Unusual Fatigue Failure of Cobalt Chrome Alloy Cementless Femoral Stem: *Implant Retrieval and Biomechanical Analysis*

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Abstract

Recent premature failures of metal total hip replacements have raised concerns about their load bearing capacity, safety, reliability, and survival rates. Specifically, femoral stem fracture is one of the most acute complications of total hip replacement (THR) and results in greater morbidity and higher cost of revision hip surgery. Femoral stem fracture incidence varies from 0.23% to 10.7% depending on geometric design and prosthetic materials. This study reports an unusual case of late fatigue failure of a cobalt-chromium alloy cementless femoral stem which functioned well for 24 years. The failure occurred at the stem/neck transition radius remote from any modular interface. The crack initiated at the top tensile side at the implant surface following a minor traumatic event. It then propagated transgranularly up to about half of the neck cross-section before final fracture occurred, which illustrates the high toughness of the implant. Fractography analysis found no intrinsic defects in the failed component. Scanning electron microscopy-energy-dispersive X-ray spectroscopy analysis revealed a chemical composition in agreement with the wrought CoCrMo alloy ASTM F1537 used in such implants. A grain size of between 6 and 70 μm was measured, which is also in agreement with the standard. Precipitates were found at grain boundaries, consistent with $M_{26}C_6$ and M_7C_3, which are often reported in cobalt-chromium alloys used in bone replacement applications. This late failure illustrates the importance of proper long-term testing of implants in regards to cyclic loading, as patients undergoing total joint replacement are increasingly younger and more active, putting implants at greater risk of long-term fatigue failure.

Keywords: Total hip replacement (THR), Cobalt-chromium, Stem failure, Fatigue life, Younger patients, Testing standards

1. Introduction

Current total hip replacement (THR) designs are achieving high levels of survivorship and, over the last two decades, are being implanted in younger and more active patients [1]. In that respect, cementless femoral fixation is favored for implant longevity due to its biological fixation and the avoidance of potential cement fatigue failure. Initial cementless femoral components were made of cobalt-chromium alloys because of their greater fatigue strength. However, due to their better overall *in vivo* biologic characteristics, titanium alloy implants are currently being favored. For the majority of these stems, the incidence of aseptic loosening is relatively low. However, other potential modes of failure, including fracture, may be more prominent over the lifespan of the implant. Fracture of the femoral stem is a recognized, yet rare complication of THR, with incidence varying from 0.23% to 10.7% depending on geometric design and prosthetic materials [2,3]. Risk factors such as inadequate supporting bone stock, high body mass index (BMI), and the presence of stress risers within the femoral component have been identified for fatigue failure [3-5]. This paper reports a rare case of a late fatigue failure at the stem/neck transition radius in a well-functioning cementless Lord THR. This stem was a fully porous coated implant with a 1-mm beaded surface spaced by 0.5 mm for osteointegration [6]. The patient provided informed consent. Microscopy investigations were used to study the cause and mode of failure. An in-depth literature review was completed in order to put the failure in the current context and explore potential suggestions and improvements.

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2. Materials and methods

In 1985, a 51-year-old healthy male underwent a left THR for idiopathic osteoarthritis with a cementless Lord stem and threaded acetabular cup. The Lord stem was introduced in the 1970s and is FDA-approved. In 2000, the patient required revision surgery for polyethylene wear and had an isolated head and liner exchange. Intraoperatively, the femoral and acetabular

components were found to be stable and direct visualization showed the femoral prosthesis trunnion to be in excellent condition. A new polyethylene insert was cemented into the existing well-fixed acetabular component. The patient returned to his previous level of activity. In 2009, the patient presented to the emergency department with acute left hip pain. The patient had stepped down from a boat onto a dock from a height of about 2 feet when he experienced an acute and sudden onset of pain in his left hip. Anteroposterior and lateral radiographs showed a crack at the base of the femoral neck/stem transition radius (Fig. 1). The remaining femoral stem and acetabular cup appeared well-fixed. This was confirmed at surgery. The patient underwent femoral component revision with an extended trochanteric osteotomy and insertion of a distally fixated modular revision femoral component. At 3 months post operation, the femoral component subsided, leading to a subsequent revision at 6 months once the fracture had united. Insets (a) and (b) in Fig. 1 show the complete fracture and its location. Onlay allografts provided additional fixation for intraoperative distal stem tip fracture. At one year follow-up, the stem is currently radiographically stable and functioning well (Fig. 2). The inset in Fig. 2 shows the loose modular stem of the first revision prior to the second revision surgery.

