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AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2017;98:1752-62

ORIGINAL RESEARCH

Shoe Orthotics for the Treatment of Chronic Low Back Pain: A Randomized Controlled Trial

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Abstract

Objectives: To investigate the efficacy of shoe orthotics with and without chiropractic treatment for chronic low back pain compared with no treatment.

Design: Randomized controlled trial.

Setting: Integrative medicine teaching clinic at a university.

Participants: Adult subjects (N=225) with symptomatic low back pain of ≥3 months were recruited from a volunteer sample.

Interventions: Subjects were randomized into 1 of 3 treatment groups (shoe orthotic, plus, and waitlist groups). The shoe orthotic group received custom-made shoe orthotics. The plus group received custom-made orthotics plus chiropractic manipulation, hot or cold packs, and manual soft tissue massage. The waitlist group received no care.

Main Outcome Measures: The primary outcome measures were change in perceived back pain (numerical pain rating scale) and functional health status (Oswestry Disability Index) after 6 weeks of study participation. Outcomes were also assessed after 12 weeks and then after an additional 3, 6, and 12 months.

Results: After 6 weeks, all 3 groups demonstrated significant within-group improvement in average back pain, but only the shoe orthotic and plus groups had significant within-group improvement in function. When compared with the waitlist group, the shoe orthotic group demonstrated significantly greater improvements in pain ($P<.0001$) and function ($P=.0068$). The addition of chiropractic to orthotics treatment demonstrated significantly greater improvements in function ($P=.0278$) when compared with orthotics alone, but no significant difference in pain ($P=.3431$). Group differences at 12 weeks and later were not significant.

Conclusions: Six weeks of prescription shoe orthotics significantly improved back pain and dysfunction compared with no treatment. The addition of chiropractic care led to higher improvements in function.

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Low back pain (LBP) is a steadily increasing global epidemic. Approximately 25% of the U.S. adult population experiences LBP during a 3-month time period, and nearly double experience back pain over the course of a year.[1] Johannes et al[2] estimated the point prevalence of chronic low back pain (CLBP) to be nearly 31% (95% confidence interval, 29.8−31.7).

Podiatrists have connected the use of foot orthoses for the relief of LBP with the thought that back pain may be related to a disruption in the kinetic chain.[3-5] However, it was not until the last decade that other investigators have begun to study the effect of foot function on the kinematics of the knee, hip, pelvis, and thorax.[6-10] Rothbart et al[11] argues that forefoot varum (forcing the foot into hyperpronation) is a leading cause of pelvic repositioning and mechanical LBP. Khamis and Yizhar,[7] and Pinto et al,[8] found that induced hyperpronation of the foot (measured via calcaneal eversion) in healthy subjects had a significant effect on pelvic

Supported by the Foot Levelers, Inc, Roanoke, VA.

The funding sponsor had no involvement in study design, data collection, analysis and interpretation, writing of the manuscript, or decision to submit for publication.

Clinical Trial Registration No.: NCT02089750.

Disclosures: Duarte received monetary payment from Foot Levelers, Inc, during the course of this study to teach unrelated courses in rehabilitation, orthopedics, and sports medicine. He was not involved in randomization or treatment of any study subject. The other authors have nothing to disclose.

http://dx.doi.org/10.1016/j.apmr.2017.03.028

alignment. Although these studies are all pilot projects containing <60 subjects, all results significantly conclude that foot dysfunction should not be overlooked as a potential contributing factor in treating individuals with LBP and dysfunction.

Integrative care is also seen as an alternative for back pain. Lind et al[12] found that individuals with LBP used conventional therapy (45%), complementary and alternative medicine (43%), or both (12%) for their pain. Chiropractic care was the most common form of integrative care used (33%).[12] Interestingly, 72.1% of chiropractors combine spinal manipulation with custom-made shoe orthotics for the treatment of pain.[13] Several recent literature reviews indicate that there are no high-quality clinical trials evaluating the effectiveness of shoe orthotics for the treatment of LBP.[14,15]

Therefore, the purpose of this randomized controlled trial was to determine the change in perceived pain levels and functional health status in patients with CLBP at the end of 6 weeks of shoe orthotic treatment alone or orthotics plus chiropractic treatment (plus group) as compared with no treatment (waitlist group). We hypothesized that shoe orthotics alone would be significantly better than no treatment for LBP and disability, and that shoe orthotics plus chiropractic treatment would be significantly better than shoe orthotics alone.

Methods

In this randomized controlled trial, 225 subjects with CLBP were randomized to 1 of 3 groups: Foot Levelers shoe orthotic, plus, or waitlist. Pain and disability were measured at baseline and at the end of 6 weeks of care or no care. An institutional review board approved the trial, and the trial was registered on clinicaltrials.gov. All patients provided written informed consent prior to study entry.

Participants

Individuals with CLBP were recruited through media advertising in a Midwestern suburban region of the United States beginning Spring 2014 through early Fall 2015 (JA Cambron, JM Dexheimer, LN Zoufal, unpublished data, 2017). Subjects were telephone screened for basic inclusion/exclusion criteria (appendix 1).

