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2022-01

Lippincott Williams and Wilkins

http://hdl.handle.net/10138/353372

Saarinen, A J, Sponseller, P D, Andras, L, Skaggs, D, Emans, J B, Thompson, G H & Helenius, I J 2022, 'Matched Comparison of Magnetically-Controlled Growing Rods with Traditional Growing Rods for Severe Early Onset Scoliosis >90 degrees. An interim report at 2-year follow-up', Journal of Bone and Joint Surgery: American Volume, vol. 104, no. 1, pp. 41-48. https://doi.org/10.2106/JBJS.20.02108

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A Matched Comparison of Magnetically Controlled Growing Rods with Traditional Growing Rods in Severe Early Onset Scoliosis ≥90 Degrees. An Interim Report on Outcomes at Two Years of Treatment.

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Funding was received from The Finnish Research Foundation for Orthopedics and Traumatology, University of Turku, Finland, and Clinical Research Institute HUCH, Finland.

Abstract

Background – Severe early onset scoliosis (EOS) requires surgical management but represents a challenge due to limited fixation points, large curve size, and fragile patients with **comorbidities**. Magnetically controlled growing rods (MCGR) have the advantage of avoiding surgical intervention for routine lengthening, but their ability to address severe EOS has not been studied.

Methods – A retrospective review of prospectively collected international database found 44 children with severe (≥90°) EOS treated with MCGR. Etiology, age, and gender matched patients treated with traditional growing rods (TGRs) were collected from the same database. Patients were evaluated at 2-year follow-up. No patients with vertically expandable prosthetic titanium ribs (VEPTR) were included. The health-related quality of life was evaluated by the Early Onset Scoliosis 24 questionnaire (EOSQ-24).

Results – The mean preoperative major coronal curve was 104° in the MCGR and 104° in the TGR group. At the 2-year follow-up, the mean major coronal curves were 52° and 66° (p=0.001). The mean T1-T12 heights were 155 mm and 152 mm preoperatively, and 202 mm and 192 mm at the two-year follow-up (p=0.088). According to the Kaplan-Meier analysis, the two-year unplanned revision free survival was 91% in the MCGR and 71% in the TGR group (p<0.005). There were no significant differences in the EOSQ-24 scores between the groups.

Conclusion – MCGRs provided significantly better major curve correction with significantly fewer unplanned revisions for severe EOS than TGRs at two-year follow-up.

Level of evidence: III.

Introduction

Early onset scoliosis (EOS) is a spinal deformity diagnosed at 10 years of age or younger[1]. Progression may lead to severe deformity, disability, and cardiopulmonary insufficiency[2,3]. Treatment options include serial casting, bracing, and surgical treatment with growth-friendly instrumentation. Operative treatment is recommended for patients with severe progressive deformities[2,3].

Operative treatment aims for deformity correction while allowing spinal and lung growth. Growth-friendly treatment options include distraction based growing rods, which may be lengthened surgically or with an external magnetic device. Thoracic height of at least 18 cm results in >45% of normal thoracic volume and is considered minimum for a satisfactory pulmonary development[2]. Seventy-five percent of the children with severe EOS treated with traditional growing rods (TGRs) reach this minimum thoracic height[4]. TGRs require recurrent surgical lengthenings approximately every six months exposing patients to wound related complications and psychological burden[4–6].

Magnetically controlled growing rods (MCGR) allow noninvasive outpatient-based lengthening and reduce the risk of deep surgical site infection as compared with TGRs[7,8]. MCGR allows for more frequent distraction and thus may more closely mimic natural growth, providing a theoretical advantage of reducing implant stress and minimizing autofusion[9,10]. However, there are additional concerns regarding failure of the magnet to lengthen and potential increase in metallosis[7,11–16].

Traditional growing rod surgery is associated with a high rate of complications, **with incidence of complications of up to** 58%[6,17,18]. Complications include wound related, implant related, and neurological complications. A similar mechanical failure rate but fewer wound related infections are reported with MCGRs as compared to TGRs[15,19,20].

Severe EOS has been defined as a major curve of 90° or more[1]. Surgical treatment of severe EOS is complicated by rigid deformity and difficult surgical anatomy resulting in a higher risk of complications[6]. Since MCGRs have fixed maximal distraction force, it is useful to know if they are effective in these larger curves. MCGRs have a larger rod diameter than TGRs, which may result in difficulties when placing these rods into the soft tissue envelope in these patients. Also, the actuator segment cannot be bent further complicating the contouring in some patients. However, this larger diameter has theoretical biomechanical advantages in terms of stronger instrumentation.

