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Corrosion of Metal Modular Cup Liners

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ABSTRACT

Numerous studies have reported on corrosion at the modular head taper, however less is known about the interface between the metal shell and liner of modular cups. This study examined the backside of a series of metal modular cup liners of two designs (DePuy Pinnacle and Smith & Nephew R3), retrieved from 67 patients. Visual inspection found evidence of corrosion in virtually all liners, with the engaging rim surface significantly more corroded than the polar regions ($P<0.001$). EDX confirmed that black surface deposits were chromium rich corrosion debris, while SEM analysis revealed considerable pitting in the vicinity of the black debris. The R3 liners were significantly more corroded that the Pinnacles ($P<0.001$); this may help to explain the higher revision rates of this design.

Modern total hip replacements (THRs) with metal-on-metal (MOM) bearing surfaces have consisted of implants with varying degrees of modularity, offering the surgeon greater flexibility during surgery. For example, the use of modular neck components allows for patient-specific adjustments to be made to features such as leg length and horizontal or vertical femoral offsets [1]. Approximately 50% of all stemmed MOM hips implanted in the UK have involved a modular acetabular cup, usually consisting of a titanium outer shell and a cobalt-chromium articulating liner [2]. Cup modularity is advantageous as it enables optimal component positioning to be achieved and also allows for a well-fixed shell to be retained during revision surgery [3,4].

Whilst the clinical advantages of increased modularity are clear, recent studies have reported evidence of considerable corrosion at component junctions, in particular in that of the femoral head taper [5–7]. Corrosion has been shown to be correlated with material loss at this taper surface [8] and the associated metal ion release is reported to result in local tissue reactions [9]. However the extent of corrosion damage at the interface between the liner and shell of metal modular cups and the clinical significance of this are currently less clear. Higgs et al [4] reported evidence of scratching and discolouration at rim of the backside of the CoCr liner in a series of 18 cups; considerable pitting and black corrosive debris were also observed at the rim by Gascoyne et al [10] in approximately 25% of their series of retrievals.

The aim of this study was: (1) to determine, using visual analysis and detailed surface assessment methods, the severity and location of corrosion on the backside of metal liners in a consecutive series of retrieved hips with two different cup designs: DePuy Pinnacle and Smith & Nephew R3 and (2) determine if there were any differences in corrosion between the two designs.

Method

This was a retrieval study of the first 67 cobalt-chromium (CoCr) alloy modular cup liners collected at our implant retrieval centre that met our inclusion criteria. The liners were from two different manufacturers and all had been coupled with titanium (Ti) alloy shells. All of the hips had a metal-on-metal articulation and we required that the metal cup liner was loose from the titanium shell (or could be separated without damaging the surfaces) so that its backside could be assessed. The retrieved hips consisted of the DePuy Pinnacle cup (n = 35) and the Smith & Nephew R3 cup (n = 32).

The Pinnacles were retrieved from 17 male and 18 female patients with a median age of 61 years (37–77) at primary surgery and a median time to revision of 59 months (10–102). The median head size was 36 mm (36–40) and the median pre-revision whole blood cobalt and chromium levels were 6.22 ppb (0.6–130) and 4.65 ppb (0.6–42.4) respectively. The median Co/Cr ratio was 1.32 (0.27–5.21). The reason for revision for these implants, as defined by the revising surgeon, was unexplained pain (n = 33) and infection (n = 2).

The R3s were retrieved from 13 male and 19 female patients with a median age of 63 years (47–72) at primary surgery and a median time to revision of 56 months (28–72). The median head size was 44 mm (38–50) and the median pre-revision whole blood cobalt and chromium levels were 13.7 ppb (1.5–116) and 4.8 ppb (1.5–45.5) respectively. The

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Table 1
Implant and Patient Data Showing Median (Range) Values with *P*-Values Indicating the Significance of Differences Between the Parameters.

	Pinnacle Hips (n = 35)	R3 Hips (n = 32)	Significant Difference?	*P*-Value
Gender (male:female)	17:18	13:19	No	0.625
Age at primary surgery (years)	61 (35–77)	63 (47–72)	No	0.061
Time to revision (months)	59 (10–102)	56 (28–72)	No	0.362
Head size (mm)	36 (36–40)	44 (38–50)	Yes	<0.001
Whole blood Co (ppb)	6.22 (0.6–130)	13.7 (1.5–116)	Yes	0.003
Whole blood Cr (ppb)	4.65 (0.6–42.4)	4.8 (1.5–45.5)	No	0.439
Co/Cr ratio	1.32 (0.27–5.21)	2.74 (0.64–6.83)	Yes	<0.001

median Co/Cr ratio was 2.74 (0.64–6.83). The reason for revision for these implants, as defined by the revision surgeon, was unexplained pain (n = 31) and femoral loosening (n = 1).

Table 1 summarises the key patient and implant data. The study design of the current work is summarised in Fig. 1.

