Focus variation measurement and advanced analysis of volumetric loss at the femoral head taper interface of retrieved modular replacement hips in replica

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Keywords: Replication, hip, retrieved, wear, corrosion, focus variation, areal, volume loss

Abstract. This paper offers a technique for non-contact assessment of material volume loss at the femoral head taper interface of modular replacement hips with novel use of the focus variation principle. A novel 3D to areal data conversion technique also allows powerful areal data analysis techniques to be applied to point cloud (3D) measurements for volume loss optimisation. Accurate characterisation of retrieved femoral head tapers is important to assess their in vivo performance particularly with respect to the bio toxicity of wear and corrosion products.

A cohort of 8 retrieved femoral heads showing a wide range of degradation (0.5mm³ < volume loss < 12mm³) [1] was selected for the development of this technique. Using this common cohort of retrieved hips, the current technique was benchmarked against the well proven roundness measurement machine (RMM) method. This existing technique generates areal (2.5D) data and exploits a range of existing areal analysis techniques to optimise volume loss assessment. For benchmarking continuity and to exploit the same areal techniques, volume loss analysis for the current technique was carried out using the software written for the existing RMM method.

The focus variation instrument’s integrated language was used to write script to convert (un-wrap) the taper surface 3D data into areal format. The current method shows a mean absolute difference in volume loss of 14% (-12% signed) from that of the benchmark with a range of 1% to 27%. The spread of measured values is significantly higher for the current method than for the benchmark. However, it is noted that replication can offer the advantage of capturing the whole taper surface on some taper types where physical access is limited for a stylus based roundness method.

The current technique is also compared to the existing Redlux™ technique in which replicated female tapers are measured using a confocal instrument. The current technique is shown to have comparable performance to the Redlux™ technique but offers a more sophisticated methodology for volume loss analysis. In addition the current technique offers new instrumentation and analysis tools to the field.
Small uncontrolled casting variations are noted in the current technique, resulting in poorer performance with small volume loss samples where the influence of this effect is most pronounced. However, given the simplified assumptions of the volume loss calculation where results may be skewed by deposits, some uncertainty will be evident with any approach.

1. Introduction

Learmonth, Young and Rorabeck [1] refer to the total hip replacement procedure as the operation of the century. Within England and Wales more than 700,000 such primary procedures were carried out between April 2003 and December 2014 with more than 71,000 in 2012, with osteoarthritis being reported as the primary diagnosis in over 90% of cases [2].

For hip resurfacing or total hip replacement designs several combinations or bearing surface material couples are used; metal or ceramic head on ceramic, metal, ceramic or polyethylene acetabular cup. Increasingly popular is the modular system of total hip replacement, Figure 1 shows the components and taper contact surfaces of a typical modular hip replacement. The modular taper interface design allows individual components to be selected to allow joint geometry to be tailored to individual recipients during surgery. However, these taper interface surfaces lack fully developed standardisation and tolerancing for; length, diameter at depth, cone angle, roundness, straightness and surface finish. Several studies have reported significant wear and the formation of corrosion products at these taper interfaces [3-5] see Figure 2. Pseudotumours caused by wear and corrosion products are commonly seen in joint capsules during revision surgery [4, 6]. The current work focuses on the “large head metal on metal” (LHMoM) design which are more prone to taper corrosion and wear due to increased bending moments at the stem/head taper interface. Though the taper interfaces of all modular systems are susceptible and the techniques and analysis detailed in the current work are applicable. A number of mechanisms have been suggested to explain the ionic contamination and metallic debris. The use of insufficient force or simple misalignment during joint assembly can result in subsequent wear from micro-motion. Femoral head and stem materials are typically dissimilar and this can result in electrochemical corrosion due to the resulting galvanic cell [7]. Goldberg et al [8] detail mechanically-assisted crevice corrosion, and the similar mechanism of fretting corrosion is offered in [9].

Quantifying taper interface material loss in recovered implants is central to the analysis of hip failure [10]. Though it should be noted there is no uniform correlation between material loss and any adverse response in the recipient as sensitivity to metal ions varies widely between individuals. A number of methods have been used to measure this taper interface volume loss;
Figure 1. Metal-on-metal hip replacement components and taper interfaces, showing; A) Femoral stem trunnion (sectioned), B) Modular taper adapter sleeve, C) Modular head, D) Acetabular cup.

