

**“FUNCTIONAL AND RADIOLOGICAL OUTCOME OF PROXIMAL
THIRD TIBIAL SHAFT FRACTURES MANAGED WITH
CONVENTIONAL INTERLOCKING INTRAMEDULLARY NAIL BY
MODIFIED TECHNIQUE”**

DISSERTATION SUBMITTED

In partial fulfillment of the requirement for the degree of

M.S. Orthopaedic Surgery

REGISTRATION NUMBER: 221912302

Branch II



TIRUNELVELI MEDICAL COLLEGE

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MAY 2022

CERTIFICATE

This is to certify that this dissertation titled “**FUNCTIONAL AND RADIOLOGICAL OUTCOME OF PROXIMAL THIRD TIBIAL SHAFT FRACTURES MANAGED WITH CONVENTIONAL INTERLOCKING INTRAMEDULLARY NAIL BY MODIFIED TECHNIQUE**” is a bonafide work done by **Dr. ARIVAZHAGAN.K**, a Post Graduate student in the department of Orthopaedics, Tirunelveli Medical College Hospital.

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He has completed the necessary period of stay in the department and has fulfilled the conditions required for submission of this thesis according to university regulations. The study was undertaken by the candidate himself and the observations recorded have been periodically checked by us.

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I solemnly declare that this dissertation titled “**FUNCTIONAL AND RADIOLOGICAL OUTCOME OF PROXIMAL THIRD TIBIAL SHAFT FRACTURES MANAGED WITH CONVENTIONAL INTERLOCKING INTRAMEDULLARY NAIL BY MODIFIED TECHNIQUE**” was prepared by me at Tirunelveli Medical College Hospital under the guidance of **Prof. & HOD, Dr. N. MANIKANDAN**, Tirunelveli Medical College Hospital, Tirunelveli, in partial fulfillment of Dr. M. G. R. Tamilnadu Medical University regulations for the award of M. S. Degree in Orthopaedics. I have not submitted this dissertation to any other university for the award of any degree or diploma previously.

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CERTIFICATE –II

This is to certify that this dissertation work title “**FUNCTIONAL AND RADIOLOGICAL OUTCOME OF PROXIMAL THIRD TIBIAL SHAFT FRACTURES MANAGED WITH CONVENTIONAL INTERLOCKING INTRAMEDULLARY NAIL BY MODIFIED TECHNIQUE**” of the candidate, **Dr. ARIVAZHAGAN.K**, with **Registration Number 221912302** for the award of M. S. Degree in the branch of Orthopaedics (II). I personally verified the Ouriginal.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from introduction to conclusion page and the result shows **15 PERCENTAGE** of plagiarism in the dissertation.

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INTRODUCTION

The tibia is the most commonly fractured long bone because of its exposed anatomical placement, which makes it prone to direct blows and high intensity trauma as a result of automobile accidents. As industrialization and urbanisation advance year after year, resulting in increased traffic, the prevalence of high energy trauma rises at the same rate.

Between the ages of 19 and 39, young males have the highest prevalence of both bone leg fractures⁵. Tibial fractures have a higher rate of nonunion and malunion than other types of fractures in the body.

Extraarticular proximal tibial fractures make up 5-11 percent of all tibial shaft fractures¹ and are frequently caused by high-velocity trauma. These fractures have become particularly problematic due to an increase in the occurrence of related comorbidities. The best surgical treatment for proximal third tibial shaft fractures is still up for debate.

Proximal third tibia fractures can be significantly more difficult to treat with intramedullary nailing than other tibial shaft fractures. Malunion with apex anterior and valgus deformity is common with these fractures^{2,3}. Intramedullary devices are preferred for treating tibial fractures because they preserve the extra articular blood supply without opening the fracture site, reducing the risk of infection. The intramedullary nailing, has become an easy option since C-arm has made closed nailing possible

Nailing of proximal tibial metaphyseal and upper diaphyseal fractures with a short proximal fragment is associated with increased mal-alignment in both the sagittal and coronal planes², unlike intramedullary fixation of diaphyseal fractures of the tibia. Expert surgeons have devised a number of adjunct procedures to improve the results and widen the indications for nailing to cover these proximal fractures.

AIM

To describe the functional and radiological outcome in patients with Proximal 1/3rd tibial shaft fractures managed by Conventional Interlocking Intramedullary Nail by modified technique.

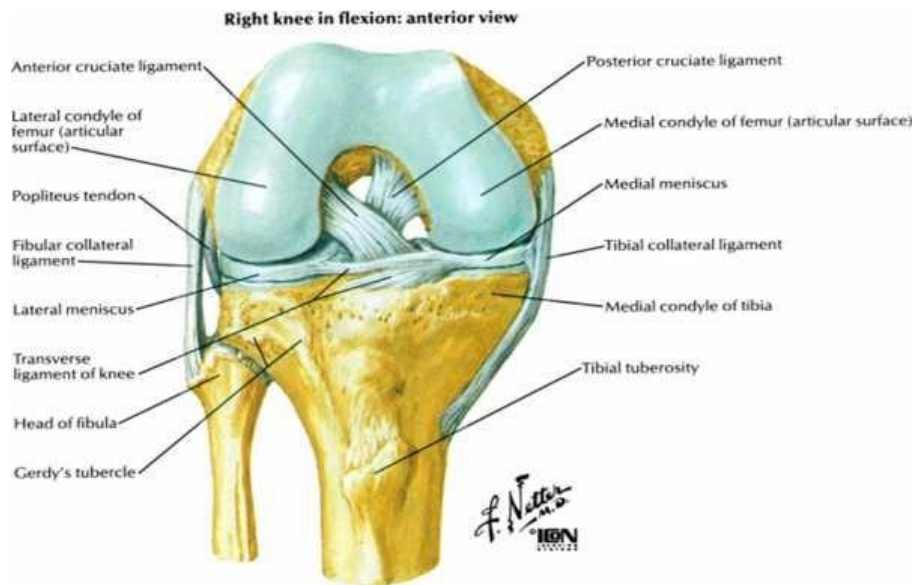
REVIEW OF LITERATURE

ANATOMICAL CONSIDERATIONS:

Tibia is the second largest bone in the body. There is an anterior angulation of proximal tibia which is about 15 degrees. The tibial plateau's posterior slope of 6 degrees gives a visible spot for the intramedullary nail to pass through, where the cancellous bone can easily be penetrated. In cut section, tibia is a triangle-shaped bone in the diaphysis. The tibial tubercle is situated about 3 cm below the articular surface. The patellar tendon attaches to the tibia at this point. Gerdy's tubercle gives attachment to the iliotibial band, which is located at the lateral surface.

The bony anatomy of proximal tibia - Medial tibial plateau, Lateral tibial plateau, Tibial spines, Muscles, ligaments and neurovascular structures. The medial tibial plateau is concave and covered with hyaline cartilage. The lateral plateau is narrower, convex, and hyaline cartilage-covered.

Both tibial plateaus are covered by a fibrocartilaginous meniscus. The intermeniscal ligament connects the menisci anteriorly while the coronary ligaments connect the menisci to the plateaus. This ligament is frequently incised and raised in order to provide direct sight of the articular surfaces. Between the plateaus lie the tibial spines. The anterior and posterior cruciate ligaments, as well as the menisci, link to the medial and lateral tibial spines.

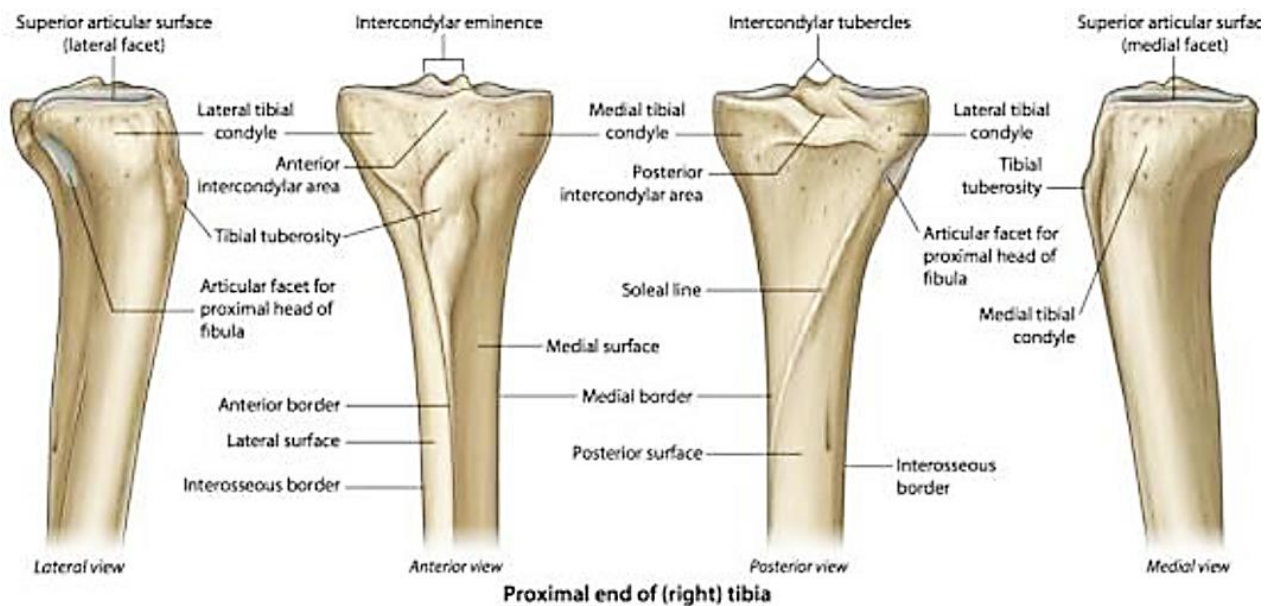


The tibial collateral ligament and the fibular collateral ligament are essential in preventing varus and valgus instability, while the ACL & PCL provide antero-posterior stability.



Proximal tibia fractures may result in neurovascular injury. The superficial and deep branches of the common peroneal nerve encircle around the fibular neck. In high-energy proximal tibia fractures there is a risk of displacement. The popliteal artery gives rise to anterior tibial, posterior tibial, and peroneal arteries at the level of proximal tibia, posteromedially. Injury to these structures can develop in high-energy proximal tibia fractures.

Schematic description of bony landmarks in Proximal tibia



CLASSIFICATION OF PROXIMAL TIBIAL FRACTURES

AO/OTA Classification of proximal tibial fractures (AO 41):

41A

Type: Tibia, proximal end segment, **extraarticular fracture** 41A

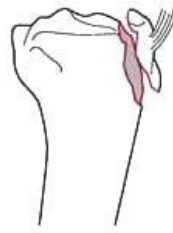
Group: Tibia, proximal end segment, extraarticular, **avulsion fracture** 41A1

Subgroups:

Of the capsular attachments
41A1.1*



Of the tibial tubercle
41A1.2



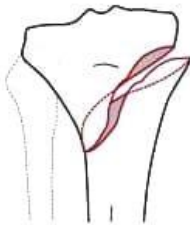
Of tibial spine (cruciate attachment)
41A1.3*



Group: Tibia, proximal end segment, extraarticular, **simple fracture** 41A2

Subgroups:

Spiral fracture
41A2.1



Oblique fracture
41A2.2



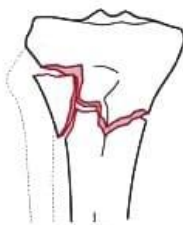
Transverse fracture
41A2.3



Group: Tibia, proximal end segment, extraarticular, **wedge or multifragmentary fracture** 41A3

Subgroups:

Intact wedge fracture
41A3.1*



Fragmentary wedge fracture
41A3.2*



Multifragmentary fracture
41A3.3



41B

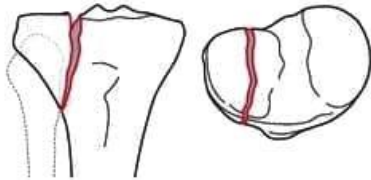
Type: Tibia, proximal end segment, **partial articular fracture** 41B

Group: Tibia, proximal end segment, partial articular, **split fracture** 41B1

Subgroups:

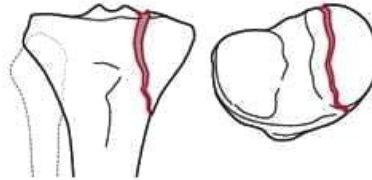
Lateral plateau fracture

41B1.1



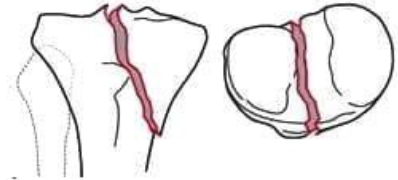
Medial plateau fracture

41B1.2



Oblique, involving the tibial spines and 1 of the tibial plateaus

41B1.3*

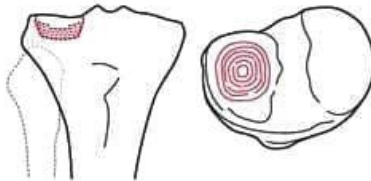


Group: Tibia, proximal end segment, partial articular, **depression fracture** 41B2

