



## Adverse condition testing with hip simulators

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### ABSTRACT

Recent clinical failures and abnormal sounds observed in certain prosthetic hip designs have directed attention to adverse condition hip simulator testing. In the present study, hip simulator wear and friction tests were made with a macroscopic separation of the bearing surfaces in the swing phase, steep acetabular cup position, increased load, poor or lacking lubrication, roughened bearing surfaces including titanium third bodies, and with combinations of these. The only conditions that resulted in squeaking were dry sliding with alumina-on-alumina and metal-on-metal, and an extreme peak load of 4 kN with serum lubricated metal-on-metal. The wear rate of metal-on-metal increased by an order of magnitude when the cup position was steep, 64°, compared with the optimal position of 48°. The increase of the peak load from 2 kN to 3 kN with the cup position of 48° increased the running-in wear of metal-on-metal, but the steady state wear rates were equally low, of the order of 1 mg per one million cycles. Crosslinked polyethylene was the superior cup material under adverse conditions, including dry sliding and roughened femoral head.

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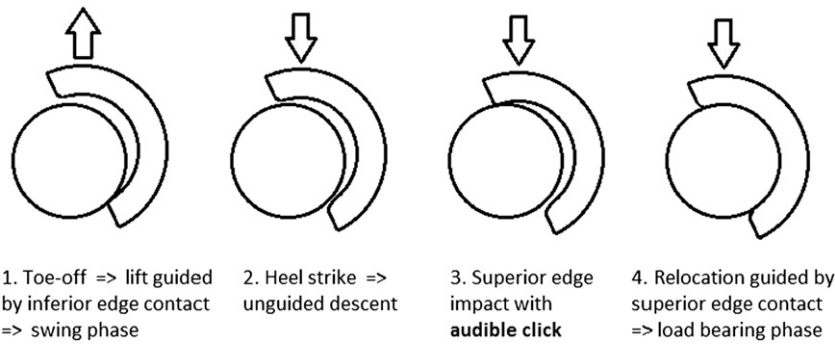
### 1. Introduction

Due to recent clinical failures of certain large-diameter CoCr-on-CoCr hip prostheses [1], more attention has been paid on adverse testing conditions in hip simulators to more closely reproduce the clinical reality where the conditions are often far from optimal. These include steep inclination angle of the acetabular cup [2], laxity of the joint [3], increased loading due to obesity or high-demand activity [4], poor lubrication or dry sliding [5], and roughening of the bearing surfaces [6] for a number of reasons, including titanium third bodies [7]. The principal difficulty is in the anticipation of the clinical relevance of each exceptional condition, or combinations of them. For instance, the percentage of patients with insufficient joint fluid is not known. State-of-the-art bearing couples show minimal wear under normal test conditions, so little that it may be difficult to measure. Under adverse conditions however, early failure may occur. Damage is easy to cause in the laboratory, but it may represent a rare event clinically, in which case it is uninteresting. A steep cup angle is so common in orthopaedics [8] that afterwards

it seems odd that steep angle tests were not made with large diameter metal-on-metal (MoM) bearings before their wide introduction in the early 2000s. Steep cup angle is presently known to be tribologically detrimental for these designs [2,9].

Laxity can lead to the separation of the bearing surfaces in gait and in other daily activities. The separation between the femoral head and the acetabular cup has been measured to be of the order of millimetres in gait studies utilizing fluoroscopy [3]. After the heel strike, an impact between the head and the cup takes place in the lax joint. This may be disadvantageous especially with hard-on-hard articulations, as the impact can cause local damage of the contacting surfaces. A click and a squeak are sounds produced by some hard-on-hard articulations [10–12]. The click is likely to result from the impact of the separated bearing surfaces after the heel strike. The squeaking is indicative of ineffective lubrication and high friction which may lead to a wear damage of the bearing surfaces. These sounds are disturbing but presently it is not known how ominous they really are. The squeak is readily reproduced in dry sliding [13]. A separation mechanism for the HUT-4 hip joint simulator [14] was implemented, and used with alumina-on-alumina (AoA) and MoM. With an ultra-high molecular weight polyethylene (UHMWPE) acetabular cup, the laxity of the joint may not be a risk in the way that it is with

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**Fig. 1.** Schematic of separation mechanism designed for HUT-4 hip simulator. Since laxity of joint is simulated, no lateral force is applied. Superior edge separation is necessary for audible click to be produced after heel strike. For illustration, lift height is exaggerated; with this much separation, joint would become unstable.

hard-on-hard articulations, but the increased propensity of the lax joint to dislocate is naturally present irrespective of the bearing materials. A dislocation can damage the bearing surface of the head which has tribological consequences. If the head is not replaced, increased UHMWPE wear by abrasion may follow.