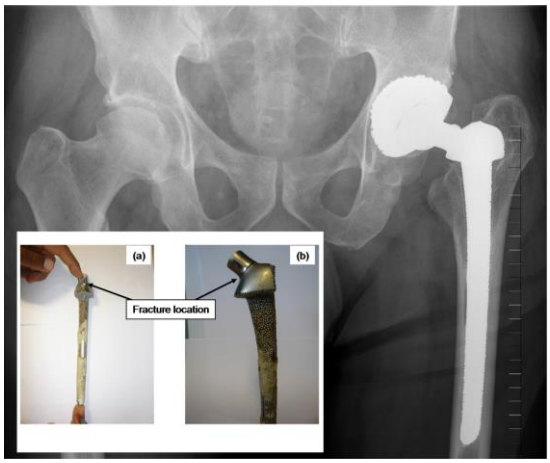

Figure 1. Anteroposterior radiograph showing prosthetic fracture at neck/stem transition. Insets (a) and (b) show the retrieved Lord femoral stem with a complete fracture at the neck/stem transition radius.

Fractography investigations were performed on both fracture surfaces using a ZEISS EVO MA10 scanning electron microscope (SEM) (Carl Zeiss International, Jena, Thüringen, Germany). The SEM was equipped with an INCAX-act energy-dispersive X-ray spectrometer (EDS) (Oxford Instruments, Tubney Woods, Abingdon, Oxfordshire, UK), which was used to investigate the chemical composition and to search for potential inclusions or precipitates that could have initiated or facilitated implant failure. In addition, the implant was sectioned for optical microscopy (OM) using a XJP-3A stereo microscope (Ancansco, Toronto, ON, Canada) and for SEM study of the grain structure. The implant section was mounted in epoxy resin using hot mounting, ground and

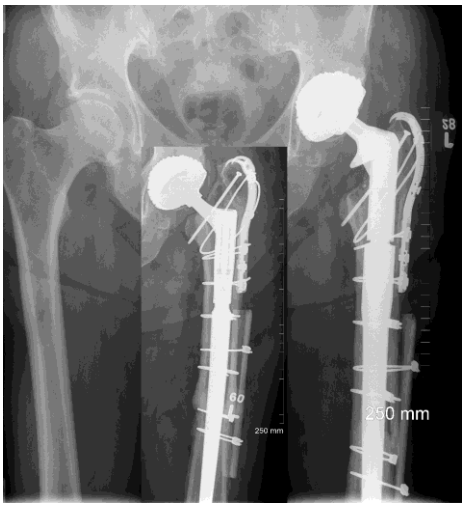

Figure 2. Anteroposterior radiograph with stable uncemented modular revision femoral stem at one year post second revision surgery. Inset shows loose modular revision stem prior to second revision.

polished, and then etched using a solution of 40 ml lactic acid + 30 ml HCl + 5 ml HNO_3 for 5 minutes to expose the grain boundaries. For comparison, SEM, EDS, and OM investigations were also performed on an unused identical implant from the same manufacturer.

3. Results

Implant failure occurred in the filler radius between stem and neck, as can be seen in insets (a) and (b) of Fig. 1. SEM images show that the crack initiated at the topside surface at the plastic deformation steps near machining feed marks due to slight stress concentrations. The arrow in Fig. 3(a) shows the crack initiation site. The crack then propagated primarily transgranularly, as can be seen in Fig. 3(a). A strong relief and

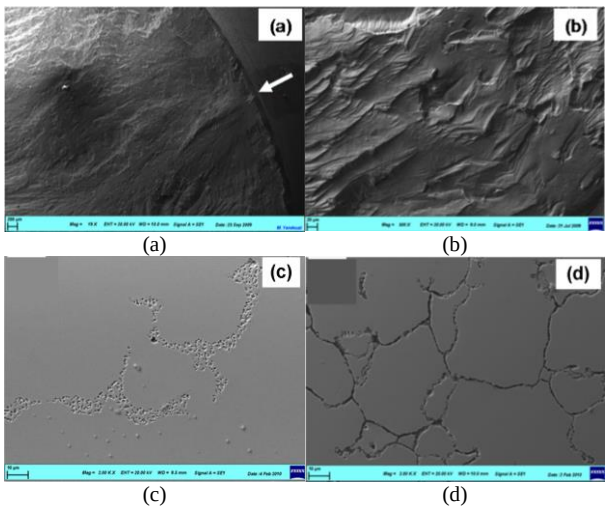

Figure 3. SEM fractography/micrography images showing: (a) the crack initiation site (arrow) at the implant surface and transgranular fracture surface; (b) a strong relief in the crack propagation phase; (c) precipitates along grain boundaries; and (d) the overall grain structure as seen in a cross-section of the broken implant.

plastic deformation features were seen across the fracture surface (Fig. 3(b)). The crack propagated through roughly half of the neck cross-section before final fracture occurred, which demonstrates the relatively high fracture toughness of the implant material. There was no evidence that inclusions or precipitates substantially promoted either crack initiation or crack propagation. The grain size, as shown in the SEM micrographs in Figs. 3(c) to 3(d), can be estimated to range between 6 and 70 µm, which falls within the range for the wrought CoCrMo alloy ASTM F1537 reported in the literature [2,3,7].

