

SHOE ORTHOTICS FOR THE TREATMENT OF CHRONIC LOW BACK PAIN: A RANDOMIZED CONTROLLED PILOT STUDY

Jerrilyn A. Cambron, DC, PhD,^a Manuel Duarte, DC,^b Jennifer Dexheimer, BS, LMT,^c and Thomas Solecki, DC^d

ABSTRACT

Objectives: The purpose of this pilot study was to investigate the feasibility of a randomized clinical trial of shoe orthotics for chronic low back pain.

Methods: The study recruited 50 patients with chronic low back pain through media advertising in a midwestern suburban area. Medical history and a low back examination were completed at a chiropractic clinic. Subjects were randomized to either a treatment group receiving custom-made shoe orthotics or a wait-list control group. After 6 weeks, the wait-list control group also received custom-made orthotics. This study measured change in perceived pain levels (Visual Analog Scale) and functional health status (Oswestry Disability Index) in patients with chronic low back pain at the end of 6 weeks of orthotic treatment compared with no treatment and at the end of 12 weeks of orthotic treatment.

Results: This study showed changes in back pain and disability with the use of shoe orthotics for 6 weeks compared with a wait-list control group. It appears that improvement was maintained through the 12-week visit, but the subjects did not continue to improve during this time.

Conclusions: This pilot study showed that the measurement of shoe orthotics to reduce low back pain and discomfort after 6 weeks of use is feasible. A larger clinical trial is needed to verify these results. (*J Manipulative Physiol Ther* 2011;34:254-260)

Key Indexing Terms: *Orthotic Devices; Shoes; Low Back Pain; Chiropractic; Biomechanics*

Low back pain affects up to 84% of the North American population at some time in their life,¹ with combined annual direct and indirect costs estimated at \$84.1 to \$24.8 billion.² One possible cause of back pain is abnormal body biomechanics. For example, abnormal foot pronation is thought to lead to increased internal rotation of the tibia and femur as well as ipsilateral anterolateral pelvic tilt, increasing strain on the pelvic

muscles leading to a rotation of the affected lumbar vertebral body during gait.³

To account for abnormal biomechanics, some practitioners prescribe customized shoe orthotics. There is some previous literature supporting the use of orthotics. In 1 biomechanical study, orthotics led to a significantly earlier onset of erector spinae and gluteus medius muscle activity during the gait cycle.³ In another study, orthotics immediately improved the economy of gait (amount of work required to walk) and maintained it for 4 weeks.⁴

The use of shoe orthotics is a common component of treatment in chiropractic care, with 81.8% of chiropractors prescribing orthotics for 20.9% of their patients.⁵ Shoe orthotics are typically prescribed for patients with low back pain to influence foot stability and to normalize the kinetic chain. It is thought that such stabilization improves the ankle, knee, hip, and low back function, therefore leading to a prevention or reduction in back pain. However, according to a 2009 Cochrane systematic review⁶ assessing shoe orthotics for prevention and treatment of back pain, the authors discovered that “there is strong evidence that the use of insoles does not prevent back pain.” They also stated that there were no clinical trials assessing the treatment effectiveness of shoe orthotics for low back pain.⁶

^a Professor, Department of Research, National University of Health Sciences, Lombard, Ill.

^b Chair of Clinical Practice Department, NUHS Whole Health Center, National University of Health Sciences, Lombard, Ill.

^c Clinical Coordinator, Department of Research, National University of Health Sciences, Lombard Ill.

^d Clinician, Department of Research, National University of Health Sciences, Lombard, Ill.

Submit requests for reprints to: Jerrilyn A. Cambron, DC, PhD, Professor, National University of Health Sciences, 200 East Roosevelt Road, Lombard, IL 60148 (e-mail: jcambron@nuhs.edu).

