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## Non-invasive out-patient treatment for severe spinal deformity in children using a magnetically controlled growing rod implant

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## **ABSTRACT**

**Background:** Scoliosis is a common spinal deformity that occurs in young children worldwide. Traditionally, an implant that lengthens with growth (growing rod) is used to treat the deformity. However, this requires multiple open surgeries under general anaesthesia for rod distraction (lengthening), is costly and associated with psychosocial consequences for the patient and family. To address such disadvantages, the following report addresses the efficacy and safety of a new magnetically-controlled growing rod (MCGR) implant for non-invasive out-patient distractions.

**Methods:** Two female patients (five years and 12 years of age at the time of surgery) treated with MCGR with a minimum of 24 months follow-up were included in this study. Each patient underwent monthly out-patient distractions. Radiological assessments entailed the magnitude of the spinal deformity, rod distraction length and spinal length. Clinical outcome assessment consisted of the degree of pain, function, satisfaction with treatment, and procedure-related complications.

**Findings:** Spinal deformity correction was achieved in the initial surgery and was maintained throughout follow-up. There was consistent gain in spinal length with each monthly distraction. Predicted and actual rod distraction lengths were similar up to 24 months of

follow-up. There were no MCGR-related complications. Throughout follow-up, both patients experienced no pain, had good functional outcome and were satisfied with the procedure.

**Interpretation:** This is the first report of the MCGR procedure in young children with severe scoliosis. Our study found that the MCGR was effective and safe, allowing for distractions on a non-invasive out-patient basis eliminating the need for surgeries and their associated complications. Such a procedure reduces time off from school for the patient and work for the parent, minimises surgical scarring and psychological distress, improves quality of life and is also cost-effective. The same technique can be used for non-invasive deformity correction in other conditions.

**Key Words:** scoliosis; children; spine; deformity; growing rod; remote control; magnet

## INTRODUCTION

Scoliosis is a lateral deviation of the spine, and commonly occurs in adolescents and young children. If left untreated, this condition is at risk for rapid progression, cosmetic disfigurement and pulmonary insufficiency.<sup>1, 2,3</sup> Historically, spinal bracing or spinal fusion (i.e. instrumentation with bone graft) had been advocated for treatment of scoliosis;<sup>4-7</sup> however, there are significant disadvantages to both procedures. Bracing is known to fail frequently in treatment of scoliosis in young children, especially the congenital or neuromuscular types.<sup>4-7</sup> More importantly, spinal fusion surgery in young children will prevent normal spine growth.<sup>4-6</sup> For example, spinal fusion in a five year-old child can result in a 12.5cm loss of spinal growth.<sup>8</sup> In addition, fused spines in growing children may lead to arrested pulmonary development and cosmetic problems.<sup>9-11</sup>

In an effort to address the limitations of spinal bracing or fusion for severe scoliosis in young children, a distractible spinal implant (growing rod) was developed.<sup>12-14</sup> Under general anaesthesia, the growing rod (GR) is inserted across the segment of spinal deformity and no fusion is performed. Distraction of the growing rods is recommended every six months, during which the child undergoes surgery again to allow the spine surgeon to re-open the surgical incision site and to distract (i.e. lengthen) the rods to mimic and maintain the normal growth of the spine. By this approach, GRs have been shown to effectively control

progression of spinal deformity as well as to gradually straighten the spine.<sup>7, 12, 13, 15-18</sup>

However, the limitations of this method of treatment are mainly related to the need for general anaesthesia and invasive surgery during repeated distractions and the associated anaesthetic and wound complications.<sup>3</sup> For example, a four year-old child who would reach skeletal maturity at the age of 13 would have to undergo 18 surgeries to distract the traditional GR. Furthermore, traditional GR surgery is associated with various socioeconomic concerns. For instance, multiple periods of hospitalisation for these procedures increase time away from school for the child and time away from work for the parent.<sup>19-21</sup> Due to the costs associated with repeat surgeries, this creates a substantial burden on health-care. In addition, repeated operations and hospitalisation may affect the child's activity level, social interactions, and psychological well-being<sup>19-21</sup> as well as a cosmetically poor surgical scar.

