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Comparison of Custom and Prefabricated Orthoses in the Initial Treatment of Proximal Plantar Fasciitis

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ABSTRACT

Fifteen centers for orthopaedic treatment of the foot and ankle participated in a prospective randomized trial to compare several nonoperative treatments for proximal plantar fasciitis (heel pain syndrome). Included were 236 patients (160 women and 76 men) who were 16 years of age or older. Most reported duration of symptoms of 6 months or less. Patients with systemic disease, significant musculoskeletal complaints, sciatica, or local nerve entrapment were excluded. We randomized patients prospectively into five different treatment groups. All groups performed Achilles tendon- and plantar fascia-stretching in a similar manner. One group was treated with stretching only. The other four groups stretched and used one of four different shoe inserts, including a silicone heel pad, a felt pad, a rubber heel cup, or a custom-made polypropylene orthotic device.

Patients were reevaluated after 8 weeks of treatment. The percentages improved in each group were: (1) silicone insert, 95%; (2) rubber insert, 88%; (3) felt insert, 81%; (4)stretching only, 72%; and (5) custom orthosis, 68%. Combining all the patients who used a prefabricated insert, we found that their improvement rates were higher than those assigned to stretching only ($P = 0.022$) and those who stretched and used a custom orthosis ($P = 0.0074$). We conclude that, when used in conjunction with a stretching program, a prefabricated shoe insert is more likely to produce improvement in symptoms as part of the initial treatment of proximal plantar fasciitis than a custom polypropylene orthotic device.

INTRODUCTION

More than two million Americans receive treatment each year for proximal plantar fasciitis (heel pain syndrome). Most find relief with nonoperative treatments,[1,3,4,5,8,11] which include shoe modification, prefabricated inserts, custom orthoses, stretching exercises, physical therapy, nonsteroidal anti-inflammatory agents, cortisone injections, night splints, and casting.[1,3,4,7–11] More than 85% of patients will be improved or fully relieved by a nonsurgical treatment program.[3,4,8] There is no consensus, however, about which treatments are the best or the most cost effective. This prospective randomized multicenter clinical trial compared the results of nonoperative treatments for proximal plantar fasciitis using four different shoe inserts and a program of Achilles tendon and plantar fascia stretching.

MATERIALS AND METHODS

Between August 1, 1994 and May 1, 1996, 236 patients (160 women and 76 men) with the diagnosis of proximal plantar fasciitis (heel pain syndrome) agreed to participate and were randomized prospectively into five different treatment groups. Fifteen orthopaedic foot and ankle centers participated in the study. All patients complained of isolated pain over the medial calcaneal tuberosity, consistent with a diagnosis of proximal plantar fasciitis. At examination, all patients had maximal tenderness over the medial calcaneal tuberosity at the insertion of the plantar fascia. None had received previous treatment for this condition, and all were 16 years of age or older. Patients with systemic disease, sciatica, or local nerve

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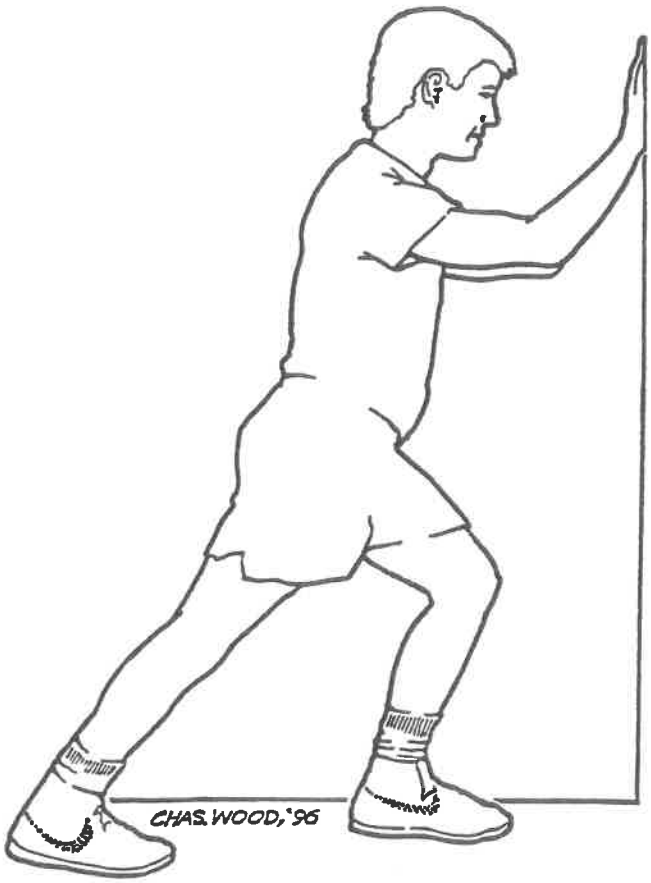

