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Retrieval analysis and principal variable analysis of 127 M2a-38mm™ metal on metal hip replacements

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Abstract

Background: The objective of this study was to investigate the factors which affected the material loss from 127 M2a-38mm™ hip replacements.

Methods: The alignment and patient data was obtained for 127 patients. The explants bearings and tapers were measured to determine the level of material loss and their geometry.

Results: 87 joints were edge wearing (EW), 28 normally wearing (NW) and 12 had edge interaction (EI). The NW joints were wearing at a mean bearing combined rate of 0.34 mm^3/yr. For the NW joints, bearing clearance was linked to the bearing combined volumetric loss rate ($r = 0.446$). The rates of loss from the head's taper was 0.21 mm^3/yr. Lower wearing and lower clearance joints had higher values of loss from the tapers. The taper loss from joints with a positive clearance were significantly higher ($p = 0.026$) than those with a negative clearance.

Conclusions: The results demonstrate that bearing loss rates for NW joints was as expected. The high number of joints showing signs of edge wearing resulted from low clearances and a low cup articular arc angle. The taper loss was lower than other similar joint designs with positive clearances resulting in greater loss.

Keywords: Retrieval analysis, Metal on Metal, M2a-38mm, Wear, Taper

1. Introduction

The performance of metal on metal implants in-vivo is multifactorial with multiple variables originating from the patient, the surgery and the implant design and finish all interacting. Previous studies have reviewed cohorts of different joints designs and the variables influencing the performance of particular interfaces such as the bearings(1-3) or the taper interfaces(4-6).

The performance of the Biomet M2a-38mm™ joints has been reported within the literature and the joint registries from around the world. The cohort within this study were followed to assess their performance as part of a different project and their 5 years revision rate was 4.6%(7). In 2013 the Finnish arthroplasty register(8) reviewed 2459 of these joints and showed a 96% survivorship at 7 years, with a later study by Lombardi et al.(9) on a cohort of 636 of these joints, demonstrating a 87% survivorship at 12 years. Biomet themselves evaluated a cohort of 4313 of these joints and found a survival rate of 90.93% at 7 years(10). As a result of changing market demand and low product utilisation, the joints ceased to be marketed in Europe in December 2012, and a voluntary field safety corrective action which was released in April 2016 after analysis of the joints performance in the national joint registry for England, Wales and Northern Ireland.

The current study aims to determine the in-vivo wear performance of a cohort of M2a-38mm™ joints, and undertakes to identify the dominant variables which affected the rate of material loss from the bearings and the taper interface of these joints.

2. Materials and Methods

2.1 Implants

The cohort consisted of 127 M2a-38mm™ retrieved femoral head and acetabular components which had been paired with Bi-metric™ uncemented titanium stems. The stems were not retrieved at the time of surgery. Each joint had patient weight, height, body mass index (BMI), age at primary surgery and functional time (time in-vivo) data. They had implant data determined from the joint specifications: neck angle, horizontal and vertical offset, neck length. The cup inclination and version angles, obtained from pre-revision radiographs, measured using TraumaCad© (Voyant HealthTM, Munich, Germany) 3 times by two individuals. The bearing clearance, the taper angle and the taper clearance angle were determined after retrieval using the methods outline later. The patient demographics and component details are given in table 1.

		All Implants	Normally Wearing	Edge Interaction	Edge Wearing	Normally Wearing vs. Edge Interaction	Normally Wearing vs Edge Wearing	Edge Interaction vs Edge Wearing
						p-value	p-value	p-value
No of Patients		127	28	12	87			
Gender split	male	33	8	1	24			
	female	94	20	11	63			
Age * (Years)		64.5 37.7 - 78.7	63.6 37.7 - 78.7	62.1 45.2 - 72.8	63.9 38.5 - 78.1	0.417	0.703	0.552
Time In-vivo (years)		6.3 1.5 - 11.8	5.9 2 - 8.5	6.3 1.5 - 9.6	6.7 2.6 - 11.8	0.457 ^{T}	0.028 ^{T}	0.511 ^{T}
Neck angle	130°	19	6	1	12	0.335	0.338	0.608
	135°	108	22	11	75			
Horizontal offset (mm)*		39.9 34.8 - 52.7	39.8 34.8 - 52.7	39.9 34.8 - 44.9	39.9 34.8 - 49.8	0.367	0.6	0.393
Vertical Offset (mm)*		31.5 25.8 - 38.6	31.5 27 – 38.6	30.8 27 – 33.8	31.6 25.8 – 36.3	0.244 ^{T}	0.964	0.337
Neck Length (mm)*		34.8 28.8 - 45.7	34.8 28.8 – 45.7	34.8 28.8 – 37.8	34.8 28.8 – 42.7	0.169 ^{T}	0.576	0.313
Bearing Clearance (µm)		78.2 26.3 - 157.5	78.1 34 - 126.4	75.5 50 - 128	78.4 28 - 165.6	0.753 ^{T}	0.956 ^{T}	0.718 ^{T}
Inclination angle (°) *		46 22 - 68	45 36 - 57	51 38 - 66	46 22 - 68	0.197	0.839	0.228 ^{T}
Version angle (°) *		13 0 - 33	14 8 - 33	14 11 - 28	12 0 - 32	0.698	0.027	0.095

Table 1 Details of Implants analysed. P-values presented are for a comparison of means using a t test, except where median is indicated (^{T}) where a Mann Whitney U test was used.

2.2 Alignment

Based on the acetabular cup wear scar location, the joints were categorised as either normally wearing (NW), edge wearing (EW) or edge interaction (EI) (Figure 1). NW joints had a wear scars, the centre of which resided within the bearing surface of the cup. The EI as those which showed a wear scar within the bearing surface of the cup but which had material loss from the rim. The EW joints were those where the deepest point of the wear scar resided at the edge or rim of the cup bearing surface.

