Clinically insignificant trunnionosis in large-diameter metal-on-polyethylene total hip arthroplasty

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Objectives
Mechanical wear and corrosion at the head-stem junction of total hip arthroplasties (THAs) (trunnionosis) have been implicated in their early revision, most commonly in metal-on-metal (MOM) hips. We can isolate the role of the head-stem junction as the predominant source of metal release by investigating non-MOM hips; this can help to identify clinically significant volumes of material loss and corrosion from these surfaces.

Methods
In this study we examined a series of 94 retrieved metal-on-polyethylene (MOP) hips for evidence of corrosion and material loss at the taper junction using a well published visual grading method and an established roundness-measuring machine protocol. Hips were retrieved from 74 male and 20 female patients with a median age of 57 years (30 to 76) and a median time to revision of 215 months (2 to 324). The reasons for revision were loosening of both the acetabular component and the stem (n = 29), loosening of the acetabular component (n = 58) and infection (n = 7). No adverse tissue reactions were reported by the revision surgeons.

Results
Evidence of corrosion was observed in 55% of hips. The median Goldberg taper corrosion score was 2 (1 to 4) and the annual rate of material loss at the taper was 0.084 mm$^3$/year (0 to 0.239). The median trunnion corrosion score was 1 (1 to 3).

Conclusions
We have reported a level of trunnionosis for MOP hips with large-diameter heads that were revised for reasons other than trunnionosis, and therefore may be clinically insignificant.

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Article focus
- It is currently unclear how much material loss and corrosion must occur at the taper junction of total hip arthroplasties (THAs) to be of clinical significance.
- We examined tapers of retrieved metal-on-polyethylene hips that had been revised for reasons other than adverse tissue reactions, suggesting that metal release was clinically insignificant.
- We aimed to quantify the volume of material loss and severity of corrosion to develop an understanding of ‘acceptable’ levels of metal release.

Key messages
- We measured median rates of taper material loss of 0.084 mm$^3$/year (0 to 0.239) and median corrosion scores for the taper and trunnion were 2 and 1, respectively (scale 1 to 4).
- Our data help define levels of metal release from the taper junction of THAs revised for reasons other than trunnionosis and therefore may be clinically insignificant.

Strengths and limitations
- A strength of this study is the large sample size (94).
- It is acknowledged that a single cobalt-chromium (CoCr) alloy head-stem combination is not as prevalent as titanium-CoCr junctions.
**Introduction**

The term ‘trunnionosis’ describes the mechanisms of material loss at the taper junction that may involve corrosion, mechanical wear or a combination of the two. Incidences of clinically significant trunnionosis in large-diameter (> 36 mm) metal-on-metal (LD-MOM) total hip arthroplasties (THAs) have been widely reported; previous studies have reported evidence of corrosion damage at the taper junction of MoP hips which has been linked to adverse tissue reactions in some patients. A recent clinical study described a consecutive series of 17 patients with MoP hips who were all found to have solid, cystic or mixed soft-tissue lesions intra-operatively, with evidence of corrosion in all cases. It is not known, however, how much material was lost from the head-stem interface in these cases and a clinically significant level of material loss has not been defined. Retrieval studies comparing the severity of trunnionosis in MoP hips with clinical data can help us understand the size of the clinical impact of taper damage in these implants. This study examined a consecutive series of 94 retrieved MoP hips of a single design. There were no symptomatic reactions to metal debris reported in any of the cases, suggesting that the level of trunnionosis in these hips was clinically insignificant. The purpose of this study was to quantify this level by 1) grading the severity of corrosion and 2) measuring the volume of material lost at the taper surface.

**Patients and Methods**

This was a retrieval study involving 94 Endo-Model Mark III (Link, Hamburg, Germany) MoP total hip arthroplasties that had been revised at a single institution and subsequently received at our centre (Table I). All hips consisted of a 38 mm cobalt-chromium (CoCr) femoral head that had been paired with a CoCr femoral stem (29 stems were retrieved). All implants had a 14/16 stem trunnion. The implants had been retrieved from 74 male and 20 female patients with a median age of 57 years (30 to 76) and a median time to revision of 215 months (2 to 324). Pre-revision radiographs were obtained for each hip in order to measure the position of the implants; the median acetabular inclination was 52° (17° to 76°). The reasons for revision, as reported by the revising surgeons, were loosening of both the acetabular component and stem (n = 29), loosening of the acetabular component (n = 58), and infection (n = 7). No adverse tissue reactions were reported.

