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Effect of increased load on the wear of a large diameter metal-on-metal modular hip prosthesis with a high inclination angle of the acetabular cup

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ABSTRACT

In some earlier hip simulator studies of large-diameter metal-on-metal (MoM) hip prostheses high, unexplained variation in wear has been observed. In the present study it was found that high variation occurs when the tribological endurance limit of the MoM device in question is being approached. When the limit is exceeded, high wear takes place uniformly, and the variation is low. Below the limit, both the wear and its variation are low. The endurance limit was exceeded by increasing the peak load from 2 kN to 3 kN, to simulate obesity. The acetabular cup inclination angle was high, 70°. Potential clinical wear problems can be predicted by hip simulator studies provided that relevant adverse test conditions are included.

1. Introduction

In a metal-on-metal (MoM) hip prosthesis, a femoral head made from CoCr alloy slides against an acetabular cup made from the same alloy. They form a ball-in-socket joint. Under normal hip simulator test conditions simulating level walking of a typical patient, with optimal position of the acetabular cup (abduction 45°, anteversion 20°), the large-diameter metal-on-metal prostheses show low wear, typically of the order of 1 mg/10^6 cycles [1–6]. In some hip simulator studies on large-diameter MoMs, the wear was usually reasonable but sometimes high wear occurred in a minority of the prostheses [7,8]. Presently, the poor clinical wear performance of the large-diameter MoMs [9,10] is considered the largest disaster in the history of not only arthroplasty but of the entire orthopaedics. The situation may be partly due to the fact that adverse condition testing was not performed (no published adverse condition hip simulator studies exist from the time of the wide introduction of the large-diameter MoMs, the late 1990s and early 2000s). Although the MoMs are no longer implanted in large numbers it is important to thoroughly unravel the causes of their tribological failure, so that the mistakes will not be repeated in the future. It is quite possible that someday, perhaps a decade or two from now, the MoM will make a comeback once again, in one form or another.

A high inclination angle of the acetabular cup (>60°) is known to be detrimental for the wear behaviour of the MoMs [9,11–15], due to the edge contact and the consequent failure of the fluid film lubrication [3,16]. In the present study, an extreme inclination angle of 70° was used. It was hypothesised that the high variation in MoM wear is due to the fact that the conditions approach the tribological endurance limit of the MoM device in question. Regarding the tribological behaviour of prosthetic joints, the endurance limit is defined here as a combination of (a) device-related parameters such as diameter, clearance, sphericity of bearing surfaces, and the arc of cup coverage, and (b) operation conditions, such as load, inclination angle of cup and type of relative motion. Above the limit the tribological behaviour of the device is unacceptable, i.e., wear and friction will inevitably – not only occasionally – be so high that serious damage to the patient and early failure of the arthroplasty would result. Well below the limit, the wear and its variation are low [1–3]. In the present study, the limit was being approached with a combination of 2 kN peak load and 70° inclination angle. Variation of wear was high. The limit was clearly exceeded when the peak load was increased to 3 kN. This value simulated obesity [17]. Wear was high and linear and its variation was low. In other words the tribological endurance limit of the MoM device in question was exceeded under the test conditions used.

2. Materials and methods

The 12-station HUT-4 hip joint simulator, the fixation and alignment of the specimens, the test procedure and the method of MoM wear measurement have been described elsewhere [1–3].

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Test 1 was run with three similar 52 mm diameter Metasul (Protasul-21WF, wrought-forged, high-carbon CoCr alloy, ISO 5832-12) MoM bearings with a diametral clearance of 0.16 mm. They were manufactured in the early 2000s by Centerpulse Orthopaedics Ltd. (Switzerland). The type of cup was Durom, introduced in 2001, and it was sub-hemispherical (165°). The cup inclination angle in the test was 70° (abduction 66°, anteversion 32°, Fig. 1). According to the definitions by Murray [18], these three angles corresponded to the anatomical inclination, operative inclination, and operative anteversion, respectively. The motion of the modular femoral head was biaxial consisting of sinusoidal flexion–extension (range 46°) and sinusoidal abduction–adduction (range 12°) that had a phase difference of $\pi/2$ [19] in order to produce a multidirectional relative motion [20]. The absolute value of the relative angular velocity during a gait cycle varied between 0.7 rad/s (heel strike and toe-off) and 2.7 rad/s (middle of stance and swing phases).

The loading direction was vertical, and so the load vector was at an angle of only 20° to the plane of the cup rim. An inclination angle higher than 70° would make the joint unstable, as the friction caused by the abduction of the head during the second (toe-off) load peak moves the contact point even closer to the cup edge [1]. The maximum value of the double-peak load cycle was 2.0 kN (minimum 0.3 kN, average 1.2 kN). The cycle frequency was 1.06 Hz, and the test length was 3 million cycles. The lubricant was HyClone Alpha Calf serum SH30212.03 diluted 1:1 with Milli-Q grade distilled water, so its protein concentration was 20 mg/ml. No additives were used. The amount of lubricant in the test chamber was 500 ml. The taper fixation surfaces of the femoral heads were isolated from the lubricant by silicone sealant. The test was run at room temperature 25 °C. In test 2, the maximum value of the double-peak load cycle was increased to 3.0 kN (minimum 0.4 kN and average 1.9 kN). Otherwise, the test conditions were as in test 1. Test 2 was run with three similar 50 mm diameter Metasul MoM bearings (52 mm diameter was unavailable as the components were no longer on the market).

