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Determining material loss from the femoral stem trunnion in hip arthroplasty using a coordinate measuring machine

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Abstract
In contrast to the articulating and taper surfaces of failed total hip replacements, volumetric wear analysis of trunnions is not routinely performed. Metal wear particles from the trunnion may contribute not only to the failures of metal-on-metal total hip replacements but also to all hip replacements utilising metal trunnions. A validation study was performed with the material removed in stages from the trunnions of an Exeter V40 stem, a Corail stem and an Accolade stem to simulate different magnitudes of wear. The material loss from the trunnions was measured both volumetrically with a coordinate measuring machine and gravimetrically with a high-precision balance. A cohort of 28 ex vivo trunnions was also measured using the coordinate measuring machine. The maximum error between the two methods was found to be 0.13 mm^3. This result was comparable with the coordinate measuring machine method for the taper surface (0.2 mm^3). The ex vivo trunnions had a median wear volume of 0.14mm^3 (range: 0.04–0.28 mm^3). This is the first study to determine the accuracy of volumetric wear measurements of trunnions by comparing against gravimetric measurements. Volumetric wear analysis of trunnions may provide additional insights into failures of modular total hip prostheses and will be performed routinely at our centre.

Keywords
Explant analysis, trunnion, volumetric wear, coordinate measuring machine, validation

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Introduction

Wear debris is known to result in negative host responses, with metal wear particles associated with adverse reaction to metal debris (ARMD) failures including pseudotumours,[1,2] while polyethylene wear is predominantly associated with osteolysis.[3] It is therefore desirable to reduce wear in prostheses, regardless of material, to improve their long-term performance.

High failure rates of metal-on-metal (MoM) total hip replacements (THRs) compared with MoM resurfacings have implicated wear of the taper junction as a potential cause of failure. The data from the 2014 National Joint Registry[4] have shown that the number of revisions per 1000 patient years for ARMD is higher for THR prostheses (7.2) compared with MoM resurfacing prostheses (3.9).

Subsequent volumetric wear analysis has found that the femoral head taper can contribute a significant percentage of the total wear volume.[5] Other studies have reported significant damage to the taper, attributing it to corrosion,[6–8] mechanical wear[5,9] or as a combination

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of both.[1,10–13] While volumetric wear analysis of the taper is routinely performed, this is not the case with femoral stem trunnions. Note that volumetric wear in MoM resurfacing prostheses is from the bearing surface only, while for MoM THR prostheses wear can occur at both the bearing surfaces and the taper trunnion junction.

Retrieval studies examining trunnions have been restricted to visual grading of fretting and corrosion,[14,15] chemical analysis[16] and profilometry,[17] with only one study reporting wear volumes for two trunnions.[9] There has been, to the authors' best knowledge, no study in the literature, which has validated a method for quantifying the volumetric wear of the trunnion surface. Langton et al.[18] and Blunt et al.[19] have previously noted that gravimetric measurements are the most accurate method for quantifying material loss due to wear. Coordinate measuring machines (CMMs) have been used extensively to quantify volumetric wear of prostheses.[5,20–23] We have previously published the results of several validation studies comparing volumetric results from a Mitutoyo Legex 322 (Mitutoyo UK Ltd, West Point Business Park, Andover, Hampshire, UK) CMM against gravimetric measurements.[20] Lord et al.[20] presented a method for measuring the wear of articulating surfaces of MoM hip components with the method found to be accurate to within 0.5 mm^3. Langton et al.[5] reported a similar method used to measure DePuy ASR and Pinnacle tapers, with an accuracy of 0.2 mm^3.

This article describes a method for the measurement of volumetric wear from femoral stem trunnions using a CMM. The method is validated against gravimetric measurements to determine its accuracy. A cohort of 28 retrieved femoral stem trunnions were then analysed using this method to provide clinical context.

