

Intramedullary Kirschner Wires Versus Titanium Elastic Nails for Pediatric Femur Fractures: Preliminary Results From a Randomized Clinical Trial in Dar es Salaam, Tanzania

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Purpose: Femur fractures in children are common injuries in the developing world. In children aged 5-12 years, these fractures have historically been treated with skeletal traction. The introduction of flexible intramedullary nails has revolutionized the care these injuries. Recently, use of intramedullary Kirschner wire (K-wire) fixation has been proposed as a low-cost alternative treatment option. The purpose of this study is to compare intramedullary K-wire to titanium elastic nail (TEN) for pediatric femur fractures in a resource-limited setting.

Methods: This is an interim analysis of an ongoing randomized clinical trial including 54 children at Muhimbili Orthopaedic Institute (MOI) in Dar es Salaam, Tanzania. All children aged 5-14 years presenting to MOI for acute traumatic diaphyseal fracture of the femur were considered for inclusion. The exclusion criteria were an injury older than 14 days, skeletal maturity, weight greater than 50 kg, metaphyseal or intra-articular femoral fracture, pathological fracture, segmental fracture patterns, and significant bone loss. Subjects were randomized to receive surgical treatment with either intramedullary K-wire or TEN. Subjects returned at 2 weeks, 6 weeks, 3 months, 6 months, and 12 months postoperatively. The primary outcome measure for this study was acceptable fracture union (modified radiographic union for tibial fractures [mRUST] score) or any complication requiring unplanned surgery (eg, deep infection, hardware failure) at 1 year after the surgery. Secondary outcomes include the Pediatric Quality of Life Inventory (PedsQL) and recovery milestones (time to walking with aids, time to independent walking, time until full activity allowed).

Results: To date, 49 patients (23 TEN, age 8.3 years; 26 K-wire, age 8.6 years) have been enrolled in the study with mean follow-up 7.2 months. Injuries were sustained in road traffic accidents (28), falls (13), crush (6), and sports injuries (1). There was no significant difference between TEN and K-wire groups in patient demographics or fracture pattern. There were similar rates of union between study groups at each measured time point. There was a positive correlation between mRUST score and Squat & Smile score. The PedsQL demonstrates improvement over the course of followup and there were no significant differences between the TEN and K-wire groups.

Conclusion: This study demonstrates preliminarily the non-inferiority of intramedullary K-wire to TEN for pediatric femoral shaft fractures. Furthermore, this study demonstrates the feasibility of implementing a randomized clinical trial for pediatric orthopaedic disorders in resource-limited settings.