

Unreamed Intramedullary Nailing Versus External Fixation for the Treatment of Open Tibial Shaft Fractures in Uganda: A Randomized Clinical Trial

Kisitu Kyengera, MMED (Ortho); Nathan N. O'Hara; Gerard Slobogean, MD; Andrea Lynn Howe, BS; Peter Joseph O'Brien, MD; David John Stockton, MD Mbarara University Hospital, Mbarara, Uganda

Purpose: In low-income countries, external fixation is often the standard of care for the definitive treatment of open tibial shaft fractures. In contrast, intramedullary (IM) nailing is the standard in most high-income countries. We performed a parallel-group, randomized clinical trial at a regional hospital in Uganda to compare unreamed IM nailing versus external fixation to treat open tibial shaft fractures.

Methods: We screened all skeletally mature patients presenting with open tibial shaft fractures to the study location. Patients were included if they presented with Gustilo-Anderson type II or IIIA open tibial shaft fracture and received definitive treatment within 24 hours. Our primary outcome was the Function Index for Trauma (FIX-IT), measured at 6 weeks, 3 months, 6 months, and 12 months after randomization. Secondary outcomes included quality of life (EuroQol 5 Dimensions 3 Levels [EQ-5D-3L]), malunion, nonunion, and deep surgical site infection. We calculated treatment effects using Bayesian models informed by prior meta-analysis data, which suggest a medium treatment benefit with IM nailing. Bayesian analyses do not produce P values but, rather, calculate the probability of treatment benefit. In these analyses, we estimate if the probability of treatment benefit in our study population continued to favor IM nailing at levels consistent with prior high-income country data.

Results: The trial enrolled 55 patients (n = 31 to IM nailing and n = 24 to external fixation) with a mean age of 39 years (standard deviation [SD]: 12), and 65% were male. IM nailing improved the 1-year average FIX-IT score by 1.4 points (95% credible interval [CrI], 0.7 to 2.1) compared with external fixation. Given these results, the probability of any improvement in the FIX-IT score with IM nailing was 99%, but the probability the difference exceeds previously reported effects was only 38%. IM nailing also increased 1-year quality of life by 0.05 points (95% CrI: 0.00 to 0.10) and decreased rates of malunion (difference, -14%; 95% CrI: -27% to -2%) and nonunion (difference, -5.3%; 95% CrI: -18% to 5%). The probability of treatment benefits with IM nailing exceeding prior estimates of quality of life, malunion, and nonunion were 45%, 73%, and 50%, respectively. The rates of deep infection did not differ between groups (difference, 0%; 95% CrI: -18% to 19%).

Conclusion: Our findings suggest that IM nailing has broad treatment benefits compared with external fixation for the treatment of open tibial shaft fractures in low-resource settings. However, it is unlikely that these treatment benefits exceed the minimal clinically important differences necessary to justify the additional costs and resources required for IM nailing, given the economic constraints in many low-income country hospitals.