

# Surgical Implant Generation Network (SIGN) Fin nail versus SIGN standard intramedullary nail for distal diaphyseal femur fractures treated via retrograde approach

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## ABSTRACT

**Introduction:** Surgical fixation of distal diaphyseal femur fractures remains a major challenge in developing countries given limited availability of fluoroscopy. The Surgical Implant Generation Network (SIGN) Standard Intramedullary Nail and SIGN Fin Nail are two modalities developed to address this challenge; the Fin Nail additionally avoids needing to place proximal interlocking screws. While efficacy of the Standard Nail has been established, outcomes following fixation with the Fin Nail are unknown. In this study, we compare outcomes of distal diaphyseal femur fractures treated with each implant.

**Methods:** A prospective cohort study was conducted from 2012 to 2013 at a single tertiary-referral center in Tanzania. Skeletally mature patients with distal diaphyseal femur fractures treated with either retrograde SIGN Standard Nail or Fin Nail were included. Patients followed-up at 6, 12, 26, and 52 weeks post-operatively. The primary outcome was all-cause reoperation. Secondary outcomes included infection, non-union, malalignment, quality of life (EQ-5D score), pain (VAS score), radiographic healing (RUST score), and function (pain with weight bearing, knee range of motion, and Squat and Smile score).

**Results:** 74 (85%) of 85 enrolled patients completed the minimum 1-year follow-up. There was no difference in rate of reoperation ( $p=1.00$ ), infection ( $p=1.00$ ), limb length discrepancy ( $p=0.47$ ), non-union ( $p=1.00$ ), or coronal or sagittal malalignment ( $p=1.00$ ,  $p=0.55$  respectively) at 1 year. There was furthermore no difference in mean EQ-5D ( $p=0.82$ ), VAS pain score ( $p=0.43$ ), RUST score ( $p=0.44$ ), maximum knee flexion ( $p=0.52$ ) and extension ( $p=1.00$ ), or Squat and Smile function ( $p=1.00$ ) between cohorts at 1 year.

**Discussion:** Outcomes associated with the SIGN Fin Nail are comparable to those associated with the SIGN Standard Intramedullary Nail at 1 year. The SIGN Fin Nail may be useful as an alternative to Standard locked IM nails for fixation of distal diaphyseal femur fractures.

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## Introduction

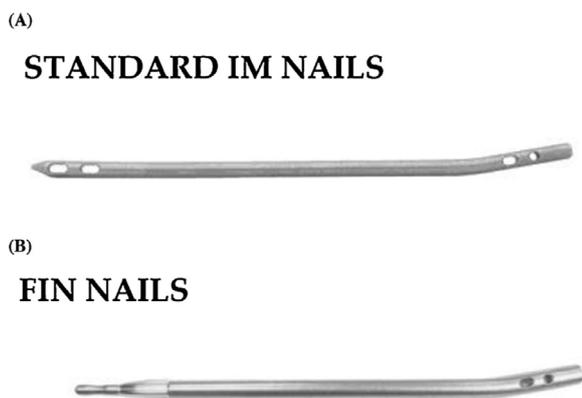
Traumatic injuries cause significant morbidity and mortality in low- and middle-income countries (LMICs) [1–4]. Road traffic accidents are responsible for the majority of these injuries, leading to over 1.2 million deaths and up to 50 million non-fatal injuries annually [5,6]. Among non-fatal injuries, femoral fractures are the

most common and pose a significant detriment to quality of life [7,8].

The treatment of femoral fractures remains challenging in developing countries due to the lack of image intensifiers and fracture tables at many trauma centers. The Surgical Implant Generation Network (SIGN) Standard Intramedullary Nail (Standard Nail) is one solution for these settings (Fig. 1A). Instead of using an image intensifier, surgeons utilize an external jig with a targeting arm to align the interlocking screws. This system is currently used by over 200 hospitals in 48 different countries [1]. While the SIGN Standard Nail has been shown to be highly efficacious for treatment of femoral fractures, locating the interlocking screw slots is

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**Fig. 1.** (A) SIGN Standard IM Nail; (B) SIGN Fin Nail. Both nails are designed to be implanted without use of fluoroscopy. The Fin Nail additionally does not require placement of interlocking screws (distal screws in antegrade approach; proximal screws in retrograde approach). Source: SIGN Fracture Care International Technique Manual (2012).

challenging, time consuming, and carries the risk of complications due to missed screws [9,10].

