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Case report

Fracture risk of tapered modular revision stems: a failure analysis

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ABSTRACT

Fractures of well-ingrown femoral components are a rare and often challenging complication after revision total hip arthroplasty. Prior series have documented catastrophic failure at the modular junction of revision femoral components. However, to the authors' knowledge, there has been only 1 report of a mid-stem fracture of a modular tapered revision stem. The present article reports 2 cases of fatigue fractures (14 months and 10 years after implantation) of a tapered modular revision stem. It presents the results of the fracture surface analysis, discusses the etiology of failure, and presents the authors' recommendations on how to best avoid this complication.

Introduction

Femoral component fracture is a rare complication in revision total hip arthroplasty (THA) [1]. It occurs most commonly in uncemented distally fixed revision stems [2,3]. Risk factors for this complication include high body mass index (BMI), increased activity level, small intramedullary canal diameter, and severe bone loss with a lack of proximal medial support [3-6]. The most commonly reported location of implant fractures in modular revision implants is at the junction of the body and stem, which presents a point of weakness [3,7]. However, fracture at a more distal location makes implant removal of the distal stem more challenging [8]. In this situation, often an extensile approach combined with a trochanteric osteotomy is necessary, and there is a risk of further violation of the already compromised bone stock. The present article reports 2 patients with a distal-stem fracture of a modular tapered revision stem (Restoration Modular Revision Hip System, Stryker Orthopaedics, Mahwah, NJ). It presents the results of the fracture surface analysis, discusses the failure mechanism, and provides recommendations on how to avoid this complication.

Case histories

Case 1

The first patient underwent primary THA for osteoarthritis of the right hip in April 2001. In November 2015, he was hit by a car and suffered a Vancouver B2 periprosthetic fracture of the right femur (Fig. 1a). At that time, the now 75-year-old male had a height of 182 cm, weight of 95 kg, (BMI of 28.5 kg/m^2). After removal of the loose femoral implant at the time of revision surgery, the hip was reconstructed using a 14 × 195 bowed tapered stem and size 23 × 70 + 0 Standard Cone Body Restoration Modular Hip System (Stryker Corporation, Kalamazoo, MI). The well-fixed 60-mm Reflection acetabular component (Smith & Nephew Inc., Memphis, TN) was retained and a new 36 mm Reflection liner (Smith & Nephew Inc.) was inserted. The construct was further stabilized with 7 Dall-Miles cables (Stryker Corporation) and 30 mL of Orthovita cancellous chips (Stryker Corporation), as well as 60 cc of fresh frozen cancellous chips were used as bone graft (Fig. 1b). All intraoperative cultures returned negative.

Initial 4 weeks follow-up radiographs showed a reduced periprosthetic fracture. Despite weight-bearing restrictions, the patient

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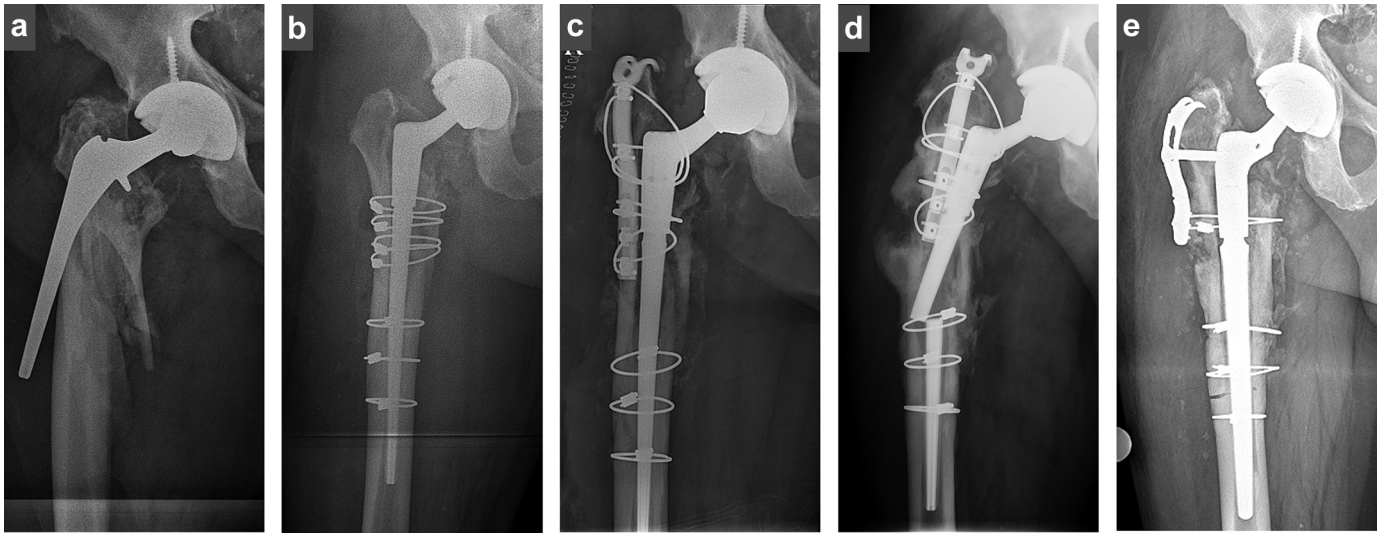

