



■ HIP

Does diametrical clearance influence the wear of Pinnacle hip implants?

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Aims

The optimum clearance between the bearing surfaces of hip arthroplasties is unknown. Theoretically, to minimize wear, it is understood that clearances must be low enough to maintain optimal contact pressure and fluid film lubrication, while being large enough to allow lubricant recovery and reduce contact patch size. This study aimed to identify the relationship between diametrical clearance and volumetric wear, through the analysis of retrieved components.

Methods

A total of 81 metal-on-metal Pinnacle hips paired with 12/14 stems were included in this study. Geometrical analysis was performed on each component, using coordinate and roundness measuring machines. The relationship between their as-manufactured diametrical clearance and volumetric wear was investigated. The Mann-Whitney U test and unpaired *t*-test were used, in addition to calculating the non-parametric Spearman's correlation coefficient, to statistically evaluate the acquired data.

Results

The hips in this study were found to have had a median unworn diametrical clearance of 90.31 μm (interquartile range (IQR) 77.59 to 97.40); 32% ($n = 26$) were found to have been below the manufacturing tolerance. There was no correlation found between clearance and bearing ($r_s = -0.0004$, $p = 0.997$) or taper ($r_s = 0.0048$, $p = 0.966$) wear rates. The wear performance of hips manufactured within and below these specifications was not significantly different (bearing: $p = 0.395$; taper: $p = 0.653$). Pinnacles manufactured from 2007 onwards had a greater prevalence of bearing clearance below tolerance ($p = 0.004$).

Conclusion

The diametrical clearance of Pinnacle hips did not influence their wear performance, even when below the manufacturing tolerance. The optimum clearance for minimizing hip implant wear remains unclear.

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Article focus

- This article focuses on the correlation between the diametrical clearance of Pinnacle hips and their wear performance.
- It also investigates whether these implants were produced to the manufacturer's specifications.

Key messages

- Diametrical clearance did not influence the bearing and taper wear rates of this series of Pinnacle hips.

- A total of 32% of hips ($n = 26$) were found to have had an unworn clearance below their manufacturing tolerance, however this did not appear to impact their wear performance.
- No significant difference was found in the diametrical clearance of edge worn and non-edge worn implants.

Strengths and limitations

- Large number of metal-on-metal (MOM) implants of the same design and head size.

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- The inability to evaluate bedding-in wear rate was a limitation of this retrieval analysis.

Introduction

In order to quantify the cup-head bearing wear of retrieved hip implants, the as-manufactured geometry of both components must first be accurately reconstructed; this also enables the preimplantation diametrical clearance of the bearing to be determined. This characteristic is defined as the difference in diameter between the head and cup components of hip arthroplasties. During these calculations, as-manufactured implants are assumed perfectly spherical, consistent with international standards.¹

The optimum clearance for minimizing bearing surface material loss is unknown. Previous studies have suggested that hip implants with lower diametrical clearances have better bearing conformity, reduced contact pressure, and are better suited to the formation of fluid film lubrication during the walking gait cycle.²⁻⁹ This is thought to reduce the amount of bedding-in (running-in) wear during the initial period following implantation, without greatly influencing longer-term, steady-state material loss.^{2,5,8,10-12} However, lower clearances increase the contact patch size, which may increase the likelihood of edge wear.^{8,9}

The manufacturing tolerance for the diametrical clearance of metal-on-metal (MOM) Pinnacle hips (DePuy Synthes, Warsaw, Indiana, USA) was 80 μm to 120 μm .¹³ A previous study has reported that some of these hips were manufactured outside this range.¹⁴ These lower values were more prevalent in implants manufactured after 2006 and were associated with higher failure rates.

This study aimed to better understand the relationship between diametrical clearance and volumetric wear. An investigation into the prevalence of Pinnacle hips manufactured outside of tolerance was also performed, examining its impact on material loss.

Methods

A total of 81 (36 mm) MOM Pinnacle hips (DePuy Synthes) were investigated in this study; all were paired with 12/14 stems, which were of either Corail or Summit designs. Their cobalt-chrome head and liner bearing components allowed articulation within these implants, which were designed to have a 100 μm diametrical clearance, with a manufacturing tolerance of approximately 20 μm (80 μm to 120 μm). A titanium shell was paired with all liners to enable fixation to acetabular bone. All implants were revised due to an adverse reaction to metal debris (ARMD) from 32 male and 49 female patients, who had a median age of 63 years (interquartile range (IQR) 57.9 to 67.4). They were implanted between 2003 and 2011 and had a median time to revision of 79 months (IQR 56 to 97). Cobalt and chromium whole blood ion levels were collected from each patient prior to revision, as well

as their full consent to analyze the retrieved implant. Figure 1 summarizes the study design.

