

1 The outcomes of pilon fracture treatment: Primary open reduction and internal fixation versus two-
2 stage approach

3 **Abstract**

4 **Introduction:** Pilon fracture is one of the challenging injuries in orthopaedic surgery. Associated
5 soft tissue injury is important factor in choosing treatment options. Two major method of treatment
6 are one stage open reduction internal fixation (ORIF) and two stage treatment (primary external
7 fixation and secondary ORIF). The latter is most accepted in literature. In current study, we
8 compared the results of these two methods.

9 **Materials and methods:** In a retrospective study, 41 patients were assigned to two groups: one
10 stage primary ORIF (21 patients) group and two stage group included external fixation and
11 secondary ORIF (20 patients). The rate of infection (superficial or deep infection, osteomyelitis),
12 malunion, nonunion, duration of hospital stay, neurovascular injury, pain intensity, and patients
13 satisfaction with AOFAS score, were compared between two groups.

14 **Results:** There was no significant difference between two groups in measured variables except
15 hospital stay which was significantly longer in two stage group.

16 **Conclusion:** Based on our findings, we recommend using one stage ORIF in patients with pilon
17 fractures type C and Tscherne 1, 2 if the patient is planned to be operated on during the first 24
18 hours after the injury.

19 **Keywords:**Pilon fracture; two stage surgery; open reduction internal fixation; external fixation;
20 infection

21 **Introduction**

22 Pilon fracture accounts for 1% of lower extremity fractures and 5-7% of tibial fractures (1, 2).
23 Despite the fact that treatment of these fractures has developed a lot in recent years, it has remained
24 difficult and challenging due to the severely injured soft tissue, high-energy pattern of the fracture
25 and severe edema (2-4). Therefore, the choice of an appropriate treatment remains controversial
26 (5, 6).

27 Several options have been introduced for the treatment of pilon fractures namely close reduction
28 and casting, combined intramedullary nailing and plate fixation, open reduction and internal

29 fixation (ORIF), minimally invasive plate osteosynthesis, external fixation (EF), the two-stage
30 treatment with EF and then ORIF; each has its advantages and disadvantages (7-12).

31 In addition to controversies about the most superior treatment option, the appropriate time for
32 treatment of pilon fractures is also conflicting (13). Numerous authors have suggested the two –
33 stage approach including primary fixation with EF followed by definite internal fixation after soft
34 tissue healing, which is the most commonly used treatment for these injuries, especially for
35 AO/OTA type C pilon fractures (14-17). One of the drawbacks of this method is long-term hospital
36 stay and increased risk of infection and lack of anatomical reduction due to delayed operation (13,
37 18-20). For these reasons, some surgeons prefer to perform early primary ORIF which was
38 associated with good outcomes (21-23) especially in less severe fractures. But when the soft tissue
39 is severely injured, the patient must be hospitalized for a long time because of delayed wound
40 healing and superficial or deep infection which may necessitate several surgeries and even
41 amputation (23-27). These complications have been reported even in minimally invasive treatment
42 of pilon fractures (11).

43 There are limited studies comparing the outcomes of primary ORIF (PORIF) and two stage
44 approaches in treatment of pilon fractures resulted in conflicting outcomes (13). In current
45 prospective study, we aimed to compare the clinical, functional and radiologic outcomes and the
46 rate of soft tissue complications in treatment of pilon fractures with PORIF and two-stage
47 approaches.

48 **Methods**

49 In a retrospective study, all patients admitted with diagnosis of pilon fracture (AO/ OTA type
50 43.C) in Taleghani hospital (Shaheed beheshti university of medicine ,Tehran,Iran) between 2012
51 and 2014 were reviewed. Among them, 10 patients were excluded due to the open fractures (2
52 patients), rheumatoid arthritis (2 patients), concomitant fracture in the lower limb (2 patients),
53 severe soft tissue damage (Tscherne grade 3) (2 patients), varicose vein (one patient), and
54 compartment syndrome (one patient). Primary ORIF was used in 21 patients by the first author
55 and two stage treatment was used by the second author. After the usual preoperative clinical and
56 radiological examination (CT scanning and x-rays) eligible patients were asked to sign the
57 informed consent. Research process confirmed by Taleghani hospital ethics committee board.

