Introducing Pelvis Semi-Rigid Material does not change Short-Term Very-Rigid Sforzesco Brace Results. A Matched Case-Control Study in AIS

Negrini S (1,2), Tessadri F (3), Negrini F (2,4), Tavernaro M (4), Zaina F (4), Zonta A (4), Donzelli S (4)

1. Department of Biomedical, Surgical and Dental Sciences, University “La Statale”, Milan, Italy
2. IRCCS Istituto Ortopedico Galeazzi, Milan, Italy
3. Orthotecnica, Trento, Italy
4. ISICO (Italian Scientific Spine Institute), Milan, Italy

Introduction

We recently introduced pelvis semi-rigid material (ethylene vinyl acetate) to improve sagittal balance, brace comfort, and adaptability of VRB, but this could also negatively impact the corrective forces on the trunk.

Hypothesis

Does the “Free Pelvis” (FP) innovation affect results in adolescents with idiopathic scoliosis (AIS) treated with very-rigid (high-density polyethylene) Sforzesco brace (VRB)?

Methods

Study Design. Matched Case-Control Study. **Participants**. *Inclusion criteria*: AIS, age 10-16, VRB prescribed 23 hours/day, x-rays available, primary curve 36-65°, Angle of Trunk Rotation 7-23°. *Cases*: VRB with FP (FPB). *Controls*: classical VRB matched for Risser (range 0/4), menarche age (10/15), weight (33.5/83), height (140/180), BMI (13.5/29), aesthetics (TRACE 4/12), plumbline distances (S1: -60/35; C7+L3: -10/115), referred brace use (22/24). **Statistics**. *Linear regression* outcome: short term variations - start to first out-of-brace x-ray. *Logistic regression* outcome: improved vs worsened. *Explanatory variable*: brace type.

