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Original research

Early outcomes after revision total hip arthroplasty with a modern modular femoral revision stem in 65 consecutive cases

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ABSTRACT

Background: We evaluated the early outcomes, including all-cause revisions, aseptic revisions, and reoperations after revision total hip arthroplasty (THA) using a single modern modular femoral stem design.
Methods: A retrospective cohort study on a consecutive series of 62 patients (65 hips) who underwent revision THA with a modern modular femoral stem system, between January 2011 and October 2015, at a single academic medical center was performed. A cumulative incidence competing risk model was used to evaluate the cumulative incidence of failure with death as the competing risk.
Results: The cumulative incidence rate of all-cause revision THA was 14.5% (95% confidence interval [CI], 6%–24%) at 2 years when accounting for the competing risk of death. The rate of aseptic revisions was 6.8% (95% CI, 0.1%–13%), and the rate of all-cause reoperations was 21.6% (95% CI, 11%–31%). Ten THA cases (15%) underwent re-revision THA for any reason: five for infection and five for aseptic failures. The mean time to re-revision was 1 year (range, 0.04–5.34). Patients with a preoperative Mallory classification of 3 or more were at greater risk for reoperation (sub-hazard rate, 3.84; 95% CI, 1.54–9.53; $P = .004$).
Conclusions: Although the high incidence of reoperation illustrates the complexity of the revision THA population, particularly related to infection and joint instability, the relatively low rate of aseptic failures, minimal radiographic subsidence, and the lack of modular junctional failures suggest that the use of this modular revision THA system may provide adequate fixation and could be considered as a viable treatment option in the setting of revision THA.

Introduction

The number of revision total hip arthroplasty (THA) procedures is projected to rise dramatically in the coming years [1]. These procedures are technically more demanding than routine primary THA. Femoral bone stock is often deficient in the revision setting due to osteolysis, stress shielding, fracture, or deformity. As such, the proximal bone stock is often nonsupportive, and distal diaphyseal engaging stems have become popular to bypass this deficient proximal bone.

To be effective for use in revision THA, a revision stem should provide durable lasting fixation, minimize complications, and improve patient outcomes, including pain and function. Modular revision stems may be an effective solution to aid the surgeon in addressing complex reconstructions in THA revision by providing customization to remedy bone deficits, deformity, limb length, and offset challenges. Prior studies, however, have demonstrated that some modular stem designs may not improve outcomes over those seen with nonmodular designs and may even introduce complications by new modes of failure, namely at the modular junction [2-7]. More recently, the addition of modular junctions at the level of the dual taper modular necks, even though vastly different from the modular proximal bodies supported within the metaphysis as in the stem design of this study, has only added to the significant concerns in our field about any added modularity in both primary and revision hip reconstruction procedures [8,9].

In response to some earlier modular stem design failures, manufacturers have improved instrumentation and stem metallurgy,

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including the process of roller hardening the tapered junction [10]. In this case series, we evaluated the early complications and the cumulative incidence rates for all-cause revision, aseptic revision, and reoperation after revision THA using a single modern modular femoral stem design. We are unaware of any recent studies reporting on the outcomes of this implant. In addition, we report on preoperative risk factors, radiographic results, and patient-reported outcomes (PROs).

Material and methods

After receiving approval from our institutional review board (IRB# 00,096,272), we performed a retrospective cohort study by querying our enterprise data warehouse for all patients who underwent revision THA (current procedural terminology codes 27,134 and 27,138) using a novel modular femoral revision system (Arcos Modular; Zimmer Biomet, Warsaw, IN) between January 2011 and October 2015. This yielded a consecutive series of 74 patients who underwent 78 revision THA cases. Data were extracted from both the data warehouse and the patient's electronic medical records. Variables of interest included patient characteristics, complications, radiographic findings, and PROs. The Social Security Death index was used to confirm or identify deceased patients. Eleven patients (12 cases) were lost to follow-up without evidence of reoperation or death and were excluded. Three of these 11 patients were from outside the local geographic region and opted to follow up with their local surgeon; follow-up reports were not available. The remaining eight patients failed to respond to routine appointment requests. Finally, one patient (one case) was incarcerated and therefore omitted. Ultimately, 62 patients (65 THA cases) were available for the final review (Fig. 1). Mean follow-up period was 2.9 years (range, 0.01–6.04). Patients with a follow-up period less than 2 years were included if they had undergone reoperation or were dead before 2 years.

