Open Reamed Interlocked Intramedullary Nailing of Long Bone Fractures of the Lower Limb Using Surgical Implant Generation Network (SIGN) Nails: Radiographic Results and Clinical Outcomes at a Minimum of 12 Months Follow-up

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Abstract: In developing countries such as the Philippines, many patients rely on humanitarian aids to meet the expense of treatment for long bone fractures of the lower limb. In this descriptive cross-sectional study, we reviewed the midterm and long term outcomes (radiographic and clinical) of patients who were recipients of free implants from SIGN Fracture Care International, who have undergone open reamed interlocked intramedullary nailing of long bone fractures of the lower limb using the SIGN intramedullary nails with a minimum of 12 months follow-up. Radiographic results were scored using the Radiographic Union Scale for Tibial fractures (RUST) score and Functional outcomes were determined using 3 different patient-reported outcome measures. A total of 139 patients were included in the study of which, 100 (71.9%) patients involved the femur and 39 (28.1%) involved the tibia. The RUST mean score was 10.33 (SD 1.31) indicating good radiographic union. Mean scores for the Modified Harris Hip Score (mHHS) was 96.82 (SD8.45); 98.04 (SD 1.97) for the Lower Limb Core Function Scale and 1.69 (SD 1.60) for WOMAC. Average scores of these tools suggested good to excellent functional outcome. Using the Spearman's rho test for correlations, a significantly high positive correlation between the radiographic results and clinical outcomes were demonstrated. These results suggestedhigh radiographic union rates and good functional outcomes.

Index Terms: Intramedullary nailing, Long Bone Fractures,Femur, Tibia,Surgical Implant Generation Network (S.I.G.N.), Radiographic results, Functional Outcome

I. INTRODUCTION

Thetibial and femoral shafts are considered the most common sites of long bone fracture [1]. The treatment methods for these fractures evolved from nonoperativetechniques such as splinting and traction to operative treatment. Closed reduction and cast immobilization have previously been regarded as the standard treatment for low-energy tibial shaft fractures, while intramedullary nailing has been generally accepted as the treatment method of choice for femoral shaft fractures. However, during recent decades, the use of intramedullary locking nails (IMLN) has become more popular [2].

Intramedullary nailing is considered to be the optimum treatment for fractures of the longbones of the lower limbs and various studies have been published describing the functional outcome of both reamed and unreamed nailing [1].Many studies have also shown that the outcome of treatment of a tibial shaft fracture with locked intramedullary (IM) nailing is superior to that of cast treatment.

Various economic analyses of management strategies for tibia and femur shaft fractures suggest that reamed intramedullary nailing is the treatment of choice [3]. However, impoverished people in developing countries couldn't always afford these surgical implants. In most institutions in our country, orthopaedicsurgeons provide management strategies that are not the standard of care, because oftentimes, patients are financially constrained and are unable to undergo interlocked intramedullary nailing.

SIGN Fracture Care is an orthopaedic humanitarian aid organization treating impoverished people in developing countries. SIGN supplies surgical implants and training to orthopaedic surgeons at no cost. Our institution has been identified as one of the more than 200 hospitals throughout 50 developing countries to receive these surgical implants since 2011. This Study will review the outcome of patients who have underwent open reamed interlocked intramedullary nailing of long bone fractures of the lower limb using Surgical Implant Generation Network (S.I.G.N.) Nails.

Evidence from numerous medical literature showthat closed reamed interlocked intramedullary nailing of long bone fractures provides the best outcome in terms of union rates (97-98%) and complication rates. Because of this, the popularity of performing an open reduction has dwindled through the years. However, the results of this investigation may provide substantial evidence to support the continued use of an implant (SIGN nails) which requires an open reduction instead of a closed technique, among patients who simply

could not afford to purchase what is considered the ideal implant of choice.

II. REVIEW OF LITERATURE

A. Intramedullary nailing

Orthopedics is a dynamic field of surgery, and in no area of orthopedic endeavor is this better seen than in the management of a fractured long bone such as the tibia and femur. It is undeniable that most fractures of the tibia will heal if treated by non-operative means. Basic concepts of bone healing would tell us that if immobilized long enough, all fractures will eventually heal [1].

