Magnetically-Controlled Growing Rods. Outcomes and Complications

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ABSTRACT

Introduction: Magnetic Expansion Control (MAGEC) Spinal Growing Rods are a novel treatment for early-onset scoliosis (EOS). Although its efficacy is supported by the literature, it is not without complications. Materials and Methods: The aim of this study was to retrospectively analyze a series of 37 cases treated with MAGEC between 2014 to 2019. We performed a retrospective study and divided the population into two groups: GI (primary procedures with MAGEC) and GII (conversions from traditional system to MAGEC). Results: The study included 19 girls and 18 boys with a mean age of 8 years and a variety of etiologies. The average postoperative follow-up time for Group I (n=28) and Group II (n=9) was 3.6 years. The average preoperative angular value (AV) of scoliosis was 64° (39°-101°) and kyphosis 51° (7°-81°). The postoperative scoliosis AV was 41° (17°-80°) and kyphosis 34° (7°-82°). We found 2 rod ruptures and one proximal union kyphosis, two proximal screw loosenings, one MAGEC distraction system failure, and one surgical site infection. Conclusions: Although our preliminary results are short term, they suggest that MAGEC could be an effective method. Keywords: Early onset scoliosis; magnetic controlled growth rods; scoliosis; pediatric spine surgery; spinal deformity. Level of Evidence: IV

Sistema de barras magnéticas. Resultados y complicaciones

RESUMEN

Introducción: El uso de sistema de barras magnéticas para el tratamiento de la escoliosis de comienzo temprano es un método utilizado en los últimos 10 años; su eficacia está respaldada por la bibliografía, pero no está exento de complicaciones. Objetivo: Analizar retrospectivamente una serie de 37 pacientes tratados con barras magnéticas en escoliosis de comienzo temprano. Materiales y Métodos: Se realizó un estudio retrospectivo entre 2014 y 2019. Se dividió a los pacientes en: grupo 1 (procedimientos primarios con barras magnéticas) y grupo 2 (conversiones de sistema tradicional a barras magnéticas). Resultados: Se incluyó a 19 niñas y 18 niños (edad promedio 8 años al operarse), las etiologías fueron variadas. Entre el grupo 1 (n = 28) y el grupo 2 (n = 9), el seguimiento promedio posoperatorio fue de 3.6 años. El valor angular promedio preoperatorio de escoliosis era de 64° (rango 39°-101°) y el de cifosis, de 51° (rango 7°-81°). El valor angular promedio de escoliosis en el posoperatorio inmediato fue de 41° (rango 17°-80°) y el de cifosis, de 34° (rango 7°-82°). Se produjeron 2 roturas de barra y una cifosis de unión proximal, 2 aflojamientos de tornillos proximales, una falla del sistema de distracción de barras magnéticas y una infección del sitio quirúrgico. Conclusiones: Nuestros resultados preliminares, aunque son a corto plazo, sugieren que la barra magnética podría ser un método eficaz en este tipo de enfermedad. Palabras clave: Escoliosis; comienzo temprano; barras de crecimiento controlado magnéticamente; cirugía; columna; deformidad de columna; pediatría. Nivel de Evidencia: IV

INTRODUCTION

Scoliosis in children <10 years of age is defined as early-onset scoliosis (EOS),1,2 and may have a neuromuscular, syndromic, congenital, or idiopathic origin.3 Its natural progression would possibly lead to severe progression of the scoliotic or kyphotic curve and compromise the development of growing organs, most frequently the lungs and heart.4,5 This alteration motivates an early treatment protocol to stop the progression of the deformity and achieve physiological development.6

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Under normal conditions, the physiological development of the thorax and its contents occurs with a variable rate of growth that extends from birth to skeletal maturity. Early spinal fusion surgery results in potential loss of spinal growth. The international literature suggests to avoid it, even more so when it involves the growing thoracic spine, due to the possibility of restriction of the development of the rib cage during the growth of the skeletally immature child. Multiple orthopedic and surgical techniques with instrumentation of the spine or without this procedure try to modulate the growth of the deformed spine, as well as the development of the thoracic cage and its contents. Yang et al. described the use of classifications to opt for a certain treatment, although the various causes of EOS continue to be a challenge when selecting an appropriate treatment for each particular patient.

