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Clinical and radiographic outcomes following retrograde SIGN fin nailing for femoral shaft fractures

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Abstract

Purpose: The Surgical Implant Generation Network (SIGN) intramedullary nail was designed for use in resource limited settings which often lack fluoroscopy, specialized fracture tables, and power reaming. A newer design iteration, the SIGN Fin nail, was developed to further simplify retrograde femoral nailing by making proximal interlocking screw placement unnecessary. Instead, the leading end of the Fin nail achieves stability through an interference fit within the proximal femoral canal. While the performance of the traditional SIGN nail has been reported previously, no large series has examined long-term clinical and radiographic outcomes of femoral shaft fractures treated with the SIGN Fin nail.

Methods: The SIGN online surgical database was used to identify all adult femoral shaft fractures treated with the SIGN Fin nail since its introduction. All patients with minimum 6 month clinical and radiographic follow-up were included in the analysis. Available demographic, injury, and surgical characteristics were recorded. Fracture alignment was evaluated on final follow-up radiographs using a previously validated on-screen protractor tool. Coronal and sagittal plane alignment measurements were recorded as deviation from anatomic alignment (DFAA), with units in degrees. Fracture healing was assessed on final follow-up radiographs, with union defined as any bridging callus and/or cortical remodeling across one cortex on orthogonal views. Clinical outcomes available in the database included knee range of motion (ROM) greater than 90° and weight-bearing status at final follow-up. Clinical and radiographic outcomes were then compared between patients with united and nonunited fractures.

Results: The database query identified 249 femoral shaft fractures stabilized with the Fin nail in 242 patients who had minimum 6 month clinical and radiographic follow-up. Final follow-up radiographs were performed at an average of 48 weeks postoperatively. Average coronal and sagittal plane alignment measured on final follow-up radiographs were 2.18° and 2.58°, respectively. The rate of malalignment (DFAA > 10° in either plane) at final follow-up was 6%. Two hundred twenty-nine fractures (92%) were united at final follow-up. Overall, 209 (84%) of patients achieved full weight bearing and 214 (86%) achieved knee ROM >90° at final follow-up. Compared to patients with united fractures, those with nonunion were less likely to achieve full weight bearing (20% vs 90%, $P < .001$) and knee ROM >90° (30% vs 91%, $P < .001$). There was no significant difference in mean DFAA between united and nonunited fractures in the coronal (2.1° vs 3.8°, $P = .298$) or sagittal (2.5° vs 3.5°, $P = .528$) planes.

Conclusion: The SIGN Fin nail achieves satisfactory radiographic alignment and clinical outcomes at minimum 6 month follow-up. The overall union rate is comparable to that achieved with the standard SIGN nail. Ease of implantation makes the Fin nail an attractive option in resource-limited settings.

Keywords: clinical outcomes, 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 traumatic injuries each year.[1] 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.[2] The incidence of long bone fractures is relatively high in this population, and these injuries are significant contributors to disability-adjusted life years lost.[3]

In resource-limited settings, patients with long bone fractures often experience significant delays in obtaining care following an injury.[4] There are many barriers to securing care, including inability to pay, lack of transportation to regional hospitals, and scarcity 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.[5,6]

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.[7] Since its introduction in 1999, the SIGN system has subsequently been adopted by more than 350 hospitals in over 50 countries worldwide. To date, the SIGN nail has been utilized in the treatment of over 250,000 long bone fractures.[8] A growing body of literature has shown favorable outcomes after treatment of femoral fractures using this system.[9–12] When compared with nonoperative treatment, the SIGN nail has also been shown to dramatically reduce costs and resource utilization.[13,14]

The SIGN Fin nail, introduced in 2003, was designed to further simplify retrograde intramedullary nailing of femoral shaft fractures. In contrast to the standard SIGN nail, the Fin nail does not require proximal interlocking screws when placed in a retrograde fashion. Instead, the theory of the nail design is that the fins achieve interference fit in the endosteum of the proximal femoral canal.[15] As shown in Figure 1, the diameter of the leading end of the nail is 1 mm smaller than that of the driving end, and the longitudinally oriented fins protrude 1 mm radially from the leading end of the nail. The interference fit provided by the fins obviates the need to place interlocking screws through the nail proximally.

