Arthroplasty Today 4 (2018) 295–299

Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Case report

Fracture of an S-ROM stem at the sleeve-stem junction

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ARTICLE INFO

Article history:
Received 19 November 2017
Received in revised form
9 February 2018
Accepted 9 February 2018
Available online 10 May 2018

Keywords:
Stem fracture
Removal technique
Breakage
Failure
Corrosion

ABSTRACT

Fracture of a well-ingrown femoral component is a rare and often challenging complication. Modular junctions and sleeve interfaces have been identified as one potential point of weakness with corrosion and fretting being contributing factors to ultimate femoral component fracture. Stem fractures at the sleeve interface were reported occasionally for the proximal ingrowth modular Emperion System (Smith and Nephew, Memphis, TN). However, this failure mechanism has been reported infrequently, often associated with corrosion at the modular junction, for the similarly designed S-ROM system (DePuy Orthopedics Inc., Warsaw, IN). We present the case of a 52-year-old patient, with a body weight of 84 kg (185 lbs) and a body mass index of 30.6 kg/m^2, who suffered a fatigue fracture of a 14 × 09 × 130 mm S-ROM stem 42 months after implantation. The present study presents the results of the surface analysis, discusses possible failure mechanisms, provides treatment guidelines, and a review of the literature revealing 15 cases of failure at the level of the stem-sleeve junction. In particular, modifiable risk factors for potential stem failure, including stem diameter, stem offset, and the resulting cantilever bending forces on the proximal sleeve-stem junction, are discussed in detail.

Introduction

Femoral component fracture in total hip arthroplasty (THA) is a rare complication that mainly affects uncemented distally fixed revision stems [1-3]. Risk factors include high body mass index (BMI), increased activity level, smaller diameter stems, and severe proximal femoral bone loss with loss of medial calcar support [2,4-6]. Contemporary diaphyseal engaging revision femoral stems often have a modular proximal body and fractures were reported at the modular junction, particularly with earlier stem designs [2,4]. Modular junctions are also used to combine a metaphyseal sleeve with a diaphyseal engaging stem allowing independent control of version to better address conditions such as metaphyseal bone loss, revision cases with stem retroversion, and excessive anatomic anteversion or retroversion in primary THA. But recent reports on the modular stem Emperion System (Smith and Nephew, Memphis, TN) demonstrated a stem fracture rate of 1.5% (8 of 547), and this stem has since been removed from commercial use [7]. The present study reports a similar failure mechanism at the sleeve-stem junction in a S-ROM Modular Hip System (DePuy Orthopedics Inc., Warsaw, IN) and includes a comprehensive review of the literature on S-ROM stem fractures [7-11]. The paper also discusses the proposed failure mechanism, potential risk factors, and surgical management of this complication.

Case history

A 52-year-old female with a height of 165 cm, weight of 83.5 kg, BMI of 30.62 kg/m^2, and no history of metabolic bone disease underwent a primary THA for osteoarthritis secondary to dysplasia of the right hip in December 2013 (Fig. 1). She already underwent contralateral total hip replacement after an injury due to a motor vehicle accident in October 1995 (cup: Implex 52 mm [Zimmer, Warsaw, IN], stem: Reality size 7 [Kinamed, Camarillo, CA], head: 28 mm + 4) with a highly satisfactory result at the last follow-up.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.artd.2018.02.004.

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https://doi.org/10.1016/j.artd.2018.02.004

