

Review Article

Comparison of intramedullary nailing and plate fixation in treatment of distal extra-articular tibial fractures: a systematic review and meta-analysis

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Abstract: Background/Aims: Intramedullary nailing (IMN) and plate fixation were widely accepted to treat distal extra-articular tibial fractures. However, the ideal treatment for extra-articular tibial fractures remained controversial. We conducted a systematic review and meta-analysis to compare the efficacy and safety of intramedullary nailing versus plate fixation in patients with distal extra-articular tibial fractures. *Methods:* PubMed, EMBASE, Web of Science, EBSCO, and Cochrane library databases were systematically searched. Randomized controlled trials (RCTs) assessing the effect of intramedullary nailing and plate fixation on distal extra-articular tibial fractures were included. Two investigators independently searched articles, extracted data, and assessed the quality of included studies. The primary outcome were malunion and nonunion. Meta-analysis was performed using random-effect model. *Results:* Seven RCTs involving 480 patients were included in the meta-analysis. Overall, compared with plate fixation, IMN resulted in low and comparable incidence of malunion (RR=1.14; 95% CI=0.60 to 2.18; P=0.69), nonunion (RR=1.57; 95% CI=0.46 to 5.34; P=0.47), deep infection (RR=0.83; 95% CI=0.34 to 2.01; P=0.68), and infection (RR=0.59; 95% CI=0.25 to 1.40; P=0.23) in patients with distal extra-articular tibial fractures. And no significant difference of secondary operations (RR=0.90; 95% CI=0.67 to 1.21; P=0.48), hospital stay (Std. MD=-0.10; 95% CI=-0.48 to 0.29; P=0.62), delayed wound healing (RR=0.87; 95% CI=0.26 to 2.99; P=0.83), knee pain (RR=5.26; 95% CI=0.30 to 92.31; P=0.26) was found after the treatment of plate fixation and IMN. *Conclusions:* Compared to plate fixation, IMN showed low and comparable incidence of malunion, nonunion, deep infection and infection in patients with distal extra-articular tibial fractures. And there was no significant difference of secondary operations, hospital stay, delayed wound healing, and knee pain after the treatment of plate fixation and IMN.

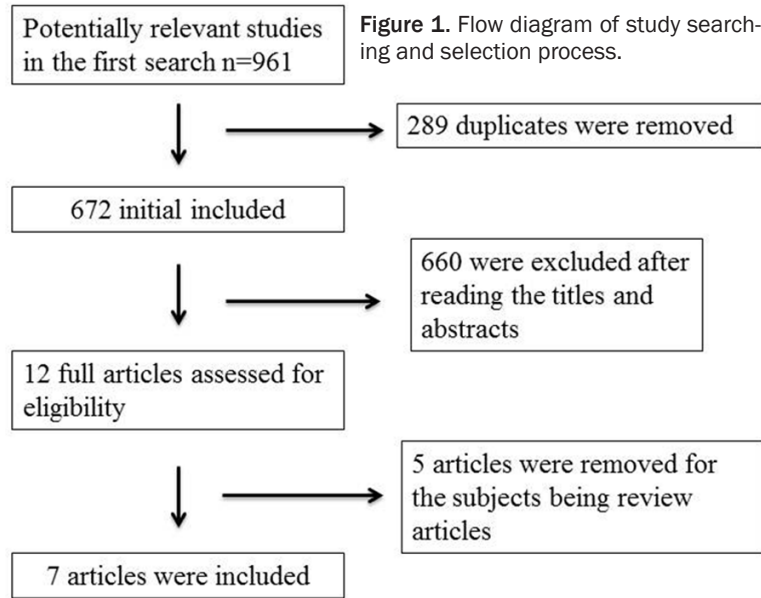
Keywords: Intramedullary nailing, plate fixation, distal extra-articular tibial fractures, efficacy, meta-analysis

Introduction

It was known that intramedullary nailing (IMN) was widely used to treat open and closed tibial diaphyseal fractures, but was limited by technically challenging reduction and stable fixation of distal extra-articular tibial fractures because of a large medullary cavity within a short distal fragment [1-3]. Nailing fixation frequently resulted in malalignment, malunion and knee pain [4-6]. Thus, novel nails and surgical techniques have been developed to solve this issue, and included multi-directional and angle-stable distal locking systems and locking screw holes at the tips of nails, and blocking screws to narrow the medullary cavity [7-9].

