A study of functional outcome of expert tibia nail in upper third tibia fractures

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Abstract

Background & Objectives: The tibia is the second longest bone of the body, located at medial side of the leg. Among all the fractures in the body, tibia is the single largest bone that is commonly involved in injuries. Owing to the increase in vehicular accidents and industrial mishaps, high velocity trauma produces tibial fractures in increasing numbers. By its location and by being subcutaneous in most of its length tibia fractures tend to be open very commonly. Due to its precarious blood supply and scanty soft tissue coverage orthopedic surgeons around the world have been fighting infections and union problems. Extra-articular proximal tibial fractures account for 5–11% of all tibial shaft fractures. This study was performed to analyze nailing for proximal tibia extra-articular fractures.

Methods: In this study we studied results of expert tibia nail for extra articular proximal 1/3rd tibia fractures. For this we have taken a sample size of 20 patients. The study period was from February 2017 and to September 2018. Patients were evaluated clinically and radiologically according to modified KLEMM and Borner scoring at the interval of 6 weeks, 3 months, 6 months, 1 year and at yearly intervals. The patients were followed up in the outpatient department. Patient follow up was for a minimum of 6 months to a maximum of 24 months (2 years).

Results: There were 10 male and 10 female patients. The male to female ratio of our study population was 1.2:1 having slight male predominance. In our study, patients were in the age group of 20-80 years with the mean age being 38 years. 10 patients out of 20 belonged to 21-40 year age group. Both right and left side were equally involved. Road traffic accident (75%) was most common mechanism of injury. According to Modified KLEMM and Borner Scoring System 75% patients had excellent results and rest 25% had good results in nailing.

Conclusion: From this study, after counting the score with the KLEMM and Borner classification and counting the average and SD value of all sample size and after getting the p value, it has been concluded that expert nailing is better for extra articular proximal tibia fracture with good results and better functional outcome.

Keywords: expert tibia nail, upper third tibia fractures

Introduction

Rising incidence of high velocity trauma due to motor vehicle accidents usually results in fractures of long bones. The tibia is the most commonly fractured long bone in the body. Due to its location, structural anatomy and sparse antero-medial soft tissue coverage the tibia is exposed to frequent injuries. Open fractures are also common in tibia than any other long bone in the body. Numerous treatment options exist for treating tibial fractures and good results have been reported with both conservative and surgical methods. To reduce the complications associated with conservative treatment, tendency towards operative management of tibial fractures is in vogue. Various operative methods like open reduction and plating, intramedullary nailing and external fixation [4-6], have their own indications, advantages and disadvantages. When the aim is stable fixation with early restoration of function without use of plaster, intramedullary nailing, for internal fixation of diaphyseal and metaphyseal fractures of the tibia, offers an attractive treatment option. Interlocking nail has widened the range of indications for medullary osteosynthesis of tibial shaft fractures to include almost every type of fracture.
The major advancement in intramedullary nailing of proximal tibial fractures was the introduction of modern implants like the Expert Tibial Nail. In these new implants the interlocking bolts can be introduced just below the tibia plateau, enabling the surgeon to treat very proximal tibial fractures with intramedullary nailing.

The Expert Tibial Nail System (ETNS) an intramedullary nailing system is indicated for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon fracture. In addition to the standard static and dynamic locking options, the ETNS features multi directional locking options in the distal and proximal part of the nail. End cap blocks the most proximal screw creating an angular stable construct.

**Nail over plate**

Nailing is minimally invasive technique compared to plating so wound related complications like infection, pain, post-operative care is minimized.

Nailing is:
- Cosmetically better
- Less hospital stay
- Option to dynamize
- Less soft tissue injury
- No periosteal stripping

**Objectives of study**

- To observe the results of expert tibia nailing technique in extra articular upper 1/3rd proximal tibia fractures
- To observe the final range of movement of knee and ankle joints, weight bearing, union.
- To measure the union time for the fracture treated by this method.
- To measure the rate of complication.

**Methodology**

**Study design**

In this study we compared the outcome and various other aspects of treating the patients of extra articular proximal 1/3rd tibia fractures with expert tibia nail. For this we have taken a sample size of 20 patients.

