External Fixation Versus Splinting of Acute Calcaneus Fractures

NCT04063657

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INSTRUCTIONS: use in conjunction with the online Initial Review Application form when no sponsor authored protocol is available.

1) Protocol Title

Title: Staged External Fixation of Acute Calcaneal Fractures

Protocol Version Date: 05/02/2019

2) Objectives

Aim:

- Determine if external fixation decreases soft tissue complications compared to splinting.
- Determine if external fixation decreases time to definitive surgical stabilization and improves final fixation compared to splinting.
- Determine if external fixation improves functional outcomes as evaluated by validated funcational scoring systems.

Hypothesis:

- External fixation improves definitive fixation and functional outcomes of acute calcaneal fractures with decreased complication rates compared to splinting

3) Background

Acute displaced calcaneal fractures are a regularly encountered orthopedic injury that can be complex to treat. Operative treatment of these fractures has been shown to have improved functional outcome scores compared to patients treated non-operatively.[1-3] Operative treatment aims to reduce the articular surface and restore radiographic parameters such as Bohler's angle, both of which have been correlated with improved long term morbidity.[4-5]

Within operative management options the definitive operative choice to minimize soft tissue and post-operative complications remains controversial. Minimally invasive and percutaneous fixation techniques of complex calcaneus fractures has been shown to decrease soft tissue complications compared to open reduction internal fixation (ORIF) techniques.[6-7] However, there is concern about the use of percutaneous techniques leading to a loss of reduction and important radiographic parameters.[6] Additionally, direct visualization that is offered in an open technique is often preferable.

Clinicians favoring an open technique have sought ways to minimize soft tissue complications by using a temporary external fixator as similar to the often utilized staged management of tibial plateau and tibial plafond fractures.[8-10] This delay is necessary for soft tissue swelling to subside prior to surgery with the external fixator allowing for prevention of early clot and fibrinous material between malaligned fracture fragments that may impede definitive reduction in the operating room. Additionally, early temporary fixation will restore native soft tissue biology and calcaneal morphology allowing for optimal healing conditions prior to definitive fixation.

Given these benefits, external fixators have been studied to treat acute calcaneus fractures definitively, in a brief-(days) or prolonged- (months) staged approach.[11-15] To date there has only been three case series describing a brief-staged technique with use of an external fixator for treatment of complex calcaneal fractures.[16-18] Our study will provide the first prospective-randomized controlled trail of this potentially practice changing protocol. The purpose of this study is to compare the efficacy of temporary external fixation vs. splinting for the treatment of acute calcaneal fractures prior to definitive surgical fixation.

Reference:

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4) Inclusion and Exclusion Criteria

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 spatients

5) Study Timelines

- Study will begin after IRB approval
- Patient recruitment will take place over two years, however this may be lonher depening on the number of patients who require definitive surgery
- The duration of the subject's participation in the study will conclude at two year postoperatively
- The primarly analysis will be complete within 3 years of the study start time

6) Study Endpoints and Procedures involved

I. Design

- Subjects will be recruited from the UC Davis Medical Center. Adults diagnosed with an acute (<1-2 days from injury) calcaneal fracture recommended for operative treatment will be offered enrollment into the study.
- A total of 100 patients will be enrolled in the study. The sample size can be calculated at 35 per treatment groups after considering multiple comparisons and using an 80% power and an $\alpha = 0.05$. This would require a minimum of 70 patients for the study; however, factoring in a 30% dropout rate, a minimum of 100 patients will be enrolled into the study with a minimum of 50 patients per group.

II. Methods

- Patients will be randomized to one of two treatment groups: temporary external fixation or temporary splinting. Both temporary treatments are those routinely used/available at the UCD health system. Subject are to wear the temporary treatment method until definitive surgery.
- Safety endpoints occur at conclusion of the definitive fixation of their calcaneal fracture.

- All subjects will receive standard perioperative and operative treatment of their injury. Patients will receive standard clinical follow up for which their healing and functional status will be continually evaluated.
- Follow up after surgery will be at 6 time points: 2 weeks, 6 weeks, 12 weeks, 6 months, 1 year, 2 years
- The research related activities are randomization, using SOS surveys at specified time points, and collecting/reporting data regarding the outcomes from routine visits and survey responses.

III. Outcomes

Primary outcome

1. Time to definitive surgery
2. Soft tissue complications (at routine follow ups which are 2, 6, & 12 weeks, and 6, 12, & 24 months after surgery)

Secondary outcomes

1. Union rate via standard weight bearing plain radiographs (harris axial/lateral views) at 6 weeks, 12 weeks, 6 months, 1 year, and 2 years after surgery. We will also obtain a 1X CT scan of the injured foot at 1 year after surgery to monitor for arthritic progression.
2. Radiographic parameters(Bohler's angle, clancaneal height/width/length, and angle of Gissan)
3. Other complications
4. Clinical outcomes will be evaluated to monitor patients' activity levels, pain, and functional status. This will be done primarly using the web-based Surgical Outcome System™ (SOS)

