# Quantifying Material Loss from the Bearing Surfaces of Retrieved Hip Replacements: Method Validation

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## Abstract

Computational methods used to quantify wear in failed hip arthroplasties are often limited by human and sampling errors. An automated software solution has been developed to overcome these shortcomings. The overarching aim of the current study was to validate this method through a comparison with gravimetric measurements. Seventy-two different wear volumes were quantified to within a mean error of 0.14 $mm^3$ and 0.10 $mm^3$ of gravimetric results for simulated cup and head components, respectively. This approach had an improved accuracy, repeatability and reproducibility over a commonly used, commercially available software solution, which bears many of the common sources of error.

## Highlights

- This article validates an automated method for quantifying wear in hip implants.
- Bearing surface wear volumes were quantified to a maximum mean error of $0.14mm^3$.
- An automated solution provides improved accuracy compared to a commercial software.
- Potential impact for a million patients world-wide with metal-on-metal hips.

## Keywords

Wear; material loss; retrieval analysis; hip replacement.

## 1. Introduction

Over 1 million patients worldwide are still implanted with metal-on- metal (MOM) hips. The performance of these implants is related to the amount of bearing wear they sustain in-vivo [1], due to the resulting release of harmful debris. Inflammation and necrosis in the surrounding tissue [2] is often a serious consequence, which results in the need for revision surgery. The volume of wear, however, can only be determined through the geometric comparison of worn and unworn regions on retrieved implants, following revision surgery.

Manufacturing tolerances impact implant dimensions [3,4]; there- fore, the exact pre-implantation form of retrieved bearing surfaces is known to be variable. Through extrapolation, however, this geometry can be reconstructed from pristine areas of the retrieved implant. Previous studies have used a range of strategies, commonly user dependent, to approximate this unworn state [5–9]. A localised, pristine region is often the basis of such estimations. These methods can be limited by human and sampling error when identifying and isolating these surface areas that are free of wear.

To overcome these limitations, an automated analysis software was developed and introduced by the current authors in a previous publication [9]. Its implementation of an iterative process allows the systematic exclusion of worn regions, maximising the number of data points that inform extrapolation of the unworn geometry.

The aim of this study was to validate the accuracy, repeatability and reproducibility of this automated analysis strategy for calculating the volume of material loss from retrieved hip implants, through a comparison with gravimetric analyses. This method was also compared to a commercially available user dependent software, which bears many of the common, potential sources of error.

## 2. Methods

Thirty-three metal components (Table 1) were iteratively worn to produce 87 different quantities of material loss, with an additional three components used as controls. As the gold standard, gravimetric analysis was used to determine wear volumes [6,7]. These measures were used to evaluate the ability of an automated software solution to quantify bearing surface material loss from geometrically captured point clouds. This approach reconstructs pristine implant surfaces by iteratively best fitting spheres to the data set, following the removal of points that are compromised by wear. Its accuracy, repeatability and reproducibility were determined through this comparison. For the remainder of this paper it will be referred to as the “automated software”.

These point clouds were also analysed using an existing, commercially available, user dependent package. This approach relies on the manual selection of an unworn area, representative of the pristine component geometry, pre-implantation. Its analysis was considered inhibited by some common limitations, present in many current methods. For the remainder of this article it will be referred to as the “Commercial Grade (CG) software”.

### *2.1. Materials*

A pilot investigation involved the analysis of ball bearings, representing the head components of hip arthroplasties. Their availability, spherical geometry and comparable density to cobalt chrome made them suitable for a preliminary software performance evaluation. This was also an opportunity to study the effect of extensive wear coverage on material loss measurements.

The main arm of the study involved the analysis of pristine Adept (MatOrtho) resurfacing hip components (n ¼ 20), which were used to assess the ability of both methods to quantify wear volumes, following wear simulation. Three Adept hips of the same head and cup size, retrieved from patients during revision surgery, were also analysed in this study. Their purpose was to ensure that patterns of wear on the simulated implants were representative of damage incurred in vivo (Table 1).

*2.2. Wear simulation*

Each ball bearing was worn to a single quantity of material loss using a double ended polishing machine (two grades of rotary polishing mop). Maximum wear coverage was an objective of this preliminary investigation, in an attempt to replicate the most challenging cases found in retrieval analysis.

The Adept hips were worn iteratively in four phases. The same polishing machinery was used for the heads, while a Dremel 3000 multitool system (Dremel, Breda, Netherlands) was utilised to wear the cups. Measures were taken to protect the non-articulating regions of the implants form loose debris. This involved covering areas that were not to be worn with a vinyl material, which was secured in place. An example of each component was used as a control (n 1⁄4 3), which remained un- worn, despite being handled and prepared in the same manner.

Wear scars commonly observed on retrieved MOM hips were replicated on the surface of each component, with specific consideration of their size, shape and location. On the ball bearings and Adept heads, an elliptical wear scar was generated near their pole and offset to one side [11–13], while a wear scar was simulated near the articulating surface edge of each cup [1,14–17]. Consistent with retrieved implants, wear was not always isolated to one scar, with smaller secondary scars and lighter scratches being also replicated [18]. The range of simulated material loss quantities was also consistent with values reported in literature [11,19–21].

