Do additional intramedullary elastic nails improve the results of definitive treatment with external fixation of open tibia fractures? A prospective comparative study

C. Ertürk a,∗, M.A. Altay a, A. Bilge a, N. Altay b, U.E. Işikan a

a Department of Orthopaedics and Traumatology, Harran University School of Medicine, Yenisehir, 63100 Sanliurfa, Turkey
b Department of Anesthesiology and Reanimation, Harran University School of Medicine, Yenisehir, 63100 Sanliurfa, Turkey

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KEYWORDS
External fixation; Intramedullary elastic nail; Open tibia fracture

Summary
Purpose: External fixation has been associated with a high incidence of complications and poor outcomes due to the instability and difficulty in treating open tibia fractures. We use intramedullary (IM) elastic nails to supplement the external fixator. We compared the results of fractures treated by external fixation with and without IM—elastic nail.

Hypothesis: The combination of external fixation with IM—elastic nails may be used as an alternative to solve problems due to the external fixators alone in open tibia fractures.

Methods: Group 1 included prospectively 26 cases (15 males and 11 females, mean age 37.5 ± 12.4 years) treated with external fixation and IM—elastic nails, whereas group 2 consisted of 28 cases (23 males and five females, mean age 30.7 ± 14.0 years) treated with standard external fixation. Functional and bone results were made using the criteria proposed by ASAMI.

Results: The mean follow-up period was 3.96 ± 2.0 years in group 1 and 3.32 ± 2.1 years in group 2. The mean duration to external fixation and mean time to union were significantly lower in group 1 (P < 0.001). In addition, bone and functional results were significantly higher in group 1 (P < 0.01), however, pin track infections were lower in group 1 (P < 0.01).

Conclusion: Our results showed the improvement in outcomes with IM—elastic nails: decreased duration of external fixation need and decreased bone healing delay. Therefore, this method may be a superior alternative for preventing complications related to external fixation in open tibia fractures.

Level of evidence: Level III: prospective comparative study.

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∗ Corresponding author. Harran University, Faculty of Medicine, Department of Orthopaedic Surgery, 63100 Sanliurfa, Turkey. Tel.: +90 414 318 31 48; fax: +90 414 315 11 81.
E-mail addresses: erturkc@yahoo.com, cemilerturk@harran.edu.tr (C. Ertürk).
Introduction

Although intramedullary (IM) nailing in closed fractures of the long bones is the gold standard, the treatment of type III B&C open fractures of these bones is still controversial. External fixation offers a quick and minimally invasive means of temporarily stabilizing open femur and tibial shaft fractures that might benefit the patient with multiple injuries or severe soft-tissue wounding [1]. Therefore, sometimes, an external fixator is inevitable in repairing an open fracture. However, pin track infections, delayed union, translation or malalignment, non-union, and patient discomfort remain the most common complications associated with external fixation [1,2]. One of the main complications, the development of delayed union and malunion, is likely due to either poor initial reduction or later loss of reduction [1–3].

In unstable diaphyseal fractures, reconstruction is known to be difficult. During surgery, priority should be given to the accurate reduction of axes and rotation and the protection of vascularization of the bone rather than its reconstruction [4,5]. Studies showed that the addition of an IM-pin increased the bending stiffness of osteosynthesis and could facilitate fracture alignment [6,7]. Several studies on non-union of long bones using the external fixator with IM—nailing have been conducted [7–10] but, we have not found any study in the literature about an acute diaphysis fracture treated with this method to maintain alignment.

In this study, it was hypothesized that external fixation with IM—elastic nails may be used as an alternative to solve problems due to the external fixators in open diaphysis tibia fractures. The present prospective controlled study aims to demonstrate an alternative method to treat open tibia fractures in order to prevent complications and increase external fixator utility. We compared cases treated with external fixation using IM—elastic nails to cases managed by standard external fixation.

