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CASE SERIES

Unplanned return to the operating room (UPROR) occurs in 40% of MCGR patients at an average of 2 years after initial implantation

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Abstract

Purpose This study calculated the rates of Unplanned Return to the Operating Room (UPROR) in early-onset scoliosis patients who had no previous spine surgery and underwent Magnetically Controlled Growing Rod (MCGR) implantation.

Methods We reviewed surgical, radiographic, and UPROR outcomes for EOS patients treated with the MCGR implant < 12 years + 11 months of age, had complete preop/postop major curve measurements, and had complete MCGR details.

Results 376 patients underwent MCGR implantation at a mean age of 7.7 years (1.8–12.9). Diagnoses included 106 (28%) idiopathic, 84 (22%) syndromic, 153 (41%) neuromuscular, and 33 (9%) congenital. The mean preop-cobb was 76.7° (9–145°), and an immediate postop correction was 41% (0–84%). We found that 38% (142/376) of patients experienced an UPROR prior to the maximal actuator length being achieved. UPROR occurred at mean 2 years (3 days–5 years) after initial implantation. Of the 142 patients who experienced UPROR there were 148 complications that lead to an UPROR. The most common reason for UPROR was anchor (55/148: 37%) or MCGR implant related (33/148: 22%). Wound related (22/148:15%), Neuro related 4/148: 3%), and other (34/148: 23%) accounted for the remaining UPROR occurrences.

Conclusion In conclusion, the MCGR UPROR rate was 142/376 (38%) after an average of 2 years post implantation. At 2-year follow-up, only 20% of MCGR patients had experienced an UPROR. However, between 2 and 5 years, the development of an UPROR increased precipitously with only 39% of MCGR patients remaining UPROR free at 5 years post MCGR implantation. The most common reason for UPROR was related to anchor or MCGR implant-related complications. This information can be utilized to set realistic expectations about the need and timing of future surgical procedures with patients and their families.

Keywords Early onset scoliosis · MCGR · UPROR · Complications

Introduction

Early onset scoliosis (EOS) represents a particularly challenging patient population because their spinal deformities need to be managed with strategies to avoid fusion. Growing constructs have provided orthopedic surgeons with an effective means of managing scoliotic curves in the youngest patients for over 30 years. However, traditional growing rod (TGR) constructs require surgical lengthening of the implants to allow for continued growth of the spine and thorax while maintaining control over the spinal deformity in both the frontal and sagittal planes [1]. The magnetic controlled growing rod (MCGR) was FDA approved in the United States in 2014. Since that time, the MCGR has become the preferred spinal implant for the treatment of patients with EOS because of their unique ability to gain spinal and thoracic length without required surgical interventions [2, 3]. Lengthenings are performed at 4-month intervals or less in a clinical setting without the need for surgery or anesthetic.

While magnetic growing rods provide a means of managing early-onset scoliosis, a high incidence of unplanned returns to the operating room (UPROR) (33%) exists [4]. Common reasons necessitating revision surgery are rod

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breakage and proximal fixation failure, which can also occur with TGR [5]. However, the most common reason for revision surgery is a failure of the magnetic rod to lengthen (failure of the noninvasive distraction mechanism), which is unique to this implant choice [6, 7].

Several studies were published assessing the potential cost-effectiveness of MCGR compared to TGR. MCGR was found to be cost-effective compared to TGR but were limited by estimates being drawn from small cohort studies or expert opinion [8–11]. Therefore, the goal of this study was to determine an updated and accurate accounting of the rates for UPROR in patients that underwent MCGR implantation from a large multi-center prospective database (Pediatric Spine Study Group: PSSG).

Materials and methods

Study design

We performed a retrospective review of prospectively collected data from a multi-site registry of patients (PSSG) diagnosed with Early Onset Scoliosis undergoing MCGR treatment from 2013 to 2019.

Level of evidence

Level II—Prognostic.

Study patients

EOS patients who had no spine surgery prior to initial MCGR implantation were reviewed. We excluded patients: Age > 12 years + 11 mo at the time of MCGR implantation; who did not have pre- and post-op major coronal cobb in the database; and who did not have rod diameter listed in the database. In 2014 and 2015, respectively, the Growing Spine Study Group (GSSG) and the Children Spine Study Group (CSSG) defined EOS as any spinal deformity that is present before the age of 10, regardless of the etiology [12, 13]. Therefore, all patients included in this study were diagnosed with scoliosis prior to the age of 10 years, regardless of age at MCGR implantation.