Open reduction, plate and screw fixation facilitated anatomic reduction and stable osteosynthesis, but soft tissue complications (e.g. wound dehiscence and infection) and disruption of vascularity could affect the union of fractures. And implant prominence frequently occurred after tibial plating [10-12]. Minimally invasive plate osteosynthesis (MIPO) technique, implants and instruments were performed through indirect reduction, small stab incisions without evacuation of the fracture hematoma, plate placement by sliding over the periosteum without disturbing the vascularity, and distal locking screws for stable fixation of the short distal fragment [13].

Comparison of intramedullary nailing and plate fixation



Currently, both IMN and plate fixation were the most commonly used treatment methods for distal extra-articular tibial fractures. Previous studies showed that IMN was associated with better clinical features compared to plate fixation, while several RCTs suggested that plate fixation technique resulted in better functional and clinical results [1, 10, 14-17]. Considering these inconsistent effects, we therefore conducted a systematic review and meta-analysis of RCTs to compare the efficacy and safety of IMN versus plate fixation for the treatment of distal extra-articular tibial fractures.

Materials and methods

This systematic review and meta-analysis were conducted according to the guidance of the Preferred Reporting Items for Systematic Reviews and Meta-analysis statement [18] and the *Cochrane Handbook for Systematic Reviews of Interventions* [19]. All analyses were based on previous published studies, thus no ethical approval and patient consent were required.

Literature search and selection criteria

PubMed, EMBASE, Web of Science, EBSCO, and the Cochrane Library were systematically searched from inception to December 2016, with the following keywords: intramedullary nailing or IMN, and plate fixation or plate osteosynthesis, and distal tibial fractures. No limitation

was enhanced. To include additional eligible studies, the reference lists of retrieved studies and relevant reviews were also hand-searched and the process above was performed repeatedly until no further article was identified. Conference abstracts meeting the inclusion criteria were also included.

The inclusion criteria were as follows: study population, patients with distal extra-articular tibial fractures; intervention, IMN; control, plate fixation; outcome measure, malunion, and nonunion; and study design, RCT.

Data extraction and outcome measures

The following information was extracted for the included RCTs: first author, publication year, sample size, baseline characteristics of patients, intervention of IMN, intervention of control, study design, malunion, nonunion, deep infection, infection, secondary operations, hospital stay, delayed wound healing, and knee pain. The author would be contacted to acquire the data when necessary.

The primary outcome were malunion, and nonunion. Secondary outcomes included deep infection, infection, secondary operations, hospital stay, delayed wound healing, and knee pain.

Quality assessment in individual studies

The Jadad Scale was used to evaluate the methodological quality of each RCT included in this meta-analysis [20]. This scale consisted of three evaluation elements: randomization (0-2 points), blinding (0-2 points), dropouts and withdrawals (0-1 points). One point would be allocated to each element if they have been mentioned in article, and another one point would be given if the methods of randomization and/or blinding had been detailedly and appropriately described. If methods of randomization and/or blinding were inappropriate, or dropouts and withdrawals had not been recorded, then one point was deducted. The score of Jadad Scale varies from 0 to 5 points. An article with

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Table 1. Characteristics of included studies

NO.	Author	IMN group						Plate group						Follow-up	Jada scores	
		Number	Age (years)	Male	Fracture type	Open fracture	Mean ISS	Number	Type	Age (years)	Male	Fracture type	Open fracture			Mean ISS
1	Polat 2015	10	34.0±9.7	9	42A1, A2, A3	-	-	15	MIPO	36.4±10.7	7	42A1, A2, A3	-	-	About 2 years	4
2	Li 2014	46	44	41	42A, B, C	17	-	46	MIPO	43	38	42A, B, C	14	-	About 14 months	5
3	Vallier 2012	45	41.0	37	42A, B, C	15	14.0	41	Standard large fragment medial plate	37.8	36	42A, B, C	15	12.6	About 22 months	4
4	Mauffrey 2012	12	50 (39-60)	7	-	0	-	12	Locking-plate	33 (24-43)	9	-	0	-	12 months	3
5	Vallier 2011	56	38.1	45	42A, B, C	21	12.6	48	Large fragment medial plate	38.5	40	42A, B, C	19	14.7	About 20 months	4
6	Guo 2010	44	44.2 (27-70)	26	43A1, A2, A3	-	-	41	MIPO	44.4 (23-69)	24	43A1, A2, A3	-	-	1 year	3
7	Im 2005	34	42 (19-65)	22	-	-	-	30	Anatomic plates	40 (17-60)	24	-	-	-	2 years	3

Intramedullary nailing (IMN), minimally invasive plate osteosynthesis (MIPO), Injury Severity Score (ISS).

