FUNCTIONAL OUTCOME OF METAPHYSEAL AND DIAPHYSEAL FRACTURES OF TIBIA TREATED WITH EXPERT TIBIAL INTERLOCKING NAIL- A PROSPECTIVE STUDY

By

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LIST OF ABBREVIATION

AO	Arbeitsgemeinschaft für Osteosynthesfragen
AP	Anteroposterior
ARDS	Adult Respiratory distress syndrome
ASIF	Association for study of internal fixation
BP	Blood Pressure
D	Distal
ETN	Expert Tibia Nail
GA	Gustilo Anderson
HS	HoraSomni
IM	Intramuscular
IV	Intravenous
NBM	Nil by mouth
P	Proximal
PG	Prostaglandin
PTN	Proximal Tibia Nail
TRP	Temperature, Pulse, Respiratory rate
Tx	Thromboxane
Dcp	Dynamic compression plate

ABSTRACT

Background and objectives:

Tibia is the most commonly fractured bone due to road traffic accidents, and other high-energy trauma and usually associated with severe soft-tissue injury. Surgical management is required for most of these fractures, with either internal or external fixation. Even though wide variety of treatment options are present for treating these fractures is still a challenge because of its wide associated complications like infection at the operated site , delayed union or non-union.

Locked intramedullary nailing has been widely accepted as a satisfactory treatment of tibial fracture. However, in patients with tibial fractures, there is a risk that the fracture will propagate into the knee / ankle or that the nail will fail because of inadequate fixation of the small distal fragment. The indications of their use have been extended to fracture closer to proximal / distal fragments with introduction of expert tibial nail. It is a new kind of low, multidirectional lock tibial intramedullary nail .Its interlocking system was developed to attain increased angular stability and to enhance the axial and lateral stability of fracture fragments.

In this study we would like to find out the functional outcome and complications associated with expert tibial nailing.

Methods:

Thirty patients with fresh tibial metaphyseal/diaphyseal fractures are treated surgically with expert tibial nail between October 2016- March 2018

Results:

Among 30 patients treated with expert tibia nail for metaphyseal/diaphyseal tibial fractures the average time taken for union was 21.8 weeks, Closed fractures and type 1 fractures united earlier (average time 18.66 weeks and 21.75 weeks respectively) compared to type 2 open fractures (average of 25 weeks)

The incidence of closed fractures is 60% and those with open fractures were 40% (Gustilo Anderson type 1 and 2), Gustilo Anderson type 3 were excluded from the study. Complications arising from expert tibia nailing in our study is malunion in one patient (3.33%), superficial wound infection in four cases (13.33%), anterior knee pain in ten patients (30%), shortening in two patients (6.67%), delayed union in 3 patients(10%) and two patients had ankle pain (6.67 %). Functional results were graded according to the criteria by **Johner and Wruh's Criteria**[79]. 43.33 % of patients achieved excellent results, 33.33 % of patients achieved good results, 16.67 % fair results were obtained and in two patient, the functional results were poor(6.67%).

Conclusion

Our results with expert tibial interlocking nailing are encouraging and demonstrate the benefits of new nailing system. Changes in the design of the nail for improved proximal and distal locking enables it to use metaphyseal/diaphyseal fractures of tibia. Locking options in different planes, provide a better stabilization of small proximal and distal fragments and achieve a higher stability of the bone implant construct. Good functional results and union rates were achieved with cautious preoperative planning and considering the principles of intramedullary interlocking nailing technique. Hence we suggest the use of expert tibial nail in metaphyseal /diaphyseal fractures of the tibia.

Key words:

Expert nail; Metaphyseal; Diaphyseal; intramedullary interlocking nailing.

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INTRODUCTION

Tibia is frequently fractured long bone in the body with an annual incidence of tibial shaft fractures is 26 per 1, 00,000 individuals[1].Because of its location, the tibia is exposed to widespread injury; it is the most frequently fractured long bone. Because one third of the tibial surface is subcutaneous all through its length, open fractures are more frequent in the tibia than in any other major long bones[2]. They are roughly three times more common in males than in females and average age of patients is about 37 years. In adolescent age group, tibia is frequently fractured bone among males and are usually documented to high energy trauma such as motor vehicle accidents. Their incidence increase again later in life with the development of osteopenia and osteoporosis[1]. High-energy trauma are usually caused by motor vehicle accidents, fall from height, direct blows and gunshots. Low-energy trauma are typically caused by sporting injuries, fall from standing height and twisting injuries. They may also be related with pathological conditions of bone[3.]

Closed reduction and cast immobilization is the standard treatment for low-energy tibial shaft fractures[4-6].

In recent decades, usage of intramedullary locking nails has become very popular, and many studies have shown that patient having tibial shaft fracture treated with IMLN had better functional outcome than those treated with cast immobilization.

The conventional method of closed reduction and cast application of tibial fractures results in delayed union, malunion and restricted range of motion at the ankle and knee joint. These were the common complications when tibial fractures were treated with a cast[7.]

Interlocking nailing has been demonstrated to be the method of choice for fixation of these fractures. The intramedullary nailing under image intensifier satisfies the objective of stable fixation with minimal tissue damage resulting in better and faster fracture unions.

Introduction of modern implants like the Proximal Tibial Nail and Expert Tibial Nail has led to major advancement in intramedullary nailing of proximal tibial fractures. Introduction of interlocking bolts below the tibia plateau in these new implants, helped the surgeon to treat very proximal tibial fractures with intramedullary nailing[8.]

Intramedullary nailing offers an attractive treatment option, however there are some problems in treatment of fracture tibia with conventional intramedullary interlocking nailing, like difficulty in manipulating fractures of proximal and distal 1/3rd tibial comminuted metaphyseal fractures. These shortcomings of conventional intramedullary interlocking nail in managing proximal and distal third fractures have been overcome by the introduction of Expert Tibial Interlocking Nail due to modifications in operative techniques, its design and advancement in locking screws.[8]

Intramedullary nailing system- Expert Tibial Nail System (ETNS) is used for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon tibiale. In addition to the standard static and dynamic locking options, the ETNS provides multi directional locking options in the proximal and distal part of the nail. End cap block the most proximal screw creating an angular stable construct. ETNS has an option for compression at the fracture site (up to 7 mm) by inserting one distal locking screw and one proximal dynamic locking screw with a compression screw

The present study is being taken to review the results of metaphyseal and diaphyseal fractures of tibia treated with Expert Tibial Interlocking Nail.

OBJECTIVES

To study the functional outcome and duration of union of metaphyseal and diaphyseal fractures of tibia treated with expert tibial interlocking nail.

REVIEW OF LITERATURE

HISTORICAL REVIEW

Tibia and fibula fractures are comparatively common and have been well-known as serious and debilitating injuries for centuries. Details of the treatment of tibial fractures are included in the Edwin Smith Papyrus, an ancient Egyptian medical text dating back to at least 1500 to 1600 BC.[9]

Hippocrates provided early information on the treatment with rest and immobilization of the injured extremity by splinting and fracture healing to follow in time for the tibia and fibula fracture. Wooden splints were used by Greeks and later by Romans and in the medieval Europe for fracture immobilization. [10]

In modern times, Bohler recommended preliminary skeletal traction for 1 to 3 weeks for difficult tibial fractures and long leg cast treatment, an approach that yielded satisfactory results. [11]

In World War I, one in five battle injuries involved unstable fractures of the lower leg, the majority of which were open. At that time, about 10% mortality rate was associated with tibial fractures and an amputation rate of over 20%. .[3]

Watson-Jones advocated long leg cast treatment for several months, or until the fracture had healed. In his study the nonunion rate was very low, but he did not mention the effect of prolonged cast immobilization on joint motion and muscle atrophy. [12]

Early in his career, Charnley (1961) described closed reduction technique for the treatment of tibia- fibula fractures (making use of the periosteal sleeve) and highlighted the limitations of the technique described. He recognized a difficulty reported by others, i.e., intactness of fibula, which lets the tibia to drift into varus and ultimately the incidence of delayed union is increased. [13]

For almost three decades the conservative school of treatment prospered, until the early 1960s, when the **Swiss Arbeitsgemeinschaft für Osteosynthesfragen (AO) group** advocated open reduction and internal fixation with plating as a primary treatment for both closed and open tibia fractures. Their rationale was that prolonged cast immobilization lead to poor results. In this approach, however, the incidence of sepsis and nonunion increases considerably, particularly in the primary plating of open fractures. [14]

In 1971 Burwell HN 84% union and 15.87% of delayed / nonunion was reported in a study conducted on 63 cases of open tibia fractures operated with plating. [15]

In 1974 Nicoll studied about 800 tibia fractures, both open and closed. [16]

He outlined the major factors affecting results.

1. Degree of initial displacement
2. Fracture comminution
3. Soft tissue damage

Anderson LD *et al* (1974) reported 95% union rate in 250 open and closed fractures treated with pins and plaster method. [17]

In 1976, Ruedi, Webb and Allgower reported 97% excellent and good results in 323 closed fractures treated with DCP in which the infection rate was less than 1%. 80% of 95 open fractures had good or excellent results and only 12% had an infection. [18]

EVOLUTION OF INTRAMEDULLARY NAILS

Evolution of intramedullary nailing has a long history. In the first decade (1940-1949) and the sixth decade (1990-1996) the greatest development of intramedullary nails was found.

According to Watson-Jones, Nicolaysen of Norway is considered to be the father of intramedullary nailing. In 16th century, Incas and Aztec used resinous wooden pegs in medullary canals of long bones.

History of intramedullary nailing is divided into 6 decades.

First decade	1940-49
Second decade	1950-59
Third decade	1960-69
Fourth decade	1970-79
Fifth decade	1980-89
Sixth decade	1990-96

First decade: Kuntscher introduced intramedullary nails for treatment of fracture shaft tibia and femur in this decade. **Maatz**, an engineering graduate and doctor played a major role in the development of sound mechanical principle of nailing and designs of nail and other instrumentation like extractors, traction apparatus and intramedullary forceps.

Iron nails for femur, tibia, humerus and both bones forearm were developed by **Kuntscher** and **Maatz**. Their methods of nailing were based on two principles.

1. ***Stable fixation:*** This allowed early return to activity.
2. ***Closed nailing:*** Point of entry of nail insertion was far from the fracture site limiting the risk of infection and non-union.

From 1945-1949 **Lottes** devised three flanged femoral and tibia nails but only tibial nails were commonly used. By the end of first decade, open nailing also became popular.

Second Decade: The first interlocking nail, **Livingstone bar**, made of vitallium was made available in this decade. This nail lacked approval because of high rate of infection and difficulty while removal. **Schneider** developed fluted nail of square shape with self-broaching features to control torque stress. **Vesley Street** developed split nail of diamond shape for tibia, femur and humerus. In 1958 **Kuntscher** developed the reaming techniques for intramedullary nailing.

Third decade: The major development in this decade was invention of image intensifier. **Kuntscher's** interlocking nail was made available in this decade. **Derweduen** of Belgium developed compression nail for tibia.

Fourth decade: Klems interlocking nail and **Gross and Kempf (GK) nails** were developed in this decade.

Fifth decade: Intramedullary nailing continued to advance in this decade. Closed nailing technique was being rapidly expanded once again to include tibial, humeral fractures and non-unions.

Sixth decade: **AO interlocking** intramedullary tibial nail was made available in this decade.

Henley MB, Meier M, Tencer AF (1993) studied how some design parameters influence on the biomechanics of unreamed tibial intramedullary nail. These included the effects of the location of the nail bend on the reduction of a high proximal fracture, and the relation of proximal locking screw hole orientation and fracture component cortical contact to the mechanical stiffness of the construct. They found that the oblique proximal locking screws significantly decreased both varus/valgus angulation and medial/lateral translation under load, compared with the parallel screws. [19]

Robinson CM, McLauchlan GJ, McLean IP, *et al* (1995) reviewed 63 patients who had distal tibial metaphyseal fracture, with or without minimally displaced extension into the ankle joint. They managed all the fractures by statically locked intramedullary nailing, with some alterations of the procedure used for diaphyseal fractures. All the fractures united, with mean time to union was 16.2 weeks (10 to 50). There was shortening of the limb by more than 1 cm, only in one patient which was revealed on radiology. There were no rotational deformities, but two patients had varus deformities of 10° and 15° respectively because of incomplete reduction of the fracture. One patient had a recurvatum deformity of 20° at the fracture site. They concluded that closed intramedullary nailing was a safe and effective method of managing these fractures. [20]

Konrath G, Moed BR, Watson JT, *et al* (1997) evaluated twenty patients with twenty fractures for efficacy of intramedullary nailing in diaphyseal tibial fractures with distal intra-articular involvement at an average of twenty-two months of follow-up were evaluated. There were 15 closed and 5 open fractures. Lag screw fixation was done for all fractures (with or without supplemental plates) with the intra-articular fracture extension or ankle fracture and intramedullary nailing of the diaphyseal tibia fracture.

For healed 19 fractures, with an average time of seventeen weeks was taken for bony union. One non-union was seen in grade IIIB open fracture which required exchange nailing and healed after sixty-two weeks. Excellent alignment was observed in nineteen fractures after healing. They concluded that the indications for intramedullary nailing of unstable diaphyseal tibia fractures may be extended to include certain fractures with distal extension into the ankle joint, as well in a tibial shaft fracture occurring in combination with ipsilateral ankle fracture.[21]

Mosheiff R, Safran O, Segal D, *et al* (1999). unreamed tibial nail (UTN) was done for 52 patients suffering from fracture in the distal tibial metaphysis , articular involvement was not present in 32 fractures(43A1, 43A2, 43A3), intraarticular extension was seen in 20 (43C1, 43C2) and metaphyseal comminution was significant in 32 fractures (43A2, 43A3, 43C2). Open fractures were 12. Distal locking was used for treating all the fracture by means of UTN. Percutaneous interfragmentary fixation was applied additionally in 13 patients. In order to facilitate bone union 22 patients underwent an additional operation. Fracture united with a very good range of knee and ankle motion in 50 out of 52 patients (dynamization, bone grafting and/or fibulectomy). Non-union with breakage of the UTN occurred in 2 patients and postoperative infections were observed in two open fracture. They concluded that when unreamed tibial nail used for the treatment of distal tibia fracture including intra-articular fracture with no comminution, had got excellent functional outcome with less complications.[22]

Krettek C, Stephan C, P. Schandelmaier P, *et al* (1999). A prospective study was conducted in 21 tibial fractures of which 10 were having proximal third and 11 were having distal third fracture, the insertion of Poller screw was done, over a mean period of 18.5 months**.** All fractures had united. At a mean of 5.4±2.1month (3to12) healing was evident radiologically with a mean–1.0° (–5 to 3) varus valgus alignment. The mean loss of reduction between the placement of the initial Poller screw and follow-up was 0.5° in the frontal plane and 0.4° in the sagittal plane. There were no complications related to the Poller screw. In 18 patients according to Karlstrom G, Olerud score the clinical outcome was not influenced by the previous or concomitant injuries and was judged as excellent in three (17%), good in seven (39%), satisfactory in six (33%), fair in one (6%), and poor in one (6%).[23]

Krettek C, Miclau T, Schandelmaier P, *et al* (1999) Intramedullary nails with small diameter was used for treating high proximal and low distal tibial fracture ,in which mechanical effect of medial and lateral blocking screw in augmenting intramedullary nail fixation was studied. They concluded from their study after the nailing of distal and proximal metaphyseal fracture primary stability will increase due to medial and lateral blocking screws and could be an effective tool for selected cases that exhibit mal-alignment or instability.[24]

Dogra AS, Ruiz AL, Thompson NS, *et al* (2000) conducted retrospective study , among 15 patients who were treated with reamed intramedullary nail which had approximately 1 cm removed just distal to the lowermost locking screw for distal tibia fracture fixation . Normal activities of daily living was achieved in all patients. All leisure activities with no symptoms could be performed by eleven patients and minor discomfort was noted in three patients, which did not preclude sport. Union was seen in all fractures, 12 uneventfully and three after a secondary surgical procedure. Malalignment was noted in three patients defined as varus-valgus angulation or recurvatum of 5° or greater. They concluded that though it is technically challenging, intramedullary nailing for dia-metaphyseal distal tibial fractures is safe and reliable method for managing these injuries.[25]

Althausen PL, Neiman R, Finkemeier CG, *et al* (2002) carried out anatomical study for incision placement intramedullary nailing and they concluded that choosing proper entry site for tibial nailing is necessary as there is individual variations in patellar tendon. Based on the assumption that for tibial nailing ideal entry point is just medial to the tibial spine at the anterior margin of the articular surface, whether a medial parapatellar, transpatellar, or lateral parapatellar incision approach can be decided by taking a preoperative fluoroscopic measurement which provides the most direct access to this entry site. The routine use of a single approach for all tibial nails may no longer be justified. [26]

Gorczyca JT, McKale J, Pugh K, *et al* (2002) concluded that by removing one centimeter from the tip of a tibial nail permitted placement of two distal interlocking screws in tibial fractures located four centimeters from the tibiotalar joint. They achieved comparable fixation strength as that of standard intramedullary nailing of tibial fractures located five centimeters from the tibiotalar joint using two distal interlocking screws. Fixation strength, was not strong enough to resist moderate compression-bending loads with these distal fractures. They concluded that until significant fracture healing occurs the patients treated with intramedullary nailing for distal tibia fractures must follow weight-bearing restrictions to prevent coronal plane malalignment of the fracture. [27]

Kumar A, Charlebois SJ, Cain EL, *et al* (2003) studied the effect of fibular plate fixation on rotational stability of distal tibial fractures managed with intramedullary nailing. Fibular plate fixation increased the initial rotational stability when the distal tibial fracture is compared with the tibial intramedullary nailing alone. However, there was no rotational structural stiffness difference between the cases treated with and without plate fixation as applied torque was increased. [28]

In 2005, Jain V, Aggarwal A, Mehtani A. *et al*, concluded the advantages of primary unreamed intramedullary nailing as rigid fixation, low incidence of infection, non-union, good functional result and early return to work. Soft tissue management is mandatory in treatment of these fractures[9]. [29]

Im GI, Tae SK (2005) compared the open plate and screw fixation with closed intramedullary nailing. Prospective study done for 64 consecutive cases of fractures which was randomly treated with either method were followed up. Closed intramedullary nailing was done for 34 patients (Group I) and remaining 30 patients were treated with open reduction and internal fixation with anatomic plates and screws (Group II). In Group I the duration of surgery was 72 minutes and Group II 89 minutes ($p = 0.02$). In Group I radiologic union was 18 weeks and in Group II 20 weeks ($p = 0.89$). In Group I superficial infection was noted in one patient and in Group II six superficial infections and one deep infection ($p = 0.03$). In Group I the average angulation was 2.8 degrees and in Group II 0.9 degrees ($p = 0.01$). In Group I, at the final follow-up the ankle dorsiflexion was 14 degrees and in Group II 7 degrees ($p = 0.001$). In Group I, the Olerud and Molander functional ankle score was 88.5% of normal side and 88.2% in Group II ($p = 0.71$). Their results highlighted that locked intramedullary nails had an advantage in the duration of operation, restoration of motion, and reduced wound problems, but plate and screws could restore alignment better than intramedullary nails. From their study they concluded that fractures associated with soft-tissue damage of Tscherne C2 or higher, intramedullary nails can be used.[30]

Nork SE, Schwartz AK, Agel J, *et al* (2005) performed a study for distal tibial fractures which were located within 5 cm of the ankle joint to assess the results of intramedullary nailing. At two institutions over a sixteen month period, 36 tibial fractures involving the distal 5 cm of the tibia were treated with reamed intramedullary nail using either two or three distal interlocking screws. Supplementary screw fixation prior to the intramedullary nailing was done among ten fractures having articular extension. Among 33 patients (92%) acceptable radiographic alignment was achieved, which was defined as $<5°$ of angulation in any plane. Follow up was not available for six patients. Average of 23.5 weeks was taken for remaining thirty fractures. They concluded that for treating distal metaphyseal tibial fractures intramedullary nailing was a valuable option. For intramedullary fixation simple articular extension was not a contraindication.[31]

Bedi A, Le TT, Karunakar MA *et al,* (2006): Proximity of the fracture to the plafond, fracture displacement, comminution, and injury to the soft-tissue envelope influenced the treatment selection for distal tibial fractures. Indications for intramedullary nailing have been expanded to include distal metaphyseal tibial fractures. Intramedullary nailing permits atraumatic, closed stabilization while maintaining the vascularity of the fracture site and integrity of the soft-tissue envelope however and concerns have been raised regarding the biomechanical stability of fixation. To prevent periosteal stripping and extensive dissections intramedullary nailing was implicated, which reduces the risk of soft-tissue complications. So study suggests that for extra-articular and when sufficient space available for two screws and nailing was done.[32]

Kasper W. Janssen, Jan Biert, *et al,* (2006): A study on extra-articular fracture of the distal third of the tibial shaft on 24 patients was performed to determine the effect of the type of treatment, open reduction and internal fixation (ORIF) or closed reduction and intramedullary (IM) nailing, on the occurrence of malalignment. The groups were assessed after a mean of 6.0 years for IM nailing patients versus ORIF who were assessed after a mean of 4.5 years. Malalignment of the tibia was seen in two patients treated with ORIF versus six patients treated with IM nailing. Furthermore, there is no difference between the ORIF versus IM nailing with regard to time to union, non-union, hardware failure or deep infections. Results suggest that alignment is difficult for the

IM nailing for distal tibial fracture. For Optimal alignment authors advised for the distal tibial fracture the use of ORIF for closed and type I open extra-articular fractures. [33]

G. I. Drosos, M. Bishay, I, *et al* (2006): On 161 patients a retrospective study for tibial diaphysis fractures (for closed or grade I open fractures) treated with intramedullary nailing. The risk of failure of union for highly comminuted fractures increased by 2.38 times, when nail dynamization was applied increased by 3.14 times, and by 1.65 times when the locking screws failed as shown by Multivariate statistical analysis using a Cox proportional hazards mode. If post reduction gap was ≥3mm the risk of nonunion increased in fractures with no or only minimal comminution. Relatively low rate of complications and satisfactory clinical results has been noted in the patients treated with Closed intramedullary nailing (is the preferred method of surgical treatment) for closed and grade I open fractures (Gustilo and Anderson classification) of the tibial diaphysis.[34]

Jan Biert, *et al* (2007): By using ORIF 12 patients were treated with ORIF and 12 patients treated with IM nailing were matched. The mean total operation time for ORIF took 107 min (range 60–195) and the mean time for IM nailing took 123 min.Broken screw was seen in one patient who was treated with an IM nail. For ORIF group the mean time is 19 weeks for radiographic union versus IM nailing group is 21 weeks (p=0.44). There was no significant difference in time to weight-bearing .Results suggest that especially, control of alignment in all directions is difficult with a nail alone in the distal third of the tibia. Authors found that IM nailing anterior knee pain is still a complication. And no difference with regard to time to union, non-union, hardware failure or deep infections between ORIF and IM nailing. For optimal alignment they advise considering the use of ORIF for closed and type I open extra-articular fractures in the distal third of the tibia. [35]

In 2008**,** Vaisto O, Toivaren J, Kannus P. *et al* , An eight year follow-up of a prospective randomized study " Anterior knee pain after intramedullary nailing of fracture of tibial shaft, comparing the different nail-insertion techniques " stated that anterior knee pain is the most common complication after intramedullary nailing of the tibia .They thought that anterior knee pain is due to the dissection of patellar tendon and its sheath during transtendinous nailing compared with a transpateller tendon approach. After intramedullary nailing of tibial shaft fracture a paratendinous approach for nail insertions does not reduce the occurrence of chronic anterior knee pain or functional outcome . After a long term anterior knee pain seems to disappear from many patients. [36]

Kuhn S, Hansen M, Rommens PM (2008) A prospective study was carried out by using Expert tibial nail and concluded favourable results and extended indications, compared to standard tibial nails. [37]

Pierre Joveniaux, Xavier Ohl,etal (2009): Study conducted on 101 patients with distal tibia fractures. Internal fixation, external fixation, limited internal fixation (K-wires or screws), intramedullary nailing and conservative treatment were used. In case of open ($p < 0.02$) fractures or Polytrauma ($p < 0.02$) external fixation was used. Similarly, among 54% of communited fractures external fixation was used, resulting in higher complication rate and worse outcome. Authors suggest that external fixation must be used as temporary solution for patients with severe skin injury in a two-staged protocol as described by Sirkin *et al*. For other cases, they recommend ORIF with early mobilization. [38]

