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SIGN Nail Experience in Manipal Teaching Hospital

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Abstract Fifty-two patients who underwent intramedullary nailing of long bone fractures using the SIGN nail at the Department of Orthopedics, Manipal Teaching Hospital from July 2010 to July 2014 were reviewed. Healing of the fracture, incidence of post-operative complications, implant failures, weight bearing capability were described and analyzed based on the medical records and official website of SIGN. Demographic of patients, fracture configuration, size of nail and screws used, the pre and post-operative radiographs were also reviewed. Post operatively with a mean follow-up of 6 months, 46.1% of the patients had beginning callus, 40.4% of the patients were already healed, 3.8% had infection and outcome was undetermined in 9.7%. No implant failure was noted in this study.

Keywords: *Sign Nail, Demography, Manipal Teaching Hospital*

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1. Introduction

Surgical Implant Generation Network (SIGN) mission began in 1968 when founder and president of SIGN, Lewis G. Zirkle, Jr., M.D., served as an army Orthopedic Surgeon in Vietnam. Working with like-minded physician, surgeons and concerned citizens, Dr. Zirkle laid the ground work for his vision of providing an all-encompassing system of training, hardware manufacturing, follow-up of patients and repeat visits to orthopedic centers in developing countries [1].

In May 1999, Dr. Zirkle initiated 4 SIGN "pilot projects" one each in Thailand and Indonesia and two in Vietnam. In 2004 it was introduced in Philippines. In 2010, SIGN nailing was introduced in the Department of Orthopedics, MTH, Nepal. A set of donated implants and their corresponding instruments were provided to the institution to be used in patients in need all for free.

SIGN has developed modern manufacturing facility for manufacturing instruments and implants for SIGN Intramedullary (IMIL) Nail system, which included intramedullary nail, interlocking screws and their instrumentation. The system was specifically designed for use in hospitals in the developing countries where CR (Computerized Radiography) imaging and sophisticated equipment were not available.

The main objective of our study was to determine the healing of the fracture, infection rate & implant failure or other complications after using SIGN Nail. It also described the demographics, fracture type, configuration, and location, number of hospital stay (pre and post operative duration), size of nails and screws, and the frequency of follow-up and the patient's weight bearing status during the follow-up.

2. Methodology

From July 1, 2015- August 31, 2015 all the charts of the patients who underwent Intramedullary nailing of long bones of lower extremity using SIGN nail system in our hospital over a period of 4 years from July 2010 – July 2014were reviewed. There were 52 documented cases in the database. Follow-up charts were accessed at the medical records department. All the patients whose records were incomplete and patients who underwent IM nailing using other system apart from SIGN Nail system were excluded from our study.

Using the OPD charts and official website www.signsurgery.org, the database of each patient were reviewed. Beginning callus was defined as presence of callus in less than 3 cortices. Healed fracture was defined as presence of callus on 3 of 4 cortices on 2 x-ray views. Infected implant was defined as presence of fever and pain, persistent of erythema, purulent drainage over the post-operative site, or ultimately dehiscence of the site.

Using the record charts, we wanted to show and describe the basic features of our study and provide simple summaries about the sample and measures of our population. With simple graphics analysis, we wanted to give a simple quantitative analysis of data.

2.1. Ethical clearance was taken from the ethical committee of our hospital before commencing of this study.

2.2. In a pilot study done prior to the original study with 10 sample size, it showed 90% of nail were introduced antegrade. With a 95% CI, the sample required was 42. [2]

3. Results

Using the STATA software, descriptive statistics were used to obtain the frequency, percentage, mean and range

amongst the 52 patients. The most number of patients who underwent SIGN nailing were of the second decade (age 21-30: N=26) (50%) followed by adolescent age group (age <21: N=15) (28.8%) and then the third decade (age 31-40: N=6) (11.5%). Thirty-five (67.3%) of the patients were of the male population while 17 (32.7%) were of the female population.

Table 1. Socio Demographic Profile

Characteristics	No.	%
Sex		
Male	35	67.3
Female	17	32.7
Age Group (years)		
<20	15	28.8
21-30	26	50
31-40	6	11.5
41-50	3	5.8
>50	2	3.9
Range	14-55	

Twenty-six (50%) of the population had tibial fractures alone while 20 (38.5%) involved the femur, 6 (11.5%) of the population however had both the femur and tibia involved. Right lower extremity was involved in 28 (53.8%) patients, Left was involved in 20 (38.5%) and 4 (7.7%) patients had both lower extremity involved. Fourty-two (80.8%) extremity were diagnosed as closed fractures while the rest 10 (19.2%) were open fractures. Twenty-five (48.1%) patients had a transverse fracture, 15 (28.8%) had a oblique fracture and 12 (23.1%) of them had a comminuted fracture. Seven (13.5%) of the fractures were in the proximal third, 34 (65.4%) were in the middle third and the rest 11 (21.1%) were in the distal third of the femur/tibia.