Bearing surface volumetric wear and diametrical clearance. The bearing surface geometry of each component was captured, in the form of point clouds, using a Zeiss coordinate measuring machine (Carl Zeiss Ltd, Rugby, UK) as shown in Figure 2. Its 2 mm ruby stylus was instructed to follow a scanning strategy in accordance with ASTM International and International Organization for Standardization (ISO) standards.^{1,15} These data were then analyzed utilizing a previously introduced, automated method (RR3D¹⁶) to measure diametrical clearance and quantify volumetric wear.¹⁷ In order to accurately quantify material loss from the bearing surface of hip arthroplasties, the as-manufactured geometry of the head and liner components must also be accurately reconstructed in the form of a perfect sphere, as illustrated in Figure 3.¹⁸ As a result, their original diametrical clearance can be calculated by subtracting the unworn diameters of both components, as shown in Figure 4. It must be noted that the perfect sphericity of these implants is an assumption based on the intended bearing design, consistent with current methods.

Taper surface volumetric wear. A Talyrond 365 roundness measuring machine (Taylor Hobson Ltd, Leicester, UK) was utilized to perform 180 vertical measurement traces along the axis of each femoral head taper, using a 5 μm diamond stylus. Volumetric wear was then quantified from the resulting rectangular representation of this surface. Protocols were informed by previously published methods.¹⁹

Statistical analysis. D'Agostino-Pearson and Shapiro-Wilk tests were used to determine normality within datasets. A non-parametric Spearman's correlation coefficient (r_s) was calculated to determine the correlation between 1) clearance and volumetric wear and 2) clearance and whole blood metal ion levels. Through this method a p -value is generated, indicating the significance of a correlation. Accounting for the possible identification of low clearance values in this series of implants, a Mann-Whitney U test or unpaired t -test would be used to evaluate statistical differences between the wear performance, blood metal ions, vertical femoral offset, horizontal femoral offset, and inclination of implants manufactured within and outside manufacturing tolerances. These analyses were further used to compare the clearance of edge worn and non-edge worn Pinnacles, while also investigating the prevalence of implants manufactured outside specifications, before and after 1 January 2007. Their year of implantation was used as a surrogate, in the absence of exact manufacturing dates. This was in accordance with a previous study, which found that the "date of implantation" is a reliable indicator of date of manufacture (correlation of 0.90 with lot number), with respect to Pinnacle hips.¹⁴

Results

The hips in this study were found to have had a median preimplantation diametrical clearance of 90.31 μm