Pedro José Labronici; José Sergio Franco, *et al* (2009): A study of 47 fractures was done. Out of that 21 patients were treated with non-reamed, interlocking intramedullary nailing, and dynamic compression plates were used for treating 26 patients (using a minimally invasive technique). The average healing time was 14.6 weeks for the patients in whom fibula fixation was done and 14.3 weeks among the patients in whom fibula fixation was not done. Among the patients in whom fibula fixation was done a considerably smaller proportion of valgus angular deviation (6.3%) was observed compared to the group of patients in whom fibula fixation was not done (32.3%). Among the studied fracture groups, there was no significant difference in fracture healing. [39]

Hansen M, Blum J, Mehler D, *et al* (2009) A biomechanical study was carried out for extra articular proximal tibial fracture to determine whether there were differences in stability between double and triple interlocked intramedullary nails used for the fixation . They concluded that for proximal tibial fracture triple proximal interlocking provided more stability in nailed patients than double proximal interlocking. [40]

Attal R, Muller M, Hansen M, *et al* (2009) A prospective, multicenter setting, evaluated 190 patients who were treated in 10 participating centers using the Expert Tibia Nail. Among them 127 patients had Polytrauma, 58 had open fractures. 5 cases were proximal tibia fractures, 108 shaft fractures, 56 distal fractures, and 21 segmental fractures. Follow up period - postoperatively, after 3 months and one year, who were evaluated radiologically and clinically with regard to malalignment, union rate and complications. Nonunion was noted in 9 cases after one year follow up (n=150). Delayed union was noted in 20 patients. The rate of open and complex fractures was high in this group. In 10 cases, dynamization was carried out. Valgus/varus and recurvatum/ antecurvatum malalignment of more than 5 degrees observed in 13 cases. Stable reduction was obtained in 144 cases. Initial reduction went into malalignment among 4 complex fractures. In 3rd degree open fractures they witnessed deep infection among two patients. 34 patients developed pain in the operated area. Total 6 screw breakage was noticed. In the treatment of tibial fractures, Expert Tibia Nail proved to be an excellent tool. As it has advanced locking options and design of the nail permits it to be used in complex fractures of the shaft as well proximal and distal metaphyseal region, helps in achieving stable fixation. The risk of complications such as malalignment and malunion was lesser. [41]

Andreas H. Ruecker, Michael Hoffmann, *et al* (2009): The main objective of distal tibial fracture treatment is to obtain stable fixation patterns with minimal soft-tissue affection. Thus, open reduction and plating has got higher risk of soft tissue break down and complication of bone healing. In tibial shaft fractures Percutaneous, minimally invasive intramedullary nailing has been demonstrated as a mode of fixation for fracture stabilization. In conclusion, intramedullary nailing of distal tibial fractures is a dependable method of fixation, having the advantages of closed reduction and symmetric fracture stabilization with a delicate soft tissue situation, but prospective randomized trials are needed to compare modern intramedullary fracture fixation with modern plate fixation in distal tibial fractures. [42]

In 2009, Khan I, Javed S, Khan G N, Aziz A, case study of 50 patients demonstrated that Intramedullary interlocking nailing is an efficient measure in treating closed and grade I and II open tibial fractures. It gives a high rate of union, less complications and early return to function. [43]

Lei M, Liu L, Yang T, *et al* (2010) evaluated the clinical effect of Expert tibial nail(ETN) in the management of the complex tibial fractures of type C. Ten cases with complex tibial fractures of type C were managed by unreamed ETN and closed reduction. There were 7 males and 3 females of the age group 23 to 50 years with an average age of 39. Fracture were caused by traffic accident in 6 cases, by crush in two cases, and by fall from height in two cases. According to Association for the Study of Internal Fixation (AO/ASIF) classification, there were 2 cases of 42-C1 fractures, 4 cases of 42-C2 fractures, and 4 cases of 42-C3 fractures; including 4 cases of closed fractures and 6 cases of open fractures (two patients with Gustilo type I and four patients with Gustilo type II).The mean duration of surgery and blood loss were 75 minutes (range, 60-110 minutes) and 55 mL (range, 20-100 mL), respectively. All the incision healed by first intension without complication of infection. All the patients were followed for a period of 12-17 months (average 14 months). X-ray films showed that no breakage of nail, iatrogenic fracture, limb shortening, and angulation deformity occurred. All fractures healed after 3-8 months (average 4.2 months). At last follow-up according to Johner-Wruh's standard for the functional recovery, excellent results were seen in 8 cases and good among 2 cases. They concluded that Expert Tibial Nail had an angular stable locking system for intramedullary nails, which could enhance axial and transverse stability for the management of complex type C tibial fractures. It would provide firm fixation and minimal invasion. [44]

Trlica J, Dedek T, Smejkal K, *et al* (2010. The ETN technique was used in 41 patients to treat 41 diaphyseal tibial fractures. All patients were followed-up prospectively. Out of forty-one fractures, thirty-one were closed whereas ten were open fractures. The injury-to-surgery interval ranged from 1h and 50 min to 25 h and 12 min (median, 8 h and 52 min). The operative time ranged from 50 to 170 min (average, 87 min). Three cases of insufficient primary reduction underwent repeat surgery during the first stay in hospital. Full weight-bearing with no pain was reported in the range of 10 to 24 weeks (average, 18 weeks) after surgery. The ETN provided sufficient stability of diaphyseal tibial fractures including those involving the metaphysis. However, in some instances, poller screws were still indispensable. Sufficient reduction was necessary before nail insertion[45]

In 2012, M. Nageshwara Rao, K. B. Vijaya Mohan Reddy, A. M. Ilias Basha, G. Praneeth Kumar Reddy , a study of 40 cases , technique of intramedullary interlocking nailing is ideal because of excellent (60%) and good results (30%).With the excellent results and the advantage of rapid rehabilitation and relatively few complications serve to be proposed intramedullary interlocking nail for tibial shaft factures for wider use.[46]

A Mahmood, JJ George Malal *et al* (2012) assessed the results of Expert tibial nailing for distal tibial fractures. A total of forty-four distal tibial fractures were treated with the nailing system. 31 of the fractures were closed while the remaining 9 were open. The usual age group of the cohort was 46.8 years with 26 males and 14 females. The standard time to radiological union was 12.5 weeks for the closed fracture group and 15.1 weeks for the open fractures. The variation in time to union between the two groups was not statistically significant. There was infection around a distal locking screw in a closed fracture which settled with screw removal. Three patients in the closed fracture group dynamization was done to hasten union while none required dynamization in the open fracture group. One patient had nonunion of a distal fibula fracture which required plating of as an additional procedure. The authors concluded that The Expert tibial nail is an effective implant for the management of both open and closed distal tibial fractures with a low complication rates. [47]

Mustafa Isik, MD; Mehmet Subasi, MD, *et al*: 2012: Thirty-eight patients who presented for distal third tibial fractures and were treated with intramedullary nailing following reduction with no additional fixation methods were selected for the study. About 15 weeks was the mean time for fracture union (range, 8–26 weeks). In 18 patients, the angular values were measured following fracture union which was higher than the values measured on postoperative day 1.The measurement done on postoperative day 1 and after fracture union on Anteroposterior view ,the mean difference was 0.79° (range, 0°–4). There was increase in angulations which was revealed by statistical analysis, was significant. If distal metaphyseal tibial fractures are reduced in an acceptable position and static locking is performed by placing at least 2 screws distal and proximal to the nail during intramedullary nailing, angulations in reduction that may develop during the period until union remain within the accepted reduction criteria, even if Poller screws, plate fixation of the fibula, or casting after nailing are not used. [48]

Young Li, Lei Liu, Xin Tang , et a (2012) in 46 patients, conducted a comparative study of low, multidirectional locked nailing with plating in the treatment of distal tibial meta-diaphyseal fractures . Group A the implant used was expert tibial nailing and with minimally invasive plating in group B patients. In group A, the mean follow-up was 24.7±2.7 months and 25.8±2.8 months in group B. None of the patient had nonunion, shortening, hardware breakdown, or deep-seated infection. Patients in group A had a significantly shorter mean operating time, hospital stay, full weight-bearing time and union time. Among group A three patients and one patient in group B presented with malalignment. And concluded that distal tibia meta-diaphyseal fractures may be treated effectively with low, multidirectional locked nails or plates. However, low, multidirectional locked nailing may represent a better surgical option, since it offers advantages in terms of mean operating time, hospital stay, full weight-bearing time and union time. [49]

In 2012,Rene Attal, M. Hansen, M. Kirjavainen, H. Bail, T. O. Hammer, R. Rosenberger, D. Höntzsch, P. M. Rommens treated 180 patients with intramedullary reamed and unreamed nailing with the ETN. As shown by their study Intramedullary ETN fixation of tibial fractures has low rates of delayed union, primary and secondary malalignment, implant-related complications, and secondary surgery. Fixation of fibula with plate had a negative effect on the healing of the tibia. [50]

In 2013, Radhakrishna A. M, Shivananda S, Santhosh Kumar G, a total of 30 cases studied, showed that the method of treatment employing closed intramedullary interlocking nailing to stabilize diaphyseal fractures of tibia is ideal because of its excellent and good results. [51]

In 2014, Maruthi C. V, Shivanna, prospective study of 60 cases managed with intramedullary interlocking nail, their findings showed that intramedullary interlocking nail is an excellent method for closed, type1, 2 and 3A open fractures of tibia. This has excellent functional outcome. [52]

Deebak Kumar ,Ganesan ram ,*et al* (2014) at Sri Ramachandra University between June 2010 to June 2013 conducted a prospective study of 60 patients having distal tibia fractures, managed surgically. 30 patients underwent closed intramedullary interlocking nail and 30 were treated with plate osteosynthesis. All the fractures united solidly with mean union time of 24.5 weeks ranging from 18 to 38 weeks. In both knee and ankle good regain of range of movements was attained in the patients who underwent nailing. Ankle stiffness was noticed in two patients who were treated with plating, which ultimately compromised the overall functional outcome and they concluded that Plate osteosynthesis by minimally invasive technique and intramedullary interlocking nailing are equally effective methods of stabilization for distal tibia fracture when considering the union rates and final functional outcome. However malunion, nonunion and secondary procedures were more frequent after intramedullary interlocking nail. [53]

In 2015, Kadiri Venkata Ranganath, H S Arun, S Hariprasad, isolated tibial diaphyseal fractures (21 closed fractures, 4 Type I open fractures, and 5 Type II open fractures) treated with closed intramedullary interlocking nailing among 30 patients- A prospective study. Their findings revealed that Intramedullary interlocking nailing is the dependable and effective for treating undisplaced and minimally displaced closed isolated tibial shaft fractures, also in open Type I tibial shaft fractures[54]

Wasudeo Gadegone, Yogesh Salphale, *et al*:(2015): A study was conducted in adults patients who sustained an extra-articular fracture of the distal tibia, to determine the efficacy of closed reduction and intramedullary nailing in dynamic mode on union, implant failure and incidence of malalignment. Study conducted on one hundred and twelve patients with distal tibial fracture that involved the distal 6 cm of the tibia and operated with reamed intramedullary nailing with use of two distal interlocking screws and one proximal screw in dynamic mode. The nailing of fibular fractures was done in 27 cases. The average time to union of the closed fracture was 15.4 weeks (range: 12 – 28 weeks). The healing times for the primarily nailed compound Grade I averaged 17.8 (range: 15 - 34 weeks). There were three cases of delayed union and two cases of nonunion. In one case there was deep infection which required exchange nailing with antibiotic impregnated nail. There was breakage of interlocking screws in three cases but fracture had united and finally concluded that the dynamic osteosynthesis of distal tibia by interlocking nail and judicious use of poller screws is an effective alternative for the treatment of distal metaphyseal tibial fractures. [55]

DenizGülabi, Halil İbrahim Bekler,*et al*(2016): 22 patients treated with traditional open reduction and internal fixation were matched with 22 patients treated with closed reduction and MIPPO on the basis of age (±3), gender, and fracture pattern (AO classification). There was no significant difference in, AOFAS score, time from injury to operation, follow-up, bone union time, delayed union, malunion and infection ($p>0.05$).There were two superficial wound infections in the ORIF group, which resolved with daily wound care. MIPPO technique can be useful for the treatment of distal tibia AO/OTA A and B type fractures with reduced hospital stay, cost-effectiveness, and infection rate. [56]

Lakhpat Yadav1 , S Srivastava2 , Rakesh Kumar(2016): This study was conducted on 20 skeletally mature patients with metaphyseal or diaphyseal fractures of the tibia treated with Expert Tibial Nail which is having advanced proximal and distal locking options. Out of 20 patients 14 (70%) patients had excellent results as they had full function as pre trauma without any residual symptoms. 3 patients (15%) had good results, 2 (10%) patients had fair results and 1 (5%) patient had poor results. Average duration of protected and unprotected full weight bearing was 4.4 weeks and 7.5 weeks respectively in their series. Authors Concluded that results with expert tibial interlocking nailing are encouraging and demonstrate the benefits of new nailing system. Changes in the design of the nail for improved proximal and distal locking enable it to be used in proximal and distal metaphyseal fractures of tibia. Contemporary nail designs also include locking options in three planes, which allow a better stabilization of small proximal and distal fragments and obtain a higher stability of the bone implant construct and recommend the use of expert tibial nail in metaphyseal and diaphyseal fractures of the tibia. [57]

Akshay Phadke, Chandrasekhar, *et al* (2016): Reamed intramedullary nailing was done among a total of 42 patients for distal tibial fracture. Fixation of fibula was done in selected cases either with nailing or a low profile plate. In the present study out of total 42 cases, in 40 cases (95.23 %) two locking screws were put distally while in 2 patients (4.76%) only single locking screw was put due to fracture geometry. All the fracture united. Union time ranged from 12-34 weeks with an average of 21 weeks. 17 fractures healed before 20 weeks, 22 fractures healed between 20 to 32 weeks while 3 fractures took 32 or more weeks to unite. In 3 cases (7.14%) with delayed union dynamization (removal of proximal static locking screw) was done after 12 weeks. In four cases malalignment was noted. In two cases 5° of varus angulation was noted. One case had varus angulation of 10 degrees. In one case anterior angulation of 10 ° was noted. Superficial infection was noted in one patient and was treated with oral antibiotics. 8 patients reported anterior knee pain but it was not severe enough to cause any functional deficit. They stated that intramedullary nailing is an effective option for the treatment of distal metaphyseal tibial fractures. [58]

Agathangelidis F, Petsatodis G(2016): incidence of malalignment and loss of fixation has been reduced ,since the introduction of tibial intramedullary nails allowing a number of distal screws for treating distal metaphyseal fractures. This biomechanical study was conducted to concentrate on the number of screws and the type of screw configuration required for stable fixation. In the composite bone model Thirty-six Expert tibial nails (Synthes, Oberdorf, Switzerland) were inserted. The models were divided into four groups with different distal locking configurations ranging from 2 to 4 screws. Each group was divided in 3 subgroups and underwent. This in vitro study showed that, when using the Expert tibial nail for unstable distal tibial fractures, the classic configuration of 2 parallel distal screws could provide the necessary stability under partial weight-bearing conditions. [59]

SURGICAL ANATOMY

The anatomy of the leg makes tibia vulnerable to open fractures. The medial border of the tibia is entirely subcutaneous and is covered only by skin and subcutaneous tissues.

There is side to side expansion of upper end of tibia, to form 2 large condyles which overhang the posterior surface of the shaft. The upper end includes: a medial condyle, a lateral condyle, an intercondylar area and a tuberosity. The tuberosity has been divided into an upper smooth area and a lower rough area. For the upper end of the tibia the epiphyseal line passes through the junction of these two parts.

The shaft has three borders and three surfaces. The anterior border is sharp and S shaped being Convex medially In the upper part and convex laterally in the lower part. It extends from tibial tuberosity above to the anterior border of the medial malleolus below. It is subcutaneous and forms the shin. The medial border is rounded and lateral or interosseous border has interosseous membrane attached with it, which in turn is attached to fibula.

The lower end of the tibia is slightly expanded and has five surfaces. The anterior surface has a smooth upper part and grooved lower part. The medial surface is subcutaneous and is continuous with medial surface Of medial malleolus. The lateral aspect of the lower end presents a triangular fibular notch to which lower end of fibula is attached. The inferior surface is articular, it articulates with talus and thus forms the ankle joint. [60]

Muscles of the Leg[61, 62]:

There is a muscular envelope around the tibia and is divided into four compartments by the unyielding deep fascia of the leg.

1. Anterior compartment:

It contains the tibialis anterior, extensor digitorum longus, extensor hallucis longus and the peroneus tertius muscles. This anterior compartment also contains the anterior tibial artery and deep peroneal nerve. The tendons are near to the tibia and following fracture in this region gliding of tendons may be restricted due to the formation of the callus. As the anterior compartment wall is unyielding, it leads to increased tissue pressure, may result in anterior compartment syndrome. This may occur Secondary to tibial fracture.

2. Lateral compartment:

Peroneus longus and peroneus brevis muscle are present in lateral compartment and fibular shaft is protected by them apart from near the ankle joint, so isolated fibular fractures owing to direct trauma are uncommon. The superficial peroneal nerve passes in between the peronei and the extensor digitorum longus in the intermuscular septum. In fracture of fibular shaft the nerve is seldom involved. In fibular neck fractures, it is at risk.

3. Posterior compartment:

Divided additionally into superficial and deep compartment.

Soleus, gastronemius, popliteus, tibialis posterior, flexor hallucis longus and flexor digitorum longus are present in it. The posterior compartment also contains posterior tibial nerve and posterior tibial artery and its large branch peroneal artery.

