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ORIGINAL STUDY

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Early internal fixation of open ankle malleolar fractures is not associated with increased complications: case control study

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The timing of definitive fixation of open ankle malleolar fractures is still controversial. This study intended to evaluate the outcome of patients who were managed by immediate definitive fixation in comparison to delayed definitive fixation following open ankle malleolar fractures. This was an IRB approved retrospective case control study of 32 patients who were treated with open reduction and internal fixation (ORIF) for open ankle malleolar fractures at our Level I trauma center 2011-2018. Patients were divided into 2 groups; immediate ORIF group (within 24 hours) and delayed ORIF group (first stage included debridement and external fixator or splinting followed by second stage of delayed ORIF). Outcomes assessed were postoperative complications (wound healing, infection, nonunion). Logistic regression models were used to access the unadjusted and adjusted associations between post-operative complications and selected co factors. The immediate definitive fixation group included 22 patients while the delayed staged fixation group included 10 patients. Gustilo type II and III open fractures were associated with higher complications rate (*p-value* = 0.012) in both groups. Comparing the 2 groups, There was no increase in complication in the immediate fixation group compared to the delayed group. Complications following open ankle malleolar fractures are usually associated with Gustilo type II and III open fractures. Immediate definitive fixation after adequate debridement was not found to increase complication rate compared to staged management.

Keywords: ankle fractures; delayed fixation; immediate fixation; malleolar fractures; open fractures; open ankle fracture.

INTRODUCTION

Ankle fractures are common injuries. Most ankle fractures occur as an isolated closed injury, while open ankle fractures are less common with a reported incidence of 1.5-5 % of all ankle fractures *(1-3)*. The ankle joint has limited amount of soft tissue coverage which adds to the complexity of its injuries. Disruption of the skin and the soft tissue coverage with the open fracture is a profound risk factor for infection and may lead to wound healing complications *(1-3)*.

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Restoration of the normal bony anatomy by stable fixation has a positive impact on the soft-tissue healing which subsequently reduces the likelihood of surgical site infection (SSI). Moreover, early joint mobilization also reduces the incidence of residual joint stiffness, muscle atrophy, and disuse osteoporosis *(4-6)*. Traditionally, open lower extremity fractures in general were treated by staged surgical treatment, with the first surgery aiming to achieve debridement and temporary stabilization while the second surgery aiming for definitive open reduction and internal fixation (ORIF) of the fracture *(4-6)*. However, with the advancement of modern surgical techniques and broad-spectrum antibiotics, immediate definitive stabilization of open fractures has become more popular with good results and low infection rates *(1,7)*.

Despite that several studies have reported the results of immediate ORIF for open ankle malleolar fractures *(5,8-13)*, most of these studies were case series with no matched comparison *(5,9-12)*. Hence, the role of primary immediate ORIF after open ankle malleolar fractures is still controversial. The aim of this study was to evaluate the outcomes of early ORIF of open ankle malleolar fractures with primary wound closure compared to delayed ORIF after debridement and ankle spanning external fixation with respect to complication rates.

MATERIALS AND METHODS

Institutional Board Review (IRB) approved retrospective case control study. The study included adult patients (older than 18 years) treated with ORIF for open ankle malleolar fractures at our Level I trauma center between 2011 and 2018 with minimum follow up of 3 months (bone and soft tissue healing). The exclusion criteria were patients under the age of 18 years, closed ankle injuries, open ankle malleolar fractures with any other treatment modality other than ORIF (e.g., external fixation as definitive treatment) and axial impaction ankle fractures (tibial plafond fractures or pilon fractures).

Open fractures were classified according Gustilo-Anderson classification *(14)*. The ankle fractures were classified according to AO/ OTA system as well as Danis-Weber classification *(15,16)*. These open ankle malleolar fractures were treated with either immediate ORIF within 24 hours of injury or staged treatment through initial irrigation and debridement with temporary stabilization by ankle spanning external fixator or splint immobilization followed by second stage of delayed ORIF. The choice between immediate ORIF versus delayed ORIF was the decision of the treating surgeon based mainly on surgeon preference. Ankle fractures treated by immediate ORIF were performed by one of the 2 senior authors who are both orthopedic-trauma fellowship trained.

