Negative Net Clearance of Large Diameter Metal-Metal Bearings is Associated with Clinical Failures

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Introduction: High failure rates have been reported with large diameter metal-metal bearings (LDMM) [1,2, 3]. Although cup position is a factor [4], acetabular non-ingrowth [3] and pseudotumors [5] have occurred with optimally positioned implants. LDMM rely on precise head-cup clearance for polar bearing and proper lubrication. However, optimal clearance is controversial. This study investigated the effect of impaction deformation [6] on diametral clearance.

Methods: A coordinate measuring machine (CMM, Legex 322, Mitutoyo, Aurora, IL) was used to determine diametral clearance (CL_d) and asphericity (A) of 35 LDMM from 5 different designs (ASR, DePuy; BHR, Smith & Nephew; Cormet, Corin, Ltd.; Durom, Zimmer; Magnum, Biomet). The inside diameter of the models and outside diameter of the cups were measured to assure an interference fit in line with the manufacturers' recommendations. Each cup was impacted in a previously described two-point loading acetabular model [6] made of 40 grade polyurethane foam (Sawbones, Vashon, WA). Impaction deformation (D) was determined by CMM. Net clearance (CL_{NET}) [7] was calculated by subtracting the combined head-cup asphericity and impaction deformation of each LDMM from diametral clearance: $CL_{NET} = CL_d - (A + D)$.

A thin layer of dye was applied to the femoral heads then oscillated in the cups under manual pressure before and after impaction [6].

Results: All cups exhibited elastic impaction deformation, which was maximal at the rim. Variables which contributed to net clearance were cup wall-thickness, supplemental fin fixation, low (<150μm) or ultra-low (<100μm) diametral clearance, depth of impaction, and cup-model interference (Table). Three of the five systems demonstrated negative net clearances (Fig 1.), with equatorial contact patterns (Fig. 2), and those were the systems with high early clinical failure rates [1]. One system has been withdrawn from the market and another replaced.

Table. Net Clearances of Large Diameter Metal-Metal Bearings

	BHR	Cormet	ASR	Durom	Magnum
n	8	6	7	8	6
INTERF	1.88±.37	2.21±.20	.63±.15	2.70±.12	.97±.24
CL_d	231±39	186±5	85±10	151±15	216±47
A	34±11	27±11	45±21	41±8	33±10
D	103±52	57±13	57±28	137±23	83±31
CL_{NET} mean±SD	94±17	101±29	**-36±27**	**-27±39**	100±70
max	107	199	**0**	19	162
min	62	86	**-75**	**-102**	**-32**

INTERF (interference) in mm; all other measurements in microns

The outside diameter of the ASR cup was 0.34±0.13mm smaller than the nominal diameter (p<0.000) resulting in an average interference of 0.63mm. Minimal resistance to impaction was noted. ASRs were impacted in a second series of models with interference 1.76±0.11mm resulting in a net clearance of -27±33μm.

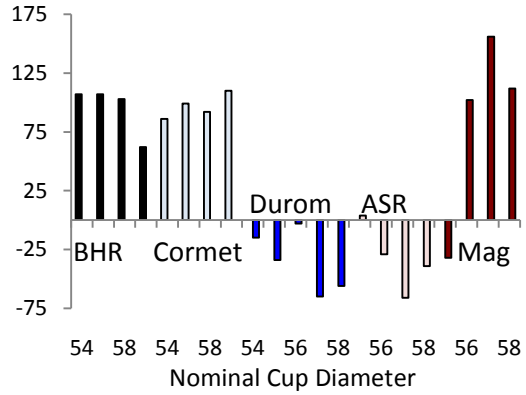

Fig. 1. Net clearance of 5 metal-metal bearings designs in microns.

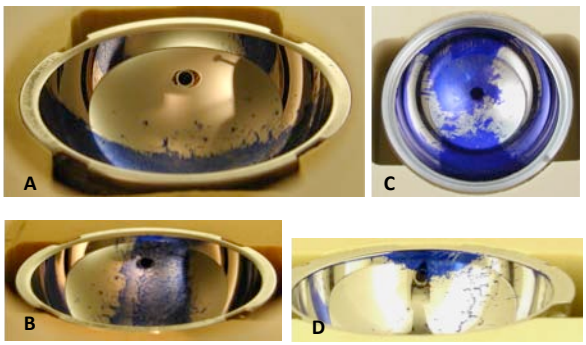

Fig. 2. Negative net clearance contact patterns: A & B) Biomet Magnum with rim-to-rim band contact; non-contact on either side of band. C) DePuy ASR with more extreme deformation resulting in non-contact at dome. D) Zimmer Durom with rim contact only.

The Magnum cups were difficult to impact due to the 8 fins. This resulted in highly variable net clearance. (Table, Fig. 1).

Discussion: Negative net clearance (NNC) may be the main cause of 'edge loading' (Fig. 2). In the Durom, NNC is caused, in part, by excessive press-fit at the rim [7]. In the ASR, inadequate press-fit, ultra-low diametral clearance and NNC contribute to a high failure rate.

Clinical failure of LDMM may be predictable from simple bench tests. NNC is not apparent during surgery, but may cause increased frictional torque and metal ion production. Although impaction deformation relaxes over time [8], the early postoperative period is critical for biological ingrowth to occur. Cobalt ions [9] suppress osteoblast function [10], which may cause acetabular non-ingrowth. NNC results from impacting insufficiently strong LDMM cups into dense acetabula. Wear simulator studies that do not model impaction deformation may be overly simplistic and may not reflect the initial variability of wear behavior of LDMM hip bearings.

REFERENCES 1 Austral Reg 2009 **2** Long CORR 2009 **3** Berenthal AAOS 2010 **4** Langton JBJS 2008 **5** Grammatopoulos ORS 2010 **6** Jin Proc IMechE 2006 **7** Grimes ORS 2010 **8** Griffin Hip Soc 2010 **9** Garbuz CORR 2009 **10** Queally JOR 2009

Acknowledgement: BHR samples provided by Smith & Nephew, Inc. Cormet samples provided by Corin, Ltd.