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The Performance of Mixed Manufacturer Metal On Metal Total Hip Replacements

Cook R [1], Latham J [1], Wood R [1]

Abstract

Using a femoral head from one manufacturer on the stem of another manufacturer poses the risk that the taper interface between the components may not contact correctly and the performance of the joint will be impaired. The cohorts in this study are a combination of modular Birmingham Hip Resurfacing (BHR) and Adept femoral heads on CPT stems. The study reviews the geometry of the taper interfaces to establish if the taper clearance angles was outside of the normal range for other taper interfaces. In addition the rates of material loss from the bearings and taper and a ranking of the stem damage were reviewed to determine if the levels of loss were above that seen for other similar joints.

The material loss analysis demonstrated that the rates or levels of loss from the bearings, taper and stem were no different to levels published for manufacturer matched joints and in many cases were lower. The results demonstrate that the taper clearance angles for the mixed manufacturer joints (BHR-CPT: 0.067 to -0.116, Adept-CPT: 0.101 to -0.056) were within the range of other studies and manufacturer matched clearances (0.134 to -0.149).

Using components from different manufacturers has not in this instance increased the level of material loss from the joints, when compared to other similar manufacturer matched joints.

Keywords: *total hip; mix and match; metal on metal*
Level of Evidence: *AAOS Therapeutic Level ?*

Introduction

The use of large diameter Cobalt Chromium femoral head components in total hip replacements has come under scrutiny due to the poor performance of these joints in-vivo. In particular the performance of the taper junction between the head and femoral components. The use of mixed manufacturer components has been a particular area of focus, where the manufacturers' variation in angle of their 12/14 tapers can result in different taper clearance angles and contact lengths 1 from those specified by the manufacturers.

1 Dr Richard Barker Cook, PhD; Professor Robert J K Wood, FREng, CEng, FIMechE, MICorr, FIMMM, FHEA, MInstPhys
University of Southampton, University Road, Southampton, SO17 1BJ, UK
(Direct reprint requests to Richard Cook)

2 Jeremy M Latham, MA, MCh, FRCS(Orth)
Southampton University Hospitals NHS Trust, remona Rd, Southampton SO16 6YD, UK

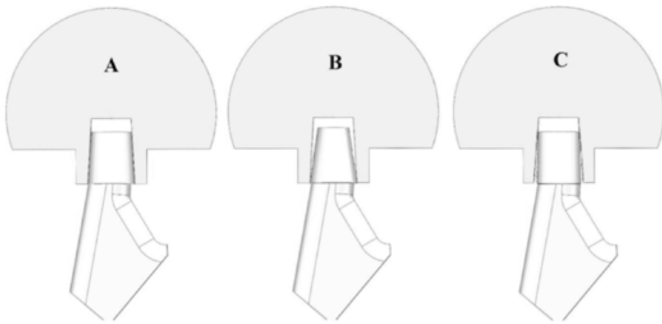

Figure 1. Taper Clearance Angle definition. A. Full length contact, taper angle = trunnion angle, clearance = 0. B. Distal contact, taper angle < trunnion angle, Clearance < 0. C. Proximal Contact, taper angle > trunnion angle, Clearance > 0

The taper clearance angle provides a means of assessing how the male and female components of a taper will contact (Figure 1). A positive clearance indicates that the taper would have contacted at the proximal / narrow diameter end of the taper, while a negative clearance is the opposite, with a distal contact at the larger diameter end of the interface. The angles for the ASR and Articuleze joints presented by Langton et al [2] were 5.670° (5.568° to 5.798°) and 5.639° (5.584° to 5.685°) (taper engagement level identified data) which, when paired with the 5° 43' Corail trunnion [3], provide clearances of -0.047° (-0.149° to 0.081°) and -0.078° (-0.133° to -0.032°) degrees. This range of clearance angles and differences in design specification is further reflected in the study of Kocagöz et al. [1] whose cohort of 50 metal femoral head had a 35:15 split between positive and negative clearance angles. The range of taper clearances within the study [1] was 7.5 to -8 arcminutes (0.125° to -0.133°), with 50% of the values between 5 and -2 arcminutes (0.083° to -0.033°).