Measuring health-related quality of life (HRQoL) in children with EOS is complicated by the young age, often severe co-morbidities, and etiological heterogeneity of the EOS population[21]. To address this, a disease specific health-related quality of life instrument, the EOSQ-24, has been developed[21]. Repetitive general anesthetics and surgical lengthening may expose children and their caregivers to additional psychological burden[22–25]. Reduced surgical interventions in MCGR may have a positive effect on the quality of life and caregiver burden though this has been challenging to demonstrate in prior studies[26,27].

The aims of this study were to compare the clinical, radiographic, and EOSQ-24 outcomes in children with severe EOS undergoing growth-friendly instrumentation with TGR vs. MCGR. We hypothesized that major coronal curve correction would be better, and risk of rod failure, and deep surgical site infection would be lower when using MCGR as compared with TGR. These clinical advantages might be reflected by a better HRQoL in the MCGR than in the TGR group. **This study had special interest in the severe early onset scoliosis as these patients may have particularly difficult surgical anatomy, MCGR has a fixed maximal distraction force, and larger diameter which may produce further difficulties in addressing severe EOS.**

Patients and Methods

This is a retrospective review of a prospectively collected international database. Inclusion criteria were age 10 years or less at the time of surgery, diagnosis of EOS according to the definition of Scoliosis Research Society, major coronal curve of 90° or more at the index surgery, minimum of two-year follow-up with at least three lengthenings, and primary intervention using MCGR or TGR. **Patients with fewer than two years of follow-up or less than three lengthenings were excluded.** Patients with prosthetic vertically expandable prosthetic titanium ribs (VEPTR) or other devices were excluded. One-hundred-eighteen patients treated with MCGRs **during 2014–2018** were identified from the database. **All EOS patients with curves ≥90° meeting other inclusion criteria were included in the MCGR cohort.** N**o first generation MCGRs were included.** These patients were matched with patients treated with TGRs **during 2006–2017** (n=619) using the etiologic classification of EOS[1] (idiopathic, neuromuscular, syndromic, and congenital), age at index surgery, and gender. **None of the MCGR instrumentations were fully deployed during the 2-year follow-up.**

The surgical technique for placement of dual TGRs was as described by Akbarnia et al[3,17]. A midline incision is used for exposure, with subperiosteal dissection limited to the planned proximal upper thoracic and distal mid-lumbar foundations to prevent premature fusion. Alternatively, two separate midline skin incisions can be used, with preservation of a central skin bridge. Hooks and/or pedicle screws are used as the foundations to secure the rods to the spine. The number and location of the anchors are based on the curve location, curve type, diagnosis, and child's age. Typically, four anchors (hooks or screws) in two levels are used for each foundation (a minimum of eight fixation points in total). Regular construct lengthening is scheduled approximately every six months. None of the patients had an anterior procedure.

The dual MCGRs were used in a similar fashion during the index surgery. Their lengthening interval was according to the treating surgeon and varied between one and six months.

Four non-ambulatory patients in the MCGR and three in the TGR group had pelvic fixation. Pelvic fixation was performed in the current study only in the non-ambulatory patients. Four patients in the MCGR and eight patients in the TGR group had a single rod construct. None of the patients underwent final fusion or completed all the planned lengthenings during the two-year follow-up.

Study Design

Patient data was collected prospectively using standardized multicenter protocol. We collected data from the following timepoints: preoperatively, at and immediately following the index procedure, **and** at two-year follow-up. We collected the following clinical data: age, height, number of lengthening procedures, and complications. The following surgical data was collected: operative time, levels of instrumentation, and type of instrumentation. Complications were collected and categorized as wound-related, implant-related, alignment-related, neurological complications, and other complications.

Radiological Data

Standing PA and lateral radiographs or sitting AP and lateral radiographs were obtained **before and after index surgery, and at 2-year follow-up**. The radiographs were then analyzed for the major coronal curve using the Cobb technique, thoracic height (T1-T12) from the upper endplate of T1 to the lower endplate of T12, and spinal height (T1-S1) from the upper endplate of T1 to the upper endplate of S1. Maximal thoracic kyphosis was measured from the lateral radiographs also using the

Cobb technique. Radiographs were evaluated for implant-related complications. **Successful lengthening was verified using radiographs in the MCGR group.** Spinal growth was analyzed during the distraction period.

