

Can bracing help adults with chronic back pain and scoliosis? Short-term results from a pilot study

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Abstract

Background: Adult scoliosis is sometimes associated with back pain. Recently, the Peak™ Scoliosis Brace was designed to alleviate pain in adult patients with scoliosis.

Objectives: To test the efficacy of the Peak Scoliosis Brace in reducing pain in adult scoliosis patients.

Study design: Prospective experimental cohort study.

Methods: A total of 20 adult females with back pain secondary to idiopathic scoliosis were included. Patients were evaluated at baseline immediately before starting bracing and after 1 month. The brace had to be worn for at least 2 h per day. The outcome measures used were Graphical Rating Scale, Roland-Morris Questionnaire, Core Outcome Measurement Index, and Oswestry Disability Index.

Results: Worst pain, back pain, and leg pain significantly improved from 7.15 to 5.85, from 6.55 to 5.25, and from 5.65 to 3.55, respectively ($p < 0.05$). A total of 75% of patients reported improved worst and leg pain, 65% improved back pain, 30% of patients achieved the minimal clinically significant difference of 2 points for worst pain, 60% for leg pain, and 25% for back pain. Roland-Morris Questionnaire and Core Outcome Measurement Index improved ($p < 0.05$) and no differences were observed for Oswestry Disability Index.

Conclusion: The Peak Scoliosis Brace led to some improvement of pain at 1 month in a group of adult women with scoliosis and chronic low back pain. The quality of life did not change significantly.

Clinical relevance

According to our data, the Peak Brace is helpful to quickly improve pain in patients with chronic low back pain secondary to scoliosis. To achieve this goal, it should be applied for at least 2 h per day.

Keywords

Scoliosis, spinal orthotics, chronic pain, pain research, low back pain, disability, conservative treatment

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Background

The impact of scoliosis during adulthood is correlated with two main parameters: the frontal curve and the sagittal profile. The Cobb angle, measured in the frontal plane, is associated with the risk of progression of the deformity, this being negligible for curves below 30° Cobb and very high for curves with over 50° Cobb.¹ The Cobb angle is also predictive of respiratory restrictive syndrome when it exceeds 70°.² The impairment of the sagittal profile is predictive of back pain and disability,³ and evaluation of this impairment has become more relevant for both the surgical and conservative approaches.⁴ For scoliosis patients with chronic low back pain (cLBP), the main approach according to the

current practice is the surgical one, aimed at both preventing progression and improving pain and quality of life. Unfortunately, surgery has quite frequent complications^{5–7} and

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Figure 1. The Peak Brace, from the back, front, and side views in a patient with a right thoracolumbar curve.

is not appropriate for patients with certain comorbidities; moreover, some patients simply do not want to undergo surgery. Despite these issues and the fact that scoliosis has been estimated to affect up to 68% of the population over the age of 60,⁸ there is scant literature about conservative treatments for adult patients with scoliosis. One case report and one case series demonstrated the effectiveness of scoliosis-specific exercise to stop progression,^{9,10} while another study reported the effectiveness of a soft brace at reducing pain within a short time.¹¹ Custom-made rigid torso braces, similar to those commonly used for children, are sometimes used in adult patients; however, only anecdotal evidence of their efficacy is available¹² and problems with comfort are quite frequent. A new brace has recently become available, the Peak™ Scoliosis Brace (Aspen Medical Products), designed to alleviate pain in adult patients with chronic pain secondary to scoliosis (Figure 1).

Objective

We designed this prospective cohort pilot study with the aim of testing the efficacy of the Peak Scoliosis Brace at reducing pain in adult scoliosis patients in the short term.

Study design

We designed a prospective experimental cohort study according to the STROBE guidelines.

Methods

Setting

Tertiary referral outpatient center for scoliosis and low back pain.

Inclusion criteria

Idiopathic scoliosis of 30° Cobb or more suffering from cLBP (lasting for at least the last 3 months), 18 years of age or more.