Fig. 1. EXERCISE 1. Lean forward against a wall, keeping one knee straight while you bend the other knee. (If both of your heels hurt, then you need to reverse this position after you have exercised each heel. If only one of your heels hurts, the painful heel is placed further away from the wall.) As you bend forward, the leg that remains straight is the one that you will be exercising. As you lean forward, you can feel your heel cord and the arch of your foot stretch. (Try to keep your heel on the ground, although as you stretch it, it will gradually lift off the ground.) STRETCH AND HOLD FOR 10 SECONDS. Then relax and straighten up. THEN STRETCH AGAIN. Repeat this 20 times. If your other heel bothers you, then you should stretch this side as well by reversing your position.

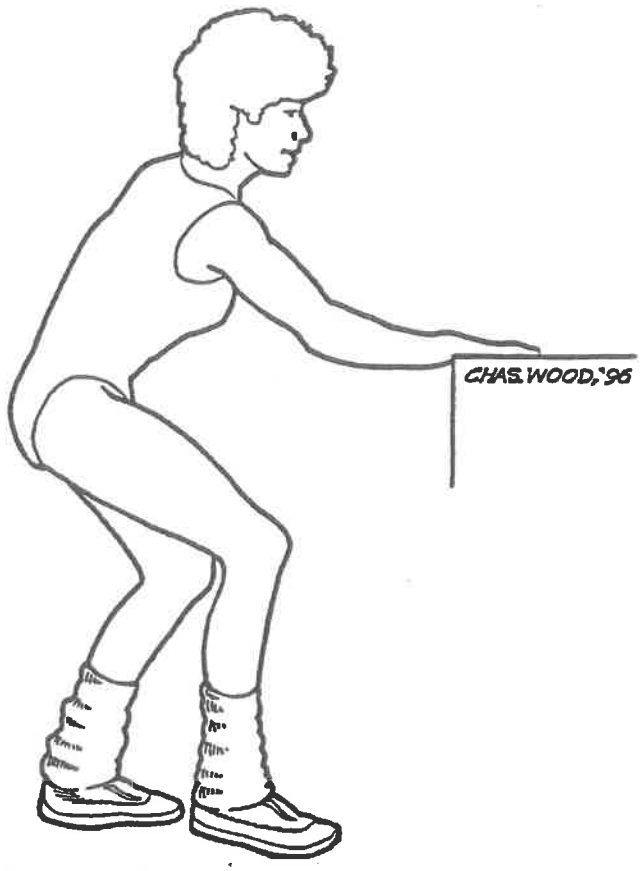

Fig. 2. EXERCISE 2. Lean forward as you lean onto a table, chair, or countertop. In this exercise, you will flex both of your knees. Squat down slowly. Try to keep your heels on the ground as long as you can as you squat down. You will feel your heel cords and the arches of your feet stretch as your heel finally starts to rise off the ground as you squat down. When you feel these structures REALLY STRETCHING, hold that position for 10 seconds. Then STRAIGHTEN UP. Repeat this 20 times.

entrapment (first branch of the lateral plantar nerve or posterior tibial nerve) were excluded. If both heels were painful, only the most symptomatic side was included. Radiographs of the heel were not required but were recorded if performed. All patients completed a self-administered, three-page, 27-question baseline questionnaire based on the Foot Function Index (FFI), a validated assessment of pain and function.[2] All patients were examined by an orthopaedic surgeon at each center who specialized in foot and ankle disorders.

