Primary hip replacement stem taper fracture due to corrosion in 3 patients

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Wear and corrosion of taper connections in modular hip prostheses have gained much attention due to the serious biological response that can occur due to the metallic debris originating from this articulation (Pivec et al. 2014). This has been observed especially for metal-on-metal (MoM) bearing articulations with large-diameter heads (Gunther et al. 2013). The biological response is attributed to cobalt (Co) and chromium (Cr) ions originating from the female taper interface of the ball head, which is made of CoCr alloy (McGrory et al. 2015, Bishop et al. 2013). No mechanical implant failures (i.e. fractures) have been documented. In contrast, bi-modular primary and revision hip systems with necks and stems made of titanium-aluminium-vanadium alloy (Ti alloy) have shown fracture rates of up to 2.4% due to corrosion without any previous biological responses (Grupp et al. 2010, Norman et al. 2014). Taper fractures of primary Ti alloy THA stems with a modular head taper have not been reported in the literature, but major taper corrosion and material loss have been found for one design in particular (Witt et al. 2014). We present 3 cases of stem taper fracture as the ultimate failure mode of this design.

Cases and analysis

The extracted prostheses were received for analysis in Hamburg between 2012 and 2014. All patients had received a BiMetric Ti stem, a M2A Magnum CoCr head with a Ti ball head insert, and a CoCr Recap/Magnum acetabular shell (Biomet, Warsaw, IN) (Table and Figure 1).

Case 1

The patient was a 62-year-old physically active man who had had an uneventful primary hip replacement until he felt a sudden snap in the right hip followed by intense pain, 4 years after surgery. Radiographs showed the broken stem taper. The

Table. Patient-, implant-, and surgery-specific data

Case no.	Weight kg	Height cm	BMI	Age at primary THA	Years in situ	Stem size	Diameter, mm head	cup	Insert offset mm
1	122	184	36	58	4.1	15	52	58	0
2	112	179	35	51	6.3	12	44	50	0
3	94	182	28	63	5.5	13	50	56	+6

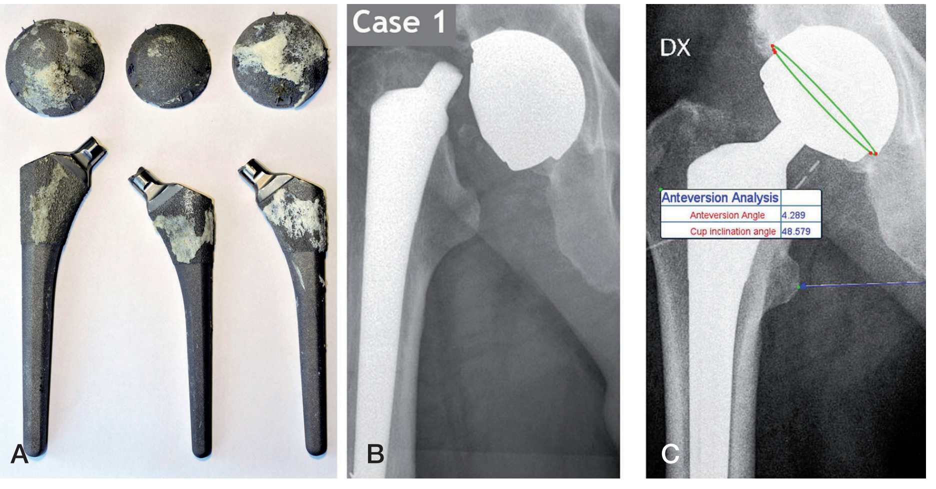

Figure 1. A. The 3 revised stems (left to right: case 1, case 2, and case 3). The bone attached to the implants is an indication of the ingrowth of the implants and the extent of bone defect caused during revision. B. Post-fracture radiograph of case 1. C. Pre-fracture radiograph of case 1. Cup angles were measured using image analysis software available at www.imatri.com (Joubert 2013).

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hip was revised to an uncemented KAR stem and a Pinnacle cup with a ceramic-on-ceramic 36-mm bearing articulation (DePuy, Leeds, UK). The surgery was uneventful. Blood serum metal ion concentrations at revision were as follows: Co, 0.9 µg/L; Cr, 2.0 µg/L; and Ti, 61 µg/L.

