Landorf KB, Keenan A-M, Herbert RD. Effectiveness of Foot Orthoses to Treat Plantar Fasciitis. Arch Intern Med 2006;166:1305-1310.

Design: randomized clinical trial

Purpose of study: to compare the effectiveness of sham, prefabricated, and custom foot orthoses in patients with plantar fasciitis

Population/sample size/setting:

- 135 patients (89 women, 46 men, mean age 48) treated for plantar fasciitis in a university podiatry clinic in Australia
- Eligibility required only a clinical diagnosis of plantar fasciitis with at least 4 weeks of symptoms
- Exclusion criteria were a major orthopedic or medical condition such as inflammatory arthritis or diabetes which could have influenced the condition

Interventions:

- All patients were fitted for orthoses with neutral position plaster casts and given return appointments in 2 to 3 weeks
- On returning at 2-3 weeks, patients were randomly given one of three orthoses: a sham orthosis (n=45), a prefabricated orthosis (n=44), or a custom orthosis (n=46)
    - The sham orthosis was made with soft ethyl vinyl acetate foam over an unmodified cast of the foot and provided minimal structural support
    - The prefabricated orthosis was a retail mold firm-density polyethylene foam sufficiently thick to fill the arches
    - The custom orthosis was made at a commercial orthotic laboratory of semirigid polypropylene from a plaster cast over which a hard plastic shell was vacuum molded
- No other treatments such as NSAIDS or steroid injections were allowed during the 12 months of followup

Outcomes:

- Primary outcomes were pain and function at 3 and 12 months, using the 100 point Foot Health Status Questionnaire in which the best score is 100
    - Outcomes were adjusted for the baseline values pain and function
    - The prefabricated group had a greater BMI than the other two groups, but this was not adjusted for in the analysis
    - A difference of 15 points was used as the effect size of interest for purposes of calculating the required sample size

- At baseline, the median duration of symptoms was 11 or 12 months, with 360 months as the longest duration of symptoms
- At 3 months, all three groups had improved compared to their baseline pain and function scores, but differences between groups were small and most were not statistically significant, since the null value of 0 was within the bounds of the 95% confidence intervals (95% CI)
    - The prefabricated group pain score was 8.7 points better than the sham group (95% CI from -0.1 to 17.6)
    - The custom group pain score was 7.4 points better than the sham score (95% CI from -1.4 to 16.2)
    - The prefabricated adjusted pain score was 1.3 points better than the custom score (95% CI from -7.6 to 10.2)
    - The prefabricated group function score was 8.4 points better than the sham group (95% CI from1.0 to 15.8)
    - The custom group function score was 7.5 points better than the sham score (95% CI from 0.3 to 14.7)
    - The prefabricated adjusted function score was 2.3 points better than the custom score (95% CI from -5.6 to 10.1)
- At 12 months, the pain and function scores had improved from the 3 month scores, but there were no remaining significant differences between the three groups

Authors' conclusions:

- Both prefabricated and custom orthoses produce small short-term benefits compared to sham orthoses, but it is not certain that these effects are clinically important
- Pooling of these results with those of three earlier studies indicate that there is no substantive difference between prefabricated and sham orthoses
- The patients had chronic symptoms, and the results may not apply to patients who have had plantar fasciitis for a shorter time
- Although the prefabricated group was heavier than the other two groups, this difference was not adjusted for in the analysis because post hoc adjustment is a known source of bias

Comments:

- A sham group was included because previous published studies had not had one, but the minimal support from as sham orthosis is not identical to no support from no orthosis, and the comparison in the study should not be interpreted to mean that a prefabricated or a custom orthosis is the same as no orthosis
- By the end of the trial, 23 patients had departed from the protocol to get other treatments such as NSAIDS, steroid injections, or a night stretch splint; it is not said

whether plantar stretching exercises were excluded from the protocol, and these exercises were not mentioned at all

- The greater BMI in the prefabricated group would be expected to work against that group in the pain and function scores; the fact that the group did as well as the custom orthosis group gains credibility from this baseline imbalance, even though it was not adjusted for in the analysis

Assessment: High quality study providing good evidence that a prefabricated and a custom orthosis are equally effective in improving pain and function of plantar fasciitis at 3 and at 12 months after they are first used