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Clinical Studies

Increasing soft tissue depth is associated with stalling of magnetically controlled growing rods

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ABSTRACT

Background: Magnetically controlled growing rods (MCGR) represent the most used implant for the treatment of early onset scoliosis (EOS). These implants lengthen through the application of a remote magnetic field but distraction force generation has been negatively correlated with increasing soft tissue depth. Given the high rate of MCGR stalling, we proposed to investigate the impact of preoperative soft tissue depth on the rate of MCGR stalling at a minimum of 2 years following implantation.

Methods: A single-center, retrospective review of prospectively enrolled children with EOS treated with MCGR was performed. Children were included if they had a minimum of 2-years follow-up after implantation and underwent advanced spinal imaging (MRI or CT) preoperatively within a year of implantation. The primary outcome was the development of MCGR stall. Additional measures included radiographic deformity parameters and gain in MCGR actuator length.

Results: About 55 patients were identified with 18 having preoperative advanced imaging allowing tissue depth measurement (Mean 5.99 ± 1.9 years, 83.3% female, mean Cobb 68.6 ± 13.8°). At a mean follow-up of 46.1 ± 11.9 months, 7 patients (38.9%) experienced stalling. MCGR stalling was associated with increased preoperative soft tissue depth (21.5 ± 4.4 mm vs. 16.5 ± 4.1 mm; p = .025) and increased BMI (16.3 ± 1.6 vs. 14.5 ± 0.9; p = .007).

Conclusions: Greater preoperative soft tissue depth and BMI were associated with the development of MCGR stalling. This data supports previous studies showing that the distraction capacity of MCGR diminishes with increased soft tissue depth. Further research is needed to validate these findings and their implications on the indications for MCGR implantation.

Background

Magnetically controlled growing rods (MCGR) allow for noninvasive distraction of the spine in patients with early onset scoliosis (EOS). Though they only received full Food and Drug Administration (FDA) approval in 2014, they have become the predominant implant of choice for growth-friendly scoliosis surgeries [1]. Compared to other growth-friendly implants, MCGRs have been shown to maintain adequate curve correction and allow for generally similar spine growth [2–4]. However, in 11% to 30% of patients with MCGR, the rods prematurely fail to lengthen, known as "stalling" [5–7].

Numerous factors, including those related to the surgical technique, the implant itself, and the patient, are thought to contribute to MCGR stalling [8]. In particular, a number of studies have found that increased body-mass index (BMI) is associated with failure to lengthen MCGR [8–11]. This is thought to be due to the increased distractive force required to lengthen the rods in patients with a high BMI, as well as the patient's increased soft tissue envelope preventing the external remote control (ERC) from lengthening the rod [9,12–14]. However, to our knowledge, only 2 studies, both at the same institution, have sought to test the latter hypothesis that increased soft tissue depth is associated with MCGR stalling, both found that increasing depth was associated with less MCGR distraction [12,13].

The purpose of this study was to determine the effect that preoperative spinal soft tissue thickness on the development of MCGR stalling. We hypothesized that increased tissue depth would be associated with higher rates of MCGR stalling and less distraction achieved at the time the rods stalled.

FDA device/drug status: Approved.

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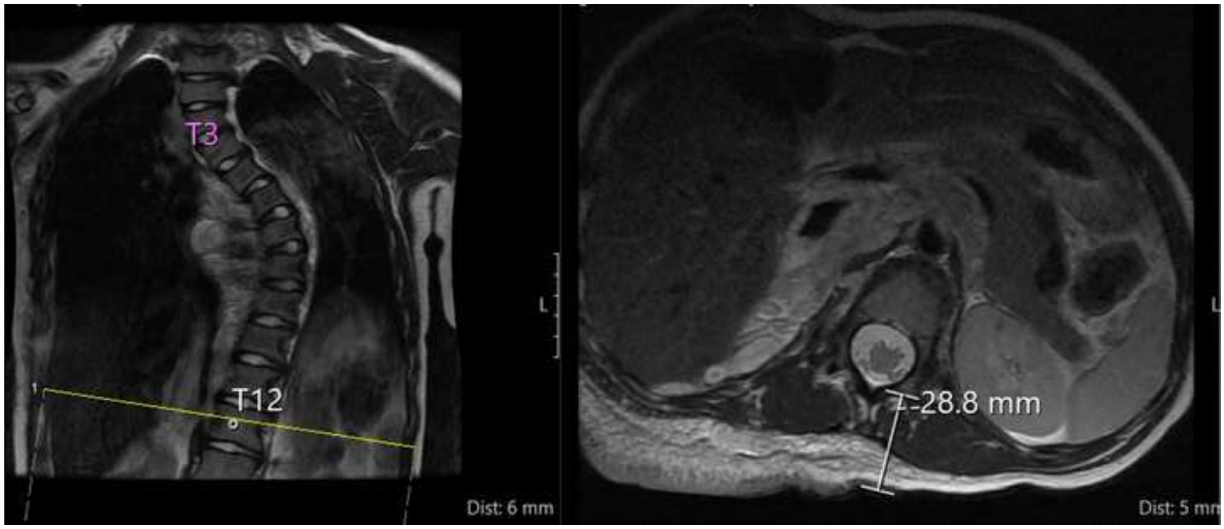

