will be enrolled in this study.

3.4 Recruitment and Consent

This study will utilize EPIC to identify subjects and use Redcap in addition to the firewall protected shared drive to manage and store relevant data.

Process of Consent

The consent for participation will be obtained on day of surgery in pre-operative holding room by the regional anesthesiology fellows, Attending Physicians, or authorized researchers that are members of the study team. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be IRB-approved, and participants will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation suited to their comprehension of the purposes, procedures and potential risks as well as their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants will have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the trial. A copy of the signed informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing that the quality of their medical care will not be adversely affected if they decline to participate in this study. If you we are unable to obtain consent at an earlier time, subjects will be given a copy of the informed consent form at their pre-surgical visit to allow them time to read through it, discuss with their relatives, and contact the study team with any questions prior to their surgery.

A copy of the signed informed consent document will be given to the patient, placed in the patient's electronic medical record and the original copy will be stored in the research regulatory binder. Any alteration to the standard consent process (e.g., us.e of a translator, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

Capacity will be assessed through the subject's ability to express understanding of the information being presented to them. The subject will be asked to state back the goals of the study and that they are willing to participate in their primary language.
If a subject requests information regarding opting out of further recruitment for all research, subjects will be directed to contact the research coordinator, Ekow Commeh at 212- 263-3851 or Avra Hammerschlag at 212-266-5835.

3.5 Duration of Study Participation

The study will remain open until 80 patients are recruited for each intervention arm of the study. The actual subject participation length will be four days.

3.6 Total Number of Participants and Sites

Recruitment will end when 160 participants have been enrolled. It is expected that there will be subjects enrolled who will be lost to follow up and be evaluated by intention-to-treat. The sites for enrollment will be the NYU Langone Orthopedic Hospital and NYU Ambulatory Surgery Center at 38th street.

3.7 Participant Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

1. Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
2. The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

3.8 Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.
Circumstances that may warrant termination or suspension include, but are not limited to:

1. Determination of unexpected, significant, or unacceptable risk to participants;
2. Demonstration of efficacy that would warrant stopping;
3. Insufficient compliance to protocol requirements;
4. Data that are not sufficiently complete and/or evaluable; or
5. Determination of futility

4 Study Procedures and Schedule

4.1 Study Procedures/Evaluations

4.1.1 Study Specific Procedures

Patients will be screened for eligibility by the surgical team during their pre-surgical office visit. Surgeons will explain the study to the eligible patient.

If patients are agreeable to participation, a research team member will provide further details and ask for participation on day of surgery. Informed consent will be obtained on day of surgery when the patient is in the

pre-operative holding room by an authorized research member. Patient will complete a baseline global health and pain assessment.

Patients in both groups will receive an interscalene nerve block with 15mL 0.5% bupivacaine. Subjects in the Pecs II block group will receive a Pecs II fascial plane block with 20mL 0.25% bupivacaine. The Pecs II block consists of an injection of 20ml of 0.25% bupivacaine 1:200,000 between the pectoralis minor and the serratus anterior muscles. This will be accomplished using ultrasound guidance to identify the appropriate anatomic structures and ensure appropriate needle localization prior to injection of 20 mL 0.25% bupivacaine 1:200,000.

Postoperatively, pain will be assessed via visual analog scale (VAS) by nursing staff during the post-operative period as per standard of care. The VAS pain scores are collected and documented in the patient's electronic medical record. Additionally, while the patient is in the PACU, an authorized research member will visit the patient and administer a pain questionnaire (NRS and McGill Pain scale). Skin testing in the axilla will be done in PACU prior to discharge. Data on PACU opioid use documented in EPIC will be collected.

4.1.2 Standard of Care Study Procedures

The subjects receiving standard of care procedures will undergo local surgeon infiltration of the surgical field with 15 mL of 0.25% bupivacaine 1:200,000. The OR nurse will obtain the local anesthetic from the operating room omnicell.

4.2 Study Schedule

4.2.1 Screening

Screening Visit (Pre-surgical office visit -30 to -1 days)

- Review medical history to determine eligibility based on inclusion/exclusion criteria.
- Review medications history to determine eligibility based on inclusion/exclusion criteria.
- Perform medical examinations needed to determine eligibility based on inclusion/exclusion criteria.
- Schedule study visits for participants who are eligible and available for the duration of the study.
- Provide participants with further details regarding their participation on day of surgery and follow up.

