



## Supplementary Material

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### **Additional results: subgroups, secondary outcome results and sensitivity analyses**

#### Primary outcome: further analysis on recovery of surgically managed participants

During the analysis, it was noted that there were differences in recovery for some subgroups of participants. The subgroup with initial surgical management had lower Olerud-Molander Ankle Scores (OMAS)<sup>1</sup> at the final follow-up than the values reported pre-injury. The mean change in this group was -11.7 (95% confidence interval (CI) 14.4 to -8.9), whereas the mean change in the nonoperative group was -5.1 (95% CI -8.0 to -2.2). This change of 11.7 points is greater than both the initial minimum clinically important difference set for the Ankle Injury Rehabilitation (AIR) trial and the minimally important change which was investigated during the trial, which was found to be 9.7 points. This decrease in function for the surgically managed group was clearly observed when looking at individual-level items in the OMAS: there were greater proportion of participants scoring the worst outcome in some items. Most notable of these was stiffness being reported in higher numbers: 33% (144/436) reported stiffness of their ankle at 24 months compared to 6% (43/669) at pre-injury. Further exploratory results on the surgically managed participants, including the other subgroup, are shown in Table i.

**Table i.** Olerud-Molander Ankle Score cohort summary at 24 months by intervention group.

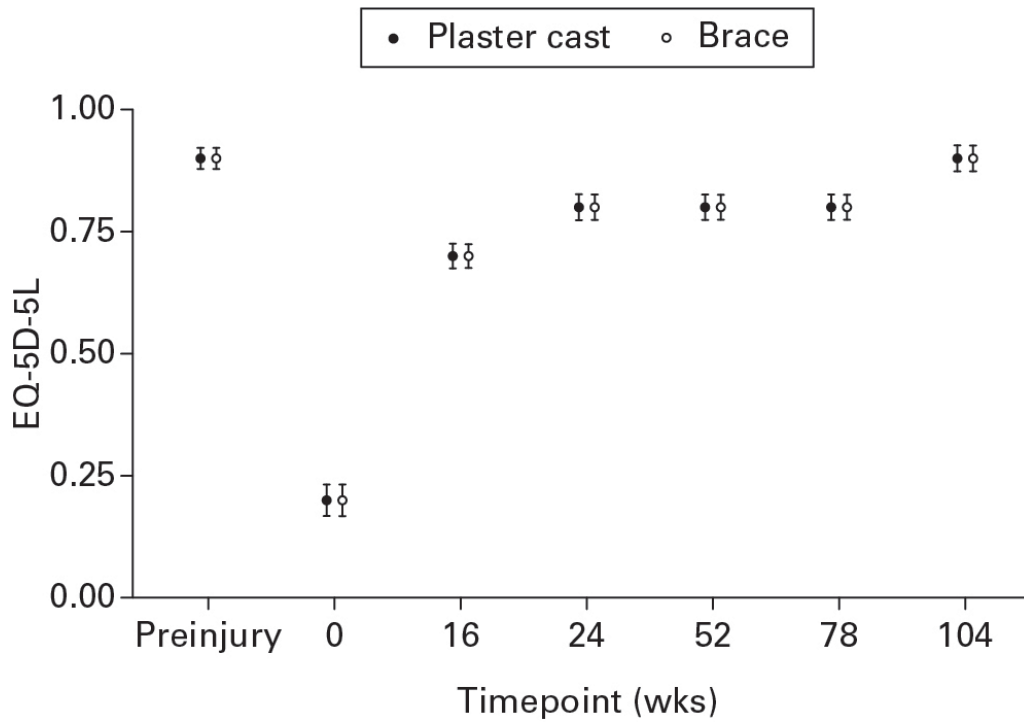
Variable	Management	Cast (n = 334)		Brace (n = 335)	
		n	Mean (95% CI)	n	Mean (95% CI)
<b>Female</b>					
Age ≤ 49 yrs	Nonoperative	28	91.8 (86.2 to 97.4)	28	88.6 (80.8 to 96.3)
	Operative	27	83.3 (76 to 90.6)	27	84.4 (78 to 90.9)
Age ≥ 50 yrs	Nonoperative	39	86.2 (79 to 93.3)	38	85.8 (78.3 to 93.3)
	Operative	36	77.8 (69.9 to 85.7)	38	77.9 (70.4 to 85.4)
<b>Male</b>					
Age ≤ 49 yrs	Nonoperative	19	93.7 (88.6 to 98.8)	20	89.2 (82.1 to 96.4)
	Operative	27	91.1 (85.4 to 96.8)	25	89.6 (84.4 to 94.8)
Age ≥ 50 yrs	Nonoperative	18	88.3 (81.5 to 95.1)	22	85.7 (76.4 to 95.0)
	Operative	21	75.2 (63.5 to 86.9)	21	88.6 (83.9 to 93.3)

