External Fixation Versus Splinting of Acute Calcaneus Fractures

NCT04063657

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Title of research study: Staged External Fixation of Acute Calcaneal Fractures

Investigator: Christopher Kreulen MD/MS, Eric Giza MD, & Phillip Wolinsky MD

California Experimental Subjects Bill of Rights

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.

Key Information about This Research Study

You are invited to participate in a research study. The purpose of this research is to see if a temporary device (known as an "external fixator") before surgery is better than splinting for your injured foot**.** You are invited to be in this study because you are an adult who has a broken heel bone that needs surgery.

Your participation in this research will involve randomization into either the external fixator or the splinting group, routine visits, and having your data collected.

One of the ways we can monitor your outcomes is through surveys. In this study we would like to use the Surgical Outcomes System (SOS) data system. The SOS is a data collection study and a large international web-based registry that allows us to collect baseline characteristics of patients undergoing orthopedic surgical procedures. In order to utilize the web-based surveys, we would like to invite you to enroll and consent for the SOS study in addition to the present study.

- Should you decided to enroll, we will provide you with additional information and documents.
- Should you decided not to participate in the SOS web-based registry, surveys may be filled out manually(listed below) during follow up visits, and data will not enter the registry.

We expect that you will be in this research study for 2 years after receiving definitive surgery for your broken heel bone. However, the actual project may take longer depending on the amount of time it takes to recruit enough patients in the study.

We expect to enroll about 100 people, here at UC Davis.

All research studies involve some risk. Risks of this study are minimal. These risks are described in detail later in this document. You may not benefit from participation in this study.

Here are some reasons you may not want to participate in this research: unwilling or unable to complete follow ups and surveys, and unwilling to be randomized into a treatment group.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

Information to help you understand research is online at
http://www.research.ucdavis.edu/policiescompliance/irb-admin/for-research-participants.

What if I have Questions?

The person in charge of this study are Dr. Christopher Kreulen MD, Dr. Eric Giza MD & Dr. Phillip Wolinsky. If you have questions or concerns about this study, please contact the research team at (916)703-9173.

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to the orthopaedic resident on call. In the case of an emergency, dial 911 from any phone.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

How is this research funded?

This research is department funded.

Dr. Eric Giza, the principal investigator on this study team, is a consultant for Arthrex, the company that designed the SOS database. The consulting fee Dr. Giza receives is in addition to his salary from the University of California. Dr. Christopher Kreulen, the Co-Investigator on this study team, is a consultant for Arthrex, the company that designed the database for this study. The consulting fee Dr. Kreulen receives is in addition to his salary from the University of California.

If you have questions, tell the study coordinator and they will put you in touch with someone to talk to.

Why is this research being done?

The purpose of this research study is to see if external fixation before surgery is better than splinting for a broken heel bone. A break in the heel bone can potentially cause a large amount of swelling in the surrounding area. This makes it difficult to have surgery right away. Sometimes, surgeons will use "external fixation" as a way to realign broken bones manually by using pins or braces from the outside of the skin before surgery. Using an external fixator device can promote the optimal healing needed before definitive surgery. However, there hasn't been a formal research study comparing temporary splinting to external fixation for a broken heel bone before definitive surgery.

What happens if I say yes, I want to be in this research?

If you decide to participate in this study, you will be asked first, to read through and sign this consent document.

You will be screened using the inclusion and exclusion criteria (Table 1). Only if you meet all inclusion and none of the exclusion criteria may you enroll in the study following voluntary informed consent.

Table 1:

Inclusion Criteria	**Exclusion Criteria**
• Voluntary consent • Age 18 to 69 • Clinical and/or advanced imaging confirming an acute calcaneal fracture that has occurred within 2 days of which, eventually definitive surgery is recommended/accepted.	• unable to consent • age <18 • Prior surgery of the affected extremity • Prisoners • Pregnant women • Inflammatory arthritis • Non-english speaking patients

The following study procedures are routine:

- Routine follow up at 2 weeks, 6 weeks, 12 weeks, 6 months, 1 year, and 2 years after surgery
- X-rays at 6 weeks, 12 weeks, 6 months, 1 year, and 2 years after surgery to see how well your broken heel bones join together
- CT scan at 1 year to see if there is any arthritis around your injury
- The external fixation devices (DePuySynthes, Inc) and the splinting material are both normally available through the UCD healthcare system.

The following procedures are for research purposes:

- Random assignment into either the "external fixation" or "splinting" treatment group.

- Collecting data and recording outcomes from the visits. This may include:
  - Demographic information
  - Wound and other complications
  - How well your heel bone joins back together and other imaging parameters
  - Time it takes to receive definitive surgery for your broken heel bone
  - Medical and Surgical history
  - Patient reported outcomes on surveys via SOS or paper at 7 time points: before surgery, 2 weeks, 6 weeks, 12 weeks, 6 months, 1 year, and 2 years after surgery. Completion of these surveys will take approximately 15 minutes or less, each time. The surveys are:
    - Visual Analogue pain score (VAS)
    - Patient-reported outcomes measurement information system 10 short form (PROMIS 10), or Veterans RAND 12 item Health survey (VR-12)
    - Foot function index questionnaire (FFI-R) or Foot and Ankle Ability measure activities of daily living (FAAM ADL), and FAAM sport
- Other notable information

During this time, you will be interacting with the UCD healthcare system team as you normally would if you were not part of the study. However, in addition however, you will also be interacting with the research team.

