Modular Hip Implant Fracture at the Stem-Sleeve Interface

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abstract

The use of modular implants in femoral stem design has grown increasingly popular over the last decade because of the theoretical advantage of more flexibility and optimization of femoral anteversion, limb length, and femoral component offset. With the benefit of increased surgical flexibility, however, modularity also carries the theoretical risks of fretting at the modular surfaces, sequelae of wear debris, and possible failure and fracture of the stem at the modular junction. Indeed, there have been an increasing number of reports of modular implants failing due to fracture at modular junctions. The S-ROM prosthesis (DePuy Orthopaedics, Inc, Warsaw, Indiana), however, has a stellar clinical record and has been used with good results in both primary and revision total hip arthroplasty. Only a single case of S-ROM failure at the stem-sleeve interface has been reported in the orthopedic literature. The aim of this case report was to present a succinct history of proximal modularity in total hip arthroplasty and to describe the only known case of this type of catastrophic failure in an S-ROM prosthesis with a metal-on-metal bearing. Despite a low level of serum metal ions on presentation, scanning electron microscopy showed findings consistent with corrosive processes and pseudotumor was seen at revision surgery. [Orthopedics. 2015; 38(3):e234-e239.]
The use of modular implants in femoral stem design has grown increasingly popular over the last decade because of the theoretical advantage of more flexibility and optimization of femoral anteversion, limb length, and femoral component offset. The S-ROM prosthesis (DePuy Orthopaedics, Inc, Warsaw, Indiana), a modification of the original Sivash Stem (Joint Medical Products, New Brunswick, New Jersey), is a pioneering proximal modular stem that first came to market in 1982. Since its introduction, the S-ROM prosthesis has provided stellar clinical performance and is used in both primary and revision total hip arthroplasty. Although several examples of other modular implant failures have been reported, only a single case of failure of an S-ROM prosthesis at the stem-sleeve interface has been reported. A review of the US Food and Drug Administration adverse event report database showed at least 6 other reported fractured necks or fractures at the neck-sleeve interface with this device design since its introduction. The current report is the only known case of this type of metal-on-metal bearing failure.

**Case Report**

A 50-year-old man underwent primary total arthroplasty of the right hip in January 2007 after failed conservative treatment of degenerative osteoarthritis. The patient received an 11×16×150-mm modular femoral stem with a neck length of 36+6 mm and a 16B-LRG ZTT proximal femoral sleeve (DePuy Orthopaedics, Inc). The femoral head was an S-ROM 36-mm M cobalt-chromium head with 6 additional mm of neck length (DePuy Orthopaedics, Inc), and the acetabulum was a Pinnacle Sector II size 56 cup (DePuy Orthopaedics, Inc) with a Pinnacle 36×56-mm metal insert (DePuy Orthopaedics, Inc). The procedure was performed through a posterolateral approach, and no complications occurred intra- or postoperatively. Approximately 3.5 years after implantation, the patient had pain in the operative hip and returned to see the original surgeon. Because of concerns about the metal-on-metal articulation of the prosthesis, revision surgery was recommended. However, the patient decided against that option because he worked as a self-employed brick mason and could not take the time off of work. He was active for another 2 years, at which point he presented to the authors’ institution for a second opinion regarding his pain. At presentation, 5.5 years postoperatively, his height was 6 feet and his weight was 240 lb, for a body mass index of 32.5. His pain occurred mainly in the groin and the anterior and lateral thigh. Pain was worsened by activity, walking more than 6 city blocks, and improved with nonsteroidal anti-inflammatory drugs. He had no history of trauma and had no infectious symptoms. Harris Hip Score was 56 on the operative leg and 88 on the contralateral side. The EuroQol 5D score was 0.69 and 82, and University of California, Los Angeles, activity score was 5. Radiographs showed an S-ROM prosthesis, with a metal-on-metal bearing surface, with good bony ingrowth of both acetabular and femoral components (Figure 1A).

