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Original Article

Treatment of segmental tibial shaft fractures: combination of external fixator with titanium elastic nails versus locking intramedullary nail

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Abstract: Objectives: This study was designed to compare clinical outcomes using external fixator combined with titanium elastic nails (EF + TENs) versus reamed locking intramedullary nail (IM) for the treatment of segmental tibial shaft fractures. Methods: Between February 2010 and September 2013, one hundred and eight patients ranging from 23 to 55 years old (mean age: 37 years old) suffering from segmental tibial shaft fractures (68 women and 40 men) were treated with either EF + TENs or IM, with 54 patients in each group. The duration of operation, radiation times, intraoperative blood loss, peri-operative hidden blood loss, postoperative clinical efficacy, and radiographic evaluation were measured to explore the benefits and drawbacks of these two techniques. Results: All 108 patients were followed up for at least 12 months. The differences in the mean radiation times and duration of operation (P = 0.451 and P = 0.082, respectively) were not statistically significant when comparing the EF + TENs group to the IM group. There was no significant difference in the time to union (P = 0.460), delayed union (P = 0.358) and malunion (P = 0.475) between the two groups. In addition, the rate of ankle pain (P = 0.475) and the total scores as measured by the functional American Orthopaedic Foot and Ankle surgery (AOFAS) score (P = 0.312) was not significantly different. No case of nonunion was observed in both groups. In comparison with IM, patients in group EF + TENs have less blood loss during the operation (P = 0.001), less peri-operative hidden blood loss (P = 0.001) and a lower rate of knee pain (P = 0.001). Moreover, EF + TENs can be used in fractures which have bone subfissures close to the joint, and can promote fracture healing by gradual mobilization as an outpatient. Conclusions: Our results indicated that compared with IM, EF + TENs has potential advantages and benefits, and should be a better technique for the treatment of segmental tibial shaft fractures.

Keywords: Segmental tibial shaft fractures, locking intramedullary nail, external fixator, titanium elastic nail

Introduction

Segmental tibial fractures occur more frequently than any other long bone fractures, which are increasing due to road traffic accidents and firearm injuries [1, 2]. Because of the anatomic location with the relatively poor soft tissue cover and blood supply, tibial shaft fractures are vulnerable to nonunion and infection [3, 4]. The management of tibia fractures still remains one of the greatest challenges to orthopedic trauma surgeons [5]. Protection of the surrounding soft tissue, biological fixation, prevention from infection, optimal union, and return to normal function remain elusive goals. Thus, a proper surgical technique for individual stabilization is especially important for tibia fractures.

A variety of treatment modalities have been suggested for this injury, most frequent management options include external fixator, intramedullary nail, and plate fixation. However, each of these treatment options is associated with certain challenges and shortcomings [6]. Historically, plate fixation require soft tissue stripping which resulted in increased risk of damaging the blood supply and subsequent infection [7]. Furthermore, frequent need for secondary rigid fixation, prolonged healing time and pin tract infection have plaqued external fixators [8, 9]. Though intramedullary nail is