There is thus a need for a more advanced and less invasive technology and methodology that would facilitate distraction of the rods, but eliminate frequent invasive operative interventions, general anaesthesia, wound complications, psychological and socioeconomic problems, and frequent hospitalisation in young children. As such, a remotely distractable, magnetically-controlled growing rod (MCGR) system (**Figure 1**) has been developed that allows frequent "non-invasive out-patient" distractions. It can mimic normal physiological growth more closely and provides continuous neurological monitoring in a conscious patient

during spinal lengthening. This technology has been validated in animal studies.<sup>22, 23</sup>The following is the first report of the use of the MCGR in human patients. The primary aim of this study is to increase the awareness of such a procedure and to evaluate its efficacy as well as safety.

## **METHODS**

### ***Study Design and Patient Sample***

This was a prospective, patient series for surgical intervention of severe scoliosis in young children who have undergone the MCGR procedure at the Duchess of Kent Children's Hospital in Hong Kong. This study was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB). All patients signed an informed consent form prior to entry into the trial. Parents and their child had to agree to be part of the study. Any individual who declined to be a part of the study underwent management with the traditional growing rod. The inclusion criteria included any patient with scoliosis with significant remaining growth potential. From November 2009 to March 2011, five patients (n=3 female; n=2 male) were treated with the MCGR. The main focus of this study, was to address the first two cases treated with MCGR with a minimum 24 months follow-up.

### ***MCGR System and Operative Procedure***

The MCGR (**Figure 1**) was comprised of a single use sterile titanium spinal distractible rod with an enlarged mid-portion containing a magnetically drivable lengthening mechanism. It can be implanted as a single rod configuration for smaller sized patients or as a pair of rods for larger patients, dependant on the surgeon's preference. The rods can be customised to different sizes to accommodate different patients' heights. We report here the outcomes of two cases: one with a single rod implant and the other with a dual rod. implant. For insertion of the MCGR, under general anaesthesia, each patient was positioned prone and two small incisions were made. In dual MCGR surgery, the magnetic component of the rods was placed at opposite ends to avoid interaction during individual distractions. Otherwise, the overall peri-operative protocol was similar to that of the traditional GR. Fusion of the cephalad and caudal ends of the rod was performed, utilizing local bone graft with graft substitutes. All patients wore a brace for 3 months post-operatively until the cranial and caudal anchoring blocks were fused. At every distraction during the intial 3 months, the brace was removed and as such it did not interfere with the procedure. The purpose of the brace was to facilitate fusion of the anchor points.

### ***MCGR Distraction Methodology***

Following surgery, each patient returned to the clinic briefly once every month until last follow-up for MCGR distraction. Amount of predicted distraction (intended distraction) in millimeters (mm) per visit was calculated based upon published growth charts<sup>8</sup> for the spine and adjusted for the number of levels instrumented. In general, patients were distracted between 1.5 to 2mm per month. We aimed to distract the spine more than the predicted spinal growth rate to allow more deformity correction.

During the out-patient distraction visits, the patients were positioned prone. A hand-held magnetic external remote controller was placed over the internal magnet for the distraction (**web-based Figure 7**). A rotating mechanism within the rod produced rod lengthening and thus distraction of the spine. The predicted lengthening was displayed on the external distraction device. The device could also be used to retract the rod if the patient experienced discomfort or pain. All distractions were performed by a single spine surgeon and the procedure itself lasted less than 30 seconds. All patients had radiographs performed after the procedure to confirm the amount of distraction obtained.

### ***Radiological and Clinical Assessment***

Pre- and post-distraction plain radiographic imaging (postero-anterior and lateral whole spine) was performed in all patients. The imaging was used to assess the degree of scoliosis (Cobb's angle<sup>24, 25</sup>), kyphosis (T1-T12), predicted versus achieved rod distraction length and spinal length. The distracted rod length was measured in millimeters (mm) and was based on the lengthened segment of the distractable segment of the rod. Spinal lengths (**Figure 2**) were measured from T1-T12, T1-S1 and the instrumented segment. All images were digitised and imported in a DICOM imaging software programme (RadWorks v5.1, Applicare, Netherlands) and measured. The measurements were performed independently by three individuals, and any discrepancy in measurement values was discussed and a final measurement was achieved by consensus. In addition, the patients' pre- and postoperative external standing body height was measured.

