Paper Session: Program Highlights

A Prospective Randomized Trial to Assess Fixation Strategies for Severe Open Tibia Fractures: Modern Ring External Fixators Versus Internal Fixation (FIXIT Study)

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Purpose: The treatment of high-energy open tibia fractures is challenging in both the military and civilian environments. Treatment with modern ring external fixation may reduce complications common in this patient population. However, no study to date has rigorously compared outcomes of modern ring external fixation with more commonly used internal fixation approaches. Our hypothesis was that modern ring fixators would reduce complications rates compared with internal fixation.

Methods: The FIXIT study is a prospective, multicenter randomized trial comparing 1-year outcomes following treatment of Gustilo-Anderson type IIIB or "severe" type IIIA open tibial shaft fractures among patients aged 18 to 64 years. Patients were randomly assigned to either modern ring fixation (external arm) or internal fixation (internal arm). The primary outcome was rehospitalization or same day surgery for at least 1 of 6 predefined major limb complications: infection, amputation, non-nion, malunion, loss of reduction and/or hardware failure, or soft-tissue problems. Kaplan-Meier was used to estimate the treatment-specific probability of at least 1 major limb complication within 365 days of randomization.

Results: The analysis included 254 patients (external: 122, internal: 132) enrolled at 20 centers over 7 years. The study group's average age was 39 years, and 63% of the patients were Gustilo-Anderson IIIB fractures. 94% of expected follow-up was achieved. The probability of at least 1 major limb complication within 365 days was higher for the external arm than the internal arm: 64.6% (95% confidence interval [CI]: 56.3% to 73.5%) versus 43.7% (95% CI: 35.7% to 53.1%), risk difference = 20.9% (95% CI: 8.3% to 32.8%, P = 0.002). The probability of at least 1 deep surgical site infection within 365 days was 26.1% (95% CI: 19.2% to 35.1%) in the external arm and 29.7% (95% CI: 22.5% to 38.7%) in the internal arm; the difference in risk was consistent with no effect (risk difference = –3.5%; 95% CI: –14.8% to 7.8%, P = 0.54).

Conclusion: This multicenter, rigorous randomized trial addresses a long-standing question regarding the potential of ring fixation to reduce complication rates associated with internal fixation of the most severe open tibia shaft fractures. The metal at the fracture site in internal fixation was thought to potentially lead to an increased infection rate compared to external ring fixators, but we did not observe an appreciable difference in deep infection. In contrast to our hypothesis, there was a clinically important advantage in the internal fixation group in the proportion of patients who sustained at least 1 major limb complication (43.7% vs 64.6%, P = 0.002). The results are informative to both surgeons and patients as we attempt to weigh the risks and benefits of these 2 different treatments for this very difficult patient population.