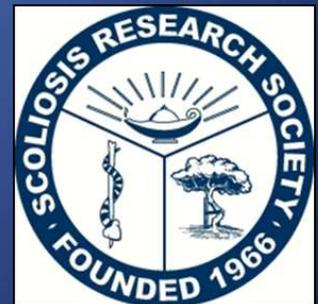


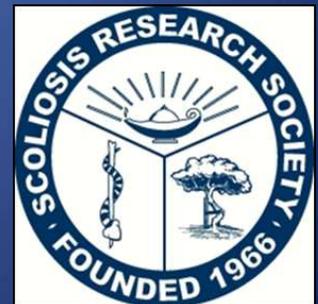
# SRS Initiative in Non- Operative Treatment of Scoliosis

Scoliosis Research Society  
Non Operative Committee



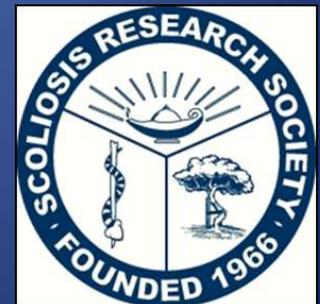
# SRS Mission Statement

“The purpose of the Scoliosis Research Society (SRS) is to foster the optimal care of all patients with spinal deformities”



# SRS Guidelines for Treatment of Scoliosis

- < 20 degrees monitor
- 20- 45 degrees Orthotic
  - Documented progression
  - Skeletal immaturity
- 45 degrees consider Surgery



# Available Non-Operative Rx for AIS

- **Exercises**
  - No proven efficacy alone for scoliosis
- **Full-Time Bracing**
  - Standard for progressive, moderate curves
  - Only statistically valid non-operative treatment
    - Weak evidence



# Effectiveness of Brace Treatment in Moderate Adolescent Idiopathic Scoliosis.

## (SRS Prospective Study)

» Nachemson: JBJS 77A, pp 815-22, 1995

- 294 pts, 25 - 35°,
  - **Observation** by 5 centers (**131** pts)
  - **Brace** (most Boston) at 3 centers (**115** pts)
  - Elec. stim. at 1 center (49 pts)
- *Brace treatment statistically much better* than observation.
- Electrical stimulation = observation.



# SRS Annual Meeting Lyon, France 2013

- Stuart Weinstein, MD
- BrAIST result





# **BRACING IN ADOLESCENT IDIOPATHIC SCOLIOSIS**

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Results of the BrAIST Clinical Trial



**Stuart L. Weinstein, MD, Lori A. Dolan, PhD,  
and the BrAIST Study Group**

# NIAMS

National Institute of  
Arthritis and  
Musculoskeletal and  
Skin Diseases



Supported by a  
grant from the

**National  
Institutes  
of Health**

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U.S. Department of Health and Human Services

## Funding Sources



**CIHR IRSC**

Canadian Institutes of  
Health Research

Institut de recherche  
en santé du Canada



**Children's Mercy**

**HOSPITAL**

[www.childrensmercy.org](http://www.childrensmercy.org)



UNIVERSITY of  
**ROCHESTER**  
MEDICAL CENTER

# Goal of BrAIST: Produce **CREDIBLE** evidence about bracing (pro or con)

- Improved research design
  - **Randomization** to eliminate selection bias
  - Outcome determined by **independent, blinded reviewers**
  - **Multicenter**, with each center enrolling into both treatment arms
  - Effect size (**risk reduction**) determined by *a priori* by families
  - Objective **dose** monitoring
  - Measures of health, function, self-image and overall **quality of life**
  - Independent **evaluation of bracing process**

# Aims

- PRIMARY

- Do braces (specifically TLSO's) lower the risk of curve progression to a surgical threshold ( $\geq 50$  degrees) in high risk patients with AIS relative to observation alone?

- SECONDARY

- To compare health and functioning, quality of life, and self-image over time in the two treatment groups.
- To determine the relationship between bracing dose (wear time) and curve response.
- To develop a predictive model for curve progression based on patient characteristics at initial presentation, and after bracing.