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. Operative data included implant size, and number of vertebral levels spanned by the construct. Duration of lengthening and total attempted lengthenings until final treatment or UPROR, and the cause of UPROR were analyzed. If the patient did not experience an UPROR, then they had to have undergone at least 3 lengthenings during the follow-up period. The PSSG database organizes UPROR into 5 categories: (1) anchor related, (2) MCGR implant related, (3) wound related, (4) neuro related, and (5) other.

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 UPROR 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 UPROR from the time of MCGR implantation. Statistical significance was pre-determined at $p < 0.05$.

Results

376 EOS patients were included who underwent initial MCGR implantation at a mean age of 7.7 years (1.8–12.9 yr). Treatment occurred between 2013 to 2019. Patients were classified by the C-EOS, which includes a term for etiology [14]. Primary EOS diagnoses consisted of 106 (28%) (I) idiopathic, 84(22%) (S) syndromic, 153 (41%) (M) neuromuscular, and 33 (9%) (C) congenital patients. The mean pre-op cobb was 77° (9–145°), and immediate postop cobb was 44° (7–117°) leading to a post-op correction that was 41% (0–84%). (Table 1) We found that 38% (142/376) of MCGR patients experienced an UPROR prior to the maximal actuator length being achieved. UPROR occurred at an average of 2.0 years (3 days–5 years) after initial implantation. 6 patients had more than 1 complication that led to an UPROR during the follow-up period. (3 patients with anchor and wound complications, 1 patient with neuro and wound complications, 1 patient with anchor and neuro complications, and 1 patient with wound and other complications.) Therefore, 142 patients experienced 148 complications that led to an UPROR. The most common reason for UPROR was anchor-related complications (55/148: 37%) or MCGR implant (33/148: 22%). Wound related (22/148:15%), Neuro related 4/148: 3%), and other (34/148: 23%) accounted for the remaining UPROR occurrences. (Table 2).

Patients that experienced an UPROR were younger at MCGR insertion (6.9 vs. 8.1 yrs.) $p = < 0.001$, and stiffer, with less initial correction (post-op Cobb 47 vs. 43) $p = 0.047$, and less percentage correction (39% vs. 42%) $p = 0.045$. Average initial frontal plane correction was 41.2% (Table 1). The diagnosis that demonstrated the most initial correction was neuromuscular (46%), and

Table 1 Overall Cohort Comparison: No UPROR vs UPROR ($N=376$)

Variable		Overall cohort		No UPROR		Experienced UPROR		p
		N	Mean ± Std [Range] %	N	Mean ± Std [Range] %	N	Mean ± Std [Range] %	
Age at implant (years)		376	7.7 ± 2.4 [1.8–12.9]	234	8.1 ± 2.4 [2.1–12.6]	142	6.9 ± 2.3 [1.8–12.9]	< 0.001
BMI		306	16.5 ± 3.4 [9.1–38.3]	183	16.6 ± 3.5 [9.5–29.5]	123	16.4 ± 3.4 [9.1–38.3]	0.8
Etiology	Idiopathic	106	28%	70	30%	36	25%	0.1
	Congenital	33	9%	16	7%	17	12%	
	Syndromic	84	22%	46	20%	38	27%	
	Neuromuscular	153	41%	102	44%	51	36%	
Gender	Female	222	59%	147	63%	75	53%	0.1
	Male	154	41%	87	37%	67	47%	
PreOp major curve angle		376	77° ± 20° [9°–145°]	234	76° ± 20° [9°–141°]	142	77° ± 19° [28°–145°]	0.7
Immediate PostOp major curve angle		376	44° ± 16° [7°–117°]	234	43° ± 16° [7°–106°]	142	47° ± 16 [15–117°]	0.047
Immediate PostOp correction (%)		376	41 ± 19 [0–84]	234	42 ± 19 [0–84]	142	39 ± 18 [0–79]	0.045
Number of lengthenings		376	10 ± 5 [3–32]	234	10 ± 4 [3–31]	142	12 ± 5 [3–32]	< 0.001
Time to first UPROR (years)		376	2.5 ± 1.3 [0.0–6.4]	234	2.8 ± 1.2 [0.1–6.4]	142	2.0 ± 1.3 [0.0–5.0]	< 0.001
UPROR vs latest follow-up (years)		376	2.5 ± 1.3 [0.0–6.3]	234	2.8 ± 1.2 [0.1–6.3]	142	2.0 ± 1.3 [0.0–5.0]	NA

UPROR unplanned return to the operating room, *NA* not assessed statistically

Table 2 UPROR Cohort—Nature of Complications leading to UPROR ($N=148$)

Complications	N (%)
Anchor related	55 (37%)
MCGR implant related	33 (22%)
Wound related	22 (15%)
Neurologic related	4 (3%)
Other	34 (23%)

148 Complications in 142 unique patients

UPROR unplanned return to the operating room

the least initial correction occurred in congenital patients (35%), $p=0.014$ (Table 3).