Methods

Validation

The study was performed to determine the accuracy of volumetric wear measurements involving THR stems. Three femoral stem trunnions were used for measurements: one Exeter V40 femoral stem, one Corail stem and one Accolade stem. These stems were obtained from hospital stock as they had recently breached the dates by which they should have been implanted. The stems were received in their unopened, sterile packaging. The Exeter stem is the most commonly used cemented stem, while the Corail and the Accolade are the two most commonly used uncemented stems according to the data from the National Joint Registry[24] 2013 for England, Wales and Northern Ireland. The Exeter V40 stem was used in 66% of all cemented hip procedures, with the Corail stem accounting for 46% of all cementless hip procedures.[24] Both the Exeter V40 and the Corail stems are Orthopaedic Data Evaluation Panel (ODEP)[25] 10A rated, while the Accolade is ODEP 3B rated. ODEP 10A rating

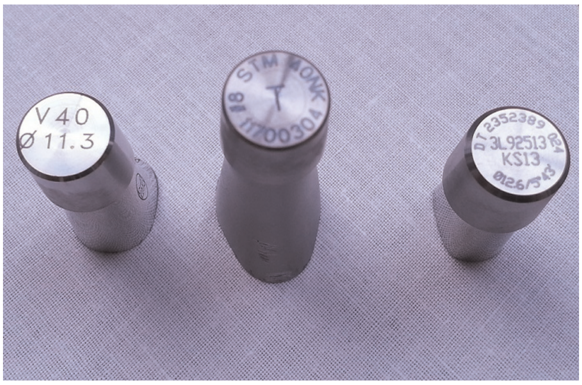

Figure 1. Photograph of sectioned trunnions used in testing.

indicates that there is strong evidence that the prosthesis meets the National Institute for Health and Care Excellence (NICE) guidelines at 10 years. ODEP[25] 3B rating indicates that a small cohort has demonstrated a revision rate of less than 3% at 3 years. The stems were sectioned at the neck junction below the trunnion to enable them to fit within the balance for gravimetric measurements (Figure 1).

Testing procedure

Gravimetric measurements were performed using a Kern ACJ320-4M (Kern and Sohn GmbH, Ziegelei, Balingen, Germany) balance with a sensitivity of 0.1 mg. For the volumetric measurements, a Mitutoyo Legex 322 CMM was used with a 5-mm-diameter ruby stylus. The manufacturer claimed measuring accuracy for the Legex 322 was 0.8 μm.

A standard measurement procedure was established to ensure consistency. Coordinate measurement machine and gravimetric measurements were performed by different authors as to blind the results. In order to avoid accidental material loss through scratching or other contact, gravimetric testing was always performed first with CMM measurements performed afterwards. For each stage of wear, a minimum of four gravimetric and three CMM measurements were taken. Trunnion wear was simulated by removing increasing amounts of material using P240 grade sandpaper. Sandpaper was utilised to allow controlled removal. The trunnion was then cleaned using compressed air to ensure all wear particles had been removed. Gravimetric and volumetric measurements were then performed. More material was then removed in stages to simulate increasing amounts of wear and the measurements were repeated for the different stages of material loss. A total of four 'wear' stages were tested, including the unworn stage.

Once all measurements were completed, the values obtained from the gravimetric tests were converted into volumes. The median wear volume for each stage of wear was then calculated and compared with the median wear values from the CMM. For the Exeter V40, the density of 316L medical grade stainless steel (8.00 g/cm^3) was used. For the Corail, the density of TiAl6V4 titanium alloy (4.42 g/cm^3)[26] was used. For the Accolade, the density of Ti-12Mo-6Zr-2Fe titanium alloy (5.00 g/cm^3) was used. For the three samples, a small ring of unworn surface approximately 2 mm in width was consistently left at the top of the trunnion to represent unworn surface. However, for the final wear stage on the Accolade, stem material was removed from the unworn surface to determine how this affected the CMM measurement accuracy.