Patients and methods

This prospective study included 54 open tibia diaphysis fractures that underwent external fixation between March 2000 and December 2009. Written informed consent was obtained from all patients, and approval to use their medical records and to re-evaluate each patient was given by the Local Research Ethics Committee (Ref No.: B.10.0.1EGO.0.11.00.01/007).

Inclusion criteria

Inclusion criteria were: one surgeon performed all the operations. All patients had an open injury of the tibia that received a primary treatment of external fixation either with or without the IM—elastic nails, with a minimum follow-up of 24 months. Exclusion criteria were: fractures located within 5 cm of the proximal or distal articular surface, fractures extending into a joint, and patients less than 16 years old were excluded. The selection of either external fixation with or without the IM—elastic nails was based on the preference of the attending orthopaedic surgeon, we were not able to randomize the treatment methods.

Patients

The soft-tissue injury was classified according to the Gustillo and Anderson [11] grading system at the time of initial assessment in the theater. 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) [12]. All patients were initially assessed in the emergency room. Irrigation, debridement, and primary skeletal stabilization were performed as soon as the patient’s general condition was satisfactory. At the same time, appropriate antibiotics and tetanus prophylaxis were given. Antibiotic treatment was started in the emergency room with 2 g of cefazolin, and continued for 3 days at a dose of 1 g every 8 h. In addition, we gave 160 mg of gentamicin to treat Gram-negative organisms in grade III fractures. For farm-related injuries, high-dose penicillin was added. Although our patients’ wounds were small (type 1 or 2 open fractures), they lived in rural and farm areas. Therefore, we preferred to use external fixation since their wounds might be dirty because of the risk of contamination in such locations. The wounds in 14 patients (all type 3 fractures) were managed using delayed primary closure and in three patients (all type 3 fractures) with skin grafting, whereas Gustilo-Anderson types 1 and 2 injuries in 37 patients were treated with secondary intention to granulate and close spontaneously.

In this study of 54 open tibia fractures, 26 were treated with external fixation with IM—elastic nails and 28 with standard external fixation. Both groups were comparable in terms of gender, fracture location, fracture comminution, grade of open fracture, and etiology (Tables 1 and 2).

The external fixation with IM—elastic nails group (group 1)

There were 26 cases (15 males and 11 females) and the average age at the time of surgery was 37.5 years (SD ± 12.4, range: 19–65 years). Patient data are shown in Table 1.

The standard external fixation group (group 2)

There were 28 cases (23 males and 5 females) and the average age at the time of surgery was 30.7 years (SD ± 14.0, range: 17–70 years). Patient data are shown in Table 2.

Surgical procedure

In group 1, we used IM—elastic nails to support the external fixator. In other words, before the reduction with IM—elastic nails, we provided alignment. Then to render the system more stable, we added an external fixator. Therefore, we chose ““C-shaped”” flexible IM—Ender elastic nails that acted as internal splints, which offered the advantages of good fixation and the control of alignment. We then applied the body of a unilateral frame or the connecting rods of an Ilizarov external fixator using a circular frame in 15 patients and a unilateral fixator in 11 patients (Figs. 1a–c and 2a–c). In group 2, standard external fixation was performed using a circular frame in 16 patients and a unilateral fixator in 12.

The frame was statically locked after reduction in all cases, both groups. Pin sites were cleaned with local
sterilization. Active hip, knee and ankle exercises as well as isotonic quadriceps movements were begun on the first postoperative day.