4.2.2 Enrollment/Baseline

Enrollment/Day of surgery (Visit 1, Day 0)

- Obtain informed consent of potential participant verified by signature on study informed consent form.
- Verify inclusion/exclusion criteria.
- Complete baseline global health and pain assessment
- Randomize to Pecs II or surgical infiltration treatment group
- Perform surgery with analgesic intervention determined by randomization
- Record vital signs, opioid usage, results of examinations, other pain assessments.
- Continue observation in PACU preceding discharge, including administration of VAS scores, pain questionnaire, and opioid usage monitoring.

4.2.3 Follow-Up Phone call (POD 1 and POD 3)

1. Phone call to patient to collect additional data on opioid use following discharge, on POD 1 and 3 after surgery

4.2.4 Withdrawal/Early Termination Visit

Subjects may discontinue their participation in the study at any time. As there is only a single intervention, and the safety of this is not in question, further follow up will not be required if a subject decides to terminate their participation in the study.

4.3 Concomitant Medications, Treatments, and Procedures

All concomitant prescription medications taken during study participation will be recorded on the case report forms (CRFs). For this protocol, a prescription medication is defined as a medication that can be prescribed only by a properly authorized/licensed clinician. Medications to be reported in the CRF are concomitant prescription medications, over-the-counter medications and non-prescription medications.

5 Risks and Benefits

5.1 Potential risks

Medication:

The potential risks associated with bupivacaine include neurologic and cardiac toxicity, if injected intravascularly. However, the risk is very low because a trained anesthesiologist using ultrasound guidance will perform the PECS II block and a trained orthopedic surgeon will be performing the skin infiltration. US guidance allows the anesthesiologist to see and avoid blood vessels when administering the medication. Additionally, the syringe of the local anesthetic will be aspirated prior to injection by the anesthesiologist and surgeon to ensure that the block needle tip is not intravascular. A PEC II block is fascial plane block and not a nerve block. The local anesthetic will be injected between the pectoralis major and serratus anterior muscle. The risk of nerve injury or intravascular injection in the PECS II is therefore similar to the surgical infiltration arm of the study. Allergic reactions to local anesthetic is possible however, any subjects with a history of allergies to local anesthetic will be excluded from the study.

Procedure:

Pecs II:

The potential risks associated with Pecs II include bleeding, nerve damage, pleural injury, infection at injection site, intravascular injection, and local anesthetic systemic toxicity. LAST is generally secondary to intravascular injection. The likelihood of this occurring is low due to the expertise of the anesthesiologist and use of ultrasound guidance.

Surgical infiltration:

The potential risks associated with surgical infiltration include bleeding, nerve damage, pleural injury, infection at injection site and local anesthetic systemic toxicity. However, the likelihood is low due to the expertise of the surgeon performing the injection, the sterile environment, and the safe practice of clinicians.

5.2 Potential benefits

Study subjects may experience better pain control, improved satisfaction, decreased need for opioids and reduced incidence of side effects. If the study is not inconclusive, the study's results may benefit future patients by showcasing Pecs II block improves pain control in the first 24 hours of an Open Subpectoral Biceps Tenodesis. Additionally, advocate for the use of Pecs II block as the standard of care for peri- and postoperative pain control in future patients undergoing Open Subpectoral Biceps Tenodesis.

6 Statistical Analysis

6.1 General Approach

The primary analysis will follow the intention-to-treat (ITT) principle in order to evaluate the true outcome of the intervention as experienced by the patient who is blinded to the intervention.

Continuous and categorical baseline characteristics will be compared using Hedges standardized difference

Normally distributed data will be compared using t tests while non-normally distributed continuous outcomes will be assessed using the Mann-Whitney U test.

It is anticipated that the data for some subjects will be incomplete for various reasons: missing daily-diary entries, refusal to answer a question on the questionnaire, onset of illness, loss-to-follow-up, etc. All occurrences of incomplete data will be investigated to carefully document the reasons for the missing data. If the primary outcome (amount of opioid utilization for the first 24 hours after surgery) cannot be ascertained with a reasonable degree of certainty, the patient will be excluded from the data analysis.

6.2 Analysis of Endpoints

Primary Endpoints:

1. Opioid utilization for the first 24 hours after surgery, including during surgery, calculated as oxycodone equivalent.

