

# Satisfactory postoperative alignment following retrograde SIGN Fin nailing for femoral shaft fractures

## A case-control study

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### Abstract

**Purpose:** In developing countries, long bone fractures following trauma are a significant contributor to morbidity, and operating room resources are often limited in these settings. The Surgical Implant Generation Network (SIGN) Fin nail may reduce the challenges of retrograde intramedullary nailing of femoral fractures without fluoroscopy. In contrast to the traditional SIGN nail placed in a retrograde fashion, the Fin nail does not require proximal interlocking screws. Instead, the nail achieves stability through an interference fit within the proximal femoral canal. The purpose of this study is to compare postoperative alignment in femoral shaft fractures treated with either a retrograde SIGN Fin nail or a standard retrograde SIGN nail.

**Method:** Using the SIGN online surgical database, we identified all femoral shaft fractures treated with a retrograde SIGN Fin nail at 2 African hospitals. Two examiners independently classified fracture patterns using the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification system. Using an on-screen protractor tool, postoperative coronal and sagittal plane alignment were measured and recorded as deviation from anatomic alignment (DFAA), with units in degrees. Available patient demographics and surgical details were also recorded. Fin nail cases were matched in a 1:1 ratio to retrograde standard SIGN nail cases based on AO/OTA fracture type.

**Results:** Twenty-eight retrograde Fin nail cases were identified, and 28 matched retrograde SIGN nail cases were selected. The Fin nail and retrograde SIGN nail groups were well matched in terms of demographics, AO/OTA fracture type, and surgical characteristics. There was no significant difference in postoperative coronal or sagittal plane alignment between the groups. There were no cases in either group of average postoperative malalignment >5° in any plane.

**Conclusion:** The SIGN Fin nail appears to achieve satisfactory radiographic alignment without the need for proximal interlocking screws, making it an attractive implant for retrograde femoral shaft fracture fixation in resource-limited settings. Further research is required to validate these findings and determine long-term Fin nail clinical outcomes.

**Keywords:** femur fractures, international, intramedullary nailing, long bone fractures, orthopaedics, postoperative alignment, radiographic alignment, trauma

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## 1. Introduction

Worldwide, nearly 5 million people die from injuries each year.<sup>[1]</sup> Approximately 1.4 million of these deaths are directly related to road traffic accidents, a substantial portion of which occur in developing countries.<sup>[2,3]</sup> In addition to the mortality attributed to injuries, survivors are subject to profound morbidity. For each mortality related to injury of any kind, an estimated 3 to 8 individuals are left permanently disabled from their injuries.<sup>[2]</sup> On an annual basis, 20 to 50 million people globally are injured in road traffic accidents alone.<sup>[4,5]</sup> The incidence of long bone fractures is relatively high in this population, and these injuries are significant contributors to years of life lost due to disability.<sup>[6]</sup>

In resource-limited settings, patients with long bone fractures often experience significant delays in obtaining care following an injury.<sup>[7]</sup> There are many barriers to securing care, including inability to pay, lack of transportation to regional hospitals, and paucity of trained personnel. Importantly, the lack of sufficient operating room resources and implants remains a major obstacle to surgical care in these settings. Due to these factors, operative

management is often delayed, and in certain circumstances, fractures are managed nonoperatively.<sup>[8,9]</sup>

The SIGN intramedullary nailing system was designed to be used in resource-limited settings at low cost and without the need for fluoroscopy, a fracture table, or power reaming.<sup>[10]</sup> The SIGN nail was designed to minimize valuable operating room resources and overcome some of the barriers to surgical care. Since its introduction in 1999, the SIGN system has subsequently been adopted by more than 50 countries worldwide and has been utilized in the treatment of over 200,000 long bone fractures.<sup>[11]</sup> A growing body of literature has shown favorable outcomes after treatment of femoral fractures using this system.<sup>[12–15]</sup> When compared with nonoperative treatment, the SIGN nail has also been shown to dramatically reduce costs and resource utilization.<sup>[16,17]</sup>

