■ FOOT & ANKLE

Use of cast immobilization versus removable brace in adults with an ankle fracture: two-year follow-up of a multicentre randomized controlled trial

A. Haque,
H. Parsons,
N. Parsons,
M. L. Costa,
A. C. Redmond,
J. Mason,
H. Nwankwo,
R. S. Kearney

From Warwick University, Coventry, UK

Aims

The aim of this study was to compare the longer-term outcomes of operatively and nonoperatively managed patients treated with a removable brace (fixed-angle removable orthosis) or a plaster cast immobilization for an acute ankle fracture.

Methods

This is a secondary analysis of a multicentre randomized controlled trial comparing adults with an acute ankle fracture, initially managed either by operative or nonoperative care. Patients were randomly allocated to receive either a cast immobilization or a fixed-angle removable orthosis (removable brace). Data were collected on baseline characteristics, ankle function, quality of life, and complications. The Olerud-Molander Ankle Score (OMAS) was the primary outcome which was used to measure the participant's ankle function. The primary endpoint was at 16 weeks, with longer-term follow-up at 24 weeks and two years.

Results

Overall, 436 patients (65%) completed the final two-year follow-up. The mean difference in OMAS at two years was -0.3 points favouring the plaster cast (95% confidence interval -3.9 to 3.4), indicating no statistically significant difference between the interventions. There was no evidence of differences in patient quality of life (measured using the EuroQol five-dimension five-level questionnaire) or Disability Rating Index.

Conclusion

This study demonstrated that patients treated with a removable brace had similar outcomes to those treated with a plaster cast in the first two years after injury. A removable brace is an effective alternative to traditional immobilization in a plaster cast for patients with an ankle fracture.

Cite this article: ***Bone Joint J*** **2023;105-B(4):382–388.**

Introduction

This paper is the two-year follow-up study of the Ankle Injury Rehabilitation (AIR) Trial,[1] comparing outcomes of patients treated with a removable brace (fixed-angle removable orthosis) to those who received a plaster cast immobilization. Patients who were allocated to these interventions had either received initial surgical treatment within three weeks preceding randomization, or were non-surgically managed.

There were multiple reasons for initiating the AIR trial, one of which was the growing number of adults suffering ankle injuries, which is expected to increase threefold by 2030.[2,3] This will put further pressure on the NHS, potentially exacerbating the impact on the injured person, as well as increasing the overall societal costs.[4,5] There is a need to find out the best way to treat patients,[6] particularly to identify the best form of support for the ankle while the bone is healing.

The most recent Cochrane review indicated that treatment with a removable brace, which allows early movement of the ankle, may reduce the stiffness and muscle atrophy associated with

Correspondence should be sent to R. S. Kearney; email: becky.kearney@bristol.ac.uk

© 2023 Authors et al.
doi:10.1302/0301-620X.105B4.BJJ-2022-0602.R3 $2.00

Bone Joint J 2023;105-B(4):382–388.

Table I. Patient characteristics for 24-month follow-up study and the full study population.

