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Original research

Clinical and radiographic outcomes of total hip replacement with a 3-part metaphyseal osseointegrated titanium alloy stem enhanced with low plasticity burnishing: a mean 5-year follow-up study

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ABSTRACT

Background: This study evaluates midterm results of a 3-part titanium alloy stem with metaphyseal fixation and a neck-metaphyseal taper junction strengthened with low plasticity burnishing (LPB). Our hypothesis is that this multimodular implant with LPB succeeds in offering the advantages of three-part modularity without junctional failure.

Methods: Twenty-eight of 32 complex primary (n = 9) and revision (n = 9) total hip arthroplasties were accounted for with minimum 2-year follow-up. Clinical and radiographic data were reviewed at a mean follow-up period of 60 months. One stem, removed for failure to osseointegrate, was submitted for sectioning and taper examination.

Results: There were no modular junction failures despite body mass indices of 20 to 40 and offsets of 34 to 47 mms. Implant survival was 96.3%, with one removal due to aseptic loosening in a patient with chronic renal failure. Taper analyses of the removed implant showed minimal damage. Preoperative and postoperative Harris Hip Scores and Oxford Hip Scores were 20 to 86 and 16 to 41, respectively. Patient satisfaction was 9.7/10. Radiographs showed stem subsidence >2 mm and radiolucencies around the metaphyseal cone only in the hip requiring implant removal.

Conclusions: This 3-part titanium alloy modular stem with LPB of the neck-metaphyseal taper junction showed good functional and radiographic results at a mean 5 years without junctional failures. Although this follow-up exceeds previously published reports, longer follow-up will be important to confirm our confidence in the additional strengthening provided by LPB.

Introduction

Complex total hip arthroplasties (THAs) resulting from anatomic variations or previous trauma and surgery often require unique solutions. Modular femoral implants have allowed surgeons to more easily address these complex cases [1-3]. But, despite the convenience of modularity, it has been associated with junctional fatigue fractures and consequences related to taper damage and corrosion [4-11].

Some modular femoral stems combine proximal modularity with distal osseointegration, bypassing missing or poor-quality proximal bone stock [12-15]. These implants have vastly simplified the challenges of complex cases by allowing independent proximal femoral version and height. But, if necessary, removal of a distal fixation stem can be both extremely difficult and destructive, requiring an extended trochanteric osteotomy (ETO) [16,17].

Other modular stem designs rely on metaphyseal fixation when adequate proximal bone stock remains. One of these designs, the S-ROM (DePuy Orthopedics, Inc., Warsaw), has undergone extensive biomechanical testing [18,19], and successful long-term clinical results have been documented [20-22]. It has a one-piece titanium ally neck-stem component that is inserted through a titanium alloy

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metaphyseal sleeve [20]. The sleeve has a bone ingrowth surface and connects to the central stem via a modular junction. The femoral neck version can be oriented completely independent of the sleeve, but, if a curved stem is chosen, the version of the neck is dependent on the anterior bow of the femur. Neck version and height are not completely independent of the sleeve and stem. Furthermore, not all metaphyseal sleeve sizes can be combined with all stem diameters, so a large metaphyseal defect cannot always be accommodated with a narrow diaphyseal canal.

The success of the S-ROM (DePuy Orthopedics, Inc., Warsaw) stem leads to 3 questions. Can a modular titanium alloy metaphyseal osseointegration implant be designed that would allow independent sizing and positioning of each of the 3 components? Can a metaphyseal component accommodate 2 modular taper junctions and still fit within the anatomic confines of the proximal femur? And, can this implant tolerate the biomechanical loads experienced by the proximal femur?

The AcuMatch M-Series (Exactech, Inc., Gainesville) was designed with these goals in mind; however, its longevity has been questioned by reports of fatigue failures [23]. To respond to these concerns, low plasticity burnishing (LPB) was added to the manufacturing process of the neck-metaphyseal taper junction in 2006 to improve fatigue strength [24]. This study evaluates 5-year clinical results and survival rates of the M-Series modular femoral implants after the addition of LPB. Our hypothesis is that this multimodular implant now succeeds in offering the advantages of three-part modularity without junctional failure.

