Tribology International 60 (2013) 70–76

Contents lists available at SciVerse ScienceDirect

Tribology International

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

The effect of acetabular cup position on wear of a large-diameter metal-on-metal prosthesis studied with a hip joint simulator

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ARTICLE INFO

Article history:
Received 23 August 2012
Received in revised form
17 October 2012
Accepted 19 October 2012
Available online 29 October 2012

Keywords:
Metal-on-metal
Acetabular cup position
Abduction angle
Edge loading

ABSTRACT

Clinically, malposition of the acetabular cup in large-diameter metal-on-metal prosthetic hip designs is associated with high wear, adverse reaction to metal debris and early failure. A steep angle of the cup ($>60^\circ$) may lead to poor tribological performance. Large-diameter CoCr-on-CoCr prostheses were run in the HUT-4 hip joint simulator so that a steep angle was included. With a correct position, the tribological behaviour was excellent, the wear rate being 0.1 $mm^3/10^6$ cycles. In the steepest position, lubrication failed and the wear rate was two orders of magnitude higher. This study stresses the importance of rigorous pre-clinical testing.

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1. Introduction

Several large-diameter metal-on-metal (MoM) prosthetic hip designs have been introduced since the early 2000s [1]. In the MoM articulation, both bearing surfaces are made from a CoCr alloy. The tribology of the MoM is very different from that of the most widely used and intensively studied metal-on-polyethylene articulation. For instance, MoM is highly sensitive to the presence of a sufficient amount of protein-containing lubricant [2], for which there actually are no guarantees. MoM designs differ from each other with respect to the clearance, sphericity, depth of the cup, and CoCr alloy used. The early failure rate of one of the widely used MoM resurfacing designs has recently proved to be unacceptable [3]. The failure appears to be related to inadequate tribological performance, especially to the high amounts of metal debris produced. The wear rates measured from retrieved components ranged from 0.51 to 95.5 mm^3/year [4]. If the abduction and anteversion angles of the cup are high, as they often are [3], the contact area may be bordered by the edge of the bearing surface leading to poor lubrication and high wear.

In the present study, the effect of cup position, 'correct' (angle $<50^\circ$) versus 'steep' (angle $>60^\circ$), on the wear of a 52 mm diameter MoM design was studied using the previously validated HUT-4 hip joint simulator [5]. In the wear test, level walking was simulated, the lubricant was diluted calf serum, and the wear was evaluated by measuring the Co-concentration of the used lubricant by atomic absorption spectroscopy (AAS) and Cr-concentration by inductively coupled plasma atomic emission spectroscopy (ICP-AES). The hypothesis was that in a MoM design that performs well in the correct position, a steep cup position causes substantially higher wear, the different amounts of wear and wear rates being quantifiable by the above methods, and being in agreement with clinical observations.

2. Materials and methods

The 12-station HUT-4 hip joint simulator and the test method have been described in detail elsewhere [5]. In brief, the femoral head made biaxial rocking motion, flexion-extension (range 46°) and abduction–adduction (range 12°). The phase difference between the two motion waveforms of nearly sinusoidal shape was $\pi/2$, so the multidirectional 'polishing effect' that is necessary for the reproduction of clinical wear mechanisms was implemented. The load waveform was of a double-peak type with a maximum of 2 kN and a minimum of 0.4 kN. The direction of loading was vertical and fixed relative to the cup. The cycle frequency was 1 Hz. The prosthesis was surrounded by an acrylic chamber containing 500 ml of lubricant, which was HyClone (Logan, Utah, USA) Alpha Calf Fraction serum SH30212.03, diluted 1:1 with Milli-Q® grade distilled water (Fig. 1).

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http://dx.doi.org/10.1016/j.triboint.2012.10.011

