External Fixation Versus ORIF for Distal Intra-articular Tibia Fractures

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abstract

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Tibia plafond fractures have historically demonstrated high complication rates. The purpose of this study was to assess the outcomes of tibia plafond fractures following treatment with definitive external fixation vs delayed open reduction and internal fixation (ORIF). Sixty patients were enrolled in a prospective cohort trial at 1 Level I trauma center. No differences were noted between the 2 treatment groups in terms of age, smoking history, presence of comorbidities, mechanism of injury, incidence of open fractures, or Orthopaedic Trauma Association fracture classification. Complete 12-month follow-up was available for 18 patients in the definitive external fixation group and 27 patients in the ORIF group. No difference was noted in articular reduction between the groups at 6 and 12 months postoperatively. Delayed union or non-union occurred in 4 (22.2%) of 18 patients in the external fixation group and 1 (3.7%) of 27 patients in the ORIF group (P=.05). Deep infection was equally likely in either group (P=.33). The ORIF group had improved Iowa Ankle Scores at 6 (23.6 ± 12.1 vs 11.1 ± 7.7; P<.05) and 12 months (5.5 ± 2.2 vs 3.1 ± 1.7; P<.05) postoperatively and improved Short Form-36 Physical Function scores at 6 months (49.7 ± 30.1 vs 25.5 ± 18.0; P<.05) postoperatively compared with the external fixation group.

External fixation and ORIF can attain bony union with adequate articular reduction and similar infection rates. Patients treated with ORIF appeared to have improved union rates and early outcomes with ankle function and Short Form-36 Physical Function scores.
Tibial plafond fractures are severe injuries that have an extraordinarily high incidence of morbidity. Historically, these patients were treated with medial-based open reduction and internal fixation (ORIF) of the tibia with bone grafting as needed to accomplish the goal of restoration of the distal fibula length and the articular surface.\(^1\)\(^-\)\(^3\) According to reports in Europe, this treatment had excellent results and low complication rates.\(^3\)\(^-\)\(^4\) When this treatment protocol was performed by many centers in North America, the results were not as acceptable.\(^5\)\(^-\)\(^13\) Many trauma centers began treating these patients with immediate external fixation and delayed internal fixation of the articular surface with minimal incisions, leaving the external fixator in place until bony union. The orthopedic literature reporting this treatment protocol for plafond fractures showed good results with low complication rates.\(^14\) The difficulty with this treatment protocol is extended use of external fixation (2-4 months), which can result in pin-tract infections, external fixator loosening, and a high incidence of malunion or nonunion.\(^14\)\(^-\)\(^16\)

In a prospective clinical study by Wyrsch et al\(^17\) on the treatment of distal tibia fractures, patients were surgeon randomized to either external fixation with limited ORIF or external fixation with delayed definitive ORIF groups. The study concluded that complications were more severe in the external fixation with delayed definitive ORIF group (ie, below-knee amputation vs pin-tract infections) and malunion was more likely in the external fixation with limited ORIF group (>5° in any plane). Sirkin et al\(^18\) reported that these differences were secondary to internal fixation of these fractures during the time when they were maximally swollen, an average of 5 days postinjury. In their study of delayed external fixation with delayed definitive ORIF, the authors found a relatively low incidence of wound complications and deep infections.\(^18\) Due to this controversy and the high complication rate associated with distal tibia fractures, the current study compared external fixation with delayed ORIF to evaluate joint reduction, infection, nonunion, malunion, and functional outcome scores at 3, 6, and 12 months postoperatively.

The authors hypothesized that (1) the external fixation group would have a higher incidence of nonunion and delayed union than the ORIF, (2) infectious complications would occur more often in the ORIF group, and (3) scoring of the functional outcome questionnaires (Iowa Ankle Score, Short Musculoskeletal Functional Assessment [SMFA], and Short Form-36 [SF-36]) would be no different between groups at 3-, 6-, and 12-month follow-up.

**Materials and Methods**

Study participants were enrolled at a Level I trauma center between June 2002 and June 2006. Patients were considered eligible for the study if they were aged 18 years or older, had sustained an isolated, unilateral open or closed plafond fracture, were independently ambulatory prior to injury, were English competent, and granted consent. Exclusion criteria included patients with pathologic fractures, prolonged steroid use, renal failure, pre-existing symptomatic ankle arthritis, Paget’s disease, ankle injuries that precluded ORIF or external fixation, decreased mental status, and type IIIC open tibia plafond fractures. Also excluded were transient patients without a fixed address, patients not living in the immediate vicinity, and patients who were prisoners. The study was approved by the Institutional Review Board.