Baseline characteristic	24-month follow-up	Lost to follow-up	p-value
Total, n	436	233	
Sex, n (%)			0.046*
Female	261 (60)	120 (52)	
Male	175 (40)	113 (48)	
Ethnicity, n (%)			< 0.001*
Asian	7 (2)	20 (9)	
Black/African/Caribbean	13 (3)	16 (7)	
Mixed	5 (1)	10 (4)	
Other	4 (1)	9 (4)	
White	405 (93)	176 (76)	
Missing	2 (< 1)	2 (< 1)	
Mean OMAS (SD)			
Preinjury	94 (14)	92 (20)	0.124†
Post-injury	21 (17)	20 (18)	0.543†
Mean age, yrs (SD)	50 (16)	39 (16)	0.506†
Age group, n (%)			< 0.001*
≤ 49 yrs	201 (46)	170 (73)	
≥ 50 yrs	235 (54)	63 (27)	
Mean BMI, kg/m² (SD)	28 (6)	28 (6)	0.697†
Mechanism of injury, n (%)			
Low-energy fall	285 (66)	143 (61)	0.313*
High-energy fall	76 (18)	33 (14)	0.327*
Road traffic accident	15 (3)	11 (5)	0.544*
Sports injury	32 (7)	17 (7)	> 0.999*
Other	33 (8)	30 (13)	0.036*
Side of injury, n (%)			0.928*
Right	214 (49)	114 (49)	
Left	221 (51)	116 (50)	
Missing	1 (< 1)	3 (1)	
Malleolus involvement, n (%)			
Lateral	412 (95)	212 (91)	> 0.999*
Medial	120 (28)	74 (32)	0.289*
Posterior	78 (18)	42 (18)	> 0.999*
Weber classification, n (%)			> 0.999‡
Operative			
A	2 (1)	2 (1)	
B	145 (65)	78 (55)	
C	59 (26)	41 (29)	
Missing	17 (8)	20 (14)	
Nonoperative			> 0.999‡
A	25 (11)	12 (13)	
B	161 (75)	73 (79)	
C	12 (6)	5 (5)	
Missing	15 (7)	2 (2)	
Fracture management, n (%)			0.024*
Operative	222 (51)	141 (61)	
Nonoperative	213 (49)	92 (39)	
Missing	1 (< 1)	0 (0)	
Advised weightbearing status, n (%)			0.564*
Full	143 (33)	76 (33)	
Partial	96 (22)	44 (19)	
None	192 (44)	111 (48)	
Missing	5 (1)	2 (< 1)	
Concurrent injuries, n (%)			0.198*
No	396 (91)	214 (92)	
Yes	34 (8)	11 (5)	
Missing	6 (1)	8 (3)	
Regular smoker, n (%)			< 0.001*
No	375 (86)	152 (65)	
Yes	60 (14)	75 (32)	
Missing	1 (< 1)	6 (3)	
Alcohol units per week, n (%)			0.336*
0 to 7	277 (64)	161 (69)	
8 to 14	85 (19)	36	
15 to 21	46 (11)	18 (8)	
> 21	28 (6)	16 (7)	
Other medication, n (%)			
Steroids	21 (5)	3 (1)	0.027‡
Any other medications	300 (69)	139 (60)	< 0.001*
Diagnosis prior to injury, n (%)			
Diabetes	19 (4)	13 (6)	0.569‡

*Chi-squared test.
†Independent-samples *t*-test.
‡Fisher's exact test.
OMAS, Olerud-Molander Ankle Score; SD, standard deviation.

traditional plaster cast immobilization.[7] However, the review indicated that additional definitive research was needed. In 2021, we reported the early results of a randomized controlled trial (RCT) comparing a removable brace and plaster cast.[8] The trial also had a planned follow-up at two years to observe the recovery trajectory of the patients and any subsequent differences between the intervention groups. In this paper, we present the two-year outcomes.

AIR recruited from 20 English NHS Trusts between 9 October 2017 and 30 September 2019. A total of 669 patients were randomized into the study: 334 were allocated to the cast and 335 to the removable brace. The mean age was 46 years (standard deviation (SD) 17) and 57% were female (n = 381). A total of 502 patients (75%) completed the primary outcome measure to assess ankle function and pain (Olerud-Molander Ankle Score (OMAS))[9] 16 weeks after randomization. The mean difference in OMAS was 1.8 (95% confidence interval (CI) -2.0 to 5.6; p = 0.357, adjusted linear regression model) in favour of the removable brace. There was a small number of safety events which did not have a statistically significant difference (odds ratio 1; p = 1.000, Fisher's exact test). The trial found that there were no clinically or statistically significant differences between the intervention groups for ankle function, quality of life, or safety events and complications in the first four months after the fracture.[8]

Methods

Trial design and recruitment. A full protocol and a description of the AIR trial's results have been published.[1,8] In the AIR multicentre trial patients were randomized using a minimization algorithm with a random factor, stratified by the recruiting centre, age group (≤ 49 years or ≥ 50 years, sex, and initial fracture management (operative or nonoperative)). Patients in the control arm were fitted with a plaster cast immobilization for

Table II. Olerud-Molander Ankle Score, Disability Rating Index, EuroQol five-dimension five-level questionnaire in the intention-to-treat population. A positive value is in favour of removable brace.

