

■ ANNOTATION

Magnetically controlled growing rods in the treatment of early-onset scoliosis

A NOTE OF CAUTION

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The **MAGnetic Expansion Control (MAGEC)** system is used increasingly in the management of early-onset scoliosis. Good results have been published, but there have been recent reports identifying implant failures that may be associated with significant metallosis surrounding the implants. This article aims to present the current knowledge regarding the performance of this implant, and the potential implications and strategies that may be employed to identify and limit any problems.

We urge surgeons to apply caution to patient and construct selection; engage in prospective patient registration using a spine registry; ensure close clinical monitoring until growth has ceased; and send all explanted MAGEC rods for independent analysis.

The MAGEC system may be a good instrumentation system for the treatment of early-onset scoliosis. However, it is innovative and like all new technology, especially when deployed in a paediatric population, robust systems to assess long-term outcome are required to ensure that patient safety is maintained.

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The treatment of young patients with progressive early-onset scoliosis necessitates the control of the deformity while permitting continued growth. This may be achieved using several methods including distraction-based techniques.¹ Traditional growing rod systems involve repeated open operations to lengthen the rods. These are commonly associated with complications including deep infection and implant failure, and a psychological toll on the child and their parents.^{2–5}

In 2009, a novel spinal implant, the **MAGnetic Expansion Control (MAGEC)** system (Nuvasive Specialised Orthopaedics, San Diego, California), received its European Conformity mark, allowing sales in the United Kingdom and Europe. This system is attractive in the management of early-onset scoliosis as it includes a magnetically driven linear actuator allowing non-invasive lengthening, potentially avoiding repeated operations and their associated complications. Given these possible benefits, the National Institute for Health and Care Excellence (NICE) in the United Kingdom recommended that the system should be considered in children with early-onset scoliosis as its use was supported by the evidence.⁶ It has subsequently been widely used in the United Kingdom. Approval by the Food and Drug Administration (FDA) has also been granted in the United States. *The Bone & Joint Journal*

recently reported the experience with this implant from Cardiff, noting a high rate of failure, significant tissue metallosis surrounding the implants at the time of revision associated with metal debris, and fractures of a drive pin within the actuator.⁷ Such findings necessitate an evaluation of our current knowledge about this device and the mechanisms in place that are designed to detect failures.

Any system spanning unfused spinal levels will be liable to fracture and anchor failure, because of continuing movement of the spine. It is currently unclear, however, if the complex internal design of the MAGEC system is associated with significantly more complications as suggested by the work of Teoh et al.⁷ Cases of failure of the actuator mechanism through fracture of a drive pin have been reported from other centres.^{8–10} Metallosis has also been noted at the time of revision in two other reports.^{8,11} To date, there remains insufficient evidence in the literature to determine if such failures are common, as there are few long-term outcome studies following the use of the MAGEC system. Hosseini et al¹¹ reported the outcome in 23 patients at a mean follow-up of two years. Complications necessitating re-operation occurred in ten patients. Six underwent revision of the rods themselves, mainly for breakage in two and problems with the anchorage in two; metallosis and failure of

lengthening necessitated revision in the remaining patients.¹¹ The Cardiff group¹² have previously reported the outcomes of a slightly larger cohort of eight patients treated with this system, with a mean follow-up of four years. Complications necessitated re-operation in six patients; one for failure of lengthening and another for fracture of a drive pin. Fractures of a rod in two patients, failures of anchorage and proximal junctional failure prompted revision in the remaining patients.¹² In a multicentre study involving 33 patients, ten revision procedures were required during the first 12 months post-operatively, including for 'rod breakage' and failure of lengthening in four and two patients respectively.¹³ La Rosa et al¹⁰ reported a fracture of a rod and one of a drive pin in ten patients, with a mean follow-up of 27 months. Two fractures of a drive pin were seen in nine patients at a mean follow-up of 29 months.⁸ In a multicentre French study of 30 cases, 24 complications occurred including six failures of the MAGEC rods to lengthen at a mean of 18 months follow-up. A total of 13 revisions had occurred in nine patients including three for 'rod breakage' and two for non-functioning rods.¹⁴ Other reports are more reassuring, with Thompson et al¹⁵ reporting proximal failure of anchorage in three of 19 patients, but no failure of a MAGEC rod itself at a mean follow-up of 22 months. Akbarnia et al¹⁶ reported on 12 patients with a mean follow-up of 2.5 years; four had undergone a re-operation but only one was for failure of a rod with loss of distraction. Dannawi et al¹⁷ encountered two 'rod breakages' in 34 patients followed for a mean of 15 months. A single centre Turkish study reported two fractures of a rod in 18 patients at a mean follow-up of 18 months.¹⁸

Given the contradictory and limited nature of the literature to date, further prospective studies reporting the long-term outcomes following the use of the MAGEC system in larger numbers are urgently needed.