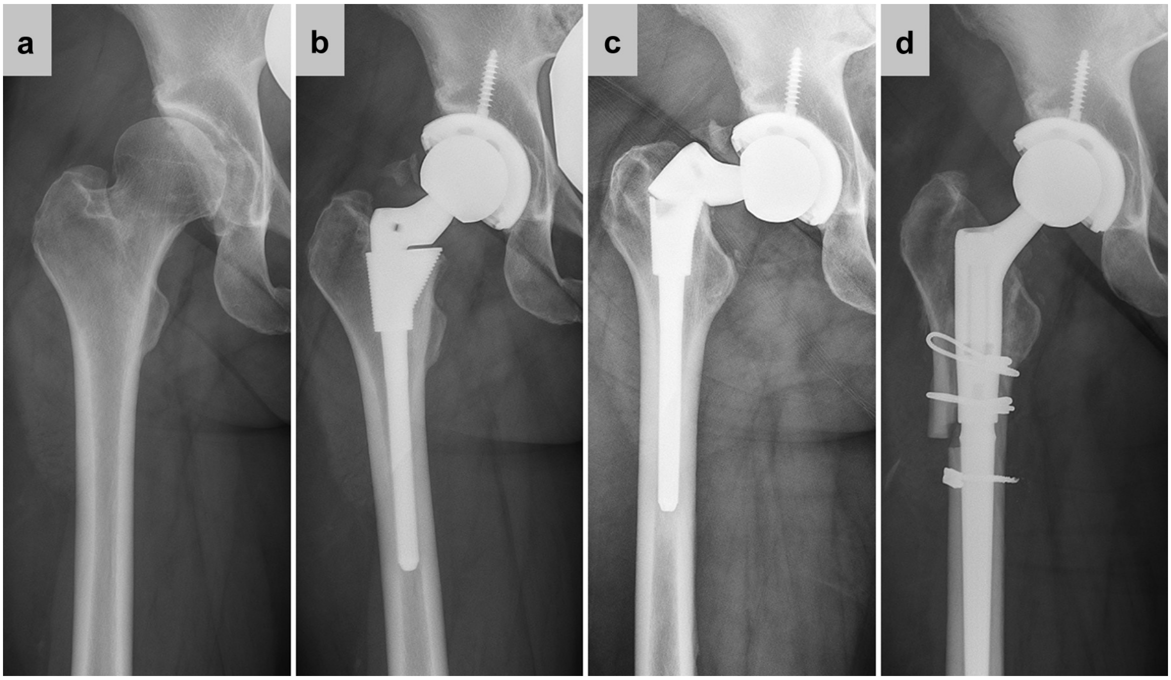


Figure 1. Chronologic radiographs (a) October 2, 2013 preoperative anteroposterior radiograph of the right hip showing secondary osteoarthritis due to hip dysplasia (b) December 18, 2014 postoperative radiograph of the right hip after total hip arthroplasty with a S-ROM prosthesis and a Pinnacle cup (c) July 5, 2017 follow-up radiograph of the right hip showing a fracture of the femoral component at the level of the sleeve-stem junction with a valgus malalignment (d) August 14, 2017 postoperative radiograph of the right hip after revision performing and ETO, implanting of a Restoration Modular Hip System and reposition of the greater trochanter with Dall-Miles cables. The original cup could be preserved.

Owing to a pre-existing developmental dysplasia at the time of primary surgery, the right hip was replaced utilizing a standard S-ROM Modular Hip System with a 14 × 09 × 130 mm stem, a 36 mm standard neck, and a 14D large proximal sleeve combined with a 36 + 0 mm Biolox ceramic head, a 54 mm Pinnacle cup and a highly cross-linked polyethylene liner (DePuy Orthopedics Inc., Warsaw, IN). The postoperative course was unremarkable.

In June 2017, she developed progressive discomfort in the right thigh reporting only a minor trauma while walking on a side walk and thrusting her right foot against a raised grate. Initial radiographs showed no evidence of fracture or loosening, and the clinical examination showed no limitation in range of motion. The patient developed worsening pain over the next few days and went to the emergency department owing to inability to bear weight on her right leg. Radiographs showed a fracture at the sleeve-stem junction of the right femoral component. There was no evidence of loosening or periprosthetic fracture (Fig. 1). Revision surgery was therefore indicated and performed in July 2017.

