

Guided Growth with Magnetic Rods in Early Onset Scoliosis. Preliminary Report

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Introduction: Early onset scoliosis (EOS) treatment with the magnetically controlled growing rod (MGR) system allows for the use of non-invasive outpatient distractions. The purpose of this study was to assess our first series of EOS patients treated with MGRs. **Materials and methods:** We conducted a review of EOS cases treated with MGRs between 2014 and 2018. The study population was divided into two groups: Group I, patients undergoing primary MGR insertion; Group II, patients undergoing conversion from conventional growth system to MGR. **Results:** The study population consisted of 19 patients. The average age at the time of surgery was 7 years and 4 months, with an average post-operative follow-up of 2 years and 7 months. Group I consisted of 12 patients and Group II of 7 patients. The mean preoperative scoliosis angle was 62° and immediate postoperatively was 42°. The mean preoperative kyphosis angle was 49° and immediate postoperatively was 34°. The average preoperative T1-T12 length was 160mm and immediate postoperatively was 176mm. The average preoperative T1-S1 length was 285mm and immediate postoperatively was 317mm. There was 1 late complication, an implant protrusion with an associated infection, in a neuropathic scoliosis patient (Group II) who required implant removal. **Conclusion:** Our preliminary results suggest that the MGR system is a safe and effective method. Although the short- and medium-term results are encouraging, further studies are warranted to overcome important and unknown challenges regarding the mechanical behavior of the implant in the long term.

Level of Evidence: IV

Key words: Early onset scoliosis, magnetically controlled growing rods.


Crecimiento guiado con barras magnéticas en pacientes con escoliosis de inicio temprano. Reporte preliminar

RESUMEN

Introducción: El tratamiento de las escoliosis de inicio temprano guiado por barras magnéticas permite realizar distracciones no invasivas y ambulatorias. El objetivo de este estudio fue evaluar nuestra primera serie de casos con escoliosis de inicio temprano tratados con el sistema de barras magnéticas. **Materiales y Métodos:** Se realizó una revisión de casos tratados con el sistema de barras magnéticas entre 2014 y 2018. Se formaron dos grupos: grupo I (procedimientos primarios con barras magnéticas) y grupo II (conversiones de sistema tradicional a barras magnéticas). **Resultados:** Se evaluó a 19 pacientes. La edad promedio en el momento de la cirugía fue de 7 años y 4 meses, con un seguimiento promedio de 2 años y 7 meses. El grupo I tenía 12 pacientes y el grupo II, 7 pacientes. Los valores angulares promedio preoperatorio y posoperatorio inmediato de la escoliosis fueron 62° y 42°, respectivamente; los de de cifosis, 49° y 34°, respectivamente. La distancia T1-T12 fue de 160 a 176 mm. La distancia T1-S1 fue de 285 a 317 mm. Hubo una complicación: protrusión del implante e infección, y fue necesario retirar el material (grupo II). **Conclusiones:** Los resultados preliminares sugieren que es un método seguro y eficaz. Si bien los resultados a corto y mediano plazo son alentadores, persisten algunos desafíos importantes e incógnitas en relación con el comportamiento mecánico del implante en un seguimiento prolongado.

Palabras clave: Escoliosis de inicio temprano; barras de crecimiento; barras magnéticas.

Nivel de Evidencia: IV

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INTRODUCTION

The literature defines EOS as a spine deformity that is present before 10 years of age.^{1,2} EOSs comprise several scoliotic conditions, including neuromuscular, syndromic, idiopathic and congenital scoliosis.³ The natural history in untreated patients may involve the progressive growth of the deformity and potential systemic involvement associated with underdevelopment of the lungs, restrictive pulmonary disease, high-blood pressure, and cor pulmonale.⁴

The literature provides abundant evidence on limited growth potential associated with early spinal fusion, especially if affecting the thoracic region, and its repercussion on lung development and function. Normal thoracic development in children under 5 years involves an average growth velocity of 1.4cm per year, 0.6cm per year in children between 5 and 10 years, and 1.2cm per year from age 10 to skeletal maturity.⁵

Therefore, several surgical techniques have been developed to facilitate trunk growth while allowing to correct the deformity and favoring the pulmonary parenchyma development, which are intended to result in a better setting for the spine and thorax to grow. These surgical procedures may be labeled with many names, “guided-growth” or “growth-friendly”, and involve different instrumentation systems.⁶ In this study, we addressed the use of MCGRs.

