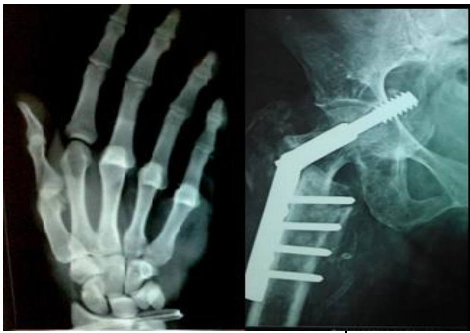

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# A study on application of newly designed device for targeting second interlocking hole in tibial fractures

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**Abstract**
**Background and Objectives**: The indication for intramedullary nailing has expanded widely. Nail design improved since first introduction but distal locking is still difficult, even with the use of image intensifier. A jig is available only for proximal locking. The jigs designed for distal interlocking have not been successful and reliable. The objective of study is studying patterns in tibial fractures. Make distal locking easy and convenient. Reduce radiation exposure. Reduce operating time.
**Methods**: A study of 23 patients who had fracture of both bones leg was under taken in NRI medical college and general hospital from January 2010 and October 2011. After performing tibial nailing, 1st medio-lateral distal locking screw was done by free hand technique and second screw locked by the distal jig designed in our institute. The purpose of study is to compare radiation time and total duration of distal locking by free hand technique and distal locking by the jig. Categorical variables are compared using paired t test. P valve of <0.05 was considered to be significant.
**Results:** The average operating time for tibial nailing was 93 mins. Distal locking of first medio-lateral screw using free hand technique was 6.8 mins (3min-15min). Distal locking of second medio-lateral screw using distal jig was 3-5 mins (2min-5min). Average radiation exposure (shots) for first screw was 6.3 shots (3 to 16 shots).second screw is 3.6 shots (2 to 6 shots). P valve is 0.001.
**Interpretation & Conclusion:** Due to significant difference between the two methods in duration of distal locking and radiation exposure. Distal locking with the jig is advantages for closed intramedullary nailing of tibial fractures. Still high learning curve is present in distal locking.

**Keywords:** Distal locking, radiation, intramedullary nail

## Introduction

The indication for intramedullary nailing has expanded widely. Nail design improved since first introduction but distal locking is still difficult, even with the use of image intensifier, thus increasing operating time and exposure to radiation.

A jig available only for proximal locking. The jigs designed for distal interlocking have not been successful and reliable. The reason being, nail under goes minimal amount of deformation due to the Herzog's bend as it is hammered in. When distal jig is attached this deformation is amplified because of the long lever arm and hence it is not reliable in targeting the distal holes. One study suggests distal locking can increase radiation exposure for the surgeon and the patient as much as 2.6 times.

Many efforts have been made over years to find a satisfactory solution to this problem.

In general the types of distal targeting devices have that been developed are:

1. Targeting device mounted on to the nail which has been abandoned, as the device could not compensate the well-known 'axis-pivot phenomenon' [1, 2].
2. Targeting device mounted onto the image intensifier. Although these devices offer good protection from the radiation, they have not been generally accepted, mainly because of their instability. Adjustment micro movements are difficult to be done as these devices can only move with the image intensifier which is not constructed to carry out this task [3, 4].
3. Various free hand techniques with the use of various instruments (Pennig) [9]. These techniques are used nowadays by most surgeons as the best available with controversial reliability.

4. Handheld targeting device
5. Radiolucent drill guides
6. Computer assisted system
7. Navigation-assisted distal locking device

The main disadvantages of the free hand techniques are
1. Prolonged exposure to radiation (direct and scattered) for both the surgeon and the patient, as there must be continuous confirmation of the correct positioning of the device [5, 6, 7].
2. Instability, as the instrument is held in the surgeon's hands. It should be taken into account that distal targeting-which is a procedure of short duration itself –is the final setting of a demanding operation and tiredness could influence the final result [8, 9].
3. Difficulty in drilling with a long and somewhat thin drill, through soft tissues and against the concave lateral aspect of the tibial metaphysic [10].

The design proposed is based on targeting the second hole after locking first by free hand technique that will reduce operating time and locking of second hole by 50%.
Hitherto we were doing distal interlocking by free hand technique with the guidance of image intensifier. Use of this new design, we assume, will reduce surgery time and help in accurately targeting the second hole.

