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Original Article

Course of treatment and rate of successful salvage following the diagnosis of deep infection in patients treated for pilon fractures (AO/OTA: 43)

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ABSTRACT

Background/Aims: The purpose of this study is to report the rate of successful salvage and describe typical treatment course for patients with infected pilon fractures.

Methods: This investigation was performed after gathering a Six-year retrospective database from a single academic trauma center including patients with pilon fractures diagnosed with post-operative deep infection.

Results: These include a rate of successful salvage in patients diagnosed with deep infection of 88.5% (46/52). Patients who were successfully salvaged required an average of 3.5 (± 2.3) procedures following diagnosis of infection, 2.5 (± 1.5) debridements and 1.1 (± 1.2) reconstructive procedures.

Conclusions: Considerable morbidity follows the diagnosis of deep infection, with 14% of patients ultimately treated with amputation. Successful salvage can be reliably anticipated in over 80% of patients, but typically requires more than 3 additional procedures.

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1. Introduction

Fractures of the tibial plafond and distal tibia resulting from an axial load to the foot are commonly referred to as pilon fractures. These are most commonly encountered following high energy mechanisms, such as motor vehicle collisions and falls from height.^{1–3}

The thin soft tissue envelope surrounding the ankle is susceptible to disruption with violent injury, resulting in open fracture wounds that commonly require secondary coverage procedures.^{4,5} Even when not associated with open wounds,

the closed soft tissue injury is often severe enough to alter surgical treatment in a variety of ways. The combination of these factors, in addition to the frequently seen osteo-articular comminution and tenuous vascular status, both chronic and acute, make pilon fractures some of the most complex injuries treated by orthopedic surgeons.

Even when treated appropriately, complications of infection and wound dehiscence are common. Several early reports of high complication rates associated with immediate operative treatment have led to modern management with a staged approach and increased emphasis on the associated soft tissue injury.^{6–12} Ovadia et al reported infection in 6% (9/145) of

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patients with pilon fractures and 3 of them subsequently had below-knee amputation.¹⁰ Wyrsh et al reported a 37% (7/19) risk of infection with three of those patients ultimately receiving a below-knee amputation, resulting in an amputation rate of 16% (3/19).¹³

Guidelines for treatment of these complications have not been established, and currently there exists wide variation in management. Measuring success associated with treatments for these complications is difficult, in part because large series of this patient population have not been studied. In addition, defining successful treatment is difficult due to a range of endpoints, including healed fracture, arthrodesis, or amputation, making true comparison difficult. We feel that an infected pilon is a limb threatening complication and we define successful salvage as clinical and radiographic evidence of bony union without ongoing signs of infection at last available follow up. For the purposes of the study amputation was considered failure although we acknowledge that this can be an acceptable functional end-point and in some cases a superior functional end-point.

No large series has been extensively studied in order to characterize the clinical pathways of limb salvage or amputation in patients who have developed a post-operative infection following definitive fixation of pilon fractures. The purpose of this study is to describe the course of treatment in operatively treated pilon fractures following the diagnosis of deep infection. This information will provide surgeons and patients with a framework to develop an individualized treatment plan and allow for an informed decision making process when presented with a diagnosis of deep infection in the setting of pilon fracture.

2. Patients and methods

Institutional review board approval was obtained for this study. All patients fifteen years or older treated definitively with ORIF of pilon fractures at our institution between January 1, 2006 and December 31, 2011 were identified from an institutional billing database. A search of Current Procedural Terminology (CPT) codes for pilon fractures (27827, 27826 and 27828) was performed using the above criteria. Radiographic confirmation of all injuries was performed by the study team using the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification of tibial pilon fractures (43A, 43B, 43C).¹⁴ Medical records were reviewed to identify patients diagnosed with deep infection during the course of their treatment. Identification of deep surgical site infection was performed utilizing the criteria defined by the Center for Disease and Control National Healthcare Surveillance Network.¹⁵ Effectively, all deep infections underwent surgical debridement.

Patient characteristics, including age, sex, race, body mass index (BMI), past medical history (hypertension, diabetes mellitus, substance abuse, psychiatric disorder), smoking status, and injury characteristics, including AO/OTA classification, open vs. closed, Gustilo and Anderson classification, the use of staged treatment, and days from injury to definitive fixation were recorded for each injury. Additionally, the total number of surgeries related to the study injury were

accounted for and further subdivided into number of operative procedures before and after the diagnosis of deep infection. The nature of the procedure performed after the diagnosis of deep infection was further classified as a debridement or reconstructive procedure. Reconstructive procedures consisted of soft tissue procedures (flap reconstruction or split thickness skin graft) and/or definitive bony procedures to include fusion and amputation. As described above, and for the purpose of this study, we defined successful salvage as clinical and radiographic evidence of bony union without ongoing signs of infection at last available follow up.

