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Prospective Evaluation of Treatment of Open Fractures
Effect of Time to Irrigation and Debridement

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IMPORTANCE The standard practice of irrigation and debridement (I&D) of open fractures within 6 hours of injury remains controversial.

OBJECTIVE To prospectively evaluate the effect of the time from injury to the initial I&D on infectious complications.

DESIGN, SETTING, AND PARTICIPANTS A total of 315 patients who were admitted to a level 1 trauma center with open extremity fractures from September 22, 2008, through June 21, 2011, were enrolled in a prospective observational study and followed up for 1 year after discharge (mean [SD] age, 33.9 [16.3] years; 79% were male; and 78.4% were due to blunt trauma). Demographics, mechanism of injury, time to I&D, operative intervention, and incidence of local infectious complications were documented. Patients were stratified into 4 groups based on the time of I&D (<6 hours, 7-12 hours, 13-18 hours, and 19-24 hours after injury). Univariate and multivariable analysis were used to determine the effect of time to I&D on outcomes.

MAIN OUTCOMES AND MEASURES Development of local infectious complications at early (<30 days) or late (>30 days and <1 year) intervals from admission.

RESULTS The most frequently injured site was the lower extremity (70.2%), and 47.9% of all injuries were Gustilo classification type III. There was no difference in fracture location, degree of contamination, or antibiotic use between groups. All patients underwent I&D within 24 hours. Overall, 14 patients (4.4%) developed early wound infections, while 10 (3.2%) developed late wound infections (after 30 days). The infection rate was not statistically different on univariate (<6 hours, 4.7%; 7-12 hours, 7.5%; 13-18 hours, 3.1%; and 19-24 hours, 3.6%; $P = .65$) or multivariable analysis (<6-hour group [reference], $P = .65$; 7- to 12-hour group adjusted odds ratio [AOR] [95% CI], 2.1 [0.4-10.2], $P = .37$; 13- to 18-hour group AOR [95% CI], 0.8 [0.1-4.5], $P = .81$; 19- to 24-hour group AOR [95% CI], 1.1 [0.2-6.2], $P = .90$). Time to I&D did not affect the rate of nonunion, hardware failure, length of stay, or mortality.

CONCLUSIONS AND RELEVANCE In this prospective analysis, time to I&D did not affect the development of local infectious complications provided it was performed within 24 hours of arrival.

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Current guidelines regarding management of open fractures recommend formal irrigation and debridement (I&D) to eliminate foreign bodies and devitalized tissue within 6 hours of injury.[1] Early I&D of these injuries is performed in an attempt to minimize the risk of infectious complications. However, trauma patients who present with open fractures often have more severe injuries that need to be managed before I&D can be performed. The effect of the timing of I&D on outcomes has not been clearly delineated. Most studies, to our knowledge, are retrospective, with variable capture of infectious complications. In addition, many studies are limited to the lower extremities and have confined their analysis to limited periods.

The purpose of this study was to prospectively examine the association between the time from injury to debridement of open fractures and infectious complications. Specifically, we examined the effect of delayed debridement on both early and late complications. Our hypothesis was that a delay in debridement is not associated with worsened outcomes.

Methods

After institutional review board approval from the University of Southern California, all patients with open extremity fractures were prospectively identified during a 3-year period ending June 2011 and followed up for the duration of their hospitalization. Verbal or written consent was not obtained because this is an observational prospective study and the treatment was not changed. After discharge, clinic visits (orthopedic and trauma surgery) and emergency department readmissions were tracked for 1 year. Patient variables collected included demographics, vital signs at hospital admission (ie, body temperature, blood pressure, heart rate, and respiratory rate), abbreviated injury scale score, and injury severity score. The time from emergency department admission to the first I&D was documented. The Gustilo classification was derived for all injuries at the time of initial debridement in the operating room. Management of fractures and all infectious complications, as well as other local complications, were documented up to 1 year after discharge. For the analysis, fractures were categorized as upper arm (humerus), forearm (radius and ulna), thigh (femur), and leg (tibia and fibula).

