"Prospective and Retrospective analysis of Functional Outcome of Distal Both bone Leg Fracture treated with Tibial Interlocking Nailing with and without Fibular plating"- A Comparative study

Dissertation submitted to



In partial fulfilment of the requirements for

M.S. DEGREE-BRANCH II ORTHOPAEDIC SURGERY MADRAS MEDICAL COLLEGE INSTITUTE OF ORTHOPAEDICS AND TRAUMATOLOGY RAJIVGANDHI GOVERNMENT GENERAL HOSPITAL THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY CHENNAI-TAMILNADU

**APRIL – 2017** 

# CERTIFICATE

This is to certify that this dissertation titled "**Prospective and Retrospective analysis of Functional Outcome of Distal Both bone Leg Fracture treated with Tibial Interlocking Nailing with and without Fibular plating**" - A COMPARATIVE STUDY is a bonafide record of work done by Dr. SATHEESH KUMAR .R during the period of his Post graduate study from June 2014 to June 2017 under guidance and supervision of **Prof.A.PANDIASELVAN** in the INSTITUTE OF ORTHOPAEDICS AND TRAUMATOLOGY, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai-600003, in partial fulfillment of the requirement for M.S.ORTHOPAEDIC SURGERY degree Examination of The Tamilnadu Dr. M.G.R. Medical University to be held in April 2017.

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## DECLARATION

I declare that the dissertation entitled "Prospective and Retrospective analysis of Functional Outcome of Distal Both bone Leg Fracture treated with Tibial Interlocking Nailing with and without Fibular plating"- A COMPARATIVE STUDY submitted by me for the degree of M.S is the record work carried out by me during the period of March 2016 to September 2016 under the guidance of Prof.A.PANDIASELVAN M.S.Ortho, D. Ortho., Professor of Orthopaedics, Institute of Orthopaedics and traumatology, Madras Medical College, Chennai. This dissertation is submitted to the Tamilnadu Dr.M.G.R. Medical University, Chennai, in partial fulfilment of the University regulations for the award of degree of M.S. ORTHOPAEDICS (BRANCH-II)) examination to be held in April 2017.

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# **INTRODUCTION**

The distal tibia fractures occurs in around 7 to 9% cases of lower extremity fractures, out of them 85% are associated with fibular fractures. The distal tibia fractures occurs by various mechanisms like road traffic accidents, fall from heights or low energy mechanism like rotational strain, etc. The amount of swelling, blisters, and open wounds are taken into account while managing distal tibia and fibula fractures.

Despite all measures, treating distal both bone fractures of leg remains as a challenge. The goals of surgery are maintaining the length and rotation, correction of sagittal and coronal alignment, and quicker return of functional range of movements of knee and ankle.

Treatment of distal both bone leg fractures includes intramedullary nailing, hybrid external fixation, plate fixation or combining any of these modalities.

Interlocking nailing of tibial fractures is advantageous as this technique allow load sharing, does not disturb extraosseous blood supply, and soft tissues are less damaged and have a relatively easy learning curve. Intramedullary nailing of distal tibial fractures with short distal fragment is associated with malalignment problem particularly in coronal plane, non union and need for secondary procedures to achieve union because of muscular forces which result in displacement of fracture and instability due to mismatch.

As there is a mismatch between the diameters of the medullary canal and the nail, with absent nail-cortex contact, the nail may sway laterally along coronally placed locking screws and stress is increased on the locking holes to maintain alignment of the fracture after surgery resulting in failure .

So various techniques have evolved to improve nailing the distal both bone fractures of leg including fibular plating (distal third fractures), unicortical plating, different nail design with different proximal bends (proximal third fractures) and blocking screws (poller screws)

# **AIM AND OBJECTIVE**

To analyse the functional outcome of distal both bone leg fractures treated with Tibial Interlocking nail with and without supplementary fibular plating

This is a study of patients who presented with distal both bone leg fractures and some of the patients underwent internal fixation with tibial interlocking nailing alone and some of the patients underwent internal fixation with tibial interlocking nailing with supplementary fibular plating in our institute of Orthopaedics and Traumatology , Madras Medical College and Rajiv Gandhi Government general hospital, Chennai.

Post operatively patients were followed up for the functional outcome of the distal both bone leg fractures and the results were analysed

### **REVIEW OF LITERATURE**

### **Evolution of interlocking nailing**

Evolution of intramedullary nailing<sup>39</sup> dates back to 500 years ago, it was recorded that Aztecs used wooden intramedullary nails.

In 1916 Kuntscher introduced cannulated nails for tibia and femur. In 1950, Lottes one of the pioneers in tibial nailing developed a rigid nail for tibia.

In 1951 Herzog modified the Kuntscher nail, by adding a proximal bend to falicitate nail insertion.

"Modney is credited with designing the first interlocking nail.

Kuntscher also designed an interlocking nail (The Detensor nail, 1968) which was then modified by Klemm Schellumm initially and by Kempf and Crosse later in 1972".

In 1986 Bone & Johnson were the first to report interlocking nail in united states. They used Grosse Kempf interlocking tibial nail in fractures of tibial shaft.

Charnley in his text "closed treatment of common fractures" stated that he believed the eventual solution to the tibial shaft fracture would be a non reamed intramedullary nail.

A fracture zone 5cm below the knee and 5cm above the ankle was required for effective use of interlocking nail. The stability provided by any nail decreases precipitously if the fracture extends into the metaphyseal region.

## Intramedullary nailing in distal tibial metaphyseal fractures

Intramedullary nailing with locking bolts is widely accepted as satisfactory treatment for tibial diaphyseal fractures. But there are varied reviews about the use of this technique for fractures in distal metaphysis.

Various supplementary procedure were used by different authors to effectively manage the metaphyseal fractures of tibia with intramedullary nailing.

#### **Distal tibial metaphyseal fractures**

#### **Poller screws**

Poller screws which are placed adjacent to the nail and perpendicular to the screws holes usually in an anteroposterior direction can be done as one possible method to improve the stability of metaphyseal fractures and has been described as a reduction tool used to over come the displacing forces at the time of introduction of intramedullary nail<sup>6</sup>.

The poller screws functionally decrease the width of the metaphyseal medulla and are definitely useful with nails of smaller diameter.

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In "1994 Krettek et al described the clinical application of blocking screws, termed poller screws as a tool for the prevention of axial deformities of proximal and distal third fractures of tibia during intra medullary nailing. The same technique has been used for femoral fractures"<sup>27</sup> too.

In 1995 Robinson et al used "percutaneous large reduction forceps to achieve the alignment and maintain the same throughout the nailing procedure. He also resected the distal few millimeters of the standard AO nail to nail the 4cm length distal metaphyseal fragments and used the distal locking bolts as lag screws through the fracture site"<sup>6</sup>.

# **Fibular plating**

In "1997 Thompson KA et al and Weber TG et al showed excellent results when supplemented with fibular plating<sup>3</sup>. In 2000 Tyllianaki also found fibular plating as an effective supplement"<sup>7</sup>.

In 2002 Goezyca et al "published their results of modified tibial nails for the distal metaphyseal fractures".

"Kenneth A Egol compared the loss of alignment in distal metaphyseal fractures treated with intra medullary nailing alone. They had immediate post operative malalignment in three cases in those treated with nailing alone, which were eventually corrected by using fibular plating or poller screws"<sup>1</sup>. "Tyllianakis in his retrospective review of intramedullary nailing in distal tibial fractures showed excellent results in 86% of patients. In their study, they fixed the concomitant lateral malleolar fractures and if not fixed they used plaster. They noted that patients with concomitant fibular fractures treated with plasters showed permanent swelling and stiffness. They also noted that fixation of fibula helped to align the tibial fracture and facilitate nail insertion<sup>7</sup>.

Moscato and his colleagues recommended "fibular plating to ensure overall alignment in supramalleolar fractures, the lateral malleolar fractures when associated with the tibial fractures can lead to incongruity of the ankle joint which may lead to post traumatic arthritis".

Robinson et al. showed that "distal metaphyseal fractures of the tibia with minimal involvement of the ankle can be treated successfully with intramedullary nailing; of 63 patients, all but five had satisfactory clinical outcomes. The authors emphasized that this technique is inappropriate for pilon fractures with significant articular involvement caused by an axial loading mechanism"<sup>6</sup>.

In "2003 James Kellam stated that fibular plating or poller screws were effective as supplementary techniques in intramedullary nailing of distal tibial metaphyseal fractures"<sup>2</sup>.

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In "2005 Sean E Nork et al compared the results of those treated with nailing alone and those treated with supplementary fibular plating"<sup>31</sup>.

In "2006 Kenneth A Egol et al advocated fibular plating and temporary unicortial plating"<sup>1</sup>.

In the study conducted by the , "The French Society of Orthopaedics and Traumatology (SOFCOT), done by P. Bonneviallea, , J.-M. Lafosse b, L. Pidhorzc A. Poichotte d, G. Asencio e, F. Dujardinf in 2010<sup>37</sup>, they concluded that

Tibial Osteosynthesis	Fibula not operated	Fibula operated
	( Tibial Non union)	(Tibial Non union)
Nailing n=6	N=5	N=1
Plating n=4	N=1	N=3
Fixator n=1		N=1

According to JBJS, 2003 Apr; 85 (4): 604 608, Anant Kumar, MD; Steven J. Charlebois, PhD; E. Lyle Cain, MD; Richard A. Smith, PhD; A. U. Daniels, PhD; John M. Crates, MD, they came to conclusion that Fibular plate fixation increased the initial rotational stability after distal tibial fracture compared with that provided by tibial intramedullary nailing alone. However, there was no difference in rotational structural stiffness between the specimens treated with and without plate fixation as applied torque was increased"<sup>33</sup>.

"In patients with ipsilateral distal tibial and fibular fractures who are treated with Russell Taylor intramedullary nailing of the tibia, rotational stability of the tibial fracture can be increased by plate and screw fixation of the fibula, which may reduce the risk of valgus malunion according to JBJS report mentioned above"<sup>33</sup>.

According to Campbell et al "In an effort to decrease the frequency of delayed union, nonunion, and infection after tibial shaft fractures, "percutaneous" plating was developed to obtain stable fixation, while preserving the fracture environment. This technique involves plating of any associated fibular fracture, prebending a 3.5-mm dynamic compression plate to match the tibial anatomy, and placing the plate and screws through small incisions"<sup>17</sup>.

