Clinical Policy: Growing Rods Spinal Surgery

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Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Growing rods (distractible spinal implants) were developed to address the limitations of spinal bracing or fusion for early onset scoliosis (EOS). Growing rods are inserted across a segment of spinal deformity where no fusion is performed. This policy addresses the medical necessity criteria for magnetic growing rods.

Policy/Criteria

I. It is the policy of Health Net of California that FDA approved magnetically controlled growing rods are may be considered medically necessary to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities, including EOS, when all of the following criteria is met:

A. Skeletally immature individual with potential for additional spinal growth who are < 10 years of age,
B. Cobb angle ≥ 30 degrees,
C. Thoracic spine height < 22 cm,
D. There is a risk of thoracic insufficiency syndrome, defined as the inability of the thorax to support normal respirations or lung growth.

Background

Early-onset scoliosis (EOS) is a rare condition defined as curvature of the spine in children >10° with onset before age 10 years. Young children with EOS are at risk for impaired pulmonary function because of the high risk of progressive spinal deformity and thoracic constraints during a critical time of lung development. The current goal in treatment of EOS is to maximize growth of the spine and thorax by controlling the spinal deformity, with the aim of promoting normal lung development and pulmonary function. The treatment of severe, early onset scoliosis is challenging and may include casting, bracing, insertion of growth rods and spinal fusion. Treatment selection depends on the age and development of the child as well as the type of curvature of the spine.

Growing rods (distractible spinal implants) were developed to address the limitations of spinal bracing or fusion for early onset scoliosis. Techniques of instrumentation include Harrington, Cotrel-Dubousset, or Luque rods. Growing rods (single or dual) are inserted across a segment of spinal deformity where no fusion is performed. Cranial and caudal anchoring foundations are made using hooks or pedicle screws. Each foundation is connected to a rod, and the rods are connected by cross-links. Distraction (lengthenings) of the growing rods is performed usually every six months in which the surgical incision site must be reopened for the distraction procedure. Once maximum spinal growth or skeletal maturity is reached definitive final fusion is performed. By this approach, growing rods could control progression of spinal

deformity as well as gradually correct the deformity. Growth rods are currently the most commonly used distraction-based technique and have the advantage of not interfering with the normal spinal growth. However, despite the advantages of growing rod surgery, the need for repeated surgeries under general anesthesia is a major drawback. Implant related complications are the most common complications in growth rod surgeries. These include rod fracture, anchor failure, or prominent implant, which can cause skin breakdown and even infection. Among the implant-related complications, rod fractures are the most common problem.

Recently, as an alternative to avoid the limitations associated with the growing rod, a remotely distractable, magnetically controlled growing rod system has been developed to facilitate outpatient rod distractions, eliminate frequent surgeries under general anesthesia and reduce wound complications, and frequent hospitalization in young children (i.e., Ellipse MAGEC Spinal Bracing and Distraction System, Irvine CA.) The MAGEC system includes an adjustable growing rod that uses a magnetic, remote controlled technology to non-invasively lengthen the growing rods placed in skeletally immature patients with severe progressive spinal deformity, without requiring repeat surgical rod lengthening. Following an initial procedure to implant the MAGEC rods, the device can be distracted or retracted noninvasively during outpatient visits by using the MAGEC External Remote Controller (ERC).

A number of small studies suggest that magnetically controlled growing rods appear to be a safe and effective nonfusion technique in the treatment of progressive EOS avoiding repeated surgical lengthening procedures. It provides adequate distraction similar to standard growing rods. The magnetically induced transcutaneous lengthening allows noninvasive distraction achieving spinal growth comparable to conventional growing rod techniques. Minimum 2-year follow-up that compared the effectiveness of magnetic growing rod versus traditional growing rods for the treatment of EOS reported major curve correction and annual T1–S1 and T1–12 growth was similar between groups throughout treatment. The magnetic growth rod patients had 57 fewer surgical procedures than traditional growth rod patients. Incidence of unplanned surgical revisions as a result of complications was similar between groups.

Growing rods have been the mainstay treatment of EOS which require repeated surgeries for distraction and are associated with an increase in complications. A meta-analysis comparing the results of single growing rods with dual growing rods in the treatment of EOS reported advantages in the coronal correction rate and lengthening by dual growing rods with fewer implant-related complications and more wound complications.