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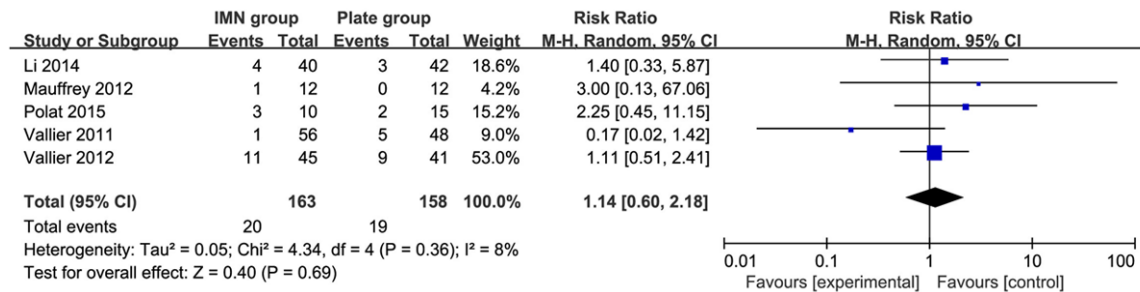


Figure 2. Forest plot for the meta-analysis of malunion. IMN: intramedullary nailing.

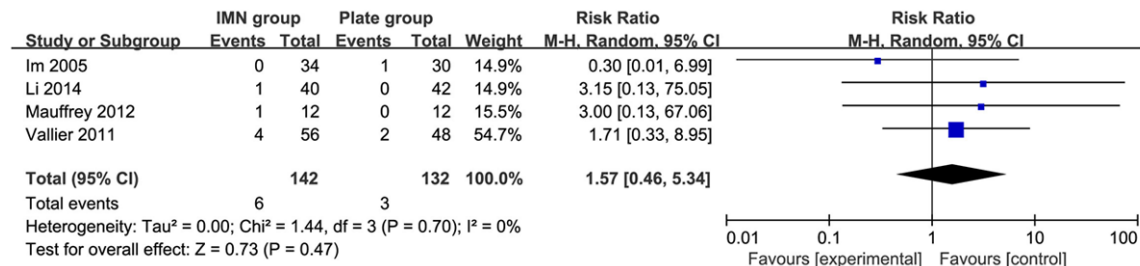


Figure 3. Forest plot for the meta-analysis of nonunion. IMN: intramedullary nailing.

Jadad score ≤ 2 was considered to be of low quality. If the Jadad score ≥ 3 , the study was thought to be of high quality [21].

Statistical analysis

Standard mean differences (Std. MDs) with 95% confidence intervals (CIs) for continuous outcomes (hospital stay) and risk ratios (RRs) with 95% CIs for dichotomous outcomes (malunion, nonunion, deep infection, infection, secondary operations, delayed wound healing, and knee pain) were used to estimate the pooled effects. All meta-analyses were performed using random-effects models with DerSimonian and Laird weights. Heterogeneity was tested using the Cochran Q statistic ($P < 0.1$) and quantified with the I^2 statistic, which described the variation of effect size that was attributable to heterogeneity across studies. An I^2 value greater than 50% indicated significant heterogeneity. Sensitivity analysis was performed to detect the influence of a single study on the overall estimate via omitting one study in turn when necessary. Owing to the limited number (< 10) of included studies, publication bias was not assessed. $P < 0.05$ in two-tailed tests was considered statistically significant. All statistical analyses were performed with Review Manager Version 5.3 (The Cochrane Collaboration, Software Update, Oxford, UK).

Results

Literature search, study characteristics and quality assessment

The flow chart for the selection process and detailed identification was presented in **Figure 1**. 961 publications were identified through the initial search of databases. Ultimately, seven RCTs were included in the meta-analysis [14-17, 22-24].