According to Collinge and Sanders, "current indications for percutaneous plating are (1) a tibial shaft fracture with periarticular metaphyseal comminution that precludes locked intramedullary nailing and (2) soft-tissue damage of such severity that it prohibits the use of standard incision". Collinge, Sanders, and DiPasquale reported the use

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of "percutaneous plating in 14 complex tibial shaft fractures. Five closed fractures healed uneventfully with no infections or skin problems. In the nine open fractures, osteomyelitis developed in one, and superficial infections developed in three. There were no malunions. They cautioned that percutaneous plating is technically challenging, and that malalignment is more frequent than with other methods of fixation. Clinical experience with this technique remains limited at this time".

According to Campbell et al "Intramedullary nailing of more distal fractures is possible, but the ability to maintain a mechanically stable reduction becomes more difficult the farther the fracture extends distally. Their analysis shows that the influence of fibular fractures on maintaining alignment in 40 distal-fourth tibial fractures treated with locked intramedullary nailing. The five tibial fractures with intact fibulas and four fractures with fibular fixation all healed in anatomical alignment. All 11 unfixed fibular fractures located at levels different from the tibial fracture were in anatomical alignment, whereas 12 (60%) of 20 unfixed fibular fractures occurring at the same level as the tibial fracture were malaligned. This study suggests that internal fixation of some fibular fractures improves stability in distal-fourth tibial fractures treated with intramedullary nailing"<sup>17.</sup>

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"Two distal locking screws are required to prevent recurvatum deformity from rotation around a single distal locking screw. The tip of the nail is cut off if necessary to allow placement of two distal screws. Cancellous lag screws are used to stabilize medial and posterior malleolar fractures. Open reduction is done if there is intraarticular displacement. The fibula is plated only if necessary for the stability of the ankle joint, or if it is severely displaced"<sup>6</sup>.

As advocated by Robinson et al., some investigators believe that plating same-level fibular fractures helps prevent malalignment in distal tibial fractures treated with intramedullary nailing..

Fibular plating has been found to be an excellent supplementary technique to intramedullary interlocking nailing in distal both bone fractures of leg as it helps in reduction and alignment peroperatively and helps in maintaining fracture alignment till union, preventing loss of initial reduction.

# ANATOMY

The bony framework of the leg consists of two bones, the tibia and fibula, arranged in parallel.

The **fibula** is much smaller than the tibia and is on the lateral side of the leg. It articulates superiorly with the inferior aspect of the lateral condyle of the proximal tibia, but does not take part in formation of the knee joint. The distal end of the fibula is firmly anchored to the tibia by a fibrous joint and forms the lateral malleolus of the ankle joint<sup>34</sup>.

The **tibia** is the weightbearing bone of the leg and is therefore much larger than the fibula. Above, it takes part in the formation of the knee joint and below it forms the medial malleolus and most of the bony surface for articulation of the leg with the foot at the ankle joint.

The leg is divided into anterior (extensor), posterior (flexor), and lateral (fibular) compartments by:

- "an interosseous membrane, which links adjacent borders of the tibia and fibula along most of their length;
- two intermuscular septa, which pass between the fibula and deep fascia surrounding the limb; and
- by direct attachment of the deep fascia to the periosteum of the anterior and medial borders of the tibia"<sup>34</sup>.

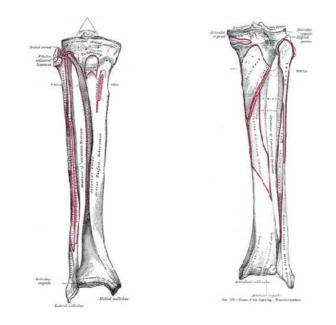
Muscles in the anterior compartment of leg dorsiflex the ankle, extend the toes, and invert the foot. Muscles in the posterior compartment plantarflex the ankle, flex the toes, and invert the foot. Muscles in the lateral compartment evert the foot. Major nerves and vessels supply or pass through each compartment.

#### Bones

#### Shaft and distal end of tibia

"The shaft of tibia is triangular in cross-section and has anterior, interosseous, and medial borders and medial, lateral, and posterior surfaces.

- the anterior and medial borders, and the entire medial surface are subcutaneous and easily palpable;
- the interosseous border of the tibia is connected, by the interosseous membrane, along its length to the interosseous border of the fibula;
- the posterior surface is marked by an oblique line (the soleal line)<sup>34</sup>.



ANTERIOR AND POSTERIOR VIEW

The soleal line descends across the bone from the lateral side to the medial side where it merges with the medial border. In addition, a vertical line descends down the upper part of the posterior surface from the midpoint of the soleal line. It disappears in the lower one-third of the tibia.

The shaft of the tibia expands at both the upper and lower ends to support the body's weight at the knee and ankle joints.

The posterior surface of the box-like distal end of the tibia is marked by a vertical groove, which continues inferiorly and medially onto the posterior surface of the medial malleolus. The groove is for the tendon of the tibialis posterior muscle. The lateral surface of the distal end of the tibia is occupied by a deep triangular notch (the **fibular notch**), to which the distal head of the fibula is anchored by a thickened part of the interosseous membrane.

### Shaft and distal end of fibula

The fibula is not involved in weightbearing. The fibular shaft is therefore much narrower than the shaft of the tibia. Also, and except for the ends, the fibula is enclosed by muscles<sup>34</sup>.

The fibula is the lateral and smaller bone of the leg. The tip of the lateral malleolus (distal seven cm of fibula) is 0.5 cm lower than that of medial malleolus. The lateral malleolus and the ligaments attached to it are very important in maintaining stability at the ankle joint

Like the tibia, "the shaft of the fibula is triangular in cross-section and has three borders and three surfaces for the attachment of muscles, intermuscular septa, and ligaments . The interosseous border of the fibula faces and is attached to the interosseous border of the tibia by the interosseous membrane. Intermuscular septa attach to the anterior and posterior borders. Muscles attach to the three surfaces"<sup>34</sup>.

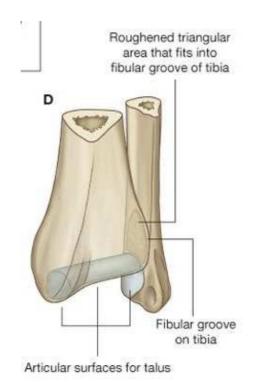
The narrow **medial surface** faces the anterior compartment of leg, the **lateral surface** faces the lateral compartment of leg, and the **posterior surface** faces the posterior compartment of leg.

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The posterior surface is marked by a vertical crest (**medial crest**), which divides the posterior surface into two parts each attached to a different deep flexor muscle.

The distal end of the fibula expands to form the spade-shaped **lateral malleolus**.

The medial surface of the lateral malleolus bears a facet for articulation with the lateral surface of talus, thereby forming the lateral part of the ankle joint. Just superior to this articular facet is a triangular area, which fits into the fibular notch on the distal end of the tibia. Here the tibia and fibula are held together by the distal end of the interosseous membrane.



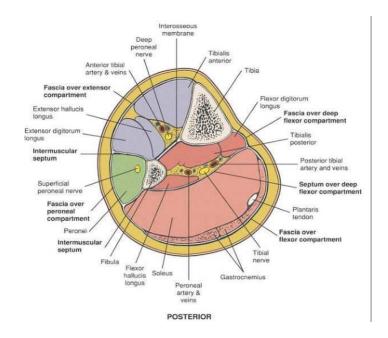
Posteroinferior to the facet for articulation with the talus is a pit or fossa (the **malleolar fossa**) for the attachment of the posterior talofibular ligament associated with the ankle joint.

The posterior surface of the lateral malleolus is marked by a shallow groove for the tendons of the fibularis longus and fibularis brevis muscles.

# Joints

#### Interosseous membrane of leg

The interosseous membrane of leg is a tough fibrous sheet of connective tissue that spans the distance between facing interosseous borders of the tibial and fibular shafts. The collagen fibers descend obliquely from the interosseous border of the tibia to the interosseous border of the fibula, except superiorly where there is a ligamentous band, which ascends from the tibia to fibula.

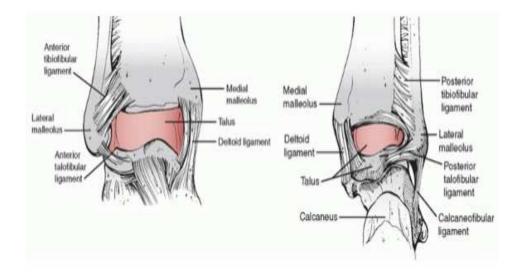


There are two apertures in the interosseous membrane, one at the top and the other at the bottom, for vessels to pass between the anterior and posterior compartments of leg.

The interosseous membrane not only links the tibia and fibula together, but also provides an increased surface area for muscle attachment.

"The distal ends of the fibula and tibia are held together by the inferior aspect of the interosseous membrane, which spans the narrow space between the fibular notch on the lateral surface of the distal end of the tibia and the corresponding surface on the distal end of the fibula. This expanded end of the interosseous membrane is reinforced by **anterior** and **posterior tibiofibular ligaments**. This firm linking together of the distal ends of the tibia and fibula is essential to produce the skeletal framework for articulation with the foot at the ankle joint"<sup>34</sup>.

Regarding the anatomic axis of tibia, "the tibial plafond is oriented in slight valgus in the frontal plane (2 degrees), and the anatomic axis passes just medial to midline of the talus. The tibial plafond is slightly extended in sagittal plane (approximating 5 to 10 degrees) and the middiaphyseal line of the tibia passes through the lateral process of the talus" according to Greys anatomy.

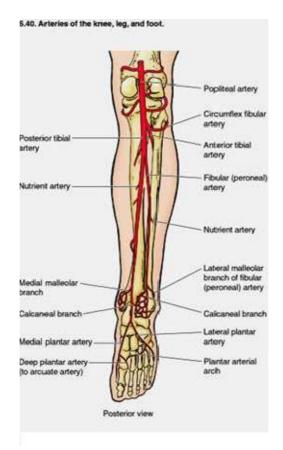


## LIGAMENTOUS STRUCTURES

Clinical anatomy of the ligamentous attachment at the ankle joint helps in better understanding of the displacement and fracture anatomy.

# **Blood supply**

The periosteal vessel and nutrient artery supplies the distal tibia.the nutrient artery originates from the posterior tibial artery at the origin of the soleus muscle. It enters the postero lateral cortex of the tibia. The nutrient artery gives three ascending branches, one descending branches and smaller branches for the endosteum.



Even in trivial injury to the distal tibia fractures this nutrient artery may be injured. To prevent avascularity, the soft tissue envelope should be preserved in the distal tibia as it is the only source of blood supply to the periostium. The anterior tibial artery is divided from the popliteal artery and provides periosteal blood supply along its course throughout the interosseous membrane.

