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A Retrospective Cohort Study on Using Fully Threaded, Cortical Screws in Locking SIGN Intramedullary Nails

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Abstract: The Surgical Implant Generation Network (SIGN) produces solid and straight intramedullary nails used for femoral or tibial fractures. These utilize interlocking screws with proximal and distal threads to purchase at the cortices. When SIGN interlocking screws are unavailable, 4.5 mm, fully threaded, stainless steel, cortical screws are sometimes used to lock the nails. This study compared the alignment, fracture healing, and screw failure rates between cases which solely used SIGN interlocking screws and those which incorporated fully threaded, cortical screws. The SIGN census from January 2018 to August 2021 was reviewed. 79 cases were included in this study. 59 solely used SIGN interlocking screws and 20 incorporated fully threaded, cortical screws. The former group had acceptable alignment in 91.5%, 3-4 bridging cortices by the 12th week in 81.4%, and no screw failure in 96.8%. The latter group had acceptable alignment in 90.0%, 3-4 bridging cortices by the 12th week in 80.0%, and no screw failure in 95.0% of cases. The chi-square test showed no significant difference in outcomes between the two groups with p= .836 for fracture alignment, p= .894 for fracture healing, p= .745 for screw failure. This study concluded that 4.5 mm, fully threaded, stainless steel, cortical screws may be incorporated to lock SIGN nails when SIGN interlocking screws are unavailable.

Keywords: SIGN, Nail, Screw, Femur, Tibia, Fracture

1. Introduction

Intramedullary nailing is the gold standard of treatment for fractures of femoral or tibial shafts to allow early full weight-bearing [1]. As a public hospital in a developing country, East Avenue Medical Center (EAMC) has been a beneficiary of the Surgical Implant Generation Network (SIGN) since 2009 for intramedullary nails.

The SIGN system utilizes a solid, straight nail with a proximal bend. Its interlocking screws feature a wide, threaded neck which tapers into a threadless core with a threaded tip to purchase at the near and the far cortices (Figure 1) [1, 5–9]. During surgeries when the necessary screw length is unavailable among the SIGN interlocking screws, a 4.5 mm, fully threaded, stainless steel, cortical screw (Figure 2) – hereafter referred to as a fully threaded, cortical screw – has been utilized to lock the nail.

Figure 1. *SIGN interlocking screw.*

Figure 2. *Fully threaded, cortical screw.*

This study aimed to review the fracture alignment, fracture healing, and screw failure rates in SIGN cases which incorporated fully threaded, cortical screws compared to cases which solely used SIGN interlocking screws.

2. Methodology

The SIGN census of EAMC from January 2018 to August 2020 was reviewed. Cases which underwent intramedullary

nailing of the femur or tibia were included in this study. Cases involving patients <18 years old, <12 weeks of follow-up, segmental bone loss, malignancy, or pre-existing osteomyelitis were excluded [11].

The cases were classified based on the locking screws used. The control group consisted of cases which used solely SIGN interlocking screws. The comparison group comprised of cases which incorporated fully threaded, cortical screws.

The cases in this study followed the SIGN technique for intramedullary nailing. The intramedullary canal was opened with an awl then reamed until chatter was heard. A nail 2 mm sizes narrower was inserted and locked as guided by the target arm. To insert the locking screws through the holes of the nail, the near cortex was drilled with a 3.5 mm drill bit. Trajectory of the pilot hole to the nail hole was confirmed with the step drill. The pilot hole was extended until the far cortex to accommodate the necessary screw length determined by the depth gauge [12].

Union was defined as 3-4 cortical continuity on orthogonal views by the 12th week after surgery [11, 13-15]. Screw failure was assessed radiographically in terms of screw loosening, pull-out, or breakage [16].

The chi-square test of independence was used to determine if there was statistically significant difference in outcome between the two groups.

Table 1. *Case Demographics.*

CHARACTERISTICS	TOTAL
Age	
18-59 years old	92.4%
> 60 years old	7.6%
Sex	
Male	88.6%
Female	11.4%
Involved Bone	
Femur	62.0%
Tibia	38.0%
Locking Screws Used	
solely SIGN Interlocking Screws	74.7%
incorporated Fully Threaded, Cortical Screws	25.3%

3. Results

Among the 59 patients who used solely SIGN interlocking screws, 91.5% had acceptable fracture alignment, 81.4% demonstrated 3-4 bridging cortices after 12 weeks, and 96.8% did not exhibit screw failure. Among the 20 patients who incorporated fully threaded, cortical screws, 90% had acceptable fracture alignment, 80% demonstrated 3-4 bridging cortices after 12 weeks, and 95% did not exhibit screw failure. (Table 2)

