ORIGINAL ARTICLE

Outcome of Intramedullary Interlocking SIGN Nail in Tibial Diaphyseal Fracture

Irfanullah Khan, Shahzad Javed, Gauhar Nawaz Khan and Amer Aziz

ABSTRACT

Objective: To determine the outcome of intramedullary interlocking surgical implant generation network (SIGN) nail in diaphyseal tibial fractures in terms of union and failure of implant (breakage of nail or interlocking screws).

Study Design: Case series.

Place and Duration of Study: Orthopaedics and Spinal Surgery, Ghurki Trust Teaching Hospital, Lahore Medical and Dental College, Lahore, from September 2008 to August 2009.

Methodology: Fifty patients aged 14 – 60 years, of either gender were included, who had closed and Gustilo type I and II open fractures reported in 2 weeks, whose closed reduction was not possible or was unsatisfactory and fracture was located 7 cm below knee joint to 7 cm above ankle joint. Fractures previously treated with external fixator, infected fractures and unfit patients were excluded. All fractures were fixed with intramedullary interlocking SIGN nail and were followed clinically and radiographically for union and for any implant failure.

Results: Fourty one (88%) patients had united fracture within 6 months, 5 (10%) patients had delayed union while 4 (8%) patients had non-union. Mean duration for achieving union was 163 $\pm$ 30.6 days. Interlocking screws were broken in 2 patients while no nail was broken in any patient.

Conclusion: Intramedullary interlocking nailing is an effective measure in treating closed and grade I and II open tibial fractures. It provides a high rate of union less complications and early return to function.

Key words: *Tibia. Diaphyseal fracture. Intramedullary interlocking nail. SIGN nail.*

INTRODUCTION

Tibia is the most commonly fractured long bone due to its superficial location. Tibial fracture is common in all ages and is a major cause of morbidity in patients with lower extremity injuries.[1]

Mostly these fractures are sustained during high energy trauma, such as motorcycle accidents, pedestrian accidents, fall from height, motor vehicle accidents and rarely gunshot injuries. Delayed union, malunion, non-union and infections are common complications of tibial shaft fractures.[1]

Proponents can be found for treatment with plaster cast, by open reduction and internal fixation with plates and screws, external fixators and by locked or unlocked intramedullary nails.[2,3] The best treatment should be determined through thoughtful analysis of the morphology of the fracture, the age and general condition of the patient and most importantly the status of the soft tissue.

Department of Orthopaedics and Spine Surgery, Ghurki Trust Teaching Hospital / Lahore Medical and Dental College, Lahore.

Correspondence: Dr. Irfanullah Khan, Gandapur Cottage, Darabin Road, Dera Ismail Khan, KPK.
E-mail: drirfan.ortho@gmail.com

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Interlocking intramedullary nailing is considered to be the treatment for closed and Gustilo type I and II open tibial shaft fractures.[1] The use of intramedullary nailing in patients who have open tibial shaft fractures has high risk of infection especially in grade 2 and grade 3 open fractures. So, many surgeons reserve intramedullary nailing for closed and grade 1 open fractures. Delayed fixation of the open fractures of the tibial shaft in multitrauma patients give significantly better radiological and clinical results when compared with emergent fixation.[4] Patients with non-union of tibial fracture show promising results with same device.[5]

Intramedullary nailing preserves the soft tissue sleeve around the fracture site and allows early motion of adjacent joints. The ability to lock nails proximally and distally provides control of length, alignment and rotation in unstable fracture and permits stabilization of fracture and achieves better union (97.5%).[6]

Main complications of intramedullary interlocking nail are superficial wound infection, deep wound infection, compartment syndrome, deep vein thrombosis, delayed union, non-union and implant failure.[6]

The Surgical Implant Generation Network (SIGN) was created as humanitarian, non-profit corporation in Washington, USA, with a goal to provide improved health care and proper orthopaedic treatment of fracture at little or no cost to people in need throughout the world.

SIGN nail was introduced by Zirkle in 1999. All implants and instrumentations (FDA-approved) were provided free of cost by SIGN, USA, to our institution.[7] It is a solid nail and has external jigs for both proximal and distal interlocking screws with slot finders by which interlocking can be achieved without an image intensifier which reduces operation time and radiation exposure.[8] As it is a solid nail so there are less chances of implant failure and more chances of union.