After informed consent, patients were randomized into five different treatment groups. Each group performed Achilles and plantar fascia stretching (Figs. 1 and 2) for approximately 10 min, twice a day. One group performed only the stretching exercises, whereas the others stretched and used one of the

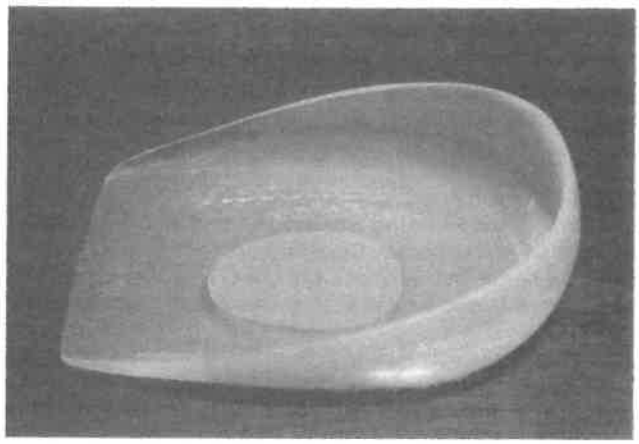

Fig. 3. Bauerfeind silicone heel pad.

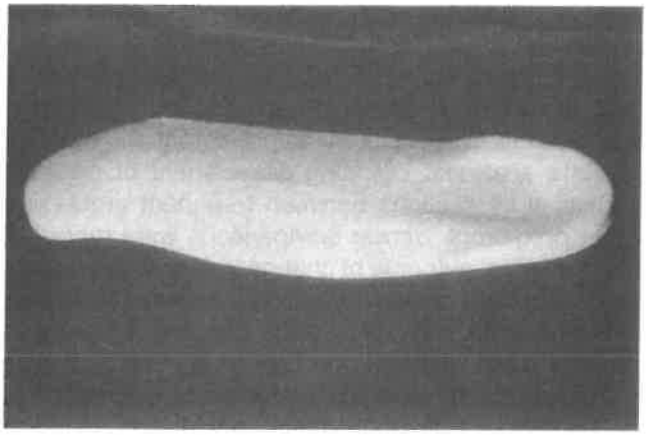

Fig. 4. Hapad felt insert.

following four shoe inserts: (1) a silicone heel pad (Bauerfeind, Kennesaw, GA) (Fig. 3), (2) a felt insert (Hapad, Bethel Park, PA) (Fig. 4), (3) a rubber heel cup (Tuli International Comfort Products, San Marcos, CA) (Fig. 5), and (4) a custom-made polypropylene neutral orthosis (Fig 6). No other treatment modalities were used in this study, including anti-inflammatory agents. All patients were given identical written instructions, which were specific for their randomized treatment protocols. Stretching exercises were demonstrated with diagrams and a written explanation.

The patients were encouraged not to change their regular shoe wear or activity level. If a patient was in the custom orthosis group, the baseline questionnaire was not filled out until the patient received the orthotic

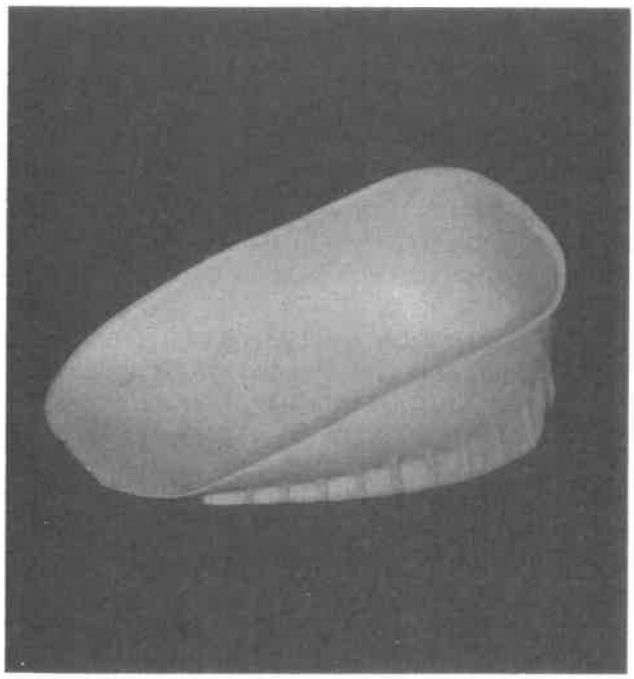

Fig. 5. Tuli Rubber heel cup.

