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Original Article

A clinical comparative study of intramedullary nailing and minimally invasive plate osteosynthesis for extra-articular distal tibia fractures

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Abstract: Introduction: The treatment of extra-articular distal tibia fractures is a difficult challenge. Minimally invasive plating osteosynthesis (MIPO) and intramedullary nailing (IMN) are satisfactory extra-articular distal tibia fractures. The optimal surgical treatment for extra-articular distal tibia fractures remains controversial. The purpose of this retrospective study was to compare the clinical and functional outcomes of patients with extra-articular distal tibia fractures treated with MIPO or IMN. Methods: For this retrospective study, a total of 266 patients with closed extra-articular distal metaphysis (AO type 43-A) or closed distal tibial fracture (AO type 42) were enrolled and included; 110 patients were treated with MIPO, and 156 patients underwent IMN. Results: There was no significant difference in the primary operation union rate, the American Orthopaedic Foot and Ankle surgery (AOFAS) score, deep surgical site infection or malalignment between the MIPO and IMN groups. However, there was a longer operation time, more prospective times, more intraoperative blood loss and more frequent anterior knee pain in the IMN groups than that in the MIPO group. There was a significantly shorter time to union in the IMN group than that in the MIPO group (138.8±11.0 vs. 153.5±17.1 days, $P < 0.05$) and a lower superficial surgical site infection in the IMN group than that in the MIPO group (1.9% vs. 8.2%, $P < 0.05$). Conclusions: We found that extra-articular distal tibia fractures can be treated satisfactorily with IMN or MIPO. Poller blocking screws have a main role in improving the efficacy of IMN. For patients with poor basic physical conditions or knee pain before fracture, MIPO is preferred to treat extra-articular distal tibia fractures. Whereas, for patients with poor local soft tissue conditions, IMN was recommended as a first choice.

Keywords: Extra-articular fracture, MIPO, IMN, functional outcome, distal tibia fracture

Introduction

The treatment of extra-articular distal tibia fractures is a hard challenge because of the peculiar anatomy of the distal tibia, paucity of soft tissue coverage, relatively poor blood supply and injury of bone and soft tissue often caused by high energy. Conservative treatment has a poor functional result and more late complications. The main purpose of operative treatment is to restore the anatomical alignment of the distal tibia and to provide sufficient stability, which promotes fracture healing and decreases late complications [1]. The traditional surgical treatment for distal tibia fractures using open reduction and international fixation (ORIF) has more serious soft tissue interference and larger blood supply destruction.

In recent years, some minimally invasive techniques, such as MIPO and IMN, have been reported to treat the distal tibia fractures [2-10]. Compared with ORIF, IMN and MIPO have been used preferentially for the management of these fractures because of minimal invasiveness, reduced blood loss during surgery, and lower surgical infection rate. Some studies [2-10] had reported their comparison results of the treatment of extra-articular distal tibia fractures by using IMN and MIPO. However, results of these studies are inconsistent and sometimes show the conflicting opinions. To date, there was no consensus on the choice of IMN or MIPO to treat extra-articular distal tibia fractures. Most studies suggested that IMN was associated with higher nonunion, a higher occurrence rate of anterior knee pain [11-14]

and a more obvious tendency towards malalignment [2-6], whereas MIPO technique was associated with higher rates of infection and implant-related complications [15, 16].

In recent years, the poller blocking screws technique is mastered by the surgeons and widely used in the treatment of metaphyseal fractures with IMN [17, 18]. These studies suggested that poller blocking screws technique of IM nailing reduces the incidence of both nonunion and malalignment. In our clinical practice, we also found that the poller blocking screws technique could reduce the malalignment, but also need more operation time and more radiation exposure risk. In the past 10 years, we have treated a large number of patients with extra-articular distal tibia fractures by using IMN and MIPO. Through a large number of cases accumulation and longer postoperative follow-up, we found that some of our opinions were different from those previously reported. Therefore, we think that it is necessary to show our study results in the treatment of extra-articular distal tibia fractures with IMN and MIPO.

