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Component Size Mismatch of Metal on Metal Hip Arthroplasty: An Avoidable Never Event

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ABSTRACT

Size mismatch of components used in total hip arthroplasty is a serious, preventable patient safety incident of unknown prevalence as many cases are not detected. Component size mismatch was found in 11 cases (0.9%) at our retrieval centre. All cases of mismatch were not detected on plain radiograph during routine clinical follow up and blood metal ion levels were elevated above the MHRA action level of 7 ppb. Root cause analysis identified manufacturer, hospital and surgeon factors that need to be addressed to reduce the incidence of this avoidable clinical problem. Retrieval analysis is the only method of confirming size mismatch and is likely to be under-represented in National Joint Registries that record the indication for revision at the time of revision.

NHS Never Events are described as "serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented" [1]. Component mismatch of orthopaedic implants is one of these Never Events. The NHS Department of Health Never Events list 2012–13 categorises this error under the wrong prosthesis category with "surgical placement of the wrong implant or prosthesis where the implant/prosthesis placed in the patient is other than that specified in the operating plan either prior to or during the procedure."

This century has seen a global drive to increase safety in healthcare and to create a culture of patient safety. In the UK, clinical governance helps minimise adverse healthcare events. Yet a study by Vincent et al showed that adverse events occur in approximately 10% of patients treated in the NHS, which cause serious consequences to patients and are a considerable drain on resources [2]. Indeed the recent publication of the Francis report [3] increased public awareness of the possibility of substandard care and patient safety incidents.

A 2009 review of the Reporting and Learning System (RLS) from the National Patient Safety Agency (NPSA) showed that Trauma and Orthopaedics was the surgical specialty with the largest proportion of Patient Safety Incidents (PSIs) (32.6%) [4]. Component size mismatch (CSM) is an avoidable complication in hip arthroplasty surgery resulting in both clinical implications for patients and financial ramifications for the healthcare systems [5]. The 2013 National Joint Registry showed that 62 out of 9676 revisions had taken place due to CSM of the head–acetabular socket (0.64%) [6]. Recent advances in hip arthroplasty design, in particular the trend towards greater modularity in hip systems, have increased the risk of CSM. Therefore there is a need for greater vigilance from the orthopaedic community regarding this complication. In addition to mismatch between the femoral head and acetabular cup, CSM can also occur at the taper junction between the femoral head and the trunnion stem (Fig. 1), although the incidence of this is unknown.

CSM should not be confused with "mixing and matching" of components from different device manufacturers [7]. It seems to have escaped the attention of published reports with only one documenting the higher wear associated when a larger femoral head was used in a metal on polyethylene design and one case study of two patients with CSM which showed the follow up at 12 and 30 months [6,7]. CSM has not been the focus of any report on metal on metal (MOM hips) and joint registries remain the only method of estimating the occurrence of MOM CSM. There are no published reports on how to detect CSM and only two reports that give any recommendations on avoidance [8,9], although these were not in metal-on-metal systems. 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 solutions to avoid this never event.

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The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2014.03.008.

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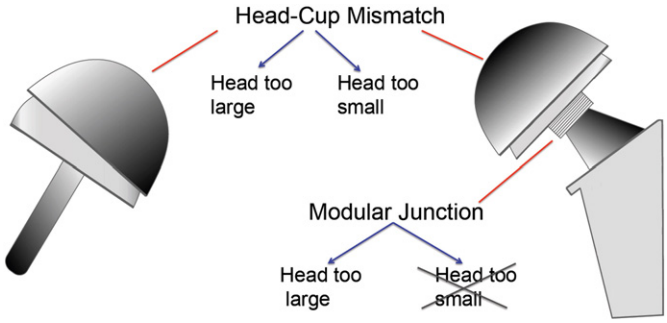

Fig. 1. Schematic demonstrating how bearing and taper CSM may occur.

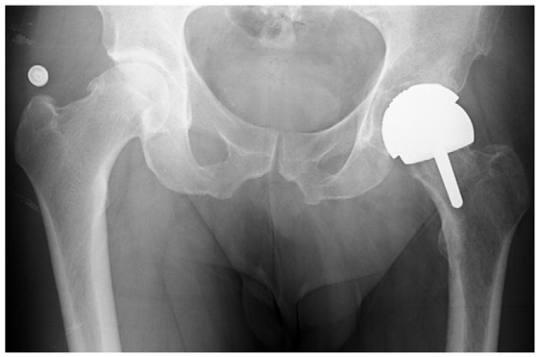

Fig. 2. Plain radiograph of BHR resurfacing with an oversized head.

