RESEARCH ARTICLE

Comparison of Temporary External Fixation and Open Reduction with Internal Fixation for the Management of Pilon Fractures: A Short-Term Outcome Prospective Clinical Trial

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Abstract

Objectives: Pilon fractures are among the difficult injuries to treat in orthopedic surgery. We aim to evaluate the feasibility, advantages, and disadvantages of temporary external fixation for pilon fractures and compare its outcomes with cases managed with internal fixation and primary open reduction.

Methods: In a prospective trial, 30 patients were divided into two cohorts: a two-stage cohort with external fixation and secondary ORIF (15 patients) and a one-stage primary ORIF cohort (15 patients). We compared the two cohorts' rates of infection (deep or superficial infection), non-union, malunion, length of hospital stay, patient satisfaction with the American Orthopaedic Foot and Ankle Society (AOFAS) score, and pain level.

Results: All assessed variables showed no significant variations between the two cohorts, except for hospital stay duration, which was substantially more prolonged in the two-stage cohort.

Conclusion: This study demonstrates that both temporary external fixation with secondary ORIF and primary ORIF are viable options for managing pilon fractures. While there were no significant differences in complications between the two treatment modalities, the two-stage approach was associated with a longer hospital stay. These findings suggest that primary ORIF may be preferable when aiming to reduce the duration of hospitalization without compromising clinical outcomes.

Level of evidence: II

Keywords: External fixation, Infection, Open reduction internal fixation, Pilon fracture, Two-stage surgery

Introduction

Pilon fractures are responsible for 1% of lower limb fractures and 5-7% of tibial fractures,[1] which often involve severe soft tissue damage and high-energy fracture patterns. The optimal management of pilon fractures remains controversial, largely due to concerns about complications from early surgical intervention, such as infection and wound complications, particularly when performed through compromised soft tissue.[2,3]

Historically, the treatment of pilon fractures has evolved from immediate open reduction and internal fixation (ORIF) to a more staged approach that includes temporary external fixation followed by delayed definitive fixation.[4,5] This change aimed to reduce soft tissue complications by allowing initial soft tissue recovery. However, there is still debate over the effectiveness of this two-stage approach compared to primary ORIF in terms of overall outcomes and complication rates.[4,6]

The current literature lacks consensus on the best treatment strategy for pilon fractures, particularly regarding the use of temporary external fixation versus primary ORIF. Most studies focus on radiological outcomes and complications, leaving a gap in understanding the associations between baseline factors and functional outcomes and if there is any difference with these different approaches.

This prospective randomized comparative study aims to between temporary external fixation for pilon fractures and compare them with cases that will be managed with primary ORIF by evaluating the primary outcome in the form of radiological union, and the secondary outcomes

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are complications, range of motion, hospital stay, operative time, and quality of reduction within a short-term follow-up period of 6 months.

Materials and Methods

This prospective randomized comparative study included 30 patients admitted to our university hospital with closed pilon fractures with an AO classification of 43B or 43C from January 2021 to July 2021 and randomly divided into two cohorts (A and B). Our institution is a university hospital, the largest tertiary referral center in Egypt, handles a very high patient flow. As the primary medical facility in the region, we receive a significant number of complex cases. Patients were randomly assigned to either the two-stage cohort (temporary external fixation followed by secondary ORIF) or the one-stage primary ORIF cohort using a computer-generated randomization sequence. Randomization was conducted in blocks of four to ensure equal allocation to each group. The allocation sequence was concealed using sealed, opaque envelopes, which were only opened after the patient's consent was obtained and the patient was ready to undergo the assigned treatment. This method ensured that the allocation was random and concealed, minimizing selection bias and maintaining the integrity of the randomization process. Cohort A underwent primary ORIF, while cohort B underwent temporary external fixation and then secondary ORIF. The ethical committee accepted the performance of the study, and informed consent was taken from all the patients. All patients or their caregivers provided written informed consent. All patient data was kept private, using each patient's secret codes and individual files. All data provided was exclusively for current medical research. Patients were followed up clinically and radiologically; the follow-up duration was six months.

The inclusion criteria for this study were as follows: adult patients aged 18 years or older, of both sexes, with an acceptable skin condition (Up to Tscherne grade 2) to perform open incisions who presented with a pilon fracture. All participants met these criteria to ensure a consistent and comparable cohort for assessing the outcomes of the two different treatment modalities.

