Magnet Fracture within a Magnetically Controlled Growing Rod: A Case Report of a New Mechanism of Failure

Conor S Jones¹, Paul Rushton², Michael Hutton¹, Oliver M Stokes¹

Abstract

Introduction: Magnetically controlled growing rods (MCGRs) have been widely adopted in the management of early-onset scoliosis since they were first described in 2012. Recent reports have highlighted concerns around their safety. To date, little is understood about the risk factors and modes of failure in these devices.

Case Report: We report a novel mechanism of device failure in a 14-year-old patient following multiple revisions of MCGRs. Clinically, there was no evidence of device failure and the MCGRs appeared radiologically intact. Explantation analysis revealed multiple compromised/non-functional components. A previously undocumented phenomenon of complete magnet fracture was also seen.

Conclusion: The absence of clinical or radiological features of device failure in this case makes the findings of great concern. Given the relative paucity of high-quality evidence surrounding the use of MCGRs, we support calls for urgent comparative studies and further investigation of risk factors for device failure.

Keywords: Spinal surgery, Scoliosis, Magnetically controlled growing rods, Implant.

Introduction

Early-onset scoliosis (EOS) is characterized by a lateral curvature of the spine before the age of 10 years. Its management is challenging due to the rapid rate of spinal, thoracic, and pulmonary development at this age. Growing rods are a recognized treatment for progressive curves, they permit guided spinal growth until sufficient skeletal maturity for definitive fusion is reached.

Unlike traditional growing rods (TGRs), which require repeated invasive distraction under general anesthesia, magnetically controlled growing rods (MCGRs) contain a telescopic actuator which can be lengthened non-invasively in the outpatient setting. Since they were first described by Cheung et al. in 2012, MCGRs have been adopted as a treatment for EOS worldwide [1].

Early reports of their use have demonstrated promising results in terms of spinal curvature control [1, 2, 3]. More recently, however, concerns have been raised about the long-term effectiveness of MCGRs and potentially high failure rate [4, 5]. Current methods of introducing surgical devices have been the subject of much controversy and concern in recent years [6]. Unlike the pharmaceutical industry, the evaluation and introduction of surgical devices are less tightly regulated. As a result, device failure can go unrecognized by the surgical community until centers have implanted enough devices, which have subsequently failed, begin to report concerns in the literature. This permits the continued use of potentially harmful devices and presents risk to patients. Case reports, therefore, play an important role in the early
Definitive fusion was performed 18 months after the second revision (39 months after the initial revision) when the patient had reached sufficient skeletal maturity. Radiologically, the rods appeared intact and there was no clinical indication of device failure (Fig. 2). Pre-explantation radiographs demonstrated coronal Cobb angle of 42° with good coronal balance.

Further revision of the concave rod was required after 21 months, with the patient aged 13 years. Radiologically, failure of the distal end cap to restrain the MCGR during distraction was noted. Following discussion with the manufacturer, the decision was made to exchange the entire MCGR, as opposed to reimplantation, due to the risk of notching and consequent failure of the in situ rod. A 4.5 mm offset rod with 90 mm actuator MAGEC rod (version 1.5) was contoured, tested, and inserted before set screw application and tightening. Distractions took place at 3-month intervals until clunking was heard.

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Intraoperatively, extensive metallosis was seen bilaterally. An additional metallosis tract remained at the site of a previously explanted device.

Explant analysis was performed by an independent retrieval center (Newcastle Upon Tyne, United Kingdom). Neither rod was able to produce any force ex vivo when tested with an external remote controller. The actuator casing was cut open to interrogate the internal components. Findings of the explanation analysis are summarized in Table 1. A previously undocumented phenomenon, complete fracture of the magnet,
was identified within the concave MCGR (Fig. 3). Both rods demonstrated compromise of the sealing mechanism (Fig. 4) and extensive accumulation of black debris. The drive pin was fractured in the concave rod only (Fig. 5).