Figueiredo et al (2016) examined the safety and effectiveness of MCGR for the treatment of pediatric scoliosis. This is an evidence-based systematic review of literature for the surgical management of patients with pediatric scoliosis using MCGR technique. A total of 6 clinical studies regarding the use of MCGR were included in this review, with a total of 68 patients, and mean age of 8.38 years. The dual-rod (DR) technique of rod construct with MCGR was used in 33.85 % and the single-rod (SR) in 66.15 % of the patients. According to the latest follow-up, using the DR construct, the spinal length increased to 347 mm with 13.92 % of total lengthening; and using the SR construct, the average lengthening was 339 mm, with 10.48 % of

total lengthening ($p < 0.05$). Post-operative complications were similar, 25 % in DR and 31.57 % in the SR group ($p > 0.05$). The authors concluded that level IV of medical evidence supports the use of MCGR as a safe and effective alternative for the treatment of severe pediatric scoliosis. They stated that recommendation Grade C supports the role of MCGR with DR construct as an option to achieve a better correction of the scoliotic curve and to maximize the post-operative T1 - S1 spinal length.

Ridderbusch et al (2017) stated that growth-sparing techniques for the treatment of EOS have developed significantly over the last years. Traditional growing rods (GRs) require repeated surgical lengthening under anesthesia. Since June 2011 these researchers have been using the MCGR to treat patients with progressive EOS. A total of 35 patients with EOS of different etiologies underwent treatment with MCGR. These researchers recorded about the preliminary results of 24 patients who fulfilled the inclusion criteria of a minimum follow-up (FU) of 12 month and greater than 3 lengthening. All patients had a minimum of 3 out-patient lengthening [mean of 4.6 ± 1.5 (range of 3 to 8)]. The mean primary curve was 63 ± 15 degrees (range of 40 to 96) and improved to 29 ± 11 degrees (range of 11 to 53; $p < 0.001$) after MCGR. The mean pre-operative thoracic kyphosis decreased from 43 ± 24 degrees (range of -32 to 86) to 27 ± 12 degrees (range of 9 to 50 degrees; $p < 0.001$) after surgery, respectively, and measured 32 ± 12 degrees (range of 12 to 64; $p < 0.05$) at last FU. The authors concluded that these findings demonstrated that MCGR is a safe and effective non-fusion technique in the treatment of progressive EOS avoiding repeated surgical lengthening procedures. It provided adequate distraction similar to standard GR. The magnetically induced transcutaneous lengthening allows non-invasive distraction achieving spinal growth comparable to conventional GR techniques.

National Institute for Health and Care Excellence (NICE)
"The case for adopting the MAGEC system for spinal lengthening in children with scoliosis is supported by the evidence. Using the MAGEC system would avoid repeated surgical procedures for growth rod lengthening. This could reduce complications and have other physical and psychological benefits for affected children and their families. The MAGEC system should be considered for use in children with scoliosis aged 2 years and over who need surgery to correct their spinal curvature, for example when conservative methods such as bracing or casting have failed."

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
22899	Unlisted procedures, spine

HCPCS Codes	Description
L1000 - L1499	Orthotic devices - scoliosis procedures

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
M41-M41.9	Scoliosis
M43.8X-M43.8X9	Other specified deforming dorsopathies

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adopted from Health Net NMP354 Growing Rods Spine Surgery Criteria based on FDA approval	10/16	
Update – no revisions. Added NICE reference April 2015	10/17	10/17
Updated references and HCPCS Codes	10/18	10/18
Updated references, revised ICD-10 diagnosis codes to scoliosis	10/19	10/19

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

Magnetically Controlled Growing Rods:

