The first magnetically controlled growing rod (MCGR) in the world – lessons learned and how the identified complications helped to develop the implant in the past decade: case report

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Abstract

Background: The first magnetically controlled growing rod (MCGR) was implanted in 2009. Since then multiple complications have been identified that have helped drive the development of the MCGR and its surgery. The aim of this report is to illustrate how identified complications in the first MCGR helped with developments in the past decade and to report a unique failure mechanism with stud fracture close to the barrel opening.

Case presentation: A 5-year old girl with a scoliosis of 58.5 degrees at T1–9 and 72.8 degrees at T9-L4 had a single MCGR inserted and anchored at T3–4 and L3–4. At postoperative 13 months the MCGR was noted to have lost of distraction between lengthening episodes due to unrestricted turning of the internal magnet. To prevent further loss of distraction, an external magnet was placed outside the skin to prevent the magnet from turning back. The overall balance was suboptimal and after the rod was fully distracted, proximal junctional kyphosis occurred. Subsequently, the MCGR was modified with an internal keeper plate to prevent loss of distraction and a dual set of these rods were implanted when the patient was 9 years old. Extension proximally to C7-T1 was done to manage the proximal junctional kyphosis. Her spinal balance improved and distractions continued. She subsequently developed add-on below and the piston rod was not aligned with the actuator. The lumbar spine was also observed to have autofusion. She subsequently had final fusion surgery performed at the age of 15 from C7-L4 leaving a residual tilt below to avoid fusion to the pelvis. The final extracted rod on the left side indicated the “crooked rod sign” on X-ray and rod dissections revealed a new failure mechanism of stud fracture close to the barrel opening. Body fluids and tissue may infiltrate the rod despite no obvious deformation or fractures resulting in hastened wearing of the threads.

Conclusions: There are various complications associated with MCGRs that are related to rod design and surgical inexperience. Repeated rod stalling is not recommended with potential stud fracture and “crooked rod sign”. Rotor stalling and thread wearing which indicates rod failure still require solutions.

Keywords: Magnetically controlled growing rod, MCGR, Distraction failure, Rotor stalling, Metallosis, Crooked rod

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Background
Growing rods are now the standard treatment option for EOS because it prevents curve deterioration while accommodating physiological spinal growth [1–3]. Traditional growing rods require surgical distractions usually every 6 months [1, 2, 4–8] but carries significant risk of anesthetic and wound complications [9]. The magnetically controlled growing rod (MCGR) has revolutionized surgery for EOS as it allows gradual outpatient lengthening [10–13]. This avoids the risks with repeated surgical lengthening [1, 14, 15] and allows more frequent distractions to mimic physiological growth [16]. Regular distractions may also prevent autofusion associated with the traditional growing rod (TGR) in which abrupt and forceful open surgical distractions are imposed [15, 17]. It has been extended to treating patients with thoracic insufficiency syndrome [18] and gradual correction of severe deformities [19, 20]. MCGRs have obvious advantages with awake distractions and avoids repeated admissions with surgery under general anesthesia. The MCGR also has cost-saving benefits over TGR [21, 22].

However, complications of MCGR are not uncommon. There are reports of unplanned reoperations of up to 46.7% of patients at 2-year follow-up [23]. Of these complications, the most common reasons for revision surgery are failure of rod distraction and proximal foundation failure. Distraction failure can be technical or mechanical in origin. Technical complications are usually avoidable and include inappropriate rod bending, and incorrect rod insertion and configuration. This leads to failures of distraction along the long axis of the rod. Mechanical failures include spontaneous bone formation near the housing unit, actuator pin fracture [24], and rod stalling/clunking. All of these lead to limitation in distraction lengthening. A unique phenomenon called the “law of diminishing returns” whereby decreasing gains in spinal lengthening is observed have been reported with the MCGR. Divergence between the intended lengthening input and achieved lengthening has been reported with distraction [25, 26]. Reductions in lengthening may be due to reduced distraction forces as the rod lengthens [27]. Poon et al [28] showed in a biomechanical study that by using an unbent MCGR, the maximum forces were 103.0, 98.8 and 95.0 N at 0, 25 and 40 mm of rod protrusion, respectively. Another concern is metallosis around the rod-anchor junction and extendable portion of the MCGR [29]. Teoh et al [29] suggested metallosis to be a result of a chronic inflammatory response to metal debris which is produced via rod pistoning or telescoping. The significance of this debris and long-term effects are concerning but still unknown.

