Metallosis following implantation of magnetically controlled growing rods in the treatment of scoliosis

SPINE

A CASE SERIES

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Aims
We present a case series of five patients who had revision surgery following magnetic controlled growing rods (MGCR) for early onset scoliosis. Metallosis was found during revision in four out of five patients and we postulated a mechanism for rod failure based on retrieval analysis.

Patients and Methods
Retrieval analysis was performed on the seven explanted rods. The mean duration of MGCR from implantation to revision was 35 months (17 to 46). The mean age at revision was 12 years (7 to 15; four boys, one girl).

Results
A total of six out of seven rods had tissue metallosis and pseudo-capsule surrounding the actuator. A total of four out of seven rods were pistoning. There were two rods which were broken. All rods had abrasive circumferential markings. A significant amount of metal debris was found when the actuators were carefully cut open. Analytical electron microscopy demonstrated metal fragments of predominantly titanium with a mean particle size of 3.36 microns (1.31 to 6.61).

Conclusion
This study highlights concerns with tissue metallosis in MGCR. We recommend careful follow-up of patients who have received this implant.

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Early onset scoliosis (EOS) is an abnormal, complex, 3D deformity of the spine which is usually progressive and diagnosed before the age of ten. The best treatment for EOS is unknown, with options ranging from bracing to surgery. The main aim of surgery is to correct the curve while maintaining growth of the spinal column until the child is close to skeletal maturity when a final operation to adjust and stabilise the curve can be performed.

Growth sparing spinal surgery in EOS can be achieved by growing rods which usually require six monthly operations to lengthen the rods under general anaesthesia throughout childhood and are associated with high complication rates. An alternative to conventional growing rods are magnetic controlled growing rods (MCGR). The main benefit of MCGR is the avoidance of repeated surgical lengthening procedures, leading to a reduction in surgical complications such as wound infections, risks associated with anaesthetic, and delayed recovery for the child. Other benefits include improved quality of life, reduction in psychological trauma to the child and family, and potential loss of earnings for parents. There are also advantages for the health service including cost savings from theatre time and consumables, as well as length of in-hospital stay.

The MCGR has a magnetic actuator, the motor, that can rotate the growing rod when used with a hand-held External Remote Controller device (ERC), thus allowing non-invasive spinal lengthening to take place in the outpatient clinic. In June 2014, the National Institute for Health and Care Excellence (NICE) approved the use of MCGR on the basis of efficacy and cost-effectiveness, having been approved in February 2014 by the United States Food and Drug Administration (FDA). In 2012, Cheung et al described the first case series of MCGR. Since then, others have also reported promising early results when using MCGR.

However, recently in our centre, a group of patients who had to undergo revision surgery were found to have evidence of metallosis,
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Metallosis is defined as aseptic fibrosis, local necrosis, or loosening of a device secondary to metal corrosion and release of wear debris.10

Patients and Methods

Study design and patients. From January 2011 to December 2015, we have implanted 14 MCGR in patients with EOS, using the MAGEC system (Ellipse Technologies Inc., Irvine, California). However, five patients required revision and four showed evidence of metallosis. The mean age of the patients at the time of initial implantation was nine years (4.5 to 11). The mean duration of MCGR from implantation to explantation was 35 months (17 to 46). The mean age at revision was 11 years (7 to 15). The weight, age and indication for MCGR were all in compliance with the recommendations of the MCGR manufacturer (Table I). This study is a retrospective analysis of prospectively gathered data from these five patients.

Informed consent was taken from both the child and parents for peri-operative photographs to be taken. Retrieval analysis was performed on the explanted rods in conjunction with the Ellipse Technologies and our engineering and electron microscopy departments. Histopathological examination was performed on intra-operative tissue samples.

Surgical procedure and our follow-up protocol. The MAGEC system comprises one or two sterile titanium implantable growth rods with a magnet in the actuator that drives the lengthening process. The diameter of the rods, which depends on the child’s body weight, was 5.5 mm. The choice of a single or a dual rod construct was the result of surgeon’s preference.

Non-invasive distraction of the MAGEC rods started between three and six months following implantation. Outpatient extension of the MCGR was then performed every eight weeks using a hand-held magnetic ERC, which was placed over the internal magnet in the MCGR. Pre- and post-extension ultrasound imaging was performed in all patients.

