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# Management of periprosthetic joint infection after total hip replacement using a custom made articulating spacer (CUMARS); the Exeter experience

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# Abstract

Periprosthetic joint infection (PJI) after THA is a major complication with an incidence of 1-3%. We report our experiences with a technique using a custom-made articulating spacer (CUMARS) at the first of two-stage treatment for PJI. This technique uses widely available all-polyethylene acetabular components and the Exeter Universal stem, fixed using antibiotic loaded acrylic cement. Seventy-six hips were treated for PJI using this technique. Performed as the first of a two-stage procedure, good functional results were commonly seen, leading to postponing second stage indefinitely with retention of the CUMARS prosthesis in 34 patients. The CUMARS technique presents an alternative to conventional spacers, using readily available components that are well tolerated, allowing weight bearing and mobility, and achieving comparable eradication rates.

## Introduction

Periprosthetic joint infection (PJI) following total hip replacement (THR) remains a serious burden for affected patients and a therapeutic challenge for treating surgeons. Despite current best practices, it is estimated that the incidence of deep infection following primary total hip replacement ranges from 1 to 3%. [1, 2] With increasing numbers of joint replacements being performed worldwide, the burden of infected cases will increase for surgeons and the health services in which they operate.[3] There remains considerable controversy on how best to manage these patients with options including;

- 1. debridement and implant retention (DAIR),
- one-stage exchange procedure that combines removal of the infected prosthesis, debridement of the infected tissues and reconstruction of the joint in the one surgical procedure followed by appropriate systemic antibiotic therapy [4, 5] and
- 3. two-stage exchange involving the removal of implants and debridement of infected tissues during a first operation followed by an interval period with systemic antibiotic therapy with eradication of infection confirmed. At the end of this period the definitive joint reconstruction is undertaken as the second stage.[4, 6-13]

When the two-stage exchange revision technique is employed, a spacer containing antibiotic loaded cement is commonly inserted, the nature of which varies from cement beads and cement blocks to an articulating spacer with a metal endoskeleton.[10-12] Depending on the type of spacer utilized, their functions may include local delivery of high-dose antibiotics, reduction of periarticular tissue contracture and scar formation and some may enable reasonable weight bearing and joint mobility. All of these factors help to reduce the complexity of the second stage reconstruction.

At our institution we initially used a two-stage revision protocol with debridement, implant removal and insertion of non-articulating cement spacers at the first stage. The interval period between the two stages was poorly tolerated by patients because of the requirement for traction, limb shortening, pain and limited mobility. In addition non-articulating spacers did little to prevent periarticular fibrosis and shortening, resulting in difficulty with exposure and reconstruction at the second stage, and prompting a desire for an alternative that was better tolerated and aided reconstruction.

The PROSTALAC system (Depuy, Warsaw, Indiana) is a temporary hip replacement created at the first stage from specialized metal and plastic components coated in antibiotic-loaded cement. The rationale for its use is delivery of antibiotic through a prosthesis that preserves leg length and maintains function during the interval phase. Its effectiveness in the eradication of infection is well-established.[11] Unfortunately the availability of this device is limited and at present it is not approved for use in many countries, including the European Union (EU).

This lack of availability prompted the development of a custom-made articulating spacer (CUMARS) that uses a standard all polyethylene acetabular component and the Exeter Universal femoral stem (Stryker Orthopedics, Mahwah, New Jersey) implanted with cement containing antibiotics tailored to the infecting organism. Since its inception in January 2001, the technique has been modified based on our experiences.

The aim of this study is to describe the results of the CUMARS treatment method in a consecutive group of patients from the introduction of this technique and to report the drivers for evolution of this technique since its introduction. This study is a retrospective, consecutive case series of patients treated with the CUMARS technique at the first stage for

periprosthetic infection, with a minimum follow-up of two years. All data was collected prospectively.

## Methods

All patients were treated at a single centre by experienced arthroplasty surgeons. All patients suspected of a periprosthetic hip infection on clinical and radiological grounds were investigated with serum C-reactive protein (CRP) assay and erythrocyte sedimentation rate (ESR). Infection was considered to be present if the CRP was greater than 10mg/L and/or the ESR was greater than 30 mm/hr [14] in combination with clinical suspicion. Pre-operative aspiration for cell count, gram stain, culture and antibiogram was performed except in the setting of acute sepsis or discharging sinus. Pre-operatively, microbiologist advice was sought for the most appropriate heat-stable antibiotic addition to the cement for the planned CUMARS construct and for post-operative systemic treatment. The cement used was either Simplex P containing colistin and erythromycin (Howmedica, Limerick, Ireland) or Palacos R containing gentamicin (Heraeus Medical, Newbury, United Kingdom). Most commonly the antibiotics added to these were vancomycin and/or gentamicin. Usually the concentration used was 3g of vancomycin and/or 2g of gentamicin being added to each mix of cement used.

