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Pin Fracture in Magnetically Controlled Growing Rods: Influence of the Year of Manufacture

Martina Tognini, BEng, MSc, Harry Hothi, BEng, MSc, PhD,†‡ Elisabetta Dal Gal, MSc,* Johann Henckel, MBBS, MRCS, PhD,‡ Masood Shafafy, MBBS, FRCS, FRCS,§ Edel Broomfield, MSc,‖ Stewart Tucker, MBBS, FRCS, FRCS,‖ John Skinner, MBBS, FRCS, FRCS,*‡ and Alister Hart, MA, MD, FRCS*‡*

Background: Magnetically controlled growing rods (MCGRs) have a known issue with fracture of the internal locking pin resulting in early revisions. The manufacturer reported that rods manufactured before March 26, 2015, had a 5% risk of locking pin fracture. Locking pins made after this date are thicker in diameter and of a tougher alloy; their rate of pin fracture is not known. The aim of this study was to better understand the impact of the design changes on the performance of MCGRs.

Methods: This study involves 46 patients with 76 removed MCGRs. Forty-six rods were manufactured before March 26, 2015, and 30 rods after that date. Clinical and implant data were collected for all MCGRs. Retrieval analysis comprised plain radiographs evaluations, force and elongation testing, and disassembly.

Results: The 2 patient groups were statistically comparable. We found that 14 of 27 patients implanted with rods manufactured before March 26, 2015 (group I) had a fracture of their locking pins. Three of the 17 patients with rods manufactured after this date (group II) were also found to have a fractured pin.

Conclusions: Retrieved rods collected at our center and made after March 26, 2015, had far fewer locking pin fractures than those made before this date; this may be due to the change in pin design.

Key Words: MCGR, retrieval analysis, pin fracture, EOS, scoliosis

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From the *The Institute of Orthopaedics and Musculoskeletal Science, University College London; ‡The Royal National Orthopaedic Hospital, Stanmore; †Department of Mechanical Engineering, University College London; ‖Great Ormond Street Hospital for Children NHS Foundation Trust, London; and §Nottingham University Hospitals NHS Trust, Nottingham, UK.

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This research was approved by London-Riverside REC: Implant Study—07/Q0401/25.

All patients provided written informed consent for their implants and associated clinical data to be investigated at our implant center.

Two surgeon authors (S.T. and M.S.) use the devices investigated in this study in their clinical practice. The senior author (A.H.) receives institutional-level funding from the manufacturer to independently collect and analyze the devices investigated in this study. The remaining authors declare no conflicts of interest.

Reprints: Martina Tognini, BEng, MSc, Institute of Orthopaedics and Musculoskeletal Science, University College London, Royal National Orthopaedic Hospital, Brockley Hill, Stanmore HA7 4LP, UK. E-mail: martina.tognini.19@ucl.ac.uk.

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Different approaches exist in treating EOS depending on its severity and the age of the patient, including observation, casting, and bracing or surgical treatments involving spine implants and fusion of vertebrae.[1–4] Magnetically controlled growing rods (MCGRs) have been used for the treatment of EOS, requiring elongation every 3 months through an external controller without open surgery, unlike traditional growing rods which need manual lengthening through repeat operations.[5]

The only widely commercially available MCGR has been the MAGEC rod (Magnetic Expansion Control, NuVasive Specialised Orthopaedics, San Diego, USA). The manufacturer issued a Field Safety Notice (FSN) on April 1, 2020, voluntarily suspending the supply of this device in the United Kingdom.[6] On the same day, the UK Medicines and Healthcare products Regulatory Agency (MHRA) issued a Medical Device Alert in line with the FSN and also informing surgeons that they should not implant MAGEC rods (unless in exceptional circumstances) until further notice.[7] In the EU, on April 5, 2021, NuVasive published a company statement communicating the temporary suspension of the CE mark due to evidence gaps in the MAGEC system. The CE mark has been reinstated in the EU, while the MAGEC system is currently not available in the United Kingdom.

