

Mechanical supports for acute, severe ankle sprain: a pragmatic, multicentre, randomised controlled trial

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Summary

Background Severe ankle sprains are a common presentation in emergency departments in the UK. We aimed to assess the effectiveness of three different mechanical supports (Aircast brace, Bledsoe boot, or 10-day below-knee cast) compared with that of a double-layer tubular compression bandage in promoting recovery after severe ankle sprains.

Methods We did a pragmatic, multicentre randomised trial with blinded assessment of outcome. 584 participants with severe ankle sprain were recruited between April, 2003, and July, 2005, from eight emergency departments across the UK. Participants were provided with a mechanical support within the first 3 days of attendance by a trained health-care professional, and given advice on reducing swelling and pain. Functional outcomes were measured over 9 months. The primary outcome was quality of ankle function at 3 months, measured using the Foot and Ankle Score; analysis was by intention to treat. This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN37807450.

Results Patients who received the below-knee cast had a more rapid recovery than those given the tubular compression bandage. We noted clinically important benefits at 3 months in quality of ankle function with the cast compared with tubular compression bandage (mean difference 9%; 95% CI 2·4–15·0), as well as in pain, symptoms, and activity. The mean difference in quality of ankle function between Aircast brace and tubular compression bandage was 8%; 95% CI 1·8–14·2, but there were little differences for pain, symptoms, and activity. Bledsoe boots offered no benefit over tubular compression bandage, which was the least effective treatment throughout the recovery period. There were no significant differences between tubular compression bandage and the other treatments at 9 months. Side-effects were rare with no discernible differences between treatments. Reported events (all treatments combined) were cellulitis (two cases), pulmonary embolus (two cases), and deep-vein thrombosis (three cases).

Interpretation A short period of immobilisation in a below-knee cast or Aircast results in faster recovery than if the patient is only given tubular compression bandage. We recommend below-knee casts because they show the widest range of benefit.

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Background

Acute ankle sprain accounts for between 3% and 5% of all UK emergency department attendances: around 1–1·5 million a year.^{1,2} Most sprains are of the lateral ligament complex.² The severity of injury is graded from I to III.³ Grade I injuries are self-limiting, with only stretching of the ligament. Grade II and III injuries are either a tear or complete rupture of the ligament complex, and are typified by inability to bear weight on the leg, and by substantial amounts of swelling.³ Incapacity, particularly in the early phase, can be extensive. Function returns in about 70% of individuals between 3 and 9 months. Residual symptoms can linger for years after the initial injury.⁴

Widespread belief exists that early management, including ice, elevation, and controlled mobilisation of the joint, is effective in promoting speedy recovery and limiting chronic symptoms. Complete immobilisation is discouraged.⁵ In UK emergency departments, the most commonly used treatments (>75% of centres) are ice, elevation, tubular compression bandage, and advice to exercise.⁶ However, systematic reviews have highlighted

a lack of quality evidence to aid clinical decision making, including whether to mobilise or immobilise the joint, and, if immobilisation is chosen, which types of supports are best.^{7,8}

The aim of this study was to compare the effectiveness of three types of mechanical support with that of tubular compression bandage in promoting recovery of function after an acute, severe ankle sprain. The primary timepoint was 3 months, but follow-up considered outcomes over 9 months, to detect longer-term complications from the injury or the treatments. We selected various supports for testing to represent a range of strategies to promote early recovery and mobilisation. Tubular compression bandage was selected as the reference treatment, because it was the cheapest and most commonly used.⁶ It provides compression, and allows movement in any plane. The Bledsoe boot (Medical Technology Inc, Grand Prairie, TX, USA) is designed to limit motion in all planes, has a foot-plate designed to facilitate mobility, and is lightweight and removable. The Aircast (DJO Incorporated, Vista, CA, USA) brace provides localised compression and support; it allows plantarflexion and dorsiflexion, but

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limits inversion and eversion (ie, the movements that caused the original injury). The final support was a non-removable below-knee cast, applied for 10 days. Including fitting, the Bledsoe boot cost £215.00, tubular compression bandage £1.44, the Aircast brace £39.23, and the below-knee cast £16.46 (2005 reference prices).⁹

Methods

Participants and setting

We did a multicentre randomised trial, with blinded assessment of outcome, and a 9-month follow-up period. This was a pragmatic trial, testing the provision of mechanical supports within the constraints of normal UK National Health Service (NHS) practice.

