

ANALYSIS OF FAILED EX VIVO 36MM METAL-ON-METAL Pinnacle HIPS



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Introduction

Metal-on-metal (MoM) total hip replacement (THR) has undergone a renaissance with it accounting for 35% of procedures in the US in 2009 [1]. Most MoM THR are 28 or 32mm in diameter but recently bearing sizes have been increased to 36mm diameter to reduce dislocation rates and improve lubrication. All devices employ cobalt chromium molybdenum as the material. The truest test of any such device is when it is implanted in the body. Recently there have been an increasing number of reports of adverse reactions related to wear debris from MoM hip resurfacings. All MoM devices have been affected by the publicity. Is this a fair situation?

Method and Materials

From a cohort of 640 patients, each implanted with a Corail Pinnacle® 36mm MoM THR, 19 pairs of femoral heads and matching acetabular cups were obtained at revision surgery (figure 1). All 19 patients who were revised reported pain. Patient details available included blood metal ion concentrations. Acetabular cup positions were measured using EBRA software. 120 patients have also attended for metal ion analysis following implementation of a mass screening program. All components were examined using a Mitutoyo Legex 322 co-ordinate measuring machine (CMM) (sensitivity better than 1µm) to determine the wear volumes from their articulating surfaces [2]. The CMM was also used to determine wear depths and wear volumes from the taper junction between the femoral head and the stem. The roughness of the articulating surfaces was measured using a ZYGO NewView 5000 profilometer (1nm resolution) [3]. This data then allowed the lubrication regime to be identified [4].

References

[1] Bozic et al, J Bone Jt Surg, 91A:1614-1620, 2009. [2] Lord et al, J Biomechanics, 43:S43-S46, 2010. [3] Joyce et al, J Eng Tribology, 223:317-323, 2009. [4] Hamrock & Dowson, J Lubrication Technology, 100:236-245, 1978. [5] Langton et al, J Bone Jt Surg, 92B:38-46, 2010.



Figure 1: The femoral head (left) and acetabular cup (right) from an explanted 36mm MoM THR.