It was a common orthopedic practice during the early 1930's that all major tibial fractures are treated with skeletal traction for 3 weeks, followed by a weight-bearing plaster cast until healing is complete. However, Watson-Jones and Coltart in 1943 did an investigation on causes of slow union of fractures on 804 fractures of the shafts of the tibia and femur which clearly showed that traction had a deleterious effect on the rate of union. In addition, many studies have compared cast management with the IM nailing of tibial shaft fractures, and functional outcome after IM nailing is better compared with cast treatment [5]. There were clearly more malunions and delayed unions with cast treatment than with IM nailing, and also patients' durations of sick leave were shorter after IM nailing [5]. Furthermore conservative treatment with long-leg casting has been shown to result in prolonged joint immobilization, restricted ambulation, and extended rehabilitation requirements to regain a preinjury level of function [6].

Decades of literature work has definitely changed our attitude in the management of long bone fractures. From conservative management, Orthopedic surgeons have been increasingly advocating surgical management for the treatment of tibial and femoral shaft fractures even at the beginning of the last century. Hey Groves (1992) introduced IM nailing of long bones, which was popularized by Kuntscher in the 1940s [4]. Intramedullary nailing has evolved since then to become the treatment of choice for the stabilization of tibial and femoral shaft fracture [4].

Intramedullary nailing is considered to be the optimum treatment for fractures of the long bones of the lower limbs and various studies have been published describing the functional outcome of both reamed and unreamed nailing.

Numerous complications have been defined including infection, compartment syndrome, deep-vein thrombosis, thermal necrosis of the bone with alteration of its endosteal architecture, failure of the metalwork and malunion and nonunion of the fracture [2]. One of the most common problems associated with tibial primarily, and retrograde femoral nailing secondarily, is chronic anterior knee pain [2]. Its incidence has been reported to be as high as 86%. It may be present even in patients who have an intact knee as with antegrade femoral nailing. Its aetiology is unclear, but a multifactorial origin has been suggested [2]. These various complication can pose a serious handicap to the patient and consequently affecting his day-to-day activities and employment opportunities.

Various modifications in the technique of intramedullary nailing were developed to address the identified causes of these complications. In a study by Zirkle et.al.in 2009, he described the operative technique of tibia and femur nailing using the Surgical Implant Generation Network (S.I.G.N.) nail. He used hand reaming to avoid thermal necrosis of the bone with alteration of its endosteal architecture which is often afforded by the use of power reaming in the preparation of the intramedullary canal [21].

Various reports of SIGN success in trauma patients was related to the speed of surgery (no frequent C-arm imaging) and the use of hand reamers [21].Hand reaming is much safer than power reaming. Thermal necrosis is avoided by hand reaming, and the bone from the flutes of the reamer can be introduced into the fracture site [23].Furthermore, reaming allows a larger nail to be introduced. The interlocking screws can be inserted quickly using SIGN technique. A larger nail that has interlocking screws placed obviates the need for a second surgery and decreases the possibility of nonunion and infection [21]. These claims however are currently not reinforced by evidence as literature review on the long term functional outcome of patients who underwent SIGN surgery showed very scarce resources.

B. Clinical assessment tools

The Harris Hip Score HHS was developed for the assessment of the results of hip surgery, and is intended to evaluate various hip disabilities and methods of treatment in an adult population. The original version was published 1969 [7].The domains covered are pain, function, absence of deformity, and range of motion. There are 10 items. The score has a maximum of 100 points covering pain, function, absence of deformity, and range of motion. The HHS score gives a maximum of 100 points. Pain receives 44 points, function 47 points, range of motion 5 points, and deformity 4 points. The higher the HHS, the less dysfunction. A total score of <70 is considered a poor result; 70–80 is considered fair, 80–90 is good, and 90–100 is an excellent result [7].

