

A Multicentre, Randomized Trial of Far Cortical Locking Versus Standard Constructs for Acute, Displaced Fractures of the Distal Femur Treated with Locked Plate Fixation

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Purpose: Fixation of distal femur fractures remains a challenge, and nonunions are common with standard constructs. Far cortical locking constructs purport to improve fracture healing compared to traditional locking bridge plates. We sought to test this hypothesis in a comparative effectiveness clinical trial.

Methods: We recruited eligible patients with OTA type 33A or 33C distal femur fractures across 16 centers. Inclusion criteria included age >18 years and fractures suitable for bridging fixation. Exclusion criteria included periprosthetic fractures. Study participants were randomized to standard locking plate fixation (NCB Distal Femur plate with standard NCB screws; Zimmer) or far cortical locking fixation (NCB Distal Femur plate with MotionLoc screws for NCB; Zimmer). To ensure prognostic balance, treatment was stratified based on age (<65 or ≥65 years), and open versus closed fractures. To maintain generalizability, standard constructs were not prescribed, allowing for use of locked screws, non-locked screws, and surgeon-preferred stiffness and working length. Subjects were rehabilitated non-weightbearing for 6 weeks, then advanced to weightbearing as tolerated. Primary outcome evaluation was radiographic healing as measured using a modification of the RUST (Radiographic Union Scale for Tibial Fractures) score on plain films at 12 weeks. Secondary outcome measures included FIX-IT instrument, Short Form-36 (SF-36), adverse events, delayed union, nonunion, malalignment, hardware failure, infection, and reoperation. Follow-up occurred at 2, 6, 12, 26, and 52 weeks.

Results: A total of 170 patients were enrolled: 86 to Standard Construct and 84 to Far Cortical Locking. There were 8 deaths and 9 patient withdrawals at 12-week follow-up. Primary outcome data have been collected in 97.8% of projected completion group. In the 170 enrolled participants, mean age was 63.3 years (standard deviation [SD] 16.2), 116 (68.2%) were women, 23 (13.5%) had open fractures, while 88 (51.8%) were OTA A and 82 (48.2%) were OTA C. At the time of abstract submission, 28 participants had 1 or more reoperations. Recruitment ended in January 2022, with primary outcome completion anticipated in April 2022, leaving time for analysis and completion before the 2022 OTA Meeting. We foresee this being the first presentation of study results.

Conclusion: Far cortical locking constructs are a novel technology that has the potential to improve fracture healing in the distal femur. This study will provide crucial evidence to support or refute its benefits.