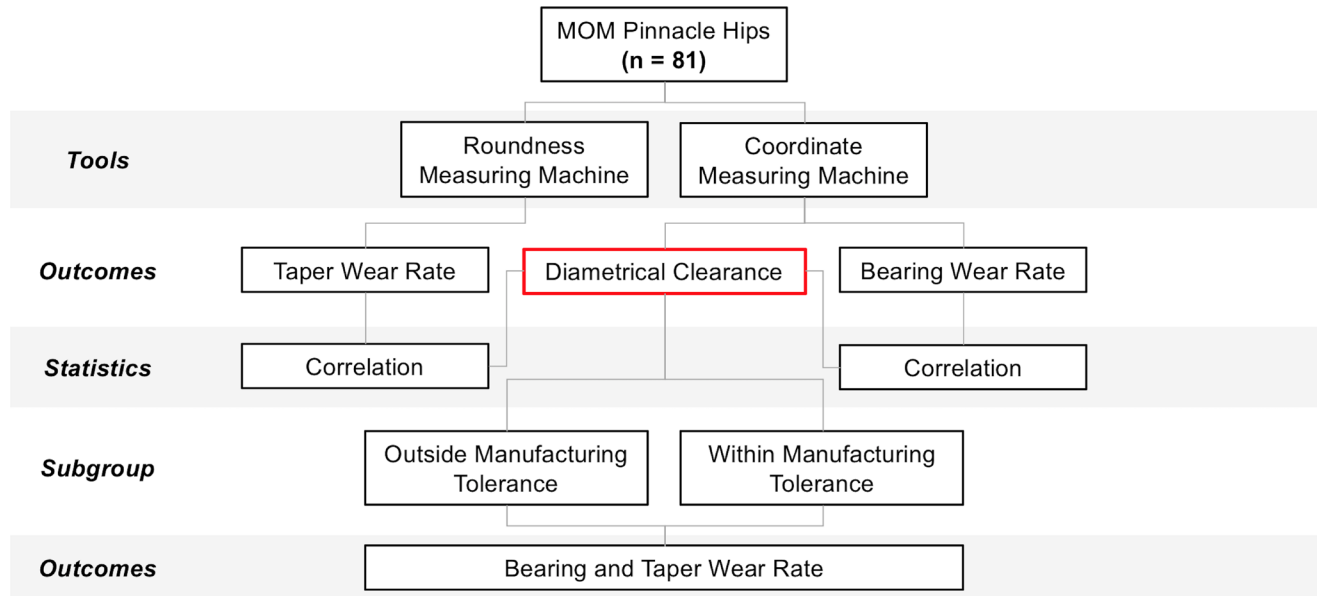


Fig. 1

A flow chart depicting the study design, which includes an investigation into the relationship between diametrical clearance and the wear rate of Pinnacle hips. MOM, metal-on-metal.

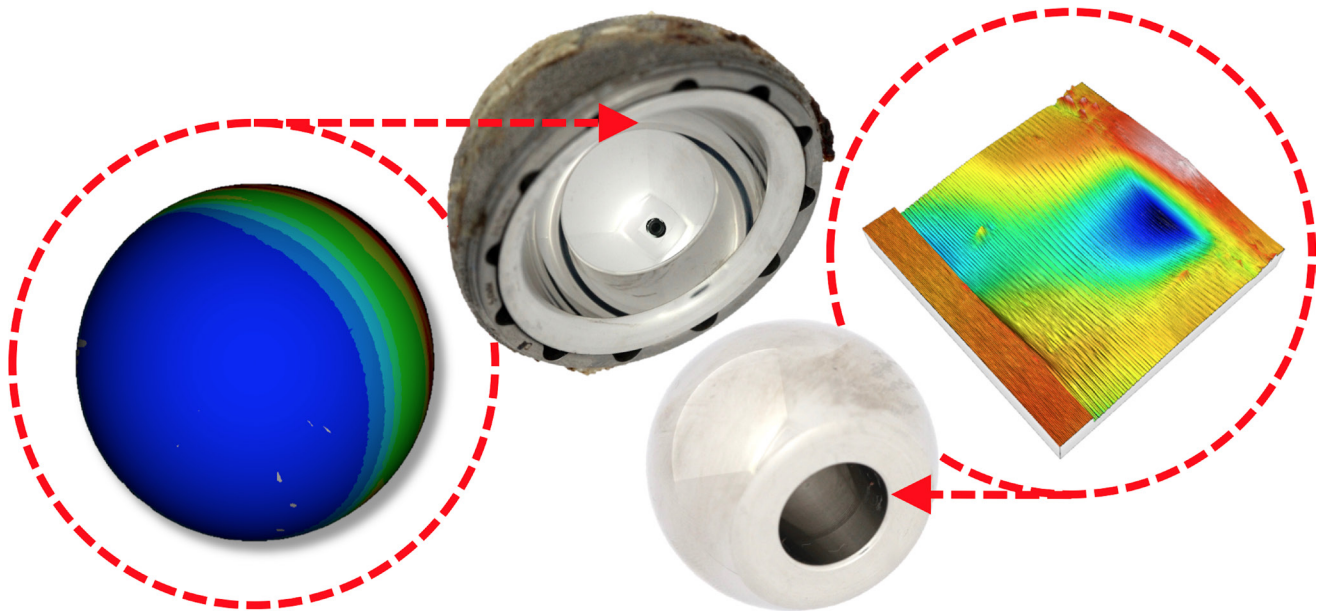


Fig. 2

Metal-on-metal (MOM) 36 mm Pinnacle head and liner components, with corresponding wear maps.

(interquartile range (IQR) 77.59 to 97.40). A total of 32% ($n = 26$) of these hips had clearances below the manufacturing tolerance for this design, as shown in Figure 5.

The median bearing and taper wear rates for these implants were 1.10 mm^3 per year and 0.36 mm^3 per year, respectively. A correlation was not found between the diametrical clearance of these implants and their bearing or taper wear rates (bearing: $r_s = -0.0004$, $p = 0.997$; taper: $r_s = 0.0048$, $p = 0.966$, Spearman's correlation coefficient).

There was no correlation between diametrical clearance and the pre-revision cobalt ($r_s = -0.0600$, $p = 0.621$) and chromium ($r_s = -0.0312$, $p = 0.796$, Spearman's correlation coefficient) whole blood metal ion levels. The median diametrical clearance of edge worn implants was $91.18 \mu\text{m}$ (IQR 79.81 to 98.17), while Pinnacles absent of edge wear had a median diametrical clearance of $82.40 \mu\text{m}$ (IQR 70.75 to 95.51); this difference was statistically insignificant ($p = 0.075$, unpaired t -test; Figure 6).