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The purpose of this pilot study was to (1) to determine the feasibility of a larger scale study of logistics, recruitment efforts, and sample size estimations; (2) to show the ability to measure change in perceived pain levels (Visual Analog Scale [VAS]) and functional health status (Oswestry Disability Index [ODI]) in patients with chronic low back pain at the end of 6 weeks of orthotic treatment compared with no treatment; and (3) to show the ability to measure the change in perceived pain level and functional health status in patients with chronic low back pain at the end of 12 weeks of orthotic treatment.

METHODS

We recruited 50 patients with chronic low back pain through media advertising in a midwestern suburban area. Patients were randomized to either a treatment group receiving custom-made shoe orthotics or a wait-list control group. After 6 weeks, the wait-list control group also received custom-made orthotics. Primary outcomes were measured using the modified ODI and the VAS for low back pain at the randomization visit and at the 6-week visit (ClinicalTrials.gov Identifier no. NCT00976664).

The National University of Health Sciences Institutional Review Board approved the trial, and all patients provided written informed consent before study entry.

Participants

Subjects were eligible if they met the following basic criteria: at least 18 years old, symptomatic with current pain between T12 and the S1 joints with or without radiating pain, and symptoms must have been present for at least 3 months. Additional exclusion criteria were assessed at the baseline examination visit (Table 1).

We screened 143 people by telephone, and 85 were eligible. Of those, 58 presented for the baseline visit; and 50 subjects were randomized. Figure 1 shows the flow of patients through the trial. Table 2 shows the baseline characteristics of the randomized subjects in each of the 2 groups.

Outcome Measures

The primary outcome measures in this study were the VAS^{7,8} for low back pain and the ODI,^{9,10} measured at the randomization and at the 6-week visits. The VAS was on a scale of 0 to 10, with 10 being the worst pain imaginable. The ODI was on a scale of 0 to 50, with 50 being the most severely disabled.

Secondary outcomes included the VAS for low back pain and ODI measures at 2, 4, 8, 10, and 12 weeks and a VAS for leg and foot pains measured at the randomization visit at 2, 4, 6, 8, 10, and 12 weeks.

Table 1. Exclusion criteria

Inclusion Criteria
Men and women must be at least 18 y old.
Subjects must be symptomatic, with current pain between T12 and the S1 joints with or without radiating pain.
Symptoms must have been present for at least 3 mo.
Exclusion Criteria
Use of custom-made orthotics in the past year.
Brain disorders (ie, dementia or Alzheimer disease) that would lead to difficulty in questionnaire completion.
Active conservative care (such as physical therapy or chiropractic care) for the low back received in the last 6 months (excluding the use of oral medications or daily at-home exercises for general well-being) to prevent overtreatment as well as possible crossover effects within this study from previous treatment.
Not fluent or literate in the English language. We were not able to provide multiple translators within this pilot study.
Current or future litigation for low back pain.
Chronic pain other than low back pain such as fibromyalgia or thyroid disease.
Low back surgery in last 6 mo.
Other conditions that may affect the outcomes of this study or exclude patients from participation in the study, including contraindications to orthotic use.
Peripheral neuropathy due to disorders such as diabetes.
Low back or leg pain that is not reproducible.

In addition, an initial screening questionnaire to collect information on basic demographic, clinical parameters, inclusion/exclusion parameters, and expectations of care was collected at the baseline visit. Consistency of orthotic use, symptoms experienced during use, how often the orthotics were worn, how comfortable they were, and other health care use was also collected every 2 weeks during each subject's participation.

Interventions

Of the 50 participating subjects, 25 were randomized into an orthotic group. Those in the orthotic group received 2 pairs of custom-made shoe orthotics (Ultra Luxury full length and dress length models; Foot Levelers Inc, Roanoke, VA). The orthotics used were flexible, with 3 arch supports situated between a synthetic top and a leather bottom. Supports were included for the medial longitudinal, lateral longitudinal, and the anterior transverse arches. The materials used in construction of the orthotics were specific to the gait cycle including a shock-absorbing polymer placed in the heel to assist in shock absorption during heel strike (Zorbacel, Foot Levelers Inc), a stiffer polymer placed in the orthotic for support in mid-stance (StanceGuard, Foot Levelers Inc), and a springy polymer in the forefoot of the orthotic to assist in toeing off during gait (Propacel, Foot Levelers Inc).