The SIGN Fin nail was designed to further reduce the challenges of intramedullary nailing of femoral fractures. In contrast to the standard retrograde SIGN nail, the Fin nail does not require proximal interlocking screws when placed in a retrograde fashion. Instead, the nail achieves stability through an interference fit within the proximal femoral canal.<sup>[18]</sup> This feature eliminates the need for a targeting arm to place proximal interlocking screws. To our knowledge, however, no prior studies have examined the performance of the SIGN Fin nail in the retrograde treatment of femoral shaft fractures in adults. The purpose of this study is to compare postoperative alignment in femoral shaft fractures treated with either a retrograde SIGN Fin nail or a standard retrograde SIGN nail.

## 2. Methods

### 2.1. Study design, subject selection, and demographic data extraction

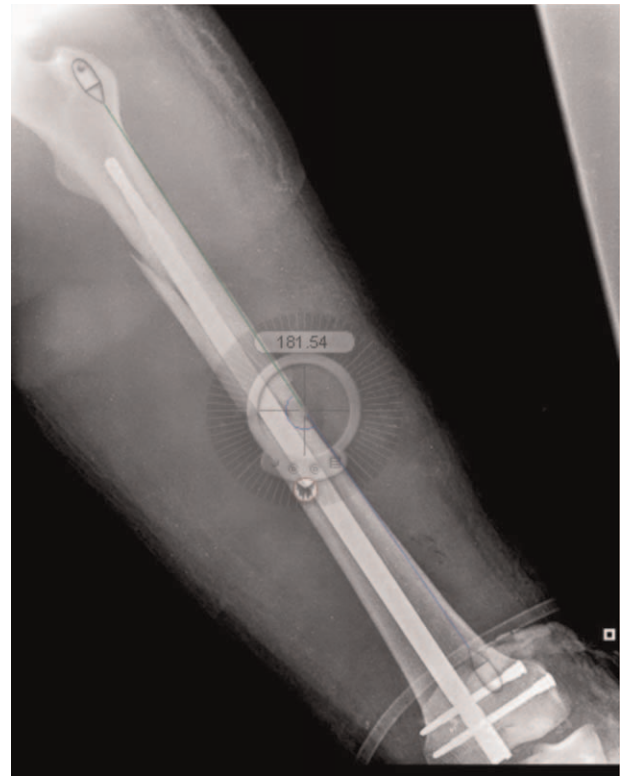
The SIGN online surgical database (SOSD) for 2 Kenyan hospitals was utilized for retrospective chart review. Established in 2003, this database is prospectively populated with anonymized clinical information about patients treated with SIGN devices. In each entry, patient demographics, implant characteristics, surgical details, and perioperative radiographs are typically available. A search query was utilized to find all acute, traumatic femur fractures treated surgically with retrograde intramedullary nailing at the 2 hospitals over a 10-month period from September 1, 2016, to July 1, 2017.

All surgical cases utilizing a retrograde Fin nail were identified by entering an additional variable in the search query. This process was then repeated to identify all cases in which a retrograde standard SIGN nail was used. A random sequence generator was then used to select potential controls from the list of standard SIGN nail cases. Controls were then evaluated and matched to Fin nail cases primarily based on AO/OTA fracture classification. Secondary factors influencing matching of cases to controls included: reduction method, time delay to surgery, open vs closed fracture, age, and sex.

Basic information including patient age, gender, injury mechanism, and laterality were recorded. Surgical details were collected including type of implant, open vs closed fracture, delay from injury to surgical fixation, reduction technique (closed vs open), and operative time.

### 2.2. Fracture classification and measurement

Two separate examiners independently classified the fracture types based on the AO/OTA classification system for femur fractures utilizing labels of 32A-C. In the case of a discrepancy,



**Figure 1.** Representative image of radiographic measurements using protractor tool.

the senior author (PW), a fellowship-trained orthopaedic trauma surgeon, reviewed fracture patterns to determine the final classification.

