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Abstract: Unstable shoe was developed as a walking device to strengthen the lower extremity muscles and reduce joint loading. A large number of studies have reported in asymptomatic adults increased electromyography (EMG) activity throughout the gait cycle in most of the lower limb muscles. However, no previous studies have explored the effects of wearing unstable shoes on trunk muscle activity in patients with chronic low back pain (CLBP). Therefore, the aim of the present study was to compare trunk muscle activity during gait using an unstable shoe and a conventional flat control shoe in patients with CLBP.

Thirty-five CLBP patients (51.1±12.4 yrs.; 26±3.8 kg/m2; 9.3±5.2 Roland Morris Disability Questionnaire score) were recruited from the Orthopedic Surgery Service at the Hospital to participate in this cross-sectional study. All participants underwent gait analysis by simultaneously collecting surface electromyography (EMG) data from erector spinae (ES), rectus abdominis (RA), obliquus internus (OI) and obliquus externus (OE) muscles, while walking on a treadmill with flat control shoes and experimental unstable shoes.

The results showed significantly higher %EMG activity in ES (mean difference: 1.8%; 95% confidence interval [CI] 1.3 to 2.2), RA (mean difference: 1.5%; 95% CI 0.3 to 2.7), and OI (mean difference: 1.5%; 95% CI 0.2 to 2.8) in the unstable shoes condition compared to the flat shoes condition. Based on these findings, the use of unstable shoes may have potential implications in promoting spine stability, particularly in improving neuromuscular control of trunk muscles in CLBP treatment.

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Dear Editor,

We are enclosing herewith an Original Article entitled "**Effects of unstable shoes on trunk muscle activity in patients with chronic low back**" for publication in "Gait & Posture" for possible evaluation.

With the submission of this manuscript we would like to undertake that the above mentioned manuscript has not been published elsewhere or is not being considered for publication elsewhere, and that the research reported will not be submitted for publication elsewhere until a final decision has been made as to its acceptability by the Journal. We also affirm that:

-This research has been reviewed and approved by an institutional review board;

-Each of the authors has read and concurs with the content in the final manuscript;

-All authors have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted.

-NO CONFLICT OF INTEREST was declared; the authors have no financial or other interest in the product (MBT shoes).

Sincerely,

Pablo Salvador Coloma

***2. Conflict of Interest Statement**

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*4. Title Page (with authors and addresses)

TITLE: Effects of unstable shoes on trunk muscle activity in patients with chronic low back pain

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Effects of unstable shoes on trunk muscle activity in patients with chronic low back pain

ABSTRACT

Unstable shoe was developed as a walking device to strengthen the lower extremity muscles and reduce joint loading. A large number of studies have reported in asymptomatic adults increased electromyography (EMG) activity throughout the gait cycle in most of the lower limb muscles. However, no previous studies have explored the effects of wearing unstable shoes on trunk muscle activity in patients with chronic low back pain (CLBP). Therefore, the aim of the present study was to compare trunk muscle activity during gait using an unstable shoe and a conventional flat control shoe in patients with CLBP.

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KEY WORDS: Unstable Shoes; Lower Back Pain; Trunk Muscles

INTRODUCTION

Unstable shoes were developed for the general population with the aim of allowing wearers to benefit from the proprioceptive stimuli of training on uneven grounds while performing the activities of normal daily living. As a result, many studies have focused on the effects of unstable shoes on the kinematics and electromyography of lower limb muscles in a standing posture and gait (1-3). However, studies related to the effects of unstable shoes on spine kinematics and trunk muscle activity are limited. In one of these studies, Buchecker et al.(4) assessed the spinal alignment, concurrent angular velocity, and EMG activity of trunk muscles during bipedal stance in asymptomatic adults. They concluded that wearing unstable shoes provoked more motion at the thoracolumbar and lumbopelvic levels, and increased lumbar erector spinae (ES) activity in a double-leg stance when compared to standard control footwear. More recently, Lisón et al.(5) reported that unstable shoes increase trunk muscle activity of the ES and rectus abdominis (RA) and affect lumbar lordosis during gait compared to control flat shoes in a sample of young healthy subjects. Thus, these authors suggest that the use of unstable shoes may have potential implications in promoting spine stability, particularly in strengthening trunk muscles in the healthy population or perhaps even in low back pain (LBP) treatment. Accordingly, previous longitudinal studies have shown the effectiveness of unstable shoes in reducing pain(6-8) and disability(8) in different populations of chronic LBP patients (nurses, golf players, and health professionals working in a hospital). Whilst recent studies on unstable shoes have provided some encouraging findings regarding the potential health benefits of these shoes, the overall body of published work is relatively small and the methodologies and focuses of these studies are diverse, and so the basic mechanism(s) by which unstable shoes influence gait pattern in either healthy volunteers or those with disability remains unclear. In particular, the precise factors determining the effectiveness of unstable shoes in LBP patients are still unknown. One possible mechanism underlying the therapeutic effect of unstable shoes on back pain is changes in trunk muscle activity (5,9,10).

