

# Scientific Assessment of Over-the-Counter Foot Orthoses to Determine Their Effects on Pain, Balance, and Foot Deformities

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**Background:** A scientific study was conducted to evaluate the effects of non–custom-molded (over-the-counter) foot orthoses.

**Methods:** Several parameters were examined, including foot, knee, hip, and back pain; balance; and reduction in flexible deformities, such as hammer toes and hallux valgus. Wherever possible, objective measurements were used, including measurements of shifts in center of pressure to assess balance and changes in bone position examined on radiographs. Forty-one individuals were analyzed using one of two types of prefabricated, non-custom insoles. Insoles were fit by an assistant trained to follow the fitting recommendations of the manufacturer under the direct supervision of a podiatric physician.

**Results:** Use of these arch supports resulted in a significant reduction in some types of foot pain associated with hallux valgus ( $P = .04$ ) and pain in the arch area ( $P = .004$ ), knee ( $P = .002$ ), and back ( $P = .007$ ) by week 4. We also measured changes in foot position documented by radiography, although some changes may be attributed to parallax associated with measurement techniques. Improvement in balance was not observed to be significant when the orthoses were worn.

**Conclusions:** Using both subjective and objective measures, we found that these over-the-counter foot orthoses were effective in bringing about changes in foot shape and concomitant relief of certain specific painful conditions. This study indicates that there is a scientific basis for attempting to relieve pain with orthoses. (J Am Podiatr Med Assoc 99(3): 206-215, 2009)

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Although many foot and ankle specialists have witnessed the benefits of arch supports based on subjective feedback from their patients and have observed improvement in gait patterns and reductions in callous formation, few studies have attempted to quantify the changes in comfort and foot morphological features associated with foot orthoses. The foot

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is clearly a complicated and dynamic structure; its function is governed by numerous factors, including individual foot shape, gait patterns, and activities. Therefore, making any type of blanket statement about the effects of foot orthoses must be viewed with some level of skepticism. Nonetheless, the purpose of this study was to determine whether a few specific claims can be evaluated in a scientific manner to determine whether a readily available over-the-counter arch support can produce measurable changes in foot position, balance, and musculoskeletal pain.

## Background

Foot orthoses have been widely used as a treatment for many types of foot ailments. Historically, it has

been a matter of debate as to whether these devices can reduce hallux valgus and hammer toe deformities, diminish foot and back pain, and improve balance to a measurable degree. A review of the literature<sup>1-8</sup> demonstrates that a variety of musculoskeletal pains can be reduced and that stability can be measurably improved.

Previous studies have demonstrated that foot orthoses can change the morphological structure and function of the foot in humans. Nawoczinski and Ludewig<sup>1</sup> conducted a highly scientific study in which multiple locations on the foot were tracked on individuals with pes planus during ambulation, with varying degrees of posting and a custom-molded orthotic device. Eighteen patients (mean  $\pm$  SD age, 28.2  $\pm$  8.3 years) who demonstrated excessive pronation based on a clinical orthopedic examination were included in the study. Each patient received two custom-molded orthoses. The first orthosis incorporated an extrinsic rearfoot and forefoot post, and the second had a high medial longitudinal arch flange in conjunction with the extrinsic rearfoot post. A three-dimensional electromagnetic tracking device was used to describe the relative position and orientation of the hallux, first metatarsal, and calcaneus during the stance phase of walking, while wearing no orthosis, or while wearing one of the two orthotic designs. They found no significant difference in first metatarsophalangeal joint dorsiflexion in the three groups ( $P = .50$ ), but they did find that the metatarsal declination angle increased significantly in the relaxed stance with both orthotic devices compared with the foot without an orthosis ( $P = .001$ ). They also found that the change in declination angle of the first metatarsal was a poor predictor of change in peak dorsiflexion of the hallux during push-off.

A study by Yung-Hui and Wei-Hsien<sup>2</sup> used pressure mapping to demonstrate that a noncustom (over-the-counter) orthotic device could reduce forefoot pressure and improve comfort in women wearing high-heeled shoes. Ten healthy women wore shoes of varying heel heights (1.0 cm [flat], 5.1 cm [low], and 7.6 cm [high]) and five different shoe insert conditions (shoe only, heel cup, arch support, metatarsal pad, and total-contact insert). They demonstrated that increased heel height results in increased impact force, increased medial forefoot pressure, and subjective discomfort ( $P < .01$  for all). They found that heel pressure and impact force were decreased when a heel cup was used ( $P < .01$ ) and that arch supports reduced medial forefoot pressure and improved subjective footwear comfort ( $P < .01$ ). Use of the total-contact insert decreased heel pressure by 25%, medial forefoot pressure by 24%, and impact force by 33.2%.