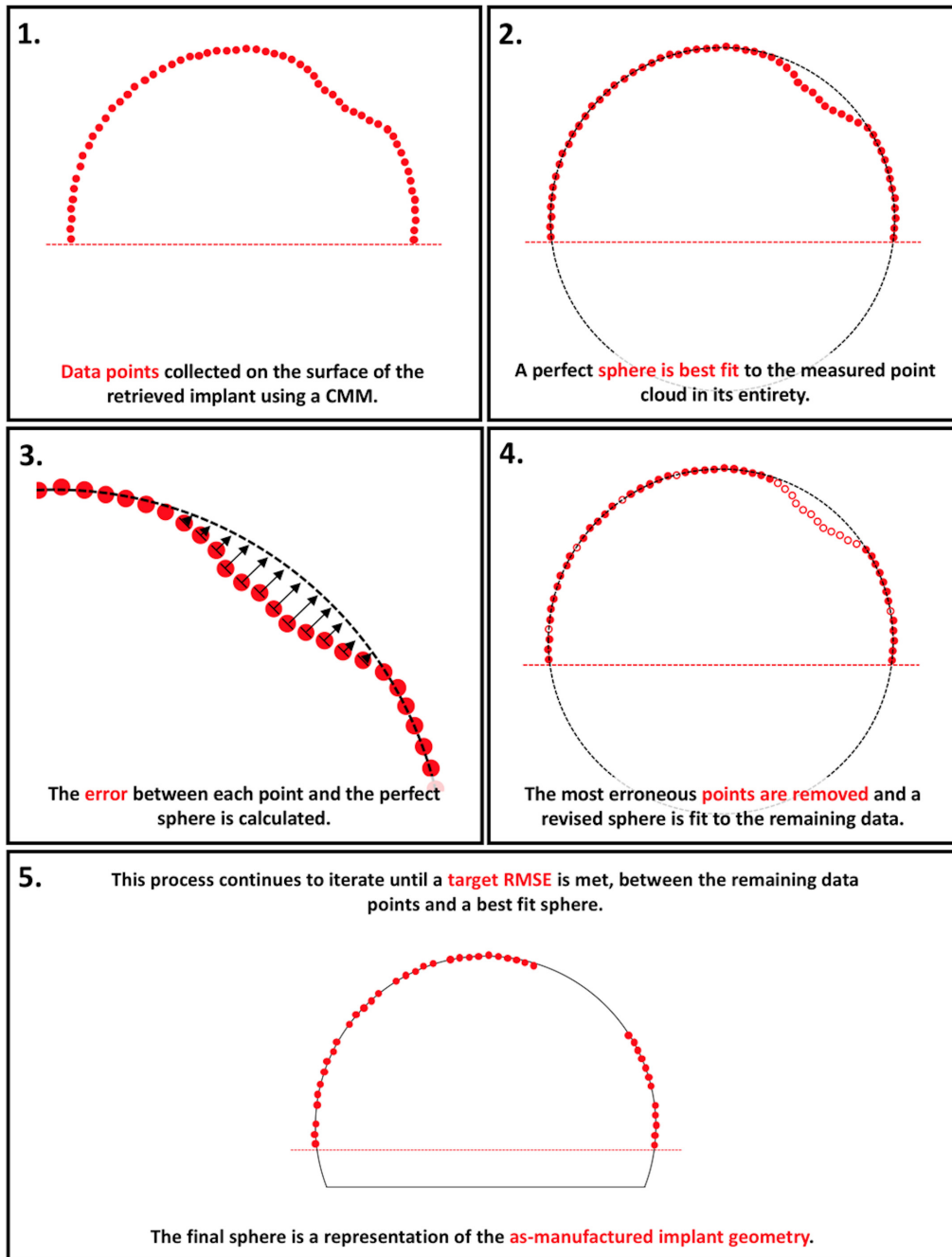


Fig. 3

A schematic diagram demonstrating the process of reconstructing the unworn implant geometry. CMM, coordinate measuring machine; RMSE, root mean square error.