Materials and methods

Inclusion and exclusion criteria

Distal tibial fracture was defined as a fracture involving the distal third, distal to the isthmus of the tibia, and 10 cm long region of metaphysis of distal tibia [19, 20]. For this retrospective study, patients with closed extra-articular distal metaphysis (OA type 43-A) or closed distal tibial fracture (AO type 42) who were treated in Xi'an Honghui Hospital from January 2016 to January 2021 were enrolled. The study was approved by the Research Ethics Committee of The Xi'an Honghui Hospital.

Patients were selected based on the following inclusion criteria: (1) age > 18 years; (2) duration of injury to operation < 2 weeks; (3) intact neurological and vascular status; (4) AO fracture classification belong to type 43-A or type 42; (5) fracture line locating in or extending to 10 cm long region of metaphysis of distal tibia; (6) treatment with IMN or MIPO.

Exclusion criteria included: (1) compound fractures; (2) multiple trauma; (3) pathological fractures; (4) open fractures; (5) diabetes patients with poor glycemic control; (6) less than 12 months follow-up; (7) follow-up information was incomplete.

Surgical technique and follow-up

The timing of the surgery was decided according to the status of the soft tissue and degree of swelling. If there are blisters or blood blisters on the skin, the operation is usually performed in 7 to 10 days. All the patients lay on the fluoroscopic operating table in a supine position. All patients received a single dose of 1.5 g cefuroxime sodium 30 mins prior to surgery as an antibiotic prevention. All patients received intravenous infusion of 1.5 g of tranexamic acid 15 mins prior to surgery to reduce intraoperative bleeding. All patients underwent surgery after application of a tourniquet at the root of the thigh.

MIPPO technique: An approximately 3-5 cm medial median longitudinal incision from the tip of the medial malleolus to the proximal end was made to prevent injury to the saphenous nerve and vein. The epiperiosteal tunnel was made either by a blunt periosteal detacher or by a blunt tip of a plate inserted through the incision towards the proximal. After traction, manipulation and reduction of the fracture, the distal tibial locking plate was positioned on the anteromedial aspect of the tibia shaft. For fractures with unsatisfactory manual reduction, pointed bone holding forceps or lag screw technology were used to help reduce fractures. After insertion of the plate and achieving reduction, the plate was fixed to the bone with a locking screw in the distal tibia and with a combination of cortical nonlocking and locking screws in the proximal tibia. The fibula was fixed when the fracture was within the syndesmosis region or the lower tibiofibular joint was unstable.

IMN technique: A medial longitudinal incision of the patella tendon of approximately 5-6 cm was made in the IMN group. After the patellar tendon was pulled to the outside, an entry portal was made in the anterior bare area of the tibial plateau. The entry point was confirmed in the C-arm with anteroposterior and lateral views. A guide wire was passed through the entry portal to the distal end of the tibia after provisional reduction of the fracture with pointed bone holding forceps. Sequential reaming was performed and fixed with suitable length IMN. The nail was fixed with 2 or 3 distal locking screws

and 2 proximal locking screws. In the IMN group, most patients needed 1 or 2 poller blocking screws to help reduce fracture, adjust the alignment or enhance the fracture stability. The fibula was fixed when the fracture was within the syndesmosis region or the lower tibiofibular joint was unstable.

Postoperative protocol

Prophylactic antibiotic therapy by intravenous administration of cefuroxime sodium (2nd generation of cephalosporin) was started during the surgery and continued until 24 hours after the operation. During the hospitalization period, all patients received low molecular weight heparin to prevent deep venous thrombosis. Rehabilitation exercises began from the first postoperative day, including quadriceps femoris training, ankle pump training and flexion and extension of adjacent joints. During the 2 weeks after the operation, a walking aid was used to assist in walking without weight bearing. Then, weight bearing was performed gradually based on the clinical and radiological improvements.

Data extraction, measurement and assessment

Operation time, perspective times by C-arm, and intraoperative blood loss in the two groups were extracted from the hospital's patient records. These data were used to evaluate the level of surgical difficulty and its impact on patients.