Figure 2. Retrieved metal-on-metal femoral head showing corrosion and wear on internal taper surface (un-sleeved type).

coordinate measuring machines (CMM) are capable as detailed in [11], though they have limited resolution in the plane perpendicular to the sample surface (vertical resolution) when compared to other techniques detailed in the current work. Roundness Measurement Machines (RMM) such as the Talyrond 365TM (Taylor Hobson, Leicester UK) [12, 13] offer the vertical resolution (30nm) and stylus tip radius (5μm) of surface profilometers and thus better accuracy than a CMM for this application. Redlux™ (Redlux Ltd, Southampton UK) have previously reported a method [14, 15] similar to that detailed in the current work where an optical instrument is used to measure taper interfaces in replica. Most recently Redlux™ have developed a non-contact optical instrument (Taperlux™) for the direct measurement of internal tapers, thought the authors are unaware of any peer reviewed publications or data using this instrument.

All existing methods for calculating volume loss at taper interfaces are subject to two inherent limitations;

No prior information about the unworn surface of the taper is available and thus nominally “unworn” region of the retrieved taper must be relied upon to establish a datum from which to calculate volume loss. Typically there are two such unworn taper regions, one distal and proximal, though the accuracy of a datum based on these can be compromised by surface roughness or even by one region being absent.

A simplified approach is taken to quantify volume loss as both material deposition and removal can occur at the interface. Thus volume loss is considered to be equivalent to the material void between the estimated position of the unworn (original) taper surface and the measured surface of the retrieved taper. Material deposited on a worn region will thus be considered as taper material and not be reported as lost material.

The method detailed in the current work involves casting elastomer replicas of femoral head tapers and using a focus variation (FV) instrument (Alicona IFM G4) to characterise the surface volume loss. The nominal characteristics of the focus variation (FV) instrument group are detailed in ISO
25178-606 [16] and its operating principles and application are detailed in [17-19] Figure 4 shows the FV instrument and rotary stage arrangement used to measure the taper replicas. The FV instrument operates by scanning through the (z) direction envelope of surface heights. The sharpness of the imaged surface texture at the sensor array for each (x,y) location in the field of view is a measure of focus precision and thus surface point heights are assigned. This approach is typically used to capture point height data for ‘areal’ surface topography characterisation (2.5 dimensional data). In addition, 3D data can also be captured, for example from an axisymmetric component with suitable mounting in a forth axis rotary stage.

Acceptance and performance re-verification standards for coordinate measurement systems employing optical distance sensors and rotary axes are detailed in ISO 10360-8 / 3 [20, 21] respectively. However, with the increased use of optical instrument in coordinate measurement type roles it is clear that there are significant gaps in CMM standards pertaining to “optical distance sensors” and particularly with respect to FV instruments. Unlike the Redlux™ confocal technique, FV is not explicitly included in the scope of [20] nor does the FV instrument used in the current work have the working volume requirements to employ the test artefacts from that standard. In addition little consideration has been given to the influence of image field stitching processes on coordinate measurement. Sun and Claverley [22] reported standard format probing errors for their own data reduction (sampling) methods for the Alicona FV instrument. Importantly they note that to ensure consistency in their results outliers were removed from their surface data by filtering even though user defined filtering of data is explicitly excluded from testing in [20]. An investigation into the simultaneous 4 axis performance of the Alicona FV instrument was carried out by Moroni, Syam, and Petro [23]. This study reports positional errors as large as 500µm when measuring test sphere positions on a heavy artefact across the instruments whole working volume, involving the simultaneous use of all 4 instrument axes. Given that only 3 axes are used independently over a small measurement range with a light sample in the current application, errors of this reported scale will not be seen. The aim of the current work is to develop a technique for the assessment of taper material loss in replica using a focus variation instrument and apply existing advanced areal volume loss analysis software. Then benchmark the technique against the existing well proven RMM technique in [12] by applying both techniques to the same group of retrieved head tapers. To apply the volume loss analysis software from [12] to the current results, script was written to process the current data and change its format. The current technique is then compared to the similar existing replication technique due to Redlux™[14, 15], though a different groups of tapers is used.