The first published case series on EOS patients undergoing MCGR surgery is from 2012, by Cheung *et al.*⁷ In 2014, the FDA approved the use MCGR system (Magec, NuVasive, CA, USA).⁸ MCGR systems offer advantages over conventional growing rod systems. Following the initial surgical placement of the instrumentation under general anesthesia, the lengthening procedures are performed in an outpatient setting, usually with the patient awake and in an outpatient clinic.⁹ Most cases do not require hospitalization nor anesthesia, thus reducing risks associated with anesthesia, surgery and hospital stays while also preventing missed school days, children suffering from social and psychological problems, and relatives facing work-related problems.¹⁰

The purpose of this study was to assess our first series of EOS patients treated with MCGRs, including indications, surgical techniques, postoperative outcomes, and intra- and postoperative complications.

MATERIALS AND METHODS

We conducted a retrospective review of pediatric patients with a diagnosis of EOS, who had undergone surgery with MCGR at a single level-3 pediatric center by 5 senior surgeons during a 4-year period (2014-2018) (level of evidence: IV). The analysis was conducted by a training spine surgeon.

The inclusion criteria were: patients with a diagnosis of EOS; surgical treatment with MCGR; complete pre- and postoperative medical records and imaging studies. Exclusion criteria: Patients not treated with MCGR systems.

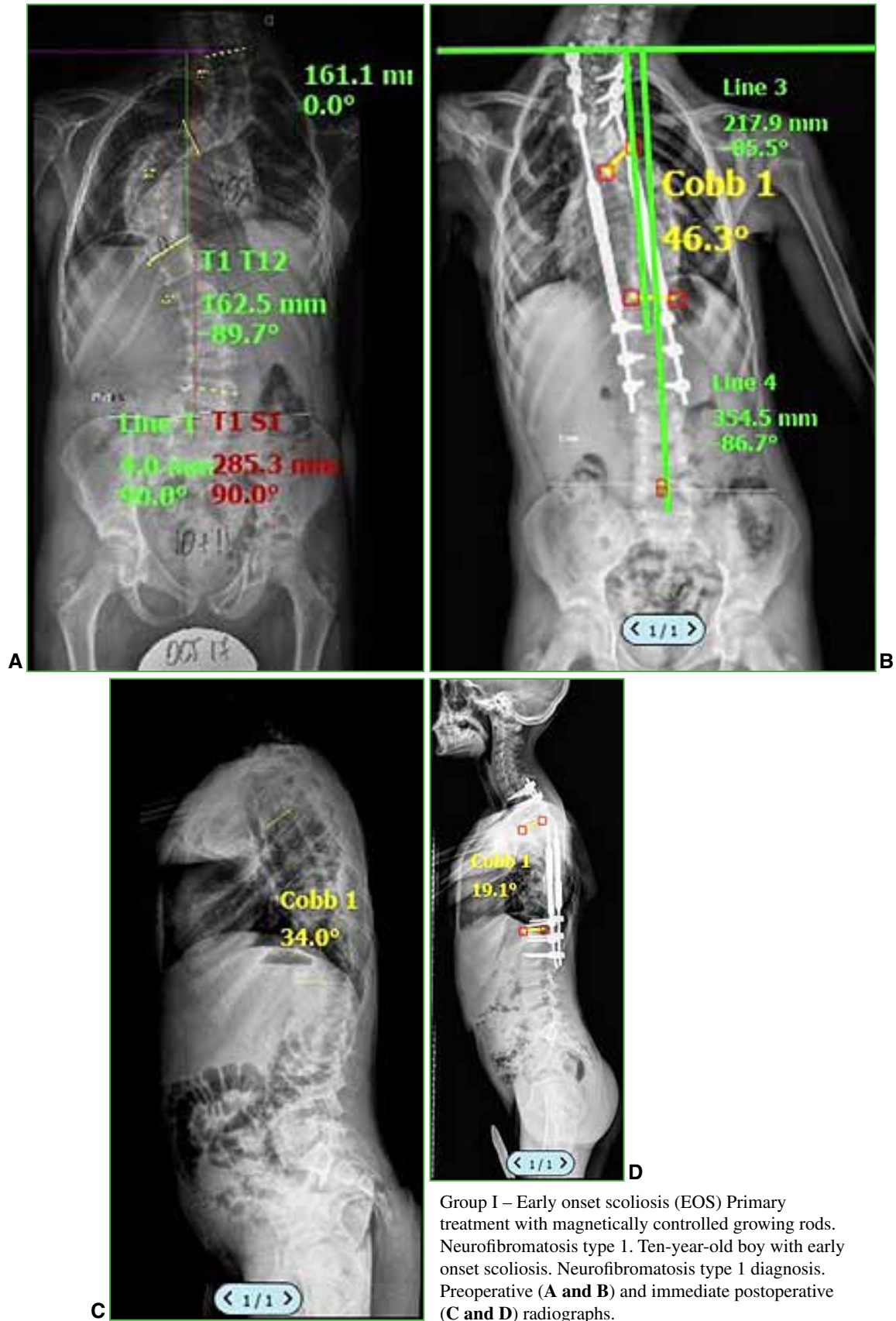
Study variables were: age, sex, etiology, previous treatments, primary MCGR or conversion to MCGR procedures; single-rod or double-rod constructs; curve pre- and postoperative angles; pre- and postoperative T1-T12 and T1-S1 lengths; and intra- and postoperative complications.

