CLINICAL ARTICLE

Extensively Coated Non-modular Stem Used in Two-stage Revision for Infected Total Hip Arthroplasty: Mid-term to Long-term Follow-up

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Objective: To determine the rate of curing the infection and mid- to long-term outcomes of using extensively coated non-modular stems in two-stage revision for infected total hip arthroplasty (THA).

Methods: The clinical data of 33 patients (33 hips) in whom extensively coated non-modular stems had been used in two-stage revision THA for deep infection were retrospectively analyzed. All operations received two-stage reimplantation, which included resection arthroplasty, thorough debridement, insertion of a hand-molded antibiotic-impregnated cement spacer with stainless steel reinforcement, a course of intravenous antibiotics, and delayed reimplantation. Microorganism-specific antibiotics had been chosen according to the results of microbiological studies performed postoperatively. All patients received i.v. antimicrobial therapy for 4 weeks and oral antibiotics to which their organisms were sensitive for a further 6 weeks. Harris hip score (HHS) and plain X-ray films were used to perform clinical and radiological evaluations.

Results: During follow-up for a minimum of 5 years, no reinfection or loosening were found. Cultures of samples taken during the second stage were all negative for infection. The mean HHS improved from 42 preoperative to 89 at the final follow-up. All granular bones had fused well with the host bones by 12 months after the surgery.

Conclusion: Using extensively coated non-modular stems combined with intramedullary allografts in two-stage revision for treating infected THAs can achieve satisfactory outcomes.

Key words: Infection; Total hip arthroplasty; Two-stage revision

Introduction

Though the incidence of infection in primary total hip arthroplasty (THA) is extremely low (0.4%–1.0%), it remains a nightmare for joint surgeons[1,2]. Because the reported cure rate ranges from 85% to 95%, two-stage revisions that use a prosthesis with antibiotic bone cement were once accepted as the gold standard for treating infected THAs[3–6].

Cemented fixation, which permits the use of antibiotics, has classically been used in reimplantation of femoral components because it reduces the risk of reinfection[4]. However, several recent reports have suggested that cemented two-staged revision has a relatively high mechanical failure rate (25%–33%)[6,7]. Many series with mid- and long-term follow-ups have reported a high incidence of loosening and failure of cement stems used in THA revisions. The main reason is that thinning and sclerosis of the interface between bone and premier prosthesis prevents formation of micro-lock at that interface[6]. For these reasons, many surgeons prefer to use uncemented stems for revision. Promising results have been reported with two-stage cementless revisions, the eradication rates being between 82% and 100% (Table 1).

It is difficult to achieve "fit and fill" because the diameters of the medullary canal of the metaphysis and diaphysis bear little relationship to each other. This problem can be overcome

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TABLE 1 Results of two-stage uncemented revision of periprosthetic infection of the hip

Author	Cases	Follow-up	Spacer/beads	Local antibiotic	Duration of antibiotics	Interval	Antibiotics after implantation	Implants	Eradication (%)	Aseptic loosening
Fehring [15]	25	41 m	Beads	Tobramycin	6 w	4.8 m		Nm stem modular	92	0
Haddad [16]	50	5.8 yrs	Beads cement ball	Gentamicin	iv for 5 d and then oral	3 w	≥3 m	Nm stem	92	8% stem
Koo [17]	22	41 m	Spacer beads	Vancomycin, Gentamicin, Cefotaxime	6 w	6–12 w		Nm stem	95	5% cup 30% stem
Masri [27]	29	≥2 yrs	PROSTALAC spacer	Tobramycin Vancomycin Cefuroxime Penicillin	6 w	12 w	iv for 5 d	Nm stem	90	0%
Fink [29]	36	24 m	Manual spacer	Vancomycin, Gentamicin Clindamycin	iv for 2 w oral for 4 w	6 w		Modular stem	100	0%
Kraay [30]	33	≥24 m	Spacer in 16 cases	Tobramycin	≥6 w iv	7.4 m		Nm stem modular	92	9% cup 0% stem
Nestor [31]	34	47 m	Resection	No	≥4 w	8 m	Different	Nm stem	82	18%
Romanò [32]	40	2 yrs	Spacer	Vancomycin, Gentamicin	4–6 w	9–16 m		Modular	97.5	2.5%