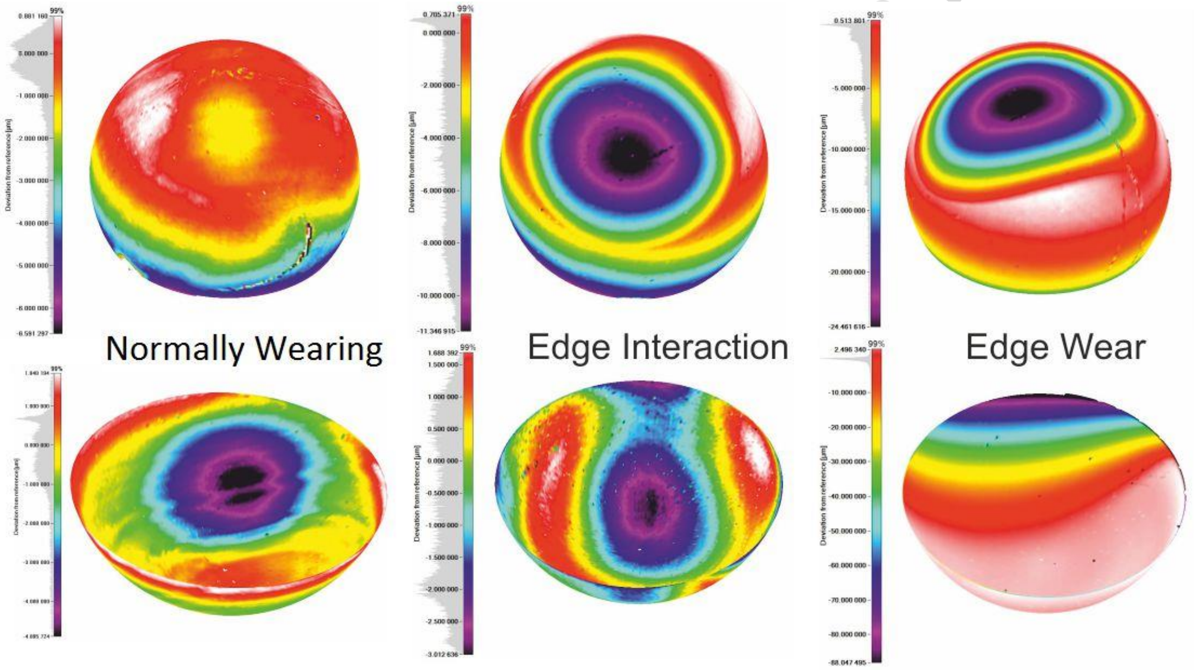

Figure 1 Wear scar category representations

2.3 Geometry and Material loss assessment

Implant geometry and the volumetric loss from the bearing and taper surfaces were obtained using an optical coordinate measuring machine (OrthoLux, RedLux, Southampton UK). The measurement procedure and validation for the spherical bearing components can be found in Tuke et al.(11). The bearing surface point cloud density was set at 1 point per degree from the pole to the edge of the component and 1 point per degree circumferentially. The femoral components were found to be non-spherical, with two different spherical radii, one for the crest and another for the lower region. The wear scar locations were all located on the region fitted by the crest radii. The linear wear was the maximum linear deviation from the fitted sphere and the volumetric loss, the volume beneath the fitted sphere and the assessed surface within the wear scar region. The bearing clearance (table 1) was determined as the diameter of the acetabular cup bearing surface minus the diameter of the sphere fit to the crest of the femoral head. Twenty of the acetabular cups of the NW joints were assessed to determine the cup articular arc angle (CAAA)(2). The mean CAAA was 156.79°.

The taper measurement method and its validation have been published previously in Cook et al.(12). The taper assessments were undertaken on a replica of the taper surface. The replica was made using Microset 202 (Microset Products Ltd, Nuneaton, UK) which has an ability to reproduce surface features with a resolution of 0.05 µm. The taper surface was imaged with a point density of 2 points per degree circumferentially and 70 points per mm along the length. The damaged regions and any regions with material deposits were excluded and a cone fitted to the remaining original taper surface. The trunnions were not assessed in this study, as the stems were retained in-vivo and were therefore unavailable for assessment. The taper clearance angle was calculated in accordance with Kocagöz et al. (6) using on a constant 4° trunnion angle.

2.4 Statistical analysis

All variables were assessed for normality and described using the appropriate summary statistics according to their distributional properties. The choice of test between groups also depended on normality (i.e. t test vs. Mann Whitney U). Similarly, tests of linear association between continuous variables were chosen according to whether both variables being tested were displaying characteristics of a normal distribution; Pearson's correlation for normal and Spearman's for non-normal. All tests were two-sided and conducted at the 5% significance level. All statistical analyses were carried out using Excel (Microsoft Corporation), Sigmaplot (Systat Software, California, USA) SPSS version 24 (SPSS software, IBM Corp., Armonk, NY) and R 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

Comparison of the wear performance between the groups demonstrates a significantly higher rate of loss from the bearing surfaces for the EW group (Table 2). However there was no significant difference between the rate of loss from the tapers in the EW and the NW group.

		Normally Wearing	Edge Interaction	Edge Wearing	All Implants	Normally Wearing vs. Edge Interaction	Normally Wearing vs Edge Wearing	Edge Interaction vs Edge Wearing
Number		28	12	87		p-value	p-value	p-value
Femoral head	Mean	0.30	0.49	4.1				
	Median	0.19	0.33	1.73		0.179	< 0.001	< 0.001

	Range	0 - 1.06	0.04 - 1.73	0.25 - 46.11				
Acetabular cup	Mean	0.04	0.09	4.23				
	Median	0.0001	0.05	1.04		0.068	< 0.001	< 0.001
	Range	0 - 0.35	0 - 0.38	0.02 - 35.12				
Bearing Combined	Mean	0.34	0.58	8.33				
	Median	0.25	0.38	2.89		0.114	< 0.001	< 0.001
	Range	0 - 1.09	0.12 - 2.11	0.29 – 81.22				
Taper	Mean	0.27	0.30	0.18	0.21			
	Median	0.19	0.33	0.06	0.10	0.605	0.110	0.045
	Range	0 - 0.80	0.004 - 0.70	0 - 1.1	0 - 1.1			

Table 2. Rates of material loss from the implants

Comparison between the bearing combined rate of loss and the independent variables for the NW joints, showed significant correlations between the bearing clearance and the bearing combined volumetric loss rate (r = 0.446, p = 0.018), with an increase in the rate of loss for the higher clearance joints (Figure 2).