In the 234 patients that did not experience UPROR the average follow-up was 3 years (0.8–6.5 years). There were no differences when comparing the cohort that developed an UPROR vs those that did not, regarding, rod diameter (4.0 vs. 4.5 vs 5.5 vs 6.0 mm $p=0.1$), or actuator size (70 vs 90 mm $p=0.34$). Additionally, preop cobb (76° vs 78°, $p=0.7$), BMI (16.4 vs. 16.6, $p=0.8$), and underlying diagnosis ($p=0.1$) were not associated with UPROR (Table 1).

The Kaplan–Meier survival analysis for MCGR UPROR is depicted in Fig. 1. At 2-year follow-up, only 20% of MCGR patients had experienced an UPROR. However, between 2 and 5 years, the development of an UPROR increased precipitously with only 39% of MCGR patients remaining UPROR free at 5 years post MCGR implantation (Fig. 1).

Discussion

With the increasing use of the MCGR, the concept of UPROR was popularized [15]. Ideally, MCGR patients would only undergo an initial implantation surgery and then revision to a new MCGR when the actuator reached its final length, or when the child was skeletally mature enough to undergo a final fusion. Therefore, any surgical procedure prior to those 2 endpoints is considered an UPROR.

It is important to recognize the context this data should be viewed within. The MCGR and TGR are two treatment paths for EOS, with certain similarities as well as distinct differences which lead to interest, but difficulties in direct comparisons. An additional element that complicates comparisons more is the asymmetric use of these two treatment modalities since the introduction of MCGR in 2014. As published by Murphy and colleagues [16], these two treatments for EOS have taken divergent paths, with TGR use plummeting and MCGR use soring over the past decade, leading to issues with comparisons, as very limited concurrent data exists between these two implants. Instead, direct comparisons of these implants require the use of historical TGR data to current MCGR data, introducing bias given overall changing treatment patterns. A final difficulty in directly comparing the rates of UPROR between MCGR and TGR, as previously described, is the fact that TGR has the advantage of planned surgical lengthenings [16]. For example, if a TGR construct had proximal anchors that failed, a revision could be performed during a planned TGR lengthening and that procedure would not be considered an UPROR, thus possibly leading to bias in the reported UPRORs for TGR. Taken together, it is understandable why we have chosen not

Table 3 Overall Cohort Comparison by Etiology

Variable		Idiopathic		Congenital		Syndromic		Neuromuscular	
		N	Mean ± Std [Range] %	*N*	Mean ± Std [Range] %	*N*	Mean ± Std [Range] %	*N*	Mean ± Std [Range] %
Age at implant (years)		106	7.7 ± 2.5 [2.7–12.5]	33	7.1 ± 2.6 [2.1–12.6]	84	7.2 ± 2.7 [1.8–12.9]	153	8.0 ± 2.0 [2.7–12.6]
BMI		93	16.5 ± 3.6 [12.2–38.3]	30	16.8 ± 2.6 [12.4–22.3]	69	16.5 ± 3.8 [10.1–29.5]	114	16.4 ± 3.4 [9.1–27.4]
Gender	Female	69	65%	19	58%	50	60%	84	55%
	Male	37	35%	14	42%	34	40%	69	45%
PreOp major curve angle		106	71° ± 19° [36°–145°]	33	72° ± 18° [9°–97°]	84	77° ± 19° [40°–141°]	153	81° ± 20° [40°–140°]
Immediate PostOp major curve angle		106	43° ± 15° [15°–72°]	33	46° ± 15° [7°–73°]	84	47° ± 19° [16°–117°]	153	43° ± 16° [11°–89°]
Immediate PostOp correction (%)		106	38 ± 21 [0–78]	33	35 ± 15 [0–79]	84	39 ± 20 [0–78]	153	46 ± 18 [0–84]
Number of lengthenings		106	10 ± 5 [3–27]	33	10 ± 5.3 [3–23]	84	11 ± 5 [3–32]	153	11 ± 5 [3–31]
UPROR	No	70	66%	16	48%	46	55%	102	67%
	Yes	36	34%	17	52%	38	45%	51	33%
Time to first UPROR (years)		106	2.6 ± 1.3 [0.1–5.7]	33	2.4 ± 1.0 [0.0–5.0]	84	2.5 ± 1.3 [0.0–5.5]	153	2.5 ± 1.3 [0.0–6.4]

