Effective Orthotic Therapy for the Painful Cavus Foot

A Randomized Controlled Trial

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Patients with a cavus or high-arched foot frequently experience foot pain, which can lead to significant limitation in function. Custom foot orthoses are widely prescribed to treat cavus foot pain. However, no clear guidelines for their construction exist, and there is limited evidence of their efficacy. In a randomized, single-blind, sham-controlled trial, the effect of custom foot orthoses on foot pain, function, quality of life, and plantar pressure loading in people with a cavus foot type was investigated. One hundred fifty-four participants with chronic musculoskeletal foot pain and bilateral cavus feet were randomly assigned to a treatment group receiving custom foot orthoses (n = 75) or to a control group receiving simple sham insoles (n = 79). At 3 months, 99% of the participants provided follow-up data using the Foot Health Status Questionnaire. Foot pain scores improved more with custom foot orthoses than with the control (difference, 8.3 points; 95% confidence interval [CI], 1.2 to 15.3 points; $P = .022$). Function scores also improved more with custom foot orthoses than with the control (difference, 9.5 points; 95% CI, 2.9 to 16.1 points; $P = .005$). Quality-of-life data favored custom foot orthoses, although differences reached statistical significance only for physical functioning (difference, 7.0 points; 95% CI, 1.9 to 12.1 points; $P = .008$). Plantar pressure improved considerably more with custom foot orthoses than with the control for all regions of the foot (difference, –3.0 N · s/cm²; 95% CI, –3.7 to –2.4 N · s/cm²; $P < .001$). In conclusion, custom foot orthoses are more effective than a control for the treatment of cavus foot pain and its associated limitation in function. (J Am Podiatr Med Assoc 96(3): 205-211, 2006)

The cavus foot is characterized by an excessively high medial longitudinal arch, and it is typically referred to as a high-arched or supinated foot type. The foot type may be more precisely described as a multiplanar foot deformity that usually features a varus rearfoot, a plantarflexed first metatarsal, and clawing of the digits (Fig. 1). Population-based studies suggest that the prevalence of the cavus foot is approximately 10%,[1] and its cause is primarily idiopathic or neurogenic in nature.[2] It is estimated that 60% of people with cavus feet experience foot pain, such as metatarsalgia, sesamoiditis, or plantar heel pain. Conditions

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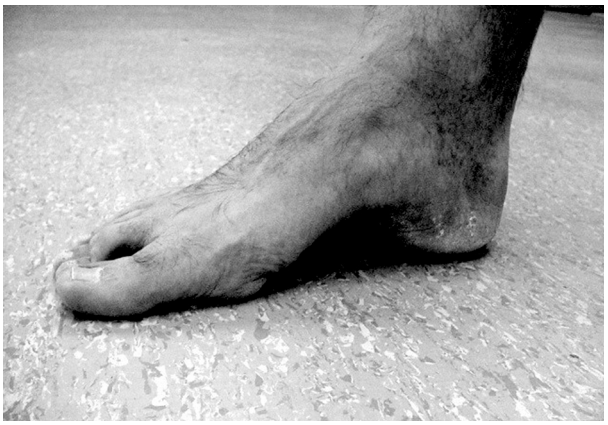

Figure 1. Photograph of the typical cavus foot featuring an excessively high medial longitudinal arch and clawing of the digits.

such as these are thought to be associated with abnormal pressure loading on the plantar surface of the foot.[3]

For at least 30 years, foot orthoses have been recommended for cavus-related foot pain because they can improve pressure distribution.[4, 5] In particular, foot orthoses customized to an individual have been shown to reduce and redistribute plantar foot pressure,[6] and they are increasingly prescribed by podiatric physicians, orthopedic surgeons, and rehabilitation specialists for patients with chronic cavus foot pain.[7, 8] Despite these anecdotal reports in favor of custom foot orthoses, there are no clear guidelines for their construction, and there is limited evidence of their efficacy for the painful cavus foot.

