Next Generation of Growth-Sparing Techniques

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

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Study Design. Prospective nonrandomized study.

Objective. To report the preliminary results of magnetically controlled growing rod (MCGR) technique in children with progressive early-onset scoliosis.

Summary of Background Data. The growing rod (GR) technique is a viable alternative for treatment of early-onset scoliosis. High complication rate is attributed to frequent surgical lengthening. The safety and efficacy of MCGR were recently reported in a porcine model.

Methods. Multicenter study of clinical and radiographical data of patients who underwent MCGR surgery and at least 3 distractions. Distractions were performed in clinic without anesthesia/analgesics. T1–T2 and T1–S1 heights and the distance inside the actuator were measured after lengthening.

Results. Fourteen patients (7 girls, 7 boys) with a mean age of 8 years, 10 months (3 yr, 6 mo to 12 yr, 7 mo) had 14 index surgical procedures. Of the 14, 5 had single-rod (SR) surgery and 9 had dual-rod (DR) surgery, with overall 68 distractions. Diagnoses were idiopathic (N = 5), neuromuscular (N = 4), congenital (N = 2), syndromic (N = 2), and neurofibromatosis (N = 1). Mean follow-up was 10 months (5.8–18.2). The Cobb angle changed from 60° to 34° after initial surgery and 31° at latest follow-up. During distraction period, T1–T2 height increased by 7.6 mm for SR (1.09 mm/mo) and 12.12 mm for DR (1.97 mm/mo). T1–S1 height gain was 9.1 mm for SR (1.27 mm/mo) and 20.3 mm for DR (3.09 mm/mo). Complications included superficial infection in 1 SR, prominent implant in 1 DR, and minimal loss of initial distraction in 3 SR after index. Partial distraction loss observed after 14 of the 68 distractions (1 DR and 13 SR) but regained in subsequent distractions. There was no neurological deficit or implant failure.

Conclusion. Preliminary results indicated MCGR was safe and provided adequate distraction similar to standard GR. DR achieved better initial curve correction and greater spinal height during distraction compared with SR. No major complications were observed during the follow-up.

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lead to an increased complication rate and more unplanned surgical procedures in severely involved children who often have other associated medical problems such as thoracic insufficiency syndrome. Bess et al8 reviewed complications of GR surgery in 140 patients who underwent a total of 897 surgical procedures. The risk of complications increased by 24% for each additional surgical procedure performed.

Surgeons’ knowledge regarding the various challenges in EOS surgery has also significantly improved during the past several years, and there has been an ongoing research to minimize complications associated with most growth-sparing procedures. Therefore, the idea of noninvasive multiple lengthening without the need for anesthesia and open surgery have been long being appealing, given the direct relationship between high complications and repeated surgical procedures.

The concept of magnetic distraction is not new. Takaso et al9 suggested that a remote magnet might be able to provide the driving force for a GR system and be used for correction of scoliosis. Soubeiran et al,10 Miladi,10 and Wilkins and Soubeiran11 reported that a magnetically expandable GR can be used for distraction between ribs, vertebra, and the pelvis. We are reporting the preliminary results of a magnetically controlled growing rod (MCGR), which eliminates the need for repeated surgical procedures and anesthesia.

Preclinical studies examining the safety and efficacy of this MCGR system in an animal model has recently been reported.12 This animal study confirmed that spinal distraction could be achieved safely with this technique, in the porcine model, without any adverse effect related to the MCGR system. The current study intends to report the safety and efficacy of this implant system (MAGEC Ellipse Technology, Irvine, CA) used in a human model.

**DEVICE DESCRIPTION**

The MCGR device was CE marked in Europe in October 2009 but is not yet approved for use in the United States. It is composed of an implantable rod, an external remote controller (ERC), and accessories (Figure 1A). The titanium rod includes a telescopic actuator portion that holds a small internal magnet. Rotation of the magnet remotely by use of the ERC causes the rod to be lengthened or shortened. The rod is implanted and secured to the spine using standard fixation components, such as hooks and/or pedicle screws as anchors. The implant system includes optional rod adapters (short straight adapter and dynamic adapter) to support physician preference of securing the rods to the construct foundations.

The handheld noninvasive ERC is electrically powered and contains 2 permanent magnets that can be rotated using gears. After the rod has been implanted, the ERC can be placed externally on the patient’s spine at the location of the actuator portion of the rod. When activated, the ERC causes the magnet on the implantable device to rotate (Figure 1B). The implants provided were sterilized by gamma radiation. It is also worth mentioning, magnetic resonance compatibility of MCGR has not been examined yet, therefore at this point, its magnetic resonance compatibility is unknown, but we know that the presence of magnets within the actuator can cause artifact on magnetic resonance images.

