1 TITLE PAGE

2 Wear at the taper-trunnion junction of contemporary ceramic-on-ceramic hips shown in a multi-
3 station hip simulator

4 AUTHORS

5 Rohan M Bhalekar¹, Simon L Smith¹, Thomas J Joyce¹.

6 CORRESPONDING AUTHOR

7 Thomas J Joyce¹

8 T: +44 (0) 191 208 6214; E-mail: thomas.joyce@ncl.ac.uk

9 ¹School of Engineering, Newcastle University, Claremont Road,
10 Newcastle upon Tyne, NE1 7RU, England, United Kingdom.

11 AUTHOR CONTRIBUTION

12 R.M.B.: Data acquisition, data analysis, interpretation of data, statistical analysis, drafting the
13 paper.

14 S.L.S.: Research design, data analysis, drafting the paper and revising it critically.

15 T.J.J.: Research design, data analysis, interpretation of data, drafting the paper and revising it
16 critically, approval of the submitted and final versions.

17 ALL AUTHORS HAVE READ AND APPROVED THE FINAL SUBMITTED
18 MANUSCRIPT.

ABSTRACT

Ceramic-on-ceramic (CoC) total hip replacements (THR) have a substantially lower wear rate than metal-on-polyethylene (MoP) hips, as shown by hip simulator testing. However, the revision rates of CoC and MoP hips are comparable. To try and explain this discrepancy the wear, at both the bearing surfaces and taper-trunnion interface of 36 mm BIOLOX[®]*delta* CoC THRs, mounted on 12/14 titanium (Ti6Al4V) trunnions was investigated using a hip simulator (n=3) and a dynamically loaded CoC sample in a separate test station. Wear was assessed gravimetrically and surface roughness measurements of the articulating and taper surfaces taken at regular intervals. Scanning electron microscopy, surface roughness and gravimetric measurements of trunnions was performed. After 5 million, the mean total wear from the ceramic articulating surfaces was 0.25 mm³ from the hip simulator test, and that from the titanium trunnions was 0.29 mm³. This metal wear may provide an explanation for adverse reaction to metal debris found in contemporary CoC hip joints. It is therefore vital to consider taper-trunnion wear in pre-clinical testing of artificial hip joints.

Keywords: total hip replacement; ceramic-on-ceramic; hip simulator; taper-trunnion junction; wear

RUNNING HEADS

Trunnion wear in hip simulator

INTRODUCTION.

Total hip replacement (THR), described as “*The Operation of the Century*”¹, is a common orthopedic surgery with the National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man recording 101,651 hip replacement procedures for 2016/17². The most commonly implanted bearing surface combination is metal-on-polyethylene (MoP)², however, the long-term limitation of using polyethylene as the acetabular component has been polyethylene (PE) wear, leading to osteolysis³. To reduce PE wear and therefore hopefully increase implant longevity, two approaches have been attempted: the improvement of PE wear resistance by crosslinking; and the introduction of hard-on-hard bearings including metal-on-metal (MoM), and ceramic-on-ceramic (CoC). Ceramic-on-ceramic THR was introduced in the early 1970s by Boutin⁴, and has gained in popularity with increasing numbers implanted each year². Over the years, ceramics have been developed to today’s fourth generation BIOLOX[®]*delta* ceramics, each generation benefiting from enhanced material properties and a corresponding reduction in wear. More than 3.8 million femoral heads and 1.5 million liners of BIOLOX[®]*delta* have been implanted worldwide since its launch⁵.

Ceramic-on-ceramic bearing couples exhibit extremely low wear rates in hip simulator tests in the range of 0.05 – 0.1 mm³/million cycles (Mc)⁶⁻⁹. This compares with MoP hips which have wear rates of 10 – 51 mm³/Mc for conventional PE and less than 20 mm³/Mc for crosslinked PE¹⁰⁻¹². Despite over 100-fold differences in wear rates between CoC and conventional PE hips, revision rates at 13 years for uncemented CoC (5.69%) and uncemented MoP (5.90%) procedures are currently very similar². The fact that ceramic wear particles may be fewer in number but more reactive than polyethylene cannot be an explanation, as ‘ceramic wear debris has shown to be less biologically active’¹³. Furthermore, wear rates for retrieved third generation

ceramic bearings reported in the literature range from 0.3 – 1.9 mm³/year^{14,15} so they show relatively good agreement with hip simulator studies.

A recent comparative retrospective observational study¹⁶ compared adverse reaction to metal debris (ARMD) for revised primary MoM and non-MoM hip implants (MoP, CoC and ceramic-on-polyethylene (CoP)) using data obtained from the NJR. Intriguingly, they showed that CoC bearings were revised for ARMD 2.35 times more when compared to other non-MoM bearings.

In CoC hips, the only sources of metal (usually titanium) would be the trunnion of the femoral stem and the acetabular shell. Of these two sources, the importance of metal debris from the taper-trunnion junction in MoM hip prostheses has been widely recognized¹⁷⁻²². To the authors' best knowledge, no *in vitro* tests have investigated material loss from the taper-trunnion junction of a modular CoC THR. Therefore, this study focused on investigating material loss, if any, at the taper junction of 36mm BIOLOX[®]*delta* CoC components mounted on titanium trunnions.

These components were wear tested in a multi station hip joint simulator over 5 million cycles. Additionally, a CoC sample was employed in a separate dynamically loaded station, with no articulating motion, to investigate material loss, if any, at the bearing surfaces and the taper-trunnion junction. Furthermore, it was appreciated that both the assembly and disassembly of the femoral head from the trunnion could produce wear at the taper-trunnion junction, therefore this important concern was investigated.

METHODS.

