Cochrane Rehabilitation

UNIVERSITÀ DEGLI STUDI DI MILANO

I.R.C.C.S. Istituto Ortopedico Galeazzi

ISICO ISTITUTO SCIENTIFICO ITALIANO COLONNA VERTEBRALE

Evidence Based PRM Approach to Idiopathic Scoliosis

Stefano Negrini

1. University «La Statale» Milan
2. IRCCS Orthopaedic Institute Galeazzi , Milan
3. ISICO (Italian Scientific Spine Institute), Milan

Trusted evidence.
Informed decisions.
Better health.

Why scoliosis is of interest for PRM physicians

Specialised vs generalist PRM: PRM and highly specialised specific competence

There are all the ingredients of PRM

- Therapies (orthosis, exercises, cognitive-behavioural approach)
- Team work and patients' management

Good for you if you like

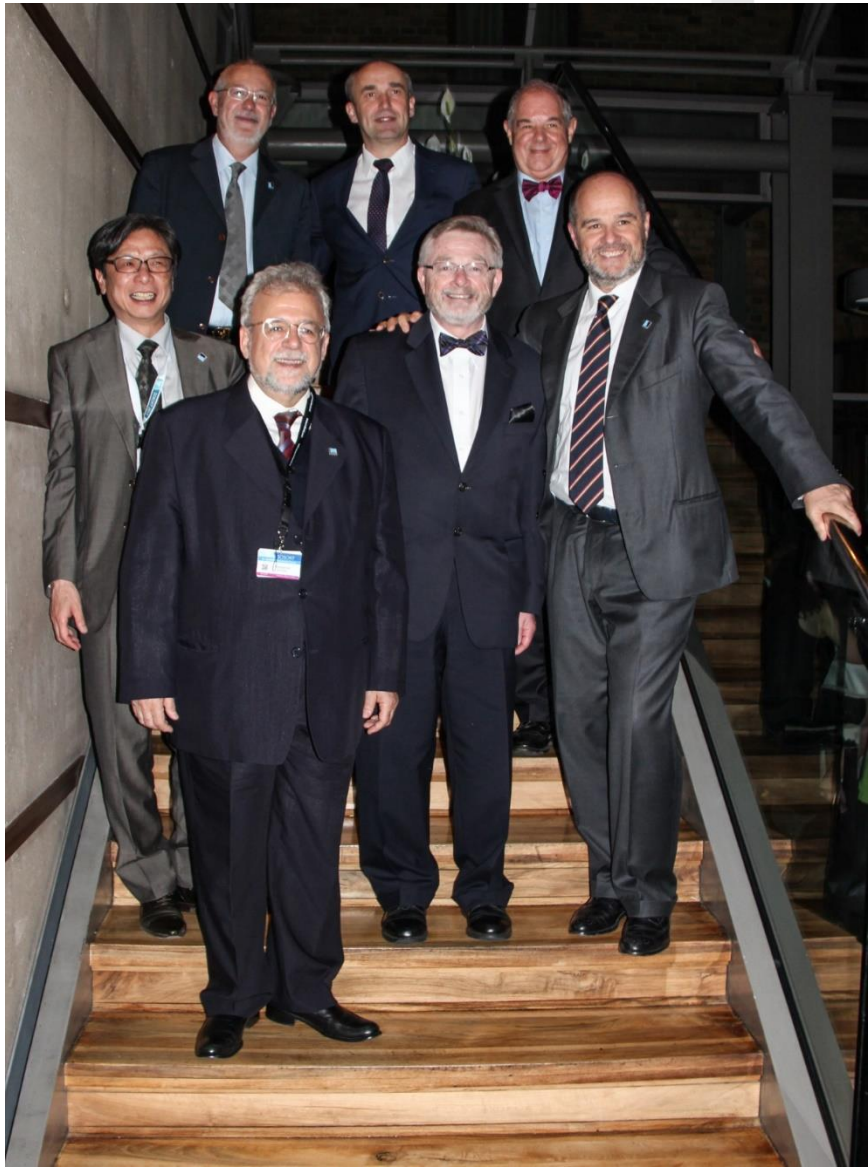
- Outpatients
- Children
- To really make a difference and not being one among the many

SOSORT

SOSORT: international Society On

Scoliosis Orthopedic and Rehabilitation Treatment

- Barcellona 2004
- Milano 2005
- Poznan 2006



Negrini *et al. Scoliosis and Spinal Disorders* (2018) 13:3
DOI 10.1186/s13013-017-0145-8

Scoliosis and Spinal Disorders

REVIEW Open Access

2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth

Stefano Negrini[1,2], Sabrina Donzelli[3*], Angelo Gabriele Aulisa[4], Dariusz Czaprowski[5,6], Sanja Schreiber[7,8], Jean Claude de Mauroy[9], Helmut Diers[10], Theodoros B. Grivas[11], Patrick Knott[12], Tomasz Kotwicki[13], Andrea Lebel[14], Cindy Marti[15], Toru Maruyama[16], Joe O'Brien[17], Nigel Price[18], Eric Parent[19], Manuel Rigo[22], Michele Romano[3], Luke Stikeleather[20], James Wynne[21] and Fabio Zaina[3]

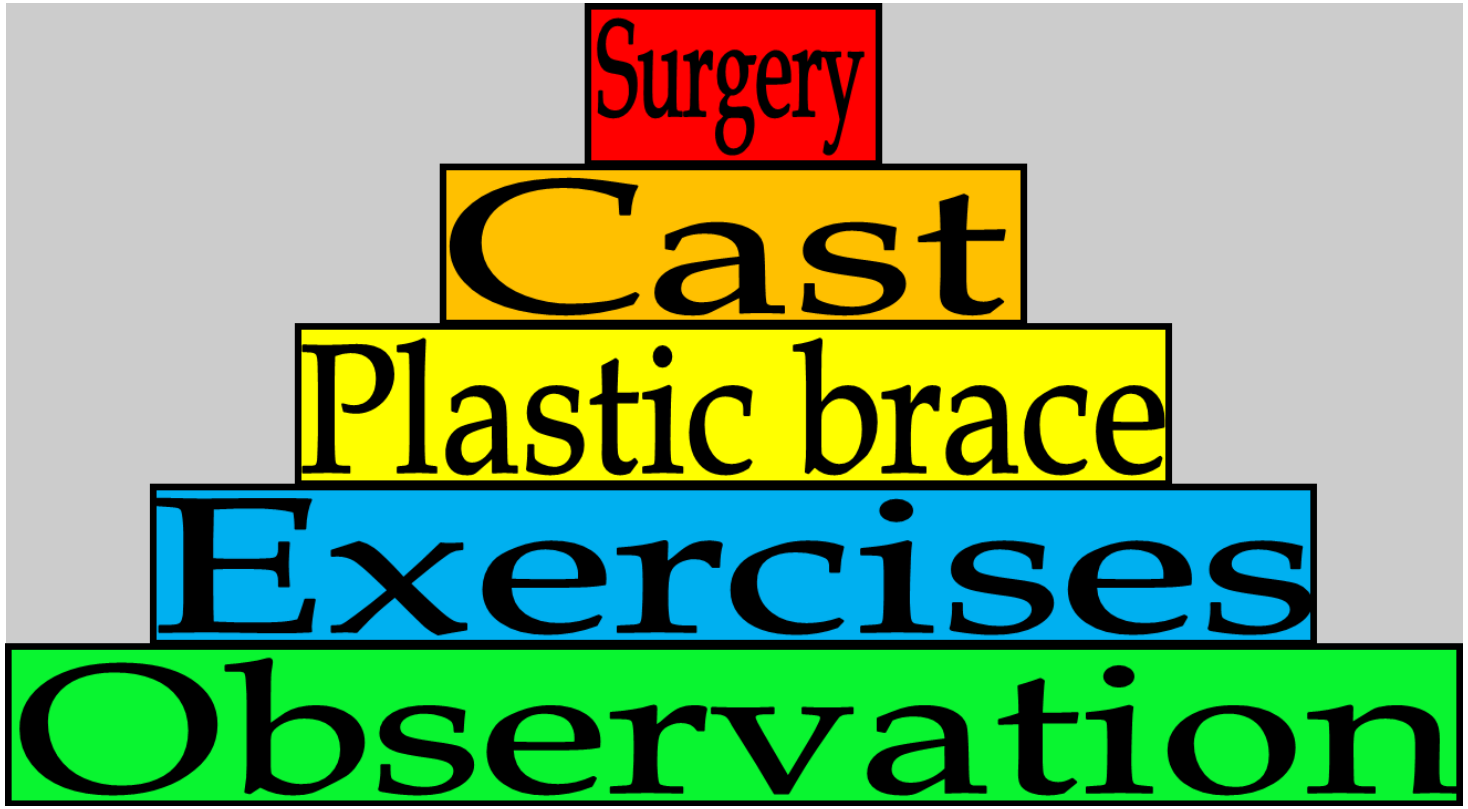
Evidence Based Clinical Practice

The integration of

- best research evidence
- with clinical expertise
- and patient values

Sackett 2000

Step by step Sibilla's theory



Sibilla P et al. Trent'anni di scoliosi. Lezione" non" magistrale. Rachide & Riabilitazione 2002. Vol 1. GSS, Milan, Italy.

