Titanium alloy femoral neck fracture—clinical and metallurgical analysis in 6 cases

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We present a case series of 6 hips in 6 male patients (average age 50 (37–56) years) who underwent revision of total hip arthroplasty (THA) as a result of a modular femoral neck fracture of an otherwise stable THA (Table 1). All 6 patients presented with acute-onset pain at a mean of 5.6 (2.3–12) years after the index procedure, following an uneventful and asymptomatic initial recovery period. The pain was located in the groin, the patients were unable to tolerate weight bearing, the involved leg was shortened, the hip was in external rotation, and emergency room radiographs revealed a fractured modular femoral neck slightly inside the female taper of the stem (Figure 1).

5 patients had their primary THA performed at our institution, and 1 patient (case 5) received his primary THA at a county hospital. 4 patients were revised at our institution. 1 patient was revised at the county hospital where the primary THA was originally performed (Vucajnik and Fokter 2012). 1 patient (case 6) sustained the fully modular neck fracture when jumping out of his truck while abroad, and received emergency treatment at a foreign clinic. All 6 patients were later followed up at our institution.

All 6 primary procedures had been performed with an anterolateral approach. The implanted acetabular components included 1 press-fit type AnCA Fit shell (Cremascoli Ortho, Milan, Italy), 1 screwed-in type RCM shell (Cremascoli Ortho), 3 press-fit type EHS cups (Wright Medical Technology, Arlington, TN), and 1 press-fit type Procotyl L cup (Wright Medical Technology). All liners were neutral. The bearing surface was ceramic-on-ceramic (Biolox Forte and Biolox Delta; CeramTec, Plochingen, Germany) in 4 cases and metal-on-polyethylene in 2 cases. All femoral components were made of titanium alloy (Ti6Al4V) with the same oval taper cone design for modular necks. The modular necks were also made of titanium alloy, and all tapers for femoral heads were of 12/14. 2 femoral stems were also proximally coated with hydroxyapatite (GSP; Cremascoli Ortho), and 4 were of fully grit-blasted design (Profemur Z; Wright Medical Technology). The implanted acetabular and femoral components, femoral neck lengths and orientation, and femoral head sizes are shown in Table 2.

Revision surgery was performed with an anterolateral approach. Standard tissue specimens were collected during the revision procedure for microbiological culture in all cases.

Table 1. Demographic data

Case	Age	Diagnosis	Height cm	Body weight kg	Body mass index	Time to revision years
1	42	Aseptic necrosis	193	110	30	3.1
2	54	Osteoarthritis	170	95	33	2.3
3	57	Osteoarthritis	170	100	35	5.2
4	37	Secondary arthritis [a]	178	107	34	6
5	56	Osteoarthritis	178	110	32	12
6	51	Osteoarthritis	176	80	26	4.8

[a] slipped capital femoral epiphysis

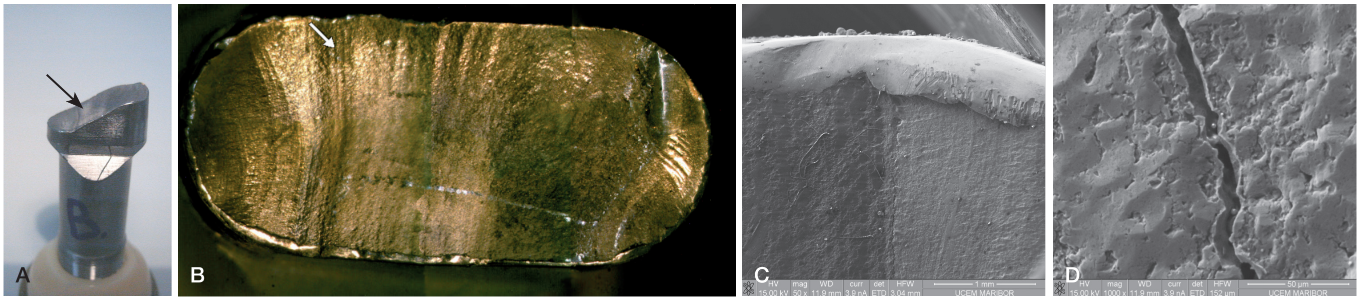

Figure 2. Appearance of the fractured modular femoral neck. A. Overview with arrow pointing to the crack. B. Photomicrograph with arrow pointing to the crack. C and D. Scanning electron micrographs of the crack.