This analysis demonstrates that there is no consistent or single design philosophy for taper contacts between manufacturers, with some opting for proximal contacts and positive clearances and others for distal contacts and negative clearances. In the case of the ASR – Corail pairings the variation in the measured angle of the tapers provide both positive and negative clearances on the same trunnion.

The analysis of retrieved joints has highlighted three sources of material loss; the bearing surfaces [4-6], the taper interface [7-11] and the cement-stem interface [12,13] each capable of triggering a reaction significant enough to require revision surgery. The ability of bearing surface wear to cause adverse reactions is clear from the retrieval studies [4-6] focused on resurfacing joints. The ability of the material loss from the taper interface to initiate adverse reactions can be demonstrated by the increasing numbers of failures in metal on polymer bearings [7-11]. The issue of debris from the cement stem interface was demonstrated by the work of Donnell et al. and Bryant et al. on the Ultima hip replacement system [12,13], with Hothi et al. [14] showing that damage was present on seven different designs of cemented stem.

The literature contains a number of retrieval studies where the values of linear [6,15-19] and volumetric loss [15,19-24] from the bearing surfaces of metal on metal joints have been presented (Table 1). However, in most studies, the values for edge-wearing components have not been differentiated from those without edge wear, meaning the values provided are not reflective of the true wear rates for these joints. Only two studies [6,17] provided linear wear rates and only one provides volumetric rates [22] which are representative of the bearing performance of well aligned components in-vivo (mean bearings combined: 1.10mm3/yr).

There are eight studies [2,19,21,23-27] in the literature which have quantified the material loss from the surfaces of female tapers of both manufacturer matched and mixed manufacturer metal on metal joints (Table 2). The published mean volumetric wear rates from these studies range from 0.85 to 0.127 mm3/year, with median values ranging from 0.132 and 0.238 mm3/year (Table 6).

Cook et al. [28] assessed the volume of material lost from the surfaces of cemented stems, showing mean rates of loss between (0.003 and 1.9mm3/yr), however these measures has a +/-16% error due to the both the complexity and variability in the geometry of different components. The accepted method for the characterization of the level of damage to cemented stems is the 5 level ranking developed by Bryant et al. [12]. Two studies have utilized this score, Bryant et al. [12] who provided a mean score of 2.9 for 105 manufacturer matched cemented components, and Hothi et al. [14] who, while not providing an average value, reported 27 of the 36 stems reviewed as having a score of 3 or over.

These previously published values of material loss and ranking obtained from retrieved metal on metal joints, provide the baseline against which the performance of other joints can be compared. The objective of this study is to determine how the levels of material loss from three sites on a group of mixed manufacturer joints relates to other previously reported levels of material loss from manufacturer matched joints. We hypothesize that the level of material loss from the bearings, taper and cement stem interfaces will not exceed that of other joint designs.

Table 1: Linear and Volumetric Wear Rates of the bearings surfaces of metal on metal joints

