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Original article

Clinical efficacy and safety of limited internal fixation combined with external fixation for Pilon fracture: A systematic review and meta-analysis

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ABSTRACT

Purpose: To compare the clinical efficacy and complications of limited internal fixation combined with external fixation (LIFEF) and open reduction and internal fixation (ORIF) in the treatment of Pilon fracture.

Methods: We searched databases including Pubmed, Embase, Web of science, Cochrane Library and China Biology Medicine disc for the studies comparing clinical efficacy and complications of LIFEF and ORIF in the treatment of Pilon fracture. The clinical efficacy was evaluated by the rate of nonunion, malunion/delayed union and the excellent/good rate assessed by Mazur ankle score. The complications including infections and arthritis symptoms after surgery were also investigated.

Results: Nine trials including 498 pilon fractures of 494 patients were identified. The meta-analysis found no significant differences in nonunion rate ($RR = 1.60$, 95% CI: 0.66 to 3.86, $p = 0.30$), and the excellent/good rate ($RR = 0.95$, 95% CI: 0.86 to 1.04, $p = 0.28$) between LIFEF group and ORIF group. For assessment of infections, there were significant differences in the rate of deep infection ($RR = 2.18$, 95% CI: 1.34 to 3.55, $p = 0.002$), and the rate of arthritis ($RR = 1.26$, 95% CI: 1.03 to 1.53, $p = 0.02$) between LIFEF group and ORIF group.

Conclusion: LIFEF has similar effect as ORIF in the treatment of pilon fractures, however, LIFEF group has significantly higher risk of complications than ORIF group does. So LIFEF is not recommended in the treatment of pilon fracture.

Fractures which occur at the end of the tibial bone and often involve high-energy ankle joint injuries are commonly described as pilon fractures or plafond fracture, accounting for about 1% of lower limb fractures and 7%–10% of all tibial fractures.[1,2] Pilon fractures most often occur in the fall from a great height and accidents of high-energy axial compression violence, and low-energy rotation shear force when skating and falling over.[3–6] Due to the anatomic features of distal tibia, severe fracture and severe soft tissue injury, nonunion, malunion, delayed union and infections often occur after surgery.[7] Therefore, the treatment of pilon fractures remains challenging to orthopedic surgeons. However, orthopedic surgeons have reached a consensus that in the treatment of pilon fracture they should follow the principle of reconstructing the anatomic joint, restoring tibial alignment, providing fast soft tissue healing, and facilitate bone union, which helps to receive satisfactory ankle function.[8–10]

Generally, the most common used surgical procedures in the treatment of pilon fracture are open reduction and internal fixations (ORIF) and limited internal fixations combined with external fixation (LIFEF). Because ORIF can restore the anatomic structure of distal tibia, it has been regarded as a safe surgical procedure with good results. However, the extensive dissection of soft tissue might lead to increased complications, such as infection, skin necrosis, tensity wheal and other complications.[11–14] LIFEF has been widely used for pilon fracture in recent years, but results in poor restoration of articular surface and high rates of traumatic arthritis.[15–17] Each method has its own advantages and disadvantages, and the treatment for pilon fractures remains controversial. Therefore, we performed a systematic review and meta-analysis to study the

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clinical efficacy and complications of LIFEF in the treatment of pilon fracture compared with ORIF.

Materials and methods

Literature search

We searched electronic databases included PubMed, Embase, Web of Science, Cochrane Library and China Biology Medicine disc for studies which compared ORIF and LIFEF for the treatment of pilon fractures. The search terms were as follow: pilon fracture, platfond fracture, distal tibial fracture, external fixation, internal fixation, ORIF and LIFEF. Articles were searched from all years to December 2015. No language restrictions were used. In addition, we searched abstracts from conference proceedings, theses and reference lists of all identified studies for further relevant studies. The unpublished investigations were not involved.

Inclusion and exclusion criteria

We included articles with patients diagnosed with pilon fracture, and the intervention of LIFEF or ORIF in experimental group. All randomized controlled trials, non-randomized trials, prospective studies, cohort studies and retrospective studies were included in the present study. And there were no age and region restriction. Articles were excluded if they were editorials, case reports, author replies, reviews and comments. Studies that included other underlying diseases that could confound or interfere with the assessment of clinical efficacy and complications were also excluded. And those studies which did not report relative outcomes were also excluded.

