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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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when measured separately with subjective or objective tools.

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

Table 1
Exclusion criteria

Suspected or confirmed malignancy as the cause for back pain, spinal fracture (current or within the last 5 years)
Previous non-day surgery to the abdomen, spine pelvis, or hips
Presence of nerve root involvement (presence of at least two of the three: myotomal weakness, altered sensation in dermatomal patterns, and/or altered knee/ankle reflexes),
Ankylosing spondylitis
Current skin conditions that may be aggravated by bracing
Osteoporosis
Rheumatoid arthritis (or taking any disease-modifying antirheumatic drugs)
Pregnancy or suspected pregnancy
Known severe spondylolisthesis
Severe scoliosis
Type I diabetes mellitus
Hyperparathyroidism
Hyperthyroidism
Inability to lie prone for at least 40 min
Inability to tolerate back extension or spinal indentation
Inability to speak or read English
Use of muscle relaxants
Hypertension or those prone to hypertension (smokers)
History of aortic aneurysm
Persons unable to wear a lumbar brace for any reason

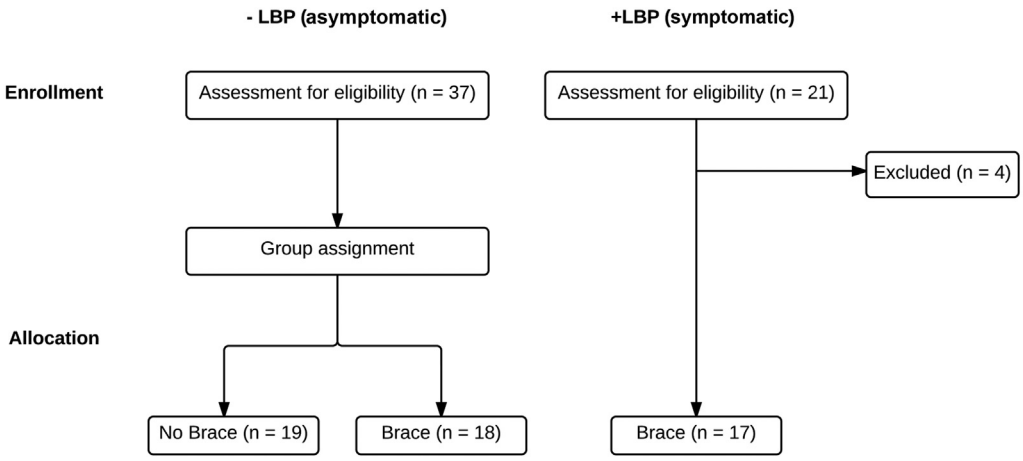

Fig. 1. Protocol flow chart.

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).

Fig. 2. Fitting of nonrigid, inelastic brace.

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 this way continually for 2 weeks with the exception of bedroom and bathroom activities. Braced participants were additionally fitted with a custom-built data logger that recorded the pressure applied by the tightened brace. The purpose of recording these data was to determine participant compliance with brace wearing. The height and mass of all participants were measured at the start of the 2-week period from which body mass index [16] was calculated.

Outcome measures

A self-reported survey of back function was obtained (primary outcome) as were objective measures of spinal stiffness and trunk endurance (secondary outcomes). These measures were obtained from all participants at the start, and end, of their 2-week period in the study.

The modified Oswestry Disability Index (ODI) [17] was used as a self-reported measure of spinal function.

Spinal stiffness was measured with a motorized indentation device. [18] In brief, the device uses a blunt probe that is advanced at a constant rate to apply a 60-N force to the L3 spinous process of a prone participant (as identified by palpation). The applied force and resulting displacement are recorded and then graphed to generate two measures of stiffness. Terminal stiffness (secant stiffness) is the maximal applied force divided by the maximal displacement, whereas global stiffness (average stiffness) is the slope of a plot of force versus displacement derived from the ascending portion of the plot. The performance of this method of spinal stiffness measurement and these particular outcomes measures has been reported elsewhere. [18].

Spinal endurance was evaluated by a modified Sorensen test [19], which is a timed test of lumbar extension against gravity. For this measure, the participants were asked to lie prone on an inclined plinth then to extend their spine until their chest is raised off the plinth. With the legs and pelvis secured to the plinth by straps, participants were asked to hold the extended posture for as long as possible or until the distance they were extended off the table decreased by 1 cm as measured by an adjustable pendant hanging from their neck. The performance of this test and its various modifications has been reported previously [19].

Analysis

Sample size was determined a priori to be a minimum of 16 based on effect sizes seen in previous studies [20]. Separate repeated measures analyses of variance were conducted for all three outcomes with a significance level of 0.05 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, New York, USA). No blinding of participants or principal investigators was used in this study given the obvious nature of the intervention and presence of pain. Separate analyses of covariance were used to analyze baseline characteristics with covariates of age, height, weight, and sex.

Results

Between June 1, 2012 and December 31, 2014, participants flowed through the study as shown in Figure 1. Four recruited participants were not enrolled because of a failure to meet the inclusion criteria (presence of nerve root involvement). Based on serial enrollment and randomization/assignment procedures, the following consecutive sample sizes were achieved: −LBP/−Brace (n=19), −LBP/+Brace (n=18), and +LBP/+Brace (n=17).