Score	Plaster cast		Removable brace		Between-group difference (95% CI)		
	n (%)	Mean (SD)	n (%)	Mean (SD)	Unadjusted	Adjusted*	p-value†
Total, n	334		335				
OMAS							
24 wks	222 (66.5)	72.7 (22.5)	227 (67.8)	71.6 (23.7)	-1.1 (-5.4 to 3.2)	-1.8 (-5.7 to 2.1)	0.373
24 mths	215 (64.4)	85.5 (20.6)	219 (65.4)	85.6 (19.9)	0.1 (-3.7 to 3.9)	-0.3 (-4.0 to 3.4)	0.866
24 mths§	334 (100)	85.0 (20.9)	335 (100)	85.2 (20.6)	0.1 (-3.4 to 3.7)	-0.1 (-3.6 to 3.3)	0.944
DRI							
24 wks	209 (62.6)	24.1 (24.3)	213 (63.6)	24.6 (25.8)	0.5 (-4.3 to 5.3)	0.4 (-4.6 to 4.7)	0.986
24 mths	178 (53.3)	22.7 (29.7)	183 (54.6)	22.2 (31.4)	-0.5 (-6.8 to 5.8)	-0.8 (-7.0 to 5.4)	0.802
24 mths§	334 (100)	23.8 (30.6)	335 (100)	25.3 (31.6)	-0.3 (-6.5 to 5.9)	-0.3 (-6.4 to 5.7)	0.911
EQ-5D-5L							
24 wks	220 (65.9)	0.767 (0.193)	227 (67.8)	0.778 (0.176)	0.011 (-0.023 to 0.045)	0.013 (-0.020 to 0.045)	0.442
12 mths	228 (68.3)	0.825 (0.171)	235 (70.1)	0.812 (0.192)	-0.013 (-0.046 to 0.020)	-0.012 (-0.044 to 0.020)	0.458
18 mths	224 (67.1)	0.849 (0.189)	232 (69.3)	0.832 (0.206)	-0.017 (-0.053 to 0.019)	-0.015 (-0.051 to 0.021)	0.405
24 mths	216 (64.7)	0.864 (0.196)	219 (65.4)	0.858 (0.191)	-0.006 (-0.042 to 0.031)	-0.005 (-0.041 to 0.031)	0.779
24 mths	334 (100)	0.855 (0.204)	335 (100)	0.854 (0.199)	-0.001 (-0.038 to 0.037)	0.000 (-0.037 to 0.037)	0.998
Initial fracture management							
OMAS scores at 24 mths‡							
Operative	111 (33.2)	81.9 (22.3)	111 (33.1)	84.1 (18.5)	N/A	N/A	N/A
Nonoperative	104 (31.1)	89.4 (17.9)	108 (32.2)	87.1 (21.3)	N/A	N/A	N/A

*Estimates of the linear regression model adjusted for patient sex, age group, fracture management, and baseline. Random effect model did not improve fit and was therefore omitted.
†p-value of the adjusted result (linear regression model).
‡Independent-samples *t*-test for the subgroup differences are omitted.
CI, confidence interval; DRI, Disability Rating Index; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; N/A, not applicable; OMAS, Olerud-Molander Ankle Score; SD, standard deviation.

a minimum of three weeks. The intervention group was fitted with a fixed-angle removable orthosis (removable brace) and given a leaflet of exercises to perform at home. The study was unblinded, and the primary outcome was the OMAS. Patients were followed up for two years, with the primary endpoint collected at 16 weeks post-randomization.

Outcomes. Following the 16-week primary timepoint, secondary data were collected for all outcome measures at 24 weeks and two years, other than quality of life (measured with the EuroQol five-dimension five-level health questionnaire (EQ-5D-5L)),[10] which was additionally collected at 12 and 18 months post-randomization. The outcome measures for the two-year follow-up study were as follows.

The primary outcome of the AIR study was the OMAS, which is a self-administered questionnaire scored on a scale between 0 and 100, where higher scores denote better function.[9,11] It is based on nine items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, support, and work/activities of daily living. The EQ-5D-5L is a validated, generic health-related quality of life measure consisting of five items each with five possible responses, which is converted to a utility score (UK crosswalk tariff) ranging from -0.654 to 1, with 0 defined as a health state equivalent to death and 1 representing full health.[10] The Disability Rating Index (DRI) is a self-administered questionnaire, consisting of 12 items related to the function of the lower limb.[12] Each item is scored using a visual analogue scale with anchor points of 0 and 100, and the summary score is simply the mean of all items. All complications and additional surgery for the index fracture were also recorded.

