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Practical considerations for volumetric wear analysis of explanted hip arthroplasties

D. J Langton,
R. P. Sidaginamale,
J. P. Holland,
D. Deehan,
T .J. Joyce,
A. V. F. Nargol,
R. D. Meek,
J. K. Lord

From North Tees Explant Centre, Farndale House, University Hospital of North Tees, United Kingdom

D. J Langton, PhD, Director, PXD Ltd
North Tees Explant Centre (NTEC), Farndale House, University Hospital of North Tees, TS19 8PE, UK.

R. P. Sidaginamale, MRCS, PhD student
T .J. Joyce, PhD, Professor of Orthopaedic Engineering
Newcastle University, Stephenson Building, NE1 7RU, UK.

J. P. Holland, FRCS, Consultant Orthopaedic Surgeon
Freeman Hospital, Freeman Road, Newcastle Upon Tyne, UK.

D. Deehan, FRCS, Professor of Orthopaedic Surgery
Freeman Hospital and Newcastle University, Freeman Road, Newcastle Upon Tyne, UK.

A. V. F. Nargol, FRCS, Consultant Orthopaedic Surgeon
University Hospital of North Tees, Farndale House, TS19 8PE, UK.

R. D. Meek, FRCS, Consultant Orthopaedic Surgeon
Glasgow Southern General Hospital, 1345 Govan Rd, Glasgow, Lanarkshire G51 4TF, UK.

J. K. Lord, PhD, Lecturer
California Polytechnic State University, Biomedical and General Engineering, San Luis Obispo 93407, USA.

Correspondence should be sent to Mr D. J. Langton; e-mail: djlangton22@doctors.org.uk

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Objectives

Wear debris released from bearing surfaces has been shown to provoke negative immune responses in the recipient. Excessive wear has been linked to early failure of prostheses. Analysis using coordinate measuring machines (CMMs) can provide estimates of total volumetric material loss of explanted prostheses and can help to understand device failure. The accuracy of volumetric testing has been debated, with some investigators stating that only protocols involving hundreds of thousands of measurement points are sufficient. We looked to examine this assumption and to apply the findings to the clinical arena.

Methods

We examined the effects on the calculated material loss from a ceramic femoral head when different CMM scanning parameters were used. Calculated wear volumes were compared with gold standard gravimetric tests in a blinded study.

Results

Various scanning parameters including point pitch, maximum point to point distance, the number of scanning contours or the total number of points had no clinically relevant effect on volumetric wear calculations. Gravimetric testing showed that material loss can be calculated to provide clinically relevant degrees of accuracy.

Conclusions

Prosthetic surfaces can be analysed accurately and rapidly with currently available technologies. Given these results, we believe that routine analysis of explanted hip components would be a feasible and logical extension to National Joint Registries.

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Keywords: Hip, Arthroplasty, Wear debris, Coordinate measuring machine, Volumetric wear, Metal ions

Article focus

- The accuracy of volumetric wear analysis of explanted hip arthroplasties has been debated.
- There is no consensus as to the effects of various scanning parameters on the accuracy of calculations.
- Some authors have suggested that accuracy increases with increasing number of measurement points. We sought to examine these statements.

Key messages

- Volumetric wear analysis of explanted hip prostheses can be carried out effectively and efficiently to provide clinically useful results.
- The assumption that several hundred thousand data points (and, by extension, prolonged scanning times) are required to produce legitimate data is not based on real world testing.

Strengths and limitations

- This is the first paper to our knowledge to document the effects of scanning techniques on measurement accuracy using real world, rather than theoretical calculations.

Introduction

Since the discovery of the importance of wear debris in the development of osteolysis, orthopaedic surgeons have looked to find

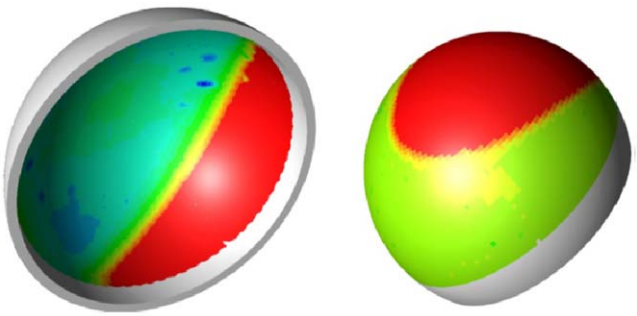

Fig. 1

CMM generated wear map of a failed metal-on-metal (MoM) ASR XL (Depuy, Leeds, United Kingdom). Red areas represent material removal of greater than 10 microns. Total volumetric wear was over 20mm3/year. Correspondingly, the patient's blood cobalt concentration was elevated more than 100 times expected levels. In the product liability case, DePuy successfully argued there was no abnormal wear of the device and the cobalt elevation was due to pre-existing medical problems/ contamination.

