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Detailed Inspection of Metal Implants

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Introduction

Detailed visual inspection is the first step in the forensic examination of failed hip components in order to report on the changes that have occurred at the bearing surface and may help explain the mechanisms of failure and wear of metal-on-metal (MOM) hips which is not fully understood. Previous studies have reported on the significance of implant design and poor cup orientation which can result in edge wearing of the implant [1, 2]; the consequential material loss can be quantified and identified on complex metrology wear maps [3]. However early failure has also been reported in well positioned, low wearing hips [1, 4], and cannot be explained through metrology alone. Visual inspection of these retrieved hips may offer unique clues as to their cause of failure.

A number of retrieval studies [5-16] have reported on the visual appearance of the bearing surfaces of hips under investigation. In many cases, regions of fine scratches, discolouration and staining have been observed. Burgett et al. [17] described the formation of protein films presenting as discoloured regions in and around wear scars in MOM bearings. These have been characterised by Wimmer et al. [13] as tribochemical reaction layers which may be beneficial to bearing lubrication. A correlation has previously been demonstrated between the width of visible wear scars on edge-worn ceramic-on-ceramic bearing surfaces and material loss [12] however similar associations in MOM hips have not been reported.

Our overarching aim is to better understand the mechanism of failure of MOM hips. Whilst many studies have described visual surface features, the relationship between detailed visual inspections of the bearing surfaces of retrieved hips and material loss remains unclear. Therefore, for this study we devised a systematic inspection protocol and analysed the findings together with their associations with volumetric material loss at the bearings surfaces of retrieved MOM hips.

Methods

Patients and Component Information: This was a retrospective study of a series of 150 LH-MOM-THA cases collected by our retrieval centre. Implants were collected from 38 contributing hospitals in the UK during the period July 2009 to January 2012. The implants were retrieved from 62 male and 88 female patients with a median age of 60.5 (30-83) years and median time to revision of 41 (12-118) months. The median head diameter was 46 (36-60) mm and the pre-revision whole blood cobalt and chromium metal ion levels were 7 (0.6-237) and 3.79 (0.2-181) respectively. The bearing surface designs consisted of the ASR XL (DePuy Orthopaedics, Leeds, UK; n=61), Magnum (Biomet, Swindon, UK; n=28), Birmingham Hip (Smith & Nephew, Warwick, UK; n=26), Cormet (Corin, Gloucester, UK: n=14), Adept (Finsbury, UK; n=12) and Durom (Zimmer, Winterthur, Switzerland; n=9). The reason for revision for each retrieved hip was determined by examining surgical notes and follow up questioning of the revising surgeon; these are therefore based on their opinion. The reasons for revision were: unexplained pain (105), aseptic femoral loosening (17), aseptic acetabular loosening (12), component misalignment (7), infection (6) and fracture (3).

Detailed Visual Inspection of Bearing Surfaces: Detailed, non-destructive macroscopic and stereomicroscopic examinations of the bearing surfaces of all 300 retrieved components were performed by an examiner experienced in retrieval analysis. A Leica M50 microscope [Leica Microsystems, Germany] at up to x40 magnification was used to examine each surface. All macroscopic examinations were performed with the naked eye at a single workstation, with the aid of a spotlight emitting ‘white light’.

The presence of 8 specific features relating to changes in the visual appearance of the surfaces was recorded. In this study these features are referred to as: (1) light scratches; (2) moderate scratches; (3) heavy scratches; (4) haziness; (5) discolouration; (6) embedded particles; (7) pitting; (8) presence of a visible wear scar, Figures 1. Table 1 describes the criteria used to define each feature.

Each component was examined by considering each surface in terms of zones consisting of quadrants and sub-quadrants, separated into the polar (P) and equatorial (E) regions of the cup and head, Figure 2. In order to quantify the severity of each feature, each zone was scored on a scale of 0 to 3 by evaluating the percentage of the surface area of the zone that exhibited the feature in question, Table 2. An overall score for each surface was determined as the sum of the scores of each zone; this was used for the assessment of each damage feature.

