



Quantifying the bearing surface wear of retrieved hip replacements

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Abstract: Accurate quantification of bearing material loss from retrieved metal-on-metal (MOM) hip replacements is key to understanding their failure. Geometric methods are currently the only means of estimating volumetric wear from retrieved implants and numerous contrasting approaches to obtain these measures have been published. Data collection strategies have been thoroughly discussed and refined to minimise the effect of error incurring factors; however, there is an opportunity to optimise the current methods of estimating the pre-wear geometry and, therefore, improve the accuracy of wear volume measurements. An automated analysis strategy to quantify volumetric wear is proposed in this study, which utilises the entire bearing surface to determine the implants pristine geometry. This involves the iterative removal of geometrically effected data points to optimise the fit and size of a perfect sphere. Once fitted, this reference geometry is compared with the measured data, in its entirety, to calculate the volume change representative of the quantity of material lost. Improving the reliability of this parameter could influence the care of a million patients that remain with MOM hip implants. Rigorous validation of this method will dominate future work, ensuring that the accuracy and reliability of this approach are sufficient to provide clinically meaningful data.

1 Introduction

The high prevalence of metal-on-metal (MOM) hip implant revision, due to adverse reactions to metal debris has been widely reported. The national joint registry currently states a 10 year cumulative probability of revisions of 17.15 and 18.2% for cemented and uncemented MOM primary hip replacements, respectively [1]. In 2017, the Medicines and Healthcare products Regulatory Agency (MHRA) published an updated Medical Device Alert, recommending that all MOM hip patients, regardless of symptoms, undergo frequent follow-up and blood metal level testing [2]. The necrotic effect of metal debris on peri-prosthetic tissue has also been well-documented [3], with the levels of blood cobalt and chromium ions being correlated with the amount of wear measured at the bearing surface during retrieval analysis [4, 5].

Clinical evidence suggests that the dose response to metal debris can differ between individual patients; the definition of clinically relevant volumes of wear is, therefore, complex and must consider influential patient factors. However, a key contributor to determine clinically relevant wear volumes is the ability to accurately quantify the amount of material lost from MOM bearing surfaces; this information may influence the management of the million patients worldwide, within which this bearing type remains implanted.

Many implant factors contribute to wear, including surface roughness and finish, cup-head diametrical clearance, lubrication mechanisms and the influence of biological and foreign body debris [6–12]. Surgical and patient factors can also affect the amount of wear seen in retrieved hips, ranging from implant positioning to patient activity levels [5, 13, 14].

Gravimetric analysis is currently considered the ‘gold standard’ for measuring material loss from orthopaedic devices [15, 16]; however, it is dependent on obtaining implant mass prior to wearing. This requirement limits its use to hip simulator research and validating new methods [17], as pre-implantation component mass is unobtainable for retrieval analysis.

1.1 Geometric bearing surface analysis

A range of tools and methodologies have been used to acquire digital representations of bearing surfaces, as seen in Table 1, most often consisting of point cloud data. Over 20 years ago, Schmidt *et al.* [19] used a roundness measuring machine to characterise the linear wear depth of retrieved hip implants, while more recently, coordinate measuring machines have been commonly used to map their surfaces [16, 23, 24]. Other methods such as the RedLux Artificial Hip Profiler have also been utilised to capture raw geometrical data, but require similar post-processing to all other approaches [27].

In the utilisation of coordinate measuring machines (CMMs), a range of strategies have also been developed to scan the bearing surface, along with numerous methods of estimating the unworn surface for comparison. When scanning the cup or head of a hip replacement, a probe is instructed to follow a predefined path along their surfaces; this has varied from parallels of latitude to meridians of longitude, with different geographical points of emanation. It is generally accepted that a sufficient number of data points are required when estimating the volume of material loss, with both the ISO standard 14242-2 and American Society for Testing and Materials (ASTM) standard F2979-14 stating a greatest acceptable point spacing of 1 and 0.5 mm, respectively [30, 31].

Bills *et al.* [15] demonstrated the importance of probing strategy when calculating bearing volume, showing a difference of over 350 mm³ when using 40 times the number of scan lines and 1/20th the original point pitch. However, through the analysis of an explanted component using a variety of scanning parameters, Langton *et al.* [29] saw no significant difference in their results, suggesting that the effect of point spacing was not as considerable as the accurate identification of the unworn surface.

