

ORTHOSIS FOR ADOLESCENT IDIOPATHIC SCOLIOSIS TREATMENT

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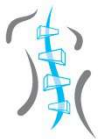
Certified McKenzie Therapist

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**INTERNATIONAL
GAZI HEALTH SCIENCES
CONGRESS**



A Common Future in Healthcare: "From Theory to Practice"



BrAIST study RCT – Weinstein et al 2013

- Multicenter RCT in USA

- 242 patients, SRS inclusion criteria
Cobb angle 25° – 40° , Risser 0-2
2 groups: 1st Bracing, 2nd Observation

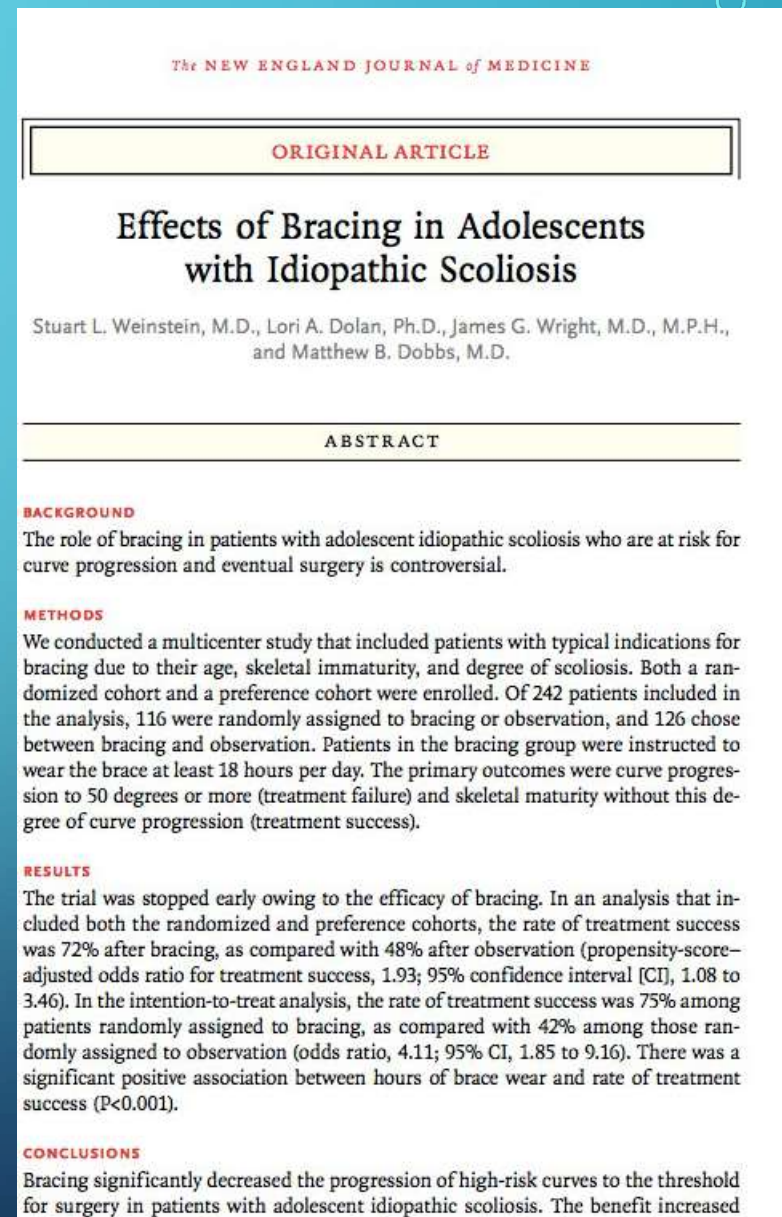
- **Results:**

Bracing success rate **72%**, Observation success rate **48%**

- The trial stopped early for ethical reasons, owing to the efficacy of bracing
- Significant positive association between hours of brace wear and treatment success

- **Conclusions:**

Bracing significantly decreased the risk of progression and is superior than natural history





Negrini et al. *BMC Musculoskeletal Disorders* 2014, **15**:263
<http://www.biomedcentral.com/1471-2474/15/263>



RESEARCH ARTICLE

Open Access

The effectiveness of combined bracing and exercise in adolescent idiopathic scoliosis based on SRS and SOSORT criteria: a prospective study

Stefano Negrini^{1,2*}, Sabrina Donzelli³, Monia Lusini³, Salvatore Minnella³ and Fabio Zaina³

Abstract

Background: Recently an RCT confirmed brace efficacy in adolescent idiopathic scoliosis (AIS) patients. Previously, a Cochrane review suggested also producing studies according to the Scoliosis Research Society (SRS) criteria on the effectiveness of bracing for AIS. Even if the SRS criteria propose a prospective design, until now only one out of 6 published studies was prospective. Our purpose was to evaluate the effects of bracing plus exercises following the SRS and the international Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) criteria for AIS conservative treatment.

Methods: Study design/setting: prospective cohort study nested in a clinical database of all outpatients of a clinic specialized in scoliosis conservative treatment.

Results: Patient sample: seventy-three patients (69 females) age 12 years 10 months - 17 months, 34.4 ± 4.4 Cobb degrees

Stud Health Technol Inform. 2006;123:519-22.

A controlled prospective study on the efficacy of SEAS.02 exercises in preparation to bracing for idiopathic scoliosis.

Negrini S¹, Negrini A, Romano M, Verzini N, Negrini A, Parzini S.

Author information

Abstract

The Lyon school has proposed a preparation to brace wearing through an intensive mobilization in order to obtain a better reduction of the braced scoliotic curve. Our aim was to verify this hypothesis.

DESIGN: A prospective controlled study on consecutive patients having idiopathic scoliosis with brace management.

OUTCOME: Results after 5 months of brace wearing were reviewed by radiographic examination without the brace.

TREATMENT: SEAS Group exercises according to the protocol SEAS.02 (Scientific Exercises Approach to Scoliosis, version 2002); CONT Group various type of exercises. Population. 110 patients (34 females), 13.5±2.4 years, 31.1 degrees ±11.1 degrees Cobb (degrees C), 14.4 degrees ±6.0 degrees Bunnell (degrees B). All parameters improved at follow-up in both groups. SEAS had better results than CONT for degrees C. Clinical results (variations of at least 5 degrees C and 2 degrees B) were better in SEAS than CONT. This study proves the efficacy of SEAS.02 exercises preparatory for bracing. Bracing demonstrated its short term efficacy.

Scoliosis



Research

Open Access

Specific exercises performed in the period of brace weaning can avoid loss of correction in Adolescent Idiopathic Scoliosis (AIS) patients: Winner of SOSORT's 2008 Award for Best Clinical Paper

Fabio Zaina*¹, Stefano Negrini¹, Salvatore Atanasio², Claudia Fusco¹, Michele Romano¹ and Alessandra Negrini²

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Email: Fabio Zaina* - fabio.zaina@isico.it; Stefano Negrini - stefano.negrini@isico.it; Salvatore Atanasio - salvatore.atanasio@isico.it; Claudia Fusco - claudia.fusco@isico.it; Michele Romano - michele.romano@isico.it; Alessandra Negrini - alessandra.negrini@isico.it

