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ORIGINAL ARTICLE

Safety and compatibility of magnetic-controlled growing rods and magnetic resonance imaging

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Abstract
Purpose Magnetically controlled growth rods (MCGRs) are a new technology for the management of early-onset pediatric deformity enabling guided spinal growth by controlling the curvature. These rods contain a rare earth magnet and are contraindicated for MRI. We have investigated the behavior MCGRs to determine whether MRI adversely affects rod properties and to determine the extent of image distortion.
Methods This is an in vitro experiment using two magnetic growth rods secured in a 1.5 T MRI. A gradient echo sequence MRI was performed to evaluate whether the rods elongated, contracted or rotated during scanning and a phantom model was used to evaluate the amount of artifact induced.
Results The rod was not activated or subsequently impaired by the process of MRI. Image distortion of 28.9 cm along the long axis of the magnet and 20.1 cm perpendicular to this was seen with extension 10.6 cm cranial to the magnet housing. No negative effect was demonstrated on the magnetic rod elongation mechanism.
Conclusions This study has demonstrated that there are no detrimental effects of MRI on the MCGR and imaging of the head and neck phantom can still be interpreted. Further in vivo study is warranted.

Keywords Scoliosis · GROWTH · MRI · Imaging · Rods

Introduction

The management of early-onset scoliosis (EOS) is challenging. Left untreated, progressive spinal curvature and vertebral rotation results in reduced thoracic volume preventing the normal maturation of lung tissue [1] Conservative treatments, such as bracing and casting, often fail to prevent progression but may buy time and delay surgical intervention [2]. This is desirable given that spinal fusion in younger patients prevents normal spinal growth and resulting in poor respiratory and cosmetic outcomes [2, 3].

Convex growth arrest, combined with posterior instrumentation, has been shown to slow deformity progression but the most reliable non-fusion surgery in infantile idiopathic scoliosis is the implantation of growing rods [4–7]. These rods control spinal curvature and guide growth, permitting a delay to fusion and therefore a more favorable respiratory and cosmetic outcome. Growing rods have traditionally required open serial invasive lengthening procedures every 6 months. Lengthening procedures are associated with healthcare costs and psychological impact on patients [8–14]. More importantly, the morbidity associated with repeated open lengthening procedures is not insignificant and is reported at 20 % per surgical procedure in the literature [8]. In response to the limitations of traditional growing rod systems, magnetically controlled growing rods (MCGR) were developed, and their safety and efficacy has been reported in humans [10–17]. The implantation of MCGRs has been supported by the

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National Institute of Clinical Excellence in the United Kingdom following a clinical and economical evaluation [18].

MCGRs are regularly lengthened in the outpatient setting with the increased frequency of elongation versus open lengthening providing a more physiological interval spinal growth while also reducing the impact on the patients and their families. As is often the case with new surgical technologies, potential shortcomings and limitations only become evident when a critical mass of cases has been followed up for a number of years. Concerns were previously raised when early distraction algorithms required monthly radiographs to be taken pre- and post-distraction to document distraction and this was addressed using outpatient ultrasound to document distraction [19]. More widespread adoption of MCGRs has now led to clinical scenarios where magnetic resonance imaging (MRI) would be a useful investigation for patients who have MCGRs implanted including those with known underlying conditions including Chiari malformations, where neural symptoms can subsequently occur. Indeed, there have been circumstances where MCGRs have not been implanted due to concerns over the safety of future MRI. Considering the 20 % incidence of asymptomatic neural axis anomalies in EOS patients, some of these anomalies may need to be followed up by interval MRI (http://bdhmedical.nl/website/wp-content/uploads/2014/11/MAGEC_Surgical-Technique_Guide.pdf). MCGRs contain a rare earth magnet and therefore the manufacturer advises that the device is not compatible with MRI [19]. Theoretical concerns include: deactivation of the MCGR magnet preventing subsequent lengthening, elongation, shortening or dislodgement of the device due to the torque from the internal ferromagnetic material when a patient moves within the magnetic field, or excessive heating due to eddy currents generated by the radiofrequency fields leading to tissue damage. The implications of these potential effects range from the need to exchange the implant, with significant associated costs, to actual harm to the patient, potentially including neural damage. Furthermore, the metal artifact associated with MRI in patients with MCGRs may be substantial, therefore rendering MRI uninterpretable within the vicinity of the implant.

