Patient Alignment and the Effects on Wear and Corrosion in 2nd Generation Small-Diameter Metal-on-Metal Total Hip Arthroplasties

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Disclosures: SM McCarthy (N), Peter Wahl (N), DJ Hall (5-Stryker), JJ Jacobs (3B-Smith & Nephew, Zimmer-Biomet, 4-Hyalex, 5-Medtronic Sofamor Danek, Nuvasive, Zimmer-Biomet, 7B-JBJS, Am., 8-JBJS, Am., 9-ABOS Inc., OREF) R Pourzal (5-Stryker, Zimmer Biomet; 8-Biotribology)

INTRODUCTION: Cobalt-chromium-molybdenum (CoCrMo) wear and corrosion product release from total hip arthroplasty (THA) into periprosthetic tissue have long been linked to painful adverse local tissue reactions (ALTR) and systemic toxicity [1,2]. Awareness of the potential dangers associated with CoCrMo wear and corrosion were first raised by widespread revisions of a variety of large diameter (>40 mm, LD), third-generation metal-on-metal (MoM) THA in the 2000s, resulting in concerns of not only the bearing modality, but the use of CoCrMo femoral heads in general [1]. Thus, CoCrMo head use has been declining in favor of ceramic heads less susceptible to tribocorrosion [3]. However, second-generation, small-diameter (28 and 32 mm, SD) MoM THA performed well, mostly in Europe, with excellent survival rates up to 20 years and few reports of ALTR [4]. It is unclear how implant characteristics and positioning, as well as patient specific factors contribute to the success of this implant design. This study aimed to characterize the tribocorrosion behavior of SD MoM THA, considering patient characteristics, component positioning, alloy microstructure, cause for revision, and resulting tissue responses.

METHODS: Thirty-nine SD MoM modular heads and metal-polyethylene-sandwich liners were collected that had been consecutively retrieved by two surgeons in Switzerland. Median (range) time *in situ* was 18.2 years (0.6 - 27.9). Inclination and anteversion angles were measured from pre-revision radiographs. Acceptable ranges of inclination and anteversion angles were defined as 30-50° and 10-25°, respectively. Additionally, adverse events from the patient's medical histories such as secondary cup migration were recorded. Bearing surfaces and head tapers were measured with an optical coordinate-measuring-machine (CMM) (OrthoLux, RedLux) to assess implant wear, head taper corrosion, and volumetric material loss. Head tapers were assessed using a modified Goldberg damage score (mGDS) (1 minimal, 2 mild, 3 moderate, 4 severe), and damage modes such as 'imprinting' and 'column damage' seen on the inner head taper were noted [5]. A subset of implants (n=20) were sectioned and etched for metallographic analysis, and alloys were characterized in a scanning electron microscope (SEM) (JEOL). Hip capsule tissue was available for 44% of cases. H&E-stained histological sections were analyzed for synovial lining integrity, inflammatory infiltrate, and tissue organization. Statistical analysis was performed with SPSS 22 software. Specifically, Pearson's Correlation and multiple linear regression models were used to identify trends between volumetric material loss as well as Co and Cr blood ion levels, and implant positioning, patient specific factors and demographics, and acting corrosion modes.

