CANAL FITTING AND TREATMENT OUTCOMES OF PATIENTS TREATED WITH SIGN FIN NAIL AT A TERTIARY HOSPITAL IN TANZANIA

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ABSTRACT

Background: The Surgical Implant Generation Network (SIGN) Fin nail is a relatively newer design of intramedullary nails that eliminates the requirement for distal locking. While various factors influencing treatment outcomes with different nail designs have been extensively studied, limited research has focused on the specific implications of using the SIGN Fin nail.

Objective: This study aimed to assess the relationship between Fin nail canal fitting and treatment outcomes in femur fractures treated with the SIGN Fin nail at Muhimbili Orthopaedics Institute.

Methods: A cross-sectional study was conducted at a tertiary hospital in Tanzania. Patients who underwent femoral fracture fixation with SIGN Fin nails between January 2016 and December 2021 were recruited from the SIGN surgical database. Radiographic measurements were performed using radiant software, fracture union at one year was assessed using the mRUST score, and weight-bearing status at 6 weeks was obtained from patient records.

Results: The mean canal diameter was 11.30±1.75 mm, and 82.2% had a canal fill of 80% or more. The reoperation rate was 5.9% (7/118). Although not statistically significant, patients with canal fill less than 80% had a higher rate of reoperation ($p = 0.074$). The union rate was 84.1% in this study, with a mean mRUST score of 9.4, and those patients with a canal fill of less than 80% were more likely to have nonunion at 1 year ($p = 0.028$). Pain on weight bearing at 6 weeks was reported by 42.9% (24/118) of participants, and this was significantly associated with canal fitting ($p < 0.001$).

Conclusion: The study found the degree of canal fitting of the Fin nail to be an important factor affecting the outcomes of femoral fractures treated with SIGN Fin nails. A higher degree of canal fill was associated with better pain outcomes and lower nonunion rates.

Key words: Canal fitting, SIGN Fin nail, Femur fractures

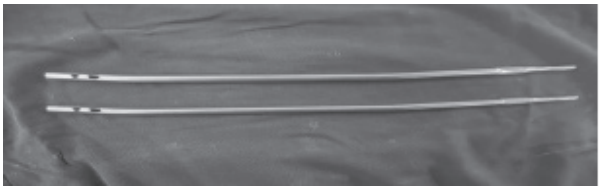
INTRODUCTION

Fixation with reamed locked intramedullary nails is considered the treatment of choice for femoral diaphyseal fractures (1,2). However, due to the lack of fluoroscopy and traction tables in many trauma centers in developing countries, such a technique is challenging to perform (3); hence, SIGN fracture care international designed nails that may be locked without fluoroscopy and are now widely used to treat femoral fractures (3,4). The SIGN Fin nail, a relatively newer design, differs from the standard SIGN nail in that it does not require distal locking, it is designed with fins that take the place of distal locking screws and provide stability by the fin flutes fitting in the canal isthmus (Figure 1). Inserting a large nail with full contact between the medullary canal and nail provides stability and offers maximal torsional, bending, and axial load resistance for length stable fractures (4,5). Several factors leading to outcomes in these nail types have been studied;

however, the effect of canal fill, which we believe to be the most important factor in the stability of a Fin nail, has not been studied.

Figure 1

The SIGN Fin nail



This study aimed at assessing the relationship between fin nail canal fitting and treatment outcomes in femur fractures treated at Muhimbili Orthopaedics Institute to provide clinicians with evidence-based recommendations on deciding the size of fin nails to use when treating femur fractures.

