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Magnetically controlled growing rods in early-onset scoliosis

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ABSTRACT

Introduction. Early-onset scoliosis (EOS) may result in disability and a reduced life expectancy. The aim of this study was to report the results of primary magnetically controlled growing rods (MCGR) in a consecutive group of patients with EOS diagnosed and operated at Aalborg University Hospital, Denmark, from 2009 and onwards and with at least two years of follow-up.

Methods. Data were extracted from the electronic patient records and the Picture Archiving and Communication System. All data were extracted by an unbiased observer. Demographics, any complication and the Cobb angles and maximal kyphosis angles preoperatively and post-operatively were recorded. Likewise, the total expansion of the MCGR and the increase in T1-T12 and T1-S1 heights were recorded.

Results. A total of 15 patients (three females) were followed for an average of 3.75 years. The Cobb angles were corrected on average by 68% and the maximal kyphosis angle by 45%. The thoracic height increased significantly with only two patients (still undergoing expansions) with a T1-S1 height below 22 cm. Four complications were recorded (one deep infection and three non-functioning rods), all resulting in rod exchange. The complication rate was 27% or 0.07 per patient per year.

Conclusions. The MCGR may reduce the deformity and support thoracic and pulmonary growth without any need for repeated surgeries. The number of complications in the present series was low compared with the literature with an average of 0.07 complications per year per patient or a total complication rate of 27%.
Funding. none.

Trial registration. not relevant.

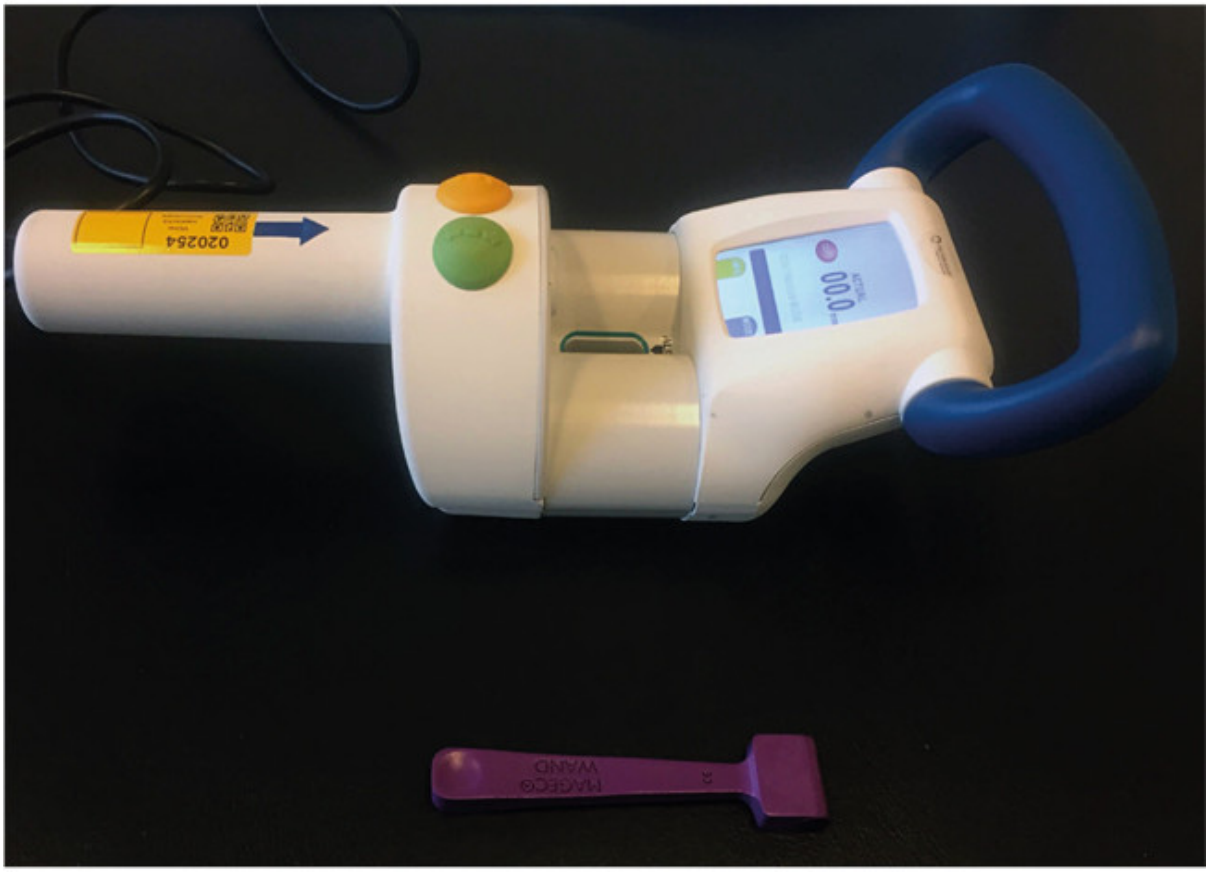
Early-onset scoliosis (EOS) defined as scoliosis (Cobb angle > 10°) presenting before the age of ten [1] is a rare but often severe condition. It is well known that left untreated, EOS may lead to increased disability and potentially life-threatening conditions such as respiratory insufficiency and pulmonary hypertension and a reduced life expectancy [2]. The aetiologies of EOS are idiopathic, neuromuscular, congenital and syndromic with a wide spectrum of underlying diagnoses [1].