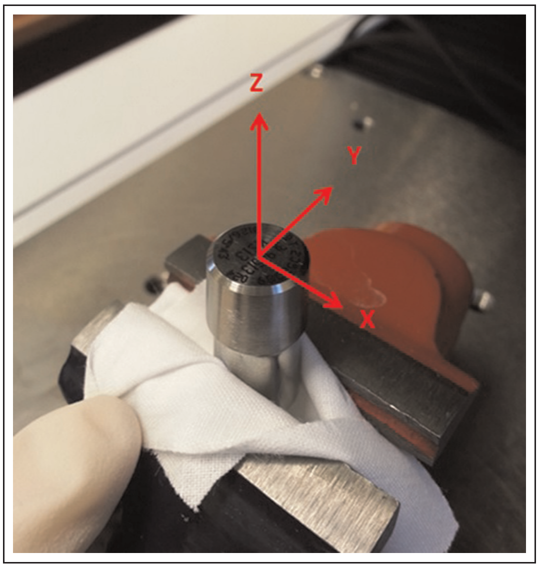

Figure 2. Coordinate system set-up for a trunnion. NB the height of the trunnion is measured negatively in accordance with the coordinate system.

CMM trunnion measurements

Customised programmes were written using the Mitutoyo 'MCOSMOS' software to measure the trunnion surfaces. As with the bearing surfaces, identification of the original surface is vital in order to accurately determine the volumetric wear.[18] The CMM programme requires the user to enter three variables in order to measure the trunnion. These variables are referenced against the coordinate system (Figure 2). The first variable is the 'length', representing the total height of the trunnion over which measurements are to be taken. The other two values correspond to the lower and upper heights of the circumferential band of unworn surface. These values were determined by analysing the trunnion from base to tip using a Mitutoyo surftest sj400 profilometer, providing a visual representation of the surface. The area with the most similar mean roughness average and peak-to-valley height values to those of a measured unused and unworn specimen was then used as the unworn Z area.

Once the trunnion location has been determined, the programme works iteratively in two stages. The initial stage generated a perfect theoretical cone representing the original perfect unworn surface. The second stage measured the entire surface and compares the data points with the perfect cone to determine any deviations, which represent the volumetric wear. This is represented in flowchart format in Figure 3.

Trunnion coordinate system. An initial 'centre point' was taken manually by the user on the flat top of the trunnion (the smaller end of the truncated cone) to determine the trunnion's position. Using this point, the CMM then automatically took three circumferential

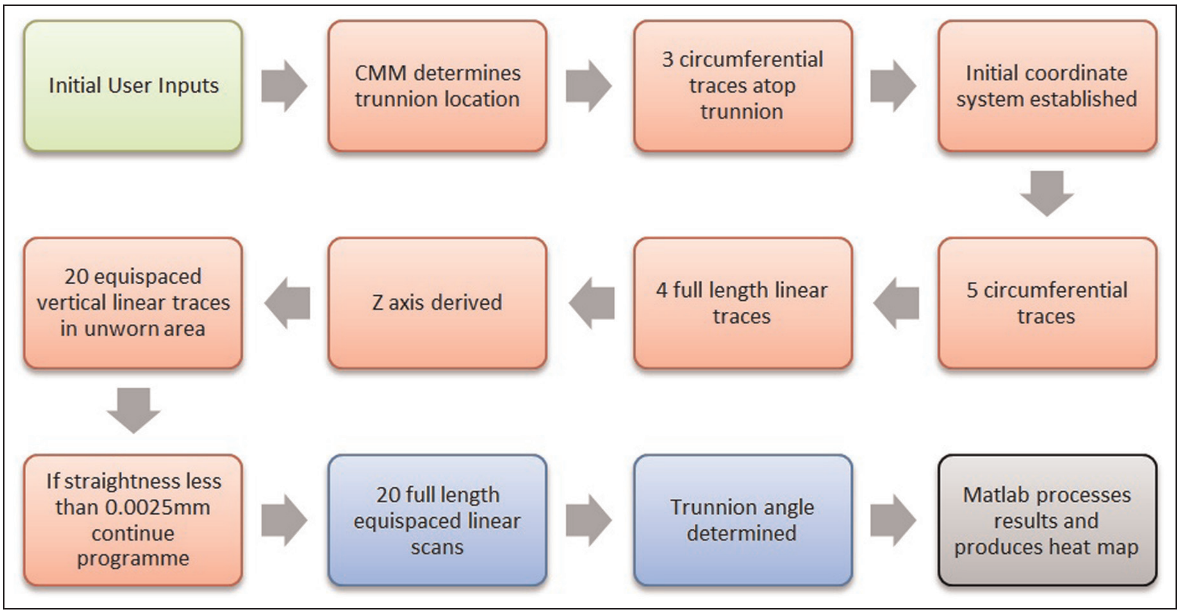

Figure 3. Flowchart for the trunnion measurement process. Green indicates the user input, red indicates CMM measurements stage 1, blue indicates measurement stage 2 and purple indicates MATLAB processes.

