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Assessing the material loss of the modular taper interface in retrieved metal on metal hip replacements

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Abstract. Measuring the amount of material loss in the case of revised hip replacements is considered to be a prerequisite of understanding and assessing the true *in vivo* performance of the implant. This paper outlines a method developed by the authors for quantifying taper material loss as well as more general taper interface parameters. Previous studies have mostly relied on visual inspection to assess the material loss at the taper interface, whereas this method aims to characterize any surface and form changes through the use of an out-of-roundness measurement machine. Along with assessing the volumetric wear, maximum linear penetration and taper contact length can also be determined. The method was applied to retrieved large head metal-on-metal femoral heads in order to quantify the material loss at this junction. Material loss from the female femoral head taper can be characterized as a localized area that is in contact with the stem taper surface. The study showed that this method has good repeatability and a low level of interoperability variation between operators.

1. Introduction

Total hip replacement is considered to be the operation of the century with over 71,000 primary procedures performed annually in the UK alone [1-2]. Large head metal on metal hips (LHMOM) and hip resurfacings accounted for 15% of hip replacements used in primary operations in 2006-2008. Following higher than normal revision rates reported (13.6% at 7 years) for these type of implant compared to other designs the use of metal on metal decreased to 5% in 2011 [2]. A LHMoM hip comprises of a monobloc acetabular cup and a modular head that is secured to the femoral stem through a taper interface (see fig. 1).

Figure 1 Metal-on-metal hip replacement taper interface

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The taper characteristics are not standardised in terms of cone angle, length of contact or surface finish and as such each manufacturer has developed its own design. The taper interface has been identified in a number of studies [4-10, 25] as a source of wear and corrosion products and there have been identified increased blood ion levels in patients with LHMoM compared to resurfacing bearings [11,18]. Fretting, corrosion and metallic debris have been identified at the taper interface during revision surgery and in several studies [6-9]. A large number of factors have been identified as possible contributors to the observed material loss including micromotion due to angle mismatch, insufficient assembly forces, galvanic cell creation due to differential head and stem materials and increased frictional torque [12-16]. Determination of the volume of material loss at this interface is vital in determining the relative contribution that this makes to the overall failure of metal-on-metal hip bearings [18-25].

Figure 2 Retrieved metal-on-metal femoral head showing clear delineation of damage to taper surface.

Most previous studies relied on either the visual assessment of taper damage (which can be clearly seen in figure 2) or measurement by means of coordinate measuring machines [5,10]. The main limitation of visual inspection and microscopy is that it does not provide a quantitative assessment of wear. Coordinate measuring machines enable the assessment of wear volume but even the use of very small styli such as one of a commonly used 1mm diameter have the potential of acting as a mechanical filter to any surface with significant topography as would be observed in the case of a roughened taper surface.

A further study an optical measurement method has been used to measure and analyse replicated taper surfaces of hip replacement devices [26]. This method requires the use of a silicon-based elastomer material to cast a negative version of the surface that is to be measured. Whilst these replica materials have been shown to be accurate in replicating surface roughness, this is the first application to attempt to use this to replicate the geometry of a taper surface such that a volume could be determined.

The aim of this study is to present a method for assessment of taper material loss that provides a resolution comparable to that of surface measurement and creates a map of the entire taper. The method development centred on three main areas: creating the measurement protocol, developing a data fitting routine based on unworn data and material loss volume calculation. To date this method has been used to measure approximately 500 taper surfaces a small selection of which are presented here for illustrative purposes.

2. Methods and materials

2.1 Measurement protocol

The tapers in this study were measured using a Talyrond 365 (Taylor Hobson Leicester UK.) roundness measuring machine. This machine can measure straightness and cylindricity and has a stated gauge resolution if 30nm with a spindle run out value of 20nm. The components were mounted in a custom designed three sphere fixture that was attached to a two axis goniometer and an x-y translation stage.

Each component underwent a centring and levelling routine such that an eccentricity of under 1µm was established between the axis of the spindle and that of the component. The stylus used for measurements was a diamond tip pointed stylus with an end radius of 5 µm. The effects due to mechanical filtering which are inherent when using ruby styli are thus minimised and as a consequence the level of detail that was recorded increased.