Posteroanterior and lateral spinal radiographs were used to study changes between pre- and postoperative Cobb angles of the main scoliotic curve, kyphosis, and lordosis (n=19). Compensatory curves were not included in the study. In addition, T1-T12 and T1-S1 length proportional variations were recorded. T1-T12 and T1-S1 lengths were defined as the distances measured on posteroanterior radiographs from the line parallel to the superior T1 endplate to the one parallel inferior T1 endplate, and from the superior T1 endplate to the inferior S1 endplate, respectively.¹¹ Construct systems and fixations levels were recorded.

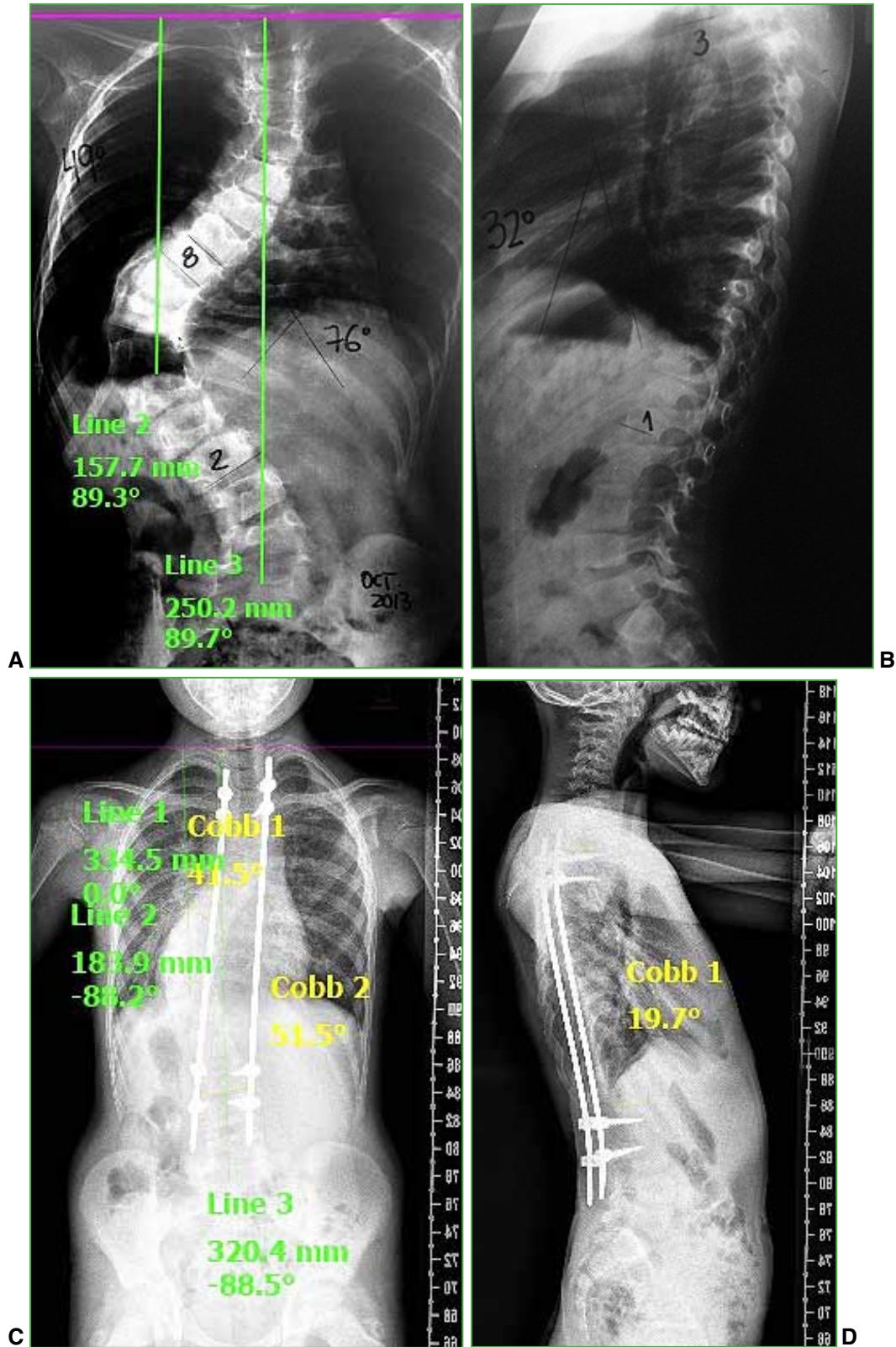
RESULTS

The study population consisted of 19 patients, 10 (52%) females and 9 (48%) males. All patients were treated with MCGR systems, with an average follow-up of 2 years and 7 months (range, 2 months to 4 years and 6 months).

The study OES etiologies included 8 patients with neuromuscular scoliosis (5 cerebral palsies, 2 spinal muscular atrophies, and 1 unspecified myopathy), 9 patients with syndromic scoliosis (1 Silver-Russell syndrome, 1 William's syndrome, 1 Marfan's syndrome, 1 Prader-Willi syndrome, 2 unspecified genetic syndromes, 2 with osteodysplasia, 1 neurofibromatosis type 1 [Figure 1], 1 with congenital scoliosis, and 1 with infantile idiopathic scoliosis [Figure 2]). The average age at the time of surgery was 7 years and 4 months (range, 4-12 years).



Group I – Early onset scoliosis (EOS) Primary treatment with magnetically controlled growing rods. Neurofibromatosis type 1. Ten-year-old boy with early onset scoliosis. Neurofibromatosis type 1 diagnosis. Preoperative (A and B) and immediate postoperative (C and D) radiographs.



Figurae2. Patient with infantile idiopathic scoliosis diagnosis who underwent surgery with conventional using a conventional double-rod system at age 5 years, and conversion surgery to MCGR at age 7 years. Preoperative radiographs (**A and B**). Conventional system postoperative radiographs (**C and D**).