Figure 1. Example image for measurement of soft tissue depth. The measurements were all performed on axial images, measuring the depth of tissues from the skin to the convex lamina at T12.

Methods

After obtaining institutional review board approval, a single-center, retrospective review of a prospectively-enrolled database was performed to identify all children with EOS undergoing surgical intervention between January 2014 and December 2020 by 4 fellowship-trained pediatric orthopedic surgeons. 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-years clinical follow-up, lacked a CT or MRI scan within 1 year of surgery to measure soft tissue depth, 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 lengthening's until final treatment or stall were also recorded. Actuator length achieved at final follow-up was measured radiographically, as well as calculated as the percentage 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 as previously described [7]. Stall was defined as failure to lengthen on 3 consecutive lengthening session spaced at 4-month intervals according to our institutional lengthening protocol. Preoperative advanced imaging (MRI or CT scan) was used to measure soft tissue depth. Depth was measured at T12, corresponding to the most common location for placement of a MCGR actuator. To standardize depth measurement, all measurements were performed on the convexity, measured from the lamina to the skin, Figure 1.

Statistical analysis

Statistical analysis was performed using IBM SPSS 27 Software (IBM Corp) and SAS 9.4 (SAS Institute). Descriptive statistics were generated. Patients were subdivided according to the functionality of their MCGR actuator (Stall or Functioning). The tissue depth was compared between cohorts using paired student *t* tests. Statistical significance was predetermined at p<.05.

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

Preoperative variable	Value*	Range
Patient Age (yr)	6.0±1.9	2.8–8.8
Weight (kg)	18.3±4.0	11–29.2
Height (cm)	107.8±14.6	80.5–137.6
Body Mass Index	15.2±1.5	12.9–16.7
Preoperative Coronal Cobb (°)	68.6±13.8	46.9–93.7
Preoperative T2-T12 Kyphosis (°)	44.7±11.6	24.8–62.4
Preoperative Sagittal Balance (mm)	21.6±33.7	-71 to 91
Independently Ambulatory	64.6% (N=31)	

* Values are listed as mean ± standard deviation for continuous variables and percentage for dichotomous variables.

Results

Over the study period, a total of 67 children were treated with MCGR for EOS by 1 of 4 pediatric orthopedic surgeons. Of these, 12 children were excluded (6 converted to MCGR from TGR/VEPTR and 6 underwent MCGR implantation at an outside hospital) leaving 55 children for study inclusion (mean age 6.3 ± 1.8 years, 64.6% female). Of these, only 18 children (Mean 5.99 ± 1.9 years, 83.3% female, mean Cobb 68.6 ± 13.8°) presented with preoperative advanced imaging obtained within 1 year of MCGR implantation for soft tissue depth assessment. A summary of preoperative patient demographics and deformity parameters is provided in Table 1. These included 5 congenital, 6 idiopathic, 1 neuromuscular, and 6 syndromic curve etiologies with 83.3% being ambulatory at the time of treatment (N = 15/18).

At a mean follow-up of 46.1 ± 11.9 months, 7 of the 18 patients (38.9%) experienced MCGR stalling, all being ambulatory patients with 71.4% of the stall cohort having congenital or idiopathic curve etiologies (N = 5/7). MCGR stall occurred at a mean of 26.9 months (range 10–37.9) following implantation with the implants achieving a mean of 44% (±26.6%) of maximal actuator length. The stall cohort demonstrated a similar final coronal Cobb magnitude to the lengthening cohort (43.1 ± 16.1° vs. 44.1 ± 13.4°; p = .89). The mean preoperative tissue depth was significantly larger in the Stall cohort (21.5 ± 4.4 mm vs. 16.5 ± 4.1 mm; p = .025). Additionally, the preoperative BMI was

Table 2
Summary of between group variables based upon MCGR Functionality at final follow-up.