Fig.1 – Tibia and Fibula

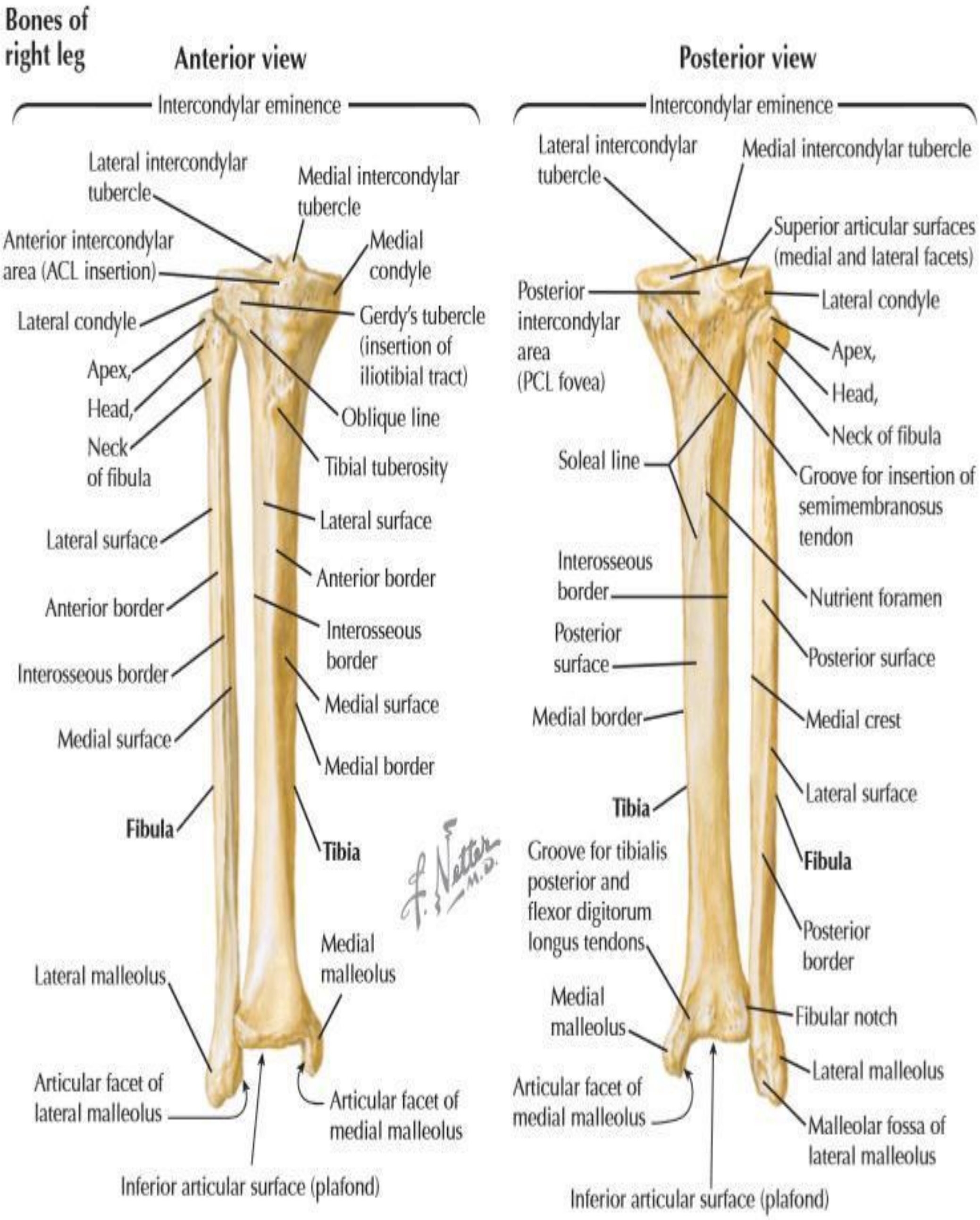


Fig. 2 – Muscles of Leg (Deep Dissection) : Anterior View

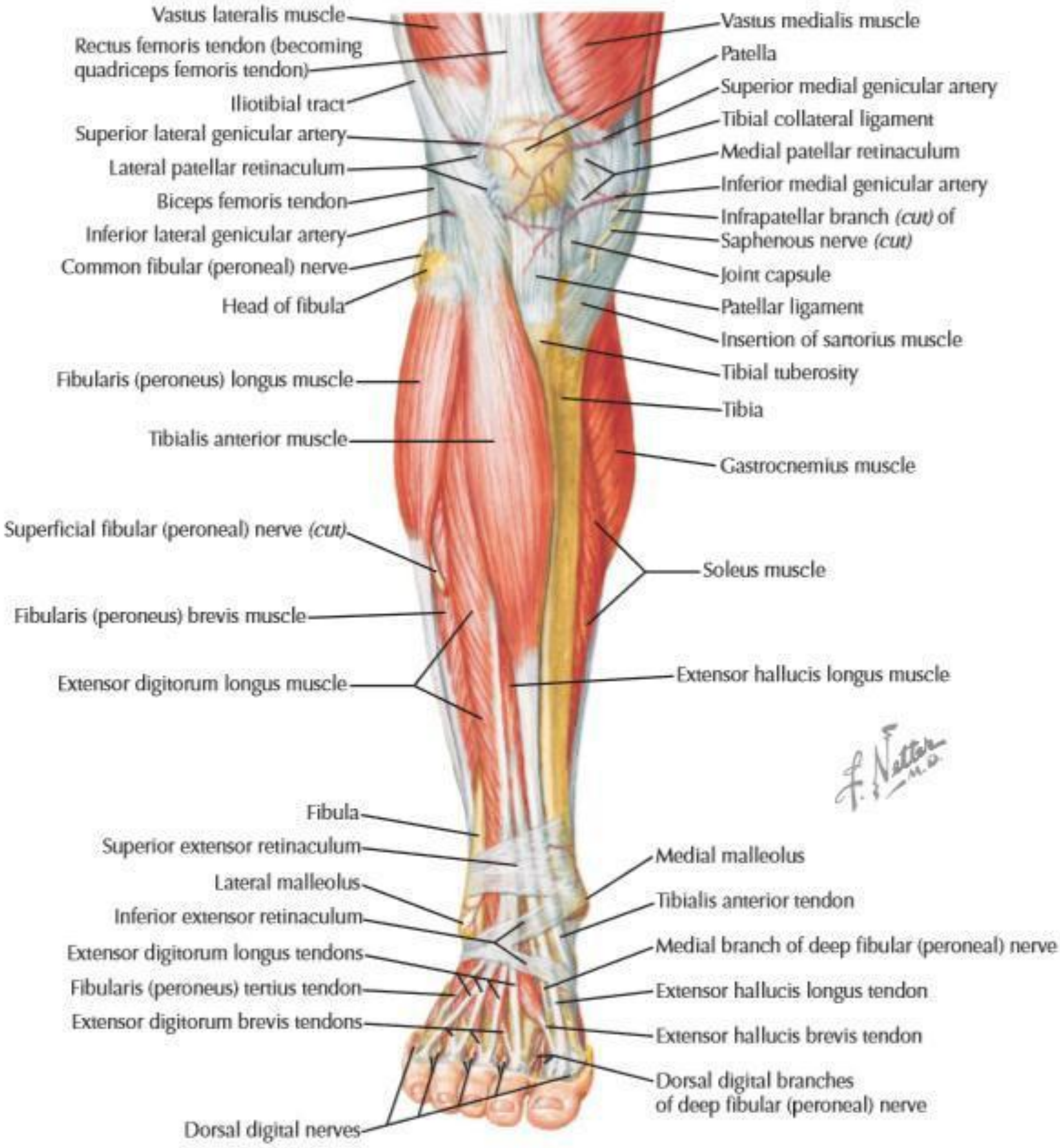


Fig. 3 – Muscles of Leg: Lateral View

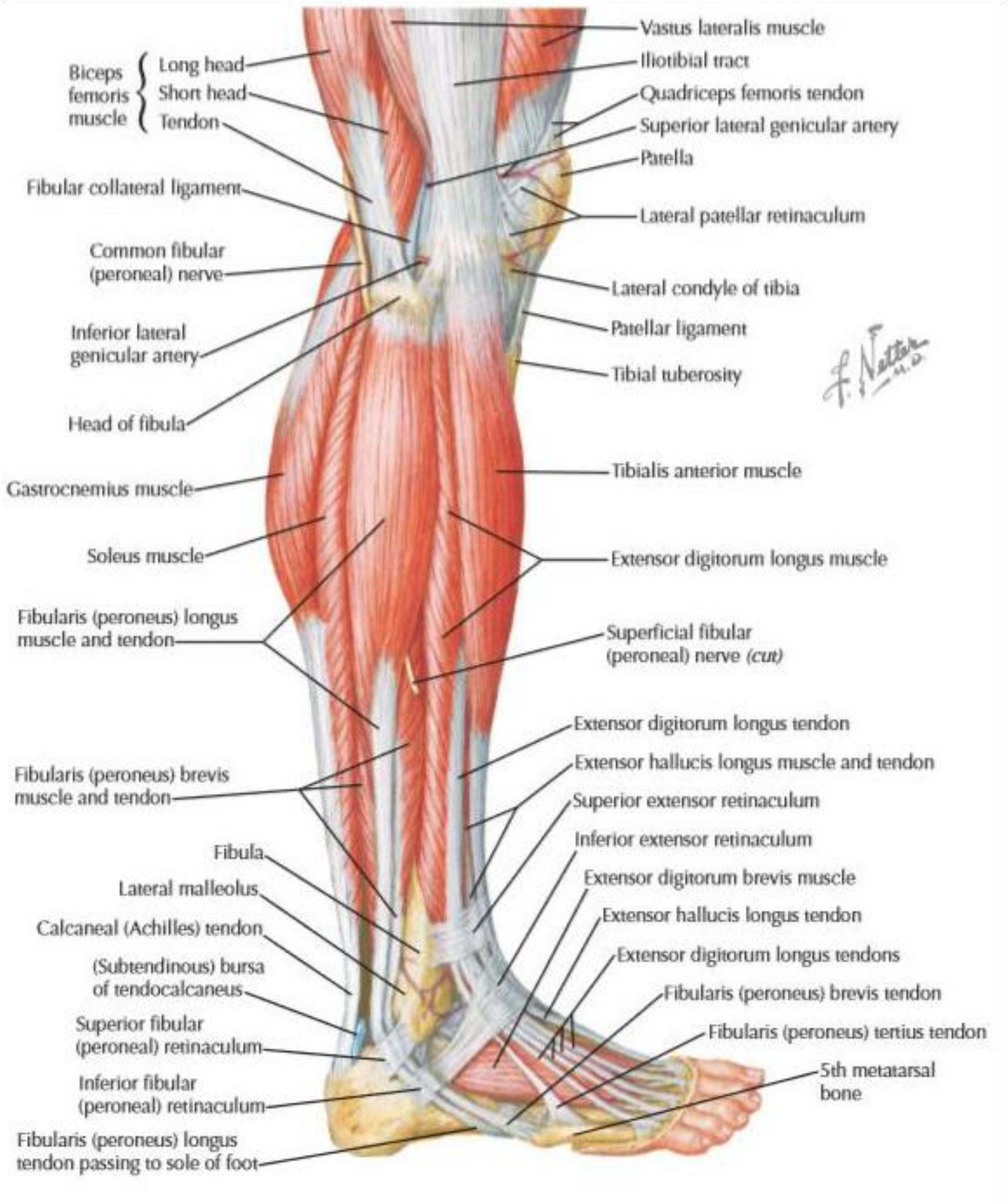
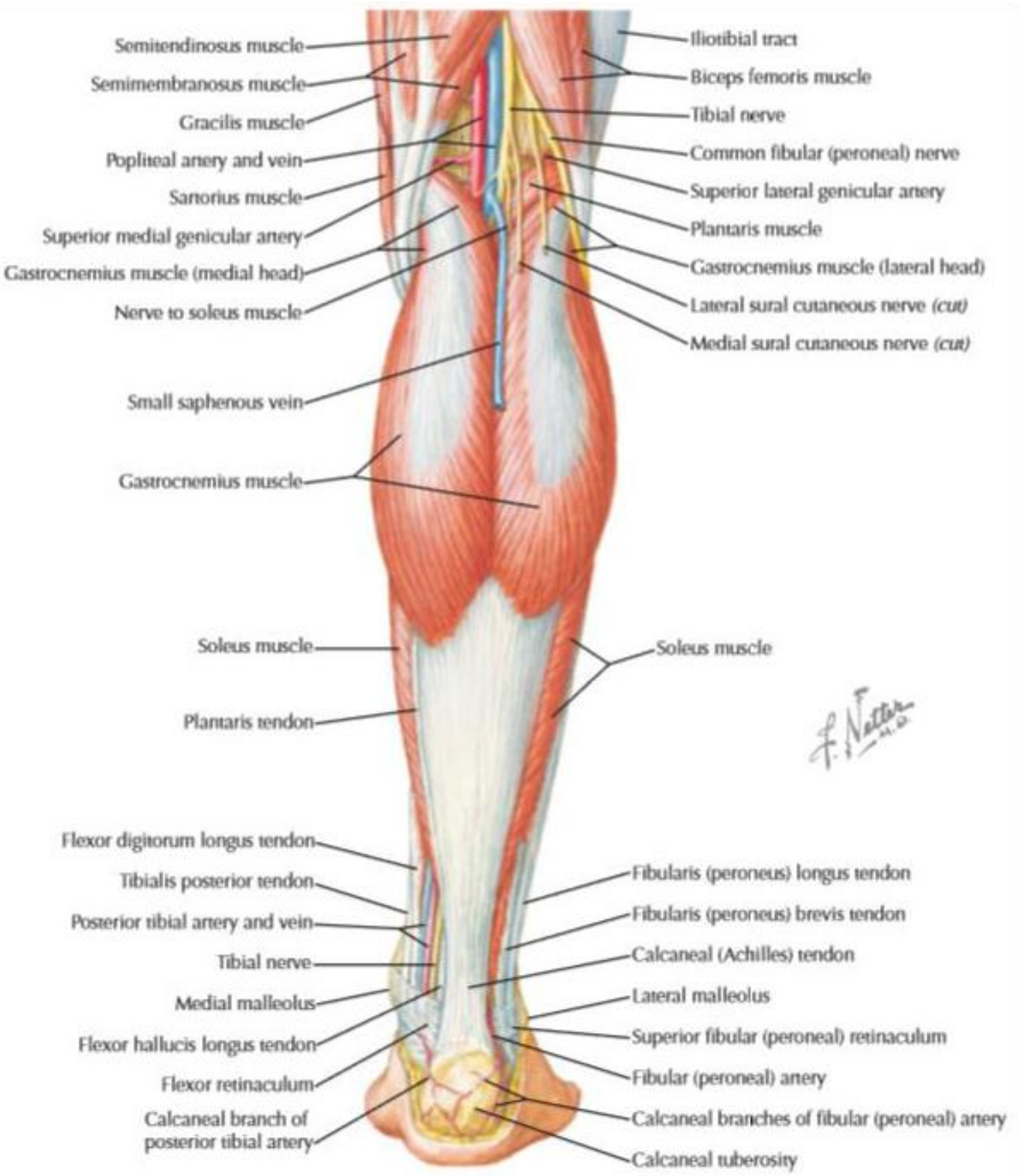


Fig. 4 – Muscles of Leg (superficial): posterior View



Interosseous membrane:

The spaces between the tibia and fibula except at its upper end is closed by a strong sheet of fibrous tissue, called as interosseous membrane , where there is a small opening for the passage of anterior tibial vessels. When the membrane is widely torn, separation of the tibia and fibula occurs. Since the majority of its fibres run downwards and outwards, the membrane helps to allocate indirect strength acting on the tibia to the fibula.

The blood supply to leg:

The main blood vessels of the leg are anterior and posterior tibial and peroneal arteries. The anterior tibial artery is one of the terminal branches of the popliteal artery and runs forward through the opening in the interosseous membrane to advance into the anterior compartment, where on the interosseous membrane it passes downwards to terminate in the dorsalis pedis artery. The posterior tibial artery is the direct extension of the popliteal artery. It passes downwards in the space amongst the deep flexor muscles and the calf muscle to terminate in the plantar arteries. The peroneal artery passes downward in close relation to the posterior surface of the tibia.

In 90% of population the described classic pattern follows, that is the division of the popliteal artery into anterior tibial, posterior tibial and peroneal artery, called as trifurcation.

But in approximately 1% of limbs, the posterior tibial artery is the extension of the popliteal artery and the other branch of the popliteal artery is a combined trunk that divided into the anterior tibial and peroneal artery. In approximately 3% of limbs, the anterior tibial artery originates from the popliteal artery superior to the popliteal muscle (high origin).

In 6% and 5% of limbs, the anterior and posterior tibial arteries, respectively, may be hypoplastic plastic or congenital absent. In these limbs, the perforating and communicating branch, respectively, of the peroneal artery is enlarged and continues to the foot as the dorsalis pedis or posterior tibial artery. The peroneal artery is congenitally absent in less than 0.1% of limbs.

The tibial blood supply is derived from three main systems:

1. The epiphyseal and metaphyseal arteries.
2. The nutrient artery
3. The periosteal artery

The periosteal blood supply comes from the neighboring musculature and supplies the outer third of the cortex, while the endosteal blood supply comes from nutrient artery which is a branch of the posterior tibial artery at the soleal line and supplies the inner two-third of the cortex.

The nutrient artery divides into three ascending branches which supply the proximal two-third of the tibia, and gives a smaller descending branch which supplies the distal one third of tibia. Hence, the proximal tibia has good endosteal blood supply, while the distal tibia has poor supply.

The soft tissue attachments to the distal tibia are less, making the periosteal blood supply scanty. This differential pattern of blood supply makes tibia susceptible to atrophic non-union at the junction of the middle and distal third. Unfortunately, majority of the open tibial fractures are at this junction.

Usually the blood flow is centrifugal, however, in case of a fracture when the endosteal blood supply is damaged, the flow is reversed and it changes from centrifugal to centripetal. When intramedullary nailing is done, the endosteal blood supply is interrupted. It is extremely important to preserve the soft tissue attachment. This is achieved by a closed intramedullary nailing.

Rhinelander[63] suggested that:

1. In Loosely fitted nails there is rapid regeneration of nutrient system and
2. In Tight medullary nailing an intra cortical regeneration of nutrient system occurs.

A nail that filled the reamed medulla completely produced rigid fixation but cause complete necrosis of the cortex. The best configuration for an intramedullary nail is one with open spaces or flutes extending longitudinally between the flanges. The flanges will give firm support to all sectors of endosteal cortex and the flutes will permit regeneration of essential medullary circulation as rapidly as possible.

Reaming:

Implantation of a medullary nail without previous reaming cause relatively minor damage to the blood circulation while the reaming process results in the destruction of all vessels in the medullary canal.

Necrosis occurs of about 50-70% in the internal cortex. Due to the anatomy of the medullary blood supply, the crucial damage is caused by the first reaming. Subsequent reaming has slight effect on cortical vascularity or viability.

Reaming is performed only to such an extent as to ensure sufficient fracture stabilization. Reaming particles, which possess bone inductive potential, are sporadically considered to be of great significance in fracture healing. Indeed, new bone formation can be perceived around the reaming dust on histology sections, if it is surrounded by vital tissue. On the other hand, the reaming dust signifies a huge amount of necrotic particles or micro sequestrae, if they are deposited in devitalized zones of the medullary canal. This must be considered in sight of the possible bacterial contamination, when conducting open intramedullary nailing. The medullary canal is irregular in size in the long axis as well as in cross section. Stable intramedullary fixation requires a firm fit for a variable distance. On reaming the medullary canal, a cylindrical channel of uniform diameter is prepared for the nail, which improves the stabilizing effect of the implant. A minimal amount of reaming is sufficient for static interlocking nailing. It is recommended that the medullary canal should be reamed 0.5-1mm larger than the chosen nail diameter to facilitate nail introduction.

Reamed versus unreamed nails:

Rhinelander showed that reaming the diaphysis of long bone eliminates the endosteal blood supply. Because endosteal blood supply is responsible for the vascular supply to the vast majority of the inner cortex, the cortex is nearly completely devascularized. In open fractures there is substantially more stripping of soft tissues and periosteum than in closed fractures. Therefore the likelihood that entire cortex has been devascularized after reaming is very high. During this period of devascularization, the risk of infection is high, especially for acute reamed nailing of highly contaminated open fractures. [63]

Rhinelander also highlighted that after reaming there is a reversal of the normal centrifugal blood supply to the cortex to a centripetal pattern. This arises within the first few weeks after nailing. Complete revascularization procedure occurs comparatively early in the fracture healing process. Non reamed nails have major advantages in open fractures because they cause less damage of the endosteal blood supply and allow more room for revascularization. The disadvantage of non-reamed nails is that they provide less stability. Delayed union, non-union and malunion are more frequent. These advantages and disadvantages in the use of these devices must be balanced. [63]

MECHANISM OF INJURY

For the tibia to get fractured, a significant amount of energy must be applied in one of three modes.

Torsional injuries (e.g., skiing injuries) are more common with low energy trauma where the foot become fixed and the body rotates about this fixed point.

Three and four point bending forces produce short oblique and transverse fractures. As the points of bending are spread further apart and as the amount of energy implied increases, comminution increases and even segmental fractures develop.

Direct violence or high energy trauma as a result of motor vehicle, motorcycle and other road traffic accidents cause severe soft tissue and bone damage. Crushing injuries can be seen in road traffic accidents and industrial injuries where high concentration of energy is applied over a small area with resulting increased damage to bone and soft tissue.

The type of fibular fracture related with that of tibia indicates the degree of soft tissue trauma involved. Severe comminution of fibula or tibiofibular diastasis specifies an unstable fracture with relative devascularization of fracture fragments and attendant high rates of delayed, non or malunion.

CLASSIFICATION OF FRACTURES

Descriptive Classification

- Open versus closed
- Anatomic location:

  proximal

  middle

  distal third

- Fragment number and position

  Comminution

  butterfly

- Configuration: transverse, spiral, oblique
- Angulation: varus/valgus, anterior/posterior
- Shortening
- Displacement: percentage of cortical contact
- Rotation
- Associated injuries

AO CLASSIFICATION OF TIBIAL FRACTURES:

Proximal fractures:

41-A: Extraarticular fracture

41-A1 avulsion

41-A2 metaphyseal simple

41-A3 metaphyseal multifragmentary

41-B: Partial articular fracture

41-B1 pure split

41-B2 pure depression

41-B3 split-depression

41-C: Complete articular fracture

41-C1 articular simple, metaphyseal simple

41-C2 articular simple, metaphyseal multifragmentary

41-C3 articular multifragmentary

DIAPHYSEAL FRACTURES

42-A: Simple fracture

42-A1 spiral

42-A2 oblique (≥30°)

42-A3 transverse (< 30°)

42-B: Wedge fracture

42-B1 spiral wedge

42-B2 bending wedge

42-B3 fragmented wedge

42-C: Complex fracture

42-C1 spiral

42-C2 segmental

42-C3 irregular

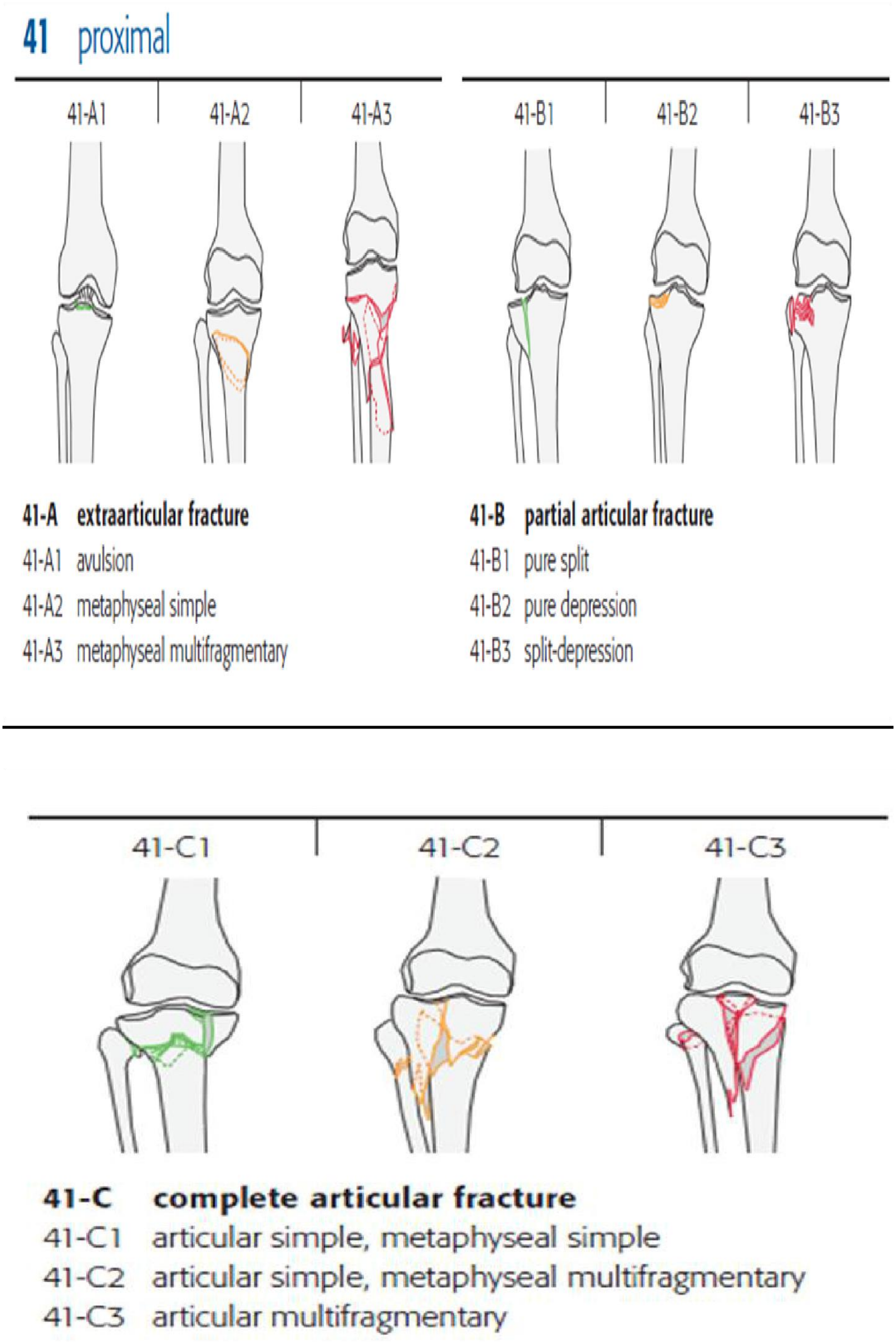


Fig. 5a - Proximal Tibial Fractures classification

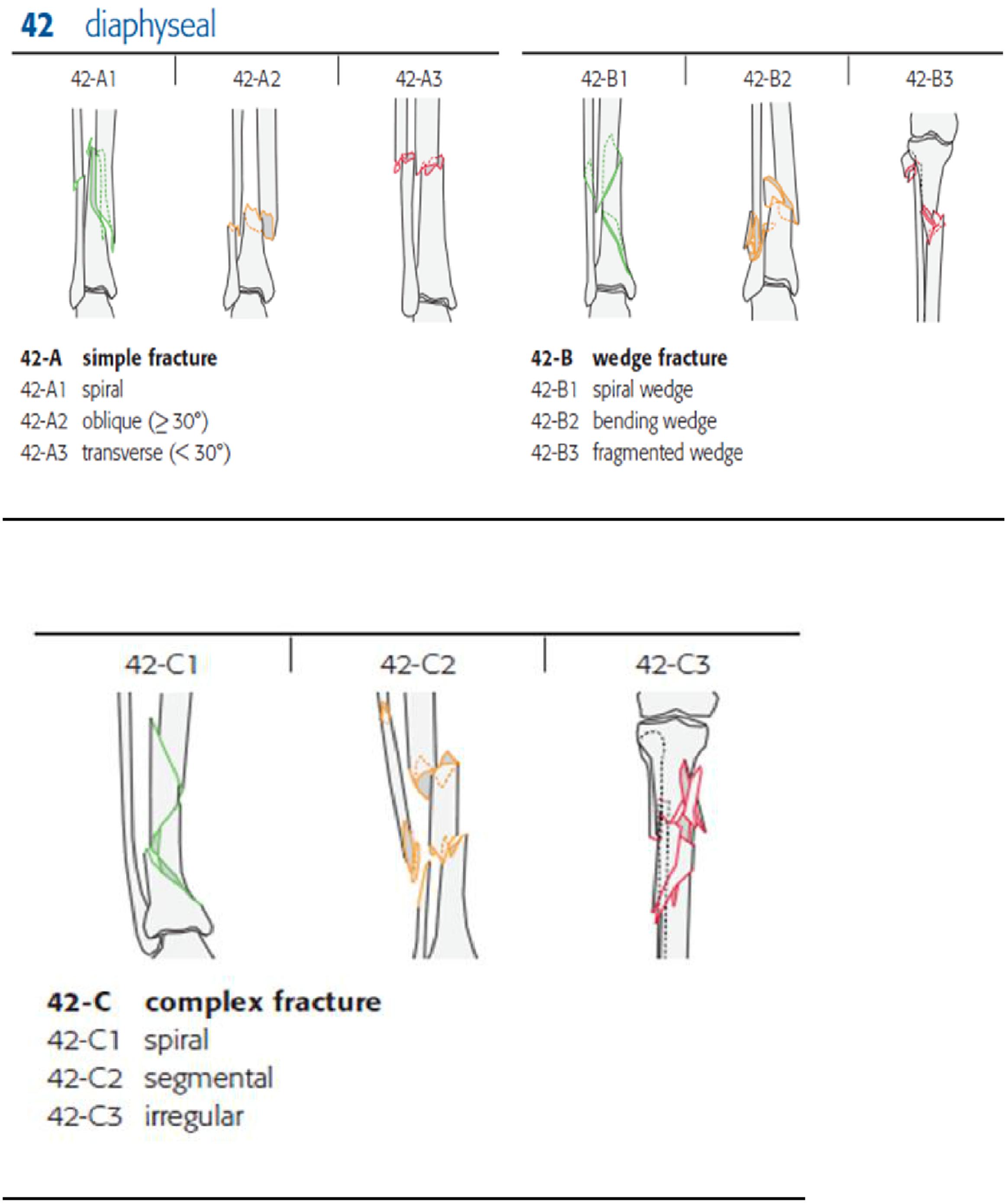


Fig. 5b – Diaphyseal tibial Fractures classification

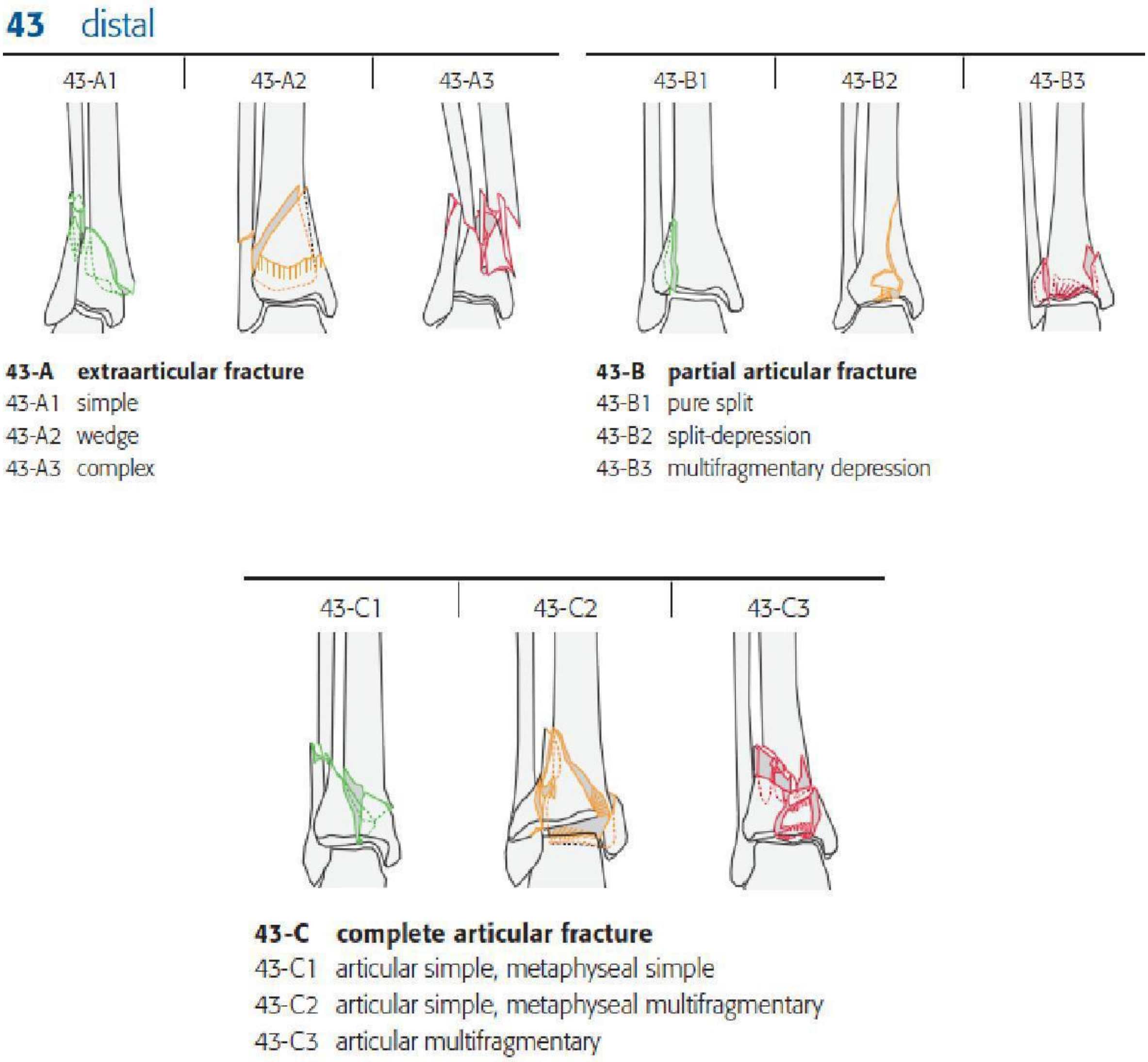


Fig. 5c – Distal tibial Fractures classification

CLASSIFICATION OF OPEN FRACTURES:-

Open fractures are classified into three major types (one of which has three subtypes), according to the mechanism of injury, the degree of soft tissue damage, the configuration of the fracture, and the level of contamination

Gustilo *et al*[64] classified fractures on the basis of compounding as follows:

Type I: Wound less than 1 cm.
No contamination,
Minimal soft tissue injury,
Low energy trauma.