Once the component alignment was established 180 vertical straightness traces were taken along the taper spaced relative to the taper axis at 2 degree intervals, in the case of a 12/14 taper this gives a maximum point spacing of 0.2mm. The direction of texture and surface structure as seen in figures 3 and 4 show that the circumferential spacing of points is less critical than the axial point spacing and vertical resolution of the method. The continuous measurement due to the indexing spindle ensures that all straightness traces are taken with respect to the same axis. This is important as any residual eccentricity from the centring and levelling process can be considered in the analysis process. The stylus deflection is recorded based on the reference position at the base of the taper.

2.2 Data leveling and fitting

The raw data is analysed through a number of procedures controlled through the application of a set of software tools developed in Matlab (The Mathworks Inc., Natick, USA). Following data capture the profile data is stitched and rolled out to give a rectangular areal map of the taper surface. The first step of the analysis is to level the surface map and remove the conical form using a linear least squares fit to all of the data. Figure 3 details the levelling and form removal process, figure 3a shows a primary unlevelled surface profile, figure 3b shows the surface profile with conic form removed.

The second step involves manual fitting of the data based on either a first or second order polynomial fit. This second data levelling function allows for the selection of which data regions are used to level the surface i.e. an area of taper surface that can be identified to have not been in contact with the male counterface. This data selection process is manual and is subjective, based on the manipulation of a 2D profile averaged from the measurement data. This method relies on the presence of unworn data at one or both of the distal and proximal ends of the taper surface so that a reliable and repeatable estimation of the original manufactured surface can be obtained. Generally speaking the female taper surfaces in question display unworn data at both distal and proximal ends as the implants of interest have short stem tapers that sit entirely within the head.

The surface to be levelled from is selected (shown as green highlighted area in figure 3b) and the type of levelling (linear or quadratic) is then superimposed. The quadratic fit is suitable for components that show signs of 'barrelling' or 'hogging' caused by the manufacturing process, such as the case shown in figure 3b. The resulting levelled profile is then shown in figure 3c.

