The NuVasive MAGEC rod Urgent Field Safety Notice concerning locking pin fracture: how does data from an independent explant center compare?

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

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STRUCTURED ABSTRACT

Study Design. Analysis of explanted **MAG**netic **E**xpansion **C**ontrol (MAGEC) growing rods.

Objective. Quantify the rate of locking pin breakage in explanted MAGEC rods and compare with the manufacturer's data.

Summary of background data. On 25 June 2019 NuVasive released an Urgent Field Safety Notice stating that MAGEC rods manufactured before 26 March 2015 had a higher than expected locking pin breakage rate of 5%. For rods made on or after that date, no pin breakages had occurred.

Methods. From our independent explant database of 139 explanted MAGEC rods supplied from 10 UK spinal centres (Belfast, Bristol, Birmingham, Edinburgh, Exeter, Leeds, Newcastle, Nottingham, Oxford and Sheffield) and 1 Danish centre (Aarhus), we divided the rods into those manufactured before 26 March 2015, and those manufactured on or after that date. MAGEC rods were cut open to fully assess internal components including locking pins. From each of the two cohorts, 10 locking pins were selected at random and their diameters were measured using a micrometer.

Results. One hundred and five explanted MAGEC rods were made before 26 March 2015 and could be disassembled to allow the locking pin to be examined. Fifty-nine percent (62/105) of these locking pins had fractured. For the MAGEC rods manufactured on or after 26 March 2015, 21% (6/29) were found to have fractured locking pins. Locking pins in MAGEC rods made on or after 26 March 2015 were of a stronger material and a larger diameter.

Conclusions. Fifty-nine percent of the locking pins in MAGEC rods manufactured before 26 March 2015 had fractured, far greater than the 5% stated in the Urgent Field Safety Notice. Locking pin fracture still occurred in MAGEC rods manufactured on or after that date, in 21% of cases. This contrasted with the 0% reported by the manufacturer.

INTRODUCTION

Magnetically controlled growing rods (MCGR), specifically the MAGEC (MAGnetic Expansion Control, NuVasive Specialised Orthopaedics, San Diego, USA) rod, have recognised potential benefits compared with conventional growing rods for the treatment of early onset scoliosis. These advantages include a reduced number of surgeries and therefore less trauma for the child and their family[1], along with a reduction in the possibility for infection.[2] In addition, the potential negative impact of multiple anaesthesia is increasingly recognised.[3] However, concerns have also been raised about MCGR, not least the amount of metallosis which has been reported.[4-6] Another concern, described regularly from the relatively early date of 2015, is that of locking pin fracture.[5,7-11] The locking pin serves to connect the magnet of the MAGEC rod to the extending bar which 'grows' when the External Remote Controller (ERC) is applied. It should be noted that different authors give this pin various names. Cheung et al called it a housing pin.[8] Jones et al christened it an actuator pin[5] while Beaven et al used the same term.[11] Teoh et al simply named it a pin[6], a descriptor mostly used by Panagiotopoulou et al too.[10] Rushton et al termed it a drive pin[12], as did Joyce et al.[9] For consistency with the Urgent Field Safety Notice it will forthwith be called a locking pin.

On 25 June 2019 NuVasive released an Urgent Field Safety Notice[13] saying that MAGEC rods manufactured before 26 March 2015 had a higher than expected locking pin breakage rate of 5%. No breakages were reported in any rods manufactured on or after that date. The insinuation of the Urgent

Field Safety Notice was that this was a minor historical issue which had been solved in later MAGEC rods.

However, these breakage rates appeared to contrast with those reported in the literature, which range from 14% to 100% (table 1). What can also be seen from the table is that the NuVasive Urgent Field Safety Notice does not give the numerator or denominator upon which their locking pin breakage rates are based, nor does it specify the method by which locking pin fracture was determined.

The aim of this study was to quantify the rate of locking pin breakage in explanted MAGEC rods and compare with the manufacturer's data. Rods manufactured before and on or after 26 March 2015 were compared.