The WOMAC (Western Ontario and McMaster Universities) index is used to assess patients with osteoarthritis of the hip or knee using 24 parameters. It can be used to monitor the course of the disease or to determine the effectiveness of anti-rheumatic medications [12].It measures five items for pain (score range 0–20), two for stiffness (score range 0–8), and 17 for functional limitation (score range 0–68) (Quitanaet.al, 2006). The test-retest reliability of the WOMAC varies for the pain, stiffness, and function subscales. When used in clinical studies, the WOMAC pain and function subscales perform comparably or better than other tests in being responsive to change from experimental interventions, but this varies for the different subscales and types of intervention [14].

The Lower Limb Instruments developed by The American Academy of Orthopaedic Surgeons (AAOS) was made through a process of literature review, consensus-building, and field-testing. It is an outcomes assessment instrument designed for the efficient collection of outcomes data from patients of all ages with musculoskeletal conditions in the lower extremity [17]. The Lower Limb Core Scale consists of seven items addressing pain, stiffness and swelling, and function, performed at an acceptable level. Comparative analysis of this scale was shown to be moderately to strongly correlated with other measures of pain and function, such as physician ratings, the SF-36, and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [17].

The Radiographic Union Scale for Tibial fractures RUST is a novel radiographic assessment for tibial shaft fractures. This scoring system was developed since radiographic assessment of tibial fracture healing continues to pose significant challenges to both routine fracture care and clinical research [18].Orthopaedic surgeons fail to achieve sufficient agreement on fracture healing when using conventional radiographic measures such as their general impression or the number of cortices bridged by callus. Moreover, the extent to which radiographic assessment of healing corresponds to patient-important outcomes is largely unknown. In an attempt to improve the assessment of radiographic outcomes of patients with tibial shaft fractures, recent studies have explored this novel radiographic assessment tool [18].

In a study by Whelan et.al. (2010) they evaluated the newly developed Radiographic Union Score for Tibial fractures (RUST). In this investigation they reviewed 45 sets of tibial shaft fractures treated with intramedullary fixation. Seven orthopedic reviewers independently scored bony union using RUST. Intraclass correlation coefficients (ICC) with 95% confidence intervals (CI) measured agreement. Overall agreement was substantial (ICC, 0.86; 95% CI, 0.79-0.91). There was improved reliability among traumatologists and overall intraobserver reliability was also substantial (ICC, 0.88; 95% CI, 0.80-0.96) [19].

III. MATERIALS AND METHODS

This is a descriptive cross-sectional study designed to evaluate the radiographic results and clinical outcomes of patients who have undergone open reamed interlocked intramedullary nailing of long bone fractures of the lower limb using Surgical Implant Generation Network (S.I.G.N.) nails at a Level III Trauma Center after a minimum of 12months follow up.

A. Study Population

All patients admitted with fracture/s of the long bones of the lower extremities (Tibia and Femur) and have undergone Open Reamed Interlocked Intramedullary Nailing using Surgical Implant Generation Network (S.I.G.N.) Nails at this institutionwith a minimum of 12 months follow-up were included in this study.Patients werealso included if any of the following criteria are met: 1) age not less than 18 years old; 2) the medical records are retrievable from the SIGN Surgical Database; 3) the data are encoded by the institutions SIGN Program from March 2011 to December 2015; 4) a follow up at a minimum of 12 months from date of operation is done for evaluation of functional and radiographic outcomes.

A total of 139 patients wereemployed in this study based on the computed sample size for frequency in a population using the OpenEpi Version 3, Open source calculator--SSPropor. To avoid type I and type II error, a 95% confidence level was set for the sampling size. An exacting degree of significance level was employed (set at 0.05) since the outcome of this evaluation has important consequences. Below is the table showing the distribution of patients who have undergone the procedure being investigated from the year 2011 up to 2015.

Table 1. Patients who have undergone Open Reamed Interlocked Intramedullary Nailing using Surgical Implant Generation Network (S.I.G.N.) Nails at a Level III Trauma Center from 2011-2015

Year	Census
2011	47
2012	70
2013	84
2014	73
2015	39
TOTAL	**313**

B. Description of the Study Procedure

Records of patients with long bone fractures of the lower limb that have undergone open reamed interlocked intramedullary using Surgical Implant Generation Network (S.I.G.N.) nails at this institution performed during the period of March 2011 to December 2015 were reviewed in this study.