Participants with severe ankle sprain were recruited between April, 2003, and July, 2005, from eight emergency departments across England. Patients had to be over 16 years of age (to ensure skeletal maturity, and avoid inclusion of epiphyseal injuries that would not be managed with the treatments tested), and unable to bear weight for at least 3 days after the injury. Weight-bearing status is used to indicate severity of sprains, since clinical grading is not possible in the acute phase. People with flake fractures of less than 3 mm were included, because such fractures should be treated as soft-tissue injuries;³ all other recent fractures were excluded. All participants had a radiograph, since the Ottawa criteria specify inability to bear weight as an indication for radiography.³ Patients were excluded from the trial if they had contraindications to immobilisation (eg, high risk of deep-vein thrombosis, as assessed by the recruiting clinician), or if the injury had occurred more than 7 days previously. The protocol was approved by the Northern and Yorkshire multicentre research ethics committee (MREC/2/3/9), and the research and ethics committees for each collaborating hospital. All individuals provided written informed consent.

Procedures

Plaster technicians, physiotherapists, and nurses were responsible for applying the supports, and all were provided with training. The treatment packages have been described in detail elsewhere.⁹ In summary, each participant had their device fitted individually to ensure correct fit and comfort. Sizing was in accordance with the manufacturers' instructions. Tubular compression bandage was applied as a double layer, from the tibial tuberosity to the base of the toes. The below-knee cast was a synthetic non-flexible cast, applied from the tibial tuberosity to the base of the toes, and was lined and padded. Protocols for progression of weight-bearing and activity were determined by the manufacturers' recommendations, recent research protocols, and results of a national survey of practice completed in the planning phase of the trial.⁶ Participants were provided with written and verbal instructions on when to remove the support (customised to each device), washing of the support, regular elevation of the leg while it was swollen, gentle mobilising exercises, pain control and application of ice packs, and what to do in the event of difficulties with the support. All participants were provided with elbow crutches. Additional physical therapy techniques were not included in the trial treatment protocol. If additional treatment was deemed necessary at any point after randomisation, this use of treatment was quantified by self-report questionnaire and considered as descriptive data alongside the outcomes of the trial.

Participants were assessed for trial eligibility at initial presentation to the emergency department. The ankle was elevated and immobilised in tubular compression bandage for 2–3 days, to ensure oedema had stabilised before randomisation, and that the injury was sufficiently severe to meet eligibility criteria. Provided participants were unable to bear weight fully at presentation and reassessment, and were otherwise eligible, consent was obtained, baseline questionnaires completed, and the participant randomised. Randomisation was stratified by centre, and administered independently by a central telephone randomisation centre (Birmingham Cancer Trials Service), ensuring allocation concealment. The intervention was applied within a few hours of randomisation. Outcomes were collected at 1, 3, and 9 months after randomisation, by postal questionnaire. Researchers masked to the treatment allocation completed data entry. Trial procedures were quality-assured to ensure integrity of randomisation, concealment, blinding, and application of treatments. A trial steering committee and data monitoring and ethics committee oversaw the trial conduct. The trial protocol was published in 2005.¹⁰

Outcome measures

The primary outcome was quality of ankle function, measured with the Foot and Ankle Score (FAOS¹¹). The FAOS also includes assessments of pain, symptoms,

