1	Damage Patterns at the Head-Stem Taper Junction Helps Understand the		
2	Mechanisms of Material Loss		
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4	Harry S. Hothi, BEng, MSc, PhD ¹		
5	Andreas C. Panagiotopoulos, MSc ¹		
6	Robert K. Whittaker, BSc ¹		
7	Paul J. Bills, BEng, MSc, PhD ²		
8	Rebecca McMillan, BSc ¹		
9	John A. Skinner, MBBS, FRCS (Eng), FRCS (Orth) ¹		
10	Alister J. Hart, MA, MD, FRCS (Orth) ¹		
11			
12	1. Institute of Orthopaedics and Musculoskeletal Science, University College		
13	London and the Royal National Orthopaedic Hospital, Stanmore, United		
14	Kingdom		
15	2. The Centre for Precision Technologies, University of Huddersfield, United		
16	Kingdom		
17			
18	Corresponding Author:		
19	Harry Hothi		
20	UCL Institute of Orthopaedics and Musculoskeletal Science (IOMS)		
21	Royal National Orthopaedic Hospital (RNOH)		
22	Brockley Hill, Stanmore, HA7 4LP, UK		
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27	Background:
28	Material loss at the taper junction of metal-on-metal total hip replacements (MOM-
29	THRs) has been implicated in their early failure. The mechanisms of material loss are
30	not fully understood; analysis of the patterns of damage at the taper can help us bette
31	understand why material loss occurs at this junction.
32	Methods:
33	We mapped the patterns of material loss in a series of 155 MOM-THRs received at
34	our centre by scanning the taper surface using a roundness-measuring machine. We
35	examined these material loss maps to develop a five-tier classification system based
36	on visual differences between different patterns. We correlated these patterns to
37	surgical, implant and patient factors known to be important for head-stem taper
38	damage.
39	Results:
40	We found that 63 implants had 'minimal damage' at the taper (material loss <1mm ³)
41	and the remaining 92 implants could be categorised by four distinct patterns of taper
42	material loss. We found that (1) head diameter and (2) time to revision were key
43	significant variables separating the groups.
44	Conclusion:
45	These material loss maps allow us to suggest different mechanisms that dominate the
46	cause of the material loss in each pattern: (a) corrosion, (b) mechanically assisted
47	corrosion or (c) intra-operative damage or poor size tolerances leading to toggling of
48	trunnion in taper.
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50	Keywords: Metal-on-metal: taper: material loss: wear: corrosion: retrieval

Abstract

Introduction

Material loss at the taper junction of stemmed metal-on-metal total hip replacements (MOM-THRs) has been implicated in the early failure of these implants [1, 2]. It is speculated that the mechanism of material loss at this junction involves either corrosion [3-6], mechanical wear (fretting) or a combination of the two [7].

Previous retrieval work has reported volumetric material loss from the head-stem taper junction as high as 25 mm³ [8], which accounts for a third of the total material loss in contemporary MOM-THRs. However, few studies have specifically looked at explaining the mechanisms [1-6] behind this material loss and therefore this remains an area of uncertainty.

Analysis of the patterns of taper surface damage can help us to understand material loss mechanisms. Bishop et al. [1] analysed retrieved components from 5 patients and identified two patterns of material loss: axisymmetric and asymmetric. They attributed the asymmetric pattern to toggling of the head on the stem trunnion whilst the axisymmetric pattern was attributed to a uniform seating of the head taper onto the stem trunnion. The numbers of hips investigated in this study are however low and the mechanisms of material loss remain unclear.

At our retrieval centre we noticed patterns of taper material loss that did not fit into the two patterns suggested by Bishop et al. [1]. Consequently, we set out to (1) identify the patterns of material loss at the head-stem taper junction in a series of 155 retrieved MOM-THRs at our centre and (2) relate these patterns to associated surgical, implant and patient factors.

Materials and Methods

This retrieval study involved a consecutive series of 155 failed MOM-THRs that had been received at our centre. The hips were retrieved from 66 male and 89 female patients with a median age of 61 years (26-83) and a median time to revision of 40 months (12-89); the reasons for revision, as reported by the revising surgeon, were given unexplained pain (n=148) and implant loosening (n=7). The median head size was 46 mm (36-58) and the median pre-revision whole blood cobalt and chromium levels were 7.4 (0.6-212.4) and 3.5 (0.2-111) respectively; the median Co/Cr ratio was 1.45 (0.03-17.70). Pre-revision plain radiographs were obtained for each implant to determine the median acetabular inclination and the median horizontal and vertical femoral offsets; these were 42° (12-68), 37 mm (6-66) and 79 mm (10-145) respectively. The implants consisted of over 10 different contemporary bearing designs together with over 9 stem designs. Table 1.