# Treatment and Data

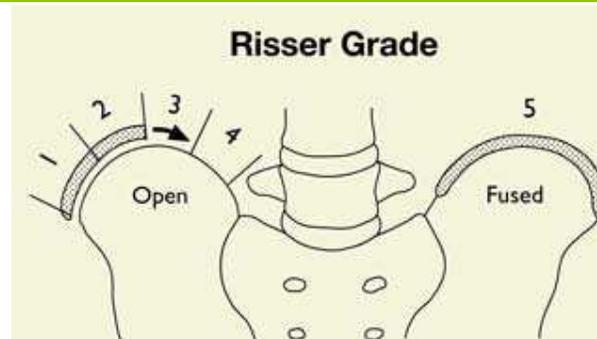
- Bracing

- Team used shape capture techniques and TLSO type they felt was most appropriate
- In-brace x-ray 4-6 weeks after each brace delivery
- Orthotist evaluation at least every 6 months
- Onset temperature monitors in each brace, data downloaded at each visit

- Both treatments: Visits every 6 months

- PA, lateral, side-benders and hand film at baseline, then PA and hand every 6 months, laterals yearly
- Self-report generic health, function, QOL and Spinal Appearance Questionnaire
- Clinical examination

# Endpoints



- **Success**

- **Cobb angle <50 degrees and Skeletal maturity**
  - Risser 4 (Risser 5 for boys) and Sanders' digital maturity stage of 7

