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Original Article

Comparing Fin Intramedullary Nailing with Standard Locked Intramedullary Nailing in the Fixation of Humeral Shaft Fractures

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Abstract

Background: Standard interlocking intramedullary nailing of the humeral shaft fractures has its attending complications such as difficulty in locking the nail distally and associated nerve injuries. **Aim:** To compare the rate of fracture healing, functional outcome and complication rate between SIGN standard locked intramedullary nail (SSLIN) and SIGN intramedullary fin nail (SIFN) in the management of humeral shaft fractures. **Method:** This is a retrospective comparative study comprising of patients who were treated with either SSLIN or SIFN for humeral shaft fractures. They were followed up until full activities of daily living was achieved. Data collected were processed with SPSS. Comparisons were made between the two groups using student *t*-test for the continuous variables and Chi-square for the categorical variables. **Results:** Forty-three patients with humeral shaft fracture were included in this study. Thirty-one of them constituted the SSLIN group while 12 of them constituted the SIFN group. At 6 weeks, radiographic evidence of fracture healing was seen in 64.5% and 58.3% of the patients in the SSLIN and SIFN groups respectively and by the third month, 96.8% and 100% of the patients respectively had achieved radiographic evidence of fracture healing. The differences were not significantly different. There was also no significant difference in the findings from the comparative assessment of functional outcomes in both groups. **Conclusion:** SIFN compared favorably with the SSLIN in terms of rate of fracture healing and resumption of functional activities. SIFN is therefore encouraged to be used for humeral shaft fractures.

Keywords: Bio-nail, external jig, fin nail, humeral shaft fracture, interlocking intramedullary nailing

Introduction

The fracture of the shaft of humerus is one of the common long bone fractures which accounts for 1%–3%[1] of all fractures and 20% of the fracture of humerus.[1,2]

Operative management of humeral shaft fracture is gaining popularity now due to the advantages associated with it such as early joint mobilisation, early return to activities of daily living (ADL) and early resumption to work.

Interest is growing on the use of interlocking intramedullary nailing which obviates the attendant complications of plate and screws at a significant rate.[3-5] In addition, it offers the advantages of utilising load sharing implants, having reduced risk of infection and fatigue failure.[4,6,7] Interlocking intramedullary nailing of the humeral shaft fractures, however, has its related complications such as difficulty in locking the nail distally due to the characteristic anatomy of the distal humerus and associated injury to the radial nerve and the lateral

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cutaneous nerve of the forearm amongst others.[8-10] In a bid to avoid these complications, modifications have currently been made to the standard interlocking nails such that the distal locking screws are replaced with mechanisms that will provide internal anchorage for the distal part of the nail within the endosteal surface of the humeral cortex. Such specialised nails are generally termed 'bio-nails' and they include seidel intramedullary nail, fixion nail, Marchetti-Vicenzi nail, Garnavos nail and halder nail.[11-16] Surgical implant generation network (SIGN®) has produced another form of bio-nail named SIGN intramedullary fin nail (SIFN).[17] This nail has been shown to provide a comparable outcome to the SIGN Standard locked Intramedullary Nail (SSLIN) in the fixation of distal diaphyseal femoral fractures without image intensifier.[18] Its use, however, has not been popularly known for humeral shaft fracture fixation. This study is, therefore, aimed at comparing the surgical outcomes between the groups of patients treated with SIFN and SSLIN, respectively, with the following objectives: comparing the rate of fracture healing, functional outcome, and complication rate between SSLIN and SIFN in the management of humeral shaft fractures.

Materials and Methods

This was a retrospective comparative study comprising patients who were treated with either SSLIN or SIFN for humeral shaft fractures over a period of 5½ years between July 2014 and December 2019 in a missionary Tertiary Hospital in Nigeria. Humeral shaft implies the part of the humerus that is 2 cm below the surgical neck and 3 cm above the olecranon fossa.[19] Inclusion criteria were fractures located within the above-stated boundaries, while exclusion criteria were fractures outside the boundaries. Patients were optimised for surgery and informed consent taken. Ethical clearance was also obtained from the ethical committee of the hospital.