They attribute this reduction in pressure and force to the perception of greater comfort compared with the noninsert shoe.

Cadaveric studies have also been used in conjunction with mechanical testing tools to demonstrate that the placement of an orthosis had a direct effect on ankle joint and subtalar joint stability. The study by Tochigi<sup>3</sup> used five fresh-frozen cadaver limbs with simulated ankle-subtalar complex instability created by transection of the anterior talofibular ligament and the interosseous talocalcaneal ligaments. Specimens were subjected to cyclic axial loads ranging from 9.8 to 668 N, and three-dimensional angular displacement measurements were made at the ankle and subtalar joints with electric goniometers. Measurements were made before and after insertion of an orthosis designed to support the medial longitudinal and transverse arches of the foot. He found that the maximum ankle internal rotation was decreased from a mean (SD) of 3.3° (0.9°) to 2.3° (0.4°) ( $P = .028$ ), but subtalar rotation was not significantly changed. He concluded that the orthosis reduced abnormal ankle internal rotation created by ligamentous resection and that the use of an arch support restored some level of stabilization by limiting internal rotation of the ankle joint.

A study by Kitaoka et al<sup>4</sup> used nine cadaveric specimens to determine the effects of arch supports when various ligaments are transected. They used two foot orthosis designs to test the effect with an intact foot, flatfoot, flatfoot with shoe and orthosis 1, and flatfoot with shoe and orthosis 2. The experiment was designed to simulate the midstance phase of gait. Loads were applied to five tendons to create an axial load equivalent to two-thirds of the standing load applied to the foot's plantar surface. A magnetic tracking system was used to monitor the position of tarsal bones during loading. They demonstrated that arch alignment improved significantly but to a limited degree (<2%) in cadaveric feet with the use of orthoses. Hindfoot valgus malalignment did not consistently improve when shoe inserts were used.

The study by Mundermann et al<sup>5</sup> was conducted on 206 military personnel and was designed to determine the frequency of stress fractures and mechanical injuries in individuals wearing noncustom orthoses versus those with no arch supports. They also evaluated the relationship between comfort and foot morphological features by using a visual analog scale and tracked injuries by using a separate questionnaire. Analysis included analysis of variance, multivariate analysis of variance, and  $\chi^2$  techniques. They found that comfort was improved to a statistically significant level and that stress fractures were reduced by more than 13% in soldiers wearing versus not

wearing foot orthoses. They also found that morphological features of the foot played a role in overall comfort with certain types of insoles. These findings indicate that certain types of arch support would be more comfortable for a given foot type than others.

Reduced lower-back pain but increased foot pain was demonstrated using a subjective measure in a study by Kelaher et al<sup>6</sup> in which they used a noncustom, prefabricated, semirigid foot orthosis. Ten patients wore semirigid arch support orthotic devices (experimental condition) for 2 months and flexible polyurethane/Sorbothane shoe inserts (control condition) for 2 months. Throughout this 18-week testing period, the patients were evaluated in the biomechanics laboratory at regularly scheduled intervals. Objective tests were used to determine participant strength, standing posture, stability, fatigue effects, and body-part discomfort. They found no significant changes in strength, posture, or stability as a function of device type. Patients reported a reduction in low-back discomfort along with an increase in foot discomfort during a fatiguing exertion task while wearing the semirigid orthotic devices compared with the control condition.

Kitaoka et al<sup>7</sup> used a cadaveric study to simulate weightbearing conditions and measured arch height and joint rotation. They examined two orthotic devices commonly prescribed as arch supports to evaluate their efficacy in stabilizing the foot. Fourteen cadaveric feet were mounted in a loading frame and were subjected to an axial load of 222, 445, or 667 N while three-dimensional positions of the talus, calcaneus, navicular, and first metatarsal were monitored with a magnetic tracking system. Each foot was tested with and without the arch supports. Arch stabilization was assessed by measuring changes in arch height and joint rotation. They found that joint rotations consistently increased when load was applied. Significant differences were observed in the metatarsal to talar abduction angle, dorsiflexion and eversion of the forefoot, eversion of the calcaneal talar joints, and talotibial dorsiflexion at the ankle. Arch height increased with both inserts to a statistically significant degree. Furthermore, the arch supports provided measurable improvement in arch stability in a simulated standing position.

