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## **Original Citation**

Hothi, Harry, Panagiotopoulos, Andreas, Whittaker, Robert, Bills, Paul J., McMillan, Rebecca, Skinner, John and Hart, A. J. (2017) Damage patterns at the head-stem taper junction helps understand the mechanisms of material loss. Journal of Arthroplasty, 32 (1). pp. 291-295. ISSN 0883-5403

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# Accepted Manuscript

Damage Patterns at the Head-Stem Taper Junction Helps Understand the Mechanisms of Material Loss

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PII: S0883-5403(16)30339-4

DOI: 10.1016/j.arth.2016.06.045

Reference: YARTH 55282

To appear in: The Journal of Arthroplasty

Received Date: 14 March 2015

Revised Date: 13 June 2016

Accepted Date: 27 June 2016

Please cite this article as: Hothi HS, Panagiotopoulos AC, Whittaker RK, Bills PJ, McMillan R, Skinner JA, Hart AJ, Damage Patterns at the Head-Stem Taper Junction Helps Understand the Mechanisms of Material Loss, *The Journal of Arthroplasty* (2016), doi: 10.1016/j.arth.2016.06.045.

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#### Damage Patterns at the Head-Stem Taper Junction Helps Understand the

#### **Mechanisms of Material Loss**

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#### 26 Abstract

#### 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 better

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 <1 mm<sup>3</sup>)

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.

49

50 Keywords: Metal-on-metal; taper; material loss; wear; corrosion; retrieval

#### 51 Introduction

52 Material loss at the taper junction of stemmed metal-on-metal total hip replacements 53 (MOM-THRs) has been implicated in the early failure of these implants [1, 2]. It is 54 speculated that the mechanism of material loss at this junction involves either 55 corrosion [3-6], mechanical wear (fretting) or a combination of the two [7].

56

57 Previous retrieval work has reported volumetric material loss from the head-stem 58 taper junction as high as 25 mm<sup>3</sup> [8], which accounts for a third of the total material 59 loss in contemporary MOM-THRs. However, few studies have specifically looked at 60 explaining the mechanisms [1-6] behind this material loss and therefore this remains 61 an area of uncertainty.

62

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.

70

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.

#### 76 Materials and Methods

77 This retrieval study involved a consecutive series of 155 failed MOM-THRs that had 78 been received at our centre. The hips were retrieved from 66 male and 89 female 79 patients with a median age of 61 years (26-83) and a median time to revision of 40 80 months (12-89); the reasons for revision, as reported by the revising surgeon, were 81 given unexplained pain (n=148) and implant loosening (n=7). The median head size 82 was 46 mm (36-58) and the median pre-revision whole blood cobalt and chromium 83 levels were 7.4 (0.6-212.4) and 3.5 (0.2-111) respectively; the median Co/Cr ratio was 84 1.45 (0.03-17.70). Pre-revision plain radiographs were obtained for each implant to 85 determine the median acetabular inclination and the median horizontal and vertical 86 femoral offsets; these were 42° (12-68), 37 mm (6-66) and 79 mm (10-145) 87 respectively. The implants consisted of over 10 different contemporary bearing 88 designs together with over 9 stem designs, Table 1.

89

#### 90 Head Taper Corrosion Assessment

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

96

#### 97 Taper Material Loss Pattern Mapping

98 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 100 include analysis of the stem trunnion in this study as the surgeon had opted to retain

101 the stem in the majority of cases. Furthermore, it has previously been shown that in 102 hips with CoCr tapers and titanium (Ti) stem trunnions, material is often lost 103 preferentially from the head taper due to a mechanism of galvanic corrosion [8]; stem 104 trunnions that macroscopically appear undamaged have been shown to exhibit 105 minimal material loss.

106 A series of 180 vertical traces were taken along the axis of the taper surface using a 107 5µm diamond styles. These traces were combined to form a rectangular surface 108 depicting both undamaged regions and regions of material loss (hereafter referred to 109 as material loss maps); these maps visually depict the distribution and severity of 110 surface damage using a colour scale; this ranges from dark red regions representing 111 the unworn regions of the taper surface whilst the transition from yellow, to green, to 112 blue indicates regions of increasing material loss from the surface, Figure 1. 113 Therefore, each material loss map creates a recognisable pattern which can be categorised by an examiner. The subtraction of undamaged surface areas from 114 115 damaged areas also allows for an estimation of material loss volume.