Nm, non-modular; w, weeks; d, days; m, months.

by using a modular stem or by having a very large variety of monolithic stems. A modular stem allows independent metaphyseal/diaphyseal sizing, stem-to-neck length options, and adjustable offset and version. Modularity can also be advantageous in helping to offset leg length in situations where there are major discrepancies[8]. However, numerous potential concerns about all modular stems have been raised, including corrosion at the taper causing lysis, fear of breakage and taper disengagement[9–11]. Extensively porous coated revision stems are designed to bypass the regions of proximally deficient bone and achieve stability and fixation in more distal femoral bone. Such stems have produced encouraging results[12,13]. Many published reports have described that good mid- and long-term results after using uncemented prostheses in two-stage revisions for treating infected THAs[7,14–17]. However, both modular and non-modular prosthesis are mentioned in these reports. Favorable features of extensively coated non-modular stems include that they are easy to use, have a high friction coefficient and achieve stable initial fixation. Long-term evaluation has shown that single prostheses are not very effective.

The purpose of the present retrospective study was to determine the rate of cure of infection and mid- to long-term outcomes (minimum 5-year follow-up) of extensively coated non-modular stems used in two-stage revision for infected THAs.

Materials and Methods

General Data

Thirty-three patients (20 men and 13 women) with 33 infected THAs who had been treated surgically from March 2005 to December 2006 were retrospectively reviewed. All patients had been subjected to a two-stage reimplantation protocol for deep chronic regional infection after THA. The underlying diagnoses leading to the index THA were osteoarthritis in 16 hips, avascular necrosis of the femoral head in 12 hips, rheumatoid arthritis in 4 hips and femoral neck fracture in one hip. Of the 33 patients, 19 had originally undergone fixation without cement, 13 patients fixation with cement and one hip was hybrid. Eighteen of the 33 patients (54.5%) had specific comorbidities including diabetes mellitus, hypertension and chronic obstructive pulmonary disease. The median age at the time of initial surgical treatment was 65 years (range, 52–79 years), and the mean follow-up was 6 years (range, 5–8 years). The period of time from the initial, clean implantation to the diagnosis of infection was 12–42 months, the average being 18 months. The most sources for the infection in our study may be hematogenous spread (dental infection, endoscopy) or contamination at the time of surgery.

All operations had been performed by a single surgeon according to a two-stage reimplantation protocol, which included resection arthroplasty, thorough debridement, insertion of a hand-molded antibiotic-impregnated cement spacer with stainless steel reinforcement, a course of intravenous antibiotics, and delayed reimplantation.

First-stage Procedure

The first-stage procedure consisted of complete removal of all foreign materials involving the prosthesis and cement, the fibrous membrane, sinus tracts, and all devitalized bone and soft tissues. This was performed via a posterolateral approach. The infected prosthetic stem was removed by a transfemoral approach in 17 patients. When removing solidly fixed cemented, cementless femoral stems or cement mantles,

extended trochanteric osteotomy was performed in 9 hips and cortical windowing of the femoral diaphysis in 8 hips. Sinus tracts were present in 15 hips; these were completely excised using methylene blue. Postoperatively, the patients were encouraged to walk with toe-touch down weight bearing.

Cup-shaped acetabulum spacers had been used to separate the antibiotic-loaded cement from the prostheses. For the stem components, the spacers were created by placing antibiotic-loaded cement around stainless steel in the shape of the medullary cavity. The antibiotics used were a combination of 2 g of vancomycin and 1 g of aminoglycoside per package (40 g) of cement.

