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ORIGINAL ARTICLE

Early experience of MAGEC magnetic growing rods in the treatment of early onset scoliosis

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Abstract
Purpose Magnetically controlled growing rod systems have been introduced over recent years as an alternative to traditional growing rods for management of early onset scoliosis. The purpose of this paper is to report our early experience of a magnetically controlled growing rod system (MAGEC, Ellipse).
Methods Review of pre-operative, postoperative and follow-up Cobb angles and spinal growth in case series of eight patients with a minimum 23 months' follow-up (23–36 months).
Results A total of six patients had dual rod constructs implanted and two patients received single-rod constructs. Four patients had MAGEC rods as a primary procedure. Four were revisions from other systems. Mean age at surgery in the primary group was 4.5 years (range 3.9–6.9). In patients who had MAGEC as a primary procedure, mean pre-operative Cobb angle was 74° (63–94), with postoperative Cobb angle of 42° (32–56) $p \leq 0.001$ (43 % correction). Mean Cobb angle at follow-up was 42° (35–50). Spinal growth rate was 6 mm/year. One sustained proximal screw pull out. A final patient sustained a rod fracture. Mean age at surgery in the revision group was 10.9 years (range 9–12.6). Mean pre-operative Cobb angle was 45° (34–69). Postoperative Cobb angle was 42° (33–63) (2 % correction). Mean Cobb angle at follow-up was 44° (28–67). Mean spinal growth rate was 12 mm/year. Two patients developed loss of distraction.
Conclusion MAGEC growing rod system effectively controls early onset scoliosis when used as either a primary or revision procedure. Although implant-related complications are not uncommon, the avoidance of multiple surgeries following implantation is beneficial compared with traditional growing rod systems.

Keywords Early onset scoliosis · Magnetic rod · Growing rod · MCGR

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Introduction

Early onset scoliosis presents at birth and up to 7 years of age. Growing rods are a treatment option when early onset scoliosis cannot be controlled by serial casts or braces. The aim of this treatment is to achieve control of the scoliosis whilst allowing a child's spine to continue to grow until a definitive correction can be made when the patient nears skeletal maturity usually after the age of 11–13 years of age [2]. Fusion procedures in this age group adversely affect spinal growth and pulmonary alveolar development, leading to development of possible thoracic insufficiency. One of the major disadvantages of traditional growing rod systems is the requirement for multiple surgical procedures to lengthen the rods as the patient grows [13]. Considering that rod lengthening is performed approximately every 6 months, it is not uncommon for a child to require as many as 15 operations during their growing rod treatment [4]. In addition to the surgical morbidity and cost associated with this treatment, the child and family must take significant time off school and work, which can be associated with poor psychological outcome [5, 10, 11]. With technological advances over recent years, magnetically controlled growing rod systems (MCGR) have been developed to address the drawbacks of traditional systems, allowing lengthening procedures to be performed in the outpatient clinic under the control of an externally applied magnet remote control device. Recently, this technology has been reported to be safe and effective at short-term follow-up [3, 7, 8]. Our aim is to report our early experience of a magnetically controlled growing rod system (MAGEC, Ellipse).

Methods

We present a series of eight patients who had insertion of magnetic controlled growth rods (MAGEC, Ellipse) for management of their early onset scoliosis with a minimum of 23 months' follow-up (23–36 months). Each patient was reviewed in clinic as part of their planned treatment protocol. Preoperative, immediate postoperative and most recent spine radiographs were reviewed to determine the degree of spinal deformity and correction, measured using Cobb angle [6]. T1–S1 length was calculated. Spinal growth rates were then calculated based on the T1–S1 increase in length between initial postoperative and final follow-up radiographs. Clinical notes were reviewed to determine number of rod lengthening procedures performed in clinic using remote control device and to record any complications during surgery or the follow-up period. Number of postoperative radiographs per year during follow-up was also determined.

Surgical procedure and follow-up protocol

The magnetically controlled growth rod (MCGR) consists of a single-use sterile titanium spinal distractible rod with an enlarged mid-portion containing a magnetically drivable lengthening mechanism. The choice of implantation of either a single or a dual rod was dependent on the patient's size and the surgeon's preference. In the first case only one rod was implanted as the other rod broke while contouring although it was contoured well away from the magnetic cylinder. This was returned back to the manufacturers for analysis.

The size of the rod was customised according to the patient's height. For insertion of MCGR under general anaesthesia, patients were positioned prone. All procedures were performed through a standard open posterior midline approach, i.e. proximally and distally to implant pedicle screws/hooks and the MAGEC rod was railroaded subcutaneously to connect to the proximal and distal anchorages. After surgery, patients were followed up in clinic for 6 weeks. In clinic, the MAGEC rods were distracted as much as the ERC would allow within the patients' comfort. The optimum protocol for frequency of rod extensions, amount of rod lengthening and role of postextension radiographs has not yet been determined, therefore this was decided on an individual patient basis. During outpatient distraction visits, patients were positioned prone. The internal rod magnets were identified using a hand-held magnet and the skin was marked with a skin marker. A hand-held magnetic external remote controller (ERC) was placed over the internal magnet. Once the magnetic field was applied, the rotating mechanism within the rod causes the rod to lengthen, thus distracting the spine.

