Title: Pilot study of the ResisTrac impact on spine pain, regional spine discomfort, and erector spinae flexion-relaxation phenomenon

Abstract

Objective: The study purpose was to assess the impact of the ResisTrac on relieving spine pain, regional spine discomfort, and altering erector spinae muscle activity patterns.

Methods: Sixty college students completed a Nordic Musculoskeletal Questionnaire (NMQ) instrument, Numeric pain Rating Scale (NRS) for low back pain, and Flexion-Relaxation Phenomenon (FRP) test at baseline and again at post-test. The study was composed of 4 compared groups with 15 participants per group: experimental group- possessed low back pain and used the ResisTrac device between tests, control #1- possessed low back pain and used no device between tests, control #2- no low back pain and used the ResisTrac device between tests, and control #3- no low back pain and used no device between tests.

The ResisTrac exercises consisted of having participants perform horizontal squats for 8 minutes using 2 bungee cord resistance bands on the sliding traction table.

Results: Spine pain decreased from 2.8±0.7 to 2.1±0.6 ($p=0.003$) in the experimental group. Additionally, the lower back specific component of the NMQ decreased from 3.3±0.6 to 1.7±0.6 ($p=0.000$). Control #1 did not demonstrate statistically significant changes throughout the study. Erector spinae FRP profile marginally improvemed after use of the device in the experimental group as well.

Conclusions: Individuals with low back pain that used the ResisTrac device demonstrated improvements in spine pain, regional spine discomfort, and marginally improved their erector spine muscle activity patterns.

MeSH Key words: Low Back Pain; Patient Outcome Assessment; Ergonomics; Self-Help Devices

INTRODUCTION

Low back pain is associated with high levels of disability and healthcare utilization.[1] It is the second most common cause for physician visits.[2] Low back pain costs between 100-200 US billion dollars per year.[3] About 2/3rds of those costs[3] are associated with absenteeism (absent from work)[4-9] and presenteeism (present at work, but with impaired performance).[10-11] Approximately 149 million days of work per year are missed due to low back pain.[12] Optimal preventative and treatment measures should be developed to lower these numbers.

Many national treatment guidelines for low back pain (2012 Institute for Clinical Systems Improvement, 2017 American College of Physicians and the American Pain Society, and the 2014 National Guideline Clearinghouse)[13-15] recommend prescribing opioids in addition to other forms of care to treat low back pain. However, the most current research on this topic (Krebs *et al* 2018) demonstrates that opioids are not more effective than non-opioid medication at improving patient outcomes and therefore other forms of care should be emphasized.[16] Additionally, opioids often have many negative side effects to include addiction, constipation, drowsiness, respiratory depression, nausea, and paranoia.[16] Safe non-opioid based methods to reduce low back pain during the workday are needed to help employees with pain that are attempting to work.

The ResisTrac device[17] is essentially a large metal traction table that is designed to help patients with low back pain and sacroiliac pain. Generally, existing lumbar traction devices use a static cable to provide a set amount of horizontal axial spine pull for a fixed period of time as they lay supine. With the ResisTrac device patients similarly lay supine, but they can modulate the amount of traction they feel is appropriate as they engage in a linear squat exercise. This is because there are bungee cords connected to their anterior waist on a belt to the device base point by their feet, allowing them to modulate how vigorously the pull is. The device has participants perform a squat on a sliding table horizontally that allows motion axially superior-inferior and left-right. If the participant wants less traction they do not have to extend their knees as much during the squat, thus it allows for greater control and potentially less patient anxiety compared to traditional traction machines. On their website, spinetraction.com they list several exercises that can be performed with the traction table. To our knowledge research on this product has not been published yet in peer-reviewed journals. It is important to understand that this product differs significantly from existing lumbar traction devices in that it uses bungee cords to mediate resistance.

