Three-year Follow-up of a Randomized Clinical Trial of Close Contact Casting vs Surgery for Initial Treatment of Unstable Ankle Fractures in Older Adults

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Introduction

A randomized clinical trial of close contact casting versus the usual practice of surgery for treating unstable ankle fractures in older adults found equivalent ankle function outcomes at 6 months.[1] Higher rates of radiological ankle malunion in the casting vs surgical groups (15% vs 3%) and non-union (medial malleolus 7% vs 1%) suggested that equivalence between the two groups may be lost if symptoms or functional limitations from posttraumatic arthritis manifest later.[2] A follow-up at least 3 years after randomization was conducted to determine if equivalence persisted over time.

Methods

This study was a pre-specified extended follow-up of a pragmatic, multi-center, equivalence, randomized clinical trial.[1] The National Research Ethics Service Oxfordshire gave approval, written informed consent was obtained. Participants were adults aged over 60 years with acute unstable malleolar fracture(s) from 24 UK centers. Participants had received surgery (usual local practice internal fixation) or close contact casting, in which a minimally padded cast was applied after closed fracture reduction by an orthopedic surgeon in an operating room under anesthesia. Data were collected at least 3 years after randomization using patient-reported postal questionnaires.

The primary outcome measure for the original trial was the Olerud and Molander Ankle Score (OMAS, range 0 to 100, higher scores indicating better ankle function) at 6 months[3], with a pre-specified equivalence margin of ±6 points. Extended follow-up used the same primary outcome equivalence margin and assessed as secondary outcomes; quality of life, pain, and a post-hoc analysis of additional operations after 6 months (Table 1). Per-protocol primary analysis was used, consistent with the main trial.[1] Random-effects models estimated

mean differences and 95%CIs between treatments adjusted for age, sex, fracture pattern, baseline score, and time to follow-up, including the center variable as a random effect. The random-effects model was also used post hoc to assess differences in OMAS for participants with vs without radiological malunion and non-union at six months. Change from baseline score was analyzed for outcomes with a non-normal distribution. The primary outcome at extended follow-up assessed equivalence with the null hypothesis that the two groups were not equivalent. For all other outcomes, tests were two-sided at the 5% significance level. Analyses were conducted with Stata v.15.0.

Results

Between September 2013 and November 2016, 450 of the 620 randomized participants (73%) responded to follow-up at median 3 (range 2.9 to 9.5) years. Responders and non-responders had similar characteristics (Table 1). Most responders lived in their own home (209 of 222 surgery [94%], 196 of 206 casting [95%]).

Surgery and casting participants had equivalent ankle function (OMAS mean surgery 79.4, casting 76.3, difference -1.3, 95%CI: -5.6 to 3.0) and no significant differences in quality of life or pain (Table 2). Twenty-two of 222 surgery (10%) and 17 of 206 casting participants (4%) had operations after 6 months, including surgical implant removals (15 surgery [7%] and 8 casting [8%]), arthrodesis (1 surgery [0.5%] and 3 casting [1.5%]), arthroplasty (1 surgery [0.5%] and 1 casting [0.5%]), and infection-related procedures (2 surgery [1%] and 0 casting). Five casting participants (2%) had internal fixations for non-union after 6 months. There was one internal fixation revision, one arthroscopy, and one hindfoot osteotomy among surgery participants. In post hoc analysis, from randomization to extended follow-up, total operating room procedures per participant (per protocol) were mean 1.2 (SD 0.5) for surgery

and 1.3 (0.6) for casting, and surgical procedures, 1.2 (0.5) for surgery and 0.3 (0.6) for casting.

Of 67 participants with radiological abnormalities at 6 months, 43 provided extended follow-up data. Those with malleolar malunion at 6-months had significantly lower OMAS scores (n=30, mean [SD]: 58.7 [33.1]) compared to those without (n=372, mean [SD]: 79.8 [23.5]; mean difference -16.4 [95%CI: -25.0, -7.8]; $p<0.001$). Participants with medial malleolar non-union at 6-months also had significantly lower OMAS scores (n=13, mean [SD]: 55.4 [38.5]) compared to those without (n=388, mean [SD]: 79.1 [23.9]; mean difference -13.9 [95%CI: -26.6, -1.2]; $p=0.032$). Treatment was not a significant covariate in these analyses.

Discussion

Equivalence in function between casting and immediate surgery strategies was maintained at 3 years. In post hoc analyses, participants with radiological malunion and medial malleolar non-union at 6 months had lower OMAS scores at three-year follow-up. These longer-term outcomes will support surgeon and patient decision-making. The findings indicate that treatment of ankle fractures in older adults should focus on obtaining and maintaining a reduction until union, by the most conservative means possible.

The study was limited by its reliance on self-reported events requiring participant recall and by loss to follow-up. However, there were sufficient data to estimate and conclude equivalence in the primary outcome.

