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A retrospective study of intramedullary tibia nailing system intended for tibia fracture

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ABSTRACT

Background: The aim of the study was to investigate the performance of the intramedullary tibia nail in the treatment of tibia fractures, mostly shaft fractures. The objective of this study was to assess the post-operative complication due to the treatment involving tibia nails.
Methods: This was a retrospective study to study the results obtained after tibia nail surgery. A total of 32 patients were selected based on inclusion and exclusion criteria (25 males and 7 females; average age- 37 years). The fracture was classified according to AO classification, the nailing device is intended for 41-A1/A2, 42 and 43-A1/A2/A3 types of fractures. The patients with at least three visits within 180 days were selected for data collection.
Results: The clinical outcomes include pain scale assessment from the baseline/enrolment to the last follow up which shows no pain (93.7%) and mild pain (6.7%) after 180 days. No implant-related problems like implant loosening.
Conclusions: For the treatment of tibia shaft fracture which can either be closed or open, intramedullary tibia nailing devices like KN-2T and KN-5T have been concluded to be the good approach.

Keywords: Intramedullary tibia nail, VAS, Tibia fracture, ASA class, Complications, AO classification

INTRODUCTION

The most common and major fractured bone in the leg is considered to be a tibia bone.[1,2] The fracture can lead to a long hospital stay and can affect the life of the patient socially, mentally, and professionally as well. Because of many factors, these injuries are not easy to manage. These factors include limited soft tissue cover, poor vascularity of the injured area, and many more. The most recognized complications include infection, mal-union, and non-union.[3-5] Several studies have addressed the epidemiology of tibial shaft fractures. One study has shown that there is a total incidence of 16.9 tibial fractures per 100,000 people in a year. The same study has also concluded that there is an incidence of 21.5 tibial fractures per 100,000 people in a year for the male population with the frequency of age ranges between the ages of 10 to 20 years. On the contrary, women have shown a total incidence of 12.3 tibial shaft fractures per 100,000 people with the highest frequency of age which lies between the age of 30 to 40 years.[6] Other large-scale study shows that of all bone injuries associated with fracture, about 33.9% are of the tibia. Tibia fractures are generally, the result of the high energy trauma (e.g., traffic accident, fall from height, etc.) which is generally found in the young population (18-39 years) i.e., 60% due to motor vehicle accidents (MVA), 20% due to fall and 20% due to other reason. The percentage is less in higher age population, 55% due to MVA, 35% due to fall and 10% due to other reason and in elderly, the percentage is 40%, 50% & 10% due to MVA, fall and other reason respectively.[7]

Many techniques are used for the operative management of fractures. These techniques include intra-medullary

nailing implants, half-pin external fixation, hybrid thin-wire external fixation, and plate fixation.

Intramedullary nailing is considered the gold standard of care for tibia shaft fracture. This is so because it helps in the reduction of surgical insult to the fractured and soft tissue.[8-9] The successful result of Intramedullary nailing is due to evolution in the understanding of bio-mechanical laws, design, material selection, functional simplicity, operational simplicity, and effectiveness.9 Advancements in operative techniques for intramedullary nailing led to the development of modern implants, in these modern nailing implants, fixation with interlocking bolts at proximal and distal ends of bone allows surgeons to treat the articular fracture with the help of intramedullary nailing. Such tibia nailing systems have static and dynamic locking options along with multi-directional choices for securing the fracture at the distal and proximal portion of the nail.[10,11]

The benefits of intramedullary nailing fixation for tibia fractures are also accompanied by some complications as well.[12] Therefore, it is important for clinicians and manufacturers to periodically assess the device's safety and performance pro-actively or reactively. The objective of this study was to assess the results of the tibia fracture fixation by the intramedullary tibia nailing system (KN-2T tibia nail and KN-5T interlocking cannulated tibia nail) manufactured by Kaulmed Private Limited, Sonipat, India.