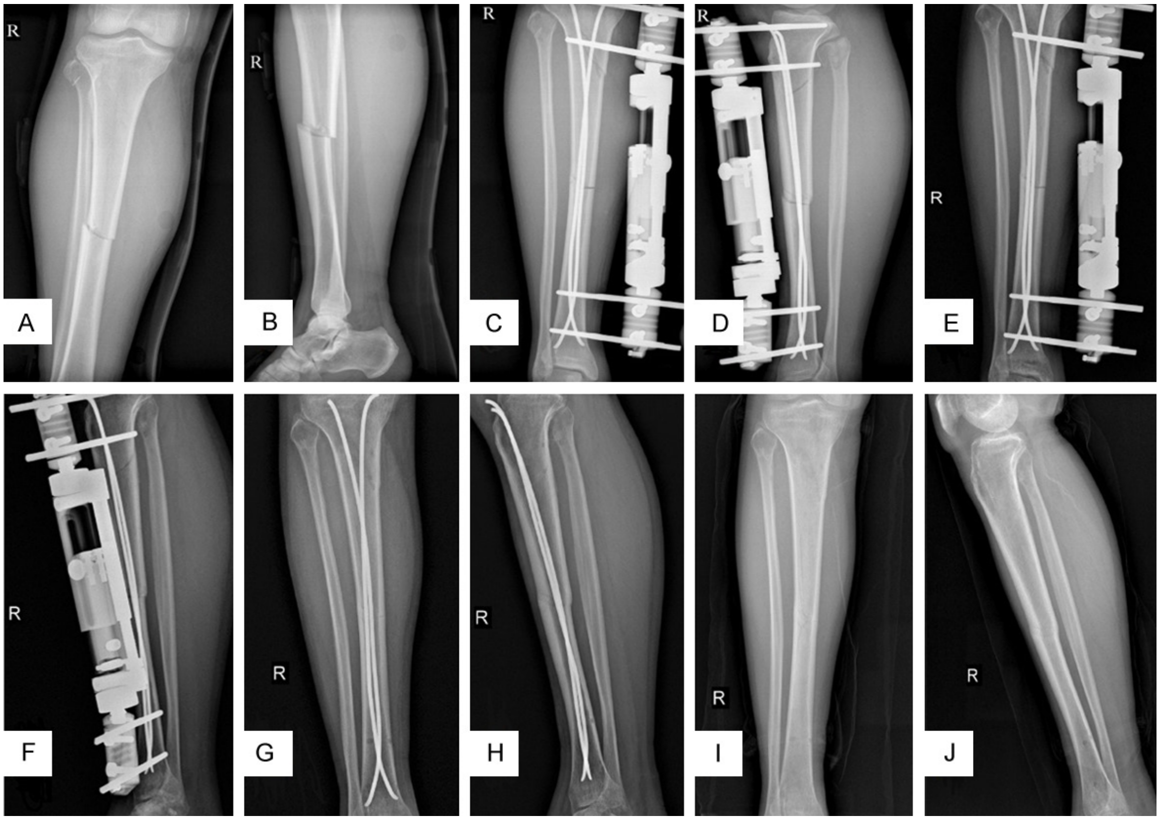

Figure 1. An unilateral external fixator combined with titanium elastic nails (EF + TENs) to treat segmental tibial fractures. A 46-year-old man with OTA classification 42-C and Tscherne grade II segmental tibial shaft fracture and have bone subfissure close to the knee joint (A, B). EF + TENs were percutaneously used with closed reduction. Two days after the operation X-ray film showed a good alignment of the fracture (C, D). One month after the operation X-ray film showed a good alignment with preliminary callus formation (E, F). The external fixator was removed three months after the operation in the outpatient department in order to obtain dynamization (G, H). Eight months after the operation the titanium elastic nails were removed with X-ray film showing good healing of the fracture (I, J).

considered as a "gold standard" for the treatment of tibial shaft fractures, it is associated with severe complications with clinically relevant sequelae. As reported, mal-alignment and knee pain were inherent problems after IM nailing [10, 11]. If the fracture is situated in the distal or proximal tibia, which is near the joint surface, IM nailing may not be a suitable choice unless supplementary devices such as blocked screws are added or the Expert Tibia Nail (ETN) is used instead. ETN has multi-axial screws and can offer a wider range of proximal and distal locking options in multiple planes to increase the stability of the implant and bone construct [12]. However, the relatively high technical and professional requirements of Expert Tibia Nail have limited its use in some hospitals. Thus we wanted to develop a new technique to treat segmental tibial fractures. The technique that we have developed used a unilateral external fixator percutaneously combined with titanium elastic nails (EF + TENs) (**Figure 1A-J**). As previously been reportedly in treating segmental tibial fractures, the unilateral external fixator and TENs offered a wider range of applications [13]. In order to show the advantages and disadvantages of this new technique, we compared it with locking intramedullary nail (IM).

