Management of Diaphyseal Tibia Fractures with Interlocking Sign Nail after Open Reduction without Using Image Intensifier

Objective: To evaluate clinical and radiological outcome of closed diaphyseal fracture of tibia by doing open reduction and fixation by inter-locking intramedullary (SIGN) nail without using image intensifier

Patients and Methods: A total number of 30 patients with isolated closed diaphyseal fracture were included in this study. Instead of using standard tibial interlocking nail system which requires image intensifier (fluoroscope) to fix the fracture without opening it, we used SIGN (Surgical Implant Generation Network) system to fix. SIGN nail surgeries including proximal and distal locking were done without using image intensifier, but the fracture was opened to reduce and fix it. Johner and Wruh’s Criteria with modification was used to measure final outcome.

Results: Out of 30 tibia fractures, male to female ratio was 4:1. Average study period was 1.3±0.25 years. Mean age of the study population was 35.75±13.16 years. Fracture pattern observed was transverse (n=12; 40%), oblique (n=05; 16.6%) and spiral (n=13; 43.3%). Five (16.6%) patients had delayed union. Three of these were also infected. All the five cases were dynamized and infected cases underwent repeated debridements to gain union. Only one patient went into infected non-union. Excellent, good, fair and poor results were achieved in 43.3%, 33.3%, 16.6% and 6.6% patients, respectively.

Conclusion: SIGN method of nailing for closed tibial diaphyseal fractures is an excellent option despite open reduction. As this surgery can be performed without the use of image intensifier, it reduces radiation hazards and requirement of costly equipment in countries like ours. Also, it is ideal in disaster situation.

Key Words: Tibial diaphysis, closed fractures, open reduction, intramedullary nailing, image intensifier

Introduction

An understanding of the diagnosis and treatment of tibial shaft fractures is of equal importance to primary care physicians and orthopedic surgeons. High-speed lifestyles with motor vehicles and motorcycles contribute to the increasing incidence of tibial shaft fractures in today's society. The tibia is currently the most commonly fractured long bone in the body. Alho et al have reported an annual incidence of 2 tibial shaft fractures per 1000 individuals.1

Most of these closed tibial shaft fractures can be treated nonoperatively with good result. Littenberg et al reviewed 2372 case reports of closed tibial fractures and compared clinical outcomes of cast treatment, open reduction and internal fixation, and closed intramedullary inter-locking nailing. They showed cast treatment to be associated with fewer superficial infections than open reduction and internal fixation. However, surgical fixation demonstrated a higher union rate at 20 weeks.2

Operative fixation is required when fracture reduction is not acceptable and it is unstable. The gold standard surgical treatment for long-bone fractures is closed interlocking nail (ILN) fixation under image intensifier. However, main drawbacks of the closed ILN are radiation exposure, cost of the nail and requirement of image intensifier and fracture table in the operating room. Open SIGN (Surgical Implant Generation Network) interlocking nail fixation has solved these problems. Also, it is far better than other cost effective methods of internal fixation e.g. Kuntscher nail in the sense that it prevents mal-rotation, shortening and angulation of fractures.3

This study attempts to determine the scope of interlocking nails used in tibia that do not require orthopaedic table and fluoroscopy to set locking screws (SIGN nails) in resource poor hospitals with comparable or optimal results to previous methods.
Materials and Methods

This is a prospective case series study carried out between August 2007 to July 2008, in the Department of Orthopaedic Surgery at Pakistan Institute of Medical Sciences, Islamabad. Total of 30 patients were included in the study. All the surgeries of SIGN interlocking nailing were done within 2 weeks of injury. Adult patients irrespective of sex, with closed diaphyseal fractures of tibia due to various causes, treatable by interlocking intramedullary (SIGN) nail were included in the study. Patients with open fractures, active infection and multiple fractures were excluded from the study. All the patients were well informed about the advantages and disadvantages of open interlocking intramedullary (SIGN) nail.