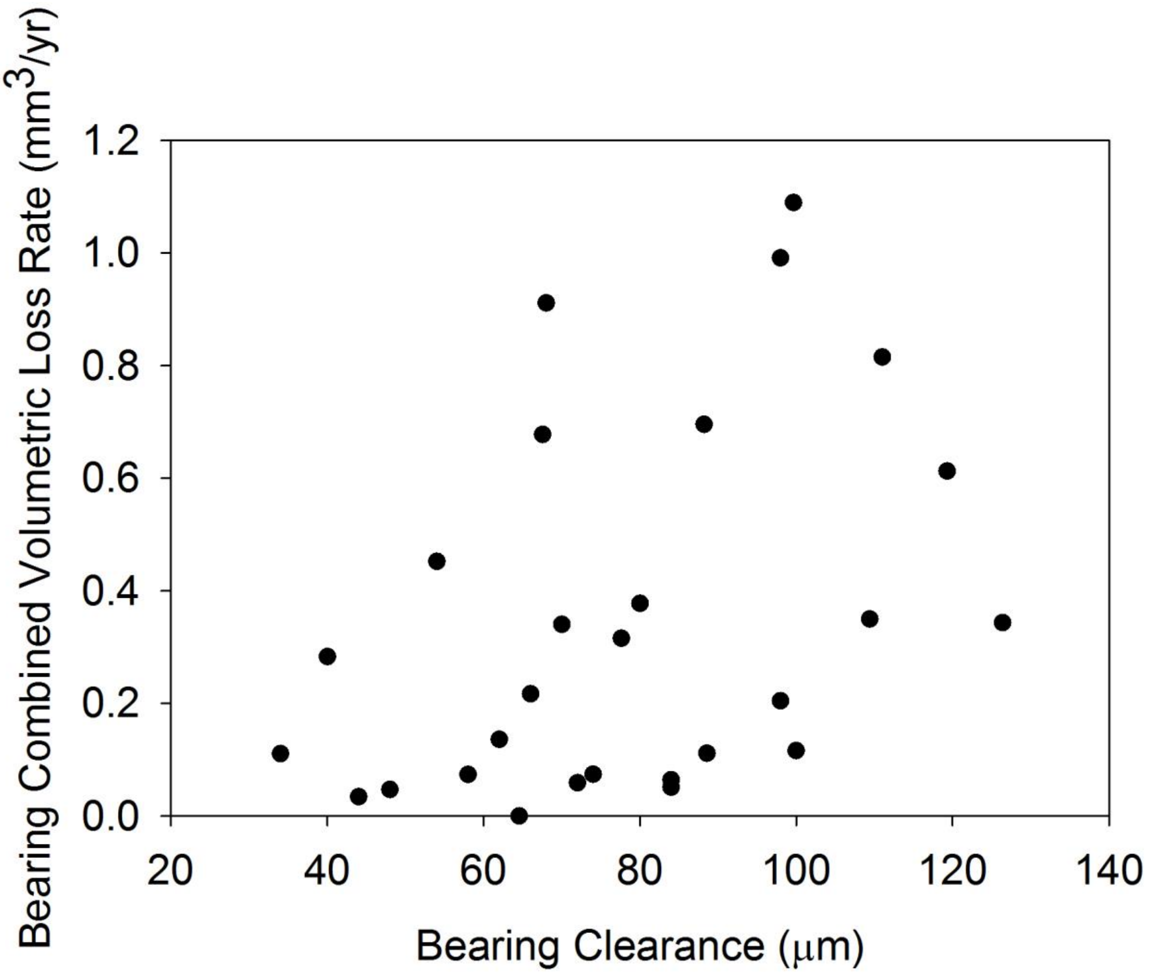

Figure 2 Bearing Clearance vs. Bearing combined volumetric loss rate for the NW Joints.

For the EW joints, the bearing combined volumetric loss rate was linked to bearing clearance ($r = 0.327$, $p = 0.018$, Figure 3) and the inclination ($r = 0.276$, $p = 0.01$, Figure 4) and version angle ($r = 0.353$, $p < 0.001$, Figure 5) of the cup.

A best subsets regressions analysis was performed for the prediction of the bearing combined volumetric loss rate for the NW and EW groups, resulting in r^2 values of 0.439 and 0.211 respectively. However, the variance inflation factor indicated that the degree of collinearity was too high (>10) between height, weight and BMI as well as the horizontal offset, vertical offset and neck length. Exclusion of BMI, neck length and neck angle as it was a non-continuous variable, resulted in new models (table 3) with r^2 values of 0.409 for NW joints and 0.201 for the EW joints.