Subgroups:

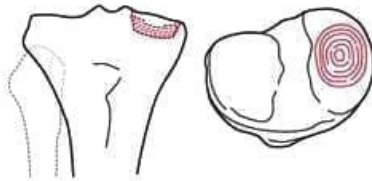
Lateral plateau fracture

41B2.1*



Medial plateau fracture

41B2.2

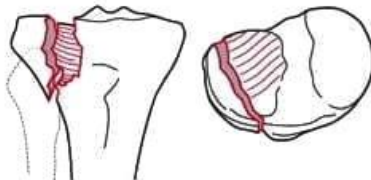


Group: Tibia, proximal end segment, partial articular, **split-depression fracture** 41B3

Subgroups:

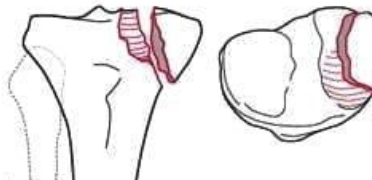
Lateral plateau fracture

41B3.1*



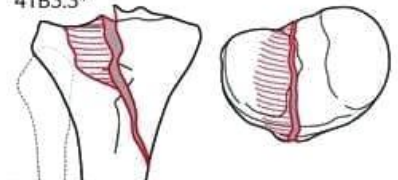
Medial plateau fracture

41B3.2*



Involving the tibial spines and 1 of the tibial plateaus

41B3.3*



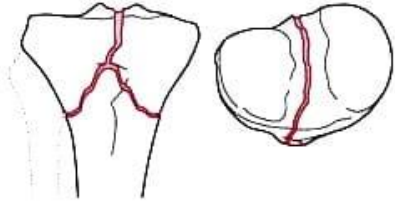
41C

Type: Tibia, proximal end segment, **complete articular fracture** 41C

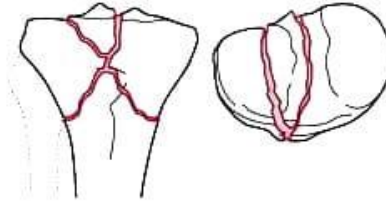
Group: Tibia, proximal end segment, complete, **simple articular, simple metaphyseal fracture** 41C1

Subgroups:

Without intercondylar eminence fracture
41C1.1



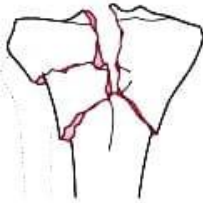
With intercondylar eminence fracture
41C1.2



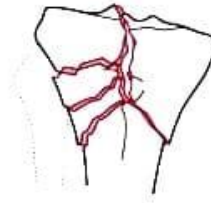
Group: Tibia, proximal end segment, complete, **simple articular, wedge or multifragmentary metaphyseal fracture** 41C2

Subgroups:

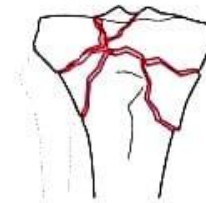
Intact wedge fracture
41C2.1*



Fragmentary wedge fracture
41C2.2*



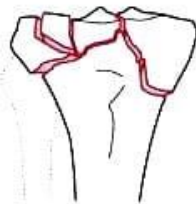
Multifragmentary metaphyseal fracture
41C2.3



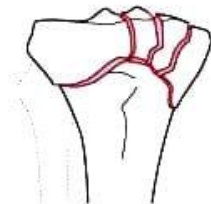
Group: Tibia, proximal end segment, complete, **fragmentary or multifragmentary metaphyseal fracture** 41C3

Subgroups:

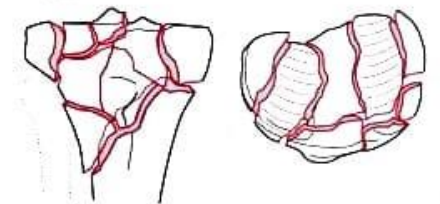
Fragmentary lateral plateau fracture
41C3.1*



Fragmentary medial plateau fracture
41C3.2*



Multifragmentary medial and lateral plateau fracture
41C3.3*



EPIDEMIOLOGY:

Among proximal tibia fractures, the incidence of high energy comminuted or segmental fractures are more common in younger age groups. Whereas low energy spiral fractures are seen in older age group people⁶. These fractures are about three times as prevalent in women than in men among patients over the age of 65. Men, on the other hand, are about twice as likely as women to have high-energy tibial fractures in younger age group.

Fall from standing height and sporting injuries are the most common causes of low energy tibial fractures. Vehicle trauma is the most common cause of high-energy tibial fractures. According to **Court-Brown and McBirnie**⁵, vehicular trauma accounted for 37.5 percent of tibial meta-diaphyseal fractures from 1988 to 1995.

Buergess et al⁷. published a study based on pedestrian injuries. He stated that “Thirty percent of pedestrian tibial fractures were bilateral, and 65 percent of patients had Gustilo type III open fractures, according to the study. Assaults (4.5%), most typically a direct blow or gunshot wound, and falls from a height are other high-energy traumas.”

Compound tibia fractures are common due to its subcutaneous position, with reported rates ranging from 12 percent to 47 percent depending on the patient population and kind of treatment facility⁵. With

high energy mechanisms, open fractures are considerably more likely, with rates as high as 63 percent observed following motorcycle accidents. The management and outcome for proximal tibia fractures mainly depend upon the condition of soft tissues.

COMPLICATIONS:

Compartment syndrome

Proximal tibia fractures have a risk of developing compartment syndrome. In 1.5 percent to 11 percent of tibial fractures, compartment syndrome has been reported. Clinicians need to be cautious about the risk of developing compartment syndrome in a proximal tibia fracture, because it can have disastrous repercussions on limb function or possibly cause renal failure due to rhabdomyolysis.

Fracture extension in to tibial plateau

It is possible for tibial metaphyseal fractures to extend occultly into the tibial plateau, which is very important. All proximal 1/3rd tibia fractures should have a preoperative CT scan of the knee to rule out a tibial plateau fracture. Preoperative recognition of intraarticular knee involvement is critical because it decides the implant of choice.

Ligament injuries of Knee:

In patients with proximal tibial fractures, there have been cases associated with ligament injuries. In a prospective study conducted under anaesthesia, it was discovered that 22% of patients with tibial diaphyseal fractures had at least one knee ligament injury.

Although knee ligamentous injuries are more common in patients with femoral diaphyseal fractures and floating knee injuries than in those with tibial fractures alone, some authors recommend that all patients with tibial fractures have their knee ligaments examined routinely. However, because evaluating knee ligamentous injuries in an acute situation is difficult, these injuries are likely to be missed at first. After fixation of tibial fracture, stability of knee joint can be examined postoperatively.

Floating knee injuries

The term "floating knee injury" refers to ipsilateral tibial and femoral fractures. High-energy mechanisms are commonly responsible for these combination injury patterns. Based on rates for two separate traumas combined, the reported rate of related vascular injury and open fracture is higher than expected. In nearly one-third of the cases, ligamentous instability of the knee has been noted.

TREATMENT OF PROXIMAL THIRD TIBIA FRACTURES

The goals of management are:

- ✓ A well aligned fracture
- ✓ Pain-free weight bearing after surgery
- ✓ Restoration of knee and ankle ROM as early as possible

The management and prognosis of proximal third tibia fractures varies depending on the soft tissue condition, fracture stability and wound contamination.

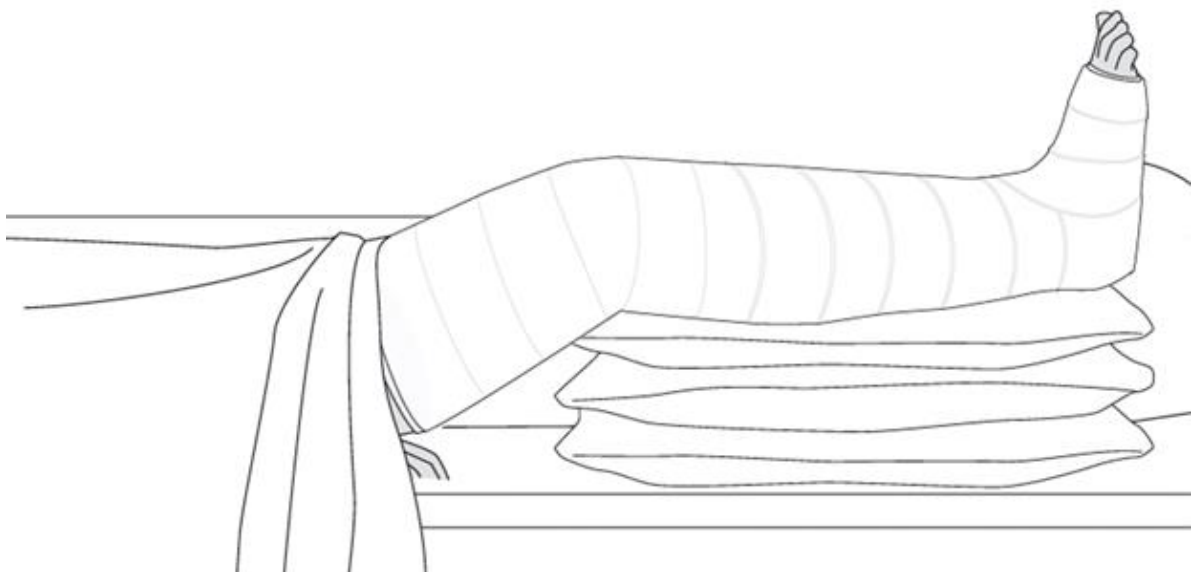
TREATMENT OPTIONS

- a) Conservative treatment
- b) External fixation
- c) Open reduction and Plating
- d) Expert tibia nail
- e) Conventional Interlocking Intramedullary nailing

Conservative management:

Conservative management of proximal tibia fracture can be done in debilitated patients, in any comorbidities where surgery cannot be done, and in undisplaced or minimally displaced fractures. It involves above knee cast/splinting.

Above knee cast



Drawbacks of conservative treatment:

-Malunion / Delayed union

-Nonunion

-Post traumatic joint stiffness

In 1989, **Sarmiento et al**⁸ mentioned that, “fractures while in cast showing excessive initial shortening or in cases showing increased angular deformity, bracing should be contraindicated.”

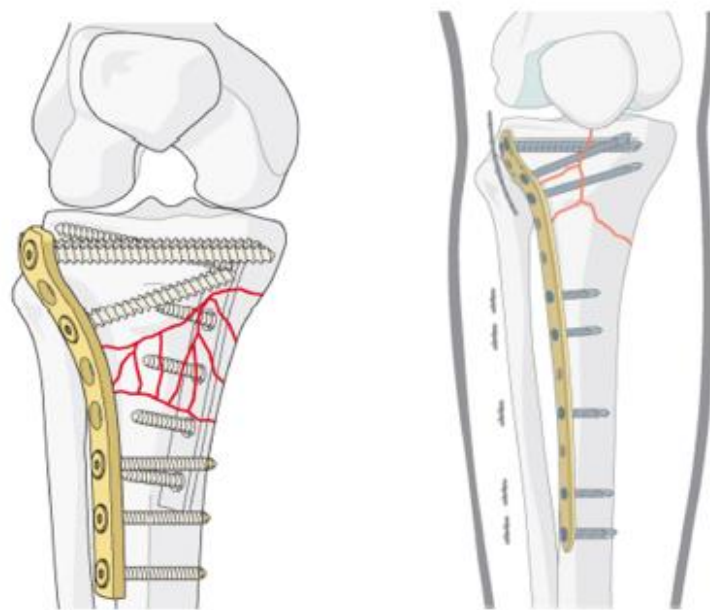
According to **Trafton**⁹, acceptable reduction criteria in tibia fractures are- “<5degrees of varus, <5 degrees of Valgus, <5 to 20 degrees of Apex anterior/posterior angulation, <0 to 10 degrees of rotation, <10 to 12mm of Shortening.

Surgical Treatment

The most common surgical method is intramedullary nailing, which is currently the preferred treatment for most displaced tibia fractures. Preoperative concerns include intraarticular extension, nail length, canal size measurement, and so on.

Plating

For proximal extraarticular fractures, plate fixation of tibia fractures is still used often. Because of the popularity of nails, mid diaphyseal fractures are less typically plated, but the procedure can be effective in some cases. These include situations where antegrade nailing isn't an option, such as a periprosthetic fracture after a total knee replacement. A distorted canal due to a tibia that is too tiny to accommodate an intramedullary nail. Nailing can be problematic due to a previous fracture or an ipsilateral tibia plateau fracture¹¹. The soft tissue state of the patient should be assessed in order to determine whether plate fixation is appropriate. In plating of proximal tibia fractures^{10,12}, preservation of soft tissues and periosteal blood supply is essential. Excessive soft tissue stripping increases the risk of developing nonunion or infection.