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- Head Taper Corrosion Assessment
- 91 A single examiner inspected all 155 head taper surfaces for evidence of corrosion
- 92 using macroscopic analysis and also light microscopy (maximum magnification 40X,
- 93 Leica Microsystems, Germany. Corrosion severity was graded using a well-published
- 94 four-tier classification system [6], which has previously been shown to be both
- 95 reproducible and repeatable [9].

- 97 Taper Material Loss Pattern Mapping
- The volume of material loss at the head taper surfaces was measured using a Talyrond
- 99 365 (Taylor Hobson, Leicester, UK), roundness measurement machine. We did not
- include analysis of the stem trunnion in this study as the surgeon had opted to retain

the stem in the majority of cases. Furthermore, it has previously been shown that in hips with CoCr tapers and titanium (Ti) stem trunnions, material is often lost preferentially from the head taper due to a mechanism of galvanic corrosion [8]; stem trunnions that macroscopically appear undamaged have been shown to exhibit minimal material loss.

A series of 180 vertical traces were taken along the axis of the taper surface using a 5µm diamond styles. These traces were combined to form a rectangular surface depicting both undamaged regions and regions of material loss (hereafter referred to as material loss maps); these maps visually depict the distribution and severity of surface damage using a colour scale; this ranges from dark red regions representing the unworn regions of the taper surface whilst the transition from yellow, to green, to blue indicates regions of increasing material loss from the surface, Figure 1. Therefore, each material loss map creates a recognisable pattern which can be categorised by an examiner. The subtraction of undamaged surface areas from

Classification of Taper Damage Patterns

In this study we considered tapers that had lost less than 1mm³ of material from their surfaces as having 'minimal damage'. All tapers with less than 1mm³ of material loss were therefore categorised as being in the minimal damage group.

damaged areas also allows for an estimation of material loss volume.

A committee consisting of two examiners experienced in retrieval analysis examined each of the remaining taper material loss maps to jointly agree how these should be categorised according to their visual appearance. The examiners were blind to all material loss data for the hips.

Bearing Surface Material Loss Measurement In order to assess the role of bearing surface wear on taper damage, we also measured the volume of material loss of the cups and heads. Measurements were carried out using a Zeiss Prismo (Carl Zeiss, Ltd., Rugby, UK) coordinate measuring machine (CMM) with a 2 mm ruby stylus. The protocol acquired up to 30,000 data points along 400 polar scan lines and data analysis was performed using an iterative least square fitting operation (Matlab, Mathworks, Inc., Natick, MA). We utilized the unworn geometry and fitting algorithms to determine the shape of the original surfaces, thus enabling us to calculate volumetric material loss. The generated wear maps were also used to determine of the implant had been edge wearing. Analysis of Clinical and Implant Variables We performed non-parametric analysis to determine the significance of differences between the different damage pattern categories that had been proposed, in relation to the clinical, implant and imaging variables described previously.

151 **Results** 152 Classification of Taper Damage Patterns 153 Our analysis revealed that there were 92 hips with material loss at the taper greater than 1mm³; a consensus was reached by the two examiners in this study to categorise 154 155 these hips into 4 different groups according to the visual appearance on their taper 156 material loss maps: (1) early axisymmetric (n=32), (2) late axisymmetric (n=21) (3) 157 asymmetric (n=33) and (4) coup-countercoup (n=6). 158 Table 2 presents examples of measured wear maps generated for each of the 4 159 categories (in addition to the minimal damage group) along with schematic examples 160 and description of each group. 161 162 Taper Corrosion Assessment 163 The mean taper corrosion score of all implant was 2.8 (1-4). The implants in the 164 minimal damage group had a mean corrosion score of 2.5 (1-4); this was significantly less (p<0.01) than implants with material loss greater than 1mm³, which had a mean 165 166 corrosion score of 2.9 (2-4). 167 168 Material Loss Measurements The median volume of material loss of all taper surfaces was 1.20mm³ (0-22.35). We 169 found that 63 implants had material loss measurements of less than 1mm³, with a 170 median of 0.65mm³ (0-0.99); these were therefore categorised in the 'minimal 171 172 damage' group. The material loss of the minimal damage group was significantly less 173 than the early axisymmetric, late axisymmetric, asymmetric and coup-countercoup groups which had median material loss volumes of 1.89mm³ (1-6.52), 4.23mm³ (1.09-174

