Comparison of surgical treatment methods in patients with closed tibia pilon fractures: A systematic review and meta-analysis of clinical and functional outcomes

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Abstract

Background: Previous studies comparing surgical fixation methods in patients with tibial pilon fractures have controversial results. This study aims to identify which surgical method provides the best clinical and functional outcomes in adult patients with closed tibial pilon fractures.

Methods: Databases including grey literature were searched for studies comparing surgical treatment methods in adult patients with closed tibial pilon fractures. PICO criteria were used to select studies. Statistical analysis was conducted with RevMan Version 5.4. The effect of compared methods was estimated using the mean difference, relative risk and corresponding 95% confidence intervals.

Results: Three RCTs and one cohort study met our inclusion criteria and were included in the meta-analysis. All studies compared External fixation combined with limited internal fixation (LIFEF) with Open reduction internal fixation (ORIF) and had an overall high risk of bias. There was no difference in superficial infection rates (p=0.55), but there was a marginal difference in osteomyelitis rates (p=0.07) and wound dehiscence (p=0.05), favoring LIFEF. Malunion and arthritis rates (p=0.53 and p=0.27 respectively) were similar. Finally, none of the two treatment methods offered a better functional score (p=0.53).

Conclusion: Both LIFEF and ORIF can be used in patients with closed tibial pilon fractures, when the condition of soft tissues allows. Overall, they offer similar early and long-term outcomes, however, patients treated with ORIF are in higher risk of developing osteomyelitis and wound dehiscence, as shown in this meta-analysis. More high-quality studies comparing treatment methods for tibial pilon fractures are needed, as treatment remains controversial.

Keywords: Tibial pilon fracture, Open reduction internal fixation (ORIF), external fixation with combined limited internal fixation (LIFEF)

1. Introduction

1.1. Background

Tibial pilon fractures are those of the distal tibia metaphysis involving the articular surface (plafond) [1]. They represent 1-10% of lower limb injuries and 5-7% of tibial fractures and occur more often in males between 35 and 40 years of age [1, 2]. They are usually high-energy injuries with axial compression, i.e. the talus impacts onto the tibial plafond, following road traffic collisions and falls from height, but they can also occur less frequently by a low-energy torsional mechanism of injury [3]. The amount of soft tissue injury, comminution and displacement is associated with the energy and mechanism of injury, thus high-energy pilon fractures are more demanding in management for the Orthopaedic surgeon [1-3].

Pilon fractures may vary significantly in injury patterns and presentation [1]. These are injuries highly associated with early and late complications affecting the ankle joint, therefore the selection and timing of surgical intervention is crucial to minimise these complications [1]. Moreover, it is usually the condition of the soft tissue envelope that defines the type and timing of surgery [12, 13]. This is the reason why there is no universally agreed method of treatment for these injuries [2]. Previous meta-analyses [4, 5] explored the clinical and functional efficacy of ORIF and LIFEF in the treatment of pilon fractures with controversial conclusions. Most of the studies analysed in these reviews are of low quality, often not separating patients.

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with open and closed injuries, hence readers should be careful in the interpretation of their results.

1.2. Aim and objectives
This study's aim was to identify the method of treatment that is more effective in terms of clinical and functional outcomes in adult patients with closed tibial pilon fractures. The objectives were to search the available literature for studies comparing treatment methods in patients with closed pilon fractures, evaluate the relevant studies and if possible, perform a meta-analysis of their results, identifying which method of treatment is superior in regard to clinical and functional outcomes.

2. Methods
This systematic review was conducted with the guidance provided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [8].

2.1. Literature search
The main databases searched were PubMed, EMBASE, Web of Science and the Cochrane Library, with no language restrictions. Additional sources were used to search for grey literature, including unpublished literature, conference papers and articles in languages other than English. References of each selected publication were manually searched for additional articles. Articles in non-English language were translated using the Babylon translator software. Keywords used for the search strategy included “pilon fracture”, “tibial pilon fracture”, “tibial plafond fracture”, “open reduction internal fixation”, “external fixation”, “limited internal fixation with external fixation”, “intramedullary nailing”, “Ilizarov” and “Ankle arthrodesis”, including MeSH terms and in various combinations.

