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Failure of an ACCIS metal-on-metal hip resurfacing prosthesis: A case report

Martin C Bone¹, Andrew Naylor¹

Abstract

The introduction of coatings on joint replacements was intended to reduce wear volumes, prevent corrosion and reduce metal ion release. However retrieval analysis to confirm their in vivo performance has been limited. The aim of study was to examine the coating on a retrieved hip prosthesis to determine if substantial damage or wear had occurred. A single ACCIS titanium niobium nitride coated hip resurfacing prosthesis was retrieved for examination. Wear volumes and surface roughness were measured to quantify the damage to the articulating surfaces. The coating had been completely removed from substantial parts of both the femoral head and the acetabular cup, corresponding to areas of wear as measured by a coordinate measuring machine. The total wear rate (61 mm³/year) was high and corresponded with the high metal ion levels recorded pre operatively (83 ppb Chromium and 110 ppb Cobalt). Roughness data indicated that the coating has a lower roughness than the substrate and substantially lower than the boundary between the coating and the substrate. The wear rate is very high and it is likely that damage to the coating resulted in accelerated wear of the prosthesis. No sudden change between the boundary of the substrate and the coating was observed that would indicate delamination or failure of the coating substrate interface layer. Whilst coatings may offer some theoretical benefits, they may also result in catastrophic failure of the prosthesis.

Keywords

Wear Analysis/Testing (Biomechanics), Tribology of Coatings, Orthopaedic Tribology,
Orthopaedic Materials, Surfaces, Blood Metal Ion Levels

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Introduction

Wear of metal-on-metal (MoM) hip replacements has been widely documented in the literature. Whilst studies have shown that MoM hip prostheses have lower wear volumes than metal-on-polyethylene (MoP) prostheses, the number of wear particles released by a MoM hip prosthesis is substantially higher (typically 7 to 30 times).¹ In the quest for lower wear rates and higher corrosion resistance, other designs of artificial hip joint have been developed and implanted. One of these is the Advanced Ceramic Coated Implant Systems (ACCIS) hip prosthesis, a ceramic surface engineered hip resurfacing, manufactured from cobalt-chromium-molybdenum (CoCrMo) with titanium niobium nitride (TiNbN) coating.^{1,2} According to the manufacturer, the introduction of a coating was intended to reduce wear, prevent corrosion and reduce metal ion release.²

1 ACCIS hip prostheses are cast and heat treated to reduce the size of block carbides on the
2 metal surfaces, as these may cause wear via abrasion.^{1,2} The surfaces are then polished
3 before undergoing a surface microfinish to remove asperities down to a nanometre level.^{1,2} A
4 TiNbN coating with a nominal thickness of 300±50 µm is then applied to the surfaces via the
5 process of physical vapour deposition (PVD).^{1,2} This is said to alter the surface chemical
6 properties of a material without affecting the macro material and biochemical properties. In non-
7 coated MoM CoCrMo alloy joints, block carbides have been identified as being useful for
8 reducing wear rates. One potential explanation as to why they were reduced in the ACCIS, is
9 that the smoother surface would provide more favourable conditions for the coating to bond to
10 the substrate.

11

12 To the authors' best knowledge there are only a limited number of studies in the literature to
13 examine the performance of the ACCIS hip.^{2,5} de Villiers et al. examined three explanted
14 resurfacing prosthesis pairs.³ In all cases there were large areas where the coating had been
15 completely removed, indicative of three body wear, exposing the CoCrMo substrate.³ The three
16 pairs had a mean time in vivo of 29 months (range 26-33 months), and average blood metal ion
17 levels of 30 ppb and 24.6 ppb for cobalt and chromium respectively. Jemmett et al.⁴ reported
18 that seven prosthesis pairs were revised due to elevated metal ion levels, after a mean period
19 or 56 months in vivo (range 41-72 months). On average the measured levels for cobalt and
20 chromium were 7 ppb and 8 ppb respectively. It was not stated whether these were total hip
21 replacement or resurfacing. This is in contrast to a study by Hamelynck and Woering, which
22 measured blood metal ions from 60 patients with the ACCIS hip resurfacing prostheses up to 24
23 months post-surgery.² The results indicated that the cobalt and chromium levels were lower
24 than the 7 ppb threshold⁶ advised by the Medicines and Healthcare products Regulatory