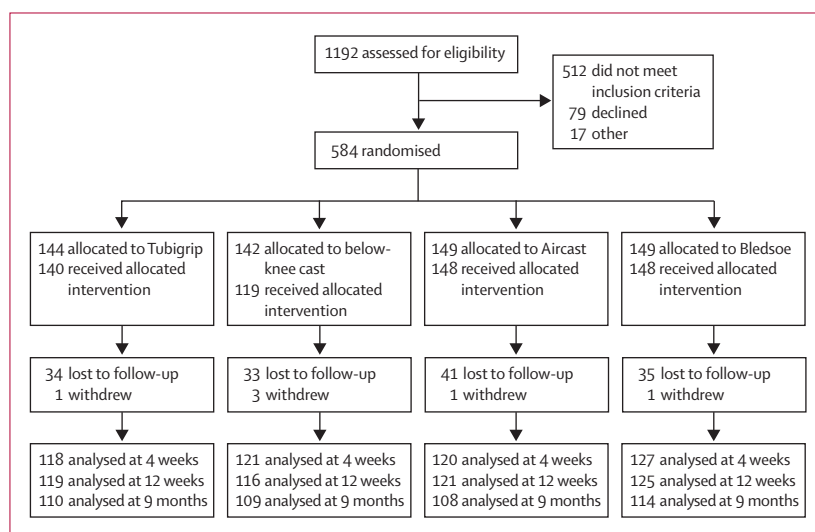


Figure 1: Trial profile

activities of daily living, and ability to do sports. All outcomes on the FAOS are given a score from 0 to 100, where 0 indicates extreme symptoms and 100 indicates no symptoms. Generic health-related quality of life was measured with the short-form 12 (SF-12 version 1),¹² in which physical and mental quality of life were each given a score from 0 to 100, the population norm being 50. We used a visual analogue to capture self-perceived benefit of the ankle supports (score 0–10, where 0 indicates no benefit and 10 indicates maximum benefit). Scores on the Functional Limitations Profile (the UK version of the Sickness Impact profile¹³) were obtained, but not reported; they proved difficult to complete, since patients found the response categories difficult to understand and complete. We obtained scores on two additional visual analogue scales of pain, and reported our findings elsewhere.⁹

Participants were asked to report additional treatments, including reattendance at the emergency department, imaging, and treatment in primary care, secondary care, or the private sector.

Sample size

Sample size was prespecified and calculated, by use of standard methods, for all primary and secondary outcomes.¹⁴ For the primary outcome, a difference of 8–10% in FAOS score was specified as the minimum clinically important difference¹⁵ at the individual level, on the basis of published studies of similar scores. We powered to test for a small to moderate between-group difference.¹⁴ Estimated standard deviations were drawn from the published literature,¹⁶ and revised by the Data Monitoring Committee after 100 participants were recruited at 4 weeks. A target of 480–520 participants was estimated to be sufficient to give 80% or higher power to detect clinically important differences in all outcomes, using a significance level of 0·05 (two-tailed).

Statistical analysis

Reporting adhered to the CONSORT statement for reports of parallel-group randomised designs.¹⁷ Analyses were by intention to treat. Data were summarised as mean (SD) unless otherwise stated. Comparisons between groups were specified a priori, to protect against possible consequences of multiple testing. In the first instance, the analysis compared each support (Aircast, Bledsoe, and below-knee cast) against tubular compression bandage. We prespecified that only when two or more treatments were significantly different from tubular compression bandage, would further comparisons be drawn. We used analysis of covariance adjusted for age, sex, and the appropriate baseline variable to establish the size and statistical significance of clinical differences at each timepoint. Our primary interest was in recovery during the first 3 months after randomisation. Sensitivity to missing data was assessed by multiple imputation.¹⁸ The analysis was undertaken using Stata, version 8 (StataCorp LP, College Station, TX, USA). To assist with