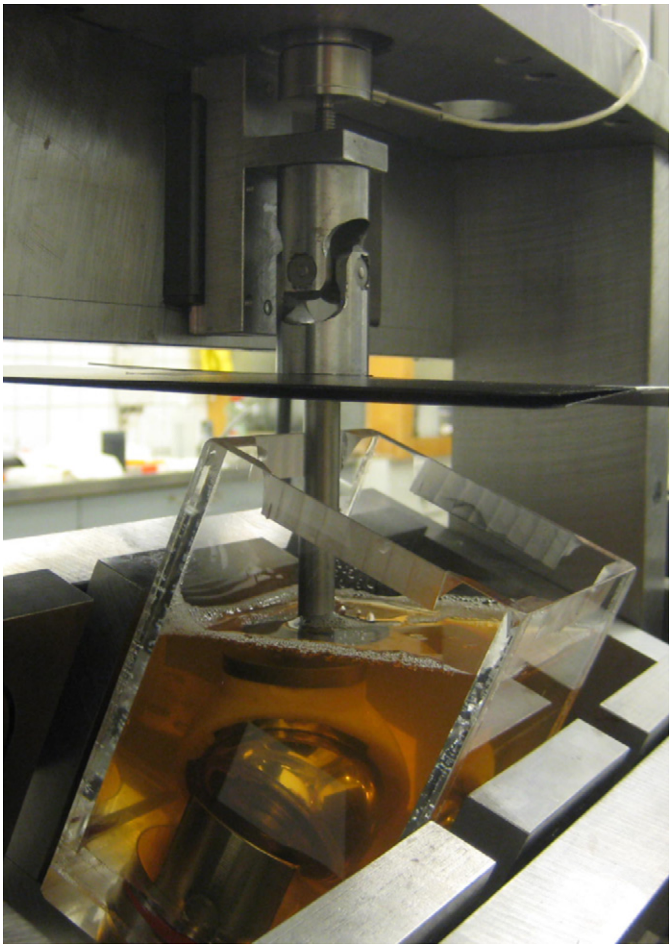

Fig. 1. Preliminary test ready for start. Lubricant chamber is filled with fresh, diluted calf serum lubricant. Cup position is 45° abduction and 20° anteversion. Direction of loading is vertical. Note load cell, linear bearing ('loading guide'), and universal joint that makes cup self-centring on head.

The protein concentration of the lubricant was 20 g/l. No additives were used in the lubricant. The lubricant and environment temperatures were monitored.

The Metasul metal-on-metal prostheses that were studied were manufactured by Centerpulse Orthopedics Ltd, Switzerland. The head and the cup with 52 mm nominal diameter of articulation were made from wrought-forged, high-carbon CoCr alloy Protasul-21 WF, ISO 5832-12. The type of cup was Durom (product number 01.00214.058, code R) having a sub-hemispheric bearing surface of 165° and a rounded edge (radius 0.5 mm) connecting the bearing surface to the flat rim. A bone cement (acrylic) mantle of 4 mm thickness was cast around the cup. The mantle had a flat loading surface (40 mm diameter) with two recesses drilled for guide pins. The cementing was done in a mold designed so that the cup was to be in a required position in the simulator with respect to abduction and anteversion (flexion) angles, and the distance from the centre of the cup to the axis of symmetry of the loading surface was 0.1 mm at most. Besides the main function, i.e., providing a practical positioning/locking/loading interface with the simulator, the additional advantages of this cementing method was that (a) the porous titanium outer surface (Fig. 2), designed for fixation by bone ingrowth, was completely and tightly covered, and thus isolated from the test (there was no micromotion of the Ti-coating against anything, and all surfaces were smooth and therefore easy to clean), and (b) it did not deform the cup (see below), the thickness of which was 4 mm only, in curing-shrinkage because the only deviation from the hemispheric form of 68 mm

Fig. 2. Fixation surface of Durom cup. Porous Protasul-Ti coating, flattened pole, and flare with sharp fins.

outer diameter was the flat loading surface. At the point of load application, the cement thickness was 3 mm.

The large head (product number 01.00181.520, code R) of the Metasul system was fixed to the femoral head holder using a 12/14–18/20 double-taper adapter (product number 01.00185.146, size M) and a double-taper pin, both made from CoCr by Centerpulse Orthopedics Ltd., Switzerland. The neck angle of the head holder made from stainless steel was 45°. All conical fixation surfaces were isolated from the test by silicone sealant. The head was carefully aligned with respect to the FE and AA axes by means of an adjustment disc of the inner cradle, to which the head holder was attached. The distance from the centre of the head to the axes was 0.02 mm at most, checked with a dial-gauge. The alignment was unaffected by the fact that the head holder together with the head was periodically removed for cleaning and inspection and then reattached for the continuation of the test. In any case, the cup was self-centring on the head so that possible misalignments had no tribological effects. The bearing surface of the head was similar to that of the corresponding resurfacing head of the Durom design.

The diameter of the heads was measured with a micrometer, and the radius of the bearing surface of the cups with a coordinate measuring machine. The roundness of the bearing surfaces was measured with a Talyrond 31c apparatus on several different planes, parallel to the equatorial plane, and inclined. The surface roughness of bearing surfaces was measured using a Mitutoyo Formtracer SV-C3100 diamond stylus apparatus with a sampling length of 0.08 mm.

Four bearing couples were available for the tests. First, a preliminary (P) test was run in station 2 of the simulator to check the viability of the setup. The cup was in the optimal, 'correct' position (Table 1). After that, three tests were simultaneously run in test stations 1, 2 and 3 of the simulator. Test 1 was a repetition of the preliminary test. In test 2, the acetabular cup was in a position 15° steeper than in test 1, and in test 3, an additional 3° steeper than in test 2 (Fig. 3). The test lengths were 3.3 million cycles. The tests were stopped every 6 days (550,000 cycles) for cleaning, inspection of bearing surfaces and change to fresh lubricant.

The Co-concentration of samples of used lubricant was measured with AAS and Cr-concentration with ICP-AES, as these are the optimal analytical methods for the two elements. In addition, Co was controlled with ICP-AES. Since the samples were digested

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