Ankle Fracture Plating: A multicenter randomized trial comparing lateral and antiglide plating in displaced lateral malleolus fractures

Introduction and Study Summary

The role of operative fixation of unstable, displaced lateral malleolus fractures is well-established.[1-3] However, the optimal type of fixation remains the subject of debate. Lag screw fixation alone is only appropriate for long oblique fractures in younger patients.[4] For all other patients, the choices for fibular stabilization most commonly involve the use of plates and screws which can be placed on either the lateral or posterior side of the bone, with or without lag screws. Lateral plating remains the most popular option, but since the description of posterior plating in 1982,[5] reports in the literature have demonstrated some advantages of posterior over lateral plating.[6-10] These advantages include less dissection, less palpable hardware, and decreased likelihood of intra-articular screw placement. However, there is only a single retrospective study in the published literature directly comparing these two methods.[11] The purpose of this randomized, prospective, multicenter study is to assess clinical, radiographic and functional results in a cohort of patients who sustained a rotationally unstable ankle and were treated surgically with one of these two constructs.

Background Discussion

Since it was first described in 1982, posterior antiglide plating has been presented as an attractive alternative to lateral plating of distal fibula fractures.[5] Biomechanical studies have shown it to be a stronger construct than lateral plating,[12] and other purported advantages include less dissection, decreased potential for intra-articular screw placement, and less palpable hardware decreasing the need for hardware removal.[6-8,10,11] However, although posterior plating has become an accepted technique for operative management of these injuries, there is little clinical information in the literature regarding this treatment, and only one published retrospective study directly comparing posterior to lateral plating.[11]

In 1996, Ostrum published a prospective study evaluating posterior plating in 32 patients, but only compared his results to a cohort of patients treated with lateral plating that was not part of his actual study group.[6] Patel et al. recently presented a retrospective comparison of both techniques, but their study only included 29 patients in the lateral plating group and 23 in the posterior group.[10] In both these studies, posterior plating was felt to be superior to lateral plating based on both the decrease in complications/re-operations related to symptomatic hardware, and improved function and pain scores.

However, in a much larger study, Lamontagneet al. showed no differences in operative time, complications or hardware removal rates in 193 patients reviewed retrospectively, and concluded that they could not recommend one treatment method over the other. They even elected not to proceed with a planned prospective study based on their results.[11] A recent retrospective analysis of 70 patients showed a 43% incidence of need for hardware removal due to pain, with 30% of these patients having peroneal tendon lesions identified intra-operatively.[13]

Inclusion Criteria

1. Patients aged 18 – 85
2. Closed Unstable Supination Eversion type Weber B fibula fracture
3. Isolated lateral malleolus fractures with subluxation of the talus
4. Bimalleolar
5. Trimalleolar
6. With or without syndesmotic dissociation
7. Soft tissue amenable to operative treatment
8. Opt for surgical treatment of their fracture
9. Willing to follow up for 1 year
10. Consent to be randomized

Exclusion Criteria

1. Aged < 18 or > 85
2. Open fracture
3. Prisoners
4. Unlikely to follow up
5. Non-English speaking
6. Pre-existing arthrosis of the ankle
7. Limitation in lower extremity function that would affect outcome scoring
8. Significant anterior comminution precluding antiglide fixation
9. Bilateral fractures

Procedure/Techniques

Surgical Technique – Lateral Plating

The patient is positioned supine on a radiolucent table and prepped in standard fashion. Tourniquets may be used if needed. The fibula is approached via a longitudinal direct lateral incision centered at the level of the fracture. Adjustments in the placement of the incision may be needed due to associated soft tissue abrasions or fracture blisters. Distally, the lateral malleolus is a subcutaneous structure. Care is taken to develop full thickness flaps to avoid wound healing problems and to avoid the sural nerve distally and the peroneal nerve more proximally. The peroneus brevis is retracted with the peroneus longus posteriorly. The peroneus tertius is retracted anteriorly.

