International Orthopaedics (2019) 43:433–440
https://doi.org/10.1007/s00264-018-3966-z

ORIGINAL PAPER

Complications in patients with intramedullary nails: a case series from a single Cambodian surgical clinic

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Received: 30 October 2017 / Accepted: 30 April 2018 / Published online: 28 May 2018

Abstract

Purpose Since its development in 1999, the SIGN nail has been used in over 190,000 surgeries spanning 55 countries. To date, however, evaluation of SIGN nail outcomes has been limited to small prospective studies or large retrospective studies using SIGN's online database. This study uses the experience of a single, independent Cambodian surgical clinic to characterize common complications, provide commentary on ways to reduce the risk of those complications, and determine whether several observed nail fractures were due to metallurgic defects.

Methods Clinic medical records were queried to identify complications in patients with SIGN nails. Data was abstracted including age, sex, mechanism of injury, and latency between injury, primary implantation, and presentation with a complication. Two nails that fractured in vivo were analyzed by light microscopy, scanning electron microscopy, and polarized light microscopy after chemical etching.

Results Fifty-four complications in 51 patients were identified. The most common complications were non-union ($n = 26$, 48%), infection ($n = 16$, 30%), flexion limitation ($n = 11$, 20%), nail fracture ($n = 4$, 7%), delayed union ($n = 4$, 7%), and malunion ($n = 4$, 7%). Other complications included broken or floating screws. Fractography revealed that two of the fractured nails most likely failed by fatigue followed by fast fracture at the site of non-union. We found no evidence of intrinsic nail defects. We identified multiple inconsistencies between SIGN's database and independent clinic records.

Conclusions Non-union and infection were common relative to all complications. Based on radiographic review, risk for non-union and malunion can be minimized by selecting an appropriate nail diameter, using multiple interlocking screws, and employing the correct implant and approach for fracture morphology when using SIGN nails. Nail fractures were unlikely to be caused by metallurgical flaws. Further study is necessary to determine the appropriate management of non-unions based on radiographic and clinical factors.

Keywords SIGN nail · Non-union · Nail fracture

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Introduction

The SIGN Fracture Care International intramedullary (IM) nail is an FDA-approved fixation device for long bones, specifically designed for use in low- and middle-income countries where resources—including image intensifiers, power reaming, and fracture tables—are limited [1]. Since its development in 1999, it has been used in over 190,000 surgeries at 300 hospital sites in 55 countries worldwide [1]. SIGN nails are often provided at no cost to hospitals and surgeons, who report operative and outcome data in an internet-accessible private registry, the SIGN Online Surgical Database (SOSD) [2]. SIGN surgeons have published several studies of surgical outcomes, and the growing prevalence of SIGN nail

implantation in the past decade increases the need to continue evaluating these outcomes in resource-restricted settings.

Evaluating the incidence of surgical complications in developing countries is an intractable challenge, complicated by low follow-up rates, elusion of post-discharge surveillance, presentation to outside clinics, incomplete or inaccurate hospital records, injury preventing representation, and death. Patients may avoid post-discharge detection through presentation to other clinics, including free or low-cost non-governmental organization (NGO) clinics that did not perform their primary operations. Despite these epidemiological challenges, several studies have prospectively and retrospectively evaluated the incidence of post-operative complications after SIGN nail implantation. Prospective studies have included small population sizes, resulting in large confidence intervals for complication rates and uncertainty with regard to the types of complications experienced [3–7]. Alternatively, retrospective studies have primarily employed the SOSD, report follow-up rates around 20%, and report overall complication rates that are below those reported by prospective studies [8, 9]. This corpus of literature has yielded few detailed descriptions of complications following SIGN nail operations.

The purpose of this study is to describe a series of 54 complications following SIGN nail surgeries, all of which were managed at an NGO surgical clinic in Phnom Penh, Cambodia.