The remaining study participants were randomized to a 6-week wait period, after which they were also given the same 2 pairs of custom-made shoe orthotics. No other

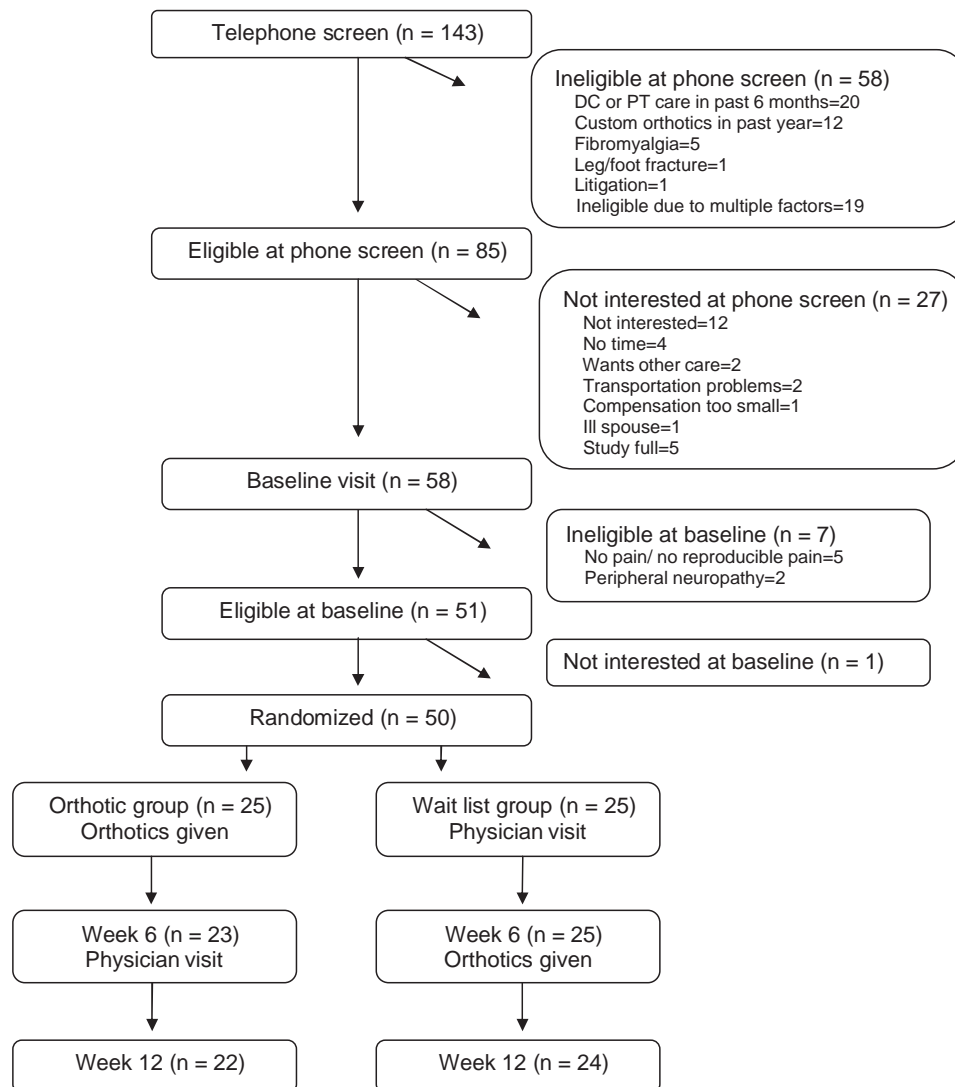


Fig 1. Flow of patients through the trial.

treatment was provided during the course of this study. If subjects did undergo other treatments outside the study parameters, the patient was not excluded from the study; and any additional outside treatments received were 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 negative side effects from the orthotics, the clinician was notified and the patient was re-examined when necessary.

