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Frequent small distractions with a magnetically controlled growing rod for early-onset scoliosis and avoidance of the law of diminishing returns

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ABSTRACT

Purpose. To assess the effect of frequent small distractions with a magnetically controlled growing rod (MCGR) on spinal length gain and achieved distraction length in children with early-onset scoliosis (EOS), and to determine whether the law of diminishing returns applies to this group of patients with MCGR.
Methods. A consecutive series of 3 males and 4 females with EOS who underwent MCGR implantation at a mean age of 10.2 years and were followed up for a mean of 3.8 years were reviewed. Distraction was aimed at 2 mm monthly. The coronal Cobb angle, T1-S1 length gain, and achieved distraction length were measured at 6-monthly intervals.
Results. The mean total number of distractions was 31. Four of the patients had problems that may have affected distractions. The mean coronal Cobb angle improved post-operatively and was maintained throughout the follow-up period. The mean T1-S1 length gain and achieved distraction length varied over the follow-up period and did not diminish with repeated lengthening.
Conclusions. Frequent small distractions with the MCGR for EOS enable T1-S1 and achieved distraction length gain without significant reduction in gain after repeated lengthening.

Key words: *magnetics; scoliosis; spine; surgery*

INTRODUCTION

The traditional growing rod (TGR) has been the mainstay surgical treatment for gradual correction of scoliosis in young children while allowing for spinal growth,[1–4] but it requires repeat distraction every 6 months via open surgery under general anaesthesia.[1,2,5] A patient with early-onset scoliosis (EOS) who undergoes TGR treatment at the age of 5 years, with predicted skeletal maturity at 13 years, may require up to 16 distraction procedures. This is a huge burden for both the child and family and increases the risk of anaesthetic and wound complications.[5–7] The overall wound complication rate has been reported

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to be 16% and increases by 24% for each additional surgical procedure.[7] In addition, repeat anaesthesia may adversely affect neurodevelopment in children.[8]

The mean gain in spinal length with the TGR decreases with each subsequent distraction and can occur as early as the first successive lengthening.[5,9] This is known as the law of diminishing returns.[5] Failure to recognise this and forcing distraction beyond the threshold that the spine can tolerate may result in implant failure and spinal injury. Proposed rationales for this phenomenon include progressive stiffness of the immature spine caused by prolonged *in situ* instrumentation or autofusion of the spinal segments.[5] Spontaneous fusion may also result from trauma to the spinal ligaments secondary to sudden and forceful distractions at infrequent intervals.

The magnetically controlled growing rod (MCGR) uses an external magnet to drive an internal distraction device and enables distraction under neurological monitoring in an outpatient setting.[10] The MCGR can be retracted if any pain occurs during the procedure. The MCGR has similar corrective power to the TGR, improved clinical outcome scores,[11–14] avoids the costs associated with the TGR,[15] and provides safe gradual correction of severe deformities.[16] Frequent small distractions are more gentle on the soft tissues and may avoid progressive stiffness or autofusion of the spinal segments. Hence, the aim of this study is to assess the effect of frequent small distractions with the MCGR on spinal length gain and achieved distraction length in children with EOS, as well as its effect on spine length and growth.

MATERIALS AND METHODS

This study was approved by the institutional review board. Between November 2009 and October 2012, a consecutive series of 3 males and 4 females were diagnosed with EOS at a mean age of 3.4 (standard deviation [SD], 2.0) years and underwent MCGR implantation (2 with a single rod owing to a small body size and 5 with dual rods) at a mean age of 10.2 (SD, 3.8) years (before skeletal maturity) and followed up for a minimum of 2 years. The diagnoses included Ehlers-Danlos syndrome (n=1), CHARGE syndrome (n=1), Noonan syndrome (n=1), congenital scoliosis (n=1), neurofibromatosis (n=2), and juvenile idiopathic scoliosis (n=1).

The MCGR was implanted as previously described.[13] Two sets of hooks or screws were used as fixation anchors at the upper and lower instrumented vertebrae that were fused with local bone grafts. The instrumented level was determined by pre-operative standing radiographs and fulcrum-bending radiographs.[17–19] No intra-operative distraction was performed to prevent any loading that might increase the internal soft tissue stiffness and reduce the amount of post-operative distractions. Any correction was performed intra-operatively under general anaesthesia with the patient in a prone position. At outpatient clinics, all concave rods were distracted first and length gain was aimed at 2 mm monthly.