Material and methods

Patients implanted with SIGN nails were identified retrospectively by electronic medical record (EMR) at Children's Surgical Centre (CSC) in Phnom Penh, Cambodia. From this cohort of patients, complications were identified by screening consultation notes, operative notes, and radiographs. CSC is not in the SIGN network, but accepts low-income patients from throughout Cambodia and Phnom Penh and thus manages patients whose primary operations were performed by SIGN surgeons in the region. Criteria for complications were guided by Audige et al. [10]. We restricted our study to local complications including nail fracture, infection (defined by 2008 Centers for Disease Control and Prevention criteria) [11], non-union, delayed union requiring management (operative or non-operative), malunion (> 5° of varus/valgus angulation in either the tibia or femur), leg length discrepancy ≥ 3 cm, flexion limitation ≤ 90° at the knee, nerve palsy, extrusion of implants through the skin, or screws that either missed the interlocks, loosened due to non-union, or broke. Non-unions were defined as fractures that were at least 6 months post-injury and, in the opinion of the treating surgeon, had no possibility of healing without further intervention, a more conservative definition than that of Brinker and O'Connor [12]. They were determined by a panel of surgeons who performed the revision operations in Cambodia and reviewed by two trauma surgeons at the University of Washington Medical Center in Seattle, WA. We excluded patients who lacked radiographs. We then queried the SIGN SOSD to obtain the date of index operation, pre-operative X-rays, and X-rays immediately post-operation for patients whose records were available.

Collected data included age, sex, mechanism of injury, latency between injury and primary implantation as recorded in the SIGN SOSD, the hospital at which the primary implantation occurred, the long bone affected, latency between implantation and presentation to CSC for complication (using implantation date from the SOSD when available), and how the complication was managed by CSC. SIGN Fracture Care International provided the total number of operations performed in Cambodia between 2003 and 2015.

For select nails, fractography was performed at the Dartmouth Biomedical Engineering Center using light microscopy and scanning electron microscopy (SEM) under × 50, × 100, and × 500 magnification to visualize the fracture surface. To expose and examine microstructure, a 3:1 hydrochloric acid:nitric acid solution (Aqua regia) was used for etching, followed by examination with a polarizing adapter.

Results

Fifty-four complications in 51 patients were identified in our study. One patient with multiple complications was included who had both aseptic femoral non-union and septic tibial non-union. Another presented with flexion limitation after 49 days and was then treated with proximal screw dynamization for hypertrophic non-union at after 309 days. The third presented with flexion limitation and non-union, followed by an infection 70 days after being treated with dynamization. Characteristics of the patient population are recorded in Table 1. There were no statistically significant differences between subgroups. Only 29 (57%) of the patients identified at CSC could be located in the SIGN database after rigorous searching. Of these, 18 (62%) had names with different spellings in the SIGN and CSC databases and were located by comparing radiographs and other data.

Data for latency between injury and implantation was available for 27 surgeries resulting in 28 complications. Data for latency between implantation and complication was available for all complications using the implantation date from either the SOSD (28 complications) or the CSC EMR (26 complications). According to SIGN, over 8700 SIGN operations have been performed in Cambodia since 2003.

Mechanisms of injury are reported in Fig. 1. The majority of complications occurred in patients undergoing treatment for femoral fractures (Fig. 2).

Non-union was the most common complication, occurring in 26 (48%) cases. Of these, 22 were atrophic or oligotrophic,

Table 1 Characteristics of study population

Characteristic	All patients ($n = 51$)	Femur complications ($n = 34$)	Tibia complications ($n = 19$)
Age: median (range)	28.5 (17–84)	28.5 (18–84)	29 (17–63)
Sex: male (%)	41 (80)	27 (84)	13 (68)
Time of injury to implantation: median (range)	2 days (0–356), ($n = 27$)	2 days (0–159), ($n = 19$[a])	38 days (0–356), ($n = 9$)
Time of implantation to complication: median (range)	269 days (16–2276)	282 days (48–2276)	271 days (16–1573)

[a] One patient had two complications at the femur and was counted twice

and four were hypertrophic. Management of non-unions ($n = 26$) included dynamization ($n = 16$), referral to a different hospital ($n = 3$), nail exchange ($n = 2$), and observation with unclear resolution ($n = 2$). Other complications included infection ($n = 16$, 30%), flexion limitation ($n = 11$, 20%), nail fracture ($n = 4$, 7%), delayed union requiring operative or non-operative management ($n = 4$, 7%), malunion ($n = 4$, 7%), and leg length discrepancy ($n = 3$, 5%) (Fig. 3).