Sample size. Data collected at two-year follow-up were considered secondary analysis, and as such were not formally part of the original power analysis that determined the study sample size for AIR. The clinically meaningful between-group difference for the OMAS outcome was defined as ten points for the main AIR trial.[13,14] Initially, 478 patients were required to evaluate this difference at the primary timepoint of 16 weeks. Recruitment exceeded planned expectations, and ethical approval was granted to continue recruitment until the end of the originally planned period, resulting in a total sample size of 669 patients.

Statistical analysis. Follow-up data analyses were conducted on an intention-to-treat basis unless otherwise specified, which was consistent with the analysis of the main study. Tests were considered statistically significant if $p < 0.05$. The between-group difference was analyzed using independent-samples *t*-tests and an adjusted mixed-effects linear regression model. The analysis was adjusted for the stratification variables (sex, age, and operative/nonoperative management) and the baseline score as fixed effects and the recruitment site as random effects. The patient sample at the final follow-up of two years was assessed to check if it was representative of the full study population using independent-samples *t*-tests or chi-squared tests, dependent on outcome type. Fisher's exact test was used for outcomes with small cell counts.

Imputation for partial missing data, such as missing item responses for OMAS, DRI, and EQ-5D-5L, was carried out using the instructions from the questionnaire manuals for scoring and handling missing items. The outcomes were

Table III. Olerud-Molander Ankle Score cohort summary.

Age	Operative (n = 364)			Nonoperative (n = 305)		
	n	24-mth mean (95% CI)	Mean change from preinjury (95% CI)	n	24-mth mean (95% CI)	Mean change from preinjury (95% CI)
≤ 49 yrs						
Female	54	83.9 (79.1 to 88.7)	-11.4 (-16.7 to -6.0)	56	90.2 (85.4 to 94.9)	-5.0 (-11.2 to 1.2)
Male	52	90.4 (86.5 to 94.2)	-8.2 (-12.4 to - 3.9)	39	91.4 (87 to 95.9)	-4.1 (-10.6 to 2.4)
Both	106	87.1 (83.9 to 90.2)	-9.8 (-13.2 to -6.4)	95	90.7 (87.3 to 94)	-4.6 (-9.1 to -0.2)
≥ 50 yrs						
Female	74	77.8 (72.4 to 83.2)	-15.8 (-21.4 to -10.2)	76	86 (80.8 to 91.1)	-4.8 (-9.9 to 0.3)
Male	42	81.9 (75.4 to 88.5)	- 9.2 (-15.3 to -3)	40	86.9 (81 to 92.8)	-6.8 (-12 to -1.5)
Both	116	79.3 (75.1 to 83.5)	-13.4 (-17.6 to -9.2)	117	86.3 (82.3 to 90.2)	-5.5 (-9.2 to -1.7)

CI, confidence interval.

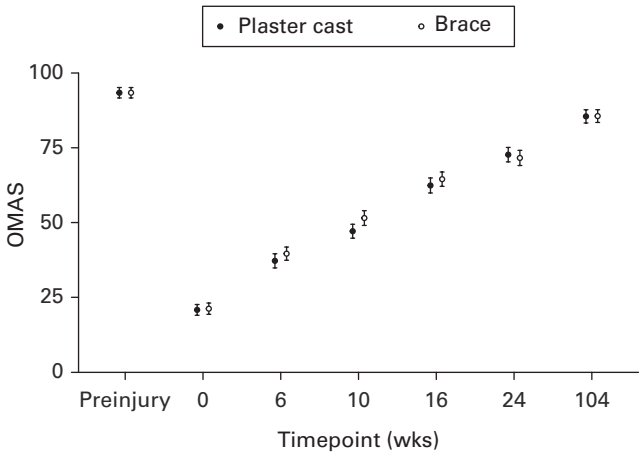

Fig. 1

Mean Olerud-Molander Ankle Scores (OMAS) with 95% confidence intervals.

reported as missing if the patient's score was incalculable due to high levels of missing items. Complications were summarized using odds ratios and tested with Fisher's exact test.

