Magnetically Controlled Growing Rods (MCGR) for Early Onset Scoliosis (EOS)

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UCSF Practical Course in Advanced Spinal techniques
Las Vegas, November 8, 2013

Disclosures (Growing Spine)
Growing Spine Foundation (a)
DePuy Spine (a,b)
Ellipse Tech. (a,b)
K2M (a,b)
Kspine (b)

Early Onset Spinal Deformity
Treating very young children with progressive EOS remains challenging...

Challenges in EOS
• Many etiologies
• Many different treatments
• High rate of complications
• Limited outcome measures
• Comparisons difficult!
Options between growing rods, nonoperative treatment, VEPTAR, Shilla, and fusion.

Practical variation exists (as each patient needs special consideration) but consensus exists on the utility of GR in EOS specifically about starting age, curve and etiology.

Vitale Study
**Development and Initial Validation of a Novel Classification System in Early Onset Scoliosis**

Brendan A. Williams, MD, Hiroko Matsumoto, MA; Daren J. McCalla, BS; Behrooz A. Akbarnia, MD; Laurel C. Blakemore, MD; Randal R. Betz, MD; John M. Flynn, MD; Charles E. Johnston, MD; Richard E. McCarthy, MD; David P. Roye Jr., MD; David L. Skaggs, MD; John T. Smith, MD; Brian D. Snyder, MD; Paul D. Spinekall, MD, MBA; Peter F. Sturm, MD; George H. Thompson, MD; Michael D. Waks, MD, MPH.

**Cobb Angle**

**Etiology**

- Congenital/Structural
- Neuromuscular
- Syndromic
- Idiopathic

---

**Results**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Not Useful</th>
<th>Useful</th>
<th>Essential</th>
<th>CVR</th>
<th>Sum of Ranks</th>
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<tbody>
<tr>
<td>COBB 1: &lt;20°</td>
<td>0</td>
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<td>14</td>
<td>0.87</td>
<td>29</td>
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<tr>
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<td>12</td>
<td>0.60</td>
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</tr>
<tr>
<td>KYPHOSIS</td>
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<td>4</td>
<td>11</td>
<td>0.47</td>
<td>26</td>
</tr>
<tr>
<td>AGE</td>
<td>5</td>
<td>0</td>
<td>10</td>
<td>0.33</td>
<td>20</td>
</tr>
<tr>
<td>PROGRESSION</td>
<td>3</td>
<td>5</td>
<td>7</td>
<td>-0.07</td>
<td>19</td>
</tr>
</tbody>
</table>

**Classification of EOS (C-EOS)**

<table>
<thead>
<tr>
<th>Etiology</th>
<th>Cobb Angle 1: &lt;20°</th>
<th>Kyphosis 1: &lt;20°</th>
<th>APR Modifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural</td>
<td>1</td>
<td>1</td>
<td>P&lt;100°/yr</td>
</tr>
<tr>
<td>Neuromuscular</td>
<td>2 21-50°</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syndromic</td>
<td>3 51-80°</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Idiopathic</td>
<td>4 &gt;90°</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Vitale et al
Validation Studies (ICEOS)

Questions to be addressed:

- Why children with EOS need treatment?
- What are the goals of treatment?
- What are the treatment options including growth friendly options?
- What are the expected outcomes?
- Can we minimize complications?
- What to expect in the future?

Natural History Untreated Scoliosis

- Infantile: 0 to 3 years
- Juvenile: 4 to 9 years
- Adolescent: 10 to 16 years
Thoracic Insufficiency Syndrome

The Inability of the Thorax to Support Normal Respiration Or Lung Growth

Campbell, Smith, et al.
J BJS Mar, 2003
J BJS Aug, 2004

Thoracic Insufficiency Syndrome Poor Quality of Life

- Among the lowest observed in pediatrics
  - Asthma
  - JRA
  - Heart transplant

Vitale, JPO, 2008

Questions to be addressed:

- Why children with EOS need treatment?
- What are the goals of treatment?
- What are the options?
- Non-fusion options
- Can we minimize complications?
- What is the expected outcomes?
- What to expect in the future?

