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Does the distance of the fixation points to the fracture affect healing in tibial shaft fractures treated with openable distal claw intramedullary nail?

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ABSTRACT

Objective: A retrospective examination was made of tibia shaft fractures treated with tibia intramedullary nail (IMN), which are designed with distal retractable claws, unlike classic imtramedullar nails. It was aimed to evaluate the effect on healing of the nail diameter and the distance between the fracture line and the proximal and distal fixation points of the IMN.

Material and Method: The study included 28 patients (18 males, 10 females; mean age 43.75 (18-69) years) treated with distal retractable claw tibia IMN (Dunitech Nite Tibial IMN Oliga Med Ankara-Turkey) for a diagnosis of unilateral tibia diaphyseal fracture between January 2020 and January 2022. The midpoint of the fracture line (F), the proximal fixation point of the locking screw (S), the distal fixation point of the retractable claw (T), and the isthmus mid-point (I) were determined as reference points. The FT, ST, and IT distances, the nail diameter (ND) and isthmus diameter (ID) were measured and the FT/ST ratio was calculated. Statistical evaluations were made of the relationships between the diameter and length measurements and the visual analog scale (VAS) and radiographic union score for tibia (RUST) scores at the end of one year.

Results: No statistically significant correlation was determined between the RUST and VAS scores and the diameter measurements or the distance between the proximal and distal fixation points of the IMN.

Conclusion: There was no effect on the fracture healing scores of the nail diameter or the distance between the proximal and distal fixation points in tibia shaft fractures treated with a tibia nail with distal retractable claws. The nail design with retractable claws provides strong fixation and stable fracture healing. The operating time is shorter resulting in less radiation exposure.

Keywords: Tibia Fracture, intramedullary nail, fracture healing

INTRODUCTION

Fixation with intramedullar nailing is the most preferred method in the surgical treatment of long bone fractures. IMN's are implants with the advantages of being minimally invasive, can be applied rapidly, provide good fracture fixation, and allow early mobilisation (1,2). Soft tissue trauma, blood loss, infection rates and wound complications are less in intramedullary fixation methods (3). The factors determining the efficacy of IMN are the nail design, whether or not it is grooved, the number and diameter of the locking screws, and bone quality. The distance between the locking screws and the fracture region is also important in stability (2,4,5).

Tibial nails designed with distal retractable claws are IMN's with a different design which are now being used in the treatment of tibial shaft fractures. In this design, while proximal fixation is made with classic locking screws, distal fixation is provided by the retractable claws attaching to the inner surface of the bone cortex. Distal retractable claws eliminate the problems of distal screw application (6,7). However, there is no study in the literature related to what the distance should be of the distal claws from the fracture region, even though these measurements are known to affect fracture healing. The question to which an answer was sought in this study was whether an increase in the distance from the fracture of the fixation claws in the distal of the fracture has a negative effect on fracture stability and associated fracture healing. As the medullar canal in the tibia widens towards the distal metaphyseal region, this could reduce the attachment strength of the claw structure in the medullar region with a larger diameter and this could have a negative effect on fracture healing. In this study, a

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retrospective evaluation was made of the results of patients applied with tibia IMN designed with distal retractable claws in the treatment of a tibial shaft fracture. It was also aimed to reveal relationships between the radiographic union score for tibia scores (RUST) and the visual analog scale (VAS).

MATERIAL AND METHOD

The study was carried out with the permission of Hitit University Non-Invasive Ethics Committee (Date: 28.09.2022, Decision No: 2022-20). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

In this study, patients who were operated for tibia fractures between January 2020 and January 2022 were analyzed. Fractures were classified according to the AO/OTA classification. The retrospective evaluations and measurements of the patients were made by two senior experienced orthopaedists and a radiologist. The patients included were those with a unilateral tibia fracture, closed or Gustilo-Anderson type 1 open fracture, AO/OTA 43 tibia diaphyseal fracture, and at least one year of recorded follow up. Patients were excluded if they had any chronic systemic disease, multiple system trauma, or more than one fracture.

When applying IMN, the patient was positioned supine with the knee in 90° flexion. Entry was made with a mid-patellar incision in the proximal tibia and the patellar tendon was separated to two sides. The medullar canal was entered with a guide K-wire. Under fluoroscopy guidance, closed reduction of the fracture was performed. The medullar canal was reamed with 8, 9, 10, 11 mm diameter reamers consecutively over the guidewire. Following the reaming procedure, a 9 mm intramedullar nail was placed. Distal fixation was provided by fully opening the distal claws with a torque screwdriver. Proximal fixation was provided by first drilling over the guide apparatus then placing the locking screws. Alignment was checked under fluoroscopy then the opeeration was terminated.