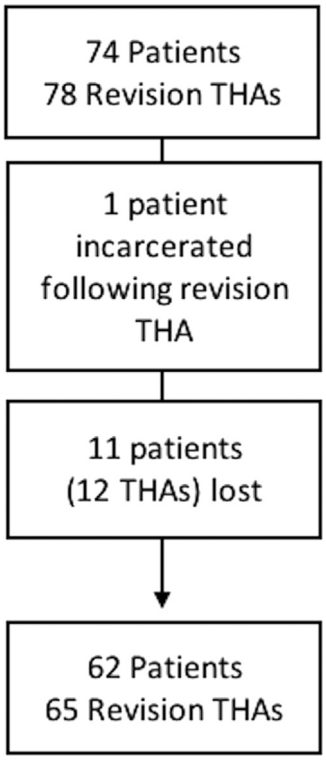

Figure 1. This flow chart demonstrates the attrition of the patients reviewed.

Care pathway

Preoperative templating allowed for adequate implant selection, and the surgical approach was based on surgeon preference. An extended trochanteric osteotomy was used in 10 cases (18%) when necessary to enable existing implant removal.

Postoperatively, the patients were partial weight bearing with either a walker or crutches for 6 weeks. After this time, all patients were permitted to progress toward full weight bearing, as tolerated. Standard of care follow-up was scheduled at 2 weeks, 6 weeks, 1 year, and 2 years. If the patients were unable to return to the clinic for follow-up, attempts were made to contact the patients for routine phone call follow-up to collect PROs and discuss any potential complications. Patients with concerns regarding their hip replacement were encouraged to return to the clinic for physical examination and radiographic evaluations.

Complications and risk factors for failure

Extensive chart reviews were performed to identify both intraoperative and postoperative complications. Those of primary interest included reasons for returning to the operating theater.

Table 1
Patient and preoperative characteristics.

Patient characteristics, 65 THA cases		Subhazard rate	95% CI	*P* value
Age at surgery, mean (range)	65 years (21–93)	0.99	0.96–1.02	.597
Female sex, n (%)	39/65 (60%)	1.18	0.44–3.11	.743
Body mass index (BMI), mean (range)	31.4 kg/m^2 (18.5–48.0)	0.97	0.89–1.04	.368
ASA score[a] ≥ 3, n (%)	33 (51%)	1.33	0.52–3.42	.557
Expired, n (%)	11 (17%)	–		
Preoperative factors				
Indication for Index Revision, n (%)				
Infection	29 (44.6%)	0.87	0.34–2.25	.772
Aseptic loosening	15 (23.1%)	1.54	0.55–4.33	.412
Periprosthetic fracture	11 (16.9%)	0.55	0.12–2.45	.431
Metallosis	6 (9.23%)	–	–	–
Dislocation	3 (4.6%)	–	–	–
Trunionosis	1 (1.5%)	–	–	–
Mallory classification, n (%)				
I	30 (46%)	[b]		
II	15 (23%)			
IIIa	1 (2%)			
IIIb	2 (3%)			
IIIc	6 (9%)	3.84	1.54–9.53	.004
Periprosthetic fractures[c]	11 (16.9%)			
Vancouver classification, n (%)				
A	1 (9%)			
B1	1 (9%)	–	–	–
B2	2 (18%)			
B3	7 (64%)			

[a] American Society for Anesthesiologists Physical Status Classification (ASA score).
[b] The sub-hazard rate for Mallory classification was based on a binary outcome of a Mallory classification ≥3 compared to <3.
[c] Mallory classification was not performed for periprosthetic fractures.

Periprosthetic joint infections were determined based on the criteria set forth by the Musculoskeletal Infection Society [11].

Radiographic outcomes

Anterioposterior pelvis and lateral views of the hip were evaluated. The Mallory classification, obtained from preoperative radiographic evaluation, was used to grade femoral bone loss [12]. One author (C.V.D.) reviewed postoperative images for all available radiographs with minimum 2-year follow-up or before failure (39/65, 60%). Radiolucencies were evaluated according to the methods described by Gruen et al. [13]. Evidence of subsidence and migration was evaluated based on comparisons with prior postoperative radiographs.

Patient-reported outcomes

PROs were measured at the last follow-up using the National Institute of Health's Patient Reported Outcomes Measurement Information System (PROMIS). The instruments included the PROMIS physical function computerized adaptive test v1.2 (PF CAT) and the PROMIS Global 10 health survey. The PF CAT has been shown to be a responsive instrument for measuring physical function in the adult reconstruction arena when compared with the hip disability and osteoarthritis outcome score for joint reconstruction [14]. The PROMIS Global 10 health survey was used to evaluate both mental health (mental health subscore) and pain (0–10 numeric pain scale) [15]. Both the PF CAT and mental health scores are reported as T-scores. A T-score of 50 represents the average score for the US population. For all outcomes, a higher score indicates more of the items being measured.