The treatment goals are three-fold 1) preservation of thoracic growth including lung growth and pulmonary function, 2) preservation of quality of life and 3) correction of deformity [3].

Non-operative treatment consists of bracing and serial casting [4]. However, patients with EOS due to an underlying neuromuscular syndrome usually do not respond favourably to bracing (radiographic progression) and serial casting may only postpone surgery for a limited amount time [4, 5].

The traditional growing rods (TGR) require distractions to be performed as open surgery in general anaesthesia every six months. It is unsurprising that the magnetically controlled growing rods (MCGR) have gained widespread use. The pain-free lengthenings are done every second to third month in the outpatient clinic using an external actuator placed on the skin of the patients (**Figure 1**). MCGR have been used as the surgical solution for EOS at our institution for the past decade. But MCGR use is not without complications. Some studies record the frequency of complications to reach 50% [6, 7].

FIGURE 1 The external actuator (to be placed on the skin of the patients) with display on 0.0 and the magnet finder (lilac colour).



The aim of this study was to report the results of primary MCGR implantation in a consecutive group of patients with EOS diagnosed and operated at Aalborg University Hospital from 2009 and onwards and with at least two years of follow-up with special regard to thoracic growth, deformity correction and complications.

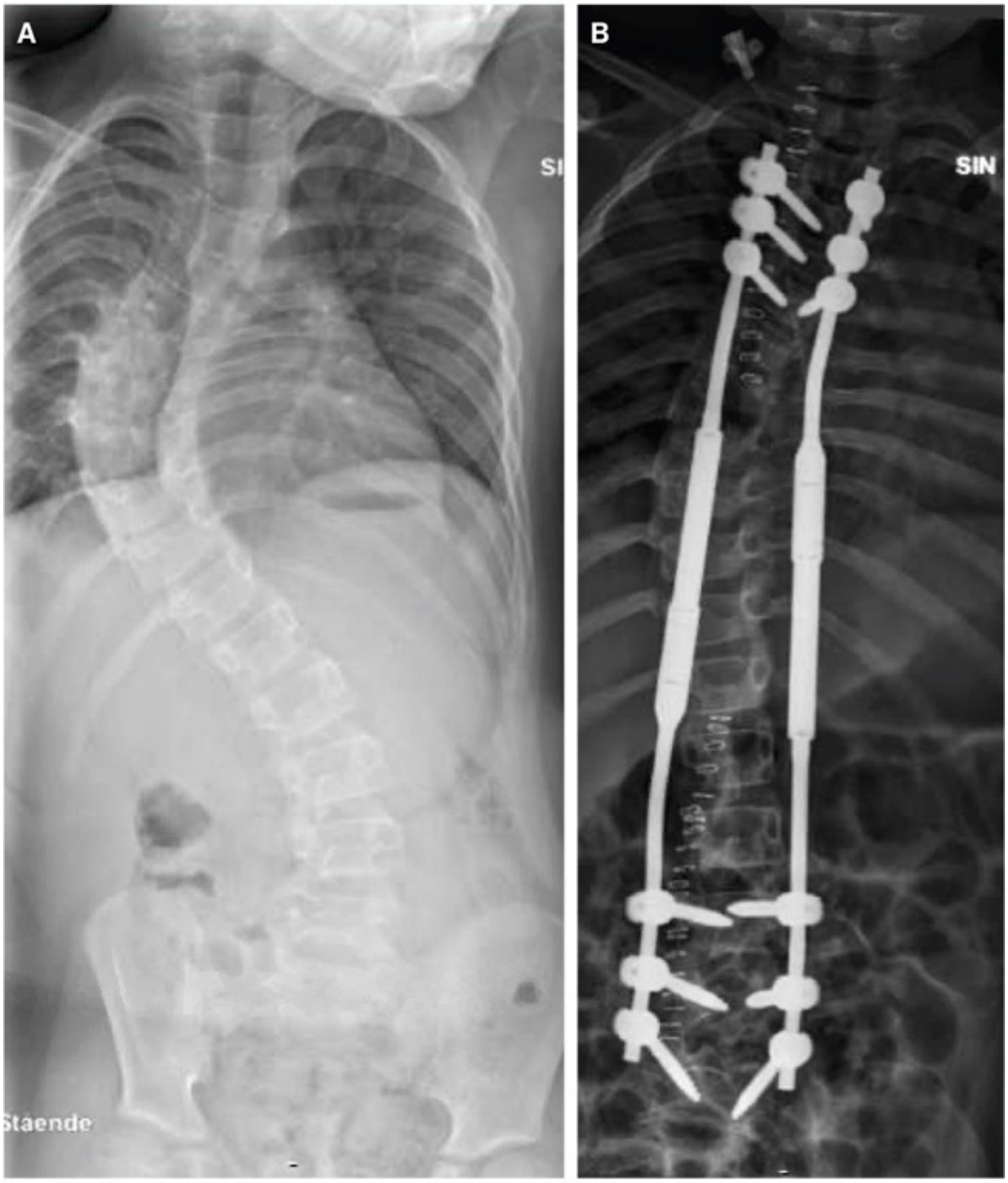
METHODS