In a prospective case-series study, Cheung et al (2012) evaluated the safety and effectiveness of a new magnetically controlled growing rod (MCGR) for non-invasive outpatient distractions in skeletally immature children with scoliosis. These investigators implanted the MCGR in 5 patients, 2 of whom have now reached 24 months' follow-up. Each patient underwent monthly outpatient distractions. These researchers used radiography to measure the magnitude of the spinal curvature, rod distraction length, and spinal length. They assessed clinical outcome by measuring the degree of pain, function, mental health, satisfaction with treatment, and procedure-related complications. In the 2 patients with 24 months' follow-up, the mean degree of scoliosis, measured by Cobb angle, was 67° (SD 10°) before implantation and 29° (4°) at 24 months. Length of the instrumented segment of the spine increased by a mean of 1.9 mm (0.4 mm) with each distraction. Mean predicted versus actual rod distraction lengths were 2.3 mm (1.2 mm) versus 1.4 mm (0.7 mm) for patient 1, and 2.0 mm (0.2 mm) and 2.1 mm (0.7 mm) versus 1.9 mm (0.6 mm) and 1.7 mm (0.8 mm) for patient 2's right and left rods, respectively. Throughout follow-up, both patients had no pain, had good functional outcome, and were satisfied with the procedure. No MCGR-related complications were noted. The authors concluded that the MCGR procedure can be safely and effectively used in outpatient settings, and minimizes surgical scarring and psychological distress, improves quality of life, and is more cost-effective than is the traditional growing rod procedure. The technique could be used for non-invasive correction of abnormalities in other disorders. The main drawbacks of this study were its small sample size and incomplete follow-up. Furthermore, the MCGR procedure was associated with increased radiation exposure from frequent radiographs. The authors noted that a prospective, large-scale, multi-center trial is underway to further validate these preliminary findings and evaluate other aspects of this technology.

In a prospective, non-randomized study, Akbarnia et al (2013) reported the preliminary results of MCGR technique in children with progressive early onset scoliosis (EOS). Distractions were performed in clinic without anesthesia/analgesics. T1-T12 and T1-S1 heights and the distraction distance inside the actuator were measured after lengthening. A total of 14 patients (7 females) with a mean age of 8 yrs + 10 mos (3 yrs + 6 mos to 12 yrs + 7 mos) had 14 index surgeries, single rod (SR) in 5 and dual rod (DR) in 9, with overall 68 distractions. Diagnoses were idiopathic (n = 5), neuromuscular (n = 4), congenital (n = 2), syndromic (n = 2) and NF (n = 1). Mean follow-up was 10 mos (5.8 to 18.2). Cobb angle changed from 60˚ to 34˚ after initial surgery and 31˚ at latest follow-up. During distraction period, T1-T12 height increased by 7.6 mm for SR (1.09 mm/mo) and 12.12 mm for DR (1.97 mm/mo). T1-S1 height gain was 9.1 mm for SR (1.27 mm/mo) and 20.3 mm for DR (3.09 mm/mo). Complications included superficial infection in 1 SR, prominent implant in 1 DR and minimal loss of initial distraction in 3 SR after index. Partial distraction loss observed following 14 of the 68 distractions (1 DR and 13 SR) but regained in subsequent distractions. There was no neurologic deficit or implant failure. The authors concluded that these preliminary results indicated MCGR was safe and provided adequate distraction similar to standard growing rod. Dual rod achieved better initial curve correction and greater spinal height during distraction compared to single rod.

The MAGEC System is composed of an implantable rod, an external remote controller (ERC), and accessories. The implanted spinal rod is used to brace the spine during growth to minimize the progression of scoliosis. Magnetic components in both the MAGEC rod and MAGEC ERC allow for distraction of the rod to be performed non-invasively and without the need for repeated surgeries as found in traditional growing rod systems.

Dannawi et al (2013) stated that conventional growing rods are the most commonly used distraction-based devices in the treatment of progressive early-onset scoliosis. This technique requires repeated lengthening with the patient anesthetized in the operating theatre. These investigators described the outcomes and complications of using a non-invasive magnetically controlled growing rod (MCGR) in children with early-onset scoliosis. Lengthening was performed on an out-patient basis using an external remote control with the patient awake. Between November 2009 and March 2011, a total of 34 children with a mean age of 8 years (5 to 12) underwent treatment. The mean length of follow-up was 15 months (12 to 18). In total, 22 children were treated with dual rod constructs and 12 with a single rod. The mean number of distractions per patient was 4.8 (3 to 6). The mean pre-operative Cobb angle was 69˚ (46˚ to 108˚); this was corrected to a mean 47˚ (28˚ to 91˚) post-operatively. The mean Cobb angle at final review was 41˚ (27˚ to 86˚). The mean pre-operative distance from T1 to S1 was 304 mm (243 to 380) and increased to 335 mm (253 to 400) in the immediate post-operative period. At final review the mean distance from T1 to S1 had increased to 348 mm (260 to 420). Two patients developed a superficial wound infection and a further 2 patients in the single rod group developed a loss of distraction. In the dual rod group, 1 patient had pull-out of a hook and 1 developed prominent metal-work. Two patients had a rod breakage -- 1 patient in the single rod group and 1 patient in the dual rod group. The authors concluded that these

results showed that the MCGR is safe and effective in the treatment of progressive early-onset scoliosis with the avoidance of repeated surgical lengthening.