**Sample Size**

Given a clinical difference in union of 10%, with an alpha of 0.05 and a beta of 0.80, 60 patients were estimated to be required in each group. Using the same alpha and beta values, 60 patients were estimated to be required for a difference in the functional outcome score of the SMFA questionnaire of 8 points and a difference in infection rate of 10%.

**Treatment Selection**

Initially, patients were randomized via sealed opaque envelopes after initial external fixation to receive either definitive ORIF or definitive external fixation by a surgeon who felt comfortable with that method (surgeon randomization). Using this methodology, patient accrual was low due to strict inclusion criteria of isolated fractures, as well as patient and surgeon concerns about the possibility of changing surgeons. Therefore, the study was changed to a prospective cohort design. All patients received initial external fixation, and then the treating surgeon performed the procedure that he or she was most confident using and treated all patients with a technique of definitive ORIF or reduction via limited ORIF and external fixation until union. All surgeons who participated in the study were fellowship-trained orthopedic traumatologists (M.A.T., F.D.S., P.J.K., W.T.O.).

Open reduction and internal fixation patients followed the staged protocol of Sirkin et al\(^18\) with initial bridging external fixation with delayed joint fixation via minimal incisions at approximately 2 weeks postinjury. The objective was to obtain anatomic articular reconstruction with limited exposure of the distal tibia articular surface using primarily percutaneous plating and screw fixation of the articular surface. Immediate or delayed bone grafting with allograft or autograft was left to the discretion of the attending orthopedic surgeon.

Approximately 2 weeks postinjury in the definitive external fixation group, an incision at the articular surface allowed visualization of the joint. Attempts were made to realign impacted fragments to anatomically reconstruct and restabilize the articular surface using screws. The length of definitive external fixation was left up to the treating orthopedic surgeon and was based on whether he or she felt that the metadiaphyseal and metaphyseal regions...
of the fracture had healed. On healing, the patient was scheduled for elective removal of the external fixator. After 2 weeks, the posterior splint was removed and the patient began active and passive range of motion of the affected ankle with weight bearing as tolerated.

Variables
The independent variable comprised the 2 treatment groups: (1) definitive external fixation and (2) definitive ORIF with removal of the external fixator. Dependent variables included joint reduction, wound infection, nonunion, malunion, Iowa Ankle Score, SF-36 score, and SF-36 score. Reduction was assessed with the modified criteria of Burwell and Charnley. With this system, developed by Marsh et al., reduction was classified as good, fair, or poor on the basis of the displacement of the fracture fragments (medial, lateral, and posterior malleoli, anterior lip, and central fragment) and the talus (tilt or subluxation) and mortise widening. All parameters were measured in millimeters except for tilt, which was measured in degrees.

Wound infection was based on positive bacterial organisms obtained from operative debridement of the wound or fracture region. Clinical healing was defined as the absence of patient-reported pain with weight bearing without a brace or cast and the absence of tenderness to palpation at the fracture site. Radiographic healing was considered for evidence of bridging callus formation on 3 of 4 cortices. Delayed union was defined as a fracture that showed a cessation of the healing process (by radiographic healing criterion) at 3 months postinjury. Nonunion was defined as a fracture that had not healed (by radiographic criterion of healing) within 6 months of injury. Malunion was defined as >5° of angulation in the coronal plane, >10° in the sagittal plane, or ≥2 mm of articular stepoff as seen on postoperative radiographs. Alignment was assessed on standing anteroposterior, lateral, and mortise radiographs of the ankle at follow-up by measuring the angle created by the intersection of the subchondral line of the plafond and a line drawn up the center of the tibial shaft. Ninety degrees was considered normal, and deviations >5° were recorded as varus, valgus, anterior, or posterior angulation.

Statistical Analysis
Demographic and background characteristics were recorded and summarized. Continuous variables were compared with unpaired Student’s t test, with significance set at P<.05. Categorical variables were compared using Mantel-Haenszel procedures. The Breslow-Day test for homogeneity was used when appropriate. Statistical significance was set at P<.05.

RESULTS
Demographic data of the 2 treatment groups were compared, and no differences were noted in terms of age, smoking history, presence of comorbidities, mechanism of injury, incidence of open fractures, or Orthopaedic Trauma Association (OTA) fracture classification (Table 1). The patients in the external fixation group were in an external fixator for a mean of 2.29±0.70 weeks prior to definitive joint reduction vs 3.03±2.18 weeks in the ORIF group (P=.177). Of the 26 patients in the external fixation group, 18 (69%) completed 12-month follow-up. Of the 34 patients in the ORIF group, 27 (79%) completed 12-month follow-up.