1.2 Data analysis: estimating the pre-wear geometry and wear volume

The development of international standards has facilitated some consistency between probing strategies employed by different

Table 1 Reported methods of quantifying material loss from the bearing surface of hip implants

First author	Year	Scanning strategy	Reference geometry	Data analysis		
				Fitting method	Points included in the fit	Volume calculation
Willert	1996 [18]	Roundness measuring machine: Talyrond (Rank Taylor Hobson, Leicester, UK) scan lines: tracks over the pole point spacing: not specified. CMM: not specified	sphere	Ideal radius defined from the origin of the measured data.	Areas affected by scratches ('walls and grooves') were eliminated.	Worn regions were identified by deviations from spherical contour lines. The wear volume was calculated formulaically using the measured linear wear values.
Schmidt	1996 [19]	scan lines: not specified CMM: not specified	sphere	Not applicable	Not applicable	Only linear wear was calculated from the maximum deviation from the assumed initial sphericity. Developed numeric programme was used.
McKellop	1996 [20]	CMM: Brown and Sharpe (DATUM Inc., Phoenix, AZ) scan lines: emanating from the pole point spacing: traces were equally spaced.	sphere	Qualistar programme (ICAMP Inc.) was used to approximate the reference geometry diameter and translate its centre to minimise the RMSE. The diameter was manually adjusted if its calculation was affected by the wear location. The process was iterated to optimise fit. Least-square regression was used to obtain a best-fit diameter.	Unworn regions, manually identified by microscopic imaging. Recesses in the pole and relief band near the rim were also excluded.	
Kothari	1996 [21]	CMM: Brown and Sharpe, North Kingston, RI scan lines: not specified point spacing: not specified.	sphere		Non-spherical regions of the cup were excluded.	Acknowledging manufacturing tolerance values, the distance between the reference and measured data defined the wear depth, while numeric integration was used to obtain the wear volume. Not specified.
Reinisch	2003 [22]	CMM: LH6 (Wenzel, Wiesthal, Germany) scan lines: 3D contour mesh point spacing: mesh spacing <1 mm.	sphere	Initial radii of the components assessed from the unworn areas.	Unworn areas	
Morlock	2006 [23]	CMM: BHN805 (Mitutoyo, Japan) scan lines: planar scans through the pole, emanating and terminating at the equator point spacing: 0.5 mm point pitch.	ellipsoid	MATLAB function varied seven degrees of freedom to minimise the sum of the squared errors between the measured points and the ellipsoidal surface to obtain the best fit.	Fraction of points with the greatest radial distance from the best-fit surface was eliminated and revised for each iteration of the optimisation procedure.	Surface of the best-fit ellipsoid was triangulated between measured points. The volume enclosed between the centroid of each triangle and its projection on the best-fit sphere was calculated. Wear volume magnitudes were summed for all triangles. Comparison of worn and pre-worn surfaces.
Bills	2007 [24]	CMM: Zeiss Prismo (Carl Zeiss Ltd., Rugby, UK) scan lines: 0.5 mm x 0.5 mm grid point spacing: 0.5 mm point pitch. Assumed to be the same [23].	NURBS	Non-uniform rational basis spline (NURBS) were used to fit a surface through the points measured in the unworn regions.	'Unworn zones', manually identified as the non-contacting portion of the bearing.	
Morlock Witzleb	2008 [25] 2009 [26]	CMM: CMM5 (SIP, Geneva, Switzerland) scan lines: concentric circles point spacing: every 5° along the scan line.	hemisphere	Reverts back to the use of a spherical reference geometry [23]. Non-linear optimisation, minimising radius deviations in the unworn surface, was used to determine the parameters of the hemisphere.	Unworn surface	Mathematical model was developed to calculate a weighted sum of the volumetric deviations within the worn regions.
Tuke	2010 [27]	3D optical profiler: RedLux Ltd. (Southampton, UK) scan lines: not specified point spacing: not specified.	sphere	Linear least-squares fit. The wear scar is then identified and excluded from the remaining fitting process.	'...only the original, unworn surface is used' once the wear scar is manually selected and excluded.	Calculated as the 'difference between the best-fit sphere and the measured data'.
Carmignato	2011 [28]	CMM: Zeiss Prismo VAST 7 (Germany) scan lines: 0.3 mm x 0.3 mm mesh point spacing: 0.3 mm point pitch.	sphere	Diameter and alignment of the reference geometry are determined by points measured in the unworn areas.	Measured diameter of an unworn sample and the unworn regions of the analysed hip.	PolyWorks Software used to calculate the volume enclosed between the reference CAD and measured data.
Lord	2011 [16]	CMM: LEGEX322 (Mitutoyo, Japan) scan lines: the equator to pole point spacing: not specified.	sphere	MATLAB function was used to calculate the radius of each measured point. The radii with the highest frequency were considered unworn. The original unworn radius was identified by the mode of the measured radii.	All points	MATLAB grid was formed from the measured points. Mean grid square wear depth was calculated as the mean depth at each corner of the square. These values were multiplied by the area of the squares and summed.

