

Assessment of material loss of retrieved magnetically controlled implants for limb lengthening

Bryan Foong, Vicky Panagiotopoulou, Harry Hothi, Johann Henckel, Peter Calder, David Goodier, Alister Hart

Abstract

Purpose: We aimed to understand material loss from the telescopic component of PRECICE nails, which are used for distraction osteogenesis of the femur or tibia. We also aimed to identify any correlation between implant performance and patient factors.

Methods: This retrieval study involved 11 magnetically controlled intramedullary nails from 9 patients who had achieved the targeted leg length. All the nails were assessed macroscopically and microscopically for material loss. All implants were radiographed to assess the internal mechanism. A Talyrond 365 (Taylor Hobson, Leicester, UK), roundness measuring machine was used to generate 3-dimensional surface maps of the telescopic to allow for measurement of material loss.

Results: Visual assessment of all the nails showed evidence of material loss from the telescopic component. The radiographs revealed that all the nails had intact internal mechanism and no evidence of fractured pins. The roundness measuring machine showed that the quantity of material loss was lowest in the latest design of the PRECICE nail. There was no significant correlation between material loss and the two patient factors (duration of the lengthening phase, the time of implantation) included in this study.

Conclusion: This study is the first to investigate the performance of the three different designs of the PRECICE system with a focus on material loss. We found that the latest design had the best implant performance. We are confident of the continued success of the PRECIEC system and reassure surgeons and patients that they are unlikely to encounter

1. Introduction

Leg length discrepancy (LLD) involves paired lower limbs that are of unequal length. Minor LLD is common in the population with prevalence as high as 90%¹⁻³. Many surgeons consider a difference of more than 20mm to be an indication for intervention⁴. LLDs greater than 20mm are an indication for corrective devices⁴ but rarer^{5,6}. Studies have found that 18.1% of the population had LLD greater than 10mm³ and only 0.1% of the population has LLD greater than 20mm⁵. Causes of LLD can be either congenital, including fibular hemimelia, or acquired, which are more common and are a result of growth plate arrests, trauma and tumours⁷. Minor LLDs are largely asymptomatic but severe cases can result in spinal pathologies like scoliosis and lower back pain^{8,9} and limb pathologies like joint pain and osteoarthritis^{10,11}.

Leg lengthening is a viable treatment for more severe LLDs (>60mm)^{6,12} and the current gold standard is external distraction via the Ilizarov technique¹³. However, this technique involves complications including pin site infection, discomfort and overall patient dissatisfaction. Intramedullary (IM) lengthening devices have had some degree of success¹⁴⁻¹⁸ but were limited due to complications like pain and implant failure^{6,18-21}. PRECICE (NuVasive Specialised Orthopaedics Inc, CA, USA) is currently the only FDA approved. The PRECICE system has 3 different designs: P1, P2 and P2.1.

Similar technology has been used in magnetically controlled growth rods (MCGR) to treat early onset scoliosis^{22,23}. MCGRs and the PRECICE system share similar patterns of damage to the telescopic component (Figure 1). MCGRs have demonstrated severe metallosis, requiring revision surgery, in some patients and this is believed to be due to a reaction to the metal ions generated by the wear process^{22,23}. This is similar to the metallosis found in metal

on metal hip replacements ^{24, 25}. However, severe outcomes associated with wear from the PRECICE nail have yet to be documented. Therefore, a comparison to MCGRs will be made in this study.

