Magnetically controlled growing rod in early onset scoliosis: a 30-case multicenter study

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Abstract

Purpose Preliminary results of magnetically controlled growing rods (MCGR) are encouraging. However, only short case series of MCGR for the treatment of early onset scoliosis (EOS) have been reported. Our aim was to evaluate its effectiveness and complications.

Methods We report a 30-case retrospective, consecutive, multicenter series of MCGR. Effectiveness was judged upon: deformity correction and difficulties to achieve desired distraction. Secondary endpoints included complications and revision surgeries.

Results Median age at surgery was 9.1 years (5 13). Mean follow-up was 18.4 months (12 33.9). Mean Cobb angle was 66° preoperatively and 44° at latest follow-up. MCGR has avoided an average of 2.03 scheduled surgical procedures per patient compared to traditional growing rod (GR). The intended total length gain was 40.1 mm per patient (5 140) and the total measured length gain was 21.9 mm (45.5% discrepancy). There were 24 complications: 7 proximal pull-outs of the hooks, 3 rod breakages, 6 failures of the lengthening of which 4 complete blockages and 2 complete blockages followed by backtracking, 1 proximal junctional kyphosis, 1 wound dehiscence, 1 superficial infection, 1 deep infection requiring implant removal, 1 pulmonary embolism, 1 pulmonary insufficiency, 1 secondary lumbar scoliosis, and 1 painful outpatient distraction. Eight patients had a gradual loss of effectiveness of distractions. There were 13 revision surgeries in 9 patients.

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Conclusions MCGR provides satisfactory deformity correction and avoids repeated surgical procedures for lengthening. However, it has substantial complication rate. Although less frequent than in GR, the law of diminishing returns also applies to MCGR.

Keywords Magnetically controlled growing rod · Early onset scoliosis · Complication · Revision · Multicenter study

Introduction

Although conservative treatment remains the standard of care for early onset scoliosis (EOS), some patients require surgery [1, 2]. Growing rods (GR) then represent a good alternative and provide satisfactory results [3]. However, they need repeated surgeries to allow spine and chest to grow every 6 9 months on average [4 7]. Of concern are significant complication rates, increased costs due to planned and unplanned procedures and psychological consequences [8 10]. The introduction of the magnetically controlled growing rod (MCGR), allowing non-invasive distraction represents a recent breakthrough. Preliminary results are encouraging in terms of effectiveness, security and comfort [3, 8, 10]. However, only relatively short case series were reported. Our aim was to evaluate the effectiveness and complications of this treatment. We report our experience in a retrospective consecutive multicenter series of 30 patients with 1 year minimum follow-up.

Materials and methods

We conducted a multicenter, consecutive, prospective series of patients operated on with MCGR for EOS, whatever the type of construct or the origin of the deformity, from October 2011 to January 2014. Indication was either failed conservative treatment or revision of a GR. Patients with less than 12 months of follow-up were excluded.

The first distraction was performed, on average, 3 months after the index procedure and, then, every 2nd or 3rd month, always in outpatient clinic. The distraction was monitored either by radiographs or ultrasound imaging, depending on the institution (Fig. 1), because the