Descriptive statistics were calculated as the median with interquartile range (IQR) for continuous variables. For categorical variables, percentage (N) was presented. Characteristics of patients who were salvaged were compared to patients who underwent amputation using Wilcoxon rank sum test or Fisher's exact test. Variables of interest included: age, BMI, hypertension, open vs. closed fractures, diabetes, and tobacco use. By rule of thumb,¹⁶ the number of candidate risk factors which can be included in the proportional odds logistic regression was estimated roughly being $46/10 = 5$. Due to limited sample size and exploratory nature of the study, the association between outcome and each of the independent variables was assessed separately by descriptive statistics and plotting the data. To assess a greater number of candidate independent variables, the penalized maximum likelihood estimation was used which will properly weight (shrink; discount) the effects of candidate risk factors to correct for over fitting. All analyses were performed using R version 3.0.1 (www.r-project.org) and STATA 12.0 SE.

3. Results

A deep infection rate of 16.1% was identified, with a total of 57 deep infections in 355 operatively treated pilon fractures (142/355 (40%) open vs. 213/355 60% closed). In this infected cohort, the initial treatment used a staged protocol including external fixation and delayed open reduction internal fixation in 82.5% (47/57). The average follow-up time was 16.9 months (SD 8.5) with a 95% follow-up. See Table 1 for clinical and operative characteristics of this retrospective cohort.

Three of fifty-seven (5.2%) patients had not healed at time of final follow-up ($\bar{x} = 20.5$ months SD = 9.5) and were excluded from further analysis. Attempted salvage was performed in fifty-two of the fifty-four patients with the remaining two patients undergoing immediate amputation following diagnosis of deep infection. The rate of successful salvage in patients diagnosed with deep infection in the setting of operatively treated pilon fractures was 88.5% (46/52) with an average follow-up time of 16.6 months, SD = 8.3. Patients who were successfully salvaged required an average of 3.5 (± 2.3) total procedures following diagnosis of infection, 2.5 (± 1.5) debridements and 1.1 (± 1.2) reconstructive procedures (see Fig. 1). Average time from injury to endpoint of treatment was 17.1 months.

Six patients went on to amputation after attempted salvage, with a mean of 5.3 (± 2.3) total procedure post-infection procedures, 2.3 (± 1.4) debridements and 3 (± 1.3) reconstructions. Two patients underwent amputation without

Table 1 – Demographic and clinical characteristics of patients undergoing attempted salvage.

Characteristic	
Age	44.2 (SD 13.9)
Gender	
Female	14 (26.9%)
Male	38 (73.1%)
BMI	27.0 (SD 6.0)
Hypertension	
Yes	19 (36.5%)
No	33 (63.5%)
Diabetes mellitus	
Yes	9 (17.3%)
No	43 (82.7%)
Tobacco use	
Yes	28 (53.9%)
No	24 (46.1%)
Gustilo & Anderson classification	
Closed	21 (40.4%)
1	2 (3.9%)
2	14 (26.9%)
3	15 (28.8%)
AO classification	
A	5 (9.6%)
B	6 (11.5%)
C	41 (78.9%)
Staged with use of external fixator	
Yes	43 (82.7%)
No	9 (17.3%)
Average follow-up (months)	17.1 ± 8.5
Time from injury to definitive fixation (days)	22.6 ± 17.7
Time from definitive fixation to diagnosis of infection (days)	85.4 ± 60.6
Number of procedures before diagnosis of deep infection	2.3 ± 1.2
Number of procedures after diagnosis of deep infection	3.8 ± 2.4
Debridement procedures	2.4 ± 1.5
Reconstruction procedures	1.3 ± 1.4
Total number of procedures	6.1 ± 2.6
Reconstructive procedures include both soft tissue and bony procedures.

Fig. 1 – Frequency of total number of operative procedures among patients undergoing attempted salvage.

attempted salvage. There was no significant correlation between hypertension, diabetes, smoking, open injuries and obesity (BMI > 30.0) and number of required procedures or success of treatment. A sub-analysis of open fractures showed a salvage rate of 93.8% (15/16) in type I and II Gustilo-Anderson fractures vs. 66.7% (10/15) in type III fractures, $p = .06$.