All patients were admitted through accident and emergency department. Thorough history with general physical and systemic examination of each patient was recorded in patients' record file. Initial immobilization of affected limb with long leg plaster of Paris as posterior splint was done. X-ray of the Tibia/Fibula, anteroposterior and lateral view including knee and ankle joint were done. After anesthesia (general or spinal) patient was operated in supine position on ordinary operating table. At the time of induction, a single high dose of third generation cephalosporin (Ceftriaxone) was given to each patient. After preliminary wash, a pneumatic tourniquet was applied above the knee. A small incision for open reduction of fracture was made. Then longitudinal incision was made over the patellar ligament at the level of the joint, about 5-6 cm long splitting the tendon longitudinally for entry portal. The proximal and distal medullary canal was reamed with hand reamer and increments of 1 mm. The nail length was measured by hand reamer and the fracture was reduced for insertion of the nail. Already measured nail was inserted and locked both distally and proximally with the help of external jig. After insertion of suction drain tube at fracture site wounds were closed.

In all of the patients, intravenous antibiotics (Ceftriaxone) was given up to the third post-operative day. Postoperative X-ray films were taken on first post-operative day. No patient was applied splint or cast after surgery and the patients were advised to start isometric quadriceps exercises and knee and ankle joints movements on the very second day after surgery. All the thirty patients were followed after discharge from hospital at set intervals of 3 weeks, 6 weeks and 12 weeks in post-operative period for at least three months, then monthly follow up till 12 months.

Data Collection Procedures

The results of evaluation of stable fixation of closed diaphyseal fractures of tibia fixed with interlocking intramedullary (SIGN) nail without using image intensifier were composed according to the data analysis during study. Data was collected on individual proforma for each patient.

Results

Thirty closed tibia fractures in 30 patients were studied. All the fractures were operated upon within 2 weeks of injury. There were 06 females and 24 males, giving a ratio of 1:4. The mean age was 35.75±13.16 years (range 18-70). Predominantly, right sided tibia was more injured as compared to left side (17 versus 13). Most common mechanism of injury was road traffic accident (n=21; 70%), followed by fall (n=6; 20%) and assault or violence (n=3; 10%). Fracture types according to geometry were transverse (n=12; 40%), oblique (n=05; 16.6%) and spiral (n=13; 43.3%). Majority of the fractures were at the junction of lower third and middle third (n=20; 66.6%); two (6%) were in the proximal third and rest (27.3%) were in the middle third. All the fractures were opened to reduce and pass nails. All the nails were in ante grade mode and statically locked proximally as well as distally. No patient was applied POP cast after surgery; however, they were kept on non-weight bearing ambulation till 6 weeks post-operative. The mean follow-up period was 1.3±0.25 years.

None of our patients had acute or chronic compartment syndrome. Wound dehiscence was seen in only three patients who got infection at the fracture site. Fracture union was attained in 5 months on the average (range 03-08 months). Five patients had delayed union. Out of these, three were also infected. After repeated debridements and intravenous antibiotics, union was achieved in two patients and one patient went into infected nonunion. For that patient we had to remove the nail and apply Ilizarov external fixator. Locking screws were removed (dynamization) in all patients with delayed union to reach union. Among these, three patients were also advised Samiento brace for protected weight bearing. No patient was bone grafted. None of our patients had implant failure. Also, no nail was removed till one year of age except the one who got infected non-union.

Eight patients had significant pain at 6 weeks post-op. It persisted till three months in only three patients including only those with non-union or delayed union. Persistent pain was noted in only one patient at the last follow up of one year. Two patients (6.6%) had anterior knee pain. Eighteen (60%) patients had obvious limp at 6 weeks post-op. This number reduced to 7 (23.3%) at 12 weeks post-op and further reduced to 01 (3.33%) at one year follow up. Post-operative range of movements at ankle and knee joint was restricted in five patients (16%) till 12 weeks follow up. In 9 patients, it improved to the extent that they had no functional compromise. Remaining three had some difficulty in squatting on the
The final functional outcome measured by Johner and Wruh's criteria with modification was based upon nonunion, infection, neurovascular injury, deformity and mobility which are depicted in Figure 1.

