

## **An Equivalence Randomized Controlled Trial Comparing Close Contact Casting (CCC) with Internal Fixation Surgery for Unstable Malleolar Fractures in Patients Over 60 Years**

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**Purpose:** The decision to treat an unstable malleolar fracture by surgery in older adults is complicated by comorbidities, increased risk of infection, surgical wound problems, and inadequate fixation due to poor bone quality. Close contact casting (CCC), is a novel casting technique that may offer an alternative to open reduction and internal fixation (ORIF). We aimed to determine the clinical and cost-effectiveness of CCC compared to ORIF in adults aged over 60 years.

**Methods:** This was a pragmatic, multicenter, equivalence randomized controlled trial incorporating health economic evaluation. Recruitment was from 24 hospitals. Exclusions were: serious limb or concomitant disease or substantial cognitive impairment. Participants were randomized using computer allocation via a 24-hour telephone service. The primary outcome, Olerud and Molander Ankle Score (OMAS), was collected at 6 months by blinded assessors. A qualitative patient-experience study was embedded.

**Results:** We randomized 620 participants (309 ORIF, 311 CCC); mean age 71 years (74% female). Follow-up assessments at 6 months were completed by 593/620 (96%) participants. Per protocol analysis showed CCC resulted in equivalent functional outcome compared to ORIF (OMAS mean difference -0.65 [95% CI (confidence interval): -3.98, 2.68]); equivalence margin preset at  $\pm 6$  points. Intention-to-treat analysis demonstrated the same equivalence. There were no differences in secondary outcomes of quality of life (mental and physical), ankle range, pain, mobility, and patient satisfaction. Complications occurred in both groups; commonest for CCC group were loss of reduction and conversion to ORIF, and for ORIF group were wound breakdown and surgery for wound/implant problems. CCC showed mean cost savings to the universal health care service (mean difference -\$968 [95% CI -2,089, 114]) and society (mean difference -\$1,026 [95% CI: -2,782, 806]). Over common willingness-to-pay thresholds, the probability that CCC was cost-effective was very high (>95%). The experiences of the treatments were similar as both groups endured the impact of ankle fracture and uncertainty regarding future function and the necessity for further interventions.

**Conclusion:** CCC provides a clinically equivalent outcome to ORIF with a cost reduction to the universal health care service and society. Identifying a nonsurgical treatment evidenced to deliver the same patient outcome must now produce a shift in the approach of surgeons in advising older patients with unstable malleolar fractures.