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Evidence based PRM approach to adolescents with idiopathic scoliosis

Stefano Negrini

Chair Physical and Rehabilitation Medicine
University of Brescia – IRCCS Fondazione Don Gnocchi Milan

Scientific Director ISICO (Italian Scientific Spine Institute) Milan

Trusted evidence.
Informed decisions.
Better health.

What is scoliosis

Bone deformity of the spine and the trunk in the 3 space plans

- Lateral curve
- Rotation
- Distortion of the sagittal curves (mostly toward flat back)
  - Kyphosis: almost always reduced
  - Lordosis: most of the times reduced
  - Thoraco-lumbar junction: kyphosis and/or lordosis

Why we treat AIS

Aesthetics now

Pain in adult age

Posture in flexion in old age

Breathing and heart difficulties (?)

Scoliosis

BioMed Central

Methodology

Open Access

Why do we treat adolescent idiopathic scoliosis? What we want to obtain and to avoid for our patients. SOSORT 2005 Consensus paper

Stefano Negrini*[1], Theodoros B Grivas[2], Tomasz Kotwicki[3], Toru Maruyama[4], Manuel Rigo[5], Hans Rudolf Weiss[6] and the members of the Scientific society On Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)[7]

The scoliosis thresholds

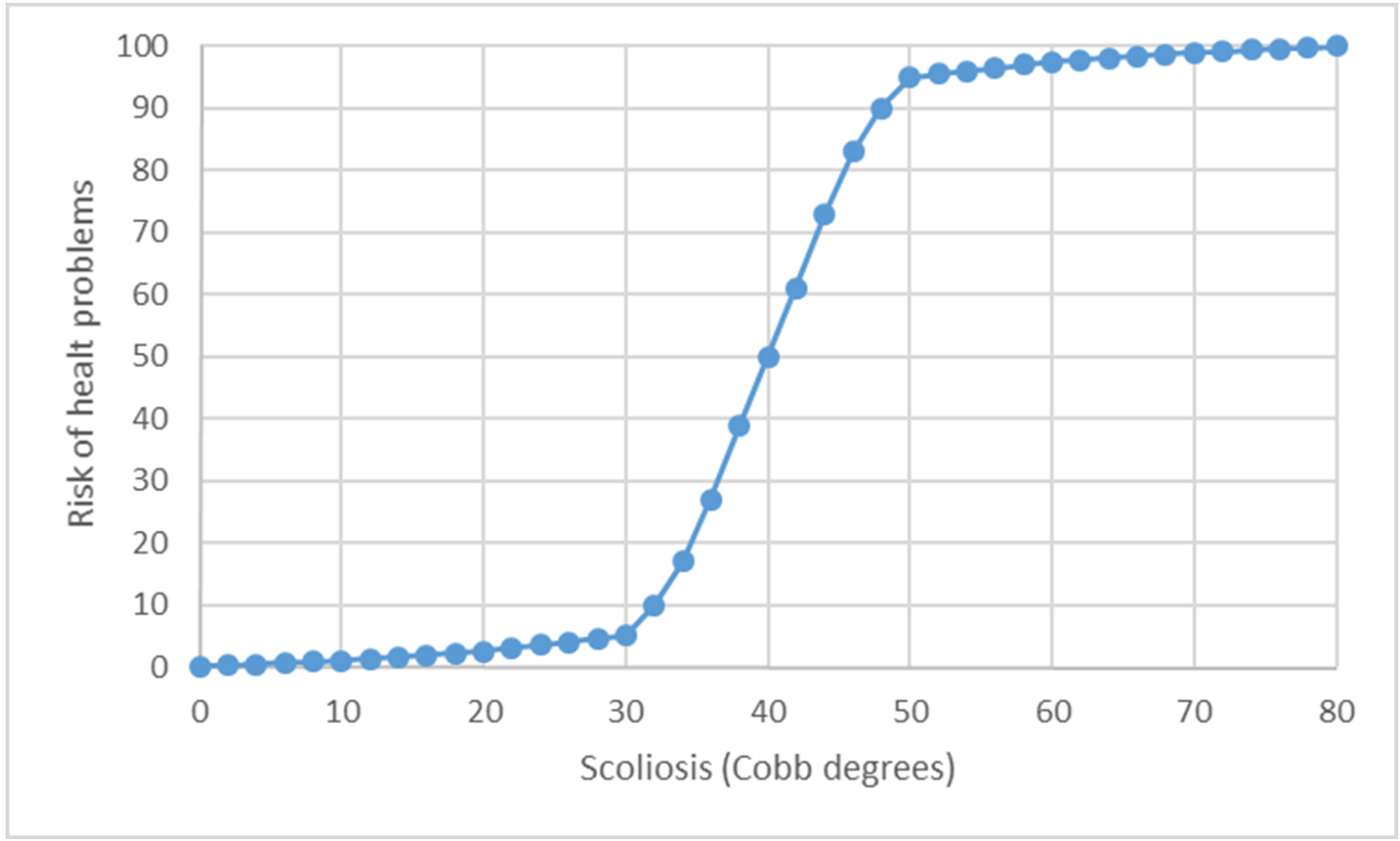
10 Cobb degrees: diagnosis

30 Cobb degrees: worsening

50 Cobb degrees: serious damage

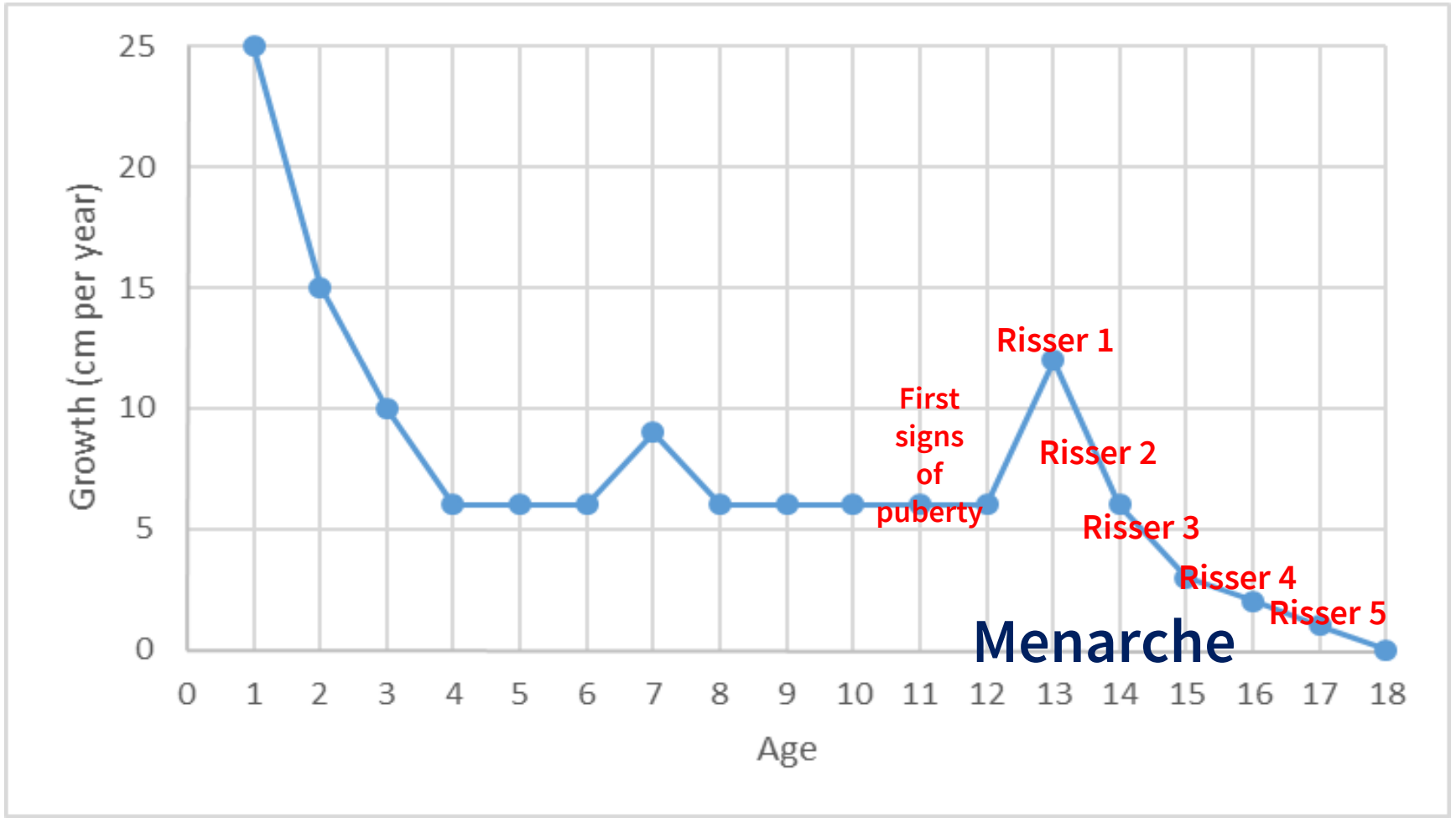
(Negative/positive prognostic factors)

