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ORIGINAL ARTICLE

Intramedullary nailing versus minimally invasive plate osteosynthesis for distal extra-articular tibial fractures: a prospective randomized clinical trial

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Abstract
Purpose The purpose of this randomized clinical trial is to compare intramedullary nailing (IMN) versus minimally invasive plate osteosynthesis (MIPO) for the treatment of extra-articular distal tibial shaft fractures.
Materials and methods Twenty-five consecutive patients with distal extra-articular tibial fractures which were located between 4 and 12 cm from the tibial plafond (AO 42A1 and 43A1) were randomly assigned into IMN (*n*: 10) or MIPO (*n*: 15) treatment groups. All patients were followed for at least 1 year. Foot function index, time to weight bearing, union time, duration of operation, length of incision, intra-operative blood loss, intra-operative fluoroscopy time, rotational and angular malalignment, rate of infection, secondary interventions and complications were compared between groups.
Results All patients completed the trial and were followed with a mean of 23.1 ± 9.4 months (range 12–52). Foot function index, weight bearing time, union time, rate of malunion, rate of infection and rate of secondary interventions were all similar between groups ($p = 0.807$, $p = 0.177$, $p = 0.402$, $p = 0.358$, $p = 0.404$, $p = 0.404$, respectively). Intra-operative blood loss, length of surgical incision, radiation time and rotational malalignment were higher in the IMN group ($p = 0.012$, $p = 0.019$, $p = 0.004$ and $p = 0.027$, respectively).
Conclusions Results of our study showed that both treatment methods have similar therapeutic efficacy regarding functional outcomes and can be used safely for extra-articular distal tibial shaft fractures, and none of the techniques had a major advantage over the other.

Introduction

Intramedullary nailing (IMN) is widely accepted as the treatment of choice for most open and closed tibial diaphyseal fractures [1]. However, reduction and stable fixation of distal extra-articular tibial fractures with IMN is often technically challenging due to a large medullary cavity within a short distal fragment [2]. In order to solve this problem, new designs of nails have been developed and surgical techniques have been described during the last two decades such as multi-directional and angle-stable distal locking systems and locking screw holes at the tips of nails, and use of (poller) blocking screws to narrow the medullary cavity [3–6]. Open reduction and plate and screw fixation allows anatomic reduction and stable ostheosynthesis for these fractures, but soft tissue complications, particularly wound dehiscence and infection, are a major problem with the open surgical technique, as well as disruption of vascularity, which may lead to nonunion. To overcome these disadvantages, the minimally invasive plate osteosynthesis (MIPO) technique, implants and instruments have been developed. In the MIPO technique, indirect reduction is performed, small stab incisions without evacuation of the fracture hematoma are used and the plate is placed by sliding over the periosteum without disturbing the vascularity. Furthermore, several distal locking screws can be used for

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stable fixation of the short distal fragment and the whole implant behaves as an angle-stable construct [7].

Currently, both MIPO and IMN are the most commonly used treatment methods in distal extra-articular tibial fractures. However, which is the ideal treatment is still controversial. Some authors argue that IMN is superior, while some authors suggest that the MIPO technique provides better functional and clinical results [8–12]. In the current literature, there are very few numbers of studies that provide strong evidence to clarify this subject. A recent systematic review on this subject could identify only four randomized clinical trials and concluded that further well-designed randomized clinical trials are necessary to give a clear answer to this problem [13]. The purpose of this randomized clinical trial was to compare IMN versus MIPO for the treatment of extra-articular distal tibial shaft fractures.

