Force testing of explanted magnetically controlled growing rods

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ABSTRACT

Study Design:

Laboratory analysis of explanted MAGnetic Expansion Control (MAGEC) growing rods

Objective:

Measure the force produced by explanted MAGEC rods compared with new rods and assess the influence of clinical variables.

Summary of background data:

MAGEC rods are increasingly used in early onset scoliosis. Some data is available describing the structure of explanted MAGEC rods but to date no study has assessed their function.

Methods:

Explanted MAGEC rods were received from seven UK and one Danish centre. The force produced by explanted rods on activation with the external remote controller was measured using a dedicated jig. Forces were compared to two unused rods as well as the manufacturer's defined standard (42 lbf). Clinical variables were collected from contributing centres where possible and correlated with the force measurements.

Results:

Forty-five MAGEC rods from 25 cases were received for analysis. The mean age at insertion was 8.6 years and rods were in vivo for a mean of 2.7 years in predominantly dual rod constructs.

Two unused MAGEC rods produced a mean force of 45.3 (0.25) and 50.2 (1.4) lbf, above the manufacturer's stated standard.

Of the 45 explanted rods 10 (22%) produced force greater or equal to manufacturer's standard, mean 46.7 (2.7) lbf. Six rods (13%) produced some force but less than the manufacturer's standard, mean 34.8 (3.6) lbf. Twenty-nine rods (64%) produced no force. The duration the rods were in vivo was significantly negatively correlated with the force produced on testing ($r=-0.63$, $P<0.005$). Of the 12 rods implanted longer than 38 months none produced any force.

Conclusions:

This is the first study of the force, and hence likely function, of explanted MAGEC rods. The majority of explanted rods produced no force whilst others produced reduced force. These findings raise questions regarding the longevity of the implant and further clinical outcome studies are recommended.

Level of Evidence: 4

INTRODUCTION

The MAGnetic Expansion Control (MAGEC) system has been used increasingly in recent years for the management of early onset scoliosis. The system has been available for use in the UK and Europe since 2009 and has recently been approved for use in the US by the FDA. The MAGEC system includes a magnetically controlled linear actuator to allow non invasive lengthening. This aims to avoid the repeated surgeries of traditional distraction growing rod treatment, a great advantage to patients and surgeons. The system is relatively new, with only limited short-medium term data available in the literature to date. Reports from the literature are mixed and whilst some good outcomes have been reported concerns have been raised regarding failure of the lengthening mechanism and tissue metallosis. [1-12]

Work to date analysing explanted MAGEC rods has identified excessive wear within the actuator. Joyce *et al.* proposed a mechanism of offset loading leading to wear debris production, which when associated with failure of the actuator's seal, may result in the tissue metallosis seen in some clinical studies as well as potential systematic spread.[6,7,11,13] This and other available analyses have considered only the *structure* of explanted MAGEC rods with no data currently available regarding the *function* of explanted rods.[14] Unlike many orthopaedic implants MAGEC rods are designed to be removed in all cases not simply from failed cases. Furthermore rods may be removed in settings when the lengthening mechanism would be likely functional, such as following anchor failure or following full lengthening of the implant. Hence a study of function of explanted MAGEC rods is of clinical relevance to surgeons. In this study we aim to assess what proportion of MAGEC rods are still able to produce force after explantation and if so assess how the force compares to before implantation. Clinical variables will be examined to assess their influence on the force produced.

MATERIALS AND METHODS

Explanted MAGEC rods were received from seven spinal surgical centres in England and one in Denmark as part of an ongoing retrieval study by Newcastle University and the Great North Children's Hospital, both in Newcastle upon Tyne, UK.

Following explantation for any clinical reason rods were transferred to the School of Engineering, Newcastle University for analysis. Clinical data for the cases including baseline demographic data, underlying diagnosis, height and weight, dates of MAGEC rod insertion and removal, construct design and reason for removal was requested from contributing centres.

The manufacturers of the MAGEC system (Nuvasive Speciliased Orthopaedics, San Diago, US) kindly provided a bespoke force testing jig including a digital force gauge (Chatillon DFE2-500, AMETEK, Largo, US). Rods were tested according to a protocol supplied by the manufacturer which is used to test rods before distribution. This involved retracting the extending rod of the MAGEC rod fully using a handheld external magnet. On the occasions this was insufficient to 'free up' the rod an external remote controller (ERC) was used to partially retract the extending rod. Rods were then trimmed or straightened to allow seating in the testing jig. A small preload (approximately 5 lbf) was applied to the MAGEC rod. An ERC was positioned to overlie the magnet portion of the MAGEC rod and used to extend against the force gauge. The ERC was applied until 'clunking' of the MAGEC rod was heard and the reading on the force gauge was then recorded. Measurements were repeated three times per rod and the mean force calculated. Explanted rods as well as two unused MAGEC rods provided by the manufacturer were assessed and compared to the manufacturer's stated standard for a functional rod of 42 lbf (perscom). The experimental setup is shown in Figure 1.