2. Methods and materials
To replicate the tapers Microset™ fluid grade 101FF grey was used with working time of 4 minutes and curing time of 30 minutes and with quoted resolution and shrinkage values of 0.1µm and less than 0.1% respectively. The taper replication was carried out using the alignment and replication fixture shown in Figure 3 this fixture (D) ensured that the taper replica mounting tube (A) and the head (C) were coaxial. The head was aligned using the square end of the mounting tube and replication compound was injected down the mounting tube to fill the; taper, extension sleeve (B) and lower mounting tube end. The compound was then allowed to cure and extracted from the head by way of the mounting tube. All of the recovered heads in the current cohort were of the design seen in Figure 1 with 12/14mm taper trunnion (A) fitting into a 12/14mm //18/20mm taper adapter sleeve (B) which remained in situ (after retrieval) in a 18/20mm head taper. Thus a gap remains between the proximal (bottom) end of the sleeve and the taper socket in the head, such a re-entrant void complicates the extraction of the replica. Consequently the voids were filled with a suitable non-curing elastomer that could later be recovered. In addition the taper casting void was extended at both ends, proximally into the non-curing elastomer and distally by way of the extension sleeve (Figure 3 (B)) this is discussed further in section 3. Figure 4 shows a replica taper and mounting tube in the FV instrument rotary stage collet (4th axis) and evidence of the casting extensions can be seen.
The instrument scans through a (z) direction envelope to capture individual fields the height of this envelope is largely determined by the curvature of the taper within the field. A series of fields are then captured along the axial length of the component, these are stitched together with 10% overlap to form a single longitudinal field. The rotary stage then increments about its precision calibrated axis to capture the next longitudinal field, the incremented angle is determined from the overlap of the longitudinal fields specified by the user (default 30%). Stitching alignment is calculated based on the; overlapping region surface point heights, point true colour information and relationship to the stage axis. Thus measurement precision and extent of overlap dictate stitching accuracy.

To minimise the (z) envelope height and thus the measurement duration the rotary stage axis was adjusted to a suitable angle (approximately 2.5°) such that the measured surface of the taper replica was perpendicular to the (z) direction. The rotational axis of the stage is only referenced for field stitching and for no other purpose. Thus any misalignment of the taper replica axis and its mounting tube only serve to increase the measurement duration and have no influence on the accuracy of the subsequent volume analysis.

Measurement duration, resolution and file size considerations dictated the use of the instruments x5 objective lens with a vertical resolution of 0.5μm. This vertical resolution value was verified by its optimisation of measured data quality (repeatability) [19] and the lack of any clear evidence of improved volume loss resolution over the effective vertical resolution range of the 5x lens (0.1 to 2μm). Due to final file size limitations points are spaced at 14μm in both the x and y directions thought this is down sampled from a native optical resolution for this configuration of 2.2 μm. For each taper measurement 8 axial measurement fields were stitched to form each of 26 longitudinal measurement regions each having approximately 2 million points. During stitching to form the taper point cloud the overall number of points was reduced by a factor of 10 to give a practical maximum for the system of approximately 4.5 million. Measurement duration varied between 1.5 and 3 hours (in temperature controlled conditions) depending on the extent of the axial runout resulting from replication fixturing misalignment.
Volume loss analysis was carried out using the Matlab™ (The Mathworks Inc., Natick, USA) software developed in [12]. In all other techniques volume loss determination is carried out in a 3 dimensional format, with the unworn taper surface being considered and fitted as a simple conic primitive. However the current software uses the more sophisticated approach of fitting the unworn taper surface as a plane to the measured taper data in areal (planar) format. This approach has the benefit of allowing the removal of potential manufacturing form errors from the retrieved taper by polynomial fitting in both the longitudinal (“hoggling” or “sagging”) and radial directions. These options are not available with the data in 3D format and thus these errors would influence the volume loss calculation. The datum plane of the unworn taper surface is then fitted to manually selected unworn taper regions and a data thresholding approach based on the Abbot-Firestone curve [24, 25] (see [12] further details) is used in place of a simple volume subtraction. However this approach requires that the measured taper point cloud (3D) data be unwrapped and transformed to point height (areal) format.