Material and methods

Patients

After institutional review board approval, we prospectively followed up 32 patients with 32 cementless THAs using the AcuMatch Modular stem (Exactech, Inc., Gainesville) between May 2010 and July 2016. A single arthroplasty surgeon performed all surgeries. Patients who failed to return for routine follow-up were contacted by phone or email. Of the 32 patients, 1 patient died before the 2-year follow-up (unrelated to the surgery) and was removed from the analysis. One patient was lost to follow-up, and two patients with retained implants were unable to communicate with us directly. One of these patients is in an acute care center, and the other had had recurrent thyroid cancer with a radical neck dissection. Two patients had moved out of the country and were unable to return to clinic but did answer the clinical evaluation questions over the phone. This resulted in 28 patients available for clinical review and 26 for radiographic review.

Indications for surgery were as follows: final stage of a two-stage revision for infection ($n = 7$), failed open reduction and internal fixation ($n = 6$), revision THA for loosening ($n = 4$), post-traumatic arthritis ($n = 4$), avascular necrosis ($n = 3$), dysplasia ($n = 2$), pseudotumor from prior metal-on-metal arthroplasty ($n = 1$), and revision of a periprosthetic fracture ($n = 1$). A posterolateral approach was used in all but 2 cases due to previous anterolateral approaches. A trochanteric osteotomy was used in 5 patients to facilitate existing implant removal. Postoperatively, patients were initially weight bearing as tolerated with a walker.

Implant

The AcuMatch Modular stem (Exactech, Inc., Gainesville) is a 3-part modular, forged titanium alloy, cementless prosthesis designed for metaphyseal bone ongrowth. The diaphyseal segment is a polished cylindrical splined clothespin tip design available in varying lengths, diameters, and curvatures. The metaphyseal segment is plasma sprayed. The neck segments are available in low or high offset and come in varying heights that can be rotated freely. Unlike the S-ROM (DePuy Orthopedics, Inc., Warsaw), which is a 2-part modular stem with a metaphyseal portion and a single neck-stem component, the AcuMatch Modular's 3 components (Exactech, Inc., Gainesville) are individually chosen and assembled. For this reason, a locking screw is inserted between the neck, metaphyseal, and stem segments to assure taper assembly between the components. To decrease risk of stem fracture, several features were introduced to maximize the strength of the multimodular connections in the metaphyseal component. A cylindrical tip was added to the male portion of the neck-metaphyseal taper to prevent excessive bending. The tip geometry of the stem-metaphyseal taper was modified to reduce point contact stresses.

The M-series stem was compared in independent laboratory testing (Greenwald, Orthopedic Research Laboratories, Cleveland) to the previously tested S-ROM stem (DePuy Orthopedics, Inc., Warsaw) and demonstrated increased fatigue strength and decreased potential for wear debris. The wear was described as Bobyn type B or mild wear (burnishing or slight roughening) (Seth Greenwald, written communication, October 2018) [18,19].

The male portion of the neck-metaphyseal junction was later enhanced with LPB, a work hardening process, in 2006 because of reported neck-metaphyseal taper fractures. This technique has been shown to increase strength to failure 40% in independent fatigue testing [24].

Radiographic and clinical outcomes

Medical records and joint registry data were reviewed to collect information on preoperative and postoperative clinical examinations, operative findings, implant component choices, and complications. The operating surgeon performed clinical evaluations at each visit, and outcomes were recorded using the Harris Hip Score [25], Oxford Hip Score [26], and a ten-point patient Likert Satisfaction Score. Radiographic evaluation included anteroposterior views of the pelvis and hip, as well as Lowenstein lateral view of the implant [27].

Radiographs were evaluated by 2 authors (S.S. and R.R.), and disagreements in findings were reconciled by discussion. Femoral geometries were categorized according to the classification system of Dorr et al [28] using preoperative anteroposterior radiographs of the hip. The calcar-to-canal ratio was calculated by dividing the canal width, measured at 10 cm below the lesser trochanter, by the calcar width, measured at the middle level of the lesser trochanter, as previously described [29]. Femurs with a ratio of 0-0.5 were considered type A, 0.5-0.75 as type B, and 0.75-1 as type C.

