Original Article

# Comparison of SIGN interlocking nailing and compression plating in the treatment of aseptic non-union of femoral shaft fractures

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## Abstract

**Background:** Aseptic non-union of the shaft of femur presents a treatment challenge with the need for prolonged hospitalization, multiple procedures and economic burden. The choice of treatment is influenced by facilities available in a specified centre.
**Aim:** To compare the results of SIGN interlocking nailing and compression plating in the treatment of aseptic non-union of femoral shaft fractures.
**Methods**: Prospective cohort study conducted over a period of thirty-one (31) months (August 2015 to March 2018). Patients with aseptic non-union of femoral shaft fractures who presented to orthopaedic units of University of Port Harcourt Teaching Hospital, Port Harcourt over the study period were recruited into the study. They were randomly grouped into two- A and B. Group A had open reduction and internal fixation with SIGN interlocking nail, while group B had their fractures fixed by compressive plate osteosynthesis. The patients were followed up for at least six months and the results compared.
**Results:** Forty out of 42 patients completed the study. The SIGN interlocking nailing group had a union rate of 80% (n=16) in six months, while the compression plating group had 95% (n=19). The observed difference was not statistically significant (p=0.342). The two groups also had statistically comparable intra-operative blood loss, wound infection rates, duration for wound healing, post-operative limb shortening and duration of post-operative hospital stay.
**Conclusion:** SIGN interlocking nailing and compression plating are effective methods of treatment of aseptic non-union of femoral shaft fractures. They are comparable with respect to variables evaluated in this study

**Keywords:** Aseptic non-union, femoral shaft, SIGN interlocking nail, compression plating.

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## INTRODUCTION

Fractures of the shaft of femur are commonly encountered in orthopaedic practice. The femur is one of the principal load-bearing bones in the lower extremity. Hence fracture involving it can cause prolonged morbidity and extensive disability unless appropriate treatment is given.[1]

Repair of fractures involves a sequence of dynamic events which ultimately restores the integrity of the bone and its biomechanical properties. Sometimes healing is compromised leading to a delayed union or non-union.[2]

Fracture non-union had been defined in various ways because of several factors that must be considered. Non-union had been

defined as a fractured bone that has not completely healed within 9 months of injury and that has not shown progression towards healing over 3 consecutive months on serial radiographs.[2,3] Hence, the absence of any clinical or radiographic evidence of progression of fracture healing for 3 months after the expected time period for healing constitutes non-union.[2,3] However, the exact time of union would differ depending on the fractured bone involved, the location of the fracture, the soft tissue condition as well as the fracture type.[2,3] Radiologically, non-union has been defined by the presence of the following criteria: absence of bone trabeculae crossing the fracture site, sclerotic fracture edges, persistent fracture lines and lack of progressive change towards union on serial radiographs.[2,3] Clinically, there should be persistent pain or motion at the fracture site which is best elicited by weight bearing.[2,3] Aseptic non-union is one in which there is no clinical or laboratory evidence of infection. In diaphyseal fractures of major long bones in adults, the diagnosis of non-union should not be made until 6 months have elapsed after the injury.[2-5]

The aetiological factors in non-union could be local or systemic. The local factors include excessive motion at fracture site, soft tissue interposition, severe soft tissue injury, infection, irradiated bone, injudicious intervention by traditional bonesetters and inherent blood supply characteristics of the involved bone. Malnutrition, chronic alcoholism, abuse of non-steroidal anti-inflammatory drugs (NSAIDs), tobacco smoking and prolonged use of steroids constitute systemic factors associated with non-union.[2, 5, 6]

Non-union can be classified as hypertrophic, oligotrophic or atrophic,[1,2,4,5,7] aseptic or septic (infected),[1,2,4,5,7,8] metaphyseal or diaphyseal.[1,2,4,5,7,8]

Treatment could be non- operative or operative.[2,5,9] Non-operative treatment includes cast- brace immobilization, electrical stimulation, bone marrow injection and shock wave therapy.[1-9] In the femur, operative treatment is favoured.[1-9] The operative procedures include plate fixation, intramedullary (IM) nailing and exchange nailing. These fixation methods may be accompanied by bone grafting (when indicated) to stimulate osteogenesis. Treatment is individualized and may involve two or more methods.[1-5,8,9]