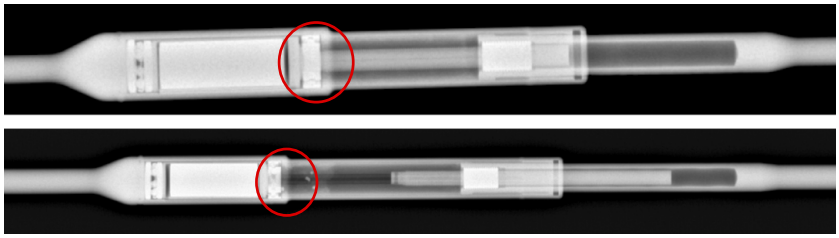

FIGURE 1. Example of the visualization of the internal mechanism, using high-energy x-ray imaging. On top, A construct with intact pin, found functional at retrieval. On the bottom, An implant showing clear pin fracture and a separation of the internal screw from the magnet area.

This action by the manufacturer and the MHRA came as a result of previous FSNs, MDAs, and reports in the literature, all highlighting issues with rod failure due to factors such as a separation of an end cap component, failure of the O-ring seal, generation of titanium wear/corrosion debris and fracture of the internal locking pin.[8–10]

In 2019, the manufacturer released a field safety notice,[11] indicating that rods manufactured before March 26, 2015, had a 5% risk of postimplantation pin fracture occurring. Rods made after this date have locking pins that are thicker in diameter and of a tougher stainless-steel alloy; the FSN indicated that these rods did not exhibit the same fracture issue based on postmarket surveillance data available at the time.

A previous retrieval study reported evidence of locking pin fractures in 62 of 105 (59%) and 6 of 29 (21%) of rods collected at their center that had been manufactured before and after this date, respectively.[12] This study also indicated that the earlier design was grade 440 stainless steel, which changed to 465 stainless steel.

The aim of this retrieval study was to better understand the impact of the design changes on the performance of MCGRs collected at our retrieval center. To achieve this, we compared the prevalence of locking pin fractures between MCGRs manufactured before and after March 26, 2015.

METHODS

This was a retrieval study investigating 76 MCGRs that were consecutively received at our center after having been removed from 46 patients. The implants were explanted by 11 different surgeons across 8 different hospitals. The implants were divided into two groups: those manufactured before March 26, 2015 (n = 46) and those that were manufactured on or after this date (n = 30). The date of manufacture was determined using the laser marks present on each rod. From this point onwards we will refer to rods manufactured before March 26, 2015, as the "Group I" and those manufactured after this date as the "Group II."

Demographics and Implant Data

For each patient in this study, we collected data on their age, gender, duration of rod implantation and the reason for rod removal. For each rod, we recorded the rod configuration (single/double rod construct and standard/offset type of rod) and its size (length of the housing tube and diameter of the distraction rod).

Evaluation of Pin Fracture

We first captured high-energy radiographs of each rod using previously published methods.[11] These were used to evaluate the structural integrity of the internal mechanism and identify rods in which the locking pin was definitively fractured (Fig. 1).

Rods unable to distract, hence presenting distraction mechanism failure, were then sectioned. Cuts were made along the weld so as to separate the rods into 3 sections (Fig. 2). This disassembly of the nonfunctional implants allowed a closer examination of the pin fracture area, confirming the pin fractures observed or suspected on radiographs. Disassembly also enabled the analysis of different mechanisms of failure, such as corrosion or cold-welding in the implants that did not present pin fracture.

Retrieval Analysis

Following the evaluation of pin fracture, rods underwent functional evaluation, using previously published methods.[13] The maximum force and the elongation

FIGURE 2. Detailed visual examination of internal components lead screw (left) and lower magnet cup (right) in a rod with a pin fracture. Circled in red: the pin.

exerted during force testing were recorded, a manual elongation test was performed and the maximum extension was noted, and finally, the overall functionality of the implant was evaluated upon disassembly, after accurate pin fracture examination. Implants not able to elongate were deemed non-functional.

