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Original Article

Clinical outcomes of patients with isolated femoral shaft fractures treated with S.I.G.N interlock nails versus Cannulated Interlock Intramedullary nails

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ABSTRACT

Objective: The S.I.G.N (Surgical Implant Generation Network Inc.) solid intramedullary nail is originally designed for tibial shaft fractures and is currently being used for femoral shaft fractures as an extended use. The nail is used in developing nations such as the Philippines, as an alternative for those who could not afford the commercially available nails. The main objective of the study is to determine whether there is a difference in clinical outcomes of patients with isolated femoral shaft fractures in Philippine General Hospital, treated with S.I.G.N intramedullary nails versus Cannulated intramedullary nails, from year 2007 to 2012. **Population:** A total of 175 patients fulfilled the inclusion criteria based from reviews of censuses, in-patient and OPD charts of the trauma section of the Department of Orthopedics, Philippine General Hospital. The Surgical Implant Generation Network (S.I.G.N) Fracture Care On-line Database was also screened for patients to be included in the study. A total of 68 patients were able to follow-up, with 48 patients in the S.I.G.N group and 20 patients for the Cannulated group.

Main outcome measures: The dependent variables of the study are radiographic and clinical union, knee range of motion, weight bearing status, and complications.

Results: The subjects were divided into patients operated with S.I.G.N nails and with Cannulated Interlock Intramedullary nails. For the S.I.G.N group, the mean age is 32.1 years and mean follow-up is 40.75 weeks post-op. The Cannulated group has a mean age of 27.9 years and mean follow-up of 35.85 weeks post-op. Radiographic union rate for the S.I.G.N group is 68.8% while for the Cannulated group is 80%. Clinical union and full weight bearing status of patients are 100% in both groups. There is no significant difference with the number of patients with full range of motion in both groups: (S.I.G.N: 85%; Cannulated: 90%). Complication rates are also non-significant (S.I.G.N: 12.5%; Cannulated: 5%).

Conclusions: There is no significant difference between patients with isolated femoral shaft fractures treated with S.I.G.N. Interlock Intramedullary nail versus Cannulated Interlock Intramedullary nail in terms of Clinical and radiographic union, weight bearing, knee range of motion and complication rate.

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1. Introduction

Fractures of the femoral shaft are among the top causes of orthopedic consults and mostly are caused by high-energy trauma.^{1,2} Surgical planning and documentation of these fractures have been guided by classification systems such as those from Winquist–Hansen and the AO/Orthopedic Trauma Association.³ Several treatment options are available for femoral shaft fractures depending on fracture pattern, degree of comminution, fracture location, and soft tissue involvement. With the advent of Interlock Intramedullary nailing, there is better angular and rotational control of fractures fragments especially for comminuted and oblique fractures of the femoral shaft.³ The work by Brumback et al, showed immediate weight bearing is possible for femoral diaphyseal fractures that retain diaphyseal cortical contact, those used with nails <12 mm, or nails with single distal interlock.⁴ In developing countries such as the Philippines, patients from poverty are unable to afford the cost of intramedullary nails. Surgical Implant Generation Network (S.I.G.N), a non-profit organization from America, has been doing charitable work in the Philippines in collaboration with some tertiary hospitals since 2002. They have been providing solid intramedullary fixation of femoral and tibial fractures for patients who could not afford commercial Cannulated interlocking nails. The S.I.G.N system was designed for fracture fixation in developing countries where intra-operative imaging and fractures tables are often not available. However, the nails were initially designed for tibial fractures,⁵ and were eventually considered for femoral shaft fractures as an extended use. Ikem et al did a prospective descriptive analysis of 40 patients with diaphyseal fractures of the tibia, humerus, and mainly the femur (65%) treated with S.I.G.N intramedullary nails. All cases were done without intra-operative imaging and results showed all cases had 100% fracture union at a mean time of 2.93 months.⁶ A retrospective study by Sekimpi et al using S.I.G.N nails in 70 patients with closed diaphyseal femoral fractures showed that all fractures healed, although two required dynamization for delayed union and with 14% complication rate. The limitation of the study however was the lack of comparative group and lack of adequate follow-up in 29% of the study population.⁷ Caalim & Reyes conducted a local prospective clinical series in 30 patients with closed diaphyseal femoral fractures treated with the S.I.G.N intramedullary nail. The authors had satisfactory results wherein all patients were able to attain fracture union, full weight bearing and acceptable hip & knee range of motion.⁸ The current literature regarding S.I.G.N intramedullary nails in femoral shaft fractures does not offer any head on comparison of the system with commercially available femoral intramedullary nails with regards to clinical outcomes. The paucity of literature in this regard has prompted the authors to conduct this study Fig. 1.