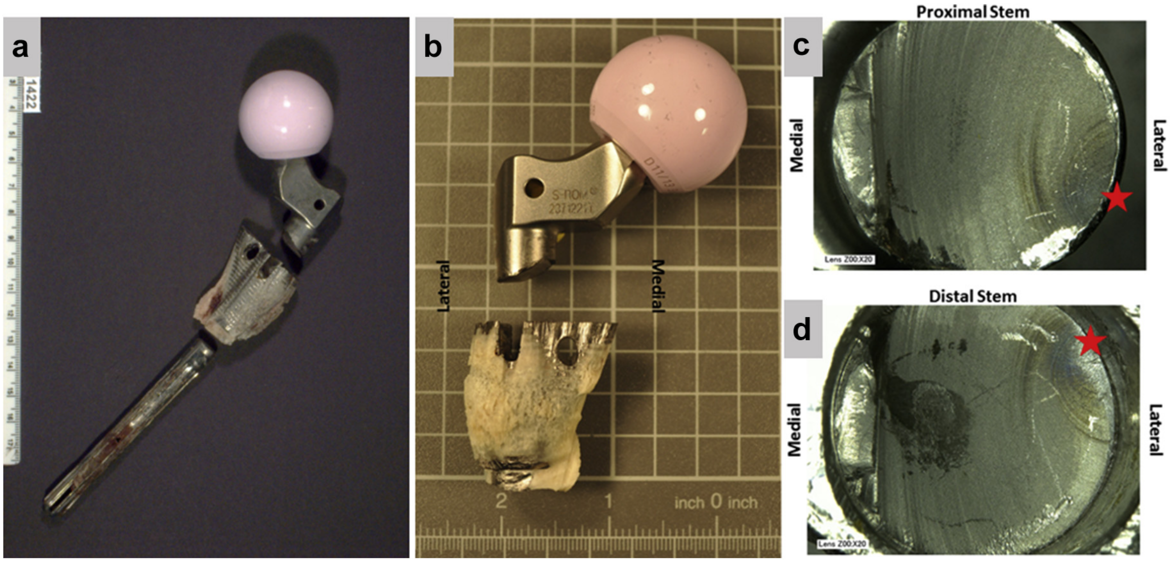
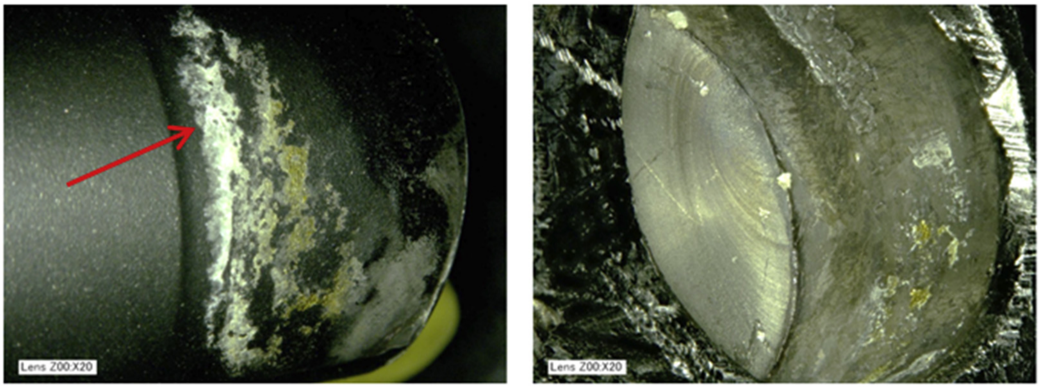


Figure 2. Macroscopic image and surface analysis of the revised S-ROM Modular Hip System. (a) The sleeve and the polished stem show substantial bony ingrown; (b) retrieved fractured component oriented to show where the fracture occurred at the stem within the femoral sleeve. Magnified images of the proximal (c) and distal (d) stems are shown highlighting the fracture origin at the red star. Beach marks propagate medially across both surfaces to the final fracture point, at medial edge.



