

## Original Research Article

# Functional outcome and complications in closed and grade I open tibia shaft fracture operated with intramedullary interlocking nail

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## ABSTRACT

**Background:** Treatment of open tibia fracture is controversial. Complications such as infection, re-operation, non-union and poor consolidation are also relatively common after these fractures. While grade II and III fractures are mostly treated with debridement and external fixator, grade I fractures are a matter of controversy. The purpose of this study is to evaluate factors affecting deep infections and fracture healing of closed and grade I open fracture of the tibial shaft treated with immediate or delayed interlocking IMN, and to study the functional outcome of the same.

**Methods:** 60 Patients admitted to our institute with diagnosis of closed or grade 1 open tibia shaft fracture aged more than 18 years old between May 2016 to December 2016 were included. After initial evaluation and investigation, they were posted for surgery. Closed reduction and fixation with intramedullary nailing were done under spinal anesthesia. After discharge patients were followed up at an interval of 3 weeks, 3 months and 6 months and were evaluated using Johner and Wruhs criteria.

**Results:** In our study, 91.67% patients have got excellent, 3.33% good and 1.67% poor results according to Johner and Wruhs criteria.

**Conclusions:** Closed and grade one open fractures of the tibia shaft, managed with interlocking intramedullary nailing involves minimal surgical trauma and negligible blood loss while provides the advantages of early ambulation, lower rate of infection, delayed union, non-union and mal-union.

**Keywords:** Grade I open, Tibia fracture, Diaphyseal fracture, Intramedullary nail, Interlocking nail

## INTRODUCTION

As industrialization and urbanization are progressing year to year with rapid increase in traffic, incidence of high energy trauma are increasing with the same speed. Long bone fracture is one of the most common associated injuries in such scenario. The long bone fractures most frequently occur in the tibial shaft.<sup>1</sup> Fractures of the tibia shaft are important for the reason that they are common and controversial. The anatomical location of the tibia makes it vulnerable to the direct blow and high energy trauma as a result of motor vehicle accidents thus

resulting in comminuted fractures, which are frequently open with significant loss of skin and soft tissues. In contrast to the rest of appendicular skeleton, tibia has precarious blood supply due to inadequate muscular cover. Tibia fractures may be associated with compartment syndrome, vascular and neural injury. The presence of hinge joints at the knee and the ankle, not allows any rotatory deformity after fracture. Because of the high prevalence of complications associated with these fractures, especially when it is an open fracture, management often is difficult, and the optimum method of treatment remains a subject of controversy.<sup>2</sup>

Among the various modalities of treatment such as conservative gentle manipulation and use of long leg cast with a window, open reduction and internal fixation with plates and screws, intramedullary fixation (including ender pins, intramedullary nails and interlocking intramedullary nails) and external fixation techniques, surgeon should be capable of using all these techniques and must weigh advantages and disadvantages of each one and adopt best possible treatment which should be determined by a thoughtful analysis of morphology of the fracture, the amount of energy imparted to the extremity, the mechanical characteristics of the bone, the age and general conditions of the patient, and most importantly the status of the soft tissues.<sup>3</sup> Three goals should be met for the successful treatment of fractures of tibia. The prevention of infection, the achievement of bony union, and the restoration of function. These goals are interdependent and are achieved in the chronological order given. For example, failure to prevent infection promotes delayed union or non-union and delays functional recovery of the limb.

Immobilization in a plaster cast has been used most commonly in the past, but it does not always maintain the length of the tibia and it leaves the wound relatively inaccessible.<sup>4,5</sup>

Open reduction and internal fixation with plates and screws has yielded unacceptably high rates of infection.<sup>6</sup> This method may be selected with more severe or local injuries associated displaced intra articular fractures of knee and ankle.

External fixation, considered the treatment of choice by many traumatologists, has the disadvantages of bulky frames and frequent pin track infections, non-union, and malunion.