Table 2. *Case Outcomes.*

OUTCOMES	solely SIGN Interlocking Screws	incorporated Fully Threaded, Cortical Screws	p-value
Fracture Alignment			.836
Acceptable	91.5%	90.0%	
Misaligned	8.5%	10.0%	
Fracture Healing after 12 Weeks			.894
3-4 bridging cortices	81.4%	80.0%	
0-2 bridging cortices	18.6%	20.0%	
Screw Failure			.745
Screw Loosening	1.6%	0%	
Screw Pull-out	1.6%	0%	
Screw Breakage	0%	5.0%	

A chi-square test of independence was performed to examine the relationship between the screws used and the outcomes using a significance level of $p < .05$. There was no significant difference in fracture alignment, X^2 (1, N=79) = 0.043, p = .835652; fracture union, X^2 (1, N=79) = 0.0179, p = .893707; or screw failure, X^2 (1, N=79) = 0.106, p = .744742. (Table 2)

4. Discussion

Around 50 patients undergo nailing at EAMC annually for fractures of the femur or the tibia. As long as available nail sizes permit, majority of these patients utilize the SIGN system. Although restocking of inventory reliably comes at regular intervals, the fast influx of patients in the setting of a densely populated metropolitan causes more demand than available supply. In a hospital catering to low-income families, surgeons must be resourceful in order to timely treat fractures and return patients to pre-morbid functionality. When SIGN interlocking screws are unavailable, fully threaded, cortical screws are used to lock SIGN nails. This technique especially proved useful in 2020 amidst the COVID-19 pandemic when travel and shipping restrictions were in place as nations implemented lockdowns and community quarantines.

After a review of available literature, this research was noted to be the first to compare locking screws among SIGN nails. The use of fully threaded, cortical screws to lock intramedullary nails was first documented in 1990 when biomechanical testing showed that its mechanical strength allowed loading up to 4500 N [10]. In an intramedullary nail, the interlocking screws serve as load-bearing constructs whose breaking point is directly proportional to its cortical contact, length, and core diameter [3, 4]. To avoid stress risers, the screw length must maximize cortical contact and its diameter must be less than 50% of the nail diameter – both criteria satisfied by fully threaded, cortical screws [10].

Upon reviewing the SIGN database from January 2018 to August 2021, 79 patients were identified who met the inclusion and exclusion criteria of this study. There was an

81.4% union rate within 12 weeks among the cases which used solely SIGN interlocking screws and 80% among those which incorporated fully threaded, cortical screws. Screw failure was not observed in 96.8% of the cases which used solely SIGN interlocking screws and in 95% for those which incorporated fully threaded, cortical screws.

The chi-square test was employed to determine significance in the difference of outcomes between the two groups with $p < .05$ showing statistical significance. It showed that incorporating fully threaded, cortical screws to lock SIGN nails is comparable to using solely SIGN interlocking screws in terms of fracture union and screw failure rate.

The findings of this study will help surgeons in decision-making when faced with the scenario of limited SIGN interlocking screws for available SIGN nail sizes. Being able to incorporate available fully threaded, cortical screws to lock SIGN nails will allow more patients to benefit from the implants.

5. Conclusion

Among the cases from January 2018 to August 2021 included in this study, 59 used solely SIGN interlocking screws and 20 incorporated fully threaded, cortical screws. Cases of the former presented with 91.5% acceptable alignment, 81.4% fracture healing within 12 weeks, and 96.8% rate of no screw failure. Cases of the latter presented with 90% acceptable alignment, 80% fracture healing within 12 weeks, and 95% rate of no screw failure. The chi-square test showed no statistical significance in outcomes between the two groups.

This study concludes that using 4.5 mm, fully threaded, stainless steel, cortical screws is comparable to using SIGN interlocking screws in terms of fracture union rate with no increased risk for screw failure. According to AO, interlocking screws are load-bearing constructs whose breaking point is directly proportional to their cortical contact, length, and core diameter [2, 3]. As long as the fully threaded, cortical screws used to lock an intramedullary nail have sufficient length to maximize cortical contact and have diameters less than 50% of the nail diameter, they are biomechanically sound to serve as interlocking screws [10].

This study can be further improved by increasing the number of cases enrolled and by stratifying the outcomes of the comparison group based on the number of fully threaded, cortical screws incorporated.

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