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Wear performance of retrieved metal-on-metal Pinnacle hip arthroplasties implanted before and after 2007

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Objectives

Previous studies have suggested that metal-on-metal (MoM) Pinnacle (DePuy Synthes, Warsaw, Indiana) hip arthroplasties implanted after 2006 exhibit higher failure rates. This was attributed to the production of implants with reduced diametrical clearances between their bearing surfaces, which, it was speculated, were outside manufacturing tolerances. This study aimed to better understand the performance of Pinnacle Systems manufactured before and after this event.

Methods

A total of 92 retrieved MoM Pinnacle hips were analyzed, of which 45 were implanted before 2007, and 47 from 2007 onwards. The 'pre-2007' group contained 45 implants retrieved from 21 male and 24 female patients, with a median age of 61.3 years (interquartile range (IQR) 57.1 to 65.5); the '2007 onwards' group contained 47 implants retrieved from 19 male and 28 female patients, with a median age of 61.8 years (IQR 58.5 to 67.8). The volume of material lost from their bearing and taper surfaces was measured using coordinate and roundness measuring machines. These outcomes were then compared statistically using linear regression models, adjusting for potentially confounding factors.

Results

There was no significant difference between the taper and bearing wear rates of the 'pre-2007' and '2007 onwards' groups ($p = 0.67$ and $p = 0.39$, respectively). Pinnacles implanted from 2007 onwards were revised after a mean time of 50 months, which was significantly earlier than the 'pre-2007' hips (96 months) ($p < 0.001$). A reduction in the time to revision was present year on year from 2003 to 2011.

Conclusion

We found no difference in the wear rate of these implants based on the year of implantation. The 'pre-2007' hips had a two-fold greater time to revision than those implanted after 2007; this may be due to the increased surveillance of MoM hips following UK regulatory advice and several high-profile failures. Interestingly, we observed a decreasing trend in the mean time to revision every year from 2003 onwards.

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Article focus

- This article focuses on the wear performance of Pinnacle systems manufactured before and after the speculated production of implants with reduced cup-head diametrical clearances, which are thought to be outside manufacturing tolerances.

Key messages

- Pinnacles implanted before 2007 and from 2007 onwards had comparable wear rates.
- The shorter time to revision of more recently implanted Pinnacles could be attributed to the increased surveillance of MoM hips, rather than to implant performance.
- An annual reduction in the mean time to revision was observed as the year of Pinnacle implantation became more recent.

Strength and limitations

- Large number of retrieved implants of a single design, together with clinical and imaging data.

- Pinnacle implantation dates were used as a surrogate for their date of manufacture.

Introduction

With an estimated 180000 Pinnacle systems (DePuy Synthes, Warsaw, Indiana) implanted worldwide,[1] it was one of the most commonly used metal-on-metal (MoM) total hip arthroplasties (THAs). In 2012, however, this MoM bearing was discontinued by the manufacturer due to low market demand.[2] Its five-year revision rate was reported to be 4.28% at that time.[3] The National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man now reports a 13.98% ten-year cumulative percentage probability of revision for this device.[4]

Two previous studies have suggested that Pinnacle hips implanted after 2006 exhibit increased failure rates.[1,5] This was attributed to an unintended reduction in the diametrical clearance between cup and head components, believed to be a deviation outside manufacturing tolerances.[1] However, a recent analysis of NJR data discovered a corresponding increase in the revision rates of all other MoM THAs implanted after 2006,[6] suggesting that increased implant surveillance may have contributed to these trends.

Diametrical clearance within hip implants is known to influence bearing and taper wear.[7-9] If Pinnacle systems, implanted after 2006, demonstrated increased volumes of material loss due to reduced clearances, patients could be at greater risk of an adverse reaction to metal debris (ARMD), and increased vigilance would be required. Retrieval analysis could help to identify this change in performance.