METHODS AND MATERIALS

Explanted MAGEC rods were received at our independent explant laboratory, from 10 UK spinal centres (Belfast, Bristol, Birmingham, Edinburgh, Exeter, Leeds, Newcastle, Nottingham, Oxford and Sheffield) and 1 Danish centre (Aarhus). We asked contributing centres to send us all the MAGEC rods they removed, whatever the indication for removal. In this way we received rods that had been removed electively at the time of conversion to definitive fusion or that had been revised because they had reached maximal distraction. We received rods that were removed for infection or proximal or distal fixation failure, as well as rods that had obviously broken or stopped growing.

MAGEC rods were cut open to fully assess internal components including locking pins as previously described.[9] We divided the rods into those manufactured before 26 March 2015, and those manufactured on or after 26 March 2015.

From each of the two cohorts, 10 locking pins were selected at random and had their diameters measured using a micrometer (Mitutoyo, Huddersfield, UK).

Categorial and continuous variables were compared using chi square and student t-tests respectively. All statistical analyses were performed with SPSS v22 (IBM-SPSS, Armonk, NY), with a $p<0.05$ considered significant.

RESULTS

One hundred and thirty-nine explanted MAGEC rods from 76 patients were consecutively assessed. Five rods from 4 patients (all dual rod constructs manufactured before 26 March 2015) could not be separated into their components to allow examination of the locking pin thus 134 rods from 75 cases were suitable for inclusion in this study. Fifteen rods manufactured before 26 March 2015 were 'Modification 1' type with the remainder of rods in this study 'Modification 2'.[14] Baseline clinical characteristics for the two cohorts are shown in Table 2. Groups were comparable in terms of age, sex, aetiology of scoliosis and construct types but rods manufactured after 26 March 2015 were more likely to have been used in a revision setting and were implanted significantly less time than those manufactured before this date. One hundred and five explanted MAGEC rods were made before 26 March 2015 and could be disassembled to allow the locking pin to be examined. Fifty-nine percent (62/105) of these locking pins had fractured. For the MAGEC rods manufactured on or after 26 March 2015, from a group of 29 which could be disassembled, 21% (6/29) were found to have fractured locking pins ($p<0.001$). Analysis of locking pins is summarised in Table 3. For ten locking pins taken from rods made before 26 March 2015, their mean diameter (+/- Standard Deviation) was found to be 0.78 (0.01) mm. For ten locking pins taken from rods made on or after 26 March 2015, their mean diameter was found to be 0.92 (0.01) mm. NuVasive had previously informed us that the earlier material was grade 440 stainless steel, which had been changed to grade 465 stainless steel in the later pins (perscom).

DISCUSSION

Fifty-nine percent of the locking pins in MAGEC rods manufactured before 26 March 2015 had fractured, far greater than the 5% stated in the Urgent Field Safety Notice. Locking pin fracture still occurred in MAGEC rods manufactured on or after 26 March 2015, in 21% of cases. In contrast NuVasive offered a value of 0% in the Urgent Field Safety Notice. These values are summarised in table 4 along with the numerator and denominator, where known.

What can explain the huge discrepancy between the values from our independent explant centre and those in the Urgent Field Safety Notice? The method of locking pin breakage assessment, as indicated in table 1, could in part be an explanation. However, the Urgent Field Safety Notice does not state how locking pin breakage was assessed, just as it does not state the numerator or the denominator behind the 5% and 0% figures. Moreover, surely examination of the locking pin itself, achieved following disassembly, must allow the most accurate assessment of pin condition?

By enlarging the diameter of the locking pin and changing it to a stronger material, so greater locking pin strength and thus fewer breakages have been achieved. This is clearly to be welcomed, but it remains that locking pin fractures still appear frequent. This data is of value to surgeons, many of whom will have patients with rods implanted of the same designs assessed in this study. It is clear that locking pin fractures are far from being eradicated in this implant, and surgeons must remain vigilant in identifying this failure mode as the associated pistoning of rods may cause significant metallosis.

Furthermore, whilst the most recent iteration of the implant, MAGEC X is now available, there is as yet no data to suggest reduced complication rates or improved clinical outcomes with this implant.