22.35), 3.43mm³ (1.04-17.03) and 2.16mm³ (1.07-4.43) respectively, Figure 2. There 176 were no other significant differences for taper material loss measurements. 177 The median volumes of material loss at the combined bearing surfaces for the 178 minimal damage, early axisymmetric, late axisymmetric, asymmetric and coupcountercoup groups were 7.87mm³ (1.07-325.98), 4.63mm³ (1.03-146.03), 6.86mm³ 179 (0-309.17), 7.95mm³ (0.58-45.94) and 7.64mm³ (4.06-17.15) respectively; there was 180 181 no significant difference. 182 183 Analysis of Clinical and Implant Variables 184 Analysis of key clinical and implant variables included in this study revealed 185 significant differences between the groups in relation to: (1) head diameter and (2) 186 time to revision. 187 The median head diameter of the early axisymmetric group was 46mm (36-56) and 188 was significantly larger (p<0.001) than that of the minimal damage and coup-189 countercoup groups, which had median head diameters of 44mm (36-52) and 40mm 190 (36-48) respectively. There were no significant differences in relation to the late 191 axisymmetric and asymmetric groups, which had median head sizes of 46mm (36-52) 192 and 46mm (42-54) respectively. 193 The median time to revision of the minimal damage and early axisymmetric groups 194 was 37 months (12-85) and 38.5 months (12-85) and was significantly less (p<0.05) 195 than that of the late axisymmetric, asymmetric and coup-countercoup groups which 196 had median times to revision of 46.5 months (25-84), 49 months (16-89) and 45

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months (35-78) respectively.

Discussion

We conducted a large-scale investigation of the taper surfaces of retrieved MOM-THR implants received at our centre and discovered patterns of taper damage that have not been previously described. This has created a new classification system that helps us better understand the mechanisms of material loss at the taper junction of hip replacements; this work highlights the importance of retrieval analysis as suggested by Jacobs and Wimmer [11]. 40% of hips had no relevant material loss from this junction. In the remaining 60%, time implanted, head diameter and possible surgical implantation technique or manufacturing tolerances were key influencing variables for the material loss.

We have built on Bishops observations of two damage patterns, namely axisymmetric and asymmetric wear, to define three further categories to produce a classification system that describes tapers with: (1) low (<1mm³) surface material loss, (2) early axisymmetric damage in which there is a circumferential band of material loss near the opening, (3) late axisymmetric in which this circumferential band additionally has vertical bands running along the taper surface, (4) asymmetric in which there are vertical bands of material loss that are localised to one region of the taper and (5) coup-countercoup in which there are two distinct and diagonally opposing regions of material loss.

The minimal damage group of tapers was the most prevalent in our collection of retrievals and had no clear pattern of material loss. These implants had the shortest time to revision out of the 5 damage categories and it is speculated that taper damage is unlikely to have been the main cause of failure in these cases. Conversely the

volume of material lost at the bearing surfaces of these implants was comparatively high and it is likely that this was the major contributing factor to failure. Indeed, it is important in studies investigating material loss at the taper to also consider the comparative loss from the bearing surface; losses from the taper junctions be may inconsequential when analysed independently without consideration of the bearings.

The early axisymmetric group of tapers had the second lowest volume of measured material loss following the minimal damage group. Virtually all material loss was lost along the circumferential bands visible on the measured wear maps; macroscopically these regions presented evidence of black corrosive deposits. Implants in this damage group had the joint highest femoral head diameters (equal to late axisymmetric and asymmetric groups). It is speculated that the larger head diameters led to increased frictional torque at the bearing surface [12, 13] that was transmitted along the taper surface leading continuous cycles of oxide film fracture and repassivation and ultimately to material loss at this interface. Imperfect tolerances between the head taper and stem trunnion may have allowed fluid ingress to occur thereby leading to the corrosive band near the taper opening.

The late axisymmetric group showed evidence of the same circumferential bands of material loss as the early axisymmetric group however these tapers additionally had vertical bands running along their surfaces, in accordance with the classification system. These implants had the same median head size as the early axisymmetric group but were implanted for a significantly longer period of time; it is thought that the additional vertical regions of surface damage are due to fluid ingress further into the taper junction over time and this is reflected by the greater volume of material lost

in this group. These findings support are terminology that separately defines the 'early' and 'late' axisymmetric. Whilst we do not believe that the asymmetric and coup-countercoup are related to the axisymmetric groups as a function of time, it is possible that the minimal damage groups could have evolved into any of the four other categories had they been implanted for a longer period of time.