Prior to the availability of Surgical Implant Generation Network (SIGN) interlocking nailing, compression plating was popular in Port Harcourt. Surgery with SIGN nail became attractive due to its low cost as the implants were donated free of charge by SIGN.[10] This is important in an environment, like Port Harcourt, Nigeria where the cost of health care is predominantly borne out-of-pocket by patients due to low health insurance coverage. The SIGN nail is a solid, stainless steel nail with slots to accommodate the interlocking screws.[10] The nail is straight but has two bends at the proximal and distal ends, which are 9 and 1.5 degree apex posterior bends respectively.[10] These two bends in the femur create an effective radius of curvature which closely approximates that of the normal human femur.[10] The nail is provided with a target arm along with instruments which allow the interlocking screws (including distal screws) to be inserted with or without an image intensifier. The SIGN nail in the medullary canal functions in load-sharing capacity [10] and may assuage the potential effects stress shielding may have on the bone when compared to compression plating. The locking screws proximally and distally prevent rotation. The aim of this study was to compare the results of SIGN interlocking nailing and dynamic compression plating (DCP) in the treatment of aseptic non-union of femoral shaft fractures at the University of Port Harcourt Teaching Hospital.

## PATIENTS AND METHODS

It was a prospective cohort study conducted over a period of thirty-one (31) months (August 2015 to March 2018). This study was carried out in the University of Port Harcourt Teaching Hospital, Port Harcourt, Rivers State, Nigeria. It is a tertiary health institution and hence attends to the bulk of the patients with orthopaedic problems in the state and

neighbouring states like Bayelsa, Abia and Imo.

The study was conducted on adult patients who presented to orthopaedic units of University of Port Harcourt Teaching Hospital (UPTH), Port Harcourt with aseptic non-union of femoral shaft fractures and had SIGN interlocking nailing or compression plating. They were patients who met the eligibility criteria.

The sample size was calculated using this formula[11]:

$$n = \frac{4Z^2 x (PQ)^2}{(d)^2}$$

Where P is set at 50% and Z at 1.96

n= the desired total sample size

Z = the assumed standard deviation set at 1.96 which

Corresponds to 95% confidence level.

P = the population in the target population estimated to have a particular characteristic. 50% (0.50) was used since there is no reasonable estimate.

Q = 1.0-P

d = the degree of accuracy desired at 20% (0.20)

$$n = \frac{4(1.96)^2 x (0.50x\ 0.50)^2}{(0.20)^2}$$

$$n = \frac{4 x 3.842 x 0.0625}{0.04}$$

$$= 19$$

Adding 10% attrition rate: 1.9

n = 19 + 1.9 = 20.9 (approximately 21 patients)

The sample size was doubled to improve the statistical strength

This gave a sample size of 42. The sample size was therefore 42 patients.

The study included patients above 18 years old with clinically and bacteriologically proven aseptic non-union of femoral shaft who were treated by SIGN interlocking nailing or dynamic compression plating.

The exclusion criteria were: fractures with intra-articular component ; metaphyseal fracture non-union ; patients below the age of 18years; patients who did not give consent; infected non-union; pathologic fracture non-union; patients who opted out of the study even after giving consent; and patients with co-morbidities e.g. diabetes mellitus.

Systematic random sampling method was utilized in the study. The eligible patients were given numbers in order of presentation to the hospital. The odd number group (group A) had SIGN interlocking nailing, while the even number category (group B) was treated by compression plating. This randomization was carried out by the authors immediately a patient gave consent to be recruited into the study. The patients were followed up for at least six months and the results compared.

## DETAILS OF THE STUDY

Patients who met the inclusion criteria and gave consent were included in the study. Pre-operative diagnosis was made by history taking, physical examination and plain radiographs. Baseline investigations such as full blood count, urinalysis, serum electrolytes, urea and creatinine, fasting blood sugar, grouping and cross-matching were done to ascertain patients' fitness for surgery. In addition, erythrocyte sedimentation rate (ESR) and C- reactive protein were requested to rule out infection (exclusion criteria). For patients above 40years, chest radiograph and electrocardiogram were carried out in addition to the above.

