

Current status of the magnetically controlled growing rod in treatment of early-onset scoliosis: What we know after a decade of experience

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Abstract

The magnetically controlled growing rod (MCGR) has had approximately 10 years of clinical experience worldwide. Clinical effectiveness to control early-onset scoliosis is consistent even at final surgery. MCGRs have significantly lower relative percentage of infection or wound complications as compared to traditional growing rods. Most common complications include foundation failure and failure of distraction. Contouring of the rod especially at the proximal segment while accommodating for the straight actuator remains a difficult task and its failure may lead to proximal junctional kyphosis. Unique complications of MCGR include clunking, temporary diminishing distraction gains, and metallosis. Temporary reductions in distraction gains are observed as the MCGR lengthens but return to normal baseline distraction gains after rod exchange. Lack of standardization for rod configuration, distraction strategies and decisions of whether to keep the rods in situ, remove without fusion surgery or to perform spinal fusion at skeletal maturity will require further study.

Keywords

actuator, complications, distraction, lengthening, magnetically controlled growing rod

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Introduction

Management of early-onset scoliosis (EOS) is not a simple task. These spinal deformities occur in young children and if left untreated, the curvature may rapidly deteriorate and lead to cosmetic disfigurement and poor pulmonary development.^{1–8} Growing rods are one of the popular treatment options for EOS because it can prevent curve deterioration while allowing spinal growth.^{9–11} In a matched cohort study with the Shilla procedure, similar growth and curve correction parameters were observed.¹² Traditionally, growing rods require open manual distractions approximately every 6 months^{9,10,13–17} but has increased risk of anesthetic and wound complications.^{1,2} Repeated surgery under general anesthesia also has potential deleterious effects on brain development. This is especially important for young children (<3 years) as sedation and anesthetic drugs may lead to poor brain development.¹⁸

Due to these limitations of traditional growing rods (TGRs), the magnetically controlled growing rod (MCGR) system has been developed to allow for gradual lengthening on an outpatient basis.^{19,20} The MCGR allows for periodical noninvasive spinal lengthening under continuous neurological observation in an awake patient by use of a large external magnet. Hence, unlike TGRs, MCGRs can be distracted during outpatient clinic visits, thereby

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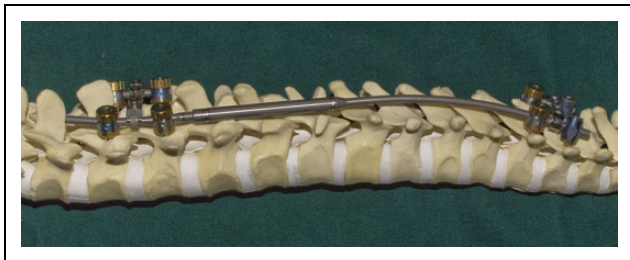


Figure 1. The MCGR with a thickened actuator portion that houses the magnet. MCGR: magnetically controlled growing rod.

avoiding the risks of repeated surgical lengthening.^{2,9,21} There is also the possibility for distractions to be carried out more frequently to mimic normal physiological growth more closely.²²

This presents a potential huge benefit for children as rod distractions no longer need to be carried out under general anesthesia. This may provide additional advantages to spine length gains by avoiding spine autofusion associated with sudden and forceful surgical distractions at irregular intervals.^{21,23} Furthermore, due to infrequent need for admissions and general anesthesia, there is potential cost-saving benefits of the MCGR over the TGR.^{24,25}

In the past few years, our understanding of the MCGR's role in the management of EOS has improved. In this review, we will highlight its history, development, and future directions with specific emphasis on instrumentation strategies and implantation configurations, and complications.

History of the MCGR

The first report of an MCGR dates back to 2004 with the Phenix rod developed by Arnaud Souberian, a French aeronautical engineer.²⁰ With a large-sized internal magnet and a permanent external magnet placed on the skin, this device allowed for lengthening 5 days out of a week and aimed to focus correction at the curve apex. Unfortunately, this device fell out of favor with the death of its inventor. The current iteration of the MCGR is the MAGEC[®] rod (Figure 1), initially developed by Ellipse Technologies, Inc. (Irvine, California, USA) and subsequently acquired by NuVasive, Inc. (San Diego, California, USA) in 2016. The first tests of this novel technology were performed by Akbarnia et al.²⁶ in Yucatan pigs. Initial findings verified the ability of the rod to safely distract using an external magnet.

