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A RANDOMIZED CLINICAL TRIAL COMPARING EXTENSIBLE AND INEXTENSIBLE LUMBOSACRAL ORTHOSES AND STANDARD CARE ALONE IN THE MANAGEMENT OF LOWER BACK PAIN

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Abstract

Study Design—Single blinded, randomized clinical trial for the evaluation of lumbosacral orthoses (LSOs) in the management of lower back pain (LBP).

Objective—To evaluate the effects of two types of LSO on self-rated disability in patients with lower back pain.

Summary of Background Data—LSOs are commonly used for the management of LBP, but their effectiveness may vary due to design. An inextensible LSO (iLSO) reduce trunk motion and increases trunk stiffness, whereas an extensible LSO (eLSO) does not.

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Methods—98 participants with LBP were randomized to three groups: 1) Standard care group (SC), which included medication and physical therapy (n=29), 2) SC with eLSO (eLSO group) (n=32), and 3) SC with iLSO (iLSO group) (n=37). Outcome measures were evaluated before and after 2 weeks of treatment: modified Oswestry Disability Index (ODI), Patient Specific Activity Score (PSAS), pain ratings, and Fear and Avoidance Beliefs Questionnaire (FABQ).

Results—There were no statistically significant differences between groups at baseline. Compared to the SC alone, iLSO group showed greater improvement on the ODI scores (p=.01), but not the eLSO group. The ODI scores improved by a mean of 2.4 (95% CI −2.2, 7.1), 8.1 (95% CI 2.8, 13.4), and 14.0 (95% CI 8.2, 19.8) points for SC, eLSO, and iLSO groups respectively. Individuals wearing the iLSO had 4.7 times higher odds of achieving 50% or greater improvement in the ODI scores compared to those assigned to SC (95% CI 1.2, 18.5, p=0.03). Both the eLSO and iLSO groups had a greater improvement in the PSAS scores compared to SC (p=.05 and p=.01, respectively), but the change did not meet the minimal clinically important difference. Pain ratings improved for all three groups, with no statistical difference between them. Finally, no significant differences across groups were found for the FABQ.

Conclusions—An iLSO led to greater improvement in ODI scores in comparison with SC and an eLSO. We surmise that the likely mechanism responsible for this difference in outcome was the added trunk stiffness and motion restriction by the iLSO.

Keywords

back pain; low back pain; randomized clinical trial; brace; lumbar belt; rehabilitation; back supports; lumbar supports; recurrent low back pain

INTRODUCTION

Lumbosacral orthoses (LSOs) are relatively inexpensive modalities that are commonly used in the management of LBP.[1, 2] Several theories are proposed for how LSOs might be effective in alleviating LBP: reducing range of motion,[3-10] improving proprioception or kinesthesia,[11-15] and stiffening of the trunk.[3, 4, 7, 13, 16-18] Increased trunk stiffness and limited range of trunk motion have been demonstrated in response to trunk perturbations when wearing a LSO.[3, 16, 19, 20] The added stiffness could reduce the overall demand on trunk muscle activity during activities of daily living, preventing muscle fatigue from compounding the symptoms of LBP.[19, 21, 22] This mechanism of LSO function could be especially effective in individuals with LBP who present with the loss of spinal stiffness[23-28] or demonstrate aberrant spinal motions on fluoroscopic imaging.[29] Augmentation of trunk stiffness depends on the LSO design and material properties. Cholewicki, et al. evaluated two types of LSOs: an extensible LSO (eLSO) made of neoprene and lycra and an inextensible LSO (iLSO) made of polyester and nylon.[20] The material properties of the iLSO were much stiffer than the eLSO. The iLSO decreased trunk displacement with perturbation and increased trunk stiffness by 14%, while there was no difference in trunk displacement or stiffness with using the eLSO compared to a no-LSO condition.

Studies that evaluated clinical outcomes with LSOs have not described the stiffness properties of the LSOs used and thus, their effectiveness in augmenting trunk stiffness is

unknown. The use of LSOs has been compared to no intervention,[30-37] and other interventions. [31, 33, 35, 36, 38, 39,40] The conclusion from the Cochrane Back Review Group about such studies to date is that it remains unclear whether LSOs are effective in treating LBP.[1] The LSO type may explain this conclusion. Therefore, there is a need for additional high quality randomized clinical trials (RCT) that examine the influence of LSO characteristics on clinical outcomes.[1]

The purpose of this study was to compare the short-term clinical outcome between patients with LBP using an iLSO or eLSO along with standard care (SC). Both LSO groups were also compared to a group receiving SC only. While trunk stiffness has been demonstrated to increase with the iLSO and not with the eLSO[20] used in this study, there are no data comparing the clinical outcomes between these two specific designs of LSOs. Our hypothesis was that the iLSO would produce greater short-term (two weeks) improvement in self-perceived disability and pain due to LBP compared to eLSO or SC alone.