The surgeries were done under general anaesthesia or subarachnoid block. Prophylactic antibiotic (1g of ceftriaxone) was given at induction of anaesthesia. Skin preparation was carried out by washing with cetrimide (3%) and chlorhexidine gluconate (0.3%) mixture (twice) followed by drying with sterile gauze. Another round of cleaning was done with 70% alcohol. Finally, the skin was painted with povidone iodine (5%). Each patient was positioned and draped in such a way that the appropriate source of bone graft

could be accessed if required without repositioning.

With patient on supine position, a lateral longitudinal skin incision centred on the fracture non-union site was made and deepened through the subcutaneous tissue to fascia lata. The fascia lata was divided in line with skin incision and retracted to expose the vastus lateralis. The interval between the vastus lateralis and lateral intermuscular septum was identified and deepened to the femur by lifting the vastus lateralis muscle anteriorly with a retractor. Haemostasis was secured. Through subperiosteal dissection, the bone ends were exposed and freshened until healthy bleeding areas were visualised. Previous implant was removed if any. Tissue sample from the non-union site for each patient was collected and sent for microscopy, culture and sensitivity. Patients with positive cultures were excluded from the study. The marrow cavities were re-established; reduction done and bone stabilized either by Surgical Implant Generation Network (SIGN) locked intramedullary nailing or dynamic compression plating depending on which category the patient belonged. All the SIGN patients had hand reaming. The platings were done with 10-12 hole 4.5mm broad DCP. The wound was closed in layers over a suction drain.

Osteogenesis was stimulated by cancellous autogenous bone grafting harvested from the iliac crests for all cases of atrophic non-union in order to bring them to the status of their hypertrophic counterpart.

Intra-operative blood loss was assessed by reading the volume of blood in a graduated suction bottle. Where irrigation fluid was used, this was subtracted. Blood in surgical pad and floor were estimated by gravimetric method [12,13] and added to that in suction bottle to give the total blood loss. In gravimetric method, a known weight of dry surgical pad was subtracted from the weight of a wet one and the difference in grams noted. A difference of one gram is equivalent to 1millilitre of blood. [12,13]

Post-operatively, antibiotics (ceftriaxone and metronidazole) were continued for 5 days for all patients. Wound drain was removed as soon as it served its purpose. Physiotherapy was commenced as soon as pain allowed.
Patients were discharged as soon as they were stable on crutches and without any post-operative complication that required in-hospital care.

Post- operative shortening (limb-length discrepancy) was determined by measuring the length of each femur from the tip of the greater trochanter to ipsilateral fibular head using a measuring tape. The observed difference if any was documented. All the measurements were done by the same investigator using same measuring tape to avoid inter and intra-observer errors respectively.

The state of the wound with respect to healing status and presence/absence of infection were assessed prior to discharge as well as during follow-up visits. Wound infection here was defined as presence of sero-purulent or purulent discharge with or without positive microbial culture.

Before discharge, patients were counselled on the need for regular follow-up. In addition, the authors obtained their contact addresses, phone numbers and folder numbers. Each patient was followed up for a minimum of 6 months. Post-operative check radiographs were obtained during follow-up visits. The study protocol was discussed with the consultants and residents of all the orthopaedic units for uniformity.

Union was defined by clinical and radiological findings.[3,8,14] The clinical parameters were absence of tenderness at the fracture site, painless weight bearing and negative findings on varus-valgus and anterior-posterior stress tests with one hand above and the other below the fracture non-union site. The radiological parameter was presence of bridging callus across the non-union site in at least three cortices in two orthogonal radiographic views.

The authors participated in the pre-operative work-up and surgical planning of all the patients and played a minimum role of assistant surgeon. When this was not possible, other orthopaedic surgeons with similar level of competence stood in for them.

To ensure standard in both techniques (SIGN interlocking nailing and compression plating), all the surgeries were done in the presence of experienced Consultant Orthopaedic Surgeons who had been trained on SIGN interlocking nailing, either as the Lead Surgeon or Assistant Surgeon.

Data collated were analyzed using the Statistical Package for Social Sciences (SPSS) version 21 (IBM Corp., Armonk, NY, USA). Tables and bar charts were used to present the results. They were expressed as proportion, mean and standard deviation. The observed differences were subjected to statistical test of significance with p-value set at 0.05.

Ethical approval was obtained from the Research and Ethics Committee of University of Port Harcourt Teaching Hospital, Port Harcourt, in line with Helsinki declaration with reference number - UPTH/ADM/90/S.II/VOL.X/823.