Cornwall and McPoil<sup>8</sup> measured transverse tibial rotation as a reflection of calcaneal inversion and eversion. They evaluated the effects of footwear and orthotic devices on transverse tibial rotation with a video system positioned in front of each patient walking at a self-selected speed under various footwear or orthotic device conditions. The results of the case studies revealed that orthotic devices decrease maxi-

um tibial internal rotation compared with barefoot walking. In addition, internal tibial rotation velocity and acceleration were decreased by the use of shoes and an accommodative over-the-counter orthosis. A rigid arch support produced a slight increase in transverse tibial rotation and a dramatic increase in transverse tibial acceleration. This is significant because it demonstrates that modifications made at the level of the sole of the foot (ie, arch supports) have a clear mechanical effect on more proximal structures and can act to influence their function.

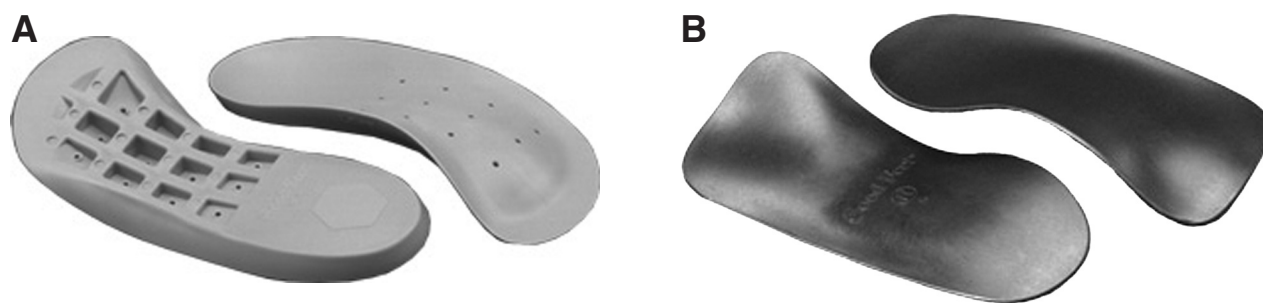
Based on this review of the literature, it is apparent that alterations in arch support may result in measurable changes in foot function, position, and various musculoskeletal symptoms. To establish whether the medical claims of improved balance and reduced deformity and pain can be supported, a clinical study was designed and implemented. Two types of over-the-counter arch support devices (Midflex and Arch Classic; Good Feet Corp, San Diego, California) were selected as part of this evaluation.

Although there are many different types of over-the-counter arch supports to choose from, the present study focused on these particular designs for a variety of reasons. First, they were readily available. Second, these supports are similar to the Alzner design arch support, which was first patented more than 40 years ago and is one of the more commonly used over-the-counter arch supports available. Third, we wanted an arch support that was relatively rigid to provide some level of manipulation of the foot structure. Two types of arch supports were studied because they differ in their bulkiness and intended applications. The Arch Classic style (Fig. 1A) is traditionally used for athletic-style shoes, and the Midflex style (Fig. 1B), which is less bulky, is usually used with lower-volume and dress shoes. Patients tried both devices to get the best possible fit for their foot and to accommodate the type of shoes that they typically wear.

The basic study design incorporated subjective and objective measurements to establish whether these devices are effective for altering foot morphological features, reducing musculoskeletal pain, and increasing stability. Most of the data reported herein represent quantitative measurements. However, in some cases, subjective data were used, such as when assessing an individual's level of pain, and this was determined by using a quantitative visual analog scale.

## Study Hypothesis

The following null hypotheses were proposed for this study: 1) a professionally fitted (but not custom-made)



**Figure 1.** The Arch Classic (A) and Midflex (B) styles of arch support.

orthosis will not alter the relative position of the bones of the foot to reduce flexible hallux valgus and hammer toe deformities, as demonstrated by weight-bearing radiographs; 2) this orthosis will not improve balance, as demonstrated by a “push test” as described herein; 3) the orthosis will not reduce pain associated with the back, hip, knee, and foot, as reported subjectively by the study participant; and 4) reduction of pain and added stability (as defined in the “Methods” section) will not be achieved in 4 weeks or less through use of the foot orthoses that are the subject of this research.

## Methods

This was a prospective study that used adult patients (>18 years old) with one of the following: hallux valgus (defined as a 1-2 intermetatarsal angle  $\geq 10^\circ$  or a hallux abductus angle  $\geq 15^\circ$ ); hammer toe deformity (defined as contracture at the level of the proximal interphalangeal joint of  $\geq 20^\circ$  when standing in  $\geq 1$  toe); or back, knee, or hip pain.

The primary study end points were 1) subjective changes in symptoms related to back, hip, knee, and foot pain during a 4-week period; 2) immediate change in foot architecture as it relates to hallux valgus and hammer toe deformities; and 3) immediate change in balance as measured by shifts in center of pressure. The safety end points for this study were adverse events (ie, increase in pain, instability, or bony deformity) and excess pain.