The term “growth-guided” or “growth-friendly” refers to a method of instrumenting the spine that allows for the development of the rib cage, abdomen, and pelvis in young patients. In 2019, Cheung et al. published the first series of EOS patients treated with magnetically controlled growing rods (MCGR). As of 2014, the US Food and Drug Administration authorized the use of the MCGR system (MCGR Magnetically Controlled Growing Rods; NuVasive, CA, USA). Since then, our institution began using MCGRs to treat EOS. Other authors have published encouraging results with this technique, and highlight the possibility of reducing the number of successive distractions in the operating room. Choi et al., and Obid et al. highlighted the advantage of being able to control the progression of the scoliotic curve in an effective and non-invasive manner, after the first surgery. Once the system is placed by conventional surgery, subsequent monitoring and distraction are performed on an outpatient basis, and consequently could not only decrease the number of surgeries and complications, and hospital cost, but also improve the child’s quality of life.

MCGRs, however, are not without complications as compared to standard growth-guided systems. Their short period of use and follow-up does not produce certainty about the full profile of potential complications, either intrinsic to the mechanical system or for inherent causes, as other forms of instrumentation do.

The aim of this study was to retrospectively evaluate our experience in a series of EOS patients treated with the MCGR system during an average follow-up of three years.

MATERIALS AND METHODS

Thirty-seven children diagnosed with EOS were retrospectively evaluated at a tertiary level institution. The MCGR system was used in a conventional surgery, four senior surgeons were in charge of the interventions between 2014 and 2020.

The inclusion criteria were: patients with EOS operated with MCGR and complete clinical records and pre- and postoperative imaging studies. The exclusion criteria were: patients with EOS treated with other methods, previous thoracic/abdominal surgery, and a history of infections or thoracoabdominal tumors.

Using full-length spine radiographs, variations in the Cobb angle of the main scoliotic curve and the kyphosis/lordosis angle were analyzed before and after MCGR placement (n = 37).

Variations of T1-T12 and T1-S1 distance on scale were recorded. Distances from T1 to T12 and from T1 to S1 were defined as the distances between the line parallel to the superior endplate of T1 and inferior to T12, and superior to T1 and superior to S1 on a posteroanterior spine radiograph, respectively. The types of construction systems and the levels of fixation were documented.

RESULTS

37 patients were evaluated, 19 girls and 18 boys, with a mean age of 8.2 years at the time of surgery (range 4-12). The etiologies of EOS were: neuromuscular scoliosis (spinal cord atrophy, myopathic, chronic non-developing encephalopathies) (17 patients), syndromic scoliosis (Silver-Rusell, William, Prader-Willi, Escobar, Marfan, neurofibromatosis, genetic, skeletal dysplasia) (14 patients), infantile idiopathic scoliosis (3 patients), congenital scoliosis (3 patients) (Figure 1).

Conversions to MCGR were performed in patients with syndromic scoliosis (6 cases), congenital scoliosis (1 case), neuropathic scoliosis (1 case), and another with idiopathic infantile scoliosis treated from the age of 2 with a plaster corset under anesthesia, successive thermoplastic corsets, and traditional growth rods, after the possibility of elongation was exhausted. (Figure 2).

The decision to use double-rod (n = 22) and single-rod (n = 15) MCGR constructions was based on height, weight, soft tissue coverage, and condition severity. The average of instrumented levels was 5.1 (range 4-6).
Figure 1. 7-year-old patient with type II spinal atrophy. A. Anteroposterior full-length spine radiograph in the preoperative period. B. Preoperative lateral full-length spine radiograph. C. Anteroposterior full-length spine radiograph, after placing the magnetically controlled rod. D. Anteroposterior full-length spine radiograph, after placing the magnetically controlled rod. E. Lateral full-length spine radiograph. Culmination of the distractions of the magnetically controlled rod. F. Lateral full-length spine radiograph. Culmination of the distractions of the magnetically controlled rod.
Figure 2. 8-year-old patient with skeletal dysplasia. A. Preoperative anteroposterior full-length spine radiograph. B. Preoperative lateral full-length spine radiograph. C. Anteroposterior full-length spine radiograph. Fatigue of the distraction material is noted. D. Lateral full-length spine radiograph. Fatigue of the distraction material is noted. E. Anteroposterior full-length spine radiograph. Removal of material and placement of magnetically controlled rods. F. Anteroposterior full-length spine radiograph. Culmination of the successive distractions with magnetically controlled rods. G. Lateral full-length spine radiograph. Removal of material and placement of magnetically controlled rods. H. Lateral full-length spine radiograph. Culmination of the successive distractions with magnetically controlled rods.

