

Baldassin V, Gomes CR, Beraldo PS. Effectiveness of prefabricated and customized foot orthoses made from low-cost foam for noncomplicated plantar fasciitis: a randomized controlled trial. Arch Phys Med Rehabil. 2009;90(4):701-6.

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

Population/sample size/setting:

- 142 patients (107 women, 35 men, mean age 47) treated for uncomplicated plantar fasciitis at a rehabilitation hospital in Brazil
- Inclusion criteria were age over 18 with a clinical diagnosis of plantar fasciitis characterized pain with the first step after wakening and maximal tenderness over the medial calcaneal tuberosity
- Exclusion criteria were complicated plantar fasciitis (anatomic or alignment alterations in the feet), pregnancy, previous foot orthoses, inflammatory arthritis, or a history of malignancy

Interventions:

- All patients received foot orthoses made from ethylene vinyl acetate (EVA)
- Randomization was to custom-made orthoses (n=70) or to prefabricated orthoses (n=72)
 - o All patients underwent the casting procedure to make a custom orthosis in order to maintain blinding, and were asked not to show the orthoses to the outcome evaluators, who were physical therapists
- Other interventions were not forbidden by the protocol, but patients were asked to report any other interventions they used
 - o 40% performed stretching exercises for the Achilles tendon, and 28% used ice or NSAIDS; the use of these did not differ between groups

Outcomes:

- Primary outcome was pain measured by a subscale of the Foot Function Index (FFI) at baseline, at 4 weeks, and again at 8 weeks
 - o This has scales for activity limitation, disability, and pain in various situations; the authors added one item to assess pain on taking the first steps in the morning
 - o A difference of 13 to 15 points was the minimum effect size considered to be clinically relevant, and the sample size was calculated accordingly
- Secondary outcome was pain on palpation of the medial calcaneal tuberosity elicited by one of the authors
- Both groups improved from baseline to the 4 and 8 week followup evaluations, but the differences between groups, adjusted for differences in baseline values, was statistically not significant, and the 95% confidence intervals for the difference did not include the minimally clinically relevant value of 13 points
- The patients were not able to tell whether they were using the prefabricated or the custom orthoses; about 80% of patients in each group thought they were using the custom orthosis

- There were no differences between groups when analyzed separately among those who did or did not use co-interventions such as stretching

Authors' conclusions:

- Prefabricated orthoses are as effective as custom orthoses for uncomplicated plantar fasciitis, and should be selected in that setting, especially when they are made of EVA

Comments:

- There was satisfactory control of threats to internal validity, and the sample size was large enough to detect a clinically relevant effect if it were present in the study population
- The description of the manufacturing process in the appendix is not as clear as it might be, but the efforts to maintain blinding are apparently successful

Assessment:

- High quality study with good evidence that foot orthoses made from ethylene vinyl acetate are equally effective for uncomplicated plantar fasciitis whether they are prefabricated or custom made