In our hospital, all patients were routinely followed up at 0, 4, 8, 12, 16, 20, 24, 32, 40, 48 and 52 weeks. The radiographs and clinical results extracted from the hospital's patient records were evaluated by all authors. Clinical union was defined as lack of pain in the full weight-bearing time. Radiological union was determined based on the modified radiological union scale for tibia (mRUST) score [21] in anteroposterior and lateral radiographs. A mRUST score of 10 or more than 10 was considered to accurately predict the healing of fractures [22, 23]. Nonunion was defined as a mRUST score less than 10 at the 12-month follow-up [23].

AOFAS scoring system [24] and occurrence of anterior knee pain associated with surgery were used to evaluate the function of the ankle and the effect of surgery on patient's knee function, respectively, at 12 months after operation follow-up examination by all authors.

Complication data including infection, malalignment (angular malalignment and rotational alignment) and nonunion were extracted from patient records. Rotational malalignment was defined as an iatrogenic rotational deformity of ≥ 10° based on clinical CT measurements [25, 26]. Angular malalignment was defined as angular deformities of ≥ 5° in the coronal or sagittal plane [6, 8, 27]. Surgical site infections (SSI) were divided into superficial surgical site infections and deep surgical site infections according to the definition of the Centers of Disease Control (CDC) [28].

Statistical methods

The statistical software package SPSS 18.0 was used to analyze the results. Descriptive statistics were provided for all baseline characteristics and study endpoints. Quantitative variables were documented as the mean ± standard deviation. Quantitative variables between the two groups were assessed by independent Student's *t*-test, while qualitative data between two groups were assessed by either the chi-square test or Fisher's exact test. A p value < 0.05 was considered statistically significant.

Results

Participants and characteristics

From January 2016 to January 2021, 266 patients with distal tibial fracture were included in the retrospective study; 110 patients were treated with MIPO, and 156 patients were treated with IMN. The mean follow-up time was 18 months (range 12-44 months). Baseline characteristics are described in **Table 1**. These characteristics were not significantly different between the two treatment groups.

The study results showed that there was a significant difference in operation time, perspective times by C-arm and intraoperative blood loss between the two groups (**Table 2**). Operation time in the IMN group was significantly longer than that in the MIPO group (109.8±18.4 mins vs. 81.8±12.6 mins). Perspective times by C-arm in the IMN group

Table 1. Main characteristics of the patients in the two groups

Characteristics	IMN (156)	MIPO (110)	*p* Value
Age	44.4±15.9	48.2±17.2	0.239
Sex (male)	93	72	0.370
Fracture type (AO type)			
AO-42	37	22	0.550
AO-43-A	119	88	0.550
Blister or blood blister	68	47	0.901

Table 2. Comparison of operation time, perspective times by C-arm and intraoperative blood loss between the two groups

Surgical data	IMN (156)	MIPO (110)	*p* Value
Operation time (min)	109.8±18.4	81.8±12.6	0.000
Perspective times by C-arm	39.6±10.9	26.1±8.7	0.002
Intraoperative blood loss (ml)	222.8±70.6	91.3±25.7	0.000

Table 3. Comparison of the clinical outcomes and main complications between MIPO and IMIL nailing groups

Clinical outcomes and main complications	IMN (156)	MIPO (110)	*p* Value
Time to union (day)	138.8±11.0	153.5±17.1	0.000
Primary operation union rate	144	105	0.446
AOFAS scores	87.3±7.7	86.3±6.9	0.057
Anterior knee pain	22	0	0.000
Malalignments	11	6	0.800
Deep SSI	1	1	1.000
Superficial SSI	3	9	0.031

were significantly more than those in the MIPO group (39.6±10.9 times vs. 26.1±8.7 times). Intraoperative blood loss in the IMN group was significantly greater than that in the MIPO group (222.8±70.6 ml vs. 91.3±25.7 ml).

Fracture healing and clinical results

The study results showed that there were significant differences in the time to union and occurrence of anterior knee pain between the two groups (**Table 3**). After excluding the data of patients with nonunion, time to union in the IMN group (138.8±11.0 days) was significantly shorter than that in the MIPO group (153.5±17.1 days). The X-ray image of the typical patient treated by IMN have been shown in **Figure 1**. The X-ray image of another typical patient treated by MIPO have been shown in **Figure 2**. Although the primary operation union rate (95.5%, 105/110) was higher in the MIPO group than that in the IMN group (92.3%, 144/156), there was no statistically significant difference between the two groups. Moreover, there was no difference in the AOFAS score between the two groups 12 months postoperatively (87.3±7.7 vs. 86.3±6.9) (**Table 3**).