Materials and methods

This study was a prospective randomized clinical trial which was held in an urban level 1 trauma center between October 2009 and May 2012. All skeletally mature patients (>18 years of age) with distal extra-articular tibial fractures which were located between 4 and 12 cm from the tibial plafond (AO 42A1 and 43A1) were included in the study. Open fractures, pathological fractures, segmental fractures, fractures with distal intra-articular extension and comminuted fractures were excluded from the study. Furthermore, poly-trauma patients, patients with simultaneous fractures of the ipsilateral extremity such as floating knee, patients with previous history of ipsilateral lower-limb fracture, congenital or neuromuscular disease or abnormality, chronic inflammatory joint disease and, finally, patients who refused participation in this clinical trial, were excluded from the study. This study was carried out in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Our institutional review board approved the study protocol and all patients gave informed consent prior to their inclusion in the study.

After making informed consent, patients were assigned into two treatment groups by flipping a coin. Patients in group 1 were treated with closed reamed IMN and patients in group 2 were treated with MIPO. Additional plate and screw fixation was performed in cases of simultaneous distal fibular fracture (fracture within the distal 7 cm of fibula) in both groups after the fixation of the tibia. All operations were performed by the same surgeon (senior author). AO/OTA classification was used for fracture classification. The distance between the tibial plafond and the most proximal end of the distal fragment was measured and recorded. Demographic characteristics of patients and duration of hospital stay was recorded.

Operative technique and follow-up

Timing of the surgery was decided according to the status of the soft tissue envelope and degree of swelling. The type of anesthesia was decided with the collaboration of the patient and the anesthesiologist. The operations were carried out on a radiolucent fracture table in the supine position, without tourniquets. Closed reduction of the fracture was performed with manual longitudinal traction and rotation and checked with fluoroscopy in both groups. In cases of poor reduction quality, external reduction clamps were used. Patients who needed open reduction were also excluded from the study. The nail was inserted distal to the subchondral plate of the plafond. Two distal static locking screws in the coronal plane were used in all patients. No blocking screws were used. During plate fixation, a small incision was made over the medial malleolus and the plate was slid towards the proximal fragment. Screws were placed with the help of the external guide through stab incisions. In all cases, first tibial fixation was performed, and then fibular fixation was performed through a lateral incision. Total duration of operation was measured using a chronometer starting with the first incision to final suture closure for tibial fixation. Operation time for fibular fixation was not added, as not all patients had fibular plate fixation. Fluoroscopy time was recorded. Total amount of bleeding during the operation was measured with the sum of blood collected in suction and the used gauze for tibial fixation. The total length of the incision that was used for fixation of the tibia was measured with a sterile tape measure.

All patients were followed at 3-week intervals until fracture union, with radiographic examinations. Later on, radiographs were taken every 3–6 months until the last follow-up. Patients were allowed weight-bearing when callus was seen on a single cortex, either on AP or lateral radiographs. At the final follow-up, all patients underwent clinical and radiological assessments. Functional outcome was assessed with the foot function index [14]. Anteroposterior and lateral radiographs were used to measure the alignment in both coronal and sagittal planes. Rotation was assessed clinically with foot thigh angle using a goniometer and compared to the contralateral uninjured side, and the difference between sides was recorded. Union was defined as detection of consolidation on at least three cortexes and clinically by lack of pain on weight-bearing without assistance. Malunion was defined as varus or valgus greater than 5° in the coronal plane (anteroposterior X-ray), or recurvatum or procurvatum greater than 10° in the sagittal plane (lateral X-ray) or external or internal rotation greater than

10° (physical examination). Any complication during the surgery and follow-up was recorded.

Statistical analysis

Continuous variables were stated as mean, median and standard deviation and categorical variables as percentages and frequency distribution. The comparison of continuous variables between independent groups was performed using Student's *t*-test or Mann–Whitney *U* test in accordance with normality testing. Comparison of categorical data was performed using Fisher's exact test. A value of $p < 0.05$ was considered statistically significant. Power analysis showed that a minimum of 7 patients in each group were needed to detect a significant difference (D:13 SD:8) in FFI and reach 80 % power with alpha at 0.05.