Figure 1. Radiologic images case 1. (a) Periprosthetic fracture Vancouver B2, (b) 4-week follow-up image after revision surgery, (c) After secondary displacement of the trochanteric fragment, revision surgery with a 125-mm trochanteric claw plate (d) Fracture of the distal stem 14 months after original revision (e) Reconstruction with a tapered revision stem and a trochanteric claw plate.

returned to early full weight-bearing 5 weeks after surgery. This resulted in a symptomatic displacement of the proximal fracture segment. A second revision surgery was therefore performed in January 2016, during which the proximal fragment was reduced and secured with a 125-mm Accord Standard Trochanteric Claw Plate (Smith & Nephew Inc.). Orthovita cancellous chips and 60 cc of fresh frozen cancellous chips were used to augment bone healing (Fig. 1c). Postoperatively, he recovered uneventfully and was eventually progressed to full weight-bearing, which he tolerated well. In March of 2017, he suffered a sudden pain in his right thigh while ambulating without a history of trauma. Radiographic evaluation at that time demonstrated a fracture through the mid-portion of the tapered stem, with associated displacement of the proximal femur (Fig. 1d).

The distal part of the fractured stem measured 121.5 mm (Fig. 1d). An extended trochanteric osteotomy was performed, extending 20 mm beyond the broken stem to gain access to the distal stem. The stem was loosened using a gigli saw, trephine reamers, a needle-tip MIDAS burr, and K-wires inserted in between the splines of the stem. Using a diamond-tip drill, a hole was drilled in the lateral aspect of stem to facilitate the stem removal using the hook of the S-ROM Extraction instrument (DePuy Synthes, Warsaw, IN). The defect was reconstructed using a bowed tapered 18 × 190 mm modular stem (Arcos Modular Femoral Revision System; Zimmer Biomet Inc., Warsaw, IN) and a 17-mm cone body. After reduction and fixation of the osteotomy fragment with 2 Dall-Miles cables, the trochanteric segment was reduced and fixed with a 100-mm trochanteric claw plate that was bolted to the body with a 50-mm screw (Fig. 1e). The patient was mobilized toe-touch weight-bearing with abductor precautions for 12 weeks postoperatively.

Implant analysis

The fracture surface analysis was performed using a Keyence Digital Microscope VHX-5000 series (Keyence Corporation of America, Itasca, IL) at 10× and 15× magnification (Fig. 2).

The fracture occurred at 121.5 mm measured from the tip of the stem (Fig. 2a). The inner diameter at the fracture site was 10.7 mm, and the outer diameter was 14.1 mm including the splines. The cross-sectional area at the fracture side was 90 mm^2 compared with 143 mm^2 for a reference 13.5-mm inner diameter (Formula 1). 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. The clamshell marks span 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 lateral 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 and a final fracture on the medial edge (Fig. 3).

$$D' = D + \tan(3^{\circ}) * (L - 120\ mm) \quad (1)$$

D, stated stem diameter; D′, actual diameter at distance (L) from the stem tip.

Case 2

A 55-year-old male with a height of 180 cm, weight of 91 kg, (BMI of 28.2 kg/m2), and no history of metabolic bone disease, underwent primary THA for osteoarthritis of the left hip in 2005. In 2007, he suffered stem fracture, which required an osteotomy and left hip revision using a 15 mm × 155 mm straight tapered Restoration Modular Hip stem, a 25 × 70 mm + 0 standard cone body (Stryker Corporation), and a claw plate. A second revision was performed in 2013 to remove the trochanteric plate at an outside institution.