Treatment Goals

- Deformity Correction (spine and chest) and maintenance of correction
- Improve pulmonary and spinal function
- Normalize the spinal growth and avoid early fusion (maintain mobility)
- Minimize complications
- Improve quality of life and the care of the patient
Fusing scoliosis early may contribute to shortening of the thoracic spine, TIS, and respiratory insufficiency

- 28 pts, early thoracic fusion before the age 9 years,
  - evaluated by pulmonary function testing at a minimum of 5 years f/u
  - compared to age matched controls
- Average age at surgery was 3.3 yrs and at follow up was 14.6 yrs.

- Thoracic spinal height
  - FVC < 50%
  - < 18 cm: 63% pts
  - 18 to 22 cm: 25% pts
  - 22 cm to normal*: 0% pts

* normal 28 cm males, 26 cm females

Questions to be addressed:

- Why children with EOS need treatment?
- What are the goals of treatment?
- What are the options?
- Non-fusion options
- Can we minimize complications?
- What is the expected outcomes?
- What to expect in the future?

Treatment Options

- Non-operative treatment (cast, Brace, traction)
- Spine based growing rods
- Rib-based distraction
- Hybrid?
- Growth modulation
- Guided growth
- Early fusion

History
Questions to be addressed:

- Why children with EOS need treatment?
- What are the goals of treatment?
- What are the options?
- Non-fusion options
  - What is the expected outcomes?
  - Can we minimize complications?
  - What to expect in the future?

Casting and Bracing is well tolerated

Growth Friendly Implant Classification

1. Distraction based
   - Growing Rods
   - VEPTR
   - MCGR
2. Guided Growth
   - Luque-Trolley
   - Shilla
3. Tension Based
   - Tether
   - Staple

Indications for Growth-Friendly Surgery

- Progressive curves not controlled or amenable to bracing or casting
- Curves where growth preservation would be beneficial
- Curves that require management of both the chest wall and the scoliosis

Skaggs

ONLY VEPTR IS APPROVED in USA

< age 8
< age 9
< age 9
< age 9
< age 8
> age 8
Non-congenital

All etiologies
All etiologies
All etiologies
All etiologies
All etiologies
All etiologies

Skaggs
Absent Ribs: Expansion Thoracoplasty by Multiple Devices

Shilla

Open Screws – no fusion
- no bone exposed
- allow rod to slide multiaxial

3 level fusion
- compression
- distraction
- derotation

Richard McCarthy

Preop  Postop  1 year Postop

Newton

Single Rod Techniques

Growing Rods
Growing Rods

Distraction Based – Rib Anchors
+- thoracotomy

Comparison of spine and Rib anchors

• All specimens eventually failed at the bone-anchor interface.

No failures were observed in the instrumentation utilized.

<table>
<thead>
<tr>
<th>Construct Type</th>
<th>Maximum load for failure (Mean &amp; Standard Deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Screw-Screw) SS</td>
<td>349 ± 89 N</td>
</tr>
<tr>
<td>(Laminar Hook-Hook) HH</td>
<td>283 ± 48 N</td>
</tr>
<tr>
<td>(Rib Hook-Hook) RR</td>
<td>429 ± 133 N</td>
</tr>
<tr>
<td>(Transverse Process-Laminar Hook-Hook) TPL</td>
<td>236 ± 60 N</td>
</tr>
</tbody>
</table>

Rib to Spine

Young’s Modulus was calculated for each construct type and no statistically significant difference was determined.
Questions to be addressed:

- Why children with EOS need treatment?
- What are the goals of treatment?
- What are the options?
- Non-fusion options
- What is the expected outcomes?
- Can we minimize complications?
- What to expect in the future?

