Lamb SE, Marsh JL, et al. Mechanical supports for acute, severe ankle sprain: a pragmatic, multicentre, randomised controlled trial. Lancet 2009;272:575-581.

Design: Randomized clinical trial

Purpose of study: to compare the effectiveness of three types of mechanical support with that of tubular compression bandages after an acute ankle sprain

Population/sample size/setting:

- 584 patients (247 women, 337 men, mean age 30) treated for acute severe (Grade II and III) ankle sprain at 8 emergency departments in the UK
- Eligibility criteria were skeletal maturity (over age 16), inability to bear weight for 3 days after injury, no fracture larger than 3 mm on x-ray
- Exclusion criteria were risk of deep vein thrombosis as judged by treating physician, and any injury that occurred more than 7 days previously

Interventions:

- Randomized to one of 4 treatments: tubular compression bandage (n=144), below-knee cast for 10 days (n=142), Aircast brace (n=149), or Bledsoe boot (n=149)
    - Tubular compression bandage was chosen as the reference intervention because it is most commonly used
    - The below-knee cast is not removable, and was left in place for ten days
    - The Bledsoe boot has a foot plate designed to facilitate mobility but limits ankle motion in all planes and is lightweight and removable
    - The Aircast brace provides localized compression and support, allowing plantar and dorsiflexion but limits inversion and eversion
- Randomization was done after 2-3 days of elevation and immobilization in tubular compression bandage, until edema had subsided and patients were still unable to bear weight
- All patients received crutches for ambulation and received instructions on support customized to each device, but physical therapy was not included in the trial protocol and was different for each individual

Outcomes:

- Primary outcome was Foot and Ankle Outcome Score (FAOS) assessed by postal questionnaire at 3 months after randomization
- FAOS has 42 questions covering pain, function, and quality of life, with emphasis on functionality and activities of daily living (ADL)
- Ankle function substantially improved in all participants
- Tubular compression bandage was the least effective treatment, and the results for the other three treatments was reported in terms of their differences compared to tubular compression
- At 3 months after randomization, there were clinically important benefits of both the below-knee cast and the Aircast brace compared to tubular

compression bandage; Bledsoe boot did not show a significant advantage over the compression bandage
    - For example, at 3 months, the FAOS quality of life score was 54 in the compression bandage group, 63 in the cast group, and 62 in the Aircast group
- Secondary outcomes included the physical and mental subscales of the SF-12; the physical subscale showed a small advantage for the cast over the tubular compression bandage at 4 weeks post-randomization (41 points vs. 39 points); at all other time intervals, the SF-12 physical and mental scores did not differ between treatment groups
- At 9 months, the FAOS differences between treatment groups had decreased and were no longer significant
- Other interventions, such as physical therapy, chiropractic, and medications, were not controlled by the study protocol, but did not differ significantly between groups

Authors' conclusions:

- Below-knee cast reduces symptoms of severe ankle sprain in the early stages of recovery, producing faster recovery of function at 3 months than interventions which do not immobilize the injured ankle
- The differences between immobilizing cast and other treatments decreases over time, and are no longer apparent at 9 months

Comments:

- Study has several strengths: most potential threats to internal validity are controlled, the main outcome (FAOS) measures important functional variables, and the setting approximates the mix of cases that are likely to occur in primary care
- The effect sizes, however, are small
- In Table 2, for example, the largest effect size for the cast over the compression bandage at 3 months is 0.36 for FAOS quality of life
- This effect size means that the difference between the cast and the compression bandage is 0.36 standard deviations; in the usual interpretation of Cohen's d (which was the method used for calculating effect size), this is a small difference
- The least effective treatment is used as the reference against which other treatments are compared; this means that the Aircast and the below-knee cast were not compared with one another (there appear to be no differences between cast, Aircast, and Bledsoe boot)
- Unlike some other studies of ankle sprain, which excluded patients with previous ankle injury, this study included these patients, who made up about half of the study sample
- The FAOS scores were adjusted for age, sex, and baseline score, which is appropriate, but it would have been interesting to have reported whether the history of a previous ankle injury made a difference in response to treatment

- More patients refused the cast than any other treatment; this may suggest that patient preference should be considered in any recommendations that arise from the results of this study

Assessment: Adequate for evidence that a below-knee cast leads to slightly faster recovery of ankle function than tubular compression bandage at up to three months in patients with acute Grade II and III ankle sprains