## INTRODUCTION

The Scoliosis Research Society defines the aims of treatment of early onset scoliosis (EOS) as to obtain and maintain deformity correction, achieve adequate spinal growth and limit complications.[1] The MAGnetic Expansion Control (MAGEC) system (Nuvasive Specialised Orthopaedics, San Diego, CA, USA) was introduced to meet these needs whilst reducing the number of operations and morbidity necessitated by conventional growing rods (CGRs). Data suggests the MAGEC system addresses coronal deformity well.[2-14] Like any non-fusion technique complications such as rod fractures and anchor failure occur.[1,3] The additional complications related to the lengthening mechanism remains unclear but reports detail mechanical failure of the actuator which can result in local and systemic metallosis.[14-17] Despite being fundamental to treatment, the growth of MAGEC rods *in vivo* and hence the instrumented spine has received little attention to date. Available studies have measured rod lengthening using various radiographic measures but no study has measured the rod lengthening achieved directly at time of removal.[2,5,9,11,18-20]

This study aims to identify the lengthening achieved by MAGEC rods *in vivo*. The clinical and explant factors influencing achieved lengthening will also be examined.

**MATERIALS AND METHODS**

Cases with adequate clinical data were identified from the database of explanted MAGEC rods based at Newcastle University and The Great North Children's Hospital, Newcastle Upon Tyne, UK. This is the largest series of independently analyzed rods and includes rods removed for all indications.

Previous explant analysis has identified 'growth marks' on the extending bar of MAGEC rods corresponding to the distractions performed during implantation.[21] The *in vivo* rod lengthening was determined by measuring the distance from the actuator opening to the most distant aspect of the 1st 'growth mark' on the extending bar (Figure 1). A further measurement was taken from the point of extending bar tapering to the most distant aspect of the 1st 'growth mark'. This measurement reflects the baseline distraction of the rod at time of initial implantation. The sum of baseline distraction and *in vivo* lengthening was calculated to identify 'total rod distraction'. All measurements were undertaken using calibrated digital photographs. Rods in which the extending bar was freely 'telescoping' in and out of the actuator were identified. This corresponds to unlinking of the actuator's magnet and leadscrew, precluding both active lengthening and accurate assessment of achieved lengthening.

The 'instrumented spinal lengthening' was calculated as follows; in cases with dual rod constructs in which neither rod was telescoping a mean lengthening of the two rods was used. In dual rod cases in which one rod was telescoping the lengthening of the non-telescoping rod was used. The lengthening in single rod constructs was included if it was not telescoping.

Following this the force produced by the rods on activation with an external remote controller (ERC) was measured as previously described.[22] Due to developments in the explant analysis over the course of the study, force data was available for 34/55 included constructs. Constructs including a rod unable to lengthen with ERC activation and/or a telescoping rod were deemed non-functional.

The influence of clinical variables on achieved lengthening was assessed using Pearson's correlation coefficient for continuous variables. Categorical variables were compared using Student t-test or analysis of variance (ANOVA) with Tukey post hoc analysis for >two groups. All statistical analyses were performed with SPSS v22 (IBM- SPSS, Armonk, NY), with a $p<0.05$ considered significant.

## RESULTS

Fifty-five MAGEC constructs (99 rods) from 53 patients were included, with two patients contributing two constructs. Rods were received from nine UK and one Danish hospital. Nine "Modification 1" rods (manufactured 2011, all 90mm actuator length) and 90 "Modification 2" rods (manufactured 2012-2017, 75 90mm and 15 70mm actuator lengths) were included. Clinical characteristics of the included constructs are detailed in Table 1.

Of the 99 rods 29 were telescoping. It could not be determined if 5 rods were telescoping e.g. extending bar fracture at actuator opening. Of the non-telescoping rods 2 had been tested with an ERC by the surgeons following explantation, altering lengthening and 2 rods from 1 patient had been removed for infection before any lengthenings. One dual rod construct had been used with 2 crosslinks in a way that precluded lengthening, this included one non-telescoping and one indeterminate rod. The remaining 60 rods were suitable for lengthening analysis. The mean lengthening *in vivo* was 21.7±10.5mm range 0-44mm. This corresponds to 8.9±8.0mm per year of implantation. The mean baseline distraction was 4.5±2.0mm. The mean 'total rod distraction' for the fifty-two 90mm actuator rods (max possible distraction 48mm) was 27.8±10.5mm and eight 70mm actuator rods (max possible distraction 28mm) was 16.1±8.6mm (p=0.006). One 70mm and two 90mm rods had reached maximum total distraction. Six constructs were removed for perceived 'full rod lengthening achieved' all of which were dual rod constructs. Three included a telescoping rod leaving 9 rods suitable for lengthening assessment. Two of the constructs included one fully distracted rod.