The fractures were categorised as fresh fractures if they were ≤3 weeks old and old fractures if they were >3 weeks old. Antibiotics were given for 5 days and extended in cases of open fractures and/or other associated injuries. The fresh fractures were reduced close, while the old fractures were reduced either by mini open or open reduction except in one case of an old (4 weeks) fracture which was reduced close. By mini open reduction, we mean that the finger was introduced through about 3 cm incision via an anterior approach, to spilt the muscle and got to the fracture site. While traction was sustained, the introduced finger was used to manipulate the fracture site to achieve reduction. After reduction, the fractures were fixed with either SSLIN or SIFN and the interlocking screws directed from lateral to medial with the aid of an external jig system. Both nails are made by SIGN fracture care international, an American-based organisation and they are provided free of charge to our patients on regular basis. SSLIN and SIFN are stainless steel, straight, solid nails having 9º bend at the proximal part of the nails. The SSLIN has two distal slots and one proximal slot with which it achieves dynamic locking and one proximal round hole with which it achieves static locking, whereas in the SIFN, the two distal slots are replaced by a fin which comprises circumferential projections that interlocks within the medullary canal when inserted. The fractures were all reduced and fixed without an image intensifier. The patients treated with SSLIN were considered as SSLIN group, while those treated with SIFN were considered as SIFN group. The surgeries were done by two surgeons.

The patients were followed up clinically and radiographically according to SIGN follow-up protocol at 6 weeks, 3 months, 6 months and beyond if there was no evidence of fracture healing and restoration of functional activities. Clinical healing was determined by full restoration of painless ADL and radiographic evidence of healing was the appearance of callus formation. The data obtained from the patients include their bio data, comparative distribution of the fractures according to Arbeitsgemeinschaftfur Osteosynthesefragen (AO) classification, reduction methods utilised, the diameter of nail used, comparative rate of fracture healing, comparative time to shoulder abduction, painless shoulder flexion-abduction-external rotation (FABER) movement, resumption of the full ADL and comparative rate of complications. The data used in the study were retrieved from prospectively collected SIGN database and were analysed using the IBM SPSS Statistics for Windows version 16, Armonk, NY, USA: IBM Corp. Comparisons were made between the SSLIN AND SIFN groups using Student's *t*-test for the continuous variables and Chi-square for the categorical variables. $P = 0.05$ was considered statistically significant.

Results

Forty-three consecutive patients with humeral shaft fracture were included in this study. Thirty-one of them constituted the SSLIN group, of which 22 (71%) were male and 9 (29%) were female, whereas 12 of them constituted the SIFN group, of which 5 (41.7%) were male and 7 (58.3%) were female. The mean age of the SSLIN group was 47.3 years ± 14.3 years, while that of the SIFN group was 42.1 years ± 13 years. Fifteen (48.4%) of the cases in the SSLIN group were fresh fractures and 16 (51.6%) were old fractures, while in the SIFN group, 11 (91.7%) were

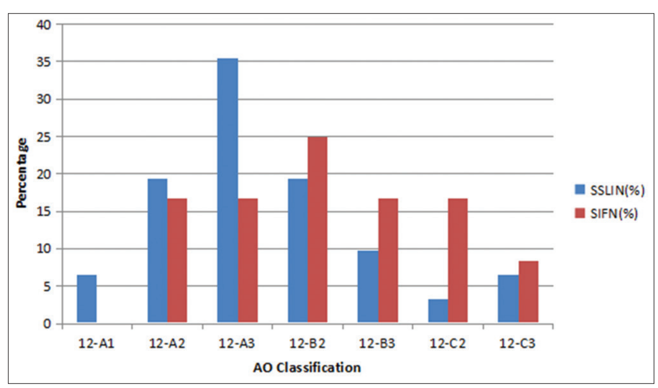

Figure 1: Comparative distribution of the fractures according to Arbeitsgemeinschaftfur Osteosynthesefragen classification in SSLIN and SIFN groups. $P = 0.60$

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fresh fractures and 1 (8.3%) was an old fracture. The two cases of open fractures (GA IIIA) were in the SSLIN Group.