The exclusion criteria for this study included patients who refused to participate after the risks and benefits were explained, those with pre-existing infections, and patients with a history of peripheral angiopathy and/or neuropathy in the injured leg. Additionally, individuals with open fractures, compartment syndrome, pathological fractures, or associated knee ligament tears were excluded. These criteria were established to minimize confounding factors and ensure the safety and accuracy of the study outcomes.

The primary radiological outcome assessed was union which was determined by union of at least 3 out of 4 cortices from 2 orthogonal radiographs, while malunion and the quality of reduction, post-operative complications, range of motion, hospital stay, operative time and quality of reduction were the secondary outcomes. The operative time data in this study refers specifically to the final procedure in the two-stage cohort, namely, the definitive ORIF surgery. The rationale for this choice is that the temporary external fixation procedure is typically performed as an emergent stabilizing measure and is not directly comparable in complexity or duration to the definitive ORIF procedure. By focusing on the final procedure, we aim to provide a consistent basis for comparison between the two cohorts.

Based on the fracture pattern and energy involved, we used the Oestern and Tscherne soft tissue grading system to categorize and predict the level of soft tissue injury associated with fracture trauma.[7] The Müller AO Classification of Fractures is a methodology for categorizing injuries based on the prognosis of the functional and patient's anatomical outcome, first published in 1987 by the AO Foundation.[8] We used the AO classification to categorize the included fractures.

ORIF procedure

The period from the time of injury to the surgery was one to two days, while in the cohort of patients managed with secondary (ORIF) was seven to twenty-one days. Prophylactic antibiotic was administrated to the patient thirty minutes before the application of the tourniquet. Several approaches were used for this goal. They may be divided into two cohorts: 1) anterior (medial, anterolateral, anterior, anteromedial, and lateral); 2) posterior (posteromedial and posterolateral). In our study 5 patients needed combined approaches of anteromedial and posterolateral approaches, while 10 only needed an anteromedial approach. According to the fracture, incisions were used alone or in conjunction with one another. In our study, we had the following sequential elements for successful surgical reconstruction of a pilon fracture as follows:

- Restoration of the fibular length only in the cases who had not comminuted fibula.
- Reconstruction of the metaphyseal shell and bone grafting.

Fibular fixation was the first procedure in the ORIF technique. Eight patients in the ORIF group had Fibular fractures of which all were fixed, while six fibular fractures were reported in the two-stage group of which all necessitated fixation as well. Using a 3.5 reconstruction plate or a 3.5 mm one-third tubular plate, plate osteosynthesis of the fibula was performed through a lateral, posterolateral, or anterolateral incision.

Fibular reduction and fixation restored the length and alignment of the lateral column and reduced the anterolateral and posterolateral fragments of the plafond still attached to the fibula, providing a guide for reducing the comminuted distal tibia. The anterolateral approach was used to expose the distal tibia and ankle joint capsule, allowing assessment of cartilage destruction and realignment of the articular surfaces. Misaligned and depressed articular surfaces were elevated, and bone defects were filled with iliac bone grafts in selected cases. After anatomical reduction was confirmed under fluoroscopy, temporary Kirschner wires were replaced with interfragmentary and cancellous screws. Buttress plates were applied as needed, and posterior malleolar fractures were stabilized with percutaneous Kirschner wires and lag screws. Throughout the procedure, careful handling of soft tissues was emphasized to promote healing and prevent complications [Figure 1].

The Temporary external fixation

In our study, 15 patients were managed by the two stages protocol in which they underwent temporary external

fixation, and after 7-21 days, they underwent open reduction and internal fixation in a similar technique to the other group [Figure 2]. The patients were chosen according to the previous criteria; history taking, counselling, general and local examination, and radiological evaluation, and all laboratory investigations were ordered. This cohort of patients was operated in the emergency 6-12 hours after arriving at the hospital. This surgical procedure involves the use of minimal tools, including motorized drilling, self-drilling, self-tapping stainless steel cortical screws, and quick closure clamps for rapid tightening without loss of reduction. Schanz screws were used to create gripping points on the tibial crest and medial heel bone, with careful placement to avoid neurovascular injury and iatrogenic fracture. Posterior pin placement helps balance the deforming forces of the triceps surae muscles, preventing equinus contracture and providing additional stability. Manual traction was applied to the exoskeleton base during ligamentotaxis to distract the joint and realign the fracture, with distraction maintained by tightening the clamps. Post-operative X-rays were performed to assess and document bone healing progress. The quality of reduction for intraarticular fractures was scored postoperatively using the radiological criteria of Burwell and Charnley.[9]