Material and methods

Patients

From February 2010 to September 2013, one hundred and eight patients (68 males, 40 females) with segmental tibial shaft fractures were enrolled in the study: 54 patients were treated with EF + TENs and the other 54 patients were treated with IM. The soft-tissue injury was graded according to the Tscherne So-

Table 1. Baseline characteristics of the two groups

	EF + TENs (n = 54)	IM (n = 54)	*P* value
Age (years)	34.4 ± 10.6	35.6 ± 9.5	0.537
Sex (male:female, n)	32:22	38:16	0.569
Level of the fracture (proximal third:Middle third:distal third, n)	10:24:20	12:22:20	0.757
Fracture side (left:right, n)	14:40	20:34	0.558
Tscherne grade (I:II, n)	34:20	40:14	0.558
OTA classification (42-A:42-B:42-C, n)	26:24:6	22:30:4	0.776
Interval from injury to surgery (days)	3.0 ± 2.4	3.2 ± 1.8	0.625

Note: The data in baseline clinical characteristics of the patients between groups were compared with X^2 test or *t* test, Data were presented as mean ± SD. EF + TENs: external fixator combined with titanium elastic nails. IM: locking intramedullary nail.

ft Tissue Classification (I, II) [14], and the geometry and degree of bone comminution were graded from type A to C using admission radiographs according to the classification of the Orthopedic Trauma Association (OTA) [15]. The inclusion criteria were as follows: (1) Age 20-55 years, (2) Segmental tibial shaft fractures with or without fibula fracture, (3) Soft tissue injury of Tscherne I, II grade, and (4) Closed fractures. The exclusion criteria were as follows: (1) Soft tissue injury of Tscherne III grade, (2) Gustillo-Anderson type I, II and III open fractures, (3) Pathological fractures, (4) Associated neuro-vascular injury requiring repair, (5) Metabolic bone disease, (6) Previous ipsilateral lower limb surgery, or (7) Mental illness precluding adequate followup. Include in the study were eight patients with fractures of the fibula, and no patients with contralateral tibi|al fractures. All patients were initially assessed in the emergency room. Primary skeletal stabilization was performed as soon as the patient's general condition was satisfactory. Detailed patient information is presented in **Table 1**.

Ethics statement

All patients were treated in the Department of Orthopaedic Surgery, The Second Affiliated Hospital and Yuying Children's Hospital of Wenzhou Medical University. This prospective cohort study with retrospective analysis was performed in accordance with the ethical standards of the Declaration of Helsinki (1964). Protocols were applied and the publishing of patients' health records was approved by the Hospital Ethical Committee. Written consent form for publication of their medical details was obtained from patients or their designated guardians.

Surgical technique

Patients from group EF + TENs were placed supine under general or spinal anaesthesia and their operations were performed by the same group of surgeons as previously reported [13]. Adequate radiological evaluation was required, and anteroposterior and lateral views were available. First of all, preliminary closed reduction was performed under C-arm guidance (Philips Inc., Netherlands.), for the purpose of diminishing deformities of rotation, angulation and severe shortened displacement. Based on the condition of the fibula fracture, we then decided whether or not to fix the fibula fracture with elastic nail (SynthesBettlach Inc, Switzerland) before managing the tibial fracture. After that, at lateral and medial aspect of the proximal (anterograde) or distal (retrograde) tibia, a 1-2 cm longitudinal incision was made. The TENs (SynthesBettlach Inc, Switzerland) were inserted in an anterograde or retrograde direction according to the soft tissue situation of the entry points and the distal or proximal occult fracture. Once, the TENs and fracture alignments were confirmed to be satisfactory, external fixation was then applied. The nail ends left outside the skin were clipped, leaving only a length of 1-cm from the cortex. After these, unilateral orthofix external fixator (OrthofixSrl Inc., Italy) was installed. The external fixator was applied where two schanz screws were inserted proximally and distally respectively. Usually, the first schanz screw should be fixed where tibial marrow cavity was relatively narrow, and the medullary cavity of the other three screws is larger, which has more room for screws adjustment in order to install the fixator easily. All schanz screws must be threaded to the opposite cortex to guarantee stability under fluoroscopy. Finally, the external