The primary outcome variable was the development of local infectious complications at early or late intervals from admission. Complications were classified as early if they occurred within 30 days of hospital admission and late if they occurred 30 days or more after admission but within 12 months of the initial injury. Infections were further stratified into superficial and deep. Secondary outcomes included local complications, including deep vein thrombosis, pulmonary emboli, nonunion, tissue necrosis, hardware failure, duration of intensive care stay, overall duration of hospital stay, and mortality. Tissue necrosis was defined as the presence of devitalized soft tissues that required surgical debridement.

For the analysis, patients were stratified into 4 groups based on the time to I&D (<6 hours, 7-12 hours, 13-18 hours, and 19-24 hours). The time of the first I&D was defined by the procedure start time in the operating room. Contingency tables were prepared to compare the distribution of demographics, vital signs at hospital admission, and injury indexes across the groups. We used χ^2 tests or the Fisher-Freeman-Halton test, where appropriate, to compare proportions, while the analysis of variance was used to compare continuous variables. Post hoc tests were performed using Bonferroni corrections in instances in which $P < .05$. All statistical analyses were performed using SPSS, version 20 (IBM SPSS Statistics).

Results

During the study period, 315 patients were prospectively enrolled in the study. The mean (SD) age was 33.9 (16.3) years, 79.0% were male, and most injuries (78.4%) were due to blunt trauma. All patients underwent I&D in the operating room within 24 hours of admission. Sixty-four (20.3%) patients had formal I&D within 6 hours of injury, 70 (22.2%) between 7 and 12 hours, 98 (31.1%) between 13 and 18 hours, and 83 (26.3%) between 19 and 24 hours. Demographics were similar across all groups. There were minor differences between the groups when the mechanism of injury was analyzed. Post hoc analysis identified a lower incidence of automobile vs pedestrian injuries in the less-than-6-hour group (6.2%) compared with the 13- to 18-hour group (25.5%) only. Further description of the demographics and injury indexes are detailed in **Table 1**.

The most common site of open-fracture injury was the leg (48.3%), followed by the thigh (21.9%), forearm (21.3%), and upper arm (8.6%). There was no significant difference with regard to injury location between the study groups. The degree of contamination, as ascertained from the Gustilo classification, also did not differ significantly between groups. Antibiotic prophylaxis was administered in all cases, with single-agent coverage used in 31.1% of cases. Fifty-nine percent of cases required internal fixation, and the frequency of this intervention was only significantly different between the less-than-6-hour group and the 19- to 24-hour group (48.4% vs 72.3%; $P = .02$) (**Table 2**).

Superficial infections (3.5%) accounted for most early wound infections (occurring within 30 days after injury). The overall early infection rate was 4.4%. There were no significant differences in the incidence of any of the early complications observed. Nonunion was the most commonly reported late (1 year) complication, occurring in 5.1% of our cohort. No significant difference was noted in the distribution of this complication or any other late complication. The duration of hospitalization and intensive care unit use did not differ across the groups (**Table 3**). The superficial infection rate between 14 and 30 days was 4.7% in the nonhardware group vs 0.5% in the hardware group ($P = .02$). There was no difference in the rate of deep infections.

The overall mortality was low (0.3%). The single fatality had also sustained an unstable C2 fracture and blunt cardiac injury following a motor vehicle collision. The patient had a periprosthetic femoral fracture, which underwent I&D at 12 hours. He ultimately developed myocardial infarction on day 4 and died of cardiac failure.