Hip simulator wear test. Three 36mm BIOLOX[®]*delta*, Pinnacle[®](DePuy Synthes, UK), CoC hip replacement bearings were tested in the 6-station anatomical hip joint simulator shown in Figure 1 (TE 86; PLINT, Phoenix Tribology Limited, UK)²³. The walking cycle applied in the simulator combines sinusoidal flexion-extension and abduction-adduction motions with the

83 excursion of 46° and 12° respectively, resulting in an elliptical wear path. The test ran for 5
84 million cycles. A double-peak load was applied to the three articulating samples with a
85 minimum value 400 N and a maximum value 2000 N²³. The term “hip simulator wear test”
86 corresponds to components subject to both dynamic loading and articulating motion.

87 Each ceramic femoral head with +5.0 associated neck length (REF 1365-320, manufacturer’s
88 code) was mounted using a plastic femoral head impactor, replicating that used in surgery, onto a
89 12/14 titanium trunnion (Ti6Al4V). When impacting, at least two firm, axially aligned blows to
90 impact the femoral head onto the trunnion were employed²⁴. In turn each trunnion was located
91 into a femoral head carrier (See Figure 2a, 2b and 2c). The 12/14 trunnions with a neck length of
92 34.5 mm were manufactured by Phoenix Tribology Limited, UK based on the Corail® (DePuy
93 Synthes, UK) stem which, when employed with 36mm ceramic heads, gives the most commonly
94 implanted CoC hip in the UK². All trunnions and femoral head carriers were marked prior to
95 testing to enable correct repositioning following cleaning and measurement intervals. Each
96 ceramic acetabular liner (REF 1218-81-754, manufacturer’s code) was held in an aluminum
97 3105 alloy pelvic insert holder with 45° cup abduction angle and 15° anteversion angle of the
98 simulator²³. This is different to the clinical situation where a titanium shell would serve to
99 connect the liner to the acetabulum, but it is common not to use a shell in hip simulators where
100 the historical focus has been on wear testing the bearing surfaces^{6,23,25}.

101 New-born-calf serum (Gibico™ life-technologies), diluted with de-ionized water to give a
102 protein concentration of 21g/L, was used as the lubricant. The lubricant was changed every
103 500,000 cycles when the components were cleaned and weighed following the relevant
104 international standard, ISO 14242-2²⁶. In addition to this, Sidel cleaner was used to remove any

visual marking seen at the internal taper of the femoral heads and the backside of the liners following disassembly²⁷.

Dynamic loading (DL) but no articulating motion test. A fourth CoC sample was subject to the same dynamic loading, with a minimum value 400 N and a maximum value 2000 N²³, but no articulating motion, referred to henceforth as the DL test station. All other testing conditions such as assembly-disassembly procedures, the same lubricant etc. was used as mentioned previously for the hip simulator wear test. It is important to note that the trunnion in the DL station was not loaded along its axis, but in the same way as the test samples, such that loading of the head was offset relative to the trunnion, replicating that seen when an artificial hip is implanted (see Figure 2a and 2b).

Wear measurement and analysis. Gravimetric wear analysis using an analytical balance (TB – 215D; Denver Instruments, Germany) with a 0.1mg sensitivity was conducted for heads, liners and trunnions after every million cycles, with measurements taken in triplicate to ensure repeatability. Taking the density of the BIOLOX[®]*delta* as 0.00437 g/mm³²⁸ and Ti6Al4V as 0.00443 g/mm³²⁹, gravimetric wear in mg was converted to volumetric wear in mm³. The average volumetric loss for heads, liners, CoC joints (heads + liners) and trunnions was plotted against the number of cycles and the slope of the linear regression line taken as the wear rate in mm³/Mc. These wear rates were obtained for components used in both the hip simulator wear test and the DL test.

Surface roughness measurements. Pre-and post-wear test three-dimensional (3D) surface roughness (Sa) measurements for femoral heads and acetabular liners used in both tests were performed using a non-contacting Zygo NewView 5000 white light interferometer³⁰ with 0.1 nm

vertical resolution. A total of 10 measurements on each articulating sample were acquired using a 10x objective lens and 2.0x manual zoom (area of view 317 x 238 μm). A two-dimensional (2D) contacting profilometer (Mitutoyo Surftest SJ-210) was used for the surface roughness (Ra) analysis of the tapers and trunnions in both tests³¹. Six linear scans for each taper and trunnion were performed with a cut off length of 0.8mm, giving each scan a total roughness evaluation trace length of 4.0 mm³². At the end of the hip simulator wear test, images of trunnion surfaces were obtained using a Vision Measuring System Quick scope QS-L (Mitutoyo, UK). The majority of the damaged area was found to be localized at the proximal-superior aspect of the trunnion. Therefore, in order to get better understanding of the trunnion topography, the non-contacting profilometer, Zygo NewView 5000, was used in these regions to obtain 3D surface roughness (Sa). Prior to these measurements, the trunnion surface was divided into two distinct areas; unworn and worn. A total of 20 measurements (10 on unworn area and 10 on worn area) on each trunnion were acquired.

Scanning electron microscopy (SEM) of titanium trunnions. Scanning electron microscopy was performed on the trunnions from the hip simulator wear test using a TM3030 SEM (Hitachi, Japan) to give high resolution images (spatial resolution < 100 nm and depth resolution >10 nm). Prior to the SEM analysis, the trunnions were cleaned with isopropanol.

Impaction test. In order to study the potential effect of material loss due to assembling and disassembling the femoral heads on the trunnions, a separate impaction test was conducted. A ceramic femoral head and titanium trunnion were assembled and disassembled eight times in an identical manner to that of the method used throughout the hip simulator test. After each disassembly procedure, the cleaning and weighing procedures, detailed previously, were carried

out. Two-dimensional surface roughness (Ra) measurements of the taper and trunnion were also repeated after each disassembly following the methodology described previously.