Figure 2. From left to right the stems shown are the splined tapered straight (a), interlocking porous coated (b), straight porous coated (c), and bowed partially porous coated slotted stem (d).

Table 2
Postoperative surgical complications are presented.

Complication	n (%)
Periprosthetic joint infection	8 (12)
Dislocation	5 (8)
Painful hardware	4 (6)
Wound dehiscence	4 (6)
Periprosthetic fracture	1 (1.5)
Neuropathy	1 (1.5)
Total	23

Each complication is counted once, but some patients may have experienced more than one.

Statistical analysis

Patient demographics, preoperative variables, and outcomes of interest are summarized using descriptive statistics. As 11 patients (17%) expired during the study period, a cumulative incidence competing risk model was used to evaluate the cumulative incidence of failure with death as the competing risk [16]. For this analysis, failure was defined three ways: (1) "all-cause revision", (2) "aseptic revision", and (3) "all-cause reoperations". All subsequent analyses were considered secondary or exploratory. Subhazard ratios of preoperative risk factors for reoperation were analyzed in a univariable competing risks model. Using robust standard errors, the model was adjusted to account for the clustering of hips within patients. For simplicity, "THA case" was used as the unit of measure as opposed to patient. The data were analyzed using a commercially available statistical software program (Stata v14.2, College Station, TX) and in R 3.4.3 [17] using the mstate package [18].

Results

The mean age of the THA cases was 65 years (range, 21–93). Sixty percent of the study group comprised women. The mean BMI was 31.4 kg/m^2 (Table 1). The primary indication for the index revision was infection (44%), followed by aseptic loosening (23%). The majority of femoral stems (92%, n = 60) were a splined tapered straight stem (Fig. 2a). In addition, three bowed, interlocking, porous coated stems; one straight, fully porous coated stem; and one bowed, partially porous coated slotted stem were used (Fig. 2).

Intraoperative complications were limited to two (3%) intraoperative femur fractures. Nineteen patients (29%) experienced at

Table 3
The initial return to the operating theater after the index revision THA.

Reoperation procedure	n (%)
Revision THA[a]	9 (53)
Hardware removal[b]	4 (24)
Irrigation and debridement	3 (18)
Head and liner exchange	1 (6)

[a] One patient underwent revision for infection after failing multiple I&D procedures at an outside facility resulting in a total of 10 cases that underwent a subsequent revision.

[b] Hardware removal included removal of a trochanteric claw on two patients with prior intraoperative fracture at the time of index revision, removal of a trochanteric claw from prior controlled extended trochanteric osteotomy, and removal of a trochanteric claw due to prior periprosthetic fracture fixed at the time of index revision.

Table 4
Reasons for reoperation after the index revision THA.

Reoperation procedure	n (%)
Infection	8 (47)
Painful hardware	4 (24)
Instability	3 (18)
Wound dehiscence	1 (6)
Non-union of periprosthetic fracture	1 (6)

least one postoperative surgical complication (Table 2). The most common complication was periprosthetic joint infections (n = 8). Overall, 17 THA cases (26%) returned to the operating theater (Table 3). Eight of 17 (47%) reoperations were due to infection (Table 4). The preoperative diagnosis for the index procedure of the hips that had subsequent infections included infection (n = 3), periprosthetic fracture (n = 1), metallosis (n = 1), and aseptic loosening (n = 2). Ten THA cases (15%) required a subsequent revision THA. The mean time to revision was 1 year (range, 0.04–5.34). Of the 10 revisions, eight required revision of both the proximal and distal stem components: six for infection, one for non-union of a periprosthetic fracture, and one for instability with subsidence of the femoral stem. Of the six who underwent subsequent revision for infection, one was performed elsewhere; one underwent stage 1 revision with an antibiotic spacer, followed by a girdlestone procedure; one underwent stage 1 revision with an antibiotic spacer and then expired; and three underwent successful stage 2 revision THA. Of the four revised for aseptic failures, two required revision of both the proximal and distal stems as previously noted. The other two were revised for instability, and revision of the stem was limited to the proximal body. There were no complications, including stem fractures, associated with modular junction failures.

