IRB Approved: 2/11/2022
Approval Expires: 1/10/2023

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: __22560_____

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

CLINICAL RESEARCH CONSENT AND AUTHORIZATION SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Correlation between intraoperative tourniquet use and limb pH, functional measures and patient-reported outcomes after ankle fracture surgery

PRINCIPAL INVESTIGATOR: Lara Atwater, MD (503) 494-6400

CO-INVESTIGATORS: Jung Yoo, MD (503) 494-6400
Darin Friess, MD (503) 494-6400
Zachary Working, MD (503) 494-5050
James Meeker, MD (503) 494-6400
Bopha Chrea, MD (503) 494-6400
Laura Sokil, MD (503) 494-6400

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

CO1450

PURPOSE: We are studying how tourniquets affect muscles and postoperative recovery after ankle fracture surgery

DURATION: Your participation in the study will consist of 5 visits and 6 sets of electronic surveys over 3 months and these will be grouped in with your routine clinic and physical therapy visits. We may ask to follow your health through the use of medical record review for up to 2 years.

PROCEDURES: If you decide to take part in this study, you will randomly be assigned to surgery with or without using a tourniquet. A small pH probe (about the size of a plastic coffee stirrer/straw) will be placed in your leg muscle and will be removed 2 hours after surgery ends. You will have 2 labs drawn during surgery. You will complete surveys electronically 2 days after surgery and at your 3 week, 6 week, and 12 week clinic visits. At your 6 week and

12 week physical therapy visits, therapists will record information including range of motion, strength and balance.

RISKS: Risks of tourniquet use include blood clots, nerve, muscle or blood vessel injury, damage to skin at the tourniquet site and pain at the tourniquet site, and in extremely rare cases, death. If you do not participate in the study, you may still be at risk of these complications as standard of care.

BENEFITS: You will not directly benefit from taking part in this research.

END OF CONSENT SUMMARY

OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

IRB#: _22560_____

Clinical Research Consent and Authorization Form

TITLE: Correlation between intraoperative tourniquet use and limb pH, functional measures and patient-reported outcomes after ankle fracture surgery

PRINCIPAL INVESTIGATOR: Lara Atwater, MD (503) 494-6400

CO-INVESTIGATORS: Jung Yoo, MD (503) 494-6406
Darin Friess, MD (503) 494-6400
Zachary Working, MD (503) 494-5050
James Meeker, MD (503) 494-6400
Bopha Chrea, MD (503) 494-6400
Laura Sokil, MD (503) 494-6400

FUNDED BY?: Unfunded

WHY IS THIS STUDY BEING DONE?

You have been invited to be in this research study because you are undergoing ankle fracture surgery. The purpose of this study is to learn more about using tourniquets during ankle fracture surgery.

A tourniquet is a device that compresses a limb in order to restrict blood flow. Tourniquets are commonly used in surgery, and have been for over 100 years, to help decrease blood loss. However, we do not know how the tourniquet affects the muscles in the leg during and after surgery, or how the tourniquet affects postoperative pain, swelling, strength and recovery. Learning more about how tourniquets affect these factors will help us determine whether it is safe and/or beneficial to use tourniquets during surgery and for how long they can be used. Participating in this study involves placement of a pH monitor in your leg during and for 2 hours after surgery to measure the chemistry of the leg muscles directly. We do not know how the chemistry in your leg muscles is related to the tourniquet.

We plan to enroll 290 OHSU participants in the study.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

CO1450

You will randomly be assigned to either the "tourniquet" group or "no tourniquet" group. You will not know which group you are in. If you are in the "tourniquet" group, a pneumatic tourniquet will be placed around your thigh and inflated to a standard pressure during the surgery. The tourniquet will remain inflated for no longer than 2 hours. This is considered standard medical practice. If you are in the "no tourniquet" group, you will not have a tourniquet inflated during your surgery. If you are in the “no tourniquet” group and your surgeon feels it necessary to raise the tourniquet for medical reasons, then they will do so at their discretion. You will still have the option of being followed afterward in the study.

Regardless of which group you are in, a 3mm wide needle poke will be used to insert a sterile catheter with a small pH probe (figure 1) in the muscles in the front of your leg during your surgery. It will record the acidity of your tissue during and after surgery. The pH recording tube will remain in the needle poke and under your wound dressing for two hours post-surgery. It will then be removed. We will collect pH measurements, by connecting a device (figure 2) to the part of the tube sticking out of your leg from the start of your surgery until two hours after surgery. The catheter will be removed before you leave the hospital, you will be awake when the catheter is removed and you will be asked a question about your pain level when the catheter is removed. We will also draw 2 blood labs during surgery (you will not be awake for the blood draws), about 4 tablespoons total.