* Corresponding author

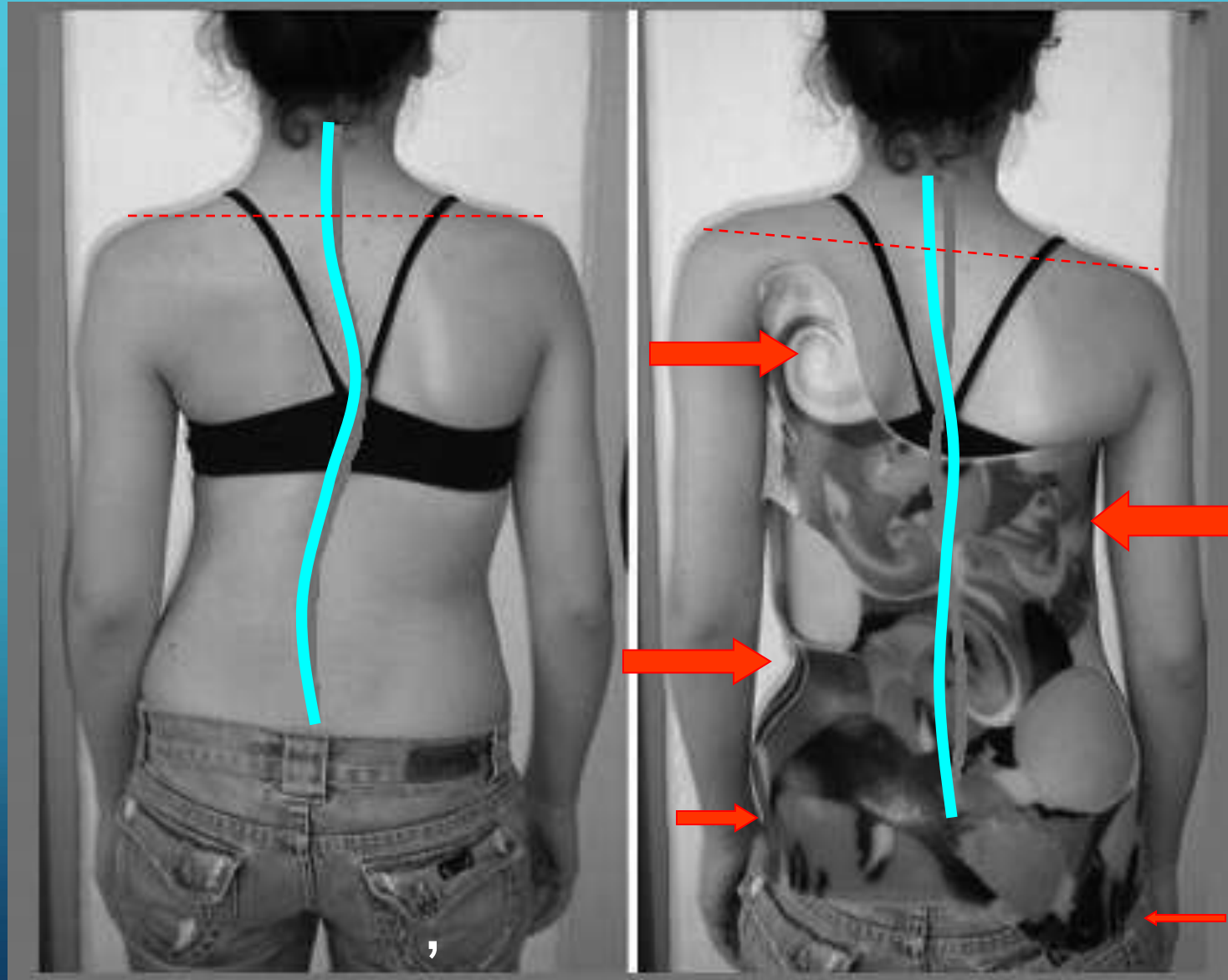


BRACE - 3D CORRECTION

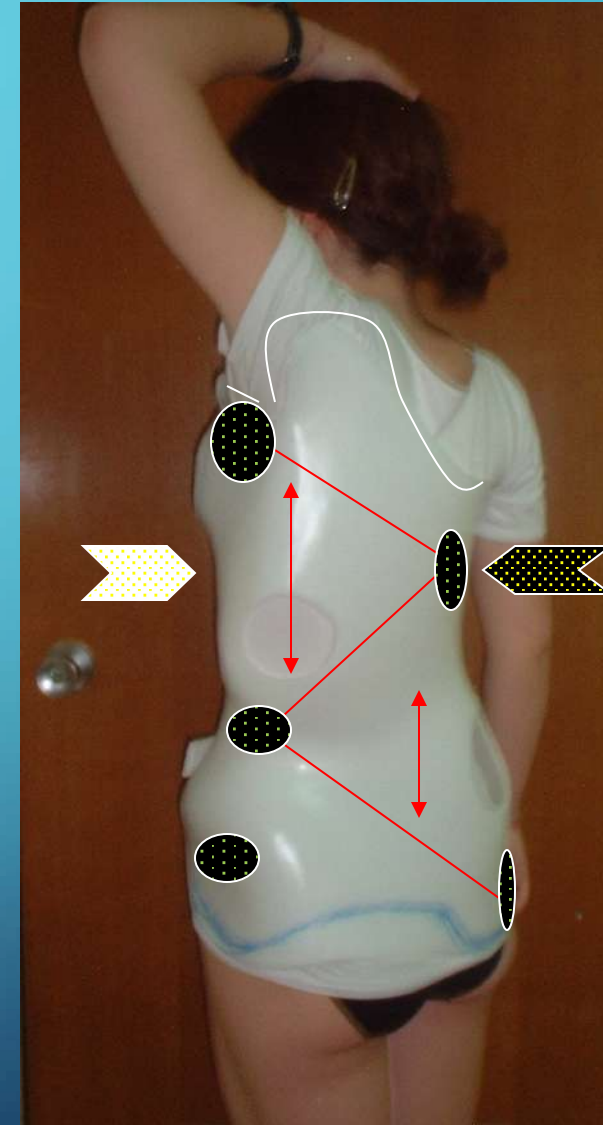
- Three-points systems in the **frontal plane**. Alignment in the frontal plane
- Pair of forces in the **transversal plane** for regional derotation
- **Sagittal** balance and physiological alignment
- Cheneau type braces more compatible with PSSE



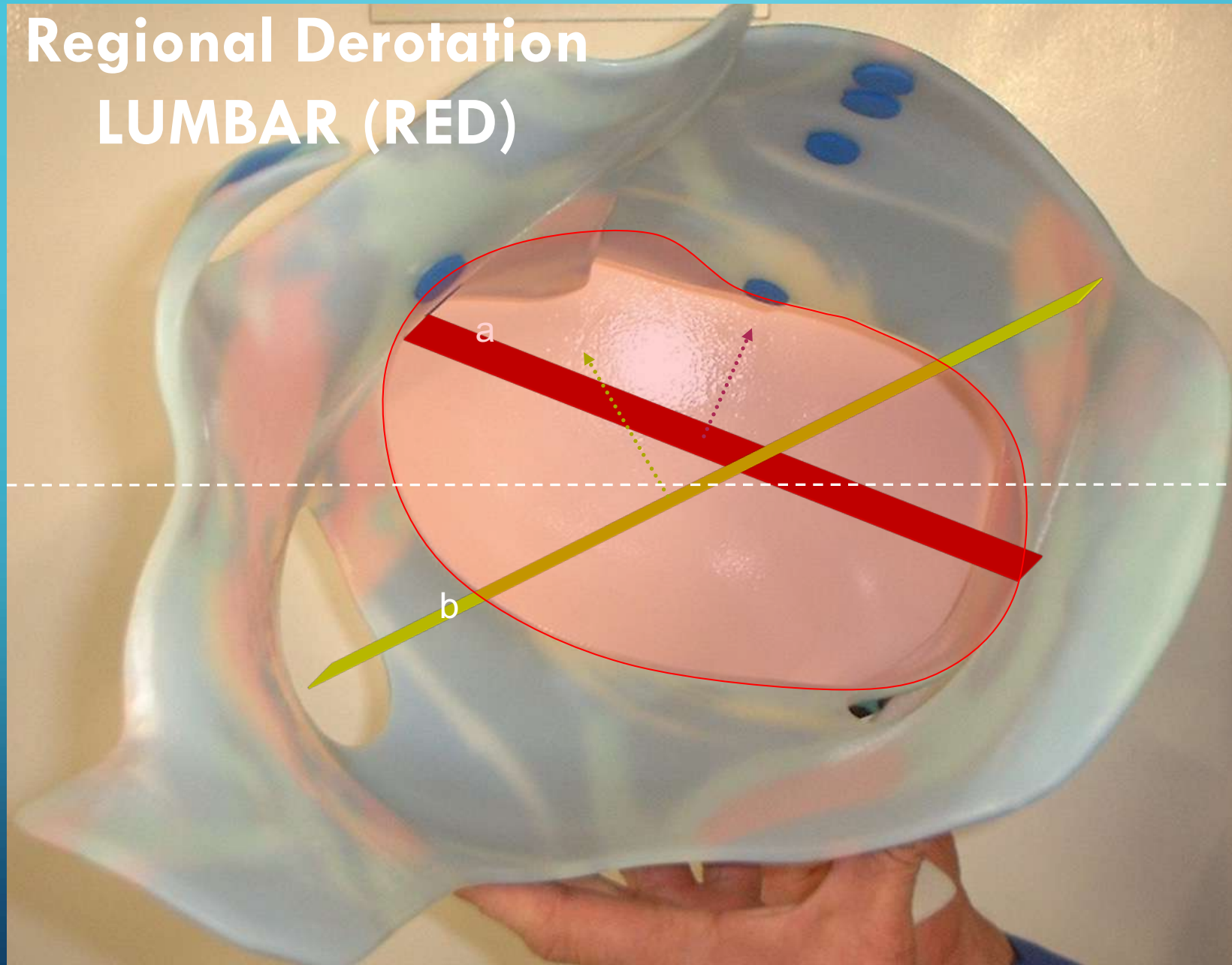
Frontal plane Correction – 3 points systems



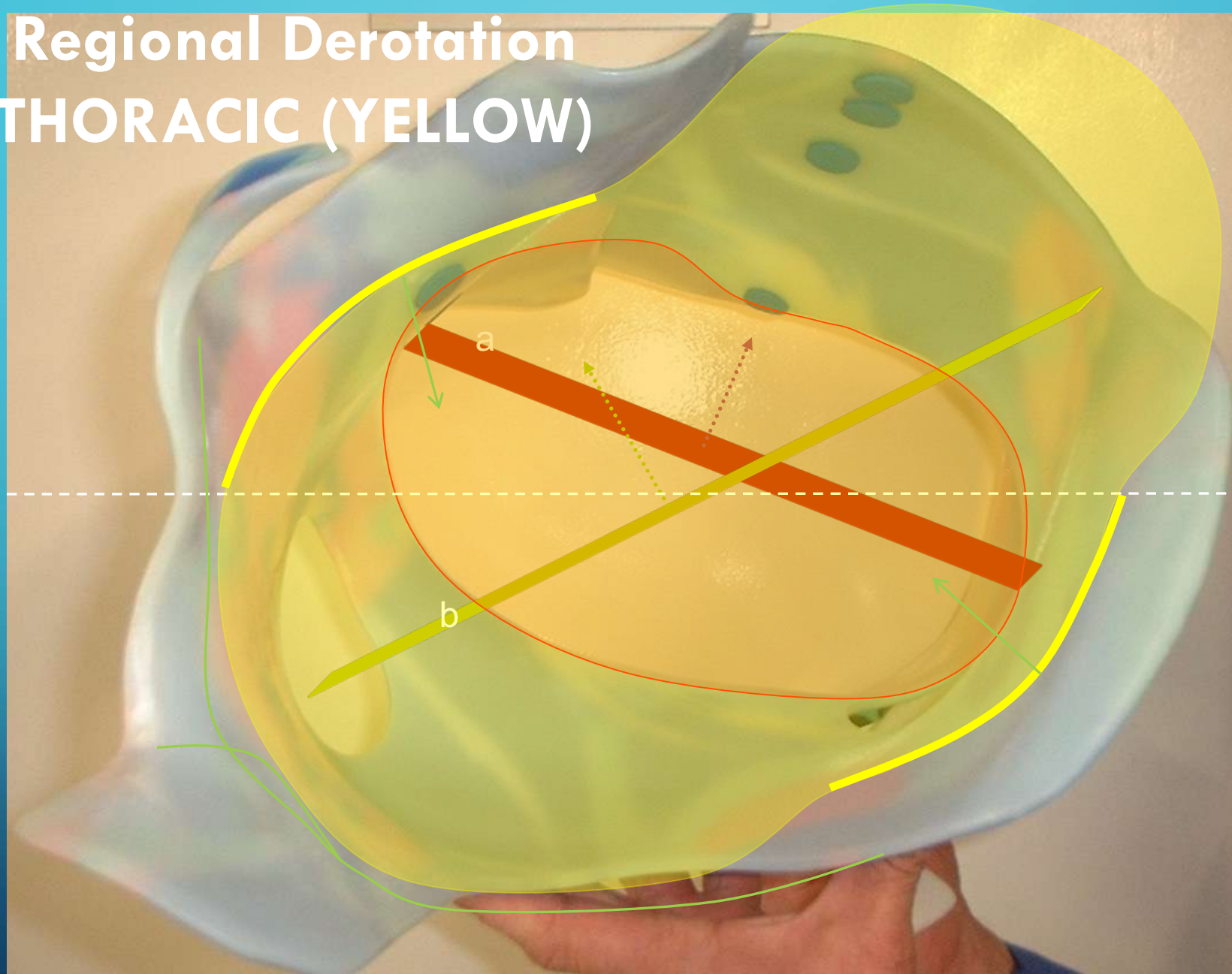
Frontal plane Correction – Press zones and expansion rooms