Traction is a well-established form of care for low back pain that has been shown to reduce protrusions of disc nuclear material, stretch soft tissues, relax muscles, mobilize joints, decrease spinal canal stenosis, widen intervertebral foramina, and reduce pain.[18-23] This is postulated to occur by relieving pressure on localized structures that induce pain and muscle guarding.[18-20]
The purpose of this study was to investigate the ability of the ResisTrac to impact spine pain, regional spine discomfort, and affect erector spinae muscle activation patterns during a functional task.

METHODS

This research experiment was reviewed and approved by the Texas Chiropractic College Institutional Review Board for human subjects in accordance with the Declaration of Helsinki.

Study Design, Rationale, and Setting

This study focused on the immediate impact of the ResisTrac on low back pain, spine discomfort, and muscle activation patterns as shown in figure 1. Sixty participants (table 1) completed a baseline Nordic Musculoskeletal Questionnaire (NMQ),[24-26] which is used to measure regional body pain/discomfort as well as a Numeric pain Rating Scale (NRS) for low back pain. After this they engaged in a Flexion-Relaxation Phenomenon (FRP) test (figure 2).[27-31] The FRP test involved standing participants attempting to flex their torso forward at their hips to reach as far down as they could and then return back upright, similar to a standing toe-touch activity. After baseline testing, half of the low back pain participants were randomized to use the ResisTrac (figure 3). Similarly, with the no low back pain groups (control #2 and #3), half of the participants were randomized to use the ResisTrac. Participants using the ResisTrac engaged in a horizontal squat on the traction table for 8 minutes at a rate of one repetition for every 2 seconds in relation to a metronome chime. They had a large Velcro belt connected around their waist and 2 bungee cords running from a clip on the anterior belt to where their feet were on the base of the traction table. Participants that did not use the traction table sat on a chair for 8 minutes as controls. Afterward, all participants a post-test NMQ, NRS and FRP test. Participants only attended 1 study session. This experiment occurred in a research lab with the ambient room temperature set to 74°F. Researchers intentionally avoided playing music in the lab background during the study. This was done to reduce the possibility that music could calm some participants and act as a covariate for perception of pain.[32]

Participant recruitment

Study participants were recruited between April-May 2018 on a college campus. Prior to enrollment, study applicants were screened to determine whether they met the inclusion and exclusion criteria (figure 4). They were

provided with a copy of the informed consent and inclusion/exclusion criteria in several classes a few weeks in advance of the study.
All study applicants provided written informed consent prior to participation. This research project utilized a convenience sample of 60 study participants with 15 participants in each of the 4 compared group and did not follow an *a priori* power analysis. No study applicants violated the inclusion/exclusion criteria for this experiment. Once the 15 participation slots per group were filled, further study applicants were dismissed. Participants were blinded to the manufacturer's claims for the product being tested, but they were able to observe the product if they were utilizing it. The researcher analyzing the study statistics was blinded as to group designation during data clustering.

Product's attributes

The ResisTrac belt is a sturdy wide elastic support belt with Velcro anteriorly to tighten around patients lumbar region as appropriate. It has a metal clip anteriorly to connect bungee traction cords, which are then anchored to the lower end of the traction table by the patient's feet. The sturdy ResisTrac metal traction table provides patients the ability to move in 4 different directions axially, inferior-superior and right-left as they lay supine. Primarily the device is used for linear squats against bungee cord resistance.

Assessments

The NMQ instrument is used to rate pain or discomfort in 12 bodily regions (eye, neck, shoulder, upper back, elbow, lower back, arm, wrist/hand, thigh, knee, calf, and feet/ankle) on a 5-point scale. On the scale "1" represents extremely comfortable and "5" represents extremely uncomfortable.[24-25] Although data was collected on all 12 regions at baseline and again at post-test, the focus of the study was limited to the upper back and lower back. Researchers intentionally did not reduce the 12 questions to 2 questions in an attempt to make it less likely that participants would remember the exact numbers they filled out at baseline testing. This survey was also followed by a 0-10 Numeric pain Rating Scale for low back pain.
The Flexion-Relaxation Phenomenon (FRP) test is commonly used in low back pain research to assess the functional electrical activity of the lower back muscles.[34] During the test, the erector spinae is relaxed at quiet standing in most healthy participants.[35] As a participant eccentrically flexes forward (the flexion phase) muscle activity increases. When they are fully flexed (full flexion phase), muscle activity lowers, which is thought to be due to the elastic fibers in the muscle supporting the weight of the upper torso.[36] Then as the participant concentrically activated their erector spinae to move back to the upright position (extension phase) muscle