*2.3. Gravimetric analysis*

Prior to and following each iteration of wear, components were cleaned and then weighed using a Mettlet Toledo MS304S analytical balance. Their mass was recorded in sequence, until 3 readings per component were identical within 0.1mg; a mean value was then calculated. Control components were also cleaned and weighed following the same protocols, ensuring that any changes in mass, unrelated to wear, was taken into account. The decrease in component mass, due to wear, was measured in order to calculate the volume of material loss, using Equation (1).

$$M_n = W_{an} + S_n \tag{1}$$

$M_n$ = net mass loss following wear simulation

$W_{an}$ = average uncorrected mass loss

$S_n$ = average increase in mass of the control component

These volumes of steel chrome and cobalt chromium were calculated, assuming their densities were 0.007833413g/mm$^3$ and 0.008333g/mm$^3$, respectively [22]. This analysis was performed in accordance with the ASTM F1714-96 and ISO 14242-2 standards [23, 24].

*2.4. Geometric data acquisition*

The surface geometry of each component was captured, in the form of point clouds, using a Zeiss Micura (Carl Zeiss Ltd, Rugby, UK) coordinate measuring machine (CMM). Its 3 mm ruby stylus was instructed to follow approximately 300 polar scan lines, along each bearing sur- face. Coordinate measurements were recorded within 0.5 mm of each other. All scan arcs emanated from the pole of each cup, terminating <1 mm from their edge; while the opposite being true for the heads, with each arc emanating 5 beyond their equator and terminating at the pole. This scanning strategy was in accordance with ISO and ASTM standards [23,24], resulting in the attainment of approximately 20,000 data points per component. Prior to and following each iteration of wear, the components were scanned three times in series, allowing any inherent error associated with the CMM and its protocols to be assessed. In excess of 350 scans were completed during this study.

*2.5. Geometric data analysis*

As previously described in detail [9], the automated software initially best fits a perfect sphere to a measured point cloud, in its entirety. The RMSE (Root Mean Square Error) between these geometries is then calculated. An error in excess of 2µm triggers an iterative process to commence, in accordance with ASTM F2979-14 [24]. With each repetition, the most erroneous points [1] are removed and a revised sphere is t to the remaining data, until an RMSE <2µm is achieved. Failure to converge below this threshold, within the defined number of iterations, results in the reanalysis of the point cloud. With each pass through the software, the error threshold for point removal decreases. The accepted sphere is then used to de ne the unworn geometry of the retrieved component. The volume difference calculated using Equation (2) is considered representative of the volume of material loss from the bearing surface of a hip component [24].

[1] If the individual error of a data point, with respect to the sphere, is more than approximately 2 standard deviations from the mean error of the entire cloud, it is removed.

$$V = G_u - G_w \quad (2)$$

$V$ = *Volume of Material Loss*

$G_u$ = *Calculated Unworn Geometry*

$G_w$ = *Measured Worn Geometry*

In contrast, when using the CG software, a portion of the point cloud is manually selected, based on the users assessment of which region is unaffected by wear. A perfect sphere, representative of the pristine geometry, is then best t to this region. This selection is informed by visual inspection of the implant and a given RMSE value, calculated between the measured point cloud and the sphere generated from a specific, selected region.

The first scan of each component, following each iteration of wear, was analysed using both software solutions. Measured wear volumes were then compared to the gravimetric results. Analysis performed by the CG software was repeated twice, by two separate observers. As the automated software provides identical result when analysing identical scans, it was performed once by a single observer. The remaining two point clouds, generated for each component, were also analysed using the automated software. This allowed the evaluation of any inherent error associated with the CMM and its protocols.

*2.6. Macroscopic, microscopic and profilometry analysis*

Each component was examined microscopically using a Leica M50 microscope (Leica Microsystems, Germany) at up to 200x magnification. Macroscopic images were collected to identify wear scar locations using a Canon 6D DSLR and Canon 100 mm L lens [18]. A Contour GT-K 3D optical profilometer (Bruker, UK) was used to collect roughness measurements and pro le plots from their worn and unworn surfaces. These analyses were performed at each stage of component wear and a comparison with the retrieved Adept components was performed.

### *2.7. Statistical analysis*

Bland-Altman plots were generated to compare the gravimetric measures of material loss with volumes calculated by both software solutions. This allowed the mean error, upper 95% limits of agreement (ULA) and lower 95% limits of agreement (LLA) to be calculated. Lin's Concordance Coefficient was calculated to determine the accuracy and repeatability of both methods, evaluated using the scale described in Table 2 [25,26].

## 3. Results

### *3.1. Ball bearing analysis*

Gravimetric analysis showed that the steel chrome ball bearings were worn to between 0.81 $mm^3$ and 107.52 $mm^3$. These quantities were compared to the measurements performed by both software solutions, Fig. 1. A mean error of 2.43 $mm^3$ was found between gravimetric measurements and the automated software measurements, with upper and lower 95% limits of agreement of 9.98 $mm^3$ and -5.11 $mm^3$, respectively. Through the same comparison, estimations made by the CG software were found to have a mean error of 13.02 $mm^3$, with upper and lower 95% limits of agreement of 38.97 $mm^3$ and -12.93 $mm^3$, respectively.