Only patients without prior spine surgeries were included. All data were extracted from the electronic patient records (Clinical Suite from DXC. Technology, version 21.0.5.0) and the Picture Archiving and Communication System using the radiographic imaging viewer (EasyViz, 8.0.8-37el7.final). Data acquisition and measurements were all done by the same unbiased observer (first author). Sex, age, weight and date of the primary surgery were recorded along withspecific diagnoses, mobility (e.g., the ability to walk), survival, complications and rod

exchanges. The following complications were recorded: No rod distraction before the rod had reached its full lengthening potential requiring rod exchange, rod malfunction (other than no distraction), rod breakage, screw breakage, screw loosening, infection, proximal junctional failure and distal junctional failure.

The height from T1-T12 and T1-S1 as well as the Risser Classification were measured on radiographs taken immediately before the primary surgery. The T1-T12 and T1-S1 height were measured again on the latest post-operative radiographs. The spinal height was measured as the perpendicular between two parallel lines passing through the centres of the chosen endplates. The Cobb angle and the thoracic kyphosis angle were measured pre- and immediately post-operatively and again on the latest post-operative radiographs. Rod size, level of instrumented vertebrae and number of anchors were recorded as noted in the procedure description and by analysing the immediate post-operative X-rays. Only the MAGEC system (Nuvasive inc., US) generation 2 was used. Two MCGR and pedicle screws anchors only were used in all cases (**Figure 2**).

FIGURE 2 Pre- (**A**) and immediately post-operative (**B**) radiographs before and after insertion of two magnetically controlled growing rods and fixation with pedicle screws.