Continued

Table 1 Continued

First author	Year	Scanning strategy	Reference geometry	Data analysis		
				Fitting method	Points included in the fit	Volume calculation
Bills	2012 [15]	CMM: Zeiss Prismo (Carl Zeiss Ltd., Rugby, UK) scan lines: polar grid, concentrating the number of points toward the pole of the implant, with the scan lines also emanating from the pole point spacing: 0.1 mm point pitch and equatorial point pitch of 0.3 mm.	sphere	Least-square regression method was used to best fit the reference geometry, which was then adjusted manually to optimise the fit through the unworn region and account for the wear scar.	All points	Comparison between reference and measured data achieved using a CAD software package, Catia (Dassault Systems, France).
Langton	2014 [29]	This method was adjusted from [16] to allow the unworn surface to be located more rapidly.		Same data processing method [16].		

Reference geometry: the geometry used to represent the pristine surface; fitting method: method of fitting the reference geometry to measured data points; points included in fit: the points to which the reference geometry was fitted [15, 16, 18–29].

research groups; however, methods of analysing this data to estimate material loss volumes remain either individualised or tailored to the approach of each researcher.

As previously discussed, to determine the volume of material loss, the original unworn geometry must be approximated. The majority of methods are based on the concept of extrapolating this pre-wear surface, often referred to as pristine, zero cycle or virgin surfaces, from an isolated region of the bearing that is considered unworn. There are, however, limitations to this approach, especially considering that the subjects under analysis are retrieved hip implants, which may have remained *in vivo* for a number of years and exposed to multiple deformation forces. Macroscopic visual analysis of these bearings suggests that considerable portions of the devices are often no longer geometrically equivalent to their pre-use state. Additionally, gradual transitions are common at boundaries between identifiably worn and unworn regions. This exposes a limitation of methods, where only a speculated worn region is considered in the calculation of material loss [26], as these factors hinder our ability to identify all worn regions in their entirety. Acknowledging these constraints, the accurate identification of the unworn regions is essential to minimise error when obtaining a reference shape for comparison.

Kothari *et al.* [21] were one of the first to adopt the approach of fitting a perfect sphere to measured data through least-square regression, once non-spherical regions were excluded. When analysing the measured data set, the identification and exclusion of points that represent geometrically affected regions are crucial in generating an accurate estimation of the pre-wear surface. However, implant sphericity can be influenced by many factors such as manufacturing tolerances and component deformation, in addition to wear. A consequential error in the defined reference sphere diameter affects its deviation from each measured data point, culminating in an even greater magnitude of error when computing the change in volume (i.e. small errors in estimated diameter can lead to large changes in estimated volume).

In an attempt to better isolate the unworn surface, Lord *et al.* [16] used the measured points with the radii of the highest frequency to define the size of the perfect sphere; assuming that the most common radii would represent the remaining points from the pre-wear surface. The advantage of this approach is that the entire bearing surface is acknowledged, considering each point individually, rather than a subset of points representing localised unworn patches. However, this method may be compromised in the analysis of implants with extensive wear, as the frequency of pristine radii would be reduced. The concept of a perfect sphere (constant radius) comparison may also lead to errors, as it assumes uniformity within the ‘off-the-shelf’ product; the variability of manufacturing tolerances may impact these calculations. Ideally, a three-dimensional (3D) reconstruction of the pre- and post-wear surfaces of the implant would be compared; however, the use of a best-fit sphere is currently the most reliable approach despite its conservatism.

Morlock *et al.* [23] considered overall bearing deformation, due to the press-fit process, significant enough to be accounted for by fitting an ellipsoidal surface to the data set. Points with the greatest deviation from this surface were then removed to optimise the fit, again advantageously considering the entire surface. However, their approach to defining the proportion of removed points that would provide the best fit was not unique to each implant, but rather a predetermined value derived from initial simulated wear experiments.

Bills *et al.* [24] fit NURBS to the areas thought to be unworn, accounting for this possible inconsistency in surface finish. This extrapolation was later refined to involve the manual adjustment of a perfect sphere to better fit the measured data, accounting for the influence of wear scars [15]. Morlock *et al.* [25] also utilised a best-fit sphere approach in later work. The outcomes of methods that require manual input may introduce inter-examiner variability; however, this may be mitigated by using robust protocols and adequate training.