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Table 2. Initial surgical data

Case	Acetabular component, mm, liner	Femoral component	Neck size, orientation	Material, head size and length in mm
1	Cremascoli Ortho RCM 56, PE	Cremascoli Ortho GSP #6	Long, straight	CoCr, 28 , +3.5 (L)
2	Wright Medical Technology EHS 54, Cer	Wright Medical Technology Profemur Z #6	Long, varus	Cer, 28, 0 (M)
3	Wright Medical Technology EHS 54, PE	Wright Medical Technology Profemur Z #5	Long, varus	CoCr, 28, 0 (M)
4	Wright Medical Technology EHS 52, Cer	Wright Medical Technology Profemur Z #8	Long, straight	Cer, 28, 0 (M)
5	Cremascoli OrthoAnCA Fit 56, Cer	Cremascoli OrthoGSP #5	Long, straight	Cer, 28, +3.5 (L)
6	Wright Medical Technology Procotyl L 52, Cer	Wright Medical Technology Profemur Z #5	Long, straight	Cer, 36, 0 (M)

CoCr: cobalt-chromium alloy; Cer: ceramic; PE: polyethylene.

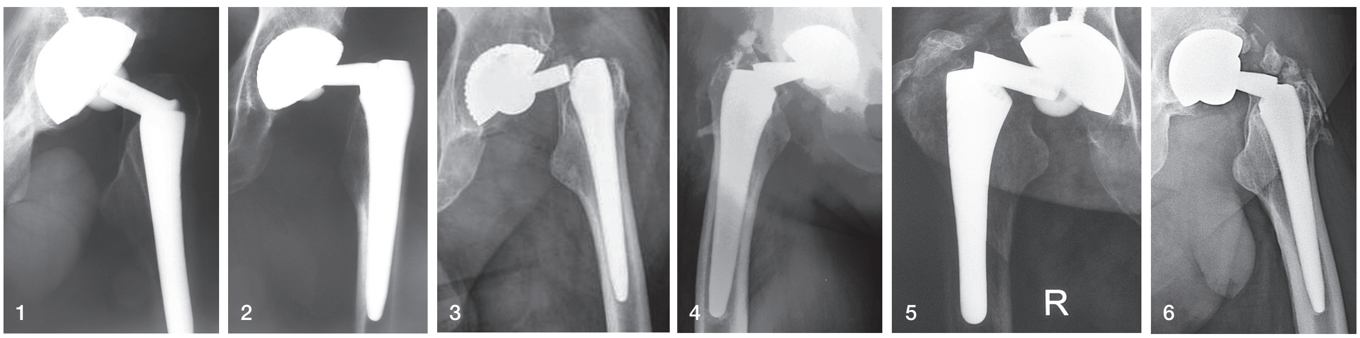

Figure 1. Emergency room radiographs of 6 patients with fractured modular femoral necks. Cases 1–6.

The portion of the fractured neck that had been engaged inside the stem taper could not be removed, and the entire femoral stem had to be revised with an extended trochanteric osteotomy approach. Cementless fluted tapered modular collarless stems (Revision stem; Limacorporate S.p.a., Udine, Italy) were used in 5 cases, and a fluted tapered modular stem with collar (MP Reconstruction prosthesis; Waldemar Link GmbH & Co, Hamburg, Germany) was used in 1 case. The acetabular components were well fixed in all cases, so only the liners were exchanged. In 1 patient, 2 additional revisions including acetabular component were needed because of femoral stem subsidence and recurrent luxations.

