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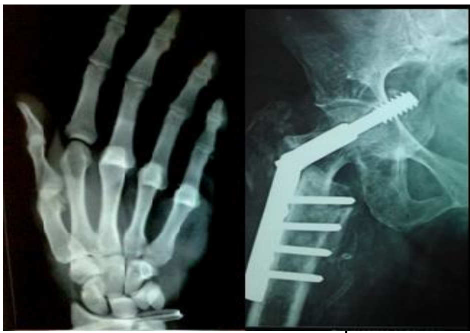

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Prospective randomized study of outcome of intramedullary interlocking nail as primary fixation method in grade 1 & 2 compound fractures of tibia

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Abstract
Fractures of tibia shaft is itself a great dilemma and becomes more difficult to treat when it becomes a compound fracture. So in this new era of fast paced technologies, an aggressive approach is required to treat such fractures in view of early rehabilitation and return to occupation. This prospective randomized study was conducted at department of Orthopedics in Mahatma Gandhi Medical College and Hospital, Sitapura, Jaipur to evaluate outcomes of intramedullary interlocking nail as primary fixation method in compound fractures of tibia. Surgery duration was less in intramedullary nail because in most of the cases fractures were easily reduced, minimal surgical exposure and associated less closure time. Intra operative image intensifier use was significantly more because of distal screw locking and determination of nail length.
Post operatively aim of the treatment was to make the patient upright, and start weight bearing as early as possible as per the personality of fracture. In follow up of cases at 12 and 24 weeks as per functional outcomes patients had very mild difficulty in performing activities of daily living. On concluding the outcome as per Johner and Wruhs Criteria at 24 weeks excellent score was found in 70% cases of ILN while it was poor in 5% cases and remaining had good to fair outcomes.

Keywords: Intramedullary nail, compound fracture, johner wruhs criteria, weight bearing

Introduction

As industrialization and urbanization are progressing year by year with rapid increase in traffic speed, incidence of high energy trauma are increasing with the same speed. High energy trauma has resulted in intricated fractures, which are usually compound injuries with loss of bone and surrounding soft tissues [1]. In these type of complex injuries, poor outcomes along with complications like malunion, delayed union, nonunion, and infection have been reported in the available literature [2-3]. In tibia, especially due to its relatively subcutaneous location as compared to other bones it is more prone to compound fracture.
There was an era when orthopaedicians used to treat compound fractures by wait and watch methods by serial debridement and POP casts as used by Winett Orr (1938), Trueta (1940), and Brown and Urban (1969) [4-6]. Although union rate was 100% but problems like difficulty in wound toileting, persistent discharge and malunion were common.
Byrd *et al* (1981), Larson & Linden (1983), Karlstorm and Olerud (1983), Court Brown *et al* (1990) have accepted external fixation as efficient method for treatment of open tibial diaphyseal fractures. But many authors reported complications such as malunion, nonunion, pin loosening, & pin tract infection.
AO introduced the concept of original "open reduction and internal fixation" and gave principles of anatomical reduction, absolute stability and rigid fixation and focus was laid on the primary bone healing. But this led to more soft tissue dissection and thought to cause complications like infection and delayed or non-union due to soft tissue damage and bone devitalization.
Than AO came up with the concept of indirect and functional reduction and relative stability in diaphyseal fractures and gave more importance to secondary bone healing which is more

Biological and needs less soft tissue dissection [7]. As such, intramedullary nails become the gold standard for the treatment of diaphyseal fractures in the lower limb [8]. But it was not indicated in open fractures because it was thought to aggravate complications like infection.

Holbrook *et al*. (1989) [9] Christie *et al* (1990) [10] Tornetta *et al*. (1994) [3] Sargeant, Lovell *et al*. (1994) [12] Tu *et al* (1995) [13] suggested that closed intramedullary nailing with an interlocking nail system is an excellent method of treating open tibial fractures [9-13]. Good results have been shown by using locking nails for both closed and grade I compound fracture of tibia (Klemn and Borner, 1986; Hooper *et al*, 1991) [14-15].

Intramedullary nail is advantageous
1) It is more biological method of fixation as it is less invasive.
2) It is a load sharing implant so patient can bear weight early.
3) It doesn't distrubs the fracture hematoma so causes secondary healing and less chances of non union
   However, complications like malalignment, anterior knee pain, implanr failure, infection have been reported.

Material and Methods
Study design
This prospective randomized study was conducted at department of orthopedics in Mahatma Gandhi Medical College and Hospital, Sitapura, Jaipur.