activity increases again. Patients with significant spine pain[34,37] as well as healthy controls that have had spine pain induced[38,39] demonstrate an aberrant FRP pattern or a generalized increase in muscle activity throughout the task (i.e., muscle guarding). Participants were instructed to take approximately 3 seconds to bring their torso to a fully flexed position and to take another 3 seconds to extend back to an upright position. They were instructed to avoid touching their toes if they were flexible, and instead to bend at their pelvis as far as they could for the full flexion phase of the FRP test.

Surface EMG data was recorded using a Bagnoli 8 (Delsys, Natick, MA, USA) unit and was processed through a VICON motion analysis system (Vicon, Centennial, CO, USA). Data were recorded at 1,000 Hz and processed with a Butterworth filter. The ground electrode was placed on the left lateral malleolus. Root Mean Square (RMS) analysis was utilized to smooth data using 500 ms epochs as shown in Fig. 2. Final data were normalized in relation to the highest RMS value per phase out of the 4 FRP phases (baseline to post-test, per participant group) in a similar method as Harvey *et al*.[40]

Statistical analysis

The data were exported from VICON as .csv files and initially organized and processed in Excel (Microsoft, Redmond WA, USA). The data were then placed in SPSS version 20.0 (IBM, Armonk, NY, USA) for analysis. Results were reported as mean $\pm$ standard deviation (SD) unless otherwise specified.

A one-way ANOVA compared groups anthropometric attributes at baseline. An independent samples *t*-test was used to compare pain levels between the 2 low back pain groups at baseline and again at post-test. A between-within ANOVA was used to compare dependent variables between tested groups at baseline and again post-intervention. An alpha level of $p \leq 0.05$ was considered statistically significant for all tests. Cohen's *d* was determined for all statistically significant interactions as recommended by Field to avoid overestimation of effect size.[41]

RESULTS

There were no statistically significant differences between groups at baseline for height, weight, age, or BMI (Table 1). Table 2 demonstrates that baseline values for NRS low back pain score, NMQ-upper back, and NMQ-lower back were similar between the experimental group and control group #1. Participants in the experimental group had a statistically significant improvement in lower back pain (p=0.003) and lower back discomfort (p=0.000), while upper back pain was unaffected. Lower back pain improved 0.7 points on a NRS and on the NMQ discomfort decreased 1.6 points. Figure 5 demonstrated that participants with low back pain that used the ResisTrac had lower back muscle activation patterns that more

closely resembled the normal patterns of the 2 no low back pain control groups (controls #2, 3).

DISCUSSION

Low back pain is a common cause of disability amongst workers. It can lead to impairment in work performance as well as absenteeism.[42] It can be categorized as acute, subacute, transient, recurrent, or chronic.[43] Acute low back pain generally improves significantly over the initial 6 weeks, with slowed improvement thereafter.[43] Some cases of acute low back pain can transition to chronic low back pain which results in long-term impairments and is much more costly to society.

Lumbar traction is a common form of lower back pain care. It has been found to be used by 77% of outpatient rehabilitation providers[44] and has the ability to centralize lower back pain if nerve roots are compressed.[45] Fritz *et al* found that mechanical traction in addition to exercise results in significant improvements in disability and fear-avoidance beliefs.[46] Traction has additionally been shown to reduce the need for lower back surgery in some instances.[47]

The overall findings of the study were that participants that had low back pain that used the ResisTrac device demonstrated improvements in lower back pain and lower back discomfort than individuals that did not use the device. Upper back pain appeared to be unaffected in this study. It could be that the device was mechanically developed to focus on sacroiliac and lower back pain and therefore was not as impactful on upper back pain.