Analysis was performed to assess for influences on the force produced by the rods on testing. Bivariate analysis using Pearson's correlation coefficient between force output and suitable continuous variables [patient age/mass/height at MAGEC insertion, time rod(s) in vivo and mass/height at time removal] was performed. Categorical variables were compared using student t test or ANOVA with Tukey post hoc analysis for >2 groups. All statistical analysis was performed with SPSS v22 (IBM-SPSS, Armonk, New York) with a $p<0.05$ was considered significant.

RESULTS

Forty-five explanted MAGEC rods were received from 25 patients. Forty-two rods were 'modification 2' type and 3 were the older 'modification 1'. Available clinical data is detailed in Table 1.

The two unused MAGEC rods produced a mean force of 45.3 (0.25) and 50.2 (1.4) lbf. These are above the manufacturer's stated standard of 42 lbf for a functional rod.

Of the 45 explanted rods 10 (22%) produced force greater or equal to manufacturer's standard, mean 46.7 (2.7) lbf. These were termed 'full force'. Six rods (13%) produced some force but less than the manufacturers standard, mean 34.8 (3.6) lbf and were classed as 'reduced force'. Twenty-nine rods (64%) produced 'no force'. Table 3 details the rods analysed for each case.

The 10 'full force' rods were explanted from 7 cases treated with dual rod constructs. Three cases had two 'full force' rods, 3 cases had one 'full force' rod with a contralateral 'no force' rod and one case had a 'full force' rod with a contralateral 'reduced force' rod. The remaining 5 'reduced force' rods were from a single rod construct, a hybrid construct (single concave MAGEC rod with convex sliding rod), a

dual rod construct with bilateral ‘reduced force’ rods and one dual rod case with a ‘reduced force’ rod with a contralateral ‘no force’ rod. The other ‘no force’ rods were used in 11 dual rod constructs in which neither rod produced force and 3 single rod constructs. In summary the constructs from 3 of the 25 patients were able to lengthen at ‘full force’ whereas in 4 cases rods were able to lengthen but with at least one rod present in the construct at ‘reduced force’. Constructs from 18 cases contained rods producing ‘no force’.

In terms of reasons for removal, 9 cases rods were removed for ‘failure to lengthen’ or ‘conversion to definitive fusion’. These are analysed together as the former commonly leads to the latter. This group included 5 bilateral constructs with neither rod producing any force and in 3 cases one rod produced ‘no force’ and the other rods produced ‘full force’. The remaining case was the hybrid construct where the single MAGEC rod had reduced force. Rods removed for anchor failure, infection, rod fracture or full lengthening achieved are grouped together as they were considered likely to function at removal. These 6 cases included 11 rods in which 3 produced ‘full force’, 3 ‘reduced force’ and 5 ‘no force’.

The duration the rods were in vivo was significantly negatively correlated with the force produced on testing ($r=-0.63$, $P<0.005$, Figure 2). Accordingly the length of time rods were implanted differed significantly between those with ‘full’ (16.8 (13.1) months) or ‘reduced force’ (21.3 (14.2) months) with those producing ‘no force’ (40.2 (12.9) months), $p=0.001$ and $p=0.03$ respectively. Length of time implanted was similar between the ‘full’ and ‘reduced’ force groups ($p=0.85$). Of the 34 rods in which the duration of implantation was known, all 12 implanted for greater than 38 months produced ‘no force’. There were no significant correlations between force produced and the other continuous variables tested.

The mean rod force between clinical groups is detailed in Table 2. There were no significant between group comparisons.

DISCUSSION

This is the first study to examine the function of explanted MAGEC rods. 64% of explanted rods produced no force and only 22% of explanted rods produced a force greater or equal to the manufacturer's stated standard. We accept that the very nature of explant analysis introduces a selection bias. Yet unlike explant analyses of most orthopaedic implants the MAGEC device is designed to be removed in all cases. So a proportion of rods could reasonably be expected still to be functional. It is notable that rods removed in clinical settings when the rod would be expected to be functional, including rod fracture or full lengthening achieved, commonly produced reduced or no force.

