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Title: **Component Size Mismatch Of Metal On Metal Hip Arthroplasty: An Avoidable Never Event**

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**Introduction**: Recent advances in hip replacement design, in particular the trend towards greater modularity in hip systems, have increased the risk of component size mismatch (CSM). CSM occurs when incorrectly sized femoral heads and acetabular cups are coupled together or when the dimensions of the paired stem trunnion and head differ to that intended by the manufacturer.
CSM is a serious, preventable patient safety incident of which the true prevalence is unknown as many cases are not detected. Retrieval analysis of failed MOM hip implants may offer a better understanding of how often CSM occurs and how it affects the integrity of the implant.

**Objectives**: Our aims were to: a) determine the prevalence of CSM in our retrievals; b) to investigate the tribological effects of CSM on the hip system and c) to identify ways of reducing this avoidable never event.

**Methods**: We performed an analysis of clinical data, imaging and retrieved implants to quantify the prevalence, type, clinical effects and cause of component size mismatch in a series of 1200 failed metal-on-metal (MOM) hips.
The laser markings on the retrieved components were used to identify their sizes and therefore determine if CSM had occurred. When CSM was suspected, physical re-assembly was performed to confirm this. Detailed macroscopic and microscopic inspection of the components was performed using a Leica M50 microscope at x40 magnification. An assessment of the corrosion of the taper surface in the case of taper CSM was performed using a peer-reviewed semi-quantitative visual corrosion scoring method [Goldberg et al. 2002].
Measurement of material loss at the bearing surfaces of CSM hips was carried out using a Zeiss Prismo (Carl Zeiss Ltd, Rugby, UK) Coordinate Measuring Machine (CMM). Material loss at the head taper junction in an example of taper CSM was measured using a Talyrond 365 (Hobson, Leicester, UK) roundness measuring machine.
To determine the effectiveness of plain radiograph as a tool for detecting CSM, 6 orthopaedic consultants and senior trainees were asked to examine a series of 10 X-rays of failed MOM hips (CSM=3) and identify the suspected cause of failure. All reviewers were blinded to the reported cause of failure and all other clinical data.
We performed a root cause analysis of factors that can contribute to CSM using a systems approach to error analysis.

**Results**: Component size mismatch occurred in 11 cases (0.9%) with the majority at the bearing surface (n=10) and one at head-stem taper junction. Cobalt or Chromium blood metal ion levels were elevated above the MHRA action level of 7ppb in all cases of mismatch and material loss at the bearing surfaces (bearing CSM) ranged from 5.7 mm3/year to 57 mm3/year.
3 out of 6 clinicians detected 1 out of the 3 cases of CSM on X-Ray. One respondent identified 2 out of 3 cases of CSM. The remaining 2 respondents failed to notice CSM on X-Ray, giving a 27.7% mean detection rate. In the case of taper CSM, the head surface was found to be severely corroded. Distinct circumferential wear scars were observed on cup surfaces (n=7), with prominent boundaries between worn and unworn regions
Root cause analysis identified manufacturer, hospital and surgeon factors that need to be addressed to reduce the incidence of this avoidable clinical problem.

**Conclusions**: Component size mismatch should be considered in patients with unexplained high metal ion levels following metal on metal hip arthroplasty. Analysis of retrieved components is the only method of confirming size mismatch and its incidence is likely to be under-represented in National Joint Registries.