PEAK SCOLIOSIS BRACE CAN REDUCE PAIN IN ADULTS WITH PAINFUL SCOLIOSIS: SIX MONTHS RESULTS FROM A PROSPECTIVE COHORT PILOT STUDY

Fabio Zaina[1], Martina Poggio[1], Sabrina Donzelli[1], Francesca Di Felice[1], Stefano Negrini[2, 3]

1. ISICO, Milan, MI, Italy

2. Clinical and Experimental Sciences Department, Brescia University, Brescia, BS, Italy

3. IRCCS Fondazione Don Gnocchi, Milan, MI, Italy

Introduction: Adult scoliosis is sometimes associated to back pain and severe curves can progress over time. The main approach for these patients is the surgical one, however surgery is not appropriate for all patients, and certain patients do not accept surgery. Despite scoliosis has been estimated to affect up to 68% of the population over 60, there is scant literature about conservative treatment for adult scoliosis. A recent paper showed the possibility for braces to reduce scoliosis progression during adulthood, but no data about pain control and quality of life were published. Recently we tested a new brace (Peak™ Scoliosis Brace - Aspen Medical Products) designed to alleviate pain for adult patients with chronic pain secondary to scoliosis showing some pain relief at one month, but no longer follow up are available.

The aim of the present study is to test the efficacy of the Peak™ Scoliosis Brace in reducing pain in adult scoliosis patients at six months.

Methods: Design: follow up of prospective experimental cohort study.

Population: 20 adults (age 67.8±10.5, curve 61.9±12.6° Cobb) with back pain secondary to Idiopathic Scoliosis. The sample size calculation was based on unpublished data collected in clinical practice.

Inclusion criteria: Adults affected by Idiopathic scoliosis of 30° Cobb or more and chronic low back pain (cLBP). Exclusion criteria: secondary scoliosis.

Outcome measures: GRS, Oswestry Disability Index (ODI), Roland Morris Questionnaire (RM), COMI.

Statistical analysis: paired t-test and non parametric tests.

Protocol: patients were evaluated at baseline immediately before starting with the brace and after 1 month. The brace must be worn for at least 2 hours per day.

Results: All parameters showed a short term improvement at one month. At six months, worst pain, leg pain and back pain were significantly improved: from 7.15 to 5.60, from 5.65 to 4.35 and from 6.55 to 5.25 ($p<0.05$). Sixty five percent of patients achieved the minimal clinically important difference of 2 points for worst pain and leg pain, 55% for back pain. RM and COMI improved ($p<0.05$), no differences for ODI.

Conclusion: The Peak Scoliosis brace showed a significant improvement at 6 month of worst, leg and back pain in the majority of patients in a group of adult women with scoliosis and cLBP. Some changes were noticed at one month, but at long term this effect was increased. The quality of life didn't change in a clinically significant way even if the patients reported satisfaction with the treatment. It's possible that a higher dosage would guarantee a better effect, and it would be important to determine the features of responders with respect to non responders in a larger study