Clinical outcome assessments were performed at every visit, whereby each patient reported their pain status (Visual Analogue Scale) and completed the Scoliosis Research Society questionnaire version 30 (SRS-30). The SRS-30 was a validated outcomes tool, commonly utilized for repeated outcome assessments, that consisted of 30 questions addressing the following domains: function/activity, pain, self image/appearance, mental health and satisfaction with management.<sup>26</sup> The score from each domain ranged from 1 to 5,

with a higher score representing a better outcome. In addition, intra- and postoperative complications were noted for each patient.

### ***Statistical Analysis***

Frequency and descriptive analysis was performed for all the data. Means and standard deviations ( $\pm$  SD) were assessed for the overall distraction and clinical outcomes.

### ***Role of Funding Source***

Our study was funded by Ellipse Technologies Incorporated who provided the funding for the purchase of the MCGR and costs imposed by Clinical Trials Centre of the University of Hong Kong. Ellipse Technologies Incorporated was not involved in any of the surgical procedures, distractions, data collection, analysis or interpretation of the results, writing or editing of the manuscript, or the decision to submit the study for publication.

## RESULTS

### *Patient Demographics*

Two female patients with 24 months minimum follow-up are reported. The time between the index surgery and subsequent distractions was approximately one month. At the time of surgery, patient 1 was five years and eight months old and was diagnosed as having scoliosis secondary to Ehlers-Danlos syndrome. Patient 1 (**Figure 3**) had a single MCGR implanted because of her small size. Patient 1's immediate preoperative body height was 111.6 cm and the body height at the 2 years follow-up was 125 cm. Patient 1's immediate preoperative arm span was 100.4 cm and the arm span at 2 years follow-up was 109.5 cm. Patient 2 had juvenile onset idiopathic scoliosis and was 12 years and one month old. This patient was grossly skeletally immature, exhibiting delayed-onset of puberty similar to a 10-year-old. She was premenarchal and had open triradiate cartilage on all physis of the hand. Patient 2 had dual MCGR implanted (**Figure 4**). Patient 2's immediate preoperative body height was 130 cm and the body height at the 2 years follow-up was 142.7 cm. Patient 2's immediate preoperative arm span was 130 cm and the arm span at 2 years follow-up was 143 cm.

Three other patients underwent this procedure during the study period but with less than

24 months of follow-up. Patient 3 had syndromic type of scoliosis. He was 12 years and 3 months old at surgery with dual MCGR implanted, and had 22 months of follow-up. Patient 4 had congenital scoliosis and she was 10 years, and 8 months old at surgery. She had dual MCGR implanted and had 16 months of follow-up. Patient 5 had neurofibromatosis. He was 14 years and 9 months old at surgery and had dual MCGR implanted, and had 9 months of follow-up.

### ***Curve Deformity Correction***

Both patients showed significant improvement in their scoliosis curve magnitude with the surgery. The scoliosis curve magnitude was measured using the Cobb's angle. For scoliosis curve measurements, a Cobb's angle of zero degrees would indicate a straight spine, but as the angle increased this would indicate a more severe curvature. In patient 1, the preoperative Cobb's angle was 74° from T9-L5. The immediate postoperative and latest follow-up Cobb's angles were 19° and 26°, respectively. In patient 2, the preoperative Cobb's angle was 60° from T5-T11. The immediate and latest follow-up Cobb's angles were 31° and 31°, respectively (**Figure 5 and Table 1**).

In patient 3, the preoperative Cobb's angle was 41° from T1-T5. The immediate and latest follow-up Cobb's angles were 36° and 32°, respectively. In patient 4, the preoperative

Cobb's angle was 60° from T4-T10. The immediate and latest follow-up Cobb's angles were 27° and 30°, respectively. In patient 5, the preoperative Cobb's angle was 56° from T2-T6. The immediate and latest follow-up Cobb's angles were 30° and 30°, respectively.