No differences were noted in articular reduction postoperatively between the groups. Fibula fractures were not more likely to be internally fixed in the ORIF group than in the external fixation group. Planned bone grafting at <6 weeks postinjury was performed in 5 patients in the ORIF group and 3 in the external fixation group; the difference was not statistically significant (Table 2).

Deep Soft Tissue Complications
Deep infection was not statistically different in either group, with 2 (11.1%) of 18 patients in the external fixation group and 1 (3.7%) of 27 patients in the ORIF group developing deep infections.
Thirteen (28.9%) of 45 fractures were open, and no differences existed in wound infection or breakdown rates between groups in patients with an open fracture ($P = .25$) (Table 3).

### Delayed Union and Nonunion

One (3.7%) nonunion occurred in the ORIF group and 4 (22.2%) nonunions occurred in the external fixation group ($P = .05$). The nonunion in the ORIF group was a type II open fracture, and 2 nonunions in the external fixation group were open type II and type IIIA fractures. Of the 4 patients with nonunion in the external fixation group, 2 went on to have an ankle arthrodesis. In the external fixation group, 1 patient developed an Achilles tendon contracture and 1 developed claw toes, which were surgically addressed.

### Functional Outcome Scores

At 6 months postoperatively, the ORIF group had significantly higher Iowa Ankle Scores (23.6±12.1 vs 11.1±7.7, respectively; $P = .002$) and SF-36 physical function scores (49.7±30.1 vs 25.5±18.0, respectively; $P = .03$) than the external fixation group. At 12 months, the Iowa Ankle Range of Motion (ROM) Score was significantly higher in the ORIF group compared with the external fixation group (5.5±2.2 vs 3.1±1.7, respectively; $P = .009$); however, this is most likely clinically insignificant. All other outcome measures were not significantly different at 3-, 6-, and 12-month follow-up. Radiographic and clinical outcomes demonstrated that, at 12-month follow-up, all fractures in the ORIF group had achieved union, whereas 1 fracture in the external fixation group did not demonstrate evidence of complete osseous consolidation on radiographic imaging.

### Discussion

Ruedi and Allgower promoted (1) reconstruction of the correct length of the fibula, (2) reconstruction of the articular surface of the tibia, (3) cancellous autograft to fill the bone defect in the metaphysis of the tibia, and (4) stabilization of the medial aspect of the tibia with a plate. However, they studied a patient population whose mechanism of injury was lower energy, usually the result of skiing accidents. In practice, most fractures of this kind are of the explosive type secondary to impaction of the talus into the tibia from a motor vehicle collision or a fall from height. Increased complications were noted in several studies using these principles in high-energy distal tibia fractures, with 1 study finding infection rates as high as 55% and wound sloughing rates of 36%. A few patients in multiple studies eventually required arthrodesis or amputation. These devastating outcomes prompted many surgeons to adopt the principle of tibial articular reconstruction without exposing the fracture. Thus, external fixation with limited ORIF was evaluated to try to achieve articular surface realignment with fewer complica-
tions. Multiple studies have shown that comparable results could be achieved with external fixation while minimizing the rate of infection and skin sloughing.14,15,17

In a prospective study of 39 fractures, Wyrsch et al17 found a 28% infection rate and a 33% wound sloughing rate in the ORIF group compared with a 5% infection rate and a 5% wound sloughing rate in the external fixation group. No differences were observed in joint reduction, union rate, clinical scores, or radiographic scores. Sirkin et al18 asserted that the differences in Wyrsch et al’s17 study were secondary to early internal fixation of these fractures when they were maximally swollen, an average of 5 days postinjury. The results were promising, with 1 infection in their closed fracture group and 2 infections in their open fracture group.18 A more recent study by Harris et al20 reported that patients treated with external fixation had increased complications and posttraumatic arthritis than patients treated with ORIF. Patients with more severe type C3 fractures were more frequently treated with external fixation vs ORIF (88% vs 46%, respectively).22

In the current study, deep infection was equally likely in both treatment groups. Historically, ORIF has resulted in wound infection rates as high as 30% to 60%.9,12,13 Using the staged approach to ORIF proposed by Sirkin et al,18 infection may be minimized with delayed internal fixation; however, the lack of statistical difference observed in the current study may be due to a type II error resulting from the need for a larger sample size. Studies by Marsh et al,14 Bone et al,15 Pugh et al,16 and Koulovaries et al13 reported that external fixation has consistently been associated with high rates of pin-tract infections, malunion, and nonunion.