Exclusion criteria

Secondary scoliosis.

Population

Between 1 April and 1 November 2015, 20 consecutive adult patients with back pain secondary to idiopathic scoliosis or degenerative scoliosis were recruited. The sample size was calculated according to the data collected during the development of the brace in the United States, and the first two patients fitted in Italy. The authors were provided with some braces to fit some patients before the study began, but were not involved in the development of the brace. Setting alpha at 0.05 and the power at 0.8, with a mean expected improvement of 2 points on the Graphical Rating Scale (GRS) of pain,¹³ 16 patients would be necessary. Taking into account the possibility of 25% dropout, we decided to recruit 20 subjects.

The brace was fitted by one of the investigators (F.Z.) after appropriate training provided by the producer. There are different sizes of the belt that are chosen according to a fitting table. The brace is very easy to fit, and the patients learn immediately how to manage it by themselves, thus representing a great advantage.

This study respected the principles of the Helsinki Declaration and was approved by the local ethics committee. All patients signed a written informed consent.

Table 1. Distribution of sagittal Schwab modifiers.

Risk	SVA	Pelvic tilt	PI-LL
0	6%	12%	56%
+	69%	41%	32%
++	25%	47%	12%

SVA: sagittal vertical axis; PI-LL: difference between pelvic incidence (PI) and lumbar lordosis (LL).

Outcome measures

Primary. GRS for evaluation of worst pain, back pain, and leg pain.¹⁴

Secondary. Disability and function were assessed using the Roland-Morris Questionnaire (RM),¹⁵ Core Outcome Measurement Index (COMI),¹⁶ and Oswestry Disability Index (ODI).¹⁷

Protocol

After a baseline clinical evaluation,¹⁸ if considered eligible, the patients were invited to participate in the trial. Following acceptance, all participants had to undergo a further evaluation after 4 weeks of brace wear. They were required to wear the Peak Brace at least 2–4 h per day. At each evaluation, they had to complete the GRS, RM, ODI, and COMI.

Statistical analysis

For normally distributed continuous variables, a paired *t*-test was applied; otherwise, non-parametric tests for ordinal data and not-normally distributed data were used. The alpha level of significance was set at 0.05.

Results

Out of 29 eligible female patients affected by scoliosis and cLBP, 20 entered the study. The mean age was 67.8 ± 10.5 , the mean curve magnitude was $61.9 \pm 12.6^\circ$ Cobb, and the average body mass index (BMI) was 24.07 ± 3.65 . The nine patients who refused to enter the study were clinically similar to those recruited (p =non-significant (NS)). They refused to enter since they were not willing to wear a brace. There were no dropouts.

Three patients suffered from osteoporosis and were under pharmacological treatment. No other musculoskeletal conditions were detected. The study included only female patients due to the convenience sampling of consecutive patients we recruited.

According to the SRS-Schwab Classification,⁴ 55% of patients showed a lumbar/thoracolumbar curve, 30% a double major curve, and 15% a thoracic one. Details about sagittal modifiers are reported in Table 1.

All the patients wore the Peak Scoliosis Brace for 2–4 h a day, in agreement with the prescription, every day for 4 weeks. After this period, all pain measures on GRS improved significantly (Table 2). In total, 75% of patients reported improved worst pain and leg pain, 65% improved back pain, but only 30% of patients achieved the minimal clinically significant difference of 2 points for worst pain, 60% for leg pain, and 25% for back pain.

In terms of disability measures, both RM and COMI improved in a statistically significant way, while ODI did not (Table 2). All but one patient reported satisfaction in wearing the brace, stating that they felt more supported.