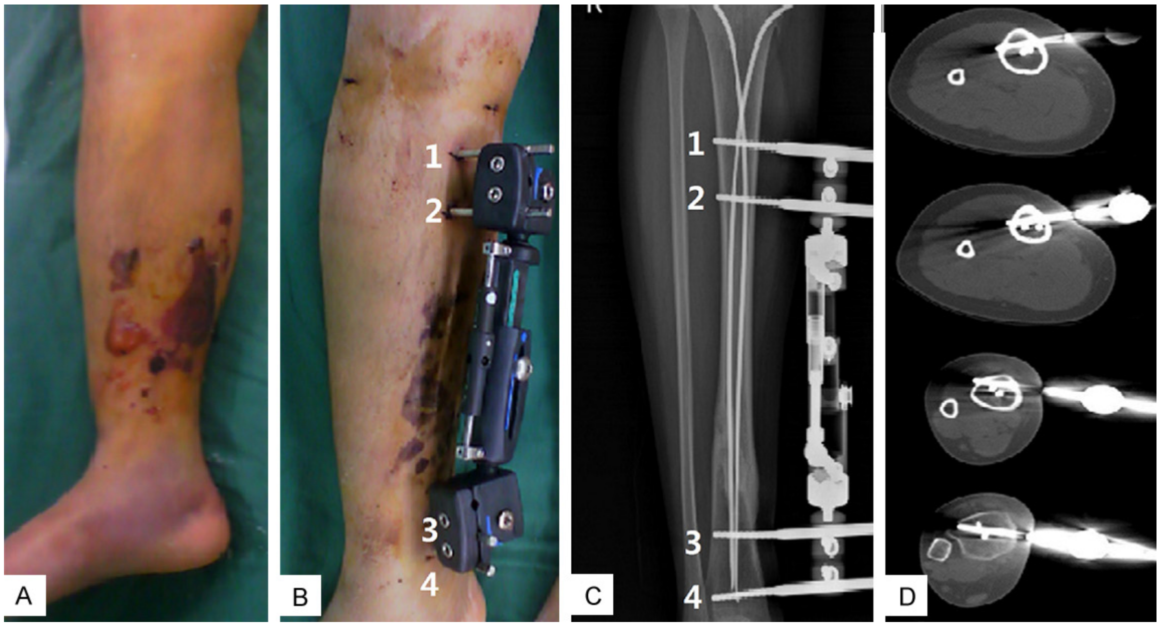

Figure 2. Surgical procedures of EF + TENs. One day after injury tension vesicle appeared (A). The EF-TENs system was used and four screws were displayed in sequence, the first schanz screw should be fixed where tibial marrow cavity was relatively narrow (B, C). Under CT scan, the image showed each planar relationship between screw and two titanium elastic nails (D).

fixator was attached to the screws. If there was still a slight angulation or displacement, we tried to adjust it by universal joint bolt and compressive rod, and then tightened up all the bolts (**Figure 2A-D**).

The reamed locking intramedullary nail (Smith & Nephew Inc.,USA) was used in all fractures for the IM group. The patients were positioned supine on the OR table with 90° flexion of the knee joint. Access of the proximal tibia was provided by a trans-tendinous approach, and static locking was done in all fractures (**Figure 3A-J**). All surgeons adhered to the same protocol [16, 17].

Postoperative management

The post-operative care was the same for all patients. Ankle and knee joint exercises were initiated 2 days after the surgery. Partial weight-bearing was allowed when radiological evidence of progress towards union was seen, usually at 6 weeks after the operation, and full weight bearing was allowed when there was radiological evidence of bone union with no pain at the fracture site [18]. When callus formation was observed, we would loosen the compression bolts and compression rods, and rely on the fixation of TENs. All the external fixators were removed in the outpatient setting in an average of 3.3 months (range 2.5-5.6 months) (**Figures 1G**, **1H** and **4E**, **4F**). TENs and IM removal were performed in the OR under anesthesia.

Outcomes assessment

Radiographic evaluation was performed using anteroposterior and lateral radiographs at the time of patient admission (**Figures 3A**, **3B** and **4A**, **4B**), immediately after the operation (**Figures 3C**, **3D** and **4C**, **4D**), and after at least 12 months of follow-up (**Figures 3E-J** and **4E-H**). We evaluated time to union, blood loss during the operation, peri-operative hidden blood loss, presence of delayed union, mal-union and non-union, knee pain, ankle pain, deep soft tissue infection and pin-tract infection. None of the patients received blood transfusion during the operation. Each patient underwent laboratory evaluation in the preoperative period and 1, 3 days postoperatively. Routine hemoglobin assessment was performed to decide on the need for a blood transfusion (blood transfusion standard Hb < 8.0 g/dL) [19, 20]. The peri-operative hidden blood loss was calculated according to the Gross equation [21,

Figure 3. Group IM treated by reamed locking intramedullary nail. A 30-year-old man with OTA classification 42-B and Tscherne grade II segmental tibial shaft fracture (A, B). Two days after the operation X-ray film showed a good alignment of the fracture (C, D). Three months after the operation X-ray film showed a good alignment with preliminary callus formation (E, F). X-ray film showed good healing of the fracture after twelve months (G, H). Post locking intramedullary nail removal (I, J).

