Arthroplasty Today xxx (2016) 1–6

Contents lists available at ScienceDirect

Arthroplasty Today

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

Case report

Early fracture of the modular neck of a MODULUS femoral stem

Katsufumi Uchiyama, MD, PhD [a, *], Takeaki Yamamoto, MD, PhD [a], Mitsutoshi Moriya, MD [a], Kensuke Fukushima, MD [a], Yojiro Minegishi, MD [a], Naonobu Takahira, MD, PhD [b], Masashi Takaso, MD, PhD [a]

[a] Department of Orthopaedic Surgery, School of Medicine, Kitasato University, Sagamihara, Kanagawa, Japan
[b] School of Allied Health Sciences, Kitasato University, Sagamihara, Kanagawa, Japan

A R T I C L E I N F O

Article history:
Received 27 July 2016
Received in revised form
7 September 2016
Accepted 9 September 2016
Available online xxx

Keywords:
Cementless
MODULUS stem
Total hip arthroplasty
Scanning electron microscopy
Finite element analysis

A B S T R A C T

We present the case of a 46-year-old woman who underwent revision surgery approximately 4 years after total hip arthroplasty because of a fracture of the modular neck of a MODULUS femoral stem. The fractured surfaces of the retrieved implant were inspected using optical and scanning electron microscopy. Three-dimensional finite element analysis was also performed to identify the stresses that might have caused the failure. We concluded that active, obese patients who are implanted with a high-offset, small-sized modular component could experience stress-induced fractures of the modular neck, with proper fixation and osseointegration of the distal stem, especially if residual bone or tissue is present on the inner surface of the neck that could contribute to micromovement and decreased proximal fixation.

Introduction

Over the past few decades, the use of modular femoral stems for total hip arthroplasty (THA) has substantially increased. However, the use of modular necks in standard primary stems has been a subject of study due to reports of fretting and corrosion failures at the modular junction [1-8]. Here, we report a fracture in the modular neck of a MODULUS (Lima Corporate, Villanova di San Daniele del Friuli, Italy) femoral stem in an obese and active patient.

Case history

The patient provided informed consent for the publication of this case study. We performed left-sided THA for advanced secondary osteoarthritis with acetabular dysplasia in a 42-year-old woman, during which we implanted a 14-mm-diameter MODULUS distal femoral stem (titanium Ti6Al4V alloy), a 125° high-offset (long type) small-sized modular neck (an A taper, to be used with stems sized 13-15 mm; titanium Ti6Al4V alloy), and a 32-mm Biolox forte ceramic head (32/0 mm) in the femur (Lima Corporate, Villanova di San Daniele del Friuli, Italy), and a 50-mm Mallory-head radial acetabular cup component (BIOMET, Warsaw, IN).

At the time of surgery, the patient was an active nurse (height, 1.47 m; weight, 70.8 kg; body mass index [BMI], 32.8 kg/m^2). Ten months following implantation, radiography revealed osteolysis around the modular neck component and cortical hypertrophy of the distal femur. One year and 3 months after implantation, radiographic examination demonstrated the progression of osteolysis and cortical hypertrophy. Three years and 2 months after the left-sided THA, the patient underwent a right-sided THA for advanced secondary osteoarthritis with acetabular dysplasia. The procedure was performed by the same surgeon at the same institute.

Three years and 8 months following the left-sided THA, the patient reported sudden-onset groin pain on the left side while helping a heavy patient out of bed and experienced immediate loss of weight-bearing ability. Radiography revealed a fracture of the modular neck component of the MODULUS (Lima Corporate, Villanova di San Daniele del Friuli, Italy) stem (Fig. 1). Revision surgery was performed using an anterolateral approach with the patient in the right lateral decubitus position. The hip was dislocated anteriorly and the fractured modular neck component was removed (Fig. 2; white arrow). The safety locking screw securing