Case 2

A 57-year-old man had had an uneventful asymptomatic primary hip replacement surgery until stem taper fracture occurred 6.3 years after surgery. The CT showed a thickened capsule but no eccentric pseudotumor. At revision, slight metallosis and gray intra-articular fluid were found. An osteotomy was needed to remove the well-fixed stem. A bone defect at the anterior acetabulum was treated with bone impaction grafting. The hip was revised to a modular uncemented revision stem (MP; Waldemar LINK, Hamburg, Germany) with a 28-mm ceramic (Biolox forte) head and a cemented cup (FAL; Waldemar LINK). 1 week before revision, the Co ion concentration in serum was 7.2 µg/L, and it went down to 1.2 µg/L 3 months after revision. At revision, the titanium ion concentration in blood was very high at 9,400 µg/L.

Case 3

A 68-year-old physically active had had uneventful index surgery and a well-functioning hip until fracture of the stem taper after 5.5 years. The CT showed a thickened capsule but no eccentric pseudotumor, as also with case 2. During revison, a bursa was found laterally and there was brown discoloration of the capsule but no pseudotumor. A cavitary defect of the anterior acetabulum was treated with bone impaction grafting. The hip was revised to a modular uncemented revision stem (MP) with a 28-mm ceramic head (Biolox forte) and a cemented cup (FAL). 1 year before revision, the metal ion concentrations in serum were as follows: Co, 2.6 µg/L; Cr, 2.2 µg/L; and Ti, 489 µg/L.

Wear analysis

Wear of the articulating joint surfaces was determined using a tactile coordinate measurement machine (BHN 805; Mitutoyo, Tokyo, Japan). Details of the method used are reported elsewhere (Bishop et al. 2013).

Separation of components

It was not possible to remove the ball head insert from the ball head without destructive measures in any of the cases. In case 1, the ball head insert was reamed off at the side to hold on to it with a vice (Figure 2, left panel). Afterwards, the broken-off stem taper piece was pushed out of the ball head insert from the back side, using a hard stroke with a heavy hammer (force above 20 kN). In the other cases, the head was cut together with the ball head insert and the broken-off stem taper piece to allow analysis of the taper interface.

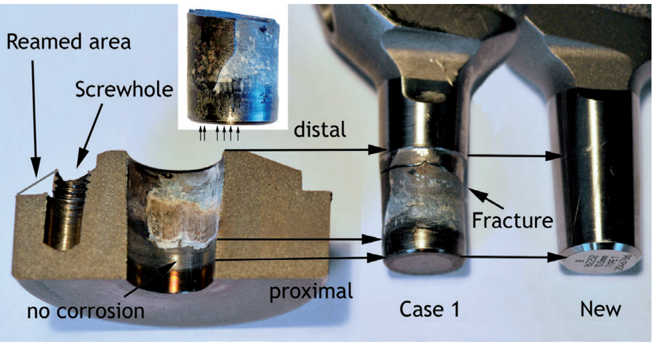

Figure 2. The cut ball head insert and stem taper (with broken-off piece placed in original position) together with a new stem taper. The screw hole was drilled into the ball head insert for removal (which was unsuccessful); reaming of the slope of the insert allowed holding on to the insert and successful removal. The distal edge of the ball head insert is imprinted circumferentially onto the stem taper (arrow). The proximal edge of the contact between male and female taper and also the edge of the corroded area are marked on the taper insert together with the corresponding position on the stem taper. The insert shows the scratches in the non-corroded area originating from entrapped bone pieces (small arrows) in the broken-off stem taper piece.

Microscopic analysis

Surfaces were metallurgically polished and imaged with scanning electron microscopy (SEM) with energy-dispersive X-ray spectroscopy (EDX) in back-scattered electron imaging mode (back-scattered electron composition (BEC) (Zeiss Supra 55 VP; Carl Zeiss AG, Heidenheim, Germany).