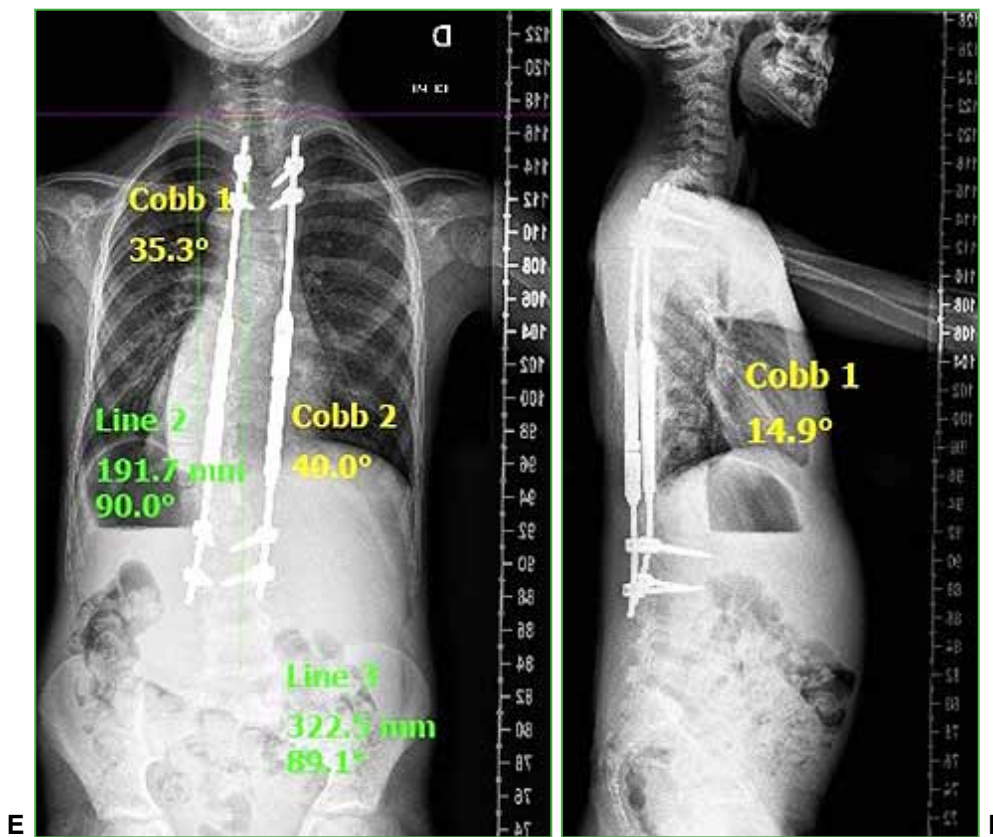


Figure 2. Patient with infantile idiopathic scoliosis diagnosis who underwent surgery with conventional using a conventional double-rod system at age 5 years, and conversion surgery to MCGR at age 7 years. Conversion surgery to MCGR postoperative radiographs (**E and F**).

Twelve patients with no previous treatments were treated with MCGR systems (Group I), with an average age at the time of surgery of 7 years (range, 4-10 years). The mean preoperative scoliosis angle was 69° (range, $45\text{-}100^\circ$) and immediate postoperatively was 38° (range, $17\text{-}80^\circ$). The mean preoperative kyphosis angle was 58° (range, $22\text{-}111^\circ$) and immediate postoperatively was 36° (range, $7\text{-}82^\circ$).

The average preoperative T1-T12 length was 147mm (range, 95-190mm) and immediate postoperatively was 169mm (range, 104-217mm). The average preoperative T1-S1 length was 253mm (range, 205-288mm) and immediate postoperatively was 306mm (range, 215-354mm).

Conversion procedures from conventional growth systems to MCGR systems were conducted on 7 patients (Group II). In 2 cases, the procedure was adopted due to complications (1 proximal screw loosening and 1 rod breakage). In 4 cases, the patients had syndromic scoliosis. And the remaining case involved a patient with infantile idiopathic scoliosis who had been treated since age 2 years with plaster corset and anesthesia, successive thermo-plastic corsets and conventional growing rod systems until their lengthening capacity became inadequate; at which time, it was decided to convert to an MCGR system.

Group II mean age at surgery was 7 years (range, 4-12 years). The mean preoperative scoliosis angle was 56° (range, $39\text{-}101^\circ$) and immediate postoperatively was 46° (range, $30\text{-}76^\circ$). The mean preoperative kyphosis angle was 39° (range, $7\text{-}81^\circ$) and immediate postoperatively was 32° (range, $4\text{-}52^\circ$).

