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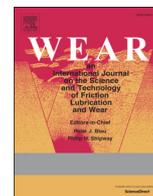
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Method for volumetric assessment of edge-wear in ceramic-on-ceramic acetabular liners

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ABSTRACT

This paper details a novel method to characterize and quantify edge wear patterns in ceramic-on-ceramic acetabular liners using a roundness measurement machine to measure the post-wear surface. A 3D surface map is produced which encompasses the measured surface covering the wear patch, the uncontrolled edge geometry and form of the bearing surface. The data is analysed to quantify linear penetration and volume. The developed method was applied in a blind study to a set of six 36 mm ceramic-on-ceramic acetabular cup liners that were measured and analysed to characterise the edge wear. The in-vitro linear wear penetration ranged from 10 μm to 30 μm . The computed volumetric wear results obtained from the blind roundness measurement study were compared against the measured gravimetric results indicating a strong correlation between the results (0.9846). This study has also highlighted that measured liners exhibited an area of localised edge wear locates above the bearing surface as well as a smearing effect on the bearing surface caused by debris from edge wear. A study was carried out to test the repeatability of the measurement method and the inter-operator variability of the analysis. The results of the study show a standard deviation for the entire measurement and analysis process of 0.009 mm^3 for first user and 0.003 mm^3 for second user over twenty datasets. Hence the method displays high repeatability of the measurement and analysis process between users. This method allows for the delineation of form and wear through the determination of local geometry changes on what is essentially a freeform surface. The edge geometry is only partially controlled from a GD&T perspective and its geometry relative to the bearing surface varies from part-to-part. This method whilst being subjective allows for the determination of wear in this area with a high level of repeatability. However the limitation of this method is that it can only measure 5mm wide band of the liner due to the limited gauge travel range of 2mm

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1. Background

The life expectancy of a hip prosthesis is commonly expected to be 15–20 years. In the UK during the last decade 711,765 primary surgeries have been carried out in comparison to 80,042 revision surgeries [1] to replace joints that have failed either prematurely or at the end of their useful life. The use of fourth generation ceramic-on-ceramic bearings have proved to be very efficient and has grown in popularity for primary hip surgery in the last decade [1]. This is due to the low reported wear volumes associated with all ceramic bearings [2] as well as the fact that ceramic debris being bio-inert overcomes the commonly reported issues of systemic cobalt chromium ion concentration as reported in metal-on-metal bearings [3,4] and issues of osteolysis induced by polyethylene wear debris in

metal-on-UHMWPE [5,6]. The interest in ceramic-on-ceramic is elevated also due to significant improvements in material properties and manufacturing process [7].

Of all current commonly used bearing surface combinations, ceramic-on-ceramic have been reported to wear at the lowest rate [8,9]. From previous simulator studies it has been observed that levels of wear in ceramic-on-ceramic bearing surface can be of the order of 0.2 $\text{mm}^3/\text{million cycles}$ [2]. With such excellent material properties and high survival rates, ceramic-on-ceramic hip prosthesis has been widely implanted into ever younger, more active patients [10–12], and yet very few long term large set retrieval studies have been carried out due to the survivorship of the implants [13–15]. The analysis of retrieved implants (explants) is an essential step in the audit of orthopaedic healthcare provision [16]. This principle holds true irrespective of whether a device has failed early [17] or has been removed after decades of use in a satisfied patient [18]. Ceramic-on-ceramic hip prosthesis are reported to squeak in-vivo [19,20]

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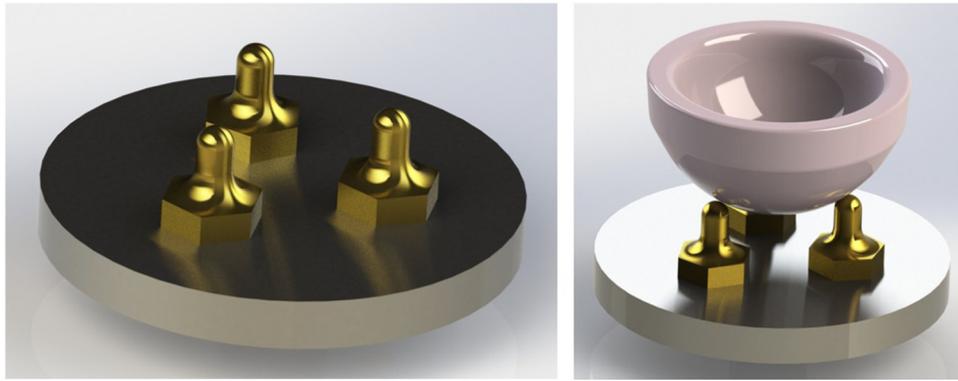