Variable	Functioning MCGR (N=11)		Stalled MCGR (N=7)		
	Mean	StDev	Mean	StDev	*t* test
Age at MCGR Implantation (yr)	6.3	1.9	5.5	2.1	0.4
Preoperative height (cm)	108.5	17.1	106.9	10.9	0.8
Preoperative weight (kg)	17.9	5.1	18.8	4.9	0.7
Preoperative BMI	14.5	0.9	16.3	1.6	**0.007**
Preoperative soft tissue depth (mm)	16.5	4.1	21.5	4.4	**0.02**
Preoperative T2–12 Kyphosis (°)	45.6	12.7	43.2	10.2	0.7
Levels spanned with MCGR	9.3	1.4	9.1	1.6	0.8
# of Lengthening's	8.3	3.3	6.7	2.6	0.3
Follow-up since surgery (months)	44.2	11.9	49.1	12.3	0.4
Final coronal cobb (°)	44.1	13.4	43.1	16.1	0.9
Coronal cobb correction Postimplantation (°)	37.2	22.6	42.5	12.2	0.6
Coronal cobb correction Postimplantation to Final (°)	-13.5	28.5	-7.6	36.0	0.7

Bold Text indicated statistical significance p<.05.

higher in children who developed MCGR stalling (16.3 ± 1.6 vs. 14.5 ± 0.9; p = .007). There were no significant differences in preoperative or final follow-up deformity parameters, Table 2.

Discussion

Although magnetically-controlled growing rods (MCGR) have been shown to provide deformity control while limiting the anesthetic exposure for children with early onset scoliosis, the technology has its own unique complication profile. Actuator stall and distraction failure are a distinctive complication in MCGR treatment, ranging from 10% to nearly 50% [2–4,7]. In this series of 18 children with EOS treated with MCGR, we identified stalling in 38.9% of the cohort (N = 7/18), developing at a mean of 26.9 months postimplantation. There was a significant difference in the preoperative mean soft tissue depth between children who developed stall and those with functioning implants (21.5 ± 4.4 mm vs. 16.5 ± 4.1 mm; p = .025).

The introduction of MCGR instrumentation was heralded as a significant advance in the surgical treatment outcomes for EOS. Although MCGR has many benefits over more traditional instrumentation techniques, studies have shown that it is not the magic bullet for EOS and has several uniquely inherent complications. One such complication is the phenomena of MCGR stalling and distraction failure, with reports of upwards of 50% of treated children developing stall distraction failure [6,15,16]. What remains to be described is the mechanistic rationale for why MCGR stalling and distraction failure occurs, and whether any preoperative patient-specific variables can be identified to determine which patients may be more prone to stalling. Previous studies have proposed progressive stiffening of the spine, referred to as the "law of diminishing returns" [10,17,18]. This hypothesis is supported by clinical reports showing a diminished yield in lengthening achieved relative to programmed lengthening over successive lengthening's [10,17–19]. However, explant analyses have shown that MCGR force generation is inversely correlated with duration of implantation [20,21], indicating that, at best, this is a multifactorial problem.

These reasons, however, do not account for the acute distraction failures within a year of implantation. In the current series, we identified a stall rate of 38.9% with 2/7 stalls occurring within 1 year of implantation (10 months and 10.6 months). Cheung et al. [9] identified early distraction failure in 45% of treated patients (N = 13/41). Shaw et al. [7] reported that the development of stalling is time dependent with 50% of implants stalling by 2 years postimplantation, increasing to 80% at 4 years. One proposed mechanism for these early failures is related to the depth of the soft tissue envelope between the MCGR actuator and the external remote controller (ERC) used to noninvasively lengthen the magnet [9]. MCGR lengthening, as implied with it name, relies upon a magnetic force produced by the ERC to effect implant lengthening. However, it is well known that there is a negative nonlinear relationship between increasing distance and magnetic force generation [22]. This has been shown to account for differences in achieved versus programmed lengthening with previous studies reporting 1.4% to 2.1% decrease in achieve lengthening per additional millimeter of soft tissue depth [12,13]. This was supported in the current series where children who developed MCGR stalling and significantly larger preoperative soft tissue envelopes than children with functioning implants (21.5 ± 4.4 mm vs. 16.5 ± 4.1mm; p = .025).