Discussion

Bracing is widely applied in children with scoliosis, but only rarely recommended to adults mainly due to issues over comfort. The newly developed Peak Brace has been designed in order to guarantee a better comfort, as reported by the patients from this study who wore the brace with satisfaction, achieving some degree of pain relief in most of the cases. About 65%–75% of patients achieved some pain relief, even if only a part of the patients achieved a clinically significant improvement of 2 points in the GRS scale. We think this result is promising since there has been a quite even if small pain relief, occurring after only 1 month of brace wear, even in patients who had been experiencing pain for many years. We can expect that a longer follow-up could show different results.

We speculate that the cause of pain relief is based on the passive spinal support provided by the brace. In fact, in these patients, pain is typically related to the difficulties in supporting the trunk and carrying the body weight, with progressive deterioration during the day, especially when they need to stand up for a long time or walk.¹⁹ These patients usually feel better while sitting and lying on a bed.²⁰ We believe that pain relief is related to the fact that the brace can provide similar support to a chair or a bed. By providing good support, we can also expect an improvement in disability issues. Within a short time, some of the measures of quality of life improved, but these changes were not clinically significant. The treatment duration was probably too short to lead to a relevant change in this outcome, and we expect that longer treatments time could change the results.

The most commonly used approach to scoliosis during adulthood is surgery. Unfortunately, the risks of complications and side effects associated with this procedure are relatively high, with some papers reporting a 39% complication rate and a 26% reoperation rate.²¹ Surgical treatment can provide stability to the spine, but quality of life and pain are not always addressed by this approach, and back pain is persistent in 10% of patients 1 year after surgery.²² A poor general health status increased the risks²³ and can exclude this option for some patients, while many

Table 2. Main outcome measures for pain and disability.

	T0 Mean/median (SD/95% CI)	T1 Mean/median (SD/95% CI)	p
Worst pain (back or leg)	7.15 ± 2.03	5.85 ± 2.81	0.011*
Back pain	6.55 ± 2.37	5.25 ± 3.21	0.049*
Leg pain	5.65 ± 3.03	3.55 ± 3.33	0.003*
RM	12.50 (11.45–15.84)	11.50 (8.42–13.67)	0.018*
COMI	5.67 (5.11–6.79)	4.82 (3.76–5.84)	0.035*
Oswestry	33.00 (25.26–38.43)	30.00 (21.05–35.74)	0.06

T0: baseline; T1: 1-month results; SD: standard deviation; CI: confidence interval; RM: Roland-Morris Questionnaire; COMI: Core Outcome Measurement Index.

*statistically significant change.

patients are not really willing to undergo surgery. For all these reasons, an effective conservative treatment is necessary. Recently, a retrospective study showed that bracing during adulthood can slow down the progression of scoliosis during adulthood, but no data were provided about pain and quality of life.²⁴ So, this is the first study to document the effect of bracing on pain and quality of life in a cohort of adults with scoliosis and cLBP.

This study has some limitations. First of all, a small number of patients were studied, even though the number was appropriate according to our sample size calculation. The study included only female patients due to the convenience sampling of consecutive patients we recruited. Another limitation is the lack of a control group. Including those who refused to wear the brace as a control group could have been very useful, but this was not planned and authorized by the ethical committee. However, as the patients were affected by chronic condition as cLBP and scoliosis, it was appropriate to design such an exploratory study to test whether any benefit could be gained using such a brace before larger and more expensive designs are considered. This is an under-researched area, and we consider this study only a starting point. The short period used to evaluate the results may also be considered a limitation, but it was decided that the period of 4 weeks of observation was cost effective for this experimental evaluation of the efficacy of this new brace.

The data provided by this pilot study will allow to design further randomized controlled trials to explore in a more robust way the effect of the Peak Brace for adult scoliosis.

Conclusion

The Peak Scoliosis Brace led to some improvement at 1 month of pain in a group of adult women with scoliosis and cLBP. The quality of life did not change in a significant way even when the patients reported being satisfied with the treatment. The follow-up time was very short, and it is possible that a longer treatment time could change these results.

Author contribution

All authors contributed equally in the preparation of this manuscript.

Declaration of conflicting interests

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