Results

A total of seven rods were explanted for analysis from the four patients (one single rod construct, three double rod constructs) who were found to have metallosis around their MCGRs during revision surgery. In all, six out of these seven rods had evidence of metallosis around the actuator.

Peri-operative findings. Patient 1 (girl, 11 years old at revision), who had a single rod MCGR construct, was lost to follow-up for six months and did not have any distractions during this period. When the patient returned, ultrasound examination revealed that the internal magnetic mechanism had collapsed, with worsening of the patient’s scoliosis curve. During revision surgery, at three years post-operatively extensive metallosis was observed and pus was also found around the lower two thirds of the MCGR, along with loosening of all the pedicle screws (Fig. 1). However, the patient was clinically well and did not exhibit any signs of infection.

Patient 2, (boy, seven years old at revision) who had a double rod MCGR construct, developed proximal junctional kyphosis at 2.5 years post-operatively. During revision surgery, one rod was surrounded by metallosis and the other fractured on retrieval at the rod–actuator junction.

Table I. Demographics of the five patients with magnetic controlled growing rods (MCGR) requiring revision

<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age at implantation of MCGR</th>
<th>Weight at implantation of MCGR (kg)</th>
<th>Aetiology of EOS</th>
<th>Primary/revision procedure</th>
<th>Rod construct</th>
<th>Reason for revision</th>
<th>Duration (mths)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>8 yrs 5 mths</td>
<td>17.5</td>
<td>Congenital</td>
<td>Primary</td>
<td>Single</td>
<td>Lost to follow-up for 6 mths - broken pin in magnetic rod and deep infection</td>
<td>37</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>4 yrs 6 mths</td>
<td>19.2</td>
<td>Syndromic</td>
<td>Primary</td>
<td>Double</td>
<td>Development of proximal junction kyphosis</td>
<td>34</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>12 yrs 6 mths</td>
<td>39.1</td>
<td>Idiopathic</td>
<td>Revision</td>
<td>Double</td>
<td>Rod breakage at distal end</td>
<td>39</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>10 yrs 5 mths</td>
<td>28.5</td>
<td>Congenital</td>
<td>Revision</td>
<td>Double</td>
<td>Failure of rod to distract with loss of alignment below the distal fixation</td>
<td>17</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>10 yrs 9 mths</td>
<td>32.4</td>
<td>Idiopathic</td>
<td>Revision</td>
<td>Single</td>
<td>Failure of rod to distract</td>
<td>46</td>
</tr>
</tbody>
</table>

EOS, early onset scoliosis
Patient 3, (boy aged 15 years old at revision) who had a double rod MCGR construct, was revised as the left rod had fractured proximal to its first distal pedicle screw at three years post-operatively. Following discussion with the patient's family, the decision was taken to proceed to definitive correction and fusion, as he was already aged 15 years. At revision surgery, both rods were found to have severe metallosis with pseudo-capsule formation around the actuator (Figs 2a and 2b).

Patient 4, (boy, 11 years old at revision) who had a double rod MCGR construct underwent revision because the MCGRs were failing to distract and, as a consequence, the patient was developing a significant distal deformity at the lumbo-sacral junction at 1.5 years post-operatively. Both rods showed evidence of severe metallosis, along with pseudo-capsule formation.

Patient 5, (boy aged 14 years old at revision), who had a single rod construct, underwent revision 3.5 years post-operatively for a non-functioning magnetic rod that had stopped distracting with the ERC and the patient's curve was deteriorating, leading to progression of the rib deformity. This patient had previously been revised from conventional growth rods, which he had since the age of four years. However, as he was having recurrent infections due to repeated surgical extension, this was revised to a single-rod MCGR construct when he was aged ten years. His single rod MCGR was revised to a conventional dual growing rod system as the patient had not achieved his predicted height, despite his age. However, metallosis was not detected in this patient.

Retrieval results of rods. The retrieval results are summarised in Table II. A total of six out of seven rods had tissue metallosis and pseudo-capsule surrounding the actuator. A total of four rods were pistoning and all rods had abrasive circumferential markings (Fig. 3). Significant amounts of metal debris were found in those with metallosis when the actuators were cut open (Figs 4a to 4c). On assessing the distraction mechanism, it was found that the locking pin had fractured, leading to free pistoning of the two cylinders which make up the device.