All MCGRs were implanted from the thoracic to the lumbar part of the spine. One proximal and one distal incision were used in all cases and the rods were tunnelled between these two incisions. Interlaminar and/or posterolateral fusion with allograft was performed on the anchor levels after decortication. To place the pedicle screws correctly, O-arm 3-D scanning and navigation using the StealthStation S7/8 were used in all cases. A thoracolumbar orthosis was used for three months after the operation. Distraction was done every second to third month starting three months after implantation of the MCGR. The distraction-to-stall method of lengthening was used in all cases on both rods.

When a distraction force of approximately 250 Nm is obtained, the internal actuator automatically stops and a clunk is felt. The alternative is to base the amount of distraction on published growth charts – "tail-gating". It was shown that the distraction-to stall method results in a satisfactory spinal height increase and produces results comparable to those of the tail-gating method [8]. The patients had digital X-rays taken immediately before and after surgery and after each outpatient lengthening session. The number of lengthening or distraction sessions was counted, and the delta distraction of both rods was measured on the digital radiographs as described previously [9].

Statistical analysis was undertaken using base R (R version 4.02). Continous variables were expressed as mean ± standard deviation or median and range. Non-parametric analysis was performed using the Wilcoxon signed rank test. A p-value of < 0.05 was considered statistically significant. The Bonferroni correction for repeated measures was applied.

The study was approved by the local ethics board at Aalborg University Hospital. As this was a quality control study using retrospectively collected data, review and approval by the National Committee on Health Research Ethics were not required under Danish law.

Trial registration: not relevant.

RESULTS

Table 1 shows the patients demographics, Cobb angles and maximal kyphosis angles preoperatively, immediately after surgery and at the last follow-up. The specific diagnoses were five with cerebral palsy, one chromosomal abnormality, one myelomeningocele, one spinal muscular atrophy type 2, one giant axonal neuropathy (GAN), one POLG1 mutation (Leigh's syndrome) and one Nemaline myopathy, two Prader Willi, one VACTERL syndrome, one Rett syndrome and one patient with multi-level congenital spinal anomalies. Eleven were non-walkers. The mean initial Cobb angle correction from preoperatively to immediately post-operatively was 67.7%, standard deviation (SD): ± 18.1%. At the last follow-up, this had decreased to a mean 60.2%, SD: ± 18.5%. The mean maximal kyphosis angle decreased from preoperatively to post-operatively by 40.2%, SD: ± 20.1% and to a mean 30.1%, SD: ± 27.4% at last follow-up.

TABLE 1 Demographics, Cobb angles and maximal kyphosis angles preoperatively, immediately post-operatively and at last follow-up, plus mean ± standard deviation and median values.

					Cobb angle, °			Maximal kyphosis angle, °		
	Age, yrs	Sex	Weight, kg	Aetiology	pre-op.	post-op.	last FU	pre-op.	post-op.	last FU
Patient ID										
1	5	Male	14	Syndromic	45	15	16	34	17	19
2	2	Male	10	Congenital	51	29	31	25	25	36
3	7	Male	30	Syndromic	75	37	39	33	25	31
4	10	Male	37.6	Syndromic	40	5	10	45	24	29
5	8	Female	22	Neuromuscular	41	14	12	30	22	24
6	10	Male	26.6	Syndromic	97	32	19	38	21	27
7	10	Male	30	Neuromuscular	44	3	5	44	35	36
8	12	Female	30	Neuromuscular	74	30	32	71	31	35
9	9	Female	22	Neuromuscular	41	2	7	80	27	32
10	9	Male	29	Syndromic	46	3	8	43	25	30
11	9	Male	25	Neuromuscular	72	45	39	38	32	31
12	7	Male	32	Neuromuscular	52	23	32	72	34	43
13	4	Male	14	Neuromuscular	38	15	22	57	14	14
14	12	Male	33	Neuromuscular	47	12	28	37	24	28
15	10	Male	33.5	Neuromuscular	42	14	22	75	38	43
Mean ± SD	8.3 ± 2.8	-	25.9 ± 8.1	-	53.6 ± 17.4	18.6 ± 13.4	21.4 ± 11.7	48.1 ± 18.2	26.3 ± 6.62	30.5 ± 7.8
Median	9.0	-	29.0	-	46.0	15.0	22.0	42.8	25.4	30.6

FU = follow-up;post-op = post-operatively; pre-op = preoperatively; SD = standard deviation.