MATERIALS AND METHODS

Trial design

The study is a RCT using an intention to treat analysis, approved by an Institutional Review Board. Following signing an informed consent and HIPAA authorization, participants were randomized into one of three intervention groups: 1) SC (Table 1) 2) SC + eLSO, and 3) SC + iLSO. Participants received two weeks of physical therapy from the time of entering into the study with the treatment frequency at the discretion of the physician or physical therapist (PT). Participating clinicians were encouraged to use a classification-based treatment approach,[41, 42] but were allowed to determine the actual treatment to reflect real-world clinical outcomes.

Treatment group assignments were randomized using an online random number generator (RANDOM.ORG). Clinicians were given a key for group assignment based on the random number. The random number was placed in a sealed standard white opaque envelope. Envelopes provided to the clinicians were numbered consecutively from 1 through 50, so the clinician did not know the group assignment until the envelope was opened after the consent was signed. The numbered envelopes were matched to patients sequentially as they sought care. The participants receiving a LSO were not told what type of LSO they were given.

Participants were treated by five PTs, with each having more than 10 years of experience. Each PT had advanced qualifications: three board certified in orthopaedic physical therapy, four certified in manual orthopaedic physical therapy, and one certified in the McKenzie method. All PTs received an initial one-hour training session and a video about the procedures for the study. Periodic meetings were held throughout the study to review the procedures.

Participants

Inclusion criteria were 18 years of age or older, with a primary report of acute, sub-acute, or chronic LBP. Exclusion criteria are listed in Table 2.

Examination and Intervention

Participants completed a review of systems, a history, symptom rating on a 0 to 10 numeric scale, and outcome measures to be described later. A standardized examination was performed.

Participants receiving a LSO received either an eLSO (Mueller Sports Medicine, Inc., Prairie du Sac, WI, USA), or an iLSO (QuickDraw Pro, Aspen Medical Products Inc., Long Beach, CA, USA). Both groups were given standardized instruction on donning and adjusting the LSO; and were instructed to wear it daily, particularly during activities that were noted to aggravate symptoms.

Outcomes measures

The primary outcome measure was the modified Oswestry Disability Index (ODI).[43] Secondary outcomes were the Patient Specific Activity Scale (PSAS), the Fear Avoidance Beliefs Questionnaire (FABQ) for both work (FABQ_W) and physical activity (FABQ_PA), and reported worst, best, and present levels of pain with a Numerical Pain Rating Scale (NPRS).

The modified ODI was used to measure self-reported disability.[44] The minimal clinically important difference (MCID) has been reported to be from six[45] to 10 points.[45-47] In addition, a 50% reduction or greater in the ODI scores has been considered a rigorous clinically important outcome.[48] The PSAS required the participant to record a minimum of three activities that aggravated symptoms on a scale from 0 (could not do the activity because of symptoms) to 10 (no problem or symptoms with the activity). The PSAS has been shown to be responsive to improvement with LBP.[44] The MCID for the PSAS for patients with chronic LBP is 1.4 to 2 points.[49]

The Numerical Pain Rating Scale (NPRS)[50] was used to record the patient's level of pain using an 11-point ordinal scale ranging from 0 “no pain” to 10 “worst pain imaginable.” Change in score between 1.5 and 2.4 represents the MCID.[45, 49] The FABQ[51] has two sections of questions (work and physical activity) and was used to quantify the patient's fear of pain and beliefs about avoiding work and physical activity. We were unable to find data related to the MCID for the FABQ.

Data Analysis

Data were analyzed using SAS version 9.2 based on an intention-to-treat analysis according to the randomized group assignment using the last observation carried forward method. To evaluate the effectiveness of the randomization scheme, treatment groups were compared in terms of baseline demographic and clinical characteristics using chi-square and an analysis of variance (ANOVA) for categorical and continuous variables respectively.

For the primary outcome, the effect of an iLSO versus an eLSO or SC alone were compared based on the change in ODI scores across groups using an analysis of covariance (ANCOVA) with treatment group as the main predictor adjusted for baseline ODI scores. To determine the odds of treatment success, we fit a logistic regression model to predict success using the more stringent 50% or greater improvement in ODI score criteria.[48] We also fit a

separate logistic regression model using the MCID of 6 points to determine the odds of outcome success by treatment group assignment.[47] Finally, we reported the number and percentage of participants in each treatment group who achieved success at both the 50% or greater and the 6-point MCID level.

The secondary outcomes PSAS, NPRS, the FABQ_W, and FABQ_PA were assessed for the differences between groups using an ANCOVA similar to the model for the main outcome. Separate ANCOVA models were fit with the change in score as the outcome and treatment group as the primary predictor, adjusted for respective baseline scores. Additionally, for the PSAS and NPRS, "success" was defined as a 2.0 and 2.4 or greater improvement respectively at two-week follow up. We fit separate logistic regression models to compute the odds ratio of a successful outcome by treatment group, first comparing each group separately (i.e., iLSO vs. eLSO vs. SC), and secondly, comparing "any LSO" (either iLSO or eLSO) to no LSO (SC group). The analyses for the FABQ_W and FABQ_PA were conducted using the ANCOVA model only, because there are no data to determine a successful versus unsuccessful treatment outcome using these scores.

