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CASE SERIES

The evolving stall rate of magnetically controlled growing rods beyond 2 years follow-up

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Abstract

Purpose Magnetically controlled growing rods (MCGR) have become the dominant distraction-based implant for the treatment of early onset scoliosis (EOS). Recent studies, however, have demonstrated rising rates of implant failure beyond short-term follow-up. We sought to evaluate a single-center experience with MCGR for the treatment of EOS to define the rate of MCGR failure to lengthen, termed implant stall, over time.

Methods A single-center, retrospective review was conducted identifying children with EOS undergoing primary MCGR implantation. The primary endpoint was the occurrence of implant stalling, defined as a failure of the MCGR to lengthen on three consecutive attempted lengthening sessions with minimum of 2 years follow-up. Clinical and radiographic variables were collected and compared between lengthening and stalled MCGRs. A Kaplan–Meier survival analysis was conducted to assess implant stalling over time.

Results A total of 48 children met inclusion criteria (mean age 6.3 ± 1.8 years, 64.6% female). After a mean 56.9 months (range of 27 to 90 months) follow-up, 25 (48%) of children experienced implant stalling at a mean of 26.0 ± 14.1 months post-implantation. Kaplan–Meier survival analysis demonstrated that only 50% of MCGR continue to successfully lengthen at 2 years post-implantation, decreasing to < 20% at 4 years post-implantation.

Conclusion Only 50% of MCGR continue to successfully lengthen 2 years post-implantation, dropping dramatically to < 20% at 4 years, adding to the available knowledge regarding the long-term viability and cost-effectiveness of MCGR in the management of EOS. Further research is needed to validate these findings.

Keywords Magnetically controlled growing rods · Early onset scoliosis · Failure · Stall

Introduction

Early onset scoliosis (EOS) represents a particularly challenging condition were clinicians are charged with controlling the spinal and chest wall deformity while allowing the child's thorax to continue to grow. The magnetically¯controlled growing rod (MCGR) system was introduced in the United States in 2014 as a revolutionary treatment approach that obviated the need for surgical lengthening of the growing rod, using instead an external remote controller to drive the lengthening of the spinal rod through the magnetic actuator [1]. Early reports assessing outcomes 2 years following implantation demonstrated high rates of success in managing these complex deformities with substantially lower complication rates compared to traditional growing rods (TGR) [1, 2]. However, more recent series using small sample sizes have assessed outcomes beyond 2 year's follow-up, showing that upwards of 52% of MCGR's fail to lengthen [3–5].

As such, we sought to quantify our institutional experience with MCGR since their initial utilization in 2014. Specifically, we sought to focus upon the premature failure of MCGR to lengthen during subsequent lengthening sessions. We defined this phenomenon as implant stalling. Specifically, a stall occurred when the MCGR failed to lengthen after 3 consecutive attempted lengthening sessions separated by 4-month intervals. Our hypothesis was that a substantial

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percentage of MCGRs would experience implant stalling beyond 2 years post implantation.

Methods

After obtaining institutional review board approval, a single-center, retrospective review was performed to identify all children with EOS undergoing surgical intervention between January 2014 and December 2020. Inclusion criteria consisted of children undergoing primary MCGR implantation with subsequent lengthening procedures performed at the study institution, and who had a minimum of 2-years clinical follow-up. Children were excluded if they had their implantation or subsequent lengthening procedures performed at an outside hospital, had < 2-year clinical follow-up, or underwent MCGR conversion from traditional growing rods.

Clinical and radiographic variables were collected, consisting of patient demographic variables as well as deformity parameters. Clinical variables analyzed included preoperative age at MCGR placement, height, weight, and diagnosis, and occurrence of any prior surgical treatment with subsequent conversion to MCGR. Intraoperative data included implant size, and number of vertebral levels spanned by the construct. Duration of lengthening and total attempted lengthenings until final treatment or stall were also recorded. Actuator length achieved at final follow-up was measured radiographically, as well as the extent of maximal actuator length based upon the maximal expansion of a 70 or 90 mm actuator.