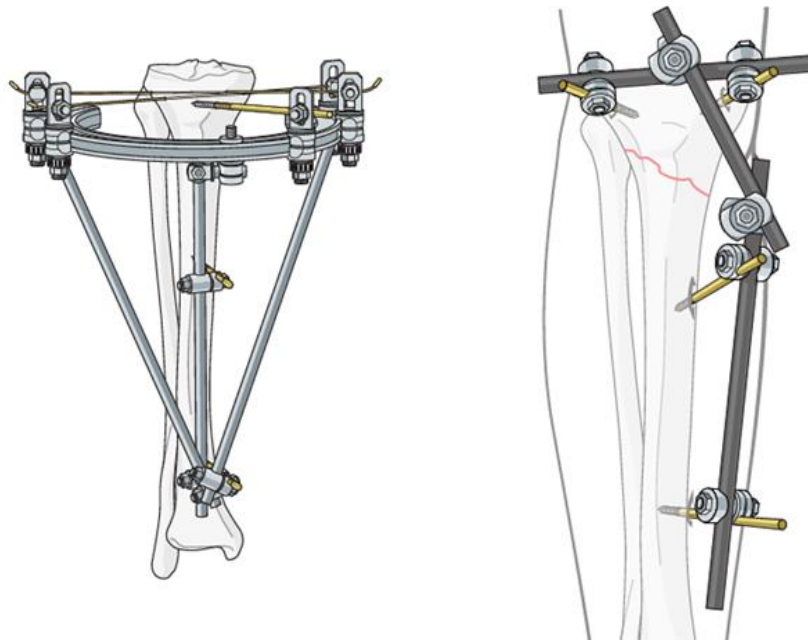


Limitations of plate osteosynthesis:

- 1) Delayed wound healing
- 2) Superficial and deep infection
- 3) Locking plate cannot correct the malalignment of fracture. Fracture has to be reduced before applying the plate.
- 4) Failure in plating can occur if the principles of applying the plate are violated

External fixators:

Management of proximal tibia fractures by external fixator has been utilized for over a century, although modern ring fixators have recently become more popular. In most cases, external fixators are not employed to treat closed fractures. Because long-term usage of external fixators is linked to a higher risk of pin site infection and nonunion. External fixators can be used for Gustilo type IIIA, IIIB, and IIIC compound fractures, especially those with a bone defect. If there is a bone defect, bone transport can be done by distraction osteogenesis. In external fixators, the stability of construct can be improved by placing the rods closer to bone, reducing the gap in between the pins on either side and increasing the size of rods and pins. In recent times hybrid external fixators and ring fixators are being used¹³.



Drawbacks of external fixators:

- Not a definitive mode of fixation
- In cases of knee spanning fixators, joint stiffness is more common
- Definitive surgical procedure like nailing or plating have to be done after 2-3 weeks to avoid infection.

Expert Tibia Nailing:

Expert tibia nail is a recently designed intramedullary nail which was developed to achieve increased angular stability and to enhance the axial and rotatory stability of fracture fragments. Currently, expert tibia nail is being used to fix proximal tibial fractures. This intramedullary nail provides multiple locking options in different planes at proximal and distal ends of tibia. This modified design is useful in retaining the angular stability in cases of proximal tibia fractures¹⁴.

The use of multidirectional interlocking screws ensures that alignment can be maintained and that stability can be preserved despite a short proximal fragment.



Disadvantages of Expert tibia nail:

- More time consuming procedure
- Costlier than conventional intramedullary nail
- Not feasible in all treatment facilities

INTRAMEDULLARY NAILING

Intramedullary nail was first introduced 500 years ago. In 1930 Steinmann pins were used in the medullary canal for stabilizing femur fractures. Later German Orthopaedician **Gerhardt Kuntscher**^{17,18} invented a metallic IM nail. This nail can be compressed during insertion, which expands after insertion and holds the endosteal surface of the bone. In 1950 he invented the technique of reaming and nailing by closed reduction without opening the fracture site. In 1951, this nail was altered by **Herzog**. He devised a proximal bend in the nail to make the nail insertion into the medullary canal easier. **Modney** designed the first interlocking nail. The invention of locked intramedullary nailing was based on the design of Kuntschner's 'Detensor' nail and modified by **Kempf and Klemmet al**^{49,50}, was a major innovation. The comparative studies between nonoperative management and IMIL nailing describes superior results with ILIM nailing.

Principles of Intramedullary nailing:

Internal splintage can be used to treat a long bone fracture. Splintage is a structure that allows for sliding between the bone and the implant. The nail works as an internal splint. Intramedullary nail transmits the axial forces to the opposing ends of fracture fragments^{15,16}. It functions by preventing rotation, translation and angulation movements by safeguarding the nail-bone contact at entry point, isthmus and opposite end of the bone.

Nailing allows for early weight bearing in stable fractures. An intramedullary nail is loaded physiologically by a composite of torsion, compression, and tension. The bone shares the loads with nail when cortical contact is made at the fracture site¹⁶.

Reaming of Medullary canal:

Reaming the medullary canal uniformly widens the canal so as to alter the bone to the nail and provide a large area of contact between the bone and the nail ; when the nail and reamer are of equal size, 1mm of reaming increases the contact area by thirty eight percent. Reaming increases the stability of the "tube inside a tube" by widening the medullary cavity, allowing for the insertion of a bigger diameter nail, improving the length of contact and reducing the working length¹⁹⁻²¹.

Bone Healing after Nailing:

Fixation with a stiff enough nail results in effective bone healing. Delay in union and non-union can occur when thin and loosely fitting nails are utilised. Nail-fixed fractures heal primarily through the creation of periosteal callus, whereas plate-fixed fractures mend primarily through the production of endosteal callus; the mechanical strength of both is equivalent at 120 days.

Advantages of nailing:

The fracture hematoma and periosteal blood flow are not disrupted with closed IMIL nailing. This aids in the early stages of fracture repair. The endosteal vasculature is disrupted by reamed nailing, while the periosteal blood flow is increased. Intramedullary nails are load sharing devices.

Reamed versus Unreamed nailing:

Reaming widens the canal diameter, which in turn increases the nail-bone contact. This improves the bone-implant construct's mechanical stability. In a study by **Keating et al.**,¹⁹ 47 nails were implanted after reaming and 41 nails were introduced without reaming in open tibial fractures. The average time to fracture union for reamed and unreamed nailing was 30 weeks for reamed and 29 weeks for unreamed nailing, respectively. The functional outcome was similar in both groups. Infection arose in two reamed nailing patients (4.3 percent) and one unreamed nailing patient (2.4 percent). Non-union occurred in 9% of fractures treated with reamed nailing compared to 12% of fractures treated with unreamed nailing. Two (4.3 percent) reamed cases and one (2.4 percent) unreamed nailing case had implant failure.

In a study by **Blachut et al.**,¹⁹ comparison of fractures treated with reamed nailing(73) and unreamed nailing(64) was done. The analysis of Infection, malunion and fracture union showed almost similar results.

Finkemeier et al.,²⁰ observed that for open fractures, the results of reamed and unreamed nailing were equivalent in terms of time to union in a research involving 94 tibial shaft fractures. In a study, **Bhandari et al**²¹ found that the probability of implant failure is higher in non-reamed nailing than in unreamed nailing.

Intramedullary nailing in tibial metaphyseal fractures:

For extraarticular tibial metaphyseal fractures, ILIM nailing can be done. The considerations here are the prevention of malalignment and the maintenance of the reduction until union. Nailing of proximal tibial metaphyseal and upper diaphyseal fractures with a short proximal fragment is linked with increased mal-alignment in both the sagittal and coronal planes, unlike intramedullary repair of diaphyseal fractures of the tibia²². To properly manage tibial metaphyseal fractures with IM nailing, different authors used various supplemental methods.

BIOMECHANICS OF DEFORMITY IN PROXIMAL THIRD TIBIA

FRACTURES:

The pull of the patellar tendon anteriorly, gastrocnemius tendon posteriorly, and the disparity between medullary canal width and nail are the main factors leading to the malalignment of the short proximal fragment²³. Malalignment is characterised by anterior and valgus angulation of the apex, as well as posterior displacement of the distal fragment. Recurvatum and varus are two other malformations.

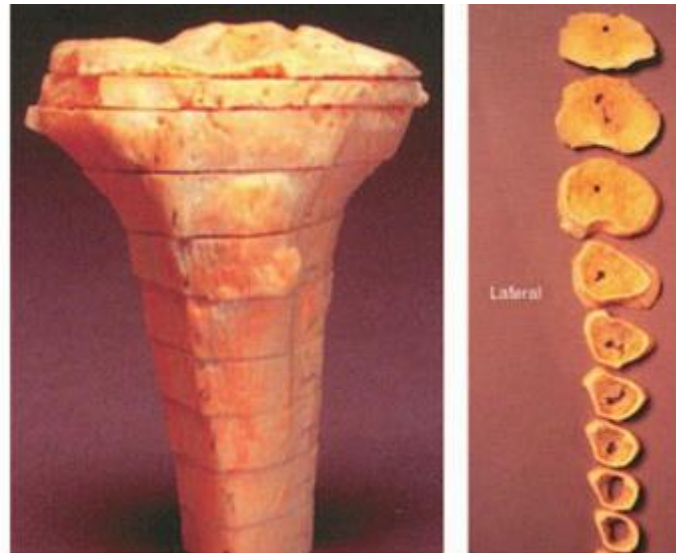
Deformities occurring during conventional technique of ILIM Nailing²⁴⁻²⁶:

- Anterior angulation
- Valgus angulation
- Posterior displacement of the distal fragment

Anatomical Considerations:

The classic **apex anterior deformity** is caused by deforming forces acting on the proximal tibia fracture. The proximal fragment is pulled into extension by the patellar tendon, while the distal fragment is pulled into flexion by the hamstring tendons and gastrocnemius muscle³⁰. When the knee is flexed for normal IM nailing, the deformity is exaggerated even more. The anterior compartment muscles begin on the anterolateral proximal tibia, while the pes anserinus inserts anteromedially on the proximal

segment. The valgus deforming forces are caused by the force put on the tibia by these attachments.

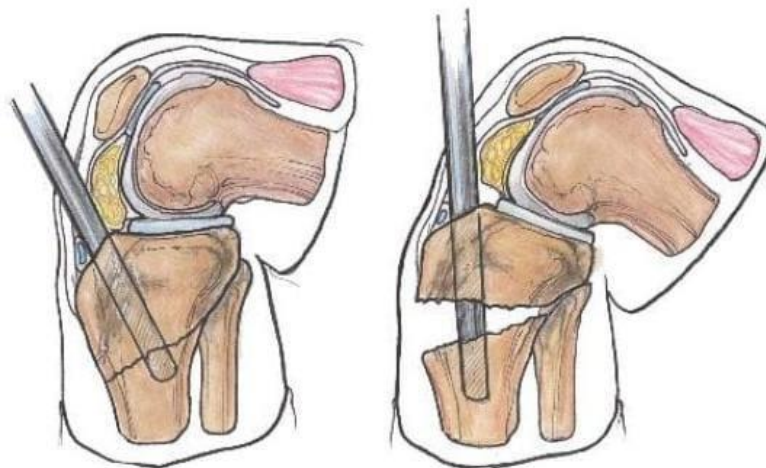


The proximal tibia's triangular bony architecture includes a broad metaphyseal region that narrows distally to form a well-defined cortical tube. The nail fits loosely in the proximal fragment in the patient with proximal tibia fracture and cannot maintain alignment³⁰. Furthermore, the tibial shaft's central axis is slightly lateral to the epiphysis's midline, and the shaft's anteroposterior width is thinner medially. The medial tibial metaphyseal cortex works as a funnel that deflects the nail laterally if the starting point is too far medially. The diminishing sagittal space and strong lateral slope of the medial wall result in a **valgus deformity**^{28,29}. Because of the erroneous starting position, the proximal section of the fracture is tilted

into valgus as the nail penetrates the diaphysis and becomes colinear with the tibial axis.