58 The patients in PORIF group underwent surgery within the first 24 hours after the accident, using
59 anteromedial approach and medial distal anatomical plate and additional lateral plates if necessary
60 for pilon fractures and one-third tubular plates for fibula fracture. . In the two-stage group, the
61 fracture was fixated using a delta frame external fixator along with fibula fixation within 24 hours
62 after the accident (figure 1,2,3) Patients were discharged from hospital 24 to 48 hours after first
63 stage surgery according to patients clinical examination. The definite treatment (ORIF) was
64 performed after one to two weeks when the soft tissue inflammation resolved. (fig4).. The distal
65 articular surface of the tibia was reduced through anteromedial approach. Tibial metaphyseal
66 comminution was also fixated using medial distal tibial anatomical locking plate and lateral plates
67 if necessary

68 After the surgery, the same rehabilitation protocol was started for patients in both groups. Patients
69 were examined clinically at 2 weeks after discharge and Clinical and radiographic examinations
70 were performed at 4 weeks, 2, 3, 6 and 9 months post-surgery. VAS score and AOFAS score were
71 detected at the final follow-up. Partial weight bearing was allowed when the callus formation was
72 observed on x-rays. The patients were allowed for full weight bearing ambulation after complete
73 union. The union was defined as three bridging cortices in two orthogonal planes and lack of
74 feeling pain under manual pressure and the ability of full weight bearing walking. Patients were
75 followed for two years after the surgery.

76 The main outcomes measured included time of hospital stay (in staged ORIF group, sum of two
77 hospital admissions period) , deep and superficial infection, osteomyelitis, neurovascular
78 problems, nonunion and malunion. In this study, each soft tissue infection that was treated by oral
79 antibiotics and without the need for surgical intervention was considered as the mild infection,
80 while any soft tissue infection that required intravenous antibiotics or irrigation and debridement
81 was considered as a severe infection (12, 13). Nonunion was defined as the absence of clinical and
82 radiographic evidences for fracture healing after 9 months and the lack of healing process
83 progression for three consecutive months (12, 28). Any angulation more than 5° in the sagittal and
84 coronal planes was considered as malunion (12, 29).

85 At the final visit, patients were asked to rate their pain intensity using visual-analogue scale (VAS).
86 On this scale, 0 represented no pain while 10 represented maximal pain. In addition, patients
87 expressed their satisfaction level from the surgical outcomes with the same criteria in which 0

88 indicated dissatisfaction and 10 revealed the maximal satisfaction. The American Orthopaedic
89 Foot and Ankle Score (AOFAS) was completed in order to evaluate the functional outcomes of
90 treatment (30).

91 Data was analyzed using SPSS statistical software ver.16. Independent samples t-test or Mann-
92 Whitney U test were used in order to compare the quantitative variables between two groups. The
93 qualitative data was compared using Chi-square test or Fisher's exact test. $P < 0.05$ was considered
94 significance.

95 **Results**

96 The patients of both groups had no significant difference in terms of the age, gender, mechanism
97 of fracture and follow-up time (Table 1). Hospital stay of PORIF group was 8.3 ± 1.8 days versus
98 13.4 ± 2.6 days in Two-stage group. It was significantly shorter in PORIF group ($p = 0.027$) (Table
99 2). It was also found that pain intensity, satisfaction, and AOFAS were not significantly different
100 in both groups (Table 2). The incidence of fractures and surgical complications in both groups
101 were presented and compared in table 3. In our study, none of the patients developed severe
102 infection and osteomyelitis. Neurovascular injury was not occurred. Two patients in PROIF
103 group and four patients in two stage group developed mild superficial infections ($p = 0.41$). All
104 patients were treated with antibiotics. One patient in PORIF developed nonunion. However, the
105 incidence of all complications was similar in both groups (Table 3). Two patients in the two-stage
106 group and 3 patients of the PORIF group suffered from malunion but the rate was not
107 significantly different between two groups ($p = 1$).