Instrumented spinal lengthening could not be calculated in 17/55 constructs (11 constructs all rods telescoping, 2 constructs telescoping uncertain, 2 constructs surgeon tested, 1 infected and 1 dual crosslinks as previously described). The mean instrumented spinal lengthening in the 38 included cases was 22.1±10.0mm, 8.4±7.2mm per year (Figure 2). Moderate correlations were present between instrumented spinal lengthening and duration of implantation (r=0.34, p=0.04) and number of lengthenings (r=0.57, p=0.002). Instrumented spinal lengthening was negatively correlated with age (r=-0.35, p=0.03) but not significantly with mass (r=-0.31, p=0.13) or height (-0.25, p=0.25) at time of insertion. The rate of instrumented spinal growth was negatively correlated with duration of implantation (r=-0.47, p=0.004). Between group comparisons are shown in Table 2. No significant differences in the rate of instrumented spinal lengthening were present between groups.

Force data was available for 34/55 constructs, of which 15 contained a telescoping rod; none of these constructs were functional on force testing. Eighteen constructs were not telescoping of which 9 were functional on testing. Force data was available for one of two constructs in which telescoping was uncertain, identifying it as non-functional. In total 25/34 constructs with force data were non-functional. Of the 21 constructs without force data 9 contained a telescoping rod, thus were non-functional.

Overall of 55 constructs 34 were non-functional at time of removal with 9 functional and 12 indeterminate. Functional constructs were *in vivo* significantly less time than non-functional constructs; 20.0±10.1 vs 39.7±15.5 months ($p<0.001$). No functional construct was removed after 35 months implantation. Where lengthening analysis was possible functional constructs had lengthened significantly less than non-functional constructs 12.3±10.1mm vs. 23.3±8.6mm ($p=0.04$). When considered as rods the force produced on testing was significantly negatively correlated with time *in vivo* ($r=-0.46$, p=<0.001) but not with the *in vivo* lengthening of the rods ($r=0.18$, $p=0.28$) or total rod distraction ($r=0.23$, $p=0.19$).

## DISCUSSION

This multicenter study represents the largest group of MAGEC cases reported and the first to measure rod lengthening directly. In this series a very small proportion (<5%) of removed rods have lengthened fully with a mean instrumented spinal lengthening of 22mm. Cheung et al. reported similar findings measuring radiographically, in the only other studies of rod lengthening at time of removal.[2,20] Seven rod exchanges were described with measurements suggesting 28mm of instrumented spinal growth per construct, if calculated similarly to this study. Rods were removed at the end of treatment in 5 cases with measurements indicating mean instrumented spinal lengthening of 27mm per construct.[2] In a further study of 22 patients rods were exchanged having lengthened by a mean of 27 and 32mm for right and left rods respectively, but instrumented spinal lengthening cannot be calculated from the provided data.[20]

It is apparent that MAGEC rods are typically removed well before maximum distraction. Interpretation of this is not straightforward as implants may be removed at completion of growth, or earlier if problems occur. Issues may be spine related including the loss of the ability to lengthen. This is common in CGRs and thought to be due to spinal stiffening or autofusion, reflected clinically as 'the law of diminishing returns'.[23] Implant problems may prompt removal directly such as rod fracture or actuator failure in MAGEC cases or indirectly including anchor failure and infections. In some included cases it is easy to conclude implant failure as the cause e.g. surgeon reported drive pin fracture. Conversely, anchor failure and infection are less likely attributable to the implant. The commonest surgeon reported reason for rod removal in this series was 'failure to lengthen', the cause of which may be spine or device related. We analyzed the function of 14/17 constructs removed for failure to lengthen, identifying only 1 as functional. It is possible device failure may co-exist with spinal causes for removal, but our findings suggest distraction mechanism failure is common. The deterioration in function appears time related with the rate of instrumented spinal lengthening inversely proportional to duration of implantation and non-functional constructs having greater duration *in vivo* than those functional. Accordingly, studies report the force produced by MAGEC rods reducing and problems achieving the desired lengthening increasing over time.[2,3,20,22,24] In keeping with our findings Cheung et al. note a return to easily achieved desired lengthening after rod exchange, indicating the fault lies with the implant rather than the spine.[2,20] Our findings together with the literature suggests that in contrast to CGRs the failure to achieve desired lengthening with MAGEC rods over time is commonly due to a deterioration in device function *in vivo*.

