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Treatment of Early-Onset Scoliosis with a Hybrid of a Concave Magnetic Driver (MCGR) and a Contralateral Passive Sliding Rod Construct with Apical Control: Preliminary Report on 17 Cases

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ABSTRACT

Background context: Magnetic controlled growth rods (MCGRs) are increasingly popular for surgical treatment of severe early-onset scoliosis (EOS), because they allow non-invasive extensions with good growth maintenance. We combined a MCGR with a contralateral passive sliding rod construct with apical control on the convex side to improve efficiency in terms of costs and 3D correction.

Purpose: To investigate the feasibility, 3D correction, spinal growth and complications of the apical control MCGR/sliding rod hybrid.

Study design: Two center retrospective cohort study.

Patient sample: A consecutive series of 17 EOS children from two European spine centers were treated with the hybrid principle: 13 primary cases and 4 conversion cases from other growth instrumentation. Median age at surgery was 9 years (range 6-18). Median follow up time was 24 months (range 12-31).

Outcomes: Cobb angles (frontal Cobb, kyphosis, lordosis), rotation, spinal length gain, growth rate and complications.

Methods: Radiographs and patient files were reviewed. All the patients received fully financed treatment within the national public healthcare systems.

Results: Mean preoperative frontal Cobb angle was 59°, reduced post-operatively to 30° and was maintained throughout follow up. Mean rotation of the apical vertebra improved from 27° to 20°, but was partially lost over time. Kyphosis decreased and lordosis was largely unaltered. Instrumented spine growth was maintained at a mean of 12 mm per year. One child had surgical revision due to progressive trunk shift, unrelated to the technique. The same child fell and acquired T1 & T2 fractures that were treated conservatively. Another child is planned for revision due to MCGR distraction failure.

Conclusion: These early results show satisfactory frontal Cobb curve reduction and maintenance of spinal growth after using a new hybrid concept of a single magnetic growth rod and contralateral apical control sliding rods.

A single magnetic growth rod in this combination may work equally well as traditional or dual magnetic growth rods. This new concept may represent a significant gain in both cost-effectiveness of growth rod treatment and 3D correction in EOS.

Level of evidence: Level IIb; Retrospective cohort

Introduction

Early-onset scoliosis (EOS) is a potentially life threatening condition that may need surgical intervention to ensure pulmonary function and development[1,2]. Several technical solutions have been developed in recent years aimed to allow for growth in a stabilized and corrected spine, and thereby retaining thoracic growth potential and pulmonary function[3–7]. Traditional distraction based growing rod systems require frequent surgical lengthening procedures[8]. Gliding systems providing "guided growth" are alternatives, e.g. the Luque Trolley[7] and the Shilla system[6]. These systems all have disadvantages: multiple planned surgical lengthening procedures, unpredictable lengthening capacity and a high frequency of reoperations[9–12].

The worldwide application of magnetic controlled growth rods (MCGR) that allow for non-invasive lengthening has increased over the recent years. Early results from several papers are promising and suggest efficacy and cost-effectiveness of the system[5,13–16]. The technique (Magec, Ellipse Technologies Inc., Irvine, California, USA) was approved in 2014 by The United States Food and Drug Administration (FDA) for use in the USA. The manufacturer recommends to use two magnetic rods per patient, that might rely on recommendations in the literature[17,18]. One of the disadvantages of the system is the relatively high initial costs of the magnetic rods. Other disadvantages of the double MCGR application may be the lack of apical control[19], and difficulties in balancing the growth action of the two rods.

We have utilized a hybrid technique, using a single MCGR to drive the lengthening on the scoliosis concave side combined with a passive sliding system with apical control on the convexity. The sliding system allows for passive lengthening during growth and interval MCGR extension procedures.

The purpose of this study is to investigate the feasibility, 3D correction, spinal growth rate and complications of a combined spinal growth principle with a hybrid system consisting of a single concave MCGR and a passive convex sliding system with apical control on the convexity. We report the early experiences and the preliminary results from two European scoliosis centers, Department of Orthopaedics, University Medical Center Utrecht, Utrecht, The Netherlands (Utrecht), and Department of Orthopaedics, Aarhus University Hospital, Aarhus, Denmark (Aarhus).

Materials and methods

Study design

This is a two-center retrospective cohort study with growth assessment, 3D correction and complication registration. All patients received fully financed treatment within the national public healthcare systems in Denmark/The Netherlands.