The three most prevalent pathogens cultured were Methicillin Sensitive *Staphylococcus aureus* (MSSA) 19 cases (26.4%), *Enterobacter* 14 cases (19.4%) and Methicillin Resistant *Staphylococcus aureus* (MRSA) 8 cases (11.1%). See Table 2 for detailed distribution of identified pathogens in this study population. Infection was polymicrobial in 23.1% (12/52). Gram positive bacteria were identified in 25 cases, and gram negative identified in 11.

The number of procedures following the diagnosis of deep infection was not found to be associated with age, BMI, diagnosis of hypertension, open vs. closed injuries, AO classification, diagnosis of diabetes mellitus, and tobacco use (Table 3). Fig. 2 shows the number of operative procedures required for successful salvage when accounting for different patient clinical characteristics.

Exploration of an association between microbial culprit and number of post-infection debridements showed that deep infections caused by *S. aureus* (MRSA = 5 & MSSA = 16) required an average of 3.1 (SD = 1.6) debridements compared to deep infections caused by other pathogens ($n = 25$) requiring an average of 1.9 (SD = 1.1) debridements, $p = .004$. The total number of procedures, including procedures for debriding and of reconstructive nature, was also higher in this group, 5.1 (SD = 2.5) vs. 2.7 (SD = 1.7), $p = .013$. Similar results were found when comparing MSSA ($n = 16$) only vs. all other pathogens. Deep infections caused by other pathogens required a total of 1.9 (SD = 1.1) debridement procedures vs. 3.4 (SD = 1.6) debridements in the MSSA group. This was also reflected in the total number of procedures, including debridements and procedures of reconstructive nature, with the

Table 2 – Identified culture results.

Pathogen	N (%)
No culture growth	3 (4.2)
MRSA	8 (11.1)
MSSA	19 (26.4)
<i>Enterobacter spp.</i>	14 (19.4)
Coagulase Negative <i>Staphylococcus</i>	4 (5.5)
<i>Staphylococcus epidermidis</i>	1 (1.4)
<i>Pseudomonas spp.</i>	3 (4.2)
<i>Stenotrophomonas maltophilia</i>	2 (2.8)
<i>Diphtheria spp.</i>	1 (1.4)
<i>Streptococcus spp.</i>	5 (6.9)
<i>Enterococcus spp.</i>	4 (5.5)
<i>Haemophilus parainfluenzae</i>	1 (1.4)
<i>Candida albicans</i>	2 (2.8)
<i>Staphylococcus haemolyticus</i>	1 (1.4)
<i>Corynebacterium diphtheriae</i>	1 (1.4)
<i>Clostridium spp.</i>	1 (1.4)
<i>Serratia spp.</i>	1 (1.4)
<i>Aeromonas spp.</i>	1 (1.4)
Total	72 (100)

MSSA: Methicillin Sensitive *S. aureus*. MRSA: Methicillin Resistant *S. aureus*.

Table 3 – Penalized proportional odds model for debridements after diagnosis of deep infection.

Characteristic	Effect	95% CI	p-Value
Age	0.4	0.17–1.12	.09
BMI	1.0	0.46–1.94	.88
Diabetes mellitus	0.8	0.17–3.71	.77
Active smoker	0.6	0.14–2.28	.43
Hypertension	3.1	0.86–11.47	.08
Open fracture	2.2	0.66–7.34	.20
AO classification	0.9	0.68–1.22	.53
Pathogen (MSSA vs. other)	8.0	2.1–30.07	.002*

Statistical significance was set at $p < .05^*$. BMI: Body Mass Index. MSSA: Methicillin Sensitive *S. aureus*.

MSSA group requiring 5.1 (SD = 2.5) vs. 2.7 (SD = 1.7), $p < .001$. These findings remained statistically significant when controlling for time to diagnosis of deep infection. No other pathogens showed a statistically significant difference in number of debridements.

Of the fifty-two patients undergoing attempted salvage, only 25% (13/52) had healed at the time of deep infection diagnosis. The average time to diagnosis of infection in those who had not healed was 66.7 days vs. 141.6 days in those that had a healed fracture. Spearman correlation analysis shows a decreased number of operative procedures in those diagnosed with deep infection at increasing time points, $\rho = -0.40$, $p = .003$. Linear regression allows for the visualization of a fair negative relationship between these 2 variables, see Fig. 3. It is

Fig. 2 – Patient clinical characteristics vs. number of operative procedures required for successful salvage.

Fig. 3 – Number of operative procedures vs. days to diagnosis of deep infection in patients undergoing attempted salvage.

possible that earlier infections involved greater compromise of the soft tissue envelope. Perhaps it represents a surgeon bias for a tendency to perform more debridements when there are retained implants that are deemed structurally necessary. No significant differences in time to diagnosis of infection were identified when comparing Gustilo-Anderson type I and II (83.7 days, $n = 16$) vs. type III fractures (70.5 days, $n = 15$), $p = .28$.

