A MATCHED CASE-CONTROL STUDY OF MODULAR MI/BRACE VS THE CLASSICAL CUSTOM-MADE SFORZESCO BRACE IN 120 CONSECUTIVE HIGH-DEGREE FEMALE AIS

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1 Background

In very-rigid brace (VRB), we introduced the "Free Pelvis" (FP) (semi-rigid material) to improve comfort, sagittal balance and brace adaptability.

We also introduced the "Adjustable Posterior Closure" to improve correction and adaptability.

These two innovations converged in a new modular VRB, the MI/brace (Modular Italian brace) (MIB).

Objective: compare the new MIB to the classical custom-made Sforzesco VRB for adolescents with idiopathic scoliosis (AIS).

- The Free Pelvis (see another poster) and the Adjustable Posterior Closure are the two innovations that allowed the development of a new modular brace

- In this pilot study, the Modular Italian brace (MI-brace) showed to have the same results as the classical very high rigidity braces

- This is the first study exploring the results of a new concept of bracing for scoliosis based on the MI-brace modular system

4 Conclusion

While better in-brace, MIB results in the frontal plane are not different from VRB in the short term. Results could change in the future with a bigger MIB group or in the medium-, long-term.

Cobb degrees results

Surface measurements: ATR and TRACE
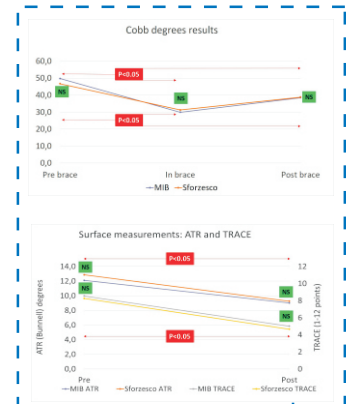
2 Methods

Matched Case-Control Study. We extracted from our prospective database all MIB and VRB at first consultation in our Institute: AIS, age 10-16, VRB 23 hours/day, x-rays available, 36-65°, 7-23° Bunnell. We matched for Risser, menarche, weight, height, BMI, aesthetics (TRACE), plumbline distances, referred brace use.

We randomly chose a subset of VRB to keep a 1:10 ratio between the groups.

We checked in-brace results (one month), and short-term out-of-brace (first control).

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

Baseline comparison	MIT		Sforzesco		P
	Media	DS	Media	DS	
Age	12,5	1,1	13,0	1,5	0,307
Age at menarche	10,6	0,9	11,8	1,1	0,013
Risser	1,0	1,2	1,6	1,4	0,169
Weight	48,6	7,5	49,8	8,6	0,658
Height	159,3	6,0	158,1	7,6	0,590
BMI	19,1	2,2	19,9	2,8	0,361
C7+L3	47,3	19,5	50,0	23,5	0,703
S1	-1,4	12,3	0,8	17,3	0,680
Brace prescription	23,4	0,9	23,2	0,4	0,192
Declared brace use	22,7	0,7	23,0	0,4	0,028
Recorded brace use	94%	2%	92%	6%	0,012
Main curve					
Thoracic	73%		67%		
Thoracolumbar	9%		17%		NS
Lumbar	18%		16%		
Rigidity					
Light	0%		5%		
Medium	9%		25%		NS
High	82%		67%		
Very high	9%		2%		

No differences
- Age, Risser
- Weight, Height, BMI
- Sagittal (C7+L3, S1 plumbline)
- Brace prescription
- Curves topography and rigidity

Differences for:
- Age at menarche: MIT - 1.2 years
- Brace wearing time: MIT -18'/day
- Brace wearing compliance: MIT +2

	Sforzesco	MIT
With brace prescription at first consultation	4431	18
INCLUSION CRITERIA		
Idiopathic scoliosis		
Age 10-16		
Prescription brace at least 21 h/d		3
Rx at prescription		
Rx at first consultation after brace wearing		3
Main curve range 36° to 65°		
ATR range 7° to 23°		
Previous brace		1
Excluded to match the samples	81%	39%
Total first selection from database	844	11
Matching: excluded because out of FPS range	Total	Above max	Below min	No data
Main curve cervical or proximal thoracic	2			
Risser >4	14	11		3
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	
TRACE <4	6		4	2
S1 <-60 or >35	54	23	2	29
C7+L3 <-10 o >115	18	4	14	0
Brace worn <22 h/d	201		184	17
Total	435			
Excluded to match the samples	52%			0%
Included	409			11

3 Results

We included 11 MIB (13±1 y, 50±11°) and 110 VRB (age 13±1, 47±7°) with no baseline differences.

All parameters improved in both groups (p<0.001).

MIB group improved more in-brace (-20±7° vs -16±6°), but we found no short-term differences for scoliosis (-9±7° vs -8±5°), ATR (-4±3° vs -4±3°) and aesthetics (-4±3 vs -4±2), and some in the sagittal plane.

References
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