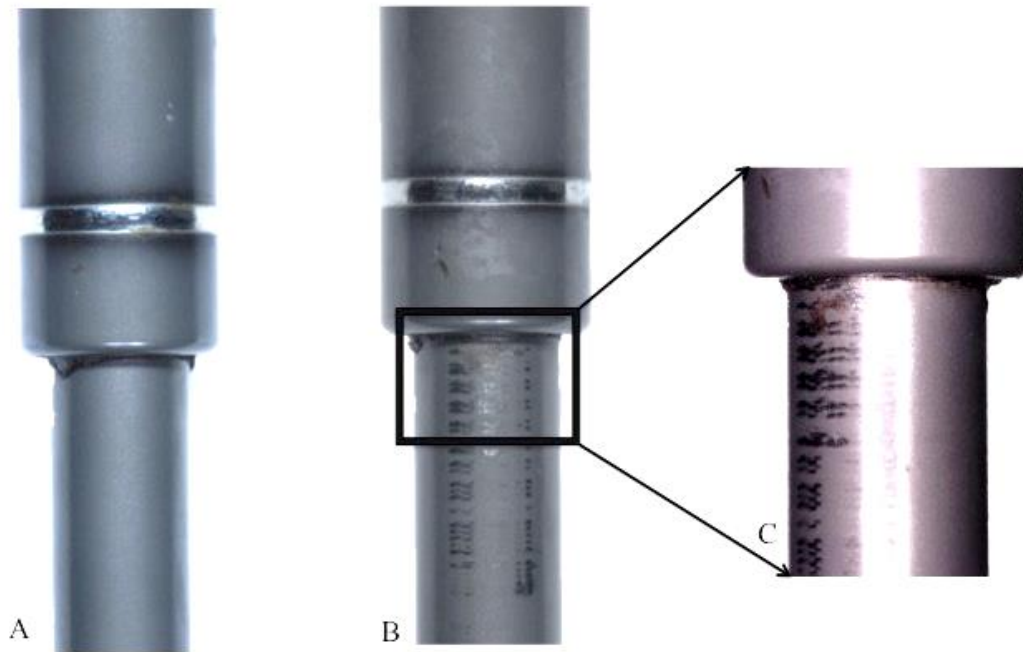


Figure 1. Unworn (A) and worn (B) surfaces on the telescopic component of the same PRECICE nail. Microscopic (C) inspection showing a more detailed image of the surface damage. The surface damage can be characterised by horizontal, black notches that occur in a regular pattern with a consistent interval of roughly 1mm.

We sought to understand the nature of wear on the PRECICE nails by assessing the amount of material loss that was present on the PRECICE nails. We aimed to identify any correlation between implant performance and patient factors.

2. Materials and Methods

This was a retrospective study including 11 retrieved nails received between 2015 and 2017 from 9 patients from one centre. Patient consent was obtained for all 11 nails. The implants were consecutively gathered without the use of any inclusion criteria. All the implants considered in this study were routinely removed after the prescribed length of implantation and were successful in lengthening the limb. The nails were decontaminated according to our

centre's protocol. The implants were from 6 male and 3 female patients with a median (IQR) age of 22 (18-38) years and a median (IQR) time in situ of 18.2 months (17-24). 7 implants were from unilateral procedures and 4 implants were from bilateral procedures. Patient demographic data have been summarised in Table 1. All implants were of the PRECICE (NuVasive Specialised Orthopedics Inc.) system and of the femoral design. 8 implants were 10.7mm in diameter and the remaining 3 implants were 12.5mm in diameter. There were 5 P1 nails, 3 P2 nails and 3 P2.1 nails. The implants were grouped based on their design. The features of the implants included in this study have been summarized in Table 2. IRB approval was obtained for this study.

Table 1. Demographic data for patients included in the study.

Patient	Nail	Age	Gender	Unilateral or Bilateral (Side)	Cause of LLD
1	Nail-1, Nail-6	22	Male	Bilateral	Short stature
2	Nail-2, Nail-4	20	Male	Bilateral	Leri Weill Dyschondrosteosis
3	Nail-5	59	Male	Unilateral (Left)	Trauma
4	Nail-9	38	Male	Unilateral (Left)	Trauma
5	Nail-10	37	Male	Unilateral (Right)	Short stature
6	Nail-11	17	Male	Unilateral (Left)	Post traumatic growth arrest of distal femur
7	Nail-3	33	Female	Unilateral (Left)	Shorter left femur due to correction of right femoral tibia vara
8	Nail-7	18	Female	Unilateral (Right)	Septic hip
9	Nail-8	18	Female	Unilateral (Left)	Right hemi-hypertrophy

Table 2. Data for implants included in the study.

Nail	Design	Diameter (mm)	Time of Lengthening (Days)	Time of Implantation (Months)
Nail-1	P1	10.7	72	17.2
Nail-2	P1	10.7	64	31.8
Nail-3	P1	12.5	29	21.9
Nail-4	P1	10.7	61	23.8
Nail-5	P1	12.5	27	18.2
Nail-6	P2	10.7	69	12.6
Nail-7	P2	10.7	64	24
Nail-8	P2	10.7	24	25.6
Nail-9	P2.1	12.5	52	14
Nail-10	P2.1	10.7	55	16.7
Nail-11	P2.1	10.7	35	17.2

2.1. Plain Radiographs

Plain radiographs of all the implants were taken to allow for the assessment of the structure of the internal mechanism, Figure 2. This was done with a focus on ascertaining whether the pin in the actuator had fractured and was worsening the wear. An intact internal mechanism is indicative of a well-functioning implant.