Analysis of two fractured SIGN nails to determine failure mechanism

Seventeen explants had been retained by clinic staff. Of these, two nails had fractured in vivo. They were preserved in formalin and transported to the Dartmouth Biomedical Engineering Center for analysis to characterize implant materials and determine the mechanism of failure.

Nail 1: The fractured SIGN nail was removed from a 27-year-old male initially treated for a diaphyseal femur fracture following an MVA in July 2014. After a fall from unknown height in May 2015, the patient presented in August 2015 with impaired mobility and non-union (Fig. 4). The patient was treated with revision IM nailing with autograft. Fractography by SEM (right) demonstrates that the nail failed by a fast fracture with a single point of initiation, although the nail's fracture plane was marred by in vivo wear. The microstructure of nail 1 was exposed by chemical etching (middle) and is presented under magnification. This revealed small, ~ 50-μm grains with signs of twinning within the grains.

Nail 2: The fractured nail was removed from a 26-year-old male with an established tibial non-union 2 years after his index operation (Fig. 5). His index surgery consisted of proximal tibial insertion (top left). He presented to CSC in November 2015 and was found to have a fracture of the nail at the distal midshaft, several inches above the distal screw insertion (middle). The patient was treated with exchange nailing and autograft. Fractography by SEM (top right and bottom left) and light microscopy (bottom right) demonstrates 1) a fast fracture with a single point of initiation and transverse propagation across the fracture surface, and 2) fatigue striations or "beach marking" consistent with a locus of progressive nail fatigue from successive loading cycles at the point of non-union.

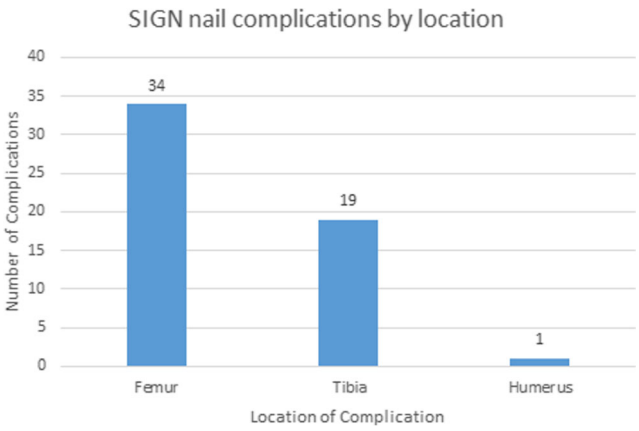

Fig. 1 Complications by location

Discussion

Complications after SIGN nail operations

Over 8700 SIGN operations have been performed in Cambodia since 2003, when the program was started in the country. In this study, 54 SIGN nail complications were identified by EMR search at CSC, making this the largest series of complications after SIGN nail operations reported in literature. No SIGN nail fractures have previously been published.

The study group consisted of a majority male population (80%). The male predominance is consistent with other studies of orthopaedic trauma in the developing world [13].

