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Outcome of tibial diaphyseal fracture fixation with Surgical Implant Generation Network (SIGN) nail

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Abstract

Introductions: Fractures of diaphyseal region of the tibial bone are amongst the most commonly seen extremity injuries in the developing countries. The surgical implant generation network (SIGN) intramedullary (IM) nail was designed for the treatment of long bone fractures in the developing nations.

Methods: From March 2008 to December 2018, a total of 104 patients with 104 tibial diaphyseal fractures were treated with SIGN IM nail. The followup visits were arranged at 6, 12, 24 weeks and one-year post operatively. During followup visits, the signs of fracture union clinically as well as radiologically and the presence of complications any were recorded and analyzed.

Results: The mean age of the patients was 32.81 (16 – 65) years, male 74 (71.2%) and female 30 (28.8%). Majority of the patients 70 (67.3%) had fractures after road traffic accidents. The mean time of surgery was 13.58 (1 – 463) days. Six (5.8%) patients had delayed union and no non-union was detected. We had 10 cases (9.6%) of mal-alignment but were on acceptable range.

Conclusions: In the developing country like Nepal, the SIGN nail is an effective surgical implant for the management of the tibial diaphyseal fractures with good result of fracture union and low rates of nonunion, mal-alignment and manageable complications.

Keywords: diaphyseal fracture, intramedullary nailing, SIGN nail, tibial fracture

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Introductions

Fractures of tibial diaphysis are the most common long bones because of its location and one third of surface length is subcutaneous leading to open fractures. Intramedullary interlocking nailing is the treatment of choice for the most open and closed tibial shaft fractures.[1]

The Surgical Implant Generation Network (SIGN) fracture care international is a non-profit organization which provides SIGN intramedullary interlocking nails along with its instrument set free of cost to the Patan Hospital, Nepal. The SIGN intramedullary nail is solid stainless steel nail, designed for the treatment of long bone fractures in low-resource settings as it can be used without image intensifier.[2,3]

The SIGN nail for long bone fractures were started at Patan Hospital (PH), Patan Academy of Health Sciences (PAHS) in 2008. This retrospective analysis aims to assess the outcome of SIGN nail in tibial diaphyseal fractures at PH.

Methods

A retrospective observational study was conducted in the Department of Orthopaedics and Trauma Surgery, PH, PAHS, Lalitpur, Nepal. Record of patients from March 2008 to December 2018 were analyzed to find out the outcome of SIGN nail in tibial diaphyseal fractures from the documented evidence of fracture union, mal-alignment, delayed union, nonunion, superficial wound infection and breakage of nail and screw. The patient record files were obtained from the record section of the PH. The patients from 16 to 65 years of age of either gender with closed and open fractures (Gustilo Anderson classification types I, II and IIIA)[4] were included. The standard SIGN nail surgical technique[5] was used to operate in all patients. Data were entered in Excel sheet for analysis.

As per protocol of the department, patients were followed up at 6, 12, 24 weeks and one year. During followup visits, the signs of fracture union clinically as well as radiologically and the presence of complications (mal-alignment, delayed union, nonunion, superficial wound infection, breakage of nail and screw) were recorded. The fracture union was defined as bridging callus on radiographs and ambulation without pain.[2] Delayed union and nonunion was defined as the absence of clinical and radiological signs of union within 6 months and 9 months respectively. Mal-alignment was defined as ≥5 degrees of angulation in any plane.[2]

The SIGN was established by Dr. Lewis G. Zirkle in 1999 with a vision of creating equality of fracture care throughout the world.[3,6] The SIGN nail is solid, with a 9-degree bend proximally, a 1.5 degree bend distally and straight between these bends. The apertures in the nail are slots rather than holes, except for the most proximal of them, which promotes axial compression at the fracture site.[5,6] The SIGN programs were started as the first four pilot programs in the countries namely Nepal, Vietnam, Thailand and Indonesia.[6] We received the first shipment of SIGN implants and instruments in 2008. The SIGN nails and instruments were provided free of charge. After using SIGN nail in the patients, we had to use online SIGN database to upload the information regarding the fracture management including photographs of pre-operative and post-operative radiographs. Shipments of replacement nails and screws were sent after 20 surgeries had been reported. The sizes of the replacements correspond to the sizes of the nails and screws reported to the database.[7]

The ethical clearance for study was obtained from the Institutional Review Committee (IRC) PAHS. The permission for the use of data from SIGN database was also obtained from SIGN office via email. The data were descriptively analyzed with the help of Statistical Package for Social Sciences (SPSS) version 20 software.