Patients

We included all patients that were operated from September 24, 2014 to May 3, 2016 and received the hybrid system consisting of a single MCGR on the concave side and a sliding system with apical control on the convexity. This yielded 17 consecutive patients (Table 1) with completed 1 year or longer postoperative radiographic follow-up, and a minimum of 4 lengthening procedures.

All the patients were skeletally immature and had a progressive scoliosis of at least forty degrees prior to primary surgery.

Surgical Techniques

Standard surgical techniques were used on all patients. The patients were placed in balanced prone position without traction, cell saver and intraoperative neuromonitoring was used according the local procedure guidelines.

Proximal and distal anchors were created through separate skin incisions, each consisting of at least 2 consecutive vertebrae. An apical anchor was created in addition unilaterally on the convex side by one or more pedicle screws. The anchor vertebrae were decorticated, facet joints removed and local and/or autologous bone graft was placed to stimulate fusion. On the concave side a MCGR was inserted under distraction. On the convexity, the sliding system was fixed to the apex and both rods were contoured proximally in kyphosis and distally in lordosis.

In Utrecht, the 5.5mm Mesa (K2M, Leesburg, Virginia, USA) and Magec systems were used. The convex sliding bar was mounted to the proximal and distal anchors by parallel connectors with the oversize hole left open for the rod (Figure 1A).

In Aarhus, the Xia (Stryker, Kalamazoo, Michigan, USA) and K2M Mesa 4.5 or 5.5 CD Horizon Legacy (Medtronic, Minneapolis, USA) system and Magec 4.5 or 5.5 rods were used. For the convex sliding part, the CB system (Cody Bünger system) was applied, mounted on the three anchors. A pre-bend oversized blunt test rod was used to tunnel subfacially to make room for the growth rods. Two longitudinal connectors and three rods were assembled and tunneled in place. The connectors were unlocked in one end to allow passive sliding (Figure 1B).

Post-operative care

Patients stayed in recovery unit up to 24 hours after surgery, unless their general condition mandated admission to the intensive care unit. No braces or restraints were applied except that the children were asked to refrain from uncontrolled load bearing (e.g. contact sports, jumping trampolines and lifting heavy loads).

The MCGR was extended by external magnetic stimulation on an outpatient basis, at approximately 2,5-3 month intervals. Biplanar radiographs were taken post-operative and at 6 months follow up intervals.

Data collection

Demographics, medical history, pre-, per- and post-operative clinical parameters were recorded from the electronic patient file. 3D deformity measurements were performed on standard digital biplanar scoliosis radiographs (Figure 1). We measured: the Cobb angle of the main curve (the postoperative scoliosis angles presented are the maximum angles of the main curve), the kyphosis and lordosis Cobb angles and the rotation according the well described Nash-Moe method[20,21]. We realize that the Nash-Moe method is less accurate than CT imaging[22], but we do not use 3D imaging routinely at our institutions.

Height gains were measured after the radiographs were calibrated with the diameter of the MCGR actuator (narrow part 9.02mm, wide part 10.50mm). The perpendicular distance between horizontal lines through midpoints of the chosen vertebral endplates was used. We measured the thoracic height (T1-T12) from upper endplate T1 to lower endplate T12, the T1-S1 height (T1-S1) from upper endplate T1 to upper endplate S1, and the instrumented height, the span of instrumentation: from the upper endplate of the most cranial instrumented level to lower endplate of the most caudal instrumented level. Length gain rates were calculated using measurements from the first post-operative radiographs as baseline and the exact follow up time. The measurements were performed in collaboration by investigators from both centers (STS and SW).

Statistics

Statistical analysis was performed with SPSS version 24.0 with a level of significance of $p<0.05$. Before and after surgery outcomes were analyzed with paired t-tests. The growth rates were tested using the null hypothesis of zero growth. If the data appeared to be non-normally distributed, the Wilcoxon signed-rank test was used.

Results

Patient demographics (Table 1)

Our series consisted of 17 patients, 9 and 8 patients respectively from each center: 13 primary cases and 4 conversion cases from other growth rod instrumentation systems. The etiology was 53% neuromuscular, 29% idiopathic and 18% syndromic. One girl was 18 years old when her growth instrumentation was converted to MCGR lengthening but she was small for age with delayed skeletal maturity.

Surgical parameters (Table 2)

Mean overall surgery time for the procedures was 192 minutes (range: 96-278). No intra-operative complications occurred. Mean admission time was 5.4 days (range: 1-12). Details on etiology, instrumented levels and hardware used are given in Table 3.