Study	Number of Hips	Joint Deign		Edge worn : non-edge worn	Time In-Vivo (Years)	Femoral Head		Acetabular Cup		Bearings Combined	
						Linear Rate (μm^3/year)	Volumetric Rate (mm^3/year)	Linear Rate (μm^3/year)	Volumetric Rate (mm^3/year)	Linear Rate (μm^3/year)	Volumetric Rate (mm^3/year)
Matthies et al.[6]	60	Modular THR		Edge Worn: 34	Mean: 2.6 (1 - 6.1)			Median: 16.87 (0.82 - 119.15)			
				Non-edge worn: 26				Median: 0.00 (0.00 - 4.77)			
	60	Resurfacing		Edge Worn: 40	Mean: 3.8 (1 - 10.1)			Median: 11.00 (0.77 - 173.81)			
				Non-edge worn: 20				Median: 0.00 (0.00- 6.18)			
Kwon et al.[16]	9	Resurfacing	Pseudotumour	9:0	Mean: 3.6 (1.1 - 6.6)	Median: 8.1 (2.75 - 25.4)		Median: 7.36 (1.61 - 24.9)			
	22		No Pseudotumour	1:21	Mean: 2.3 (1.0 - 5.8)	Median: 1.79 (0.82 - 4.15)		Median: 1.28 (0.18 - 3.33)			
Underwood et al.[17]	122	Combined	Edge worn	78				Mean: 31.90 (0.77–245.55)			
			Non-edge worn	44				Mean: 0.85 (0-6.18)			
Matthies et al.[18]	72	Combined	Pseudotumour		Mean: 3.1 (1 - 5.75)	Median: 5.3 (0 - 84.1)		Median: 6.8 (0 – 180)			
	33		Control		Mean: 3.3 (1.1 - 7.9)	Median: 2 (0 - 62.1)		Median: 2.2 (0 – 64.3)			
Hart et al.[29]	45	Resurfacing			Mean: 2.7	Median: 8.7		Median: 5.6			
Glyn-Jones et al.[15]	18	Resurfacing	Pseudotumour	7:11	Mean: 3.9 SD: 2.1	Mean: 8.4 SD: 8.7	Mean: 3.3 SD: 5.7	Mean: 16.1 SD: 21.4	Mean: 2.5 SD: 6.3		
	18		Control	6:12	Mean: 2.5 SD: 1.9	Mean: 2.9 SD: 3.9	Mean: 0.8 SD: 1.2	Mean: 1.0 SD: 1.5	Mean: 0.4 SD: 0.8		
Nawabi et al.[19]	94	Combined	Unexplained Pain	8:27	Mean: 3.25 (1.5 - 8.6)					Median: 2.6 (0 - 128.2)	Median:0.3 (0 - 29.3)
			Control	37:22	Mean: 2.5 (1 - 6.5)					Median: 12.8 (0 - 232.1)	Median:1.5 (0 - 94.3)
	10	Resurfacing	Combined		Mean: 1.9 (1.5 - 4.2)					Median: 3.3 (0 - 128.2)	Median:0.3 (0 - 26.2)
	24	THR	Combined		Mean: 3.75					Median: 2.2	Median:0.3
					(1.5 - 8.6)					(0 - 85.6)	(0 - 29.3)
Morlock et al.[22]	12 Heads 17 Cup	Resurfacing	Non-edge worn				Mean: 0.402 SD: 0.584		Mean: 0.584 SD: 1.39		Mean: 1.10 SD: 1.7
Witt et al.[30]	30 Heads 28 Cups	Modular THR	Combined		Mean: 3.5 SD: 1.6		Mean: 1.96 SD: 4.92		Mean: 1.05 SD: 2.25		
Lord et al.[20]	32 Heads 22 Cups	Resurfacing	Combined				Mean: 8.72 (0.21-31.91)		Mean: 11.02 (0.30-63.59)		Mean: 22.66 (0.51 - 95.50(
Hothi et al.[23]	10 S-ROM stem	Modular THR	Combined		Mean: 5.3 (3.3 - 7)						Median: 3.92 (1.20 - 7.81)
	10 Corail stem	Modular THR	Combined		Mean: 4.7 (4.2 - 6.4)						Median: 3.21 Range: 0.87 - 62.12
Matthies et al.[21]	110	Modular THR	Combined		Mean: 3.7 (1 - 7.1)		Mean: 3.10 Median:1.31 (0.06-45.66)		Mean: 2.56 Median:0.62 (0.04-39.62)		
Sidaginamale et al.[24]	116	Modular THR	Combined		Mean: 4.8 (0.6 - 9.1)						Median: 2.02 0.27 – 68.9
	83	Resurfacing	Combined								Median: 7.35 Range: 0.62 - 95.5
This Study	22 BHR	Modular THR	Combined	16 : 8	Mean: 7.5 (4.7 - 9.6)	Mean: 4.5 Median: 2.5 (0.9 - 39)	Mean: 1.99 Median: 0.7 (0.17 - 21.1)	Mean: 7.3 Median: 1 (0.4 - 105.2)	Mean: 2.94 Median: 0.43 (0.11 – 45.2)		Mean: 4.94 Median: 1.15 (0.36 - 66.4)
	22 Adept	Modular THR	Combined	10 : 12	Mean: 6.8 (3.3 - 10.3)	Mean:1.9 Median: 1.4 (0.3 – 9)	Mean: 0.57 Median: 0.28 (0.08 - 4.7)	Mean: 3.9 Median: 1.8 (0 - 29.6)	Mean: 1.41 Median: 0.38 (0 - 16.7)		Mean: 2.07 Median: 0.74 (0.19 - 21.4)
	16 BHR	Modular THR	Non-edge worn		Mean: 7.3 (4.7 - 9.6)	Mean: 1.9 Median: 1.5 (0.9 - 3.6)	Mean: 0.55 Median: 0.4 (0.17 - 1.46)	Mean: 0.9 Median: 0.8 (0.4 - 1.5)	Mean: 0.40 Median: 0.33 (0.1 – 1)		Mean: 0.96 Median: 0.74 (0.36 - 2.28)
	10 Adept	Modular THR	Non-edge worn		Mean: 6.2 (3.3 - 10.3)	Mean: 1 Median: 0.8 (0.3 - 2.1)	Mean: 0.24 Median: 0.21 (0.08 - 0.5)	Mean: 0.9 Median: 0.6 (0 - 2.8)	Mean: 0.37 Median: 0.22 (0 - 1.6)		Mean: 0.41 Median: 0.32 (0.12 - 0.94)