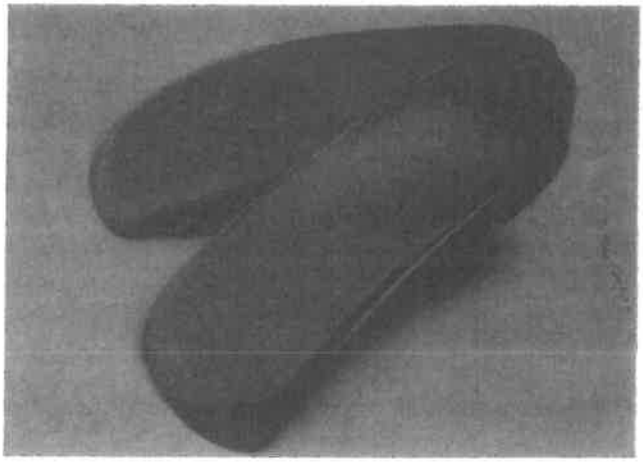

Fig. 6. Polypropylene orthoses (courtesy of Prolab, San Francisco).

device. No randomized patient failed to complete the baseline questionnaire. The orthoses were made in a uniform manner. All orthoses were made at Prolab (San Francisco, CA).

Each center had reviewed a Prolab instructional video on casting technique. The orthoses were made from a negative cast of the patient's foot while the subtalar joint was in a neutral position. Either ¼ inch or 3/16 inch polypropylene was used for each orthosis, with the thickness determined by the weight of the patient. The casts were sent to Prolab by second-day air. Prolab fabricated the polypropylene orthoses within 72 hrs, and sent them back by second-day air to be dispensed. The time from casting to dispensing each orthotic device was 10 to 12 days.

Eight weeks after initiating treatment, each patient was asked to return for a follow-up examination and questionnaire. The follow-up questionnaire consisted of 27 questions. The requirement that patients not have had any previous treatment for their heel pain led to slower-than-anticipated enrollment. A total of 236 patients were randomized from an original goal of 300.

Because of the potential difficulty in assessing change in pain, our baseline and follow-up questionnaires included two indices of symptoms: one dichotomous and one numeric. The dichotomous outcome was based on a question at week 8 that asked patients to rate the change in their heel pain as "all better," "much better," "slightly better," "unchanged," or "worse." This was dichotomized as response (all, much, or slightly better) versus nonresponse (unchanged or worse).

The primary numeric outcome measure was based on the pain subscale of the FFI.[2] Both the baseline and follow-up questionnaires contained pain subscale questions from the FFI. The questions were scored

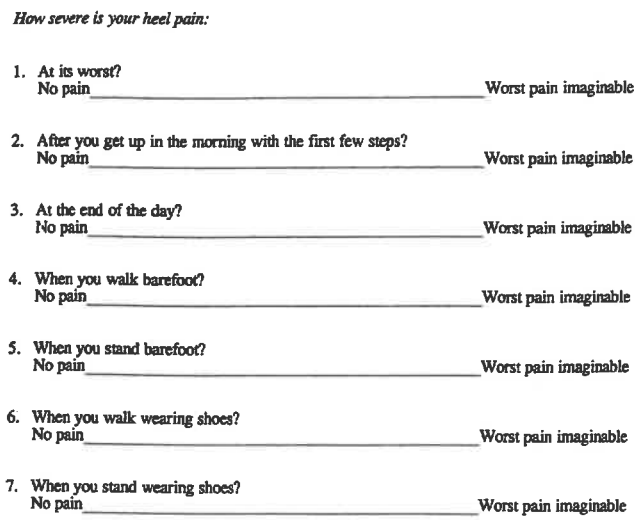

Fig. 7. Foot Function Index Pain Subscale.

from zero (no pain) to 9 (worst pain imaginable), depending on the location marked by the patient on the visual analog scale (Fig. 7). The sum of these scores was then expressed as a percentage of the maximum possible score, so that resulting overall score ranged from zero (no pain on any question) to 100 (worst pain imaginable on all applicable questions). The change in this overall pain score was used as the primary numerical outcome.