Results

A total of 25 patients were included in this study and all patients completed the clinical trial (100 % follow-up rate). Of the 25 patients, 15 (60 %) were treated with MIPO, and 10 (40 %) were treated with IMN. There were 9 (36 %) female and 16 (64 %) male patients with a mean age of 34.5 ± 10.2 years. All patients were followed for at least 1 year with a mean of 23.1 ± 9.4 months (range 12–52). Both groups were comparable with each other in terms of demographic characteristics and fracture pattern except for sex distribution (Table 1). Nineteen patients were operated on under spinal anesthesia, and the remaining 6 were operated on under general anesthesia. Four patients in the MIPO group and 2 patients in the IMN group underwent simultaneous fibular fixation (*p*: 0.702). The mean duration of the operation was similar in both groups (51 min versus 57 min, $p = 0.461$). The mean blood loss, the length of incision and the radiation time was higher in the IMN group compared to the MIPO group (*p*: 0.012, *p*: 0.019 and *p*: 0.004, respectively). The time between the initial injury and operation time, and hospital stay was similar in both groups (*p*: 0.953, *p*: 0.984, respectively) (Table 2).

The time until identification of callus on radiographs was similar between groups. Thus, weight bearing was allowed at a similar time on follow-ups in both groups (*p*:

Table 1 Comparison of baseline characteristics of the patients

	Treatment		Significance (*p* value)
	MIPO (*n*:15)	IMN (*n*:10)	
Age, years ± SD	36.4 ± 10.7	34.0 ± 9.7	0.567
Sex (M/F)	7/8	9/1	0.040*
Side (right/left)	9/6	7/3	0.691
The distance between fracture and plafond, cm ± SD	8.0 ± 2.2	8.7 ± 1.7	0.376
Associated fibular fracture (yes/no)	6/9	8/2	0.402
AO/OTA classification			
42A1	11	6	0.276
42A2	1	3	
42A3	3	1	

* Significant *p*

Table 2 Comparison of intra-operative variables

	Treatment		Significance (*p* value)
	MIPO (*n*:15)	IMN (*n*:10)	
Type of anesthesia (spinal/general)	12/3	7/3	0.653
Time interval between the injury and operation, days ± SD	6.5 ± 4.2	6.7 ± 2.8	0.953
Duration of operation, min ± SD	51.4 ± 19.1	57.0 ± 15.4	0.461
Blood loss, cc ± SD	84.3 ± 71.8	211.5 ± 161.6	0.012*
Length of incision, cm ± SD	5.6 ± 1.8	6.6 ± 0.9	0.019*
Radiation time, ms ± SD	398.6 ± 172.1	736.4 ± 337.8	0.004*
Fibular fixation (yes/no)	4/11	2/8	0.702
Hospital stay, days ± SD	9.2 ± 4.5	9.3 ± 3.1	0.984