UPROR unplanned return to the operating room

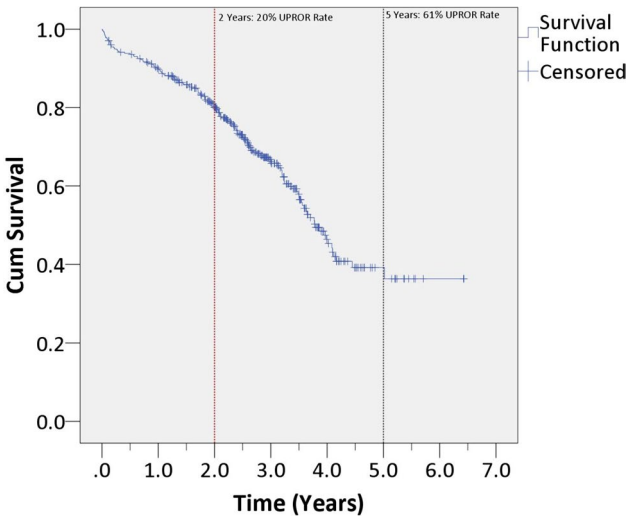

Fig. 1 Kaplan–Meier survival analysis for MCGR UPROR

to present a direct comparison between TGR and MCGR or make a value statement about the utility of either implant in comparison to the other, rather we are presenting an accurate data-driven accounting of the UPRORs associated with MCGR over time to allow a more complete understanding of the expected clinical longevity of this implant for physicians and patients.

As described, there are multiple issues that lead to UPROR, including infection, anchor pull out, and neurologic issues, the incidences of which may or may not be different in MCGR vs TGR constructs, with the MCGR technology having introduced an additional variable which leads to UPROR, device failure to lengthen. The utility of this study to is give an accurate accounting of UPROR for the MCGR as this implant was introduced with the promise of being a "one and done" solution for patients with EOS. Obviously, MCGR continues to provide the advantage of avoiding planned surgical lengthenings and the associated risks with repeated general anesthesia exposures at a young age, but the inherent complications of surgical treatment of EOS still exist including infection, anchor failure, and neurologic complications [17]. But given the known advantages of MCGR, we felt it was important to determine an accurate accounting of the rates of UPROR in an EOS patient population that had no previous spinal surgery, and their first spinal surgery was initial MCGR implantation. This research scenario hopefully allowed for the MCGR to lengthen and function appropriately in the most conducive environment. Even in this optimistic environment, the UPROR rate was still 38% (142/376). 142 patients experience 148 UPRORs. The UPRORs occurred at an average of 2.0 years (3 days–5 years) after initial implantation. The most common reason for UPROR was anchor-related complications (55/148: 37%) or MCGR implant (33/148: 22%). Wound related (22/148: 15%), Neuro related (4/148: 3%), and other (34/148: 23%) accounted for the remaining UPROR occurrences. Our findings are in direct contradiction to early-term follow-up studies which reported a significant reduction in UPROR rates for MGCR-treated patients [1, 2], thus emphasizing the importance of longer-term follow-up. This represents a good example of Scott's parabola regarding the rise and fall of a surgical technique [23]. A surgical procedure shows great promise at the outset and becomes the standard

treatment after reports of encouraging results. Then falls into disuse or less use as negative outcome reports accumulate with longer term follow-up.

Our 38% UPROR rate is similar to those reported by Lebel, Cheung and Tahir [18–20], with notable exceptions: our patient population is much larger and our exclusion criteria were intended to create an environment to allow the MCGR to lengthen and function at its most optimal level. Lebel et al. reported on 47 MCGR patients followed to MCGR graduation with 45% of patients experiencing UPROR [20]. Cheung et al. reported 40% of their cohort experiencing an UPROR due to rod distraction failure at a mean of 6-year follow-up [19], and Tahir et al. reported a 43.8% UPROR rate in children followed to MCGR graduation [18].