### *3.2. Metal-on-metal adept hip analysis*

#### *3.2.1. Comparison of simulated and retrieved adept implants*

As shown in Fig. 2, the size and location of the wear scars were well matched, with respect to retrieved and simulated components that shared comparable material loss values. A mirrored finish was achieved on the surface of the Adept heads, resulting in indistinguishable worn and unworn regions, with the exception of light scratches (Fig. 2). A comparison of the corresponding surface pro les demonstrated that wear grooves on the Adept cups, formed during wear simulation, were deeper and more numerous (Fig. 3). This was also consistent with the microscopic assessments of these implants.

#### *3.2.2. Comparison of gravimetric and software measurements*

Gravimetric analysis showed that the simulated Adept head components were worn to between 0.38 $mm^3$ and 103.69 $mm^3$, Fig. 4. Utilizing Bland-Altman plots, the volumes measured by the automated software had a mean error (bias) of 0.14$mm^3$ when compared to gravimetric results; while 0.64 $mm^3$ and -0.35 $mm^3$ were calculate as their upper and lower 95% limits of agreements, respectively. The automated software reconstructed the pristine diameter of the heads, measured prior to wear, to a median error of 0.51 μm. As seen in Fig. 6, estimations made by the CG software had a larger bias of 7.51 $mm^3$, with upper and lower 95% limits of agreements of 15.55 $mm^3$ and -0.52 $mm^3$, respectively. A consistent overestimation of gravimetric measurements is observed in Fig. 4 for the CG software, with the formation of a linear trend. Lin's Concordance Coefficient suggests an 'almost perfect' agreement ($\rho_C$ 1⁄4 0.9999) between gravimetric results and those generated by the automated software. Only a 'moderate' agreement was achieved through the application of the CG software ($\rho_C$ 1⁄4 0.9455).

Following wear simulation, the material loss volumes from the Adept cups ranged from 0.33 $mm^3$ to 101.06 $mm^3$, Fig. 5. The measurements of volumetric material loss generated by the automated software was found to have a mean error of 0.10$mm^3$ (Fig. 6), with respect to gravimetric measurements. Bland-Altman plots displayed broader 95% limits of agreement compared to the heads, calculated as 2.36 $mm^3$ and -2.16 $mm^3$ for the upper and lower limit, respectfully. The automated software reconstructed the pristine diameter of the cups, measured prior to wear, to a median error of 1.64μm. Analysis of the same scans using the CG software package resulted in a substantially greater mean error of 13.67 $mm^3$. A calculated Lin's Concordance Coefficient ($\rho_C$) of 0.9991 suggests an 'almost perfect' agreement between gravimetric and auto- mated software measurements of the cup components. However, the CG software was found to have a 'poor' agreement to the gold standard ($\rho_C$ = 0.8657).

**4. Discussion**

This study demonstrates the ability of an automated analysis method to quantify bearing surface wear volumes within a mean error of 0.14 $mm^3$ and 0.10 $mm^3$ of the gravimetric measurements, for cup and head components respectively, which were representative of retrieved implants. Furthermore, primary wear scars were successfully positioned to correlate with literary findings [11–18,27]. These errors were consistent for all material loss measures, which spanned the large range of wear volumes previously quantified in retrieval studies [11,19–21].

This automated software benefits from reduced sampling error, as it can more reliably identify unworn data points, maximising the number of coordinates used to reconstruct the unworn geometry of retrieved implants. Its automation enables repeatability and reproducibility of the measurements, allowing the same estimations to be obtained during the analysis of identical point clouds. As a result, the CMM strategy for data acquisition is isolated as the only remaining source of variability. This is currently the most common method for this application [5,6,8,11]; however, a recent study demonstrated the potential of an optical method of capturing geometric data that could also be analysed using this automated software [28].

The Lin's Concordance Coefficients presented in this study, suggests that cup component material loss is more difficult to quantify to the same degree of accuracy as the heads. The results for both software solutions conform to the same trend, which has also been observed in a previous study [22]. These measurements could, therefore, be fundamentally restricted by limitations associated with their geometric analysis. The importance of data collection at the extremities of the acetabular articulating surface has previously been discussed [29], with International Standards emphasising the need to scan within 1 mm of their edge [24]. This has a greater impact on cup component measurements, as their primary wear scars are most commonly located in this region.

Appropriate measures were taking, during this study, to ensure that the entire bearing surface was captured. However, errors in implant alignment, both physically and computationally, can result in the loss of data at the limits of each scan. Error can also be incurred during the definition of this boundary, as many implant designs have a gradual transition between bearing surface and rim.

As with all methods, this software relies on portions of the bearing that have remained unaltered from its pre-implantation state, following its time in-vivo [5]. The importance of isolating these regions from the measured point cloud was emphasised by the ball bearing analysis. It demonstrated that in cases in which wear coverage is greater than approximately 75%, there is a detrimental effect on the quality of pristine geometry approximation and measurement accuracy. However, in the authors experience, the majority of retrieved components reveal wear scars that cover a smaller region.