Femoral Stem

Modular Femoral Sleeve

Figure 3. Corrosion and debris observed on the femoral stem and the modular femoral sleeve. Small remnants of bone ongrowth seen proximally on femoral stem (indicated by an arrow).

Surgical technique

Surgery was performed through a posterior approach. The broken proximal segment of the femoral stem was removed from the surgical site (Fig. 2). The sleeve was ingrown into the metaphysis. Using a combination of pencil tip burrs and thin osteotomes, the bone-implant interface was disrupted. To improve the extraction force for the sleeve, a carbide burr was used to drill a hole in the lateral aspect of the visible sleeve to accommodate the hook (from the Stryker Restoration modular proximal body extraction tool) of the S-ROM Extraction instrument (DePuy Synthes, Warsaw, IN). The sleeve appeared to be cold welded to the stem, and direct removal was not possible. Therefore, the decision was made to proceed with an extended trochanteric osteotomy (ETO). A prophylactic distal Dall-Miles cable was placed. Based on templating, the ETO was measuring 130 mm from the tip of the greater trochanter. After ETO, the distal splines of the stem were well fixed and bone ongrowth had occurred into the splines. Flexible osteotomes and 2.0 mm K-wires were used to disrupt the interface, but the stem was still well fixed, and it was difficult to gain access to the diaphysis circumferentially due to the proximally metaphyseal sleeve. We then used the carbide tip burr to burr through the proximal stem distal to metaphyseal sleeve allowed for better visualization. The sleeve was then removed. A size 11 trephine was passed over the stem up to the distal tip. At this point, the stem loosened and could be removed.

The reconstruction was performed using a 15 × 155 mm tapered modular revision stem with a 19 + 20 mm proximal body and a 36 + 7.5 mm head (Restoration Modular Revision Hip System, Stryker, Kalamazoo, MI). The trochanteric osteotomy segment was fixed with 2 Dall-Miles cables.

Postoperative imaging demonstrated adequate reduction of the trochanteric segment and a well-sized and positioned implant. The patient was mobilized toe-touch weight bearing (Fig. 1).

Surface analysis

The retrieved S-ROM implant was cleaned and analyzed using a Keyence VHX digital microscope (Keyence Corporation of America, Itasca, IL). Surface analysis was performed in our biomechanical laboratory (Fig. 2).

The S-ROM femoral stem fractured within the connection to the modular sleeve; the stem diameter was 14 mm at the point of fracture. The damage patterns on the fracture surfaces of both the proximal and distal portions of the fractured stem were consistent with fatigue fracture due to cyclic loading (Fig. 2). The clamshell, or beach marks, spans most of the fracture surface of the implant, indicating a low-load, high-cycle fatigue failure. Macroscopic imaging revealed the origin of the fracture at the anterolateral edge of the stem. No material defects or other stress concentrations were noted at the origin of the fracture. The clamshell marks show propagation of the fracture medially through the cross section of the stem until the final fracture near the medial edge. The implant stem and sleeve were assessed visually at the modular junction for any evidence of corrosion and fretting. Both the stem and the sleeve had moderate corrosion and fretting on the lateral side adjacent to the origin of the fracture (Fig. 3) [12]. The femoral sleeve had substantial bone ongrowth and no visible signs of damage on the outside surface.

Discussion

The S-ROM Modular Hip System is known to be a reliable option in primary as revision THA offering excellent long-term results [7,13]. The present study presents a fatigue fracture of the stem at the sleeve-stem junction in an S-ROM System. This mechanism of failure has been reported previously [8,9]. Although an infrequent occurrence of this implant, its continued reporting deserves further investigation.