Cheung et al.¹⁹ described the very first experience with the MCGR in humans. Of the five patients implanted in that clinical trial, two patients completed a 2-year follow-up at the time of reporting. Initial results showed sequential lengthening of the rods with each distraction, which was performed at 1.5–2 mm per month. There were no complications and the functional outcome using the 30-item Scoliosis Research Society (SRS-30) questionnaire was good. Since this initial experience, there have been five subsequent

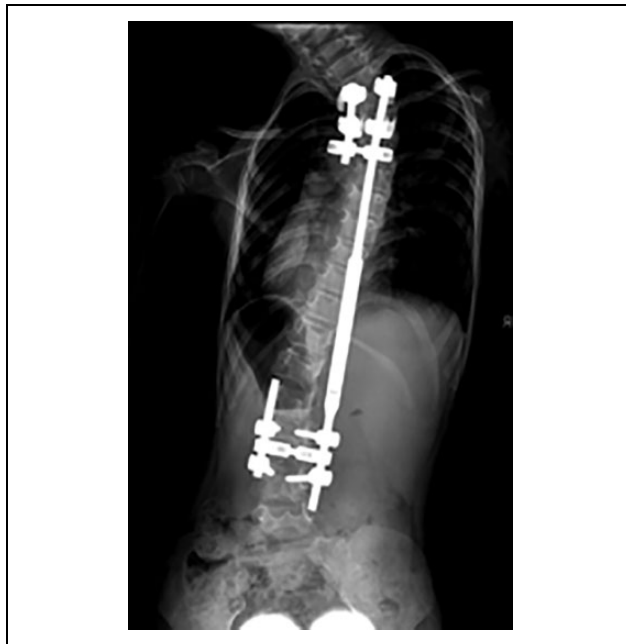


Figure 2. The first generation MCGR can be identified without any expanded portion in the shaft of the rod. MCGR: magnetically controlled growing rod.

structural modifications of the MCGR.²² Loss of distraction was encountered between distraction sessions of the first implanted MCGR in 2009. Because of this, the original rod design (Figure 2) required the insertion of a “keeper plate” or stainless steel plate within the rod next to the magnet to prevent it from rotating on its own without the external magnet. This “second generation” rod (Figure 3) was introduced in 2010 with an increased rod shaft diameter from 9 to 10.5 mm to house this steel plate. The third modification was in 2012 to the welding procedure of the junction between the actuator and the rod shaft. Rod fractures were a concern and the switch in the welding technique from a pulsed laser to a continuous laser reduced the occurrence of any weak points on the rod surface. Essentially, the entire enlarged portion of the rod became a continuous segment without breaks. Two other modifications were made since 2015. Firstly, a smaller sized actuator (70 mm) was made for smaller sized children. Secondly, the actuator pin has been reinforced to avoid pin fracture (Figure 4).²⁷

Current MCGR

Currently, these MCGRs come in two configurations: standard and offset depending on the direction of rod extension from the housing portion of the rod. These rods house an actuator with a magnet inside that is driven by an external magnet, called a remote controller (Figure 5), to distract the rod. Careful insertion of the MCGR is necessary as the standard and offset rods extend in different directions. An arrow is placed on the rod to avoid incorrect rod insertion and subsequent distraction failure. The actuator cannot be

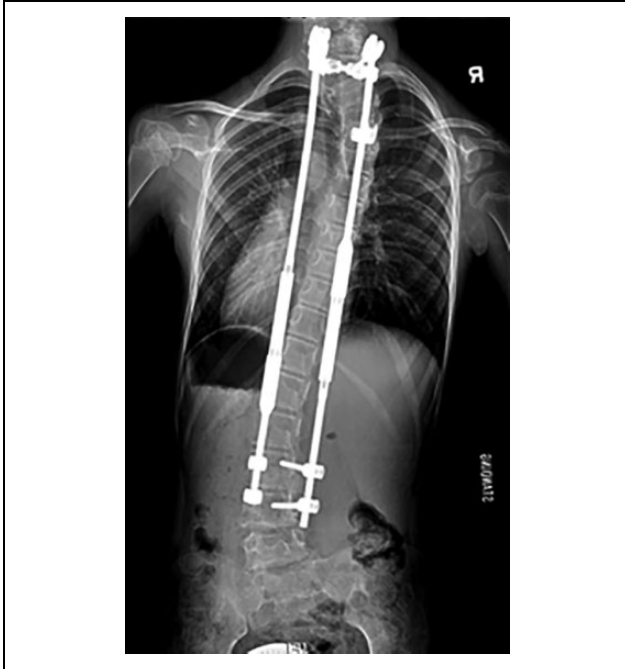


Figure 3. The second generation MCGR with an increased actuator diameter due to the keeper plate. The rods are inserted in one standard and one offset configuration. MCGR: magnetically controlled growing rod.