Preliminary tests of this visual grading method revealed that this is a reliable method; the repeatability of scores for a sample of 30 implants by the same examiner was determined to be substantial, as defined by Landis and Koch [23], with a Kappa value of 0.68. Repeat assessments of the surfaces were carried out by the examiner on a separate day and Kappa values were determined by comparing the overall scores for each surface between the two separate occasions that they were determined. Similarly, the repeatability of this method was determined by comparing the overall scores from the first examiner with scores determined by a second independent examiner with the same sample of 30 implants. The repeatability was also determined as being substantial, with a Kappa value of 0.62.

Measurement of bearing surface material loss: Measurement of the volume of material loss at the bearing surfaces of each component was performed using a Zeiss Prismo (Carl Zeiss Ltd, Rugby, UK). A 2mm ruby stylus was used to record up to 300,000 data points along 400 polar scan lines at a speed of 3mm/s, using previously published protocols [3]. An iterative least square fitting operation was used to analyse the measurement data, which was segmented such that only the unworn bearing geometry was used in mapping the distribution of material loss [3]. The wear maps generated were used to determine if edge loading of the hip had occurred by identifying the region of greatest wear on the cup surface, in a similar approach to a previous study by Matthies et al. [7].

Statistical analysis: The univariable associations between the eight surface features and the volumetric material loss at the cup and head bearing surfaces were assessed using simple linear regression models. Multiple linear regression models were subsequently used to assess the simultaneous contribution of the inspection scores, found significant in univariable analyses, on the wear outcome variables. All statistical analysis was performed using Stata/IC version 12.1 [StataCorp, College Station, TX, USA] and throughout a p value < 0.05 was considered significant.

Results

The total volumetric material loss was a median of 1.70 mm^3 (0.062 – 200.26 mm^3) from the cup bearing surface and 4.05 mm^3 (0.11 – 228.29 mm^3) from the head bearing surface.

Detailed Inspection of Cup: Clear wear scar (R^2=70%), moderate scratching (R^2=23%), discoloration (R^2=72%) and haziness scores (R^2=33%) were all found to be significantly positively correlated with cup wear volume in univariable analysis ($p<0.01$). Light scratching was significantly negatively correlated with cup wear volume (R^2=5%, p=0.03). Clear wear scar and discoloration scores remained significant predictors ($p<0.01$, $p<0.01$), together explaining 77% of the variance in the cup wear volume.

Inspection of Head: Clear wear scar (R^2=73%), moderate scratching (R^2=34%), discoloration (R^2=67%), and haziness scores (R^2=47%) were all found to be significantly positively correlated with head wear volume in univariable analysis. Light scratching was found to be marginally insignificantly negatively correlated with head wear volume (R^2=4%, p=0.06). Clear wear scar and discoloration scores remained significant predictors in the multiple linear regression model ($p<0.01$), together explaining 79% of the variance in the head wear volume.

Discussion

The rate of revision of large diameter (head diameter >36mm) is high. The 5 and 9 year revision rates of MOM-THAs were reported by the National Joint Registry of England, Wales and Northern Ireland as 7.65% and 17.66% respectively [18], whilst the Australian Joint Registry reported revision rates of 9.6% and 18.1% at 5 and 12 years respectively [19]. This compares to less than 3% at five years for conventional total hip replacement using either ceramic or polyethylene bearings [18]. Retrieval analysis of failed hip components plays a significant role in understanding mechanisms of failure and visual inspection is an important tool in this. A number of studies have commented on visual surface changes of retrieved hips however the interpretation of these observations and their relevance in relation to metrology analysis is unclear.

Our study is the first to present methods for detailed, systematic inspection of metal bearing surfaces and also to report on how these findings correlate with measured material loss. We have developed a protocol for quantifying visual surface changes by considering the cup and head in terms of zones, similar to the approach used by Goldberg et al. [20] for scoring corrosion and fretting of tapered modular hips junctions; this scoring method has been shown to be significantly positively correlated with material loss at the head taper [21].

In the current study, we found that severity of specific bearing surface changes were associated with material loss; this may help in understanding the reasons for early implant failure. We found that for retrieved hips that had higher material loss at the bearing surface, there was an increase in the visual severity of moderate scratching, discolouration, haziness and the size of the wear scar for both cup and head. In the majority of cases, there was no evidence of heavy scratching, pitting or embedded particles; when heavy scratches were observed, they were suspected as being due to retrieval damage.