The aim of this study was to determine the outcome of intramedullary interlocking SIGN nail in closed and Gustilo type I and II open diaphyseal tibial fractures.

METHODOLOGY

This study was conducted in Department of Orthopaedics and Spine Surgery, Ghurki Trust Teaching Hospital, Lahore Medical and Dental College, Lahore, after taking approval from ethical committee of institution. This study was completed in one year from September 2008 to August 2009. It comprised fifty patients of 14-60 years of age of either gender, who had closed and Gustilo type I and II open tibial fractures reported within 2 weeks, whose closed reduction was either not possible or unsatisfactory and fracture was located 7 cm below knee joint to 7 cm above ankle joint. Fractures previously treated with external fixator, infected fractures and unfit patients were excluded.

After evaluation of the patient according to Advance Trauma Life Support (ATLS) protocol, patients fulfilling the inclusion criteria admitted through Emergency Department and Orthopeadic Outpatient Department were operated for fracture fixation with intramedullary interlocking SIGN nail. Patients were followed clinically and radiologically with biplane radiographs to observe bone healing and implant failure at postoperative first day after 2 weeks, 1 month, 2 months, 3 months, 6 months and if needed at 9 months and clinical evidence of bone healing was scored according to pain and mobility scale proposed by Sikorski and Barrington and radiological bone healing was assessed according to Hammer *et al.* radiological assessment of callus formation.[9,10]

The collected data was transferred and analyzed using Statistical Package for Social Sciences (SPSS) version 11.0. The variables to be analyzed included demographic information (age, gender), pain, mobility and callus formation. Duration for union was calculated in days and patients were labeled as union, delayed union or non-union.

The variables were presented using simple descriptive statistics using mean and standard deviations for quantitative data like age. Frequency and percentage of qualitative data like gender (male, female), pain (4 grades, Yes/No), mobility (6 grades, Yes/No) and callus formation (5 grades, Yes/No) were calculated for all follow-up visits. Postoperative complication like implant failure (breakage of nail or breakage of one or more interlocking screws) was observed and reported as frequency distribution.

RESULTS

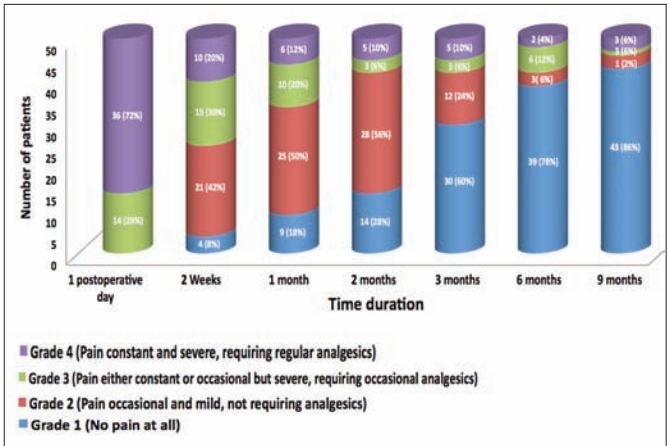
The study was conducted in Ghurki Trust Teaching Hospital, Lahore, including 50 patients during 01 year from September 2008 to August 2009.

The mean age of 50 patients was (33.28 ± 13.83 years) with the youngest patient being 17 years of age and oldest 60 years. Thirty six (72%) patients were less than 40 years of age while 14 (28%) patients were more than 41 years of age.

Out of 50 patients, 44 (88%) patients were male and 6 (12%) patients were female. Male to Female ratio was 7.3 : 1.

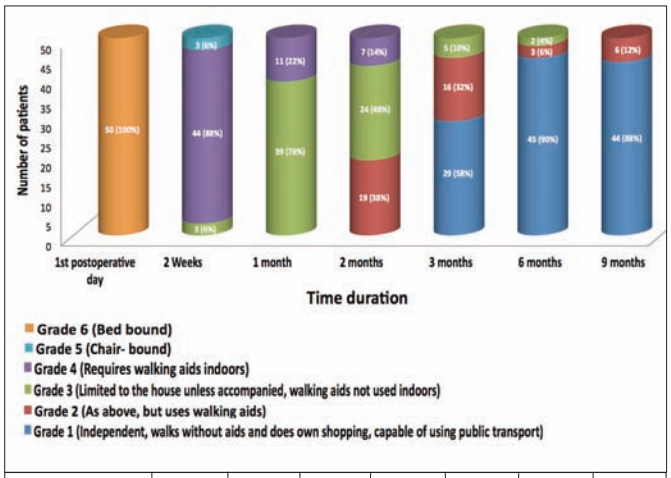
Thirty nine (78%) patients had closed type of fracture while 11 (22%) patients had open type of fracture. Among the latter, 8 (72.72%) patients had Gustilo type I fracture while 3 (27.27%) patients had Gustilo type II fracture.