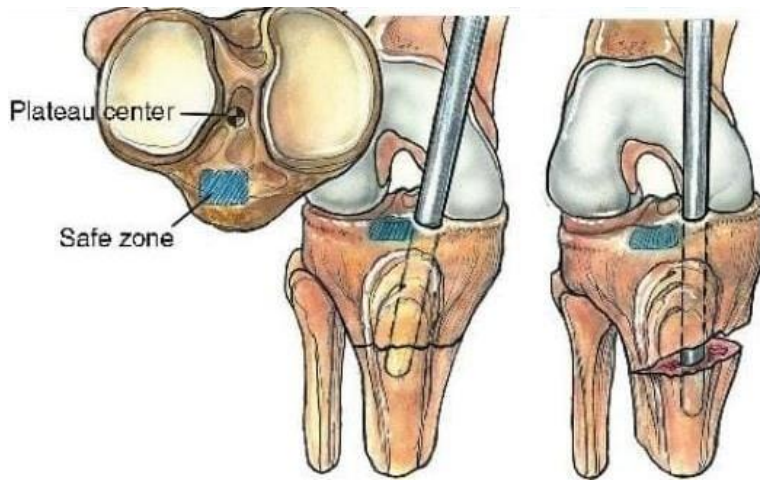
Technique Errors and Implant Design

Technique errors have been shown to contribute to malreduction of proximal tibia fractures. The starting point is an essential component of any IM nailing procedure. As mentioned, a starting point that is located too far medially will result in **valgus deformity**. A starting point too distal results in a posterior entrance angle, which predisposes to **apex anterior deformity**³⁰. In addition, in fractures with comminution of the posterior cortex, the nail may not be contained in the proximal fragment, leading to apex anterior angulation.



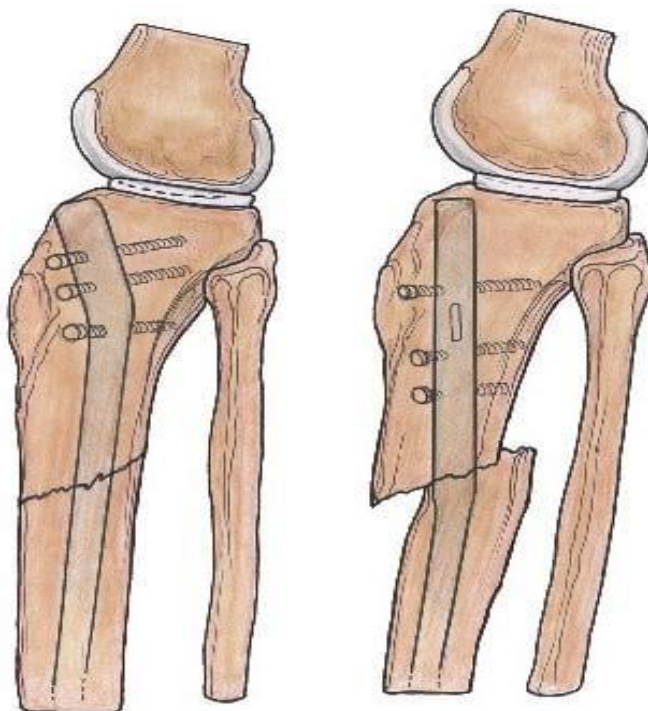
Apex anterior deformity due to

- too distal entry point
- further accentuated as the knee is flexed



Valgus angulation due to
- too far medial entry point

The geometry of the nail must be considered when choosing implants. If the proximal bend (ie, Herzog curve) of the IM nail is located at or distal to the fracture, it can cause **posterior displacement of the distal fragment**. In a biomechanical study, **Henley et al** noted that “the more distal the bend in the nail, the greater the propensity for fracture displacement.” They referred to this phenomenon as the "wedge effect"²⁵



Posterior displacement of the
distal fragment due to,
- Herzog bend of the IM nail is
located at or distal to the fracture
-knee in flexion

What does the literature Say?

In 1996, **Tornetta et al**³¹ in their study concluded that “Semi extended position can prevent the anterior translation and antecurvatum deformities”

In 1997, **Buchler et al & Tembcke et al**³² advocated a “laterally placed entry point to prevent valgus angulation.”

In 2003, **Laflamme et al** suggested that “more oblique screws can be used to maintain the alignment.”³³

In 2006, **Sean E Nork et al**³⁴ described “the use of temporary unicortical plating of tibia with a medially placed femoral distractor that was used efficiently to achieve reduction in proximal 1/3rd tibia fractures.”

Laflamme et al and Nork³³ demonstrated the wedging effect, when the Herzog’s bend is distal to the fracture site resulting in malalignment of the fragments. So they suggested use of nails with more proximal bend.

Henley et al²⁵ stated that “a nail with proximal bend at or below fracture site results in anterior translation of the proximal fragment as the nail wedges against the cortex. Also, they found that inserting medio- lateral screws in one plane can allow nail to slide on the screws, centralising the nail in the medullary cavity”

In a study by **Lang et al**²³, out of 32 proximal tibial fractures treated with statically locked nailing, there was >5 degrees angulation in 84% and > 1 cm displacement in 59%.

Techniques to maximize the outcome:

The incidence of malreduction associated with IM nailing of proximal tibia fractures has substantially decreased with the use of new techniques and reduction adjuncts such as,

- Nailing in semi-extended position (suprapatellar nailing)
- Universal distractors
- Blocking/poller screws
- Percutaneous clamping
- Supplementary plating

In several small retrospective studies with a total of 183 patients treated with IM nailing using one or more of these techniques, the reported malreduction rate ranged from zero to 15.5%, with an average rate of 8.2

Study	No. of Fractures	Management	No. of Malreductions (%)
Benirschke et al ³	13	Temporary plating, external fixator	0
Cole et al ^{9,7}	13	Blocking screws	1 (7.7)
Tornetta and Collins ¹¹	25	Semiextended position	0
Buehler et al ⁹	14	Universal distractor	1 (7.1)
Ricci et al ¹⁰	12	Blocking screws	1 (8.3)
Nork et al ¹⁵	37	Temporary plating, universal distractor	3 (8.1)
Vidyadhara and Sharath ¹²	45	Semiextended position, blocking screws	7 (15.6)
Kim et al ²³	9	Temporary plating	1 (11.1)
Wysocki et al ¹⁶	15	External fixator	1 (6.7)

Nailing in Semi-extended Position

Tornetta and Collins³¹ performed IM nailing of proximal tibia fractures with the knee in 15[degrees] to 20[degrees] of flexion. They used a partial medial parapatellar approach with lateral subluxation of the patella to establish the starting point. The semi-extended position minimized the deforming extension force of the quadriceps muscle on the proximal fragment. None of the 25 patients treated with IM nailing in this semi-extended position had >5[degrees] of apex anterior angulation, and 19 patients had no anterior angulation

In a cadaver study, **Gelbke et al.**,³⁵ examined patellofemoral contact pressures and forces exerted during suprapatellar tibial nailing. They determined that the pressures were below values known to be detrimental to articular cartilage. In another cadaver study, **Eastman et al** demonstrated that the risk of damage to the menisci or intermeniscal ligament is similar in pattern and incidence to that of a standard patellar tendon approach³⁶. Although these two recent studies support the use of approaches performed with semi-extended positioning, further research and clinical correlation is necessary to validate the efficacy and safety of these newer approaches.

Blocking Screws :

Poller screws, which are commonly known as blocking screws, were popularized by **Krettek et al**³⁷ in 1999. The screws guide the nail in the manner of the "poller" traffic control devices that guide traffic in Europe. Blocking screws serve to narrow the medullary canal in the tibial metaphysis and substitute as a cortex to keep the nail in the correct position.

Coronal and sagittal blocking screws can be used concomitantly to reduce multidirectional force vectors (ie, correct both apex anterior angulation and valgus deformity). In a study of 2 tibial fractures managed with IM nailing and blocking screws, **Krettek et al** 4 reported that all fractures went on to union, with a mean coronal alignment of -1.0[degrees] (range, -5[degrees] to 3[degrees]) and a mean sagittal alignment of 1.6[degrees] (range, -6[degrees] to 11[degrees])³⁸. **Ricci et al** also reported on the use of blocking screws with IM nailing of proximal tibia fractures in a series of 12 consecutive patients³⁹. One patient had an angular deformity >5[degrees] postoperatively; however, none of the patients had an angular deformity >4[degrees] in the plane in which the blocking screws were inserted.

Unicortical Plating

Some authors have advocated unicortical plating of proximal tibia fractures to maintain reduction before IM nailing⁴⁰. This technique has been referred to as reduction plating⁴². A short (eg, four- or six-hole) one-third tubular or small fragment plate is placed anteriorly, anteromedially, or posteromedially across the fracture and secured to both the proximal and distal fragments with at least two unicortical screws. The drawbacks of unicortical plating are the need to open the fracture site and perform additional soft tissue dissection and the potential need to evacuate a fracture hema-toma. These disadvantages can be minimized by placing the plate percutaneously through two small incisions. The plates can be removed after IM nailing, or they may be retained as an additional adjunct to prevent the recurrence of deformity. Unicortical screws can be replaced with bicortical screws to improve construct stability⁴¹. However, the surgeon must make this choice based on the degree of relative stability desired.

Universal Distractor

The universal distractor can be used to help reduce proximal tibia fractures and maintain reduction during IM nailing²⁹. Schanz pins are inserted from the medial side into the proximal and distal fragments and are placed parallel to the joint in a manner that will not interfere with nail or

interlocking screw placement⁶. The distractor maintains length and joint alignment and improves stability during nailing. In addition, the pins can function as blocking screws to help direct the nail. **Buehler et al** reported that 1 of 14 proximal tibia fractures (7%) treated with this technique had malreduction of [greater than or equal to]5[degrees]²⁹. **Nork et al** described a technique that involved inserting the proximal Schanz pin, which doubled as a coronal blocking screw, into the posterior half of the proximal fragment⁶. An external fixator can be used in the same fashion as the universal distractor, following the same principles⁴³.

Nailing in Flexion/Locking in Extension

Buehler et al described a technique in which IM nailing is performed with the knee in maximal flexion and interlocking screws are placed with the knee in full extension²⁹. Hyperflexion allows for nail insertion parallel to the anterior cortex of the proximal fragment. Placement of the interlocking screws with the extremity in full extension allows for final fixation in a position of optimal fracture reduction, thus mitigating the effect of deforming forces.

OUR SURGICAL TECHNIQUE

The Surgical technique followed in our study is similar to nailing in flexion and locking in extension technique. The variation from the conventional ILIM nailing technique that we have described in our study is discussed here.

The Modifications done in our technique are,

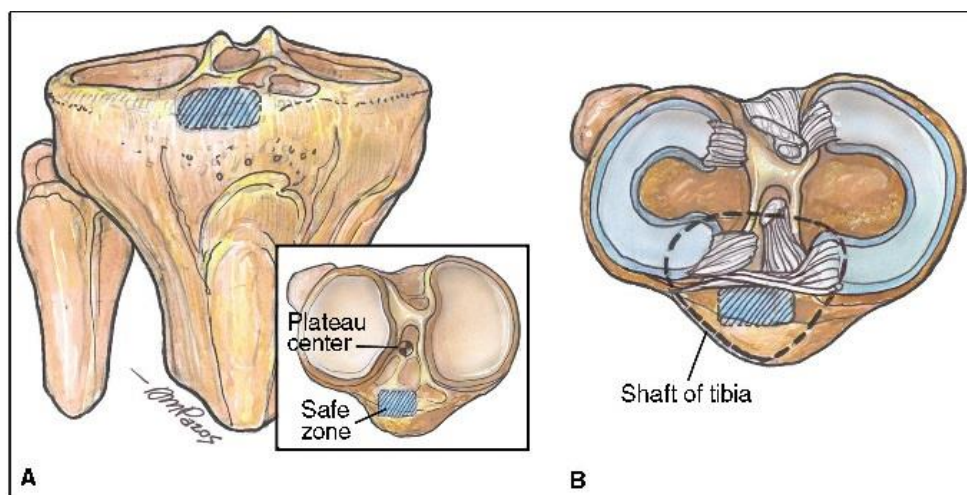
- High level and more lateral entry point
- Over reaming of the entry site
- Burying the proximal end of nail in to the medullary cavity
- Jig removal and knee extension
- Free hand locking of proximal screws after locking the distal anteroposterior screw first

Entry Point – More proximal and Lateral entry:

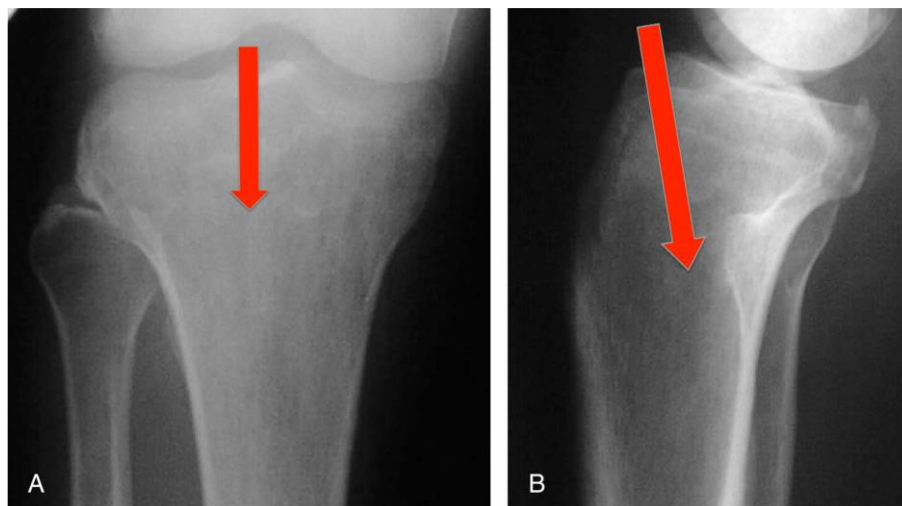
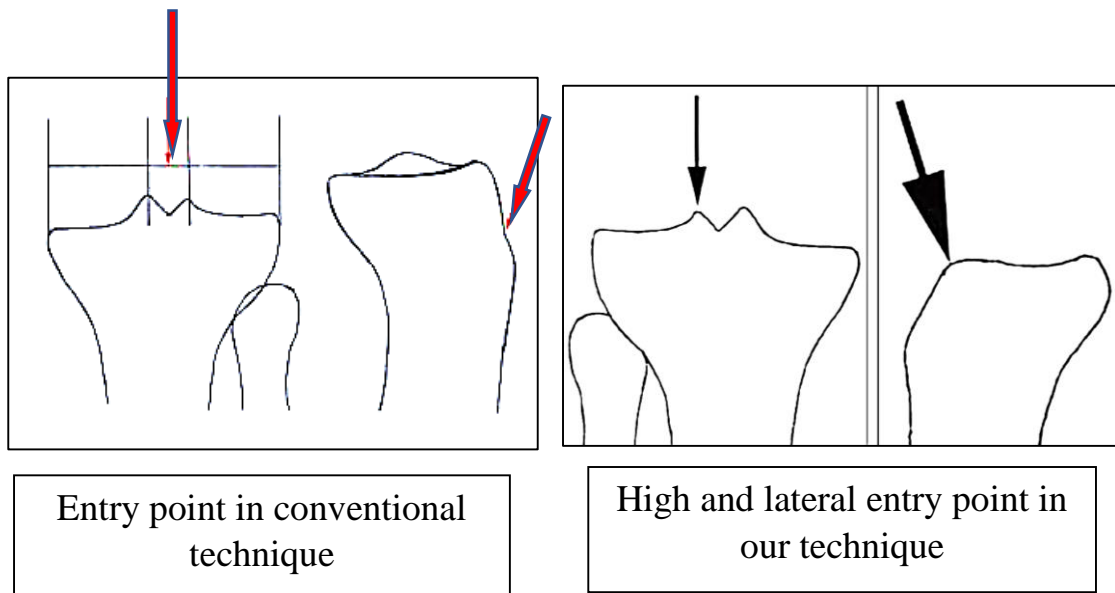
Use of the proper entry point is critical to achieve good outcomes in patients with proximal tibia fractures. In conventional technique⁴⁴ the entry point lies 1.5 cm distal to the knee joint line and in line with the centre of medullary canal on AP view.

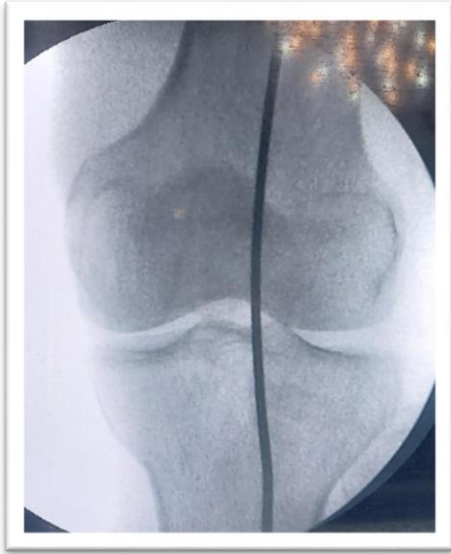
In the study by **Tornetta et al**, the ideal “safe zone” for intramedullary nail placement was described as 9 ± 5 mm lateral to the mid point of the tibial plateau and 3 mm lateral to the center of the tibial tubercle⁴⁵.

A proximal starting point permits a less eccentric portal to the axis of the tibial canal in the sagittal plane. In a cadaver biomechanical study, a more proximal starting point was shown to have smaller hoop stresses and angular deforming forces during nail insertion compared with more distal insertion points⁴⁷.



“Safe zone” is the area proximal to tibial tubercle and anterior to the articular surface, which includes the intermeniscal ligament and menisci. This is 9 mm lateral to midline, 3 mm lateral to the center of the tibial tuberosity and 23 mm wide, which is just medial to the lateral tibial spine in the AP view. In lateral view, entry point lies at the junction of anterior edge of tibial plateau and the slope of the anterior cortex⁴⁶.





Over reaming of the entry site:

After passing the guide wire, serial reaming of the medullary canal is done till appropriate size of the canal is reached. This is followed by over reaming of the entry site alone. Over reaming means reaming the proximal fragment with a 13mm reamer or entry reamer. This technique aids in easy burying of the nail inside the medullary cavity in the subsequent step.



Burying the Proximal end of the nail into the medullary canal:

After insertion of nail of appropriate size, the nail is hammered inside the medullary canal till the tip of the nail is inside the medullary canal. This is confirmed under image intensifier. In regular nailing, the nail tip is just buried inside the entry point and not inside the medullary canal. This step allows the posterior fall back of the nail inside the medullary canal after the removal of jig in the next step.



Jig removal and Knee extension:

Jig is removed after the nail is buried inside the entry site and the knee is extended. This reduces the anterior angulation of the proximal fragment which was more pronounced when the knee was in flexion. After knee extension, mild traction is given at the distal leg which allows posterior fall back of the nail inside the medullary cavity. This reduces the residual coronal or sagittal angulation if any, which is confirmed clinically and also under the image intensifier. Whereas in traditional technique, locking of all the screws is done with the intact jig and flexed knee. This may result in persistent anterior angulation of the proximal fragment throughout the procedure.



Intraop clinical picture showing the anterior angulation of proximal fragment, which was reduced after removal of jig and extending the knee



Free hand locking of proximal screws:

In contrast to traditional technique, in our study locking of all the holes is done with knee in full extension. After removal of jig, knee is extended along with axial traction. Under image intensifier guidance, reduction is confirmed in both AP and lateral views. Then the distal Anteroposterior locking is done first to prevent the rotation of the nail inside the medullary cavity. Followed by the locking of proximal screws by free hand technique. Then finally distal mediolateral locking is done.

Initial distal AP Locking



Free hand Proximal locking



Distal medio lateral locking



MATERIALS AND METHODS

Study Design: Cross Sectional Study

Study Population: Patients with Proximal 1/3rd Tibial fracture

Sample size: 20 patients

Study duration: 2 years

Study setting: Department of Orthopaedics, Tirunelveli Medical College Hospital

INCLUSION CRITERIA:

1. Age above 18 years
2. Both Genders
3. Extra articular fractures proximal 1/3rd tibia
 - AO type 41A2.1, 41A2.3, 41A3 with fracture line 6cm below the articular margin.
 - AO type 42 – Upper diaphyseal fractures
4. Closed fractures, type I, type II and type IIIA of Gustilo Anderson compound fractures⁵⁸.

EXCLUSION CRITERIA

- Age < 18 yrs
- Intraarticular fractures/Tibial plateau fractures
- Compound grade IIIB and IIIC fractures
- Segmental / comminuted / Pathological fractures of tibial shaft
- Fracture in non functional /Paralytic limb , Knee joint with FFD or Stiff knee

PREOPERATIVE ASSESMENT

- Proper history and thorough clinical examination of the patient
- Xray AP and lateral views of the leg.
- CT scan to ruleout intra articular extension.
- Fracture classification based on AO system.
- Length of the proximal fragment and Nail size were measured.

IMPLANTS

Tibia Nail set



Tibia Nail



Jig



Conical Bolt



4.9 mm locking bolt



SURGICAL PROCEDURE

Position of the Patient:

Under spinal anaesthesia, patient in **supine position with 90 degrees of knee flexion** on a radiolucent table.



Skin Incision & Approach :

The skin incision made from the inferior pole of patella to the tibial tuberosity. In our study we used the **midline patellar tendon splitting approach**.



Entry Point and guide wire insertion:

Using bone awl, a high and more lateral entry was taken in the tibial metaphysis as discussed before. Medullary cavity was opened with a bone awl. Further the instruments must not touch the posterior cortex. Guide wire was then inserted in to the entry site, advanced across the fracture site after closed reduction, till the distal end of tibia. Position of guide wire was confirmed under image intensifier.



Reaming and Nail insertion:

Medullary canal was enlarged by serial reaming, followed by the over reaming of the entry site. Then tibia nail of appropriate size was inserted with the knee in flexion of about 90 degrees. The nail was then hammered inside the medullary cavity till the tip of the nail got buried inside the entry site, which was confirmed under image intensifier.



Jig removal and Initial distal locking :

The jig was removed and the knee should be extended . After confirming reduction, the distal anteroposterior locking was done with a 4.9mm locking bolt of appropriate size.

Free hand proximal locking and distal locking:

Then 2 proximal locking bolts were inserted by free hand technique under image intensifier with knee in extension. After that, distal mediolateral locking was done. Either one or both the mediolateral locking shall be done.



Wound closure:

Thorough wound wash given and wound was closed in layers after achieving complete haemostasis. Sterile dressing was done.



POST OPERATIVE PROTOCOL

- ❖ Postoperatively the limb is kept in elevation to reduce edema
- ❖ Ankle pumping exercises started on the day of surgery to prevent DVT and improve limb circulation
- ❖ From 2nd POD - Isometric quadriceps strengthening exercises started.
 - Knee bending is started and gradually increased
 - Active and passive knee bending and straight leg raising exercises done.
 - Static and dynamic quadriceps strengthening exercises continued.
- ❖ From 3rd POD - Non-weight bearing walking with walker support is started.
- ❖ Wound condition checked and sterile dressing done once in 3 days.
- ❖ At the time of discharge, full range of movements of knee were achieved.
- ❖ Suture removal done on 12th POD

FOLLOW UP:

- Regular followup was done to assess the wound status, clinical and radiological union and rehabilitation purposes.
- Xrays taken during every followup visit to assess the union. Xrays taken at 3,6,9,12 weeks and then once a month.
- Partial weight bearing started after 6 weeks.
- Full weight bearing started at an average of 12 weeks after assessing the radiological signs of union.
- All the patients were followed up every 2 weeks till fracture union, followed by every month upto 1 year.

ANALYSIS OF FUNCTIONAL OUTCOME

MODIFIED KARLSTROM OLERUD SCORING SYSTEM⁴⁸

Table 1. Modified Functional Evaluation System by Karlstrom-Olerud				
Sr. No.	Measures	3 points	2 points	1 point
1	Pain	No	Little	Severe
2	Difficulty in walking	No	Moderate	Severe Limp
3	Difficulty in stairs	No	Supported	Unable
4	Difficulty in previous sports	No	Some sports	Unable
5	Limitation at work	No	Moderate	Unable
6	Status of skin	Normal	Various colors	Ulcer /Fistula
7	Deformity	No	Little, up to 7°	Remarkable, >7°
8	Muscle atrophy	< 1 cm	1-2 cm	>2 cm
9	Shorter lower extremity	< 1 cm	1-2cm	>2 cm
10	Loss of motion at knee joint	< 10°	10-20°	>20°
11	Loss of Subtalar motion	< 10°	10-20°	>20°

INTERPRETATION

Excellent	33 Points
Good	32-30 Points
Satisfactory	29-27 Points
Moderate	26-24 Points
Poor	23-21 Points

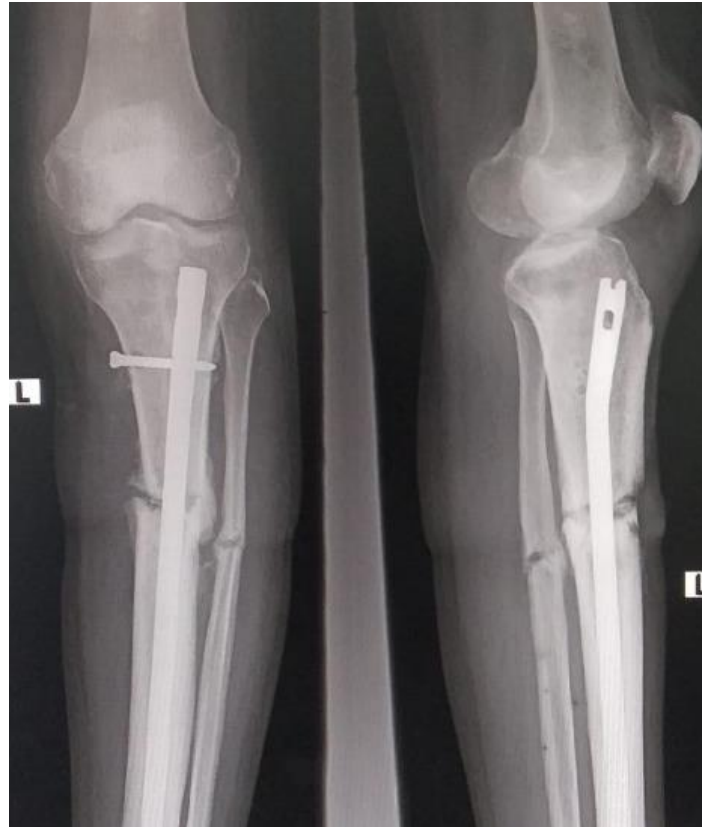
COMPLICATIONS AND THEIR MANAGEMENT

1. Superficial Wound infection

In our study 1 patient had superficial wound infection. Pus culture sensitivity was taken and appropriate IV antibiotics was given for 3 weeks followed by oral antibiotics for 3 weeks. Infection subsided after regular dressing and antibiotics and the patient achieved union after that.