Power and sample size calculations

Initial sample size and power calculations were performed based on results reported in the literature and indicated that 50 patients per group would yield 97% power. However, we were not able to recruit the full 50 participants per group, and recalculated the power using the actual numbers. We found that with 29, 32, and 37 participants in the SC, eLSO, and iLSO groups respectively, with an overall mean baseline ODI score of 36.8 and 16.1 standard deviation, we would have 80% power to detect a 6-point change between any pair-wise group comparison.

RESULTS

Of the 148 participants screened, 98 met all eligibility requirements, gave informed consent, and were randomized into one of the three groups (Figure 1). Treatment groups were well matched with no significant differences in any baseline characteristics (Table 3). All 98 participants completed the 2 week study.

Participant Reported LSO Use

Across both LSO groups, 50 participants turned in a completed diary, 25 from each group. The mean wearing time for the eLSO was 4.8 hours daily with 78% reporting wearing the LSO daily. The mean wearing time for the iLSO was 5.0 hours per day, with 62% reporting wearing the LSO daily. No adverse events were reported during the study.

ODI

The within-group mean improvement in ODI scores between baseline and follow up was 2.4 (95% CI −2.2, 7.1) for the SC group, 8.1 (95% CI 2.8, 13.4) for the eLSO, and 14.0 (95% CI 8.2, 19.8) for the iLSO. Thus, the mean improvement in both the eLSO and iLSO treatment groups reached the MCID (6-point change or greater), but not in the SC group (Figure 2 and Table 4). Results of the ANCOVA to assess differences in treatment effects between groups

suggested that participants in the iLSO group had greater improvement in the mean ODI score compared to the SC group (Table 5).

At the more stringent 50% improvement threshold for success, 3 (10%), 5 (16%), and 13 (35%) of participants in the SC, eLSO, and iLSO group, respectively, reported a successful outcome for the ODI. At the MCID of six points, 11 (38%), 19 (59%), and 24 (65%) of participants in the SC, eLSO, and iLSO group, respectively, reported a successful outcome for ODI (Table 6).

A separate logistic regression model for treatment success (50% or greater improvement) versus unsuccessful treatment for the ODI, with success as the dependent variable and treatment group as the independent variable, showed that individuals wearing the iLSO had 4.7 times higher odds of achieving success compared to those assigned to SC (95% CI 1.2, 18.5). We then fit a similar logistic model using the six-point MCID improvement in ODI score to define success. This model showed that participants in the iLSO group had 3.0 times higher odds of success compared to those in the SC group (95% CI 1.1, 8.3) (Table 7).

PSAS

The mean improvements in PSAS scores between baseline and follow up for the SC, eLSO, and iLSO groups were −0.4 (95% CI −1.3, 04), −1.2 (95% CI −1.9, −0.5), and −1.8 (95% CI −2.6, −1.0) respectively. Therefore, none of the groups achieved the MCID in the mean PSAS score of 2 points (Table 4). The ANCOVA revealed that participants in both the eLSO and iLSO group reported greater improvement in PSAS scores than participants in the SC group (Table 5). Successful outcome was reported by 6 (21%), 10 (31%), and 13 (35%) of participants in the SC, eLSO, and iLSO group respectively (Table 6). No significant findings were noted in the logistic regressions to predict successful outcome (Table 7).

NPRS, FABQ_W and FABQ_A

All three groups met or exceeded the MCID in pain scores (Table 4). At this threshold, 16 (55%), 24 (75%), and 26 (70%) participants reported a successful outcome for NPRS in the SC, eLSO, and iLSO group, respectively (Table 6). We found no significant differences across groups in mean change in NPRS scores (Table 5) or in the odds of success (Table 7). Lastly, no significant differences across groups were found for the FABQ_PA or the FABQ_W (Tables 4 and 5).

Number Needed to Treat

The number needed to treat (NNT) was calculated based on the ODI outcomes. We calculated the NNT to achieve a 50% decline from baseline to follow-up (2 weeks) including all participants. Comparing the iLSO group to SC, the NNT was 3.9 (95% CI 2.2, 15.2), and comparing the eLSO group to SC, the NNT was 29.0 (95% CI 5.0, ∞). Comparing iLSO to eLSO the NNT was 6 (95% CI 2.5, ∞)

DISCUSSION

We examined two types of LSOs with known stiffness properties and known effects on trunk stiffness.[20] The results suggest that an iLSO would be beneficial as an additional intervention to SC in the short-term for a number of patients with LBP. The iLSO group yielded greater improvement in clinical outcomes compared to SC on the ODI, whereas the eLSO group did not differ from SC. Participants with improved ODI scores included patients who were overweight, had high hip to waist ratios, high body mass indexes, and with acute, subacute, and chronic LBP. Overall, 75% and 70% of participants in the eLSO and iLSO groups respectively demonstrated improvement in the pain scores that met the MCID, while only 55% met the MDIC in the SC group. Other studies have found similar results.[30, 35]

The NNT with the iLSO indicates that for every four patients with LBP who receive an iLSO, there should be one less outcome where the ODI fails to improve by at least 50%. This result is difficult to compare to studies involving different outcome measurements and thresholds.[52] The 50% change in the ODI appears to be a more rigorous threshold than used in other studies.[48] Future studies would benefit from the use of standardized outcomes measurement tools for comparative treatment interpretations.