This study aimed to better understand the performance of Pinnacle systems, with an objective to uncover the effect of a potential manufacturing change on hips implanted from 2007 onwards. Bearing wear rate (mm^3/year) was the primary outcome measure, using statistical analysis to control for other potentially confounding variables. The null hypothesis was that there was no difference in bearing wear rate between Pinnacle hips implanted before and after 1 January 2007.

Patients and Methods

This retrieval study examined patient and implant data collected from a consecutive series of 92 MoM Pinnacle hip implants received at our centre. The acetabular components consisted of a cobalt-chromium liner paired with a titanium shell, while all heads were 36 mm in diameter, composed of cobalt-chromium and paired with Corail (n = 52) or Summit (n = 40) titanium femoral stems (both DePuy Synthes). These stems shared the same taper diameter (12/14), method of fixation (cementless), and other comparable dimensional and topographical design features.

The implants were separated into two groups: those with a primary implantation date before 2007 (pre-2007) and those implanted from 2007 onwards (2007 onwards). The rationale for using 1 January 2007 as the boundary between the two groups was based on speculation that a change in the way Pinnacle implants were manufactured had occurred in 2006, acknowledging the delay between manufacture and implantation date. Patient gender, age, and blood metal ion levels (cobalt (Co) and chromium (Cr)) were collected for both cohorts, along with the time to revision and positioning measurements of the implants.

Patient demographics. The 'pre-2007' group contained 45 implants retrieved from 21 male and 24 female patients, with a median age of 61.3 years (interquartile range (IQR) 57.1 to 65.5); the '2007 onwards' group contained 47 implants retrieved from 19 male and 28 female patients, with a median age of 61.8 years (IQR 58.5 to 67.8).

The reasons for revision were unexplained pain confirmed as ARMD post-revision (n = 88), infection (n = 1), femoral loosening (n = 1), malposition (n = 1), and recurrent dislocations (n = 1).

Measurement of bearing surface material loss. The volume of bearing surface material loss from the retrieved Pinnacle implants was measured using a Zeiss Prismo (Carl Zeiss Ltd, Rugby, UK) coordinate measuring machine (CMM). Utilizing previously published protocols,[10] a 2 mm ruby stylus followed a number of polar scan lines on each surface, collecting up to 30000 data points. An iterative least-squares fitting method was used to analyze the data, and wear maps were produced through the comparison of the unworn geometry and the bearing surface. This provided a means of illustrating the position of worn regions and identifying the presence of edge wear.

Measurement of head taper material loss. A rectangular representation of each taper surface was produced using a Talyrond 365 roundness measuring machine (Taylor Hobson Ltd, Leicester, UK), from which topographical features were identified and volumetric material loss quantified. This reconstruction was the result of combining 180 vertical traces recorded by a 5 μm diamond stylus, which translated along the taper axis of each femoral head. Previously published protocols were used to formulate this method.[11]

Statistical analysis. First, statistical analysis was used to compare the patient, implant, and surgical characteristics of both groups. These included gender, age, time to revision, stem design, inclination, horizontal offset, vertical offset, and edge wear. The categorical variables were compared using Fisher's exact test, while all continuous characteristics were compared using the unpaired *t*-test. The second stage of the analysis compared the bearing wear rate and taper wear rate of the two groups. Allowing for potentially confounding factors, the following comparisons were performed using linear regression: 1) unadjusted, not considering possible confounding factors; and 2) adjusted, adjusting for patient/hip characteristics.

Table I. Summary of the comparison between patient, implant, and surgical characteristics of the two groups

Category	Pre-2007 (n = 45)	2007 onwards (n = 47)	p-value
Gender, n (%)			0.67*
Female	24 (*53*)	28 (*60*)	
Male	21 (*47*)	19 (*40*)	
Mean age, yrs (SD)	61.3 (6.2)	61.8 (8.1)	0.77†
Mean time revision, mths (SD)	96 (14)	50 (20)	<0.001†‡
Stem design, n (%)			0.04*‡
Corail	20 (*44*)	32 (*68*)	
Summit	25 (*56*)	15 (*32*)	
Mean inclination, ° (SD)	47.6 (8.1)	43.5 (7.6)	0.02†‡
Mean horizontal offset, mm (SD)	44.8 (6.0)	43.0 (7.4)	0.23†
Mean vertical offset, mm (SD)	79.6 (8.8)	75.0 (11.1)	0.04†‡
Edge wear, n (%)			0.08*
No	11 (*24*)	20 (*43*)	
Yes	34 (*76*)	27 (*57*)	