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Table 1. Demographics and Clinical Details

Characteristic	Total (N = 315)	Hours				P Value
		<6 (n = 64)	7-12 (n = 70)	13-18 (n = 98)	19-24 (n = 83)	
Age, mean (SD)	33.9 (16.3)	37.0 (17.2)	33.8 (15.8)	32.4 (17.8)	33.4 (14.2)	.37
Age ≥55 y, No. (%)	**36** (11.4)	8 (12.5)	10 (14.3)	12 (12.2)	6 (7.2)	.51
Male sex	**249** (79.0)	46 (71.9)	54 (77.1)	81 (82.7)	68 (81.9)	.35
Mechanism of injury, No. (%)						
MVC	**56** (17.8)	13 (20.3)	13 (18.6)	12 (12.2)	18 (21.7)	.03[a]
MCC	**46** (14.6)	7 (10.9)	17 (24.3)	12 (12.2)	10 (12.0)	
AVP	**57** (18.1)	4 (6.2)	10 (14.3)	25 (25.5)	18 (21.7)	
Fall	**62** (19.7)	15 (23.4)	15 (21.4)	19 (19.4)	13 (15.7)	
GSW	**67** (21.6)	17 (26.6)	12 (17.1)	24 (24.5)	14 (16.9)	
Other[b]	**27** (8.6)	8 (12.5)	3 (4.3)	6 (6.1)	10 (12.0)	
Vital sign at hospital admission, No. (%)						
HR, mean (SD)	94.2 (23.2)	91.0 (25.6)	95.3 (21.4)	97.5 (25.6)	91.8 (19.0)	.24
SBP <90 mm Hg	**12** (3.8)	4 (6.2)	3 (4.3)	3 (3.1)	2 (2.4)	.65
GCS score ≤8	**7** (2.2)	2 (3.1)	3 (4.3)	2 (2.0)	0	.26
Head AIS score ≥3, No. (%)	**26** (8.3)	3 (4.7)	7 (10.0)	10 (10.2)	6 (7.2)	.60
Chest AIS score ≥3, No. (%)	**60** (19.0)	10 (15.6)	14 (20.0)	23 (23.5)	13 (15.7)	.52
Abdominal AIS score ≥3, No. (%)	**17** (5.4)	4 (6.2)	3 (4.3)	7 (7.1)	3 (3.6)	.72
ISS score ≥25, No. (%)	**32** (10.2)	4 (6.2)	7 (10.0)	12 (12.2)	9 (10.8)	.67

Abbreviations: AIS, Abbreviated Injury Scale; AVP, automobile vs pedestrian; GCS, Glasgow Coma Scale; GSW, gunshot wound; HR, heart rate; ISS, Injury Severity Scale; MCC, motorcycle crash; MVC, motor vehicle collision; SBP, systolic blood pressure.

[a] Post hoc tests showed that AVP cases were least likely to receive irrigation and debridement in the first 6 hours compared with the 13- to 18-hour group.

[b] Includes assault injuries, crush injuries, and penetrating animal bite (n = 1).

Table 2. Management of Injuries

Characteristic	Total (N = 315)	Hours, No (%)				P Value
		<6 (n = 64)	7-12 (n = 70)	13-18 (n = 98)	19-24 (n = 83)	
Location of fracture						
Upper arm	**27** (8.6)	8 (12.5)	5 (7.1)	9 (9.2)	5 (6.0)	.58
Forearm	**67** (21.3)	19 (29.7)	11 (15.7)	21 (21.4)	16 (19.3)	
Thigh	**69** (21.9)	11 (17.2)	18 (25.7)	22 (22.4)	18 (21.7)	
Leg	**152** (48.3)	26 (40.6)	36 (51.4)	46 (46.9)	44 (53.0)	
Gustilo classification						
I	**70** (22.2)	9 (14.1)	13 (18.6)	33 (33.7)	15 (18.1)	.09
II	**94** (29.8)	22 (34.4)	24 (34.3)	28 (28.6)	20 (24.1)	
IIIa	**95** (30.2)	18 (28.1)	22 (31.4)	23 (23.5)	32 (38.6)	
IIIb	**41** (13.0)	9 (14.1)	8 (11.4)	10 (10.2)	14 (16.9)	
IIIc	**15** (4.8)	6 (9.4)	3 (4.3)	4 (4.1)	2 (2.4)	
Single antibiotic treatment	**98** (31.1)	20 (31.2)	23 (32.9)	35 (35.7)	20 (24.1)	.38
Hardware implant[a]	**186** (59.0)	31 (48.4)	41 (58.6)	54 (55.1)	60 (72.3)	.02[b]

[a] A total of 59.0% of patients had hardware implantation at their initial operation. Subsequent hardware implantation resulted in an overall rate of 91.8% (289 of 315 patients).