2. Non union

One patient had nonunion due to deep infection. Despite appropriate antibiotics, the patient failed to achieve union. Hence implant exit was done and external fixation with limb reconstruction system was done.

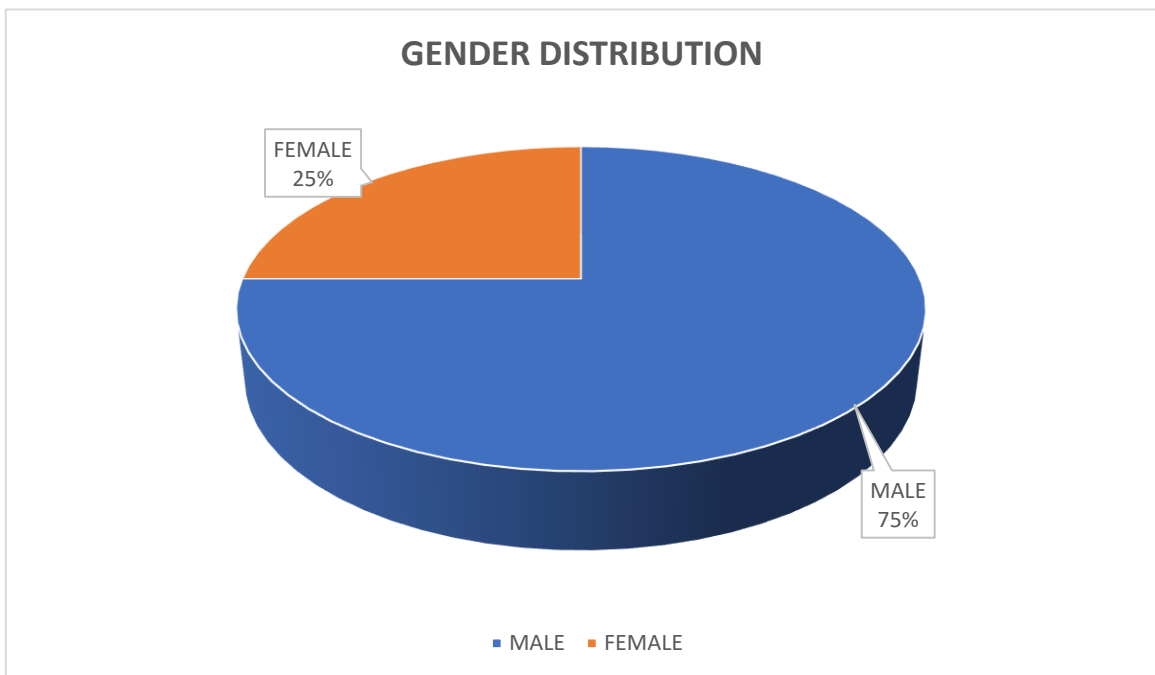


Other expected complications were malunion, knee pain/stiffness and implant failure. In our study none of the patients had these complications except for one superficial infection and one non union. Out of 20 patients 19 patients achieved union without any malalignment including the patient with superficial infection. None of the patient had malunion or malreduction by our surgical technique.

ANALYSIS OF RESULTS

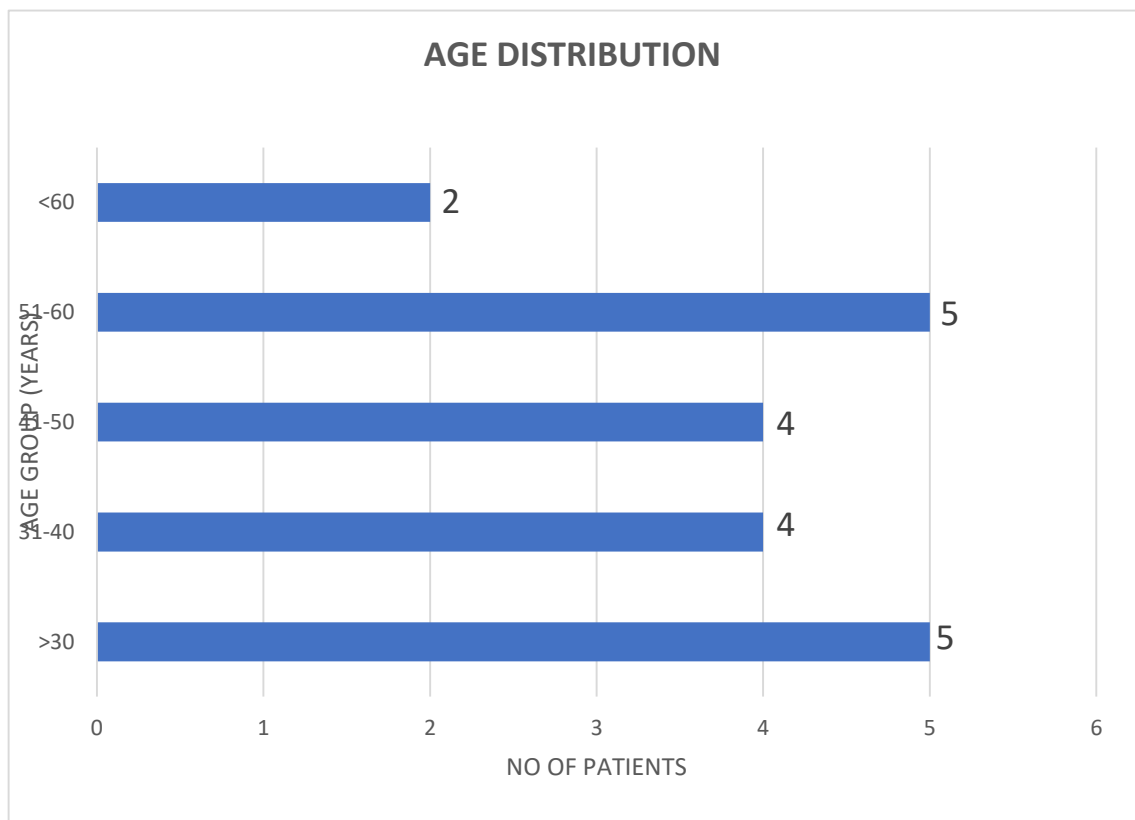
GENDER WISE DISTRIBUTION

SEX	No. of Patients	Percentage
MALE	15	75%
FEMALE	5	25%
Total	20	100%



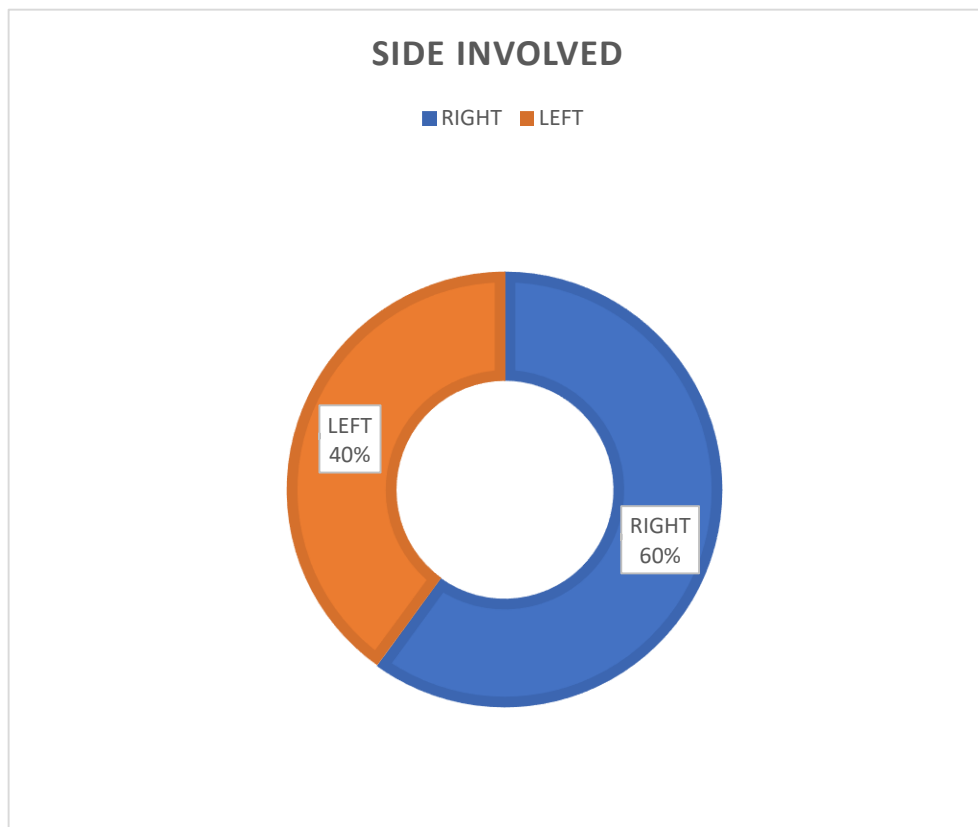
AGE WISE DISTRIBUTION

Age group	No. of patients	Percent
<30 yrs	5	25%
31-40 yrs	4	20%
41-50 yrs	4	20%
51-60 yrs	5	25%
>60 yrs	2	10%



