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Case report

Fatigue fracture of a cemented Omnifit CoCr femoral stem: implant and failure analysis

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ABSTRACT

A cemented, cast CoCr alloy, Omnifit Plus femoral stem was retrieved following mid-stem fracture after 24 years in vivo. The patient was an active 55-year-old male with a high body mass index (31.3) and no traumatic incidents before stem fracture. Fractographic and fatigue-based failure analyses were performed to illuminate the etiology of fracture and retrospectively predict the device lifetime. The fracture surfaces show evidence of a coarse grain microstructure, intergranular fracture, and regions of porosity. The failure analysis suggests that stems with similar metallurgical characteristics, biomechanical environments, and in vivo durations may be abutting their functioning lifetimes, raising the possibility of an increased revision burden.

Introduction

Femoral stem fracture is an established but infrequent complication of total hip arthroplasty. The first generation of Charnley-type, stainless steel femoral stems fractured in approximately 4.1% of patients [1], with fatigue failure attributed to insufficient stem cross-sectional area and inadequate cement support [1,2]. Since the 1970s, improvements in stem design [1] and metallurgy [3] have markedly reduced the incidence of femoral stem fracture. However, reports of femoral stem fracture have continued to surface in the orthopaedic literature, with causes ranging from corrosion at the head-neck interface [4-6] to defects caused by laser etchings [7-9]. Some investigators [10-12] have reported that insufficient proximal bone support may predispose femoral stems to fracture via fatigue loading, while others [13] have suggested that distal fixation is adequate in this system.

A previous report [14] of 9 fractures of cemented, collarless, cast CoCr stems and 1 fracture of a cemented, collared, forged CoCr stem (Omnifit and Omnifit Plus, Osteonics, Allendale, NJ) has linked failure to a coarse metallic grain structure; intergranular corrosion and porosity; and proximal bone loss. Between December 2006 and May 2016, the FDA Manufacturer and User Facility Device Experience database [15] reported at least 13 Omnifit femoral stem fractures occurring at either the neck or mid-stem. Additionally, reports of fractures of forged CoCr femoral stems of various designs, formulations, and manufacturers have also been presented in the literature [7,8,16,17]. Despite improvements in stem design and metallurgy, femoral stem fracture remains a rare but serious complication of total hip arthroplasty.

This case report analyzes the causes of fracture of a cemented, collared, bipolar, cast CoCr alloy, Omnifit Plus femoral stem. We present the results of a stress analysis of the femoral stem based on conditions of both proximal and nonproximal bone support. Furthermore, to elucidate the role of proximal bone support on femoral stem lifetime, we use linear elastic fracture mechanics theory to retrospectively predict the expected device lifetime of the femoral stem for conditions of both proximal and nonproximal bone support.

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Case history

A 55-year-old male patient (height, 72 inches; weight, 230 lb; body mass index, 31.3) had a right hemiarthroplasty in 1990 to treat a femoral neck fracture. The implanted device was a cemented, collared, cast CoCr alloy, Omnifit Plus stem (size #6, 25-mm neck) coupled with a modular, skirted femoral head (26 mm, +10 mm neck extension) and a UHR Universal Head (53 mm). The femoral neck extension was employed presumably to avoid a leg-length discrepancy due to a low femoral neck resection resulting from femoral neck fracture. After 24 years, the patient presented with progressive right hip pain to the point of requiring crutches for ambulation. Physical examination demonstrated weak abduction and flexion muscle activity, and pain associated with straight leg raises, passive flexion, and external and internal rotation. Radiographs (Fig. 1) revealed a mid-stem fracture, acetabular osteolysis, proximal implant migration, and a loose cement mantle. The femoral head appeared to be eccentrically positioned slightly above the center of the outer bipolar component. Additionally, a protrusio acetabular deformity was noted, as was a cortical hypertrophy in the medial mid-femoral diaphysis (Fig. 1).

The patient was scheduled for revision surgery in November of 2014 to remove the failed components and convert the hemiarthroplasty to a total hip arthroplasty. During revision surgery, the distal aspect of the broken stem was found to be well fixed and required an extended trochanteric osteotomy for removal. At the most recent follow-up (approximately 12 months), the patient has shown recovery from the revision surgery, demonstrating acceptable range of motion, return to activities of daily living, and markedly decreased pain.

The implant failure outlined in this article was not reported to the MedWatch program (FDA), as the senior surgical author believed the failure to be an accepted complication of this type of surgery.