The most recent radiographs were compared to the first postoperative clinic radiographs to evaluate bony remodeling and changes in implant positioning. Leg length assessments were made by comparison of the difference from a horizontal pelvic reference line to the lesser trochanters in both the legs. Stem subsidence was assessed by measuring implant migration relative to the greater trochanter, as described by Callaghan et al [30], or if the greater trochanter could not be used as a fixed point, relative to the lesser trochanter, as described by Malchau et al [31]. Radiolucencies around the stem and metaphyseal portions of the implant were also recorded in the 14 gruen zones [32]. Spot welds were defined as a newly formed bone bridge between the endosteal and porous implant surfaces. Stress shielding was defined as an area with diminished cortical density between 2 areas of spot welds when compared over a period of time. Shelf formation was defined as endosteal new bone bridging the intramedullary canal in an apparent attempt to support the tip of the implant; however, if this bone was in contact with the distal stem tip and there were no new radiolucencies

Table 1
Demographics and clinical outcomes.

Demographics and Outcomes	Primary THA (n = 9)			Revision THA (n = 19)		
	Mean (n)	Minimum	Maximum	Mean (n)	Minimum	Maximum
Male/female	5/4	—	—	8/11	—	—
Age (y)	48	25	77	62	45	88
BMI (kg/m^2)	29	21	36	27	20	40
Follow-up (months)	66	33	98	59	26	95
Dorr Femur type	Type A: 43% Type B: 43% Type C: 14%			Type A: 53% Type B: 42% Type C: 5%		
High offset neck	67%	—	—	63%	—	—
Total offset (mm)	40.4	34	47	41	34	47
Harris Hip Score[a]						
Preoperative	20	0	59	21	0	65
Postoperative	92	83	100	83	40	100
Oxford Hip Score[b]						
Preoperative	18	12	27	15	0	29
Postoperative	44	37	48	39	13	48
Postoperative Satisfaction Score[c]	9.9	9	10	9.7	8	10

BMI, body mass index; THA, total hip arthroplasty.
[a] Score out of 100.
[b] Score out of 48.
[c] Score out of 10.

or reactive lines around the stem, this was defined as a pedestal around a s— stem [33]. Finally, we recorded whether the clothespin tip was compressed at the final radiographic follow-up visit.

Statistics

Patient demographics and clinical and radiographic outcomes are presented as descriptive statistics. Mean and standard deviations are provided when applicable. Wilcoxon signed-rank analysis was used to assess significance in outcomes data preoperatively and postoperatively. Kaplan-Meier survival analysis was performed to assess survivorship. Statistics were performed using the SPSS software, version 25 (IBM, Armonk).

Results

Baseline demographic and clinical findings are presented in Table 1, grouped by primary and revision THAs. For the entire 28-patient cohort, the mean follow-up time was 61 months (range: 26-98), mean patient age at implantation was 58 years (range: 25-88), body mass index was 28 (range: 20-40), and the average total offset used was 40.8 mm (range: 34-47 mm).

Clinical results

Function improved in all patients after the procedure. Preoperative Harris Hip Score averaged 20 (range: 0 to 65) and improved to an average of 86 (range: 40 to 100) at the last follow-up visit ($P = .002$). Preoperative Oxford Hip Score averaged 16 (range: 0 to 29) and improved to an average of 41 (range: 13 to 48) at the last follow-up ($P = .001$). Final patient satisfaction score averaged 9.7 (range: 8 to 10) on a 10-point Likert Scale (Table 1).

Radiographic results

Anteroposterior and lateral radiographs were available in 26 patients (Table 2; Figs. 1 and 2). There was one case of stem subsidence >2 mm and radiolucencies around the metaphyseal cone, occurring in the same patient that required implant removal. Radiolucencies were seen along the polished stem tip in 35% of cases, spot welding around the distal portion of the metaphyseal cone in 58% of cases, and proximal stress shielding at the calcar in 27% of cases. There were no findings of shelf formations around apparent unstable stems. Fifteen percent of cases had pedestals surrounding a stable distal stem.