Data analysis

Two authors assessed the included articles independently and used the "MINORS appraisal scores" to evaluate the risk of bias of included retrospective trials.[18] And other authors extracted relative data using a pre-designed data extraction form. All disagreements were resolved through discussion. The description of all outcomes we assessed were dichotomous data, and we extracted the number of events happened and the number of patients in each group, then we calculated the relative risks (*RR*) and 95% confidence interval (*CI*) for all results. We assessed the degree of heterogeneity between the included studies through visual examination of the combined data presented in the forest plots, and we tested the heterogeneity using a standard chi-square test. $p < 0.05$ was considered significantly different. We used RevMan 5.3 (Cochrane Collaboration, London, UK) to calculate all statistical tests and the risk of bias.

Results

Identification and selection of studies

A total of 933 articles (242 from Embase, 18 from Cochrane library, 276 from PubMed Medline, 347 from Web of Science, 35 from China Biology Medicine disc and 15 from other sources) were obtained from the initial search. All studies were selected strictly according to the criteria described. After 646 duplicates, 123 reviews, 3 conference papers, 33 case reports, 5 short surveys, 15 comments, and 2 editorials were removed. There were 106 studies for the full-text screening, and 97 studies were ultimately excluded because they were not pertinent to ORIF and LIFEF. Finally 9 trials were included in present study. The selection process and reasons for exclusion were summarized in Fig. 1.

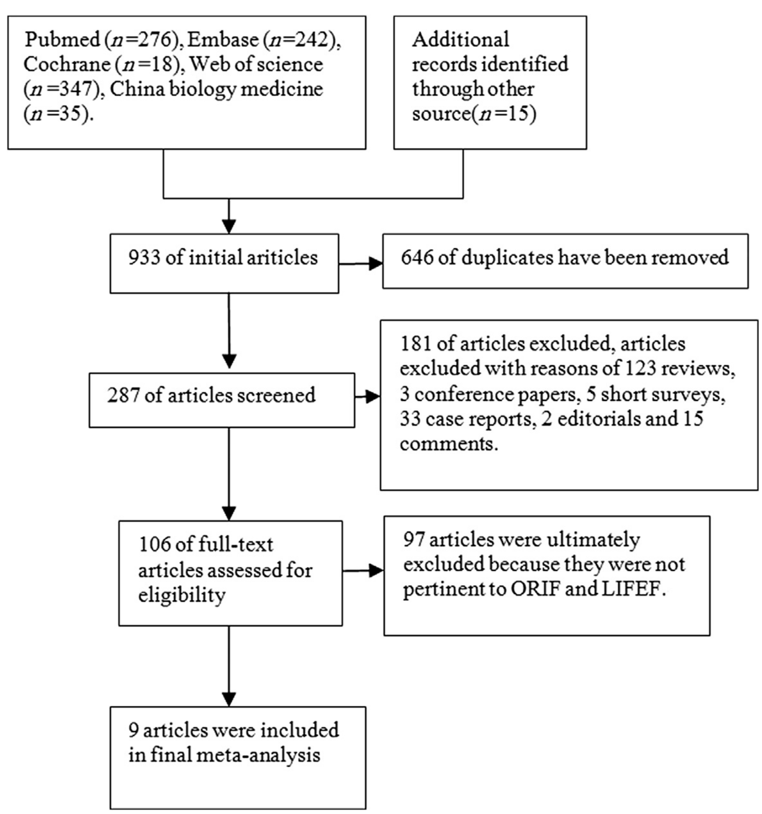

Fig. 1. Flow chart summarizing trials selection process.

Description and quality of studies

Nine articles directly comparing LIFEF and ORIF for the treatment of pilon fracture were included in this meta-analysis, including one randomized controlled trial (RCT),[19] one cohort study[12] and 7 retrospective studies.[15,20–25] Totally 498 fractures in 494 patients were included in this study, and all eligible patients were followed up for at least 12 months. The demographic characteristics of patients are summarized in Table 1. Methodological quality of RCT and non-RCT studies were evaluated with the "assessing risk of bias" tool of Cochrane and methodological index for non-randomized studies (MINORS) form, respectively. Results are summarized in Table 2.