The larger number of moderate scratches observed in higher wearing bearing surfaces may be evidence of 3^{rd} body particles, such as hydroxyapatite coating or bone fragments, becoming trapped between the cup and head during normal articulation. Although there was little evidence of embedded particles or pitting in the surfaces examined, pitting was slightly more prevalent and was observed near the equator of heads. This suggests that either the 3^{rd} body particles were dislodged from the bearings or disintegrated at some point.

In contrast, a negative association was found between light surface scratches and volumetric wear. It was reported by the examiner that in many cases where a clear wear scar was visible, this feature often consisted of a distinct transition at the scar boundary between a heavily scratched region and one which had considerably fewer scratches or in some cases was polished in appearance. There was however an association with haziness of the surface, which is described in this study as being due to a region of densely packed light scratches that are indistinguishable from each other.

Discolouration of the surface strongly correlated with material loss. In heavily worn components, discolouration scores of at least one were recorded in all surface zones, in contrast to the zone-specific location of wear scars. The precise source of discolouration is unclear; it may be due to poor bearing lubrication or may be evidence of surface films or tribolayers. Surface deposits, such as denatured proteins, may also visually be described as discoloured regions however these were not actively included in scoring of this feature as they do not alter the morphology of the underlying surface. These were identified (and excluded) as discoloured areas with a notable change in texture under the examiners finger.

The visible discolouration changes of the bearing surfaces may also be due to tribocorrosion of the CoCr components, where the passive oxidised surface film is removed, exposing the underlying metal to corrosion. Some of these changes may be attributed to the formation of tribolayers created from proteins during tribochemical reactions, as described by Burgett et al. [17] and which have been suggested as being beneficial to the lubrication properties of MOM bearings [13]. However the strong associations with moderate surface scratching suggest that third body wear may further accelerate the tribocorrosion process and contribute to the loss of material and release of metal ions.

Multiple linear regression showed that the wear scar score, together with discolouration, was one of the most significant predictors of material loss. Scoring of this feature was specifically characterised by the surface coverage of the distinct scar boundary as opposed to the normal discolouration and was found to occur primarily near the equator of the cup and closer to the polar zones of the head. Pourzal et al. [16] reported on the appearance of these wear scars under scanning electron microscopy (SEM), demonstrating the 'sudden change' in the composition and direction of scratches at the scar boundary.

Future work relating to bearing surface assessment will require detailed characterisation of surface damage observed microscopically, using SEM and surface profilometry, which will aid in understanding failure mechanisms. This may involve identifying and quantifying micro-grooves and surface depressions that are unique in appearance to pitting, such as elliptical shaped Dongas described by Nguyen et al. [22]. Additional work may involve developing protocols for visual assessment of the neck-stem taper junctions of modular neck hips, similar to previous work evaluating the stem-head taper [20, 21].

Our study has contributed to the work on retrieval analysis of metal hips, showing that detailed visual inspection of the bearing surface can offer clues as to the mechanisms of failure. We have highlighted key surfaces changes that may be associated with increased wear. The prevalence of moderate scratching in highly worn hips suggests 3rd body wear as an important area of future investigation. Whilst correlations with these parameters are significant, we do not suggest that visual inspection be performed as an alternative to accurate metrological assessment but rather as a complimentary tool in retrieval analysis.

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Table 1

Table 1: Bearing surface changes recorded during detailed visual inspection

Image	Surface feature	Description
a	Light Scratching	Visible scratches that are not detectable under a fingernail run across the surface.
b	Moderate Scratching	Visible scratches that can be detected under a fingernail run across the surface.
c	Heavy Scratching	Scratches with depth clearly visible and that will catch a fingernail running across the surface.
d	Haziness	A change in the surface appearance whereby surface scratches are so densely packed together that one scratch is indistinguishable from the next. This will often result in a reduction in the reflectivity of the surface.
e	Discolouration	A change in the appearance, commonly observed as a 'staining' of the surface.
f	Embedded Particles	Hard, third-body particles that have become embedded in the surface.
g	Pitting	Indentations in the surface that have dimensions similar in length and width.
h	Wear Scar	A region (or regions) on the bearing surface that has a distinct boundary marking the transition from one feature to another. This will often be observed as an abrupt change from a discoloured and lightly scratched region to one which is notably less scratched or discoloured.