Table 2 shows the total distraction in mm for the convex and concave rod and the number of distractions, T1-T12 height and T1-S1 height in cm preoperatively and at the last follow-up, follow-up time in years and the number of proximal and distal anchors. The mean increase in T1-T12 height from immediately preoperatively to the last follow-up was 51.3 mm SD ± 22.3 mm. The mean increase in T1-S1 height from immediately preoperatively to the last follow-up was 84.0 mm SD: ± 36.1 mm. The differences in Cobb angles and maximal kyphosis angles pre- and post-operatively and between preoperatively and the last follow-up were all significant with p-values ≤ 0.001. Likewise, the increases in the T1-T12 and T1-S1 heights from preoperatively to the last follow-up were all significant with p-values ≤ 0.001. The Bonferroni correction requires that all p-values are below 0.008.

TABLE 2 Total expansion of the convex and concave rods and number of distractions, T1-T12 heights and T1-S1 heights preoperatively and at last follow-up, follow-up time, number of proximal and distal anchors, and mean ± standard deviation and median values.

	Distractions									
	expansion, mm			T1-T12, height, mm		T1-S1, height, mm			Proximal	Distal
	concave rod,	convex rod	n	pre-op.	last FU	pre-op.	last FU	FU time, yrs	anchors, n	anchors, n
Patient ID										
1	38	35	17	183	210	281	328	2.9	6	4
2	60	56	33	147	204	223	323	6.8	5	4
3	25	31	11	183	247	290	395	3.0	6	6
4	19	24	19	205	262	328	416	3.2	4	4
5	34	34	8	210	271	333	423	2.3	6	6
6	29	28	11	228	258	357	420	2.0	6	4
7	20	26	15	240	296	360	424	2.8	6	6
8	16	13	12	199	235	316	368	5.3	6	4
9	22	23	14	201	241	321	380	3.5	6	6
10	27	30	10	214	272	340	421	2.2	6	6
11	62	66	30	209	272	309	438	6.0	4	4
12	37	31	10	216	230	357	401	2.5	6	6
13	32	31	31	156	249	230	379	6.9	4	4
14	31	33	13	239	326	360	507	4.3	6	4
15	24	31	13	246	272	399	441	2.7	6	6
Mean ± SD	31.5 ± 13.5	32.7 ± 12.8	16.5 ± 8.2	205 ± 29	256 ± 31	320 ± 49	404 ± 46	3.75 ± 1.7	5.5	4.9
Median	28.7	31.0	13.0	209	258	328	416	3.0	-	-

FU = follow-up; post-op = post-operatively; pre-op = preoperatively; SD = standard deviation.

We did not register any intraoperative complications. Three out the of the 15 patients had the complication “no rod distraction” on one of the rods before the rod had reached its full lengthening potential. The non-functioning rods were exchanged for new ones and the repeated lengthenings were continued. Mild-to-moderate metallosis around the rods was seen in all the three above-mentioned cases at surgery. One patient had deep wound infection and required reoperations with subsequent exchange of the rods. No other complications were recorded. Our total complication rate is 27% with a 7% infection rate. The revision rate per patient per year of follow-up was 0.07 (number of complications/number of patients/average follow-up time). Two patients had rod exchange because the rods had reached their full lengthening potential, making it a planned revision. In six patients at or near maturity, it was decided to stop lengthenings. These six patients will be followed for signs of rod breakage and screw loosening, etc. and controlled in the outpatient clinic annually. So far, none of these patients have experienced any complications. One patient at or near maturity had the MCGR removed and underwent final scoliosis surgery without any complications. One death was recorded in the observation period caused by the severe underlying disease.