## Surgical Technique

All procedures were performed through a posterior approach. Prior to opening the joint, fluid was aspirated and sent for urgent cell count and gram stain. Five tissue samples were taken for further microbiology analysis and extended microbiological culture prior to perioperative intravenous administration of antibiotics. In all cases a meticulous tissue debridement and lavage was performed, implants and loose cement were removed and the bone stock was assessed. In appropriate cases, the condition of any well-fixed femoral

cement mantle was assessed. Once satisfied that a clean substrate for re-implantation existed, the CUMARS was constructed and implanted.

# **CUMARS Temporary Spacer Technique**

For the acetabular side, an appropriately sized Exeter Contemporary flanged cup (Stryker Orthopedics, Mahwah, New Jersey) was liberally coated in acrylic cement, mixed with the addition of up to 5g of antibiotics, tailored to the infecting organism when known. For the femoral side, an appropriately sized Exeter Universal stem (Stryker Orthopedics, Mahwah, New Jersey) was similarly coated with this custom cement (Figure 1). The principle used for fixation of the CUMARS was one of macroscopic fit to the contours of the bony cavities, rather than microscopic interlock with cancellous bone that is performed during a properly cemented primary THR. Once the relevant component was coated in its antibiotic cement, it was inserted into the respective compartment whilst the cement was still in the doughy phase. This enabled the cement to conform to the bony contours of the femur or acetabulum without bony interdigitation, with the intention of facilitating extraction of the spacer at the second stage. When the cement had almost cured, the implants were removed from the cavity, in the hope that this would prevent microscopic interlock between the cement and the bone, and the cement covered implant was then re-inserted. This 'near fit' provided reasonable initial torsional and longitudinal stability. No suction drains were used and post-operatively patients were able to weight bear as tolerated. Broad-spectrum IV antibiotics were given in the immediate peri-operative period and then adjusted according to the definitive antibiogram of the infecting organism prior to discharge. Oral antibiotics were substituted once the CRP level had fallen below 50 mg/L, again following microbiological advice and the results of intra-operative tissue samples. Patients were discharged on oral antibiotics for no less than six weeks and reviewed by their local doctor

with weekly CRP measurements. Patients were reviewed at six weeks and if the clinical and inflammatory markers were satisfactory, the second stage surgery was planned.

In response to higher than anticipated post-operative pain, thought to be due to the intentional 'near fit' of the CUMARS construct, the early surgical technique was very quickly modified. Removal of the implant and cement at the second stage had proven to be relatively easy and emphasis at the first stage was therefore altered to favor better fixation of the CUMARS, rather than its removal at the second stage. As a result, the cement-covered implants were inserted into their respective cavities and enough compression applied to achieve more secure fixation. On the femoral side, this meant insertion of the cement-covered stem, followed by firm compression without the subsequent removal of the stem described above. In some instances cement was injected into the cavity followed by insertion of the stem into the cement mantle.

As we gained experience with this technique, it became clear that if the infection was eradicated, a stable CUMARS implant could provide for pain free mobilization, allowing considerable delay before the second stage was required and indeed potentially obviate the need for the second stage procedure indefinitely. Our experience with the CUMARS technique therefore includes a group of patients who decided not to proceed to the second stage and who continue to live with the "temporary" prosthesis.

# <u>Later Modifications to the CUMARS Technique (Long-term Spacer)</u>

As a result of the experience gained with better fixed implants, and because many patients appeared to live happily with their CUMARS, we modified the technique for some patients, creating a construct that was fixed as securely as possible with the heavily antibiotic-laden cement. Patients for whom this technique was selected were lower demand patients with comorbidities, for whom we hoped we could avoid the need for further revision surgery. We

acknowledged that the high concentrations of antibiotics would weaken the physical properties of the cement and would lead to loosening in fit and active patients, so we continued to use the original two-stage approach for this group of patients.

For the purposes of analysis, we have divided patients into those for whom the intention was to proceed to a second stage operation (temporary spacer) and those whose implants were intended to remain in place indefinitely (long-term spacer).

# Post-operative review

Patients were reviewed post-operatively at standard intervals with monitoring of haematological markers. Eradication of infection was defined as a period of no less than two years with normal laboratory inflammatory markers and no clinical stigmata of infection.

Clinical outcomes were measured prospectively using Oxford scores, [15] Harris Hip [16] and modified Charnley-D'Aubigne-Postel [17, 18] scores.

## <u>Analysis</u>

All patients treated for PJI with a CUMARS construct between January 2001 and August 2010 (allowing for a minimum two-year follow-up) were included in this retrospective analysis of prospectively collected data. Patients with a documented failure of eradication following first stage CUMARS were also included in the analysis, irrespective of the length of follow-up. All patient records and outcome scores were available for review.