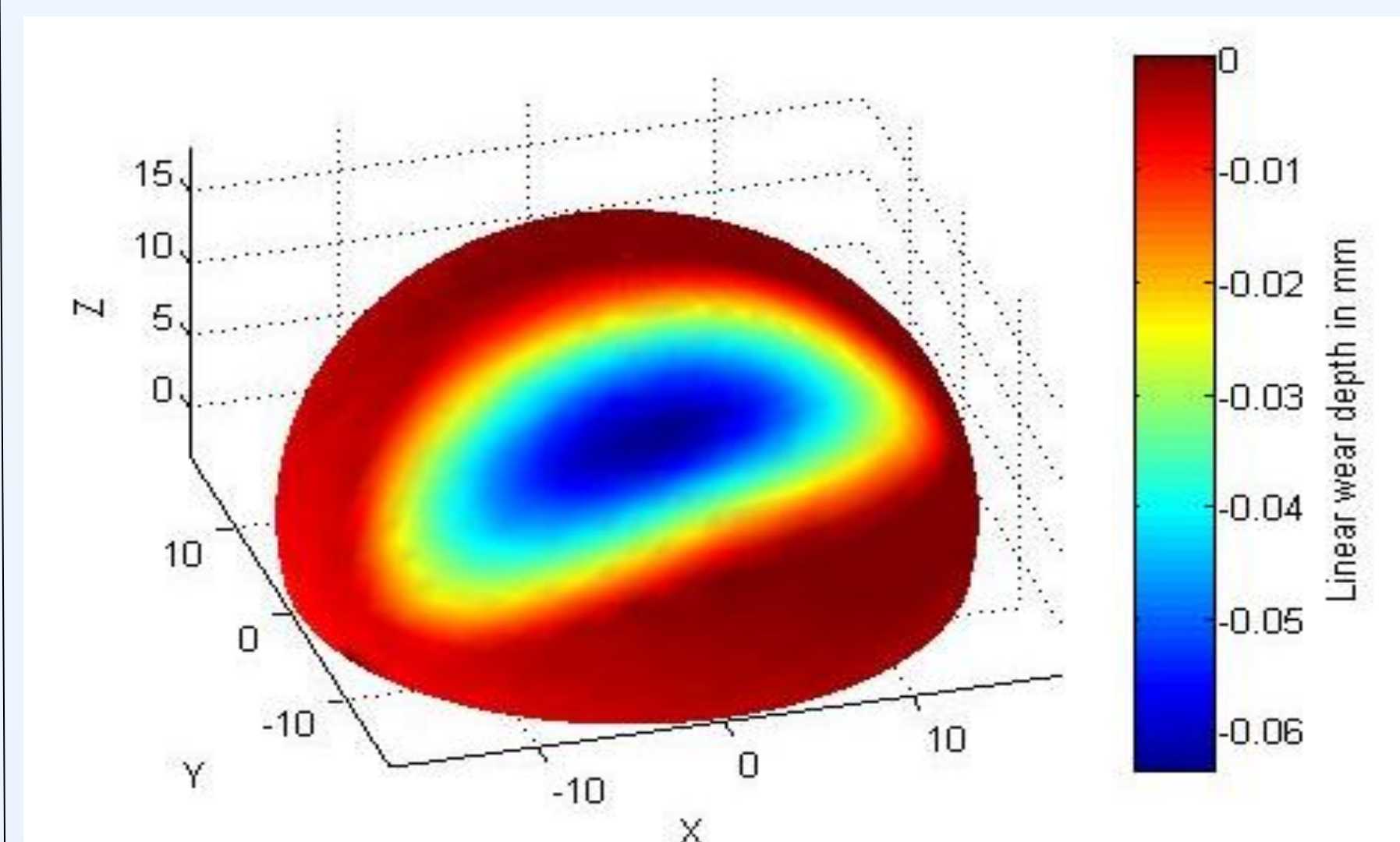


Figure 2: Image of most worn 36mm femoral head. Associated with high acetabular cup inclination (77°). Wear volume (dark blue) 18mm³.