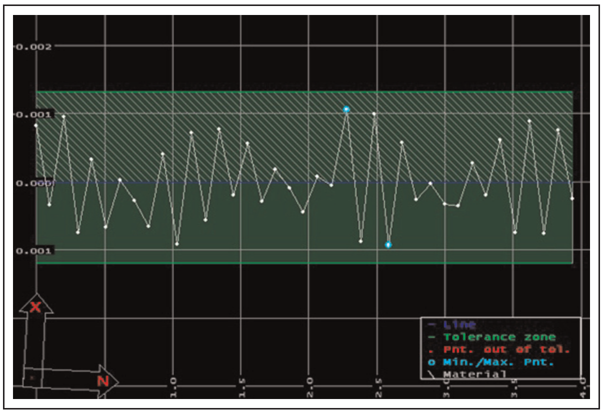

Figure 4. Unworn Corail linear trace. NB the green region indicates the tolerance zone.

traces on top of the trunnion to determine an initial XY plane from which the Z-axis zero value is referenced (Figure 2). The initial Z-axis (the cone axis) was derived by the CMM as the axis through the centre point of these initial circular traces.

Five equispaced circumferential traces were taken by the CMM around the trunnion at various heights, beginning at the base and working towards the tip. Four linear traces were then taken over the full length of the trunnion at 90° intervals around the circumference. These scans provided more data points from which to derive the Z-axis.

Stage 1: theoretical cone generation. For stage 1, a series of 20 equispaced vertical linear traces were then taken around the circumference over the area initially specified as unworn by the user. The straightness of each of these 20 traces was calculated by the CMM. The CMM accepted each trace if it was found to have a straightness value of less than 0.0025 mm (Figure 4). This value was based upon the authors experience with the stems. If a different stem design was measured, with a different roughness then the straightness would have to be altered accordingly. Straightness is defined as the distance between two parallel planes touching and enclosing the data points at the minimum distance to each other.[27] Any of the 10 traces with straightness values greater than 0.0025 mm were rejected. The accepted traces were then used to generate a perfect theoretical cone. A minimum of five traces were required to continue the scans. If this was not achieved, the generated cone was not of sufficient precision to continue and the user had to reassess the location from which to best determine the unworn area.

The Z-axis was defined as the principle axis of the theoretical cone described above, with the data points from stage 2 referenced in relation to this axis. The angle of the cone was used during the MATLAB calculation of the wear volume.

Stage 2: contour measurement. Once the initial stage was completed, a series of 20 full-length, equispaced vertical linear 'contour scans' were then performed around the trunnion using a point pitch of 0.3 mm from the base to the tip. It should be noted that smaller point pitches may also be used. The Exeter stem had a smoother surface finish than that of the grooved Corail stem, which was designed for the use of ceramic heads.

Data processing. To process the ASCII data files produced by the CMM, a customised MATLAB programme was developed. Using the trunnion angle provided by the CMM programme, MATLAB was then able to produce a three-dimensional heat map detailing the wear on the surface. It also provided a maximum linear wear depth and wear volume. In addition to the trunnion angle, the MATLAB programme required the user to input a height value corresponding to the location of the identified unworn region. If the trunnion was projected from a worn region, then spurious data points are created and the wear calculation was inaccurate.