Gross visual inspection of the prosthesis revealed a fracture at the distal end of the modular neck component, a few mm below the edge of the stem on the tension side. No impingement between the prosthesis femoral neck and acetabular cup was noted in any case. There was no evidence of metal debris, and there were no scratches or evidence of wear on the acetabular liner. Fragments of distal modular necks remained firmly engaged with the taper of the stem. So-called beach marks, indicative of fatigue failure, were evident on visual inspection of the fracture surfaces of the modular necks (Wilson et al. 2010). Microbiological cultures did not reveal any bacterial growth. At the latest follow-up 3.3 (1–11) years after the latest revision for modular neck fracture, all patients had stable implants on radiographs and could walk without crutches. Their mean Harris hip score was 82 (62–96), and their mean SF-36 score for Physical Component Summary (PCS) and Mental Component Summary (MCS) was 41 (31–56) and 41 (25–56), respectively. (Normal values of PCS and MCS for the general population are 50).

Detailed analysis of the metallurgical changes in their material (Ti6Al4V) at both the macroscopic level and the microstructural level were carried out on 1 fractured modular femoral neck (from case 5) by light microscopy (Olympus BX61 with the image analysis system), scanning electron microscopy (SEM) (Sirion 400 NC), and energy-dispersive X-ray (EDX) analysis (Oxford INCA 350) (Wagner 1997, Krishan et al. 2013). A thin crack was found, spreading from the outer periphery to the center of the modular femoral neck and acting as a border between 2 fracture surfaces, probably representing the transition from the fatigue zone to the rapid fracture zone (Figure 2).

Analyses of the surface area to check for a titanium oxide layer were also performed on 2 points of 1 fractured modular femoral neck using a Thermo VG Scientific Microlab 310F high-resolution field emission scanning spectrometer of Auger electrons (AES), scanning Auger electron microscopy (SAM), SEM, and X-ray photoelectron spectroscopy (XPS). A stable, continuous, tightly adherent oxide film measuring 450 nm was found with no traces of hydrogen, chloride, or other halide ions.

In the next step, classical metallographic samples were prepared from the material of the modular femoral necks in an undamaged area. For this purpose, the samples were only brushed and polished to minimize the influence of metallographic preparation regarding changes in chemical compo-

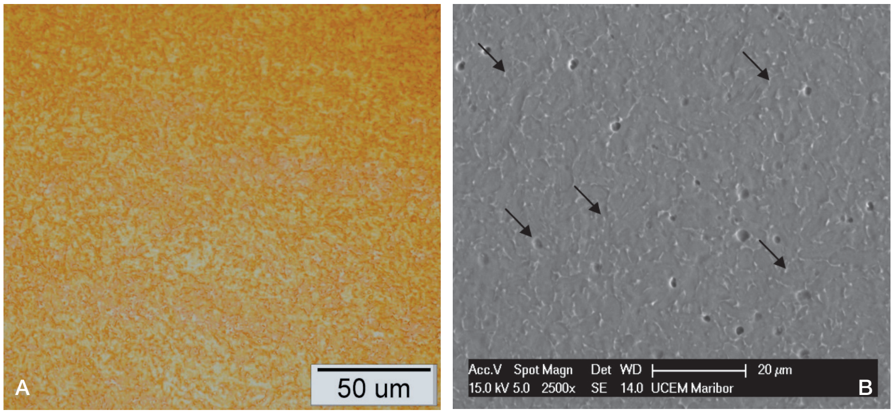

Figure 3. Typical optical photograph (A) and scanning electron micrograph (B) of Ti6Al4V alloy that was used for the modular neck.