108

109 **Discussion**

110 The most important finding of this study was that the clinical, radiographic, functional and
111 subjective outcomes of treating pilon fracture (type C) without severe soft tissue damage were the
112 same in both PORIF and two-stage methods.

113 Pilon fractures are of the most challenging injuries in orthopedic surgery. These injuries are very
114 difficult to treat that are often associated with less favorable results. Since these fractures are
115 usually caused by severe trauma and are associated with involvement of the articular surface, the

116 desired results are not achieved in many patients and many of them will have life-long struggle
117 with pain and discomfort of this problem.

118 Currently, appropriate method and timing for the treatment of pilon fracture is not yet clear. It is
119 assumed that high levels of infection and wound healing problems related to the surgery, is due to
120 the damaged and swollen soft tissue in these fractures (17,25,31). Therefore, a two-stage protocol
121 including maintaining the primary fibular length and external fixation of tibia and then delayed
122 ORIF during the improvement of the soft tissue was widely used (14-17).

123 In a retrospective study by Dickson et al it was found that the perfect articular reduction and
124 anatomical joint alignment were obtained in 81% and 96% of patients who were treated by a two-
125 step method, respectively. Radiographic studies revealed 28% of patients who had degenerative
126 changes. Postoperative complications were observed in 35% of patients, including loss of
127 reduction (11%), requirement for arthrodesis (11%) and amputation below the knee following
128 failed arthrodesis (3%) (14). Recently Lavini et al reported that using external fixator and ORIF
129 can be very helpful for improving the soft tissue. However, it is stated that maintaining the external
130 fixator after plate fixation had an important role in reducing the complications (32). Patterson et al
131 treated 22 pilon fractures and found that 77% of patients had good results. Additionally anatomic
132 reduction was achieved in 73% of patients. In this study, there was no case of infection or
133 complications in soft tissue (15). Sirkin et al also treated open and close pilon fractures with a two-
134 stage procedure and stated that the high rate of infection and soft tissue complications in patients
135 is due to the early ORIF while the soft tissue was damaged. In the study of Sirkin and his
136 colleagues, 17% of patients with close pilon fractures suffered from partial-thickness skin necrosis
137 and one another (3.4%) developed a chronic draining sinus secondary to osteomyelitis. All of these
138 patients were treated well. In the open fracture group, 10.5% had partial-thickness skin necrosis
139 and 10.5% had osteomyelitis, which in one case led to below-knee amputation (17).

140 In addition to prolonging the hospital stay and treatment period and consequently increasing the
141 financial burden, there is concern that delayed surgery be along with an increased risk of
142 complications such as infection or difficulty in achieving anatomical reduction (18-20). These
143 problems have caused some surgeons to consider PORIF for pilon fractures. White and his
144 colleagues treated 95 patients with pilon fractures using PORIF. 88% of patients underwent
145 surgery within the first 48 hours after the injury. Reduction was anatomical in 90% of them. Deep

146 infection or dehiscence required debridement had occurred in 6 patients (33). Additionally Chen
147 et al and Gao et al reported good results and few complications in the treatment of pilon fractures
148 with ORIF (22, 23). In the study of Li and his colleagues, the LCP plate with MIPO technique was
149 used in order to treat pilon fractures and the outcomes were very satisfactory. Superficial infection
150 was seen in only one patient (34). In another study, Paluvadi et al used MIPO technique and
151 concluded that MIPO led to an increased union time but this technique had important role in
152 reducing the rate of nonunion and infection. The superficial and deep infection had occurred in
153 10% and 2% of the patients (11). Richards et al compared ORIF and external fixation in the
154 treatment of pilon fractures and concluded that both techniques were associated with union of the
155 fractures, sufficient articular reduction and the same rate of infection. However, the early outcomes
156 seemed to be better in patients with ORIF group (10).