Complications

There were 3 intraoperative complications. One patient sustained a calcar fracture during impaction of the final implant, and this was treated with a single cable. This patient showed no implant subsidence and had positive spot welds around the metaphyseal cone at the final follow-up visit. One patient sustained a nondisplaced femoral shaft fracture during removal of a prior cemented stem; this was treated with 3 cables. Another patient required an ETO when we were unable to remove the spout and metaphyseal reaming jig. After performing the ETO, the jig was removed and the ETO was repaired with cables. This patient did go onto successful union.

One stem was revised for loosening at 33 months due to failed osseointegration in a patient with chronic renal failure, human immunodeficiency virus, and hepatitis C. The index procedure was performed for posttruamatic arthritis. The AcuMatch M-series stem (Exactech, Inc., Gainesville) was chosen because the patient was at higher risk for postoperative infection and the polished stem of the implant was theorized to be easier to remove should the implant require revision. This patient was revised with a Restoration Modular stem (Stryker Orthopedics, Mahwah) and subsequently did effectively integrate the stem with a good functional outcome. This removed stem was submitted for taper examination and sectioning (Fig. 3). Analysis procedure on the examined stem

Table 2
Radiographic analysis.

Radiographic Findings	Rate	Percent incidence
Leg length difference >4 mm	10 out of 26 (average abnormality 4.4 mm)	38%
Stem subsidence >2 mm	1 out of 26	4%
Radiolucencies around stem	9 out of 26	35%
Radiolucencies around metaphyseal cone	1 out of 26	4%
Spot welding around metaphyseal cone	15 out of 26	58%
Proximal stress shielding	7 out of 26	27%
Distal cortical hypertrophy	2 out of 26	8%
Pedestal around stable stem	4 out of 26	15%
Clothespin tip compressed	15 out of 26	58%

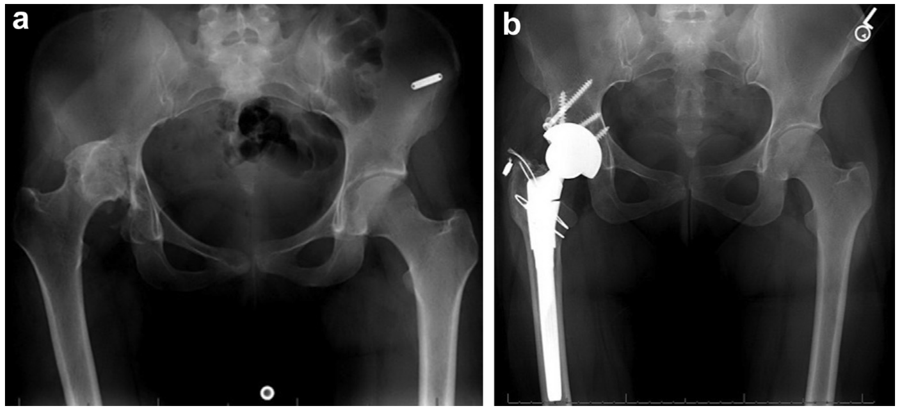

Figure 1. Preoperative (a) and final follow-up radiographs at 74 months (b) of a 25-year-old woman who presented from an outside country with chronic right hip fracture dislocation after a motor vehicle accident. A trochanteric osteotomy was performed for visualization, and femoral head autograft was used to reconstruct the posterior acetabulum. The modular femoral stem allowed for restoration of her native leg length.

included sectioning of the implant to isolate the tapers using a low-speed diamond saw. Tapers were evaluated by light microscopy for evidence of wear and corrosion. The modular junctions demonstrated minimal wear.

Survivorship

There were 2 reoperations: 1 for a nonunion of a greater trochanter osteotomy and 1 for failure to osseointegration. The estimated survival rate with reoperation for any reason as an end point was 92.7% (95% confidence interval, 83% to 100%) at a mean follow-up time of 61 months. The estimated survival rate with revision of the femoral component as an end point was 96.3 (95% confidence interval, 89% to 100%) at a mean follow-up time of 61 months (Fig. 4).

Discussion

We present a series of cases that show good outcomes and 96% survival at a mean follow-up period of 5 years in an implant that combines 2 modular junctions within a metaphyseal component that fits within the anatomic constraints of the proximal femur. There were no instances of implant failure in this implant with the LPB-strengthened neck-metaphyseal taper junction.