Most recently, SIGN developed the Fin Nail, which avoids needing to place (in the retrograde approach) proximal interlocking screws altogether (Fig. 1B). This nail possesses longitudinal “flutes” that create interference fit with the medullary canal. The Fin Nail theoretically offers comparable rotational stability while decreasing operative time as compared to interlocking screws [11]. A potential drawback is decreased longitudinal stability for comminuted, length unstable fracture patterns [11]. Despite these theorized benefits, adoption of the Fin Nail remains limited; from 2003 to 2009, only 3.3% of all femur fractures reported on the SIGN Online Surgical Database were treated with a Fin Nail [12].

While there is a growing body of evidence supporting use of the SIGN Standard Nail for femoral fractures, little is known about outcomes associated with the Fin Nail. In this study, we compare outcomes between the SIGN Standard Nail and the Fin Nail in the treatment of distal diaphyseal femur fractures via retrograde approach.

## Materials and methods

A prospective cohort study was conducted at a single trauma center in Dar es Salaam, Tanzania with enrollment between July 2012 and July 2013. Institutional review board approval was obtained from the National Institute for Medical Research (Dar es Salaam, Tanzania) and the University of California, San Francisco (UCSF) (San Francisco, USA). All study procedures were conducted in accordance with ethical standards.

Patients possessing AO/OTA Type 32 [13] femoral fractures in the distal third of the diaphysis treated with either the SIGN Standard Nail (SIGN Fracture Care International, Richland, WA) or SIGN Fin Nail, using a retrograde surgical approach, were enrolled if they provided consent and did not meet the following exclusion criteria: (1) AO/OTA Type 33 fracture (based on the rule of squares); (2) radiographic or intraoperative evidence of pathologic fracture; (3) prior surgery of affected femur; (4) delayed presentation (>6 weeks post-injury); (5) clinical signs of surgical site infection prior to or during surgery; (6) severe Traumatic Brain Injury (GCS < 12 at presentation); (7) severe burns (10% TBSA); or (8) unable to adhere to 1-year follow-up schedule (patient or treating surgeon’s discretion).

Patients were screened and enrolled postoperatively. Information recorded at enrollment included age, gender, BMI, employ-

ment, fracture type (open versus closed), comorbidities, mechanism of injury, time from injury to presentation, and time from presentation to surgery.

The type and size of implant as well as the number of proximal and distal interlocking screws were at the discretion of the treating surgeon.

Patients followed-up at 6, 12, 26, and 52 weeks postoperatively. The primary outcome measure was all-cause reoperation. Complications that warranted reoperation were evaluated by an adjudication committee; a primary outcome event was considered to have occurred if the adjudication committee found that reoperation was indicated, regardless of whether the reoperation occurred.

Secondary outcome measures included infection, non-union, malalignment, quality of life (EQ-5D Swahili), pain (Visual Analogue Scale), radiographic healing (Radiographic Union Scale for Tibia fractures, RUST) [14], weight-bearing status, knee range of motion, limb length discrepancy, and functional outcome (Squat and Smile score) [15]. Baseline quality of life was established at enrollment by asking patients to recall their pre-injury state using the EQ-5D questionnaire; this method has been previously validated [16].

Anteroposterior (AP) and lateral plain film radiographs were obtained preoperatively, postoperatively, and at all follow-up visits. Preoperative radiographs were used for OTA fracture classification; postoperative radiographs were assessed for degree of bone loss and immediate postoperative angulation at the fracture site; follow-up radiographs were assessed for healing and used to calculate RUST score.

Data was collected by local research assistants on password protected laptops and stored on REDCap, an electronic data capture tool [17]. Descriptive statistics and Fisher’s Exact test were performed using SPSS 21 (IBM, Armonk, New York). Only patients evaluated at 1 year postoperatively were included in the final analysis of the primary outcome; the remainder were designated lost to follow-up.

## Results

### Baseline & immediate post-operative characteristics

A total of 85 patients with distal diaphyseal femur fractures were treated with the SIGN Standard Nail (57) or SIGN Fin Nail (28) via retrograde approach during the study period (Table 1). Of these, 74 (85%) patients completed the minimum 1-year follow-up visit (Standard Nail 86%; Fin Nail 89%) and were included in the final analysis.