Results

The position of the cup was close to the Lewinnek zone in all cases (Lewinnek et al. 1978): case 1, 49° inclination/4° anteversion; case 2, 52°/16°, and case 3, 52°/15°. The positions estimated from the AP radiographs might differ from the true positions, due to the small area of the cup face available to define reference points, but they were sufficiently accurate to discount gross misalignment. All bearing articulations retrieved showed some wear (case 1, head 7.4 mm^3/cup 0.0 mm^3; case 2, 88/1.2 mm^3; case 3, 12/0.5 mm^3). Only case 2 showed higher wear, in accordance with the slightly elevated Co ion concentration reported (Gunther et al. 2013). Titanium concentrations for all cases were high to very high, and clearly above the level in control patients (< 1 µg/L) (Gofton and Beaule 2015).

The fracture surfaces revealed fatigue fractures with rest lines radiating out from the origin of the crack (Figure 3). The location of the crack origin was always located on the lateral side, with the highest bending load during activities. All fractures occurred about 1–4 mm inside the taper contact (Figure 3). White deposit identified as titanium oxide (TiO_2) by EDX analysis was always found at the taper interface (Figures 2 and 3).

Analysis of the stem-insert taper interface showed large areas of transfer of material from the male to the female side.

Figure 3. Upper panel: Stem fracture surface with fatigue cracks radiating out from the origin of the crack (black arrows) as a series of concentric rings (rest lines; left to right: cases 1 to 3). Case 3 had 3 crack origins, which subsequently coalesced into a unified fracture.

Lower panel: All the fractures occurred slightly inside the female taper (about 1–4 mm proximally from the open end). The broken-off male stem taper piece remained inside the female ball head insert taper.

The taper contact area is divided into a small intact region (proximal) and a large corroded region (distal, Figure 2). Signs of small bone fragments were identified in the intact contact region, suggesting contamination that prevented incomplete seating ("jamming") during assembly. The male stem tapers showed a circumferential impression of the distal edge of the female insert taper (Figure 2).

The cut, assembled taper interface from case 2 was analyzed using SEM. The fracture originated in the large corrosion cavities (up to 500 µm wide), which were found close to the distal end of the taper (Figure 4). The gap between the male and female taper surfaces narrowed to about 40 µm in width at the proximal end of these cavities. The thin gap was filled with titanium oxide. Moving proximally at the taper interface, the oxide layer narrowed and became very thin until there was direct contact between asperities at the most proximal intact region (Figure 4C).

Discussion

None of the patients had clinical symptoms, and there was no major CoCr wear of the bearing articulation. Fractures, therefore, occurred without warning due to mechanically induced tribocorrosion at the ball head insert/stem taper interface (Gilbert et al. 2011). Hip joint loading was high in all 3 cases, since several risk factors came together: MoM bearings with possible high friction moments, large head diameters, active patients, and high body weight or additional offset (in case 3) (Bishop et al. 2008).

The type-1 taper of the BiMetric stem has a smooth surface, which has been shown to be less susceptible to corrosion than ridged surfaces (Panagiotidou et al. 2013), but extensive corrosion-related issues have been reported for this particular taper (Witt et al. 2014). Smooth taper surfaces may be more susceptible to contamination and mismatch in taper angles, since there are no ridges to "absorb" any particles caught in the taper interface or deform to adjust for angle differences.