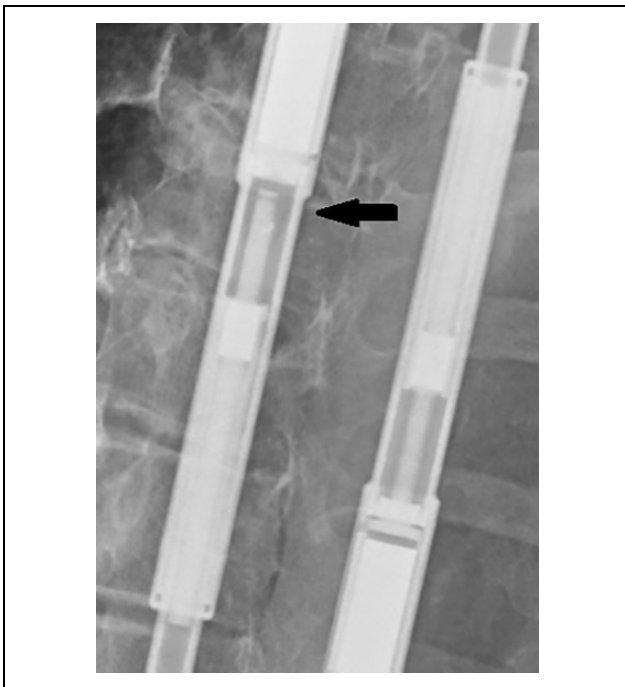


Figure 4. Fractured actuator pin.

contoured but the rod segment proximal and distal to the actuator can be contoured to fit the anchors. Two sizes of actuators (70 and 90 mm) are available depending on patient size. The rod diameter comes in selection of 4.5, 5.5, and 6 mm.



Figure 5. External remote controller used for outpatient distractions.

Case selection

Similar to TGR, MCGRs are used for patients with EOS and a sizeable Cobb angle (i.e. 50°), large potential for further spine growth and observed curve progression. Essentially, any type of scoliosis is amenable to MCGR treatment with consistent length gains especially with primary surgery.²⁸ This has also been shown in congenital scoliosis^{23,28,29} and fixation to the pelvis,³⁰ whereby distraction gains are similar to that found in idiopathic or syndromic patients. However, Keskinen et al.³¹ have shown that conversion cases do not fare as well in terms of growth gains. This may be related to the already stiffer spines contributed by previous TGR surgeries. Larger comparative studies at longer follow-up are required to study this relationship further.

There are several unique applications of the MCGR's gradual distraction utility. Thoracic insufficiency syndrome is commonly treated by vertical expandable prosthetic titanium rods (VEPTR).³² A hybrid with the MCGR can help patients wean off ventilator and achieve some spine length gain. However, these patients do not have enough growth potential to sustain continuous distractions.³³ The MCGR can also be used to gradually correct severe deformities.^{34,35} In such situation, it acts like an internalized halo-gravity traction device to allow for awake correction and reduces risk of neurological complications and technical difficulties during the definitive fusion surgery. Skov et al.³⁶ utilized an interesting construct, whereby the MCGR was only used on the concave side while a sliding rod construct was used on the convex side to control the apical vertebrae similar to the Shilla technique.³⁷ The short-term results appear to be quite promising and similar to dual MCGR technique.

The MCGR is not advised if patients require magnetic resonance imaging (MRI) to assess a pathology such as syringomyelia. Although no adverse effects have been shown with using the MRI,^{38,39} image artifacts of up to 30 cm of image distortion have been observed. Hence, the spinal cord lesion cannot be monitored adequately.