To the authors' knowledge, no previous studies have explored the immediate effects of wearing unstable shoes on trunk muscle activity in patients with chronic LBP. Therefore, the purpose of this work was to compare the EMG activity levels of trunk muscles (ES, RA, obliquus internus [OI], obliquus externus [OE]) during gait in a sample of chronic LBP patients when wearing unstable shoes compared to conventional flat control shoes.

METHODS

Subjects

Forty-three patients aged 18 to 65 years with a diagnosis of nonspecific chronic LBP lasting at least 3 months were recruited from the Orthopedic Surgery Service at the Hospital to participate in this cross-sectional study. Exclusion criteria were: Roland Morris Disability Questionnaire (RMDQ) score < 4, obesity (BMI ≥ 30 kg/m^2), diagnosis of a spinal tumor or infection, spinal fracture, lumbar radiculopathy, systemic disease (autoimmune, infectious, vascular, endocrine, metabolic, or neoplastic disease), fibromyalgia, previous spinal surgery, or musculoskeletal injuries in the lower limbs. None of the participants had previously worn unstable shoes prior to the start of the study. This research was approved by the Hospital's Ethics Committee and followed the ethical guidelines set out in the Declaration of Helsinki. All participants were informed of the aims of the study and gave their written informed consent prior to their participation.

Shoe condition

For the unstable shoe condition we used Masai Barefoot Technique (MBT, model AFIYA 5) shoes (Figure 1). This shoe is characterized by a rounded sole in the anterior-posterior direction and a flexible heel which provides an unstable base of support, while the control shoe we used has a flat sole (John Smith Classic).

Study protocol

All tests were conducted in the biomechanics laboratory at the University. Prior to testing, an expert gave all participants a 15 minute briefing on how to use the unstable shoes correctly. After this, all the participants underwent a 20 minute habituation period consisting of walking on a treadmill (BH Fitness Columbia Pro) at the same speed as in the experimental procedure in order to familiarize themselves with the nature of the measurements. Since inclination can alter the distribution of plantar loading, a 0% slope was set on the treadmill to remove this effect(5). After the familiarization stage, but before data collection, participants performed submaximal voluntary isometric contractions (SVIC) in order to normalize muscle EMG assessment, as recommended for LBP patients(11).

The treadmill tests consisted of two (unstable and flat shoe conditions) ×1 min walking trials at a walking speed of 1.44 m/s. This design criterion was necessary to allow for speed-independent identification of the EMG characteristics of unstable shoes. The order of the acquisitions was randomly established for both shoe conditions, and the two tests were separated by a minimum of 15 min so that the participants would not experience residual fatigue from the previous test.

Electromyographic and electrogoniometry analysis

The EMG signals from the ES, RA, OI, and OE muscles were recorded on each participant’s right-hand side using the ME6000s computer-based electromyograph (Mega Electronics Ltd., Kuopio, Finland). Surface electrodes were positioned on the muscles according to SENIAM (surface EMG for non-invasive assessment of muscles) recommendations(12). The EMG sensors were pre-gelled self-adhesive bipolar Ag/AgCl disposable 20-mm-diameter surface electrodes (BIO LEADLOK) with a 2 cm interelectrode distance. The electrodes were longitudinally placed in the center the ES (2 cm lateral to L3 spinous processes), RA (3 cm lateral to the umbilicus), OI (2 cm medially in a horizontal plane from the anterior superior iliac spine), and OE (midway between the anterior superior iliac spine and ribcage) muscles, and a reference electrode was placed on the skin covering the last rib. Given that the left-hand side signal is more prone to interference from heart beat bursts(13), and in order to simplify and make the recording sessions shorter, only the EMG signals from the right-hand side muscles were recorded. These signals were amplified to produce approximately 2.5 V, then A/D converted (14-bit resolution) at 1000 Hz, filtered with a Butterworth high pass filter (the cut-off frequency was 8 Hz) and a low pass filter (with a cut-off frequency of 500 Hz). EMG data were rectified and smoothed by calculating their root mean square, with a time window of 0.01 seconds.

A twin-axis electronic goniometer (TSD130A, Biometrics Ltd., Gwent, UK) was integrated to collect ankle range of movement (ROM) data (plantar flexion and dorsiflexion) and was used to determine every walking cycle, defined as the time from initial foot contact to the start of the following ipsilateral contact(5).