Fig. 1. Image displaying a CAD model of a custom made 3-Sphere fixture.

which appears to be linked to edge-loading [21]. Also, it has been reported that an unusual stripe pattern of wear can occur in some retrieved acetabular cup liners [22] and it has further been postulated that this is caused by cup liner edge loading [23]. The combined measurement challenge of wear occurring at the edge of the acetabular liner of a low-wearing ceramic-on-ceramic prosthesis is therefore considerable.

Various wear measurement methods have been developed to measure wear in hip prostheses [20,24–26], yet current recognised industrial practice regarding in vitro measurement of wear for hip joint prostheses involves either gravimetric assessment or co-ordinate measurement [27].

Due to the considerable challenge in determination of edge wear geometrically, current literature regarding assessment of edge-wear in acetabular cup liners has been confined to in-vitro simulator studies and use of gravimetric measurement only. This approach is clearly limited due to the lack of spatial characterisation and determination of wear extent and location [24]. Geometric characterisation of wear is essential in determining the contact conditions during gait and subsequent calculation of point and magnitude of the maximum stress condition. It is therefore vital that a robust and reliable method for geometric measurement and analysis of edge wear is created.

This paper details a novel method to characterize edge wear distribution in ceramic-on-ceramic acetabular liners and ascertain wear volume and linear penetration using a roundness measurement machine (RMM). The method is able to measure wear from the bearing surface and beyond the edge and eliminates the limitations of previous geometric methods which focused on just the bearing surface.

2. Method and materials

2.1. Study design

Six 36mm diameter ceramic-on-ceramic bearings (BIOLOX[®] delta, Pinnacle[®], DePuy Synthes, Leeds, UK) were tested on the Leeds II hip joint simulator (Institute of Medical and Biological Engineering, University of Leeds) for three million cycles under edge loading conditions. Edge loading between the femoral head and acetabular cup occurred during gait due to dynamic separation driven by translational mismatch between the centres of rotation of the femoral head and acetabular cup [28]. This method was proven to generate clinically relevant wear mechanisms on the femoral head and acetabular cups and generate the bimodal wear debris distribution seen clinically with ceramic-on-ceramic bearings [29–32].

Under such condition the wear occurred on the chamfer region of the acetabular cup. At the end of three million cycles, the components were cleaned from contaminants using local standard operating procedures before measured in a temperature and humidity controlled environment using a microbalance (Mettler-Toledo XP205, UK) under which they were measured before the test commenced. The wear volume was determined gravimetrically by dividing the mass loss by the density of BIOLOX[®] delta (0.00437 g/mm³).

Upon completion of the simulator test, components were measured in a blind study at EPSRC CIMAM, University of Huddersfield. The method uses a Talyrond 365 (Ametek, Leicester, UK) stylus-based RMM to measure the worn acetabular surfaces. A 3D surface map is then produced encompassing the area of the liner edge that contains the wear patch. The data is analysed to remove form effects due to the edge geometry and linear penetration and wear volume are then computed in further steps detailed in the following sections. The results obtained from RMM method were compared against the gold standard gravimetric method. Further cup liner 6 was measured 20 times to test repeatability and inter-operator variability.

2.2. Roundness measurement method

In order to assess edge wear without any pre-wear geometric data, the area surrounding the edge of each acetabular cup liner was measured using a Talyrond 365 stylus-based roundness measurement machine. The Talyrond 365 is able to measure straightness, roundness and cylindricity and has a stated gauge resolution of 30 nm with a spindle runout value of 20 nm [33]. A diamond tip pointed stylus with an end radius of 5 μm was used for the measurement to eliminate mechanical filtering error. Given the nano-meter precision of RMM, the room temperature was maintained at 20 °C ± 1 to prevent thermal expansion errors. Prior to performing a measurement the component was mounted on a custom designed three sphere fixture, as seen in Fig. 1, that was attached to a two-stage goniometer and an x-y translation stage. Each component then underwent a centring and levelling routine to establish an eccentricity of under 1 μm between the axis of the spindle and that of the component.