Script was written using Alicona’s integrated language to achieve this unwrapping and format transformation. The script processing involved; axial alignment of the point clouds by fitting a conic primitive to unworn regions of the data set, perpendicular trimming of the point cloud ends to match the extent of each sample’s taper surface measured by the RMM technique for, “unwrapping” of the point cloud to a point height format for final volume loss analysis. The “unwrapping” process was achieved by extracting longitudinal taper surface profiles at intersections of the taper point cloud (at 1° rotational increments) and a plane passing through the tapers rotational axis. The resulting profiles were resampled to achieve the same uniform ‘14μm’ sample spacing as the original measurements, giving approximately 0.5 million points in each point height file. Volume loss analysis was carried out on two sets of the resulting point height data for the samples; one set was filtered using a spline S filter with a nesting index [26] of 50μm and the other had no filter applied. Unworn regions of the taper surface map (see Figure 8 (1)(u)) were then selected in the Matlab™ software [12], automated polynomial form fitting to these regions then allowed removal of manufacturing form errors in the taper. The taper surface map was then levelled with respect to a plane fitted (linear least square) to the unworn regions (fitting can also be polynomial). The taper surface map was then thresholded (Figure 8 (2)) to the “zero” height level of the cumulative surface height plot (Abbot-Firestone curve Figure 8 (3)) the zero height having been defined by the unworn region selection in the previous step. This thresholding delineates the surface debris above and defines the volume loss below the surface of the nominally unworn original taper.

In conventional use the; selection of unworn regions, thresholding process and determination of polynomial form all require experience and judgement (but show good interoperability [12]). Therefore, in the current study the specified default selections are made in all cases to limit bias. Thus it is possible that better agreement with the benchmark results in [12] could have been achieved if the current processing had been carried out by an experienced operator.

3. Results and discussion

3.1. Benchmarking against the existing RMM method

Table 1 shows the volume loss data for the retrieved femoral head tapers acquired by both the RMM [12] and the FV method detailed in the current work. Replication and measurement of samples 3 and 6 was repeated four times and the mean values of volume loss, standard deviations and coefficients of variation are shown and included in the main volume difference analysis. The FV volume loss data is expressed with respect to the RMM data in both mm³ and percentage terms and ‘absolute’ mean values are quoted. For comparison volume difference values are given for the FV in both filtered and unfiltered form. Repeatability data is also given for the RMM technique, thought this data is from a sample not measured in the current study and has a lower volume loss than the samples reported for the current study.
Table 1. Volume loss data for the FV and RMM technique including repeatability data with mean, standard deviation (σ) and coefficient of variation (Cv) values. Cell colouring indicates where mean repeatability values are used.

| Sample | No Filter | 50µm Filter |
|--------|-----------|-------------|
|        | Vol       | RMM Vol     | Diff | Vol Diff | Diff |
|        | mm³       | mm³         | %    | mm³      | %    |
| 1      | 0.23      | 0.22        | 0.01 | -5.15    | 0.17 | 0.05 | -23.70 |
| 2      | 0.78      | 0.54        | 0.24 | -30.92   | 0.63 | 0.15 | -19.39 |
| 3      | 1.93      | 1.91        | 0.01 | -0.77    | 1.91 | 0.02 | -0.93  |
| 4      | 2.39      | 1.79        | 0.60 | -25.21   | 1.83 | 0.56 | -23.49 |
| 5      | 2.89      | 2.29        | 0.60 | -20.79   | 2.27 | 0.62 | -21.47 |
| 6      | 4.99      | 5.22        | -0.23| 4.69     | 5.17 | -0.19| 3.75   |
| 7      | 7.41      | 5.84        | 1.57 | -21.18   | 6.03 | 1.39 | -18.72 |
| 8      | 11.67     | 12.38       | -0.71| 6.10     | 12.21| -0.54| 4.62   |
| mean   | 0.50      | 14.16       |      | 0.44     | 14.28|      |

Repeatability

| Sample | Volume loss (mm³) | σ/mean |
|--------|------------------|--------|
|        | range            | mean   | σ     | Cv    |
| No Filter |                   |         |       |       |
| 3      | 1.76 to 2.06     | 1.91   | 0.126 | 0.066 |
| 6      | 5.00 to 5.36     | 5.22   | 0.154 | 0.030 |
| 50µm Filter |                 |         |       |       |
| 3      | 1.76 to 2.07     | 1.91   | 0.131 | 0.069 |
| 6      | 4.85 to 5.35     | 5.17   | 0.221 | 0.043 |
| RMM    | 0.60 to 0.69     | 0.64   | 0.023 | 0.036 |

The RMM technique [12] captured 180 axial taper profiles with 3500 points in each (total 630,000 points). This same study, and that due to Underwood et al [13] also show the insensitivity of the volumetric analysis to the number of longitudinal profiles captured. As a consequence of the acquisition technique in [12] the taper surface data is in the form of a point height map (.sur) instead of the more conventional CMM point cloud format.