Regional Derotation LUMBAR (RED)

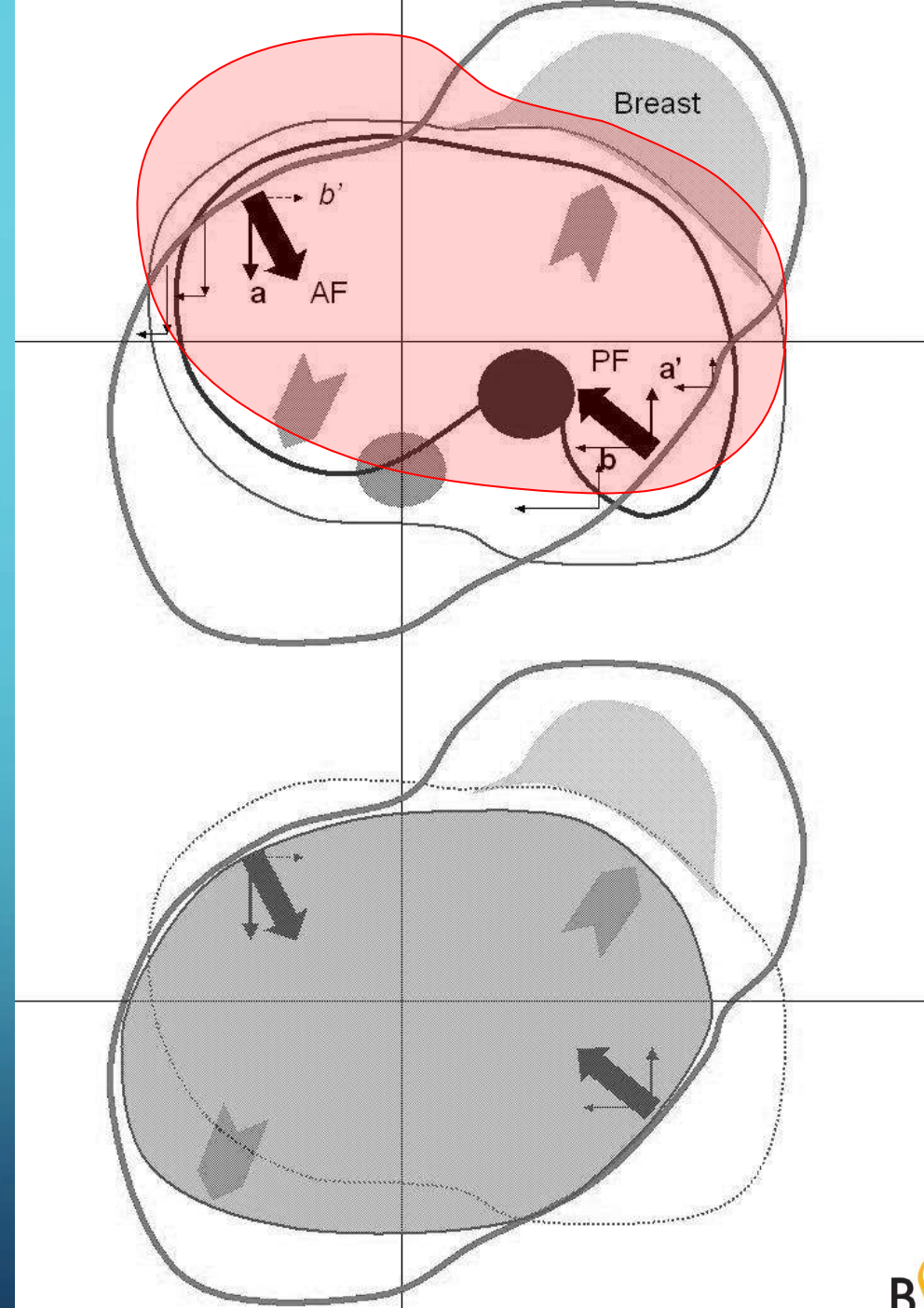
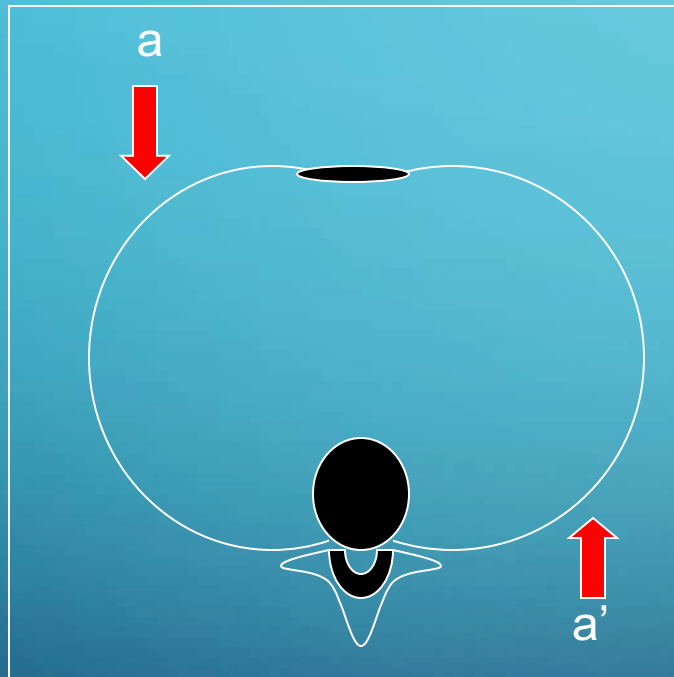


Regional Derotation THORACIC (YELLOW)