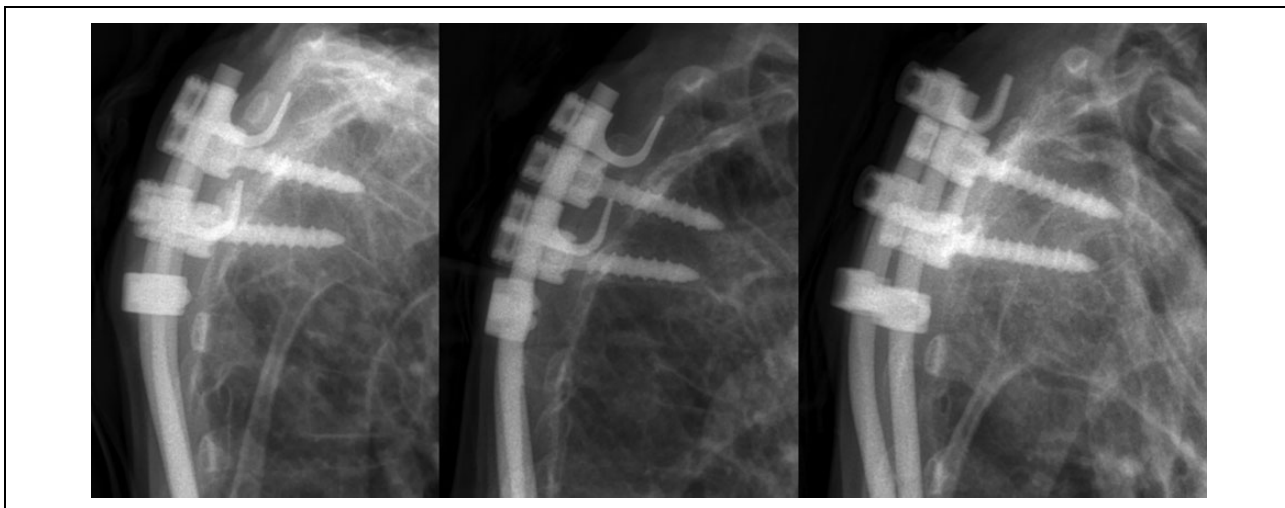


Figure 6. A case with intact upgoing rib hooks (left), ploughing of the hooks (middle), and proximal foundation failure with loosening of hook anchors (right).

Nevertheless, the efficacy of the distraction mechanism is maintained without any loss of distraction. There is also no heating concern with regards to surrounding soft tissue.⁴⁰

Anchors

Instrumentation levels usually incorporate the end-to-end vertebrae to maintain control of the major curve. Some curves with significant shift may require recruitment of more proximal and distal levels to achieve balance. However, this should be avoided if possible as reoperation due to foundation failure (Figure 6) is not uncommon and the additional revised levels will need eventual fusion as well.^{28,41} In the longest follow-up study to date with multiple graduates, final fusion occurs at 6.5 years after initial implantation and all patients required extension of fusion levels 2 levels proximally and distally.²⁸ The position of the neutral or stable vertebrae governs whether longer fusions are necessary as the added-on levels will need to be instrumented.

The choice of instrumentation strategy is especially difficult for small-sized children. Clinical examination of the patient's body size and understanding of the length of the spinal column is necessary to decide whether MCGRs are able to fit. Although 70 mm actuators are available, this may already be too long for smaller sized children. The surgeon must bear in mind that the 70 mm is only the length of the actuator. Additional length is reserved for the proximal and distal foundations and also for rod contouring as the actuator segment is straight and cannot be contoured. Delaying MCGR surgery with further casting or bracing, or with a period of halo-traction may be necessary until the rods can be inserted without sacrificing levels.

With the straight actuator segment and MCGR distractions, there is a risk for proximal junctional kyphosis (PJK). Contouring of the rod to the correct sagittal alignment may

be more difficult than TGRs, and thus overbending of the proximal rod may be necessary. Hence, the prevalence of PJK is high with up to 30% in some reports but not all require reoperation (approximately 15%).^{28,41-44} In general, the proximal levels of T1 or T2 should be avoided if possible as more cranial levels may be needed in the final fusion surgery to address the PJK. Conversion to rib anchors may help prevent these complications and has been well-established in TGR surgery.^{45,46} However, its role in MCGR and whether the rate of PJK is lower for rib hooks as compared to screws require future study.

Pedicle screws are generally preferred by most surgeons due to their stronger pullout strength as compared to hooks.²² However, hooks are less stiff and may also allow more vertebral rotation, which is an advantage during differential lengthening. In addition to the advantages of rib hooks described above for PJK, rib-based implants also avoid disruption of peri-spinous musculature that is associated with spine autofusion.^{21,47}

Rod configuration and implantation

Similar to TGR, dual rods are preferred over single rods for MCGR surgery.⁴⁸ Dual rods have been shown to produce increased distraction forces and to allow for differential correction.^{17,19} Single rods may only be used in very thin patients without adequate soft tissue coverage and if the severe rotational and gibbus deformities preclude rod insertion.

