

General

Comparative Effectiveness of Sacroiliac Belt versus Lumbar Orthosis Utilization on Nonspecific Low Back Pain: a Crossover Randomized Clinical Trial

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Background

Back braces are commonly utilized in the management of low back pain (LBP).

Objective

The aim of this study is to evaluate (1) user satisfaction with a sacroiliac belt versus a lumbar orthosis and (2) the effect of a sacroiliac belt versus a lumbar orthosis on pain, functional disability status, and analgesic use for subjects with subacute or chronic non-specific LBP.

Methods

This is a prospective randomized crossover study. For the two-week study period, control group subjects wore the Horizon 627 Lumbar Brace ("lumbar orthosis") during the first week and the Serola Sacroiliac Belt ("sacroiliac belt") during the second week; experimental group subjects wore the sacroiliac belt during the first week and the lumbar orthosis during the second week. User satisfaction (Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 [QUEST 2.0] score), functional disability status (Oswestry Disability Index [ODI]), pain, and analgesic use were recorded.

Results

Overall, the sacroiliac belt demonstrated significantly higher user satisfaction than the Horizon brace (QUEST Score = 20.31 vs. 16.17, $p = 0.0375$) for the entire study period. Significant negative correlations were identified between user satisfaction and functional disability ($t = -4.71$, $p < 0.0001$), pain magnitude ($t = -6.81$, $p < 0.0001$) as well as pain frequency ($t = -6.66$, $p < 0.0001$).

Conclusion

In this prospective randomized crossover study, subject satisfaction was associated with improvements in functional disability, pain magnitude and pain frequency. The sacroiliac belt demonstrated significantly higher user satisfaction and similar effectiveness compared to the lumbar orthosis.

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INTRODUCTION

With a lifetime prevalence of 65-80%, lower back pain (LBP) is pervasive.¹ While most cases resolve during the acute (<4 weeks) stage, 20% progress to the chronic stage (>12 weeks), manifesting as chronic, debilitating pain resulting in functional disability.^{2,3} Lower back pain can have three distinct sources: axial lumbosacral, radicular, and referred.⁴ The etiologies are variable and can be differentiated based upon the patient history, examination and imaging if required. The resulting opportunity costs are devastating, accounting for two-thirds of the estimated \$100 billion in total costs borne by Americans annually due to LBP.⁵

Treatment options for LBP cover a wide spectrum.⁵ Since most patients with acute or subacute low back pain will heal over time, management is initially conservative. This may include superficial heat, exercise, massage, acupuncture, and lumbar support devices.⁵⁻⁷ Patients may then progress to pharmacological treatment such as nonsteroidal anti-inflammatories or skeletal muscle relaxants.⁵⁻⁷ Surgical management may be recommended for patients with disabling back pain who are unresponsive to conservative measures, as well as any red flag indications.⁸

Lumbar support devices, such as back braces and belts, have proved popular as treatment modalities for LBP with no associated reports of serious harm.⁵ One previous study found that long-term use of a lumbar orthosis had no adverse effects on motor function or clinical outcomes.⁹ Although they are safe to use, there is conflicting evidence regarding their effectiveness. A systematic review published by the Cochrane Library concluded that there is a need for further trials to elucidate the effectiveness of lumbar supports.¹⁰

This prospective crossover study aims to identify which lumbar support device may offer superior patient outcomes through evaluating (1) user satisfaction with a sacroiliac belt versus a lumbar orthosis, and (2) the effect of a sacroiliac belt versus a lumbar orthosis on pain, functional disability status and analgesic use in subjects with subacute or chronic non-specific LBP.

MATERIALS AND METHODS

STUDY DESIGN

This is a prospective randomized crossover study. Subjects were recruited and consented at an orthopedic spine clinic affiliated with a large tertiary academic teaching hospital.

ETHICAL CONSIDERATIONS

This study was approved by the Institutional Review Board of Lifespan – Rhode Island Hospital (Board Reference # 418517; 45 CFR 46.110 (4),(7)).

SUBJECTS

The inclusion and exclusion criteria were adapted with modifications from a similar trial conducted by Calmels et al. (2009).¹¹ Male or female subjects between age 18 and 65

with new-onset or recurring nonspecific LBP lasting greater than 1 month (as diagnosed by a spine specialist), and have no contraindications to step I or step II analgesics (NSAIDs or benzodiazepines) were recommended a back brace for the management of LBP and provided written consent were eligible.