The median bearing wear rate of hips produced below the manufacturing tolerance was 1.52 mm³ per year (IQR 0.61 to 5.69); hips within these specifications had a median bearing wear rate of 1.08 mm³ per year (IQR 0.30 to 4.31, Figure 7); this difference was not statistically significant ($p = 0.395$, Mann-Whitney U test). Pinnacles manufactured below and within tolerances had median taper wear rates of 0.22 mm³ per year (IQR 0.05 to 1.17)

and 0.43 mm³ per year (IQR 0.08 to 1.64), respectively ($p = 0.653$, Mann-Whitney U test; Figure 8). These differences were statistically insignificant. A comparison of their whole blood metal ion levels can be seen in Table I. The horizontal and vertical femoral offsets of the Pinnacle hips were comparable between the two groups ($p = 0.818$ and $p = 0.264$, unpaired t -test). Implants manufactured below the specified tolerance had a median inclination of

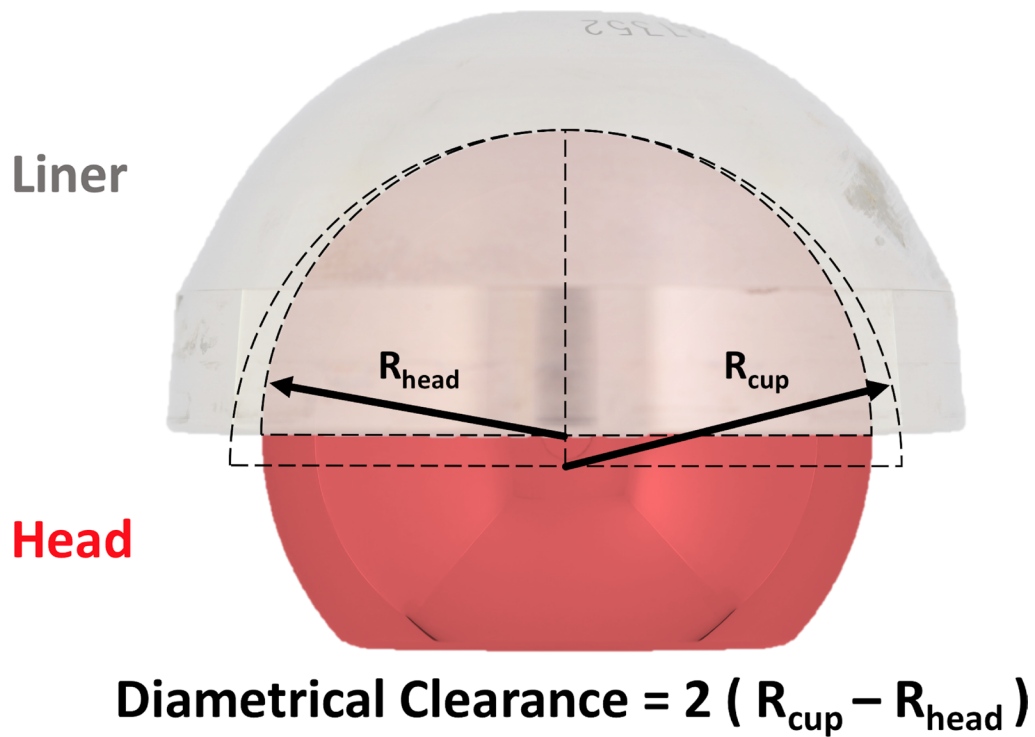


Fig. 4

Diametrical clearance between a head and liner component of a hip arthroplasty.

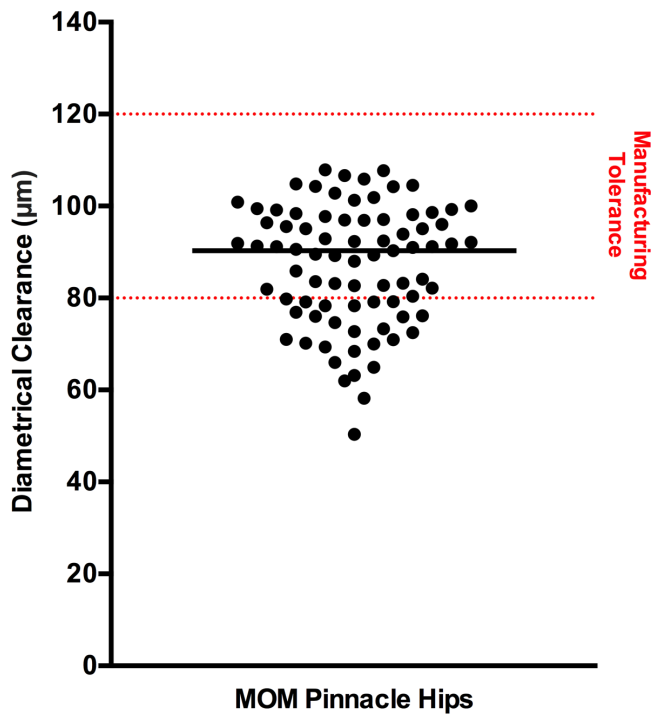


Fig. 5

The diametrical clearance of 81 metal-on-metal (MOM) Pinnacle hips. The black horizontal line represents the median value, while the red lines denote the manufacturing tolerance.