The procedure to define the measurement height requires a vertical trace of the acetabular liner through the wear area. Using this vertical trace, Z-axis values of the first and last roundness trace are determined to cover the required area of the edge and bearing surface. After establishing the component alignment, 500 horizontal roundness traces were measured at height intervals of 0.01 mm covering 5 mm of Z-axis height that includes the wear patch on the edge of acetabular cup liner. Each horizontal trace captures 3600 points and thus each

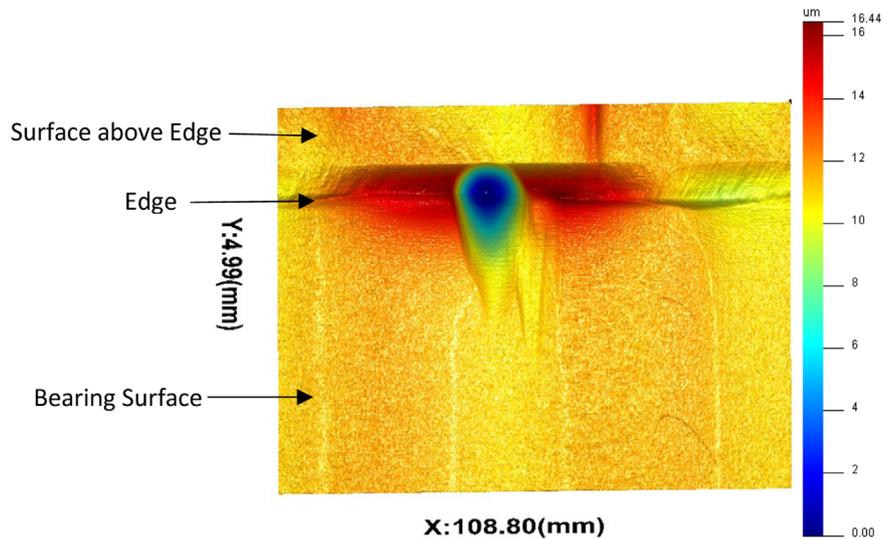


Fig. 2. 3D surface map of cup liner 5 generated by stitching 500 roundness traces.

cup measurement typically consist of 1.8 million points (500 roundness traces). The continuous measurement achieved due to the indexing spindle ensures that all circular traces are taken with respect to the same axis. These 500 individual traces are converted to linear and combined to create 3D surface, which is effectively a height map. An example of such 3D surface can be seen in Fig. 2 below.

Each individual trace is efficient in precisely displaying the form of the acetabular cup liner at that particular height (see Fig. 3). These individual traces are exported as point cloud data and reconstructed to generate the measured surface in Matlab.

2.3. Volumetric analysis

Analysis of the raw data is performed through a number of procedures organized through the utilisation of a set of software programs developed in Matlab (The Mathworks Inc., Natick, USA). The first step of the analysis is to stitch the individual circular traces at the corresponding height and develop the actual surface of acetabular cup liner (Fig. 4). Further the conical form is levelled and a linear least square fit for all of the data, including the worn area, is used to unwrap and roll out a rectangular areal map of the acetabular cup liner (Fig. 5). The proposed method does not

depend on the estimated radius, it is therefore robust with respect to the estimated cylindrical form. The cylindrical coordinates (radius (r), angle (θ) and height (h)) are computed using the following formulas:

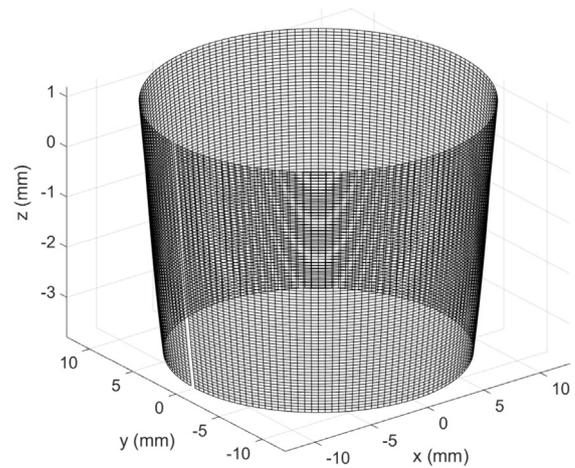


Fig. 4. Measured surface with decimated data for better visualization (Matlab).