Radiographic outcomes (Table 4, 5, 6)

Overall, primary scoliosis curve correction was 49% from 59° (range: 26-86) to 30° (range:8-49) (Table S1, Supplementary Appendix), p<0.01. This correction was maintained throughout follow up (Figure 2). The rotation was reduced 33%, from 27° to 18°, p<0.01, but increased slightly to 20°. Kyphosis decreased and lordosis was largely unaltered, both were unaltered throughout follow up.

The average T1-S1 height increased from preoperative 309 mm to 334 mm after primary correction, and grew to 347 mm at 1 year follow up (Figure 3), averaging an annual T1-S1 growth rate of 12 mm/year during the first postoperative year, p<0.01. The instrumented height (the span of the instrumentation) increased from an average of 237 mm pre-operatively to 258 mm after primary correction, and grew to 273 mm at 1 year follow-up. Averaging an annual instrumented growth rate of 13 mm during the first postoperative year, p<0.01. The length gains per year indicate a steady growth of approximately 1 cm/year in all length parameters. The primary and conversion cases showed similar length gains during the entire follow-up with an instrumented spinal growth rate in primary cases of 12±10 mm/year and 13±5 mm/year for the conversion cases.

Complications

One defect MCGR was encountered before implantation but no procedure related adverse events were registered during implantation. Four instrumentation related complication occurred after implantation (Table 1, Supplementary Appendix). One due to selection of the caudal instrumentation level in an 11-year-old girl with osteogenesis imperfecta. The resulting progressive trunk shift between 3 and 6 months follow up was solved by surgically reversing the sliding convex rod into lumbar distraction. The same girl fell and acquired low energy T1-T2 fractures (AO Type A1), located above the proximal instrumentation. She was treated conservatively with a cervicothoracic brace and the following lengthening procedure was one month postponed, allowing fracture healing without sequelae.

In three occasions the MCGR failed to distract at one of the lengthening sessions. One failure may be accounted to too much tension as the subsequent lengthening procedures were successful. Another patient was planned for MCGR revision but distraction was successful when light head traction and external compression was applied during general anesthesia and open procedure was cancelled. Distraction was achieved in subsequent lengthenings. One patient with normal lengthening for 1.5 year, is planned for earlier final fusion since lengthening failed the last 9 months and a CT scan shows obvious facet fusions. Some patients experienced anxiety at the first lengthening procedure but this declined in the subsequent procedures and some patients experienced minimal discomfort especially when the actuator stalled. Pain level was minimal, only a few patients were administered a few doses of paracetamol for the lengthening procedures. No early/late infections or obvious material failures were experienced.

Discussion

These preliminary results suggest that a combination of a single MCGR as growth engine and a contralateral passive sliding system with apical control is feasible although some complications were identified.

The 49% frontal Cobb angle correction and maintenance was comparable to other MCGR results reported in the literature (32-58% correction)[14–16,23,24]. In 2013, Dannawi et al.[15] presented similar 1-year results for 34 MCGR patients, with a T1-S1 growth rate of 10.4

mm/year. Akbarnia et al.[23] published 2-year results of 12 patients with a slightly lower growth rate of 8.1 mm/year. Hickey et al. (2014)[14] showed growth rates of only 6 mm/year in their 2 year follow up although this was 12 mm/year in the conversion cases.

Considering the median age of our study population, the instrumented length gain was within the expected annual spinal growth, which is estimated between 1 and 1.8 cm/year (closer to 1cm/year)[25]. If this hybrid approach indeed works equally well as double MCGRs, it may represent another significant gain in cost-effectiveness of growth rod treatment in early-onset scoliosis. Whether the additional apical control is another advantage, remains to be investigated.

Obviously, our data are preliminary and with longer follow up we should anticipate new complications such as rod breakage, screw pull-out or lack of spine growth/length gain. However, the absence of such complications in 16 of our first 17 patients is encouraging. Another limitation of this study is the relatively large variation in length gain measurements, with even a slight decrease in one or more of the post-operative height parameters in three patients at last follow up. In these cases, the decrease may be explained by the fact that some of the early postoperative radiographs were in prone position while subsequent imaging was performed in standing or sitting position. We re-evaluated the dataset without the outliers and the resulting length gain rates were similar. However, this emphasizes the need for standardized radiographs. Finally, there were differences between the groups operated at the two institutions (e.g. age at index surgery, proportion of conversions), together with the limited number of patients this made direct comparisons between the two hybrid techniques inappropriate. On the other hand, the merged data may be considered more representative for the hybrid approach in general.