Demographic profile of patients who satisfied the inclusion criteria were gathered and analyzed. Patients' fractures were classified according to whether Close or Open. Open fractures were further classified using the Gustilo-Anderson Classification system for open fractures. Depending on the fracture type, single, double or triple antibiotic therapies (cefazolin, gentamycin, penicillin G) applied in subjects with open fractures was classified accordingly as listed. Distribution of fracture types according to the classification systems was also analyzed.

A common post-operative protocol was employed among patients with long bone fractures of the lower limb who have undergone open reamed interlocked intramedullary

using Surgical Implant Generation Network (S.I.G.N.) nails. On the first postoperative day, patients began knee and hip exercises. Patients treated with static interlocked intramedullary nailing were allowed immediate partial to full weight-bearing. Follow up were done at 2weeks, 1month, 3months, 6months and annually thereafter post-operatively. Radiographs were taken on each clinic visit and details of the follow up were encoded at the SIGN surgical database.

Patients who have met the criteria for a minimum of 12 months post-operative follow up were then included in the assessment of radiographic and functional outcomes after having undergone the procedure being investigated. These patients were given various validated questionnaires to be answered during the recent post-operative follow-up. The following validated functional outcome questionnaires were used in this study:

a. Modified Harris Hip Score (mHHS)
b. American Academy of Orthopaedic Surgeons (AAOS) lower limb core function score
c. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

The Modified Harris Hip score is a patient-report, 7-item version of the Harris Hip Score. It consists of all HHS items except those on hip range of motion and deformity. It covers two domains, pain and function. The pain scale consists of seven descriptions of pain ranging from "none or ignores it," to "totally disabled, crippled, pain in bed, bedridden." A numerical value is assigned to each statement and the patient receives a score based on the statement chosen. Scores range from zero to 44. The higher the score, the less subjective pain the patient feels. A score of 44 is assigned if the patient indicates pain is absent, moderate but tolerable pain receives a score of 20 and disabling pain receives a score of zero.

The function domain includes a number of scales with corresponding number of items for which scores are assigned according to the response reported by the patient. A higher score is better. The different scales assessed in the function domain include Functional Activities (Shoes/socks scale, Stairs scale, Sitting scale and Public transportation scale) and Gait (Limp scale, Support scale, and Distance walked scale).

The American Academy of Orthopaedic Surgeons (AAOS) lower limb core function score is a downloaded Microsoft Excel program. The patient answers on the questionnaires which are then encoded on the program with subsequent generation of the standardized and normative scores for each sample population. The treatment outcome represents the standardized score, and the degree of functional outcome with reference to the general population represents the normative score. Higher standardized scores (on a scale of 100) indicate better outcomes and with a mean Normative Score 50. Thus, a patient scoring above 50 on a particular scale is above the general population's average, while a patient scoring below 50 on a scale is below the general healthy population's norm.

The Lower Limb Core Scale questionnaire consists of seven questions. The answer for each questions are rescaled to derive the mean score, from which standardized scores and normative scores are computed, and subsequently compared to the standardized and normative scores of the general population assessing the functional outcome of the operative intervention to the involved lower limb of the patients.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) measure clinically-significant, patient-relevant symptoms in pain, stiffness, and physical function in patients with osteoarthritis (OA) of the hip and/or knee following intervention. The questionnaire consists of 24 items with 3 subscales: pain (5 items), stiffness (2 items), and physical function (17 items). It uses descriptive adjectives: none, mild, moderate, severe, and extreme, which are translated to a numerical, ordinal scale (0-4). The pain, stiffness, and physical function subscales are summed to a maximum score of 20, 8, and 68, respectively. A global score is most commonly calculated by adding the 3 subscale scores and is reported as a percentage from the highest possible score of 96. Lower scores indicate lower levels of dysfunction.

Radiographs of patients on each follow up were collected and encoded in the SIGN surgical database. Radiographs at 12 months follow-up and beyond were scored using the RUST score. Table 2 shows the factors assessed and the corresponding scores for the RUST score.