No author associated with this paper has disclosed any potential or pertinent conflicts which may be perceived to have impending conflict with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.artd.2016.09.004.
* Corresponding author. 1-15-1 Kitasato, Minami-ku, Sagamihara, Kanagawa 252-0374, Japan. Tel.: +81-42-778-8111.
E-mail address: katsufu@cf6.so-net.ne.jp

http://dx.doi.org/10.1016/j.artd.2016.09.004

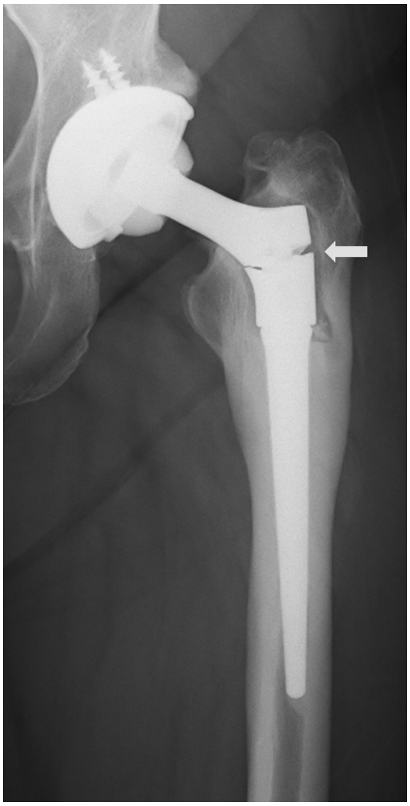

Figure 1. Radiographic examination of the patient's left total hip arthroplasty at 3 years and 8 months postoperatively showing a fracture of the modular neck component.

the 2 modular components was also broken. We could only remove the distal fragment of the screw, which remained within the stem, by turning it with a small flat chisel (Fig. 2; black arrow). An extended trochanteric osteotomy was performed to remove the remnant of the fractured modular neck, which was still coupled to the stem (Fig. 2; gray arrow), by hammering from the bottom rim of the component. Because the surface at the stem taper junction appeared to be scratched (Fig. 3), the surgeon attempted to replace the distal stem, but it was not possible without risking extensive damage to the bone. Leaving the distal stem in situ, the modular neck was replaced with a new 135° standard-offset modular neck

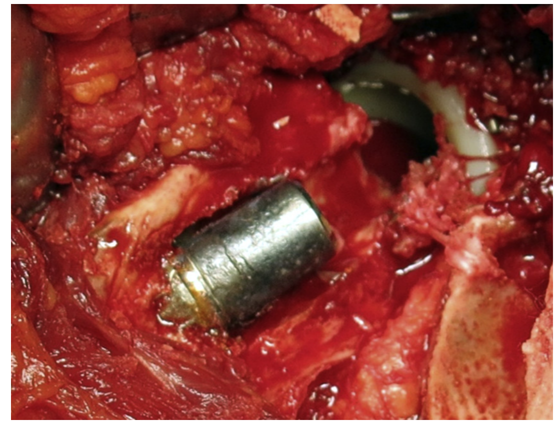

Figure 3. Intraoperative picture of the tapered portion of the proximal stem with evidence of scalloping and pitting.

and a Delta ceramic head (32/0 mm). The greater trochanter was then reattached using a pin-sleeve system (AI-medic, Tokyo, Japan) [9] and ultra-high-molecular-weight polyethylene fiber cable (although the fiber cable is not observable on the radiographic images; NESPLON Cable System; Alfresa Pharma Co., Osaka, Japan) [10]. The properly fixed, cementless acetabular cup was preserved along with its highly cross-linked polyethylene liner (Fig. 4). One year postoperatively, the patient's pain resolved and she was able to return to work without using a walking aid.

We requested that the manufacturer investigate the cause of the component fracture, and Lima Corporate agreed to provide the information reported in this study without any conflicts of interest.

Fracture rate of the MODULUS femoral stem—Lima Corporate postmarket surveillance data

The clinical and mechanical safety of the MODULUS system is confirmed by the low in vivo breakage rate associated with the implant; the total breakage rate, according to the company's post-market surveillance data, is 0.084%, which includes all reported breakages that occurred between November 2001 and November 2015 (13 breakages in a total of 15,444 MODULUS prostheses implanted worldwide). The patient's BMI was known in 11 of the 13 breakages. The average BMI was 31.72 kg/m^2 and was <25 kg/m^2 in only 2 cases. The breakage rate specifically related to modular neck of the MODULUS is significantly lower, with the breakage reported

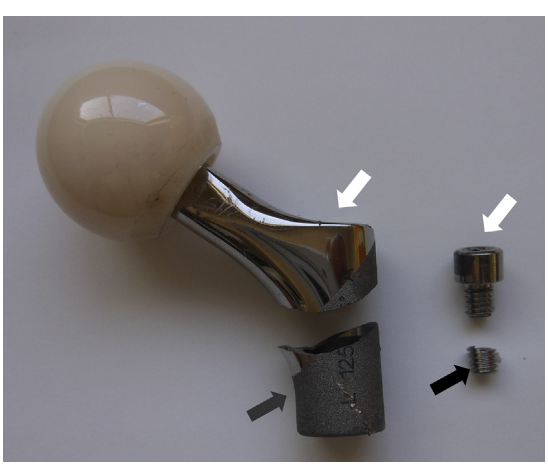

Figure 2. Picture of the broken components after retrieval.