Duration of study
November 2015 to September 2017.
Informed consent was taken from the patients who are included in this study for the selection criteria.

Method of collection
The ethical committee of Mahatma Gandhi Medical College, Jaipur was informed about the intended work and permission was obtained to conduct the work.

Number of cases
In this study 20 patients attending Orthopaedics OPD in Mahatma Gandhi Hospital during November 2015-September 2017 of grade 1 and 2 compound fracture of tibia and willing to undergo the study were taken. These will be selected based on inclusion and exclusion criteria.

Eligibility criteria
Inclusion criteria
All adults and elderly patients of both genders with grade 1 and 2 compound fracture of tibia attending MGMC&H Casualty/OPD/IPD

Exclusion criteria
- Patients below 18 years or above 65 years of age
- Grade 3 Open fracture
- Pathological fracture
- Patient not fit for anesthesia

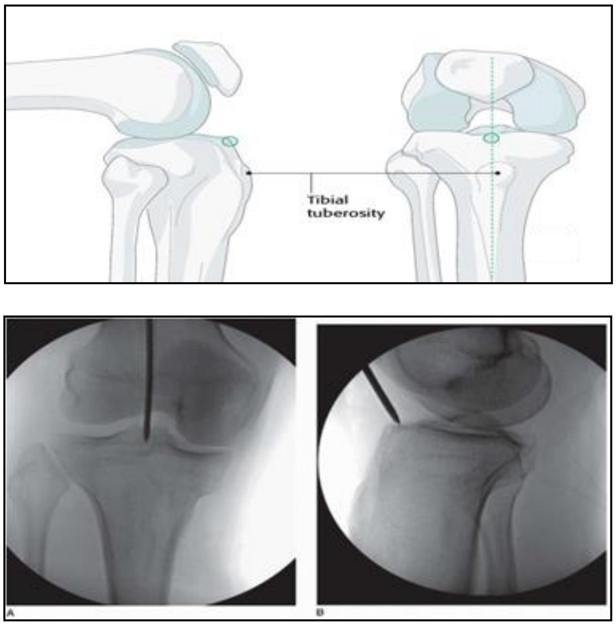
Patients underwent full investigations pertaining to pre-anesthetic checkup and for open fracture care irrigation of wound with saline, temporary immobilization by POP slab and antibiotics along with tetanus prophylaxis were administered perioperatively. Following fitness for anesthesia, patients were taken up for surgery and the study was recorded in a proforma.

Following the treatment patients were followed up at outpatient department at regular intervals for clinical and radiological evaluation. The patients were followed up till fracture union and functional recovery. If necessary, subsequent follow up was done.

Surgical technique
Position
A standard operating table was used; patient was taken in supine position. Rotational alignment was measured by aligning the iliac crest, patella, and second ray of the foot.

Nail diameter
Nail diameter was determined under image intensifier control, or by placing the Measuring Device on the tibia and position the square marking over the isthmus. If the transition to the cortex was still visible to the left and right of the marking, the corresponding nail diameter was used.

Incision & entry portal
It was made by making a 3 to 5 cm incision along the medial border of the patellar tendon, extending from the tibial tubercle in a proximal direction.



Picture 1: Showing entry point for antegrade tibial nailing

Awl was inserted through the metaphysis anteriorly to gain access to the medullary canal under C-ARM control to make entry portal which is located along the medial slope of the lateral tibial eminence on the antero-posterior view and just anterior to the articular margin on lateral imaging.

Technique
Awl was removed and canal opener was used to open the medullary canal further.
Ball-tipped guide wire was inserted through the entry portal into the tibial canal and was passed across the fracture site into the tibia under fluoroscopic guidance The guide wire should be centered and slightly lateral within the distal fragment on anteroposterior and central lateral views and advanced to within 1.0 cm to 0.5 cm of the ankle joint.
Canal was reamed in 0.5-mm increments, starting with a reamer smaller than the measured diameter of the tibial canal. Reaming was done with the knee in flexion to avoid excessive

reaming of the anterior cortex. Fracture reduction was held during reaming to decrease the risk of iatrogenic comminution. Guide rod was prevented from being partially withdrawn during reaming. Reaming was stopped after cortical contact ("chatter") was first heard.

Nail diameter was choosen 1.0 to 1.5 mm smaller than the last reamer used.