Table 2. Physical Examination Findings

Physical Examination	No.	%
Dexterity		
Both	4	7.7
Left	20	38.5
Right	28	53.8
Extremity Involved		
Femur	20	38.5
Femur & Tibia	6	11.5
Tibia	26	50
Fracture Type		
Closed	42	80.8
Open	10	19.2
Configuration of Fracture		
Transverse	25	48.1
Oblique	15	28.8
Comminuted	12	23.1
Location of Fracture		
Proximal	7	13.5
Middle	34	65.4
Distal	11	21.1

The most common size of the nail used was 320 X 9 mm nail for the Tibia and 360 X 10 mm for the femur. The most common length of the proximal screw was 35 mm for Tibia and 40 mm for Femur and distal screw was 40 mm for Tibia and 50 mm for the Femur respectively. Fifty patients underwent antegrade nail introduction while 2 patientsunderwent retrograde nailing for distal fracture of the femur.

Table 3. Management

	No.	%
Approach		
Antegrade	50	96.1
Retrograde	2	3.9
Diameter of Nail inserted (mm)		
8	7	13.4
9	26	50
10	17	32.7
11	2	3.9
Length of Nail inserted (mm)		
28	3	5.7
30	16	30.8
32	21	40.4
34	10	19.2
36	2	3.9

Size of Screws (mm)	Most Proximal		Distal of the 2 Proximal	
	No.	%	No.	%
25	2	3.9	-	-
30	6	11.5	3	5.7
35	20	38.5	15	28.9
40	16	30.8	19	36.5
45	7	13.4	10	19.2
50	1	1.9	4	7.8
55	-	-	1	1.9
Total	52		52	

Size of Screws (mm)	Proximal of the 2 Distal		Most Distal	
	No.	%	No.	%
25	-	-	-	-
30	7	13.4	2	3.9
35	15	28.9	8	15.4
40	20	38.5	18	34.5
45	8	15.4	12	23.1
50	2	3.8	9	17.4
55	-	-	3	5.7
Total	52		52	

The mean follow-up of patients in our study was 6 months (range 1.2-24 months). Twenty-four (46.1%) of the patient had beginning callus during the period of the follow-up, 21 (40.4%) of the patients were already healed. Outcome for 5 (9.7%) of the patients was undetermined while 2 (3.8%) of the patients had infection.

Thirteen (25%) of the patients were ambulatory and on full weight bearing while 30 (57.7%) were on partial weight bearing with bilateral axillary crutches. 5 (9.7%) of the patients were non weight bearing while 4 (7.6%) had removal of the implant.

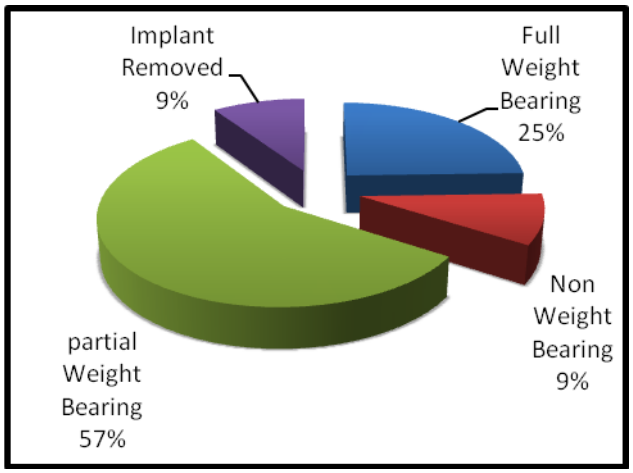

Figure 1. Weight Bearing Status

Most of the patients were operated within 1 week after admission with a mean of 6 days (range 3-11 days). Most patients were then discharged after 5 post-op days.

Two patients were currently on follow-up with Ilizarov clinic because of multiple injuries whose extremity involved were treated with IM nailing. One patient had common peroneal nerve palsy suffered pre-operatively. One patient underwent removal of the nail and antibiotic beads application. One patient had distal third fracture ended up in tibiocalcaneal fusion after sign nailing.

Table 4. Length of Hospital Stay (in days)

	No.	%
Pre-operative Duration		
1-7	40	77
8-15	9	17.3
>15	3	5.7
Range	1-19	
Length of Hospital Stay		
1-7	5	9.6
8-15	37	71.2
>15	10	19.2
Range	5-29	
Post-Operative Duration		
1-7	46	88.4
8-15	4	7.8
>15	2	3.8
Range	3-25	

4. Discussions

Since the mid1950s intramedullary nail technique for fixation of fracture have gained universal acceptance. Closed IMIL nail fixation is the procedure of choice for lower extremity long bone shaft fractures, especially in polytrauma patients. [3,4]. This method of treatment has been the subject of debate since its introduction because surgeons are concerned of damage to the intramedullary circulation, fat embolism, and complications from misapplication of the technique secondary to lack of understanding of the biomechanical principles of intramedullary nail fixation.