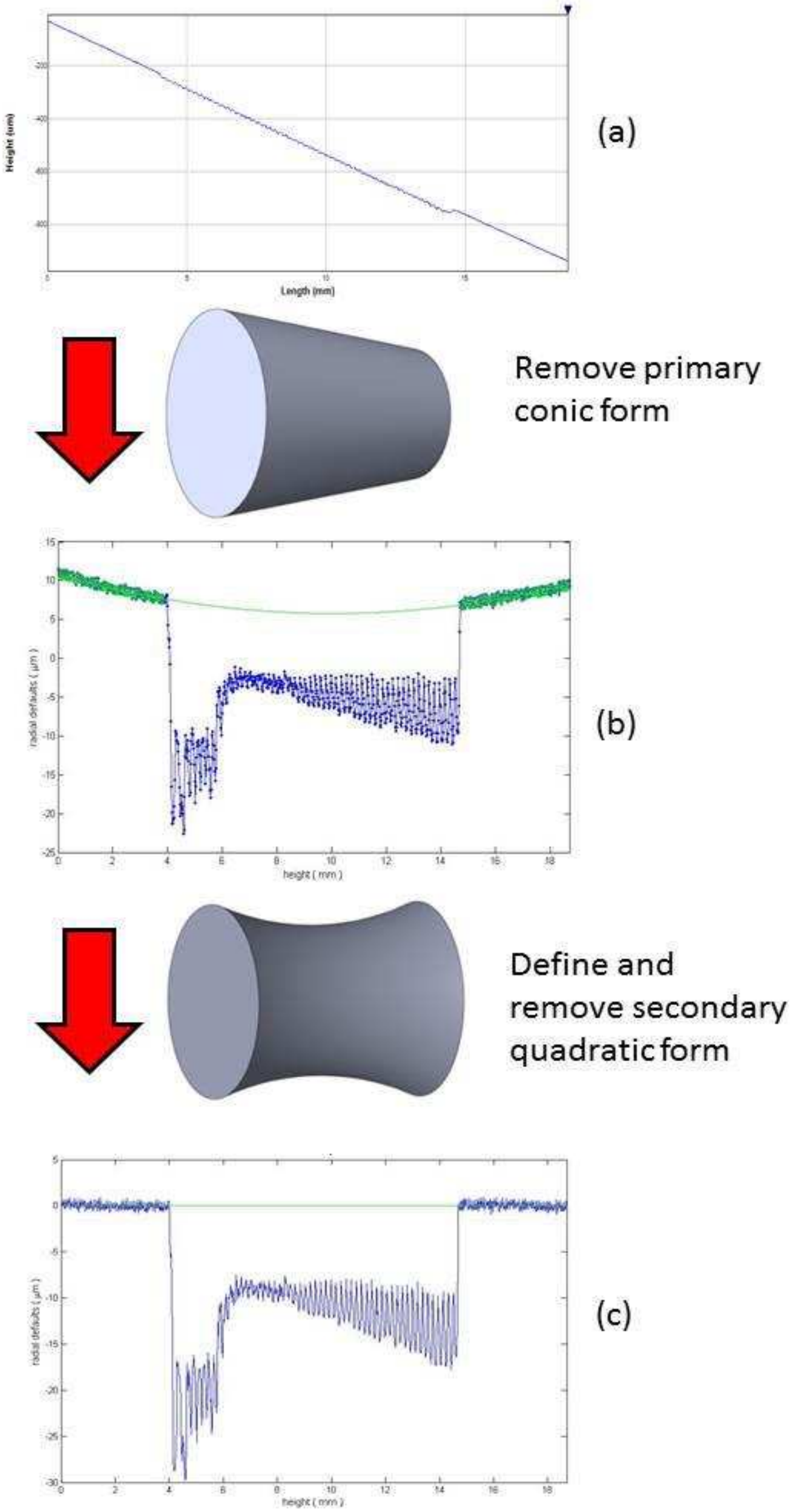

Figure 3 Removal of form deviation from a measured taper using Matlab protocol

At this point the volume of material loss can be calculated. The x axis of figure 4 describes the measured height of the taper in mm while the y axis describes the degree spacing of the vertical plots from 0-360 degrees. The Matlab model corrects for scaling on the y axis to take into account the shape of the cone by recovering the slope data from the original straightness profiles and producing a surface map such as shown in figure 4.

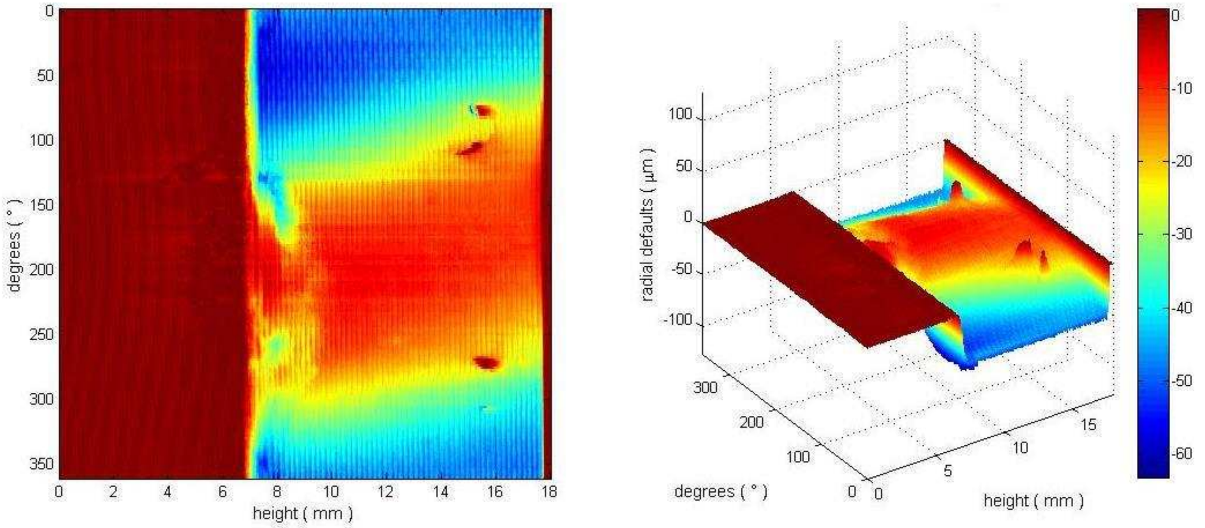

Figure 4 Example of levelled and fitted taper surface map

2.3 Volume calculation

The final step of the method is to determine the volume. The theoretical volume using cylindrical coordinates is:

$$V = \int_{\theta=0}^{2\pi}\int_{z=0}^{h}\int_{r=0}^{r(z,\theta)} dV = \int_{\theta=0}^{2\pi}\int_{z=0}^{h}\int_{r=0}^{r(z,\theta)} dr(rd\theta)dz$$