After the study was completed, researchers performed a post-hoc power analysis using G*Power version 3.1.9.4 (Universität Kiel, Germany) to determine the study's power.[48,49] Analyzing differences between two dependent means (matched pairs) for low back pain groups, utilizing two tails, an effect size of 0.5 (medium), alpha error probability of 0.05, and total sample size of 15, the power of the study was 0.437. To have 80% power the study would need 27 participants per compared study group.

Limitations of the study were: a placebo group or comparative traction table use group was not utilized. The placebo effect can be powerful at times and a similar study with a placebo table would be needed to corroborate the findings of this study. Additionally, participants only engaged in one iteration of care. Normally passive care is provided 2-3 times per week for 2-3 weeks. A longer duration study would be more informative, but it was cost-prohibitive for the study our lab undertook.

Some future directions of research that may stem from this study are: 1) analyzing the traction table in a longer duration multi-week study at reducing low back pain, and 2) comparing the ResisTrac directly to the prototypical traction table regarding its impact at lowering spine-related pain and symptoms as well as worker injury rates.

Conclusion

These preliminary results suggest that the ResisTrac demonstrated an ability to help participants decrease lower back pain and discomfort. This research adds to the body of knowledge supportive of lumbar traction to help reduce low back pain that may be disc or muscle-related. Additional research should be performed with a larger sample size and over multiple weeks in relation to other forms of passive modalities to better understand the impact of this form of traction.

Funding sources and conflicts of interest

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Figure captions and Tables

Figure 1. Illustration of the study design and 4 groups compared at 15 participants per group. The entire study session took approximately 25 minutes per participant. The Nordic Musculoskeletal Questionnaire (NMQ), Numeric pain Rating Scale (NRS), and Flexion Relaxation Phenomenon (FRP) were recorded at baseline and post-test.

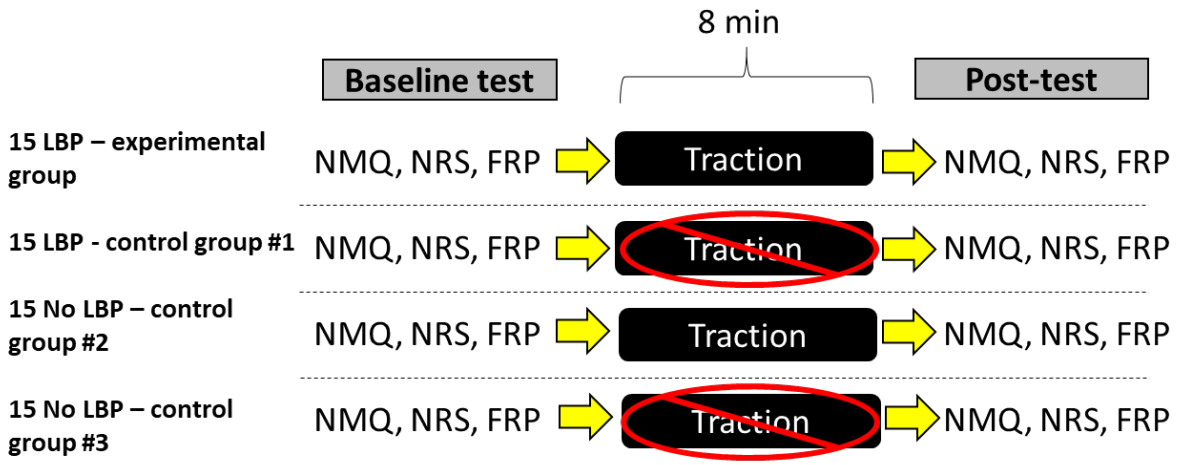


Figure 2.Illustration of the Flexion-Relaxation Phenomenon test. (a) Participant engaged in a standing toe-touch test to measure the Flexion-Relaxation Phenomenon (FRP) of their erector spinae muscles using surface EMG (sEMG), and (b) a sample graph showing each of the 4 phases of the FRP test for a healthy participant summarized in 500 ms root mean square epochs. Data was recorded for approximately 15 seconds per participant as they slowly moved through each of the 4 positions of the FRP test.