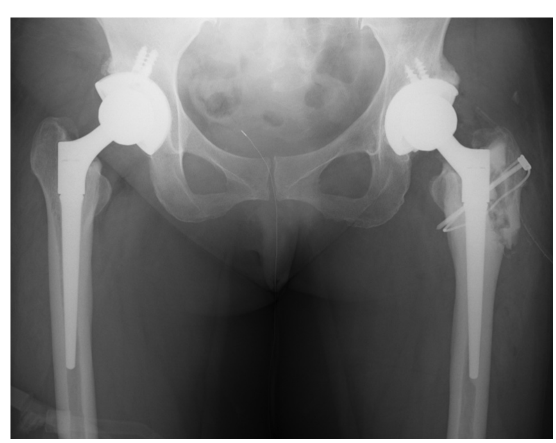

Figure 4. Immediate postoperative radiographic control image after revision of the broken components.

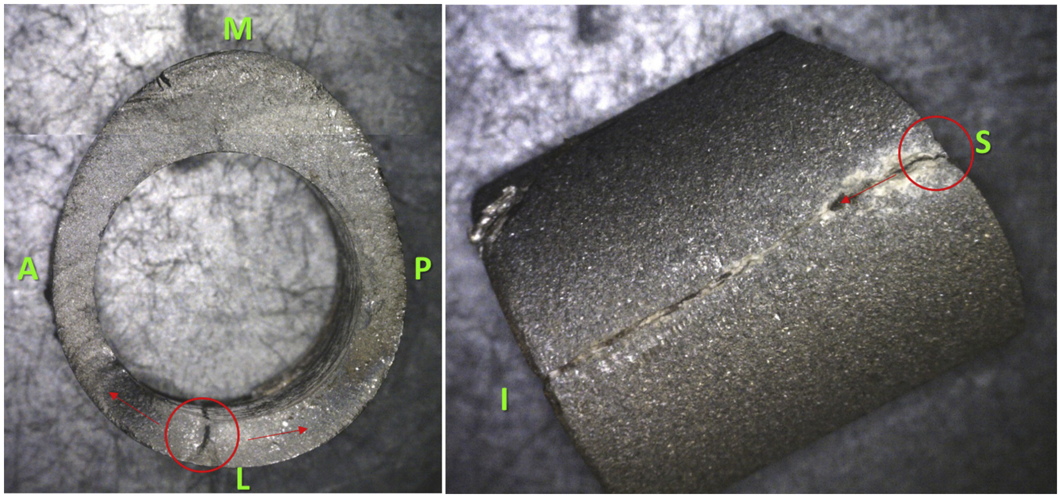

Figure 5. Pictures of the neck fracture surfaces (left: inferior fragment from the top; right: inferior fragment from the side). We identified the anterior, medial, posterior, and lateral zones of the neck with the letters A, M, P, and L, respectively. The letters I and S denote the inferior and superior parts of the neck fragments, respectively.