The primary endpoint for this study was to characterize the occurrence and time to occurrence of MCGR stalling. We defined implant stalling as a failure of the MCGR to lengthen after 3 consecutive lengthening sessions spaced at 4-month intervals. Failure to lengthen was diagnosed based on radiographic appearance of the actuator. Our institutional protocol is to lengthen MCGR implants at 4-month intervals. Implants that failed to lengthen were maintained on an every 4-month lengthening schedule prior to reattempting to lengthen. Time to stall was recorded as the time from implantation to the first occurrence of failure in MCGR lengthening. Data was collected at three time-intervals: preoperative, first erect post-operative, and most recent follow-up or at the occurrence of stalling. Final follow-up variables included terminal deformity parameters, height gained, and unplanned return to operating room (UPROR).

Statistical analysis

Statistical analysis was performed using IBM SPSS 27 Software (IBM Corp, Armonk, NY) and SAS 9.4 (SAS Institute, Cary, NC). Descriptive statistics were generated. Clinical and radiographic variables were first examined for normality with the Shapiro–Wilk test. Univariate analysis was performed to identify variables associated with implant stalling using Student's *T* tests and Mann–Whitney tests for two-group comparison were used as appropriate. Additionally, a Kaplan–Meier survival curve was created for the study endpoint of implant stalling from time of MCGR implantation. Statistical significance was pre-determined at $P < 0.05$.

Results

Over the study period, a total of 67 children were treated with MCGR for EOS by one of four pediatric orthopaedic surgeons. Of these, 19 children were excluded (7 converted to MCGR from TGR/VEPTR, 6 underwent MCGR implantation at an outside hospital, 5 had undergone only one lengthening session, and one child was deceased) leaving 48 children for study inclusion (mean age 6.3 ± 1.8 years, 64.6% female). Primary EOS diagnoses consisted of 16 idiopathic, 14 syndromic, 14 neuromuscular, and 4 congenital patients. Children were followed for a mean 56.9 months ± 17.4 (range of 27 to 90 months). A summary of preoperative patient demographics is provided in Table 1.

Children began with a mean preoperative coronal Cobb of 68.2 ± 15.4° (range 27.4°–100°) and improved to a mean postoperative coronal Cobb at most recent follow-up of 52.2 ± 17.1° (range 15.9 to 96.0°), resulting in a mean 16.0(± 2.2)° deformity improvement. Implant stall occurred in 23 children (48.0%), at a mean of 26.0 ± 14.1 months (range 4–58.9 months). These implants underwent a mean 7.4 (± 3.8, range 0 to 18) lengthening sessions with these children achieving a mean gain of 17.0.2 (± 8.9)mm in actuator length and a mean total of 35.8% (± 20.3%) of maximal actuator length prior to implant stalling. Curve etiology did not influence the

Table 1 Summary of patient and radiographic variable for children undergoing MCGR implantation for EOS

Preoperative variable	Value[a]	Range
Patient age (year)	6.3 ± 1.8	2.9–9.4
Weight (kg)	18.6 ± 5.7	11–41.6
Height (cm)	108.1 ± 14.2	78–139.4
Body mass index	15.5 ± 2.1	11.8–23.5
Preoperative coronal cobb (°)	68.2 ± 15.4	30.7–100.0
Preoperative T2–T12 kyphosis (°)	43.2 ± 16.9	8.3–78.5
Preoperative sagittal balance (mm)	20.5 ± 33.1	− 71 to 91
Preoperative coronal balance (mm)	6.9 ± 21.4	− 41 to 60
Independently ambulatory	64.6% (*N* = 31)	
Vertebral levels spanned	10.0 ± 1.3	6 to 13 levels

[a]Values are listed as mean ± standard deviation for continuous variables and percentage for dichotomous variables

development of MCGR stalling ($P = 0.2$). Children with implant stalling were not more likely than children without stalling to undergo revision surgery (Stall:69.6%% ($N = 16/23$) vs 60.0% ($N = 15/25$); $P = 0.489$) or implant removal (Stall:56.5% ($N = 13/23$) vs 76.0% ($N = 19/25$); $P = 0.153$). Univariate analysis for continuous variables associated with MCGR stalling failed to identify any significant patient or deformity factor, Table 2. Children with stalled implants did not experience any significant difference in coronal deformity magnitude or correction at any time point.