Risk of problems in adulthood due to AIS

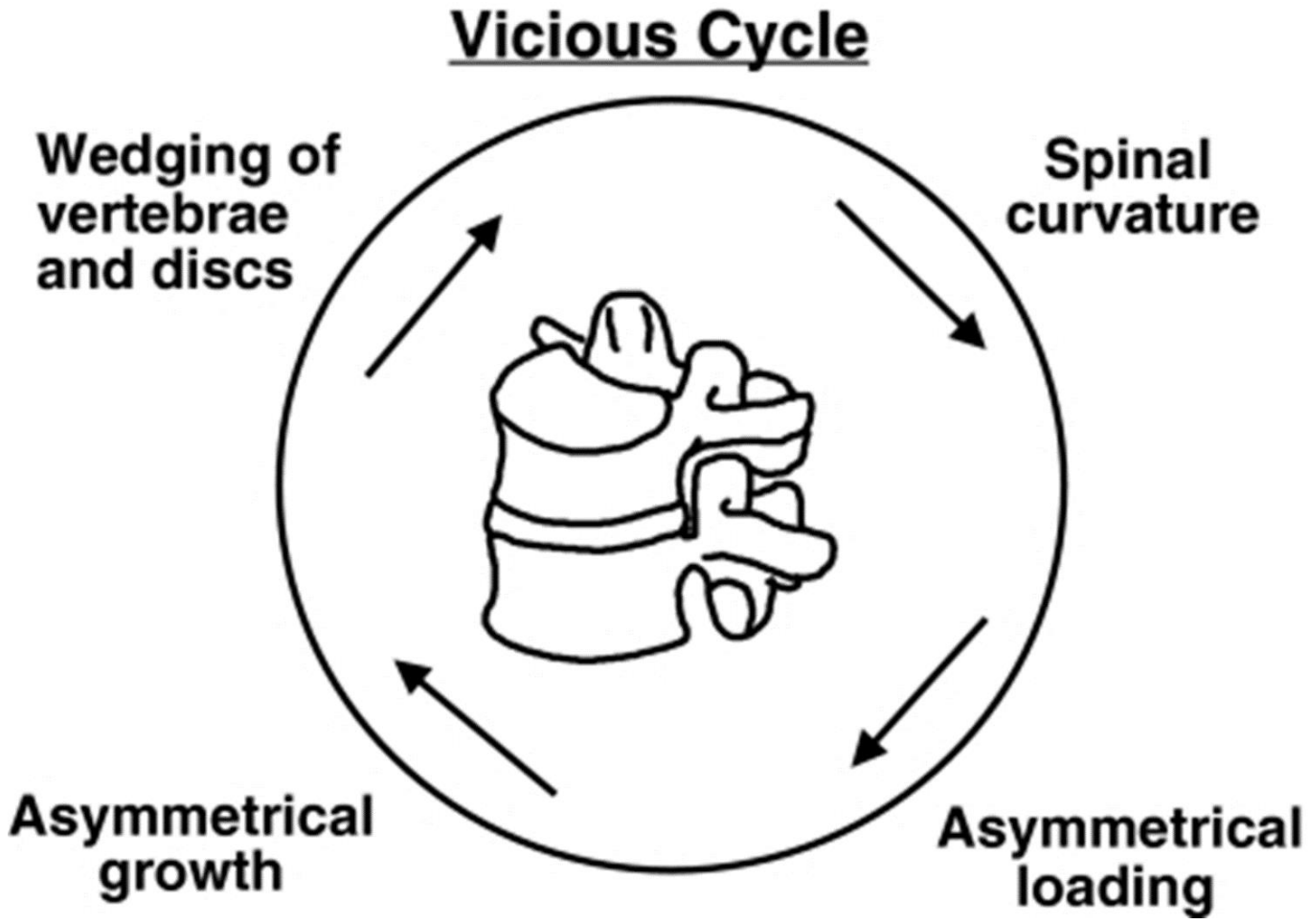


Negrini S et al. 2011 SOSORT guidelines: Orthopaedic and Rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis. 2012 Jan 20;7(1):3. doi: 10.1186/1748-7161-7-3.