We surmise that the main mechanism for the difference seen in outcomes between the iLSO, eLSO, and the SC groups is due to the added trunk stiffness and motion limitation that the iLSO provides. The augmentation of trunk stiffness with an iLSO is expected to lead to a small reduction in trunk muscle activation.[19] This hypothesis is supported with experimental data.[21, 22] Thus, an iLSO may reduce pain and improve function by reducing the activity of spinal muscles that are over-active to produce intrinsic compensatory stiffness to the spine.[53-58] In addition, aberrant intervertebral motion,[24, 28, 29] indicative of changes in motor control, may well be the type of problem that will respond favorably to the addition of extrinsic trunk stiffness. It is presently unknown what effect the style of orthosis, used in the present study, has on individual segmental motions. However, it can be deduced from the overall range of lumbar motion that the iLSO must reduce segmental motions at some spinal levels.

Our intent was to blind participants to the type of the LSO they received, but we cannot be assured that some participants did not deduce the type of orthoses they were using. Participants were not informed which type of orthosis was hypothesized to provide best results. The physical therapists were not blinded, and this potentially could bias the study. However, outcomes were self-reported, not by a physician or physical therapist, which should help to control for this bias.

In the present study, patients were not classified as to the type of LBP. Individuals with LBP may have more favorable response when matched to an intervention that offers a high probability for success.[41, 42] Even without optimal patient selection, this study demonstrated substantially better outcomes when iLSO was used in addition to SC when compared with SC alone.

While participants were taught how to don the LSO and were given specific instructions on how to wear the LSO, we were unable to directly verify that LSOs were worn according to the instructions, or that they did not displace on the subject during activity. None of the participants reported discomfort with the LSO and the compliance rate of 62-78% was similar to another study.[38] Future investigations would benefit from automated logging to monitor LSO use and dose-response.

It is important to study the long-term outcome with the use of a LSO, as well as patient behavior if a LSO is readily available when LBP episode starts. Future studies determining the mechanism for the LSO to assist with LBP may also provide insight into better design of the LSOs. If the increase in stiffness is an important factor in improving function and reducing disability, then specific interventions and behaviors that accomplish this along with the short-term use of a LSO may provide improvement in the management for some aspects of LBP.

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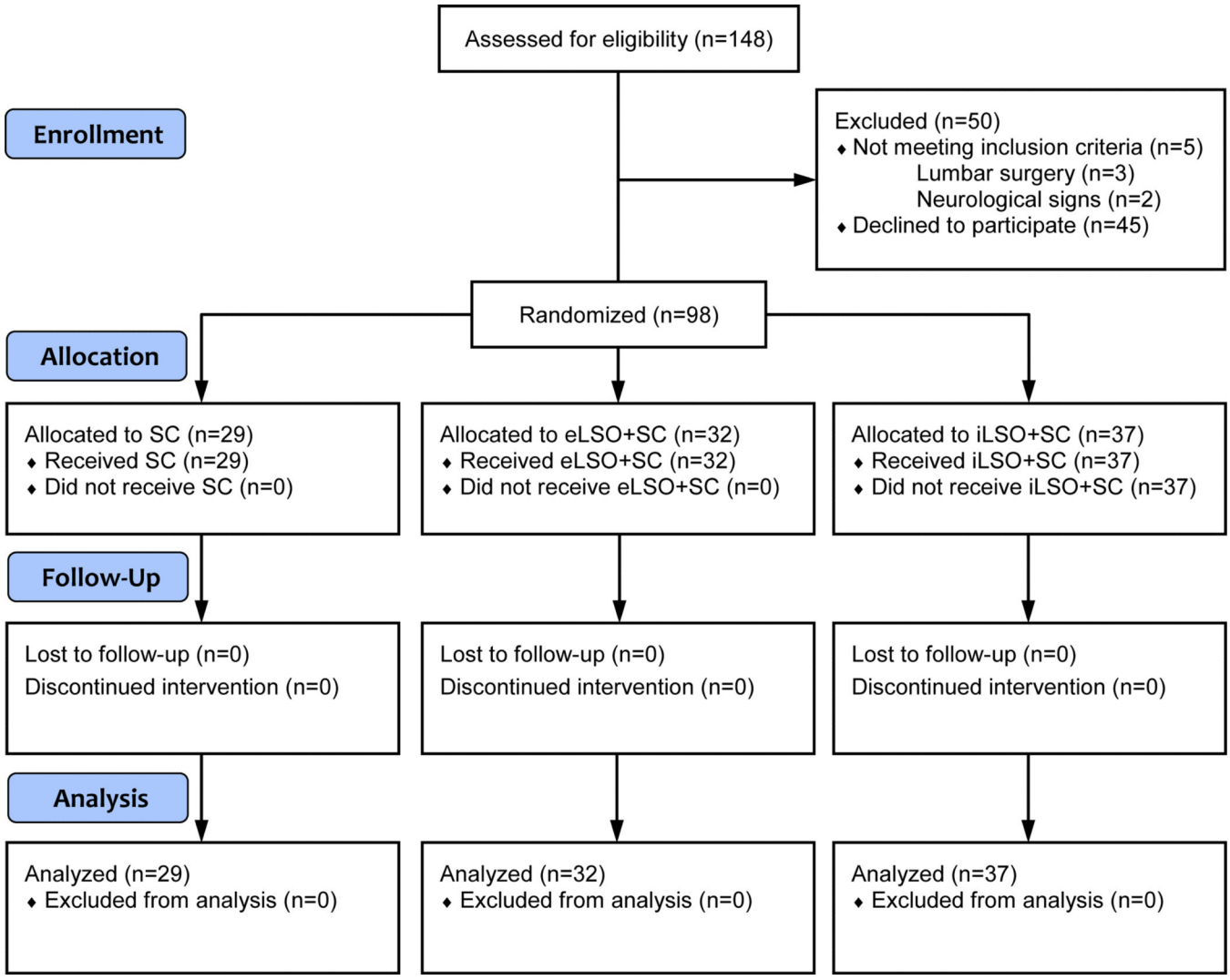