Measurements were taken on the radiological images of the fracture retrieved from the patient records (**Figure 1**). The medullar canal mid-point of the fracture line (F) and the mid-point of the tibial isthmus (I) were taken as reference points on the radiographs. The most distal point from the proximal locking screws (S), and the most proximal point of the retractable claws making the distal fixation (T) were determined. The distances between these points were measured as FT, ST, and IT, and the isthmus diameter (ID) was measured (**Figure 2**). In addition to these measurements, parameters such as operation time, hospital stay, union time, delayed union, development of nonunion, open fracture, and necessity for secondary surgery were examined. The development of an axial or rotational deformity on the radiographs was analyzed.

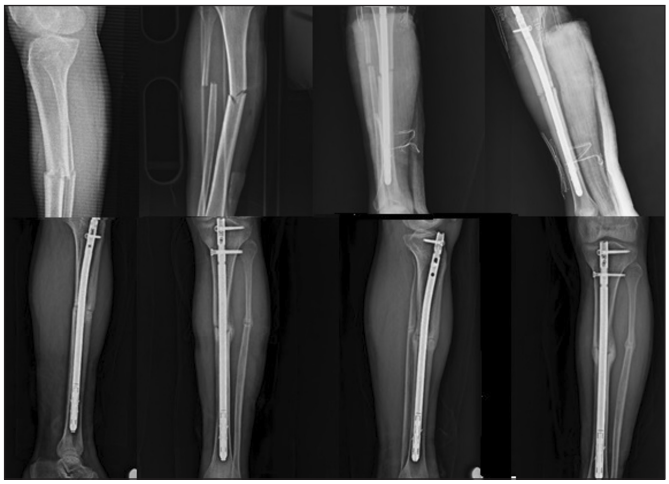

Figure 1. The appearance of the intramedullary nail in the direct radiographs of the patients

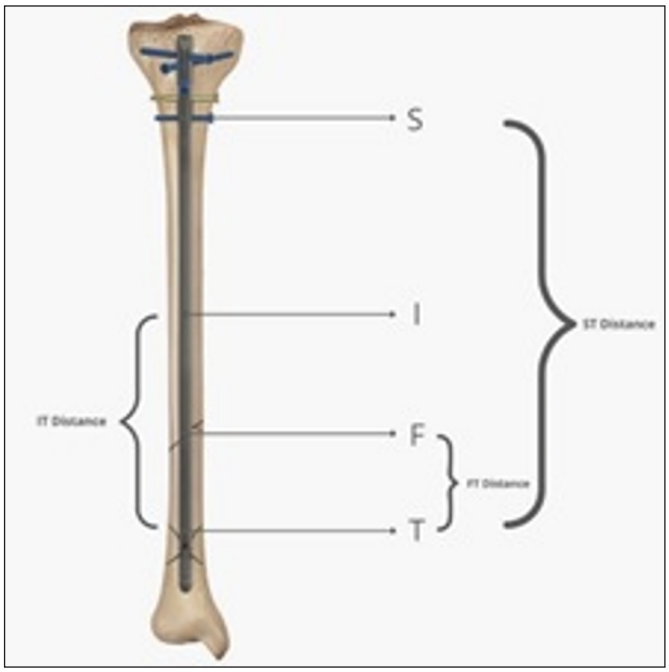

Figure 2. Length and diameter measurements drawing

RUST score for radiological healing and the VAS for functional healing of the patients were examined at the end of one year and recorded. The relationships between the distance and diameter measurements and the VAS and RUST values were statistically evaluated.

Statistical Analysis

The SPSS (Version 22,0, SPSS Inc, Chicago, IL, USA) package program was used to perform statistical analyses on the data gathered in this study. The normal distribution of the data was tested with the Shapiro-Wilk tests. Descriptive statistics of continuous variables were reported using median (min-max) and mean ± standard deviation (SD). Descriptive statistics of categorical data were reported as numbers and percentages (%). Correlations between numerical variables were investigated with Spearman correlation coefficient in accordance with the depending on data distribution. The statistical significance level was evaluated as $p<0.05$.