Non-union was the most common complication presenting to CSC. Other SIGN nail studies have identified non-unions after operation, but there is no evidence suggesting that SIGN nails are prone to this complication [14]. Moreover, non-unions with and without nail fractures and/or infections have been observed in studies of other nail designs in first-world countries. Patient-dependent risk factors for non-union include tobacco use, NSAID use, poor nutrition, advanced age, metabolic bone disease, and medical comorbidities such as diabetes. Patient-independent risk factors include fracture

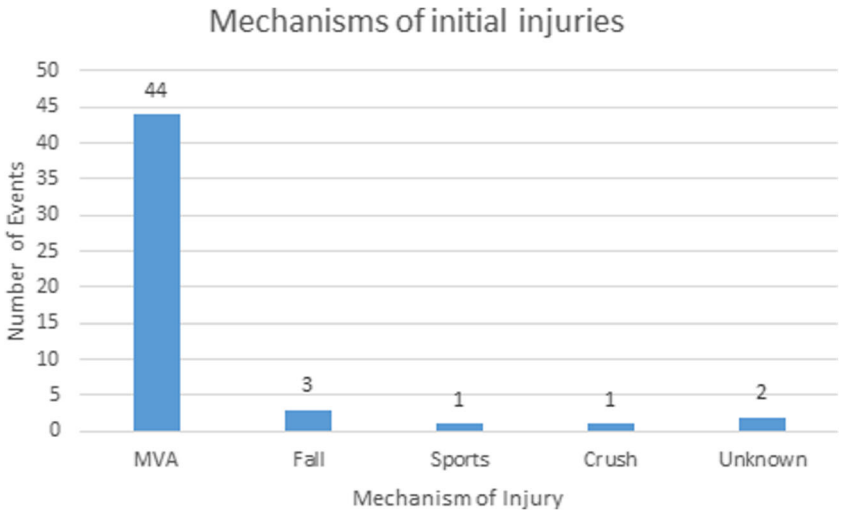

Fig. 2 Mechanisms of initial injuries in patients who presented with complications to a free surgical clinic in Phnom Penh, Cambodia

characteristics, instability, inadequate blood supply, inadequate bone contact, the quality of the surgical team, inappropriately sized nails, and infection [15–17]. In low- and middle-income countries, prevalence of these risk factors increases the non-union risk. In this series, the majority of nails in cases of non-union had a single distal interlocking screw and several nails were inappropriately sized. Interestingly, one case of femoral non-union initially identified as a complication at CSC was managed conservatively by an outside hospital and went on to heal. This case, along with anecdotal reports from SIGN surgeons, raises the possibility that some fractures categorized as non-unions in this series may have continued to union with conservative or medical management alone. Unfortunately, follow-up data from these patients was too incomplete to study how management of non-unions and delayed unions affected outcomes. Femoral non-union was more commonly observed than tibial non-union in our series.

Infection was the second most common complication in this series. Of these, 10 (63%) presented with an additional complication, including leg length discrepancy, protruding screws, and non-union or delayed union. Post-discharge infection is a concern in low- and middle-income countries due to the high proportion of patients who are implanted after high-energy traumas or poly-traumas with open fractures, and there is a perception that infection rates are intrinsically higher in these areas. In addition, the prevalence of tobacco use among men in Cambodia is estimated at 49% by the WHO and is associated with infection and osteomyelitis after fractures of the tibia and femur. Furthermore, climatic and hygienic conditions within many operating rooms in Cambodia do not meet the standards of most developed nations. It is not uncommon for surgical observers to include the occasional winged arthropod, at least as eager but far more unwelcome than a visiting medical student. However, two similar studies utilizing the SOSD have reported low rates of post-operative infections (3.2% for femoral fractures and 6.9% for tibial fractures with 23.1% follow-up