	Tubigrip (n=144)	Below-knee cast (n=142)	Aircast (n=149)	Bledsoe (n=149)	Total (n=584)
Age (years), mean (SD)	31 (11·2)	30 (10·5)	29 (10·7)	30 (10·7)	30 (10·8)
Female, n (%)	64 (44%)	54 (38%)	65 (44%)	64 (43%)	247 (42%)
Ethnic group white, n (%)	135 (94%)	133 (94%)	140 (94%)	141 (95%)	549 (94%)
Employed, n (%)	114 (79%)	107 (75%)	117 (79%)	114 (77%)	451 (77%)
Body-mass index (kg/m ²), mean (SD)	26·5 (5)	27·0 (5)	26·1 (6)	25·8 (5)	26·3 (5)
Any previous ankle injury, n (%)	70 (49%)	71 (50%)	76 (51%)	66 (44%)	283 (49%)
Days to application of trial support, mean (SD)	3 (1·3)	3 (1·6)	3 (1·3)	3 (1·4)	3 (1·4)
FAOS, mean (SD)					
Pain	39·5 (16·7)	39·2 (18·0)	36·6 (15·0)	38·2 (16·7)	40·5 (15·6)
Symptoms	39·1 (15·3)	41·1 (17·2)	37·5 (16·3)	40·2 (17·5)	39·1 (11·6)
Activities of daily living	59·8 (14·6)	58·0 (13·6)	55·4 (13·4)	57·5 (14·2)	59·1 (11·6)
Sport	16·2 (19·6)	14·1 (18·4)	11·7 (16·3)	14·1 (16·9)	14·5 (18·0)
Quality of life	27·3 (22·0)	20·4 (21·0)	20·9 (20·6)	23·9 (21·1)	23·6 (21·1)
SF-12, mean (SD)					
Physical health	35·8 (9·8)	36·0 (9·2)	34·0 (9·0)	35·7 (9·5)	35·4 (9·4)
Mental health	51·5 (11·0)	52·0 (10·5)	49·5 (12·0)	51·4 (11·4)	51·1 (11·3)

Data are frequency (%) unless otherwise stated. FAOS=foot and ankle score. SF-12=short-form 12.

Table 1: Baseline characteristics at trial entry by randomisation group

interpretation of the data, standardised effect sizes were calculated and interpreted according to Cohen.¹⁹

Role of the funding source

The sponsor was the National Co-ordinating Centre for Health Technology Assessment (NCCHTA). The NCCHTA commissioned the trial, approved the design,

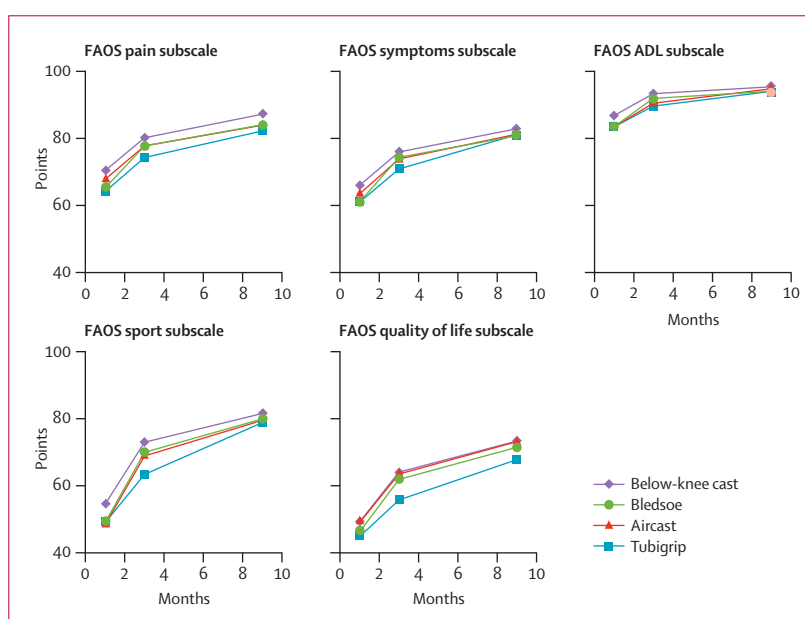


Figure 2: Recovery on the foot and ankle score subscales (pain, symptoms, activities of daily living, sports activity, and quality of life) by treatment group
ADL=activities of daily living. FAOS=foot and ankle score.

and monitored data collection, data analysis, and interpretation. Aircast supports were supplied by Aircast Ltd Partnership (Stragglethorpe, UK) at reduced price. Bledsoe boots were supplied by Bhraum Medical (Sheffield, UK) at reduced cost. Neither company had any role in the design, data collection, analysis, interpretation, or writing of the report. The corresponding author had full access to all the data in the trial, and had final responsibility for the decision to submit for publication.