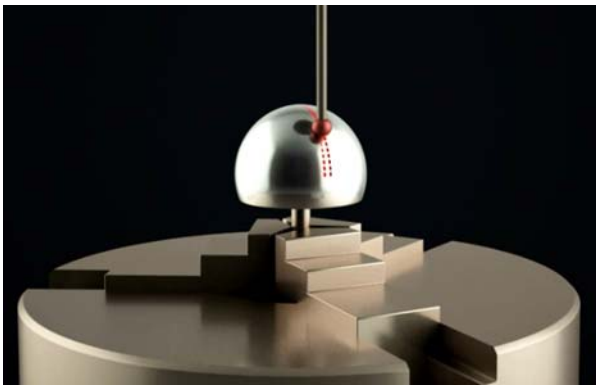

Fig. 2

A graphic representation of a metallic hip resurfacing component undergoing CMM examination. The ruby probe makes several linear traces from equator to pole: known as contours. In the image, the CMM has completed one contour trace and is midway through the second. Each dashed line represents a measurement point. The distance in millimetres between each point in the contour is known as the point pitch.

lower wearing, biocompatible bearing materials.[1] The analysis of retrieved implants (explants) is an essential step, therefore, in the audit of orthopaedic healthcare provision. This principle holds true irrespective of whether a device has failed early[2] or has been removed after decades of use in a satisfied patient.[3]

Volumetric wear analysis of explanted prostheses refers to the calculation of the total volume of material lost from prostheses during their use, after they have been removed from the body. There are a number of techniques, but all rely on the same fundamental methodology. Volumetric wear analyses have underpinned a number of published works on hip replacements spanning the last twenty years.[4-11] Despite this apparent widespread clinical acceptance, some metrologists have cast doubt on certain measurement techniques.[12,13] These concerns have been reiterated by clinicians.[14] The issues are further complicated by vested agendas in the field of litigation, where the identification of abnormal wear can have major financial implications for the plaintiff or manufacturer (Fig 1).[15]

The initiation of the National Joint Registries (NJRs) of Australia and England and Wales were great steps forward in the monitoring of the performance of various designs of hip and knee arthroplasties.[16,17] However, when products do not perform as well as expected there is often a lack of information as to the factors underlying device failure.[18] The next logical step in the 21st century is to expand simple product tracking into more in depth, routine independent analysis. Last year a parliamentary select committee stated that "explanted joints should be analysed and subsequent data generated should be reported to the NJR and published."[19] At present however, some would argue that there is a lack of consensus in terms of scanning protocols and techniques, the clinical relevance of the tests and in fact the practicalities of explant testing.

It is important, therefore, to describe the methods and accuracy of wear analysis as these are critical factors in the consideration of the clinical application of such tests. All wear measurement techniques rely on measuring a number of points on the material's surface and comparing these to an idealised surface. The number of points that are required to produce accurate results is a particular area of contention. For example, Bills et al's[13] theoretical experiments found that the measurement of a perfect sphere would result in a volumetric wear error of 346.614mm^3 if only 25 scan lines were used with a point pitch of 0.5mm to measure a total number of points of 2000.[13] The ISO standard which was published in 2002 recommended a minimum space between points of 1mm.[20] We investigated the criticisms of volumetric wear analysis made recently by means of real world practical tests using a coordinate measuring machine (CMM), the most commonly used technology in this area.[11,21] We tested the hypotheses that neither the total number of measured points nor the spaces between points would create clinically significant errors. The number of points taken over a surface affects the duration of scanning by a large amount. We therefore also sought to examine the speed at which clinically relevant results could be obtained in order to determine the practical implications of routine explant analysis.

How does a coordinate measuring machine (CMM) work?. A CMM is a precision measurement tool which uses a ruby probe to stroke over the surface of a component, recording data as it does. This data consist of a series of measured points in Cartesian form (e.g., one point would read as: x = 10, y = 0, z = 0). These values are distances (in mm) that the measured point lies away from the 'origin' in each direction. The origin in the case of explanted hip measurement is the original centre of the head or cup (i.e., the central point of the sphere

Table I. Summary of testing parameters and results.

Test	Contours	Pitch (mm)	Max point distance (mm)	Number of points	Volumetric loss (mm^3)
1	16	0.5	7.069	1072	0.7
2	16	0.3	7.069	1776	0.65
3	16	0.1	7.069	5216	0.66
4	32	1.0	3.534	1088	0.65
5	32	0.5	3.534	1952	0.73
6	32	0.3	3.534	3264	0.61
7	32	0.1	3.534	10432	0.58
8	72	1.0	1.571	2448	0.7
9	72	0.5	1.571	4824	0.54
10	72	0.3	1.571	7344	0.57
11	144	1.0	0.785	4896	0.61
12	144	0.5	0.785	9648	0.68
13	144	0.3	0.785	15984	0.64

immediately after the component has been manufactured). The CMM points are collected in a series of linear scans from the pole to the equator or *vice versa*. These linear traces are known as contours. As the probe progresses along each contour it measures points at a set interval: called the point 'pitch'. Figure 2 illustrates these parameters.