It is noted that surface point height distribution of the FV technique is subject to a greater level of noise including outliers than is the RMM technique. This observation is in line with that expected for the comparison of surface topography data acquired by contact stylus and focus variation instruments. This raises the question of applying a noise (S) filter [26] to the FV data to offset the influence of the increased magnitude of this high frequency band in the FV data. For optical CMM little guidance is available in this respect and [20] prohibited user specified filter settings for re-verification purposes, but in practice filtering “noise” from the FV data is a logical step and Table 1 shows the comparison of the filtered and unfiltered data. On average a 50µm noise filter produced only a limited effect on the volume loss difference values. However, the effect on samples 1 and 2, those with smallest volume loss is significant and it is clear that this noise frequency band can play an important role. This
strongly indicates that the use of such a filter is appropriate. Thus the volume loss difference values calculated from the filtered data will be reported in the current work. An absolute mean difference in volume loss from the RMM values of approximately 0.4 mm$^3$ or 14% (-12% signed) is seen for the whole sample group with ranges of 0.02 to 1.39 mm$^3$ and 0.93 to 23.7% respectively. Coefficients of variation (standard deviation/mean) values show the two techniques to have similar variability. However, it is considered likely that the RMM technique would maintain similar absolute variation values over larger volume loss samples and thus show better repeatability in general than the current technique.

Figure 5 shows the difference in volume loss from the RMM technique for the FV technique in % terms, and the samples have been numbered in order of increasing volume loss. The sample results are in two distinct groups, those with minimal difference in volume loss and those with a greater difference. Importantly, where the difference is appreciable it is negative and the replica technique is reporting lower volume loss than the RMM technique by approximately 20%. In general it is noted that the replication in this group of samples is subject to the type of form defect discussed and illustrated with respect to Figure 9. In addition it could be argued that with the exception of samples 3 and 7 that a trend is apparent where low volume loss in the sample is associated with higher measured difference in volume loss. This result would suggest that the resolution of the current technique is such that its accuracy decreases over the range of volume loss magnitudes seen in the sample.

![Figure 5. Plot of sample number with % volume loss difference from RMM](image)

**Figure 5.** Plot of sample number with % volume loss difference from RMM

**Figure 6** shows the deviation map representation of the point cloud FV measurement from sample 5. The false colour scale indicates the deviation from a conic primitive fitted to the unworn regions of the taper as seen in **Figure 8** (u). **Figure 6** shows a number of features of interest A) to E); (A) shows the fine pitch tooling marks of the original (unworn) femoral taper sleeve surface (**Figure 1** (B)). (B) Shows a degree of corrosion on the exposed distal surface of the taper where it has been in contact with bodily fluids adjacent to the taper contact region. (C) Shows the approximate distal and proximal extent of the contact region of the femoral stem trunnion and the sleeve taper surface (**Figure 1** (A) and (B) respectively). (E) shows the somewhat more coarse pitch of the tooling marks of the trunnion surface having been transferred from that surface during service. The current technique resolves these characteristic features of retrieved taper surfaces that are also noted in studies using other measurement techniques both directly and in replica [13, 14].
The regions labelled (D) show evidence of surface striping in the axial direction indicated by the black arrows. These stripes correspond to the spacing of the 26 longitudinal measurement regions created by the incremental steps of the FV rotary stage. The mechanism responsible for this form variation associated with stitching is not fully understood. It is thought to be related to the averaging of point height data in the overlap regions of the stitching process and is thought to be limited to the range of surface roughness heights. The effect causes a local variation in taper surface height of approximately 1.5μm amplitude with an angular wavelength of approximately 14°. It is noted that this variation is small in comparison to the real form variations.