In spite of all previously discussed limitations, each method has been validated to some degree, but only a minority were directly

assessed on their ability to estimate the volume of material lost from a worn, retrieved hip bearing. Carmignato *et al.* [28] and others evaluated the uncertainty of their methods following the ‘Guide to the expression of uncertainty in measurement’. Numerous factors have been discussed in this short communication that may influence the quantification of material loss from hip implants; a lack of conformity between validation methods makes it difficult to directly compare and assess these different strategies.

1.3 Summary

Methods of scanning the bearing surface geometry of retrieved hip implants using coordinate measuring machines have been well-developed. However, it is acknowledged that the current analysis approaches to quantifying wear volumes need further refinement. This is largely due to the challenges in accurately defining the pre-worn surface geometry. Many currently used methods attempt to extrapolate the unworn geometry from localised patches, believed to be pristine. Some methods consider larger portions of the bearing surface, which may enable better estimation of the unworn geometry; however, the analysis method could be refined to more reliably identify points that hinder an optimum perfect sphere estimation.

Building on previous methods, this short communication aims to introduce an automated analysis strategy to quantify material loss volumes, which maximises the number of measured points used to reconstruct the pristine geometry by (i) considering data points across the entire bearing surface and (ii) through iterative removal of data points that are not representative of the unworn geometry until a defined root-mean-square error (RMSE) target is met.

2 Material and methods

2.1 Measurement of bearing surface

Point cloud representations of each bearing surface (cup and head) were generated using a Zeiss Prismo (Carl Zeiss Ltd., Rugby, UK) coordinate measuring machine and a previously published scanning strategy [15]. This involved a 2 mm ruby stylus following a number of longitudinal scan lines between the bearings pole and equator. The number of these paths is determined by the size of the component, allowing the distance between the points at the equator to remain below 0.5 mm, in accordance with the ASTM standard [30]. The point pitch along each line is also maintained at this distance. For example, a 40 mm diameter head would be analysed using just in excess of 250 scan lines, accumulating around 17,500 data points.

2.2 Quantification of wear

The point clouds of each component, generated using a CMM, were directly imported into a custom developed software package. Initially, a sphere was best fitted to all the measured data points. The target RMSE between these two geometries was defined as $<2\ \mu\text{m}$, in accordance with ASTM F2979-14 [30]. With each iteration, both the RMSE and the individual error of each data point from the best-fit sphere were calculated. Measured points were then removed from the model if their individual error was not within ~ 2 standard deviations of the mean error and located on the worn side of the components, relative to the best-fit sphere. This process was repeated, with a new best-fit sphere defined with each iteration; the process was allowed to continue until the RMSE converged to a value below $2\ \mu\text{m}$ or until the maximum number of iterations were performed. The maximum number of iterations was initially defined as 100 in order to optimise the processing speed; this was increased if the RMSE did not converge below $2\ \mu\text{m}$.

The data points remaining at the end of this iterative process were used to define the unworn geometry of the retrieved component. The difference in volume between (i) this unworn geometry and (ii) the

geometry formed by all the measured data points was calculated and considered representative of the volume of material loss from each component.

2.3 Specimen specifications

Twelve retrieved MOM hips were analysed in this paper, utilising the previously described method to obtain a volumetric estimation of material loss for both their cup and head components, with wear maps being generated for all specimens. Implant selection was based on visual assessment, with the aim of including components displaying the broad range of wear volumes seen in previous retrieval analysis studies.

3 Results

The volumes of material lost from the 12 retrieved MOM hips are reported in Fig. 1, with a worn map of each component demonstrating the location of any change in the surface geometry. The median volume of material loss was $27.02\ \text{mm}^3$ (0.36–120.72) and $24.16\ \text{mm}^3$ (1.39–78.50) from the cup and head components, respectively; while the median total bearing wear volume was $51.18\ \text{mm}^3$ (1.74–174.90). The location of the wear scar varied in size and shape; however, all displayed a gradual transition from the estimated pristine surface to worn regions. The wear maps generated for these implants also suggested that all acetabular cup components analysed in this paper were edge wearing, with the wear scar increasing in size as the wear volume increased. A trend in wear scar shape and location was also seen in the head components, as they were all worn nearer the pole in an elliptical pattern.

4 Discussion and conclusion

Building on previous research, we have presented an automated method of estimating volumetric wear from the bearing surfaces of hip implants. This approach considers data points across the entire surface, rather than localised unworn patches, in the estimation of the pristine geometry. Its ability to identify wear scars on 12 retrieved MOM implants has also been demonstrated, as the generated wear maps corresponded to patterns identified during their visual assessment (Fig. 2). The estimated range of volumetric material loss was also comparable with values reported in previous investigations into similar implant designs [32].

