

# 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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**STUDY DESIGN:** Single blinded, randomized clinical trial for the evaluation of lumbosacral orthoses (LSO) 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:** LSO are commonly used for the management of LBP, but their effectiveness may vary due to design. Inextensible LSO (iLSO) reduces trunk motion and increases trunk stiffness, whereas an extensible LSO (eLSO) does not. **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 -2.0, 6.5), 8.1 (95% CI 3.04, 13.2), and 14.0 (95% CI 9.2, 18.8) 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.

## SELECTED QUOTATIONS

### Introduction

“Several theories are proposed for how LSOs might be effective in alleviating LBP... added stiffness could reduce the overall demand on trunk muscle forces during activities of daily living, preventing muscle fatigue from compounding the symptoms of LBP.<sup>18,20,21</sup> This mechanism of LSO function could be especially effective in individuals with LBP... or who demonstrate aberrant spinal motion...The iLSO [Aspen QuikDraw Pro]...increased trunk stiffness by 14%.” (Pg. 1733-1734)

### Materials and Methods

“Participants received 2 weeks of physical therapy from the time of entering into the study... Inclusion criteria were 18 years of age or older, with a primary report of acute, subacute, or chronic LBP.” (Pg. 1734)

“The Primary Measure [of the study] was the modified Oswestry Disability Index.” (Pg. 1734)

### Results

“At the more stringent 50% improvement threshold for success, 3 (10%), 5 (16%), and 13 (35%) of participants in the SC, eLSO, and iLSO groups, respectively, reported a successful outcome for the ODI. At the MCID of 6 points, 11 (38%), 19 (59%), and 24 (65%) participants in the SC, eLSO, and iLSO groups, respectively, reported a successful outcome for ODI.” (Pg. 1739)

“Individuals wearing the iLSO [Aspen QuikDraw Pro] had 4.7 times higher odds of achieving success [a reduction in ODI of  $\geq$  50% improvement] than those assigned to SC.” (Pg. 1739)

### Discussion

“Participants with improved ODI scores included patients who were overweight, had high hip-to-waist ratios, had high body mass indexes, and with acute, subacute, and chronic LBP.” (Pg. 1740)

“An iLSO may reduce pain and improve function by reducing the activity of spinal muscles that are overactive to produce intrinsic compensatory stiffness to the spine.” (Pg. 1740)

## DATA FROM TABLES

- 51% of patients obtained initial pain relief with first use of an iLSO. (Table 3, pg. 1737)
- 65% of patients with an iLSO received a successful ( $\geq$ 50%) Minimum Clinically Important Difference drop of 6-point on the Oswestry Disability Index (ODI). (Table 6, pg. 1740)
- 35% of patients showed a successful ( $\geq$ 50%) drop on the Patient Specific Activity Scale (PSAS) with an iLSO. (Table 6, pg. 1740)
- The likelihood that a patient achieved a good outcome was 4.7 times higher if they got an iLSO and SC, than if they got SC alone. (Table 7, pg. 1741)