In addition to the primary outcome measures, other measures included time to start of improvement, change in pain under various specific circumstances, and change in activity. Results for these additional measures are not shown because they are qualitatively similar to those presented for response rates and for change in overall pain score.

The key variable expected to influence outcome was treatment assignment. This was analyzed as assigned (i.e., on an intent-to-treat basis) even for patients who reported poor compliance with recommended use. Prior duration of pain was reported by patients as <1 month, 2 to 3 months, 4 to 6 months, 6 to 12 months, or >1 year. These categories were scored 1 to 5, respectively, to obtain a numerical predictor. Additional predictors included prior history of similar heel pain, overall pain score at baseline, weight, body mass index, and hours spent standing per day (which was dichotomized as <8 versus ≥8), and the type of floor (hard versus carpeted) patients stood on at work.

The association of treatment with response rates was analyzed by Fisher's exact test for association in general two-way contingency tables.[6] Exact 95% confidence intervals for response rates within each treatment group were obtained from the binomial distribution. In addition, the groups using the three prefabricated inserts were combined, and pairwise comparisons were made with the orthosis group and with the stretching-only group. Logistic regression was used to evaluate numeric predictors and for multivariate analyses, including assessment of possible statistical interactions between treatment group and other predictors. Similar comparisons were made for the numerical outcome of change in overall pain score, using analysis of variance and multiple regression. For each outcome, comparisons among groups were carried out while controlling for all other predictors that were statistically significant predictors of either outcome. Fisher's exact test and analysis of variance were also used to assess the comparability of the groups on baseline measurements, with the Kruskal-Wallis test used for measurements that were not normally distributed.

RESULTS

Of the 236 patients randomized, 200 returned for a visit after 8 weeks of treatment. Table 1 gives the dropout rates by treatment group and summaries of the baseline characteristics for those who completed the week 8 visit. There were no statistically significant differences among the groups on rate of dropout or any baseline characteristics, although duration of pain approached statistical significance, the custom orthosis group tended to have higher weights and body mass indices, and more patients in the silicone group had had a transient episode of heel pain in the past.

Analyses of Response Rates

The response rates for each treatment group are summarized in Table 2. These showed statistically significant variation, with the silicone insert group showing the best rate and the custom orthosis group the worst (Fig. 8). Pairwise comparisons that were statistically significant included: (1) stretching-only versus silicone insert ($P = 0.0055$), (2) custom orthosis versus silicone insert ($P = 0.0019$), and (3) custom orthosis versus rubber insert ($P = 0.046$) (Table 3). The combined group of prefabricated inserts appeared to have a better response rate than either the stretching-only group ($P = 0.022$) or the custom orthosis group ($P = 0.0074$). Other variables that appeared to influence response rates (when added to treatment group in a multivariate logistic regression model) were: (1) any prior history of similar heel pain (no nonresponses among those with a prior history; $P = 0.0095$), (2) duration of pain (longer duration associated with less response, $P = 0.088$), and (3) baseline pain score (higher scores weakly associated with less response,