Currently, a considerable amount of inter-centre variability exists between methods of analysing geometric data, to quantify material loss from the bearing surface of retrieved hip arthroplasties [9]. Specifically, their approach to identifying unworn data points and estimating the as-manufactured geometry. The automated software provides improved accuracy, repeatability and reproducibility compared to a user-dependent, CG available software, which shares common limitations with many of these methods. Furthermore, the measurement variability generated by the CG software emphasises its dependence on user competency and experience.

There are fundamental requirements associated with the acquisition of accurate material loss measurements, which have been highlighted by these findings. Reliable pristine portions of the bearing surface must have prevailed, to which a perfect sphere can be best fit to an acceptable RMSE value. This representation of the pre-implantation geometry must also be informed by the maximum number of data points, which are uncompromised by wear. In the present study, an RMSE within 1 μm was found to generate the most accurate results, which is half that of the 2 μm threshold reported in the international standards [23,24].

### *4.1. Limitations*

Gravimetric analysis is the gold standard for measuring material loss from orthopaedic implants, when a measurement of the unworn component is possible [5,10]. However, changes in mass, irrespective of the bearing surface, can have a detrimental effect on results. Straying wear debris is a source of such errors, especially considering the design features found at the backside of both Adept components. However, to manage this limitation, the components were handled exclusively with gloves and kept in airlock bags; these regions were also covered during the wear process and compressed air was utilised to remove any loose particles.

Replicating surface topography during wear simulation is an important objective, as it influences the measurable surface area. Despite the comparable surface roughness displayed by the head components, the cups had a considerably rougher surface finish. This is attributed to the adoption of a different polishing tool, used to overcome their restrictive geometry. As measurements within micron scale grooves are ordinarily unachievable using a probe of this scale (3 mm radius), these topographical differences would not have resulted in probe penetration bias[2].

## 5. Conclusion

The current study provides evidence validating the ability of a developed software to accurately quantify material loss from the bearing surface of hip replacements to within 0.14 $mm^3$ of gravimetric measurements. Contrasting results found between cup and head measurements prompts further method refinement, which should allow both components to be analysed to equal levels of accuracy. Limitations associated with user-dependent solutions were also highlighted, promoting the adoption of an automated software.

As an indicator of implant performance, retrieval analysis will bene t considerably from these reliable measures of volumetric wear. It could allow an improved understanding of the failure mechanisms of metal-on-metal hip replacements. Additionally, the true toxicity of cobalt chromium could be better defined, following the acquirement of more reliable correlations with

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[2] Inability of the probe to contact an equal amount of surface area, due to greater implant roughness.

blood ion levels and observed necrosis. However, in defining clinically relevant metal quantities, the contrasting dose response between individual patients must be considered [30,31]. Dissemination of such a method could also facilitate improved conformity in the analysis of an implant design, to collectively determine its success or failure.

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| **Components** | **n** | **Material** | **Diameter** (mm) |
|---|---|---|---|
| **Ball Bearings** | 16 | Steel Chrome | 40 |
| **Adept Hip Resurfacing** | 20***** | Cobalt Chromium | 42 |
| **Retrieved Adept Hip Resurfacing** | 3 | Cobalt Chromium | 42 |

**10 heads and 10 cups*

***Table 1.*** *Components included in this study.*

| **Strength of agreement** | **Coefficient Value** |
|---|---|
| Almost perfect | > 0.99 |
| Substantial | > 0.95–0.99 |
| Moderate | 0.90 – 0.95 |
| Poor | < 0.9 |

***Table 2.*** *Scale used to determine the strength of agreement represented by each value of Lin's Concordance Coefficient.*