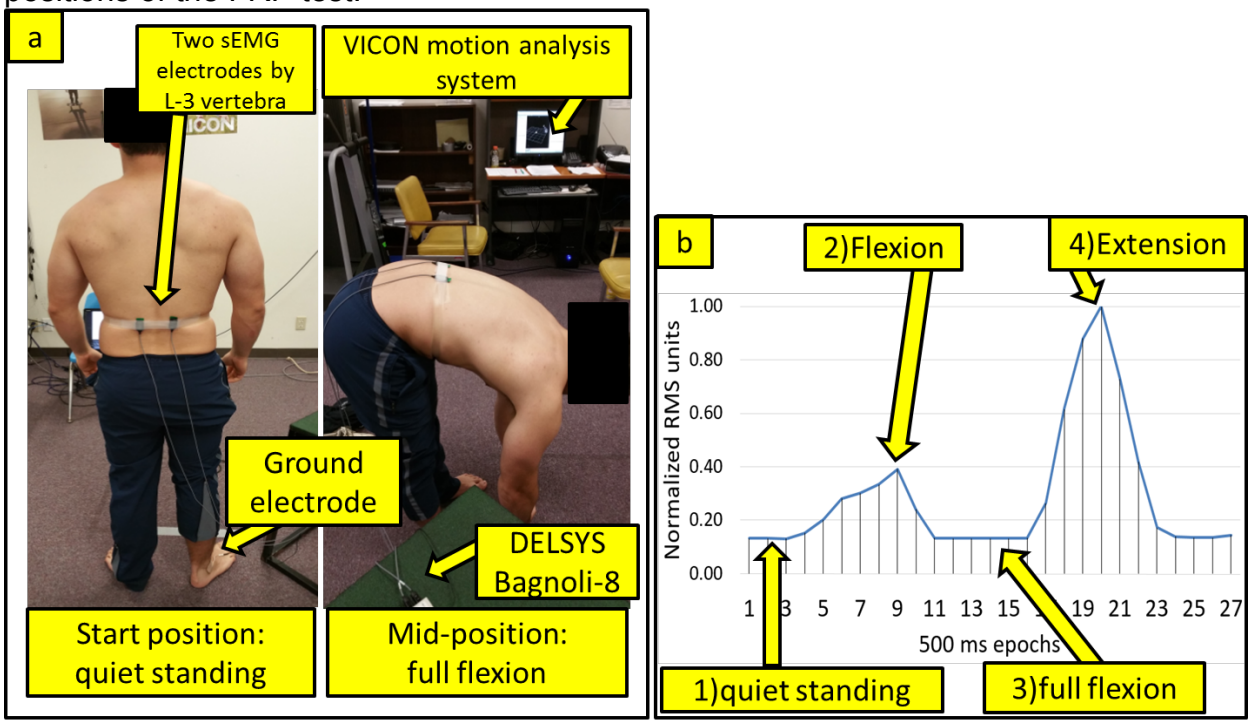


Figure 3. Image of a participant connected on the ResisTrac for the horizontal leg press against 2 bungee cords of resistance. Participants engaged in this exercise for 8 minutes. They would bend their knees until they reached 90 degrees and then extend their knees to just under lockout. Participants were asked to extend their knees at the same

pace as an online metronome set to chime every 2 seconds. Participants also had silver reflective markers placed on a few points on their limbs, but ultimately that data was not used in this study from the 3D motion analysis software.