TABLE 1
Summaries and Comparisons of Baseline Measurements

Measurement	Treatment group					Overall P value[a]
	Stretching only	Custom orthosis	Silicone	Rubber	Felt	
N Randomized	46	42	51	50	47	
Dropped out before week 8, N (%)	7 (15.2)	8 (19.1)	9 (17.7)	7 (14.0)	5 (10.6)	.82[b]
All summaries below are for the remaining 200 who returned for the week 8 visit:						
Remaining N	39	34	42	43	42	–
Female, N (%)	28 (71.8)	23 (67.7)	25 (59.5)	30 (69.8)	29 (69.1)	0.80[b]
Median age (yr)	47	48.5	49.5	44	48	0.39[c]
(range)	(25–81)	(23–69)	(30–75)	(27–69)	(26–76)	
Median weight (lb)	174	197	180	176	186	0.36[c]
(range)	(126–285)	(126–280)	(120–275)	(125–280)	(120–285)	
Median body mass index (kg/m^2)	28.0	29.3	28.0	27.1	28.1	0.49[c]
(range)	(21.6–50.5)	(21.5–46.6)	(20.0–43.6)	(20.4–50.2)	(18.3–48.9)	
Self-reported duration of pain, N (%)						
<1 month	9 (23.7)	3 (8.8)	3 (7.1)	6 (14.3)	0 (0.0)	
2–3 months	12 (31.6)	12 (35.3)	15 (35.7)	14 (33.3)	12 (28.6)	
4–6 months	7 (18.4)	7 (20.6)	5 (11.9)	7 (16.7)	12 (28.6)	.089[d]
6–12 months	4 (10.5)	8 (23.5)	8 (19.1)	9 (21.4)	9 (21.4)	
>1 year	6 (15.8)	4 (11.8)	11 (26.2)	6 (14.3)	9 (21.4)	
Any history of similar heel pain, N (%)	3 (7.9)	4 (11.8)	9 (21.4)	3 (7.1)	5 (11.5)	0.34[b]
History of similar pain on same side, N (%)	2 (5.3)	4 (11.8)	3 (7.1)	3 (7.1)	4 (9.5)	0.89[b]
Overall pain score, mean ± SD	55.8 ± 21.4	64.1 ± 21.2	58.2 ± 20.4	65.1 ± 19.3	59.5 ± 18.6	0.21[e]

N, number of patients; yr, year; lb, pounds; kg, kilograms; m, meters; SD, standard deviation.
[a] Test for whether all differences among the groups are consistent with chance variation.
[b] By Fisher's exact test.
[c] By Kruskal-Wallis test, because data were not normally distributed.
[d] By Kruskal-Wallis test, after numerically scoring the categories as 1 to 5. *P*-value by χ^2 test is 0.20.
[e] By analysis of variance.

$P = 0.16$). When controlled for these other variables in this multivariate model, evidence for group differences persisted (overall, $P = 0.011$), with estimated response rates better in the silicone insert group than in the stretching-only group ($P = 0.019$) or the custom orthosis group ($P = 0.010$) and also better for the rubber insert group than for the stretching-only ($P = 0.026$) or custom orthosis ($P = 0.030$) groups. Weight and body mass index had very little influence on response rates, and controlling for these produced no substantial changes in the results.

TABLE 2
Response Rates by Group

Group	Responses (N)	Total N	% Responses	95% CI
Stretching only	28	39	71.8	55.1–85.1
Custom Orthosis	23	34	67.6	49.5–82.6
Silicone	40	42	95.2	83.8–99.4
Rubber	38	43	88.3	74.9–96.1
Felt	34	42	80.9	65.9–91.4
All prefabricated	112	127	88.2	81.3–93.2

Response is defined as the patient reporting that heel pain is all, much, or slightly better. Nonresponse is when the patient reports that pain is unchanged or worse.
CI, confidence interval.

There was no change in these overall results when we re-examined the data using a new definition of response as "all or much better," and nonresponse as "slightly better, unchanged, or worse."

Analyses of Pain Scores (Foot Function Index Pain Subscale)

Ten subjects who completed week 8 questionnaires failed to respond to the pain questions used for the overall pain score; therefore, changes could be calculated for only 190 subjects. Table 4 summarizes the changes in pain scores within treatment groups. All groups tended to show improvements, as indicated by the negative mean changes. Although the difference between the stretching-only and rubber insert groups approached statistical significance ($P = 0.055$), the overall *P*-value for differences among the groups was 0.35. Patients with higher initial pain scores tended to improve more ($P = 0.0001$), those with longer duration of pain tended to improve less ($P = 0.010$), and those with prior history of similar pain showed a slight tendency to improve more ($P = 0.30$). Controlling for these factors in a multivariate model caused the differences between the groups to parallel the findings on response rates somewhat more closely, with the

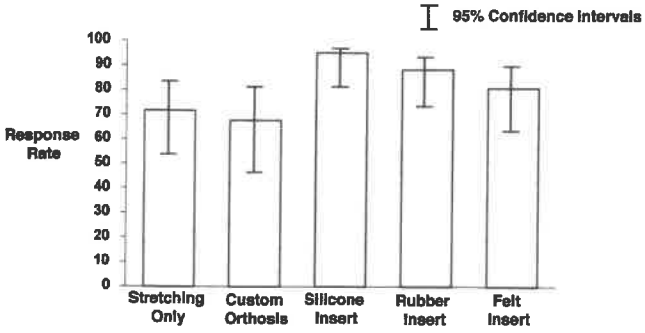

Fig. 8. Response rate by treatment group.

prefabricated inserts tending to produce more improvement than the custom orthosis or stretching-only, but no differences were statistically significant (all pairwise comparisons, $P > 0.19$; overall, $P = 0.54$). Higher weight and body mass index were associated with slightly better improvements but were not statistically significant ($P = 0.24$), and they resulted in no substantial change when added to the multivariate model used for Table 4.