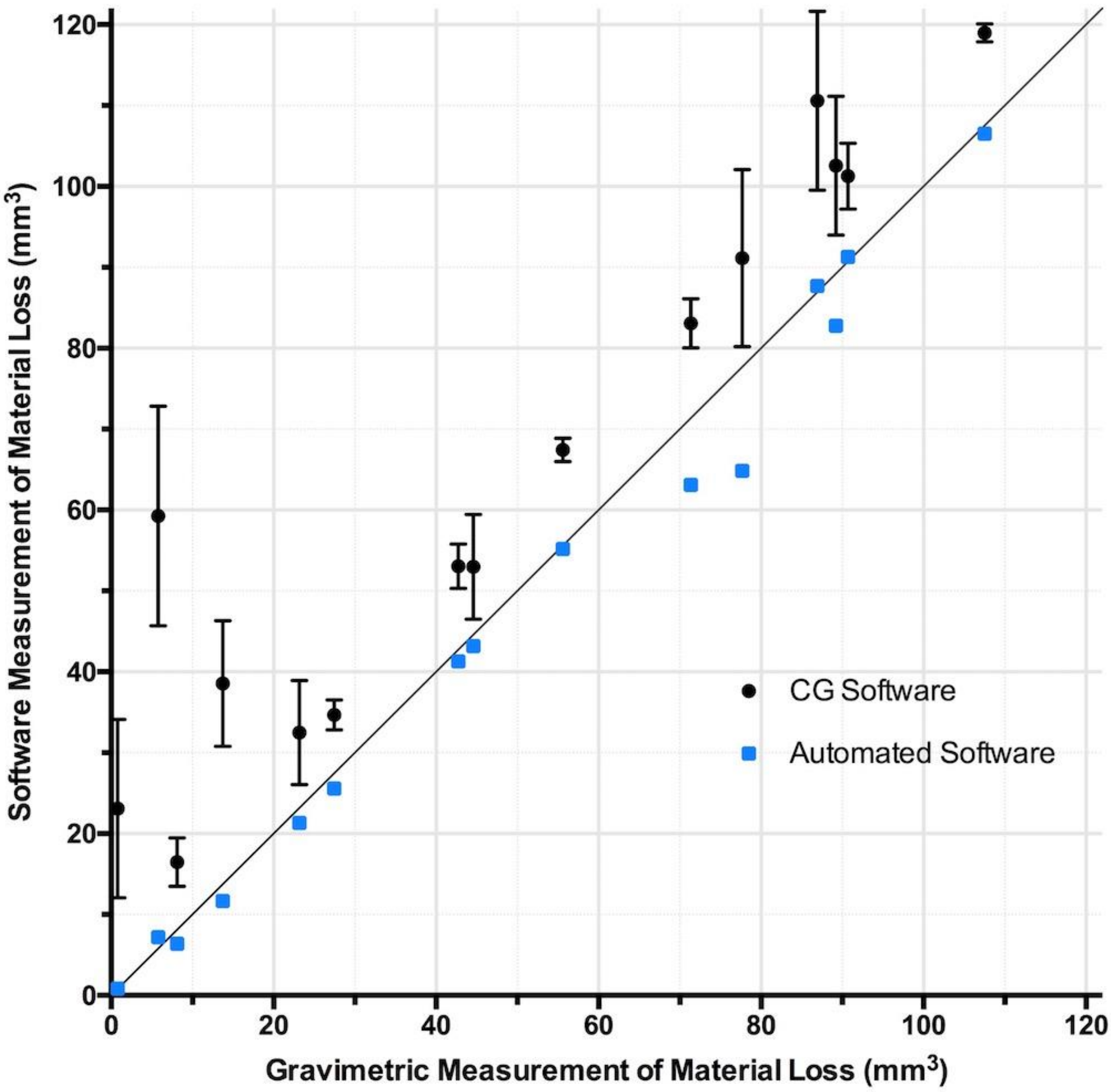


***Fig. 1.*** *Comparison of the gravimetric measurement and both software estimations of material loss from the steel chrome ball bearings. The error bars represent the results generated by four observers (mean and range). The diagonal line represents the points at which estimations are equal to the true measurement.*

