Effects of customized foot orthotics on reported disability and analgesic use in patients with chronic low back pain associated with motor vehicle collisions

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Abstract

Objective: The purpose of this study was to compare reported disability due to chronic low back pain following a motor vehicle collision between groups of those using customized foot orthotics and those not using orthotics.

Methods: Sixty-six consecutive patients referred from primary care medical physicians for the complaint of chronic (>3 months) low back pain following a motor vehicle collision were included. Thirty patients received “usual care” that included prescription of an exercise therapy program in addition to analgesics. Thirty-four patients received the same therapy along with customized foot orthotics. All patients completed the Oswestry Disability Index at the initiation of the study and at 8-week follow-up. The number of participants using any type of prescription analgesic for their back pain at baseline and at 8 weeks was also recorded.

Results: All patients completed treatment, and the baseline and 8-week questionnaires. Both treatment groups were well matched in terms of age, sex distribution, and duration of low back pain, as well as baseline Oswestry Disability Index score. At 8 weeks, although both groups had improved, the group that used orthotics had a lower Oswestry Disability Index than the usual care group ($P < .05$), with a smaller proportion of the orthotics group using any form of prescribed analgesics for back pain ($P < .05$).

Conclusions: In this study, patients with chronic low back pain following a motor vehicle collision who used orthotics in addition to usual care had improved short-term outcomes compared with usual care alone.

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Introduction

Although a recent study has suggested that customized foot orthotics may be beneficial in chronic low back pain,¹ there remains a paucity of trials confirming their effectiveness.² There are reasons, from a biomechanical perspective,³⁻⁷ to prescribe orthotics; but trials in primary care practice settings and in a wide variety of clinical populations are required before their routine use can be recommended. Cambron et al¹ measured the change in perceived Oswestry Disability Index scores in participants with chronic low back pain at the end of 6 weeks of orthotic treatment compared with no orthotics. They found that changes in Oswestry Disability Index scores were greater at 6 weeks in the group treated with customized foot orthotics compared with a wait-list control group. Furthermore, they demonstrated that these changes were apparent within the first 6 weeks of orthotic use; and although persisting up to 12 weeks, there was no further improvement in the period from 6 to 12 weeks of orthotic use. In other words, clinical benefit is evident in the first 6 weeks of orthotics use. This has been observed in another, uncontrolled trial.⁸ The participants in the study of Cambron et al, however, were primarily drawn from the community by advertisement; and they did not specifically target a clinical population.

As chronic low back pain following motor vehicle collisions is a common clinical problem, developing in 60% of those who reportedly have whiplash-associated disorders, and is itself associated with work-related disability and increased health care utilization,^{9,10} there is a need to determine if customized foot orthotics are effective in this clinical group. The purpose of this pragmatic study was to compare reported disability due to chronic low back pain following a motor vehicle collision between groups receiving usual care and using customized foot orthotics, and those receiving usual care and not using orthotics.

Methods

Participants

During 3 months in 2009, primary care physicians from 2 primary care clinics in Edmonton, Alberta, Canada, referred patients with musculoskeletal disorders, especially chronic pain. The clinics had similar clinical populations near the inner city, mainly lower socioeconomic and worker populations. Oswestry

Disability Index, current medication use, before and after exercise therapy and other treatments, was typically collected at 6 to 8 weeks postconsultation. The same consultant was involved in patient care in both clinics, using the same exercise therapist (physiotherapist) for both clinics. Data were collected by the author in both practices, patients provided consent, and approval for this was obtained from the College of Physicians and Surgeons of Alberta as part of an ethics approval for practice audit.

Intervention

Consecutively referred patients, in a 3-month period in 2009, with chronic low back pain that was attributed (by the patient) to a motor vehicle collision were considered for the study. Referring physicians were encouraged to refer patients whose chief symptom was chronic (greater than 3 months) low back pain with little or no spinal pain above the T12 region and who had stated that their back pain onset followed (within days) a motor vehicle collision. A medical history and a physical examination were performed; and usual care consisted of education, referral to the clinic's physiotherapist for further spinal assessment, a tailored exercise program (that generally ran for 6-7 weeks), and advice to continue follow-up with the primary care medical physician for analgesic medications. The author and the primary care medical physicians routinely, as part of their usual practice, avoided prescribing other modalities for chronic low back pain, such as injection procedures, chiropractic therapy, acupuncture, or massage therapy, but allowed patients to seek these out if they so desired. The primary care medical physicians had a typical medication regimen, which included any of nonsteroidal anti-inflammatory drugs, acetaminophen products, cyclobenzaprine, narcotics, and gabapentin. They tended not to use antidepressants, antipsychotics, or sedatives. These patients had already received any appropriate investigations to rule out fractures, radiculopathies, and other nonbenign causes of back pain.

