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Analysis of explanted magnetically controlled growing rods from 7 UK spinal centers

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Conflicts of Interest and Source of Funding

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The device is FDA-approved or approved by corresponding national agency for this indication
Acknowledgements

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STRUCTURED ABSTRACT

Study Design Analysis of explanted MAGnetic Expansion Control (MAGEC) growing rods.

Objective To analyze explanted MAGEC rods used in management of early onset scoliosis and identify the mode of failure in such cases.

Summary of Background Data Magnetically controlled growing rods are increasingly used as the option of choice for early onset scoliosis. However, being more complex than conventional growing rods they are perhaps more likely to succumb to multifarious failure modes. In addition, metallosis has been reported around failed MAGEC rods.

Methods Explanted MAGEC rods from 7 UK spinal centers were obtained for independent analysis. Thirty-four MAGEC rods, from 18 children, explanted for reasons including failure of rod lengthening and maximum rod distraction reached, were cut open to allow internal components to be evaluated and assessed.

Results Externally, all MAGEC rods showed localized marks, which were termed ‘growth marks’ as they indicated growth of the rod in vivo, on the extending bar component. After cutting open, titanium wear debris was found inside all 34 (100%) MAGEC rods. Ninety-one percent (31/34) of MAGEC rods showed measurable wear of the extending bar, towards the magnet end. Substantial damage to the radial bearing was seen inside 74% (25/34) of MAGEC rods while O-ring seal failure was seen in 53% (18/34) of cases. In 44% (15/34) of MAGEC rods the drive pin was fractured but this was felt to be an effect of rod failure, not a cause.
Conclusions

The combination of high volumes of titanium wear debris alongside O-ring seal damage likely accounts for the metallosis reported clinically around some MAGEC rods. Based on this explant data, a failure mechanism in MAGEC rods due to the natural off-axis loading in the spine was proposed. This is the largest data set reporting a complete analysis of explanted MAGEC rods to date.
**INTRODUCTION**

Non-invasively lengthened growing rods are used increasingly in the treatment of early onset scoliosis. The most commonly used implant is the MAGnetic Expansion Control (MAGEC) system (Nuvasive Specialised Orthopaedics, San Diago, CA, USA). This has been licensed for use in Europe since 2009\(^1\) and has recently been approved by the US Food and Drug Administration.\(^2\) Implants can be lengthened using an external remote controller. This aims to limit the number of surgeries and reduce the medical and psychological complications these children commonly experience with conventional growing rods.\(^3\)-\(^6\) In addition, there is increasing concern regarding the effect of repeated general anesthetics on the developing brain.\(^7\) In terms of engineering, the MAGEC system, including a magnet driven non-invasive lengthening mechanism, is far more complex than conventional growing rod implants. Any implant spanning multiple levels of unfused spine will be liable to failure through rod fracture or anchor point failure as is seen commonly with traditional growing rods.\(^3\)-\(^5\) Yet it remains unclear if the MAGEC system will be associated with an additional burden of complications.

In the UK, the National Institute for Health and Care Excellence (NICE) offered guidance in 2014 in its document “The MAGEC System for spinal lengthening in children with scoliosis” (MTG18).\(^1\) Here, it is stated that “The MAGEC system should be considered for use in children with scoliosis aged 2 years and over who need surgery to correct their spinal curvature”.\(^1\)
Analysis of explanted MAGEC rods

To date, long term clinical outcomes of the MAGEC system are lacking. Of available data MAGEC rod failure as a cause for revision has been reported in 0-38% of cases. Aside from rod fracture or anchor failure the MAGEC system may fail through failure of its internal mechanism, presenting clinically as an inability of the rod to lengthen or loss of length. Authors have reported drive pin fractures within failed rods. Significant metallosis surrounding MAGEC rods at time of implant removal has also been described.