Materials and Methods

Study demographics

The implants reviewed within this study are shown in Table 3. They are mixed manufacturer head and stem combinations formed of cemented collarless tapered cobalt-chrome Zimmer CPT stems paired with either an Adept LDMH (Finsbury Orthopaedics) (n=22) or a BHR large diameter modular head (LDMH) (Midland Medical technologies; Smith and Nephew) (n=22).

Ethical approval was granted by the National Research Ethics Service Committee South Central = Southampton A.

Study	Number of Hips		Head Sizes (mm)	Time In-Vivo (Months)	Cumulative mm³	Taper Rate (μm³/year)	Taper Rate (mm3/year)
Nawabi et al. [19]	58	Unexplained Pain: 25	Mean: 46 (38 – 53)			Mean: 1.4 (0 – 18.1)	
		Control: 33	Mean: 45 (38 – 53)			Mean: 0 (0 – 30.6)	
Matthies et al. [21]	110		Mean: 46.2 (38 – 60)	Mean: 44.2 (12 - 85)	Median: 2.02		Mean: 0.85 Median: 0.54 (0 – 4.29)
Hothi et al. [23]	10	S-ROM stem	36	Mean: 63.5 (40 - 84)			Median: 0.132 (0.015–0.518)
	10	Corail stem	36	Mean: 56 (50 - 77)			Median: 0.238 (0.0002–2.178)
Hothi et al. [25]	150	Mixed Manufacturer	Mean: 45.9 (38 - 60)	Mean: 42.2 (7 - 118)	Mean: 1.52 (0.13–25.89)		
Langton et al. [2]	63	ASR XL	Median 45.5 (39 - 57)	Median: 33 (11 - 64)		Median: 5.92 (0.57 to 32.78)	Mean: 0.44 (0.02 to 8.34)
	48	Articuleze (Pinnacle)	36 (+1 40)	Median: 42 (12 - 75)		Median 1.39 (0.24 to 106.6)	Mean: 0.127 (0.01 to 3.15)
Sidaginamale et al. [24]	116	Mixed Pinnacle, ASR and BHR		Mean: 4.8 (0.6 - 9.1)			Median 0.2 (0.01 – 8.34)
Brock et al. [26]	22	ASR Taper - Corail stem		Mean: 51 (+/-23)			Median: 0.714
	12	ASR Taper - S-ROM stem					Median: 0.494
	50	Pinnacle Taper - Corail stem					Median: 0.402
	20	Pinnacle Taper – S-ROM stem					Median: 0.123
Hothi et al. [27]	61	Pinnacle Taper – Corail stem	36mm	Median: 73.5 12-128			Median: 0.36 (0 - 3.45)
	17	Pinnacle - S-ROM stem					Median: 0.06 (0 - 0.52)
	42	Pinnacle – Summit stem					Median: 0.35 (0 – 2.46)
This study	22	BHR	Mean: 45.3 (42 - 52)	Mean: 90 (56 - 115)	Mean: 1.84 Median: 1.91 (0 - 4.2)		Mean: 0.26 Median: 0.22 0 - 0.9
	22	Adept	Mean: 47.1 (42 - 54)	Mean: 81.8 (39 - 124)	Mean: 1.11 Median: 0.58 (0 – 7.85)		Mean: 0.16 Median: 0.08 0 – 1.04

Table 2. Linear and Volumetric Wear Rates from tapers of metal on metal joints

	BHR	Adept
Number of joints	22	22
Time In-Situ (months)	90 (56 - 115)	82 (39 - 124)
Head Size	42mm n = 8 46mm, n = 10 50mm, n = 4	42mm n = 3 44mm n = 1 46mm n = 7 48mm n = 5 50mm n = 5 54mm n = 1

Table 3 Joint Demographics.

