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Material Loss at the Head Taper Junction of the Metal-on-Metal Pinnacle Total Hip Replacement

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Introduction

The ASR XL (DePuy) total hip replacement (THR) is a notable example of a modern metal-on-metal (MOM) implant design that has demonstrated unacceptable survival rates, leading to its recall by the manufacturer; national joint registries have reported revision rates at 7 years of 40% when paired with the Corail stem [1].

The ASR XL THR has a considerably greater risk of revision than the ASR resurfacing hip, which used the same bearing design. This suggests that material loss at the head-stem junction may be responsible for the greater percentage of THR failures observed in this design. The Pinnacle MOM-THR (DePuy) however used the same Corail stem as the ASR XL THR but demonstrated better clinical results, with revision rates of less than 10% at 7 years [1].

The ASR XL and MOM Pinnacle are two designs that have been widely used in hip replacement surgery. The reasons for the differences in the failure rates of the two designs are not fully understood. Comparing the mechanisms of failure of both hips will help surgeons understand whether patients with MOM Pinnacle hips will experience the same types of problems as with those seen with the ASR XL.

The aims of this retrieval study were to investigate the significance of differences between the ASR XL and MOM Pinnacle in relation to: (1) pre-revision whole blood Co/Cr ratios, (2) visual evidence of taper corrosion, (3) volumetric material loss at the bearing surfaces and (4) volumetric material loss at the taper surfaces.

Methods

This study involved a series of failed MOM hips consisting of the ASR XL (n=30) and Pinnacle (n=30), all that had been used with a Corail stem. The bearing material in each design was cobalt-chromium and the Corail stem is of a cementless titanium 12/14 design.

The ASR XL and Pinnacle had a median head diameter of 47mm (39-55) and 36mm (36-40) respectively, and a median time to revision of 38.5 months (12-74) and 55 months (14-86) respectively. Pre-revision whole blood metal ion levels were collected for each Table 1 summarises patient and implant data for the hips in this study.

The female taper surfaces of all 60 heads were examined macroscopically and microscopically to assess the severity of corrosion. Each surface was graded with a score of between 1 (no corrosion) and 4 (severe corrosion) using a well-published scoring system, which has been shown to be statistically reliable.

A Zeiss Prismo (Carl Zeiss Ltd, Rugby, UK) coordinate measuring machine (CMM) was used to determine the volume of material loss at the cup and head bearing surfaces. Up to 300,000 data points were collected using a 2mm ruby stylus that was translated along 400 polar scan lines on the surface. The raw data was used to map regions of material loss by comparing with the unworn geometry of the bearing.

A Talyrond 365 (Hobson, Leicester, UK) roundness measuring machine was used to measure the volumetric material loss at each of the head taper surfaces. Published protocols were used to take a series of 180 vertical traces along the taper surface using a 5µm diamond stylus; worn and unworn regions were mapped and used to calculate material loss.

Neither the volumetric measurement data nor corrosion scores were normally distributed. Therefore non-parametric tests were performed to assess the statistical significance of differences between the two designs in relation to the parameters under investigation in this study.

Results

Both the whole blood Co ion levels and the Co/Cr ratios, Figure 1, of the ASR XL hips were significantly greater than the Pinnacles ($p<0.05$). There was no significant difference between the whole blood Cr ion levels between the two designs ($p=0.0542$).

18 of the ASR XL hips presented evidence of edge wearing of the cup, compared with 14 Pinnacle hips; this difference was not significant ($p=0.438$). The length of the stem trunnion contact engagement length with the taper was approximated as being 10.5mm for both

designs. The median time to revision of the ASR XL hips was significantly less than the Pinnacle hips ($p<0.01$).

There was visual evidence of corrosion in 93% (n=28) and 90% (n=27) of head tapers for the ASR XLs and Pinnacles respectively. Moderate to severe corrosion was observed in 67% (n=20) of ASR XLs compared to 60% (n=18) of Pinnacles. There was however no statistically significant difference between the scores of the two groups ($p=0.927$).

Figure 2 presents the distribution of material loss rates for the bearing and taper surfaces of the two designs in this study. The median total bearing surface (combined cup and head) rate of material loss for the ASR XL and Pinnacle hips was 4.45mm^3/year (0.32-22.85) and 4.03mm^3/year (0.87-62.12) respectively. There was no significant difference between the two groups ($p=0.928$).

The median material loss rate at the taper surfaces of the ASR XL and Pinnacle hips was 0.62mm^3/year (0-4.20) and 0.30mm^3/year (0-3.12); this difference was not significant ($p=0.198$).

Discussion

The work of this study presents comparisons of retrieval findings between the ASR XL and Pinnacle MOM-THRs; these hip designs were two of the most commonly implanted in patients worldwide.

