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Would your intraoperative results differ if you were a four-handed orthopedist in intramedullary nail surgery for tibial fractures?

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Abstract

The present study aimed to present the intraoperative results of a fixation device that assists in fracture reduction during closed intramedullary nail application in tibial shaft fractures and provides a temporary stable fixation until the last stage of surgery. The fixation device used in our study consists of two custom-made bone clamps and a joint system that connects the clamps. Patients diagnosed with closed tibial shaft fracture between 01.01.2020 and 20.12.2021 were included in our retrospective study. Twenty-one patients who underwent closed intramedullary nailing and used a fixation device in the intraoperative period (Group 1) and 21 patients who underwent closed intramedullary nailing without a fixation device (Group 2) were included in the study. Both groups were compared in terms of duration of the operation, amount of bleeding, wound infection, intraoperative fluoroscopy time, preoperative period, follow-up time, varus and valgus deformity, limb shortness, malrotation, nonunion, and deep vein thrombosis. In Group 1, the mean duration of operation was 72.62±8.78minutes; the mean amount of bleeding was 31.10±6.13ml, and the mean intraoperative fluoroscopy time was 76.81±11.83 s. In Group 2, the mean duration of operation was 87±13.12 minutes; the mean amount of bleeding was 29.81±6.01ml and the mean intraoperative fluoroscopy time was 100.71±11.50 s. Intraoperative fluoroscopy time, varus deformity, and malrotation were significantly different between the groups (p=0.001, p=0.030, p=0.001, respectively). In the study, it was observed that the intraoperative fixation device decreased intraoperative fluoroscopy time, varus, and rotational deformity. It was considered that the fixation device would reduce the radiation exposure of the health personnel in the intraoperative period and reduce the malunion rate due to varus and rotational deformity.

Keywords: Tibial shaft fracture, intraoperative reduction, fixation device, intramedullary nail

Introduction

Tibial shaft fractures are the most common long bone fractures with an incidence of 26/100.000 as a result of high-energy trauma [1,2]. These fractures usually occur as a result of high-energy trauma, traffic accidents and sports injuries [3]. Conservative treatment (circular casting), plateosteosynthesis, external fixation systems, or intramedullary nailing (IMN) are implemented in the treatment of these fractures. Although these methods have different advantages and disadvantages, IMN method is used most frequently. Closed IMN (CIMN) is considered as the gold standard in the treatment of long bone fractures since it provides both axial and rotational stability and allows early load bearing [3-5]. In order for IMN to be the gold standard; intraoperative reduction of the fracture in accordance with the anatomy of the tibia, stability of the reduction throughout the intraoperative period, prevention of malrotation, stable proximal and distal screw fixation should be ensured.

The most important intraoperative steps in CIMN are; sterile covering of the fractured extremity, correct determination of the entry hole of the CIMN, closed reduction of the fracture in accordance with the anatomic structure in order to prevent malunion, threading the guidewire, reaming the medulla with reamers while the fracture is reduced, placing the appropriate thickness of the IMN into the medulla, and inserting the proximal and distal screws. One of the most crucial steps is reaming the medulla with reamers while the fracture is fully reduced. IMN performed without reduction results in failure. Although traction and reduction has been carried out with manual traction and reduction under the guidance of a scope since the past, it is not possible for this method to provide a stable anatomical reduction until placement of the IMN, to prevent reduction disorders that may cause malunion and to allow the limb to be mobilized easily in the intraoperative period. Since stable fixation cannot be achieved in manual reduction, it is necessary to check with

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fluoroscopy whether the fracture line is slipping while reaming the medulla and whether the gait wire is out of the medulla. Therefore, methods such as distractors, external fixators, adjustable knee and tibial positioners, tibial and femur triangles, Esmarch technique, hanging leg technique have been performed as an alternative to manual traction to achieve fracture reduction in the intraoperative period [6-8]. All of these methods have been developed to prevent disruption of fracture reduction during intraoperative reaming of the tibial medulla and placement of the CIMN. We tried to develop a technique that provides stable reduction of the fracture during surgery.

The aim of this study was to demonstrate the intraoperative results of the fixation device (TALTFIX), which assists fracture reduction during CIMN implantation in tibial shaft fractures and provides a temporary stable fixation until the last stage of surgery. In addition, we tried to determine the advantages of the fixation device to the surgeon and the patient in the intraoperative period.