During resection arthroplasty, samples for microbiological and histopathological studies were always obtained from joint fluid and tissues suspected to be infected. Deep periprosthetic infection was diagnosed if two or more cultures of intraoperative specimens yielded the same microorganism, there was frank purulence surrounding the prosthesis at the time of resection, there was evidence of acute inflammation on intraoperative histopathologic examination, or there was a sinus tract communicating with the prosthesis. Diagnoses of deep periprosthetic infection were based on positive cultures from operative specimens in 12 hips, intraoperative pathology in 23 hips and presence of sinus tracts in 15 hips (more than one of these characteristics was present in some cases). Of the 21 hips where cultures of operative specimens were negative, the diagnosis of infection was based on positive intraoperative pathology in 11 hips, frank purulence in 6 hips (with positive pathology) and sinus tracts in 4 hips. Causative infective organisms included *Staphylococcus aureus* in eight hips, *Staphylococcus epidermidis* in three hips and streptococcus in one hip.

Microorganism-specific antibiotics were chosen according to the results of microbiological studies performed postoperatively. All patients received i.v. antimicrobial therapy for 4 weeks and oral antibiotics (chosen according to known sensitivities of infecting microorganisms) for 6 weeks after the course of i.v. antibiotics. Patients in whom no causative organism had been identified by culture received i.v. vancomycin and cefuroxime for 4 weeks and oral rifampin for a further 6 weeks.

Second-stage Procedure

Second-stage reimplantation procedures were considered only after the following criteria had been fulfilled; (i) persistent normalization of C-reactive protein concentration; (ii) persistent normalization of blood leukocyte count; and (iii) absence of clinical symptoms of infection for at least 2 weeks after discontinuation of antimicrobial therapy. Because the erythrocyte sedimentation rate has shown to be high following infection, this variable was not considered when making reimplantation decisions. Aspiration before reimplantation was not routinely performed because many patients refused aspiration and false-negative cultures can occur. During the second stage of the two-stage reimplantation procedure, samples for microbiological and histopathological studies were always taken from joint fluid and deep tissues before administration of any further antibiotics. When any evidence of infection was detected histologically and clinically, the first-stage procedure was repeated and the second-stage procedure postponed. The mean time from first-stage resection arthroplasty to reimplantation was 20 weeks (range, 12–36 weeks).

Reimplantation was performed without extended trochanteric osteotomy via a posterolateral approach in 24 patients. In the nine patients whose implants were removed via a transfemoral approach, extended trochanteric osteotomy was opened to remove the spacer. Early healing of the osteotomy was observed in all patients. Uncemented press-fit acetabular cups were used in the revisions and screws were used to assist fixation in 26 hips. Extensively coated non-modular stems (anatomic medullary locking) were used on the femoral side and impaction bone grafting technique in 11 hips on the acetabular side. Cortical bone grafting was used in 10 hips and intramedullary impaction bone grafting on all femoral sides. Postoperatively, the patients were allowed to walk with the aid of two crutches for 3 months.

Evaluation Index

Treatment was considered successful in patients whose reimplanted prostheses remained infection-free state at final follow-up. Treatment was considered a failure in patients who (i) required permanent resection arthroplasty because of persistent infection after the first-stage procedure; (ii) had recurrent periprosthetic infection resulting from the original or a different microorganism after second-stage reimplantation; or (iii) required reoperation for mechanical loosening of the reimplanted prostheses. Outcomes were determined at last documented visits or when clinical failure occurred. Serial radiographs were examined for component stability, migration and loosening. The Harris hip score (HHS) was used to assess functional outcome in all 33 patients; there enough data to calculate this score in all cases. Reinfection was defined by the same criteria as were used to diagnose the index infection.