## RESULTS

Forty out of the 42 patients recruited completed the study. Two patients, one from each treatment group were lost to follow-up leading to attrition rate of 4.7%. The forty patients (20 in each group) had comparable socio-demographic characteristics as shown in Table 1. The predominant age group was 30-39 years (8 patients for the interlocking group, and 9 for the plating category). The SIGN interlocking group had 14 males (70%) and 6 females (30%) while the compression plating group had 12 males (60%) and 8 females (40%) respectively.

The commonest cause of injury for interlocking nailing and plating groups was motor vehicle accident- 13 (65%) and 10 (50%) patients respectively. The interlocking group had no case of assault while the plating group had 1 (5%) as shown in Figure 1.

**Table 1: Comparison of demographic characteristics of patients between SIGN interlocking nailing and compression plating groups**

| Socio-demographic characteristics | Groups in the study | | Total N=40 n (%) |
|---|---|---|---|
| | Interlocking nailing N=20 n (%) | Compression plating N=20 n (%) | |
| **Age category** | | | |
| 20 – 29 years | 5 (25.0) | 5 (25.0) | 10 (25.0) |
| 30 – 39 years | 8 (40.0) | 9 (45.0) | 17 (42.5) |
| 40 – 49 years | 6 (30.0) | 5 (25.0) | 11 (27.5) |
| 50 – 59 years | 1 (5.0) | 1 (5.0) | 2 (5.0) |
| | *Chi square=0.150; p-value=0.985* | | |
| **Sex** | | | |
| Male | 14 (70.0) | 12 (60.0) | 26 (65.0) |
| Female | 6 (30.0) | 8 (40.0) | 14 (35.0) |
| | *Chi Square=0.440; p-value=0.507* | | |

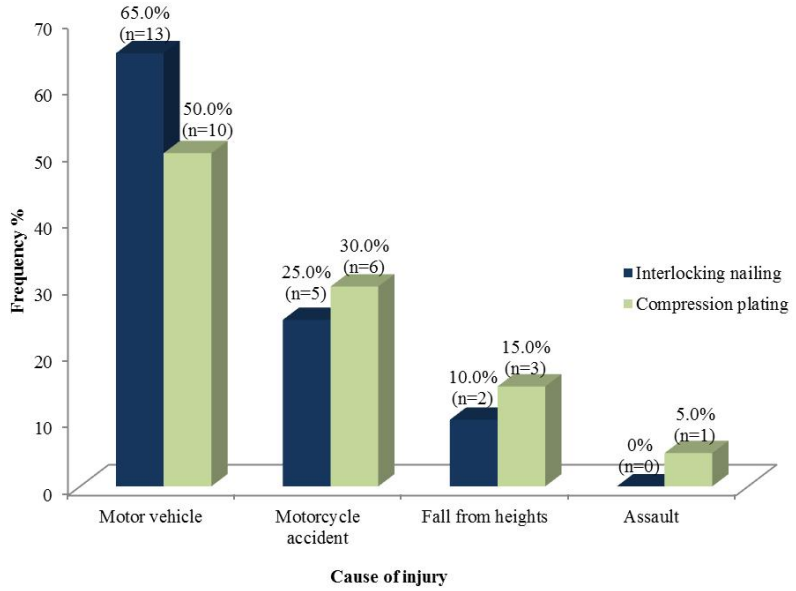


**Figure 1: Distribution of cause of injury between patients in two groups in the study**

Nineteen patients (95%) in the interlocking group had closed fractures while 1 (5%) had open fracture. The distribution of closed and open fractures in the compression plating group was 18 (90%) and 2 (10%) respectively. This is shown in Figure 2.

