CASE REPORT

Chronic Infection Leading to Failure of a Composite Femoral Stem: A Report of Two Cases

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Introduction

The use of the Epoch (Zimmer, Warsaw, IN) composite femoral stem for total hip arthroplasty (THA) has gained considerable popularity in recent years since being redesigned in the image of the Versys (Zimmer, Warsaw, IN) fully coated stem system. Proposed advantages of this composite stem include an extensive area of titanium fiber metal coating for porous ingrowth, multiple neck and metaphyseal options, graduated lengths based on component diameter, and its low modulus of elasticity. The material components include a solid cobalt-chromium-molybdenum alloy core and a polyetheretherketone (PEEK) polymer matrix—which are designed to closely match the stiffness of a normal femur to potentially reduce femoral stress shielding. The device has performed well in clinical trials at short- and long-term follow-ups, demonstrating excellent implant stability, histologic osseous ingrowth, and good proximal bone density preservation [1, 4, 6, 13]. A prospective study on 31 cases demonstrated no stem component revision at 10.1 years mean follow-up, but acetabular

component revision in 8 cases (3 for liner dissociation, 5 for polyethylene wear) [13]. Complications with this stem have been minimal, and the perceived benefits are attractive [4, 6, 10]; consequently, the Epoch composite femoral stem is being used with increased frequency.

We describe two cases of a previously unreported mechanism of failure for the Epoch composite femoral stem. In both cases, the patients developed late, chronic prosthetic infections with subsequent loosening of the femoral component and delamination of the PEEK from the cobalt-chromium-molybdenum alloy core. The fiber metal coating remained well-fixed to the host bone and the PEEK composite, yet was dissociated from the central core. Both patients required two-stage exchange procedures to eradicate the infection and manage the septically loose components.

Case Report

Case 1

The first patient is a 55-year-old man who underwent a primary right THA in April 2007, secondary to end-stage osteoarthritis. The patient's extensive past medical history included a remote right hip septic arthritis which required several open debridements to eradicate a staphylococcus infection (speciation unknown) 20 years prior. Via a posterior approach, a size 15 composite (Epoch, Zimmer, Warsaw, IN) LM body, extended offset femoral stem and a 58-mm titanium acetabular component with a highly cross-linked polyethylene liner were implanted. A 36-mm + 3.5-mm neck length cobalt-chromium-molybdenum alloy femoral head was utilized. At the 3-week follow-up, the patient was progressing well with therapy, and radiographs demonstrated good position of the femoral stem component (Fig. 1a). At the 6-week follow-up, the patient presented in severe discomfort with frank dislocation of his right THA which he states occurred several days previously, while he was bending over. A head and liner exchange was undertaken, with a 40-mm head and a +7-mm neck implanted for increased stability.

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Fig. 1. **a** This is an anteroposterior radiograph of the right hip, taken 3 weeks postoperatively, which demonstrates that the femoral component is in good position with no evidence of loosening, subsidence, dislocation, or migration as compared to initial postoperative films. **b** This is a radiograph taken 3 years postoperatively, which shows the presence of a fracture in the peak of the composite femoral stem. Cortical thickening of the femur is evident near the distal stem, with progressive radiolucency and subsidence. These findings reveal a delamination of the composite material from its cobalt-chromium-molybdenum alloy core and consequent loosening of the stem. **c** This is a radiograph taken 5 years postoperatively, which reveals a stem in greater varus with continued fragmentation and delamination of the composite material from its core. This was found to be a result of chronic prosthetic infection. There is also fracturing of the proximal lateral femoral cortex.

