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Does external fixator pin site distance from definitive implant affect infection rate in pilon fractures?

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ABSTRACT

Introduction: Tibial pilon fractures are often treated with initial external fixation followed by delayed definitive fixation. It has been postulated that the external fixator pin site may correlate with infection risk. The purpose of this study was to determine whether external fixator pin-site distance from definitive implants impacts the risk of deep infection in pilon fractures.

Materials and methods: A retrospective cohort study was completed at a single level 1 trauma center. All patients ages 15–65 who underwent open reduction and internal fixation (ORIF) of a distal tibial fracture (AO/OTA Classification 43) from 2007 to 2013 were included. The final study population was 133 patients. The impact of external fixation pin location (relative to the definitive implant location) on postoperative infection was measured.

Results: As a continuous variable, the distance between the closest pin site and plate was 62.1 $\pm$ 44.1 mm in the infected cohort and 62.2 $\pm$ 49.7 mm in the non-infected cohort ($p = 0.991$). Further analysis was performed by grouping the distances into less than 0 mm (i.e. overlapping), >0.0 – 25.0 mm, >25.0 – 50.0 mm, >50.0 – 75.0 mm, >75.0 – 100.0 mm, and >100.0 mm of separation. No significant differences were noted with regards to the risk for infection.

Conclusions: Staged care has been shown to be an effective treatment strategy for AO/OTA type 43 fractures. There are many variables to consider when placing an external fixator construct. In this cohort, pin site distance from definitive implant location was not associated with an increase in deep infections.

Level of evidence: Level III.

Introduction

Despite advances in technique and implant technology, high-energy fractures of the distal tibial pilon remain a difficult problem for orthopaedic traumatologists. Due to a combination of soft tissue injury, articular disruption, and metaphyseal comminution, these fractures are predisposed to complications and poor outcomes, including deep infection.

The predominant treatment algorithm for these fractures has evolved over time. Although Ruedi initially showed promising results in a group of skiers treated with immediate open reduction and internal fixation (ORIF) [1], similar results have not been reproducible in the United States, possibly due to higher energy mechanisms and differences in patient demographics. In 1993, Teeny and Wiss reported on a group of 60 Ruedi type III fractures caused by falls and motor vehicle crashes, treated with early internal fixation [2]. The deep infection rate in this group was 37%, a significant difference from the low infection rate experienced in the Swiss population treated by Reudi. In 1979, Kellam et al described the intra-operative use of a spanning traction device as a way of over-distracting the fracture and allowing improved visualization. In the early 1990s, it became popular to place similar external fixator traction devices as a means of temporarily splinting severely comminuted pilon fractures [3–5].

Since the early 1990s the mainstay of treatment of these fractures has been application of an external fixator device as a temporizing measure followed by definitive fixation in a delayed fashion [6]. The goal of delayed treatment is to allow soft tissue swelling to dissipate which decreases the risk of wound dehiscence and skin necrosis while the external fixator maintains length of the fracture. Use of this technique has demonstrated decreased infection rates [7,8]. Patterson and Cole reported on a group of 22 Arbeitsgemeinschaft fur Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) type 43 C3 fractures treated via delayed fixation. In this group there were no deep tissue infections and all but one fracture healed with a “good” outcome [7,8].

Pin site infection is the most common complication of external fixation, occurring up to 63% of the time [9–13]. Despite the high

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prevalence of infected pin sites, major complications are relatively rare and most often associated with use of external fixation as definitive fixation or in limb lengthening situations in which the device is left in place for an extended period of time [14]. Nevertheless, pin sites are a potential nidus for bacterial colonization and inoculation of deep tissues, leading several authors to recommend that pin sites be placed beyond the zone of anticipated internal fixation [15,16]. Literature has been unclear regarding the importance of pin site locations as they relate to the incidence of deep infection when external fixation is employed as a temporizing measure. Two groups have studied this question explicitly with differing findings. Laible et al found no correlation between pin site distance and definitive implants in a group of 79 tibial plateau fractures temporarily stabilized with an external fixator [17]. In contrast, Shah et al evaluated a series of tibial plateau and tibial pilon fractures treated with a 2-stage protocol in hopes of explaining the importance of pin site distance. The combined plateau and pilon group demonstrated a statistically significant increased rate of deep infections in the overlapping group [18]. However, when examined individually, the pilon group failed to show a difference in infection rate. Furthermore, their cohort was characterized as either “overlapping” or “nonoverlapping.” This binary classification does not provide any insight into risk imparted by absolute distance of the pin site from definitive implants.

