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Prospective Randomized Comparison of Locked Plates vs. Non-Locked Plates for the Treatment of High-Energy Pilon Fractures.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Objectives: To compare the radiographic and functional outcome of patients with high-energy pilon fractures treated with locked versus non-locked plates.

Design: Randomized prospective trial.

Setting: Academic level 1 trauma center.

Patients: From December 2006 to December 2008, 60 consecutive patients with 62 AO/OTA type A, B and C tibial pilon fractures were enrolled in the study. 32 of the fractures were treated using locked plates and 29 were treated with non-locked plates. Follow up data was available for 33 of the 60 patients.

Intervention: Treatment with locked vs. non-locked plates.

Main Outcome Measures: Short Musculoskeletal Function Assessment (SMFA) questionnaire and the American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale. Radiographic measurements on AP and lateral views for the quality of reduction and maintenance of alignment immediately postoperatively compared to the latest follow up.

Results: There were no significant differences in the mechanism or injury pattern, the average age of the patients, the ratio of males to females, the tourniquet time, the operative time, the interval to surgery, the AHS, or the SMFA scores. 1/15 fractures in the locked plate group lost reduction at the latest follow up compared 3/19 fractures in the non-locked group.

Conclusions: In this study there appears to be no difference between the two constructs. Thus, one must question the routine use of locked plates in the treatment of high energy pilon fractures.

Key Words: pilon;implant;randomized;fracture;trauma

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

INTRODUCTION

Fractures of the tibial plafond account for less than 1% of all fractures of the lower extremity but comprise approximately 7-10% of all tibia fractures (1, 2). High-energy pilon fractures are often associated with marked comminution and extensive soft tissue injury. The goal of operative treatment includes anatomic reduction of the articular fragments and realignment of the limb while avoiding additional soft tissue trauma. Surgical treatment of pilon fractures is associated with a complication rate varying from 10-55%, including soft tissue problems, nonunions, malunions, implant failure, joint stiffness and post-traumatic arthrosis (2-8).

Historically, the use of non-locked plates for pilon fractures has resulted in loss of reduction in as many as 30-42% of cases (2) A conventional non-locking plate relies on bicortical screw purchase to obtain contact and friction between the plate and underlying bone. Screw toggle can occur in a non-locking plate which may lead to screw loosening and loss of reduction (9, 10). With locked plates, screw toggle does not occur and frictional contact between the plate and the bone is not required for stability (9, 10). With recent advances in locked plate technology, improved outcomes have been reported in the fixation of comminuted fractures of the distal radius and proximal humerus (11, 12). To our knowledge, no study has compared the efficacy of standard non-locked vs. locked plates in the treatment of pilon fractures. The purpose of this prospective study is to compare the clinical and radiographic outcomes of patients treated with either locked or conventional non-locked plates in the management of high-energy pilon fractures.

PATIENTS AND METHODS

Between December 2006 and December 2008, 101 skeletally mature patients presented to the authors' institution with acute high-energy pilon fractures. 60 patients (59%) (62 fractures) were enrolled and

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randomized to be treated either with a locked (L) or non-locked plate (NL) based on their medical record number. A majority of patients were initially treated with a spanning external fixator with or without fibular fixation at the surgeon's discretion to restore length and alignment and allow soft tissue healing. This was followed by a definitive open reduction internal fixation (ORIF) 10-21 days following the initial surgery. Inclusion criteria included all open or closed pilon fractures in skeletally mature patients. Patients who were not skeletally mature and/or patients under the age of 18 were excluded. All patients were treated by fellowship trained orthopaedic traumatologists. This study was approved by the Institutional Review Board and informed consent was obtained from all study participants.

Postoperative care was similar for both groups. All patients remained strict toe-touch weight-bearing immediately postoperatively for approximately 3 months. A graduated physical therapy protocol was initiated on postoperative day one with crutches or a walker. The protocol was directed at gait training, active and passive lower extremity range of motion exercises and endurance training. Splint immobilization was employed until wound healing, followed by immobilization with a removable cast-type boot. At approximately three months, weight-bearing was advanced as tolerated with supervision of physical therapy. This was followed by weaning of assistive devices for gait and the initiation of proprioception and endurance activities.

