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Consideration of non-bearing surface condition and its potential effect on hip wear simulation test results

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ABSTRACT

Material loss during hip simulator studies is commonly attributed to wear occurring within the bearing surfaces. Potential mass loss from the non-bearing surfaces and its contribution to the overall gravimetric measurement results are seldom mentioned in the literature. In this study, CoCrMo alloy disc samples and resurfacing cups with various surface conditions were immersion tested in serum solution for up to 1200 h. Gravimetric measurement results showed that the static immersion and cleaning induced weight loss for a cup alone could be in the same order of magnitude as a typical hip simulator tested wear loss reported in the literature for a metal-on-metal hip joint. Since in a hip wear simulator the parts to be tested are generally immersed in serum or other physiologically relevant solutions and cleaned periodically before gravimetric measurement, it is highly possible that material loss can also occur from the non-bearing surfaces, affecting the accuracy, repeatability and comparability of hip simulation tested wear results. Accordingly, non-bearing surface conditions and the potential material loss from the non-bearing surfaces have to be considered in designing hip simulator test protocols and in analysing wear results. The results presented in this paper pertain to *in vitro* wear simulator studies and have little clinical relevance to the performance of any implant *in vivo*.

1. Introduction

Hip wear simulator tests are widely used throughout the world for the research and development of hip joint prostheses and for their preclinical validations. An advanced simulation testing system applies physiological loads and motions in flexion–extension, abduction–adduction and internal–external rotation on the joint device to be tested under lubricated conditions [1,2]. Gravimetric measurement is performed after simulation testing for predetermined cycles so that the amount of material loss from a femoral head and its pairing acetabular cup are obtained, and the wear rate is calculated. Since it uses more physiologically relevant testing conditions, wear simulation test is regarded as more accurate than other basic wear tests such as pin-on-disc or pin-on-plate [3]. As such, hip wear simulation test has become an important regulatory requirement for validation of a new joint device with new materials and/or new designs. Simulation tested wear rate has become one of the important criteria for validations and for ranking of implants with different materials and designs.

However, it should be pointed out that the amount of material loss during a simulation test is generally small. This is especially true for the new generation metal-on-metal (MoM) bearings. For example, Scholes and Unsworth [4] presented a list of simulation tested wear rates published in the literature over the past ten years for CoCrMo MoM hip joints with different diameters. The steady state volumetric wear rate cited from 17 studies was in the range of 0.07–1.23 mm^3 per million cycles (mm^3/MC), with an average of 0.38 mm^3/MC and a large standard deviation of 0.29 mm^3/MC. Using a density of 8.3 mg/mm^3 for CoCrMo alloy, the equivalent gravimetric wear rate is calculated as 0.6–10.2 mg/MC (average 3.2 and standard deviation 2.4 mg/MC). For such small quantities of material loss and with the existing gravimetric measurement techniques, simulation wear results can be affected by many factors such as sample configuration, cleaning methods and gravimetric measurement procedures. Efforts have been made in the past in various aspects to minimise testing errors and to improve reliability of simulation wear results. This is highlighted in the national and international standards for hip wear simulation tests such as ASTM F1714 [1] and ISO 14242 [2,5]. Based on these standards, routine validation tests and extensive studies have been carried out to evaluate the effect of many other factors, such as diameter, clearance, lubrication conditions and material combinations on wear behaviour of various hip joint devices [6–8].

Notwithstanding these achievements, it appears that material loss during hip simulator studies is commonly attributed to wear occurring within the bearing surfaces. Potential mass loss from the non-bearing surfaces and its contribution to the overall gravimetric measurement results are seldom mentioned in the literature. This is

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Table 1
Substrate chemical composition (in wt%) of CoCrMo specimens.

Element	Cr	Mo	C	Ni	Fe	Mn	Si	Co
Acetabular cup (ISO5832 specification)	26.50–30.00	4.5–7.0	≤0.35	<1.0	<1.0	<1.0	<1.0	bal
Disc sample	28.22	5.53	0.27	0.36	0.38	0.41	0.78	bal

in spite of the fact that corrosion, dissolution and mechanical action may occur on the non-bearing surfaces when a metallic joint device is immersed in testing solution during simulation tests as well as during the subsequent cleaning stage.

For the new generation MoM hip joint, the bearing surfaces are generally polished to a very high surface finish, e.g. following the international standard of ISO 7202 for orthopaedic joint prostheses. However, the materials, the design, and the surface finish of non-bearing surface vary over a wide range. It can be machined, blasted, titanium coated, hydroxyapatite (HA) coated, beaded, non-beaded and so on. Even a coating of same material can be porous or non-porous, sintered, thermal sprayed or plasma sprayed at various temperatures and using different techniques. Under given kinematics and kinetic conditions such as those described in ISO 14242, a variation in the non-bearing surface condition is less likely to affect the wear process occurring in the articulating surfaces during a simulation test if the contact conditions are unchanged. However, a change in non-bearing surface may well affect the overall gravimetric measurement result and thus affect the simulation tested wear rate. This is because different surfaces can have different chemical (corrosion), physical (dissolution) and mechanical (strength, integrity) properties.