Table 1. Group I: Early onset scoliosis (EOS) patients with no previous treatment

Patient	Etiology	Age	Preoperative				Postoperative				
			Cobb	Kyphosis	T1-T2	T1-S1	Cobb	Kyphosis	T1-T12	T1-S1	Complications
1	Williams's S	6	70	37	143	258	36	11	170	335	-
2	NF1	10	98	28	162	258	46	19	217	354	-
3	CP	7	47	60	159	247	43	60	183	297	-
4	CP	7	100	111	157	242	80	77	171	293	-
5	CP	4	95	86	95	205	75	82	104	215	-
6	Neuropathic scoliosis	5	91	51	118	210	29	17	154	271	-
7	Osteodysplasia	9	46	22	190	313	17	42	168	313	-
8	Prader-Willi S	6	65	64	160	278	22	31	171	312	-
9	Myopathic scoliosis	9	68	22	162	288	22	11	202	351	-
10	SMA	7	45	103	132	212	36	40	168	321	-
11	SMA	7	60	60	136	256	23	7	170	333	-
12	Congenital scoliosis	10	45	55	157	271	36	36	157	283	-
Average		7.2	69.2	58.2	147.6	253.2	38.7	36.1	169.6	306.5	0

NF1: Neurofibromatosis type 1; S: syndrome; SMA: spinal muscular atrophy.

Table 2. Group II Early onset scoliosis (EOS) patients undergoing conversion surgery from conventional systems to MCGR systems

Patient	Etiology	Age	Preoperative				Postoperative					
			Cobb	Kyphosis	T1-T2	T1-S1	Cobb	Kyphosis	T1-T12	T1-S1	Complications	
											Rods	MCGR
1	Silver-Russell S	12	39	33	275	507	39	33	275	507		
2	CP	4	101	50	117	234	76	50	138	249		Implant removal
3	Syndromic scoliosis	9	67	56	168	283	59	52	172	292	PSL	
4	Marfan's S	5	44	7	182	309	43	4	173	315		
5	IIS	7	43	11	185	334	40	14	191	341		
6	Chondrodysplasia	9	51	81	122	238	30	46	158	280	RB	
7	Escobar's S	8	48	41	170	317	38	30	180	319		
Average		7.7	56.1	39.8	174.1	317.4	46.4	32.7	183.8	329	2	1

CP: cerebral palsy; IIS: infantile idiopathic scoliosis; MCGR: magnetically controlled growing rod system; S: syndrome; PSL: proximal screw loosening; RB: rod breakage; Rods: conventional growth rod system.

The average preoperative T1-T12 length was 174mm (range, 117-275mm) and immediate postoperatively was 183mm (range, 138-275mm). The average preoperative T1-S1 length was 317mm (range, 234-507mm) and immediate postoperatively was 329mm (range, 249-507mm).

Double-rod constructs were used in 13 cases, and single-rod constructs in 6 cases. The instrumented levels averaged 5 (range, 4-6).

We recorded 1 late complication: an implant exposure and deep infection with *Staphylococcus aureus*, in a neuropathic scoliosis patient (Group II), who required surgical toilet, debridement and implant removal.

DISCUSSION

The MCGR distraction system was designed as an alternative to the existing treatments for early spine deformities, with the advantage of allowing recurrent non-invasive lengthening procedures that usually do not require anesthesia procedures. The MCGR system also fulfills the functions of conventional growing techniques, such as allowing the spinal, thoracic and pulmonary growth.^{9,12} MCGR placement surgical technique is similar to that of conventional systems procedures, and its advantages become apparent during the postoperative period as it allows non-invasive outpatient distractions with the patient awake, although in very young patients the procedure may require some mild sedation. The distraction procedure begins by locating the actuator with a magnet, then at this location the external remote controller is placed, which had been calibrated in millimeters to the distraction length for the rod/s in the actuator area.⁹ The procedure takes just a few seconds, and in some cases evidence of the implant distraction maneuver may be discernable in the form of a clicking sound. MCGR procedures do not require hospitalization nor anesthesia, thus preventing risks associated with anesthesia, surgery, and those inherent to hospital stays, thus also preventing missed school days, children suffering from social and psychological problems, and relatives facing work-related problems.¹⁰ Only two of our series' patients experienced pain during magnetic distraction, which led to the lengthening procedure suspension, and in both cases resulted in 3mm distractions and complete pain relief with no need for hospitalization or anesthesia. The subsequent distraction procedures produced no complications in these two patients.