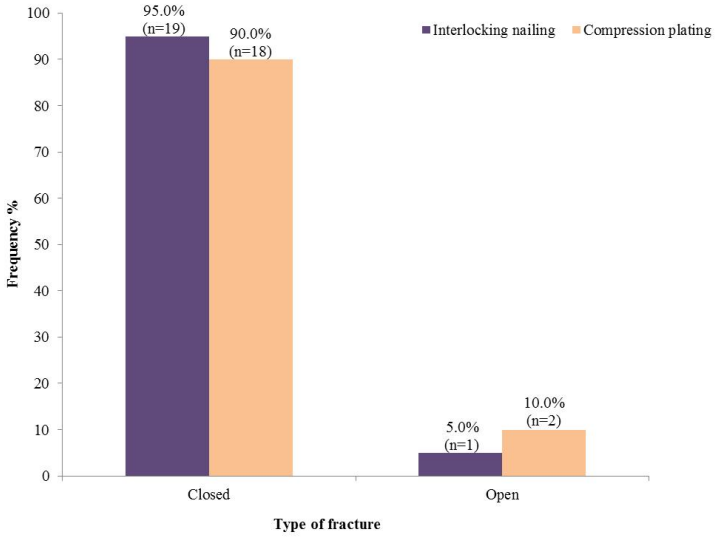


**Figure 2: Distribution of type of incident fracture amongst group in the study**

**Table 2: Initial treatment given to patients among groups in the study**

| | Groups in the study | | |
|---|---|---|---|
| **Initial treatment given** | **Interlocking nailing n (%)** | **Compression plating n (%)** | **Total n (%)** |
| Traditional bone setting | 16 (80.0) | 15 (75.0) | 31 (77.5) |
| Hospital care | 4 (20.0) | 5 (25.0) | 9 (22.5) |
| **Total** | **20 (100.0)** | **20 (100.0)** | **40 (100.0)** |

*Fisher's exact test p value=0.500*

**Table 3: Distribution of type of hospital care given to patients prior to presentation with non-union**

| | Groups in the study | | |
|---|---|---|---|
| **Type of surgical hospital care** | **Interlocking nailing n (%)** | **Compression plating n (%)** | **Total n (%)** |
| Conservative (skeletal traction) | 2 (50.0) | 2 (40.0) | 4 (44.4) |
| Surgical treatment | 2 (50.0) | 3 (60.0) | 5 (55.6) |
| **Total** | **4 (100.0)** | **5 (100.0)** | **9 (100.0)** |

*Fisher's exact test p value=0.643*

**Table 4: Distribution of specific hospital treatment received by patients among groups in the study prior to presentation with non-union**

| | Groups in the study | | |
|---|---|---|---|
| **Specific hospital treatment received** | **Interlocking nailing n (%)** | **Compression plating n (%)** | **Total n (%)** |
| Interlocking | 2 (50.0) | 0 (0.0) | 2 (22.2) |
| Plate fixation | 0 (0.0) | 3 (60.0) | 3 (33.3) |
| Skeletal traction | 2 (50.0) | 2 (40.0) | 4 (44.4) |
| **Total** | **4 (100.0)** | **5 (100.0)** | **9 (100.0)** |

*Fisher's exact test=4.230*

**Table 5: Comparison of the mean time between original injury and presentation (in weeks) between groups in the study**

| | Groups in the study | | | |
|---|---|---|---|---|
| | **SIGN Interlocking nailing Mean duration of hospital stay ±SD (weeks)** | **Compression plating Mean duration of hospital stay ± SD (weeks)** | **t** | **p-value** |
| Time between original injury and presentation (in weeks) | 69.62±44.54 | 66.50±22.731 | 0.280 | 0.177 |

SD- Standard deviation

**Table 6: Comparison of the time and rate of union with serial x-rays during follow-up period among patients in the two groups**

| | | Groups | | |
|---|---|---|---|---|
| | | **SIGN Interlocking nailing** | **Compression plaiting** | **Total** |
| **Follow-up** | **Union** | **n (%)** | **n (%)** | **n (%)** |
| **3 weeks** | Yes | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | No | 20 (100.0) | 20 (100.0) | 40 (100.0) |
| | | *Fisher's exact p-value =1.000* | | |
| **6 weeks** | Yes | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | No | 20 (100.0) | 20 (100.0) | 40 (100.0) |
| | | *Fisher's exact p-value =1.000* | | |
| **12 weeks** | Yes | 4 (20.0) | 3 (15.0) | 7 (17.5) |
| | No | 16 (80.0) | 17 (85.0) | 33 (82.5) |
| | | *Fisher's exact p-value =1.000* | | |
| **18 weeks** | Yes | 12 (60.0) | 18 (90.0) | 30 (75.0) |
| | No | 8 (40.0) | 2 (10.0) | 10 (25.0) |

| | | | | |
|---|---|---|---|---|
| | | *Fisher's exact p-value =0.065* | | |
| **6 months** | Yes | 16 (80.0) | 19 (95.0) | 35 (87.5) |
| | No | 4 (20.0) | 1 (5.0) | 5 (12.5) |
| | | *Fisher's exact p-value =0.342* | | |