116

#### 117 Classification of Taper Damage Patterns

In this study we considered tapers that had lost less than 1mm<sup>3</sup> of material from their surfaces as having 'minimal damage'. All tapers with less than 1mm<sup>3</sup> of material loss were therefore categorised as being in the minimal damage group.

121 A committee consisting of two examiners experienced in retrieval analysis examined 122 each of the remaining taper material loss maps to jointly agree how these should be 123 categorised according to their visual appearance. The examiners were blind to all 124 material loss data for the hips.

126 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.

#### 137 Analysis of Clinical and Implant Variables

We performed non-parametric analysis to determine the significance of differencesbetween the different damage pattern categories that had been proposed, in relation to

140 the clinical, implant and imaging variables described previously.

#### 151 **Results**

#### 152 Classification of Taper Damage Patterns

Our analysis revealed that there were 92 hips with material loss at the taper greater than  $1 \text{mm}^3$ ; a consensus was reached by the two examiners in this study to categorise these hips into 4 different groups according to the visual appearance on their taper material loss maps: (1) early axisymmetric (n=32), (2) late axisymmetric (n=21) (3)

asymmetric (n=33) and (4) coup-countercoup (n=6).

Table 2 presents examples of measured wear maps generated for each of the 4
categories (in addition to the minimal damage group) along with schematic examples
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 165 less (p<0.01) than implants with material loss greater than  $1 \text{mm}^3$ , which had a mean 166 corrosion score of 2.9 (2-4).

167

#### 168 Material Loss Measurements

The median volume of material loss of all taper surfaces was 1.20mm<sup>3</sup> (0-22.35). We found that 63 implants had material loss measurements of less than 1mm<sup>3</sup>, with a median of 0.65mm<sup>3</sup> (0-0.99); these were therefore categorised in the 'minimal damage' group. The material loss of the minimal damage group was significantly less than the early axisymmetric, late axisymmetric, asymmetric and coup-countercoup groups which had median material loss volumes of 1.89mm<sup>3</sup> (1-6.52), 4.23mm<sup>3</sup> (1.09-

175 22.35), 3.43mm<sup>3</sup> (1.04-17.03) and 2.16mm<sup>3</sup> (1.07-4.43) respectively, Figure 2. There
176 were no other significant differences for taper material loss measurements.

The median volumes of material loss at the combined bearing surfaces for the minimal damage, early axisymmetric, late axisymmetric, asymmetric and coupcountercoup groups were 7.87mm<sup>3</sup> (1.07-325.98), 4.63mm<sup>3</sup> (1.03-146.03), 6.86mm<sup>3</sup> (0-309.17), 7.95mm<sup>3</sup> (0.58-45.94) and 7.64mm<sup>3</sup> (4.06-17.15) respectively; there was 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.

The median head diameter of the early axisymmetric group was 46mm (36-56) and was significantly larger (p<0.001) than that of the minimal damage and coupcountercoup groups, which had median head diameters of 44mm (36-52) and 40mm (36-48) respectively. There were no significant differences in relation to the late axisymmetric and asymmetric groups, which had median head sizes of 46mm (36-52) and 46mm (42-54) respectively.

The median time to revision of the minimal damage and early axisymmetric groups was 37 months (12-85) and 38.5 months (12-85) and was significantly less (p<0.05) than that of the late axisymmetric, asymmetric and coup-countercoup groups which had median times to revision of 46.5 months (25-84), 49 months (16-89) and 45 months (35-78) respectively.

198

200 Discussion

201 We conducted a large-scale investigation of the taper surfaces of retrieved MOM-202 THR implants received at our centre and discovered patterns of taper damage that 203 have not been previously described. This has created a new classification system that 204 helps us better understand the mechanisms of material loss at the taper junction of hip 205 replacements; this work highlights the importance of retrieval analysis as suggested 206 by Jacobs and Wimmer [11]. 40% of hips had no relevant material loss from this 207 junction. In the remaining 60%, time implanted, head diameter and possible surgical 208 implantation technique or manufacturing tolerances were key influencing variables 209 for the material loss.