Assessment of radiological evidence of loosening after reconstruction was performed by one of the authors (Z-k.Z.) who was blinded for this purpose. Anterior-posterior radiographs of the pelvis and lateral radiographs of the hip were evaluated at every follow-up visit. Acetabular bone defects were assessed according to the classification of D'Antonio *et al.*[18] and the stem according to that of Pak *et al.*[19] (Table 2). In the area of the acetabular component, radiolucency was classified according to the criteria of DeLee and Charnley[20], and in that of the stem those of Gruen *et al.*[21]. Migration of the implants was assessed according to the criteria of Nunn *et al.*[22] and Wetherell *et al.*[23]. After correction for the magnification factor and pelvic rotation, horizontal and vertical cup migrations were determined. Any deviation greater than the accuracy of the measurement technique (determined to be 2 mm) was defined as a definite migration. Definite radiographic loosening of the cup or the stem was defined as migration of 5 mm. Fixation of the femoral stem was assessed radiographically

TABLE 2 Distribution of the bone defects (hips)

Acetabulum*	Femur†
Type I 13 (39.4%)	Type I 8 (24.2%)
Type II 9 (27.3%)	Type II 10 (30.3%)
Type III 10 (30.3%)	Type IIIa 12 (36.4%)
Type IV 1 (3.0%)	Type IIIb 3 (9.1%)
Type V 0	Type IV 0

*, Classification described by D'Antonio *et al*.[18]
†, Classification described by Pak *et al*.[19]

using the criteria ofEngh *et al*.[24] (bone-ingrowth fixation, stable fibrous fixation, unstable fixation).

Statistical Analysis

Statistical analysis was performed with SPSS 16.0 for Windows. The means, standard deviations, medians, and minimum and maximum were determined. Both the time course of all patients' variables and differences between the study groups at each follow-up were calculated. A level of significance of $P \leq 0.05$ was specified for all statistical test methods.

Results

At a minimum of 5 years of follow-up (range, 5–8 years) of 33 patients who had been treated by two-stage revision for infected THAs, no reinfection and loosening were found. Cultures of samples (three samples/patient) taken during the second stage were all negative for infection. The mean HHS improved from 42 preoperatively to 89 at the final follow-up. At final follow-up, two patients had dull pain when they moved and three patients had mild limps. According to the system of DeLee and Charnley[20], a radiolucent line adjacent to the acetabular component was seen in zone 1 on three hips and in zone 2 on four hips; no radiolucent lines were seen in zone 3. All radiolucent lines were less than 2 mm and there was no evidence of progressive widening. The range of motion was well improved at the final follow-up. Leg-length discrepancy more than 2 cm was found in 3 patients.

According to the method described by Engh *et al*.[24], 30 patients achieved stable bone ingrowth and the remaining three had stable fibrous ingrowth. Allogeneic cortical bone plate grafts were used in 10 hips on the femoral side. Twelve months after revision, nine of these cortical bone plates had fused with the host bones (Figs 1,2), whereas one remained unfused, but was found to have fused by the 24 month follow-up. Impaction bone allografts were used in 11 hips for acetabular bone deficiency and in all femoral canals. All morselized

