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

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The objective of this study was to investigate the design, alignment and patient specific factors which affected the level of material loss for the bearing surfaces and taper of a cohort of M2a-38mm™ MoM hip replacements.

Introduction

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% [1]. In 2013 the Finnish arthroplasty register[2] reviewed 2459 of these joints and showed a 96% survivorship at 7 years, with a later study by Lombardi et al. [3] 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. As a result 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 NJR

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.

Methods and Cohort

The cohort consisted of 127 M2a-38mm™ retrieved femoral head and acetabular components which had been paired with Bi-metric™ uncemented titanium stems. Measurement of geometry and the volumetric loss from the bearing and taper surfaces were obtained using a non-contact optical coordinate measuring machine (OrthoLux, RedLux, Southampton UK)

Normally wearing joints had wear scars, the centre of which resided within the bearing surface of the cup. The edge interaction joints were classified as those which showed a wear scar, the centre of which resided within the bearing surface of the cup but which had material loss from the rim of the cup. The edge wearing joints were those where the deepest point of the wear scar resided at the edge or rim of the cup bearing surface (Figure 1)

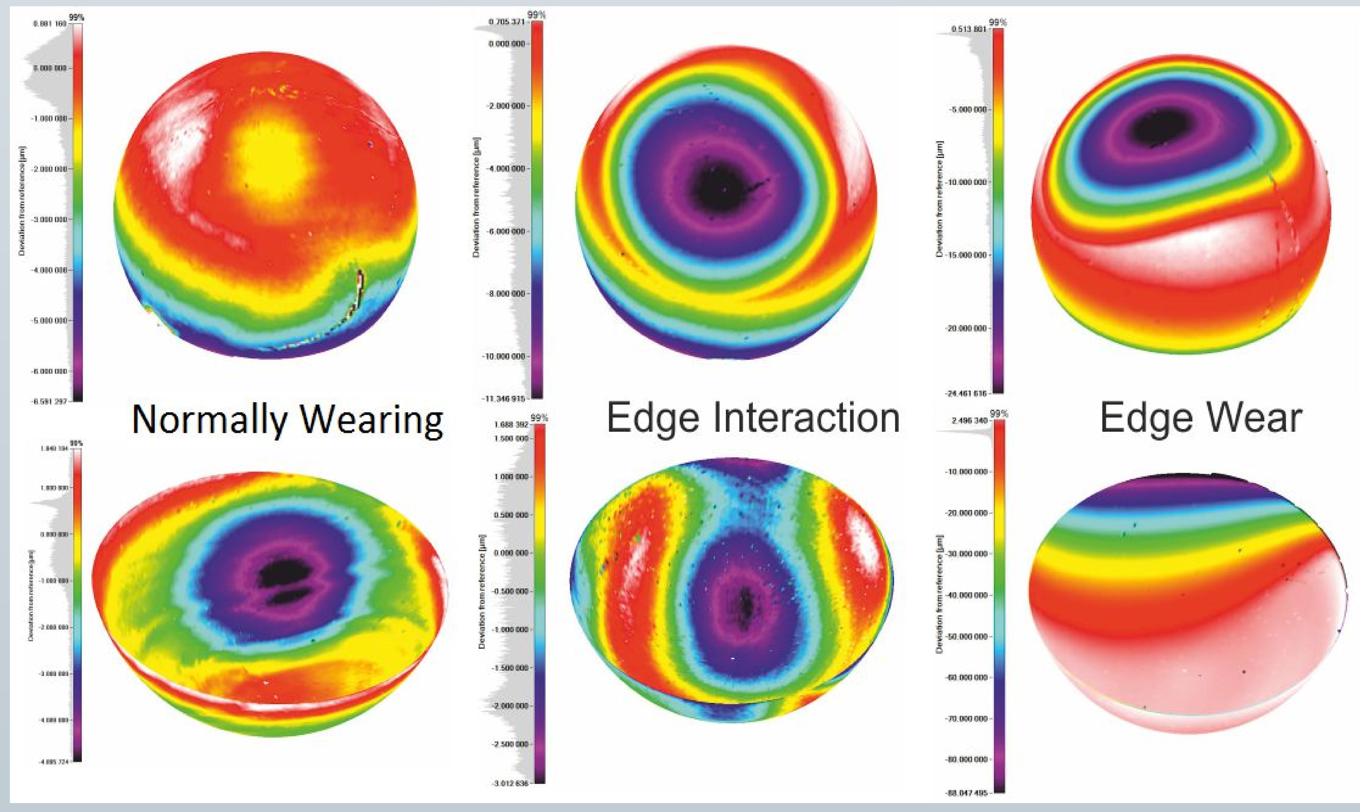

Figure 1 Examples of bearings from the three categorises

Each joint had patient specific data for their weight, height, body mass index (BMI), age at primary surgery and functional time. They also had implant and positional data including neck angle, horizontal and vertical offset, neck length, cup inclination and version angles, the bearing clearance, the taper angle and taper clearance angle based on the perfect trunnion angle of the Bi-metric™ stem. 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

P-values presented are for a comparison of means using a t test, except where median is indicated (*) where a Mann Whitney U test was used.

Results

For the NW joints, the bearing clearance was significantly linked to the bearing combined volumetric loss rate (r = 0.446, p = 0.018), with an increase in the rate of loss from the bearings for the higher clearance joints (Figure 2). Twenty of the acetabular cup bearing surfaces of the well aligned joints were also assessed to determine the cup articular arc angle (CAAA) as defined by Underwood et al.[4] The mean CAAA was 156.79° (154.78° – 158.56°).