The 37 patients were divided into two groups: group 1 (n = 28), those who initially underwent treatment with the MCGR system, the average age at surgery was 8.1 years (range 4-12), with an average follow-up of 3.1 years (range 1-6), from 2014 to 2020.

In group 1, the mean angular value of scoliosis was 64° (range 39°-101°) before surgery, and 41° (range 17°-80°) in the immediate postoperative period. The mean angular value of kyphosis preoperatively was 51° (range 22°-111°) and 34° (range 7°-82°) postoperatively.

The average recorded preoperative distance T1-T12 was 147 mm (range 95-190) and 169 mm (range 104-217) in the immediate postoperative period. The mean preoperative T1-S1 distance was 253 mm (range 205-288) and 306 mm (range 215-354) in the immediate postoperative period (Table 1).
Table 1. Primary MCGR system placement.

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<th>T1-S1 preop. (mm)</th>
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Group 2 was made up of the population converting from a traditional system to MCGR. It consisted of nine patients, with a mean age at the time of surgery of 7 years (range 4-12). The mean angular value of preoperative scoliosis was 56° (range 39°-101°) and 46° (range 30°-76°) in the immediate postoperative period. The mean angular value of preoperative kyphosis was 39° (range 7°-81°) and 32° (range 4°-52°) in the immediate postoperative period.

The mean preoperative T1-T12 distance was 174 mm (range 117-275) and 183 mm (range 138-275) in the immediate postoperative period. The mean preoperative T1-S1 distance was 317 mm (range 234-507) and 329 mm (range 249-507) in the immediate postoperative period (Table 2).

### Table 2. Conversion of conventional distraction rod system to magnetically controlled rods.

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<th>Other complications</th>
<th>Follow-up (year/months)</th>
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<td>T3-T4-T5 L1-L2</td>
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M = male; F = female; NECE = non-evolving chronic encephalopathy; PSL = proximal screw loosening; preop. = preoperative; postop. = postoperative; intraop. = intraoperative.
Seven complications occurred. In group 2, there were two cases of loosening of proximal screws, one kyphosis of the proximal joint, and one of mechanical failure at the level of the BM drum. There was one case of rod rupture and one of mechanical failure in the magnet in Group 1, but no reason could be determined. Distal screw loosening occurred only in group 2, with double-rod systems (Figures 3 and 4).

A distant complication was detected in group 2, it was exposure of the implant and deep infection by *Staphylococcus aureus*, in a patient with neuropathic scoliosis. Treatment consisted of cleaning, debridement, and removal of the implant, with good results.

![Figure 3. Breakage of the pin of the rod magnet.](image-url)
DISCUSSION

Traditional distraction systems require many surgeries in children with spinal deformity, which predisposes them to more frequent complications, such as infections or spontaneous fusion due to continuous surgical damage to the tissues surrounding the implant. Even when the interval between procedures is extended, the rate of complications remains significant.19

The possibility of psychological damage and a worse quality of life due to the multiple surgeries and hospitalizations, such as successive reinterventions for distraction,20,21 and the socioeconomic impact, due to the high costs for the medical care system and also for the relatives, should be taken into account to decide a treatment according to each patient.17,22,23

The MCGR distraction technique was designed as one more treatment option for EOS. The ability to perform repeated non-invasive and ambulatory distractions, together with the fact that it does not require anesthetic procedures, makes this device a particularly appealing alternative for patients with EOS.9-12