Following reports of early failures of the MAGEC system, the British Scoliosis Society (BSS) audited its members in 2016. Data were received from 11 of 17 centres using the device and included 195 patients (369 rods) treated since its introduction onto the United Kingdom market. Unplanned revision surgery occurred in 43 patients (22%). Fracture of a rod occurred in 11 (6%), 13 (7%) had a fracture of a drive pin and 14 (7%) had failure of lengthening without an obvious fracture of a drive pin. Metallosis was noted in ten patients (23%) undergoing unplanned revision surgery. Following the original audit, more recent data have been received from three of the 11 centres, noting four more cases of fracture of a drive pin in their original cohort giving an incidence of failure of a drive pin of 8%. Similar investigations are being undertaken by the European Paediatric Orthopaedic Society which plans to survey its members in 2017 to identify patients treated with the MAGEC system and to assess the clinical outcomes.¹⁹

The implications to patients and healthcare providers if the MAGEC system proves to perform poorly are signifi-

cant. Currently, about 125 patients are treated with this system annually in the United Kingdom. It is difficult to estimate the number of patients treated worldwide. It is likely to be quite extensively used in the United States. Whilst the local effects of metallosis are striking in the images provided by Teoh et al,⁷ it is the systemic effects of metal debris that are potentially the most worrying. It should be noted that, like most traditional growing rods, the MAGEC system is made predominantly from titanium alloy (TiAl6V4), with an increase in the serum level of titanium associated with their use.²⁰ Patients treated with the MAGEC system have also been shown to have significantly higher serum levels of vanadium than those treated with conventional systems.²⁰ The long-term effects of raised levels of metal ions in children is unknown. Most studies have focused on the potential carcinogenesis related to cobalt/chrome based on arthroplasties in adults.²¹ Wear debris from arthroplasties containing titanium has been shown to induce aneuploidy *in vitro* and *in vivo* in a dose dependent manner.²²

Any necessary revision surgery carries a burden of morbidity for the child but also significant financial implications. Despite a pair of MAGEC rods costing around £14 000, the initial cost analyses, available at the time of NICE approval, suggested a saving after three years compared with conventional growing rods.^{23,24} These cost analyses and national guidance may need to be revisited once the true survival of the implant becomes clear.

Over the last 20 years, patients have repeatedly suffered as a result of poorly performing orthopaedic implants, such as the 3M Capital hip (3M Health Care Ltd., Loughborough, United Kingdom).²⁵ A novel implant may be used for many patients before adequate clinical data, upon which to assess its suitability for widespread use, becomes available. In response to the failures of previous implants, safer strategies for the introduction of new technology have been suggested, but none have been implemented.

The stepwise approach described by Malchau et al^{26,27} is conceptually attractive. The first step is to identify the incidence and severity of the problem. The incidence of the early-onset of scoliosis is low but the effects on the patient are severe. The second step proposes a solution, in this case MAGEC. The third step defines the extent of the 'Universal Dilemma', which is the gap between the pre-clinical results (e.g. animal or biomechanical testing) and actual clinical outcomes.²⁶ This gap has yet to be defined for the MAGEC system. The fourth step is to identify the compromises driven by this dilemma. This might now be coming to light with the various reports of failure that have been published. The fifth and final step is to define the cost-effectiveness. NICE relied on data suggesting significant cost-effectiveness in the context of clinical effectiveness ('clinical proficiency')²⁸ when it recommended the use of MAGEC for the treatment of early-onset scoliosis. That consideration may have to be reconsidered in the light of new data.