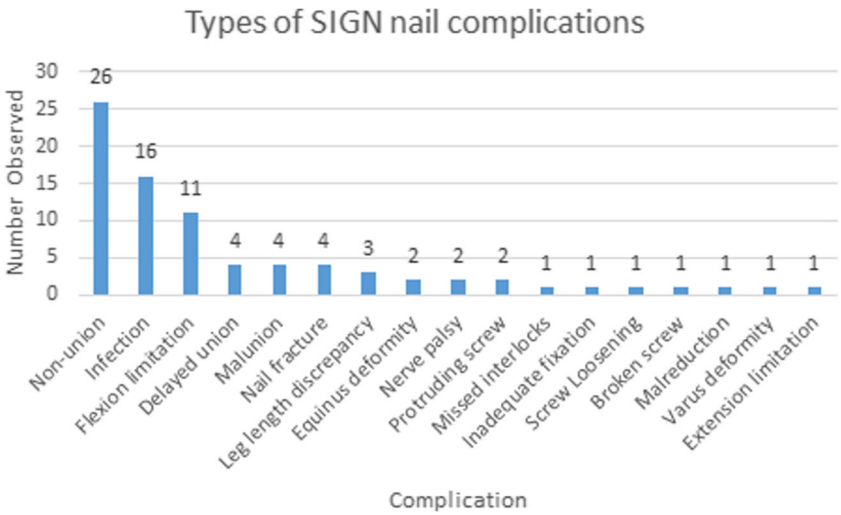

Fig. 3 Complications by type

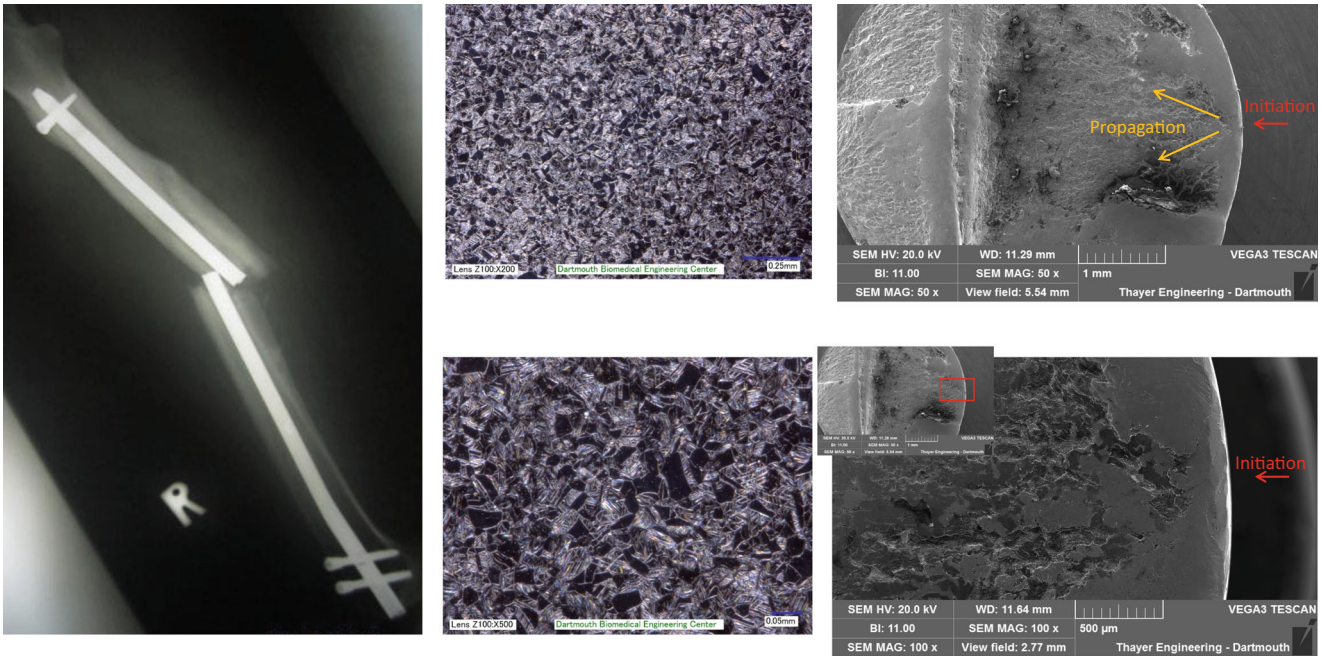

Fig. 4 Vignette of SIGN nail 1

after over 34,000 operations) [8, 9]. These infection rates are low considering environmental factors; by comparison, surgery performed in developed nations are complicated by infection at a reported rate of 0–6% for femoral fractures and 1.8–12.5% for tibial fractures [7, 18–21].

