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Is the proximity of external fixator pins to eventual definitive fixation implants related to the risk of deep infection in the staged management of tibial pilon fractures?

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ABSTRACT

Introduction: In the staged management of tibial pilon fractures, overlap between definitive internal fixation and external fixation pin sites has been investigated as a risk factor for infection with equivocal conclusions. Our aim was to determine if overlap or proximity of definitive internal fixation to external fixation pin sites influences the risk of deep infection.
Patients and methods: We reviewed 280 AO/OTA 43B or 43C type distal tibia fractures in 277 patients at two level-one trauma centers. Patients underwent staged management using early temporizing external fixation followed by definitive open reduction and plate fixation. Primary outcome was the association between pin site overlap and the development of deep infection. Secondary outcome was the relationship between development of deep infection and the distance from pin site to definitive fixation.
Results: The average duration between external fixation and definitive internal fixation was 14 days. 24% of fractures developed deep infection requiring surgical intervention. There was no association between pin site overlap and the development of deep infection ($p = 0.18$). There was no relationship between infection and the distance between proximal plate extent and pin site ($p = 0.13$).
Discussion: We identified no association between pin site overlap and the development of deep infection. We suggest that temporizing external fixation pins should be placed so as to obtain optimal stability of the construct with lesser emphasis on aiming to be absolutely outside the zone of future fixation.
Level of evidence: Level III Therapeutic Retrospective Comparative study.

Introduction

Treatment of fractures of the distal tibial plafond remains one of the more challenging problems facing orthopaedic trauma surgeons. The treatment of these fractures has evolved over recent decades. Rüedi and Allgöwer demonstrated improved clinical outcomes with early primary open reduction internal fixation in the 1970s [1]. However, their series of pilon fractures were generally lower energy twisting injuries in skiers. High-energy pilon fractures resulting from motor vehicle/motorcycle collisions or crushing injuries can result in significant wound complications and development of infection. Subsequent research has indicated a decreased rate of soft tissue complications with a two-staged protocol [2,3]. This protocol consists of initial fracture stabilization by spanning external fixation, then followed by open reduction and internal fixation once soft tissues allow.

An issue of the two-staged protocol is the creation of pin-tracts in the tibia shaft proximal to the zone of injury. These pin tracts create a communication between deep tissues and the outside environment with resultant risk of a colonized deep wound within the surgical field.

Colonized pin tracts are a recognized concern for deep infection in cases where temporizing external fixation is being definitively replaced with intramedullary nailing [4,5], however, the impact on plate osteosynthesis is less clear. A recent study of a series of tibial plateau and pilon fractures indicated that the risk of infection increased when definitive plate fixation overlapped with external fixator pin sites [6]. An earlier study examining the relationship of

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pin site overlap in staged treatment of tibial plateau fractures alone suggested no increased risk associated with pin site overlap [7].

In our opinion, understanding the relationship between pin site location and definitive plate fixation is important for two reasons. The first is that the stability of temporizing external fixation is affected by the distance of the tibial pin sites to the fracture, thus attempts to keep pins well clear of planned definitive fixation may compromise stability. Secondly, avoidance of plate overlap with pin sites may lead surgeons to bias towards shorter constructs, possibly compromising definitive stability [8].

Our goal was to evaluate whether pin site overlap did indeed result in higher rates of infection, and if so, to determine whether there was length-dependent relationship between pin sites location and definitive fixation influencing the risk of infection. We hypothesize that there is not an association between the development of deep surgical infection and overlap of the definitive surgical construct with external fixator pin tract sites.