Scanning Electron Microscopy (SEM)

We selected 5 fractured pins (2 from group II and 3 from group I) to perform SEM analysis on their fracture sites. The driving pins were retrieved from the disassembled constructs and the pins were mounted on the holders so that they faced the scanner. A scanning electron microscope (Hitachi S-3400 N) was used at 20 kV at a working distance of 10 mm. Images at 228× and 2k× magnification were acquired for each pin surface.

Statistical Analysis

We compared the patient, implant, and surgical characteristics of both groups. The categorical variables were compared using the Fisher exact test, while all continuous characteristics were compared using the unpaired *t* test, the Mann-Whitney test. All statistical analyses were performed using *SPSS* (*IBM SPSS Statistics for Mac, Version 27.0*) with a $P < 0.05$ considered statistically significant.

Potential or Perceived Conflict of Interest

Two surgeon authors (S.T. and M.S.) use the devices investigated in this study in their clinical practice. The senior author (A.H.) receives institutional-level funding from the manufacturer to independently collect and analyze the devices investigated in this study.

Institutional Review Board Approval

This study was performed after obtaining institutional review board (IRB) approval from the London-Riverside Research Ethics Committee (REC, Approval Number: 07/Q0401/25). Informed parental consent was obtained for each patient in this study.

RESULTS

Demographics

The MCGRs in this study were retrieved from 20 male and 26 female patients with a median (range) age of 9 years (1–14) and a median time to rod removal of 38 months (15–110) (Fig. 3). Table 1 summarizes patient demographics and implant characteristics for both groups I and II; there were no significant differences between the 2 groups, with an exception for the rod size in diameter. Patients with a mix of the 2 generations (I and II) of implants were excluded from the demographic analysis (n = 2). Thirty-nine patients had dual-rod construct and 13 patients had single-rod construct.

Thirteen patients in group I had undergone a planned removal of their rods, while 14 patients underwent early revision procedures. Eleven patients in group II had undergone removal as planned and 6 patients had an early revision of their rods. A planned removal occurred following the maximum rod lengthening, final fusion, or a scheduled exchange; early revisions occurred due to a failure of rod distraction, infection, and/or other complications.

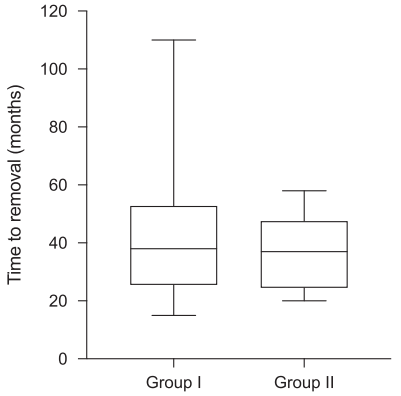

FIGURE 3. Box plots showing comparing group I and group II for the time to removal.

Retrieval Analysis

Only 13 of 46 rods in group I compared to 18 of 30 rods in group II were able to be expanded following removal (Table 1). Excluding the implants that underwent pin fracture failure, most constructs failed due to a "cold-welding" between the moving parts of the MCGRs. The term "cold-welding" here is used to describe the scenario in which the build-up of debris between the 2 extendable components was to a great enough extent that the components were unable to move.

The measures of maximum force, maximum elongation, and maximum manual elongation of the functional implants were significantly higher in group I ($P = 0.012$, $P < 0.001$, $P = 0.003$, respectively) compared to group II.

Evaluation of Pin Fracture

Results of the pin fracture evaluation are shown in Table 2. Seventeen patients experienced a pin fracture in at least one of these rods. In 14 patients, pin fractures occurred in rods belonging to group I, while 3 patients with pin fractures had rods from group II (Fig. 4). This was statistically different from the distribution of patients implanted with group I or group II rods in the nonpin fractured patients ($P = 0.030$).