What is a clinically relevant amount of wear?. Of the routinely used bearing surface combinations, ceramics are known to wear at the lowest rate.[22,23] Al-Hajjar et al[24] found in a recent simulator study that alumina-on-alumina bearings wore at a mean (standard deviation [SD]) rate of 0.74 mm^3/million cycles (SD 1.73). The same group studied the difference in wear rates of a popular ceramic on ceramic (CoC) THR under standard and microseparation conditions. They found that the wear rates under microseparation conditions increased to 0.22mm^3/million cycles from less than 0.1mm^3/million cycles under standard conditions.[24-26] Walter et al however reported *in vivo* rates of 9.7mm^3/year for ceramic components revised for squeaking.[27] Studies of explanted devices have shown that metal-on-metal (MoM) bearings wear at rates from as low as 0.3 to as high as 95.5mm^3/year.[7,28] Contemporary metal on polyethylene (MoP) joints have been shown to wear at more than 25mm^3/year.[29]

We would argue, therefore, that volumetric wear techniques which can provide results to within an accuracy of 1mm^3 provide useful clinical information in the study of MoM and MoP joints and in the differentiation between well-functioning and poorly functioning CoC joints. Errors of 0.5mm^3 and below, we would argue, are only relevant in the lowest wearing ceramic bearings in the idealised environment of the hip simulator. If one considers a total error in the calculation of volumetric loss from a device explanted after, for example, five years *in vivo*, this total error would equate to an error in wear rate measurement of only 0.1mm^3/year.

Methods

Part one: the effect of scanning parameters on volumetric wear calculations. A 36mm diameter ceramic head was used for the tests reported in the first part of this investigation (Table I). It had been revised after one year due to recurrent instability. A number of different combinations of contours and pitches were used to calculate the volumetric loss from the ceramic component. In between each test the component was removed and then replaced in a different position in order to identify errors due to physical alignment of the component on the CMM worktop.

We used a custom designed volumetric wear programme to analyse data produced by a Legex 322 coordinate measuring machine (Mitutoyo, Andover, United Kingdom) at the North Tees Explant Centre (NTEC). Our methods have been validated using gold standard gravimetric testing and the techniques have been peer reviewed multiple times in orthopaedic journals.[21,28,30-32]

Some modifications have been made to our published method in order to increase the speed of identifying the unworn area of the scanned component. Rather than taking seven individual points to identify unworn surfaces, the CMM operator inputs the number of degrees in two planes, which dictate the surface area over which the ruby performs continuous contour traces. This method allows the unworn surface to be located more rapidly and also has the advantage of recording over 300 points to calculate the spherical form. In general these initial traces consist of 180° traces in one direction and three 70° traces in a perpendicular plane working from 10° above the equator towards the pole. If the initial traces are unsuccessful in locating a spherical form within the manufacturing limits then the coordinate system automatically rotates 10° around the z axis and repeats the sequence. If the CMM fails to identify an unworn surface after rotating around 360° then the area over which it attempts to locate original surface is sequentially reduced.

Table II. The relationships between changes in contour numbers, pitch distance and changes in the volumetric loss calculation. Spearman rank correlation used for non-parametric data and Pearson's used for parametric data.

	Correlation coefficient	Significance
Number of contours	-0.287	0.341
Pitch	0.313	0.293
Number of points	-0.322	0.283
Maximum distance between points	0.287	0.336

The effect of the number of scan contours . Our published method (the LJL method[21]) uses 72 contour traces progressing from the equator to the pole at intervals of 5°. Points are taken every 0.3mm along the trace (the 'pitch') using a measurement speed of 5 mm per second. With an implant of this diameter, this leaves the points a maximum distance of 1.57 mm apart. The ISO 14242 standard recommends that the point distance be no greater than 1 mm.[20] We therefore carried out four tests to examine the effect of point spacing. The first scan used 16 contours (maximum point spacing of 7.07mm), the next 32 contours (maximum point spacing of 3.53mm), the third 72 contours (maximum point spacing of 1.57mm) and the final scan used 144 contours, which gave a maximum point spacing of 0.78mm. A point pitch of 0.5mm was used throughout and the resulting volumetric loss was calculated.

The effect of point pitch . 13 tests were carried out to investigate the effect of the point pitch. Firstly, using 16 contour scan programmes, points were taken at a distance of 0.5 mm, 0.3 mm and 0.1 mm apart (a 1 mm pitch with this limited number of contours produced too few points to allow the software to calculate a volume). Next, using 32 contour programmes, scans were carried out with point pitches of 1mm, 0.5 mm, 0.3 mm and 0.1 mm. Finally, 72 and 144 contour programmes with pitches of 1 mm, 0.5 mm and 0.3 mm were performed (for these longer scans the large amounts of data produced with 0.1 mm cannot be handled satisfactorily by the memory of the hardware).