Table 2. Radiographic Union Scale for Tibial fractures

Cortex	Fracture line visible, no callus Score = 1	Visible fracture line and callus Score = 2	No fracture line visible callus Score = 3	Total score Min: 4 Max: 12
Anterior				
Posterior				
Lateral				
Medial				

The RUST score assesses the presence of bridging callus and that of a fracture line on each of 4 cortices seen on 2 orthogonal radiographic views (medial and lateral cortices on the anteroposterior X-ray, anterior and posterior cortices on

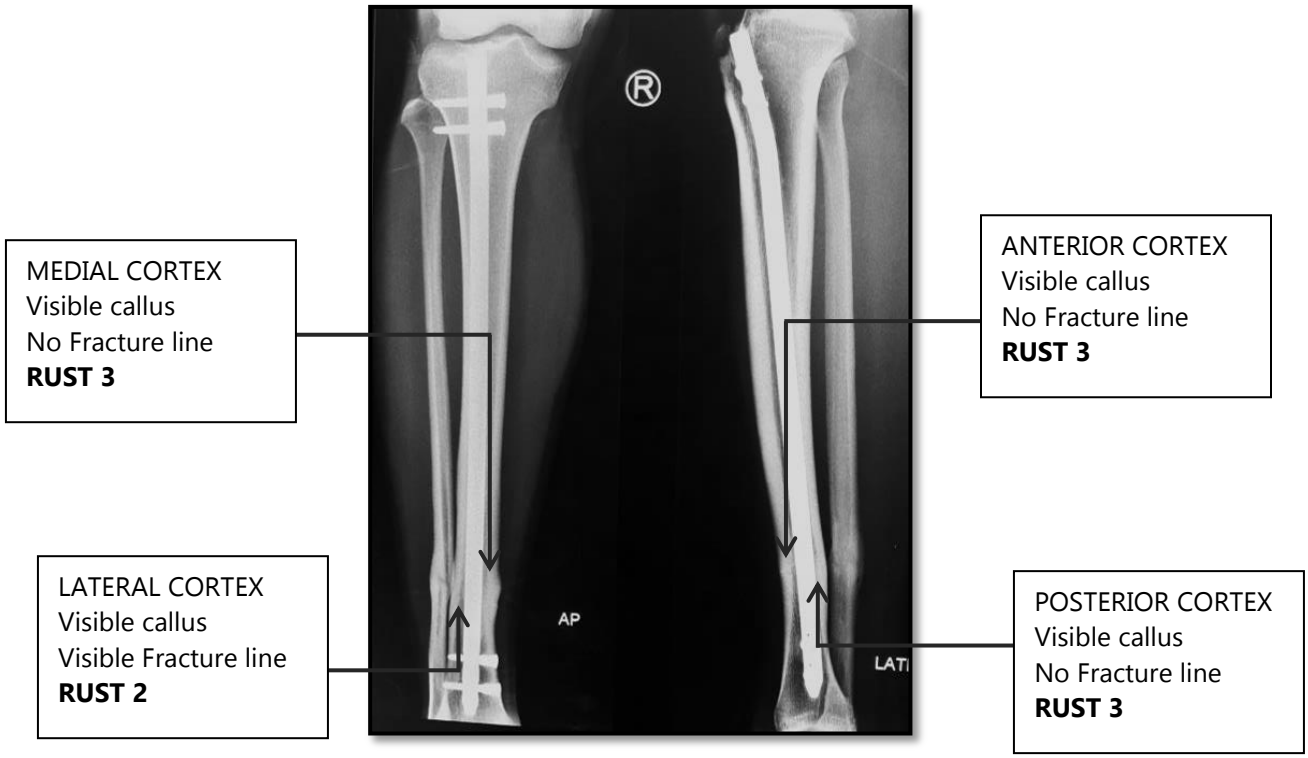

Figure1. Anteroposterior and lateral views of the right Tibia-fibula of a SIGN patient at 34th month post-operative follow-up showing the scoring of Radiographic Union Scale for Tibia Fractures of 11.

the lateral X-ray). Each cortex receives a score of one point if it is deemed to have a fracture line with no callus, two points if there is callus present but a fracture line is still visible, and three points if there is bridging callus with no evidence of a fracture line.The individual cortical scores are added to give a total for the set of films with 4 being the minimum score indicating that the fracture is definitely not healed and 12 being the maximum score indicating that the fracture is definitely healed. Radiographic fracture union was defined when bony callus was evident on at least 3 cortices in standard AP and Lateral views and with RUST score ≥ 7.