Anteroposterior standing radiographs were taken pre- and post-operatively and 6-monthly thereafter. Parameters including coronal Cobb angle,

Table
Patient characteristics

Diagnosis	Sex	Age at implantation (years)	Rod implanted	Upper to lower instrumented vertebra	No. of distractions	Follow-up (months)	Problems that may have affected distractions
Ehlers-Danlos Syndrome	F	5.6	Single	T3/4 to L3/4	41	62	Conversion from single rod to dual rod at 3 years
CHARGE Syndrome	M	12.2	Dual	T3/4 to T12/L1	31	59	Conversion from traditional growing rod to magnetically controlled growing rod; stopped distractions on the convex rod at ~2 years for gradual curve correction
Congenital scoliosis	F	10.5	Dual	T3/4 to T12/L1	44	53	-
Neurofibromatosis	M	14.6	Dual	T1/2 to T12/L1	19	44	-
Juvenile idiopathic scoliosis	F	9.2	Dual	T3/4 to T12/L1	31	38	Concave rod removed at 9 months owing to dysfunction; convex rod slippage at 15 months
Noonan syndrome	F	14.7	Single	T1/2 to T10/11	41	37	Slippage of the rod at the end of each distraction starting at 3 months
Neurofibromatosis	M	4.8	Dual	T2/3 to L2/3	10	27	-

T1-S1 length gain, and achieved distraction length (measurement of the housing unit length) were measured by an independent assessor using the Centricity Enterprise Web V3.0 (GE Medical Systems). Measurements were calibrated and corrected for magnification using the diameter of the housing unit (9.02 mm) of the MCGR.[13,20] The T1-S1 length gain and achieved distraction length were calculated as the difference between 2 consecutive measurements. T1-S1 was measured from the upper endplate of T1 to the top of the sacrum. The achieved distraction length was measured on the housing unit length of the concave or convex rod.

Any implant complications or slippage of the distraction mechanism were recorded. The slippage was identified by a 'clunking' sound or feeling during distractions. Clunking may occur when the internal tissue stiffness is greater than the force generated by the internal motor resulting in an inability to rotate the internal magnet a full turn to generate distraction force.

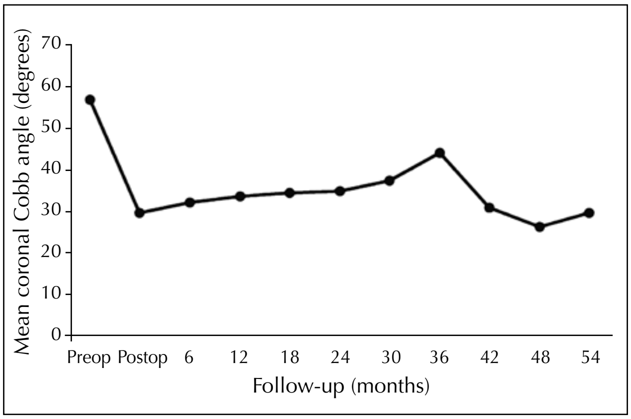

Figure 1 The mean coronal Cobb angle in patients with early-onset scoliosis treated with the magnetically controlled growing rod.

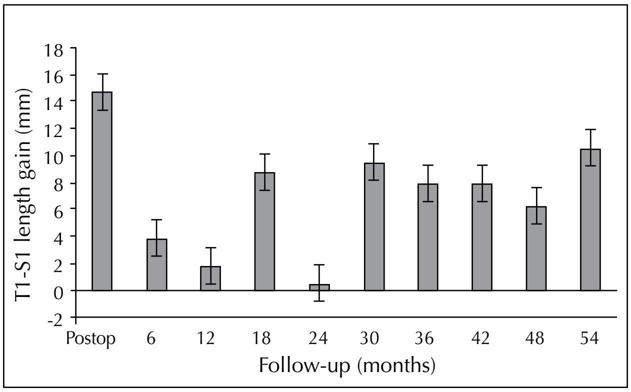

Figure 2 Means and standard errors of T1-S1 length gain in patients with early-onset scoliosis treated with the magnetically controlled growing rod.