Conclusions

This preliminary report suggests that the application of a single MCGR combined with a contralateral sliding rod construct with apical control is feasible with few complications. Curve correction and spinal growth were on par with dual MCGRs. In seventeen patients, there was one unplanned surgery due to an adverse event not specifically related to this hybrid technique, and one definitive fusion is planned earlier because of spontaneous facet fusion.

This new concept may represent a significant gain in cost-effectiveness of growth rod treatment of early-onset scoliosis.

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Figure legends:

Figure 1A: University Medical Center Utrecht, The Netherlands; Combined single magnetic rod and parallel block sliding rod system.

Frontal and sagittal plane radiographs: pre-operative, first post-operative and at last follow-up. The relevant length measurements are sketched.

Figure 1B: Aarhus University Hospital, Denmark; Combined single magnetic rod and CB system.

Frontal and sagittal plane radiographs: pre-operative, first post-operative and at last follow-up.

Figure 2: Frontal Cobb angle:

Frontal Cobb angle over time. °, mean value (95% confidence interval). N=17 patients.

Figure 3: T1-S1 Height:

T1-S1 Height over time. mm, mean value (95% confidence intervals). N=17 patients.

TABLES

Table 1: Patient demographics

	All (n=17)	Utrecht (n=9)	Aarhus (n=8)
No. of Patients (Male : Female)	4 : 13	3 : 6	1 : 7
MCGR Case (Primary : Conversion)	13: 4	8 : 1	5 : 3
Etiology (no. of patients) **Neuromuscular : Idiopathic : Syndromic**	9 : 5 : 3	4 : 4 : 1	5 : 1 : 2
Frontal Cobb preoperative (°) **Mean; (95%CI); Range**	64 (58-70); 42-86*	63 (53-72); 42-86	66 (58-74); 46-84*
Age at surgery (years) **Median; Range** **Age at primary surgery** **Age at MCGR surgery**	8.8 (6.4-15.8) 9.0 (6.4-18.1)#	8.2 (6.4-9.3) 8.3 (6.4-9.3)	11.0 (6.9-15.8) 11.9 (6.9-18.1)
Postoperative FU (months) **Median; Range** **FU from primary surgery** **FU from MCGR surgery**	25 (12-65) 24 (12-31)	24 (12-36) 24 (12-30)	29 (12-65) 20 (12-31)
MCGR lengthening procedures (No.)	105	57	48

FU: follow up. MCGR: magnetic controlled growth rod
Primary surgery: first scoliosis growth instrumentation surgery.
*Including pre-primary growth instrumentation Cobb angles in conversion cases.
One patient was still skeletal immature at age of 18 years.

Table 2: Surgical details

	Utrecht (n=9)	Aarhus (n=8)
Surgery time (minutes): Mean; Range	200 (135-278)	183 (96-260)
Days of admission (days): Mean; Range	6.4 (3-12)	4.3 (1-7)
Instrumented levels* (No. of levels): Mean; Range	13 (11-16)	14 (12-16)

*Defined as the full span of the instrumentation (from the highest to lowest level of fixation).

