# EFFECTS OF NEGATIVE CLEARANCE ON THE WEAR PERFORMANCE OF A MODERN METAL-ON-METAL IMPLANTS IN A HIP SIMULATION STUDY

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**Statement of Purpose:** One of the critical factors in metal-on-metal hip implant design is diametrical clearance (D.C.), i.e., the difference between inner diameter of an insert and the outer diameter of a femoral head. If the diameter of a head is slightly smaller than the inner diameter of an insert, a polar contact bearing will occur (Fig 1). In contrast, equatorial contact bearings will occur if the diameter of a head is slightly larger than the inner diameter of an insert (Fig 2). The latter bearing type may experience seizing and loosening of the implants, which occurred in some of the failed first generation implants due to poor manufacturing techniques [1]. The purpose of this study was to evaluate the effect of negative clearance on the wear of a modern metal-on-metal hip implant using a hip simulation machine.

**Fig 1. Polar Bearing**

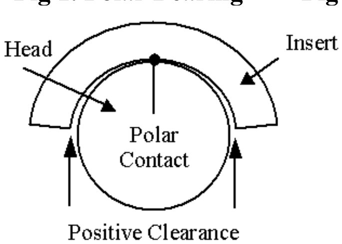
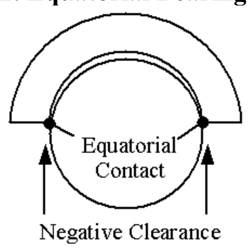



**Fig 2. Equatorial Bearing**




**Methods:** Femoral head components and acetabular inserts made of CoCrMo (ASTM F1537) were used. The test specimens were arranged in two groups (four sets for each). Group A: Negative Clearance with diametrical clearance of -8.0 ± 2.5 µm, and group B: Positive Clearance with diametrical clearance of 80.5 ± 8.2 µm. The inserts used in both groups had the same nominal diameter of 28 mm. The heads used in group A were custom-made to a larger diameter to achieve the effect of negative clearance. The diameters for the implants were measured by CMM (Brown & Sharpe, North Kingstown, RI). All articulating surfaces were polished to an Ra of 0.01 µm.

The wear test was performed on an 8-station hip joint simulator (MTS, MN) using the Paul-type physiological loading (2000 N max, +/- 23° biaxial rocking motion at 1 Hz), with an inverted position (i.e., the head located on top of the insert) for 3 million cycles. The interface was lubricated with bovine serum (HyClone Lab, UT), which contained 0.2% sodium azide and 20mM EDTA. The protein concentration was 61 mg/ml (approximately 90%). Wear was assessed by measuring the weight loss every half million cycles. The weight loss was converted to volumetric wear using a density of 8.86 g/cm3 [2]. One additional weighing was performed at 90K cycles to demonstrate the rapid wear-in of the components. The surface morphology was evaluated by light microscopy.

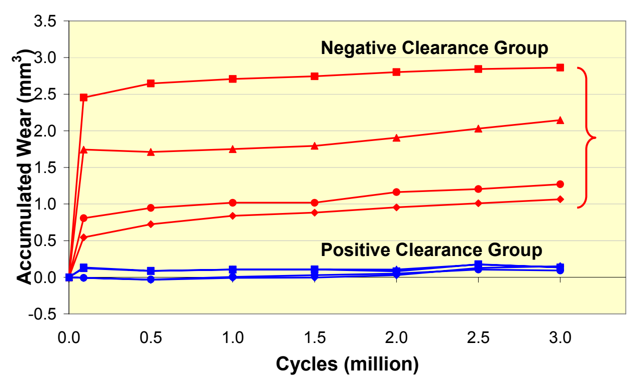
**Results / Discussion:** The wear results for both groups consisted of a rapid wear-in period and a stabilized wear period (Fig 3), which were consistent with the trends in previous studies [1,2]. The differences among sets were similar in the Positive Clearance Group. As anticipated, the initial motion for the Negative Clearance Group was erratic during each cycle, which was due to the equatorial contact for the heads and inserts. Although no seizure occurred between the components, the jerky motion resulted a different wear surface (photo not shown). The Negative Clearance Group had more than 100 times of wear than the Positive Clearance Group in the first 90,000 cycles (Table 1). Very little wear was detected for both groups after 1 million testing cycles (Fig 3), suggesting the establishment of fluid film lubrication.

**Table 1. Summary of the Wear Study Results**

| | Testing Period | Negative Clearance Group | Positive Clearance Group |
|---|---|---|---|
| **Wear Rate ($mm^3$/million -cycle)** | Wear-in (0 to 0.09M) | 15.41 ± 9.75 | 0.67 ± 0.88 |
| | Stabilized (0.5 to 3M) | 0.13 ± 0.04 | 0.05 ± 0.03 |
| **Diametrical Clearance (µm)** | Initial D.C. (0M) | -7.94 ± 2.45 | 80.45 ± 8.17 |
| | Wear-in (0.09M) | -1.84 ± 3.06 | 68.77 ± 5.20 |
| | Final D.C. (3M) | 4.57 ± 2.78 | 70.74 ± 6.41 |

The diametrical clearance of the Negative Clearance Group changed from a negative to a positive value (Table 1). In contrast, the diametrical clearance for the Positive Clearance Group was reduced at the end of the test. Both results suggested the wear-in process contributed to the optimization of the bearing surface of each femoral ball and metal insert pair.

**Fig 3. The Impact of Negative Clearance on Wear**




**Conclusions:** The current study demonstrated that wear simulation was able to distinguish between good and sub-optimal designs and could be used as a prediction tool for clinical performance of metal-on-metal total hip prostheses.

**References:**

[1] Chan et al., CORR 1999, 369: p10-24
[2] Liao et al., ORS 2004, p1454