The effect of misalignment of the origin (centre of the sphere) in the x or y direction. In our experience, it is the failure to identify the remaining unworn surface to a reasonable degree of accuracy that is the primary cause of inaccurate and/or irreproducible measurements. In order to investigate this effect, we used theoretical worst outcome scenarios to compound this source of error. As Bills et al[13] and Carmignato et al[14] suggested that measurement errors are magnified when smaller numbers of points are recorded, the data generated by the 16 contour 0.5 mm pitch scan and 16 contour 0.3 mm scans (the scan sets with the smallest number of points) were fed back into the CMM. The origin (the calculated centre of the sphere) was then shifted sequentially by one micron, two microns and three microns in the positive and negative x, y and z directions. The volumetric wear was recalculated at every stage. A further test was carried out to examine the effect of a multidirectional shift. This took the form of a three micron shift in the x direction, followed by a three micron shift in the y direction and then a three micron shift in the z direction. This was then also performed for the scan with the largest number of points –the 144 contour 0.3 mm pitch scan.

Part two: blinded gravimetric study. Six Finsbury 42mm diameter femoral head components were sent from the precision engineering company Redlux. The diameters of the components had been measured using Mitutoyo (Andover, United Kingdom) laser micrometers (LSM-506 and LSM-600) at Finsbury (DePuy, Leeds, United Kingdom) – and were weighed. The components had then undergone material removal and been weighed to determine by gravimetric means the volume of material which had been removed.

These tests had been carried out as part of an internal validation process for explant analysis for the Redlux company itself. No information was given to the NTEC about the dimensions, amount of material lost or the form of the components and the area of material removal was not identifiable. An operator at the NTEC with no previous experience of explant testing performed all of the tests which involved single scans using 0.3 mm point pitch consisting of 16, 72 and 270 contour programme scans. The 270 scan size was chosen so that point spacing at the equator of the component was less than 0.5 mm. The wear depth and dimensional results obtained from the laser micrometers were also compared with the CMM generated results.

Results

Part One: the effect of varying contours, pitches and total number of points. Varying contour numbers, point pitch and total number of points had no consistent effect on the measurement of volumetric wear (Table II) (Figures 3 and 4). Progressing from theoretically the most inaccurate result of 0.70 mm^3 (a 16 contour trace at 0.5 mm pitch with only 1072 points) to theoretically the most accurate result of 0.64 mm^3 (a 144 contour trace with point pitch of 0.3 mm and a total number of points of 15 984), there was a total volumetric difference of 0.06 mm^3.

Out of all 13 tests there was a maximum difference between the largest measured volume and the smallest measured volume of 0.19 mm^3. Multiple regression of log normalised data using the number of contours and point pitch distance as explanatory variables identified that these variables had no significant effect on the calculated volumetric material loss (r squared = 0.114, p = 0.547).

Shifting the determined centre of the sphere had a greater impact on the calculated volumetric loss than the scanning parameters discussed above. Figure 5 shows the impact of the failure to identify the unworn surface accurately and Figure 6 shows the distribution of the measurement points when such an error takes place.

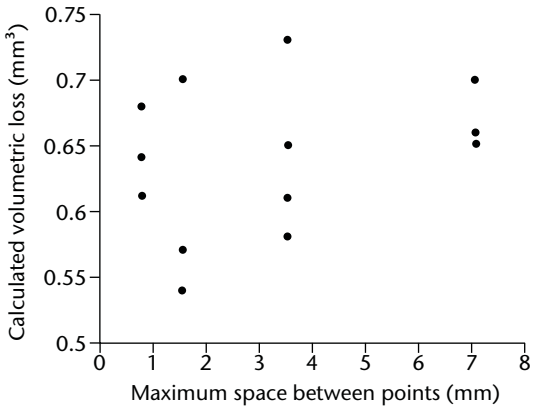

Fig. 3

Graph showing the effect of increasing the maximum distance between the measured points and the calculated volumetric loss.

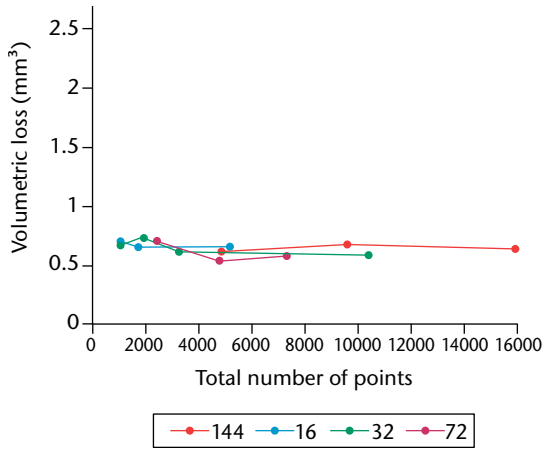

Fig. 4

Graph showing the effect of the number of measured points and the number of scan contours on the calculated volumetric loss. The Y axis is extended to 3mm³ in order to allow comparison with the effects of the centre point shifts in figure 5.