Figure 1. Tibial shaft fracture of a 32-year-old male

Results

The total 104 patients with 104 tibial diaphyseal fractures, 91 (87.5%) underwent closed reduction of the fracture and 13 (12.5%) required open reduction and fixation with SIGN nail. The mean age of the patients was 32.81 (16 – 65) years, male 74 (71.2%) and female 30 (28.8%). Seventy (67.3%) had fractures following road traffic accidents. The mean time of surgery was 13.6 (1-463) days. Six cases were subjected to late SIGN nail surgery because they required other mode of treatment at the time of presentation. Among these six patients, three had open fractures with Gustilo Anderson type IIIA and two had open fracture type II, which were treated.

Table 1. The characteristics of the patients' tibial diaphyseal fractures who underwent Surgical Implant Generation Network (SIGN) nail fixation (N=104)

Characteristics	N (%)
Age (in years)	
Mean	32.8±12.3
Range	16-65
Sex	
Male	74 (71.2%)
Female	30 (28.8%)
Mode of injury	
RTA	70 (67.3%)
Fall	31 (29.8%)
Physical assault	2 (1.9%)
Sports injury	1 (1%)
Side of limb injured	
Right	65 (62.5%)
Left	39 (37.5%)
Type of fracture	
Closed	80 (76.9%)
Open (type I)	13 (12.5%)
Open (type II)	8 (7.7%)
Open (type IIIA)	3 (2.9%)
Morphology of fracture	
Oblique	31 (29.8%)
Comminuted	28 (26.9%)
Transverse	23 (22.1%)
Spiral	21 (20.2%)
Segmental	1 (1%)
Level of fracture	
Proximal third	5 (4.8%)
Middle third	59 (56.7%)
Distal third	40 (38.5%)
Associated fibula fracture	
Fractured	85 (81.7%)
Intact	19 (18.3%)

Table 2. The size of the SIGN nails used for fixation of tibial diaphyseal fractures (N=104)

Nail	mm	N (%)
Length	260	1 (1%)
	280	11 (10.6%)
	300	31 (29.8%)
	320	43 (41.3%)
	340	14 (13.5%)
	360	4 (3.8%)
Diameter	8	33 (31.7%)
	9	50 (48.1%)
	10	20 (19.2%)
	11	1 (1%)

Table 3. The number of locking screws used for SIGN nail fixation of tibial diaphyseal fractures (N=104)

Number of proximal locking screws	N (%)	Number of distal locking screws	N (%)
1 screw	50 (48.1%)	1 screw	4 (3.8%)
2 screws	54 (51.9%)	2 screws	100 (96.2%)

initially with external fixators. One patient had presented with non-union following open reduction internal fixation with locking compression plate done at another center.



Figure 2. Good union of tibial diaphyseal fracture four months after fixation with SIGN nail

The length of the nail used was 320 mm in forty-three (41.3%) patients and the diameter of the nail used was 9 mm in fifty (48.1%) patients. The mean time to union of the fracture excluding delayed union was 14.7 (12-20) weeks.

There were 6 (5.8%) delayed union, zero non-union and 10 (9.6%) mal-alignment (all were ≤10 degrees; 7 (6.7%) valgus, 3 (2.9%) varus). Three patients (2.9%) with open fractures Gustilo Anderson type IIIA developed superficial wound infection requiring extended period of appropriate intravenous antibiotics to heal. There was no breakage of nail or screw or revision surgery recorded. Three patients (2.9%) had knee stiffness till 3 months, and recovered good range of motion at 6 months after surgery with the help of extensive physiotherapy. All patients regained full range of motion at the final followup of one year.