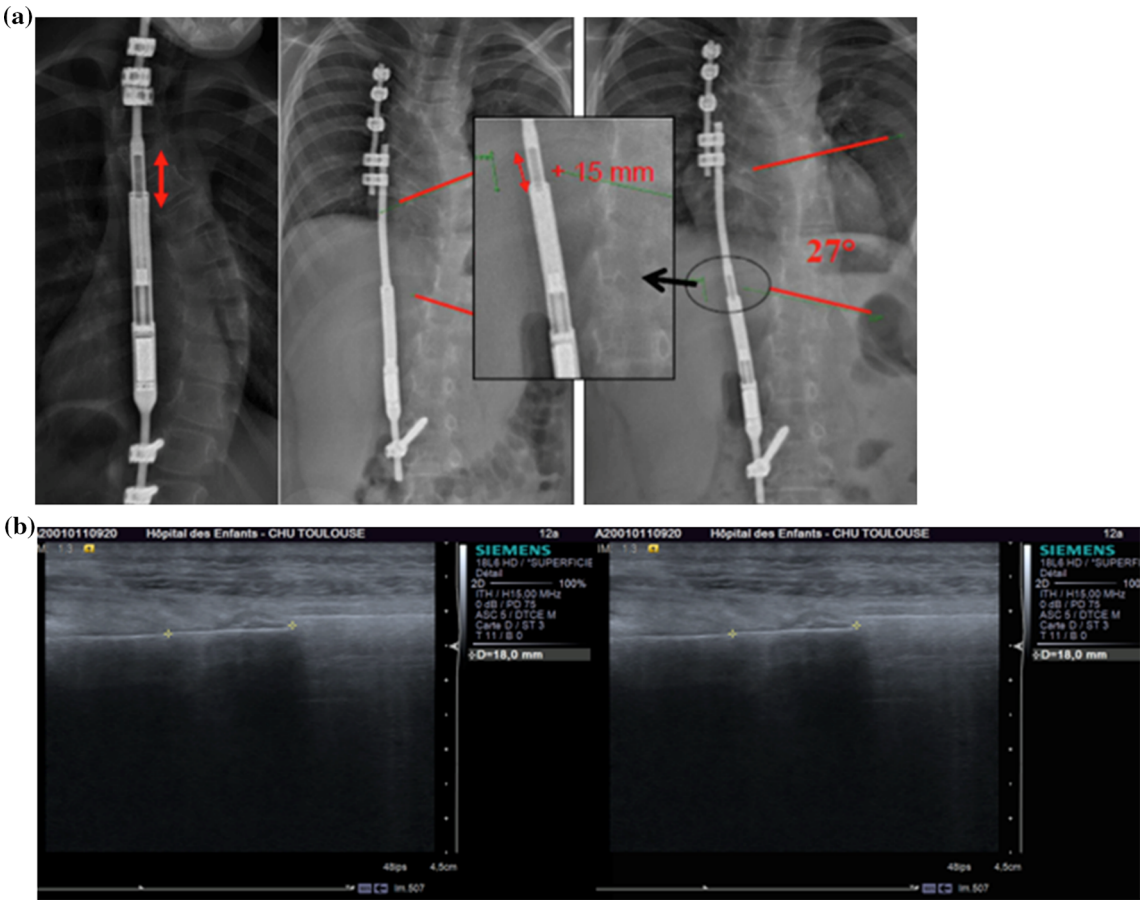

Fig. 1 Radiographic (**a**) and ultrasound (**b**) monitoring of the distraction before and after a distraction session

radiographic or ultrasound measures are reliable, reproducible and comparable [11, 12].

The type of construct, the instrumented levels, the rate and amount of distractions (as performed with the external actuator and as actually measured on radiographs or ultrasound imaging) were recorded, as well as the number of distraction procedures per session (in case the desired length was not achieved with a single procedure), complications and revision procedures.

Radiographic analysis included preoperative, immediate postoperative and latest follow-up AP and lateral full-spine views and also radiographs performed in case of a complication and/or a revision procedure. Cobb angle, T4 T12 kyphosis, L1 L5 lordosis, T1 S1 and T1 T12 distances were measured by a single observer (JL).

Effectiveness was judged upon: deformity correction (Cobb angle, T1 S1 and T1 T12 distances), difficulties to achieve desired distraction and number of surgical procedures avoided by using non-invasive distraction. The desired distraction varied between 2 and 6 mm per procedure. It was a subjective choice of the surgeon, determined in outpatient clinic just before the distraction. It relied on: the total distraction already obtained, clinical examination (pain, stiffness), the difficulties during the previous distraction and, of course, Dimeglio's data according to the age of the patient [13].

For the calculation of the number of surgeries avoided by patient, we have counted one surgical distraction every 6 months with standard GR. Thus, for every period of 6 months without surgical resumption from the day of installation of MCGR (whatever is the indication of the surgery), we counted a surgery avoided per patient.

Secondary endpoints included: complications, revision surgeries, MCGR implant survival to 'revision' event, whatever the cause, and the presence of risk factors for difficulties with distraction procedures and for revision surgeries.

We evaluated the influence of the following factors: origin of EOS, history of GR treatment, age at surgery, type of construct (single or dual rod), proximal and distal limits of instrumentation, preoperative Cobb angle, T4 T12 kyphosis angle, L1 L5 lordosis angle and total number of distraction procedures.

All statistical analyses were carried out using the statistical software R®. Characteristics of the population are given by group size (percentage) for categorical variables. Means and standard deviation (±SD) are generally provided for quantitative variables. A paired Student's T test was used to compare the means. All comparisons were two-sided. $p < 0.05$ was considered significant.

Results

Thirty patients were included (16 boys, 53%, 14 girls, 47%). Mean age at surgery was 9.1 years [5 13] and mean follow-up was 18.4 months (12 33.9).

