Un-blinded Title Page

SAFETY AND COMPATABILITY OF MAGNETIC-CONTROLLED GROWING RODS AND MAGNETIC RESONANCE IMAGING

Authors: Henry R Budd[1] MBChB(Hons) FRCS(Orth)

Oliver M Stokes[1] MB BS, MSc FRCS (Tr&Orth)

Judith Meakin[2], PhD

Jonathan Fulford[3], PhD

Michael Hutton[1]

Affiliations:

1Exeter Spine Unit, Princess Elizabeth Orthopaedic Centre, Royal Devon & Exeter NHS Foundation Trust, Barrack Road, Exeter, United Kingdom

2Physics, College of Engineering, Mathematics and Physical Sciences, University of Exeter, UK

3Exeter NIHR Clinical Research Facility, University of Exeter Medical School, University of Exeter, UK

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Correspondence: Michael Hutton

Consultant Spinal Surgeon

Peninsula Spinal Spine Unit

Princess Elizabeth Orthopaedic Centre

Royal Devon & Exeter NHS Foundation Trust

Barrack Road

Exeter

United Kingdom

Tel: +44 (0) 1392 411 611

Email: mikehutton@me.com

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Nicholas Budd, Mechanical Engineer MEng AMIMechE

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Abstract:

Purpose:

Magnetically controlled growth rods (MCGRs) are a new technology for the management of early-onset paediatric 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 was seen with the phantom model measured from the magnet housing.

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.

INTRODUCTION

The management of early-onset scoliosis (EOS) is challenging. Left untreated, progressive spinal curvatures and vertebral rotation serves to reduce thoracic volume which prevents 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 can lead to poor respiratory and cosmetic outcomes.[2,3]

Convex growth arrest, combined with posterior instrumentation, has been shown to slow 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 hence more favourable respiratory and cosmetic outcomes. 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.[8-10] In order to minimize the limitations of traditional growing rod systems magnetically-controlled growing rods (MCGR) were developed, and their safety and efficacy has been reported in humans.[10-13] . Their implantation is supported following a clinical and economical evaluation by the National Institute of Clinical Excellence in the United Kingdom as part of an evidence medical technologies guidance. [14].

MCGRs are lengthened in the outpatient clinic, more closely mimicking spinal growth and reducing the impact on 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 raised by early distraction algorithms requiring monthly radiographs taken pre- and post-distraction to document distraction. This concern was addressed by using outpatient ultrasound to document distraction.[15] More widespread adoption of MCGRs has now led to clinical scenarios where magnetic resonance imaging (MRI) would be a useful investigation in patients who have MCGRs implanted such as patients with known conditions including neurofibromatosis where neural symptoms subsequently occur. Indeed there have been circumstances where MCGRs have not been implanted due to concerns over 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.[16] MCGRs contain a rare earth magnet, therefore the manufacturer advises that the device is not compatible with MRI.[15] Theoretical concerns include: deactivation of the MCGR magnet preventing subsequent lengthening, lengthening, shortening or dislodgement of the device due to the torque resulting from the internal ferromagnetic material when a patient moves within the MRI magnetic field, or excessive heating due to eddy currents generated by the

radiofrequency fields associated with MRI, 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, which could include 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 & 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 (Figure 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 and some displacement. The rig comprised two 5 kg perforated concrete blocks with initially two 3 l bottles (containing demi water, $CuSO_4.5H_2O$, 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 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 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. 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 150mm 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 5 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 themselves 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-hours prior to performing the MRI protocols. Following completion of the experiments the time to full elongation was serially assessed at 5-minute intervals for 30 minutes, and then repeated 1-hour 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 minutes and 52 seconds on each occasion measured.

The mean maximal image artifact was 28.9 cm [range 28.3-29.1 cm] on the axial images (Figure 2) at the level of the MCGR internal magnet and in the long axis of the magnet. The mean artifact perpendicular to the long axis of the magnet was 20.1cm (range 18.2-22.3 cm). The artifact extended a mean of 10.6cm cranial to the end of the MCGR on sagittal sequences (Figure 3), 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 has subsequently received support from healthcare regulators in the United Kingdom (National Institute of Health, NICE) and Food and Drug Administration (FDA) approval in the United States (2014) [10,17-19]. As is often the case with new technologies, now that a critical mass of surgeries have 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 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 tumour 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 tumour 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 before or after the experiment. This suggests that there is no detrimental effect on the MCGR extension mechanism or internal motor by the MRI protocol employed. There was no discernable 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 [21-23]. 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 single-rod strategy could be considered in such patients, placing the motor unit at the caudal end of the

construct. While non-magnetic non-motorised technology including a piezoelectric ultrasound driven motor now being applied in a number of innovations this has not yet been applied to growing 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 30cm. 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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FIGURES

FIGURE LEGENDS

Figure 1. MCGR held in a jig entering MR gantry

Figure 2. Coronal T2-weighted MRI

Figure 3. Axial T2-weighted MRI