Sikorski and Barrington pain and mobility scale scores showed that as time passed and fractures were healing,



Grades of pain	1st post operative day	2 Weeks	1 month	2 months	3 months	6 months	9 months
Grade 1 No pain at all	0 (0%)	4 (8%)	9 (18%)	14 (28%)	30 (60%)	39 (78%)	43 (86%)
Grade 2 Pain occasional and mild, not requiring analgesics	0 (0%)	21 (42%)	25 (50%)	28 (56%)	12 (24%)	3 (6%)	3 (6%)
Grade 3 Pain either constant or occasional but severe, requiring occasional analgesics	14 (28%)	15 (30%)	10 (20%)	3 (6%)	3 (6%)	6 (12%)	1 (2%)
Grade 4 Pain constant and severe, requiring regular analgesics	36 (72%)	10 (20%)	6 (12%)	5 (10%)	5 (10%)	2 (4%)	3 (6%)

Figure 1: Grades of pain.



Grades of morbidity	1st post-operative day	2 Weeks	1 month	2 months	3 months	6 months	9 months
Grade 1 Independent, walks without aids and does own shopping, capable of using public transport	0(0%)	0(0%)	0(0%)	0(0%)	29(58%)	45(90%)	44(88%)
Grade 2 As above, but uses walking aids	0(0%)	0(0%)	0(0%)	19(38%)	16(32%)	3(6%)	6(12%)
Grade 3 Limited to the house unless accompanied, walking aids not used indoors	0(0%)	3(6%)	39(78%)	24(48%)	5(10%)	2(4%)	0(0%)
Grade 4 Requires walking aids indoors	0(0%)	44(88%)	11(22%)	7(14%)	0(0%)	0(0%)	0(0%)
Grade 5 Chair- bound	0(0%)	3(6%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Grade 6 Bed bound	50(100%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)

Figure 2: Grades of mobility.

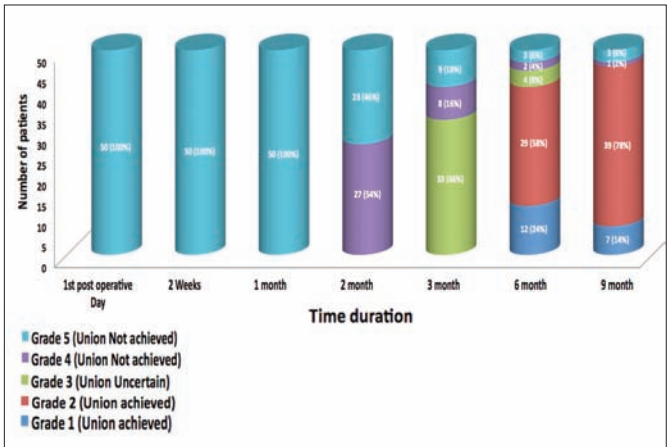
pain was decreased (occasional or no analgesic was needed). At 3 months, 60% patients had no pain, at 6 months 78% patients had no pain and at 9 months, 86% patients had no pain (Figure 1).

As pain settled, mobility was improved and patients were walking with walker or crutches and almost 58% of the patients were independently full weight bearing ambulant at 3 months and this figure was 90% at 6 months and 88% at 9 months (Figure 2).

For radiological assessment of union, 66% patients had bridging callus at fracture site on 3 months. At 6 months, union was achieved in 82%. At 9 months, 14% patients had homogenous bone at fracture site while 78% patients had massive bone trabeculae crossing fracture and fracture line was barely discernible (Figure 3).

Forty one (82%) patients united within 6 months, 5 (10%) patients had delayed union while 4 (8%) patients had non-union. Mean duration of union was 163 ± 30.6 days (23.3 weeks).

Interlocking screws were broken in only 2 patients while no nail was broken in any patient.