Bekmez et al. found that using the MCGR system (n = 10) instead of conventional rods (n = 10) resulted in fewer procedures.19 Although Rolton et al. reported the possibility of cost savings starting in the third year when compared to conventional growth rods,18,24 Rushton et al., in 2019, suggested that rods should be changed after approximately three years of placement due to the possibility of failure of the distraction system, which can increase costs.25

MCGR placement is technically similar to a conventional procedure, but the distraction of the system is performed by an internal mechanism of magnets. Such movement can be confirmed by ultrasound,26 which also reduces the risk of excessive radiation.27,28 In our practice, we started using this ultrasound method several years later.
ago, which does estimate distractions in millimeters, but does not assess implant status or curve angle, and is subject to inter- and intra-observer subjective variability. For this reason, we believe that it is necessary to take a radiograph at least once a year to examine the evolutionary state of the deformity and the instrumentation.

The comparison between single- and double-rod MCGR systems is important, although the double-rod system would achieve greater stability and better mechanical control of the spine, many times, the size of the patient and skin coverage can not provide optimal conditions, this suggests opting for a single-rod system.

The time intervals for distraction and the number of millimeters to distract in each procedure can vary from as little as two months for the first distraction or six months between the first and second. There is insufficient data in the literature on the subject, or on the number of millimeters that must be distracted, although it is known that distractions before three months are associated with a higher risk of instrumentation failure.

Our protocol included distractions every three months, all procedures were conducted in the office, and the use of the operating room was unnecessary, even with two cases of pain. The average number of distractions was four in group 1 (n = 28) and five in group 2 (n = 9). System distraction was, on average, 4.49 mm for group 1 and 4.37 mm for group 2.

Complications are not uncommon with the MCGR system. Some authors, such as Teoh et al., and Lebon et al., have published high complication rates at two years of follow-up, such as broken rods or actuator, loosening of proximal anchors, local metallosis, possible increase of titanium in blood with or without vanadium and surgical site infection. However, in the latest reports, the frequency of complications is variable, and can be compared with those of traditional distraction systems, as shown by Akbarnia et al., with 66.7% complications in a population of 12 patients and Heydar et al., with a complication rate of 6% in a population of 16 patients.

In our series of 37 patients, the rate of complications was 18.9%, comparable to that of the series by Ridderdubsch et al., and Keskinen et al. reporting 20% (n = 24) and 30% (n = 50), respectively. Loosening of proximal screws, mechanical failure of the rod, and MCGR rupture were the most frequent complications in our series (5.4% each). It was not possible to determine the origin of the rod’s mechanical failure, and severe metallosis was found around the MCGR during the definitive fusion surgery in several of our patients that passed the postoperative follow-up of this study. Although the publications by Cheung et al. and other authors mention rod slippage failure, they connect it with a greater BMI, age, distances between the ends of the structure, and shorter distances between the internal magnets.

Rod fracture occurred in our groups 1 and 2, both with single- and double-rod systems. Hosseini et al. published a similar fracture rate for both single (1/8) and double (2/15) rod systems. Choy et al. reported a similar difference in fracture rate for 4.5 mm and 5.5 mm systems; in our cases, they occurred only in 5.5 mm rods. There was a late complication: removal of the implant associated with exposure of the material and infection of the wound. This complication is not frequent in the published series.

Soft tissue infection is frequent in most series, our only case of infection was associated with material exposure, this association is even less frequent, Choi et al. only reported one case similar to ours. Deep or superficial infections due to dehiscence have also been described, but they are rare.

The limitations of this study are the small number of cases and the inclusion of patients treated at a single institution, so homogeneity for a better analysis is not reached, and the short-term follow-up, despite the patients’ continued control.

**CONCLUSIONS**

Our results show that the use of MCGRs as a treatment for EOS is currently reliable, as they control and maintain the physiological development of thoracolumbar growth. The low rate of complications, particularly infections, and the low comorbidity associated with the few surgical interventions, lead us to maintain that it is a safe and effective method for the treatment of EOS.

Although the short- and medium-term results in our series are encouraging, there are still major obstacles and unknowns about the mechanical behavior of the implant in long-term follow-up.
REFERENCES