Given that the majority of rods implanted for a mean of 2.7 years were non functional and no rod implanted longer than 38 months was able to produce the manufacturer's stated standard force our findings raise questions about the longevity and cost-effectiveness of the implant. Given the high cost of the initial and any replacement implants these findings are pertinent to the cost analyses that have influenced the implant's adoption. The available cost analyses suggest a saving using the MAGEC system after 3-6 years. Rolton et al. suggested a cost saving using MAGEC rods after 5 years but do not appear to account for replacement of MAGEC rods during or at the end of this period.[15] Su et al. from a US payer's perspective identified a saving after 3 years with a MAGEC failure rate of 13% per year necessitating the change of a single rod. Polly et al. identified a cost saving after 6 years from a US provider perspective assuming an annual failure rate of the MAGEC rods of 4.4% and rods being replaced routinely after 3.8 years, to allow for more growth.[16]

There remains a paucity of literature assessing the outcomes of this treatment over the anticipated lifetime of the implant with most studies reporting outcomes at less than 3 years.[1,6,17-19] The limited available longer term studies report

less favourable results.[9] The present study is not a study of clinical outcomes. We have no estimation for the number of rods implanted over the course of the study period in the various centres. It is clear that the findings suggest further work must be undertaken urgently to assess the survivorship and costs associated with the MAGEC implant.

Applying our laboratory study of explanted rods to assess whether the explanted constructs were likely functional at time of removal is not straightforward. Traditional growing rod (TGR) treatment typically aims to achieve the maximum lengthening with each open distraction. This has been shown to equal or exceed the child's natural spinal growth over this time, potentially through stimulating growth plates via the Hueter-Volkmann law.[20] To apply this distraction force the applied force must overcome the stiffness of the spine. Nordeen et al. identified that when using TGRs this force increased over the course of treatment, from 142N at the time of first distraction to 608N by the 10th lengthening.[21] This likely results in the observed 'law of diminishing returns' regarding the lengthening achieved over time with TGRs.[22] The force a MAGEC rod must produce to distract the spine has not been identified. Specifically it is unknown if awake lengthenings, typical of MAGEC, require greater force to overcome greater soft tissue tension. Feasibly the MAGEC system in avoiding multiple surgical exposures may limit the stiffening of the spine over time seen with TGRs. Notwithstanding this it appears that, similar to TGRs, the lengthening achieved with MAGEC rods decreases over time.[23] We have shown that at least in some cases this is likely multifactorial both relating to reduced force produced by the MAGEC rods as well as the presumed stiffening of the spine over time. In regard spinal stiffening it is noteworthy that the manufacturer's force standard of 42 lbf is approximately 187 N. This corresponds to the force required for no more than the first 3-4 lengthenings in work by Nordeen et al.[21] Whilst many MAGEC users employ a similar philosophy to TGRs, as discussed, others propose 'following' rather than 'stimulating' growth, aiming to lengthen according to the

normative data provided by Dimeglia and Canavese[12,24,25] This technique will likely require less force from the MAGEC rods but again this value, to date, not been determined. Irrespective of the strategy used it is irrefutable that rods must actively lengthen to be functional. Using this measure, in 7 of the 25 cases all rods present in the construct were able to produce some force. Thus these may have been functional at the time of explantation.

It is apparent that after time in vivo a proportion of rods produce less force and others cease to produce any force. Currently the relationship between the force produced and the internal findings is not known. But considering these findings alongside the previous explant analysis by Joyce et al. excessive wear maybe one underlying cause. Feasibly wear debris within the casing increases the friction between the internal components limiting the force produced when activated by the ERC. Accordingly wear debris has been seen to foul bearings and 'pack' the potential space between the rotating magnet and leadscrew and inner aspect of the actuator casing.[13] It is possible that the rods producing 'no force' may be associated with excessive wear debris limiting any rotation of the internal components. Drive pin fracture may have occurred in some cases. Further work is necessary to correlate force measurements and internal analysis of explanted MAGEC rods.

This study has several limitations. The testing rig used is dissimilar to the clinical environment. In vivo both the loading and extension of a rod are not linear as in this experiment, moreover rods are subject to offset loading due to the anteriorly placed centre of mass relative to the rods. This could lead to increased friction between actuator components limiting their free movement and force produced. Furthermore the ERC is positioned optimally to the actuator on the testing jig, maximizing magnetic field strength and presumably the torque imparted to the internal mechanism. It has been shown that an increased distance between actuator and ERC, caused by the soft tissues clinically, has a deleterious affect on lengthening.[26] In summary whilst the testing environment is far from reproducing the

conditions in vivo it should be ideal for achieving the maximum force from the rods. Clinical data was unfortunately not available for a proportion of the rods analysed. It remains that further work is necessary to link explant analysis with clinical variables. Despite these limitations we feel the available data has allowed us to produce clinically meaningful results of use to deformity surgeons.

