A new protocol to improve pain in adults with scoliosis: the role of night-time bracing

Night-time bracing can reduce pain in adults with scoliosis:

Six months results of a retrospective controlled study

Conclusions

Night-time bracing shows interesting positive results on worst pain and pain at six months in adults with severe scoliosis and back pain. These preliminary results open a new perspective on the conservative approach to symptomatic spinal deformities during adulthood. Moreover, it will help design more robust studies to verify what we found and identify the population more responsive to this approach.

Background/Objectives

Severe scoliosis can lead to chronic low back pain (cLBP) and may progress in adulthood. While daytime bracing is commonly used to alleviate pain and improve function, the role of night-time bracing remains unclear. This study aimed to assess the six-month effectiveness of a custom-made night-time brace in reducing pain in adults with scoliosis, compared to a prefabricated brace worn for 2–4 hours during the day.

Table 1. Characteristics of the custom brace group (TLSO).

Age	**62.3+-9.5**
BMI	23.1+-3.8
Curve (°Cobb)	60.4+-17.7
Single/Double Curve	18 single (72%)
	7 double (28%)
Localization	9 thoracic (36%)
	8 thoraco-lumbar (32%)
	8 lumbar (32%)
Diagnosis	15 AIS (60%)
	3 JIS (12%)
	6 adult scoliosis (24%)
Exercises (Min/week)	117.9+-48
Previous exercises	12 yes (48%), from 7.3+-6.2 months
	13 no (52%)
Wearing hours	7.2+-2.2

Table 2. Baseline and six months values of pain and disability. Comparisons were made intra and intergroup.

	TLSO brace				Peak brace			
	Baseline	6 Months	P value intragroup		Baseline	6 Months		P value Intergroup post treatment
	Mean/ median (SD/95% CI)	Mean/ median (SD/95% CI)		P value Intergroup pre treatment	Mean/median (SD/95%CI)	Mean/median (SD/95%CI)	P value Intragroup	
Worst pain (back or leg)	5.9±1.9	4.±2.5	0.01*	0.09	7.15±2.03	5.6±2.13	0.007*	0.06
Back Pain	5.7±1.9	3.6±1.9	0.001*	0.28	6.55±2.37	5.25±2.69	0.06	0.07
Leg Pain	4.9±2.9	3.3±3.4	0.22	0.01*	5.65±3.03	4.35±2.66	0,04*	0.01*
COMI	4.2±2.0	3.1±1.3	0.19	0.04*	5.67 (5.11–6.79)	4.18 (3.34-5.02)	0.002*	0.11
ODI	28.7±15.1	23.8±10.8	0.06	0.51	33.00 (25.26–38.43)	33.05 (26.30-39.79)	0.96	0.04*

Figure 1. A patient at baseline and wearing a custom-made brace. Frontal and lateral view.

Figure 2. Changes of worst pain.

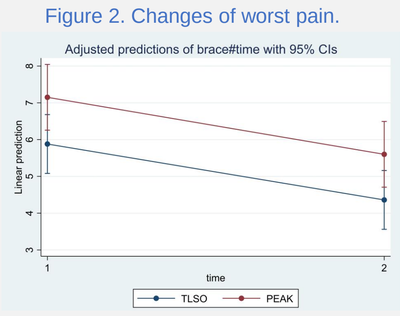
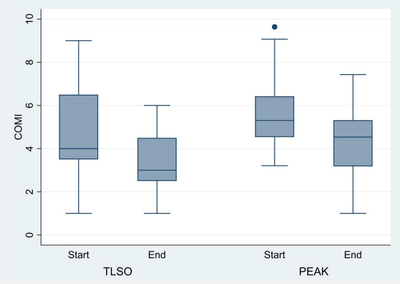


Figure 3. There is no significant effect of TLSO brace compared to PEAK over time for COMI score.



Results

Pain Improvement

Both groups experienced similar improvements in back and leg pain (table 2). However, after two-ways ANOVA, we found there was a statistically significant improvement in the worst pain scores in the TLSO Group (F=6.32, p=0.0158). This improvement was also significant over time from the start to the end of the study (F=20.54, p=0.000) (Figure 2).