210

We have built on Bishops observations of two damage patterns, namely axisymmetric 211 212 and asymmetric wear, to define three further categories to produce a classification system that describes tapers with: (1) low (<1mm<sup>3</sup>) surface material loss, (2) early 213 214 axisymmetric damage in which there is a circumferential band of material loss near 215 the opening, (3) late axisymmetric in which this circumferential band additionally has 216 vertical bands running along the taper surface, (4) asymmetric in which there are 217 vertical bands of material loss that are localised to one region of the taper and (5) 218 coup-countercoup in which there are two distinct and diagonally opposing regions of 219 material loss.

220

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.

230

231 The early axisymmetric group of tapers had the second lowest volume of measured 232 material loss following the minimal damage group. Virtually all material loss was lost 233 along the circumferential bands visible on the measured wear maps; macroscopically 234 these regions presented evidence of black corrosive deposits. Implants in this damage 235 group had the joint highest femoral head diameters (equal to late axisymmetric and 236 asymmetric groups). It is speculated that the larger head diameters led to increased 237 frictional torque at the bearing surface [12, 13] that was transmitted along the taper 238 surface leading continuous cycles of oxide film fracture and repassivation and 239 ultimately to material loss at this interface. Imperfect tolerances between the head 240 taper and stem trunnion may have allowed fluid ingress to occur thereby leading to 241 the corrosive band near the taper opening.

242

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.

255

256 It is suggested that the large femoral head size of the asymmetric group was an 257 important influencing factor in taper damage. These tapers presented evidence of 258 material loss localised to one region along the engaged area of the taper-trunnion 259 interface. This damage pattern may be explained by considering the significance of 260 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 261 components were more susceptible to taper junction corrosion. This increased 262 263 flexibility may have been present in this asymmetric damage group of implants. This 264 may therefore have led to a scenario in which normal patient weight bearing created a 265 cavity on one side of the taper junction sufficiently large enough for fluid ingress and 266 therefore corrosion to occur preferentially in this region.

267

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 implantfactor 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.

282

#### 283 Conclusion

In this retrieval study we discovered 63 implants with material loss of <1mm<sup>3</sup> 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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We are grateful for the support of Gwynneth Lloyd and Elizabeth Ellis for their coordination of the Retrieval Centre and Radu Racasan, Bob Skinner and Siva Mahindan for their support in metrology measurements.

		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 Bloo	d Chromium (ppb)	-	3.5	0.2-111
Cobalt/Chromium Ratio		-	1.45	0.03-17.70
	<b>Biomet Magnum</b>	32	-	-
	Corin Cormet	10	-	-
	DePuy ASR XL	26	-	-
	DePuy Pinnacle	18	-	-
Bearing	<b>Finsbury Adept</b>	14	-	-
Design	S&N BHR	27	-	-
0	Wright Conserve	6	-	-
	Zimmer Metasul	4	-	-
	Zimmer Durom	8	-	-
	Others	10	-	-
	CLS	6	-	-
	Corail	35	-	-
	CPCS	4	-	-
C.	СРТ	11	_	-
Stem	S-ROM	7	_	-
Design	Synergy	7	_	-
	Taperloc	24	-	-
	Zweymuller	12	-	-
	Others	49	_	_

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

Taper Damage	Example	Schematic Example	Description
Minimal Damage (a)	Head Taper Opening	Head Taper Opening	Total volumetric material loss <1mm <sup>3</sup> .
Early Axisymmetric (b)	Head Taper Opening	Head Taper Opening	Circumferential band of material loss located near the opening of the head taper.
Late Axisymmetric (c)	Head Taper Opening	Head Taper Opening	Circumferential band of material loss located near the opening of the head taper together with vertical bands of material loss running uniformly along the taper axis.
Asymmetric (d)	Head Taper Opening	Head Taper Opening	Vertical band(s) of material loss running along the taper axis, localised to one region of the taper.
Coup- countercoup (e)	Head Taper Opening	Head Taper Opening	Two regions of maximum material loss that are diagonally opposing on the taper surface.

**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  $1 \text{ mm}^3$  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