Analysis of explanted implants has proven valuable particularly in the study of complex implants such as joint replacements. Such analyses have allowed mechanisms of failure to be understood and improvements to the design of prostheses to be made in the case of hip, knee, finger and toe implants. To date analysis of explanted spinal implants has focused primarily on disc arthroplasty. Explanted MAGEC rods are yet to be analyzed in significant numbers, although a recent report on 7 rods from a single center has been offered. We wished to add to this current debate by examining a greater number of failed MAGEC rods from multiple spinal centers. We aimed to analyze explanted MAGEC rods used in management of early onset scoliosis and identify the mode of failure in such cases.
METHODS AND MATERIALS

MAGEC rods were received from 7 spinal centers around the UK as part of an ongoing retrieval analysis project, under the auspices of the Northern Retrieval Registry. The Northern Retrieval Registry is an independent organization of orthopedic surgeons and bioengineers based in the north-east of England which undertakes assessments of explanted orthopedic devices. Thirty-four MAGEC rods, from 18 children, explanted for reasons including failure of rod lengthening and maximum rod distraction reached were analyzed. This included 10 generation 1 and 24 generation 2 rods. All but one rod had been used in a dual rod construct.

All rods were cut open, initially at the weld where the coned bar joined the outer casing [Figure 1], using a Dremel (Racine, Wisconsin, USA) cutter. Cutting took place in stages until the weld was sufficiently weak that it could be broken by hand. Employing this methodology, alongside cutting at the coned bar end, ensured that any contamination due to cutting would be minimal. Once opened, the internal components were removed. Photographs were taken throughout the disassembly process. Dimensional measurements were taken at the narrowest (most worn) point of the extending bar using a micrometer (Mitutoyo UK, Huddersfield, UK). Any internal debris was collected and analyzed using Energy-Dispersive X-ray spectroscopy (EDX) allowing the individual chemical elements of the debris to be identified. Where appropriate, the International Standards Organization (ISO) standard on explant analysis, ISO 12891-2:2014 “Retrieval and analysis of surgical implant – Part 2: Analysis of retrieved
Analysis of explanted MAGEC rods

surgical implants" was followed.\textsuperscript{20} A schematic diagram showing a MAGEC rod in cross-section and illustrating the terms used is shown in Figure 1. Individual components and features, which were indicative of the state of the explanted MAGEC rod, were assessed by a single observer (SLS) using the grading system described in Table 1.
RESULTS

Table 2 summarizes the grading results from the explanted MAGEC rods. Values given as mean (S.D) unless otherwise stated. All 34 rods showed ‘growth marks’ on one side of the extending bar. A typical example is shown in figure 2. It is important to note that these marks did not extend around the entire circumference of the extending bar component. All 34 MAGEC rods had some internal wear debris (minimum grade of 2 on the wear debris quantity scale). Eighteen rods (53%) contained ‘copious’ (grade 4) wear debris [Figure 3] which amounted to 1g mass in one particularly affected rod. This wear was identified as titanium by EDX analysis in all cases.

Thirty-one of 34 rods (91%) showed evidence of localized wear from the extending bar, towards the magnet end of the MAGEC rod. Measurements of the diameter of the extending bars (mean diameter 6.33mm (0.01) in unworn regions) showed them to have been reduced by a mean of 0.22mm (0.20). One rod was reduced by 1.07mm (17% of original size). The reduction in diameter was often so substantial that it was visible to the naked eye [Figure 4]. In the MAGEC rods 25 (74%) had non-functioning radial bearings (grade 3 or 4) [Figure 5], 18 (53%) had badly damaged O-ring seals (grade 3 or 4) [Figure 6] and 15 (44%) had a fractured drive pin (grade 4) [Figure 7].
This paper has reported on an analysis of 34 explanted MAGEC spinal rods, which is the largest in the scientific literature to date. Findings were similar in all explanted rods and there were three common observations. Firstly, localized marks indicating growth of the rods, here called ‘growth marks’, [Figure 3], were seen. Secondly, localized wear on the extending bar, at the magnet end [Figure 4] was a common feature. It was noted that these two features were always at 180 degrees to each other [Figure 4]. Thirdly, the main element in the debris that was found inside all 34 MAGEC rods was titanium. As both the outer casing and extending bar of MAGEC rods are made from titanium, one or both of these components is likely the source of the titanium wear debris. An explanation for these three similarities and thus the failure mechanism of MAGEC rods is offered in figure 8.

It is likely that off axis loading of implants, as indicated in figure 8, occurs in the spine. The spine not only allows torsion and bending in different planes, but it has natural curvatures. It is not a straight column and the weight bearing axis lies anterior to posterior instrumentation in most cases. We know loading on the implants can be substantial and sufficient to cause fracture or breakage of instrumentation.\textsuperscript{8}

Figure 8 offers an explanation of how titanium wear debris was generated. Although created towards the magnet end of the MAGEC rod (away from the end with the O-ring seal), debris was often so copious that, when combined
with the frequency (53%) of damaged O-ring seals, it was likely able to escape
from the MAGEC rod and enter the surrounding tissues. This would therefore
explain the metallosis reported recently around 6 of 7 MAGEC rods examined
in a separate study. These authors suggested that metallosis was likely
caused by the ‘growth marks’ but we feel that a more likely explanation is the
larger volumes of titanium wear debris escaping from inside the MAGEC rods.