Clinic visits

Subjects who were eligible at the telephone screen were invited to attend a baseline examination visit. On arrival at the baseline examination visit, subjects were asked to complete self-administered questionnaires, provide informed consent, and undergo medical history and low back examination by a licensed chiropractic clinician or trained intern to verify the physical inclusion and exclusion criteria (see appendix 1).

All eligible and interested subjects then underwent an orthotic assessment including a standing static evaluation of posture (Foot Posture Index)[16] and foot pressure mapping (3D BodyView Imaging Unit[a]). Images of the bottom of the foot were quantified based on a color replacement algorithm,[a] which was used to calculate the Staheli index, Chippaux-Smirak index, arch angle, and arch index.

Once the orthotics returned from production, the subject was scheduled for the randomization visit. During the randomization visit, the patient was randomized and the clinician/intern discussed procedures for proper use of orthotics with those in the Foot Levelers shoe orthotic or plus groups and reminded those in the waitlist group that she/he would receive orthotics at the week 6 visit. Those randomized to the Plus Group immediately began chiropractic treatment.

Subjects were asked to return for a week 12 follow-up visit to check-in with the physician and complete questionnaires.

List of abbreviations:

CLBP	**chronic low back pain**
LBP	**low back pain**
MCID	**minimal clinically important difference**
ODI	**Oswestry Disability Index**

Randomization process

Prior to study initiation, a randomization scheme was created by a research fellow not associated with this trial. Randomization was based on a random numbers table with each random allocation being placed in consecutively numbered, sealed manila envelopes.

Interventions

Foot Levelers shoe orthotic group

Seventy-five of the 225 participating subjects were randomized into the Foot Levelers shoe orthotic group and received 2 pairs of custom-made leather shoe orthotics containing supports for the medial longitudinal, lateral longitudinal, and anterior transverse arches (Moderate Luxury Full Length and the Tight Fitting Luxury $^{3}/_{4}$ Length dress models[a]). The materials used in construction of the orthotics were specific to the gait cycle and included a shock absorbing polymer placed in the heel to assist during heel strike (Zorbacel[a]), a stiffer polymer for support in mid-stance (StanceGuard[b]), and a springy polymer in the forefoot of the orthotic to assist in toe-off (Propacel[a]). The size and shape of the orthotic supports were made based on the height and weight of the patient related to the foot scan and measurements taken. Additional modifications to orthotics were made on a case-by-case basis, dependent on patient presentation and/or comfort level post−break-in period.

Some evidence exists suggesting a 1- to 2-week break-in or acclimation period with orthotic use for foot and ankle dysfunction[17,18]; however, little is known about acclimation for patients with LBP. Instructions regarding the break-in period (approximately 2−3wk) were provided, including informing the subjects to gradually increase the amount of time the orthotics were worn and disclosing there may be a slight increase or change in symptoms while the body acclimates to the orthotics.

Plus group

Seventy-five of the 225 participating subjects were randomized into the plus group. These subjects also received 2 pairs of custom-made shoe orthotics, in addition to 6 weeks of chiropractic treatment for 1 to 4 visits per week. The chiropractic care could include treatment of the cervical, thoracic, and/or lumbar spine, and the lower extremities for the LBP complaint. Specific therapies allowed in this study included hot/cold packs, brief manual massage, or chiropractic manipulations, including high-velocity, low-amplitude manipulation and/or flexion-distraction therapy.

These chiropractic techniques along with the ancillary care have been widely used in practice and in clinical studies. Many studies have investigated the use of high-velocity, low-amplitude

manipulation[19-26] and flexion-distraction therapy[27-40] for the treatment of CLBP,[19-26] which are among the most common types of chiropractic manipulations used in practice[13] and are considered to be established treatments based on practice guidelines.[41] The decisions regarding the type(s) of care to use were made by 7 different licensed chiropractic physicians with at least 3 years of clinical experience, and all manipulations were administered by those physicians, whereas initial intake and ancillary care could have been provided by an intern.

In practice, the amount of care a patient receives may vary based on pain severity and chronicity. According to research, most chiropractic cases resolve within 6 weeks of intervention[41] and include 2 to 3 weekly visits[42] for a total of 5 to 18 visits.[19-40,43] In 1 study on high-velocity, low-amplitude manipulation for LBP, clinical and statistical improvements for CLBP were more likely with 3 to 4 chiropractic treatments per week rather than 1 to 2 times.[25] Therefore, in this study, plus group subjects were asked to complete 1 to 4 visits per week for each of the 6 weeks of chiropractic care for a range of 6 to 24 visits total.

Waitlist group

The remaining study participants were randomized to a 6-week wait period, after which they were also given the same 2 pairs of Foot Levelers custom-made shoe orthotics. Subjects were not excluded from the study for treatment outside of the study parameters, but such treatment was discouraged and documented.

Patient safety

Patients completed biweekly questionnaires to assess pain level, disability, and the use, comfort, and effects of the shoe orthotics. If the patient mentioned any side-effects from care, the clinician was notified and the patient was reexamined if necessary. No patient in the study experienced any adverse event.

Outcome measures

All assessments were collected either in the traditional paper format or online through SurveyMonkey,[c] a secure online web-based service. The primary outcome measures in this study were the average LBP level measured by the numerical pain rating scale and low back disability measured by the Oswestry Disability Index (ODI) at baseline, 6 weeks, 12 weeks, and after an additional 3, 6, and 12 months.