Results

The study design is shown in figure 1. 680 people were potentially eligible—ie, had severe sprains. 79 people declined to participate. The most frequent reason for refusal to participate was unwillingness to accept a below-knee cast (46), Bledsoe boot (9), tubular compression bandage (4), or Aircast brace (2), or unwillingness to participate in the research after a full explanation had been given. 584 participants were randomised. Postal questionnaires were received from 83% of

randomised participants at 1 month, 82% at 3 months, and 76% at 9 months. There were no differences in loss to follow-up between the trial groups, and no suggestion of differences between those lost to follow-up and those remaining in the trial at 9 months.

Acceptance of treatment after randomisation at clinic was high. The Aircast and Bledsoe boot were almost universally accepted, with only one participant in each group declining. Four participants refused the tubular compression bandage; eight participants refused the below-knee cast. A further 15 participants did not receive a cast because of a clinical decision, unavailability of staff to apply the cast, or the participant being unable to return to the hospital for cast removal. Serious adverse events were rare. Three participants (one each allocated to Aircast, tubular compression bandage, and a below-knee cast) had a deep-vein thrombosis, and two (one with tubular compression bandage, and one with Aircast) developed a pulmonary embolus. Two cases of cellulitis were reported, one each in the Aircast and Bledsoe

	N	Tubigrip	Below-knee cast	Aircast	Bledsoe
		Mean	Difference* (95% CI)	Difference† (95% CI)	Difference‡ (95% CI)
FAOS quality					
1 month	482	43	6 (0.1 to 11.8)	5 (−1.0 to 10.7)	2 (−3.9 to 7.6)
3 months	478	54	9 (2.4 to 15.0)	8 (1.8 to 14.2)	6 (0 to 12.3)
9 months	440	65	6 (−0.7 to 13.2)	6 (−0.9 to 13.0)	4 (−2.9 to 10.8)
FAOS symptoms					
1 month	480	60	4 (1.0 to 8.5)	2 (−2.6 to 6.9)	−1 (−5.4 to 3.9)
3 months	478	69	3 (−1.4 to 8.2)	3 (−2.0 to 7.5)	3 (−2.3 to 7.2)
9 months	440	79	0 (−4.4 to 5.3)	0 (−4.8 to 5.0)	−1 (−5.9 to 3.7)
FAOS pain					
1 month	481	62	5 (0.4 to 9.8)	4 (−1.2 to 8.2)	1 (−4.0 to 5.3)
3 months	477	73	5 (0.3 to 10)	4 (−1.1 to 8.5)	3 (−1.4 to 8.1)
9 months	439	81	4 (−0.7 to 9.4)	2 (−3.2 to 7.0)	2 (−3.3 to 6.7)
FAOS activities of daily living					
4 weeks	453	82	3 (−0.3 to 6.3)	0 (−2.7 to 4.0)	0 (−3.3 to 3.2)
12 weeks	393	89	4 (0.4 to 6.6)	1 (−2.0 to 4.2)	2 (−0.7 to 5.4)
9 months	357	93	1 (−1.9 to 4.3)	1 (−2.1 to 4.1)	0 (−3.3 to 3.2)
FAOS sports					
4 weeks	438	45	5 (−1.7 to 11.8)	0 (−1.0 to 12.9)	0 (−7.0 to 6.4)
12 weeks	382	62	9 (1.6 to 15.7)	5 (−2.3 to 11.9)	6 (−1.0 to 12.9)
9 months	352	77	2 (−4.8 to 9.6)	1 (−6.5 to 8.0)	1 (−6.1 to 8.1)
SF-12 physical					
4 weeks	451	39	2 (0.0 to 0.4)	−1 (−3.6 to 0.8)	−1 (−3.5 to 0.8)
12 weeks	396	47	2 (−0.8 to 4.0)	−1 (−3.2 to 1.7)	1 (−1.4 to 3.4)
9 months	356	50	0 (−2.5 to 3.1)	0 (−2.5 to 3.1)	0 (−2.5 to 3.0)
SF-12 mental					
4 weeks	451	43	−1 (−3.4 to 2.2)	0 (−2.7 to 3.0)	1 (−1.8 to 3.8)
12 weeks	396	48	0 (−2.7 to 2.7)	3 (0.3 to 5.8)	3 (0 to 5.2)
9 months	356	48	1 (−1.8 to 4.2)	2 (−1.2 to 4.7)	1 (−1.5 to 4.3)