The significantly greater whole blood Co/Cr ratios found in the ASR XL group compared to the Pinnacle group are of interest. It is speculated that a Co/Cr ratio of greater than 1 may be an indicator of corrosion of an implant whereby more Cr ions are retained on the surface, whilst comparatively more Co ions are released into the blood. In the current study we found wear rates at the bearing surfaces of both designs to be comparable, suggesting that the significantly greater Co/Cr ratios in the ASR XL hips must be due to greater corrosion at the taper junction than the Pinnacles.

Although the ASR XL hips had been implanted for a significantly shorter period of time, our visual assessment of the corrosion of the taper junctions found that corrosion scores were comparable between the two designs; indeed, a marginally greater number of ASR XL tapers had evidence of moderate to severe corrosion. This finding, coupled with the elevated Co/Cr ratios suggests that the ASR XL design is more susceptible to corrosion at the taper junction than the Pinnacle hip.

We found that the median rate of material loss at the ASR XL taper was over twice that of the Pinnacle taper. Whilst not statistically significant, this difference may be due to a greater risk of corrosion at this interface in the ASR XL design.

The differences in material loss and corrosion that were observed at the taper junctions may be explained by considering the larger head sizes of the ASR XL hips in comparison to the Pinnacles. It has previously been shown that increasing head size is correlated with greater visual evidence of corrosion and that increased frictional torque along the taper junction due a larger head diameter can increase the risk of fretting-corrosion.

It is suggested therefore that the combination of the larger head sizes of the ASR XLs coupled with the comparatively short, rough surface of the Corail trunnion results in a cumulative effect leading to greater corrosion at the taper junction.

Significance

The results of the study suggest that the combination of (1) increased frictional torque in the larger ASR XLs and (2) the rough Corail trunnion surface, results in greater corrosion at the taper junction in comparison to the Pinnacle hips; this helps to explain the higher risk of revision in this hip design.

	ASR XL Hips	Pinnacle Hips
Gender (Male : Female)	13 : 17	15:15
Age at Primary Surgery (years)	57 (43-78)	62.5 (26-73)
Time to Revision (months)	38.5 (12-74)	55 (14-86)
Head Diameter (mm)	47 (39-55)	36 (36-40)
Whole Blood Cobalt (ppb)	11.54 (0.6-167)	4.25 (0.6-130)
Whole Blood Chromium (ppb)	7.28 (0.2-66)	3 (0.6-42.4)
Co/Cr Ratio	2.27 (0.03-13)	1.33 (0.76-3.07)

Table 1: Patient and Implant Data, values presented as median (range)