To build the evidence base for orthotic therapy, we tested the effect of custom foot orthoses on foot pain, function, quality of life, and plantar pressure in people with a cavus foot type. The research design was a prospective, randomized, single-blind, sham-controlled trial.

Materials and Methods

Participants

A community sample of participants was recruited in Sydney, Australia, by referral from health-care providers and advertisements in the local media. Eligible participants were men and women 18 years or older who had musculoskeletal foot pain for more than 1 month and bilateral cavus feet of any etiology. The criterion for the cavus foot type was established using the Foot Posture Index, which is a diagnostic clinical tool that quantifies weightbearing foot posture and has demonstrated acceptable reliability and validity in the literature.[9-12] A cavus foot was defined by a Foot Posture Index score of –2 or less, which is 2 SD below the reported normal mean of +5.[13] Study exclusion criteria were pregnancy, recent foot trauma, current use of ankle-foot orthoses, and lack of willingness to return for follow-up. The study was approved by the Human Ethics Committee of the University of Sydney.

Interventions

On enrollment, participants provided written consent and were randomly assigned to one of two intervention groups. Participants were informed that they would be given an orthotic device that may be different from their past experience. Members of the treatment group were fitted with a pair of custom foot orthoses molded from neutral-suspension plaster casts of the feet by an experienced podiatric physician (J.B.) (Fig. 2). The casts were scanned using a three-dimensional laser scanner, and the orthoses were fabricated from 3-mm polypropylene using a computer-aided design–computer-aided manufacturing milling machine to a standardized prescription that had been previously developed and pilot tested.[14] The orthoses were covered with full-length 3-mm Poron Medical urethane (Rogers Corp, Woodstock, Connecticut), which is a commonly used and effective material for absorbing shock and reducing pressure.[15, 16] The exact prescription guidelines for the custom foot orthoses are shown in Table 1. The key feature of the device is the contoured flexible shell molded to the exact morphological features of the patient's foot. With the addition of a full-length cushioned top cover, the orthotic device aims to reduce and redistribute abnormal plantar pressures.

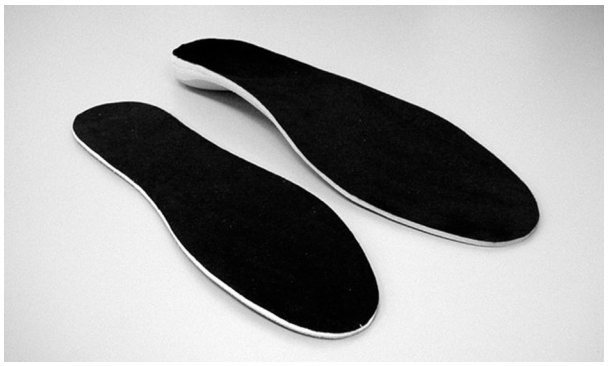

Figure 2. The treatment group received custom foot orthoses (right), and the control group received sham insoles (left).

Table 1. Comparison of the Prescription Guidelines and Materials Used for Each Intervention

Prescription	Custom Foot Orthoses	Control
Cast/scan modifications		Nil
Balance	Metatarsals 1–5	
Tissue expansion	20% medial arch expansion	
Corrected calcaneus position	0°	
Intrinsic forefoot	0°	
Shell shape		Nil
Length	Proximal to metatarsal heads	
Forefoot width	Standard (1–5)	
Lateral heel expansion	6 mm	
Heel cup height	12 mm	
Shell material	3-mm polypropylene	Nil
Shell posting		Nil
Extrinsic heel post	Lateral half only	
Motion	0°	
Elevation	0 mm	
Heel lift	0 mm	
Top cover		
Style	Full length	Full length
Material	3-mm Poron/ Kashmeer	3-mm latex foam/ Kashmeer

For the control group, casts were made of both feet using the same technique as for the treatment group. However, the casts were not used to fabricate the intervention. Instead, members of the control group were given sham insoles made from flat, nonsupportive, 3-mm latex foam, a material shown to be least effective at reducing pressure (Fig. 2).[17] Both interventions were purchased from an independent supplier to avoid conflict of interest (Virtual Orthotics, Sydney, Australia). The cost was US$87 for the custom foot orthoses and US$3 for the sham insoles.