Type II: Wound more than 1 cm,
Moderate contamination,
Moderate soft tissue injury,
Moderate comminution of bone.
Moderate velocity trauma.

Type III: A) More than 10cm wound,
Highly contaminated,
Severe soft tissue injury or crushing,
Comminution at fracture,
No periosteal stripping,
Usually soft tissue coverage possible.

Type III: B) More than 10cm wound
Highly contaminated,
Very severe soft tissue injury with loss of coverage, periosteal stripping,
Bony coverage poor, often require soft tissue reconstructive surgery

Type III: C) Any open fracture with vascular injury which needs repair.

The injury in a Gustilo type I open injury may be treated in the same way as a comparable closed fracture. In most cases this involves surgical fixation. The outcome of these injuries is similar to that of their closed counterpart.

Classification of soft tissue injuries[65]:

The AO/ASIF group has proposed an open fracture classification to grade soft tissue injury

to be used in conjunction with the AO/ASIF alpha numeric fracture classification system. The soft tissue grade incorporates the degree of injury to the integument (IO for open injuries), muscle tendon injury (MT), and neurovascular injury (NV).

Skin lesions I0 (open fractures):

I01 = skin breakage from inside out

I02 = skin breakage from outside in <5cm, contused edges

I03 = skin breakage > 5cm, devitalized edges, circumscribed degloving

I04 = full thickness contusion, abrasion, skin loss

I05 = extensive degloving

Muscle / tendon injury (MT):

MT1 = No muscle injury

MT2 = Circumscribed muscle injury, one muscle group only

MT3 = Extensive muscle injury, two or more muscle groups

MT4 = Avulsion or loss of entire muscle groups, tendon laceration

MT5 = Compartment syndrome / crush syndrome

Neurovascular injury (nv):

NV 1 = No neurovascular injury

NV2 = Isolated nerve injury

NV 3 = Localized vascular injury

NV 4 = Combined neurovascular injury

NV 5 = Subtotal or total amputation

BIOLOGY OF FRACTURE HEALING WITH INTRAMEDULLARY NAILING

There are many advantages with intramedullary nailing in fracture healing compared to other modes of treatment options. Union is usually rapid because unlike rigid plate fixation external callus is rarely completely suppressed. This is due to the fact that a nail can never be completely rigid. Dynamically locked nails promotes movement at the fracture site along with axial micro motion and helps in the external bridging callus formation. This may be due to the fact that as the medullary blood supply is absent the periosteal vascular supply rises.

Intramedullary nailing avoids ―stress protection osteopenia and thus the risk of late refracture after nail removal is rare. Controversy exists regarding the damage to the vascular supply following reamed and non-reamed intramedullary nailing. Intramedullary nailing in any of its forms harms the endosteal blood supply. This blood supply is rapidly regenerated when a loose fitting nail is used. But when a reamed well-fitting nail is used, the viability of the bone depends on the alternative periosteal blood supply. If this blood supply is imperfect following some soft tissue damage, the whole of the diaphysis may get devascularized especially in the tibia[57]. This leads to two problems. Initially, there may be a delayed union, as revascularization can occur only slowly and secondly, the dead bone is predisposed to infection. Considerable surgical judgement is required in choosing the type of intramedullary nailing.

BIO MECHANICS OF INTERLOCKING INTRAMEDULLARY NAILS

All the intramedullary nails, regardless of their types, act as flexible internal splints providing stability for the fracture fragments from within. It is a load sharing device in which stress shielding is minimal due to the fact that it is situated close to the neutral axis of the bone where strain is minimal. The strain induced is now considered the most important factor in later stage of fracture callus remodeling.

Intramedullary locked nails, in addition to 3 point fixation and elastic impingement mainly provide stability by anchorage of the bone both proximal and distal to the fracture site by interlocking screws/bolts.

The mechanical behavior of IM nails depends on both material and geometry of the design.

Material:

Venable and Stuck in 1934 discovered an inert alloy of chromium, molybdenum and nickel and named it Vitallium. Later 18/12 SMO stainless steel, titanium and super alloys came into use. Most of the Orthopaedic nails are made of 316L stainless steel.

The bending rigidity depends on the moment of inertia of the design which is proportional to the fourth power of the radius and the quantity of the material, which is to say that the bending stiffness increases as the diameter and thickness of the nails increases. A 25% increase in diameter of the nail will double its bending strength. [66]

The rotation stiffness depends on the configuration of the cross section of the nail. Clinically, bending strength and stiffness can be increased by using unslotted thick nail with large diameter.

When an implant is loaded to failure, the resulting load deflection curve would show the structural properties of the implant.

Load Deflection Curve:

The elastic phase is the working area of the medullary implant. Part of the elastic portion is the stiffness of the object. The higher the stiffness, the more rigid is the object. As stiffness decreases the object turn into more flexible. An object will return to its original shape following load removal. As the load exceeds the proportional limit, a plastic deformation occurs and the shape of the object changes. Hence, the implant should not be overloaded beyond its proportional limits.

Material properties are defined geometrically in the stress strain curve. The stress is defined as load per unit area and strain is the change in length divided by the original length.

Stress Strain Curve:

The slope of this curve is called ‗modulus of Elasticity (Young's modulus). It is the constant proportionality between the stress and strain. It is a material property. E.g. a material with a high modulus is stiff, i.e. for high stress, little strain is produced.
Titanium has more strength because of low modulus.

Strength is the stress at which the implant fails. The yield strength is, at which the implant undergoes plastic deformation.

The structural characteristics and mechanical factors important in the design and evaluation of intramedullary implants are strength, stiffness and rigidity.

Fatigue failure occurs when an implant is cyclically loaded to a certain stress level.

Intramedullary nails are designed to share the load with the bone for a limited period, as the fracture heals. They are designed to bear significant loads for few million cycles, until fracture unites.

Working length is defined as the length of the nail spanning the fracture site from its distal point of fixation in the proximal fragment to its proximal point of fixation in the distal fragment. A less technical definition states that it is the distance between the two points on either side of the fracture where the bone firmly grips the metal. Thus, working length is the unsupported portion of the nail between the two major bone fragments and reflects the length of nail carrying the majority of the load across the fracture site.

The bending stiffness of a nail is inversely proportional to the square of its working length, while the torsional stiffness is inversely proportional to its working length. Shorter working length means stronger fixation.

Working length is affected by various factors. A nail has a shorter working length in bending, in fixation of a transverse fracture than in stabilizing a comminuted fracture. Two techniques which modify the working length are medullary reaming and interlocking. Medullary reaming prepares a uniform canal and improves nail bone fixation towards the fracture, thus reducing the working length. Interlocking screws also modify the working length in torsion by fixing the nail to the bone at specific points. The torsional stability is substantially improved by this technique and is directly related to the distance between the two fixation points. Weight bearing with an interlocked nail further improves the nail bone contact as the nail bends under axial load, reducing the working length and adding to the overall stiffness of the fixation.[66]

Interlocking nail can be locked in two modes – Dynamic and Static

1. **Dynamic locking** refers to transfixation only in the shorter fragment which is susceptible to rotational instability and allows intermittent compression of the fracture site during early weight bearing. It is indicated in fractures of the lower third and upper third of the shaft with no comminution and the contact area between the two major fragments is at least 50% of the cortical circumference.

2. **Static locking** refers to the placement of transfixing screws above and below the fracture. It controls the rotation, bending and axial loading. It is indicated when the fracture is comminuted, unstable to compression or subjected to rotational forces.
   Dynamization means removal of either the proximal or distal locking screws to allow increased axial loading of the tibia. There is no certain time interval when dynamization should be done. However, a general guide line would be 6-8 weeks postoperatively if there are no signs of fracture healing on X-ray. Ultrasound can help for the early diagnosis of fracture healing. Dynamization is not indicated if it compromises the tibial construct. In a nail locked statically, screws in the longer fragment (either proximal or

distal) should be removed and these screws if removed should not produce angulation or rotational deformity.

DESIGN OF EXPERT TIBIAL NAILS:

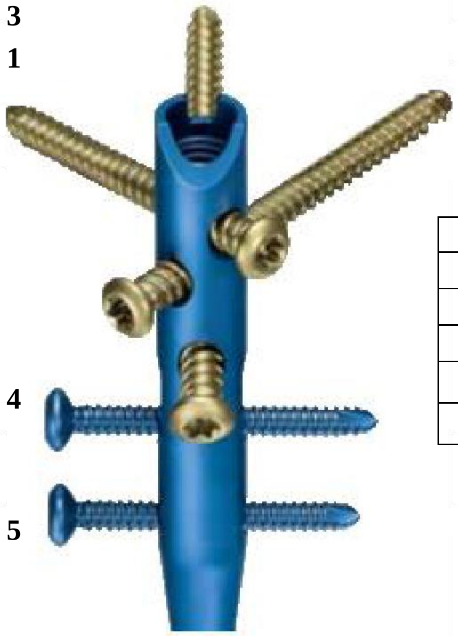
Numerous multiplanar locking options for expanded proximal and distal indications. New anatomic bend for facilitated nail insertion and extraction. Cannulated nails for reamed or unreamed techniques, enabling nail insertion over guide wire. Solid nails for unreamed technique. Possibility to block one oblique locking screw with the end cap for absolute angular stability. The first oblique locking hole lies at a distance of 14mm from the tip and second one at the distance of 20mm from the tip. The distal most locking hole lies within 5mm from the distal tip.

- The nails are available in length from 240mm to 420mm in 10mm increments.
- The locking bolts are self-tapping.
- For proximal medio-lateral holes and distal holes, 3.9mm diameter locking bolts are used.
- For proximal oblique and anterio-posterior holes, 4.9mm diameter locking bolts are used.
- For distal holes 3.9mm diameter locking bolts are used.

Locking bolts are available in length from 18mm to 50mm in 2mm increments.

Fig 6: Proximal and Distal Locking options for expert tibia nail

3
1
4
5



2

Screw direction	Screw size	Drill bit size
1^{st} :Oblique	4.9 mm	4 mm
2^{nd} : Oblique	4.9 mm	4 mm
3^{rd} : AP Oblique	4.9 mm	4 mm
4^{th} ML (dynamic)	3.9 mm	3.2 mm
5^{th} ML (Static)	3.9 mm	3.2 mm

1
3
2
4

Screw direction	Screw size	Drill bit size
1^{st} :ML	3.9 mm	3.2 mm
2^{nd} : AP	3.9 mm	3.2 mm
3^{rd} : ML	3.9 mm	3.2 mm
4^{th} Oblique for 9 and 10mm nail	3.9 mm	3.2 mm
4^{th} Oblique for 8 mm nail	3.6 mm	2.8 mm

Fig 7: Instruments used for expert tibia nailing

Cannulated nails
Of 8,9,10,11,12 mm

Reammers
Starting from
8mm

Guide wires

BONE AWL

PROXIMAL JIG

Sleeves

1. 80mmx10mm
2. 80mmx4.5mm
3. 80mmx3.2mm trocar

Drill bits

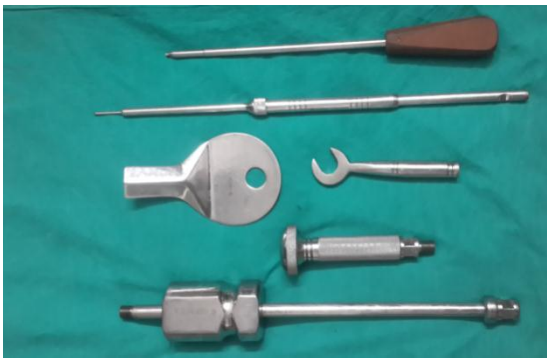
1. 4mm
2. 3.2mm
3. 2.8mm

Screws

1. 4.9mm
2. 3.9mm
3. 3.6mm

Other general instruments

1. Screw driver 3.5mm
2. Depth gauge
3. Tissue protector
4. Spanner



PROXIMAL INTERLOCKING

In a study conducted by Freeman AL and Craig MR *et al* on Biomechanical comparison of tibial nail stability in a proximal third fracture they concluded that more proximal fracture patterns should have multiple interlocking screws placed to prevent loss of reduction and improve mechanical stability. [67]

Matthias Hansen *et al* reported that triple proximal interlocking provides more stability in nailed proximal tibia fractures than double proximal interlocking. [68]

DISTAL INTERLOCKING

EXPERT TIBIAL NAIL has been used in the stabilization of more proximal and more distal fracture patterns.

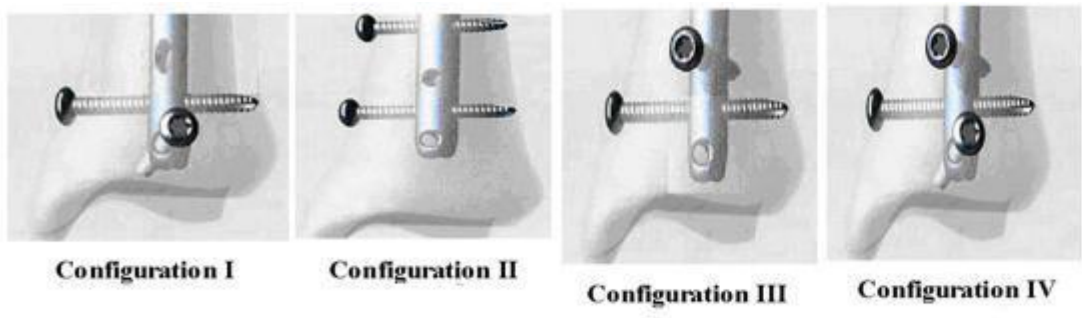
Brennen L. Lucas *et al* conducted a study on Biomechanical comparison of distal locking screws for distal tibia fracture intramedullary nailing Overall, when choosing intramedullary fixation (expert tibia nailing) for the treatment of distal tibia metaphyseal fractures, our data suggest that two medial to lateral screws may provide the necessary biomechanical stability for satisfactory fixation and clinical beneficial, because this not only saves operative and fluoroscopy time, but also may be economically advantageous compared to three distal locking screws and/or an oblique screw. [69]

Filon Agathangelidis *et al* conducted study on Distal Locking Screws for Intramedullary Nailing of Tibial Fractures and this biomechanical study showed that, using the Expert tibial nail for unstable distal tibial fractures, 2 parallel distal screws could provide the necessary stability under partial weight-bearing conditions. The use of 2 screws in a biplanar fashion, and even 3 or 4 screws in a bi- or triplanar fashion, does not appear to be justified unless technical difficulties are encountered during the implantation of the initial 2 screws. In the clinical settings, controlled trials comparing the use of multiple locking strategies are necessary to confirm these results. [70]

Chen *et al* showed that there is no statistical difference in nail stability between two parallel (medial to lateral) and two perpendicular (one medial to lateral, one anterior to posterior) nails in anterior, posterior, medial or lateral directions, or torsional loading. [71]

In our study minimum of two screws were put distally and the configuration pattern depended on the fracture type and pattern.

Fig 8: Different Configuration patterns for distal locking



ACCEPTABLE REDUCTION FOR TIBIAL FRACTURE.

Regardless of the treatment method chosen, the most important consideration is an acceptable reduction. Acceptable reduction denotes a position of fracture fragments that minimize angulatory, rotational and length deviation from what is normal for the patient. The primary concern is, the effect malunion will have on gait and stresses on the knee and ankle joint. Cosmetic and radiographic appearances are of minimal concern and are never by themselves indications for operative treatment**.**

Nicoll EA (1964) stated that more than 10^0angulation in any plane and shortening more than 2cms was unacceptable.[16]

Dehne *et a*l (1961), Sarmiento A (1976) and Brown PW *et al* (1969) reported satisfactory function when angulation was less than 10^0. None of the authors advocated reoperation for symptoms of malunion of 10^0 or less.[14,72,73]

Rockwood and Green prefer to set goal of 5^0 for varus and valgus angulation. 10^0 for anterior and posterior angulation and 10^0 or less for rotation and 1cm or less for leg length discrepancy, however, more deformity have to be accepted to obtain union but it is preferable to prevent a malunion than to correct it later. The most commonly used clinical guide for reduction is the alignment of the anterosuperior iliac spine with the middle of patella and the second toe in the anteroposterior plane. Rotation and lateral alignment are best determined by comparison to opposite extremity. [62]

Although tibial metaphyseal fracture may heal with 100% displacement, delayed and non-union are more common in adults with this degree of displacement. No distraction should be tolerated because as little as 5mm of distraction may increase healing time of tibial fracture to 8-12 months.

METHODS OF TREATMENT

Every fracture of the tibial metaphysis must be assessed individually, and it can be dangerous to establish fixed routines of treatment.

1. Closed reduction and plaster immobilization:

For closed fractures and low energy open fractures (stable fractures), closed reduction is done by simple manipulation under anaesthesia. A long leg cast with adequate padding over the malleoli, back of the head and neck of the fibula is applied with 15-20 degree of flexion at the knee for 4-6 weeks. Later, Sarmiento cast (patellar tendon bearing cast) is applied for about 8 weeks[62]. Some of the advantages are, firstly fracture hematoma is not disturbed and secondly there is no risk of infection. But it is also associated with disadvantages such as 1) It does not always maintain the length of the tibia.
2) Requires a good deal of patience and time both from the physician and a patient.

2. Pins and Plaster:

Unstable and open fractures can be treated with plaster casts incorporating transfixation pins. Here two Steinmann pins are inserted in the proximal end and distal end of tibia. Closed reduction is done and below knee plaster cast is applied. Care has to be taken not to distract the fragments when the cast is applied and provided, the pins are removed after 3 to 6 weeks. This method has been valuable for distal tibial fractures, including those with joint extension, especially the rotation type of pilon fractures. This method has an advantage of maintaining the length, prevention of rotation and allows the mobilization of knee. This has the disadvantage of pin tract infection and pivoting of the bone and angulation at the fracture site. [17]

3. Transfixation by screws:

To treat long oblique (more than three shaft diameters) or spiral fractures that range into the metaphysis, fixation with a lag screws can be done. One or more screws may be used. Rarely is fixation by screws alone sufficient, but this technique may be useful to supplement external fixation by stabilizing large butterfly fragments to one of the principal fragments. It requires stabilization externally with a plaster cast. This is not a stable fixation and is not an accepted method of treatment today.

4. Fixation by Plate and Screws:

Fixation with plates is most appropriate for closed tibial fractures and open fractures (Gustilo's type I) with good soft tissue exposure. Advancement in this technique is using minimally invasive percutaneous plate osteosynthesis. In this technique the fracture hematoma is preserved and soft tissue coverage problems are comparatively less to that of open plating. Plating has its own disadvantages. It is a load bearing device and hence may lead to delay in union and breakage of implant. The difficulty in closure of skin is a major problem encountered in the leg. The stripping of soft tissue required for application of a plate, however, has led to an unacceptable rate of infection in patients with open tibial fractures. Also after plate removal, a period of about 3 months should be allowed for obliteration of screw holes before strenuous activity can be undertaken.

Most authors now recommend plating for tibial shaft fractures associated with displaced intraarticular fractures of the knee and ankle. [62]

5. External Skeletal Fixation:

The popularity of external skeletal fixation for the management of open fractures has waxed and most often indicated for type IIIB and IIIC open fractures of tibia and fibula[74]. Multiple tensioned wires on a ring are useful to stabilize juxta – articular fractures and can be combined with percutaneous cannulated screws for fixation of intra articular fractures. By using the principles of distraction osteogenesis or segment transport, bone defects can be replaced and leg length equalized without needing bonegraft.[62,75]

External fixators provide rigid fixation with a relatively low rate of deep infection but they have the disadvantages of frequent pin-tract infections and malunion, a poor appearance and loss of reduction after removal and this technique has long learning curve and has a higher complication rate than intramedullary fixation.

6. Intramedullary Nailing:

This is the most accepted surgical treatment modality. Healing is rapid with abundant callus. These are load sharing devices hence implant induced osteopenia is not encountered.

Intramedullary nails, such as Lottes and Ender nails, used without reaming, have been employed successfully in the treatment of open tibial fractures and have showed lower rates of post-operative infection. As there tends to be shortening or displacement of such fractures around these small nails, they are contraindicated for comminuted fractures. The locking of intramedullary nails to the major proximal and distal fragments reduces the prevalence of malunion. [62]

OPEN TIBIA FRACTURES

These are the essential steps to be taken[76, 77] (listed in the order in which they are taken):

1. Treat the open tibia fracture as an emergency. A delay of over 8 hours can allow a contaminated fracture to become infected.
2. Start intravenous antibiotic treatment before debridement and irrigation. Give cefazolin for type I fractures. Cefazolin and an aminoglycoside for type II and type III fractures. For farm injuries or any type of soil contamination, add 10 million units of penicillin. If the patient is allergic to penicillin and cephalosporin, prescribe clindamycin or vancomycin
3. Perform adequate debridement and irrigation. The aim is to transfer a contaminated wound to a relatively clean wound. Repeat debridement in 48 to 72 hours is a necessity in type III open fractures.
4. Stabilize the fracture: usually vis hybrid external fixator.

5. Reconstruct the soft tissue in 3 to 5 days. Early soft tissue reconstruction is the key for preventing wound sepsis. If the wound is left open for several days, hospital bacterial flora will colonize the wound.
6. Delay bone grafting until complete wound healing (4 to 6 weeks) is ensured. For type III open fractures, use autogenous bone graft. For type I and II fractures with fracture comminution, autogenous bone grafting can be done at wound closure.
7. Begin early rehabilitation
8. Recognize and effectively treat complications e.g., compartmental syndrome, wound sepsis, and gas gangrene

COMPLICATIONS

Complications are common after fractures of the tibia and fibula and whether it is related to the fracture or to its management. Following are the usual complications:

1. **Infection:** Infections are more common in the fractures with less soft tissue cover and bone is subcutaneous and most commonly infections are seen in open fractures. In open fracture the prevalence of infection correlate directly with the extent of soft tissue damage. The rate of infection for type I fractures has ranged from 0-3%;and 2to7% for type II ; overall range for type III is from 10-25%; 7% for type IIIA, 10-11% for type III B and for 25 to 50% for type IIIC. Principles for general management of infection include drainage of the contaminated area, debridement of all devascularized bone and soft tissues, stable fixation, appropriately timed soft tissue coverage and careful use of appropriate antibiotics.
2. **Loss of skin and soft tissue:** It is the common problem in open fractures of tibia. In closed fracture the skin and soft tissue injury is important as well. To reduce the incidence of contamination and delayed union early full thickness soft tissue coverage is essential.[78]
3. **Delayed and Nonunion:** In distal tibia delayed and nonunion is a common problem that is severe and disabling. The factors which are more responsible for nonunion or delayed union include fracture displacement, bone loss, associated fibular fractures,

comminution and infection. Excessive motion at the fracture site which occurs due to inadequate fixation or internal fixation is another causative factor.