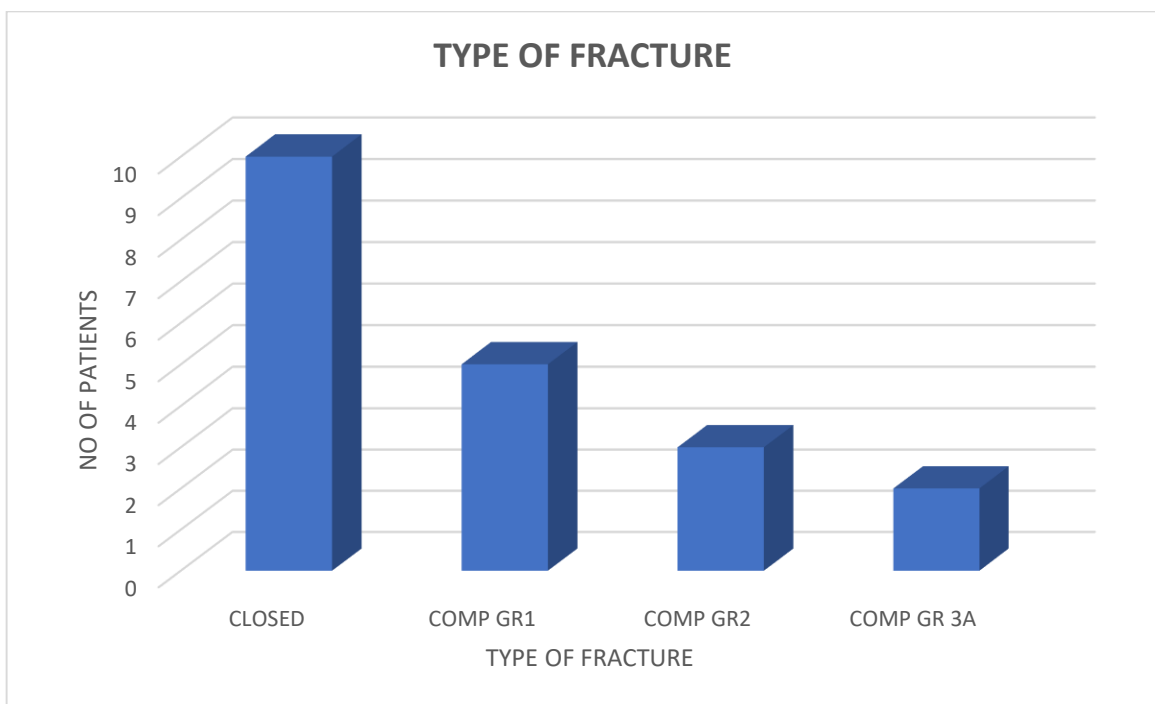
SIDE DISTRIBUTION

SIDE	PATIENTS	PERCENTAGE
RIGHT	12	60%
LEFT	8	40%



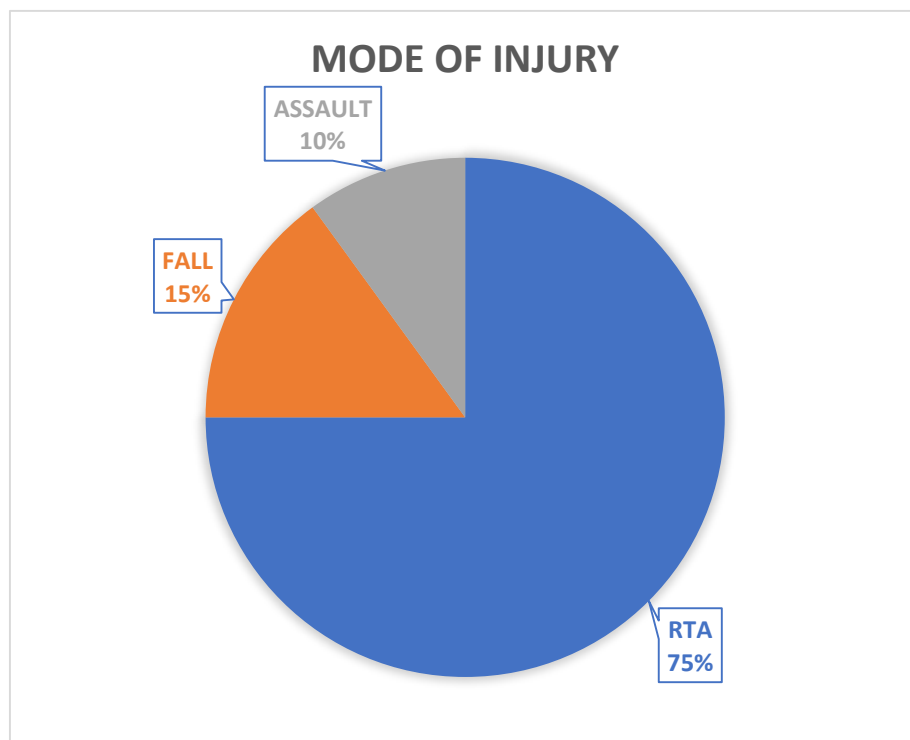
FRACTURE TYPE:

TYPE OF FRACTURE	PATIENTS	PERCENTAGE
CLOSED	10	50%
GRADE 1 COMPOUND	5	25%
GRADE 2 COMPUND	3	15%
GRADE 3A COMPOUND	2	10%



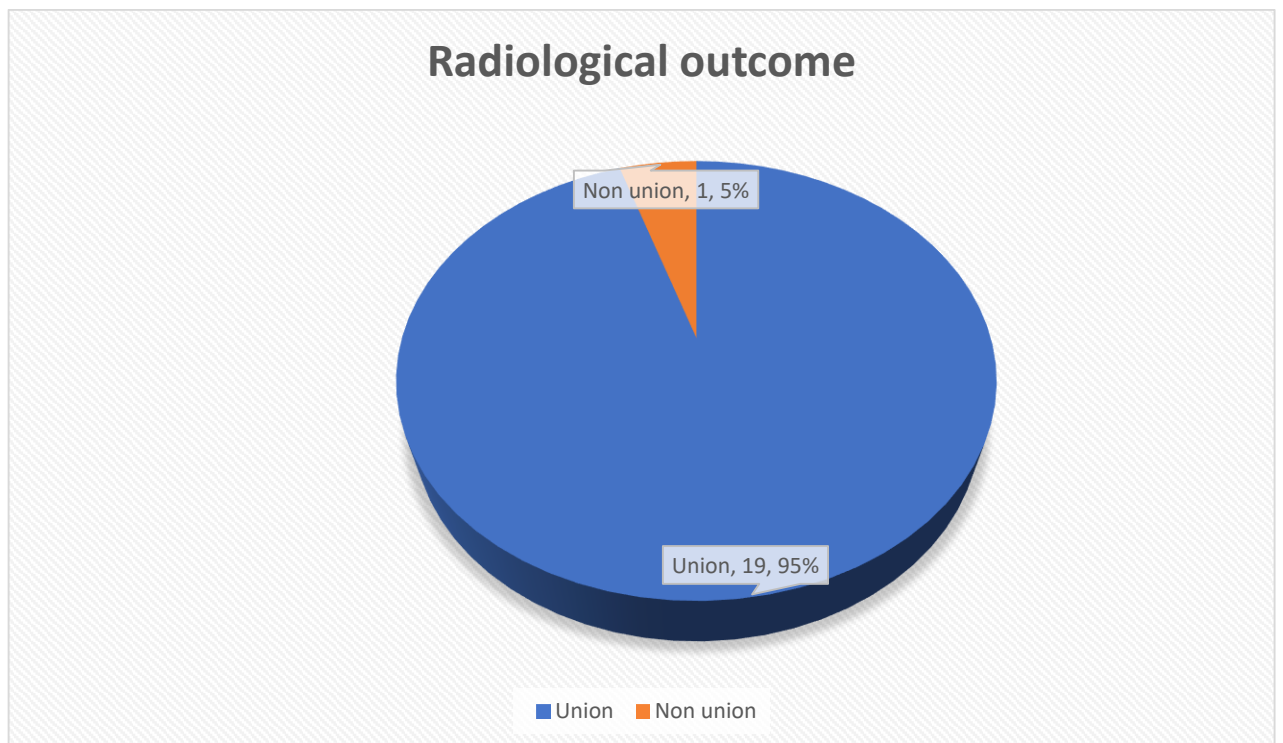
MODE OF INJURY

MODE OF INJURY	PATIENTS	PERCENTAGE
RTA	15	75%
FALL	3	15%
ASSAULT	2	10%



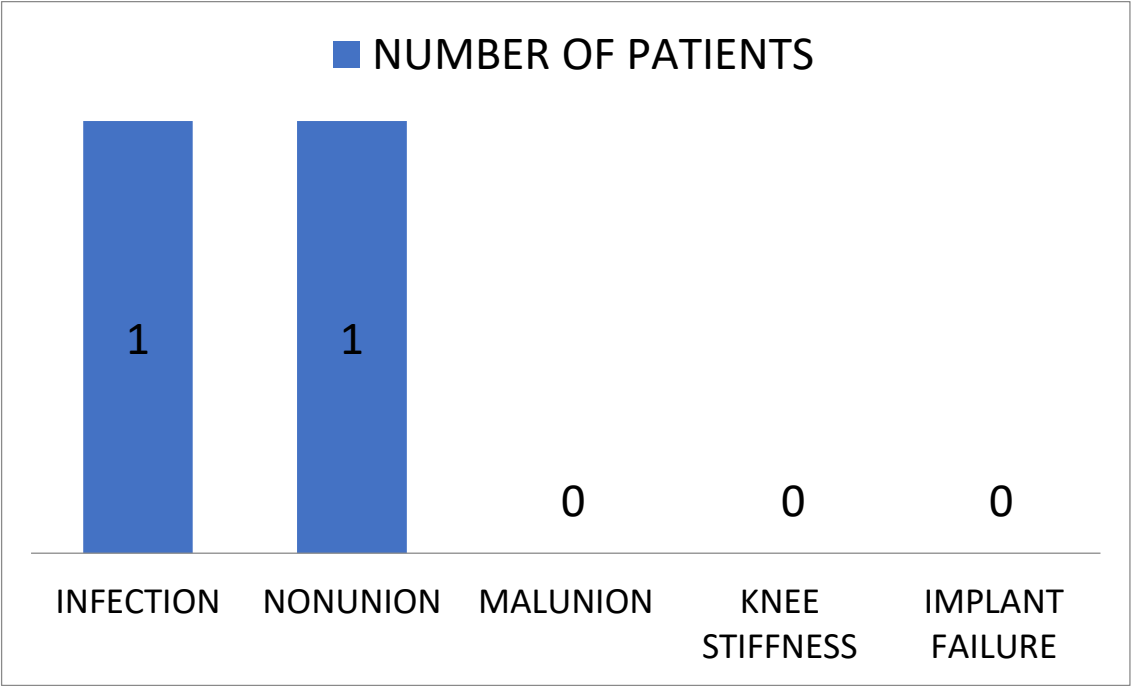
RADIOLOGICAL OUTCOME

RADIOLOGICAL OUTCOME	Patients	Percentage
UNION	19	95%
NONUNION	1	5%
TOTAL	20	100%



COMPLICATIONS

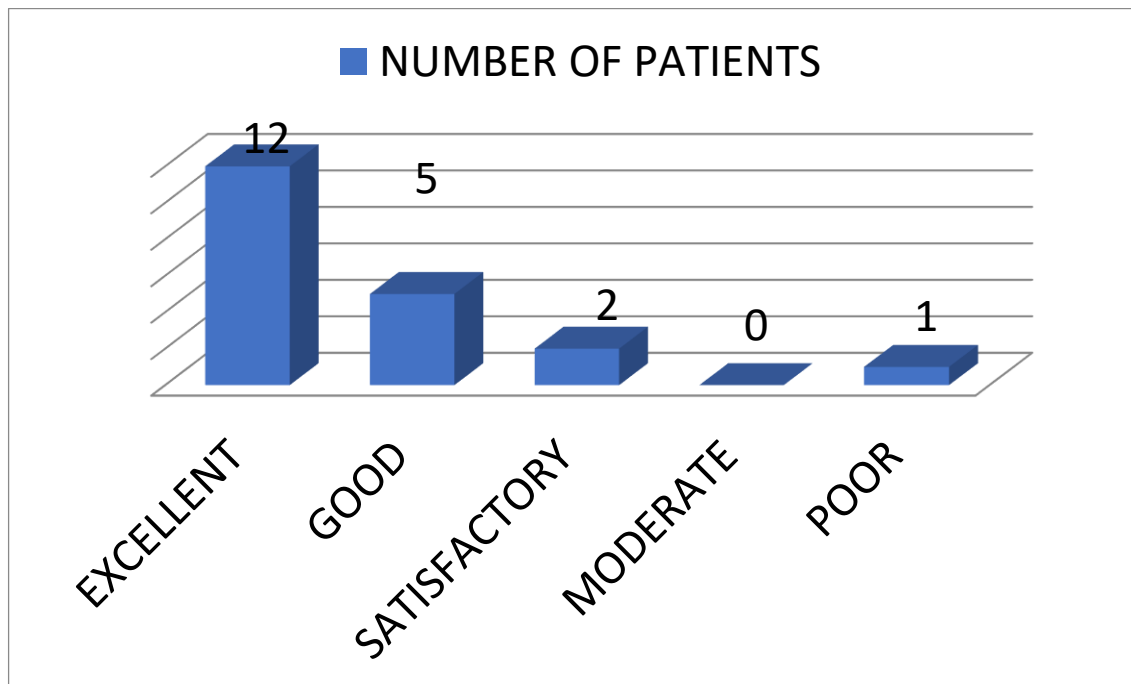
COMPLICATION	NO. OF PATIENTS	PERCENTAGE
Superficial Infection	1	5%
Non union	1	5%
Malunion	-	-
Implant failure	-	-
Knee stiffness	-	-



FUNCTIONAL OUTCOME

MODIFIED KARLSTROM OLERUD SCORING

RESULTS	PATIENTS	PERCENTAGE
EXCELLENT	12	60%
GOOD	5	25%
SATISFACTORY	2	10%
MODERATE	0	-
POOR	1	5%
TOTAL	20	100%



CASE ILLUSTRATION

Case 1

Name - Thangamani

Age/Sex – 55/F

Diagnosis - Closed proximal 3rd Isolated tibia # (L)



Immediate Postop



3 months followup



6 months followup



Clinical pictures



Case 2

Name - Selvam

Age/Sex – 19/M

Diagnosis - Grade 1 compound # Both Bone leg proximal 3rd (L)

Pre op Xrays



Immediate Postop



3 months followup



6 months followup



Clinical pictures



Case:3

Name - Karpagavalli

Age/Sex – 37/F

Diagnosis - Grade 1 compound Proximal 3rd both bone leg # (R)

Pre op Xrays



Immediate Postop



3 months follow up



6 months followup



Postop clinical pictures



Case 4:

Name - Esakki

Age/Sex – 28/M

Diagnosis - Closed Proximal 3rd Isolated tibia # (L), With Extra articular calcaneum #

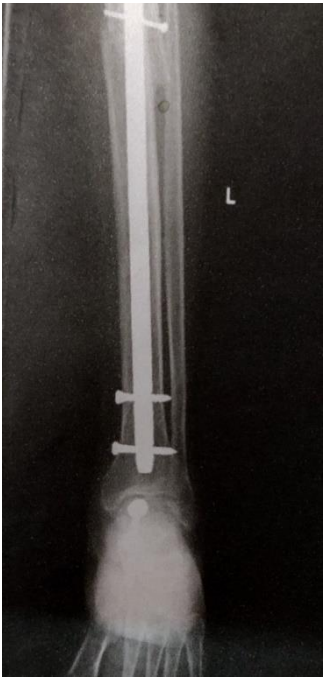
Preop Xrays



Immediate Postop



3 months followup



6 months followup



Postop clinical pictures



DISCUSSION

Intramedullary nailing is one of the treatments of choice for proximal third tibial shaft fractures. In the beginning, there were large incidences of valgus and flexion mal-alignments in the cases treated with intramedullary nailing in proximal third tibial fractures due to poor understanding of tibial anatomy and the deforming forces acting on proximal segment. In recent times, with use of new techniques like proximal and lateral starting point, use of blocking screws, adjunctive plating it is now possible to obtain and maintain acceptable reduction in these fractures.