Patient demographics (age, gender) were documented as well as the mechanism of injury, fracture laterality, open fracture grade, fracture classification, wound site, time from injury to surgery, operative interventions, and follow up data. Pre-operative radiographs were reviewed for fracture classification; intra-operative radiographs were reviewed for the method of fixation. Follow up radiographs were reviewed for time to bony union and any post-traumatic complications including early post-traumatic arthritis.

The outcome measurements included complication rate. The complications included superficial infection (resolves with antibiotics), deep infection (requires implant removal), nonunion and malunion. Nonunion defined as failure to heal at any components of the fracture within 6 months. Malunion is defined as loss of tibiotalar alignment >5° or fibular angular deformity in any plan. The wound healing complications included necrosis and wound dehiscence.

Description of the surgical technique: The procedure began with debridement and irrigation of the open wound with 6-9 liters of normal saline. All patients had initial irrigation and debridement and antibiotics according to the standard protocol. Devitalized tissues and foreign bodies were removed. Skin edges were sharply debrided, and the wound was extended, if needed. Debridement and irrigation were completed. For the immediate ORIF group, a completely new set of prepping was done, and all surgeons changed their gowns and gloves. ORIF was applied to each fracture according to the fracture pattern. Anatomical reduction of the fibula and restoration of length was achieved with either a

plate, multiple lag screws or fibular nail. All wounds were irrigated again before closure. Wounds were closed primary in layers using absorbable sutures for the deep and subcutaneous tissues and nylon for the skin. The wounds were covered with sterile dressings and the patient was placed in L and U Splint or cam boot.

The delayed ORIF group patients were managed on two stages; first, irrigation and debridement as the same protocol for the immediate ORIF group, then either stabilized by U and L shaped splint or an external fixator was applied. The second sage was usually done one to two weeks after first stage. The timing of second stage was dependent on the status of soft tissues. The second stage was ORIF using the construct appropriate for the fracture orientation *(8,13)*.

Description of the post-operative period: Each patient had follow-up appointments weekly until the sutures were removed. Sutures were removed 10-14 days post-operatively if no wound complications were encountered. After the soft tissues healing, rehabilitation was initiated with passive and active range of motion exercises. Patients were restricted to partial weight bearing in CAM boot for approximately six weeks, depending on the fracture severity, the fixation stability, and the bone quality. Full weight bearing was allowed when there was radiographic evidence of bone healing. Patients who had a syndesmotic fixation were instructed to keep non-weight bearing for 3 months.

Description of the Statistical analysis: Quantitative variables were summarized using mean and standard deviations (SD). In cases of skewed distribution, median and interquartile range (IQR) was used. Categorical variables were described using frequency and proportions. Students t-test, Chi- squared test and Wilcoxon sum rank test (for skewed data) were used to compare the differences between delayed and immediate ORIF groups. Logistic regression models were used to access the unadjusted and adjusted associations between post-operative complications and selected co factors. P-values less than 5% were considered statistically significant. All analyses were carried out using STATA v.15.

RESULTS

After review of 152 patients' charts for possible inclusion, 32 patients matched the inclusion/exclusion criteria and they were included in the study. The included patients were divided into two groups; 22 patients in the immediate ORIF group and 10 in the delayed ORIF group. Mean age at the time of injury was 51 years old (range 18-89). There were 18 male patients and 14 female patients. There was no statistically significant difference between the two groups regarding mean age or gender ratio. Most of the fracture types were classified as Gustilo-Anderson Type II (56%) and AO / OTA 44-B (69%). The patients were classified by Gustilo and Anderson classification into grade I: 3 patients, grade II: 18 patients, grade III: 11 patients. There was no statistically significant difference in AO/OTA classification, weber classification, or the Gustilo and Anderson open fracture classification between the two groups. ORIF within 24 hours of the injury was performed for the early ORIF group (average 10 hours with range from 2-24 hours). Four patients in the early ORIF group were fixed on the lateral side using fibular nail to allow for less soft tissue dissection, none of them had any wound complications. All patients were followed up until the bony union. The mean follow up was 23 months (range 1-60). The mean time to bony union was 10 weeks (8-16) for both groups. Table I shows the descriptive statistics of the entire cohort and by groups. Figures 1-3 shows a case of immediate ORIF fixation group (injury film, clinical photo, intra-operative fluoroscopic images and final follow up radiographs).