Recently, the world’s first MCGR patient just undergone her final fusion surgery. It is thus timely to report this clinical case and our own course of understanding the MCGR through the first decade of its use. Specifically the complications of this case with developments in clinical practice and rod modifications are highlighted.

Case report
On 3rd November 2009, the first MCGR (Table 1) was implanted in a 5-year-old girl with Ehlers-Danlos Syndrome (type VI). This patient was born with generalized hypotonia and a flail right upper limb. She had a curve of 58.5 degrees at T1–9 and 72.8 degrees at T9-L4 with a single MCGR anchored at T3–4 and L3–4 (Fig. 1). An extra short rod was placed on the other side to facilitate any additional MCGR without changing the foundation. At postoperative 13 months, the MCGR failed to distract between lengthening episodes due to unrestricted turning of the internal magnet. The rod returned to the pre-distraction state at follow-up indicating a loss of distraction. The unrestricted turning was observed through internal testing by the developer. There was increasing truncal shift and shoulder elevation. An external magnet was placed outside the skin to prevent the magnet from turning back (Fig. 2). The rod was redesigned with an internal keeper plate added to prevent further loss of distraction (Fig. 1). The overall balance was suboptimal and after the rod was used up, she developed proximal junctional kyphosis (PJK) as well as a “crooked rod sign” (Fig. 3).

At 9-years-old, a set of dual MCGRs with the new design were inserted with extension proximally to C7-T1. Her spinal balance improved and distractions continued. She subsequently developed adding-on [30] below (Fig. 1). At 15-years-old, the rods failed to distract with frequent rotor stalling. A “crooked rod sign” was again

| Table 1 Summary of surgeries |
|---|
| **Age of patient** | **5 yr** | **9 yr** | **15 yr** |
| Rod inserted | Single right standard MCGR | Dual MCGR: left standard, right offset | Fusion |
| Distraction episodes (rod lengthened) | 26 distractions (37.6 mm) | 28 distractions (left rod 46.4 mm, right rod 46.7 mm) | – |
| Complications related to implant | Loss of distraction, crooked rod sign, metallosis | Crooked rod sign, metallosis | Nil |
| Complications related to surgery | Proximal junctional kyphosis | Distal adding-on, autofusion | Nil |
observed on radiographs (Fig. 4). No further distractions were possible. Autofusion was also observed in the lumbar spine. Final fusion surgery was performed from C7-L4 leaving a residual tilt below to avoid fusion to the pelvis as she was a candidate for the para-Olympics table tennis team and we wanted to maintain mobility. Gross metallosis observed around the actuator and extendable portion of the rod was debrided (Fig. 4).

The rods were extracted for visual inspection, X-ray examination and dissection (Fig. 5). On the external appearance, from the anteroposterior (AP) view, the two MCGRs were aligned. However, from the lateral view, the piston rod in the left MCGR showed a “crooked rod sign” close to the barrel opening. Dissection of the left rod revealed that the “crooked rod” radiographic sign was caused by fracture of the stud close to the barrel opening (Fig. 6). The rotor and stud could not drive the piston rod to extend due to this complete material failure. Part of the stud remained inside of the piston rod and the fracture site could have repetitive frictions caused by rod stalling during distraction sessions with magnet rotation. Corrosion could be seen at the stud fracture site and the barrel opening of the sleeve portion (Fig. 6).

Additionally, the debris from inside of the sleeve was collected on petri dishes and observed under light microscopy (Fig. 7). Morphologically, wear particles were seen for the left rod with fracture (Fig. 7: A&B Left), whereas for the right rod, the debris was larger and had the appearance of screw thread tracks (Fig. 7: A&B Right). The concentrations of elements (mg/kg) in the sample were measured by inductively coupled plasma optical emission spectrometers (ICP-OES; Agilent 700 Series; Agilent Technologies, Inc.; US). The testing process followed the instructions from the manufacturer (https://www.agilent.com/cs/library/usermanuals). The ICP-OES revealed the elements from the debris contained both metal wear particles (Titanium, Aluminum, Vanadium, Neodymium) and human tissues (Calcium, Phosphate, Potassium, Sulfur, Sodium) (Table 2). For the left rod there was predominantly metal particles, whereas for the right rod, elements from human tissues were increased.
Fig. 3  

a Lateral radiographs preoperatively.  
b Initial single rod insertion with development of proximal junctional kyphosis after the revised rod.  
c A crooked rod sign in which the extendable portion of the rod is not inline with the actuator can be seen.  
d Extension to C7-T1 was performed.