Clinical efficacy of LIFEF

We evaluated the clinical efficacy of LIFEF in the treatment of pilon fracture by nonunion, malunion/delayed union and assessed excellent/good rate by Mazur ankle score.[26] For nonunion, 5 studies with 269 fractures were included.[12,15,19,21,22] The rate of nonunion was 9 of 106 in LIFEF group and 7 of 163 in ORIF group, respectively. The meta-analysis showed no significant difference in nonunion between 2 groups, the pooled *RR* was 1.60 (95% *CI*: 0.66 to 3.86, $p = 0.30$) and the heterogeneity among the studies was not significant ($I^2 = 0\%$) (Fig. 2). For malunion/delayed union, 4 studies[15,19–21] with 261 fractures reported the results of malunion/delayed union. The rate of malunion or delayed union was 19 of 92 fractures in LIFEF group and 13 of 169 fractures in ORIF group. The meta-analysis showed a significant difference in malunion/delayed union between 2 groups with the overall *RR* value was 2.52 (95% *CI*: 1.28 to 4.97, $p = 0.007$). LIFEF group had a higher malunion/delayed union rate than ORIF group did. The heterogeneity among the studies was not statistically significant ($I^2 = 0\%$) (Fig. 2). For excellent/good rate assessed by Mazur ankle score, 6 studies[12,19,20,22,24,25] with 350 fractures used the Mazur ankle score to assess the function of ankle after surgery. The excellent/good rate was 117 of 148 fractures in LIFEF group and 172 of 202 fractures in ORIF group, and the overall *RR* value was 0.95 (95% *CI*: 0.86 to 1.04, $p = 0.28$). The result showed no significant difference between 2 groups. The heterogeneity among the studies was not significant ($I^2 = 0\%$) (Fig. 3).

Complications of LIFEF

We assessed complications including infection and arthritis after surgery. For infection assessment, seven studies[12,15,19–23] with 370 fractures were included in this meta-analysis. The rate of deep infection was 32 of 142 fractures in LIFEF group and 20 of 228 fractures in ORIF group, the overall pooled *RR* value was 2.18 (95% *CI*: 1.34 to 3.55, $p = 0.002$), suggesting a significant difference between the two groups and a higher rate of deep infection in LIFEF group. The heterogeneity among the studies was not significant ($I^2 = 22\%$) (Fig. 4). And for arthritis, six studies[15,19–23] with 325 fractures were included in the meta-analysis. The rate of arthritis was 72 of 124 fractures in LIFEF group and 93 of 201 fractures in

Table 1
Description of the studies included in the meta-analysis.

Authors	Year	Case No.	Fractures	Age (years)	Gender (male/female)	Follow-up (months)
Davidovitch et al[15]	2011	20	21	43	12/8	12
		26	26	39	17/9	
Duan et al[23]	2014	12	12	23–67	7/5	36
		11	11	21–64	7/4	
Guo et al[20]	2015	26	26	41.2 ± 9.6	8/18	12
		52	52	40.7 ± 10.1	14/38	
Harris et al[21]	2006	16	16	57.6	7/9	26
		60	63	40.6	38/22	
Huang[25]	2013	33	33	36.5 ± 18.5	23/10	36
		43	43	35.5 ± 17.5	25/18	
Pan[24]	2013	22	22	40.5 ± 23.5	13/9	24
		31	31	41.5 ± 22.5	19/12	
Richards et al[12]	2012	27	27	46.96 ± 13.1	NR	12
		18	18	40.66 ± 13.3	NR	
Wang et al[19]	2010	29	29	37.2 ± 10.9	26/3	24
		27	27	40.1 ± 10.7	25/2	
Xiao et al[22]	2005	22	22	18–65	14/8	16
		20	20	23–54	12/8	

Table 2
Methodological index for non-randomized studies (MINORS) form in the meta-analysis comparing LIFEF and ORIF.

Authors	Year	Criteria												Total
		1	2	3	4	5	6	7	8	9	10	11	12	
Davidovitch et al[15]	2011	2	1	1	2	1	2	2	2	1	1	2	2	19
Duan et al[23]	2014	2	1	1	2	1	2	2	1	1	1	2	1	17
Guo et al[20]	2015	2	1	2	2	1	2	2	2	1	2	2	2	21
Harris et al[21]	2006	2	1	1	2	1	2	2	2	1	1	2	2	19
Huang[25]	2013	2	1	1	2	0	2	2	2	2	1	2	1	18
Pan[24]	2013	2	0	1	1	0	2	2	1	1	1	2	1	14
Richards et al[12]	2012	2	2	1	2	1	2	2	2	1	1	2	2	20
Xiao et al[22]	2005	2	0	1	2	0	2	2	1	1	1	1	2	15

The criteria included the following items: (1) a clearly stated aim; (2) inclusion of consecutive patients; (3) prospective data collection; (4) endpoints appropriate to the aim of the study; (5) unbiased assessment of the study endpoint; (6) a follow-up period appropriate to the aims of the study; (7) <5% loss to follow-up; (8) prospective calculation of the sample size; (9) an adequate control group; (10) contemporary groups; (11) baseline equivalence of groups; (12) adequate statistical analyses. Items were scored as follows: 0 (not reported); 1 (reported but inadequate); or 2 (reported and adequate). The ideal global score for comparative studies was 24.