Previous studies have examined the immediate postoperative alignment achieved by the Fin nail when used in the retrograde treatment of femoral shaft fractures in adults.[16,17] To our knowledge, however, no large study has investigated the long term clinical and radiographic performance of the SIGN Fin nail when used in this fashion. The purpose of this study is to examine long term clinical and radiographic outcomes in a large series of femoral shaft fractures treated with the SIGN Fin nail (Figs. 2–4).

2. Methods

This study was determined to be exempt by the University of Wisconsin Institutional Review Board.

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

The SIGN online surgical database (SOSD) was utilized for retrospective chart review. Established in 2003, this database is prospectively populated with anonymized clinical information about patients treated with SIGN implants. In each entry, patient demographics, implant characteristics, surgical details, and radiographic images are typically available.

A search query was utilized to identify all femur fractures treated with the SIGN Fin nail using a retrograde approach. The SOSD was reviewed for each patient, and cases with less than 6 months of clinical and radiographic follow-up were eliminated.

Basic demographic information, including patient age and gender, was collected. Surgical and injury details were also collected, including the dimensions of the implant, fracture pattern, and fracture location. Finally, available clinical outcome measures including fracture union (Y/N), full weight-bearing status (Y/N), and knee ROM >90° (Y/N) obtained at the most recent follow-up visit were recorded.

2.2. Radiographic analysis

Cases that met inclusion criteria were divided between 3 separate senior-level orthopaedic resident examiners for radiographic analysis.

First, the final follow-up radiographs were examined to determine if the fracture was united. Fracture union was defined as either bridging callus or remodeling across at least 1 cortex on both orthogonal views. If this was not evident, the fracture was considered nonunited regardless of the designation given in the SIGN database.

Alignment of the fractures at the time of most recent follow-up was then measured using a validated 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 AP and lateral views of postoperative x-rays to determine coronal and sagittal alignment, respectively (Fig. 1). For nonunited fractures, similar measurements were performed on initial postoperative films for comparison purposes.

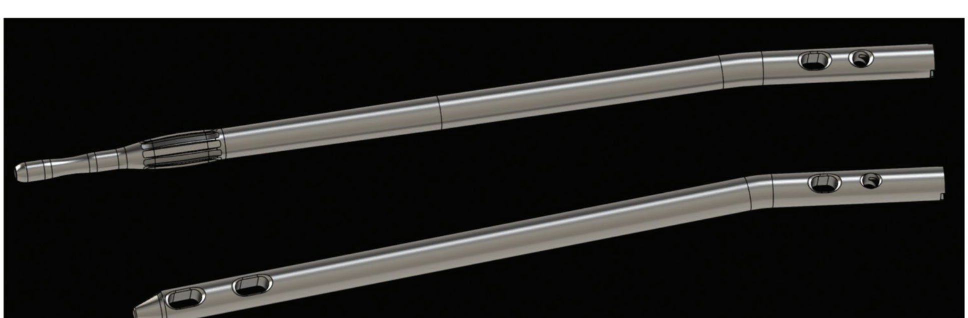

Figure 1. Depiction of the SIGN Fin nail (top) compared to standard SIGN nail (bottom). Note the longitudinally oriented "fins" near the leading end of the nail.

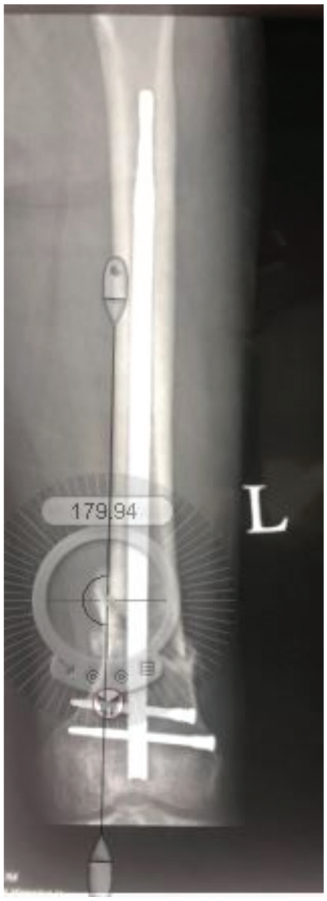

Figure 2. Representative image of radiographic measurement technique using the previously-validated on-screen protractor tool.