At presentation, white blood cell count was 6.0×10⁹/L (reference range, 4.5-11.0×10⁹/L), erythrocyte sedimentation rate was 7 mm/h (reference range, 0-13 mm/h), and C-reactive protein level was 2.1 mg/L (reference range, <8.0 mg/L).
Serum metal ion levels were obtained and showed a cobalt level of 1.5 μg/L and a chromium level of 0.8 μg/L. Metal artifact reduction sequence magnetic resonance image (MRI) obtained at that time showed thickened soft tissue with decreased signal intensity near the neck of the femoral component and heterogeneous signal in the trochanteric region, suggestive of osteolysis (Figures 1B-C). The patient elected to be monitored closely. Six months later, he returned for follow-up with no progression in pain, stable findings on radiographs, white blood cell count of 6.10×10⁹/L (reference range, 4.5-11.0×10⁹/L), erythrocyte sedimentation rate of 7 mm/h (reference range, 0-13 mm/h), and C-reactive protein level of 1.6 mg/L (reference range, <8.0 mg/L), cobalt level of 1.0 μg/L, and chromium level of 1.0 μg/L. The decision was made to continue annual surveillance. The patient returned 1 year later with no progression in symptoms. Repeat metal artifact reduction sequence MRI and serum metal ion levels (cobalt, 1.0 μg/L; chromium, 0.9 μg/L) showed no significant changes.

Approximately 7 years postoperatively, the patient presented to the emergency department with acute onset of “feeling his hip give out,” with marked pain and inability to bear weight. This episode was atraumatic and occurred while the patient was walking through a convenience store. Before the acute incident, he had no increase in pain and no mechanical symptoms, such as grinding, clicking, or squeaking, that had been cited in other cases of component failure.¹,³,⁴,⁷,⁸,¹¹ Radiographs performed at the time showed a fracture of the femoral stem at the sleeve-stem interface (Figure 2). Laboratory values on admission showed a white blood cell count of 8.5×10⁹/L (reference range, 4.5-11.0×10⁹/L), erythrocyte sedimentation rate of 7 mm/h (reference range, 0-13 mm/h), and C-reactive protein level of 1.31 mg/L (reference range, <8.0 mg/L). The cobalt level was 0.8 μg/L, chromium level was 0.9 μg/L, and titanium level was 36 μg/L.

The patient underwent revision arthroplasty 2 days after admission. A posterolateral incision was used. The proximal portion of the prosthesis with the femoral head was easily removed after dislocation, and a transverse stem fracture was noted several millimeters below the proximal end of the metaphyseal sleeve (Figure 3). A combination of high-speed burrs was used to debride bone around the proximal metaphyseal sleeve, after which a vice grip and a slap hammer were used to remove the proximal sleeve and the attached remaining portion of the femoral prosthesis. Based on the remaining metaphyseal femoral bone stock deficiency and significant necrosis of periprosthetic soft tissues involving the abductor muscles, the decision was made to use a revision stem with midstem modularity to optimize stem fixation and stability.

After the stem was removed, the femoral canal was prepared and a Stryker restoration modular 155-mm conical distal stem was placed (Stryker Orthopaedics, Mahwah, New Jersey) with a 23-mm calcar body. The metal head was replaced with a Stryker Biolox 36-mm ceramic head with a +2.5-mm neck length. The acetabular cup appeared well fixed in the operating room; however, the metal liner from the acetabulum was removed and a 36-mm DePuy Pinnacle polyethylene liner was placed. Postoperatively, the patient did well and was discharged on postoperative day 4.
Although preoperative MRI showed no obvious adverse tissue reaction, at the time of surgery, significant thickened necrotic periprosthetic pseudocapsule involving the abductor muscles was found. This was debrided and was found on pathologic examination to contain necrotic tissue and evidence of reactive debris. Additionally, examination of the fracture surfaces of the implant at the time of surgery showed areas of blackened surface that were concerning for corrosive change.