Only 9.6% (5/52) of patients were diagnosed with deep infection within three weeks of definitive fixation. Although the salvage rate for this population was 100% (5/5) no significant differences were identified when compared to those diagnosed with deep infection after three weeks from definitive fixation. Table 4 shows differences in outcomes between the two groups. A sub-analysis was performed to evaluate the correlation between the number of soft tissue coverage procedures as part of the initial treatment and the number of procedures required for definitive treatment of deep infection. A total of 31 patients presented with open injuries. Of these, 25.8% (8/31) required procedures for soft tissue coverage at the time of initial treatment. Seven patients required one soft tissue coverage procedure and the remaining patient required

an additional procedure during initial treatment. There was no correlation identified between the number of procedures performed as part of the initial treatment with the amount of procedures required for the definitive treatment of deep infection (Spearman's $\rho = -0.09$, $p = .65$). Further analysis was performed to evaluate the association between the need for soft tissue coverage and the success of attempted salvage. Of the thirty-one open fractures, salvage was obtained in 80.6% (25/31) of patients. 16% (4/25) of those obtaining salvage required at least one soft tissue coverage procedure vs. 66.7% (4/6) of those that did not obtain salvage, $p = .04$.

4. Discussion

No large series have been extensively studied in order to characterize the clinical pathway towards limb salvage in patients who have developed post-operative infections following definitive fixation of tibia pilon fractures. The majority of literature reports consist of case series which conclude that success of salvage is not obtained in the first attempt, but that secondary revisions may be required in order to achieve it.^{17–20} Additionally, comparison between reports is difficult given that broad spectrums of techniques were used for attempted salvage and include patients with non-infected non-unions as well as patients with shaft and proximal tibia fractures.

The purpose of this study was to describe the course of treatment in operatively treated pilon fractures in the setting of deep infection. In 2012, Yusof et al characterized the number of operative procedures required for successful salvage in infected, open Gustilo type IIIB, tibia fractures.²¹ The rate of successful salvage was 81.8% with 18.2% (2/11) of patients having unresolved non-unions at the time of final follow-up. Only two of the eleven patients were diagnosed with a pilon fracture (AO/OTA: 43), both of which healed. The average total number of operative procedures in the successful salvage population was 3.8 (SD = 1.0) with an average of 2.3 (SD = 0.7) debridements and 1.4 (SD = 0.9) reconstructive procedures. The authors also found a correlation between the number of debridements in those who presented with acute infection compared to those who presented with late infection, however, this was not quantified.

If the infection was diagnosed following healing, which occurred in only 25% of our cohort, the debridement for treatment typically included removal of implants. This would occasionally involve removal of only the regionally involved implants, while leaving implants that may require an approach remote from the site of infection. All patients were managed via a multidisciplinary team including infectious disease specialists. Antibiotic use was typically parenteral via peripherally inserted central catheter. Serial monitoring of inflammatory markers, ESR and CRP were utilized as adjuncts to gauge success of treatment. Rifampin was routinely employed as multimodal drug therapy when implants were retained.

Retention of implants was left to the treating surgeon in situations when healing had not yet occurred. Any necrotic/infected cortical bone would routinely be removed, if debridement left a critical-sized defect, then the treating

Table 4 – Differences in outcomes by time from definitive fixation to diagnosis of infection.

Time from definitive fixation to diagnosis of infection	Within 21 days (n = 5)	After 21 days (n = 47)	p
Follow up	14 months $\pm$ 7.5	17.4 months $\pm$ 8.6	.34
Average number of procedures before diagnosis of infection	1.6 $\pm$ 0.5	2.4 $\pm$ 1.2	.08
Average number of procedures after diagnosis of infection	4 $\pm$ 1.9	3.7 $\pm$ 2.4	.52
Debridements	2.6 $\pm$ 1.5	2.4 $\pm$ 1.5	.77
Reconstructions	1.4 $\pm$ 0.5	1.3 $\pm$ 1.4	.53
Total procedures:	5.6 $\pm$ 2.4	6.1 $\pm$ 2.6	.74
Salvage rate	100% (5/5)	89.1% (41/47)	.40

surgeons at our institution would routinely manage with local antibiotic delivery via methylmethacrylate spacer either in block form similar to the technique of Masquelet, or with beads.

As this is a retrospective review, no specific technical protocol was utilized. Implant retention, removal, and utilization of local antibiotics were entirely at the discretion of the treating surgeon, all of whom are experienced in managing post-traumatic infections and non-unions.

