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Case Report

Actuator pin fracture in magnetically controlled growing rods: two cases

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Abstract

BACKGROUND CONTEXT: Magnetically controlled growing rods (MCGRs) are used in the management of early-onset scoliosis (EOS). Each MCGR contains a telescopic actuator that serves as the distraction element when stimulated by an external remote controller (ERC), permitting non-invasive lengthening in the outpatient clinic.

PURPOSE: This report highlights a subtle cause of MCGR failure. We present the first two reported cases of lengthening pin fracture in patients with dual-MCGR constructs.

STUDY DESIGN: We present two cases of patients with EOS treated with dual-construct MAGEC (MAGnetic Expansion Control, Ellipse Technologies Inc, Aliso Viejo, CA, USA) MCGRs.

METHODS: A 12-year-old boy presented describing a "popping" sensation in his thoracic spine and resultant grating 36 months following MCGR insertion.

RESULTS: A plain radiograph revealed a subtle fracture of the lengthening pin within the actuator of the right MCGR. Following identification of this case of implant failure, we reviewed the most recent radiographs of all nine of our patients treated with this MCGR in our institution, resulting in the discovery of bilateral MCGR lengthening pin fractures in an otherwise asymptomatic 11-year-old girl.

CONCLUSIONS: Clinicians should have a high index of suspicion of structural implant failure when presented with histories similar to those reported in our first case, or following unsuccessful distraction of MCGRs. In such cases new radiographs should be taken, and all previous images should be reviewed for evidence of this phenomenon. Centers that document MCGR lengthening with ultrasound should obtain plain radiographs every 6 months to evaluate the structural integrity of the implant.

Introduction

The diagnosis of early onset scoliosis (EOS) is given to patients who present before 10 years of age, independent of etiology [1]. Because of the rapid spinal, thoracic, and pulmonary development at this age, treatment of EOS has become challenging. Curve progression renders the thoracic cage incapable of supporting normal lung maturation [2]. Conservative treatment fails to prevent progression [3,4], and spinal fusion inherently prevents normal spinal growth [3,4], resulting in poor cosmetic and respiratory outcomes [5].

Growing rods guide spinal growth, restricting curve progression until the patient reaches sufficient skeletal maturity

FDA device/drug status: Approved (MACEC Spinal Bracing and Distraction System, Ellipse Technologies, Inc).

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to undergo definitive spinal fusion [6]. Conventional growing rods require invasive surgical distraction under general anesthesia, with consequent impact on patients and families. Magnetically controlled growing rods (MCGRs) have been developed to address these shortcomings, which can be lengthened non-invasively in the outpatient clinic [7–11].

The MAGEC (MAGnetic Expansion Control, Ellipse Technologies Inc, Aliso Viejo, CA, USA) MCGRs contain a distraction element in the form of a telescopic actuator. The actuator contains a small magnet, which rotates upon stimulation by an external remote controller (ERC). This rotation consequently causes overall distraction of the rod. Both the outer casing and inner lengthening pin of the actuator are visible to plain radiographs.

Ultrasound is routinely used to document MCGR distraction in our institution [12]. With a plain radiograph, an investigation of a patient who experienced a "popping" sensation in his back was performed, revealing a pin fracture in the MCGR. Recognition of this phenomenon mandated retrospective evaluation of our series of patients, whereby another patient with a MCGR pin fracture was identified. We present the first two reported cases of lengthening pin fracture in patients with dual-MCGR constructs.

Cases

Case 1

A 12-year-old boy with idiopathic scoliosis, treated with MCGRs 36 months previously, presented to our clinic, describing a "popping" sensation in his thoracic spine and a subsequent grating sensation.

The patient initially presented at 8 years old and despite bracing, his thoracic curve progressed from 24° to 55°. At the age of 9 years and 9 months, the patient was treated with dual MCGRs, reducing the thoracic curve to 38°. Following surgery, thoracic height increased from 210 mm to 226.