MATERIALS AND METHODS

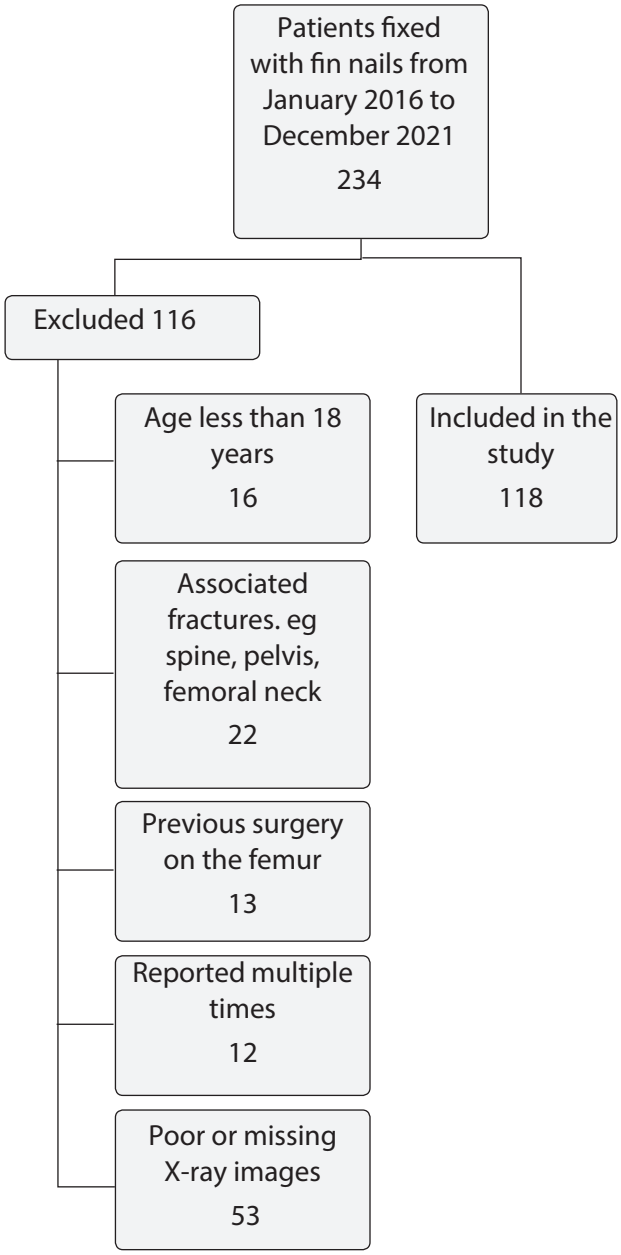
This was a cross-sectional study. Patients with femoral diaphyseal fractures treated with SIGN Fin nail at Muhimbili Orthopaedics Institute (MOI) in the SIGN surgical database from January 2016 to December 2021.

Ethical clearance to conduct this research was sought from the Institutional Research Ethical Review Board of Muhimbili University of Health and Allied Sciences.

We included all patients aged 18 years and above with femur diaphyseal fracture treated with the SIGN Fin nail and excluded participants with no or poor postoperative AP radiographs, radiographic evidence of pathological fracture, prior surgery of the affected femur, associated neck of femur fracture as well as floating knee injury. Patients who underwent femur fracture fixation with the SIGN Fin nail at MOI between January 2016 and December 2021 were searched and obtained from the SIGN Surgical Database (SSD). The researcher logged into the MOI database in the research section, and then a query to search for all cases operated between January 2016 and December 2021 using SIGN Fin nail was entered. A total of 234 cases were obtained, 116 cases were excluded from the study because they did not meet the inclusion criteria, leaving a total number of 118 participants, which were all included in this study (Figure 2). Then, case notes were pulled from MOI medical records.

Figure 2

Study population flow chart



Social demographics and other relevant data were obtained from the SSD, including sex, age, duration of injury, fracture pattern and nail diameter. Radiographs of all participants were downloaded from the SSD and converted to DICOM format and then stored in a password-protected flash drive. The femoral isthmus was identified on the AP radiograph, and the canal diameter was measured at that level using Radiant software. (AP radiograph is the most accurate and reliable method of estimating the femoral canal diameter, and intra-rater reliability was higher in AP radiograph compared to the measurements on CT and lateral radiograph at the isthmus diameters) (6). Magnification was adjusted using the known nail diameter from the SIGN database, a method similar to that of Conn *et al*. (7).