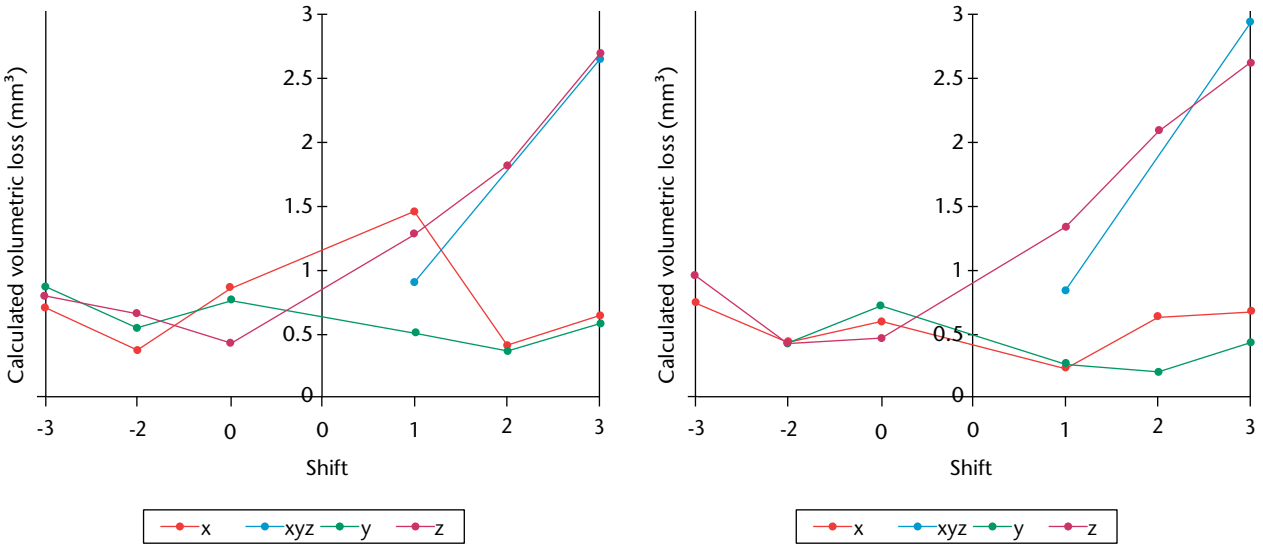

Fig. 5

Graph showing the effect of misalignment of centre of sphere. The two charts show the effect of various extents of shifts (measured in microns) of the centre of the sphere on the calculated volumetric loss. In the tests on the left, a point pitch of 0.1mm was used. On the right, a point pitch of 0.5mm was used.

Part Two: blinded study. The LJL method was found to overestimate the wear volume consistently. The errors were normally distributed. For the 16 contour scans the mean (SD) error was 0.470 mm^3 (0.264), for the 72 contour scans it was 0.525 mm^3 (0.185) and for the 270 contour scan it was 0.480 mm^3 (0.210).

The CMM determined radius of the components was a mean of -0.3 microns (SD 0.69) from the laser measurements (i.e., within the stated resolution of the CMM accuracy). This accurate identification of the original dimensions of the components, coupled with the appearance of the histograms made it highly likely that the root cause of the overestimation of wear was due to the measurement of form deviation as wear.

The image in Figure 7 shows a histogram, representative of the scans in this study. In the published LJL method the modal radius value is taken as the 'start point' for the wear measurements. It is clear however that in low wear cases such as those in this analysis, the 'form', which is in essence the 'waviness' of the as manufactured surface, can account for a large proportion of the measured 'wear'. The LJL method can easily be modified to account for this form error if the operator has prior knowledge of the spherical form typically produced by the manufacturer of the

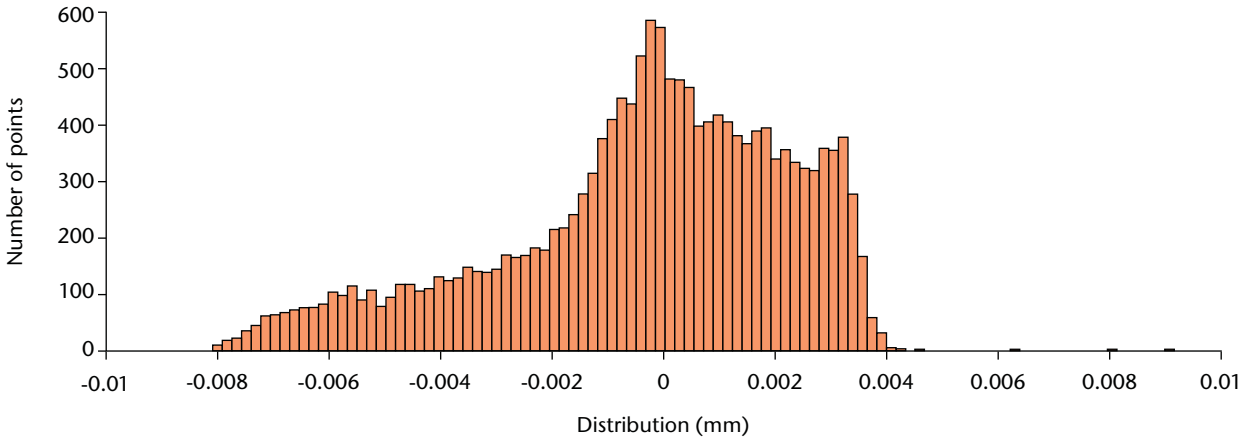

Fig. 6

This histogram shows the point distribution of measured data in the form of a frequency histogram. Each point is a distance from the centre of the sphere. If this centre point is improperly calculated, spurious measurements can occur, as is shown here. If the measured data is expressed using a histogram, the effect of misalignment can be identified. This histogram was generated from a multiaxial 3 micron XYZ shift The point distribution is highly irregular - see figure 7 for comparison.