Agency (MHRA) in the UK. In 2015 Lapaj reported on a cohort of 11 titanium niobium TiNb coated hip prostheses with time in vivo ranging from 1 month to 56 months.⁵ No gross failure of the TiNb coating was reported, however all implants had evidence of defects in the coating including pinholes and blisters with delamination.⁵ Due to the limited number of studies available, the aim was to examine a retrieved ACCIS hip prosthesis to determine how the coating had performed in vivo. The objectives of the study were to:

1. Quantify the volumetric wear from the articulating surfaces
2. Measure the surface roughness of the coating, the exposed substrate and the boundary between the two regions and determine if there is any disparity

Methods

Patient and Prosthesis Details

A single uncemented ACCIS hip resurfacing prosthesis (Implantcast GmbH, Buxtehude, Germany) consisting of a 48 mm diameter femoral head (cemented); and a 52 mm diameter acetabular cup (uncemented), was obtained for volumetric wear analysis and measurement of articulating surface roughness. The prosthesis was in vivo for 22 months and revised due to high blood metal ion levels. The patient was female, was a healthy weight (BMI < 25), and was 41 years of age at the time of the revision. The patient had a history of Perthes disease and acetabular dysplasia, for which she had previously undergone periacetabular osteotomy. The ACCIS prosthesis was implanted by a consultant orthopaedic surgeon at Morriston Hospital, Swansea, UK. The surgeon had implanted approximately 200 of these prostheses by the time of her surgery. The patient had had no prosthesis implanted prior to the ACCIS, and had undergone no other arthroplasty procedures to replace other joints of the body.

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1 Prior to revision surgery the metal ion levels were 83 ppb Cr and 110 ppb Co. A macroscopic
2 examination of the explanted hip resurfacing was conducted prior to taking volumetric wear and
3 surface finish measurements. At the time of revision there were no signs of corrosion or wear
4 debris in the surrounding tissue.

5
6 **Volumetric Wear Analysis**

7 Volumetric wear was measured using a Mitutoyo Legex 322 (Mitutoyo Corporation, Kawasaki,
8 Kanagawa, Japan) Coordinate Measuring Machine (CMM), which has a manufacturer claimed
9 scanning accuracy of 0.8 μm . A 5 mm diameter scanning probe was used for the
10 measurements, whilst the results were processed using a custom MATLAB programme
11 described in detail elsewhere.⁷ This wear volume methodology has been validated and found
12 accurate to within 0.5 mm^3 .^{7, 8}

13
14 **Surface Roughness Analysis**

15 Surface roughness measurements were performed using a ZYGO NewView 5000 (Zygo
16 Corporation, Middlefield, CT, USA) white light interferometer (resolution 1nm). Measurements
17 were taken at three key areas for both the head and cup: 1) where the coating was still intact; 2)
18 where the coating was completely removed exposing the CoCrMo substrate; 3) along the
19 edge/boundary between the coated surface and the exposed substrate. Three measurements
20 were taken from each of these key areas, from which both micrographs and 3D topographical
21 plots were obtained.

22 From the plots, three roughness parameters were selected: average roughness (S_a); skewness
23 (S_{sk}); and kurtosis (S_{ku}). Average roughness (S_a) is described as the arithmetic mean of the z
24 axis heights (peaks and valleys) obtained from the plots, and hence the calculated values

provided an indication for the variation in heights. Guidelines for metal hip prostheses specify a 50 nm threshold for average roughness measurements only.⁹ S_{sk} and S_{ku} are dimensionless values. S_{sk} is a measure of surface *amplitude* with positive values indicative of a high number of peaks above the surface; negative values indicative of a high number of valleys below the surface. S_{ku} is a measure of surface *pitch* with high positive values indicative of a high number of sharp peaks and/or valleys. Root mean square roughness (S_q) was initially considered, but discounted after reviewing the findings of a separate study, revealing similar S_a and S_q values for orthopaedic applications.¹⁰

Results

Volumetric Wear

The TiNbN coating had been removed over a large region of both the femoral head and acetabular cup revealing a wear scar of the CoCrMo substrate (Figure 1). The total wear volume was 112 mm³ of which 50 mm³ was from the femoral head and 62 mm³ from the acetabular cup. This equated to a wear rate of 61 mm³/year. The wear scar on the femoral head formed an irregular elliptical shape, while the wear scar of the acetabular cup extended to a large but localised section of the rim of the acetabular cup (Figure 2). The regions of coating removal identified by the CMM were found to correlate with the worn sections of the prostheses (Figures 1 and 2). Although it is clear that the observed volumetric wear is primarily a result of removal of the TiNbN coating, a smaller level of material loss of the CoCrMo substrate will have occurred.