Clinic Visits

Each interested subject underwent a telephone screen before attending the baseline visit. This telephone survey

was used to determine preliminary inclusion and exclusion parameters. If the subject was eligible, he or she was invited to attend a baseline screening visit.

Upon arrival at the baseline visit, a research assistant (RA) briefly described the visit and asked the subject to complete 3 self-administered questionnaires: a VAS, an ODI, and an initial screening questionnaire. If the subject continued to be eligible, the RA fully described the study and administered the institutional review board–approved informed consent.

After administration and signing of the informed consent, the subject underwent a medical history and a low back examinations by 1 of the licensed chiropractic research clinicians or a trained upper trimester intern under the clinician’s supervision. The purpose of this examination was to verify the physical inclusion and exclusion criteria for participation in the trial and to assure

Table 2. Baseline characteristics of the randomized subjects in the study

	Orthotics Group (n = 25)	Wait-List Control Group (n = 25)	P
Men (%)	40	48	.56
Married (%)	48	36	.39
White (%)	83	83	1
At least some college (%)	64	88	.06
Age (average ± SD)	51 ± 16	53 ± 16	.83
Range	19-72	22-83	
Foot pain present			.35
Foot pain, both (%)	28	24	
Foot pain, right (%)	12	0	
Foot pain, left (%)	16	16	
Foot pain, none (%)	44	60	
Leg pain present			.09
Leg pain, both (%)	16	20	
Leg pain, right (%)	20	8	
Leg pain, left (%)	16	0	
Leg pain, none (%)	48	72	
Use of store shoe orthotic (%)	12	20	.70
Duration of pain (average ± SD)	13 ± 16	10 ± 12	.70
Range (y)	0.5-50	0.5-50	
Confidence in orthotics	6.7 ± 2.1	6.0 ± 2.3	.30
Range, out of 10 (highest)	3-10	0-10	
Today's LBP, out of 10	5.0 ± 2.2	4.3 ± 1.9	.32
Past week's LBP, out of 10	5.4 ± 2.2	4.8 ± 1.9	.41
Today's leg pain, out of 10	3.2 ± 2.7	2.4 ± 2.8	.27
Past week's leg pain, out of 10	3.4 ± 2.9	2.5 ± 2.9	.23
Today's foot pain, out of 10	3.8 ± 2.7	2.6 ± 2.7	.13
Past week's foot pain, out of 10	2.9 ± 2.4	2.7 ± 2.8	.09
Oswestry, out of 50	10.0 ± 4.9	10.4 ± 5.4	.80

LBP, low back pain.

safety for the treatment and data collection portions of the study.

After the low back examination, if the clinician determined the patient was eligible, he or she underwent an orthotic assessment including a standing static evaluation of posture, a dynamic evaluation of gait and lower extremity function, and foot-pressure mapping using a force platform attached to a laptop computer. Certain information from the foot pressures, posture, and gait information were sent to Foot Levelers, Inc, for custom-made orthotic production.

Once the orthotics returned from production, the subject was contacted and asked to come to the clinic for the randomization visit. Upon presentation for the randomization visit, the subject completed the outcome measures (VAS and ODI). The RA briefly reconsented the patient and explained the randomization process to ensure understanding and compliance before randomization. The RA then randomized the subject by opening a sealed manila envelope with the next randomization assignment. The clinician disclosed the outcome of randomization to the subject and discussed procedures for proper use of orthotics for those in the orthotics group and reminded those in the wait-list control group that she/he would receive orthotics at