Next, the fracture site is exposed by sharp elevation of the periosteum away from the fracture on both the proximal and distal fracture fragments, in order to be able to see the bony apposition of the reduction. The fracture hematoma and callus is gently debrided from the fracture site. Reduction of the fracture is then performed using clamps.

Once the fracture is reduced, an anterior to posterior directed lag screw(s) is placed if possible. A lateral flat or precontoured plate is placed on the reduced fracture and fixed with locked or unlocked screws. Proximal screws should be bicortical if possible.

Care should be taken to confirm that no distal screws are intra-articular. Flouroscopic evaluation should include an antero-posterior, lateral and mortise view to assess fibular reduction, length, implant placement and mortise reduction.

If a medial malleolar fracture is present, the medial malleolus is reduced and stabilized as determined by the surgeon. If a posterior malleolar fracture is present and is determined to require fixation, anterior to posterior versus posterior to anterior lag screw fixation is employed based on surgeon preference. Once the fractures are stabilized, the syndesmosis should be evaluated with intraoperative stress views. Indications for syndesmotic fixation include more than 2mm of lateral translation, talarsubluxation, or 3mm of anterior-posterior translation. If syndesmotic instability is present, reduction of the syndesmosis is performed with large reduction clamps and confirmed with direct visualization or with intraoperative fluoroscopy. Syndesmotic fixation can be performed with one or two screws through the lateral plate based on surgeon preference.

Surgical Technique- Posterior Plating

The patient is positioned supine with a small bump under the ipsilateral hip in order to ease access to the fibula. If desired, a pneumatic tourniquet may be applied to the affected thigh for use during the surgical procedure. The affected limb is prepped and draped free. The bump may be removed after lateral fixation for easier access to the medial side. The fibula is approached via a posterolateral incision behind the fibula. The incision is kept behind the posterior border of the fibula, but may be adjusted slightly based on soft tissue considerations. Deeper tissues are incised in line with the skin incision. Care must be taken proximally in the wound to avoid injury to the superficial peroneal nerve which crosses the field approximately 7cm proximal to the distal tip of the fibula. Next, the peroneal fascia is divided and the peroneal tendons and musculature are retracted posteriorly. With gentle elevation of the periostium about the fracture site the fibula should be exposed. Care should be taken to avoid exessive stripping of fracture fragments as well as iatrogenic disruption of the syndesmotic ligaments as they insert anteriorly on the fibula. The plate is placed on the posterior or posterolateral surface with an attempt to place the plate over the spike of the distal fragment. Proximal bicortical screws are used. If needed, lag screws through the plate and screws in the distal fragment may be utilized, but should be avoided if near the peroneal tendons. Efforts should be made to avoid plate positioning that impinges on the peroneal tendons. Indications for syndesmotic fixation are the same as in the lateral plating section. Syndesmotic fixation can be performed with one or two screws through or anterior to the posterolateral plate, depending on surgeon preference based on the position of the plate.

Medial and posterior malleolus fractures

The surgeon will reduce and stabilize the medial and posterior malleoli as indicated and document this in the data sheets.

Data Sheets

Operative data sheets will be filled out immediately after the surgery, indicating the type of fixation and the radiographic analysis of the reduction.

Protocol Instructions: Fracture Characteristics Form

The PI at each center will fill out the *Fracture Characteristics* form.

- Question 2: This question is to note blisters at the time of the surgical intervention.
- Question 3: An anterior collicular fracture is defined as per Pankovitch. It involves only the most distal anterior part of the medial malleolus and has minimal to no deep deltoid attached. A supracollicular fracture involves the entire medial malleolus and has the deep deltoid attached to it.
- Question 4: The measurement of the posterior malleolus may be based on plain radiographs and estimated based on the AP or externally rotated view. If a CT scan was obtained, this should be used.
- Question 5: Please mark all that apply. Anterior comminution should be noted if there is comminution at the anterior distal extent of the fracture. Posterior spike comminution refers to the posterior spike on the inferior fragment being multifragmentary. Plafond impaction should be sought out and documented if it occurs.
- Questions 6 and 7: The distances on from the tip of the fracture to the anterior and posterior fracture sites are measured and documented in millimeters.