Written instructions for a progressive wearing schedule and footwear advice were provided. Participants with their own orthoses, insoles, shoe inserts, and so on did not use them at any time during the study. Routine treatment, such as medication, physical therapy, and massage, were continued as usual.

Outcome Measures

Two planned primary outcome measures, foot pain and function, were evaluated using the Foot Health Status Questionnaire at baseline and after 3 months: 0 points indicates the worst score and 100 points indicates the best score. The Foot Health Status Questionnaire was selected because it is an accurate, valid, and reliable means of measuring patient-based, foot health–specific quality of life before and after treatment.[18, 19]

Secondary outcomes, selected before the study, were general health–related, quality-of-life measures based on four domains of the 36-Item Short-Form Health Survey: physical functioning, general health, vitality, and social functioning.[20] These outcomes were measured at baseline and after 3 months and are included in the Foot Health Status Questionnaire.[19]

Explanatory Outcome

To understand the mechanism of action underlying orthotic therapy for the painful cavus foot, plantar pressure was recorded using the Pedar-mobile in-shoe system (Novel GmbH, Munich, Germany), which is an accurate, reliable, and valid measure of in-shoe pressure.[21, 22] Plantar pressure was measured before and after the intervention at baseline wearing a standardized shoe (Dunlop Volley; Pacific Dunlop Ltd, Melbourne, Australia) (size range, 5–12) and sock (Brooks; Texas Peak Pty Ltd, Tullamarine, Australia). After a familiarization period, data were collected at 50 Hz for approximately 40 steps on a 10-m walkway. To prevent a disturbance in gait pattern and to ensure a natural gait, cadence and walking speed were monitored but not controlled.[23]

Pressure data were processed by a research assistant not involved in participant contact. Nine straight-line walking steps from a random foot of each participant were selected in the Novel software (Novel GmbH). The foot was then divided into three anatomically and clinically relevant regions (rearfoot, midfoot, and forefoot) as previously reported.[14] For each region of the foot, the pressure–time integral ($N \cdot s/cm^2$) was analyzed. The pressure–time integral is calculated by summing the peak pressure values that occurred in each frame of foot contact, and multiplying this by the frame interval (ie, the time for one frame). The pressure–time integral provides an understanding of the plantar pressure load distribution applied over time, and previous results suggest that it is a better indicator of cavus pressure loading characteristics than either peak pressure or contact time individually.[3]

Sample Size

The required sample size was estimated *a priori* assuming a power of 80% and an α level of .05.[24] Based

on historical data, sample size was calculated to detect a clinically important difference between groups of 10 (SD = 20) points in Foot Health Status Questionnaire scores,[18] giving a required minimum sample size of 67 participants in each group, with loss to follow-up of 5%.

Randomization

Participants with painful cavus feet were randomly allocated to receive either custom foot orthoses or the control after their first appointment. The randomization code was developed off-site using computer-generated permuted block lengths of 4, 6, or 8 and stratified for cavus etiology (neurogenic or idiopathic/other). The investigator who recruited participants and potential participants was blinded to the randomization process through telephone allocation by a third party not involved in the study.

Blinding

Participants were blinded to treatment allocation for the duration of the study. To encourage blinding, all of the participants in both groups had plaster casts made of their feet at the first appointment and were advised that they would receive an intervention based on the cast parameters, although casts were used only to fabricate the custom foot orthoses. Furthermore, extra care was taken to design an appealing, realistic, and convincing control (Fig. 2). Blinding of the investigator was not appropriate because of the potential need for ongoing contact with the participants concerning adverse effects. However, to minimize assessor bias, primary outcome measures were self-reported, and the investigator was blinded to all data entry and processing by a research assistant not involved in participant contact.