The percent of the femur canal occupied by the nail at the isthmus was obtained by dividing the nail diameter and the canal diameter at the isthmus. Reoperation status was obtained from the database and patient case notes. This was considered to have occurred if the participant was taken to the theater for the operation of the same limb other than fin nail removal due to a healed fracture at any time after the first surgery of fin nail application. Union in this study was assessed on plain radiograph images that were at least 1 year from surgery using the modified Radiographic Union Score for Tibial Fractures (mRUST). Scoring was performed by the principal investigator (mRUST score has been validated for use in assessing femur fracture union treated with intramedullary nails with excellent inter- and intra-observer reliability (8). Weight-bearing status was obtained from the SSD, as information must be inquired about and filled in the SSD during the follow-up of all patients treated for femur fracture using SIGN nails. Additionally, the patient case notes were reviewed for this information.

An Excel spreadsheet was used to manage the data, and Stata version 14 was used to analyze the data. Relevant frequencies and tables were generated for all variables. Means and proportions were calculated for appropriate variables. The canal fitting was grouped into two categories, i.e., those with nails occupying less than 80% of the canal and those with nails occupying 80% of the canal or more. This was taken based on the recommended amount of canal that should be occupied by IMN (paediatric flexible nail that is also nonlocking) (9–11). The distribution of variables among the two groups of canal fitting was assessed, and chi-square tests were used to obtain the p values. A logistic regression model was used to assess the associations between canal fitting and the primary and secondary outcomes. Then, multivariate logistics was performed for variables that were distributed differently among the canal fitting groups to obtain odds ratio, confidence intervals and P values. The level of significance was 0.05.

RESULTS

This study included 118 participants with a mean age of 33.6 years, with the majority 92 (78%) being less than 40 years of age. Most of the participants were males with a male-to-female ratio of 4:1. Motor-traffic crashes accounted for 96.6% of the mechanism of injury among the participants. More than half of the study participants 65 (55%) had a transverse (32A3) fracture, and comminuted fractures (32C) were found in 5% of the participants. The majority of the fractures were closed (104, 88%). The time from injury to surgery was 3 days or less in 54 (45.8%) and more than a week in 55 (46.6%).

Table 1

Social demographic characteristics and baseline information

Variable	Frequency (n=118)	(%)
Age group (years)		
18-29	51	43.2
30-39	41	34.7
40-49	10	8.5
50-69	11	9.3
Above 69	5	4.3
Mean age in years (± SD)	33.6 (±14.5)	
Sex		
Male	94	79.7
Female	24	20.3
Mechanism of injury		
Motor Traffic Crash	114	96.6
Fall From height	4	3.4
AO/OTA Classification		
32A1	6	5.1
32A2	21	17.8
32A3	65	55.1
32B	17	14.4
32C	6	5.1
Fracture type		
Closed	104	88.14
Open	14	11.86
Time of injury to surgery (days)		
0-3	54	45.8
4-7	9	7.6
>7	55	46.6
Canal diameter (mm)		
Mean SD	11.301.75	

Mean canal diameter of the participants was 11.3 mm. The majority of the fractures were fixed using a nail size of 10 mm 54 (45.7%), and a few 5 (4%) were fixed using a nail size of 8 mm.