Where we define the following parameters:

h - height of the cone;

r – radius of the cone at height z;

$$V = \int_{\theta=0}^{2\pi}\int_{z=0}^{h}\left(\int_{r=0}^{r(z,\theta)} rdr\right)dzd\theta = \int_{\theta=0}^{2\pi}\int_{z=0}^{h}\frac{r^2(z,\theta)}{2}dzd\theta$$

$$r(z,\theta) = R_{med}(z,\theta) + \underbrace{\varepsilon(z,\theta)}_{excentricity} \qquad (\,\varepsilon(z,\theta) \ll R_{med}(z,\theta)\,)$$

$$\varepsilon_{max} = \max_{\substack{0<z<h \\ 0<\theta<2\pi}}\left(\,\varepsilon(z,\theta)\right)$$

The mathematical function that describes the radius of the cone which contains all data is:

$$r_{max}(z,\theta) = R_{med}(z,\theta) + \varepsilon_{max}$$

The corresponding volume is:

$$V_{max} = \int_{\theta=0}^{2\pi} \int_{z=0}^{h} \frac{{r_{max}}^2(z,\theta)}{2} dzd\theta$$

Therefore the expression of the volume of material loss is found by:

$$V_{material\ loss} = V_{max} - V = \frac{1}{2} \int_{\theta=0}^{2\pi} \int_{z=0}^{h} \left({r_{max}}^2(z,\theta) - r^2(z,\theta)\right) dzd\theta$$

$$V_{material\ loss} = \frac{1}{2} \int_{\theta=0}^{2\pi} \int_{z=0}^{h} \left(2R_{med}(z,\theta)(\varepsilon_{max} - \varepsilon(z,\theta)) + {\varepsilon_{max}}^2 - \varepsilon^2(z,\theta)\right) dzd\theta$$

However, the radial error ε is of the order of a micrometre, and R_{med} is of the order of a millimetre.

Because $\frac{|\varepsilon|}{|R_{med}|} \sim 10^{-3}$ and we can neglect the second order terms in ε^2 . As a result the volume that we want to determine is:

$$V_{material\ loss} \sim \int_{\theta=0}^{2\pi} \int_{z=0}^{h} R_{med}(z,\theta)(\varepsilon_{max} - \varepsilon(z,\theta))\, dzd\theta \quad [1]$$

This is applied to create a cumulative probability density function of the surface's height and a Abbott-Firestone [27] curve is generated that can then be used to identify the volume of material loss. Once the second fitting operation is completed, debris and agglomerates that are proud of the surface can be removed from the analysis by data thresholding using the Abbott-Firestone curve.

These curves are a useful tool for understanding a wide range of engineering surfaces and it is extensively used in the area of sealing and bearing surfaces since the 1930s, most commonly in the manufacture of internal combustion engine cylinder bores. The method, however, has wider use in the area of surface characterization and is useful for understanding the functional properties of surfaces that appear to have similar parametric roughness values. As the Abbott-Firestone curve generated uses areal information then material wear volume can be calculated directly.

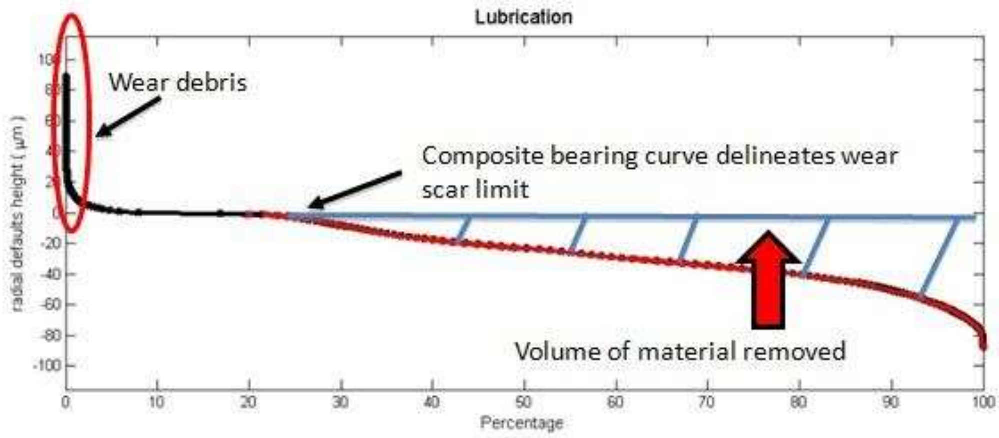

Figure 5 Abbott-Firestone curve showing area of wear debris and identification of material loss

The curve presented in figure 5 is generated based on the measurement data presented in figure 4. It is important to note the high aspect ratio at the left part of the curve which is due to debris sat on the taper surface. Due to the small volumes being measured this must be removed from the analysis as it has the potential to skew the volume calculation significantly. This determined volume of removed material highlighted in figure 5 is correlated with the cone form parameters that were determined at the first step of the levelling and fitting process defined in section 2.2.