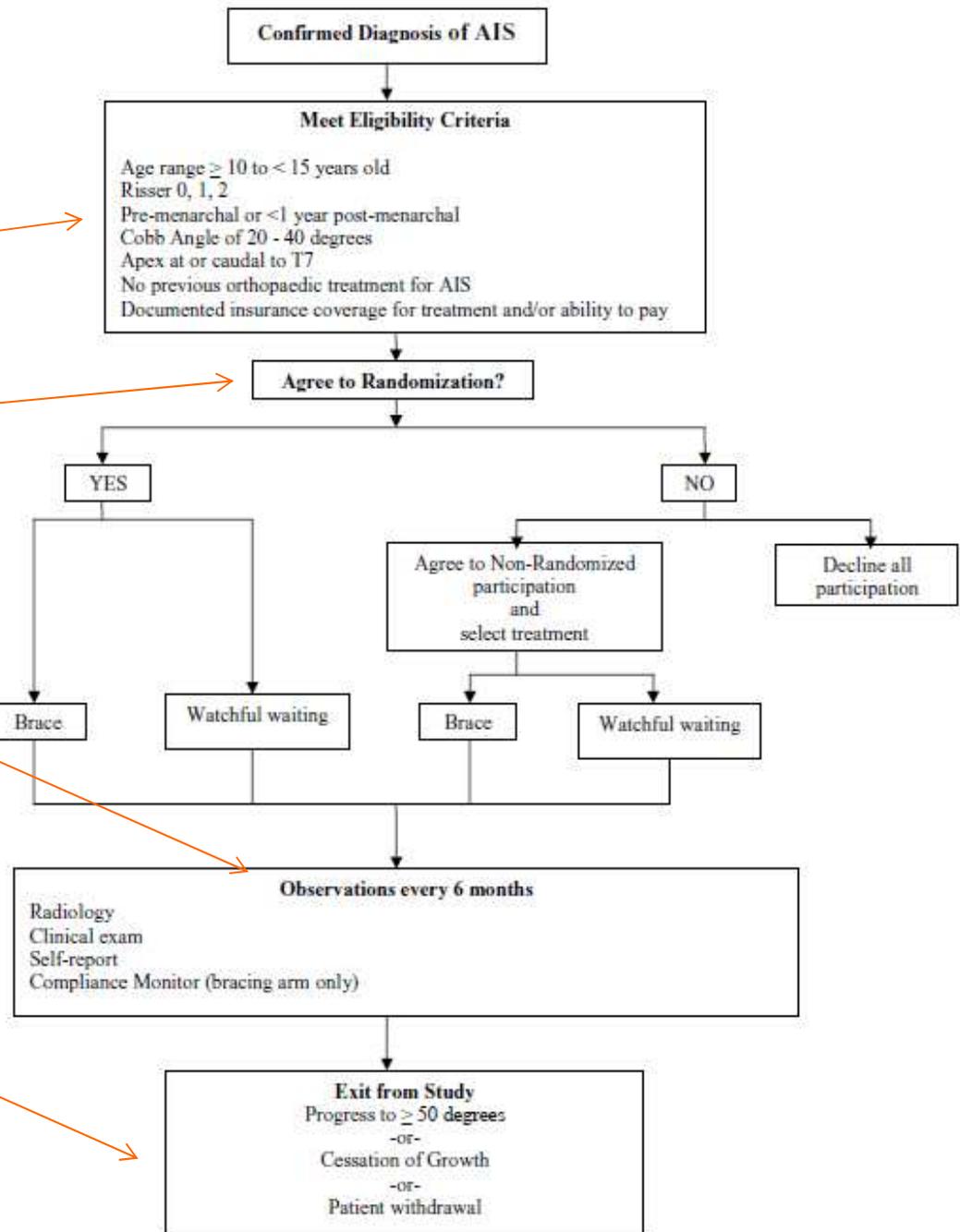
- **Failure**

- Cobb angle  $\geq 50$  degrees or surgery (prior to skeletal maturity)
  - \*common indication for spinal instrumentation and fusion\*

Endpoints determined by consensus of 2 blinded reviewers

# Final Protocol

- Population
- Treatment assignment
- Treatment
- Observation periods
- Data collection
- Exit from Study



Enrollment April 2007 to March 2011  
25 institutions US and Canada

# Primary Analysis Results (Level II evidence)

Raw Success and Failure Rates by Treatment in the Primary Analysis Population

Treatment	Success (%)	Failure (%)	Total
Braced	105 (71.9)	41 (28.1)	146
Observed	46 (47.9)	50 (52.1)	96
Total	151 (62.4)	91 (37.6)	242

Unadjusted Odds Ratio 2.78 (1.62 – 4.77)

**Adjusted Odds Ratio 1.93 (1.08 – 3.46)**

(adjusted for propensity score and length of FU)

# Randomized Analysis Results (Level I evidence)

Raw Success and Failure Rates by Assigned Treatment in the Randomized Population

Treatment	Success (%)	Failure (%)	Total
Brace	38 (74.5)	13 (25.4)	51
Observed	27 (41.5)	38 (58.5)	65
Total	65 (56.0)	51 (44.0)	116

(unadjusted) Odds Ratio 4.11 (1.85 – 9.16)