**Aims and Objectives of Study**
1. To study the type of injury and various types of tibial shaft fractures.
2. To make distal interlocking screw fixation easy and convenient
3. To reduce radiation exposure
4. To reduce operating time of second distal screw

**Materials and Methods**
A study of 21 patients who had fracture of both bones leg and 2 bone models was under taken in NRI medical college and general hospital from January 2010 and October 2011. The purpose of study is to compare radiation time and total duration of distal locking by free hand technique and distal locking by the jig we proposed.

**Inclusion Criteria**
All simple diaphyseal fractures of tibia Patients who attained skeletal maturity when assessed radiographic closed and Gustilo type I and type II and type III A open Diaphyseal fractures of the leg.

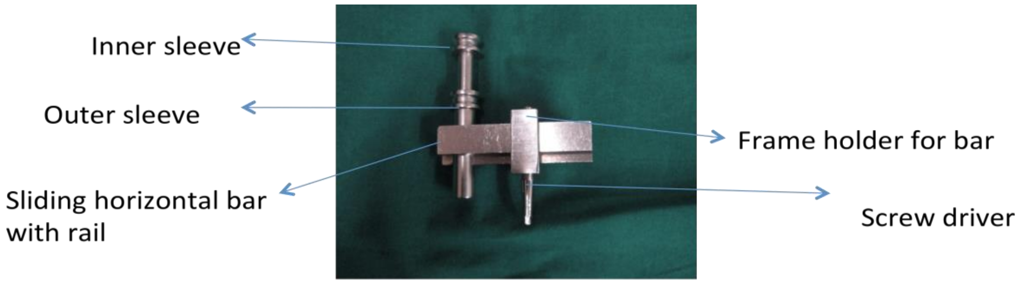
**Exclusion criteria**
Compound and contaminated fracture
Grossly osteoporotic
Paralysed limbs
Unmotivated patients
1. Pregnant women
2. Distal comminuted fractures of tibia
3. Age less than 18years

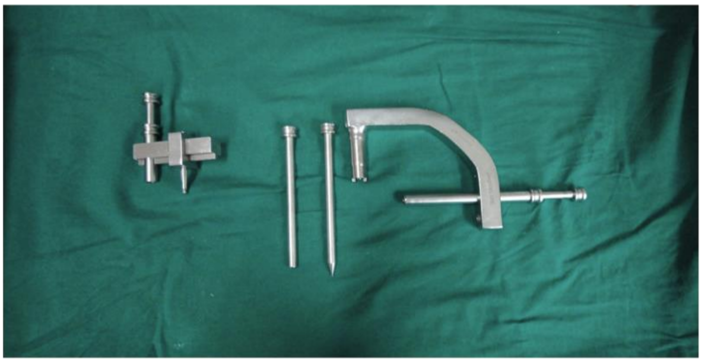
All patients underwent a primary survey and hemodynamic stabilization in the emergency department. The presence of other fractures, neurovascular status of the limb and systemic evaluation was done subsequently on secondary survey.
Appropriate anteroposterior and lateral radiographs were taken and the limb immobilized on a Plaster of Paris. The fracture patterns were classified according to the Orthopaedic Trauma Association classification. Open fractures were classified according to the criteria of Gustilo and Anderson.

**Distal Jig**
The distal locking jig devised for this study is utilized only after, screw is passed through first interlocking hole.
Its consists of two parts
1. A frame which is reference to the locked screw by means of a hexagonal screw driver.
2. A slide bar which passes through the frame and moves along the long axis of tibia. The bar contains a targeting hole, which can accommodate two drill sleeves.

The targeting hole is aligned with the distal interlocking hole in the nail and the sliding bar is fixed in that position by tightening the screw in the frame.

**Operative Procedure**
All cases were managed under spinal anaesthesia/general anaesthesia. Pre-operatively a calcaneal Steinmann pin was put for some of the patients. An image intensifier with a C-arm was used in all the cases to provide fluoroscopic guidance.
The patient was positioned supine on the radiolucent table. he can lie on the table with straight knee and it is pulled out of the table on the side and knee kept hanging on side of the table or knee is bent at 90°and hip external rotated. Longitudinal traction if required was applied along the calcaneal skeletal pin. Rotational alignment was achieved by aligning the anterior superior iliac spine, patella and second ray of the foot.