Alignment of the immediate postoperative x-rays was measured independently by 2 examiners utilizing an on-screen protractor tool (Screen Protractor; Iconico Inc, New York, New York). This tool allows for overlay of the protractor arms on radiographs viewed on the SOSD. With the origin of the protractor placed at the fracture site, measurements were taken on both the anteroposterior (AP) and lateral views of postoperative x-rays to determine coronal and sagittal alignment, respectively (Fig. 1).

Postoperative alignment was quantified by measuring the deviation from the normal anatomical axis of the femur. These numbers were recorded as the DFAA with units in degrees. All cases and controls had at least one x-ray (AP or lateral) sufficient for analysis. If there was a deficiency in one of the orthogonal views on postoperative films, this measurement was excluded from average DFAA calculations and the maximum deviation was registered as the DFAA measured on the only available x-ray.

### 2.3. Statistical analysis

Patient demographics and surgical characteristics were summarized by N (%), mean (SD), or median (interquartile range) for both groups. Chi-square, T, or Wilcoxon rank sum tests were used to compare the patient and surgical characteristics of both groups. The average DFAA on the AP and lateral images were compared between the 2 groups using a repeated measures ANOVA univariately and after controlling for nail length. The

maximum deviation in any plane was similarly analyzed using repeated measures ANOVA.

### 3. Results

28 consecutive Fin nail cases were identified during the study period. All had adequate postoperative radiographs in at least one plane. These cases were successfully matched to control cases of retrograde femoral shaft fixation with the standard SIGN nail. Eighteen of the Fin nail cases were performed at one of the Kenyan hospitals (site A), and the remaining 10 were performed at the other hospital (site B). Twenty-two matched controls were from site A, and 6 were from site B. There were no differences between the 2 groups with respect to patient demographics, surgical details, or fracture classification (Tables 1 and 2).

Road traffic accidents accounted for 85% of the injuries in the Fin nail group and 93% in the standard SIGN nail group. The fracture patterns were predominantly A-type and length stable fracture patterns, with only 25% in each group categorized as B- or C-type fractures. The average operating room time was 90 minutes in both groups, with an average of 30 minutes dedicated to fracture reduction. The average delay from injury to the time of surgery was 6 days for both groups. Open fractures accounted for 14% of patients (4/28) in each group. The only significant difference between the 2 groups was the length of the intramedullary device; the average Fin nail length was 320.7 mm, which was significantly shorter than the average SIGN nail length of 388.6 mm ( $P < .001$ , see Table 1). Median Fin nail length was 330 mm, while the mode length was 280 mm. In the SIGN nail group, both the median and mode length were 400 mm.

There were no significant differences between groups in average DFAA in either the coronal or sagittal planes (Table 3). Average DFAA for measurements on the AP radiograph (coronal plane) was 1.6° (95% CI: 1.1, 2.0) in the Fin group and 1.0° (95% CI: 0.6, 1.4;  $P = .066$ ) in the standard SIGN nail group. Average DFAA on the lateral view (sagittal plane) was 1.4° (95% CI: 0.9, 1.8) for the Fin nail group and 1.0° (95% CI: 0.6, 1.4;  $P = .197$ ) for the standard SIGN nail group. No cases in either group had average DFAA greater than 5° in any plane. As shown in Table 3,