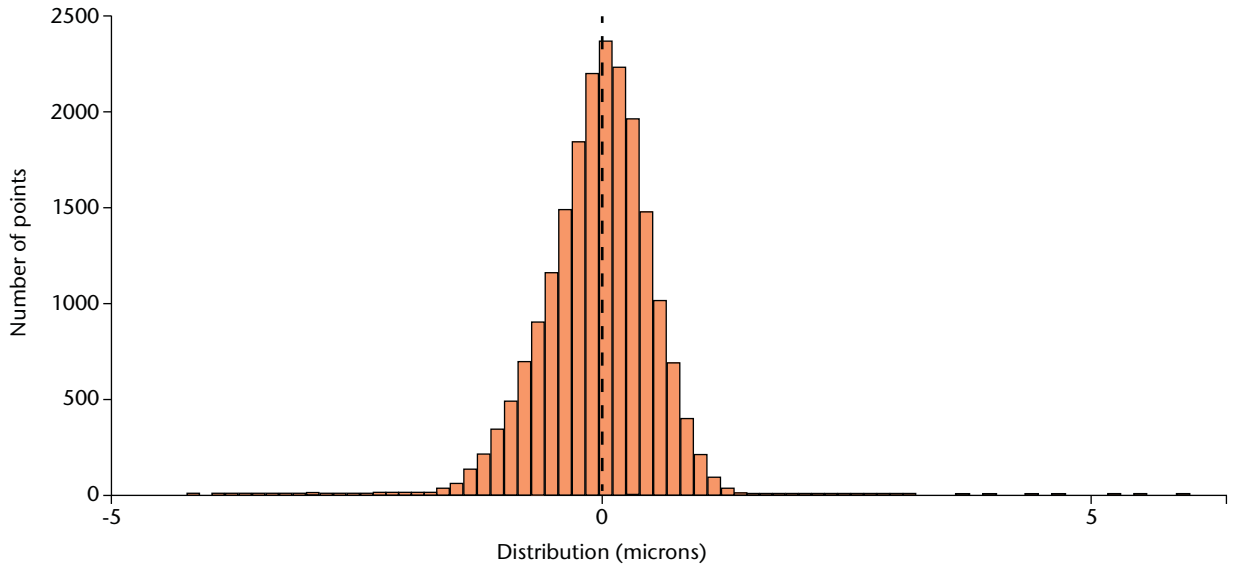

Fig. 7

This histogram was generated from one of the successful head scans in the blinded study. The points in this histogram are normally distributed as the area and extent of wear was small and localised. Wear depths were less than five microns in this case. Using the LJL method, which assumes wear for all measurements smaller than the modal radius (i.e., all points to the left of the dashed line in this case), a volumetric loss of 0.61 mm^3 was calculated.

component under examination. Or, it can easily be identified post analysis from the normal distribution of the histogram. In the example shown in Figure 7, over 70% of the measured points are within two microns of the modal value. As the point distribution is essentially normally distributed, the modal value is within one micron of the mean value. The operator can therefore apply a form filter by inputting a radial value which, rather than the modal value, is (modal value - 1*standard deviation) (Fig 8). Applying this form filter to the results increased the accuracy as shown in Figure 9. Regression analysis using the 16, 72 and 270 contour scans to explain the variation in gravimetric results returned R squared values of 88.8, 99.5, and 98.0 ($p < 0.001$ in each case).

Scanning time required to obtain results with clinical relevance. Using 16 contour scans, two complete bearing surfaces (two heads and two cups) can be completed in a mean time of forty five minutes. CMMs can also run automated programmes overnight unsupervised. During a normal working week this would mean (allowing for preparation and transfer of the components to and from the CMM workspace) that 40 head and cup combinations