Six centers with one experimented surgeon per center participated in the study: Toulouse (nine cases), Marseille (six cases), Lyon (five cases), Luxembourg (five cases), Lille (four cases), Rennes (one case).

Diagnoses were sorted in four groups: neuromuscular (11 cases, 37%), syndromic (9 cases, 30%), idiopathic (7 cases, 23%) and congenital (3 cases, 10%). Five patients (17%) had been previously treated with GR prior to the use of an MCGR. Single rod construct was used in 20 cases (67%) and a dual rod in 10 (33%). There was no recommendation for single or dual rod constructs (it was a personal choice of the surgeon). Standard titanium rods (diameter 5.5 mm) were used in all the cases. Mean proximal level of instrumentation was T2 (T1 T4) and mean distal level was L3 (T10 S1). There were two selective instrumentations ending in T10 and T12. The construct included pedicular screws and hook claws in 25 cases (83%), pedicular screws and hooks in three cases (10%), pedicular screws only in 1 case (3%) and sublaminar bands combined with screws in 1 case (3%). We used three types of hook claws (sublaminar pedicular, laminolaminar, pediculo-transverse). Pedicular screws were used for distal fixation in all cases.

Any patient had brace after Magec® rod insertion. Sports activities, excepting contact sports, were allowed for some patients (swimming, badminton, running).

Analysis of primary endpoint: effectiveness of MCGR

Reliability of distraction procedures

All patients had at least one distraction session except for one whose MCGR was explanted 3 months postoperatively with no further implantation. It was a patient who underwent two surgical revisions for loosening of the proximal instrumentation in the first 3 months after rod insertion (3 weeks and 2 months after rod insertion). Thus, it was decided to stop the treatment by Magec rod. A total of 171 distractions were performed among the 29 other patients, corresponding to an average of 5.9 per patient (1 13). A total of 278 procedures were necessary, corresponding to an average of 1.6 per session, with 1 4 procedures per session. It was decided to repeat the procedure when the desired length gain was not obtained and deemed insufficient. Mean time between two scheduled distraction sessions was 89 days (70 192 days). The

Table 1 Total intended and total measured distraction per patient with the difficulties observed during the follow up

Patients	Total intended distraction (mm)	Total measured distraction (mm)	Difficulties observed
1	48	45	None
2	78	23	Gradual loss of effectiveness
3	19	19	None
4	8	8	None
5	120	36	Gradual loss of effectiveness
6	83	33.1	Gradual loss of effectiveness
7	27.5	24.6	None
8			0 distraction
9	45.5	43.4	None
10	49	31.5	Complete blockage
11	28	4.6	Complete blockage
12	54	38.5	Gradual loss of effectiveness
13	35	6.4	Complete blockage
14	40	22	Gradual loss of effectiveness
15	65	18	Gradual loss of effectiveness
16	29	25	None
17	24	22	None
18	28	25	None
19	5	5	None
20	12.5	12.5	None
21	50	16.8	Blockage followed by backtracking
22	13	13	None
23	5	5	None
24	28	10	Gradual loss of effectiveness
25	52	28	Complete blockage
26	91	24.3	Gradual loss of effectiveness
27	13	11	None
28	40	21.5	Blockage followed by backtracking
29	49	42.5	None
30	24.2	19.7	None
Total	1163.7	634.4	

intended total length gain (which corresponds to the addition of the 278 desired distractions done) was 1163.7 mm corresponding to the 171 sessions for the 29 patients, representing an average of 40.1 mm per patient (from 5 to 140) and 6.8 mm per session (2 35). Total measured length gain was 634.4 mm, representing an average of 21.9 mm per patient (5 43.4) and 3.7 mm per session (0 18.3) (Table 1). Total measured length included only the distractions done during magnetically induced lengthenings. The gain obtained during insertion surgery was excluded. This represented a 45.5% discrepancy between the length gain commanded to the remote control and the length gain actually measured either on radiographs or ultrasound imaging (Fig. 2). Measured length gain equaled commanded length gain in 15 patients (52%), with no difficulty encountered throughout follow-up. In the 14 remaining patients (48%), 8 (28%) had a gradual loss of effectiveness of distractions, 4 (14%) had a complete and permanent blockage and 2 (7%) presented a blockage followed by a backtracking causing loss of length gained from previous distractions (Table 1; Fig. 3).