Ex vivo cohort. A cohort of 28 DePuy Corail femoral stems was obtained following revision surgery. The trunnions were cleaned using acetone and lint-free cloth to remove surface deposits. The majority of the revisions were due to ARMD failure, with a minority revised solely due to loosening of the femoral stems. Of the 28 femoral stems, 23 were paired with a metal femoral head and the remaining 5 paired with a ceramic femoral head. The location of unworn sections of all trunnions was determined visually and using a profilometer. Once this was completed, the trunnions were measured using the CMM.

In THR arthroplasties, which involve a modular neck connection, the head is press fitted on to the stem. Successful engagement depends on a close match between the cone angles of the trunnion and the taper. However, due to the manufacturing process, identical angles for both components and thus direct contact over the entire length of the trunnion are nearly impossible.[12] Therefore, the taper and trunnion are designed so that engagement occurs preferentially at either the base or tip of the trunnion depending on the relative angle between the two.[12] Here, tip refers to the smaller end of the truncated cone, while base refers to the larger end of the cone. As a result, the end (base or tip) of the trunnion not in contact with the taper was hypothesised to be relatively undamaged.

Results

Validation results

The median volumetric and gravimetric results for the three new samples are shown in Figure 5. For the unworn stage (stage 0), the Corail trunnion had a higher measured CMM wear volume of 0.13 mm^3 compared with the V40 and the Accolade, both at 0.05 mm^3. The maximum error between individual measurements for all other stages was $\pm$0.02 mm^3 for the Corail and $\pm$0.03 mm^3 for both the V40 and the

Accolade (as shown by the error bars in Figure 5). For the final wear stage on the Accolade stem, where material was removed from the unworn surface, the CMM was unable to obtain an accurate volumetric measurement. Figure 6 shows a Bland–Altman plot of all the results, while Figure 7 shows the correlation between CMM and gravimetric measurements for the three stems. The 95% confidence intervals are also presented. Figure 8 shows the wear maps generated by MATLAB with the theoretical cone projected from 1 mm below the top of the trunnion.

Retrieval analysis

A median wear volume of 0.14 mm^3 (range: 0.04–0.28 mm^3) was measured for the 28 explanted trunnions. Twenty-seven of the trunnions were found to have lost less than 0.2 mm^3, with Figure 9 showing a typical wear map. For the more heavily worn trunnions, the wear was predominantly located at the base of the trunnion, while the tip was relatively unworn. In several cases, the surgical retrieval process caused damage to the base of the trunnion resulting in it 'flaring' out at two points located approximately 180° apart from each other.

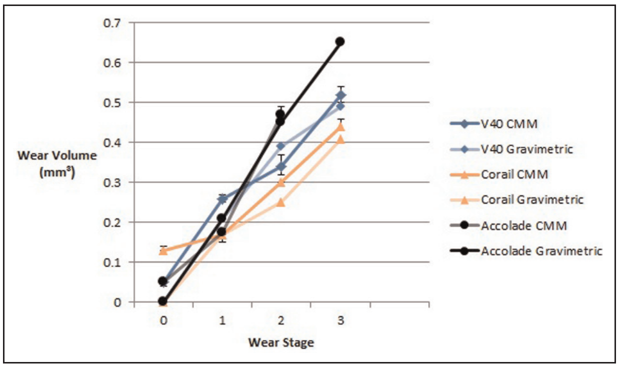

Figure 5. CMM versus gravimetric result comparison for the V40, Corail and Accolade trunnions.

Discussion

This article describes a method for measuring the volumetric wear of retrieved femoral stem trunnions. The maximum error was 0.13 mm^3 with the error decreasing with increasing wear volumes. In the unworn state, the Corail stem may have had a greater measurement error than the other two stems due to the grooved pattern on the surface. The maximum error was comparable to that of the taper (0.2 mm^3).[5] To the authors' best knowledge, this is the first study to validate a method for calculating volumetric wear for the trunnion against gravimetric measurements. In addition, this is the largest cohort of retrieved femoral stem trunnions to undergo volumetric wear analysis that has been reported in the literature.