Fig. 4  

Pre-final surgery posteroanterior and lateral radiographs identified a crooked rod sign and autofusion of the lumbar spine (top left). Final fusion surgery from C7-L4 was performed (top right) leaving a residual tilt at L4-sacrum. Intraoperative photo showed extensive metallosis around the actuator and extendable portion of the rod (bottom).
The patient is now more than 2 years after the final fusion surgery with maintenance of the Cobb angle correction. The overall balance remains unchanged without any loosening of the implant.

**Discussion and conclusions**

The MCGR and its surgical technique have gone through many iterations to solve various problems exhibited by this patient’s journey. The first MCGR or Phenix rod was developed by Arnaud Souberian, a French aeronautical engineer, in 2004 [12]. However, this rod fell out of use due to its large-sized internal magnet and the need for a permanent magnet to be placed on the skin. The widely adopted MCGR is the MAGEC® rod, initially developed by Ellipse Technologies, Inc. (Irvine, CA, USA) and subsequently acquired by NuVasive Inc. (San Diego, CA, USA) in 2016. The first tests of this novel technology were performed by Akbarnia et al [31] in Yucatan pigs which verified the mechanism of safe distractions using an external magnet. Subsequently, Cheung et al [13] described the very first experience with the MCGR in humans which supported its role in managing EOS. Since that initial experience, there has been six subsequent iterations or generations of the MCGR [16]. A “keeper plate” or stainless steel plate was inserted within the rod next to the magnet to prevent it from rotating on its own without the external magnet as illustrated in this patient. The “second generation” rod was introduced in 2010 with an increased rod shaft diameter from 9 mm to 10.5 mm to house this steel plate. The third generation rod was introduced in 2012 with a change from...
the previous pulsed welding method to a continuous welding method at the junction between the actuator and the rod shaft to reduce the risk of rod fractures. Since 2015, various other modifications have been made to allow a smaller sized actuator (70 mm) for smaller children, and reinforcement of the actuator pin [24]. The newest iteration of the MCGR is called MAGEC X which has since been withdrawn from use due to actuator cap dislodgement.

This report encompasses the entire journey of the first patient with MCGRs implanted till graduation. The encountered complications helped to improve the rod design. Loss of distraction was encountered between distraction sessions of the first single rod. The original rod design required the inclusion of a keeper plate which is a small stainless steel plate within the rod next to the magnet to prevent the rotor from rotating in the absence of the rotating magnetic field imposed by the external magnetic controller [16]. Although dual rods are generally preferred due to the large distraction forces and the possibility for differential correction [8, 13], only a single rod was possible due to her small physical size at the age of 5. The decision to use a claw construct may have led to PJK whereby no further kyphotic changes were observed after revision surgery with pedicle screws.

**Table 2** Inductively coupled plasma results of the powder from the dissected MCGRs

|                  | Ti  | Al  | V   | Nd  | Ca  | P   | K   | S   | Na  |
|------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Fractured rod (left rod) | 21.952 | 9.3580 | 0.6785 | 0.0098 | 0.4778 | 0.9521 | 0.0827 | 2.3633 | 2.3531 |
| Intact rod (right rod)  | 1.8060 | 2.5216 | 6.1628 | 0.0029 | 4.4487 | 5.0345 | 0.4316 | 1.8293 | 3.4970 |

All listed in mg/kg.

Elements from the MCGR (red): Ti: Titanium; Al: Aluminum; V: Vanadium; Nd: Neodymium. Elements not from MCGR (blue): Ca: Calcium; P: Phosphate; K: Potassium; S: Sulfur; Na: Sodium.
drawback to this was instrumentation into the cervical spine at final surgery. Another reason for the PJK could be flattening of the thoracic kyphosis by the actuator which extended into the thoracic spine for the early rods (Fig. 3). Building more proximal kyphosis was achievable when the patient was older and was physically big enough to accommodate longer rods for contouring. Often it is technically impossible to bend the rod much within a small distance between the proximal foundation and the actuator [32].