157 Despite recent advancements in medical science and technology, the treatment of pilon fractures
158 remains challenging and none of the available treatment methods can be considered as the gold
159 standard (1). Noteworthy the problem may be due to different design studies, several survey
160 methods and different statistical samples.

161 Bacon and his colleagues compared the results of two-stage method and definitive external fixation
162 and stated that although the period for fracture union was longer in two-stage group (1.39 to 5.24
163 weeks), but the rate of nonunion (16 % vs. 8.30%), malunion (8% vs. 1.23%) and infection (12%
164 vs. 5.38%) were higher in the external fixator group. However, differences were not statistically
165 significant between two groups. The authors noted that they couldn't comment on the superiority
166 of any of these methods and future clinical trials are needed (12). Blauth et al also compared
167 clinical and radiological outcomes of 51 pilon fractures treated with a) primary ORIF, b) minimally
168 invasive osteosynthesis for reconstruction of the articular surface and transarticular external
169 fixation for 4 weeks and c) two-stages method in a retrospective study. They found that
170 significantly none of the patients of two-stage group needed the arthrodesis. In addition, the range
171 of ankle motion and rate of return to the previous job were higher and pain intensity and the
172 limitations in leisure activities were lower in two-stage group. However, the differences were not
173 significant. Finally Blauth et al concluded that the treatment of pilon fracture with two-stage
174 method was preferable to other methods (35). In a recent study by Tang et al, it was revealed that
175 the incidence of superficial and deep infection, rate of union and mean of AOFAS were the same

176 in PORIF and delayed ORIF groups. However, the time for fracture union, duration of surgery and
177 hospitalization period were significantly shorter in the PORIF group (6).

178 In current study, we compared the results of PORIF and two-stage treatment of pilon fractures type
179 C without severe soft tissue damage (Tscherne type 3). In the two-stage group, ORIF delayed
180 between 7 to 14 days in order to soft tissue healing. Actually the goal of our study was that whether
181 the use of two-stage method can improve outcomes and prevent complications such as infection
182 effectively or not? No patient was found with severe infection or osteomyelitis, and although the
183 rate of mild infection was higher in the two-stage group but the difference was not statistically
184 significant. Nonunion had occurred in one case in the PORIF group who was hospitalized in the
185 psychiatric hospital and did not cooperate with the treatment that likely played an important role
186 in the occurrence of nonunion. Two patients in the two-stage group and 3 patients of the PORIF
187 group suffered from malunion. The results of subjective evaluation (pain intensity and satisfaction)
188 were similar in both groups. It should be noted that in overall the intensity of the persistent pain
189 was high in both groups and many of the patients required different painkillers resulted in low
190 satisfaction from the treatment outcomes. Based on the expectations, the duration of
191 hospitalization in the two- stage group was significantly higher than PORIF group which was
192 pointed out in previous studies. This finding can play an important role in selecting the treatment
193 method based on the costs and creating a more favorable psychological environment for patients
194 and their relatives with earlier discharge.

195 Similar to all other studies, the current study also had its limitations. The number of the patients in
196 the studied groups did not seem enough and it is likely that if the number of patients increased, the
197 difference between the two groups was statistically significant in some variables. In addition, our
198 patients were followed for a short period and mid- and long-term results are needed. **We did not**
199 **compare articular surface reduction and it is recommended for future researches.**

200 **Conclusions**

201 Treatment of type C AO-OTA pilon fractures in patients with Tscherne grade 1, 2 of soft tissue
202 using PORIF or two-stage method including primary external fixation and delayed ORIF was
203 associated with the same clinical, radiological, functional and subjective outcomes. Furthermore,

204 the rate of complications was the same. Therefore, given the shorter hospital stay, the authors
205 recommend using PORIF in treatment of pilon fractures without severely damaged soft tissue.

206 **Disclosure**

207 The authors report no conflict of interest concerning the materials or methods used in this study
208 or the findings specified in this paper.

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