Statistical analysis

Pre-operative and postoperative Cobb angles and T1–S1 lengths were evaluated using paired t test, SPSS v20 software (IBM, Armonk, New York).

Results

The majority of patients were males ($n = 6$). A total of six patients had dual-rod constructs implanted and two patients received single rod-constructs. Four patients had MAGEC rod insertion as a primary procedure. Four were used as revisions from other growing rod systems. Mean age of patient at surgery in the primary group was 4.5 years (range 3.9–6.9). Mean age of patient at surgery in the revision group was 10.9 years (range 9–12.6). Mean follow-up was 28 months (range 23–36). Six patients had idiopathic curves, one was syndromic and one was congenital. Patients had rod extensions in clinic every 6–8 weeks. Scoliograms were performed on average 11 times per year (8–17).

Patients who had MAGEC as a primary procedure

Mean pre-operative Cobb angle was 74° (63–94), with immediate postoperative Cobb angle of 42° (32–56) $p \leq 0.001$ (43 % correction). Mean Cobb angle at most recent follow-up was 42° (35–50). Preoperative, postoperative and final follow-up Cobb angles for primary and revision procedures are shown in Table 1. Mean initial percentage lengthening was 27 % (15–33). Two of the four patients experienced a complication (Table 2). Excluding patient 3, who developed a proximal junctional kyphosis, spinal growth rate was 6 mm/year for the rest of the group. Mean T1–S1 length for primary procedures was 215 mm, increasing to 273 mm postoperatively ($p \leq 0.001$) and 286 mm at final follow-up (Table 3).

Table 1 Preoperative, postoperative and final follow-up Cobb angles

	Patient	Age	Cobb angle			
			Preop	Postop	FFU	% Correction
Primary	1	6.9	68	39	44	35.3
Primary	2	2.8	94	56	39	58.5
Primary	3	4.5	63	40	50	20.6
Primary	4	3.9	71	32	35	50.7
Revision	5	12.6	34	34	28	17.6
Revision	6	11.3	38	38	43	−13.2
Revision	7	9.1	37	33	37	0.0
Revision	8	10.6	69	63	67	2.9

Patients who had MAGEC as a revision procedure

Mean pre-operative Cobb angle was 45° (34–69), with immediate postoperative Cobb angle of 42° (33–63) (2 % correction). Mean Cobb angle at most recent follow-up was 44° (28–67) (Table 1). Mean initial percentage lengthening was 8 % [3–10]. Two of the four patients experienced loss of distraction (Table 2). For the other patients, mean spinal growth rate was 12 mm/year. Mean T1–S1 length was 306 mm, increasing to 328 mm postoperatively and mean of 373 mm at final follow-up for patients without complications (Table 3).

Complications

There were two complications in patients who had MAGEC as a primary procedure (Table 2). One patient sustained a fracture of a single-rod construct 6 months post surgery. Another patient had pull out of proximal screws 3 months post insertion. In the patients who had MAGEC as a revision procedure there were two complications. One patient had loss of distraction noted 25 months post surgery, which required retainer magnet to hold distractions. Another patient did not achieve spinal growth as expected, which is likely due to loss of distraction or autofusion.

Discussion

In our consecutive series of patients treated with MAGEC MCGR we found that scoliosis was well controlled. Cobb angle was significantly reduced following surgery in patients who had MAGEC performed as a primary procedure and this was maintained at follow-up. For patients who had MAGEC used as a revision procedure, Cobb angles were maintained at follow-up. There is very little published literature on the use of MAGEC as a revision procedure; however, comparing our results for MAGEC performed as a primary procedure, or results for correction and control are comparable. For example, Dannawi et al. [8] recently reported 32 % improvement in Cobb angle, compared with our initial correction of 43 %. Akbarnia et al. [3] also found a 43 % improvement in Cobb angle following surgery in 14 patients who had MAGEC performed as a primary procedure [3, 8] and Cheung et al. [7] found 57 % correction.