The patients in the study were included based on the following selection criteria:

**Inclusion criteria**

- The patient with injuries associated with fractures of the tibia.
- Age limit: 18 years onwards
- Both male and female
- Skeletally mature patients with:
  1. Diaphyseal fractures of proximal one third of tibia
  2. Extra articular metaphyseal fractures of proximal tibia (simple, wedge or complex)
  3. Segmental fractures of tibia or combination of these one of which fracture lies in the proximal one third of tibia.

**Exclusion criteria**

- Patients with pathological fractures.
- Patients with fractures within 5 cm of articular surface of the tibia were excluded
- Patients with intraarticular extension of fractures
- Skeletally immature patients
- Grade IIIC open fractures

**Primary & pre-operative management**

Patients satisfying the selection criteria were identified after emergency management as per ATLS protocol in the casualty. History taking, general examination and local examination were conducted in the trauma care centre. Once stabilized, relevant X-rays were asked for. Fractures were classified according to AO classification.

Necessary investigations for surgical fitness were conducted. Closed fractures with edema were splinted and regular calf girth charting was done with oral proteolytic enzymes, intravenous antibiotics and limb elevation. Surgery was done after swelling subsided. The closed fractures were operated as soon as the fitness for anesthesia was obtained. Open fractures were dressed daily after primary thorough debridement. Once the wounds healed surgery was planned.

**Surgery:** All surgeries were done under image control on plain table in supine position.

**Anesthesia:** Spinal/ EA/ Spinal + EA/ GA

**Postoperative regime:** The patient was immobilized with an above knee posterior slab and care was taken to prevent dependent edema of limb. Intravenous antibiotics were given for first 3 days followed by oral antibiotics in closed fractures. However in open fractures intravenous antibiotics were given till trauma wound showed signs of healing. A post-operative X-ray was advised when the patient could be shifted comfortably, usually after 48 hours of surgery. Depending on the post-operative fracture stability and pain tolerance of the patient, quadriceps strengthening exercises, knee and ankle mobilization exercises and non-weight bearing-crutch walking were started. After suture removal between 10-15th day, the patient was discharged with either partial or non-weight bearing-crutch walking depending upon the stability of the fixation.

**Data collection, follow-up & evaluation**

Data related to demographics, mechanism of injury, details of trauma, hospitalization detail, operation description, post-operative rehabilitation, complications, clinical and functional outcome were collected during the period of hospital stay and follow up visits in the OPD clinic. Follow up was conducted regularly at the interval of 6 weeks, 3 months, 6 months, 1 year and at yearly intervals. The patients were followed up in the outpatient department. Patient follow up was for a minimum of 6 months to a maximum of 24 months (2 years).

**Modified KLEMM and Borner scoring system**

| Final score | Rom Knee & ankle | Muscle atrophy | Alignment | Pain | Union |
|-------------|-----------------|----------------|-----------|------|-------|
| Excellent   | 4               | 4              | 4         | 4    | 4     |
| Good        | 3               | 2              | 3         | 3    | 3     |
| Fair        | 2               | 1              | 2         | 2    | 2     |
| Poor        | 1               | 0              | 1         | 1    | 1     |

Excellent: 15 – 19  
Fair: 5 - 9  
Good: 10 – 14  
Poor: 0 – 5

At the time of follow up a thorough clinical evaluation was done for progress of union, healing of trauma wound and joint stiffness. Once the fracture had shown early signs of union, partial weight bearing was started on the injured limb. On follow up the patients were evaluated clinically and radiologically according to modified KLEMM and Borner scoring.
Statistical analysis: Descriptive statistical methods and expression of results in terms of mean, chi-square test and others using Microsoft excel software with significant p value <0.05 were used for computation of data.

Results
We took 20 patients for study. There were 10 male and 10 female patients. The male to female ratio of our study population was 1.2:1 having slight male predominance. In our study, patients were in the age group of 20-80 years with the mean age being 38 years. 10 patients out of 20 in nailing belonged to 21-40 year age group. Both right and left side were equally involved, Road traffic accident (75%) was most common mechanism of injury. Mean injury surgery interval was 36 hours. The average hospital stay for expert tibia nailing was 12 days. In the present study, the average time duration of surgery from positioning to final dressing was 139 minutes.

