



■ **BIOMATERIALS**

A retrieval analysis of the Precice intramedullary limb lengthening system

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The Precice nail is the latest intramedullary lengthening nail with excellent early outcomes. Implant complications have led to modification of the nail design. The aim of this study was to perform a retrieval study of Precice nails following lower-limb lengthening and to assess macroscopical and microscopical changes to the implants and evaluate differences following design modification, with the aim of identifying potential surgical, implant, and patient risk factors.

Methods

A total of 15 nails were retrieved from 13 patients following lower-limb lengthening. Macroscopical and microscopical surface damage to the nails were identified. Further analysis included radiology and micro-CT prior to sectioning. The internal mechanism was then analyzed with scanning electron microscopy and energy dispersive x-ray spectroscopy to identify corrosion.

Results

Seven male and three female patients underwent 12 femoral lengthenings. Three female patients underwent tibial lengthening. All patients obtained the desired length with no implant failure. Surface degradation was noted on the telescopic part of every nail design, less on the latest implants. Microscopical analysis confirmed fretting and pitting corrosion. Following sectioning, black debris was noted in all implants. The early designs were found to have fractured actuator pins and the pin and bearings showed evidence of corrosive debris. The latest designs showed evidence of biological deposits suggestive of fluid ingress within the nail but no corrosion.

Conclusion

This study confirms less internal corrosion following modification, but evidence of titanium debris remains. We recommend no change to current clinical practice. However, potential reuse of the Precice nail, for secondary limb lengthening in the same patient, should be undertaken with caution.

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Keywords: Precice lengthening nail, Corrosion, Implant degradation

Article focus

- To undertake macroscopical and microscopical evaluation of the Precice intramedullary nail system.
- To record differences following implant modification including levels of degradation and evidence of corrosion.
- To question a need for change in clinical practice and hypothesize the ability to reuse the implant in the same patient.

Key messages

- All implants demonstrated macroscopical and microscopical degradation.
- The degradation was less in the most recent implant design, but was not statistically lower.
- The earliest designs had evidence of internal corrosion and actuator pin damage, which was not seen in the latest design. There was, however, evidence of biological substances within the latest nails.

Table I. Demographics of implants and patients

Design	Implants, n	Gender, male:female	Modification	Diameter, mm	Type	Mean weight, kg (range)	Mean BMI, kg/m ² (range)	Mean time of implantation, days (range)
P1	6	5:1	N/A	10.7 (n=3); 12.5 (n=3)	Antegrade femur (piriformis) (n=4); retrograde femur 10° (n=1); antegrade femur (trochanteric 10°) (n=1)	76.12 (48 to 117.7)	28.00 (19 to 45)	606.7 (252 to 953)
P2	9	4:5	P2 (n=4)	10.7 (n=3); 12.5 (n=1)	Retrograde femur (n=2); antegrade femur (n=2)	64.00 (48 to 93)	29.67 (19 to 35)	647 (379 to 768)
			P2.1 (n=5)	8.5 (n=3); 12.5 (n=2)	Antegrade tibia (n=3); antegrade femur (n=2)	67.60 (46 to 90)	24 (21 to 27)	353.2 (99 to 586)

BMI, body mass index; N/A, not applicable

Strengths and limitations

- This is the first report of evaluation of the Precice nail implants and confirms an improvement in nail design following modification.
- It does not highlight a need for change in clinical practice and raises the potential issue of internal corrosion leading to actuator pin fracture if further lengthening with the same implant was to be considered.
- Only one nail of each design underwent formal micro-CT and subsequent sectioning to allow scanning electron microscopy and energy dispersive x-ray spectroscopy. Therefore, firm conclusions cannot be made regarding the effect to all nails.

Introduction

Limb-lengthening is a well-established orthopaedic practice following on from the concept of distraction osteogenesis pioneered by Ilizarov.¹⁻³ Traditionally, limb-lengthening is achieved using external fixators; however, complications, such as pin-site infection, joint stiffness, pain, deformity, and fracture following removal of the frame, have led to innovation in implant design. The use of an intramedullary nail has been successful in reducing external fixation application time and has led to intramedullary lengthening implants.⁴⁻⁸

The latest device to be used is the Precice Intramedullary Limb Lengthening System (originally Ellipse Technologies Inc., Irvine, California; now NuVasive Inc., San Diego, California). This is a magnet-operated telescopic internal lengthening device with an outer casing of titanium alloy (Ti-6Al-4V). A cylindrical rare earth magnet (Ti) is connected to a gear box and screw shaft assembly including an actuator pin within the nail. Two rotating rare earth magnets in an external remote controller (ERC) are held on the patient's limb over the magnet within the nail. The resulting rotation of the implant magnet produces either desired lengthening or shortening with sub-millimetre accuracy.⁹⁻¹⁴ The technology is based on the MAGEC rod (NuVasive Inc.) used as a 'growth rod' in the treatment of early-onset scoliosis.¹⁵