Evaluation was performed with a Philips FEI XL-30 (FEI Company, Hillsboro, Oregon) scanning electron microscope. Examination of the fracture surfaces showed severe corrosive changes consisting of pitting and scalloping. A clear clamshell pattern characteristic of fatigue fracture radiated from the corroded area on the anterolateral surface of the fracture site. Energy dispersive x-ray spectroscopy showed high levels of oxygen and calcium in addition to titanium and aluminum at the fracture surface (Figure 2 and Figure 4).

**Discussion**

Since its release, the S-ROM prosthesis has offered stellar clinical performance and has been prominently used for more than 30 years in complicated and uncomplicated revision and primary total hip arthroplasty. Although modular prostheses allow for considerable surgical flexibility, there was initial concern and skepticism about the S-ROM stem because of possible fretting of the modular surfaces, sequelae of wear debris, and possible failure and fracture of the stem at the modular junction. However, except for 1 case report and several possible instances in the US Food and Drug Administration database over all years of use, the S-ROM has had no other reports of catastrophic failure or fracture at the modular junction or neck.

Fracture of femoral components is a rare complication in total hip arthroplasty, with Charnley estimating the...
incidence of stem fractures in implants before forged cobalt-chromium molybdenum and titanium alloys to be 0.23%. The prevalence increased to 6.0% in men weighing more than 75 kg, and the incidence with other designs may be as high as 11.0%. Most femoral component fractures reportedly occur in the stem; however, fractures of the neck have been reported in modular designs. The locations of these fractures range from the proximal head-neck junction to the neck-stem junction, and factors contributing to fracture include corrosion and fretting at the modular interface, or head-neck junction, defects in welding the neck to the prosthesis, and high use of laser etching in the region.

There are examples of fracture in the modular neck of modern hip implants. Most prominently reported is the Profemur-Z (Wright Medical Technology, Arlington, Tennessee), which in the Australian market has shown an unacceptably high failure rate of 11.2% at the modular stem-body tapered junction. Similarly designed modular implants have fractured 1 to 2 mm proximal to the body-stem junction, and the cause is believed to be a repetitive bending moment, leading to fracture initiation, propagation, and ultimate failure.

The previous case report of failure of an S-ROM stem was a metal-on-polyethylene articulation. Macroscopically, blackened areas of the implant showed areas of corrosion, and further microscopic analysis performed by DePuy Orthopaedics, Inc, showed evidence of fatigue fracture secondary to micromotion and cyclic loading at the stem-sleeve interface.

In the current case, despite a low level of metal ions on presentation and at the time of fracture and no obvious pseudocapsule on MRI, there was evidence of macroscopic corrosion denoted by areas of blackened surface on the implant. An area of thickened pseudocapsule was debrided at the time of surgery and was found on pathologic examination to contain necrotic tissue and evidence of debris reaction. Scanning electron microscopic evaluation also showed scalloping and pitting, consistent with a corrosive process causing weakening of the implant and susceptibility to cyclic fatigue fracture.

**Conclusion**

This case report, although describing a seemingly extremely rare occurrence in the S-ROM stem, reaffirms the trade-off between versatility during implantation and the long-term robustness of modular implants. This implant had a metal-on-metal articulation, possibly increasing the risk of corrosive processes at the modular junction that could result in failure. However, the use of metal-on-metal devices has decreased significantly, with only 1% of hip resurfacing procedures and 2% of large heads using metal-on-metal total hip replacements. Although double modular devices seem to be at higher risk for implant fracture, any modular junction can have substantial fretting and corrosion and subsequent fracture. Although diagnostic tools such as metal ion levels and MRI are useful, these may not be able to predict catastrophic fractures. However, a differential diagnosis of taper corrosion should be considered when evaluating symptomatic patients with a modular implant.

**References**

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stems at the neck-shoulder junction. *J Arthroplasty*. 2001; 16(2):236-238.

