Meets 2018 Common Rule Requirements

Naval Medical Center San Diego
CONSENT TO PARTICIPATE IN RESEARCH
Title: *Randomized Controlled Trial Comparing Clinical Outcomes of Patients Treated Surgically with Suture Button versus Fibulink Fixation for Acute Ankle Syndesmosis Injuries*
Principal Investigator: *LCDR Benjamin Wheatley, MD*

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

Dr. Benjamin Wheatley and the research team are conducting a research study to find out more about the different methods of fixation for ankle syndesmosis injuries, also known as high ankle sprain injuries. Syndesmosis is a fibrous joint in which two adjacent bones are linked by soft tissue. When there is injury to this joint, surgery may be required to fix it. You have been asked to participate in this study because you have presented to Naval Medical Center San Diego (NMCSD) with an ankle syndesmosis injury that requires a surgery to fix. This study will be conducted at NMCSD, and approximately **50** participants will be enrolled. The total duration of your participation will occur over the 1 year after your surgery, and will involve a baseline visit for consenting, randomization, and answering additional questions at your standard of care, and follow-up appointments. To conduct this study, we will also collect information from your medical record.

The benefit of this study is learning more about the impact of different fixation methods for ankle syndesmosis injuries (high ankle sprain injuries). However, there are a few risks associated with study procedures that will be explained in detail in Section 4 of this consent form.

Your decision and participation is entirely voluntary, which means you do not have to take part if you do not want to, and will not affect your future care at NMCSD. The alternatives to participation in this study are to not participate. Both of the fixation methods that will be studied are considered standard of care, so either option is available to you outside the study. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you have presented to NMCSD with an ankle syndesmosis injury, also known as a high ankle sprain, that requires a surgery to fix. The purpose of this research study is to learn about the two different methods of fixation for ankle syndesmosis injuries and how each impacts patient outcomes and satisfaction. The two groups are: suture button fixation and Fibulink implant fixation (see Appendix A for images).

Description of fixation techniques:
Suture button fixation: A suture button device consists of a fiber thread attached between 2 small metal buttons. These are available in various sizes and the doctor typically decides on a size during surgery. Under fluoroscopic guidance (like an x-ray movie), a drill hole is performed above and parallel to the distal tibia (shin bone closer to the ankle) joint line from outside to inside. A guide needle will be inserted from outside to inside through the drill hole to bring the button over the bone and to firmly apply the round button on the outer side of the fibula (the thinner bone running parallel to the shin bone). Fixation will be achieved with a surgical knot. The specifics, such as button placement and size, are determined on a case-by-case basis depending on patient needs and surgeon assessment.

Fibulink fixation: Under fluoroscopic guidance, a drill hole is performed above and parallel to the distal tibia (shin bone closer to the ankle) joint line from outside to inside. A tibia screw is inserted from outside to inside through the drill hole, the retention suture is released, and the handle is removed. A tensioning cap (like a circular plastic knob that can be rotated to apply torque to the screw to insert it further) is inserted over the tubes. The tube is clamped and pulled outwardly to deploy the link. The knob is turned to engage the link and allow for tension adjustment. The specifics, such as implant size and placement, are determined on a case-by-case basis depending on your needs and surgeon assessment.

Both procedures use a high-strength suture or string to connect the two bones together. The suture button procedure will have a hole drilled all the way through both bones with buttons on either side to squeeze the bones together as shown in Appendix A. The Fibulink fixation procedure also uses a hole that is drilled through the fibula and into the tibia but not all the way through. An anchor is inserted into the tibia and a button placed on the outside of the fibula to pull the two bones together as shown in Appendix A. Both procedures provide flexible fixation of the syndesmosis to allow some motion in the syndesmosis which does normally have some motion when not injured.

The duration of participation per visit is about 30 minutes for the baseline visit and an additional 15 minutes at your follow-up appointments after your surgery.

There will be about 50 people taking part in the study at NMCSD over a period of 2 years.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will be assigned by chance to a study group. Your chance of being assigned to each group is 50-50 or 1 in 2. Neither you nor the researcher(s) can choose the group to which you will be assigned. Each group is considered standard of care and currently practiced by the doctors at NMCSD. The first group involves suture button fixation. The second group involves the Fibulink implant. We do not have enough data to determine if one method is better than the other.

The treatment arm is not blinded to the surgeon or you, which means that the surgeon will know and you can find out at any time after randomization which group you have been assigned. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either of the groups.