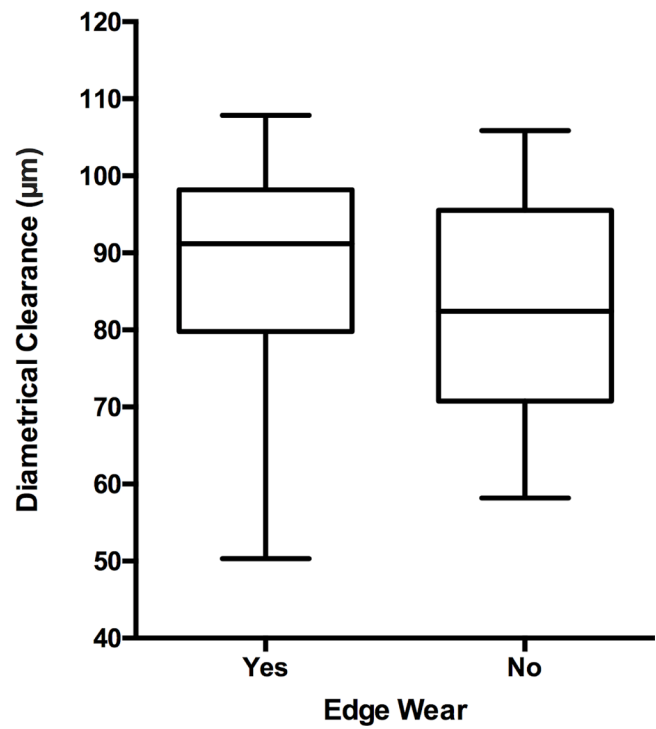


Fig. 6

Box and whiskers plot displaying the median diametrical clearance of implants that were and were not edge worn.

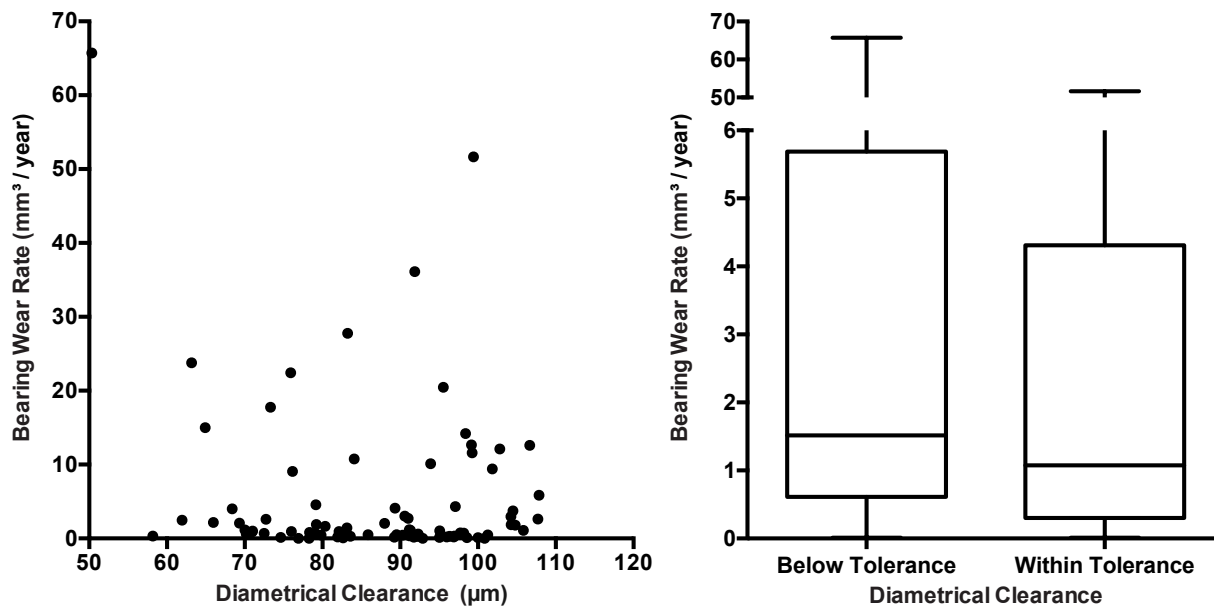


Fig. 7

Bearing wear rate of each implant plotted against its diametrical clearance (left); box and whiskers plot representing the bearing wear rate of Pinnacles with a diametrical clearance below and within the manufacturing tolerance (right).

43.19 (37.73 to 49.38), while hips within this tolerance had a median inclination of 46.19 (IQR 42.91 to 51.93; $p = 0.045$, unpaired t -test).