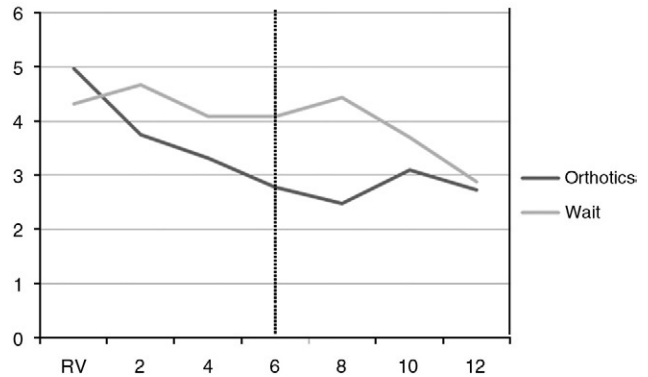


Fig 2. Change in VAS for low back pain from randomization visit to week 12. Wait-list control group received orthotics at week 6 visit.

the week 6 visit. The RA then returned to explain the follow-up procedures to the subject and gave her/him 3 stamped addressed envelopes containing a VAS, ODI, and follow-up questionnaires to be completed during the following two 2-week intervals.

Randomization Process

A predetermined randomization scheme (blocked randomization) was performed before study initiation. Randomization was based on a random numbers table with each individual randomization sequence being placed in consecutively numbered sealed manila envelopes. Subjects were randomized to custom-made shoe orthotics group or a wait-list control group.

Follow-Up Calls and Visit

Each subject was contacted every 2 weeks for 12 weeks via telephone to be reminded to complete and mail back the appropriate follow-up questionnaire packet (containing the VAS, ODI, and follow-up questionnaires). If the packet was lost, a new packet was immediately sent to the subject for completion. During the week 4 telephone call, the participants were asked to schedule a return trip to the clinic for a week 6 follow-up visit. During this week 6 visit, all subjects were seen by a research clinician. The orthotics group subjects discussed any changes in symptoms with the clinician and the clinician assessed proper fitting of the orthotic. The wait-list control group subjects received their orthotics and had them fitted in their shoes. An RA administered the VAS, ODI, and follow-up questionnaires. The subjects were given 3 follow-up questionnaire packets and asked to mail them at weeks 8, 10, and 12.

Upon receipt of the week 12 questionnaires, an honorarium check of \$20 was sent to the subject along with a letter of gratitude.

Table 3. Visual Analog Scale (mean ± SD) in the orthotics and wait-list control groups at randomization, week 6, and week 12 visits

Visit	Orthotics Group	n	P ^a	Wait-List Control Group	n	P ^b	P ^c
RV	5.0 ± 2.2	25		4.3 ± 1.9	25		
Week 6	2.8 ± 2.6	23	<.0001	4.1 ± 2.3	25		.0007
Week 12	2.7 ± 2.5	22	.0001	2.9 ± 2.3	24	.0003	.3913

Out of 10 (worst pain). RV indicates randomization visit.

^a Compared with RV.

^b Compared with 6-week visit.

^c Between groups.

Table 4. Oswestry Disability Index (mean ± SD) in the orthotics and wait-list control groups at randomization, week 6, and week 12 visits

Visit	Orthotics Group	n	P ^a	Wait-List Control Group	n	P ^b	P ^c
RV	10.0 ± 4.9	25		10.4 ± 5.8	25		
Week 6	6.2 ± 5.2	23	.0001	10.2 ± 5.4	25		.002
Week 12	6.1 ± 5.3	22	.0001	8.9 ± 5.5	24	.054	.0336

Out of 50 (most severe disability).

^a Compared with RV.

^b Compared with 6-week visit.

^c Between groups.

Blinding

Because of the nature of the study, neither subjects nor research personnel were blinded to the treatment group allocation of participants.

Statistical Methods

Baseline data were collapsed using descriptive statistics, with χ^2 or *t* test analyses used to determine if there were group differences for each variable described. The primary analyses of group differences in change in the VAS for low back pain and the ODI scores from the randomization visit to the 6-week visit were assessed using the Wilcoxon rank sums test.