Analysis of Subgroups

Subgroups defined with the demographic and medical history variables generally showed patterns similar to those in Tables 2 and 4, with the groups using prefabricated inserts having higher response rates and more improvement in pain. A key exception resulted from subgrouping the patients according to whether they reported standing all day (≥8 hr) versus not (<8 hr). Unfortunately, many subjects failed to answer the question about hours of standing per day, so only 115 subjects could be included in this analysis. Table 5 shows that comparisons of the custom orthosis group to the other insert groups were different depending on whether or not the patients reported standing ≥8 hr/day. The results for the custom orthosis tended to be comparable to the other inserts among those who did not stand all day but appeared to be much worse for patients who did stand ≥8 hr/day. Testing this difference in how the custom orthosis compared with the others by including interaction terms in logistic and multiple regression models resulted in P-values of $P = 0.0050$ for response rate and $P = 0.11$ for change in overall pain score.

DISCUSSION

This is the first prospective randomized clinical trial on the treatment of proximal plantar fasciitis (heel pain syndrome). The specific goal of the trial was to evaluate the initial 8 weeks of treatment. Although there are numerous modalities available for the initial treatment of heel pain, it has not been evident which is the best or most cost effective.[3,4,8–11] We chose treatment protocols and prefabricated shoe inserts that were used most often in clinical practice. The custom

TABLE 3
Pairwise *P*-Values from Fisher's Exact Test Comparing Response Rates Between Groups

	Stretching only	Custom orthosis	Silicone	Rubber	Felt
Stretching only	–	0.80	0.0055	0.093	0.43
Custom orthosis	0.80	–	0.0019	0.046	0.20
Silicone	0.0055	0.0019	–	0.43	0.088
Rubber	0.093	0.046	0.43	–	0.38
Felt	0.43	0.20	0.088	0.38	–

Response is defined as the patient reporting that heel pain is all, much, or slightly better. Nonresponse is when the patient reports that pain is unchanged or worse.

TABLE 4
Changes from Baseline to Week 8 in the Overall Pain-Score Derived from the Subscale for Pain of the Foot Function Index

Treatment group	Univariate analysis		Controlled for covariates[a]	
	Mean change in pain-score	95% CI	Mean change in pain-score	95% CI
Stretching only	−15.8	−26.4 to −5.1	−17.2	−25.5 to −8.9
Custom orthotic	−19.0	−29.2 to −8.7	−16.9	−25.7 to −8.1
Silicone	−22.9	−30.0 to −15.8	−23.9	−32.0 to −15.9
Rubber	−27.7	−37.4 to −18.1	−24.5	−32.3 to −16.7
Felt	−18.8	−26.3 to −11.3	−20.2	−28.2 to −12.2
All prefabricated	−23.3	−27.9 to −18.6	−22.9	−27.5 to −18.4

Overall P-values for differences between groups are $P = 0.35$ univariate and $P = 0.54$ controlled for covariates.
[a] From a multivariate model including baseline overall pain-score, duration of pain, and history of similar heel pain.