Analyses adjusted for sex, age, and baseline score. Difference=mean difference between the support and tubular compression bandage with the 95% CI of the mean difference. ES=effect size. FAOS=foot and ankle score. SF-12=short-form 12. *Tubigrip/below knee cast. †Tubigrip/Aircast. ‡Tubigrip/Bledsoe.

Table 2: Disease-specific outcomes by randomisation group

groups. There were no discernible differences in adverse events between the groups.

Table 1 shows the baseline characteristics of participants. Ankle function was substantially impaired in all participants. The median interval between time of injury and application of treatment was 3 days (IQR 2 days), with no differences between the groups.

Figure 2 gives recovery at 1, 3, and 9 months, by treatment group. Table 2 gives estimates of the treatment effects for quality of ankle function and secondary outcomes. Tubular compression bandage was the least effective treatment. The Bledsoe boot offered no significant advantage over tubular compression bandage. We noted clinically important benefits at 3 months in quality of ankle function with the below-knee cast compared with tubular compression bandage (mean difference in quality of ankle function 9%; 95% CI 2.4–15.0%, $p<0.007$) as well as in pain, symptoms, and activities. The Aircast brace was not as wide-ranging in its benefits as the below-knee cast, but effect on quality of ankle function at 3 months was similar to that of the below-knee cast (table 2). There were no differences in outcomes between the groups at 9 months. In terms of generic health-related quality of life, the below-knee cast was the only treatment to show a significant advantage over tubular compression bandage on the physical subscale of the SF-12; the benefit was limited to the earliest phases of recovery. Mental health-related quality of life was adversely affected by the injury in all groups, especially at 4 weeks. The groups randomised to Aircast and Bledsoe had better mental health-related quality of life at 3 months than did people allocated to other treatments.

Table 3 shows self-rated benefit, compliance, and health-service use. Compliance data were available from 449 participants at 4 weeks, when most individuals who were randomised to receive a below-knee cast or a Bledsoe boot were no longer wearing a support. Roughly half of people provided with an Aircast were wearing a support at least occasionally, and two-thirds of people provided with tubular compression bandage reported still wearing a support. Use of physiotherapy, orthopaedic services, and other health services was similar across all groups during follow-up, with no significant differences in health service resource use between tubular compression bandage and any of the treatments (table 3).

Discussion

Contrary to popular clinical opinion,⁵ a period of immobilisation was the most effective strategy for promoting rapid recovery. This was achieved best by the application of a below-knee cast. The Aircast brace was a suitable alternative to below-knee casts. Results for the Bledsoe boot were disappointing, especially in view of the substantial additional cost of this device. Tubular compression bandage, which is currently the most commonly used of all the supports investigated,⁶ was, consistently, the worst treatment.