The baseline characteristics of the seven eligible RCTs in the meta-analysis were summarized in **Table 1**. The seven studies were published between 2005 and 2015, and sample sizes ranged from 24 to 104 with a total of 480. Their baseline characteristics were similar. The follow up time varied from 1 year to 2 years. Of these seven RCTs, five studies reported the malunion [14, 16, 17, 22, 23], four studies reported the nonunion [14, 16, 17, 24], four studies reported the deep infection [14, 16, 17, 24], five studies reported the infection [14, 16, 17, 22, 24], five studies reported the secondary operations [14-16, 22, 23], two studies reported the hospital stay [17, 22], two studies reported the delayed wound healing [14, 17], and three studies reported the knee pain [17, 22, 23]. Jadad scores of the six included studies varied from 3 to 5, all four studies were consid-

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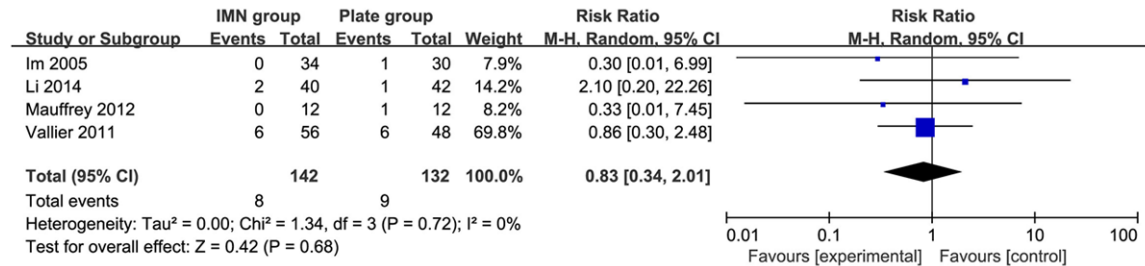


Figure 4. Forest plot for the meta-analysis of deep infection. IMN: intramedullary nailing.

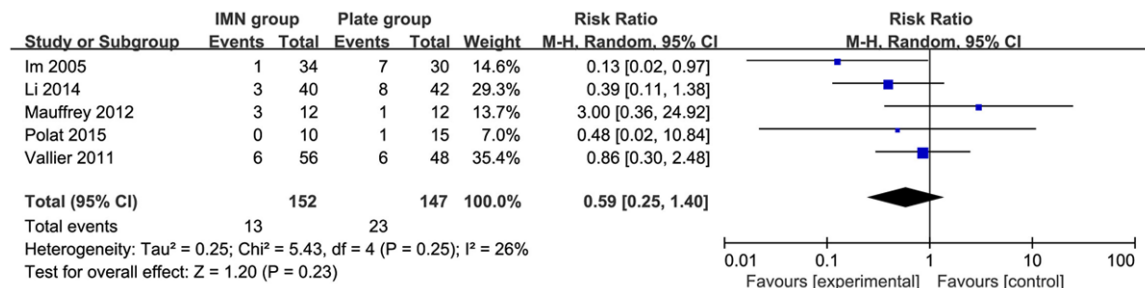


Figure 5. Forest plot for the meta-analysis of infection. IMN: intramedullary nailing.

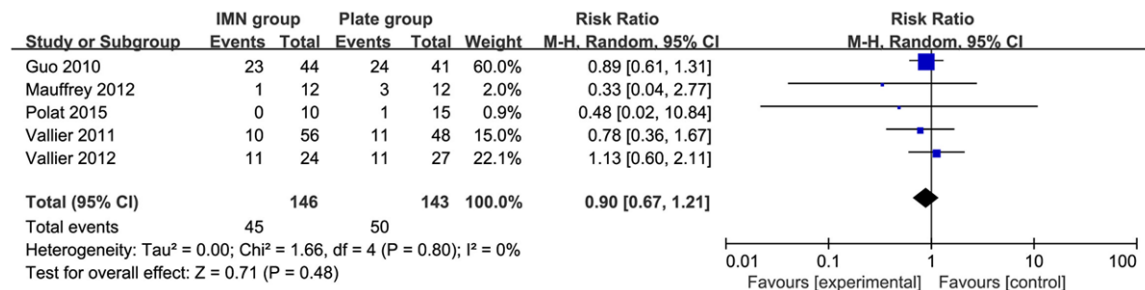


Figure 6. Forest plot for the meta-analysis of secondary operations. IMN: intramedullary nailing.

ered to be high-quality ones according to quality assessment.

