A Prospective Randomized Study Comparing Suture Anchor and Soft Tissue Pectoralis Major Tendon Techniques for Biceps Tenodesis

NCT03529162

Informed Consent Form

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3/19/2019

SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	A Prospective Randomized Study Comparing Suture Anchor and Soft Tissue Pectoralis Major Tendon Techniques for Biceps Tenodesis

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

RESEARCH STUDY CONSENT FORM

Participant:		**IRB #:**	29091
	First Name / Last Name		
Principal Investigator (PI)	Christopher Kim, MD	**Contact Phone #**	(314) 256-3850
	First Name / Last Name Credentials		
Title of Project:	A Prospective Randomized Study Comparing Suture Anchor and Soft Tissue Pectoralis Major Tendon Techniques for Biceps Tenodesis		

"You" refers to the person who takes part in the research study.

You are being asked to take part in a research study conducted by Dr. Christopher Kim, Dr. Scott Kaar and colleagues because of your recent injury and planned surgery.

This consent document may contain words that you do not understand. Please ask the research study doctor or research staff to explain anything that you do not understand.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

Biceps Tenodesis is a procedure that involves cutting the attachment of the biceps tendon from within the shoulder joint, and the reattaching the tendon down on your arm. This procedure is performed routinely to help with pain. There are many different ways to perform this procedure and all are commonly used by many surgeons. We do not know if there are any differences between the techniques. The purpose of this research is to compare the clinical effects of two techniques to repair a tendon in your shoulder: the suture anchor and pectoralis major tendon techniques. Both techniques are routinely performed at Saint Louis University during arthroscopic rotator cuff repair. One technique uses an FDA approved device named the Mitek Quick Superanchor Plus, the other technique does not use a device. We are comparing these two techniques to determine if there a difference in how well your shoulder works, your level pain, and the appearance of your bicep (arm) muscle. We are planning to enroll approximately 80 patients for this study, which will be conducted at Saint Louis University Hospital and at SLUCare Orthopaedic Clinic.

2. WHAT AM I BEING ASKED TO DO?

You consent to be randomly assigned to one of the two surgical techniques. You have a 50% chance of being assigned to either technique. The assignment is randomly generated by a computer program and will not be determined by you or your surgeon. This randomization is part of the experiment design and would not take place other than for purposes of this research study. One technique involves a suture anchor device that is attached to the bone and holds your muscle in place. The other technique involves tying the tendon around your chest muscle.

Prior to surgery and after surgery, you will be asked to complete questionnaires and undergo shoulder examinations at clinic visits that occur 3, 6, and 12 months after your surgery. These examinations are routinely performed in patients with your condition. These questionnaires are called visual analog scale (VAS) for pain and a single assessment numerical evaluation (SANE) of your shoulder. In addition, you will complete the quick Disabilities of the Arm, Shoulder, and Hand (DASH), the American Shoulder and Elbow Society (ASES) score, and the Long Head of the Biceps (LHB) score questionnaires for the study. You will be examined at each visit and your shoulder range of motion and strength will be tested. Finally, we will be using EMR/EPIC to access your medical record in order to evaluate the images of your shoulder.

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?

The time you may spend on this research study is 12 months, with three clinic appointments at 3, 6, and 12 months after your surgery. You would spend this amount of time in the clinic after your surgery regardless of your participation in the study.

The research study should be completed within two to three years.

4. WHAT ARE THE RISKS?

There are certain risks and discomforts that may occur if you take part in this research study.

Both techniques are widely used, and so the risks are similar. If you receive the suture anchor technique, it is possible for the anchor to “pull out” of the bone, resulting in failure of the repair and the biceps tendon falling down your arm If you are randomized to the pectoralis major technique (PMT), there is a possibility that the sutures break, causing the tendon to again fall down your arm.

Breach of Confidentiality: Every effort will be made to protect your research study data. There is, however, always the possibility of a breach of confidentiality.

The research team is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

You may not benefit from this research study. Your condition may get better, stay the same, or worsen. Even though you may not receive any benefit, society may benefit in the future because of what the researchers learn from this research study.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to be in this research study. If you decide not to participate, you will still be receiving standard of care treatment. Choosing not to participate in this study will in no way affect the clinical care you will receive.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published but your name or identity will not be revealed and your record will remain private. In order to protect your information, Dr. Christopher Kim and the study team will keep track of your information by using a four-digit code instead of your name. The master list of codes will be saved on a secure SLU server. The hardcopy of the master randomization list with the identifying information will be kept in a locked cabinet in an office. The coded patient assessments will be kept in a study binder in a locked office.

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons who take part in research), other University officials, and SSM Health Saint Louis University Hospital representatives may review your research study records. The Food and Drug Administration (FDA) may also review your research study records, including your medical record. State laws or court orders may also require that information from your research records be released.

Some information about your participation in this study will be kept in your medical record. Authorized Saint Louis University and Hospital staff have access to this information. Systems are in place to keep medical record information confidential. It is possible this information could be shared with insurance or healthcare providers who are authorized to have your medical records.

8. WHAT ARE THE COSTS AND PAYMENTS?

Because this research provides standard treatment and follow-up tests for the disease or condition being studied, insurance carriers ordinarily cover the costs. You should check with your insurance company to verify that they cover standard of care procedures. You will be responsible for any costs not covered by your health insurance company including any co-payments and/or deductibles.

You will not be paid for your participation in this research study.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will have the right to determine whether an injury is related to your participation in this study or happened because of your medical

condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow the study doctor's instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

10. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call Dr. Christopher Kim or Dr. Scott Kaar at (314) 768-1050.

If you have questions, concerns or complaints about your rights as a research participant and would like to talk to someone not on the research team, please contact the Saint Louis University Institutional Review Board (IRB) at 314-977-7744 or irb@slu.edu.

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. The research study doctor or research study staff will let you know of any new information that may affect whether you want to continue to take part in the research study.

The investigator may take you out of the research study if something happens to make this necessary.

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and state any concerns. I have been asked if I wish to speak directly to the researcher or research study doctor responsible for this research study. The research team has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent

I give my informed and voluntary consent to take part in this research study. I will be given a copy of this consent document for my records.

_____
Print Name of Participant

_____ _____
Signature of Research Participant (18 and over) Date

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP

This form is valid only if the IRB's approval stamp is shown below.

IRB #: 29091
Approved: 03-19-19
Expires: 03-18-20
Board #: 3
Saint Louis University

I certify that I have explained to the above individual(s) the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the subject/patient has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**

First Name / Last Name	*Credentials*
Printed Name of Consenting Research Team Member	

NOTE: The Principal Investigator or Research Team Member that signs here must be authorized in the IRB-approved protocol to obtain informed consent and must sign at the SAME time on the same day as the above signatures are obtained.