The three protocol groups did not differ from each other demographically in terms of age, height, weight, or sex (Table 2). These same variables were not associated statistically with any of the three outcome measures. No participants were lost to follow-up.

Baseline ODI scores were as follows: −LBP/−Brace (0.42±0.90), −LBP/+Brace (0.83±1.76), and +LBP/+Brace (10.41±5.87). Among the groups, ODI change scores decreased significantly for the +LBP/+Brace group ($p<.001$) compared with the other two groups. The +LBP/+Brace group's ODI score decreased 3.71 points on average (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) on average compared with the −LBP/+Brace group. Change scores for the Sorensen test were significantly increased in the +LBP/+Brace group over the 2-week period ($p=.037$) compared with the −LBP/−Brace group (22.47s 95% CI 8.14–36.80). Spinal stiffness did not change significantly between groups.

No adverse events were reported.

Table 2
Subject demographics

Group	Sample size (n)	Mean age±SD (y)	Mean height±SD (cm)	Mean weight±SD (kg)	Gender (male, female)
−LBP/−Brace	19	36.1±15.3	172.6±10.2	71.9±17.3	11, 8
−LBP/+Brace	18	33.1±12.9	172.2±11.1	71.9±16.4	9, 9
+LBP/+Brace	17	39.2±12.0	169.8±11.9	73.5±13.1	8, 9
Total	54	36.1±13.5	171.6±10.9	72.4±15.5	28, 26
ANOVA		0.414	0.726	0.939	0.804

SD, standard deviation; LBP, low back pain; ANOVA, analyses of variance.

Discussion

This study demonstrates that lumbar function, as 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. In fact, in participants with back pain, some measures of spinal function improved statistically although these changes did not meet or exceed the minimal clinically important change [21].

These results are congruent with previous studies that measured the effect of bed rest on the cross-section area of spinal muscles obtained via magnetic resonance imaging. After approximately 14 days of complete bed rest (a form of immobilization), some changes in spinal muscle volume were noted [22] with increasing effect at 27 and 55 days [23]. These results support our observations in that if total voluntary reduction of spine motion creates minimal changes in cross-sectional area at 2 weeks, it would be unlikely that atrophy would occur with bracing over the same period, as it has been shown that bracing of this type reduces, but does not extinguish spinal motion [8].

Still, studies exist that demonstrate muscle atrophy in back pain patients [24–27]. In these cases, atrophy has been shown to follow back injury or the onset of LBP. That atrophy can occur in back pain [24–27] but did not occur either after rest [22,23] or after bracing in this study, together suggest that if atrophy does occur concurrently with brace use, it is most likely due to the injury and or disuse from the injury rather than from nonrigid, inelastic bracing by itself.

A unique feature of this experiment is that spinal function was measured by a self-reported measure and objective measures. This feature is significant in that recent evidence from patients with complete knee replacements suggests that subjective and objective measures capture different aspects of knee function; postsurgical subjects report changes in knee function over time, whereas physical measures of knee function from their artificial joint remain unchanged [14,15]. Similarly, subjective measures of spine function by themselves (eg, modified ODI) may not fully capture the functional status of a person's spine; a recent systematic review has suggested that self-reported measures of spinal function correlate poorly with objective measures [28]. As such, this study demonstrates that in both subjective and objective realms, spinal function does not decrease with short periods or inelastic bracing.

Importantly, this study does not address what may occur if the nonrigid, inelastic brace used in this study is worn for longer than 2 weeks. Although our study did not address this possibility, we speculate that a slow decline toward decreased spinal function with further brace use is unlikely given the inherent spine motion still allowed by the brace (unlike further atrophy that does occur with bed rest beyond 2 weeks). We cannot rule out the possibility of reduced spinal function or atrophy with prolonged brace use but believe that should it be observed, it would be more likely to result from self-imposed inactivity or neurologic injury.

Although this study included three groups (−LBP/−Brace, −LBP/+Brace, and +LBP/+Brace), we did not include a fourth +LBP/−Brace group. Although the addition of this group may have provided us with information regarding the natural history of back pain with respect to our outcomes, the benefit of adding this group was not thought to outweigh withholding this group of participants from treatment.

Additionally, we were not able to confirm the compliance of participants in wearing their braces over the prescribed 2-week period. Although we took steps to mitigate this possibility by developing a sensor within the brace to monitor compliance, the sensor did not remain viable in most participants over the 2-week period of use. Fortunately, the participants were not able to ascertain the functional status of the sensor during the 2-week test period. Therefore, we assume braced participants believed that they were being monitored for their brace usage over the length of the study.

Although the effects of rigid versus nonrigid bracing are quite well-known in the extremities, it is possible that clinicians transpose the unwanted effects of rigid extremity bracing to all bracing applications. A recent survey (Alberta, Canada), showed that approximately 50% of clinicians (MDs, DCs, PTs) believed that nonrigid back braces cause muscle atrophy. This result suggests a potential gap in knowledge, which leads to varied clinical practice with respect to brace prescription for acute LBP. Although our findings in this present study are not definitive, taken as a whole with other studies showing similar results (and a lack of studies showing the contrary), the most challenging barrier in this area may not be discerning the effect of bracing on spinal function in acute LBP patients, but the knowledge translation and uptake needed to inform clinical opinion.

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