Statistical methods. Statistical analyses were performed using Minitab® 17.1.0 statistical software. The volumetric wear rates of CoC joints and titanium trunnions were analyzed using a 2-Sample t-test with a significance level of 0.05. Pre and post-test surface roughness measurements for femoral heads, acetabular liners and trunnions were analyzed using a paired t-test, again with a significance level of 0.05.

RESULTS.

In the following sections, wear of the ceramic components from the hip simulator wear test will firstly be offered as it is the most common way that results have been presented in the scientific literature. The wear of the titanium trunnions used in the hip simulator wear test is then given. Next, the wear of the ceramic components and the titanium trunnions used in the DL test is presented. Following the wear data, results of 3D surface roughness (Sa) measurements on the articulating surfaces of the ceramic bearings used in both tests are given. Visual and scanning electron microscopic images taken on the taper-trunnion junction post-test, are also displayed for components used in the hip simulator wear test. Then the 2D surface roughness (Ra) measurements on the surface of the tapers and the trunnions used in both tests are presented. Furthermore, 3D surface roughness measurements (Sa) on the unworn and worn areas of the hip simulator wear test trunnions are presented. Finally, the results of the impaction test, and its influence on the wear and surface roughness of trunnions, are given.

Wear of CoC joints and titanium trunnions from the hip simulator wear test. After 5 million cycles, the volumetric wear rate (mean $\pm$ standard deviation) for the femoral heads was

0.036 $\pm$ 0.005 mm³/Mc, and for the acetabular liners it was 0.031 $\pm$ 0.002 mm³/Mc. For the CoC joints, the mean volumetric wear rate was therefore 0.067 $\pm$ 0.003 mm³/Mc. For the trunnions it was 0.061 $\pm$ 0.015 mm³/Mc, with a range of 0.045-0.075 mm³/Mc. These results are presented in Figure 3. The volumetric wear rate of the CoC joints and titanium trunnions were not significantly different ($p = 0.592$). The total volumetric wear over 5 million cycles was 0.25 mm³ for the CoC joint and 0.29 mm³ for the titanium trunnion.

Wear of CoC joint and titanium trunnion from the DL test. After 5 million cycles of dynamic loading but no articulating motion, the mean volumetric wear rates were 0.033 mm³/Mc for the femoral head and 0.032 mm³/Mc for the acetabular liner. The mean volumetric wear rates for the CoC joints and titanium trunnions were 0.065 mm³/Mc and 0.012 mm³/Mc respectively. The total volumetric wear over 5 million cycles was 0.23 mm³ for the CoC joint and 0.05 mm³ for the titanium trunnion. The wear rate of the DL test trunnion (0.012 mm³/Mc) was lower than the hip simulator trunnions (0.061 mm³/Mc) as shown in Figure 4.

Three-dimensional (3D) surface roughness (Sa) of articulating surfaces used in both the hip simulator wear test and the DL test. Table 1 shows the mean surface roughness (Sa), pre and post-test, for the articulating surfaces used in both tests. There was no statistically significant difference in the Sa values pre and post-test for either the femoral heads ($p = 0.184$) or the acetabular liners ($p = 0.184$) used in the hip simulator wear test. Similarly, pre-and post-test measurements of Sa did not show a statistically significant difference for either the femoral head ($p = 0.111$) or the acetabular liner ($p = 0.139$) used in the DL test.

Visual and microscopic inspection of the taper-trunnion junction used in the hip simulator wear test. The femoral head and trunnion assembly is shown in Figure 5a. On the trunnions,

material loss (as indicated by reduction in mass and decrease in roughness) was seen visually at the proximal-superior end and the distal-inferior end, as shown in Figures 5b and 5c respectively. Optical micrographs taken with x0.65 magnification at the proximal-superior end and the distal-inferior end are shown in Figures 5d and 5e respectively. Unworn and worn areas are clearly visible, with the original circumferential machining marks evident in the unworn areas.

The proximal-superior end of a test trunnion can be seen at x2.5 magnification using an optical microscope in Figure 6a, and at x500 magnification with an SEM in Figure 6b. Again, two distinct areas are shown in the SEM image; a worn area and an unworn area with the original machining marks.

As can be seen in Figure 7b, at disassembly a visual inspection of the internal taper of the femoral head revealed a grey colored ring at the proximal end of all the femoral tapers. The majority of the grey colored area was observed at the superior half of the femoral taper. After cleaning with Sidol, these grey colored areas were removed.

Two-dimensional (2D) surface roughness (Ra) of the taper-trunnion surfaces used in the hip simulator wear test. There was no statistical difference ($p = 0.210$), pre and post-test, for the femoral taper surfaces with Ra (mean $\pm$ standard deviation) values of 0.351 ± 0.142 and $0.302 \pm 0.071 \mu\text{m}$ respectively. However, Ra of the trunnions showed a statistically significant decrease ($p < 0.001$) from 0.612 ± 0.070 to $0.527 \pm 0.090 \mu\text{m}$ in pre and post-test measurements respectively. Figure 8 shows an evaluation profile trace obtained over the distal-inferior end of a test trunnion displaying the worn area.

Two-dimensional (2D) surface roughness (Ra) of the taper-trunnion surfaces used in the DL test. There was no statistical difference ($p = 0.862$), pre and post-test, for the femoral taper

surfaces with Ra (mean $\pm$ standard deviation) values of 0.365 ± 0.093 and 0.355 ± 0.055 μm respectively. Similarly, the Ra of the trunnion did not show any statistically significant difference ($p = 0.146$) with Ra values of 0.541 ± 0.040 and 0.520 ± 0.045 μm pre and post-test respectively.