**Visual assessment of corrosion.** We performed both macroscopic inspection and microscopic analysis (Leica M50, Leica Microsystems, Wetzlar, Germany) of the female head taper and male stem trunnion surfaces to determine the presence and severity of corrosion. A widely published semi-quantitative scoring method was used to grade each surface with a score between 1 (no corrosion) and 4 (severe corrosion). This method grades the increasing severity of corrosion based on visual evidence of black deposits, pitting or other obvious surface damage. It has previously been demonstrated to be both repeatable and reproducible. All corrosion assessments were completed by a single examiner experienced in retrieval analysis.

**Measurement of head taper material loss.** We used a Talyrond 365 (Taylor Hobson Ltd, Leicester, United Kingdom) roundness-measuring machine to measure the volume of material lost from the taper surface of each femoral head. Methods for this measurement have previously been published and use a 5 μm diamond stylus to capture data from 180 vertical traces taken along the axis of the taper. The annual rate of material loss (mm³/year) was calculated by dividing the total measured volume by the duration of implantation.

**Statistical analysis.** Non-parametric Mann-Whitney U tests were performed to determine the significance of differences in the rates of corrosion and material loss at the taper surfaces between men and women. We then performed linear regression analysis to determine the relationship between the rate of material loss (mm³/year) at each MoP head taper and potential explanatory variables of time to revision, age, acetabular component inclination, and gender.

We confirm that all investigations were conducted in conformity with ethical principles of research, that informed consent for participation in the study was obtained and that institutional approval of the human protocol for this investigation was obtained.

**Results**

**Corrosion assessment.** We found that approximately 45% of the MoP head tapers had no evidence of corrosion (score 1), 38% were mildly corroded (score 2), 13% were moderately corroded (score 3) and 4% were severely corroded (score 4) (Fig. 1). The four tapers with signs of severe corrosion all had evidence of black surface.

**Table I.** Implant and patient demographic data for the MoP hips. Median and range (where applicable) values presented.

| Characteristics                  | Values          |
|----------------------------------|-----------------|
| Gender (M:F)                     | 74:20           |
| Age at primary surgery (yrs)     | 57 (30 to 76)   |
| Time to revision (mths)          | 213 (2 to 324)  |
| Head size (mm)                   | 38              |
| Trunnion design                  | 14/16           |
| Inclination (°)                  | 52 (17 to 76)   |
| Reason for revision              | Loosening of the acetabular component and stem (n = 29); loosening of the acetabular component (n = 58); infection (n = 7) |

Leica Microsystems, Wetzlar, Germany.

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deposits. The median (range) corrosion score of the head tapers was 2 (1 to 4). There appeared to be minimal surface damage (corrosion score 1 or 2) in 93% of stem trunnions with a median corrosion score of 1 (1 to 3). Comparison of corrosion scores between taper and trunnion, in the 29 cases where both components were retrieved, revealed that there was no significant difference between the two component surfaces (p = 0.282).

**Material loss measurement.** The median volume of total material loss measured at the MOP head taper surfaces was 1.45 mm$^3$ (0 to 4.53). The median rate of material loss annually was 0.084 mm$^3$/year (0 to 0.239) (Fig. 2).

**Statistical analysis of influencing MOP variables.** The median rate of material loss at the MOP head taper was 0.081 mm$^3$/year (0 to 0.239) in men and 0.0845 mm$^3$/year (0 to 0.165) in women. This difference was not statistically significant (p = 0.89) (Fig. 3).

We found a weak negative correlation between patient age at the time of the original arthroplasty procedure and rate of taper material loss ($r = -0.2307$; $p = 0.033$) (Fig. 4). There was no correlation between the time to revision and rate of material loss ($r = 0.0075$; $p = 0.9452$). Similarly, we did not find any significant correlation between acetabular component inclination and rate of material loss ($r = -0.0834$; $p = 0.5263$).

**Discussion**

This study is one of the first retrieval studies to quantify the volume of material loss from the taper junction of a large number of retrieved MOP hips of a single design. We found that the annual rate of taper material loss was considerably less than 1 mm$^3$/year and a large percentage (84%) of head tapers presented evidence of little to no corrosive damage. Similarly, we observed minimal levels of corrosion on the corresponding stem trunnions that were retrieved.