The midterm success of this implant is likely due, in part, to its design of a titanium alloy-titanium alloy taper junctions and LPB. The titanium alloy-titanium alloy junctions decrease rates of corrosion when compared with modular stems with dissimilar metals or cobalt-chromium-molybdenum components [4]. LPB is a work hardening surface-enhancement method patented by Lambda Technologies (Cincinnati) that produces compressive residual stress to metal subsurfaces and an improved surface finish [24,34]. Originally used to treat turbine blades in aircraft engines, the process uses cold work hardening to enhance both thermal and biomechanical stability in biomedical devices [24,35]. LPB was added to the AcuMatch M-series implant (Exactech, Inc., Gainesville) in 2006, and independent fatigue testing has shown a 40% increase in the fatigue strength of the neck segment and an increased implant lifespan by 10-fold [24].

Our study showed no modular junction failures and good implant survival without radiologic signs of loosening or metallic debris. In the case that failed to osteointegrate, sectioning of the implant and taper analysis showed no abnormal wear properties such as fretting or corrosion. Although there have been reports of fracture of this M-series implant, it remains a rare phenomenon, and to our knowledge, there are no reported fractures since the addition of LPB [23]. In 2010, Paliwal et al. published 3 cases of this implant failing, 2 of which occurred nearly identically at the stem taper junction with characteristics of fatigue failure [23]. Importantly, these implants were placed before the LPB process implementation. The Emperion is also an all-titanium alloy implant, and fractures occurred at the stem-sleeve junction. Shah et al. found 8

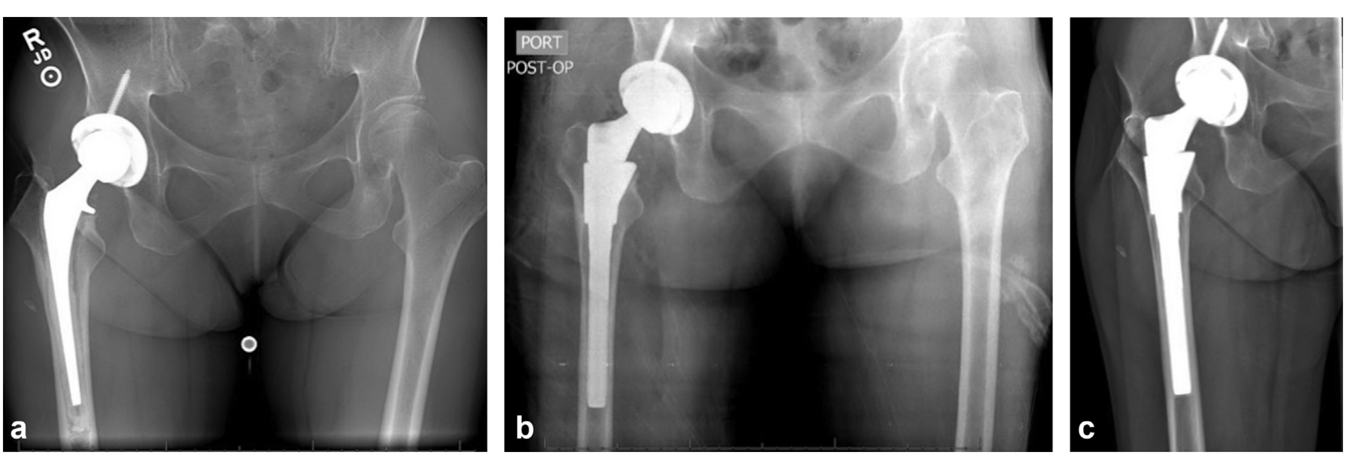

Figure 2. A woman, 61 years old, underwent revision of a primary cemented total hip arthroplasty for aseptic loosening (a). Comparison of immediate postoperative (b) and final follow-up (55 months) (c) radiographs shows stress shielding about the calcar region and spot welding around the distal metaphyseal cone. There are lucencies around the distal polished stem tip in Gruen zones 2, 3, and 4 without evidence of subsidence. Patient was doing well at the final follow-up visit.