Three-dimensional (3D) surface roughness (Sa) of trunnion surfaces used in the hip simulator wear test. Figures 9a and 9b show images acquired by the non-contacting profilometer on the a) unworn and b) worn areas at the proximal-superior end of a test trunnion respectively. On the unworn area, the original machining marks could be seen, however, they were not observed on the worn area. The Sa of the trunnions on the unworn and worn areas showed a statistically significant decrease from 0.558 ± 0.060 to 0.312 ± 0.028 μm respectively ($p < 0.001$).

Impactation test. The effect of assembly and disassembly on the wear of the taper-trunnion junction was minimal. Figure 10 shows a graph of weight loss against number of impactations. If there were any weight changes in the trunnion due to assembly and disassembly, they were below the sensitivity (0.1mg) of the analytical balance. Moreover, there was no statistically significant difference in the Ra values pre and post-test, for either the trunnion ($p = 0.187$) or the femoral taper ($p = 0.193$). Table 2 shows the mean surface roughness (Ra) pre and post impactation test for the femoral taper and the trunnion. Additionally, a light grey discoloration was observed on the internal taper of the femoral head during this test as shown in Figure 11, however, it was removed during the cleaning procedure.

DISCUSSION.

This is the first long term hip simulator study to report wear generated from the taper-trunnion junction of a contemporary CoC hip joint. Retrieval studies of hip prostheses have indicated that material loss and debris formation is not only limited to the articulating surfaces but also arises from the taper-trunnion junction^{17,18,33-35}.

Some may suggest that it is not possible to test both the taper-trunnion junction and the bearing surfaces in a single test. We would contend that this is not only possible but it is essential. If bearing surfaces show low wear, yet wear at the trunnion takes place, then this needs to be identified so that patients are protected and surgeons are not led to believe in a ‘low wear’ bearing combination that actually causes material loss elsewhere. However, these statements are founded on the test set up reproducing the clinical situation as closely as possible. We believe our hip simulator does this, due to dynamic loading being applied to the test samples (See Figure 2b and 2c) such that toggling of the femoral head on the trunnion, as seen on explanted hip prostheses^{18,35}, can be reproduced.

Wear at the taper-trunnion junction of CoC prostheses used in the hip simulator wear test: ceramic-on-metal contact. Based on the hip simulator wear data, the metal trunnions (total wear = 0.29 mm³) wore at a similar amount to that of the bearing surfaces (total wear = 0.25 mm³). Trunnion wear was also indicated by other experimental data. The trunnion surfaces measured with a 2D contacting profilometer showed a statistically significant ($p < 0.001$) decrease in surface roughness (Ra) post-test (see Figure 8). Furthermore, the worn area of the trunnions showed a statistically significant ($p < 0.001$) decrease in 3D surface roughness (Sa) compared to that of the unworn area (see Figure 9). This decrease in roughness was due to an elimination of the original machining marks.

A retrieval study¹⁸ investigated the taper wear of 126 large diameter (≥ 36 mm) MoM hips. Analysis of the position of the taper damage suggested that a toggle effect from the femoral head was causing the damage at the taper surface. Another retrieval study of modular MoM hips³⁵ also suggested that the wear at the taper-trunnion junction was generated by the toggling of the cobalt chromium (CoCr) femoral head on the stem. As a similar wear pattern was observed in this simulator study it is suggested that there is a similar toggling of the ceramic femoral head, as shown in Figure 12. However, in this study wear was apparent on the trunnion, likely due to the relative hardness of the ceramic compared to the titanium.

The femoral head tapers showed a statistically insignificant change ($p > 0.05$) in the 2D surface roughness (Ra) post-test indicating minimal material loss from the femoral head tapers. A grey colored ring, visible at the proximal end of femoral taper, likely indicated adhesive wear from the titanium trunnion onto the ceramic taper. This is in agreement with an explant study³⁴ which noted metallic material transfer on the ceramic taper surface of CoC and CoP retrievals. The same study reported no fretting corrosion or material loss at the ceramic tapers, again this is in agreement with our experimental results. The explant study also quantified the volumetric material loss from retrieved trunnions with the wear rate ranging from 0.0-0.37 mm³/year. If one million cycles in the hip simulator is equivalent to 1 year *in vivo*³⁶, then the mean wear rate (0.061 mm³/year) of the titanium trunnions obtained in the *in vitro* test reported here is within the range obtained from this retrieval study.

Might there be a difference in taper-trunnion wear between CoC hips and CoP hips? To begin to answer this question, one should probably start by considering wear at the bearing surfaces. Here, one would expect far less wear from CoC hips than from CoP hips. However, this result is not reflected in data from the largest joint registry in the world, the NJR. Here, CoP hips show

lower revision rates than CoC hips. We speculate that a possible reason could be greater damage at non-bearing surfaces (i.e. the taper-trunnion) of CoC hips compared to CoP. The reason being that the PE liner could act to ‘soften the blow’ of peak forces during gait and other activities. An indicative engineering comparison of a CoP hip with a CoC hip might be a mallet in comparison with a hammer. While both transmit loads, mallets are deliberately softer to lessen damage to materials. We will explore this hypothesis in future work.

A possible explanation for adverse reaction to metal debris (ARMD) in CoC hip implants.

Ceramic-on-ceramic hip joints, as an alternative to conventional MoP, have shown lower wear in both *in vitro*^{6-9,25,37-40} and retrieval studies^{14,15}. However, the overall risks of revision for an uncemented THR at 13 years are similar at 5.69% and 5.90% for CoC and MoP respectively².

We accept that reasons for revision are multi-factorial, including infection, dislocation and fracture. However, we question why, particularly at longer follow-ups shown in established joint registries, the potential wear related benefits of all-ceramic articulations do not appear to be seen.

