A PROSPECTIVE RANDOMISED STUDY OF
THE NATURAL HISTORY OF IDIOPATHIC
SCOLIOSIS VERSUS TREATMENT WITH THE
SPINECOR BRACE: INTERIM RESULTS.

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INTRODUCTION

• Natural History of Idiopathic Scoliosis
  – Lonstein and Carlson (1984)
    • Risk of Progression = 68%
      – Cobb angle 20-29 degrees
      – Risser 0 1 or 2

• Treatment Less than 30 Degrees
  – Styblo K (1992)
  – Guillaumat M (1980)
INTRODUCTION

- Limitations of Current Rigid Brace Treatment
  - Constraints placed on bone structures, such as the rib cage during growth.
  - Integrity of muscular system: maintenance through physiotherapy
  - Permanent correction with rigid brace.
  - Poor cosmetic/esthetic outcome.
INTRODUCTION

• Alternative Treatment Approach:
  – Flexible Brace:
    • Maintain Neuromuscular Integrity:
      – Posture, Movement
    • Synchronise with patient growth
    • Esthetic outcome /
    • Better patient compliance

  – Early Treatment (15 to 30 Degrees):
    • Initiate prior to the development of:
      – Prevent bone structure deformation
      – Soft-tissue adaptation
INTRODUCTION

Corrective Movement Principle

SpineCor Brace
BASIC HYPOTHESIS

• We want to demonstrate that the treatment with the dynamic corrective brace provides better results than the natural evolution of the disease.
METHODS

**Recruitment visit:** Before being accepted in this study, each patient will received a recruitment examination including:

- A regular and neuro-muscular clinical examination.
- A regular P.A and lateral X-ray to determine the original Cobb angle.
- An X-ray to evaluate bone age (optional).
- A supine P.A. X-ray to establish the reducibility
METHODS

• **Inclusion Criteria:**
  
  – Diagnosed Idiopathic scoliosis:
    
    • High risk of evolution:
      
      – Family history/ other prognostic factor)
      
      – Proven progressive (Cobb angle increase of 5° or more during last six months).
    
    • No significant pathological malformation of the spine under X-ray examination.
    
    • Girl or boy.
    
    • Initial Cobb angle equal or above 15°.
    
    • Initial Cobb angle equal or less then 30°.
    
    • Risser 0,1 or 2.
METHODS

- **Exclusion criteria:**
  - Postural scoliosis: complete reduction with supine x-ray with a leg length discrepancy.
  - Patient who can not accept protocol rules.
  - Previous treatment: rigid brace, other, except physiotherapy or shoe lift. For the later, the treatment must be interrupted if the patient is randomised as a control patient.
  - Congenital malformation of the spine such as Spina Bifida aperta or Spondylolisthesis.
METHODS

Initial Recruitment Visit

Treated

Fitting

Initial Exam (3 Weeks)

Yes

Worsening of more than 5 Degrees

Control

Verification

4-6 Weeks

Follow-up (4 - 6 Months)

End of Treatment
METHODS

PATIENT EVALUATION

Clinical Exam  Postural Exam  P/A, lateral x-ray
METHODS

• Special cases:
  • Failure:
    - Cobb angle worsen by more than 5° from the original angle.
  • Withdrawal:
    ✓ The patient or parents want to withdraw from the study.
    ✓ Impossible to continue the treatment with the same physician because of a situational change.

• Note to the file:
  ✓ Insufficient compliance:
# METHODS

<table>
<thead>
<tr>
<th>Age</th>
<th>Initial Cobb angle (Deg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>Control</td>
<td>12 ± 2</td>
</tr>
<tr>
<td>Thoracic</td>
<td>11</td>
</tr>
<tr>
<td>Thoracolumbar</td>
<td>8</td>
</tr>
<tr>
<td>Lumbar</td>
<td>2</td>
</tr>
<tr>
<td>Double</td>
<td>12</td>
</tr>
<tr>
<td>Treated</td>
<td>12 ± 2</td>
</tr>
<tr>
<td>Thoracic</td>
<td>5</td>
</tr>
<tr>
<td>Thoracolumbar</td>
<td>9</td>
</tr>
<tr>
<td>Lumbar</td>
<td>1</td>
</tr>
<tr>
<td>Double</td>
<td>4</td>
</tr>
</tbody>
</table>
## RESULTS

Percentage of patients improved, stable and worsened at the last available visit.

<table>
<thead>
<tr>
<th></th>
<th>Improved</th>
<th>Stable</th>
<th>Worsened</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (n=33)</td>
<td>12</td>
<td>35</td>
<td>52</td>
</tr>
<tr>
<td>Treated (n=20)</td>
<td>76</td>
<td>14</td>
<td>5</td>
</tr>
</tbody>
</table>
RESULTS

**Survival Analysis**: Cumulative Probability of Success. Survival function for the treated group with Brace and the control group. Initial Visit in reference to the last available visit or end of treatment.