The Kaplan–Meier survival analysis from MCGR stalling is depicted in Fig. 1. At 2-year follow-up, approximately 50% of MCGR's continue to successfully lengthen. However, between 2 and 4 years, the development of implant stalling increased precipitously with only 15% of MCGR's continuing to successfully lengthen at 4-year follow-up.

Complications

Thirty-two out of 48 patients (66.7% of the studied cohort) experienced an unplanned return to operating room (UPROR). In all, there were 55 unplanned reoperations, accounting for 1.12 (±1.1) reoperations per UPROR patient. The most common reoperation was MCGR revision for rod failure/stall, accounting for 49% of the total reoperations ($N = 27/55$ reoperations in 22 children), followed by anchor revision for loosening (8 reoperations in 6 children) and irrigation and debridement (I&D) for a surgical site infection (9

Table 2 Summary of patient and deformities variables between children who experienced MCGR stalling and those that continued to successfully lengthen

Variable	Functioning MCGR			Stalled MCGR			*T*-test
	N	Mean	StDev	*N*	Mean	StDev	
Age at MCGR implantation (year)	25.0	6.0	1.8	23.0	6.5	1.9	0.4
Preoperative height (cm)	25.0	104.7	14.5	23.0	111.7	13.2	0.1
Preoperative weight (kg)	25.0	17.2	4.4	23.0	20.1	6.6	0.1
Preoperative BMI	25.0	15.3	1.8	23.0	15.7	2.5	0.5
Preoperative coronal cobb (°)	25.0	70.8	15.2	23.0	65.3	15.3	0.2
Preoperative coronal balance (mm)	25.0	8.2	21.2	23.0	5.5	21.9	0.7
Preoperative T2–5 Kyphosis (°)	25.0	16.2	12.4	23.0	12.5	11.9	0.3
Preoperative T2–12 Kyphosis (°)	25.0	44.8	19.0	23.0	41.4	14.6	0.5
Preoperative sagittal balance (mm)	25.0	21.9	35.6	23.0	19.0	30.9	0.8
Follow-up since surgery (months)	25.0	39.1	13.1	23.0	47.5	19.1	0.1
Final coronal cobb (°)	25.0	58.6	17.9	23.0	55.1	17.2	0.5
Coronal cobb correction post implantation (°)	25.0	27.0	18.0	23.0	27.3	18.4	1.0
Coronal cobb correction post-implantation to final (°)	25.0	17.2	22.3	23.0	14.7	22.5	0.7