**MATERIALS AND METHODS**

The study protocol was approved by the appropriate ethical committee at each study site, and patients gave consent for participation in the study. From November 2009 to December 2010, a total of 33 patients underwent the MCGR procedure at 4 centers. There were no study sites in the United States because the device had not been approved by the FDA. Clinical and radiographical data were collected prospectively before and after the initial surgery and before and after each spinal distraction. Preoperative work up and planning was similar to any pediatric spinal deformity assessment including upright posteroanterior and lateral scoliosis radiographs, supine bilateral bending and posteroanterior traction and hyperextension lateral radiographs when deemed appropriate by the treating physician.

Fourteen patients met the inclusion criteria, which included (1) EOS of any etiology; (2) a clear indication for an operative intervention (e.g., documented failed nonoperative treatment and curve progression); and (3) having completed at least 3 outpatient distractions. Surgical technique for MCGR implantation, except the rod, is basically not different from traditional GR technique that has been well documented in previous literature.1 Selecting the instrumentation length for each MCGR surgery was on the basis of the selection criteria surgeons normally used for their standard GR surgery. The length of MCGR instrumentation was usually long from the
and 68 spinal distractions with an average of 4.9 distractions per patient. The initial index procedures included 5 single-rod (SR) and 9 dual-rod (DR) insertions. All patients were kept in thoracolumbosacral orthosis brace for 3 to 6 months after index MCGR procedure but none underwent bracing after MCGR lengthening.

Patients were followed for an average of 10 months. Mean time between index surgery and the start of first distraction was 66 days. The mean interval between subsequent distraction procedures was 43 days.

There were 11 thoracic and 3 thoracolumbar/lumbar curves. The mean preoperative Cobb angle was 60° and was corrected to 34° immediately after initial surgery and was maintained at 31° at the time of latest follow-up. Similarly, mean preoperative maximum thoracic kyphosis was 39° and changed to 31° and 48° postoperatively and at latest follow-up, respectively (Table 1). The average coronal Cobb correction was also compared between patients who had SR and patients who had DR, and there was no significant difference in the initial and final correction between the 2 groups ($P = 0.91$ and $P = 0.85$) (Table 2; Figures 2A–F).

Mean preoperative T1–T12 height for all 14 patients was 178 mm and increased to 196 mm ($P < 0.05$) and 208 mm ($P < 0.05$) after initial surgery and latest follow-up, respectively. Mean T1–S1 height also changed from 292 mm preoperatively to 322 mm ($P < 0.05$) after initial surgery and to 338 mm ($P < 0.05$) at the latest follow-up.

In patients with SR, the mean preoperative T1–T12 height was 178 mm, which increased to 196 mm immediately after index surgery ($P < 0.05$) and to 204 mm at the latest follow-up ($P < 0.05$). The average monthly T1–T12 height increase was 1.09 mm. The mean preoperative T1–S1 height was 295 mm, which increased to 322 mm immediately after index surgery and to 331 mm at the latest follow-up ($P < 0.05$). The average monthly T1–S1 height increase was 1.27 mm.

Similarly, in patients with DR, the mean preoperative T1–T12 height was 178 mm, which increased to 198.4 mm immediately after index surgery and to 210.5 mm at the latest follow-up ($P < 0.05$). The average monthly T1–T12 height increase was 1.97 mm. The mean preoperative T1–S1 height was 290.6 mm, which increased to 322 mm immediately after index surgery and to 342 mm at the latest follow-up ($P < 0.05$). The average monthly T1–S1 height increase was 3.09 mm.

The average monthly T1–T12 growth was not significantly different between the SR and DR groups ($P = 0.21$); however, there was a significant difference between average monthly T1–S1 growth in the 2 groups ($P < 0.05$).