The comparative distribution of the fractures according to AO classification in both groups is shown in Figure 1. There was no significant difference in the distribution ($P = 0.60$).

All the patients in the SSLIN group had antegrade approach for the insertion of the nails, while 11 (91.7%) of those in the SIFN group had the antegrade approach. One (8.3%) of the SIFN group had retrograde approach. Other intraoperative parameters are shown in Table 1.

Comparative time to radiographic evidence of fracture healing in the two groups is shown in Table 2.

Table 1: Intra-operative parameters of surgical implant generation network standard locked intramedullary nail and surgical implant generation network intramedullary fin nail groups

Intra-operative parameters	Groups	Frequency (%)
Fracture reduction		
Open	SSLIN	20 (64.5)
	SIFN	2 (16.7)
Mini open	SSLIN	1 (3.2)
	SIFN	3 (25.0)
Close	SSLIN	10 (32.3)
	SIFN	7 (58.3)
Nail diameter (mm)		
7	SSLIN	0 (0.0)
	SIFN	2 (16.7)
8	SSLIN	23 (74.2)
	SIFN	8 (66.7)
9	SSLIN	8 (25.8)
	SIFN	2 (16.7)

SIGN: Surgical implant generation network, SIFN: SIGN intramedullary fin nail, SSLIN: SIGN standard locked intramedullary nail

There was also no significant relationship between the time to observed radiographic evidence of fracture healing and whether the fracture was fresh or old in the SSLIN and SIFN groups, respectively ($P = 0.19$ and 0.42).

Findings on the comparative assessment of functional outcomes in the two groups are summarised in Table 3.

With regard to complication rate, one (3.2%) patient in the SSLIN group had a deep infection, one (3.2%) had a screw penetrating into the shoulder joint, and there were two (6.5%) cases of nail prominence at its entry point. None of these complications was reported in the SIFN group.

Discussion

There has been a significant improvement in the surgical treatment of humeral shaft fracture through the development of new generation of intramedullary nails. Good outcomes have repeatedly been reported with the use of the standard conventional interlocking nails;[3,20-24] however, variable outcomes have been reported concerning the use of the 'bio nails'.[13-16,25-27]

In this study, middle-aged male patients predominate in the SSLIN group, while in the SIFN groups, young women were mostly affected. This is contrary to common literature reports, whereby humeral shaft fracture has two-peak distribution amongst the young male and older female.[28,29] About half of the cases in the SSLIN group were fresh fractures, while fresh fractures constitute a greater percentage in the SIFN group. This appears to be in favour of the SIFN group. On the other hand, considering the distribution of the fractures based on AO classification [Figure 1], the SIFN group had more unstable fractures than the SSLIN group.

Open reduction was used for most (64.5%) of the fractures in the SSLIN group, while fractures in the SIFN group were majorly achieved either by mini-open reduction (25%) or by

Table 2: Time to observed radiographic evidence of fracture healing in both SIGN standard locked intramedullary nail and SIGN intramedullary fin nail groups

	Groups	At 6 week, *n* (%)	At 3 months, *n* (%)	At 6 months, *n* (%)	*P*
Radiographic evidence of healing	SSLIN	20 (64.5)	10 (32.3)	1 (3.2)	0.80
	SIFN	7 (58.3)	5 (41.7)	0	

SIGN: Surgical implant generation network, SIFN: SIGN intramedullary fin nail, SSLIN: SIGN standard locked intramedullary nail

Table 3: Periodic comparative assessment of functional outcomes in surgical implant generation network standard locked intramedullary nail and surgical implant generation network intramedullary fin nail groups

Variables	Groups	At 1.5 months, *n* (%)	At 3 months, *n* (%)	At 6 months, *n* (%)	After 6 months, *n* (%)	*P*
Shoulder abduction >90°	SSLIN	13 (41.9)	11 (35.5)	6 (19.4)	1 (3.2)	0.76
	SIFN	5 (41.7)	6 (50.0)	1 (8.3)	0	
Painless shoulder FABER movement	SSLIN	10 (32.3)	15 (48.4)	5 (16.1)	1 (3.2)	0.63
	SIFN	3 (25.0)	9 (75.0)	0	0	
Full ADL	SSLIN	12 (38.7)	18 (58.1)	1 (3.2)	0	0.38
	SIFN	3 (25.0)	9 (75.0)	0	0	