The impact of a patient body habitus on MCGR outcomes has been previously investigated [8,9]. In addition to soft tissue depth, we also identified that the preoperative BMI was higher in children who developed MCGR stalling (16.3 ± 1.6 vs. 14.5 ± 0.9; p = .007). Cheung et al. [9] reported a significantly higher BMI in children who developed rod slippage compared to those with uncomplicated lengthening's (15.4 ± 5.8 vs. 12.0 ± 1.7, p = .006). Furthermore, the UK based National Institute of Health and Care Excellence (NICE) recommends that in addition to patient age, BMI <25 kg/m^2 be included as a variable for MCGR treatment selection [8]. However, Seidel et al. [12] found that BMI did not serve as a correlate for soft tissue depth and that BMI was not independently predictive of lengthening percentage. Body mass index has long been shown to be a poor predictor of obesity as it is significantly correlated with both body fat percentage and lean body mass [23].

This manuscript cannot be viewed without recognition of its limitations. As a single center, retrospective review, there are certain inherent limitations in the study design. Although our series included patients treated by 1 of 4 fellowship-trained pediatric orthopedic surgeons, all children followed a standardized lengthening protocol which minimizes treatment effects. Additionally, with the small sample size and high exclusion rate, there is the potential for selection bias and the data presented may not sufficiently represented the total treated cohort. Additionally, the children were not followed to skeletal maturity so the true impact of soft tissue depth on treatment outcomes remains unclear.

Conclusion

In conclusion, we identified that the preoperative soft tissue depth was a significant risk factor for the development of MCCR stalling. This data supports current literature which suggests the careful consideration of preoperative or postoperative soft tissue depth and body habitus be included in the selection of implants for the treatment of EOS. Children with larger body habitus and paraspinal soft tissue envelopes may be at a higher risk of developing MCGR actuator stalling and the development of additional complications over their treatment course which should be accounted for in the decision-making process. Further research is needed to validate these findings and assess their long-term impact on patient outcomes.

Declaration of Competing Interest

Dr Shaw is a committee member for NASS, POSNA, and AAOS; Mr Jamnik reports nothing to disclose; Ms McClung reports nothing to disclose; Mr Thornberg reports nothing to disclose; Dr Ramo reports receiving publishing royalties from Saunders/MosbyElsevier; Dr McIntosh reports being a paid speaker for Nuvasive.

Ethical approval

Approved by IRB: #052011-039

Author contribution

KAS: Data Analysis, Data Interpretation, Manuscript drafting, Manuscript Approval, Accountable.

AJ: Study Design, Data Analysis, Data Interpretation, Manuscript Approval, Accountable.

AM and DT: Data Analysis, Data Interpretation, Manuscript editing, Manuscript Approval, Accountable.

BAR and ALM: Study Design, Data Analysis, Manuscript editing, Manuscript Approval, Accountable.

Informed consent

Not applicable

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References

[1] Murphy RF, Neel GB, Barfield WR, et al. Trends in the utilization of implants in index procedures for early onset scoliosis from the pediatric spine study group. J Pediatr Orthop 2022;42(9):e912–e9e6.

[2] Lebel DE, Rocos B, Helenius I, et al. Magnetically controlled growing rods graduation: deformity control with high complication rate. Spine (Phila Pa 1976) 2021;46(20):E1105–E1e12.

[3] Tahir M, Mehta D, Sandhu C, Jones M, Gardner A, Mehta JS. A comparison of the post-fusion outcome of patients with early-onset scoliosis treated with traditional and magnetically controlled growing rods. Bone Joint J 2022;104-b(2):257–64.

[4] Kim G, Sammak SE, Michalopoulos GD, et al. Comparison of surgical interventions for the treatment of early-onset scoliosis: a systematic review and meta-analysis. J Neurosurg Pediatr 2022;31:342–57.

[5] Thakar C, Kieser DC, Mardare M, Haleem S, Fairbank J, Nnadi C. Systematic review of the complications associated with magnetically controlled growing rods for the treatment of early onset scoliosis. Eur Spine J 2018;27(9):2062–71.