Protocol Instructions: Surgical Summary

The *Surgical Summary* report should be filled out by the operative surgeon, but ***verified in its entirety*** by the PI at each center.

- Question 1: While the bone density is a subjective measure, please use the following to guide your answer: High bone density is "young" bone. It resists compression by clamps and can be reduced using the tines of a clamp without substantial collapse. It supports screws with "great bites." Osteopenic bone is "old" bone. It is weak and can be crushed with a clamp if applied too strongly. The tines of a clamp impale the bone and the reduction is often difficult to obtain using only the clamps. The screw purchase is best described as "poor," with the surgeon concerned about the strength of fixation or drawn to using locked screws. Moderate is all in between.
- Question 2: The concavity of the incision is the circumscribed side of a curve. Thus if the incision is parallel with the tibia and then is directed anteriorly to the foot, it is concave anteriorly and vice versa.
- Questions 4 -7, 9-14: These refer to the specific fixation used. Please be complete in filling this out.

- Question 8: Please make a precise measurement from the tip of the fibula to the distal most extent of the plate, similar to questions 6 and 7 on the *Fracture Characteristics* form.
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Protocol Instructions: Radiographic Assessment

The measurements on this form will be used for statistical analysis. All measurements should be made with calipers or a high quality goniometer. ***If possible, the same person should measure all fractures at each institution to improve consistency.*** All measurements are made on both the AP and mortise views at the intervals listed. All measurements are to be made on radiographs with the foot in ***neutral dorsiflexion.***

- Question 1: The medial clear space should be measured at the middle of the medial joint line and ***perpendicular*** to the medial malleolar articular surface. It should ***not*** be measured at the corner of the joint. Similarly, the superior joint space should be taken in the middle of the joint. The lateral joint space may not be visible clearly on the AP radiograph. If this is the case, do not list a number. Subluxation is defined as ***any*** subluxation of the talus judged from the appearance of the joint congruence, and the lateral margin of the talus to the lateral margin of the tibia.
- Question 2: Congruence on the lateral radiograph with the foot in neutral is noted.
- Question 3: The location at which the posterior cortex of the fibula crosses the joint is documented. In most ankles, this is ***at*** the level of the posterior most aspect of the subchondral line of the distal tibia. It is noted as at the level of the posterior aspect of the joint, or anterior or posterior to it. This must be on a perfect lateral radiograph (see figure 1).
- Question 4: The talocrural angle is measured (see figure 2). The angle is in the neighborhood of 80°.
- Question 5: The fibular distance is defined as the distance between a transverse line at the tip of the medial malleolus to a transverse line at the tip of the fibula (see figure 3). Simply put, it is a measurement of how much more distal the fibula is than the medial malleolus on the AP radiograph.

Follow-up

Follow-up will be clinical, radiographic, and patient based (see grid).

Protocol Instructions: Clinical Follow-up Evaluation

This one page, 9 question form is to be ***completed by the physician or qualified physician extender*** at the 2, 6, 12, 26, and 52 week postoperative visits.

- Question 1: Please use a goniometer to measure the degree of active and passive dorsiflexion and plantarflexion.
- Question 2: Please differentiate from a patient describing sensitivity only to light touch vs. they describe the lateral incision is bothersome to them with or without light touch

- Questions 6 – 7: Flat foot and toe touch weight bearing are considered the same.

Protocol Instructions: AOFAS Clinical Rating System

This one page, 9 question form is to be ***completed by the physician or qualified physician extender*** at the 2, 6, 12, 26, and 52 week postoperative visits.