Figure 3

Nail diameters used for fracture fixation

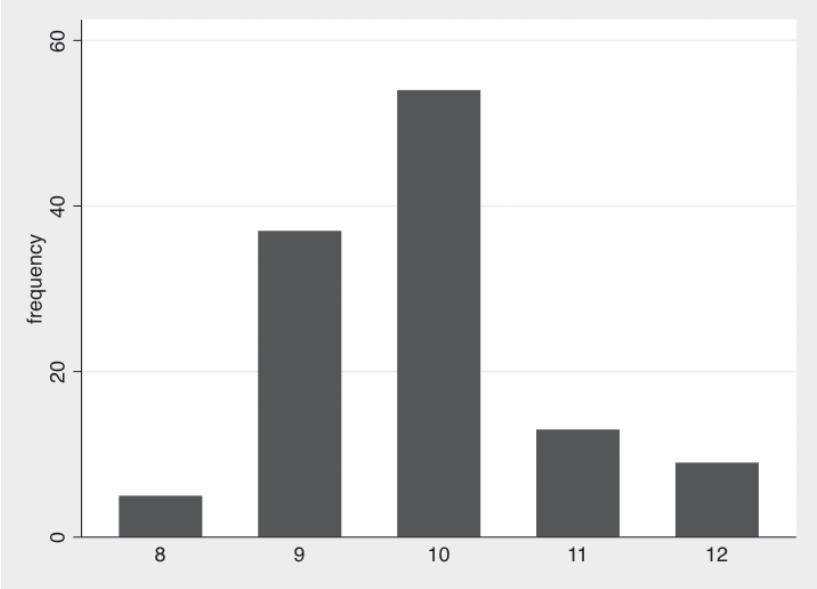
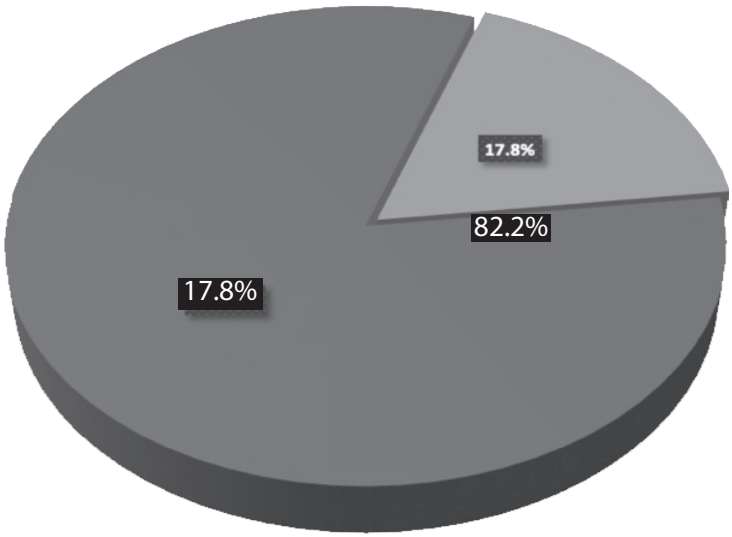


Figure 4

The canal fitting of participants



A substantial portion of the study participants (82.2%; 97) had a fin nail occupying 80% of the canal or more.

The percentage of canal fill did not differ significantly between age groups (p=0.235). However, there was a trend toward a higher proportion of patients aged 18-29 years having canal fill >=80%. There was a significant difference in the proportion of males versus females in the two groups (p=0.050), with a higher proportion of males having canal fill >=80%. The mean time from injury to operation among the two groups did not differ significantly (p=0.318). There was a trend toward having a more fitting nail canal fill of more than 80% in closed fractures; however, this was not significant (p=0.714). The percentage of canal fill did not differ significantly between mechanisms of injury (p=0.702). There was a trend toward a higher proportion of patients with AO classification 32A1 having canal fill >=80% (p=0.086).

Table 2

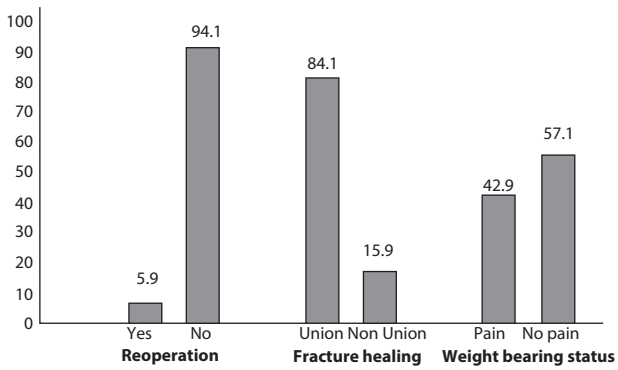
Social demographic and baseline characteristics and canal fill