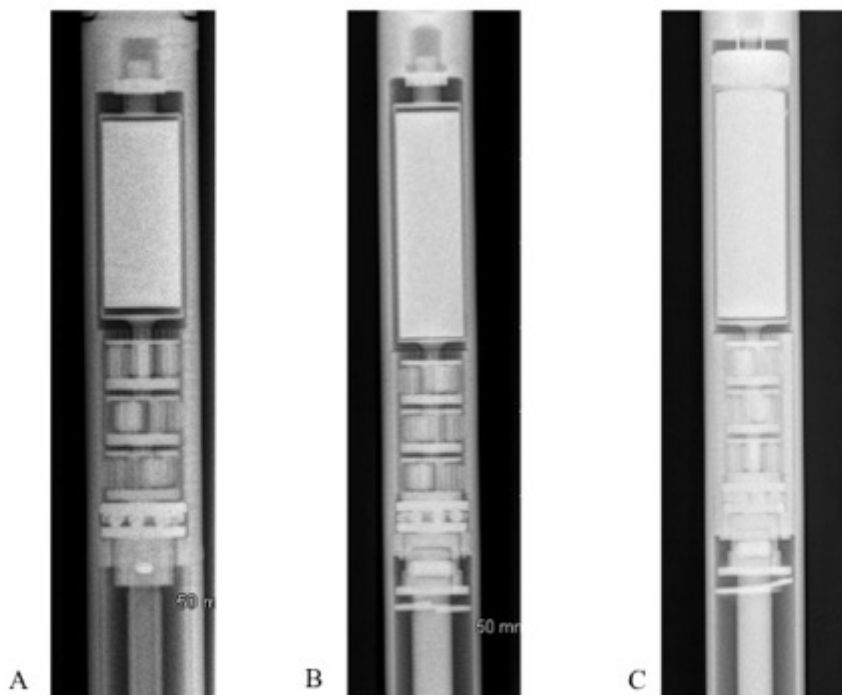


Figure 2. Plain radiographs of three retrieved PRECICE nails. A is a P1 nail, B is a P2 nail and C is a P2.1 nail. The internal mechanism appears to be intact in all three implants.

2.2. Macroscopic Inspection

All of the PRECICE nails were visually inspected along the telescopic component to assess for the location and extent of wear. The indication for wear was the presence of regularly spaced scratches. Other aspects of surface damage, such as the location, colour, vertical length and broadness, were also taken note of.

2.3. Microscopic Inspection

Microscopic inspection was carried out to further assess wear. A Keyence VHX-700F series light microscope (Keyence Co., Japan) was used at a magnification of 20x. Signs of wear that were previously missed in the macroscopic assessment were taken note of.

2.4. Wear

The nail is made from medical grade titanium alloy (Ti-6Al-4V) and has a smaller telescopic component housed within a larger actuator component. The actuator component houses the internal mechanism that includes a magnetic, neodymium iron boron (NdFeB), spindle that is connected to a series of gears that is connected to a threaded drive shaft. The amount of wear was measured from the visibly damaged area of the telescopic component, close to the lip of the actuator component, using a Talyrond 365 (Taylor Hobson, Leicester, UK), roundness measuring machine (RMM). The nail was firmly fixed to the spindle of the machine. Using a 5 μ m diamond stylus, 75 traces were taken every 2° along the vertical axis (Figure 3).