The patient returned to normal functional capabilities for the next 3 years, but was seen in July 2010 for acute right hip pain. Radiographs revealed a fracture at the distal extent of the femoral coating and a lucency surrounding the femoral stem measuring up to 9 mm (Fig. 1b). At the distal end of the stem, cortical thickening of the femur was noted. The findings were consistent with a chronic prosthetic infection and septic loosening of the composite femoral stem. Component migration was secondary to delamination of the outer composite porous core around the tip of the stem. Due to his significant medical comorbidities (end-stage liver disease, hepatitis C, and a bleeding diathesis), including severe thrombocytopenia, the patient was deemed an unacceptably high risk for surgery at that time. He was given an extended course of intravenous antibiotics and his weight bearing was to be protected with crutches or a walker. The patient's wound ultimately began spontaneously draining, and over the next 1.5 years, he was hospitalized with episodic exacerbations of right hip pain due to his chronic infection but was consistently unable to receive medical clearance for surgery. During this time, the patient was kept on long-term suppressive antibiotics with bactrim and cefadroxil and intermittent negative pressure wound therapy.

In April 2012, the patient was admitted to the hospital for intractable hip pain and radiographic evidence of subsidence of the femoral stem. The component had now violated the lateral cortex of the femur, and a fracture had propagated proximally (Fig. 1c). Aspiration contents from the hip grew *Proteus mirabilis*, *Acinetobacter baumannii*, and diphtheroids on aerobic culture medium. In his extended preoperative hospital stay, the patient received intravenous antibiotics (vancomycin, cefepime, and metronidazole) until 7 days prior to the operation when all antibiotics were stopped to allow for the highest yield of culture results during surgery. He underwent explantation of his implants and reimplantation of an antibiotic spacer. The remaining fragments of the proximal femur and greater trochanter were reattached with

cables. Intraoperative cultures revealed *P. mirabilis* and *Enterococcus faecalis*. Intraoperatively, it was noted that the porous coating was well-fixed to his bone distally; however, there was frank delamination from the composite stem (Fig. 2). The implant was identified protruding from the lateral aspect of the femoral cortex. The inner core was tapped from a distal-to-proximal direction to remove the stem in a retrograde fashion. The canal was accessed through the existing fracture of proximal femur (a natural ETO), affording good visualization of the canal. The remaining fiber metal material still attached to the bone was debrided with the combination of a pencil-tip, high-speed bur, and cement removal osteotomes, after which the canal was reamed and prepared for the spacer. Despite requiring 12 units of packed red blood cells, 10 units of platelets, and 5 of fresh frozen plasmas, the patient tolerated the surgery without further complications. He is currently awaiting the second stage of the procedure and is convalescing well with his articulating spacer in place.

Case 2

The second patient is a 47-year-old man with osteoarthritis who underwent a primary THA of the right hip in October 2007. During the operative procedure, a cementless size 15 composite, standard body, standard neck offset femoral stem (Epoch, Zimmer, Warsaw, IN) was inserted, along with a 36-mm + 3.5-mm neck length femoral head. Early postoperative radiographs demonstrated no evidence of subsidence, osteolysis, or loosening (Fig. 3a). He ultimately recovered well with a near complete return to his standard level of preoperative function.

In August 2009, approximately 2 years from the index procedure, the patient returned reporting a 5-month history of progressively worsening pain in his right thigh that had prevented him from ambulating without crutches. On radiographic examination with AP pelvis and AP and lateral

Fig. 2. These are photographs of the retrieved composite femoral stem, showing delamination of the porous PEEK coating from the cobalt-chromium-molybdenum alloy core on the distal one third of the stem. The PEEK coating absent from the stem here remained well affixed to the patient's femur upon explantation of the stem.

views of the right hip, the acetabular prosthetic component showed stable alignment and appeared well-fixed; however, the femoral stem had subsided several centimeters within the femoral canal as compared to his previous radiographic examination (Fig. 3b, c). Blood work demonstrated a white count of 10.6, ESR of 18, and CRP less than 0.5. Hip aspiration revealed a white blood cell count of 21,000/mL with 91% neutrophils and positive cultures for group A beta-hemolytic *Streptococcus*. The patient subsequently underwent a

successful two-stage exchange arthroplasty. Intraoperative findings showed delamination of the implant coating with detachment and fragmentation of the titanium fiber metal mesh and composite from the inner core of the prosthesis (Fig. 4). The insertion handle was for the stem attached to the proximal body to remove the femoral component from the femoral shaft. A curette was used to debride the femoral canal contents of the apparent pseudomembrane that had formed. A back-cutting, canal curette was used to remove debris and