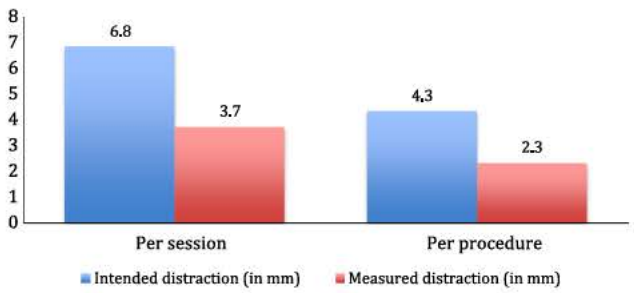

Fig. 2 Intended and measured distractions, per session and per procedure. *N* 29, one patient being excluded because of 3 month explantation

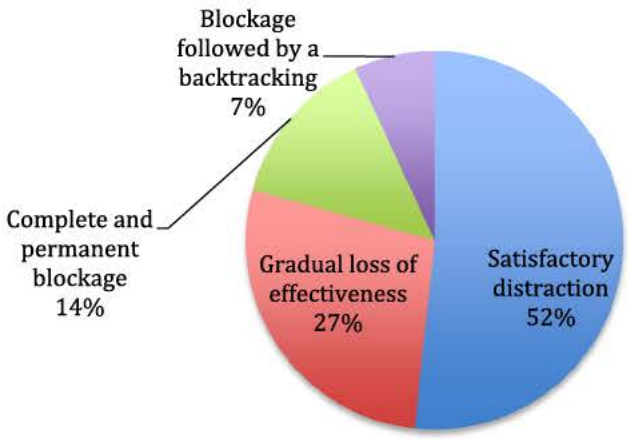

Fig. 3 Reliability of distraction

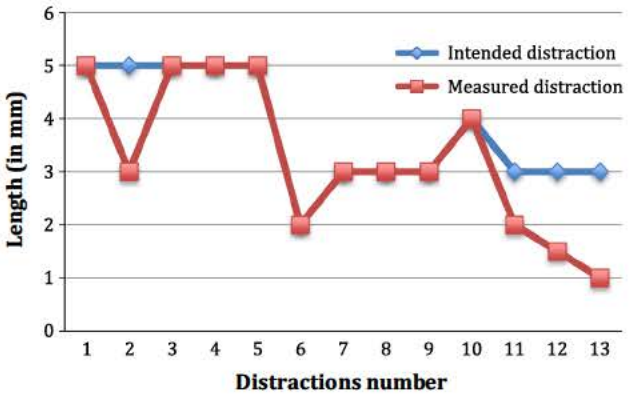

Fig. 4 Satisfactory distraction in a 7 year old boy with idiopathic scoliosis treated with a submuscular single rod MCGR. Thirteen distraction sessions provided a total 42.5 mm gain at the latest follow up

Gradual loss of effectiveness started between the 3rd and 6th distraction sessions, most often after the 4th (4 cases). Cases of blockage occurred at the 2nd, 3rd, 5th and 8th distraction sessions. The two cases of backtracking were noticed at the 3rd and 9th sessions.

Figure 4 shows a case of satisfactory distraction and Figs. 5, 6 and 7 display three examples of gradual loss of effectiveness.

Deformity correction (Tables 2; 3)

Mean Cobb angle was 66° (SD ±18) preoperatively, 40° (±14) postoperatively ($p < 0.001$) and 44° (±14) at latest follow-up ($p = 0.013$) (Fig. 8).

Mean thoracic kyphosis was 39° preoperatively, 35° postoperatively ($p = 0.015$) and 42° at latest follow-up ($p < 0.01$).

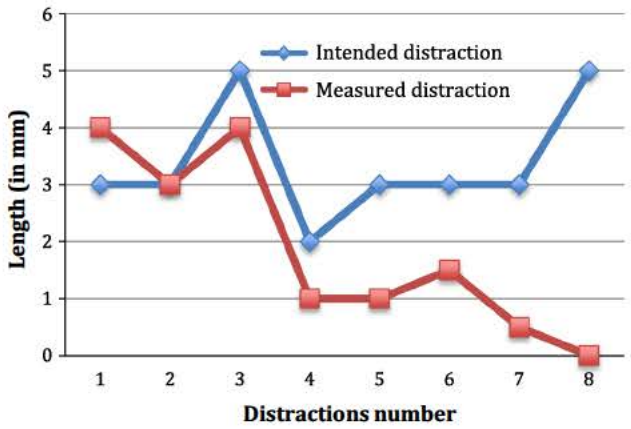

Fig. 5 First example of loss of effectiveness of repeated distractions over time in a 9 year old girl with syndromic scoliosis treated with a dual rod submuscular MCGR. The discrepancy between intended and measured length gain started at the 5th session and worsened from the 7th