Materials and Methods

This retrospective study included patients admitted to the emergency department of Malatya Turgut Özal University hospital between 01.01.2020 and 20.12.2021 with a diagnosis of closed tibial shaft fracture. Patients over 18 years of age, with closed tibial shaft fracture, indication for IMN, no additional fractures and complete documentation were included in our study. Patients under 18 years of age, with open tibial fractures, old fractures (unoperated for more than 3 weeks), incomplete documentation and additional fractures were excluded. Among 30 patients who were diagnosed with tibial fracture and underwent CIMN using a fixation device, 2 patients with open fractures, 4 patients with old fractures, 2 patients with multiple fractures and 1 patient with incomplete documentation were excluded from the study between January, 1st, 2020 and December, 20th, 2021. The remaining 21 patients were classified as Group 1 (patients with TALTFIX). Among 32 patients who underwent CIMN with manual distraction and reduction without TALTFIX, 3 patients with open fractures, 5 patients with old fractures, 1 patient with multiple fractures and 2 patients with incomplete documentation were excluded from the study. The remaining 21 patients were designated as Group 2 (patients without TALTFIX). All operations were carried out by the same orthopedist and the same IMN set was used. Patients were informed about the study and informed consent was obtained. The study approval was obtained from the local ethics committee of Malatya Turgut Özal University Faculty of Medicine (Approval date and number: 29.03.2022/2022-10). All procedures in the study complied with the ethical standards of the Declaration of Helsinki. The fixation device consisted of two custom-made bone clamps and a joint system that connects the clamps (Figure 1, Figure 2). This fixation device allows closed reduction of the tibial shaft fracture, stable fixation during the intraoperative period and compression-distraction of the fracture ends.

Surgical Procedure

The patients in both groups underwent spinal anesthesia, tourniquet and the same brand of intramedullary nail implant were implemented. All patients received three cortical screws proximally and three cortical screws distally. In both groups, intraoperative CIMN surgery was carried out with the knee flexed at 90 degrees and the extremity suspended from the table or placed on the table. In group 1, an incision of 3 cm was performed on the proximal and distal parts without opening the fracture line (Figure 3). In group 1, after the tourniquet was inflated, a 5cm incision was performed at the level of the patellar tendon. An entry hole was opened through the center of the tendon under fluoroscopic guidance. Two bone clamps of the fixation device were fixed to the proximal and distal bones through these 3cm incisions. By means of the bone clamps of TALTFIX, the fracture was fully reduced under fluoroscopic guidance and the fracture was fixed with an inter-clamp joint apparatus (Figure 4). The guidewire was inserted into the medulla. TALTFIX provided stability during the reaming of the medulla and the IMN was inserted (Figure 5). In some cases, the gaps in the fracture line after IMN placement were closed intraoperatively with the compression feature of the joint between the two bone clamps of the fixation device. Three freehand screws were inserted at the distal side to the nail and three screws were inserted proximally with nail gags. A stable fixation was provided with the fixation device throughout the infrapatellar IMN surgery and the reduction of the fracture was prevented during the intraoperative period. Afterwards, the clamps of the fixation device were detached and the wounds were cleansed and stained. An incision of 5cm was made at the patellar tendon level after inflation of the tourniquet in Group 2. The access hole was drilled through the center of the tendon under fluoroscopic guidance. The fracture was manually distracted and reduced with the help of an auxiliary personnel and a guidewire was implemented. Distraction and reduction were achieved manually during reaming of the medulla. Fluoroscopy was necessary to visualize fracture reduction during each reaming procedure. The IMN of appropriate thickness was then inserted into the medulla. Freehand 3 screws were inserted distal to the nail and 3 screws were inserted proximally with nail gland apparatus (Figure 6). Afterwards, the wounds were cleaned and dressed.

Post-Operative Evaluation

Postoperative antibiotic therapy was started in all patients. Low molecular weight heparin sodium was prescribed to prevent deep vein thrombosis. Nonsteroidal anti-inflammatory drugs were also initiated. On postoperative day 1, extremity exercises were commenced and the fractured extremity was mobilized by providing a tolerable weight load to the fractured extremity. Patients were discharged on postoperative day 3. Patients were recalled for follow-up visits once a week for the first month and once a month in the following months. After the callus was visible in the two cortices on the radiographs of the patients, full load was provided.