The patient underwent rod distraction at 3-month intervals without complication. On each occasion, rods were distracted maximally in the prone position, and the amount of lengthening was documented by plain radiographs for 18 months following implantation and subsequently by ultrasound. Over the course of 10 lengthening sessions, the rods failed to distract on one occasion; however, in subsequent sessions, normal distraction was demonstrated. Over the distraction period, the patient's rods distracted by a total of 15 mm on the right, and 26 mm on the left. The patient's most recent radiographs (36 months after initial surgery) demonstrate a further reduction of Cobb angle to 32° and further gain in thoracic height by 15 mm.

Following an episode of sneezing, the patient experienced a "popping" sensation in the region of the thoracic spine and subsequent grating. There was no history of trauma. He presented for review and a plain anterioposterior radiograph was requested, which revealed a subtle fracture of the pin within the actuator of the right MCGR (Fig. 1). As a result of the pin fracture, which precludes further MCGR distraction, and the attainment of sufficient skeletal maturity, the patient underwent definitive spinal fusion. At the time of revision surgery, the MCGR's ability to resist compressive force was lost as demonstrated by a pistoning action. Metallosis was identified in the soft tissues surrounding the housing of the distraction element (Fig. 2). An osseous tunnel (Fig. 3) had formed around the implant.

Case 2

Following identification of the first case of MCGR lengthening pin fracture, we reviewed the most recent radiographs of all nine of our patients treated with MCGRs in our institution. This process identified a further patient with MCGR lengthening pin fracture in an otherwise asymptomatic 11-year-old girl. The plain radiograph demonstrated bilateral MCGR lengthening pin fractures (Fig. 4). Review of a radiograph taken 6 months previously (26 months following surgery) revealed that breakage of the left rod (concaved) preceded that of the right (convex).

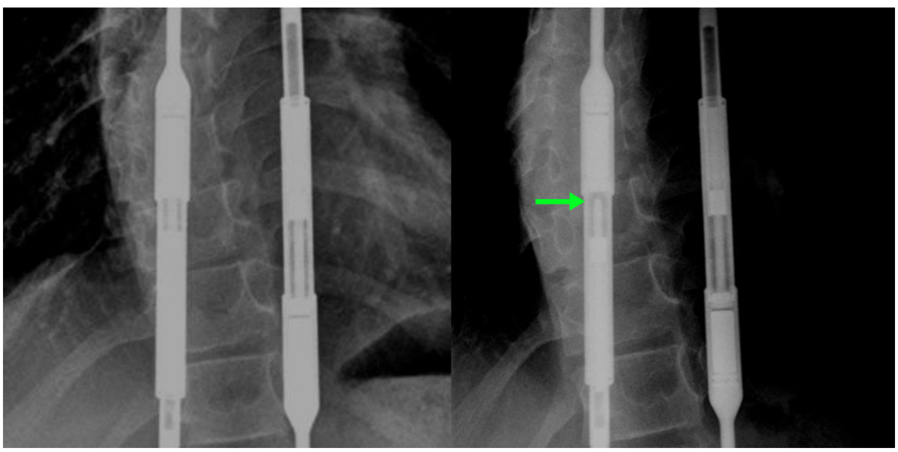

Fig. 1. Anterioposterior radiographs demonstrating MAGEC rods of first patient (Left) before and (Right) after lengthening pin fracture (green arrow) within right rod.