From all of our work on explanted MAGEC rods, our main concern is internal wear of the MAGEC rods, as explained in our first paper.[9] When combined with the common (in 53% of cases[9]) damage to O-ring seals, we believe this explains the metallosis seen clinically with many MAGEC rods upon their removal.[6,12] The long-term implications of this titanium debris on the child are not known. In this regard to the generation of internal wear debris and damage to the O-ring seal, whether the locking pin is broken or intact makes relatively little difference. As such, locking pin fracture may be a distraction from the underlying concern with MAGEC rods. We also believe that such internal damage helps to explain the lack of force generation [14] and relatively low amounts of growth[15] seen in explanted MAGEC rods.

Our study has limitations. We have examined explanted rods from multiple centres and from a variety of patients. However, such patient diversity is to be expected across scoliotic patients and we would also note that we receive explants that are considered to have been functional at removal. Therefore, we feel that our sample is representative. Moreover, the 134 explanted and disassembled MAGEC rods we have reported on in this paper is by far the largest reported to date in the scientific literature. We accept that most of our explant cohort is made up of rods made before 26 March 2015. However, given that we have been collecting explanted MAGEC rods since 2016, that an average time in vivo of our rods is 35 months[15], plus it takes us a little time to receive the rods and then disassemble them, this preponderance is to be

expected. We continue to analyse rods and most of our recent explants are manufactured on or after 26 March 2015.

We remain concerned that nascent spinal registries are unable to currently provide us with complication rates or numbers of MAGEC rods implanted.[12] The manufacturer will not give us this latter basic information. While we fully accept the potentially paradigm changing nature of MAGEC rods, the remarkable difference between our independent explant results and those stated by the manufacturer in the Urgent Field Safety Notice leave us alarmed. Surgeons must be aware that locking pin fractures unfortunately appear to be an ongoing failure mechanism for MAGEC rods. Even patients with recently produced rods are still at risk of this failure mode.

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Tables

Source	Method of fracture identification	No. of pin fractures	Cohort size	Breakage rate
NuVasive UFSN 2019 (pre-26 March 2015 rods)	?	?	?	5%
NuVasive UFSN 2019 (on or after 26 March 2015 rods)	?	?	?	0%
Jones et al 2016 [5]	X-ray	3	18 rods	17%
Teoh et al 2016 [6]	Disassembly	7	7 rods	100%
Panagiotopoulou et al 2017 [10]	X-ray	3	9 rods	33%
Joyce et al 2018 [9]	Disassembly	15	34 rods	44%
Beaven et al 2018 [11]	?	4	28 children	14%

Table 1 – locking pin fracture rates reported in the Urgent Field Safety Notice (UFSN) compared with the literature

		Pre 26 March 2015 rods	On or after 26 March 2015 rods	P
Total number of rods		105	29	
Number of patients*		59	18	
Age at insertion [range]		8.2 [3.5-13.8] (n=89)	8.2 [4.4-13.0] (n=27)	0.94
Rods implanted in females		54 (n=89)	12 (n=27)	0.18
Aetiology of scoliosis	Idiopathic	56	17	0.94
	Syndromic	24	8	
	Congenital	5	2	
		(n=85)	(n=27)	
Duration of implantation (months) [range]		40.3 [5-75] (n=89)	28.7 [1-61] (n=27)	<0.001
Rods in primary vs revision cases		73:13 (n=86)	11:16 (n=27)	<0.001
Construct; single:dual:hybrid		8:96:1	2:27:0	0.86

* Two patients had dual rod constructs with one rod manufactured before 26 March 2015 and the other rod manufactured after this date

Table 2 – Group comparisons between the two cohorts of MAGEC rods

	Pre 26 March 2015 rods	On or after 26 March 2015 rods	P
Total number of rods	105	29	
Number of locking pins fractured	62	6	
Fracture rate	59%	21%	<0.001

Table 3: Comparison of observed locking pin fracture rates for rods manufactured before and on or after 26 March 2015.

	Rods made before 26 March 2015	Actual numbers	Rods made on or after 26 March 2015	Actual numbers
NuVasive UFSN	5%	?	0%	?
This study	59%	62/105	21%	6/29

Table 4 – Comparison of locking pin fracture rates between NuVasive Urgent Field Safety Notice (UFSN) and this study

Figure 1 – Image of explanted MAGEC rod (above). Below is a diagram indicating the locking pin (white vertical line) and that it connects the magnet (light blue) via the leadscrew (red) to the extending bar (black).