2.4 Repeatability Study

A study was carried out to test the repeatability and reproducibility of the method. The component selected to conduct the study consisted of a retrieved femoral head which displayed a small amount of material loss to test the limit of sensitivity of the method.

In this process the component was measured 20 times. Each measurement was distinctive and followed the procedures outlined previously, the component being positioned and levelled for each individual measurement. This was done to ensure that any influences of the centring and levelling process are taken into account when analysing the data. This was done by a single operator.

The analysis process was performed blindly by two operators to assess inter-observer repeatability of the analysis process. The operators both used the specifications outlined by the method to analyse the data. This included the operator having to perform the form removal process as well as any thresholding required to estimate the volume of material loss.

3. Method validation

A study has been conducted to ascertain the validity and accuracy of the algorithms implemented in the analysis process for estimating the volume of material loss. A mathematically generated file that replicates a 12/14 taper configuration was created to test the robustness of the volume analysis process.

The virtual taper surface was generated with a taper length of 10mm. A material loss region was simulated in a section of the taper with a length of 8mm and an equal depth of 100μm as seen in figure 6 below. The material loss region consisted of a sawtooth pattern that repeats for 10 consecutive instances. The file consists of 360 vertical traces and each trace contains 2500 data points which is representative of a taper measurement dataset from the Talyrond out-of-roundness measurement machine.

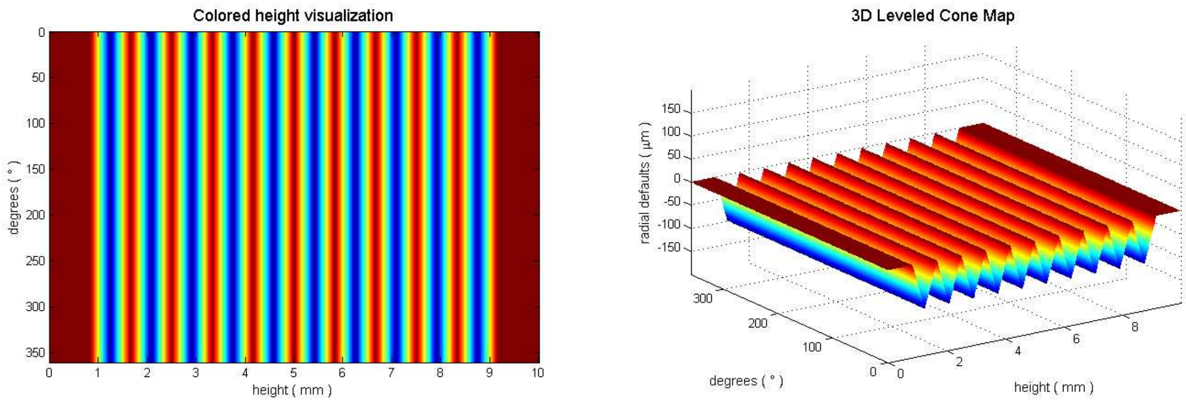

Figure6 Virtual taper data file containing a region of material loss

The fitting procedure was carried out as previously detailed and by excluding the data in the area of simulated material loss (data displayed in blue, figure 7) area an adequate fit was obtained.

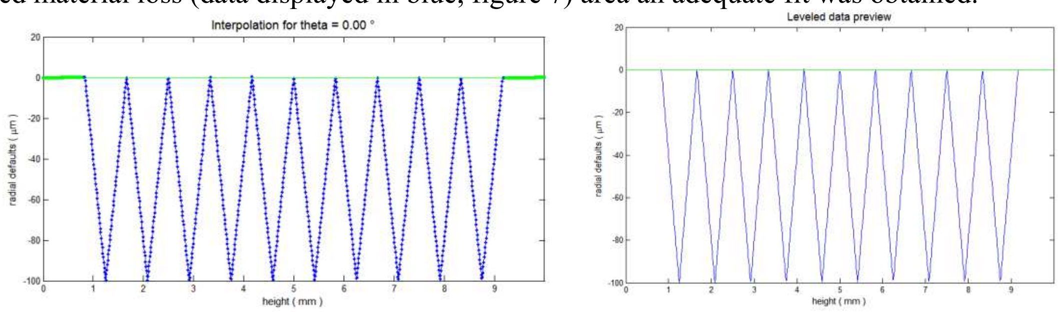

Figure 7 Levelling process showing selected unworn data in green (left) and subsequent fitting (right)