The ex vivo titanium alloy Corail stem trunnions had lower surface wear compared with wear volumes for articulating and taper surfaces reported in the literature.[5,20] The study by Langton et al. reported median wear volumes in excess of 2 mm^3 from the taper surfaces of a cohort of 111 MoM femoral heads.[20] This was a factor of 10 greater than the wear volumes measured for the trunnions in this study. To the authors' best knowledge, there is only one other study offering volumetric wear values of retrieved trunnions. Bishop et al.[9] examined two retrieved 12/14 titanium trunnions using a CMM reporting wear volumes of 0.020 and 0.035 mm^3. These values were significantly lower than

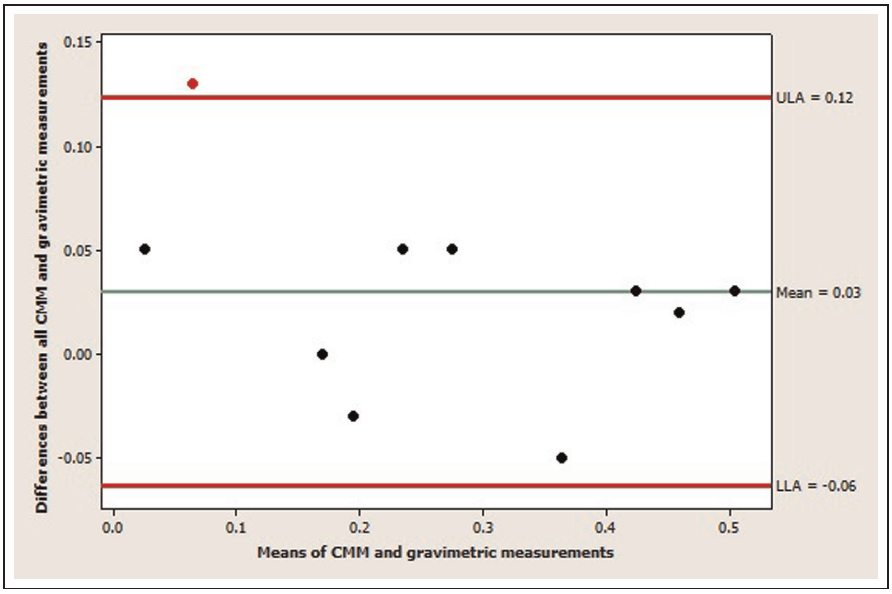

Figure 6. Bland–Altman plot of the validation results. Note that LLA is the lower level of acceptance, while ULA is the upper level of acceptance.