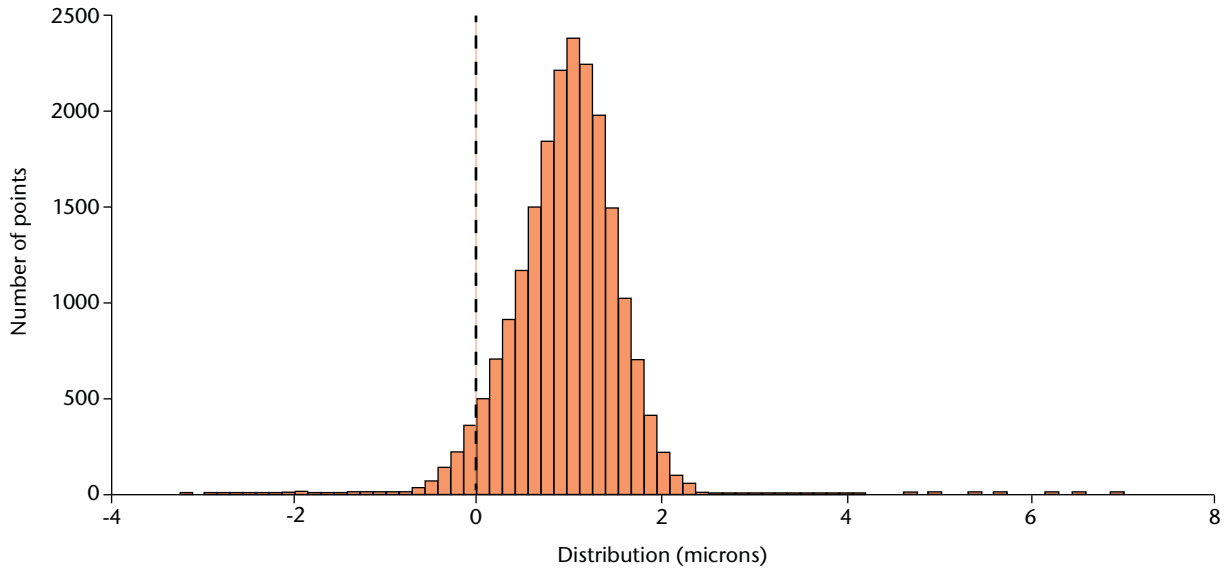

Fig. 8

In cases with extremely low wear and a known form, the accuracy of the measurements can be enhanced by using a form filter. In this histogram, instead of commencing the wear measurements from the modal radius, wear is only assumed if the measured points are a distance of 1 micron less than the modal radius (dashed line in the image).

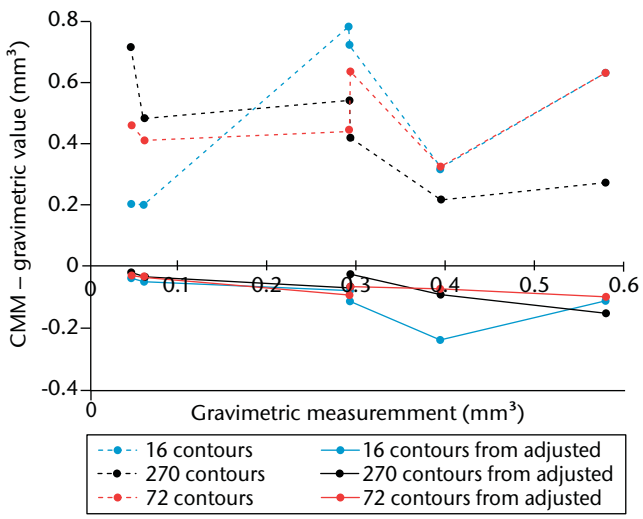

Fig. 9

Graph showing the accuracy of the CMM calculated values with and without form filter, compared with the gold standard gravimetric tests.

could be scanned at a comfortable working pace. This would mean that in a year, an efficiently running facility could process over 2 500 head and cup combinations. This amounts to roughly one quarter of the revision burden of England and Wales.[17]

Discussion

We have previously shown evidence that volumetric wear analysis can be used to obtain reproducible results to within a clinically relevant margin of accuracy.[21,28,30,31]

We have now shown in the current paper that the effect of point spacing appears to be much less important than the identification of the unworn surface in order to obtain accurate results. The advantage of using a CMM to identify the original surface is that there is no manipulation of data; it is all done as an automated process. The test results reported in this paper show that the scans can be carried out using an operator with no previous advanced training.

Volumetric wear analysis is conducted at a number of centres throughout the world. These centres report similar volumes of material loss from MoM bearings despite a number of different measurement protocols being used.[5,6,9,11] These findings run contrary to recent conclusions made by two metrology centres, which stated that point spacing is critical to accuracy. Likewise, the international standard ISO14242 from 2000 placed emphasis on the distance between measurement points. The international standard ISO 14242 advises that investigators "produce a full three-dimensional contour mesh of the articulating surface of the test specimen" by connecting the measured points. It is stated that investigators must "ensure the mesh spacing is no greater than 1 mm in the horizontal plane or along any arc."[20] Yet, as mentioned above, the results generated from centres around the world are remarkably consistent, irrespective of the number of points measured or the spaces between those measured points. The difference in findings between Bills,[13] Carmignato[14] and ourselves is easily explained. In the LJL technique the volume of the generated mesh itself is not simply subtracted away from the volume of the idealised sphere. Instead, the wear depth of each group of four adjacent measured points is averaged to give a

single, mean depth. The distance of this depth from the original unworn surface (i.e., the radius) is then multiplied by the surface area of the quadrilateral created by the joining of these four points to calculate and individual 'block' of wear. The process is repeated for all points on the object and the blocks added to give a total volume of material loss. This is the fundamental difference between the two methods. The implications are that if one were to take a perfect sphere which has, by definition, exactly the same radius from the centre to every point imaginable on the surface of the sphere, the LJL method would calculate a wear volume of zero. The result would be the same, independent of whether 100 points were taken or an infinite number. Using the Bills et al[13] and Carmignato et al[14] methods however, a calculation of zero wear volume would never be possible in practice, even were the sphere to be perfect. Bills et al's method returns an error of 346.614mm^3 even with the combination of 25 scan contours and a point pitch of 0.5 mm to give a total number of 2000 points.[13]