The aim of the current study was to examine a large cohort of AO/OTA type 43 fractures to determine whether external fixator pin-site distance from definitive implants impacts the risk of deep infection [26]. A secondary goal of the study was to identify other potential risk factors for deep infection after definitive fixation.

Materials and methods

After institutional review board approval, a retrospective chart review was performed on 178 patients who underwent open reduction and internal fixation (ORIF) of a distal tibial fracture as defined by a type 43 fracture pattern by the AO/OTA classification from 2007 to 2013 by four fellowship-trained foot and ankle or trauma specialists at a single level 1 trauma center.

The inclusion criteria were: (1) all sub-types of the 43 AO/OTA classification (2) age 15–65 years old. Patients were excluded if (1) no external fixation was placed prior to ORIF (2) postoperative ORIF radiographs did not show the external fixation pin holes and thus no measurements of pin-plate separation were possible (3) no postoperative clinical follow up of at least 6 months. Of the 178 patients who met inclusion criteria, 15 patients were excluded for not having prior external fixation placed, 17 for not having adequate postoperative radiographs, and 13 for having inadequate clinical follow-up, resulting in a final study population of 133 patients.

The treatment protocol was at the discretion of the treating surgeon. Twelve percent (16/133) underwent placement of external fixation at an outside facility not associated with our health system. In these cases, the traumatologist managing the definitive fixation had no input into the design of the external fixator or pin placement. In each situation, a staged protocol was followed. The average interval from the time of external fixator placement to definitive fixation was 18 days. Intravenous antibiotics were administered upon admission for all open fractures and continued until final wound closure. At the time of definitive fixation, intravenous antibiotics were given within 1 h of incision and for an additional 24 h for closed wounds. At the time of definitive fixation, pin sites were debrided and irrigated. The skin was not closed and a sterile bandage was placed which was left for approximately two days.

A chart review was performed to collect patient and injury demographics including diagnosis of diabetes mellitus, tobacco use, body mass index (BMI), gender, and the presence of an open fracture. Operative details were also recorded including tourniquet use, fibular ORIF, and time interval between external fixation and definitive ORIF. Initial injury radiographs, computed tomography (CT) scans, and postoperative ORIF radiographs were reviewed by two orthopaedic residents. To evaluate for pin-plate separation, measurements were made using Carestream PACS (Centricity; GE, Waukeshaw, WI), the hospital’s medical imaging database, in which magnification was accounted for by measurement tools within the software. Values from the tip of the plate to the closest tibial external fixation pin site were recorded to the closest 1/10th of a millimeter (Fig. 1). These values were measured twice by each resident, and the average of the four values were included in the analysis. Inter- and intra-observer reliability values were not calculated as this was not felt to be necessary due to the simplicity of the measurement. Each fracture was classified according to the AO/OTA classification. If there was disagreement regarding the classification, then the images were reviewed together, and consensus was reached. The reviewers were blinded to the deep infection status of the patients.

A postoperative infection was defined as a deep infection requiring irrigation and debridement similar to other published reports on this topic [17–19]. Superficial cellulitis which was treated only with intravenous or oral antibiotics was not included as an infection for this study.

A biostatistician completed the statistical analysis of the collected data using SPSS (SPSS, version 22, Chicago, IL). All potential risk factors which might influence the rate of deep infection were evaluated for a univariate association using independent-samples t tests for continuous variables and chi-square calculation for discrete variables when possible. When the sample size was insufficient to support a chi-square calculation then a Fisher exact test was performed, and p-value recorded for a two-tailed test with clinical significance defined as $p < 0.05$. The number of days between external fixator placement and definitive fixation was evaluated as both a dichotomous variable (less than or equal to 7 days) as well as a continuous variable. Pin site-plate separation was evaluated as a nominal variable as discrete groups of separation ($\leq$0, >0.0 – 25.0 mm, >25.0 – 50.0 mm, >50.0 – 75.0 mm, >75.0 – 100.0 mm, and >100.0 mm) using a Chi-square goodness of fit test to determine whether the observed sample differed significantly from expected values. Additional testing of pin site-plate separation as a continuous variable was performed with student’s t-test.