Since gaining United States Food and Drug Administration approval for lengthening of the femur and tibia in 2011, failures have been reported resulting in modification

Table II. Indications for limb lengthening

Diagnosis	Patients, n
Post-traumatic shortening	4
Pseudoachondroplasia	1
Turner's syndrome	2
Hemihypertrophy	1
Léri-Weill dyschondrosteosis	1
Idiopathic short stature	2
Femoral shortening with adolescent Blount's disease	1
Tibial shortening associated with Talipes equinovarus	1

in the design of the nail.^{16,17} The initial modular implant is now manufactured as a monobloc nail due to breakages occurring between the initial connecting segment welds and the internal mechanisms have been changed to produce a stronger, more robust device with an increase in the size of the actuator driving pin. The derotation 'crown' following breakage has also been removed in the latest design. MAGEC rod failures have been recently reported, however, with breakage and implant corrosion leading to tissue metallosis, adding caution when using these devices.¹⁸⁻²⁰

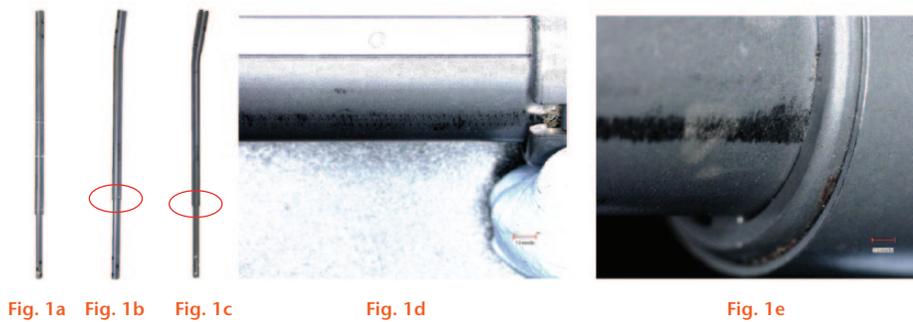
The aim of this study was to analyze Precice lengthening nails following retrieval, which was part of the routine treatment pathway. The retrieved nail was then analyzed both macroscopically and microscopically to evaluate any alteration to the nail and assess resultant differences following changes in implant design.

Materials and Methods

Retrieval analysis was undertaken on 15 Precice nails from 13 consented patients (approved by Health Research Authority, 07/Q0401/25). The details of the patients are shown in Table I. Femoral lengthening patients underwent extension of the nail at a rate of 0.33 mm three times per day; for tibial lengthening, the rate was 0.33 mm twice per day.

Indications for lengthening are listed in Table II.

The median femoral lengthening was 55 mm (interquartile range (IQR) 35 to 60) and the median tibial lengthening was 30 mm (IQR 27.5 to 40). All patients obtained the planned length with no implant failures. One tibial nail was removed prior to regenerate consolidation due to valgus deformity during lengthening. The deformity was



a) First-generation nail, shown by the presence of three welds and supported by the lot numbers referred to as P1. b) Second-generation nail, shown by the absence of welds and supported by the lot numbers referred to as P2. c) Second-generation nail, second modification, shown by the absence of welds and crown and supported by the lot numbers, referred as P2.1. d) Part of the crown on the actuator of a retrieved P2 (a magnification of the circled area of Figure 1b). e) Absence of the crown on a retrieved P2.1 nail (a magnification of the circled area of Figure 1c).

corrected using fixator-assisted exchange nailing, with implantation of a Trigen Meta-nail (Smith & Nephew, Memphis, Tennessee). Consolidation occurred in all patients uneventfully with no requirement for bone grafting. No patients developed a superficial or deep infection. All the nails were removed following regenerate consolidation, which is recommended by the manufacturers, as the long-term effects of the magnet within the nail remaining *in situ* are unknown.

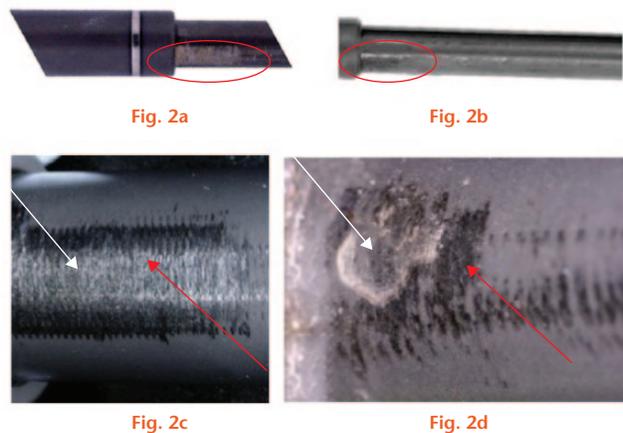
Implant analysis was undertaken using techniques previously reported in retrieved implant assessment.^{19,21-23} Following implant retrieval, the first implanted nail was found to be fractured at the weld between the two parts of the nail, resulting in difficulty in retrieval of the distal part. All other nails were removed without complications.

