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### Wear



journal homepage: www.elsevier.com/locate/wear

## Quantifying the wear of acetabular cups using coordinate metrology

Ben Morris<sup>a</sup>, Lifong Zou<sup>b</sup>, Matt Royle<sup>c</sup>, David Simpson<sup>d</sup>, Julia C. Shelton<sup>c,\*</sup>

<sup>a</sup> Barts and The London School, School of Medicine and Dentistry, London, UK

<sup>b</sup> Center for Adult Oral Health, Institute of Dentistry, Barts and The London School of Medicine and Dentistry, London, UK

<sup>c</sup> Queen Mary University of London, School of Engineering and Material Science, Mile End Road, London E1 4NS, UK

<sup>d</sup> Corin, Cirencester, UK

#### ARTICLE INFO

Article history: Received 13 October 2010 Received in revised form 18 March 2011 Accepted 10 May 2011 Available online 17 May 2011

Keywords: Hip prostheses Wear measurement CMM Coordinate metrology Metal-on-metal

#### ABSTRACT

In an ageing population where individuals demand a pain free and active existence, hip arthroplasty has become one of the most important operations of later life, with developments increasing the longevity of this prosthesis. Accurate assessment of wear is an important way to assess how well hip prostheses perform over time. This paper describes a new protocol to accurately locate and map the wear of acetabular cups. 16 metal-on-metal acetabular cups were tested in a hip simulator for up to 6 million cycles at a range of angles of inclination in order to create a large range of wear volumes. Unworn and worn regions of acetabular cups were digitised in two separate scans using a CMM. The two scans were superimposed in order to allow calculation of maximum depth, wear volume loss and rim damage. Values obtained from the CMM protocol (CMM) were compared to the wear volume determined gravimetrically (G); a strong correlation (CMM = 0.992G-0.504) was established. The CMM protocol established was shown to be a methodology more powerful than many existing geometric protocols which could be used to assess explants and implants tested *in vitro*.

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#### 1. Introduction

Joint arthroplasty has improved significantly over the last 50 years to become one of the most successful operations in medical practice [1], bringing pain relief for many patients suffering from diseases and disorders of the hip. Modern metal-on-metal (MoM) total hip arthroplasty has been performed since the 1960s, with devices such as the McKee-Farrar being the predicates for today's modern MoM bearings [2]. However, despite the long history, many drawbacks have been found, the most serious of these being the risk of failure over young patients' lifetimes [3] due to a range of factors including the expanding patient population, increasing life expectancies and greater complexity of cases. An additional problem with MoM hip prostheses, particularly hip resurfacing arthroplasty, is metallosis, hypersensitivity and the possible development of pseudotumours [4]. The revision rate after three years for young patients can be as high as 4.5% and increases to 6.6% in patients over 65 [5]. This may therefore be considered a suboptimal treatment option for the 18% [6] of patients who are under 60 years old and require hip surgery, as well as the older patient population; for these patients prostheses with longer lifetimes are required. Many factors, such as roughness and shape of the articulating surfaces, clearance and material of the bearing surface influence the longevity of the prosthetic hip.

Quantification of wear is an essential part of understanding why prostheses fail in vivo. Quantifying the extent of wear of the acetabular component and thereby understanding wear processes is one way of analysing the cause of failure retrospectively, and ultimately will support improvements in the design of new generations of prostheses. Wear measurements in vitro have been published using both gravimetric [7] and geometric [8] analysis, as well as by looking at wear particles and ions levels in the lubricant [9]. In vivo, the only real indicator of wear of metal components is by determining the metal ion levels in blood serum or urine [10]; plain X-ray films are useful in diagnosing infection, loosening and bone deformities [11] but wear cannot be readily quantified due to the insufficient resolutions of the technique. Retrieval analysis of components must use geometric analysis, as the original mass is often unknown and bone tissue or other material is often firmly attached to or ingrown into the retrieved specimens.

*In vitro*, gravimetric analysis involves weighing the prosthesis before and after the component has been tested in a hip simulator; the volumetric loss is established using the component's material density. However, the mass difference detected is often a few milligrams in components that are typically 200–300 g in mass [12,13] and therefore detecting the difference can be difficult and prone to experimental error. As the lubricant used in the hip simulator is normally diluted foetal calf serum, proteins are deposited on the surface of the components, and it has recently been suggested

<sup>\*</sup> Corresponding author. Tel.: +44 20 7882 8877; fax: +44 20 7882 5532. *E-mail address*: j.shelton@qmul.ac.uk (J.C. Shelton).

<sup>0043-1648/\$ –</sup> see front matter 0 2011 Elsevier B.V. All rights reserved. doi:10.1016/j.wear.2011.05.014

that other surface changes may also occur [14]. Although correction factors have sometimes been utilised [15] the changes remain small and detecting the true wear of the bearing surface is difficult. Components which are tested in adverse conditions such as at a high angle of inclination or including lateralisation, may exhibit extra-articular wear or rim damage. In these situations gravimetric analysis will over estimate the wear of the bearing surface, and details of where the damage actually occurs can be missed.