FABER: Flexion, abduction, external rotation, ADL: Activities of daily living, SIGN: Surgical implant generation network, SIFN: SIGN intramedullary fin nail, SSLIN: SIGN standard locked intramedullary nail

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close reduction (58.3%) [Table 1]. Mini open or close reduction was majorly performed in the SIFN group due to the fact that most of the cases were fresh fractures. Intramedullary nail size 8 was mostly used for the patients in both groups [Table 1].

Fracture union in this study was based on the combination of clinical, mechanical, and radiographic evidences of fracture healing. Clinically and mechanically, the fracture union was determined by restoration of painless ADL and radiologically, by the presence of callus. Fracture union in this study was not absolutely based on the appearance of three-cortices bridging callus. Studies have shown that disagreement and variability exist amongst clinicians and researchers with regard to clinical and radiographic definitions of fracture healing.[30,31] Certain studies on the reliability of plain radiography in assessing fracture healing concluded that radiographs do not define union with enough accuracy and are generally inconclusive in determining the stage of union.[32-34] In a systematic review done in 2008, out of 59 studies that used clinical criteria in defining union, absence of pain or tenderness at the fracture site on weight-bearing, absence of tenderness at the site of fracture, and the ability to weight bear were the most commonly used criteria to define fracture healing.[31] Patient-centred approaches assessing quality of life and function are gaining popularity in the assessment of fracture union.[31,35] These are the points on which SIGN protocol on the assessment of fracture healing is now based.

In terms of time to radiographic evidence of healing, there was no statistically significant difference between the two groups. At 6 weeks, radiographic evidence of fracture healing was seen in 64.5% and 58.3% of the patients in the SSLIN and SIFN groups, respectively, and by the 3rd month, 96.8% and 100% of the patients, respectively, had achieved radiographic evidence of fracture healing [Table 2]. Similarly, good results have also been reported with the use of other humeral bio-nails such as fixion nail and Halder nail with union rates of 100% at 4 months[14] and 95% at 6 weeks,[16] respectively. Ruffilli *et al*. reported union rate of 93.7% with Marchetti-Vicenzi nail.[36]

Moreover, there was no significant difference in the findings from the comparative assessment of functional outcomes in both groups. At 6 months, 96.8% and 100% of the patients in the SSLIN and SIFN groups, respectively, could achieve shoulder abduction beyond 90º, painless shoulder FABER movement, and full ADL, although all the patients in the SIFN group had actually achieved full resumption of ADL by the 3rd month. Figures 2a-d below showed serial photographs a patient who was treated with SSLIN while Figures 3a-d presents that of one of the patients in the SIFN group.

From the above, although the differences in the findings were not statistically significant, it was observed that the SIFN presented radiographic evidence of fracture healing and resumption of functional activities earlier than SSLIN group. A potential confounding factors which may explain this is the fact that most of the fractures fixed in the SIFN group were fresh fracture. However, it was statistically shown that there was no relationship between the rate of fracture healing and whether the fracture was fresh or old in the two groups ($P = 0.19$ and 0.42). It is also worthy of note that these relatively better outcomes were observed in the SIFN group in spite of having more unstable fractures in the group as shown in Figure 1.

With respect to the complication rate, the SSLIN group had a complication rate of 12.9%, while no complication was reported for the SIFN group. The reason for this may be explained from the relative small size of the SIFN group.

This study is limited by small sample size, especially on the part of the SIFN group.