In an effort to explore the impact of low follow-up rates on infection surveillance in the SOSD, a prospective study of 141 SIGN implantations was conducted in Malawi in 2013 with aggressive post-discharge follow-up. The authors traveled over 2000 km "on, at times, barely passable roads" in order to

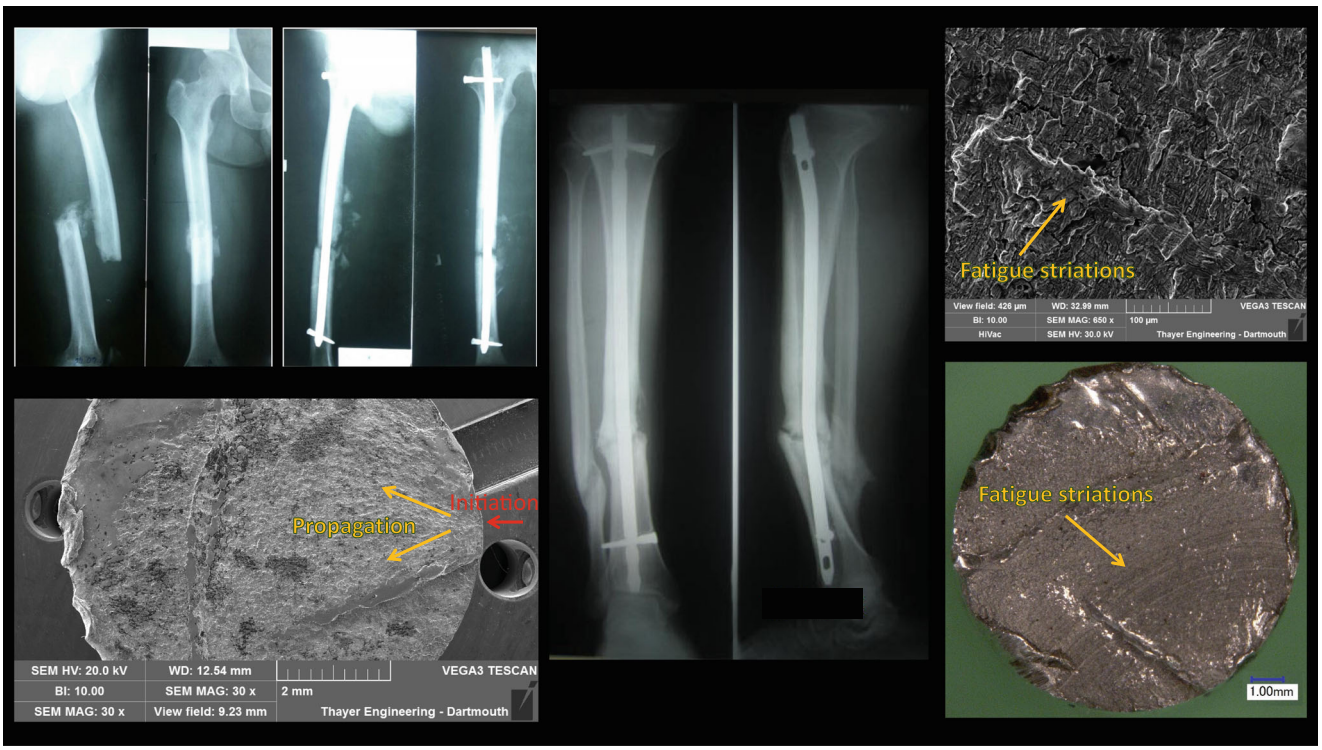

Fig. 5 Vignette of SIGN nail 2

achieve 79% follow-up, yielding an overall infection rate of 6%, and a deep infection rate of 5% [14]. This and other studies of SIGN operations have concluded that low follow-up rates do not have a significant influence on overall infection rates because patients with no complications are the most likely to avoid follow-up, often citing cost of transportation [8, 14]. A possible confounder in determining post-discharge infection rates in previous studies is presentation of patients to an outside hospital, as seen in our study. We expect that this phenomenon varies considerably by geographic region and by accessibility to centralized health care infrastructure.