[b] Post hoc testing using Bonferroni correction identified significance between the less-than-6–hour and 19- to 24-hour groups only.

After adjusting for differences significant at $P < .05$ (mechanism of injury and hardware implant), the time to I&D was not associated with an increased risk of infectious complications (**Table 4**). There was no difference in the rate of nonunion, hardware failure, length of stay, or mortality.

Discussion

To our knowledge, this is the largest and most comprehensive prospective study to date that evaluates the effect of early

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Table 3. Outcomes of Treatment

Outcome	Total (N = 315)	Hours[a] <6 (n = 64)	7-12 (n = 70)	13-18 (n = 98)	19-24 (n = 83)	*P* Value
Early complications						
Any wound infection	**14** (4.4)	3 (4.7)	5 (7.5)	3 (3.1)	3 (3.6)	.65
Superficial wound infection	**11** (3.5)	3 (4.7)	4 (5.7)	2 (2.0)	2 (2.4)	.50
Deep surgical site infection	**3** (1.0)	0	1 (1.4)	1 (1.0)	1 (1.2)	>.99
Wound dehiscence	**3** (1.0)	2 (3.1)	0	1 (1.0)	0	.19
Deep vein thrombosis	**1** (0.3)	0	1 (1.4)	0	0	.42
Pulmonary embolus	**3** (1.0)	0	1 (1.4)	1 (1.0)	1 (1.2)	>.99
Nonunion						
Necrosis	**3** (1.0)	1 (1.6)	0	2 (2.0)	0	.42
Hardware failure	**1** (0.3)	1 (1.6)	0	0	0	.20
Late complications						
Any wound infection	**10** (3.2)	2 (3.1)	4 (5.7)	3 (3.1)	1 (1.2)	.49
Superficial wound infection	**1** (0.3)	0	1 (1.4)	0	0	.42
Deep surgical site infection	**9** (2.9)	2 (3.1)	3 (4.3)	3 (3.1)	1 (1.2)	.68
Wound dehiscence	**1** (0.3)	0	0	1 (1.0)	0	>.99
Deep vein thrombosis	**1** (0.3)	0	0	1 (1.0)	0	>.99
Pulmonary embolus						
Nonunion	**16** (5.1)	4 (6.2)	4 (5.7)	5 (5.1)	3 (3.6)	.88
Necrosis	**1** (0.3)	0	1 (1.4)	0	0	.42
Hardware failure						
Intensive care unit length of stay, mean (SD)	9.8 (13.0)	8.4 (8.2)	14.6 (22.8)	9.1 (7.9)	6.5 (4.2)	.10
Hospital length of stay, mean (SD)	15.1 (13.7)	13.2 (10.4)	17.8 (27.5)	14.8 (14.3)	15.1 (13.7)	.48
In-hospital mortality	**1** (0.3)	0	0	1 (1.0)	0	>.99

[a] Values are presented as number (percentage) unless otherwise indicated.

Table 4. Effect of Time to I&D of Infection Risk

Time to I&D, h	AOR (95% CI)[a]	*P* Value
<6	1 [Reference]	.65
7-12	2.1 (0.4-10.2)	.37
13-18	0.8 (0.1-4.5)	.81
19-24	1.1 (0.2-6.2)	.90

Abbreviations: AOR, adjusted odds ratio; I&D, irrigation and debridement.