Table 1. Baseline demographics and clinical characteristics of responders and non-responders at extended follow-up

	Responders (n=450)		**Non-responders (n=170)**	
Characteristics	**Surgery (n=226)**	**Casting (n=224)**	**Surgery (n=83)**	**Casting (n=87)**
Age, mean (SD), y	68.5 (6.2)	70.7 (7.1)	73.6 (7.6)	73.5 (8.5)
Sex, No. (%)				
Male	63 (27.9)	56 (25.0)	19 (22.9)	22 (25.3)
Female	163 (72.1)	168 (75.0)	64 (77.1)	65 (74.7)
Ankle fracture classification, No. (%)				
Infrasyndesmotic/trans-syndesmotic	197 (87.2)	192 (85.7)	75 (90.4)	78 (89.7)
Suprasyndesmotic	29 (12.8)	32 (14.3)	8 (9.6)	9 (10.3)
Olerud-Molander Ankle Score, preinjury, mean (SD)[a,b]	91.2 (16.3)	89.7 (16.8)	86.1 (18.4)	82.4 (18.9)
SF-12 mental score preinjury, mean (SD)[a,c]	54.0 (7.8)	55.1 (7.1)	53.1 (8.8)	52.9 (8.2)
Missing data	1	0	1	0
SF-12 physical score preinjury, mean (SD)[a,c]	51.8 (8.4)	50.6 (9.9)	49.3 (9.6)	47.0 (11.1)
Missing data	1	0	1	0
EQ-5D score preinjury, mean (SD)[a,d,e]	0.91 (0.17)	0.89 (0.17)	0.89 (0.15)	0.83 (0.23)
Missing data	20	17	11	13
EQ-5D score day of randomization, mean (SD)[d,e]	0.06 (0.25)	0.08 (0.25)	-0.01 (0.27)	0.03 (0.26)
Missing data	32	29	17	18
Mini-Mental State Examination score, mean (SD)[d]	28.4 (1.9)	28.2 (2.1)	27.4 (2.5)	27.1 (2.8)
Missing data	20	17	12	13
Medical history, No. (%)				
Heart disease	29 (12.8)	30 (13.4)	9 (10.8)	14 (16.5)
Non-insulin-dependent diabetes	20 (8.9)	17 (7.6)	11 (13.3)	9 (10.6)
Cerebrovascular accident/transient ischemic attack	10 (4.4)	12 (5.4)	4 (4.8)	9 (10.6)
Osteoarthritis	55 (24.3)	70 (31.3)	29 (34.9)	30 (35.3)
Depression	24 (10.6)	26 (11.6)	11 (13.3)	12 (14.1)
Clinical outcomes at 6 Months				

Olerud-Molander Ankle Score, n; mean (SD)[b]	225; 67.6 (20.3)	224; 65.7 (22.2)	73; 61.2 (23.6)	70; 61.4 (22.7)
Missing data	1	0	0	1
SF-12 mental score, n; mean (SD)[c]	225; 52.9 (9.7)	224; 53.0 (9.4)	73; 49.1 (12.2)	70; 49.7 (10.2)
Missing data	1	0	0	1
SF-12 physical score, n; mean (SD)[c]	225; 46.4 (9.7)	224; 45.2 (10.2)	73; 43.1 (10.7)	70: 41.2 (11.3)
Missing data	1	0	0	1

Abbreviations: EQ-5D, EuroQol 5 dimensions questionnaire[4]; IQR, interquartile range; SF-12, 12-item Short Form health survey[5]

[a] Participants recalled preinjury status.

[b] Range 0 to100, with higher scores indicating better ankle function.

[c] Range 0 to 100, with higher scores indicating better functioning.

[d] The majority of missing scores relate to early study participants, before the measure was introduced.

[e] Range typically from 0 (death) to 1 (perfect health); negative scores can be obtained, reflective of a patient's quality of life being worse than death.

Table 2. Primary and secondary outcomes at extended follow-up (per-protocol analysis)

	Surgery		Casting		
Measure	**No.**	**Mean (95% CI)**	**No.**	**Mean (95% CI)**	**Adjusted difference (95% CI)[a]**
Olerud-Molander Ankle Score[b]	220	79.4 (76.3 to 82.5)	203	76.3 (72.7 to 79.9)	-1.3 (-5.6 to 3.0)
SF-12 mental score[c]	204	51.9 (50.7 to 53.2)	190	52.7 (51.3 to 54.0)	0.5 (-1.2 to 2.2)
SF-12 physical score[c]	204	47.2 (45.8 to 48.7)	190	44.7 (42.9 to 46.4)	-0.8 (-2.6 to 1.1)
EQ-5D score[d] (change from baseline)	187	-0.75 (-0.79 to -0.71)	177	-0.68 (-0.74 to -0.63)	0.04 (-0.01 to 0.09)
Olerud-Molander Ankle Score pain rating[e]	221	1.8 (1.7 to 1.9)	205	1.9 (1.8 to 2.1)	0.09 (-0.1 to 0.3)
EQ-5D score pain rating[f]	219	1.5 (1.4 to 1.6)	205	1.5 (1.5 to 1.6)	0.05 (-0.1 to 0.2)

Abbreviations: EQ-5D, EuroQol 5 dimensions questionnaire; SF-12, 12-item Short Form health Survey.

[a] Differences were adjusted for baseline outcome values, age, sex, recruitment hospital, fracture pattern (trans-syndesmotic and Infrasyndesmotic vs suprasyndesmotic) and time to follow-up.

[b] Range 0 to100, with higher scores indicating better ankle function.

[c] Range 0 to 100, with higher scores indicating better functioning.

[d] Range typically from 0 (death) to 1 (perfect health); negative scores can be obtained, reflective of a patient's quality of life being worse than death.

[e] Scores were from 1 to 5, with 1 indicating "non" and 5 indicating "constant and severe".

[f] Score were from 1 to 3, with 1 indicating "no pain or discomfort" and 3 indicating "extreme pain or discomfort".

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Conflict of interest disclosures

Prof Willett declares design royalties from ZIMMER, outside the submitted work, for intramedullary bone fixation implants.

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Group information

The Ankle Injury Management trial group details were reported previously.[1]

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