When reaming was completed, length of the nail was determined by placing the tip of a guide wire of the same length at the most distal edge of the entry portal. Length of the overlapped portions of the guide rods was subtracted from the full length of the guide rod to determine the length of the nail.

Insertion device alongwith proximal locking screw guide was attached to the nail. Apex of the proximal bend was directed in the nail posteriorly.

Nail was inserted with the knee in flexion. Rotational alignment was evaluated by aligning the iliac crest, patella, and second ray of the foot.

When the nail was passed well into the distal fragment, guide wire was removed to avoid incarceration; and during final seating of the nail, traction was released to allow impaction of the fracture. When the nail was fully inserted, the proximal end lies 0.5 to 1.0 cm below the cortical opening of the entry portal. This position is best seen on a lateral fluoroscopic view. The distal tip of the nail should lie 0.5 to 2.0 cm from the subchondral bone of the ankle joint. Distal fractures require nail insertion near the more distal end of this range. If fracture compression is planned, the nail should be appropriately countersunk to prevent prominence once the fracture is compressed.

Proximal locking screws were inserted using the jig attached to the nail insertion device. Drill sleeve was placed through a small incision down to bone. Length of the screw was measured by depth gauge. Number of interlocking screws was inserted depending upon fracture characteristics.

Distal locking was performed by using a freehand technique after "perfect circles" obtained by fluoroscopy. In the lateral position, fluoroscopic beam is adjusted until it was directed straight through the distal screw holes and the holes appeared perfectly round.

ST pin was placed through a small incision overlying the hole and tip was centered in the hole. Taking care not to move the location of the tip, ST pin was brought in line with the fluoroscopic beam and hammered through the near (medial) cortex. Position of the pin was checked with fluoroscopy to ensure that it has passed through the screw hole. When proper position was confirmed, pin was driven through the far (lateral) cortex using a power drill.

Screw length was measured using depth gauge.

After screw insertion, lateral image was obtained to ensure the screws have been inserted through the screw holes. Two distal locking screws were used in most fractures.

Armamentorium of Interlocking Intramedullary Nail

a

b

c

d

e

f

Fig 7: a, b: Clinical picture of wound and preoperative radiograph of a 23 year old male with h/o RTA who sustained grade 1 compound fracture of proximal 1/3rd tibia, **c.** Medial Parapatellar approach used for insertion of a nail, **d.** Immediate post-operative radiograph showing inter locking tibia nail in-situ, **e.** Radiograph after 1 year showing fracture union, **f.** Clinical picture of patient in standing position after 1 year of nailing. This patient had good functional outcomes without any complications in group A.

a

b

c

d

e

f

Fig. 8: A 45 year old male with h\o RTA sustained grade II compound segmental fracture of right tibia with Proximal 1\3rd fibula, **a.** Immediate postoperative radiograph showing nail in-situ, **b.** Radiograph after 6 month showing signs of fracture union in 3 cortices. After this Nail Removal was done after 8 months after the fracture union was evident and PTB was applied, **c.** Radiograph after 1 year showing evident sequestrum and presented as chronic osteomylitis with pus discharging sinus, **d.** Radiograph showing Sequetrectomy, **e.** Clinical picture of patient in standing position, **f.** patient having wound healing problem at sinus site after sequestrectomy. This patient had poor outcomes after nailing in group A.

Results

In our study maximum no. of patients 55% were in 18-30 years of age group. The mean age was 32.4 years. Similarly the maximum no. of patients were male (80%) as compared to female (20%). The male to female ratio was approximate 4:1.

Table 1: Level of fractures

Level	No. of Patients
Proximal third	2 (10%)
Middle third	6 (30%)
Distal third	12 (60%)
Total	20 (100%)

Chi-square test (Fisher extract test), 2 degree of freedom, P =0.4493

Most of the fractures requiring fixation were either in the distal third of shaft (60%), or middle third of the shaft (30%) whereas proximal third of the shaft included only (10%).

Table 2: Wound Management

Wound management		No. of Patients
Primary closure		11
Delayed primary closure		5
Secondary closure	Simple	2
	SSG	1
	Myoplasty	0

In majority of cases wound management was done by primary closure (55%), followed by delayed primary closure (25%) and secondary closure was required in 15%.

Table 3: Time of partial weight bearing

Partial weight bearing	No. of Patients
2-7 day	7 (35%)
8-15 days	5 (25%)
16-21 days	5 (25%)
>21 days	3 (15%)

Chi-square test (Fisher extract test), 3 degree of freedom, P <0.0001****

The average duration of partial weight bearing was 14 days (Range 2-28 days).