The patient presented in July 2017, reporting 2-3 months of left hip pain. Radiographs demonstrated loosening of the proximal and mid-stem portion of the femoral component with a fracture of the distal aspect of the stem (Fig. 4a and b).

The distal stem was removed using an extended trochanteric osteotomy. The revision was performed using a 21 × 195 mm Restoration Modular straight tapered stem (Stryker Corporation) and a 25 × 70 mm + 0 standard cone body. The osteotomy fragment was reduced and fixed in place with 4 Dall-Miles cables (Fig. 4c).

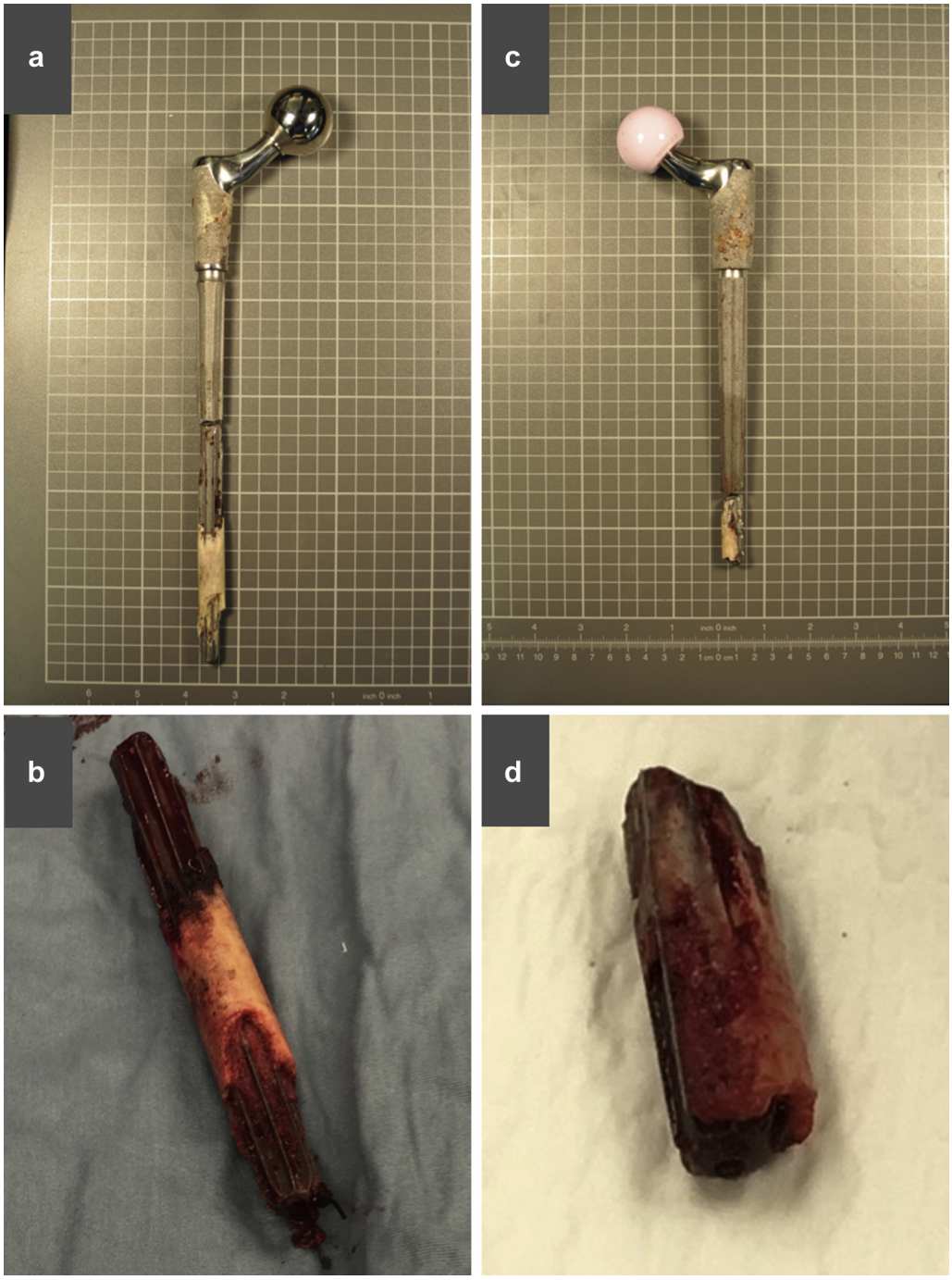

Figure 2. Macroscopic photographs of the fractured Restoration Modular Revision Hip System: (a, b) is case 1. (c, d) is case 2.