		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			

If the safe zone defined by Lewinnek et al. [5] is considered (Figure 3), then 62 of the joints were positioned in the “safe zone”, 41 of those were edge wearing, 17 were normally wearing and 4 were showed edge interaction. When the variables affecting the combined bearing wear rate of the joints positioned within the safe zone was considered (one outlying point was excluded from the analysis), significant correlations were found between the bearing clearance (r = 0.263, p = 0.041) and the Functional time (r = 0.352, p = 0.005).

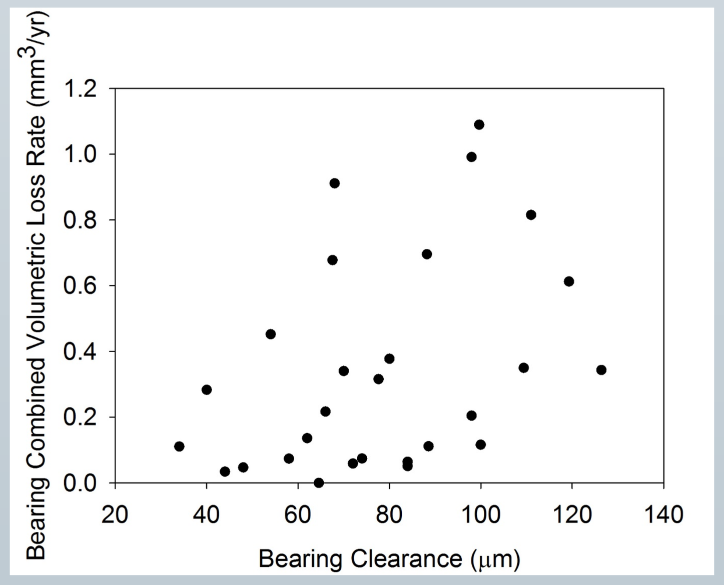

Figure 2 Bearing clearance vs. Femoral head volumetric loss for the NW joints.

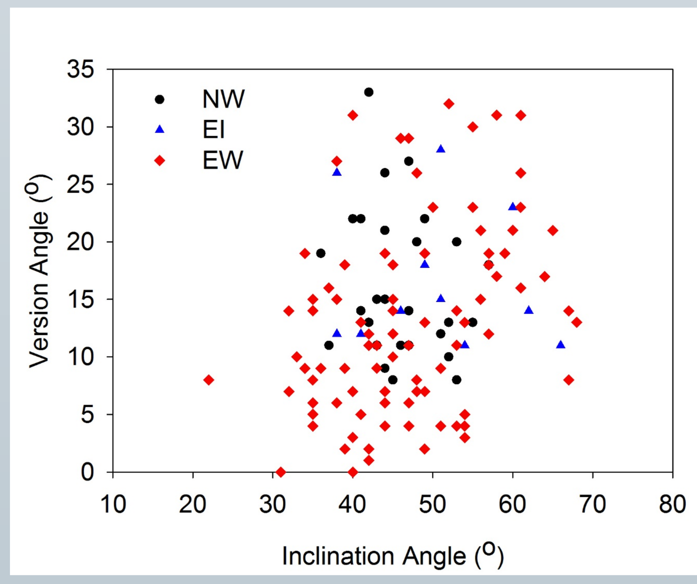

Figure 3 Version and inclination angle values of the bearings from the three different joint classifications.

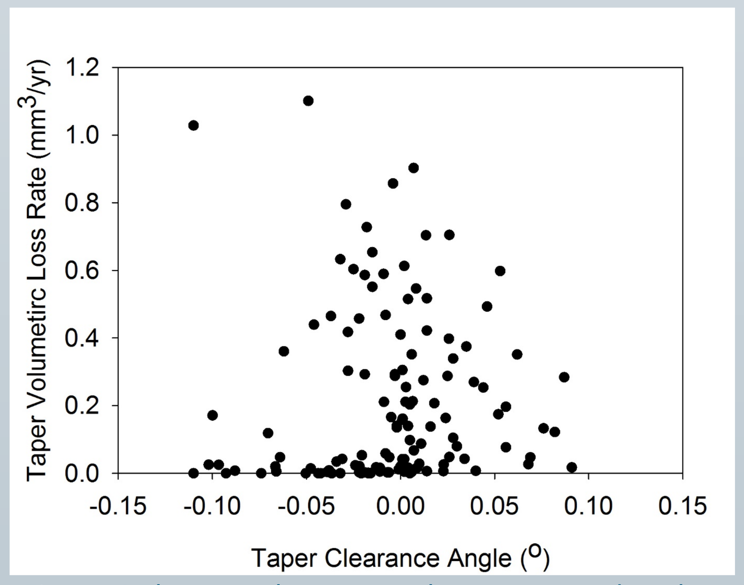

Figure 4 The taper loss rate values compared to the taper clearance

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. It was linked to 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 regression analysis of these variables provided a r^2 of 0.157. The taper clearance angles ranged from -0.11° to 0.09° 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 4).

The analysis of the independent variables and their effects on the bearing and taper loss rates, identified a number of significantly links. However it is noticeable that even when the significant variables are used in combination, only 11% of the variation in bearing loss and 15.7% of the taper loss could be explained.

Conclusions

The rates of loss from the well aligned bearings from this cohort were lower than those reported for other MoM bearings, with lower clearances providing lower wear rates.

Analysis of the effect of positioning demonstrated that edge wearing could occur in components which were considered to be well aligned in-vivo. This was attributable to the combination of a low CAAA and low bearing clearance predisposing the joint to edge wearing.

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.

References

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