Coated Surface

The TiNbN coated surfaces of the femoral head yielded a low mean S_a value of 33.61 nm (StDev 4.21); along with a negative mean S_{sk} value of -2.38 (StDev 2.40); and a high mean S_{ku}

1 value of 56.71 (StDev 53.00) (Table 1). The TiNbN surfaces of the acetabular cup returned
2 values somewhat lower in magnitude: for both S_a (18.19 nm, StDev 5.11); S_{sk} (-1.53, StDev
3 1.94); and S_{ku} (36.57, StDev 19.90). An example micrograph and topographical plot obtained
4 from the femoral head, showing a uniform surface, is shown in Figure 3.

5
6 **Substrate Surface**

7 The exposed CoCrMo surfaces of the femoral head showed mean S_a values of 44.61 nm
8 (StDev 10.68). These were seen to be higher than for the cup (14.88 nm, StDev 0.26). The
9 mean S_{ku} values were in the same approximate range for both the head (16.32, StDev 9.49)
10 and the cup (12.77, StDev 13.61). The femoral head yielded a negative mean S_{sk} value (-1.64,
11 StDev 0.45). A micrograph and topographical plot of the exposed CoCrMo surface is shown in
12 Figure 4. In contrast to this, the acetabular cup yielded a positive mean S_{sk} value (1.20, StDev
13 0.77). A micrograph and topographical plot obtained of the exposed CoCrMo surface of the
14 acetabular cup is shown in Figure 5.

15
16 **Boundary surface**

17 Measured values taken at the TiNbN-CoCrMo boundary were comparable for both the femoral
18 head and acetabular cup, with: very high mean S_a values reported for the head (245.55 nm,
19 StDev 12.7) and cup (211.29 nm, StDev 8.34); low mean S_{sk} values for the head (0.3, StDev
20 0.03) and cup (0.09 StDev 0.36); and low mean S_{ku} values for the head (2.36, StDev 0.19) and
21 cup (2.5, StDev 0.45). The topography at the TiNbN-CoCrMo boundary is very similar for both
22 femoral head and acetabular cup. A distinct ridge is visible where the TiNbN coated surface and
23 exposed CoCrMo surface meet, as exemplified by a micrograph and a topographical plot
24 obtained from the femoral head (Figure 6).

Discussion

The wear rate reported here ($61 \text{ mm}^3/\text{year}$) is high. Lord et al previously noted that the mean wear rate for a cohort of 22 DePuy Articular Surface Replacement (ASR) hip resurfacings was $22 \text{ mm}^3/\text{year}$, a third of the value noted in this study.⁷ A later paper by Langton et al, examining a cohort of 57 ASR hip resurfacings suggested that a combined wear rate of above $2.3 \text{ mm}^3/\text{year}$ was sufficient to cause a wear related failure.¹¹ Comparison of the current wear rate ($61 \text{ mm}^3/\text{year}$) with those reported by previous studies for other types of hip resurfacings further demonstrates the extremity of the wear reported here. For instance, a study by Witzleb et al. examined 2 Birmingham Hip Resurfacing (BHR) prostheses reporting a mean wear rate of $15.6 \text{ mm}^3/\text{year}$ (range $8.4 - 22.8 \text{ mm}^3/\text{year}$).¹²

To the authors' best knowledge there is only one other study offering wear rates for TiNbN coated hip resurfacing prostheses.³ Total wear rates of 6.90 , 8.28 and $16.22 \text{ mm}^3/\text{year}$ were reported for three prostheses in vivo for between 26 and 33 months. These wear rates were substantially lower than that reported in the present study.