The patient was mobilized partial weight-bearing with abductor precautions for 12 weeks.

Implant analysis

The fracture occurred at 37.0 mm measured from the tip of the stem. The inner diameter at the fracture location was 9.0 mm, and the outer diameter was 12.2 mm (Fig. 2c). The inner cross-sectional area was 63 mm^2 compared with 143 mm^2 for a 13.5 mm inner diameter (Formula 1). Analysis of the fracture surface was not possible because the damage of the fracture surfaces incurred while the patient continued to ambulate with the fractured stem in place (Fig. 2d).

Discussion

The present article reports the first 2 reported cases of a fatigue fracture of a tapered Restoration Modular revision stem. Fracture of femoral components was a major complication in early stem designs, with a prevalence of up to 6% [9]. Technological progress decreased the occurrence of femoral fractures significantly. However, the prevalence may increase in complex revision situations (0.8%-2.3%) [2,10-12]. Revision modular tapered stems have a known point of weakness at the modular interfaces [3,4,7]. Corrosion, fretting, and particulate debris have been observed at this spot [7,13], and most stem fractures occur in this region [14].

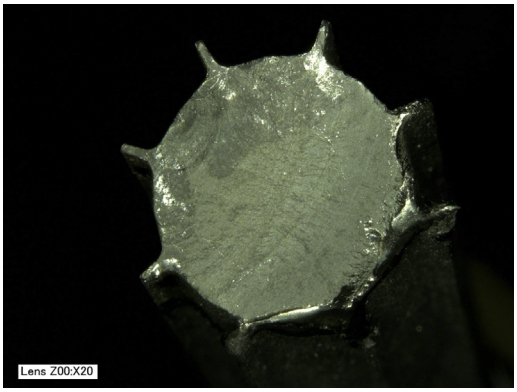

Figure 3. Microscopic imaging of the fracture surface. The clamshell markings showed a lateral origin and were consistent with fatigue fracture due to cyclic loading. The marks showed propagation through the cross-section of the stem from 11 to 5 o'clock.

However, reports describing fractures through the mid-stem portion of a modern tapered stem are rare [5,11]. To the best of our knowledge, only 1 other report of a distal fracture of a comparable tapered stem in a modular revision system (MP Reconstruction Hip Stem; Waldemar Link GmbH & Co. KG, Hamburg, Germany) exists [8].

The search for reported events for the Restoration hip system in the US Food and Drug Administration's Manufacturer and User Facility Device Experience database revealed 12 more entries citing a stem fracture event. However, there is only 1 other report that specifically named a fracture in the distal portion of the stem (Table 1). Most reports lacked detailed information about the distance of the fracture from the tip of the implant as well as the implant diameter at the fracture site (Table 1).

Reasons for failure

The reasons for fracture within the diaphyseal region of the stem are most likely multifactorial. Risk factors include elevated BMI, high activity level, small medullary canal diameter, severe bone loss, and lack of medial bone support [3-6]. Surgeons seem to adapt stem size to gender, age, and height but not to body weight [15]. Prior reports of monoblock revision stem failures most commonly describe fractures through stems with an outer diameter of <14 mm. In a consecutive series of 100 patients implanted with diaphyseal engaging revision stems, Carrera et al [10] reported 2 fractures, both at a stem diameter of 12 mm. Both were successfully revised with stems of 14 and 16 mm diameters. Landa et al [11] reported 3 cases of fractured uncemented, fully porous-coated Echelon femoral revision stems (Smith & Nephew Inc.) with 13, 14, and 15 mm diameters, respectively. Sotereanos et al [16] suggest that the primary reason for femoral component failure in primary THA is undersized stem diameter. The stem diameter influences the section modulus, and ultimately the fracture toughness, to the third power (Formula 2). From the biomechanical perspective, undersizing refers to the relation of the stem diameter to the body weight. A sufficient filling ratio is obligatory for uncemented stems. Based on his observations of fractured monoblock stems (Solution [DePuy Synthes] and Echelon stems), Busch et al [2] recommended avoiding stems with diameters <13.5 mm.