METHODS

This was a retrospective study that was organized at Jawahar Lal Nehru Hospital, Mauritius from December 2021 to May 2022. Clinical data on safety and performance were collected from the patient file who received treatment that includes fixation with the intramedullary tibia nailing system. A total of 32 patients were selected for the study who had undergone tibia fracture surgery involving treatment with an intramedullary tibia nailing system.

Inclusion criteria

Male or female, aged 18 years or above, skeletally mature patients with tibia fracture as per the indications of intramedullary tibia nailing system were included in the study.

Exclusion criteria

The patients with condition or disease that could intervene in the bone healing and/or may result in fixation failure or complication such as active cancer, neuromuscular disorder, etc., during post-operative care; patients/subjects who has inadequate tissue coverage at the operative site; subjects with substance abuse/alcohol issue; fractures that are not manageable using Intramedullary tibia nailing fixation and morbid obesity; any uncontrollable systemic disease that, in opinion to the investigator would preclude participation in the study (eg., uncontrolled elevated blood pressure, cardiovascular disease, etc.) or put the patient at risk due to the surgical procedure; subject with rapid joint disease, osteoporosis and; subject having suspected or documented metal allergy or intolerance. Patients with previous tibia surgery were excluded from the study. Only those patients were included in the study whose follow-up data for at least three visits were available.

The indication for the Intramedullary tibia nailing system (KN-2T tibia nail and KN-5T interlocking cannulated tibia nail) manufactured by Kaulmed Private Limited, includes stabilization of proximal and distal tibia fracture like certain intra-articular fractures of tibial head and Pilon tibia and open and closed tibia shaft fracture, and tibia malunions and nonunions. As per AO classification, fracture types of 41-A1/A2, 42, 43-A1/A2/A3, and a combination of these fractures are indicated.

The intramedullary cannulated tibia nail construct used for fixation of tibia fracture is made of titanium alloy (Ti-6Al-4V) and stainless steel (316 L). The construct of the KN-2T tibia nailing system consists of KN-2T tibia nail, ⌀4.4 mm locking bolt, ⌀4.8 mm locking bolt and end cap, and KN-5T Tibia nailing system consisting of KN-5T Interlocking cannulated tibia nail, ⌀4.5mm locking bolt, compression screw and end cap.

The KN-2T tibia nail features an innovative oblique locking option with three locking bolts that provide increased stability of proximal fragments in proximal tibial fractures. The proximal end of the nail also has two mediolateral (ML) locking options that enable primary compression or secondary controlled dynamization. The nail end cap securely locks proximal locking bolts to create a fixed angle construct. Besides that, it also prevents bone ingrowth. The distal end segment of the nail features an oblique locking option that increases the stability of distal fragments and simultaneously prevents soft tissue damage. There are two ML and one anterior-posterior (AP) locking option that provides stabilization of distal fragments (Figure 1).

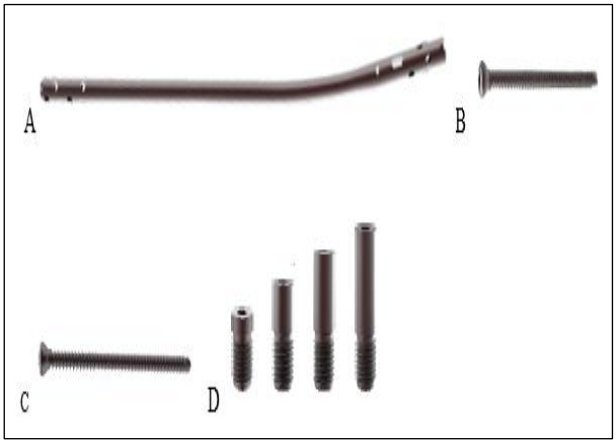

Figure 1: (A) KN-2T tibia nail (B) ⌀4.4 mm locking bolt, self-tapping; (C) ⌀4.8 mm locking bolt, self-tapping; and (D) nail end caps.

The KN-5T interlocking cannulated tibia nail features two unique oblique locking options that provide stability of proximal fragments along with two ML locking options and one oval hole that is used to achieve dynamization. The distal locking holes feature four oblique locking options and one oval hole that are used in a specific configuration for static, dynamic, and reconstruction methods (Figure 2).

