

**Outcomes of Intramedullary Nailing Versus External Fixation in the Treatment of Open Tibial Fractures: 3 to 5-Year Follow-up Study of a Randomized Clinical Trial**

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**Purpose:** Open tibial fractures are common injuries in low and middle-income countries. A randomized clinical trial (RCT) compared outcomes of intramedullary nailing (IMN) versus external fixation (EF) in adults with open tibial fractures in sub-Saharan Africa and found no difference in reoperation, although questions about late infection and union remained after 1 year. The purpose is to ascertain any differences in outcomes with longer-term follow-up.

**Methods:** The RCT included adults  $\geq 18$  years with acute AO/OTA type-42 open tibial shaft fractures who were randomly assigned to statically locked, hand-reamed IMN or uniplanar external fixation. These patients were re-evaluated 2 to 5 years after treatment. The primary outcome was death or reoperation for the treatment of deep infection, nonunion, or malalignment. Ongoing complications such as persistent fracture-related infection, nonunion, or malalignment were collected and analyzed. Secondary outcomes included quality of life as measured with the EuroQol-5 Dimensions (EQ-5D) questionnaire, function as measured with the Function Index for Trauma (FIX-IT) score, radiographic alignment, and healing as measured with the modified Radiographic Union Scale for Tibial fractures (mRUST).

**Results:** Of the 240 RCT patients, 121 (50.4%) (65 managed with IMN and 56 managed with EF) returned for follow-up at a mean of 4.0 years (range, 2.9-5.1 years). There were no significant differences in demographic factors or key injury characteristics between those with and without longer-term follow-up. 27 composite primary events occurred with rates of 21.5% and 23.2% in the IMN and EF groups, respectively (relative risk [RR] = 0.93, 95% confidence interval [CI] 0.48-1.80;  $P = 0.83$ ). There were no significant differences between the groups in terms of the rates of deep infection, nonunion, and malalignment. Four of these events (2 in the IMN group and 2 in the EF group;  $P = 0.88$ ) were newly detected at longer-term follow-up. Persistent complications in the form of ongoing fracture-related infection or nonunion were present at long-term follow-up in 29.6% of patients who sustained a primary event. FIX-IT scores, EQ-5D index, radiographic alignment, and mRUST scores were similar between the two groups at longer-term follow-up.

**Conclusion:** This study expands follow-up for the first RCT assessing IMN versus EF for the treatment of open tibial fractures in sub-Saharan Africa. While no differences in primary events were detected at a mean of 4 years after injury, fracture-related infection and nonunion complicate management of these severe injuries in nearly a quarter of patients.