Based on the levelled dataset a bearing area curve is generated to determine the volume of material loss. The image below, figure 8, shows the representation of the bearing area curve where zero defines the levelled surface plane and the y axis shows the height difference from that plane. The determined volume of material loss using the analysis method is 16.25 mm^3. This was found to be accurate to two decimal places to the theoretical volume determined through numerical integration.

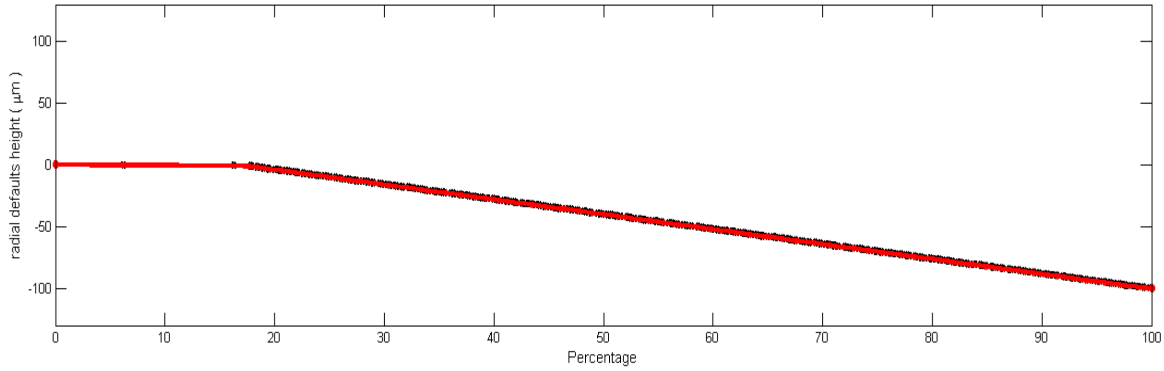

Figure 8 Bearing area curve shows the distribution of point heights in relation to the fitting plane

4. Results

Retrieved samples from three patients that had undergone revision surgery were analysed, all were large head metal on metal hip replacements. Prior to measurement a visual inspection of the taper interface was performed and the damage to the taper surface was graded using the Goldberg scale [9].

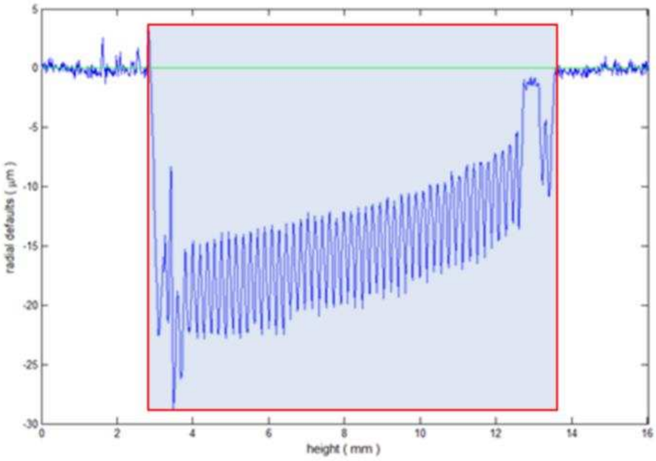

Figure 9 – Extracted profile from measured taper surface – area of contact highlighted.

Upon analysis it was clear that whereas areas to the distal and proximal end of the taper surface exhibited a relatively smooth surface finish with low amplitude texture, the area of contact showed evidence of material loss and a distinct higher amplitude textured imprint (see figure 9, above, highlighted area) with a wavelength, in this case, of approximately 0.2mm. Accumulated corrosion debris was identified at the distal end of each head taper. In the case of sample 3 shown as the lower image in figure 10 the debris forms a continuous band along the distal end of the taper. Further debris was present in localised small patches of the contact area of the taper. These could not be readily removed from the analysis and further cleaning of the component was not possible.