Patients experiencing pin fractures had comparable age at surgery and time to removal to patients with intact pins at removal (Table 2). The 3 rods in group II with a pin fracture had been revised after 54, 25, and 39 months.

Pin fracture cases implanted with double rod constructs had pin fracture in both rods in 3 cases of 16. Of the remaining 13 patients with one rod of a dual-rod construct with pin fracture, only 3 contralateral rods were found functional at retrieval.

High-energy x-ray imaging was able to show a clear fracture of the locking pin in virtually all cases. For 2 implants, x-ray imaging did show evidence of debris, but

TABLE 1. Clinical and Implant Data and Results From the Retrieval Analysis for Groups I and II

	Generation		
	Group I	**Group II**	***P***
Patient data			
No. patients	27	17	
Age at surgery (y)	9 (1-14)	7 (4-11)	0.304
Time to removal (mo)	37.6 (15-109.6)	37.4 (19.6-58.3)	0.828
Sex			
Male	14	6	0.354
Female	13	11	
Reason for removal			
Broken rod	0	2	
Pullout	2	1	
Pin fracture	4	1	
No rod lengthening	3	2	
Infection	3	0	
Full rod extension	6	8	
Conversion to final fusion	7	3	
Other	2	0	
Implant data			
No. implants	46	30	
Construct type			
Single	8	4	0.754
Double	38	26	
Configuration			
Standard	27	20	0.630
Offset	19	10	
Size (length)			
70 mm	10	15	0.013*
90 mm	36	15	
Size (diameter)			
4.5 mm	16	16	0.154
5.5 mm	30	14	
Functional testing			
Max force (LBF)	46.7 (34.0–54.0)	39.5 (16.9–54.2)	0.012*
Force elongation (mm)	16.0 (11.0–26.0)	11.3 (5.0–16.0)	< 0.001*
Manual elongation (mm)	27.5 (24.0–48.0)	23.0 (15.5–30.0)	0.003*
Disassembly			
Functional state			
Functional	13	18	
Internal screw—telescopic rod stuck	5	2	
Telescopic rod—housing tube stuck	11	7	
Other	2	0	

*$P < 0.05$ statistically significant.
Numerical results are shown as medians (range). *P* values are reported for the difference in medians between the 2 rod groups.

TABLE 2. Clinical and Implant Data and Results From the Retrieval Analysis for the Pin Fracture and No Pin Fracture Groups

	Pin fracture		
	No	**Yes**	***P***
Patient data			
No. patients	29	17	
Age at surgery (y)	9 (1-14)	9 (5-12)	0.500
Time to removal (mo)	37.4 (15.0-58.3)	38.5 (19.1-109.6)	0.191
Sex			
Male	13	7	0.698
Female	16	10	
Generation			
Pre	14	14	0.030*
Post	15	3	
Reason for removal			
Broken rod	2	0	
Pullout	3	0	
Pin fracture	0	4	
No rod lengthening	2	3	
Infection	3	0	
Full rod extension	11	3	
Conversion to final fusion	7	6	
Other	1	1	
Implant data			
No. implants	56	20	
Construct type			
Single	8	4	0.722
Double	48	16	
Configuration			
Standard	34	13	0.794
Offset	22	7	
Size (length)			
70 mm	21	4	0.178
90 mm	35	16	
Size (diameter)			
4.5 mm	28	4	0.033*
5.5 mm	28	16	

*$P < 0.05$ statistically significant
Numerical results are shown as medians (range). *P* values are reported for the difference in medians between the 2 rod groups.

the assessment of pin fracture was inconclusive. Sectioning of these 2 implants confirmed the presence of pin fracture in the area, as shown in Figure 2. Both implants belonged to group I.

SEM

Analysis of the fracture sites of the pins showed that all examined had failed due to brittle fractures, characterized by a rough surface with no evidence of ductility (Fig. 5). The fracture initiation point was not identifiable from the pictures taken.