Both groups were compared in terms of duration of operation (minutes), amount of bleeding (ml), wound infection, intraoperative fluoroscopy time (seconds), preoperative time (days), follow-up time (months), varus and valgus deformity, limb shortness, malrotation, nonunion and deep vein thrombosis. The duration between staining of the extremity, tourniquet inflation and skin closure was considered as the operative time. Nonunion was defined as nonunion if a delay in fracture healing was observed at the 9th postoperative month and there was limited progression in the following 3 consecutive months [9]. Malunion criteria were defined as rotation deformity of more than 10°, varus or valgus deformity of more than 5°, and shortening of more than 5 mm [10].

Statistical Analysis

The analysis of the data included in the study was conducted with SPSS (Statistical Program in Social Sciences) 25 program. It was examined with the Kolmogorov Smirnov Test whether the data conformed to the normal distribution [11]. The significance level (p) was considered as 0.05 for the comparison tests. Since the variables were not normally distributed (p>0.05), the analysis continued with nonparametric test methods.

Comparisons in independent paired groups were conducted with the Mann Whitney U test since the normality assumption was not fulfilled. Categorical data were analyzed by cross tabulations and chi-square analysis.

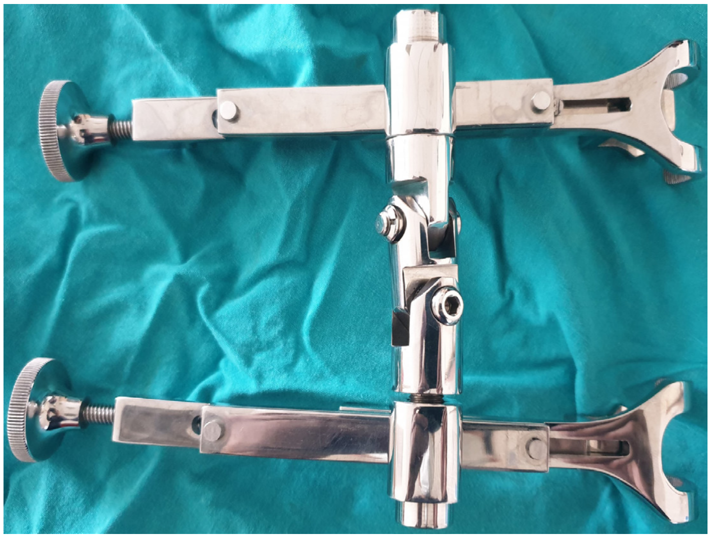

Figure 1. View of fixation device

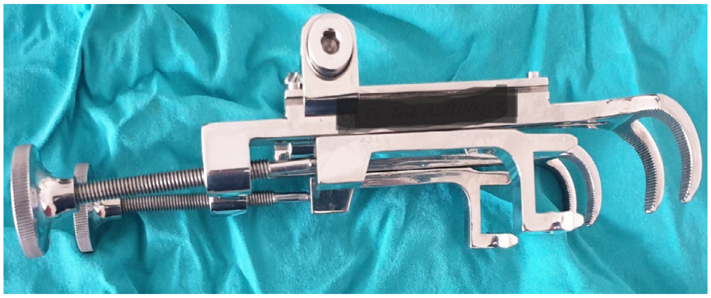

Figure 2. Side view of fixation device

Figure 3. Proximal and distal incision for fixation device clamps

Figure 4. Placement of fixation device clamps

Figure 5. Placement of the intramedullary nail

Figure 6. Roentgenography

Results

Forty two patients were included in the study. In group 1, the mean patient age was 30.52±9.64 years; 15 of 21 patients were male; and the mean follow-up period was 14.76±2.28 months. In group 2, the mean patient age was 29.81±10.22 years, 16 of 21 patients were male, and the mean follow-up period was 14.71±2.26 (14-20) months. The demographic characteristics of the two groups are listed in Table 1. Eleven patients in Group 1 and ten patients in Group 2 had fibula fractures. There was no difference between the two groups in terms of age, gender, duration of hospitalization and postoperative follow-up (Table 1). The fracture pattern and mechanism of injury are presented in Table 2.