Secondary Endpoints:

1. Patient reported NRS scores in PACU and at 24 hours
2. Patient Reported NRS scores on POD 1 and POD 3
3. Reaction to surgical subpectoral incision (signs include patient movement, tachycardia, etc.)
4. Skin assessment of sensation in PACU (axilla, distal to surgical dressing)

Normally distributed data such as the primary outcome variable will be compared using the two-sample t-test. In the case that the data are not normally distributed, the Wilcoxon rank-sum test will be used instead. Categorical variable will be compared using the Chi-Squares unless other tests such as the Fisher's exact test are more appropriate.
All endpoints will be evaluated as fits the data set with graphical figures such as scatter plots, box-and-whisker plots, and frequency histograms to visualize the distribution of these outcomes and their relationships to covariates and treatment assignment. When appropriate descriptive graphical and tabular methods will also be estimated and presented in a graphical figure.

6.2.1 Baseline Descriptive Statistics

The following patient data will be recorded: age, gender, height, weight, date of admission, date of discharge, laterality, surgical approach, implants used, duration of surgery, contamination, ASA, comorbidities (smoking, cardiac history, diabetes etc.), and medications. This information will be accessible in the patient's medical record.

6.3 Sample Size

80 subjects will be enrolled

Based on published reports (Reynolds et al) and our clinical experience, we estimate that patients in the Pecs group will use only 25 mg of oxycodone-equivalent, while patients receiving the infiltration will use 32 mg. Using a 2-sided, 2-sample t test, an α value of 0.05 and assuming a common SD of 13, a power analysis revealed that 72 subjects were needed per group for a power of 0.90. We chose to enroll 80 subjects per arm to allow for potential dropout and an increased power.

6.4 Enrollment/Randomization/Masking Procedures

We will utilize randomization.com to generate a block randomization assignments for all 160 participants. Someone that is not a stakeholder in the study will make randomization envelopes, which include the study ID number, the treatment assignment, and dosage specifics. These randomization envelopes will then be distributed to the anesthesiologist pre-operatively by the authorized researcher after informed consent is obtained.

6.5 Breaking the Study Blind/Participant Code

If there is any adverse event related to the drug, we will break the blind for the subject and randomization will be disclosed to the patient.

7 Assessment of Safety

An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

7.1 Definition of Adverse Events (AE)

Serious Adverse Event

Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening but are clearly of major clinical significance. They may jeopardize the subject and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

7.2 Definition of Unanticipated Problems (UP)

Unanticipated Problems Involving Risk to Subjects or Others

Any incident, experience, or outcome that meets <u>all</u> of the following criteria:

- <u>Unexpected in nature, severity, or frequency</u> (i.e., not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
- <u>Related or possibly related to participation in the research</u> (i.e., possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)
- <u>Suggests that the research places subjects or others at greater risk of harm</u> (including physical, psychological, economic, or social harm).

This definition could include an unanticipated adverse device effect, any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s)).

7.3 Classification of an Adverse Event

7.3.1 Severity of Event

For AEs not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

7.3.2 Relationship to Study Agent

The clinician's assessment of an AE's relationship to study agent (drug, biologic, device) is part of the documentation process, but it is not a factor in determining what is or is not reported in the study. If there is any doubt as to whether a clinical observation is an AE, the event should be reported. All AEs must have their relationship to study agent assessed. In a clinical trial, the study product must always be suspect. To help assess, the following guidelines are used.

1. ***Related*** *– The AE is known to occur with the study agent, there is a reasonable possibility that the study agent caused the AE, or there is a temporal relationship between the study agent and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study agent and the AE.*
2. ***Not Related*** *– There is not a reasonable possibility that the administration of the study agent caused the event, there is no temporal relationship between the study agent and event onset, or an alternate etiology has been established.*

For all collected AEs, the clinician who examines and evaluates the participant will determine the AE's causality based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

1. ***Definitely Related*** *– There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to drug administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the drug (dechallenge) should be clinically plausible. The event must be pharmacologically or phenomenologically definitive, with use of a satisfactory rechallenge procedure if necessary.*
2. ***Probably Related*** *– There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the drug, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfill this definition.*
3. ***Possibly Related*** *– There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of the trial medication). However, other factors may have contributed*

to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related," as appropriate.

4. ***Unlikely to be related*** *– A clinical event, including an abnormal laboratory test result, whose temporal relationship to drug administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the trial medication) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).*
5. ***Not Related*** *– The AE is completely independent of study drug administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.*

7.3.3 Expectedness

The PI, Dr. Furgiuele, will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study agent.