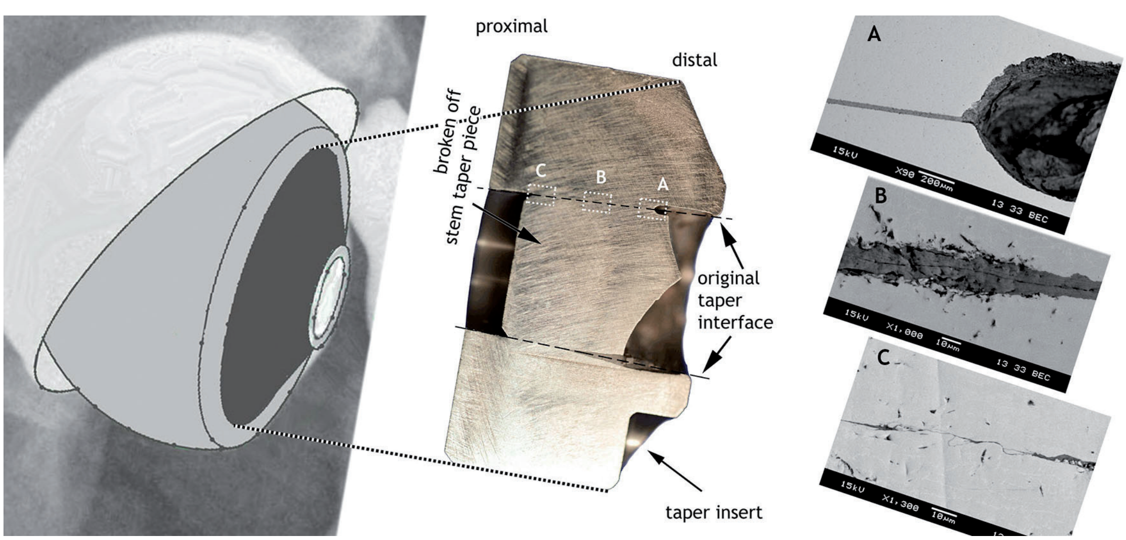

Figure 4. Left panel: Orientation of cup and head in case 2. Middle panel: Aligned orientation of the cut ball head insert with the fractured stem taper piece (dashed lines: original taper surface; areas A, B, and C for SEM are highlighted). Right panel: A. SEM of the corrosion cavity at the location of conversion to a smaller gap. B. SEM image of the middle of the taper articulation. The line down the middle of the dark TiO_2 layer marks the location of the original metal interface. The bulk titanium material was converted directly to TiO_2 by corrosion. C. SEM of the proximal end of the articulation. Tight junction between male and female taper surfaces with asperity contact and thin oxide layer.

Case 1 showed pronounced scratches at the proximal end of the male stem taper interface, probably due to contamination with bone during assembly. This may have prevented the taper from fully seating, resulting in increased micromotion during in vivo loading (Jauch et al. 2011) and thus promoting the observed formation of thick layers of TiO2 (Grupp et al. 2010). In the other 2 cases, biological material was also found in the taper interface, but not in such a clear form as in case 1. The high fixation strength of the broken-off stem taper tip in the ball head insert was due to the thick layers of TiO2 (Figure 4). Conversion of the Ti alloy to oxide creates high pressure at the taper interface, since the volume of oxide is 70% higher (Ti has a Pilling-Bedworth ratio of 1.7), making it almost impossible to disassemble the components ("cold welding").

Titanium ion concentrations were drastically higher than the levels in control patients (< 1 µg/L) (Gofton and Beaule 2015). For titanium concentrations in serum, the Mayo Clinic Medical Laboratories specify a value below 1 µg/L for a patient without a titanium implant and a value of 1–3 µg/L for a well-functioning implant; concentrations of > 10 µg/L have been suggested to indicate possible prosthesis wear (Gofton and Beaule 2015). However, the Mayo Clinic also states that "increased serum titanium concentration in the absence of corroborating clinical information does not independently predict prosthesis wear or failure" (http://www.mayomedicallaboratories.com (July 21, 2015)). Consequently, despite the very high values in all 3 patients, it would have been difficult to predict implant failure from the elevated titanium ion concentrations.

The 3 hips showed a very similar failure pattern, which allows us to speculate about the failure mechanism—insufficient stability at the taper interface resulting in increased micromotion during loading, facilitating fretting and crevice corrosion and ultimately resulting in fracture of the stem taper.

The last implantation of the implant combination in question was performed in 2011. On February 10, 2015, the Australian Department of Health issued a hazard alert due to a higher than expected revision rate. For surgeons with patients implanted with this combination, no direct advice can be given regarding identification of a possible isolated taper problem prior to failure. High Ti ion concentrations may be associated with the corrosion process, but there are insufficient data available to use them as a basis for making decisions.

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MMM, DB, and JG: analysis and writing of manuscript. HE, CCV, and AH: surgery, analysis of specimens, and writing of manuscript.

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