Secondary analyses included group differences in change in the VAS for leg pain, and foot pain was also assessed using the Wilcoxon rank sums test. Change in the VAS for low back, leg, and foot pains between the randomization visit and week 12 visit for the orthotics group was assessed using paired *t* tests.

RESULTS

Most subjects enrolled in this study were white women in their 50s with baseline back pain levels of 5 of 10. Approximately 40% had leg pain and 50% had foot pain. There were no significant differences in baseline characteristics between the orthotics group and the wait-list control group (Table 2).

Primary Outcomes

The changes in low back pain and disability from the randomization visit to the 6-week visit were significantly

different between groups ($P = .0007$ for low back pain VAS and $P = .002$ for ODI, Fig 2). In the orthotics group, there was a reduction of 2.3 on the VAS for low back pain and 3.7 on the ODI. In the wait-list control group, there was a reduction of 0.2 on the VAS and 0.2 on the ODI.

There was a significant pre-post change in the orthotics group for both the VAS and ODI (Tables 3 and 4) between the randomization visit and the week 6 visit ($P < .0001$, $P = .0001$, respectively) as well as between the randomization visit and the week 12 visit ($P = .0001$, $P = .0001$, respectively). However, there were no significant differences between the week 6 visit results and the week 12 visit results ($P = .92$, $P = .94$, respectively).

In the wait-list control group, there were no differences in VAS or ODI between the randomization visit and the week 6 visit ($P = .81$, $P = .55$, respectively). However, there was a statistically significant difference in VAS between the week 6 and week 12 visits ($P = .003$) and a trend in ODI between week 6 and week 12 visits ($P = .054$).

Secondary outcomes showed a significant group difference between the randomization visit and the week 6 visit for the VAS for foot pain but not for the VAS for leg pain (Tables 5 and 6).

During the study, all subjects were allowed to seek alternate or additional care if necessary for low back, leg, or foot pain. Only 3 subjects did so. One subject in the orthotics group sought care during weeks 6 to 8 for “follow-up” care from his/her “general practitioner.” During this time, the subject did indicate that the orthotics were very comfortable; so the follow-up was most likely not related to the orthotic usage. Another subject in the orthotics group sought care during weeks 0 to 2 and again during weeks 4 to 6 for a gout flair-up. This subject described pain in the left

Table 5. Leg pain VAS (mean ± SD) in the orthotics and wait-list control groups at randomization, week 6, and week 12 visits

Visit	Orthotics Group	n	P ^a	Wait-List Control Group	n	P ^b	P ^c
RV	3.2 ± 2.7	25		2.4 ± 2.8	25		
Week 6	2.1 ± 2.4	23	.02	2.3 ± 3.1	25		.0937
Week 12	1.3 ± 2.2	22	.0013	1.4 ± 2.1	24	.0156	.2055

Out of 10 (most pain).

^a Compared with RV.

^b Compared with 6-week visit.

^c Between groups.

Table 6. Foot pain VAS (mean ± SD) in the orthotics and wait-list control groups at randomization, week 6, and week 12 visits

Visit	Orthotics Group	n	P ^a	Wait-List Control Group	n	P ^b	P ^c
RV	3.8 ± 2.8	25		2.6 ± 2.7			
Week 6	1.8 ± 2.4	23	.0002	2.7 ± 2.9			.0019
Week 12	1.6 ± 2.0	22	.0006	2.0 ± 2.6		.0801	.0251

Out of 10 (most pain).

^a Compared with RV.

^b Compared with 6-week visit.