2. Methodology

The study design is a 50-year retrospective cohort and was conducted at a university-based tertiary hospital. A total of 175 patients fulfilled the inclusion criteria based from reviews of censuses, in-patient and out-patient charts. The Surgical

Implant Generation Network (S.I.G.N) Fracture Care On-line Database was also screened for patients to be included in the study. The patients were selected with the following inclusion criteria:

Inclusion criteria

1. Isolated diaphyseal femoral shaft fracture, located between 5 cm distal to the lesser trochanter and 5 cm proximal to the adductor tubercle.⁹
2. Gustilo classification closed or open type I.
3. Fractures fixed with either S.I.G.N Interlock nails or any of the commercially available Cannulated Interlock Intramedullary nail (Stryker, Smith and Nephew, Zimmer, Orthopedic International).
4. Fractures fixed in ≤ 30 days from time of injury.
5. Follow-up of ≥ 4 weeks.

Exclusion criteria

1. Bilateral fractures.
2. Gustilo open fracture type II and III.
3. With other associated long bone fractures.
4. Conversion Intramedullary nailing from external fixator.
5. Pathologic fractures.

Outcomes assessment

The dependent variables measured in the study are the clinical and radiographic union, knee range of motion, weight bearing status, and complications post-operatively. Blinding and randomization of subjects according to treatment arms were not done since the study is retrospective. Fig. 2

1. Radiographic union – presence of bridging callus formation in four cortices on anterior and lateral radiographs.¹⁰ The presence of callus at the fracture site was described as:
 - a. Union – callus in four cortices.
 - b. Abundant callus but with fracture line at least in one cortex.
 - c. No callus formation.
2. Clinical union – absence of pain at fracture site on range of motion and full weight bearing of the lower extremity.
3. Knee range of motion – measurement of active knee flexion using a standard goniometer starting from an extended knee position (baseline zero degrees). The range of motion was divided in the following range:
 - a. Full range of motion ($0-140^\circ$).
 - b. Intermediate ($\geq 90 < 140^\circ$).
 - c. Limited range ($\leq 90^\circ$).
4. Weight bearing status
 - a. Full weight bearing – 100% of body weight
 - b. Partial – up to 50% of body weight

Fig. 1 – The Surgical Implant Generation Network (S.I.G.N) intramedullary nail is straight solid stainless steel nail, with an apex posterior bend on the proximal (9°) and distal ends (1.5°).⁵

Fig. 2 – (Left) Radiographic union at fracture site; (Right) abundant Callus but with fracture line in at least one cortex.

- c. Non-weight bearing
- 5. Post-operative complications
 - a. Non-union
 - b. Mal-union
 - c. Infection
 - d. Nail breakage
 - e. Screw breakage
 - f. Screw loosening
 - g. Repeat surgery
 - h. Peri-implant fracture

3. Results

3.1. Patient characteristics

The population is grouped according to the type of intramedullary nails used, namely the S.I.G.N nail and the commercially available Cannulated nails (Zimmer, Orthopedic International, Smith & Nephew). For the S.I.G.N group, only 48 out of 88 (54.5%) and 20 out of 87 (22.9%) patients for the Cannulated group have follow-up of ≥ 4 weeks post-op. There is no significant difference in the mean of both times to surgery and latest follow-up for both groups. The fractures classification system of Winquist and AO/OTA were used to tabulate fracture configuration and shows no significant difference in frequency. The Gustilo classification system was also used to determine the number of patients with closed or open I fractures. There is no significant difference in the distribution of subjects with this regard [Table 1](#).