Subjects who used a lumbar belt during the last six months, have LBP radiating beyond the knee and/or accompanied by neurological signs (including sciatica), underwent a spinal operation within 5 years of the study, have secondary LBP due to an accident at work, have a history of spinal arthrodesis, suffer from LBP with an inflammatory, tumor, or infectious cause, have a contraindication to step I or step II analgesics (NSAIDs or benzodiazepines), are pregnant or have cognitive conditions preventing them from properly comprehending the protocol or to reliably record the data were not eligible (Table 1).

35 subacute or chronic LBP patients who were ineligible for surgical intervention or preferred non-invasive interventions were originally enrolled by the principal investigator, an orthopedic spine surgeon at the above clinic. 1 control group subject was lost to follow-up. 3 control group subjects and 1 experimental group subject were excluded from analysis due to incomplete forms (Figure 1). The final subject population consisted of 30 subjects, with 16 in the experimental group and 14 in the control group.

EQUIPMENT

Subjects were issued two commercially available braces: (1) the Horizon 627 Lumbar Brace (“lumbar orthosis”) (Aspen Medical Products, LLC, Irvine, CA) and (2) the Serola Sacroiliac Belt (“sacroiliac belt”) (Serola Biomechanics, Inc., Loves Park, IL).^{12,13} Subjects were instructed on how to wear each brace. The lumbar orthosis is applied by securing the brace tightly around the abdomen, with the back panel centered on the lower back. The brace is then tightened and adjusted as necessary. The sacroiliac belt is applied to the middle of the lower back and secured around the front of the body at the inguinal crease. The belt can then be adjusted as required.

DATA COLLECTION

After providing informed consent and enrolling in the study, subjects were randomized into two groups: (1) experimental and (2) control. Control group subjects were instructed to wear the lumbar orthosis for the first 7 days and wear the sacroiliac belt for the subsequent 7 days. Experimental group subjects were instructed to follow the reverse order: wear the sacroiliac belt for the first 7 days and wear the lumbar orthosis for the subsequent 7 days. To prevent any reporting bias, subjects were not informed which brace was “experimental” or “control.”

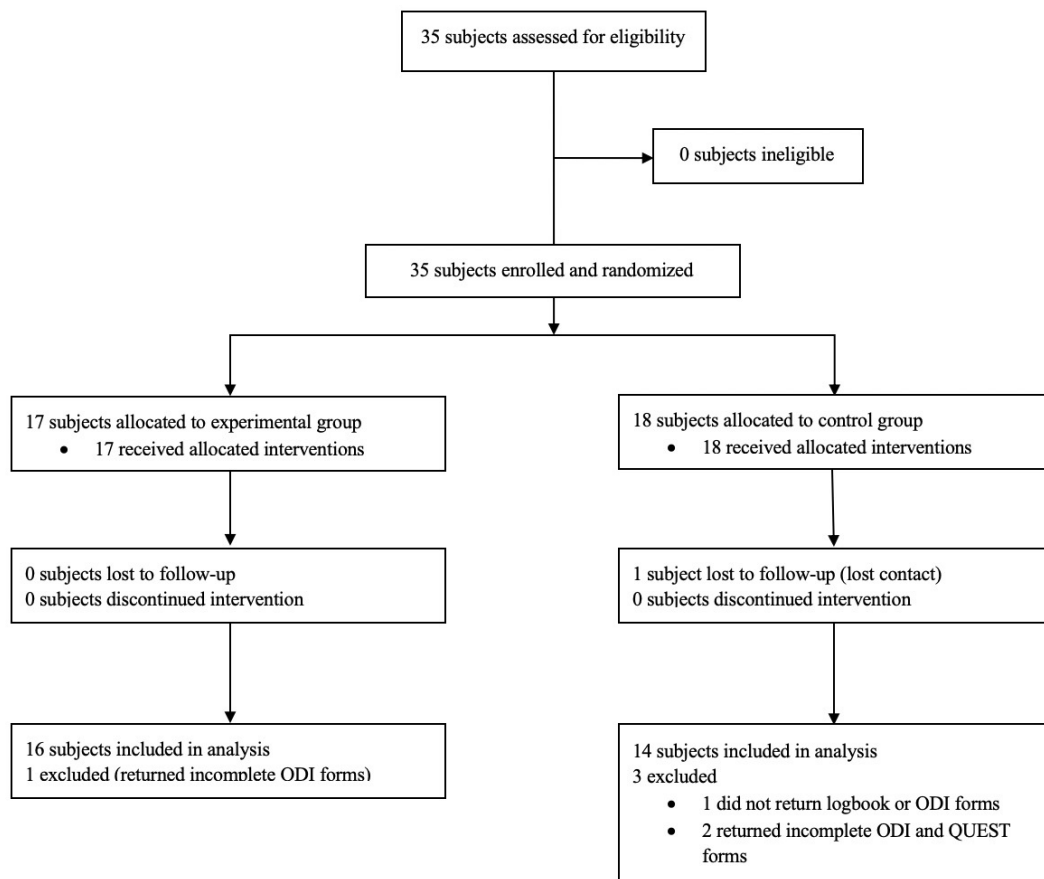
Subjects recorded the following outcome measures for each day: (1) pain magnitude, as assessed using the Numerical Rating Scale (NRS)¹¹; (2) pain frequency, as assessed on a 6-point ordinal scale (0 = none, 1 = rarely, 2 = sometimes, 3 = often, 4 = a lot, or 5 = all the time); (3) analgesic use, as assessed by the medication’s name and daily dosage; (4)