2.2. Inclusion and Exclusion Criteria
All randomised controlled trials (RCTs) and non-randomised prospective or retrospective comparative studies were selected for eligibility check based on inclusion criteria formulated by the PICO framework:
1. Patients were adults aged 18 years and older, with closed tibial pilon fractures.
2. The experimental intervention used in the study was LIFEF.
4. Primary outcomes (clinical and functional) included bone healing time, nonunion, malunion, wound dehiscence, superficial infection, osteomyelitis, post-traumatic arthritis and functional score. Secondary outcomes included additional operations, length of hospital stay and cost of treatment.

Case reports, Case-Series and Review articles were excluded from the process. Also excluded were patients younger than 18 years of age and patients with open injuries.

2.3. Data extraction and quality assessment
Two authors extracted the data of selected studies independently, including study, patient and fracture characteristics, number of patients per intervention group and outcomes. The level of evidence for each study was assessed using the Center for Evidence-Based Medicine (Oxford, UK) rating scale [9] and the risk of bias was evaluated with the ROBINS-I [10] and RoB-2.0 [11] assessment tools for non-randomised and randomised studies respectively. Any differences in the search results were discussed and agreed between the authors.

2.4. Statistical analysis
The meta-analysis was performed using the Review Manager 5.4 software by the Cochrane collaboration [12]. Outcomes included in the meta-analysis were superficial infection, osteomyelitis, wound dehiscence/skin necrosis, malunion, post-traumatic arthritis and functional score. Dichotomous data were analysed using the risk ratio (RR) and continuous data using the mean difference (MD) with 95% confidence intervals (CI). Heterogeneity among studies was identified with the $I^2$ value, and if $>50\%$, the random effect model was used for the meta-analysis; if $I^2 < 50\%$, the fixed effect model was used. Sensitivity analysis was not performed as all the included studies were found to have the same quality.

3. Results
3.1. Literature search and characteristics of included studies
The search results and data screening are illustrated in Figure 1. A total of 1406 articles resulted from the search. After screening all the eligible articles, only 4 studies met the inclusion criteria [13-16]. These included three randomised controlled trials [13, 15, 16] and a prospective cohort study [14], published between 1996 and 2018. They involved a total of 184 patients with 184 fractures of the tibial pilon, treated either with ORIF (86 patients) or LIFEF (87 patients). The average patient age was 37.8 years of age (Table 1). No studies comparing LIFEF with other methods of surgical treatment were found to meet our inclusion criteria.

Table 1: Characteristics of included studies [13-16]

<table>
<thead>
<tr>
<th>Author – Year</th>
<th>Country</th>
<th>Design (LoE)</th>
<th>Patients (n)</th>
<th>Interventions compared</th>
<th>Age</th>
<th>Fracture classification</th>
<th>Type of fracture</th>
<th>Follow-up (months)</th>
<th>Results favored</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goluboviz et al., 2007 [14]</td>
<td>Serbia</td>
<td>Cohort (II)</td>
<td>47</td>
<td>LIFEF: 25 ORIF: 22</td>
<td>20-72 (45.8)</td>
<td>C1: 7* C2: 10</td>
<td>C</td>
<td>24</td>
<td>ND</td>
</tr>
<tr>
<td>Wang et al.,</td>
<td>China</td>
<td>RCT</td>
<td>56</td>
<td>LIFEF: 29</td>
<td>37.2 ±</td>
<td>B3: 2*</td>
<td>C</td>
<td>24</td>
<td>ND</td>
</tr>
</tbody>
</table>
### 3.2. Risk of bias of included studies