More recently, the IDEAL Framework (idea, development, exploration, assessment, long-term study) was developed as a rational mechanism for reducing the morbidity associated with poorly performing novel implants.²⁹⁻³¹ Broadly, this system and the stepwise approach of Malchau,²⁷ suggest initial evaluation with small prospective trials, followed by large, multicentre, ideally randomised, prospective studies, before the widespread adoption of an implant. Long-term monitoring using registries would form an integral part of that evaluation.²⁸⁻³¹

In the absence of the application of these logical approaches in the United Kingdom, the optional 'Beyond Compliance' initiative potentially offers an improvement on the current practice of the introduction of a new implant, but at present it includes only hip and knee arthroplasties and its impact remains limited.³² Implants continue to be introduced through 'substantial equivalence' routes, avoiding the need for large-scale trials before widespread introduction. At the time of evaluation by NICE in the United Kingdom, only three peer reviewed case series of patients treated with the MAGEC system were available, and only two patients with follow-up of more than two years had been described.^{17,24,33-35} In the United States, the MAGEC system was cleared by the FDA via the 510(k) route. To do so a device must have the same intended use and be "at least as safe and effective, that is, substantially equivalent, to a legally marketed device" (i.e. predicate device). Technological characteristics employed must be the same as the predicate device or if different "does not raise new questions of safety and effectiveness".³⁶ In this case the MAGEC system was felt 'substantially equivalent' to the Harrington rod system, which involved static distraction instrumentation and had been introduced into clinical practice in the 1950s.³⁷ The MAGEC actuator mechanism had been previously approved by the FDA when used within intramedullary nails,³⁸ i.e. the Harrington Rods and intramedullary nails were considered to be predicate devices.³⁹ Such judgments are surprising as it is established from other orthopaedic implants that even minor changes can lead to morbidity through unforeseen consequences.⁴⁰

As a result of the current ways in which new implants are introduced into clinical practice, we rely heavily on registries for post-market surveillance.⁴¹ Registries have proved to be valuable in this role, recognising both poorly performing joint arthroplasties and bone cement.⁴² Most recently, the Australian and United Kingdom National Joint Registries identified the Articular Surface Replacement hip as an outlier, leading to its withdrawal.^{43,44} Using registries as a means of post-market surveillance is also favoured by the FDA.⁴⁵ The British Spine Registry (BSR)⁴⁶ was established in 2012 with goals that included improving patient safety and monitoring the outcomes of surgery. Recognising the lack of long-term clinical data at the time of evaluation of the MAGEC system, NICE suggested that appropriate data be captured using a registry.⁶ Furthermore, NHS England

mandated the registration of all patients treated with the MAGEC system, within the United Kingdom, on the BSR.⁴⁷

We have assessed the compliance with BSR registration of units treating patients with the system. The hospital and date of surgery for all patients treated with it in a NHS centre between 01 April 2014 and 31 March 2016 was provided by the manufacturer. These data were cross-referenced with the BSR. Data were analysed to assess the number of patients treated in each centre and compliance with registration in the BSR. Over the course of the study, 234 operations were performed in 19 NHS centres. National usage was consistent during this time with a mean of 29.3 cases per quarter. There was a wide variation in the number of patients treated with the system by different centres, with a median of seven patients/unit (interquartile range 4.0 to 16.5). Only 65 of the 234 patients (28%) were entered onto the BSR. The rate of entry varied considerably between centres (0% to 100%). Six (32%) made no entries. No unit that had treated more than four patients had 100% BSR entry. There was no significant change in the proportion of patients registered on the BSR per quarter during the study. As a result of the failure to comply with the NHS England mandate, current data for the MAGEC system in the United Kingdom is inadequate and cannot be used to identify the rates of re-operation after the use of the MAGEC system. Feedback has been provided to centres with poor compliance with the registry and they have been encouraged to place all patients on the BSR retrospectively and to record complications prospectively. Future work will identify whether this information will lead to a change in practice.

It has been suggested that a fully operational registry should capture > 80% of the national data. The rate of registration of 28% of patients treated with the MAGEC system on the BSR is unacceptable.^{48,49} Such poor quality data is not only seen in the BSR. The Canadian Spine Outcomes and Research Network also reports significant variation in the rates of registration of patients between centres.⁵⁰ Follow-up is also poor in most other national registries, with only two of the 13 spine registries examined by McGirt et al⁴⁹ reporting follow up of > 75% of patients, one year post-operatively. One such successful registry, SweSpine, was evaluated by Fritzell et al,⁵¹ who identified factors thought influential in its success. Considering these factors, it seems likely that greater commitment by surgeons, hospitals and regulators is required to improve compliance.

