Original Article

Surgical Implant Generation Network (SIGN) Solid Intramedullary Interlocking Nail in the Lower Extremity: An Observational Study from Western Nepal

Orthopaedic Section

MANOJ KUMAR CHAKRABORTY, PABIN THAPA, BRIJESH SATHIAN

ABSTRACT

Background: Intra-medullary nail fixation has become the standard of treatment for both femoral and tibial shaft fractures. It functions as internal splints that allow secondary fracture healing. The axial and rotational stability of the conventional hollow interlocking nails depends primarily on the locking screws. Surgical Implant Generation Network (SIGN) was formed in 1999, with the vision of creating an equality of fracture care throughout the world. This system has been utilized at a variety of facilities in low income countries throughout the world.

Objective: To evaluate the efficacy of SIGN nailing in the long bones of the lower extremity.

Method and Materials: This was a hospital based, retrospective study which was conducted in the Orthopaedics Department of the Manipal College of Medical Sciences, Pokhara, Nepal between May, 2010 and August, 2011. A total of 24 cases with fractures of the femur and the tibia were studied. Both closed and open types of fractures were included and the fracture fixation was done by using SIGN interlocking solid nails and instrumentation. The analysis was done by using descriptive statistics and the testing of the hypothesis. The data was analyzed by using Excel 2003, the Statistical Package for the Social Sciences (SPSS) for Windows Version 16.0 (SPSS Inc; Chicago, IL, USA) and the EPI Info 3.5.1 Windows Version.

Results: Out of the 24 patients, 16 (66.7%) were males and 8 (33.3%) were females. The average age of the patients was 29.58, with a range of 13-60 years. An intra-medullary interlocking SIGN nail was performed in 18 (75%) tibial and 6 (25 %) femoral fractures, with 41.7 % being right sided and 58.3% being left sided. The types of fractures which were included were closed= 66.67 % and open fractures= 33.33%. According to the Gustilo-Anderson classification, 4.17 % were Gustilo I, 25 % were Gustilo II and 4.17 % were Gustilo III a. Open reduction was done in 58.3 % and closed reduction was done in 41.7 % of the cases. Reaming was done in all the cases and no post-operative infections were noted. There was a significant relationship between the type of fracture and factors like the affected side, the method of the fracture reduction and the location of the fracture.

Conclusion: The SIGN solid intramedullary interlocking nail shows promising results in comparison to the hollow nail because of its better strength, better accuracy in distal locking and surprisingly better results in infection and non-union

Key Words: SIGN , tibia, femoral, Nepal

INTRODUCTION

Fractures which involve the shaft of the long bones are common worldwide. The methods which are used to achieve skeletal stabilization could vary considerably. These long-bone fractures in the femur and the tibia may be treated with external splints: Plaster of Paris, Fiber cast, external fixation (fixator), and skin traction or internal splints: Rush nails, Kuntschner nails, plates, and screws, in addition to interlocking nails [1].The intra-medullary nail or rod is commonly used for long-bone fracture fixation and it has become the standard treatment for most of the long-bone diaphyseal and selected metaphyseal fractures. Intramedullary nails function as internal splints that allow secondary fracture healing [2]. The axial and rotational stability of the conventional hollow interlocking nails depends primarily on the locking screws [3].

Surgical Implant Generation Network (SIGN) was formed in 1999, with a vision of creating an equality of fracture care throughout the world. While this system has been utilized at a variety of facilities in low income countries throughout the world, the SIGN techniques and implants have also been used in the settings of disaster relief [4,5].

The SIGN solid, stainless steel nail was designed for use in the tibia and it is strong enough for slots rather than holes, to accommodate the interlocking screw. The nail is straight but the proximal and distal ends of the nail have a 9 and 1.5 degree apex posterior bend, respectively. The nail is also used for femoral intra-medullary (IM) nailing and these 2 bends create an effective radius of curvature which closely approximates that of the normal human femur. There are 4 iterations of the interlocking screw which broke in less than 0.5% of the SIGN interlocking nail surgeries [6].Therefore, our objective was to evaluate the efficacy of SIGN interlocking nailing in the long bones of the lower extremity.