7.4 Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an AE or SAE may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor. All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate RF. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE. UPs will be recorded in the data collection system throughout the study.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The sponsor should also be notified if the investigator should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

7.5 Reporting Procedures – Notifying the IRB

7.5.1 Unanticipated Problem Reporting

Incidents or events that meet the OHRP criteria for UPs require the creation and completion of an UP report form. It is the site investigator's responsibility to report UPs to their IRB. The UP report will include the following information:

1. Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
2. A detailed description of the event, incident, experience, or outcome;
3. An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
4. A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are SAEs will be reported to the IRB within 7 days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within 7 days of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within 7 days of the IR's receipt of the report of the problem from the investigator.

7.6 Safety Oversight

It is the responsibility of the Principal Investigator, and co-investigator, David Furgiuele, MD to oversee the safety of the study at his/her site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan. Adverse Events such as development of an allergy to local anesthetic, inadvertent intravascular injection of local anesthetic and infection at site of injection will be reviewed every three months. Serious adverse events are rare and are unlikely to occur but if a serious adverse event occurs, steps will be taken to address it. Study recruitment will cease temporarily while a data safety monitoring team convenes to review the event. Medical monitoring will include a regular assessment of the number and type of serious adverse events.

8 Source Documents and Access to Source Data/Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial. It is acceptable to use CRFs as source documents. If this is the case, it should be stated in this section what data will be collected on CRFs and what data will be collected from other sources.

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct

such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

Access to study records will be limited to IRB-approved members of the study team. The investigator will permit study-related monitoring, audits, and inspections by the IRB/EC, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

9 Quality Assurance and Quality Control

QC procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated to the site(s) for clarification/resolution.

Following written SOPs, the monitors will verify that the clinical trial is conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirements (e.g., Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP)).

The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

10 Ethics/Protection of Human Subjects

10.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and/or the ICH E6.

10.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

10.3 Participant and Data Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor, other authorized representatives of the sponsor, representatives of the IRB or pharmaceutical company supplying study product may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at NYU Langone Medical Center. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by NYU Langone Medical Center research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the NYU Langone Medical Center.

11 Data Handling and Record Keeping

11.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Clinical data (including AEs, concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into Redcap. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

11.2 Study Records Retention

Study documents will be retained for the longer of 3 years after close-out, 5 years after final reporting/publication.

11.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH E6:
1. 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
2. 5.1 Quality Assurance and Quality Control, section 5.1.1
3. 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site PI/study staff to use continuous vigilance to identify and report deviations within 7 working days of identification of the protocol deviation, or within 7 working days of the scheduled protocol-required activity.

Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

11.4 Publication and Data Sharing Policy

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy, and the Section 801 of the Food and Drug Administration Amendments Act of 2007, requires that all clinical trials be registered in a public trials registry such as ClinicalTrials.gov, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIH IC grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

FDAAA mandates that a "responsible party" (i.e., the sponsor or designated principal investigator) register and report results of certain "applicable clinical trials":

1. Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations of a product subject to FDA regulation;
2. Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies.
3. NIH grantees must take specific steps to ensure compliance with NIH implementation of FDAAA.

12 Study Finances

12.1 Funding Source

There is no funding source available.

12.2 Costs to the Participant

There are no expected costs to the subjects.

12.3 Participant Reimbursements or Payments

Participants will not receive any financial compensation for participation in this study.

13 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Management Unit (CIMU) with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULMC investigators will follow the applicable conflict of interest policies.

14 References

1. Nho SJ, Strauss EJ, Lenart BA, Provencher MT, Mazzocca AD, Verma NN, Romeo AA. Long head of the biceps tendinopathy: diagnosis and management. J Am Acad Orthop Surg. 2010 Nov;18(11):645-56.doi:10.5435/00124635-201011000-00002. PMID: 21041799.
2. Mazzocca AD, Rios CG, Romeo AA, Arciero RA. Subpectoral biceps tenodesis with interference screw fixation. Arthroscopy. 2005 Jul;21(7):896. doi: 10.1016/j.arthro.2005.04.002. PMID: 16012508.
3. Levy DM, Meyer ZI, Campbell KA, Bach BR Jr. Subpectoral Biceps Tenodesis. Am J Orthop (Belle Mead NJ). 2016 Feb;45(2):68-74. PMID: 26866316
4. Reynolds JW, Henshaw DS, Jaffe JD et al. Analgesic benefit of Pectoral Nerve Block II Blockade for Open subpectoral biceps tenodesis: A randomized, prospective, double-blinded, controlled trial. *Anesthesia Analgesia*. 2019 26; 129 (2): 538-542
5. Tran DQ, Elgueta MF, Aliste J, *et al* Diaphragm-Sparing Nerve Blocks for Shoulder Surgery. *Regional Anesthesia & Pain Medicine* 2017;**42:**32-38.
6. Arena C, Dhawan A. Mini-open Subpectoral Biceps Tenodesis Using a Suture Anchor. *Arthrosc Tech*. 2017;6(5):e1625-e1631. Published 2017 Sep 18. doi:10.1016/j.eats.2017.06.019
7. https://www.nysora.com/regional-anesthesia-for-specific-surgical-procedures/thorax/pectoralis-serratus-plane-blocks/ accessed Oct 10, 2020
8. Blanco R. The 'pecs block': a novel technique for providing analgesia after breast surgery. *Anesthesia*. 2011; 66:847-848
9. Blanco R, Farjardo M, Parras Maldonado T. Ultrasound description of Pecs II (modified Pecs I): a novel approach to breast surgery. *Rev Esp Anestesiol Reanim*. 2012;59:470-475