The overall complication rate (including infection) was 22% (7 out of 32). Gustilo classifications II and III were more likely associated with higher complication rates (*p-value*= 0.012) in both groups.

To compare the two groups regarding the outcome and complications, an adjusted association statistical analysis was conducted. There was no infection in the immediate ORIF group and one deep infection (osteomyelitis) in the delayed ORIF group. Overall, five patients developed complications in the delayed ORIF group (50%) versus 2 complications in the immediate ORIF group (9%); this difference was

Table I. — Descriptive statistics of entire cohort and by groups

Factor	Cohort	Delayed ORIF	Immediate ORIF	p-value
N	**32**	**10**	**22**	
Age, mean (SD)	48.7 (23.1)	58.5 (21.5)	44.2 (22.9)	0.11
Gender				
Male	18 (56%)	6 (60%)	12 (55%)	0.77
Female	14 (44%)	4 (40%)	10 (45%)	
Mechanism of Injury				
Auto vs pedestrian accident	2 (6%)	0 (0%)	2 (9%)	0.35
Motor vehicle Accident	14 (44%)	6 (60%)	8 (36%)	
Fall	16 (50%)	4 (40%)	12 (55%)	
Fracture site				
Right	22 (69%)	9 (90%)	13 (59%)	0.080
Left	10 (31%)	1 (10%)	9 (41%)	
Wound site				
lateral	3 (9%)	0 (0%)	3 (14%)	0.22
medial	29 (91%)	10 (100%)	19 (86%)	
Open fracture Grade				
G1	3 (9%)	1 (10%)	2 (9%)	0.012
G2	18 (56%)	2 (20%)	16 (73%)	
G3	11 (34%)	7 (70%)	4 (18%)	
AO/ OTA classification				
44-A	4 (13%)	0 (0%)	4 (18%)	0.19
44-B	22 (69%)	9 (90%)	13 (59%)	
44-C	6 (19%)	1 (10%)	5 (23%)	
Danis- Weber Classification				
Weber A	4 (13%)	1 (10%)	3 (14%)	0.12
Weber B	14 (44%)	7 (70%)	7 (32%)	
Weber C	14 (44%)	2 (20%)	12 (55%)	
Number of Comorbidities				
0	22 (69%)	3 (30%)	19 (86%)	<0.001
1	5 (16%)	2 (20%)	3 (14%)	
2	5 (16%)	5 (50%)	0 (0%)	
Follow up/ weeks, median (IQR)	92.0 (16.0, 164.0)	12.0 (10.0, 12.0)	126.5 (80.0, 241.0)	<0.001
Post- op Complications				
No	25 (78%)	5 (50%)	20 (91%)	0.009
Yes	7 (22%)	5 (50%)	2 (9%)	

statistically significant (p= 0.009). The immediate ORIF group developed the following complications: one patient had mild post-traumatic arthritis treated non-operatively and one patient had residual ankle pain because of osteochondral injury at the talar dome and posterior malleolus. The delayed

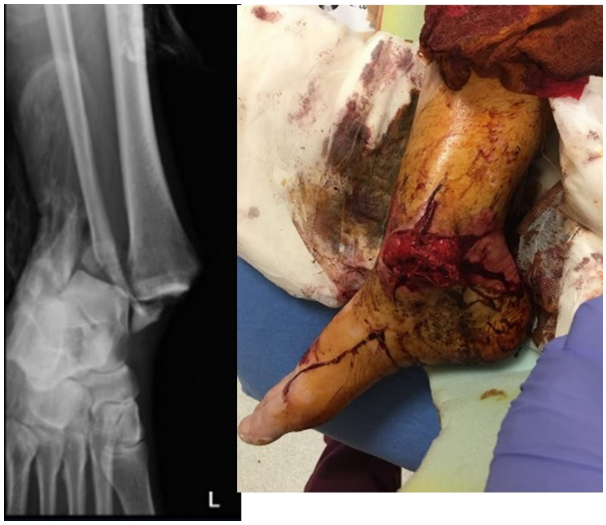

Figure 1. — An AP view of open ankle fracture case (A) and clinical photo (B).