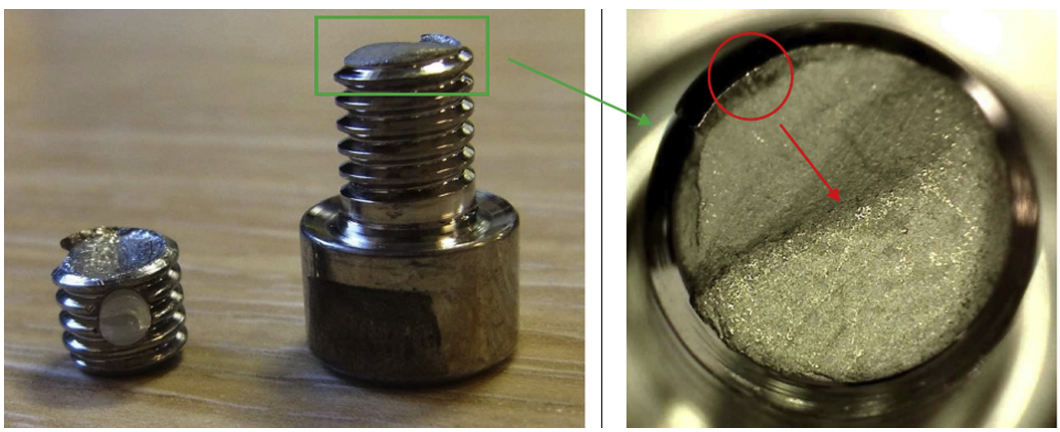

Figure 6. Broken screw (right: fracture surface of the superior screw fragment).

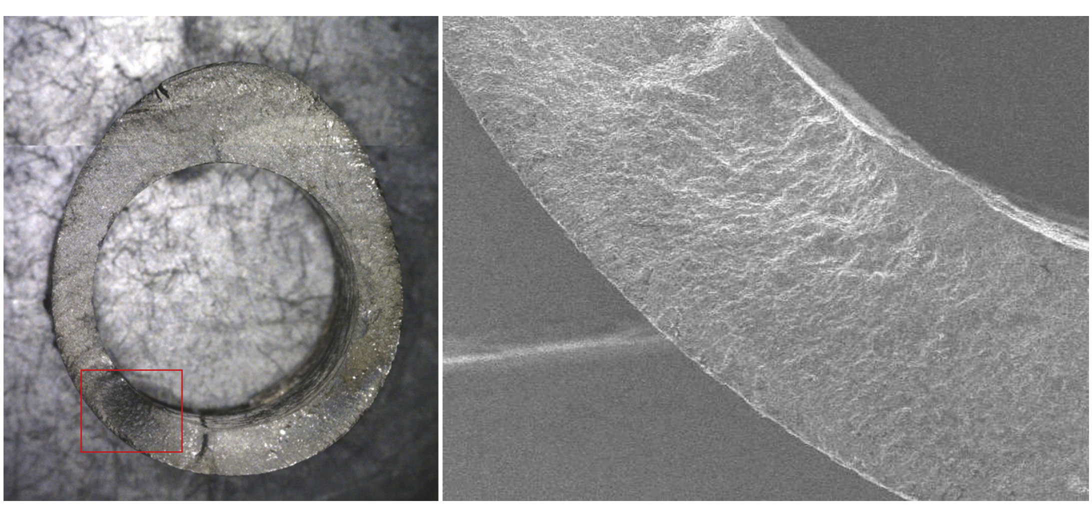

Figure 7. SEM analysis of the fractured surfaces of the neck.

Please cite this article in press as: K. Uchiyama, et al., Early fracture of the modular neck of a MODULUS femoral stem, Arthroplasty Today (2016), http://dx.doi.org/10.1016/j.artd.2016.09.004

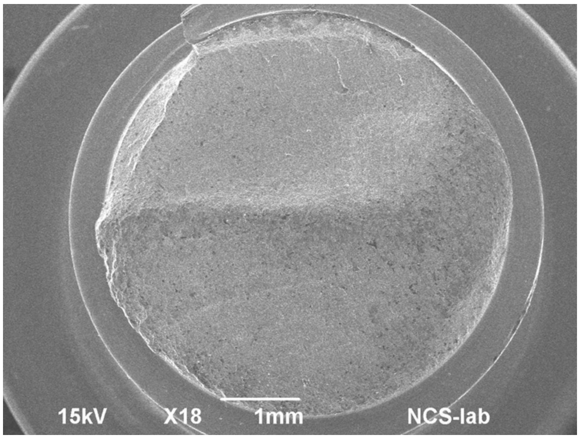

Figure 8. SEM analysis of the fractured surfaces of the screw.

in this paper being the first example (0.006%; 1 breakage in a total of 15,444 MODULUS prostheses implanted).