Main complications

The study results showed that there were significant differences in nonunion and anterior knee pain between the two groups. All patients in the MIPO group had no anterior knee pain during the 12-month follow-up. However, 22 patients in the IMN group (14.1%) suffered from anterior knee pain during the 12-month follow-up. After the primary operation, there were 12 patients with nonunion in the IMN group and 5 patients in the MIPO group at 12 months postoperatively.

In total, 14 SSI were observed, 10 (9.1%) in the MIPO group and 4 (2.6%) in the IMN group. There were one deep SSI and 9 superficial SSI in the MIPO group. There were one deep SSI and 3 superficial SSI in the IMN group. The results showed that there was no significant difference in deep SSI rate between the two groups. However, the superficial SSI rate in the MIPO group (8.2%) was higher than that in the IMN group (1.9%). All infections in the two groups were treated with antibiotics, surgical debridement, removal of the implants or skin grafting.

Seventeen malalignments, including rotational and angular malalignment, were observed, 6 (5.5%) in the MIPO group and 11 (7.1%) in the IMN group. There was no significant difference between the groups in terms of rotational malalignment and angular malalignment. Rotational malalignment was seen in 2 (1.8%) patients treated with MIPO and 4 (2.6%) with IMN, without showing significance (P=0.14). Angular malalignment occurred in 4 (3.6%) patients treated with MIPO and 7 (4.9%) patients treated with IMN (P=1.0).

Discussion

Plates seem to be the obvious choice for distal tibia fracture more than a decade ago. However,

Figure 1. Radiological image of a typical patient treated by IMN. The preoperative anteroposterior X-ray (A1) and the preoperative lateral X-ray (A2) showed that the fracture had not healed and the plate had been broken. An anteroposterior X-ray (B1) and lateral X-ray (B2) at 1 month after the operation showed that the fracture lines were clear. An anteroposterior X-ray (C1) and lateral X-ray (C2) at 5 months after the operation showed that the fracture lines were blurred and had healed well.