Clinical and radiological evaluation

Patients were clinically and radiographically evaluated at 2-week intervals for the first 2 months and at 4-week intervals from 2 months on. Follow-up radiographs were used to evaluate alignment, bone contact and callus formation. Fracture healing was evaluated using standard radiographic projections, and union was defined by the presence of a mature bridging callus in at least three of the four cortices in anteroposterior and lateral radiographs. Clinical union was defined as complete when the patient was able to bear full weight on the operated leg without pain or support. The external fixator in group 1 was removed if an adequate bridging callus was observed on radiograph. Because, after removing external fixation on the bone in, there is already a support IM, whereas in group 2, fixator removal was performed when the union was determined to be mature. The healing status of the fracture was evaluated by analyzing the fracture alignment on radiographs after loosening of the external fixators but before their removal. In most cases, a plaster cast or orthosis was placed after the external fixator was removed. Final evaluation of clinical and roentgenographically results were performed using the medical records and radiograms prepared or taken at the time of the latest visit during the periodical follow-up period. The results were evaluated to the classification of the Association for the Study and Application of the method of Ilizarov (ASAMI) [13]. The bone results were based on four criteria: union, infection, deformity, and leg length discrepancy. Functional results were based on five criteria: presence of a limp, stiffness of the knee or the ankle, pain, soft-tissue sympathetic dysfunction, and the ability to perform previous activities of daily living (ADL). Pin site infections were graded according to Paley [14] as follows: grade I (soft-tissue inflammation), grade II (soft-tissue infection), or grade III (bone infection). Shortening was evaluated as greater than 2.5 cm. Malalignment was evaluated as varus/valgus angulation greater than 7 degrees. Translation was evaluated as a loss of reduction: 50% of diaphyseal diameter or reduction.

Statistical analysis

All statistical analyses were conducted using the SPSS 16 computer program. The mean age, follow-up period, time to union for the tibia, and the duration of external fixation for the tibia were analyzed using the Mann-Whitney U test. Furthermore, pin track infection, shortening, malalignment, translation and non-union were analyzed using the chi-square ($\chi^2$) test. Values of $P < 0.05$ were significant.
Table 2  Patient data of group 2.

<table>
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<tr>
<th>Case</th>
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<th>Gustilo grade</th>
<th>ACP</th>
<th>EF</th>
<th>Difficulties</th>
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<th>Functional result</th>
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<td>P</td>
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<td>Excellent</td>
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<td>Poor</td>
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<td>I</td>
<td>P</td>
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<td>Excellent</td>
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<tr>
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<td>25/M</td>
<td>GW</td>
<td>B1</td>
<td>3A</td>
<td>I</td>
<td>P</td>
<td>Excellent</td>
<td>Excellent</td>
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<td>A1</td>
<td>3A</td>
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<td>U</td>
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<td>M/S/T</td>
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<td>A3</td>
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<tr>
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<td>GW</td>
<td>C1</td>
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<td>P/N</td>
<td>Poor</td>
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<td>GW</td>
<td>B1</td>
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<td>P</td>
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<tr>
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<td>GW</td>
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<td>3A</td>
<td>I</td>
<td>M/S/T</td>
<td>Fair</td>
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<tr>
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<td>2</td>
<td>I</td>
<td>M</td>
<td>Good</td>
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<tr>
<td>28</td>
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<td>TA</td>
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<td>1</td>
<td>I</td>
<td>P</td>
<td>Excellent</td>
<td>Excellent</td>
<td></td>
</tr>
</tbody>
</table>

TA: traffic accident; GW: gunshot wounds; OTA: Orthopedic Trauma Association classification; ACP: additional coverage procedures; EF: external fixation; U: unilateral; I: Ilizarov; P: pin track infection; M: malalignment; S: shortening; T: translation; N: non-union.

Results

The mean follow-up period was 3.96 ± 2.0 years (range 2–8 years) in group 1 and 3.32 ± 2.1 years (range 2–10 years) in group 2. Group 1 had significantly older people than group 2 (P < 0.05). Specific properties of the two groups are presented in Table 3.

The mean duration of the external fixation was shorter in group 1. The average time for fractures of the tibia was 2.54 ± 0.7 months in group 1, whereas it was 6.0 ± 2.2 months in group 2. The mean time for fracture union was shorter in group 1. The average time for tibia fracture healing was 3.38 ± 0.6 months in group 1, whereas it was 6.55 ± 1.8 months in group 2. The mean duration to external fixation and mean time to union were significantly lower in group 1 (P < 0.001).