Implant. Since inception, there have been three Precice nail implant designs. This study included six of the first-generation design (P1), while the remaining nine implants were second-generation (P2), further subdivided into four P2 and five P2.1 designs (Figs 1a to 1c).

Macroscopical inspection. All nails were macroscopically inspected for the extent of surface damage. Any areas of implant damage and alteration were documented by performing digital single-lens reflex photography using a Canon EOS 5D Mark II camera (Canon Inc., Oita, Japan) with EF 100 mm f/2.8 Macro IS USM lens (Canon Inc.).

The different nail designs could be clearly distinguished by macroscopical inspection. The P1 nail incorporated welds between the components; the P2 was distinguishable from the P2.1 by the presence of the crown at the junction between the larger diameter casing and telescopic smaller diameter rod (Figs 1d and 1e).

Microscopical inspection. The damaged areas were microscopically assessed for signs of fretting or pitting using a Keyence VHX-700F series optical microscope (Keyence Co., Osaka, Japan). Using from 20× to 50× magnification, microscopical inspection was applied for measuring the total length of degradation, since the macroscopical inspection did not account for the whole length of surface damage.



Patterns of damaged surface on the telescopic part of the nail. a) Retrieved P1 nail with wide marks on the telescopic part. b) Marks on retrieved P2.1, narrower compared with the marks of P1. c) Fretting (red arrow) and pitting (white arrow) corrosion present on the surface degradation on the telescopic part of P1 nail under the optical microscope (50× magnification). d) Fretting (red arrow) and pitting (white arrow) corrosion present on the telescopic part of P2.1 nail shown by the microscopic inspection (50× magnification).

Plain radiographs. All nails were radiographed using a medical x-ray machine at 60 kV and 4 mA to examine the type and the state of the internal mechanism, including examination for actuator pin fracture. The true length achieved during the patient's treatment was calculated radiologically by comparison of the internal threaded rod distance of the study nails with a control unlengthened nail with a reference radiographical ruler.

Lengthening. The amount of implant lengthening (in mm) was measured as visual degradation, as degradation under microscopy (using 20× magnification), and radiologically. This was also expressed as a ratio of length of visual degradation / achieved length, length of microscopical degradation / achieved length, and radiological length / achieved length, respectively.

X-ray micro-CT. We selected two P1 nails, one P2 nail, and one P2.1 nail to perform micro-CT analysis using a Nikon XTH 225 (Nikon Metrology Inc., Brighton, Michigan). Each scan took approximately 50 minutes and included

Table III. Lengthening data of the implants from initial aim, achieved length, time of lengthening treatment, surface degradation from the forensic analysis, and the radiological estimation of the explanted nails

Design	Mean initial length aim, mm (range)	Mean achieved length, mm (range)	Mean time of lengthening, days (range)	Length achieved as measured by forensic methods, mm (range)		
				Macroscopic inspection	Microscopic inspection	Radiological inspection
P1	37.0 (25 to 50)	35 (25 to 45)	44.50 (29 to 60)	24.50 (19 to 30)	27.50 (25 to 30)	31.00 (25 to 37)
P2	42.50 (25 to 60)	53.75 (25 to 65)	54.25 (24 to 69)	39.00 (20 to 58)	41.75 (20 to 60)	49.75 (26 to 60)
P2.1	33.75 (20 to 50)	38 (25 to 50)	52.80 (29 to 75)	27.00 (10 to 38)	33.40 (16 to 48)	36.70 (25 to 50)
p-value				0.4645	0.3342	0.5813

3177 views in 11° increments, with one frame per view and a frame exposure of 1000 milliseconds. The x-ray tube voltage was set to 152 kV with a current of 86 mA, and a copper filter of 0.25 mm. Scans were reconstructed at the full 25 µm isotropic resolution.

Mechanical sectioning. Using micro-CT scanning, we were able to identify areas for sectioning without damaging the internal mechanism. The nail was securely held and sectioned using an undercut tool made of tungsten carbide with a width of 1.2 mm, on a manual lathe.

Scanning electron microscopy (SEM). SEM (Hitachi S-3400N, Tokyo, Japan) was performed to identify signs of fretting and/or pitting on parts from the internal mechanism.

Energy dispersive x-ray spectroscopy (EDS). EDS (Oxford Instruments, Abingdon, United Kingdom) was used for the determination of elemental composition of debris and deposits at a working distance of 10 mm. This was to identify whether the deposits seen were of biological origin or a corrosion product.

Statistical analysis. SPSS Statistics (version 22.0; IBM Corp., Armonk, New York) was used for statistical analysis; a p-value < 0.05 was considered as significant. We performed non-parametric analysis of variance (ANOVA) Kruskal–Wallis tests. Surface degradation by macroscopical and microscopical inspection was compared across the different nail designs. We also looked for any signs that an increased weight of the patient had an impact on the surface degradation on the telescopic part.

Results

All the implants had macroscopically visible marks on the telescopic part of the nail; these were directly related to the number of lengthening increments undertaken. Fretting and pitting were observed on these sites during microscopical inspection.