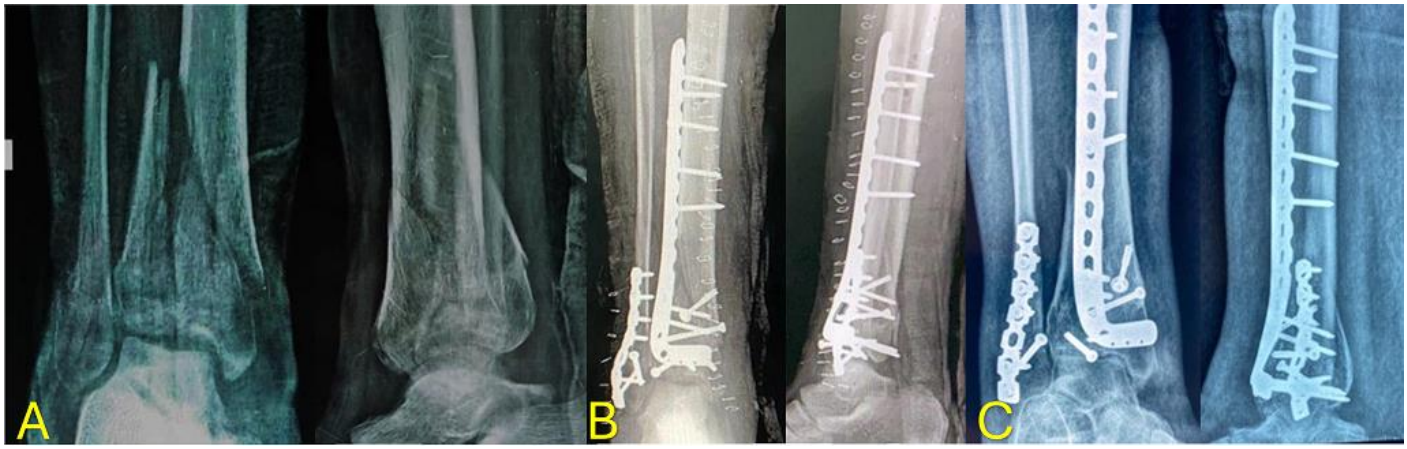

Figure 1. Radiographs from a patient from the ORIF group. In 1-A the radiographs show the preoperative xrays; in 1-B the x-ray shows an immediate post-operative x-ray while in 1-C the radiograph shows a 6-month follow-up x-ray of the same patient

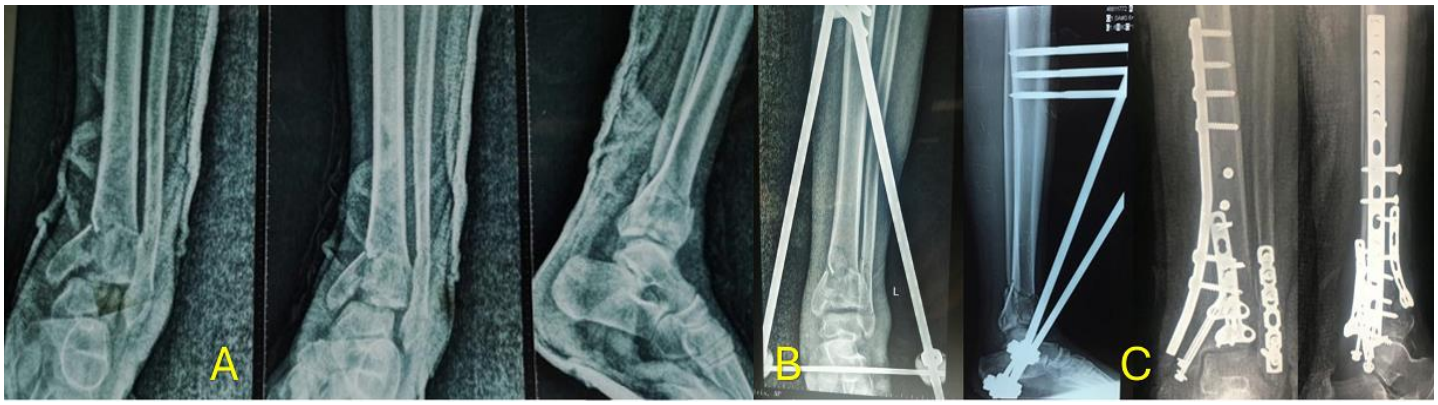

Figure 2. Radiographs from a patient from the two-stage group. In 1-A the radiographs show the preoperative xrays; in 1-B the x-ray shows an immediate post-operative x-ray with an exfix while in 1-C the radiograph shows a 6-month follow-up x-ray of the same patient after having been fixed with secondary ORIF

All patients received post-operative instructions that included a regimen of third-generation cephalosporin antibiotics (Ceftriaxone) administered intravenously, starting on the day of surgery and continuing for 48 hours. Anticoagulation treatment was also initiated and maintained until the patients reached the stage of partial weight bearing. In addition, patients were instructed to begin physiotherapy the day after surgery, focusing on quadriceps strengthening exercises and knee range of motion exercises to facilitate recovery.