Figure 7 and 8 show the volume loss analysis images from the Matlab™ software [12], for sample 5 measured with the RMM and FV techniques respectively. Parts (1) and (2) cover unworn region assignment with levelling and surface height thresholding respectively. Part (3) shows the Abbot-Firestone curve representation of volume loss after thresholding.
Figure 7. Volume loss analysis images for sample 5 measured by RMM. Showing the processing stages 1)-3) Unworn fitted regions are labelled (u)

Figure 8. Volume loss analysis images for sample 5 measured by FV. Showing the processing stages 1)-3) Unworn fitted regions are labelled (u)

The two figures are not to the same scale due to outliers in the FV data, and the surface maps are offset as they have different stating points on the taper surface. The listed volume loss values correspond to those in Table 1, and the FV technique reports a volume loss approximately 20% lower than the RMM technique.

Figure 9 shows two profiles from the same relative location on the two surface maps from Figure 7 and 8 the profiles are located at the broken white lines on their respective surface maps. Despite the difference in scale the approximate broken line triangles with their heights show how the extent of wear and thus volume loss is under reported in the FV dataset. The consequences of the linear fit and levelling to zero height of the taper surface maps can be seen in Figure 9 (a) and (b). Importantly it should be noted that the distal unworn fitted regions of the two surfaces have different form. This difference means the zero height line to which the surfaces are thresholded is fitted at a lower relative position for the FV surface than for the RMM surface, and is largely responsible for the discrepancy in measured volume loss values.
Figure 9. Levelled and linear fitted surface height map profiles for sample 5. Extracted from the locations of the white dotted lines in the respective surface height maps in Figure 7 and 8. Unworn fitted regions are labelled (u)

Figure 9 (a) and (b) also show broken curved lines, which, given the shape and orientation of the unworn regions might be interpreted as the likely shape of the tapers original manufactured surface. For an accurately reported surface levelling to such a polynomial fitted surface may improve the accuracy of volume loss analysis.

The type of replication discrepancy seen in Figure 9 was noted as the main replication fault during testing and eliminating it fully did not prove possible. It was to mitigate this issue that the extensions of the replica casting void as noted in Figure 4 were arranged. At the distal end, distortions in the replica caused by displacement stiction at the mounting tube junction were alleviated by moving the junction away from the measured surface by adding the extension sleeve (Figure 3 (B)). At the proximal end it was found that moving the physical end of the replica away from the measured surface reduced distortions in this region. The reason for this improvement is not clear and it is noted that in
the Redlux™ study that this proximal extension was not possible, nor were any such replication distortions reported. The non-curing elastomer used in the current study caused a number of difficulties with the replication process such as adhesion to and extraction of the replica. It is considered that the most significant difference between the techniques developed in the current study and that due to Redlux™ is this arrangement at the proximal end of the taper replica. It is however, not clear if this makes a significant contribution to the noted difference in accuracy.

Table 2 shows the volumetric loss data from the Redlux™ replication technique [15] for comparison to those of the current technique. The Redlux™ technique uses Microset™ fluid grade 202 blue, with quoted resolution and shrinkage values of 0.05μm and less than 0.1% respectively. This technique was validated by comparison to the gravimetric analysis of seven fabricated tapers with simulated wear designed to emulate that of typical recovered head tapers. For each taper replica 844,000 data points were acquired at half degree increments radially and approximately 14μm axial spacing, using a helical global sampling strategy. The taper validation measurements were reported over a range of volume losses of 0.46 to 4.67mm³ and volume loss repeatability was reported for two recovered head tapers over three repeated measurements. All measured volumes were larger than their respective gravimetric values, and no correlation was noted between the magnitude of simulated wear and the difference in measured volumes. The recovered heads and manufactured tapers in the Redlux™ study were all of the same design and included no modular taper sleeve, the 12/14mm taper trunnion fitted directly into a 12/14mm taper modular head (as in Figure 2).