CI, confidence interval.

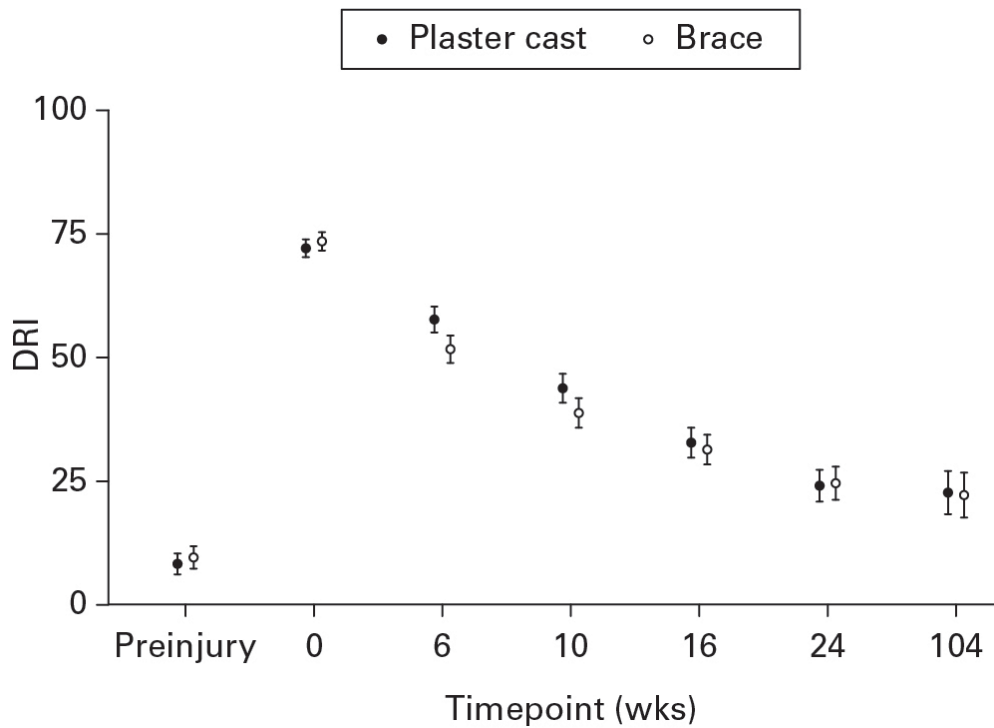
### Secondary analyses results: quality of life, Disability Rating Index, and complications

The secondary outcome results did not have any statistically significant differences, although this was expected as the study was not powered for these analyses.

The Disability Rating Index (DRI)<sup>2</sup> had a mean difference of -0.8 in favour of the cast (95% CI -7.0 to 5.1;  $p = 0.802$ ). The quality of life, measured using the EuroQol five-dimension five-level health questionnaire (EQ-5D-5L)<sup>3</sup> had a mean difference of -0.005 in favour of the cast group (95% CI -0.041 to 0.031;  $p = 0.779$ ). Over the course of the study, participants' EQ-5D-5L and DRI outcomes show a clear recovery trajectory, although not reaching the same levels as pre-injury (Figure a for the EQ-5D-5L and Figure b for the DRI). In order to understand the recovery trajectory further, the individual domains of the EQ-5D-5L had been analyzed. It was found that a high proportion of participants had recovered to the preinjury levels for anxiety (89% ( $n = 388$ )), and self-care (95% ( $n = 416$ )). However, the other three domains had significantly lower proportion of participants reaching their pre-injury levels, particularly the pain domain, where surgically managed patients were most affected (Tables ii and iii). In conclusion, pain was one of the key reasons affecting the participant's quality of life, two years after the injury.