Histology. Histology was performed on tissue samples taken from around the growing rods in the four patients with metallosis. Microscopical examination consistently showed accumulation of black and grey granular particles, hyalinised fibrous tissue, and chronic inflammation reaction with lymphoid and plasma cell infiltrates (Fig. 5).

Electron microscopy. Analytical electron microscopy of the material seeping out of the actuator due to pistoning demonstrated metal fragments, composed predominantly of titanium, with a mean particle size of 3.36 microns (1.31 to 6.61) (Fig. 6).

Microbiology. Intra-operative tissues samples grew coagulase negative Staphylococcus in patient 1, but there was no growth in the other three, nor in the patient without metallosis.

Discussion
In our centre, MCGRs have been used since 2011 and the early results were encouraging. The incidence or the clinical implications of metallosis following MCGR though
are unknown and appear to be a unique complication of MCGRs, as metallosis has not been described following the use of conventional growing rods. However, in metal-on-metal total hip arthroplasty, there have been reports of metallosis and pseudotumour formation.\textsuperscript{11,12}

Histology from the four patients presented showed a chronic inflammatory response in reaction to the metal debris, which is suggestive of metallosis. This is an uncommon condition and is defined as local damage and changes in tissue characteristics provoked by a metallic foreign body in the host.\textsuperscript{13} None of our patients exhibited any features to suggest pseudotumour formation, which has been associated with metal-on-metal hip arthroplasties. A pseudotumour is defined as a granulomatous lesion or a destructive cystic lesion, which is neither infective nor neoplastic, and should be at least 5 cm in size and resemble a tumour.\textsuperscript{12}

The locking pin in the magnetic actuator was found to be broken in the explanted rods that were analysed. The locking pin measures 6 mm × 2 mm and connects the magnet to the lead screw. As the magnet is rotated by the ERC, the lead screw moves the rod in the actuator, and thus lengthens the MCGR. With a broken locking pin, this mechanism fails and leads to rod pistoning or telescoping, which in turn is presumed to have led to the formation of metal debris inside and around the actuator, and would account for the metal debris detected when the actuator was cut open. Soft-tissue metallosis occurs as a result of this metal debris, leading to the formation of a pseudo-capsule by the immune system which is a possible mechanism of metallosis and rod failure. However, not all the rods pistoned, therefore this mechanism of failure is unlikely to explain fully the reason for the appearance of metallosis.

All of the rods examined had circumferential wear markings, suggesting they had been caused prior to failure of the locking pin, rather than by pistoning. It seems likely that these areas of damage could have been the main cause of the metallosis. These circumferential abrasive wear mark-
ings on the rods are caused by stress during the process of MCGR lengthening. These rings could be a source of corrosion and metal reaction in the surrounding tissue.

All seven rods have been returned to the manufacturer with a view to improving future versions of the MCGR, and alterations are being made to the locking pin to prevent further breakages. In the past, clinical studies have led to design refinement of the rod, with the addition of a keeper plate intended to maintain rod length, preventing slippage and loss of distraction when the rod is placed under high stress.\textsuperscript{7}

In conclusion, MCGR (Ellipse) is an evolving technology which needs further refinement. This study highlights concerns with metallosis as a consequent failure of the mechanisms in MCGRs. We recommend close follow-up of children treated with this device.

\textbf{Take home message:}
Early reports of this device have shown promising results, and there has been no previous documentation of metallosis following MCGR implantation. The clinical long-term implications of this metallosis are currently unknown and close follow-up in this group of children is indicated.

\begin{table}
\centering
\caption{Retrieval analysis of the seven explanted magnetically controlled growing rods}
\begin{tabular}{llll}
\hline
Patient & Tissue metallosis & Rod & Markings on the rod \\
\hline
1 & +++ & Pistoning & +++ \\
2 & Right + & Intact & +++ \\
   & Left - none & Right: broken at retrieval & +++ \\
3 & Bilateral +++ & Both pistoning & +++ \\
   & Left: broken prior to revision & +++ \\
4 & Bilateral +++ & Right: intact & +++ \\
   & Left: pistoning & +++ \\
5 & Patient 5 had no metallosis, therefore explanted rod was not analysed & & \\
\hline
\end{tabular}
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References
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