These methods to fix your ankle injury are considered standard of care and used by the doctors involved in this study in their routine practice. If your doctor determines that you would benefit more from a specific method than the other, you would receive that method, and not be included in the study.

The total time you will participate in this study will be for 1 year after your surgery. The following will occur over the course of 1 year while you're in the study:

Baseline Visit: At this visit, in addition to your standard of care assessments, you will be consented for the study, which involves you reviewing this document and signing it. After you have been consented, you will be randomized to one of the two groups described above. Your method of fixation will be determined based on the group to which you have been assigned. We anticipate this visit will require no more than about 30 minutes of your time. You are welcome to taking more time should you need it.

At Baseline, the following procedures are considered research-related:
- Consenting
- Randomization

Everything else will be done as a part of your routine care procedures determined by your care provider team.

Follow-up visits: There will be no additional visits for the study, instead data for research will be collected each time you visit with your doctor for your follow-up appointments after your surgery. In addition to your standard of care assessments, you will be asked to provide details about your function (e.g. limitations in performing activities of daily living, distance you can walk, types of terrain you can walk on, any limping etc.), pain level, and satisfaction (your perception of your recovery and progress). You will also be asked questions to determine if you followed the instructions provided to you by your doctor for post-operative recovery, as well as questions to assess the level of your satisfaction with the fixation method assigned to you. These questions would not require more than 15 minutes (in addition to your time for routine assessments by your doctor). These data will be collected until your 1 year post-operative follow-up visit with your doctor.

At follow up visits, the following procedures are considered research-related:
- Questions about your function and pain
- Questions about your satisfaction with treatment
- Questions about your adherence with the instructions provided by your doctor

Everything else will be done as a part of your routine care procedures determined by your care provider team.

Data collected for Research: To conduct this study, we will also extract the following information from your medical record:
- MRN (medical record number)
- Demographics – age, sex, height, weight
- Past medical and surgical history
- Social history (use of tobacco, alcohol, recreational drugs)
- Mechanism of injury
- Injuries sustained
- Type of surgery
- Physical exam
- Pain scores
- Functional status
- Concomitant medication
- Imaging results
- Complications

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, your participation may involve some added risks or discomforts. These include the following:

Risk of Randomization: You will be assigned to a study group at random (by chance). Your assignment is based on chance rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. Your assigned study group might also prove to be less effective or have more side effects than the other study groups(s), or other treatments available for your condition.

Risks associated with Data Collection:
Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

The following illustrate the risks of all methods of fixation. You may be exposed to these risks regardless of your participation in the study, and thus, these risks are not considered research-specific. However, because of randomization, you may not be able to choose the group you are assigned to and can be exposed to risks associated with the assigned method of fixation.

Risk associated with suture buttons or Fibulink
There are risks associated with either method of fixation, such as bleeding, infection, significant pain, blood clots, reactions to anesthesia, and death. You would be exposed to these risks regardless of your participation in the study. Patients randomized to either group may also be at risk for implant breakage or loosening, malreduction (imperfect replacement or dislocation), re-operation, soft tissue complications (e.g. tendon or ligament injury, nerve dysfunction, injury to blood vessels, skin problem etc.), failed stabilization of the operated joint, overcompression (overtightening of the syndesmosis where the distance between the tibia and fibula, the shin bones, may be decreased more than it should), or damage to the neurovascular bundle (i.e. damage to the nerve and vein that pass through the ankle). We do not have enough data at this time to determine if any one method is superior to the other. If we are unable to adequately fix the fracture using either device we may use a screw to hold the correct alignment. If we use a screw instead then you will not be included in the study. Additionally, the decision to fix the syndesmosis is made during surgery. After fixing your fracture we will test the syndesmosis to determine if it needs to be fixed. There is a chance that after giving consent we find that you do not need fixation of the syndesmosis. If you do not have fixation of the syndesmosis during surgery then you will not be included in the study.

Unknown Risks:
Because this is a research study, there may be some unknown risks that are currently unforeseeable. Subjects will be informed of any significant new findings.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The possible benefits to others are we may learn more about the impact of different methods of fixation for ankle syndesmosis injuries.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

The alternatives to participation in this study are to not participate. As use of suture buttons and Fibulink are both considered standard of care, either option is available to you outside the study. Your method of fixation will be determined by your doctor based on his assessment of your health and injuries. In case you do not want to have surgery, your doctor will discuss any non-surgical care options available.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Benjamin Wheatley, MD
LCDR, MC, USN
Phone: (619) 532- 5101
Email: benjamin.m.wheatley.mil@mail.mil

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

University of California, San Diego (UCSD). UCSD will only receive non-identifiable information from this study.