22]. Delayed union was defined as lack of any healing on plain radiographs within three months. Non-union was defined as lack of any healing on plain radiographs within six months. The length of the affected extremity was compared with the unaffected side, > 2 cm difference was defined as shortening. Mal-union was defined as > 5° ante-/recurvation, > 5° varus/valgus deformity or > 15° rotation difference [23]. At the final follow-up examination, the American Orthopaedic Foot and Ankle Surgery (AOFAS) score [24] was used to evaluate the function of the ankle and foot.

Statistical analysis

All statistical analyses were conducted using the SPSS 19.0 software (SPSS Inc, Chicago, IL, USA). The mean age, follow-up period, duration of operation, radiation times, the time to union, blood loss during operation, peri-operative hidden blood loss and AOFAS scores were presented as mean ± standard deviation (mean ± SD) and tested by Student's t test. Furthermore, pin track infection, ankle pain, knee pain, delayed union, malunion and non-union were analyzed by chi-square (X^2) test or Fisher probabilities. Values of $P < 0.05$ were considered as statistically significant.

Results

All 108 patients were followed up for at least 12 months. No hardware failure of EF + TENs or IM was observed. The average follow-up time of the EF + TENs group was 23.2 ± 9.0 months and the IM group was 24.5 ± 8.5 months, respectively. There were no significant

Figure 4. EF + TENs used in distal tibia shaft fractures. A 53-year-old man with OTA classification 42-B and Tscherne grade II segmental tibial shaft fracture (A, B). Two days after the operation X-ray film showed a good alignment of the fracture (C, D). The external fixator was removed 3 months after the operation in the outpatient department (E, F). Twelve months after the operation, the titanium elastic nails were removed with X-ray film showed good healing of the fracture (G, H).

differences in the baseline demographic data between the two groups (**Table 1**). As shown in **Table 2**, the mean radiation times and operating time in the IM group was comparable to that of the EF + TENs group (13.6 ± 3.2 vs 14.0 ± 2.2, P = 0.451; 68.5 ± 12.7 vs 72.6 ± 11.5, P = 0.082, respectively). Nevertheless, there was less blood loss during the operation (P = 0.001) and peri-operative hidden blood loss (P = 0.001) in the EF + TENs group compared to the IM group. There was no significant difference in the time of union (5.9 ± 2.2 vs 6.2 ± 2.0 months, P = 0.460) between the two groups (**Table 2**). Two cases of mal-union were found in the IM group, acceptable alignment of the tibia was obtained in the other 106 patients. In the IM group, one case had 6 degrees of recurvatum deformity and another one had 9 degrees of valgus deformity. No patient in either group had > 10° varus/valgus or ante-/recurvatum mal-alignment, rotational mal-alignment of > 15° and shortening of > 2 cm. There was no significant difference in the mal-union (P = 0.475) between the two groups. Four cases of pin track infection were diagnosed in the EF + TENs group but none in the IM group, and no cases of severe infection occurred in any of our patients. The rate of pin track infection was 7.4% in EF + TENs group, less than those reported in studies using external fixator alone [2, 25]. Four cases with delayed union were observed in EF + TENs group which ultimately achieved union without further surgical procedures. However, 8 cases with delayed