The wear was evaluated from the Co and Cr concentrations of the used lubricant analysed by atomic absorption spectroscopy (AAS) and inductively coupled plasma atomic emission spectroscopy (ICP-AES) as described elsewhere [1–3,21]. At intervals of 0.375 million cycles on the average the test was stopped, and the test chambers and the specimens were removed. The lubricant was thoroughly mixed, its volume was measured and two 20 ml samples were taken. After this the specimens and their holders were cleaned and the test was continued with fresh lubricant. The first 375,000 cycles was considered running-in.

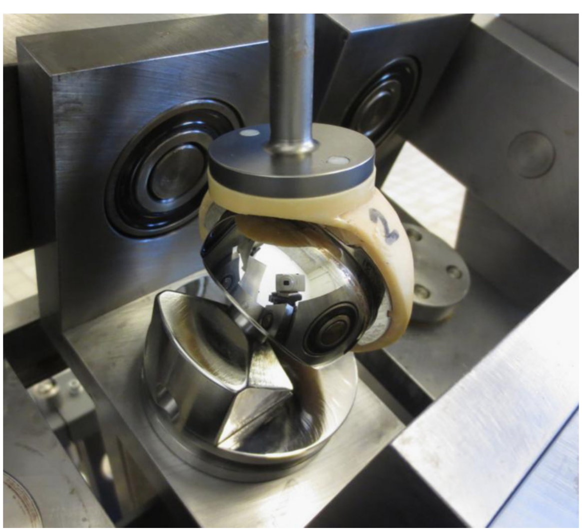

Fig. 1. Close-up of test station no. 2 of HUT-4 hip joint simulator showing 50 mm diameter Metasul MoM hip installed, without lubricant chamber. Gait of right hip is simulated. Durom acetabular cup is cemented to a position of 70° inclination (66° abduction, 32° anteversion). At this moment, i.e., maximum extension (outer cradle) and neutral abduction–adduction (inner cradle) of the femoral head, and maximum load of the second (toe-off) load peak (vertical loading bar above the joint), high friction almost dislocates the joint as the motion is momentarily purely abduction of head. Hence, 70° proved to be close to the highest possible inclination angle that could be run with.

The roundness of the components was measured with a Talyrond 31c apparatus. Maximum inscribed method was used with the cups, and minimum circumscribed method with the heads. Hence the out of roundness values obtained reflected the magnitude of linear wear (depth of the wear pit). The cups were measured near the rim and on a plane parallel to the rim. Considering the arc of coverage of Metasul cups, 165°, and the rounding of the edge, the measurement took place approximately along the 10° latitude. Since the direction of load was at an angle of 20° to this plane, it was estimated that the linear wear was 94% (cos 20°) of the out-of-roundness value. The heads were measured approximately along the 45° latitude so that the stylus traversed the centre of the wear mark. Since the direction of load was at an angle of 45° to this plane, it was estimated that the linear wear was 71% (cos 45°) of the out-of-roundness value.

The surface roughness R_a of the components was evaluated with a Mitutoyo Formtracer SV-C3100 contact stylus instrument using an evaluation length of 0.4 mm and a sampling length of 0.08 mm. The R_a values were measured on the centre of load bearing surface in the direction of abduction–adduction after the wear tests.

3. Results

Squeak did not occur in test 1 but it was common in all three stations in test 2, in which the darkening of the serum was conspicuous (Fig. 2). In test 1, the serum temperature was on the average 5 °C, and in test 2, 16 °C above the room temperature due to frictional heating. In both tests, the contact on the cup was bordered by the edge. High variation and non-linearity in wear was observed in test 1 (Fig. 3a). A general trend was that the wear rate decreased with increasing number of cycles. The highest wear rate was

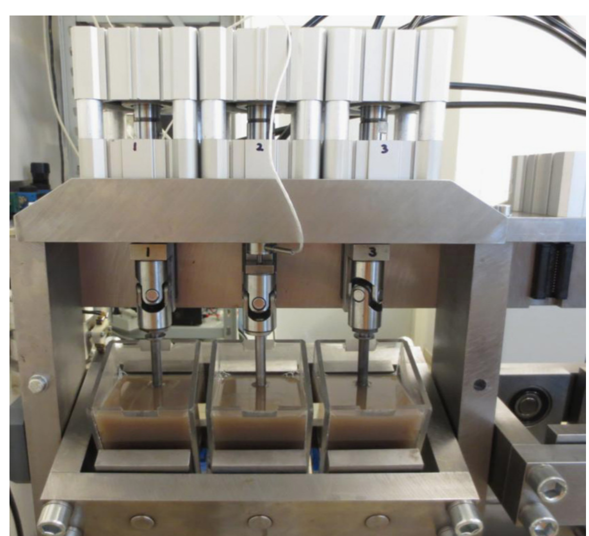

Fig. 2. Test stations 1 to 3 of HUT-4 hip simulator after 3 million cycle test with three 50 mm Metasul MoMs, 70° inclination of cup, and 3 kN peak load. Note pneumatic double-piston loading system capable of increased loads up to 6 kN per station, load cell in station 2, universal joints making acetabular cups self-centring on femoral heads, and uniform darkening of serum lubricant due to high wear.