4. **Compartment syndrome:** After fracture of tibia anterior compartment syndrome is most common to occur and it is seen commonly in shaft fractures than distal third. After the open fracture of the tibia the chances that compartment syndrome may develop should not be over looked. Gustilo R B *et al* reported that in compartment syndrome fasciotomy is required for the open tibial fracture in 2.7% of the patients. Blick*et al* reported that patients who had an acute open tibial fracture the occurrence of compartment syndrome is 9.1%. For the patients in whom the clinical diagnosis of compartment syndrome is made decompressive fasciotomy is the treatment required.[75,77]
5. **Bone defects:** in case of open fractures and bone being subcutaneous in this region bone loss can be anticipated.
6. **Malunion and shortening:**

- The four most important criteria for judging position of the tibia are angulation in the anteroposterior and mediolateral planes, shortening, rotational malalignment, and displacement.
- In proximal third and distal third fractures malunion is more common
- In AP and lateral plane if Malalignment< 10mm it is acceptable
- If clinical symptoms like ankle or knee pain is present and if Malalignment more than 15 to 21^0 osteotomy is required. External rotation is more acceptable than internal rotation. More than 10^0 Internal rotation may cause gait disturbances, whereas, 20^0 external rotation usually does not cause a significant gait disorder.
- In tibial fractures Shortening of some degree is common. < 1cm of Shortening is acceptable. Many authors believed that especially in early weight bearing protocols physiologic shortening allows impaction of the fracture site and promotes union,[62]

7. **Vascular injuries:** Except in high energy trauma that causes comminuted, markedly displaced, and often open tibial fracture, vascular injuries are rarely to occur at the time of tibial fracture. Upper portion of the tibia where the anterior tibial artery passes from behind through the interosseous membrane is the most common site of vascular injury. The artery may be lacerated by a fracture fragment or occluded by direct pressure from the bone or soft tissue swelling. Primary amputation is required for irreparable vascular damage at the level of the injury.

8. **Nerve injury:** Peroneal nerve injury rarely occurs when the high energy trauma causing proximal fibular fractures with gross varus displacement of the distal fragment or direct trauma to the fibular neck
9. **Joint stiffness and ankylosis:** The uncommon complication which occurs after tibial fracture is bony or fibrous ankylosis, but joint stiffness may involve the knee, ankle, or subtalar joint. Opinion is divided according to the cause of this joint stiffness; some consider that it occurs from the prolonged immobilization, while others believe it occurs due to initial soft tissue injury or from secondary infection**.**

10. **Traumatic arthritis:** Unless there is intra articular extension of the fracture traumatic arthritis is unusual
11. **Reflex sympathetic dystrophy:** After tibial fractures in patients who cannot bear weight early and in those who are immobilized in casts for long periods, reflex sympathetic dystrophy (Sudeck's Osteodystrophy) is most common. These patients usually have severe fractures with significant soft tissue damage. The massive sympathetic response in the leg and foot is manifested initially by swelling and pain and later by atrophy of the limb. Radiographically, reflex sympathetic dystrophy appears as spotty areas of demineralization in the bones of the foot and distal tibia. Gradual remineralization occurs as weight bearing progresses. Reflex sympathetic dystrophy generally can be treated by gradual weight bearing. Sympathetic nerve blocks may also be of benefit. In patients with deformity of the foot, usually equinovarus, a double upright ankle foot orthosis with a lateral T-strap may be helpful. [62]
12. **Refracture:** An inadequately healed fracture may refracture if the cast is removed too soon or if unusually heavy stress is applied to a healed but still weaker than normal tibia. Osteopenia beneath the compression plate has been a frequently reported complication of rigid fixation with compression plates.
13. **Fat embolism:** Fat embolism occurs in 0.5-2% of patients with single long bone fracture. Fat embolism can occur after tibial fracture and the signs and symptoms being same as after other fractures. An incidence of 19% of fat embolism in isolated tibial fracture in healthy young skiers has been reported. [62]

MATERIALS AND METHODS

1. SOURCE OF DATA:

- Patients admitted in Department of Orthopaedics in BLDE (Deemed to be University)'S Shri B.M.Patil's Medical College, Hospital and Research Centre, Vijayapura with diagnosis of diaphyseal / metaphyseal tibia fractures.
- The patients will be informed about study in all respects and informed written consent will be obtained.
- Period of study will be from October 2016- March 2018.
- Follow up period will be 1st month, 3rd month, and 6th month.

At start of study, permission was taken from hospital ethical committee and informed consent was obtained from all the patients. Thirty patients with metaphyseal/diaphyseal tibia fractures were selected for the study.

Inclusion criteria:

1. Patient aged 18 years and above.
2. Closed & Compound fractures Type 1 and Type 2, according to Gustilo Anderson classification
3. Diaphyseal fractures of tibia
4. Extra-articular metaphyseal fractures of proximal and distal tibia (simple, wedge, or complex)
5. Segmental and comminuted diaphyseal fractures of tibia

Exclusion criteria:

1. Patients below the age of 18 years
2. Compound fractures of Tibia, type 3, according to Gustilo Anderson classification
3. Comminuted intra-articular fractures
4. Polytrauma
5. Associated with neurovascular injuries
6. Contralateral tibia fractures
7. Patient medically unfit for surgery
8. Pathological fractures.
9. Patients treated conservatively

Preoperative preparation of patients:

- Patients were advised nil per orally 6-8 hours before surgery
- As per the requirement and need iv fluids were connected
- If needed adequate amount of compatible blood was arranged
- ½ cc TT injection given to patient if patient not taken in previous last 5 years
- Parts preparations of the involved entire lower limb with private parts and back done
- Written consent was taken after informing in their local language
- Tranquilizers HS
- IV Antibiotic was given half an hour before surgery after giving test dose
- Patient was shifted 30 minutes before surgery to operation theater

Before the operation, the length of the nail is calculated by subtracting 2 cm from the measurement taken from medial knee joint line to the tip of medial malleolus clinically on the normal limb and medullary canal is measured at the isthmus on the x-ray of the fractured limb. Accordingly implants were kept with nails 2cm above and below the measured length and 1mm above and below the required diameter were also kept. In this study cannulated stainless steel multidirectional interlocking Intramedullary nails (Expert tibia nails) were used.

Surgical technique:

Spinal or general anesthesia was used for operating the patients. Patient is placed in supine position over a radiolucent operation table. Free positioning of injured limb is done, over the edge of operation table with 90 degrees of knee flexion to relax the gastrocsoleus muscle and allow traction by gravity. The uninjured leg is placed in abduction, flexion and external rotation to ensure free movements of the image intensifier from AP to lateral plane. The table is adjusted to a comfortable operating height.

AO pneumatic tourniquet/Esmarch rubber tourniquet was used in all patients. The affected limb is thoroughly scrubbed from mid-thigh to foot with betadine scrub. The limb is painted with betadine solution from mid-thigh to foot. Rest of the body and other limb is properly draped with sterile drapes. Sterile gloves are applied to the foot and sterile drape over the leg from knee joint to ankle.

Determination of nail length

Hold the radiographic ruler parallel to the tibia shaft in such a way that the proximal end comes to lie at the level of the intersection point. Mark the skin at the appropriate point. Position the image intensifier over the distal tibia align the measuring ruler at the skin marking. With correct reduction, we can read off the required nail length on the image intensifier picture at the level of the epiphyseal cartilage.

Another way to measure the length of hollow and tubular nails is done by subtracting the exposed length of guide rod from its total length of 950mm.

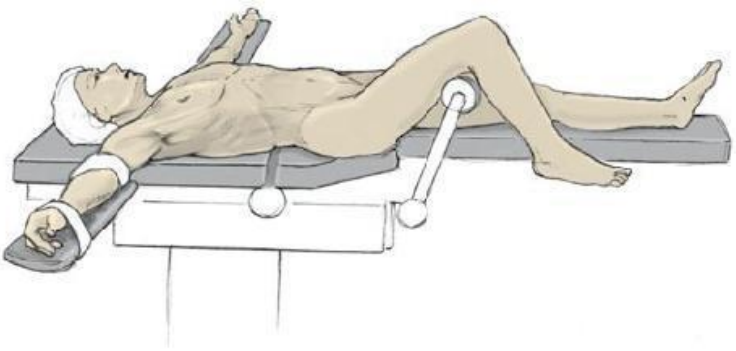
Determination of Nail Diameter:

The marking on the radiographic ruler may be used to determine the diameter of the medullary canal. Position the square marking over the isthmus. If the transition to the cortex is still visible both on the left and right of the marking, the corresponding nail diameter may be used.

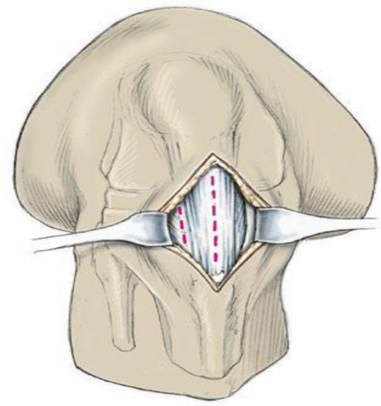
Procedure:

A vertical patellar tendon splitting incision over the skin from centre of the inferior pole of patella to the tibial tuberosity, about 5 cm long is made. Split the patellar tendon vertically in its middle and retract it to reach the proximal part of tibial tuberosity. Next step is to determine the point of insertion. In the AP view the entry point is in line with the axis of the intramedullary canal and medial to lateral tubercle of the intercondylar eminence. Whereas, in lateral view the entry point is at the ventral edge of the tibia plateau. If the insertion point is too distal, there is a danger of fracturing the distal cortex of the main proximal fragment.

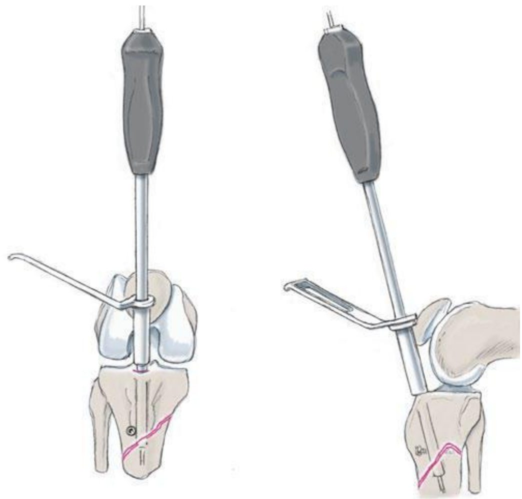
On the other hand, inserting too far proximally bears the risk of the opening the knee joint, patella comes in the way of zig or removal of the nail may be difficult. After choosing the point of insertion, curved bone awl is used to breach the proximal tibia cortex in a curved manner, so that from perpendicular position, its handle comes to be parallel to the tibia shaft. In the metaphyseal cancellous bone, create an entry point, making sure it is in line with the centre of medullary canal. Point of entry is broadened with a curved tibial awl.



POSITION OF PATIENT ON FRACTURE TABLE



MID PATELLAR OR PARAPATELLAR INCISION



OPENING THE MEDULLARY CANAL WITH CANNULATED CANAL CUTTER

Fig.9.Surgical technique

In the proximal third medullary canal is widened, 3mm diameter x 950mm length ball tipped guide wire passed into the proximal fragment's medullary canal and under the guidance of image intensifier the fracture fragments reduced, by maintaining longitudinal traction in the line of tibia.

After reduction, the tip of ball tipped guide wire is adjusted to pass in the distal fragment up to 0.5-1 cm above the ankle joint under image intensifier. Confirm its containment within the tibia by anteroposterior and lateral view. Sequential reaming of medullary canal is done, starting from 8mm reamer size to 0.5 to 1mm larger than the diameter measured using radiographs. Reaming is done with 0.5 mm increments, initially with the end cutter reamer and then replaced by side cutter reamer. Then the ball tipped guide wire is replaced with a smooth guide wire using a medullary tube. The assembled nail is placed over smooth guide wire.

Insert the connecting screw through the insertion handle and coupling block, then screw this assembly into the proximal end of the selected nail. Make sure that the notches of the insertion handle fits suitably into the grooves of the coupling block. The coupling blocks ensure a torque-resistant connection between insertion handle and the nail. The insertion handle guides the nail and controls rotation during insertion. Insertion handle is applied to the medial side of the tibia for insertion and proximal locking. Whole assembly with a combination wrench id tightened. Check that the assembly is firmly screwed together. Over tightening should not be done.

Nail is inserted as far as possible into the manually into the medullary canal using the mounted insertion instruments. Under the guidance of image intensifier nail is passed through the fracture site.

Insertion can be aided by gentle blows with the slotted hammer. Insert the nail until it is slightly counter sunk in the bone. Check the placement of nail in situ under image intensifier in both AP and lateral planes.

Usually we did proximal locking first, but in the presence of gap at the fracture site we carry out distal locking first, which enables the use of the rebound technique to prevent diastasis.

The insertion handle is used to locate the holes in the proximal locking bolts. The insertion handle of the insertion instrument is semi-circular with multidirectional locking facility. For medio-lateral locking option 3.9 mm locking screws are used. The dynamic locking option permits primary compression or secondary dynamization. For proximal oblique screws, 4.9mm locking screws were available. Drilling and introduction of the screw must be strictly monocortical to prevent lesions of the poplitial artery, the tibial and common peroneal nerve and injury's to the proximal tibio fibular joint. The skin is incised. Insert the trocar into the protection sleeve and push it down on to the surface of tibia through the corresponding hole in the insertion handle. Trocar is removed and drill sleeve is inserted. To prevent the drill bit from sliding off the tibial surface, ensure that the drill guide is sitting firmly on the bone and is not deflected by the skin or soft tissue.

Drill through both the cortices using the drill it. We used the power drill. Determine the required length of the locking bolt by reading it directly of the calibrated drill bit or by measuring with the depth gauge. When using the depth gauge, we added 2 mm to the measurement found so that the bolt can find purchase in the opposite cortex.

Hexagonal screw driver is used for the insertion of locking bolt. Incised wound is washed with betadine and normal saline, patellar tendon sutured with delayed absorbable sutures and skin is sutured. Fracture site is visualized in C-arm and if distraction is noted, compression at the fracture site is obtained by gentle hammering of the heel. It is important to maintain compression at the fracture site because a gap of 1mm will take at least 10 months to unite.

Next step, free hand technique is used for distal locking under the guidance of an image intensifier which provides a convenient technique for targeting the distal locking holes.

The leg is extended over the table from its flexed position. In expert tibial nail four distal locking holes are present two in medio lateral plane, one anteroposterior plane and one in oblique plane. In our study we locked minimum of two distally, depending on the extent and pattern of fracture other screws were placed. The image intensifier is positioned in the anteroposterior arrangement with the beam exactly at the anterior aspect of the tibia with foot held in neutral position. Adjust the image intensifier until the most distal hole is clearly visible and appears completely round.

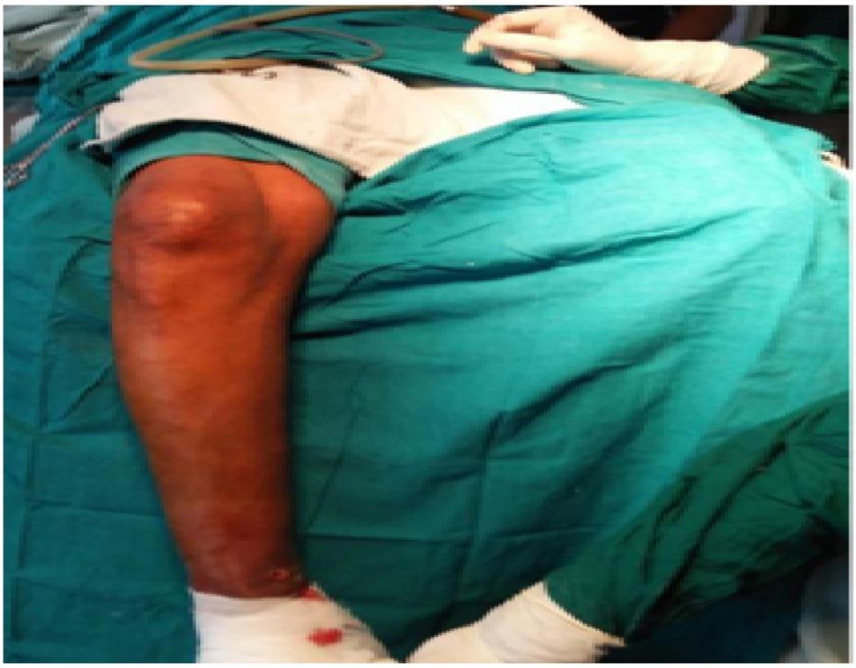
Place a scalpel on the skin with the blade over the centre of the hole to determine the stab incision point. Make a stab incision. Place the tip of the 2.5mm "K" wire centered in the locking hole image. Adjust it until the K wire is in line with the X-ray beam and appears as radio opaque solid circle in the centre of the outer ring. Hammer the K wire into the bone. The DCP drill sleeve is passed over the K wire and the sleeve is held firmly over the bone. The K wire is removed and with drill bit both the cortices are drilled. Measurement of the hole is done using depth gauge for locking bolts.

Add 2mm to the reading to ensure that the locking bolt will engage the far cortex. For distal locking 3.9mm screws are used but only for 8mm nail distal most screw which was oblique 3.6mm screws were used. In all the fractures 2 to 3 screws were used to achieve adequate stability distally. Insert the locking bolt and tighten with hexagonal screw driver. Position of the screw is again confirmed under image intensifier. The entire leg and the fracture site is washed with betadine and normal saline, skin is sutured. Sterile dressing applied over the wound. Compression bandage given. Elastocrepe bandage is applied over the dressing. Above knee slab is also considered if the fracture fixation is not stable. Tourniquet is deflated, capillary filling and peripheral arterial pulsations checked.

SURGICAL TECHNIQUE

Fig 10: Intra Operative Photographs

10.1. PARTS PAINTED AND DRAPED.



10.2. SKIN INCISION **10.3.TIBIAL AWL INSERTION**

10.4. DETERMINE ENTRY POINT

ANTERIO POSTERIOR **LATERAL**

10.5. INTRODUCING BALL-TIP GUIDEWIRE

10.6. REAMING

10. 7.INSERTION OF THE NAIL

10.8. DISTAL LOCKING

10.9 WOUND CLOSED

10.10 STERILE DRESSING

10.11 CREPE BANDAGE APPLIED

Postoperative Care:

Immediate

- Nil per orally for 4 to 6 hours postoperatively was advised to patient
- IV fluids / blood transfusion given based on the requirement and intra-operative patient assessment.
- IV antibiotic: injection Ceftriaxone with sulbactum given for 5 days and injection amikacin for3 days.
- IV / IM analgesics
- Tranquilizers HS
- Limb elevation over pillows
- Watch for active bleeding
- Active toe movements
- TPR/BP chart every hourly
- Input/output chart

Check X-ray of the operated tibia (full length) including knee and ankle joints in both AP and lateral views. Postoperatively elasto-crepe bandage is applied and limb is kept in elevation. IV antibiotic is given for 5 days postoperatively. Culture from wound if necessary is sent. Switch over to oral antibiotic is done on the postoperative day 5. Analgesics if required given for the patient. Based on the tolerance and general condition of the patient, they are kept non weight bearing with the assistance of walker on next postoperative day according to the general condition and tolerance of patient. On 12th postoperative day skin sutures/staples were removed .Based on the type of fracture, rigidity of fixation and associated injuries, partial weight bearing was gradually started.

Further follow up is done at 1st month, 3rd month, and 6th months and each patient is individually assessed clinically and radiographically according to the proforma.

The management protocol in this study was as follows:

a. The fixation of fractures was done as an elective procedure
b. Life threatening injuries or complications were given priority Appropriate referral was given to neuro surgeon, plastic surgeon and vascular surgeon for the management of their respective injuries. Physician reference was given for any medical illness.
c. Preoperative antibiotics started just before induction and continued for five postoperative days.
d. We used image intensifier for all cases.
e. All fractures were treated with closed interlocking intramedullary nails.

Wound inspection was done on second postoperative day and suture/ staple removal was done on 10-12th postoperative day.

FOLLOW UP:

At the follow-up, patients were assessed clinically and radiologically as follows:

CLINICAL

- Swelling
- Tenderness
- Any mobility at the fracture site
- Range of motion at knee and ankle joints
- Any other complication

RADIOLOGICAL

X-rays of leg, both AP and lateral views were taken to note any

- Angulation
- Bending of nail
- Breakage of screws/nail
- Displacement of fracture fragments
- Signs of union i.e. callus formation.
- Malunion – varus/valgus, anterior angulation >5^0

We used **Johner and Wruh's Criteria**[79] for evaluating the final results of tibial metaphyseal/ diaphyseal fractures treated with expert tibial nailing.

Criteria	Excellent (%)	Good (%)	Fair (%)	Poor (%)
Nonunion/infection	None	None	None	Yes
Neurovascularinjury	None	Minimal	Moderate	Severe
Deformity				
Varus/valgus	None	2-5	6-10	>10
Pro/recurvatum	0-5	6-10	11-20	>20
Rotation	0-5	6-10	11-20	>20
Shortening	0-5mm	6-10mm	11-20mm	>20mm
Mobility				
Knee	Full	>80	>75	<75
Ankle	Full	>75	>50	<50
Subtalar	>75%	>50	<50	
Pain	None	Occasional	Moderate	Severe
Gait	Normal	Normal	Mild limp	Significant
Activities				
Strenous	Possible	Limited	Severely limited	Impossible

OBSERVATION AND RESULTS

30 patients with tibial metaphyseal/diaphyseal fractures were treated with closed Expert tibial intramedullary interlocking nailing in Department of Orthopaedics in BLDEU'S Shri B.M.Patil's Medical College, Hospital and Research Centre, Vijayapura. Period of study from October 2016- March 2018.

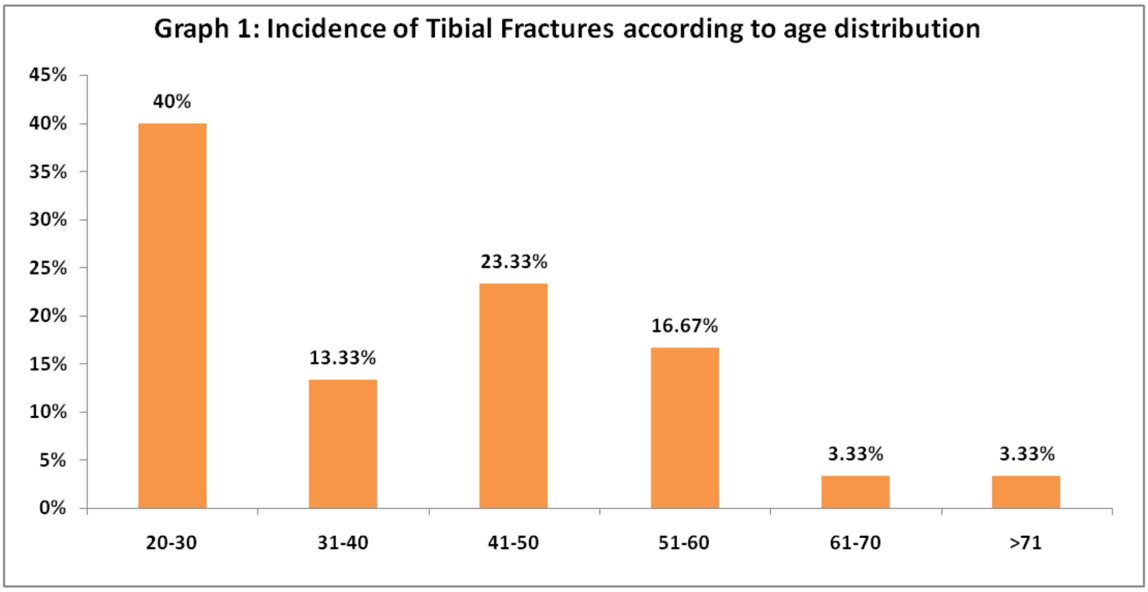
At least for a period of 6 months, patients follow up was done. We obtained follow up of all patients. Following factors were observed and tabulated as follows.

1. AGE DISTRIBUTION :

In our study, most of patients were in the age group ranging from 20-30 years. With mean age group of 40.1 years.