Blood supply to the distal tibia become more compromised due to underlying soft tissue injury in case of distal tibial fractures. Hence non union, poor wound healing, hard ware problems were encountered while doing open reduction and internal fixation with plate osteosynthesis.

## Ossification

The tibia ossifies from one primary and two secondary centers. The primary centers appears in the shaft during the seventh week of the intra uterine life. The secondary centers for the upper end appears just before birth and fuses with the shaft at 16-18 years. The upper epiphysis usually includes the tibial tuberosity.

A secondary centre for the lower end appears during the first year, forms the medial malleolus by the seventh year and fuses with the shaft by the 15-17 years. Separate secondary centers may appear for the medial maleolus and tibial tuberosity.



#### Metaphyseal fractures of distal tibia

# Definition

Metaphyseal Zone is defined as the area within a square the sides of which are the same length as the widest part of the articular surface.

# Classification

# **1. AO/OTA Classification**

According to AO/OTA classification metaphyseal fractures of tibia and fibula in the proximal end is designated as 41 and in the distal end as 43.The malleolar segment is an exception is classified as the fourth segment of the tibia/fibula (44). Type A is extra articular, Type B is partial articular type C is complete articular.

# **AO/OTA Classification of Distal Tibial/fibular Metaphysis is 43**

- A Extra articular fracture
- A1 Extra articular, Metaphyseal simple
  - 1. Spiral
  - 2. Oblique
  - 3. Transverse

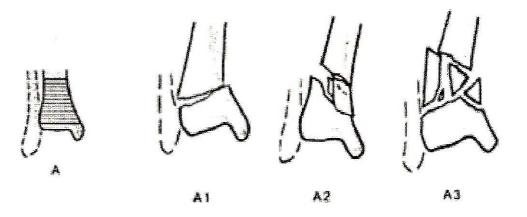
A2 - Extra articular fracture, Metaphyseal wedge

- 1. Posterolateral impaction
- 2. Anteromedial wedge
- 3. Extending into the diaphysis
- A3 Extra articular fracture, Metaphyseal complex
  - 1. Three intermediate fragments
  - 2. > 3 intermediate fragments
  - 3. Extending into the diaphysis
- B Partial articular fracture
- B1 Partial articular fracture, Pure split
  - 1. Frontal
  - 2. Sagittal
  - 3. Metaphyseal multifragmentary
- B2 Partial articular fracture, Split depression
  - 1. Frontal
  - 2. Sagittal
  - 3. Of the central fragment

B3 – Partial articular fracture, Multifragmantary depression

- 1. Frontal
- 2. Sagittal
- 3. Metaphyseal multifragmentary
- C Complete articular fracture
- C1 Complete articular fracture, Articular simple, Metaphyseal simple
  - 1. Without depression
  - 2. With depression
  - 3. Extending into diaphysis
- C 2 Complete articular, Articular simple Metaphyseal multifragmentary
  - 1. With asymmetric impaction
  - 2. With depression
  - 3. Extending into diaphysis
- C3 Complete articular fracture, multifragmentary
  - 1. Epiphyseal
  - 2. Epiphyseo metaphysis
  - 3. Epiphyseo metaphyseo diaphyseal <sup>18</sup>

AO/OTA Classification of Distal Tibial Metaphysis





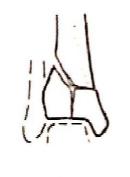




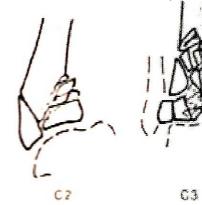


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CI



Grade I	Clean wound of less than 1 cm in length
Grade II	Wound larger than 1 cm in length without extensive soft
	tissue damage
Grade III	Wound associated with extensive soft tissue damage;
	usually longer than 5 cm,
	Open segmental fracture
	Traumatic amputation,
	Gunshot injuries
	Farmyard injuries,
	Fractures associated with vascular repair
	Fractures more than 8 hours old
III A	Adequate periosteal cover
III B	Presence of significant periosteal stripping
III C	Vascular repair required to revascularize leg

2.Gustilo Anderson	<b>Classification of com</b>	pound fractures <sup>18</sup> :
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# 3. Taylor and Martin SUD classification of metaphyseal fractures<sup>14</sup>

Taylor and martin proposed a classification of metaphyseal fractures (SUD) in which the main fracture is characterized as stable (S), unstable (U) or with diaphyseal extension (D).

These are further divided into three subtypes.

Taylor and Martin SUD classification of metaphyseal fractures

S-Stable

- S.0 extra articular
- S.1 -<2mm displacement
- S.2 ->2mm displacement
- U-Unstable
- U.0 extra articular
- U.1 -<2mm displacement
- U.2 ->2mm displacement
- D Diaphyseal Extension
- D.0 extra articular
- D.1 -<2mm displacement
- D.2 ->2mm displacement

According to Taylor and Martin with progression from type S to type D, treatment shifts towards external fixator and away from open reduction. Conversely with progression from subgroup 0 to subgroup 2 open reduction is indicated.

# **Treatment options**

The amount of malalignment and shortening considered acceptable also is controversial. Tarr et al. and Puno et al. demonstrated that "distal tibial malalignment may be more poorly tolerated than more proximal alalignment. The recommendations in the literature vary widely: 4 to 10 degrees of varus-valgus malalignment, 5 to 20 degrees of anteroposterior malalignment, 5 to 20 degrees of rotatory malalignment, and 10 to 20 mm of shortening. In general, we agree with Trafton's recommendation and strive to achieve less than 5 degrees of varus-valgus angulation, less than 10 degrees of anteroposterior angulation, less than 10 degrees of rotation, and less than 15 mm of shortening. Maintaining fracture alignment is difficult in certain fracture types, and if repeated attempts at realignment have been unsuccessful, operative fixation is indicated"<sup>17.9</sup>.

## **Non- operative Management**

Conservative management of distal both bone fractures of leg resulted in significantly high rate of complications. Sarmiento et al in 1989 concluded that "bracing was contraindicated in fractures with excessive initial shortening or ones showing increasing angular deformity while in cast. Most series of closed treatment have reported 25 to 40% incidence of ankle and subtalar joint stiffness after prolonged casting and immobilization<sup>35</sup>. Thus operative intervention is needed in most of the distal both bone leg fractures.

## **Plates and screws**

High incidence of soft tissue complications occurs in open reduction and plate fixation of tibia in the range of 10 to 15% in many series, but the recent advances in plating techniques and designing have reduced these complications significantly. Indirect reduction and percutaneous plating (LISS – Less Invasive stabilization System) is indicated in a tibial shaft fracture with periarticular metaphyseal comminution that precludes the use of standard incisions according to Collinge and Sanders<sup>36</sup>.

#### Hybrid fixators and External fixators:

Thomas A Russell preferred hybrid fixator or plate & screw technique with open and indirect reduction technique in metaphyseo diaphyseal transition or metaphyseal unstable fractures of distal leg. Bono CM et al proposed a treatment "algorithm for proximal tibial fractures with minimal or severe soft tissue injury, He preferred external fixation when the distal fragment is too short and nailing only when it is long"<sup>21,1</sup>.

Variety of external fixators are available. The fixator chosen should provide adequate stability, permit progressive weight bearing, and allow dynamization and destabilization as the fracture heals. Fixator systems that accommodate pin placement in more than one plane and have the ability to include the foot are most useful. Lighter weight, lower cost, and less interference with visualization of the bone on radiographs also are desirable attributes if they do not compromise the stability and versatility of the system. Single-unit fixators with large universal joints readily permit adjustments to fracture reduction after the frame is applied. These fixators tend to be less stable because they do not allow wide pin spacing, and it is more difficult to add a second plane of fixation. Modular fixators allow greater freedom in placement, but are more difficult to adjust when the frame is completed. Pin removal and replacement may be necessary to improve reduction. Newer pin clamp designs with ball joint or pivoting mechanisms increase the adjustability of these constructs to some extent<sup>17</sup>.

#### Locked compression plate

Introduction of locked compression plate has changed the plating technique and the outcome in metaphyseal fractures significantly.

Locked plate designs function as fixed-angle devices whose stability is provided by the axial and angular stability at the screw-plate interface instead of relying on the frictional force between the plate and bone, which is thought to preserve the periosteal blood supply around the fracture site. Locked plates are indicated for fracture management in osteoporotic bone and in periarticular fracture patterns, making them a feasible treatment option for distal tibia metaphyseal fractures<sup>4</sup>.

Though the locked compression plate with MIPPO(Minimally Invasive Percutaneous Plate Osteosynthesis) technique eliminates the soft tissue problems associated with open reduction and internal fixation, it cannot help in fracture reduction. The fracture alignment has to be restored before applying the locked compression plate<sup>4</sup>.

In the treatment of distal tibial fractures, locked compression plates provide more stable fixation than intramedullary nailing in vertical loading but were **less effective in the cantilever bending**. In fracture patterns, in which the fibula cannot be effectively stabilized, locked plates offer improved mechanical stability when compared with locked nails alone. In this study fibular plating is done as a supplementary procedure in the nailing group to improve the stability.

# Disadvantages of locking compression plate in distal tibial metaphyseal fractures<sup>21</sup>.

- 1. Soft tissue complications in conventional open reduction and plating of tibia
- Development of superficial wound problems increased the risk of deep infection six fold.
- 3. Malalignment is more frequent in percutaneous plating than with the other methods of fixation.
- 4. Fracture alignment could not be aided by the locked plate (no lag effect through the plate). It has to be restored before applying the plate.
- 5. Locked compression plating needs careful preoperative planning. If applied without following the principles of plating and the order of putting the screws, failures are not uncommon.
- 6. Rarely late pain over the distal tibial plate and screws may occcur.

## **Poller screws**

Poller screws placed adjacent to the nail and perpendicular to the screw holes usually in an anteroposterior direction has been found to improve the stability of distal tibial metaphyseal fractures.

#### PATHOPHYSIOLOGY OF INTRAMEDULLARY NAILING

#### Nailing without reaming

Smaller diameter implants are used in nail insertion without reaming. The advantages are less heat production and less disturbances of the endosteal blood supply resulting in considerable less bone necrosis, which appears to be one of the risk factors for the development of post operative infection.

"The influence of nail diameter on blood perfusion and mechanical parameters studied in dog models by Hupel TM et al. Following segmental osteotomy of the tibia, it was shown that a loose fitting nail did not affect cortical perfusion as much as right fitting nail and it allowed more complete cortical revascularization at 11 weeks post nailing. On the other hand stiffness and load to failure were not found to be different"<sup>27</sup>.