Table 1 Wear volumes of retrieved components

Sample	Diameter (mm)	Taper material loss (mm^3)	Taper Max. Linear Penetration (μm)	Taper contact length(mm)	Goldberg score	Head bearing wear (mm^3)	Cup bearing wear (mm^3)
1	48	1.06	5	12	2	1.41	1.14

2	44	5.80	38	11	3	6.86	2.75
3	54	25.19	80	11	4	10.34	3.17

Bearing surfaces of each component were measured using a Zeiss Prismo co-ordinate measuring machine in accordance with a previously published method [28,29] and all results are presented in table 1. Sample 3 has a value for taper material loss volume that is roughly two times higher than that relating to bearing wear suggesting that in some cases taper material loss could be a major contributor to the overall material loss from the implant.

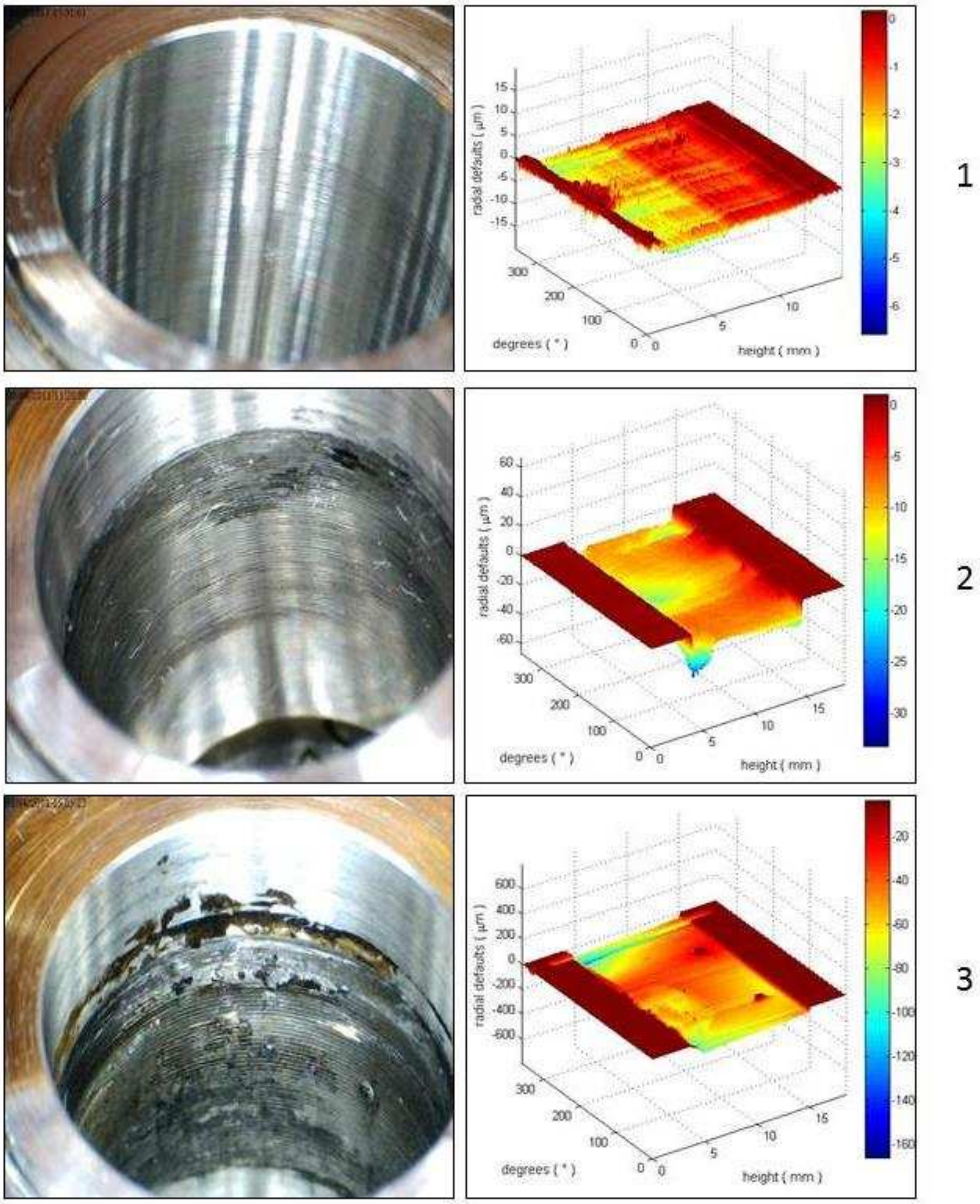

Figure 10 Taper measurements compared to visual Goldberg [9] score.