Failure to identify the unworn surface successfully appears to have a far greater impact. Misalignment of the centre of the idealised sphere can produce either over or under measurement of material loss. We strongly advise that the measurement process should produce some check in order to recognise the effect of coordinate system misalignment. Misalignment using the LJL technique is readily identified in the majority of occasions with the use of a histogram to represent the measurements (Figs 5 and 6).

The results of the blinded study showed that the LJL method consistently overestimated wear loss. We have not identified this in our own previous internal tests, however, we have never attempted to measure losses as small or localised before. The smallest volume of loss tested in our previous validation was 3.6mm^3. To put these errors into clinical context they have been charted in Figure 10 against previously published work from simulator and retrieval studies.

The over measurement of wear by the LJL method can be explained by 'form error'. Form is the natural variation or 'waviness' of the surface which has been produced by the manufacturing process. Form error is inevitable if there is lack of knowledge of the manufactured form of the component under analysis. Form error can in fact be remedied to some extent if operators have sufficient knowledge of the typical sphericity values produced by the manufacturer, or if the wear is localised, the form (or sphericity) of the component can be identified. For example, in the blinded study, the LJL technique successfully identified the original radius to within one micron on each occasion. The resulting histograms revealed, to all practical purposes, a normal distribution. with the median point distance from the centre lying within one micron of the modal value. Using the outputted data, one can calculate that over 68% of points were less than one micron larger or smaller than the modal value. Given the

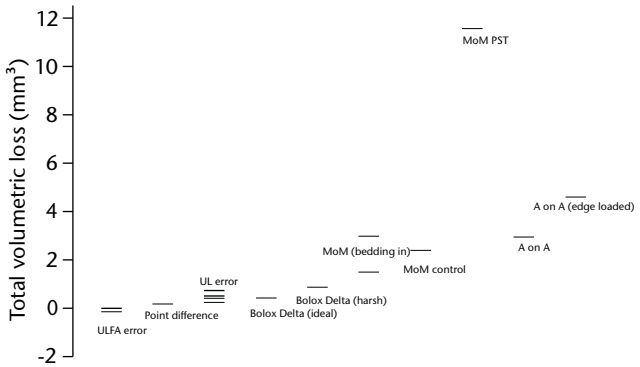

Fig. 10

Graph showing comparison of error with the wear rates of bearing combinations reported in the literature. 'LJLFA', LJL method with form adjustment; 'Point difference', effect of volumetric calculation caused by variation in the number of measurement points; A on A, alumina on alumina. 'Biolox Delta ideal' and 'harsh' refer to simulator studies by Al Hajjar et al[22,24]. Metal-on-metal (MoM) bedding in wear refers to simulator studies on the ASR (Depuy).[25,26] MoM 'control'/'pseudotumour (PST)' refer to wear rates of MoM explants associated with/without PST.

symmetrical distribution of the points, these micron sized variations are clearly indicative of the manufactured form. In cases such as these, with minute amounts of material loss, accuracy can be improved by adjusting for the form of the component. Here, instead of using the modal value, the wear measurements should be calculated using modal radius - (0.5 * 1 SD of point deviation from modal value). Alternatively, the form error can be treated as a constant value and the modal technique retained.

In this paper we have shown clear evidence that it is in fact the identification of the unworn (or, more accurately in most components, the least worn) portions of bearing surfaces that has the greatest impact on the calculation of volumetric material loss. Scanning time, data analysis and future guidance should devote more time to the successful alignment of the coordinate system relative to the original centre rather than the measurement of extra points beyond those proven to be relevant. Large numbers of points are not required to produce results with sufficient accuracy for clinical application. Scanning times can therefore be reduced significantly. These considerations, combined with a technique that does not need technicians with advanced training, opens the possibility for rapid, mass screening of failed explants. By our calculations, one dedicated CMM could process over two thousand hip bearing surfaces per year.

Working on these principles, the authors of this study have now initiated the Northern Retrieval Registry (NRR), collaboration between a number of hospitals in North Tees, Durham, Sunderland and Newcastle. This initiative has been developed with the intention of carrying out routine analysis of all hip explants retrieved in these hospitals. Assessment of bearing surfaces, modular interfaces, and fixation surfaces, combined with patient and

surgical information will hopefully allow the identification of design factors associated with clinical success or failure. In time this will hopefully allow the streamlining of existing hip designs, the facilitation of new design development and the early identification and elimination of hazardous designs.[33]

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- D. Deehan: Preparation of study plan, Results write up
- A. V. F. Nargol: Preparation of study plan, Results write up
- R. D. Meek: Preparation of study plan, Results write up
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