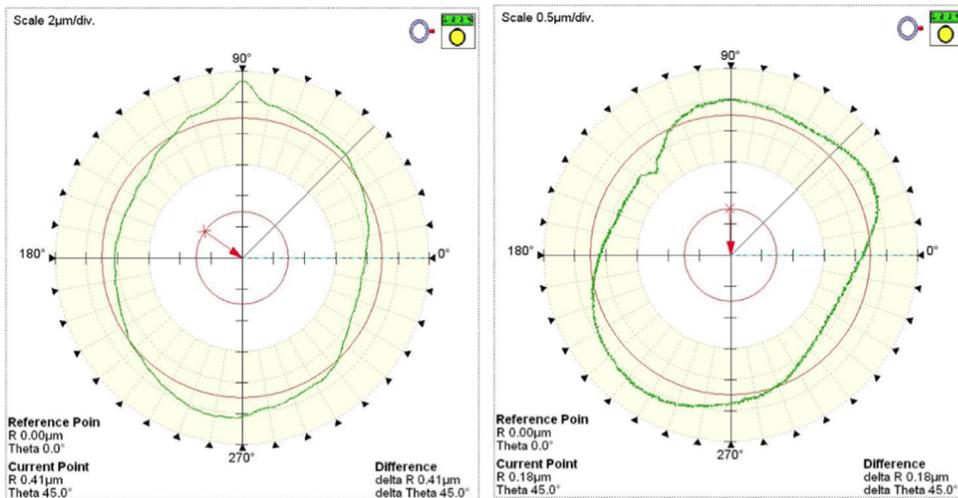


Fig. 3. Image displaying individual roundness traces.

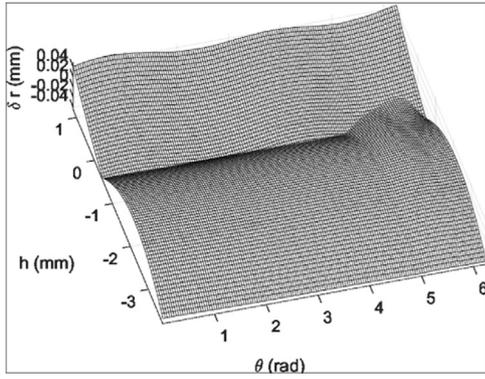


Fig. 5. Unwrapped and form removed surface of the cup liner in cylinder co-ordinates (Matlab).

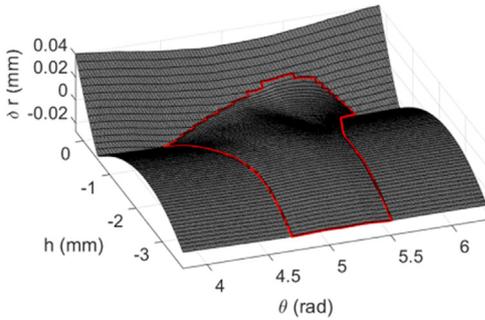


Fig. 6. Proximal surface and wear boundary (Matlab).

$$\begin{cases} r = \sqrt{x^2 + y^2} \\ \theta = \text{atan}\left(\frac{y}{x}\right) \\ h = z \end{cases}$$

The second step is to detect the boundary of the wear and generate an approximation of the unworn surface. To perform this task a manual segmentation process is implemented. Firstly the form has been removed with a first degree polynomial in *h* direction and a second degree is used in θ direction, then the surface has been manually cropped along the θ axis, an example is shown in Fig. 6. The polygon file format has been saved and imported in CloudCompare (<http://www.cloudcompare.org/>) where the point cloud is meshed and the wear region is accurately segmented. This segmented mesh is used in Matlab to define the wear boundary. Fig. 6 below displays a Matlab plot of the surface and the manually segmented wear which is marked by red line.

This segmentation process is manual, hence it is operator dependent. In all the analyzed liners the wear was visible once the form was removed. This method relies on the existence of unworn data proximal to the worn part of the liner's edge to obtain a reliable datum for reconstruction of the original manufactured surface.