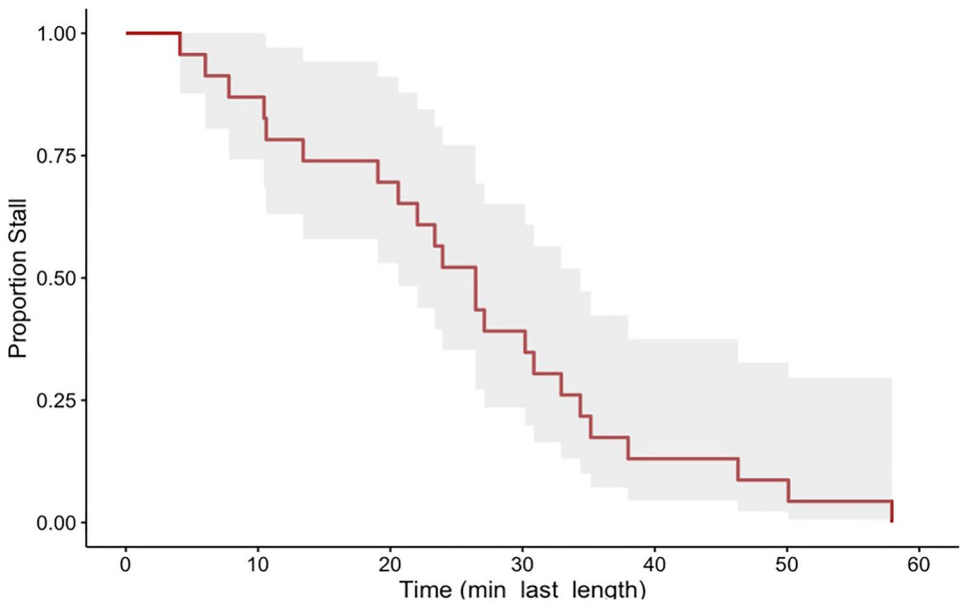

Fig. 1 Depiction of Kaplan–Meier survival curve for successful MCGR lengthening prior to implant stalling

reoperations in 6 children; 5/6 with neuromuscular EOS and 1 syndromic EOS). An additional 4 children underwent 4 reoperations for combined indications (e.g. rod revision with anchor revision and/or I&D), and 23 children were converted to posterior spinal fusion. The patients that experienced UPROR demonstrated no significant differences in deformity parameters at any point but did exhibit significantly longer follow-up than the uncomplicated patients, Table 3.

Discussion

Magnetically controlled growing rods have been recognized as a promising technology in the treatment of EOS which allow for implant lengthening without repeated general anesthetic exposures or surgical incisions as required in TGR. However, previous studies have raised concern with regard to the longevity of MCGR implants for functional spinal lengthening [3, 4, 6]. In this retrospective, single-center review of 48 children undergoing primary MCGR treatment, we identified that MCGR implants have unreliable long-term functionality, with 50% of children demonstrating MCGR stalling at 2 years post-implantation, increasing precipitously to > 80% at 4 years. Andras et al. [7] stated following an initial minimal lengthening episode, subsequent lengthening attempts should be pursued as 91% of those patients successfully lengthened after one or two subsequent attempts. In our patient cohort, once the MCGR began to stall, subsequent attempts did not result in successful lengthening.

Since the introduction of MCGR implants for EOS in 2014, this treatment approach has been largely promoted as the magic bullet for the management of EOS. Previous studies have shown that MCGR implants have the ability to provide comparable curve correction as compared with TGR but with significantly fewer surgical procedures [1, 8]. However, with the introduction of any new technology, there are also new mechanisms of failure, and the failure of implant distraction, termed implant stalling, is exclusive to MCGR. MCGR stalling has been recognized as the most common surgeon-reported reason for implant removal [9, 10], with failure of distraction occurring in upwards of 40% of treated children [2–4]. However, this has been shown to vary from as low as approximately 10% of children at 2-years post-implantation [2] to as high as 48% at more than 3 years post-implantation [4]. In the current study, we found a time dependent association between MCGR stalling and follow-up post-implantation, ranging from 50% at 2 years post-implantation to > 80% at 4 years. Given the significant amount of stalling that was experienced within this cohort in addition to the high UPROR rate, a valid concern arises regarding longevity and cost-effectiveness of the implant.

The mechanistic reason for MCGR stalling is not well understood in the literature. A postulate is that the magnetic actuator generates an insufficient force to continue to lengthen the spine over time with successive lengthening sessions resulting in decrease yield or complete failure to lengthen [9, 11, 12]. This "law of diminishing returns" has been proposed to represent progressive stiffness or even auto-fusion of spanned spinal segments over the treatment course [11], as has been reported in the TGR literature [13, 14]. However, it has also been reported that this diminished distraction gain is rather a progressive failure of magnetic actuator that is reversed with MCGR exchange [12]. Explant analysis of MCGR implants have identified that duration of implantation is directly correlated with the extent of lengthening with implanted MCGRs of greater duration being significantly less likely to be functional at the time of explant [6]. Force testing of explanted implants further supports this explanation with force production being negatively correlated with the duration of treatment [10].