The numerical pain rating scale includes numbers from 0 to 10, wherein the patient selects the number that best describes the LBP during a specified time period. Four separate scales were measured: LBP level now, typical or average pain level in the last 2 weeks, pain level at its best in the last 2 weeks, and pain level at its worst in the last 2 weeks.

The numerical pain rating scale is one of the most frequently used methods for the measurement of clinical pain. Although the numerical pain rating scale has been previously assessed for validity and reliability, only 1 study has attempted to characterize its responsiveness in patients with LBP.[44] Although previous pain research has shown the use of a composite mean of the now, average, and worst scores,[45] newer research indicates that composite measures of pain are not statistically better than individual pain ratings, specifically for studies assessing change in pain with group comparisons and large samples.[46] Therefore, the typical or average pain over the last 2 weeks was used as our primary outcome measure.

One of most commonly used measurements in the literature for low back disability, particularly in studies involving orthotics, is the ODI,[47-52] a condition-specific questionnaire covering 10 areas of daily living. The measured areas include pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling. Each category is scored on a continuum from 0 to 5 points, for a possible total score of 50, described as 100% disability. Validity measures of the ODI have demonstrated Pearson correlation coefficients between .76 and .99,[48,53,54] and reliability measures have demonstrated an intraclass correlation coefficient of .83 for test-retest reliability.[54]

To better assess treatment effect and adherence to care, consistency/frequency of orthotic use (number of days and number of hours worn), symptoms experienced during use, comfort levels, and other health care utilization for LBP were collected every 2 weeks of participation via self-report survey by the participant. Adherence to care was defined as at least 1 chiropractic treatment per week for 6 weeks (plus group) and at least 8 days of orthotic wear time every 2 weeks post−break-in period (Foot Levelers shoe orthotic group and plus group). No participant was excluded for noncompliance.

Data collection through 6 weeks was completed for all participants by mid-October 2015.

As secondary outcome measures, the numerical pain rating scale for average LBP and ODI measures were also collected at a week 12 follow-up visit and again via mail or online 3, 6, and 12 months after the date of that final visit.

Blinding

Because of the nature of the study, neither subjects nor research personnel were blind to the treatment group allocations.

Statistical analysis

The sample size for this study was calculated for a 2-sided independent samples t test with type I error rate of $\alpha = .05$. Samples of 64 per group would provide 80% power to detect a medium effect size. Effect size is calculated as the difference in the means divided by the SD of the difference, where 0.5 is considered a medium effect and 0.8 is considered a large effect. The previous pilot study demonstrated a large effect size.[50] Calculating for a medium effect size is more conservative, but increases the likelihood of detecting meaningful differences in the study. Correcting for a potential of <20% withdrawal rate, the sample size of 75 subjects per group was set.

Minimal clinically important difference (MCID) scores of at least 30% change from baseline were statistically assessed[55] by group through secondary chi-square analyses ($df = 2$).

Patients were analyzed according to their randomly assigned treatment (intention-to-treat analysis), regardless of whether or not they received the full treatment or were lost to follow-up.

Baseline characteristics were summarized with basic descriptive statistics and stratified by treatment group. Tables and analyses include imputed week 6 data (taken from week 4 when no week 6 survey was completed); therefore, sample sizes may be different then numbers reported in figure 1. Baseline differences by treatment were tested using 1-way analysis of variance or chi-square tests (table 1). Each within-group mean change score was tested at each follow-up point against zero using paired t tests, a 95% confidence interval was calculated for each mean change score, and means were compared across the 3 groups at each time point using 1-way analysis of variance (tables 2 and 3). Multiple linear regression was