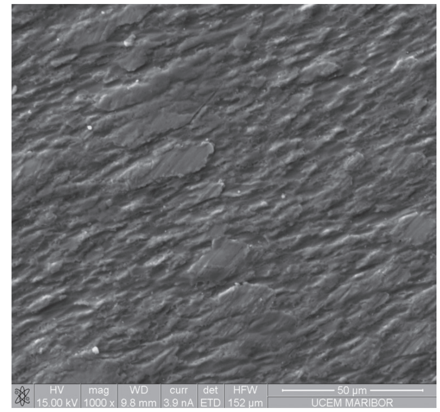

Figure 4. Characteristic scanning electron micrograph of the outer surface of a modular femoral neck.

sition. The EDX chemical composition of each sample was determined with at least 12 EDX measurements at different positions on the characteristic places. EDX analysis showed that the alloys contained approximately 6 (SD 0.19) wt% Al, 90 (SD 0.39) wt% Ti, and 4 (SD 0.43) wt% V. Typical microstructures (optical and SEM) are shown in Figure 3. According to the chemical composition supplied by the manufacturers, the EDX values, and the available literature (Wanhill and Barter 2012, Terlinde et al. 2003), such microstructures are typical for α–β titanium alloy and they belong to a group of duplex microstructures. Taking this into account, the gray grains correspond to the primary α phase (Figure 3B), which shows more or less equiaxed morphology. The size of α grains is 5–10 μm. The secondary phase is the transformed β phase, which is visible as a white region. In the microstructure, there are also co-oriented α lamellae (transformation α) separated by "ribs" of retained β (see arrows).

Macroscopic observation of the outer surface of all modular femoral necks showed that the surface was compact (Figure 4), but pitting effects were visible in some regions. Detailed SEM examination of the external surfaces showed some kind of wear, because there was no uniform roughness apparent.

Additionally, conditioning tests were done for verification of corrosion resistance (Colić et al. 2010) of the material, on special samples in the form of plates (10 mm × 10 mm × 1.5 mm), which were cut off from the undamaged area of the modular femoral neck. The surface of each plate was 2.4 cm^2. 7 plates were prepared for incubation with 4 mL of complete medium (10% fetal calf serum in RPMI 1640 medium, with 2-mercaptoethanol and antibiotics), so the surface-to-volume ratio (SVR) was 4.2 cm^2/mL. The recommended SVR according to ISO standards is 2–6 cm^2/mL. All samples were placed in 96% alcohol in a glass tube and sonicated for 10 min in an ultrasonic bath. After that, the samples were placed on a Petri dish and dried in a sterile laminar flow cabinet under UV for 1h. The samples were then placed in another glass tube and 4 mL of complete medium was added. The samples were kept under sterile conditions in an incubator for 7 days. The control medium was incubated likewise but without the alloys. The medium was collected in transportable plastic tubes and prepared for inductively coupled plasma atomic emission spectrophotometric analysis (ICP-AES) (Perken-Elmer) for detection of the concentrations of metal ions (Ti, Al, and V). Triplicate absorbance readings per element were recorded for each sample. The results of ICP analyses showed that the release of ions after 7 days in the samples were: Al, 153 ppb; Ti, 396 ppb; and V, 80 ppb.

Discussion

Modular neck hip prostheses have gained popularity in the last 3 decades. After the introduction of modular stems in revision THA, several device companies now offer femoral stems with a modular junction between the neck and body of the stem for primary THA. The advantage of these so-called dual-taper stems is that the surgeon has an intraoperative choice of neck version, length, and offset independently of the stem size and fixation, allowing him or her wider options for hip-center restoration (Traina et al. 2009, Archibeck et al. 2011).

However, these benefits of modularity may be shadowed by the increased risk of complications. Apart from the potential for dual-taper corrosion to lead to the release of metal debris and adverse local tissue reactions similar to those seen in patients with failed THA or metal-on-metal bearings (Fokter et al. 2009, Lindgren et al. 2011, Gill et al. 2012, Cooper et al. 2013), increased risk of modular neck fracture has been documented in some studies (Grupp et al. 2010, Paliwal et al. 2010). Similar catastrophic failures of dual-taper stems, resulting from modular neck fractures, have been reported recently in case reports (Wright et al. 2010, Atwood et al. 2010, Dangles and Altstetter 2010, Soteranos et al. 2013, Elman and Levine 2013), but these serious complications have not been reported in a larger cohort of patients.