DISCUSSION

Our analysis of 76 MCGRs found that 17 of 46 rods manufactured before March 26, 2015, had a locking pin

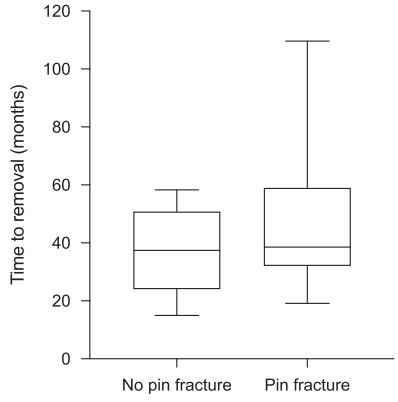

FIGURE 4. Box plots comparing rods with a pin fracture and rods without a pin fracture for the time to removal.

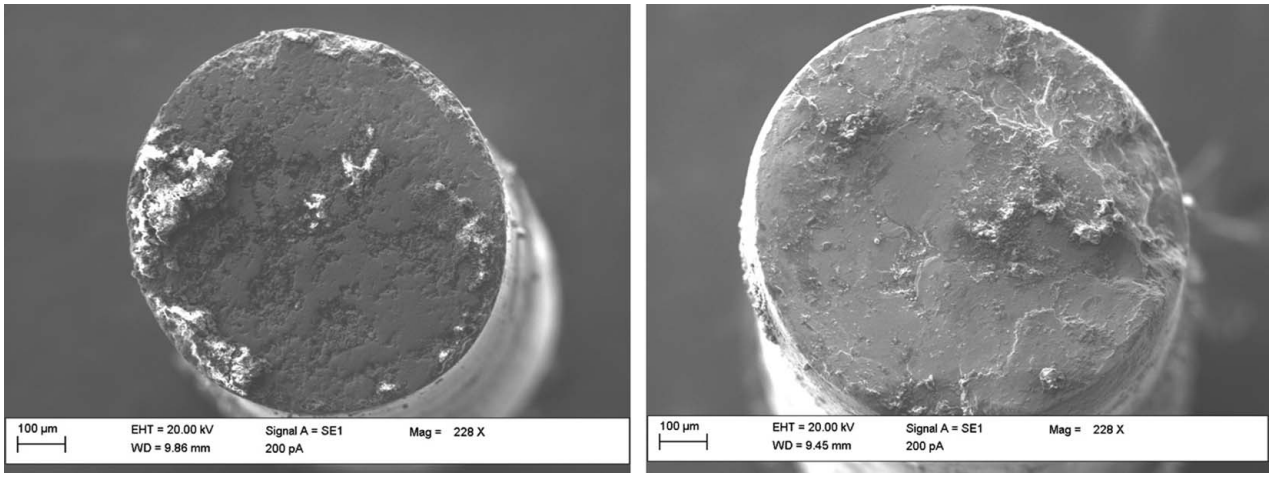

FIGURE 5. SEM pictures of the pin fracture surface from group I (left) and group II (right), showing a rough irregular surface, typical of brittle failure.

fracture. Three rods of 30 manufactured after this date also had a pin fracture. Rods with a pin fracture had been implanted for a significantly greater period of time and had greater rod diameter size than rods without a pin fracture.

The urgent field safety notice published in June 2019 reported that approximately 5% of the total number of devices manufactured before March 26, 2015, failed due to a locking pin fracture. Market surveillance data at the time of the FSN indicated that this issue was not seen in rods manufactured after this date, which was attributed primarily to the increased diameter of the internal locking pin and a strengthening of the material used.

Our study does show evidence of a significantly greater number of pin fractures in group I of retrieved rods collected at our center and suggests that while pin fracture may still occur in the newer designs, its prevalence is much reduced. A retrieval study by Joyce et al[14] reported that 62 of 105 (59%) rods collected at their center that had been manufactured before March 26, 2015, had a locking pin fracture and 6 of 29 (21%) manufactured after this date had a fractured pin; this too demonstrates a lower prevalence of fracture in newer rods.