C. Data Processing and Analysis

Baseline demographic profile wasdescribed using frequency count distribution. Clinical variables being investigated were detailed using frequency count distribution and measures of central tendency.To determine the correlation between radiographic and clinical outcomes, the Spearman's rho test for nonparametric correlations was used.Differences between groups were considered significant if the probability of chance occurrence was ≤0.05.

D. Ethical Consideration

This study utilized an informed consent form to be filled up by patient and/or responsible representatives prior to enrollment of the patient to the study. A letter of permission addressed to the Hospital Director thru the hospital's Institutional Review Board was sent prior to commencement of the investigative period.The identity of patients was kept strictly confidential and no information revealing the identity of any individual was included in the final report.

IV. RESULTS

From the 313 total number of long bone fractures of the lower limb who have undergone open reamed interlocked intramedullary using Surgical Implant Generation Network (S.I.G.N.) nails and have met the inclusion criteria, we computed the necessary sample size for frequency in the population and a total of 139 (44.41%) was subsequently enrolled in this study. Records of these patients were then retrieved from the SIGN surgical database. Of the 139 patients, 100 (71.9%) involved the femur and 39 (28.1%) involved the tibia. Among the patients included in the study, 115 (82.7%) were males and 24(17.3%) were females with mean age of 41 years (range 18 to 64years). Most of the patients were closed fractures with 114 (82.0%) cases of the sample and 25 (18.0%) cases were open fractures. (Table.3)

Table 3. Demographic profile of patients with long bone fractures of the lower limb who have undergone open reamed interlocked intramedullary using Surgical Implant Generation Network (S.I.G.N.) nails performed at a Level III Trauma Center during the period of March 2011 to December 2015

	Number of Patients (N=139)	% from total number of patients
SEX		
MALE	115	82.7
FEMALE	24	17.3
AGE (years)		
< 21	17	12.2
21- 30	82	59.0
31- 40	18	12.9
41- 50	13	9.4
> 50	9	6.5
Type of Long Bones		
Femur	100	71.9
Tibia	39	28.1
Type of Fracture		
Close	114	82.0
Open	25	18.0

The identified cases of open fractures were further classified using the Gustilo-Anderson classification system. There were 6 (4.3%) cases classified as Type I, 8(5.8%) cases each under Type II and Type IIIA open fractures while 3(2.2%) cases were classified as Type IIIB open fractures. (Table.4)

Table 4. Distribution of open fractures according to Gustilo-Anderson Classification

Gustilo-Anderson Classification of Open Fractures	Number of Patients (N= 139)	% from total number of patients
I	6	4.3
II	8	5.8
IIIA	8	5.8
IIIB	3	2.2
IIIC	0	0

The average follow-up period for the sample population was at 40 months post-operatively with a range of 12 months (minimum requirement for determining the midterm to long term functional outcome) up to 68 months. Out of the 139 patients included in the study, all had good radiographic union with Radiographic Union Scale for Tibial fractures (RUST) mean score of 10.33 (SD 1.31) with a range of 8-12 RUST score. One hundred patients (71.9%) had RUST scores of 10-12 denoting that radiographic reviews showed no fracture line and with visible callus on at least three or all four cortices. Thirty-nine patients (28.1%) had scores ranging from 7-9 using the parameters - visible callus and presence of fracture line, while none were reported with RUST score of 4-6 which would indicate that no fracture healing occurred post operatively. (Table 5)

Table 5. Distribution of Radiographic Union Score for Tibia (RUST)

RUST	Number of Patients (N= 139)	% from total number of patients
4-6 (fracture not healed)	0	0
7-9 (w/ fracture healing)	39	28.1
10-12 (fracture healed)	100	71.9