An explant study⁴¹ found extensive wear on the titanium trunnion which was fitted into the ceramic femoral head of the failed prostheses. Furthermore, wear debris particles isolated from the periprosthetic tissue were shown to be the same as that of the trunnion metal alloy. A recent clinical study by Matharu *et al* found more ARMD in CoC hips than MoP hips¹⁶. This is despite there being fewer metallic components in a CoC hip than a MoP hip. This *in vitro* study has shown that one source of metal debris in a CoC hip is the taper-trunnion junction.

While it may be that CoCr wear particles are more cytotoxic than titanium alloy wear particles⁴², we would caution that the history of hip arthroplasty from Charnley onwards has shown that the generation of volumes of wear debris should be avoided. Moreover, titanium wear from joint replacements has been shown to induce aneuploidy *in vitro* and *in vivo*⁴³. The potential links of

titanium wear debris to metallosis in children fitted with spinal implants have recently been described ⁴⁴.

Modularity of femoral heads and femoral stems with different offsets potentially allows surgeons to restore the natural anatomy of the hip. In this wear test the same type of CoC hip prosthesis with identical neck lengths were used. A retrieval study on the taper-trunnion junction of CoC, CoP and MoP hip prostheses found no correlation between the head offset and the material loss ³⁴. However, another retrieval study on large diameter MoM hips found a positive correlation between the head offset and the material loss ¹⁸. Therefore, further investigations in this area are likely to be of value.

Wear at the articulating surfaces of CoC joints used in the hip simulator wear test. As shown in Table 3, previous CoC hip simulator studies have not reported wear from the taper-trunnion junction and offered only wear at the bearing surfaces ^{6-9,25,37-40}. The mean wear rate of the CoC joints reported in this study, $0.067 \pm 0.003 \text{ mm}^3/\text{Mc}$, is comparable to wear rates found in the literature ^{6-9,25,37-40}. The surface roughness (Sa) of the articulating surfaces showed negligible change. Pre-test values for heads and liners were 0.003 ± 0.002 and $0.005 \pm 0.001 \text{ }\mu\text{m}$ respectively, while post-test they were 0.004 ± 0.001 and $0.005 \pm 0.001 \text{ }\mu\text{m}$ respectively. These values are comparable to post-test roughness values from other simulator studies ^{6-9,25,37-40} as seen in Table 3. These relatively unchanged roughness measurements imply minimal wear of the articulating surfaces.

Importance of the DL test. The major difference between the two tests described in this paper was that the motion (gait) was applied to the hip simulator wear test samples while no articulating motion was applied to the DL test sample. By the Archard wear equation we would

expect to see substantially more material loss from the articulating surfaces of the wear test samples than from those of the DL sample. Perhaps surprisingly, we found that this was not the case and that there was a comparable amount of wear from the wear test samples (0.25 mm^3) as from the DL sample (0.23 mm^3). We postulate that material loss from the bearing surfaces of the DL sample may be due to fretting wear. This has been reported previously for alumina rubbing against alumina⁴⁵ but is a topic that deserves further investigation in relation to CoC hips.

Importance of the impaction test. The results from the impaction test confirmed that the assembling/disassembling procedure had no effect on either the gravimetric or surface roughness measurements for either the titanium trunnion or the taper of the ceramic femoral head.

Limitations. This *in vitro* test had a number of limitations. Firstly, there were only three articulating CoC samples. Two further samples were required for the DL test and the impaction test, both of which were fundamental to this investigation. As these samples were all the latest fourth generation of ceramic BIOLOX[®]*delta*, obtaining such samples for independent testing was both difficult and expensive as this project was unfunded. Secondly, the trunnions of actual Corail[®] (DePuy Synthes, UK) femoral stems could not be used as these could not be sourced and would anyway lack sufficient material from which to manufacture the double-ended trunnions employed in the hip simulator. Instead, titanium surrogates had to be manufactured. Thirdly, there is potential for wear to occur at the ceramic-metal interface on the backside of the acetabular liner and pelvic insert holder of the simulator. Due to the current design of the simulator, an acetabular shell cannot be accommodated. However, the simulator will be redesigned so that an acetabular shell can be incorporated in future tests. Fourthly, impaction force and number of impactions were not measured during the tests reported in this paper. However, the same author (RMB) undertook all impactions and employed a consistent

technique. Lastly, analysis of wear debris within the lubricant was not undertaken. In part this was because the wear was so low that such an analysis would be challenging.

CONCLUSION.

Based on the gravimetric measurements, bearing surface wear rates were similar to those of the trunnions from the hip simulator wear test. This metallic wear debris may provide an explanation for the adverse reaction to metal wear debris reported in CoC hip arthroplasty, and for the similarity in clinical performance between CoC and MoP hips. No other long-term hip simulator studies have measured wear at the taper-trunnion junction. This *in vitro* study confirms the necessity of measuring taper-trunnion junction wear in pre-clinical testing to fully understand the mechanisms of material loss. We suggest that other researchers with hip simulators now begin to measure such taper-trunnion wear and that ISO14242⁴⁶ be amended so that such wear is considered.

ACKNOWLEDGMENTS.

The authors would like to thank Mr Michael Foster for acquiring data from the scanning electron microscope and Messrs. Stephen Harrison, James Rose and Lewis Sholder for assistance in the hip simulator test. RMB's PhD studentship was provided by School of Engineering, Newcastle University. The authors have no conflicts of interest to declare. We thank the paper's reviewers for their helpful and insightful comments.

REFERENCES

1. Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. *Lancet* 2007;370(9597):1508-1519.
2. The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man: 14th annual report, 2017.