![Figure 1. Functional results of patients at last follow up of one year](image)

Although duration of surgery varied in different patients according to the configuration of fractures but the average time required for one procedure of interlocking intramedullary (SIGN) nailing was about 60 minutes ranging from 50 to 80 minutes. As all the procedures were carried out after the application of tourniquet so there was no significant amount of blood loss during the surgery. In our thirty surgeries, there was no need for blood transfusion during the operation. In patients with no complications, the hospital stay was about 7 to 10 days. The range of hospital stay was seven to forty days, the average being 12.5 days. Long stay was due to wound infection.

During the course of each follow up visit, every patient was assessed for the functional and radiological outcome based upon Johner and Wruh’s Criteria with modification (Table I).4

### Table I. Johner and Wruh’s Criteria with Modification

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Excellent</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonunion/infection</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>Neurovascular injury</td>
<td>None</td>
<td>Minimum</td>
<td>Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Deformity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varus/valgus</td>
<td>None</td>
<td>2-5°</td>
<td>6-10°</td>
<td>&gt;10°</td>
</tr>
<tr>
<td>Anterior/Posterior</td>
<td>0-5°</td>
<td>6-10°</td>
<td>11-20°</td>
<td>&gt;20°</td>
</tr>
<tr>
<td>Shortening</td>
<td>0-5 mm</td>
<td>6-10 mm</td>
<td>11-20 mm</td>
<td>&gt;20 mm</td>
</tr>
<tr>
<td>Mobility</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee</td>
<td>Full</td>
<td>&gt;90 %</td>
<td>90 - 75 %</td>
<td>&lt;75 %</td>
</tr>
<tr>
<td>Ankle</td>
<td>Full</td>
<td>&gt;75 %</td>
<td>75-50 %</td>
<td>&lt;50 %</td>
</tr>
<tr>
<td>Pain</td>
<td>None</td>
<td>Occasional</td>
<td>Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Gait</td>
<td>Normal</td>
<td>Normal</td>
<td>Mild limp</td>
<td>Significant limp</td>
</tr>
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Discussion

Fractures involving the shaft of long bones are common worldwide and tibial fractures are among the most common lower limb injuries to be treated by an orthopedic surgeon.5 The most common fracture of the lower limb occurs at the tibial diaphysis.6 There are different methods of achieving achieve skeletal stabilization that could vary considerably,
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depending on the configuration of the fracture line and the geographical location of the surgeons’ practices. Intramedullary nailing can be considered the “gold standard” for the treatment of tibial midshaft fractures, but there are concerns about their use in distal tibia fractures because of some technical difficulties.7 Government hospitals in Pakistan are so over burdened with trauma victims that most wards are full of such patients. The burden of poverty and disasters like earth quake, flood and bomb blasts affect the budgets health care system. Government hospitals now charge the patients for many services. Patients have often to sell possessions to pay for an implant, which delay surgery for several weeks. The working poor, who have no assets, suffers the most. The Surgical Implant Generation Network (SIGN) was established in January, 1999 as a humanitarian, nonprofitable organization in the State of Washington, USA, to provide free of cost and one of the best treatments for long bone fractures in developing countries. SIGN nail is a unique FDA approved solid interlocking nail which can be used in both tibia and femur with same design and instrumentation.

The most common cause of morbidity and mortality in the most productive period of life worldwide are road traffic accidents causing fractures.8 It is not surprising, therefore, that these fractures occur most in people aged between 18 and 55 years with peak in fourth decade with male predominance.9,10 Our study also validate the same facts with mean age of 35 and male to female ratio of 4:1.