### ***Spinal Growth and Lengthening***

There was a consistent gain in instrumented segment length with each distraction, and no reduction in the rate of length gained with subsequent distractions (**Figure 6**). The mean monthly increase in T1-T12 and T1-S1 in both the single and dual MCGR patients was found to be more than the predicted spinal growth according to published growth charts.<sup>8</sup>

### ***Predicted Versus Actual Rod Distraction***

At a minimum 24 months of follow-up, there was no decrease in the length gain per distraction. For patient 1 with the single MCGR, there was one event of loss of distraction, which occurred during the fourth distraction. However, there was no loss of distraction length with subsequent distraction visits. The overall mean predicted distraction length was 2.3mm ( $\pm$ SD=1.2mm) for the single MCGR patient, and 2.0mm ( $\pm$ SD=0.2mm) and 2.1mm ( $\pm$ SD=0.7mm) for patient 2 with the right and left dual MCGR, respectively. The achieved length per distraction was 1.4mm ( $\pm$ SD=0.7mm) for the single MCGR patient, and 1.9mm

( $\pm$ SD=0.6mm) and 1.7mm ( $\pm$ SD=0.8mm), respectively, for the right and left dual MCGR patient. The overall mean achieved instrumented segment length gain per distraction was 1.9mm ( $\pm$  SD=0.4mm). These results demonstrate that the majority of increase in the MCGR length is translated into increase in length of the spine and therefore patient height

### ***Clinical Outcome Assessment***

The VAS pain score for both patients was 0 preoperatively and in all stages of follow-up. The mean SRS-30 score was well maintained throughout follow-up (**Table 2**). Both patients were satisfied with their medical management, had excellent function/activity, self image/appearance, and mental health scores.

### ***Complications***

There were no intraoperative complications. Postoperatively, patient 1 had a superficial wound infection that was controlled by antibiotics and regular dressing. Forty-three distractions were performed in total and there was only one event of loss of distraction. This event occurred after the fourth distraction and in the patient with a single MCGR. The post-distraction radiograph of the fourth distraction showed good rod length gain, but loss of correction occurred gradually over the subsequent month. Such loss of correction was found

to be related to the excessive bending moment on the single rod, leading to slippage of the magnetic mechanism, and was eliminated with the addition of a retainer magnet, and in subsequent cases a change in the rod design. Since then, there has been no further loss of distraction. There were no complications of neurological deficit, prominent or broken implant.

## **DISCUSSION**

We report the use of a MCGR for the treatment of severe scoliosis in young children. At 24 months of follow-up, preliminary clinical results with the MCGR have produced substantial evidence and health-care benefits supporting its role as an alternative to the traditional GR surgery. The MCGR was able to correct the spinal deformity as well as facilitate normal spinal growth with distraction methods in a “non-invasive out-patient” basis. Furthermore, both patients reported no pain on follow-up and their clinical outcome assessment was positive. In addition, there were no MCGR-related complications throughout the follow-up period. Shorter follow-up (i.e. less than 24 months) of the other 3 patients showed similar outcomes to the first two patients who were followed for 24 months or greater. Overall, our initial clinical experience utilising the MCGR has proved to be safe and effective in correcting the spinal deformity and maintaining this correction in children.

Traditional GR surgery has been shown to be an effective surgical treatment for severe scoliosis in young children.<sup>12, 13, 15, 17</sup> This operative technique has allowed for spinal growth while preventing curve progression. However, manual rod distraction has required repeated, albeit infrequent, invasive procedures under general anaesthesia.<sup>12, 13, 27</sup> Not only does this affect a child's daily function with repeated admissions to hospital and open surgery, but this also leads to an increased rate of anaesthetic and wound complications.<sup>3, 27</sup> In one multi-centre study, the overall wound complication rate was 16% and was found to be increased by 24% for each additional surgical procedure.<sup>3</sup> There is, therefore, a possible advantage for less invasive technology and methodologies.

Throughout the years, numerous reports in the literature have surfaced describing the optimal interval of rod lengthening procedures. Yilmaz *et al*<sup>28</sup> showed that distraction at one month intervals led to more body height percentage increase in a porcine model. Animal-based studies have also noted that intermittent distraction can stimulate vertebral growth.<sup>28, 29</sup> In human studies utilising traditional GR, gains in spinal length depended on frequent lengthening procedures and were most effective when performed at intervals of six months or less.<sup>12</sup> Noting the safety and efficacy of the MCGR technology in animal studies,<sup>22,</sup><sup>23</sup> human applications were performed. Our study in humans has noted that MCGR allowed remote distraction on an out-patient basis without the need for sedation or anaesthesia;

therefore, rods could be distracted at much more frequent time intervals and mimicked normal spine growth better than the traditional GR technology.