Statistical Methods

All statistical analyses were performed according to a preestablished plan (SPSS version 12.0.1; SPSS Science, Chicago, Illinois). Treatment effect was assessed on an intention-to-treat basis by mean pain and function scores at 3 months using a linear regression approach to analysis of covariance (ANCOVA) to adjust for any baseline differences between groups, with baseline pain and function scores as respective covariates, specified *a priori*.[25] General health–related, quality-of-life, and pressure data were also analyzed using ANCOVA, with baseline quality-of-life and shoe-only pressure data as respective covariates. Precision of treatment effect was based on the 95% confidence interval (CI) and $P < .05$.[26]

Results

Participant Characteristics

Of 474 adults screened for inclusion between December 9, 2003, and January 24, 2005, 154 (32.5%) enrolled in the trial, with 75 randomly allocated to custom foot orthoses and 79 to the control (Fig. 3). The physical characteristics of the participants were similar between groups (Table 2), and there were no differences in foot pain or function scores at baseline ($P > .05$) (Table 3). Cavus severity ranged from mild (Foot Posture Index score of –2) to severe (Foot Posture Index score of –12), and etiology was classified according to Statler and Tullis[8] as congenital (130 patients had idiopathic and 1 had residual clubfoot), neuromuscular (16 had Charcot-Marie-Tooth disease, 4 had poliomyelitis, and 1 had polyneuropathy), or traumatic (2 had osseous malunion). Foot pain was bilateral in 68% of the cases, and common diagnoses included metatarsalgia, plantar heel pain, and midfoot osteoarthritis. Overall, 153 participants (99%) were followed up at 3 months, and compliance was high, with 80% of the treatment group and 79% of the

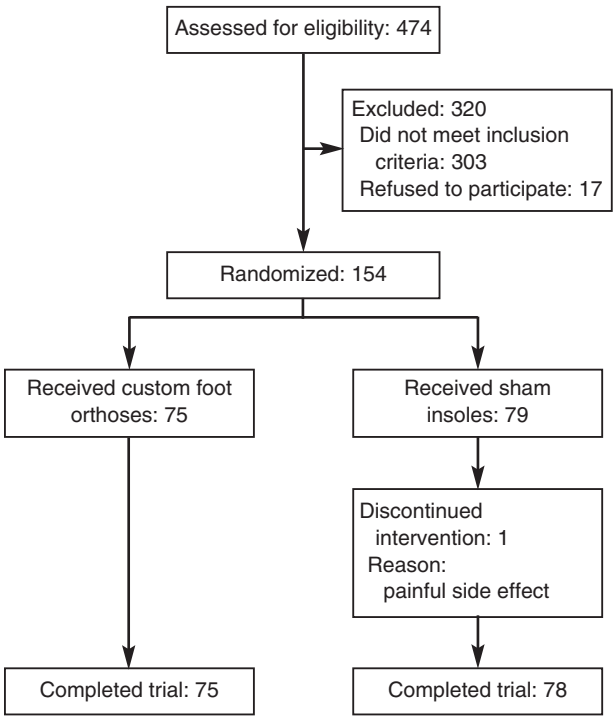

Figure 3. Flow of participants through the trial.

Table 2. Baseline Characteristics of the Study Participants

Characteristic	Custom Foot Orthoses (n = 75)	Control (n = 79)
Age (years)	49.8 (14.3)	49.5 (14.4)
Female (No. [%])	39 (52)	48 (61)
Body mass index (kg/m^2)	28.1 (6.1)	27.4 (6.0)
Foot Posture Index score	–4.4 (2.7)	–4.5 (2.7)
Standing or walking (h/day)	7.1 (3.3)	7.4 (3.4)
Pain duration (years)	7.3 (9.4)	8.9 (11.4)
Previous use of foot orthoses (No. [%])	45 (60)	34 (43)

Note: Values are given as mean (SD) unless otherwise indicated. There were no significant differences between groups ($P > .05$).

control group reporting that they wore their intervention for most of their shoe-wearing time.

