Does Intraoperative 3D Fluoroscopy Accurately Assess Syndesmotic Reduction Following Traumatic Ankle Injury?

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Protocol Title: Does Intraoperative 3D Fluoroscopy Accurately Assess Syndesmotic Reduction Following Traumatic Ankle Injury?

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Population: All patients of age 18-75 who are skeletally mature, and have unilateral, acute, displaced ankle fractures with preoperative evidence of syndesmotic disruption or intraoperative evidence of syndesmotic instability following malleolar fixation.

Site: UT Houston – Texas Medical Center

Site Address: University of Texas Health Science Center – Houston
[redacted]

Study Duration: October 1, 2016 through October 1, 2017

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Abstract

Injury to the ankle syndesmosis is commonly associated with rotational ankle fractures, occurring in 23-52% of cases[1-4]. Accurate syndesmotic reduction and stabilization of the ankle mortise has been shown to correlate with improved functional outcomes in these patients[1,4,5]. Despite multiple techniques to improve reduction accuracy, syndesmotic malreduction remains common[1,6]. Use of the contralateral, uninjured ankle as a template for the reduction of the injured ankle syndesmosis by Summers et. al has shown the lowest malreduction rate of 6% (1 / 18 patients), however, CT scan of the uninjured ankle was not used as comparison[7]. Use of intraoperative CT scans can also reduce the rate of syndesmotic malreduction but can be cumbersome and is often unavailable or unfamiliar to the surgeon[8]. Intraoperative 3-dimensional fluoroscopy is new technology that isometrically focuses on a single point and can generate CT scan-like images, yet operates like a conventional C-arm.

This prospective, observational study will enroll patients with unilateral, unstable, rotational ankle fractures with preoperative or intraoperative evidence of syndesmotic instability to assess ability of 3D fluoroscopy to aid in accurate syndesmotic reduction. Patients with syndesmotic instability will undergo reduction of the syndesmosis followed by provisional fixation with a clamp or Kirshner wire. The reduction quality will be initially compared to the contralateral ankle mortise and talar-dome lateral radiographs using the technique of Summers[7]. After the attending surgeon is satisfied with the reduction quality, 3D fluoroscopy will be used to generate additional images to assess syndesmotic and fibular reductions. The number of times that the surgeon changes the reduction of either the syndesmosis reduction (primary outcome) or fibular fracture reduction (secondary outcome) because of information provided by 3D fluoroscopy will be recorded. Fixation of the syndesmosis by screw or suture button device will then be performed according to surgeon preference in a standard fashion. A limited postoperative bilateral ankle CT scan will be performed to assess the accuracy of reduction.

Research Question

Can intraoperative 3D fluoroscopic technology accurately assess syndesmotic reduction in operative acute ankle fractures and fracture-dislocations with associated syndesmotic injury and does it lead the surgeon to alter the reduction after using the standard technique of comparison fluoroscopic images of the contralateral, uninjured ankle?

Hypothesis

We hypotheses that intraoperative 3D fluoroscopy will frequently lead the surgeon to change the reduction of the syndesmosis and/or fibular fracture and that the use of novel 3D fluoroscopy technology will yield a low rate of syndesmotic malreduction.

Specific Aims

Specific aim #1: Identify the frequency where intraoperative 3D fluoroscopy leads to a change in the syndesmotic reduction after using the standard technique of contralateral ankle fluoroscopic imaging by Summers et al[7].

Specific aim #2: Describe use of 3D fluoroscopy in assessment of ankle and syndesmotic reduction quality to the orthopedic community.

Specific aim #3: Ascertain patient functional outcomes using Patient-Reported Outcomes Measurement Information System (PROMIS) physical health outcomes on patients at 6 month follow-up.

Relevance to the current orthopaedic trauma literature

Despite numerous publications documenting persistent syndesmotic malreduction following acute ankle trauma, a gold standard technique is yet to exist for intraoperative assessment of syndesmotic reduction. Currently, the technique used most commonly by the orthopedic community is use of comparison contralateral (uninjured) radiographs to assess fibular length, rotation, and syndesmotic reduction. Some authors suggest direct open visualization of the syndesmotic reduction at the time of fixation. This pilot study aims to describe the use of 3D fluoroscopy and feasibility of use intraoperatively for acute ankle syndesmotic injury.

