

Δ Locked Plating versus Nailing for Proximal Tibia Fractures: A Multicenter RCT

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Purpose: Both intramedullary (IM) nails and locked plates are utilized for their treatment of extra-articular proximal tibia fractures. The purpose of this study was to evaluate the radiographic, functional, and patient-based outcomes of locked plates (P) versus IM nails (N) for proximal tibia fractures.

Methods: All adult patients with A1-3 or C1 proximal tibia fractures were offered entry into an OTA-funded randomized controlled trial (RCT). Randomization was with permuted blocks for open and closed fractures using a HIPAA (Health Insurance Portability and Accountability Act)-compliant web-based system. Patients requiring articular reduction were excluded. Demographics, fracture characteristics, surgical variables, radiographs, walking ability, Short Musculoskeletal Function Assessment (SMFA), bother index, and EQ-5D (EuroQol 5 Dimensions) were assessed based on available patients at each time point (3, 6, and 12 months). Comparisons were made with Graphpad software.

Results: 108 patients were randomized and 99 patients (76 M; 23 F) aged 20 to 87 years (average, 46) treated with nails (52) or locked plates (47) were followed. There were no differences in demographics or injury pattern. Average ISS was 11.2 (11.8 N; 10.7 P), 36% were open, 18% had simple intra-articular extension, and 52% smoked. Compartment syndrome was more common in the nail group (4:1). Surgical time did not differ between the groups (180 [P] vs 155[N] min, $P = 0.7$). 40% of nails were done in relative extension and 42% had blocking screws. Malalignment $>5^\circ$ occurred in 3 patients in each group. Walking ability, stair climbing, pain, and use of supports were graded using categorical values. There were no differences at any time point between the groups. 50% of both groups were full weight-bearing at 3 months. At 1 year, the average patient could walk >10 blocks, walk stairs using a railing, and needed no supports. 7% of both nails and plates lacked at least 5° of extension. There was no difference in the SMFA, bother index, EQ-5D, or EQ Index at 3, 6, or 12 months ($P = 0.55-0.98$). At 1 year the average scores were: SMFA 28.4, bother 26.6, EQ-5D 0.70, and EQ health 70. There were 3 deep infections in the nail group (2 closed; 1 open) and 1 deep (open) and 2 superficial infections (1 closed; 1 open) in the plate group. Nonunions occurred in 4 nails and 5 plates. 20 and 17 adverse events occurred in the nail and plate groups, respectively.

Conclusion: With the number studied, we found no difference in the radiographic, functional, or patient-based outcomes of nails compared with locked plates for proximal tibia fractures. Patients have substantial disability at 1 year regardless of treatment. Complications were common, but rates did not differ between groups.

Δ OTA Grant

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.