

**The AIM Trial Extended Follow-up: Three-year Outcomes from an Equivalence Randomized Clinical Trial Comparing Close Contact Casting with Internal Fixation Surgery for Unstable Malleolar Fractures in Patients Over 60 Years**

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**Purpose:** The AIM Trial was previously reported at OTA 2015 and published in *JAMA* (2016). Close contact casting (CCC), a novel casting technique, was compared with open reduction and internal fixation (ORIF) surgery for the initial treatment of unstable malleolar fracture in older adults. There was equivalence between the treatment groups in terms of ankle function at the primary endpoint of 6 months. There were no differences in secondary outcomes of quality of life (mental and physical), ankle range, pain, mobility and patient satisfaction. However, there was a greater number of participants with radiological malunion in the casting group, leading to concerns about the potential for later deterioration in ankle function. The duration of follow-up was extended to investigate the important clinical uncertainty about whether equivalence would be maintained in the longer term.

**Methods:** The AIM Trial was a pragmatic, multi-center, equivalence, randomized controlled trial incorporating health economic evaluation. 620 participants aged 60 and over (mean: 71) were randomized to ORIF or CCC. Recruitment was from 24 hospitals. The primary outcome was the Olerud and Molander Ankle Score (OMAS). Secondary outcomes were: pain, health-related quality of life (EQ-5D-3L and SF-12), and additional operating room procedures. Longer term follow-up was via postal questionnaire at least 3 years post intervention. Consistent with the published protocol, the primary analysis was per protocol with an equivalence margin pre-set at +/- 6 OMAS points. Current Controlled Trials ISRCTN04180738.

**Results:** Follow-up assessments at median 3 years (range 2.9 to 9.5 years) post intervention were completed by 450/620 (73%) participants, 90/620 did not respond or did not agree to participate, 35/620 had died, and 45/620 had withdrawn. OMAS mean difference between CCC and ORIF was 1.2 [95%CI: -3.1, 5.5]. Analyses of secondary outcomes will be presented.

**Conclusion:** Equivalence in functional outcome between CCC and ORIF is maintained at 3 years. These longer term outcomes provide additional evidence to support surgeons and patients when offering or selecting CCC as an alternative to surgery in older adults with an unstable ankle fracture.