Mean score for the Modified Harris Hip Score (mHHS) was 96.82 (SD 8.45). Distribution of Modified Harris Hip Scores for patients who underwent the procedure being reviewed in this study revealed good to excellent functional outcome with 135 (97.1%) getting mHHS scores of 91-100. (Table 6)

Table 6. Distribution of Modified Harris Hip Scores (mHHS)

Harris Hip Score	Number of Patients (N= 139)	% from total number of patients
<70 (Poor)	0	0
70-80 (Fair)	0	0
81-90 (Good)	4	2.9
91-100 (Excellent)	135	97.1

The mean standardized score for the Lower Limb Core Scale was 98.04 (SD 1.97). All 139 patients included in the study had a Lower Limb Core Scale which was above the normal population's average set at 50 indicating a good clinical outcome. (Table 7)

Table 7. American Academy of Orthopaedic Surgeons (AAOS) lower limb core function scores

Lower Limb Core Function Score	Number of Patients (N= 139)	% from total number of patients
0-50	0	0
51-100	139	100

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The mean WOMAC global score was 1.69 (SD 1.60). The distribution of WOMAC global scores of patients as shown in the table below, revealed all 139 patients having WOMAC scores below 50. Lower scores in WOMAC indicates better outcome in terms of pain, stiffness and function subscales. (Table 8)

Table 8. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) mean scores for subscales (N=139)

WOMAC Score	Number of Patients (N= 139)	% from total number of patients
0-50	139	100
51-100	0	0

The results of the radiographic assessments for all patients included in this study were correlated against the results of the three self-report assessment tools used to describe the clinical outcome. The succeeding tables below show the cross tabulation of clinical and radiographic scores. Of the 100 (71.9%) patients who had a RUST score of 10-12, all demonstrated an AAOS LLC standardized score above 50 and a WOMAC global score of below 50. However, only 99 of the 100 patients with RUST score of 10-12 reported excellent scores (91-100) formHHS. (Table 9,10 and 11)

Table 9. Cross-analysis of RUST Scores with mHHS

RUST		mHHS Modified Harris Hip Score			
		<70 (Poor)	70-80 (Fair)	81-90 (Good)	91-100 (Excellent)
Radiographic Union Score for Tibia	4-6	0	0	0	0
	7-9	0	0	3	36
	10-12	0	0	1	99

Table 10. Cross-analysis of RUST Scores with AAOS Lower Limb Core Function Score

RUST		American Academy of Orthopaedic Surgeons (AAOS) Lower Limb Core function	
		0-50	51-100
Radiographic Union Score for Tibia	4-6	0	0
	7-9	0	39
	10-12	0	100

Table 11. Cross-analysis of RUST Scores with WOMAC Score

RUST		Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)	
		0-50	51-100
Radiographic Union Score for Tibia	4-6	0	0
	7-9	39	0
	10-12	100	0

Using the Spearman's rho test for correlations, the radiographic results and clinical outcome of patients who have undergone open reamed interlocked intramedullary nailing of long bone fractures of the lower limb using Surgical Implant Generation Network SIGN nails were determined accordingly. The results showed that there is a significantly high positive correlation between the radiographic results and clinical outcome as represented on the table below. (Table 12)

Table 12.Correlation between the radiographic results and clinical outcome of patients who have undergone open reamed interlocked intramedullary nailing of long bone fractures of the lower limb using Surgical Implant Generation Network SIGN nails

		RUST
mHHS	Correlation Coefficient	.841**
	Sig. (2-tailed)	.000
	N	139
AAOS-LLC	Correlation Coefficient	.809**
	Sig. (2-tailed)	.000
	N	139
WOMAC	Correlation Coefficient	.856**
	Sig. (2-tailed)	.000
	N	139

**Sig at p < .01

Significant positive relationship was observed between the results of Radiographic union score for tibia Fractures (RUST) and Modified Harris Hip Score (mHHS) (***r***=.841, ***p***<.01), Radiographic union score for tibia Fractures (RUST) and American Academy of Orthopaedic Surgeons (AAOS) lower limb core function score (***r***=.809, ***p***<.01), and Radiographic union score for tibia Fractures (RUST) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (***r***=.856, ***p***<.01).