The most common mechanism of injury in both cohorts was road traffic injury; Standard Nail patients most commonly experienced automobile crash (49%), whereas Fin Nail patients most commonly experienced motorcycle crash (43%), but these differences were not significant ( $p=0.26$ ,  $p=0.64$  respectively). There was one closed fracture in each cohort; the remainder were open injuries ( $p=1.00$ ). Although not significant, there was a trend towards treating complex fractures (AO/OTA 32C) with Standard Nail ( $p=0.09$ ); additionally, wedge fractures (32B) were non-significantly overrepresented in the Fin Nail cohort ( $p=0.06$ ).

Fin Nail patients tended to experience greater time between presentation and surgery, although this difference did not meet threshold for significance (Standard Nail:  $10.0 \pm 10.3$  days vs. Fin Nail:  $14.6 \pm 12.2$  days,  $p=0.08$ ). Seven Standard Nail patients experienced immediate post-operative coronal malalignment ( $>5^\circ$ ) (6 varus, 1 valgus) compared to no Fin Nail patients ( $p=0.09$ ). Additionally, 1 Standard Nail patient exhibited sagittal recurvatum misalignment ( $>5^\circ$ ) versus no Fin Nail patients ( $p=1.00$ ).

**Table 1**  
Baseline and Immediate-Postoperative Patient Demographics and Injury Characteristics.

	Standard Nail		Fin Nail		Total n = 85	p-value
	n = 57	(%)	n = 28	(%)		
Age						
18-29	27	(47)	10	(36)	37	0.36
30-39	12	(21)	9	(32)	21	0.29
40-49	11	(19)	2	(7)	13	0.20
50-59	3	(5)	2	(7)	5	1.00
60-69	1	(2)	1	(4)	2	1.00
Not Available/Unknown	3	(5)	4	(14)	7	0.21
Gender						
Male	48	(84)	22	(79)	70	0.55
Female	9	(16)	6	(21)	15	
Employed						
Yes	14	(25)	10	(36)	24	0.31
No	43	(75)	17	(61)	60	0.21
Not Available	0	(0)	1	(4)	1	0.33
Mechanism of Injury						
Motor Vehicle Crash	28	(49)	10	(36)	38	0.26
Motorcycle Crash	21	(37)	12	(43)	33	0.64
Pedestrian vs. Auto	1	(2)	2	(7)	3	0.25
Fall from Height	5	(9)	1	(4)	6	0.66
Other	2	(4)	2	(7)	4	0.60
Not Available	0	(0)	1	(4)	1	0.33
Open versus Closed Fracture						
Open	56	(98)	27	(96)	83	1.00
Closed	1	(2)	1	(4)	2	
OTA Classification						
32A Simple Fracture	27	(47)	10	(36)	37	0.36
32B Wedge Fracture	23	(40)	18	(64)	41	0.06
32C Complex Fracture	7	(12)	0	(0)	7	0.09
Time from Injury to Presentation						
<24 hours	38	(67)	20	(71)	58	0.81
24-72	10	(18)	5	(18)	15	1.00
>72	4	(7)	0	(0)	4	0.30
Not Available	5	(9)	3	(11)	8	1.00
Time from Presentation to Surgery						
0-7 days	29	(51)	11	(39)	40	0.36
8-14	17	(30)	5	(18)	22	0.30
15-21	0	(0)	3	(11)	3	0.03
22-28	6	(11)	2	(7)	8	1.00
>28	4	(7)	5	(18)	9	0.15
Not Available	1	(2)	2	(7)	3	0.25
Post-op Malalignment						
Coronal Malalignment (>5°)	7	(12)	0	(0)	7	0.09
Could Not Assess	2	(4)	1	(4)	3	1.00
Sagittal Malalignment (>5°)	1	(2)	0	(0)	1	1.00
Could Not Assess	38	(67)	22	(79)	60	0.32

## Outcomes

At 1 year, 3 (5%) Standard Nail patients and 1 (4%) Fin Nail patient required reoperation (Table 2,  $p=1.00$ ). In the Standard Nail cohort, 1 patient required reoperation due to missed interlocking screws, while 2 patients (4%) experienced surgical site infections. In the Fin Nail group, no patients developed infections ( $p=1.00$ ), but 1 patient required reoperation after a second traumatic event yielded a broken nail; the nail was removed and replaced with a retrograde Standard Nail.

In the Standard Nail cohort, 5 (10%) patients developed limb length discrepancy (defined as  $\geq 1$  cm) compared to 4 (17%) patients in the Fin Nail cohort ( $p=0.47$ ). In all cases, the operated leg was shorter. No patients experienced non-union or exhibited coronal malalignment, in either cohort at 1 year. However, 4 (8%) Standard Nail patients and 1 (4%) Fin Nail patient experienced sagittal malalignment ( $>5^\circ$ ) ( $p=0.55$ ).