In this study, CoCrMo disc samples and resurfacing acetabular cups of various surface conditions were immersed in serum solution followed by cleaning at intervals of 120–150 h for up to 1200 h. This paper presents the gravimetric measurement results and discusses the potential effect of non-bearing surface on the accuracy, repeatability and comparability of hip simulation (*in vitro*) wear results. It should be mentioned that the back surfaces of the resurfacing cups used in this study only simulate the conditions that may be used in hip wear simulation tests. They are different from the implantable cups of similar types which are HA coated and which cannot be tested directly in a hip wear simulator and measured using gravimetric method because of the known issues of HA coating dissolution in an aqueous medium [9,10]. In addition, a joint device *in vivo* is fixed in position; whilst the parts tested in this study as well as those tested in a hip simulation test must be periodically removed from the solution and cleaned before gravimetric measurement. Consequently, the results presented in this paper only pertain to wear simulator studies and have little clinical relevance to the performance of any implant *in vivo*.

2. Materials and experimental procedures

Ten disc samples were used in this study. The material was as-cast CoCrMo alloy conforming to ISO 5832 specifications as given in Table 1. The samples had a diameter of 25 mm and thickness of 12 mm. They were cast in the same batch so that their chemical compositions and microstructures were identical; however, their surface conditions were different. As shown in Table 2 and Fig. 1, the surfaces of sample DA were in the as-received condition without further processing. One flat surface of sample DG was wet ground with SiC paper from 120 to 1200 grit, and polished using 2400 grit SiC paper; whilst the other surfaces were in as-received condition. All surfaces of sample DB were blast cleaned, and all surfaces of sample DP were wet ground and then polished with 2400 grit SiC paper.

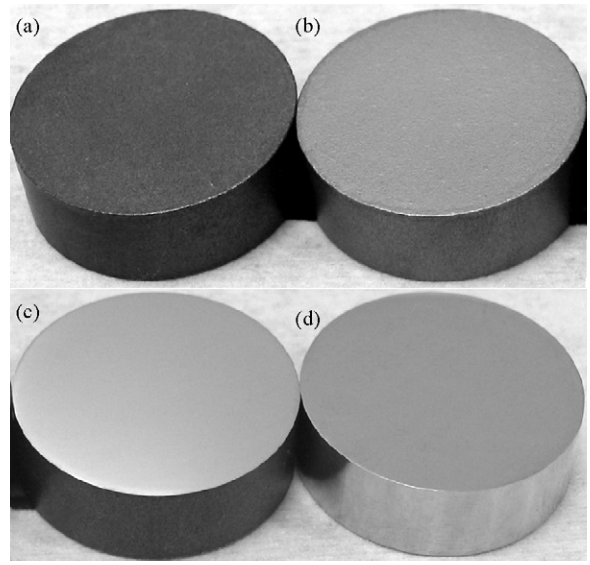

Fig. 1. 25 mm diameter CoCrMo disc samples with (a) as-received and unprocessed (DA), (b) blasted (DB), (c) one-surface ground and polished (DG) and (d) polished (DP) surfaces.

Table 2
Sample ID and surface finishes of disc samples.

Sample ID	Surface condition
DA	As-received and unprocessed surfaces.
DG	One flat surface was ground and polished. The other surfaces were in as-received condition.
DB	All surfaces were blast cleaned.
DP	All surfaces were ground and polished.

To verify the results obtained with disc samples, four CoCrMo alloy resurfacing acetabular cups, including three beaded and one beadless, were also used in this study. The bearing surfaces of these cups were manufactured to the same designed geometry and surface finish (Ra ∼ 0.02 μm). The back surface of three beaded cups varied from as-received cast (CA), blast cleaned (CB) and blast clean plus nitric acid passivation (Cpa) treated. The beads in the back surface were cast-in and they are integral with the cup [11]. This can avoid the beads dislodging as it has been reported for other types of beaded devices [12]. The beadless cup (Cbls) was cast as beadless, and the back surface was further machined to remove the top surface layer and to produce a smooth finish. The back surface conditions selected in this study only represent those that can be used in hip wear simulation tests. They are different from the actual implantable devices which have to undergo further production processes. Table 3 shows the sample

Table 3
Sample ID and back surface conditions of acetabular cups. Bearing surfaces were all polished to a finish of Ra ∼ 0.02 μm.

Sample ID	Back surface condition
CA	Beaded, as-received and unprocessed cast surface.
CB	Beaded, blast cleaned.
Cpa	Beaded, blast clean and passivation treated in 30% HNO_3 for 20 min.
Cbls	Backside was cast as beadless, further machined to produce a smooth finish (Ra ∼ 3.2 μm).