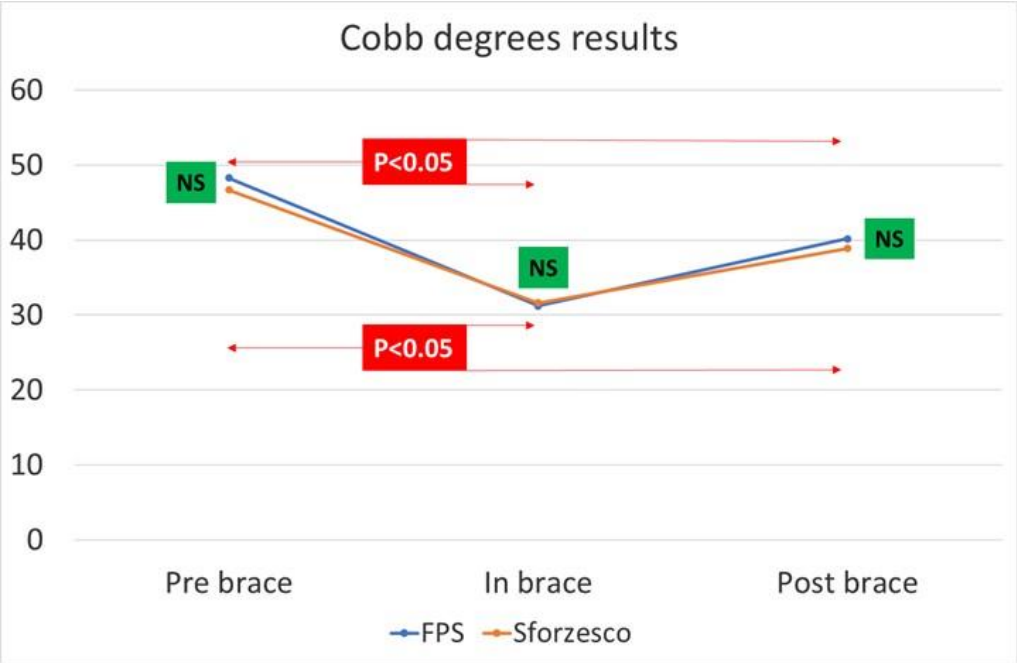
Results

We included 777 VRB (36% of the initial 4431) and 25 FPB (26%), age 13±1, 47±7° and 48±10° Cobb, 11% and 16% males, respectively. **Baseline characteristics** differed only for bracing before first consultation (+26% VRB), reported brace use (+12’/day FP) and recorded compliance (+1% FPB). The sensitivity analysis provided the same results. **°Cobb corrections**. *Short-term (5±2 months)* -7.8±0.2 for VRB and -8.1±1.3 for FPB (p= 0.83); *in-brace* -15.2±7.7 and -17.4±6.5, respectively (p=0.21). Type of brace influenced °Cobb neither short-term (coeff. -0.30, CI95% -2.4;1.8 R^2=0.0001), nor in-brace (2.2, CI95% -0.64;5.1 R^2=0.002). Brace type didn’t affect odds of improvement (OR 0.60, CI95% 0.3;1.4 adj R^2=0.002).

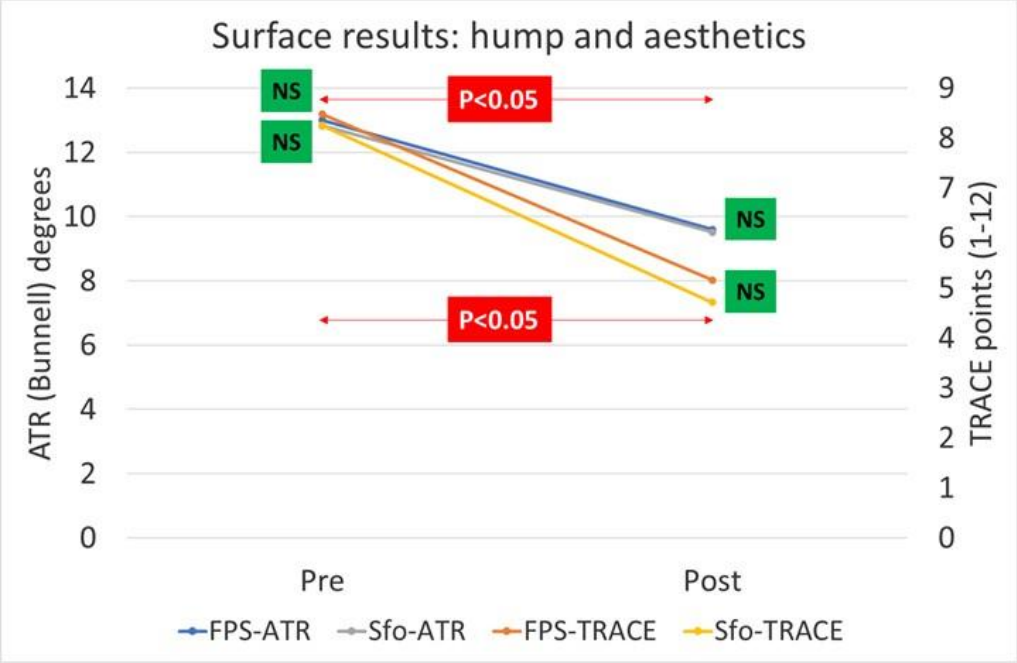
Conclusion

FP's introduction for comfort, adaptability, and sagittal balance does not change in-brace and short-term results of classical Sforzesco VRB. Semi-rigid pelvis material (“Free Pelvis”), introduced to improve comfort, adaptability, and sagittal balance, does not change in-brace and short-term efficacy of classical Sforzesco very-rigid brace for high-degree AIS.

The Free-Pelvis has radiographic (A) and clinical (B) results similar to classical very-rigid bracing.


Cobb degrees results
60
50
40
30
20
10
0
NS
P<0.05
NS
NS
P<0.05
Pre brace
In brace
Post brace
FPS
Sforzesco

A


Surface results: hump and aesthetics
ATR (Bunnell) degrees
14
12
10
8
6
4
2
0
TRACE points (1-12)
9
8
7
6
5
4
3
2
1
0
NS
NS
P<0.05
NS
NS
P<0.05
Pre
Post
FPS-ATR
Sfo-ATR
FPS-TRACE
Sfo-TRACE

B