For spinal growth, we found that there was a consistent gain in T1-T12, T1-S1 and instrumented segment lengths with each distraction. The mean monthly increase in T1-T12 and in T1-S1 matched or even exceeded the predicted monthly spinal growth in 5-10 year olds.<sup>8</sup> A similar comparison could also be made with traditional GR surgery.<sup>13</sup> In terms of the rod construct, there was consistent gain in instrumented segment length with each distraction.

There have been reports of decreasing gain in spinal length achieved from repeated lengthening of the traditional GR.<sup>27,30</sup> Sankar *et al*<sup>27</sup> proposed a "law of diminishing returns" whereby the average T1-S1 gain from a given surgical lengthening decreased significantly with repeated lengthening. Failure to recognize this and forcing distraction beyond what the spinal column could tolerate would result in implant failure, if not spinal trauma. A possible explanation for this phenomenon could be progressive stiffness of the immature spine that developed from prolonged instrumentation or even "autofusion" of the spinal segments spanned by the traditional GR.<sup>27</sup> Such spontaneous fusion of the instrumented segments may result from trauma to the spinal ligaments from sudden and forceful distractions at such infrequent intervals while more regular and smaller distractions using the MCGR may avoid such problems. In the serial lengthening of our patients, we found good correlation between

the predicted versus actual distraction lengths, and no difficulty with distraction on a monthly interval up to the longest follow-up of 24 months.

In our series, there were no major rod or wound complications, and the objective clinical outcome assessments were excellent as shown by the pain and SRS-30 scores. This was an especially significant result, as these patients would require more frequent follow-up with out-patient distractions at closer intervals. In essence, there was no objective evidence that patients had any problems or complaints with the use of MCGR. This would be in significant contrast with traditional techniques whereby the patient would need to be admitted and have the wound reopened under general anaesthesia for the distraction procedures.

With the current indications, a definitive spinal fusion procedure is still required at skeletal maturity for these patients with MCGR. However, with remote and non-invasive distractions, there is the potential to treat earlier and milder cases of scoliosis using this as an internal brace and thus avoiding the need for spinal fusion. Such an approach would be similar to the external bracing treatment for many patients.

In today's environment, any innovative treatment option must also address its economical viability. In comparison to the traditional GR technology, the MCGR provides a substantial decrease in health-care costs. Although the MCGR instrumentation costs more (HK\$50,000, US\$6,451) than traditional GR (HK\$25,000, US\$3,225), the traditional GR

procedure is associated with frequent surgeries (twice per year until skeletal maturity), spinal cord monitoring, use of general anaesthesia, hospitalisation, drug use, manpower, consumables, time off of work for the parent, etc. Alternatively, since we hope to achieve a more physiologic growth in patients with the MCGR, they are required to come to the hospital once a month for a non-invasive, out-patient distraction with a duration of less than 10 minutes, including physician consultation. With growing experience with the MCGR and proper training, “home-based” distractions may be possible in the future.

The main limitation using the MCGR was the increased radiation exposure with frequent radiographs. This problem would likely be solved when the relationship between predicted and actual rod distraction lengths is better understood. At that stage, it would not be necessary to obtain repeated radiographs pre- and post-distraction to confirm the length of obtained rod distraction. In fact, routine radiographs can be taken every six months to document the truncal growth and alignment change as is the case for the current follow-up protocol for the traditional GR. This point could be further addressed with a longer follow-up.

Treatment of scoliosis in growing children is a challenge for both surgeons and families. It is a long-term commitment for both parties and obliges the surgeon to carefully select their patients. The families should be aware of the efforts required to be involved in this type of treatment, the potential risks and benefits, and the possible complications. From our

preliminary clinical findings, the MCGR appeared to match -- if not exceed -- the traditional GR<sup>13</sup> in its ability to maintain growth rate over time. Yet, it is definitely much less traumatic to young patients because they do not have to bear the peri-operative psychological burden or the pain associated with repeated operations. Currently, we have performed MCGR surgery on five patients in total. The other three patients have shown a VAS pain score of 0 and similar clinical and radiological outcomes as the two patients described in this report with no rod or wound complications (**web-based - Figures 7-9 and Tables 3-7**). Longer-term follow-up results are underway to further validate our current findings and trends.