Table 2. Details of intra- and post-operative variables in the two groups

	EF + TENs (n = 54)	IM (n = 54)	X^2	*P* value
Follow-up time (months)	23.2 ± 9.0	24.5 ± 8.5	--	0.442
Duration of operation (min)	72.6 ± 11.5	68.5 ± 12.7	--	0.082
Radiation times	14.0 ± 2.2	13.6 ± 3.2	--	0.451
Bone union time (months)	5.9 ± 2.2	6.2 ± 2.0	--	0.460
Blood loss during operation (ml)	42.4 ± 14.3	176.6 ± 32.7	--	0.001*
Peri-operative hidden blood loss (ml)	56.4 ± 12.3	327.8 ± 43.3	--	0.001*
Pin track infection (%)	4 (7.4%)	--	--	--
Ankle pain (%)	0 (0%)	2 (3.7%)	0.51	0.475
Knee pain (%)	4 (7.4%)	24 (44.4%)	19.29	0.001*
Delayed union (%)	4 (7.4%)	8 (14.8%)	1.50	0.358
Malunion (%)	0 (0%)	2 (3.7%)	0.51	0.475
Nonunion (%)	0 (0%)	0 (0%)	--	1.000

Note: The data between groups were compared with *t* test, X^2 test or Fisher probabilities, Data were presented as mean ± SD. *P < 0.05. EF + TENs: external fixator combined with titanium elastic nails. IM: locking intramedullary nail.

Table 3. Functional outcome scores as measured by AOFAS

	Pain	Function	Alignment	Total
EF + TENs	38.3 ± 6.6	44.4 ± 6.0	9.4 ± 0.8	93.4 ± 6.8
IM	36.4 ± 7.1	45.0 ± 5.5	9.3 ± 0.9	92.1 ± 6.5
P value	0.153	0.589	0. 543	0.312

Note: The data between groups were compared with *t* test, Data were presented as mean ± SD. EF + TENs: external fixator combined with titanium elastic nails. IM: locking intramedullary nail.

union in IM achieved union after secondary procedures (removal of distal locking screws in the operating room) [26]. There was no ankle pain and 4 cases of knee pain in the EF + TENs group. However, there were 2 cases of ankle pain in the IM group, and 24 cases of knee pain in the IM group. We also found no significant difference in terms of function and total AOFAS scores (P = 0.312) (**Table 3**). The functional results were good with a mean score of 93.4 points in the EF + TENs group and 92.1 points in the IM group. And there was no significant difference in the pain (38.3 ± 6.6 vs 36.4 ± 7.1, P = 0.153), alignment (9.4 ± 0.8 vs 9.3 ± 0.9, P = 0.543) and function (44.4 ± 6.0 vs 45.0 ± 5.5, P = 0.589) between the two groups. Detailed complications were described in **Tables 2** and **3**.

Discussion

In this study, we described an external fixator combined with two titanium elastic nails as a novel method for treating segmental tibial fractures. The advantages of elastic nails are that the pins are inserted percutaneously, without the need for reaming. The small diameter of the nails causes minimal interference, which prevents damage to the periosteal blood supply and resultant soft tissue trauma. In surgery, the two titanium elastic nails were placed in close proximity to reduce the fracture and maintain alignment to support the external fixator. Moreover, because of the elastic nails' biomechanical support, external fixators could be removed without full union within two or three months. The lower rate of pin track infection in the EF + TENs group maybe due to the fact that the external fixator screws into the cancellous bone area, which use the surface spraying of hydroxyapatite, have a good stimulation of the skin and reduce inflammatory reaction of the surrounding soft tissue. At the same time, the combined fixation can be dismantled without waiting for complete osseous healing, it also reduces the chance of pin track infection. When delayed union occurs, IM group may require additional surgery. However, it can be avoided through gradual mobilization in the outpatient setting in the EF + TENs group [13]. Combination of an external fixator with titanium elastic nails in our series is a minimally invasive approach that maximizes tissue preservation and provides reliable stability for fractures.

IM nailing is the conventional treatment option for tibial shaft fractures. However, it is known to be a challenging technique in the treatment of proximal and distal quarter tibia fractures. The long lever arm and metaphyseal enlargement make fracture reduction and nailing technically difficult. Other well-described difficulties associated with this technique include intra-articular extension, hardware failure and/or metaphyseal fixation difficulty [27]. Technical difficulties with distal nail fixation, risk of nail propagation into the ankle joint, and discrepancies between the diaphyseal and metaphyseal diameter of the intramedullary canal further complicate this procedure [6, 10]. In cases with a long-lever arm, the short segment left for distal locking and poor endosteal fit with little nail-cortex contact prohibit fracture alignment while allowing for considerable nail mobility. This can result in a higher rate of mal-alignment and increased stress on the locking screws leading to a greater risk of screw failure, nail migration or ankle penetration [23, 28].