Table 3. Case reports published on Profemur Z modular neck fractures

Authors (reference)	Age years	Body mass index	Time to revision years	Femoral component size #	Neck size, orientation	Articu-lation
Wright et al. 2010	49	39	4	4	Long, varus anteverted	MoM
Atwood et al. 2010	30	29	2	NA	Long, straight	CoC
Wilson et al. 2010	62	26	2	5	Long, 8° retroverted	CoC
Dangles and Altstetter 2010	63	NA [a]	3.5	NA	Long, retroverted	MoM
Skendzel et al. 2010	55	31	3.7	NA	Long, varus	NA
	67	35	3.4	NA	Long, varus	NA
Ellman and Levine 2013	59	30	5	3	Long, varus	MoM

[a] 128 kg. NA: not available; CoC: ceramic-on-ceramic; MoM: metal-on-metal.

The concept that modular tapers are susceptible to mechanically assisted crevice corrosion, a combination of fretting and crevice corrosion, was developed in the early 1990s (Gilbert et al. 1993). Reports of corrosion at the taper interface were published mostly from retrieval studies (Cook et al. 1994, Goldberg et al. 2002, Kop and Swarts 2009). However, case reports showing that catastrophic failure may occur because of this phenomenon were published soon afterwards (Gilbert et al. 1994, Collier et al. 1995). We believe our series to be the largest reported series of modular neck fractures of this particular modular neck distal taper design in the English-based literature.

The Morse taper-type modular neck hip prosthesis with oval neck-stem taper for rotational resistance was introduced by Cremascoli Ortho, an Italian manufacturer, in the late 1980s (Krishnan et al. 2013), and the company merged into the US-based Wright Medical Technology in the year 2000. Although the design of the femoral stem changed considerably, the design of the taper and the material of the modular neck, i.e. titanium alloy, remained unchanged. By promising several distinct advantages intraoperatively and potential ease of revision by exchanging only the neck in an otherwise well-fixed femoral component, the implant was quite popular in central Europe with about 1,000 implanted at 2 centers over a 20-year period (from 1992 to 2012). The early studies with the implant design showed no problems regarding modular femoral components (Antonietti et al. 2003). However, after the introduction of the prosthesis onto the US market in 2002 and the growing popularity of modularity, several case reports were published reporting catastrophic failure of the implant (Skendzel et al. 2010). These failures had been attributed at first to the particular stem design of the Profemur Z, but other authors have shown that modular neck fracture can occur in different stem types (Sotereanos et al. 2013). Some details of the 6 published case reports dealing with 7 male patients who sustained a fracture of the Profemur Z modular neck made of titanium alloy are given in Table 3.

Apart from all patients being male, some other patient characteristics were similar in our group of patients and in the patients published to date by other authors. According to the World Health Organisation criteria, all patients reported were at least overweight (Report WHO 1998, Davey et al. 2013, Roos et al. 2014). Changed patient factors may, critically, increase the bending moment, which is increased further by the use of particular modular neck and stem configurations. Skendzel et al. (2010) reported that long varus necks increased the bending moment by a factor of 3 compared to short varus necks, and the stress in the modular stem configuration is concentrated at the modular junction. All 6 patients in our series and all other patients reported had a long modular neck implanted at the primary THA, and, in total, 6 of 13 also had a varus neck orientation.

Dangles and Altstetter (2010) searched the Federal Drug Administration Manufacturer and User Facility Device Experience (FDA MAUDE) database from January 1, 2000, to May 19, 2009, and found 37 breakages of the Profemur modular femoral neck prosthesis.