Before enrollment of the first patient, the study protocol and the informed consent form were reviewed by an independent institutional review board (Clinical Science Corp, Skokie, Illinois). To participate in the study, all of the patients were required to satisfy the inclusion and exclusion criteria (Table 1). Sixty-two patients were screened from our private practice to identify 41 individuals who met the inclusion and exclusion criteria; who presented with foot, knee, hip, or back pain and with either hallux valgus

or hammer toe deformities; and who completed all of the required visits.

After signing the informed consent form, patients were fit for either the Midflex or the Arch Classic arch support insoles. The device selected was based on the type of shoe most commonly worn by the participant and the fit of the device. The Midflex arch support is a thin, semirigid device comparable with a dress or slim orthosis. The Arch Classic insole is a thicker, slightly more flexible device. These devices are based on the original Alzner footbed design. Fitting was performed by an experienced fitter in accordance with the manufacturer’s fitting protocol and was confirmed by a podiatric physician.

Each patient was given a “pretreatment” questionnaire that collected demographic information and asked questions about the type and intensity of pain experienced. Each study participant then had baseline photographs taken of the feet while standing with and without the arch supports in place. The position and appearance of the feet and toes were recorded at the beginning of treatment and again after 4 weeks.

Radiographs were taken with and without the arch supports in place. Anteroposterior and lateral radiographic views were taken of both feet in a weightbearing position, with patients standing in their approximate normal angle and base of gait as ascertained by observing them walk. Radiographic views were standardized with the anteroposterior radiographs taken with the patient standing and the head of the radiography machine angled  $15^\circ$  from vertical. Lateral radiographs were taken with the patient standing in full weightbearing and the head of the radiography machine pointing  $90^\circ$  from vertical. Supported (with orthoses) and unsupported (without orthoses) feet were then compared to determine differences in angular relationships between bones. On the lateral views, the following measurements were compared: metatarsal declination angle, calcaneal inclination angle, cyma line position, metatarsophalangeal and interphalangeal angles, and distance between the

**Table 1. Inclusion and Exclusion Criteria**

Inclusion Criteria	Exclusion Criteria
Age $\geq$ 18 y	Previous surgery to the foot that involves either hallux valgus or hammer toes
Presence of one or more of the following conditions	Amputation of either a portion of the foot or the entire foot
Hallux valgus and hammer toe deformities	A limb-length discrepancy $>$ 1.0 inch
Intermittent back, hip, or knee pain	Back or knee pain attributable to structural or organic defects, such as slipped disks, degenerative nerve diseases, and neuropathy, and currently or previously under the care of a physician
Foot pain, including plantar fasciitis or calcaneal bursitis, and hammer toes	Currently or previously under the care of a physician for debilitating arthritis in the feet or lower legs
Signed the informed consent form and able to comply with the scheduling regimen for this study	Requires custom-molded shoes, braces, or other shoe modifications
	Walks with the aid of a device such as a cane, walker, crutches, scooter, or wheelchair
	Primarily walks in shoes with heels $>$ 1 inch or wears sandals as the primary shoes
	Currently under the care of a physician for depression or any other type of psychiatric disorders or treated for psychiatric disorders in the 3 mo before screening for this study

plantar navicular and the support plane (arch height measurement) (Fig. 2).

Measurements on the anteroposterior view include all of the following: metatarsus adductus angle, 1-2 intermetatarsal angle, hallux abductus interphalangeus angle, metatarsophalangeal joint angulation (hallux abducto valgus angle), and tibial sesamoid position. Radiographs were captured as high-resolution digital images and were measured by using markers placed by the observer. Angular measurements were accurately recorded to  $0.1^\circ$  with digital radiographic analysis software (Millbrook Inc, Carrollton, Texas).

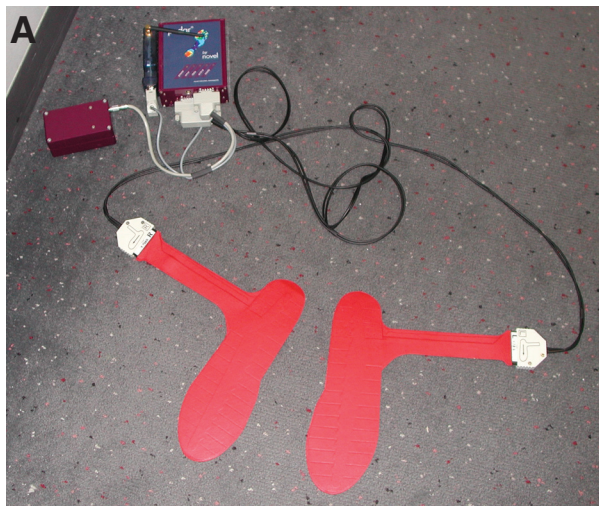
A novel technique was developed to objectively assess sense of balance. Herein, balance was defined as the ability of a study patient to resist shifts in center

of pressure when the shoulder is pushed from behind, in a standardized manner. We believe that this is a meaningful measure of stability (ie, resistance to shifts in body position in response to a “push”).