11. SOURCE OF FUNDING:

There is no funding for this project.

12. LOCATION OF THE RESEARCH:

Naval Medical Center San Diego

13. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements associated with this research study.

14. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records may be looked at by staff from the Naval Medical Center San Diego, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

Research records will be kept confidential to the extent allowed by law. A record of your progress while in this study will be kept in a confidential file accessible only to the study team. Your record will be labeled with a unique study-specific id instead of any information that could identify you directly. Only the study team will know how to link research records to your personal information. Your information will be kept private, and any publications and presentations will not include any information that can identify you.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

A description of this clinical trial will be available on http://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 results. You can search this Web site at any time.

LCDR Benjamin Wheatley, MD
LT Kennedy Ringelberg, MD
Ashley Hughey
Janine Lopez
Nipha Sivilay

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

15. USE OF INFORMATION AND SPECIMENS

The information collected as part of this research will not be used or distributed for future research studies.

Additionally, all information collected as part of this research will be assigned a study number that only the study staff will be able to identify to protect confidentiality. None of your personal information such as name, or medical record number will be used in any publications.

16. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

17. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

18. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must inform the study personnel. If you decide to no longer participate in this research study, the researcher will withdraw your data from analysis and publication.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if they determine this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

19. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the section below.

If you suffer any injury directly related to your participation in this research study, immediate medical attention is available at the Naval Medical Center, San Diego, or at another closer medical treatment facility, if applicable. Any injury resulting from your participation in this study will be evaluated and treated in keeping with the benefits or care to which you are entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

20. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: LCDR Benjamin Wheatley, MD
Phone: 619-532-5101
Mailing Address: 34800 Bob Wilson Drive, San Diego, CA 92134

Naval Medical Center San Diego Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP POC: Johanna Peterson
Phone: (619)-532-5524

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at: (619) 532- 9927 or the Clinical Investigation Department at: (619) 532-6099 at 34800 Bob Wilson Drive, San Diego, CA 92134.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

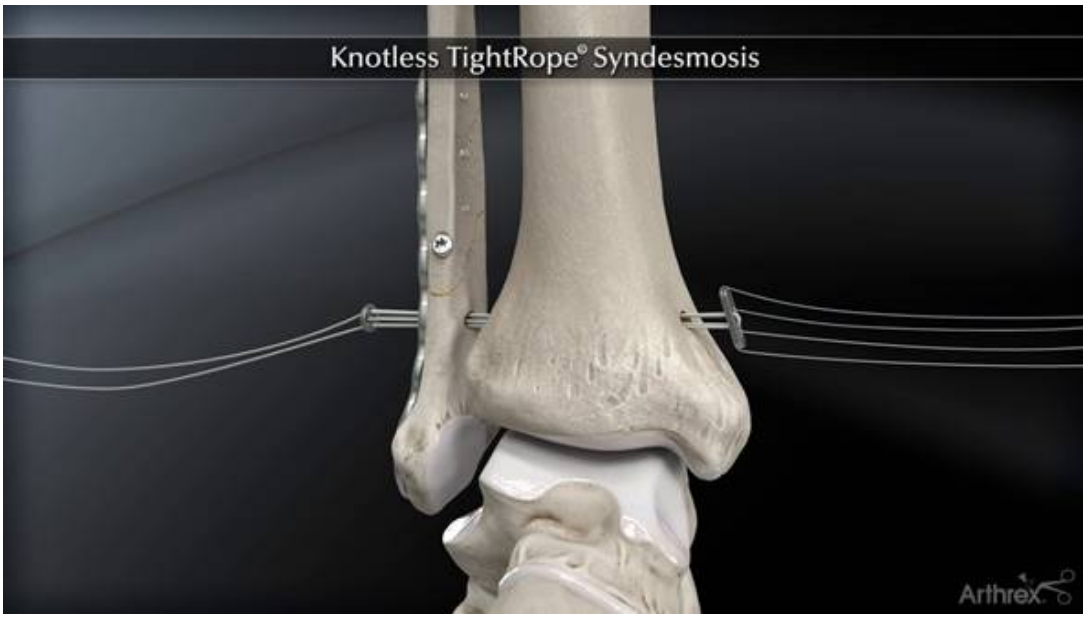
SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

Appendix A

Suture button for ankle syndesmosis fixation



Fibulink for ankle syndesmosis fixation