RESULTS

The mean follow-up period was 3.8 (SD, 1.1) years and the mean total number of distractions was 31 (SD, 13). Four of the patients had problems that may have affected distractions (Table). The mean coronal Cobb angle improved from 56.9° (SD, 10.9°) pre-operatively to 29.8° (SD, 6.3°) post-operatively and was maintained throughout the follow-up period (Fig. 1). The mean T1-S1 length gain and achieved distraction length varied over the follow-up period but did not diminish with repeated lengthening (Figs. 2 and 3). The mean T1-S1 length gain was 3.9 (SD, 3.7) mm during the first 6 months and 10.6 (SD, 2.7) mm during the ninth 6 months. The mean achieved distraction length was 8 (SD, 3.8) mm for the convex rod and 5.2 (SD, 4.0) mm for the concave rod during the first 6 months, and 5.3 (SD, 6.3) mm and 7 (SD, 8.8) mm, respectively, during the ninth 6 months.

DISCUSSION

Prior to growing rod technology, spinal bracing or fusion had been advocated for treatment of EOS.[21–24]

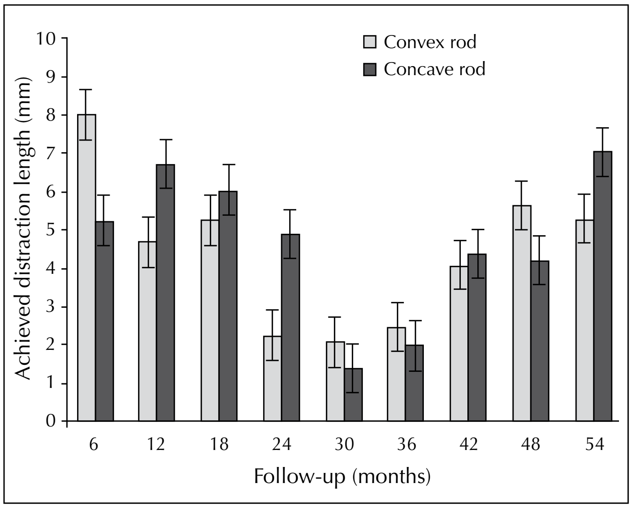

Figure 3 Means and standard errors of achieved distraction length in patients with early-onset scoliosis treated with the magnetically controlled growing rod.

The TGR was developed to address the limitations of spinal bracing or fusion.[1,2,25] With the TGR, open surgical distraction is recommended every 6 months to correct the spinal deformity and facilitate spine growth.[1–4,24,26,27] However, TGR is associated with limitations of repeat surgery under general anaesthesia[6,7] and the law of diminishing returns[5] caused by autofusion of the spine due to prolonged immobilisation by a rigid device or trauma to spinal ligaments.

The optimal interval for the distraction procedure remains debatable. In an animal model, distraction at monthly intervals led to a higher percentage gain in body height.[28] Others also suggest that intermittent distraction can stimulate vertebral growth.[28,29] In patients with TGR, spinal length gain is most effective when distraction is at intervals of ≤6 months, which balances the spinal length gain and the anaesthetic and surgical risk.[1] The MCGR enables distraction in an outpatient setting and eliminates the need for open surgery. Hence, distraction can be more frequent and even mimic normal physiological growth.

Sankar et al.[5] have suggested that during multiple lengthening procedures with the TGR, limited intra-operative distraction is obtained and the effectiveness of lengthening diminishes over time with regard to spinal length gain. They also have suggested that initial instrumentation should be delayed and lengthening should be limited when gains are minimal.[5] This is undesirable because spinal deformities should be controlled while maintaining spinal growth. In our patients with MCGR, there was no significant reduction in T1-S1 length gain over the study period. Comparable to Sankar et al.,[5] our study assessed T1-S1 length gain in patients with EOS and showed that the MCGR had consistent length gains at 6-monthly intervals which is absent with the TGR. Both studies included patients with at least 2 years of follow-up. Our study had a mean follow-up of 3.8 years as compared to 3.3 years in the TGR study.[5] In our study, the mean T1-S1 length gain was 3.9 mm from the first 6 months and 10.6 mm from the ninth 6 month assessment. In the TGR study, the T1-S1 length gain at the latest follow-up was less than half of that at the first follow-up.[5] This suggests that frequent small distractions with the MCGR are less likely to result in reduction of length gain over time as seen in TGR patients.