Figure 1.

Flow Diagram of Study Participants Throughout the Study Period.

Standard care (SC) included medication, advice, and physical therapy. The eLSO intervention consisted of an extensible orthosis plus standard care (eLSO). The iLSO intervention consisted of an inextensible orthosis plus standard care (iLSO).

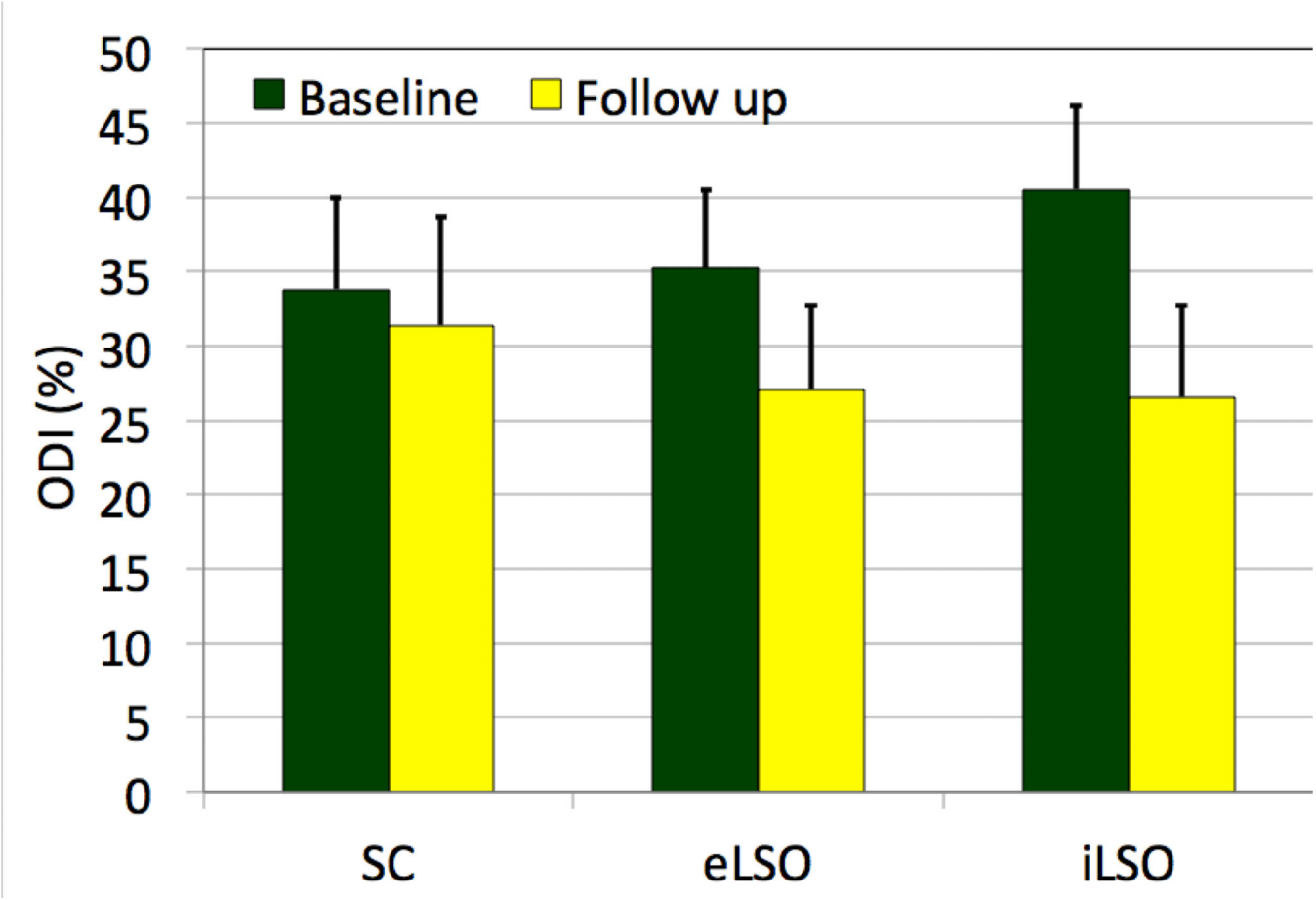

Figure 2.

Mean Oswestry Disability Index Scores for Each Treatment Group: Pre and Post Treatment. Mean scores and confidence intervals for the Oswestry Disability Index (ODI) at baseline and at 2-weeks for the standard care (SC), extensible orthosis (eLSO+SC), and inextensible orthosis (iLSO+SC) groups.

Table 1

Treatments given to participants as standard care

Standard Care:
Physician advice and medication (no injections during the study period)
Treatments included in the physical therapy regimen:
Posture and activity education
Stabilization exercise
Centralization exercise
Aerobic exercise
Manual therapy: mobilization/manipulation
Electrical stimulation
Traction
Soft tissue manipulation / massage
Cold pack/moist heat, ultrasound

Table 2

Exclusion Criteria

Previous spinal surgery
Litigation related to LBP
Neurological disease or injury
Systemic inflammatory disease
Current pregnancy
Acute fracture
Tumor or metastatic disease
Systemic or spinal infection
Presence of pathological reflexes (e.g., Babinski)
Presence of lower extremity pain upon cervical motion
The presence of two or more of the following signs: diminished lower extremity strength following a myotomal distribution, diminished sensation, and/or absence of deep tendon reflexes.

Table 3

Baseline subject demographic and clinical characteristics. (Continuous variables reported as *Mean* (*SD*) unless otherwise stated).