Fig. 3. **a** This is a radiograph of the right hip, taken 3 weeks postoperatively, which demonstrates that the femoral component is in good position without evidence of subsidence, osteolysis, or loosening as compared to the initial postoperative films. **b** This is an anteroposterior radiograph of the right hip taken 2 years postoperatively, which shows a stable, well-fixed acetabular component but with femoral stem subsidence of several centimeters within the canal as compared to the initial postoperative radiograph in Fig. 3a. **c** This is a lateral radiograph of the right hip, also at 2 years postoperatively, which redemonstrates the femoral stem subsidence within the femoral canal as in Fig. 3b.

Fig. 4. Explantation of the composite femoral stem revealed delaminated fragments of the titanium fiber metal mesh and PEEK composite from the inner cobalt-chromium-molybdenum alloy core.

composite material still affixed to the femoral canal. For the material that was difficult to remove, long canal osteotomes were used to break the bond between the fiber metal and the bone. Long reamers were subsequently used to further prepare the femoral canal for the spacer. Intraoperative fluid from the affected hip demonstrated no growth on aerobic, anaerobic, AFB, and fungal culture mediums. Pathology results from the intraoperative femur were potentially consistent with osteomyelitis, with significant granulation tissue and neutrophilic infiltrate (results were difficult to distinguish fibrous tissue in the canal versus femoral bone shavings as reported on the pathology report). After 6 weeks of intravenous vancomycin administration via PICC line, the patient was given a 2-week drug holiday and then underwent reimplantation without complication. The newly placed femoral stem was a 23-mm ZMR XL taper stem (Zimmer, Warsaw, IN) by 185-mm in length. Post-revision radiographs at 2-weeks, 3-months, and 6-months follow-up visits confirmed excellent prosthetic alignment, with no evidence of fracture, component subsidence, loosening, or dislocation. Clinically, the patient had no further complications and returned to his full preoperative level of function.

Discussion

The use of a composite femoral stem for THA has gained momentum as it affords the potential for improved load transmission from implant to bone and has already exhibited satisfactory overall clinical outcomes. One recent prospective study reports no stem component revisions in 31 THA cases utilizing composite femoral stems after a mean of 10.1 years of follow-up [13]. The numerous neck options, graduated stem length, and metaphyseal body size options allow the component to restore the natural biomechanics of the hip joint. Overall, the Epoch composite stem design has the potential to decrease the incidence of such hip implant-

related complications as stress shielding, leg length discrepancy, and thigh pain [4, 6].

There is a paucity of modern literature regarding composite femoral stem component failure in primary THA. It has been previously demonstrated that the results of the soft interface proplast-coated femoral stem were unfavorable, with reports demonstrating high rates of aseptic loosening and osteolysis [5]. Clinical results have been relatively successful to this point for the Epoch composite stem, as with the intermediate-term follow-up of the femoral implant by Akhavan et al., who demonstrated improvement in average Harris hip scores (56 to 97), no instances of component migration, and only one hip with osteolysis [1]. Similarly, White et al. reported Harris hip score improvements from 57 to 92 in a cohort of 31 composite stems implanted in 27 patients, with no stem requiring revision at the 10.1-year follow-up time point [13]. To our knowledge, this is the first report of a localized prosthetic infection causing debonding and failure of the porous coating on a composite femoral stem. In each case of the two cases, we believe that the infectious focus around the prosthetic stem caused the composite material—particularly at the distal end of the stem—to delaminate, thus debonding part or all of the outer porous coating. This erosion caused the composite material and the stem to fracture, resulting in a prosthetic loosening, subsidence, and finally, complete component failure.

Surgical site infection in primary THA is a relatively rare occurrence; a recent systematic review has demonstrated an incidence of infection ranging between 0.2 and 1.1% in the period leading up to and including 5 years postsurgery [12]. A documented yet uncommon complication associated with chronic prosthetic infection is the loss of structural integrity of the prosthesis and resultant septic loosening and migration of the acetabular component [9] or more rarely of the femoral stem [14]. However, the potential deleterious effects of an infection on a composite femoral stem have not been reported.