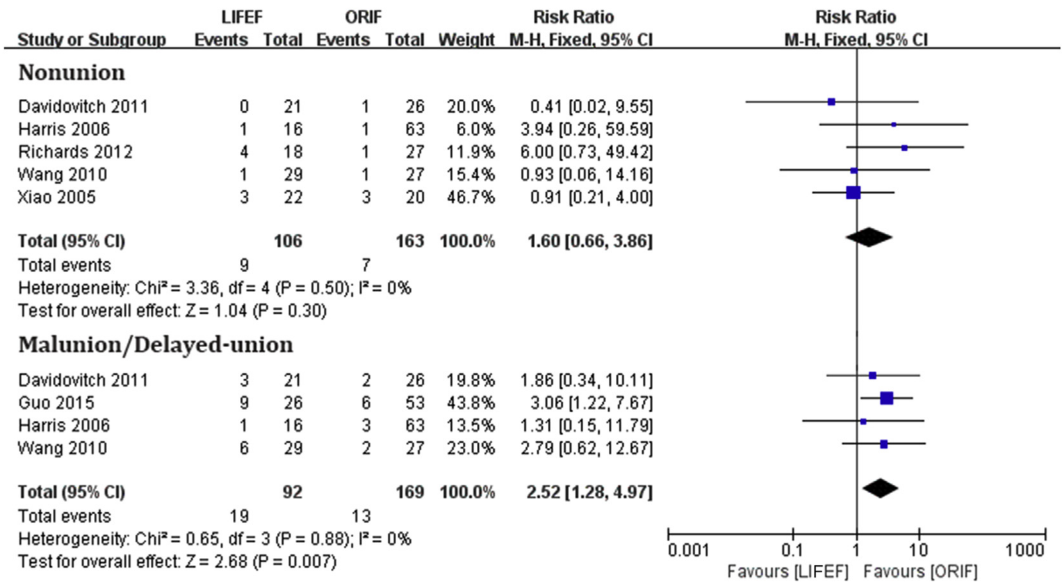

Fig. 2. Outcome of nonunion and malunion/delayed-union (LIFEF versus ORIF).

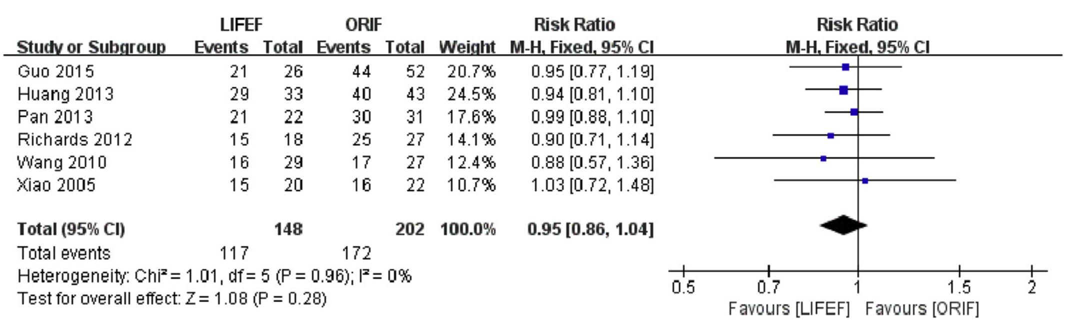

Fig. 3. Outcome of excellent/good rate by Mazur ankle score (LIFEF versus ORIF).

ORIF group, with the pooled *RR* value of 1.26 (95% *CI*: 1.03 to 1.53, $p = 0.02$), suggesting a significant difference between the two groups and a higher rate of arthritis in LIFEF group. The heterogeneity among the studies was not significant ($I^2 = 34\%$) (Fig. 5).

Discussion

Because of the complexity of fracture and severe soft tissue damage, the treatment of pilon fractures remains challenging to orthopedic surgeons. LIFEF and ORIF have been widely used in the treatment of pilon fracture in recent years, but the superiority remains controversial. Previous studies have reported varied results comparing ORIF and LIFEF procedures.[27] Thus, it is essential to conduct a meta-analysis to evaluate the clinical efficacy and complications of ORIF and LIFEF in the treatment of pilon fractures and provide references for orthopedic surgeons.