Causes for failure

Risk factors of implant failure are most likely multifactorial and include elevated BMI, high activity level, small medullary diameter, severe bone loss, and lack of proximal medial support [2,4-6]. However, surgeons seem to adapt stem size to gender, age, and height but not to body weight [14]. Prior reports of nonmodular revision stem failures most commonly describe fractures through stems with small diameters ranging from 12 to 14 mm [5,15,16]. Sotereanos et al [17] suggest that a primary reason for femoral component failure in primary THA is inadequate stem diameter due to undersizing. Busch et al [1] recommended avoiding stems with diameters less than 13.5 mm. In the current case, the fractured stem had a diameter of 14 mm at the level of fracture (Fig. 2). In addition, the patient matched further risk factors for fracture including increased body weight of 84 kg as well as a physical active lifestyle.

Literature review revealed 15 cases of S-ROM stem fracture (Table 1). The Food and Drug Administration's Manufacturer and User Facility Device Experience database search for the time period of January 1, 1990 to August 28, 2017 contained only 1 unverified

Table 1
Reported fractures of S-ROM stems in literature.

Author	Stem (mm)	Neck (mm)	Sleeve (mm)	Head (mm)	Cup (mm)	Liner	Reason for failure	Location	Age at DOS	Weight	BMI	Years to failure	Corrosion
Current study	14 × 9 × 130	36 STD	14D Large	36 + 0 Biolox	54 Pinnacle	Polyethylene	Fatigue	Stem-sleeve	52	84	30.6	3	Moderate
Parisi et al. [8]	16 × 11 × 150	36 + 6	16B Large ZTT	36 + 6 Co-Cr	56 Pinnacle	Metal	Fatigue	Stem-sleeve	50	109	32.5	7	Macroscopic
Mehran et al. [9]	18 × 13 × 160	36 + 8L	18F Large ZTT	n/a	54 Howmedica	Polyethylene	Fatigue	Stem-sleeve	61	n/a	n/a	9	n/a
Waly et al. [10]	14 × 9	36 STD	14B	28 ceramic	48 Pinnacle	Ceramic	Fatigue	Stem-sleeve	64	70	28	7	Large corrosion pit
Shah et al. [7]	13	STD	n/a	36 Oxinium		Polyethylene	Fatigue	Stem-sleeve	77	n/a	34	10	n/a
Patel et al. [11]	20 × 15	36 + 8L	20B Large ZTT	n/a	60	n/a	n/a	Stem-sleeve	55	n/a	n/a	<1	n/a
Patel et al. [11]	18 × 13	36 + 8L	18B Large ZTT 28 + 0 ceramic	28 + 0	50 Duraloc	Polyethylene	n/a		54	n/a	n/a	5	n/a
Huot Carlson et al. [18]	11.6[a]	n/a	n/a	n/a	n/a	n/a	Fatigue	Stem-sleeve	62	n/a	31.6[a]	14	Severe
Huot Carlson et al. [18]	11.6[a]	n/a	n/a	n/a	n/a	n/a	Fatigue	Stem-sleeve	n/a	93	31.6[a]	n/a	Severe
Huot Carlson et al. [18]	11.6[a]	n/a	n/a	n/a	n/a	n/a	Fatigue	Stem-sleeve	n/a	n/a	31.6[a]	13	Severe
Huot Carlson et al. [18]	11.6[a]	n/a	n/a	n/a	n/a	n/a	Fatigue	Stem-sleeve	68	68	31.6[a]	4	Severe
Huot Carlson et al. [18]	11.6[a]	n/a	n/a	n/a	n/a	n/a	Fatigue	Stem-sleeve	60	79	31.6[a]	4	Severe
Huot Carlson et al. [18]	11.6[a]	n/a	n/a	n/a	n/a	n/a	Fatigue	Stem-sleeve	71	n/a	31.6[a]	15	Severe
Huot Carlson et al. [18]	11.6[a]	n/a	n/a	n/a	n/a	n/a	Fatigue	Stem-sleeve	69	128	31.6[a]	5	Severe

STD, standard; DOS, date of surgery.
[a] Values for all 7 cases reported by Huot Carlson et al. [7-11,18].

report of a fractured S-ROM stem in 2014. In our case, biomechanical surface analysis showed damage patterns consistent with fatigue fracture due to cyclic loading rather than significant corrosion and fretting.