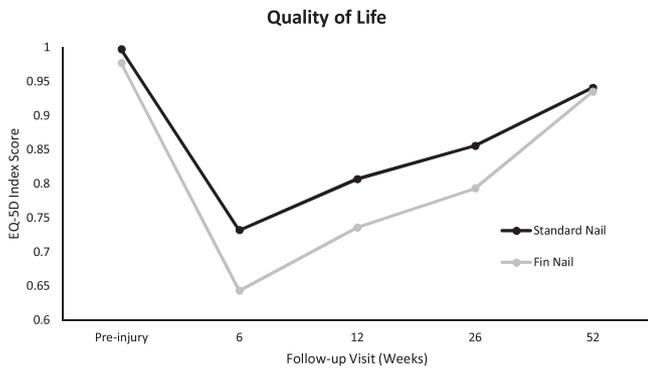
EQ-5D quality of life indices (Fig. 2) indicated a significant reduction in quality of life immediately post-injury in both groups, with gradual improvement over the 1 year follow-up period. There was no statistically significant difference in EQ-5D score between groups at any time point except at 12 weeks ( $p=0.04$ ).

The VAS pain scale (Fig. 3) indicated patients treated with Fin Nail had greater levels of overall pain than Standard Nail patients initially, but this difference was only statistically significant at 12 weeks ( $p=0.01$ ). Pain equalized between both groups over time, with no difference at 1 year ( $p=0.43$ ). Similarly, although more patients in the Fin Nail group reported pain on weight bearing at

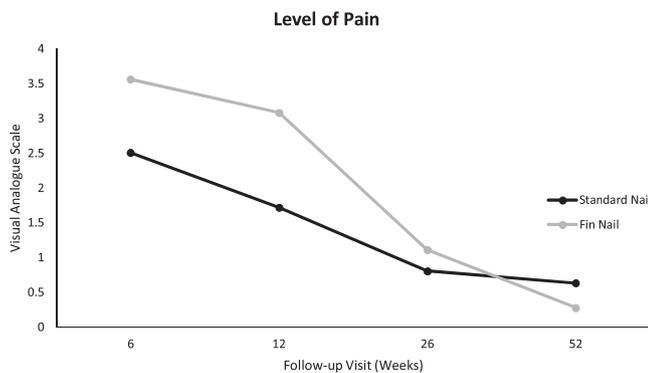
**Table 2**

Primary and Secondary Operative Outcomes at 1 year. Rates of reoperation (overall and secondary to missed screws, infection, or repeat trauma), limb length discrepancy ( $>1$  cm), non-union, coronal malalignment ( $>5^\circ$ ) and sagittal malalignment ( $>5^\circ$ ) at 1 year post-operatively.

	Standard Nail		Fin Nail		p-value
	n = 49	(%)	n = 25	(%)	
Reoperation	3	(5)	1	(4)	1.00
Missed screws	1	(2)	n.a.		
Infection	2	(3)	0	(0)	1.00
Repeat trauma	n.a.		1	(4)	
Limb length discrepancy ( $>1$ cm)	5	(10)	4	(17)	0.47
Non-union	0	(0)	0	(0)	1.00
Coronal malalignment ( $>5^\circ$ )	0	(0)	0	(0)	1.00
Sagittal malalignment ( $>5^\circ$ )	4	(8)	1	(4)	0.55



**Fig. 2.** Quality of life as measured by EQ-5D Swahili Version comparison. The pre-injury score was assessed by having patients use free recall to report their pre-injury state. P-values were  $p=0.13$  (pre-injury),  $p=0.07$  (6wk),  $p=0.04$  (12wk),  $p=0.13$  (26wk), and  $p=0.82$  (52wk).



**Fig. 3.** Pain as measured by Visual Analogue Scale comparison. P-values were  $p=0.11$  (6wk),  $p=0.01$  (12wk),  $p=0.37$  (26wk), and  $p=0.43$  (52wk).

12 weeks ( $p=0.04$ ), this difference equalized over time (Table 3). There was no statistically significant difference at any time point in RUST score (Fig. 4), maximum knee flexion or knee extension, or score on the Squat and Smile functional test (Fig. 5).