The evaluation of plain radiographs and micro-CT confirmed that all designs had common features including the magnet, gear box, and piston, including a collar with ball bearings. There were differences noted within the internal mechanisms, which are described in detail below.

Sectioning revealed actuator pin fractures in both P1 nails, while the P2 and P2.1 nails had intact pins. SEM revealed fretting and pitting on the internal parts, while EDS revealed corrosive debris in the P1 design. There

were only biological deposits in the latest P2 and P2.1 modifications.

Macroscopical inspection. This revealed two different patterns of surface degradation on the telescopic part of the implants. All P1 implants sustained deeper marks, starting as narrow horizontal lines with wider horizontal lines close to the actuator part of the nail (Fig. 2a). Some of the implants had black debris on the markings. Biological tissue was located in the gap between the outer shell and the telescopic part of some of the implants.

In the P2 and P2.1 designs, the marks were less visible, and all appeared to be of equal width (Fig. 2b). The marks were noted to be deeper on the telescopic rod closer to the wider outer casing.

Microscopical inspection. On microscopical inspection of the surface, damage to the telescopic part, fretting, and pitting was noted on all designs, as shown by the red and white arrows, respectively, in Figures 2c and 2d.

Plain radiographs. The lengthening recorded forensically and radiographically is presented in Table III. The state of the internal mechanism was further analyzed and the plain radiographs showed no signs of fracture of the internal mechanism. Representative radiographs from four implants are shown in Figure 3. Although all P1 nails had the same external appearance, radiographical analysis confirmed differences in the internal mechanisms. The implant identification numbers (lot numbers) that represented the earliest nails inserted were designed with a longer frame around the actuator pin, highlighted with a red circle in Figure 3a. Later implanted P1 nails with higher lot numbers were noted to have a smaller frame around the pin, the red circle seen in Figure 3b. The P2 and P2.1 internal design had two metallic rings surrounding the thread mechanism of the nail, highlighted by arrows in Figures 3c and 3d.

X-ray micro-CT. We selected four implants: two P1 nails (including one early and one late design), one P2 nail, and one P2.1 nail for further analysis. The scans confirmed the same differences between the designs, as the plain radiographs demonstrate in Figure 4; the black arrows highlight the metallic rings. The difference in size of the actuator pins can also be clearly seen.

Mechanical sectioning. The four nails were sectioned using plain radiographs and micro-CT scans as guides for the mechanical sectioning (see Table IV for the forensic

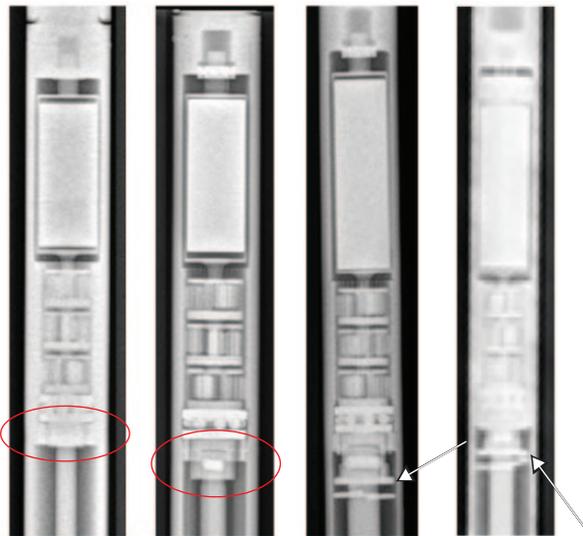


Fig. 3a

Fig. 3b

Fig. 3c

Fig. 3d

Plain radiographs of different internal mechanisms in retrieved Precice nails. a) Radiograph of early P1 design, with a longer frame compared with the rest of the designs. b) Radiograph of the later P1 design with a smaller frame. c) Radiograph of P2 design with an arrow showing the metal rings close to the actuator pin. d) Radiograph of P2.1 design with an arrow showing the metal rings.

analysis performed and the main findings). The internal mechanism of the early P1 design is featured in Figure 5, the P1 later design is featured in Figure 6, the P2 is featured in Figure 7, and the P2.1 is featured in Figure 8.

All internal parts were found intact apart from the actuator pins of both P1 designs (Figs 5c and 6c). Black debris was found in all the sectioned implants on the threading of the telescopic part, as seen in Figure 6e. In the P2.1 example, a black rubber ring (Fig. 8g) was retrieved, which was not present in the other nail designs. It is presumed that this was inserted to prevent fluid ingress from the movement of the telescopic part during lengthening. There was scratching on the surface of the ring, denoted by the white arrow in Figure 8g.

The dimensions of the actuator pin range from 1 mm in diameter and 4 mm in length in P1 designs, to 2 mm in diameter and 6 mm in length in P2 designs.