All fractures were followed for a minimum of 6 months. If there was no evidence of fracture union by 6 months, follow-up continued at monthly intervals until union. Clinically, healing was defined as no pain at the fracture site with full weight bearing. Radiographic healing was defined as bridging callus across 3 of 4 cortices. All x-rays were reviewed by both a junior resident and the senior author. Standard antero-posterior, mortise, and lateral radiographs were obtained at each visit. Soft tissue complications including wound necrosis and infection were assessed clinically by the examining physician at each follow up visit. If infection was suspected, further laboratory studies including complete blood count (CBC), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) were obtained. Surgical intervention for soft tissue complications was performed at the discretion of the attending surgeon.

Data collected included basic demographic information, degree of soft tissue injury, fracture pattern, medical comorbidities, tobacco use, associated injuries, mechanism of injury, fixation technique, time to definitive fixation, operative time, tourniquet time, treatment of delayed/nonunion, postoperative soft tissue complications, and postoperative angulations .

Functional outcomes were assessed using the SMFA and the AOFAS Ankle Hindfoot Scale (AHS) at the latest follow up**(13) (14)**. Radiographic outcomes were assessed by an independent observer. Coronal and sagittal plane angulations of the tibia relative to talus were measured immediately postoperatively and at the latest follow up. A change of > 5 degrees was considered to be a loss of reduction.

On the lateral view, the angle between the line longitudinal to the long axis of tibia and the line connecting the anterior and posterior aspects of the tibial plafond were measured. On the mortise view, the angle between the long axis of the tibia and the line parallel to the articular surface of the talus was measured.

Categorical variables were compared with either the chi square test or the Fisher's exact test when data was sparse. Continuous variables were compared with the Wilcox rank sum test. A power analysis showed that to detect a difference of 20%, 40 patients were needed each group. The study was ended early due to financial resources and decreased patient enrollment.

RESULTS

Demographic information, mechanism of injury and OTA fracture classifications are summarized in Table 1 with no significant difference between the two groups. Of the 60 patients in the study (62 fractures), 33 patients (34 fractures) had at least 12 months radiographic follow up with an average of 35.6 months (range 12 to 74 months). 25 patients were excluded because of insufficient follow up, one patient expired and one

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patient was randomized but was treated definitively with an external fixator. Five patients in the locked plate group and 7 patients in the non-locked group used tobacco products. No patients had diabetes.

Table 2 summarizes the SMFA and AHS functional outcome scores. There were 9 patients in group L with an average follow up of 34.6 months (range 13-59) and 12 patients in group NL with an average follow up of 36.5 months (range 12-67). There were no significant differences in the functional outcome scores of patients in either group.

Table 3 summarizes the treatment and complication data. Both groups had a similar interval from the date of injury to the date of definitive fixation. Four patients in the NL group and one patient in group L had definitive fixation with ORIF foregoing the external fixator. Operative time, tourniquet time, and estimated blood loss were also similar between the two groups. There was a similar rate of complications between the two groups including non-union, malunion, infection, implant failure, and painful implants. One patient in the L group had a loss of reduction and 3 patients in the NL group had a loss of reduction [p=0.481]. Seven (46.7%) patients in the L group and 3 (15.8%) patients in the NL group required a secondary procedure. There was no significant difference in the average time the subsequent procedure between the groups. Lastly, in terms of final outcomes at the most recent follow up visit, there was no significant difference between the two groups.

DISCUSSION

Our study was designed to evaluate and compare the efficacy of standard vs. locked plates in the treatment of pilon fractures. Locked plate constructs create a fixed angle device that provides rigid fixation of the comminuted articular fragments as well as preserve the periosteal blood supply, which in theory would allow for earlier joint mobilization and bone healing with a decreased rate of infection, non-union, and loss of reduction(15). Lateral column fixation can be achieved with an anterolateral plate for the distal tibia or fixation of the fibula (16). Medially, a buttress plate is used to resist the varus collapse of the distal tibia.