Table 4 Mean, Median and range of values of material loss from the implant surfaces

	Femoral Head	BHR-CPT	Adept-CPT	Acetabular Cup	BHR-CPT	Adept-CPT	Bearings Combined	BHR-CPT	Adept-CPT	Taper	BHR-CPT	Adept-CPT
Normal Wear: Edge Wear		16:6	10:12									
Clearance (mm)		0.220 0.211 0.16 – 0.33	0.181 0.180 0.13-0.23									
All Samples Cumulative Linear Loss (μm)		35 18.5 5 - 318	12.6 7.7 2 - 56.5		58 7.3 2.7 - 859	27 11 0 - 190						
All Samples Linear Loss rate (μm/yr)		4.5 2.5 0.9 - 39	1.9 1.4 0.3 - 9		7.3 1 0.4 - 105.2	3.9 1.8 0 - 29.6						
Non-edge Wearing Cumulative Linear Loss (μm)		14 11 5.2 - 24	5.3 5.9 2.3 - 8.6		6 6 3 - 12.8	5.3 4.7 0 - 19.5						
Non-edge Wearing Linear Loss rate (μm/yr)		1.9 1.5 0.9 - 3.6	1 0.8 0.3 - 2.1		0.9 0.8 0.4 - 1.5	0.9 0.6 0 - 2.8						
All Samples Cumulative Volume Loss (mm³)		15.64 5 1.13 - 172.6	4.62 2.1 0.6 - 30.4		23.38 3.49 0.5 - 369.3	9.18 3.09 0 - 107.1		39.02 9 1.73 - 541.9	13.80 4.97 0.6 – 137.5		1.84 1.91 0 - 4.2	1.11 0.58 0 - 7.85
All Samples Volume Loss rate (mm³/yr)		1.99 0.7 0.17 - 21.1	0.57 0.28 0.08 - 4.7		2.94 0.43 0.11 – 45.2	1.41 0.38 0 - 16.7		4.94 1.15 0.36 - 66.4	2.07 0.74 0.19 – 21.4		0.26 0.22 0 - 0.9	0.16 0.08 0 – 1.04
Non-edge Wearing Cumulative Volume Loss (mm³)		3.98 2.8 1.13 - 8.6	1.36 1.45 0.6 - 2.1		2.94 2.20 0.5 - 7.6	1.88 1.57 0 - 6.3		6.92 5.87 1.73 – 13.62	2.26 2 0.6 – 3.92		1.97 2.34 0 - 4.2	0.76 0.47 0 - 1.9
Non-edge Wearing Volume Loss rate (mm³/yr)		0.55 0.4 0.17 - 1.46	0.24 0.21 0.08 - 0.5		0.40 0.33 0.1 - 1	0.37 0.22 0 - 1.6		0.96 0.74 0.36 – 2.28	0.61 0.32 0.12 – 0.94		0.28 0.30 0 - 0.9	0.14 0.08 0 - 0.4

Material loss assessment

The volumetric material loss measurements for the bearing and taper surfaces of each joint in the study were obtained using a non-contact optical coordinate measuring machine (OrthoLux, RedLux, Southampton UK). The measurement procedure and validation for spherical components can be found in Tuke et al. [31]. Direct assessment of the bearing surfaces was performed with a point cloud density of 1 point per degree circumferentially and 1 point per degree from the pole to the edge. The regions of damage on the bearing surfaces were identified and removed and a sphere fitted to the remaining points. The linear wear was assessed as the maximum linear deviation from the fitted sphere in the center of the wear scar and the volumetric loss measured as the volume beneath the fitted sphere and the assessed surface within the wear scar region.