**Table 1**  
Study group demographics.

Recorded demographic	Fin nail (n=28)	SIGN nail (n=28)	P-value
Gender—female	7 (25.0%)	4 (14.3%)	.503
Age, years	33.8 (12.3)	30.3 (9.2)	.238
Mechanism			.504
Fall	3 (11.1%)	2 (7.1%)	
Other	1 (3.7%)	0 (0.0%)	
Road traffic accident	23 (85.2%)	26 (92.9%)	
Laterality—left	15 (53.6%)	13 (46.4%)	.79
Length stable pattern—yes	23 (82.1%)	25 (89.3%)	.705
Open fracture—yes	4 (14.3%)	4 (14.3%)	1
Time until surgery, days	6.0 (4.8–8.2)	6.0 (3.8–8.0)	.399
OR time, minutes	90.0 (60.0–115.0)	90.0 (62.2–105.0)	.931
Reduction time, minutes	30.0 (20.0–43.8)	30.0 (25.0–45.0)	.679
Reduction method			
Closed	13	14	
Open	10	14	
Unknown	5	0	
Nail diameter, mm	10.1 (1.0)	10.5 (0.9)	.227
Nail length, mm	320.7 (33.3)	388.6 (24.0)	<b>&lt;0.001</b>

Values reported: n (%), mean (SD), or median (interquartile range). Statistically significant  $P$ -values (<0.05) are indicated in bold.

**Table 2**  
AO/OTA fracture classification between groups.

AO/OTA Fracture type	Nail type	
	Fin (n=28)	SIGN (n=28)
A1	1	1
A2	5	6
A3	15	14
B1	1	1
B2	2	2
B3	3	3
C1	1	1
C2	0	0
C3	0	0

there were also no significant differences between groups in maximum coronal or sagittal plane DFAA. After controlling for nail length, there were still no significant differences in average DFAA in either plane.

### 4. Discussion

Long bone fractures caused by road traffic accidents account for a large portion of the disease burden in developing countries.<sup>[6,19]</sup> The trends seen in our limited data set confirm that road traffic accidents account for the majority of long bone fractures presenting to 2 trauma care centers in Kenya. Overall, 90% of those patients selected for analysis in our study were injured as a result of a traffic-related injury.

The SIGN nail was designed to treat long bone fractures in resource-limited settings where the lack of operative resources represents a significant barrier to appropriate care.<sup>[11]</sup> Multiple studies have subsequently shown that the SIGN nail is an effective treatment choice in these circumstances.<sup>[12,14,15,20–22]</sup> Carsen et al<sup>[23]</sup> recently analyzed the postoperative radiographs of 500 cases in which the standard SIGN nail was used to treat fractures of the femoral shaft. The authors found that 10% of cases demonstrated fracture malalignment greater than 5°. These results are in keeping with a large North American study which reported a 9% incidence of angular malalignment greater than 5°.<sup>[24]</sup> The cohort of Fin nails in the current study adds to the established literature documenting satisfactory radiographic alignment following femoral shaft fixation with the standard SIGN nail. Of the 28 consecutive Fin nail cases studied, none resulted in postoperative malalignment >5°. Our study did not examine long-term outcomes following Fin or standard SIGN nail placement; however, other studies have demonstrated excellent long-term clinical outcomes achieved with this nailing system.<sup>[21,25]</sup>

**Table 3**  
Postoperative fracture alignment measurements.

DFAA angle	Fin nail	SIGN nail	P-value
AP	1.6 (1.1, 2.0), n=27	1.0 (0.6, 1.4), n=28	.066
Lateral	1.4 (0.9, 1.8), n=22	1.0 (0.6, 1.4), n=24	.197
Maximum	1.9 (1.5, 2.4), n=28	1.5 (1.0, 1.9), n=28	.153
AP*	1.3 (0.7, 1.9), n=27	1.3 (0.7, 1.8), n=28	.953
Lateral*	1.2 (0.7, 1.8), n=22	1.1 (0.6, 1.6), n=24	.772
Maximum*	1.7 (1.1, 2.2), n=27	1.8 (1.2, 2.3), n=28	.827

Values reported as mean (95% CI) from RM-ANOVA.

\* After controlling for nail length.