Variable	SC n=29 30%	eLSO n=32 33%	iLSO n=37 38%	Total N=98	p[a]
Gender					0.46
Female	18 (62%)	22 (69%)	20 (54%)	60 (61%)	
Male	11 (38%)	10 (31%)	17 (46%)	38 (39%)	
Race					0.66
Caucasian	8 (28%)	10 (31%)	8 (22%)	26 (27%)	
African American	21 (72%)	22 (69%)	29 (78%)	72 (73%)	
Age[b]	45.0 (16.6)	48.8 (15.6)	50.4 (14.0)	48.4 (15.3)	0.38
Waist to hip ratio	0.9 (0.1)	0.9 (0.1)	0.9 (0.1)	0.9 (0.1)	0.16
Height (cm)	26.3 (1.6)	26.1 (2.1)	26.4 (1.9)	26.3 (1.8)	0.75
Weight (kg)	87.3 (19.1)	78.0 (20.0)	88.7 (21.5)	84.8 (20.6)	0.09
BMI[b]	29.9 (7.6)	26.8 (5.5)	30.2 (7.9)	29.0 (7.2)	0.13
Back and buttock pain	29 (30%)	32 (33%)	37 (38%)	98 (100%)	1.0
One or both thigh pain					0.98
No	17 (59%)	18 (56%)	21 (57%)	56 (57%)	
Yes	12 (41%)	14 (44%)	16 (43%)	42 (43%)	
Pain past the knee					0.29
No	21 (72%)	28 (88%)	31 (84%)	80 (82%)	
Yes	8 (28%)	4 (13%)	6 (16%)	18 (18%)	
Paresthesia					0.26
Missing	0 (0%)	0 (0%)	2 (5%)	2 (2%)	
No	19 (66%)	19 (59%)	17 (46%)	55 (56%)	
Yes	10 (34%)	13 (41%)	18 (49%)	41 (42%)	
Education (years)	14.9 (2.2)	14.9 (2.9)	14.9 (2.3)	14.9 (2.4)	0.97
Mean (SD) Range	11 - 17	7 - 17	10 - 17	7 - 17	
Education (categorized)					0.75
Missing	4 (14%)	5 (16%)	10 (27%)	19 (19%)	
Less than HS grad	1 (3%)	3 (9%)	2 (5%)	6 (6%)	
HS graduate	7 (24%)	6 (19%)	6 (16%)	19 (19%)	
Post HS education	17 (59%)	18 (56%)	19 (51%)	54 (55%)	
Number of previous episodes					0.74
0	6 (21%)	9 (28%)	6 (16%)	21 (21%)	
1	4 (14%)	1 (3%)	4 (11%)	9 (9%)	
2-4	8 (28%)	8 (25%)	9 (25%)	25 (26%)	
>4	11 (38%)	14 (27%)	17 (46%)	42 (43%)	
Duration of symptoms					0.80
≤ 14 days	5 (17%)	6 (19%)	9 (24%)	20 (21%)	
≤ 3 months	5 (17%)	6 (19%)	4 (11%)	15 (15%)	
3 months to 1 year	6 (21%)	10 (31%)	8 (22%)	24 (24%)	