Orthotics and usual care group

Patients referred to the author by one of the primary care clinics received orthotics in addition to usual care. Following assessment, each patient completed an Oswestry Disability Index, referring specifically to back pain. The author then obtained foam impressions of each patient in the seated position, with the patient asked to relax their lower limb and allow the examiner to place downward pressure on the knee, along the axis

of the tibia with the knee flexed to 90°. This created the foam impression. All participants received a standardized orthotic composed of Footmaxx Premium Allsport orthotic (Footmaxx, Toronto, Ontario, Canada) composed of a semirigid module, vinyl reinforcement, polyurethane foam cushioning, and large profile metatarsal pad aligned with the third metatarsal ray and placed distal to the semirigid module. Participants were provided lifts for correction of leg length discrepancies if measured to be 1.5 cm or greater, and the lift was provided at a measure of half this discrepancy. None of the participants received valgus or varus postings. Participants received their orthotics within 1 week of the moulding, and all received the same general instruction on use and footwear. By the time of follow-up, 8 weeks later, participants would have had the opportunity to be using orthotics for up to 7 weeks.

Usual care group

Patients consecutively referred to the author from a second primary care clinic received usual care. The author undertook the same clinic activities as stated above for the orthotics group. This usual care group was advised that orthotics treatment would become available in the near future or that they could seek out orthotics currently at other locations. As orthotics are not yet a standard or proven therapy in this clinical group and as they could be offered at a later date, no ethical concerns regarding standard of care were raised. Most patients chose to proceed with usual care.

Inclusion/exclusion criteria

The inclusion criteria were age more than 17 years; able to read and write English at the grade 8 level or higher; and current pain from T12 or lower, with or without radiating pain, present for at least 3 months, with this pain being attributed by the patient to a previous motor vehicle collision. As well, patients were included if they were seated within the interior of a car, truck, sports/utility vehicle, or van in a collision (any of rear, frontal, or side impact); had no loss of consciousness; were 18 years of age or more; and presented with low back pain onset within 3 days of their collision. Exclusion criteria included current use of customized foot orthotics, neurological disorder (including sciatica with objective neurological signs), cancer, spinal stenosis, spinal or lower limb surgery, recent or complicated fracture, known inflammatory arthropathy, severe osteoarthritis of the lower limb joints, prosthetic joints, amputation, or congenital

lower limb deformity. Mild to moderate lower limb joint osteoarthritis was not an exclusion, as this is a common condition in primary care, especially in older patients with chronic low back pain.

Participants in the usual care group were excluded if they obtained orthotics during the study period. Patients were also excluded if they had pain above the T12 level, for any reason, for 2 or more days per week (ie, if they had neck or upper back pain, it was relatively minor compared with the low back pain); were injured in a non-motor vehicle event; or were admitted to hospital.

Patients had chronic low back pain after a motor vehicle collision, with no significant, confounding injuries elsewhere. Referring physicians were aware of these criteria in order to refer patients who were likely to meet the criteria for further evaluation by the author.

Outcome measures

At baseline, participants completed the Oswestry Disability Index, a 10-item questionnaire that indicates the extent to which a person's functional level is restricted by pain.⁹ Scores range from 0 to 5 for each item, with higher scores indicating a greater degree of restriction by pain. The scores for each item are added, divided by the denominator of a possible total score of 50, and then converted into a percentage. Thus, the scores range from 0% (no restriction due to pain) to 100% (severe restriction due to pain). After 8 weeks, on clinical follow-up with the author, participants completed again the Oswestry Disability Index. In addition, at baseline and at follow-up, the medications the claimant was using, including type and number of different classes of medications, were recorded to determine if the participant was using some form of prescribed analgesic and if this was specifically for the back pain. No data were gathered on the possibility of reinjury during the study period or compliance with orthotics use. No data were gathered on the dosage of medications or use of over-the-counter medications. No attempt was made to verify the causal link between the motor vehicle collision and chronic low back pain. No data were gathered regarding other treatment modalities sought by the participant or on precollision back pain. Only analgesic use was ultimately recorded, without specifying the exact classes of drugs or number of drugs used (ie, use of 1 analgesic or more constituted "analgesic use"). Compliance with the exercise therapy program was documented as per the judgement of the treating therapist, who considered that attendance at all scheduled appointments was required to meet the definition of compliance.