Discussions

The mean time to fracture union in our series, excluding the cases of delayed union was 14.7 weeks, slightly earlier than 15 weeks[2], 16.4 weeks[3], and 23.2 weeks[8]. The rate of fracture union in our study was 94.2% (98 out of 104 cases) within 6 months of surgery with regained full knee range of motion, whereas 5.8% (6 out of 104 cases) patients developed delayed union which had also united within 9 months of the surgery. All delayed union occurred in patients with open fractures of type 1, 2 and 3A (2 patients in each type), similar to the studies reporting fracture union rate of 92%[8], 97.2%[9] and 90.6%[10]. A systematic

review and meta-analysis have shown >90% return to full weight bearing status and favorable range of motion in 6 months, which is similar to our study.[11]

In our series, road traffic accident (67.3%) was the major cause for tibial diaphyseal fractures. Similar findings were reported by other authors.[2,8] Majority of our patients were young with mean age 32.8 years and male patients 74 (71.2%) predominated, because most of the young male in the developing countries like ours, are the source of income generation for the family. Hence, they had to spend most of the time out at work which makes them vulnerable to injury, as reported by others.[2,8,9]

Among 104 fractures, 91 (87.5%) were reduced by closed reduction whereas only 13 (12.5%) required open reduction. Although our center has image intensifier available, we took the advantage of subcutaneous position of tibia as a reference to confirm closed reduction by tactile sensation without image intensifier. In developing countries where image intensifier is not available, open reduction of the closed fractures are commonly performed and their results show no significant difference in increased complication rate between closed or open reduction.[2] But in cases with difficult reduction, we used image intensifier to confirm the reduction and negotiation of the SIGN nail. In those cases where closed reduction failed by all means, required open reduction. So, the patients who underwent open reduction 13 (12.5%) were mostly open fractures or those who presented late to the hospital.

Intramedullary interlocking nailing is the gold standard treatment for the diaphyseal fractures of the tibia. These are commonly done with the use of an image intensifier. But the resource-poor countries of the world like ours, where expensive image intensifiers are not available in most of the hospitals, SIGN interlocking nailing can be used successfully without the use of image intensifiers.[5,12] In our series, 320 mm length and 9 mm diameter was the most frequently used size of the nail with majority of the nails locked with two proximal and two distal screws. The distal locking screw insertion is considered a difficult task for all intramedullary nailing system.[13] But in SIGN nailing technique, the instrument set in its asset has an external jig and a slot finder which is very helpful to achieve successful locking of the nail. This system does not require the use of an intra-operative image intensifier.[5,12] This innovative technique has been helpful for us and probably other resource constrain countries where most of the hospitals do not have image intensifier.

The associated fibular fracture at or near the same level of tibia fracture has increased tendency of fracture mal-alignment. We had 10 cases (9.6%) of mal-alignment, but all had angle of ≤10 degrees. Valgus mal-alignment in 7 patients (6.7%) was the commonest in our series, similar to other studies.[2] All 10 mal-alignment had fracture of the distal third of tibia. Among 104 fractures, 40 (38.5%) occurred at the distal third. So, among 40 distal third fractures, 10 (25%) had mal-alignment, of which 7 had a fibular fracture at the same level or within 3 cm of the level of the tibial fracture and 3 who developed varus mal-alignment had fibular fracture at the proximal third of fibular shaft. Technical error and other mechanical forces acting on the surgical construct are the risk factors for mal-alignment.[14,15]

In our series, we had only 3 (2.9%) patients with open fracture type IIIA who developed superficial infection. Open fractures are risk factor for the development of infection, as shown 3 (8.3%) of 36 open fractures types I to III developed infection[9] and 14 (8.6%) had infection[2] and 3% infection[16] rate in tibia fractures in a study in Nepal. We managed all 3 cases of type IIIA and 2 cases of type II open fractures initially with external fixator due to the risk of infection. So, we delayed SIGN nailing in these patients till the healing of soft tissues. Secondary intramedullary nailing following external fixation was controversial due to infection risk, which was shown as high as 44%.[17] But another study has shown better results and mentioned secondary intramedullary nailing as a reliable procedure

for tibial shaft provided surgery is done early, before onset of external fixation pin site infection.[18] We had relatively low rate of infection as compared to other studies probably due to less number of type III and type II open fractures in our series.[2,9] Another factor for low rate of infection could be because of solid nature of the SIGN nail which is devoid of the dead space as compared to the hollow nails.

There were few limitations of this study. The first being its retrospective nature, second was its reliance on the online surgical database and third was non-comparison with the tibial diaphyseal fracture fixation with other types of tibial nail.

Conclusions

Our findings show SIGN nail is an effective surgical implant for the management of the tibial diaphyseal fractures with good result of fracture union 98 (94.2%) which enables early mobilization and weight bearing. It has shown low rates of complications like 9.6% of mal-alignment, 5.8% of delayed union and 2.9% of superficial infection.

Conflict of interests

None

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