Scanning electron microscopy

The fractured surfaces of the retrieved implant were inspected by optical and scanning electron microscopy (SEM) by Lima Corporate (Fig. 5). The neck fracture occurred where the small diameter of the male taper of the stem engaged the neck component. The crack originated in the lateral part of the neck (red circle) and propagated medially (red arrows). Figure 5 also shows the crack propagation along the inferior fragment of the neck. It was reported that this crack occurred in vivo and was not caused by the removal of the neck during revision surgery. Figure 6 (left) shows that the screw broke close to the minor cross-section at the level of the poly pin. The origin and propagation of the fracture are highlighted by a red circle and a red arrow, respectively (Fig. 6). SEM analysis of the retrieved broken components revealed that the system formed by the MODULUS neck and the locking screw experienced a double fatigue rupture. (1) The neck experienced a bending fatigue failure induced by low stresses; breakage occurred at the level of the final threaded part where the screw was inserted. The crack started in the lateral part of the neck and propagated medially (Fig. 7). (2) The screw experienced a bending fatigue failure along the border that was induced by low-level loads, as evidenced by the flat progression and the absence of plastic deformation involving the whole section. The breakage most likely originated from the lateral part of the screw and propagated medially (Fig. 8).

Finite element analysis

Finite element analysis (FEA) was performed by Lima Corporate to assess the geometrics of the broken components. The analyses were performed using three-dimensional models of the system components and the FE software package included in AnSys V11.0. The volume mesh used was composed of 2-mm tetrahedral elements with intermediate nodes. To obtain more precise results, mesh modeling was densified to 1 mm at the taper region. The testing conditions were the same as those described in ISO 7206-4 and ISO 7206-8. The stem axis was tilted 9° in the anteroposterior plane and 10° in the medial-lateral plane with respect to the applied load. Safety loads for the stem size were evaluated by stress level comparisons; after the mechanical test was completed, the stress distribution was calculated by FEA at survival loads. The maximum stresses used were under the safety limit of the material being studied. Finite element method simulations for small stem sizes (13 and 15 mm) were performed to define the load levels that produced that stress distribution on the bodies.

Both analyses described above demonstrated that a stress level above the maximum was required in order for the lateral side of the neck to be affected, as shown by the red arrows (Figs. 9 and 10). This region matched the origin of the fracture in the actual neck.

Discussion

Benazzo et al. [11] reported good long-term results with the MODULUS modular cementless system for the treatment of hip dysplasia. The authors raised concerns regarding the possibility of

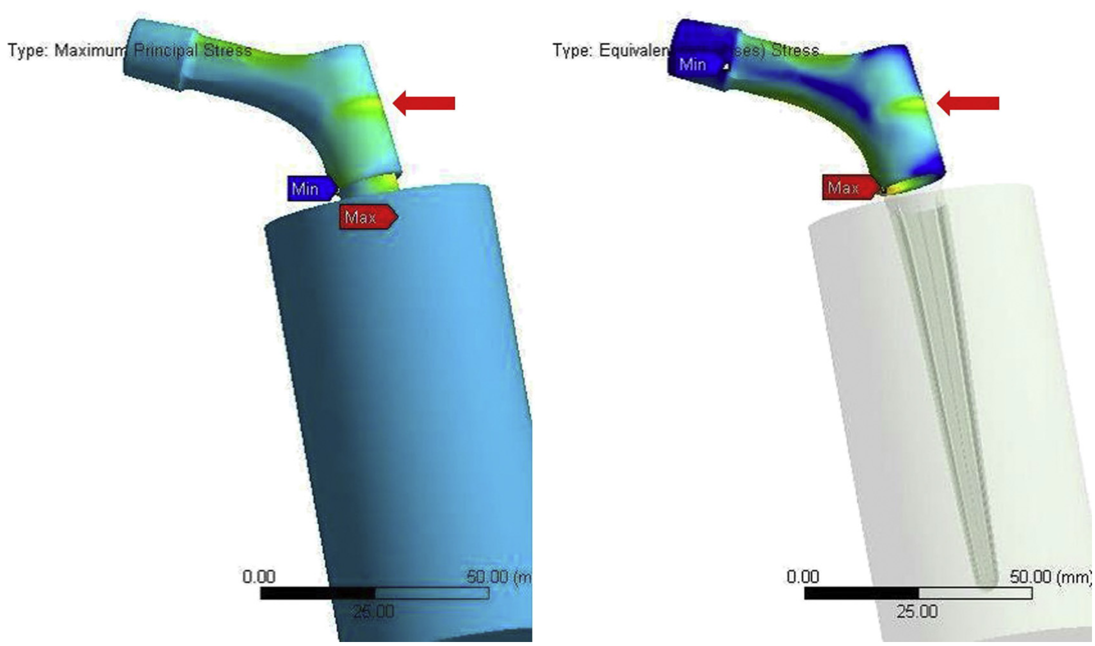

Figure 9. FEA of the involved components showing the stress distribution for a 13-mm neck and a 125° stem at 2400 N.