Once a defined wear boundary is imported in Matlab, the third step is to generate the second surface which is an effective approximation of unworn surface. To generate the required unworn surface, the points inside the wear boundary are deleted and the missing surface inside the boundary is regenerated by applying linear interpolation. It should be noted that a linear interpolation in cylindrical coordinates corresponds to an arc of a circle in Cartesian coordinates. In this step the original form is used, without removing any polynomial form, in order to perform the correct volume computation.

The final step of the method is to determine the volume, in order to compute the volumetric wear both surfaces are interpolated.

The volume of each surface can be computed as [34]:

$$V_i = \int_{\theta_0}^{\theta_1} \int_{h_0}^{h_1} \left(\int_0^r \rho d\rho \right) d\theta dh = \int_{\theta_0}^{\theta_1} \int_{h_0}^{h_1} \frac{r^2(\theta, h)}{2} d\theta dh$$

Since the number of available points is large, the integrals are evaluated using the trapezoidal rule.

The wear is then computed as the difference between the volumes of the surface with the wear area included and the one with it removed from the analysis.

3. Results

A set of six 36 mm ceramic-on-ceramic acetabular cup liners were measured and analysed as a blind study. A height map of the measurement was exported and rendered to generate a 3D surface of each liner. By examining these 3D surfaces it was noted that each liner had a singular area of localised wear. The in-vitro linear wear penetration ranged from 10 μm to 30 μm as shown in Table 1. In each case the 3D surface was segmented to establish the mean plane value and eliminate areas of form error not immediately adjacent to the wear patch so as to locally normalise the data and eliminate error from the calculated linear wear value. The greater level of resolution resulting from the segmentation process led to a greater level of definition of the distribution of edge wear and highlighted an area immediately adjacent in which wear appears to 'smear' onto the bearing surface.

The results of linear wear and volumetric wear obtained from roundness measurement method are shown in Table 1. As expected a correlation between linear wear and volumetric wear can be observed. It is however apparent from this set that there is some variance in the wear sector length over which edge wear occurs. It is observable from Fig. 7 that liner 6 and liner 4 have a similar degree of linear wear penetration, yet the volumetric wear of liner 6 is significantly lower than that of liner 4. This difference is due to a combination of several factors including test conditions, positioning, fixturing and local head-liner geometry. The wear affected area can be estimated by the combination of the segmented sector length and wear depth which is defined in the segmented surface as X and Y axes.

The computed volumetric wear results obtained from the blind roundness measurement study were compared against the measured gravimetric results in Fig. 8 below. Upon examination it is noted that the maximum and minimum difference in compared volumetric wear is 0.13 mm^3 to 0.05 mm^3 respectively. The mean and median difference in volumetric wear comparison is calculated to be 0.074 mm^3 and 0.07 mm^3 respectively. The high level of agreement between the geometric and gravimetric methods shows that for ceramic-on-ceramic liners the developed method has the required resolution and is suitable for characterisation of true edge wear volumes. Sharipo-Wilk test of both RMM ($P=0.462$) and Gravimetric ($P=0.234$) verified the normal distribution of data (SPSS). The calculated correlation coefficient of 0.9846 (Table 2) indicates a strong correlation and provides confidence that the method is capable of determining sub 0.1 mm^3 wear volumes.

From Fig. 8, a systematic discrepancy can be observed between gravimetric and metrology wear volumes results. This can

Table 1

Linear and volumetric wear results obtained from roundness measurement method.

Liner	1	2	3	4	5	6
Linear wear (μm)	10.59	23.92	14.71	29.48	16.44	27.66
Wear sector length (deg)	65.5	94	90.5	111	93	84
Volumetric wear (mm^3)	0.061	0.285	0.109	0.362	0.114	0.177