Figure 3. Representative lateral radiograph depicting a nonunited fracture.

Figure 4. Representative lateral radiograph of a united fracture.

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.

2.3. Statistical analysis

Patient demographics and injury/surgical characteristics were summarized by N (%) or mean (SD) for both groups. Univariate T and chi-squared tests were used to compare the available demographic and clinical characteristics as well as DFAA between united and nonunited fractures.

3. Results

3.1. Cases/demographics

The initial database search yielded 4751 cases in which the Fin nail was used in the retrograde treatment of femoral shaft fractures. After eliminating cases without adequate follow-up or incomplete datasets, 242 patients with 249 femoral shaft fractures stabilized with the Fin nail were identified. Each of these cases had clinical and radiographic follow-up greater than 6 months from the date of surgery. Seventy-two percent of the patients were male with a mean age of 29.2 ± 15.0 years. Details of the fracture location (proximal, middle, distal) and pattern (transverse, oblique, comminuted, segmental) as entered in the SIGN database is shown in Table 1. The predominant fracture location and pattern were distal and transverse, respectively.

Table 1

Study group/fracture characteristics

Recorded characteristic	Fin nail cases (n=249)
Gender, (n, %)	
Male	180 (72.2)
Female	69 (27.8)
Age, years (mean, SD, range)	29.2, 15.0, 6–96)
Nail diameter, mm (mean, SD, range)	9.45 (0.90, 7–12)
Nail length, mm (mean, SD, range)	304.3 (39.9, 160–360)
Fracture pattern, (n, %)	
Transverse	101 (40.6)
Oblique	51 (20.5)
Comminuted	95 (38.2)
Segmental	2 (<0.1)
Fracture location, (n, %)	
Proximal	27 (10.8)
Middle	72 (28.9)
Distal	150 (60.2)
Union (n, %)	229 (92.0)
WB status, full (n, %)	209 (83.9)
Knee ROM, > 90° (n, %)	214 (85.9)
Coronal alignment, DFAA (mean, SD)	2.18 (3.92)
Sagittal alignment, DFAA (mean, SD)	2.58 (3.82)
Coronal malalignment, DFAA>10 (n, %)	15.0 (6.0)
Sagittal malalignment, DFAA>10 (n, %)	15.0 (6.0)

Values reported: n (%), mean (SD).

3.2. Radiographic analysis and clinical outcomes

Final follow-up radiographs were performed at an average of 48 weeks postoperatively. As shown in Table 1, average coronal and sagittal plane alignment measured on final follow-up radiographs were 2.18° and 2.58°, respectively. The rate of malalignment (DFAA > 10° in either plane) at final follow-up was 6%. At the time of final follow-up 229 fractures (92%) were determined to be united based on previously defined criteria. Full weight bearing and knee ROM> 90° was noted in 228 cases (91.6%) and 232 cases (93.2%), respectively.

3.3. United vs nonunited fractures

Compared to patients with united fractures, those with nonunion were less likely to achieve full weight bearing (20% vs 90%, $P<.001$) and knee ROM >90° (30% vs 91%, $P<.001$), see Table 2. There was no significant difference in mean DFAA between united and nonunited fractures on the final Anteroposterior (2.1° vs 3.8°, $P=.298$) or lateral (2.5° vs 3.5°, $P=.528$) views. Initial postoperative radiographs of nonunited fractures were also measured retrospectively and reported in Table 3.

Table 2

Radiographic and clinical outcome comparison between united/nonunited groups

Radiographic/clinical outcome	United (n=229)	Nonunited (n=20)	*P* value
Final coronal alignment, DFAA (mean, SD)	2.09 (3.55)	3.78 (7.69)	.298
Final sagittal alignment, DFAA (mean, SD)	2.53 (3.59)	3.54 (6.38)	.264
Weight-bearing status, full (n, %)	205 (89.5)	4 (20)	<.001
Knee ROM, > 90° (n, %)	208 (90.8)	6 (30)	<.001

Table 3

Initial postop alignment vs final alignment among nonunited fractures

Radiographic measurement	Postoperative	Final follow-up	Final follow-up*
Coronal alignment, DFAA (mean, SD)	0.69 (0.55)	3.78 (7.69)	0.65 (0.60)
Sagittal alignment, DFAA (mean, SD)	0.81 (0.82)	3.54 (6.38)	0.98 (1.23)

* Single outlier removed from dataset.