Overall, there is no consensus on whether a single or dual rod should be used for a particular patient. In general, a dual rod construct would provide better stability, and therefore reduce likelihood of implant fracture.<sup>31</sup> However, as the implants are placed superficially, dual rods may be bulky and be palpable or cause discomfort under the skin. For these reasons, single rods may be preferable in thin or small individuals.

Given the advantages of the MCGR distraction system for correction of spine deformity, such technology has potential widespread applications in medicine. For example, the MCGR can have application within limb deformity correction, thoracic insufficiency syndrome, limb lengthening, limb salvage procedures or any conditions in which slow progressive change is required.

## **CONCLUSIONS**

This is the first published report using the MCGR for the treatment of severe scoliosis in young children. Based on our initial experience with substantial follow-up, we have found the MCGR to be effective and safe for the treatment of such spinal deformity providing such benefits in a non-invasive, out-patient manner in comparison to traditional methods. It is likely that this is associated with considerable decrease in health-care costs, and improvement in health-care delivery and patient quality of life. Additional, prospective large-scale studies are underway to further validate the initial findings of this study and to assess other parameters of this technology. Nonetheless, it is without question that the development of the MCGR is a tremendous progressive advancement in the treatment of young children with scoliosis and a significant "breakthrough" in medical technology with global applications.

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## **AUTHORS AND CONTRIBUTORS**

Kenneth Man-Chee Cheung was responsible for the surgery, conception and study design, out-patient distractions, data interpretation, and editing the final manuscript. Jason Pui-Yin Cheung was responsible for the literature search, data collection and analysis, data interpretation, surgery and writing of the manuscript. Dino Samartzis was responsible for the, literature search, study design, interpretation of the findings, and writing the manuscript. Kin-Cheung Mak was responsible for the data collection, interpretation of the findings, the surgery, and writing the manuscript. Yat-Wa Wong, Wai-Yuen Cheung and Keith Dip-Kei Luk were responsible for interpretation of the findings, surgery, and editing the final manuscript. Behrooz A. Akbarnia was responsible for conception, multi-centre study design, coordinating the multi-centre trial, participation in the first surgical procedure and editorial comments of the final manuscript.

## **CONFLICT OF INTEREST**

Kenneth Man-Chee Cheung received grant/research support from Ellipse Technologies Incorporated and is a consultant for the company. Behrooz Akbarnia received grant/research support from Ellipse Technologies Incorporated, and is a consultant and stock/shareholder for the company.

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## FIGURE LEGENDS

**Figure 1:** The single magnetically controlled growing rod fixed to a spine model (cervical vertebra at top of figure, sacrum at bottom of figure). The enlarged portion housing the distraction mechanism is indicated by the red arrow.

**Figure 2:** Spinal length measurement. **(A)** T1-T12 is measured from the center of the upper endplate of the T1 vertebrae to the center of the lower endplate of the T12 vertebrae. T1-S1 is measured from the center of the upper endplate of the T1 vertebrae to the center of the upper endplate of the S1 vertebrae. **(B)** Instrumented segment is measured from the center of the upper endplate of the most cranial instrumented vertebrae to the center of the lower endplate of the most caudal instrumented vertebrae.

**Figure 3:** Patient 1 with a single magnetically controlled growing rod. **(A,B)** Pre-operative, **(C,D)** immediate post-operative, and **(E, F)** at latest follow-up.

**Figure 4:** Patient 2 with dual magnetically controlled growing rod. **(A,B)** Pre-operative, **(C,D)** immediate post-operative, and **(E, F)** at latest follow-up.

**Figure 5:** Change in magnitude of coronal spinal deformity.

**Figure 6:** Spinal length gain for instrumented deformity segment.

### Extra Web-Based Figures

**Figure 7:** The magnetically controlled growing rod device. The magnetic external remote controller is used for out-patient distractions.

**Figure 8:** Mean change in magnitude of coronal spinal deformity for patients 3, 4 and 5.

**Figure 9:** Predicted versus actual rod distraction lengths in patients who received the magnetically controlled growing rod. (A) Patient 3; (B) Patient 4; (C) Patient 5.

MCGR= magnetically controlled growing rod

\* Note: Patient 3 had a conversion from the traditional growing rod to the MCGR.