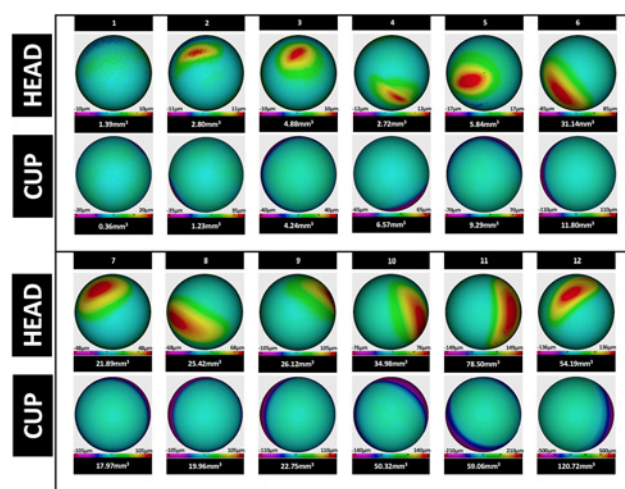


Fig. 1 Wear maps of 24 paired MOM hip implant components and the volume of material lost from their surface, both estimated using the proposed method

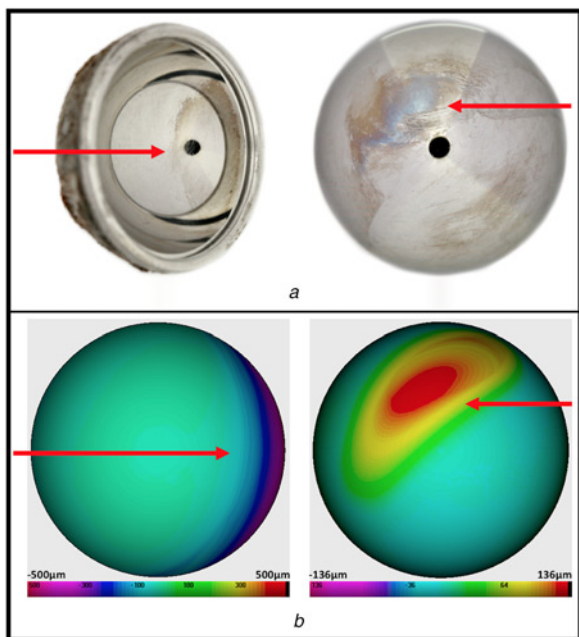


Fig. 2 Cup (left) and head (right) components of a retrieved MOM hip replacement

a Macroscopic image

b Wear map generated using the proposed method. Red arrows indicate the location of the worn regions

Numerous methods have been developed to quantify the volume of material loss from the bearing surfaces of retrieved hip implants; however, to be considered a truly reliable indicator of their performance, measurement accuracy is key. As gravimetric analysis is unachievable without pre-wear data, at present, geometric methods remain the only feasible approaches to obtain this parameter during retrieval analysis. Error incurring factors associated with geometric measurement strategies have been extensively discussed, providing sufficient information to minimise their influence on volumetric estimations through protocol refinement. Inconsistencies between methods primarily stem from their differing approach to estimate the virgin surface of the implants and obtaining a volume of material loss from the acquired data.

As demonstrated by the number of contrasting methods described in this short communication, a definitive conclusion has yet to be reached, regarding the most accurate approach to estimate the pre-wear geometries. These approximations are dependent on the presence of a reliable unworn region and should be recognised as a limitation; however, through consideration of the entire measured data set, their accuracy can be optimised.

There are many reasons for hip revision surgery, and similarly high implant wear may occur due to multiple factors associated with the surgeon, implant and patient. In understanding the mechanisms of failure, it is important that this methodology is combined with clinical imaging and patient data. Recent MHRA alert updates regarding the surveillance of MOM's hips emphasise the sustained relevance of accurate wear measurements. Their acquirement could further our understanding of individual patient sensitivity to metal debris, in response to smaller changes in dose. Quantifying such clinically relevant wear volumes would also benefit surgeons in the management of who, when and how to revise their patients. The concepts described in this method could also be useful in building on the previous work investigating the wear of knee replacements [33, 34].

Future work will present the validation of this method, with the intention of demonstrating its accuracy and repeatability when analysing retrieved implants that exhibit the full spectrum of wear values recorded in previous research. This method could provide reliable and clinically relevant data that may enhance our

understanding of MOM hip failure mechanisms and impact the management of the million patients, within which these devices remain implanted.

5 References

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