Reports of fractured modular revision stem systems are rare. Azzam et al [5] reported a fracture through a 13 × 155 mm Restoration HA (Stryker Corporation) stem after primary THA in a patient with a weight of 300 lb. All 12 reports of fracture of a Restoration stem in the Manufacturer and User Facility Device Experience database report a diameter ≤16 mm (Table 1). The diameter of the fractured tapered modular MP Reconstruction stem, reported by Bicanic et al [8] was not mentioned. The modular revision tapered stems used in the current cases had a diameter of 14 mm and a length of 195 mm with a bowed, tapered design or 15 mm and a length of 195 mm with a straight, tapered design, respectively. While this appears to be more than the recommended 13.5 mm [2], the fracture of the stem occurred at a diameter <11 mm. In addition, both patients had additional risk factors including increased body weight of 95 kg (case 1) and 91 kg (case 2) as well as a physical active level.

The main reason for selecting a tapered stem design is its low subsidence rate and reliable secondary stability attributed to it [17,18]. Higher angles of taper are believed to have advantages in subsidence and secondary stability [17]. Splines should resist rotational forces and improve primary stability for easy bony on-growth. However, the tapered design causes a significant decrease in cross-sectional area distally. In general, the stated stem diameters name the outer diameters of the stem including the

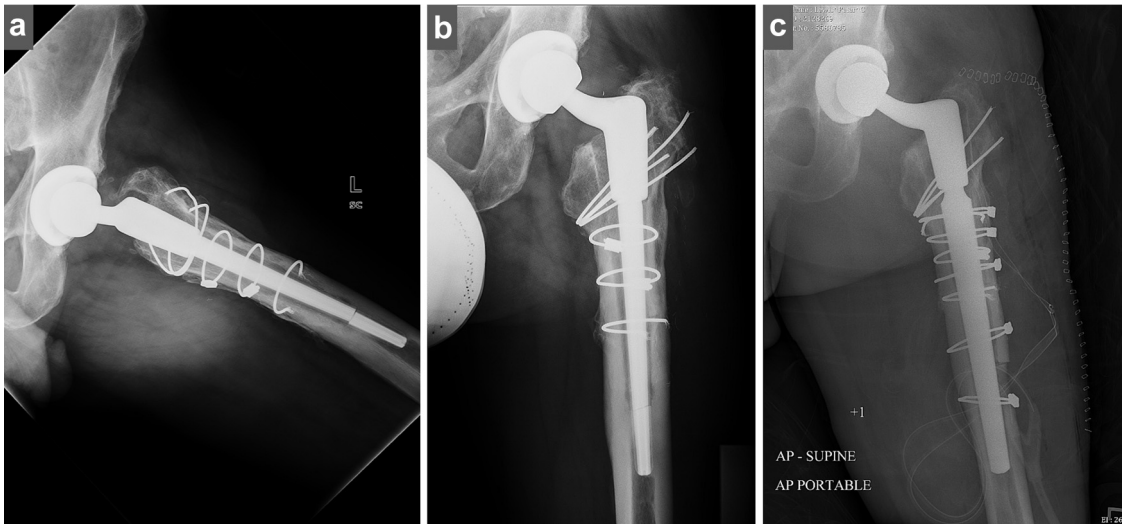

Figure 4. Radiologic images case 2. (a, b) Frog and anteroposterior (AP) view of the left hip 7/2017, demonstrating loosening of the femoral stem with a fracture of the distal aspect of the stem, (c) postoperative AP view of the left hip after surgery.

Table 1
In June 2009, Stryker Howmedica Osteonics Corp, Mahwah, NJ initiated a recall for several Restoration stems due to concerns about raw material quality.

Product number	Stem size [mm]	Stem design		Fracture location (distance from tip)	Fracture confirmed	Date of report
6276-7-015	15 × 155	Conical	Straight	37 mm	Yes, case 2	pending
6276-7-214	14 × 195	Conical	Bowed	122 mm	Yes, case 1	3/22/2017
6276-7-216	16 × 195	Conical	Bowed	n/a	Yes	9/4/2014
6276-7-215	15 × 195	Conical	Bowed	127 mm	Yes	3/14/2016
6276-7-315	15 × 235	Conical	Bowed	n/a	Yes	12/20/2012
n/a	n/a	n/a	n/a	n/a	Yes	5/22/2014
6276-7-316	16 × 235	Conical	Bowed	n/a	Yes	9/20/2013
6276-7-215	15 × 195	Conical	Bowed	n/a	Yes	12/5/2012
6276-5-014	14 × 127	Plasma	Straight	n/a	No	8/6/2012
n/a	n/a	n/a	n/a	Proximal	Yes	7/5/2011
6276-7-317	17 × 235	Conical	Bowed	n/a	Yes	6/1/2011
6276-7-216	16 × 195	Conical	Bowed	n/a	No	5/9/2011
6276-5-416	16 × 217	Plasma	Bowed	n/a	Yes	8/4/2010
n/a	n/a	n/a	n/a	Proximal	No	7/15/2004