Figure 2 illustrates the risk of bias for the studies included in the meta-analysis. All four studies were found to have high risk of bias in the randomisation and allocation concealment processes, both of each introduced selection bias in the studies. Although none of the studies used blinding in the selection of participants, the three RCTs \(^{[13, 15, 16]}\) reduced performance bias by balancing co-interventions between the two groups. In contrast, there was a significant difference in co-interventions between the groups in the study by Goluboviz \(^{[14]}\), introducing performance bias. No blinding was used in outcomes assessment, however there was detailed explanation for some methods used, with objective criteria. Therefore, it is unclear how and at what point this may have introduced detection bias in the studies. The article by Wyrsch \(^{[13]}\) provided detailed data for each patient and there were significant differences in the fracture severity between the two groups, which introduced detection bias. Outcomes were available for all studies, but two studies \(^{[13, 14]}\) did not provide any statistical analysis.
3.3. Meta-analysis results

Post-operative complications: Three studies \cite{13-15} reported infection (superficial and osteomyelitis) rates post-operatively in a total of 131 patients and were included in the meta-analysis. Subgroup analysis was performed for superficial infection and osteomyelitis. The rate of superficial infection was 15 of 67 and 7 of 64, whereas the rate of osteomyelitis was 0 of 67 and 6 of 64 in the LIFEF and the ORIF groups respectively (Figure 3). Meta-analysis showed no difference in superficial infection between the two groups (RR 1.70, 95% CI 0.30 to 9.78, p=0.55), but the heterogeneity among the studies was significant ($I^2=58\%$). In contrast, the risk of osteomyelitis in the ORIF group was significantly higher than in the LIFEF group (RR 0.20, 95% CI 0.04 to 1.15, p=0.07) and there was no heterogeneity between the studies ($I^2=0\%$). Meta-analysis of the overall effect showed no difference between the two groups (RR 0.94, 95% CI 0.39 to 2.31, p=0.90) with acceptable heterogeneity ($I^2=47\%$). Skin breakdown/necrosis was reported in two studies \cite{13, 14}. The rate was 0 of 38 in the LIFEF group and 7 of 37 in the ORIF group (Figure 4). The meta-analysis favored LIFEF (RR 0.13, 95 CI 0.02 to 0.97) with no heterogeneity ($I^2=0\%$) and the result was statistically significant (p=0.05). Bone healing complications were mentioned in all four studies; however, meta-analysis was only feasible for malunion (Figure 5). Three studies with 145 fractures were included \cite{14-16} and no heterogeneity was identified ($I^2=0\%$). The rate of malunion was 6 of 74 and 4 of 71 for the LIFEF and ORIF groups respectively, with no difference between the two groups (RR 1.48, 95% CI 0.43 to 5.05, p=0.53). All studies were included in the meta-analysis for post-operative arthritis \cite{13-16}. 168 patients were analysed and the rate was 50 of 86 in the LIFEF group and 40 of 82 in the ORIF group (Figure 6). There was no difference between the two groups (RR 1.14, 95% CI 0.9 to 1.43, p=0.27) and heterogeneity was low ($I^2=2\%$).

Functional outcome: Functional or clinical score was reported in all studies, however only two were included in the meta-analysis \cite{13, 15}; the other studies \cite{14, 16} did not provide standard deviations and therefore were ineligible for statistical analysis. Heterogeneity was high ($I^2=71\%$) when analysing the overall functional score, but low ($I^2=0\%$) when looking at the number of good and excellent functional scores (Figure 7). There was no statistically significant difference in the mean functional score between the two groups (MD 4.88, 95% CI -10.31 to 20.07, p=0.53). The rate of good/excellent score was 18 of 48 and 18 of 38 in the LIFEF and ORIF groups respectively; the results did not favor any of the two methods of treatment (RR 0.93, 95% CI 0.60 to 1.44, p=0.74).
4. Discussion
No specific method of surgical treatment has shown to be superior over another in the treatment of tibial pilon fractures [3]. Due to the complexity in the management of these injuries, it is difficult to perform a well-designed high-quality study to evaluate which of the various treatment methods is more effective [3]. The two most recommended surgical interventions are ORIF and LIFEF, and previous meta-analyses have tried to identify which one offers the best clinical and functional outcomes [4-7]. However, the studies analysed in these reviews included both open and closed injuries, which may have affected the results. Therefore, the purpose of this review was first, to isolate the studies with closed injuries, and second, try to identify studies that compared LIFEF with other methods of surgical treatment. This is the first meta-analysis comparing different treatment methods in closed tibial pilon fractures.