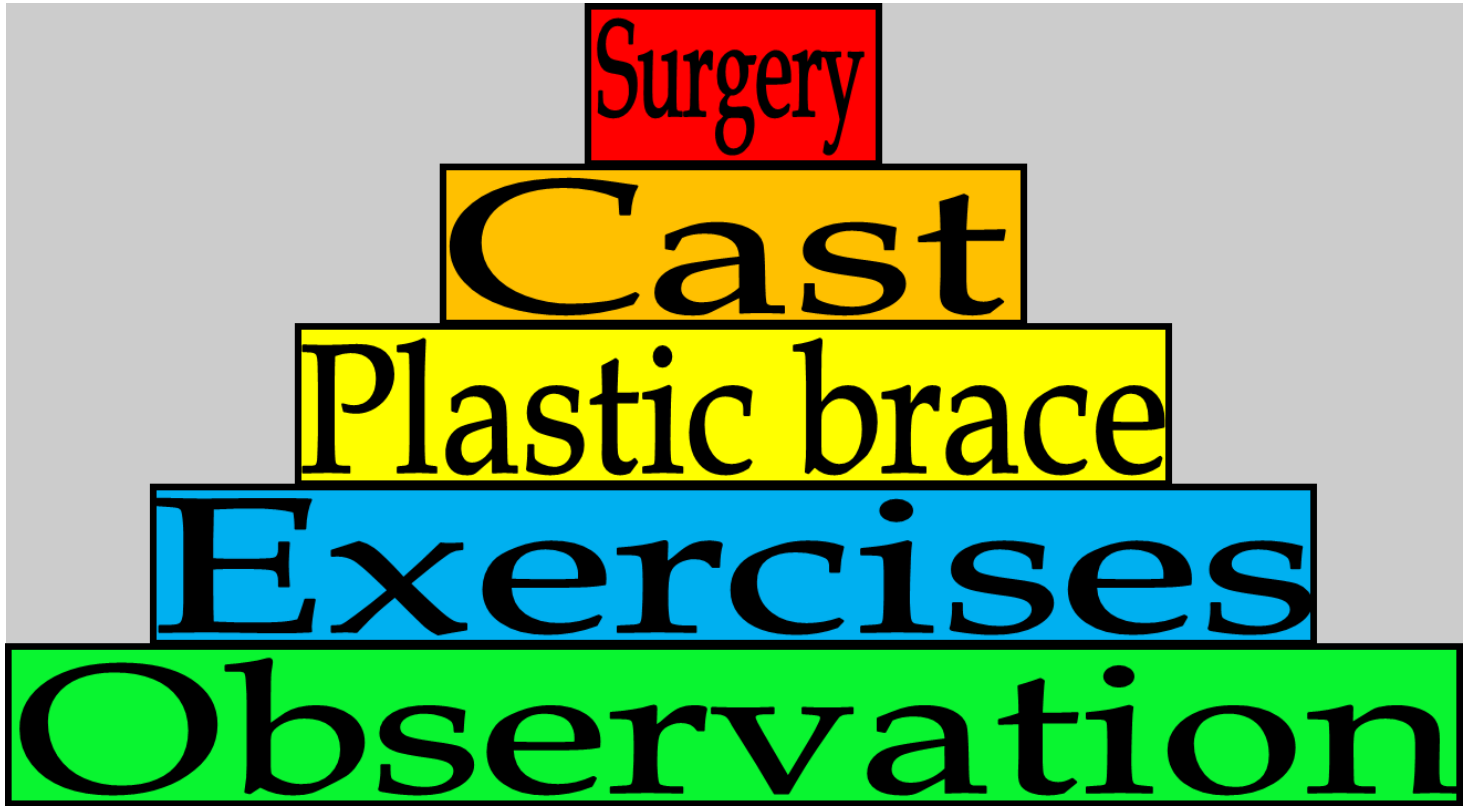
Growth curve



Pathogenesis: Stokes' vicious cycle

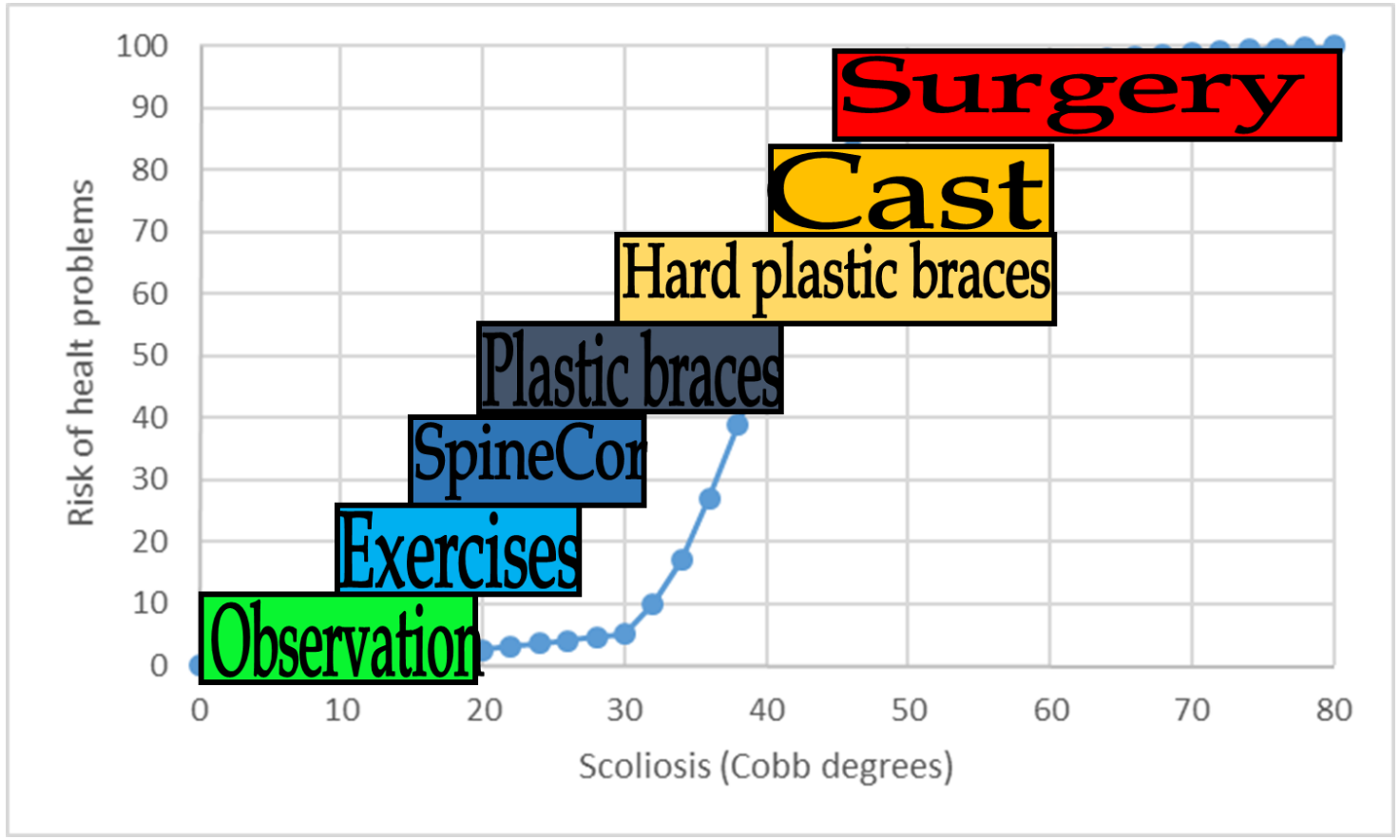


Step by step Sibilla's theory



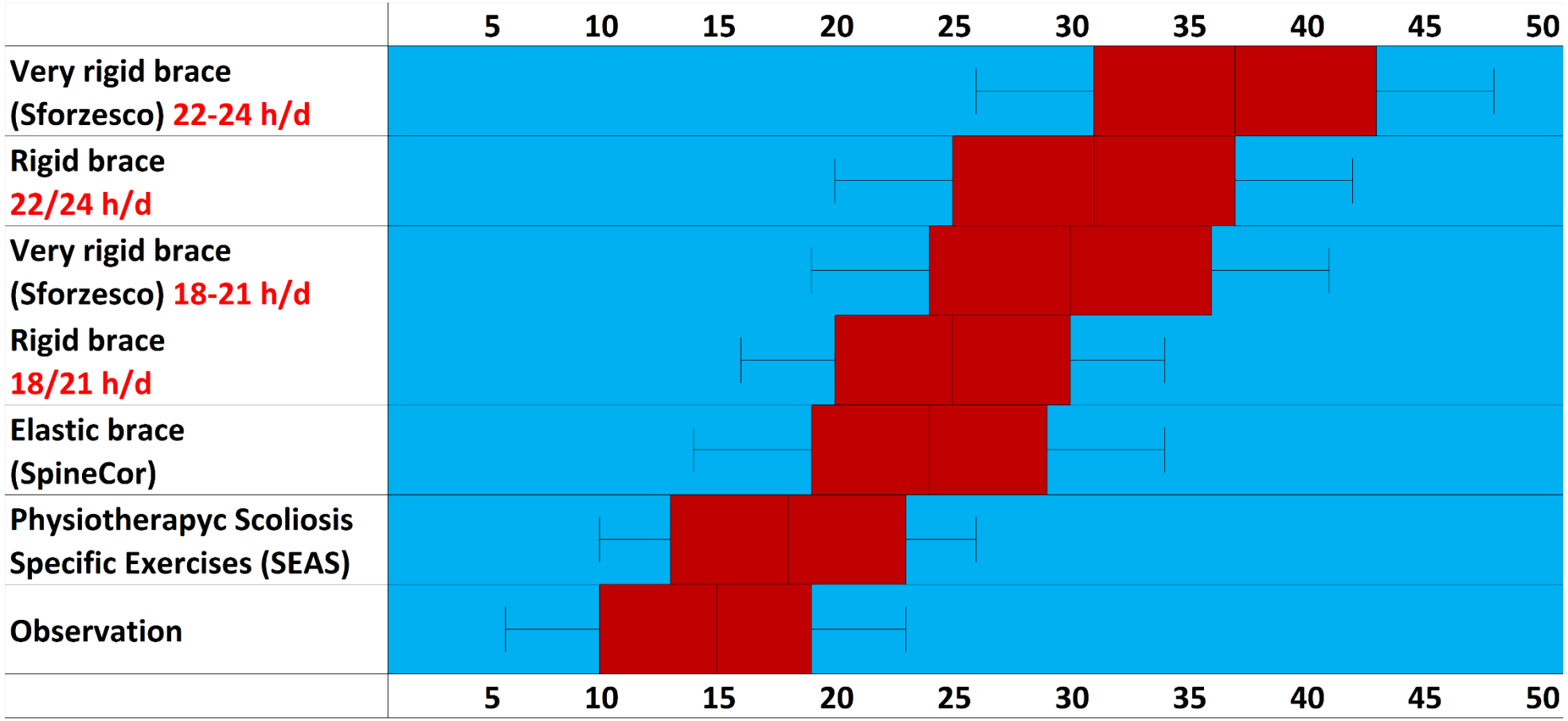
Sibilla P et al. Trent'anni di scoliosi. Lezione" non" magistrale. Rachide & Riabilitazione 2002. Vol 1. GSS, Milan, Italy.

ISICO step by step approach



Negrini S et al. 2011 SOSORT guidelines: Orthopaedic and Rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis. 2012 Jan 20;7(1):3. doi: 10.1186/1748-7161-7-3.

Step by step approach in real life (1934 patients)



US RCT financed by NIH (5 million dollars)

Stop by the Ethical Committee

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effects of Bracing in Adolescents with Idiopathic Scoliosis

Stuart L. Weinstein, M.D., Lori A. Dolan, Ph.D., James G. Wright, M.D., M.P.H., and Matthew B. Dobbs, M.D.

Weinstein (US) 2014

Population: 116 RCT; 126 QRCT treated 12 months; 20-40° Cobb, Risser 0-2

Treatment: Bracing vs observation

Results:

- The trial was stopped early owing to the efficacy of bracing in avoiding 50° curves
- Overall treatment success 72% after bracing vs 48% with observation
- RCT treatment success 75% after bracing vs 42% with observation
- Positive association between hours of brace wear and rate of success (P<0.001)

Negrini et al – Cochrane, 2015

Braces for idiopathic scoliosis in adolescents (Review)

Negrini S, Minozzi S, Bettany-Saltikov J, Chockalingam N, Grivas TB, Kotwicki T, Maruyama T, Romano M, Zaina F

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2014, Issue 2.

