

**Increasing Brace Comfort, Durability and Sagittal Balance through Semi-rigid Pelvis Material does not change Short- Term Very-Rigid Sforzesco Brace Results. A Matched Case- Control Study of 436 High Degree AIS not previously braced**

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Background

Very-rigid braces, like the Sforzesco brace (VRB), have shown promising results also in high-degree surgical curves of Adolescents with Idiopathic Scoliosis (AIS). We recently introduced the “Free Pelvis” (FP) innovation, semi-rigid material (ethylene vinyl acetate) used in VRB to improve 1) comfort, reducing the hard contact with the pelvis, 2) sagittal balance, allowing the patient to achieve automatic pelvis positioning, and 3) brace adaptability, allowing to change the pelvis diameter with growth while keeping trunk correction. Nevertheless, these changes could also harm the corrective forces on the trunk.

Objective

To verify if the FP innovation impacts on the efficacy of the Sforzesco VRB for high-degree AIS.

Methods

We performed a matched Case-Control Study comparing the Sforzesco brace classical version (VRB) versus the Free Pelvis one (FPB). We extracted from our prospective database all FPB and VRB at first consultation in our Institute. Inclusion criteria were: AIS, age 10-16, VRB prescription 23 hours/day, standing full-spine x-rays available at first and second consultation, the primary curve between 36 and 65°, Angle of Trunk Rotation between 7 and 23° Bunnell. We matched for Risser (range 0 to 4), menarche age (10 to 15), weight (33.5 to 83), height (140 to 180), BMI (13.5 to 29), aesthetics (TRACE index 4 to 12), plumbline distances (S2: -60 to 35; C7+L3: -10 to 115), referred brace use (22 to 24). We excluded from VRB all AIS with parameters out of the FPB patients' range. Since we found a different distribution between the groups, post-hoc we also excluded previously braced patients. We checked in-brace radiographic results at one month, and short-term out-of-brace radiographic and clinical results. We used descriptive statistics according to the type of variables and their distribution. We used unpaired and paired t-test to check the differences between and within the groups, respectively.

## Results

Out of a total of 4431 VRB and 96 FP, respected the inclusion criteria, 27% and 30%, respectively. Of the remaining, we matched 34% and 69%, resulting in 416 VRB (12% males, age  $13\pm 1$ ,  $46\pm 7^\circ$  Cobb) and 20 FP participants (10% males, age  $13\pm 1$ ,  $49\pm 10^\circ$  Cobb) (NS). At baseline, we found two statistically but not clinically significant differences: reported brace

use (+12'/day FP) and recorded compliance (+1% FP). All parameters improved statistically ( $p < 0.001$ ) and clinically, without differences among groups in-brace (FP  $-17 \pm 8^\circ$  vs VRB  $-15 \pm 6^\circ$  Cobb) and at short-term ( $5 \pm 2$  months) for scoliosis ( $-8 \pm 6^\circ$  vs  $-8 \pm 5^\circ$  Cobb), ATR ( $-3 \pm 2^\circ$  vs  $-4 \pm 4^\circ$  Bunnell), aesthetics ( $-3 \pm 2$  vs  $-3 \pm 2$  points), S1 ( $-6 \pm 11$  vs  $-4 \pm 15$  mm) and C7+L3 ( $-8 \pm 17$  vs  $-4 \pm 19$ ).

### Conclusion

FPB results were not different from those of the classical VRB in-brace and in the short-term. The FP innovation does not impair the mechanical correction of VRB.