4.1. Literature search and quality assessment
Literature search identified numerous studies comparing LIFEF with ORIF for tibial pilon fractures [13-36]. The majority were retrospective [17-19, 21-26, 28-35], with only five prospective
articles being identified, two cohort studies [13, 15, 16, 20] and four RCTs [13, 15, 16, 20]. Most articles included both open and closed injuries and their results were variable, with some favoring LIFEF [17, 20, 21, 31, 32, 35], some favoring ORIF [23, 27, 28] and some finding no difference between the two [18, 19, 22, 24-26, 29, 30, 33, 34, 36]. Only three studies [14-16] excluded open injuries from their analysis and were eligible for entry in this review; a fourth study [13] provided detailed data for each of their patients and therefore was also eligible for entry. Quality assessment was undertaken only for the included articles.

The study by Wysch et al. [13] is a multi-centre RCT, comparing patients with open or closed tibial pilon fractures treated either by ORIF or LIFEF. Although not corresponding to the initial inclusion criteria for this review, the authors provided detailed information for each of the patients independently, making it possible to exclude patients that did not fulfill our criteria. The randomisation technique described – ‘randomised surgeon design’ – was not equivalent to a true randomisation process. According to this, the on-call surgeon determined which patient would receive either ORIF or LIFEF. However, there were four EF surgeons and two ORIF surgeons, and the number of on-calls per surgeon was not provided, increasing the possibility of a patient to be allocated in the LIFEF group, hence introducing selection bias [37]. No blinding methodology was mentioned. No deviations from intended interventions were noticed and outcome data were available for all participants. However, this study has a major negative, as it did not provide any statistical analysis, and from the data provided, there was a significant difference in fracture severity numbers between the two groups, which may have affected the results. Description of outcome assessment was poorly detailed, and the clinical score used to assess function was created for this study, therefore it was not previously validated.

The article by Goluboviz et al. [14] is a prospective cohort study which included 47 patients with closed tibial pilon fractures treated at a single centre with ORIF or LIFEF. No eligibility criteria for entering the study were mentioned, introducing selection bias. Interventions were clearly defined, however details on surgeons involved were not reported, which reduced the study’s reproducibility. Due to the design of the study, randomisation was not performed and there was no information on how patients were allocated into each group. Demographic data were poorly mentioned and the difference between groups was not defined, allowing for confounding factors to influence the results [37]. Although no deviations from interventions were recorded, co-interventions were not balanced between the two groups, i.e. the LIFEF group received four days of antibiotics after surgery, whereas the ORIF group did not. No additional analysis was performed to reduce this performance bias [37]. There was some information on criteria used for outcome assessment, but there was no information provided about the assessors and no statistical analysis was conducted in this study.

Wang et al. [15] performed a single-centre RCT which compared ORIF and LIFEF in patients with closed tibial pilon fractures. Eligibility criteria for entry in the study were clearly defined and patients were assessed with CT imaging by two surgeons not attending surgery, on whether they could be treated by both interventions before entering the study. This reduced influencing bias, however, there was no description of how the assessment was performed and therefore the entry of participants could have been controlled. The randomisation process was questionable; odd and even numbers were used to allocate participants in each group. In addition, no blinding of patients was performed. The same surgical team performed all the interventions, which reduced inter-surgeon variability. No apparent imbalances were evident within patient characteristics among groups. Overall, selection bias was introduced before and during the randomisation process [37]. There were no deviations from intended interventions amongst groups and all the co-interventions, such as fibula fixation and antibiotic prophylaxis post-surgery, were balanced between the two groups, reducing performance bias [37]. Participants from both groups adhered to their original intervention and were analysed in the group they were assigned at randomisation. However, the methods described for outcome assessment were highly variable, and some may have been obscured by the fact that assessors were aware of the intervention performed (observer assessment bias).

