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## **Analysis of a Surface Engineered Metal on Metal Hip Resurfacing: A Case Study**

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### Introduction

The ACCIS prosthesis is a ceramic surface engineered hip resurfacing, manufactured from cobalt-chromium-molybdenum (CoCrMo) with a titanium niobium nitride (TiNbN) coating [1]. The coating is designed to increase the wear resistance of the prosthesis. However damage to such coatings can result in additional wear debris, which may accelerate wear and provoke an adverse host response *in vivo*.

### Methods

A single ACCIS hip resurfacing prosthesis (head and cup) was obtained for volumetric wear analysis and measurement of surface roughness. The patient was female and 41 years old at the time of the revision, which was undertaken due to high metal ions. The prosthesis was *in vivo* for 22 months. Prior to revision surgery the metal ion levels were 83ppb Cr and 110 ppb Co. Volumetric wear was quantified from the articulating surfaces of the femoral head and acetabular cup using a Mitutoyo Legex 322 Coordinate Measuring Machine (manufacturer claimed scanning accuracy of 0.8 $\mu$ m) with the results analysed using a custom MATLAB programme [2]. Roughness measurements (including Sa, Sq and skewness) were obtained using a ZYGO NewView 5000 non-contacting profilometer, which had previously been used to measure explanted metal-on-metal hip resurfacings [3].

### Results

The gold-coloured TiNbN coating had been completely removed over a large region of both the femoral head and acetabular cup revealing the silver-coloured CoCrMo substrate (Figure 1). Volumetric wear analysis confirmed that the regions of coating removal correlated with the worn sections of the prostheses (Figures 1 and 2). The total wear volume was 112 mm<sup>3</sup> of which 50 mm<sup>3</sup> was from the femoral head and 62 mm<sup>3</sup> from the cup. This equated to a wear rate of 61 mm<sup>3</sup>/year. The wear scar on the femoral head formed an irregular elliptical shape, while the wear scar of the acetabular cup extended to a localised section of the rim of the acetabular cup.

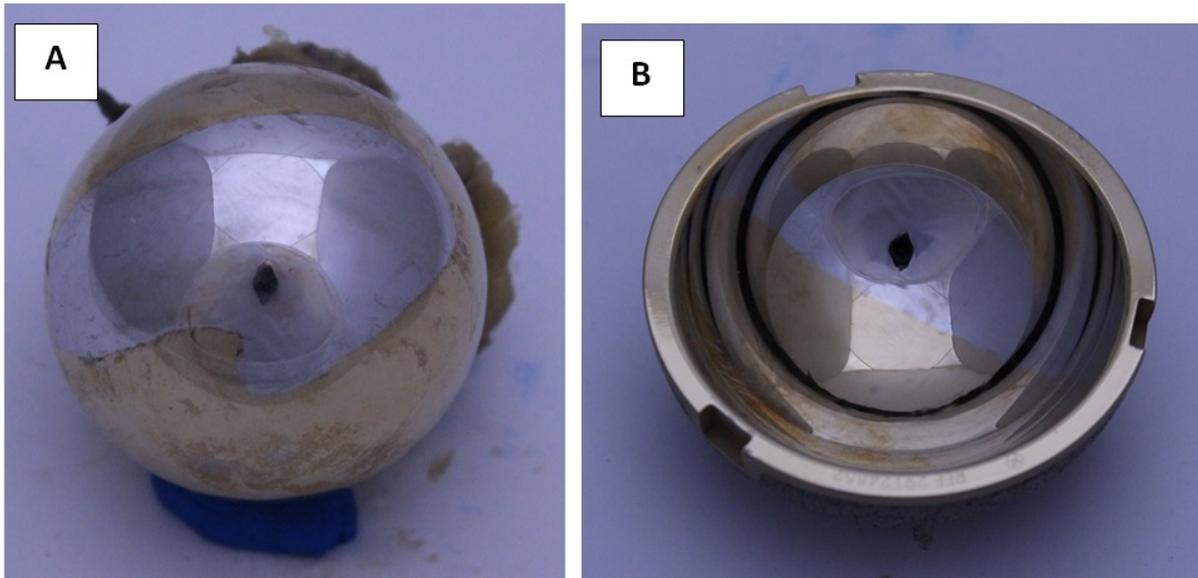


Figure 1: Photos of the femoral head A) and acetabular cup B) showing the removal of coating in the wear scar