Corrosion or other surface damage will result from the exposure of metal components to the environment of the human body. It is important therefore to distinguish between levels of material loss that result in changes to patient outcome and levels that are not of clinical consequence. No adverse tissue reactions were reported for...
the cases in this study, suggesting that the level of trunnionosis quantified was clinically insignificant. It is difficult to define a specific volume of metal that may be released from the taper junction before a clinical effect is detected; indeed, individual patient response is likely to play a considerable role in defining clinical relevance. Our study contributes to this discussion by helping improve the understanding of what may be acceptable levels of material loss and corrosion.

MOP THAs have been used worldwide for several decades, however, reports of trunnionosis in these implants have only become prevalent in recent years. It may be argued that this problem has always existed but improvements in imaging techniques and knowledge gained from LD-MOM implants have made detection of this phenomenon easier. Indeed, it was suggested by Whitehouse et al. that the clinical presentation of taper damage in MOP hips is at risk of being misdiagnosed as infection.

Another explanation is that the increase in reported problems may be due to design changes introduced at the head-stem junction in contemporary hip implants. The implants investigated in the current study were introduced in 1986; these were found to have low corrosion damage scores and median rates of material loss (0.084 mm$^3$/year) at the taper junction with no evidence of adverse tissue reactions after approximately 20 years of use. In contrast, Whitehouse et al. presented a consecutive series of 17 contemporary MOP implants that were all revised within a median of 47 months due to adverse local tissue reactions resulting from corrosion at the taper junction.

The lower severity of taper damage of the MOP hips in the current study in comparison with the previous study may be explained by considering the design differences between the two groups: the 14/16 trunnions in the current study were thicker than the 12/14 stem trunnions in the previous study; the engaging length of the trunnion was longer in the current study (14 mm versus 10 mm); the trunnion surface in the current study is macroscopically smoother than the surface of the contemporary stems; and the implants in the current study employed a single CoCr alloy at the taper junction, rather than a titanium (Ti) stem with CoCr head.

It has previously been reported that mixing of alloys at the head-stem junction, most often with Ti/CoCr combinations, leads to a process of galvanic corrosion whereby one surface is preferentially corroded over the other. In these cases, retrieval evidence has shown that the CoCr head is corroded by the Ti stem with chromium-rich black deposits found on the head taper surface and signs of imprints of the trunnion-threaded surface. We therefore speculate that the use of a single CoCr alloy for both the stem and head in the current MOP hips is likely to have minimised the corrosion that may otherwise have occurred. It is acknowledged that the majority of surgeons in the United States will utilise a Ti-alloy stem with a CoCr head and that the CoCr-CoCr head-stem junction is less common. However, the results of this study help add to the discussion of the influencing factors behind clinically significant levels of trunnionosis seen in MOP hips; the material and design combination used at the head-stem junction may be key to controlling corrosion and material loss.

It has also been shown previously that shorter, rougher trunnions increase the risk of taper damage. The design of the comparatively longer, smoother trunnion surfaces in the current study may therefore help explain some of the low volumes of material loss observed, due to a distribution of contact stresses over a larger surface area.

Our analysis of taper retrieval findings with clinical data found that patient age at the time of primary arthroplasty was a significant negative predictor of trunnionosis severity; younger patients appeared to have more material lost from the taper surface. These findings may be explained by considering younger patients as being more physically active, thereby transferring greater stresses to the junction, however, there are many other confounding variables, such as body mass index, which may influence this and should be explored in future work.

We acknowledge the limitations of this study. Only one implant was investigated with a taper junction material combination that is not widely used, however, our findings may inform future designs. Additionally, imaging protocols similar to MOM hips may have detected some form of adverse reaction, although all were asymptomatic.

In conclusion, we have reported our findings of trunnionosis in a series of 94 retrieved large-diameter MOP hips. We found that trunnionosis does occur in these hips but the annual rate of material loss was notably less than that of previously reported MOM taper junctions. No adverse tissue reactions were reported by the revising surgeons, suggesting that the level of trunnionosis in this study may be clinically insignificant.

We speculate that the lower severity of trunnionosis may be due to the use of a single CoCr alloy at the taper junction, and a trunnion design that has a long engaging length, a smooth surface topography and a larger diameter compared with contemporary 12/14 trunnions.

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C. Lausmann: Study design, Data interpretation, Manuscript writing.
J. Henckel: Study design, Data interpretation, Manuscript writing.
T. Gehrke: Study design, Data interpretation, Writing the paper.
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A. Hart: Study design, Data interpretation, Manuscript writing.

ICMJE Conflicts of Interest
None declared.