In a sensitivity analysis, multiple imputations were carried out to account for those patients lost to follow-up at the final two-year assessment. The randomization strata, baseline score, and the earlier follow-up scores (including the primary 16-week score) were used to extrapolate the missing scores at the two-year follow-up along with key baseline predictors for missingness: patients' weight and height, patients who smoke and take other medications, and if the medial or posterior malleolus was affected during the injury. The datasets were imputed 20 times, with the imputed datasets and the corresponding regression results pooled using Rubin's rules.[15]

All analyses were implemented in R v. 4.1.2 (R Foundation for Statstical Computing, Austria). The R-packages lme4 and lmerTest were used for the primary statistical analysis, and the mice package was used for the imputation analysis.

Results

Of the 669 patients recruited into the study, 436 completed the final two-year follow-up; 216 remained in the cast group and 220 patients in the brace group, with a total of 44 withdrawals and 189 patients lost to follow-up. To check if the final sample was representative of the total study population, baseline demographic data were compared between the patients at two-year follow-up and the lost-to-follow-up population. It was found that there were important differences in demographic data and baseline characteristics such as sex, age group, smoking status, steroids, and other medications (Table I).

The results for the final two-year follow-up showed that there was no statistically significant difference between the two intervention groups. The mean adjusted difference for the primary outcome OMAS was -0.3 in favour of the plaster cast (95% CI -4.0 to 3.4; p = 0.866, linear regression model). This is smaller than the target difference of ten points which was considered clinically meaningful. It is also consistent with the results from the primary analysis at 16 weeks,[8] and supports the conclusion that both interventions have clear and similar recovery trajectories over two years of follow-up (Table II). Both intervention groups had substantial improvement from baseline to a high function level, with mean scores of 85.5 (95% CI 83.3 to 87.7) and 85.6 (95% CI 83.5 to 87.7) out of 100 for the brace and plaster cast, respectively (Figure 1).

The primary OMAS outcome measure was also evaluated according to the predefined AIR trial analysis subgroups of sex (female/male), age group (≤ 49 years and ≥ 50 years), and initial management (operative/nonoperative). While no statistically significant differences between the cast and brace were evident when analyzing the subgroups, examining the recovery trajectories from preinjury scores to the final follow-up revealed different patterns of recovery. The results showed that patients aged 50 years and above who were operatively managed had the lowest mean score of 79.3 (95% CI 75.1 to 83.5) at 24 months. This group also had the largest mean deficit from preinjury compared to the other subgroups (Table III). In contrast, the younger age group that was managed nonoperatively had the best recovery, with a mean deficit of only -4.6 (95% CI -9.1 to -0.2), and the highest final follow-up score of 90.7 (95% CI 87.3 to 94.0). A detailed breakdown for the cohorts is shown in Table III. Further details on operatively and nonoperatively managed patients can be found in Supplementary Material, as well as results on the secondary analysis and sensitivity analysis for missing data.

Table IV. Analysis of complications (intention-to-treat population). Numbers shown are complications reported at least once per participant.

Complications	Plaster cast, n (%)	Removable brace n (%)	OR (95% CI)	p-value*
Total, n	334	335		
Surgical patients only				
Wound infection requiring antibiotics†	12 (6.6)	20 (11.0)	1.7 (0.8 to 4.0)	0.195
Wound breakdown/dehiscence†	10 (5.5)	16 (8.8)	1.7 (0.7 to 4.2)	0.310
Further surgery for ankle fracture†	16 (8.8)	23 (12.6)	1.5 (0.7 to 3.2)	0.309
All patients				
Pressure sore/ulcer	12 (3.6)	6 (1.8)	0.8 (0.5 to 1.2)	0.309
Numbness at side of foot	63 (18.9)	53 (15.8)	0.8 (0.5 to 1.2)	0.809
Nonunion of fracture	12 (3.6)	10 (3.0)	0.8 (0.3 to 2.1)	0.672
Deep vein thrombosis	5 (1.5)	4 (1.2)	0.8 (0.2 to 3.7)	0.795
Pulmonary embolism	2 (0.6)	1 (0.3)	0.5 (0.0 to 9.6)	0.624
Chronic regional pain syndrome	2 (0.6)	5 (1.5)	2.5 (0.4 to 26.3)	0.451

*Fisher's exact test.
†Numbers are only applicable to those who had operative management: cast (n = 182), removable brace (n = 182).
CI, confidence interval; OR, odds ratio.