Table 3: Instrumentation; individual details

Patient#	Age	Sex	Etiology	Previous treatment	Concave side (Upper levels <-> Lower levels)	Convex side (Upper levels <-> Lower levels)	Apical levels
Utrecht 1	7.5	F	Neuromuscular	None	5.5mm MCGR (T4;T5↔L4;L5)	5.5mm rods + PB (T4;T5↔L4;L5)	T12
Utrecht 2	8.2	M	Idiopathic	None	5.5mm MCGR (T3;T4↔T12;L1)	5.5mm rods + PB (T3;T4↔T12;L1)	T7
Utrecht 3	6.7	F	Neuromuscular	Brace	5.5mm MCGR (T3;T4↔L5;S1;S2;ilium)	5.5mm rods + PB (T3;T4↔L5;S1)	T12;T11
Utrecht 4	9.0	F	Neuromuscular	Brace	5.5mm MCGR (T2:T3;T4↔L4;L5)	5.5mm rods + PB (T3;T4:T5↔L4;L5)	T10
Utrecht 5	8.7	F	Syndromic	MCGR +Shilla	4.5mm MCGR (T3;T4↔T12;L1)	4.5mm rods + PB (T3;T4;T5↔T12;L1)	T10
Utrecht 6	9.3	M	Idiopathic	None	5.5mm MCGR (T3;T4↔L1;L2)	5.5mm rods + PB (T2;T4↔L1;L2)	T8;T9;T10
Utrecht 7	8.8	M	Neuromuscular	Brace	5.5mm MCGR (T3;T4↔L3;L4)	5.5mm rods + PB (T3;T4↔L3;L4)	T8;T9;T10
Utrecht 8	7.2	F	Idiopathic	Brace	5.5mm MCGR (T3;T4↔T12;L1)	5.5mm rods + PB (T3;T4↔T12;L1)	T9
Utrecht 9	6.4	F	Idiopathic	None	5.5mm MCGR (T2;T3↔T12;L1)	5.5mm rods + PB (T3;T4↔T12;L1)	T8
Aarhus 1	6.9	F	Neuromuscular	Brace	4.5mm MCGR (T3;T4↔L3;L4)	4.5mm rods + CB (T3;T4↔L3;L4)	T10;T11
Aarhus 2	9.8	F	Idiopathic	CB system	4.5mm MCGR (T4;T5↔L2;L3)	4.5mm rods + CB (T4;T5↔L2;L3)	T9;T10
Aarhus 3	10.2	F	Neuromuscular	Brace	5.5mm MCGR (T4;T5↔L4;L5)	4.5mm rods + CB (T4;T5↔L4;L5)	T10;T11
Aarhus 4	18.2	F	Neuromuscular	CB system	5.5mm MCGR (T3;T4↔L3,L4)	4.5mm rods + CB (T3,T4↔L3,L4)	T10;T11
Aarhus 5	11.7	F	Neuromuscular	Brace	5.5mm MCGR (T3;T4↔L2;L3)	4.5mm rods + CB (T3;T4↔L2;L3)	T7;T8
Aarhus 6	12.2	F	Syndromic	Brace	4.5mm MCGR (T3;T4↔L3;L4)	4.5mm rods + CB (T3;T4↔L3;L4)	T9;T10
Aarhus 7	12.6	F	Neuromuscular	Brace	4.5mm MCGR (T1,T2↔L3,L4)	4.5mm rods + CB (T1,T2↔L3,L4)	T10,T11
Aarhus 8	12.9	M	Syndromic	CB system	5.5mm MCGR (T2,T3↔L1,L2)	4.5mm rods + CB (T2,T3↔L1,L2)	T7,T8

Age: Age at magnetic rod implantation. M: Male. F: Female. PB: Parallel block. CB: Cody Bunger system. MCGR: magnetic controlled growth rod.

Table 4: 3D correction; Angle and rotation (°); mean±SD(range)

	Pre-op	Post-op	Last FU
Frontal Cobb	59 ± 17 (26-86)*	30 ± 12 (8-49)	31 ± 12 (12-59)
Rotation Nash-Moe	26 ± 9 (13-42)	18 ± 8 (5-31)	20 ± 9 (7-36)
Kyphosis T4-T12	27 ± 18 (2-67)	20 ± 12 (4-53)	21 ± 15 (0-60)
Lordosis L1-L5	38 ± 17 (6-65)	34 ± 13 (17-57)	39 ± 12 (19-59)

Radiographs evaluated: pre-op, before magnetic rod implantation surgery; post-op, before discharge from hospital; and at last follow up. FU: follow up.

*Immediate before magnetic rod implantation; Pre-primary growth instrumentation: 64±14 (42-86).

Table 5: Spinal length in mm; mean±SD(range)

	Pre-op (n=17)	Post-op (n=17)	1 year FU (n=17*)
T1-S1	309 ± 36 (270-387)	334 ± 30 (298-387)	347 ± 29* (308-388)
T1-T12	193 ± 20 (165-237)	205 ± 15 (187-230)	215 ± 17* (190-248)
Instrumented	237 ± 40 (173-308)	258 ± 40 (189-340)	273 ± 43* (212-320)

Radiographs evaluated: pre-op, before magnetic rod implantation surgery; post-op, before discharge from hospital; and at 1 year. FU: follow up.

*Two patients missed the 1 year follow up, measures from the nearest later radiographs were applied.

Table 6: Spinal length gain rate standardized to mm/year; mean±SD(range)

	Length gain rate at 1 year FU (N=17)*	Length gain rate at last FU (n=17)
T1-S1	12 ± 12 (-7-35)	13 ± 11 (-7-34)
T1-T12	8 ± 7 (-2-20)	9 ± 7 (-2-24)
Instrumented	13 ± 11 (-9-37)	12 ± 10 (-9-30)

Length gain rates were calculation based on exact radiographic follow-up time after MCGR implantation. FU: follow up.

*Two patients missed the 1 year follow up, measures from the nearest later radiographs were applied.