

Modern External Ring Fixation Versus Internal Fixation for Treatment of Severe Open Tibial Fractures: An Observational Trial

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Purpose: Previous results of a randomized controlled trial evaluating the 1-year probability of major limb complication in severe open tibial shaft fractures treated by either modern ring external fixation (MREF) or internal fixation (IF) have been reported. The current study reports results of the observational arm of the same study protocol.

Methods: This prospective observational study included patients aged 18 to 64 with severe open tibial shaft fractures and candidates for a randomized trial comparing MREF and IF, who refused randomization and consented to enrollment in an observational arm. The primary outcome was major limb complication within 365 days after randomization refusal, including amputation, infection, soft-tissue problems, nonunion, malunion, and loss of reduction/implant failure. Analyses were performed for the observational cohort alone (MREF: n = 53, IF: n = 123) and combined randomized and observational cohorts (MREF: n = 174, IF: n = 249). Analyses were performed unadjusted with Fisher Exact tests and then using generalized linear models (GLM) to control for patient and injury factors.

Results: In the observational cohort, MREF patients were younger (31.3 vs 36.6 years, $p = 0.01$), had a lower body mass index (BMI) (26.7 vs 28.8, $p = 0.04$), and were more likely to have planned bone defect treatment (62.3% vs 32.5%, $p < 0.001$). One year postoperatively, MREF patients had higher rates of major limb complication (55.7% vs 37.1%, $p = 0.005$), nonunion (33.6% vs 18.6%, $p = 0.001$), and pin-tract infection (15.1% vs 0.8%, $p = 0.004$). In the combined cohorts, MREF patients had higher rates of major limb complication (59.3% vs 40.3%, $p < 0.001$), implant failure (14.6% vs 1.3%, $p < 0.001$), and pin-tract infection (18.9% vs 0.8%, $p < 0.001$). These findings remained significant both before and after adjusting (p -values for GLMs reported). Across all analyses, no significant difference was detected in rate of deep infection (MREF 17.3% vs 19.0%, $p = 0.75$, observational; MREF 23.6% vs 24.1%, $p = 0.78$, combined).

Conclusion: Similar to previously reported randomized results, the current study suggests severe open tibial shaft fractures treated with MREF have a higher risk of limb complications without reduction in deep infection risk.