Table 1. Patient demographic data

	Group 1	Group 2	p value
Number of patients	21	21	_
Gender (male/female)	15/6	16/5	0.726
Age(years)	30.52±9.64	29.81±10.22	0.817
Preoperative time (days)	4.67±2.18	3.86±2.01	0.250
allow-up period (month)	14.76±2.28	14.71±2.26	0.939

Table 2. Fracture pattern and injury mechanism of the patients

	Group 1 n(%)	Group 2 n(%)
Fracture pattern		
43A1	7(33.3)	8(38)
43A2	6(28.5)	5(23.8)
43A3	6(28.5)	7(33.3)
43B1	0	0
43B2	2(9.5)	1(4.7)
43B3	0	0
43C1	0	0
43C2	0	0
Injury mechanism		
Traffic accident	7(33.3)	8(38)
Slipping and falling	5(23.8)	5(23.8)
Sports injury	4(19)	3(14.2)
Falling from a height	5(23.8)	5(23.8)

In group 1, the mean duration of operation was 72.81±2.34 minutes; the mean amount of bleeding was 31.10±6.13ml, and the mean intraoperative fluoroscopy time was 73.05±1.98 seconds. In group 2, the mean duration of operation was 74.38±2.84 minutes; the mean amount of bleeding was 29.81±6.01ml, and the mean intraoperative fluoroscopy time was 98.05±14.15 s (Table 3). A significant difference was found between the groups in terms of fluoroscopy time (p=0.001). There was no significant difference between the groups in terms of duration of operation, amount of bleeding, deep vein thrombosis, wound infection, and nonunion (Table 4). One patient in Group 1 developed superficial infection at the distal screw incision and two patients in Group 2 developed superficial infection at the surgical entry hole incision site (Table 4). Patients recovered with antibiotherapy treatment. There was no significant difference between the groups in terms of infection.

Table 3. Intraoperative data comparison

	Group 1 (mean±sd)	Group 2 (mean±sd)	p value
Duration of operation (min)	72.81 ± 2.34	74.38 ± 2.84	0.064
Blood loss (ml)	31.10 ± 6.13	29.81 ± 6.01	0.496
Intraoperative fluoroscopy time (s)	73.05 ± 1.98	98.05 ± 14.15	0.001*

sd; standard deviation, test value; Mann Whitney Test Value, p value; statistical significance, *p<0.05; there is a statistically significant difference between the groups. ml: milliliter, s: second

Table 4. Comparison of complications between Group 1 and Group 2

	Group 1 n(%)	Group 2 n(%)	p value
Deep vein thrombosis	1(4.8)	0	0.235
Nonunion	0	0	*
infection	1(4.8)	2(9.5)	0.545

%; percentage, p; Chi-square Test p value (χ2), *; since it is a single value, statistical comparison cannot be made and consequently p value cannot be measured.

In Group 1; the varus deformity (°), valgus deformity (°), shortness (mm), malrotation (°) were 0.86±1.28, 0.86±0.91, 1.86±1.31, and 1.48±1.33, respectively. In Group 2; the varus deformity (°), valgus deformity (°), shortness (mm), malrotation (°) were 1.76±1.64, 0.62±1.16, 2.19±1.75, and 4.81±2.99, respectively (Table 5). There was a significant difference between the groups in terms of varus and rotational deformity (°) (p=0.030, p=0.001). No significant difference was detected between the groups in terms of valgus deformity (°) and shortness (mm) (p=0.147, p=0.651).

Table 5. Comparison of radiologic results between Group 1 and Group 2

	Group 1(meant±sd)	Group 2(mean±sd)	p value
Varus deformity (°)	0.86 ± 1.28	1.76 ± 1.64	0.030*
Valgus deformity (°)	0.86 ± 0.91	0.62 ± 1.16	0.147
Shortness(mm)	1.86 ± 1.31	2.19 ± 1.75	0.651
Malrotation (°)	1.48 ± 1.33	4.81 ± 2.99	0.001*

%; percent, p; Chi-square Test p value (χ2), mm: millimeter, (°): Degrees, *p<0.05; statistically significant difference between groups.