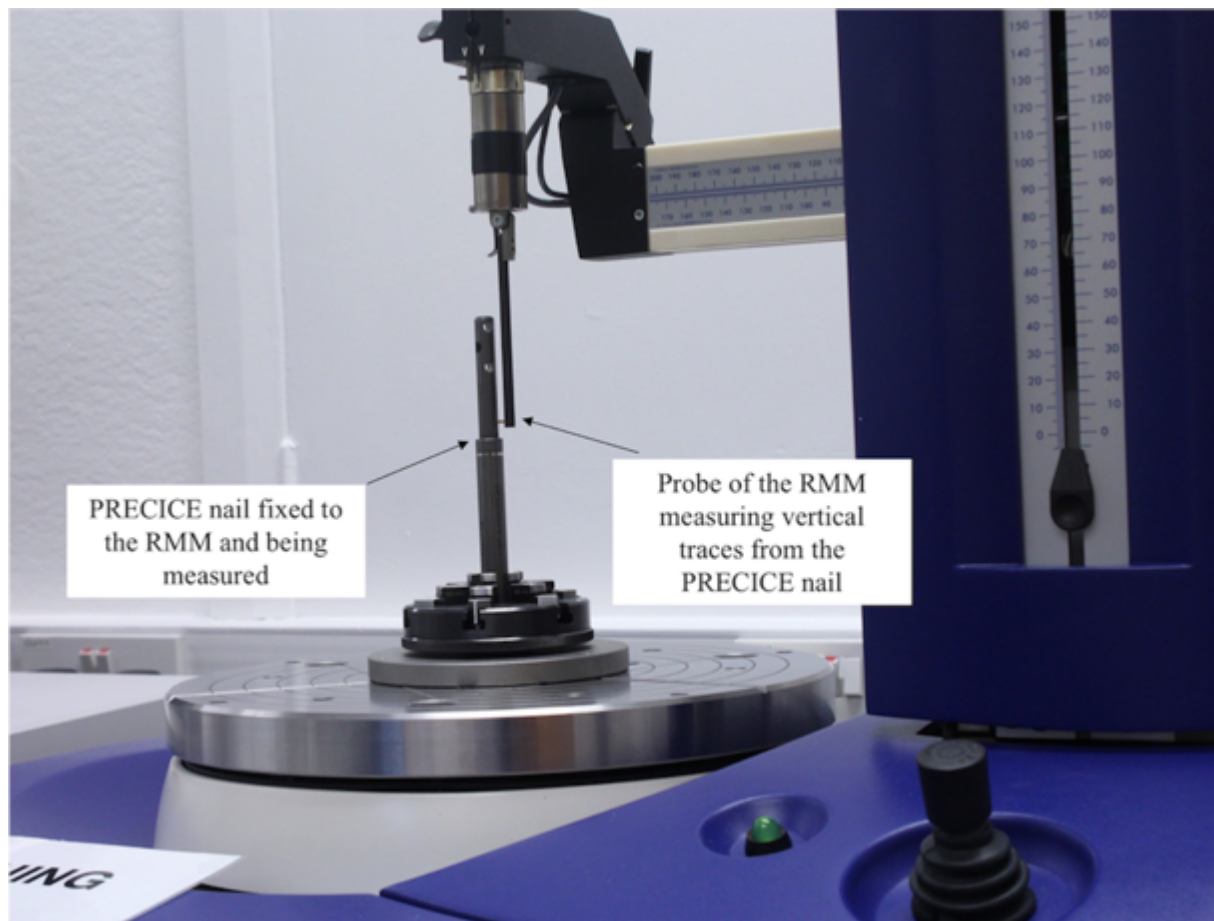


Figure 3. Picture illustrating the setup of the RMM with a PRECICE nail fixed and being measured.

A trace refers to a vertical line measured, starting from the bottom of the telescopic component, next to the lip of the actuator component. Each trace was 10mm long. The dimension of the measured area was 10mm x 150°. The measurement was repeated on the relatively unworn area on the opposite side of the telescopic component. Using the Talymap Gold 7.1 surface profiler, the traces were processed into a surface map. The resulting surface map diagrammatically depicted the extent of surface damage using a colour scale (Figure 4). The scale ranges from red that indicates an undamaged area to yellow, green and finally blue, representing a gradual increase in the severity of damage to the surface²⁶. The Extract Profile function was used to extract vertical, 2-dimensional linear traces from the surface maps that depicted the valleys on the implant surface. The Surface of a Hole operator was used to

measure the depth of the material loss by measuring the area of all the valleys for each of the traces. The measurement with the largest value was considered the trace with the most material loss and was included in the study. Following that, 4 more traces that were 2° and 4° on either side of the initial trace were included. Five 10mm traces were obtained from each nail. The following ratio was used as a measure of the extent of wear:

$$\text{Material Loss} = \frac{\text{Area of valleys of a trace from the visibly worn region}}{\text{Area of valleys of a trace from the visibly unworn region}}$$

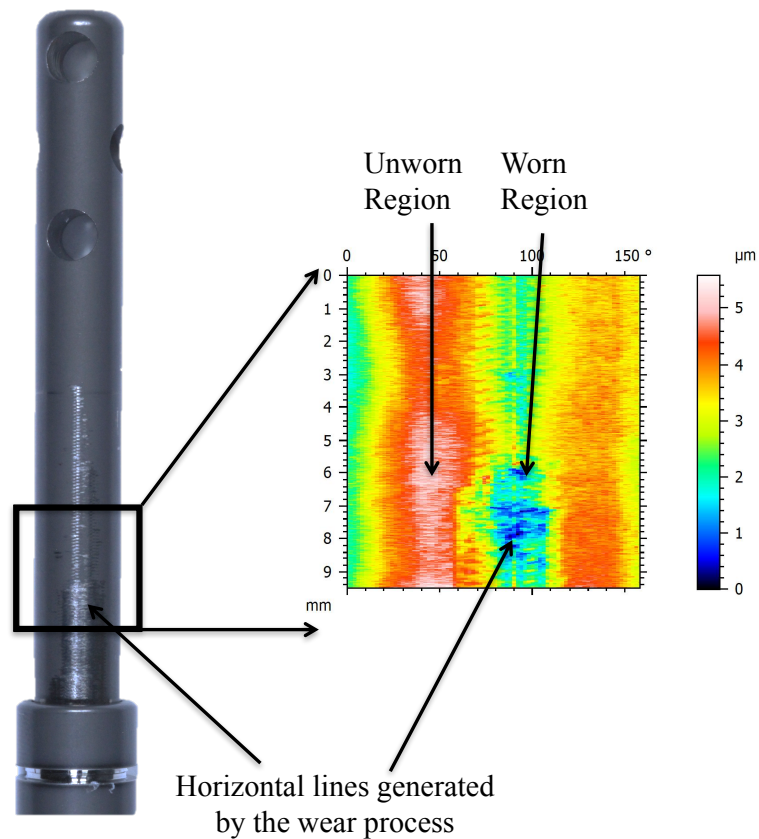


Figure 4. Surface Map of a PRECICE nail with arrows indicating the location of the worn region (green and blue) as well as the adjacent unworn regions (red and yellow). Horizontal lines correspond to the presence of notches on the surface of the implant.