A MCID was achieved in 44% of cases in the TLSO group and 30% in the Peak group, indicating no significant difference between the groups (chi²=0.93, p=0.34).

Leg Pain: 8% of TLSO group reached the MCID, compared to 15% in the Peak Group (chi²=0.55, p=0.46).

Back Pain: 4% of TLSO group reached the MCID, compared to 20% in the Peak Group (chi²=2.88, p=0.09).

Logistic Regression Analysis

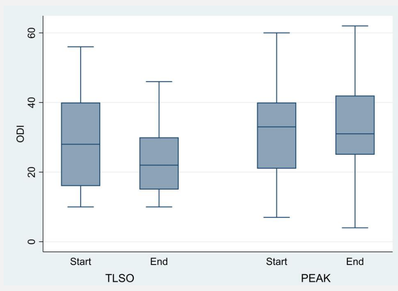
The analysis indicated that the odds of improvement were not different between the two braces. COMI total results were 55% higher in TLSO group (OR=0.55, p=0.34, 95% CI 0.2-1.9). ODI results were 29% higher in TLSO group (OR=0.71, p=0.61, 95% CI 0.2-2.6) (Figure 3).

ODI: 32% of TLSO group showed improvement, compared to 25% in the Peak group. This difference was not statistically significant (chi²=0.26, p=0.607) (Figure 4).

Night-time bracing (TLSO Group):
included 25 women, average age 62.3 years (±9.5), with an average spinal curvature of 60.4° Cobb (±17.7°). They wore the brace for an average of 7.2 hours per day (±2.2 hours) (Table 1).

Day-time Prefabricated Brace (Peak Group): Included 20 women, average age 67.8 years (±10.5), with an average spinal curvature of 62° Cobb (±13°). They wore the brace for 2 to 4 hours daily.

Figure 4: There is no significant effect of brace or time on ODI score.



Materials and Methods

Design

We designed a retrospective cohort study with a historical control group.

Participants

We included adults with Idiopathic or degenerative scoliosis of 30° Cobb or more and cLBP which started wearing a custom-made night-time brace to improve pain.

Exclusion criteria: Secondary scoliosis, surgically treated patients, incomplete data.

We compared the results to a historical cohort from the same clinical prospective database treated with a prefabricated brace worn during the day[10].

Outcome measures

We focused on pain as a primary outcome and disability as a secondary one. For pain, we applied the Graphical rating scale (GRS) for back pain, leg pain and worst pain (higher level of pain between leg and back). For the quality of life, we used the Oswestry Disability Index (ODI) and the Core Outcome Measure Index(COMI)[11].

Protocol

We compared the baseline evaluation made before the start of the brace treatment with the one made after 6 months of treatment with the brace. We also compared the results of the study group with the historical control group[10,12]. The dosage recommended was night-time, and the assessment self-reported. The brace was a custom-made 3 or 4 mm polyethene built applying CAD-CAM technology. It was a TLSO, rigid, frontal and sagittal action, monocot with ventral closure[13]. We designed the braces to support the trunk and spine, avoiding any attempt to correct the deformity, trying to make them effective for pain and comfort (Figure 1). An expert physician checked the braces with an orthotist to optimise the effect and comfort.

Statistical analysis

Description of data was done according to the type of variables; we checked the distribution of questionnaires before defining the statistical tests needed. The skewness and Kurtosis resulted to be withing the range to consider the distribution normal.

To compare differences between brace treatments and changes over time we used two-ways ANOVA.

We also checked results according to the Minimal clinically important differences (MCID) which is 10 points at the ODI and 2 points at COMI and GRS [10].

We defined improvement as a change equal or greater than the MCID and we checked the association between the proportion of clinically meaningful improved patients and the brace type with chi2. We ran a logistic regression model to see if the OR of reaching results is higher with one of the braces used to treat patients.

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