Please cite this article in press as: K. Uchiyama, et al., Early fracture of the modular neck of a MODULUS femoral stem, Arthroplasty Today (2016), http://dx.doi.org/10.1016/j.artd.2016.09.004

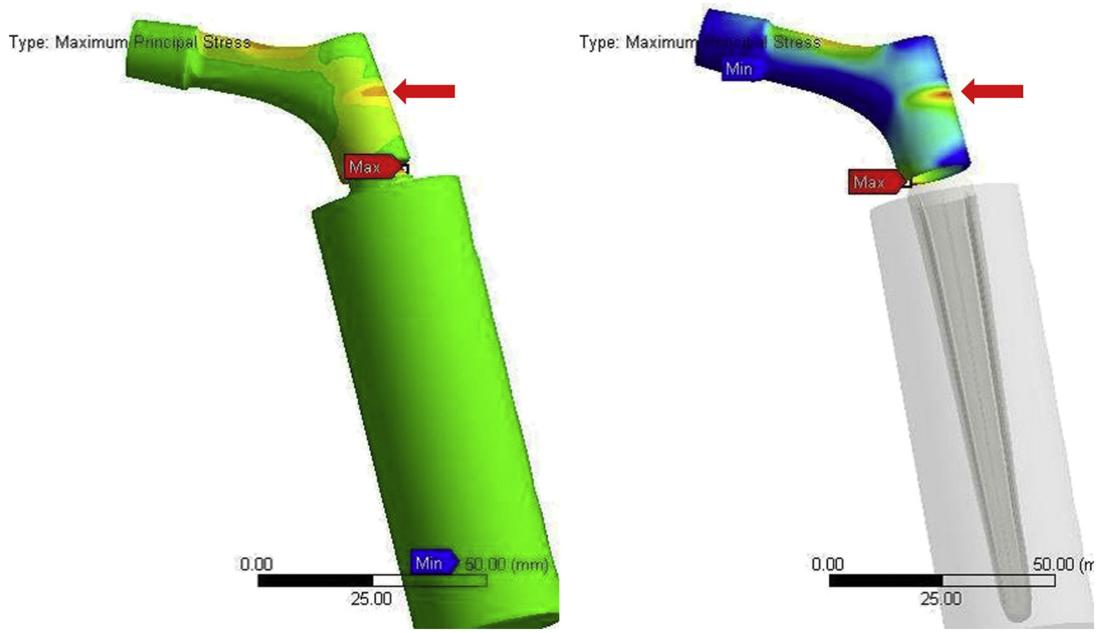

Figure 10. FEA of the involved components showing the stress distribution for a 15-mm neck and a 125° stem at 2600 N.

fretting of the modular surfaces, the sequelae of wear debris, and possible failure and fracture of the stem at the modular junction. However, fractures of femoral components are rare in THA with the MODULUS system (fracture incidence, 0.084%), especially when only the modular neck is considered (fracture incidence, 0.006%).

SEM revealed weakening of the implant and increased susceptibility to cyclic fatigue fractures. Clear signs of these processes were present in some areas of both the neck (the inner surface along the propagation of the crack, together with rough bone/tissue residuals) and the locking screw (both the head and the threaded section). Relative in vivo micromovements between the neck and the stem, favored by the presence of bone/tissue residuals on the inner surface of the neck [12], could have significantly contributed to the breakage of the prosthesis in this case.

In the present case, proximal osteolysis appeared around the proximal stem while the distal stem remained properly fixed and osseointegrated. It is likely that the lack of bony support proximally, in addition to distal fixation, played a causal role in the eventual breakage. This mechanism is in line with the findings of FEA. Computational reproduction of the initial crack propagation demonstrated that higher than expected stress concentrations are possible and can affect the relevant components, leading to breakage in the same region and with the same path as the retrieved components.

Neck fracture may be caused by material factors, including patient- or surgeon-selected stem designs. Wilson et al. [5] suggested that the risk factors for neck fracture include long modular stems, especially in heavier patients. Wodecki et al. [1] showed that small femoral stems are also associated with a risk of fracture of the female part of the stem where the modular neck is inserted. The authors concluded that care should be taken when long varus necks are present, as they are usually the indication for the use of modular necks.