http://www.thecochranelibrary.com

WILEY

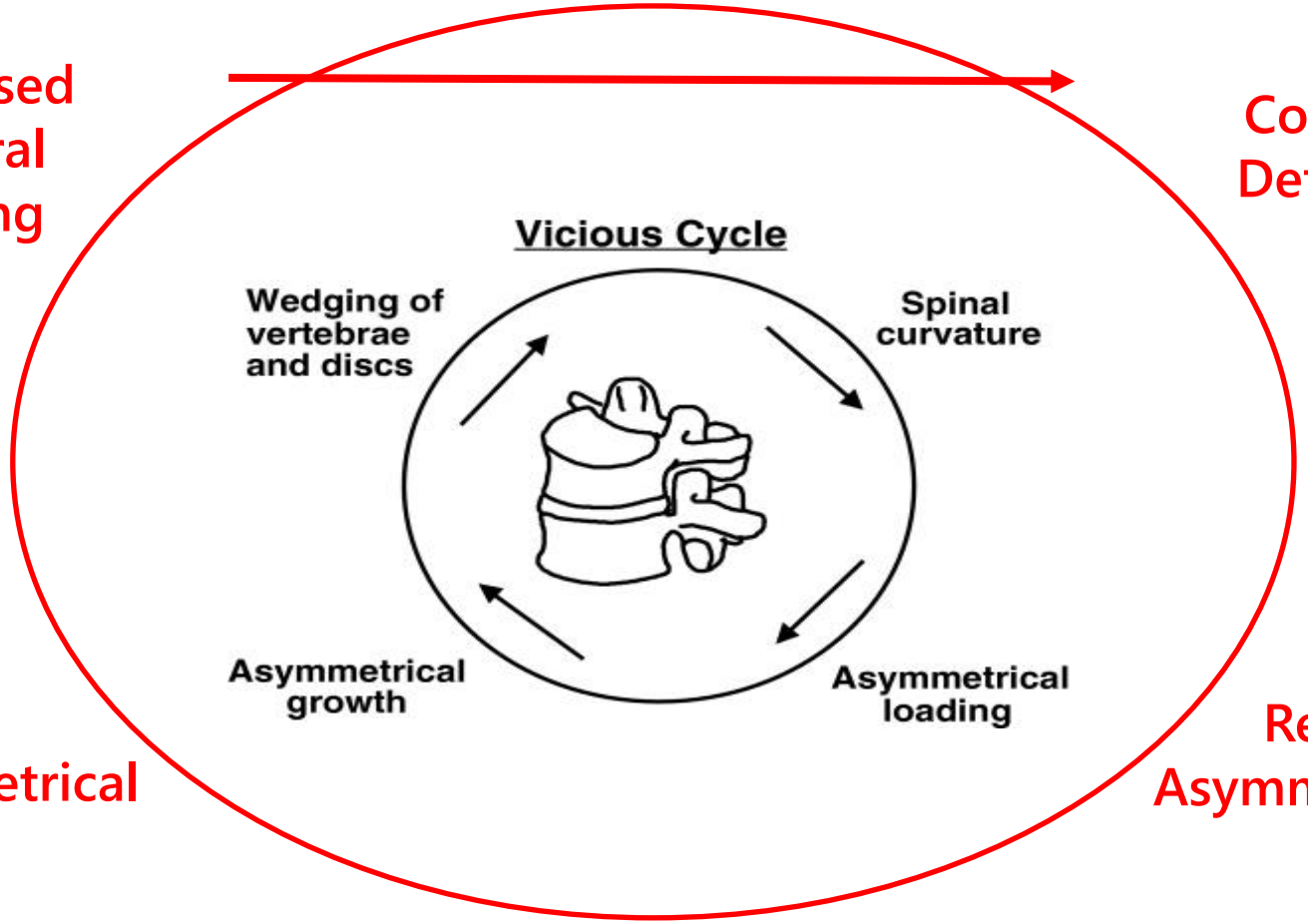
Implications for practice

According to the actual evidence, bracing is a viable treatment for adolescent idiopathic scoliosis: it reduces failures (low quality evidence), it curbs curve progression (very low quality evidence), and it helps in high degree curves above 45° (very low quality evidence). In low degree curves, elastic bracing is effective in 15-30° (low quality evidence), but less effective than rigid bracing in 20-30° (very low quality evidence). Unfortunately the strength of the actual evidence is from low to very low, due to the methodological quality of the studies. The high rate of failure of RCTs demonstrates the big difficulties in performing RCTs in a field where parents reject randomization of their kids. Nevertheless, all papers retrieved were fairly coherent, even if it must be recognised that further research could change the actual results.

The bracing virtuous cycle

Decreased Vertebral Wedging

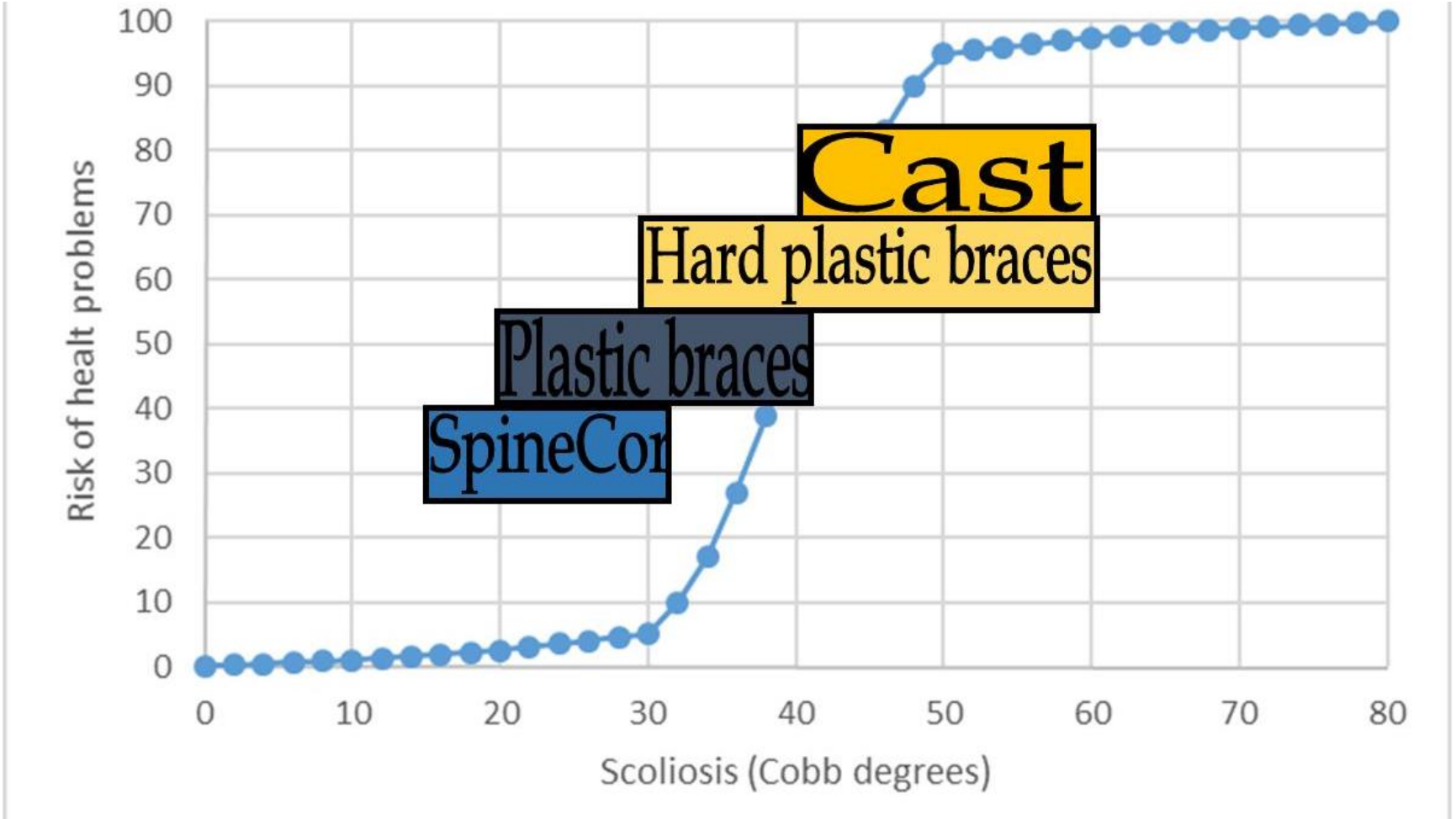
Corrected Deformity



Asymmetrical Growth

Reversed Asymmetrical Load

Correct prescription



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Type of brace:
No experts consensus

Scoliosis

BioMed Central

Research

Open Access

'SOSORT consensus paper on brace action: TLSO biomechanics of correction (investigating the rationale for force vector selection)'

M Rigo*[1], S Negrini[2], HR Weiss[3], TB Grivas[4], T Maruyama[5], T Kotwicki[6] and the members of SOSORT

Patients' management: Experts consensus

Scoliosis

BioMed Central

Research

Open Access

Guidelines on "Standards of management of idiopathic scoliosis with corrective braces in everyday clinics and in clinical research": SOSORT Consensus 2008

Stefano Negrini*[1], Theodoros B Grivas[2], Tomasz Kotwicki[3], Manuel Rigo[4], Fabio Zaina[1] and the international Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)

Negrini *et al. Scoliosis* 2011, **6**:8
http://www.scoliosisjournal.com/content/6/1/8

Scoliosis

METHODOLOGY Open Access

Brace technology thematic series - The Sforzesco and Sibilla braces, and the SPoRT (Symmetric, Patient oriented, Rigid, Three-dimensional, active) concept

Stefano Negrini[1*], Gianfranco Marchini[2] and Fabrizio Tessadri[3]

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Physiotherapic Scoliosis Specific Exercises (PSSEs)

Trusted evidence.
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Cochrane: Romano 2012

Date of search: March 2011

Included studies: 2

Total population: 154

Results:

- Low quality evidence from one RCT that exercises as an adjunctive to other conservative treatments increase the efficacy of these treatments.
- Very low quality evidence from a prospective CCT that scoliosis-specific exercises can reduce brace prescription as compared to usual physiotherapy

Last RCTs (new Cochrane by Romano)

Author	Reference	°Cobb	Technique	Duration	Outcome
De Sousa Dantas D	J Phys Ther Sci, 2017	?	Klapp	1.5 mo	Strength, ATR
Diab AA	Clin Rehabil, 2012	10-30°	head positioning	2 mo	Surface measures
Kim G	J Phys Ther Sci, 2016	20-30°	Schroth vs Pilates	3 mo	°Cobb
Kumar J	Clin Diagn Res, 2017	10-15°	task oriented	2 mo	°Cobb, function
Kuru T	Clin Rehabil, 2014	10-20°	Schroth	1 year	°Cobb
Monticone M	Eur Spine J, 2014	10-20°	SEAS	End of growth	°Cobb
Schreiber S	Plos One, 2016	10-45°	Schroth	6 mo	°Cobb
Schreiber S	Scoliosis, 2015	10-45°	Schroth	6 mo	QoL
Zapata KA	Ped Phys Ther, 2015	10-45°	stabilization	2 mo	Pain, function
Zeng Y	Spine, 2017	25-40°	SEAS vs bracing	1 year	°Cobb

Aims of exercises for AIS

Reduce progression

Avoid bracing

Improve (train) functions able to counteract the pathological action today and in the future (pubertal growth spurt and adulthood)

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Which exercises ?