In an attempt to address these concerns regarding MRI compatibility of MCGRs, the following in vitro study was undertaken.

Materials and methods

Both the standard configuration and off-set MAGEC magnetic-controlled growth rods (Ellipse Technology, CA, USA) were investigated. The rods were held in a rig

Fig. 1 MCGR held in a ceramic jig secured within the gantry of the 1.5 T Phillips magnetic resonance imaging scanner

(Fig. 1), which was devised to partially immobilize the rod within a 1.5 T Philips (The Netherlands) MR scanner whilst permitting rod rotation, elongation and shortening. The rig comprised two 5 kg perforated concrete blocks with initially two 3 l bottles (containing demi water, $CuSO_4 \cdot 5H_2O$, NaCl and H_2SO_4) placed either side of the long axis of the MCGR. Within the rig, the rod motion was rotationally unrestricted allowing rotation about the axis of the static magnetic field as well as longitudinal migration to a maximum of 20 cm and elongation or shortening. The rods were initially lengthened 5 mm to allow any potential magnetic field induced shortening or lengthening to occur. Imaging of the phantoms was undertaken using a quadrature body coil with coronal and axial gradient echo sequences (Repetition time 167 ms, echo time 2.3 ms) undertaken for evaluation of artifacts at a level equivalent to the upper thoracic and cervical spine. To assess the extent of artifacts superior to the long axis of the MCGR, the setup was rearranged such that a 25 cm bottle phantom was placed in an 8-element SENSE head coil with the top of an MCGR placed in contact with the inferior bottle surface with sagittal sequences taken in this position. Gradient echo scans were repeated with the same imaging parameters as utilized previously.

The following investigations were made:

1. Rotational and linear displacement of the MCGRs as they were moved towards and into the scanner bore.
2. Elongation or shortening of the MCGRs as a result of MRI scanning.
3. MCGR ability to elongate before and immediately after each MRI protocol. Following completion of the experiments, both rods were re-assessed for ability to lengthen. This was repeated again, 1-hour later. Assessment of elongation was performed using an RS 150 mm electronic caliper.

4. Temperature change of the MCGR outer casing (qualitatively assessed by touch).
5. Evaluation of the severity and extent of metal artifacts, adjacent to and cranial to the MCGRs, following each MRI protocol utilizing the Philips MRI analysis software. The maximal total artifact length present was measured on five occasions to allow calculation of the mean distortion.

Results

On placement on the scanner bed, whilst remote from the scanner bore, the MCGRs rotated within the phantom to align with the surrounding magnetic field. Furthermore, the phantom-MCGR composite could be rotated and moved in all directions with minimal manual exertion within the confines of the restraining rig.

During the entire period of investigation, following placement of the phantom-MCGR composite in the centre of the MRI bore, neither MCGR demonstrated any further rotation, or linear displacement. There was no lengthening or shortening of the MCGRs during the repeated MCGR protocols.

The ability of the MCGRs to elongate following the MRI protocol on removal was not impaired. The time required to fully elongate each MCGR was tested 24 h prior to performing the MRI protocols. Following completion of the experiments, the time to full elongation was serially assessed at 5-min intervals for 30 min, and then repeated 1 h after the MRI exposure had concluded. The time to achieve full elongation was identical before and after the MRI protocols taking a total of 5 min and 52 s on each occasion measured.

The mean maximal image artifact was 28.9 cm (range 28.3–29.1 cm) on the axial images (Fig. 2) at the level of the MCGR internal magnet and in the long axis of the magnet. In addition, the impact on coronal image quality is depicted in Fig. 3. The mean artifact perpendicular to the long axis of the magnet was 20.1 cm (range 18.2–22.3 cm). The artifact extended a mean of 10.6 cm cranial to the end of the MCGR on sagittal sequences (Fig. 4), therefore not affecting the obtained images of the head and neck model.

There was no detectable heating of the MCGR outer casing as a result of the MRI scanning.