EOSQ-24

24-item EOS questionnaire (EOSQ-24) is a validated health-related quality of life instrument developed for assessing the HRQoL of EOS patients[21]. **EOSQ-24 consists of 24 domains categorized in Health-related Quality of Life, Family burden, and Satisfaction.** We analyzed EOSQ-24 scores preoperatively and at the 2-year follow-up. **Seventeen patients in the TGR group had preoperative and 15 postoperative EOSQ-24 data. These patients were matched with MCGR patients who all had EOSQ-24 data.**

Statistical Analysis

Categorical parameters were analyzed using chi-squared tests. Continuous parameters were analyzed using independent-samples t-tests. Kaplan-Meier analysis was used for analyzing the different follow-ups between the groups. Mann-Whitney U tests were used for comparison of EOSQ-24 scores between the groups. Wilcoxon's signed-rank test was used to compare pre- and postoperative domains. As the length of follow-up was different between the groups, the data was analyzed using the Kaplan-Meier survival method. Statistical significance was set at $p<0.05$.

Source of Funding

The authors have received external funding to institutions from industry. This funding was used for research leaves of the authors, but the funding source did not have any role in the analyses or writing of the manuscript.

Results

Clinical Characteristics

Clinical and radiographic baseline characteristics were similar between the groups except for gender in four patients (Tables I and II).

Radiographic Outcomes

The mean preoperative major curve was 104° (range, 90°–130°) in the MCGR and 104° (90°–139°) in the TGR group (p=0.472, Table II). After the index procedure, the mean major curves were 53° (range, 21°–85°) and 57° (range, 20°–104°), respectively (p=0.161). After two years of follow up, the mean curves were 52° (range, 22°–98°) and 66° (range, 31°–103°), respectively (p=0.001).

The **mean preoperative thoracic** height was 155 mm (range, 108–202 mm) in the MCGR and 152 mm (99–210 mm) in the TGR group (p=0.336). This increased to 184 mm (range, 141–260 mm) and 177 mm (range, 118–233 mm) after the index procedure, respectively (p=0.113). After two years of follow-up the mean thoracic heights were 202 mm (range, 149–280 mm) and 192 mm (range,129–256 mm), respectively (p=0.088). The mean annual T1-T12 growth during the first 2 years of distraction was 10 and 11 mm (p=0.388), respectively. Twenty-eight children in the MCGR and 26 in the TGR group reached the minimum T1-T12 height of 18 cm during the 2-year follow-up period (relative risk [RR] 1.08, 95% confidence interval [CI] 0.773–1.501, p=0.827). The sagittal radiographic parameters are shown in Table II. Thoracic kyphosis decreased more in the MCGR at the index surgery than in the TGR group with no statistical difference at two-year follow-up.

Complications

There was significantly less complications in the MCGR group during the 2-year follow-up (10 vs. 26, RR 0.385, 95%CI 0.212–0.699, p=0.001, Table III). In the MCGR group, seven children

had at least one complication, as compared to 17 children in the TGR group (RR 0.412, 95%CI 0.190–0.893, p=0.030). **There were no new neurologic deficits in either group. One patient in the MCGR had a dural tear. Two patients in the TGR group had a neuromonitoring change during the index surgery**. During the 2-year follow-up, there were nine unplanned revisions in the MCGR group and 22 in the TGR group (RR 0.409, 95%CI 0.213–0.786, p<0.01). There was one deep surgical site infection in the MCGR group and 11 in the TGR group (RR 0.091, 95%CI 0.012–0.674, p<0.01). **One patient in the MCGR group had a failure to lengthen during the follow-up.** According to the Kaplan-Meier curve the two-year unplanned revision free survival was 91% in the MCGR group and 71% in the TGR group (p<0.001, Figure I).

Health Related Quality of Life

Pulmonary function domain was significantly better in the MCGR group (p=0.036, Table IV). There were no other statistically significant differences.

Discussion

MCGRs provided significantly better correction of scoliosis with similar spinal growth than TGRs in the treatment of severe EOS. The risk of complications including deep surgical site infection, unplanned revision, and rod fracture was significantly lower in the MCGR than in the TGR group. Apart from the pulmonary function domain, improved deformity correction and reduced risk of complications was not reflected in the EOSQ-24 scores.

Repetitive surgical procedures expose patients to wound-related complications, recurrent anesthetics, analgesics, and require inpatient stays. Noninvasive lengthening of the MCGR is painless, swift, and is conducted on an outpatient clinic[28]. We hypothesize that this has positive impact on the HRQoL of children with severe EOS. In a previous study the HRQoL was similar in children treated using TGR

or MCGRs [26]. Evaluating the HRQoL in severe EOS may differ from moderate EOS. Severe EOS carries a significant risk of cardiopulmonary compromise and early death, which may lead to lower HRQoL than in moderate deformities[2,6,29].