Figure 3. — An AP (A) and lateral (B) radiographs taken at the final follow up visit showing fracture bony union.

ORIF group had the following complications: one case developed osteomyelitis treated with implant removal, antibiotics beads application (calcium sulphate mixed with vancomycin and tobramycin), fixation with circular external fixator that was removed after infection was resolved and bone healed, and one case developed post-traumatic arthritis, two cases had delayed wound healing, and one had superficial wound infection of skin graft.

Patients who underwent an immediate procedure versus a delayed procedure had less post-operative complications (9% vs. 50%, respectively, p=0.009). Patients in the immediate ORIF group were less likely to result in complication with an unadjusted odds ratio of 0.10 (95% CI: 0.01 – 0.68, p=0.018). The odds of having a post-operative complication were still lower than the delayed ORIF group after adjusting for complications increase in the delayed group, however, the difference was non-significant (Adjusted OR 0.04, 95% CI: 0.00 – 1.98, p=0.104). Table II and III shows the results of the logistic

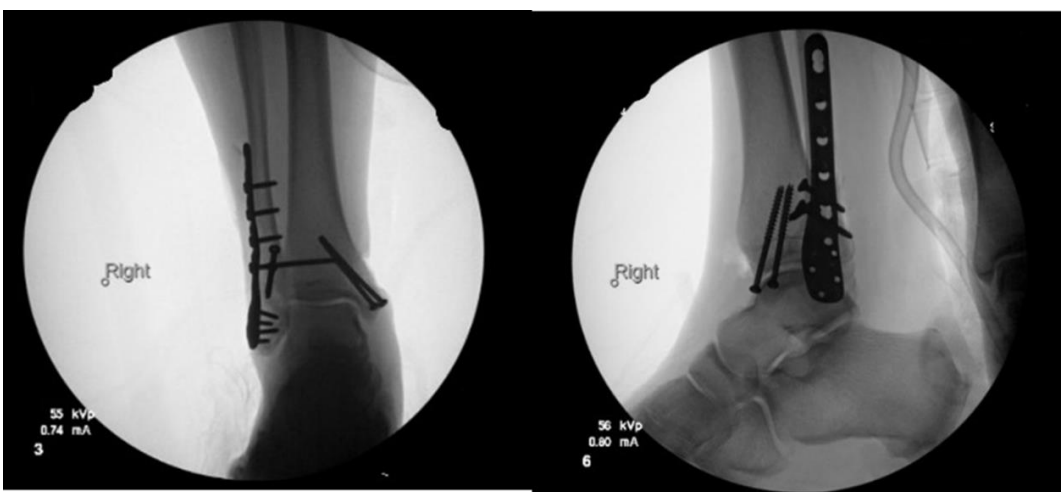

Figure 2. — An AP (A) and lateral (B) intra-operative fluoroscopic images of the fracture fixed using anatomical distal fibular plate and screws.

Table II — Unadjusted association

Factor	Odds Ratio	CI 95%	p-value
Age	1.03	0.99-1.07	0.219
Gender			
Male	1.05	0.19-5.69	0.957
Female			
Mechanism of Injury			
Auto vs pedestrian accident			
Motor vehicle Accident	1.73	0.31-9.57	0.528
Fall			
Fracture site			
Right	1.18	0.19-7.43	0.863
Left			
Open fracture Grade			
G1			
G2	0.40	0.03-5.96	0.506
G3	0.75	0.05-11.65	0.837
AO/ OTA classification			
44-A			
44-B	1.13	0.10-13.04	0.925
44-C			
Danis- Weber Classification			
Weber A			
Weber B	1.20	0.09-15.26	0.888
Weber C	0.50	0.03-7.54	0.617
Number of Comorbidities			
0			
1	1.58	0.13-19.42	0.719
2	9.50	1.09-82.72	0.041
Follow up	1.00	1.00-1.01	0.43
Post- op Complications			
Delayed Group			
Immediate Group	0.10	0.01-0.68	0.018

regression models used to access the unadjusted and adjusted associations.

