A MATCHED CASE-CONTROL STUDY OF THE FREE PELVIS VS THE CLASSICAL VERY-RIGID SFORZESCO BRACE IN 436 HIGH DEGREE AIS NOT PREVIOUSLY BRACED

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1 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 to improve comfort, sagittal balance and brace adaptability. Nevertheless, these changes could also hare corrective forces on the trunk.

<u>Objective</u>: verify if the FP innovation impacts on the efficacy of the Sforzesco VRB for high-degree AIS.

◆ The Free Pelvis is an innovation that reduces strain on the patient pelvis and allows a proper sagittal balance

◆ The Free Pelvis is safe since it does not change the results of the very rigid braces

4 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.

2 Method

<u>Case-Control Study</u>: we We extracted from our prospective database all FPB and VRB at first consultation in our Institute.

<u>Inclusion criteria</u>: AIS, age 10-16, VRB 23 hours/day, x-rays available, 36-65° Cobb, 7-23° Bunnell. We matched for Risser, menarche, weight, height, BMI, aesthetics (TRACE), plumbline distances, brace use.

Post-hoc we also excluded previously braced patients. We checked in-brace (one month), and short-term out-of-brace results.

We used descriptive statistics and unpaired/paired t-test according to variables and distribution.

Cobb degrees results

Surface results: hump and aesthetics

	Sforzesco	FP
With brace prescription at first consultation	4431	96
INCLUSION CRITERIA		
Idiopathic scoliosis		8
Age 10-16		4
Prescription brace at least 23 h/d		19
Rx at first consultation after brace wearing		33
Main curve range 36° to 65°		3
ATR range 7° to 23°		
Excluded to match the samples	73%	70%
Total first selection from database	1211	29

Matching: excluded because out of FPS range	Total	Above max	Below min	No data
Main curve cervical or proximal thoracic	1			
Risser >4	14	11	3	1
Menarche <10 o >15	11	2	9	0
Weight <33.5 or >83	89	21	23	45
Height <140 or >180	26	13	11	2
BMI <13.5 or >29	14	14	0	0
TRACE <4	6		4	2
S1 <40 or >35	54	23	2	29
C7+L3 <-10 o >115	18	4	14	0
Brace worn <22 h/d	201		184	17
Previous brace	361	361		
Totals	795			

| Excluded to match the samples	66%	31%
Included	416	20

No differences for:
- Age, Risser, Age at menarche
- Weight, Height, BMI
- Sagittal (C7+L3, S1 plumbline)
- Curves topography and rigidity

Differences for:
- Brace wearing time: FP +12'/day
- Brace wearing compliance: FP +1%

	FP		Sforzesco		
	Media	DS	Media	DS	P
Age	13,2	1,5	13,0	1,5	0,633
Age at menarche	11,4	1,0	11,8	1,1	0,118
Risser	1,5	1,4	1,6	1,4	0,703
Weight	49,2	10,1	50,0	8,9	0,691
Height	159,8	9,1	158,1	7,6	0,358
BMI	19,2	3,1	19,9	2,9	0,289
C7+L3	47,8	28,7	49,7	23,9	0,722
S1	2,0	18,0	0,6	17,4	0,734
Declared brace use	23,2	0,5	23,0	0,4	0,032
Recorded brace use	93%	2%	92%	6%	0,000
Main curve					
Thoracic proximal	5%		1%		
Thoracic	65%		67%		
Thoracolumbar	20%		17%		NS
Lumbar	5%		16%		
Rigidiy					
Light	5%		5%		
Medium	15%		25%		
High	65%		68%		NS
Very high	15%		2%		
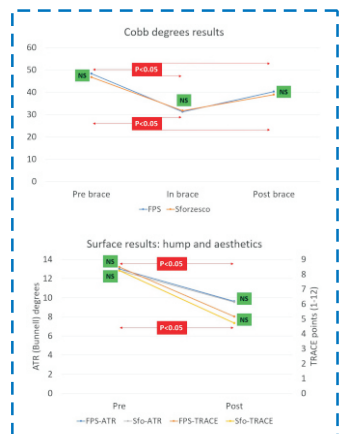
3 Results

We included 416 VRB (12% males, age 13±1, 46±7°) and 20 FP (10%, 13±1, 49±10°).

At baseline brace use (+12'/day FP) and compliance (+1% FP) were different.

All parameters improved statistically (p<0.001) and clinically, without differences among groups in-brace (FP -17±8° vs VRB -15±6° Cobb) and at short-term (5±2 months) for scoliosis (-8±6° vs -8±5° Cobb), ATR (-3±2° vs -4±4° Bunnell), aesthetics (-3±2 vs -3±2 points), S1 (-6±11 vs -4±15 mm) and C7+L3 (-8±17 vs -4±19).

Refereces
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