Table No. 1: Incidence of Tibial Fractures according to age distribution

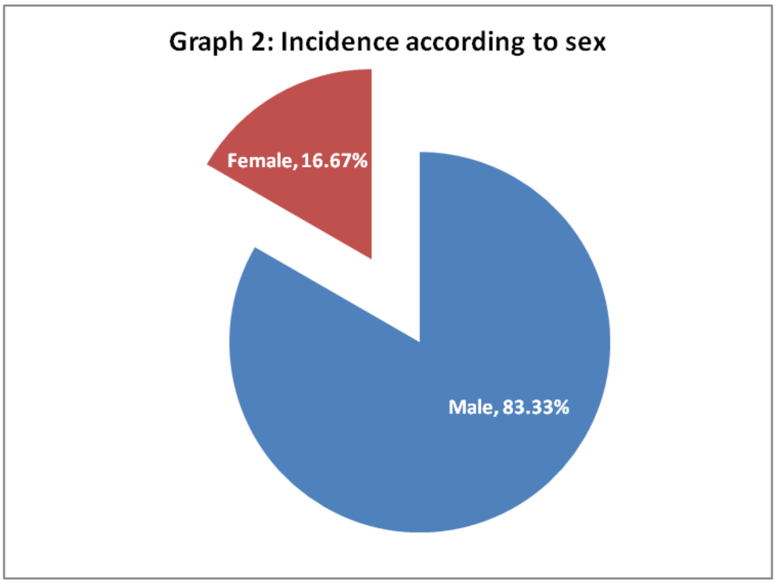
Age group	Percentage
20-30	40%
31-40	13.33%
41-50	23.33%
51-60	16.67%
61-70	3.33%
>71	3.33%



2. SEX DISTRIBUTION: Out of 30 patients 25 were male and 5 were female.

Table No. 2: Incidence according to sex

Age group	No. of cases	Percentage
Male	25	83.33%
Female	5	16.67%



3. SIDE OF FRACTURE:

In our study 16 cases had sustained right side tibia fracture and 14 cases had sustained left side tibia fracture.

Table No. 3: Incidence according to side of fracture

Side of Fracture	No of Cases	Percentage
Right side	16	53.33%
Left side	14	46.67%

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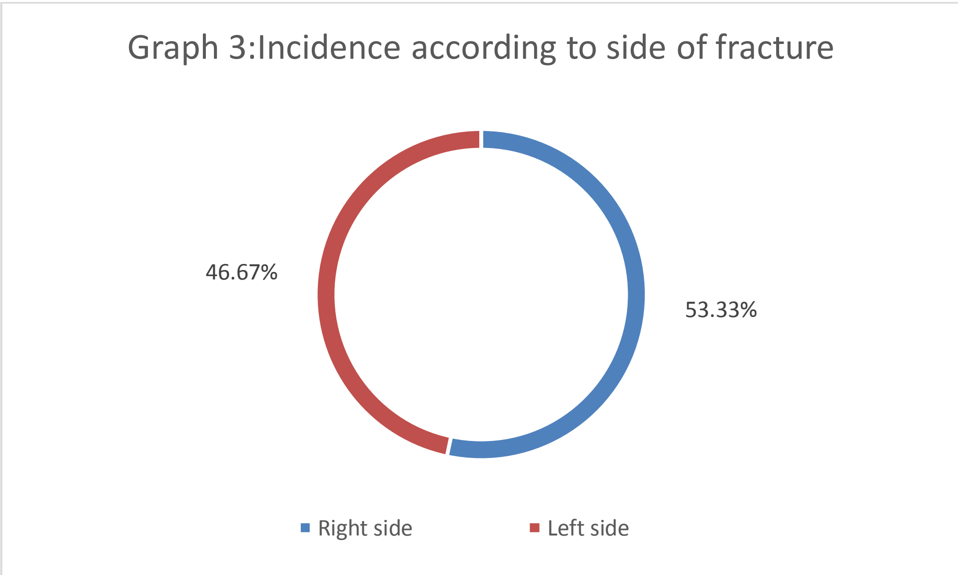
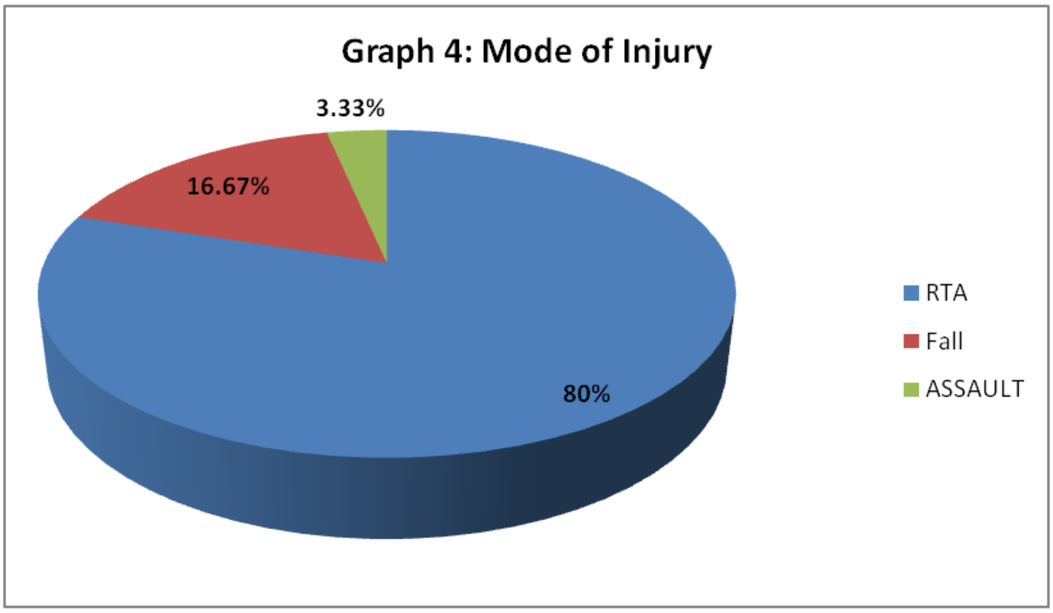


4. MODE OF INJURY:

The mode of injury for 24 patients were road traffic accident which accounted for about 80 %, 5 were due to fall which accounted for 16.67 %, 1 was due to assault which accounted for 3.33 %.

Table No. 4: Mode of injury

Mode of injury	No of Cases	Percentage
RTA	24	80%
Fall	5	16.67%
ASSAULT	1	3.33%



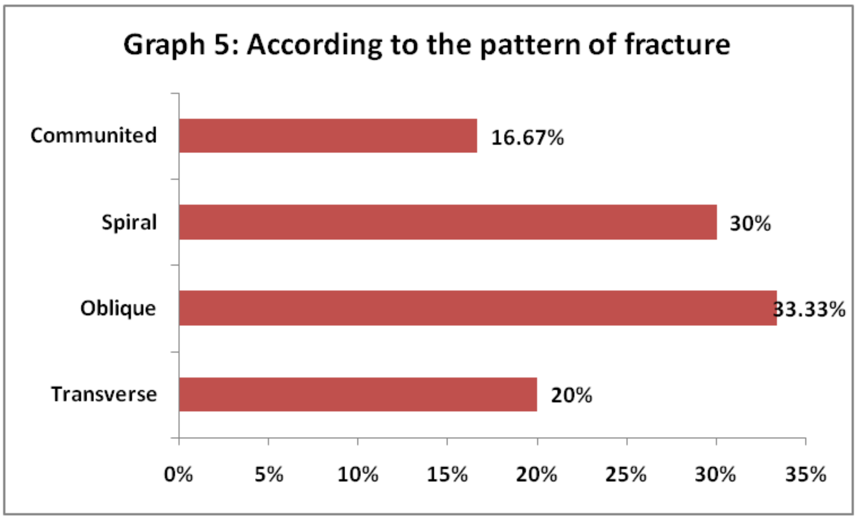
5. PATTERN OF FRACTURE

In our study 10 patients had oblique fractures, 9 had spiral fractures, 6 had transverse fractures and 5 sustained communited fractures.

Table No. 5: According to the pattern of fracture

Fracture pattern	No. of cases	Percentage
Transverse	6	20%
Oblique	10	33.33%
Spiral	9	30%
Communited	5	16.67%

Oblique fractures were more commonly seen in our study.

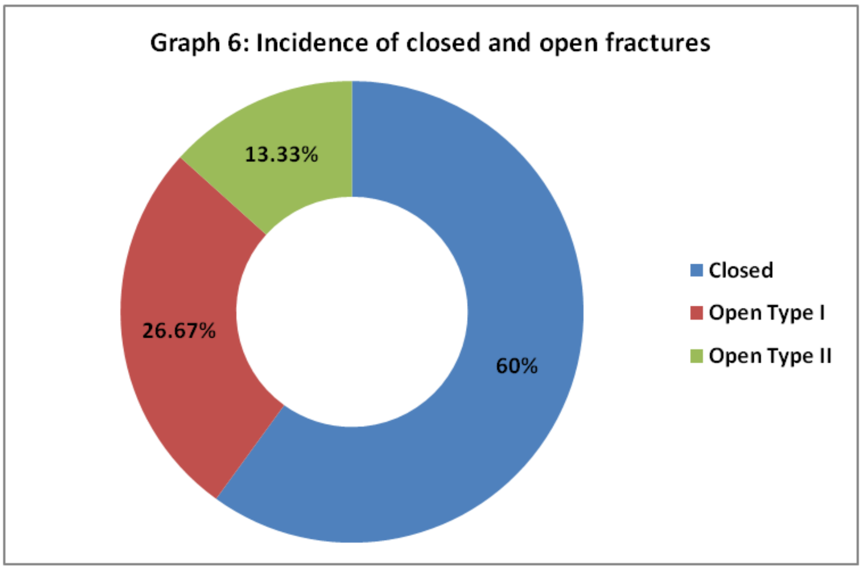


6. TYPE OF FRACTURES

We classified tibial fractures into closed and open. The open fractures were classified according to Gustilo's grading. Open fractures of tibia treated definitely with external fixator were excluded from the study.

Table No. 6: Incidence of closed and open fractures

	Closed	Open	
		Type I	Type II
No. of Cases	18	8	4
Percentage	60%	26.67%	13.33%



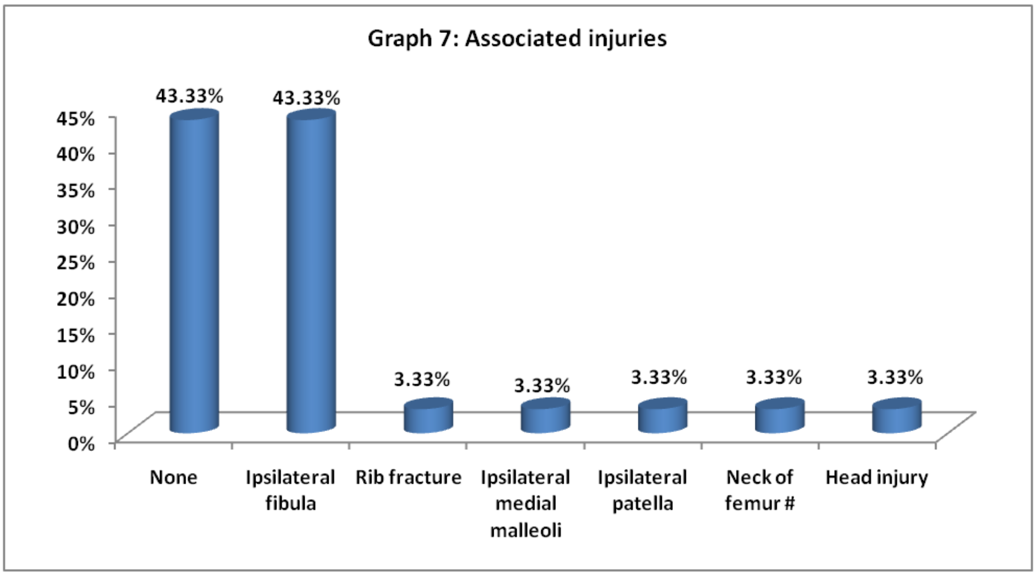
7. ASSOCIATED INJURIES

Table No. 7: Associated injuries

Nature of Injury	No. of Cases	Percentage
None	13	43.33%
Ipsilateral fibula	13	43.33%
Rib fracture	1	3.33%
Ipsilateral medial malleoli	1	3.33%
Ipsilateral patella	1	3.33%
Neck of femur #	1	3.33%
Head injury	1	3.33%

These associated injuries may delay surgery and predispose for many complications, Polytrauma head injury and chest injury play important role in outcome.

There were 13 patients who had no associated injuries and 13 patients who had ipsilateral fibula fracture .There was one patient with head injury and was operated immediately after neurosurgical clearance. One patient had ipsilateral medial malleoli fracture which was treated by Percutaneous AO cannulated screw. One patient had ipsilateral patella fracture which was treated by k wires and tension band wiring. There was one patient who had neck of femur fracture, was treated with bipolar prosthesis.

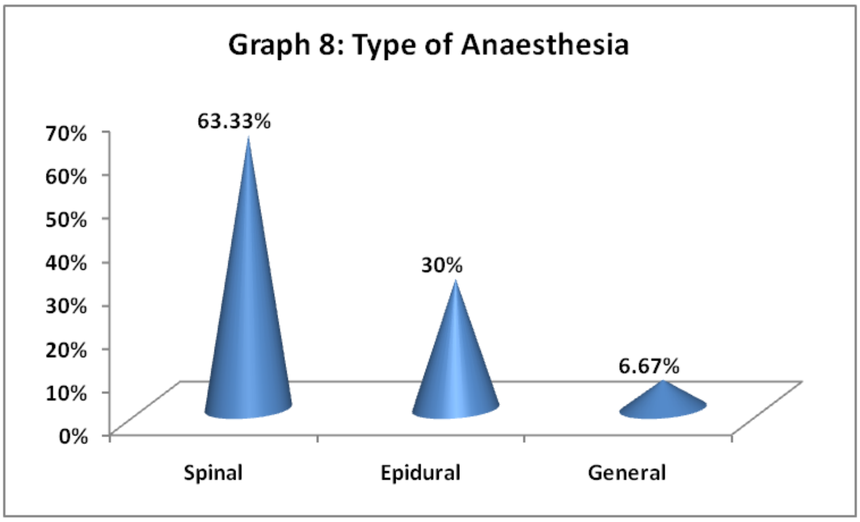


8. TYPE OF ANAESTHESIA:

19 cases were operated under spinal anaesthesia, 9 under epidural anaesthesia and 2 case under general anaesthesia.

Table No. 8: Type of Anaesthesia

Type of Anaesthesia	No. of Cases	Percentage
Spinal	19	63.33%
Epidural	9	30%
General	2	6.67%



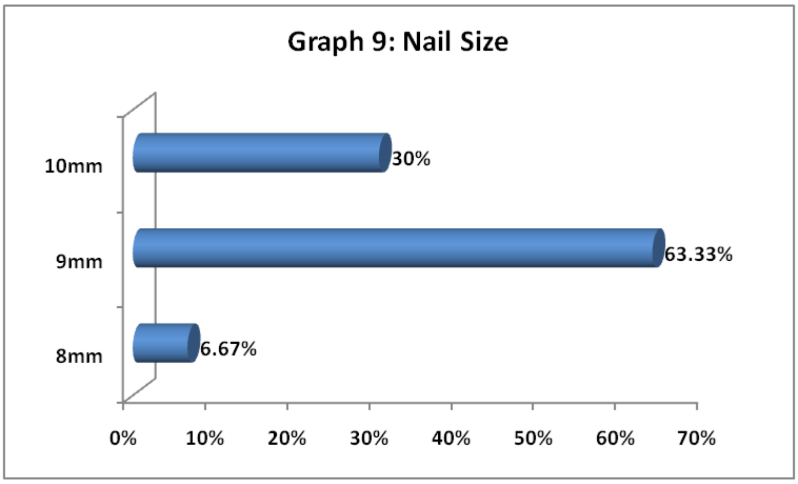
Approach: All the 32 nails were inserted through a patellar tendon splitting approach.

9. NAIL SIZE

Nail size and locking: Majority of the nails inserted were 9mm in 19 patients, 9 nails were of 10mm diameter and 2 were of 8mm diameter.

Table 9: Nail Size

Nail size	No. of Cases	Percentage
8mm	2	6.67%
9mm	19	63.33%
10mm	9	30%



10. PATIENT MOBILIZATION:

Joint mobilization exercises were started for all the patients on 1 post-operative day. Irrespective of fracture configuration partial weight bearing was delayed for 6 weeks. The average period of commencement partial weight bearing was 7 weeks and full weight bearing was 13.43 weeks.

Table 10- COMMENCEMENT OF PARTIAL WEIGHT BEARING

Partial weight bearing(PWB)	Number of patients	Percentage
6 weeks	19	63.33%
8weeks	9	30%
>10 weeks	2	6.67%
Total	30	100.00%

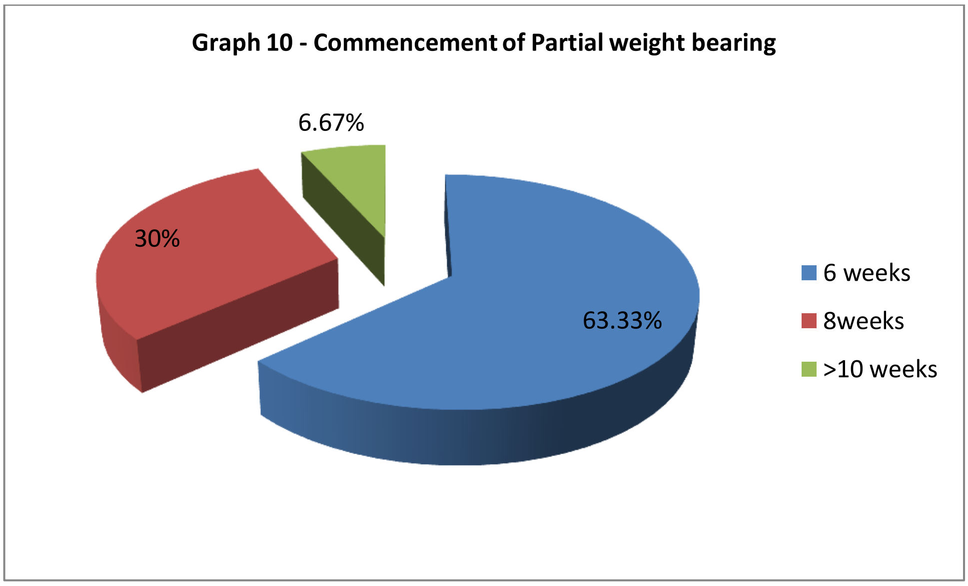
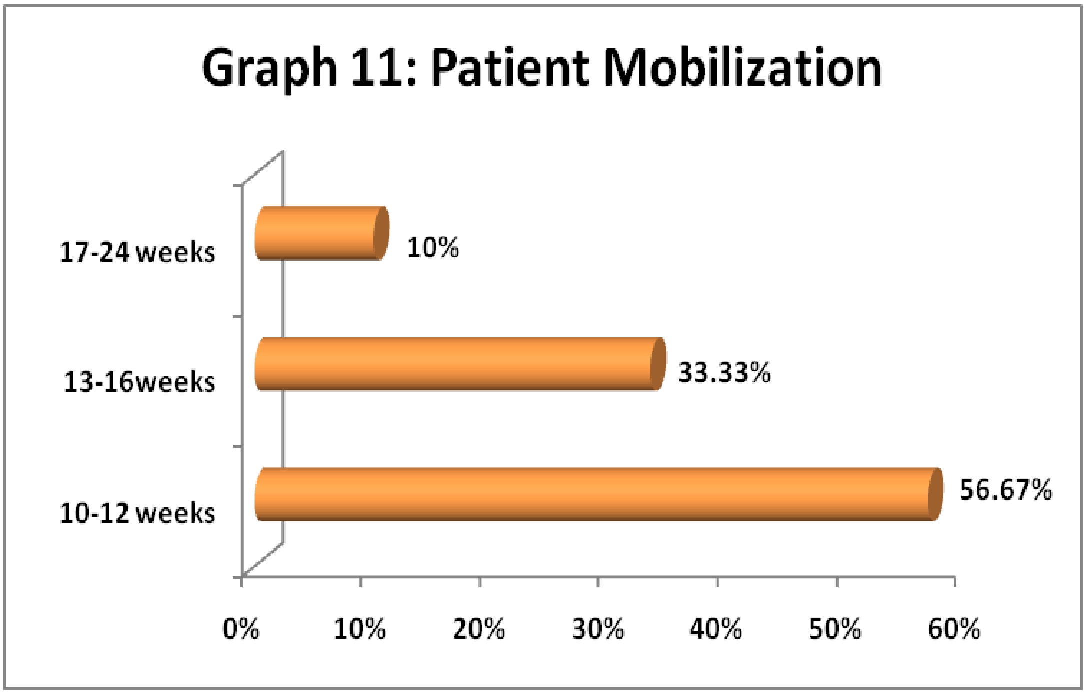


Table No. 11: COMMENCEMENT OF PARTIAL WEIGHT BEARING

Full weight bearing (FWB)	Number of patients	Percentage
10-12 weeks	17	56.67%
13-16weeks	10	33.33%
17-24 weeks	3	10%
Total	30	100%



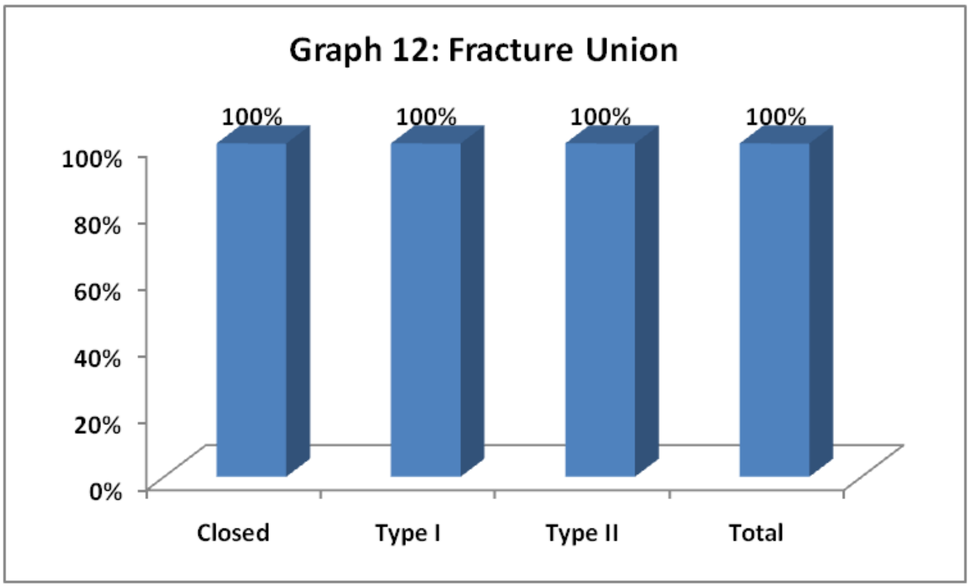
12. UNION:

20.33 weeks was the average time taken for union, closed fracture and Type I open united earlier at (18.66 weeks and 21.75 weeks respectively) when compared to Type II fracture took 25 weeks

100% of the fractures united with 3 fractures showing a delayed union

Table No. 12: Fracture Union

Type of Fracture	Union Rate
Closed	100%
Type I	100%
Type II	100%
Total	**100%**



13. SECONDARY PROCEDURE:

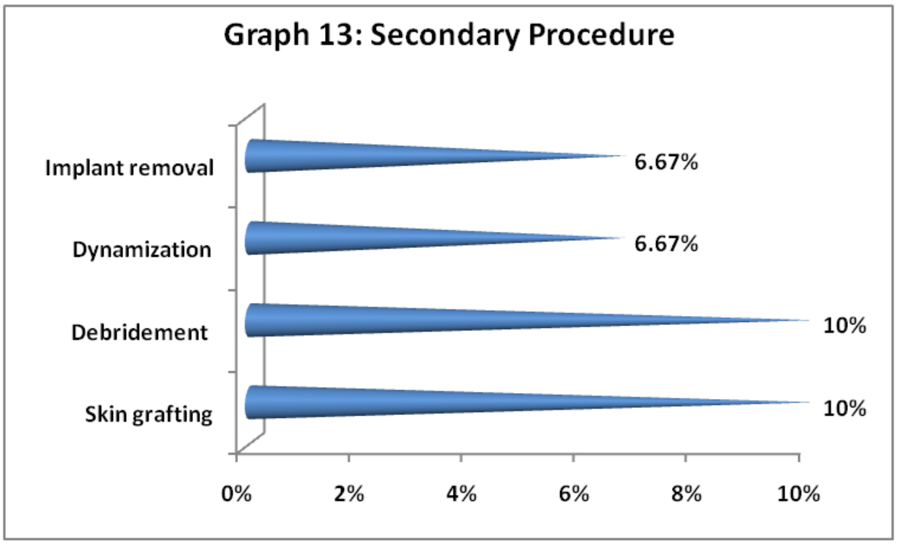
Skin grafting was done to cover the traumatic wound in 2 type II fractures whereas debridement was done in 3 cases.