Notwithstanding the reduction in MAGEC function over time it is uncertain how the achieved lengthening compares with CGRs over the implant's lifetime. Studies of CGRs are based mostly on radiographs which can be unreliable due to posture, sagittal plane abnormalities and projection issues. Direct measurement at lengthening procedures has also been reported. Results indicate an initial lengthening up to 17mm. Gains per lengthening reduce gradually to around 8-11mm for the 2$^{nd}$-6$^{th}$ lengthening and approximately 6mm thereafter up to the 10th lengthening.[25,26] MAGEC rod lengthening has been studied both with radiographs and ultrasound identifying rod lengthening of 7-16mm/year for the first 2-3 years *in vivo*.[3,5,9-11,18,19] This is the first study to measure MAGEC rod lengthening directly and suggests that the MAGEC lengthening achieved in this study would be surpassed on average by 2-3 CGR lengthenings, typically at 12-18 months post implantation. Direct comparison of lengthening between MAGEC and CGRs is limited to one retrospective study of 12 cases treated with MAGEC rods with a matched group of CGRs, noting no significant differences in T1-T12 or T1-S1 lengthening over follow up. Notably there was a trend towards greater annual lengthening with CGRs but follow up for CGRs was 4.1 years vs 2.5 years for MAGEC, which given the known reduction in achieved lengthening over time in CGRs limits the conclusions that can be drawn.[6]

Interpretation of data describing spinal lengthening is complex as the 'desired' lengthening is unclear. Given that the majority of these cases were juveniles, with growing rods implanted from the upper thoracic spine to upper-mid lumbar spine, an instrumented annual spinal lengthening of 8.4mm could be considered satisfactory, matching normal spinal growth of 0.7cm and 1cm/year for T1-T12 and T1-S1 respectively.[27] The lengthening achieved with a growing rod system is also influenced by the lengthening regime, with CGRs shown able to stimulate growth and surpass physiological spinal growth with a lengthening interval of ≤6 months.[28,29] MAGEC rods can be used to 'tailgate' growth aiming to follow rather than stimulate growth, with such regimes aiming for lengthening of approximately 11mm/year in juveniles.[5] Our data showed no difference in lengthening between different lengthening intervals or regimes.

The average duration of implantation of a MAGEC construct was 35 months with the majority of constructs having been removed for mechanical failure. Whilst there is an unavoidable selection bias to explant studies, unlike most orthopedic implants, all MAGEC rods are explanted and we receive rods for analysis following removal for any indication. We were able to test the force produced by 34/55 constructs, identifying 25 as non-functional. These constructs together with the 9/21 constructs including a telescoping rod (thus failed) but without force data confirms at least 62% (34/55) of received constructs were mechanically failed. Furthermore only 50% of constructs without a telescoping rod but with force data were functional. Assuming a similar failure rate in the non-telescoping group without force data suggests that around 73% (40/55) of those constructs received for analysis may be non-functional at mean 35 month follow up. We failed to identify a functional construct implanted >35months. Presently the number of cases treated with MAGEC rods in the contributing centers is unknown, precluding calculation of implant survivorship, yet the number of non-functional constructs removed within 3-4 years is alarming. This raises concerns not only about the clinical effectiveness of the implant but given the costs of the implant, questions whether they provide value for money. Available cost analyses are limited, mainly based upon data from small groups with short follow up and hence limited complications or include a high proportion of cheaper single rod constructs, but suggest rods should be *in vivo* 3-6 years to be financially equivalent to CGRs.[30-35]

Like any implant it is likely that the MAGEC system is better suited to certain cases. We identified instrumented spinal lengthening was negatively correlated to age at insertion. In addition to age Cheung et al. also identified more lengthening issues in heavier and taller children.[20] Ahmad et al. identified increased disparity between intended and achieved lengthening for older and heavier children, but only for the concave rod.[24] We did not identify a difference in lengthening between primary and revision cases or single vs. dual rod cases, with the literature also unclear on this. [5,7,8,10] Like Lebon et al. we did not identify differences in lengthening achieved based upon etiology of scoliosis.[3] Similar to all current studies our sub-analyses are limited in statistical power and further work is needed in this area.