Methods

Study design

A retrospective cohort study, approved by the institutional review board, was performed. We identified potential cases using two methods – first, we queried our institutions' orthopaedic trauma billing database to identify all patients who underwent operative treatment for AO/OTA type 43B and 43C pilon fractures at two American College of Surgeons (ACS) level-1 trauma centers from January 2001 to December 2015. We then utilized the Research Patient Data Registry (RPDR) at our institution, which can identify patients with specific demographics, diagnoses, laboratory tests, medications, molecular medicine, health history, microbiology, procedures, providers, and/or transfusion services. The RPDR was queried for patients aged 18 years or older who underwent open reduction internal fixation for a pilon fracture (CPT codes 27826, 27827, 27828) at any time during the period from January 2001 to December 2015. Images were reviewed by a trauma fellow or trauma-trained attending surgeon to confirm eligibility of the fracture based on the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification [9]. Fractures deemed mainly tibial shaft with extension into the tibial plafond and trimalleolar ankle fractures were excluded. Where there was conflict in classification, group discussion was used to reach consensus. Patient records were then evaluated to identify cases where patients underwent temporizing external fixation followed by definitive internal fixation. In each case, removal of external fixation and definitive plate osteosynthesis were performed in a single setting – there were no documented cases of staged external fixator removal and definitive fixation.

Outcome and explanatory variables

Demographic, injury, fracture, surgery, and comorbidity data were extracted from the medical records. BMI was collected only when reported within a range of six months prior to or after the fixation. Smoking was classified positive when a patient was smoking at the time of surgery or quit smoking less than two weeks prior to the operative intervention. Radiographs were reviewed to establish whether pin site ghost tracts were overlapped by definitive internal fixation. The length of overlap was measured. In cases where there was no overlap, the distance between the proximal extent of internal fixation and the distal-most pin ghost tract was documented.

Deep infection was defined as requiring one or more subsequent surgical debridement interventions, with or without positive cultures. We categorized cases performed for symptomatic hardware removal but yielding positive cultures as positive for deep infection.

Statistical analyses

Continuous variables are presented as medians with interquartile ranges (IQR), categorical and ordinal variables as absolute numbers with percentages. In univariate analyses, the association between development of deep infection and our explanatory variables was determined using Chi-squared and Mann-Whitney U tests as appropriate. Kaplan-Meier survival estimates were calculated to investigate the effects of pin site overlap on the development of deep infection, considering the time to occurrence of this complication and follow-up duration. The log rank test was used to compare the survival curves. Multiple cox proportional hazards regression analysis was performed to evaluate the association between risk factors and post-operative deep infection on a time-to-event basis. All statistical analyses were performed using STATA® 13.1 (StataCorp LP, TX, USA). A p-value of <0.05 was considered statistically significant.

Results

We identified 280 AO/OTA 43B or 43C type fractures (54 (19%) resp. 226 (81%)) in 277 patients that underwent initial stabilization using spanning external fixation followed by definitive surgical intervention. The majority of patients (70%) were male, and median age was 46 years. Patients waited a median duration of 15 days (range 8–20) between primary stabilization and definitive fixation. Additional demographic and injury characteristics are presented in Table 1.

Of the patients analyzed, 20% (55/277) exhibited pin site tracts that were overlapped by definitive internal fixation. Median distance between pin site and proximal definitive implant was 41 mm (IQR 7–72 mm; range -66–137 mm) for the complete cohort. For patients without overlap, median distance was 52 mm (IQR 28–80 mm; range 2–137 mm). 24% (67/277) of patients developed a deep infection requiring surgical intervention. 17 infections occurred in the group where definitive ORIF construct overlapped the pin tract sites (17/55,31%); and 50 infections occurred in the group without overlap (50/175, 29%). There was no univariate association between pin site overlap and the development of deep infection ($p = 0.18$) (Table 2). There was no relationship between infection and the distance between proximal plate extent and pin site ($p = 0.13$) (Table 2).

An analysis of the relationship between duration of external fixation and the development of deep infection demonstrated that there was not an association between number of days in the external fixator and eventual infection ($p = 0.64$) (Table 3).