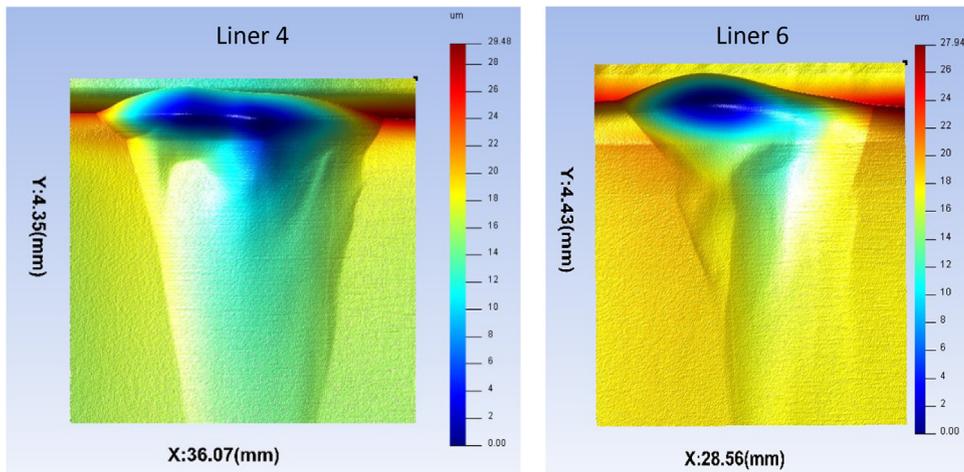


Fig. 7. Image showing wear distribution and linear wear penetration in liner 4 and liner 6. This data is cropped to focus on the wear patch.

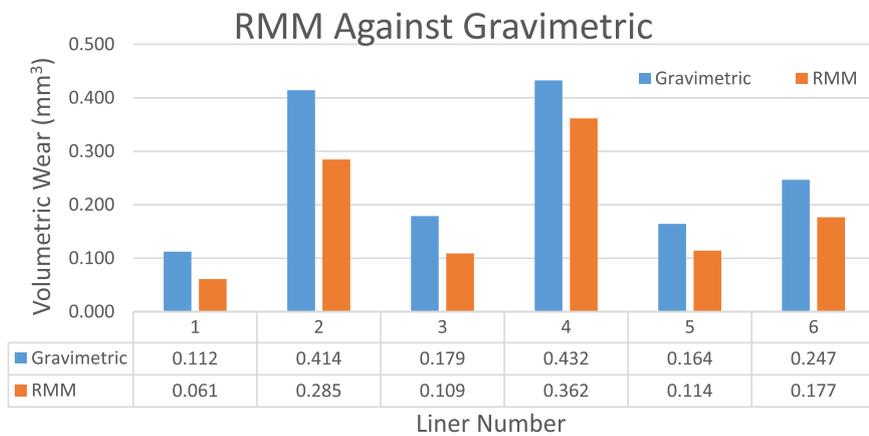


Fig. 8. Roundness measurement results compared to gravimetric results.

Table 2
This table displays results of the Pearson's correlation coefficient analysis between two methods when correlation was studied for set of 6 cups.

Sample Size	6
Pearson Correlation coefficient r	0.9846
Significance level	P=0.0004
95% Confidence interval for r	0.8610 to 0.9984

be a result of many factors including wear occurrence in other areas of the liner, inability of the RMM to capture the complete wear scar due to gauge travel limitation and gravimetric measurement errors.

4. Repeatability study

A study was carried out to test the repeatability and reproducibility of the measurement method and the inter-operator repeatability of the analysis. Acetabular cup liner 6 was selected from the set to conduct the study as it exhibited a low amount of wear yet the linear wear penetration was high. This would give an opportunity to test the resolution of the presented method.

In this study, acetabular cup liner 6 was measured twenty times. Each measurement followed the previously outlined procedure and the component was positioned and levelled on Talyrond 365 for every single measurement. This ensures that any influences of the centring and levelling process are taken into

account while studying repeatability. It must be noted that the measurements were done by a single operator.

Blinded analysis process was performed by two operators (both operators are authors) to assess inter-operator repeatability of the analysis process. Both operators followed 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 segmentation necessary to estimate the volume of material loss.

The results of the repeatability and reproducibility study are presented in Table 3 and show that both operators achieved a good agreement in terms of determined mean, median and range values.

The study was blindly conducted on an in-vitro simulated acetabular cup liner and had no information related to initial geometry. However, it can be concluded that the standard deviation of the entire measurement and analysis process is 0.009 mm³ for first user and 0.003 mm³ for second user. Hence the method

Table 3
Results of the inter-operator variability study for analysis of volumetric wear. This table displays difference in the mean, median, range and std. deviation between the results obtained by 2 individual users.