Outcomes

In the primary analysis, mean (SD) foot pain improved 31.2 (25.8) points with custom foot orthoses and 20.3 (22.7) points with the control (ANCOVA-adjusted difference, 8.3 points; 95% CI, 1.2 to 15.3 points; $P = .022$). Mean (SD) function improved 25.6 (27.2) points with custom foot orthoses and 14.6 (20.6) points with the control (adjusted difference, 9.5 points; 95% CI, 2.9 to 16.1 points; $P = .005$). In the secondary analysis, quality-of-life data generally favored the custom foot orthoses, although differences reached significance only for physical functioning (adjusted difference, 7.0 points; 95% CI, 1.9 to 12.1 points; $P = .008$) (Table 3).

In the explanatory analyses, plantar pressure loading was reduced more with custom foot orthoses than the control for the whole foot (adjusted difference, –3.0 N · s/cm^2; 95% CI, –3.7 to –2.4 N · s/cm^2; $P < .001$), rearfoot (adjusted difference, –1.2 N · s/cm^2; 95% CI, –1.5 to –0.9 N · s/cm^2; $P < .001$), and forefoot (adjusted difference, –2.1 N · s/cm^2; 95% CI, –2.8 to –1.4 N · s/cm^2; $P < .001$). At the midfoot, plantar pressure increased with the custom foot orthoses and decreased with the control (adjusted difference, +0.6 N · s/cm^2; 95% CI, 0.2 to 1.0 N · s/cm^2; $P = .003$) (Table 4). Of note, mean (SD) contact time did not significantly differ between groups before intervention (custom foot orthoses 756 [104] ms; control 749 [96] ms; $t = 0.427$; $P = .670$) or after intervention (custom foot orthoses 724 [92] ms; control 720 [92] ms; $t = 0.302$; $P = .763$).

Adverse Effects

Fewer adverse effects were reported with custom foot orthoses than with the control (7 [9%] *versus* 12 [15%]). Adverse effects were minor and included additional foot pain (4 [5%] *versus* 12 [15%]), ankle instability (2 [3%] *versus* 0), and skin irritation (1 [1%] *versus* 0).

Discussion

Principal Findings

There was evidence of a moderate effect for custom foot orthoses on foot pain and function in participants with a cavus foot type. Foot pain scores improved by 74% with custom foot orthoses, compared

Table 3. Foot Pain, Function, and Quality-of-Life Outcomes

End Point	Baseline: Custom Foot Orthoses (n = 75)	Baseline: Control (n = 79)	After Treatment (3 mo): Custom Foot Orthoses	After Treatment (3 mo): Control	Difference (95% CI)[a]	*P* Value
Primary outcome						
Foot pain	42.0 (19.5)	46.7 (18.1)	73.2 (24.6)	67.0 (22.2)	8.3 (1.2 to 15.3)	.022
Function	57.3 (23.5)	60.2 (23.5)	82.9 (22.8)	74.8 (23.8)	9.5 (2.9 to 16.1)	.005
Secondary outcome						
Physical functioning	66.3 (22.4)	71.4 (23.4)	78.4 (22.6)	74.8 (21.5)	7.0 (1.9 to 12.1)	.008
General health	70.0 (26.6)	73.3 (24.2)	73.5 (24.1)	77.0 (20.7)	–1.6 (–7.0 to 3.8)	.564
Vitality	47.3 (18.2)	50.2 (20.1)	55.8 (19.4)	53.4 (17.9)	4.1 (–0.6 to 8.8)	.085
Social functioning	76.7 (22.4)	82.0 (21.4)	85.3 (21.4)	88.4 (16.1)	–0.4 (–5.2 to 4.5)	.886

Abbreviation: CI, confidence interval.

Note: Values are given as mean (SD). There were no significant differences between groups at baseline ($P > .05$). Lower scores indicate greater severity of foot pain, greater limitation of function, and decreased quality of life.

[a]Differences between groups are calculated using analysis of covariance: positive values favor custom foot orthoses.