Assessment of the complications showed that patients in the removable brace suffered more complications in the surgically managed group (Table IV). However, we were not powered to detect a statistically significant difference, therefore while we recognize this pattern, there is insufficient evidence to conclude that the removable brace is harmful. When observing the complications for all patients, there was a small difference in the number between the intervention groups. Analyzing the timing of the safety events showed that approximately 66% of complications were reported within 16 weeks (n = 188), and 33% were reported between 16 weeks and 24 months (n = 96). Overall, the complication rates were low apart from a few exceptions (Table IV). Only 1% of patients experienced chronic regional pain syndrome that was classed as a serious adverse event, and there was no significant difference between the plaster cast and removable brace.

Discussion

One of the initial motivations for the study was that we hypothesized that there may be potential benefits to using a removable brace due to the early range of motion. The results of the AIR trial have definitively shown that there are no such benefits either in the short (16 weeks) or long term (24 months).

Overall, both participant groups had positive recovery trajectories from baseline, although the final follow-up scores did not reach the self-reported preinjury levels for either intervention group. These patterns were similar for all secondary outcomes. Hence, as there were no statistically significant or clinically meaningful differences between the cast and brace groups, we recommend that factors such as patient preference and cost should be taken into consideration when choosing the most appropriate form of ankle protection.

Additionally, while it was seen that most participant groups had positive recovery trajectories from baseline, a key finding is that most patients are unlikely to recover to their preinjury state. Patients who are surgically managed, and hence more likely to have more complex fractures, are also more likely to have ongoing issues with their ankle. We further recommend that it is advisable to discuss expectations with patients and consider further care to ensure they have the best recovery.

The safety and complications results showed potential patterns emerging where the brace group had higher complications in the surgical group. However, due to limited power, it is not possible to conclude that the brace would be harmful to use. Despite these patterns, when considering the complication rates for all patients not exclusive to the surgical group (such as wound infection), there is only a small difference in numbers between allocation groups (Table IV). Therefore, given the current evidence, we conclude that both interventions are safe and effective.

The main limitation of the study is the large proportion of patients lost to follow-up. Although the study reported 35% of patients missing at 24 months, it retained 436 responses. This number was greater than the number required to detect a clinically meaningful difference of ten points on the OMAS, which was 382, based on the assumptions outlined in the protocol paper.[1] Hence, the sample was sufficiently large to make reliable inferences about the intervention effects and the recovery of patients over the course of the study follow-up period. However, the missing population was noticeably different from those who remained in follow-up, with missing responses tending to be from younger patients (Table I). Additionally, a higher percentage of patients who had surgical management for their ankle fracture were lost to follow-up, as well as male patients. Nevertheless, the imputation analysis showed that these results did not differ from the findings of the main analysis.

A further limitation of the study is that although patients in the brace group were provided with a leaflet of exercises to perform, no data were collected on the patient's compliance. However, AIR was designed to be a pragmatic study; the use of information leaflets was standard practice for many sites. This is likely to reflect patient behaviour beyond the trial setting.

Before the AIR trial, the existing literature was limited to a few studies, one of which limited participation to patients who received operative care in 2015.[16] Another RCT in 2012 was completed in Canada with 110 patients, with questionable generalizability to the UK setting and a non-validated measure of function as the primary outcome measure (return to work). In summary, neither of the previously reported trials

provided definitive evidence and more high-quality research was needed.

The primary results from the AIR trial have made a significant contribution having recruited a large and unprecedented number of patients from the ankle fracture population, of both surgically and non-surgically managed patients. It provides a strong basis for the results presented here and ample evidence for alternative fracture management plans. The longer-term results presented in this paper provide further evidence on the recovery trajectory of patients, with no difference in the intervention groups, further supporting the conclusions from the primary results. In addition, long-term follow-up shows the need for ongoing care as patients do not recover to preinjury levels.

The results show neither the removable brace nor the plaster cast to be superior for patients' outcomes. The safety results have shown that for nonoperative patients there is little difference between the two interventions. There was insufficient evidence to conclude that the brace was harmful for patients who initially had surgical management. With these findings, clinicians can be reassured that the removable brace is a suitable alternative in the short and longer term, and these results can be used to manage patients' expectations of recovery.