Rayan et al. [16] performed a single-centre RCT, comparing ORIF with LIFEF in 42 patients with closed pilon fractures. They clearly provide their inclusion and exclusion criteria. The method of randomisation is questionable as they report it was performed by ‘flipping a coin’, introducing selection bias. Patients from both groups received the same pre-operative management and it was a single-surgeon study, thus reducing confounding factors. A clear intra-operative and post-operative plan is also reported. Outcome measures are detailed but results are in the vast majority insufficiently reported; however, there are no missing data.

4.2. Meta-analysis results

Post-operative complications concern most surgeons treating tibial pilon fractures, as they may lead to additional operations and increased morbidity. Infection is a particular problem affecting these patients. A subgroup analysis for superficial infection and osteomyelitis was performed, showing no difference in the superficial infection rates between the groups (p=0.55), corresponding to the findings of the individual studies [13-15]. However, heterogeneity was significant, probably due to different study designs and classification schemes, variables between patients (additional injuries, comorbidities) and differences in co-interventions [14], and hence the result should be interpreted with caution. In contrast, all studies showed higher rates of osteomyelitis in the ORIF group, which was reflected in the meta-analysis. The result was borderline not statistically significant (p = 0.07) with no heterogeneity between the three studies. The results could be explained by the extent of trauma during surgery; LIFEF causes minimal soft tissue injury and bone exposure, hence minimizing deep infection but increasing pin tract infection, whereas ORIF requires more surgical trauma, which carries a higher risk for deep infection/osteomyelitis [15]. The same applies for wound dehiscence, as confirmed by the result of the meta-analysis, which favored the LIFEF group (p=0.05). Among bone healing complications, meta-analysis was only feasible for malunion, the rates of which slightly favored the ORIF group, but with no statistically significant results (p=0.53). Wang et al. [15] also reported rates of delayed union favoring the ORIF group, but similar rates in time for union for both groups, confirmed by other studies [26, 33, 35]. Nonunion results are conflicting, with some reporting similar rates [15] and others favoring LIFEF [27]. With regards to arthritis, no method was found to be superior in the meta-analysis, corresponding to the findings of each of the studies [13-16]. The meta-analysis of functional outcomes showed similar results in the two groups, but with high heterogeneity, probably because of different clinical scores used to assess patients. Analogous results are confirmed by other studies not
included in the meta-analysis [21, 26, 30, 33], while other studies favored ORIF [27, 28] or LIFEF [32, 35].

4.3. Definitive management of tibial pilon fractures – the evidence

The treatment of tibial pilon fractures has advanced over the years due to the availability of new surgical concepts and technology, but still they remain challenging to treat [1, 2, 8, 38, 39]. Many strategies are reported in the literature, including ORIF; different types of EF (with or without minimal osteosynthesis, hybrid frames, Ilizarov frames) and minimally invasive techniques, in one or two operative stages [40]. Although there is controversy on which method is superior, most authors agree that it is the soft tissue envelope that determines the type and timing of surgery and that not all surgical methods are indicated for all patients [2, 39].

ORIF: Outcomes are variable after the use of primary ORIF for tibial pilon fractures; older studies report high rates of complications, especially for severe and open injuries [41-44], and hence this method still today, is not usually indicated at an early stage; instead it is preferred when the soft tissue condition is improved, usually during the 2nd week following the injury [3]. Despite that, more recent studies have shown acceptable results of soft tissue complications when primary early ORIF was used [45-49]. Moreover, minimally invasive plate osteosynthesis (MIPO) has gained popularity, as it uses a percutaneous technique with minimal soft tissue dissection and may reduce the rate of complications [50]. The reports vary however, with some authors favoring it [50], while others not finding any advantage by its use [51]. A combination of an anteromedial with a lateral approach is usually preferred [40], but Deivaraju et al. [52], found that overall, anterolateral plating was superior to medial plating in terms of bone healing complications. In addition, the routine use of locking plates in these injuries is questionable, as they do not seem to offer any advantage over non-locking plates [53].