### Table 2. Volume loss data for the RedluxTM technique
including repeatability data with mean, standard deviation (σ) and coefficient of variation (Cv) values [15]

| Volume loss | Sample | Gravimetric (mm³) | Redlux (mm³) | Difference from Gravimetric (%) |
|-------------|--------|-------------------|--------------|--------------------------------|
| 1           |        | 1.72              | 1.73         | 0.01                           |
| 2           |        | 2.58              | 2.61         | 0.03                           |
| 3           |        | 2.22              | 2.32         | 0.01                           |
| 4           |        | 0.46              | 0.47         | 0.01                           |
| 5           |        | 0.72              | 0.86         | 0.01                           |
| 3 (2)       |        | 4.67              | 4.8          | 0.01                           |
| 4 (2)       |        | 2.78              | 2.82         | 0.01                           |
| **mean**    |        | **0.065**         | **4.58**     |                                |

| Repeatability | Sample | Volume loss (mm³) | Cv |
|---------------|--------|-------------------|----|
|               | 1      | 2                 | 3  | mean | σ     | σ/mean |
| a             | 0.55   | 0.85              | 0.57| **0.66** | 0.17 | 0.255  |
| b             | 7.47   | 7.15              | 7.24| **7.29** | 0.17 | 0.023  |

Comparing the data in Table 1 and Table 2 and Redlux™ and the current technique, approximate overall ranges in volume loss difference from their respective benchmarks are noted to be 1 to 19% (0.01 to 1.4 mm³) and 1 to 24% (0.02 to 1.39 mm³) respectively. These show a similar overall spread of results, though the Redlux™ technique has better accuracy having approximate mean (absolute) values of volume difference of 5% (0.06 mm³) compared to that of the current technique 14%
Mean repeatability of the two techniques is similar with standard deviations of approximately 0.17mm$^3$ over the two repeated samples in each case. Again the current technique performs better relatively when coefficient of variation is used though the same caveat regarding this metric applies. Only the repeatability aspect of the Redlux™ study was carried out with retrieved heads showing real wear. Assessing the volume loss due to simulated wear is more straightforward than real in vivo wear, thus the most meaningful comparison for the current and Redlux™ techniques is the repeatability data. Therefore it is reasonable to say that the current technique performs well in comparison to the existing replication technique due to Redlux™. However, both of these replication based techniques show significant outliers in their results of the order of 20 to 30% variance, though fewer are noted in the Redlux™ data. These extreme values in both cases are reported for samples with low volume loss and thus perhaps the replication process in general may not be appropriate for measuring low volume loss. For the Redlux™ technique Cook et al [14, 15] make no comment about the possible correlation of process accuracy and scale of sample volume loss. A distinct difference is also noted in that all the Redlux™ results are reported as increases in volume difference and the opposite trend is apparent in the current technique, the reason for this and or its significance are not known.

Having noted the accuracy limitations of the current technique compared to the RMM technique it is noted that replication has the advantage of allowing the whole taper surface to be captured. Unlike a stylus technique where approximately 0.5mm of taper surface at both distal and proximal ends is not measured due to stylus access issues and run up. In certain cases this may be the difference between capturing and not capturing the crucial unworn regions on a retrieved taper. It is also noted that when used independently the current technique’s performance is somewhat better given the flexibility of the Matlab™ software [12] and an experienced operator. For example the potential hogging defect of a replicated surface could be accounted for by the operator applying a polynomial level approach without the knowledge of where the form error originated. This is not to say that this approach is justified and rigorous unbiased techniques were applied in the current work.

4. Conclusions
A new volume loss analysis technique for retrieved femoral head taper surfaces has been described and its performance compared to existing techniques. Against the noted contact stylus benchmark technique mean absolute variation in volume loss is approximately 14% and repeatability is likely to be less good overall. The new technique is shown to perform well in comparison to the existing Redlux™ replication technique for retrieved tapers. Benchmarked performance is least good for tapers with small volume loss, and data may suggest this is also the case for the Redlux™ technique. Thus, replication techniques may have an inherent limitation with respect to resolving small (sub 1mm$^3$) volume losses.

A characteristic type of replication defect which causes the under reporting of volume loss is noted and identified as the significant source of error in the method. Results suggest that noise should be filtered from the point height data sets before volume loss analysis is carried out.

The script developed to unwrap the captured point cloud data to point height format has been demonstrated and allows the use of existing software which provides flexible volume loss analysis.

Further development may improve replication process control which is central to the techniques accuracy.

5. Acknowledgement
The authors gratefully acknowledge the UK’s Engineering and Physical Sciences Research Council (EPSRC) funding of the EPSRC Centre for Innovative Manufacturing in Advanced Metrology (Grant Ref: EP/I033424/1).
Permission for the collection and analysis of the retrieved heads was granted by the National Research Ethics Service

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