Quality of Life Outcomes

- EOSQ being collected prospectively

RESULTS (cont’d)

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Cobb Angle (Pre-Initial to Post Final)</th>
<th>% Correction</th>
<th>Increase in T1-S1 Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single with apical</td>
<td>85° → 65°</td>
<td>23%</td>
<td>6.4cm</td>
</tr>
<tr>
<td>Single w/o apical</td>
<td>61° → 39°</td>
<td>36%</td>
<td>7.6cm</td>
</tr>
<tr>
<td>Dual w/o apical</td>
<td>92° → 26°</td>
<td>71%</td>
<td>11.8cm</td>
</tr>
</tbody>
</table>

Growth per Year (cm)

- Total Group         1.21
- Under 5 years       1.19
- 5-10 year           1.13
- Under treatment     1.01
- Post final fusion group 1.66
Early onset scoliosis treated with Growing Rods has more growth and better Cobb correction but more surgeries compared to Shilla

Lindsay M. Andras, MD; Elizabeth R. A. Joiner, BS; Richard E. McCarthy, MD; Scott J. Luhmann, MD; Paul D. Sponseller, MD; John B. Emans, MD; David L. Skaggs, MD and Growing Spine Study Group

- 37 GR  37 Shilla
- Same FU (4.1 vs 4.6)
- T1-S1 ( 8.5 vs 6.4)
- Cobb angle Change ( 36 vs 23)
- Number of surgeries (7 vs 2.8)
Questions to be addressed:

• Why children with EOS need treatment?
• What are the goals of treatment?
• What are the options?
• Non-fusion options
• What is the expected outcomes?
• Can we minimize complications?
• What to expect in the future?
Significance of sagittal alignment

- Syndromic patients with early onset scoliosis with thoracic kyphosis over 40 degrees who undergo growing rod treatment should be monitored very closely for complications, particularly for implant failure.

Questions to be addressed:

- Why children with EOS need treatment?
- What are the goals of treatment?
- What are the options?
- Non-fusion options
- Can we minimize complications?
- What is the expected outcomes?
- What to expect in the future?
The use of remotely controlled lengthening devices has been previously reported. (Takaso et al., Soubeiran et al.)

Goal of MGR: To reduce frequency of surgeries while still providing distraction.

Growth modulation with current Growing Rod (GR) techniques require frequent surgical lengthening and has a high risk of complications.

The complication risk increased by 24% for each additional surgical procedure.

Growth-guided procedures, may reduce the number of procedures, but do not provide any distraction.

2012
Magetically controlled growing rods (MGR) were developed to allow for non-invasive lengthening
Pre-clinical studies has shown promising results

7-9 levels were un-instrumented between cephalad and caudal foundations
7 mm of remote distraction was performed weekly for 7 weeks in EG under sedation
Implants were removed at week #7
Animals were sacrificed 3 weeks after implant removal
MCGR was shown to be **safe and effective** in this study.

No complication resulted directly from distraction.

MCGR distinguishes itself by:

- Distraction accuracy / prediction
- Ability to shorten

**CONCLUSIONS**

Materials and Methods

- **33 MCGR** patients in 4 centers (Hong Kong, London, Cairo and Ankara)

14 patients met the inclusion criteria:

1. EOS of any etiology
2. Minimum of 3 distractions

- T1-T12, T1-S1 and height of instrumented spine was measured

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**MCGR Technology**

- Implantable spinal rod with magnetic actuator
- External remote controller non-invasive adjustment

**Example of current physician directed adjustable rod. Requires surgical intervention for adjustment**

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**Next Generation of Growth-Sparing Technique**

*Preliminary Clinical Results of a Magnetically Controlled Growing Rod in 14 Patients With Early-Onset Scoliosis*

Belkoff, A. Alkhazine, M.D., Kenneth Cheung, M.D., Hadi Naouri, F.R.C.S., Hazem Elbissawi, M.D., Mohammad Yavari, M.D., Zalene Donna, F.R.C.S., and Nima Rahimi, M.D.
Materials and Methods

• 14 patients: (7 M, 7 F)
• Mean age: 8 y + 10 m (3 y+6 m to 12 y+7 m)
• 14 initial surgeries
• 68 distractions

Etiology
- Idiopathic
- Neuromuscular
- Congenital
- Syndromic
- NF

14%
7%
36%
29%

Results

• 5 single rod (SR) and 9 dual rod (DR)
• Average of 10 months follow up (6-18).
• An average of 4.9 distractions per patient