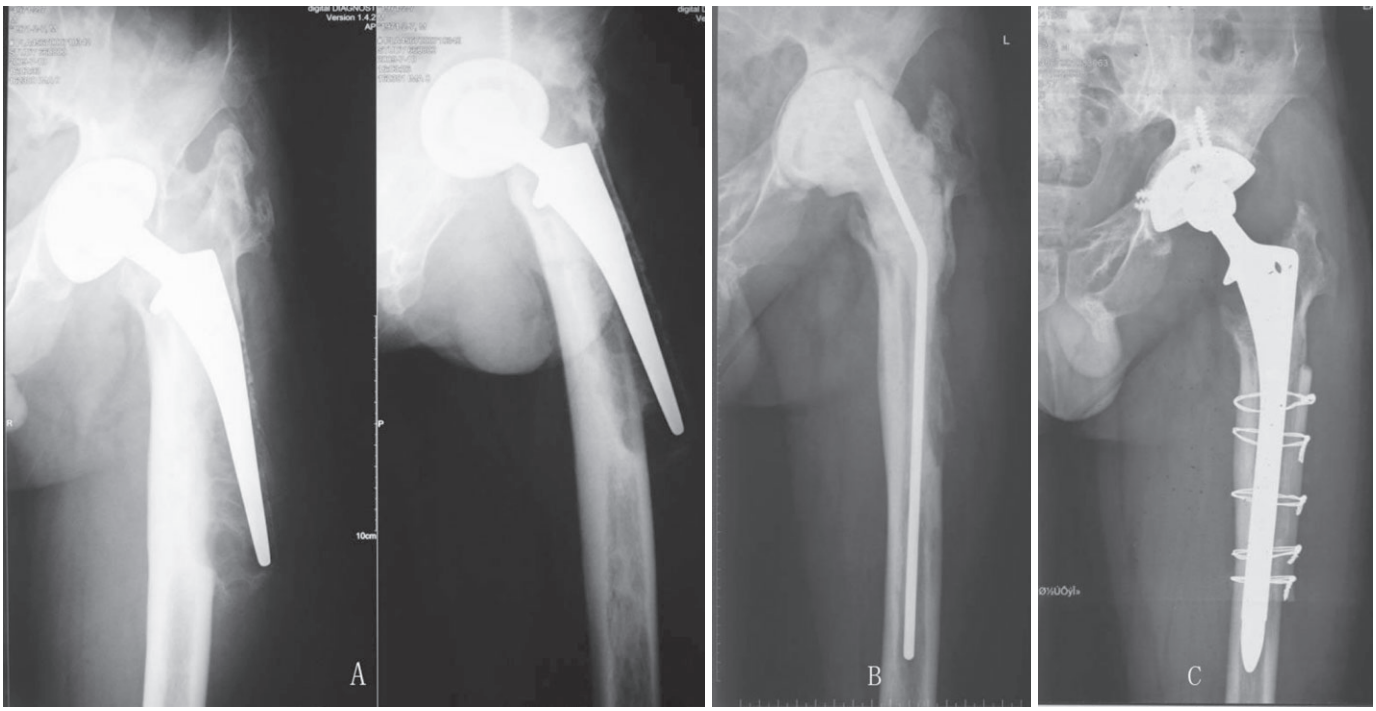

Fig. 1 A 39-year-old man 7 years after THA complicated by infection with femoral bone defect Paprosky IIIa.
(A) X-ray films before revision.
(B) X-ray film 1 month after removal of component and placement of an antibiotic-impregnated cement spacer.
(C) X-ray film showing a well-fixed extensively coated non-modular stem 5 years after reimplantation.