Open reduction and internal fixation of tibial shaft has been associated with high infection and nonunion because of soft tissue dissection and possible devitalization of fracture fragments.11,12 In general, indirect reduction techniques are used to reestablish proper tibial length, alignment, and rotation prior to nailing while preserving the local fracture biology.13 However, nonanatomic reduction has been shown to decrease the strength of a healing fracture and to be a significant risk factor for reoperation. A recent clinical investigation also identified a lack of cortical continuity as 1 of 3 factors predictive of reoperation following operative treatment of tibial shaft fractures.14 In a very recent study conducted at Stanford University, California, USA, authors compared open reduction with distal reduction in tibial interlocking nailing.15 No statistically significant differences existed between the groups in terms of infection or fracture healing. Contrary to general understanding supported by literature, none of the patients from open reduction group developed nonunion or infection. The authors concluded that open reduction is a safe technique and that the failure to judiciously use such techniques can result in prolonged surgery, increased radiation exposure, further soft tissue injury from multiple reduction attempts, and acceptance of suboptimal osseous alignment. We encountered infection in three patients out of which 2 were controlled earlier but one went into infected nonunion which had to be treated with Ilizarov ring fixator.

Closed interlocking nailing using image intensifier for fixing these fractures is a standard practice around the world now.16 However, many factors like less surgical expertise, non-availability of image intensifier and fracture table for closed inter-locking nailing was the reason for open intra-medullary nails for treatment of these fractures.17 In our study, non affordability of the patients was the single most common reason of using SIGN nail after open reduction of fracture. We used image intensifier in 2 patients only for distal locking of screws so radiation exposure was virtually nil during surgeries of other patients. In a study conducted by Tsafaloutas et al, a mathematical method was used to estimate the entrance surface dose (ESD) to the patient and the scattered dose (Ds) to the operating surgeon during various fluoroscopically guided surgical orthopaedic procedures. The estimated Ds rates for the hands, chest, thyroid, eyes, gonads and legs of the operating surgeon were on average 0.103, 0.023, 0.013, 0.012, 0.066 and 0.045 mGy min(-1), respectively.18 Fluoroscopy used in an operating theatre environment could lead to a radiation exposure equivalent to between 250 and 3500 chest radiographs.19 Several techniques have been described for locking distal screws, which fall into five categories: computer-assisted, nail-mounted guides, image-intensifier-mounted techniques, hand-held guides and free-hand techniques.20 In routine practice, it appears that a free-hand technique is the most commonly used. This relies on using an image intensifier to obtain perfect circles for distal screws.21 We could achieve successful locking in all but 3 patients. Two were addressed during surgery with fluoroscopy guidance but one patient was missed which was revealed on postoperative x rays. In a similar study on SIGN nail conducted at Nigeria, Innocent et al report 100 % success rate of distal locking screws with SIGN’s nail mounted guide.22

We could achieve excellent and good results in 76.6 % patients which is higher than 70.6 % quoted by a recent Indian study in which author used the same Johner and Wruhs’ criteria in patients treated with tibial IL nail.23 Oswaldo et al reported results almost similar to present study.24 But a Chinese study using same criteria obtained almost 51 % combined excellent and good results. This study was conducted on earthquake victims which justifies this low percentage.25

It is pertinent to mention that, in centers where image intensifier facility is available, SIGN interlocking nails can be used with closed method as well. However, the exclusion of an image intensifier automatically eliminates the harmful effect of an increased dose of...
radiation to both the Orthopaedic surgeon and the patient. Patient receives standard and quality fracture treatment with a definite overall reduction in treatment cost.

Conclusion

From the data above, we conclude that SIGN nail is an excellent option for closed tibia diaphyseal fractures, particularly in countries like Pakistan where there is lack of treatment facilities. With problems like shortage of electricity, non-availability of expensive equipment (image intensifier, power drives, traction tables etc.), over-burdened hospitals and poor socioeconomic conditions, SIGN nail is a true blessing for both patients and Orthopaedic surgeons. Moreover, all these qualities of SIGN nailing system make it an ideal choice in disaster situations.

References