Take home message

- A removable brace is as effective as traditional immobilization in a plaster cast for patients with an ankle fracture. This applies long-term to patients treated both operatively and nonoperatively.

Supplementary material

Tables and figures summarizing the subgroup results and recovery patterns of the participants for the primary and secondary outcomes, as well as the results for the imputation model for missing data. The quality-of-life outcome (EuroQol five-dimension five-level health questionnaire) was analyzed by each of the five domains, and a summary of the complications that occurred for surgically managed participants is also presented.

References

1. **Kearney RS**, **McKeown R**, **Stevens S**, **et al**. Cast versus functional brace in the rehabilitation of patients treated for an ankle fracture: protocol for the UK study of ankle injury rehabilitation (AIR) multicentre randomised trial. *BMJ Open*. 2018;8(12):e027242.
2. **Court-Brown CM**, **Caesar B**. Epidemiology of adult fractures: A review. *Injury*. 2006;37(8):691–697.
3. **Kannus P**, **Palvanen M**, **Niemi S**, **Parkkari J**, **Järvinen M**. Increasing number and incidence of low-trauma ankle fractures in elderly people: Finnish statistics during 1970-2000 and projections for the future. *Bone*. 2002;31(3):430–433.
4. **McPhail SM**, **Dunstan J**, **Canning J**, **Haines TP**. Life impact of ankle fractures: qualitative analysis of patient and clinician experiences. *BMC Musculoskelet Disord*. 2012;13:224.
5. **McKeown R**, **Kearney RS**, **Liew ZH**, **Ellard DR**. Patient experiences of an ankle fracture and the most important factors in their recovery: a qualitative interview study. *BMJ Open*. 2020;10(2):e033539.
6. **Willett KM**, **Gray B**, **Moran CG**, **Giannoudis PV**, **Pallister I**. Orthopaedic trauma research priority-setting exercise and development of a research network. *Injury*. 2010;41(7):763–767.
7. **Lin C-WC**, **Donkers NAJ**, **Refshauge KM**, **Beckenkamp PR**, **Khera K**, **Moseley AM**. Rehabilitation for ankle fractures in adults. *Cochrane Database Syst Rev*. 2012;11:CD005595.
8. **Kearney R**, **McKeown R**, **Parsons H**, **et al**. Use of cast immobilisation versus removable brace in adults with an ankle fracture: multicentre randomised controlled trial. *BMJ*. 2021;374:1506.
9. **Olerud C**, **Molander H**. A scoring scale for symptom evaluation after ankle fracture. *Arch Orthop Trauma Surg (1978)*. 1984;103(3):190–194.
10. **The EuroQol Group**. EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy*. 1990;16(3):199–208.
11. **McKeown R**, **Parsons H**, **Ellard DR**, **Kearney RS**. An evaluation of the measurement properties of the Olerud Molander Ankle Score in adults with an ankle fracture. *Physiotherapy*. 2021;112:1–8.
12. **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.
13. **Keene DJ**, **Mistry D**, **Nam J**, **et al**. The Ankle Injury Management (AIM) trial: a pragmatic, multicentre, equivalence randomised controlled trial and economic evaluation comparing close contact casting with open surgical reduction and internal fixation in the treatment of unstable ankle fractures in patients aged over 60 years. *Health Technol Assess*. 2016;20(75):1–158.
14. **van den Berg C**, **Haak T**, **Weil NL**, **Hoogendoorn JM**. Functional bracing treatment for stable type B ankle fractures. *Injury*. 2018;49(8):1607–1611.
15. **White IR**, **Royston P**, **Wood AM**. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med*. 2011;30(4):377–399.
16. **Dehghan N**, **McKee MD**, **Jenkinson RJ**, **et al**. Early weightbearing and range of motion versus non-weightbearing and immobilization after open reduction and internal fixation of unstable ankle fractures: a randomized controlled trial. *J Orthop Trauma*. 2016;30(7):345–352.
17. **Devlin NJ**, **Shah KK**, **Feng Y**, **Mulhern B**, **van Hout B**. Valuing health-related quality of life: An EQ-5D-5L value set for England. *Health Econ*. 2018;27(1):7–22.

Author information:

A. Haque, MSc, Research Associate
H. Parsons, PhD, Associate Professor in Medical Statistics
J. Mason, DPhil, Professor in Health Economics
H. Nwankwo, PhD, Research Fellow
Warwick Clinical Trials Unit, University of Warwick, Coventry, UK.