Variable	SC n=29 30%	eLSO n=32 33%	iLSO n=37 38%	Total N=98	p[a]
> 1 year	13 (45%)	10 (32%)	16 (43%)	39 (40%)	
Constant pain					0.47
Missing	0 (0%)	0 (0%)	2 (5%)	2 (2%)	
No	15 (52%)	15 (47%)	18 (49%)	48 (49%)	
Yes	14 (48%)	17 (53%)	17 (46%)	48 (49%)	
Episodes Increasing in frequency					0.26
Missing	1 (3%)	0 (0%)	1 (3%)	2 (2%)	
No	16 (55%)	10 (31%)	14 (38%)	30 (41%)	
Yes	12 (41%)	22 (69%)	22 (59%)	56 (57%)	
Weeks since onset	n=18	n=22	n=23	n=63	0.52
Mean (SD)	10.3 (10.1)	17.5 (15.6)	13.7 (15.2)	14.0 (14.2)	
Range	1 - 40	1 - 52	0 - 52	0 - 52	
Symptoms worsening					0.60
Missing	1 (3%)	0 (0%)	1 (3%)	2 (2%)	
No	17 (59%)	14 (44%)	19 (51%)	50 (51%)	
Yes	11 (38%)	18 (56%)	17 (46%)	46 (47%)	
Symptoms with first use of LSO					0.44
Missing	0 (0%)	3 (9%)	1 (3%)	4 (4%)	
Feels better	NA	15 (47%)	19 (51%)	50 (51%)	
No change or worse	NA	14 (44%)	17 (46%)	44 (45%)	
Baseline outcome measures					
ODI % score	33.8 (16.2)	35.6 (14.8)	40.5 (16.7)	37.0 (16.1)	0.19
PSAS	4.3 (2.7)	4.8 (1.8)	4.3 (2.3)	4.4 (2.3)	0.46
NPRS	7.6 (1.8)	7.6 (2.0)	7.6 (2.3)	7.6 (2.0)	0.96
FABQ_PA	18.3 (5.6)	17.2 (7.5)	17.0 (6.2)	17.5 (6.4)	0.64
FABQ_W	18.6 (17.5)	19.7 (18.0)	21.0 (16.2)	19.9 (17.0)	0.84
Is condition better, worse, or same over past week(s) prior to treatment?					0.52
Missing	1 (3%)	0 (0%)	2 (5%)	3 (3%)	
Better	16 (55%)	14 (44%)	20 (54%)	50 (51%)	
Worse	5 (17%)	11 (34%)	6 (16%)	22 (22%)	
No change	7 (24%)	7 (22%)	9 (24%)	37 (38%)	
Mean LSO wearing time (hours per day)	NA	4.8	5.0	NA	
Medication Treatment					
Narcotic	5 (17%)	6 (19%)	7 (19%)	18 (18%)	1
Muscle Relaxant	7 (24%)	3 (9%)	5 (14%)	15 (15%)	0.24
NSAID	13 (45%)	15 (47%)	14 (38%)	42 (43%)	0.74
Antidepressant	2 (7%)	4 (13%)	3 (8%)	9 (9%)	0.75

BMI: Body Mass Index; LBP: Low Back Pain; ODI: Oswestry Disability Index; PSAS: Patient Specific Activity Scale; FABQ_PA: Fear and Avoidance Beliefs Questionnaire Physical Activity subscale; FABQ_W: Fear and Avoidance Beliefs Questionnaire Work subscale. NPRS: Numerical Pain Rating Scale.

Treatment groups: standard care alone (SC), extensible LSO+SC (eLSO), and inextensible LSO+SC (iLSO).

[a] p-values refers to differences across treatment groups.

Table 4

Mean (95% CI) differences in outcome measure scores between baseline and follow

Outcome Measure	SC	eLSO	iLSO
ODI	2.4 (−2.2, 7.1)	8.1 (2.8, 13.4)	14.0 (8.2, 19.8)
PSAS	−0.4 (−1.3,0.4)	−1.2 (−1.9, −0.5)	−1.8 (−2.6, −1.0)
NPRS	2.4 (1.4, 3.5)	3.3 (2.2, 4.4)	3.3 (2.3, 4.3)
FABQ_PA	1.5 (−1.0, 4.0)	−0.1 (−3.0, 2.7)	−0.1 (−2.1, 2.3)
FABQ_W	0.6 (−3.2, 3.3)	4.4 (−0.1, 8.9)	5.6 (1.9, 9.3)

Treatment groups: standard care alone (SC), extensible LSO+SC (eLSO), and inextensible LSO+SC (iLSO).