Balance was quantified based on shifts in center of pressure in 30 sec, as recorded with the Pedar pressure measurement system (Novel GmbH, Munich, Germany). Measurements were made with the participant standing barefoot and with the arch support in place but without shoes. In either case, the Pedar sensors were in direct contact with the patient’s skin (Fig. 3). The patient was knocked off balance slightly by allowing a 5-lb weight to swing like a pendulum from a fixed height into either the right or left shoulder, with the goal being to strike the individual in the area of the central portion of the scapula. The weight was raised to a standard position and was allowed to swing into the patient. Before swinging the weight, a “test push” was performed so that the patient was not simply startled as a result of the pushing pressure. The order of testing was randomized as well (ie, sometimes the first push was performed with the arch support in place and sometimes without the arch support in place). Displacement of the center of pressure was measured based on the change with and without the arch support in place. Figure 4 shows a sample of how the data were measured to show the shift in center of pressure after the push. Overall shifts in pressure were calculated by determining the maximum length and width of the area circumscribed



**Figure 2.** The arch height is determined by measuring the perpendicular distance between the horizontal surface and the closest point on the navicular bone.



**Figure 3.** A, Pedar sensors are connected via wireless interface and are used to measure plantar pressures. B, Shifts in pressure are converted into shifts in center of pressure to evaluate the stability of the test patient after a “push.”

by the shifts in center of pressure demonstrated graphically. Stability was determined by calculating this area and comparing the area with and without the arch support in place.

Subjective evaluations of overall foot comfort and of intermittent back, knee, and hip pain were performed before dispensing arch supports and at 2 and 4 weeks of follow-up. Visual analog scales were used to assess level of pain. Patients were also asked to log their use of anti-inflammatory medications, types of shoes worn, and amount of time wearing the test arch support.

Study participants were evaluated for overall foot comfort and for back, hip, and knee pain at 2 and 4 weeks of follow-up. In addition, patients were asked for their overall impression of the arch supports dispensed, including ease of use and any concerns that they may have.

## Results

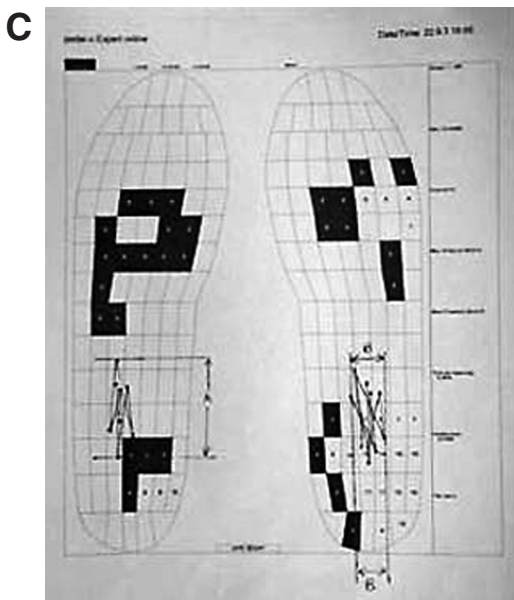
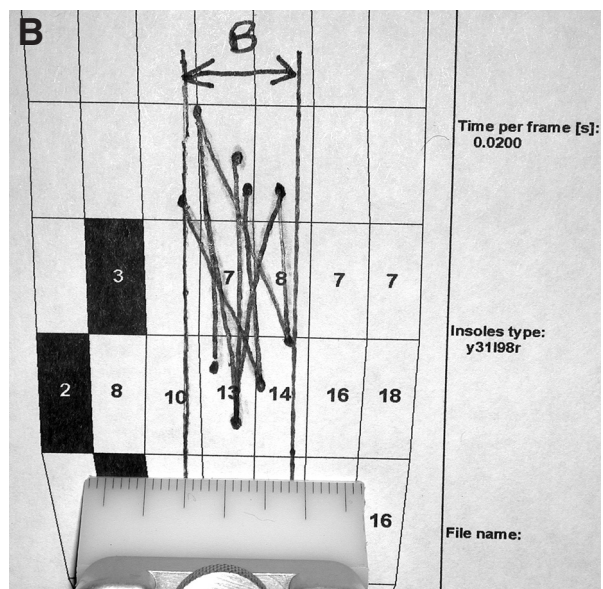
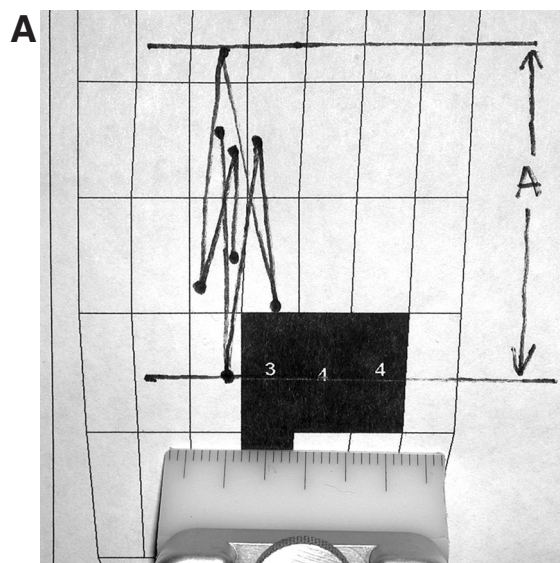
Ultimately, 41 patients were completely evaluated from an initial pool of 62. Of those not completing the study, 15 were lost to follow-up (ie, took the arch supports but never returned for follow-up visits), three could not fit the devices in their shoes, and three could not wear them because of discomfort immediately on dispensing. The mean age of the patients was 46.3 years (range, 26–69 years), with 29 women and 12 men. Two-way analysis of variance demonstrated