• Mean interval between index MCGR and the first distraction was 66 days
• Mean interval between two subsequent distractions was 43 days

<table>
<thead>
<tr>
<th>Etiology</th>
<th>Single Rod</th>
<th>Dual Rod</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idiopathic</td>
<td>30%</td>
<td>28%</td>
</tr>
<tr>
<td>Neuromuscular</td>
<td>40%</td>
<td>42%</td>
</tr>
<tr>
<td>Congenital</td>
<td>10%</td>
<td>8%</td>
</tr>
<tr>
<td>Syndromic</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>NF</td>
<td>2%</td>
<td>3%</td>
</tr>
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</table>

Initial and final Cobb correction were significant in each group.

Results (Height)

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre Index</th>
<th>Post Index</th>
<th>Final</th>
<th>Total Grow</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>177.9</td>
<td>197.7</td>
<td>208.2</td>
<td>10.5</td>
<td>&lt;0.05</td>
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<tr>
<td>Single</td>
<td>177.8</td>
<td>196.4</td>
<td>204</td>
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</tr>
</tbody>
</table>

Results (Height)
Results - Mean Monthly T1-S1 Height Change

- MCGR Single Rod
- MCGR Dual Rod
- Dimeglio 5-10 years
- Original GR (Akbarnia)

Mean Monthly T1-S1 Height Change (mm/mo)

P<0.05

Case one: 5.5 y/o Female (NM)

- Pre Index
- Post Index

T1-T12: 176 mm
T1-S1: 251 mm

T1-T12: 181 mm
T1-S1: 261 mm

Pre-operative
Most recent
Result

GSSG Data (average follow up 28 months)

<table>
<thead>
<tr>
<th>Cobb Angle (°)</th>
<th>Pre-operative</th>
<th>Most recent</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic Spine Height (mm)</td>
<td>Pre-operative</td>
<td>Most recent</td>
<td>Result</td>
</tr>
<tr>
<td>GSSG</td>
<td>77.6 ± 16.7</td>
<td>41.3 ± 16.6</td>
<td>47% deformity correction</td>
</tr>
</tbody>
</table>
| MAGEC Data (average follow up 7.6 months)

<table>
<thead>
<tr>
<th>Cobb Angle (°)</th>
<th>Pre-operative</th>
<th>Most recent</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic Spine Height (mm)</td>
<td>Pre-operative</td>
<td>Most recent</td>
<td>Result</td>
</tr>
<tr>
<td>MAGEC</td>
<td>58.8 ± 12.3</td>
<td>31.4 ± 9.3</td>
<td>47% deformity correction</td>
</tr>
<tr>
<td></td>
<td>186 ± 28</td>
<td>212 ± 28</td>
<td>14% increased thoracic spine height</td>
</tr>
</tbody>
</table>
MCGR
Cheung, Cheung, Samartzis, Mak, Wong, Cheung, Akbarnia, Luk (Lancet April 19, 2012)

- Five patients, 2 with over 24 months follow-up
- Monthly distractions
- Scoliosis from 67 to 29 at 2 years
- 1.9 mm increase per distraction
- No Anesthesia, No pain
- No complications

Scoliosis

Spinal Length

MCGR (Case 1)
MCGR (Case 1)

Pre Op AP

Post Op AP

MCGR (Case 2)

Pre Op AP

Post Op AP

MCGR - Case 2

12.3 mm

Post Distraction June 2010

Courtesy of Ken Cheung, MD, University of Hong Kong, HK

Traditional Growing Rods Versus Magnetically Controlled Growing Rods in Early Onset Scoliosis: A Case-Matched Two Year Study


48th Annual Meeting of Scoliosis Research Society September 18-21, 2013 – Lyon, France
INTRODUCTION

2012-13

- Early clinical results of MCGR:
  - Safe and effective
  - Significant reduction in the number of surgical procedures

INTRODUCTION

- The purpose of this study was to perform a case-matched comparison of MCGR and TGR patients with 2 years of follow-up

METHODS

- Retrospective review of MCGR patients who met the following criteria:
  - < 10 years old
  - Major curve ≥30º
  - No previous spine surgery
  - ≥ 2-year follow-up