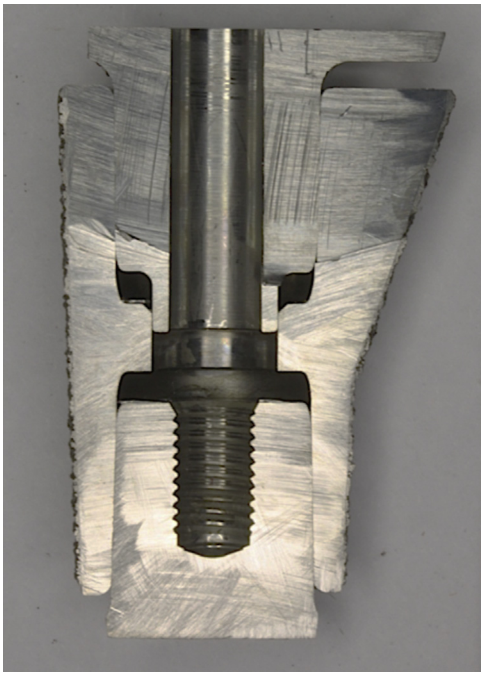

Figure 3. The sectioned metaphyseal taper housing. It was cut sagitally with the neck portion at the top of the image and the stem portion at the bottom. The wear at the taper junctions was mild.

fractures at a mean 3.1-year (1.1-4.8 years) follow-up in the Emperion femoral stem (Smith and Nephew, Memphis). They determined that high body mass index and high offset (mean: 40.2 mm) contributed to the high fracture rate [36]. Although our sample size is smaller, our population experienced no junctional failures despite higher average offset (40.8 mm) and a longer average follow-up period (61 months).

While studies continue to show satisfactory survival outcomes of modular femoral systems, concerns regarding fracture and fretting-corrosion of these multijunctional stems have led to a number of implant failures and recalls [7-11]. Despite the increasing number of reports of modular implants failing, the S-ROM prosthesis (DePuy Orthopedics, Inc., Warsaw) has a stellar clinical record with good results in primary and revision THA [20,37]. Midterm results of 795 S-ROM stems (DePuy Orthopedics, Inc., Warsaw) by Cameron et al found only 2 cases of aseptic loosening after a mean follow-up of 11 years [38]. Longer term results up to 20 years have been reported with excellent survivorship, with no cases of aseptic loosening or junctional failures [21]. Time will tell if the AcuMatch M-series (Exactech, Inc., Gainesville) with LPB implant will match the long-term success of the S-ROM (DePuy Orthopedics, Inc., Warsaw), which was beyond the scope of the present study.

This is the first study to discuss descriptive radiographic outcomes of this proximal fixation modular stem type. The bone loss around the femoral stem after THA is commonly explained by stress shielding because of changes in the distribution of load after placement of the femoral implant. Revision surgery in severely stress-shielded bone can be technically challenging due to lack of proximal bony support. Therefore, the preservation of proximal bone stock is a fundamental goal in THA. It has been generally held that stress shielding can be minimized by using proximally porous-coated stems made of lower modulus alloys such as titanium alloy [39]. Prior reports using proximally fixed modular titanium alloy stems have found stress shielding to still be a prominent radiologic finding at the calcar region (Gruen zone 7) in 74%-78% of cases, resulting in loss of cortical thickness and calcar height [20,40]. Compared with other studies, we found radiologic evidence of stress shielding in 27% of cases. This supports evidence that stress shielding is multifactorial, and the design of the M-series implant may prove to be advantageous in minimizing bone loss from stress shielding compared with similar devices.

The design of this implant allows solution to complex anatomic revision challenges while preserving proximal bone stock; however, its use is limited in smaller femurs. The removable neck and the avoidance of stem osseointegration may make removal less destructive than distal fixation stems. This is particularly desirable