MCGRs can be placed in two standard rod configurations or one standard and one offset configuration. Internal mechanical testing from manufacturers suggests that increased distraction forces may be applied if both rods are placed in standard configuration. While one standard and one offset configuration may allow for differential correction, two standard rods have their magnets too close to each other to allow for differential lengthening. For

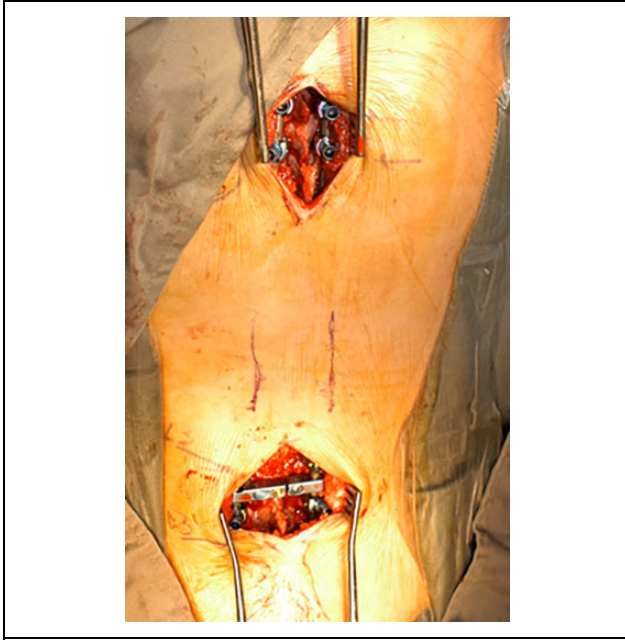


Figure 7. Subfascial insertion of MCGR rods. MCGR: magnetically controlled growing rod.

neuromuscular scoliosis where pelvic obliquity is common, standard and offset configuration may be particularly useful with this function. Another advantage of standard and offset configuration as compared to two standard rods is the reduction of “cross talk,” whereby magnets placed too close to each other create a stronger internal magnetic field.⁴⁹ In such situations, a larger external distraction force is necessary for distraction and rod slippage or clunking may occur, which limits the successfulness of lengthening. This clunking event refers to the inability for the rod’s internal magnet to complete a full revolution and results in stalling and the magnet flips back to its original position. Clinically, sudden jerky movements are observed as compared to the normal “wobble” feeling during a smooth distraction.

Like TGRs, MCGRs should be inserted subfascially (Figure 7) to prevent skin impingement. For insertion and exchange of the MCGR through the mini-incisions, a chest drain can be used to help the MCGR pass through the subfascial plane.⁵⁰ Bending of the rod too close to the motor should be avoided as it may damage it and lead to distraction problems. Whether intraoperative distractions should be performed is controversial. The authors’ practice is to achieve overall balance without loading the implants to reduce the risk of early clunking, implant failure, and anchor plowing. In these situations, early clunking is difficult for the surgeon to distinguish between a genuine rod problem or due to overloading of the rod.

Distractions

MCGRs typically are distracted 1–2 months after implantation. The frequency of distractions may vary from once

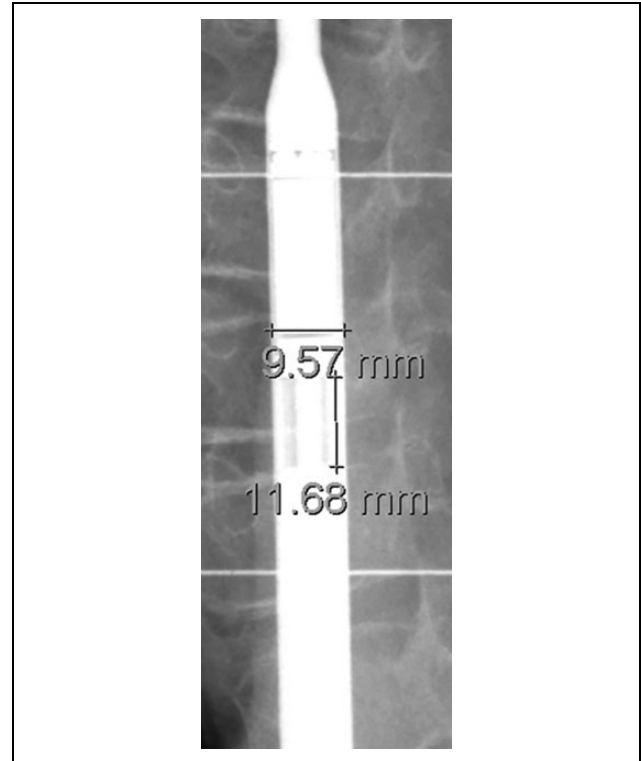


Figure 8. Radiographic measurement of distracted length.

monthly to 6-monthly, and these decisions are usually influenced by patient convenience (availability of distraction services and distance required for patients to travel) rather than exact science. Those who distract at frequent intervals may adopt a standard distracted length (approximately 2 mm) per month while those with 6-monthly intervals may distract until clunking to achieve maximum lengthening.⁵¹

Monitoring the amount of length gain is crucial as this confirms that the MCGR remains functional. X-rays can be used to measure the amount of distracted length by the height of the housing portion of the rod (Figure 8). Since the maximum length distractible is 4.8 cm, the measured distance provides indication for when rod exchanges are required. Ultrasound (Figure 9) is a popular option for monitoring MCGR distractions as it provides similar information without radiation exposure.⁵² It has been shown to correlate well with radiographs with a shallow learning curve.^{53,54} With the ultrasound, radiographs should only be obtained occasionally to assess the deformity and rod integrity.