The cumulative incidence of all-cause revision was 14.5% (95% CI, 6%–24%) at 2 years when accounting for the competing risk of death (Fig. 3). Similarly, the cumulative incidence rate of aseptic revision was 6.8% (95% CI, 0.1%–13%; Fig. 4). Finally, the cumulative incidence of all-cause reoperations was 21.6% (95% CI, 11%–31%; Fig. 5).

Patients with a preoperative Mallory classification of 3 or more were at greater risk for reoperation (sub-hazard rate, 3.84; 95% CI, 1.54–9.53; $P = .004$; Table 1).

Of the 65 hips, 39 (60%) had a minimum 2-year follow-up X-ray or had failed before that. Of the X-rays available, only one case presented with subsidence. This case required an additional revision of the femoral stem at 1.64 years due to both the subsidence and instability. This patient had significant preoperative bone loss with a type 4 Mallory classification. Five hips demonstrated femoral radiolucencies. Four of these were limited to the Gruen zone 1, which is associated with the proximal femoral bone loss. Only one of the four patients with lucency in the Gruen zone 1 had a radiolucent line longer than 2 mm. Finally, one hip had lucencies in Gruen zones 2, 5, and 6, and the widths ranged from 1 to 4.5 mm. This patient has not reported any postoperative complications.

The mean PF CAT T-score at the last follow-up was 37 (range, 20–58; 95% CI, 34.2–39.1). These scores demonstrate a wide range of physical function in these patients from poor to above average. Similarly, there was a wide range of mental health scores with a mean Global 10 Mental health score of 42 (range, 20–63; 95% CI, 39.4–45.0). The median numeric pain scale score was 4 with an interquartile range of 1–6.

Discussion

This retrospective cohort study of a consecutive series of patients undergoing revision THA with the use of a modern modular revision THA system demonstrated a cumulative incidence rate of 14.5% for all-cause revision at 2 years, 6.8% for aseptic revision, and 21.6% for any reoperation when accounting for the competing risk of death. The high incidence of reoperation illustrates the

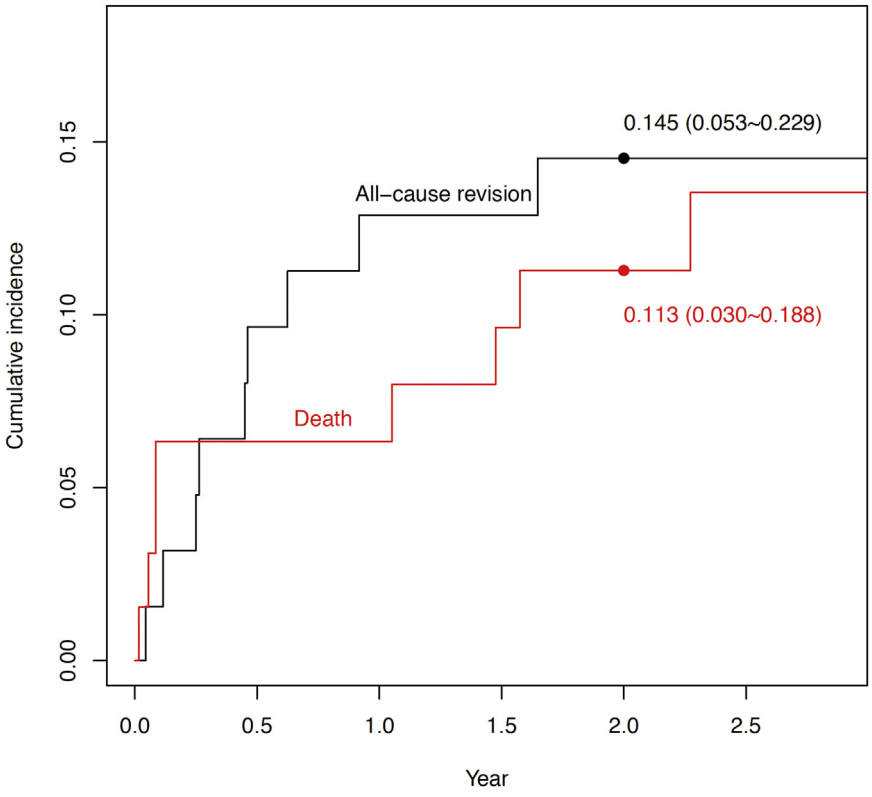

Figure 3. A cumulative incidence curve showing the incidence rate of all-cause revision THA after revision THA when accounting for the competing risk of death.