Metallosis and wear is an important issue with several types of implant. For
example, the high revision rates of many types of metal-on-metal hips, which
in turn have been linked to wear debris generated at the bearing surfaces and the taper-trunnion junction, have been a major concern within
contemporary orthopedics. While the effects of titanium debris may not be
the same as those from the cobalt-chromium used in metal-on-metal hips, the
history of orthopedics from Charnley onwards has shown that the generation of
volumes of wear debris should be avoided. Such volumes do not have to be
substantial. It has been suggested that wear rates of above 2.3mm/year
(approximately 2 pin heads) from the articulating surfaces of a metal-on-metal
resurfacing hip is sufficient to lead to a wear related failure and thus a revision
operation. In fact, the amount of metal debris from a taper-trunnion surface
of a modular hip which can lead to revision is even less, with a median of
0.4mm/year being reported from a cohort of 104 metal-on-metal hips revised
for wear related failures. Given that, in the worst case wear of a MAGEC rod
reported here, over 1g of worn titanium material was collected, as titanium has
a density of 4.420kg/m³ this equates to over 200mm³ of volumetric wear from
a single MAGEC rod.
It should be considered that the significant wear observed may not only contribute to implant failure and local tissue metallosis. The potential systemic effects of large volumes of metal debris in children are potentially the most worrisome. Titanium wear from joint replacements has been shown to induce aneuploidy \textit{in vitro} and \textit{in vivo}.\textsuperscript{30} The long term effects of raised titanium levels in children is currently unknown with most studies to date having focused on the potential carcinogenesis related to cobalt chromium based joint replacements in adults\textsuperscript{31} although recent links to heart failure have also been reported.\textsuperscript{32,33}

It should be noted that wear affects all spinal implants and hence is not limited to the MAGEC system. Wear has been demonstrated on explant analysis of both growth-friendly and static implants.\textsuperscript{34,35} Accordingly, surgeons using conventional growing rods commonly observe implant wear and some tissue metallosis at time of re-operation. Notwithstanding this, the main cause of concern of many surgeons contributing to this work, who are experienced in the use of other early onset scoliosis implants, was the extent of the soft tissue contamination encountered when removing the MAGEC system, which on occasion was alarming. This experience is also reflected in other reports.\textsuperscript{13} We aim to attempt to quantify the extent of tissue metallosis encountered in future work.

Regarding drive pin fracture, which others have implied is a cause of failure, figure 8 indicates that drive pin fracture is instead an effect of this failure.
mechanism. Off axis loading would create high friction between the extending bar and the internal surface of the outer casing. The wear debris generated, and seen inside all 34 explanted MAGEC rods, exemplifies this high friction. The drive pin therefore has not only to transmit the torque from the magnet which causes the MAGEC rod to ‘grow’ but also to overcome a frictional force it was not designed to deal with.

Clearly, there is more work to be done, particularly in correlating clinical details to failure modes. This will be the subject of future publications. Another limitation is that there is an inevitable selection bias when dealing with failed implants. However, our view would be that we are seeing a range of worn MAGEC rods, with only the degree of wear varying between individual implants. In other words, we see a common feature, that of localized wear, in all of the 34 explanted MAGEC rods which we have examined to date. There is additional engineering work still to be done. At present, we have an indication of the amount of wear from the extending bar (A-B in table 2). We do not have such an indication from the other part of the wear couple, namely the internal aspect of the outer casing. Wear from the internal aspect of the outer casing could help to explain the lack of wear measured on three (9%) extending bars (bars 5, 23 and 31 in table 1) when wear debris was seen from inside all 34 MAGEC rods. We acknowledge that MAGEC rods have been produced in various generations, as the design has progressed over recent years.\textsuperscript{1,36} Our analysis relates to generation 1 and generation 2 rods, while generation 3 rods have recently been introduced. However, there are numerous common factors
between the generations and, as many generation 1 and 2 rods remain implanted, we therefore feel the findings of our analysis are timely and relevant.