Discussion

This study is, to the best of our knowledge, the first to investigate the compatibility of MCGRs with MRI. The use of MCGRs to treat EOS was first reported in 2012 and the device subsequently received support from healthcare regulators in the United Kingdom (National Institute of Health, NICE) and the Food and Drug Administration (FDA) approval in the United States (2014) (http://www.nice.org.uk/guidance/mtg18/resources/guidance-the-magec-system-for-spinal-lengthening-in-children-with-scoliosis-pdf, http://www.accessdata.fda.gov/cdrh_docs/pdf14/K140613.pdf) [10, 20]. Now, that a critical mass of surgeries has been performed and cases have been followed up for a critical time period new questions or potential concerns regarding the implant are beginning to be asked. The incidence of neural axis anomalies in EOS patients, which may require monitoring by serial MRIs, has started to pose a problem for clinicians. This in vitro study was devised to investigate how the MCGR would behave when subjected to common

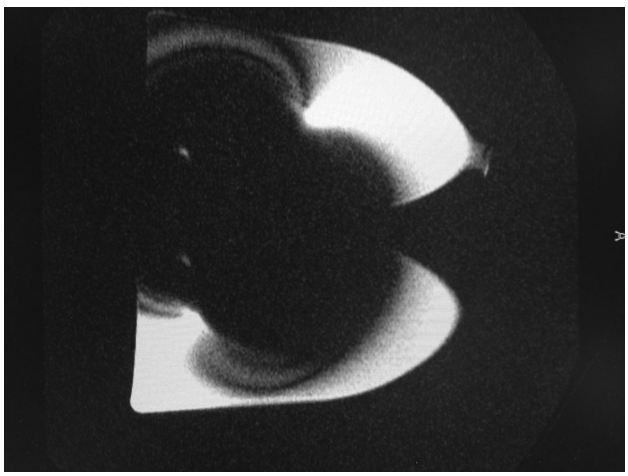

Fig. 2 Axial T2-weighted MRI showing the extent of artifact in the long axis of the magnet

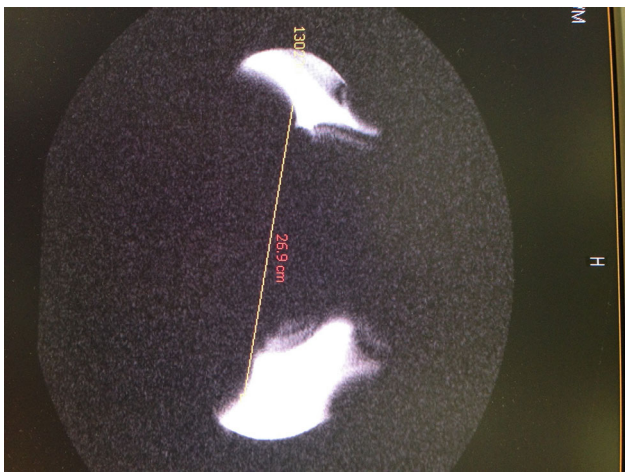

Fig. 3 Coronal T2-weighted MRI demonstrating the gross artifact on induced by the ferromagnetic core

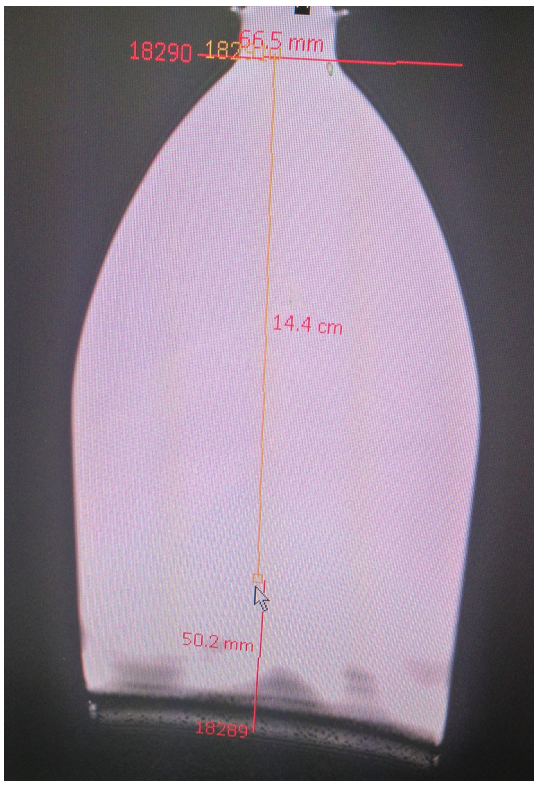

Fig. 4 Sagittal T2-weighted MRI of the horizontal phantom bottle placed cranial to the magnet housing with artifact extending proximally