The taper assessments were performed on a casting of the taper surface. The casting was made using Microset 202 (Microset Products Ltd,

		Vs. CPT Trunnion angle of 5° 40' or 5.667°		Vs. Zweymuller Trunnion angle of 5° 38' or 5.633°		Vs. Synergy Trunnion angle of 5° 40' secs or 5.667°	
Bearing Manufacturer	Retrieved head Taper Angle (Degrees)	Taper Angle Clearance (Degrees)	Taper Angle Clearance (Minutes)	Taper Angle Clearance (Degrees)	Taper Angle Clearance (Minutes)	Taper Angle Clearance (Degrees)	Taper Angle Clearance (Minutes)
Adept n = 22	5.690° 5.696° (5.610° - 5.767°)	0.024° 0.030° (0.101° to -0.056°)	1.463 1.799 (1.799 to -3.333)	0.057° 0.063° (0.134° to -0.023°)	3.443 3.779 (3.779 to -1.353)	-	-
BHR n = 22	5.662° 5.663° (5.551° - 5.734°)	-0.005° -0.005° (0.067° to -0.116°)	-0.314 -0.272 (4.030 to -6.961)	-	-	-0.005° -0.005° (0.067° to -0.116°)	-0.314 -0.272 (4.030 to -6.961)
Metasul	-	-0.034°	-2.04	-	-	-	-

Table 5: Table 3 Mean, median and range of the Taper Angles and Clearance angles.

Nuneaton, UK) replication material which has the ability to reproduce the surface with a resolution of 0.05 µm. The measurements of the taper surface were collected with a point density of 2 points per degree circumferentially and 70 points per mm along the length. The damaged regions of the taper surface and any regions with material deposits were excluded and a cone fitted to the remaining original surface. The volumetric loss was assessed as the volume beneath the fitted cone within the wear scar region. Validation of this method has been published [32] and the limits of agreement (95%) of the material loss were -0.0416 to 0.173 mm3 with a taper angle shown to be within 0.0024°.

Volumetric loss and the angles of the retrieved trunnions was not assessed. The surfaces of the trunnions were perceived to have some level of deformation or damage along their full lengths. This provided no original surface to which to apply a cone fit, meaning any volumetric value or angle assessment would have had unquantifiable and inconsistent levels of error, with the magnitude of the error varying with the level of damage to the trunnion. In order to assess the taper clearance angles, the manufacturers stated trunnion angle for the CPT (5° 40 minutes), as well as the Finsbury orthopedics Zweymuller Alloclassic (5° 38 minutes) [33] and the Synergy stem (5° 40 minutes) were gathered. The Alloclassic stem and the synergy stem represent the manufacturer matched stem parings for the Adept and BHR heads. It is of note that both the BHR and Adept heads were marketed initially without a specified stem pairing and these were subsequently identified as appropriate. In addition the Metasul and Durom female taper (5° 38 minutes) [34] was reviewed in relation to the CPT trunnion to define manufacturers specified taper clearance for this pairing.

Stem grading

The stems were graded using the criteria described by Bryant et al. 2013 [4]. The scale classifies stems into one of five categories based on the area of damage to the stem surface from within the cemented region. The categories are 1: <10%, 2: 10-25%, 3: 25-50% 4: 50-75% and 5: >75% of the surface.

Results

The bearing surface analysis identified 18 out of the 44 joints (BHR = 6, Adept = 12) as being edge worn. The exclusion of the edge wearing joints from the data sets, provided a mean wear rate for the joints in-vivo of 0.24 and 0.55 mm^3/year for the femoral heads and 0.37 and 0.4 mm^3/year for the acetabular cups of the Adept and BHR joints respectively (Table 4). The wear rate of the non-edge worn femoral heads was significantly higher for the BHR joints ($p = 0.006$), but there was no significant difference between the levels from the acetabular cups ($p = 0.865$).

Analysis of the tapers demonstrated a range of levels of material loss. The mean rate of volumetric loss from the Adept and BHR female taper surfaces respectively was 0.16 and 0.26mm^3/year (Table 4). Comparison of the means of the two rate of loss using a 2 sample t-test showed there was no statistically significant difference ($p = 0.179$). There was also no significant difference between the rates of volume loss from the tapers of the joints with edge worn bearings and those without for either the BHR ($p = 0.113$), the Adept pairings ($p = 0.639$) or the two groups combined ($p = 0.444$).