METHODS

- Each MCGR patient was matched to a TGR patient by:
  - Etiology
  - Gender
  - Single vs. dual rods
  - Pre-op age (+/- 10 months)
  - Pre-op major curve (+/- 20º)

- Etiologies were classified per C-EOS (Vitale):
  - Idiopathic
  - Congenital/Structural
  - Neuromuscular
  - Syndromic

- One male MCGR patient was matched to a female TGR patient since a male-male match could not be found
**METHODS**

Spinal growth calculation: “Annual T1-S1 Growth”

\[
\text{Annual T1-S1 Growth (mm/year)} = \frac{\Delta \text{ in T1-S1 from post index to latest F/U}}{\text{Length of follow-up}}
\]

**RESULTS**

- **MCGR patients:**
  - Mean age = 6.8 years
  - Mean follow-up = 2.5 years

- Follow-up was greater for TGR patients by **1.6 years**

- **Distribution of etiologies:**
  - 4 Neuromuscular
  - 4 Syndromic
  - 3 Idiopathic
  - 1 Congenital

<table>
<thead>
<tr>
<th>Major Curve</th>
<th>Pre-op (mean)</th>
<th>Post-op (mean)</th>
<th>≥2 Yr Post-op (mean)</th>
<th>Overall Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCGR</td>
<td>59°</td>
<td>32°</td>
<td>38°</td>
<td>35%</td>
</tr>
<tr>
<td>TGR</td>
<td>60°</td>
<td>31°</td>
<td>41°</td>
<td>32%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T1-S1 Spinal Length</th>
<th>MCGR</th>
<th>Post-op (mean)</th>
<th>≥2 Yr Post-op (mean)</th>
<th>Overall Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCGR</td>
<td>270 mm</td>
<td>295 mm</td>
<td>307 mm</td>
<td>38 mm</td>
</tr>
<tr>
<td>TGR</td>
<td>264 mm</td>
<td>311 mm</td>
<td>347 mm</td>
<td>77 mm</td>
</tr>
</tbody>
</table>

- **Overall curve correction**
  - Similar between groups throughout treatment (\(p > 0.1\))

- **Overall increase in T1-S1**
  - Greater in TGR compared to MCGR (\(p=0.01\))
  - Possibly due to additional follow up of TGR patients (1.6 years)

- **Annual T1-S1 growth**
  - 7 mm/year for MCGR
  - 11 mm/year for TGR patients
  - This difference did not reach statistical significance due to sample size (minimum 10 mm/year to show significance)
### RESULTS (Procedures)

<table>
<thead>
<tr>
<th></th>
<th>Total Open Surgeries</th>
<th>Total Lengthenings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MCGR</strong></td>
<td>16</td>
<td>137 (non-invasive)</td>
</tr>
<tr>
<td><strong>TGR</strong></td>
<td>78</td>
<td>49</td>
</tr>
</tbody>
</table>

### Implant Complications

<table>
<thead>
<tr>
<th></th>
<th>MCGR</th>
<th>TGR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implant Complications</strong></td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td><strong>Wound Complications</strong></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><strong>Medical Complications</strong></td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td><strong>Number of Revisions</strong></td>
<td>4</td>
<td>23</td>
</tr>
</tbody>
</table>

- **MCGR revisions included**: anchor pull out, prominent implants and collapse of device (all cases were generation 1 devices)
- **TGR revisions included**: anchor pull out, rod breakage, prominent implants, planned surgery to exchange connector

### Compassionate Use in U.S.

- **8+11 year old boy with Idiopathic EOS**
Compassionate Use in U.S.

8+11 year old boy with Idiopathic EOS

Summary MCGR

- Major curve correction was similar between MCGR and TGR patients throughout treatment.
- Overall gain in T1-S1 was greater in TGR compared to MCGR, however, TGR had longer follow-up.
- MCGR patients had 62 fewer surgical procedures than TGR patients and more non-invasive lengthenings.
- Need to build consensus and develop practice guidelines for non-invasive lengthenings to reduce surgeon variability and improve reproducibility.

THANK YOU