Some reported complications associated with MCGR systems at 2-year follow-ups include: rod breakage, actuator breakage, anchor loosening, local metallosis and increased serum titanium and vanadium levels, and surgical wound infection.^{10,13,14} Our study series included a single case of implant removal associated with protrusion and deep infection of the wound in a neuropathic scoliosis patient (Group II), amounting to a 5% complication rate.

Patients treated with conventional growing rod systems require surgical distractions on average every 6-12 months. These systems involve patients undergoing surgeries and being administered anesthesia on multiple occasions, which increases the risks of complications such as superficial and/or deep infections, spontaneous fusion of the instrumented segments, rod breakage, implant loosening or protrusion, and psychological disorders, including post-traumatic stress disorder and depression due to repeated surgeries. Other factors to be considered include disadvantages to children and parents as a result of time missed from school and absence from work.^{6,10,12,15,16}

Bess *et al.*, in their series of 140 patients treated with conventional growing rod systems, reported a 58% complication rate.¹³ Beaven *et al.*, in their series of 28 patients treated with the MCGR system, reported a 29% complication rate.⁹ A systematic literature review of patients treated with the MCGR system and with a minimum of 2-year follow-up reported an overall complication rate of 46%.¹⁷

A comparative study on the MCGR system (n=10 patients) versus conventional growing rod systems (n=10 patients) showed a significant decreased number of surgeries associated with the MCGR system.¹⁸

Any revision surgery implies increasing a child morbidity risk while also resulting in a significant financial cost both for the child's family and the health system. Although the initial cost of an MCGR system is significantly higher, MCGR-system cost savings are greater than those of conventional growing rod systems as from the third year following insertion.^{19,20}

There is no consensus in the literature regarding the procedure frequency and amount of distraction per session. Our protocol consisted of distractions every 3 months, averaging 3-5mm per session,^{17,21} which results in 4 distractions a year and an annual MCGR-system lengthening of 12-20mm.

Rushton *et al.* established what proportion of implanted MCGRs were able to produce the same distraction force as the manufacturer's stated standard force before implantation. Of the 45 MCGRs implanted for a mean of 2.7 years, 10 (22%) produced force greater or equal to manufacturer's standard, 6 (13%) produced some force but less than the manufacturer's standard, and 29 (64%) produced no distraction force.²²

Another key factor is the use of single-rod or double-rod constructs. Although the double-rod system may offer greater stability and mechanical control of the spine,^{23,24} it is common that the patient's size and skin coverage may prove inadequate for dual rod instrumentation and so it is necessary to resort to a single-rod system. Our study included 13 cases with double-rod constructs and 6 with single-rod constructs.

After the distraction procedures in outpatient clinic, radiographic control studies were performed to confirm distraction length in millimeters, proper anchorage, and curve correction. A new measuring system based on ultrasound scanning has recently been described to control lengthening and reduce the risk of excessive radiation exposure.^{7,25} We have introduced this new method to our practice. While it provides an estimated distraction expressed in millimeters it has some limitations: it does not assess the implant state nor the curve angle and is subject to interobserver variability (operator-dependent study). Therefore, we deem necessary a plain radiographic study at least once a year.

The limitations of this study include: a limited number of cases, the heterogeneous nature of our patient population, and a short postoperative follow-up period.

CONCLUSION

The preliminary results of the MCGR system for the guided-growth treatment in EOS patient in this case series has shown to be beneficial in terms of thoracic and spinal growth, and a non-invasive outpatient method that does not require the use of anesthesia and has a lower complication rate. Therefore, we consider it an alternative to conventional growing rod systems in patients with high morbidity or surgical risks.

Our preliminary results suggest that the MCGR system is a safe and effective method. Although the short- and medium-term results are encouraging, further studies are warranted to overcome important and unknown challenges regarding the mechanical behavior of the implant in the long term.

Conflict of interests: Authors claim they do not have any conflict of interest.

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