2.5. Statistics

Statistical analysis was performed using the Prism (GraphPad, La Jolla, California). A p-value < 0.05 was considered significant throughout the study. The non-parametric Kruskal-Wallis

test was carried out when comparing all three design variations while the Mann-Whitney test was carried out when comparing between two designs.

3. Results

3.1. Plain Radiographs

The plain radiographs showed no evidence of damage to the internal mechanism. The pin in the actuator was intact for all implants in this study.

3.2. Visual Inspection

All 11 retrieved PRECICE nails showed evidence of regularly spaced marks on the telescopic component of the implant. The marks occurred at intervals of 0.3 millimeters. The broadness of the region of damage on each implant was observed to be restricted to one side of the implant. The vertical length of the region of damage was observed to span the part of the telescopic component that had been extended. The three different designs were observed to display different patterns of wear. The P1 nails displayed broad, horizontal marks that were broader when close to the actuator and narrower away from it (Figure 5). The P2 nails displayed narrow marks that were of relatively equal broadness along the vertical axis. The location of the marks on the implant surface corresponded to the location of the anti-rotation slots (Figure 6). The P2.1 nails also displayed similar narrow marks that were of relatively equal broadness along the vertical axis (Figure 7).

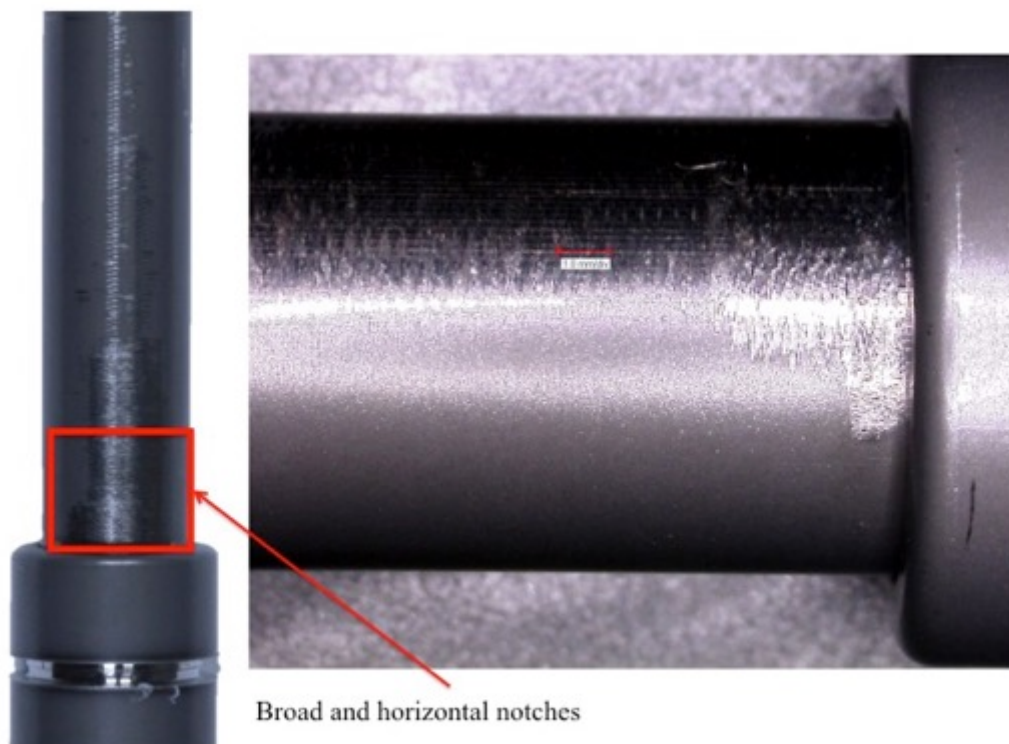


Figure 5. Image of a P1 nail showing broad, horizontal notches on the telescopic component that are broader close to the lip of the actuator component and narrower away from the actuator component.