The treatment of diaphyseal fractures of long bones by techniques requiring prolonged immobilization of the fracture or convalescence, or both results to joint stiffness, or malunion and nonunion may occur. The difficulty in achieving perfect method of fracture treatment that would safely stabilize the fracture so firmly that soft tissue and joints could be mobilized early and continuously during healing and, when applicable, ambulation with full weight bearing could be allowed. The method nearly approaching this perfection is intramedullary fixation of long bone shaft fractures

Satisfactory stabilization of long bone shaft fracture by IMIL fixation is possible under the following circumstances:

Non locking nails can be considered when a simple fracture occurs at the narrowest part of the medullary canal (isthmus); not only are translational shearing forces eliminated, but rotational forces are also well controlled. If the medullary canal is disproportionate between the two fragments than it results in poor control of rotational forces; thus, IMIL techniques are necessary. Ideally, the position of the interlocking screws should be at least 2 cm away from the fracture site so as to provide sufficient stability to allow early functional activity postoperatively. Axially unstable comminuted fractures are best treated with static nails [5].

The anatomic curvature of the bones must be considered in selecting the size and type of nail and determining the amount of intramedullary reaming necessary. Biomechanically, non locking nails maintain the stability by a curvature mismatch between the bone and the nail, inducing longitudinal interference fit. If the curvature mismatch is big, more reaming is required in the smaller fragment. The entry of portal is very important for all IMIL nails and should be in the region that will minimize the insertional forces. In the femur it is at the piriformis fossa which is in line with the medullary canal. In the femur the starting point at the pyriformis fossa led to the most neutral anatomic alignment regardless which IMIL nail is used. The lateral starting point led to varus and gapping of the lateral cortex with all nails [6-8]. Placing the starting point too anterior from the piriformis fossa (≥6 mm) creates a major risk of proximal femoral bursting with nail insertion because of increased hoop stresses. The risk is lower for medial and lateral malpositioning [9]. For the tibia, the offset between the entry point and the alignment of the canal leads to strong forces on the postero-medial cortex. Starting the IMIL nail at the level of the fibular head decreases the forces of insertion in the tibia.

Sufficient diameter and continuity of the medullary canal are required for IMIL nail techniques. Excessive reaming should always be avoided because it decreases the cortical thickness thereby significantly weakens the bone and increases the risk of thermal necrosis.

A perfect IMIL nail does not exist till date. The varying anatomic curvature of bones make such a nail impossible, but improvement in the design and more anatomic nails continues to evolve. Bone specific nails may be designed for each bone and each kind of fracture, or for fractures in different anatomic regions of the same bone. Ideal IMIL nail should meet the following requirements:

- To provide sufficient stability & maintain alignment and position, it should be biomechanically strong thus we should include interlocking transfixing screws as necessary
- To have a desirable physiological stimulus to union it should be constructed to allow contact-compression at the fracture surfaces
- For future removal of the implants it should be placed in accessible areas

IMIL nailing is not a technique to be used casually. The surgeon should expect and take all necessary precautions to decrease the complications. To minimize the complications the following considerations are recommended:

- Adequate preoperative planning is necessary.
- The patient should be fit to undergo a major surgical procedure.
- All size (lengths and diameters) of nails and screws should be available before surgery.
- Appropriate instruments, trained assistant surgeon and nursing staff and optimal operating room conditions are necessary.

- We should avoid undue stress and strain during convalescence if not the nail may bend or break.
- Whenever possible closed IMIL nailing techniques should be applied as it leads to higher rate of union with fewer complications. The technique results in minimal scarring of the thigh and leg muscles, thus, early mobilization and weight bearing can be started post-operatively. Open nailing is to be done only if the fracture is irreducible or if it is a open fracture. [10,11].

Interlocking fixation may be static or dynamic. Static fixation controls bending, axial and rotation force and makes the implant a more load-bearing device with the risk for a decreased fatigue life. In a non-isthmal, comminuted fractures of the tibia and femur it is desirable to use static IMIL nails. Dynamic fixation controls rotational and bending force but allows nearly full axial load transfer by bone. Dynamic fixation is applied in axially stable simple fractures and in some cases of non-unions.

Dynamization technique involves conversion of the static mode of IMIL nail to a dynamic mode by removing the screws from the longest fragment. In our study dynamization was necessary in two patients with femoral fractures. Dynamization potentially increases the fatigue life of nail and screws as it decreases the load bearing capacity of the bone and also increases compression forces at the fracture site and if adequate cortical stability or bone regeneration is not present then shortening of the bone may be resulted.

Because the implants are load-sharing devices, early weight bearing on the injured limb is possible in most simple fractures and some selective comminuted fractures [12]. Thus, mobilization out of bed within 24 hours after surgery is allowed with these injuries. This rapid mobilization and speedy healing leads to decreased hospital stays, shorter periods of disability, and obvious economic benefits for the patient. In the series of Winquist et al [13] more than 500 patients of closed femoral nailing showed a postoperative infection rate of 0.9%. In the study by Warmbrod [14] the prevalence of infection after OPEN technique ranged from 1.7% to 9% of cases. Thus, the infection rate after open nailing is low, but is clearly not as low as the rate after closed femoral nailing. In our series, which was a mixture of closed and open nailing the infection rate was 3.8 % which is comparable to the above studies.

Limitations

The study is limited to relate fracture healing as to Roentgenographic unions in which plain roentgenograms show bone trabeculae/callus formation or cortical bone crossing the fracture site.

Declaration of Conflicting Interests

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