MATERIALS AND METHODS

This was a hospital based, retrospective study which was conducted in the Orthopaedics Department of the Manipal College of Medical Sciences, Pokhara, Nepal, between May, 2010 and August, 2011. A total of 24 cases with shaft fractures of the femur and the tibia were studied. Patients with closed and open fractures were included. The fracture fixation was performed by using SIGN interlocking nails and instrumentation, which was donated by the SIGN organization of RICHLAND, WA, USA for poor people.

The closed tibial and femur fractures were managed in the Emergency Department by immobilizing the fractures with a posterior slab of plaster of Paris for the tibia and a Thomas splint with skin traction for the femur. All the necessary investigations were sent and the patients were then admitted.

All cases of open fracture were resuscitated in the Casualty Department. After the wound inspection, a sterilized dressing was applied and the fracture site was splinted. Anti-tetanus toxoid, antibiotics and analgesics were given and the required investigations were sent. The patients were shifted to the emergency operation theater where the fractures were evaluated and the wounds were assessed on the basis of the Gustilo- Anderson classification and were managed accordingly. Most of the fractures were irrigated by using about 3-6 liters of 0.9% normal saline and they were managed by using 1st generation cephalosporin and aminoglycosides which were added to the contaminated wounds.

Plain radiographs were taken pre-operatively in the Radiology Department to determine the fracture configuration and its suitability for the interlocking nail insertion. Also, radiographs were taken post-operatively to determine the position of the SIGN nail and the locking screws. The SIGN nails were inserted according to the manufacturer's instructions. All the nails were statically locked, but not all the possible screw holes were used.

All the patients had a similar post-operative regime. In stable fractures, early weight-bearing as tolerated, was recommended. The weight-bearing was determined by the stability of the fracture. The time to achieve full weight-bearing was significantly delayed in the high-energy and the open fractures. No cast or brace was applied and the patients were discharged after the suture was removed after 14 days. The analysis of the outcome of the treatment with respect to the time of the fracture union and the presence of complications was performed. The fracture union was assessed clinically and radiologically at 6 weeks and at monthly intervals. The clinical criteria of the union included the absence of pain and local tenderness on stressing the fracture site or on full weight bearing on the operated limb. The radiological healing of the fracture was defined as the presence of a callus around the fracture circumference with a density which was similar to that of the adjacent cortex, or the obliteration of the fracture line, whichever was earlier. The healing of the fracture was considered as complete when both the clinical and the radiological criteria of the union were fulfilled to the satisfaction of the authors and the independent observers. A delayed union was recorded when the fracture was united between 4 and 6 months, while a non-union was noted when the union had not occurred after 8 months of treatment.

The analysis was done by using descriptive statistics and the testing of hypothesis. The data was analyzed by using Excel 2003, the Statistical Package for the Social Sciences (SPSS) for Windows Version 16.0 (SPSS Inc; Chicago, IL, USA) and the EPI Info 3.5.1 Windows Version. The Chi-square test was used to examine the association between the different variables. A p-value of < 0.05 (two-tailed) was used to establish statistical significance

RESULTS

Out of 24 patients, 16 (66.7%) were males and 8 (33.3%) were females. The average age of the patients was 29.58, with a range of 13-60 years. In this study, the intra-medullary interlocking nail was used in 18 (75%) tibial and 6 (25 %) femoral fractures, with 41.7 % of them being right sided and 58.3% of them being left sided. The fractures were proximal shaft in 8.3 % cases, mid shaft in 33.3% cases, and distal shaft in 58.3 % cases, with 25% of them being communited, 16.7% of them being oblique, 4.2% of them being segmented, 16.7 % of them being spiral and 37.5 % of them being transverse. The mode of injury was road traffic accidents in 66.7% cases, 29.2 % were due to fall injuries and 4.2 % were caused by crush injuries. The types of fractures which were included were closed- 66.67 % and open- 33.33%. According to the Gustilo-Anderson classification, 4.17 % were Gustilo I, 25 % were Gustilo II and 4.17 % were Gustilo III a. The fracture reduction was closed in 41.7% and open in 58.3 % of the cases. Reaming was done in all the cases. There were no post-operative infections.