MCGR provides satisfactory deformity correction and thoracic growth[30–32]. Repetitive lengthenings with TGRs may lead to unwanted autofusion which may further limit the spinal growth[9]. Similar but less severe effect has been reported in MCGRs[33]. In the present study, spinal growth was satisfactory in both groups. Final fusion may be unnecessary after traditional growing rods, but children with severe EOS may obtain additional spinal length at final fusion[4,34]. Final fusion is currently seen as indicated after MCGR as these rods produce metallosis around the lengthening site[14]. It remains unclear whether the outcomes of final fusion would improve more in severe EOS than in typical EOS after MCGR[35]. In the present study, **none of the patients reached final fusion during the first two years of follow-up.**

There were significantly fewer complications and unplanned revisions in the MCGR group. In previous studies, MCGR has been associated with fewer deep surgical site infections than TGR, which was also seen in this series[15]. Additionally, the larger diameter of the MCGR seems to be advantageous in children with severe EOS as more effective major curve correction and lower risk of rod breakage. Interestingly, the soft tissue envelope appeared to tolerate the larger rod diameter even in children with severe EOS and the benefits on the soft tissue of remote-controlled lengthening reducing the need for repeated surgical procedures seems to outweigh any potential issue from that standpoint. **In a previous study, higher initial cost of MCGR was compensated during the treatment with the reduced need of surgical procedures[36].**

Limitations

Severe EOS is a rare clinical condition. Despite our multicenter international database, we were able to collect data on 44 such children treated using the MCGRs. **The international multicenter database collection limited the number of surgical variables to be collected. Thus, the current study lacks the exact knowledge on the type of skin incision (two skin incisions vs. long midline), the type of proximal anchors used (hooks vs. screws), diameters of the rods used, and the number of surgeons performing the index surgery in the cohorts. It is possible that smaller rod diameter has contributed into the higher risk of rod fractures in the TGR cohort. Eight patients in the TGR cohort and four patients in the MCGR cohort were operated using a single rod construct. Use of a single rod construct is not according to the current recommendations[3], but this may also reflect the difficulties in placing the convex rod in severe ≥90° curves. The first generation of MCGR relatively often lost the distraction obtained[7]. This study did not include the first-generation MCGR devices. Concerns has been raised regarding the metallosis around the actuator at the time of revision surgery[14]. Two patients in the TGR group had preoperative traction, which may indicate more rigid curves. The findings of this study are limited to an interim report with two-year follow-up. The results reported may deteriorate during longer follow-up. Changes in the overall care during the different inclusion periods may have affected the outcomes. The multicenter data collection prevented us to record the possible changed strategies to reduce perioperative infections over the study period. The inclusion criteria based on the implant selection prevented us from evaluating whether the patients with excessive thoracic kyphosis were excluded from MCGR implantation.**

Propensity-score matched analysis can be used for improving the selection of the control group. In observational studies the true propensity score is never known resulting into inaccuracies and limitations when applied to a random experiment from observational data[37]. Consequently, we selected each TGR patient one-by-one, matching them for etiology of EOS classification, age

(+/-1 year), and gender. This method limited the number of controls we were able to use and resulted into more females in the MCGR cohort. The inclusion criteria based on the implant selection prevented us from evaluating whether the patients with excessive thoracic kyphosis were excluded from MCGR implantation.

HRQoL was evaluated using EOSQ-24 outcome questionnaire validated in 2011[21]. For this reason, EOSQ-24 data was available on only 17 patients in the earlier enrolled TGR group, while all patients with MCGRs had EOSQ-24 questionnaires available. **Pulmonary function data was not available for these two cohorts. Traditional growing rods were mainly used before the development of the magnetically controlled growing rods. This resulted into shorter follow-up time in the latter group and prevented matching by the total follow-up time. This may have resulted in selection bias and changes in the clinical care of these patients. Therefore, the key outcomes were compared at 2-year follow-up and Kaplan-Meier analyses were used to compare the unplanned revision free survival.**

Conclusions

For the treatment of severe EOS ≥90°, MCGRs provided significantly major curve correction with significantly fewer unplanned revisions and deep surgical infections during 2-year follow-up. No patients achieved skeletal maturity and/or definitive fusion during the follow-up.

Figure legend

Figure I. The Risk of unplanned revisions according to the Kaplan-Meier curve.

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