TABLE 5
Primary Measures of Outcome by Hours Spent Standing Per Day

Standing per day	Treatment group	Reported improvement in pain			Change in pain-score, baseline to week		
		N	Rate of success	95% CI	N	Mean change in pain-score	95% CI
<8 hr	Stretching only	13	61.5	31.6 to 86.1	12	−9.1	−21.2 to 2.9
	Custom orthotic	14	85.7	57.2 to 98.2	13	−24.7	−37.3 to −12.0
	Silicone	15	86.7	59.5 to 98.3	15	−27.2	−38 to 16.4
	Rubber	12	91.7	61.5 to 99.8	12	−32.9	−51.8 to −14.0
	Felt	15	66.7	38.4 to 88.2	14	−14.9	−26.9 to −3.0
	All prefabricated	42	81.0	65.9 to 91.4	41	−24.7	−32.2 to −17.2
8+ hr	Stretching only	10	70.0	34.8 to 93.3	10	−28.8	−45.2 to −12.9
	Custom orthotic	9	44.4	13.7 to 78.8	8	−1.9	−32.7 to 28.9
	Silicone	7	100	65.2 to 100	6	−12.6	−37.6 to 12.5
	Rubber	10	100	74.1 to 100	10	−31.6	−55.3 to −7.9
	Felt	10	90.0	55.5 to 99.7	9	−20.8	−35.3 to −6.4
	All prefabricated	27	96.3	81.0 to 99.9	25	−23.2	−34.1 to −12.2

CI, confidence interval.

polypropylene orthosis was chosen because it is one of the most frequently prescribed orthoses in the United States for proximal plantar fasciitis (P. Scherer, California College of Podiatric Medicine, personal communication, 1994). Beyond the initial medical consultation, the costs of the treatments in this study vary substantially, from no cost for the stretching, $8 for the felt insert, $12 for the rubber insert, $40 for the silicone insert, to approximately $300 for the custom orthosis.

All five treatment groups demonstrated improvement in both pain scales at the 8-week follow-up. The FFI, when controlled for covariates (baseline pain, duration of pain, and a prior history of similar heel pain), indicated that the greatest diminution in pain was in the rubber insert and silicone insert groups, followed by the felt insert, stretching-only, and custom orthosis groups. The differences in FFI changes were not statistically significant, but the trends mirrored the results for response rates, which showed statistically significant differences. Response rates also showed improvement in all groups. All of the prefabricated inserts, as well as the stretching-only, appeared to be at least as effective in reducing pain as the much more expensive custom orthotic device.

We examined multiple factors that might have influenced the results of the study, including gender, weight, body mass index, type of floor surface at work, baseline pain score, history of previous heel pain, compliance with the stretching program, use of shoe inserts, and duration of symptoms. Controlling for these factors in multivariate analyses confirmed that the univariate findings could not be explained by chance imbalance among the treatment groups in any of these factors. Obesity, for example, may predispose a person to proximal plantar fasciitis, but it does not deter improvement during the first 8 weeks of treatment.

The only factor that appeared to influence the relative effectiveness of the treatments was standing ≥8 hr/day. Among patients who did not stand 8 hr, the custom orthotic device produced results similar to those of the prefabricated inserts. Among those standing ≥8 hr/day, however, the results of treatment with the custom orthotic device were much poorer. This finding requires further confirmation, because of the large amount of missing data regarding hours of standing/day. It may be that the varying success of the different inserts, both prefabricated and custom orthosis, is directly related to their shock absorption characteristics. The silicone insert is the most shock absorbent, followed by the rubber insert, felt insert, and plastic orthosis. Patients who stood on their feet for ≥8 hr each day were those who most needed a well cushioned, shock absorbent insert. A custom orthosis made of more shock absorbent material might have performed better than the polypropylene insert.

Given the restraints of clinical practice, we were not able to offer a group of patients no treatment, therefore, the stretching group, in effect, became the control group for the study. This group, however, reported a remarkable 71.8% response rate. The degree of improvement with stretching only is not entirely unexpected. Several large retrospective studies on the nonsurgical treatment of proximal plantar fasciitis demonstrate that the single most effective treatment preferred by their patients was Achilles and plantar fascia stretching.[3,4,11] Proximal plantar fasciitis results in chronic inflammation, degeneration, and repair of the plantar fascia where it arises from the medial calcaneal tuberosity. A tight Achilles tendon or con-

tracted plantar fascia places increased stress on the inflamed fascia during gait. A stretching program of the Achilles tendon and plantar fascia should be considered a cornerstone of any effective treatment plan.

In conclusion, this prospective randomized clinical trial found that the use of relatively inexpensive prefabricated inserts, along with Achilles tendon and plantar fascia stretching, is more effective than a custom polypropylene orthosis for the initial treatment of proximal plantar fasciitis.

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