Canal fill	<80	>= 80	P value
Age groups (years) (%)			
18-29	9 (42.86)	42 (43.3)	0.235
30-39	5 (23.81)	36 (37.11)	
40-49	4 (19.05)	6 (6.19)	
>50	3 (14.29)	13 (13.4)	
Sex n (%)			
Male	20(95.2)	74 (76.3)	0.050
Female	1(4.8)	23(23.7)	
Number of days from injury			
Mean ± SD	12.8±15.0	11.4±17.8	0.318
Fracture type			
Closed n (%)	19(90.5)	85 (87.6)	0.714
Open n (%)	2(9.5)	12(12.4)	
Mechanism of injury n (%)			
Mtc	20(95.2)	94(96.9)	0.702
Fall from height	1(4.8)	3(3.1)	
AO classification			
32A1	0 (0.0)	6(6.2)	0.086
32A2	7(33.3)	14(14.4)	
32A3	8(38.1)	57(58.8)	
Others	6(28.6)	20(20.6)	

The reoperation rate in this study was found to be 5.9% (7 participants underwent reoperation). Among the mentioned reasons for reoperation were nonunion for 6 and infection for 1 participant. Eighty two participants had radiographs at one year, and of these 69 (84.1%) patients achieved union and 13 (15.9%) patients had not united. Out of all participants, 56/118 participants attended the 6-week follow-up. Among these participants, 32 (57.1%) patients reported being pain-free at 6 weeks after the operation, while 24 (42.9%) patients reported experiencing pain. This suggests that the majority of patients were able to bear weight without significant discomfort.

Figure 5

Outcomes of patients treated with SIGN Fin nails



The percentage of patients requiring reoperation was higher among those with <80%

canal fill, although the difference did not reach statistical significance (p = 0.074). The proportion of patients experiencing pain at 6 weeks post-surgery was significantly higher among those with a canal fill of <80% compared to those with 80% or more (p < 0.001). The proportion of patients with nonunion was significantly higher among the participants who had <80% canal fill (p = 0.025). The mean mRUST score was also significantly lower (9.1±2.9) in this group (p = 0.0113).

Table 3

Comparing canal fill and outcomes

	Canal fill		
	<80%	>/= 80%	P value
Reoperation (n= 118)			
Yes	3(14.3)	4(4.1)	0.074
No	18(85.7)	93(95.9)	
Pain at 6 weeks (n=56)			
Yes	13(92.9)	11(26.2)	0.000
No	1(7.1)	31(73.8)	
Union status (n= 82)			
Yes	9(64.3)	60(88.2)	0.025
No	5(35.7)	8(11.8)	
mRust scores mean (±SD)	9.1(±2.9)	10.7±2.2	0.0113

Figure 6

Example of a fracture fixed with a nail occupying >80% of the canal diameter went to union after 8 months

