

A Randomized Trial Comparing Anti-Gravity Treadmill Therapy versus Standard of Care: It's Safe and Patients Like It

Daniel Stinner, MD, PhD; METRC Group

Purpose: Early controlled weightbearing using anti-gravity treadmill therapy can allow patients with lower extremity periarticular fractures to load the limb in a controlled environment, thereby potentially reducing the negative consequences of prolonged non-weightbearing while avoiding complications associated with premature return to full weightbearing. We hypothesized that patients randomized to anti-gravity treadmill therapy would report better outcomes compared with standard of care with no differences in complication rates or fracture healing.

Methods: This prospective, multicenter randomized trial (RCT) compared outcomes following periarticular fractures of the knee (plateau/distal femur) and ankle (pilon) definitively treated with a plate. Adult patients were randomly assigned to either 10 weeks of anti-gravity treadmill therapy (intervention) or standard of care defined as non-weightbearing for a minimum of 8 weeks (control). The primary outcomes were 6-month Knee injury and Osteoarthritis Outcome Score (KOOS) for plateau/distal femur fractures, and Ankle Osteoarthritis Scale (AOS) scores for pilon fractures. Secondary outcomes included 6-month PROMIS (Patient-Reported Outcomes Measurement Information System) physical function (PF) scores, 12-month fracture healing and complications, and patient satisfaction. Linear regression, accounting for follow-up time was used to estimate the effect of treatment assignment on patient reported outcomes. Fisher's exact test was used for categorical outcomes.

Results: There were 78 patients (intervention: n = 38, control: n = 40) enrolled at 10 centers over 2 years. The average AOS scores were 28 and 50 for the intervention and control groups, respectively (adjusted difference: -19.5, 95% confidence interval [CI]: -39.3, 0.30; P = 0.05). The average KOOS scores were 54 and 60 in the intervention versus control groups, respectively (adjusted difference: -6.1, 95% CI: -18.4, 6.2; P = 0.32). There was no difference between intervention and control groups in PROMIS PF scores (43.9 vs 44.5; adjusted difference: -2.2, 95% CI: -7.1, 2.8; P = 0.38), fracture healing (80% vs 83%, P = 0.99), or complications (8% vs 5%, P = 0.67). Patients in the intervention group reported higher satisfaction with their therapy (9.5 vs 8.5, P = 0.01).

Conclusion: This RCT supports our hypothesis that anti-gravity treadmill therapy is safe for lower extremity periarticular fractures. Moreover, patients receiving the intervention were more satisfied with their therapy. There was a trend toward improved outcomes among patients with pilon fractures suggesting that anti-gravity treadmill therapy may optimize recovery for patients with these injuries.