- 372 3. Ingham E, Fisher J. Biological reactions to wear debris in total joint replacement. *Proc*
373 *Inst Mech Eng [H]* 2000;214(1):21-37.
- 374 4. Boutin P. Alumina and its use in surgery of the hip. (Experimental study). *La Presse*
375 *medicale* 1971;79(14):639-640.
- 376 5. CeramTec. BIOLOX® Advanced Ceramics. [Available from:
377 [https://www.ceramtec.com/ceramic-materials/biolox/delta/.](https://www.ceramtec.com/ceramic-materials/biolox/delta/)]
- 378 6. Smith SL, Unsworth A. An in vitro wear study of alumina-alumina total hip prostheses.
379 *Proc Inst Mech Eng [H]* 2001;215(5):443-446.
- 380 7. Nevelos JE, Ingham E, Doyle C, Nevelos AB, Fisher J. The influence of acetabular cup
381 angle on the wear of "BIOLOX Forte" alumina ceramic bearing couples in a hip joint
382 simulator. *J. Mater. Sci. Mater. Med.* 2001;12(2):141-144.
- 383 8. Essner A, Sutton K, Wang A. Hip simulator wear comparison of metal-on-metal,
384 ceramic-on-ceramic and crosslinked UHMWPE bearings. *Wear* 2005;259(7-12):992-995.
- 385 9. Spinelli M, Affatato S, Corvi A, Viceconti M. Ceramic-on-ceramic vs. metal-on-metal in
386 total hip arthroplasty (THA): Do 36-mm diameters exhibit comparable wear
387 performance? *Mat.-wiss.u. Werkstofftech* 2009;40(1-2):94-97.
- 388 10. Smith SL, Unsworth. A comparison between gravimetric and volumetric techniques of
389 wear measurement of UHMWPE acetabular cups against zirconia and cobalt-chromium-
390 molybdenum femoral heads in a hip simulator. *Proc Inst Mech Eng [H]*
391 1999;213(6):475-483.
- 392 11. Ali M, Al-Hajjar M, Partridge S, Williams S, Fisher J, Jennings LM. Influence of hip
393 joint simulator design and mechanics on the wear and creep of metal-on-polyethylene
394 bearings. *Proc Inst Mech Eng [H]* 2016;230(5):389-397.
- 395 12. Fisher J, Jin Z, Tipper J, Stone M, Ingham E. Presidential guest lecture: Tribology of
396 alternative bearings. *Clin Orthop Res* 2006(453):25-34.
- 397 13. Liu F, Fisher J. Effect of an edge at cup rim on contact stress during micro-separation in
398 ceramic-on-ceramic hip joints. *Tribol Int* 2017;113:323-329.
- 399 14. Lusty PJ, Watson A, Tuke MA, Walter WL, Walter WK, Zicat B. Orientation and wear
400 of the acetabular component in third generation alumina-on-alumina ceramic bearings:
401 An analysis of 33 retrievals. *J Bone Joint Surg Br* 2007;89(9):1158-1164.
- 402 15. Walter WL, Insley GM, Walter WK, Tuke MA. Edge loading in third generation alumina
403 ceramic-on-ceramic bearings: Stripe wear. *J Arthroplasty* 2004;19(4):402-413.
- 404 16. Matharu GS, Pandit HG, Murray DW, Judge A. Adverse reactions to metal debris occur
405 with all types of hip replacement not just metal-on-metal hips: a retrospective
406 observational study of 3340 revisions for adverse reactions to metal debris from the
407 National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. *BMC*
408 *Musculoskelet Disord* 2016;17(1):1-12.
- 409 17. Langton DJ, Jameson SS, Joyce TJ, Hallab NJ, Natsu S, Nargol AVF. Early failure of
410 metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement: A
411 consequence of excess wear. *J Bone Joint Surg Br* 2010;92(1):38-46.
- 412 18. Langton DJ, Sidaginamale R, Lord JK, Nargol AVF, Joyce TJ. Taper junction failure in
413 large-diameter metal-on-metal bearings. *Bone Joint Res* 2012;1:56-63.
- 414 19. Matthies AK, Racasan R, Bills P, Blunt L, Cro S, Panagiotidou A, Blunn G, Skinner J,
415 Hart AJ. Material loss at the taper junction of retrieved large head metal-on-metal total
416 hip replacements. *J Orthop Res* 2013;31(11):1677-1685.

20. Nassif NA, Nawabi DH, Stoner K, Elpers M, Wright T, Padgett DE. Taper design affects failure of large-head metal-on-metal total hip replacements. *Clinical Orthopaedics and Related Research* 2014;472(2):564-571.
21. Meyer H, Mueller T, Goldau G, Chamaon K, Ruetschi M, Lohmann CH. Corrosion at the cone/taper interface leads to failure of large-diameter metal-on-metal total hip arthroplasties. *Clin Orthop Res* 2012;470(11):3101-3108.
22. Esposito CI, Wright TM, Goodman SB, Berry DJ. What is the Trouble With Trunnions? *Clin Orthop Res* 2014;472(12):3652-3658.
23. Saikko V. A 12-station anatomic hip joint simulator. *Proc Inst Mech Eng [H]* 2005;219(6):437-448.
24. Heiney JP, Battula S, Vrabec GA, Parikh A, Blice R, Schoenfeld AJ, Njus GO. Impact magnitudes applied by surgeons and their importance when applying the femoral head onto the Morse taper for total hip arthroplasty. *Arch of Orthop and Trauma Surg* 2009;129(6):793-796.
25. Affatato S, Traina F, Toni A. Microseparation and stripe wear in alumina-on-alumina hip implants. *Int J Artif Organs* 2011;34(6):506-512.
26. ISO14242-2. Implants for surgery — Wear of total hip-joint prostheses Part 2: Methods of measurement. 2016.
27. Saikko H-GP. Low wear and friction in alumina/alumina total hip joints: A hip simulator study. *Acta Orthop* 1998;69(5):443-448.
28. Masson B. Emergence of the alumina matrix composite in total hip arthroplasty. *Int Orthop* 2009;33(2):359-363.
29. Ratner BD HA, Schoen FJ. An introduction to materials in medicine. Amsterdam: Elsevier Academic Press; 2004.
30. Joyce TJ, Langton DJ, Jameson SS, Nargol AVF. Tribological analysis of failed resurfacing hip prostheses and comparison with clinical data. *Proc Inst Mech Eng [J]* 2009;223(3):317-323.
31. Langton D, Ahmed I, Avery P, Bone M, Cooke N, Deehan D, Duffy P, Foguet P, Green S, Holland J and others. Investigation of Taper Failure in a Contemporary Metal-on-Metal Hip Arthroplasty System Through Examination of Unused and Explanted Prostheses. *J Bone Joint Surg Am* 2017;99(5):427-436.
32. ISO4288. Geometric Product Specification (GPS) — Surface texture — Profile method: Rules and procedures for the assessment of surface texture ICS. 1998.
33. Pastides PS, Dodd M, Sarraf KM, Willis-Owen CA. Trunnionosis: A pain in the neck. *World J Orthop* 2013;4(4):161-166.
34. Kocagoz SB, Underwood RJ, Macdonald DW, Gilbert JL, Kurtz SM. Ceramic heads decrease metal release caused by head-taper fretting and corrosion. *Clin Orthop Res* 2016;474(4):985-994.
35. Bishop N, Witt F, Pourzal R, Fischer A, Rütschi M, Michel M, Morlock M. Wear patterns of taper connections in retrieved large diameter metal-on-metal bearings. *J Orthop Res* 2013;31(7):1116-1122.
36. Schmalzried TP, Szuszczewicz ES, Northfield MR, Akizuki KH, Frankel RE, Belcher G, Amstutz HC. Quantitative assessment of walking activity after total hip or knee replacement. *J Bone Joint Surg Am* 1998;80(1):54-59.