The shape of the wear scars corresponded with those seen previously on worn and explanted hip resurfacings.¹³ The edge wear seen on the acetabular cup is a common feature of worn and retrieved monoblock metal cups.¹³

At 83 ppb Cr and 110 ppb Co , the metal ion levels are high however this is perhaps unsurprising given the high wear rate. It is important to note that these ion values do not include Ti, Nb or N clearly demonstrating substantial wear of the substrate has occurred. For context, the current MHRA guidelines for the UK state that "Blood metal ion level $>7 \text{ ppb}$ indicates potential for soft tissue reaction".⁶ Previously it has been shown that elevated blood metal ion

1 concentrations are associated with early failure of metal-on-metal hip implants secondary to
2 adverse reactions to metal debris, and that Co concentrations greater than 20 ppb are
3 frequently associated with metal staining of tissues and the development of osteolysis.¹⁴
4 Another paper showed that for ion concentrations above 4.5 ppb, abnormal wear was
5 indicated.¹⁵ The same paper also suggested that a whole blood Co of 100 ppb was associated
6 with a wear rate of between 21 – 59 mm³/year.¹⁵ Those values fit well with the 110 ppb and 61
7 mm³/year reported in this case.

8 A possible explanation of the high wear rate is that the failure of the TiNbN coating resulted in
9 third body wear particles that accelerated the wear process. A similar process was seen
10 previously with the LPM proximal interphalangeal joint prosthesis, which utilised a similar type of
11 TiNb coating.¹⁶ Retrieval analysis confirmed that the surfaces had experienced extensive
12 damage to the TiNb coating with multi and multidirectional scratching on the articulating
13 surfaces indicating a third body wear¹⁶. The coating was described as acting as a “hard grinding
14 paste” accelerating wear on the articulating surfaces. It is possible the same process may have
15 occurred in the ACCIS hip prosthesis.

16 This present study correlates with the findings of de Villiers et al³ and Jemmett et al⁴ who both
17 reported that the use of coatings for metal hip resurfacings does not prevent metal ion release.
18 However in contrast to this, Hamelynck and Woering¹ noted that the metal ion levels for a cohort
19 of 200 ACCIS resurfacing prostheses showed no raising of either cobalt or chromium at a
20 maximum follow up of 24 months. Cobalt and chromium metal ion levels from 60 patients were
21 reported in the Hamelynck and Woering study¹, however these results were obtained from three
22 major hospitals, all in developed countries. It is also worth stating that the Hamelynck and

1 Woering study¹ is a white paper published with the support of the manufacturer of ACCIS,
2 Implantcast.

3 The S_a roughness values of both the coated and uncoated surfaces were within the 50 nm
4 guidelines offered by the relevant ISO Standard.⁹ For comparison Joyce et al. reported on a
5 cohort of explanted DePuy ASR hip prostheses, noting mean S_a values ranging from 25 to 135
6 nm.¹⁷ Joyce et al also measured a single un-implanted prosthesis with reported head and cup
7 S_a values of 10 and 12 nm respectively. From this present study, the S_a values from both the
8 coated TiNbN; and exposed CoCrMo surfaces (Table 1) fell below the 50 nm ISO standard
9 threshold.⁹ However, the S_a values at the boundary were substantially higher than this standard
10 (246 nm for femoral head; 211 nm for acetabular cup).

11 Other roughness parameters (combination of negative skewness and high kurtosis) indicated
12 that the exposed surface of the head (Figure 4) had sharp valleys along the surface. Peaks
13 were found on the articulating surface of the acetabular cup, whilst unidirectional troughs were
14 found on the articulating surface of the femoral head. These phenomena have been noted
15 previously by de Villiers et al.³ after examining the surfaces of an explanted TiNbN acetabular
16 cup using energy dispersive x-ray spectroscopy (EDS) de Villiers et al. found that the majority of
17 the asperities were composed of Titanium, Niobium and Nitrogen leftover from the TiNbN
18 coating with a small minority of the asperities composed of CoCrMo from the substrate.³ This
19 sheds more light on the exposed CoCrMo surfaces of the ACCIS femoral head and acetabular
20 cup reported in this present study. It is prudent to assume that the hard asperities composed of
21 Titanium, Niobium and Nitrogen visible on the surface of the cup (Figure 5) were responsible for
22 creating the unidirectional scratches on the surface of the head (Figure 4).

1 Hauert et al. have previously shown that other types of coating are also susceptible to failure.¹⁸
2 The study reported on a first metatarsophalangeal (MTP) prosthesis manufactured from CoCr
3 with a diamond like carbon (DLC) coating.¹⁸ Upon revision the prostheses underwent retrieval
4 analysis which determined that the cause of failure was due to the interface layer between the
5 substrate and the coating.¹⁸

6 One limitation of the study is that it was based on a single explanted prosthesis. Ideally more
7 samples would have been analysed, however the ACCIS is a relatively uncommon prosthesis
8 which is not currently recorded in National Joint Registry.¹⁹ It is hence difficult to offer a
9 comparison on the clinical performance to other similar hip resurfacing prostheses. The authors
10 of this study are keen to see further details of the clinical record of the ACCIS prosthesis, and
11 hope that long term follow up reports covering more substantial patient cohorts are published in
12 due course.