RESULTS: Median (range) inclination and radiographic anteversion angles were 44° (32 - 61) and 22° (0 - 47), respectively. Common reasons for revision included adverse reaction to metal debris, periprosthetic fracture, and component malposition. Median (range) volumetric material loss of the heads and metal liners were 3.71 mm^3 (0.17 - 82.32) and 14.13 mm^3 (4.32 - 241.47), respectively, with a combined median bearing surface material loss of 18.85 mm^3 (5.78 - 273.81). Pearson's correlation revealed no correlation between total bearing wear and any patient demographics (time *in situ*, BMI, sex, age) or inclination and anteversion angles. However, cases with secondary dislocation of the cup exhibited higher material loss (p=0.045) (Fig. 1). Multiple linear regression showed that liner wear volume correlated negatively with inclination angle (coef=-2.23, p=0.029) and increased if secondary cup dislocation occurred (coef=-59.95, p=0.004) (Fig. 2). Head wear volume did not correlate with surgical alignment, but there was a trend with patient age at revision (p=0.076). Multiple linear regression showed this correlation to be significant (coef=-0.46, p=0.03) when controlled for time *in situ* (coef=0.59, p=0.17). Head taper damage score distribution was 20.5% minimal, 30.8% mild, 20.5% moderate and 28.2% severe. 44% of head tapers had no measurable material loss. The median (range) head taper material loss from cases with measurable wear was 0.02 mm^3 (0.0, 9.35) for all head tapers and 0.4 mm^3 (0.0, 9.35) for those with an mGDS of 4. Metallography showed heads were made of high-carbon alloy with characteristic carbide presence. 67% (100% of those with mGDS=4) of cases had imprinting of stem taper topography in the head taper, while 12.8% (45% of those with mGDS=4) exhibited a chemically-driven column damage-like pattern in the modular junction. Head taper material loss did not correlate with any patient or surgical positioning factors. Local tissue responses were mild to moderate, with marked particle-laden macrophages but little to no lymphocytic responses. Co and Cr ion whole blood ion levels were 2.1 ug/L (0.5, 73.5) and 2.2 ug/L (0.3, 29.10), respectively. Patients with secondary dislocation had higher Co ion levels (p=0.036). Cr ion levels correlated with inclination angle (p=0.041) and exhibited a trend with total wear volume (p=0.069) and secondary dislocation (p=0.071). However, after multiple linear regression with those input factors, only inclination angle (coef=0.34, p=0.009) and wear volume (coef=0.038, p=0.019) were significant.

DISCUSSION: This relatively large cohort of SD MoM retrievals exhibited remarkably low wear, especially compared to later generations of LD MoM bearings. Although wear and time *in situ* were found to be independent, the theoretical wear rate of 1.67 mm^3/year is close to what wear simulators have predicted in the past, and ~66% of bearing couples exhibited little wear beyond the running-in period. When plotting total wear over time (Fig. 1), it can be seen that the non-linear relationship is driven by multiple outliers. These outliers can in part be explained by secondary dislocation of the cup, following periprosthetic fracture or development of osteolysis of the acetabulum. However, other unknown factors, such as patient activity levels, probably have a large impact. Regarding head wear, there was a negative correlation with age, which could be considered a proxy measure for patient activity. Considering that all patients in this cohort come from Switzerland, it may be assumed that various patients engaged in activities such as hiking or skiing, resulting in multiple outliers. Our analysis revealed that wear on the liner is mainly driven by cup alignment, particularly with the occurrence of secondary dislocation. The wear maximum in those cases was located close to the edge of the liners (Fig. 2). While higher inclination angles correlated with lower liner wear, it has to be considered that this population was mostly within the recommended inclination range. Inclination angles outside of the range would have likely resulted in edge loading and high wear. Material loss from the taper was inconsequential compared to bearing wear. While cases with severe damage occurred, the median total material loss of those was less than half that reported for MoP devices [6]. This may be related to the use of a high carbon CoCrMo in these femoral heads, resulting in less penetration of topography imprinting and a different type of column damage formation. Interestingly, none of the implants in this cohort exhibited a lymphocyte dominated ALTR, which is not surprising considering the overall mild wear and corrosion conditions. In addition, Co levels were mainly driven by the occurrence of secondary cup dislocation, and not bearing wear or corrosion.

SIGNIFICANCE: Second-generation SD MoM THA components have an exceptional survival rate [4] and experience little wear *in vivo*. It is important to study well-functioning THA components in order to identify parameters, both metallurgically and surgically, that result in the best patient outcomes. While the use of SD MoM maybe obsolete, the use of high carbon CoCrMo may be useful in metal-on-polyethylene bearings to minimize taper damage.

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ACKNOWLEDGEMENTS: This study was funded by NIH grant R56 AR070181-06A1.

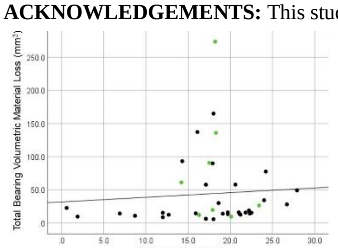

Figure 1 (Left): Scatterplot of volumetric material loss over time in situ. Green dots represent patients with a secondary cup dislocation, the black dots are patients without.
Figure 2 (Right): Representative optical CMM heat maps of material loss in CoCrMo liners. The low wearing liner (left) had a material loss value 8x less than the secondarily dislocated high wearing liner (right).