* Significant *p*

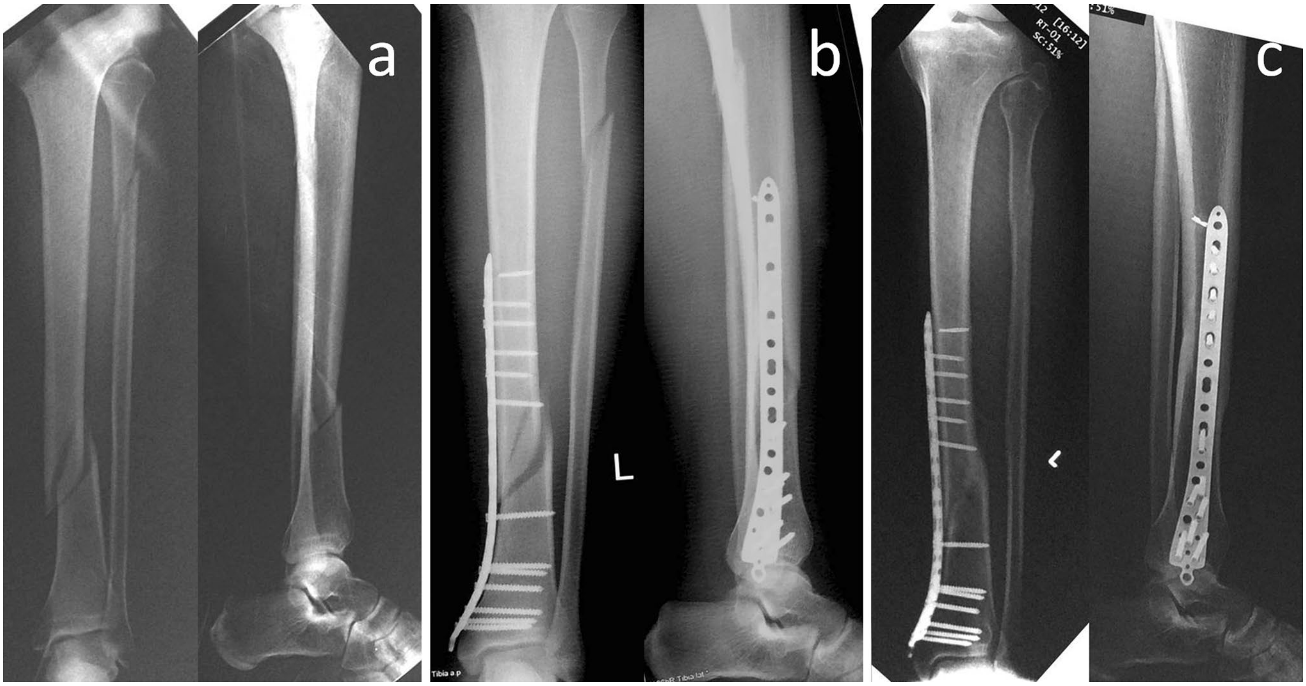

Fig. 1 A patient treated with MIPO. **a** Pre-operative, **b** early post-operative, and **c** final radiograph