Radiological outcomes were assessed to determine the success of the treatment and categorized as union, non-union, malunion, or delayed union. Union was defined as a typical, properly aligned bone union occurring within three months of surgical reduction. Non-union was identified if the fracture line remained visible without bridging callus six months after the initial injury, indicating a lack of bone union six months post-surgery. Delayed union was defined as a properly aligned bone union that occurred beyond the usual three-month period but within six months following

surgery. Malunion referred to a bone union that occurred but was never correctly aligned. Any case of delayed union, malunion, or non-union was considered a "poor radiological result."

Statistical method

The data were coded and entered using SPSS version 26 (I.B.M. Corp., Armonk, NY, U.S.A.). Mean and standard deviation (SD) were used to express the data for quantitative variables, and frequencies (the number of patients) and relative frequencies (percentages) were utilized to describe the data for categorical variables. Cohort comparisons were made using an unpaired t-test.[10] Using the Chi-square (X2) test, categorical data were compared. An exact test was applied when the anticipated frequency was less than 5.[11] Statistics were considered significant for P-values under 0.05.

Results

In our study, 30 patients were followed up and constituted the basis of this study. The follow-up period was six months. The two cohorts had no statistical significance variation in their demographic and baseline features. The demographics and baseline features of the patients that were included are displayed in [Table 1].

Table. shows the demographic characteristics of the population

Variables		Group A (primary ORIF)	Group B (two-stage)	P-value
Age (Mean ± SD)		30.27± 8.27	34.13 ± 11.82	0.317
Sex	*Male (N, %)*	10 (66.7%)	11 (73.3%)	1
	Female (N, %)	5 (33.3%)	4 (26.7%)	
History of diabetes	*Yes*	1 (6.7%)	2 (13.3%)	1
	No	14 (93.3%)	13 (86.7%)	
Smoking	*Yes*	5 (33.3%)	4 (26.7%)	1
	No	10 (66.7%)	11 (73.3%)	
Occupation	*Teacher*	1 (6.7%)	0	0.915
	Retailer	1 (6.7%)	0	
	Mechanic	1 (6.7%)	1 (6.7%)	
	Manual worker	0	2 (13.3%)	
	Housewife	4 (26.7%)	4 (26.7%)	
	Farmer	4 (26.7%)	3 (20%)	
	Driver	2 (13.3%)	1 (6.7%)	
	Delivery man	1 (6.7%)	2 (13.3%)	
	Carpenter	1 (6.7%)	2 (13.3%)	
Fracture type according to AO classification	*B2*	1 (6.7%)	1 (6.7%)	0.957
	B3	2 (13.3%)	2 (13.3%)	
	C1	3 (20%)	3 (20%)	
	C2	4 (26.7%)	3 (20%)	
	C3	5 (33.3%)	6 (40%)	
Oestern and Tschren soft tissue grading system	*1*	8 (53.3%)	6 (40%)	0.464
	2	7 (46.7%)	9 (60%)	
Degree of impaction (mm)		6.47± 1.96	6.87± 2.33	0.614

In our study, cohort B, which underwent two-stage surgeries, had longer hospital stays compared to cohort A, which had shorter stays with one-stage surgery [Table 2]. Operative times showed no significant difference between the cohorts. Fibular fixation was performed in any case with fibular fracture, with variations in the types of plates used, but without significant differences between cohorts in frequency (13 in the ORIF group and 12 in the 2-stage group) or in the fixation methods. Anatomic reduction was achieved similarly across both cohorts, with comparable radiological outcomes, including rates of union, malunion, and non-union. Functional outcomes, assessed by the patient-reported functional 100-point AOFAS score, showed no significant difference between cohorts. Range of motion (ROM) was similar, with most patients in both cohorts achieving ROM equal to the contralateral side. However, cohort A had a higher rate of soft tissue complications compared to cohort B, showing statistical significance. There

was no significant difference in arthritis incidence between the cohorts. Age did not significantly affect clinical outcomes such as AOFAS score, arthritis, union, or infection. A significant relationship was found between the degree of impaction and poorer outcomes, including delayed union and malunion. None of the cases that had arthritis required arthrodesis up until their follow-up period of 6 months. Two cases of non-union, one from each cohort had undergone revisional surgery to attack non-union. Two cases of deep infection in the primary fixation group had to undergo surgical debridement. The degree of soft tissue injury correlated with post-operative skin complications, particularly in patients with higher-grade injuries, and the anteromedial approach was associated with a higher rate of skin complications compared to the posterolateral approach. For detailed statistical data, please refer to [Table 2].