	EW $r^2 = 0.201$					NW $r^2 = 0.409$				
Variable	Coef.	Std. Error	t	P	VIF	Coef.	Std. Error	t	P	VIF
Constant	-13.766	40.19	-0.34	0.73	0.00	1.513	1.953	0.78	0.45	0.00
Height	-8.108	20.59	-0.39	0.70	1.52	-0.991	1.208	-0.82	0.42	3.15
Weight	-0.087	0.12	-0.73	0.47	1.41	-0.003	0.006	-0.49	0.63	2.10
Age at Surgery	-0.083	0.19	-0.44	0.66	1.26	0.000	0.006	-0.07	0.95	1.37
Time in-vivo	0.346	1.05	0.33	0.74	1.37	0.038	0.048	0.80	0.44	1.45
Horizontal OFFSET	0.565	0.65	0.86	0.39	2.07	0.056	0.029	1.93	0.07	4.54
Vertical OFFSET	0.010	1.04	0.01	0.99	1.89	-0.055	0.033	-1.65	0.12	2.24

Cup Inclination	0.193	0.17	1.12	0.27	1.32	-0.007	0.016	-0.45	0.66	2.02
Cup Version	0.380	0.22	1.74	0.09	1.54	-0.005	0.011	-0.47	0.65	1.26
Clearance Crest	0.102	0.06	1.75	0.09	1.09	0.004	0.003	1.54	0.14	1.30

Table 3. The Best subsets regression models for the prediction of the bearing combined wear rates of the EW and NW groups.

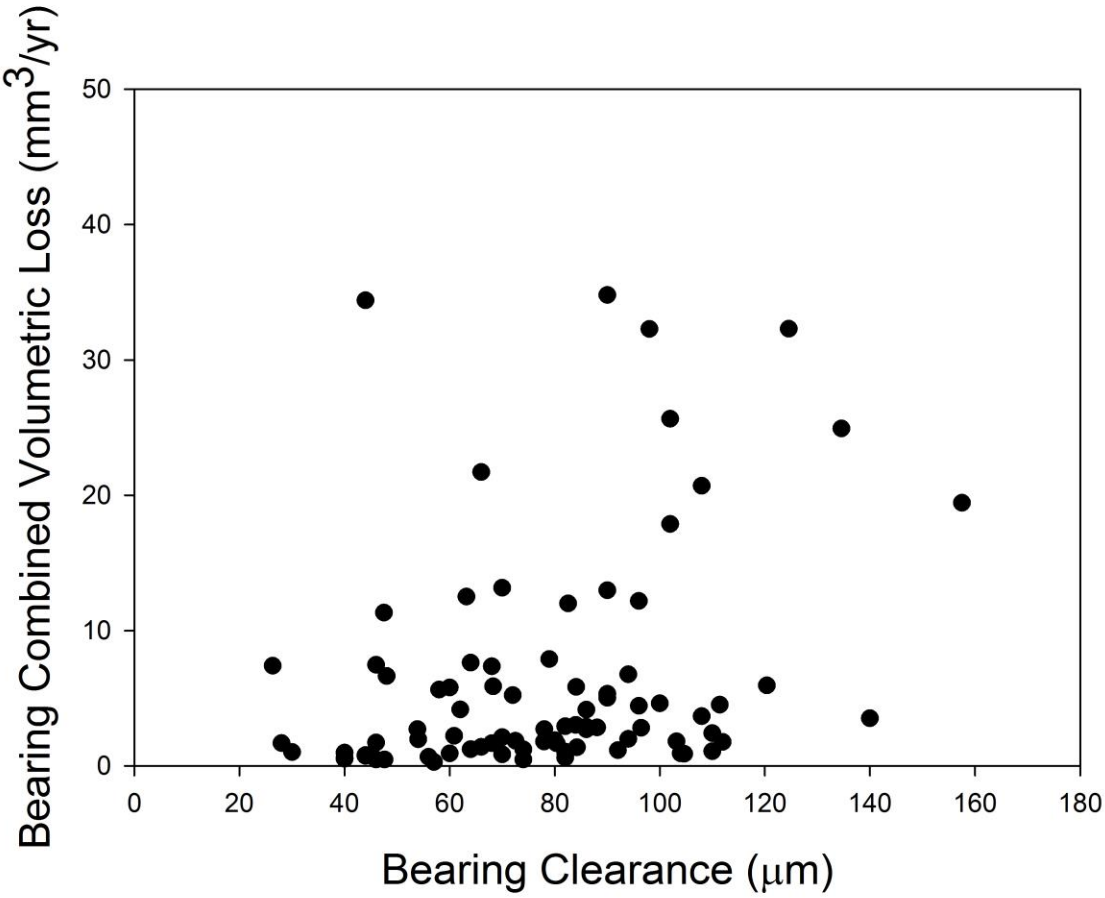

Figure 3 Bearing Clearance vs. Bearing combined volumetric loss rate for the EW Joints.