In comparison with the recent literature, T1–S1 initial lengthening was higher in our patients who had MAGEC as a primary procedure. Our mean initial lengthening was 27 %, compared with between 5.4 and 10 % reported by other studies using MAGEC [3, 7, 8]. The mean initial T1–S1 lengthening in our patients who had MAGEC as a revision procedure was 8 %. The mean subsequent annual growth rate in our group of patients was less than anticipated and in comparison with the recent literature. Although there is no consensus in the literature regarding the optimum interval between rod extensions, our aim is to perform regular extensions in clinic to allow spinal growth to occur as naturally as possible. The benefit of this has previously been demonstrated in patients treated with traditional growing rod systems, where patients who underwent rod lengthening more frequently than 6 monthly had significantly greater spinal growth and curve correction compared with those lengthened less frequently [1]. Our practice is to perform distractions in clinic every 6–8 weeks. Excluding patient 3 who developed proximal

Table 2 Spinal growth rates mm/year

	Patient	Age	Spinal growth (mm/year)	Fixation levels	Complications
Primary	1	6.9	7	T2–L3	Fracture of single rod (6 months post surgery)
Primary	2	2.8	8	T3–L4	
Primary	3	4.5	−13	T2–L3	4 proximal screws pullout (3 months post surgery), proximal junctional kyphosis
Primary	4	3.9	2	T2–L5	
Revision	5	12.6	11	T4–L2	
Revision	6	11.3	4	T4–L4	Failure of construct to distract (25 months post surgery)
Revision	7	9.1	−1	T5–L5	Failure of construct to distract
Revision	8	10.6	13	T2–L5	

Table 3 T1–S1 lengths for primary and revision procedures

	Patient	Age	T1–S1 length (mm)				
			Preop	Postop	Initial lengthening	% Initial lengthening	Final follow-up
Primary	1	6.9	236	307	71	30	309
Primary	2	2.8	248	284	36	15	301
Primary	3	4.5	192	256	64	33	235
Primary	4	3.9	186	245	59	32	248
Mean		4.5	215.5	273		27	
Revision	5	12.6	349	376	27	8	395
Revision	6	11.3	291	299	8	3	309
Revision	7	9.1	278	307	29	10	306
Revision	8	10.6	304	332	28	9	351
Mean		10.9	305.5	328.5		8	

junctional kyphosis and the two patients with loss of distraction, we achieved a mean spinal growth of 6 mm/year for primary and 12 mm/year for MAGEC performed as revision (T1–S1). Considering the mean age of patients in our primary procedure group was 4.5 years, we would expect their annual spinal growth to be closer 10 mm/year [9]. Patients who had MAGEC performed as a revision procedure were older (mean age 10.9 years) and their annual spinal growth rate is as expected according to age and also in comparison with patients of similar ages who have had MAGEC rods in other studies [9]. For example, Dannawi et al. [8] recently reported spinal growth rates of 10 mm/year and Cheung et al. [7] reported 15 mm/year.

The obvious benefit of the magnetic growing rod system is that repeat operations to perform rod lengthening are avoided, which is one of the main drawbacks of growing rods [13]. This is particularly useful in patients with high risk of complications from general anaesthesia, such as respiratory tract infection [14]. Considering that the minimum follow-up of patients in our series was 23 months, it is likely that all patients would have required at least three to four further surgeries to lengthen rods if a traditional growing rod system had been used. Importantly, it is well documented that the rate of complications increases in relation to the number of surgical procedures performed. For example, Bess et al. [4] reported that 58 % of 140 patients treated with traditional growing rod systems experienced at least one complication at a mean follow-up of 5 years. The occurrence of a rod fracture in one of our patients was unfortunate (13 %), but it is a known complication of growing rod treatment. As previously reported by Yang et al. [15] it occurs in 15 % of patients treated with traditional growing rods and as we found in our case of fracture it is more likely to occur in ambulant patients with single-rod constructs. In the series by Bess et al. [4], rod fracture occurred in 24 % of patients. Screw pullout occurred in one of our patients. This patient had a preoperative kyphosis and initial correction of coronal and sagittal balance was achieved; however, proximal fixation with screws failed and was revised to a hook construct. Two patients in the revision group experienced loss of distraction, which is a known implant-related complication unique to MCGR. It may be more likely to occur in patients who have MCGR as a revision procedure because in general these patients will have stiffer spines as a result of previous surgery. There were no infections in our series of patients.

The main limitation of the MCGR procedure is potential increased radiation exposure from frequent radiographs. Although radiographic evaluation is important to ensure adequacy of control of scoliosis and also to detect implant-related complications such as loss of distraction [7], it may not be necessary to perform scoliograms after each extension. With further evaluation of magnetic growing rod technology the optimum interval for radiographic evaluation is likely to become apparent. Improving our understanding of the relationship between predicted and actual rod distraction lengths and the significance of partial loss of distraction may result in fewer radiographs being performed. In our own practice we have started using ultrasound to measure rod distraction, which will reduce the number of radiographs required to confirm distraction has occurred.

Conclusion

We have shown that the MAGEC magnetic growing rod system effectively controls the progression of early onset scoliosis when used as either a primary or revision procedure. Although implant-related complications are not uncommon, the avoidance of multiple subsequent surgeries following implantation of magnetic rods is a clear benefit compared with traditional growing rod systems. Our early experience of this device confirms it to be safe and effective in the management of early onset scoliosis. Further study is required to determine the optimum initial correction, rate of distractions and method of monitoring spinal growth.

Conflict of interest None of the authors has any potential conflict of interest.

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