### Table 1. Summary of Radiographical Results of All Patients at Preoperative, Postoperative, and Latest Follow-up Time Points

<table>
<thead>
<tr>
<th></th>
<th>Mean Preop</th>
<th>Mean Postop</th>
<th>Latest Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobb angle</td>
<td>60°</td>
<td>34°</td>
<td>31°</td>
</tr>
<tr>
<td>Maximal thoracic kyphosis</td>
<td>39°</td>
<td>31°</td>
<td>48°</td>
</tr>
<tr>
<td>Total T1–T12 (mm)</td>
<td>178</td>
<td>198</td>
<td>208</td>
</tr>
<tr>
<td>Total T1–S1 (mm)</td>
<td>292</td>
<td>322</td>
<td>338</td>
</tr>
</tbody>
</table>

*Preop indicates preoperative; Postop, postoperative.*

### Table 2. Comparison of Coronal Cobb Correction Between Patients With SR and Patients With DR

<table>
<thead>
<tr>
<th></th>
<th>Mean Preop</th>
<th>Mean Postop</th>
<th>Correction</th>
<th>Final</th>
<th>Correction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single rod</td>
<td>68°</td>
<td>38°</td>
<td>43%</td>
<td>36°</td>
<td>46%</td>
</tr>
<tr>
<td>Dual rod</td>
<td>56°</td>
<td>32°</td>
<td>42%</td>
<td>29°</td>
<td>48%</td>
</tr>
</tbody>
</table>

*Preop indicates preoperative; Postop, postoperative.*
DISCUSSION

Treatment of EOS with growth-sparing techniques ideally has 2 main goals: to correct the spinal deformity and allow for spinal (and indirect pulmonary) growth. These goals have to be met as we try to minimize complications.

Few but valuable studies have shown the effect of thoracic spinal fusion on pulmonary function. Karol et al.\(^3\) showed that the extent of the spine fused correlated with the forced vital capacity. Fusion in the upper thoracic spine was found to be associated with diminished pulmonary function because 8 of 12 patients with a fusion level of T1 or T2 had a forced vital capacity of less than 50%, but only 4 of 16 patients with a fusion beginning caudad to T3 had a forced vital capacity of 50%.

Complications included superficial wound infection in 1 patient with SR (treated medically with antibiotics and frequent wound cleaning dressing), prominent implant in 1 patient with DR, and partial loss of initial height in 3 patients with SR (21%) after index surgery. Partial loss of distraction was the most common complication after 11 of the 68 distractions (2 DR and 9 SR). This loss was regained and maintained in subsequent distractions. No patient experienced any other implant-related complication and none needed rod exchange or revision of the anchors. Review of the radiograph at final follow-up did not show any proximal junctional kyphosis either. Finally, there was no neurological deficit at initial surgery or after lengthening.

Figure 2. (A–F) Posteroanterior and lateral radiographs of a 5.5-year-old girl with neuromuscular scoliosis and right thoracic curve of 45° before (A, B) and after (C, D) dual MCGR. The patient has had monthly MCGR lengthening during the course of 7 months and achieved 12 mm and 31 mm of T1–T12 and T1–S1 height, respectively (E, F). MCGR indicates magnetically controlled growing rod.
less than 50%. None of the 7 patients with a proximal level of fusion at T6 or caudal had a forced vital capacity of less than 50% at the time of follow-up.

Dimeglio et al.16 studied the growth of the spine and thoracic cage in children from birth to the onset of adulthood. They showed that T1–T12 had an average height of 110 mm at birth in both sexes and reached 180 mm at 5 years of age (average monthly growth of 1.16 mm and annual growth of 14 mm from birth to 5 yr) and then reached 220 mm at the age of 10 (average monthly growth of 0.67 mm and annual growth of 8 mm from 5–10 yr). Likewise, the average monthly T1–S1 growth from birth to 5 and from 5 to 10 years is 2 mm and 1.2 mm, respectively.

Previous studies on standard GR have shown that initial T1–S1 elongation achieved at index GR implantation is equal to T1–S1 height growth achieved during the subsequent distractions during the next 2 years (each is about 50% of the total T1–S1 achieved from preindex GR to 2-yr follow-up).17 In 2005, Akbarnia et al.18 reported that the average T1–S1 length increase was 12.1 mm per year for 23 patients with EOS who underwent dual GR surgery and were followed for at least 24 months. In a subsequent study published in 2008, they reported a mean T1–S1 increase of 14.6 mm/yr for a series of patients with dual GR with postoperative follow-up in the range of 3 to 11 years.19 In a more recent study, GR has shown to significantly increase the T1–T12 height, and this increase was positively correlated with the number of lengthenings but did not depend on the underlying etiology.20 In a study of 20 patients with EOS, Olgun et al.21 found that the growth of the vertebral body heights within the instrumented levels (7.0 ± 2.9 mm) is significantly more than those outside the instrumentation levels (5.2 ± 3.4 mm) and concluded that GR had stimulated the growth of the vertebral height compared with the instrumented levels.