Table 1. (A) Eligibility requirements and (B) exclusion criteria for the study.

A. Eligibility Requirements	B. Exclusion Criteria
- Male or female, age 18-65 - Has undergone treatment for: - An initial episode of nonspecific low back pain (LBP) lasting >1 month - Recurring nonspecific LBP lasting >1 month - No contraindications to: - Step I or II analgesics - NSAIDs - Benzodiazepines - Recommended a back brace for LBP management - Provided written consent for participation	- Lumbar belt use during the last 6 months - LBP irradiating beyond the knee and/or accompanied by neurological signs (including sciatica) - Spinal operation within 5 years preceding the study date - Secondary LBP due to a work accident - History of spinal arthrodesis - LBP with an inflammatory, tumor or infectious cause - Contraindications to: - Step I or II analgesics - NSAIDs - Benzodiazepines - Pregnant - Higher functions do not enable proper comprehension of protocol or reliable data recording

LBP = Low back pain

NSAIDs = Non-steroidal anti-inflammatory drugs

**Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the trial.**

brace use, as assessed by the number of hours the brace was worn each day (there were no restrictions on how few or many hours the brace should be worn).

Subjects' functional disability status was assessed using the Oswestry Disability Index (ODI), a validated 10-question survey designed for subjects with LBP.^{12,13} Subjects completed this on days #0, 7 and 14. User satisfaction was assessed using the Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 (QUEST 2.0) 8-item subscale, a validated tool used in the orthopedic literature.¹⁴ Subjects completed this on days #7 and #14. The subjects'

EMRs were reviewed as needed and with consent to obtain relevant background data.

STATISTICAL ANALYSIS

All statistical analyses were conducted in Stata. Each of the primary outcome measures (functional disability, user satisfaction, pain, analgesic use) were compared between the sacroiliac belt and lumbar orthosis using a two-sample t-test at the 90% significance level.

Pain was measured in four ways: (1) total pain magnitude, (2) total pain frequency, (3) change in pain magni-

tude relative to baseline, and (4) change in pain frequency relative to baseline. Total pain magnitudes and frequencies were summed separately for weeks 1 and 2, as well as for the entire study period. Mean changes in pain magnitude and frequency relative to baseline were also calculated separately for weeks 1 and 2 (by dividing the total pain magnitude/frequency for the week by 7, then subtracting the day #0 pain magnitude/frequency), as well as for the entire study period (by dividing the study period total pain magnitude/frequency by 14, then subtracting the day #0 pain magnitude/frequency) ([Table 2A](#)).

Analgesic use was measured in two ways: (1) number of pills consumed, and (2) change in number of pills consumed relative to baseline. The number of pills consumed was summed separately for weeks 1 and 2, as well as for the entire study period. The change in number of pills consumed relative to baseline was also calculated separately for weeks 1 and 2 (by dividing the number of pills consumed during each week by 7, then subtracting the number of pills consumed on day #0), as well as for the entire study period (by dividing the total number of pills consumed during the study period by 14, then subtracting the number of pills consumed on day #0) ([Table 2B](#)).