SEM. All parts had debris from foreign materials, as shown by the arrows on both the images from the optical microscope and the SEM (Figs 5 to 8). The internal bearings from both sectioned P1 nails had black deposits on their surfaces with fretting and pitting present. Signs of fretting and pitting were observed on the fractured areas of both actuator pins evaluated.

The parts of the internal mechanisms of P2 and P2.1 nails also had black deposits and signs of fretting. In P2 and P2.1 nails, the actuator pins were intact but black deposits had accumulated on their surfaces.

EDS. EDS showed that all the metallic parts (pin and bearings) were made of stainless steel, as confirmed by the presence of iron, chromium, and carbon.

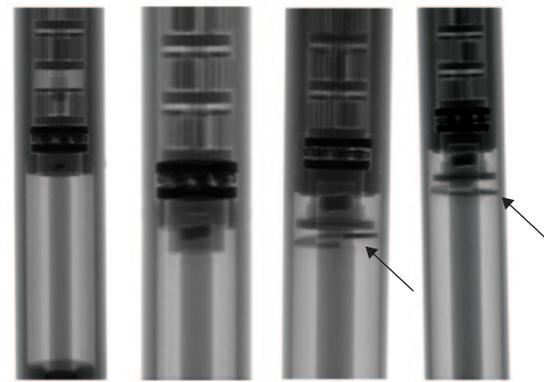


Fig. 4a

Fig. 4b

Fig. 4c

Fig. 4d

Micro-CT of different internal mechanisms/designs. a) Micro-CT of early P1 design with the arrow showing the increased frame. Comparing the pin with the micro-CT scans of the other designs shows a smaller pin, which sectioning revealed a fragment of the pin missing. b) Micro-CT of later P1 design with a larger actuator pin. c) Micro-CT of P2 and d) micro-CT of P2.1 designs revealed a similar internal mechanism. Presence of metal rings is shown with arrows.

In the early P1 design, pin and bearings, phosphorus, sulphur, and high amounts of oxygen were found indicative of corrosive debris. Titanium transfer from the nail to the internal parts was also detected. In the later P1 nail, sulphur and a high amount of oxygen on the pin were also noted as corrosive deposits.

In the newer designs, the bearings had no sulphur or phosphorus and only a small amount of oxygen was seen, which was not enough to determine the presence of corrosion. The presence of oxygen within the internal mechanism was presumed to be of biological origin, which raises the possibility of fluid ingress within the nail. Titanium was also found deposited on the bearings transferred as a result of wear from the nail.

Statistical analysis. Using the Kruskal–Wallis one-way ANOVA test, we found no significant differences between the designs when comparing the ratio of length of visual degradation / achieved length, the ratio of length of microscopic degradation / achieved length, or the ratio of radiological length / achieved length, between the different designs.

However, there was a trend of decreased macroscopical degradation with the least worn being P2.1, where P1 nails have a median rate of 0.84 (IQR 0.67 to 0.96), P2 0.73 (IQR 0.72 to 0.86), and P2.1 0.68 (IQR 0.51 to 0.74).

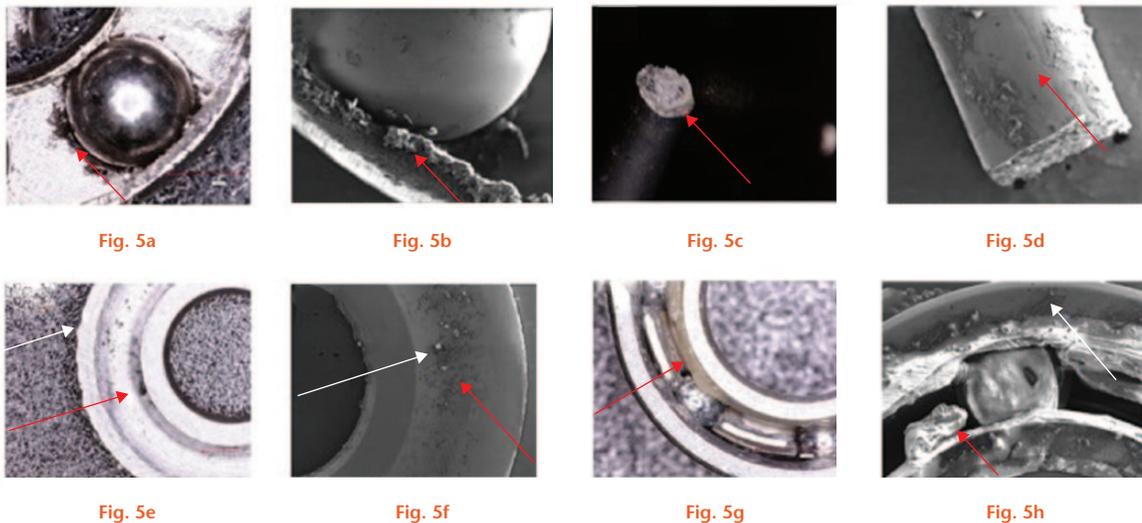
No correlation between patient weight and surface degradation was found in either the macroscopical rate ($p=0.23$) or the microscopical rate ($p=0.43$).