Hickey et al (2014) reported the early experience of a magnetically controlled growing rod system (MAGEC, Ellipse). These investigators performed a review of pre-operative, post-operative and follow-up Cobb angles and spinal growth in case series of 8 patients with a minimum 23 months' follow-up (23 to 36 months). A total of 6 patients had dual rod constructs implanted and 2 patients received single-rod constructs. Four patients had MAGEC rods as a primary procedure; 4 were revisions from other systems. Mean age at surgery in the primary group was 4.5 years (range of 3.9 to 6.9). In patients who had MAGEC as a primary procedure, mean pre-operative Cobb angle was 74˚ (63 to 94), with post-operative Cobb angle of 42˚ (32 to 56) $p \leq 0.001$ (43 % correction). Mean Cobb angle at follow-up was 42˚ (35 to 50). Spinal growth rate was 6 mm/year. One sustained proximal screw pull out. A final patient sustained a rod fracture. Mean age at surgery in the revision group was 10.9 years (range of 9 to 12.6). Mean pre-operative Cobb angle was 45˚ (34 to 69). Post-operative Cobb angle was 42˚ (33 to 63) (2 % correction). Mean Cobb angle at follow-up was 44˚ (28 to 67). Mean spinal growth rate was 12 mm/year. Two patients developed loss of distraction. The authors concluded that the MAGEC growing rod system effectively controlled early onset scoliosis when used as either a primary or revision procedure. They stated that although implant-related complications are not uncommon, the avoidance of multiple surgeries following implantation is beneficial compared with traditional growing rod systems.

Jenks et al (2014) noted that the MAGEC system comprises a magnetically distractible spinal rod implant and an external remote controller, which lengthens the rod; this system avoids repeated surgical lengthening. Rod implants brace the spine internally and are lengthened as the child grows, preventing worsening of scoliosis and delaying the need for spinal fusion. The Medical Technologies Advisory Committee at the National Institute for Health and Care Excellence (NICE) selected the MAGEC system for evaluation in a NICE medical technologies guidance. A total of 6 studies were identified by the sponsor (Ellipse Technologies Inc.) as being relevant to the decision problem. Meta-analysis was used to compare the clinical evidence results with those of one conventional growth rod study, and equal efficacy of the 2 devices was concluded. The key weakness was selection of a single comparator study. The External Assessment Centre (EAC) identified 16 conventional growth rod studies and undertook meta-analyses of relevant outcomes. Its critique highlighted limitations around study heterogeneity and variations in baseline characteristics and follow-up duration, precluding the ability to draw firm conclusions. The sponsor constructed a de-novo costing model showing that MAGEC rods generated cost savings of £9,946 per patient after 6 years, compared with conventional rods. The EAC critiqued and updated the model structure and inputs, calculating robust cost savings of £12,077 per patient with MAGEC rods compared with conventional rods over 6 years. The year of valuation was 2012. NICE issued a positive recommendation as supported by the evidence (Medical Technologies Guidance 18).

The British National Health Service's draft policy on "Non-Invasively Lengthened Spinal Rods for Scoliosis" (NHS, 2014) provided the following selection criteria for the use of the MAGEC System:

- Spinal surgeon feels that an instrumented spinal fusion will result in an unacceptable reduction in final height and respiratory function, and
- Member is between the ages of 2 and 11 for girls and 2 and 13 for boys. Some children are not as skeletally mature as their chronological age so a radiograph confirming bone age within the acceptable age limits is satisfactory. Use outside the specified chronological and skeletal age range may be appropriate if the patient is particularly small for age, has late development or has an increase in respiratory risk.

The NHS also noted the following exclusion criteria regarding the use of the MAGEC system:

- Infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device
- Metal allergies and sensitivities
- Person with pacemaker
- Person requiring MRI imaging during the expected period device will be implanted
- Person younger than 2 years old
- Person weighting less than 25 lb (11.4 kg).