Self – correction

Stabilization

Scoliosis

BioMed Central

Research

Open Access

Physical exercises in the treatment of idiopathic scoliosis at risk of brace treatment – SOSORT consensus paper 2005

Hans-Rudolf Weiss*†[1], Stefano Negrini†[2], Martha C Hawes†[3], Manuel Rigo[4], Tomasz Kotwicki[5], Theodoros B Grivas[6], Toru Maruyama[7] and members of the SOSORT

Autocorrection 3D	97%	90%	0%	7%
Theoretical information for the patient and family	87%	53%	27%	7%
Stabilisation	87%	50%	23%	13%
Self perception	87%	43%	33%	10%
Activities of daily living	83%	53%	20%	10%
Muscular endurance	83%	30%	33%	20%
Psychological aspects	77%	43%	20%	13%
Respiratory education	77%	27%	27%	23%
Neuromotorial control of the spine	70%	33%	30%	7%
Proprioception and tactile	70%	27%	33%	10%
Equilibrium	70%	20%	37%	13%
Restoring of physiological spinal curvatures (sagittal plane)	67%	57%	7%	3%

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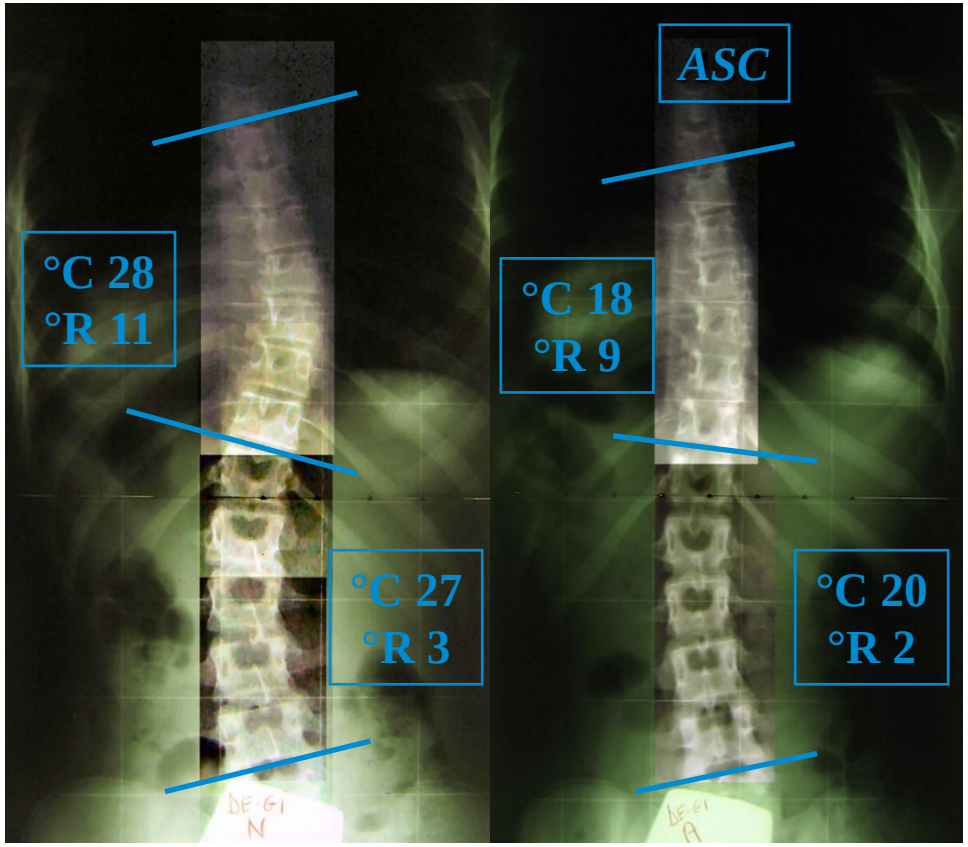

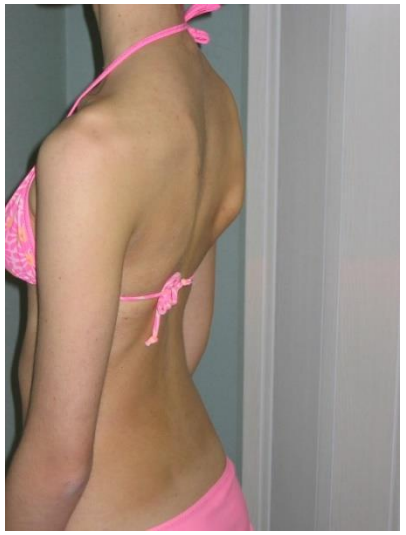

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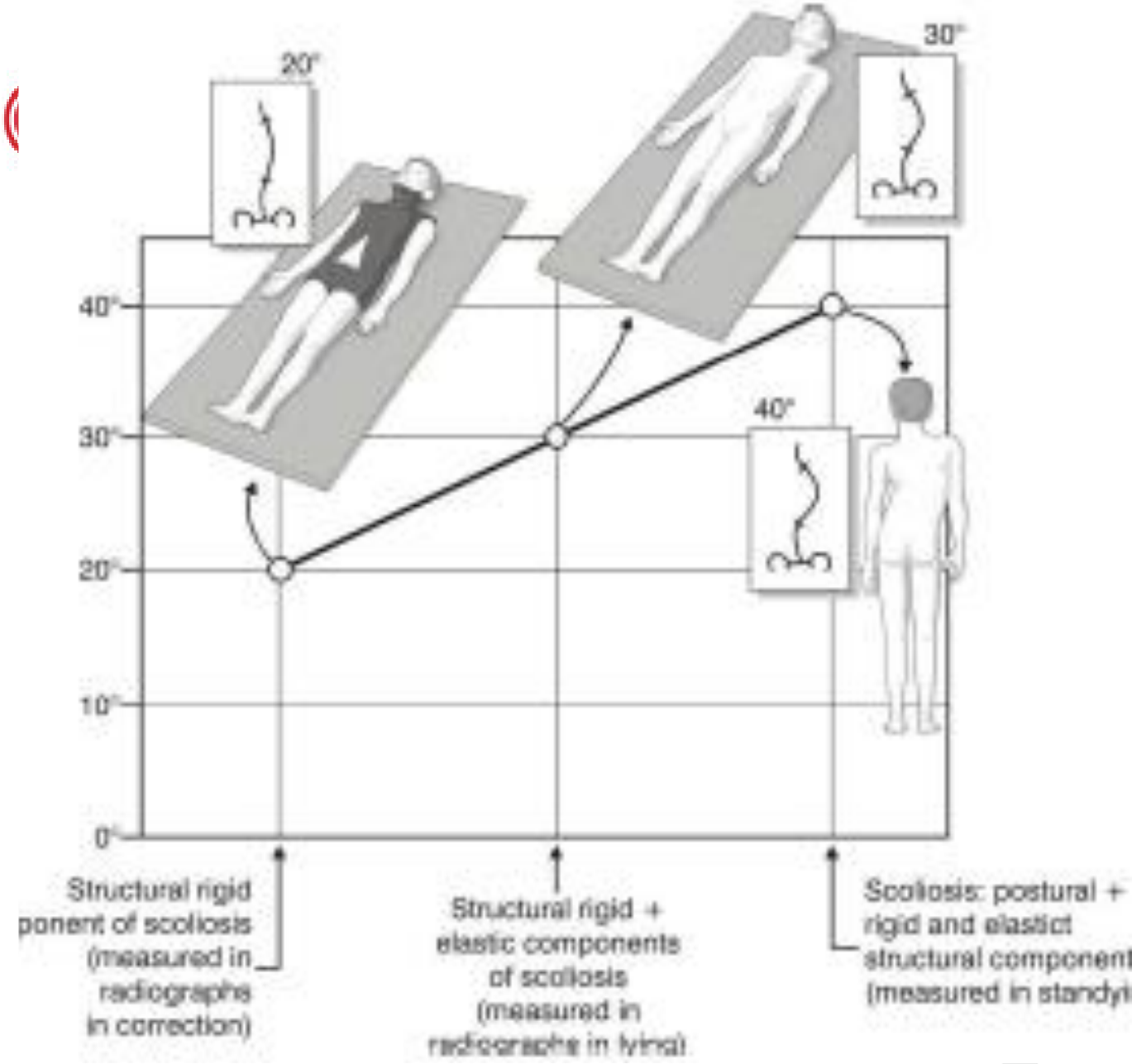
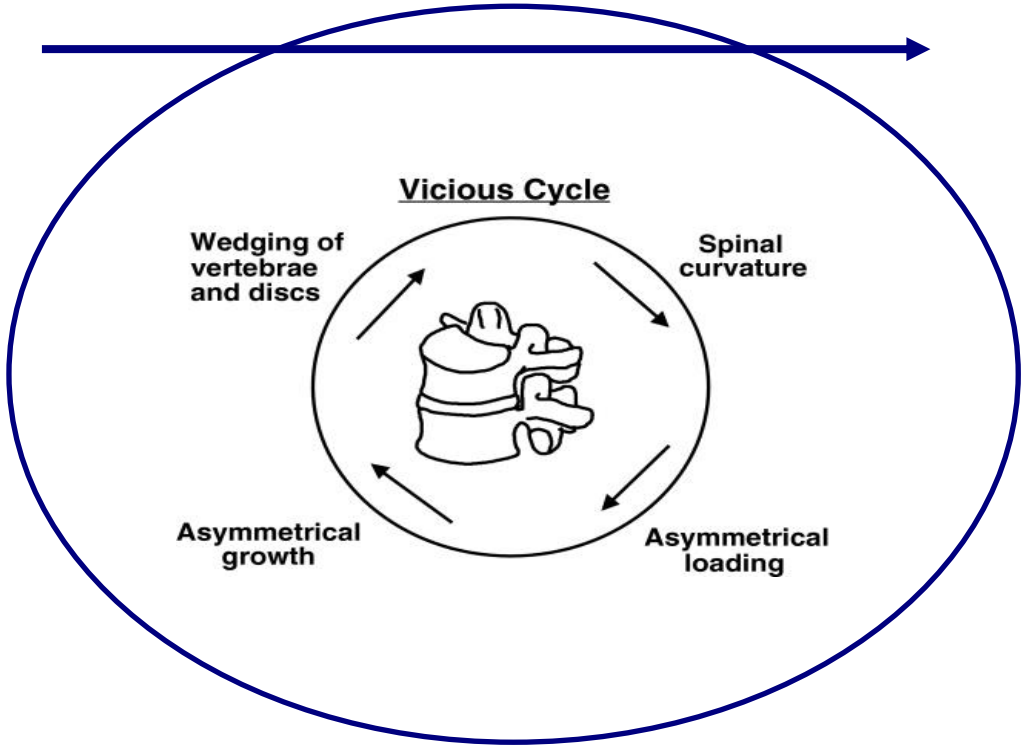
How exercises work