The importance of registries should be clear to all those responsible for the care of these patients, with the clinical necessity and mandate from NHS England for registration of MAGEC cases undeniable. There is an international applicability to this concept, not only for MAGEC, but also for other innovative products that might have long-term clinical consequences. Despite this, logistical support is a common obstacle. One centre in the United Kingdom reporting their experience of implementing the registry

concluded “the support for BSR in NHS hospitals is woefully inadequate”.⁵² Surgeons must work with their hospitals to facilitate both the resources and time to input data. The cost of these provisions was estimated by an institutional spine registry in the United States to be \$160 per patient.⁴⁹ As the cost of the implants alone is tens of thousands of pounds, euros or dollars, such a small sum is a pittance. Although increased financial input will be needed to drive improvement, the investment is likely to be highly cost-effective. Many ways of funding registries are available. A financial contribution by industry funds the successful United Kingdom National Joint Registry, and this model might be more widely applicable. Financial encouragement to hospitals from NHS governing bodies for the registration of patients may also lead to improved compliance, by helping surgeons negotiate resources. Again, this has international applicability.

There are ‘carrots and sticks’, and surgeons should note that in another similar setting regulators used punitive tactics successfully to promote the use of registries. The SWISSspine registry was introduced to monitor outcomes after the introduction of lumbar disc replacements and reported a rate of registration of 80% during the first three years. The details of patients registered by surgeons were compared with data provided by the manufacturers. Surgeons failing to submit patients to the registry risked having their certification to use lumbar disc replacements withdrawn.⁵³ Whether regulators choose a carrot or stick approach to improve the quality of data on spine registries remains to be seen. In the absence of reliable registry data, surgeons should be aware of alternative methods of recording suspected implant-related ‘adverse incidents’, such as the Yellow Card system provided by the Medicines & Healthcare products Regulatory Agency (MHRA)⁵⁴ in the United Kingdom (recommended by the BSS).

In addition to monitoring clinical outcomes of the MAGEC system, we must also learn from any failures which are encountered. The independent analysis of failed implants has proved to be valuable, particularly in the study of complex devices such as arthroplasties. Such analyses have allowed mechanisms of failure to be understood and improvements to be made to the design of components.^{55,56} Teoh et al⁷ reported the first such analysis of seven MAGEC rods explanted at their centre, identifying significant metal debris within the actuator as well as fractures of a drive pin. Although these findings are valuable, it is clear that many more rods must be analysed in greater detail before we can thoroughly understand the mechanisms of failure. Centres have been established in Newcastle and London to analyse explanted MAGEC rods independently. We urge surgeons to ensure all explanted MAGEC rods are sent for analysis.

Surgeons using the MAGEC system have a responsibility to limit the number of failures through the careful selection of patients and close monitoring of their cases to ensure that failures are recognised. The role for the MAGEC

system in revision cases is uncertain with increased complications and limited spinal growth noted in some studies.¹¹⁻¹³ Our audit of the BSR identified that 30% of constructs remain single rather than dual rod. This is surprising given the experience gained with traditional growing rods. In keeping with traditional growing rods, there is increasing evidence that single MAGEC rod constructs may be associated with a poorer correction of the curve and a higher rate of complications than dual rod constructs. It is apparent that dual MAGEC rod constructs should be used where possible.^{10,12,17,57,58}

Fractures of a drive pin can be easily recognised on plain radiographs.⁸ Surgeons should review their cases to ensure that all patients with a fractured drive pin are identified as failed pistoning rods and are likely to be associated with significant metallosis. Though ultrasound is a useful method of measuring distraction, we would agree with other authors who suggest that plain radiographs should be obtained every six months for surveillance, as well as to record if rods fail to distract on two successive occasions.^{8,59}

The innovative MAGEC system is potentially a great advance in the management of patients with early-onset scoliosis. It is used widely but infrequently in most spine centres in the United Kingdom. The long-term clinical outcome is not known. Despite a mandate from NHS England to register all cases on the BSR, compliance is inadequate and does not allow a robust evaluation of the system. Notwithstanding this, experience gained in the United Kingdom suggests that failures are not uncommon and may be associated with significant metallosis. Surgeons are urged to exercise caution when selecting patients for treatment using the MAGEC system, to enter their patients prospectively on a registry, to monitor them closely and to send all explanted MAGEC rods for independent analysis.



Take home message:

- Current knowledge of the MAGEC system suggests caution in its use and close monitoring.
- Surgeons should ensure all cases are placed on a registry and send all explanted MAGEC rods for independent analysis.

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