Distal and proximal jig

The affected leg was cleaned and draped from mid thigh to the mid-foot. The image intensifier was draped with a sterile isolation drape. A five centimeter incision was made medial to the patellar ligament or patellar tendon-splitting approach.
Using a curved awl, the medullary canal was opened proximal to the tibial tuberosity at the level corresponding to the proximal tip of the fibular head. The centre of medullary cavity is on the medial half of tibial tuberosity. The bone awl was centered in the medullary canal. A curved 3.2 mm ball tipped guide wire was inserted to the level of the fracture.
The proximal fragment was reduced to the distal fragment. Under C-arm guidance, the guide wire was advanced in to the distal fragment, centring both in anteroposterior and lateral views. The guide wire was introduced 0.5 to 1 cm proximal to the ankle joint. The entire tibia was reamed using cannulated reamers over the guide wire in 0.5 mm increments until the desired diameter has been achieved. A nail 1 to 1.5 mm smaller than the final reamer was selected. The 3.2 mm guide wire was exchanged for a 3 mm non balled tipped guide wire; a medullary exchange tube was used to avoid loss of fracture reduction.
The selected nail was attached to the proximal drill guide with the hexagonal bolt. The nail was driven over the guide rod until the nail has entered the metaphysis of the distal fragment. The guide wire was then withdrawn. The nail was driven further until the proximal tip of the nail was countersunk into the tibial entry portal. With the final hammer blows for seating the nail, the traction was released from the leg and counter pressure applied through the foot to close any fracture gap.
Two proximal locking screw was inserted in to the proximal locking hole with the help of proximal jig. Two or Three distal locking screws were inserted using a free hand technique with the help of image intensifier and jig we designed for second medio-lateral screw.
Distal locking by free hand technique, the patient leg placed between the source of the x-ray beam and the aiming device. The image intensifier is positioned so that the locking hole appears as a perfect circle on monitor.
Distal locking by the jig, after locking the first medio-lateral screw by the free hand technique. The jig is mounted on the first screw by means of a hexagonal screw driver, which is a part of jig. The centre of the jig hole is aligned with the centre of second medio-lateral locking hole on vertical and horizontal axis under c-arm guidance.

**Post-Operative Regime**

Post operatively all the patients were mobilized non-weight-bearing with crutches or walker from third post-operative day of surgery. Mobilization of the knee and ankle was also started in the immediate postoperative period. Sutures were removed on tenth day of surgery.
X-ray of the involved leg was taken post operatively including both knee and ankle joints in the same film. Patients were followed up clinically and radiographically at one month, two months, four months and six months and yearly intervals. Data was collected by verbal communication, clinical examination and radiographic features. At the time of admission fractures were classified according to the Orthopaedic Trauma Association classification. Nature of the injury was also noted. In the post-operative radiographs tibial malalignment was measured. The degree of the tibial angulation [varus or valgus] was measured on the anteroposterior radiographs by determining the angle formed by the intersection between the perpendicular lines drawn from the tibial plateau and tibial plafond.
At the end of six months, the range of movement [dorsiflexion and plantar flexion] at the ankle and knee was determined.

**Results**

During the year 2010 – 2011, two bone models and21 patients of age between 19 – 60 years of age group with tibial shaft fractures were treated by intra medullary inter locking nail. Observations thus obtained have been recorded as under:

**Age**

Tibial shaft fractures in the age group less than 30 years comprising of 9 cases and age group more than 30 years comprising of 12 cases in the present study.

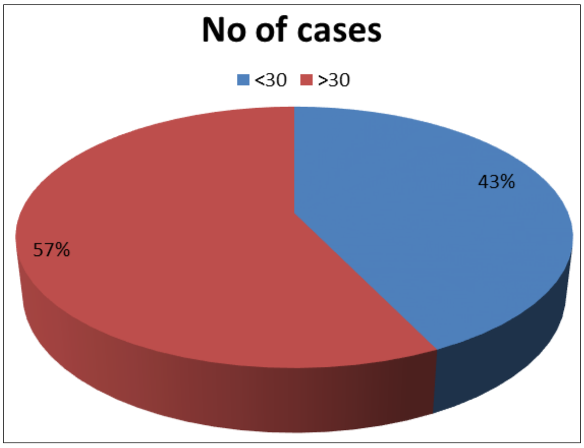



**Fig 1:** Age in the study group

### Sex

In the present study sex distribution is 20 male and one female.

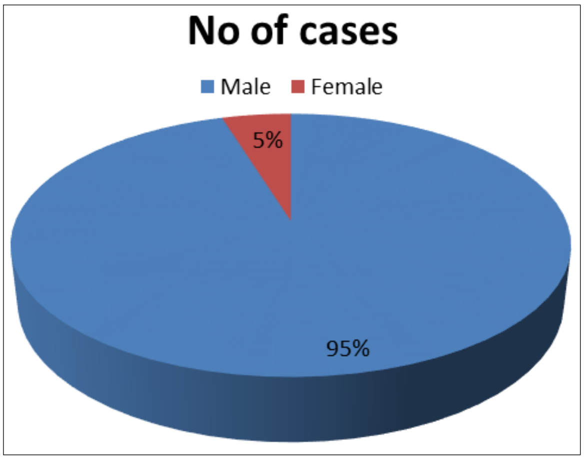



**Fig 2:** Sex of the patients

### Side involved

8 cases involved on right side and 13 cases involved left side.