[a] Logistic regression (by multivariable analysis) controlling for mechanism of injury and use of hardware implant.

debridement on open extremity fractures, controlling for the extent of wound contamination using the Gustilo classification. Both upper and lower fractures were studied, multiple time frames up to 24 hours were analyzed, and infectious complications up to 1 year were tracked. Our findings suggest that the time until I&D of open fractures performed within the first 24 hours has no effect on early or late complications.

There have been several retrospective and a few limited prospective studies that examined the effectiveness of early debridement solely in tibia fractures. In a retrospective analysis of 103 patients with open tibia fractures, Khatod and colleagues[2] found no increase in the infection rate for patients who received I&D in less than 6 hours vs those who were treated after 6 hours. Similarly, Tripuraneni and colleagues[3] showed in a retrospective review of 206 patients with open tibia fractures that there was no difference in infectious outcomes based on I&D at less than 6 hours, 6 to 12 hours, and 12 to 24 hours. Enninghorst and colleagues[4] prospectively showed in a study of 89 patients that I&D of open tibia fractures within a mean of 8 hours left injury severity as the only determinant of infectious complications among patients with blunt trauma. There was no difference in infectious complications between the early (<6 hours) and late (>6 hours) I&D groups.

Investigators have limited most studies on this subject to lower extremity or tibial fractures alone and specifically to Gustilo grade III open-fracture injuries. In a retrospective study of 67 patients with grade III open tibia fractures, Singh et al[5] demonstrated no significant difference in the infection rate for early (<6 hours) vs late (>6 hours) I&D. Pollak[6] showed in a prospective study of 307 patients with Gustilo grade III lower extremity open fractures that there was no difference in infectious complications for the 3 debridement groups (<5 hours, 5-10 hours, and >10 hours).[2] At the Great Western Hospital in England, Al-Arabi et al[7] showed in a prospective study of 237 patients with long-bone fractures during a 9-year period that there was no difference in infectious complication rates for I&D at less than 6 hours or more than 6 hours.

The historic recommendation to perform I&D of open fractures within a 6-hour window is not clearly supported by contemporary publications. In fact, although varying time points have been examined, these studies demonstrate that a delay in the time to I&D does not negatively affect the infection rate.

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In our study, both upper and lower fractures were examined, with delays of up to 24 hours having no effect on the infectious complication rate. Trauma patients may present with associated torso or intracranial injuries that require emergency intervention, precluding immediate fracture I&D. The results of this analysis can help trauma care professionals optimize workflow when there are competing priorities. There was no difference in infection rates as long as the I&D was performed in the first 24 hours. Because the infection rate is already so low and antibiotic prophylaxis is used, the timing may not matter. This extended window of 24 hours to perform the I&D allows for the prioritization of severe injuries, streamlines the treatment of multiple-injured trauma patients, and allows better coordination and use of our ever-decreasing surgical resources.

Despite its prospective design, our investigation has several limitations. Because it was an observational study, patient treatment was not standardized. Although all patients received antibiotic prophylaxis, the choice of agent was not standardized. This difference, however, was corrected for and did not affect our findings. Second, the time measure that we used is based on hospital admission and not the time of injury. Although using the time of injury would be ideal, we were unable to obtain this information for all patients. With short prehospital times (on average, 20 minutes for our center), this variable is unlikely to have significantly affected our results. The strength of this study, however, included the prospective data collection, which allowed objective documentation of infectious complications for up to a year. This documentation mitigates the extent of errors, a major challenge in many previous studies in which tracking and interpreting infection data were attempted retrospectively. The study groups were well distributed, homogeneous, and allowed for effective examination of multiple periods of up to 24 hours.

Conclusions

In this prospective analysis, the time to I&D did not affect the development of local infectious complications provided it was performed within the first 24 hours after arrival.

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Study concept and design: Inaba, Okoye, Chan, Schnüriger.
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Drafting of the manuscript: Srour, Inaba, Okoye, Chan, Skiada.
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