Knee stiffness was experienced by 11 patients (20%). Ten of these occurred following femoral fractures; six nails were retrograde insertions and four were anterograde. Impaired knee mobility has been documented after retrograde femoral insertion of SIGN nails, but the sample size is small [7]. Knee stiffness after antegrade femoral nailing is an uncommon but reported complication. There are several potential explanations for post-operative knee stiffness in the antegrade nailing cohort. In patients with a femoral shaft fracture, significant ipsilateral knee injuries occur in up to 50% of patients. The true incidence of associated meniscal, ligamentous, and osteochondral injury to the knee after femoral shaft fracture is unknown because of missed injuries and variable patient cohorts studied. An undiagnosed associated knee injury increases the risk for knee stiffness and is a possible explanation for knee stiffness in the antegrade nailing cohort. Additionally, standard post-operative protocol after antegrade nailing includes early active and passive knee range of motion, often guided by physical therapy. If this is not encouraged early, the patient may be at risk for developing knee stiffness. In patients with limited follow-up visits, knee stiffness may result from a lack of early detection and intervention. The patients in this cohort are unlikely to have access to physical therapy; thus, even if knee stiffness is detected post-operatively, it may not be optimally managed.

Additional complications included leg length discrepancy, protruding screws, inadequate fixation, and screw loosening. The inadequate fixation resulted from proximal screw insertion into a comminuted fragment in the proximal femur that migrated superiorly after the operation. Screw loosening was due to mechanical failure. Both cases with protruding screws were referred back to the operating hospital. In one, the patient manually removed the screws extruding through her skin at two years post-op and experienced an infection with a weeping sinus two years later, which precipitated her appointment.

While no SIGN nail implant fractures have been previously reported, four were identified in this study, and two were analyzed by fractography. Failure was determined to be a result of a combination of cyclic stress and nail fatigue followed by rapid fracture in one nail. The other appeared to fail from a single traumatic event. However, the fracture surface was worn from remaining in vivo, limiting our ability to analyze the fracture surface for beach marking, and radiographic atrophic non-union suggested a fatigue failure. Microstructure analysis revealed a uniform, small-grained structure with twinning, free of voids, indicating no stress risers from a metallurgical standpoint. Based on these results, the nails likely were manufactured appropriately, but weakened at the point of non-union prior to fracture. Thus, fatigue failure secondary to non-union was thought to be the most likely underlying mechanism for these nail fractures. This does not represent an intrinsic problem with the nail.

Previous reports of SIGN nail complications

There have been several previous efforts to characterize the incidence and types of SIGN nail complications in developing world hospitals, though most studies have had population sizes of 50 or fewer. Prospective cohort studies of SIGN nails in Uganda ($n = 50$ patients), Nigeria ($n = 40$, $n = 37$), and Pakistan ($n = 50$) found complication rates between 12.5 and 28%, with types and proportions of observed complications similar to our study, but no broken nails [3–5, 7]. Young, et al. evaluated multiple primary endpoints in their prospective study of 141 patients in Malawi, but primarily focused their discussion on rates of infection and death [14]. Our study could not evaluate death as a complication because these patients do not present, and it is unlikely that implant type is the major determinant of mortality following long bone fixation.

More scholarship is necessary to evaluate the complications of SIGN nails relative to alternative treatment options. In a retrospective cohort study comparing 48 SIGN nails to 20 cannulated nails, no statistically significant differences were seen with respect to radiographic union, superficial surgical site infection, or overall complications [6]. However, future studies should be appropriately powered to detect statistical significance for differences in complication rates of the magnitude observed in the study. These complication rates should be interpreted in light of the challenging working environments and postoperative risks of the developing world.