Results

There were 22 deep infections out of 133 patients (16.5%) which underwent irrigation and debridement (Table 1). The cohort of 133 patients included 43 females (32.3%) with an average age of 43.8 $\pm$ 14.7 years. The mechanisms of injury were motor vehicle accidents in 87 patients (65.4%), motorcycle accidents in 10 patients (7.5%), and falls from height in 36 patients (27.0%). Fifty-three (39.8%) of the fractures were open and underwent initial irrigation and debridement at the time of external fixation application. Fractures were classified as type A in 9 (6.77%) cases, type B in 17 (12.87%) cases, and type C in 107 (77.4%) cases. The average separation between the closest external fixation pin and the plate was 62.2 $\pm$ 48.5 mm (mm), and 8 (6.0%) plates overlapped with the closest pin site. One-hundred eight of 133 (81%) pilon fractures were accompanied by a fracture of the fibula. Of the 108 fibula fractures, 92 (85.0%) underwent open reduction and internal fixation; 12 (13.0%) of these underwent ORIF at the time of external fixation placement, and the remaining 80 (86.9%) underwent ORIF at the

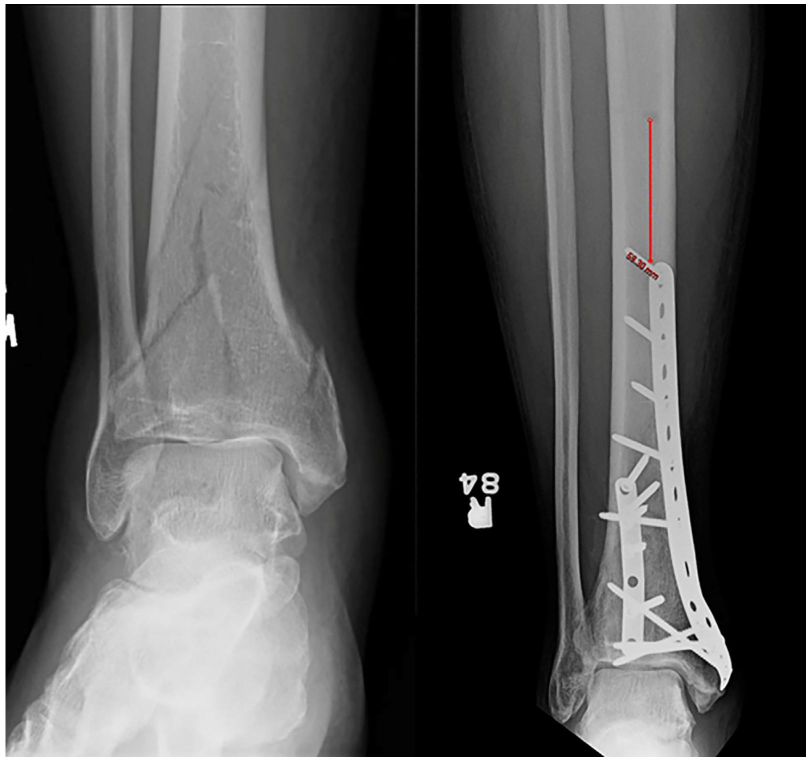

Fig. 1. Anteroposterior radiographs from the initial injury (right) and after definitive fixation (left) of a distal tibia fracture. The measurement was made from the proximal aspect of the plate to the closest external fixator pin site.

Table 1
Risk factors associated with development of a deep infection.