**Figure a.** Mean EuroQol five-dimension five-level health questionnaire values with 95% confidence intervals.



**Figure b.** Mean Disability Rating Index values with 95% confidence intervals.

**Table ii.** EuroQol five-dimension five-level health questionnaire: patients reaching or exceeding their pre-injury level at two-year follow up. Lost-to-follow-up population have been excluded.

Domain	Plaster cast, n (%)	Removable brace, n (%)	Total, n (%)
Total	216	220	436
Anxiety	189 (43.3)	199 (45.6)	388 (89.0)
Mobility	164 (37.6)	170 (39.0)	334 (76.6)
Pain	145 (33.3)	144 (33.0)	289 (66.3)
Self-care	205 (47.0)	211 (48.4)	416 (95.4)
Usual activity	176 (40.4)	174 (39.9)	350 (80.3)

**Table iii.** EuroQol five-dimension five-level health questionnaire by initial fracture management and number of participants reaching or exceeding their preinjury level at two-year follow up. Lost-to-follow-up population have been excluded.

Domain	Nonoperatively, n (%)	Operatively, n (%)	Total, n (%)
Total	213	223	436
Anxiety	186 (42.7)	202 (46.3)	388 (89)
Mobility	173 (39.7)	161 (36.9)	334 (76.6)
Pain	164 (37.6)	125 (28.7)	289 (66.3)
Self-care	202 (46.3)	214 (49.1)	416 (95.4)
Usual activity	176 (40.4)	174 (39.9)	350 (80.3)

Following the complication patterns seen in the surgically managed patients, the complications that were applicable to all participants were filtered to isolate the surgically managed participants and identify any trends. It appears for this subset there were no apparent patterns to suggest the brace has higher complications for the surgically managed group (Table iv).

**Table iv.** Complications for surgically managed participants.

Complications	Cast, n (%)	Removable brace, n (%)	OR (95% CI)	p-value*
Total	182	182		
Pressure sore/ulcer	8 (4.3)	5 (2.7)	0.8 (0.5 to 1.3)	0.793
Numbness at side of foot	50 (27.5)	42 (23.1)	0.7 (0.5 to 1.3)	0.399
No-union of fracture	8 (4.4)	5 (2.7)	0.6 (0.2 to 2.2)	0.574
DVT	2 (1.1)	3 (1.6)	1.5 (0.2 to 18.2)	1.00
Pulmonary embolism	1 (0.5)	1 (0.5)	1 (0.0 to 78.9)	1.00
CRPS	1 (0.5)	4 (2.0)	4.0 (0.3 to 201.2)	0.372

\*Fisher's exact test

CI, confidence interval; CRPS, complex regional pain syndrome; DVT, deep vein thrombosis; OR, odds ratio.

### Sensitivity analysis (imputation model results)

As the trial had 35% lost to follow-up at 24 months, a sensitivity analysis was undertaken to observe the findings based on an imputed dataset for missing data. The imputation analysis results for the 24-month follow up concurred with the main results. The differences between the intervention groups were found to be even more negligible with tighter confidence intervals. The OMAS reported a difference of -0.1 in favour of plaster cast (95% CI -3.6 to 3.3;  $p = 0.944$ ), the DRI reported -0.3 in favour of the plaster cast (95% CI -6.4 to 5.7;  $p = 0.911$ ), and the EQ-5D-5L had difference 0.00 (95% CI -0.037 to 0.037;  $p = 0.998$ ) (Table ii).

## References

1. **Olerud C, Molander H.** A scoring scale for symptom evaluation after ankle fracture. *Arch Orthop Trauma Surg (1978)*. 1984;103(3):190–194.
2. **Salén BA, Spangfort EV, Nygren AL, Nordemar R.** The Disability Rating Index: an instrument for the assessment of disability in clinical settings. *J Clin Epidemiol*. 1994;47(12):1423–1435
3. **The EuroQol Group.** EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy*. 1990;16(3):199–208