15 Attachments

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

15.1 OPIOID EQUIVALENTS

Notes from Lamplot (2013)

OPIOID AND ROUTE	DOSE (MG)	CONVERSION FACTOR
MORPHINE IM/IV	10	1.0
HYDROMORPHONE IM/IV	1.67	6.0
HYDROCODONE ORAL	30	0.3
TRAMADOL ORAL	100	0.1
OXYCODONE ORAL	20	0.5
VICODIN 5/500	6 tabs	1.7

Opioid	Oral Equianalgesic Dose (mg)

Buprenorphine	0.3
Oxymorphone	1.5
Butorphanol	2
Hydromorphone	2
Oxycodone	7
Hydrocodone	10
Morphine	10
Methadone	10-20
Tramadol	40
Propoxyphene	43-45
Codeine	80
Meperidine	100

16.2: Baseline Assessment

PROMIS Item Bank v.1.0 – Pain Intensity – Scale

Pain Intensity – Scale

Please respond to each item by marking one box per row.

	In the past 7 days…	Had no pain	Mild	Moderate	Severe	Very severe
PAINQU6	How intense was your pain at its worst?....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAINQU8	How intense was your average pain?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
		No pain	**Mild**	**Moderate**	**Severe**	**Very severe**
PAINQU21	What is your level of pain right now?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PROMIS Scale v1.2 – Global Health Physical 2a

Global Health – Physical 2a

Please respond to each question or statement by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global03	In general, how would you rate your physical health?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	**Mostly**	**Moderately**	**A little**	**Not at all**
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

1. Medication Usage Record

Thank you for participating in our research study and helping us improve pain control for patients undergoing Open Subpectoral Biceps Tenodesis.

Patient: _____

Pain medication: **Percocet**

Please record the following information in the log below:

1. Time when you take your pain medication
2. How many pills you took at each time
3. Pain score on a scale of 0-10 (0 being no pain and 10 being the worst pain imaginable)
4. Any additional pain medications (such as Advil), therapies (such as ice packs) and side effects (such as itching or nausea).

Time	Number of pills of Percocet	Pain Score (scale of 0-10)	Additional pain medications, therapy or side effects

What was your pain score on a scale from 0 to 10 (0 being no pain and 10 being the worst imaginable pain) 24 hours after the end of surgery, i.e., on _____ at _____ ?

1. McGill Pain Scale

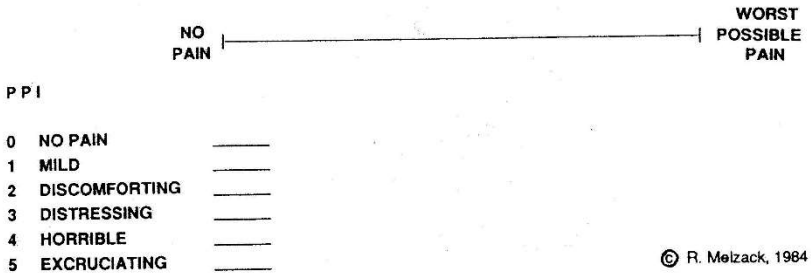


Fig. 1. The short-form McGill Pain Questionnaire (SF-MPQ). Descriptors 1–11 represent the sensory dimension of pain experience and 12–15 represent the affective dimension. Each descriptor is ranked on an intensity scale of 0 = none, 1 = mild, 2 = moderate, 3 = severe. The Present Pain Intensity (PPI) of the standard long-form McGill Pain Questionnaire (LF-MPQ) and the visual analogue (VAS) are also included to provide overall intensity scores.