Mechanisms of initial injury

In our study, motor vehicle accidents were the cause of 86% of the initial injuries in patients who had been implanted with a SIGN nail and later presented to CSC with a complication. A significant proportion of orthopedic trauma in the developing world is the result of motor vehicle trauma. According to the World Health Organization, three people are killed and 100 injured on Cambodian roads daily [22]. In Phnom Penh and surrounding areas of Cambodia, motorbikes are the primary means of conveyance and are involved in the majority of traffic accidents [23]. Despite a high vehicle volume, traffic signs and lights are scarce and inconsistently heeded, sidewalks are often shared with motorbikes, and at most intersections, there do not

appear to be rules governing traffic flow beyond common sense and caution. This is a ripe environment for orthopaedic trauma. Cambodia has the highest motorcycle death rate in Southeast Asia, with motorcyclist fatalities increasing by about 30% from 2007 to 2011 [24]. Low- and middle-income countries have a rate of femoral shaft fractures roughly twice that of high-income countries [25].

Limitations

Complications of SIGN nails observed at CSC may be under reported due to the specificity of the search terms used in EMR review. Like many clinics in the developing world, clerical errors are common within the EMR (only 57% of patients presenting to CSC could be located in the SIGN database and only 62% of these were listed under the same name) and details surrounding diagnosis and management are often incompletely reported.

Due to retrospective study design, we were unable to locate much of the clinical data that was used to determine the presence of surgical site infections. Although this does not differ significantly from retrospective chart review in developed countries, some patients' documented clinical histories would benefit from photos or laboratory data in instances where infection was not otherwise evident. In addition, we were unable to rely on comprehensive documentation of medical comorbidities, which may be relevant for future studies of implant infection in similar cohorts.

This study lacks denominator data, making the total complication rate for these operations impossible to derive. The clinic in which the complications were identified did not perform the primary SIGN nail operations; thus, it was not possible to determine the incidence rate of SIGN nail complications out of the 8700 primary surgery performed in Cambodia during this period. Cambodia is a unique practice setting in which the potential for complications is likely much higher than in the developed world. As such, a well-designed implant may be prone to a higher complication rate due to impaired wound healing, operational error, secondary infection, or refracture. The number of complications observed in this study should be interpreted with respect to the thousands of primary operations performed by SIGN in Cambodia since 2003.

Recommendations

Based on the data obtained in this case series, we make several recommendations. To reduce the rate of non-union, we recommend the use of appropriately sized nails with a tibial canal diameter ratio between 0.8 and 0.99 [17] and femoral nail diameters yielding similarly intimate fit. Selection of larger diameter nails may also decrease the risk of fatigue fractures such as those observed in our study [26]. Surgeons should also consider the use of two distal interlocking screws to increase construct stability.

SIGN uses both radiographic (e.g., cortical union) and clinical ("squat and smile") criteria for diagnosing femoral non-unions [27]. We recommend further study of outcomes following non-unions to determine their appropriate management based on complete clinical and radiographic features.

We reiterate the recommendation of several authors that an adequately powered, independent, prospective, multicenter study with aggressive, standardized post-discharge follow-up be performed comparing SIGN nails to other implant types. However, we acknowledge the difficulty of accomplishing this in resource-poor settings where SIGN nails are needed most.

Finally, we hope that future observations of surgical complications continue to be coupled with cost-benefit analysis, as free and low-cost orthopaedic devices such as SIGN nails have previously been shown to improve outcomes for a growing number of patients in developing countries who could not otherwise afford treatment [28].

Acknowledgments The authors would like to thank SIGN Fracture Care International and Dr. Lewis Zirkle for providing data and contextual information for this study.

Compliance with ethical standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required. This article does not contain any studies with animals performed by any of the authors. The Dartmouth Biomedical Engineering Center performed implant analysis pro bono and SIGN allowed use of a subset of its database without charges.

Conflict of interest The authors declare that they have no conflict of interest.

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