Visual Assessment of Corrosion

Macroscopic and stereomicroscopic examinations of the backside of all 67 metal liners were performed independently by two experienced observers (A and B) to assess the presence and severity of surface corrosion. A scoring scale of 1 (no corrosion) to 4 (severe corrosion), as defined by Goldberg et al [11], was used to quantify corrosion, which was identified as discoloured or dull regions or areas with evidence of pitting, etching or black debris. This scoring method was originally developed for the inspection of femoral head tapers however the grading criteria are applicable for the cup liner backside. Scores were assigned separately to the polar and equatorial regions of the liner, Fig. 2, and overall scores were determined following assessment of the surface as a whole. A Leica M50 microscope [Leica Microsystems, Germany] at up to ×40 magnification was used to assist in examinations.

The severity of corrosion at the taper surfaces of the corresponding femoral heads was also determined by a single examiner using the method defined by Goldberg et al [11].

Scanning Electron Microscopy (SEM)

The liners were viewed in a JEOL JSM (Tokyo, Japan) scanning electron microscope (SEM) using secondary electron detection at an accelerating voltage of 20 KV. This was used to further examine corroded regions identified macroscopically and microscopically and compare with visually pristine areas on the liners. The elemental composition of corrosion deposits visually identified as black debris was then analysed using energy-dispersive X-ray spectroscopy (EDX) within the SEM system.

Statistical Methods

Cohen's weighted Kappa statistic (κ) was used to assess the inter-observer reproducibility of the corrosion scores as determined by the two independent examiners, where κ ≤ 0 = poor, 0.01–0.20 = slight, 0.21–0.40 = fair, 0.41–0.60 = moderate, 0.61–0.80 = substantial, 0.81–1 = almost perfect [12].

The Mann–Whitney U test was used to determine if there was a significant difference between the corrosion scores of: (1) the polar and equatorial regions of both liner designs and (2) the overall corrosion scores for the two designs.

Non-parametric Spearman correlation tests were used to determine the significance of any associations between the liner corrosion scores and (1) femoral head size (R3 only), (2) Co/Cr ratio and (3) head taper corrosion score. Associations with head size for the Pinnacle hips were not considered as virtually all heads were 36 mm.

Kruskal–Wallis non-parametric ANOVA tests were used to determine the presence of any statistically significant differences between the overall corrosion scores of the two designs (separately) in relation to (1) time to revision, (2) patient age at primary surgery, (3) Co and Cr blood metal ion levels, (4) Co/Cr ratios. Post-hoc analysis was then performed using Mann–Whitney tests to identify which particular differences were significant.

Results

The inter-observer reproducibility of the corrosion scores determined by the two examiners was found to be almost perfect (κ = 0.856) indicating that this is a reliable method of visual inspection.

Visual Assessment of Corrosion

Fig. 3A and B plot the distribution of corrosion scores for the Pinnacle and R3 cup liners by examiner A. The polar regions of all Pinnacle liners (n = 35) were observed to have either mild or no corrosion, whilst 46% (n = 16) of liners had evidence of moderate or severe corrosion at the equatorial region. 94% (n = 30) of the R3 liners had either mild or no corrosion at the pole whilst 78% (n = 25) of liners were moderately or severely corroded at the equator. Corrosion scores were significantly

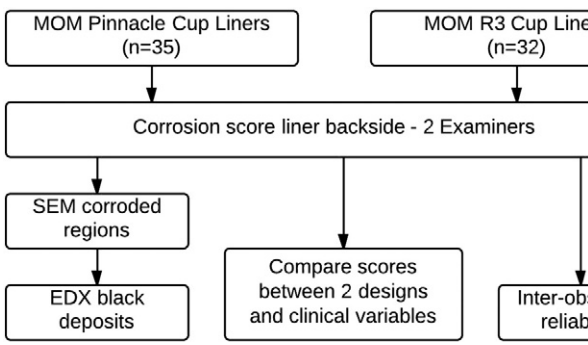

Fig. 1. Summary of study design.

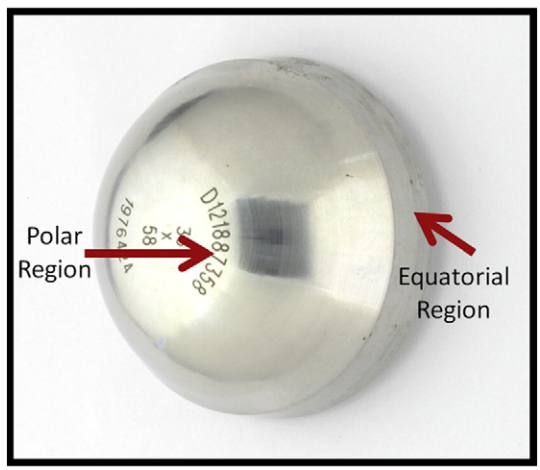

Fig. 2. Polar and equatorial/rim regions of the backside of the cup liner.