that there was no significant difference in the distribution of age, sex, or types of deformities between the two types of arch supports. Because the objective of this study was to determine the overall response to over-the-counter orthoses, and not to compare one device with the other, they were grouped together for all subsequent analyses.

## Evaluation of Pain

Patients were asked to evaluate their average and peak pain levels. Pain was rated by marking a visual analog scale. Patients could not view previously marked scales on subsequent 2- and 4-week visits. Each patient was asked to evaluate levels of back, hip, knee, and foot pain. Foot pain was further broken down into hallux valgus pain, toe pain, arch and heel pain, and “other” pain.

Responses were determined by measuring the distance between the zero point on the visual analog scale and the center of the mark made by the patient. Measurements were made with a digital micrometer accurate to 0.005 inches. A visual analog scale score of zero represented no pain, and a score of 10 represented the worst pain imaginable. Incremental differences were determined by using the micrometer process described. Measurements were repeated, and the mean was calculated. All of the measurements were performed by the same individual (A.L.) to ensure consistency. The mean and standard deviation



**Figure 4.** The center of pressure area is calculated by determining the length (A) and width (B) of the excursion area using a center of pressure map (C).

were calculated for all of the results. Values measured before dispensing of arch supports were compared with those calculated at 2 and 4 weeks. Data collected in this way formed matched pairs, and a *t* test was used to determine whether there was a statistically significant difference. *P* values were calculated, and statistical significance was considered to be present if  $P \leq .05$ . Based on the data collected, we found statistically significant improvements in hallux valgus pain, arch and heel pain, knee pain, and back pain. No statistically significant improvement was found in toe and hip pain. Detailed results are found in Table 2.

### Center of Pressure and Balance

All of the patients were evaluated with the Pedar system for alterations in balance. Patients were gently pushed off balance with the device described previously while standing on the Pedar sensors. This resulted in a footprint superimposed on a graphic display of center of pressure. Balance was evaluated by calculating the shift in center of pressure in the anteroposterior and mediolateral directions. A square was formed by the anterior- and posterior-most points and the medial- and lateral-most points. The area of the square was then measured with a digital micrometer. Smaller square areas represented a smaller shift in center of pressure, and greater square areas represented a larger shift in center of pressure. Center of pressure shifts were recorded with and without the patient standing on the arch support. Measurements were made in random orders, and in each case, each patient experienced a “test push” so that he or she would not be startled when the actual data were recorded. The inertia of the pendulum was a constant, but it was not scaled to account for the participant’s body mass.

Although the data indicate that mean stability improved with the arch supports, the difference was not significant ( $P > .05$ ). Table 3 shows that the right and left feet were analyzed individually and collectively.