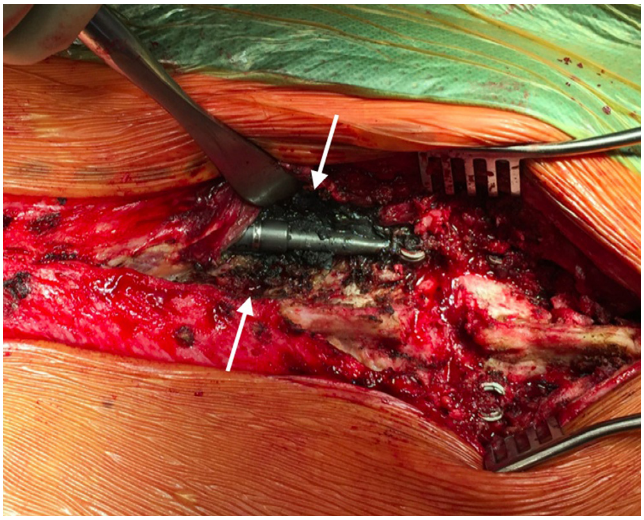

Fig. 2. Intraoperative photograph demonstrating metallosis (white arrows) in the soft tissues surrounding the housing of the distraction element of the MCGR.

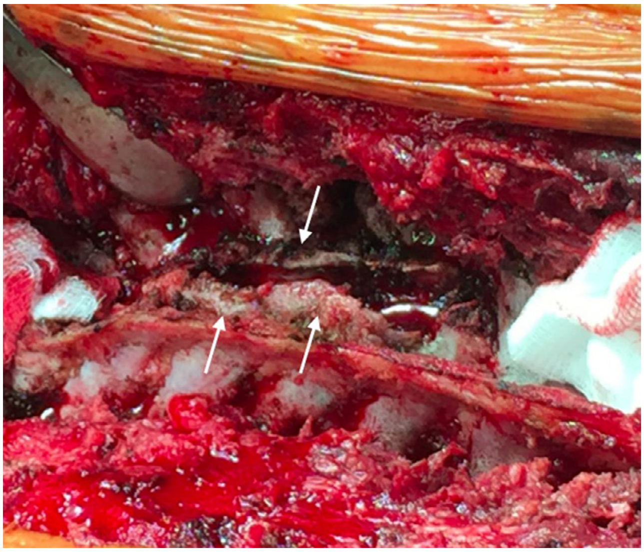

Fig. 3. Intraoperative photograph demonstrating an osseous tunnel (white arrows) which was found to be enveloping the MCGR at the time of revision surgery.

The patient had undergone insertion of dual MCGRs at the age of 8 years for EOS, in another institution. Her preoperative Cobb angle measured 68° and was reduced to 32° following surgery. Thoracic height increased from 179 mm to 200 mm.

Distractions of the MCGRs were performed in our institution because the patient had moved to our geographic area with her family. The patient attended for a total of nine distraction sessions; two of the distraction clinics were after a radiograph had been obtained, showing the lengthening pin fracture. The lengthening pin fracture was not diagnosed, however, because of a low index of suspicion by the treating clinicians. On these occasions, ultrasound failed to document any distraction. Over the entire distraction period, the left rod increased in length by 13 mm and the right by 11 mm. Cobb angle increased slightly to 35°, and T1–T12 height increased by a further 9 mm. This patient was skeletally immature at the time of revision surgery; therefore, the