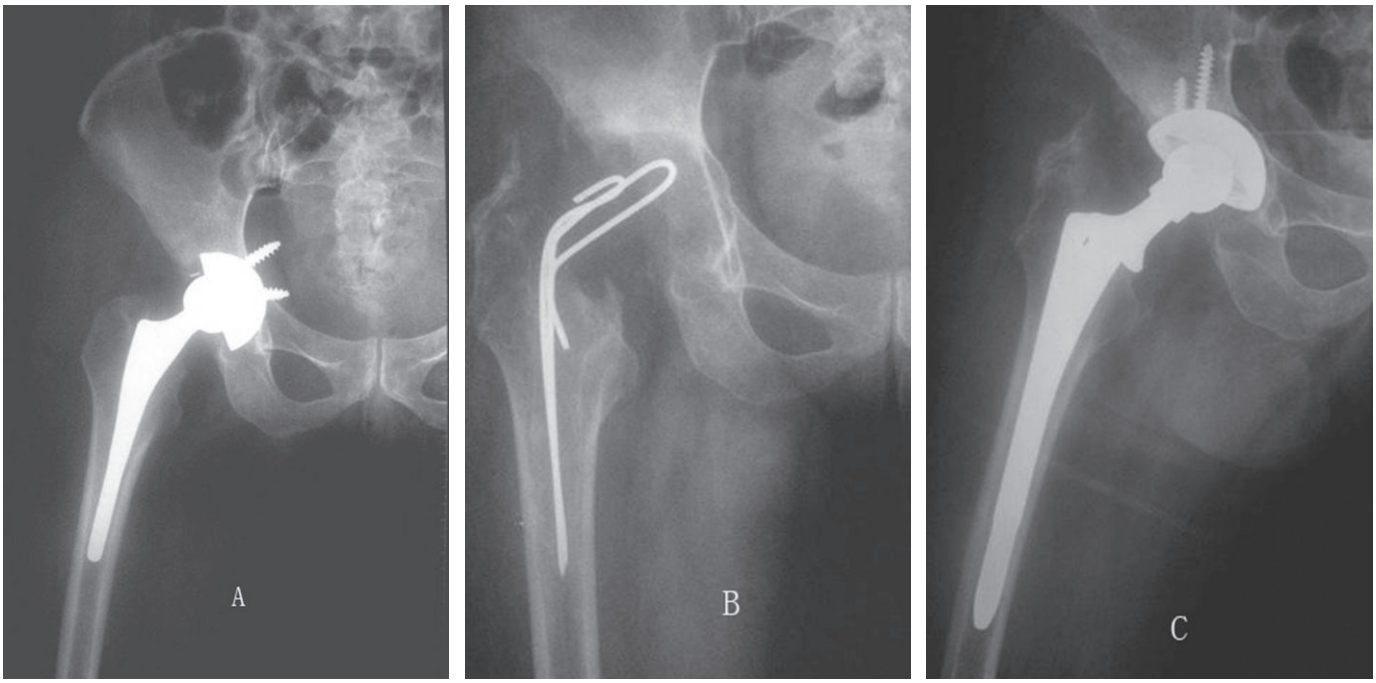

Fig. 2 A 54-year-old man 10 years after THA complicated by infection.
(A) X-ray films before revision.
(B) X-ray film 2 months after removal of component and placement of an antibiotic-impregnated cement spacer.
(C) X-ray film showing a well-fixed extensively coated non-modular stem 5 years after reimplantation.

bone allografts had fused well with the host bones 12 months postoperatively.

Discussion

In the present investigation, two-stage surgery using extensively coated non-modular stem was chosen for treating patients with infectious hip arthroplasties. We achieved equivalent or even better clinical and radiological outcomes than studies reporting similar procedures with modular stems.

This study has a number of limitations. The sample size was small and the rate of positive cultures low (12/33). We believe there were two reasons for the latter. First, bacteria that cause periprosthetic infection usually occur in very small numbers in the form of a biofilm, which means they are often sessile, and are characterized by a slow rate of reproduction[25,26]. Second, bacterial cultures of specimens from patients who have been managed with oral or parenteral antibiotics before the diagnostic aspiration is performed are frequently negative. The reported rates of negative culture of preoperative aspirates range from 7% to 50%. The phenomenon of abuse of antibiotics is very common. We believe that rigorous removal of all foreign material and radical debridement of inflamed and necrotic tissues are essential for the success of any form of septic prosthesis revision[27,28].

During the last three decades, cementless revision stems have become an appealing option for the arthroplasty surgeon treating patients with deficient femurs. These stems are suitable for use with various types of bone deficiency and are compatible with extended trochanteric osteotomies. Modular stems offer the advantage of adjustment and restoration of joint kinematics including leg length, version and offset, regardless of the exact position of the distal part of the stem. However, modular prostheses are costly and concerns about the potential complications of fretting and fracture at the modular junction have been raised. Lakstein *et al.* reported six patients with fractures at the mid-stem junctions of modular revision hip implants in a database of patients who had undergone revision arthroplasty[11]. Risk factors for fractures of the modular junction include excessive body weight, inadequate proximal osseous support consequent to trochanteric osteotomy, reduced preoperative bone stock, osteolysis, loosening and/or undersized implants. Barrack believes that modular stems introduce increased complexity, cost and potential complications and are unnecessary in revision total hip arthroplasty[3]. Using modular cementless prostheses, Fink *et al.* achieved stable bone-ingrowth fixation in 94% of their patients and two subsidences. In our study we used non-modular stems: there was no reinfection, loosening or subsidence[29]. Thus, using extensively coated non-modular stems in two-stage revision for treating infected THAs can achieve satisfactory outcomes.