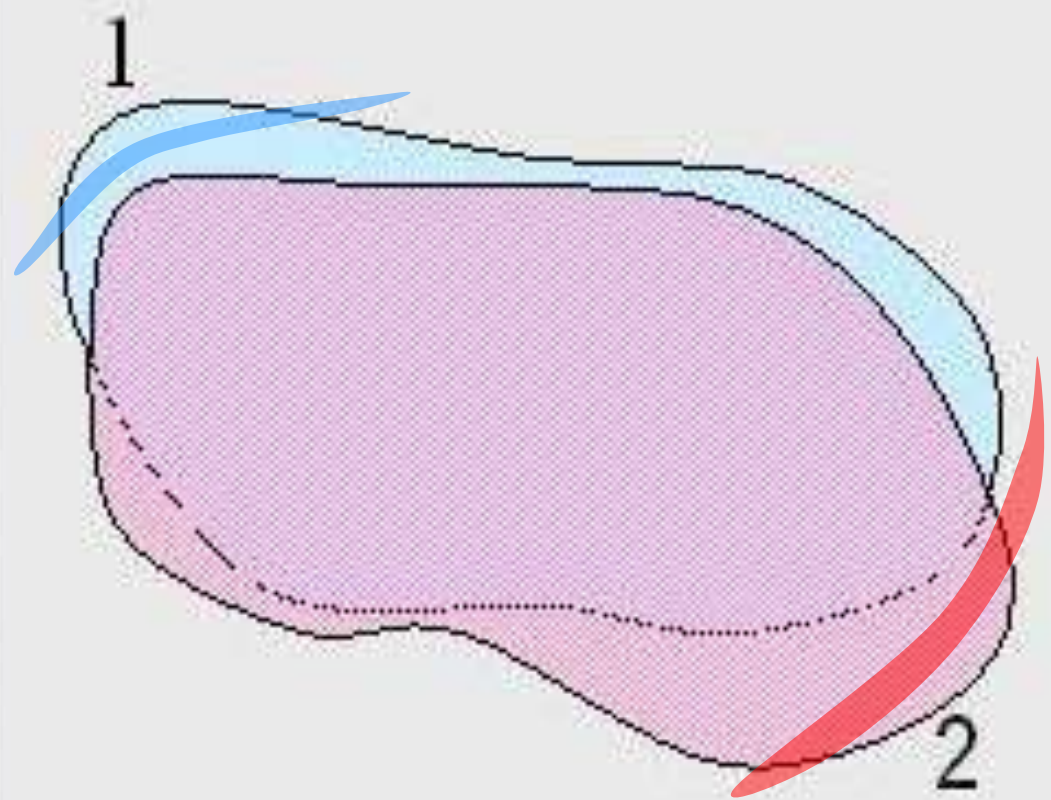
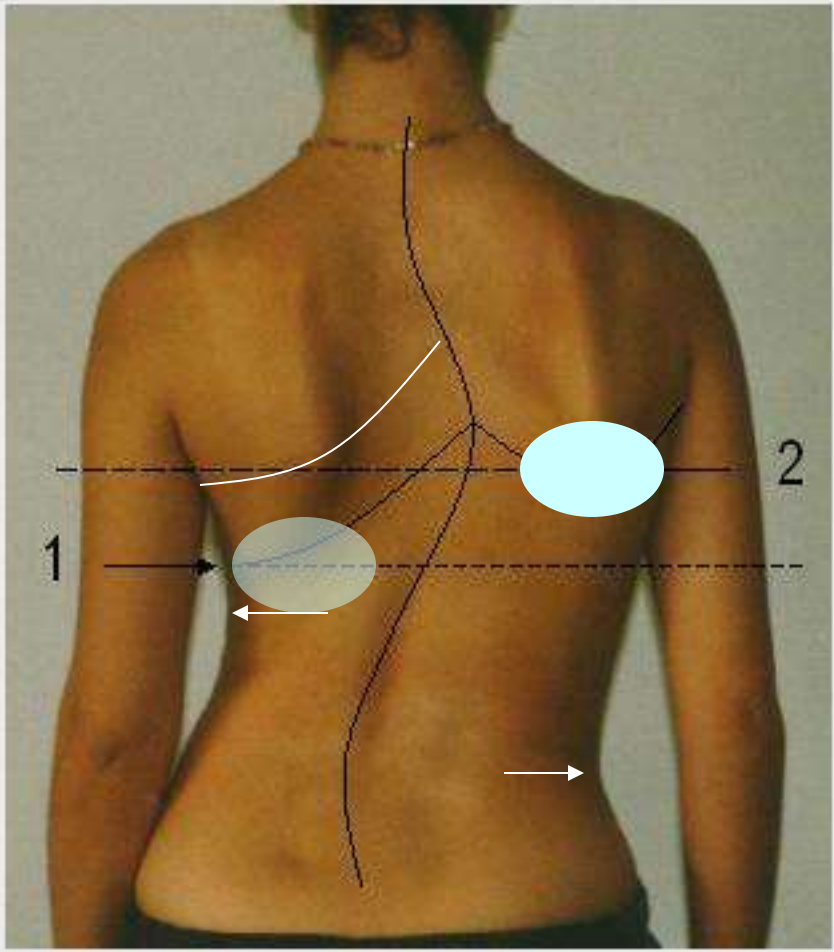


Regional Derotation

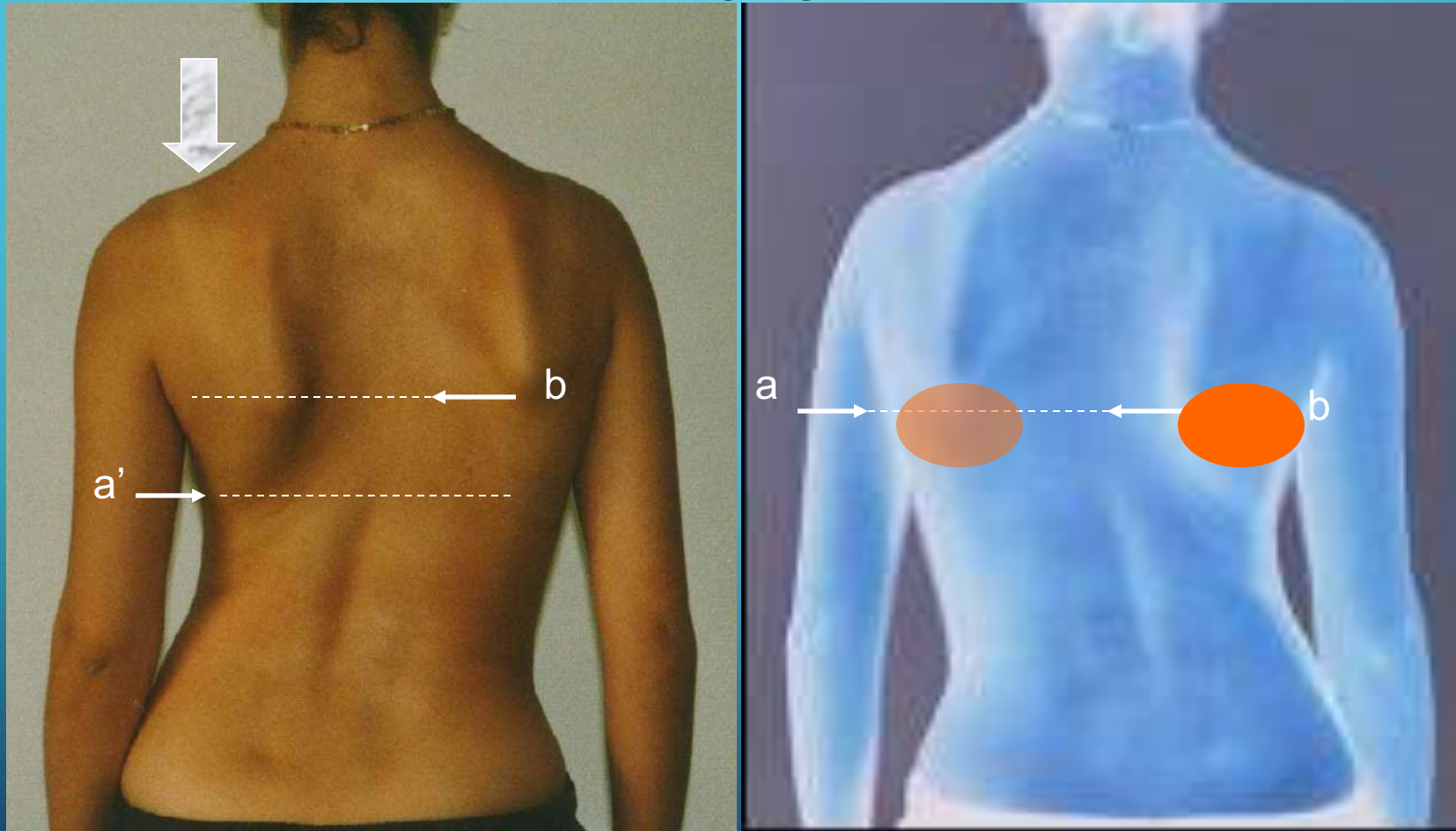
Local Derotation



The pads for derotation, acting on the dorsal and ventral rib humps should be at the same level

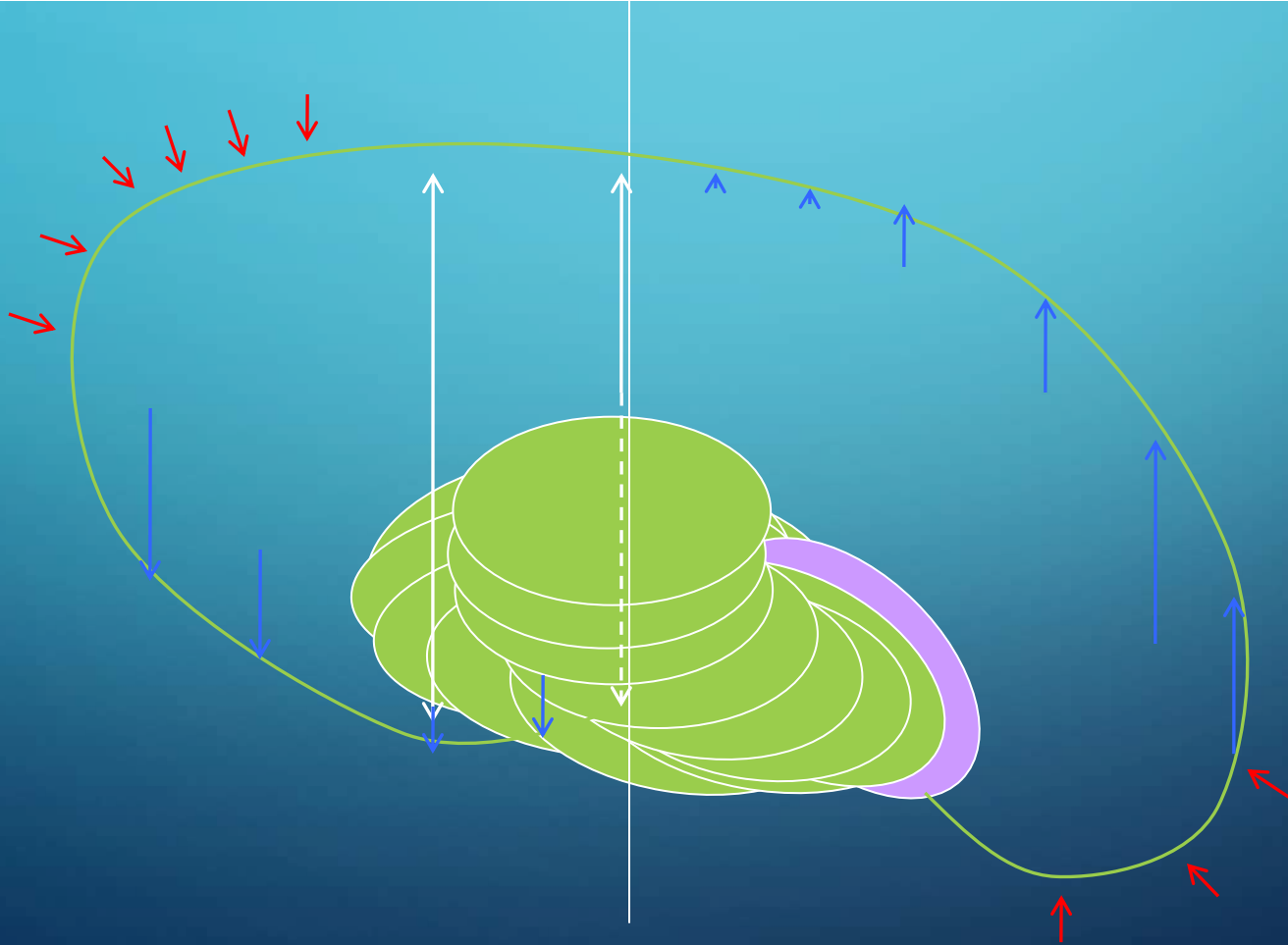


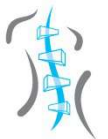
The pads for derotation, acting on the dorsal and ventral rib humps should be at the same level