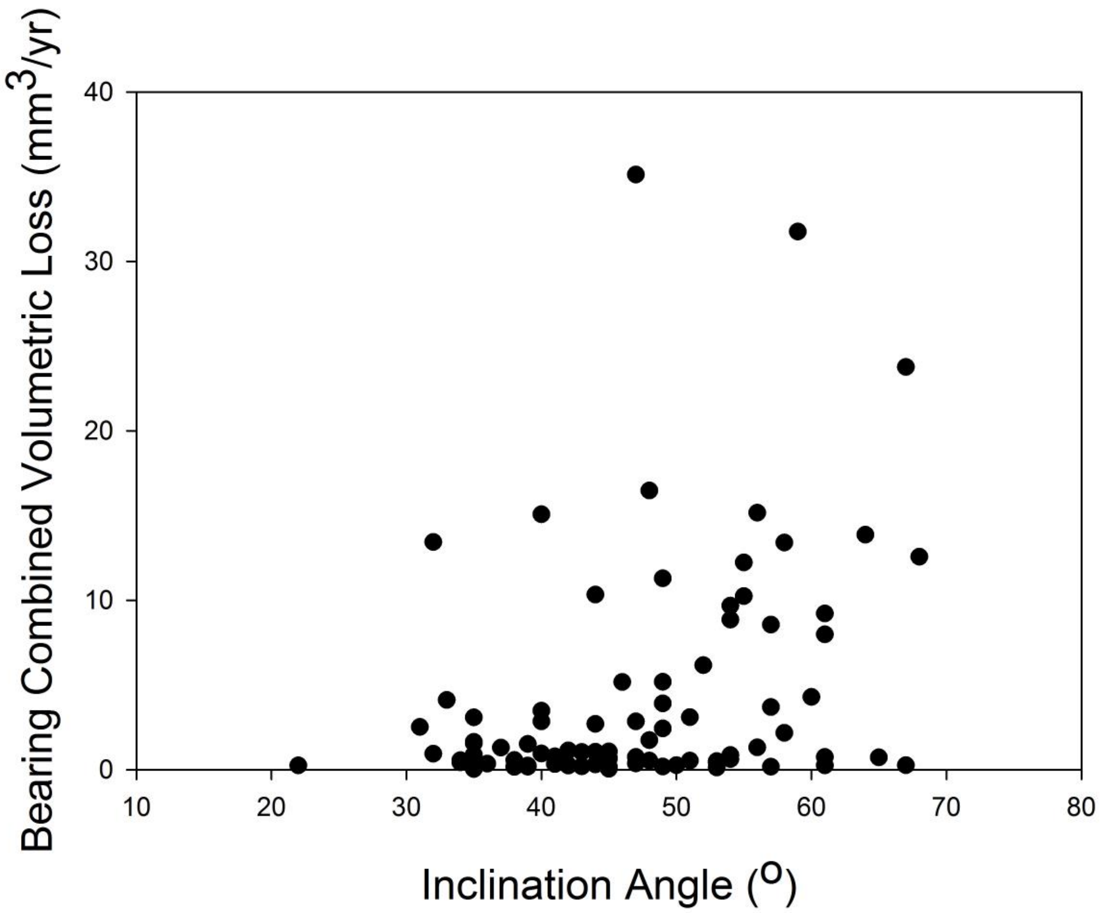

Figure 4 Cup Inclination Angle vs. Bearing combined volumetric loss rate for the EW Joints.

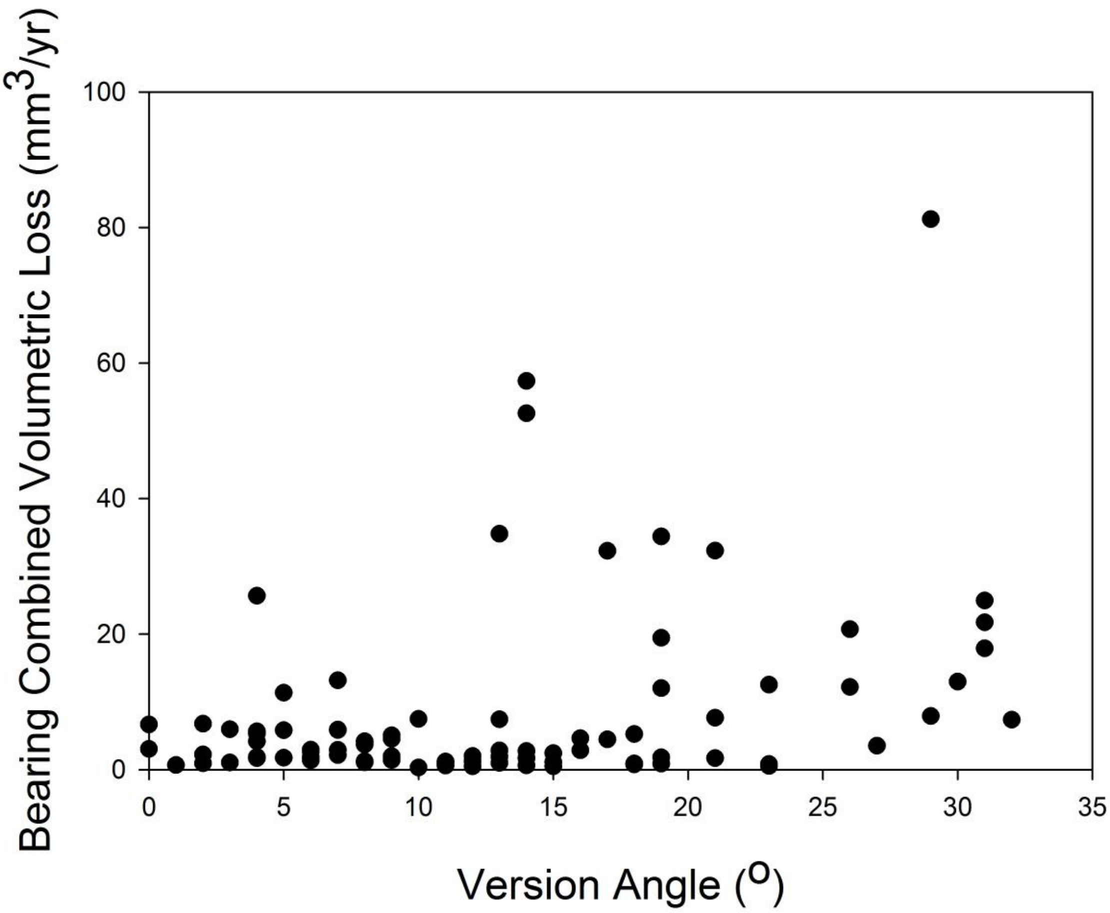

Figure 5 Cup Version Angle vs. Bearing combined volumetric loss rate for the EW Joints.

The positioning of the joints was reviewed with regards to the bearing classification (Figure 6). If the safe zone defined by Grammatopoulos et al(13) is considered, then 59 (46.4%) of the joints were positioned in the "safe zone", 29 of those were EW (33.3% of the EW group), 22 were NW (78.5% of the NW group) and 8 were showing EI (66.7% of the EI group).