Table 2

Table 2: Inspection criteria used to quantify each surface feature

Inspection Score	Criteria
0	No visible evidence of the feature in question
1	<25% of the bearing surface zone exhibits visible evidence of feature
2	Between 25% and 75% of the bearing surface zone exhibits visible evidence of feature
3	>75% of the bearing surface zone exhibits visible evidence of feature

Legends to Figures

Figure 1: Examples of bearing surface features observed microscopically: **(a)** Light scratches, **(b)** Moderate scratches, **(c)** Heavy scratches, **(d)** Haziness, **(e)** Discolouration, **(f)** Embedded particles, **(g)** Pitting and **(h)** Clear wear scar

Figure 2: **(a)** Cup bearing surface considered in terms of 8 zones: 4 zones in the polar (P) regions and 4 zones in the equatorial (E) regions; **(b)** Head bearing surface considered in terms of 8 zones: 4 zones in the polar (P) regions and 4 zones in the equatorial (E) regions

Figure 1

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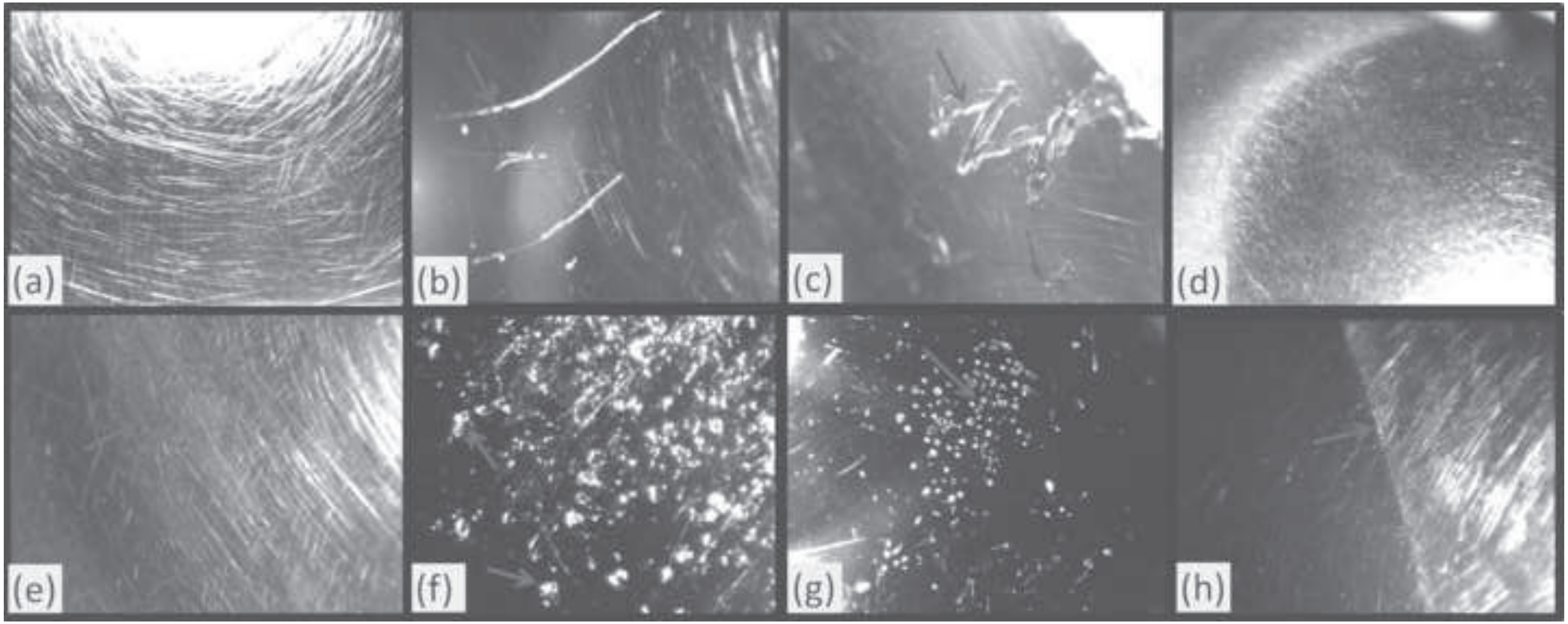

Figure 2

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