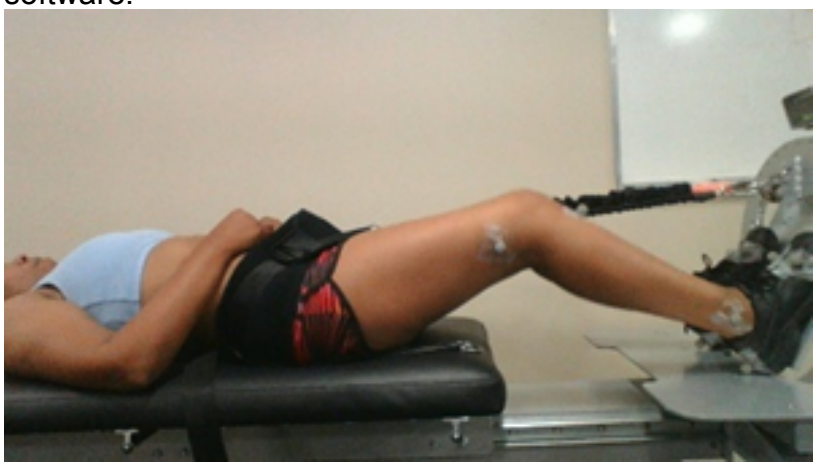


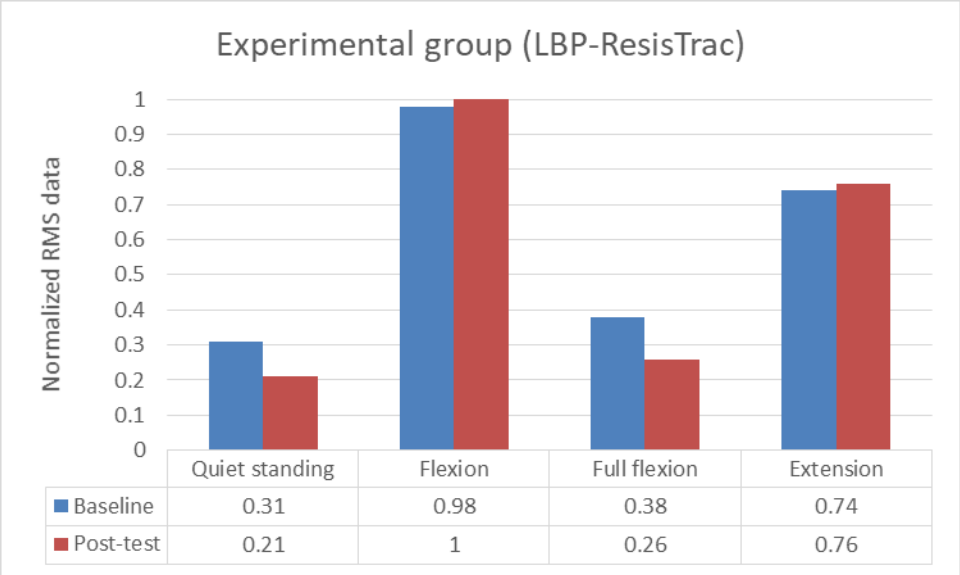
Figure 4. Study inclusion and exclusion criteria.

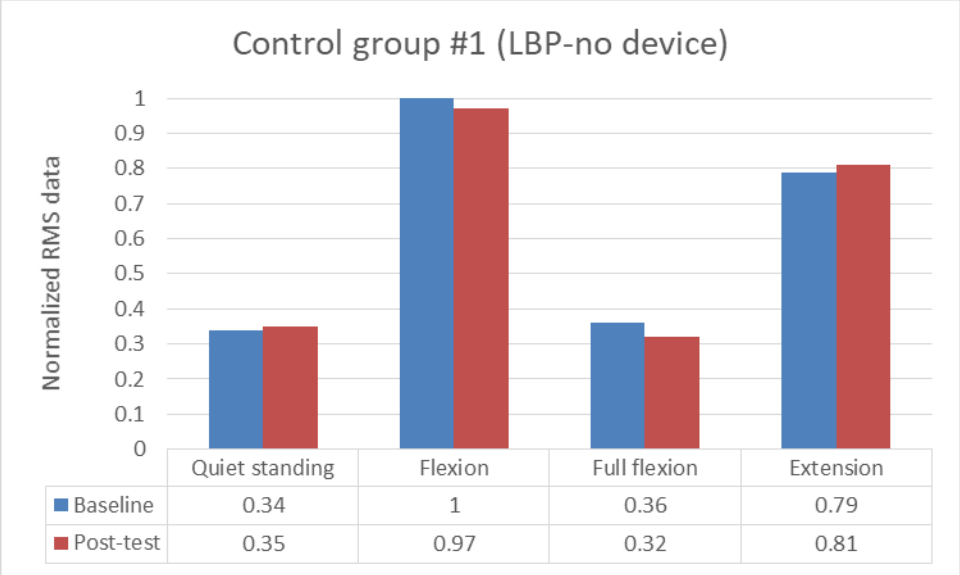
Inclusion criteria were:
1) college students 18-65 years of age 2) provide written informed consent 3) participants without low back pain for control groups 4) participants with low back pain for one control group and experimental group