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 has undergone at least 3 lengthening sessions after implantation, resulting in some patients with only 0.8 years of follow-up after implantation. In a recent study by Shaw et al., MCGR implant survival drops precipitously with time from implantation [21]. The data in this study shows a similar pattern. The Kaplan–Meier survival analysis for MCGR UPROR is depicted in Fig. 1. At a 2-year follow-up, only 20% of MCGR patients had experienced an UPROR. However, between 2 and 5 years, the development of an UPROR increased precipitously with only 39% of MCGR patients remaining UPROR free at 5 years post MCGR implantation. As such, this data is skewed toward under-reporting MCGR UPROR.

In the PSSG, the patients were classified by the C-EOS, which includes a term for etiology. In this study, the primary EOS diagnoses consisted of 106 (28%) (I) idiopathic, 84(22%) (S) syndromic, 153 (41%) (M) neuromuscular, and 33 (9%) (C) congenital patients. 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's sagittal and coronal balance. These patients often require assistance during these radiographs to maintain an upright posture in either the sitting or standing position which can significantly influence these measures. Additionally, many patients in this database did not have sagittal plane radiographic measurements, therefore no statistical comparisons could be made to correlate pre-operative and post-operative thoracic kyphosis with UPROR.

Table 1 highlights that no statistically significant differences occurred when comparing the cohort that developed an UPROR vs those that did not regarding underlying E-COS diagnosis ($p = 0.1$). Interestingly, younger patients at MCGR insertion (6.9 vs. 8.1 yrs.) $p = < 0.001$, and stiffer patients with less initial correction (post-op Cobb 47° vs. 43°) $p = 0.047$, and less percentage correction (39% vs. 42%) $p = 0.045$ were more likely to experience an UPROR. These findings may be statistically significant, but not clinically relevant. However, the authors believe that it is important to discuss with families that younger patients with stiffer curves may be at a higher risk to develop UPROR. This information can be utilized to set realistic expectations about need and timing of future surgical procedures with patients and their families.

UPROR due to wound related complications was 22/148 (15%) in this cohort. A pervious series of 992 EOS patients in the PSSG database reported an SSI rate of 3% at a mean of 13.1 months following MCGR implantation [22]. In that series SSI was defined as infection that required subsequent I&D and antibiotic therapy. This project was not intended to evaluate the SSI rate but rather accurately account reasons for UPROR. Therefore, our wound complication rate may be higher due to possible return to the operating room for wound breakdown or dehiscence that was not associated with underlying deep or superficial infection.

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.

In conclusion, this study was designed to evaluate the MCGR in an optimal environment for device function. Even in this optimal environment, the UPROR rate was 142/376 (38%) after an average of 2 years post implantation. At 2-year follow-up, only 20% of MCGR patients had experienced an UPROR. However, between 2 and 5 years, the development of an UPROR increased precipitously with only 39% of MCGR patients remaining UPROR free at 5 years post MCGR implantation. The most common reason for UPROR were related to anchor or MCGR implant-related complications. This data will allow accurate informed consent in regard to the performance of the MCGR and assist physicians in setting realistic expectations about the need and timing of future surgical procedures when using this device in EOS.

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Author contributions All authors contributed to the study's conception and design. Material preparation, data collection and analysis were performed by Amy L. McIntosh, Anna Booth, and Matthew E. Oetgen. The first draft of the manuscript was written by Amy L. McIntosh and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript. Amy L. McIntosh, MD: substantially contributed to the design, data acquisition/interpretation, drafted and revised critically for important intellectual content, approved the final version to publish, agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy

or integrity of any part of the work are appropriately investigated and resolved. Anna Booth, BSN: substantially contributed to the design, data acquisition/interpretation, drafted and revised critically for important intellectual content, approved the final version to publish, agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Matthew E. Oetgen, MD: substantially contributed to the design, data acquisition/interpretation, Drafted and revised critically for important intellectual content, approved the final version to publish, agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Data availability Data will not be available.

Declarations

Conflict of interest Mrs. Anna Booth has no relevant financial or non-financial interest to disclose. Dr. Matthew E. Oetgen has no competing interests to declare that are relevant to the content of the article, however, does report being a consultant/advisor for Medtronic. Dr. Amy L McIntosh is a paid speaker for NuVasive.

Ethical approval PSSG sites must have IRB approval to participate. (Our site IRB #052011–039).

Consent to participate Depending on local site requirements informed consent was obtained from participants and/or their parents/guardians. Consent was obtained at our site.

Consent for publication Depending on local site requirements informed consent which includes information with regard to publishing their data. Consent was obtained at our site.

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