In addition to comparing outcome measures by time within groups (i.e., week 1 versus week 2 within each group) ([Table 3A](#)), outcome measures for the two braces were also compared within the overall data ([Table 3B](#)). For the latter comparison, the overall outcome data for the sacroiliac belt was curated by combining week 1 data from the experimental group with the week 2 data from the control group, and the overall outcome data for the Horizon brace was curated by combining week 2 data from the experimental group with the week 1 data from the control group (i.e., combining data from the time periods in which each brace was used) ([Table 3B](#)).

RESULTS

COHORT

The final 30-subject study population consisted of 23 females and 7 males, with an age range of 22 to 88 years and an average age of 57.03 years.

USER SATISFACTION

The sacroiliac belt yielded a significantly higher mean QUEST score than the lumbar orthosis within both the experimental group (24.42 versus 17.24, $p = 0.0106$) and overall data (20.31 versus 16.17, $p = 0.0375$). No statistically significant difference in mean QUEST scores was found between the sacroiliac belt and lumbar orthosis within the control group (25.76 versus 28.61, $p = 0.6181$) ([Table 4](#)).

FUNCTIONAL DISABILITY

No statistically significant difference in mean ODI was found between the sacroiliac belt and lumbar orthosis users within the experimental group (0.351 versus 0.318, $p =$

0.2831), control group (0.224 versus 0.175, $p = 0.2339$) or overall data (0.243 versus 0.250, $p = 0.7849$) ([Table 4](#)).

PAIN

Pain Scale/Magnitude: No statistically significant difference in mean total pain magnitude was found between the sacroiliac belt and lumbar orthosis users within the experimental group (33.59 versus 29.94, $p = 0.3687$), control group (22.25 versus 21.00, $p = 0.3853$) or overall data (25.19 versus 24.03, $p = 0.5579$).

Changes in Pain Magnitude: No statistically significant difference was found for mean change in pain magnitude between the sacroiliac belt and lumbar orthosis users within the experimental group (+0.445 versus -0.076, $p = 0.3687$), control group (-0.759 versus -0.938, $p = 0.3853$) or overall data (-0.206 versus -0.373, $p = 0.5579$).

Pain Frequency: No statistically significant difference in mean total pain frequency was found between the sacroiliac belt and lumbar orthosis users within the experimental group (24.41 versus 23.06, $p = 0.5700$), control group (17.69 versus 17.31, $p = 0.8195$) or overall data (19.22 versus 18.75, $p = 0.7187$).

Changes in Pain Frequency: No statistically significant difference was found for mean change in pain frequency between the sacroiliac belt and lumbar orthosis users within the experimental group (-0.160 versus -0.353, $p = 0.5700$), control group (-0.598 versus -0.652, $p = 0.8195$) or overall data (-0.365 versus -0.433, $p = 0.7187$) ([Table 4](#)).

ANALGESIC USE

Amount of Analgesic Used: No statistically significant difference in total amount of analgesics used was found between the sacroiliac belt and lumbar orthosis users within the experimental group (12.88 pills versus 11.71 pills, $p = 0.7001$), control group (12.56 pills versus 14.38 pills, $p = 0.5065$) or overall data (12.47 pills versus 11.11 pills, $p = 0.4588$).

Changes in Analgesic Use: No statistically significant difference was found for mean change in analgesic use between the sacroiliac belt and lumbar orthosis users within the experimental group (+0.311 pills versus +0.143 pills, $p = 0.7001$), control group (-0.498 pills versus -0.501 pills, $p = 0.5065$) or overall data (-0.220 pills versus -0.222 pills, $p = 0.4588$) ([Table 4](#)).

RELATIONSHIP BETWEEN USER SATISFACTION AND REMAINING OUTCOME MEASURES

Functional Disability: For Week 1 ($t = -4.74$, $p < 0.0001$), Week 2 ($t = -3.83$, $p = 0.001$) and the overall data ($t = -4.71$, $p < 0.0001$), a statistically significant negative correlation was identified between QUEST score and ODI after controlling for brace type. Thus, lower functional disability was associated with higher user satisfaction.