Kaplan-Meier analysis (Fig. 1) demonstrated no difference in time to deep infection between patients with and without overlap of the pin sites with definitive implants ($p = 0.30$). When controlling for age, sex, diabetes, smoking status, fracture type, and open fracture in multiple cox proportional hazards regression analysis, pin site overlap was still not associated with deep infection ($p = 0.71$) (Table 3).

Discussion

Currently, the influence of definitive fixation overlapping with temporizing external fixation pin sites on the development of deep infection in pilon fractures is poorly defined. The available literature examining the issue of pin site overlap as a whole is inconsistent. In a combined cohort of pilon and plateau fractures, Shah et al. found that there was a significant influence of pin site

Table 1
Demographic Characteristics.

	Entire Cohort (n = 277)	Patients with ex-fix overlap (n = 54)	Patients without ex-fix overlap (n = 223)	p-value
Age				
Median (IQR) years	46 (36-55)	44 (35-54.5)	47 (36-55)	p = 0.68
BMI				
Mean (IQR)	27.5 (24.2-31.3)	26.3 (23.4-29.3)	27.8 (24.4-31.6)	p = 0.59
Time between primary stabilization and definitive fixation				
Median (IQR) days (n=280 fractures)	15 (8-20)	14 (6-20)	15 (8-21)	p = 0.60
Sex				
Male (%)	195 (70%)	38 (70%)	157 (70%)	p= 0.99
Female (%)	82 (30%)	16 (30%)	66 (30%)	
Smoking				
Yes (%)	75 (27%)	14 (27%)	61 (28%)	p= 0.87
No (%)	195 (70%)	38 (73%)	157 (72%)	
Unknown	7 (3%)			
Diabetes				
Yes (%)	18 (6%)	5 (9%)	13 (6%)	p= 0.35
No (%)	259 (93%)	49 (91%)	210 (94%)	
Charlson Comorbidity Index				
0	152 (55%)	32 (59%)	120 (54%)	p= 0.40
1	69 (25%)	13 (24%)	56 (25%)	
2	33 (12%)	3 (6%)	30 (14%)	
3	13 (5%)	4 (7%)	9 (4%)	
4	5 (2%)	2 (4%)	3 (1%)	
5	4 (1%)		4 (2%)	
8	1 (<1%)		1 (<1%)	
Mechanism of injury				
Fall (%)	174 (62%)	31 (56%)	143 (64%)	p= 0.66
Motor vehicle crash (%)	65 (23 %)	14 (26%)	51 (23%)	
Motorcycle crash (%)	17 (6%)	5 (9%)	12 (5%)	
Other (%)	24 (9%)	5 (9%)	19 (8%)	
AO classification				
43B (%)	54 (19%)	2 (4%)	52 (23%)	p= 0.001*
43C (%)	226 (81%)	53 (96%)	173 (77%)	
Fracture side				
Left (%)	141 (50%)	25 (46%)	116 (52%)	p= 0.417
Right (%) (n=280 fractures)	149 (50%)	30 (54%)	109 (48%)	
Open fracture				
Yes (%)	91 (33%)	19 (35%)	72 (32%)	p= 0.718
No (%) (n=280 fractures)	189 (67%)	36 (65%)	153 (68%)	

overlap on the development of deep infection [6]. They reported a 24% rate of deep infection in cases of overlap, compared to just 10% in cases without overlap (p = 0.033). In contrast, Laible et al. found that there was no influence of pin site infection, or distance from definitive fixation to pin sites on the risk of developing deep infection in the staged fixation of tibial plateau fractures [7].

The inconsistencies seen in the literature are perhaps not surprising when considering that even in cases of intramedullary nailing following external fixation, there is no clear increased risk of infection, despite mandatory communication between pin sites and definitive fixation. Previous studies have suggested a deep infection rate anywhere between 0% and 67% in staged management of both open and closed lower extremity shaft fractures using temporizing external fixation followed by intramedullary nailing [4,5,10–13]. A recent systematic review suggested a relatively low overall infection rate of 3.6% in femur fractures, and 9% of tibia fractures treated with staged external fixation followed by intramedullary nailing. Prolonged duration of external fixation ($\geq$ 28 days) was identified as a probable risk factor for deep infection [4].