Table 1 Characteristics of participants in the orthotics group and usual care group at baseline

Group	Age (y, mean $\pm$ SD, range)	Sex distribution (% female)	Prescribed analgesic use (% yes)	Oswestry Disability Index (mean $\pm$ SD, range)
Usual care (n = 32)	39.2 $\pm$ 10.4, 22-58	62.5	75.0	37.0 $\pm$ 11.4, 14-58
Orthotics (n = 34)	35.4 $\pm$ 9.6, 22-63	55.9	73.5	39.6 $\pm$ 11.6, 12-60

Statistical methods

Data were analyzed using SPSS 11.0 (Macintosh version; SPSS Inc, Chicago, Illinois). Descriptive statistics were calculated for the cohorts, as were baselines and follow-up scores for Oswestry Disability Index. The mean change in the Oswestry Disability Index scores between groups at follow-up was compared by the Student *t* test. Proportions of participants with compliance with exercise therapy and use of prescription analgesics at baseline and follow-up were compared using the χ^2 test with Yates correction.

Results

For the orthotics group, 52 patients had been referred; and 18 were excluded (10 had frequent [more than 1 day per week] neck and/or upper back pain, 2 had incomplete data, 2 did not read or write English at a grade 8 level, 2 had recent abdominal surgery, 1 had severe knee osteoarthritis, and 1 had obtained orthotics elsewhere). For the usual care group, 56 participants were referred. Of these, 24 were excluded (12 had frequent [more than 1 day per week] neck and/or upper back pain, 1 had incomplete data, 4 did not read or write English at a grade 8 level, 2 had osteoporotic fracture, 2 had severe hip or knee osteoarthritis, and 3 had obtained orthotics elsewhere). Thus, there were 34 partici-

pants in the orthotics group and 32 participants in the usual care group at baseline. Of these, no participants were lost to follow-up in the orthotics group; and 2 participants were lost to follow-up in the usual care group.

The baseline characteristics of the participants in both groups are shown in Table 1. There were no significant differences between groups. At follow-up, the therapist-reported compliance with exercise therapy was 81% in the orthotics group and 72% in the usual care group, with no difference between groups.

At 8 weeks, although both groups had improved, the orthotics group had a lower Oswestry Disability Index score than the usual care group ($P < .05$), with a smaller proportion of the orthotics group using prescribed analgesics for pain ($P < .05$; Table 2). There was no statistically significant correlation between any of age, sex, or duration of low back pain, and the change in Oswestry Disability Index scores over time.

Discussion

This study shows that, in a primary care setting, the addition of customized foot orthotics to the treatment of chronic low back pain following motor vehicle collision may improve clinical outcomes and reduce prescription analgesic use.

Limitations

There are a number of limitations to this study. First, it was not a randomized controlled study. There could be a number of factors that affected the observed outcomes, including participant characteristics not measured, producing a selection bias. The author, although involved in the care of the participants, did not have contact with any of them in the interval between baseline and follow-up; and the measures are unlikely to have been influenced by the author. It is possible that the primary care physicians and treating exercise therapist learned of the participant's use of orthotics and that this may have influenced how they treated the

Table 2 Follow-up Oswestry Disability Index scores and prescription analgesic use in the orthotics group and usual care group at 8 weeks

Group	Change in Oswestry Disability Index from baseline	Prescription analgesic use (% yes)
Usual care (n = 30)	16.2 $\pm$ 10.5 (0-40)	56.7
Orthotics (n = 34)	23.1 $\pm$ 11.1 (2-46) *	29.4 *

* Indicates statistically significant difference between groups.

participants, thus affecting outcomes. It is also possible that there was a selection bias due to practitioner style and treatments between the 2 groups because the participants were from 2 clinics. At the same time, the author was involved in the clinical care in all participants, as were the very same exercise therapist and, in some cases, the same primary care physician. Thus, treatment approaches were highly standardized and very similar in both clinics. Furthermore, it is not possible to create a placebo control for foot orthotics. Much of the response could have been due to placebo effect. At the same time, placebo effect could be a factor in both exercise therapy and medication use. All of these therapies, in clinical practice, are subject to placebo or therapist effect. It is also important to note that not all orthotics are the same and that the orthotics used for these patients may have resulted in different clinical outcomes than if other types of orthotics were used.

Given the innocuous nature of orthotics, however, compared with medications and the ease with which orthotics may be provided, their use in clinical practice should be further considered both for patient convenience and possibly for cost-effectiveness if they reduce the need for other therapies. Further studies will be required, with larger participant numbers, in a variety of clinical populations. As well, economic data should be gathered in future studies to quantify cost-effectiveness. If orthotics do nothing more than lead to similar outcomes as “usual care” but at less cost, they would likely be a preferred intervention.

Conclusions

In this study, patients with chronic low back pain following a motor vehicle collision who used orthotics in addition to usual care had improved short-term outcomes compared with usual care alone.

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No funding sources or conflicts of interest were reported for this study.

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