Relative Risk of Failure = 44%

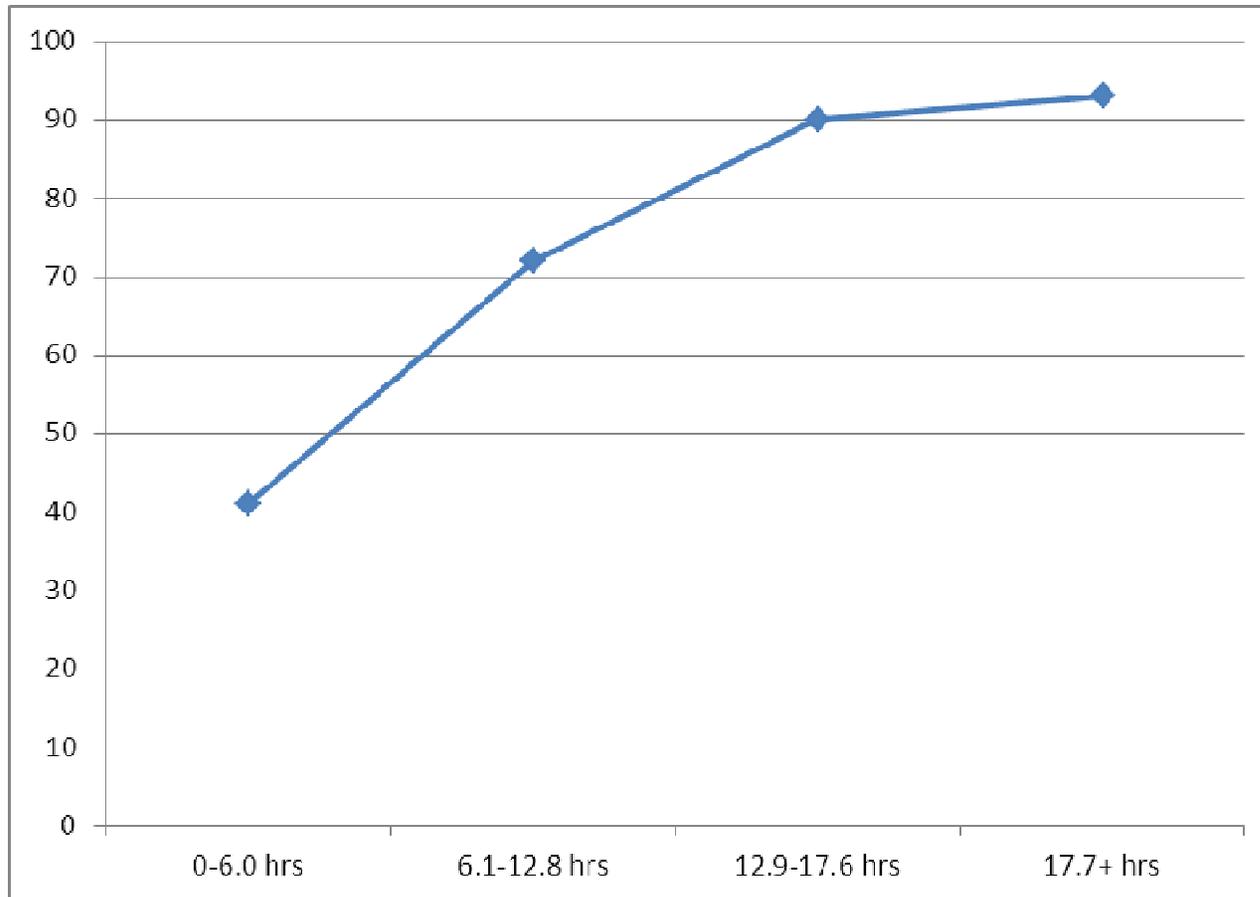
Relative Risk Reduction (in failure rates) = 56%

Attributable Risk Reduction = 33%

Number Needed to Treat = 3

# Brace Dose and Response n=116\*

On average, subjects wore the brace 12 hours per day (range 0 to 23)



\*preliminary data

**As the average hours per day increased, so did the success rate (p<0.0001)**

# Primary Study Conclusions

Bracing significantly decreased progression in high risk curves in adolescent idiopathic scoliosis to the threshold for surgery

and

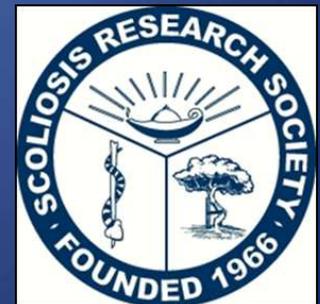
Gains in benefit were seen with increasing hours of brace wear.

# References

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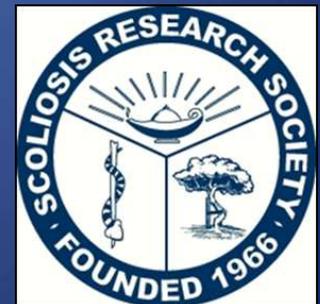
# Summary of BrAIST

- 56% reduction of treat failure
- Number needed to treat = 3
- Compliance is important
- 40 % of observation had not failed at skeletal maturity



# Implication of BrAIST

- Early detection is important
- Compliance is important
- Improve indication for bracing
- Cost saving with bracing vs surgery
- Reconsider screening examinations



# Upcoming Meetings

## 20th IMAST Meeting

July 16-19, 2014

Valencia, Spain



## 49th Annual Meeting

September 10-13, 2014

Anchorage, Alaska



**Thank you**

