

Management of Closed Femur Fractures with the SIGN Intramedullary Nail in Two Developing African Countries

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Purpose: The Surgical Implant Generation Network (SIGN) intramedullary nail was designed for use in developing settings that often lack fluoroscopy or power instrumentation. Our purpose was to evaluate the clinical and radiographic outcomes of closed femoral shaft fractures fixed with the SIGN nail in two developing African countries.

Methods: Data from the SIGN online database was reviewed for all closed femur fractures treated with the SIGN nail at two mission hospitals in sub-Saharan Africa. Demographics, time to surgery, fracture classification (AO/OTA), antegrade versus retrograde approach, open versus closed reduction, number of follow-ups, time to union, and complications were recorded. Only patients with at least one follow-up visit were included in the analysis.

Results: Between September 2008 and November 2012, 471 patients were treated with the SIGN nail for closed femur fractures. Of these, 235 patients (240 fractures) returned for at least one postoperative visit. Average age was 43.3 years (Range 14-87). Average time from injury to fracture fixation was 6.1 days (Range 0-60 days). Nails were placed antegrade in 137 fractures (57%) and retrograde in 103 fractures (43%). Open reduction was performed in 208 cases (87%). Average length of follow-up was 99.7 days (range 15-838 days). Average number of follow-up visits per patient was 1.6. Average time to union was 96.1 days (Range 21-707 days) for those patients (154 fractures, 64%) with enough follow-up to show radiographic union. Overall, 26 complications occurred in 23 patients (9.6%). The most common complication after retrograde nailing was knee stiffness, representing 7 of 14 complications (50%) in this group. Varus mal-union of proximal femoral shaft fractures accounted for 5 of 12 complications (42%) after antegrade nailing. Other complications included deep infection in four patients (1.5%), nonunion in three patients (1%), and peri-prosthetic fractures at the proximal tip of the nail after retrograde nailing in two patients (0.8%). Revision surgery was performed in 12 patients (5%).

Conclusion: Closed femur fractures can be managed successfully in developing countries using the SIGN nail with acceptable rates of complications and reoperation. Predictable complications related to surgical approach and fracture location were observed. Although radiographic union was confirmed in only 64% of fractures, many patients were lost to follow-up prior to the time of expected radiographic union. Known geographic and financial barriers common in the developing world create a disincentive for asymptomatic patients to return for routine follow-up visits. Low rates of deep infection and nonunion were seen despite the fact that open reduction was performed in the vast majority of cases. These favorable outcomes further support the utility of the SIGN nail for intramedullary fixation of closed femur fractures in the developing world.

- The FDA has not cleared this drug and/or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an "off label" use). For full information, refer to page 496.

Δ The Design of a Prospective Observational Study to Evaluate the Outcomes of Operatively Treated Femoral Shaft Fractures in Sub-Saharan Africa

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Purpose: We designed a prospective study to compare the outcomes of intramedullary nailing and plate fixation of femoral shaft fractures at a tertiary referral center in Sub-Saharan Africa. In the current study, we aim to describe the design of this prospective investigation, the challenges discovered during implementation, and the novel approaches used to successfully conduct a clinical study in a low-resource environment.

Methods: The study design is a prospective observational study enrolling skeletally mature patients with OTA type-32 femoral shaft fractures who undergo surgery at a single center in Sub-Saharan Africa. The primary outcome is reoperation, and secondary outcomes are EQ-5D (EuroQol), clinical and radiographic union, and return to work. Our power analysis suggested that 330 patients would be needed to address the primary hypothesis. Follow-up data are collected at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year postoperatively. Incentives to encourage follow-up include (1) free follow-up care, (2) a dedicated Saturday research clinic, (3) phone and SMS (text messaging) appointment reminders, and (4) transportation (for 1-year follow-up only). All data entry is performed using portable laptops with secure, web-based data entry using Research Electronic Data Capture (REDCap). Images of plain radiographs are collected and transmitted electronically using mobile phones with customized data entry forms using Open Data Kit (ODK). There are two part-time local research coordinators and two primary investigators at the local site. The study was approved by the ethical review board of both the US institution and the Ministry of Health in Tanzania.

Results: In the first year after initiating the study, we have enrolled 313 patients (719 radiographically screened, 331 clinically screened, 313 enrolled). The population consists primarily of young (mean age, 31.7 years) men (88.9%) with isolated femoral shaft fractures suffered in road traffic accidents (79.2%) treated with open reduction and locked medullary nailing without C-arm. The follow-up rate at 6 months is 69% (99/144). The two part-time local research coordinators are able to successfully manage the day-to-day operations of the study including electronic data entry and patient follow-up coordination. Important challenges overcome include navigating the local IRB, training local coordinators, and subcontract initiation. The most common reasons for loss to follow-up include the failure to collect accurate contact information at baseline and lack of transportation.

Conclusion: Medical centers in many low-income countries treat an extremely high volume of traumatic injuries, but there is very little research from these settings to guide treatment decisions. We have designed a prospective study to determine the outcomes of femoral shaft fractures, with successful enrollment and short-term follow-up despite the high clinical volume and shortage of resources. The collaborative effort between institutions has fostered locally appropriate solutions that we believe can serve as a model to inform future studies.

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See pages 91 - 132 for financial disclosure information.