Primary outcome: malunion and nonunion

These two outcome data were analyzed with a random-effects model, the pooled estimate of the five included RCTs suggested that compared to plate fixation, IMN showed low and comparable rate of malunion (RR=1.14; 95% CI=0.60 to 2.18; P=0.69), with low heterogeneity among the studies (I²=8%, heterogeneity P=0.36) (Figure 2). Consistently, there was low and similar incidence of nonunion between IMN and plate fixation (RR=1.57; 95% CI=0.46 to 5.34; P=0.47), with no heterogeneity among the studies (I²=0%, heterogeneity P=0.70) (Figure 3).

Sensitivity analysis

Low heterogeneity or no heterogeneity was observed among the included studies for malunion and nonunion. Thus, we did not perform sensitivity analysis by omitting one study in each turn to detect the source of heterogeneity.

Secondary outcomes

Compared with plate fixation, IMN resulted in low and comparable deep infection (RR=0.83; 95% CI=0.34 to 2.01; P=0.68; Figure 4), infection (RR=0.59; 95% CI=0.25 to 1.40; P=0.23; Figure 5). In addition, these two intervention showed similar secondary operations (RR=0.90; 95% CI=0.67 to 1.21; P=0.48; Figure 6),

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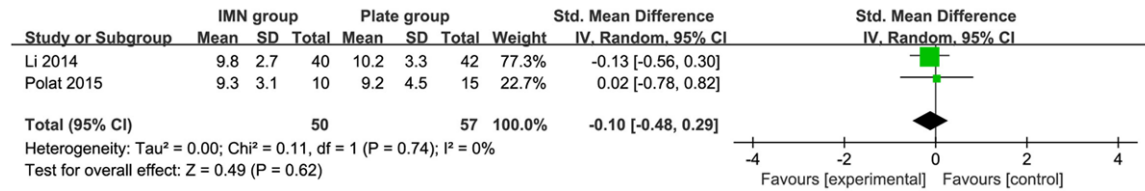


Figure 7. Forest plot for the meta-analysis of hospital stay (day). IMN: intramedullary nailing. Std. Mean Difference: standard mean difference.

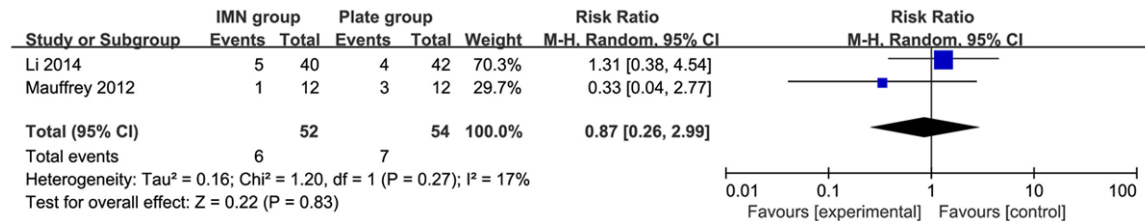


Figure 8. Forest plot for the meta-analysis of delayed wound healing. IMN: intramedullary nailing.

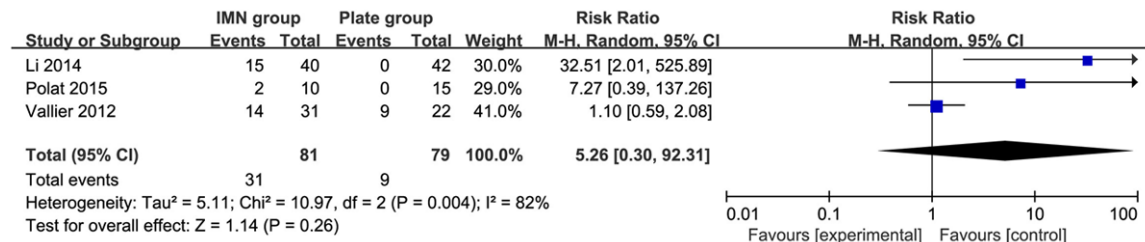


Figure 9. Forest plot for the meta-analysis of knee pain. IMN: intramedullary nailing.

hospital stay (Std. MD=-0.10; 95% CI=-0.48 to 0.29; $P=0.62$; **Figure 7**), delayed wound healing ($RR=0.87$; 95% CI=0.26 to 2.99; $P=0.83$; **Figure 8**), knee pain ($RR=5.26$; 95% CI=0.30 to 92.31; $P=0.26$; **Figure 9**).