3.2. Surgical considerations

The subjects were also classified according to the orientation of nail insertion, being antegrade or retrograde approach. There is a significant difference between the frequency distribution of the two groups; with the S.I.G.N group having the larger number of patients inserted using the retrograde approach. The method of fracture reduction is either by open, or closed by using a fracture table for reduction. A significant difference was shown regarding this parameter, as the Cannulated group has a higher number of patients done by using closed reduction. The number of screws inserted at the proximal and distal site of the femur was also noted [Table 2](#).

Table 1 – Patient demographics and frequency distribution table according to fracture classifications.

		S.I.G.N	Cannulated nails	P-value	Verbal interpretation
Age (years)		32.08	27.85	0.149	Not significant
Sex	Male	41	20	0.096	Not significant
	Female	7	0		
Time to surgery (days)		12.21	14.05	0.241	Not significant
Follow up (weeks)		40.75	35.85	0.637	Not significant
Classification					
Closed		46	17	0.147	Not significant
Gustilo open type I		2	3		
Winquist					
0		19	6	0.853	Not significant
I		13	5		
II		7	5		
III		6	3		
IV		3	1		
AO/OTA					
A	1	3	2	0.197	Not significant
	2	10	7		
	3	17	3		
B	1	1	0		
	2	6	5		
	3	0	1		
C	1	8	0		
	2	0	1		
	3	2	1		

Table 2 – Frequency distribution table of patients according to nail orientation, type of reduction, and number of screws.

	S.I.G.N	Cannulated nails	P-value	Verbal interpretation
Nail orientation				
Antegrade	36	19	0.05	Significant
Retrograde	12	1		
Reduction				
Closed	0	2	0.026	Significant
Open	48	18		
No. of screws				
Proximal	1	3	0.246	Not significant
	2	45		
Distal	1	2	0.879	Not significant
	2	46		

3.3. Antegrade S.I.G.N nail: Piriformis vs greater trochanteric entry

The subjects in the Antegrade S.I.G.N group were also described with regards to the entry point of nail insertion namely the Piriformis fossa or the greater trochanter. There is higher number of patients with entry point at the greater trochanter (65.7%) as compared to patients inserted with nails via the Piriformis fossa (34.3%) [Table 3, Fig. 3](#).

3.4. Outcome measures

The results of the radiographic union showed that there is no significant difference in the radiographic union of patients between the two groups on latest follow-up. Union rate for the S.I.G.N group is 68.8% while for the Cannulated group is 80%. Majority of the patients in both groups have complete union while 31% of the patients in the S.I.G.N group and 20% in the Cannulated group show a fracture line in at least one cortex. No patient in either group has non-union in the fracture site. All patients in both groups achieved clinical union at follow-up. There was no finding of pain on fracture site on range of motion and weight bearing on the affected extremity. There is no significant difference with regards to the knee range of motion of both groups at the latest follow-up. Majority of patients in both groups (S.I.G.N: 85%; Cannulated: 90%) have full range of motion of the knee. However, there are still a number of subjects with intermediate range of motion $\geq 90^\circ < 140^\circ$ (S.I.G.N: 8.33%; Cannulated: 10%) and limited range of motion (S.I.G.N: 6.25%). All patients were able to stand on 100% of their body weight without eliciting pain. There is no significant difference with regards to the complication rates between the

Table 3 – Frequency distribution table of patients with Antegrade S.I.G.N nails inserted via the Greater trochanteric or Piriformis fossa.