The intra-medullary nailing, locked or unlocked has become an attractive option since image intensifier has made closed intramedullary nailing possible. Nail is a load sharing device and is stiff to both axial and torsional forces. Closed nailing involves least disturbances of soft tissue, fracture hematoma and natural process of bone healing as compared to other forms of internal fixation.<sup>7-9</sup> The locking of intramedullary nails to the major proximal and distal fragments decreases the prevalence of malunion of comminuted fractures.

**METHODS**

**Study population**

In this study, 60 cases of closed and grade I open fracture shaft tibia, admitted under Orthopaedics department in our institute, treated with intramedullary interlocking nail was studied during the period from May 2016 to December 2016.

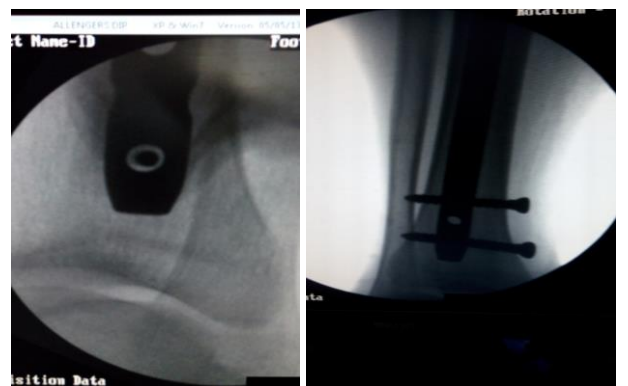
Case selection was done according to the history, clinical examination and radiological (X-ray) findings. Soon after admission, clinical data was recorded as per the case record form. Age, sex, mode of trauma, type of injury and all other vital parameters were noted. After all initial evaluation to rule out other associated fracture and pre-operative investigation they were posted for surgery. The average interval between admission and surgery was 6 hours in average. An intra-medullary nailing was done using image intensifier guidance under spinal anesthesia.



**Figure 1: Entry taken under c-arm image intensifier.**



**Figure 2: Guide-wire inserted and position confirmed.**



**Figure 3: Nail inserted and distal locking done in free-hand technique.**



Figure 4: Proximal locking done through zig.

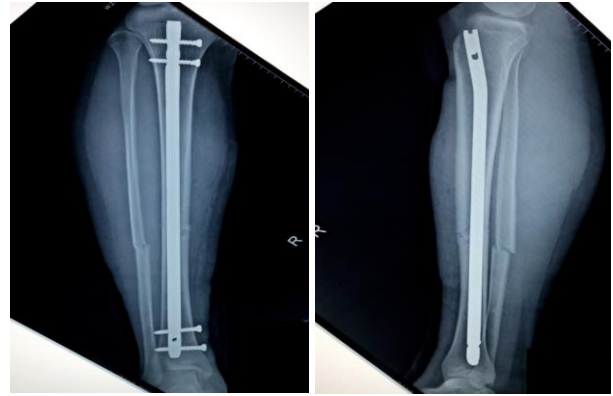


Figure 5: Immediate post-operative X-rays.

Table 1: Johner and Wruh’s criteria.

S. no.	Criteria	Excellent	Good	Fair	Poor
1	Non-union	None	None	None	Yes
2	Neurovascular injury	None	Minimal	Moderate	Severe
3	Deformity				
	Varus/valgus	None	2-5 degree	6-10 degree	>10 degree
	Pro/recurvatum	0-5 degree	6-10 degree	10-20 degree	>20 degree
	Rotation	0-5 degree	6-10 degree	10-20 degree	>20 degree
	Shortening	0-5 mm	6-10 mm	10-20 mm	>20 mm
4	Mobility				
	Knee	Full	>80%	>75%	<75%
	Ankle	full	>75%	>50%	<50%
	Subtalar	>75%	>50%	<50%	
5	Pain	None	Occasional	Moderate	Severe
6	Gait	Normal	Normal	Minimal limp	Significant limp
7	Strenuous activities	Possible	Limited	Severely limited	Impossible

The wound, where present, were closed after proper debridement over a corrugated rubber drain. Next day full weight bearing mobilization were started for most of the patients and were discharged after 3 days of intravenous antibiotics, followed by oral antibiotics for next two weeks.