*Fisher's exact test
†Unpaired *t*-test
‡Statistically significant

Table II. Comparison of the blood metal ion levels of the two groups

Parameter	Pre-2007	2007 onwards	p-value*
Median cobalt (Co), ppb (range)	7.70 (1.00 to 101.60)	7.23 (0.60 to 130.00)	0.4288
Median chromium (Cr), ppb (range)	2.50 (0.50 to 59.60)	5.70 (0.56 to 90.00)	0.4182
Median Co/Cr ratio (range)	2.71 (0.83 to 10.20)	1.42 (0.66 to 5.98)	0.0006†

*Unpaired *t*-test
†Statistically significant

Table III. Comparison of the bearing and taper wear rates of the two study groups, reporting the median and interquartile range (IQR) for each group

Outcome	Pre-2007	2007 onwards
Median bearing wear rate, mm^3/yr (IQR)	2.3 (1.6 to 9.7)	3.8 (2.8 to 8.1)
Median taper wear rate, mm^3/yr (IQR)	0.81 (0.10 to 1.64)	0.19 (0.03 to 0.75)

To limit the number of variables in the analysis, only the characteristics found to be different between groups ($p < 0.1$) were adjusted for. Both study outcomes were analyzed on the log scale. A small constant was added before the transformation so that patients with zero wear rates could be included in the analysis. As a result of the log transformation, the wear rate of the '2007 onwards' group relative to the wear rate of the 'pre-2007' group was obtained as a ratio. The corresponding confidence intervals were also reported, along with p-values indicating the significance of the results.

We confirm that all investigations were conducted in conformity with ethical principles of research, that informed consent for participation in the study was obtained, and that institutional approval of the human protocol for this investigation was obtained.

Results

Comparison of surgical, implant, and patient factors. The two groups in this study were comparable, in regard to age ($p = 0.77$), gender ($p = 0.67$), horizontal femoral offset ($p = 0.23$), and edge wear ($p = 0.08$) (Table I). All other compared characteristics were somewhat different, as highlighted in Table I. These included the time to revision, paired stem design, inclination, and vertical offset.

In regard to the individual whole blood measures of Co and Cr, the difference between the two groups was not statistically significant; however, the Co/Cr ratio was found to be significantly greater in the 'pre-2007' group (Table II).

Comparison of wear rates. The median bearing wear rate of the 'pre-2007' and '2007 onwards' groups was 2.3 mm^3/year and 3.8 mm^3/year, respectively ($p = 0.39$). The median taper wear rate of the pre-2007 implants was 0.81 mm^3/year, while the '2007 onwards' group had a median rate of 0.19 mm^3/year ($p = 0.005$) (Table III). These comparisons are presented in Figures 1 and 2.

There was no difference in the bearing wear rate between the groups in either the unadjusted regression analysis or after adjusting for possible confounding factors (time to revision, stem design, edge wear, cup inclination, and vertical offset; Table IV). However, taper wear rate was significantly lower in hips implanted from 2007 onwards, when no other factors were taken into account (unadjusted analysis). On average, material was lost from these tapers at only around half the rate recorded from