^c Between groups.

foot, indicating that the orthotics were comfortable to uncomfortable. The patient continued in the study until completion, however, discontinued the use of the orthotics. The final subject in the wait-list control group sought care during weeks 6 to 8 from a podiatrist and again during weeks 10 to 12 from a primary care physician. This subject indicated that the orthotics were comfortable to very comfortable and was very satisfied with the study, possibly indicating that the visits to the podiatrist and primary care physician were not related to side effects of the orthotics. No other subjects sought additional care for their low back, leg, or foot symptoms.

DISCUSSION

There are only a few previous studies on shoe orthotics for reduction of low back pain. In 1 observational study, shoe inserts were used by a group of patients with low back pain resulting in 78% of subjects reporting good or excellent improvements in pain after 1-year follow-up.¹¹ Another observational study of patients with low back pain and abnormal foot pronation that considerably changed posture during gait studied the use of shoe orthotics that led to 80% of participants reporting at least 50% improvement in their low back pain 1 year after treatment.¹² Finally, in a nonrandomized comparative study, low back pain subjects using custom-made shoe orthotics led to more than twice the improvement in alleviation of low back pain for twice as long compared with nonrandomized subjects using traditional back-pain treatments.¹³

Aside from observational studies, there was 1 crossover study assessing customized shoe orthotics vs placebo for patients with low back pain. Back pain significantly decreased with the “real” orthotics; however, the decrease

was not a clinically significant amount.¹⁴ There is 1 clinical trial in the literature comparing 3 treatment groups: an orthotics group; a chiropractic manipulation plus orthotics group; and a control group for patients who spent at least 6 hours per day standing or walking on a hard surface and had discomfort in the lower extremities, spine, and/or foot.¹⁵ Both the orthotics group and manipulation plus orthotics group improved; however, there was no assessment between the groups, and the results were not stratified by location of pain.

This pilot study showed significant changes in back pain and disability with the use of shoe orthotics for 6 weeks compared with the wait-list control group. It appears that such improvement was maintained through the 12-week visit, but the subjects were not continuing to improve during this time. This information is helpful in that it calls for larger studies to investigate these results.

There were several limitations to this study. First, the subjects and clinicians were aware of group assignment, possibly leading to biased (patient administered) outcomes. As well, the subjects selected for this study only came from 1 region of the United States, a majority were white women in their 50s, and included only a small number of patients. A greater number and diversity of patients (eg, age, sex, and race) should be considered for future studies. The comparison group was the wait-list control rather than an alternate treatment. The reason for this was because we wanted to know the effect of orthotics vs no treatment. A placebo could have been used; however, we did not know of an effective placebo for shoe orthotics. As well, only 1 type of orthotic was used in this study. It is possible that other orthotics would result in different findings. It is also recognized that many practitioners who use orthotics use a multimodal treatment, including foot manipulation or other therapies; but these were not done in this study. The wait-list may have affected the way that the subjects

completed the outcome measures; however, we did not inquire about their disappointment or effect of waiting for their orthotics. Another limitation was the use of VAS to measure pain. Several subjects commented that they described their symptoms in various other ways such as discomfort or stiffness and that they did not know how to respond to the VAS measurement tool. In addition, the natural history of back pain can lead to increases and decreases in pain over time, for which we have no control. Finally, there are many possible diagnoses included for patients with “chronic low back pain,” and some diagnoses may respond better to shoe orthotics than others. Until better diagnostic methods are determined, we do not have the ability to truly differentiate the various possible sources of back pain. These limitations should be considered when larger studies are being developed.

CONCLUSIONS

This pilot study showed that the measurement of shoe orthotics to reduce low back pain and discomfort after 6 weeks of use is feasible. A larger clinical trial is needed to verify these results.

Practical Applications

- This study showed improvements in back pain and disability between the randomization and week 6 visit with the use of orthotics compared with a wait-list control group.
- Improvements in pain and disability were maintained through the 12-week visit, but the subjects wearing orthotics were not continuing to improve after the first 6 weeks.
- Secondary outcomes showed a significant group difference between the randomization visit and the week 6 visit for the VAS for foot pain but not for the VAS for leg pain.

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