It is suggested that the large femoral head size of the asymmetric group was an important influencing factor in taper damage. These tapers presented evidence of material loss localised to one region along the engaged area of the taper-trunnion interface. This damage pattern may be explained by considering the significance of flexural rigidity of femoral stem components. Porter et al. [14] reported on the wide variation in flexural rigidity between different stem designs such that more flexible components were more susceptible to taper junction corrosion. This increased flexibility may have been present in this asymmetric damage group of implants. This may therefore have led to a scenario in which normal patient weight bearing created a cavity on one side of the taper junction sufficiently large enough for fluid ingress and therefore corrosion to occur preferentially in this region.

The coup-countercoup damage patterns appear to predominately (some corrosion may still occur) be due to mechanical factors: a toggling of the stem trunnion inside of the head taper such that there are increased localised contact stresses between diagonally opposing ends of the trunnion and the surfaces of the taper. It is speculated that the occurrence of toggling was due to either poor surgical assembly of the stem and head components intraoperatively or due to poor size tolerances between the two mating

surfaces. It is however unclear from our current data if it is the surgical or implant factor which is the dominant influencing factor.

It is important to note that mechanical factors, such as micromotion of the trunnion in the taper, may also be involved to some extent in the other damage patterns observed and may exacerbate the dominate corrosion mechanisms in these cases. Furthermore, this mechanical movement may also result in changes to the trunnion surface, for example due to fretting. Future studies involving a greater number of retrieved stems should also consider damage patterns on this surface in their work.

Conclusion

In this retrieval study we discovered 63 implants with material loss of <1mm³ at the taper junction (minimal damage group) and the remaining 92 implants could be described by 4 distinct patterns of material loss at the taper surfaces.

By comparing this patterns with surgical, implant and patient factors, we identified key damage mechanisms as being corrosion, mechanically assisted corrosion and either poor surgically or poor component size tolerances.

The knowledge gained from this study will allow (1) a more comprehensive understanding of the failure at the taper junction, (2) better clinical surveillance of patients with large head MOM THRs in-situ and (3) better design of future implants.

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299 References

- 300 [1] Bishop N, Witt F, Pourzal R, Fischer A et al. 2013. Wear patterns of taper
- 301 connections in retrieved large diameter metal-on-metal bearings. J Orthop Res, 31:
- 302 1116-1122.

303

- 304 [2] Langton DJ, Sidaginamale R, Lord JK, Nargol AVF and Joyce TJ. 2012. Taper
- junction failure in large-diameter metal-on-metal bearings. Bone Joint Res, 1: 56-63.

306

- 307 [3] Jacobs JJ, Urban RM, Gilbert JL, Skipor AK, Black J, Jasty M, Galante JO. 1995.
- Local and distant products from modularity. Clin Orthop Relat Res, 319: 94-105

309

- 310 [4] Collier JP, Suprenant VA, Jensen RE et al. 1991. Corrosion at the interface of
- 311 cobalt-alloy heads on titanium-alloy stems. Clin Orthop, 271: 305.

312

- 313 [5] Gilbert JL, Buckley CA, Jacobs JJ. 1993. In vivo corrosion of modular hip
- 314 prosthesis components in mixed and similar metal combinations. The effect of
- crevice, stress, motion, and alloy coupling. J Biomed Mater Res, 27:1533.

316

- 317 [6] Goldberg JR, Gilbert JL, Jacobs JJ, Bauer TW, Paprosky W and Leurgans S.
- 318 2002. A multicentre retrieval study of the taper interfaces of modular hip prostheses.
- 319 Clin Orthop, 401: 149-161.

- 321 [7] Higgs G, Kurtz S, Hanzlik J, MacDonald D, Kane WM, Day J, Klein GR, Parvizi
- J, Mont M, Kraay M, Martell J, Gilbert J and Rimnac C. 2013. Retrieval analysis of

323 metal-on-metal hip prostheses: Characterising fretting and corrosion at modular 324 interfaces. Bone Joint J, 95-B (SUPP 15) 108. 325 326 [8] Matthies AK, Racasan R, Bills P, Blunt L, Cro S, Panagiotidou A, Blunn G, 327 Skinner J and Hart AJ. 2013. Material loss at the taper junction of retrieved large head 328 metal-on-metal total hip replacements. J Orthop Res, 31(11): 1677-1685. 329 330 [9] Hothi HS, Matthies AK, Berber R, Whittaker RK et al. 2014. The reliability of a 331 scoring system for corrosion and fretting, and its relationship to material loss of 332 tapered, modular junctions of retrieved hip implant. The Journal of Arthrplasty, 29(6): 333 1313-1317. 334 335 [10] Landis JR and Koch GG. 1977. The measurement of observer agreement for 336 categorical data. Biometrics, 33: 159-174. 337 [11] Jacobs JJ and Wimmer MA. 2013. An important contribution to our 338 339 understanding of the performance of the current generation of metal-on-metal hip 340 replacements. J Bone Joint Surg Am, 95(8): e53. 341 342 [12] Dyrkacz RMR, Brandt J, Ojo OA, Turgeon TR and Wyss UP. 2013. The 343 influence of head size on corrosion and fretting behaviour at the head-neck interface 344 of artificial hip joints. J Arthroplasty, 28: 1036-1040.