Bending stress on the femoral component can be derived from the Euler-Bernoulli beam theory. Carlson et al. proposed an approach with

$$\sigma = \frac{M\gamma}{I} - \frac{F}{A} = \left(\frac{4FO}{\pi R^3} - \frac{F}{\pi R^2}\right) \tag{1}$$

where R is the radius, M is the moment, γ is the distance from the neutral axis, I is the area moment of inertia, F is the force through the hip joint, O is the offset and A is the section area [18]. This mathematical equation supports the clinical findings reported by Huot Carlson et al. [18] where the stem diameter was smaller ($P = .047$) and the offset higher ($P = .009$) for 7 fractured compared to 71 nonfractured, revised stems.

Modular hip designs have a known point of weakness at the modular- or sleeve-junction interface. Corrosion, fretting, and particulate debris have been observed at this junctional interface [19,20] and most fractures occur in this region [21]. The Emperion stem was taken off the market, leaving S-ROM the only modular proximal ingrowth stem design available. The titanium surface of the stem has a higher resistance to corrosion than cobalt-chromium-molybdenum [19]. Incomplete contact between male and female component interface promoted corrosion and fretting at the stem-sleeve junction in 88% and 65% of the stems, respectively [18,22]. The extent of corrosion was not related to anatomic or demographic pattern but to surgeon-determined activity levels [18]. Corrosion might reduce the area of inertia that ultimately weakens the stem's fracture resistance (Eq. 1) [10,18]. However, in line with almost all reported failures, our surface analysis showed damage patterns consistent with fatigue fracture due to cyclic loading rather than significant corrosion and fretting as the underlying cause of failure [8-10,18].

All cases share a similar site of the fracture at about 5-10 mm into the sleeve. This is in line with biomechanical testing that showed that fractures typically occurred within 5 mm of the stem-sleeve interface [11]. In the S-ROM design, the sleeve achieves fixation through bony ongrowth producing peak bending forces and lever arm concentrated at the level of the stem-sleeve interface and both S-ROM and Emperion stem fractures tend to occur proximal of the sleeve [7,23].

The cumulative bending loads are influenced by body weight, activity level, and offset (Eq. 1). The combination of offset and stem

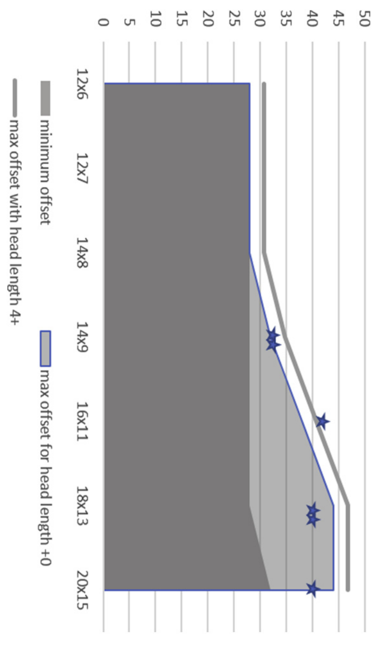


Figure 4. Maximum offset in mm (y axis) available for each stem size (x axis). Stars mark offset-stem-size combination of fractured implants. The affected combinations rather had a high offset.

diameter mainly influences the fracture resistance of the implant. Figure 4 displays the relations between stem size and offset for the reported fractured implants. The maximum offset available for the S-ROM system increases with increasing stem diameter. Most fractured implants had a high offset in relation to the available offset range for each stem size.

Summary

The present study reports a rare but recurrent fatigue fracture mechanism in the S-ROM Modular Hip System. Small stem diameter, high offset, high activity level, and corrosion and fretting seem to increase the risk of fracture. Cold welding and distal bony ongrowth can complicate implant removal. The S-ROM System is a reliable option in primary and revision THA; however, the surgeon should be aware of this rare complication and possible difficulties during implant removal.

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