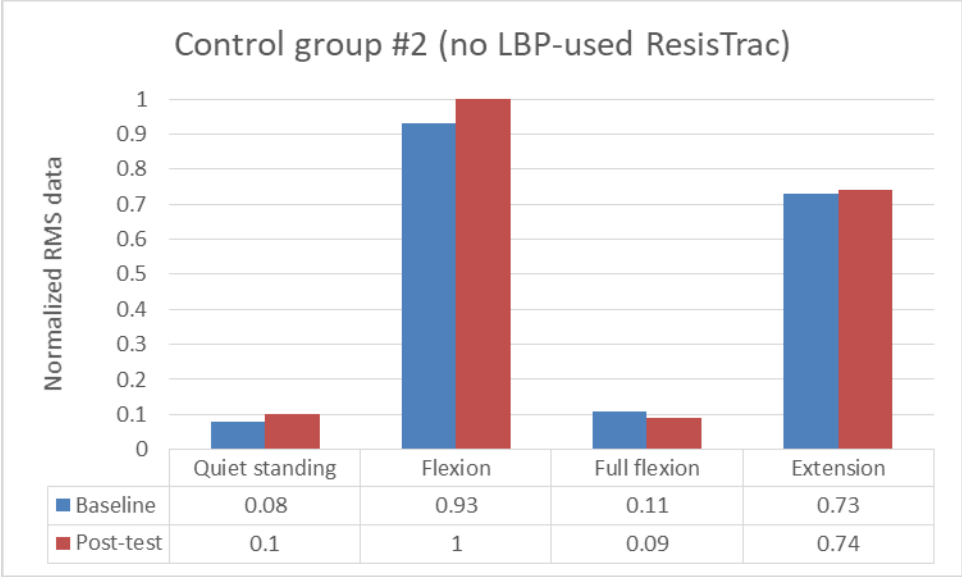
Study participants with any of the following were excluded from the study:
1) pregnant 2) spine or lower limb surgery 3) twisted ankle 4) skin disease affecting the lower back 5) sunburn affecting the lower back

Figure 5. Baseline and post-test results for the surface EMG flexion relaxation phenomenon (FRP) test. All data normalized to highest sEMG reading per group amongst the four phases of the FRP test (the

1.00), pre and post. Note how at post-test the LBP-ResisTrac group demonstrated reduced muscle tension during quiet standing and full flexion in relation to control group #1. This was reflective that the device was helping to relax the localized musculature and correlates with the decrease in pain seen on the NRS and functional NMQ. The graphs for control groups #2 and #3 were as expected since those participants did not have any baseline pain. This data does demonstrate though that the device, when utilized as described in this study, did not impair muscle activation patterns in healthy individuals.