Nonetheless, the T1-S1 length gain is not most representative for explaining diminishing returns, because the instrumented segment does not involve the entire spine or represent the normal spinal growth potential. In addition, spinal length can also be affected by other parameters such as curve deterioration. Fortunately, in our patients, the coronal Cobb angle correction was well-maintained throughout the study period. The authors believe that the achieved distraction length gain is more representative of increasing stiffness of the spine. Previous concerns for using the achieved distraction length for the TGR are valid due to anchor migration and difficulties in finding a reliable point for measurements.[5] However, as the MCGR distracts, an easily recognisable section of the rod can be observed on plain radiographs, and the amount of distraction can be directly measured. As evidenced in our series, the concave and convex rods did not expand symmetrically despite the planned 2-mm distraction. Reasons for this may be multifactorial including distraction of the concave rod first, rate of rod slippage, and curve flexibility. Nevertheless, the consistent length gain obtained suggests that the law of diminishing returns did not apply to our patients.

Sankar et al.[5] did not mention whether the age presented in their study was the age at implantation or diagnosis. We can only assume that there may be a difference in the mean age of implantation in our patients and theirs (10.2 vs. 5.7 years). There may be issues with differences in growth rates which may be highest nearer to puberty. Nevertheless, the aim of our study was to assess any reduction in the amount of distraction obtained rather than the absolute magnitude of distraction length. The magnitude of each TGR distraction is likely larger as the rod is distracted to its limit during each surgery. However, this does not mimic normal spinal growth, compared to what the MCGR can provide with smaller increments per distraction. Thus, despite the greater soft tissue stiffness in older patients in our study, smaller intervals and less forceful distractions allow more consistent length gain.

It is important to note that there were some reductions in spinal length gain at occasional timepoints during the early distraction period in our patients with the MCGR. Likely causes for early difficulties to distract may include slippage of the distraction mechanism and changes in the rod systems. Rod exchanges, if any, usually occur near the 2-year post-operative mark when the rods have already been distracted up to 48 mm, which is the maximum distractable length obtainable by the rod's housing unit.

Slippage or a 'clunking' sound and feeling during distraction may occur when the internal tissue stiffness is larger than the distraction forces. This may be related to reductions in distraction forces due to the longer distance between the external and internal magnets, patient positioning, abnormal rod bending forces, and tissue stiffness. The significance of slippage is still unknown, as there is constant length gain in these patients. Further discussions regarding its causes and risk factors are beyond the scope of this study.

There were some special circumstances where rod change may have affected the achieved distraction length. In the patient with Ehlers-Danlos syndrome, she had revision to a dual rod construct 3 years after the index implantation after the maximum (48 mm) rod distraction had been achieved and she was of appropriate size for dual rod implantation. Dual rod systems have been shown to gain more distraction length than single rod systems.[1,13] Thus, the difference in early and late distraction length gains may be related to the number of rods implanted. In the patient with CHARGE syndrome, he had a conversion from TGR to MCGR after 3.5 years and 4 open distractions. These infrequent open distractions with the TGR may have contributed to soft tissue stiffness limiting distraction outcomes. In the patient with juvenile idiopathic scoliosis and dual rod implantation, she had a non-functioning concave rod which was removed 8 months after implantation. This patient's remaining convex rod and the single rod in the patient with Noonan syndrome both had suspected difficulties in rod distractions due to multiple rod slippage.

Limitations of this study include its small sample size and variation in EOS aetiology. Longitudinal follow-up will be interesting to see whether there is a 'breaking point' in which the rod's internal distraction forces can no longer overcome the external forces. A larger-scale study with more patients is required to demonstrate this. Also, the effect of 3- or 6-monthly distraction intervals is not known. Reduced length gain may have occurred if the MCGR was not distracted as frequently, as prolonged immobilisation may have induced spinal stiffness. Further understanding of differential correction and distraction length is also important. All patients had an expected distraction length of 2 mm to mimic normal spine growth. However, in patients with shoulder imbalance, one rod may have been distracted more than the other for correction. Furthermore, the response to rod slippage with different distraction lengths requires further analysis. Studies directly comparing the TGR and MCGR are required to draw conclusions regarding the distraction length and other clinical parameters such as balance and rib hump correction, which are equally important as growth gain.

CONCLUSION

Frequent small distractions with the MCGR for EOS enable T1-S1 and achieved distraction length gain without significant reduction in gain after repeated lengthening. The law of diminishing returns is hence not observed in this group of patients. This study further supports the role of MCGR in the treatment of patients with EOS and serves to focus attention on the distraction frequency and its potential effect on spine length and growth.

DISCLOSURE

Kenneth Man Chee Cheung is a consultant for Ellipse Technologies.

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