Besides the distraction failure due to the initial rod design, mechanical failures may occur such as actuator pin fracture [24] which has been improved by increased diameter of the pin with stronger material. However, breaks have still been reported with up to 21% in one series [33]. More importantly is the rotor stalling (slippage or clunking) which is more common in patients with increased body habitus such as older age and increased body mass during natural growth, as well as reduced distance between the two internal magnets due to cross-talk [27]. With MCGR wear, the stud threads in the rod may deform causing a failure of the internal distraction mechanism. Infiltration by body fluids and tissue may also occur which results in fastened wearing via corrosion of the threads as evidenced by the apparently intact right rod. However, close examination of the particles in the rod revealed screw compression marks and increased human tissue elements suggesting a seal fragmentation and failure. Further distractions are not achievable without revision surgery. This may be more important in those who routinely distract till stalling [34]. Radiologically, this appearance forms a “crooked rod sign” in which the extendable portion of the rod and the actuator are not in a parallel relationship [35]. Upon dissection of the final extracted rod however, we found a complete fracture of the threaded stud, which represents an extreme case of stud deformation and complete failure of rod extension, with metal wear particles accumulated inside the rod.

We speculate that there was corrosion inside of the barrel opening and wear marks on the piston rods was found to be associated with metallosis. Most MCGRs develop metallosis after prolonged use. This is observed around the rod-anchor junction and extendable portion of the MCRG in patients undergoing revision surgery [29]. This may be caused by increased wearing of the rod with creations of “growth marks” that occurs with each lengthening [36]. Up to 67% of patients at repeated surgery have been reported with such findings [37]. The long-term effect of the metallosis is unclear and is thus a concern as these are young patients who have yet to childbear. This may be a result of design defects and/or the O-ring seal failure (junction where the MCRG is extended) leading to metal-on-metal friction between the sleeve portion and the piston rod. Increased titanium, vanadium and neodymium concentrations in the muscle tissues surrounding the MCRG are found with chronic inflammations and phagocytotic black particles [38]. Titanium and vanadium are generated mainly at the barrel openings due to metal-on-metal contact, whereas the neodymium from the magnet rotor within the barrel is likely to be released from the barrel opening during distractions. The presence of neodymium proves that the O-ring seal has failed. Interestingly, there were more non-MCRG elements found in the intact rod as compared to the broken rod. We suspect that with a complete failure, further human tissue/fluid infiltration is limited while the intact rod continues to undergo cyclic loading with continuous wearing.

Best indications for surgery, advantages of dual rod constructs as well as signs of early complications and rod failure have been established. Despite a decade of use, aspects such as appropriate distraction intervals and technique, dealing with sagittal plane deformities and the long-term implications of metallosis still require further investigation. The best distraction frequency and amount of distractions per episode are important clinical questions as they influence lengthening outcomes. The Pediatric Spine Study Group is currently undergoing a multicenter randomized controlled trial in attempt to answer this question (ClinicalTrials.gov #NCT04058561). Modifying the surgical technique to maximize changes in the sagittal and axial plane is also important for further study. In addition, the effects of MCRG on lung function and vertebral remodeling with growth is unknown. Decision-making at graduation is also controversial. Whether rods should be removed or kept in-situ, or if fusion is needed are still debated.

Abbreviations
AP: Anteroposterior; EOS: Early onset scoliosis; ICP-OES: Inductively coupled plasma-optical emission spectrometers; MCRG: Magnetically controlled growing rod; PJK: Proximal junctional kyphosis; TGR: Traditional growing rod

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Authors’ contributions
JPYC contributed to the study design, data acquisition, analysis and interpretation, performed the surgery, and wrote/revised the manuscript. KYS contributed to the mechanical data acquisition and analysis. KMCC performed the surgery. TZ contributed to the study design, data acquisition, analysis, and interpretation and wrote the manuscript. All authors approved the submitted version and have agreed both to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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