During all the tests, ankle ROM and EMG data from selected muscles were simultaneously collected during treadmill walking for a total of 60 seconds; the first ten walking cycles during the central 20 seconds were globally analyzed using Megawin software (version 3.0.1) for Windows. For subsequent analyses, the mean values for this period of ten walking cycles for each EMG variable were used. EMG amplitude data were normalized to the maximum signal collected during SVIC and expressed as a percentage (%SVIC).

Statistical analysis

An a priori analysis of effect size and sample size was conducted at an α level of 0.05 and for the desired power of 80%. Effect size was estimated using Cohen's d, based on results from previous studies which studied similar dependent variables (EMG-activity data from the trunk muscles)(6), with the use of unstable footwear as the independent variable. The result was an estimated minimum sample size of thirty-five subjects (calculated using G*Power software, version 3.0.10)(14).

Data-assessment for the normal distribution (using the Kolmogorov–Smirnov test) revealed that while the %EMG data for the RA and ES were normally distributed, the data of the OI and OE muscles were not normally distributed. As a consequence, paired t-tests (RA and ES) and non-parametric Wilcoxon signed-rank tests (OI and OE) were used to compare the variables studied in each of the shoe conditions. Prior to the aforementioned tests, unpaired t-tests and the Mann–Whitney U test were used to explore the data for differences in gender and age (≥ 50 years vs. < 50 years). Statistical analyses were performed using SPSS software, version 18.0 for Windows (SPSS Inc., Chicago, IL, USA), and statistical significance was set at $p < 0.05$ for all the analyses.

RESULTS

A total of 43 nonspecific chronic LBP patients were screened in this study. Eight patients were excluded for not meeting the inclusion criteria, and 35 patients were finally enrolled (51.1 ± 12.4 yrs.; 26 ± 3.8 kg/m^2; 9.3 ± 5.2 RMDQ score). There were no missing data and no statistically significant gender or age-related differences for any of the studied variables and so all the data were pooled for subsequent analysis.

The results showed significantly higher %EMG activity in ES (mean difference: 1.8%; 95% confidence interval [CI] 1.3 to 2.2), RA (mean difference: 1.5%; 95% CI 0.3 to 2.7), and OI (mean difference: 1.5%; 95% CI 0.2 to 2.8) in the unstable shoes condition compared to the flat shoes condition (Table 1).

DISCUSSION

To the best of our knowledge, this is the first study to investigate the immediate effects of wearing unstable shoes on trunk muscle activity during gait in chronic LBP patients. Our results show that the unstable shoes produced significantly higher ES, RA, and OI %EMG muscle activity levels compared to conventional flat shoes. These results in LBP patients are concordant with previous studies performed in healthy subjects. Thus, Lisón et al.(5) analyzed trunk muscle activity during gait in 48 healthy adults, reporting significantly higher ES and RA %EMG muscle activity levels compared to control flat shoes. Similarly, also in line with these results, Buchecker et al.(4) assessed the EMG activity of trunk muscles during bipedal stance in 27 asymptomatic adults and concluded that wearing unstable shoes increased the electromyography activity of lumbar ES muscular structures compared to standard control footwear.

Unstable shoes were developed with the aim of inducing an unstable posture (based on their rounded sole in the anterior-posterior direction and its flexible heel), hence providing proprioceptive stimuli and promoting neuromuscular control and muscular strengthening. Previous studies in asymptomatic adults have shown a clear increase in center of pressure (CoP) displacements in the anterior-posterior direction in bipedal stance compared with that of traditional flat-sole shoes(2,15). Effects in the medio-lateral direction have also been noted in asymptomatic adults (2,3), and as a result, higher EMG lower-limb and trunk-muscle activity (involved in maintaining joint movement and positional control) has also been reported(2-5).

In addition, there are also differences in postural control during standing in chronic LBP patients compared to healthy individuals(16-18). For instance, during a more challenging standing condition (with visual occlusion), people with chronic LBP demonstrate increased CoP displacement and velocity which is thought to result from their impaired ability to maintain postural stability(19). Other work has modelled mechanisms by which altered motor control strategies in this region serve as a potential cause and/or effect of LBP(20,21); this work describes three inter-coordinated subsystems that are collectively responsible for adapting to the spinal stability requirements during various postures and movements (passive, active, and neural subsystems), and points out that dysfunctional neuromuscular-control strategies (e.g. muscle activation levels or muscle-contraction coordination) could result in clinical instability. Indeed, it is well established that chronic LBP patients demonstrate a variety of apparently dysfunctional neuromuscular-control strategies(22).