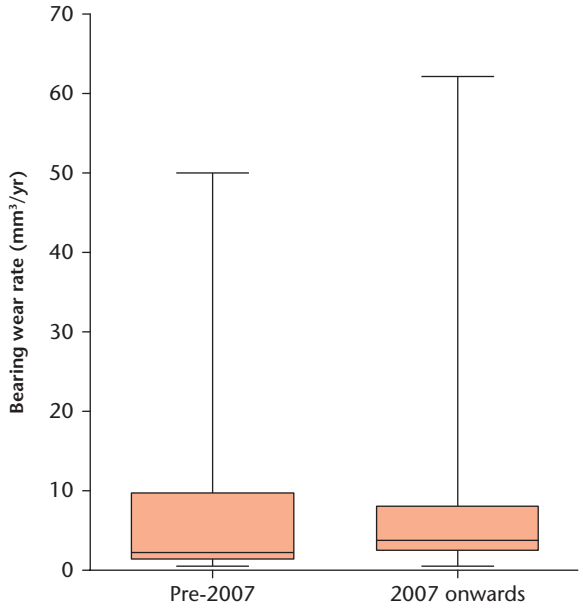

Fig. 1

Graph showing the comparison of the bearing wear rate of the 'pre-2007' and '2007 onwards' groups.

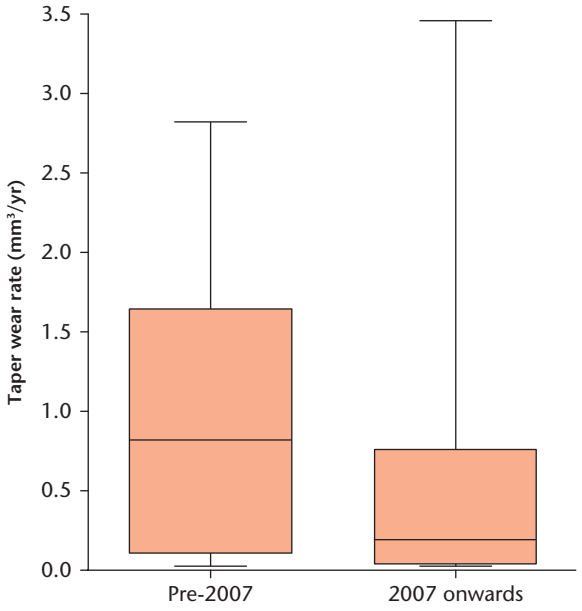

Fig. 2

Graph showing the comparison of the taper wear rate of the 'pre-2007' and '2007 onwards' groups.

Table IV. Summary of the regression analyses performed to compare the study outcomes between the two groups, both before and after adjusting for potentially confounding variables

Adjustments	Ratio (95% CI)*	p-value†
Bearing wear rate		
None	1.22 (0.77 to 1.92)	0.39
Time to revision, design, edge wear	0.97 (0.48 to 1.98)	0.94
+ Inclination, vertical offset	0.84 (0.38 to 1.87)	0.67
Taper wear rate		
None	0.52 (0.33 to 0.82)	0.005‡
Time revision, design, edge wear	0.72 (0.34 to 1.49)	0.37
+ Inclination, vertical offset	0.70 (0.31 to 1.59)	0.39

*The differences in wear rate between groups are reported as ratios, due to the log transformation of the outcomes, specifically, the wear rate from 2007 onwards relative to the wear rate in the pre-2007 period
†Regression analysis
‡Statistically significant
CI, confidence interval

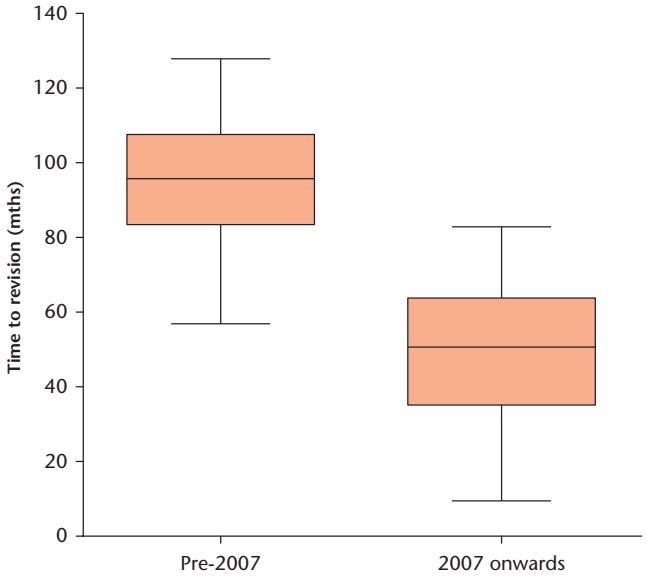

Fig. 3

Box plots representing the time to revision for both groups of implants.

the 'pre-2007' group. Nevertheless, after adjusting for potentially confounding factors (as with the bearing wear rate analysis), the difference in taper wear rate between the groups was not statistically significant, as seen in Table IV.