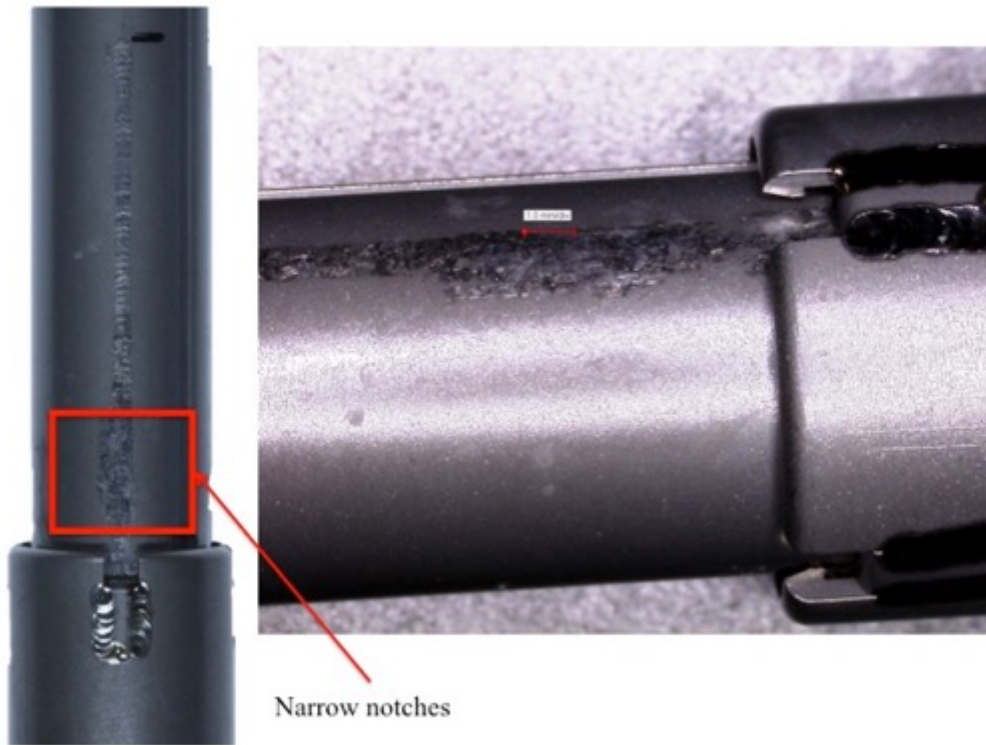


Figure 6. Image of a P2 nail showing narrow notches on the telescopic component that correspond to the location of the slots of the anti-rotation mechanism.

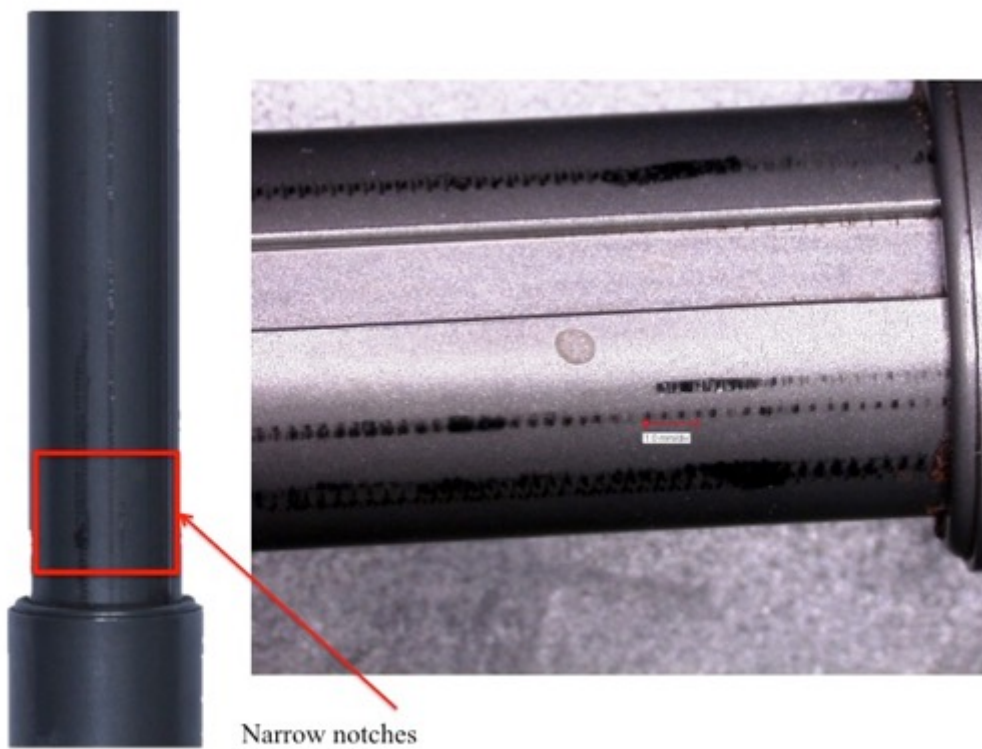


Figure 7. Image of a P2.1 nail showing narrow notches on the telescopic component.