Cheung et al.22 first reported two-year results of two patients with MCGR surgery and showed that the actual and predicted rod distractions were closely comparable. Patients experienced no MCGR-related complications and were satisfied with their treatment at the latest follow-up.22 The average monthly T1–T12 and T1–S1 growth in our study is comparable, yet slightly higher than the traditional techniques. We think that this difference may be because of more frequent distractions, especially during the more rapid phase of growth; however, we expect that the spinal height achieved by MCGR will finally be similar to the above-mentioned numbers. A larger cohort of patients with longer postoperative follow-up needed to confirm this finding with more definitive conclusions.

Both single and dual standard GR have been commonly used with reproducible results. In our study, selection of single versus dual MCGR mainly depended on surgeon’s preference. The literature on standard GR has shown that dual GR are more advantageous than single GR in terms of lower rate of rod fracture, better rate of deformity correction, and achieving a higher rate of spinal growth.4,13 Despite being a small study, the current study confirms the same trends.

Timing of subsequent distractions mainly depended on the surgeon’s preference based on the age, growth potential, curve flexibility, and diagnosis. The usual interval between distractions in the standard GR technique is between 6 to 9 months13; however, distraction in MCGR is noninvasively done and it can be done more frequently (with shorter intervals) if the physician prefers.

The correction of scoliosis in our study was 43% after initial MCGR and improved to 48% at final follow-up and both were comparable with the reported standard GR studies. The use of MCGR seems to be effective in correcting the coronal deformity and maintaining scoliosis curve correction (Tables 1 and 2).

We did not observe any major complication related to the MCGR in this series intraoperatively and perioperatively. Partial loss of distraction occurred in some patients with SR that were easily managed in subsequent distractions. It is important to mention that the observed distraction losses were from a first generation design. This issue was resolved by the addition of a magnetic lock that keeps rod length where the ERC positions it. The lock prevents the rod from shortening while it is implanted. Although we have not observed any implant-related complications that needed revision, we think that the revision surgery for rod exchange and anchor replacement is not different from similar procedures in the standard GR surgery. There are still some debates regarding proximal junctional kyphosis in growth-friendly procedures. Increased maximal thoracic kyphosis at final follow-up is thought to be the result of increase outside of the instrumented region but no clear proximal junctional kyphosis was observed in any of our patients.

Similar to traditional GR technique, longer span of the MCGR rods is usually preferred. The amount of deformity correction achieved in initial MCGR surgery is the result of internal bracing of the spine and almost pure distraction. This is to provide distraction over a length of unfused spine to stimulate growth. Also, the very young and growing spine tends to add to the deformity as the child grows. Extending the instrumentation in a later date will further affect the growth by creating more levels of unwanted fusion.

Autofusion in traditional GR technique has a complex pathophysiology but its main contributing factor is the technical error in unnecessary dissection of the uninstrumented, unfused vertebra. It can theoretically happen in MCGR, although we think that noninvasive distractions will reduce the incidence of this phenomenon in MCGR. We have not seen any autofusion incident in our reported patients until the latest follow-up.

Growth guided procedures (i.e., Shilla) have been introduced to minimize the number of surgical procedures as they guide the spinal growth in direction of the implants.3 The procedure does not apply any distraction to the spine. No study exists to compare the increase in length of T1–T12 and T1–S1 with the standard GR. We think that MCGR combines both advantages of reduction of surgical procedures and applying distraction at the same time.

Regarding the effects of electromagnetic field (<8–10 T) on humans, there currently is no evidence for any persistent or major side effect for repeated distraction especially in a local field; therefore, it is considered to be reasonably safe.20
Finally, longer follow-up and a larger group of patients are needed to determine the overall outcome of this technique and noninvasive method of lengthening and characterize its complications.

CONCLUSION

Our study shows that MCGR is a safe and effective growth-sparing modality in treatment of progressive EOS and may be considered a viable alternative to the traditional GR technique. It allows the similar growth of the T1–T12 and T1–S1 to what has been previously observed in normal children and those patients with EOS who underwent the standard GR procedure. We did not observe any major implant-related complication. Overall, the patients with DR showed better initial correction of coronal deformity and better monthly height increase of T1–T12 and T1–S1. A study with additional follow-up and a larger cohort is underway to confirm these initial findings.

> **Key Points**

- MCGR techniques (both SR and DR) achieved and maintained similar initial scoliosis Cobb correction compared with the standard GR surgery.
- Mean monthly T1–T12 and T1–S1 growths were comparable with both normal growth and the growth after the standard GR procedure.
- MCGR reduces the number of open surgical procedures required for lengthening and may significantly reduce the number of complications.

**References**