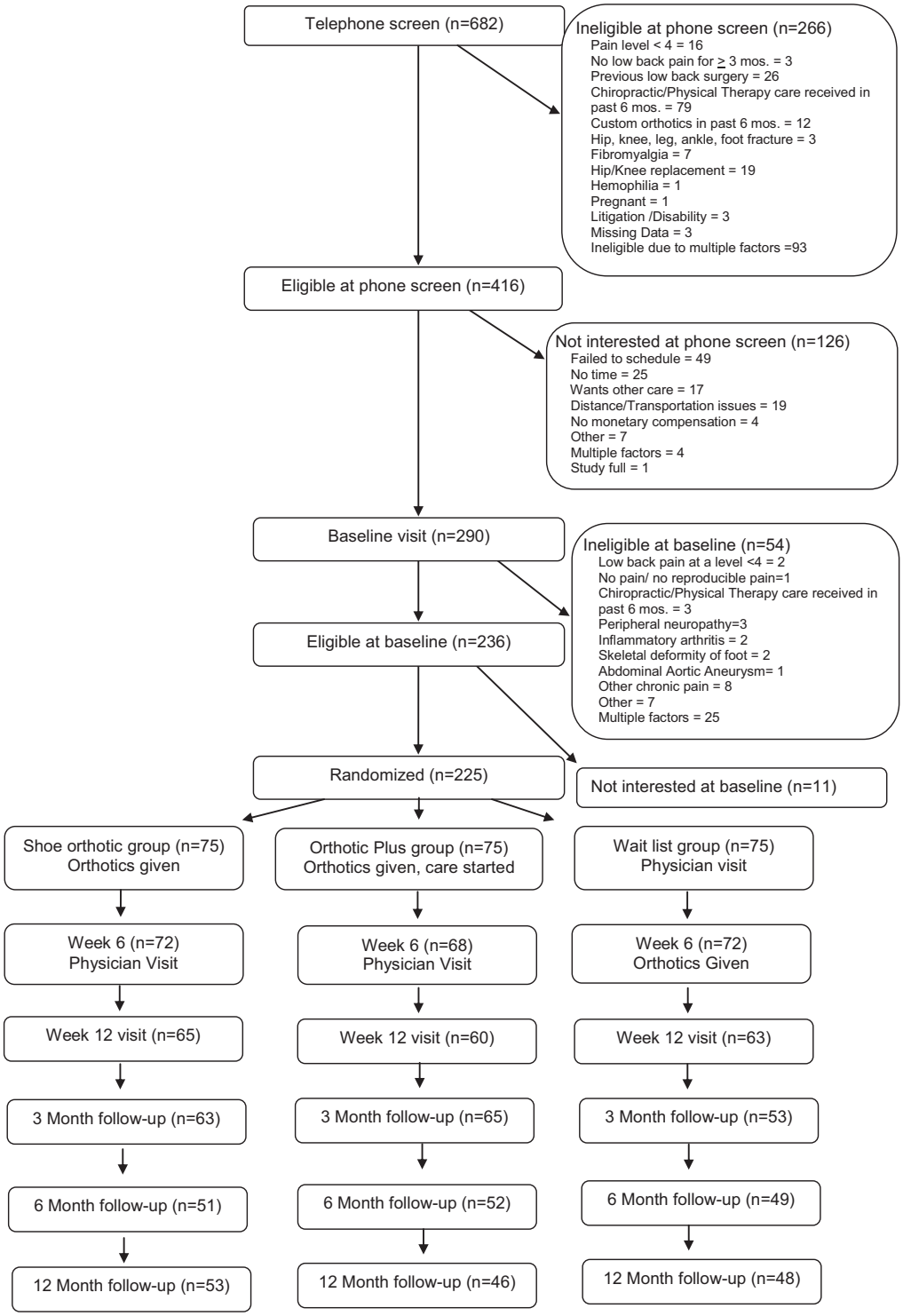

Fig 1 Flowchart of the participants. Abbreviation: DC/PT, Chiropractic or physical therapy.

used to test for treatment effects on change scores at each time point, adjusting for baseline outcome values (table 4).

Results

A total of 682 people underwent the telephone screen, and 416 were eligible. Of those, 290 presented for the baseline visit, and 225 subjects were randomized (see fig 1). There was no evidence of significant differences across treatments for any baseline characteristics (see table 1).

The most common types of chiropractic therapies administered to plus group participants included brief manual massage (77.6%); thoracic and sacroiliac high-velocity, low-amplitude manipulation (45.8% and 58.3% respectively); and flexion-distraction mobilization (54.6%) (table 5). Most study participants were compliant

Table 1 Baseline characteristics of the randomized subjects

Characteristics	Foot Levelers Shoe Orthotic Group (n=75)	Waitlist Group (n=75)	Plus Group (n=75)	P*
Men	45	40	43	.8041
Married	60	62 (n=74)	59 (n=71)	.9292
White	65	76	72	.3464
Some college	89	83	85 (n=74)	.4987
Employed	71	77	73	.6463
Age (y)	52±15	53±15	50±17	.4645
Range	18–86	22–85	19–84	
Any hip, knee, leg, ankle, or foot pain in the last 2wk	81	81	83	.9706
Back pain began suddenly (vs. gradually)	32	20	21	.1726
Years of back pain	9.6±10.0	10.0±9.0	9.5±9.6	.9445
Range	0.2–50	0.25–34	0.25–54	
Back pain is constant (vs. intermittent)	52	51	53	.9480
Level of back pain right now from 0–10	4.2±2.1	4.3±2.0	4.0±2.0	.7821
Range	0–9	0–8	0–8	
Typical or average level of back pain last 2wk	5.5±1.8	5.6±1.7	5.7±1.9	.8770
Range	1–9	2–10	1–10	
Back pain at its best during the last 2wk	2.8±1.9	2.8±1.8	3.0±1.9	.7680
Range	0–9	0–7	0–9	
Back pain at its worst during the last 2wk	7.4±1.5	7.5±1.7	7.3±2.1	.8610
Range	4–10	3–10	0–10	
Quadruple numerical rating scale	48.0±14.8	48.5±15.3	47.8±16.4	.9647
Range	16.7–86.7	13.3–83.3	6.7–83.3	
ODI total score out of 50	12.6±6.1	12.4±5.6	13.3±7.4	.7039
Range	2–32	2–29	2–38	

NOTE. Values are mean ± SD, percentages, or as otherwise indicated.

* *P* value from 2 *df* chi-square test for categorical variables and 2 *df* 1-way analysis of variance for continuous variables, testing null hypothesis: all 3 groups are equal.

with treatment. In the plus group, 86.7% of participants were compliant with chiropractic care and 96.8% were compliant with orthotic use. In the Foot Levelers shoe orthotic group, 92.5% were compliant with orthotic use. By the end of week 6, the plus and Foot Levelers shoe orthotic group participants wore the orthotics an average of 11.9 and 12.9 days, respectively, over a 2-week period. Number of hours worn daily may have impacted the overall study result, but seemingly increased after the break-in period (table 6).