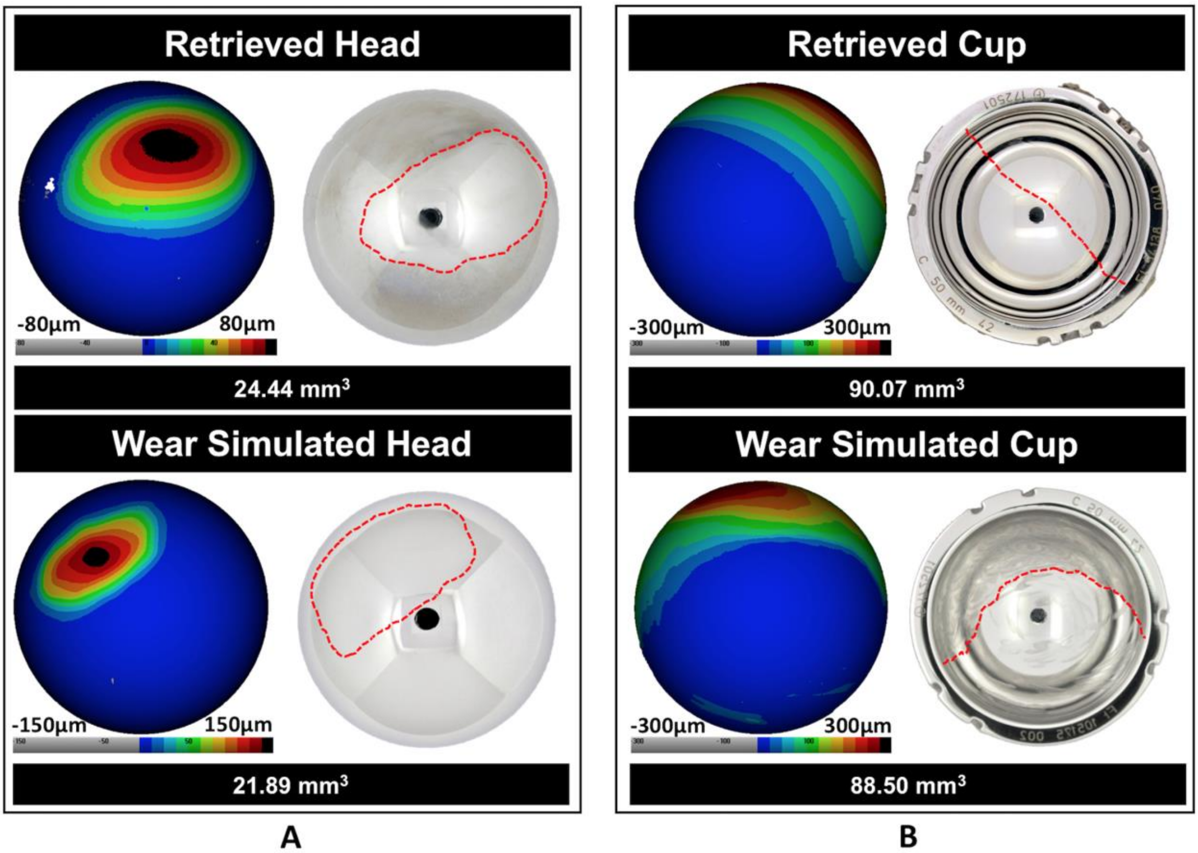


***Fig. 2.*** *Wear maps and macroscopic images of retrieved and simulated Adept (A) head and (B) cup components, generated using the automated software. Red lines indicate the visible boarder of the primary wear scar.*