Anterior knee pain was the most common immediate complication in 25% of the patients in this study. All these patients also developed mild restriction of range of motion at knee joint. 15% patients of nailing developed superficial wound infection which healed with regular dressing. 30% patients of plating patients developed superficial wound infection in which 20% healed with regular dressing and 10% patients needed debridement under anesthesia. 5% patient had non-union of the fracture in nailing and 10% patients had non-union of the fracture in plating.

According to Modified KLEMM and Borner Scoring System 75% patients had excellent results and rest 25% had good results in nailing. In plating, 35% had excellent results, 55% had good results and 10% had fair results.

Taking into consideration modified KLEMM and borner scoring system and calculating the score at 6 week, 3 months and 6 months with p value being significant at 0.005 covering 95% of the cases and controls the following results were obtained.

Nailing

| Follow up Period | 1.5 months | 3 months | 6 months |
|------------------|------------|----------|----------|
| SD mean          | 2.62       | 2.34     | 1.82     |
| Average          | 5.65       | 9.65     | 15.55    |

P- Value

| p value         |
|-----------------|
| 0.1184          |
| 0.4997          |
| 0.00004479      |

At 1.5 months the p value was 0.118 which is higher than 0.05 so the study is insignificant. At 3 months the p value was 0.4997 which is more than 0.05 so study was insignificant. But at 6 months the p value was 0.00004479 which was much less than 0.05 so the study was significant at 6 months which shows nailing has more advantages over plating.

Discussion
In recent years, the indications for use of the intramedullary nail system were expanded to include the treatment of a wide spectrum of tibial fractures. This new, multidirectional locked intramedullary system involves multiple locking options in different planes at the proximal ends. The system has an angular stability locking system that enhances the axial and lateral stability of the fracture fragments. Because of this modified design, the new system has advantages over the traditional tibial intramedullary nail in dealing with both proximal tibial fractures. A biomechanical study showed that the addition of two proximal oblique screws significantly enhanced the stability of the intramedullary fixation construct compared with the original approach to fixation as in proximal tibia the medullary cavity is broad causing much instability which involved the use of two transverse screws fixation. In terms of varus – valgus and flexion – extension, the appendage of oblique screws increased the angular stability. In addition, there are 3 advanced distal locking options in this new tibial intramedullary nail. The set-up involved antero posterior locking option placed very distally, which allowed for optimized bone purchase and prevented damage to the soft tissue. These design modifications ensure that angular stability is retained and angle-stable locking reflects a potential to maintain fixation stability of distal tibia fractures. All of these design modifications allow for better fixation of metaphyseal tibial segments through multiple interlocking holes in close proximity to either end of the nail. The use of multidirectional interlocking screws ensures that alignment can be maintained and that stability can be preserved despite a short proximal segment. Non-unions are important issues in the clinical treatment of tibial fractures. A Prospective Cohort study with one and half year follow up duration was taken up at a Tertiary Care Hospital and Research institute in Surat in which the cases were defined as adults having extra articular proximal one third tibia fracture (open / close) and treated with close reduction and expert tibia nailing. The aim of the study was to study the outcome of the above mentioned modality of treatment.

The study lasted for one year and eight months starting from February 2017 to September 2018. Total 20 cases were taken for the examination during this period. As compared Ramesh chand meena et al. study of Intramedullary nailing versus proximal plating in the management of closed extra-articular proximal tibial fracture: a randomized controlled trial took 53 patients divided into cases and controls which is comparable to our sample size of our study. Another study Ding-Chuan Zhu et al. studied Comparison of closed reduction and expert tibia nailing with open reduction and plate and screw fixation in the treatment of two segmental tibial fractures with sample size of 53 cases divided into cases and controls which is also comparable to our study sample size. These cases and controls were followed up in a prospective manner and all findings and examination were noted at 1.5 months, 3 months and 6 months. They were evaluated on the bases of KLEMM and Borner scoring system along with other intra op and post op findings which could provide a useful data of comparison of both treatment modalities.