The recall (Z-2145-2009 and Z-248-2009) included both stem sizes reported in this article (6276-7-214 and 6276-7-015). However, the specific LOT-numbers (CAXR30AE and CAXF4AP) of the 2 presented cases were not affected.

splines. The actual solid-core diameter is even less. It was already shown that the individual design of the splines has a measurable influence on axial stability with broader splints being superior [17]. The decreasing diameter of the solid core also reduces the stems resistance to repetitive bending forces, further increasing the risk for fatigue fracture (Formula 2). Table 2 shows the effect of stem taper and the resulting diameter for the Restoration stem.

Adjusted recommended stem size

According to the technical guide for the Restoration Modular Revision Hip System (Stryker Corporation), the diameter for all stems is measured 120 mm from the tip. The reported diameters are the outer diameters including the splines. For all stems, the diameter of the solid core tapers by 3 degrees and the splines taper by 2 degrees. This results in an increased difference between the inner core and outer spline diameter towards the tip of the stem. Table 2 displays the actual distance, measured from the stem tip, where different tapered stem sizes reach a recommended inner diameter (excluding the splines) of 13.5 mm. In tapered stems the stem diameter at the level of bony ingrowth is most important when judging resistance to cyclic bending forces.

$$W = \frac{\pi}{32} D'^2 \tag{2}$$

W, section modulus; D′, actual diameter.

Competitive stem designs, for example, Arcos Modular Femoral Revision System and ZMR Revision Hip System (Zimmer Biomet Inc., Warsaw, IN), differ in geometry of the splines, the taper degree, and the level where the outer stem diameter is defined. The diameter of the Arcos STS stem, for example, is measured 102.5 mm (for the 150 mm version) or 142.5 mm (for the 190 mm version) from the tip. Its splines taper between 2.8 and 2.9 degrees (calculated based on the stem dimensional information). For the monoblock Wagner SL Revision Hip Stem (Zimmer Biomet Inc.) the difference between outer diameter and inner core diameter is between 2.0 and 4.0 mm (14-12 mm for a size 14 × 190 mm stem) at the mid-shaft section and between 2 and 5.8 mm (10.37-8.7 mm for a size 14 × 190 mm stem) at the distal section. The geometry of the splines defines the overall cross-sectional area. In general, designs with wider splines and less difference between outer and inner diameter may be more resistant to bending forces.

Both reported cases share a combination of a relatively small inner medullary canal diameter, a high BMI, and increased activity level as well as a lack of medial bone support. Both stems appear to be undersized and further reaming of the femoral canal to fit a bigger stem size could have been possible, additional support by a strut allograft or modification of postoperative activities are additional options in patients with small tapered revision stems [2].

Summary

The stem design, presence of splines, and the overall taper of the stem reduces the effective cross-sectional area and makes tapered modular revision stems more vulnerable to fracture if medial proximal bone support is missing. This article reports on minimal distal bone support required for different stem sizes. Stems with decreased taper angles of their splines compared with the stem with narrow splines might be at an increased risk for fracture.

Table 2
The actual outer diameter including splines at different levels measured from the tip of the stem.

Conical stem size	Diameter at following distances to the stem tip (mm):				Distance to stem tip (mm) where diameter is ≥13.5 mm
	30	60	90	120	
14	9.3	10.9	12.4	14.0	110
15	10.3	11.9	13.4	15.0	91
16	11.3	12.9	14.4	16.0	72
17	12.3	13.9	15.4	17.0	53
18	13.3	14.9	16.4	18.0	34
19	14.3	15.9	17.4	19.0	15
20	15.3	16.9	18.4	20.0	0

Gray shaded fields mark the “safe-zone” of stem diameters of at least 13.5 mm. Calculations were based on the data from the Restoration Modular Revision Hip System Technical Guide (Stryker Corporation, Literature Number: LRMH-TSG, MS/GS 2.5 m 1/06) and Formula 3, assuming a linear taper angle.

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