3.3. Wear

The wear values for all the traces were greater than 1, except for 2 traces, and is summarized in Table 3. This shows that the RMM measured some degree of wear in all traces from the worn region of the telescopic component. The difference in wear between the three PRECICE nail designs was found to be significant ($p=0.04$). The earlier designs appeared to have a higher median wear value compared to the more recent designs. The median (range) wear value was 1.63 (1.19-2.17) for the P1 group, 1.56 (1.37-3.97) for the P2 group and 1.2 (1.15-1.37) for the P2.1 group. However, the P2 group had the greatest spread in results with an interquartile range (IQR) of 2.6, compared to the P1 (0.98) and P2.1 (0.22) groups. This is summarized in Figure 8. The initial design (P1) was compared against the subsequent redesigns (P2 and P2.1) and the difference in wear was found to be insignificant ($p=0.376$). However, when each individual design group was compared with another, it was found that the P2.1 group had significantly lower wear compared to both the P1 ($p=0.03$) and P2 ($p=0.007$) groups.

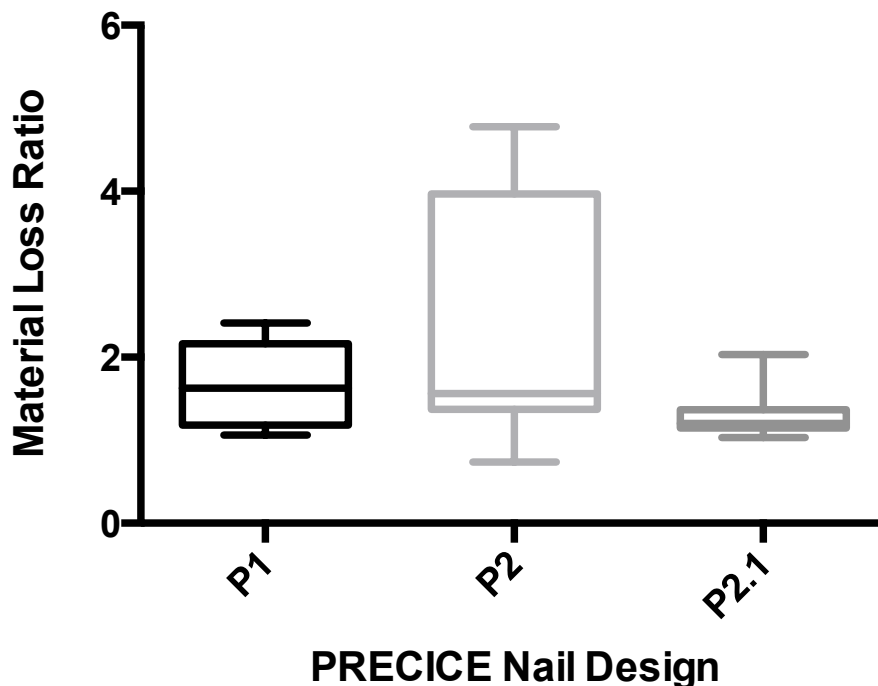


Figure 8. Box and Whisker plot summarizing the wear ratios for the three different design groups.

Table 3. Table showing the wear values for each of the traces for each PRECICE nail.

Trace	1	2	3	4	5
Nail-1	1.07	1.07	1.12	1.09	1.06
Nail-2	1.63	2.04	2.09	1.55	1.27
Nail-3	1.19	1.18	1.38	1.25	1.23
Nail-4	2.28	2.23	2.41	2.26	2.16
Nail-5	2.10	2.17	2.36	2.09	2.07
Nail-6	1.27	1.37	1.48	0.913	0.739
Nail-7	3.97	4.74	4.78	4.46	3.55
Nail-8	1.52	1.56	1.58	1.57	1.42
Nail-9	1.20	1.17	1.18	1.15	1.09
Nail-10	1.20	1.05	2.03	1.54	1.03
Nail-11	1.36	1.37	1.42	1.25	1.32

3.4. Correlation with Patient Factors

Two key patient factors were taken into consideration when analyzing the material loss data derived from the RMM. The material loss values were normalized for the duration of the lengthening phase as well as the time of implantation. When statistically tested, it was found that the differences between the groups were not significant for the duration of the lengthening phase ($p=0.147$) as well as the time of implantation ($p=0.301$).

4. Discussion

This is the first retrieval study to use state-of-the-art metrological techniques to investigate the performance of the PRECICE system by quantifying the wear from the telescopic component. This study will also be the first to attempt to develop an analysis protocol on retrieved IM nails.

The PRECICE system comprises of 3 different designs. The P1 was the first design and was modular with external welds on the actuator component. Due to the occurrence of fractures at the welds, the P1 was redesigned into the P2, which had the external welds removed and an external anti-rotation system included. The P2.1 is a modified version of the P2 with the anti-rotation system moved to the internal aspect of the implant. All the designs were included in this study to explore the differences across the three variations.