Grades of callus formation	1st post-operative day	2 Weeks	1 month	2 months	3 months	6 months	9 months
Grade 1 Union achieved	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	12 (24%)	7 (14%)
Grade 2 Union achieved	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	29 (58%)	39 (78%)
Grade 3 Union uncertain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	33 (66%)	4 (8%)	0 (0%)
Grade 4 Union not-achieved	0 (0%)	0 (0%)	0 (0%)	27 (54%)	8 (16%)	2 (4%)	1 (2%)
Grade 5 Union not-achieved	50 (100%)	50 (100%)	50 (100%)	23 (46%)	9 (18%)	3 (6%)	3 (6%)

Figure 3: Grades of callus formation.

DISCUSSION

Fractures treatment options available for diaphyseal tibial fracture include plaster cast immobilization, dynamic compression plate, external fixation and intramedullary interlocking nail. Plaster cast has been the most common method of treatment but its use has been limited by fracture morphology, type and pattern of fracture. It is also associated with malunion and poor patient compliance.[2] Fixation with dynamic compression plate require period of immobilization after fixation and stripping of soft tissue which lead to unacceptable rate of infection.[11] Intramedullary interlocking nail solved the problem of malunion, ability to control length, early mobilization and weight bearing and good patient compliance.

In this study, we used intramedullary interlocking SIGN nail which was donated by Surgical Implant Generation Network (SIGN) founded by Dr. Lewis Zirkle from America.[7] It is a solid nail and there is no cannulation for guide wire which other nails do have. This assembly has got jigs for both proximal and distal interlocking screws so interlocking can be done even without the aid of image intensifier.[8,12] As this nail is non-cannulated so it is difficult to do it by closed technique and one has to open the fracture site. Since tibia is a sub-cutaneous bone so now closed nailing is done in most cases and in difficult cases the fracture site is opened. SIGN initiative has provided SIGN IM locked nail that is versatile and

can be applied in treatment of femur and tibia shaft fractures with good outcomes. This initiative can go a long way in provision of equality of fracture care in resource poor countries.[13] They maintain a very reliable database and SIGN database is one of the largest collections of fracture cases from lower and middle income countries.[14,15]

Majority 72% of these patients were less than 40 years of age which is the prime earning group of our society so their early return to work was very important and this was possible with intramedullary fixation.

In this study, 88% patients were male and 12% patients were female. This shows that in our society male are more exposed to accidents. Joshi *et al*. studied 56 cases of tibial fractures in India in which 52 were male and only 4 were female and road traffic accidents was cause in most of cases.[16] Another study by Ali *et al*. conducted in Karachi, Pakistan, also noted a demography of 88.39% male patients and 14.6% female patients with tibial fractures.[17]

In this study, 78% fractures were closed and 22% were open among which 8 patients had Gustilo type I and 3 patients had Gustilo type II fractures. Ali Djahangiri *et al*. operated 96 tibial fractures in which 72.91% fractures were closed and 27.09% fractures were open.[18]

Range of motion exercises at knee and ankle were started as soon as pain allowed while weight bearing was allowed according to fracture configuration. Early weight bearing was allowed in case of transverse and short oblique fractures while for oblique and comminuted fractures weight bearing was delayed until bridging callus was seen on radiograph.

Pain and mobility of patients was assessed according to Sikorski and Barrington pain and mobility scale and were graded on each follow-up visit.[9,10] It showed early and considerable relief in pain and early mobilization. Most of patients required occasional or no analgesia and were able to walk both indoor and outdoor with walking aid and later on without it.

In this study, overall union rate was 92% and average time to union was comparable to previous studies. Drosos *et al*. fixed 157 fractures with intramedullary interlocking nail and shown overall union rate of 97.5% with average time to union 25.8 weeks.[6] In another study by Nork *et al*. who operated 36 tibial fractures with intramedullary interlocking nail and had mean union time of 23.5 weeks.[19] In another study, the overall union rate was 90.6% and average time to union was 24 weeks.[18] Shah *et al*. fixed 36 tibial fractures with intramedullary interlocking SIGN nail and his overall union rate was 97.2% and mean time to union was 22 weeks.[8]