Although stem and/or neck fractures are rare, they necessitate early, additional, and unexpected surgery if they occur. If the surgeon has the opportunity to choose the type and model of the implant, he/she is responsible for selecting the appropriate implant according to not only the patient anatomy but also the patient's physique and physical activity level. Moreover, the selection of different parameters within the same system, like high offsets and small implants, is a risk factor for fracture in heavy and very active patients.

Summary

In conclusion, the case reported in this article represents a special situation of concentrated stress on the modular neck with only the distal stem remaining properly fixed and osseointegrated following the fracture of a MODULUS component. Surgeons should consider the potential pitfalls of a surgical technique that requires assembly of the prosthesis within the femoral canal and the potential consequences of debris contamination of the Morse taper assembly. We believe that the cause of the breakage was a lack of bony support proximally, in addition to the use of distal fixation. Moreover, our findings suggest that active and obese patients implanted with high-offset, small modular components are at increased risk of experiencing stress-induced fractures of the proximal component. This report demonstrates the importance of cooperation between surgeons and manufacturers in the investigation of the causes and effects of such adverse events, in order to reduce the incidence of such events in patients undergoing THA.

Acknowledgments

I would like to express my deepest gratitude to Mr. Luca Giorgini and Mr. Matteo Boccalon of Lima Corporate who provided helpful comments and suggestions. I would also like to thank Mr. Naoto Uno and Mr. Junichi Hamanaka of Lima Corporate who offered continuing support and constant encouragement.

References

[1] Wodecki P, Sabbah D, Kermarrec G, Semaan I. New type of hip arthroplasty failure related to modular femoral components: breakage at the neck-stem junction. Orthop Traumatol Surg Res 2013;99:741–4.
[2] Mehran N, North T, Laker M. Failure of a modular hip implant at the stem-sleeve interface. Orthopedics 2013;36:e978–81.

[3] Lakstein D, Eliaz N, Levi O, Backstein D, Kosashvili Y, Safir O, et al. Fracture of cementless femoral stems at the mid-stem junction in modular revision hip arthroplasty systems. J Bone Joint Surg Am 2011;93:57–65.
[4] Wright G, Sporer S, Urban R, Jacobs J. Fracture of a modular femoral neck after total hip arthroplasty: a case report. J Bone Joint Surg Am 2010;92:1518–21.
[5] Wilson DA, Dunbar MJ, Amirault JD, Farhat Z. Early failure of a modular femoral neck total hip arthroplasty component: a case report. J Bone Joint Surg Am 2010;92:1514–7.
[6] Grupp TM, Weik T, Bloemer W, Knaebel HP. Modular titanium alloy neck adapter failures in hip replacement—failure mode analysis and influence of implant material. BMC Musculoskelet Disord 2010;11:3.
[7] Atwood SA, Patten EW, Bozic KJ, Pruitt LA, Ries MD. Corrosion-induced fracture of a double-modular hip prosthesis: a case report. J Bone Joint Surg Am 2010;92:1522–5.
[8] Briant-Evans TW, Norton MR, Fern ED. Fractures of Corin 'Taper-Fit' CDH stems used in 'cement-in-cement' revision total hip replacement. J Bone Joint Surg Br 2007;89:393–5.
[9] Takahira N, Itoman M, Uchiyama K, Takasaki S, Fukushima K. Reattachment of the greater trochanter in total hip arthroplasty: the pin-sleeve system compared with the Dall-Miles cable grip system. Int Orthop 2010;34:793–7.
[10] Oe K, Jingushi S, Iida H, Tomita N. Evaluation of the clinical performance of ultrahigh molecular weight polyethylene fiber cable using a dog osteosynthesis model. Biomed Mater Eng 2013;23:329–38.
[11] Benazzo FM, Piovani L, Combi A, Perticarini L. MODULUS stem for developmental hip dysplasia: long-term follow-up. J Arthroplasty 2015;30:1747–51.
[12] Jauch SY, Huber G, Hoenig E, Baxmann M, Grupp TM, Morlock MM. Influence of material coupling and assembly condition on the magnitude of micromotion at the stem-neck interface of a modular hip endoprosthesis. J Biomech 2011;44:1747–51.