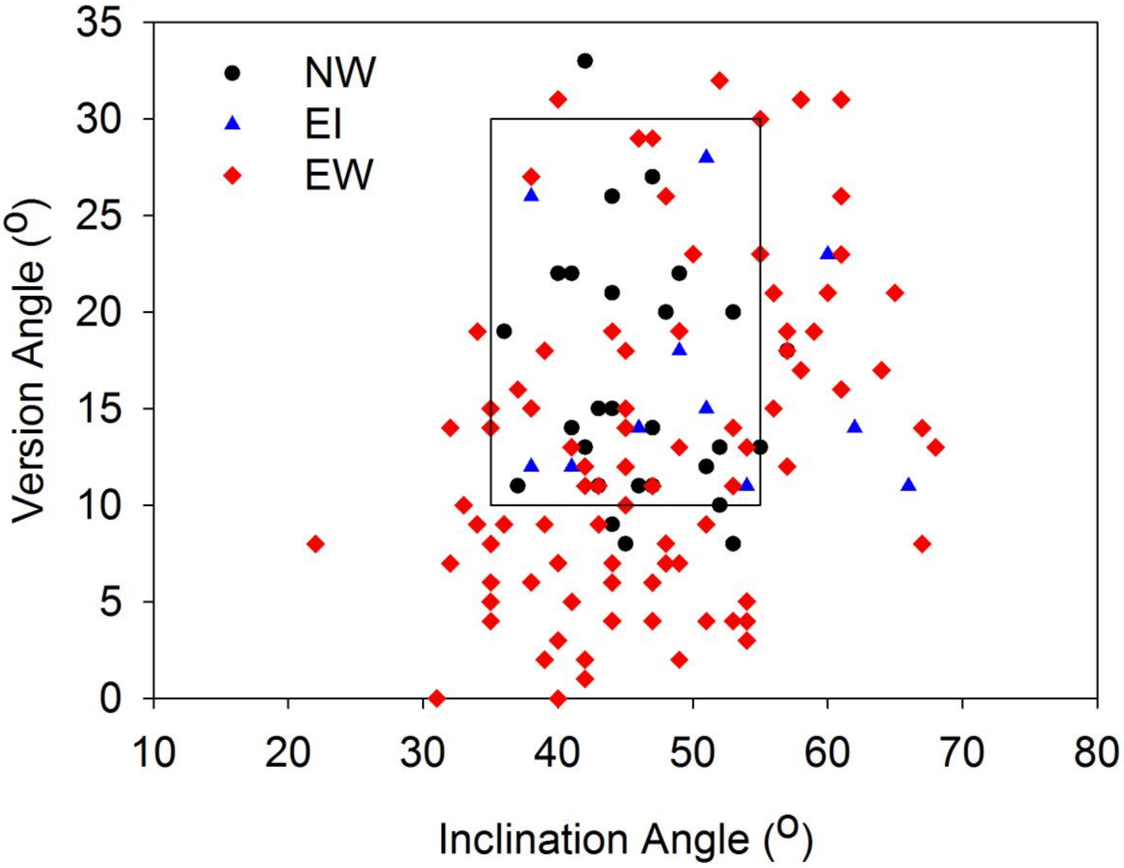

Figure 6. Version and inclination angle values of the bearings from the three different joint classifications, showing the safe zone of Grammatopoulos et al (13)

The taper loss wasn't linked to any variables in the NW group. When the tapers were considered as a full cohort, the volumetric loss rate was significantly linked to 3 variables, the bearing clearance r = -0.281 ($p < 0.01$), patient weight r = 0.253 ($p < 0.01$) and bearing combined volumetric rate r = -0.278 ($p < 0.01$).

A best subsets regressions analysis was performed for the prediction of the taper volumetric loss rate for the whole study cohort, resulting in a r^2 value of 0.242. However, as with the bearing wear the variance inflation factor indicated that the degree of collinearity was too high (>10) between height, weight and BMI as well as the horizontal offset, vertical offset and neck length and the taper angle and taper clearance . Exclusion of BMI, neck length and taper clearance angle as well as the neck angle as it was a non-continuous variable, resulted in a new model (table 4) with an r^2 of 0.188.

Variable	Coef.	Std. Error	t	P	VIF
Constant	-0.435	2.343	-0.19	0.85	0.00
Height	-0.259	0.334	-0.77	0.44	1.72

Weight	0.004	0.002	2.08	0.04	1.47
Age at Surgery	-0.004	0.003	-1.56	0.12	1.22
Time in-vivo	-0.007	0.015	-0.46	0.65	1.27
Horizontal Offset	0.006	0.009	0.62	0.54	2.15
Vertical Offset	-0.005	0.014	-0.34	0.73	1.90
Cup Inclination	-0.001	0.003	-0.38	0.71	1.21
Cup Version	0.003	0.003	0.93	0.36	1.30
Clearance Crest	-0.002	0.001	-2.69	0.01	1.09
Taper angle	0.303	0.580	0.52	0.60	1.04
Bearing Combined	-0.004	0.002	-1.95	0.05	1.17

Table 4 Best subsets regression model for the prediction of the taper volumetric wear rate for the whole cohort combined.

The taper clearance angle values were not significantly correlated to the rate of loss from the taper for the whole cohort, however, observation of the data implied an effect (Figure 7). The taper clearance angles ranged from -0.11° to 0.09^{O} and when the median volumetric rate of loss was compared between those with a positive clearance to those with a negative clearance using a Mann-Whitney Rank Sum Test, the difference was found to be significantly different p = 0.026.