Discussion

IMN implantation is the gold standard method in tibial shaft fractures [12]. In order to achieve a successful outcome in the postoperative period in the IMN treatment of these fractures, the fracture should be stabilized and fully reduced at every stage of the surgery in the intraoperative period. Many methods have been developed to achieve this stability and reduction. These include manual reduction, traction table, auxiliary external fixator system. Although manual reduction is simple and convenient, it leads to an increase in the surgeon's workload, an increase in the number of assistive personnel, an increase in radiation time and inadequate stabilization [13]. The risk of calcaneal fracture and contamination may increase with the use of a traction table [14]. Assistive external fixator systems and multiplanar fracture reducers have been utilized successfully in the reduction of fractures [15-17]. In our study, we was developed the TALTFIX, which functions as an auxiliary external fixator to maintain fracture stability and complete reduction during the intraoperative period.

In the study of Yao et al. a distraction supporting device was used in tibial fracture. The mean duration of operation was 75.3±10.5 (minutes), the amount of bleeding was 60.1±27.2(ml), infection rate was 7%, deep vein thrombosis was 0% and delayed union rate was 4% [18]. The multiplanar fracture redactor was used in the study by Zhao et al. The mean duration of surgery was 91.2±26.1 minutes; the mean amount of bleeding was 95.0±58.3ml; infection rate was 0%; deep vein thrombosis was 1%; and delayed union rate was 0% [19]. In Laurentin's literature review study, the average nonunion rate in tibial fractures was reported to be 11% [20]. In Patel's study, the nonunion rate was detected as 4% [21]. Although nonunion was not observed in our study, results compatible with the literature data were obtained.

In the study by Ke lu et al., the intraoperative fluoroscopy time was 122 ± 24.3 seconds in patients who underwent IMN with infrapatellar opening for tibial shaft fracture [22]. In Ladurner's study, intraoperative fluoroscopy time was 126 ± 30 seconds [23]. In Jinzhu Zhao's study, intraoperative fluoroscopy time was 68.53 ± 8.69 seconds [24]. In our study, fluoroscopy time was observed to be significantly lower in the TALTFIX group. It was thought that TALTFIX would decrease the radiation exposure of the healthcare team by decreasing the intraoperative fluoroscopy time in the intraoperative period.

Malunion (varus, valgus, shortness, translation) is inevitable in tibial shaft fractures if a complete reduction is not performed. Blachur et al. found a malunion rate of 4% in their study [25] whereas Rathwa et al. found a malunion rate of 8% in their study [26]. In the study of Kang et al. the malunion rate was found to be 25% in the tibial shaft group who underwent IMN [27]. In Hendrickx's study, the malunion rate was 7.5% and the rotational malalignment rate was 1.3% [20]. In our study, results that are more successful were obtained in terms of varus and rotational deformity (°) in the group using TALTFIX compared to the group without TALTFIX.

The important phase in IMN surgery is the reduction of the fracture during reaming and the fixation device provides us with this. The fixation device decreased intraoperative fluoroscopy time, varus and rotational deformity. Reduced fluoroscopy time will reduce the radiation exposure time for the surgical team. Reducing the development of varus and rotational deformity will prevent the patient's fracture from turning into malunion in the advanced period. In addition, it can be said that the fixation device can be the 3rd and 4th hand of the orthopedist in long bone fractures and 'increase the number of hands under the control of the orthopedist to four' by facilitating fracture reduction and providing stable fixation.

Conclusion

According to the results obtained from this study, intraoperative fixation device decreased fluoroscopy time, varus and rotational deformity. It was thought that the fixation device will reduce the duration of radiation exposure of the hip and the rate of varus and rotational deformity development in the intraoperative period.

The retrospective design of this study, enrollment of some patients after the treatment and insufficient number of the patients are the limitations of the study.

Conflict of interests
The authors declare that there is no conflict of interest in the study.

Financial Disclosure
All authors declare no financial support.

Ethical approval
Ethics committee approval for this study was obtained from the Scientific Research

Ethics Committee of Malatya Turgut Ozal University University with decision number of 2020/10 on March, 29th, 2022.

Informed Consent

Written informed consent was obtained from all participants who participated in this study.

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