Early Versus Delayed Weightbearing Following Operatively Treated Ankle Fracture (WAX): A Randomized Controlled Trial and Health Economic Evaluation

Christopher Bretherton*; Xavier L. Griffin, PhD; WAX Trial investigators*

Purpose: This study aimed to determine the clinical and cost-effectiveness of an early weightbearing strategy (2 weeks postoperatively) compared to a delayed weightbearing strategy (6 weeks postoperatively) after ankle fracture surgery.

Methods: A pragmatic, multicenter, randomized noninferiority trial including 561 participants (aged ≥18 years) who received acute surgery for an unstable ankle fracture in 23 hospitals were assigned to either a delayed weightbearing (n = 280) or an early weightbearing rehabilitation strategy (n = 281). Patients treated with a hindfoot nail, those who lacked protective ankle sensation (e.g., peripheral neuropathy), or lacked the capacity to consent were excluded. Neither participants nor clinicians were blinded to the treatment. The primary outcome was ankle function measured using the Olerud and Molander Ankle Score (OMAS) at 4 months post-randomization. The prespecified noninferiority OMAS margin (ΔT) was –6 points and superiority testing were undertaken in the event of noninferiority. Secondary outcomes included health-related quality of life, complications, and cost-effectiveness evaluated from a Health Service (HS) and personal social services (PSS) perspective and expressed in terms of incremental cost per quality-adjusted life year (QALY) gained.

Results: Primary outcome data were collected from 86% (n = 480) of participants. At 4 months post-randomization, the mean OMAS score was 65.9 in the early weightbearing and 61.2 in the delayed weightbearing group; adjusted mean difference 4.47 (95% confidence interval [CI] 0.58, 8.37; P = 0.024) (superiority testing adjusted difference = 4.42; 95% CI 0.53 to 8.32, P = 0.026) in favor of early weightbearing. 16.4% (n = 46) of participants in the early weightbearing group and 13.9% (n = 39) in the delayed weightbearing group experienced 1 or more complications (adjusted odds ratio 1.18, 95% CI 0.80, 1.75; P = 0.40). The mean costs from the HS and PSS perspective in the early and delayed weightbearing groups were £725 and £785 respectively (mean difference £60 [95% CI £342 to £232]). The probability that early weightbearing is cost-effective exceeded 80%.

Conclusion: An early weightbearing strategy was found to be clinically superior and highly likely to be cost-effective compared to the current standard of care (delayed weightbearing).