Table 4: Time of full weight bearing

Full weight bearing	No. of Patients
3-5 weeks	13
6-8 weeks	6
9-11 weeks	0
>11 weeks	1

Chi-square test (Fisher extract test), 3 degree of freedom, P <0.0001***

The average duration of full weight bearing was 5.5 weeks in ILN group (range 3-20 weeks).

Table 5: Infection

Infection			No. of Patients
No			16 (80%)
Infection	Superficial		3 (15%)
	Deep	Chronic osteomyelitis	1 (5%)
		Others	0 (0%)
Total			20 (100%)

Chi-square test (Fisher extract test), 3 degree of freedom, P =0.0341*

The above table depicts that the superficial infection of the proximal incision site or wound site was encountered in 3 patients. This was cleared by regular dressing and the usual oral antibiotics. One patient had chronic osteomyelitis.

Table 6: Union Time

G-A grades	12-14 weeks	14-16 weeks	16-18 weeks	>18 weeks	Non-union
Grade 1	3	5	2	0	0
Grade 2	6	1	0	2	1

The union of the fractures was assessed by standard radiological and clinical criteria. Due to presence of nail we couldn't stress the fracture site, hence loss of pain on walking was deemed a better clinical indicator of union.

All 10 (100%) grade I Gustilo's fracture united within 18 weeks of nailing. In grade II Gustilo's fracture, 7 (70%) united within 18 weeks and 2(20%) took more than 18 weeks and 1 went into nonunion.

Johner and wrush criteria

Table 7: Shortening

Shortening in Length (cm)	No. of Patients
<1.5 cm	1
≥1.5 cm	1
No shortening	18
Total	20

Chi-square test (Fisher extract test), 2 degree of freedom, P =0.8345

The above table depicts that only 2 patients had shortening of length.

Table 8: Varus/Valgus Malalignment

Varus/Valgus	No. of Patients
$2\text{-}5^0$	2
$6\text{-}10^0$	0
$>10^0$	0
Normal	18
Total	20

Chi-square test (Fisher extract test), 3 degree of freedom, P =0.1713

The above table depicts that none of patients had gross varus or valgus angulation (>10 degree). Two patients had varus/ valgus angulation of 2-5 degree.

There was no rotational malalignment (>10 degree) in the fracture union patients.

Table 9: Ankle mobility in group A & B

Ankle mobility	No. of Patients
Terminal dorsiflexion loss (10^0)	2
Terminal planter flexion loss (10^0)	1
Plantar flexion Absent	0
Dorsiflexion absent	1
Full	16
Total	20

Chi-square test (Fisher extract test), 4 degree of freedom, P =0.769

Around 80% patients had full mobility at ankle whereas terminal loss of dorsiflexion as well as planter flexion was present in 15% patients.

Table 10: Knee Mobility in Group A & B

Knee mobility	No. of Patients
Stiff Knee	0
Functional ROM	2
Full ROM	18

Chi-square test (Fisher extract test), 2 degree of freedom, P =0.2053

Around 90 % had regained full ROM at knee after nailing. In 2 patients (10%) functional ROM knee was present. The above table depicts that none of patients presented with stiff knee.

Table 11: Pain

Pain	No. of Patients
Occasionally	6
Moderate	2
Severe	0
No	12

Chi-square test (Fisher extract test), 3 degree of freedom, P =0.3430

Occasional pain, not limiting activities of daily living, occurred in 30% subjects which was basically anterior knee pain or pain at screw site.

Table 12: Functional Outcome

Outcome	No. of Patients
Excellent	14
Good	4
Fair	1
Poor	1

Chi-square test (Fisher extract test), 3 degree of freedom, P =0.4065

The outcome was assessed by Johner and Wrush criterias in our study which showed excellent results in 70% cases. Poor outcome was only in 5% cases.

Table 13: List of Complications

Complications	No. of Patients
Osteomylitis	1
Delayed Union	3
Non Union	1
Implant Failure	0
Shortening	2
Varus Valgus	2
Rotation	0
Stiff joint	0
Anterior Knee Pain	8

Discussion

Fractures of tibial shaft is itself a great dilemma and becomes more difficult to treat when it becomes a compound fracture. As industrialization and urbanization are progressing year by year with rapid increase in traffic speed, incidence of high energy trauma are increasing with the same speed. So in this new era of fast paced technologies, an aggressive approach is required to treat such fractures in view of early rehabitilation and return to occupation. Available literature suggests that open fractures of the tibial shaft are both common and may be fraught with complications like malunion, delayed union, nonunion, and infection.