Between 12 and 16 weeks based on the progress of fracture healing dynamization was carried out in 2 patients.

Implant removal done in 2 patients after one and half year

Table No. 13: Secondary Procedure

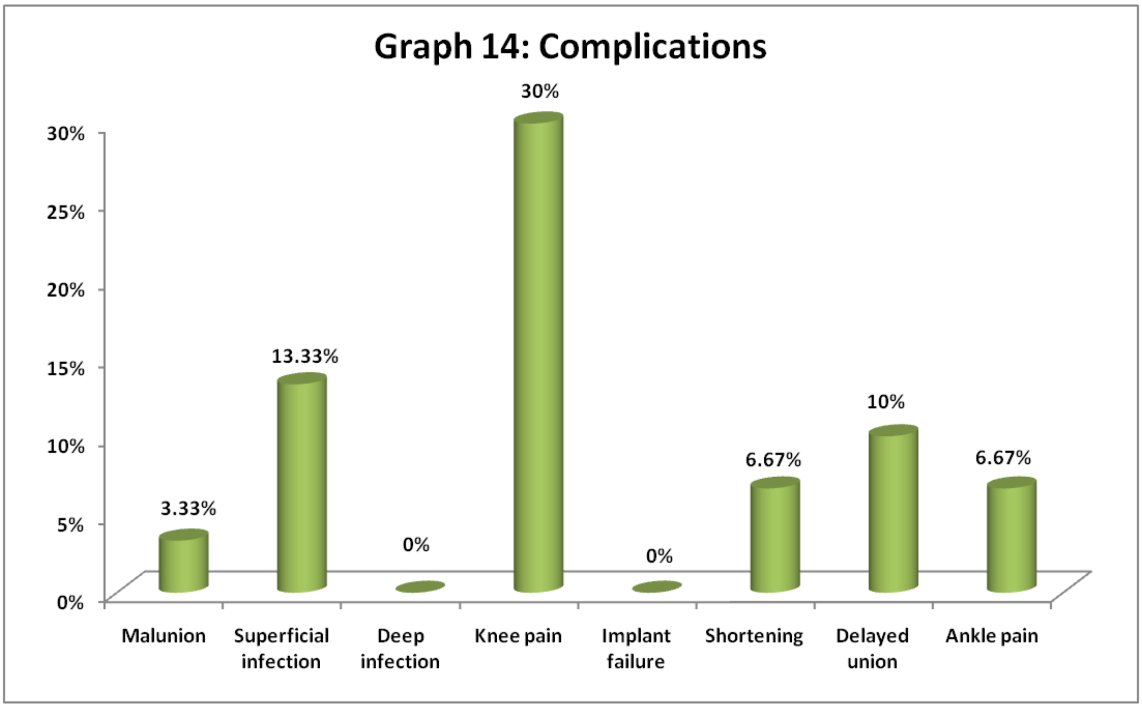
Procedure	No. of Cases	Percentage
Skin grafting	3	10%
Debridement	3	10%
Dynamization	2	6.67%
Implant removal	2	6.67%



14. COMPLICATION:

Table No. 14: Complications

Complications	No. of Cases	Percentage
Malunion	1	3.33%
Superficial infection	4	13.33%
Deep infection	0	0%
Knee pain	10	30%
Implant failure	0	0
Shortening	2	6.67%
Delayed union	3	10%
Ankle pain	2	6.67%



Infection:

Four patients had superficial infection (13.33 %) out of which two patients had from the proximal incision site for nail insertion and two patients from the distal screw locking incision site. None of the patients had deep infections.

Malunion:

One case (3.33%) of malunion was found with 5 degree of apex angulation and valgus angulation of 5 degrees,

Shortening: Two case (6.25%) showed a shortening of 1cm and 0.5cm respectively.

Knee pain:

Ten cases (30%) complained of knee joint pain at final follow up.
All were of mild variety and were treated with analgesics.

Range of motion:

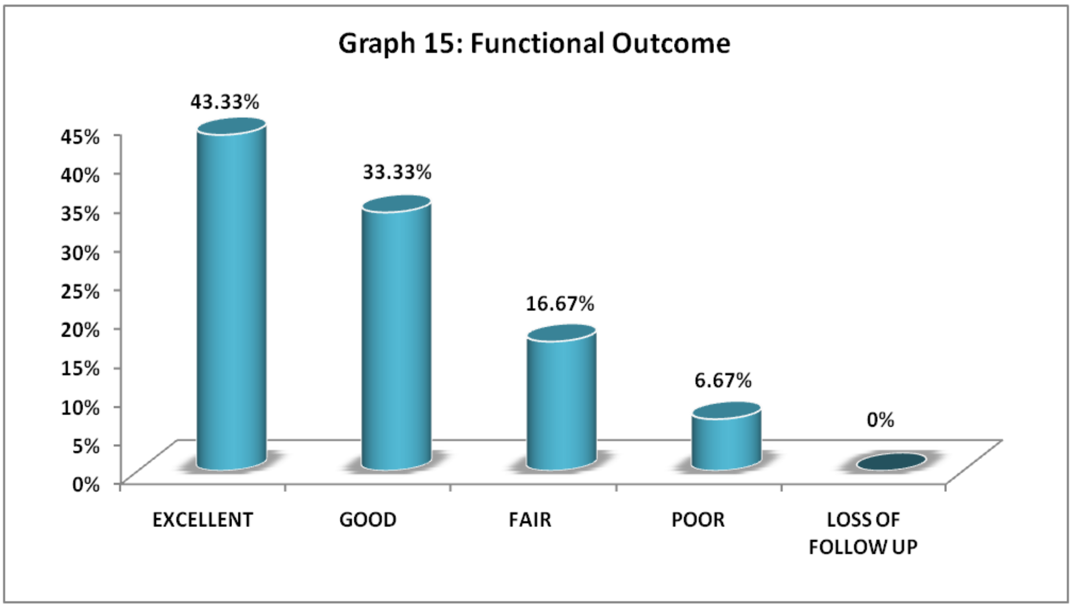
All 30 patients had > 75 % ROM, full ankle motion was observed in 18 patients. Two patient showed a loss of < 50 % of motion at ankle compared to the normal side while ten patients showed <50% of loss of joint motion at subtalar joint.

15. FUNCTIONAL RESULTS:

Functional results were graded according to the criteria by **Johner and Wruh's Criteria**[79]. 43.33 % of patients achieved excellent results, 33.33 % of patients achieved good results, 16.67 % fair results were seen and in two patient, the functional results were poor (6.67%).

Table No. 15: Functional outcome

FUNCTIONAL OUTCOMES	NO.OF PATIENTS	PERCENTAGE
EXCELLENT	13	43.33 %
GOOD	10	33.33%
FAIR	5	16.67 %
POOR	2	6.67 %
LOSS OF FOLLOW UP	0	0%
TOTAL	30	100%



CASE 1

Pre-Operative

3 MONTH POSTOPERATIVE RADIOGRAPHS

6 month radiograph showing radiological union

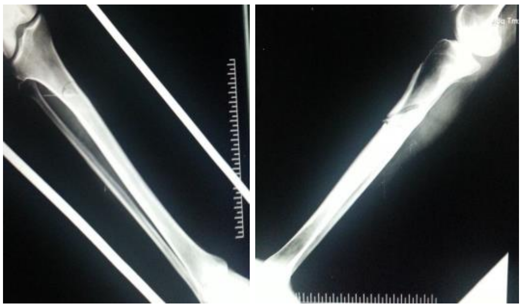
SITTING CROSS LEGGED

COMPLETE WEIGHTBEARING

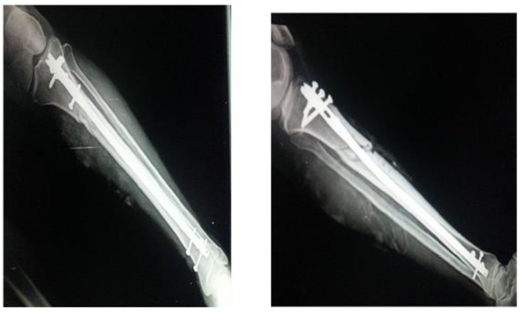
SQUATTING

WEIGHT BEARING

CASE 2



PRE OPERATIVE



POST OPERATIVE

6 MONTHS RADIOGRAPH SHOWING UNION

SITTING CROSS LEGGED **KNEE FULL FLEXION**

KNEE EXTENSION

CASE 3

PREOPERATIVE X-RAYS POST OPERATIVE X-RAYS




RADIOLOGICAL UNION X-RAYS AFTER 28 WEEK

COMPLETE WEIGHT BEARING **WEIGHT BEARING**

SITTING CROSS LEGGED

CASE 4

PRE OPERATIVE

POSTOPERATIVE 10WEEKS

18WEEKS

SITTING CROSS LEG

COMPLETE WEIGHT BEARING

SQAUTTING

WEIGHT BEARING

COMPLICATIONS

1. Delayed union

Pre-operative

20 weeks follow up

2. MALUNION

3. SUPERFICIAL INFECTION

Superficial infection at distal locking incision.

Superficial infection at site of fracture (type 2)

DISCUSSION

Fractures of the tibia and fibula are comparatively common and have been recognized as serious and debilitating injuries for centuries. Descriptions of the treatment of tibial fractures are included in the Edwin Smith Papyrus, an ancient Egyptian medical text dating back to at least 1500 to 1600 BC[9.]

Fractures of the proximal/distal third of the tibial shaft are tricky to treat with intramedullary nails as the diameter of the nail is smaller compared to the wide metaphyseal fragment which offers little resistance to deforming forces. This makes alignment in both sagittal and coronal planes dependent on the operative reduction and fixation. A small angulation in the proximal fracture can be accentuated by the nail as it is passed.

The surgical management of metaphyseal/diaphyseal tibial fractures has changed over the past 35 years in a large part due to an improved understanding of the significance of the soft tissue envelope. Precisely, the restoration of the osseous anatomy while overlooking the often-traumatized soft tissue envelope frequently led to poor postoperative outcomes and high complication rates. Although numerous treatment approaches and protocols have been described, there is no consensus regarding the optimal management of these challenging injuries. Likewise, long-term outcome data from randomized comparative treatment methods remains lacking. What does appear to be clear, however, is that the surgeon must balance the extent of osseous reduction and stability, particularly that of the articular surface, within the tolerances of the soft tissue envelope. Although the severity of these injuries, complexities of a variety of treatment methods, and the limitations of management having been well documented in the literature, excellent long-term results of management continue to elude the patients sustaining these fractures.

The treatment of tibial fractures remains controversial. Identifying treatment alternatives that reduce the risk of need for a subsequent operation, as well as costs to the health care system, will be a significant contribution to the practice of orthopaedics[80]. Rigid fixation has been shown to reduce the rate of infection, promote healing and facilitate rehabilitation of open tibial fractures[68]. There is no consensus on the best method of obtaining and maintaining alignment and stability of the tibia[82]

Open fracture being more common in tibia being a subcutaneous bone adds on to increase the complication rates more and is of important concern in deciding the management plan and selection of implant for definitive care. Furthermore, displacement of open tibial fracture fragment leads to periosteal stripping of the anterior tibial surface, rendering this exposed cortical bone avascular[83]. Open fracture of tibia are amongst the most complex to manage, because of the poor soft tissue cover and blood supply[81].

Although numerous wound management and fixation possibilities have been proposed, problems with infection, delayed healing and prolonged disability have persisted[67]. Variables such as comminution, displacement, bone loss, infection and general condition of the patient are more important prognostic factors in tibial fractures.

Closed fractures and Type I and some Type II open fractures with minimum soft tissue injuries and slight to moderate displacement of the bone can be treated with immobilization in a cast. Past experience with cast immobilization for open fractures led to a high incidence of non-union, infection, deformity and long term disability[84].
Brown and Urban *et al*[85] and Puno *et al*[86] reported an infection rate of 15% and malalignment rates as high as 70% in open fractures treated by plaster cast application.

Plate fixation provides for rigid immobilization of the fracture. But it is associated with high rate of infection, non-union, implant failure and problems with wound closure[15]. Bach and Hansen[87] reported a prevalence of infection of 35% and a prevalence of osteomyelitis of 19 percent after fixation with plaster and screws. Compared with prevalence of 13 percent and 3 percent respectively after external fixation. Outcome of plate fixation of distal tibia fracture did not depend on the fixation method or surgical approach but, when possible, the medial plating via MIPO technique is a favourable method of treatment[88].

External fixation has its own definitive indications like in very bad communited fractures and open type 3 fractures, it has its advantage of preserving the periosteal blood supply of tibia and also relative ease of application, but these are associated with the high rate of pin track infection, difficulties in managing soft tissue and the potential for malunion. Nonunion rate was found to be significantly higher in type II and III open fractures, high-energy fractures, fractures managed by external fixation using a bilateral frame in study conducted by Papaioannou[88]. When using external fixation, the complication rate was higher and functional outcomes were worse. External fixation must be reserved for trauma with severe skin injury as a temporary solution in a two-staged protocol as described by Sirkin *et al*[89] and Pierre Joveniaux[90].

Fractures of tibia continue to pose vexing problems to the Orthopaedic surgeons; chief among them is selecting the optimal method of treatment. Every fracture of tibia must be assessed individually and it can be difficult to establish fixed routine of treatment for these fractures. Internal fixation of diaphyseal and metaphyseal fractures of the tibia with plates may lead to ulceration of skin overlying plate, deep infection leading to osteomyelitis and refracture and delayed union. Intramedullary nailing offers an attractive treatment option, however there are some problems in treatment of fracture tibia with conventional intramedullary interlocking nailing like difficulty in manipulating fractures of proximal and distal 1/3rd tibia communited metaphyseal fractures.

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Due to the technical restrictions of the available implants such as the Unreamed Tibial Nail for the stabilization of distal metaphyseal fractures, new intramedullary tibial implants have been developed. As a result the Proximal Tibial Nail was designed and clinical investigation was started in 1999. For the first time it offered proximal locking options in three different planes with near angular stability of the nail-screw construct. Hansen *et al*[91] showed excellent clinical results in the management of proximal tibial fractures. In their prospective clinical study only one out of the thirteen patients who were treated primarily by intramedullary PTN nailing showed a secondary malalignment greater 3° in any plane (21). The good clinical results of the PTN led to the design of a universal tibial intramedullary implant. These shortcomings of conventional intramedullary interlocking nail in managing proximal and distal third fractures have been overcome by the introduction of Expert Tibial Interlocking Nail due to changes in operative techniques, its design and advancement in locking screws. The Tibial Nailing System was a prototype implant, which showed most of the properties later found in the Expert Tibial Nail. The proximal multidirectional interlocking of the PTN was incorporated in addition to the standard medio-lateral locking options. Four multidirectional locking options were available distally. In 2004 a prospective multicentric clinical study was conducted. Due to combined outcome from the different study centers the prototype nail was modified by adding a 2° incline to the 8° proximal nail radius for stress free insertion and a better fit in the intramedullary canal. In 2005 the modified nail became the "Expert Tibial Nail" and was introduced worldwide.

Thus expert tibial nail design allows better control in metaphyseal tibial segments through multiple interlocking holes in close proximity to either end of the nail. Multidirectional interlocking screws ensure that alignment is well maintained and stability preserved despite a short proximal or distal fragments. We evaluated our results and compared them with those obtained by various other studies

Age and Sex Distribution:

The mean age of the patients in the present study was 40.1 years, majority of the patients were males accounting for 25 (83.33%) cases. In the series by Gregory and Sanders[93] mean age was 30 years while in series of Duwelius *et al*[94] mean age was 40.5 years. In a study conducted by A Mahmood *et al*[95] the average age group of the cohort was 46.8 years with 26 males and 14 females. The average age in a study of 20 distal metaphyseal fractures treated with expert tibial nailing conducted by Lakhpat *et al* [57]was 42.8 years (range 18 to 72 years) and out of 20 patients 16 were male and only 4 of the 20 were female.

Study	**Average age**	**Males**	**Females**
Mahmood *et al*	46.8	65%	35%
Lakhpat *et al*	42.8	80%	20%
Akshay Phadke *et al*	46.19	78.60 %	21.40%
Present study	40.1	83.33 %	16.67%

The worldwide incidence of tibial fractures in males is 41 per 100,000 per year. The higher incidence of open tibial fractures in young males corresponds with their activity level whereas the incidence again increases in elderly individuals due to osteoporosis [96].

Mode of Injury:

In the present study the leading cause of the injuries were road traffic accident accounting for 80% of cases. Majority of patients sustained fracture both bone leg due to road side accidents (80%), followed by history of fall in a study conducted by Lakhpat *et al* [57]. Our study correlates with the study conducted by Barbieri *et al*[97] in which they observed 75% due to high energy trauma ; Studies by Gregory and Sanders[93] (85.10%) and also in a prospective study conducted by Nandakumar *et al*[98] showing 70% due to RTA .This indicates that the incidence of fractures can be brought down by road safety measures. Ipsilateral patella fracture in one patient (3.33%), ipsilateral medial malleolus fractures in one patient (3.33%) and head injury in 1 patient (3.33%).

Incidence of closed and open fractures:

In the present study the incidence of closed fractures were 60 % and those with open fractures were 40 %(Gustilo Anderson type 1 and 2), Gustilo Anderson type 3 were excluded from the study. In a study conducted by Lakhpat *et al*[57] on Functional Outcome of Expert Tibial Intramedullary Nailing For Metaphyseal And Diaphyseal Fractures of Tibia had closed fractures in 17 patients (85%) and open fractures in 3 patients (15%). 14 (70%) had a closed fracture, while 6 (30%) had a compound fracture according to the study conducted by Nandakumar *et al*[98]wich was similar to a study conducted by ovadis *et al*[99] also showing 30% open type fractures.

Study	Closed	Open
Lakhpat *et al*[57]	85%	15%
Nandakumar *et al*[98]	70%	30%
Ovadis *et al*[99]	70%	30%
Present study	60 %	40%

Associated Injuries:

Thirteen fractures were associated with ipsilateral fibula fractures. The outcome of the isolated fractures of tibia was not different from rest of the fractures. Other associated injuries were rib fracture in 1 patients (3.33%), ipsilateral medial malleoli in one patient (3.33%), ipsilateral patella fracture in one patient (3.33%), and head injury in 2 patients (3.33%). In study, conducted by Akshay Phadke *et al*[58] out of 42 patients 85% of patients had ipsilateral fibula fractures out of which 75% of fibula were fixed and remaining were left because there were more proximal fractures. In 19 (95%) cases both tibia and fibula were fractured and in 1 (5%) cases only tibia was fractured in a Lakhpat *et al*[57] study on Functional Outcome of Expert Tibial Intramedullary Nailing and when compared with and without Fixation of fibula fractures, fibula fixation usually results in better alignment.

Duration between Injury and Surgery:

The average duration of time interval between injury and intramedullary nailing is 2 days in present study. Numerous studies have stressed on early debridement and stabilization of open fractures of tibia. Some recent reports have questioned this belief. Shankar *et al*[101] suggests that their experience indicates the incidence of complications correlates more with the severity of the injury when compared with time gap from injury to treatment. Delay of 6 to 18 hours did not reflect a proportional increase in incidence of complications. Henley *et al*[19] opined that the risk of developing an adverse outcome was not increased by aggressive debridement/ lavage and definitive fixation up to thirteen hours from the time of injury when early prophylactic antibiotic administration and open fracture first aid were instituted. In the present study, all the patients with open fractures were administered antibiotics on admission and irrigation combined with thorough debridement was carried out within 12 hours of admission.

Approach and Knee Pain:

Anterior knee pain is the most common complication following IM nailing of tibial fractures with reported rates of 19% to 73%.[102, 103,104,105.] The etiology is probably multifactorial and the contributing factors remain largely unknown. Other proposed causes include postoperative thickening of the patellar tendon, fat pad scarring and adhesions[106], infrapatellar nerve damage[107], and proximal interlocking screw pain. In a large series of 443 tibial fractures treated with IM nails, knee pain was found to be inversely correlated to fracture union[108] .Toivanen *et al*[109] concluded that a paratendinous approach for nail insertion does not reduce the prevalence of chronic anterior knee pain or functional impairment. In our study we routinely discuss the risk of anterior knee pain with patients prior to IM nailing. We used a patellar tendon splitting approach in all the 30 patients, knee pain was found in 10 patients (30%) with kneeling activities.

Nail Size and Locking:

Average diameter of the nails used in the present study was 9mm. Majority of the nails were of 9mm diameter (63.33%). Reaming of the IM canal is typically used for closed fractures as it allows the insertion of a larger nail and promotes healing ' also produces tight bone implant construct that provide load sharing and resistance to bending or angulation at the fracture site[110] . Unreamed small diameter nails, despite interlocking may not provide adequate stability, especially in proximal and distal third fractures and after dynamization. A large prospective RCT on this issue of reaming and non-reaming has shown little difference between the outcomes of these two techniques with a slight edge toward reamed nailing[111].

Patient mobilization:

On the 1 postoperative day after the patient has recovered from anesthesia Patients were encouraged to move knee and ankle joints. Irrespective of the fracture configuration partial weight bearing was delayed till 6 weeks. Full weight bearing was allowed based on clinical and radiological assessment of fracture healing. The average period of commencement of full weight bearing was 13.33 weeks in the present study.

Seventeen patients (56.67%) in the present study were allowed to full weight bearing by 12 weeks, 10 patients (33.33%) were allowed to full weight bearing by 16 weeks and in 3 patients (10%) the full weight bearing was allowed after 24 weeks.

Larsen *et al*[112] allowed partial weight bearing for 6 weeks in early postoperative period. No cases of compartment syndrome, fat embolism or peroneal nerve palsy in the present study were reported.

Lakhpat yadav[57] in his study had average interval of protected full weight bearing was 3.8 weeks, while average interval of unprotected full weight bearing was 7.5 weeks.

Nandakumar bhairi[98] reported 55% cases of his patients started weight bearing at 8 weeks, 40% at 7 weeks, the one-week difference was because of mild pain. In one case, the delay was due to the loss of regular follow up.

Union:

In this study Union was defined as the presence of bridging callus on two radiographic views and the ability of the patient to bear full weight on the injured extremity Akshay Phadke Pandy *et al*[58].

The mean interval of the radiological union in the present study was 21.8 weeks. Closed fractures and type 1 fractures united earlier (average time 18.66 weeks and 21.75 weeks respectively) compared to type 2 open fractures (average of 25 weeks). Average time taken for clinical union was 13.4 weeks while average duration of radiological union was 16.8 weeks in a study conducted by Lakhpat *et al*[57] on 20 patients to evaluate the Functional Outcome of Expert Tibial Intramedullary Nailing For Metaphyseal And Diaphyseal Fractures of Tibia.

In a study conducted by A Mahmood *et al*[95] on outcome of expert tibial nailing for distal tibial fractures ,All 40 patients were followed up to full radiological union of their tibia fractures. The average time to radiological union was 12.5 weeks for the closed fracture group and 15.1 weeks for the open fractures.

Nandakumar Bhairi[98], reported the average time for union in all the patients was 15 weeks. 2 patients presented with signs of delayed union where in dynamization was done at 20 weeks.

In a study conducted by Akshay Phadke *et al*[58] The time for union ranged from 12-34 weeks with an average of 21 weeks. 17 fractures healed before 20 weeks, 22 fractures healed between 20 to 32 weeks while 3 fractures took 32 or more weeks to unite.

Studies	Union time
Lakhpat	16.8 weeks
A Mahmood	14 weeks
Nandakumar	15 weeks
Akshay Phadke	21 weeks
Present study	21.8 weeks

Secondary Procedure:

Skin grafting was done to cover the traumatic wound in 3 type II fractures. All the procedures requiring soft tissue coverage were done after nailing

Dynamization allows the fracture site to be compressed during early weight bearing and enhance fracture healing. Dynamization was done in 2 cases by removing either the proximal or distal bolts, depending on the progress of fracture healing in between 12 and 16 weeks.

Templeman *et al*[76] performed dynamization between a period of 6 and 12weeks in their study.

Singer *et al*[109] suggested dynamization to be done between 8 and 12 weeks if the healing is delayed.

COMPLICATIONS

Complications resulting from expert tibial nailing in our study were malunion in one patient (3.33%), superficial wound infection in four cases (13.33%), anterior knee pain in ten patients (30%), shortening in two patients (6.67%), delayed union in 3 patients

(10%) and two patients had ankle pain (6.67 %).None of the patients had deep infection, wound dehiscence deep vein thrombosis, compartment syndrome or non-union.