346	[13] Hexter A, Panagiotidou A, Singh J, Skinner J, Hart A. 2013. Corrosion at the
347	head-trunnion taper interface in large diameter head metal-on-metal total hip
348	arthroplasty: a comparison of five manufacturers. Bone Joint J, 95-B (9)
349	
350	[14] Porter DA, Urban RM, Jacobs JJ, Gilbert JL et al. 2014. Modern trunnions are
351	more flexible: A mechanical analysis of THA taper designs. Clin Orthop Relate Res,
352	472: 3963-3970.
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		Number	Median	Range
Gender (Male : Female)		66 : 89	-	-
Age at Primary Surgery (years)		-	61	26 - 83
Time to Revision (months)		-	40	12-89
Femoral Head Diameter (mm)		-	46	36-58
Inclination °		-	42	12-68
Horizontal Offset (mm)		-	37	6-66
Vertical Offset (mm)		-	79	10-145
Whole Blood Cobalt (ppb)		-	7.4	0.6-212.4
Whole Blood Chromium (ppb)		-	3.5	0.2-111
Cobalt/Chromium Ratio		-	1.45	0.03-17.70
	Biomet Magnum	32	-	-
	Corin Cormet	10	-	-
	DePuy ASR XL	26	-	-
	DePuy Pinnacle	18	-	-
Bearing	Finsbury Adept	14	-	-
Design	S&N BHR	27	-	-
	Wright Conserve	6	-	-
	Zimmer Metasul	4	-	-
	Zimmer Durom	8	-	-
	Others	10	-	-
	CLS	6	-	-
	Corail	35	-	-
	CPCS	4	-	-
Stem	CPT	11	-	-
Design	S-ROM	7	-	-
Design	Synergy	7	-	-
	Taperloc	24	-	-
	Zweymuller	12	-	-
	Others	49	-	-

 Table 1: Patient and implant data for the MOM-THRs

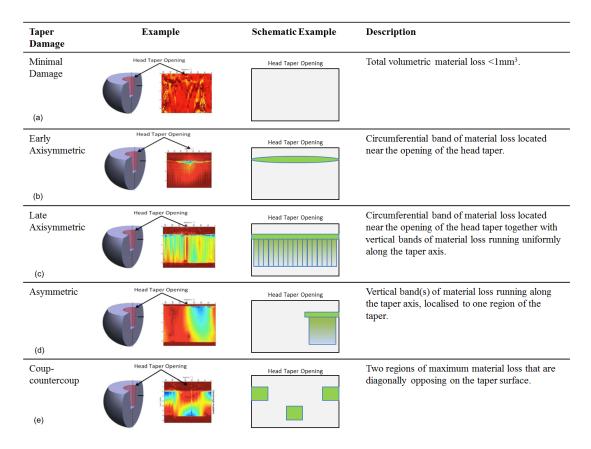


Table 2: Taper damage classification system developed by a committee of two experienced examiners. Dark red regions represent the unworn regions of the taper surface whilst the transition from yellow, to green, to blue indicates regions of increasing material loss from the surface. The minimal damage group (a) consisted of tapers with less than 1 mm^3 of material loss whilst the remaining material loss maps were visually assessed by the committee and jointly categorised into 4 groups (b - e).

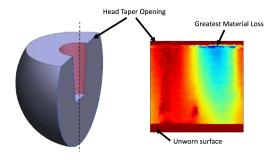


Figure 1: Example of material loss map generated. Red regions represent unworn surfaces whilst blue regions represent areas with the greatest material loss

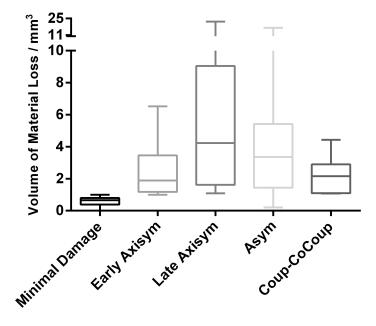


Figure 2: Volumetric material loss measured for the five categories