Methods

Study design:

A prospective, observational study proposes to enroll patients with unilateral, unstable, rotational ankle fractures with preoperative or intraoperative evidence of syndesmotic instability to assess ability of 3D fluoroscopy to aid in accurate syndesmotic reduction. Patients with syndesmotic instability will undergo reduction of the syndesmosis followed by provisional fixation with a clamp or Kirshner wire. The reduction quality will be initially compared to the contralateral ankle mortise and talar-dome lateral radiographs using the technique of Summers7. After the attending surgeon is satisfied with the reduction quality, 3D fluoroscopy will be used to generate additional images to assess syndesmotic and fibular reductions. The number of times that the surgeon changes the reduction of either the syndesmosis reduction (primary outcome) or fibular fracture reduction

(secondary outcome) because of information provided by 3D fluoroscopy will be recorded. Fixation of the syndesmosis by screw or suture button device will then be performed according to surgeon preference in a standard fashion. A single postoperative bilateral ankle CT scan will be performed to judge the accuracy of the injured ankle reduction to the uninjured ankle, the current gold standard. The patient outcome variables studied will include American Orthopedic Foot and Ankle Society (AOFAS) scores at 3 and 6 months as well as use of PROMIS patient physical health outcome measures using the Research Electronic Data Capture (REDCap) software survey system. Subjects unable to return to clinic for their 3 and 6 month follow-up visits will be asked to complete the AOFAS over the phone with the researcher. At that time, they will be asked for their e-mail address and sent a link to complete the PROMIS survey.

Study Subjects:

Inclusion criteria

- Patients 18-75 years of age, skeletally mature; and
- Patients with unilateral, acute, displaced ankle fractures with preoperative evidence of syndesmotic disruption or intraoperative evidence of syndesmotic instability following malleolar fixation.

Exclusion criteria

- Patients skeletally immature;
- Patients less than age 18 years and more than age 75;
- Patients with previous ankle trauma to either ankle;
- Patients with bilateral ankle injuries;
- Patients with previous osseous injuries to the tibia or fibula; and
- Patients with isolated syndesmotic injury and no fracture (i.e. high ankle sprains)

Sample Size:

In 2015, 40 patients were treated operatively for a syndesmotic disruption at Memorial Hermann Hospital. For patient enrollment collection over 8-9 months, the estimated sample size is 30 patients.

Data Collection / Handling:

Data will be collected and maintained by research personnel, residents, fellows, and faculty from the Department of Orthopaedic Surgery. The orthopedic trauma fellow (B.C.) will be primarily responsible for data handling and storage. Data will be stored in locked departmental research facilities and on password-protected networks and devices of departmental research personnel and residents. When the data collection is complete, patient identifiers will be removed prior to the sharing of data for statistical consult and analysis.

Data Analysis:

Injury radiographs and intraoperative fluoroscopy will be reviewed by the orthopedic trauma fellows and fellowship-trained orthopedic traumatologists to identify patients with acute syndesmotic instability in association with ankle fractures.

Statistical analysis will be performed using Microsoft Excel and SPSS. Continuous variables will be presented as a range, with mean and standard deviation. Categorical variables will be expressed as percentages. Logistic regression and multivariate analysis may be used to assess significant associations between predictor variables. A p value of <0.05 will be used for the significance testing.

Time Schedule

1) Complete IRB review process - September 2016

2) Execution through sponsored projects administration – October 2016

3) Start patient enrollment – November 1, 2016

4) Patient enrollment November 1, 2016 – July 1, 2016

5) Data analysis July 2017

6) Submission for publication September 2017

Risks

Use of 3D fluoroscopy is increasingly used at Hermann Memorial Hospital for treatment of orthopedic trauma patients. It may lead to slightly increased total radiation dosage delivered to the patient compared to the current technique using 2D fluoroscopy. There is additional radiation exposure to the ankles and feet from the postoperative CT scan.

Benefits

This novel technology is beginning to be used in orthopedic trauma to improve 3-dimensional understanding of complex injures. This study may lead to improved syndesmotic reduction and possibly improved patient reported functional outcomes.

Budget:

[redacted]

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