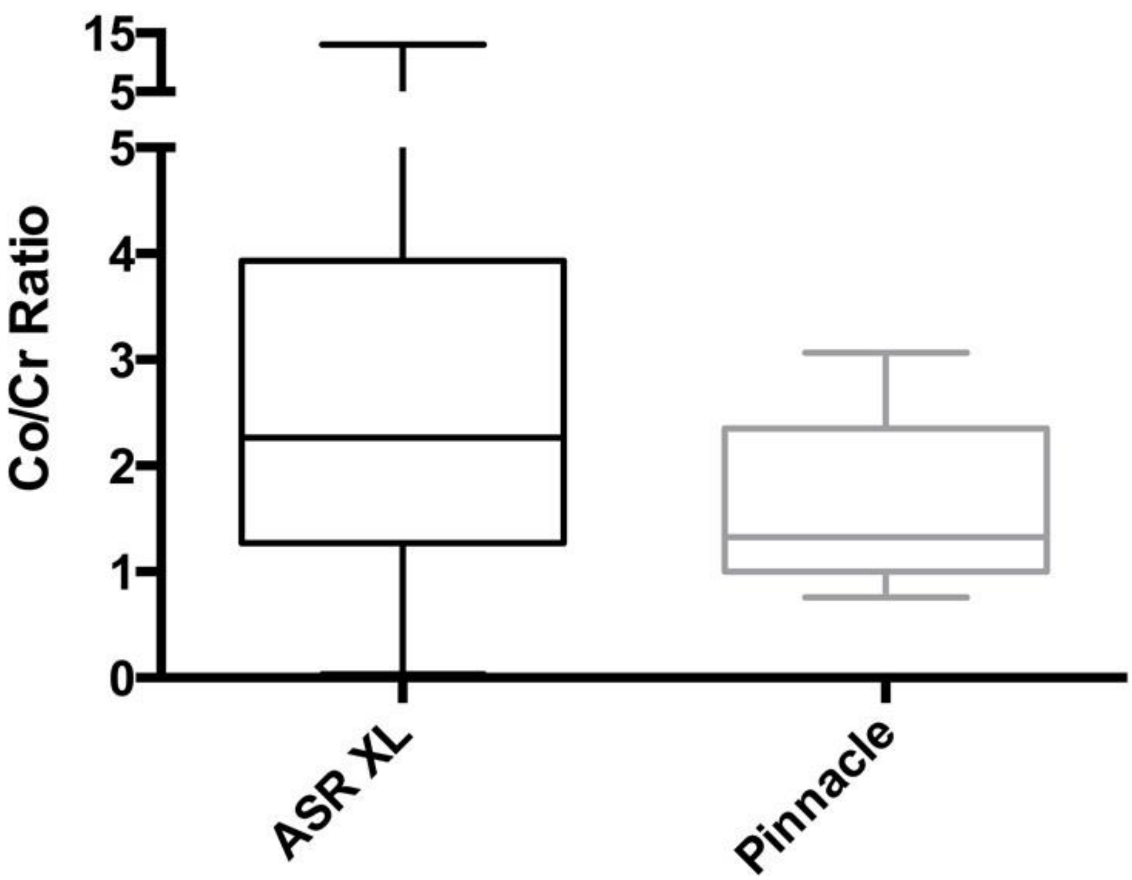

Figure 1: Summary of Co/Cr ratios of the ASR XL and Pinnacle hips

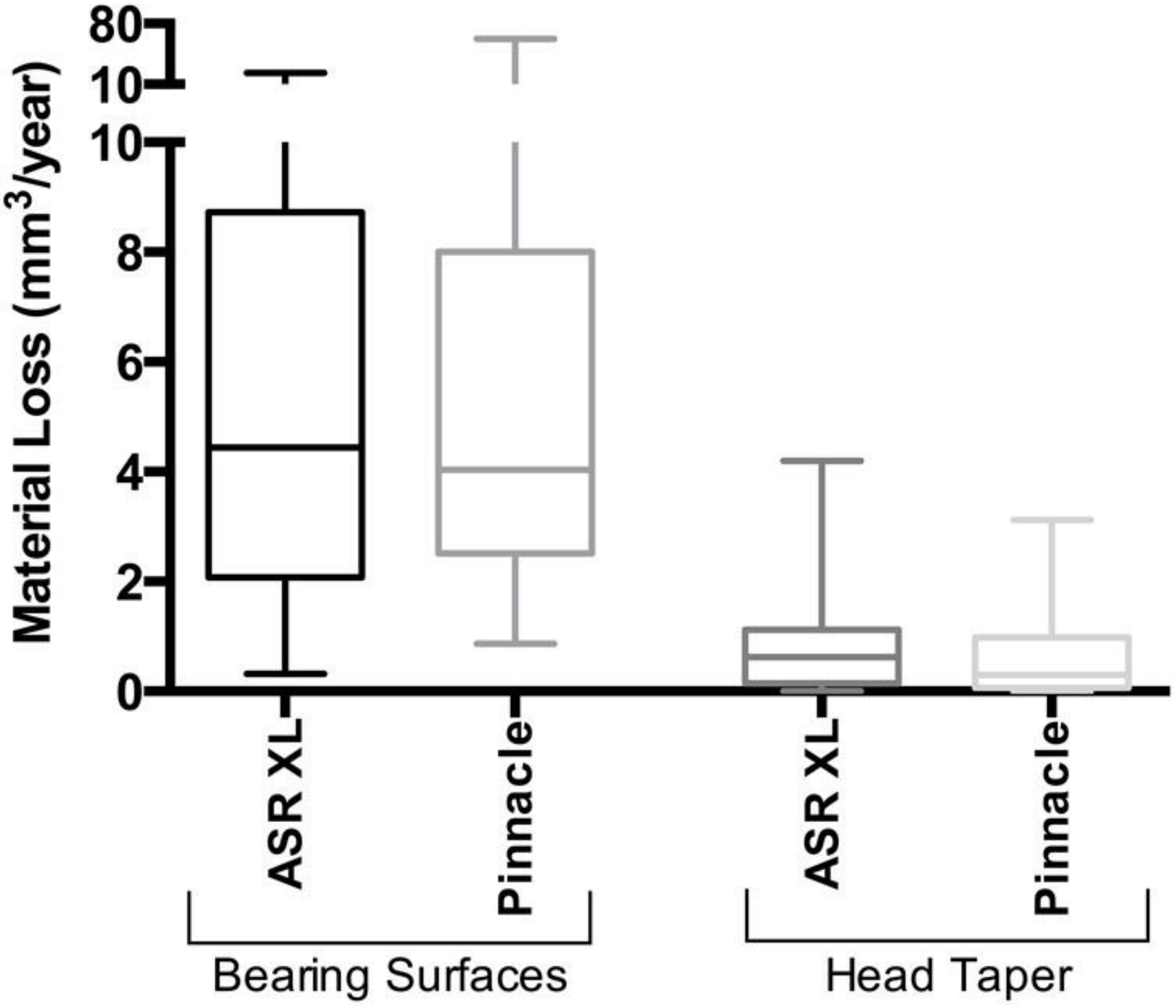

Figure 2: Summary of material loss rates at the bearing and taper surfaces of the ASR XL and Pinnacle hips