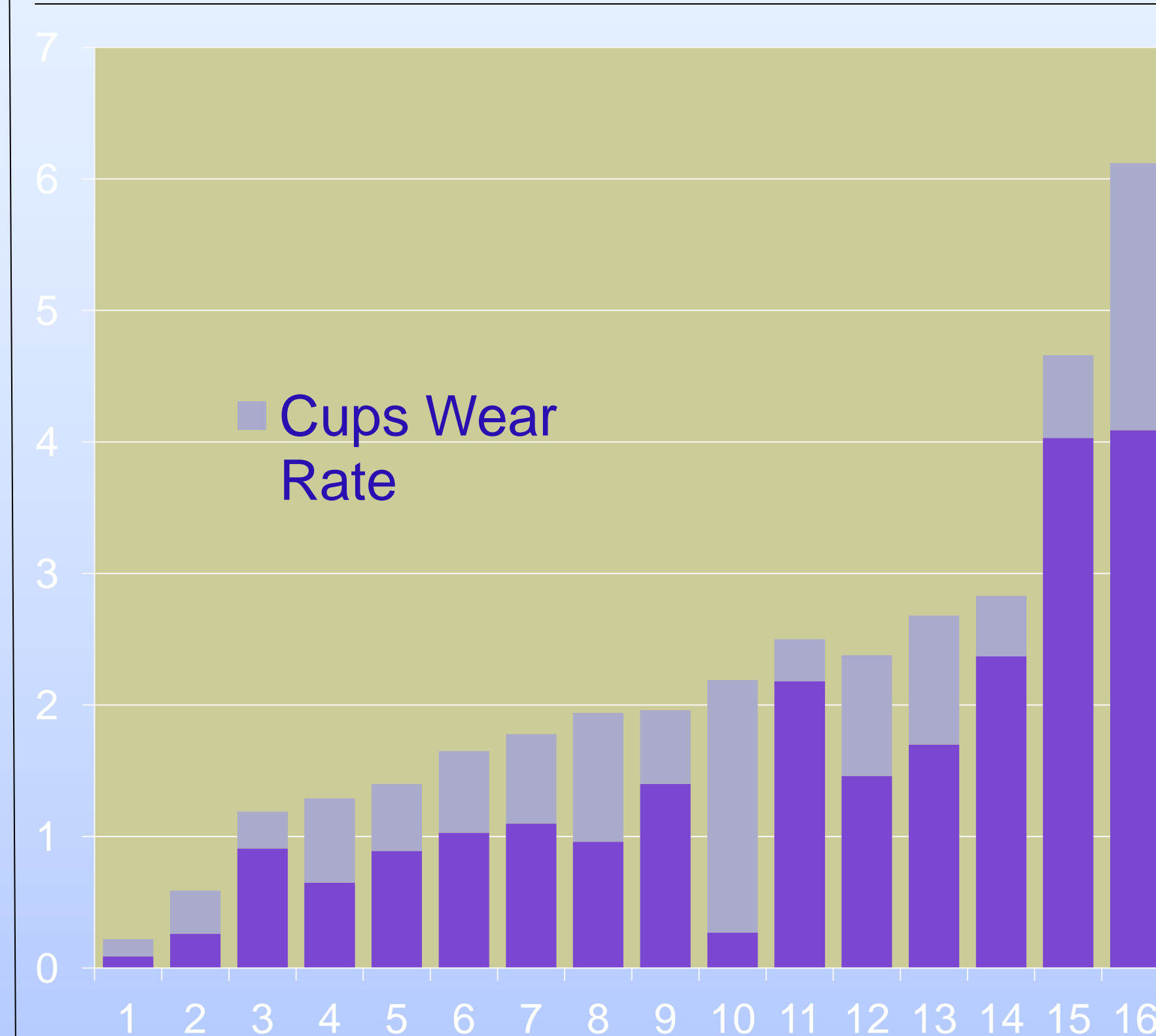


Figure 3: Wear rates (mm³/year) of 16 pairs of explanted MoM heads and cups.