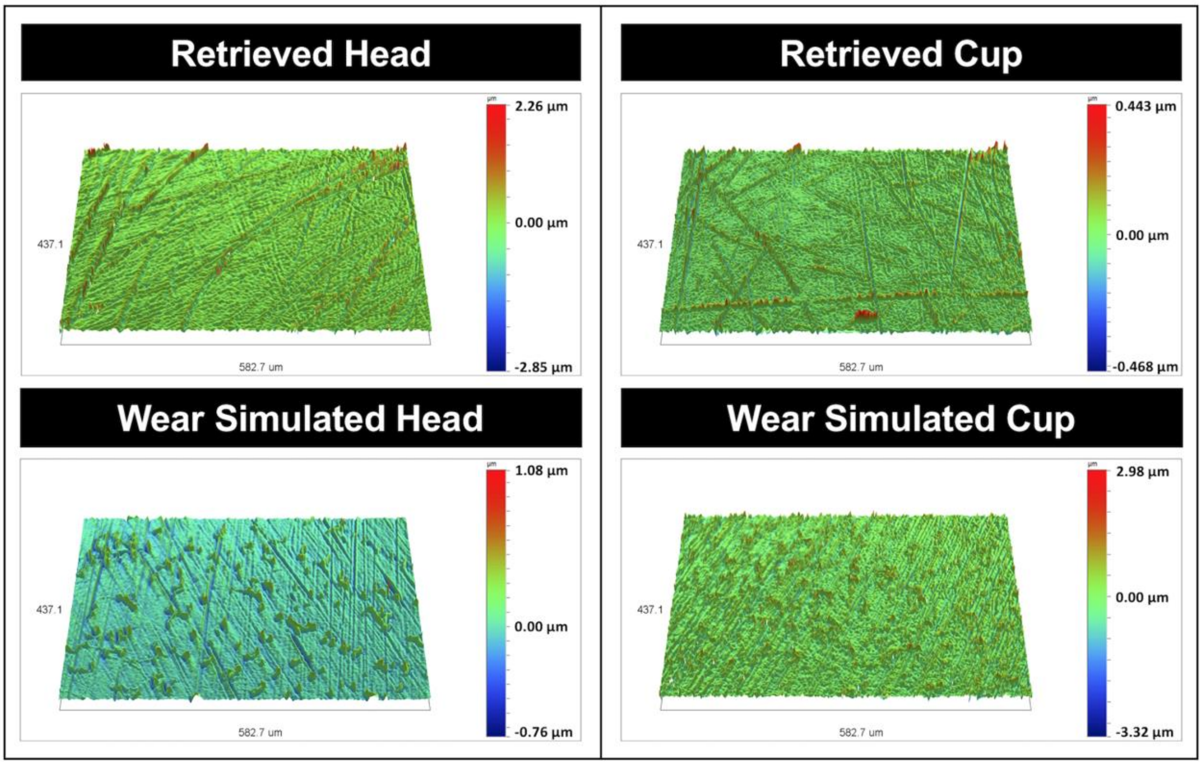


***Fig. 3.*** *Comparison between the surface pro les of retrieved and simulated Adept components.*

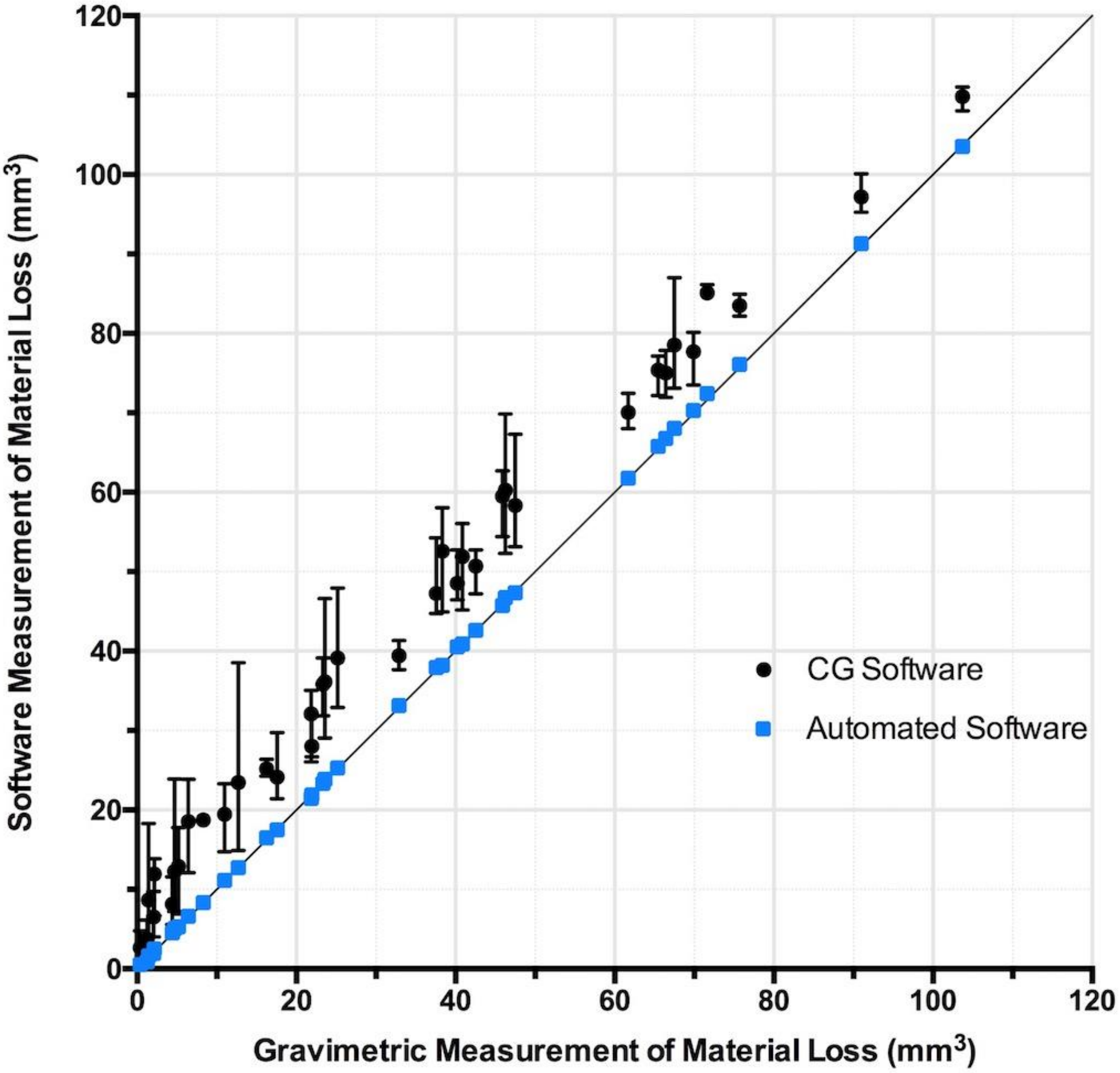


***Fig. 4.*** *Comparison of the gravimetric measurement and both software estimations of material loss from the cobalt chrome Adept heads. The error bars represent four results generated by two observers (mean and range). The di- agonal line represents the points at which both measurements are equal (line of equality).*