After 6 weeks, average LBP decreased significantly in all 3 groups (see table 2 and fig 2), demonstrating <1-point improvement in the waitlist group, but 1.9- and 2.3-point improvements in the Foot Levelers shoe orthotic and plus groups, respectively. Decreases in pain from baseline remain significant in all 3 groups for all time points up to 12 months. The between-group assessment of average pain demonstrated no significant differences at baseline, but a significant difference in week 6 average pain scores ($P<.0001$) and in change scores between groups ($P<.0001$). The within-group change scores from baseline to every follow-up through 12 months were statistically significant. However, there were no significant between-group differences at week 12 or later.

Within-group disability scores were significantly improved in the Foot Levelers shoe orthotic and plus groups after 6 weeks of care, with an average of 2.3- and 4.3-point improvements in the 2 groups, respectively (see table 3 and fig 3). However, the within-group scores were not significantly different pre-post waitlist group. The mean ODI scores did not differ across the 3 treatments at baseline ($P=.7039$), but at week 6 the mean scores varied across treatments ($P=.0146$), and there was strong evidence that the mean change scores varied with treatment ($P<.0001$). Improvements across time remained significant up to 12 months in all 3 groups. There is some evidence of a difference in mean change between treatments at 3 months after the 12-week point ($P=.0231$), with less improvement in the waitlist group. Mean change is not different between groups at 12 weeks, or at 6 or 12 months later.

Adjusted for baseline values (see table 4), there was a significantly higher improvement in the Foot Levelers shoe orthotic group compared with the waitlist group for both outcomes ($P<.0001$ for average pain, $P=.0068$ for the ODI). The addition of chiropractic care to the orthotic treatment demonstrated better outcomes than orthotic care alone, with the contrast being statistically significant for the ODI ($P=.0278$) but not for average pain ($P=.3431$). Changes were not significantly different between groups at later time points for either outcome.

The MCID (proportions of patients with ≥30% improvement in pain or disability) is summarized and compared across treatment groups in tables 7 and 8. The 3 groups are significantly different at 6 weeks ($P<.0001$ for both pain and disability). Similar to results for continuous change scores, the best results were in the plus group, in which 70% had a decrease in pain and 56% a decrease in disability of ≥30% compared with baseline, followed by 58% and 38% in the Foot Levelers shoe orthotic group and only 22% and 20% in the waitlist group, respectively. When comparing only the Foot Levelers shoe orthotic group and the waitlist group at 6 weeks, the Foot Levelers shoe orthotic group is significantly better than the waitlist group ($P=.0174$ for

Table 2 Change in average NPRS (out of 10)

	Waitlist Group		Foot Levelers Shoe Orthotic Group		Plus Group		
NPRS	Mean ± SD (95% CI)	*P** Intragroup	Mean ± SD (95% CI)	*P** Intragroup	Mean ± SD (95% CI)	*P** Intragroup	*P*† Intergroup
BL	5.6±1.7 (5.2 to 6.0)		5.5±1.8 (5.1 to 5.9)		5.7±1.8 (5.2 to 6.1)		.8770
W6	4.9±1.8 (4.5 to 5.3)		3.6±2.0 (3.1 to 4.0)		3.4±2.1 (2.9 to 3.9)		<.0001
W6-BL change	−0.7±1.8 (−1.1 to −0.3)	.0012	−1.9±2.2 (−2.4 to −1.4)	<.0001	−2.3±2.3 (−2.9 to −1.8)	<.0001	<.0001
W12	3.5±1.8 (3.0 to 3.9)		3.2±1.9 (2.7 to 3.6)		3.2±2.2 (2.7 to 3.8)		.6829
W12-BL change	−2.2±1.9 (−2.7 to −1.8)	<.0001	−2.4±2.3 (−2.9 to −1.8)	<.0001	−2.5±2.5 (−3.2 to −1.9)	<.0001	.7650
3M	3.3±2.0 (2.7 to 3.9)		3.3±2.3 (2.8 to 3.9)		3.2±2.2 (2.6 to 3.8)		.9581
3M-BL change	−2.2±2.3 (−2.9 to −1.6)	<.0001	−2.2±2.6 (−2.8 to −1.5)	<.0001	−2.4±2.7 (−3.2 to −1.7)	<.0001	.8442
6M	3.8±2.2 (3.1 to 4.4)		3.2±2.5 (2.4 to 3.9)		3.4±2.6 (2.6 to 4.1)		.4157
6M-BL change	−1.9±2.6 (−2.6 to −1.2)	<.0001	−2.4±2.5 (−3.1 to −1.7)	<.0001	−2.3±3.3 (−3.2 to −1.4)	<.0001	.6498
12M	3.5±2.2 (2.8 to 4.1)		2.8±2.2 (2.2 to 3.4)		3.0±2.3 (2.3 to 3.6)		.2940
12M-BL change	−2.2±2.7 (−3.0 to −1.4)	<.0001	−2.5±2.6 (−3.2 to −1.8)	<.0001	−2.6±2.6 (−3.4 to −1.8)	<.0001	.7543

Abbreviations: 3M, 3 months; 6M, 6 months; 12M, 12 months; BL, baseline; CI, confidence interval; NPRS, numerical pain rating scale; W6, week 6; W12, week 12.