These cases seem to indicate that there could be a correlation between the volumetric and linear material loss in the case of the taper although a sample of a much greater size would need to be undertaken to verify this. Maximum linear values occur at the distal end of the taper in all three cases. There are signs of asymmetric wear in sample 3 which could be attributed to a toggling effect which has been previously described [5].

5. Repeatability study results

The results of the repeatability and reproducibility study are presented in table 2 and show that both operators achieved a good agreement in terms of determined mean, median and range values.

Whilst it is not possible in this study to fully separate the errors stemming from the measurement and analysis process an understanding of the error source contributors to the uncertainty budget can be gauged as well as the interoperability of the analysis process.

Table 2 Results of the inter-observer repeatability study for estimation of material loss volume

	Operator 1 - material loss volume (mm^3)	Operator 2 - material loss volume (mm^3)	Interoperability (mm^3)
Mean	0.641	0.639	0.038
Median	0.639	0.636	0.035
Range	0.598 - 0.685	0.572 – 0.709	0.004-0.085
Standard deviation	0.023	0.043	0.021

The study was conducted on a retrieved femoral head taper and thus had no previous information related to initial geometry. This prevents the determination of the systematic error relating to the process. It can however be concluded that the standard deviation of the entire measurement and analysis process is 0.023 for the first operator and 0.043 in case of the second operator. This shows a high repeatability of the measurement and analysis process and good reproducibility between operators.

The study further showed that when considering individual datasets agreement between operators was good with an overall standard deviation of interoperability of 0.021. As both operators blindly analyzed the same datasets this error contributor relates solely to the analysis process and shows that skilled operators can reach agreement over the results. The notion of skilled operators refers to being able to perform the fitting process and discerning if any data thresholding is necessary.

6. Discussion

The taper measurement technique developed in this study has been shown to have a stable analysis algorithm and the measurement process itself has been shown to have a high level of repeatability with a low level of interoperability variation. As this part of the study was performed in a blinded way there can be confidence in the overall robust nature of the measurement method as a whole. As all analysis is offline and post-process this can also be revisited and repeated if necessary. A number of contributors to overall measurement uncertainty have been identified for this technique, however, until representative physical artefacts are developed it will be impossible to fully validate any taper measurement technique.

An advantage of this technique that has been demonstrated is that data can be determined to a sub-micron level repeatedly. This high level of resolution allows for a more accurate data fitting and better delineation of areas of material loss, surface deposits and virgin surface. The resolution of the stylus is such that there is concurrent acquisition of form and topographic data. This technique measures the true surface of the measured taper negating any errors, no matter how small, that may be induced through use of replication. Furthermore use of a contacting stylus allows for fully traceable metrology.

A general limitation to the technique may be considered to be the level of subjectivity within the selection and fitting of the unworn zone within the analysis, however, the blinded repeatability study appears to suggest that the effect of this is minimal.

It is true that the efficacy of the technique does rely on the presence of some unworn data at both the distal and proximal ends of the taper surface. In a small number of cases this may not be possible in which case it is suggested that the method uncertainty may increase. A further limitation in the technique is that the acquisition time per measurement is relatively high (>1 hour per dataset). This however is analogous to accurate measurement of a similar data density using a co-ordinate measuring machine but with the advantage of a higher level of resolution.

In the case of components which have debris on the contact area of the taper surface it is clear that the presence of such agglomerates will lead to an underestimation of the overall material loss in such an area. It is therefore clear that a robust cleaning protocol is developed to remove this debris – something which was not possible in this study, albeit the presence of debris in these cases was minimal.

7. Conclusion

The paper describes a method for measuring the material loss from femoral head taper surfaces that has been shown to be robust and which allows for micron-sized textural features to be measured. The analysis process by use of a two-stage levelling and fitting routine enables the removal of the cone shape to isolate the wear regions. The fitting process is controlled by the user allowing for the selection of unworn areas as the secondary fitting reference. The flexibility of the two-stage fitting process is that through user definition manufactured form error can be accounted for and removed from the analysis.

There are limitations to the amount of information that such a small study of retrieved components can provide with respect to the material loss mechanism but it allows for the identification and quantification of such material loss. The main advantage of the method compared to those used previously is in the accuracy of the measuring equipment and the measurement resolution allowing for imprinted texture to be identified and mapped. It is noteworthy that this work has already contributed towards the development of a standard guide for measurement of orthopaedic tapers [30].

A modification of this method has been used for the assessment of textured male taper surfaces but is not presented in this paper.

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