In group 1, bone results were excellent in 25 cases (96.2%) and poor in one case (3.8%). In group 2, 15 cases (53.6%) were rated excellent, two cases (7.1%) good, five cases (17.9%) fair, and in six cases (21.4%) poor. Twenty-five cases (96.2%) in group 1 and 17 cases (60.7%) in group 2 yielded satisfactory results. Functional findings in group 1 were excellent in

Table 3  Specific properties of the two groups.

<table>
<thead>
<tr>
<th>Property</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Mean ± SD</th>
<th>Mann-Whitney U-test</th>
<th>P value</th>
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</thead>
<tbody>
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<td>Age (years)</td>
<td>1</td>
<td>26</td>
<td>37.5 ± 12.4</td>
<td>224.00</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>28</td>
<td>30.7 ± 14.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up (years)</td>
<td>1</td>
<td>26</td>
<td>3.96 ± 2.0</td>
<td>286.500</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>28</td>
<td>3.32 ± 2.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of external fixation (months)</td>
<td>1</td>
<td>26</td>
<td>2.54 ± 0.7</td>
<td>17.50</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>28</td>
<td>6.0 ± 2.2</td>
<td></td>
<td></td>
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<tr>
<td>Union time (months)</td>
<td>1</td>
<td>26</td>
<td>3.38 ± 0.6</td>
<td>11.00</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>28</td>
<td>6.55 ± 1.8</td>
<td></td>
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</tbody>
</table>
Figure 1  a: AP/lateral radiograph of an open tip 3 unstable tibial fracture; b: elastic nails were placed in the bone to maintain alignment and to support the external fixator; c: postoperative state 4 years after the fracture healed. Elastic nails were not removed unless they caused irritation.

25 cases (96.2%) and poor in one case (3.8%). Fifteen cases (53.6%) were rated excellent, and three cases (10.7%) good, four cases (14.3%) fair, and six cases (21.4%) poor in group 2. Twenty-five cases (96.2%) in group 1 and 18 cases (64.3%) in group 2 yielded satisfactory results. There was difference between two groups according to bone and functional results at final follow-up ($P < 0.01$) (Tables 1 and 2).

Complications

Postoperatively, there were three cases (11.5%) of pin track infection in group 1 whereas there were 15 cases (53.6%) in group 2. In group 1, three cases with grade I infections were treated by local care using Betadine solution and oral antibiotics with resolution of infection. In group 2, there were three cases (10.7%) with grade I and eight cases (28.6%) with grade II pin track infection. These cases also were treated by antibiotic therapy. However, in group 2, the severity of the grade III pin tract infections in four cases (14.3%) led to early external fixator removal. These cases were managed with a cast. In these cases, shortening, malalignment and translation were observed in two cases, and shortening and non-union were observed in one case each. No pin track osteomyelitis occurred. There was a significant difference in terms of pin track infection between the groups ($P < 0.01$). Shortening was observed in one fracture in group 1 and in seven fractures in group 2.
Malalignment was observed in one fracture in group 1 and in six fractures in group 2. Translation was one fracture in group 1 and in six fractures in group 2. Non-union developed in five cases in group 2. These cases were classified as a poor clinical and radiological result (Tables 1 and 2).

Discussion

It was hypothesized that external fixation IM—elastic nails would present some advantages in terms of the maintenance of fracture alignment during healing process. In addition, this combination may be used as an alternative to solve problems due to the external fixators. Our results show that the mean duration to external fixation, mean time to union, and pin track infections were significantly lower in group 1. Additionally, bone and functional results were significantly better in group 1. Therefore, elastic IM—nailing confers several advantages over open tibia fracture treatment with an external fixator.

However, our study had major limitations. This study is the limited number of cases and not randomized. There is no homogenous group according to the Gustilo and Anderson classification or the OTA classification.