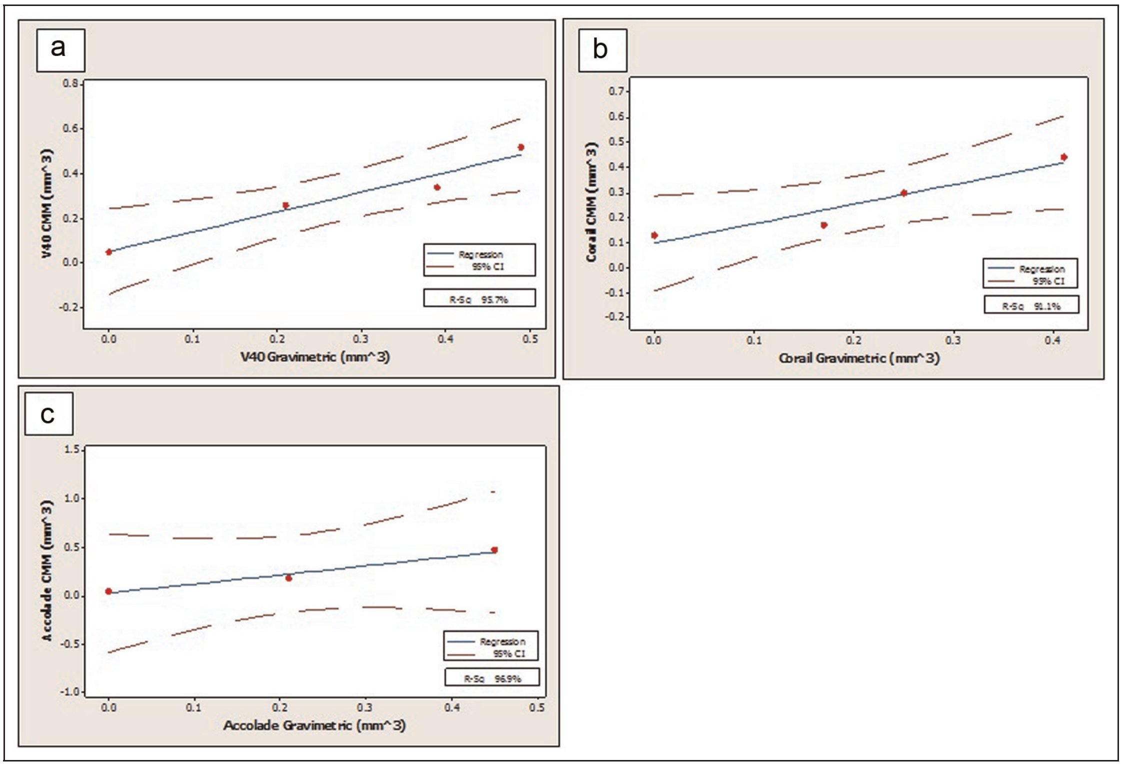

Figure 7. Graph showing the CMM and gravimetric volumetric wear results for (a) V40 stem, (b) Corail stem and (c) Accolade stem. The 95% confidence intervals are also presented.