The survival rate of cementless implants in aseptic hip revisions is believed by some to be higher than that of

cemented implants[10,12,30,31]. A few reports have described the stability of cementless fixation after septic revision using mostly non-modular implants. Hofmann *et al.* achieved stable bone-ingrowth fixation in 96% of their cases using non-modular cementless prostheses[32]. Fehring *et al.* achieved stable bone-ingrowth fixation in 96% of their cases using non-modular and modular cementless prostheses with proximal fixation[15]. Masri *et al.* achieve 95% bone-ingrowth fixation after more than two years using cementless non-modular stems. The rate of early loosening of cementless revisions stems reportedly varies from 0% to 18%[27]. Sanchez-Sotelo *et al.* ascribed the relatively high rate of mechanical failure to the large proportion of proximal fixation uncemented femoral stems used in their study[33]. It has been suggested that using cementless components designed for distal fixation may decrease the rates of mechanical failure after reimplantation. In our opinion, the low rates of subsidence (0%), loosening (0%) and high rate of bone-ingrowth fixation (91%) of the cementless non-modular revision stem system we used are attributable to the distal fixation procedures in viable bone.

Our data lend support to the contention that two-stage cementless revisions of infected total hip arthroplasties using non-modular stem combined with local and systemic antibiotic therapy regimens lead to high rates of eradication of infection comparable to the rates achieved by two-stage cemented revisions with antibiotic-loaded cement. We believe four factors contribute to the success of our procedure. First, we believe rigorous removal of all foreign material and radical debridement of inflamed and necrotic tissues are essential for the success of any form of septic prosthesis revision[26–28]. Second, we knew the nature of the infecting microorganism and its antibiotic susceptibility in many of our cases. Third, we administered specific systemic therapy with antibiotics of high bioavailability to which the bacteria were likely highly sensitive (or definitely sensitive in patients from whom positive cultures had been obtained) coupled with high doses of vancomycin and gentamicin as local antibiotics on a regular basis. Although the rate of positive cultures was low, vancomycin and gentamicin have a broad spectrum of activity[15,30]. Four, the treatment regime is effective. The 4-week duration of parenteral antibiotics we used seems short. However, it is consistent with the recommendations of Nestor *et al.*[31] and Romanò *et al.*[34]. Also, the total duration of antibiotic treatment of 3 months in our patients is consistent with the recommendations of Zimmerli[35] and Trampuz and Zimmerli[36]. The spacer period we used is also short, but has been used by Fehring *et al.*[15] and Nestor *et al.*[31]. Moreover, the 100% rate of eradication suggests our protocol is adequate.

It is widely accepted that two-stage revision surgery further depletes bone stock. In the face of this bone loss, allografts are frequently necessary to help with final reconstruction. The use of allograft bone in total hip revision for septic failure remains controversial[37]. Because allografts act as potential sequestra, they may lead to a high rate of recurrence of infection in infected two-stage revisions. Previous studies have examined the use of allografts in the final reconstructions after infection, and there does not appear to be an increase in reinfection rate. Berry *et al.* used various combinations of morselized and bulk allografts in the second stage of revision for infection, and reported only two recurrent infections in 11 patients at a mean follow-up of 4.2 years[38]. Alexeeff *et al.* used massive structural allografts in the second stage of a two-stage procedure in 11 patients. They reported no further sepsis at a mean follow-up of four years[39]. We used morselized allografts from a femoral head for acetabular reconstruction in 11 patients. We used cortical bone grafting in 10 hips and intramedullary impaction bone grafting on all femoral sides, none of which developed subsequent reinfection. We conclude that, provided the infection is well controlled, two-stage revision with uncemented prostheses allows the use of allografts and is safe and effective.

With good control of the infection during the first-stage, using extensively coated non-modular stem combined with allograft in two-stage revision for treating infected THAs can achieve satisfactory outcomes.

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