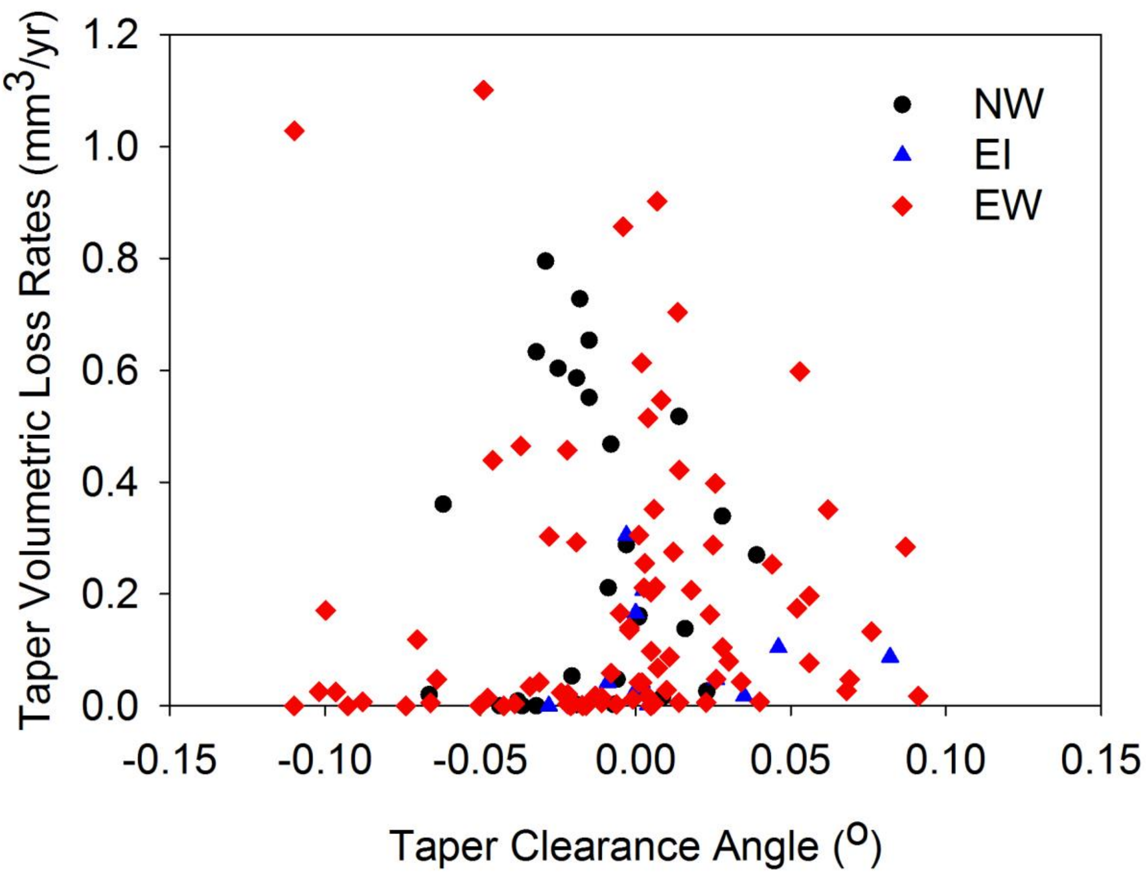

Figure 7. The taper loss rate values compared to the taper clearance

4. Discussion

Of the 127 joints reviewed in this study, 87 of them were EW and exhibited wear rates which were significantly higher than those of the EI and NW groups. 28 of the joints were classified as NW with the mean rate of loss from the bearings combined being 0.34 mm^3/yr. Only two studies have presented volumetric rate measures from well aligned bearings, Morlock et al.(14) reported mean bearing combined rates of 1.10 mm^3/yr for a cohort of resurfacing joints, while Cook et al.(15) reported mean rates of 0.96 and 0.41 mm^3/yr for BHR and Adept modular total hip replacements respectively, all of which are higher than that reported here.

The correlation analysis for the groups provided a number of significant correlations between the rates of material loss from the joints and the patient and joint specific variables. In both the NW and the EW group the bearing loss rate was positively correlated to the bearing clearance, implying that a lower clearance was linked with a lower rate of volumetric loss.

This is in agreement with the findings of previous retrieval studies on MoM joints,(3) and hip simulator studies(16-19) that lowering the clearance enhances the wear performance of MoM bearings. Smith et al. showed that a reduction in clearance from 250-300µm to 80-120µm resulted in a 4 fold reduction in running in wear and two fold reduction in steady state wear. Likewise Rieker et al. showed that changing the clearance from 300 to 100µm afforded a nearly 70% reduction in running in wear. Both Hu et al.(18) and Tuke et al.(20) demonstrated that the effect was due the changes which occur to the bearings during running in, with the wear patch formed on the femoral head conforming towards the radius of the cup and an optimal contact area. The larger the clearance, the greater the material loss required to obtain this. Further to this, Brockett et al.(19) also showed that as the bearing clearance increased, the lubricant film thickness decreased which resulted in an increase in friction between the bearings, likely due to increase asperity contact between the bearing surfaces.

There have been concerns raised about low clearance joints, with evidence of deformation during insertion resulting in negative clearances and equatorial contact between the femoral and acetabular components(21). The cohort of M2a-38mm™ components reviewed in this study showed no evidence of equatorial contact and the high wall thickness of the acetabular cups likely precluded this as a factor. Hu et al.(22) also expressed concern about the lubricant starvation of low clearance bearings if the synovial fluid viscosity were higher than that of the 25% bovine serum used in simulator studies. While this could have been an issue, it is not present in the results for the NW group. This may in part be due to the non-spherical nature of the M2a-38mm™ femoral head components, with one radius over the cap and a lower radius to the sides (median radial difference

4.5µm). The work of Meng et al.(23) found that the non-spherical shape enhanced the lubrication of the bearing above a constant clearance joint, although no wear data was presented.

High inclination and both high and low version angles were significantly linked to higher acetabular wear in the EW group. However, the link between the rates of loss from the bearings and the component positioning were weak, with joints positioned within the 'safe zone'(13) showing evidence of edge wear and joints positioned outside this zone showing normal wear. The accuracy of implant positioning assessment from conventional radiographs has been an area of debate, particularly when compared to positioning measured obtained via CT imaging. Studies comparing the two techniques conflict with Kalteis et al. (2006) finding no significant difference between CT and plain radiograph assessment for inclination, but significant errors in the determination of anteversion(24), while Lu et al. using a more comprehensive Bland-Altman analysis found no significant difference in the measured anteversion and a 2.3° ± 1.8° difference in inclination(25) although this was not considered clinically significant. In this study every effort was made to ensure the accuracy of the positioning measures, with assessment performed 3 times by two individuals.