The Fin nail was introduced to further simplify intramedullary nailing of long bone fractures in resource-limited settings. Shahabuddin et al<sup>[26]</sup> demonstrated excellent clinical outcomes in a case series of pediatric diaphyseal femur fractures treated in antegrade fashion using specialized pediatric Fin nails. In their study, pediatric Fin nails demonstrated equivalent clinical outcomes with no differences in complication rates when compared with standard pediatric SIGN nails. The authors' analysis did not include postoperative radiographic assessment of fracture alignment. To date, there have been no studies comparing adult Fin nails to standard SIGN nails with regard to immediate postoperative alignment.

Our case-control study showed no statistical differences in postoperative coronal or sagittal plane alignment between the 2 groups. Additionally, there were no cases of average maximum postoperative malalignment greater than 5° in either group. These favorable results suggest that the Fin nail is capable of achieving satisfactory fracture alignment when used in a retrograde fashion for fixation of femoral shaft fractures in adults. As the Fin nail design eliminates the requirement for proximal interlocking screw placement, we hypothesized that the surgical time required to place the Fin nail would be less than the time required for placement of the standard retrograde SIGN nail with at least one proximal interlocking screw. However, the average recorded surgical time was equivalent in both groups (Fin nail: 90.0 minutes (95% CI: 60.0–115.0); SIGN nail: 90.0 minutes (95% CI: 62.2–105.0),  $P=.931$ ). Since the methods of recording operative time may vary between surgeons and institutions, a true comparison of the average operative times required for placement of the Fin nail and the retrograde SIGN nail would best be accomplished with a prospective comparative study.

The SOSD is a robust registry that serves as a model for trauma system data tracking globally. In their large review of the SOSD, Carsen et al<sup>[23]</sup> found that >90% of patients treated for femur fractures with the standard SIGN nail had orthogonal imaging adequate for evaluation of post-operative alignment.<sup>[23]</sup> Our study found the registry to be similarly adequate but somewhat less comprehensive, with only 80% of the 56 selected cases containing orthogonal views for analysis. Given the relatively small number of Fin nail cases available for analysis, however, we included all cases with at least one adequate postoperative radiographic view available. Average DFAA calculations were then performed independently for both the AP and lateral views.

There are several limitations to our study. First, our study does not assess long-term clinical or functional outcomes after fixation of femoral shaft fractures with the Fin nail or standard SIGN nail. However, the primary purpose of the current study was to assess the immediate postoperative alignment achieved with the Fin nail and to compare this with the alignment achieved with the standard retrograde SIGN nail. To that end, the SOSD provided adequate data to address that primary study aim. The retrospective nature of our study design carries with it some inherent limitations, but these are mitigated to some degree by the fact that the data in the SOSD was initially gathered in a prospective manner. Furthermore, analysis of radiographic alignment was performed specifically for our study and therefore was not subject to recall bias. Our inclusion of several cases without complete orthogonal imaging was another potential limitation of this study. However, similar numbers of Fin nail cases and matched retrograde SIGN nail cases had only a single adequate postoperative radiograph. Cases and controls from 2 hospitals were aggregated and not matched based on location of

surgery. This could theoretically represent a source of selection bias, but the patient populations, operating room resources, and techniques used at these 2 hospitals are quite similar.

Long bone fractures following road traffic accidents contribute significantly to the overall disease burden from musculoskeletal trauma in the developing world. The SIGN nail was developed to facilitate intramedullary nailing of long bone fractures in resource-limited settings, and the SIGN system has been widely implemented with remarkable success. The SIGN Fin nail further simplifies long bone fracture treatment by eliminating the requirement for interlocking screws and is a valuable addition to the SIGN armamentarium. To our knowledge, the current study is the first to investigate the postoperative alignment achieved when using the SIGN Fin nail to treat adult femoral shaft fractures. Our results suggest that, compared with a retrograde standard SIGN nail, the Fin nail is equally effective in achieving satisfactory postoperative alignment of femoral shaft fractures treated in a resource-limited setting. Future, larger scale studies are required to corroborate these findings and to investigate the clinical performance characteristics of the SIGN Fin nail.

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