Regardless of mechanistic understanding for the stalling phenomena, it does have direct implications on the cost-effectiveness of MCGR treatment. Previous studies have investigated the time points to cost neutrality for MCGR in the treatment of EOS compared with TGR, estimated from 3 to 6 years [15, 16]. However, these cost analyses are based upon certain assumptions regarding the functional longevity of the MCGR implants, the complication rate, and implant costs which may not correctly represent real-world circumstances. Only 2 studies to date have reviewed actual costs

Table 3 Summary of comparison of variables between patients who did and did not undergo unplanned return to the operating room (UPROR)

	Levels spanned—right	Levels spanned—left	Total # of lengthenings	Immediate post-op cobb (°)	Immediate cobb correction (°)	Follow-up (months)
UPROR patients ($N=32$)	10.0 ± 1.2	10.1 ± 1.3	7.8 ± 3.6 (0–14)	40.8 ± 12.8	27.5 ± 15.0	60.2 ± 16.5
Uncomplicated patients ($N=16$)	9.6 ± 1.8	9.8 ± 1.5	8.6 ± 3.1 (5–18)	41.5 ± 14.3	26.4 ± 23.5	50.4 ± 18
P value	0.5	0.6	0.4	0.9	0.8	0.08

UPROR, unplanned return to operating room, Post-op, post-operative

of care for children with EOS treated with MCGR, with varying results. Harshavardhana et al. [17] reported on the payer costs of 9 children treated with MCGR, finding that when compared with previous reported payer costs of TGR, MCGR were at least 40% more cost effective than TGR.

However, Oetgen et al. [18] reported on the hospital charges and payer reimbursements for 16 children treated with MCGR, compared to 21 children with TGR. MCGR treatment resulted in significantly higher charges than TGR despite received statistically similar average percentage reimbursements (MCGR: 43% vs TGR: 46%). The charge difference in this study largely represented implant cost differences (MCGR: $31,621 vs TGR: $8966) [18], which were significantly higher than implant cost estimated utilized in previous cost-analysis studies [15, 16]. Luhmann et al. [19] performed a cost analysis of MCGR with implant costs more closely representing the values reported by Oetgen et al. [18] and found that MCGR did not meet cost neutrality in comparison to TGR after 6 years of simulated care, further calling into question the cost effectiveness of MCGR at their current price point. Although concerning, it is important to recognize that MCGR implants continue to carry the advantage of avoiding surgical construct lengthening and the potential developmental concerns associated with repeated general anesthesia exposures at young age [20]. Additionally, the current study indicated that despite the high rate of stalling, there were no differences in coronal plane deformity or the rate of revision surgery due to implant stalling.

This study has several inherent limitations which warrant consideration. As a retrospective review, there are inherent biases with the presented data. The inclusion criteria for our cohort dictate that each patient have undergone at least 2 lengthening sessions after implantation, resulting in some patients with only 6 months of follow up information after post implantation. As identified in the Kaplan–Meier, implant survival from stalling drops precipitously with time post-implantation. As such, our data may be skewed toward under-reporting implant stalling for patients early in their treatment course with the potential to experience complications and/or experience implant stalling later in their post-implantation follow-up. However, the mean follow-up was not statistically difference between stalled and functioning implant cohorts.

Additionally, our data represents a heterogenous population of patients with various indications for MCGR implantation. Given the mixed etiologies represented in the patient cohort, there are some significant limitations when performing radiographic measurements of non-ambulatory and neuromuscular children sagittal and coronal balance. These patients often require assistance during these radiographs to maintain upright posture in either the sitting or standing position that can significantly influence these measures. The etiology breakdown also has direct implication on the UPROR data. The SSI rate, 12.5% ($N = 6/48$) in the current study is higher than previous reports using only MCGR implants, reported as low as 3% by Suresh et al. [21] at a mean of 13.1 months following implantation in a series of 992 EOS patients in the PSSG database. All SSI in the current series occurred in neuromuscular ($N = 5/6$ SSI patients, 4/5 nonambulatory) and syndromic patients ($N = 1/6$). These etiology cohorts accounted for 62.5% ($N = 30/48$) of the reported patient cohort which, given their known increased risk for SSI [22], may result in the SSI rate being non-representative.