Risk Factor			Infection group (N = 22)	No infection group (N = 111)	Odds ratio (95% confidence interval)	p-value
Male			16 (72.7)	74 (66.7)	1.33 (0.48-3.68)	0.579
Age (years)*			42.9 ± 13.4	43.9 ± 15.0		0.787
BMI (kg/m2)*			31.3 ± 9.5	29.2 ± 6.3		0.292
Comorbidities						
	Diabetes		2 (9.1)	10 (9.0)	1.01 (0.20-4.96)	1.000
	Tobacco		10 (45.5)	49 (44.1)	1.05 (0.42-2.64)	0.910
	HTN		3 (13.6)	30 (27)	0.43 (0.12-1.54)	0.184
Tourniquet duration (minutes)			113.9 ± 34.3	106.6 ± 37.6		0.534
OSH external fixation placement			1 (4.5)	15 (13.5)	0.30 (0.03-2.43)	0.31
Open fracture			18 (81.8)	35 (31.5)	9.77 (3.07-31.01)	<0.0001^
Pin site infection			0 (0.0)	7 (6.3)	0 (0-∞)	0.361
Interval Between Ex-Fix and ORIF						
	≤ 7 days		4 (18.2)	18 (16.2)	1.14 (0.34-3.79)	1.000
	> 7 days		18 (81.8)	93 (83.8)	(Reference)	–
Pin-plate separation*			62.1 ± 44.1	62.2 ± 49.7		0.991
Pin site-plate separation groups						
	≤ 0 mm		2 (9.1)	6 (5.4)		0.580
	0.01 - 25 mm		3 (13.6)	19 (17.1)		
	26 - 50 mm		2 (9.1)	29 (26.1)		
	51 - 75 mm		4 (18.2)	18 (16.2)		
	76 - 100 mm		3 (13.6)	13 (11.7)		
	> 100 mm		8 (36.4)	26 (23.4)		
AO/OTA Fracture Type						
	A		0 (0.0)	9 (8.1)		0.297
	B		2 (9.1)	15 (13.5)		
	C		20 (90.9)	87 (78.4)		
		C1	0 (0.0)	3 (2.7)		0.694
		C2	4 (18.2)	18 (16.2)		
		C3	16 (72.7)	66 (59.5)		
Tourniquet Use			12 (54.5)	61 (55.0)	0.98 (0.39-2.46)	0.972
Fibula ORIF			21 (95.5)	71 (64.0)	11.83 (1.53-91.27)	0.003^

* Indicates continuous variables presented as mean ± SD; ^denotes statistical significance at <0.05.

time of definitive fixation of the pilon fracture. The average tourniquet time was 109.0 ± 36 min with tourniquet use in 73 (54.9%) of the cases.

When examining the impact of external fixation pin location on postoperative infection, there did not appear to be any contribution. As a continuous variable, the distance between the closest pin site and plate was 62.1 ± 44.1 mm in the infected cohort and 62.2 ± 49.7% in the non-infected cohort (p = 0.991). Further analysis was performed by grouping the distances into less than 0 mm (i.e. overlapping), >0.0 – 25.0 mm, >25.0 – 50.0 mm, >50.0 – 75.0 mm, >75.0 – 100.0 mm, and >100.0 mm of separation. No significant differences were noted with regards to the risk for infection. Additionally, there was no significant difference in the infection risk between fractures treated with provisional external fixation at an outside facility as compared to those treated at our institution (p = 0.238). Other factors which were not found to impact infection rate included the presence of pin-site infection treated with oral antibiotics (p = 0.226), or definitive fixation performed less than seven days after external fixation (p = 0.821).

81.8% (18/22) of patients with a postoperative infection had sustained an open fracture, which was found to be a significant risk factor (p < 0.0001). Additionally, fibular ORIF at the time of definitive tibial fixation was also found to be a significant risk factor for an infection. 21/22 (95.5%) of postoperative infections had undergone fibular fixation compared to 71/111 (64.0%) of cases which did not lead to future infection (p = 0.003). Neither fracture classification nor tourniquet use affected the infection risk, and patient age, gender, and medical comorbidities also did not reach significance.

Discussion

There is debate in the literature whether the distance between external fixator pin site and location of definitive fixation is a risk factor for post-operative infection. The primary objective of this study was to determine whether that distance was significant in pilon fractures treated with a staged protocol (AO/OTA type 43). The deep infection rate in the current study was 16.5%, and the published rate varies from 2% to 37% depending on the series. The infection rate documented within this cohort is comparable to recently-published rates in similar studies which has trended around 15% [18,20]. The proximity of the external fixation pins to the definitive internal implants was not identified as a risk factor for a postoperative infection in this cohort.

Shah and colleagues reported on a group of high-energy tibial plateau and pilon fractures treated at their institution. While they were able to show a relationship between infection rate and pin-site overlap, their statistical analyses were limited to the combination of plateau and pilon fractures; no analysis was performed for the individual fracture types. While both are prone to complications, tibial plateau and tibial pilon fractures are unique entities which require unique considerations in management. Combining these as a single cohort fails to account for this. Additionally, their analysis of the effect of pin site distance was limited to a binary classification as either "overlapping" or "nonoverlapping." By doing this, pin sites located even a few millimeters from definitive plate fixation were classified as "nonoverlapping," which may obscure differences in infection rates that might exist between pins located close to as opposed to far from definitive fixation. Of note, the rate of overlap in Shah's cohort was 17% as compared to only a 6% rate of pin/plate overlap in our cohort.