and relevant MRI protocols. An upper thoracic, cervical and head MRI protocol was selected for use in this study as it was considered to be the most likely protocol to be encountered clinically considering the requirement to evaluate and monitor known Arnold Chari malformations and syringomyelias.

The MRI compatibility of non-invasively expandable magnetic total joint endo-prostheses used for limb salvage surgery following malignant tumor resection in children has been studied using phantom and cadaveric models [20]. These prostheses were found to be MRI compatible with no reported evidence of magnetic forces on the implant, no hazardous heating, or prosthetic lengthening during gradient echo MRI sequences. The elongation mechanism, in the tumor prosthesis, is controlled by a polyacetal insert that reaches melting point in response to an applied electromagnetic field heating a ring with a ferrous centre. This leads to sliding of the spring-loaded titanium rod through a polymeric tube, thus increasing length. Concerns about the MRI compatibility of the MAGEC MCGRs, however, are more significant due to its extension mechanism, which has a higher concentration of ferromagnetic material and the close proximity of neural tissue to the device in EOS patients.

The results of this study demonstrated no operational change in the MCGR lengthening mechanism following exposure to the static and time varying magnetic fields together with the radiofrequency radiation used in MR imaging. The rod elongation mechanism functioned normally following scanning with no change in the time to reach full distraction after the experiment. This suggests that there was no detrimental effect on the MCGR extension mechanism or internal motor by the MRI protocol employed. There was no discernible temperature increases to the outer casing of the implant following the MRI protocol in keeping with reports evaluating cardiac leads and cochlear implants, although the current study utilized a relatively low energy dissipation scanning sequence and tested the rod in isolation [21, 22]. Furthermore, subjecting the MCGRs to the MRI protocols did not result in any elongation or shortening of the rod.

Unfortunately, the acquired images were significantly degraded by metal-induced artifacts, which extended nearly 30 cm from the magnet within the MCGR. Therefore, only cranial and cervical regions would be suitable targets for MRI studies in EOS patients treated with MCGRs. This limitation should therefore be considered prior to implantation of MCGRs in patients with known neural axis abnormalities requiring surveillance. Currently, a single-rod strategy could be considered in such patients, placing the motor unit at the caudal end of the construct. While non-magnetic non-motorized technology including a piezoelectric ultrasound driven motor is now being applied in a number of medical innovations this has not yet been applied to growth rods [23].

Conclusions

This study is, to the best of our knowledge, the first to demonstrate that subjecting MCGRs to MRI protocols at 1.5 T has no detrimental effect on the extension mechanism. The magnet in the MCGR extension mechanism, however, leads to distortion of acquired images circumferentially up to 30 cm. Extrapolation of the results of this in vitro study suggests that head and neck imaging might be safe and feasible in EOS patients treated with MCGRs, however more caudal anatomical regions will not be visualized due to metal artifact. In addition, the current study does not provide any data assessing the torque that may occur when an individual moves in a magnetic field during a scanning procedure, particularly at fields higher than the 1.5 T currently used, or the degree of localized heating that may arise when MRI sequences with greater energy dissipation are used. Thus, further assessments are required before the absolute MRI safety and compatibility of MCGRs and MRI can be confirmed.

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Compliance with ethical standards

Conflict of interest Ellipse Technologies donated the two magnetically controlled growing rods that were used in this study.
OMS has previously received travel grants from Ellipse Technologies to support attendance at academic spinal meetings. OMS has previously received an honorarium from Ellipse Technologies for preparing and delivering a symposium at an academic spinal meeting. None of these disclosures relates to this study.
The authors have no other financial or competing interests to disclose in relation to this work.

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