In summary this is the first study to assess the force produced by explanted MAGEC rods. We have identified, from a multicentre cohort, that the majority of explanted MAGEC rods are incapable of force production by the time of explantation. Less than a quarter of explanted rods were able to produce the force comparable to the manufacturer's standard. These findings suggest caution in the use of the implant until long term clinical outcome studies are available to assess the survivorship and costs associated with its use.

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Figure 1 – Photograph detailing the testing jig setup; MAGEC rod (centre) being tested on the force measurement jig. To the top of the image the ERC can be seen, towards the bottom on the image is the force gauge (reading 23.4 lbf). Beneath the force gauge is the aluminium baseplate of the force jig.

Figure 2: Time explanted rods in vivo vs. force. Solid line; line of best fit for explanted rods. Dotted line; manufacturer's standard 42lbf.

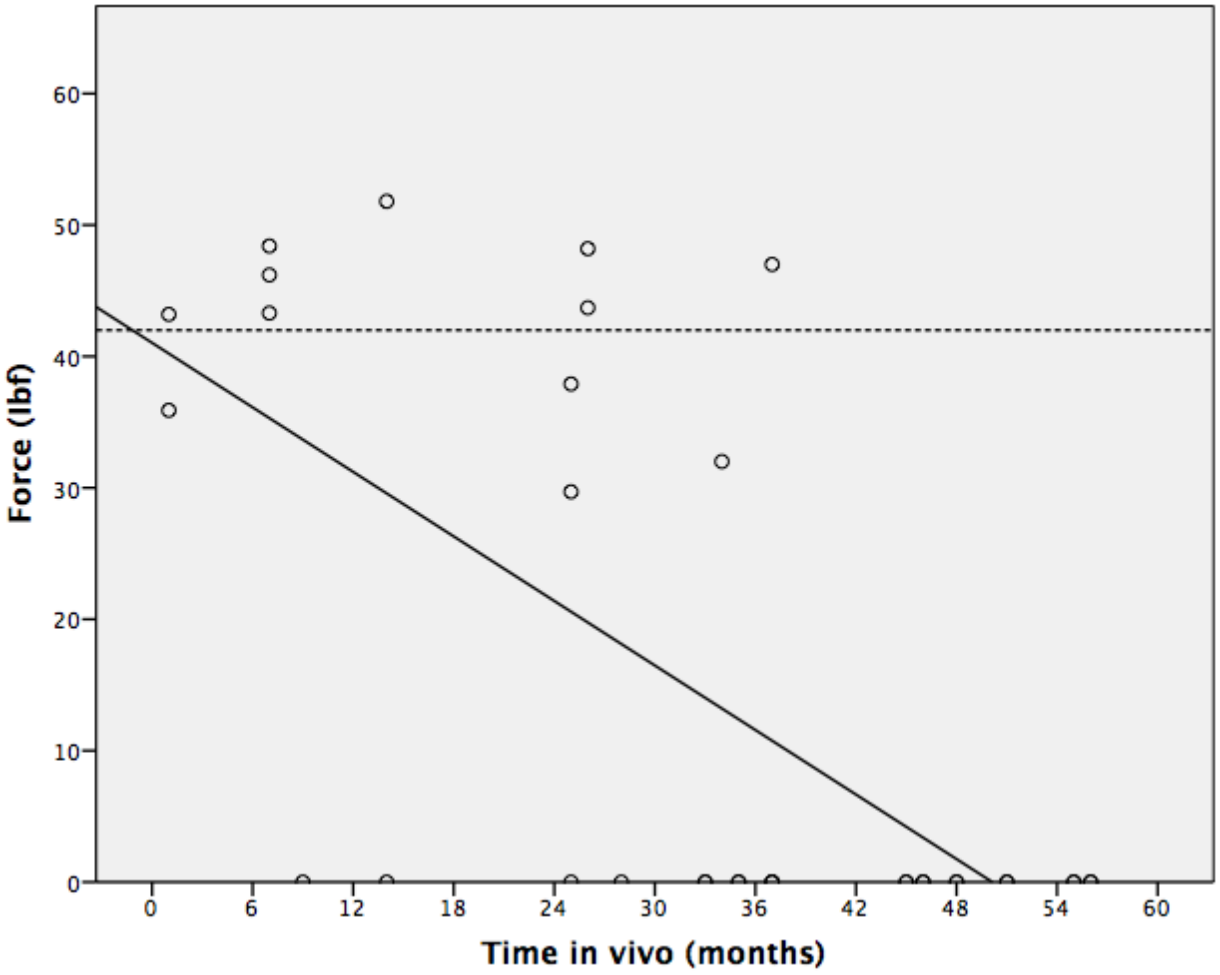

Table 1: Baseline clinical data. Values given as mean (S.D) unless otherwise stated.