N. Parsons, PhD, Professor of Medical Statistics, Warwick Medical School, University of Warwick, Coventry, UK.

M. L. Costa, PhD, FRCS, Professor of Orthopaedic Trauma, Oxford Trauma and Emergency Care, Nuffield Department of Rheumatology, Musculoskeletal and Orthopaedic Sciences, University of Oxford, Oxford, UK.

A. C. Redmond, PhD, FFPM, RCPS(Glasg), Professor of Clinical Biomechanics, Leeds Institute for Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK.

R. S. Kearney, PhD, Professor of Trauma and Orthopaedic Rehabilitation, Bristol Trials Centre, University of Bristol, Bristol, UK.

Author contributions:

A. Haque: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft.
H. Parsons: Conceptualization, Methodology, Investigation, Formal analysis, Writing – review & editing.
N. Parsons: Conceptualization, Methodology, Funding acquisition, Supervision, Investigation, Writing – review & editing.
M. L. Costa: Conceptualization, Methodology, Funding acquisition, Supervision, Investigation, Writing – review & editing.
A. C. Redmond: Conceptualization, Methodology, Funding acquisition, Supervision, Investigation, Writing – review & editing.
J. Mason: Conceptualization, Methodology, Investigation, Writing – review & editing.
H. Nwankwo: Writing – review & editing.
R. S. Kearney: Conceptualization, Methodology, Funding acquisition, Project administration, Supervision, Investigation, Writing – review & editing.

Funding statement:

The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: this trial was funded by the National Institute for Health Research (NIHR) commencing 1 January 2017, as part of a personal fellowship to R. S. Kearney (NIHR: CDF-2016-09-009) and supported by the NIHR Oxford Biomedical Research Centre. The views expressed are those of the authors and not necessarily

those of the NIHR or the Department of Health and Social Care. The funders had no role in considering the study design or in the collection, analysis, interpretation of data, writing of the report, or decision to submit the article for publication.

Acknowledgements:
The AIR trial collaborators
Jonathan Young and Eamon Ramahandany (University Hospitals Coventry and Warwickshire), Mike Kelly (North Bristol), Nima Heidari (The Royal London Hospital), Richard Jeavons and Rajesh Nanda (North Tees and Hartlepool), Carolyn Chadwick, Chris Blundell, Mark Davies and Howard Davies (Northern General Hospital), Raju Aluwhalia and Ines Reichert (Kings College Hospital), Sultan Qasim (Royal Victoria Informary), Atif Malik (Milon Keynes University Hospital), Jordi Ballester (St Helens and Knowsley Teach Hospital), Verity Currall and Simon Burtt (Luton and Dunstable University Hospital), Sandeep Kapoor (The Rotherham NHS Foundation Trust), Fraser Harrold and Alasdair Macinnes (Ninewells Hospital and Medical School), Harish Karup, Holly Morris, Suranga Giurushihe, Melinda Hav, Abdul Moees, Hemanta Das and Vishal Rajput (United Lincolnshire Hospitals NHS Trust), Aamir Zubairy (East Lancashire Hospitals NHS), Andrew McAndrew (Royal Berkshire Hospital), Rupinderbir Deol (Lister Hospital), Syed Anjum, Togay Koc, Ahmed Abde Azaz, Zine Beech, Mike Dean, Zoe Lin, Jo Round (University Hospital Southampton NHS Foundation Trust), Craig White (South Tees Hospital NHS Foundation Trust), Yadu Shankarappa (Bedfordshire Hospitals NHS Foundation Trust), and Jit Mangwani (Leicester Royal Infirmary).

Ethical review statement:
This study was approved by the National Research Ethic Committee on 4 July 2017 (17/WM/0239), with each trial site granting individual NHS trust approval before recruitment at each site. This study was prospectively registered on 24 July 2017.

Open access funding:
The open access fee was funded by the National Institute for Health Research.

Open access statement:
This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives (CC BY-NC-ND 4.0) licence, which permits the copying and redistribution of the work only, and provided the original author and source are credited. See https://creativecommons.org/licenses/by-nc-nd/4.0/

Trial registration number:
ISRCTN15537280

This article was primary edited by G. Scott.