All of the stems examined displayed evidence of damage to their surfaces which would have been within the cement mantle. The mean Bryant score for the BHR and Adept coupled stems was 2.4 and 2.9 respectively. There was no statistically significant difference in the level of stem damage between the BHR and Adept groups ($p = 0.498$), nor was there a significant difference in the stem score for the edge worn and non-edge worn bearings (BHR: $p = 0.481$, Adept: $p = 0.899$, combined: $p = 0.763$).

The assessment of the BHR and Adept female taper surfaces showed a difference in the mean taper angle (5.690° vs. 5.662° respectively). This difference in the taper angle of the two joints was approaching significance ($p = 0.054$). The taper angles of the joints resulted in different taper clearance angles when compared to the manufacturer specified trunnion angle for the CPT (Table 5). The BHR taper angle was similar to that of the CPT trunnion, but provided a negative clearance of -0.005 degrees. In contrast the Adept taper provided a positive clearance angle of 0.024°. Based on the taper angles assessed in this study, the manufacturer matched pairings would have provided mean clearances of 0.057° and –0.005° for the Adept-Alloclassic and the BHR-Synergy respectively and -0.034° for the Metasul-CPT, Table 5.

The correlation between the head size, bearing clearance, time in-situ, offset, taper angle and taper clearance vs. ideal CPT (tapers only) on the volume of loss from the bearing surfaces and the taper and the stem grading was investigated. The only significant correlations were found between the BHR taper loss and the head size ($r = 0.438$, $p = 0.042$) and the CPT derived offset with the stem grading of the Adept group ($r = -0.577$, $p=0.019$).

Inter site

When the volume of material loss from the bearings was compared to that of the taper and the stem grading from the whole data set ($n = 44$), only one significant correlation was found between the bearing surface wear and the stem grading (Head $r = -0.435$, $p = 0.007$, Cup $r = -0.333$, $p = 0.044$). However, removal of an edge worn BHR sample which had lost 172.6 mm^3 and 369.3 mm^3 from the femoral head and acetabular cup respectively rendered this relationship non-significant.

Separate analysis considering the different joint designs and the edge worn and non-edge worn joints separately failed to provide any significant correlations between the material lost from the different sites.

Discussion

In order to determine if the bearing surfaces were performing as would be expected, the results from the wear analysis in this study need to be compared to those of previous studies on similar joints. Table 1 contains linear [6,15-19] and volumetric loss [15,19-24] measures from the bearing surfaces of retrieved metal on metal joints. However, in most studies, the values for edge-wearing components have not been differentiated from those without edge wear, meaning the values provided by most studies are not reflective of the true wear rate for these joints. Only three [6,16,17] out of the six studies provided linear wear rate values which are representative of a well aligned components in-vivo and two of those only presented values for the acetabular cups.

The mean linear wear rates of reported by Underwood et al. [17] were higher than those reported in this study. However, Matthies et al. [6] provided median wear rates for 0 µm/year (0 - 4.77) and 0 µm/year (0 - 6.18). The inference of this is that 37 or more of these 74 retrieved joints had no measureable wear. This may be a reflection of the shorter time in-situ of these joints compared to the current study, or a difference in the ability of the roundness machine measurement technique to pick up low levels of wear compared to the RedLux technique. However the maximum linear wear rates presented for these joints are higher than this study.

The mean volume loss rate of the non-edge wearing femoral head components published by Morlock et al. [22] was lower than from the BHR femoral components in this study. However, the mean volume loss rates from the Adept femoral heads, the acetabular surfaces and the bearings combined for both designs from this study were below the values presented.

When the rates of the whole data, incorporating the edge worn values are compared to the rates of loss those of the previous studies [15,19-23,30], the current values sit within the range presented in Table 1.

The volumetric wear rate of the non-edge wearing joints demonstrate that the BHR joints had double the rate of volume loss from the femoral heads compared to the Adept. This difference can be explained in part by the lower clearance (40μm less) of the Adept joints (Table 4). The Adept clearance is high enough to overcome any fears around deformation during insertion [35] and high friction due to lubricant starvation [36], but low enough to reduce the volume lost as a result of the running in wear associated with higher clearance joints [17,37].