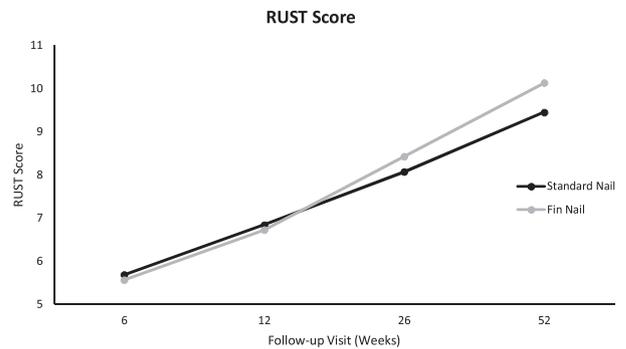
**Discussion**

The aim of this prospective cohort study was to compare outcomes between patients with distal diaphyseal femur fractures treated with retrograde intramedullary nailing via the SIGN Standard Nail versus the SIGN Fin Nail. We demonstrate no significant difference in any endpoint at 1 year post-surgery; patients exhibited comparable rates of reoperation, infection, non-union, malalignment, radiographic signs of healing, and functional outcomes. Patients treated with the Fin Nail initially exhibited lower EQ-5D-scored quality of life, higher VAS pain scores, and were more likely to experience pain with weight bearing; however, this did not persist at final follow up.

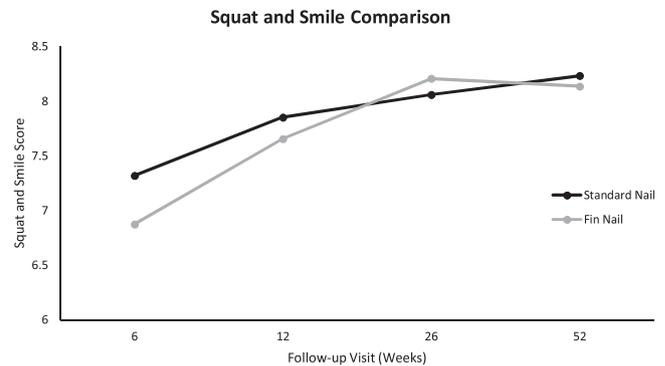
The observation of increased pain in the Fin Nail group at 12 weeks has not been previously reported. We hypothesize this

**Table 3**  
Number patients who reported pain with weight bearing.

Time	Standard Nail		Fin Nail		p-value
	Pain	No Pain	Pain	No Pain	
6 Weeks	2	33	2	11	0.29
12 Weeks	2	26	6	12	0.04
26 Weeks	0	30	0	17	1.00
52 Weeks	2	30	1	17	1.00



**Fig. 4.** RUST score comparison. P-values were  $p=0.81$  (6wk),  $p=0.8086$  (12wk),  $p=0.60$  (26wk), and  $p=0.44$  (52wk).



**Fig. 5.** Squat and Smile comparison. Functional scores graded on a 10-point scale. P-values. P-values were  $p=0.28$  (6wk),  $p=0.48$  (12wk),  $p=0.63$  (26wk), and  $p=1.00$  (52wk).

might be secondary to the less rigid fixation the Fin Nail provides compared to an interlocking nail, resulting in increased motion. This difference did not persist at later time points, presumably after fracture healing has occurred. Further study is needed to clarify if this is a true difference, and to evaluate the pathophysiology of this finding.

Although the SIGN Standard Nail has FDA approval (K163589) as a medical device, it is almost exclusively used in developing settings where the implants are provided charitably by the SIGN organization. While there is little literature offering direct comparison of SIGN nailing and fluoroscopy-assisted nailing in “developed” settings, Panti et al. retrospectively compared patients with femoral shaft fractures managed by SIGN Standard nailing and commercially-available interlocking intramedullary nailing (Stryker, Smith and Nephew, Zimmer, Orthopedic International) in the Philippines [18]. At final follow-up, all patients in both groups achieved clinical union without pain on weight-bearing; there were comparable rates of complications (including reoperation, malunion, SSI, deformity, proud proximal screw, screw loosening, screw breakage) between both groups. The authors concluded that the SIGN Standard Nail is comparable to gold standard, commercially available nails. Similarly, although SIGN nailing presents a theoretically increased risk of malalignment due to lack of fluoroscopy, Carsen et al. found that patients treated with SIGN nailing had excellent postoperative radiographic outcomes comparable to those reported by a Level I trauma center in the United States [19]. Limitations of the SIGN nail include the need for training by a SIGN surgeon educator, and the theoretical risks of fluoroscopy-unassisted nailing including angulation, inappropriately sized nail, hardware prominence, screw loosening, or iatrogenic injury [1].