Treatment of segmental tibial fractures remains challenging for orthopaedic surgeons, particularly in the presence of compromised soft tissue. Segmental tibial fractures usually require prolonged healing and rehabilitation times due to their poor blood supply. Conventional open reduction and internal fixation techniques involve extensive dissection and periosteal stripping, which increase the risk of soft tissue complications and the incidence of delayed union and nonunion [29]. Nowadays, minimally invasive therapies are the preferred treatment for these injuries. With reduction in soft tissue damage, external fixation has become a well-established method by many authors for dealing with these injuries. However, recent studies challenge these due to a higher incidence of pin-track infection, higher risk of malunion, and difficulties related to soft tissue management.

Although prolonged healing time, malunion, nonunion, frequent need for secondary operation and pin track infection often appears using external fixation, our results compare more favorably than previous reports. Pin tract infection remained the most common complication, with an incidence of 7.4%, which is much less than that reported for external fixators alone [25]. It was reported that malunion developed in 25.6% of tibial shaft fractures treated by indirect reduction and stabilization with an external fixator [30]. However, no patient developed this complication in our study. Moreover, there was no patient who needed reoperation or developed nonunion in our EF + TENs group. We think that early external fixator removal with elastic nails biomechanical supporting led to this favorable result. In comparison with external fixation alone, our "hybrid treatment approach" employing a combination of external fixator with two titanium elastic nails resulted in less healing time, lower rate of nonunion and pin track infection.

Locked IM nail is a well-accepted treatment method, but postoperative knee pain, destruction of the endomedullary blood supply, iatrogenic propagation of the fracture, inadequate distal fixation and hardware failure leading to malunion were often reported [10, 31]. We observed risks of inferior alignment and a high frequency of anterior knee pain after IM nailing, which is consistent with early studies [10, 31]. Less incidence of knee pain occurred in the EF + TENs group. One of the reasons may be because management using EF + TENs do not require partition of the patellar tendon. At the same time, a low rate of infection, malunion and a high rate of union have been observed in our study.

In comparing with external fixators alone, one of the advantages for IM nailing is immediate stabilization with access for management of the soft tissues. Patients undergoing IM nailing had a lower incidence of postoperative infection, malunion, nonunion, and less healing time compared with external fixator alone [32]. However, the results from our study demonstrated that while comparison with the combination of an external fixator with two titanium elastic nails, the advantages of intramedullary nailing become no longer evident. In addition, the indicators of soft tissue injury, delayed healing, and healing time used to compare the efficacy of two methods showed no obvious differences between the two methods.

The limitations of the present study were that: (1) This was a single centre study which enrolled only a small number of patients. To further confirm these results, higher quality randomized controlled trials with a larger sample size is needed. (2) The average follow-up was a relatively short period and thus most cases of post traumatic arthritis have not developed yet. A larger sample size containing more fracture patterns and longer follow-up would be helpful in a future study.

The EF + TENs method has synergistic effects in that it involves the advantages of both external fixation and titanium elastic nails. Its technological characteristics fit the treatment principles for segmental tibial fractures stabilization: (1) Further damages to tibial blood supply, the surrounding tissue and the endomedullary blood supply are prevented as much as possible; (2) No foreign matter is left in the wound, and there is minimal damage to the soft tissue, which promotes the prevention and control of infection; (3) It is an effective and rapid operation for reduction of the fracture which is beneficial for wound management; (4) It yields excellent stability, which creates a good environment for initial recovery of function; (5) Less blood loss during operation and peri-operative hidden blood loss; (6) It can be used in fractures which have bone subfissure close to the joint; (7) EF can be removed earlier, which reduces the probability of infection and inconvenience; (8) Gradual mobilization can promote fracture healing, which can be easily accomplish in the outpatient setting; (9) Lower rates of knee pain.

In conclusion, augmented titanium elastic nails with external fixators is a good solution for preventing complications and improving the treatment of segmental tibial fractures. Its benefits include its simplicity, minimal soft-tissue damage, no periosteal stripping and less blood-supply disruption of the fracture site. The EF + TENs theory is a good supplement for the treatment of segmental tibial shaft fractures.

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Disclosure of conflict of interest

None.

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