Figueiredo et al (2016) examined the safety and effectiveness of MCGR for the treatment of pediatric scoliosis. This is an evidence-based systematic review of literature for the surgical management of patients with pediatric scoliosis using MCGR technique. A total of 6 clinical studies regarding the use of MCGR were included in this review, with a total of 68 patients, and mean age of 8.38 years. The dual-rod (DR) technique of rod construct with MCGR was used in 33.85 % and the single-rod (SR) in 66.15 % of the patients. The mean pre-operative main coronal curve for the DR was 65.9°, and for the SR was 69.6° ($p > 0.05$). At the latest follow-up, it was 36.8° for DR and 43.0 degrees for SR ($p < 0.05$). The mean pre-operative T1 - S1 spinal length was 298.7 mm for the DR and 303.5 mm for the SR group ($p < 0.05$). According to the latest follow-up, using the DR construct, the spinal length increased to 347 mm with 13.92 % of total lengthening; and using the SR construct, the average lengthening was 339 mm, with 10.48 % of total lengthening ($p < 0.05$). Post-operative complications were similar, 25 % in DR and 31.57 % in the SR group ($p > 0.05$). The authors concluded that level IV of medical evidence supports the use of MCGR as a safe and effective alternative for the treatment of severe pediatric scoliosis. They stated that recommendation Grade C supports the role of MCGR with DR construct as an option to achieve a better correction of the scoliotic curve and to maximize the post-operative T1 - S1 spinal length.

In a prospective, non-randomized, radiological study, Thompson et al (2016) evaluated the preliminary results of using the MAGEC System to treat children with EOS. Between January 2011 and January 2015, a total of 19 children were treated with MCGRs and underwent distraction at 3-monthly intervals. The mean age of this study cohort was 9.1 years (4 to 14) and the mean follow-up 22.4 months (5.1 to 35.2). Of the 19 children, 8 underwent conversion from traditional growing rods. Whole spine radiographs were carried out pre- and post-operatively: image intensification was used during each lengthening in the out-patient department. The measurements evaluated were Cobb angle, thoracic kyphosis, proximal junctional kyphosis and spinal growth from T1 to S1. The mean pre-, post-operative and latest follow-up Cobb angles were 62° (37.4 to 95.8), 45.1° (16.6 to 96.2) and 43.2° (11.9 to 90.5), respectively ($p < 0.05$). The mean pre-, post-operative and latest follow-up T1-S1 lengths were 288.1 mm (223.2 to 351.7), 298.8 mm (251 to 355.7) and 331.1 mm (275 to 391.9), respectively ($p < 0.05$). In all, 3 patients developed proximal pull-out of their fixation and required revision surgery: there were no subsequent complications. There were no complications of out-patient distraction. The authors concluded that the findings of this study showed that MCGRs provided stable correction of the deformity in EOS in both primary and revision procedures. They have the potential to reduce the need for multiple operations and thereby minimize the potential complications associated with traditional growing rod systems.

In a prospective, non-randomized study, Heydar et al (2016) evaluated the safety, effectivity profile of MCGR in patients with EOS. A total of 18 patients with progressive EOS were treated by MCGR, 2 of them had undergone final fusion operation. Patients were followed-up for a minimum time of 9 months from the time of initial surgery. Radiological data were analyzed in terms of Cobb angle, kyphosis angle, T1-T12 and T1-S1 distances in pre-operative, post-operative and last follow up. The mean pre-operative Cobb and kyphosis angle were 68° (44 to 116°), 43° (98 to 24°), it was corrected to 35° (67 to 12°), 29° (47 to 21°) immediately after initial operation and maintained at 34.5° (52 to 10°), 33° (52 to 20°) at last follow up, respectively. The mean pre-operative T1-T12 and T1-S1 distance were 171 mm (202 to 130), 289 mm (229 to 370), it was increased to 197 mm (158 to 245), 330 mm (258 to 406) immediately after initial operation and further increased to 215 mm (170 to 260), 35 7mm (277 to 430) at last follow-up, respectively; 2 patients had undergone final fusion, they had overall mean Cobb angle correction of 66° (62 to 70), kyphosis angle change of 53° (26 to 80). Total height gain in T1-T12 and T1-S1 of 80.5 mm (67 to 94) and 119 mm (105 to 133), respectively. The authors concluded that MCGR is safe and effective technique in correction of EOS deformity and in maintaining the correction during non-surgical distraction procedures. A further correction of the deformity and more spinal height gain can be achieved in the final fusion operation.