DISCUSSION

Open ankle fractures are uncommon injuries. The overall incidence of open ankle fractures ranging between 1.5% to 5% of ankle fractures in general *(2,3,17)*. Open ankle fractures are considered a high-risk injuries with increased incidence of complications and reoperations. Simske et al. *(18)* reported the complication rate associated with open ankle fracture to be 33% vs 11% in the closed fractures. In this study we report a similar complication rate of 22% associated with these fracture type.

Table III — Adjusted association

Factor	Odds Ratio	CI 95%	p-value
Age	1.03	0.99-1.07	0.219
Fracture site			
Right	0.32	0.02-4.51	0.396
Left			
Open fracture Grade			
G1			
G2	0.72	0.02-28.32	0.86
G3	0.21	0.01-7.88	0.398
Number of Comorbidities			
0			
1	0.93	0.05-16.48	0.962
2	1.51	0.06-38.83	0.804
Post- op Complications			
Delayed Group			
Immediate Group	0.04	0.00-1.98	0.104

The standard treatment of open ankle fractures is still considered unresolved dilemma. The literature is controversial about the best approach to these fractures. Treatment ranges from staged fixation (first surgery for debridement and temporary stabilization and second surgery for ORIF) to immediate definitive fixation with primary/ delayed closure *(10,13,19)*. Orthopedic surgeons treating open ankle fractures might be in challenging situation to decide the best option for patients with open ankle fractures. Staged fixation for an open fracture has been considered the safest approach for a long time. However, the longer hospital stays, additional implant costs, additional procedures and delayed patients' recovery are major limitations. On the other hand, immediate internal fixation in the setting of open fractures may potentially increase the risk of infection and wound healing complications *(20,22)*. Direct comparisons between these two different treatment methods was generally lacking in the literature as most studies are case series that lack control group *(5,9-12)*. At this study, we tried to compare the two treatment strategies regarding the complication rates which was found to be more in the delayed ORIF group compared to the immediate ORIF group (50% vs 9%, respectively).

Historically, early internal fixation for open fractures after adequate debridement started in early Seventies. Ketenjian and Shelton reviewed fifty-five open fractures treated by immediate internal fixation, eighteen of them involved the ankle *(6)*; all ankle fractures united without evidence of infection or wound healing issues *(6)*. This was followed by Chapman and Mohaney study on 1979, they reported 13 % infection rate in a cohort of 94 open fractures to include 30 ankle fractures treated by immediate ORIF. The infection rate was 1.9% in small clean open (type I) wounds, 8% in large open (type II) wounds, and 41% in (type III) wounds *(21)*.

There were many studies presenting case series for primary immediate ORIF of open ankle fractures *(5,9-12)*. Despite that there was no comparison group in these studies, they consistently showed that open ankle fractures can be safely treated by early immediate ORIF. In 1984, Franklin et al. *(10)*, described a standard protocol for treatment of open ankle fracture. Their results showed excellent functional outcome in 74% of their patients, 26% fair or poor results. Their patients were treated by immediate open reduction; however, the wounds were not closed primarily in their series, and were treated by delayed primary closure which would

result in delay in rehabilitation, need for another surgery and prolonged hospitalization *(10)*. In 1993, Johnson and Davlin *(5)* reported better results in immediate internal fixation of open ankle fracture. There were no deep infections or nonunion in their cohort. More recently, Joshi el al. *(9)* reported the results of immediate ORIF of open ankle fractures in a prospective study including 30 patients. There were no cases of deep infections. There was 13% incidence of superficial skin necrosis and 6% incidence of loss of reduction, resulting in residual ankle stiffness. The authors, similar to our results, found that open fracture type I and II, were associated with better functional results and less complications.