Modular titanium-alloy neck failures in THA were reported recently in a larger group of patients (Grupp et al. 2010). Over a 2-year period, 5,000 titanium-alloy modular neck adapters in combination with titanium-alloy modular short hip stems (Metha Short Hip Stem Prosthesis; Aesculap AG, Tuttlingen, Germany) were implanted, and 68 of the implanted neck adapters (1.4%) failed on average 2 years postoperatively. The retrieved prostheses showed a similar fracture pattern, with the fracture starting in the anterolateral area at the upper part of the cone where there is maximum mechanical stress. The reason for failure was attributed to fretting, fretting corrosion, and crevice corrosion, which led to the loss of fatigue strength of the titanium alloy. The combination of factors listed above, and also contamination of the cone adapter with fluids or particles, increased the rate of failure. The authors concluded that the change to cobalt-based alloy modular necks increases the safety of the cone connection (Grupp et al. 2010). Thus, the modulus of elasticity of titanium alloy is approximately half that of cobalt-chromium alloy. For a given load, modular necks with a higher degree of stiffness (i.e. made of cobalt-chromium alloy) will bend less and reduce the potential for fretting and fretting corrosion to occur. Unfortunately, we have no data regarding the contamination of the cone adapter with tissue debris at primary THA. Of course, orthopedic surgeons in our community are aware of the importance of thorough cleaning of the connecting parts before coupling, but total dryness when performing THA is sometimes difficult to achieve. However, using cobalt-chromium modular necks in combination with titanium-alloy stems is associated with other problems of mixed alloy couples, resulting in calcar erosion and pseudotumour formation (Molloy et al. 2014)—and has shown substantially higher mass loss secondary to fretting corrosion in the laboratory setting—so it was not considered for final design testing by a competitive manufacturer (Sotereanos et al. 2013). No metal ion analysis was performed in 4 patients treated at our institution; nor was metal ion status obtained in 2 patients treated at other institutions, which is a major drawback of our study. However, no membranes, metalosis, or pseudotumour formation were noted or described in the operative reports, corrosion resistance verification showed a very small degree of ion release in the complete medium, and the titanium oxide layer was stable, suggesting that there was no clinically important metal ion release problem in our patients.

The titanium alloy in question (Ti6Al4V) belongs to the category α–β alloys (Wahnill et al. 2012), which contains limited amounts of β-stabilizers (in our case V) the majority of which cannot strengthen the phase. Hence α-stabilizers (Al) are added. The relative amounts and distribution of α and β phases are controlled by processing and heat treatment; an important fact is that the final mechanical and other properties of the alloy depend on this. When β transforms to α the morphology of the transformation α is very different to that of the primary α. In our case, the microstructure contains mostly the α phase, and on this basis it was concluded that alloy was annealed (Gaspar 2012). It is known that annealing of Ti6Al4V reduces its strength substantially, but that it is beneficial to the fracture toughness, long/large fatigue crack growth, and stress corrosion cracking resistance (Peters et al. 2012). On the other hand, the literature (Filip et al. 2003) suggests that microstructure, grain size, and consequently morphology, affect the mechanical properties and tensile strength of Ti-6Al-4V, and thereby also the fatigue behavior. By detailed observation of the Ti6Al4V microstructure, we found out that it is bimodal and fine-grained with some co-oriented α-lamellae. Moreover, recently it was found (Knobbe et al. 2010) that most of the cracks in the Ti6Al4V microstructure initiate on the boundary between two α-lamellae. On this basis, and from the fact that our investigation also demonstrated the existence of such elements (α-lamellae), which could be reasons for the initiation and further propagation of a crack, the thesis was set that the material used for a modular femoral neck should contain as little of these microstructure elements as possible.

Considering the state of the investigated exterior surface of the modular femoral neck, which shows no signs of optimal design (Oberwinkler et al. 2010), there were conditions for the formation of a crack on the surface after long-term dynamic fatigue. The surface should be as smooth as possible without any residual stresses from machining (Zhai et al. 2000). In contrast, surface roughness of our investigated modular femoral neck had a relief with distances between valleys and peaks measuring some μm.

In conclusion, the best way of avoiding the complication of neck fracture is to refrain from using fully modular stems in primary THA.

All the authors contributed equally to the preparation of this manuscript.

No competing interests declared.

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