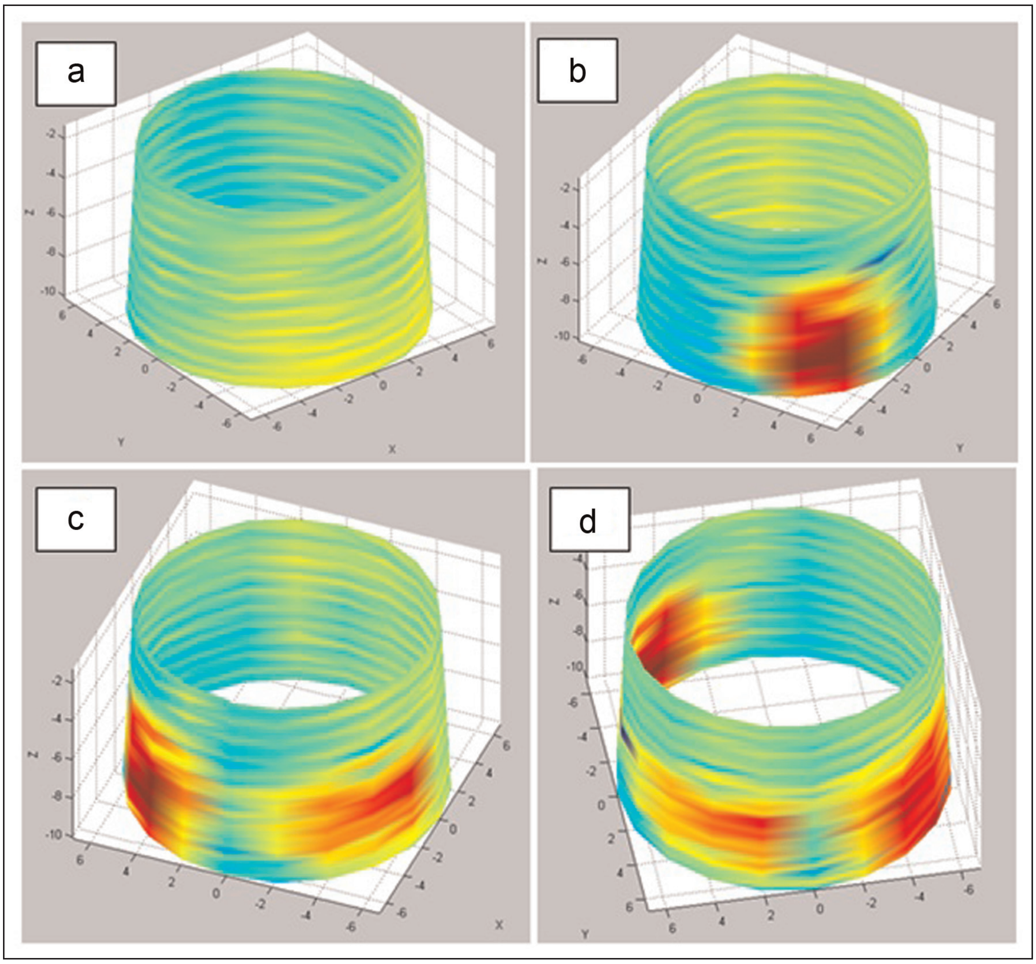

Figure 8. CMM wear maps for the Corail trunnion showing increasing wear from (a) to (d). NB green indicated unworn surface; red is worn surface.

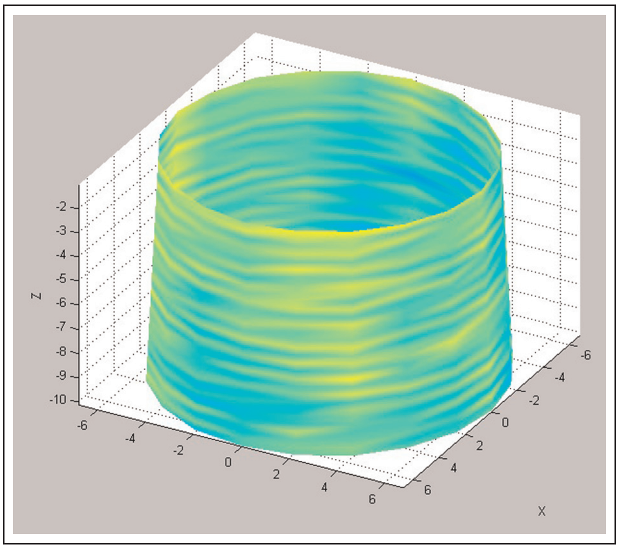

Figure 9. CMM wear map showing minimal wear on a retrieved trunnion.

the values reported for the respective taper surfaces (8.1 and 2.6 mm^3).[9] It may seem counterintuitive that the apparently softer titanium stem trunnion showed lower wear than the apparently harder cobalt chromium (CoCr) alloy of the femoral head taper.

Moharrami et al.[28] provided a potential explanation to this apparent paradox by measuring the relative hardness values of titanium stems and CoCr femoral head tapers. The study found that titanium stems oxidised preferentially to the CoCr surfaces, significantly increasing the surface hardness.[28] The harder oxidised titanium stems were then able to damage the unoxidised CoCr alloys, resulting in wear of the head taper in preference to the trunnion.[28]

There were limitations to this study. The first of these was the small number of trunnions tested. Ideally, testing would have included multiple samples from a wider variety of manufacturers; however, obtaining unused stems from hospital stock proved extremely challenging. Therefore, the most commonly implanted cemented and uncemented stems were tested.[24] The measurement error of 0.13 mm^3 is directly comparable to that of the taper surface (0.2 mm^3).[5] In addition, the CMM measurements had a high level of repeatability with a maximum difference of $\pm$0.03 mm^3 between individual measurements, demonstrating that this method is both accurate and reproducible.

The second limitation was that the location of the wear was known in all but one case, allowing an unworn section of the trunnion to be selected for the measurement. For the Accolade where the material was removed from the unworn surface, the CMM was unable to accurately calculate the wear volume. However, in THRs, the taper trunnion angles are designed so that engagement occurs primarily at the tip or base of the trunnion, leaving a relatively undamaged section where no contact occurred.[12] The cohort of ex vivo prostheses analysed followed this trend supporting the validation method of using a profilometer to identify the undamaged surface.

As a result of this study, ex vivo volumetric wear measurements will be performed on all retrieved femoral stem trunnions received at our research centre. Further studies will then examine the relationship between trunnion and taper wear.

Declaration of conflicting interests

D.J.L. is the director of PXD. PXD has received money through medicolegal consultations concerning failed metal-on-metal hips; as has A.V.F.N. Newcastle University has also received money through medicolegal litigation on the same subject.

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