* Paired *t* test of mean change against zero.

† One-way analysis of variance with 2 *df*.

Table 3 Change in ODI (out of 50) from baseline to week 6

	Waitlist Group		Foot Levelers Shoe Orthotic Group		Plus Group		
ODI	Mean ± SD (95% CI)	*P** Intragroup	Mean ± SD (95% CI)	*P** Intragroup	Mean ± SD (95% CI)	*P** Intragroup	*P*† Intergroup
BL	12.4±5.6 (11.1 to 13.7)		12.6±6.1 (11.2 to 14.0)		13.2±7.3 (11.6 to 14.9)		.7039
W6	12.4±7.3 (10.7 to 14.1)		9.9±7.3 (8.2 to 11.6)		8.9±6.9 (7.3 to 10.6)		.0146
W6-BL change	−0.05±4.8 (−1.2 to 1.1)	.9230	−2.3±5.0 (−3.4 to −1.1)	.0002	−4.3±5.5 (−5.6 to −3.0)	<.0001	<.0001
W12	9.6±6.3 (8.0 to 11.3)		8.8±7.4 (7.0 to 10.7)		8.4±7.2 (6.5 to 10.2)		.6047
W12-BL change	−3.1±5.2 (−4.4 to −1.8)	<.0001	−3.6±5.4 (−4.9 to −2.3)	<.0001	−4.7±5.9 (−6.3 to −3.2)	<.0001	.2543
3M	9.8±7.2 (7.8 to 11.8)		8.6±8.1 (6.6 to 10.7)		7.7±6.6 (5.9 to 9.5)		.3384
3M-BL change	−2.1±6.2 (−3.8 to −0.4)	.0189	−3.5±5.4 (−4.9 to −2.2)	<.0001	−5.4±6.7 (−7.2 to −3.5)	<.0001	.0231
6M	8.9±7.6 (6.7 to 11.1)		9.0±9.3 (6.4 to 11.6)		9.0±8.6 (6.6 to 11.4)		.9975
6M-BL change	−3.4±7.1 (−5.4 to −1.4)	.0016	−3.5±5.7 (−5.1 to −1.9)	<.0001	−4.8±6.8 (−6.7 to −2.9)	<.0001	.4827
12M	9.0±8.1 (6.7 to 11.4)		8.1±8.0 (5.9 to 10.3)		8.3±7.7 (6.0 to 10.5)		.8274
12M-BL change	−2.9±8.4 (−5.4 to −0.5)	.0192	−3.7±5.6 (−5.3 to −2.2)	<.0001	−4.9±6.9 (−7.0 to −2.9)	<.0001	.3915

Abbreviations: 3M, 3 months; 6M, 6 months; 12M, 12 months; BL, baseline; CI, confidence interval; W6, week 6; W12, week 12.

* Paired *t* test of mean change against zero.

† One-way analysis of variance with 2 *df*.

Table 4 Between-group differences in disability (ODI) (out of 50) and average pain (NPRS) (out of 10)

	NPRS			ODI		
NPRS/ODI	Difference* (95% CI)	SE	$P^{\dagger}$	Difference* (95% CI)	SE	$P^{\dagger}$
Change at W6						
Waitlist group	1.3 (0.7 to 1.9)	0.3	<.0001‡	2.3 (0.6 to 3.9)	0.8	.0068‡
Plus group	−0.3 (−0.9 to 0.3)	0.3	.3431	−1.9 (−3.5 to −0.2)	0.8	.0278‡
Change at W12						
Waitlist group	0.2	0.3	.4655	0.6	0.9	.5355
Plus group	−0.004	0.3	.9902	−0.9	0.9	.3204
Change at 3M§						
Waitlist group	−0.04	0.4	.9269	1.4	1.1	.2197
Plus group	−0.1	0.4	.7073	−1.6	1.1	.1450
Change at 6M§						
Waitlist group	0.6	0.5	.2150	0.04	1.3	.9731
Plus group	0.2	0.5	.7152	−1.1	1.3	.3847
Change at 12M§						
Waitlist group	0.6	0.4	.1725	0.8	1.3	.5282
Plus group	0.1	0.4	.8145	−0.7	1.3	.5910

NOTE. Positive values indicate a higher level of pain or disability. Foot Levelers shoe orthotic group is the reference for all models.
Abbreviations: 3M, 3 months; 6M, 6 months; 12M, 12 months; CI, confidence interval; NPRS, numerical pain rating scale; W6, week 6; W12, week 12.
* Contrast to reference group, adjusted for baseline values.
† Student *t* test of estimated regression coefficient against zero, $df=1$.
‡ $p<0.05$.
§ Follow-up begins 3 months after week 12 visit.