ODI- Oswestry Disability Index; PSAS- Patient Specific Activity Scale; FABQ_PA-Fear and Avoidance Beliefs Questionnaire Physical Activity subscale; FABQ_W- Fear and Avoidance Beliefs Questionnaire Work subscale.

Table 5

Results of ANCOVA for the outcome measures.

Outcome measure[a]	Overall model p value	Pairwise difference in group means at follow up with 95% CI		p-value
ODI	0.0001	SC vs eLSO:	5.3 (−2.0, 12.6)	0.16
		SC vs iLSO:	9.4 (2.2, 16.6)	0.01
		eLSO vs iLSO:	4.1 (−2.8, 11.1)	0.24
PSAS	<0.001	SC vs eLSO:	−1.0 (−2.1, 0.0)	0.05
		SC vs iLSO:	−1.4 (−2.3, −0.4)	0.01
		eLSO vs iLSO:	−0.3 (−1.3, 0.7)	0.50
NPRS	0.001	SC vs eLSO:	−0.7 (−2.1, 0.8)	0.37
		SC vs iLSO:	−0.9 (−2.3, 0.5)	0.20
		eLSO vs iLSO:	−0.3 (−1.6, .1.1)	0.72
FABQ-PA	0.62	SC vs eLSO:	−1.2 (−3.5, 3.4)	0.53
		SC vs iLSO:	−1.2 (−4.8, 2.5)	0.49
		eLSO vs iLSO:	−.1 (−4.8, 2.3)	0.97
FABQ-W	0.31	SC vs eLSO:	3.6 (−1.7, 8.9)	0.18
		SC vs iLSO:	4.3 (−0.8, 9.4)	0.10
		eLSO vs iLSO:	0.7 (−4.3, 5.7)	0.78

Treatment groups: standard care alone (SC), extensible LSO+SC (eLSO), and inextensible LSO+SC (iLSO).

ODI- Oswestry Disability Index; PSAS- Patient Specific Activity Scale; FABQ_PA-Fear and Avoidance Beliefs Questionnaire Physical Activity subscale; FABQ_W- Fear and Avoidance Beliefs Questionnaire Work subscale.

[a]Difference in mean change in scores from baseline to follow up by treatment group, adjusted for baseline score.

Table 6

Number and percentage of participants in each group that achieved a successful outcome for the Oswestry Disability Index (ODI), the Patient Specific Activity Scale (PSAS), and the Numerical Pain Rating Scale (NPRS)

Treatment Success	SC (n=29)	eLSO (n=32)	iLSO (n=37)
ODI[a]	3 (10%)	5 (16%)	13 (35%)
ODI[b]	11 (38%)	19 (59%)	24 (65%)
PSAS[c]	6 (21%)	10 (31%)	13 (35%)
NPRS[d]	16 (55%)	24 (75%)	26 (70%)

Treatment groups: standard care alone (SC), extensible LSO+SC (eLSO), and inextensible LSO+SC (iLSO).

[a] Success was defined as a 50% or greater improvement in ODI scores.

[b] Success was defined as the Minimal Clinically Important Difference of 6 pts.

[c] Success was defined as the Minimal Clinically Important Difference of 2 pts.

[d] Success was defined as the Minimal Clinically Important Difference of 2.4 pts.

Table 7

Results of the separate logistic regression models predicting successful treatment outcomes for the Oswestry Disability Index (ODI), the Patient Specific Activity Scale (PSAS), and the Numerical Pain Rating Scale (NPRS).

Outcome Measure		OR (95% CI)	p
ODI			
Model 1:			
ODI, Success at 50% improvement (ref= SC)			
	eLSO	1.6 (0.3, 7.4)	0.54
	iLSO	4.7 (1.2, 18.5)	0.03
Model 2:			
ODI, Success at 6-pt improvement (ref=SC)			
	eLSO	2.4 (0.8, 6.7)	0.10
	iLSO	3.0 (1.1, 8.3)	0.03
PSAS			
Model 1:			
PSAS, Success at 2-pt improvement (ref= SC)			
	eLSO	1.7 (0.5, 5.6)	0.35
	iLSO	2.1 (0.7, 6.4)	0.21
Model 2[a]:			
No LSO versus any LSO (ref=SC)		1.9 (0.7, 5.4)	0.22
NPRS			
Model 1:			
NPRS, Success at 2.4-pt improvement (ref=SC)			
	eLSO	1.5 (0.6, 3.5)	0.41
	iLSO	1.7 (0.7, 4.1)	0.20
Model 2[b]:			
No brace versus any brace (ref=control)		1.6 (0.7, 3.4)	0.23

Treatment groups: standard care alone (SC), extensible LSO+SC (eLSO), and inextensible LSO+SC LSO).

[a]Model 2 for PSAS compared the standard care treatment group versus either the iLSO or eLSO as a combined category.

[b]Model 2 for NPRS compared the standard care treatment group versus either the iLSO or eLSO as a combined category.