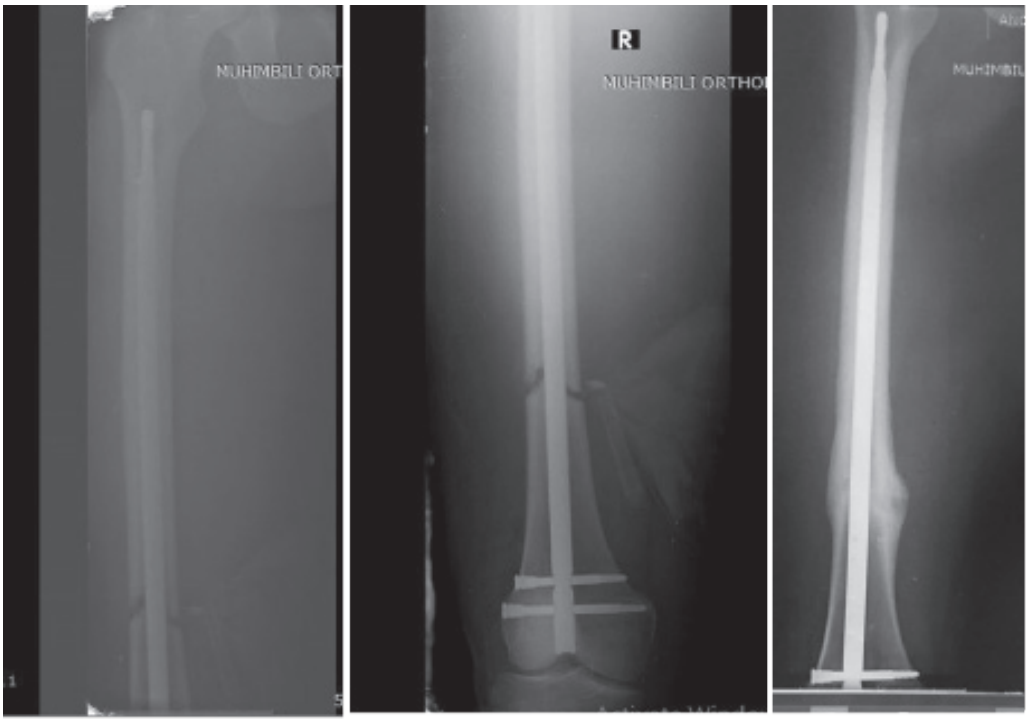
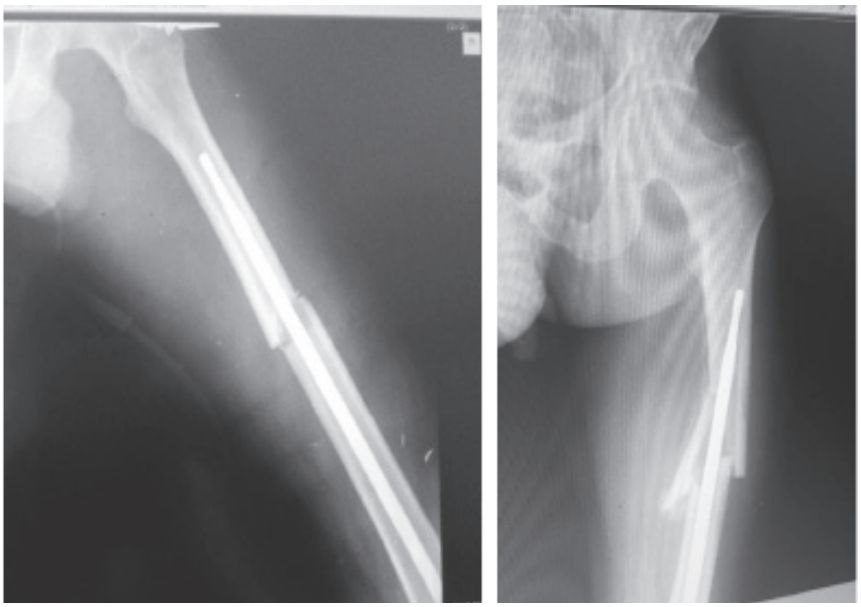


Figure 7

Example of a fracture fixed with a nail occupying <80% of the canal diameter went to nonunion



The results indicate that patients with a nail filling less than 80% of the canal are almost 4 times more likely to undergo reoperation than those with canal fill greater than or equal to 80%, but this difference did not reach statistical significance (p = 0.093). After adjusting for others, female patients still had significantly higher odds (AOR = 6.2) for reoperation than male patients, with a p value of 0.02 after other factors were adjusted for. AO Classification of 32A1/2 have a lower risk of reoperation than those with other AO classifications, but the results are not statistically significant.

Individuals with a canal fill of less than 80% are 36.6 times more likely to have pain on weight bearing at six weeks compared to those with a canal fill of >/=80%. After controlling for the other predictor variables, including sex and AO classification, the odds ratio for this variable was still significantly high (73.4, 95% CI = 5-104.6, P = 0.002).

The likelihood of having a non-united fracture at one year was four times higher when the canal fill was <80% after fin nailing compared to those with a canal fill of 80% or more, and after considering potential confounding factors (sex and AO classification), the adjusted odds further increased to 5.3 (p = 0.028). The odds of nonunion were higher in males, but this difference was not statistically significant. Fracture pattern also did not significantly affect union at one year (p = 0.189).