Diametrical clearances outside the manufacturing tolerance were more prevalent in Pinnacle hips produced from 2007 onwards; preimplantation clearances of below 80 μm were determined to have occurred in 21.43% and 43.59% of implants manufactured before and after 1 January 2007, respectively ($p = 0.004$, unpaired t -test). The median bearing wear rate of implants manufactured before 2007 was 1.06 mm³ per year (IQR 0.26 to 9.16), while Pinnacles produced from 2007 onwards had a bearing wear rate of 1.15 mm³ per year (IQR 0.43 to 2.96; $p = 0.801$, Mann-Whitney U test).

Discussion

This analysis of 81 retrieved MOM Pinnacle hips found that the magnitude of their as-manufactured diametrical clearance did not directly influence their bearing and taper wear rates. Interestingly, a third of all hips were found to have been manufactured with clearances below their specified tolerance; this was more common in hips implanted from 2007 onwards. This did not, however, appear to influence the amount of bearing material loss that occurred.²⁰

These findings are consistent with the understanding that both low and high clearance values offer contrasting benefits to wear performance, which can also vary with in vivo conditions. Additionally, during the steady state phase of implant life, clearance is known to have a reduced influence on wear, compared to the initial period

of bearing conformation.^{2,8,10-12} As this was a retrieval study, investigating this bedding-in wear was, however, unachievable.

The minimization of wear, within MOM hips, has previously been associated with obtaining a clearance value within a specific optimal zone. Here, a compromise is achieved between the benefits of contrasting clearance values; however, this range has not been clearly defined. Lower clearances are said to reduce friction between articulating components, through the formation of fluid film lubrication and reduced contact pressure. On the contrary, higher clearances reduce the size of the contact patch, minimizing the risk of edge wear.^{2,5,8,10-12} Negative clearance (larger diameter head than cup) should also be avoided, which is often a result of a suboptimal pairing of tolerances or component deformation, in vivo.²¹ This can increase frictional torque and possibly lead to acetabular loosening.⁸ Although a manufacturing tolerance of 80 μm to 120 μm is reported for the Pinnacle design, it is unclear whether these values are best suited to minimize its wear.

Designed by the same manufacturer, the MOM Articular Surface Replacement (ASR) was produced to similar specifications; however, Birmingham MOM hips (Smith & Nephew, London, UK) had a larger diametrical clearance of 200 μm.²² Comparing data from The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) for these two designs, Birmingham hips display lower revision rates.²³ It has been previously suggested that despite being detrimental to the formation of an elastohydrodynamic lubrication (EHL) film,