The exercises virtuous cycle

Reduced Vertebral Wedging

Improved Posture

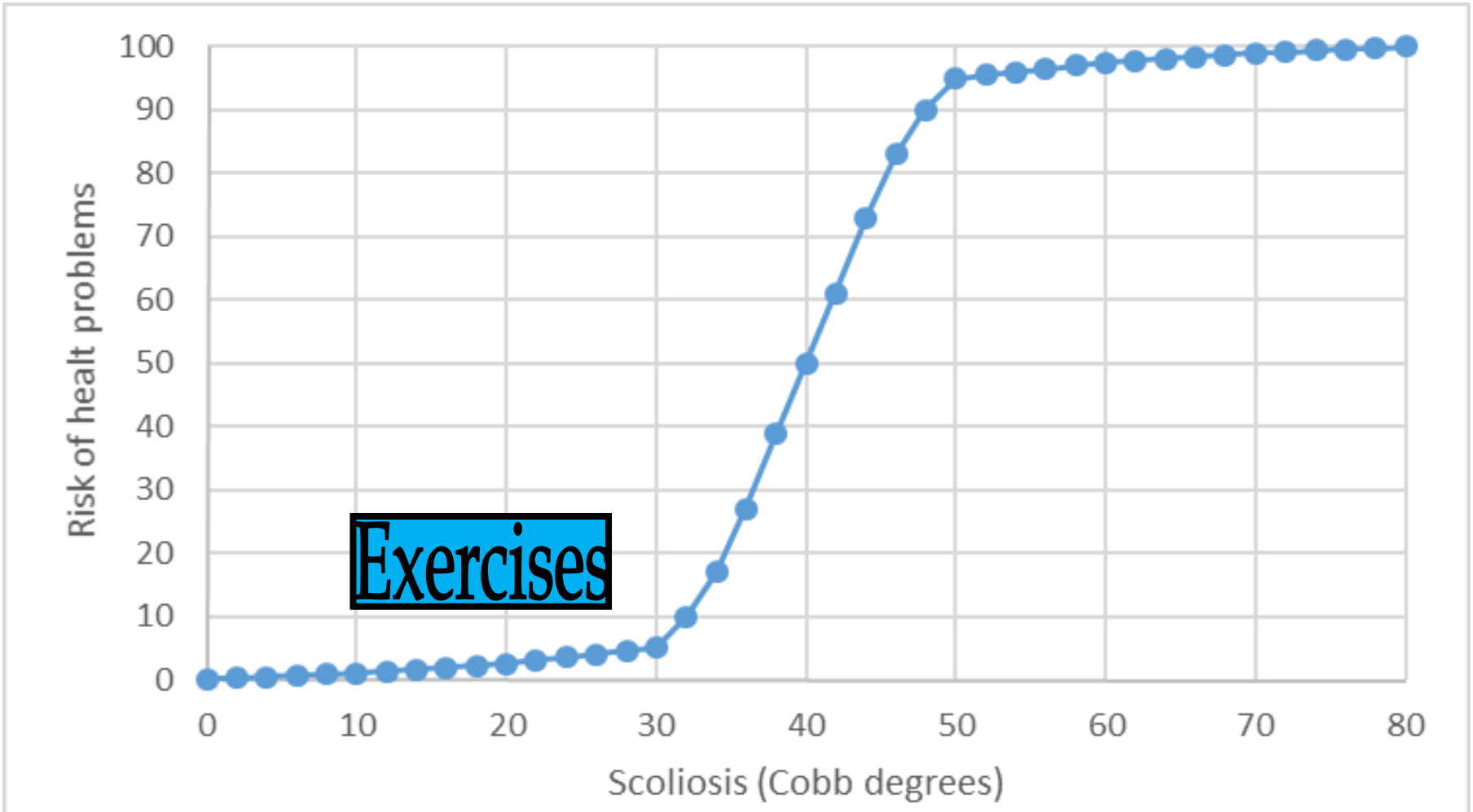


Reduced Asymmetrical Growth

Reduced Asymmetrical Load

Improved Movement Strategy

Indications



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Conclusions

Trusted evidence.
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DOI 10.1186/s13013-017-0145-8

Scoliosis and Spinal Disorders

REVIEW Open Access

2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth

Stefano Negrini[1,2], Sabrina Donzelli[3*], Angelo Gabriele Aulisa[4], Dariusz Czaprowski[5,6], Sanja Schreiber[7,8], Jean Claude de Mauroy[9], Helmut Diers[10], Theodoros B. Grivas[11], Patrick Knott[12], Tomasz Kotwicki[13], Andrea Lebel[14], Cindy Marti[15], Toru Maruyama[16], Joe O'Brien[17], Nigel Price[18], Eric Parent[19], Manuel Rigo[22], Michele Romano[3], Luke Stikeleather[20], James Wynne[21] and Fabio Zaina[3]

2016 SOSORT Guidelines

		Low		Moderate		Severe	
		Min	Max	Min	Max	Min	Max
Infantile		Obs3	Obs3	Obs3	TTRB	TTRB	Su
Juvenile			PPSE	PSSE	FTRB	HTRB	
Adolescent	Risser 0	Obs6	SSB	HTRB		TTRB	
	Risser 1			PSSE		FTRB	
	Risser 2						
	Risser 3						
	Risser 4	Obs12	SIR				
Adult up to 25 y		Nothing	PSSE	Obs12	SIR	Obs6	
Adult	No Pain			PSSE		Obs12	HTRB
	Pain	PSSE	SSB		HTRB	PSSE	Su
Elderly	No Pain	Nothing	PSSE	Obs36	PSSE	Obs12	HTRB
	Pain	PSSE	SSB	PSSE	HTRB	PSSE	Su
	Trunk decompensation	Obs6			PTRB		

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End-growth results according to SRS & BrAIST criteria of a fully personalized conservative approach to AIS

Stefano Negrini,[1,2] Sabrina Donzelli,[3] Francesca Di Felice,[3] Jorge Hugo Villafane,[2] Fabio Zaina[3]

1. Clinical and Experimental Sciences Dpt, University of Brescia (Italy)
2. IRCCS Fondazione Don Gnocchi Milan (Italy)
3. ISICO (Italian Scientific Spine Institute) Milan (Italy)

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Methods 1

Retrospective observational study nested in a prospective database including all outpatients of an Institute with 26 Centres

Two (partially overlapping) populations selected according to SRS and BrAIST inclusion criteria:

Inclusion criteria	SRS	BrAIST
Age	10 or more	10-15
Risser	0-2	
Degree cobb	25-40°	20-40°
Prior treatment	no	
Menarche	Premenarchal, <1 year postmenarchal	