[6] Cheung JPY, Yiu K, Kwan K, Cheung KMC. Mean 6-year follow-up of magnetically controlled growing rod patients with early onset scoliosis: a glimpse of what happens to graduates. Neurosurgery 2019;84(5):1112–23.

[7] Shaw KA, Bassett P, Ramo BA, et al. The evolving stall rate of magnetically controlled growing rods beyond 2-years follow-up. Spine Deform 2023;11:487–93.

[8] Tognini M, Hothi H, Dal Gal E, et al. Understanding the implant performance of magnetically controlled growing spine rods: a review article. Eur Spine J 2021;30(7):1799–812.

[9] Cheung JPY, Yiu KKL, Samartzis D, Kwan K, Tan BB, Cheung KMC. Rod lengthening with the magnetically controlled growing rod: factors influencing rod slippage and reduced gains during distractions. Spine (Phila Pa 1976) 2018;43(7):E399–405.

[10] Ahmad A, Subramanian T, Panteliadis P, Wilson-Macdonald J, Rothenfluh DA, Nnadi C. Quantifying the 'law of diminishing returns' in magnetically controlled growing rods. Bone Joint J 2017;99-b(12):1658–64.

[11] Lorenz HM, Braunschweig L, Badwan B, et al. High correlation between achieved and expected distraction using magnetically controlled growth rods (MCGR) with rib to pelvis fixation in pediatric spine deformity. J Pediatr Orthop 2019;39(5):e334–e3e8.

[12] Seidel CP, Gilday SE, Jain VV, Sturm PF. How much does depth matter? Magnetically controlled growing rod distraction directly influenced by rod tissue depth. Spine Deform 2022;10(1):177–82.

[13] Gilday SE, Schwartz MS, Bylski-Austrow DI, et al. Observed length increases of magnetically controlled growing rods are lower than programmed. J Pediatr Orthop 2018;38(3):e133–e1e7.

[14] Mooney I, Toner JF, Murphy RF. Failing to appreciate that an excessive soft tissue envelope may lead to spinal MCGR dysfunction: don't do this case report. J Pediatr Orthop Soc N Am 2020;2(3). doi:10.55275/JPOSNA-2020-128.

[15] Saarinen AJ, Sponseller PD, Andras LM, et al. Matched comparison of magnetically controlled growing rods with traditional growing rods in severe early-onset scoliosis of ≥90°: an interim report on outcomes 2 years after treatment. J Bone Joint Surg Am 2022;104(1):41–8.

[16] Welborn MC, Bouton D. Outcomes of MCGR at > 3 year average follow-up in severe scoliosis: who undergoes elective revision vs UPROR? Spine Deform 2022;10(2):457–63 Mar.

[17] Agarwal A, Kelkar A, Garg Agarwal A, Jayaswal D, Jayaswal A, Shendge V. Device-related complications associated with magec rod usage for distraction-based correction of scoliosis. Spine Surg Relat Res 2020;4(2):148–51.

[18] Cheung JPY, Bow C, Cheung KMC. Law of temporary diminishing distraction gains": the phenomenon of temporary diminished distraction lengths with magnetically controlled growing rods that is reverted with rod exchange. Global Spine J 2022;12(2):221–8.

[19] Noordeen HM, Shah SA, Elsebaie HB, Garrido E, Farooq N, Al-Mukhtar M. In vivo distraction force and length measurements of growing rods: which factors influence the ability to lengthen? Spine (Phila Pa 1976) 2011;36(26):2299–303.

[20] Rushton PRP, Smith SL, Forbes L, Bowey AJ, Gibson MJ, Joyce TJ. Force testing of explanted magnetically controlled growing rods. Spine (Phila Pa 1976) 2019;44(4):233–9.

[21] Rushton PRP, Smith SL, Kandemir G, et al. Spinal lengthening with magnetically controlled growing rods: data from the largest series of explanted devices. Spine (Phila Pa 1976 2020;45(3):170–6.

[22] Jebelli A, Mahabadi A, Yagoub MCE, Chaoui H. Magnetic force calculation between magnets and coils. Int J Phys 2020;8(2):71–80.

[23] Romero-Corral A, Somers VK, Sierra-Johnson J, et al. Accuracy of body mass index in diagnosing obesity in the adult general population. Int J Obes (Lond) 2008;32(6):959–66.