

Clinical Study

A non-randomized clinical trial to assess the impact of nonrigid, inelastic corsets on spine function in low back pain participants and asymptomatic controls

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Abstract

BACKGROUND CONTEXT: Although previous studies suggest braces/corsets can reduce acute pain, no prior study has assessed back function after bracing with both self-reported and objective measures. Use of both self-reported and objective measures of spine function together may be important given evidence they assess unique aspects of function.

PURPOSE: The aim was to assess both self-reported and objective measures of spinal function before, and after, use of a nonrigid, inelastic lumbar brace.

STUDY DESIGN/SETTING: This was a non-randomized clinical trial.

PATIENT SAMPLE: The sample included acute low back pain (LBP) participants and asymptomatic controls.

OUTCOME MEASURES: Oswestry Disability Index (ODI), spinal stiffness, and muscle endurance were the outcome measures.

METHODS: Three groups were studied: –LBP/–Brace (n=19), –LBP/+Brace (n=18), and +LBP/+Brace (n=17). Both groups of braced participants were instructed to wear the brace continually for 2 weeks with the exception of bedroom and bathroom activities. Before and after the 2-week period, three measures of spinal function were performed: spinal stiffness via motorized indentation of the L3 spinous process, a modified Sorensen test (timed lumbar extension against gravity), and the ODI. Repeated measures analyses of variance were conducted for all three outcomes.

RESULTS: Among the groups, ODI scores decreased significantly for the +LBP/+Brace group ($p<.001$) compared with the other two groups. The +LBP/+Brace mean ODI score decreased 3.71 points (95% confidence interval [CI] 2.01–5.40) compared with the –LBP/–Brace group and decreased 3.48 points (95% CI 1.77–5.20) compared with the –LBP/+Brace group. Change scores for the Sorensen test were significantly increased in the +LBP/+Brace group ($p=.037$) compared with the –LBP/–Brace group (22.47s 95% CI 8.14–36.80). Spinal stiffness did not change significantly between groups.

CONCLUSIONS: This study demonstrates that lumbar function assessed by self-reported and objective measures does not worsen when nonrigid, inelastic bracing is used for short periods of time for those with, or without, back pain. These data add to the existing literature that suggests short-term use of nonrigid, inelastic bracing for acute LBP does not decrease spinal function

FDA device/drug status: Not applicable.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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Keywords:

Acute low back pain; Bracing; Corset; Oswestry Disability Index; Spinal stiffness; Indentation; Sorensen test; Endurance

Introduction

Rigid casting is used to immobilize joints with the therapeutic goal of mending disrupted tissues (eg, fracture). Although complete joint immobilization aids in healing of disrupted tissue, it can also result in unwanted atrophy and dysfunction [1]. Alternatively, if complete joint immobility is not achieved, tissue mending is reduced, but atrophy may not be as pronounced.

Incomplete immobilization is the most probable outcome when nonrigid, inelastic bracing of the spine is used. Specifically, nonrigid, inelastic bracing has been shown to increase trunk stiffness [2–4] and decrease trunk motion [5–8], but vertebral movement is not extinguished; nonrigid bracing neither eliminates vertebral motion [8] nor reduces spine loading [9]. The lack of complete immobilization with nonrigid external bracing is likely the result of nonrigid brace materials [2,10] and/or the inability of the brace to fully embrace the joint thereby allowing residual joint movement. As such, any loss of muscle function associated with nonrigid spine bracing is more likely to be associated with disuse and/or neurologic injury rather than by bracing itself.

Although bracing is not thought to prevent low back injury [11], there is increasing support for the idea that braces may attenuate acute low back pain (LBP). Although the most recent systematic review on this issue was equivocal [11], recent studies suggest that short-term bracing for acute back pain reduces pain [10,12], improves self-reported function [10], and does not cause loss of muscle strength [13]. Although unequal in type of brace, pathology and duration of pain, as a whole, these studies suggest that when used in acute back pain, braces may offer pain reduction together with improved mobility not unlike crutches for a sprained ankle; weight transfer through the brace and an increase in stability (or reduction, but not elimination of range of motion) can decrease pain and aid ambulation. In addition, these braces may provide a cost-effective alternative compared with other forms of treatment for acute LBP (at publication, the brace used in this study was available online for \$115 USD [<http://www.ebay.com/bhp/aspen-back-brace>]).

Unfortunately, no prior studies have assessed spinal function using self-reported and objective measures of back function together in the same cohort. As recent evidence suggests [14,15], self-reported and objective measures quantify unique domains of musculoskeletal function. Therefore, it may be important that several types of

functional measures are used concurrently to ensure a comprehensive assessment of spinal function.

Given the above, the objective of this study was to use both self-reported and objective measures of back function before, and after, 2 weeks use of an inelastic, but nonrigid lumbar brace (ie, corset). Our hypothesis was that bracing in this manner would not alter spinal function in asymptomatic or symptomatic participants.

Materials and methods

Participants

Within the greater Edmonton region (population ~1 million), recruitment of participants occurred indirectly and directly through posters, advertisements, announcements, and word of mouth. Inclusion criteria differed for asymptomatic and symptomatic participants. Asymptomatic participants were included in the study if they did not have back pain within the last 6 weeks and had no prior history of spine surgery. For symptomatic participants, inclusion criteria required current LBP of less than 6 weeks in duration. Additional exclusion criteria are listed in Table 1. Participants meeting inclusion criteria were enrolled in the study after providing written informed consent. Data were collected in a clinical setting by the principal investigators. This study was approved by the University of Alberta's Health Research Ethics Board.

Protocol and intervention

Asymptomatic participants were randomized into two groups (Fig. 1): those who did not wear a brace (–LBP/–Brace) and those who wore a brace (–LBP/+Brace). Randomization to either group was assigned alternately on enrollment. All symptomatic participants wore braces (+LBP/+Brace). Both groups of braced participants (–LBP/+Brace; +LBP/+Brace) were sized and fitted for braces as per the manufacturer's instructions (QuikDraw Brace, Aspen Medical Products, CA, USA). The braces themselves were constructed of inelastic material (webbed nylon) fastened at the waist then tightened by the participant through a series of pulleys drawn together by two cords (Fig. 2). In this way, the brace can be described as nonrigid and inelastic (the containing volume can deform, but the volume cannot increase). Braced participants were instructed by the principal investigators within a clinical setting to tighten the brace until they believed their trunk motion restricted and to wear the brace in

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