DISCUSSION

Patients with EOS constitute a very diverse group, which is also evident from the present case series. Neuromuscular diseases were the main cause of EOS in the present case series. Several patients had severely compromised pulmonary function and were either using some kind of respiratory support or had a story of repeated bronchopulmonary infections. Five of the patients had progressive neuromuscular disease. Most of the

patients would not have tolerated the repeated surgeries, which are an inevitable part of TGR treatment. Repeated spine surgeries in children have also been shown to have adverse psychological effects [10].

The deformity correction in the present series was satisfactory and supprior to those reported in most other case series [3, 6, 11-14]. The deformity correction is explained by a high number of patients with neuromuscular disease and hypotonus (collapsing spine), the use of double rods and the fact that only primary cases were included. The decrease from immediately post-operatively to last follow-up is a constant part of the treatment with MCGRs and is an almost universal fact [14]. The mean correction of the maximal thoracic kyphosis angle in the present study must be considered adequate. It is inevitable that some correction will be lost simply due to the distractions which tend to increase the thoracic kyphosis. We did not register any cases of proximal or distal junctional failure. We took great care to bend the upper part of the rods into a configuration resembling the high thoracic kyphosis present and not to force a reduction of this part of the curve.

A T1-T12 height of 22 cm is considered adequate [15]. All but two of the patients reached this limit – and the last two of the patients are still undergoing repeated distractions. A T1-S1 height of 45 cm at skeletal maturity is considered normal. However, given the patients in the current case series, it would be a mistake to believe that they can reach this value of normality. The total amount of distraction of the MCGRs averaged approximately 33 mm or on average approximately 9 mm annually. Without doubt the correction of the Cobb angle and the kyphosis angle has contributed to the increase in T1-T12 and T1-S1 height. The distraction capability depends on several factors – the most common being mechanical malfunction of the rod. As the MCGR is capable of delivering a force of only 250 Nm, the weight of the patient is probably also a factor.

The number of complications compares favourably with other case series [3, 6, 7, 11-14]. We attribute this to the use of pedicle screws as anchors, to the use of the O-arm/navigation, the use of a thoracolumbar brace for three months, the exclusion of conversion cases from TGR and the high number of anchors. It is a fact that after a certain number of distractions, the MCGR will stop functioning and will often do so before the MCGR has reached the full 48 mm of distraction. However, the “law of diminishing returns” may be counteracted with the exchange of the MCGR [16] – a fact we can corroborate.

Two of the patients cannot strictly be classified as EOS patients as they were 12 years of age at surgery. The first case was the patient with Retts syndrome, epilepsy and severely compromised respiratory function. She has only recently entered puberty (18 years old). The second was the patient with GAN. He was a candidate for intrathecal injections with a vector-mediated therapy for GAN. In the first case, we wanted the surgery to be as minimal as possible and in the second case ordinary scoliosis surgery would have excluded the possibility of gene therapy as it requires intrathecal injection at the level of the third lumbar vertebra.

For the same reasons, we opted to leave in the rods in six cases to avoid further surgery in these very frail patients with severely compromised respiratory function and a multitude of other diseases. Currently, this has not resulted in additional surgeries. Our normal strategy would be instrumented fusion after stopping distractions.

The limitations of the current consecutive case series are obviously the small number of patients and the retrospective design. However, this is not unusual as EOS is a rare disease with diverse aetiologies. The number of cases in other case series falls in the 15-44 range [3, 6, 7, 11-14]. The use of MCGR was first described in 2012 in a case series with five patients [17]. We are unable to report any quality-of-life measures. In most cases, we would have to rely on a proxy judgement of the quality of life because of the severity of the underlying diseases in our case series, and the usual quality-of-life measures used for EOS patients are not validated for use in Danish language. However, a large multicentre study comparing MCGR with TGR has reported improvements in quality-of-life measures and concluded that MCGR with a reduced number of surgeries has better psychosocial effects

[18].

CONCLUSIONS

Based on the present findings, our conclusion is that the MCGR may reduce the deformity and support thoracic and pulmonary growth with no need for repeated surgeries. The number of complications in the present series was low compared with the literature with an average of 0.07 complications per year per patient or a total complication rate of 27%.

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Conflicts of interest Potential conflicts of interest have been declared. Disclosure forms provided by the authors are available with the article at ugeskriftet.dk/dmj

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