### Nailing with reaming

Nailing with reaming produces various local and general changes in the body.

## **Local Changes**

"Tibial reaming enhances periosteal blood flow and increases muscle perfusion. It reduces endosteal blood flow for a period but this seems to have little clinical effect. Unlike femoral reaming, it seems to have little coagulative effect and does not cause adult respiratory distress syndrome (ARDS). Reamed nailing of closed tibial diaphyseal fractures gives better clinical results than unreamed nailing. This is not true of severe open tibial fractures, where the results of reamed and un-reamed nailing appear to be very similar"<sup>17</sup>.

## **General Changes**

These include pulmonary embolism, temperature related changes of the coagulation system and humoral, neural and inflammatory reaction.

The development of post traumatic pulmonary failure following early femoral nailing in the multiple injured patients is associated with the reaming procedure.

"Wenda et al measuring intramedullary pressure intra operatively, found values between 420 - 1510 mm Hg with reaming procedures, as compared with 40 - 70 mm Hg in cases where used without reaming".

#### **Complications of Intramedullary Nailing**

There are a number of complications associated with intramedullary nailing, such as knee pain, neurologic abnormalities, vascular damage, hardware breakage, and increased bone damage.

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#### **Knee Pain**

This is the most common complication associated with intramedullary tibial nailing. In the three major studies of this complication, "Keating et al (108) reported an incidence of 57%, Court-Brown et al (109) reported 56.2%, and Toivanen et al (110) reported 69%. The pain is situated over the proximal end of the nail and is associated with most normal activities. Court-Brown et al found that 91.8% of patients with knee pain experienced pain on kneeling, 60.5% found pain on squatting, 56.5% experienced pain on running, and even 33.7% were in pain at rest. These surgeons used a pain analogue score and showed that 38.5% of patients had mild pain, 12.4% had moderate pain, and 5.4% had severe pain; the rest of the patients were pain free. Thus, 82.3% of patients had either no pain or only mild pain. The only difference between the groups of patients with and without pain that those with pain were younger and more active. Keating et al noted a high incidence of knee pain with a patellar-tendon splitting approach compared with a parapatellar approach. Court-Brown et al and Toivanen et al, however, could find no association between the approach and the presence of knee pain. All three studies agreed that nail removal resolved or improved the symptoms in most cases.

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There are a number of obvious reasons such as a prominent nail or heterotopic ossification of the patellar tendon. In most cases, however, the origin is more difficult to define. Tornetta et al have suggested that the pain is due to intra-articular damage to the menisci or their associated ligaments. This reason may be true if a solid or unslotted nail is used, as it is usually inserted through the anterior part of the knee joint, but in the three series detailing knee pain, the nails were more flexible slotted nails that were inserted below the knee joint. If it were soft tissue damage, it would be surprising if nail removal resolved the problem, which it unquestionably does in most cases. It has been suggested that the shape of the proximal end of the nail may affect the incidence of pain, but in a study comparing reamed and unreamed nails, virtually the same incidence of knee pain was found with two very different nail shapes. Recently Vais et al have advanced the theory that knee pain is multifactorial in origin but may be related to flexion strength deficiency of the thigh muscles. Proximal tibial discomfort can also be caused by a prominent anteroposterior cross screw head"<sup>17</sup>.

### **Neurologic Abnormalities**

Reports of neurologic damage following intramedullary nailing are very variable with the incidence varying from 2% to 30%. "Court-Brown et al noted a 2% incidence of sural and saphenous nerve damage following distal cross screw insertion but encountered no other neurologic problems. Koval et al, however, reported that 30% of limbs had some degree of neurologic compromise that had not been evident preoperatively. Of the 18 patients that they detailed, 11 demonstrated superficial or deep peroneal paresthesias, three had a complete foot drop, and four demonstrated combined sensory and motor deficits involving both tibial and peroneal nerve distributions. They noted that 16 of the neurologic complications were transient. Williams et al also found a significant number of neurologic complications after intramedullary nailing. They reported that common peroneal nerve lesions were seen preoperatively in 10% of patients, but they found that 80% of these lesions resolved. After surgery, they found that a further 19% of patients had common peroneal nerve lesions, of which 21% failed to resolve. Robinson et al undertook a prospective analysis of patients treated by reamed intramedullary nailing and showed that 5.3% developed peroneal nerve dysfunction with no evidence of a compartment syndrome. They noted that all the patients were young and that the fractures were associated with varus deformation and little soft tissue injury. All patients recovered muscle function in less than 4 months, although some did complain of residual tightness in the extensor hallucis longus or a sensory deficit. It is possible that the apparent neural dysfunction in this series of patients was actually caused by thermal damage to the extensor hallucis longus and not by nerve damage"<sup>17</sup>.

Damage to the common peroneal nerve at the fibular neck can undoubtedly be caused by drill or proximal screw damage. It is interesting to note that a number of recently designed intramedullary nails have two oblique proximal cross screws rather than anteroposterior and lateral cross screws. If the surgeon rotates the nail as it is introduced into the tibia, it is comparatively easy for the anteromedial-posterolateral cross screw to damage the common peroneal nerve. <sup>17</sup>

It is difficult to explain the considerable variation in the incidence of neurologic abnormalities among studies. Possibly, some surgeons detect minor neurological disturbance more readily than others, although a complete foot drop is not easily missed. The incidence of neurologic abnormalities can be minimized by correct adherence to the operative technique, and particular attention must be paid to avoid distraction at the fracture site, as this could certainly produce nerve damage. It is also important to place the patient correctly on a nailing table and to avoid direct pressure over the common peroneal nerve. If a frame or distractor is used to stabilize a fracture prior to nailing, it is important to avoid placing pins near the common peroneal nerve. Distal screw nerve damage should be avoidable by attention to surgical detail. Once the skin is

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incised, care should be taken to protect the soft tissue before drilling and inserting the cross screws.

#### Vascular Damage

The most feared vascular complication of tibial nailing is drill damage to the popliteal artery in the area of the arterial trifurcation . "Avoidance of the complication is achieved by meticulous attention to surgical detail. If an anteroposterior cross screw is used, it is important to pass the drill slowly through the nail and to feel for the posterior tibial cortex, which may well provide little resistance in osteoporotic bone. Damage to the medial inferior genicular artery has also been noted , and there is a report of distal cross screw occlusion of the posterior tibial and peroneal arteries" . It should be emphasized that severe vascular complications of intramedullary nailing are rare and should be avoidable by using correct nailing techniques<sup>17</sup>.

## Hardware Breakage

Nail and screw breakage rates depend on the size of the nail that is used and the type of metal from which it is made. Larger reamed nails have larger cross screws, and the incidence of nail and screw breakage is greater with unreamed nails that utilize smaller screws. "Screw breakage associated with the use of unreamed nails has been quoted as being as high as 52%, with most series experiencing 10% to 20% screw breakage . With reamed nails, the incidence is between 0% and 2.9%. Titanium nails are associated with lower screw breakage rates. Riemer et al quoted a 2% breakage rate for titanium screws and a 25% breakage rate for stainless steel screws used in unreamed nails. Gaebler et al showed that with unreamed nails, the odds of fatigue failure of locking screws were three times higher in Gustilo III fractures compared with closed fractures. Whittle et al have studied the fatigue failure of tibial nails and screws in detail.

Screw breakage is rarely problematic and not infrequently, it serves to reduce a slightly distracted fracture and facilitate union. Removal of broken cross screws is usually straightforward but necessitates an incision on the opposite side of the leg. The two halves have to be removed through separate incisions in a conventional manner or, if the distal end of the cross screw does not protrude sufficiently through the cortex, a trephine can be used to remove the distal fragment. An easy alternative is to retract the nail sufficiently to align the two parts of the screw, remove the proximal piece of the screw, and hammer the distal piece through the distal cortex using a thin metal punch. The distal screw fragment can then be removed from the soft tissues or can be left if it is asymptomatic"<sup>17</sup>. Broken nails tend to be associated with untreated nonunions, and it is wise to treat a suspected nonunion by exchange nailing before the nail breaks. "Few nails break these days, and the highest incidence is 6% . Broken cannulated nails are usually easily removed using a long hook, but solid nail fragments can be difficult to remove and may even require bone fenestration to aid removal".

## **Thermal Necrosis**

Thermal necrosis of the tibial diaphysis following reaming is an unusual, but serious, complication. Its true incidence is unknown, but there are occasional references in the literature. "Danckwardt-Lillestrom stated that intermittent reaming without appreciable pressure should not cause bone damage, and it is likely that applying excessive force causes thermal damage, particularly to blunt reamers. Some force must be applied to the reamer to facilitate its passage down the intramedullary canal, but there are no guidelines as to what degree of force should be applied. Eriksson and Albrektsson showed that temperatures above 47ŰC may be deleterious to bone, and Leunig and Hertel emphasized that a tourniquet should not be used for tibial nailing, as it eliminates heat convective transfer by shutting down the global blood flow to the whole limb. It is obviously important to keep the reamer bits sharp and to take care when reaming. Thermal necrosis has been reported to present with a cutaneous blister soon after surgery, which is followed by soft tissue and bone death and osteomyelitis. It is reasonable to suppose that less severe cases of thermal necrosis exist, and it is probable that a number of cases of tibial osteomyelitis have been caused by thermal necrosis that has not been severe enough to cause skin damage. This would seem to be the logical explanation for the unexplained dropped hallux noted by Robinson et al after reamed tibial nailing. All of their patients recovered muscle function within 4 months. The condition was attributed to peroneal nerve dysfunction but probably represented thermal necrosis of a lesser degree than that recognized by Leunig and Hertel. Giannoudis et al have shown that the generation of heat during reaming is greater with narrow intramedullary canals, and they suggest that excessive reaming should not be used if the canal is narrow. If this is the case, an 8- or 9-mm nail should be used. If thermal necrosis occurs, the treatment is the same as for osteomyelitis"<sup>17</sup>

## **Bone Damage**

Intramedullary nailing can cause perioperative propagation of the fracture. This is rarely a problem, as the use of a statically locked nail stabilizes the fracture. "An incorrect starting point or failure to aim the nail correctly down the intramedullary canal may well result in bone damage, however. It has been estimated that this complication occurs in up to 8% of cases . Georgiadis et al "have drawn attention to the specific problem of the displacement of an occult posterior malleolar fragment during nailing. As about 2.3% of patients with tibial fractures have coexisting ankle fractures, it is obvious that surgeons will encounter posterior malleolar displacement from time to time. Diagnosis is made at the time of screening the ankle to insert the distal cross screw. Treatment is carried out by the use of percutaneously inserted leg screws to stabilize the ankle fracture"<sup>17</sup>