Discussion

The Precice Intramedullary Limb Lengthening System is the latest implant in limb reconstruction surgery. This study has demonstrated that the early generation P1 designs had developed internal corrosive debris and confirmed actuator pin fracture, which was not recognized

Table IV. Forensic analysis of the four sectioned nails with the results from the imaging analysis, the detailed macroscopical inspection, the surface seen using scanning electron microscopy (SEM), and the elemental composition observed by performing energy dispersive x-ray spectroscopy (EDS)

Design	Radiographs / micro-CT	Surface damage on telescopic part	SEM	EDS
P1	Early design	Deep marks with different width, wider closer to the actuator part	Fractured site of the actuator pin, fretting and pitting corrosion, and presence of black debris on the parts of the internal mechanism	Presence of phosphorus and sulphur, high amount of oxygen, and titanium transfer
P1	Late design		Actuator pin fractured in two parts, fretting and pitting corrosion, and presence of black debris on the internal parts	Presence of sulphur, high amount of oxygen
P2		Shallow marks with same width	No pin fracture, fretting corrosion on the bearings, and presence of black deposits	Absence of phosphorus and sulphur
P2.1			No pin fracture, fretting corrosion on the bearings, pitting corrosion on the pin, and presence of black deposits	Absence of phosphorus and sulphur



Microscopic inspection of internal parts of early P1 design. a) Microscopic picture of the ball bearing where black debris was found (arrow). b) Scanning electron microscopy (SEM) with presence of foreign materials on the ball bearing (arrow). c) Fractured site of the pin (arrow) showing a brittle fracture with no evident initiation or end points of the crack. d) SEM showed the rough surface of the fracture, combined with black debris on the side of the actuator pin (arrow). e) Black deposits on the plain bearings (red arrow) and fretting more prominent on the exterior part of the bearing (white arrow). f) SEM revealed black debris (red arrow) and biological material (fluorescent debris, indicated by the white arrow). g) The ball bearing previously situated at the bottom of the gearbox had a fat-like substance (arrow), most likely lubricant to facilitate motion within the internal mechanism. h) SEM confirmed the presence of fat-like substance (red arrow) and black debris (white arrow).

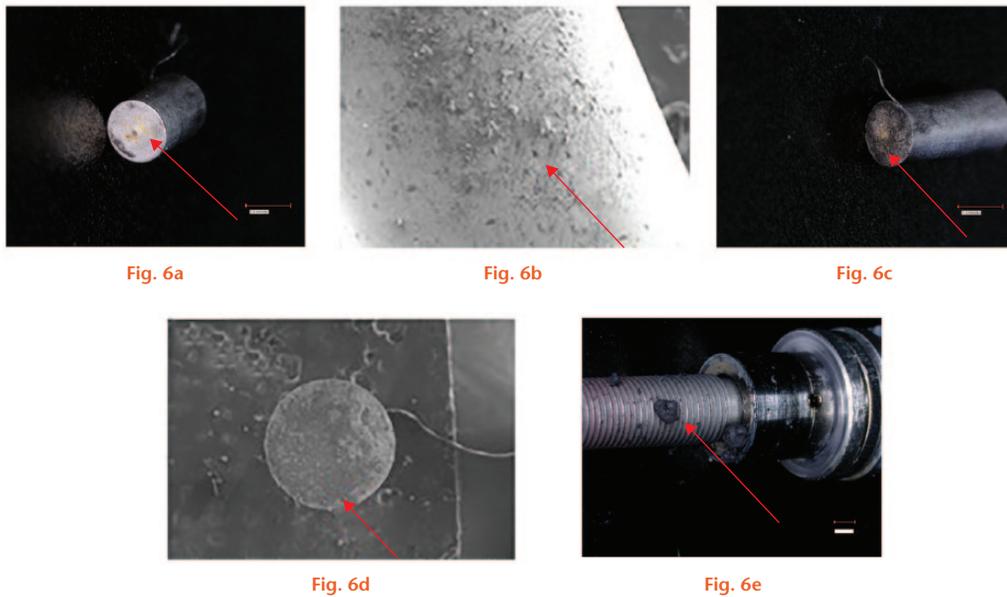
clinically. There was no corrosion debris seen internally in the later P2 and P2.1 designs, but the presence of biological deposits suggests that fluid ingress still occurred. Deposits of titanium wear particles were seen on all the internal stainless-steel bearings with degradation in the form of scratches seen on the smaller diameter telescopic part of the nail.