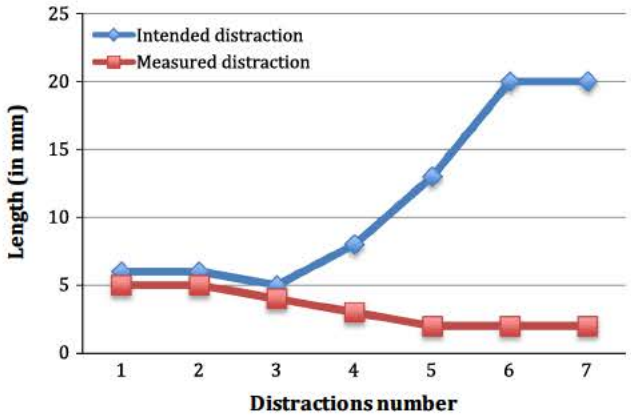

Fig. 6 Second example of loss of effectiveness of repeated distrac tions over time in an 8 year old girl with neuromuscular scoliosis treated with a dual rod submuscular MCGR. In this case, it was a conversion of a standard growing rod. The discrepancy between intended and measured length gain started at the 4th session and increased in each session

Mean T1 T12 distance was 184 mm preoperatively, 218 mm postoperatively ($p < 0.001$), and 220 mm at latest follow-up ($p = 0.727$).

Mean T1 S1 distance was 290 mm preoperatively, 349 mm postoperatively ($p = 0.004$) and 355 mm at latest follow-up ($p = 0.582$) (Fig. 9).

Scheduled surgical procedures avoided

On the basis of a surgical distraction scheduled every 6 months with traditional GR, the use of MCGR has avoided a mean of 2.03 scheduled surgical procedures per

patient [$CI_{95\ \%} = (1.56; 2.51)$] during the total observation period.

Analysis of secondary endpoint: safety of treatment

Complications

There were 24 complications in 17 patients (57%): 7 proximal loosening in 5 patients, 3 rod breakages in 2 patients, 6 failures of the lengthening of which 4 complete blockages and 2 complete blockages followed by back-tracking, 1 proximal junctional kyphosis (PJK) in spite of non-aggressive distractions, 1 wound dehiscence with implant exposure, 1 superficial infection, 1 deep infection requiring implant removal, 1 pulmonary embolism at day 3 treated with thrombectomy, 1 pulmonary insufficiency requiring tracheotomy, 1 secondary lumbar scoliosis, and 1 painful outpatient distraction.

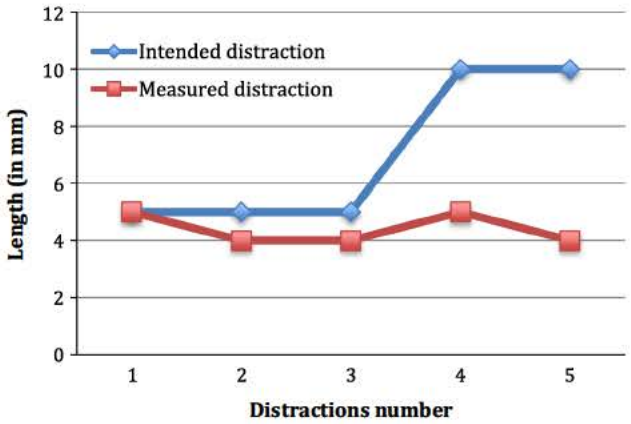

Fig. 7 Third example of loss of effectiveness of repeated distractions over time in a 9 year old boy with idiopathic scoliosis treated with a single rod submuscular MCGR. The discrepancy between intended and measured length gain started at the 4th session

Revisions (Fig. 10)

There were 13 revision surgeries in 9 patients (30%), 5 patients had 1 and 4 patients had 2 revisions: 2 for wound excision, 5 for hook loosening, 3 for rod breakage, 2 for non-functioning rod, and 1 for proximal junctional kyphosis.

Four patients had their MCGR removed at revision: three had a spinal fusion and one was treated with bracing. The five remaining patients had their MCGR treatment resumed.

Complications and revision surgeries were both more frequent in syndromic and neuromuscular scoliosis, although not significantly (Table 4).

The survival analysis in our series indicated a survival rate without revision from 0.5 to 27.9 months. In other words, the probability to have any revision at 27.9-month follow-up was 50% (Fig. 11).