**Survival Time**

- **Control**
  - 24 months CI: 19-30

- **Treated**
  - 35 months CI: 32-38

Log Rank = .0067
# RESULTS

Cumulative Probability of Success  
Initial visit vs last available visit or end of Treatment

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Treated with Brace</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Months</td>
<td>0.66 (CI: 0.47-0.86)</td>
<td>1.0 (CI: 1.0-1.0)</td>
</tr>
<tr>
<td>24 Months</td>
<td>0.60 (CI: 0.39-0.81)</td>
<td>0.92 (CI: 0.78-1.0)</td>
</tr>
<tr>
<td>30 Months</td>
<td>0.30 (CI: 0.0-0.73)</td>
<td>0.76 (CI: 0.46-1.0)</td>
</tr>
</tbody>
</table>

*Note:* The results at 30 months represents a small number of patients as reflected by the size of the Confidence Interval.
RESULTS

Survival Analysis: Cumulative Probability of Success. Survival function for the treated group without brace and the control group. Initial Visit in reference to the last available visit.

Survival Time

Control

24 months CI: 19-30

Treated

36 months CI: 33-40

Log Rank = .0169
## RESULTS

Cumulative Probability of Success
Initial visit vs last available visit.

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Treated Without Brace</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Months</td>
<td>.66 (CI: .47-.86)</td>
<td>1.0 (CI: 1.0-1.0)</td>
</tr>
<tr>
<td>24 Months</td>
<td>.60 (CI: .39-.81)</td>
<td>1.0 (CI: .1.0-1.0)</td>
</tr>
<tr>
<td>30 Months</td>
<td>.30 (CI: 0-.73)</td>
<td>.83 (CI: .53-1.0)</td>
</tr>
</tbody>
</table>

**Note**: The results at 30 months represents a small number of patients as reflected by the size of the Confidence Interval.
CONCLUSION

- This is the first prospective randomised study on Scoliosis patients investigating the Cobb angle between 15 and 30 degrees.

- This interim evaluation reveals a strong tendency where 52 percent of the control group worsen, compared to the treated group who showed a worsening of only 5 percent.

- This interim result which shows this large difference in worsening between treated and non-treated patients questions the logic of continuing this prospective randomised study.
Birth date: 1985-07-02
Age: 13-y, 2-m

**PROTOCOL TREATED**

Starting date: 1998-09-22

X-Ray date: 1998-09-22

Risser: 0

**File Number:** 1913289

26°

42°

17°
Birth date: 1985-07-02
Age: 13-y, 10-m

PROTOCOL TREATED

Starting date: 1998-09-22

X-Ray date: 1999-05-19

File Number: 1913289
Birth date: 1985-07-02
Age: 17-Y, 8-m

**PROTOCOL TREATED**

Starting date: 1998-09-22
Weaning date: 2000-04-19
X-Ray date: 2003-03-05
Risser: 4

Weaning time: 35 months

**File Number**: 1913289
Birth date: 1983-12-17
Age: 15-y, 2-m

**PROTOCOL TREATED**

Starting date: 1999-01-12

X-Ray date: 1999-01-12

Risser: 1

**File Number:** 1854327

45°  20°  43°
Birth date: 1983-12-17
Age: 19-y, 5-m

**PROTOCOL TREATED**

Starting date: 1999-01-12
Weaning date: 2000-08-23
X-Ray date: 2003-04-24
Risser:

Weaning time: 32

**File Number**: 1854327
Birth date: 1985-08-08
Age: 14-y, 1-m

**PROTOCOL TREATED**

Starting date: 1999-09-15

X-Ray date: 1999-08-10

Risser: 1

**File Number:** 1371044
Birth date: 1985-08-08
Age: 14-y, 6-m

**PROTOCOL TREATED**

Starting date: 1999-09-15

X-Ray date: 2000-02-16

**File Number:** 1371044
Birth date: 1985-08-08
Age: 16-y, 9-m

**PROTOCOL TREATED**

Starting date: 1999-09-15

Weaning date: 2000-05-21

X-Ray date: 2002-05-09

Weaning time: 24 months

**File Number:** 1371044
Special Case

1998-2003
April 7\(^{th}\), 1998: Elsewhere General

- T6 to T12 $\rightarrow$ 30\(^{\circ}\) Right

- T12 to L5 $\rightarrow$ 29\(^{\circ}\) Left
July 22nd, 1999: Sainte-Justine Hospital

- T6 to T12 → 41° Right
- T12 to L5 → 36° Left
July 22\textsuperscript{nd}, 1999:

Sainte-Justine Hospital

41°  36°
July 22\textsuperscript{nd}, 1999:

Sainte-Justine Hospital

Brace Setting

33°  27°
February 13th, 2002:
Sainte-Justine Hospital
Weaning date
December 18th, 2003:
Sainte-Justine Hospital
Weaning time:
22 months