Pain: A statistically significant negative correlation was identified between QUEST score and pain magnitude for Week 1 ($t = -7.25$, $p < 0.0001$), Week 2 ($t = -3.70$, $p = 0.001$) and the overall data ($t = -6.81$, $p < 0.0001$). Thus, lower pain magnitude was associated with higher user satisfaction.

Table 2. Variables calculated for the quantification of pain and analgesic use (“Calculated Variable”), the time period for which each variable was calculated (“Time Period”), and the corresponding method of calculation (“Method of Calculation”).

A. Measurement of Pain		
Calculated Variable	Time Period	Method of Calculation
(1) Total Pain Magnitude	Week 1	Summation of Pain Magnitudes for Days #1-7
	Week 2	Summation of Pain Magnitudes for Days #8-14
	Overall	Summation of Pain Magnitudes for Days #1-14
(2) Total Pain Frequency	Week 1	Summation of Pain Frequencies for Days #1-7
	Week 2	Summation of Pain Frequencies for Days #8-14
	Overall	Summation of Pain Frequencies for Days #1-14
(3) Change in Pain Magnitude	Week 1	Subtraction of Day #0 Pain Magnitude from Division of Week 1 Total Pain Magnitude by 7
	Week 2	Subtraction of Day #0 Pain Magnitude from Division of Week 2 Total Pain Magnitude by 7
	Overall	Subtraction of Day #0 Pain Magnitude from Division of Overall Total Pain Magnitude by 14
(4) Change in Pain Frequency	Week 1	Subtraction of Day #0 Pain Frequency from Division of Week 1 Total Pain Frequency by 7
	Week 2	Subtraction of Day #0 Pain Frequency from Division of Week 2 Total Pain Frequency by 7
	Overall	Subtraction of Day #0 Pain Frequency from Division of Overall Total Pain Frequency by 14
B. Measurement of Analgesic Use		
Calculated Variable	Time Period	Method of Calculation
(1) Number of Pills Consumed	Week 1	Summation of Number of Pills Consumed for Days #1-7
	Week 2	Summation of Number of Pills Consumed for Days #8-14
	Overall	Summation of Number of Pills Consumed for Days #1-14
(2) Change in Number of Pills Consumed	Week 1	Subtraction of Number of Pills Consumed on Day #0 from Division of Total Number of Pills Consumed during Week 1 by 7
	Week 2	Subtraction of Number of Pills Consumed on Day #0 from Division of Total Number of Pills Consumed during Week 2 by 7
	Overall	Subtraction of Number of Pills Consumed on Day #0 from Division of Total Overall Number of Pills Consumed by 14

Table 3. Table representation of the study groups and time periods compared for the study.

A. Comparison of Outcome Measures by Time, Within Groups		
Study Group	Time Period (Brace Used)	
Experimental	Week 1 (Sacroiliac Belt)	Week 2 (Lumbar Orthosis)
Control	Week 1 (Lumbar Orthosis)	Week 2 (Sacroiliac Belt)
B. Comparison of Outcome Measures for the Overall Data		
Study Group	Time Period (Brace Used)	
Experimental	Week 1 (Sacroiliac Belt)	Week 2 (Lumbar Orthosis)
Control	Week 1 (Lumbar Orthosis)	Week 2 (Sacroiliac Belt)

For Table 3B, the two time periods shaded in gray were compared with the two time periods shaded in black.

No significant correlation, however, was identified between QUEST Score and change in pain magnitude for Weeks 1 ($t = -1.00$, $p = 0.327$) or 2 ($t = -0.33$, $p = 0.740$), showing the lack of any meaningful relationship between change in pain magnitude and user satisfaction. A statistically signif-

icant negative correlation was identified between QUEST Score and pain frequency for Week 1 ($t = -8.66$, $p < 0.0001$), Week 2 ($t = -3.90$, $p < 0.0001$) and the overall data ($t = -6.66$, $p < 0.0001$), showing that lower pain frequency is associated with higher user satisfaction. No significant corre-

lation, however, was identified between QUEST Score and change in pain frequency for Week 1 ($t = -0.22$, $p = 0.825$) or Week 2 ($t = \text{approximately } 0.000$, $p = 0.997$), showing the lack of any meaningful relationship between change in pain frequency and user satisfaction.