Interlocking nailing has been increasingly used to treat both acute and chronic injuries to long bones. Kuntscher nail^{49,50} that forms the basis of modern-day IM nailing was mostly used in resource poor hospitals, but K nail does not control rotation and not applicable to comminuted fracture.

The surgical technique followed in our study is a novel procedure and therefore no other literature has described this technique previously. So, we have compared the results of our technique with that of other techniques which are being followed elsewhere.

Supplementary procedures like point reduction forceps, unicortical plating, manipulation with schanz pins percutaneously and femoral distractor can be used to achieve the alignment.

In our study we did not use such supplementary techniques to achieve reduction. The modified surgical technique itself corrected the mal

alignment which gave excellent results both functionally and radiologically, thereby avoiding excess instrumentation or implant fixation.

Operative time (Range 45-90 minutes) compared to the operation time reported in other centers using fluoroscopy. The Impact of tibia IM interlocking nailing intervention was evident through early discharge from hospital, early weight bearing, early healing and early return to pre-morbid status. Hospital stay for patients done IM locked nail (3-7 days; mean 5 days) was remarkably reduced compared to the patients treated by traditional methods of traction (42-84 days; mean 62 days). Majority (76%) of patients could partially bear weight between four and six weeks and full painless weight after 12 to 16 weeks. **O.O.Soren et al**⁵² study about interlocking nailing in long bone fractures shows surgical duration 60-180 min and postoperative hospital stay 1-3 weeks. Therefore, our study shows that patient treated with tibia interlocking nail can able to get back to their socio-economic activities earlier than traditional methods of treatments.

Court-Brown et al.^{54,55} studied 25 patients of tibial fracture with average union time of 15.4 weeks with no infection, malunion, non-union or delayed union. Overall, infection rate for orthopaedic surgery ranges from 1% to 12.5%. In our study infection rate in patients treated with tibia interlocking nail seems to be minimal.

Ikemi et al.⁵¹ have shown that IM nailing can achieve union rates as high as 90% in 18 weeks. In our study, healing rate is 95% and mean duration

of union is 16-18 weeks. These results are encouraging when compares to study of **Ricci *et al.*** which reported mean duration of healing of 13 weeks⁵⁶, study of **Ikemi *et al.***⁵¹ which reported mean duration of healing 19 weeks of fracture and the study done in Turkey mean time of union was five months. **Larsen *et al.***⁵⁷ studied 45 patients with reamed interlocking nail in tibia shaft fracture whom average time to fracture healing was 16.7 weeks.

Sean E. Nork *et al.*⁶ studied 35 pt. with proximal tibia fracture treated with Intramedullary nailing and found 97.3% pt. have final angulations within five degree and concluded that Intramedullary nail offer an attractive alternative for proximal tibial fractures. Our study shows that there was negligible angulation to no angulation at all.

As interlocking IM nail is load bearing device, it provides more stiffness and implant stability and that helps in early mobilization, early weight bearing, early healing of fracture and less chances of implant failure evident from the above facts that IM intramedullary nailing is a safe and quite effective for treatment of proximal third tibia fracture.

In terms of functional outcome, our study shows excellent outcome in 60% of patients, good outcome in 25%, satisfactory in 10% and poor in 5%. We have used the Modified Karlstrom Olerud scoring to assess the functional outcome postoperatively.

Finally, in our study we have achieved an excellent to satisfactory outcome in 95% of patients which is better than the results of 94% excellent

to satisfactory outcome obtained by **C.Krettek et al**^{36,37}, using the modified Karlstrom-Olerud scoring.

The comparison of results and outcome of patients treated with other techniques are discussed below:

References	Infection%	Union rate%
Bhandari <i>et al.</i> nailing ⁶⁹	2.5	96.5
Lindvall <i>et al.</i> nailing ⁶⁵	28	77
Beuhler <i>et al.</i> nailing ²⁹	0	92.9
Prabhav- expert tibia nail ⁶⁸	15	95
Our study	5	95

STUDY	NO OF CASES	EXCELLENT	GOOD	FAIR
Ding-Shuang,Leilu,Feng Gao (Expert tibia nail)	33	62%	21%	17%
M.Hansen,P.M ,S.Kuhn , Rommens ⁶⁷ (Expert tibia nail)	26	58%	19%	23%
Our study	20	60%	25%	10%

CONCLUSION

- Proximal third tibial fractures are difficult to manage by the traditional nailing technique due to the occurrence of malalignments.
- Based on the above results we conclude that, intramedullary interlocking nailing by our modified technique is an effective way in achieving alignment in proximal third tibia fractures.
- The advantages of our technique are,
 - Less time consuming procedure
 - No need for postop immobilization
 - Shorter hospital stay and early return to activities
 - No postop complications like implant failure or malalignment
- Soft tissue complications associated with plating can be avoided with usage of intramedullary nailing as it is minimally invasive. Hence it is obvious that, intramedullary nailing is better than plating in case of extra articular proximal tibia fractures.
- Considering other options of management like expert tibia nail, our surgical technique is advantageous in cost efficiency, implant availability, less invasiveness and less complex procedure.
- Although the study population and study period are limited, based on the results obtained we conclude that our technique is a viable surgical option in the management of proximal third tibial fractures.

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PROFORMA

1. Name:
2. Age/Sex:
3. Address:
4. Phone No:
5. Mode of Injury/Duration:
6. Associated Comorbidities:
7. Diagnosis:
8. Preop X-ray Knee with Leg, Leg with Ankle AP/Lat view:
9. Procedure Done:
10. Post Op Protocol:
11. Postop xray:
12. Postop Functional Score:
13. Radiological Union:
14. Complication:
15. Rehabilitation Protocol:

CONSENT FORM

Format for Informed Consent Form for Parent / Guardian of the Subjects

Informed Consent form to participate in a research study

Study Title:

Study Number: _____

Subject's Initials: _____ **Subject's Name:** _____

Date of Birth / Age: _____

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. []

(ii) I understand that my son / daughter's participation in the study is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected. []

(iii) I understand that the Ethics Committee and the regulatory authorities will not need my permission to look at my son / daughter's health records both in respect of the current study and any further research that may be conducted in relation to it, even if he/she withdraws from the trial. I agree to this access. However, I understand that my son / daughter identity will not be revealed in any information released to third parties or published. []

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). []

(v) I agree for the participation of my son/daughter in the above study. []

Signature (or Thumb impression) of the Subject's parent /Legally Acceptable Guardian

Date: ____/____/____

Signatory's Name: _____

Signature: _____

Or

Representative: _____

Date: ____/____/____

Signatory's Name: _____

Signature or thumb impression of the Witness: _____

Date: ____/____/____

Name & Address of the Witness: _____

**நோயாளிகளுக்கு அறிவிப்பு மற்றும் ஒப்புதல் படிவம்
(மருத்துவ ஆய்வில் பங்கேற்பதற்கு)**

ஆய்வு செய்யப்படும் தலைப்பு:

பங்கு பெறுவரின் பெயர்:

பங்கு பெறுவரின் வயது:

		பங்கு பெறுவர் இதனை குறிக்கவும் ✓
1.	நான் மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்களை படித்து புரிந்து கொண்டேன். என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டுள்ளது என அறிந்து கொண்டேன்.	<input type="checkbox"/>
2.	நான் இவ்வாய்வில் தன்னிச்சையாக தான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும், எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.	<input type="checkbox"/>
3.	இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்து மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.	<input type="checkbox"/>
4.	இந்த ஆய்வின் மூலம் கிடைக்கும் தகவலையோ, முடிவையோ பயன்படுத்திக் கொள்ள மறுக்க மாட்டேன்.	<input type="checkbox"/>
5.	இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக் கொள்கிறேன் எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்து கொள்வதுடன், ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ, அல்லது எதிர்பாராத, வழக்கத்திற்கு மாறான நோய்குறி தென்பட்டாலோ உடனே இதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.	<input type="checkbox"/>

பங்கேற்பவரின் கையொப்பம் / இடம்

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம் / இடம்

ஆய்வாளரின் பெயர்

மையம்

கல்வியறிவு இல்லாதவற்கு (கைரேகை வைத்தவர்களுக்கு) இது அவசியம் தேவை

சாட்சியின் கையொப்பம் / இடம்

பெயர் மற்றும் விலாசம்

Sl. no	NAME	AGE / SEX	DIAGNOSIS	PROCEDURE	COMPLICATION	UNION PERIOD	MODIFIED KARLSTRÖM OLERUD SCORE	RESULTS	MODE OF INJURY	ASSOCIATED INJURY
1	Karpagavalli	38/F	Grade 1 compound Proximal 3 rd #BB leg (R)	CRIF with ILIM nailing	-	16 weeks	33	Excellent	RTA	-
2	Thangamani	54/F	Closed proximal 3 rd Isolated tibia # (L)	CRIF with ILIM nailing	-	14 weeks	33	Excellent	Assault	Head injury
3	Esakki	28/M	Closed Proximal 3 rd Isolated tibia # (L)	CRIF with ILIM nailing	-	16 weeks	33	Excellent	RTA	Calcaneal fracture
4	Selvam	19/M	Grade 1 compound #BB leg proximal 3 rd (L)	CRIF with ILIM nailing	-	14 weeks	33	Excellent	RTA	-
5	Sathish Pandi	23/M	Closed BB leg # proximal 3 rd (R)	CRIF with ILIM nailing	-	14 weeks	33	Excellent	RTA	-
6	Niraukulathan	63/M	Grade 3A compound Proximal 3 rd # Isolated tibia (R)	CRIF with ILIM nailing	Superficial infection	18 weeks	29	Satisfactory	RTA	Pelvic fracture
7	Balamurugan	35/M	Grade 3A compound Proximal 3 rd # BB leg (R)	CRIF with ILIM nailing	Non union	-	22	Poor	RTA	Acetabular fracture
8	Pandaramm	25/M	Closed BB leg # proximal 3 rd (R)	CRIF with ILIM nailing	-	15 weeks	33	Excellent	RTA	Head injury Elbow dislocation
9	Ramathal	54/F	(R) Grade 2 compound #BB leg proximal 3 rd	CRIF with ILIM nailing	-	16 weeks	33	Excellent	RTA	-
10	Ganesan	55/M	Closed BB leg # proximal 3 rd (L)	CRIF with ILIM nailing	-	14 weeks	32	Good	Assault	-

S.No	NAME	AGE / SEX	DIAGNOSIS	PROCEDURE	COMPLICATI ON	UNION PERIOD	MODIFIED KRALSTROM OLERUD SCORE SCORE	RESULTS	MODE OF INJURY	ASSOCIATED INJURY
11	Santharaman	55/M	(R) Closed BB leg # proximal 3 rd	CRIF with ILIM nailing	-	14 weeks	33	Excellent	RTA	-
12	Natarajan	42/M	Closed BB leg # proximal 3 rd (L)	CRIF with ILIM nailing	-	15 weeks	30	Good	RTA	-
13	Chellappa	50/M	(L) Gr 1 compound BB leg # proximal 3 rd	CRIF with ILIM nailing	-	16 weeks	29	Satisfactory	Fall injury	Head injury
14	Chidambaram	48/M	(R) Gr 1 compound BB leg # proximal 3 rd	CRIF with ILIM nailing	-	16 weeks	33	Excellent	RTA	-
15	Isaiselvi	48/F	Closed BB leg # proximal 3 rd (L)	CRIF with ILIM nailing	-	14 weeks	31	Good	Fall injury	-
16	Kanagaraj	64/M	(R) Grade 2 compound #BB leg proximal 3 rd	CRIF with ILIM nailing	-	17 weeks	33	Excellent	RTA	-
17	Kumaresan	35/M	(R) Gr 1 compound BB leg # proximal 3 rd	CRIF with ILIM nailing	-	15 weeks	33	Excellent	RTA	-
18	Stephen raj	18M	Closed BB leg # proximal 3 rd (L)	CRIF with ILIM nailing	-	13 weeks	33	Excellent	RTA	Femur fracture
19	Karutha Pandi	38/M	(R) Grade 2 compound #BB leg proximal 3 rd	CRIF with ILIM nailing	-	14 weeks	32	Good	RTA	
20	Kasimbath	55/F	(R) Closed BB leg # proximal 3 rd	CRIF with ILIM nailing	-	15 weeks	30	Good	Fall injury	Bimalleolar fracture