37. Nevelos JE, Ingham E, Doyle C, Nevelos AB, Fisher J. Wear of HIPed and non-HIPed alumina-alumina hip joints under standard and severe simulator testing conditions. *Biomaterials* 2001;22(16):2191-2197.
38. Tipper JL, Firkins PJ, Besong AA, Barbour PSM, Nevelos J, Stone MH, Ingham E, Fisher J. Characterisation of wear debris from UHMWPE on zirconia ceramic, metal-on-metal and alumina ceramic-on-ceramic hip prostheses generated in a physiological anatomical hip joint simulator. *Wear* 2001;250-251(PART 1):120-128.
39. Richardson HA, Clarke IC, Williams P, Donaldson T, Oonishi H. Precision and accuracy in ceramic-on-ceramic wear analyses: Influence of simulator test duration. *Proc Inst Mech Eng [H]* 2005;219(6):401-405.
40. Al-Hajjar M, Leslie IJ, Tipper J, Williams S, Fisher J, Jennings LM. Effect of cup inclination angle during microseparation and rim loading on the wear of BIOLOX® delta ceramic-on-ceramic total hip replacement. *J Biomed Mater Res* 2010;95 B(2):263-268.
41. Milošev L, Antolič V, Minovič A, Cör A, Herman S, Pavlovčič V, Campbell P. Extensive metallosis and necrosis in failed prostheses with cemented titanium-alloy stems and ceramic heads. *J Bone Joint Surg Br* 2000;82(3):352-357.
42. Dalal A, Pawar V, McAllister K, Weaver C, Hallab NJ. Orthopedic implant cobalt-alloy particles produce greater toxicity and inflammatory cytokines than titanium alloy and zirconium alloy-based particles in vitro, in human osteoblasts, fibroblasts, and macrophages. *J Biomed Mater Res- Part A* 2012;100 A(8):2147-2158.
43. Daley B, Doherty AT, Fairman B, Case CP. Wear debris from hip or knee replacements causes chromosomal damage in human cells in tissue culture. *J Bone Joint Surg Br* 2004;86(4):598-606.
44. Joyce TJ, Smith SL, Rushton PRP, Bowey AJ, Gibson MJ. Analysis of Explanted Magnetically Controlled Growing Rods From Seven UK Spinal Centers. *Spine* 2018;43(1):E16-E22.
45. Stachowiak GB, Stachowiak GW. Fretting wear and friction behaviour of engineering ceramics. *Wear* 1995;190(2):212-218.
46. ISO14242-1. Implants for surgery — Wear of total hip-joint prostheses Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test. 2014.

FIGURE LEGEND

- 493 Figure 1 The six-station anatomical hip joint simulator showing three CoC test components
494 immersed in diluted new-born-calf serum.
- 495 Figure 2 a) A DL station, b) Schematic of femoral head, acetabular liner and trunnion in test and
496 DL station set up, c) A test station
- 497 Figure 3 Mean gravimetric measurements of uncorrected CoC joints and uncorrected trunnions.
498 Error bars represent standard deviation.
- 499 Figure 4 The mean gravimetric measurements of titanium trunnions used in the hip simulator
500 wear test and the DL test. Error bars represent standard deviation.
- 501 Figure 5 a) A femoral head and trunnion assembly showing the different anatomical planes , b)
502 and c) a test trunnion showing wear from the proximal-superior end and distal-inferior end
503 respectively, d) and e) optical microscopic images of a test trunnion captured at x0.65
504 magnification showing worn and unworn areas of the proximal-superior end and distal-inferior
505 ends respectively.
- 506 Figure 6 a) An optical microscopic image at x2.5 magnification and b) Scanning electron
507 microscopy (SEM) image of the test trunnion at x500 magnification showing worn and unworn
508 areas.
- 509 Figure 7 a) A femoral head and trunnion assembly showing the different anatomical planes, b)
510 An internal taper of a test femoral head showing grey colored ring.
- 511 Figure 8 An evaluation profile obtained over the distal-inferior end of a test trunnion ($R_a = 0.321$
512 μm). The red arrow indicates the worn area.