The EDS chemical composition measurement results of the broken implant for the matrix/grain interior as well as for the grain boundaries are shown in Table 1. Strong similarities can be observed between the grain interior and specifications for the low-carbon CoCrMo alloy ASTM F1537. EDS analysis suggests that the grain boundary precipitates are richer in chromium and molybdenum as compared to the alloy matrix, which hints to metal carbides that can be seen along grain boundaries in Fig. 3(c). Primarily chromium-carbides of the types $M_{26}C_6$ and M_7C_3 are often reported [8]. Furthermore, chemical composition and microstructure were practically identical in both the old broken implant and the new unused implant, which leads to the conclusion that the material and the manufacturing process are identical for both broken and new implants. This seems to exclude material or manufacturing defects as the primary cause of failure and highlights the role of fatigue overload as the main cause of prosthesis fracture in this case.

Table 1. ASTM F1537 specification and chemical composition of the failed implant as measured using SEM-EDS.

	C	Cr	Fe	Mn	Mo	N	Ni	Si	Co
Specification for ASTM F1537	0.149 -	26.0 - 30.0	0.75	1.0	5.0 - 7.0	0.25	1.0	1.0	bal.
Matrix / Grain interior	-	27.02 - 28.97	0.30 - 0.69	0.83 - 1.07	5.51 - 8.55	0.04 - 0.57	1.91 - 2.10	0.87 - 1.14	bal.
Precipitates / Grain boundaries	-	32.29 - 34.27	0.20 - 0.30	0.48 - 0.96	10.51 - 34.78	0.15 - 3.61	0.93 - 1.77	0.96 - 2.25	bal.

4. Discussion

Prosthetic fracture in total hip arthroplasty is a relatively uncommon, yet catastrophic event. Reported prevalence rates have varied widely [3-5,7]. A voluntary retrospective survey of the American Association of Hip and Knee Surgeons members in 1995 reported a metal femoral stem fracture rate of 27/10,000 surgeries (0.27%) [9]. The present study presents a case of a late fracture of a cementless Lord femoral stem. Femoral prosthetic failures have been classified into broad categories such as implant design, implant defect, and prosthetic fatigue. Using detailed microcopy analysis and comparison with an identical non-implanted component, this report suggests a pure mechanical fatigue failure of the stem with no evidence of intrinsic material defects or faulty design. As opposed to previously reported madreporic prosthetic failures [6], our stem fractured at the neck/stem transition radius after twenty-four years of stable and pain-free activity. No history of major trauma or acute change in the patient's activity level prior to implant fracture was reported. Also, our metallurgy analysis suggests that there were no anomalies in the chemical composition or microstructure of the prosthesis when compared to those of a control stem as well as current ASTM standards.

In short to moderate follow-up, the Lord femoral prosthesis has had good success with survivorship, quoted at 94% at 13 years [10]. Two other studies reporting on its survivorship [6,11] noted two fatigue stem fractures within the shaft [12]. These failures were attributed to the stems being made from cast material, whereas forged femoral components have decreased grain size and less inclusion defects, leading to a substantially increased femoral prosthetic fatigue strength when compared to that of cast or annealed implants [13]. However, inconsistencies in metallurgy or surface damage of even forged implants can lead to significant stress risers [14]. Although not identified in this current stem, Woolson *et al.* reported that fatigue fracture was the primary mode of failure in 5 out of 10 prosthetic failures. The fractures were found to have been initiated or promoted by surface laser etching [4]. Lee *et al*. reported that laser etching at the lateral neck/shoulder junction of two stems had caused heat-induced structural changes, leading to local stress risers and ultimately to early implant failure [14]. Fatigue can occur within the stem even if there has been adequate distal fixation but poor proximal stabilization. This may occur in primary total hip patients due to a mismatch between implant geometry and bony anatomy [12,15,16], and in revision settings where proximal bone loss is a common concern [3,17,18].