**Table 7: Comparison of the mean intra-operative blood loss between groups in the study**

| | Groups in the study | | t | p-value |
|---|---|---|---|---|
| | **SIGN Interlocking nailing Mean ± SD** | **Compression plating Mean ± SD** | | |
| Blood loss (mls) | 505.00±276.20 | 500.00±264.57 | 0.058 | 0.144 |

S.D- Standard deviation

**Table 8: Comparison of wound status prior to discharge between groups in the study**

| | Groups in the study | | |
|---|---|---|---|
| **Condition prior discharge** | **SIGN Interlocking nailing n (%)** | **Compression plating n (%)** | **Total n (%)** |
| Wound healed | 3 (15.0) | 6 (30.0) | 9 (22.5) |
| Wound not healed | 16 (80.0) | 13 (65.0) | 29 (72.5) |
| Wound infected | 1 (5.0) | 1 (5.0) | 2 (5.0) |
| **Total** | **20 (100.0)** | **20(100.0)** | **40 (100.0)** |

*Fishers exact=1.513; p value=0.519*

**Table 9: Comparison of wound status during follow-up period among patients in the two groups**

| | | Groups | | |
|---|---|---|---|---|
| **Follow-up** | **Wound status** | **SIGN Interlocking nail n (%)** | **Compression plating n (%)** | **Total n (%)** |
| **3 weeks** | Wound healed | 19 (95.0) | 17 (85.0) | 36 (90.0) |
| | Wound not healed | 0 (0.0) | 2 (10.0) | 2 (5.0) |
| | Wound infected | 1 (5.0) | 1 (5.0) | 2 (5.0) |
| | | *Fisher's exact test =1.979; p-value =0.737* | | |
| **6 weeks** | Wound healed | 20 (100.0) | 20 (100.0) | 0 (0.0) |
| | Wound not healed | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | Wound infected | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | | *Chi-square =0.000; p-value = 1.000* | | |
| **12 weeks** | Wound healed | 20 (100.0) | 20 (100.0) | 0 (0.0) |
| | Wound not healed | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | Wound infected | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | | *Chi-square = 0.000; p-value = 1.000* | | |
| **18 weeks** | Wound healed | 20 (100.0) | 20 (100.0) | 0 (0.0) |
| | Wound not healed | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | Wound infected | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | | *Chi-square = 0.000; p-value = 1.000* | | |
| **6 months** | Wound healed | 20 (100.0) | 20 (100.0) | 0 (0.0) |
| | Wound not healed | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | Wound infected | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | | *Fisher's exact test =0.000; p-value = 1.000* | | |

**Table 10: Comparison of post-operative shortening between groups**

| Shortening | Groups in the study: SIGN Interlocking nailing n (%) | Groups in the study: Compression plating n (%) | Total n (%) |
|---|---|---|---|
| 1 – 2 cm | 4 (40.0) | 5 (62.5) | 9 (50.0) |
| 3 – 4 cm | 6 (60.0) | 3 (37.5) | 9 (50.0) |
| **Total** | **10(100.0)** | **8 (100.0)** | **18 (100.0)** |

*Fisher's exact p value=0.637*

**Table 11: Comparison of mean duration of post-operative hospital stay between groups in the study**

| Duration of hospital stay | Groups in the study: Interlocking nailing Mean duration of hospital stay ± SD | Groups in the study: Compression plating Mean duration of hospital stay± SD | t | p-value |
|---|---|---|---|---|
| Post-operative hospital stay (days) | 10.35±3.61 | 14.85±3.45 | -4.024 | 0.918 |

SD – Standard deviation

Thirty-one patients (77.5%) were initially treated by traditional bone setters, while 9 (22.5%) had hospital care elsewhere prior to presentation with non-union. Those that had initial hospital treatment were managed by skeletal traction (4 patients), plate fixation (3 patients) and locked intramedullary nailing (2 cases). These are illustrated in Tables 2 through 4.

The mean time between original injury and presentation was 69.62 weeks (17 months) for the SIGN interlocking group, and 66.5 weeks (16 months) for the compression plating patients. This is shown in Table 5.