Risk factors for difficult distractions and revision surgeries

Mean postoperative thoracic kyphosis was higher in cases where difficulties with distraction (blockage, backtracking, loss of effectiveness) were encountered (41° vs. 30.8°, not significant). Difficult distractions were more frequent in idiopathic (36%) and neuromuscular (36%) scoliosis (not significant) (Table 5).

Table 2 Radiographic results

	Preoperative		Postoperative		Latest follow up	
	Mean	SD	Mean	SD	Mean	SD
Cobb angle (°)	66	±18	40	±14	44	±14
Thoracic kyphosis (°)	39	±17	35	±17	42	±16
Lumbar lordosis (°)	48	±15	41	±16	48	±15
T1 T12 distance (mm)	184	±28	218	±30	220	±26
T1 S1 distance (mm)	290	±41	349	±36	355	±34

SD standard deviation

Table 3 Comparison of radiographic results

	Preoperative/postoperative			Postoperative/latest follow up		
	Difference	%	*p*	Difference	%	*p*
Cobb angle	26°	39	<0.001	+4°	+9	0.013
Thoracic kyphosis	4°	10	0.015	+7°	+17	0.001
Lumbar lordosis	7°	15	0.025	+7°	+15	0.025
T1 T12 distance	+34 mm	+16	<0.001	+2 mm	+1	0.727
T1 S1 distance	+59 mm	+17	0.004	+6 mm	+2	0.582

Revision ($n = 9$) and revision-free ($n = 21$) groups were not different in terms of the following factors: age at MCGR implantation, preoperative Cobb angle, thoracic kyphosis and lumbar lordosis, the type of construct (single or dual rod), history of GR treatment, the number of distraction sessions and the instrumented levels (Table 6).

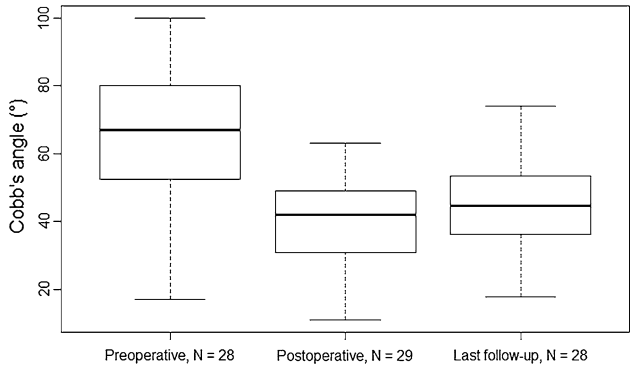

Fig. 8 Cobb angle at different times of follow up

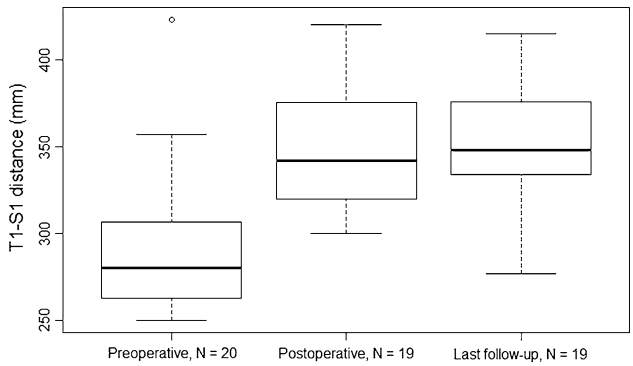

Fig. 9 T1 S1 distance at different times of follow up

All five patients previously treated with standard GR did not need revision. Dual rod constructs tended to have fewer revisions (not significant). Idiopathic and neuromuscular scoliosis tended to have more revisions (not significant).

Discussion

Fusionless spinal instrumentation for EOS was first introduced in 1963 by Paul Harrington [14]. Twenty years later, Moe reported the first GR [15]. Many different techniques have been developed ever since, but mechanical GRs remain the most popular worldwide [3, 8]. The goal is to correct the spinal deformity while allowing growth of the spine and chest. However, GR requires repeated surgeries for lengthening and the complication rate is correlated to the number of lengthening procedures [16 18]. Repeated general anaesthesia in children bears the risk of developing post-traumatic stress, speech disorders and long-term cognition disorders [19, 20].

MCGR is, therefore, promising on this regard as it allows non-invasive outpatient distraction procedures [21]. It also seems to be cost-effective in saving hospitalization costs [22, 23].