RESULTS

The study included 28 patients with a unilateral AO/OTA 42 tibia diaphyseal fracture treated with distal retractable claw tibia IMN in our clinic. The patients comprised 10 (35.7%) females and 18 (64.3%) males with a mean age of 43.75±17.89 years. In all the patients, fixattion was applied with a 9 mm diameter intramedullary nail. The mean operating time was 36.68±8.87 mins and the mean length of stay in hospital was 8.96±6.26 days. In five (17.9%) patients, the fracture was Gustilo-Anderson type 1 open fracture. Delayed union developed in four (14.3%) patients and union was obtained without the need for any additional surgical procedure. The mean time to union was 15.28 weeks (range, 12-26 weeks). No axial or rotational misalignment was observed on the radiographs during follow up. The descriptive statistics of the demographic and clinical characteristics of the patients are shown in **Table 1**.

Table 1. Statistics on socio-demographic and clinical characteristics

	n	Percent (%)
Gender		
Male	18	64.3
Female	10	35.7
Mechanism		
Fall	22	78.6
Traffic accident	5	17.9
Crush İnjury	1	3.6
Side		
Right	17	60.7
Left	11	39.3
Fracture type		
Closed Fracture	23	82.1
Open Fracture	5	17.9
AO Classification		
A2	14	50
A3	14	50
Union		
Delayed Union	4	14.3
Complete Union	24	85.7
	Mean±SD	**Median (min-max)**
Age	43.75±17.89	45.5 (17-69)
Hospitalization Days	8.96±6.26	6 (3-24)
Operation Time (minute)	36.68±8.87	37.5 (22-53)
Number of Scopy Shots	35.11±13.14	33.5 (15-56)
Union time (week)	15.28±3.88	14 (12-26)

There was no statistically significant correlation between radiological length measurements (FT, ST, IT) with radiological fracture healing score (RUST) and visual analog scale (VAS).

There was no statistically significant relationship between radiological length measurement ratio (FT/ST ratio) with radiological fracture healing score (RUST) and visual analog scale (VAS).

There was no statistically significant relationship between radiological diameter measurement ratio (ND/ID ratio) with radiological fracture healing score (RUST) and visual analog scale (VAS).

There was no statistically significant relationship between radiological diameter measurement difference (ID-ND diameter difference) with radiological fracture healing score (RUST) and visual analog scale (VAS) (**Table 2**).

In four patients, the nails were removed on patient request without any problems after full fracture union. Deep vein thrombosis, pulmonary embolism, infection or compartment syndrome, shortness or malunion, refracture development, intramedullary nail failure or breakage in the locking screw or claw structure were not observed in any patient.

DISCUSSION

The biomechanical characteristics of different IMN designs used in tibia shaft fractures can change the duration of application, duration of radiation exposure, fracture stability, healing and the functional effect. Nail designs which are easy to apply and provide stable fracture healing should be more preferred. Shorter operating times, less radiation exposure and stable fracture fixation have been obtained with different IMN designs used in tibia fractures. However good the stability is in locking IMN's, there are the disadvantages of difficulties in application (6-9). The ease of application of expandable nail designs or nails with retractable claws for distal fixation is a great advantage for orthopaedic surgeons (6,7,10,11). Nails designed to be completely expandable without locking screws eliminate the complications that can develop during

Tablo 2. Relationships between the RUST and VAS scores and the F-T, S-T, I-T distances, the FT/ST ratio, the diameter difference in the ID-ND, and the ND/ID ratio).

	F-T distance (mm)	S-T distance (mm)	FT/ST ratio	I-T distance (mm)	ID-ND difference (mm)	ND/ID ratio
RUST Score						
r	-.234	-.118	-.206	-.293	.004	-.004
p	.230	.551	.292	.130	.983	.983
VAS Score						
r	.131	-.045	.120	.247	.006	-.006
p	.505	.819	.542	.205	.977	.977