Variable **(number of cases available data)**	
Sex (n=19)	12 Female 7 Male
Age at insertion (n=19)	8.7 (2.6)
Underlying aetiology (n=19)	11 idiopathic 6 syndromic 2 congenital
Mass at insertion (n=12)	25.8kg (7.7)
Age at insertion (n=20)	8.7 years (2.6)
Primary vs revision (n=17)	12 primary 5 revision
Construct (n=25)	20 dual rods 4 single rod 1 hybrid
Number of lengthenings (n=12)	11.1 (4.9)
Duration rods in vivo (n=20)	2.6 (1.4) years
Reason for removal (n=15)	6 failure of rods to lengthen 3 conversion to definitive fusion 2 rod fracture 2 full lengthening achieved 1 infection 1 anchor failure

Table 2: Rod force according to clinical variables.

Variable (number rods)		**Force (lbf)**	**Between group comparisons**
Sex	**Female (n=21)**	18.1 (21.9)	Between group comparisons ns
	Male (n=15)	14.9 (21.9)	
	Unknown (n=9)	8.1 (16.2)	
Diagnosis	**Idiopathic (n=20)**	12.4 (18.8)	Between group comparisons ns
	Syndromic (n=9)	10.2 (20.3)	
	Congenital (n=3)	40.5 (9.6)	
	Unknown (n=13)	16.5 (22.1)	
Primary vs. revision	**Primary (n=22)**	15.5 (21.3)	Between group comparisons ns
	Revision (n=9)	13.3 (20.7)	
	Unknown (n=14)	15.4 (21.6)	
Construct	**Single rod (n=4)**	7.4 (14.9)	Between group comparisons ns
	Dual rod (n=40)	15.3 (21.4)	
	Hybrid (n=1)	32.0 (N/A)	
Reason for removal	**Rod fracture (n=3)**	22.5 (19.9)	Between group comparisons ns
	Anchor failure (n=2)	46.0 (3.2)	
	Infection (n=2)	39.6 (5.2)	
	Failure to lengthen (n=12)	8.2 (19.3)	
	Conversion to fusion (n=3)	10.7 (18.5)	
	Full lengthening achieved (n=4)	0.0 (0.0)	
	Unknown (n=19)	16.1 (21.9)	

Table 3: Duration of implantation, reason for removal and force on testing for each case

Case	Rods	Duration in vivo (month)	Reason removal	Mean Force (lbf)
1	1	26.7	Anchor failure	43.7
	2			48.2
2	3	34.8	Conversion to fusion	32.0
3	4	1.2	Infection	43.2
	5			35.9
4	6	37.3	Failure to lengthen	0.0
	7			0.0
5	8	45.1	Conversion to fusion	0.0
	9			0.0
6	10	25.7	Rod fracture	0.0
	11			37.9
7	12	25.5	Rod fracture	29.7
8	13	Unknown	Unknown	46.2
	14			47.6
9	15	46.9	Unknown	0.0
	16			0.0
10	17	56.9	Unknown	0.0
	18			0.0
11	19	Unknown	Unknown	0.0
	20			0.0
12	21	7.8	Unknown	43.3
	22			48.4
13	23	28.1	Unknown	0.0
14	24	9.6	Unknown	0.0
15	25	48.2	Full length achieved	0.0
	26			0.0
16	27	37.7	Failure to lengthen	47.0
	28			0.0
17	29	35.4	Failure to lengthen	0.0
	30			0.0
18	31	Unknown	Unknown	34.1
	32			39.3
19	33	51.7	Failure to lengthen	0.0
	34			0.0
20	35	Unknown	Unknown	0.0
21	36	Unknown	Unknown	0.0
	37			0.0
22	38	55.4	Failure to lengthen	0.0
	39			0.0
23	40	Unknown	Conversion to fusion	47.8

	41			0.0
24	42	14.5	Failure to lengthen	0.0
	43			51.8
25	44	33.2	Full length achieved	0.0
	45			0.0