Table 4. Plantar Pressure Outcomes

Foot Region	Shoe Only (N • s/cm²)		Shoe/Intervention (N • s/cm²)		Difference (95% CI)[a]	*P* value
	Custom Foot Orthoses (n = 75)	Control (n = 79)	Custom Foot Orthoses	Control		
Whole foot	17.3 (3.6)	17.9 (4.0)	12.8 (2.9)	16.2 (3.6)	–3.0 (–3.7 to –2.4)	<.001
Rearfoot	7.9 (2.1)	7.8 (2.4)	6.0 (1.4)	7.1 (2.1)	–1.2 (–1.5 to –0.9)	<.001
Midfoot	3.5 (3.2)	3.4 (2.6)	3.8 (1.6)	3.2 (2.5)	0.6 (0.2 to 1.0)	.003
Forefoot	13.2 (3.8)	14.1 (4.3)	10.0 (2.8)	12.6 (3.9)	–2.1 (–2.8 to –1.4)	<.001

Abbreviation: CI, confidence interval.

Note: Values are given as mean (SD). There were no significant differences between groups for the shoe-only condition ($P > .05$).

[a]Differences between groups are calculated using analysis of covariance: negative values indicate a reduction in pressure loading.

with 43% with the control. Function scores improved by 45% with custom foot orthoses, compared with 24% with the control. From experience, this difference is clinically worthwhile, although it does not reflect how many participants completely recovered to normal levels. Resolution of foot pain to normal levels, ie, greater than 85 points on the Foot Health Status Questionnaire,[27] occurred in 20 participants with custom foot orthoses (27%) and 12 with the control (15%).

Comparison with Other Studies

There is an emerging evidence base from the results of several randomized controlled trials supporting the use of custom foot orthoses for a variety of painful foot conditions.[28-33] However, there is a relative paucity of scientific literature evaluating the effect of orthotic therapy for the painful cavus foot. This study is the first randomized controlled trial to investigate the effectiveness of custom foot orthoses for treatment of the painful cavus foot.

Mechanism of Orthotic Therapy for the Cavus Foot

Insights into the mechanism of the custom orthotic device were provided by the pressure-loading data. Overall, the custom foot orthoses reduced plantar pressure by 26%, compared with a 9% reduction with the control. This threefold improvement in pressure distribution with custom foot orthoses was due to the contoured flexible shell molded to the exact morphological features of the participant's foot and the full-length cushioned top cover. Specifically, the custom orthotic device was shown to significantly increase pressure at the midfoot and decrease pressure at the rearfoot and forefoot, supporting preliminary hypotheses that the mechanism of pain relief is by reduction and redistribution of plantar pressure loading.[6, 14]

A small reduction in pressure may also explain the improvement in foot pain in the control group. Although the control group received an insole made from a material with limited shock-absorbing qualities,[17] it was not completely inert, reducing pressure loading by 9%. This is a limitation of the study. However, if the control group had been given an insole with no pressure-reducing qualities (flat plastic, thin leather, etc), there would have been a risk of increased pain with the "harder" insole. Furthermore, convincing blinded participants of the potential merit of the harder insole would have been difficult, and noncompliance or dropouts may have resulted. Future randomized controlled trials comparing custom foot orthoses with an inert and harmless intervention are warranted.

Other Findings

Custom foot orthoses generally had a greater effect on health-related quality of life than the control, particularly for physical functioning and, to a lesser extent, vitality. This indicates an increase in physical activity with the use of custom foot orthoses. These findings are similar to those of Davies et al,[34] who reported significant improvement in physical and mental health status with the use of custom foot orthoses in an at-risk patient population with diabetes. Further research in this area investigating the overall physical and psychological benefits of orthotic therapy may prove to be most interesting in the future.

Conclusion

The results of this study indicate that custom foot orthoses are more effective than a control for reducing cavus foot pain and associated limitation in function. The key feature of a successful orthotic device for

this patient population is a contoured flexible shell molded to the exact morphology of the foot, with a full-length cushioned top cover. Such a device has the effect of reducing and redistributing abnormal plantar pressure loading. For patients presenting to the clinician with painful cavus feet, custom foot orthoses are an effective treatment option.

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