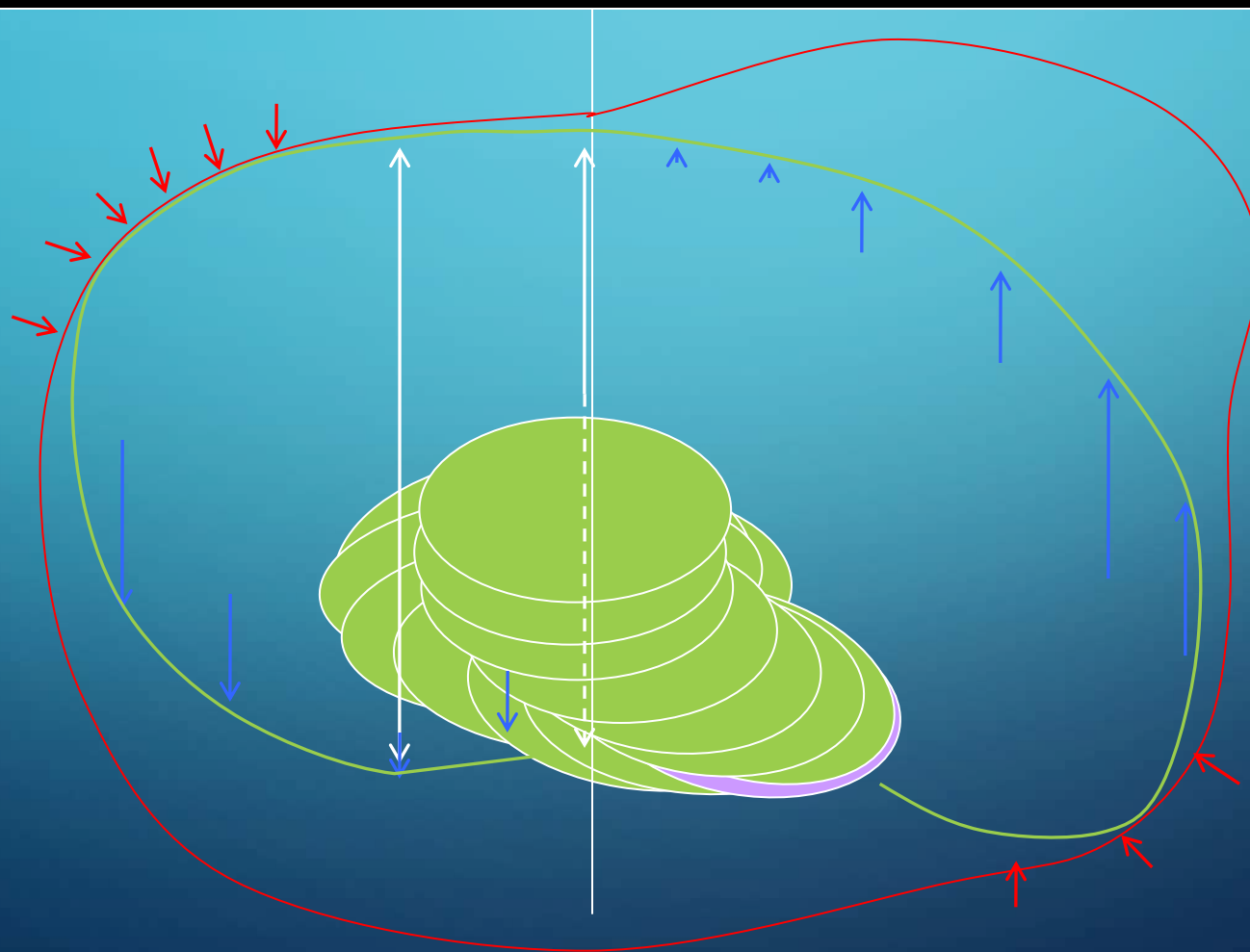
Mirror effect

Breathing mechanics (Dynamic effect)

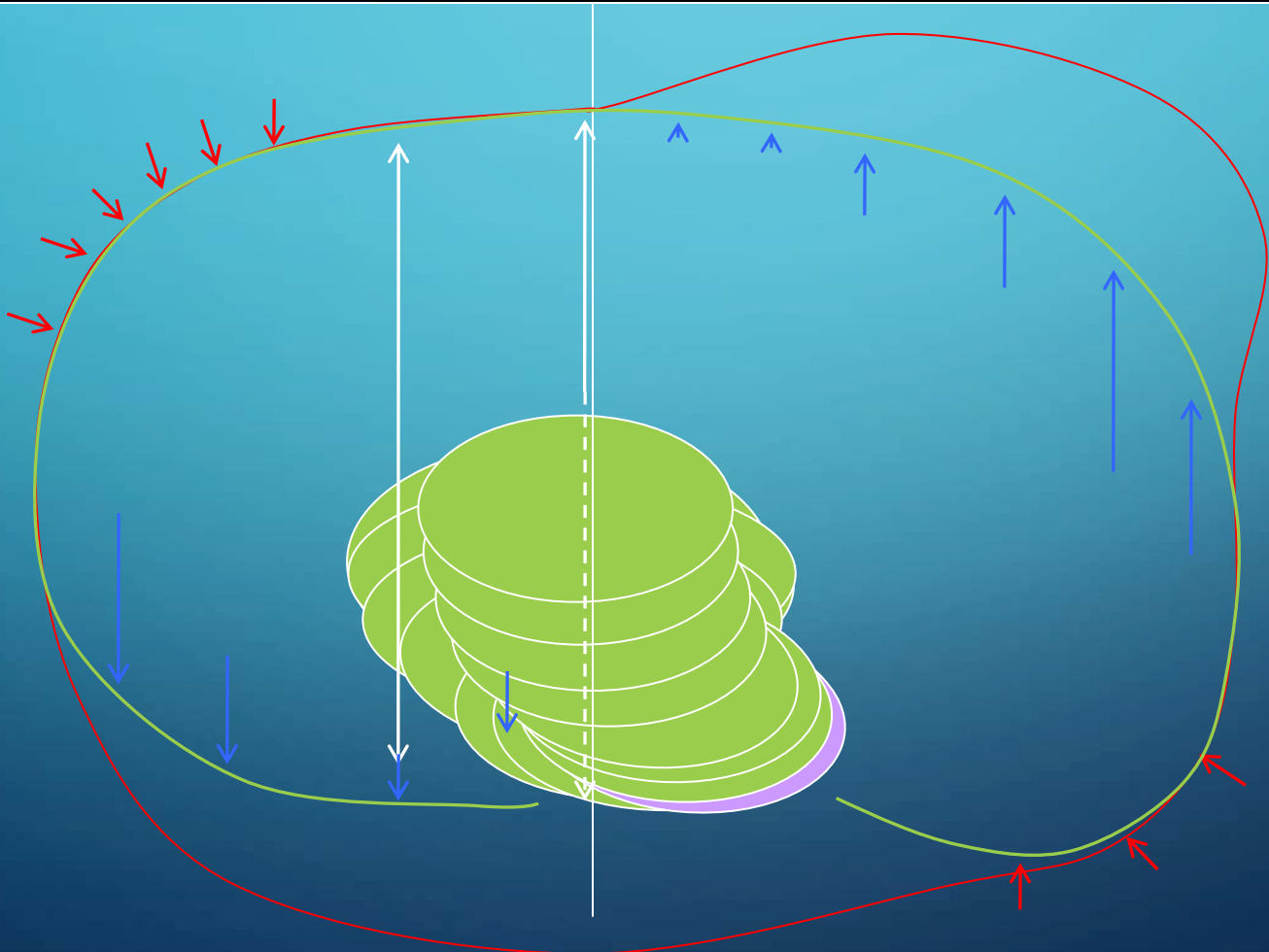




Breathing mechanics creating an internal pair-of-force for derotation and partial correction of the structural flat back



Breathing mechanics creating an internal pair-of-force for derotation and partial correction of the structural flat back