Discussion

Our analysis of 92 Pinnacle implants found no significant difference in the bearing or taper wear rates between components implanted before 2007 and from 2007 onwards. Interestingly, the time to revision and the whole blood Co/Cr ratios were significantly greater in hips implanted before 2007.

Small diametrical clearances between bearing surfaces have been shown to reduce wear in MoM implants; however, reductions from optimal ranges may result in increased friction due to insufficient lubrication.[1,8] A recent study suggested that a manufacturing change in 2006 caused Pinnacle implants to experience a clearance reduction, which may have impaired their performance.[1] Data collected in our analysis suggest that the aforementioned reduction, if present, did not affect implant performance as no significant difference was found between the bearing or taper wear rates of hips implanted before 2007 and from 2007 onwards.

Implant time to revision. In this study, Pinnacles implanted from 2007 onwards were revised significantly earlier than in the 'pre-2007' hips (Fig. 3). As both groups were found

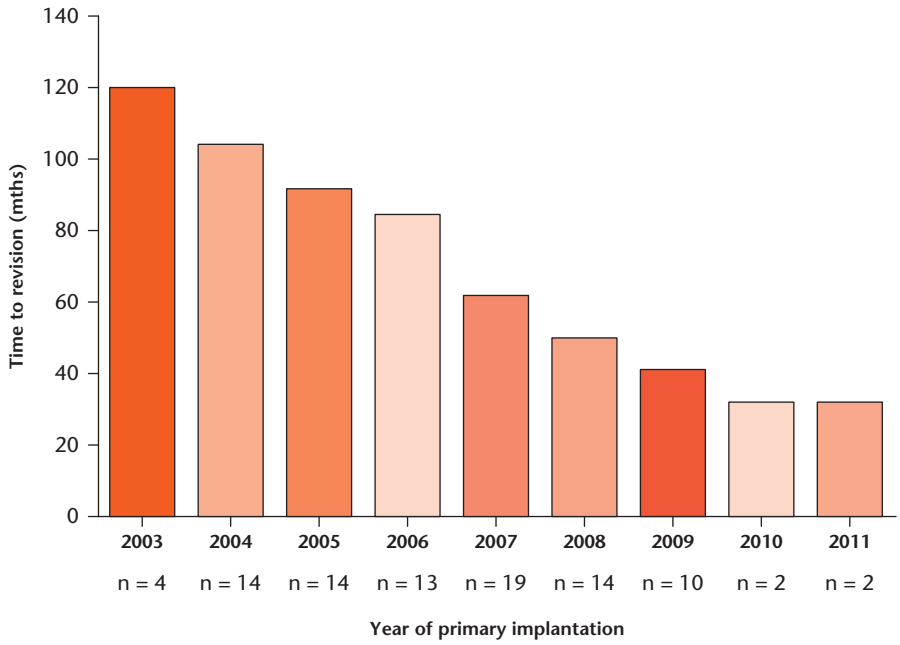

Fig. 4

Bar chart plotting the year of primary implantation against the mean time to revision.

to have comparable wear rates, this trend could be attributed to the increased surveillance of MoM hips in the later years, rather than implant performance. Increased vigilance after 2007 would likely be associated with the coinciding high coverage and attention received by MoM implants, for example, due to the failures that led to the recall of ASRs (DePuy Synthes) in 2010.[12] Additionally, as advised by the Medicines and Healthcare products Regulatory Agency (MHRA), from 2012 onwards, patients with these MoM hip arthroplasties would have been monitored annually, allowing for earlier detection of ARMD with improved imaging modalities including metal artefact reduction sequence (MARS)-MRI.[13]