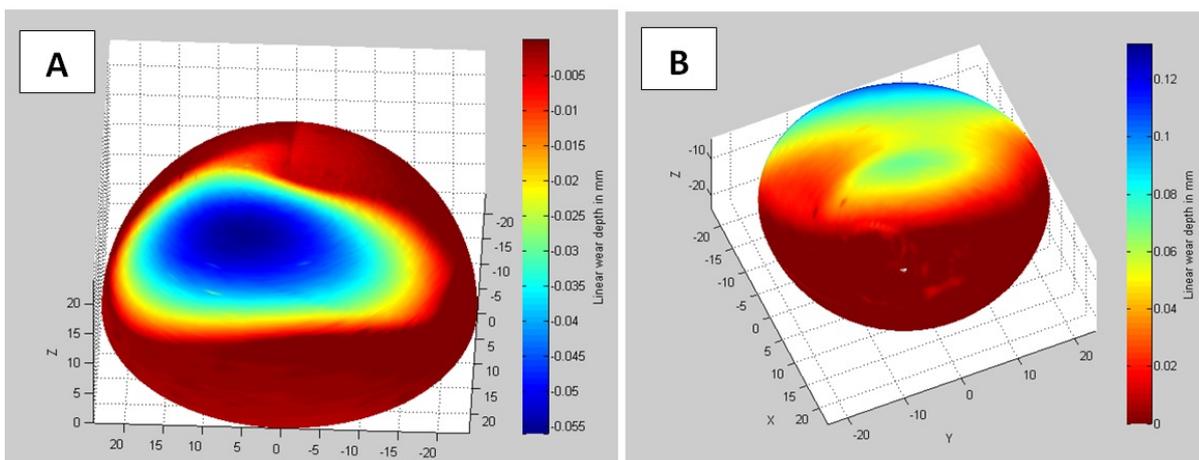


Figure 2: Coordinate Measuring Machine MATLAB plots of the femoral head A) and acetabular cup B) showing the wear scar in each case. Blue indicates the greater wear depths.

Roughness measurements of Sa, Sq, kurtosis and skewness were taken over three regions of the articulating surfaces of the femoral head and the acetabular cup. These regions were the TiNbN coating, the CoCr substrate where the coating had been removed, and the boundary between these two regions. Comparative data for Sa is shown in figure 3 below.

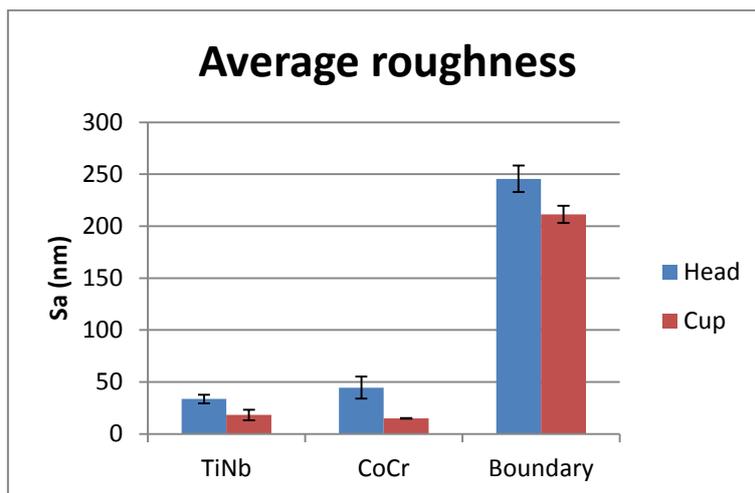


Figure 3 – comparison of Sa roughness between TiNbN, CoCr and boundary regions of the articulating surfaces of the explanted femoral head and acetabular cup. Error bars indicate standard deviations.