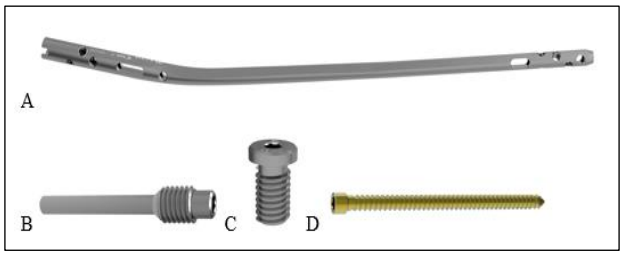

Figure 2: (A) KN-5T interlocking cannulated tibia nail; (b) compression screw; (c) nail end cap; and (d) ⌀4.5 mm locking bolt, self-tapping.

Treatment

All the patients were treated using reamed intramedullary nailing. During surgery, the patient is positioned in the supine position with a knee angle between 70°-90°. The steps followed are opening of the medullary canal followed by reaming, nail insertion, distal locking, and proximal locking. The post-operative care includes partial or normal weight bearing if cortical contact is achieved in case of a closed fracture, while in open fracture cases, the tissue damage is treated first, followed by nail implantation and then post-operative care. The clinical outcomes were measured using pain assessment using the VAS scale (Figure 3), time taken for callus formation, bone union, and full weight bearing. All the surgeries performed and radiographs are assessed by the same surgeon.

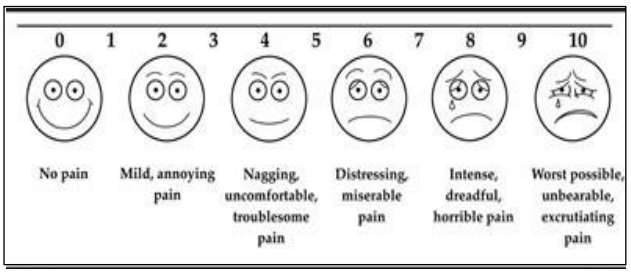

Figure 3: Visual analogue scale.

The pain VAS is a uni-directional scale starting from one to ten in which each number signifies the different intensity of pain. The VAS pain score has been used in different populaces catering to different diseases or conditions incorporating pain such as rheumatic maladies.[13-15] The safety results were assessed by collecting data on the incidence of complications following the surgery. The subject with at least three consecutive post-operative follow-up visits within an interval of 180±30 days are included in the study. The data of pain scale using VAS and complications due to device were recorded from each visit. The radiographic data (X-rays), if available, were also recorded for the clinical evaluation. X-ray reports were used for assessment of bone union, Non-union, implant failure, or implant migration. The patient's medical history was analyzed and their ASA (American Society of Anesthesiologists physical status classification system) grades were recognized for assessing the fitness of the patient before surgery. The ASA class is a reliable and independent predictor of medical complications and mortality following surgery.[16] All the mathematical calculations were done using Microsoft excel.

RESULTS

In the study, 32 subjects that were operated on using an intramedullary nailing system were selected for the study, out of which the number of males and females were 25 (78%) and 7 (21%) respectively. The average age of the patients enrolled is 37 years; the youngest patient in the data set was 21 years while the oldest was 68 years of age (Table 1).

Table 1: Demographic data.

Demographics	N (%)
Sample size	32 (100%)
Mean age (years)	37
Range (years)	Youngest: 21
	Oldest: 68
Male	25 (78%)
Female	7 (21%)

As per ASA grade, 26 patients were considered in class I (Health individuals) and 6 patients felt under class II (A patient with mild systematic disease) with no medical history of previous surgery. The most common cause of injury was a road accident involving two-wheelers followed by slip and fall, sports injury, and falls from height (Table 2). The fracture patterns recorded in the patient data were categorized as per AO classification based on the X-ray radiographs. (Table 3).