A reduced threshold for revision surgery could be another contributor to this trend, resulting in more recent implants being removed from patients who were possibly not previously considered for such revision treatment. In 2010, the MHRA advised surgeons that whole blood metal ion levels greater than 7 ppb were to be considered in order to identify patients who required additional follow-up.[14] This may have influenced their consideration of revision surgery even when dealing with asymptomatic patients.[15]

The authors of a recent study using Pinnacle revision rates from the NJR[6] may have been misled by the same trend in the absence of wear measurements. The addition of these data can provide a better insight into implant performance; however, it can only be obtained through retrieval analysis. This evidence raises doubts regarding the use of 'revision rate' and 'time to revision' as reliable indicators of implant performance, especially in the analysis of hips with large ranges of implantation dates. Figure 4 clearly demonstrates an annual reduction in the mean time to revision as the year of Pinnacle implantation becomes more recent. As the trend is also evident between 2003 and 2007, a change in the performance of the implants from 2007 onwards could not be reliably identified through the analysis of this parameter.

Whole blood metal ions. Cobalt and chromium ions released from Pinnacle implants during wear can be identified in the blood. The presence of these particles can cause necrotic and inflammatory changes in the periprosthetic tissue,[16] including ARMD,[15] prompting symptoms that often justify implant revision. Patients in this study demonstrated levels consistent with typical revision cases while no significant difference was seen between the two groups. The significantly greater Co/Cr ratio found in the blood of patients from the 'pre-2007' group is consistent with their greater taper wear rates in the unadjusted analysis, as corrosion in this area is known to result in elevated Co blood levels compared with Cr.[17] A previous study into Pinnacle implants suggested that taper wear rate accelerates over time,[18] which may explain the lower rate of material lost from this area in examples implanted since 2007. Increasing vertical femoral offset has also previously been shown to be a risk factor for greater corrosion.[18]

A limitation of this study was the use of Pinnacle implantation dates as a surrogate for their date of manufacture, since the discrepancy between these events can vary depending on the length of time the implants remain unused. Without an exact date for the speculated change in Pinnacle manufacture, the date of 1 January 2007 was

used to separate the two groups, which may have resulted in some affected hips being included in the pre-2007 group. This classification method was, nevertheless, consistent with previous investigations into the same trend. As with all retrieval studies, we do not know the as-manufactured dimensional state of the components prior to implantation and how this would have impacted the individual clearances of each implant.

Another possible limitation is the number of variables that differed between the two groups, which could have had a confounding effect. However, statistical measures were taken in order to account for the characteristics that were significantly different between the groups, and all analysis was performed by a medical statistician. While this is one of the largest retrieval studies to have investigated this topic, we acknowledge that all studies are at some risk of Type II errors; this may be mitigated in future studies that involve larger sample sizes.

In conclusion, this study found no significant difference in the bearing wear rate of Pinnacle hips implanted before 2007 and from 2007 onwards. Therefore, the hypothesized decline in their performance after 2006 could not be supported. The time to revision was found to decrease consistently as the year of primary implantation increased. We speculate that this is due to stricter MoM implant surveillance in later years. Future research into the performance of these hips should be wary of this trend, especially in the absence of retrieval data.

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Author Contributions
- S. Bergiers: Designed the study, Collected, analyzed, and interpreted the data, Wrote the manuscript.
- H. S. Hothi: Designed the study, Interpreted the data, Wrote the manuscript.
- J. Henckel: Designed the study, Interpreted the data, Wrote the manuscript.
- A. Eskelinen: Designed the study, Collected and interpreted the data, Wrote the manuscript.
- J. Skinner: Designed the study, Interpreted the data, Wrote the manuscript.
- A. Hart: Designed the study, Collected and interpreted the data, Wrote the manuscript.

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Conflict of Interest Statement
- None declared