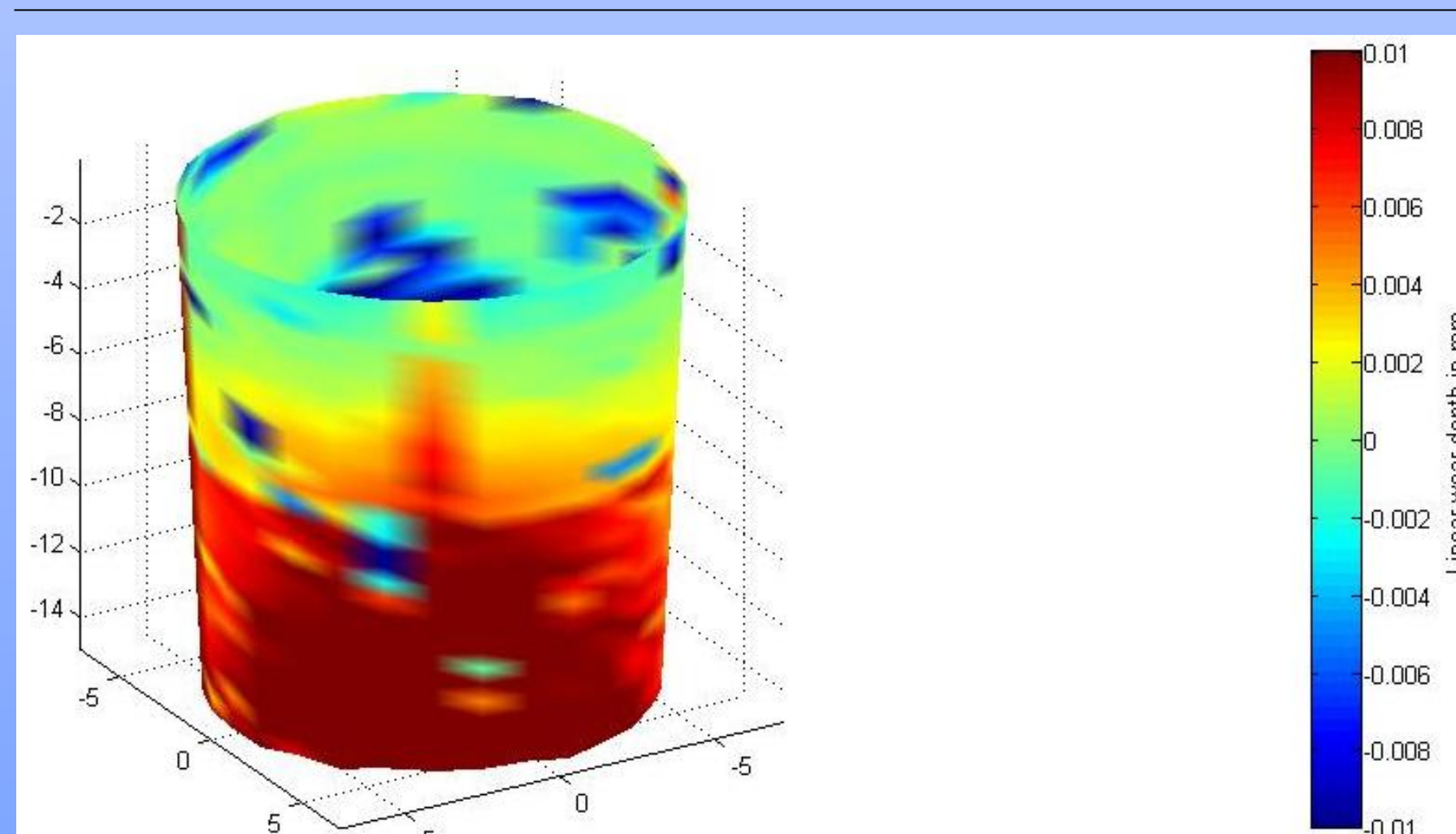


Figure 4: Taper damage from femoral head – 2.2mm³ wear volume (dark red), 19µm max wear depth.

Results

From the articulating surfaces, a range of wear volumes per component were measured, from 1 to 18mm³ (figure 2). The paired head plus cup wear volumes ranged from 3 to 23mm³. Femoral head wear rates were usually greater than cup wear rates, means of 0.21mm³/month and 0.06mm³/month respectively being measured. Of the explants, 14 pairs were found to have low bearing surface wear rates of <3mm³/year (figure 3). In each of these cases, significant damage was identified at the internal taper junction of the femoral heads (figure 4). Roughness values of the articulating surfaces were typically in the range of 0.010 to 0.030µm Ra, so that the implants were operating under mixed lubrication. Articulating surface roughness measurements showed little increase over unworn areas. In total, 28 patients have been revised or listed for revision due to Adverse Reactions to Metal Debris (ARMD [5]). This represents an overall failure rate of 4.3% at mean 3.5yrs (range 1.8-5yrs). Blood Cobalt (Co) and Chromium (Cr) concentrations were generally low. Median cup inclination/ anteversion angles in the ARMD cases were 46° and 11°.

Conclusion

To the authors' best knowledge this is the first time that the ex vivo wear volumes and wear rates of these modern 36mm MoM THRs have been reported. It is also one of the first papers to report on taper wear. The low wear of the articulating surfaces corresponded with the relatively unchanged values of surface roughness. Mechanical failure at the head/stem interface appears to be a critical factor in the development of adverse reactions following MoM THR. Taper damage should be considered as another potential source of metallic debris alongside that which may originate from the articulating surfaces.