	Tubigrip	Below-knee cast	Aircast	Bledsoe
Self-perceived benefit (3 months)				
Median (IQR)	5 (2–7)	7 (5–9)	7 (6–8)	8 (5–9)
n	116	113	119	120
Self-perceived benefit (9 months)				
Mean	5.0	6.9	7.0	7.3
Median (IQR)	5 (2–8)	8 (5–9)	8 (5–9)	8 (7–9)
n	109	106	106	111
Are you still wearing the support (at 1 month)? (n [%])				
Not at all	32 (30%)	91 (83%)	57 (51%)	92 (77%)
Now and then	23 (21%)	9 (8%)	18 (16%)	11 (9%)
Frequently	27 (25%)	6 (5%)	27 (24%)	11 (9%)
Most or all of the time	26 (25%)	4 (4%)	10 (9%)	5 (4%)
Total	108	110	112	119
Health service resource use (n [%])				
Emergency department attendance	4 (3.9%)	8 (7.8%)	4 (4.0%)	3 (2.7%)
NHS consultant appointment	0 (0%)	4 (3.9%)	5 (5.0%)	5 (4.5%)
Private consultant appointment	5 (4.9%)	3 (2.9%)	2 (2.0%)	2 (1.8%)
NHS physiotherapy appointment	16 (15.7%)	19 (18.4%)	17 (16.8%)	16 (14.5%)
Private physiotherapy appointment	15 (14.7%)	14 (13.6%)	8 (8.2%)	14 (12.8%)
General practitioner attendance	31 (30.4%)	22 (21.4%)	20 (19.8%)	28 (25.5%)
Osteopath/chiropractor or other	3 (3.0%)	6 (5.9%)	3 (3.0%)	4 (3.6%)
Scans or radiographs	9 (8.8%)	5 (4.9%)	7 (6.9%)	13 (11.8%)
Hospital admission	2 (2.0%)	0 (0%)	1 (1.0%)	1 (1.0%)
Prescription items	22 (21.6%)	16 (15.5%)	19 (19.0%)	14 (12.7%)
Over the counter items	33 (32.4%)	50 (48.5%)	36 (36.0%)	44 (40.0%)
Total	102	103	101	110

Table 3: Self-reported benefit, compliance, and frequency of use of health service resources by randomisation group

The recovery process from ankle sprains is well documented. Acute inflammation is followed by assimilation of swelling, laying down of new tissue, and eventually strengthening of the new tissues.⁵ These stages reflected in the initial pain, symptoms, and limitation in basic functions in the early phase (4–6 weeks), followed by restoration of higher-level functions and confidence in performance thereafter.²⁰ Recurrent instability and re-injury can occur where healing is incomplete.²⁰

We measured outcomes using self-report, as is common practice in most pragmatic trials of similar interventions. Self-reported status is generally accepted as an adequate proxy for objectively measured function.¹¹

The below-knee cast had a wide-ranging effect—it reduced symptoms and pain in the early stage, and promoted faster recovery of function at 3 months. The below-knee cast might not be as effective as the Bledsoe boot and Aircast at minimising mental-health problems. However, within the context of the trial, the participants were not given any indication of the best treatment. Emotional response and acceptance might be different if patients were aware that the below-knee cast, although inconvenient in the short term, is likely to yield faster recovery. The Aircast brace is the next best treatment.

This finding is consistent with a recently published trial, which compared elasticated supports with the Aircast brace.²¹

The difference between the effectiveness of tubular compression bandage, and that of the below-knee cast, was greater than the minimum clinically important difference for the primary outcome¹⁵ and the SF-12.²² Effect sizes are suggestive of small to moderate effects. These are consistent with worthwhile improvements in outcome,¹⁹ especially in view of the pragmatic nature of this trial. There were no substantial differences in the patterns of use of health service resources between the trial groups, suggesting the effects are attributable to the bracing method. The advantages conferred by treatments other than tubular compression bandage seems to decrease over time: differences in outcome are much more pronounced at 3 months than at 9 months.