    - The SOS is currently a UCD IRB approved study (IRB # 1192222). It is a large international web-based registry that permits collection of baseline characteristics of patients undergoing orthopedic procedures. The data is collected using direct entry into a web-based collection system called the Surgical Outcome System (SOS). By completing these surveys, the investigator surgeon has the opportunity to monitor the subjects progress after treatment, even when they are not scheduled to see the provider. The investigator surgeon will also be able compare the outcomes to the average de-identified global data.
    - In order to utilize the web-based surveys, we would invite patients to dual enroll and consent into SOS. If, the subject forgoes SOS participation, the surveys may be filled out manually and this data will not be part of SOS.
    - Subjects fill out surveys before visits at 7 total time points: preoperatively, & postoperatively at 2, 6, and 12 weeks and 6 months, 1 and 2

years. The surveys may include the 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

IV. **Analysis:** The data will be analyzed for differences between splinting and external fixator treatement groups. Data will be stratified and analyzed for further differences in outcomes based on other factors (ie: demographics, comorbidities..)

- To assess significance the alpha level will be set at <0.05.
- Continuous data will be reported as means, standard deviation(SD), range, with 95% confidence intervals
- Categorical data will be reported as frequencies or percentages with 95% confidence intervals

7) Data and/or Specimen Management and Confidentiality

☒I understand that the UC Davis Health Electronic Health Record (EMR/EPIC) also contains the clinical data for Marshall Medical Center (MMC). I understand that MMC patient data cannot be accessed for research purposes and that I must take the necessary steps to ensure that MMC data is not accessed, used, or disclosed for UC Davis Health research purposes.

Since this is a prospective study, the PI/research team are part of the data collection process. Thus, the data will be identifiable at first to the research team. However, all efforts will be made to de-identify the data. A coding system will be used to assigned a unique code to each subject. Only authorized research staff members will have access to data.

All identifiable electronic data will be maintained on an encrypted device requiring password for access. Passwords will not be shared and will be protected from access.

If protected health information or personal information from the medical records will be stored on an encrypted device, investigators will follow applicable university policies (UC Davis Hospital Policy 1313, UCDHS P&P 2300-2499, and UC Business and Finance Bulletin on Information Security (IS-3).

All paper records will be stored in a locked room/file-cabinet with access limited to only individuals who have a right and need for access.

8) Data and/or Specimen Banking

If the patient also provides voluntary consent to enter the SOS web-based registry, the subject will be dual consented and also enrolled into the SOS. The data will enter the main SOS global registry(de-identified).

9) Provisions to Monitor the Data to Ensure the Safety of Subjects

This is a minimal risk study. There are no anticipated risks specific to study participation. There are no experimental procedures and participation in this study is not anticipated to affect the medical treatment of enrolled subjects.

Subjects will be randomized into two temporary treatments are likely to benefit from either arm of the study.

Procedures performed are currently standard of clinical practice for management calcaneal fractures.

In order to protect the rights and welfare of the subjects, an initial site set-up visit will be performed to ensure proper documentation. Further monitoring (including the close out visit) will take place as needed by our internal Research staff. The PI reviews and track all complications as standard care.

10) Withdrawal of Subjects

- Subjects can voluntarly withdrawl at anytime
- Otherwise, the subjects are withdrawn if:
    - They have inadequate follow up without communicating with research staff.
    - Their health changes, and staying in the study is no longer in his or her best interest
    - They do not follow the study rules or no longer meet requirments to be in the study
    - The researchers terminate the study.

11) Risks to Subjects

There are no physical risks in this study.

There is the risk of randomization in this study.

There is a privacy risk, since we will record data which poses the risk of loss of confidentiality. The risk will be minimized through the processes described above. This study will abide by all applicable law, regulations, and standard

operating governing the protection of human subjects, student information and protected health information.

12) Potential Benefits to Subjects

These subjects are not likely to received any benefit from the proposed research, but others may benefit from the knowledge obtained

13) Multi-Site Research: Not applicable

14) Community-Based Participatory Research: Not applicable

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15) Sharing of Results with Subjects

Subjects will be aware of the survey scores as they are self-reported. Subjects will be aware of which treatment option they receive as they are visible. The results of this study will not be shared with other subjects or others.

16) Prior Approvals: IRB approval

17) Provisions to Protect the Privacy Interests of Subjects

The subjects' privacy interests will be protected, as information will only be made available to those directly involved in the research study. The information will be stored in a password-protected spreadsheet which will have a assigned a code to protect patient confidentiality. The code will be kept separate from the data. At the completion of the data analysis, the code key will be destroyed.
The subjects will feel at ease as researchers will treat them with respect and address any of their questions/concern

18) **Compensation for Research-Related Injury:** Not applicable as study is minimal risk

19) **Economic Burden to Subjects:** No different from routine care, and thus billed to insurance.

20) **Drugs or Devices:**

The devices used in this study is FDA approved and thus not investigational. The device will be used as intended by FDA.

21) **Review Requirements**

Are there any contractual obligations or other considerations that require IRB review of this research, or review at intervals other than those required by the Common Rule or FDA? If yes, check box: NO