Ultimately, one RCT, one cohort study and seven retrospective studies has been included in this systematic review and meta-analysis. The overall outcome showed a difference between two methods. For clinical efficacy assessment, the outcomes showed no significant difference in excellent/good rate and the rates of nonunion, malunion/delayed union, the pooled *RR* value was 2.52

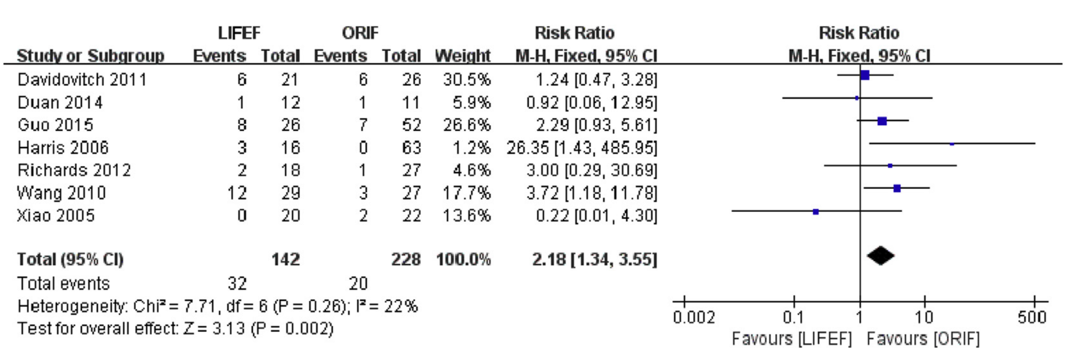

Fig. 4. Outcome of infections (LIFEF versus ORIF).

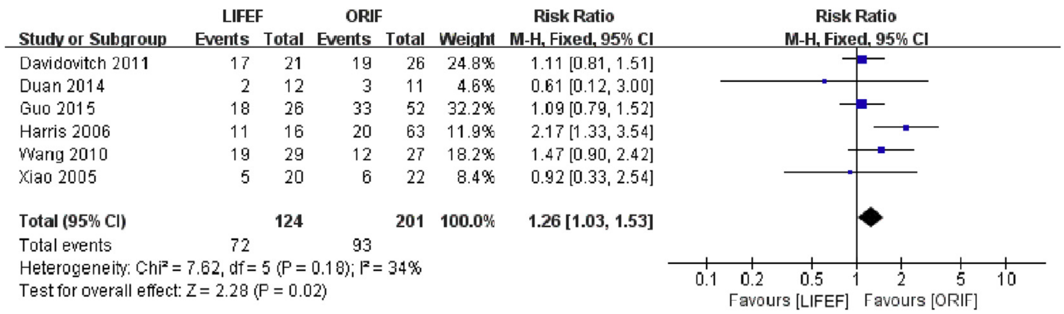

Fig. 5. Outcome of arthritis (LIFEF versus ORIF).

(95% *CI*: 1.28 to 4.97, $p = 0.007$), indicating a significant difference between the two groups. LIFEF group had a higher malunion/delayed union rate than ORIF group did. For assessment of complications, we analyzed infections and arthritis after surgery, the pooled *RR* value was 2.18 (95% *CI*: 1.34 to 3.55, $p = 0.002$), and 1.26 (95% *CI*: 1.03 to 1.53, $p = 0.02$), showing a significant difference between the two groups. These two complications were significantly more common in the LIFEF group than in the ORIF group, which was opposite to previous studies.[15,19,22]

There were several limitations in our studies. First, this meta-analysis was limited primarily because most of the studies included were retrospective studies, which were more likely to have various kinds of bias. To confirm these outcomes, more high-quality RCTs should be conducted. Second, subgroup analysis was not performed on different types of pilon fractures because of small sample size and different classification standards used in original studies. Third, confounding factors such as underlying diseases and the use of drugs may confuse the outcome, however, there was still no way to control these confounding factors and bias and no established method to assess how these confounding factors and bias affect the overall outcome. Furthermore, we did not analyze the skin necrosis and tensity wheal because of data deficiency.

Based on this meta-analysis, LIFEF has similar effect as ORIF in the treatment of pilon fracture, however, LIFEF group has a significantly higher risk of complications than ORIF group does. So LIFEF is not recommended in the treatment of pilon fractures.

Fund

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