Patients were followed up after 3 weeks, 3 months and 6 months. In every follow up, the patients were assessed both clinically and radiologically for the signs of infections, bony union and the range of motion at the knee and the ankle. Dynamization was done only in those cases where the fractures did not show good signs of union between 6-10 weeks. Final outcome was evaluated by Johner and Wruhs criteria.

**Statistics**

*Sample size calculation*

The sample size is calculated using the method described for assessment of clinical outcome from a single group interventional study.

The data used in the calculation is based on the previously published literature of findings on clinical outcomes of intra-medullary nailing in open fractures of tibia and their complications, in patients presenting to a tertiary care hospital in India.

$$n = \frac{(z_{\alpha} + z_{\beta})^2 \theta(1-\theta)}{(\theta - \theta_0 - \delta)^2}$$

Where

- $\alpha = 0.05$
- $1-\beta = 0.9$
- $\theta = 0.80$
- $\theta_0 = 0.86$
- $\delta = 0.1$

**Variables description**

- $\alpha$ : One-sided significance level
- $1-\beta$ : Power of the test
- $\theta$ : Expected success proportion of sample
- $\theta_0$ : Known success proportion
- $\delta$ : True difference of mean response rates,  $\delta > 0$ , the superiority margin or value of  $\delta < 0$ , the non-inferiority margin
- N: Required sample size.

The proportion of patients showing good to excellent outcome (responder rate) based on the Johner and Wruh’s

criteria was reported to be around 86% (proportion of 0.86). To achieve the success rate of 80% for the said study intervention with 95% level of significance ( $\alpha=0.05$ ) and if a difference of <10% in responder rate is considered to be of no clinical significance the required sample size giving a 90% power ( $\beta=0.1$ ) will be 54. Presuming a 10% drop out, the minimum sample size for this study is 60 subjects (N=60).

**Statistical analysis**

Qualitative data will be represented in form of frequency and percentage. Association between qualitative variables will be assessed using the chi-square test with continuity correction for all 2x2 tables and without continuity correction in rest and Fischer exact test for all 2x2 tables where p-value of chi-square test is not valid due to small count. Quantitative data will be represented using mean±SD, median with range. Analysis of quantitative data between a qualitative variable with two subgroups will be done using unpaired t-test if data passes "Normality test" and by Mann-Whitney test if data fails 'Normality test'. Results will be graphically represented where necessary. SPSS version 17 will be used for most analysis. P value less than 0.05 will be considered as significant.

**Inclusion criteria**

Inclusion criteria were patients of either sex of age 18 and above; fracture tibia or tibia and fibula both in same leg; closed and open Gustilo-Anderson grade-I fractures; all those fractures of tibia which are in the diaphysis (7-8 cms distal to knee and 4-5 cms proximal to the ankle joint); unilateral or bilateral tibia fractures.

**Exclusion criteria**

Exclusion criteria were patient less than 18 yrs age; any associated fracture (other than fibula) in the same limb; fractures other than diaphysial one; open fractures of tibia which are gustilo grade II and III; patient who having arthritis involving knee and ankle; pathological tibia fracture.

**Ethics**

The study was conducted as per national and international guidelines for conducting research in human subjects.

The protocol was submitted to institutional ethics committee for review and study was initiated only after obtaining approval from the committee.