Very few studies have investigated the results of MCGR. Cheung et al., in 2012, reported on the effectiveness and safety in a two-patient case series with 2-year follow-up [10]. Cobb angle was improved, on average, from 67° to 29° with no implant-related complication and a superficial infection. They found that the healthcare costs of MCGR are substantially lower than with traditional GR. Although MCGR instrumentation costs more (HK$50,000; US$6451) than traditional GR (HK$25,000; US$3225), the latter is associated with further costs due to frequent

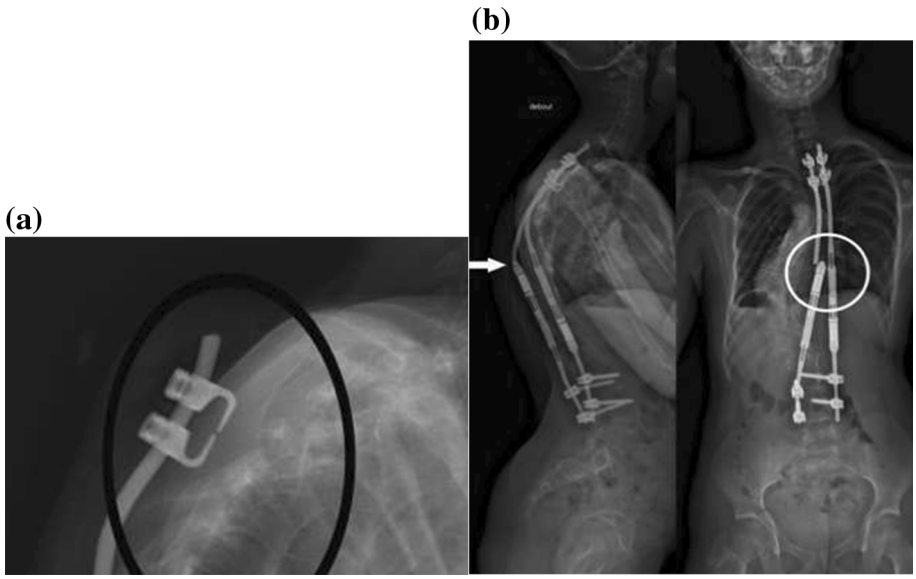

Fig. 10 Examples of mechanical complications. **a** Pull out of proximal hook claw. **b** Rod breakage

Table 4 Complications and revisions according to the diagnosis of EOS

	Idiopathic		Congenital		Syndromic		Neuromuscular		*p*
	N 7	%	*N* 3	%	*N* 9	%	*N* 11	%	
Revisions	0	0	1	33	4	44	4	36	0.19
Complications	4	57	1	33	5	56	7	64	0.95

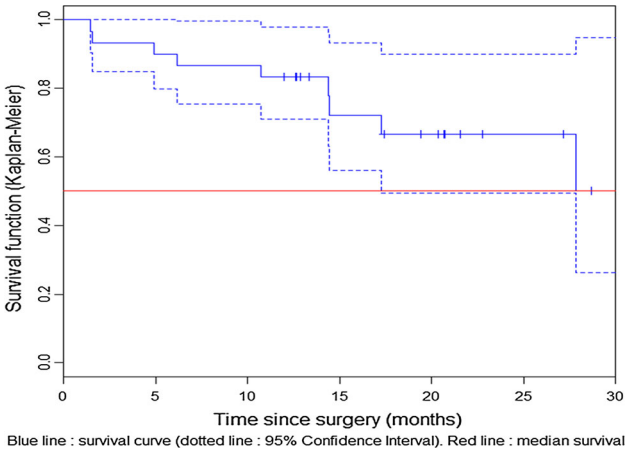

Fig. 11 Revision free survival of MCGR

operations, spinal cord monitoring, use of general anaesthesia, hospital stays, drug use, manpower, consumables, and time off work for the parents.

Akbarnia et al. confirmed these encouraging results in 2013 in a 14-patient prospective series. Cobb angle was improved, on average, from 60° to 31° at 10-month follow-up with a superficial infection and a painful rod [8].

The current series demonstrates satisfactory coronal deformity correction over time, and little improvement of T1 T12 and T1 S1 distances with MCGR, in accordance with the literature [8 10, 24 27], although with a higher complication rate. Indeed, we report 57% of complication in our series against 38.8% in the series of Choi et al. in 2016 (about 55 cases with a mean follow-up of 19.4 months) [26]. Concerning the revision rate, it is quite similar in both series with 27.8% in Choi et al.'s, vs 30% in ours [26]. This high rate of revision resulted in a revision-free survival of only 50% at 27.9 months in our study. However, with the non-invasive distraction of MCGR, an average 2.03 surgical procedures per patient were avoided at the end of follow-up if compared to a standard GR treatment.