Duration of external fixation could be one factor contributing to the differing results seen in the three studies examining pin site overlap after temporizing external fixation. In this cohort the median duration of external fixation was 15 days (range 8–20) Labile et al. similarly found no relationship between pin site overlap and development of deep infecton in the staged management of high-energy tibial plateau fractures. Their mean duration of external fixation was only 10 days (range 2–28). In contrast, the mean duration of external fixation prior to definitive open fixation in the cohort examined by Shah et al. was 20 days (range 2–156). It is possible that the differing results can be attributed to the longer average duration of external fixation in the solitary study that did identify a relationship between pin site overlap and the development of infection. This certainly correlates with the existing evidence for the rate of deep infection in intramedullary nailing after external fixation.

In this cohort, we could not identify a relationship between duration of external fixation and the development of deep infection. However, this could simply be due to a relatively low event rate, and this study not being sufficiently powered to identify or rule out this relationship.

Another factor known to influence the development of soft tissue complications in pilon fractures is the severity of initial injury [13–15]. The previous study identifying a relationship between pin site overlap and the development of pin site infection included only complete articular (C type) injuries [6]. The current study included both partial (B type) and complete (C type) articular injuries. It is possible that the higher rate of deep infection seen in the previous study could be attributed to energy of the initial injury, rather than pin site overlap.

Standard protocol in staged fixation of pilon fractures includes removal of external fixation pins, followed by a thorough debridement of pin sites before proceeding with definitive fixation. Animal models would suggest that debridement of pin sites is

Table 2
Univariate analyses.

	Deep infection (n = 67)	
		p-value
Age		
Median (IQR) years	43 (36 - 54)	0.803
BMI		
Mean (IQR)	28.9 (24.2 - 32.8)	0.406
Charlson Comorbidity Index		0.923
0	38 (57%)	
1	13 (19%)	
2	10 (15%)	
3	3 (5%)	
4	1 (2%)	
5	2 (3%)	
Time between primary stabilization and definitive fixation		
Median (IQR) days	15 (7 - 20)	0.575
Distance		
Median (IQR) mm	28 (-2 – 60)	0.046
Sex		
Male (%)	54 (81%)	0.035
Female (%)	13 (19%)	
Smoking		
Yes (%)	23 (63%)	0.125
No (%)	42 (34%)	
Unknown (%)	2 (3%)	
Diabetes		0.339
Yes (%)	6 (9%)	
No (%)	61 (91%)	
AO classification		0.081
43B (%)	8 (12%)	
43C (%)	59 (88%)	
Open fracture		0.335
Yes (%)	25 (37%)	
No (%)	42 (63%)	
Overlap		0.176
Yes (%)	17 (25%)	
No (%)	50 (75%)	

Table 3
Multiple cox proportional hazards regression for outcome of time to infection.

Variable	Hazard Ratio (95% Confidence Interval)	p-value
Age	• (0.98 – 1.02)	0.97
Sex		0.052
Female	Ref	
Male	1.83 (0.99 – 3.38)	
Open Fracture		0.84
Closed	Ref	
Open	1.06 (0.62 – 1.78)	
Diabetes		0.28
No	Ref	
Yes	1.62 (0.68 – 3.84)	
Smoking		0.07
Non-smoker	Ref	
Smoker	1.65 (0.98 – 2.81)	
AO Type		0.24
43-B	Ref	
43-C	1.58 (0.74 – 3.37)	
Overlap pin sites and definitive ORIF		0.71
No	Ref	
Yes	1.12 (0.62 – 2.01)	
Duration in external fixator	1.01 (0.98 – 1.04)	0.64

extremely effective in reducing the development of deep infection for staged intramedullary nailing after temporizing external fixation [16]. It is possible that the thorough debridement of a pin site can reduce risk of deep infection to baseline even in cases of pin site overlap, thus negating any associated risk.