	Frequency	Percent
Greater trochanteric entry	23	65.7%
Piriformis	12	34.3%
Total	35	100%

Fig. 3 – (Left) Greater trochanteric entry; (Right) Piriformis entry.

two groups on latest follow-up. The complication rate in the S.I.G.N group is 12.5% while it is 5% in the Cannulated group. From the patients with complication in the S.I.G.N group, 4 out of 6 needed additional surgeries. In the other hand, the only patient with complication in the Cannulated group also required an additional surgery. For the types of complications, majority is Superficial Surgical Site Infection (S.I.G.N: 4pxs, Cannulated: 1) for which all required an additional surgery. The other complication requiring surgery in the S.I.G.N group is the correction of a malrotation deformity of the distal femur [Tables 4 and 5](#).

4. Discussion

Interlock Intramedullary fixation of diaphyseal fractures of the femur has proven to be the gold standard of treatment. They provide angular and rotational stability despite fracture comminution, and results to high union rate and low complication rate. Unfortunately in a third world country such as the Philippines, not everyone has the finances to procure funds for the ideal implant. The introduction of the S.I.G.N nail as an alternative free of charge, has been very appealing to the surgeons hoping to give service to the less fortunate. However, this implant was not specifically designed for the femur. It was originally made for tibial fractures, hence the design of an apex posterior bend on the proximal (9°) and distal ends (1.5°).⁵ Concerns of developing peri-prosthetic fractures, especially on the areas of the proximal and distal bends, as well screw loosening and breakage continue to linger amongst surgeons. There have been descriptive and case series studies regarding its use in the femur, but never with a comparative data along with the gold standard of treatment. The big question that still stands is, are we giving our patients treatment comparable to the ideal? Or are we subjecting them to unwarranted risk in exchange for a free implant?

The study population for this paper was divided into patients treated with S.I.G.N nails and Cannulated Interlock Intramedullary nail. The mean age of both groups are

Table 4 – Frequency distribution of patients according to outcome measures.

	S.I.G.N	Cannulated nails	P- value	Verbal interpretation
Radiographic union				
Union in 4 cortices	33	16	0.346	Not significant
Callus but with fracture line at least one cortex	15	4		
No callus	0	0		
Clinical union				
Yes	48	20	1.000	Not significant
No	0	0		
Range of motion				
0–140	41	18	0.515	Not significant
>90 < 140	4	2		
<90	3	0		
Weight bearing status of patients				
Full	48	20	1.000	Not significant
Partial	0	0		
Non-weight bearing	0	0		
Complication				
None	42	19	0.354	Not significant
With complications	6	1		
Repeat surgery				
No	44	19	0.539	Not significant
Yes	4	1		

comparable as well as the mean time to surgery, which is almost 2 weeks post injury. The main reasons for the delay in the surgery could primarily be attributed to 1) conflict in elective O.R. Scheduling, 2.) lack of blood donors 3.) delay due to pre-op conferences. The percent of patients with follow-up was also small for both groups. However, there is a large number of follow-up (54.5%) in the S.I.G.N group since there is better record keeping and there is an on-line database

Table 5 – Frequency distribution table of complications in both S.I.G.N and Cannulated nails.

	S.I.G.N	Cannulated nails	P-value	Verbal interpretation
Infection				
SSSI	3	1.0	0.8	Not significant
Cellulitis	1	0.0	1.0	Not significant
Deformity	1	0.0	1.0	Not significant
Proud proximal screw	1	0.0	1.0	Not significant
Mal-union	0	0.0	1.0	Not significant
Nail breakage	0	0.0	1.0	Not significant
Screw breakage	0	0.0	1.0	Not significant
Screw loosening	0	0.0	1.0	Not significant
Peri-implant fracture	0	0.0	1.0	Not significant

available. For the nail orientation, the surgeons did not state the reason for choosing either antegrade or the retrograde approach. The peculiarity of the S.I.G.N system, rests on its external jig, which can be used for either retrograde and antegrade approach. Based from the results, there is still a larger population, which chose to use the antegrade group. The group of subjects with antegrade S.I.G.N nails was further classified regarding their choice of entry point at the proximal femur. The recommended entry point for antegrade nailing is the Piriformis since it points straight to the axis of the femoral canal. In the contrary, the S.I.G.N surgical technique manual recommends insertion of the nail via a greater trochanteric entry to permit allowance for the proximal bend of the nail. Theoretically, the reason behind this is to avoid the risk of developing a proximal peri-implant fracture while inserting a S.I.G.N nail via a straight axis through the Piriformis. In the results of this study, there are 34.3% of S.I.G.N patients inserted via the Piriformis fossa, and none had a peri-implant fracture.