Variable		Type of Fracture				Total	P value
		Closed	Gustilo I	Gustilo II	Gustilo III a		
Affected Side	Left	8	0	4	1	13	0.472
	Right	8	1	2	0	11	
Affected Bone	Femur	6	0	0	0	6	0.261
	Tibia	10	1	6	1	18	
Fracture Reduction	Closed	8	0	1	1	10	0.249
	Open	8	1	5	0	14	
Gender	Female	7	0	1	0	8	0.47
	Male	9	1	5	1	16	
Location of Fracture	Distal	9	0	5	0	14	0.292
	Mid	6	1	0	1	8	
	Proximal	1	0	1	0	2	

[Table/Fig-1]: Comparison of type of fracture with different clinical variables

[Table/Fig-1] depicts that there were no statistical relationships between the affected side, the affected bone, the fracture reduction technique, gender, location of the fracture and the type of fracture.

DISCUSSION

Long bone fractures are quite common in the most productive period of life due to increasing road traffic accidents and fall injuries [1,7]. These fractures occur mostly in people who are aged between 20 and 50 years, with a greater vulnerability of males to trauma [8]. In our study, 66.67% of the patients had met with road traffic accidents and 66.7% were males.

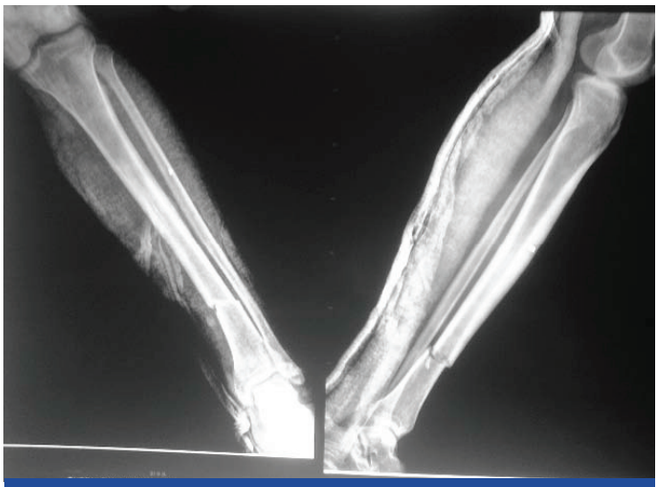
An interlocked intra-medullary nail is the universally accepted fixation device which is used for closed diaphyseal fractures of the long bones. It is a load-sharing implant and consistent satisfactory results have been reported with their use [9,10]. Intra-medullary nailing after reaming is now accepted as the method of choice to treat close femoral fractures, but its use remains controversial with regards to open tibial fractures [11]. But with appropriate soft-tissue treatment, IM nailing gives good results in the treatment of open tibial fractures [12]. The use of unreamed intra-medullary nails avoids pin-track infection, a complication of external fixation which is popularly used in treating open fractures, but it may potentially compromise the stability at the site of the fracture [13,14,15]. The management of open tibial fractures with reamed IM nails is controversial. While reamed nails offer improved stability to the fracture, their use carries a theoretical risk of increasing infection and non-union as a consequence of disturbing the endosteal blood supply [16].