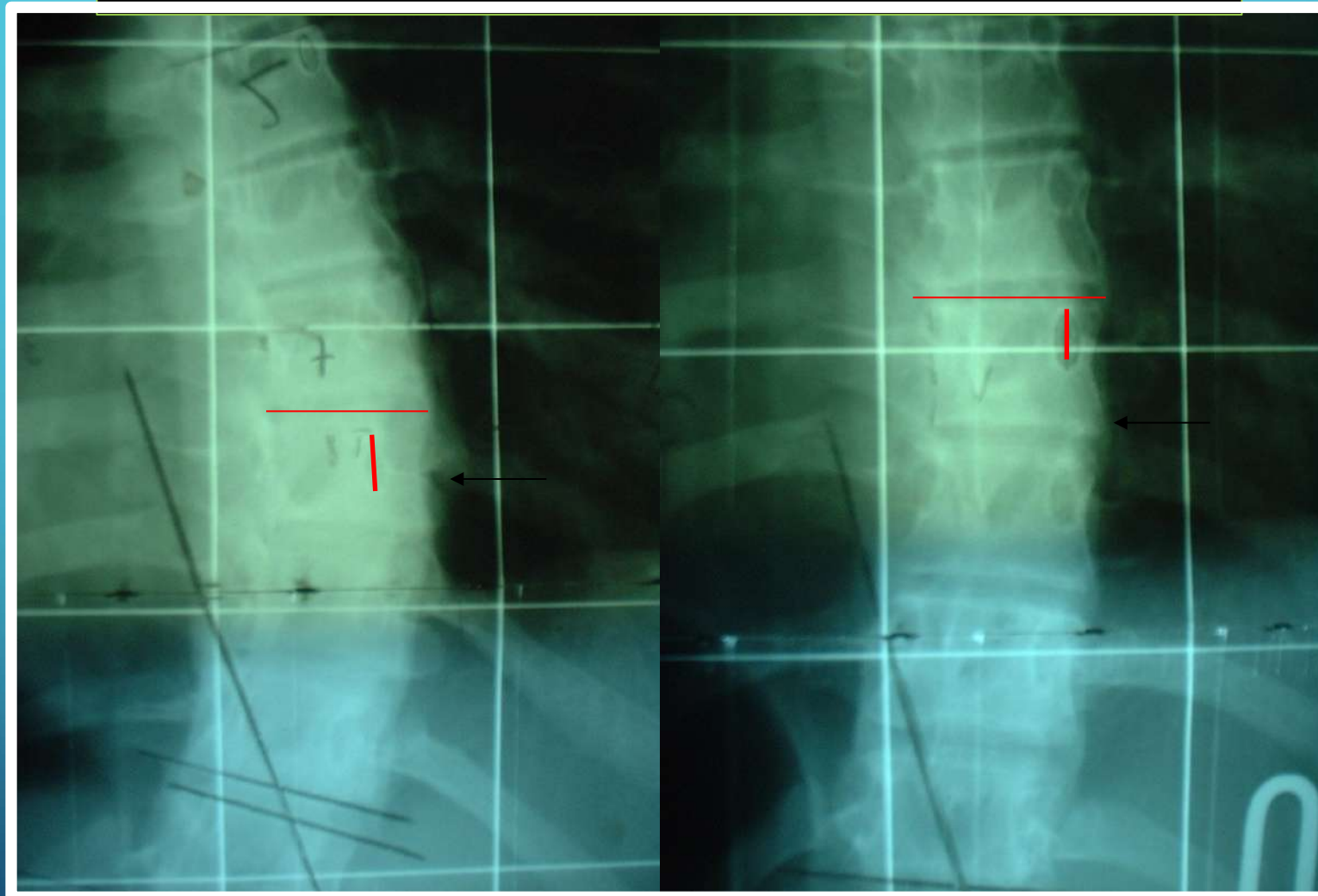


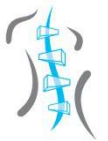
FRONTAL PLANE: REDUCTION OF THE COBB ANGLE



Minimum 30% of in-brace correction

Transversal plane: Reduction of the axial rotation



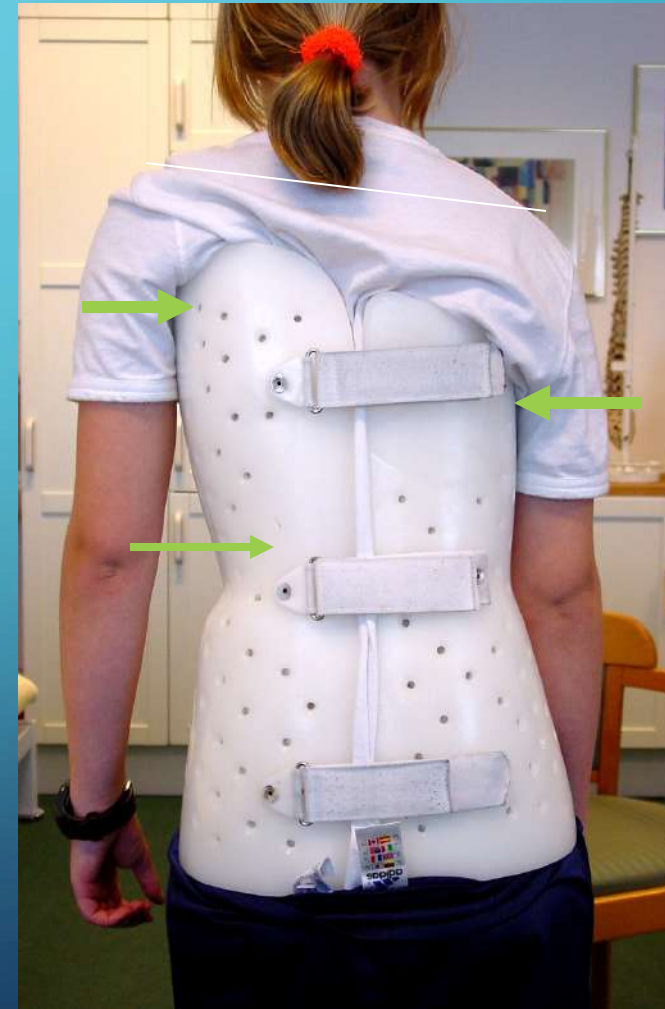


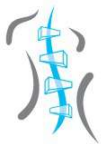
Sagittal plane alignment



BOSTON WITH UPPER THORACIC EXTENSION

PRINCIPLE SUPPORTED BY PERIE D ET AL. SPINE 2003





Introduction

How to improve quality of treatment?

- Predictive factors for success?
- Predictive factors for failure?

- Literature review in electronic databases (Pudmed, EMBASE, CINAHL, Google Scholar, Scopus)

- Level of Evidence according to Journal of Bone and Joint Surgery updated guidelines

- Totally, 121 articles were analyzed to make best-evidence synthesis

Bracing In The Treatment Of Adolescent Idiopathic Scoliosis: Evidence To Date

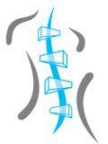
This article was published in the following Dove Press journal:
Adolescent Health, Medicine and Therapeutics

Nikos Karavidas 

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Abstract: Brace effectiveness for adolescent idiopathic scoliosis was controversial until recent studies provided high quality of evidence that bracing can decrease likelihood of progression and need for operative treatment. Very low evidence exists regarding bracing over 40° and adult degenerative scoliosis. Initial in-brace correction and compliance seem to be the most important predictive factors for successful treatment outcome. However, the amount of correction and adherence to wearing hours have not been established yet. Moderate evidence suggests that thoracic and double curves, and curves over 30° at an early growth stage have more risk for failure. High and low body mass index scores are also associated with low successful rates. CAD/CAM braces have shown better initial correction and are more comfortable than conventional plaster cast braces. For a curve at high risk of progression, rigid and day-time braces are significantly more effective than soft or night-time braces. No safe conclusion on effectiveness can be drawn while comparing symmetrical and asymmetrical brace designs. The addition of physiotherapeutic scoliosis-specific exercises in brace treatment can provide better outcomes and is recommended, when possible. Despite the growing evidence for brace effectiveness, there is still an imperative need for future high methodological quality studies to be conducted.

Keywords: scoliosis, brace, non-operative treatment, orthosis, evidence



In-brace correction (IBC) is defined as the percentage of Cobb angle reduction during an X-ray with the brace fitted on the patient

Predictive factor	Study	Level of Evidence	Treatment success	Treatment failure
In-brace correction	Katz and Durani ³⁸	III	Min 25% IBC for double curves	
	Castro et al ³⁹	II	Min 20% IBC to recommend bracing	
	Landauer et al ⁴⁰	IV	IBC >40% and good compliance	
	Weiss and Rigo ⁴¹	IV	Positive, no values mentioned	
	Goodbody et al ⁴²	III		IBC <45%
	Xu et al ⁴³	III	Min 10% IBC	
	Weiss et al ⁴⁴	III	Average 66% IBC and success rate	
	De Mauroy et al ⁴⁵	II	Average IBC 70% and success rate	
	Van de Bogaart et al ⁴⁶ (SR)	NA	Strong evidence	
	El Hawary et al ⁴⁷ (SR)	NA	Level of Evidence III	

- **IBC is strong predictor of treatment success**
- No consensus on the cut-off percentage which increases the risk for failure
- Further research is necessary to establish a minimum in-brace correction rate



Predictive factor	Study	Level of Evidence	Treatment success	Treatment failure
Compliance	Weinstein et al ⁵	I	Average 12.9h, dose-effect response of bracing	
	Rowe et al ⁴⁸ (meta-analysis)	NA	Proportion of success: 0.93 for 23h, 0.6 for 8h, 0.62 for 16h	
	Katz and Durani ³⁸	III	Min 18h decrease likelihood of progression	
	Landauer et al ⁴⁰	IV		Bad compliance correlated with curve progression
	Rahman et al ⁴⁹	II	11% failure for compliant (>90% of prescription)	56% failure for non-compliant (< 90% of prescription)
	Brox et al ⁵⁰	II	19.5% failure for compliant (>20h)	55.7% failure for non-compliant (<20h)
	Aulisa et al ⁵¹	II	94.3% success in compliant (min 18h)	41.3 % progression in non-compliant
	Kuroki et al ⁵²	III	67.7% success for compliant (>15h)	
	Karol et al ^{53,54}	II	Patients at Risser 0, min 18h prescription	
	Thompson et al ⁵⁶	III		30% progression >50° in compliant (>13h)
	Lou et al ^{55,60,61}	II	Prognostic model: Cobb angle, risk for progression, IBC, quantity and quality of bracing	
	Van de Bogaart et al ⁴⁶ (SR)	NA	Moderate evidence	
	El Hawary et al ⁴⁷ (SR)	NA	Level of Evidence I	