The main goal of treatment for femoral shaft fractures is to provide stability for painless ambulation and range of motion of the lower extremities. For this study, both the radiologic and clinical union was obtained on latest follow-up. The investigators were unable to identify the time to radiographic union since the subjects do not follow a uniform timetable of follow-up check up. Some patients were lost to follow-up for several weeks and then show up at the out-patient clinic already with radiographic union. The radiographic union however, does not correlate clinically. Thirty one percent (31%) form the S.I.G.N group and twenty (20%) from the Cannulated group have patients showing abundant callus in both groups but with a fracture line in one cortex. Interestingly, all patients from this study show clinical union and are capable of full weight bearing on follow-up. For the knee range of motion, majority of the subjects in either treatment arm have full range of motion (S.I.G.N: 85%; Cannulated nails: 90%). Patients that belong to the intermediate and limited range of motion in either group have their latest follow-up ranging from 4 to 6 weeks. All except two patients belong to the antegrade group. From chart reviews, these patients have not yet completed the protocol of ambulation therapy and range of motion exercises from the Department of Rehabilitation.

Complication rate between the two groups statistically have shown to be non-significant. Majority of the complications that were recorded are superficial surgical site infections. These patients were diagnosed using the criteria of the C.D.C guidelines for Surgical Site Infection by Mangram et al.¹¹ The study population also consisted of patients with open type 1 fractures with adequate debridement. Infection rates of open type 1 fractures are reported to be 0–2%.¹¹ Surprisingly, all the subjects with infection are closed fractures. The type of fracture reduction however all require opening the fracture site in the S.I.G.N system since the system does not use intra-operative imaging to insert a guidewire. The patient from the Cannulated interlock group with infection also had open reduction because the surgery was already 11 days post-injury, and it was difficult for the surgeon to do a closed reduction. Management of the infections comprised of operative debridement antibiotic suppression, and retention of hardware until fracture union.¹² Another complication in the

S.I.G.N group was deformity correction of a malrotated distal fragment. The repeat surgery was due to the morbidity from surgical error. The repeat surgery for the patient was repositioning of the distal fragment and reinsertion of the distal interlock screws. No reports from either group showed any implant failure, peri-implant fracture, screw loosening, screw and nail breakage.

5. Conclusions

There is no significant difference between patients with isolated femoral shaft fractures treated with S.I.G.N Interlock Intramedullary nail versus Cannulated Interlock Intramedullary nail in terms of clinical and radiographic union, weight bearing, knee range of motion and complication rate. The S.I.G.N Interlock Intramedullary nails is comparable to the gold standard of treatment of femoral shaft fractures in terms of clinical outcomes and be used as a cheaper alternative for less fortunate patients.

6. Limitations of the study

The limitations of the study are as follows:

1. Poor patient follow-up and lack in uniformity of follow-up periods.
2. A lack of randomization and blinding.
3. Retrospective study.
4. The surgeries were performed by different surgeons hence the variability of surgeon skills.
5. No clear indication regarding reason by the surgeon for doing an antegrade or retrograde approach.
6. No patient-rated outcome assessment tool was used to determine functional outcomes.

7. Recommendations

A multi-center approach will be most beneficial in local data gathering. In local setting, it is quite difficult to recall patients due to poor data keeping, and poor follow-up and regional difficulties.

This will decrease the disadvantages that were pointed. Strict compliance to follow-up should also be implemented to patients, and surgeons should be aggressive in contacting and locating patients. A prospective randomized trial might be difficult since the S.I.G.N nails are free of charge while the commercially available nails are purchased by the patients. An ambispective study might be more appropriate to increase the number of subjects.

Conflicts of interest

All authors have none to declare.

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