While positioning is a factor, there are also implant and patient specific factors which can increase the risk of edge loading. Both Underwood et al.(2) and Jeffers et al.(26) demonstrated that a low CAAA and a low bearing clearance can independently increase the risk of edge wearing. Low clearances result in larger contact patches on the bearing surfaces and overlap of the patch and the edge of the bearing surface results in edge wear. As such a lower CAAA will exacerbate this problem, by bringing the cup edge closer to the scar. The joints in this study had both low clearances and an average CAAA of 156.79^{o}, which is at the lower end of the range previously published (2, 27), with only the ASR joint design having a lower CAAA. This is further supported by the positive and significant correlation between the rate of loss from the bearings and the functional time, which demonstrated an increasing rate of loss with time in-vivo. In addition, patient specific factors such as joint laxity and activity levels can increase the bearing wear. Joint laxity wasn't assessed, but can be present post-op or develop with time due to changes in the soft tissues or stem migration. Joint laxity can result in microseparation(28, 29) where during the swing phase the femoral component can microseparate from the cup; at heal strike the head makes contact with the rim prior to relocation in the cup during the stance phase. This will give rise to a wear scar with an EI or EW appearance and increased wear compared to an NW joint. Microseparation, cup positioning and CAAA are not independent. The more lax a joint, the greater the lateral separation and the higher the risk of rim contact during the strike phase of the gait cycle(29), with a low CAAA and poor cup positioning reducing the required separation distance which results in rim contact. This may explain the comparatively low levels of loss from some bearings exhibiting edge wear, but also the appearance of edge wear scars in well positioned components. A measure of the patients' activity levels would have afford us a greater understanding of the wear values. The rates of loss from this study, as is consistent with other retrieval works, is based on loss per year, with no consideration of the number of wear cycles the patient has subjected their joint to. Joints from more active patients would be expected to have increased levels of wear compared to less active patients due to the increased number of cycles to which the joint was subjected.

The levels of loss from the taper junctions in this study were lower than those reported in a number of previous works(4, 5, 30-33), only the pinnacle-articuleze(4) pairing and pinnacle S-ROM(5) were lower. The loss from the taper junctions were significantly, but weakly correlated to 3 variables. Bearing clearance and the rate of loss from the bearings combined were negatively correlated to the taper volumetric loss.

The link between bearing and taper wear likely lies in the frictional torque generated by the bearings, although this is an area of debate. The link between the bearing wear rate and the taper wear is in agreement both in trend and magnitude (r^2 = 7.7%) with that of Hothi et al.(5). Hothi et al.(5) excluded torque as a factor as they found a negative association between bearing wear and taper wear, however bearing clearance wasn't considered in their analysis. Langton et al.(4) found there to be no correlation between their taper wear rate and the bearing clearance and bearing wear rates.

Frictional torque has been demonstrated to increase fretting corrosion(34, 35). Hu et al.(22) demonstrated a link between clearance, lubricant viscosity and frictional torque, with lower clearance joints in individuals with higher viscosity synovial fluids increasing the frictional torque. However, other simulator studies have contradicted this, with Brockett et al.(19) measuring higher friction for higher clearance joints due to reduced lubricant film thicknesses. In both studies new components were used and as Tuke et al.(20) hypothesizes, the frictional torque is likely to increase during the course of in-vivo service due to changes in the bearings. It was notable however, that the tapers exhibiting loss all showed asymmetric wear or toggling, with the highest loss at the distal end of the taper. This is suggestive of toggling(36) which previous works have link to increased lever arms (4) and medio-lateral offsets(37) although no off-set, neck length of other implant specific factors were correlated to the taper loss in this study.

While not correlated to the taper loss, positive taper clearance angles were associated with higher rates of loss when compared to negative taper clearances. This contrast with the findings of Cook et al.(15) who showed a reduced rate of loss in the Adept-CPT tapers which had positive clearances compared to the BHR-CPT combinations which has negative clearances, and Kocagöz et al.(6) who found no differences between positive and negative clearances.

The independent variables and their effects on the bearing and taper loss rates was determined using best subsets regression analysis. The resultant models explained 20.1% and 40.9% of the variation in bearing loss for the EW and NW group respectively and 18.8% of the taper loss.

5. Conclusions

The combined rates of loss from the well aligned bearings from this cohort were 0.34 mm^3/yr, with lower clearances providing lower wear rates. Analysis of the effect of positioning demonstrated that edge wearing could occur in components, which, according to the Grammatopoulos et al(13) definition were considered to be well aligned in-vivo. This was attributable to the low CAAA and low bearing clearance although joint laxity may have also had an effect but was not assessed. The rate of material loss from the tapers was lower than the majority of previously reported rates in the literature, with high taper loss linked to patient weight, bearing wear and low bearing clearances. Positive taper clearance angles were linked to higher levels of taper loss when compared to those with negative clearances.

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6. References

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Article summary: This study is one of the largest single joint design retrieval analysis reviews undertaken and provides a number of key findings relating to joint performance which only a study of this size could present. This is the third paper to provide in-vivo wear rates for well aligned bearings. These are hugely valuable to manufacturers, designers and the community as a whole. The link between wear and bearing clearance is hugely important as it provides evidence that backs up the in-vitro testing results and many manufacturers design justification. The taper clearance angle effect on taper performance, is interesting for any joint design using a metal head and not just metal on metal joints. The publication of the low clearance and CAAA issue with regards to these joints will also be of interest to the community.

Conflicts of interest

Conflict of Interest: Richard Cook has undertaken paid retrieval analysis work for Biomet. John Britton and Geoff Stranks have both received research an institutional support as principal investigators from Biomet. Toby Briant-Evans and Jamie Griffiths have both undertaken Biomet funded fellowships.