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

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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 review[6] 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]

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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