13
14 **Conclusion**

15 To summarise, it is likely that wear of the coating produced TiNbN debris, which in turn led to
16 wear of the CoCrMo substrate and the high metal ions measured. This type of failure has been
17 reported previously for LPM finger prostheses¹⁶ which utilised a similar coating, as well as for
18 other explanted ACCIS hip prostheses. So whilst surface coatings of orthopaedic implants
19 theoretically offer benefits, failure of such coatings can result in catastrophic damage to the
20 implant.

21
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2 We also want to acknowledge Professor Thomas Joyce of Newcastle University and Pryers
3 Solicitors LLP, York, for securing the prosthesis for analysis.
4

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7 not-for-profit sectors.
8

9 **Declaration of Conflicts of Interest**

10 MCB has received consulting fees for medicolegal work concerning other failed metal-on-metal
11 hips. Newcastle University also received money through medicolegal litigation for the same
12 work.
13

14 **Appendix 1**

15 ***List of abbreviations***

16 MoM: metal-on-metal
17 MoP: metal-on-polyethylene
18 ACCIS: Advanced Ceramic Coated Implant Systems
19 CoCrMo: cobalt-chromium-molybdenum
20 TiNbN: titanium niobium nitride
21 PVD: physical vapour deposit
22 MHRA: Medicines and healthcare products regulatory agency
23 CMM: Coordinate Measuring Machine
24 S_a: average roughness

- 1 S_{sk} : skewness
- 2 S_{ku} : kurtosis
- 3 ASR: Articular Surface Replacement
- 4 BHR: Birmingham Hip Resurfacing
- 5 EDS: energy dispersive x-ray spectroscopy
- 6 MTP: metatarsophalangeal
- 7

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Figure 1. The ACCIS hip femoral head (A) and acetabular cup (B) showing the removal of gold coloured TiNbN coating in the wear scar (please refer to the online version of the manuscript for the colour version of this figure)

137x67mm (150 x 150 DPI)

Figure 2. Coordinate Measuring Machine MATLAB plots of the ACCIS hip femoral head (A) and acetabular cup (B) showing the wear scar in each case, blue indicating greater wear depth (please refer to the online version of the manuscript for the colour version of this figure)

300x132mm (150 x 150 DPI)

Figure 3. Micrograph (left) and topographical plot (right) taken from the coated TiNbN surface of the femoral head. S_a 29.2 nm, S_{sk} -5.07, S_{ku} 117

154x58mm (150 x 150 DPI)

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Figure 4. Micrograph (left) and topographical plot (right) taken from the exposed CoCrMo surface of the femoral head. S_a 50.9nm, S_{sk} -1.99, S_{ku} 10.8

156x61mm (150 x 150 DPI)

Figure 5. Micrograph (left) and topographical plot (right) taken from the exposed CoCrMo surface of the acetabular cup. S_a 14.7 nm, S_{sk} 0.572, S_{ku} 4.48

157x64mm (150 x 150 DPI)

Figure 6. Micrograph (left) and topographical plot (right) taken at the TiNbN-CoCrMo boundary surface of the femoral head. S_a 204.9 nm, S_{sk} 0.228, S_{ku} 2
153x58mm (150 x 150 DPI)

Table 1. Roughness parameters calculated from topographical plots for both the ACCIS hip femoral head and acetabular cup.

		<u>Femoral Head</u>			<u>Acetabular Cup</u>		
		S_a (nm)	S_{sk}	S_{ku}	S_a (nm)	S_{sk}	S_{ku}
Coated Surface (TiNbN)	Mean	33.61	-2.38	56.71	18.19	-1.53	36.57
	StDev	4.21	2.40	53.00	5.11	1.94	19.90
Exposed Surface (CoCrMo)	Mean	44.61	-1.64	16.32	14.88	1.20	12.77
	StDev	10.68	0.45	9.49	0.26	0.77	13.61
Boundary Surface (TiNbN-CoCrMo)	Mean	245.55	0.30	2.36	211.29	0.09	2.50
	StDev	12.70	0.03	0.19	8.34	0.36	0.45

Preprint version