- Question 2e: Please use a goniometer to measure the flexion plus extension sagittal motion.
- Question 2f: Please use a goniometer to measure inversion plus eversion hindfoot motion and compare it to the goniometer measurement of the uninjured side to get the percent of normal grading.

Protocol Instructions: SF-12v2 Health Survey

This one page, 12 question form is to be ***completed by the patient*** at the pre-operative visit and 6, 12, 26 and 52 week postoperative visits. It is important that the patient be instructed to ***fill out the form at the pre-operative visit as if they were answering the questions just prior to their injury***. This will provide the best baseline function assessment of the patient and will be the bases of comparison for the subsequent forms. At all postoperative time points, the form should be filled out by the patient based on how they feel at that follow-up visit.

Protocol Instructions: Short Musculoskeletal Functional Assessment (SMFA)

This two page, 46 question form is to be ***completed by the patient*** at the pre-operative visit and 6, 12, 26 and 52 week postoperative visits. It is important that the patient be instructed to ***fill out the form at the pre-operative visit as if they were answering the questions just prior to their injury***. This will provide the best baseline function assessment of the patient and will be the bases of comparison for the subsequent forms. At all postoperative time points, the form should be filled out by the patients based on how they feel at that follow-up visit.

Data Analysis/Sample Size

Primary Analysis:

We will summarize mean functional scores with means and standard deviations. We will calculate a mean difference in functional at final follow up across both treatment groups with an independent t-test. The test will be two sided and our threshold for statistical significance will be $p<0.05$. Standardized mean differences (immediate post-op to final follow up) across both interventions will also be compared.

Secondary Analyses:

We will employ repeated measures analysis of variance looking at time, treatment, and the interaction between the two to compare the change in functional status in both the posterolateral vs lateral plating groups at discharge 6, 9, and 12 months post-operatively. Functional scores

will be compared across apriori subgroups (<60 vs 60 or greater years, good vs. poor bone quality, and syndesmotic injury or not). These secondary analyses will be deemed hypothesis-generating. We will adjust our level of statistical significance for multiple subgroup analyses (p=0.01).

Sample Size:

We consider an important difference to correspond to a moderate effect as reported by Cohen as well as a minimally important difference in the SF-12 as reported by Ware. In both cases, the value is 1/2 the standard deviation, equivalent to 5 point difference in score. Specifying an alpha level=0.05, a type II error rate=0.20 (study power=80%), we will require a sample of at least 63 patients per group (Total 126 patients) to ensure detection of a ½ standard deviation difference between treatment groups. Adjustment for an anticipated 10% loss to follow up and 2% crossover rate will require the enrollment of 144 patients (72 patients per treatment arm).

Across 144 patients, we anticipate approximately 25% associated syndesmotic injuries (36 patients). Our study will have 80% power to detect at least 8 point SF-12 differences as great as among patients with syndesmotic injuries compared to those without such injuries.

Data Grid:

Clinical									
Case Report Form	*Completed By*	*PreOp Visit*	*Post-Op*	*2 week PostOp*	*4 week PostOp*	*6 week PostOp*	*12 weekPost Op*	*26 weekPost Op*	*52 week PostOp*
Inclusion/Exclusion	Physician	X							
Patient Information	Physician	X							
Fracture Characteristics	Physician	X							
SF 12v2	Patient	X			X OR X		X	X	X
SFMA	Patient	X			X OR X		X	X	X
Surgical Summary	Physician		X						
Clinical Evaluation	Physician			X	X OR X		X	X	X
AOFAS Clinical Rating System	Physician			X	X OR X		X	X	X
Radiographic Evaluation	Physician		X		X OR X		X	X	X
Adverse Event	Physician	*As Needed*							
Radiographic Images									
AP	Physician	X	X		X OR X		X	X	X
Lateral	Physician	X	X		X OR X		X	X	X
Mortise	Physician	X	X		X OR X		X	X	X

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