Our original hypothesis was that the advantage of the fixed angled construct of a locked plate would provide enough stability to treat both columns with one plate. **B**ased on our data however, there was no statistical difference in number of fractures that lost reduction when comparing techniques. Similarly, there was no difference in the SMFA functional or bother index, or AHS functional outcome scores.

There are several limitations of this study that need to be discussed. The power of the study is insufficient thus the potential for a Type II B error must be considered. The percentage of patients available for final follow-up was only slightly better than 50%. Furthermore, we had a heterogeneous group of pilon fractures (OTA classes B and C). Although the radiographic assessment of fracture healing and OTA fracture classification were performed by both a resident and senior orthopedic surgeon, there was no intra or inter observer reliability testing done. In terms of functional outcome scores, the SMFA has been validated and is an accepted measurement tool and while the AOFAS AHS score has not been validated, a recent study showed it can provide useful information(17).

In conclusion, based on our prospective randomized trial, we did not find a difference in long-term radiographic outcomes, complication rates, or functional results when comparing locked to non-locked plate constructs. Thus, one would question the need for routine use of locked constructs in the treatment of high energy pilon fractures.

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Table 1. Patient Demographics and Mechanism of Injury

	Lock	NonLock	P
patients	**n =15**	**n = 19**	
Age	43.2 +/- 13.8	36.6 +/- 14.6	0.281
Gender			0.601
Males	10 (66.7%)	11 (57.9%)	
Females	5 (33.3%)	8 (42.1%)	
Mechanism of Injury			0.422
Fall <10	4 (26.7%)	7 (36.8%)	
Fall >10	7 (46.7%)	4 (21.1%)	
MVC	2 (13.3%)	6 (31.6%)	
Other	2 (13.3%)	2 (10.5%)	
OTA-Class (fractures)	**n= 16**	**n=21**	0.359
43-A1	0 (0%)	1 (5.3%)	
43-C1	0 (0%)	3 (15.8%)	
43-C2	3 (20.0%)	4 (21.1%)	
43-C3	12 (80.0%)	11 (61.9%)	

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Table 2.
Functional Outcome Scores

	Lock n =9			NonLock n = 12			P Value
	Mean	**Median**	**95% CI**	**Mean**	**Median**	**95% CI**	
Ankle Hind Foot Scores	64.7	74	40.17, 89.17	73.5	73.5	48.98, 79.19	0.9859
SMFA Functional Index	36.0	22.1	8.97, 62.94	27.3	29.8	14.54, 39.95	0.7540
SMFA Bother Index	24.7	14.6	1.2, 48.14	34.9	31.25	17.18, 52.62	0.3357

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Table 3. Treatment Data

	Lock			NonLock			P
	n =15 Mean	Median	95% CI	n = 19 Mean	Median	95% CI	
Interval to ORIF (days)	14.6	15	11.01,18.19	11.7	14	8.32,15.05	0.508
Operative Time (min)	148.93	142	111.39, 186.48	162.1	157	131.32, 192.89	0.487
Tourniquet Time (min)	90.93	90	78.5, 103.37	101.6	100	84.04, 119.14	0.334
Estimate Blood Loss (mL)	134	150	86.68, 181.32	185.3	200	120.17, 250.35	0.332
Complications							
Nonunion	3 (18.8%)			2 (9.5%)			0.634
Malunion	1 (6.7%)			0 (0%)			0.441
Infection	4 (26.7%)			1 (5.3%)			0.146
Hardware Failure	1 (6.7%)			0 (0%)			0.441
Painful Hardware	2 (13.3%)			0 (0%)			0.187
Secondary Procedure	7 (46.7%)			3 (15.8%)			0.068
Interval to Secondary Procedure	2.4 +/- 2.4			21.8 +/- 26.6			0.173
Loss of Reduction	1 (6.7%)			3 (15.8%)			0.481
Final Outcome							0.157
Healed without complication	8 (53.3%)			16 (84.2%)			
Healed with complication	5 (33.3%)			2 (10.5%)			
Healed with fusion	2 (13.3%)			1 (5.3%)			

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