Fixation of Distal Tibia Fractures (UK FixDT): A Randomized Controlled Trial of Locking Plate Fixation Versus Intramedullary Nail Fixation in the Treatment of Adult Patients with a Displaced Fracture of the Distal Tibia

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Purpose: The treatment of displaced, extra-articular fractures of the distal tibia remains controversial. These injuries are difficult to manage due to limited soft-tissue cover, poor vascularity of the area, and proximity to the ankle joint. Most fractures are displaced and require surgical fixation to achieve the best outcome. The 2 most common forms of fixation are intramedullary nail fixation and locking plate fixation. Our objective was to assess ratings of disability in patients who have sustained a distal tibia fracture treated with either an intramedullary nail fixation or locking plate fixation.

Methods: Adult patients with an acute fracture of the distal tibia were eligible for this multicenter randomized clinical trial. Patients were excluded if there was a contraindication to intramedullary nailing, the fracture was open, the fracture extended into the ankle joint (iecintra-articular fracture), there was a contraindication to anesthesia, or there was evidence that the patient would be unable to adhere to trial procedures or complete questionnaires. Interventions were intramedullary nail fixation, which involves the insertion of a metal rod into the hollow center of the tibia, versus locking fixation, which involves attaching a plate on the surface of the tibia with fixed-angle locking screws. All surgery was performed according to the preferred technique of the operating surgeon. The Disability Rating Index (DRI) score was the primary outcome. Secondary outcomes were the Olerud and Molander ankle score, the EQ-5D 3L health-related quality of life questionnaire, complications, and radiographs at 3, 6, and 12 months postoperatively. Resource use was collected to inform the health economics evaluation.

Results: 320 patients were randomized into the trial. There was a statistically significant and clinically important difference in the DRI at 3 months in favor of nail fixation (8.8 (4.3, 13.2); $P < 0.001$). This difference reduced at the primary end point of 6 months (4.0 [-1.0, 9.0], $P = 0.114$) and again at 12 months (2.3 [-3.0, 7.7], $P = 0.394$). Secondary outcomes showed the same pattern. There was no difference in the number of complications but further surgery was more common in the locking plate group. The economics evaluation showed that nail fixation was cheaper than locking plate fixation over the 12 months of the trial.

Conclusion: This study shows that intramedullary nail fixation provides faster recovery for patients with a fracture of the distal tibia and costs less than locking plate fixation. If operative fixation is required, patients with this injury should be offered an intramedullary nail as the treatment of choice.

See pages 401 - 442 for financial disclosure information.