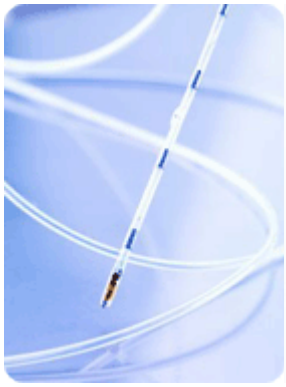

Figure 1: pH catheter; this will be inserted into your muscle

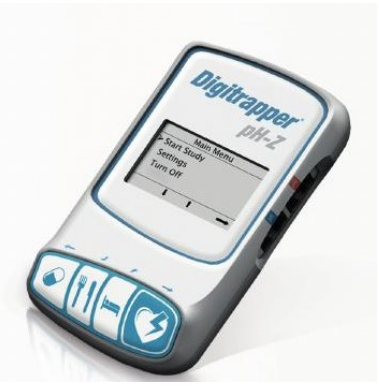

Figure 2: Digitrapper ® recorder; this will be attached to the (left) catheter to display the pH measurements

Once you leave the hospital, you will be emailed surveys electronically four times (2 days, 3, 6 and 12 weeks postoperatively) and have two physical therapy sessions where measurements are taken. We will ask you questions about your pain, how it impacts your life, and your mobility after surgery and each set of surveys should take about 30 minutes total. . Measurements will be collected by a physical therapist, including ankle range of motion, leg muscle strength and balance, and will take about 45 minutes. This study will take 3 months to complete, however, all of the visits and timing of surveys will be grouped in with your routine postoperative clinic and physical therapy visits. You will be emailed a link for surveys that you will complete electronically.

We will review your medical records for certain information including age, sex, medical problems, medications, height, weight, BMI, physical exam results, fracture type, lab results, nature of surgical procedure and will monitor your medical records throughout the study period for complications related to the surgery. Information in your medical record that is related to your ankle fracture may be collected for research purposes for up to two years after your surgery.

ACCESS TO YOUR TEST RESULTS

The results of your blood tests will be placed in your medical record. The physical therapy assessments will be available as part of the medical record created at the time of therapy. You will not receive the results of the pH measurements or surveys**.** The results of pH tests will not be made available to you because the research is still in an early phase and the meaning of the results is unknown.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:

The tourniquet will be placed and removed during surgery, you are not awake for any time the tourniquet is in place. Intraoperative risks of tourniquet use include blood clots, nerve, muscle or blood vessel injury, damage to skin at the tourniquet site and pain at the tourniquet site, and in extremely rare cases, death.

If you do not participate in the study, you may still be at risk of these complications as tourniquets are routinely used intraoperatively as standard of care.

Risks of placing the catheter in your tissue include infection, bleeding or bruising at the site of the catheter. The catheter is no larger than a plastic coffee stirrer/stick. You will be awake when the catheter is removed postoperatively, The pain of catheter removal is similar to removing an IV and is very well tolerated.

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Access to your data will be restricted to the principal investigator and the study team in a secure electronic database at OHSU. It will be stored password protected in a secure location. We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form. The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study. There is a minimal risk of loss of confidentiality, however there are risks due to use of unsecured phone and email encounters.

WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?
You may choose not to be in this study. You do not need to participate in this study to receive the standard of care for your ankle fracture surgery.

WHO WILL SEE MY PERSONAL INFORMATION?
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Access to your data will be restricted to the principal investigator and the study team. It will be stored password protected in a secure location.

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records, including your medical records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

We may continue to use and disclose your information as described above indefinitely.

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

COMMERCIAL DEVELOPMENT:
Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?
There will be no cost to you or your insurance company to participate in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?:
If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Karalynn Lancaster at (503) 494-5348.

If you are injured or harmed by the study procedure you will be treated. OHSU does not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

WHERE CAN I GET MORE INFORMATION?
If you have any questions, concerns, or complaints regarding this study now or in the future, contact PI Lara Atwater (503) 494-6400 or Karalynn Lancaster at (503) 494-5348.

This research has been approved and is overseen by an Institutional Review Board (“IRB”), a committee that protects the rights and welfare of research participants. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?

We ask you to attend your routine postoperative clinic and physical therapy visits. We as that you complete surveys given to you and participate in measurements or exercises with physical therapists at these visits.

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Karalynn Lancaster
3181 SW Sam Jackson Park Rd, OP-31
Portland, OR 97239
lancaska@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

The data we will collect from you will not be stored with your name or any other identifier. Therefore, there will not be a way for us to identify and destroy your materials if you decide in the future that you do not wish to participate in this research.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Use of an Interpreter: Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

If applicable:

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.

Summary of Visits / Surveys Associated with this Study AFTER screening:

	Pre-op Day 1	Surgery Day 1	2 hours Post-op	2 days Post-op	3 week	6 weeks	12 weeks
Consent Discussion, medical history (in person or telephone), preoperative labs and imaging	In clinic						
Randomized to tourniquet or no tourniquet	X						
Insertion of pH catheter, intraop pH measurements		X					
Removal of pH catheter			X				
Physical therapy measurements						In person	In person
VAS pain score (in person or email)	email		in person	email		email	email
FAAM and PROMIS PI and PF (email)	email				email	email	email