It has been consistently noted that patients with increased BMI are at greater risk of reaching an implant failure point due to fatigue loading [13,19-21]. Another potential cause of this late fracture is faulty implant design. Vatani *et al*. reported 9 prosthetic failures in a series of 35 THR patients completed over an eight-month period. In these cases, the failures were attributed to an inadequate implant neck radius, which led to abnormal force transmission and ultimately to prosthesis fracture [22]. The use of a skirted modular femoral head has been linked to prosthetic failure within the femoral trunnion of a cobalt-chromium uncemented stem [23,24]. Lam *et al.* showed that the skirted modular construct caused local oxygen depletion, leading to intergranular and crevice corrosion [25]. This mechanism can also be at play in stem designs with modular necks [26]. The time to failure in these patients ranged from 1.8 to 4.2 years and was noted to occur in patients with relatively high BMIs and long modular neck components. Prosthetic fracture was thought to be due to micro-motion leading to crevice formation and corrosion at the neck/stem junction, ultimately leading to fatigue crack propagation. Having said that, the patient in the current case was not overweight and the stem was fixed throughout its length with the failure site remote from any modular interface, thus making corrosive wear as the main failure cause unlikely.

Fractography investigations in this work showed that the crack initiated at the implant surface, most probably at the plastic deformation slip steps near surface machining feed

marks, and propagated primarily transgranularly. As such, no evidence exists that inclusions or precipitates substantially promoted crack initiation or crack propagation. The strong relief and plastic deformation features across the fracture surface (Fig. 3(b)) hint to three possible scenarios for the fracture progression. First, the implant may have been subjected to overload fatigue during the final state of its implantation life, which led to crack initiation, substantial plastic deformation ahead of the crack tip during crack propagation, and ultimately to implant failure. Particularly, the strong relief at the crack initiation site suggests that high loads such as those experienced during fall, jumping, or other extreme activities may have initiated the crack. Second, further compressive loading during subsequent patient activities after initial cracking may have further deformed the fracture surface. This is supported by the relatively long time span of six months between the detection of the initial crack preceding the first revision and the implant retrieval at the second revision. Third, the strong relief of the fracture surface may also result from partial intergranular crack propagation at some locations. This assumption is supported by the strong precipitation along grain boundaries (Fig. 3(c)), which can weaken grain boundaries and favor crack initiation and propagation along grain interfaces. However, although grain boundary carbides typical for the CoCrMo alloy ASTM F1537 may have contributed to accelerate the crack propagation, particularly in the final stage of implant failure, their contribution is estimated to be minor for the current investigated implant. This assumption is supported by the fact that the crack initiated at the surface and propagated primarily transgranularly. Microscopy investigations in the current study suggest that the crack was initiated at the tensile topside in the filler radius transitioning from the stem to the neck. This further highlights the hypothesis of overload fatigue as main failure cause, with the implant having good quality as compared to standard specifications and a new unused implant from the same manufacturer.

Retrospectively, it is likely that this patient simply exceeded the number of allowable fatigue cycles of the implant corresponding to his body weight and activity level, leading to inevitable failure. In fact, in order for a femoral prosthesis to be approved for clinical use within the United States, material testing must be completed to ensure the device meets standards set by the American Society for Testing and Materials (ASTM) and the International Organization for Standardization (ISO). However, ASTM standard specifications for hip femoral prosthesis (ASTM F 2068-03) are based upon mechanical testing where the stem is embedded in bone cement up to 80 mm below the center of the highest offset and then fatigue tested for 10 million heel-strike cycles [27]. However, actual average patient activity has been estimated to be 1.9 million cycles annually [28]. Considering this fact and the fact that certain patients can have even higher levels of activity and BMI, it is not unreasonable that a group of patients may exceed the current standards of implant longevity testing after just about 5 years. Therefore, as the uncemented femoral stem has become a popular choice of arthroplasty surgeons for younger and more active patients, the ability to surpass the material's intrinsic mechanical limits through reasonable daily activity is concerning. This calls for further material research and arthroplasty patient monitoring in order to better understand the long-term behavior of THRs.

5. Conclusion

A rare case of late Lord prosthesis implant failure was described. Detailed OM, SEM, and EDS analyses showed no intrinsic material or manufacturing defects or anomalies. Rather, their results support fatigue overload as the primary cause of implant failure. The results of the current study together with previous literature raise questions on current THR durability testing standards. The current fatigue life requirements seem potentially insufficient for patients with higher level of activities, particularly for younger patients and those with high body mass. Therefore, the continual monitoring of arthroplasty patients seems required to better predict and improve the long-term behavior and survival of implanted femoral prostheses. This could allow reassessing existing testing standards.

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