## **MATERIALS AND METHODS**

This is a prospective and retrospective study of 20 patients distal both bone leg fractures– 10 patients treated with interlocking nailing alone and 10 patients treated with interlocking nailing with supplementary fibular plating. The study was done after getting clearance from Hospital ethical committee. Those who fulfilled the inclusion criteria given below, were invited to participate in the study. Informed consent was obtained from all the patients willing to take part in the study. The Study period is from March 2016 to September 2016

## • Inclusion Criteria:

- Lower end of tibia (Lower Metaphysis)
- Acute Fractures
- Closed Fractures
- Grade I and II compound Fractures(Gustilo Anderson Classification)
- Age above 16 yr

## • Exclusion Criteria

- Grade III compound Fractures
- Proximal and Mid shaft Tibial fractures
- Head injuries and Uncontrolled Medical comorbid conditions( Poorly controlled Diabetes Mellitus)

- Vascular Injuries

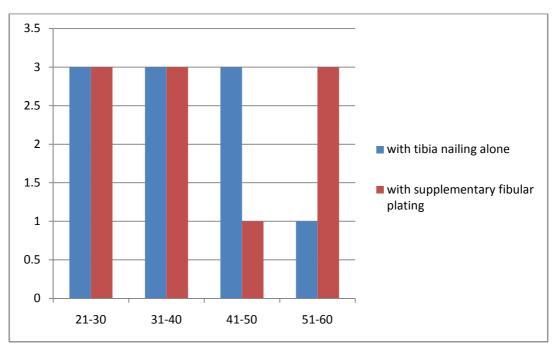
# Methodology:

Among the operatively treated patients in the Institute of Orthopaedics and Traumatology, Madras Medical College and Rajiv Gandhi Government General Hospital from august 2014 to september 2016 we have selected 20 patients

Age interval in years	<b>Tibial Interlocking</b>	With supplementary
	nailing alone	fibular plating
21-30	3	3
31-40	3	3
41-50	3	1
51-60	1	3

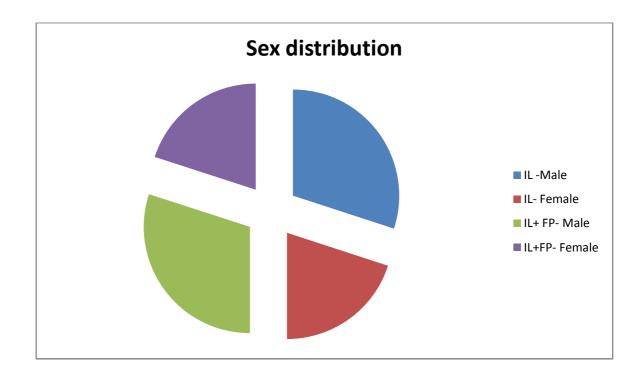
# Age distribution of Patients

## Age distribution:



# Sex Distribution:

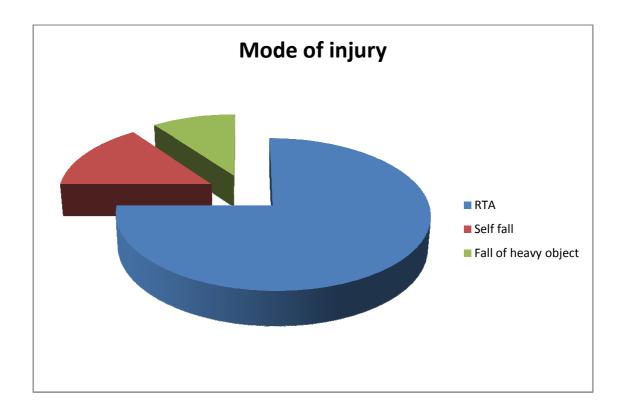
Sex distribution	Male	Female
Patients treated by interlocking nail alone	6	4
Patients treated with tibial		
interlocking nailing with	6	4
supplementary fibular	0	т
plating		



# Mode of Injury:

Road Traffic accident constitutes the injury in 15 cases, self fall from height in 3 cases and fall of heavy objects in 2 cases

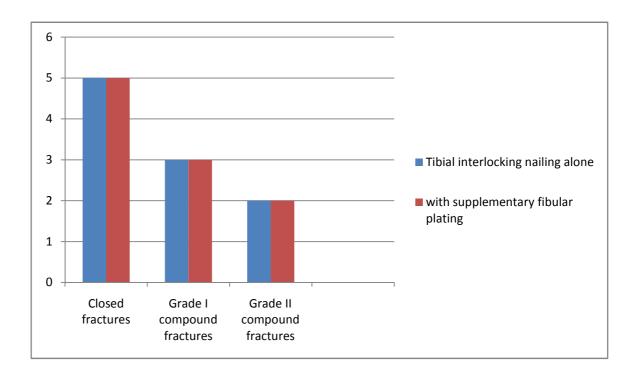
Mode of injury	Tibial Interlocking	With supplementary
	Nailing alone	fibular plating
RTA	7	8
Self fall	2	1
Fall of heavy object	1	1



# **Gustilo Anderson Classification:**

Classification	Tibial Interlocking Nailing alone	With supplementary fibular plating
Closed fractures	5	5
Grade I compound fractures	3	3
Grade II compound fractures	2	2

# **Gustilo Anderson Classification:**



## **AO/OTA classification:**

Classification	Tibial Interlocking Nailing alone	With supplementary fibular plating
43A2	7	7
43A1	3	3

The mean delay between the injury and the surgery was 2 weeks

The mean diameter of the medullary canal at the level of isthmus was 9 mm and at the fracture site was 18 mm.

# **OUTCOME:**

Alignment and reduction preoperatively, postoperatively and at healing was the main outcome measured with an emphasis on loss of initial reduction on follow up.

# **Fibular plating**

Fibular plating was selected for the following reasons,

- 1. correction of alignment before insertion of nail
- 2. Maintaining the alignment or to improve the stability of bone implant complex
- 3. For achieving rotational stability

## **OPERATIVE PROTOCOL**

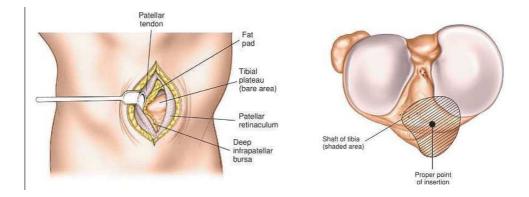
## Pre operative planning

X ray of the injuried leg in AP & Lateral views taken. The fracture tendency for valgus or varus and antecurvatum or recurvatum malalignment was noted. The angle of malalignment was measured.

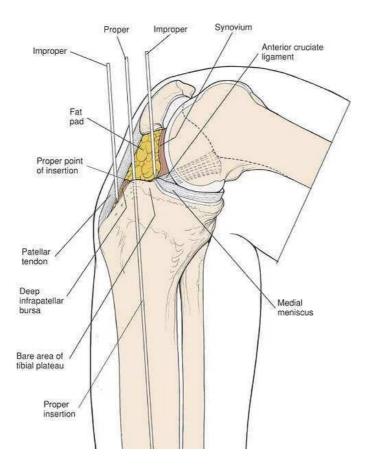
Fracture location from the distal articular surface was measured. The length of fracture was also measured. The diameters of medullary canal at isthumus and at the level of fracture were measured. Approximate length of the nail was measured in the contralateral leg, from the tibial tuberosity to medial malleolus.

#### **Operative Protocol:**

The nails used were cannulated stainless steel nail, with 2 proximal (mediolateral) and 3 distal (2 mediolateral and 1 anteroposterior) locking options, of diameter 8, 9 or 10 mm.



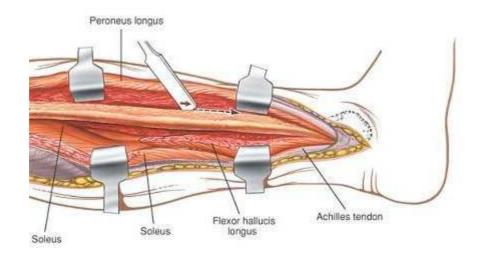
Then through a patellar tendon splitting approach, entry point was made in the midline, progressive reaming done and guide wire was passed under image intensifier control, reduction verified, if not satisfactory fracture site opened tibia reduced and intramedullary nail introduced and locked with one or two proximal screws and two or three distal screws.



Closed reduction was done in fourteen cases. In the remaining cases, closed reduction was attempted and we had to do open reduction as there was a marked overriding of the fragments and difficulty in aligning tibia and achieving reduction or delay of 6 weeks before surgery.

The alignment was confirmed in both coronal and sagittal plane with image intensifier.

For cases done with supplementary fibular plating, through a posterolateral incision, skin, subcutaneous tissue and fascia incised. Fibular fracture site exposed, freshened and reduced.



The peroneal muscles are retracted anteriorly. The interosseous membrane is stripped from the anterior border of the fibula ina proximal to distal direction. The muscles are stripped from the anterior asurface of fibula.

After achieving the proper alignment and reduction, fibular plating done with appropriate one third tubular plate(usually a six or seven holed plate) and cortical and cancellous screws of different sizes.once proper length and rotation of fibula is achieved, in fresh cases the tibia aligns itself and malalignment in both sagittal and coronal planes could be avoided.In those delayed cases where alignment of fibula does not result in alignment of tibia, open reduction and internal fixation with intramedullary nail is done. Tourniquet was not used in any cases, All cases were done under spinal anesthesia

Intra operative pictures:

**Fibular Plating:** 



Intra operative pictures for tibia Interlocking Nailing

**Draping:** 

Patellar tendon Splitting approach





# Awl Insertion:

# Reaming





# **Insertion of Nail:**





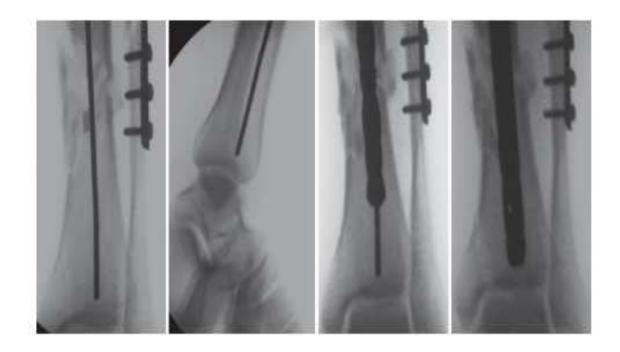
**Applying Locking bolts:** 







## **C- Arm Pictures**



## **Post operative treatment**

Non weight bearing for 6 weeks. After development of callus formation partial weight bearing is started which is continued till complete union. Then full weight bearing is allowed after clinical and radiologic union is seen. In one case the distal screw purchase in fibula is poor as it is so osteoporotic, we recommended non weight bearing till radiological evidence of union. In that cases cast support was given for 4 weeks.

