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

Results of the BrAIST Clinical Trial

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

NIAMS
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Shriners Hospitals for Children

Supported by a grant from the National Institutes of Health

U.S. Department of Health and Human Services

CIHR IRSC
Canadian Institutes of Health Research

Children's Mercy Hospital
www.childrensmcery.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 (≥ 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 ≥ 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

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Success (%)</th>
<th>Failure (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Braced</td>
<td>105 (71.9)</td>
<td>41 (28.1)</td>
<td>146</td>
</tr>
<tr>
<td>Observed</td>
<td>46 (47.9)</td>
<td>50 (52.1)</td>
<td>96</td>
</tr>
<tr>
<td>Total</td>
<td>151 (62.4)</td>
<td>91 (37.6)</td>
<td>242</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Success (%)</th>
<th>Failure (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brace</td>
<td>38 (74.5)</td>
<td>13 (25.4)</td>
<td>51</td>
</tr>
<tr>
<td>Observed</td>
<td>27 (41.5)</td>
<td>38 (58.5)</td>
<td>65</td>
</tr>
<tr>
<td>Total</td>
<td>65 (56.0)</td>
<td>51 (44.0)</td>
<td>116</td>
</tr>
</tbody>
</table>

(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)

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

*preliminary data
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


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