Table 5 Chiropractic therapies used during plus group participant visits (n=703)*

Chiropractic therapies used	%
Cold packs	
Cervical	0.0
Thoracic	0.0
Lumbar	0.06
Lower extremity	0.0
Hot packs	
Cervical	4.7
Thoracic	24.7
Lumbar	28.3
Lower extremity	0.01
Brief manual massage	
Cervical	4.4
Thoracic	24.5
Lumbar	38.3
Lower extremity	10.4
HVLA manipulation(s)	
Cervical spine	8.2
Thoracic spine	45.8
Lumbar spine	24.9
Sacroiliac joint	58.3
Knee	0.01
Ankle	1.1
Foot	0.07
Flexion distraction	
Rhythmic traction	23.3
Automated long axial distraction	30.6
Mobilization	54.6

Abbreviation: HVLA, high-velocity, low-amplitude manipulation.
* Percentages may be higher because >1 treatment may have been administered per visit.

pain and $P<.0001$ for disability). Compared with the Foot Levelers shoe orthotic group, the addition of chiropractic care in the plus group demonstrates a significant improvement in pain ($P=.0312$) but not disability ($P=.1383$).

Discussion

To our knowledge, this is the first large-scale clinical trial assessing orthotics for treatment of LBP. As hypothesized, LBP and dysfunction were significantly improved with custom-made shoe orthotics compared with a waitlist group, and disability was more significantly improved with the addition of chiropractic care. However, scores were not significantly different between the Foot Levelers shoe orthotic group and plus group. This lack of difference is difficult to understand; however, a floor effect may have come into play with the pain measures. Future research may want to focus on the difference in pain scores for patients with higher baseline levels of pain.

The MCID data in this study mirrored the change score data in that there were significant group differences for pain and disability at week 6. The effect of care was no longer significantly different between groups after this time point; however, after week 6, all treatment groups were provided with orthotics so it is not surprising that differences in group effects were negligible. It is noteworthy that for most time points after week 6, the MCID data remained relatively stable, with no large decreases in the proportion of subjects who had at least 30% improvement in pain or disability compared with baseline, potentially demonstrating a lasting effect of care with the orthotic treatment.

There are several small-scale or lower-quality studies investigating the use of shoe orthotics for the treatment of LBP demonstrating mixed results.[11,50-52,56-60] Likewise, the studies that included chiropractic care along with shoe orthotics demonstrated

Table 6 Percent of subjects using orthotics on a daily basis

Week No.	Hours of Orthotic Use	Foot Levelers Shoe Group n	Foot Levelers Shoe Group %	Plus Group n	Plus Group %
Week 2	0	0	0.0	0	0.0
	1–3	10	14.1	9	13.4
	4–7	27	38.0	20	29.8
	8–12	31	43.7	32	47.8
	>12	3	4.2	6	9.0
	Total	71	100	67	100
Week 4	0	1	1.4	0	0.0
	1–3	4	5.6	4	5.9
	4–7	28	39.4	16	23.5
	8–12	31	43.7	42	61.8
	>12	4	9.9	6	8.8
	Total	68	100	68	100
Week 6	0	2	3.0	1	1.6
	1–3	3	4.5	5	7.9
	4–7	19	28.4	11	17.5
	8–12	36	53.7	38	60.3
	>12	7	10.4	8	12.7
	Total	67	100	63	100

trends toward improvement of LBP and/or lower extremity symptoms[61-64]; however, there was some variability in outcomes.

One small-scale study assessed an orthotics group, orthotics plus chiropractic group, and a no treatment group. This study demonstrated that chiropractic plus shoe orthotics improved foot and ankle symptoms, activities of daily living, sport and recreation, and quality of life in workers with LBP whose job required them to stand at least 6 hours daily[63]; however, there was no significant benefit in reducing pain levels in any of the groups compared with baseline. Inconsistency of orthotic use was described as potentially confounding the study results. Our study did measure frequency of use of the orthotic and found that participants were compliant with orthotic wear throughout the study, which most likely improved the reliability of our results. We also calculated between-group differences to determine group effects.

A similar small-scale study compared chiropractic plus orthotics versus chiropractic plus sham orthotics.[64] The results demonstrated that both groups improved, but there were no

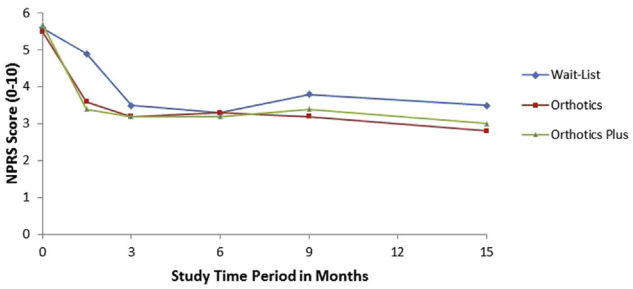

Fig 2 Mean NPRS scores from baseline through 12-month follow-up. Follow-up data were collected 3, 6, and 12 months after the week 12 visit (reflected as 6, 9, and 15 months). Abbreviation: NPRS, numerical pain rating scale.