**Time of union corroborated with serial radiographs**

During the follow-up visits (Table 6), it was observed that union was first noticed at 12 weeks in both groups. At this time, 4 patients (20%) in the SIGN interlocking group had their fractures united while 3 patients (15%) in the compression plating group had union.

At 18 weeks, SIGN interlocking group had a union rate of 60% (12 patients), while the compression plating group had 90% (18 patients). The observed difference was not statistically significant (p=0.065).

At 6 months, the SIGN interlocking group had 80% union (16 patients) while the compression plating group had 95% (19 patients). The observed difference was not statistically significant (p=0.342).

Table 6 also revealed that 4 patients (20%) in the SIGN interlocking group did not achieve union within the duration of follow-up. For the plating category, 1 patient (5%) failed to achieve union. The observed difference was not statistically significant (p=0.342).

**Intra-operative blood loss**

A comparison of intra-operative blood loss between the two groups (Table 7) revealed that the SIGN interlocking nailing group had a mean blood loss of 505.0±276.2mls while the compression plating group had 500.0±264.5mls. The difference was not statistically significant (p= 0.144).

**Wound healing and wound infection**

Prior to discharge, 3 patients (15%) in the interlocking group had their wounds healed, while 6 (30%) in the compression plating group achieved wound healing as shown in Table 8. The observed difference was not statistically significant (p= 0.519). Only 1 patient (5%) in each group had superficial wound infection.

During the 3 weeks follow- up visit (Table 9), 19 patients (95%) in the interlocking group had satisfactory wound healing, while 17 (85%) in

the plating group had their wounds completely healed. The observed difference was not statistically significant (p= 0.737). Superficial wound infection was still 1 patient (5%) for each group.

At 6 weeks follow-up visit, the 20 patients (100%) in each group had their wounds healed including the ones that had wound infection during earlier visits. These remained unchanged during 18 weeks through 6months follow-up visits (Table 9).

**Post –operative shortening**

Table 10 showed a post-operative shortening of 1-4cm in both groups. Six patients among the SIGN interlocking group had significant shortening of >2cm while 3 in the compression plating category had same. The observed difference was not statistically significant (p=0.637).

**Duration of post-operative hospital stay**

Table 11 showed that the SIGN group had a mean post-operative hospital stay of 10.3±3.6 days while the plating group had 14.8±3.4 days. The difference was not statistically significant (p= 0.918).

## DISCUSSION

The management of non-union poses a challenge to the orthopaedic surgeon. Hence treatment options continue to evolve and existing ones continue to be compared.

This study revealed that both the SIGN interlocking nailing and compression plating groups have similar socio-demographic characteristics. The preponderant age bracket was 30-39 years for both study groups. This is active age group and hence prone to musculoskeletal injuries. This compares favourably with the finding of Ikpeme *et al* [8] in Calabar. This might be due to the fact that both studies took place in South-south Nigeria, hence similar demographics. Nwagbara[14] in Enugu (South-east Nigeria) reported a preponderance of 18- 29 years age bracket. This difference may be due to the fact that the study was carried out in a different geopolitical zone. Male to female ratio was 2.3:1 for the interlocking group and 1.5:1 for the plating group. The male preponderance seen is similar to the findings of other investigators. [8,15-17] Fractures are commoner in males within the first four decades of life in our environment. [8]

The patients in both groups are also comparable with respect to the cause of the injury. Majority of the injuries were caused by motor vehicle accident, 13 cases (65%) for the SIGN interlocking group and 10 cases (50%) for compression plating category. This agrees with the finding of Nwagbara [15] in Enugu.

The study revealed statistically comparable union rates of 80% (n=16) and 95% (n=19) for the SIGN interlocking and compression plating groups respectively in 6 months. Wu and Shih [17] in Taiwan reported a union rate of 86.5% in 3-7 months for 32/37 cases of femoral shaft non-union fixed with locked intramedullary nail (Grosse-Kempf). Wu and Shih finding is comparable with the result of this study probably due to the fact that infected cases were ruled out in both studies. Hierholzer *et al* [18] reported a union rate of 98% in 24 months for 71 patients out of 72 that had exchange nailing. The higher union rate achieved by Hierholzer *et al* in contrast to the finding for SIGN interlocking patients may be partly due to longer duration of follow- up of 24 months unlike the present study that limited the duration of follow-up to 6 months.[18] The difference may also be due to the fact that all the patients in Hierholzer *et al* [18] work had initial hospital treatment (interlocking nailing) unlike this study where majority of the SIGN interlocking patients (80%) were initially treated by traditional bone setters. The union rate (80%) observed in the SIGN group did not also compare favourably well with 100% union obtained by Kim *et al* [19] in 16-18.5 weeks in 19 patients with aseptic femoral non-union that had exchange nailing. This may be partly due to the reasons given earlier or partly due to difference in sample size.