Discussion

This case adds to the growing body of literature, highlighting the high potential for mechanical failure of MCGRs [8, 9]. The risk of experiencing a complication associated with TGRs increases by 24% with each successive operation and reaches 47% by the seventh procedure [10]. MCGR technology was, therefore, developed to allow non-surgical distraction in the outpatient setting. However, a recent review of studies with minimum 2-year follow-up has demonstrated complication and reoperation rates of 48% and 44%, respectively [4]. Furthermore, the majority of MCGRs are non-functional at the time of removal and rarely distract fully in situ with mean distraction of 22 mm over their lifetime [9].

Surgeons should be aware that catastrophic implant failure of MAGEC rods can occur in the absence of obvious clinical or radiographic findings. The compromised sealing mechanism is thought to enable fluid and material to pass from the rod internals to localized tissues resulting in metallosis [9, 11]. Furthermore, MCGRs have demonstrated greater release of titanium and vanadium ions into the blood than TGRs [12]. The long-term health implications of this remain unknown.

Table 1: Summary of explant analysis. Bold denotes

| Component          | Convex rod | Concave rod |
|--------------------|------------|-------------|
| Extending bar       | Extensive wear resulted in polished appearance. | Unilateral concentration of growth bands with polished appearance of distal, opposite side indicative of off-axis loading. |
| Thrust bearing      | Grease and debris visible | Grease and debris visible |
| Magnet              | Unremarkable | Broken in two pieces |
| Debris              | ++          | ++           |
| Radial bearing      | Evidence of disintegration. Voids in the bearing cage were visible where more rolling elements would have originally been housed. Heavily contaminated with black wear debris. | Contaminated with debris. Free to rotate. |
| Drive pin           | In position. Intact. | Broken in two pieces. |
| O-ring seal         | Compromised. | Compromised. |

It is understood that single rod constructs should be avoided [13]. However, other risk factors for device failure remain poorly understood. Patient, implant, and operative factors are likely to contribute. The patient in this case was 13 years old at the time of implantation toward the older limit of the implant’s intended use. Manufacturing processes could feasibly have also contributed. MCGRs have undergone multiple iterations since their initial development [8]. In June 2019, the manufacturer of MCGRs released an urgent field safety notice recognizing the issue of fractured internal locking pins in early versions of the
device manufactured prior to March 26, 2015. The manufacturer stated that these models are no longer available for sale or implantation [14]. In our case, the concave rod was marked A170213-09. The number, we believe, reveals that this rod was made on February 13, 2017, as part of batch 09. Given the average lifespan of around 35 months, few MCGRs from 2017 have been analyzed to date [9]. We are, therefore, unable comment on whether this was an isolated issue, or whether it could occur in other devices produced at this time. In March 2020, the MAGEC System Model X, a newer modification of the device was withdrawn from the market due to safety concerns [15]. The subsequent increase in use of “older” models further increases the clinical relevance of this issue.

**Conclusion**

Given the relative paucity of high-quality evidence surrounding the use of MCGRs and implications of device failure, we support calls for urgent comparative studies and further investigation of the risk factors for device failure.

**Clinical Message**

The rapid uptake of MCGRs has not been matched by thorough evaluation of risk factors and mechanisms of device failure. We report a novel mechanism of device failure in a 14-year-old patient involving complete fracture of the magnet component. The absence of clinical or radiological features of device failure in this case makes the findings of great concern. Many patients around the world are currently living with this implant in situ. We support calls for urgent comparative studies and further investigation of risk factors for device failure.

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| Conflict of Interest: Nil |
| Source of Support: Nil |

**Consent:** The authors confirm that informed consent was obtained from the patient for publication of this case report.

**How to Cite this Article**

Jones CS, Rushton P, Hutton M, Stokes OM. Magnet Fracture within a Magnetically Controlled Growing Rod: A Case Report of a New Mechanism of Failure. Journal of Orthopaedic Case Reports 2021 August;11(8):6-10.