The Precice nail provides stability for the lengthened bone, allowing accurate controlled distraction and retraction whilst enabling continual physiotherapy to maintain joint movement. As an intramedullary device, the nail theoretically prevents regenerate deformity and fracture following weight-bearing. It has also been shown to have improved patient satisfaction and faster regenerate consolidation when compared with femoral lengthening using external fixators.¹² There has been modification of the initial design to strengthen the nail, following break-age through implant welds (P1) and subsequent crown

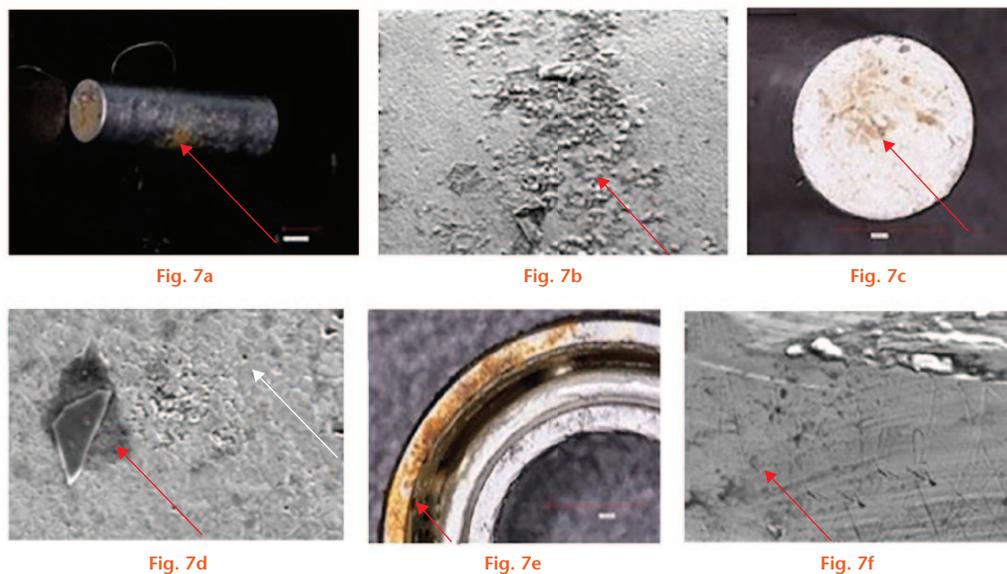
failures (P2, initially designed to control rotation), which has led to the current P2.1. The actuator pins were also increased in size to withstand the forces required during lengthening.¹⁶ All these changes were demonstrated by the analysis performed in this study. With improvement in implant strength in the latest design, there has been an associated decrease in surface degradation with less visible markings, both macroscopically and microscopically.

There is also no evidence of corrosion debris within the P2 and P2.1 nails studied. The presence of biological deposits may suggest fluid ingress, which could contribute to corrosion occurring over time. This finding needs to be considered due to the combination of stainless steel bearings and actuator pin with a titanium casing, especially with all implants demonstrating titanium wear deposited throughout the internal mechanism.

Concern has recently been raised regarding the use of the MAGEC rods in the spine, due to the risk of



Microscopic inspection of internal parts of a later P1 design. a) Non-fractured part of the actuator pin with presence of debris (arrow). b) Scanning electron microscopy (SEM) showed black debris on the side of the pin. c) Fractured site of the pin, with black debris, but with no clear indentation of the initiation and endpoints of the fracture. d) The initiation point was not evident using the SEM, suggesting a more brittle fracture. e) Black stained materials on the thread mechanism of the nail.



Microscopic inspection of internal parts of P2. a) Foreign material on the pin (arrow) while b) scanning electron microscopy (SEM) showed no presence of black debris, only biological deposits on the side. c) Minor presence of black debris on the top of the pin (arrow), while d) SEM showed some black debris (red arrow) and pitting corrosion (white arrow). e) Ball bearing with debris and deposits (arrow), which f) under SEM inspection revealed presence of black debris (arrow).

implant failure.¹⁸⁻²⁰ High rates of failure and significant tissue metallosis surrounding the revised implants were associated with metal debris and fractures of the drive pin within the actuator.¹⁸ Panagiotopoulou et al¹⁹ reported skin breakdown and significant soft-tissue contamination as a result of the corrosive process. With the local effects of metallosis being highlighted further concern over the potential systemic effect has also been raised, with an increase in serum levels of titanium and vanadium found following treatment with the MAGEC system.²⁴

However, there are fundamental differences in the use of the MAGEC rod and the Precice nail. The 'growing rods' in scoliosis treatment remain *in situ* for several years, with intermittent lengthening undertaken as the child grows. In limb-lengthening, the Precice nail is used to obtain the length gradually but over a continuous period of up to 1 mm per day. Once the bone has fully consolidated, the nail's removal is planned. It is therefore unlikely that a corrosive process will have sufficient time to cause an actuator pin fracture or other internal mechanism damage that compromises the use of the implant.