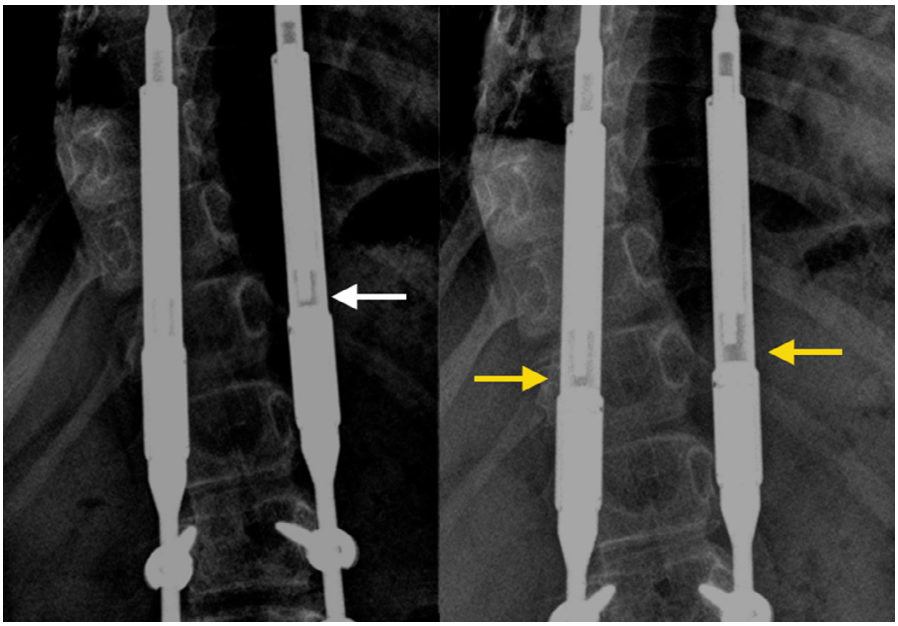

Fig. 4. Anterioposterior radiographs of second patient, taken at intervals every 6 months, demonstrating progression of pin breakage from (Left) left only (white arrow) to (Right) bilateral (yellow arrows).

MCGRs were revised to new MCGRs. Metallosis was observed in the soft tissues surrounding the housing of the distraction elements of both MCGRs.

Discussion

Growing rods are the most reliable of the non-fusion technologies for EOS patients [13,14]. They guide spinal growth, restrict curve progression, allowing development of the thoracic cage and lung maturation until patients reach sufficient skeletal maturity to undergo definitive fusion [6]. Under general anesthesia, conventional growing rods are lengthened at 6-month intervals via open surgery [7]. Repeated operations and frequent hospital admissions, however, are associated with adverse medical and psychosocial effects for patients and their families [15,16]. In a series of 140 patients, with a mean follow-up of 5 years, Bess et al. reported that the risk of complications increased by 24% for each additional surgical procedure performed [16]. The MCGR technology was developed to overcome the disadvantages of previous growing rod systems [7–11].

Nine patients have been treated with MAGEC (MAGnetic Expansion Control, Ellipse Technologies Inc.) dual rod constructs at our institution. No other identifiable structural faults have been observed in the remaining cases. At the time of writing, the remaining seven patients had undergone a mean of seven (range 2–12) distractions. Mean time between rod placement and most recent distraction clinic was 25.5 months (range 8–40). None of these patients have experienced any major complications.

The MCGR contains a telescopic actuator that serves as the distraction element. Each actuator holds a small cylindrical magnet, which is rotated when stimulated by an external remote controller (ERC) with subsequent MCGR lengthening. As a result MCGRs lengthening is performed noninvasively in the outpatient clinic without the necessity for general anesthesia, invasive surgery, or their associated risks [7–11]. Distraction of MCGRs can also be performed more regularly, which may mimic normal spine growth more accurately than earlier growing rod systems [7,8].

At our center, distraction is performed in the outpatient setting at 3-month intervals. Patients are positioned prone and the MCGRs are lengthened using the ERC. The degree of MCGR lengthening is documented using ultrasound imaging as previously described [12]. All patients are lengthened maximally, in our institution, as far as the ERC allows before "clunking" of the implant. "Clunking" occurs when the compressive force in the patient's tissues exceeds the strength of the motor in the MCGR. There have been no reports comparing distraction amounts or techniques, and maximal distraction to "clunking" is a recognized distraction technique. To date, no patients have reported pain during this procedure and analgesia is not required. It is possible that the high levels of stress placed on the actuator as a result of maximal distraction may increase the risk of lengthening pin fractures; however, as all other patients at our institution have been subject to the same method of distraction and have not demonstrated pin fractures, this is unlikely. Further investigation and multicenter collaboration is required to compare distraction techniques and assess their impact, if any, on the incidence of mechanical failure of the implant.