Control group #2 (no LBP-used ResisTrac)
Normalized RMS data
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Quiet standing
Flexion
Full flexion
Extension
Baseline 0.08 0.93 0.11 0.73
Post-test 0.1 1 0.09 0.74

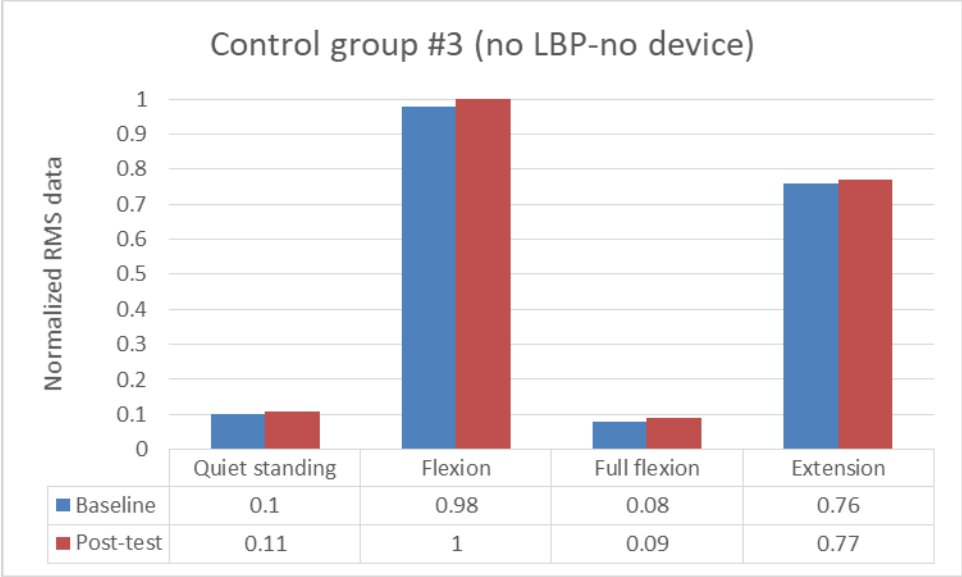

Control group #3 (no LBP-no device)
Normalized RMS data
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Quiet standing
Flexion
Full flexion
Extension
Baseline 0.1 0.98 0.08 0.76
Post-test 0.11 1 0.09 0.77

Table 1. Baseline participant demographics for the study groups compared. Data analyzed with a one-way ANOVA. The data demonstrates that all 4 groups were reasonably similar in attributes.

	LBP-traction	LBP - no traction	No LBP-traction	No LBP- no traction	
	Experimental	Control #1	Control #2	Control #3	*p* value
Sex (M/F)	8/7	6/9	9/6	7/8	
Age (y)	26.1±3.7	27.8±4.3	27.6±4.7	27.7±4.9	0.664
Mass (kg)	73.1±13.3	68.9±13.1	72.3±12.4	73.7±12.7	0.742
Height (m)	1.78±0.10	1.76±0.11	1.75±0.10	1.78±0.10	0.839
Body Mass Index (kg/m^2)	22.9±2.9	22.2±4.2	23.7±4.0	23.4±4.2	0.732
Age range (yrs)	22-36	23-36	22-38	24-35	

Most data listed as mean ± SD.

Table 2. Baseline and post-test results for the low back pain Numeric pain Rating Scale and Nordic Musculoskeletal Questionnaire pain/discomfort (1-5) scale. For the NMQ 5= maximal discomfort and 1= no discomfort. The LBP-traction group (experimental group) improved lower back pain from 2.8 to 2.1 and lower back discomfort from 3.3 to 1.7. The no traction control group did not demonstrate any improvement in pain or symptoms.

	LBP-traction	LBP - no traction	
	Experimental	Control #1	*p* value
Low back pain-base	2.8±0.7	2.9±0.6	0.308
Low back pain-post	2.1±0.6	2.8±0.4	
p value	0.003	0.334	
NMQ UBP-base	2.5±0.7	2.7±0.8	0.644
NMQ UBP-post	2.3±0.8	2.6±0.6	
p value	0.217	0.719	
NMQ LBP-base	3.3±0.6	3.5±0.6	0.715
NMQ LBP-post	1.7±0.6	3.3±1.1	
p value	0.000	0.670	

Most data listed as mean ± SD.