A Prospective, Randomized Controlled Trial Comparing the Fibular Nail versus Standard ORIF for Fixation of Ankle Fractures in Patients Under 65 Years of Age *Timothy White, MD, FRCS*; Kate Bugler, Mb ChB, MRCS; Margaret McQueen, MD FRCS; Charles Court-Brown, MD; Royal Infirmary of Edinburgh, GREAT BRITAIN

Purpose: The technique of open reduction and internal fixation (ORIF) of ankle fractures with plates and screws has not changed substantially since the 1960s. Three principal complications are associated with this type of surgery. First, wound dehiscence and infection, with published rates of up to 30%, and higher rates in patients with diabetes and neuropathy. Second, there is a risk of construct failure, particularly in osteoporotic bone. Third, the scar or prominent hardware may cause later irritation and require further surgery. We have previously reported that fibular nailing in the elderly is associated with a significantly reduced complication rate and better cost-effectiveness when compared to ORIF. We hypothesized that fibular nailing in younger patients would result in comparable outcomes, with a reduced rate of wound and hardware problems.

Methods: 100 patients aged 18 to 64 years with unstable ankle fractures requiring fixation were randomized to undergo fibular nailing or standard stabilization using AO techniques. Immediate weight-bearing in cast was permitted. Outcome measures were assessed over 2 years postoperatively and included: the accuracy of reduction, development of wound complications or radiographic arthritis, range of movement, Olerud and Molander score (OMS), and patient satisfaction. The mean age was 44 years (range, 18-64) and 56 patients were women. 25% of patients were smokers, three were diabetic, and 35% had some form of comorbidity, most commonly hypertension or ischemic heart disease. 27 injuries occurred during sport and two after an assault; the remainder occurred after a simple fall from a standing height.

Results: Patient satisfaction with the surgical scar was higher after fibular nailing (visual analog scale mean 0.75; range, 0-5) than for ORIF (mean 1.5; range, 0-7). Superficial wound infections that resolved with oral antibiotics occurred in two patients in each group. Six patients requested removal of the nail, and five further requested removal of the locking screws. In the ORIF group, nine patients requested plate and screw removal. Patient-reported outcome scores were comparable for the two groups. Two failures of fixation occurred in the fibular nail group: one in a patient with neuropathy, and one in a patient who developed a postoperative pulmonary embolism and failed to attend follow-up. One failure of fixation occurred in the ORIF group. All other patients went on to an anatomic union without complication.

Conclusion: The fibular nail allows accurate reduction and secure fixation of ankle fractures, with comparable radiographic and patient-reported outcome at 2 years, and a greater patient satisfaction with the appearance of the surgical scars. Neuropathy should be a contraindication to early weight-bearing.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.