## **Follow up**

All the fractures were followed through till union of fracture with clinical and radiological examination at intervals of 4 to 6 weeks. The maximum follow up was 12 months.

On follow up axial alignment was assessed and functional analysis was quantified using Kalstrom – Olerud score.

Radiographs were analyzed for correction, maintenance of position or loss of reduction.

Fracture was defined as united when patient was able to bear full weight on the injured limb without pain and without support and when radiographs showed bridging callus in at least 3 cortices.

## **Complications of fibular plating**

Complications were divided into those which were related to fibular plate and those which were not.

Complications related to fibular plate are the soft tissue problems in open reduction and fibular plating such as development of superficial wound resulting in skin necrosis ( as a result of extra hardware), which might increase the risk of infection by six fold.

Complications not related to fibular plating per se may be compartment syndrome, breakage of locking screws and tendon or neurovascular injury

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## **DATA ANALYSIS**

Data analysis was done using repeated measures ANOVA T- test.

Repeated measures designs are popular because they allow a subject to serve as their own control. This improves the precision of the experiment by reducing the size of the error variance on many of the Ftests.

Within-subject designs are those in which multiple measurements are made on the same individual at different point of times. Here the variable in our study were the angle at the fracture site measured within the subjects at different point of times.

Kalstrom-Olerud score was used to asses the functional outcome. It is an independent measurement, not influenced by other co-morbid conditions and associated injuries<sup>11</sup>.

## Parameters of Karlstrom- Olerud scoring system were

- 1. Residual angulation (0 to 3 points)
- 0 -- 0 point
- 1 to 3 -- 1 point
- 4 to 5 -- 2 points

>5 -- 3 points

2. Fracture Healing (0 to 3 points)

Union < 12 weeks -- 0 point

Delayed union > 12 weeks -- 1 point

Delayed union requiring secondary procedures -- 2 points

Non union > 6 months -- 3 points

3. Cast Support (0 to1 points)

No cast support -- 0 point

Cast support -- 1 point

# Outcome

0 & 1 points Excellent

- 2 & 3 points Good
- 4 points Satisfactory

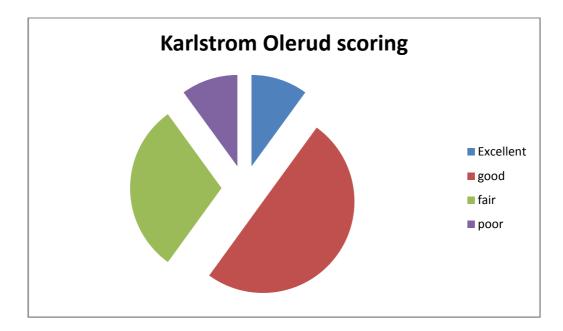
5 points Fair

6 & 7 points Poor

## RESULTS

All the relevant data were analysed.

The Fractures treated with tibial interlocking nailing without fibular plating were analysed and 5(50%) cases were malunited and deformed. Karlstrom- Olerud scoring was excellent in one(10%) patient, good in 5 patients(50%), fair in 3 (30%) patients and poor in 1 (10%) patients



The mean delay in surgery for this group is 2.2 weeks

Radiologically the mean post operative varus/valgus alignment was

8.6 degrees . The mean duration of time of union is 12.70 weeks.

4 patients needed cast support. The average follow up is 8 months(

lowest - 4 months , longest - 18 months)

All the fractures treated with supplementary fibular plating in addition to tibial interlocking nailing eventullay united in a mean period of 11.60 weeks

Karlstrom-Olerud score was excellent in 6 fractures (60%), good in 3 patients (30%) and fair in 1 patient (10%) **Karlstrom Olerud scoring-with** supplementary fibular plating Excellent good 🔳 fair poor

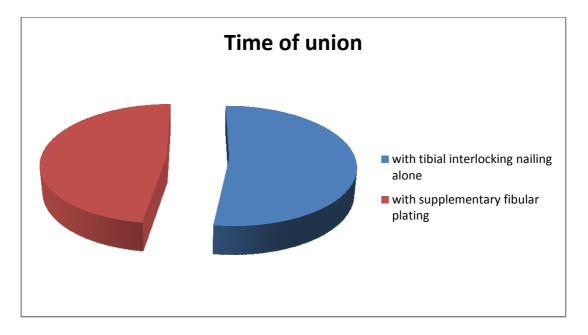
The mean delay between the injury and the surgery was 1.8 weeks Radiologically the mean post operative varus/valgus alignment was 2.10 degrees.

The alignment was maintained till union with the mean remaining the same in the coronal plane. The average follow up is 10.3months(lowest- 6 months, longest – 24 months) The p- value for varus/ valgus angulation with equal variances assumed is 0.0016 and with equal variances not assumed is 0.0064. Thus it is statistically significant that the p- value is < 0.05

The p- value for time of union is 0.3425( p value >0.05), so it is statistically insignificant

## DISCUSSION

In our study the mean time of union for patients treated with tibial interlocking nailing alone is 12.70 weeks, whereas the mean time of union for patients treated with tibial interlocking nailing with supplementary fibular plating is 11.6 weeks



The mean varus / valgus angulation for patients treated with tibial interlocking nailing alone is 8.6 degrees whereas the mean varus / valgus

angulation for patients treated with tibial interlocking with supplementary fibular plating is 2.1 degrees.

Fracture union was rather difficult to define and measure. "Sarmiento et al in 1984 specified criteria for the judgment of union.

- 1. The ability of the patient to bear weight without pain.
- 2. Absence of clinically detectable movements across the fracture site.
- 3. Visible bridging callus across the fracture on plain radiograph".

"Panjabi et al in 1985 proved that cortical continuity was the best predictor of mechanical strength and the author suggested that measurement of number of cortices bridged was the most reliable measure to assess fracture healing".

In the current series, the union was defined based on the ability to bear weight in the affected leg without pain and when the radiograph shows us bridging callus in at least three of the four cortices

We cannot over emphasize the potential advantages of intramedullary nailing than any other form of fixation like external fixator or plating in tibial factures. But the problems in extending the indication to metaphyseal fractures have to be analysed and resolved.

The management of tibia fractures has evolved significantly over the last 10 to 15 years . Intramedullary nailing has become the standard of care for most of these injuries, especially in cases with significant soft tissue damages. The lack of interference fit of Intramedullary nails in the distal tibial metaphysis has prompted some surgeons to add fibular plating in the hopes of improving fracture stability.

In this study where the fibular fixation with plate is done for distal both bone fractures it has shown significant difference in varus / valgus angulation when compared to patients without fibular fixation it is comparable with a recent retrospective study by Egol and colleagues that suggests a higher failure rate in patients whose fibulas were not plated<sup>1</sup>. "These patients present a range of fixation configurations ranging from 1 to 3 distal locking screws. The proximal fixation in these cases is not mentioned. The authors note that the number of distal locking bolts had an effect on the rate of malalignment. Although triple locking distally has become the standard at our institution for this fracture type, other centres commonly use 1 or 2 distal locking screws".

It is possible that fibular plating becomes more important when fewer points of fixation are used in the tibia. "In a similar biomechanical evaluation of distal tibia fractures, Kumar and colleagues found some beneficial effect of plating the fibula when a nail is used to stabilize the tibia"<sup>38</sup>.

In our study for the patients treated with tibial interlocking nailing we encountered 50 % malunion which was comparable with study conducted by Lesch GJ et  $al^{29}$  in his review of 38 cases for distal both bone leg fractures where he encountered 79% of malunion i.e. angulations of 5 degrees or more in frontal or sagittal plane and required secondary procedures to achieve in 38 % of cases and in another study Jen Nork et al<sup>31</sup>, "in their review stated that previously reported rates of unacceptable alignment after medullary nailing of distal third both bone fractures have ranged from 54% to 86%". Hence alternate forms of fixation like supplementary fibular plate or external fixation is suggested.

Chen AL "compared the intrinsic stability in tibial intramedullary nail construct in distal third disphyseal fractures without isthmal support, between two mediolateral distal locking screws and two perpendicular (one medio lateral & one antero posterior) distal locking screws. He concluded that fixation stability of intramedullary nail is not significantly influenced by distal locking screw orientation in response to sagittal, coronal or rotational forces"<sup>30</sup>.

In contrary, Smucker et al "found two parallel locking bolts being a better construct than perpendicular locking bolts in their study".

To overcome these issues various techniques have been developed like slight medial entry point as suggested by Buehler et al and Lembcke O et al and modifications in nail designs including different proximal bends and more oblique screws.

In distal third fractures "fibular plating and cutting the distal few millimeters of nail distal to the distal screws hole to allow two cross locking screws in the distal fragment, one cross screw across fractures site as lag screw and use of large reduction forceps and temporary unicortical plating, percutaneous manipulation with Shanz pins, femoral distractor have been the supplementary procedures used to achieve the alignment"<sup>9</sup>.

According to Egol et al "The authors concluded that fibula fracture stabilization offers protection against loss of fracture reduction when distal metaphyseal tibia-fibula fractures with intramedullary fixation are being managed"<sup>1</sup>.

Our data support these clinical findings, suggesting that Intramedullary nail fixation of a comminuted unstable distal tibia-fibula fracture without fibular stabilization may be unable to maintain fracture reduction under physiologic loading.

The amount of malalignment and shortening considered acceptable is controversial. Tarr et al and Puno et al demonstrated that distal tibial malalignment may be more poorly tolerated than more proximal malalignment<sup>9</sup>. Trafton's recommendation is generally agreed by many authors.

According to our study the acceptable malalignment is less than 5 degrees of varus- valgus angulation, 10 degrees of anteroposterior angulation, and 10 degrees of rotation and 15mm of shortening.

64

In this study we encountered malalignment in five cases of distal third fractures(50%) treated with interlocking nailing for tibia alone, whereas malalignment was encountered in only one case(10%) of distal tibia fractures treated with interlocking nailing for tibia with fibular plating.

We found that interlocking nailing when supplemented with fibular plating did influence the stability or the functional outcome.

When compared to other techniques described for preventing metaphyseal malalignment during nailing in distal both bone fractures of leg, fibular plating is not technically demanding, do not require any special instrumentation and do not need any special design modification in the nail.

There is no significant increase in radiation exposure for applying fibular plating.