It is important when interpreting and comparing these results as percentages to be mindful that the value of a 5% pin fracture rate from the manufacturer is relative to all rods (including those well-functioning/not removed) manufactured before March 26, 2015, whereas individual studies, including ours, can only be considered representative of a much smaller dataset investigated. It is clear that the size of the denominator will have a considerable impact on the percentage values reported. While the denominator used by the manufacturer in determining a 5% pin fracture rate is not known, it is likely to be in the order of several thousand rods and therefore significantly greater than current datasets reported by us and others. Retrieval analysis cannot tell us the risk of failure of a device; this can only be determined through a comparison of the total number of failures versus the total number implanted in all patients, as in the FSN or ideally using national registry data. While there are over 25 spine registries globally,[15] including the British Spine Registry (created in 2012), it is acknowledged that these may not yet have reached data completeness levels so as to provide comprehensive information on implant performance.

As these registries mature, the rate of pin fractures occurring nationally and internationally may become clearer. It is important, however, to consider that the failure of MCGRs is multifactorial and a clinical failure of the implant might involve surgical/patient factors and not necessarily translate into a nonfunctional implant, and vice versa. Retrieval analysis can therefore provide information that may enhance the quality of registry data,[16] and these studies can also help to identify surgeon, implant, and patient (SIP) factors which may influence the risk of failure.

Our study analyzed the mechanisms of failure of implants not having a pin fracture. Both in groups I and II, most of the implants that were found not able to distract were stuck at the junction between the housing tube and the telescopic rod. The junction in this region gained particular interest lately, as the manufacturer developed a new design iteration with an end-cap component probably aimed at enhancing its performance. The latest design iteration was withdrawn from the market due to the risk of separation of the newly designed end-cap component.[13] The junction is also responsible for isolating the rod's internal mechanism from the patients' fluids and tissues. We cannot establish if it is the pin fracture or the failure of this junction that is the primary mechanism of failure, yet we speculate the 2 phenomena to be intertwined.

Images from SEM analysis of 5 fractured pins showed brittle fracture occurring in all pins. No clear evidence of a crack initiation point was identifiable. This result suggests that the fracture occurred abruptly, probably due to a combination of corrosion and mechanical indentation mechanisms. Locking pins, or driving pins, transmit the rotational force generated from the magnet to the internal screw of the distraction mechanism. It is not

clear if the fracture happened during the distraction procedure or independently of this.

Although not significantly, the median age at implantation in group I (9 y) and group II (7 y) were different. An older patient population could potentially result in a higher BMI, which might influence the mechanical stress the rods undergo during treatment. The difference in age at implantation could also explain the differences in reasons for removal, as patients implanted at an older age (group I) are more likely to reach the end of growing rod treatment compared to younger patients (group II). The most common reason for removal in younger patients (group II), on the other hand, was full rod extension.

We acknowledge the limitations of this study: as discussed previously, the comparatively small sample size means that these results may not be representative of the wider patient population, and this remains true of all retrieval studies. In addition, this study does not involve a consecutive series of explanted implants from the wider population and we acknowledge that need for more comprehensive clinical data in future studies.

CONCLUSIONS

We found that 17 of 46 retrieved rods at our center that had been manufactured before March 26, 2015, had a fracture of their locking pins. Three of the 30 rods manufactured after this date were also found to have a fractured pin. While the mechanisms and risk factors for failure are multifactorial, our retrieval evidence and clinical experience to date suggest that the use of thicker, tougher locking pins in newer designs have had a beneficial impact on their performance. Future studies involving a larger number of consecutive series of explanted rods from a wider population, together with greater clinical and imaging data, may help in understanding of why pin fractures still occur in some newer generation rods.

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