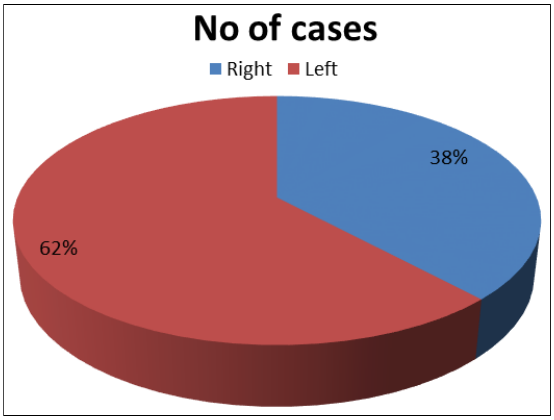



**Fig 3:** Operative site

### Mode of injury

The common mode of injury was Road Traffic Accident

### Interval between injury and operation

77.77 percent of the cases were operated within 10 days of injury whereas only 22.22 percent of the patients could be operated within 20 days of injury.

**Table 1:** Interval between injury and operation

| Interval | No. of cases | Percentage |
|---|---|---|
| 1 – 10 days | 13 | 61.90 |
| 11 – 20 days | 8 | 38.1 |
| Total | 21 | 100 |

### Anaesthesia used

**Table 2:** All the lower limb fractures were operated under spinal anaesthesia

| Type of anaesthesia | No. of cases | Percentage |
|---|---|---|
| Spinal anaesthesia | 21 | 100 |
| General anaesthesia | 0 | 0 |
| Total | 21 | 100 |

### Duration of operation

**Table 3:** Duration of Operation

| Duration of operation | No. of cases | Percentage % |
|---|---|---|
| < 60 min | 2 | 8.69 |
| 1hr – 1hr59min | 13 | 56.2 |
| 2hr 0r more | 9 | 39.1 |
| Total | 23 | 100 |

**Table 4:** Distal locking by free hand technique and distal jig

| Cases | 1st screw free hand technique | 2nd screw distal jig | Radiation exposure of 1st screw | Radiation exposure 2nd screw |
|---|---|---|---|---|
| 1 | 4mins | 2mins | 4shots | 2shots |
| 2 | 4mins | 3mins | 5 shots | 3shots |
| 3 | 7mins | 5mins | 8shots | 6 shots |
| 4 | 5mins | 3mins | 6 shots | 3shots |
| 5 | 7mins | 3mins | 4shots | 3shots |
| 6 | 6mins | 3mins | 5shots | 2shots |
| 7 | I2mins | 5mins | 10shots | 5shots |
| 8 | 10mins | 5mins | 8 shots | 3 shots |
| 9 | 6mins | 4mins | 4 shots | 3 shots |
| 10 | 12mins | 5mins | 10shots | 4shots |
| 11 | 6mins | 3mins | 4shots | 2shots |
| 12 | 8mins | 4mins | 7shots | 4shots |
| 13 | 4mins | 3mins | 5shots | 3shots |
| 14 | 6mins | 4mins | 5 shots | 4shots |
| 15 | 3mins | 2mins | 4shots | 4shots |

| | | | | |
|---|---|---|---|---|
| 16 | 4mins | 3mins | 3shots | 4shots |
| 17 | 5mins | 3mins | 5shots | 3shots |
| 18 | 12mins | 3mins | 16shots | 4 shots |
| 19 | 4mins | 3mins | 4shots | 3shots |
| 20 | 6mins | 3mins | 6shots | 4shots |
| 21 | 12mins | 5mins | 10 shots | 4shots |
| 22 | 6mins | 2mins | 6shots | 2shots |
| 23 | 9mins | 3mins | 7shots | 3shots |

The difference in timings between the two techniques for inserting distal screws are statically highly significant.

**Discussion**

The present study consisted of 23 cases of tibial shaft fractures treated with intramedullary inter locking nails, treated in the department of orthopaedics, N R I general hospital, chinakakani, Guntur during the year 2010-2011. The results obtained have been compared with the results obtained by other works using the same technique.