To our knowledge, no study exists which provides outcomes specifically for distal diaphyseal femur fractures treated with the

SIGN Standard Nail, making comparison to prior literature difficult. A study conducted at the same center in 2011 using the SIGN Standard Nail for fixation of closed femoral shaft fractures reported a 5% rate of infection and 4% rate of limb shortening [9]. A similar study by Sekimpi et al. reported an overall complication rate of 28% with both antegrade and retrograde Standard Nail, with retrograde approach used in 46% of patients and overrepresented among patients who developed complications [1]. Sekimpi et al. reported half of patients who experienced complications required reoperation.

Only one prior study provides outcomes for the SIGN Fin Nail. Shahabuddin et al. compared 13 pediatric patients treated with Fin Nail to 5 pediatric patients treated with a locking intramedullary nail at a single center in Pakistan [20]. The authors reported no reoperations or other major complications in the Fin Nail cohort after a mean follow-up period of 41 weeks (10–80). In our study, only one patient in the Fin Nail cohort required reoperation, and this was secondary to repeat trauma. Cumulatively, our study extends existing knowledge regarding Fin Nail outcomes to new populations in terms of both age (adult), geographic region (Tanzania), and via a larger sample size.

Data from the SIGN Online Surgical Database, an online repository on data for patients treated by any SIGN Nail, also provide avenues for comparison. From 2003 to 2011, the retrograde approach was chosen for 21.5% of femur fracture fixations with an infection rate of 0.8% [21]. When only patients with registered follow-up are considered, the overall rate of infection across all femur fractures was 3.2%. The rate of infection in open fractures, specifically, has been cited at 5.3%, although the published results did not differentiate between Standard Nail and Fin Nail [12]. Nevertheless, an infection rate of 4% as identified in this study is consistent with previously reported rates of infection and suggests that both the Standard and Fin Nail are safe for use in developing settings.

There are several limitations to this study. As a prospective cohort study, treatment assignment was non-random, offering potential for confounding and bias. More patients were treated with Standard Nail (57) than Fin Nail (28), yielding unequal cohorts. This reflects current practice at our center and other developing settings, where Fin Nail is less commonly used given a lack of outcomes data. A future randomized controlled trial with equal assignment to treatment arms is needed to conclusively differentiate between these two modalities. Additionally, we noted that fractures treated with Fin Nail tended to be less complex. This is consistent with the manufacturer's indications for the Fin Nail: simple or wedge fracture patterns in a distal location, allowing the nail's "fin" to be placed near the isthmus. Although the differences in fracture type were not significant and did not alter outcomes on subgroup analysis, future studies should consider excluding 32C fractures and randomizing to allow stronger comparison. Finally, although the current study is the largest hitherto reported for the Fin Nail, the study population limits its statistical power and ability to detect a true difference between treatment groups. Future studies should consider prolonging enrollment to increase statistical power. Additional research is also needed on the biomechanical aspects of the Fin Nail, and how it compares with the Standard Nail and other implants. Nevertheless, despite these weaknesses, this study provides novel data on outcomes, permits comparison between two promising treatment modalities in developing countries, and promotes future exploration in this area – ideally via a large, randomized controlled trial.

## Conclusions

In conclusion, our data suggest the SIGN Standard Nail and SIGN Fin Nail provide comparable clinical, radiographic, and functional outcomes in the treatment of distal diaphyseal femur fractures via

retrograde approach. The Fin Nail is a novel implant that may decrease operative time and reduce missed interlocking screws in settings where an image intensifier is not available.

## Declaration of Competing Interest

Max Bolun Liu declares he has no financial or other conflicts of interest in connection with this article.

Syed Haider Ali declares he has no financial or other conflicts of interest in connection with this article.

Billy Thomson Haonga declares he has no financial or other conflicts of interest in connection with this article.

Edmund Ndalama Eliezer declares he has no financial or other conflicts of interest in connection with this article.

Patrick David Albright declares he has no financial or other conflicts of interest in connection with this article.

Saam Morshed declares he has no financial or other conflicts of interest in connection with this article.

David Shearer declares he sits on the Board of Directors of SIGN Fracture Care International, the manufacturer of both implants utilized in the study. In this capacity, he receives no payment or compensation of any kind from the company, which is a non-profit entity that provides orthopaedic implants free of charge to surgeons in developing countries.

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