Table 4

Logistic regressions

Outcome variable	Independent variables	Crude Odds Ratio (95% CI)	P value	Adjusted Odds Ratio (95% CI)	P value
Reoperation	Canal fill				
	<80	3.875(0.8-19)	0.093	3.12 (0.3-15)	0.72
	>/= 80%	ref			
	Sex				
	Female	12.11(2-67)	0.004	6.2 (1.8-20)	0.022
	Male	ref			
	Ao Classification				
	32A1/2	Ref			
	32A3	1.7 (0.2- 16)	0.640	1.6 (0.8-12)	0.321
	Others	2.2 (0.2- 25.5)	0.538	2.1(0.6-8)	0.620

Pain on weight bearing at 6 weeks	Canal fill				
	<80	36.6 (4.3, 63.6)	0.001	73.4(5, 104.6)	0.002
	>/= 80%	Ref			
	Sex				
	Female	Ref			
	Male	1.7(0.5, 5.9)	0.386	1.2 (0.3, 5.4)	0.784
	AO Classification				
	32A1/2	1.2(0.3, 4.4)	0.787	0.26 (0.02, 2.5)	0.247
	32A3	Ref			
	Others	1.6(0.5, 5.6)	0.464	1.3 (0.1,1.01)	0.053
Fracture union at 1 year	Canal fill				
	<80	4.2 (1-15)	0.0405	5.3(1-23)	0.028
	>/= 80%	Ref			
	Sex				
	Female	Ref			
	Male	3.3 (0.4-27)	0.20	2.6(0.3-23)	0.393
	AO Classification				
	32A1/2	Ref			
	32A3	2.1(0.4-10)	0.391	3.5(0.5-22)	0.189
	Others	2.2 (0.3-15)	0.424	2.8(0.4-22)	0.323

DISCUSSION

This study assessed the effect of canal fitting (judged by the percentage of the femoral canal occupied by the nail) of the fin nail on the outcomes of patients treated with the SIGN Fin nail. Fin nails do not have distal locking screws, and their stability is thought to come from the proximal locking screws and the fitting of the nail fins at the isthmus (8).

To our knowledge, there is no single published study that has assessed this in fin nails, but a hand full have, in other nail types with locking screws both proximally and distally (9,12–14).

The study findings revealed that the majority of participants with femoral shaft fractures were young males who experienced high-energy injuries. The average age of the participants was 33.6 years, with a predominant age group between 18 and 40 years. This finding aligns with previous studies that also identified a higher prevalence of femur shaft fractures in individuals aged 20-40 years.

In a study by Liu *et al.* (3), comparing SIGN Fin nails to SIGN standard nails, similar findings were observed, with a majority of participants in the FIN nail group being young males. Motor traffic crashes were also identified as the most common mechanism of injury, accounting for 86% of participants treated with SIGN Fin nails. This similarity is attributed to the studies being conducted in the same setting, where motor traffic accidents are the primary cause of femur fractures among young males.

A similar observation was made in a study conducted in Benin, a West African country by Chigblo *et al*. (15) where the majority of fractures occurred in individuals under 50 years old, primarily due to motor traffic crash incidents. This corresponds to our study findings because, in both of the settings, young men tend to use motorcycles as their means of transport to and from work.

A study by Curtis *et al.* (16) in the UK found the majority of femur fractures occurred in men in their second and third decades, which aligns with our study findings. However, their study also revealed a bimodal distribution, indicating a second peak in older women, a common finding in many other studies (3,15,17–18). In contrast, our study did not observe this second peak among older women. This discrepancy may be attributed to the fact that fragility fractures tend to occur at the proximal femur, and in our setting, these fractures are more likely to be treated with a standard SIGN nail rather than an FIN nail, which was the focus of our study.

Regarding canal fitting, our study did not find any significant differences among different age

groups. However, females were more likely to have a canal fill of more than 80% compared to males, this may be due to the fact that males have wider canal diameters as compared to females.

The rate of reoperation in this study was found to be 5.9%. Among patients treated with SIGN Fin nails at MOI, this rate was slightly higher than that reported by Liu *et al.* (3) when they compared standard and fin SIGN nails. The small difference could be because in their study, the Fin nail group had a smaller sample size of 27, and they followed their patients for one year.