In our series the mean ratio of fracture segment to the tibial length was only 16% which denotes that even such short fracture segments can be safely and effectively managed by intramedullary nailing when supplemented with fibular plating in distal both bone fractures of leg.

We had excellent to satisfactory outcome in 85% by Kalstrom-Olerud for patients treated with supplementary fibular plating scoring which is comparable to the results of studies conducted by Tyllianikis el  $al^7$  with 86% excellent to satisfactory.

### **Effect of malunion**

Importance of achieving anatomical reduction in fractures of tibia cannot be over emphasized.

We have analysed the mismatch between the diameters of medullary canal at the level of isthmus (i.e. maximum possible nail size ) and at the fracture site in all cases which was comparable to a study conducted by "Van der Schoot et al who reported a 15 year follow up of 88 patients with fractures of lower leg<sup>8</sup>. 49% had healed with malalignment of at least 5 degrees. More arthritis was found in the knee and ankle adjacent to fracture than in comparable joints of the uninjured leg"<sup>8</sup>.

There is a possibility of more degenerative changes in the ankle as the malaligned fractures recorded by Puno RM et al "long term effects of tibial angular malunion of knee and ankle joints in his 28 tibial fractures with an average follow-up of 8.2 years. His analysis showed that greater degrees of ankle malalignment produce poorer clinical results"<sup>9</sup>.

"Kyro A in his series of 64 tibial shaft fractures concluded that malunion of tibial shaft fractures seem to be especially harmful in distal fractures, in fractures with marked previous displacement, in fractures caused by high energy injury and among patients less than 45 years of age"<sup>10</sup>.

We found that there was a significant mismatch between them. The diameter of medullary canal at the level of isthmus was 9 mm compared to 18 mm at the level of fracture site. The mismatch explained the cause of instability in metaphyseal fractures when treated with intramedullary nailing.

The primary aim of the study was to analyze the effectiveness of achieving and maintaining the coronal plane alignment and its aid in reduction in distal both bone fractures of leg treated with intramedullary nailing with and without using supplementary fibular plating .

As described in various literatures the malalignment in these circumstances were significantly high when done without any supplementary procedures.

"James Kellam in his commentary and perspective on the effect of fibular plate fixation on stability of simulated distal tibial fractures treated with intramedullary nailing by Anand Kumar et al concluded that meticulous intramedullary techniques combined with use of fibular plate fixation or blocking screws will achieve the best results in maintaining the reduction of distal tibial fractures till union"<sup>2</sup>.

"A.Bedi,T.T.Lee and M.A Karunakar in their studies proved that in patients with ipsillateral distal tibial and fibular fractures who are treated with Russel and Taylor intramedullary nailing of tibia,rotational

stability of the tibial fracture can be increased by plate and screw fixation of the fibula, which may reduce the risk of varus/valgus malunion"<sup>8</sup>.

Fibular plating improved the stability of the metaphyseal fractures after nailing and promoted union in our study.

The ratio of short metaphyseal fragment to the total tibial length was analysed. The total length of the tibia was approximately derived from the length of the nail used.

The mean ratio was found to be 16%.

Even such short metaphyseal fragments had been effectively stabilized till union with intramedullary nailing when supplemented with fibular plating.

"The proportion of fractures that lost alignment were minimal among those receiving stabilization of the fibula in conjunction with intramedullary nailing in many studies as compared with those receiving intramedullary nailing alone as comparable to the study conducted by Paige Whittle A et al in their analysis of 40 patients treated with locked intramedullary nailing and concluded that that 60 percent of fractures without supplementary fibular plating".

The reduction should be ensured in two planes with image intensification after placing the fibular plate and before applying the tibial locking screws.

#### CONCLUSION

We conclude that fibular plating, when supplemented the intramedullary nailing of distal both bone fractures of leg,

- Were effective in achieving the fracture alignment especially in fresh fractures.
- 2. Improves not only angular stability but also rotational stability.
- 3. Maintained the fracture alignment till union, preventing loss of initial reduction.

The analysis of this group of patients confirmed the hypothesis postulated by emphasizing the importance of the fibular fracture within a single biomechanical and pathological entity of distal fractures of the tibia. In particular, it confirms the value of double surgical fixation, as a complement to stability but also as assistance to reduction when nailing is indicated.

In closed nailing procedures, reduction of both tibial and fibular lesions is even more difficult to obtain if treating a torsion injury resulting in a fracture with a rotational component, ensuring fibular osteosynthesis first anatomically reduces any horizontal displacement. These strategies now remain to be validated in a prospective study. In our comparative study we have found statistically significant varus/ valgus angulation difference, the time of union difference is not statistically significant.

However a long term follow up and a larger sample study is needed to further validate our findings

## **CASE ILLUSTRATIONS**

## CASE - 1

Mrs Banu

Age- 35 y/F

Mode of injury- Road Traffic Accident

Interval between injury and surgery- 3 weeks

Diagnosis- Grade I compound Both bone Fractures Right Leg

AO Classification- 43A2

Associated injuries- Nil

Procedure Done- Closed Tibial Interlocking Nailing and ORIF

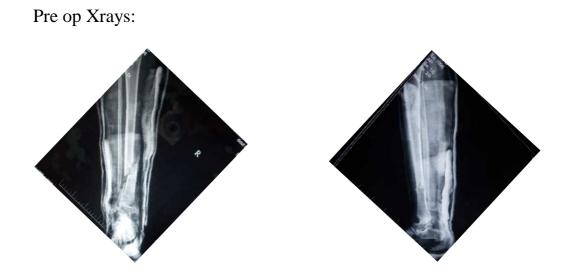
with  $1/3^{rd}$  tubular plating for fibula

Time of union: 11 weeks

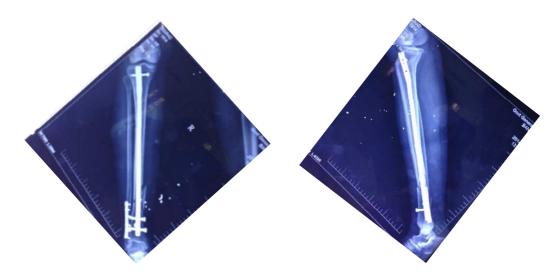
Kalstrom Olerud Scoring- 0 (Excellent)

Range of Motion - Knee Flexion: 130 degrees,

Ankle- Normal range of movements



Post Op Xrays



## Follow up (11 weeks)





## **Clinical Pictures:**





## **CASE - 2**

Name : Mr. Jayachandran

Age- 27 y/ m

Mode of injury - Road Traffic Accident

Interval between injury and surgery- 8 days

Diagnosis- Closed fracture both bone left leg

AO classification- 43A2

Associated injuries- Nil

Procedure done – closed tibial interlocking nailing and 1/3rd

tubular plating for fibula

Time of union-11 weeks

Kalstrom Olerud scoring- 0 (Excellent)

Range of motion – Normal

Pre op xrays:





follow up(11 weeks)



Follow up:



## CASES with Tibial Interlocking Nailing alone:

## CASE - 3

Name: Ramu

Age-50/M

Mode of injury- Road Traffic Accident

Interval between injury and surgery- 3 weeks

Associated injuries - Nil

Diagnosis: Grade I compound distal both bone leg fracture left.

AO classification- 43A2

Procedure Done: Closed interlocking intramedullary nailing with locking with 3 screws (anteroposterior, oblique and transverse) was done.

Time of union : 18 weeks

Cast support- yes

Kalstrom Olerud Scoring : 6 (poor)

## Pre-operative x-ray AP and lateral



## Immediate post operative x-rays





## **Radiological assessment at 6 months post -operatively**



20 degree varus angulation



6 degrees Anterior angulation

There is a 20 degree varus angulation and a 6 degree anterior angulation at the end of union of distal tibia. There was no rotational malalignment

**Clinical Pictures** 





## CASE - 4

Name: Saravanan

Age-35/M

Mode of injury- Fall of heavy object

Associated injuries – Nil

Interval between injury and surgery- 2 weeks

Diagnosis: Grade II compound distal both bone fracture left.

AO classification- 43A1

Procedure Done: Closed interlocking intramedullary nailing with locking with 3 screws (anteroposterior, two lateral screws) was done.

Time of union:12 weeks

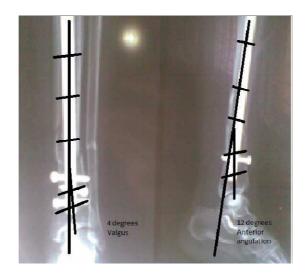
Cast support: yes Kalstrom Olerud Scoring: 5 (fair)

Pre op Xrays:





## **Post op Xrays**



There is a 12 degree anterior angulation as seen in the lateral film and a 4 degree valgus angulation in the AP film. There was no rotational malalignment.

## **Clinical pictures:**





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MASTER CHART

Patients Treated with Tibial Interlocking Nailing alone

	Kalstrom Olerud Scoring 2 (good) 1 (Excellent) 3(good) 5 (fair)		3 ( good)	5 (fair)	6 (poor)	5 (fair)	3(good)	3 (good)			
	Time of follow up (months)	8	5	16	9	18	5	6	4	8	4
	Cast support	No	No	No	Yes	No	Yes	Yes	Yes	No	No
	Time of union	10 weeks	11 weeks	14 weeks	18 weeks	10 weeks	12 weeks	18 weeks	12 weeks	11 weeks	11 weeks
ıtive	Anterop osterior Angulati on	5deg	3 deg	8 deg	7 deg	4 deg	10 deg	6 deg	12 deg	8 deg	8 deg
Postoperative	Varus/ Valgus Angulation	8 deg Valgus	3 deg valgus	5 deg valgus	10 deg Valgus	7 deg varus	15 deg varus	20 deg varus	4 deg valgus	4 deg valgus	10 deg varus
	AO Classifica tion	43A2	43A1	43A2	43A2	43A1	43A2	43A2	43A1	43A2	43A2
	Diagnosis	Grade I compound both bone Right leg	Closed fracture both bone left leg	Closed Fracture both bone left leg	Grade II compound both bone fracture both bone Right Leg	Grade I compound fracture both bone Right Leg	Closed fracture both bone left leg	Grade I compound distal both bone leg fracture left	Grade II compound fracture both bone	Closed fracture both bone Right leg	Closed Fracture both bone Right Leg
4	Delay between injury and surgery	2 weeks	2 weeks	3 weeks	1 week	3 weeks	2 weeks	3 weeks	2 weeks	1 week	3 weeks
	Mode of Injury	RTA	RTA	RTA	Self fall	RTA	Self fall	RTA	Fall of heavy object	RTA	RTA
	IP NO	46014	14675	13850	5030	1576	62043	18869	6906	61730	63197
	Age/ Sex 23y/m 33y/F 30y/F 30y/M		31y/M	60y/F	50 y/F	35y/M	35y/m	43y/M			
	Name	Manikandan	Rajalakshmi	Rosy	Raja	Chandra	Pattammal	Ramu	Saravanan	Velu	Ramasamy
	SI.No 1		5	3	4	S.	9	L	8	6	10