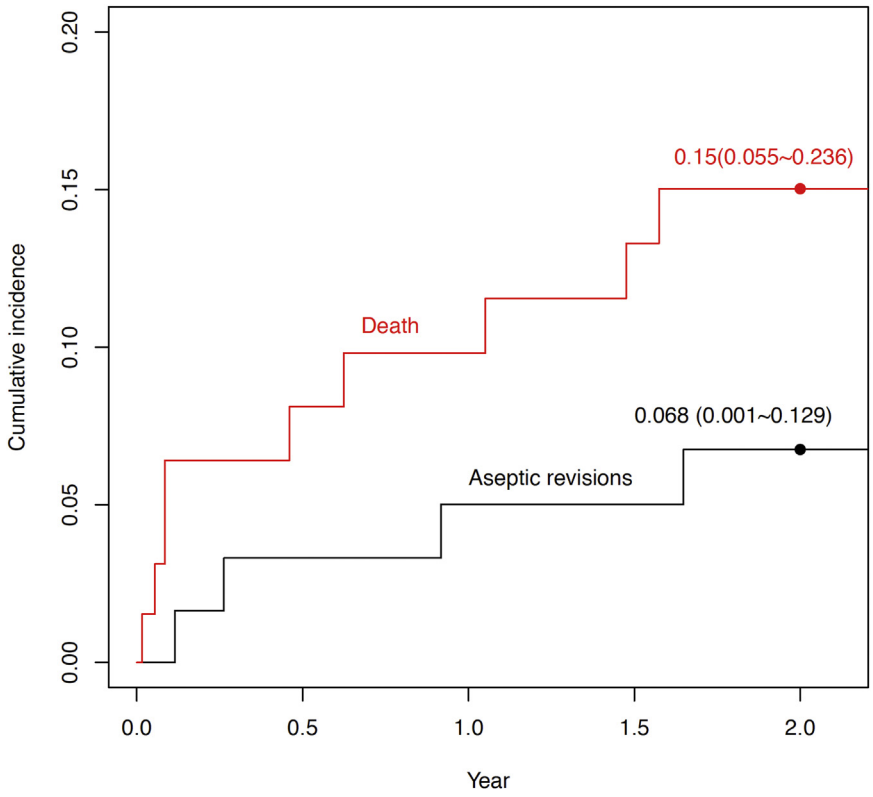

Figure 4. A cumulative incidence curve showing the incidence rate of aseptic revision THA after revision THA when accounting for the competing risk of death.

complexity of the revision THA population, particularly related to infection and instability. However, with a relatively low rate of aseptic failures, minimal radiographic subsidence, and the lack of modular junctional failures, the use of this modular revision THA system may provide adequate fixation and should be considered as a viable treatment option in the setting of revision THA.

Limitations of this study are primarily related to the retrospective study design. All background clinical and operative data were obtained retrospectively by means of a review of our institutional database and electronic medical records. Despite attempts at routine clinical follow-up, 12 of 78 revision THA cases (17%) were ultimately deemed lost to follow-up. In addition, the sample size was too small to preclude evaluating differences between historical controls. In addition, during the study period, the use of PROs at our institution was modified from common legacy scales to the PROMIS PF CAT and the PROMIS Global 10 health survey. This did not allow for pre-post comparisons, and thus, the PROs presented are used for descriptive purposes only. Regardless, at the last follow-up, the wide range of scores in this series further emphasizes the complexity of these cases. Finally, this study has an inherent risk for individual scientific bias as the funding source was the manufacturer of the implant that was evaluated, and several investigators have a financial relationship with that manufacturer. To mitigate the potential impact of this source of bias, neither the sponsor nor those investigators were involved in the data collection or analysis of the data. In addition, a separate, nonconflicted investigator assumed the role of senior author, reviewed the results, assisted with the manuscript development, and approved the final draft. Furthermore, the primary outcomes of interest, the cumulative incidence rates, were determined by an independent statistician.