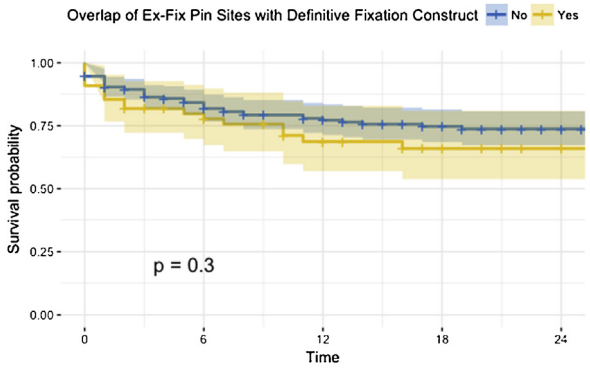

Fig. 1. Kaplan Meier Analysis with Log Rank Test. No significant difference in survival is seen between overlap group and non-overlap group (p = 0.30).

Defining the relationship between external fixator pin sites from temporizing fixation and definitive internal fixation is important for several reasons. Initial stability achieved with the external fixator is influenced by the working length of the construct. Increasing the distance between the proximal and distal points of fixation increases the working length, and decreases the stability that can be achieved at the fracture site. Attempts to maximize this distance out of fear of the risk of pin site overlap with definitive fixation may compromise initial stability of the external fixator construct. Similarly, avoidance of pin site overlap could theoretically lead a surgeon to compromise on plate length during the definitive procedure, resulting in sub-optimal fixation in the proximal segment or a short working length of the final construct that concentrates stress at the fracture site, risking plate fracture or nonunion [8].

To the best of our knowledge, the current study is the largest cohort to date examining the influence of definitive fixation overlapping with temporizing external fixation pin sites on the development of deep infection. Further, it is the only study that focuses solely on tibial pilon fractures, of which the majority are treated with two-staged delayed plate osteosynthesis. In this setting, we were unable to identify a significant influence of pin site overlap on the development of deep infection (p = 0.18), nor were we able to identify any relationship between the distance from definitive fixation to pin sites in cases where there was no overlap (p = 0.13).

The overall reported deep infection rate of 24% in this study is slightly higher than what has been previously reported [2,3,6,7,17]. One possible reason for this is the inclusion of patients who had positive deep cultures when symptomatic hardware was removed. Many of these cases may otherwise appear indolent, with symptoms attributed to hardware prominence, and may not always be identified as cases of deep infection in other series.

Limitations of this study include its retrospective and observational nature. Selection bias in treatment may exist where a surgeon may have been more likely to be careful to distance their external fixator pin sites for injuries that had more soft-tissue injury or higher perceived infection risk. Additionally, the time period of the study spans a significant period of time over which surgical techniques and technology have continued to evolve.

Conclusion

Understanding the relationship between infection risk and overlap of definitive fixation with pin sites from temporizing external fixation is an important factor in deciding on initial and definitive constructs when treating tibial pilon fractures. The evidence presented here shows no association between overlap of the definitive construct with pin sites and the risk of developing deep infection.

When treating these injuries in a staged protocol, initial external fixation should be applied in a manner that respects local soft tissue injury, and provides for adequate stabilization. We were unable to identify any clear association between the duration of external fixation and the development of deep infection in this cohort. However, limiting the duration of external fixation to the minimum required time to achieve acceptable soft tissue conditions, and performing a thorough debridement of pin sites are known to reduce deep infection after temporizing external fixation and should be employed routinely. Definitive fixation should be appropriate for the goals of stabilization as dictated by the fracture type. Based on our study results, construct length should not be compromised for the sake of avoiding pin site overlap.

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Declaration of Competing Interest

The authors report that they have no conflicts of interest.

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