There are many variables to consider when developing external fixator constructs. A treating surgeon must use their discretion to weigh these variables. Lengthening the construct, spanning a joint, and placing pins in metaphyseal bone all may have negative impacts on the construct. With the current data available in the literature, it is difficult to weigh the risk of infection and then make quantitative decisions—if it lowers the risk of infection to not overlap a pin site with the definitive implants, how far away should it be? Ultimately, many variables are considered on a case by case basis based on the literature and treating surgeon's experience. In this cohort, the pin site distance to definitive plate location did not affect the deep infection rate.

In addition to the pin site to plate distance, several other possible risk factors for infection were investigated (Table 1). In this cohort, open fractures and the presence of fibular ORIF at the time of definitive fixation were found to be statistically significant risk factors for the presence of deep infection. Open fracture is a well-documented risk factor for deep infection in pilon fractures and was confirmed as such within this cohort of patients. In 2015 Molina et al published on a cohort of 500 pilon fractures and found open fracture to be a risk factor after multivariate regression analysis controlled for fracture type [20]. It is therefore worth reinforcing that open fracture remains a risk factor in multiple studies.

The influence of fibular ORIF was a particularly interesting finding as this has not been clearly established as a risk factor in the literature. One advantage of fibular stabilization is the restoration of fibular length which can be used as a guide to help anatomically reduce the tibia [21,22,23,24]. A disadvantage of fibular fixation is the second incision necessary for fixation and the potential complications of that incision. To evaluate the influence of fibular fixation on complications and quality of articular reduction, Williams et al evaluated a cohort of pilon fractures with associated fibula fractures treated definitively in an external fixator with limited percutaneous fixation of select metaphyseal fragments. Patients undergoing primary fibular ORIF showed a significantly higher complication rate related to fibular fixation, including a 23% rate of deep infection, but with a trend toward improved angular alignment and articular reduction as compared to a demographically similar group who did not undergo fibular fixation. This led the authors to suggest that surgeons use discretion when deciding to use fibular fixation and to only pursue it if the advantages of length restoration outweigh the risks [25]. One factor which might contribute to the higher infection rate seen in the fibular ORIF group is the severity of soft tissue injury which might not be accounted for in the OTA classification scheme. Within the infected group, 16 of 21 (77%) fractures undergoing fibular ORIF were characterized as OTA type C3 as compared to 39 of 71 (55%) non-infected pilons with fibular ORIF. While not statistically significant this trend suggests that infected pilons with fibular ORIF tended to be higher energy fractures. The number of cases in our cohort limited the ability to perform a multivariate analysis which might help to better characterize the significance of fibular ORIF in contributing to deep infections. It is possible that the presence of fibular ORIF may only be serving as a proxy to suggest a higher energy fracture with more comminution and greater soft tissue injury.

There are several limitations of this study. Any retrospective study is limited based on the available data in the medical record; it is possible that not all deep infections were captured. The relatively modest number of patients limited the ability to perform a multivariate analysis. One deficiency in our data that might provide additional insight is total operative time, which was not available for the majority of the cohort. Although presence of an open fracture was noted, the soft tissue injury was not further classified. Additionally, surgical approach was not assessed. Finally, the independent variable of the study was the presence of a deep infection. This was defined as the need to return to the operating room for a formal irrigation and debridement. In this cohort, this decision was based on individual surgeon discretion.

Conclusion

Pilon fractures remain one of the most difficult fracture types to treat, often with high complication rates. Staged care with initial external fixation followed by delayed internal fixation has been shown to be an effective treatment strategy for AO/OTA type 43 fractures. There are many variables to consider when placing an external fixator construct. In this cohort, pin site distance from definitive implant location was not associated with an increase in deep infections. Ultimately, treating surgeons will need to use their judgement to determine the appropriate external fixation construct. Subsequent research may help inform these decisions.

Conflict of interest statements

No other authors had conflicts of interest to report.

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