V. DISCUSSION

The primary goal in the management of long bone fractures of the lower limb is to achieve union in order to enable weight-bearing in the early postoperative period. Also achieving the normal length and alignment of the bone and providing functional movement angle to the knee and hip are of utmost importance [19]. The requirements of an ideal union have been incorporated in the development of various techniques of osteosynthesis. These would include providing mechanical stability, avoiding any separation among the

fractured parts, reformation of the endosteal vascular continuity, maintenance of the integrity of the periosteal tissue and allowing a certain stress on the fracture line. With these principles in mind, we are able to make correct decisions as to what treatment modality is best suited for a fracture, particularly that of the lower extremity.

Intramedullary nailing osteosynthesis has evolved since it was introduced in the 1940's. An advantage of this technique is that it affords correct alignment of fracture fragments providing a stable fixation while allowing functional weightbearing. It also doesn't limit the movements of the adjacent joints and thus enables early weightbearing [5].

In our institution, open reamed interlocked intramedullary nailing has been in the forefront of our armamentarium in the management of long bone fractures of the lower extremities. With the commencement of the SIGN Fracture Care International Program in our institution on March 2011, we have afforded this treatment modality to the most impoverished of patients, those who could barely find the money for any form of internal fixation for their fractures. Although the gold standard for treatment of femur and tibia shaft fractures is closed intramedullary nailing, performing an open reamed interlocked intramedullary nailing to these patients is still suitable.

In this study, we reviewed the long term radiographic results and functional outcomes of our patients who were recipients of the free implants from the SIGN Fracture Care International Program. Using the RUST scale, we have reported good union rates accounting for all 139 patients included in the sample population, with rust scores ranging from 8 to 12. The good union rate may be attributed to a feature of this technique which uses hand reaming for the preparation of the intramedullary canal. By doing so, we are able to preserve the endosteal vascular continuity thus promoting union and subsequently avoiding the complications which are often times afforded by power reaming [20].

There have been a limited number of studies about evaluating the functional outcomes after treatment of diaphyseal femur and tibia fractures. In our study, multiple outcome measures including Modified Harris Hip Score (mHHS), American Academy of Orthopaedic Surgeons (AAOS) lower limb core function score, and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) were utilized. Average scores of these instruments suggested very good or good functional results.

Following locked intramedullary nailing; deep infection or osteomyelitis prevalence has been reported as less than 1% in literature [20]. Even though treated with open reduction, none of the patients in our study showed deep infection or osteomyelitis. Even those who were treated after an open fracture (18.0%) did not develop such complications as none were apparent on the results of the functional outcome assessment tools employed in this study.

In literature, it is reported that early IM nailing osteosynthesis can be performed in Gustilo type I, II and IIIA open fractures which are debrided and irrigated in the first 8 hours following trauma [22]. In our study, although we failed to define the average interval from trauma to operation for open fractures we acknowledged that the major factor causing the extension of this period was the financial or bureaucratic procedures for the material supply. This problem was amply addressed by the provision of intramedullary nails from the SIGN Fracture Care International Program, thus allowing early IM nailing and consequently contributing for the low account of infection and other complications.

VI. CONCLUSIONS

Results of our study show that open reamed interlocked intramedullary nailing osteosynthesis using Surgical Implant Generation Network (S.I.G.N.) nails may be a treatment of choice for long bone fractures of the lower limb in adults owing to its high union rates, low complication risks and good functional results.

Furthermore, the use of Radiographic Union Score for Tibia (RUST) in the assessment of radiographic results is reliable and correlates well with the clinical outcomes as reported using the three validated, patient-reported outcome measures specifically the Modified Harris Hip Score (mHHS), American Academy of Orthopaedic Surgeons (AAOS) Lower Limb Core Function Score, and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

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The principal author of this study however, has not received or will not be receiving benefits for personal or professional use from SIGN Fracture Care International. Although it has been declared that the company is associated to the subject of the research paper, the research findings included in this study may not necessarily be related to the commercial interests of SIGN Fracture Care International.

The terms of this arrangement have been reviewed and approved by the Institution's Ethics Review Committee, in accordance with its policy on objectivity in research.

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