Distraction of the PRECICE nail occurs via a magnetic internal mechanism that interacts with a magnetic external remote controller (ERC), regulating distraction or retraction in a non-invasive manner. The device is surgically removed once lengthening and bone consolidation is achieved. Due to the non-invasive nature of its lengthening, the PRECICE nail is becoming an increasingly popular treatment for severe LLDs, compared to the traditional external frames used in the Ilizarov method, with clinical studies providing promising early results. The P2 design has been shown to be successful with accuracy of lengthening close to 100%^{19,27,28}. The PRECICE system is also the only IM lengthening device that is FDA approved and commercially available.

The MAGEC system of MCGRs share the same manufacturer (NuVasive Specialised Orthopaedics Inc), as well as a similar mechanism as the PRECICE system. However, studies on the MAGEC system have suggested a possible link between high wear and metallosis in patients ^{22,23}. The PRECICE system does not share the same incidence of metallosis despite visual assessments showing similar patterns of surface damage as MAGEC rods.

We found that all 11 retrieved PRECICE nails examined in this study showed signs of surface damage on the telescopic component. There was no evidence of pin fracture in any of the implants. This could be a possible reason for the improved performance of the PRECICE system compared to the MAGEC system.

We observed that the notches were regularly spaced and is likely to reflect the regularity in the frequency and degree of lengthening. This suggests that the notches are caused by the edge of the actuator component scratching against the surface of the telescopic component. The notching could be related to the bending moment ²³ generated by a lateral deviation in the mechanical axis of the lower limb due to the lengthening of the IM PRECICE nail ²⁹. However, the pattern of notching was different between the P1 and the P2/P2.1 designs. In the P2 implants, the location of the notches corresponded to the location of the external anti-rotation slots (Figure 9). This led us to believe that the anti-rotation mechanism has a role to play in the pattern of notching



Figure 9. Image of Nail-7 (P2) showing relatively severe surface damage and wear occurring in a location corresponding to the position of an anti-rotation slot. In this implant, the anti-rotation slot seems to be intact with no visible sign of crack propagation.

Wear was observed to decrease as the designs were improved. This suggests that the design modifications seem to have an effect in improving the overall performance of the implant by reducing the amount of wear from the telescopic component. The results of this study have shown that there is indeed a difference in material loss across the three variations. The P2.1 design seemed to be the most superior in this respect as it had the lowest median wear values as well as the smallest IQR. The P2 design had the greatest IQR due to the presence of very high wear value, especially in Nail-7. The area of the greatest damage corresponded to the location of one of the anti-rotation slots (Figure 9), suggesting that the severe damage could be related to the anti-rotation mechanism. This could potentially be worsened if fractures occurred at the anti-rotation slots. Such occurrences have been reported in P2 implants ⁶. Fragmented and displaced material from the fracture could be a possible cause of increased scratching and wear. Such fractures motivated the moving of the anti-rotation mechanism internally in the P2.1 as well as discontinuation in the use of the P2. This modification is likely to have contributed to the improvement in wear in the P2.1 group observed in this study.

This is the first study that is attempting to quantify the extent of wear sustained on the telescopic component of PRECICE nails and identify possible factors that contribute to an

increase in wear. Aside from the difference in design, further implant factors such as implant diameter did not affect material loss ($p=0.056$). Patient factors (duration of lengthening and time of implantation) included in this study did not seem to influence material loss either. We suggest that future work expand on this study by including a wider range of patient and surgeon factors such as surgical technique, surgeon experience, patient BMI and activity levels. Other limitations of the study include a small sample size. The PRECICE nail is a relatively new implant and a small number of surgeries are being carried out with them. Therefore, only a small number of retrieved nails were available in the centre. Only femoral nails were included in this study to provide a better basis for comparison. This is due to the different biomechanics in the femur and tibia. Future work should expand on this by assessing tibial nails and comparing them with the femoral nails.

This study has contributed to the work on retrieval analysis of IM implants by showing that employing metrological methods commonly used for the analysis of hip implants can offer insight into the extent of surface damage and wear sustained on the telescopic component of PRECICE nails. We suggest that further work be done to improve the protocol developed in this study to better understand the mechanism of damage. Further examination into the characterization and quantification of the surface damage is required and this can be achieved using additional methods such as surface profilometry, scanning electron microscopy as well as the coordinate measuring machine.

5. Conclusion

This retrieval study is the first to investigate the performance of the three different designs of the PRECICE system. It is also the first to attempt to develop a retrieval analysis protocol for IM nails. We believe that the absence of pin fractures in the PRECICE system may contribute

to a lower failure rate compared to the MAGEC system. In terms of wear, we found that implant performance was best in the latest design (P2.1). We also found that the anti-rotation mechanism was a likely cause of increase wear in the P2 design. We recommend that a combination of visual and metrological techniques be employed in the analysis of retrieved PRECICE nails. Our results can reassure surgeons and patients that they are unlikely to encounter problems associated with increased wear due to corrosion or mechanical wear.

6. References

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