Our findings confirm that severe ankle sprains have a protracted recovery period, and effects on ankle function are, for a few people, longlasting, and possibly, permanent.²³ A recent systematic review reported that most recovery occurs within the first 6 months after the sprain, and re-injury rates stabilise thereafter.²⁴ About 25% of the CAST trial participants had at least moderate impairment persisting at 9 months, which is broadly consistent with published rates.^{24,25} Further small reductions in the number of people experiencing pain and instability might occur after 9 months.²⁴ Future studies should establish whether additional treatments such as physiotherapy²⁶ or surgery²³ are useful adjuncts to mechanical supports, and the time at which they should be applied. All the mechanical supports studied seemed safe. Thromboembolic events occurred in less than 1% of our sample, which was lower than in other series.²⁷

We tested a short duration (10 days) of complete immobilisation. Previous studies have compared immobilisation for longer periods (around 6 weeks), and have shown that removable supports are more effective than tubular compression bandages,²¹ or increased immobilisation.⁷ However, the number of high-quality trials has been insufficient to support definitive conclusions.⁸

We believe the internal validity of the study to be good. We achieved acceptable levels of power for the prespecified comparisons (>80% for all comparisons). Follow-up was maintained at reasonable levels, in view of the study population, and there was no evidence of selective attrition bias. This was a pragmatic trial and we cannot draw conclusions about the mechanism by which the treatment effect is attained. One possibility is that those people who were randomised to but refused to wear the cast might account for the treatment effect. We would argue against this since the fraction of people not receiving a below-knee cast was small. We were unable to attain accurate reports on compliance to the bracing protocols in other groups, and compliance in

the acute phase is probably similar across all groups. Reply rates about outcomes relating to sport were low, because these questions were not relevant to all participants. The activities-of-daily-living scale was not well completed, possibly because of the length of this section of the questionnaire and repetitive nature of the items. Additional analyses indicated that the findings were insensitive to different methods of handling missing data.

The methods adopted were consistent with a large pragmatic trial, where the intention is to test the effectiveness of health-care interventions within the patterns, constraints, and variability of normal service delivery.²⁸ We used practical, routinely used diagnostic criteria to establish injury severity. Although several algorithms exist to classify ankle sprain severity, they are difficult to implement in the acute situation. A national survey has shown that stress radiography or imaging are not used routinely in the UK for sprains, and although we could argue that careful elucidation of an injury grade could assist in interpretation of the study, it would add non-standard, potentially influential procedures to the patient-management pathway. Additional treatments were allowed in accordance with normal clinical practice, and addressed in our overall assessment.

We included a range of emergency departments, from small local hospitals to large teaching hospitals. Trial participants were similar to the English population, as described in the 2001 census²⁹ and the 2004 Health Survey for England,³⁰ in terms of sex, height, body-mass index, employment, education, and ethnicity. Compared with SF-12 population norms, adjusted for age and sex, the participants had, as expected, substantially impaired mobility but similar levels of mental health.³¹

A limitation of our study was that we were unable to measure compliance with the supports accurately. Below-knee casts were not universally accepted at the clinic, and the prospect of receiving a below-knee cast was one of the most common reasons for declining entry into the trial. We were able to assess if participants accepted the other supports in the emergency department, but longer-term compliance was measured by self-report. A potential second criticism is the delay between presentation and randomisation. This was essential to confirm the injury severity, and to allow initial swelling to resolve before application of the support (a common practice in most emergency departments in the UK). All treatments were provided within a short period of initial injury, and we believe little or no bias has been introduced. Clinicians were allowed to apply tubular compression bandage in this interim period.

Thus, we recommend the use of a 10-day below-knee cast for the management of severe ankle sprains, or alternatively, an Aircast brace. Neither tubular compression bandage nor the Bledsoe boot is recommended.

Contributors

SL wrote the original protocol. SL, MC, JH, and JM participated in the trial design, data analysis, interpretation of results, drafting, and approval of the final manuscript.

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Conflict of interest statement

We declare that we have no conflict of interest.

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