In this study, 82% (41 patients) fractures united within 6 months while 10% (5 patients) fractures united between 7 and 9 months which means delayed union and 8% (4 patients) fractures were not united till 9 months which means non-union. Patients who did not have their fracture united till 6 months underwent second surgery for bone graft or dynamization. After that they were followed-up and ultimately 5 more patients were united before 9 months and labelled as delayed union. Djahangiri *et al*. did dynamization in 50% cases to achieve union in delayed union cases.[18] Cause of delayed union may be due to their old age, fracture configuration, co-morbidities like diabetes mellitus, hepatitis C and few of them were smokers. Two patients were cases of polytrauma, one had contralateral femur and tibia fracture along with head injury and ended in non-union while other had ipsilateral femur and tibia fracture and ended in delayed union. Shah *et al*. who did intramedullary interlocking SIGN nail in 36 fractures achieved 86.1% union within 6 months, 11.1% delayed union and 2.77% non-union.[8] Drosos *et al*. had 75.2% union in 6 months, 12.4% delayed union and 12.4% non-union.[6]

Debate continues over whether nails should be inserted after reaming of medullary canal or not. Reaming of canal allows insertion of larger diameter nail, which significantly increases mechanical strength. Reaming significantly reduces endosteal blood supply, although this seems to be compensated for by increased periosteal blood flow. There is some evidence that fractures nailed after reaming heal more quickly, perhaps because of increased periosteal blood flow. Heat necrosis of the entire shaft can result if canal is small, bone is hard and reamers poorly maintained.[20] Recently, developed inflatable nails avoid reaming and interlocking screws in tibial fractures and reflect a new principle for stabilization of long-bone fractures.[21] The main advantage of the expandable nail is that if affords. satisfactory axial, rotatory, and bending stability with decreased radiation exposure to operating staff and the patient.[22]

Implant failure which means breakage of nail or one or more interlocking screws is one of the complications of this procedure. In this study, no nail was broken while interlocking screws were broken in 2 patients. In one study, by Joshi *et al*. in India, 3.33% patients had nail breakage and 13.33% patients had screw breakage.[16] In another study, by Vidyadhara *et al*. 2.22% patients had nail breakage. Major causes of implant failure are non-union and strength of implant. In case of non-union breakage of one or more interlocking screw perhaps represent an autodynamization event. The two distal holes are the most common site of nail failure because of stress concentration caused by the hole effect and slot effect. Nicking the area by drilling around the distal holes during distal locking further weakens the strength of the nail holes and increases stress.[23] In this study, there was no nail breakage despite non-union in few cases. It is because SIGN nail is a solid nail it has no cannulated area for guide wire which gives extra strength. Distal third fractures are more prone to nail

Appendix A: Sikorski and Barrington pain and mobility scale.

Pain

1. No pain at all.
2. Pain occasional and mild, not requiring analgesics.
3. Pain either constant or occasional but severe, requiring occasional analgesics.
4. Pain constant and severe, requiring regular analgesics.

Mobility

1. Independent, walks without aids and does own shopping, capable of using public transport.
2. As above, but uses walking aids.
3. Limited to the house unless accompanied, walking aids not used indoors.
4. Requires walking aids indoors.
5. Chair- bound.
6. Bed bound.

Appendix B: Hammer *et al.* classification of fracture healing from radiographs.

Grade	Radiological assessment		
	Callus formation	Fracture line	Stage of union
1	Homogeneous bone structure	Obliterated	Achieved
2	Massive. Bone trabeculae crossing fracture line	Barely discernible	Achieved
3	Apparent. Bridging of fracture line	Discernible	Uncertain
4	Trace. No bridging of fracture line	Distinct	Not achieved
5	No callus formation	Distinct	Not achieved

failure. Increasing the 'fracture-locking hole' distance, delaying weight bearing, and using dynamisation with caution can nonetheless prevent nail failure. Smaller diameter nails with inadequate length should be avoided. Design modifications to increase the distal thickness of the nail and to reduce locking hole size may reduce failure.[23] The SIGN tibial nail, despite its slightly smaller diameter, can provide similar construct stiffness and stability, when compared to a larger hollow nail for stabilisation of tibial shaft fractures.[24]

CONCLUSION

Intramedullary interlocking nailing is an effective measure in treating closed and grade I and II open tibial fractures. It provides a high rate of union less complications and early return to function. Solid nail like SIGN nail has advantage of less chances of implant failure as nail is more stronger. Jigs for both proximal and distal interlocking screws decrease dependence on image intensifier and also decreases operating time.

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