Table2. shows the postoperative evaluation of the patients

Variables		Group A (primary ORIF)	Group B (two-stage)	P-value
Total hospital stay (days)		3.53± 81.06	17.4 ± 2.26	0.001
Operative time (min)		187.73± 10.47	184.4± 16.33	0.511
Methods of fibula fixation	*Recon. Plate*	2	5	0.818
	1/3 semi-tubular plate	6	1	
	NO	7 (46.7%)	9 (60%)	
Usage of T plate	*Yes*	7 (46.7%)	9 (60%)	0.464
	NO	8 (53.3%)	6 (40%)	
Usage of the medial plate	*Yes*	6 (40%)	5 (33.3%)	0.705
	NO	9 (60%)	10 (66.7%)	
Usage of leg screws	*Yes*	4 (26.7%)	5 (33.3%)	1
	NO	11 (73.3%)	10 (66.7%)	
Quality of reduction according to the AO classification	*poor*	2 (13.3%)	2 (13.3%)	0.94
	fair	2 (13.3%)	2 (13.3%)	
	good	4 (26.7%)	2 (13.3%)	
	anatomic	7 (46.7%)	9 (60%)	
Union after 6 months	*union*	8 (53.3%)	8 (53.3%)	1
	malunion	2 (13.3%)	3 (20%)	
	delayed	4 (26.7%)	3 (20%)	
	Non union	1 (6.7%)	1 (6.7%)	
AOFAS at six months		81.67± 11.13	84.33± 6.78	0.435
ROM at 6 months	*Limitation <25%*	4 (26.7%)	4 (26.7%)	1
	Limitation>25%	3 (20%)	2 (13.3%)	
	Equal	8 (53.3%)	9 (60%)	
Arthritis after 6 months	*Yes*	5 (33.3%)	6 (40%)	0.705
	No	10 (66.7%)	9 (60%)	
Soft tissue complications	Yes	9 (60%)	5 (33.3%)	0.01
	No	6 (40%)	15 (66.7%)	

Discussion

Our study compared the outcomes of primary open reduction and internal fixation (ORIF) versus a two-staged fixation approach for pilon fractures. The optimal method for managing pilon fractures remains a topic of debate, as there is still no consensus on the gold standard for fixation.[12] The literature provides limited comparative studies on these two techniques, with existing reports yielding inconsistent results which highlights the need for further research and randomized controlled trials comparing primary fixation to two-staged fixation of closed pilon fractures.[13]

In our study, the two-staged fixation cohort exhibited a longer hospital stay compared to the primary ORIF cohort, similar with previous studies.[13,14] This prolonged hospitalization may raise concerns as increased healthcare costs, the heightened risk of hospital-acquired infections, and potential psychological distress for patients. However, these concerns were not prominent in our study, as the infection

rates in the two-staged cohort were significantly lower than those in the primary fixation group and treatment in our hospital was free of charge. The extended hospital stay in our two-staged cohort was largely due to the administration of prophylactic intravenous second-generation cephalosporins and antiedematous medications such as chymotrypsin and trypsin.

To address this in settings where longer hospital stay could be an issue, we propose patients with external fixators could be discharged home with proper post-operative instructions and close outpatient follow-up until they are ready for the second surgery. This approach would allow patients to be admitted shortly before the definitive procedure, potentially reducing the challenges associated with fracture reduction and addressing the financial and psychological burdens of prolonged hospitalization.

In our study, the primary fixation cohort had more soft tissue complications, such as superficial and deep infections, than the two-stage with (P = 0.01), which was considered a statistical significance variation between the two studied cohorts.