The primary research institution will be here at UCD.

The treatment assignment will be chosen by chance, like flipping a coin. You will have a 1 in 2 chance of being placed in either group. Since the splinting material and the external fixator device are visible, you and the doctor will see which treatment group you are in.

How is being in this study different from my regular health care?

If you take part in this study, the main difference between your regular care and the study is that you will be randomized into one of the two temporary treatment groups, fill out multiple surveys, have your health information entered into the SOS registry, and we will collect outcomes of the study for research purposes.

What are my responsibilities if I take part in this research?

If you take part in this research study, you will be responsible for adhering to the routine follow up visits, in addition to filling out the surveys in a timely fashion.

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. You can choose to be in the study or not be in the study.

If you decide to be in the study, you can choose to leave the study at any time, and it will not be held against you. If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Please let the researchers know if you choose to leave the study. We will tell you how to leave the study safely. We may ask you to come in for a final study visit to check your health.

If you decide to leave the research, contact the study team so the investigator can work with you to create a safe plan for your withdrawal. This may include changing the temporary treatment method you have to address the broken heel bones.

If you have also enrolled in the SOS registry, the investigator can also assist you to remove yourself from the SOS system. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- your health changes and staying on the study is no longer in your best interest;
- you do not follow the study rules or you no longer meet the requirements to be in the study; or
- the study is stopped by the sponsor or researchers.

Is there anyway being in this study could be bad for me?

There are no additional anticipated physical risks with being in this study.

Risks associated with randomization: You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) 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. It might also prove to be less effective or have more side effects than the other study groups(s), or standard treatments available for your condition.

Risk of privacy of your health information which cannot be guaranteed (see the section below regarding what happens to the information collected for the research).

As with all research, there is a chance that confidentiality could be compromised. To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the specimens and information we collect, and on the data resulting from the research.

Will being in this study help me in any way?

Your participation in the study may benefit other people in the future by helping us learn more about benefits of external fixator over splinting before surgery. Future patients may benefit from the information obtained from this study.

Will being in this study cost me anything?

You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered. Only the costs of research or experimental procedures will be paid by the study**.** Since the procedures and follow ups are standard of care, your insurance will be billed.

You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities.

You or your insurance company will have to pay for all costs for medical care related to participation in this study, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all the costs for your medical care just as you would if you did not take part in this study.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

What happens if I am injured or get sick because of this study?

If you are injured as a result of being in this study, the University of California will provide the necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by the University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may contact the IRB Administration at (916) 703-9151 or HS-IRBAdmin@ucdavis.edu.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

Both your doctor and the study sponsor have taken precautions to protect the data collected for this research. These precautions include for example developing and using unique user ids and passwords to access the registry, not sharing that information with other people, special security clearance for your email address in the database, and using an electronic data storage system that is designed to ensure the

security of patient health information according to HIPAA regulations. The information collected about you for this research may be shared with others such as the study staff, sponsor, other researchers, and federal and foreign government agencies as fully described in the accompanying HIPAA Research Participant Authorization. This information is shared for monitoring the quality of the research data, performing clinical and scientific research, medical product development and marketing analysis. Publications or presentations that result from this study will not contain personal information that may identify you.

If the research team is likely to uncover abuse, neglect, or reportable diseases, this information may be disclosed to the appropriate authorities.

The monitors, auditors, and the IRB will be granted direct access to your research records to conduct and oversee the study**.** We may publish the results of this research. However, we will keep your name and other identifying information confidential.

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. We may also show your medical records to study monitors, auditors, the IRB, and the FDA. These groups are obligated to maintain your confidentiality. The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study
- Arthrex Inc (owner of SOS if you decide to dual consent)

If you agree to participate in this research study, a signed copy of this consent document will be filed in your electronic medical record (EMR) to ensure people caring for you at UC Davis Health will have the information they need about this research study when they provide care for you.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

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

Will I receive any results from this research?

Since the surveys are self-reported, you will know what you report. You will be aware of which temporary treatment method you receive. However, the outcomes of the research will not be shared.

Will information or leftover specimens be used for other research?

During this research, the study team will obtain information about you. They will also collect biological specimens from you such as blood or urine. The information and specimens will be used for this research and may also be used for other research studies here at UC Davis. We may also share the information and specimens with other institutions for research. Before using the information and specimens for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information and specimens came from. We will not ask for additional consent from you to use your information and specimens for the additional research.

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1436830	June 14, 2019

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Do not write below this line. For IRB stamp and version date only.

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