We found more people requiring reoperation among those with canal fitting of less than 80%; however, this did not reach the level of significance (p =0.093). Millar *et al.* (12) in their study were able to significantly associate the need for exchange nail and canal fit. In his study, patients who had a nail fit of less than 88 ± 6% developed more nonunion and needed exchange nails (p<0.001). This was a case–control study with a power of more than 80%.

A study in the US by Nielsen *et al*. (9) did not find a significant association between canal fitting and complications, including reoperation; however, his study included the paediatric population, which may have different fracture healing characteristics. However, in another paediatric study, the reoperation rate was 7%, and when canal fitting was assessed, less than 40% of canal fitting was associated with higher reoperation rates (13).

In this study, it was found that at one-year follow-up, 15.9% of the fractures had not united. This indicates that a majority of study participants who had follow-up X-rays at one year had achieved radiological union by this time. However, it is worth noting that the observed nonunion rate was higher than 2.3% reported by Eliezer *et al.* (17) in a one-year prospective study at the same center. This difference may be attributed to the low sample size (44 fractures fixed with a fin nail) in the study by Eliezer *et al.* (17) and the low follow-up rate in our study (69.5%) (often those with uneventful healing may not attend follow-up appointments). Our observed nonunion rate was also high compared to that reported by Serrano *et al.* (2), where their study employed a nail that locks both proximally and distally.

The results of our study suggest that the degree of canal occupied by the fin nail is an important factor affecting the union of fractures. This is likely since the stability of the nail is largely dependent on its fit within the canal, and therefore, a higher degree of canal fill may provide better stability and promote fracture healing.

Our finding of a significantly higher risk of nonunion among those with a canal fill of less than 80% compared to those with a higher degree of canal fill is consistent with previous research. For instance, Millar *et al.* (12) reported a higher rate of nonunion among patients with a canal fit of less than 70%. Nonetheless, certain studies have indicated that there is no significant disparity in the rates of union among groups with different canal fits (2,14). However, it is important to note that these studies utilized nails that were locked both proximally and distally. Moreover, these studies used a different criterion to group participants based on the difference between canal and nail diameters (<1mm 1-2mm and >2mm) rather than the degree of canal occupied by the nail as used in this study. This highlights the importance of standardized criteria for defining canal fill and other factors that may affect fracture healing in future studies.

In this study, canal fitting had a significant impact on weight bearing, as participants with less than 80% canal fit were more likely to experience pain during weight bearing at 6 weeks compared to those with 80% or more canal fit (p = 0.001). The study found that 57.1% of participants had no pain on weight bearing after 6 weeks, which is a smaller proportion compared to that of Liu *et al*. (3) in the same hospital, where 81.8% of patients treated with fin nails were able to walk pain free at 6 weeks. We think this is because their sample size was lower 13 patients at 6 weeks (3). These results show that if a fin nail is not placed fit in the canal, there may be instability and movements at the fracture site, resulting in pain during weight bearing.

Pain at 6 weeks in this study was analyzed in 47% of the participants due to non-attendance showing a low follow-up rate at our institution and may be a source for bias when interpreting these results; for example, one explanation could be that patients with no pain did not come for follow-up. Notably, this is the first study to explore the relationship between canal fitting and pain during weight bearing, as previous studies have only assessed pain during weight bearing after femur fracture fixation. While this study provides valuable insights into the association between canal fill and outcomes after femur fracture fixation, the limitations inherent in its

retrospective single center design, potential bias from excluded radiographs, a significant non-attendance leading to 52.5% of participants not analyzed for pain at six weeks, loss to follow-up and the need to consider other influential factors should be acknowledged.

CONCLUSION

Our study found the degree of canal fitting of the fin nail to be an important factor affecting patient outcomes. A higher degree of canal fill was associated with better pain outcomes and lower nonunion rates. Therefore, surgeons should aim for a canal fill of at least 80% during preoperative planning and when implanting SIGN Fin nails, moreover, further prospective studies with larger sample sizes should be performed to further investigate the impact of canal fill on fracture outcomes and provide more robust evidence for clinical decision-making.

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Conflict of interest: None to declare.

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