- **Moderate to strong evidence (Level I or II)** that limited brace wearing time is related to increased risk of treatment failure
 - Monitoring devices and team management can increase compliance



Predictive factor	Study	Level of Evidence	Treatment success	Treatment failure
Curve magnitude	Emans et al ⁶²	III		Higher initial curve increase surgery rate
	Katz and Durani ³⁸	III		Double curves >35°
	Sun et al ⁶³	III		Cobb angle >30°
	Ovadia et al ⁶⁴	III	Low baseline Cobb angle, less progression	
	Karol et al ⁵⁴	II	No correlation, Insignificantly lower success rate for Cobb 20°-30° than >30°	
	Xu et al ⁶⁵	III	No correlation	
	Sun et al ⁶⁶	III	No correlation	
	Van de Bogaart et al ⁴⁶ (SR)	NA	Limited evidence that curve magnitude is not related to treatment success	Moderate evidence, curve magnitude is not related to treatment failure
	El Hawary et al ⁴⁷ (SR)	NA		Level of Evidence II, Cobb angle >30°

- Some studies found limited evidence whether brace treatment success is dependent on curve magnitude
 - Low evidence (Level III) for brace effectiveness even for curves over 40°
 - Some studies found curve magnitude as prognostic factor for failure (Cobb angle > 30°)
 - Evidence remains debatable



Predictive factor	Study	Level of Evidence	Treatment success	Treatment failure
Curve type	Emans et al ⁶²	III	Apex T8-L2 better IBC and control	
	Katz and Durani ³⁸	III		Double curves, thoracic Cobb >35°
	Sun et al ⁶³	III		Cobb angle >30°
	Thompson et al ⁵⁶	III		Cobb angle >30°
	Kuroki et al ⁵²	III		No correlation
	Sun et al ⁶⁶	III		No correlation
	Xu et al ⁶⁵	III		No correlation
	Van de Bogaart et al ⁴⁶ (SR)	NA	Moderate evidence	
	El Hawary et al ⁴⁷ (SR)	NA	Level of Evidence II	

- Moderate evidence that double curves, over 30° have more potential for treatment failure

Predictive factor	Study	Level of Evidence	Treatment success	Treatment failure
Growth stage	Hanks et al ⁶⁷		Risser sign and menarche significant prognostic factors. Recommended no bracing > Risser 1	
	Sun et al ⁶³	III		Lower Risser grade and pre-menarche significant factors
	Sun et al ⁶⁶	III		Lower Risser grade and pre-menarche not significant factors
	Ovadia et al ⁶⁴	III	High Risser score	
	Aulisa et al ⁵¹	II		Low Risser sign
	Xu et al ⁶⁵	III		Low Risser sign
	Karol et al ⁵⁴	II		Risser 0 and OTC Risser 0- & Cobb >30° 63% progression risk, Risser 0+ & Cobb>30° 32.4% progression risk
	Katz and Durani ³⁸	III		No correlation
	Kuroki et al ⁵²	III		No correlation
	Xu et al ⁶⁵	III		No correlation
	O'Neill et al ⁶⁹	III		No correlation
	Dolan et al ⁷⁰	II		Sanders scale + Cobb + treatment give best fitting-prediction model
	Van de Bogaart et al ⁴⁶ (SR)	NA	Conflicting evidence for growth stage and menarche	
	El Hawary et al ⁴⁷ (SR)	NA		Level of Evidence II for Low Risser

- Earlier growth stage increased the risk of failure
 - Conflicted/Moderate evidence



Predictive factor	Study	Level of Evidence	Treatment success	Treatment failure
BMI	O'Neill et al ⁶⁹	III		Over-weight 3.1 times more likely to fail
	Gilbert et al ⁸¹	III		High BMI frequently late diagnosed, but not more likely to surgery
	Goodbody et al ⁴¹	III		High and low BMI more likely to fail, compliant not significant
	Sun et al ⁶⁵	III		Low BMI prognostic factor for failure
	Vachon et al ⁸²	III		No correlation
	Zaina et al ⁸³	III		No correlation
	Van de Bogaart et al ⁴⁶ (SR)	NA		Limited evidence for low BMI, conflicting evidence for high BMI

- High and low body mass index scores are also associated with low successful rates
 - Limited evidence



Other prognostic factors

Predictive factor	Study	Level of Evidence	Treatment success	Treatment failure
Rotation (Vertebra and Trunk)	Upadhyay et al ⁸⁴	III	Reduction of in-brace rotation	
	Ovadia et al ⁶⁴	III	Low ATR	
	Yamane et al ⁸⁵	III		Insufficient in-brace rotation correction
Lumbar Pelvic relationship (LPR)	Katz and Durani ³⁸	III		LPR > 12°
Erα and TPH-1 genes	Xu et al ⁸⁶	III	Potential predictors of brace outcome	
Initial Cobb Angle Reduction Velocity	Mao et al ⁸⁷	III	ARV better predictor than IBC	
Osteopenia	El Hawary et al ⁴⁷ (SR)	NA		Level of Evidence II



Award Presentations

**Brace and Physiotherapeutic Scoliosis Specific Exercises (PSSE)
for Adolescent Idiopathic Scoliosis (AIS) treatment: A prospective study
following Scoliosis Research Society (SRS) criteria**

Karavidas Nikos, PT, MSc

- **Brace > Natural history**

- **Aim of the study:
Brace and PSSE**

(complete non-operative
treatment)

for Adolescent Idiopathic Scoliosis
(AIS)

- **Prospective study**
- **SRS inclusion criteria**
 - (>10 years, Cobb angle 25° – 40°, Risser 0-2,
< 1 year post-menarche, no prior treatment)
- **102 consecutive patients**
- (87 females-15 males, mean age 12.8 years, Risser 0.48,
Cobb Th 29.2° , Cobb Lu 27.8°)
- Average follow-up 26.4 months
- 7 drop-outs (6.8%), 95 included for main statistical
analysis, paired t-test

Treatment protocol

- **Cheneau type brace + PSSE**
- **Brace** wearing time according to curve magnitude and growth stage
- **PSSE** 5 times/week, 30 minutes, 1 supervised session/week – BSPTS and Schroth



- 1) Curve progression ($>5^\circ$)
- 2) Reaching surgical threshold $>40^\circ$
- 3) In-brace correction
- 4) Compliance
- 5) SRS-22 questionnaire
- 6) Angle Trunk Rotation (ATR) by scoliometer
- 7) Control Group (excluding PSSE compliance A)

Brace Compliance A (full-compliance)	90%-100% of recommended hours	PSSE Compliance A (full-compliance)	5 days/week or more
Brace Compliance B (partial compliance)	70%-90% of recommended hours	PSSE Compliance B (partial compliance)	3-4 days/week
Brace Compliance C (no compliance)	$<70\%$ of recommended hours	PSSE Compliance C (no compliance)	< 3 days/week

Results

Curve progression

		Curve	Progression		
Main analysis	62 stable 65.3%	22 improved 23.2%	11 progressed 11.5%	Total 95 patients	Success rate 88.5% (84/95)
Worst case analysis	62 stable 60.8%	22 improved 21.6%	18 progressed 17.6% 7 Drop-outs (6.8%) considered as fails	Total 102 patients	Success rate 82.4% (84/102)

Pre-treatment		Post-treatment		Statistical significance
Cobb angle Thoracic	29.2° (25° – 40°)	Cobb angle Thoracic	28.3° (10° – 51°) 95% CI -0.45 to 2.06	p= 0.21
Cobb angle Lumbar	27.8° (25° – 40°)	Cobb angle Lumbar	26.1° (14° – 39°) 95% CI 0.74 to 2.71	p= 0.0008*

	Surgical	Range	
Cobb angle >40° (surgical threshold)	6 patients	6.4%	Success rate 93.6% (89/95)
Cobb angle >50°	1 patient	1.1%	Success rate 98.9% (94/95)

Results

Predictive factors (In-brace correction / compliance)

	Mean Cobb angle pre-treatment	Mean Cobb angle in-brace	% in-brace correction
Thoracic	29.1°	14.9°	49.71%
Lumbar	27.8°	10.6°	61.71%

	Compliance PSSE A	Compliance PSSE B	Compliance PSSE C	Total
Compliance brace A	<u>62 (65.3%)</u>	12 (12.6%)	3 (3.1%)	<u>77 (81%)</u>
Compliance brace B	4 (4.3%)	3 (3.1%)	2 (2.1%)	9 (9.5%)
Compliance brace C	0 (0%)	2 (2.1%)	7 (7.4%)	9 (9.5%)
Total	<u>66 (69.6%)</u>	17 (17.8%)	12 (12.7%)	

Results

Quality of Life - Aesthetics

Pre-treatment	Score	Post-treatment	Score	Statistical significance
Pain	22.3	Pain	22.5	p= 0.17
Mental health	18.3	Mental health	18.9	p= 0.003*
Self-image	19	Self-image	20.4	p= 0.0001*
Function	22	Function	22.5	p= 0.0006*
Total SRS-22	81.4	Total SRS-22	83.6	p= 0.0001*

Pre-treatment		Post-treatment		Statistical significance
ATR Thoracic	9.3° (4° – 15°)	ATR Thoracic	7.1° (10° – 51°)	p= 0.002*
ATR Lumbar	7.4° (3° – 13°)	ATR Lumbar	5.1° (14° – 39°)	p= 0.001*

Results

Control group

Control group:

- **Compliance PSSE B and C**
(excluding full compliants with PSSE)
- More representative group to brace alone without PSSE
- **Importance of PSSE compliance to enhance treatment result**