In the present study, initially conducted on the 2 bone models, then 20 males (86.95) and 1 female (4.3%). Road traffic accident was responsible for 100 percent of the patients. Most of the patients reported within 3 days of injury (72.8%). Of these 38.4 percent patients reported on the day of injury.

The average operating time in the present study was 93mins. Minimum time for IMIL is 1 hour and maximum time is 3 hours. Prolonged surgery time is due to difficulty in entry point, fracture reduction, secondary procedure and distal locking.

Average distal locking time was 14 mins. Minimum time required is 5min and maximum time required 35 min. Knudsen *et al.* (1991) [1] reported average distal locking time in15 to 20 mins. Krettek *et al.* [2] in 1997 reported average distal locking time is 16.7 ±8.6min. Geroge Anastopoulos *et al.* [3] in 2007 reported average distal locking time with jig is 6.4mins.

Distal locking of first screw by free hand technique averaged 6.8min. Minimum time being 3min, and maximum 15 min. A. Hashemi-Nejad *et al.* [4] in 1994 average time was 4 to 5mins.

Distal locking second screw by distal jig, average time was 3.5mins. Minimum time being 2min and maximum was 5 min. Maximum time taken due to formation of maltract. A. Hashemi-Nejad *et al.* [4] in 1994 average time was average1 to 2min.

Radiation exposure which was displaced on c-arm display number of shots for each screw noted. For first screw average c-arm shots was 6.3 shots. Minimum being 3 shots maximum 16 shots. For second screw average c-arm shots was 3.4 shots and minimum being 2 shots and maximum 6 shots.

Current study all the cases suture removal done on 10 to 14th post operative days. Depending on type of fracture partial and full weight bearing done. All cases united four cases required dynamization. One case infected.

When compared with the results using other techniques [5], radiation exposure during distal locking was 36 seconds (19.08 minutes of surgical time for distal locking and 81 seconds of total fluoroscopy time) forthe freehand technique versus 15 seconds (17.06 minutes of surgical time during distal locking and 69 seconds of total fluoroscopy time) for the Orthofix*1* targeting device (three distal screws). Levin *et al.* [6] documented 2.7 minutes of fluoroscopy time (range, 0.6–6.6 minutes; 12 mrem average of radiation exposure) for distal locking of tibial nails. Sanders *et al.* [7] required a mean fluoroscopy time of 3.44 minutes, and Tsalafoutas *et al.* [8] recently reported an average 137 ± 111 mGy and 5.7 ± 3.5 minutes of radiation exposure for tibial fracture nailing. Nevertheless, a comparison with similar techniques is beyond the scope of this study.

Like other methods circular hole not required like Pennig *et al*. MacMillan and Grosse and Knudsen *et al*. [9, 10, 1] this jig is a simple method to achieve distal locking screw fixation for the IMIL nails. The jig eliminates three of the four variables in locating a distal locking hole. The four variables when locating and drilling the second distal hole are the x, y and z moments for the hole, as well as distal and proximal migration of the C-arm of the image intensifier. Using the jig eliminates the x y axis and the distance between the holes, thus only the z axis (rotational movement) needs to be aligned. With the holes aligned, there is no necessity to move the image intensifier to obtain perfectly round holes as the distance between the holes in the nail is the same as the distance between the inserted part and the hole in the jig. The same type of jig could be designed for other nail systems. It reduces the operating and screening times. It is also a helpful tool to address the problem of the offset drill hole.

Although these techniques reduce the problems of radiation and cortical defects, there are still difficulties to be addressed. As compared to other methods two surgeons required one for stabilizing the device and other for drilling and surgeon hand near to the source. A. Hashemi-Nejad *et al.* [4] in 1994 developed long handle distal jig. Other includes involuntary movements that occur during the change from locating the holes to aiming the drill, or wire, and drilling the hole; additionally, the path of the drill bit is difficult to monitor. There are cost advantages to using readily available equipment to aid distal screw location.

Other methods like sound navigation system and c-arm attached jigs which are costly not available everywhere. We feel although surgery time and radiation exposure time decreased still high learning curve present.

**Conclusion**

It's simple method, utilising an locally developed jig. The jig eliminates three of the four variables in locating a distal locking hole. It reduces the operating and screening times. It is also a helpful tool to address the problem of the offset drill hole. There are cost advantages to using readily available equipment to aid distal screw location. Although these techniques reduce the problems of radiation and cortical defects, there are still difficulties to be addressed. As compared to other methods two surgeons required one for stabilising the device and other for drilling. Involuntary movements that occur during the change from locating the holes to aiming the drill.

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**Conflict of interest:** None

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