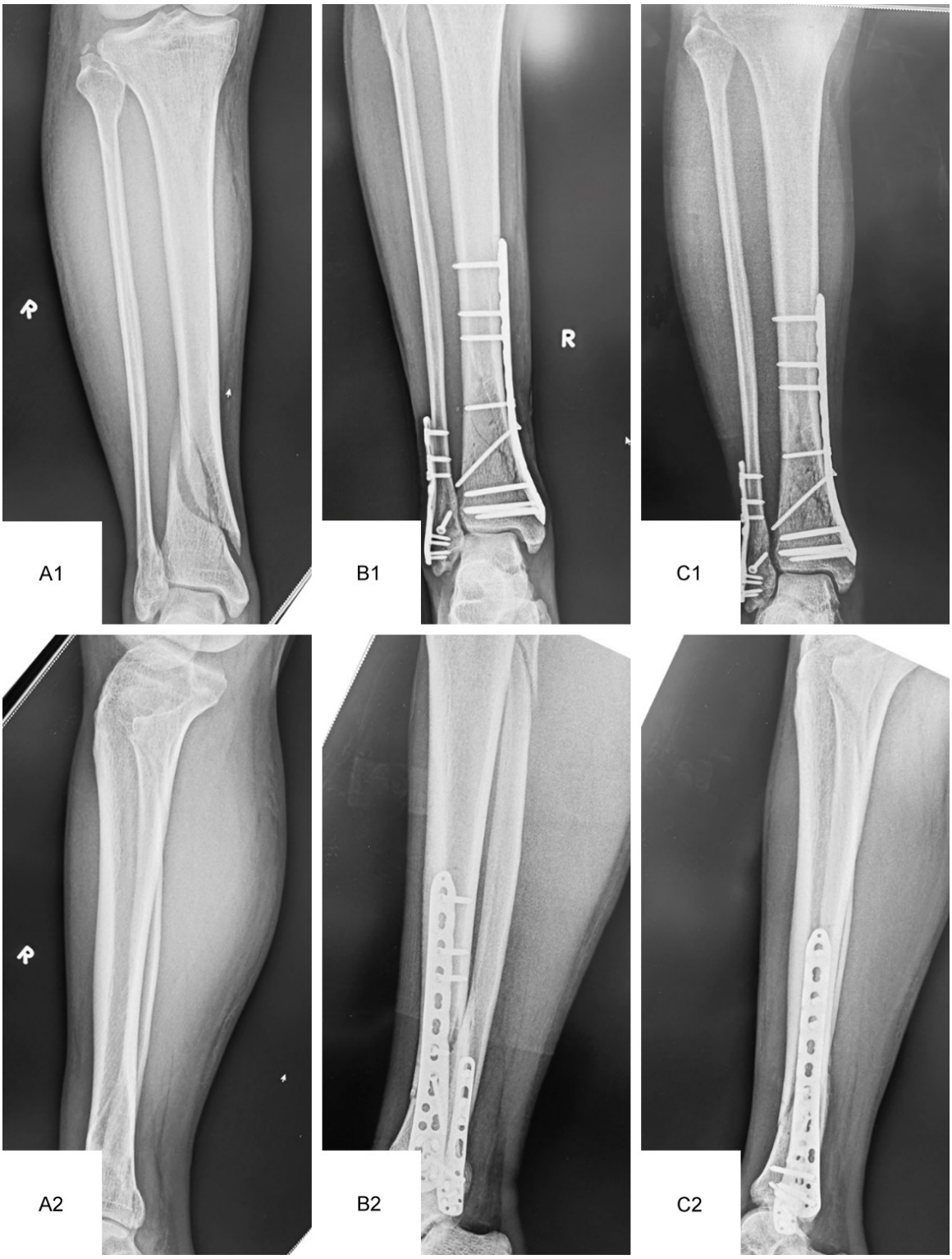

Figure 2. Radiological image of a typical patient treated by MIPO. The preoperative anteroposterior X-ray (A1) and the preoperative lateral X-ray (A2) showed that nonunion of the femur shaft was clear. An anteroposterior X-ray (B1) and lateral X-ray (B2) at 1 month after the operation showed that the fracture lines were still clear. An anteroposterior X-ray (C1) and lateral X-ray (C2) at 6 months after the operation showed that the fracture lines were blurred and had healed well.

with the development of IMN technology, more patients with distal tibia fractures are treated with intramedullary nails. Some studies have compared MIPO techniques with IMN techniques [29-34]. The results of these studies are inconsistent and sometimes show conflicting opinions. To date, the optimal surgical treatment for extra-articular distal tibia fractures remains controversial. From the retrospective study, we found that all patients treated with IMN or MIPO for distal tibia fractures had satisfactory clinical results and limb function. Our results show that there was no significant difference in the primary operation union rate, AOFAS score, deep SSI or malalignment between the MIPO group and the IMN group. However, our results also show that there was a longer operation time, more perspective times, more intraoperative blood loss and more frequent anterior knee pain in the IMN groups than that in the MIPO group. However, there was a significantly shorter time to union and fewer superficial SSI in the IMN group than that in the MIPO group.

Our study results show that intraoperative blood loss in the IMN group was significantly greater than that in the MIPO group (222.8±70.6 ml vs. 91.3±25.7 ml). Intraoperative blood loss is rarely used as a comparative index, perhaps because the IMN and MIPO techniques are minimally invasive surgeries. This difference was confirmed because tibial reaming increased intramedullary bleeding. The operation time and intraoperative fluoroscopy times in the IMN group were significantly longer than those in the MIPO group, which is also different from those reported in the literature [1, 35]. In their study results, MIPO was associated with a longer operative time due to complicated indirect reduction techniques of MIPO. However, in our study, we confirmed that IMN was associated with a longer operative time and intraoperative fluoroscopy times because it would spend more times that poller blocking screw techniques helped fracture reduction and enhanced fracture stability under fluoroscopic guidance. We found that a poller blocking screws used during the operation generally increased the operation time more than 8 minutes and intraoperative fluoroscopy more than 10 times. More than 80% of patients in the IMN group needed poller blocking screws to help fracture reduction or enhance fracture stability.