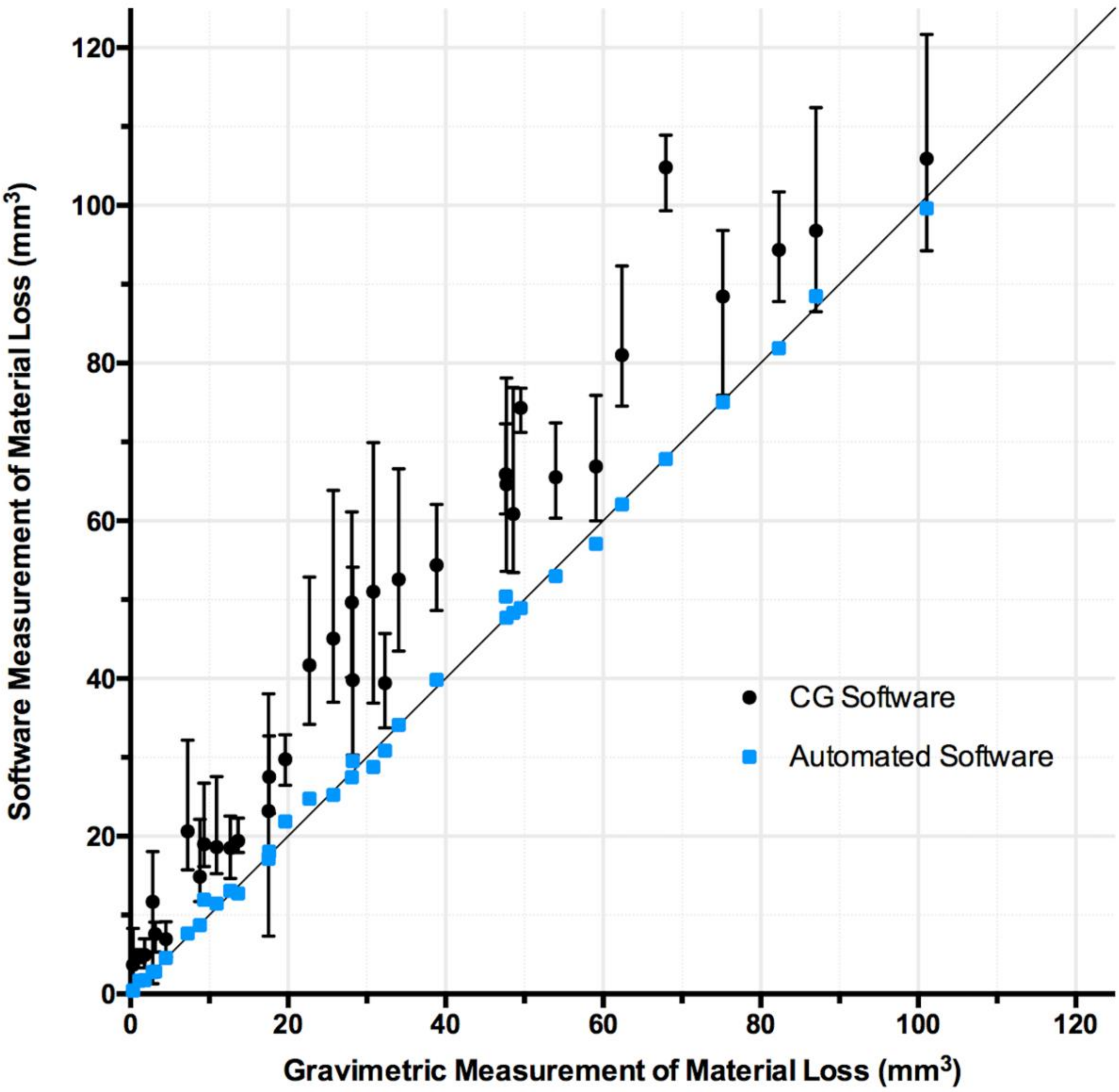


***Fig. 5.*** *Comparison of the gravimetric measurement and both software estimations of material loss from the cobalt chrome Adept cups. The error bars represent the two results generated by both observers (mean and range). The diagonal line represents the points at which both measurements are equal (line of equality).*

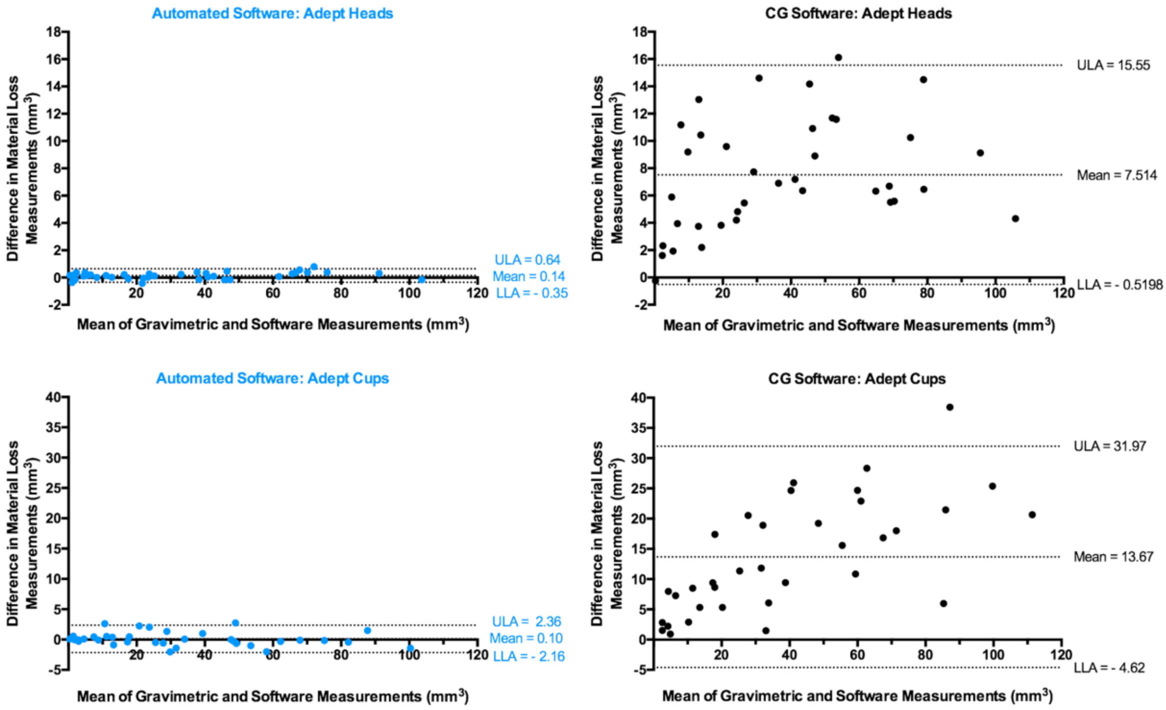


***Fig. 6.*** *Bland-Altman plots displaying the difference between the gravimetric measurements and estimations made by both software solutions of material loss from the Adept heads (top) and cups (bottom). The mean, upper 95% limits of agreement (ULA) and lower 95% limits of agreement (LLA) are also noted.*