Spearman correlation coefficient

the application of locking screws and the lengthening of the operating time (12,13). The nail design we used in our study was preferred because it has these features. We think that the average operation times, the necessity of using fluoroscopy and the length of hospital stay are reduced. In fracture fixation made with classic locking intramedullar nails, the distance of the distal screws from the fracture line is important in stabilty. Pourmokhtari (4) used the definition of functional length in IMN's. This definition is basically the distance between the points fixed to the bone with screws in the proximal and distal of the nail. The placement of these screws affects the biomechanics of the fracture. The closer the screw is to the fracture region, the greater the exposure to pressure. Therefore, to increase fracture stability, there should be a distance of at least 2 cm between the screws at the end of the nail and the fracture region (4). Similarly, Eveleigh (14) named the part remaining between the fixation points in the proximal and distal of the IMN as the "working length". This definition may also be at the point which is fixed when the nail is in contact with the medullar canal wall. The torsional rigidity of an IMN and the bone structure where it is applied is in inverse proportion to the working length of the nail. It was also stated that intramedullar implants of similar diameter have similar bending rigidity (14). In another study it was reported that a distance of more than 3cm between the distal screw region and the fracture line in femoral IMN could cause complications such as non-union, malalignment, fixation failure, or progressive reduction loss (15). While research of classic locking IMN's is still ongoing there should also be examinations of IMN's of different designs. In nails designed with distal fixation applied with retractable claws, the effects on fracture healing of the claws placed close to or far from the fracture line are not known.

In our study, the ST distance, defined as the working length, was measured as 25.2 cm on average. No relationship was observed between ST distance and torsional or an axial deformity. In addition, ST distance had no effect on fracture healing. Although the lengths between the proximal and distal fixation points were reported as biomechanical fracture fixation failure in other nail designs, we found that it had no effect on the retractable claw nail design used in our study. Because although mechanical stability is very important, in our opinion, the biological aspect of fracture healing is also important. We found the fracture point and retractable claw FTs to be 8.7 cm on average. Despite this, no problems were observed in fracture stability and fracture healing. This showed us the biomechanical durability of the removable distal hook fixation.

Another important point in IMN is the nail diameter. The ratio of the diameter of the femoral intramedullary canal in the isthmus region (FI ratio) as ≥ 2 has been presented as a parameter predicting complications (15). A previous biomechanical study reported that it is possible to increase the stability of locking IMN and provide the least movement in the fracture region with the use of the thickest nail and performing the least reaming (16). However, the use of the smallest diameter nails is more often recommended because they can be applied more quickly with a shorter operating time and less radiation exposure (17). In all the cases in the current study with a large diameter (mean 13.3 mm) medullar canal, small diameter (9 mm) nails were used. However, the absence of serious rates of union problems shows the functional strength of the retractable claw design. The design of the distal claw means that it can be opened in an intramedullar canal of up to 38mm. It is thought that even if the IMN is of small diameter, when there is strong distal and proximal fixation, no problems will be experienced in fracture healing. There is a clear need for biomechanical studies showing the fixation strength, and new studies are being planned in this respect.

Another important parameter defined in tibial shaft fractures is the ratio of the nail diameter to the intramedullar canal diameter. It has been reported that this ratio should be between 0.80 and 0.99 for ideal fracture healing (18). In the current study cases, the mean nail-canal ratio was 0.68 (0.52-0.81) but this was not consistent with the fracture healing scores. With further studies of larger patient series applied with IMN and where union problems are seen, this ratio could be significant. In the current study, no cases of non-union were seen and delayed union was determined in 14.3%. The most commonly observed fracture healing problems after IMN in patients with tibia shaft fracture have been reported to be delayed union at 22.8% and non-union at 16% (19, 20). A nail diameter/reamer diameter ratio of 0.80-0.99 in the application of tibia IMN has a positive effect on fracture healing (19). In the current study, the IMN diameter was 9 mm and the reamer diameter was 10 or 11 mm in all the patients. As the nail/reamer diameter ratio in this study was 0.81-0.90, this supports the literature.

Limitations

The limitations of our study were the use of a single type of intramedullary nail and the lack of comparison with a different intramedullary nail. In addition, the number of patients remained small because it was a single-center study. Another limitation was the inability to perform biomechanical studies.

CONCLUSION

In the application of Dunitech Nite Tibial Intra Medullary Nail to AO/OTA 42 A2 and A3 fractures, the distance between the fracture line and the proximal screw and the distal retractable claw had no effect on the fracture healing scores. Even though the nail diameter was small, fracture healing and positive functional results were obtained. The complication rate was low. As the distal claw structure in the design of the nail provides extremely good attachment, there is no need for distal screw fixation. In this way, the ease-of-application results in a shorter operation with less exposure to radiation.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Hitit University Non-Invasive Ethics Committee (Date: 28.09.2022, Decision No: 2022-20).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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