There is no consensus on how distractions are performed and may vary between patients due to anatomical considerations and if clunking occurs. The authors elect a standardized procedure during these outpatient distractions for all patients. Outpatient distractions are performed with patients in prone position or in sitting. The ultrasound is first used to measure the current rod length prior to distractions. Then a small handheld magnet can be used to identify the internal magnet position over the skin surface and this position is marked on the skin. The targeted distraction

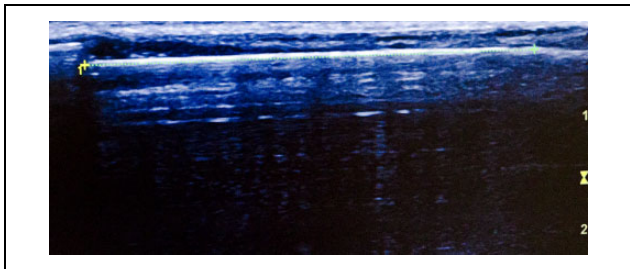


Figure 9. Ultrasonic measurement of distracted length.

length input is set in the external remote controller and the device is placed over this skin marking. The available controller provided by industry is made by two larger magnets and a central slit between the magnets should be placed over the skin marking to optimize the effect of the magnets' magnetic fields. Usually, an alternate distraction technique is utilized, whereby one rod is distracted to the targeted length followed by the other rod. Patients with big humps may only allow access for one magnet. In cases with clunking, the alternating technique with smaller targeted distraction lengths (approximately 0.2–0.5 mm) can be applied to try and reduce the stresses internally.

Complications

Complications of MCGR are not uncommon. At 2-year follow-up, up to 46.7% of patients may have had an unplanned operation.⁴¹ In a recent systematic review, the complication rate can reach up to 44.5% with unplanned revision surgery up to 33% at 29.7 months follow-up.⁵⁵ The most common causes of reoperation are failure of rod distraction and proximal foundation failure. Similar to TGRs, MCGRs still have a high risk of implant-related complications like rod fractures (Figure 10) and PJK⁵⁶ but may have reduced rate of infections.⁵⁷ Kwan et al.⁴¹ suggested that patients undergoing more frequent distractions (1 week to 2 months interval) may have higher risk of PJK and failure of rod distractions. Conversely, foundation failures may occur more frequently in distraction intervals of 3–6 months.

Failure to distract the MCGR can be technical or mechanical in origin. Technical complications are more severe as they are avoidable and often lead to complete distraction failure and require revision surgery. This may include inappropriate bending of the rod near the expanded portion of the rod and incorrect rod insertion and configuration leading to inability to distract along the long axis of the rod. Mechanical failures include spontaneous bone formation (Figure 11) near the housing unit limiting further distractions, actuator pin fracture²⁷ which has been rectified with the most recent rod modification, and clunking. Several risk factors for clunking include increased body habitus such as older age and increased body mass index, as well as reduced distance between the two internal magnets due to cross talk.⁴⁹ Increased body habitus is associated with a thicker subcutaneous layer and this increases the distance between the

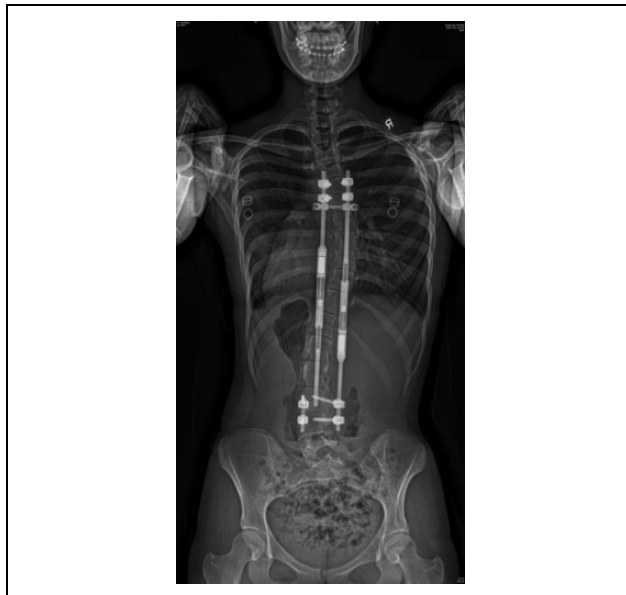


Figure 10. MCGR fracture. MCGR: magnetically controlled growing rod.