The early reports of MCGRs used to treat EOS patients have been encouraging [7,8]; however, it is not until a critical mass of procedures have been performed until potential issues with new devices become evident. Fracture of conventional growing rod implants has been reported to occur in 15% of cases [17]. Rod fractures most commonly occur above or below the tandem connectors, and near to the thoracolumbar junction of the spine [17]. Small case series have demonstrated MCGR fractures in around 0%–17% [9–11], most of which have occurred outside of the distraction element [10,11]. A single case of lengthening pin fracture within the actuator of the MAGEC (Ellipse Technologies Inc) MCGR has been reported in the literature [9]. In a series of six patients, the fracture occurred in a single-rod construct, using an early-generation MAGEC MCGR; the radiographic appearance, however, was not shown. The authors reported that the MCGR had subsequently been redesigned to minimize the risk of lengthening pin fracture within the actuator. Data from studies involving conventional growing rods indicate that single-rod constructs are more prone to fracture than dual rods [17]. Both of the patients in our series, however, had dual-MAGEC rods constructs, using second-generation devices.

As demonstrated by the identification of our second case, lengthening pin fracture can occur insidiously and asymptomatically. Although ultrasound did not adequately demonstrate distraction in the second patient, it was considered that failure to distract was a reflection of minimal skeletal growth in this patient in the period of time between distraction clinics, rather than a failure of the MCGRs' lengthening mechanism. The protocol previously reported by the corresponding author (OMS) for using ultrasound to document distraction [12] advises surveillance plain radiographs every 6 months. We adhere to this protocol at our institution, and a radiographic review led to the identification of the second case. The identification of this case was delayed, however, because of the lack of knowledge that lengthening pin fracture was a likely potential mode of failure of this implant. The use of ultrasound to document MCGR lengthening was introduced to reduce patient exposure to ionizing radiation [12]. However, as the pin lies within the casing of the actuator itself, it is not visible ultrasonographically, but is evident on radiographs which should be obtained every 6 months, or when ultrasound fails to demonstrate rod distraction.

Because of the lack of trauma preceding each of our patients' presentations, we postulate that these fractures may have occurred as a result of fatigue failure. Yamanaka et al. recently reported metallurgic analyses of fractured titanium rods implanted in two patients [18]. One patient, an 11-year-old boy, suffered fracture of a growing rod after twisting his body. Analysis revealed granular-like morphology consistent with fatigue cracking over 59.9% of the fracture surface.

Complete fracture then occurred as a result of external loading along the path of crack propagation. Removal of MCGRs at the time of surgery in our first case demonstrated the presence of metallosis; it is therefore possible that a similar etiology could underlie the mechanism of pin fracture in our cases.

We recommend that if ultrasound is used as the primary imaging modality to document MCGR lengthening, plain anterioposterior radiographs every 6 months are obtained to allow implant surveillance and, furthermore, a radiograph should be obtained if there is a failure of rod lengthening in two successive distraction clinics. Following this report of lengthening pin failure, we suggest that all centers who implant MCGRs retrospectively evaluate the most recent radiographs of all of their patients who have been treated using this implant.

Following the attainment of sufficient thoracic height, we advise that patients treated with MCGR constructs should undergo definitive fusion with removal of the MCGR. This is because of a risk of mechanical failure and resultant metallosis, as seen in the cases we report. Furthermore, the sagittal profile created by MCGRs is suboptimal, because of the length of the distraction element, which must not be manipulated with rod-benders. This sagittal profile can be improved by removal of MCGRs and definitive fusion.

Conclusions

Clinicians should have a high index of suspicion of structural implant failure when faced with histories similar to those reported in our first case, or following unsuccessful distraction of MCGRs. In these cases new radiographs should be performed and thoroughly assessed for lengthening pin fracture. We also recommend that all previously obtained images should be reviewed for evidence of this phenomenon.

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