

Immediate Versus Delayed Weightbearing for Fractures of the Pelvis, Acetabulum, Distal Femur, and Proximal and Distal Tibia: A Feasibility Randomized Controlled Trial

Peter Mittwede, MD; Casey Loudermilk; Alice Bell; Murali Kovvur, BS; Joshua Lawrence; Vivian Li, BA; David Okhuereigbe, MS; Kristin Turner; Jordan Brand, MD; Daniel J. Cunningham, MD; Daniel J. Johnson, MD; Aresh Sepehri, MD; Mark Gage, MD; Eric Hempten, MD; Jason W. Nascone, MD; Marcus F. Sciadini, MD; Gerard P. Slobogean, MD, MPH; Nathan N. O'Hara, PhD; Robert V. O'Toole, MD

Purpose: Early weightbearing is frequently allowed following fixation of hip and lower extremity diaphyseal long bone fractures, but many lower extremity fractures are prescribed 6-12 weeks of restricted weightbearing. Our objective was to perform a feasibility study of a randomized trial of immediate versus delayed weightbearing as tolerated (WBAT) for fractures of the pelvis, acetabulum, distal femur, and proximal and distal tibia.

Methods: This feasibility randomized controlled trial was performed at 1 academic Level I trauma center. Eligible patients were those with a fracture of the pelvis, acetabulum, distal femur, or proximal or distal tibia, and they were assigned to immediate WBAT or delayed (at least 6 weeks) weightbearing postoperatively. Our 4 feasibility criteria were: (1) enrollment (surgeon and patient agreement to participate in 50% of eligible cases), (2) follow-up (target >90% follow-up at 3 months), (3) correct documentation of weightbearing status (target 100%), and (4) correct documentation of primary outcomes of reoperation and hardware failure (target 100%).

Results: Surgeons allowed inclusion of 57/121 (47%) of eligible patients into the study (by fracture: 71% pelvis, 44% acetabulum, 37% distal femur, 43% proximal tibia [36% tibial plateau], 53% distal tibia). 47/57 (82%) of these patients agreed to participate. The most common reasons for surgeon refusal were excessive joint impaction (23%), poor bone quality (16%), and excessive fracture comminution (14%). Early follow-up rates have been excellent (94%). Correct documentation of postoperative weightbearing status and primary outcome has been achieved in all cases. There have been 2 reoperations (1 hardware failure and 1 wound infection) in the immediate WBAT group and none in the delayed weightbearing group.

Conclusion: Three of 4 eligibility criteria were achieved, with only the overall 50% enrollment goal falling short at 39%. A larger weightbearing trial appears feasible for certain fractures, and this feasibility trial can inform future study design by using characteristics of fractures (excessive joint impaction, fracture comminution) and patients (poor bone quality) that may make surgeons unwilling to allow randomization.