External fixation: A wide range of EF constructs is reported in the literature [54]. Temporary ankle spanning EF has traditionally been used for reducing soft tissue swelling and allowing for assessment with CT scanning and definitive surgery planning [55]. Ramlee et al. [54] analysed the biomechanical properties of three types of bridging EF devices used in severely comminuted pilon fractures, suggesting that the Delta frame construct should be considered for these injuries, because of the higher stability it provides. Because more severe pilon fractures are difficult to reduce by ligamentotaxis alone, limited ORIF was introduced [3], and there have been numerous studies comparing the efficacy of this method compared to ORIF [13-35]. Other studies have introduced hybrid EF devices, which comprise of a partial ring in the epiphysis and conventional EF in the tibia diaphysis, sparing the ankle joint [3]. The results are promising as it is shown to provide good stability and allow early ankle mobilization [56], with some authors reporting better union rates – equal to ORIF – when comparing with conventional EF [57]. Lastly, several studies compared the efficacy of Ilizarov circular frames with other forms of fixation [58-62]. Bacon et al. [58] reported similar outcomes when using Ilizarov EF or ORIF, while Endres et al. [59] found the Ilizarov technique superior in bone healing and deep infection, but with high incidence of pin-tract infections. The functional score though, was significantly better when using circular frames [59. 60], especially in a hinged rather than a fixed position of the ankle joint [61].

Intramedullary nail (IMN): Only few studies have investigated the treatment of simple tibial pilon fractures with IMN [63-65]. Marcus et al. [63] reported low complication rates but emphasized in the need for high level of experience to produce great results. Other authors compared IMN with EF [64] or MIPO [65] and found comparable complication rates and functional outcomes, but still, this method of fixation is only suitable for highly selective patients with low-grade fractures and in the hands of very experienced surgeons.

Arthrodesis: Some studies consider primary arthrodesis for severely comminuted pilon fractures. Beckwitt et al. [66] reports a lower rate of nonunion and similar functional outcomes to ORIF in a relatively young cohort of patients with these injuries. They continue to conclude that performing primary arthrodesis in severely comminuted pilon fractures reduces the need for further operations. On the other hand, Haller et al. [67] suggest that ORIF should be even considered in patients over the age of 60, as they showed similar results in patients below and over 60 years. Therefore, arthrodesis should not be justified based on age alone.

4.4. Limitations and strengths of this review

The main strength of this review is the formulation of a clear scientific question using PICO criteria and the use of clear methods in order to deliver an answer. In contrast to previous meta-analyses [4, 7], an attempt was made to isolate the group of patients with closed injuries, because the management of open injuries differs significantly, and it has probably affected the results. Another important point is the search of grey literature and articles in non-English language, which identified one of the four studies included in the meta-analysis. However, there are limitations in this review, such as the small number and variation of patients, introducing heterogeneity in the meta-analysis of some outcomes, so the interpretation of the results should be thoughtful.

4.5. Implications for trauma care and future research

This review confirms that the literature on the management of tibial pilon fracture is inadequate. This is in part due to the relatively low incidence of the injury and the fact that high-quality studies such as RCTs are difficult to design and implement with such complex injuries. Because the management of these fractures largely depends on the severity of injury and the condition of the soft tissues, there is a need for carefully designed level I studies who will look at closed and open injuries independently, stratifying the patients according to severity of injury and soft tissue condition, taking into consideration additional factors such as comorbidities etc. To our knowledge, a large, multi-centre RCT comparing EF versus ORIF in closed pilon fractures is currently ongoing in the UK and the aim is to be completed by August 2022 [68].

4.6. Conclusion

The management of tibial pilon fractures remains controversial. This study aimed to identify which surgical method is more effective in adult patients with closed injuries. Four studies were eligible for entry in this review, all comparing LIFEF with ORIF. The meta-analysis showed no difference in the overall infection rates, malunion, post-operative arthritis symptoms and functional outcome between the two methods. However, the rate of osteomyelitis and wound dehiscence was higher in the ORIF group.
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None.

Conflict of interest
The authors declare that there are no conflicts of interest.

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