Prior to our study, there were two other studies which compared immediate definitive fixation to delayed one of open ankle fractures *(8,13)*. In 1989, Bray et al. *(8)* evaluated 31 open ankle fractures (15 managed by closed immobilization and delayed definitive fixation and 16 with immediate ORIF). One case in each group had infection. The authors found that the fractures treated with immediate ORIF showed less impairment of range of motion but had a greater incidence of chronic ankle swelling. The hospitalization time was significantly shorter for the patients treated by immediate open reduction. The authors concluded that immediate ORIF of open ankle fractures speeds up the recovery with no greater incidence of infection than encountered with conservative staged treatment *(8)*. In a recent study, Peterson et al. *(13)* looked at 88 patients with open ankle fractures. The cohort was divided to into two groups of the early fixation and staged fixation. The overall infection rate was 6.8%. The authors reported no difference in infection rate between early fixation and delayed fixation group. However, the early fixation group had shorter hospital stay, fewer number of reoperations but similar outcomes for pain, ambulation, and radiographic evidence of osteoarthritis at 12 months follow-up. The overall infection rate in our cohort was 3%. Both in our study and in Peterson et al's study, the immediate fixation group didn't have any cases of deep infection *(13)*. This absence of infection in cases of immediate fixation group may be explained by the fact that early stabilization of the fracture fragments maximizes the ability of the soft tissues to resist infection and to heal so that optimum functional results can be obtained. However, probably due to small sample sized of all case control studies *(8,13)* including our study, there is no enough data to suggest that immediate ORIF can actually decrease the infection risk after open ankle fracture compared to delayed management.

Hulsker et al. *(22)* conducted a review of 15 articles regarding open ankle fractures. They found that immediate ORIF of open ankle fractures is safe and leads to good functional outcome. The most reported complications after immediate internal fixation were deep infection (8%) and skin necrosis (14%). In our study, the results were similar to Hulsker et al. *(22)* study, which shows better results of the immediate ORIF group than the delayed group. It is worth noting that Hulsker et al recommended for open fracture II and III wounds to be managed by either secondary intention or delayed primary closure while our results and those of Peterson et al. *(13)* support primary wound closure with the immediate internal fixation for open fracture II and IIIA. For cases in which primary closure cannot be obtained, negative pressure wound dressing is applied and wound is covered with flap or a graft as soon as possible.

Our study outcomes of the immediate ORIF group showed that the immediate fixation of the open ankle fracture with meticulous steps of management, antibiotics, intraoperative debridement and irrigation and good soft tissue handling can lead to similar complications rates to those of delay fixation and that early fixation can eventually result in a better outcome through allowing shorter treatment period, which makes the immediate fixation of the open ankle fractures a safe option. As open ankle fractures are more common in elderly patients above 75 *(18)* and because aging population are expected to constitute higher percentage of the populations in the future, open ankle malleolar fracture is expected to become more common; so, finding a safe treatment option that can allow the patients to faster return of activity is an important goal to achieve.

The authors acknowledge some limitations of this study. The small sample size of the study prevented

more advanced statistical analysis. In addition, the patients were not randomized to the treatment group, but rather were treated based on the preference of the treating orthopedic surgeon. It could have been that more severe injuries or more sick patients were treated by staged approach. Moreover, the inherent limitation of the study due to its retrospective nature of this cohort. Due to relative rarity of the pathology (open malleolar ankle fracture), it may not be possible to easily perform a prospective study between two main treatment options (early Vs delayed ORIF). However, we think, especially considering the results of similar studies (especially Peterson et al. *(13)*) that our results are strong enough to convince orthopedic surgeons with positive value of the early ORIF treatment for open malleolar ankle fractures.

CONCLUSION

Immediate ORIF for open malleolar ankle fractures is an alternative treatment option to the standard two stage treatment involving delayed ORIF. Our results show that immediate ORIF does not carry increased risk regarding the deep infection, or the wound healing compared to the delayed protocol.

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