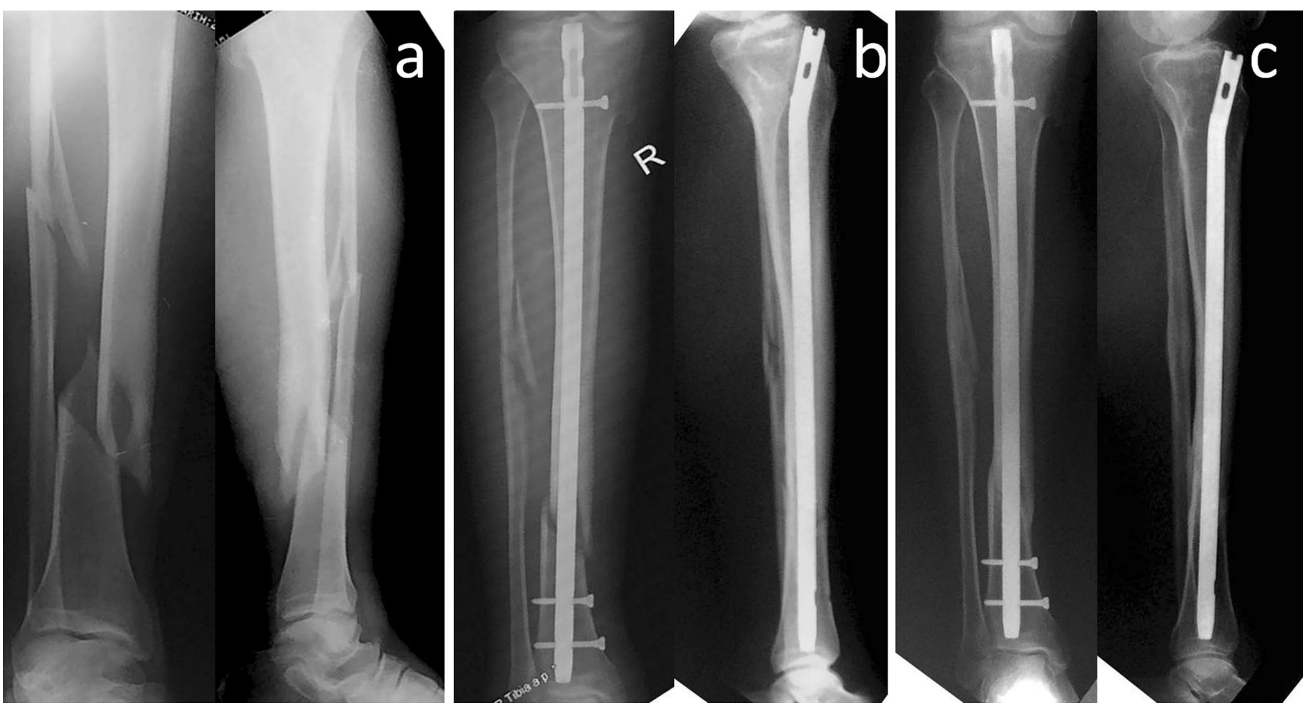

Fig. 2 A patient treated with IMN. **a** Pre-operative, **b** early post-operative, and **c** final radiograph

0.177). The union was achieved in all patients with a mean of 131.8 ± 14.6 days (range 108–157), and union time was not different in treatment groups (*p*: 0.402) (Figs. 1, 2). Two patients in the MIPO group (15° external rotation and 10° varus) and 3 patients in the IMN group (12°, 15° and 20° external rotation) had malunion (*p*: 0.358). Foot function index at the final follow-up was similar in both groups (*p*: 0.807). Patients in the IMN group had significantly

Table 3 Comparison of final outcome measures

	Treatment		Significance (p value)
	MIPO (n:15)	IMN (n:10)	
Follow-up, months ± SD	22.7 ± 11.0	23.8 ± 7.1	0.790
Foot function index, score ± SD	25.3 ± 16.4	25.7 ± 11.1	0.807
Weight-bearing time, days ± SD	45.6 ± 22.2	39.5 ± 17.8	0.177
Union time, days ± SD	133.9 ± 15.2	128.8 ± 13.8	0.402
Malunion (yes/no)	2/13	3/7	0.358
Alignment			
Coronal plane, degrees ± SD	1.9 ± 2.6	2.9 ± 2.5	0.375
Sagittal plane, degrees ± SD	1.8 ± 2.2	0.6 ± 1.3	0.131
Rotation, degrees ± SD	1.6 ± 4.4	7.2 ± 7.2	0.027*
Superficial infection	1	0	0.404
Secondary interventions (implant removal)	1	0	0.404

* Significant p

higher rotational malalignment (p: 0.027). Comparisons of final outcome measures are summarized in Table 3.

Complications

One of the patients in the MIPO group presented with clinical signs of implant-related infection at the end of the 4th month. The implants were removed and the wound was debrided. Deep tissue samples were taken for bacterial culture and methicillin-sensitive *Staphylococcus aureus* (MSSA) was isolated. The patient received 4 weeks of antibiotherapy and during this time interval he used a patellar tendon-bearing (PTB) brace. At the final follow-up he had completely recovered, without any signs of radiographic, clinical or laboratory signs of osteomyelitis. The rate of infection was similar between groups (p: 0.404). Two patients in the IMN group complained about anterior knee pain which lasted around 6 months and had subsided to a clinically irrelevant state at the final follow-up. Two patients in the MIPO group complained about slightly prominent implants and screws over the medial malleolus. No secondary intervention was performed in any other case (p: 0.404).

