**A Pilot Randomized Clinical Trial to Compare Intramedullary Nailing to Uniplanar External Fixation for Open Tibial Shaft Fractures in Tanzania**

*Max Liu, BA[1]; David Shearer, MD[1]; **Kurt Yusi, MD**[1]; Saam Morshed, MD[1]; Edmund Eliezer, MD[2]; Billy Haonga, MD[2]*
*[1]University of California San Francisco, San Francisco General Hospital, Orthopaedic Trauma Institute, Institute for Global Orthopaedics and Traumatology, San Francisco, California, USA; [2]Muhimbili Orthopaedic Institute, Dar es Salaam, TANZANIA*



**Background/Purpose:** The incidence of severe musculoskeletal injuries continues to climb in low- and middle-income countries (LMICs). Much can be gained from conducting research in these settings to evaluate treatments and therapeutic outcomes. The randomized controlled trial (RCT) is the most rigorous study design and provides the most unbiased results. However, conducting a large-scale RCT in developing settings poses significant challenges. Indeed, a recent scoping review of clinical orthopaedics research conducted in LMICs found that between 2004 and 2014, only 22 RCTs achieved Level 1 evidence. We report a pilot prospective RCT comparing superficial infection rates between the intramedullary (IM) nail and external fixator (EF) for the treatment of open tibia fractures in Tanzania.

**Methods:** Enrollment for the 2-month pilot RCT began in December 2015. All patients with open tibia fractures who presented to the study center were screened for eligibility. Patients with AO/OTA Type 42 open tibia fractures who met criteria were invited to enroll in the study. Any open fracture wound that was primarily closable at the index operation was included (Gustilo Type I, II, or IIIA). Patients were randomized to receive either a SIGN (Surgical Implant Generation Network) interlocking IM nail or AO single bar, uniplanar EF. All patients were invited for a follow-up wound check at 2 weeks. The primary outcome was surgical site infection (SSI) incidence as defined by CDC guidelines. All data entry was conducted on REDCAP using password-protected laptops. Four international investigators, two local investigators, and three local research coordinators served as the core research team for this study.

**Results:** 95 patients presented with open tibia fractures at the study site during the2 -month enrollment period and were screened for eligibility. Among patients screened, 40 patients (42%) met the eligibility criteria and all eligible patients consented to participate in the study (100% enrollment rate). 20 participants were randomized to each treatment arm. 38 patients (95%) were male and 2 (5%) were female. The average age was 33 ± 12 years (range, 18-70; median, 29). The most common mechanism of injury was road traffic injury (92.5%). 5% of patients had associated injuries (3 floating knees and 2 mild head injuries). The mean time from injury to presentation was 11.9 ± 7.4 hours. The mean time from presentation to surgery was 11.6 ± 8.9 hours. IM nail operations took on average 88 ± 88 minutes while EF operations took 47 ± 14 minutes (P = 0.0465). 39 patients attended the 2-week wound check visit. One patient could not be contacted. A total of 12 patients (30%) had superficial site infections; 7 (17.5%) were in the EF group and 6 (15%) were in the nail group (P = 1.000). No patients had deep infections.

**Conclusion:** In summary, this pilot study achieved a high screening rate, enrollment rate,

See pages 49 - 106 for financial disclosure information.

and early follow-up using the established protocol. These data demonstrate the feasibility of implementing and executing a large-scale RCT for open tibia fractures in this setting. Many unique solutions were developed to address the lack of available research infrastructure that may be useful to other investigators aiming to conduct research in LMICs. Based on the results of this pilot, this investigation will be expanded into a large-scale RCT powered to address the primary research hypothesis with follow-up to 1 year.