In addition to the limitations already discussed, the MAGEC system has undergone modifications since its initial release aiming to improve performance. Despite this, our findings remain relevant as rods included in this series were manufactured as recently as 2017 thus many patients are still undergoing treatment with rods of the types included in this study There appear to be few differences between the Modification 1 and Modification 2 rods in this study, aside the removal of a circumferential weld on the actuator casing in the newer implant. The most recent iteration (MAGEC X) has no such external welds. The manufacturer states MAGEC X includes, "a reinforced locking pin and a robust actuator seal designed to further contain and reduce the release of titanium wear debris".[36] To date there is no data to suggest that MAGEC design changes have had any effect on clinical outcomes. Given the proposed failure mechanism of offset loading we would suggest caution to concluding all issues will be resolved by such changes.

Clinical data was incomplete for some included cases. It is possible that a dual rod construct with one telescoping rod could actively lengthen through the remaining rod and hence deemed 'functional' by some. We counter this and offer our definition of a functional construct, as in only 1 out of 6 cases with this finding plus available force data, was the remaining non-telescoping rod able to produce force. Furthermore given that when telescoping rods are identified on radiographs they are typically removed quickly by surgeons to avoid the significant metallosis that telescoping can cause.[17] Surgeons should note that obvious radiographic changes may not be present in failed or telescoping rods (Figure 3). Further study of the radiographic appearances of failed MAGEC rods is needed.

This multicenter explant study presents the largest dataset of cases managed with the MAGEC system. It identifies that the average instrumented spinal lengthening in patients treated with the MAGEC system is 22.1mm. Rods are very rarely removed having reached their maximal distraction. Rather the rate of spinal lengthening appears to reduce over time with a high rate of lengthening mechanism failure by around 3 years implantation. This questions the MAGEC system's ability to meet 2 of the 3 fundamental aims of treatment in EOS; adequate spinal growth and limiting complications. Prospective clinical studies comparing MAGEC rods with other systems in management of EOS are required urgently.

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Figure 1: Photograph of explanted MAGEC rod showing ‘growth marks’ on extending bar (left) and actuator (right). Measurements of *in vivo* lengthening (red) and baseline distraction (green) shown.