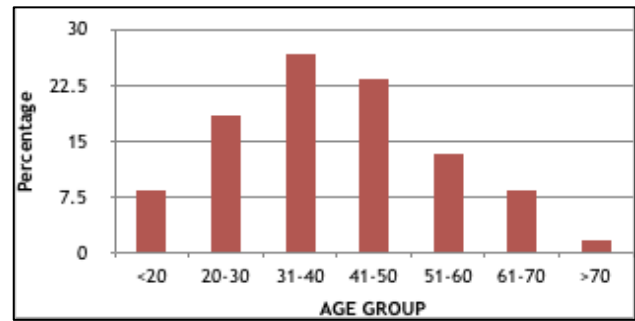
**RESULTS**

The present study consists of 60 patients having tibia fracture treated by closed intramedullary interlock nailing.

I have studied the functional outcome of patients treated with intramedullary interlock nailing.

**Age**

We had patients ranging from >18 years to 70 years. Majority of the patients were in age group 30-50 years (50%). Average age in our series was 45 years. People between age of 30-50 years are more prone to accident according to their increased vehicular usage.



**Figure 6: Distribution of age group.**

**Sex**

We had 46 males (76.67%) and 14 females (23.33%) patients in our study. The male- female approximate ratio is 3:1. The preponderance of males is because of males are more outgoing, hence more vulnerable to vehicular accidents and due to usual society practice, certain tasks which involve high risk are done by males. e.g. working at height, driving, labour and travelling.

**Table 2: Distribution of sex.**

Gender	Number	Percentage (%)
Female	14	23.33
Male	46	76.67
<b>Total</b>	<b>60</b>	<b>100</b>

**Table 3: Distribution of mode of trauma.**

Mode of injury	Number	Percentage (%)
Vehicular accidents	54	90.00
Fall	6	10.00
<b>Total</b>	<b>60</b>	<b>100</b>

**Mode of injury**

In our study 54 patients were having history of road traffic accident (90%) and 6 patient had history of fall from height (10%).

**Side of involvement**

In our study 38 patients had right side involvement and 22 patients had left side involvement.

The results are showing non-significant involvement of right side.

**Closed or open fractures**

We had 56 (93.33%) cases of closed fractures and 4 (6.67%) cases of grade-I open fractures in our study.

**Type of fracture**

According to AO-OTA classification, Type-A accounted for 59.99%, Type -B for 33.34% and Type -C for 6.67%.

In our study Type A i.e. simple type of fracture were most common.

**Table 4: Distribution of type of fracture.**

Classification	Number	Percentage (%)
A1	14	23.33
A2	10	16.66
A3	12	20.00
B1	12	20.00
B2	4	6.67
B3	4	6.67
C1	4	6.67
C2	0	0
C3	0	0

**Follow up of patients**

After discharge patients were followed up at 3 weeks, 3 months and 6 months. The time of return to work and full activities were noted.

**Table 5: Distribution of functional activity level.**

Parameters for classification	Number	%
<b>Knee pain</b>		
Occasional	2	3.33
Moderate	2	3.33
Nil	56	93.34
Non union	1	1.67
Neuromuscular injury	0	0
Deformity	1	1.67
<b>Gait</b>		
Minimal limp	2	6.67
Significant Limp	1	1.67
Normal	57	95.00
<b>Strenuous activity</b>		
Impossible	1	1.67
Limited	2	3.33
Severely limited	2	3.33
Normal	55	91.67

**Knee range of motion, squatting and sitting cross legged**

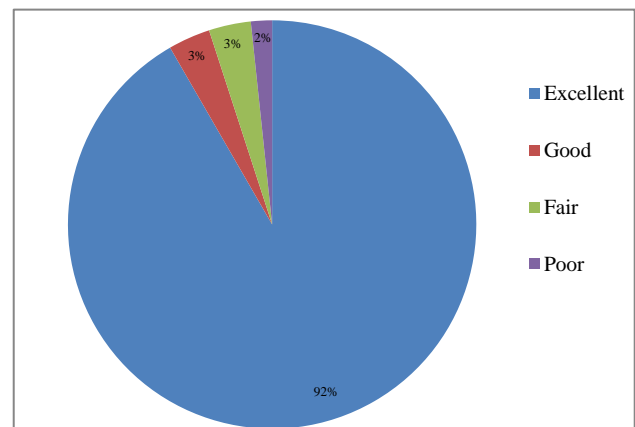
Taking consideration in to Indian life style and working pattern, we had given much importance to knee range of motion which is necessary for squatting and sitting cross legged.