	Kalstrom Olerud Scoring	0 (Excellent)	0 (Excellent)	2 ( good)	1 (Excellent)	2 (good)	1 (Excellent)	1 (Excellent)	6 (fair)	2 ( Good)	1 (Excellent)
Time of	follow up (months	24	12	×	9	μ	8	9	L	14	10
	Cast support	No	No	No	No	No	No	No	Yes	No	No
Ē	l ime of Unio n	11 week s	11 week s	13 week s	13 week s	10 week s	10 week s	10 week s	16 week s	11 week s	11 week s
erative	Anteropos terior Angulatio n	1 deg	1 deg	2 deg	3 deg	5 deg	2 deg	2 deg	6 deg	4 deg	2 deg
Postoperative	Varus/ Valgus Angulatio n	1 deg varus	1 deg valgus	3 deg valgus	1 deg valgus	2 deg varus	2 deg valgus	2 deg varus	5 deg varus	2 deg varus	2 deg varus
	AO Classific ation	43A2	43A1	43A2	43A1	43A2	43A2	43A2	43A2	43A1	43A2
	Diagnosis	Grade I compound fracture distal both bone Right leg	Grade I compound distal both bone right leg	Closed fracture both bone right leg	Closed fracture both bone left leg	Grade II compound fracture distal both bone left leg	Closed fracture distal both bone left leg	Closed Fracture both bones right leg	Grade II compound Fracture both bone Right leg	Grade I compound Fracture both bone Right leg	Closed fracture both bone left leg
- L	Delay between injury and surgery	3 week	3 weeks	1 week	1 week	2 week	2 week	2 weeks	1 week	2 week	1 week
	Mode of Injury	RTA	Self fall	RTA	RTA	Fall of heavy object	RTA	RTA	RTA	RTA	RTA
	IP No	29409	60894	32000	27359	14424	75775	57876	72977	74043	79262
	Age/Se x	35y/F	58y/M	29y/M	29y/F	55y/F	34Y/M	55y/M	25y/M	33y/F	27/M
	Name	Banu	Ramalingam	Devaraj	Sasikumar	Desammal	Saibharath	Subramani	Thanveer Ahmed	Kaliammal	Jayachandran
	S.No	1	2	ŝ	4	5	9	L	8	6	10

Patients Treated with Tibial Interlocking Nailing and supplementary fibular plating

## PROFORMA

SI.No:

Patient name :

Age / Sex : IP.No :

Occupation :

Address :

Phone no :

Date of injury :

Mode of injury :

Right/Left

Fracture classification

AO :

Simple / compound ( Grade )

Level of fibula fracture :

Associated injuries :

Interval between injury& surgery :

Weight bearing started on :

Post op Varus/ Valgus angulation

Cast support :

Side :

Time for union :

Complication :

Secondary procedures :

Final outcome :

Karlstrom – Olerud Score ( 0-7 points ) :

Residual angulation (0-3):

Fracture healing (0 - 3):

Cast support (0-1):

#### INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013 Telephone No.044 25305301 Fax: 011 25363970

#### **CERTIFICATE OF APPROVAL**

To

Dr.Satheesh Kumar.R. Post Graduate in M.S. (Orthopaedics) Inst. of Orthopaedics & Traumatology Madras Medical College Chennai 600 003

Dear Dr.Satheesh Kumar.R.,

The Institutional Ethics Committee has considered your request and approved your study titled "PROSPECTIVE AND RETROSPECTIVE ANALYSIS OF FUNCTIONAL OUTCOME OF DISTAL BOTH BONE FRACTURE LEG TREATED WITH TIBIAL INTERLOCKING NAILING OR PLATE OSTEOSYNTHESIS WITH AND WITHOUT FIBULAR PLATING "- NO. (II) 36032016.

The following members of Ethics Committee were present in the meeting hold on 22.03.2016 conducted at Madras Medical College, Chennai 3

1.Dr.C.Rajendran, MD., :Chairperson 2.Dr.R.Vimala, MD., Dean, MMC, Ch-3 3. Prof. Sudha Seshayyan, MD., Vice Principal, MMC, Ch-3 4.Prof.P.Raghumani, MS, Dept.of Surgery, RGGGH, Ch-3 5.Dr.Baby Vasumathi, Director, Inst. of O&G,Ch-8 6.Prof.M.Saraswathi, MD., Director, Inst. of Path, MMC, Ch-3: Member 7.Prof.Srinivasagalu,Director,Inst.of Int.Med.,MMC,Ch-3 : Member 8.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3 9.Thiru S.Govindasamy, BA., BL, High Court, Chennai 10.Tmt.Arnold Saulina, MA., MSW.,

:Deputy Chairperson : Member Secretary : Member : Member : Lay Person : Lawyer :Social Scientist

We approve the proposal to be conducted in its presented form.

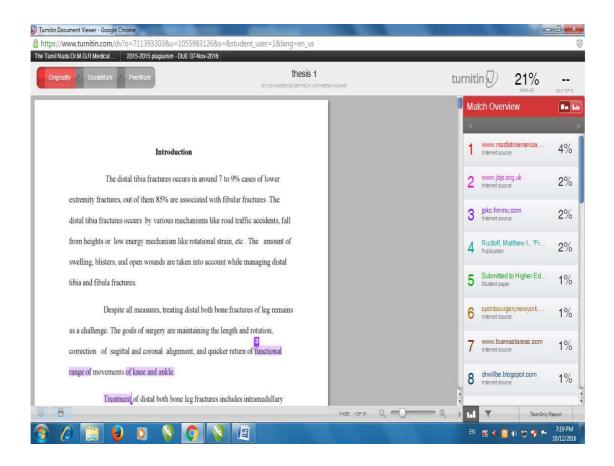
The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.



Member Secretary – Ethics Committee MEMBER SECRETARY INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE CHENNAI-600 003

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#### Introduction

The distal tibia fractures occurs in around 7 to 9% cases of lower extremity fractures, out of them 85% are associated with fibular fractures. The distal tibia fractures occurs by various mechanisms like road traffic accidents, fall from heights or low energy mechanism like rotational strain, etc. The amount of swelling, bisters, and open wounds are taken into account while managing distal tibia and fibula fractures.

Despite all measures, treating distal both bone fractures of leg remains as a challenge. The goals of surgery are maintaining the length and rotation, eorrection of sagittal and eoronal alignment, and quicker return of functional range of movements of kace and ankle.

Treatment of distal both bone leg fractures includes intramedullary nailing , hybrid external fixation, plate fixation or combining any of these modalities.

Interlocking nailing of tibial fractures is advantageous as this technique allow load sharing, does not distarb extraosseous blood supply, and soft tissues are less damaged and have a relatively easy learning curve.

Intramedullary nailing of distal tibial fractures with short distal

fragment is associated with malalignment problem particularly in coronal plane,

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### PATIENT CONSENT FORM

Study Detail	:	"Prospective and Retrospective analysis of Functional Outcome of Distal Both bone Fracture Leg treated with Tibial Interlocking Nailing with and without Fibular plating"- Comparative study
Study Centre	:	Rajiv Gandhi Government General Hospital, Chennai.
Patient's Name	:	
Patient's Age	:	
Identification Number	:	

Patient may check ( $\sqrt{}$ ) these boxes

- a) I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction.
- b) I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected.
- c) I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

d) I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

- e) I hereby consent to participate in this study.
- f) I hereby give permission to undergo detailed clinical examination, Radiographs & blood investigations as required.
  Signature/thumb impression

Patient's Name and Address:

Signature of Investigator

Investigator's Name:

(Dr. Satheesh Kumar R)

#### <u> ஆராய்ச்சி ஒப்புதல் கடிதம்</u>

#### ஆராய்ச்சி தலைப்பு

காலில் ஏற்படக்கூடிய இரண்டு எலும்பு (Tibia & Fibula) முறிவு குறித்த ஆராய்ச்சி

ராஜீவ் காந்தி அரசு பொது மருத்துவமனைக்கு வரும் நோயாளிகளிடம் காலில் ஏற்படக்கூடிய இரண்டு எலும்பு (Tibia & Fibula) முறிவு குறித்த ஆராய்ச்சி

நடைபெறுகிறது.

பெயர்	:	தேதி	:
வயது	:	உள் நோயாளி எண்	:
பால்	:	ஆராய்ச்சி சேர்க்கை எண்	

இந்த ஆராய்ச்சியின் விவரங்களும் அதன் நோக்கங்களும் முழுமையாக எனக்கு தெளிவாக விளக்கப்பட்டது.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்துகொண்டு எனது சம்மதத்தை தெரிவிக்கீறேன்.

இந்த ஆராய்ச்சியில் பிறரின் நீர்பந்தமின்றி என் சொந்த விருப்பத்தின்பேரில் பங்கு பெறுகின்றேன். இந்த ஆராய்ச்சியில் இருந்து நான் எந்நேரமும் பின்வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்துகொண்டேன்.

நான் இந்த ஆராய்ச்சியின் விபரங்களைக் கொண்ட ஆராய்ச்சித் தகவல் தாளைப் பெற்றுக் கொண்டேன்.

இதன் மூலம் எந்த பின்விளைவும் ஏற்படாது என்று மருத்துவர் மூலம் தெரிந்து கொண்டு, நான் என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்தீரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள சம்மதம் தெரிவிக்கீறேன்.

கையொப்பம்

#### <u>குராய்ச்சி தகவல் தாள்</u>

ராஜீவ் காந்தி அரசு பொது மருத்துவமனைக்கு வரும் நோயாளிகளிடம் காலில் ஏற்படக்கூடிய இரண்டு எலும்பு (Tibia & Fibula) முறிவு குறித்த ஆராய்ச்சி நடைபெறுகிறது.

முடிவுகளை அல்லது கருத்துகளை வெளியிடும்போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிட மாட்டோம் என்பதையும் தெரிவித்துக் கொள்கீறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த சிறப்பு சிகிச்சையின் முடிவுகளை ஆராய்ச்சியின்போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிக்கப்படும் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம்

பங்கேற்பாளர் கையொப்பம்

நாள் : இடம் :