Ridderbusch et al (2017) stated that growth-sparing techniques for the treatment of EOS have developed significantly over the last years. Traditional growing rods (GRs) require repeated surgical lengthening under anesthesia. Since June 2011 these researchers have been using the MCGR to treat patients with progressive EOS. A total of 35 patients with EOS of different etiologies underwent treatment with MCGR. These researchers recorded

about the preliminary results of 24 patients who fulfilled the inclusion criteria of a minimum follow-up (FU) of 12 month and greater than 3 lengthening. The mean age at surgery was 8.9 ± 2.5 years. Correction of the primary curve after the index surgery and after lengthening was measured on standing radiographs using the Cobb technique; T1-T12 and T1-S1 spinal length were also measured. Intra-operative and post-operative complications were recorded. The mean FU was 21.1 ± 7.3 months. All patients had a minimum of 3 out-patient lengthening [mean of 4.6 ± 1.5 (range of 3 to 8)]. The mean primary curve was 63 ± 15 degrees (range of 40 to 96) and improved to 29 ± 11 degrees (range of 11 to 53; $p < 0.001$) after MCGR. The mean major curve after most recent lengthening was 26 degrees (range of 8 to 60; $p < 0.07$). The T1-T12 as well as the T1-S1 length increased significantly ($p < 0.001$). The mean pre-operative thoracic kyphosis decreased from 43 ± 24 degrees (range of -32 to 86) to 27 ± 12 degrees (range of 9 to 50 degrees; $p < 0.001$) after surgery, respectively, and measured 32 ± 12 degrees (range of 12 to 64; $p < 0.05$) at last FU. In 1 patient a loss of distraction occurred making rod exchange necessary; 3 patients developed a proximal junctional kyphosis and in another patient a screw pull out occurred that required revision surgery. The authors concluded that these findings demonstrated that MCGR is a safe and effective non-fusion technique in the treatment of progressive EOS avoiding repeated surgical lengthening procedures. It provided adequate distraction similar to standard GR. The magnetically induced transcutaneous lengthening allows non-invasive distraction achieving spinal growth comparable to conventional GR techniques.

La Rosa et al (2017) presented a series of 10 patients with early-onset scoliosis (EOS) managed with magnetically controlled growing rod (MCGR) (Ellipse TM MAGEC System, Irvine, CA). These investigators implanted MCGR in 10 patients affected by EOS. Scoliosis and kyphosis angles, T1-T12 and T1-S1 length were evaluated pre-operatively, post-operatively, and at the last follow-up. A visual analog scale (VAS) score was used to evaluate pain during out-patient rod distraction procedures. The mean follow-up was 27 months. All patients attended distractions of the magnetic rod through an external remote control every 3 months. The mean predicted distraction was 3 mm at each lengthening session. The mean Cobb angle value was 64.7 ± 17.4 degrees (range of 45 to 100) pre-operatively and 28.5 ± 13.9 degrees (range of 15 to 59) at the latest follow-up. The mean T1-S1 length value was 27.1 ± 5.4 cm (range of 16 to 34.8 cm) pre-operatively and 32.8 ± 4 cm (range of 26.5 to 39) at the latest follow-up. The mean T1-T12 length value was 16.2 ± 2.7 cm (range of 10 to 19 cm) pre-operatively and 20.6 ± 2.9 cm (range of 15.5 to 23.5 cm) at the latest follow-up. The average monthly T1-T12 height increase was 0.8 mm, whereas the average monthly T1-S1 increase was 0.9 mm; 2 patients experienced a rod breakage and 1 patient had a pull-out of the apical hooks. The authors concluded that although implant-related complications could occur, as in all EOS growing rods procedures, MCGR can be effectively used in patients with EOS. This spinal instrumentation can overcome many of the complications related with the traditional growing rods implants. This procedure can be effectively used in out-patient settings, minimizing surgical scarring,

surgical site infection, and psychological distress due to multiple surgeries needed in the traditional growing rods system, improving quality of life, and saving health care costs.

Orthotic devices -hyphen scoliosis procedures

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The Magnetically Controlled Growing Rod:

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