The possible causes of restriction of movement range from associated trauma at the time of injury, wasting of quadriceps tendon due to prolonged immobilization in cast and lack of physiotherapy due to less patient compliance.

In this study, there were 91.67% of the patients developed no postoperative restriction of movement, while rest 8.33% developed slight restriction in range of motion.

**Table 6: Mobility of knee joint.**

Mobility of knee	Number	Percentage (%)
<75%	1	1.67
>75%	2	3.33
>80%	2	3.33
Full	55	91.67
Total	60	100



**Figure 7: Distribution of functional outcome.**

**DISCUSSION**

We undertook a study of 60 cases of tibia shaft fracture which operated with closed intramedullary interlocking nailing. Most of the study population was of middle age between 30-50 years with male preponderance. Union problem with this technique was negligible.

The rate and type of complication such as implant failure, wound gapping has not been observed. Acceptable range of movement with going back to activities of daily living was observed in our study. Study by Ekeland et al, in 45 patients noted the average age of patients to be around 35 years and average age was seen to be around 37 years in a

study Brown et al in a study titled “The Epidemiology of Tibial Fractures”.<sup>10,11</sup>

In this present study majority of the patients were in age group 30-50 years (50%). Average age was 45 years. Brown et al, in their study noted male incidence to be around 81.3%, while the female around 18.7%.<sup>11</sup> In present study 46 males (76.67%) and 14 females (23.33%).

In study of Radhakrishna et al was 86.7%.<sup>12</sup> In present study 90% tibia fracture because of road traffic accident.

In present study simple transverse tibia fracture were 23.33%, spiral 16.66%, and 20% oblique type. Brown et al reported 37.2% transverse and oblique fractures and Ekland et al reported 42% transverse and oblique fractures.<sup>10</sup> In Radhakrishna et al study reported 30% transverse and oblique fractures.<sup>12</sup>

Final assessment in our study was done at 6 months using the Johner and Wruh’s criteria, taking into account of the following objective and subjective symptoms of gait, pain, deformity, range of motion of knee, ankle and subtalar joints, shortening,

Neurovascular disturbances, ability to do strenuous activities, radiological union and presence or absence of non-union. Functional outcome was graded into excellent, good, fair and poor.

In our study, 91.67% patients have got excellent, 3.33% good, 3.33% have fair and 1.67% poor results. In comparison with study of Ekland et al reported 64.4% excellent, 28.8% good, 4.4% as fair and 2.4% poor results.<sup>10</sup>

## CONCLUSION

Majority of the patient were middle aged between 30-50 years, predominantly male with a ratio of 3:1. Right side was predominantly affected and mostly was closed fracture with only 4 open fracture (Grade 1). According to AO classification, Type-A accounted for 59.99%, TYPE-B for 33.34% and Type-C for 6.67%. After discharge patients were followed up at 3 weeks, 3 months and 6 months. The time of return to work and full activities were noted. The average union time was 22 weeks. There were 91.67% of the patients developed no postoperative restriction of movement and were. While 8.33% developed restriction in range of motion.

The present series shows that closed fractures and Grade 1 open fractures of the tibia shaft, managed with interlocking intramedullary nailing involves minimal surgical trauma and negligible blood loss. It provides the advantages of early ambulation, lower rate of infection, delayed union, non-union and malunion. It is viable

option for fracture of the tibia in public hospital set up as it is cheaper causes minimal morbidity; shorten operative time and hospital stay.

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*Conflict of interest: None declared*

*Ethical approval: The study was approved by the institutional ethics committee*

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