The bone union rate of 95% in 6 months achieved for the compression plating group is better than 88.2% reported by Nwagbara.[14] It is also higher than 75% (for 11 out of 16 patients treated by plate fixation) reported by Wu and Shih[17] in 3-7 months. Whereas compression plating with broad DCP was used in this study,

Wu and Shih [17] did not specify their technique of plate fixation nor the type of plate used.

The comparable mean intra-operative blood loss seen in this study may be due to the fact that both fixations were done open. This also suggests that reaming associated with interlocking nailing did not contribute significantly to intra-operative blood loss. The mean intra-operative blood loss of 505mls for the SIGN interlocking nailing patients is more than mean blood loss of 400mls reported by Wu and Shih [17] for the 32/37 femoral shaft non-union fixed with locked IM nailing. Also, the mean intra-operative blood loss of 500mls for the compression plating group is much less than average of 1500mls reported by Wu and Shih.[17] Unlike the present study where majority of the patients were initially managed by traditional bone setters, all Wu and Shih patients that were treated by plate fixation had another implant prior to presentation with non-union.[17] These had to be removed intra-operatively before plate fixation of the femoral non-union. This additional procedure may have increased soft tissue dissection, prolong the duration of surgery and hence more bleeding. Furthermore, Wu and Shih[17] did not report their method of estimation of intra-operative blood loss. In addition, their study was retrospective; hence whatever method of intra-operative blood loss estimation used may not have been uniformly applied.

Both treatment groups had superficial wound infection rate of 5% (n=1) each at the time of discharge. These were incidental findings in patients with close fractures prior to presentation with non-union. The similar infection rate for the two study groups might be due to the fact that the surgeries were done in same environment. This compares fairly well with 1 case of deep wound infection out of 16 cases for plating group and 1 out of 11 cases for Huckstep nailing patients reported by Wu and Shih. [17] At 3 weeks follow-up visit, the SIGN interlocking group had delayed wound healing of 5% (1 patient) which was statistically comparable to 10% (2 patients) recorded in compression plating group. In the study of Hierholzer *et al* [18] where effectiveness of exchange nailing was evaluated in the treatment of non-union, delayed wound healing was responsible 0.08% of complications reported.

The groups compared have clinically comparable post-operative shortening. The post-operative shortening of 50% (10 out of 20 patients) observed in the SIGN group is higher than that of 36% (26 out of 72 patients) reported in a related study.[18] The difference may be related to initial treatment given. In the former, most of the patients (80%) were originally treated by traditional bone setters unlike the latter patients that had interlocking nailing before presenting with non-union. The post-operative shortening of 3-4cm seen in 3 out of 20 patients (15%) in the compression plating group differs from 4 out of 17 patients reported by Nwagbara.[14] Whether the difference is related to surgical technique, injury severity and or initial treatment given is unclear.

Both groups evaluated had comparable post-operative hospital stay. This may be due to comparable wound healing and wound infection rates observed in this study or similar local protocol with respect to fracture care in the centre where the study took place.

The present study was limited by the small sample size and this will limit its generalizability.

## CONCLUSION AND RECOMMENDATION

SIGN interlocking nailing and compression plating are effective methods of treatment of aseptic non-union of femoral shaft fractures. Both methods are comparable with respect to rate of union, time of union, wound infection rate, duration of wound healing, intra-operative blood loss, post-operative limb shortening and duration of post-operative hospital stay.

Therefore, the authors recommend their continued use in treatment of aseptic non-union of femoral shaft fractures. However, multi-centre studies with larger sample size, longer duration of follow-up backed with meta-analyses are needed to have a widely accepted comparison of these two treatment options.

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There are no conflicts of interest.

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