Discussion

Distal tibial extra-articular fractures located between 4 and 12 cm from the tibial plafond are a dilemma for orthopedic surgeons in terms of management. If surgical treatment is decided on, the second question arises as to the type of fixation method: external fixation, open reduction and plate fixation, MIPO, or IMN, which can all be used as the definitive surgical treatment [9, 11]. However, the advantages of MIPO and IMN are addressed by many surgeons, and currently MIPO and IMN are widely accepted as treatments of choice. This study compared the clinical, radiographic and functional results of IMN and MIPO in patients with distal tibial extra-articular shaft fractures.

The results of our study showed that both MIPO and IMN are equally effective in terms of functional outcomes (foot function index). Similarly, in several previous studies, although different scores have been used for evaluation, functional outcomes have been found equal in both treatment modalities, which is consistent with our findings. Guo et al. [8] compared MIPO and IMN in a series of 85 patients with distal tibial fractures and reported statistically similar AOFAS scores in both groups. Li et al. [11] compared three different surgical techniques (MIPO, IMN and external fixation) in the treatment of distal tibial fractures using the Mazur ankle score and reported equal functional outcomes in all groups. Im et al. prospectively compared closed reduction and IMN versus open reduction and plate and screw fixation for distal tibial fractures in a series of 64 patients. Although they reported equal functional ankle scores, ankle dorsiflexion was better in patients in the IMN group [15]. In distal tibial extra-articular fractures, as the ankle plafond is intact, the ankle function is usually protected regardless of the technique used for fixation. On the other hand, it is well known that anterior knee pain can be seen after IMN. As the MIPO technique does not involve any surgical incision around the knee, it is free from this complication. Although most of these symptoms (anterior knee pain) regress with time, some patients may need removal of the IMN, and even removal may not solve the problem. Yang et al. compared the results of IMN versus open reduction and plating in distal tibial fractures and reported anterior knee pain in almost half of their patients (6/13) whereas there were no patients with knee symptoms in the plating group. Two of their patients' symptoms continued after the removal of IMN [6]. Janssen et al. [10] retrospectively compared MIPO and IMN in matched pairs of patients with distal tibial fractures, and found statistically more frequent anterior knee pain during kneeling and squatting in the IMN group. Similarly, in our series 2 out of 10 patients treated with IMN had anterior knee pain. From a functional point of view, both treatment methods resulted in similar ankle function, but anterior knee pain seems to be a disadvantage of the IMN technique.

An ideal fracture treatment method should provide anatomic or at least acceptable fracture alignment in the tibia, because any malalignment or malrotation may cause post-traumatic osteoarthritis in neighboring ankle and knee joints in the long term [16]. In recent systematic meta-analysis, malalignment was found to be more common in IMN compared to plate and screw fixation in distal tibial fractures [13, 17, 18]. However, in these meta-analyses, studies that reported both open reduction and minimally invasive techniques were included. Open surgeries using direct reduction techniques provide direct visualization of the fracture and usually ensure accurate fracture reduction and alignment. On the other hand, the MIPO technique uses an indirect reduction technique similar to IMN. Im et al. [15] reported that the rate of malunion which exceeds the acceptable range (>5° varus/valgus, >10° procurvatum/recurvatum) was significantly higher in the IMN group. Similarly, Vallier et al. [9] reported that malalignment (>5°) was more common in the closed IMN group compared with the open reduction and plate fixation group. In both of these randomized trials, plate fixation was performed under an open surgical approach; however, IMN was performed with closed techniques. On the other hand, studies which compared IMN and MIPO found a similar malunion rate. In studies performed by Guo et al. and Li et al. [8, 11] malalignment was found to be equal in both groups. Similarly, we could not find any significant difference between angular malalignment in our patients. There were only 2 patients (1 in each group) who had angular malunion, among all patients. However, malrotation was better restored in the MIPO group. Thus, we believe that the rate of malunion is equal in IMN and MIPO techniques. Controversial findings in the literature result from the evaluation of studies using different surgical techniques in the same analysis.