It is worth noting that our deep infection rate of 16% is higher than in previous reports.^{4,6,12} We believe this is related in some part, to the large percentage of open fractures in our population (over 30 of the 57 infections were open fractures and 142 of 355 (40%) identified in the general cohort) compared to most of the previously published literature (38.7%,⁴ 22%,⁵ and 20%¹²). Additionally, the high incidence of 43C fractures (37/47, 78.7%) may also be a contributing factor for such a high. This also highlights the importance of the data regarding treatment, as it likely impacts a higher percentage of patients than would otherwise be predicted, if referencing previous reports that included far fewer patients.

The microbial spectrum of this series compares to that described by Cierny and Mader.²² The majority of cases identified in this study were caused by *S. aureus*, with a total of 27 cases, followed by *Enterobacter* with 14 cases. On the contrary Yusof et al found that the majority of their cases involved *Pseudomonas* including the two of a total of eleven patients that had failed to unite. Our results demonstrated an increased number of debridements and total surgical procedures after a diagnosis of deep infection in cases involving *S. aureus* even after controlling for time to infection.

The secondary aim of this paper was to look for risk factors that associated with number of operative procedures (debridements and reconstructive procedures) after the diagnosis of deep infection among 46 salvaged patients. The interested risk factors include age, BMI, hypertension, open skin, open/closed fracture, diabetes, and smoke. We performed both univariate analysis and the penalized multivariable proportional odds model and both indicated that there is not enough evidence to identify an association between risk factors and the outcome.

The strengths of this study include the large number of patients identified, accounting for debridements and reconstructive procedures after a diagnosis of deep infection, 95% follow-up, with only 3 patients with insufficient data, and the optimal statistical models used to analyze these variables. Currently, there are no previously published reports describing the course of treatment and rate of successful salvage in such a large series of operatively treated pilon fractures (AO/OTA: 43).

The limitations of this study include its retrospective nature. Additionally, we did not separate the number of reconstructive procedures needed for soft tissue or bony healing. We also did not control for surgeon or his/her experience; however, the authors believe this accurately reflects the typical pattern of experience at trauma centers, and increases the generalizability of the data presented. An additional limitation is that we did not include an injury severity scale as part of the logistic regression analysis. However, previous literature has shown a limited utility of the lower-extremity injury-severity indices

currently available (Mangled Extremity Severity Score (MESS), Predictive Salvage Index (PSI), Nerve Injury, Ischemia, Soft-Tissue Injury, Skeletal Injury, Shock, and Age of Patient Score (NISSA); and the Hannover Fracture Scale (HFS)) for discriminating between the limbs requiring amputation and those likely to be salvaged successfully.²³ The low performance of the indices in specific injury-pattern groups indicates that these lower-extremity injury-severity scoring systems have limited usefulness and cannot be used as the sole criterion by which amputation decisions are made. Due to the limited sample size of our population it is not possible to include this variable as part of our logistic regression model and therefore adjust. The authors are confident with the fact that there are other variables that take precedence for statistical analysis inclusion in this highly specific patient population (AO, Gustilo & Anderson, age and past medical history).

5. Conclusion

Considerable morbidity follows the diagnosis of deep infection, with 14% of patients ultimately treated with amputation. Successful salvage can be reliably anticipated in over 80% of patients, but typically requires more than 3 additional procedures. Independently, diabetes, smoking, open fractures, and obesity did not decrease the success of salvage. However, patients diagnosed with *S. aureus* deep infection are at increased risk for requiring a greater number of procedures to definitively treat.

Acknowledging the limitations, the authors can support the following treatment recommendations. All patients can be offered salvage with reasonable expectations of success, but should anticipate and plan for three to four additional procedures and a protracted course. Given nearly 20% of the infections in our series included gram negative organisms, consideration should be given to initiating broader empiric treatment to include coverage for both *Staphylococcus* and *Enterobacter* species, with transition to organism specific therapy directed by intraoperative culture results. A close working relationship with infectious disease specialists is helpful. Debridements should include removal of implants when feasible, and priority should be given to soft tissue management, incorporating free flaps as necessary for bony coverage. The authors agree with traditional recommendations of smoking cessation and nutritional optimization. Further prospective multicenter studies evaluating functional outcomes, pain level and overall patient satisfaction are required in order to determine whether salvage is the best option for this specific patient population.

This series serves as a framework for discussions regarding anticipated success of and course of treatment, helping align patient and surgeon expectations, and provides surgeons and patients a framework for discussions regarding optimal, individualized treatment.

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Conflicts of interest

All authors have none to declare.

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