When a single outlier was removed, there was no statistical difference in immediate postop and final follow-up alignment amongst nonunited fractures.

4. Discussion

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.[8] Multiple studies have subsequently shown that the SIGN nail is an effective treatment choice in these circumstances, with union rates above 90% in multiple series.[9,11,12,18–20]

Previously, Carsen et al[21] 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°, similar to rates seen at North American centers. [22] More recently, Liu et al[17] published a prospective study of 85 distal femur fractures treated with the standard SIGN nail or SIN Fin nail. At 1 year follow-up, the authors identified no difference in the rate of fracture malalignment between the 2 implants. Finally, Wilson et al conducted a multicenter case-control study comparing radiographic outcomes achieved using the SIGN Fin nail vs the standard SIGN nail. On immediate postoperative radiographs, the authors found no difference in overall alignment or rates of malalignment >5° between groups.[16] The current study builds upon this previous work by examining postoperative radiographic alignment at a minimum of 6 months following surgical fixation. The relatively low rate of malalignment >10° in any plane (6%) suggests that the SIGN Fin nail is able to successfully maintain satisfactory fracture alignment for a minimum of 6 months, at which time most femoral shaft fractures have healed.

In a recently published meta-analysis of 14 studies, Usoro et al[23] showed favorable clinical outcomes in 47,169 cases treated with the standard SIGN nail. The authors found that greater than 90% of cases demonstrated full weight bearing, favorable knee range of motion, and radiographic union. Liu et al[17] demonstrated similarly favorable results in their prospective series, and the authors found no difference in rates of nonunion, pain scores, leg length discrepancy, or knee range of motion when comparing the standard SIGN nail and the SIGN Fin nail in the treatment of distal femur fractures. In our large cohort of 249 fractures treated with the SIGN Fin nail, more than 90% of cases demonstrated radiographic union, the ability to bear full weight and to flex the knee > 90°, indicating favorable long-term clinical performance of the SIGN Fin nail.

There are several limitations to our study. 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 is initially gathered in a prospective manner. The clinical outcome measures of knee range of motion (>90°) and weight bearing status (full/partial) were recorded in binary rather than continuous fashion. This diminished our ability to quantitate these outcome variables and compare our results to other existing literature. The theory of the SIGN Fin nail is that the fins achieve interference fit in the endosteum of the proximal femoral canal sufficient to maintain length, alignment, and rotation during fracture healing. The amount of interference fit required or obtained by the SIGN Fin nail has not been measured or reported. However, the prospective comparative study by Liu et al[17] found no difference in limb length discrepancy, nonunion, or coronal/sagittal plane malalignment between patients treated with the SIGN Fin nail and the standard SIGN nail. Strengths of our study include the requirement of minimum 6-month clinical and radiographic follow-up. Additionally, by including a comparison between immediate postoperative alignment and alignment at final follow-up, our study suggests that satisfactory alignment can be successfully maintained with the SIGN Fin nail for a minimum of 6 months, by which time femur fractures typically unite. Furthermore, the pragmatic design of our study (including data from multiple SIGN hospitals) suggests that favorable outcomes are realistic among hospitals that utilize the SIGN intramedullary nail system.

Long bone fractures 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 it has been widely implemented with remarkable success. The SIGN Fin nail further simplifies femur fracture treatment by eliminating the requirement for interlocking screws on one side of the fracture. Our results suggest that the Fin nail is effective in achieving satisfactory and durable postoperative alignment of femoral shaft fractures. Further, the union rates and clinical outcomes are favorable and comparable to those achieved using the standard SIGN nail. Future investigations will be required to further elucidate the role of the SIGN Fin nail in femur fracture treatment globally.

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