Treatment: personalised conservative approach

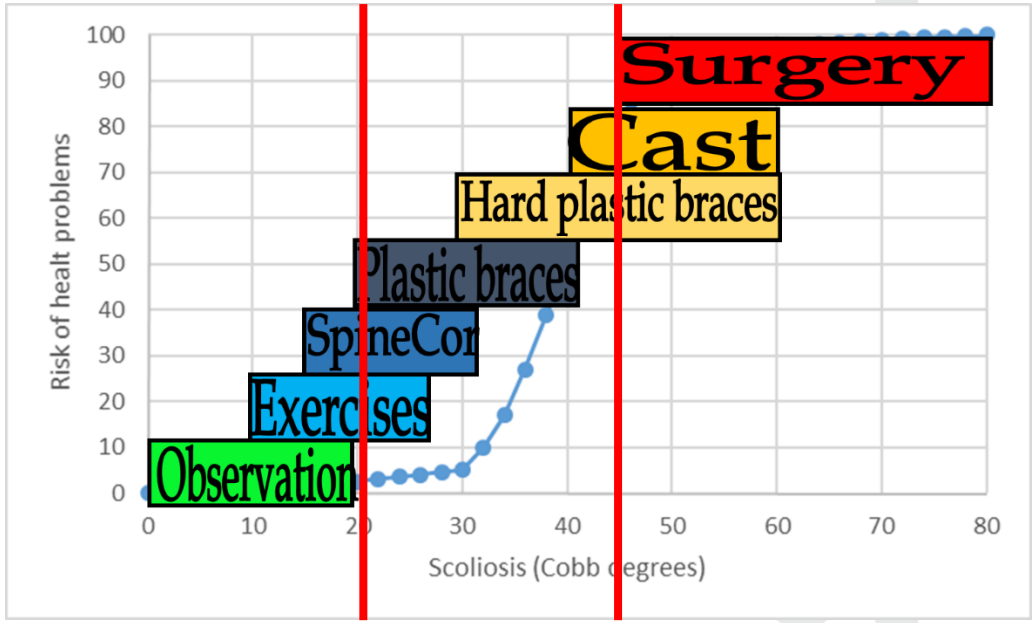
Observation

Physiotherapic Scoliosis Specific Exercises: **SEAS** (Scientific Exercises Approach to Scoliosis) school

Soft brace: **SpineCor 20 h/die**

Plastic brace: **Sibilla 18-23 h/die**

Very rigid plastic brace: **Sforzesco 18-23 h/die**



1. Negrini S et al. 2011 SOSORT guidelines: Orthopaedic and Rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis. 2012 Jan 20;7(1):3.
2. Richards BS et al. Standardization of criteria for adolescent idiopathic scoliosis brace studies: SRS Committee on Bracing and Nonoperative Management. Spine. 2005 Sep 15;30(18):2068-75; discussion 2076-7.
3. Weinstein SL et al. Design of the Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST). Spine. 2013 Oct 1;38(21):1832-41

Methods 2

Patients exit the study if:

- Reached Risser 4
- Surgery or end of treatment was prescribed by physician

Outcomes

Outcome criteria	SRS-SOSORT Consensus[1]		SRS[2]		BrAIST[3]
Percentage of patients	End <30°	Improved ≥5°	Progressed ≥5°	End ≥45°	End ≥50°

1. Negrini S et al; SOSORT Boards; SRS Non-Operative Committee. Recommendations for research studies on treatment of idiopathic scoliosis: Consensus 2014 between SOSORT and SRS non-operative management committee. Scoliosis. 2015 Mar 7;10:8.
2. Richards BS et al. Standardization of criteria for adolescent idiopathic scoliosis brace studies: SRS Committee on Bracing and Nonoperative Management. Spine. 2005 Sep 15;30(18):2068-75; discussion 2076-7.
3. Weinstein SL et al. Design of the Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST). Spine. 2013 Oct 1;38(21):1832-41

Results 1

Populations

	Total population	Age (yy.mm)	% Females	Number of drop-out	Reached end of observation
SRS	777	12.07±1.02	80.3%	42	735
BrAIST	768	12.08±1.03	83.4%	81	687

Treatments proposed

	SRS	BrAIST
Observation	0,1%	0,3%
PSSE (SEAS School)	6,2%	6,9%
Soft brace (SpineCor)	9,4%	6,8%
Rigid brace (Sibilla)	49,4%	44,1%
Very rigid brace (Sforesco)	41,2%	49,1%

Results 2

Population according to SRS criteria

Outcome criteria	SRS-SOSORT Consensus		SRS		BrAIST
	End <30°	Improved ≥5°	Progressed ≥5°	End ≥45°	End ≥50°
Start of observation	59.0%	38.2%	16.6%	0	0
End of observation	72.2%			3.1%	1.8%

Population according to BrAIST criteria

Outcome criteria	SRS-SOSORT Consensus		SRS		BrAIST
	End <30°	Improved ≥5°	Progressed ≥5°	End ≥45°	End ≥50°
Start of observation	59.4%	38.1%	18.5%	0	0
End of observation	71.2%			3.3%	1.9%

Why scoliosis is of interest for PRM physicians

Specialised vs generalist PRM: PRM and highly specialised specific competence

There are all the ingredients of PRM

- Therapies (orthosis, exercises, cognitive-behavioural approach)
- Team work and patients' management

Good for you if you like

- Outpatients
- Children
- To really make a difference and not being one among the many

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Scoliosis Conservative Orthopedic and Rehabilitation Treatment

Introduction to the World Master Course

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25 outstanding lecturers

- 11 countries, 4 continents
- 21 SOSORT, SRS & ISSLS Presidents & award winners

Faculty members 2021

Carl Eric Aubin

(Montréal, Canada) PhD, Engineer, Professor of Mechanical Engineering at the Polytechnique and at the University of Montreal, and scientist at Sainte-Justine University Hospital Center

Angelo Gabriele Aulisa

(Rome, Ita) MD, Orthopedic Surgeon – SOSORT Executive Committee Member, PASB brace developer

Marco Brayda-Bruno

(Milan,Italy) MD, Spine Surgery - Scoliosis Dept IRCCS Istituto Ortopedico Galeazzi, Head of Department, Research Director, Fellowship Program Director

Stefano Negrini

(Milan, Ita) MD, Physical and Rehabilitation Medicine specialist – SOSORT Founder and Past President, ISICO Founder and Scientific Director, SPoRT (Fondazione) brace developer

Claudio Lamartina

(Milan,Ita) MD, Orthopaedic Spine Surgeon Deputy Editor of European Spine Journal

Jeb McAviney

(Sydney, Australia) Chiropractor, CEO at ScoliCare

Joe O'Brien

(Boston, USA) President of the National Scoliosis Foundation – SOSORT Past President

René - Marten Castelein

(Utrecht, The Netherlands) Professor and Chair, Department of Orthopaedic Surgery, University Medical Center Utrecht,

Kenneth MC Cheung

(Hong Kong, China) MD, Head of the Department of Orthopaedics and Traumatology, University of HK, Queen Mary Hospital

Christine Coillard

(Fra) MD, Orthopedic Surgeon, Spinecor brace developer

Sabrina Donzelli

(Milan, Ita) MD, Physical and Rehabilitation Medicine specialist – ISICO Research

Steven Glassman

(Louisville,USA) Professor, Orthopedic Surgery, University of Louisville School of Medicine

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Ferran Pellisé Urquiza

((Barcelona, Spain) MD, Orthopedic Surgeon, Hospital Quirónsalud Barcelona

Manuel Rigo

(Barcelona, Spa) MD, Physical and Rehabilitation Medicine specialist – SOSORT Founder and Past President, Rigo Cheneau System brace developer

Charles Rivard

(Montreal, Can) MD, Pediatric orthopedic surgeon, Spinecor System developer

Elisabetta D'Agata

(Barcelona, Spa) Psychologist

Jean-Claude De Mauroy

(Lyon, Fra) MD, Physical and Rehabilitation Medicine specialist– SOSORT Past-President, ART brace

Francesca Di Felice

(Milan, Ita) MD, Physical and Rehabilitation Medicine specialist – ISICO Research

Axel Hennes

(Bad Sobernheim, Germany) PT, Asklepios-Katharina Schroth Senior Schroth Instructor, ISST-International founder (International Schroth 3dimensional Scoliosis Therapy)

Timothy Hresko

(Boston, USA) MD, Orthopedic Surgeon, Associate Professor of Orthopaedic Surgery, Harvard Medical School

Tomasz Kotwicki

(Poznan, Pol) MD, Orthoped Surgeon – SOSORT Founder Past President

Michele Romano

(Milan, Ita), PT – ISICO Founder and Physiotherapic Director, SEAS developer, SOSORT Past President

James Wynne

(Boston, USA) MD, Vice-President, Director of Education, Resident Director, Boston Brace/National Orthotic Prosthetic Company

Fabio Zaina

(Milan, Ita) MD, Physical and Rehabilitation Medicine specialist – SOSORT Past President

Until now: 221 participants from 51 countries

22 Europe: Austria, Belgium, Bosnia Herzegovina, Croatia, Finland, France, Greece, Ireland, Italy, Latvia, Macedonia (FIROM), Moldova, Portugal, Romania, Russian Federation, Slovakia, Slovenia, Spain, Switzerland, The Netherlands, Ukraine, United Kingdom

17 Asia: Armenia, Cambodia, China, Dubai, Hong Kong, India, Indonesia, Macau, Malaysia, Mongolia, Philippines, Saudi Arabia, Sri Lanka, Syria, Taiwan (R.O.C.), Turkey, Thailand

6 Americas: Brazil, Canada, Colombia, Mexico, Peru, USA

4 Africa: Egypt, Morocco, Nigeria, South Africa

2 Oceania: Australia, New Zealand

7 professions

81 physicians

53 chiropractors

45 physical therapists

18 orthotists

4 other professions

Course organization

Live lessons: 16

Theoretical **modules**: 16

Self-administered **lectures**: 42

Online **discussions groups**: 44

Papers to read and comment: 3 to 6 per module

Self-evaluation learning tools

Patients real cases

Cochrane Rehabilitation

UNIVERSITÀ DEGLI STUDI DI MILANO

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Thank you!

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