Geometric analysis is one of the most versatile forms of analysis as it not only quantifies the wear, but identifies the location and its corresponding wear depth precisely. With the correct methodology, the same protocol can be used to assess prostheses tested in vitro as well as those from explants. Methodologies reported in the literature use out of roundness (OOR) machines or coordinate measuring machines (CMM). OOR protocols have been reported to provide a resolution of 10 nm [16]. However, although 3D reconstruction is possible, it is often lengthy [17]; the calculation of volumetric wear from maximum depth has been reported [18], but the paper makes assumptions about the size and shape of the wear scar. The method is therefore not applicable with all wear scars, for example, where scars approach the acetabular rim, or scars that have resulted from the component impinging or subluxing, such that they are not circular. CMM protocols have the benefit of being able to locate the wear scar and map the depth, thereby generating the volume loss; these have been used in retrieval analysis [19] as well as in vitro testing [20]. However, CMMs have been traditionally been less accurate than OOR machines [21], and the process has been reported to take longer [22]. The speed of recording has been an issue in previous studies as unworn sections have been mapped to a sphere of best fit by manually altering the size of the sphere until an optimum fit is obtained. In addition, the rim of the acetabular cups are often excluded from OOR protocols [16] and previous CMM protocols [19] as knowledge of the virgin rim is seldom known, therefore calculating changes here is difficult.

In this study, we propose a three-dimensional coordinate surface measurement methodology to quantify the wear of hip prostheses using a methodology to maximise the performance of the digitisation process, reducing the uncertainty and cancelling the positioning error of the CMM; thereby giving an accurate measurement for wear depths of less then 3  $\mu$ m. The methodology must satisfy the following criteria: (1) accurately locate the wear scar; (2) accurately map the dimensions and depth of the scar; (3) distinguish between wear and plastic flow of the material. Moreover, this study aims to validate the methodology by comparing geometric with gravimetric results, which is currently the gold standard for wear measurement.

#### 2. Materials and methods

#### 2.1. Components

Thirteen 40 mm diameter and three 48 mm diameter MoM hip replacement components (high carbon Co–Cr–Mo alloy to ASTM F75) supplied by Corin (Cirencester, UK) were tested on an eight orbital station hip simulator (MTS Systems, USA) for up to 6 million cycles. A wide range of wear volumes were generated, due to differing bearing surfaces, altering the cup angle of inclination (35°, 50° and 60°), and changing the number of test cycles.

#### 2.2. Calibration and reproducibility of the CMM

A coordinate measuring machine (CMM) (Insice, Renishaw, UK) was used to evaluate the components following the completion of wear testing. A spherical 1.000 mm diameter silicone nitride stylus was selected to digitise the articulating surface of the cups.

A UKAS standard sphere of 50.000 mm diameter (certificate number 45382) was selected to carry out the reproducibility test, as the size of the sphere covers the size of the research object, a 48 mm diameter hip cup. This standard sphere has the geometric property of the hip cup, which is competent to represent the dynamic scanning process.

This standard sphere was scanned three times, removing and relocating the sphere between scans. The scanning sampling interval was 0.1 mm and motion of probe was uni-direction in +X of the axis system, scanning speed was set to be 500 mm/s to be inline with the scanning strategy that was employed for the hip components. The maximum difference from the three digitised images was found to be 0.0031 mm, resulting in a volumetric reproducibility of 0.3 mm<sup>3</sup>. As this is calculated over a much larger area than the small wear scars analysed in this study, so this reproducibility of the wear scar volumes will be much lower than this.

The quoted uncertainty of the CMM used is 0.020 mm, however, with the methodology described a much lower effective resolution and reproducibility was obtained.

#### 2.3. Measurement methodology

The cup was mounted in a putty fixture (Extrude, type 0, Germany) allowing it to be solidly attached to the base plate of the scanner and tilted to 45°, Fig. 1. Following visual inspection the worn area was identified by two independent observers, as the surface texture changed and reflection of white light differed from the unworn surface. The cup was not scanned before wear testing as the methodology would then not be transferable to explant analysis. The cup was positioned on the fixture with the wear scar at the lowest point in the measurement sphere of the CMM, thus allowing the maximum number of data points to be collected in this area of interest. Two scanning steps were carried out, scan 1 was performed over more than half the cup which contained the wear scar by taking traces in a single direction at a speed of 500 mm/min with a sampling interval of 0.100 mm, as previously described in [23]. A slower speed of 200 mm/min was also attempted, no difference between the two speeds was noted. This was followed by a 2nd scan, of more than half the cup, Scan 2, which was taken following a rotation of the component by 135° about its axis of symmetry to an unworn section of the cup, see Fig. 2a. This scanning strategy ensured that the systematic positioning uncertainty in each digitised co-ordinates in the two scans were identical. The room temperature was maintained at  $21 \pm 5$  °C.

#### 2.4. Image analysis and registration

Using a 3D image analysis software package (Cloud, UCL, UK), scan Images 1 and 2 for each component were registered and subtracted to obtain the difference between the two surfaces which could be interpreted as volume loss due to wear.

From scan Image 1, unworn areas were selected by manually painting the area around, but not including the wear scar (shown in Fig. 2b where the light yellow colour area is the 'common' area (for interpretation of the references to color in this text, the reader is referred to the web version of the article)). The rim is also included as it is a critical feature. Within the common area, based on mathematical least square fit, in the registration procedure using the Iterative Closest Point (ICP) algorithm the two surfaces were superimposed; at this superposed position the difference along the vector of the surface at each digitised point was then calculated and displaced on the computer screen corresponding to the position where the cursor was positioned on the image.

In order to assess the reproducibility of the software, the first cup was analysed five times. The volume loss generated ranged Download English Version:

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