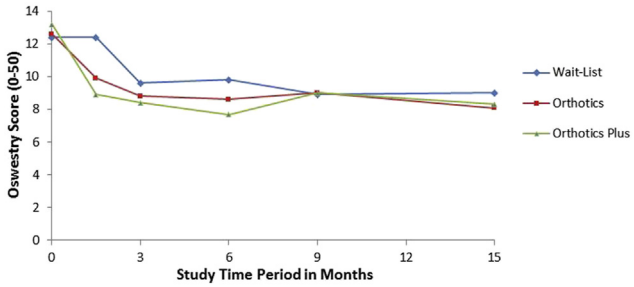

Fig 3 Mean ODI scores from baseline through 12-month follow-up. Follow-up data were collected 3, 6, and 12 months after the week 12 visit (reflected as 6, 9, and 15 months).

significant differences between the groups in terms of pain or disability, indicating that the orthotics did not add to the treatment benefit. The authors in this study commented that future trials should include subjects who wear orthotics in a weight-bearing capacity each day because lack of such wear may have affected their outcomes. Our study included subjects who were manual and nonmanual laborers, but we did not measure the amount of standing on a daily basis to compare findings.

A previous feasibility study by this research group[50] demonstrated changes in CLBP and disability with the use of shoe orthotics for 6 weeks compared with a waitlist control group. This prior study demonstrated results similar to the current large-scale study.

Of note is that none of the 3 previous studies[50,63,64] assessed MCID scores in their analyses; therefore, the results cannot be fully compared with our current findings regarding MCID.

Study limitations

There were possible study limitations present in this clinical trial. First, our subjects were diagnosed with several low back conditions, and some diagnoses may respond better to shoe orthotics and/or chiropractic care than others. Subjects and clinicians were aware of the group assignment, possibly affecting the care rendered and the self-report outcomes of pain and disability. Finally, the natural history of LBP and other psychological and/or

Table 7 Proportion of patients with MCID of ≥30% decrease in pain (numerical pain rating scale) from baseline

MCID	Waitlist Group (n=75) n/N	Waitlist Group (n=75) %	Foot Levelers Shoe Orthotic Group (n=75) n/N	Foot Levelers Shoe Orthotic Group (n=75) %	Plus Group (n=75) n/N	Plus Group (n=75) %	P*
Week 6	16/74	21.6	42/73	57.5	48/69	69.6	<.0001
Week 12	33/63	52.4	44/65	67.7	38/60	63.3	.1891
Month 3	32/53	60.4	37/63	58.7	36/55	65.4	.7429
Month 6	24/49	49.0	37/51	72.5	32/52	61.5	.0537
Month 12	26/48	54.2	33/53	62.3	28/46	60.9	.6830

* Chi-square test $df=2$.

Table 8 Proportion of patients MCID of with ≥30% decrease in disability (ODI) from baseline

	Waitlist Group (n=75)		Foot Levelers Shoe Orthotic Group (n=75)		Plus Group (n=75)		
MCID	n/N	%	n/N	%	n/N	%	*P**
Week 6	15/74	20.3	28/73	38.4	39/69	56.5	<.0001
Week 12	25/61	41.0	33/64	51.6	37/60	61.7	.0750
Month 3	23/52	44.2	33/63	52.4	32/55	58.2	.3502
Month 6	26/49	53.1	29/51	56.9	32/51	62.7	.6134
Month 12	24/48	50.0	30/53	56.6	26/46	56.5	.7551

* Chi-square test $df=2$.

physiological events may have led to changes in pain over time, for which we had no control.

Conclusions

This large-scale clinical trial demonstrated that LBP and disability were significantly improved after 6 weeks of Foot Levelers shoe orthotics care compared with a waitlist group, and that the addition of chiropractic care with the orthotics demonstrated a significant improvement in the disability scores compared with orthotics alone. The within-group change scores from baseline to every follow-up through 12 months were statistically significant. However, there were no significant between-group differences at week 12 or later.

Suppliers

a. Foot Levelers, Inc.
b. StanceGuard; Stance Healthcare.
c. SurveyMonkey; SurveyMonkey.

Keywords

Chiropractic; Low back pain; Orthotic devices; Rehabilitation; Shoes

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Acknowledgments

We thank the university administrators, clinicians, interns, and research assistants who helped with this clinical trial.

Appendix 1 Exclusion criteria

1. Use of custom-made orthotics in the last 6mo.
2. Ongoing active conservative care (eg, physical therapy, chiropractic care) for the low back, leg, or foot received in the last 6 months (excluding the use of oral medications or daily at-home exercises for general well-being) to prevent overtreatment and possible crossover effects within this study from previous treatment.
3. Current or future litigation for LBP.
4. Not fluent or literate in the English language. We were not able to provide multiple translators within this study.
5. Brain disorders (ie, dementia, Alzheimer disease) that would lead to difficulty in questionnaire completion.
6. Chronic pain other than LBP (eg, fibromyalgia, multiple sclerosis).
7. Clinically significant chronic inflammatory spinal arthritis.
8. Spinal pathology or fracture.
9. Progressive neurologic deficits because of nerve root or spinal cord compression, including symptoms/signs of cauda equina syndrome.
10. History of bleeding disorder.
11. Known arterial aneurysm.
12. Previous lumbar spine surgery.
13. Severe skeletal deformity of the foot.
14. Peripheral neuropathy caused by disorders such as diabetes.
15. LBP pain or leg pain that is not reproducible.
16. Current pregnancy.
17. Other conditions that may affect the subjects' ability to participate throughout the duration of the study or exclude patients from participation in the study, including contraindications to orthotic use or chiropractic spinal manipulations.

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