	User – 1 Volumetric Wear (mm³)	User – 2 Volumetric Wear (mm³)	Inter-operator Variability (mm³)
Mean	0.1780	0.1810	0.0071
Median	0.1790	0.1816	0.0071
Range	0.1603 – 0.1899	0.1749 – 0.1846	0.0000 – 0.0151
Std. Deviation	0.0090	0.0031	0.0043

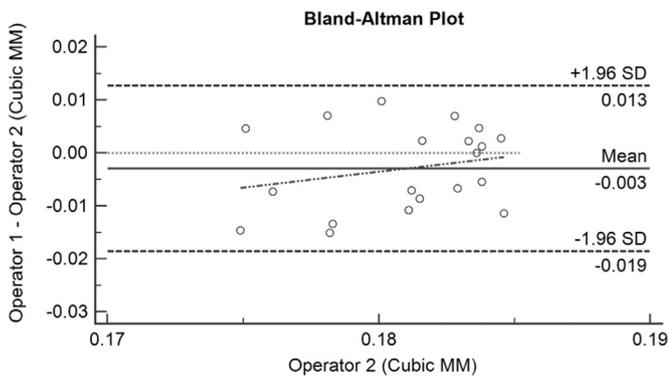


Fig. 9. Bland-Altman Plot with line of equality showing inter-operator variability and regression line stating absence of proportional bias problem.

displays high repeatability of the measurement and analysis process and good reproducibility between users.

This study further showed that when considering individual datasets agreement between users was good with an overall standard deviation of inter-operator variability of 0.004 mm^3 . The Bland-Altman plot is displayed below in Fig. 9 to graphically examine results in detail. Normal distribution of differences was verified by Shapiro-Wilk test, and the normality was accepted ($P=0.164$) (SPSS). Operator-2 being more experienced, analysis results of operator-2 are taken as reference instead of taking the mean of two operators. The 95% limit of agreement (1.96 Standard Deviation) range is presented by dashed line for the visual judgement of how well measurements from two users agree. This 95% confidence interval of limit of agreement is -0.019 to 0.013 mm^3 . The solid line indicates the mean of paired differences in measurements from two users which is -0.003 mm^3 . The distance of mean line from the zero provides an estimate of the bias between two measurements. The significance for t-score is given to be 0.312 which is insignificant and accepts the null hypothesis that bias is not proportional.

One of the main contributing factors affecting volumetric wear measurement is user dependent wear boundary selection process which affects the repeatability and reproducibility of analysis process. Centring and levelling process is also a contributing factor from the measurement process.

5. Discussion

As the study was performed blind there can be confidence in the overall robust nature of the volumetric wear measurement method. The clear advantage of the roundness measurement method over the gravimetric technique is that it can be used for components with no pre-wear data available such as post-operative retrievals. This is especially important given the current 'Beyond Compliance' agenda and the universally recognised need for greater post-market surveillance of orthopaedic implants. The ability of the method to provide a form removed 3-dimensional representation of the measured surface allowing the user to visualise the extent and geometry of the edge wear area and depth of linear wear penetration over a freeform geometry through the use of a coloured height map in Fig. 2 is of significant value.

This study has also highlighted the phenomenon of wear smearing from the edge onto the bearing surface. It appears that previous studies that have measured wear by only analysing data from the bearing surface, fitting spherical [25,26] or ellipsoid figures to data [30] but reported edge wear have in some cases been observing this 'smear' effect rather than the full extent of edge wear damage. The extent of such 'smear' effect of acetabular liner

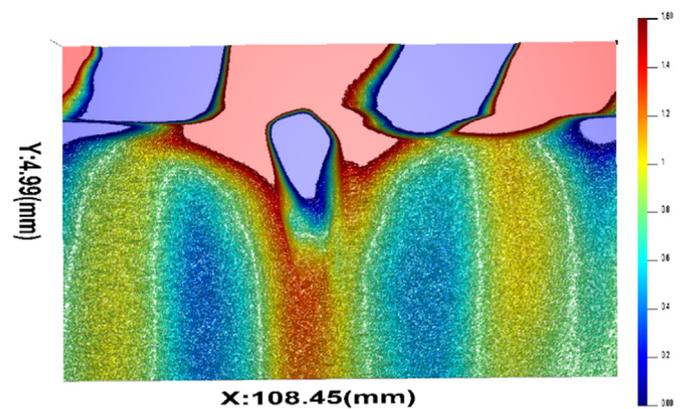


Fig. 10. Extent of smear effect highlighted after thresholding process.