The rate of union is another factor in final clinical outcomes. Both treatment methods resulted in similar union rates in our study. This finding was also consistent with findings in the relevant literature. Although the etiology of nonunion is multifactorial, it is well known that surgical technique is one of the most important determinants of union. As both surgical techniques are minimally invasive, they do not disrupt the fracture hematoma and impair the healing process. Guo et al. reported no patients with nonunion in their series. Li et al. reported only 2 patients (1 patient in IMN and 1 patient in the MIPO group) with nonunion [8, 11]. Besides the union rate, union time was also similar between groups. Xue et al. reviewed 14 studies that compared IMN versus plating and analyzed 842 patients, and concluded that union time was equal in both techniques [13].

The distal tibia is one of the locations where post operative infection is likely to occur because of the thin soft tissue envelope and high incidence of open fractures. In the case of plate fixation, particularly on the medial side, the subcutaneous location of the plates may also contribute to the occurrence of infection. The rate of infection is reported to be higher in plate fixation compared with IMN in studies in which an open reduction and plating technique was used [19]. On the other hand, when the MIPO technique is used, the rate of infection seems to be equal in both groups. In our study, there was one infection in the MIPO group and infection subsided upon removal of the implants. In a meta-analysis, the rate of infection was found to be equal with both techniques [18]. The infection is not only dependent on the surgical technique itself. There are other factors which may play a role in the occurrence of infection, such as patient related co-morbidities, open fracture with contamination, operating room conditions and severity of soft tissue injury. According to our experience, MIPO should be delayed until the soft tissue coverage is adequately healed.

Considering other variables, we have found statistically less blood loss, less fluoroscopy time, shorter duration of operation and smaller incision length in the MIPO group. Shorter incision length is an important advantage in preventing post-operative infection and wound problems. However, there was only 1 cm difference between the two groups in our study (5.6 versus 6.6 cm). Although this difference was statistically significant, we think that it can be neglected clinically. We found greater blood loss in the IMN group (84 versus 211 cc). Intramedullary reaming may be the major reason for this difference. Finally, we found greater use of fluoroscopy in the IMN group. From the surgeon's point of view, any surgical technique which necessitates less fluoroscopic control during the operation is an important advantage. One of the problems with the IMN technique is the proper locking of the distal screws. Several easier locking techniques and systems have been proposed [20]. In our study we used a standard external guide system to lock the IMN. We have used fluoroscopy control mostly for distal locking in this series. This may explain why the fluoroscopy time in the IMN group was greater than in the MIPO group. Furthermore, the difficulties in distal locking increased the operation time in the IMN group. Unlike in our study, Guo et al. [8] reported that fluoroscopy time was longer with MIPO due to the indirect reduction technique, which is more complex than IMN. Lie et al. [11] reported longer operation times with MIPO. Fluoroscopy time and duration of operation may vary in accordance with the fracture type, the type of implant and surgeon's experience with the technique. Thus, it is hard to standardize all these variables and to make a definitive judgment on this issue.

There are some strengths and limitations of this study. This is a randomized clinical trial (level 1 evidence) and no patients dropped from the study. Both groups were homogenous regarding several baseline characteristics. All operations were performed by the same surgeon. The major limitation of our study is small number of patients; however, the power analysis was over 80 %. Secondly, although tibial fractures are common, only 10 % of all tibial fractures occur at the distal end, and among these fractures most of them have intra-articular extensions. Thus, a very few number of patients could be included in accordance with our strict inclusion criteria.

In conclusion, both treatment methods have similar therapeutic efficacy regarding functional outcomes and can be used safely for extra-articular distal tibial shaft fractures. Although we have detected some statistically significant differences in length of incision, radiation time, blood loss, and rotational alignment, none of these minor benefits influenced the final clinical outcome. Neither technique had a major advantage over the other. However, progression in techniques and implants continues to develop, thus progress towards the solution of problems in each technique may disrupt the current balance. Retrograde tibial IMN may be a solution in the near future [21].

Conflict of interest The authors declare that they have no conflict of interest.

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