The patient's data was recorded for three follow-ups after the discharge from the hospital. The bone union is defined as the visible callus bridging the fracture in at least three consecutive radiographs. The average time is taken for callus formation, bone union, and full bearing is 8 weeks, 15 weeks and 12 weeks with a range of 7-10 weeks, 13-18 weeks, and 10-20 weeks respectively (Table 4). All the observations showed good results. The clinical performance is assessed based on the improvement in the pain scale (VAS) from the baseline visit i. e.; from the day of the screening or patient enrolment for the surgery to the last follow-up visit. At last visit 30 patients (93.7%) showed no pain while 2 patients (6.3%) showed mild pain (Table 5). No complications related to implants like

implant loss, migration, bending, corrosion, and related issues have been found. Post-operative care includes rehabilitation exercise followed by physiotherapy starting from the initial to 6 months. All the patients assessed showed good post-operative results at all the visits with no complications. The device showed the result as intended with no cases of failure, non-union, or infections.

Table 2: Aetiology.

Fracture cause	N (%)
Motor vehicle accidents	18 (52.9)
Slip and fall	8 (23.5)
Other (sports, etc.)	6 (17.6)

Table 3: AO fracture classification.

AO fracture type	N
41-A1/A2	1
42	30
43-A1/A2/A3	3

Table 4: Patient clinical evaluation data.

S. no.	Evaluation criteria	Recovery time (range in weeks)
1.	Callus formation	7-10
2.	Bone unions	13-18
3.	Full wright bearing	10-20

Table 5: Result of VAS score.

Visit time (days)	No. of patients					
	No pain	**Mild pain**	**Nagging**	**Distress**	**Intense**	**Worst possible**
30±15	0	18	12	2	0	0
90±30	10	22	0	0	0	0
180±30	30	2	0	0	0	0

DISCUSSION

The tibia which connects with the knee and ankle is one of the strongest bones in the human body. A broken tibia is a fracture that generally results due to high energy trauma and requires immediate medical attention to avoid complications related to uneven bone union, non-union, or deformity that can occur if not treated timely. Adequate treatment can heal the tibia fracture in time and the person will be able to achieve mobility and weight bearing quickly.

The treatment used for tibia fracture varies on the type and region of fracture. The fractures at the proximal and distal end are treated using a plate fixation device and the shaft fractures are treated from the intramedullary nailing devices. Although nails are also used to stabilize the fracture fragment at the distal and proximal end using screws.

The present study shows the treatment of tibia fracture using an intramedullary nailing device which was designed and manufactured by Kaulmed Private Limited, India. A study of 45 patient by Poblocki et al evaluated the complicated after the tibia nail treatment.[17] The study shows that the most commonly occurred complication is infection, non-union and mal-unions that include deformity due to changing of limb axis, rotation of faction against each other. In another meta study, evaluating the complication followed by intramedullary tibia nail treatment for tibia shaft fracture, it was observed that early complication includes compartment syndrome and deep infection, late complication includes malunion, rotation mal-alignment, Anterior knee pain and non-union while implant related complication include screw breakage and nail breakage/failure.[18]

Although in the present study, pain was observed as major clinical outcome for which data shows good result in pain reduction in less duration. No major complication non-union, mal unions and deep infection were observed, although some cases were reported with infections which was managed through medication and delayed bone union no major complication that may require re-surgery.

Limitations

The limitation of the present study was the sample size, retrospective design and no statistical significance considered data analysis. Only descriptive data with mean, range and frequency was shown. These limitations can be avoided using different study design with large sample size.

CONCLUSION

This study shows that intramedullary tibia nailing devices like KN-2T Tibia nail and KN-5T interlocking cannulated tibia nail can be considered as good approach to treat tibia shaft fracture (open and closed). The device performance, clinically and functional can be evaluated using VAS and radiograph (X-rays). The tibia fracture management using tibia nails offers significant results in terms of blood loss, mean operating time, hospital stay, weight bearing and duration of hospital stay. Such treatment can be considered as the gold standard for the tibia shaft fracture.

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