**Table 2. Pain After Dispensing of Arch Supports**

	Average Pain			Peak Pain		
	Pretreatment	2 wk	4 wk	Pretreatment	2 wk	4 wk
<b>Back pain (n = 23)</b>						
Average	0.33	0.25	0.19	0.69	0.54	0.47
Standard deviation	0.21	0.22	0.22	0.23	0.34	0.35
P value		.06 <sup>a</sup>	.007 <sup>a</sup>		.03 <sup>a</sup>	.006 <sup>a</sup>
<b>Hip pain (n = 13)</b>						
Average	0.30	0.33	0.18	0.63	0.57	0.39
Standard deviation	0.22	0.19	0.18	0.33	0.29	0.34
P value		.72	.22		.59	.15
<b>Knee pain (n = 24)</b>						
Average	0.24	0.21	0.11	0.46	0.43	0.25
Standard deviation	0.15	0.15	0.15	0.28	0.33	0.28
P value		.57	.002 <sup>a</sup>		.70	.005 <sup>a</sup>
<b>Hallux valgus pain (n = 8)</b>						
Average	0.46	0.26	0.25	0.78	0.41	0.45
Standard deviation	0.25	0.33	0.30	0.15	0.41	0.33
P value		.10	.04 <sup>a</sup>		.06	.05 <sup>a</sup>
<b>Arch pain (n = 24)</b>						
Average	0.36	0.23	0.21	0.57	0.42	0.39
Standard deviation	0.20	0.18	0.19	0.27	0.31	0.28
P value		.003 <sup>a</sup>	.004 <sup>a</sup>		.009 <sup>a</sup>	.004 <sup>a</sup>
<b>Toe pain (n = 12)</b>						
Average	0.23	0.26	0.20	0.44	0.43	0.28
Standard deviation	0.26	0.27	0.29	0.38	0.35	0.29
P value		.69	.58		.96	.25

<sup>a</sup>Improvement in pain is statistically significant.

### Radiographic Changes in Position

Evaluation of radiographs taken with and without arch supports indicates that there is a measurable and statistically significant increase in arch height. Similarly, there is an increase in the calcaneal declination angle and the metatarsal declination angle. There is also a statistically significant decrease in the 1-2 intermetatarsal angle, which is indicative of decreased hallux valgus deformity. Changes in toe position were too difficult to measure. Due to the difficulty in measuring angular deformity of multiple overlapping toes on lateral radiographs, no statistical evaluation could be made for this portion of the study. Radiographic findings are summarized in Table 4.

Although the radiographic changes measured herein are reported to be statistically significant, we acknowledge that there is a parallax effect that may have an influence on outcome. Similarly, no power calculations have been performed, and this may also have an impact on the value of the statistical conclusions drawn herein.

### Discussion

The data collected herein demonstrate scientific support for the hypothesis that an over-the-counter arch support can reduce painful symptoms in the foot, knee, and back. It has long been believed that arch supports are instrumental in reducing heel and arch

**Table 3. Stability and COP Measurement Indicates the Area Circumscribed by COP in 41 Patients**

	Left Foot		Right Foot		Average	
	Without Support	With Support	Without Support	With Support	Without Support	With Support
Average area (mm <sup>2</sup> )	458.39	435.96	538.85	482.63	498.62	459.30
Standard deviation (mm <sup>2</sup> )	287.02	346.39	324.44	369.34	305.73	358.12
P value		.671		.137		.263

Abbreviation: COP, center of pressure.

Note: Improvement in stability is not statistically significant.

**Table 4. Radiographic Changes With and Without Arch Supports in 41 Patients**

	Left Foot			Right Foot			Average		
	Without Support	With Support	P Value	Without Support	With Support	P Value	Without Support	With Support	P Value
Average 1-2 intermetatarsal angle (°)	8.78	7.46	<b>.042</b>	9.64	8.53	.053	9.21	8.00	<b>.048</b>
Average hallux abductus angle (°)	16.54	15.93	.112	15.43	15.07	.32	15.99	15.50	.216
Average arch height (cm)	3.67	4.92	<b>.021</b>	3.41	4.69	<b>.019</b>	3.54	4.81	<b>.020</b>
Average first metatarsal declination angle (°)	24.03	27.21	<b>.046</b>	23.83	26.88	<b>.050</b>	25.62	27.05	<b>.048</b>
Average calcaneal inclination angle (°)	26.54	27.92	.19	25.71	28.82	<b>.047</b>	26.13	28.37	.119
Tibial sesamoid position	3.2	2.9	.14	2.8	2.7	.33	3.0	2.8	.24

Note: Values in boldface indicate statistical significance ( $P \leq .05$ ).

pain, and these data support this as well. Note that study patients were also permitted to take anti-inflammatory medications, and the effect that this may have on the pain data cannot be determined.

These data also support the belief that this improvement in symptoms is a result of changes in the bony position of the foot associated with using arch supports. However, the influence of parallax on these changes may obscure our ability to determine the exact degree of change affected.

The claim of increased stability seems to be supported but is not statistically significant. The positive trend showing stability coincides with anecdotal claims from those who wore the arch supports and indicated that they felt more stable when wearing them. The lack of statistical significance may be attributable to the relatively small sample pool (ie, study power too low), or could be a problem with the actual method of data collection. The push test used to disturb a person's balance may not actually reflect real-life tests. In particular, this is a quasistatic test and may not reflect the situation when individuals are walking with the arch supports in place. The measurement of stability by considering center of pressure shifts is novel for the evaluation of arch support and still needs independent evaluation to be considered a validated technique.