513 Figure 9 Surface topography images of a titanium trunnion a) unworn with machining marks
514 visible ($S_a = 0.565 \mu\text{m}$) and b) worn ($S_a = 0.284 \mu\text{m}$).

515 Figure 10 Gravimetric measurement of Impaction test trunnions. Error bars represent standard
516 deviation.

517 Figure 11 An internal taper of an impaction test femoral head showing discoloration prior to
518 cleaning.

519 Figure 12 A test ceramic femoral head and trunnion assembly with applied load and applied
520 motions, showing toggling and the material loss at two distinct areas (shown in red).

521

522 Figure 1 The six-station anatomical hip joint simulator showing three CoC test components

523 immersed in diluted new-born-calf serum.

524

525 Figure 2 a) A DL station, b) Schematic of femoral head, acetabular liner and trunnion in test and

526 DL station set up, c) A test station

527

528 Figure 3 Mean gravimetric measurements of uncorrected CoC joints and uncorrected trunnions.

529 Error bars represent standard deviation.

530

531 Figure 4 The mean gravimetric measurements of titanium trunnions used in the hip simulator

532 wear test and the DL test. Error bars represent standard deviation.

533

534 Figure 5 a) A femoral head and trunnion assembly showing the different anatomical planes , b)

535 and c) a test trunnion showing wear from the proximal-superior end and distal-inferior end

536 respectively, d) and e) optical microscopic images of a test trunnion captured at x0.65

537 magnification showing worn and unworn areas of the proximal-superior end and distal-inferior

538 ends respectively.

539

540 Figure 6 a) An optical microscopic image at x2.5 magnification and b) Scanning electron
 541 microscopy (SEM) image of the test trunnion at x500 magnification showing worn and unworn
 542 areas.

543

544 Figure 7 a) A femoral head and trunnion assembly showing the different anatomical planes, b)

545 An internal taper of a test femoral head showing grey colored ring.

546

547 Figure 8 An evaluation profile obtained over the distal-inferior end of a test trunnion ($R_a = 0.321$

548 μm). The red arrow indicates the worn area.

549

550 Figure 9 Surface topography images of a titanium trunnion a) unworn with machining marks

551 visible ($S_a = 0.565 \mu\text{m}$) and b) worn ($S_a = 0.284 \mu\text{m}$).

552

553 Figure 10 Gravimetric measurement of Impactation test trunnions. Error bars represent standard

554 deviation.

555

556 Figure 12 An internal taper of an impactation test femoral head showing discoloration prior to
557 cleaning.

558

559 Figure 12 A test ceramic femoral head and trunnion assembly with applied load and applied

560 motions, showing toggling and the material loss at two distinct areas (shown in red).

Table 1 Mean surface roughness (Sa) of femoral heads and acetabular liners used in the hip simulator wear test and the DL test.

Sa (in μm)		Pre-test (Mean $\pm$ SD)	Post-test (Mean $\pm$ SD)
Hip simulator wear test	Heads	0.003 $\pm$ 0.002	0.004 $\pm$ 0.001
	Liners	0.005 $\pm$ 0.001	0.005 $\pm$ 0.001
DL test	Heads	0.005 $\pm$ 0.001	0.006 $\pm$ 0.001
	Liners	0.005 $\pm$ 0.001	0.004 $\pm$ 0.001

Table 2 Mean surface roughness of femoral taper and trunnion used for an impaction test.

Ra (in μm)	Before test (Mean $\pm$ SD)	After test (Mean $\pm$ SD)
Femoral taper	0.324 $\pm$ 0.084	0.254 $\pm$ 0.054
Trunnion	0.602 $\pm$ 0.068	0.598 $\pm$ 0.042

Table 3 Laboratory wear rates found for different ceramic-on-ceramic hip joints under standard testing conditions compared with this study.

Study	CoC materials	Surface roughness (μm)		CoC wear rate (mm^3/Mc) (Mean $\pm$ SD)	Trunnion wear rate (mm^3/Mc) (Mean $\pm$ SD)
		H:Heads and L:Liners Pre-test	Post-test		
Smith <i>et al</i> ⁶ (2001)	BIOLOX [®] <i>forte</i>	H: 0.001	H: 0.004	0.097 ± 0.039	Not measured
Nevelos <i>et al</i> ⁷ (2001)	BIOLOX [®] <i>forte</i>	H+L:~ 0.005	H+L : ~ 0.005	~ 0.05	Not measured
Nevelos <i>et al</i> ³⁷ (2001)	BIOLOX [®] <i>forte</i>	-	No change detected	0.09 ± 0.04	Not measured
Tipper <i>et al</i> ³⁸ (2001)	BIOLOX [®] <i>forte</i>	H: 0.005-0.008	No change detected	0.05 ± 0.02	Not measured
Richardson <i>et al</i> ³⁹ (2005)	Alumina-on-Alumina	-	-	< 0.01	Not measured
Essner <i>et al</i> ⁸ (2005)	Alumina-on-Alumina	H+L:~ 0.01	-	< 0.1	Not measured
Spinelli <i>et al</i> ⁹ (2009)	BIOLOX [®] <i>forte</i>	H: 0.01	H: 0.01	-	Not measured
		L: 0.01	L: 0.01		
Al-Hajjar <i>et al</i> ⁴⁰ (2010)	BIOLOX [®] <i>delta</i>	-	H+L:~ 0.005	0.05	Not measured
Affatato <i>et al</i> ²⁵ (2011)	Alumina-on-Alumina	-	-	0.11 ± 0.03	Not measured
This study	BIOLOX [®] <i>delta</i>	H: 0.003 ± 0.002	H: 0.004 ± 0.001	0.067 ± 0.003	0.061 ± 0.015
		L: 0.005 ± 0.001	L: 0.005 ± 0.001		