We accept that, in the UK and other countries, spinal implant registries are not as developed as those for hips and knees. Therefore, it is currently difficult to estimate what percentage of spinal rods, both MAGEC and others, ‘fail’. Indeed there may be debate over the definition of failure if, as in the case of growing rod systems, they are expected to be removed from the body, unlike an artificial hip or knee joint which is intended to last the lifetime of the person implanted with it. However, the fact that we have received multiple MAGEC rods from multiple spinal centers in the UK implies that there are shared issues with the implant, rather than a single center or a single surgeon. Moreover, the common features identified from failure analysis of the MAGEC rods and described in this paper, which thus indicate a shared failure mode, are of concern.

All explanted MAGEC rods showed localized wear of the extending bar that resulted in copious amounts of titanium wear debris. Localized wear was due to off axis loading due to the weight bearing axis of the spine being anterior to the implants. The titanium wear debris from inside the MAGEC rods, alongside damage to O-ring seals, explains the metallosis seen clinically. The relatively high number of non-functioning MAGEC rods examined at our retrieval center suggests an appreciable revision rate and calls into question the cost-benefit argument offered by NICE in 2014. Notwithstanding this, surgeons should consider the findings of this study together with the data available for other implants used to manage early onset scoliosis. There remains no ideal implant,
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with major complications commonly encountered with most available systems.\(^3\)

Yet, given the paucity of long term clinical data for the MAGEC system, reported cases of significant metallosis in children, together with the findings from the current study, we urge caution in the use of the MAGEC system.
REFERENCES


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Figure 1 – Schematic diagram of a MAGEC rod in cross-section showing the key components. From left to right: extending bar (black); O-ring seal housing (green) with O-ring seal (purple); main actuator outer casing (blue and yellow tubes); leadscrew (red); radial bearing (orange); drive pin (white vertical line); magnet (light blue); thrust bearing (purple); and coned bar (black).
Figure 2 - ‘Growth marks’ (shown within red oval) on the extending bar of an explanted MAGEC rod. Note that the marks do not extend around the circumference of the extending bar. The rule to the bottom left gives scale.
Figure 3 – The internal components of an explanted MAGEC rod. Here the end of leadscrew can just be seen; most of the leadscrew being encapsulated by copious amounts of wear debris that has taken on the internal shape of the outer casing. The end of the extending bar is then visible to the left of the debris.
Figure 4 – An explanted MAGEC rod showing the extending bar below the outer casing. They have been placed like this so that the localized area of wear (red arrow) becomes clearer. Wear is primarily towards the magnet/leadscrew end of the extending bar. Also just visible to the left hand side is a pen nib which points to the ‘growth marks’. Note that the growth marks and the localized area of wear on the extending bar are at 180 degrees to each other.
Figure 5 – The radial bearing of this explanted MAGEC rod was found to have been destroyed. The inner cage of the radial bearing is protruding to the right of the outer race, and three rolling elements are missing from the cage in this view alone.
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Figure 6 – image of an O-ring seal from an explanted MAGEC rod that had split in two
Figure 7 – The drive pin connecting the cylindrical magnet to the leadscrew of this explanted MAGEC rod had fractured. Upon disassembly, the central section of the drive pin normally within the leadscrew was pushed out (red arrow) and photographed with the broken piece of the drive pin (yellow arrow).
Figure 8 – Schematic diagram of the operation of a MAGEC rod, with the outer casing shown in blue and the extending bar shown in red. Idealized operation of a MAGEC rod is shown in the center. However, the effect of the reality of off axis loading is shown on the right hand side. Off axis loading causes the extending bar to contact on the internal surface of the outer casing (A). Note that this contact will just be on one side of the MAGEC rod. As the rod ‘grows’ in vivo so these marks are repeated. The other end of the extending bar impinges on the
analysis of explanted MAGEC rods

internal surface (B) of the outer casing causing localized wear, at

approximately 180 degrees to the marks at (A).
### Analysis of explanted MAGEC rods

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<th>O-ring seal</th>
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<th>Drive pin</th>
<th>Wear debris quantity</th>
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Table 1 – Grading system applied to key components and amounts of wear from each explanted MAGEC rod.
Analysis of explanted MAGEC rods

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# Analysis of explanted MAGEC rods

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Table 2 – results of grading internal components of MAGEC rods and measurements of wear on the extending bar (ext. bar) components