Figure 11. Calcified deposits at the extendable portion of the rod.

external remote controller and the internal magnets, thereby reducing the amount of force that can be transferred to the MCGR.⁵⁸ Hence, lengthening outcomes may be suboptimal in more obese patients. The ability to lengthen the rod reduces with 2.1%/mm of tissue depth.⁵⁸

A unique phenomenon observed from TGR is the “law of diminishing returns,” whereby decreasing gains in spinal lengthening is observed and may occur as early as the first successive lengthening.^{21,47} This has been contributed by progressive stiffness of an immature spine with prolonged instrumentation in situ or autofusion as a result of trauma to spinal ligaments after forceful distractions at infrequent intervals.²¹ The short-term results with MCGRs contradict in terms of diminishing returns and may be related to the large variations in distraction techniques and frequencies.^{23,49,59,60} Ahmad et al.⁵⁹ suggested in the short-term follow-up that this rate of decline is gradual as compared to the rapid decline seen in TGR. There is apparent divergence observed between targeted (intended amount of lengthened input in the external remote controller) and

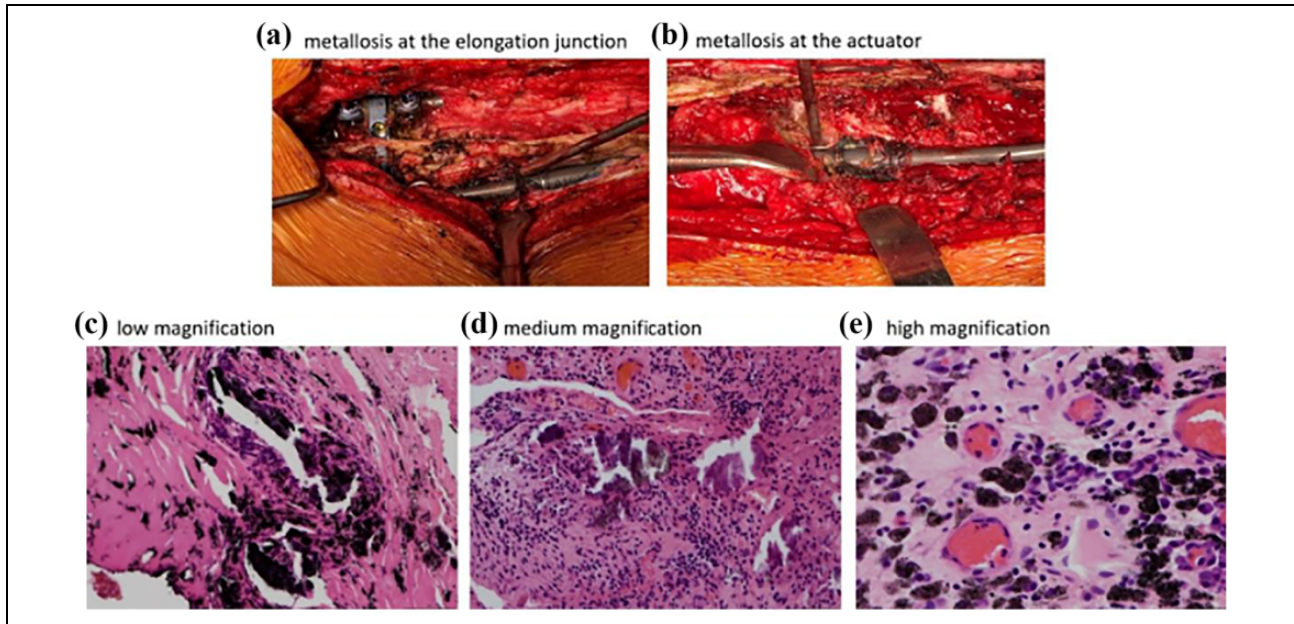


Figure 12. Metallosis as pseudo-membrane formation around the elongation junction (a) and actuator with black pus-like material (b). Microscopic examination of the soft tissues showed accumulation of black and grey granular particles (c: low magnification 0.5 mm), hyalinised fibrous stroma, and chronic inflammation reaction with macrophages infiltrates (d: medium magnification 100 µm). High magnification (e: high magnification 10 µm) investigations revealed multinucleated giant cells with black particle accumulation.