Methods

Assessing the Prevalence of CSM

We reviewed a consecutive series of 1200 failed MOM hips for possible CSM. These hips were received at our implant retrieval centre from 38 contributing hospitals between 2008 and 2013. We then interrogated the clinical data, operative details from the revision surgery and pre-revision imaging data on the implants labelled as CSM to determine at what stage CSM was detected and how it was detected.

Investigating the Tribological Effects of CSM

Detailed Inspection of the Retrieved Components

All components were photographed on receipt at the retrieval laboratory using a Canon 650D DSLR camera. They were decontaminated and the laser etched referenced numbers were entered into our database. A review of the prevalence of CSM in the hips at our centre was performed by two examiners, experienced in retrieval analysis. When CSM was suspected from examination of component reference numbers, physical re-assembly was performed, with particular caution taken not to remove surface features of bearing and taper junction surfaces. Detailed macroscopic and microscopic inspection of the components was performed using a Leica M50 microscope at × 40 magnification for retrieval features, such as scratches and circumferential wear scars near the equator of the cup.

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 [10].

Measurement of the Bearing Surfaces

To investigate how CSM affected the wear characteristics of the implant, measurement of the volume of material loss from both bearing surfaces was performed. We chose five implants to represent the spectrum of the problem. These implants were selected for detailed surface measurements as they represented examples of the three types of CSM that may occur: (1) an over-sized head; (2) an under-sized head and (3) a size mis-match at the taper junction. Measurement of material loss from the cup and head bearing surfaces was carried out using a Zeiss Prismo (Carl Zeiss Ltd, Rugby, UK) Coordinate Measuring Machine (CMM). Measurements were carried out using a 2 mm ruby stylus at a measurement speed of 3 mm/s using a previously described measurement protocol that has been optimized for accuracy and minimizes measurement uncertainty [11]. The total number of data points obtained for each component was up to 300,000, dependent on the component diameter and angular coverage. The measurement data were analysed through use of an iterative intelligent least square fitting operation. The data were segmented so that only the unworn geometry was used in the fitting process, and through use of a fitting histogram this was optimized such that the surface fitting standard deviation was minimized. This method is robust against phenomena such as edge wear, which can adversely affect fitting and thus wear measurement [11]. This method allows for accurate repeatable determination of the unworn component geometry, thus allowing direct determination of the magnitudes of linear and volumetric wear and accurate mapping of the material loss distribution.

Measurement of the Taper Surfaces

The volume of material loss at each of the head taper surfaces was then measured using a Talyrond 365 (Hobson, Leicester, UK) roundness measuring machine, using previously published methods [11]. Vertical measurement traces were taken along the taper axis using a 5-micron diamond stylus. The vertical traces from each head taper were combined into a rectangular surface map and the unworn surface on the taper was manually selected in order to level the data obtained. A generated Abbott–Firestone curve was then used to calculate the volume of material loss of the digitally regenerated taper surface, taking into account its conical shape.

Identifying Solutions to Avoid CSM

Root Cause Analysis

We performed a comprehensive analysis of factors that can contribute to CSM using a systems approach to error analysis [12]. Manufacturer, hospital, surgeon/individual factors were explored and we identified potential defences, barriers and safeguards that could be implemented to minimise the occurrence of mismatch.

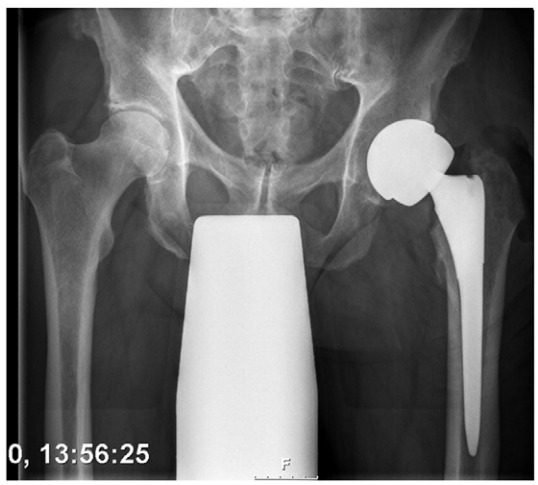

Fig. 3. Plain radiograph of a modular BHR with an oversized head.