Alike in Choi et al.'s study [26], most of the revisions and complications (rod breakage and proximal pull-outs) were not related to the MCGR implant itself. The distraction system failed in two cases only in our series. It was a backtracking of the rod with, both times, complete loss of the gained length. To the best of our knowledge, failure of the system with backtracking has been reported twice before in the literature: one case by Ridderbusch et al. [27] and six cases by Choi et al. [26].

As regards the other complications and revisions, we were not able to identify any risk factor, and these complications frequently occur both in MCGR and GR treatments [17, 26, 28, 29].

Some authors found a higher rate of rod breakage with single rod constructs [6, 17]. This hypothesis was not verified in the current series with a total of three breakages, of which two occurred in the same patient with a dual rod construct. Rod breakage rates in GR varied from 15% for Yang et al. [30] to 24% for Bess et al. [16]. Hickey et al. reported a single breakage in a six-patient series (13%) [9].

There was a gradual loss of effectiveness over the course of treatment in half of the cases. The so-called 'law of diminishing returns' described in GR seems applicable to MCGR from the 4th distraction session onward. The phenomenon was first reported by Sankar et al. [31] and represents the gradual decrease in length gain with each subsequent lengthening and over time, despite an increased distraction force applied. It may be explained by tissue scaring and stiffening of the instrumented segment [31, 32].

Rolton et al. [24] found also loss of effectiveness and incomplete distractions. In his study, the true to intended distraction ratio was calculated as 0.33; and the patients who had undergone previous surgery gained less distraction than the others.

Table 5 Influence of postoperative kyphosis and diagnosis upon distraction

	Trouble free distraction (*n* 15)		Problematic distraction (*n* 14)		*p*
Postoperative kyphosis (°)	30.8	±8	41	±1	0.18
Diagnosis					0.52
Idiopathic	2	13%	5	36%	
Congenital	2	13%	1	7%	
Syndromic	6	40%	3	21%	
Neuromuscular	5	33%	5	36%	

Table 6 Risk factors for revision surgery

	Revision free		Revision		*p*
	N 21	Range	*N* 9	Range	
Age at MCGR implantation (years)	9	(7; 11)	9	(8; 11)	0.42
Preoperative Cobb angle (°)	66	(52.2; 80)	73	(56.2; 77)	0.88
Preoperative thoracic kyphosis (°)	44.4	(33.9; 49.7)	32.5	(14.5; 40.8)	0.21
Preoperative lumbar lordosis (°)	50	(37; 59)	50.5	(31; 61.2)	0.90
Dual rod construct	8	38%	2	22%	0.67
History of GR treatment	5	24%	0	0%	0.29
Number of distraction sessions	5	(4; 8)	5	(1; 6)	0.19
Number of procedures per session	8	(5; 14)	6	(1; 11)	0.12
Proximal level instrumented					0.24
T1	6	29%	1	11%	
T2	7	33%	7	78%	
T3	5	24%	1	11%	
T4	3	14%	0	0%	
Distal level instrumented					NA
T10	1	5%	0		
T12	0		1	11%	
L1	0		1	11%	
L2	2	10%	1	11%	
L3	4	19%	2	22%	
L4	10	48%	3	33%	
L5	2	10%	0		
S1	2	10%	1	11%	
Diagnosis					0.19
Idiopathic	7	33%	0	0%	
Congenital	2	10%	1	11%	
Syndromic	5	24%	4	44%	
Neuromuscular	7	33%	4	44%	

It was not statistically significant in our study, but difficult distraction (blockage, backtracking, loss of effectiveness) was more frequent in case of marked postoperative thoracic kyphosis and in neuromuscular and syndromic cases. Syndromic and neuromuscular cases also tended to be more prone to surgical revisions.

We acknowledge several weaknesses to this study: the constructs and levels of instrumentation were heterogeneous, distractions were monitored either with radiographs or ultrasound imaging and the follow-up was relatively small. However, it represents the largest series of MCGR to date.

Conclusion

MCGR is a reasonable option in case of contraindicated or failed conservative treatment in EOS. It provides satisfactory deformity correction and avoids repeated surgical procedures for lengthening. However, it has substantial complication rate. Although less frequent than in GR, the law of diminishing returns also applies to MCGR.

Compliance with ethical standards

Conflict of interest There is no conflict of interest or funding or grants in this study.

Ethical approval Ethics Committee gave its agreement for this work.

Informed consent Informed consent was obtained from all individual participants included in the study.

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