### Discussion

The wear rate reported here (61 mm<sup>3</sup>/year) is high. Lord et al previously noted that the mean combined head and cup wear rate for a cohort of 22 DePuy Articular Surface Replacement (ASR) hip resurfacings was 22 mm<sup>3</sup>/year [2], a third of the value noted in this study. A later paper by Langton et al, examining a cohort of 57 ASR hip resurfacings suggested that a combined wear rate of above 2.3mm<sup>3</sup>/year was sufficient to cause a wear related failure [4]. The shape of the wear scars corresponded with those seen previously on worn and explanted hip resurfacings [2,5]. The edge wear seen on the acetabular cup is a common feature of worn and retrieved monoblock metal cups [6].

A possible explanation of the high wear rate is that the failure of the coating resulted in debris generation, which in turn may have resulted in three body abrasive wear accelerating the wear process. Such a process has been seen previously with the LPM proximal interphalangeal joint prosthesis, which utilised a similar type of TiNb coating [7]. Care should therefore be taken utilising surface coatings as failure can result in wear debris which may accelerate the wear process. Indeed the catastrophic failure of other coatings in orthopaedic applications has been reported previously [8,9].

At 83ppb Cr and 110 ppb Co the ion concentrations were remarkably high. It should be noted that these were Co and Cr ions, not Ti or Nb or N, so it is clear that substantial wear from the CoCr substrates had taken place. For context, the current Medicines and Healthcare products Regulatory Agency (MHRA) guidelines for the UK state that “Blood metal ion level >7ppb indicates potential for soft tissue reaction” [10]. The at least 10-fold higher concentration of metal ions in this case, is not a positive sign. Previously it has been shown that elevated blood metal ion concentrations are associated with early failure of metal-on-metal hip implants secondary to adverse reactions to metal debris, and that Co concentrations greater than 20 ppb are frequently associated with metal staining of tissues and the development of osteolysis [11]. Another paper showed that above 4.5ppb, abnormal wear was indicated [12]. The same paper also suggested that a whole blood Co of

100ppb was associated with a wear rate of between 21 and 59mm<sup>3</sup>/year [12]. Those figures fit well with the 110ppb and 61 mm<sup>3</sup>/year reported in this case.

From the roughness data it could be seen that the unworn TiNbN surface showed the lowest roughness (Sa and Sq) values. This is perhaps unsurprising as these represented the 'unworn' region of the articulating surfaces. At mean values of 33 (SD 4) and 18 (SD 5) nm for head and cup respectively, these are within the 50 nm guidelines offered by ISO/British Standards for the articulating surfaces of metal orthopaedic implants [13]. Interestingly the worn CoCr surfaces, at 45 (SD 10) and 15nm (SD 1) respectively, are rather similar to the TiNbN values. A previous paper measuring the roughness of a cohort of 7 explanted ASR hip components found mean values between 25 and 135 nm Sa [3]. Therefore the CoCr roughness values offered in this case study are of a similar order of magnitude. The highest roughness values were found at the boundary between the TiNbN coating and the worn CoCr. This is seen in figure 3, and comparative Sa values were 246 (SD 13) and 211 (SD 8) nm respectively. Visual images of this boundary region did not indicate a complete and sudden removal of the surface coating, in contrast to a coating failure mode seen in a different orthopaedic implant [8,9].

Two recent papers have highlighted apprehensions with TiNbN coatings [14,15]. However, there were also earlier concerns expressed [16]. In addition it was known that the ACCIS TiNb coating used in a finger implant was associated with a failure rate of 40% at 41 months [17]. Such a high failure rate led to the British Society for Surgery of the Hand undertaking an audit [18]. Therefore questions of how such an implant was brought to market, on what basis the CE mark was awarded, pre-clinical in vitro testing and the interaction with joint registries ought to be considered, as they should with more well-known failures [19]. It is difficult to know how many might have been implanted in the UK, as the ACCIS hip is not listed in the 2014 National Joint Registry and therefore, presumably, less than 1000 have been implanted [20].

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