Several alternatives to modular revision femoral stems may be effective and, as such, should be mentioned. Cemented stems are rarely used in the setting of revision THA, primarily due to the loss of proximal metaphyseal cancellous bone and a sclerotic endosteum and canal that inhibits sufficient cement interdigitation [19,20]. Extensively porous coated stems improve upon this by affording the potential for biologic ingrowth over an extended length of the intact host bone and can be used to bypass proximal defects. However, these stems require an extended length of scratch interference fit of approximately 4 cm (or two cortical

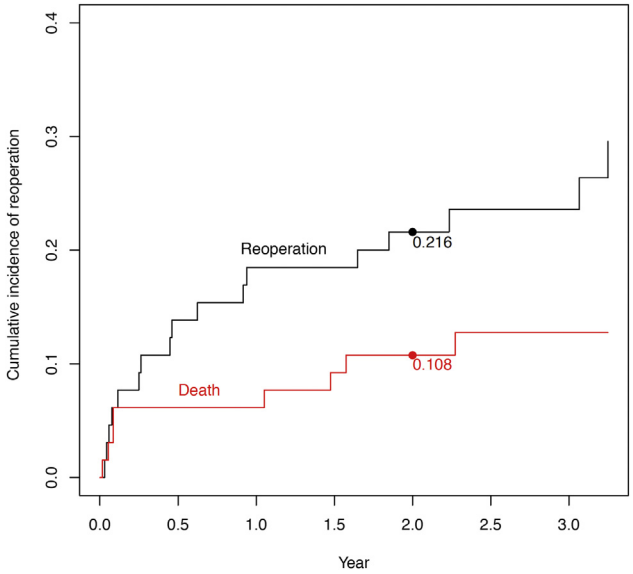

Figure 5. A cumulative incidence curve showing the incidence rate of all-cause reoperations after revision THA when accounting for the competing risk of death.

diameters), which is not always available. They are also associated with outcomes that depend particularly on the extensiveness of bone loss and have been associated with a high incidence of subsidence and thigh pain [21,22].

Nonmodular titanium splined tapered stem designs, such as that popularized by Heinz Wagner (Wagner SL Revision; Zimmer Biomet, Warsaw, IN), may offer the advantages of bone ingrowth onto the less extensively porous grit-blasted titanium. This design allows for reamed tapered diaphyseal engagement to bypass defects and wedge fit engagement of the diaphysis, potentially with less required total distance of interference fit [23,24]. Indeed, it is this predicate stem design that many current modular revision hip systems have used as the foundation for the distal diaphyseal modular segment, and this design affords significant potential advantages over extensively porous coated cobalt-chromium stem designs. Disadvantages however include the possibility of the diaphyseal engagement to sit too proud or too low, a known incidence of subsidence, the need for the surgeon to "buy" the version during distal stem engagement, and the lack of opportunity to use other proximal body geometries, which may be used to fill proximal metaphyseal bone segment deficiencies [25].

The addition of the modularity in revision THA adds simplicity and technical ease as the surgeon is able to achieve axial and rotational stability through distal stem engagement and then use the modular proximal body to optimize length, offset, and femoral version. The modular proximal body offers advantages beyond just hip mechanics as it allows for varying diameters of cone bodies and even broach bodies to fill any remaining proximal intact bone to promote additional bone ingrowth. Another added benefit of the modularity was demonstrated in our series where re-revision THA for instability was limited to exchange of the proximal body while retaining the stem. This is particularly attractive in the setting of a well-fixed diaphyseal engaged stem that, in the setting of a nonmodular stem choice, could have required more extensive surgical procedures, such as the use of an extended trochanteric osteotomy or trephines to aid in its revision.

Prior studies have demonstrated adequate survival and acceptable complication rates when using modular femoral stem systems [26,27]. Previously, we reported an aseptic loosening rate of 3% using a modular femoral stem system, and similar to this study, we identified infections and instability as the major postoperative complications [26]. Modern modular femoral stem designs, such as the one used in the present study, have been updated to include additional proximal body geometries, as well as multiple distal stem designs with varying lengths of splined tapered stems, fully porous coated stems, bowed stems, and even interlocking stem designs (Fig. 2). Although several of the options available with the stem were used in the present study, two of the authors prefer the use of the splined tapered straight design as represented by the dominant use of that over the extensively porous coated cylindrical stems.

Conclusions

In summary, the use of a modern modular femoral stem system for revision THA demonstrated a relatively low incidence of aseptic failure (6.8%) at 2 years. Only two of such systems required removal of the distal stem. This, combined with minimal radiographic evidence of subsidence, and no failures at the modular junction are reassuring findings in this series. A number of all-cause failures or reoperations were related to infection and instability, illustrating the complexity of revision THA in general, and this is likely a finding independent from the implant. Given the promising outcomes of this study, the use of modern modular revision THA systems may improve the surgeon's ability to more successfully revise these complex cases. As there are very few, if any, additional reports in the literature on this implant, further studies, including midterm outcomes, are recommended.

Acknowledgments

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