Analgesic Use: A statistically significant positive correlation was identified between QUEST score and total amount of analgesic used for Week 1 ($t = 1.70$, $p = 0.099$) and the overall data ($t = 1.97$, $p = 0.058$), but not for Week 2 ($t = 1.63$, $p = 0.113$). Thus, the Week 1 data and overall data suggest that a larger amount of analgesic used is associated with higher user satisfaction. No significant correlation, however, was identified between QUEST Score and change in analgesic use for Weeks 1 ($t = -0.87$, $p = 0.392$) or 2 ($t = -0.63$, $p = 0.534$), implying a lack of any meaningful relationship between change in analgesic use and user satisfaction.

DISCUSSION

LBP is often multifactorial in nature and carries a significant psychological component, making user satisfaction an essential component of effective management.^{14,15} To the authors knowledge, our study is the first to directly compare a lumbar orthosis with a sacroiliac belt in the management of LBP. Our study revealed that the sacroiliac belt demonstrated significantly higher user satisfaction and similar effectiveness when compared to the lumbar orthosis.

Several previous studies have examined how user satisfaction and outcomes are associated across multiple orthopedic disciplines. One study showed that the patients most satisfied with their orthosis were the ones with milder disabilities and who used the orthosis for less than one year.¹⁶ Furthermore, the experience of the patient can relate to their subsequent compliance which may have implications on the device efficacy.¹⁷ This is corroborated by our finding that the higher user satisfaction with the type of brace used correlates with significant improvements in multiple outcome measures. Higher user satisfaction, on average, was associated with lower functional disability, as well as lower pain magnitude and frequency, regardless of the type of support device used. The association between higher user satisfaction and higher analgesic use indicates that minimizing biopsychological factors, such as pain, may improve user satisfaction and thus effectively manage chronic conditions such as LBP.

The smaller size of the sacroiliac belt compared to the lumbar orthosis can pose a concern for decreased effectiveness in stabilizing the affected lumbar region and alleviating pain on the part of the sacroiliac belt. However, this concern is alleviated by the lack of any significant difference in pain and functional disability between the users of the two braces, which suggests that the sacroiliac belt is just as effective in these aspects as the lumbar orthosis while yielding higher user satisfaction.^{18,19} A possible explanation for this equal effectiveness is that increased stability provided by the sacroiliac belt at the base of the spine may also contribute to stability in the lumbar spine, simi-

larly to how the base of a column of blocks provides stability for the blocks above.¹³

The most significant finding is that the sacroiliac belt achieved significantly higher user satisfaction than the lumbar orthosis while achieving comparable levels of reduction in pain magnitude, pain frequency and analgesic use.¹⁷ Prior studies investigating hand orthosis, found that the crucial factors underpinning satisfaction of an orthosis were comfort, effectiveness, and ease of use.²⁰ A lumbar orthosis is beneficial in providing the same benefit as bed rest – reducing repeated irritations to the disc and nerves caused by movement, thereby reducing back pain and muscle spasm – while allowing users to continue some daily activities and avoid stasis caused by prolonged bed rest.²¹ By restricting movement of the lumbar spine, however, the lumbar orthosis replicates several negative effects of bed rest – particularly lumbar muscle atrophy and weakness, as well as psychological frustrations due to movement restriction. According to Mitchell et al., these effects were associated with more severe and costly back injuries in subjects injured while wearing a lumbar orthosis compared to those injured without an orthosis.²¹ A sacroiliac belt avoids these pitfalls by allowing full range of spinal and pelvic motion; this may also explain the significantly higher satisfaction achieved by the sacroiliac belt.

Although lumbar braces are a safe and readily available conservative treatment option in the management of LBP, little is known regarding their overall effectiveness or comparison between devices.²² The systematic review conducted by the Cochrane Library concluded that it remained unclear on the effectiveness on lumbar support for treatment of low back pain and that special attention should focus on the type of lumbar support used.¹⁰ Our study aims to address these limitations in the prior literature, and demonstrated that user satisfaction was associated with improvements in functional disability, pain magnitude and pain frequency. Moreover, there were appreciable benefits to using a sacroiliac belt compared to a lumbar orthosis.

Despite the strengths of this study, there are several limitations to consider. Firstly, the lack of a significant washout period may have resulted in some confounding of effects between the brace used in the first week and the brace used in the second week. Other potential weaknesses are a somewhat limited sample size ($n = 30$) and a female-skewed study population (23 females, 7 males), both of which were caused by limitations in time, location, and resources, and may somewhat restrict the power of this study. A follow-up study with a significantly larger sample size may help address this issue.