Table 1: Different Comparative study of Nailing and Plating for proximal tibia fractures

| Year | Study author | Total/nailing/plating | Study Topic |
|------|--------------|-----------------------|-------------|
| 1995 | Lang et al.  [85] | 50/25/25 | Comparison of closed reduction and expert tibial nailing with open reduction and plate and screw fixation in the treatment of two segmental tibial fractures |
| 2003 | Bhandari et al. [87] | 24/12/12 | Intramedullary expert nailing versus proximal plating in the management of closed extra-articular shaft tibial fracture |
| 2015 | Ramesh Chand meena et al. [86] | 44/22/22 | Intramedullary expert nailing versus proximal plating in the management of closed extra-articular proximal tibial fracture: a randomized controlled trial |
The selection of cases was done by random method so that any kind of selection bias could be avoided. Both cases and controls were given appropriate and equal pre op, intra op and post op due care.

In the present study, early weight bearing exercise was started considering fracture pattern, bone and soft tissue condition. As nail being a weight sharing implant, it also helps in preventing regional osteoporosis. Initially partial weight-bearing exercise (sole contact or up to 15kg) is started. Once it was tolerated by patient, gradually load was increased on fractured limb. In plating group, weight bearing was delayed until signs of radiological and clinical union appeared. Early weight bearing promoted callus formation and prevented osteoporosis. Weight bearing exercise is essential for building and maintaining healthy bones. In the present study, when patients begin weight-bearing activities, fracture pattern, fracture localization, the condition of the soft tissue and the quality of the bone should be taken into account. The increase in load is determined according to the fracture pattern and localization, the condition of the soft tissue, bone quality as well as the absence or presence of load-induced pain. The concept of dynamization helped in the case of nailing in preventing non-union.

A greater number of days in the hospital impose higher healthcare costs and economic burdens to society. In the present study, patients in group A had a significantly shorter length of hospital stay, which would result in reduced healthcare costs. Patients in both groups have achieved satisfactory functional results. Notably, anterior knee pain after nailing the tibia should not be ignored. The occurrence of anterior knee pain is frequently associated with tibial intramedullary nailing with an incidence reported to be between 12% and 25% of cases. In the present study, 10% patients experienced some degree of chronic knee pain. Screw impingement was a major complaint in follow up cases of nailing. Wiss et al. [86] in their series documented proximal screw backout in 3% of cases. In present study, implant failure was due to screw back out, in which rate is much lower in nailing as compared to plating in proximal tibia fractures. The average intra-op blood loss was 125 ml in expert tibia nail. There are total 15% in expert tibia nail that got infected. One out of 20 i.e. 5% in nailing went into non-union. These rates are comparable to below mentioned studies. The lower rates of non-union in nailing can be attributed to less periostial damage and dynamic nature of nail.

Table 2: Comparison of Infection and Union rate of Different Studies with our study

| References          | Infection % | Union rate % |
|---------------------|-------------|--------------|
| Bhandari et al. [87] nailing | 2.5        | 96.5         |
| Lindvall et al. [88] nailing     | 28         | 77           |
| Beuhler et al. [89] nailing     | 0          | 92.9         |
| In Present study      | 15         | 95           |

The non-union rate is higher in plating cases than the expert tibia nail cases.

After the completion of 6 months follow up of all 40 patients, the data was analyzed which showed that according to modified KLEMM and Borner classification, there was no significant difference noted in the outcome between cases and controls whereas at 6 months the p value being significantly lower, the null hypothesis was rejected and alternate hypothesis of expert tibia nail leading to better outcome than proximal tibia plating in upper one third extra articular tibia fractures was accepted.

Strengths of study
- Randomization minimizing selection bias
- Tertiary care hospital with utmost and equal care to both study groups
- Similar way of implant insertion

Drawbacks of study
- Less sample size due to study time limitation.
- Poor patient compliance in some cases like hygiene, timely follow up and disobeying strict non weight bearing for certain months
- Infection and co morbidities and other associated fractures may hamper results

Recommendations
On the basis of the observation and the conclusions of the study,
- Expert tibia nail being a comparatively newer modality of treatment compared to plating and it needs to be studied further with comparison group

Conclusion
From this study, after counting the score with the Klemm and Borner classification and counting the average and SD value of all sample size and after getting the p value, it has been concluded that Multidirectional locked nailing may be considered a better surgical option as it offers advantages in terms of range of motion, blood loss, mean operating time, hospital stay, full weight-bearing time and union time, infection rate. There is no significant difference in patient’s recovery at 1.5 and 3 months but it is proved that functional outcome is better with nailing at 6 months. Nailing helps in early recovery of patient’s functions with less non-union.

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