Moreover, MoM tests were run in the present study without separation in the HUT-4 simulator with (a) normal conditions, (b) steep cup position of  $64^\circ$ , and (c) increased peak loads of 3 kN and 4 kN. Friction tests were run with the BRM simulator [13] with several different bearing couples and tribological conditions.

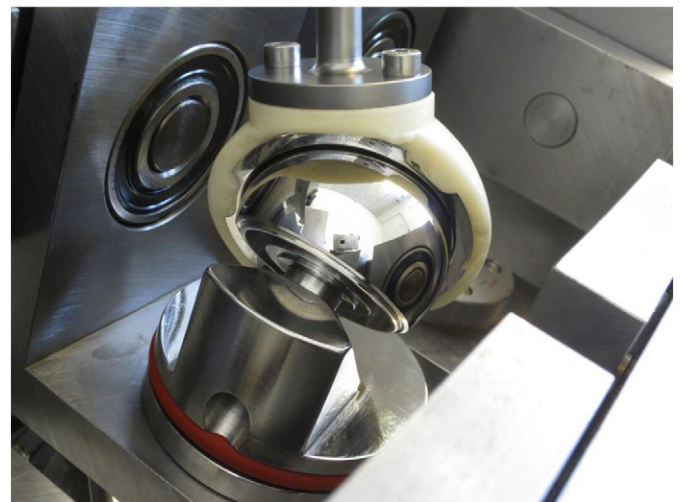
The variety of possible combinations of adverse test conditions and bearing couples is overwhelming. The present study reports several experiments that are considered relevant and interesting, with a view to directing attention to the possibilities and importance of adverse condition testing. It was hypothesized that adverse testing conditions in hip simulators can be predictive of implant behaviour in clinically relevant, sub-optimal conditions, and therefore the possible negative results are worthy to be taken seriously as the earliest warning signals before new prosthetic hip designs are taken into clinical trials, not to mention large scale clinical use.



**Fig. 2.** Separation mechanism, operated by vertical springs and counter-pressure on piston rod side of pneumatic loading cylinder of the HUT-4 hip joint simulator. In this system test with  $28\text{ mm}$  AoA, cup inclination angle was  $64^\circ$ , lift height (vertical separation) was  $1.0\text{ mm}$ , and lubricant was distilled water. Arrow indicates where spacers are placed for adjustment of vertical separation.

## 2. Materials and methods

A separation mechanism was constructed into the HUT-4 hip joint simulator (Figs. 1 to 3) described in detail elsewhere [14]. In the normal walking simulation, the load is implemented by a pneumatic cylinder, a proportional pressure controller and a double-peak input signal. The signal is adjusted so that the maximum load is 2 kN (Fig. 4). After the toe-off, during the swing phase, the cylinder pressure is allowed to exhaust freely. The true load does not however decrease below 300 N before the next heel strike occurs, and no separation takes place. The load is measured with a force transducer fixed to the piston rod. The loading surface of the connecting piece that is pressed downwards by the transducer is horizontal. Between the vertical loading bar of the acetabular component and the connecting piece there is a universal joint that makes the cup self-centering on the head. The connecting piece has one degree of freedom, vertical translation, as it moves along a linear bearing. This assembly functions as the load guide. For separation studies, a constant pressure was applied to the piston rod side to lift the piston together with the force transducer during the swing phase. The gain of the load control was increased so that the maximum load during the load bearing phase was still 2 kN. The connecting piece together with the rail, universal joint, loading bar and the acetabular component was lifted upwards by two vertical springs so that the connecting piece remained in continual contact with the force



**Fig. 3.** Metasul 50 mm MoM bearing of HUT-4 hip simulator test with swing phase separation. In this photograph separation is  $1.0\text{ mm}$  vertically. Bone cement was cast around acetabular component in a hemispherical 68 mm diameter mould that had a recess 40 mm in diameter for formation of flat loading surface (top). As this surface was horizontal in the test, the position of the cup in this case was  $59^\circ$  abduction and  $30^\circ$  anteversion, and so effective inclination was  $64^\circ$ . Femoral neck angle was  $45^\circ$ . Loading direction was vertical.

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