With all the above in view—and assuming that lumbopelvic region muscle-activity coordination is important for generating mechanical spinal stability—we hypothesize that the stimulus provided by introducing an element of imbalance (using unstable footwear) in a population that could require enhanced spinal stabilization (i.e. chronic LPB patients) might explain the higher level of muscular activation found in our study. On the one hand, ES and RA muscles may be able to generate trunk flexion/extension moments, while OI and OE muscles are perhaps involved in generating the side-bending moments required to control the anterior-posterior and medio-lateral instability induced by the unstable shoes. Therefore, it seems reasonable to speculate that co-contraction of the ES-RA (antagonist muscles in the sagittal plane) and the right and left OI and OE muscles (antagonist muscles in the frontal and transverse planes) may contribute to stabilization of the lumbar spine. Without a doubt, co-contraction can distribute internal forces more evenly and so, may be important for injury prevention. In particular, increased co-contraction of the trunk muscles can increase spine stability(5,10) and furthermore, may also help to prevent LBP(9).

Overall, our EMG results in this context could be interpreted as a compensatory mechanism for counteracting the trunk instability induced by unstable shoes and thus, may have implications for challenging dysfunctional postural control systems during gait in patients with LBP, as well as for producing a general increase in trunk muscle strength. In this regard, Bergmark(23) categorized two systems of muscles that contribute to spinal stability: a local system directly attached to the vertebrae, and a global system that transfers the load to the thoracic cage and pelvic girdle. The local system is now generally understood to include deep muscles (including the multifidus, transversus abdominis, diaphragm, and pelvic floor), whereas the global system is usually described as comprising the large superficial muscles such as the ES, RA, OI, and OE, inter alia(22). In addition to changes to the local system that seem to be associated with LBP, neuromuscular control strategies in the global muscles are also altered in these patients(22,24). As such, co-activation of abdominal (RA, OI, and OE) and low back (ES) musculature, also known as "abdominal brace", increases spinal stability(25) and paraspinal stiffness(26). Indeed, exercise protocols based on abdominal bracing have been proposed as an effective therapeutic approach in instability-related chronic LBP patients(22).

As pointed out in several recent studies(27,28), interventions incorporating trunk neuromuscular training, including proprioceptive exercise, perturbation, and correction of body sway, are believed to be beneficial in increasing the physiological status of the spine. Specifically, clinical benefits to rehabilitation with proprioceptive or balance training have been demonstrated in chronic LBP patients(29). Moreover, unstable shoe use has already been shown to produce significant reductions in pain and disability in this population(6-8). Therefore, on the basis of the results we present here, it is plausible that the increase in abdominal and lumbar muscle activity produced by wearing unstable shoes may explain the improvements in pain and disability reported in chronic LBP patients. Nonetheless, it should also be borne in mind that the increase in muscle activity reported in this study, while statistically significant in ES, RA and OI, was numerically small, which led to questioning its clinical relevance. In addition, because of the cross-sectional nature of this study we cannot undertake that the effects of using unstable shoes will persist over time.

Finally, this study has some limitations. Firstly, specific variations in unstable-sole construction challenge the postural-control system differently(4). The angular degree of the curved sole is closely related to the stability of standing posture and muscular activity while walking(15). Consequently, the changes established for spine kinematics and trunk muscle activity while wearing a particular unstable shoe model may not extrapolate well to other types of related footwear. Secondly, omission of indwelling EMG signals prevented analysis of deep muscles, including the multifidus and transversus abdominis which also play a significant role in stabilizing the lumbar spine.

In summary, we conclude that the use of unstable shoes may have potential implications in promoting spine stability, particularly in improving neuromuscular control of trunk muscles in chronic LBP treatment. Our findings could be used to develop future randomized controlled trials or prospective cohort studies aiming to clarify the biomechanical and clinical consequences of unstable shoes on the gait patterns of subjects with chronic LBP.

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CONFLICT OF INTEREST STATEMENT

No conflict of interest was declared; the authors have no financial or other interest in the product (MBT shoes).

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6. Table(s)

Table 1. Comparison of electromyographic activity values (%submaximal voluntary isometric contractions, %SVIC) between flat and unstable shoes.

	Flat shoes	Unstable shoes	*p*
ES, %SVIC	23.6 ± 8	25.4 ± 8.5	< 0.001
RA, %SVIC	38.3 ± 15.8	39.8 ± 16.8	0.015
OI, %SVIC	28 (22.8)	29.6 (27.8)	0.001
OE, %SVIC	24.5 (15)	25 (18)	0.065

ES: erector spinae, RA: rectus abdominis, OI: obliquus internus, OE: obliquus externus. Data are expressed as mean ± standard deviation for the paired t-tests, or median (interquartile range) for the non-parametric Wilcoxon signed-rank tests.

7. Figure(s)

Figure 1. Unstable test shoe used in the study (MBT, model AFIYA 5). The illustration shows the electronic goniometer array used for assessing the ankle range of movement.

***Research Highligts**

- Unstable shoes increase erector spinae muscle activity during gait in CLBP patients.
- Unstable shoes increase RA and OI muscle activity during gait in CLBP patients.
- Unstable shoes may have potential implications in promoting spine stability.