In previous studies, several authors showed that articular complications (stiffness, subluxations, dislocations) are related to the duration of external fixation [1,2,15]. To reduce the complication rate and the duration of external fixation, several procedures that a reduction unites to provide accurate fracture reduction [16,17], limb axial alignment grid [18], and tailoring frame design [19] to meet the requirements of individual cases.
In our study, before one or two months, external fixators were removed without full union because IM biomechanical support persisted in group 1. Therefore, in group 1, external fixators were removed 3.4 months earlier in tibial fractures. In the present study, the IM–elastic nails were placed in the bone to maintain alignment to support the external fixator. The advantages of elastic nails are that the pins are inserted percutaneously; reaming is not necessary; the small diameter of the nails interferes minimally, so there is less disturbance of the IM blood supply. The surface area of the bone at the fracture site is also not restricted, and cyclic loading of the fracture can occur. When applied diaphysis of bone, internal splints by a three-point construct that, under stress, develops a force in the direction opposite to the elastic deformation of the nails are effective at achieving union in good alignment [6,7].

The use of augmented external fixation with a single flexible IM nail is not a new concept. In 2004, Shevstov et al. [20] reported the results of an experimental and clinical study that found a relationship between lengthening by external fixators and IM–nailing performed following the principles of the elastic stable IM–nailing. Their results showed that these findings were likely caused by an intense periosteal reaction and endosteal regeneration. In recent studies, flexible IM nails with an external fixator have often been used in limb lengthening [21–23]. In addition, in our previous study, we used the elastic nails with an external fixator in intertrochanteric fractures [24]. In group 1, the mean time to union has been achieved 3.3 months in tibia fractures. Furthermore, in group 1, the mean time to union was shorter compared with what has been reported in several other studies [15,17,25].

Pin track infection is an ordinary problem in external fixation [1,2,15–17,25–27], but group 1 patients had five times less. Group 1 only had a few cases of pin track infection. We think early fixator removal led to this result. Another reason of the less pin track infection may be due to weight-bearing forces at the pin–bone interface tolerated by IM pin. Furthermore, elastic nails facilitate a balanced load distribution because they are flexible. Some experimental studies have confirmed our results. Hente et al. [28] found an increase in callus binging stiffness between the third and seventh week, converging at the tenth week. Thus, they showed that pin loosening started after the eighth week. They recommended fixator removal before pin loosening, leading to infection. However, the greatest weakness in this approach is the potential for IM sepsis secondary to IM contamination. In combined technique, we used unreamed nails. Nowadays, bone lengthening using an external fixator with IM–nailing is widely used [29]. In bone lengthening, the IM device is used with a kühner’s nail that completely fills the medullary space. However, a serious risk of sepsis is not currently associated with this procedure. Therefore, we do not believe that the technique proposed in this study poses any greater risk of sepsis than the risk that exists from the standard use of an external fixator.

Malunion, loss of reduction and non-union are certainly more commonly seen in patients treated with external fixation, and rates of up to 20% are quoted in the published literature [18,25]. According to our study, combined technique achieved superior alignment compared with the standard technique. Thus, in group 1, patients had more less the shortening, varus/valgus angulation, loss of reduction, and non-union rate than patients in group 2.

This combined method has synergistic effects in that it involves the advantages of both external fixation and IM–nailing. We believe that the augmented IM–elastic nail with external fixators is a good solution for preventing complications and improving the efficiency of treatment. However, in this paper, we do not claim to have the most accurate indications for treating open tibia fractures. Although this study included types 1, 2, and 3A open tibia fractures, we think that this technique should be used for external fixation for types 3B and 3C open tibia fractures. Furthermore, in the present study, we have used Ender elastic nails, nowadays, obtain these nails can be a problem. For this reason, we think the titanium elastic nails can be used in accordance with the same concept.

Conclusions

Based on the clinical and radiological results of what is, to our knowledge, the first controlled study of the subject, augmented IM–elastic nails with external fixators seem to decrease the duration of external fixation and the bone healing period and to improve clinical and radiological outcome. Further larger long-term prospective comparative series are needed to support these results.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References

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