A recent study by Pollak et al24 reported that, compared with age-matched controls, patients with tibia plafond fractures had significantly decreased general health on SF-36 outcome measures at an average 3.2 years postinjury. Thirty-five percent had ankle stiffness, 29% had persistent swelling, and 33% had ongoing pain.24 Sands et al25 performed a retrospective review of 64 patients with plafond fractures treated with ORIF and reported a 5% deep infection rate. They were able to acquire SF-36 forms on 27 of the 64 patients, which showed a decrease in all 8 categories with significantly decreased physical function and role limitations attributed to physical health. In these studies, patients with tibial plafond fractures were compared with age-matched controls and showed significant decreases in health assessments.

The results of the current study contradict those of Wyrsch et al,17 who used similar assessment criteria based on patient pain and function and surgeon observation of gait and ROM. In their study, no difference existed in clinical scores.17 The current study used a staged approach to ORIF, which allowed soft tissue swelling, prior incisions, and fracture blisters to begin healing. This could have improved early clinical scores. Improved operative techniques could account for improved long-term scores on the SF-36 function and vitality questionnaires. Throughout the study period, the only significant differences observed in outcome measures were seen in the 6-month ankle function score, the 6-month SF-36 functional physical score, and the 12-month ankle ROM score.

Marsh et al20 assessed the long-term results of 35 plafond fractures treated with a hinged external fixator using the Iowa Ankle Score, Ankle Osteoarthritis Scale, SF-36, and radiographic studies 5 to 12 years postinjury. They reported that the majority of patients had diminished health and function and increased pain compared with age-matched controls.20 Arthrosis correlated little with clinical outcomes,20 a result also reported by Etter and Ganz4 and Ovadia and Beals.7 In those studies, 9 patients with previous ankle scores had increased scores after longer follow-up. This is consistent with a study of external fixation by Marsh et al,26 which showed that ankle osteoarthritis scores tended to improve after longer follow-up (12 to 24 months). The current study followed patients to 12 months, and no long-term perceived improvements were seen in clinical outcomes beyond 1 year postinjury. Anglen27 published a comparison study of ORIF vs external fixation and reported that patients treated with hybrid fixation had lower clinical scores, a slower return to function, a higher rate of complications, more nonunions and malunions, and more infections. Patients with worse injuries were treated with definitive external fixation,27 so that comparative study may not be as reliable as the current prospective study.

This study has some limitations. Initially, the study comprised 60 patients, but data were collected for only 45 (75%) patients at 12-month follow-up. Based on the sample size, the power of this study to detect a difference in infection rate, SMFA-dysfunction score, and SMFA-Bother score was 7.1%, 25%, and 60.8%, respectively. One should consider that the results may represent a type II error. The study initially included randomization, yet patient accrual was low, and, thus, the study format was changed to a prospective cohort. A study by Ioannidis et al29 reported that, with the exception of larger treatment effects, nonrandomized study results correlated well with those of their randomized counterparts. In the current study, no ability existed to blind surgeons, radiologists, or patients from knowing which treatment they received. In addition, the surgeons, the procedures they performed (ie, plating vs no plating of the fibula), and the brands of external fixators they used varied.

In light of the limitations, this study represents a prospective analysis of the
outcomes of 2 different treatment methods for a specific injury, using validated objective and subjective outcome measures. All participating surgeons were fellowship trained in orthopedic trauma surgery, and patients were acquired from 1 institution, thereby standardizing patient care and treatment. This is the first prospective comparative study of isolated distal tibia pilon fractures that compares 2 treatment strategies and includes clinical, radiographic, and functional outcomes.

Treatment of distal tibia plafond fractures continues to have a high complication rate. Patients undergoing external fixation with articular reduction and leaving the external fixator until bony union may be at an increased risk of developing a nonunion. These patients seem to have no difference in articular reduction immediately postoperatively. Patients being treated for distal tibia plafond fractures should be counseled about high complication rates with any treatment method. External fixation and ORIF can attain bony union with adequate articular reduction, but external fixation may be associated with a higher risk of delayed union or nonunion. Patients may have improved early functional outcomes with ORIF vs external fixation.

REFERENCES
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