CONCLUSION

The aim of this study was to help address a lack of comprehensive comparisons between different forms of mechanical back support devices, which carry significantly less hazards than alternative LBP management methods. Through these findings, this study contends that a sacroiliac belt yields significantly increased satisfaction over a lumbar orthosis by appreciably reducing restrictions on mobility

Table 4. Type of brace, corresponding outcome measures and corresponding p-values measured for the: A. Experimental group over Week 1 and Week 2; B. Control group over Week 1 and Week 2; C. Overall two-week study period.

A. Experimental Group																	
(A) Time Frame	(B) Brace Used	(C) Mean QUEST	(D) QUEST p- Value	(E) Mean ODI	(F) ODI p- Value	(G) Mean Pain Scale	(H) Pain Scale p-Value	(I) Pain Scale Change	(J) Pain Scale Change p-Value	(K) Pain Frequency	(L) Pain Frequency p-Value	(M) Pain Frequency Change	(O) Pain Frequency Change p-Value	(P) Total Analgesic Use (pills)	(Q) Total Analgesic Use p-Value	(R) Average Analgesic Use Change	(S) Average Analgesic Use Change p-Value
Week 1	Sacroiliac Belt	24.42	0.0106	0.351	0.2831	33.59	0.3687	0.445	0.3687	24.41	0.5700	-0.160	0.57	12.88	0.7001	0.311	0.7001
Week 2	Lumbar Orthosis	17.24		0.318		29.94		-0.076		23.06		-0.353		11.71		0.143	
B. Control Group																	
(A) Time Frame	(B) Brace Used	(C) Mean QUEST	(D) QUEST p- Value	(E) Mean ODI	(F) ODI p- Value	(G) Mean Pain Scale	(H) Pain Scale p-Value	(I) Pain Scale Change	(J) Pain Scale Change p-Value	(K) Pain Frequency	(L) Pain Frequency p-Value	(M) Pain Frequency Change	(O) Pain Frequency Change p-Value	(P) Total Analgesic Use (pills)	(Q) Total Analgesic Use p-Value	(R) Average Analgesic Use Change	(S) Average Analgesic Use Change p-Value
Week 1	Lumbar Orthosis	25.76	0.6181	0.224	0.2339	22.25	0.3853	-0.759	0.3853	17.69	0.8195	-0.598	0.8195	12.56	0.5065	-0.498	0.5065
Week 2	Sacroiliac Belt	28.61		0.175		21		-0.938		17.31		-0.652		14.38		-0.501	
C. Overall Study Period																	
(B) Brace Used		(C) Mean QUEST	(D) QUEST p- Value	(E) Mean ODI	(F) ODI p- Value	(G) Mean Pain Scale	(H) Pain Scale p-Value	(I) Pain Scale Change	(J) Pain Scale Change p-Value	(K) Pain Frequency	(L) Pain Frequency p-Value	(M) Pain Frequency Change	(O) Pain Frequency Change p-Value	(P) Total Analgesic Use (pills)	(Q) Total Analgesic Use p-Value	(R) Average Analgesic Use Change	(S) Average Analgesic Use Change p-Value
Sacroiliac Belt		20.31	0.0375	0.243	0.7849	25.19	0.5579	-0.206	0.5579	19.22	0.7187	-0.365	0.7187	12.47	0.4588	-0.220	0.4588
Lumbar Orthosis		16.17		0.250		24.03		-0.373		18.75		-0.433		11.11		-0.222	

while making no significant sacrifices in stabilization and pain management effectiveness.

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AUTHOR CONTRIBUTIONS

Conceptualization, DL, SA, OT, DY, DA, CL, AE, AD.; methodology, DL, SA, OT, DY, DA, CL, AE, AD.; formal analysis, DY, DA, AE.; investigation, DL, SA, OT.; writing—original draft preparation, DL, SA, OT.; writing—review and editing, DY, DA, CL, AE, AD.; supervision, AE, AD.; project administration, DA.; funding acquisition, AE, AD. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: This study was approved by the Institutional Review Board of Lifespan – Rhode Island Hospital (Board Reference # 418517; 45 CFR 46.110 (4),(7)).

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