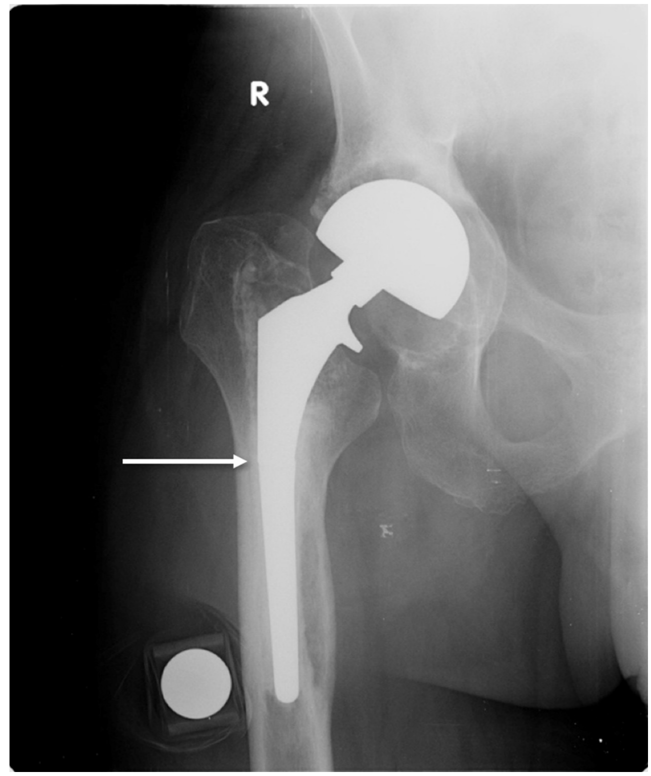

Figure 1. Radiograph of the primary implant reveal a mid-stem fracture, acetabular osteolysis, proximal implant migration, and a loose cement mantle. The location of fracture is denoted by the white arrow.

Fractographic and metallographic analysis

Optical inspection of the implant revealed failure at the mid-portion of the stem, at approximately 38% of the stem length, measured from the collar (Fig. 2). Low-magnification photographs (Fig. 3) show a large apparent grain structure at the location of fracture.

Fracture surfaces were imaged using a scanning electron microscope (Quanta, FEI, Hillsboro, OR) at the University of California (Berkeley, CA). The fracture surfaces revealed intergranular fracture (Fig. 4a) along with regions of porosity (Fig. 4b) intermittently dispersed on the fracture surface. Observations of fatigue striations are likely masked by martensitic twinning in the alloy structure.

A cross-section immediately distal to the fracture surface was cut and polished using a water-cooled metallurgical diamond saw and progressively finer metallurgical preparation equipment at the Thayer School of Engineering at Dartmouth College (Hanover, NH). Surfaces were etched using a mixture of HCl and HNO_3 (Aqua regia etchant, 3:1 molar ratio) for microstructural characterization. Optical microscopy of the etched surfaces revealed a large dendritic grain structure (Fig. 5a) with generally uniform distribution of carbide precipitates within the grains and a typical accumulation of carbide precipitates at the grain boundaries (Fig. 5b). Grain size (per ASTM E112-13) was measured to be 1.3 ± 0.6 mm (average ± standard deviation).

Stress analysis

Implant stresses at the location of fracture were estimated for 2 conditions: (i) proximal bone support and (ii) fixation exclusively distal to the fracture site (ie, distal fixation). For the case of proximal bone support, an assumption of load sharing between the stem, cement, and bone enabled composite beam theory to be used to estimate stresses at the location of fracture. A 2-dimensional free-body diagram of the leg (Fig. 6a) was used to estimate the angle of joint contact force (θ) and the magnitude of muscle force (F_m). The femoral stem neck dimensions, *a* and *b*, were measured using patient radiographs, and the distance from the greater trochanter to the leg center-of-mass, *c*, was estimated using established anthropometric data [18]. Hip joint contact force has been reported to be approximately 2 times body weight during normal gait [19], and this assumption was used here. As the gluteus medius is thought to provide the largest contribution to peak hip contact force [20], a force reduction assumption was used whereby all

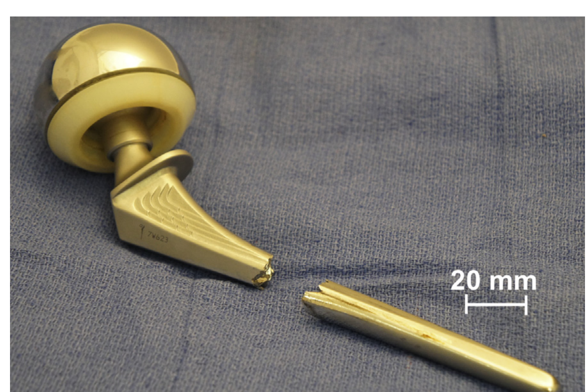

Figure 2. Photograph showing failure at the midportion of the stem, at approximately 38% of the stem length, measured from the collar.