Wound infections in our study predominantly occurred in the anteromedial incisions, whereas the posterolateral incisions were less (P = 0.016). This finding may be attributed to differences in vascularity between the two sites and the longer exposure times associated with the anteromedial incision, which is often required to address the most complex aspects of the fracture.[15,16] In the primary fixation cohort, 60% (9/15) of patients experienced soft tissue complications, including two cases of deep infection requiring surgical debridement. In contrast, the two-staged fixation group had a lower incidence of soft tissue complications, with only 33.3% (5/15) of patients affected.

In the primary fixation cohort, a positive correlation was observed between soft tissue complications and the Oestern and Tscherne soft tissue grading system, with a higher incidence of complications in grade 2 injuries compared to grade 1. This supports the rationale for two-stage surgeries, allowing initial soft tissue recovery before definitive fixation.

A meta-analysis by Erichsen et al. reviewed nine studies that compared external fixation and primary ORIF in Pilon fractures. Seven of them documented superficial wound infections. It reported a 20% incidence of superficial infections in the external fixation cohort (32 out of 158 fractures) compared to 6% in the ORIF cohort (13 out of 218 fractures). The analysis concluded that the ORIF cohort had a lower prevalence of superficial wound infections. Regarding deep wound infections, eight studies reported 14 cases in the ORIF cohort (n=238) and 15 cases in the external fixation cohort (n=168). Meta-analysis revealed no significant variation in deep wound infection rates between the cohorts. This higher reported infection incidence with could be high due to some studies categorizing pin tract infections as wound complications, influencing the overall results, especially as some studies used the external fixator as a method of definitive fixation and didn't remove it until bone union occurred. Furthermore, eight studies documented nonunion rates of 9% (14 out of 155 fractures) in the external fixation cohort and 5% (13 out of 258 fractures) in the ORIF cohort, with no significant differences in incidence or heterogeneity between the groups. [17]

In their meta-analyses published in 2018, Cui et al. demonstrated that the superficial infection rate was sixteen cases per 142 cases in the two-stage ORIF cohort and 35 cases per 150 cases in the limited internal fixation combined with external fixation (LIFEF) cohort. The meta-analysis revealed no appreciable heterogeneity and a greater incidence of superficial infection in the LIFEF cohort. The deep infection rate was nine out of 139 fractures in the LIFEF cohort and 14 out of 142 fractures in the two-stage ORIF cohort.[18]

Similar to our findings, Sajjadi 2018 et al. found that pain intensity was not significantly different in both cohorts, and there were no significant variations in the two cohorts' satisfaction and AOFAS scores.[13]

Both Richards et al.[19] and Harris et al.[20] discovered that the external fixation cohort had significantly worse physical function scores than the ORIF cohort (P = 0.03) and (P = 0.002), respectively. The external fixation procedure was used more commonly in Arbeitsgemeinschaft für Osteosynthesefragen (AO) 43 C3 fractures. Several articles demonstrated that 43 C fractures frequently receive external fixation procedures, incorrectly associated with less favorable functional outcomes than ORIF. In our study, we reported that there was no statistical significance variation between cohorts with (P = 0.154) in the clinical assessment of union.

This study has its limitations; the small sample size of the analyzed cohorts may limit the generalizability of our findings. Additionally, mid- to long-term follow-ups are needed to assess additional long-term complications, such as post-traumatic osteoarthritis.

Conclusion

Based on the results from the present study, both primary ORIF and the temporary external fixation followed by secondary ORIF appeared to be comparable concerning the final range of ankle motion and hindfoot scores. Both had similar union rates and time to union. The variations were the post-operative soft tissue complications. The soft tissue complications were slightly higher in the primary ORIF cohort than those treated with the two-stage protocol. Moreover, the hospital stay was significantly longer in the two-stage protocol cohort than in the primary fixation cohort, with a statistical significance variation between the two cohorts. Soft tissue complications occurred in Type C AO fractures and in grade two soft tissue injury according to Oestern and Tschren grading system more than in grade one. Hence, in cases of type C pilon fractures with significant soft tissue compromise, a two-stage operation may offer benefits by minimizing soft tissue complications. However, larger randomized controlled trials are required to validate this approach and confirm its clinical efficacy. The authors advise employing primary ORIF in managing Pilon fractures without significantly injuring soft tissue because of the reduced hospital stay and less procedures. According to the authors, the study's resources, methodology, and conclusions were all used without

conflicts of interest.

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Declaration of Informed Consent: This study does not contain any identifiable personal information, images, or details that could identify the individuals involved. All data presented in this study have been anonymized to maintain participant confidentiality in accordance with ethical guidelines. Additionally, informed consent was obtained from all participants, where applicable, and the study was conducted in compliance with relevant ethical standards.

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