Symptomatic relief of common foot discomfort, such as arch pain, has previously been shown to respond to custom-molded arch supports; however, the current test demonstrates improvement with a non-custom device. Similarly, other types of nonorganic musculoskeletal aches and pains, particularly those related to the stress and shock waves associated with walking and running, seem to be improved with some types of footwear. Although we did not test for reduction of stress and shock, it has been previously re-

ported in the literature that shoe modification and arch supports may be useful for reducing these types of injuries and associated pain.<sup>9</sup> It is possible that this may explain why these patients reported relief from back pain.

Fit of the over-the-counter arch support is a critical element for the relief of pain and for achieving proper support. Although we strove for a best fit by making available a variety of sizes and two different styles of support, it is obvious that some people found the devices tested to be uncomfortable. There are many different styles, sizes, and levels of flexibility available with over-the-counter devices. Yet, even with this variety, feet are not perfectly symmetrical in appearance or in their need for support. In some cases, a custom device may still be the only solution to get proper fit.

Although we strove to control as many variables as possible, there are several points to consider when evaluating the data at hand. Regarding radiographic measurements of arch height, there is an inherent inaccuracy that occurs when comparing the study patient standing barefoot with the same patient standing with the orthosis in place. When the orthosis is placed under the heel, there is an elevation of the heel, which may create an apparent increase in arch height. It may also result in errors in angular measurements attributable to a parallax effect. As a gross estimate of the extent of the error, we measured the thickness of the thicker Arch Classic device in the heel region. The amount of heel lift associated with this orthosis would result in a heel elevation of 6 mm. Using a single example from one patient with a men's size 11 shoe, we found that the distance to the ball of the foot was approximately 180 mm and the distance to the navicular bone was 90 mm anterior to the central heel. Using simple geometry, this would create an

apparent elevation of the navicular bone of approximately 3 mm. Because the mean increase in arch height in this study was 13 mm, this represents a false elevation in the arch of approximately 23%.

Another potential inaccuracy revolves around the pendulum swing/instability portion of the study. More specifically, the inertia from the swinging pendulum may have had a proportionately greater effect on patients of smaller body mass. There are other aspects that may have created a bias in the data reported. Although the quantity of anti-inflammatory drugs used was recorded, this introduces a confounding factor when assessing the relief achieved as a direct result of the use of these orthoses. A much larger sample size would be necessary to separate the independent effects of these two variables on pain.

There was also no control for footwear, and it is possible that the interaction between shoes and the orthosis may have affected the therapeutic effects of the combination. Similarly, activity levels and the amount of time that the shoes and orthosis were worn may also have an undetermined effect on the outcome of this study.

## Conclusions

In this study, we attempted to prove that an over-the-counter arch support could reduce a variety of ailments that have been associated with foot function. The data collected consisted of subjective and objective measurements, including changes in bone position as measured by weightbearing radiographs and subjective assessment by patients regarding their symptoms. In addition, a new test was described that used shifts in center of pressure in each foot in response to a measured push on one shoulder.

Based on these results, we demonstrated that there was a statistically significant decrease in the 1-2 intermetatarsal angle and an increase in the metatarsal declination angle and arch height. No statistically significant improvements were found in toe position, hallux abductus angles, or calcaneal declination angles. These measurements collectively indicate that arch height is increased when an arch support is used.

There are some uncertainties in the radiographic measurements introduced by elevation of the heel when wearing an orthosis during radiography. Theoretically, this could create a parallax effect, which may create the illusion of a decreased 1-2 intermetatarsal angle or elevation of the medial arch. Although we believe that the extent of this effect is minimal, it cannot be absolutely determined using the existing data.

In this study, there were measurable changes in a variety of symptoms after initiation of arch support use. There was a statistically significant improvement in arch and back pain and a reduction in knee and hallux valgus pain after 4 weeks but not after 2 weeks. There was no statistically significant improvement in hip or toe pain and no improvement in knee and hallux valgus pain after 2 weeks.

The claims of increased balance associated with the use of arch supports was not statistically supported herein. However, there was a 10% improvement in balance, as demonstrated by a proportionate decrease in center of pressure shifts in response to a measured push of the shoulder of the patient.

In summary, we found that foot morphological features, stability, and painful symptoms can potentially be altered through the use of an over-the-counter arch support. Although no comparisons were made with custom-molded orthoses, we anticipate that future studies will show even greater benefits with these devices if tuned to the specific problems experienced by the study patient.

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