In a study by Kaltenecker et al, no infections were reported after the treatment of sixty-six type-I and II open tibial fractures with nailing after reaming, which was consistent with our results.[17] Court-Brown et al. recently reported a rate of infection of 6 per cent (one of eighteen) for type-IIIA fractures and of 13 per cent (three of twenty-four) for type-IIIB fractures which were treated with the insertion of a Grosse-Kempf nail after reaming [18, 19]

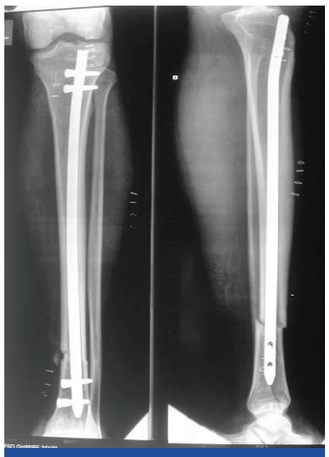
[Table/Fig-2] depicts the closed fracture of the left distal tibia following road traffic accidents in a POP slab. [Table/Fig-3] shows that after the fixation of the sign nail with two proximal and distal interlocking screws, the fracture was stabilized. In one of the femoral fractures [Table/Fig-4] , there was gapping at the fracture site after nailing, for which we did dynamization after two months. Another case [Table/Fig-5], a posterior malleolus of the tibia was fractured during distal locking and it was fixed by using a screw. These two iatrogenic complications were found, which may be because different surgeons were operating the cases. Which is a learning curve will be automatically corrected in future. A limitation of this study was the less number of cases, because until now we have operated only 24 cases. Further studies with a larger sample size are required to get a statistical significance.

CONCLUSION

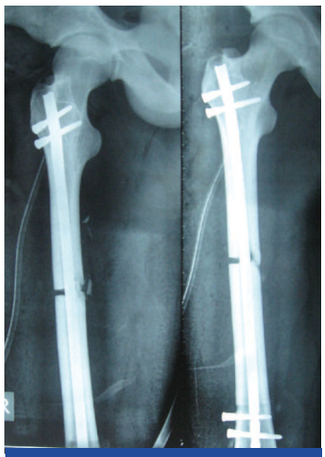
Although it is too early to list the merits and demerits of SIGN nail with our limited number of cases, our initial experience has been encouraging. Stability against rotation, bending and axial loading



[Table/Fig-2]: Pre-op Fx Distal Tibia (L) AP & Lateral views



[Table/Fig-3]: Post-op Fx fixed with SIGN nail. AP & Lateral views



[Table/Fig-4]: Gapping at fracture site after nailing

[Table/Fig-5]: Posterior malleolus of tibia was fractured during distal locking which was fixed with screw

length, telescoping, segmental fractures, infection and non-union were found to be better with SIGN nail use, with the advantage of mobilization and early weight bearing.

SIGN nail and system shows promising results in comparison to hollow nail, because of its better strength, better accuracy in distal locking and surprisingly better results in infection and non-union. This study showed that the complication rates were minimal and within an acceptable range. None of our cases developed infections. It has the added advantage of reduced costs to the patient whilst, at the same time, ensuring a high-quality fracture care which is comparable to any type of care which is achieved in the developed countries. It is possible to treat the poorer section of people in developing countries like Nepal by using this equipment. Proficiency in the use of these SIGN interlocking nail instrumentation will develop with practice.

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AUTHOR(S):
1. Dr. Manoj Kumar Chakraborty
2. Dr. Pabin Thapa
3. Dr. Brijesh Sathian

PARTICULARS OF CONTRIBUTORS:
1. Prof & HOD, Orthopedics Department, Manipal College of Medical Sciences, Pokhara, Nepal.
2. PG 2nd Resident, Orthopedics Department, Manipal College of Medical Sciences, Pokhara, Nepal.
3. Assistant Professor & Managing Editor in Chief NJE, Dept. of Community Medicine, Manipal College of Medical Sciences, Pokhara, Nepal, Manipal College of Medical Sciences, Pokhara, Nepal.

NAME, ADDRESS, TELEPHONE, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Manoj Kumar Chakraborty
Prof&HOD, Orthopaedics Department, Manipal College of Medical Sciences, Pokhara, Nepal.
Phone: 00977-9726155900
E-mail:drmkc2010@yahoo.com

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