Our study showed that the maximum no. of patients were in 18-30 years of age group. Young generation was more prone as they are the individuals who were physically energetic, engaged in increased multiple outdoor activities, and thus are subjected to high-velocity injuries. Our study was supported by Bonatus *et al*. [16], in which the mean age was 30.3 years, C.M. court – Brown *et al* [6] found mean age of 35 years. Our study shown male predominance with 16 male patients (80%) which is in confinement with the studies done by Hooper [15] *et al* having male predominance 80% and similarly Abdelaal *et al* with [17] (80%). The prevalence of males is higher because of their more outdoor activities, while women are mostly involved in the domestic activities especially in our country.

In cases of compound fracture, surgical interval plays a critical role, as delay exceeding golden period can promote to complications [18]. In our study mostly patients were operated within 24 hours only and almost all of these were devoid of complications. So our study supports the concept immediate surgical intervention.

In our study almost all of the Grade I fractures healed within 18 weeks who underwent primary nailing whereas in grade II majority of fractures 70% healed within 20 weeks and one had nonunion whereas 2 had delayed union and were given bone marrow injection.

This is supported by K.N. Hamza *et al* (1971) [19] who found that rigid fixation with intramedullary nail seldom led to non-union. So patients with nailing healed faster because with this we were able to mobilize the patient early and started aggressive postoperative rehabitailation as it was feasible with this form of treatment.

The union time in our study well corroborates with the studies by Ekeland *et al* [20] and Vaquero *et al* [21] with average union time of 16 wks and 21 weeks respectively. Moreover Bradford Henley (1989) [22] also found average period for union to be 5.5 months.

The nails being used for tibia were interlocking nails which were having addition of transfixation screws compared to K Nail and had been designed anatomically for insertion by the closed nailing technique.

Our study showed that 16 patients were devoid of infection. The superficial infection of the wound site was encountered in 3 patients. This was cleared by regular dressing and the usual oral antibiotics as this is the era of newer and efficacious antibitics. Klaus W. Klemn & Martin Borner [14] (1986) found that deep infection developed in 2.2% tibial fractures after nailing. Per Edwards (1965) [23] found poor outcome of fractures of shaft of tibia due to infection and it was directly related to secondary contamination through devitalized areas of the skin. So debridement has to be performed no matter how many times to obtain good outcomes and prevent infection in open fractures.

The average duration of partial weight bearing was 14 days (Range 2-28 days). Full weight bearing was 5.5weeks. Depending upon pattern of fracture, early partial weight bearing was started as early as possible by patient because mechanical loading of injured bone is conducive to its bone healing. Arne Ekeland *et al* (1988) [24] found that median time of full weight bearing was only 30 days. Klaus W. Klemn & Martin Borner (1986) [14] suggested that in comminuted fractures, partial weight bearing was possible but full weight bearing could not be permitted until follow up radiographs had shown good callus formation around six to eight weeks. If full weight bearing was allowed before the appearance of bridging callus, nail might bend. So we decided weight bearing time according to the fracture pattern and consolidation.

According to Johner and Wruhs criteria [25], The outcome of our study was excellent in 70% cases. Our study was of very short duration so better conclusion of results can be given only after long follow up. Kaare Solheim & Olar B. (1973) [26] suggested that admirable results may be achieved with IM nailing without reaming and with supplementary plaster immobilization. Good or fair result were seen in 96% cases after 2 ½ years follow up.

Functional outcomes regarding occupation were based on Per

Edwards.
(1965) [23] criteria's, Almost all the patients resumed their occupation with slight difficulty in performing activities of daily living in 2 patients.

Conclusion

Our study concluded that in Grade I and II compound tibial shaft fracture intramedullary interlocked nailing is an excellent modality, leading to accepted union with a mild delay but permissible early weight bearing leading to low patient morbidity**.** It is a strong fixation method, providing rotational stability and earliest return to resumption of work, as the rate of healing is suitable with this method.

The advantages of IM nailing over the external fixator are that we can start early range of motion exercises and weight bearing leading to shorter duration of hospital stay and supple joint function. Also, residual deformities like shortening, angulation and rotation are minimal with this form of treatment. Though its use in more severe fractures i.e. Grade III has to be still evaluated.

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