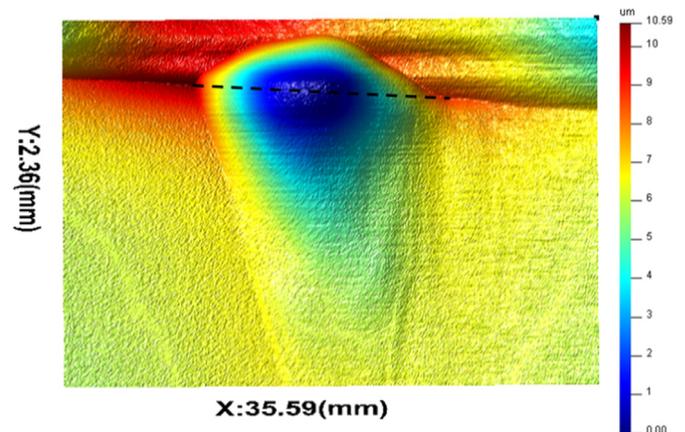


Fig. 11. Displays disregarded edge wear beyond bearing surface.

number 1 can be seen in Fig. 10 where higher peaks have been threshold in order to highlight smaller value of smeared effect. This method also allows to measure edge wear beyond the bearing surface and edge, which currently is a limitation for other geometric wear measurement methods as the fitted sphere or ellipsoid only measure the bearing surface. In Fig. 11, the worn edge is connected using black dotted line to display the edge wear beyond bearing surface. It is therefore clear that a large set study of edge worn components using this new technique would be of great value in determining more realistic levels of in-vivo edge wear from retrievals. Furthermore such information can be essential for in-vitro testing to explore the wear formation patterns of various gait movements and acetabular cup abduction angle which than can be compared directly to data from retrieved components to study failure modes.

The vast majority of published orthopaedic wear measurement methods involve use of co-ordinate measurement with accuracy of $1\text{--}3 \mu\text{m}$. As demonstrated, this method can resolve data at a sub-micron level repeatedly which is essential in the case of ceramic-on-ceramic bearings which exhibit extremely low levels of wear. In addition this technique allows for robust accurate data fitting and finer delineation of worn and unworn surface than has been achieved previously albeit with an element of subjectivity. The stylus resolution provides simultaneous acquisition of form and topographic data whilst allowing for fully traceable metrology.

The limitation of this method is that it relies on the presence of localised worn area which is commonly expected in case of ceramic acetabular cup liner. Other limitation is the 2mm gauge travel length of RMM used for this study permits only a around 5mm wide band to be measured, although there are other RMMs available with gauge travel length of 4mm gauge travel length can

overcome this limitation. In some cases like cup liner number 4 and 6, the extent of the wear area covers larger area that is beyond the gauge travel limit of 2mm permitted by Talyrond 365 and hence the wear patch is not fully measured. In analysis process, the wear boundary segmentation is subjective to the operator and can induce operator errors.

6. Conclusion

The paper details a novel method for characterising edge wear in ceramic-on-ceramic acetabular liners and quantifying wear volumes in the transition area between the bearing surface and outer geometry. In addition the analysis process uses fitting routines for the removal of the freeform surface to isolate the wear regions. The segmentation process is controlled by the user allowing for the selection of worn surfaces and defining the wear boundary.

The study carried out showed a strong correlation between wear volumes determined using the gravimetric method and the roundness measurement method. This provides a strong basis for using the roundness measurement method as a suitable approach for assessing edge wear in retrieved ceramic-on-ceramic acetabular cup liners.

The method allows for the measurement of wear from both the bearing surface and beyond the edge thus eliminating the limitations of previous methods that focused on only the bearing surface.

The repeatability and reproducibility of the measurement method has been demonstrated as well as the inter operator reproducibility and repeatability of the analysis process. The method has a high resolution and is capable of characterizing edge wear in ceramic-on-ceramic cup liners with wear volumes of between 0.5 mm^3 and 0.1 mm^3 .

The measured liners exhibited an area of localised edge wear locates above the bearing surface as well as a smearing effect on the bearing surface caused by debris from edge wear.

There are limitations to the amount of information that such a small study of simulated components can provide with respect to the material loss mechanism. However with further research on data stitching or upgrading gauge travel range, this method has the potential to characterise retrieved components and ascertain the entire cup edge wear volume that has been potentially underestimated by current methods.

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