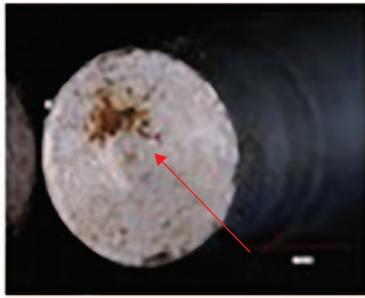


Fig. 8a

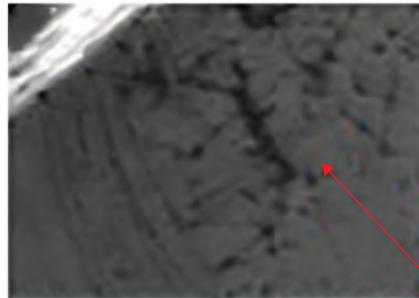


Fig. 8b

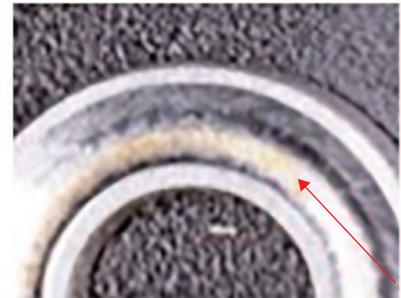


Fig. 8c

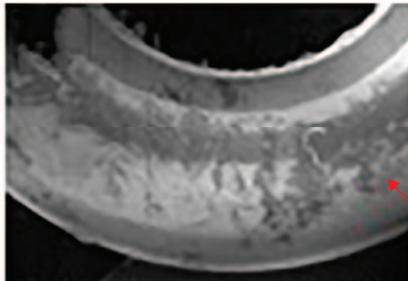


Fig. 8d

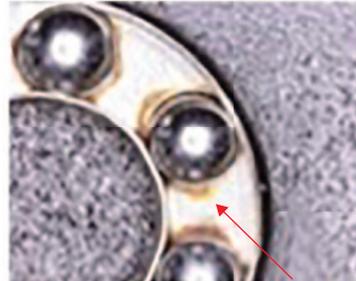


Fig. 8e



Fig. 8f



Fig. 8g

Microscopic inspection of internal parts of P2.1. a) Presence of foreign substances on the pin (arrow), while b) under the scanning electron microscopy (SEM) we observed black debris. c) The plain bearing had a small amount of foreign debris, which d) was more extended when we performed SEM (arrow). e) On the ball bearings, there was foreign materials (arrow), but not that extended, as f) SEM revealed. g) On the rubber ring, there was scratching on both sides (arrow).

The Precice lengthening nail may perhaps also be considered for reuse in patients who require further lengthening within the same limb. The concept of the 'dormant nail' involves leaving the nail in place following initial lengthening and regenerate consolidation. The distal locking bolts can then be removed and the nail retracted using the ERC. The nail is then ready to undergo a secondary lengthening. The bone can be re-osteotomized and locking bolts replaced, and the nail undergoes a second lengthening episode. Another example is when the initial lengthening performed does not use the full availability of the nail. Dependent on the length of nail used, lengthening can be performed up to a maximum of 8 cm. In some patients this could be staged so that an initial lengthening is performed, for example up to 4 cm. Regenerate bone healing then occurs before a second osteotomy is performed to complete the subsequent 4 cm of lengthening. It is likely that in both these

scenarios the nails will remain within the limb for several years rather than months. In these patients, there is a cost implication to be considered in using a new implant, as the Precice nail is expensive. Reusing the same nail, however, should be undertaken with caution, as our study suggests the possibility of internal corrosion leading to potential implant failure, although in the latest designs this may be low, as no corrosion was seen within the P2.1 implant studied.

There are limitations within this study. The implants were evaluated as they were retrieved from patients and so there are differences to the time *in situ* and differences in lengthening undertaken. Only one nail from each design has been evaluated with micro-CT, mechanical sectioning, SEM, and EDS. We are therefore unable to draw any firm conclusions that can be applied to all nails. We have demonstrated less degradation and no evidence of corrosive debris within the newer designs.

We do, however, accept that there was no statistical difference between the degradation seen, and recognize the limitation of the small numbers analyzed, which could lead to a type 2 error. From the available evidence, the Precice nails all achieved the clinical outcomes of lengthening and subsequent good bone formation. Therefore, we would not advocate any change to current clinical practice. Further investigations are required to confirm the potential corrosion identified within the latest P2.1 design, and mechanical testing is needed to evaluate the potential of reusing the implant in secondary lengthening. Studies could also be performed to evaluate serum levels of titanium and vanadium to see if they are elevated during limb lengthening, as has been seen in the patients who had a MAGEC rod inserted.²⁴ This finding is especially important, as the P2.1 design has confirmed degradation with titanium deposits following lengthening.

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Author Contributions

- V. C. Panagiotopoulou: Designing the study, Analyzing the data, Writing the manuscript.
- K. Davda: Collecting the data.
- H. S. Hothi: Analyzing the data, Writing the manuscript.
- J. Henckel: Analyzing the data.
- A. Cerquiglini: Analyzing the data.
- W. D. Goodier: Participating surgeon, Editing the manuscript.
- J. Skinner: Editing the manuscript.
- A. Hart: Editing the manuscript.
- P. R. Calder: Designing the study, Participating surgeon, Writing the manuscript.

Conflict of Interest Statement

- None declared

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