It has been reported that the pathogenesis of implant-related infections is a result of biofilm formation on the artificial prosthesis surface by microorganisms [2]. These

microorganisms live closely together, attached to the surface of the prosthesis in a highly hydrated extracellular matrix [11]. The difficulty in treating prosthetic infections is due to this relatively antimicrobial-resistant stationary state that the aforementioned microbes enter within the biofilm as a result of depleted metabolic substrates and accumulation of degradation products [8]. Bacterial biofilm resistance to antibiotics has also been hypothesized to be due to restricted drug penetration by the matrix material via formation of a reaction-diffusion barrier that prevents lethal antibiotic doses from penetrating past the surface of the biofilm [3]. For example, antibiotics such as oxacillin, cefotaxime, and vancomycin have been shown to have limited biofilm penetration [7], likely by the aforementioned pathophysiologic mechanism. In our cases, it appears that the chronic infection led to loosening of the component and mechanical failure of the PEEK from the cobalt-chromium-molybdenum alloy core. The infectious process at the composite femoral stem may have accelerated the biologic processes at the implant-bone interface, and in these two cases, appears to have led to a debonding of the surrounding PEEK polymer matrix from the forged alloy core as facilitated by a local environment alteration and debris formation due to the presence of infection.

The biomechanical principles of the composite stem model are such that its forged alloy core provides a foundation of strength to withstand the extrinsic forces on the hip, and the surrounding PEEK polymer matrix mimics the natural femur's flexibility through a low modulus of elasticity. It is possible that this additional attachment interface is susceptible to mechanical breakdown in the setting of the harsh environs of a chronic infection. Subsequent delamination of the coating and component failure is then made possible in such a setting. That is, once the proximal body of the implant had debonded due to the presence of an infection, the load stresses from the body would be transferred to the distal portion of the stem, overloading the metallic components and causing fragmentation of the implant from fatigue failure. This mechanical consequence is appreciated to some extent in Fig. 1b, where cortical thickening is present at the tip of the femoral stem. It is additionally plausible that the converse occurred, whereby initial mechanical failure of the composite stem became secondarily infected given that debris or necrotic tissue within the femoral canal might limit access to normal immune defenses and leave the host susceptible to infection, although this seems less likely given what is already known about periprosthetic infections as a cause for implant failure through induction of osteolysis with the inflammatory response.

Of note, there was a delay of several months between clinical suspicion and verification of a prosthetic infection and the ultimate surgical intervention for the patients in this report. We believe that a delayed diagnosis of a prosthetic infection with this composite stem may lead to greater deleterious effects at the composite core interface. Additionally, chronic antibiotic suppression as a mode of management of prosthetic infection with this implant may not be a prudent option. Intraoperatively isolated organisms in the patient in case 1 (*Proteus mirabilis* and *E. faecalis*)

demonstrated susceptibility of only the *Proteus* organism to the combination of long-term antibiotics (bactrim and cefadroxil) that had been prescribed to him. Therefore, it may not only be difficult to choose the most effective chronic suppressive antibiotics to cover all infective organisms, but this gives credence to the statement that an organism's growth in biofilm on an implant can be recalcitrant to an antibiotic which it would otherwise be susceptible to. Ultimately, should this implant become infected, there appears to be a high likelihood that a reoperation will be necessary to clear the infection as long-term antibiotics will not suffice. In patients with significant medical comorbidities at high risk for prosthetic implant infection, the mechanical benefits from this prosthesis may not outweigh the potential morbidity or mortality implicated for a poor surgical candidate requiring revision surgery for a chronic antibiotic-resistant arthroplasty infection (chronic suppression also may not be a viable option in these patients). Further in depth studies need to be performed regarding infection and such composite core interfaces.

Disclosures

Conflict of Interest: Bryan M. Saltzman, MD, Bryan Haughom, MD, and Julius K. Oni, MD have declared that they have no conflicts of interest. Dr. Levine reports personal fees from Zimmer, Conmed, and Biomet during the conduct of the study and personal fees from Defending Physician Cases and Human Kinetics (Book), outside the submitted work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was waived from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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