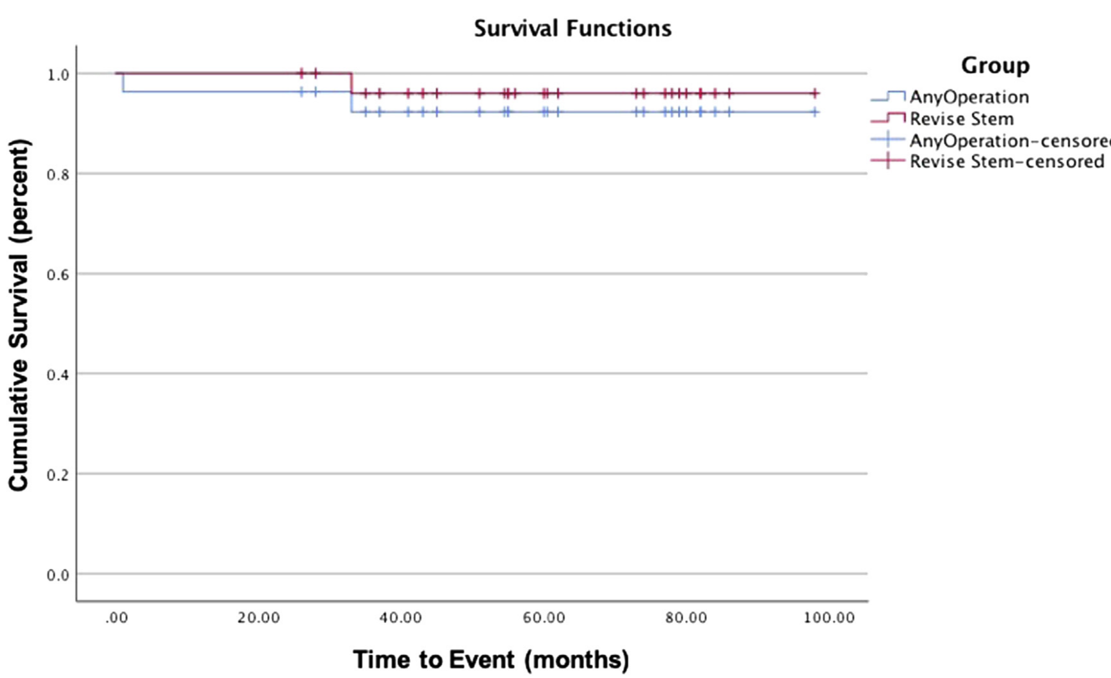

Figure 4. Kaplan-Meier survival curve was calculated at a 61-month mean follow-up. Estimated survival until reoperation for any reason (blue line) was 92.7% (95% confidence interval, 83% to 100%). Estimated survival until revision of the femoral component (red line) was 96.3 (95% confidence interval, 89% to 100%). Dashed lines refer to censored cases, defined as the last follow-up time point of individual patients.

when implanting an implant in a two-stage revision after periprosthetic infection in a patient with multiple comorbidities. Removal of a solidly fixed implant has not been experienced by the authors but the metaphyseal fixation, the ability to remove the neck component, and the polished distal stem would logically make removal less destructive of bone than a distal osseointegrated revision stem. The complete interchangeability of the 3 components allows solutions to extreme differences in metaphyseal and diaphyseal defects. However, the metaphyseal cone is too bulky to fit into the confines of some smaller dysplastic femurs. The smallest metaphyseal implant, a size 21, is 21 mm across proximally and 19.7 mm distally, which do limit the applications of the stem in this select patient population.

Our study, although prospective, is not without limitations. First, while the 2- to 8-year follow-up cases in this study did not reveal any implant failures, it is impossible to extrapolate these finding to long-term survival estimates. There is a need for longer term follow-up to ensure that there are no late junctional failures or adverse local tissue reactions. Second, this is a relatively small sample size, and it is possible that we are underpowered to identify failures that would have a low rate of occurrence at our follow-up period, specifically implant failure.

Conclusions

This unique 3-part modular stem with metaphyseal fixation shows good functional and radiographic results at a mean 5-year period without junctional failures after the addition of LPB at the neck-metaphyseal taper junction. Proximal stress shielding and lucencies around the distal stem are seen in patients doing well without any apparent adverse outcomes. There was one case that failed to osseointegrate. The possibility of easier removal especially in second stage reimplantation after infection is attractive. Neither definitive recommendations regarding safety or longevity of this implant nor claims of noninferiority to comparable modular implants can be made given the short follow-up and low sample size of this study group. Further follow-up is important to support confidence in this unique stem design.

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