achieved (actual length measured on radiographs or ultrasound) lengthening with increasing MCGR distraction.^{58,61} One interesting observation suggests that the reductions in lengthening are due to reduced distraction forces as the rod lengthens rather than internal spinal stiffness.⁴⁹ The ability to distract returns to normal baseline after rod exchange with a new MCGR. These findings suggest that transient diminishing gains are caused by a rod design problem, in which the mechanical properties prevent achievement of full 4.8-cm rod lengthening. This is supported by a recent biomechanical study on gradual reductions in maximum force output by the MCGR. Poon et al.⁶² showed that by using a straight MCGR, the maximum force at 0 mm was 208.0 N, at 25 mm was 199.6 N, and at 40 mm was 192.0 N. There is a decrease in maximal force generated as the rod is lengthening, which is a possible rationale for these transient reductions in distraction length gains. It is important to note that this study used a straight rod rather than a bent rod which does not match the clinical scenario. The change in force output may be more pronounced in a bent rod. Rush-ton et al.⁶³ corroborated with these findings using force testing of explanted MCGRs showing that the duration of rod implantation is inversely proportional to the reduction in force generated by the rods. In their study, no force can be generated if the MCGR has been implanted for over 38 months. The effect of wear at the distractable portion of the rod on force output should also be studied in the future.

With longer follow-up, MCGR users have observed metallosis (Figure 12) around the rod-anchor junction and extendable portion of the MCGR in patients undergoing

revision surgery.⁶⁴ This may be caused by increased “growth marks” or wear of the rod with lengthening.⁶⁵ In the authors’ experience, up to 67% of patients at repeated surgery would have such findings.²⁸ Teoh et al.⁶⁴ suggested that metallosis is a result of a chronic inflammatory response to metal debris, which is produced via rod pistoning or telescoping. It may be a result of rod defects or the O-ring seal failure (junction where the MCGR is extended), leading to increased wear. In these revision surgeries, a pseudo-capsule formation occurs around the actuator and microscopic examination shows accumulation of black and gray granular particles, hyalinized fibrous tissue with lymphoid, and plasma cell infiltrates. The significance of this debris and long-term effects are still unknown. The MCGRs are made of Ti-6Al-4V ASTM F136 titanium alloy. However, in addition to raised serum titanium and aluminum ion levels also observed with TGR, patients with MCGR also have raised vanadium ion levels.⁶⁶ The MCGR also contains boron in its actuator but was not found in the serum.⁶⁶ Future study should investigate whether the more prevalent magnet alloy neodymium (Nd₂Fe₁₄B) is found in the serum. Hence, this is a concern especially since these patients with EOS are young and have yet to reach childbearing age.

Moving forwards

There are still many aspects of MCGR treatment that require further research and understanding. Issues like the best distraction frequency and amount of distractions per episode are important to discern as they relate to

lengthening outcomes. Changes that occur in the sagittal and axial plane with successive distractions also require further study. Most utilize X-rays to observe for any implant fracture or loosening. The role of other methods like low-dose CT to determine spontaneous fusion and migration of foundation anchors have yet to be determined. The effects of MCGR on lung function and vertebral remodeling with growth should be determined. The actual benefits of MCGR over TGR in health-related quality of life measures are unclear in the early follow-up.^{67–69} Similarly, short-term follow-up studies have observed similar results in terms of spinal growth with the MCGRs compared to TGR, VEPTR, and Shilla and Luque trolley systems.⁷⁰ This will need to be revisited at graduation surgery. The decision-making at the time of MCGR graduation is also uncertain. For TGRs, one study suggested that only 38% (10/26) patients at skeletal maturity are suitable for implant removal without spinal fusion.⁷¹ However, nine of these patients had progression of the deformity after implant removal resulting in an additional surgery for fusion. Whether patients can or should remove their MCGRs without fusion or whether every patient needs final fusion should be studied. These are all pertinent questions that hopefully combined multicenter databases such as the Pediatric Spine Study Group (PSSG) will answer in the coming decade.

Conclusions

MCGR is a significant advancement in the treatment of EOS. It provides benefits of noninvasive outpatient lengthening and thus allows for more frequent distractions with smaller lengthening increments. There is still high prevalence for complications and revision surgery similar to TGRs but has reported reduced risk for infection. Despite this, MCGR reduces the need for regular surgery to distract the rods and may have significant benefits in terms of social and psychological aspects including patient satisfaction.

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