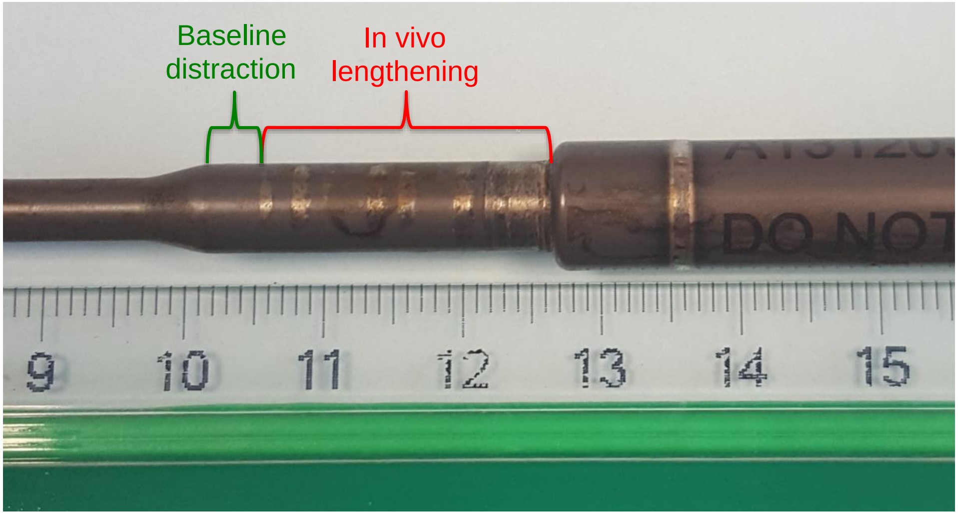


Figure 2: Histogram showing distribution of instrumented spinal lengthening

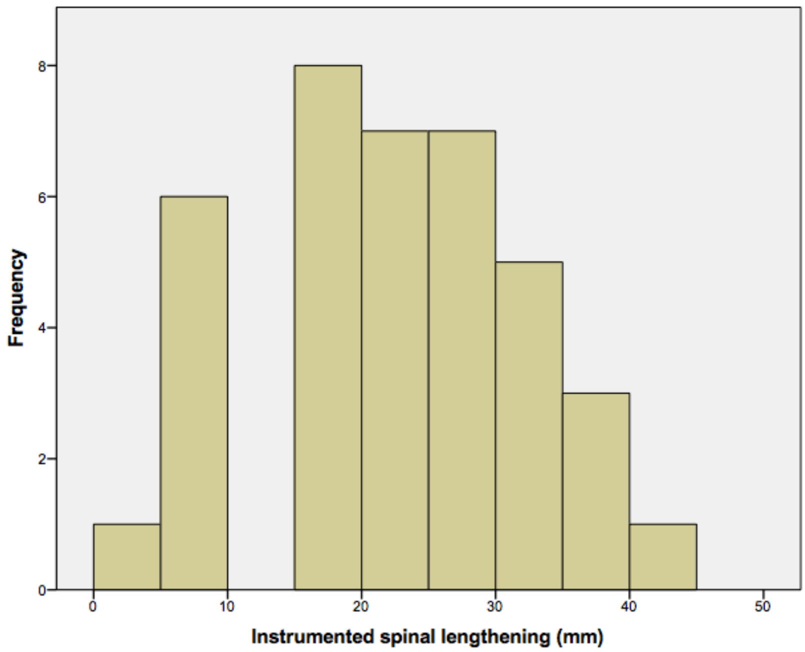

Table 1: Included constructs

| **Variable** | | **Value (range)** |
|---|---|---|
| Sex (n=54) | Female | 34 |
| | Male | 20 |
| Etiology (n=52) | Idiopathic | 31 |
| | Syndromic | 16 |
| | Congenital | 5 |
| Age at insertion (n=55) | | 8.50 years (3.6-13.8) |
| Height at insertion (n=31) | | 1.23m (0.87-1.44) |
| Mass at insertion (n=36) | | 25.3kg (12.5-41.0) |
| Primary vs Revision (n=52) | | 38:14 |
| Dual rod/ single rod/ hybrid construct (n=55) | | 46:8:1 |
| Reported frequency of lengthenings (n=44) | 6-8 weekly | 15 |
| | 8.1-12 weekly | 27 |
| | >12 weekly | 2 |
| Reported number of lengthenings (n=42) | | 10.2 (0-27) |
| Lengthening protocol (n=47) | Clunk | 25 |
| | Tail-gate/ fixed length | 19 |
| | Mixed | 3 |
| Time *in vivo* (months) (n=55) | | 35.0 (1.2-75.0) |
| Reason for removal (n=50) | Failure to lengthen | 17 |
| | Drive pin fracture | 3 |
| | Rod fracture | 7 |
| | Definitive fusion | 10 |
| | Perceived full rod lengthening | 6 |
| | Anchor failure | 5 |
| | Infection | 1 |
| | Progressive deformity | 1 |

Table 2: Group comparisons of instrumented spinal lengthening. Values given as mean± S.D

| **Variable** | | **Instrumented spinal lengthening (mm)** | **P** |
|---|---|---|---|
| Sex | Female (n=25) | 21.6 ± 9.4 | 0.73 |
| | Male (n=13) | 22.9 ± 11.4 | |
| Etiology | Idiopathic (n=23) | 22.3 ± 8.5 | 0.53 |
| | Non-idiopathic (n=13) | 19.9 ± 12.1 | |
| Primary vs Revision | Primary (n=26) | 23.3 ± 10.4 | 0.17 |
| | Revision (n=11) | 18.6 ± 8.7 | |
| Construct | Single rod (n=3) | 15.0 ± 7.0 | 0.18 |
| | Dual rod (n=35) | 22.7 ± 10.1 | |
| Reported frequency of lengthenings | 6-8 weekly (n=13) | 23.2 ± 10.1 | 0.65 |
| | 8.1-12 weekly (n=18) | 21.6 ± 9.5 | |
| Lengthening protocol | Clunk (n=16) | 21.0 ± 9.7 | 0.37 |
| | Tail-gate/ fixed length (n=15) | 24.3 ± 10.4 | |
| Reason for removal | Mechanical failure of MAGEC (failure to lengthen, drive pin fracture, rod fracture) (n=18) | 22.8 ± 8.9 | 0.05 ψ between group comparison sig. 0.04 |
| | Definitive fusion/ full length achieved (n=13) | 25.1 ± 10.2 ψ | |
| | Anchor failure/infection/ progressive deformity (n=4) | 11.5 ± 7.9 ψ | |