Discussion

Distal tibial extra-articular fractures were defined as the location site between 4 and 12 cm from the tibial plafond and were challenging for orthopedic surgeons in terms of management. The ideal surgical approach for distal tibial extra-articular fractures was still controversial. Our meta-analysis clearly suggested that compared to plate fixation, IMN showed low and comparable incidence of malunion, nonunion, deep infection and infection. IMN and plate fixation resulted in similar secondary operations, hospital stay, delayed wound healing, and knee pain.

A meta-analysis and systematic review was performed to compare nailing and plating for

the treatment of distal tibial metaphyseal fracture, and the results showed higher functional score and lower risk of infection in the nailing group. But both RCTs and retrospective studies were included and there was no subgroup analysis [25]. In 2014, only four RCTs and four retrospective studies were included in one meta-analysis that showed no significant difference of superficial infection and deep infection between nailing and plate fixation [26]. One recent meta-analysis included only five RCTs and some retrospective studies, and results demonstrated that IMN was associated with a lower rate of delayed wound healing and superficial infection, and plate fixation could reduce malunion and knee pain. There was no significant difference of deep infection, delayed union, removal of instrumentation, or secondary procedures between these two interventions [27].

Our meta-analysis included up to seven RCTs for data analysis, and further confirmed that no significant difference of deep infection, delayed

union/nonunion, and secondary procedures was found between IMN and plate fixation. However, this meta-analysis demonstrated IMN resulted in a low and similar malunion, delayed wound healing, knee pain and hospital stay compared to plate fixation. Compared to the recent meta-analysis [27], another 2 RCTs with high quality were included in our meta-analysis [14, 22], and retrospective studies were excluded for analysis because the retrospective studies often overestimated the treatment effects due to selection bias.

In addition, MIPO and IMN were revealed to be equally effective in terms of functional outcomes (foot function index) [22]. Similarly, patients with distal tibial fractures achieved statistically similar American Orthopaedic Foot and Ankle surgery (AOFAS) scores after MIPO and IMN treatment [15]. MIPO and IMN were found to result in similar Mazur ankle score and equal functional outcomes in the treatment of distal tibial fractures [16]. However, MIPO was reported to have statistically less blood loss, less fluoroscopy time, shorter duration of operation and smaller incision length compared to IMN [22]. In this meta-analysis, plate group included MIPO, large fragment medial plate, locking-plate and anatomic plates, and it was not available to analyzing blood loss, duration of operation and incision length. More studies comparing IMN and MIPO were needed to focus on these indexes.

Several limitations should be taken into account. Firstly, our analysis was based on only seven RCTs and six of them have a relatively small sample size ($n < 100$). Overestimation of the treatment effect was more likely in smaller trials compared with larger samples. The follow-up time in the included studies varied from 1 year to 2 years, and longer follow-up time was needed to evaluate some index including malunion and nonunion. Different follow-up time and one or two level symptomatic degenerative disc diseases might have an influence on the pooling results. Next, MIPO, large fragment medial plate, locking-plate and anatomic plates were included in the plate group, and more studies were demanded to compare blood loss, duration of operation and incision length of MIPO and IMN. Finally, some unpublished and missing data might lead bias to the pooled effect.

IMN and plate fixation could achieve low and comparable risk of malunion, nonunion, deep infection and infection in patients with distal extra-articular tibial fractures. And there were similar incidence of secondary operations, hospital stay, delayed wound healing, and knee pain between these two interventions. Thus, the selection of ideal surgery treatment for distal extra-articular tibial fractures should be based on surgeon's expertise and experience. More studies with large sample were needed to compare the blood loss and duration of operation of MIPO versus IMN.

Disclosure of conflict of interest

None.

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