Nandakumar Bhairi *et al*[98]In his study ,four cases among 20 cases had complications that include nail breakage, delayed and non- union, and one segmental fracture with 50 anteroposterior angulations.

In a study conducted by Mohammed and Ramaswamy Saravanan[95] on 65 patients Complications resulting from tibial nailing were superficial wound infection in seven cases, anterior knee pain in five patients, leg pain (four patients), pain at screw site (two cases), infection of the nail (one patient), wound dehiscence (one patient), ankle pain (one case), deep vein thrombosis (one case), compartment syndrome (one case) and distal screw breakage in one patient.

Akshay Phadke *et al* [58]did a study on 42 patients and in four cases malalignment was noted. In two cases 5° of varus angulation was noted. One case had varus angulation of 10 degrees. In one case anterior angulation of 10 ° was noted. One patient had superficial infection and was treated with oral antibiotics. 8 patients reported anterior knee pain but it was not severe enough to cause any functional deficit.

Lakhpat Yadav *et al* [57]reported Complications restricted ankle movements in 3patients, restricted knee movements in 2 patients, valgus at ankle seen in 2 patients, anterior knee pain in 2 patients, delayed union seen in 2 patients.

Different studies	Malunion	Nonunion	Superficial infection	Deep infection	Implant failure	Knee pain	Ankle pain	Shortening	Delayed union
Nandakumar *et al*[90]	5%	5%			5%				5%
Mohammed at al[86]		23%	10%	1.5%	1.5%	7.6%	1.5%		
Akshay Phadke *et al*[88]	9.5%	0%	2.3%			19%			12%
Lakhpat Yadav *et al*[87]	10%	0%	5%			10%	15%		10%
Sanders *et al*[107]	9%	5%	5%		15%				
Present study	3.33%	0%	13.33 %	0%	0%	30%	6.67%	6.67%	10%

Malunion:

Regardless of the treatment method chosen, the most important consideration is an acceptable reduction. Acceptable reduction means a position of fracture fragments that minimize angulatory, rotational and length deviation from what is normal for the patient. . The most commonly used clinical guide for reduction is the alignment of the anterosuperior iliac spine with the middle of patella and the second toe in the anteroposterior plane. Rotation and lateral alignment are best determined by comparison to opposite extremity. Although tibial metaphyseal fracture may heal with 100% displacement, delayed and non-union are more common in adults with this degree of displacement. No distraction should be tolerated because as little as 5mm of distraction may increase healing time of tibial fracture to 8-12 months.

Nicoll EA[16] (1964) stated that more than 10 angulation in any plane and shortening more than 2cms was unacceptable. Dehne *et al*[14] (1961), Sarmiento A [72](1976) and Brown PW *et al*[73] (1969) reported satisfactory function when angulation was less than 10°.None of the authors advocated reoperation for symptoms of malunion of 10° or less.

Rockwood and Green prefer to set goal of 5^0 for varus and valgus angulation 10^0 for anterior and posterior angulation and 10^0 or less for rotation and 1cm or less for leg length discrepancy, however, more deformity have to be accepted to obtain union but it is preferable to prevent a malunion than to correct it later. [113]

In present study one patient had malunion with 5^0 of apex and 5^0 valgus angulation. Patient did not have any cosmetic or functional disturbance and no surgical intervention was done.

Yong Lei Liu *et al* did a study on comparison of low, multi directional locked nailing and plating in the treatment of distal tibial meta diaphyseal fractures. The mean postoperative angulation in the coronal plane (varus/valgus) was 2.4 ± 2.2 (range, 0-9°) in group A and 2.0 ± 1.6 (range, 0 -6°) in group B (p = 0.480, group A vs. group B). In the sagittal plane, the mean extent of postoperative ante-/recurvatum was 1.7 ± 1.6 (range, 0 -7) in group A and 1.4 ± 1.3 (range, 0- 4) in group B (p = 0.383, group A vs. group B) . [114]

Akshay Phadke *et al* in their study defined malalignment as angulation in a coronal plane (varus-valgus) of >5°, Sagittal plane (antero-posterior) angulation of >10° or >10 mm of shortening. Malrotation was evaluated by comparing the amounts of internal and external rotation of the injured extremity with those of the uninjured extremity. In four cases malalignment was noted. In two cases 5° of varus angulation was noted. One case had varus angulation of 10 degrees. In one case anterior angulation of 10 ° was noted.
The primary concern is, the effect malunion will have on gait and stresses on the knee and ankle joint. Cosmetic and radiographic appearances are of minimal concern and are never by themselves indications for operative treatment. [58]

Infection:

The current study had no deep infection. Four cases (13.33%) developed superficial soft tissue infection, two at proximal nail entry point and two at distal locking screw. One patient among the four was diabetic. They were treated by appropriate antibiotics, pus was sent for culture and sensitivity and appropriate antibiotics were instituted. The infection subsided with regular dressings of the wound.

Singer *et al* suggested that in cases of infection associated with intramedullary nailing, use of antibiotics for a period of 2 to 6 weeks is useful. Keating *et al* concluded that irrespective of the type of fixation used, sufficient soft tissue and bony debridement followed by adequate soft tissue coverage is the key to minimize deep infection in open fractures of tibia. The use of antibiotic bead pouches reduces the incidence of infection further. If infection occurs, it is not necessarily a catastrophic complication and can be eradicated with prompt measures.[109]

Range of Motion:

In a study conducted by Sanders RW *et al* the results showed Mean arc of knee motion was 124.4 degrees for the affected extremity compared with 127.2 degrees for the contralateral knee. One patient (2.7%) complained of mild pain at the scar, but no patient complained of anterior knee pain either at the PF joint or at the anterior proximal tibia. [115]

P. Slatis& P. Rokkanen et a reported the range of movement in the knee joint was good in only 58 per cent of the cases at the end of the treatment and reported that this was due to the tenderness in the knee region at the site of introduction of the nail. The distal joints had a better range of movement which was considered good in 62 per cent in the ankle joint and in 71 per cent in the tarsus. [116]

Akshay Phadke *et al*[58] did a study on expert tibial nailing for tibia and reported 8 patients with anterior knee pain but it was not severe enough to cause any functional deficit. In the study, 5 patients had <25° while 2 patients had >25° loss of ankle motion.[58]

The average range of knee joint was 141 degrees. (Range 128 - 161 degrees) and that of ankle movements was 84 degrees (range 45-109 degree) in tibial fracture treated by reamed nailing in a study reported by Larsen *et al*[112].

In the study by Robinson *et al*, 5 patients lost ankle motion: 4 had mild (<25%) and one patient who had crush injury to the ipsilateral foot had marked loss of ankle motion.

The average range of knee joint motion in present study was 130 degrees and 60% of patients showed full ankle motion compared to the normal limb. In comparison to the normal side, two patient showed <50 % of ankle motion

Functional outcome:

Functional results were graded according to the criteria by Johner and Wruh's Criteria[79]. 43.33 % of patients achieved excellent results, 33.33 % of patients achieved good results, 16.67 % fair results were achieved and in two patient, the functional results were poor (6.67%).

Nandakumar Bhairi *et al* aimed at highlighting the efficacy of surgical treatment of distal tibia by analyzing results using, arene ekland, bjorne thoresse criteria. His study had 65% excellent, 25% good and 5% each fair and poor. [98]

Akshay Phadke *et al* in his study on expert tibial nail Evaluation of functional outcome was done by Klemm and Borner's criteria - Out of 42 patients, 33 (78.57%) patients had excellent results while 5 (11.90%) patients had good results, while 4 (9.52%) patients had fair results. [58]

Lakhpat Yadav *et al*[57] in his study results were evaluated as Excellent, Good, Fair, and Poor on the basis of Johner R, Wruh's SD criteria: 9 Out of 20 patients 14 (70%) patients had excellent results as they had full function as pretrauma without any residual symptoms, 3 patients (15%) had good results, 2 (10%) patients had fair results and 1 (5%) patient had poor results.

CONCLUSION

Our results with expert tibial interlocking nailing are encouraging and demonstrate the benefits of new nailing system. Changes in the design of the nail for improved proximal and distal locking enables it to use in metaphyseal/diaphyseal fractures of tibia. A better stabilization of small fragments has been achieved by the availability of locking option in three planes, thus providing a higher stability of the bone implant construct. Complications were comparable to other studies .Good functional results and union rates were achieved with vigilant preoperative planning and respecting the principles of intramedullary interlocking nailing technique hence we recommend the use of expert tibial nail in metaphyseal/diaphyseal fractures of the tibia.

SUMMARY

In this study a total of 30 patients with tibial metaphyseal/diaphyseal fractures were treated with Expert tibial intramedullary interlocking nailing in BLDE (Deemed to be University)'S Shri B.M.Patil's Medical College, Hospital and Research Centre, Vijayapura from October 2016- March 2018. At least for a period of 6 months, patients were followed up. All the patients were obtainable for follow up.

- All patients were evaluated clinically and radiologically before and after surgery and minimum of 6 months follow up was done.
- In the present study mean age was 40.1 years, majority of the patients were males accounting for 25 (83.33%) cases.
- Road traffic accidents was the common mode of injury accounting for 80 % of cases and 16 patients had fracture of right side and remaining 14 patients had left side tibia fracture.
- The incidence of closed fractures were 60% and those with open fractures were 40% of which Gustilo Anderson type 1 and 2 were 26.67 % and 13.33% respectively, Gustilo Anderson type 3 were excluded from the study.
- Six fractures showed a transverse pattern, ten were oblique, five were communited and nine were spiral. (43.33%) of the cases were associated with ipsilateral fibula fractures.
- Nineteen cases were operated under spinal anaesthesia, 9 under epidural anaesthesia and 2 case under general anaesthesia. Transtendinous approach was used in all the 30 cases
- The average duration of time interval between injury and intramedullary nailing was 2 days.

- Majority of the nails inserted were 9mm.
- The average period of commencement of full weight bearing was 13.43 weeks. Seventeen patients (56.67%) in the present study were allowed to full weight bearing by 12 weeks, 10 patients (33.33%) were allowed to full weight bearing by 16 weeks and in 3 patients (10%) the full weight bearing was allowed after 17 weeks.
- The average time taken for union was 20.33 weeks, closed fracture and Type I open united earlier at (18.66 weeks and 21.75 weeks respectively) when compared to Type II fracture took 25 weeks
- Complications resulting from expert tibial nailing in our study were malunion in one patient (3.33%), superficial wound infection in four cases (13.33%), anterior knee pain in ten patients (30%), implant failure o% , shortening in two patients (6.67%), delayed union in 3 patients(10%) and two patients had ankle pain (6.67%).
- Functional results were graded according to the criteria given by Johner and Wruh's Criteria[79]. 43.33 % of patients achieved excellent results, 33.33 % of patients achieved good results, 16.67 % fair results were obtained and in two patient, the functional results were poor (6.67%).

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ANNEXURE I

B.L.D.E. UNIVERSITY'S

SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR-586 103

INSTITUTIONAL ETHICAL COMMITTEE

Institutional Ethical Committee B.L.D.E.U's Shri B.M. Patil Medical College BIJAPUR-586 103. INWARD No. 61/2016 Date 06/10/16

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 04/10/2016 *at* 3-00pm *to scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected & revised version synopsis of the Thesis has been accorded Ethical Clearance.*

Title funtional outcome of metaphyseal and diaphyseal fractures of tibia treated with expert tibial interlocking nail - a prospective study

Name of P.G. student Prashant B. Kembanal Dept Orthopaedics

Name of Guide/Co-investigator Dr Ashok.R.Nayak Professor Orthopaedics

DR.TEJASWINI. VALLABHA
CHAIRMAN
INSTITUTIONAL ETHICAL COMMITTEE
BLDEU'S, SHRI.B.M.PATIL
MEDICAL COLLEGE, BIJAPUR.

Following documents were placed before E.C. for Scrutinization

1) Copy of Synopsis/Research project.
2) Copy of informed consent form
3) Any other relevant documents.

ANNEXURE II

B.L.D.E. (Deemed to be University) SHRI B.M.PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTER, VIJAYAPURA-586103

INFORMED CONSENT FOR PARTICIPATION IN DISSERTATION/RESEARCH

I, the undersigned,________________ , S/O D/O W/O _________________, aged ____years, ordinarily resident of _____________ do hereby state/declare that Dr. Prashant B Kenganal of Shri. B. M. Patil Medical College Hospital and Research Centre has examined me thoroughly on _______________ at _______________ (place) and it has been explained to me in my own language that I am suffering from _________________ disease (condition) and this disease/condition mimic following diseases. Further Dr. Prashant B Kenganal informed me that he/she is conducting dissertation/research titled "FUNCTIONAL OUTCOME OF METAPHYSEAL AND DIAPHYSEAL FRACTURES OF TIBIA TREATED WITH EXPERT TIBIAL INTERLOCKING NAIL- A PROSPECTIVE STUDY" under the guidance of Dr. Ashok. R. Nayak requesting my participation in the study. Apart from routine treatment procedure, the pre-operative, operative, post-operative and follow-up observations will be utilized for the study as reference data.

Doctor has also informed me that during conduct of this procedure like adverse results may be encountered. Among the above complications most of them are treatable but are not anticipated hence there is chance of aggravation of my condition and in rare circumstances it may prove fatal in spite of anticipated diagnosis and best treatment made available. Further Doctor has informed me that my participation in this study help in evaluation of the results of the study which is useful reference to treatment of other similar cases in near future, and also I may be benefited in getting relieved of suffering or cure of the disease I am suffering.

The Doctor has also informed me that information given by me, observations made/ photographs/ video graphs taken upon me by the investigator will be kept secret and not assessed by the person other than me or my legal hirer except for academic purposes.

The Doctor did inform me that though my participation is purely voluntary, based on information given by me, I can ask any clarification during the course of treatment / study related to diagnosis, procedure of treatment, result of treatment or prognosis. At the same time I have been informed that I can withdraw from my participation in this study at any time if I want or the investigator can terminate me from the study at any time from the study but not the procedure of treatment and follow-up unless I request to be discharged.

After understanding the nature of dissertation or research, diagnosis made, mode of treatment, I the undersigned Shri/Smt ____________________________ under my full conscious state of mind agree to participate in the said research/dissertation.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to ____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date: Dr. Ashok R. Nayak (Guide) Dr. Prashant B. Kenganal (Investigator)

Signature of patient:

Signature of doctor:

Witness: 1.

2.

Date:

Place

ANNEXURE –III

SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE,

VIJAYAPURA - 586103

PROFORMA

CASE NO. :

NAME :

AGE/SEX :

I P NO :

DATE OF ADMISSION :

DATE OF SURGERY :

DATE OF DISCHARGE :

OCCUPATION :

RESIDENCE :

Presenting complaints with duration :

History of presenting complaints :

Family History :

Personal History :

Past History :

General Physical Examination

Pallor:	present/absent
Icterus:	present/absent
Clubbing:	present/absent
Generalized lymphadenopathy:	present/absent
Built:	poor/moderate/well
Nourishment:	poor/moderate/well

Vitals

PR: RR:

BP: TEMP:

Other Systemic Examination:

Local examination:

Right/ Left Leg

Gait:

Inspection:

a) Attitude/ deformity

b) Abnormal swelling

- Site
- Size
- Shape
- Extent

c) Shortening

d) Skin

e) Compound injury if any

Palpation:

a) Local tenderness

b) Bony irregularity

c) Abnormal movement

d) Crepitus

e) Swelling

Movements:		Active	Passive
Knee:	Flexion		
	Extension		
Ankle:	Plantar Flexion		
	Dorsi flexion		

Measurements:

Leg length

Leg circumference

Neurological examination:

KEY TO MASTER CHART

M	–	Male
F	-	Female
R	-	Right
L	-	Left
Moi	-	Mode of injury
Rta	-	Road traffic accident
Nof	-	Neck of femur
If	-	Ipsilateral fibula
Ip	-	Ipsilateral patella
Imm	-	Ipsilateral medial malleolus
Inf	-	Infection
S	-	Shortening
Akp	-	Anterior knee pain
Kp	-	Knee pain
Dyn	-	Dynamization
Ir	-	Implant removal
D	-	Debridement
Du	-	Delayed union
Mu	-	Mal union
Ap	-	Ankle pain
Pts	-	Patellar tendon splitting
Sa	-	Spinal anaesthesia
Ga	-	General anaesthesia
Ea	-	Epidural anaesthesia
Sl	-	Static locking
Dl	-	Dynamic locking
E	-	Excellent
G	-	Good
P	-	Poor
F	-	Fair
Dm	-	Diabetes mellitus
Htn	-	Hypertension
A	-	Asthma

MASTER CHART

SL.NO	NAMES	AGE	SEX	SIDE	IP NO	MOI	PATTERN	OPEN/CLOSED	ASSOCIATED INJURY	CO MORBID	APPROACH	TYPE OF ANESTHESIA	NAIL SIZE	LOCKING	PWB	FULL WEIGHT BEARING	Union	PAIN	DEFORMITY	ROM KNEE	ROM ANKLE	ROM SUBTALAR	SHORTENING	GAIT	SECONDARY PROCEDURE	COMPLICATIONS	FUNCTIONAL RESULTS
1	SAGAR GODKE	20	M	L	315	RTA	OBLIQUE	CLOSED	NONE	NIL	PTS	SA	10x32	SL	6	10	19	NIL	2 DEGREE APEX ANGULATION	>75 %	>50 %	<50 %	NIL	N	-	NIL	G
2	VIVEK RAVINDRA	28	M	R	446	RTA	COMMUNITED	OPEN TYPE I	NONE	NIL	PTS	SA	9x34	SL	6	16	28	KNEE PAIN	3 DEGREE APEX ANGULATION	>75 %	> 50 %	N	NIL	N	IR	AKP	G
3	GURUBAI	80	F	L	719	RTA	SPIRAL	CLOSED	#NOF (L)	HTN	PTS	EA	9x28	SL	12	18	18	NIL	NONE	N	N	N	NIL	N	-	INF	G
4	SANTOSH RAMCHANDRA	45	M	R	1513	RTA	OBLIQUE	CLOSED	HEAD INJURY	NIL	PTS	EA	10x32	SL	8	12	16	NIL	NONE	N	N	N	NIL	N	-	NIL	E
5	RAVATAPPA	28	M	L	2699	RTA	TRANSVERSE	CLOSED	NONE	NIL	PTS	SA	10x30	DL	6	12	17	NIL	3 DEG APEX 2 DEG VALGUS ANGULATION	> 75 %	>50 %	< 50 %	NIL	N	-	AKP	F
6	PARASAPPA	22	M	R	5452	RTA	COMMUNITED	OPEN TYPE II	NONE	NIL	PTS	SA	10 X 32	SL	8	16	28	NIL	NONE	> 75 %	> 50 %	< 50 %	NIL	N	IR	PALPABLE SCREWS	F
7	MEGHANA NAIR	25	F	L	11062	RTA	SPIRAL	CLOSED	NONE	NIL	PTS	SA	9x30	SL	8	12	24	NIL	NONE	N	N	N	NIL	N	-	AKP	G
8	BABAGOUDA	35	M	R	14563	RTA	OBLIQUE	CLOSED	NONE	NIL	PTS	GA	9x32	SL	6	10	18	NIL	NONE	> 75 %	> 50 %	< 50 %	NIL	N	D	INF	F
9	SHARANAPPA	30	M	L		ASSAULT	TRANSVERSE	OPEN TYPE I	NONE	NIL	PTS	SA	9x34	DL	6	12	24	NIL	NONE	N	N	N	NIL	N	NIL	NIL	E
10	KEMU CHAVAN	36	M	R	17810	FALL	SPIRAL	OPEN TYPE II	NONE	NIL	PTS	SA	9x30	SL	8	16	28	KNEE PAIN	5 DEGREE APEX ANGULATION	>75 %	> 50 %	< 50 %	NIL	N	SG/DYN	DU/AKP	F
11	MUDANNA GOLAPALLE	25	M	R	18713	RTA	COMMUNITED	CLOSED	IF	NIL	PTS	SA	9x28	SL	8	16	24	NIL	NONE	> 75 %	> 50 %	< 50 %	NIL	N	DYN	DU	F
12	ESHWAR	59	M	L	19995	RTA	COMMUNITED	CLOSED	IF	NIL	PTS	SA	9x28	SL	6	13	18	NIL	NONE	N	N	N	NIL	N	-	S/KP	E
13	UMESH	60	M	L	19996	RTA	SPIRAL	OPEN II	IP/IF	NIL	PTS	EA	10x32	SL	6	15	20	NIL	NONE	N	N	N	NIL	N	SG	NIL	E
14	NAREEMA	42	F	L	22170	RTA	OBLIQUE	CLOSED	IF	DM	PTS	SA	10x32	SL	6	10	12	KNEE PAIN	3 DEG APEX ANGULATION	> 75 %	N	N	NIL	N	IR	INF/KP	G
15	NAGAPPA	60	M	R	24439	RTA	TRANSVERSE	CLOSED	IF	A	PTS	EA	9x32	DL	6	11	18	NIL	NONE	N	N	N	NIL	N	-	NIL	E
16	SUBHADRA	36	F	L	24740	RTA	OBLIQUE	OPEN II	IF	NIL	PTS	EA	10x34	DL	6	16	24	NIL	NONE	N	N	N	NIL	N	SG	NIL	E
17	LOKESH	45	M	R	24753	FALL	OBLIQUE	CLOSED		DM	PTS	SA	9x32	SL	6	16	17	NIL	NONE	N	N	N	NIL	N	-	NIL	E
18	PRAVEEN	25	M	R	24765	RTA	OBLIQUE	OPEN I	IF	NIL	PTS	SA	8x30	SL	8	12	18	NIL	2 DEG APEX ANGULATION	> 75 %	> 50 %	< 50 %	NIL	N	D	INF	G
19	SUBHAS	22	M	L	25510	FALL	SPIRAL	CLOSED	IF	HTN	PTS	SA	9x28	SL	6	13	17	NIL	NONE	N	N	N	NIL	N	-	INF	E
20	MAHANTESHAPPA	41	M	R	26540	RTA	TRANSVERSE	OPEN I	IF	NIL	PTS	EA	9x28	DL	8	18	28	NIL	3 DEG APEX ANGULATION	N	N	N	NIL	N	-	NIL	G
21	GURAYYA	28	M	L	26750	RTA	SPIRAL	OPEN I	NONE	NIL	PTS	GA	10x30	SL	8	12	24	ANTERIOR KNEE PAIN	NONE	> 75 %	> 50 %	<50 %	NIL	N	-	AKP	G
22	RAMMANNA	55	M	R	27143	FALL	OBLIQUE	CLOSED	NONE	DM	PTS	SA	10x28	SL	12	24	28	KNEE PAIN	3 DEGREE VALGUS 5 DEGREE APEX ANGULATION	> 75 5	< 50 %	-	5mm	LIMP	D	DU/S	P
23	PUNDALIK	25	M	R	28110	RTA	OBLIQUE	CLOSED	NONE	NIL	PTS	EA	9x28	SL	6	12	20	NIL	NONE	> 75%	> 50 %	< 50 %	NIL	N	-	NIL	G
24	LAGAMAKKA KAVADI	50	F	L	33495	RTA	OBLIQUE	CLOSED	IF	NIL	PTS	SA	8x30	SL	6	11	17	NIL	NONE	N	N	N	NIL	N	-	NIL	E
25	BASANNA	60	M	R	38270	RTA	COMMUNITED	OPEN TYPE I	NONE	NIL	PTS	SA	9x30	SL	6	12	18	NIL	NONE	N	N	N	NIL	N	-	NIL	E
26	SALIM	50	M	R	41179	RTA	SPIRAL	OPEN I	RIB	NIL	PTS	EA	9x34	SL	6	10	16	NIL	NONE	N	N	N	NIL	N		AP	E
27	SHRISHAIL	22	M	R	37726	FALL	TRANSVERSE	CLOSED	NONE	NIL	PTS	SA	9x32	DL	8	12	20	KNEE PAIN	5 DEG APEX ANGULATION	N	N	N	NIL	N	-	KP	G
28	GURUBALLAPPA	65	M	L	39468	RTA	SPIRAL	CLOSED	IF/IMM	NIL	PTS	EA	9x28	SL	6	12	17	KNEE PAIN	5 DEGREE APEX 5 DEGREE VALGUS ANGULATION	> 75 %	< 50 %	< 50 %	10mm	LIMP	-	MU/KP	P
29	TUKARAM	40	M	L	32702	RTA	SPIRAL	OPEN I	IF	NIL	PTS	SA	9x32	SL	6	11	18	NIL	NONE	N	N	N	NIL	N	-	NIL	E
30	SHANKAR	44	M	R	36497	RTA	TRANSVERSE	CLOSED	IF	NIL	PTS	SA	9x28	DL	6	13	16	NIL	NONE	N	N	N	NIL	N	-	KP	E