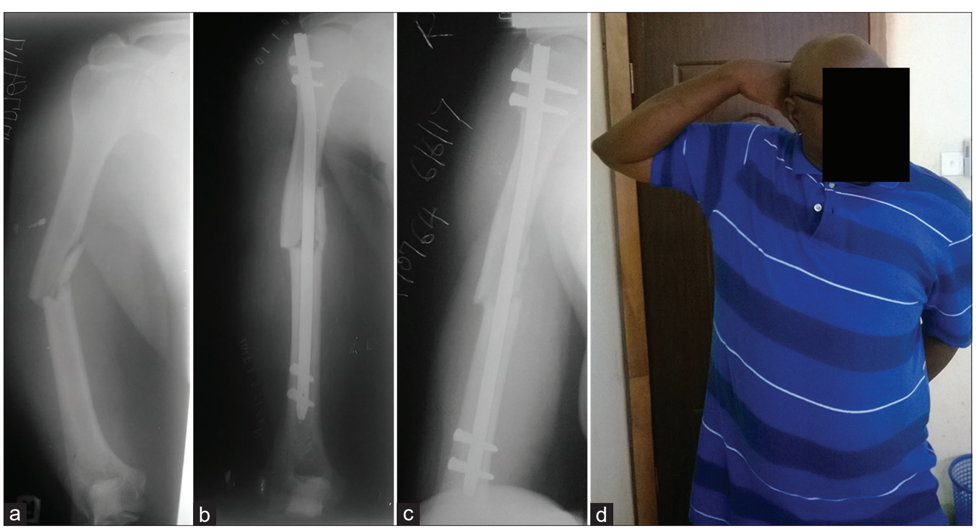

Figure 2: (a) Pre-operative radiograph showing Arbeitsgemeinschaftfur Osteosynthesefragen 12-B1 fracture. (b) Immediate post-operative radiograph showing standard surgical implant generation network intramedullary nail. (c) Three-months post-operative radiograph. (d) Photograph showing the index patient performing shoulder Flexion, abduction, external rotation exercise at 3 months

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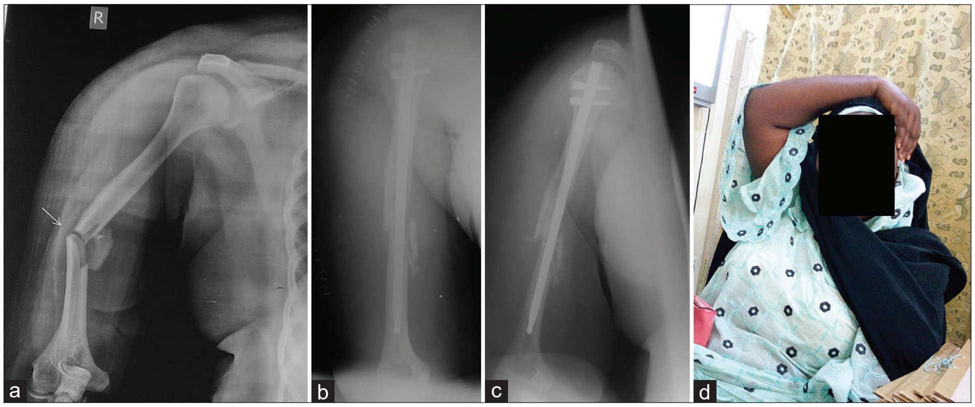

Figure 3: (a) Pre-operative radiograph showing Arbeitsgemeinschaftfur Osteosynthesefragen 12-B1 fracture. (b) Immediate post-operative radiograph showing Surgical implant generation network intramedullary fin nail. (c) One-month post-operative radiograph. (d) Photograph showing the index patient performing shoulder Flexion, abduction, external rotation exercise at 6 months

Conclusion

SIGN intramedullary fin nailing compared favourably with the SSLIN in terms of rate of fracture healing and resumption of functional activities. Moreover, there is reduced risk of injury to the radial nerve and lateral cutaneous nerve to the forearm and avoidance of challenges associated with humeral distal locking due to the characteristic flat shape of the humerus. It is, therefore, encouraged to use SIFN in the surgical treatment of humeral shaft fractures. We also recommend further similar study using a larger sample size.

Financial support and sponsorship

Nil.

Conflicts of interest

Surgical implant generation Network (SIGN) at 451 Hills Street, Suite B, Richland, WA 99354 USA provided the instrumentations and implants free of charge for all the patients. The provision was not specifically for this study, but it is in line with their efforts to generally help patients in the developing countries have their fractures treated by internal fixation if indicated without paying for the implants.

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