Additionally, 67% of the patients in the current cohort experienced UPROR. This data aligns with studies reporting long-term follow-up in children treated with MCGR. Lebel et al. [23] reported on 47 MCGR patients followed to MCGR graduation, reporting complication development in 66% of patients with 45% experiencing UPROR. This is further supported by Cheung et al. [3] who reported a 70% complication rate for 40% of their cohort experiencing an UPROR for rod distraction failure at a mean of 6-year follow-up and Tahir et al. [8] who reported a 43.8% UPROR rate in children followed to MCGR graduation. Furthermore, Tahir et al. [8] reported no difference in UPROR for children treated with MCGR as compared with children treated with TGR when followed to definitive fusion. These findings are in direct contradiction to early-term follow-up studies reported a significant reduction in UPROR rates for MGCR treated patients [1] emphasizing the importance of long-term follow-up.

Finally, this study includes patients treated during the COVID-19 pandemic, which has been shown to complicate and delay patient care in various categories of care as well as post-surgical care. However, this study represents one of the largest single-center studies on primary MCGR with results extending beyond 2 years of clinical follow-up, with all surgeries performed by one of four pediatric orthopedic fellowship trained surgeons practicing at a high-volume specialty center. The determination of implant stall was verified utilizing multiple radiographs over 3 attempted lengthening sessions. We understand there has been recent literature published suggesting that the stall phenomenon can be overcome by repeated attempts at lengthening, however our study is in direct contradiction to this proposal as no implant that stalled regained the ability to lengthen with subsequent attempts [7]. Interestingly, implant stall was not found to be associated with an increased rate of UPROR (Stall: 69.6%% ($N = 16/23$) vs 60.0% ($N = 15/25$); $P = 0.489$). However, many children who experienced MCGR stalling undergo a period of observation, especially though approaching the maturity necessary for a definitive spinal fusion. As such, the UPROR data in the Stall cohort may be biased toward under-reporting UPROR.

In conclusion, this study identified a high rate of implant stalling with the utilization of MCGR for the management of EOS. Only 50% of implants were functionating 2 years post-implantation, a value which continued to drop precipitously to < 20% at 4 years. This data expands the available literature on several assumptions regarding MCGR longevity in cost-effectiveness modeling for EOS treatment. Further research is needed to confirm these findings as well as to re-evaluate the cost-effectiveness of MCGR treatment in light of these high rates of implant failure and reoperation.

Author contribution KAS: data analysis, data interpretation, manuscript drafting, manuscript approval, and accountable. PB: study design, data analysis, data interpretation, manuscript approval, and accountable. BAR: study design, data analysis, manuscript editing, manuscript approval, and accountable. AM: data analysis, data interpretation, manuscript editing, manuscript approval, and accountable. DT: data analysis, data interpretation, manuscript editing, manuscript approval, and accountable. AJ: data collection, data analysis, manuscript editing, manuscript approval, and accountable. C-HJ: study design, data analysis, statistical analysis, manuscript editing, manuscript approval, and accountable. CEJ: study design, data interpretation, manuscript editing, manuscript approval, and accountable. ALM: study design, data analysis, manuscript editing, manuscript approval, and accountable.

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Data availability Data is maintained by the author's institution and is available upon request.

Declarations

Conflict of interest Dr. Shaw is a committee member for NASS and AAOS; Dr. Bassett reports nothing to disclose; Dr. Ramo reports receiving publishing royalties from Saunders/MosbyElsevier, Ms. McClung reports nothing to disclose; Mr. Thornberg reports nothing to disclose, Mr. Jamnik reports nothing to disclose; Dr. Jo reports nothing to disclose; Dr. Johnston reports receiving publishing royalties from Saunders/MosbyElsevier, IP royalties from Medtronic, is a board/committee member for GSSG, POSNA, and SRS, and editorial board member for Jounral of Children's Orthopaedics; Dr. McIntosh reports being a paid speaker for Nuvasive.

Ethical approval Approved by IRB: #052011-039.

Informed consent Not applicable.

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