The rate of union or nonunion is a main factor in evaluating final clinical outcomes. Our study results show that there was no statistically significant difference in the primary operation union rate between the two groups. Our result was also consistent with results in other reports [3, 36]. However, some reports [32, 33, 37-39] have shown that distal extra-articular fractures of the tibia treated with IMN have a significantly lower primary operation union rate in comparison to MIPO. Although nonunion is associated with many factors, surgical technique is one of the most important determinants of union. We think that the higher union rate in our study could be attributed to two factors. One factor is that both surgical techniques are minimally invasive which do not disrupt the fracture hematoma or impair the healing process. Another main factor is that the poller blocking screws in the IMN group helped the fracture anatomical reduction and enhanced the fracture stability, which could increase the fracture healing ability.

Time to union is another main factor in evaluating final clinical outcomes. Our study results show that time to union in the IMN group (138.8±11.0 days) was significantly shorter than that in the MIPO group (153.5±17.1 days). The results were consistent with most research results [1, 3, 10, 29]. We think that the shorter time to union in the IMN group could be attributed to the reasonable biomechanics and micromotion of the fracture, which could accelerate the fracture healing process [40, 41].

The higher rates of malalignment in IMN to MIPO were reported in most previous studies [3, 6, 9]. Some reports showed that the rates of malalignment after IMN were up to 35%. However, our results show that there was no significant difference between the groups in terms of rotational malalignment and angular malalignment. Rotational malalignment was seen in 2 (1.8%) patients treated with MIPO and 4 (2.6%) with IMN, without showing significance (P=0.14). Angular malalignment occurred in 4 (3.6%) patients treated with MIPO and 7 (4.9%) patients treated with IMN (P=1.0). Compared with previous some studies, the lower rates of malalignment in IMN group maybe be attributed to the use of poller blocking screws to help fracture anatomical reduction and adjust the alignment of the tibia. Bleeker NJ et al. also reported that adjusting

the alignment by bilateral draping might be effective in reducing malalignment after definitive treatment of distal extra-articular tibia fractures [33].

The main complications in our study showed that there was no significant difference in deep SSI between the two groups; however, the superficial SSI rate in the MIPO group (6.4%) was higher than that in the IMN group (1.9%). A higher rate of SSI after MIPO has also been extensively reported [1, 3, 42]. A higher rate of SSI in MIPO might be explained by three reasons. The first reason is that the medial side of the distal tibia has a poorer soft tissue envelope. The second reason is that there is a less soft tissue compromise in IMN than that in MIPO [43]. Therefore, we suggest IMN treatment for patients with poor local soft tissue conditions, such as blisters, blood blisters and obvious redness and swelling, to reduce the incidence of infection.

There were some limitations in this study. First, there were more than three different surgeons performing fixation of distal tibial fractures during the 6-year period. Second, as a single center and retrospective study, there are some uncontrolled factors that may have influenced our conclusion. Finally, we think that the absence of a standard surgical procedure to guide the use of poller screws may also have interfered the study results. Evidently, the larger cohorts, prospective and multicenter studies evaluating to use IMN and MIPO in treatment of extra-articular distal tibia fractures would be further needed.

Conclusion

Based on our study results, we found that extra-articular distal tibia fractures can be treated satisfactorily with IMN or MIPO. Both surgeries have similar results for the primary operation union rate, AOFAS, deep SSI and malalignment, although there were significant differences in operation time, perspective times by C-arm, intraoperative blood loss, time to union, occurrence of anterior knee pain and superficial SSI rate. Poller blocking screws have a main role in improving the efficacy of IMN. For patients with poor basic physical conditions or knee pain before fracture, MIPO is preferred to treat extra-articular distal tibia fractures. Whereas, for patients with poor local soft tissue conditions, IMN was recommended as the first choice.

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Informed consent was obtained from all individual participants included in the study. The authors affirm that human research participants provided informed consent for publication of the images in **Figures 1** and **2**.

Disclosure of conflict of interest

None.

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