There are eight studies [2,19,21,23-27] in the literature which have quantified the material loss from the surfaces of female tapers (Table 2). Matthies et al [21] and Hothi et al [23] provide values for the cumulative loss from the surfaces of 2.02 mm^3 (Median) and 1.52 mm^3 (Mean), higher than the mean and median values in this study for the Adept tapers, but a higher median and lower mean (0.22 mm3 difference) when compared to the BHR joints.

Comparing the material loss values in this study with those of previous studies (Table 2), the loss is beneath that of Matthies et al. [21] obtained from a range of different joint designs, Hothi et al. [23] for Corail – Ultamet head pairings and the ASR XL tapers presented by Langton et al. [2]. Only the mean values for the Articuleze-Pinnacle joints (difference BHR: 0.133, Adept: 0.033 mm^3/year) and the median value for the S-Rom stem – Ultamet head parings were less than those presented here. In both of these studies [2,23] the head sizes were 36mm which is 6mm smaller than the smallest head considered in this cohort, a known variable in the performance of tapers and the S-Rom stem also has an 11/13 taper rather than a 12/14 which may have influenced the performance.

Comparison of the volumes of loss from the bearings to the taper and stem showed no significant correlations, demonstrating that the loss occurring at these individual sites was independent of what was occurring at the other sites. The results also showed no correlation between joint specific variables such as offset, clearance, head size and time in-situ and the levels of material loss.

The clearance angles for the combinations in this study are within the range presented by Kocagöz et al. [1] and the manufacturers, with the average clearance for each group maintaining the positive or negative clearance which would have been specified for that joint design. The clearance angles were not correlated to the volume of loss from the taper, in agreement with the findings of Kocagöz et al. [1] for the visual grading of taper damage vs. taper clearance.

The closer match of angle seen in the current mixed manufacturer taper and trunnions has advantages. The taper engagement length between the two surfaces will be higher than those with a more extreme taper clearance and larger engagement lengths have been shown to reduce the volume loss from the taper [23]. The horizontal lever arm of distally contacting tapers detailed by Langton et al. [2] will be reduced, which has also been linked to heightened volume loss [2] and the gap between the two surfaces at the larger diameter (open) end of the proximally contacting tapers will be reduced, minimizing the access to fluid entering the interface.

It is clear from this study that there is no consensus on what is an appropriate taper clearance angle. The clearance angles for manufacturer matched pairings demonstrate that the Metasul-CPT and BHR Synergy tapers were designed with a negative clearance of -0.034° and -0.005° respectively, while the Adept-Alloclassic pairing had a positive clearance of 0.057°. Different manufacturers have designed for different clearances and contact locations. The clearances within the study by Langton et al. [2] for the ASR-Corail pairings (-0.149° to 0.081°), the BHR-synergy parings (-0.116° to 0.067°) and the Adept-Alloclassic pairings (-0.023 to 0.134) in this study, demonstrate that both negative and positive clearance angles are possible within the same joint design on a particular stem due to the tolerances of the taper manufacturing.

A review of cemented stems within the previous studies [12-14,38-42], demonstrates that damage is identifiable on a range of designs and materials. Using the data available in the Bryant et al. [12] paper, it was possible to demonstrate that there was no significant difference between the mean stem damage rankings in their study and this work ($p = 0.147$).

It is of note that while the performance of the three interfaces with regards to material loss does not differ and is in many cases better than manufacturer matched options. These joints had the potential to suffer from material loss at all three interfaces, which in combination elevated the overall volume of material released into the patient.

Conclusions

This study has shown that the material loss from the bearing, taper and cement-stem interface of these mixed manufacturer total hip replacements is equal to and in many cases lower than that published by other centers for manufacturer matched joints. The taper clearance angles of these mixed manufacturer joint pairings are within the normal range for modular taper connections of manufacturer matched joints and has maintained the proximal or distal nature of the taper which the manufacturer matched joints would have produced. The use of mixed manufacturer joints has not in this instance adversely affected the performance of the joints when compared to other similar manufacturer matched joints.

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Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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