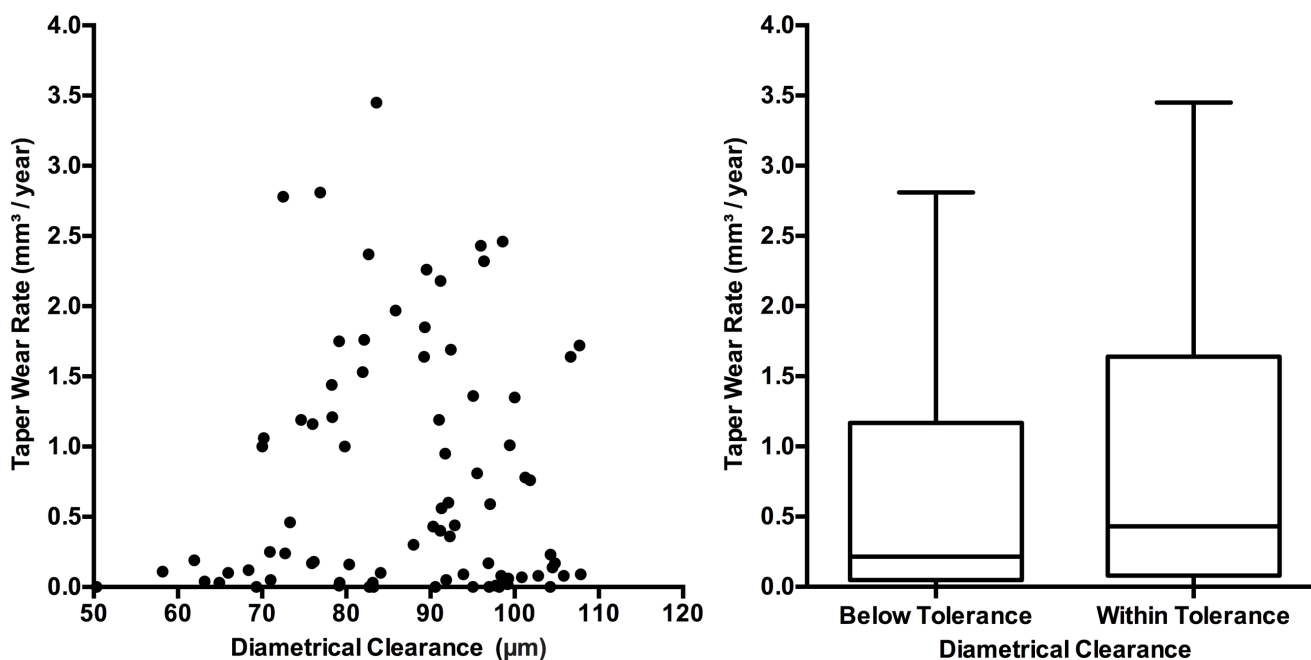


Fig. 8

Taper wear rate and diametrical clearance plotted for each implant (left); box and whiskers plot representing the taper wear rate of Pinnacles with a diametrical clearance below and within the manufacturing tolerance (right).

Table I. Whole blood metal ion levels of Pinnacle hips with as-manufactured diametrical clearances below and within their manufacturing tolerance.

Metal ion	Median whole blood ion level, ppb (IQR)		p-value
	Below tolerance	Within tolerance	
Cobalt (Co)	8.5 (5.4 to 18.6)	6.7 (3.8 to 22.7)	0.361*
Chromium (Cr)	5.4 (2.7 to 9.7)	2.8 (1.6 to 10.4)	0.135*
Co/Cr	1.9 (1.3 to 2.9)	2.1 (1.3 to 3.2)	0.477*

*Mann-Whitney U test.

clearances of similar magnitude to the Birmingham hip provide improved lubricant recovery during the swing phase of walking gate.⁵ This becomes increasingly important with lubricating synovial fluids of greater viscosity, in order to maintain fluid film thickness between components and thus reducing frictional torque.⁵ Historically, most MOM hips have had clearance values between the range formed by these two designs. Nevertheless, implant performance is influenced by multiple surgeon, implant, and patient factors, making it difficult to isolate the contribution of clearance to these outcomes.^{24,25} For example, cup articular arc angle is another implant design feature that also contributes to edge wear, which could counteract or complement the effect of clearance.^{8,9,21}

As previously mentioned, reduced clearance between MOM hip components is thought to increase the size of their contact patch, thereby reducing its distance to the rim. Consequently, this increases the probability of edge loading and wear.^{8,21} In the present study, the prevalence of edge wear was not affected by the investigated diametrical clearances. Implant positioning could have

been a confounding factor; however, these implants were collectively well positioned, with respect to the Lewinnek safe zone.²⁶ Nevertheless, they were not necessarily all perfectly positioned, as the Lewinnek criteria do not account for factors such as functional positioning.²⁷ Previous studies have often only considered optimal conditions, neglecting the effect of implant positioning and adverse clinical conditions.^{11,28–30}

The design of a medical device is scrutinized to ensure its safety and functionality; therefore, manufacturers must remain true to their proven concept. Moreover, adhering to approved specifications during production is imperative to providing the best opportunity for implant success. In this study, examples of Pinnacle hips were found to have been produced below their manufacturing tolerance; however, no significant difference was found in their wear performance. This suggests that these lower clearance values may not be suboptimal compared to the values specified by the manufacturer of this hip design. Nevertheless, the reader must be reminded that these were all failed implants, revised for ARMD, which may have been influenced by even the lowest levels of material loss. As a result, it is difficult to make a specific evaluation regarding an optimum clearance range.

In agreement with a previous study,¹⁴ examples manufactured below tolerance were more prevalent in Pinnacles produced after 1 January 2007. However, there was again no significant difference in their bearing or taper wear rates, compared to hips manufactured pre-2007.³¹

A limitation of this retrieval analysis, compared to simulator studies, is that the bedding-in wear rate could not be isolated from the results, despite it being the stage at which clearance has the largest influence on wear.^{2,8,10-12} The reader should also be reminded that the as-manufactured geometry of these implants was obtained through a process of postdiction, contrary to preimplantation measurements. The method used to calculate these dimensions could be somewhat limited in the scenario of a non-spherical original state. As this study only analyzed one implant design, it is also difficult to define an optimum clearance range for MOM implants, considering the number of other design features that can contribute to wear.

In conclusion, the present study found no correlation between implant clearance and wear performance. Following reconstruction, a number of implants from this series of hips were found to have had a diametrical clearance below their specified manufacturing tolerance; however, this did not appear to impact their mechanical wear. Considering the large number of variables that influence the wear of MOM hips and the conflicting benefits of contrasting clearance values, the optimum range that minimizes material loss should be considered design specific, rather than a single universal range.

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Author contributions:

- S. Bergiers: Designed the study, Collected, analyzed, and interpreted the data, Wrote the manuscript.
- H. 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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Ethical review statement

- 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.

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