	Compliance PSSE A	Compliance PSSE B	Compliance PSSE C	Total
Compliance brace A	<u>62 (65.3%)</u>	12 (12.6%)	3 (3.1%)	<u>77 (81%)</u>
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Total	<u>66 (69.6%)</u>	17 (17.8%)	12 (12.7%)	

	IBC Thoracic	IBC Lumbar	62 stable	22 improved	11 progressed	Total 95 patients	Success rate
Whole group	49.7%	61.7%	65.3%	23.2%	11.5%		88.5% (84/95)
Control group	47.7% (p=0.12)	59.3% (p=0.14)	68.9%	13.8%	17.3%	Total 29 patients	82.7% (24/29) (p=0.03)*

Results

A-A compliance group

A-A compliance group:

- Fully compliant with both brace and PSSE
- Positive effect of adherence to treatment protocol

	Compliance PSSE A	Compliance PSSE B	Compliance PSSE C	Total
Compliance brace A	<u>62 (65.3%)</u>	12 (12.6%)	3 (3.1%)	<u>77 (81%)</u>
Compliance brace B	4 (4.3%)	3 (3.1%)	2 (2.1%)	9 (9.5%)
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Total	<u>66 (69.6%)</u>	17 (17.8%)	12 (12.7%)	

	IBC Thoracic	IBC Lumbar	stable	improved	progressed	Total	Success rate
Whole group	49.7%	61.7%	65.3%	23.2%	11.5%	95 patients	88.5% (84/95)
A-A compliance group	52.3% (p=0.08)	62.6% (p=0.10)	70.9%	29.1%	0%	62 patients	100% (62/62) (p=0.0002)*

Results

Case 6



Pre-treatment



In-brace



Post-treatment



Pre-treatment



Pre-treatment



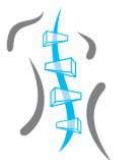
In-brace



Post-treatment



Post-treatment



Results

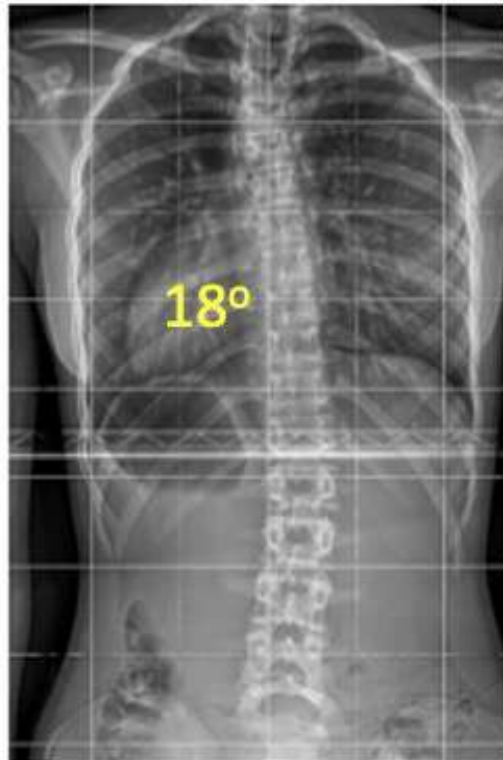
Case 5



Pre-treatment



In-brace



Post-treatment



Pre-treatment



Pre-treatment



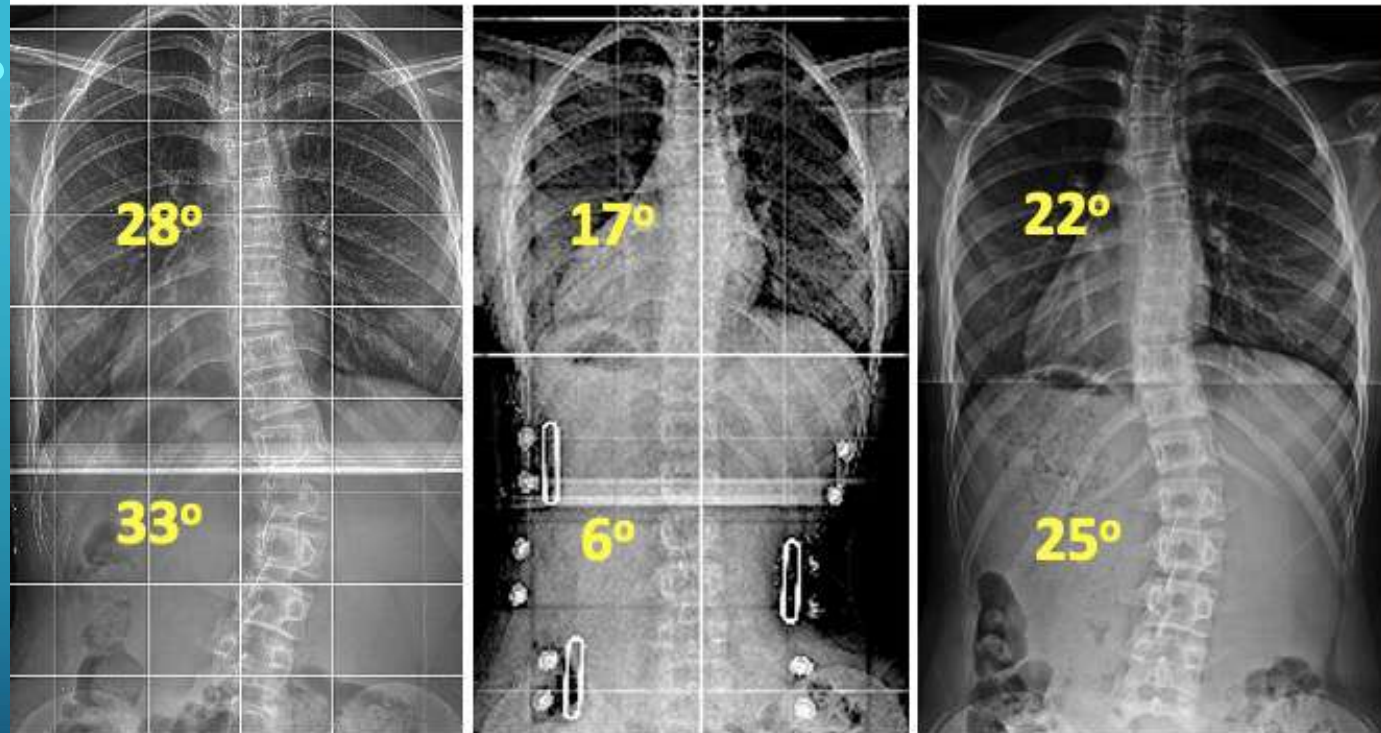
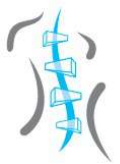
In-brace



Post-treatment



Post-treatment



Pre-treatment

In-brace

Post-treatment



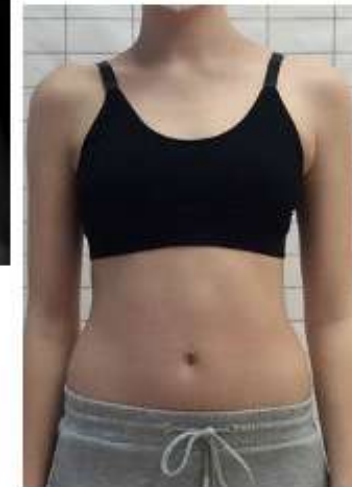
Pre-treatment



Pre-treatment



In-brace



Post-treatment



Post-treatment

Brace and PSSE

➤ Negrini et al (2009)

Lyon / Sforzesco – SPoRT brace + SEAS
48 subjects, SRS inclusion criteria
96% not progressed
0% > 45°

➤ Kwan et al (2017)

Boston brace + Schroth
24 subjects, SRS inclusion criteria
79% not progressed
70.8% full brace compliance

Brace alone (no PSSE)

➤ Ovadia et al (2009)

RSC brace (no PSSE)
93 subjects, SRS inclusion criteria
83.8% not progressed
Retrospective design (selection bias?)

➤ Kuroki et al (2015)

OMC brace (no PSSE)
31 subjects, SRS inclusion criteria
67.7% not progressed

➤ Aulisa et al (2015)

Lyon brace (no PSSE)
69 subjects, SRS inclusion criteria
98.5% not progressed
Only Single thoracic curves
No analysis for drop-outs (16.7%)

➤ Pasquini et al (2016)

Cheneau P brace (no PSSE)
37 subjects, SRS inclusion criteria
92% not progressed

➤ Weiss et al (2019)

Gensingen brace (no PSSE)
28 subjects, SRS inclusion criteria
85.7% not progressed

Brace alone (no PSSE)

(End result < 50°)

➤ BrAIST study

Weinstein et al (2013)

Boston brace (no PSSE)
242 subjects
SRS modified inclusion criteria (20° – 40°)
72% success rate (not reaching > 50°)

➤ Weiss et al (2019)

Gensingen brace (no PSSE)
28 subjects, SRS inclusion criteria
92.9% success rate (not reaching >50°)



Conclusions

Strengths

- Large sample size (95 patients)
- Power calculation
- Group with high risk of progression
- Efforts to reduce selection and measurement bias (prospective database, consecutive patients, assessors blinded)

Limitations

- Follow-up stopped at the end of brace treatment
- No data for long-term
- No brace sensors to measure compliance
- No actual control group with brace alone

- **A complete non-operative treatment with bracing and PSSE achieved a success rate of 88.5% (no progression >5°)**
 - **Similarly, only 6.4% > 40° and 1.1% >50°**
- **Brace and PSSE, with good compliance and IBC, is effective and can significantly reduce the need for surgery**
 - **Brace + PSSE > Brace alone**
- **Brace and PSSE significantly improved aesthetics and QoL**



**Schroth Scoliosis
&
Spine Clinic**

Thank you for your attention

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Certified Schroth ISST Therapist

Certified SEAS Therapist

Certified Schroth Best Practice Therapist

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