# **Results**

Between January 2001 and August 2010, 76 hips in 75 patients underwent treatment for hip infection using a CUMARS construct at the first stage. There were 38 females and 37 males in the study with ages ranging from 37 to 93 years (mean 71.5, SD 10.7). The reasons for revision are listed in Table 1.

Of these 76 cases, 42 (55.3%) continued to the second stage (two of which had repeated first stage, as described below) at a median 20.4 weeks (IQR 17.6 weeks, range 28 days-2.7 years) between stages (Figure 2). Thirty-four cases (44.7%) have elected to remain with the first stage CUMARS in situ. There were 63 cases from January 2001 to August 2010 where the original, "temporary spacer" technique was used, and 13 cases from January 2006 to July 2010 where a better attempt to insert a more well fixed stem was made (the long-term spacer technique). All of the "long-term spacer" cases have so far retained their CUMARS components, compared with 42 (67%) of the "temporary spacer" technique group (p<0.001).

Overall, those cases with successful eradication of infection for a minimum of two years had an average time from implantation of the 1st stage to end of the review period or death of 6.7 years, ranging from 2.1-12.1 years. Twenty-eight patients (36.8%) died over the course of the review, four of which were within two years of the first stage procedure. Of these, one patient died from intra-abdominal sepsis three weeks following the first stage of the planned two-stage treatment, whilst the remaining patients died of reasons unrelated to the PJI or its treatment. Pre-operative scores were compared with the most recent post-operative scores available, using the Wilcoxon test for paired non-parametric data. There was a significant improvement in modified Charnley-D'Aubigne-Postel (p<0.001 for pain and function, p=0.002 for range of motion), Harris (p=0.004 for pain and p<0.001 for function) and Oxford hip scores (p<0.001).

A summary of the culture results at time of treatment with the CUMARS construct is presented in Table 2. The details of the seven cases where no organism was identified are as follows: three patients were revised on clinical and radiological suspicion of deep infection, including the presence of a large amount of frank pus and more than 100 white cells per

high power field seen at microscopy; two patients had chronically discharging sinuses; one patient was systemically unwell and had a CRP of 177 and one patient was on suppressive oral antibiotic therapy for 10 years prior to acceding to revision with a loose hip and bone stock erosion. All of these patients had received antibiotics preoperatively.

# **Eradication of Infection**

Sixty-four (84.2%) cases met the criteria for eradication of infection at a mean of 6.7 years (SD 2.6, range 2.1-12.1) after first stage surgery. There were nine cases that failed this definition of eradication as follows: three patients maintained adequate function with suppressive oral antibiotics and had no further revisions. Two patients underwent repeat single stage revision due to poor function and persistently abnormal inflammatory markers. Eradication was achieved in both cases after repeat first stage. One patient failed eradication despite three first stage revisions, the latter two not involving a CUMARS construct due to extensive bone involvement of the proximal femur. This patient underwent definitive second stage three years later. One patient was revised elsewhere 4.0 years after their second stage for a loose cup and recurrence of infection with the same infective organism. Three weeks following the first stage procedure, one patient developed acute sepsis secondary to infected haematoma and intraperitoneal collection. The hip was lavaged and debrided with prosthetic retention and a laparotomy performed. This patient died the following week due to multi organ failure and sepsis. The final patient has failed eradication despite initial two-stage revision and two further first stage revisions and currently remains on oral suppressive therapy. There were also three patients who died of unrelated causes before reaching the two-year mark (at 9 months and 1.3 years post first-stage and 12 months post second stage).

## **Complications**

Other than failure of eradication, there was an overall complication rate of 22%, with unplanned revision as an endpoint occurring in 13%, described further in Table 3.

# Secondary Analysis

Of the 76 cases treated with the CUMARS technique, 34 (44.7%) patients have reported acceptable function and have elected to postpone the second stage indefinitely. All of the 13 cases performed with the "long-term spacer" technique have postponed their second stage. For the purpose of analysis, this group of delayed two-stage cases were compared to the remaining 42 cases of patients who have undergone definitive second stage. Including one early failure in each group, the median time in situ was 5.6 years for the delayed group (IQR 3.3, range 0.12 - 12.05) compared with 8.0 years of combined time in situ for the two-stage group (IQR 4.28, range 0.08 - 11.04) ( Figure 3), with a median time to second stage of 20.4 weeks (IQR 17.6 weeks, range 28 days-2.7 years).

There was no statistical difference in cure rates between the delayed and two-stage groups, or the "temporary spacer" and "long-term spacer" techniques as analyzed by the chisquared test (p=0.302 and p=0.965 respectively). Comparing modified Charnley-D'Aubigne-Postel, Harris and Oxford hip scores there was no statistical difference between the groups except for Harris function (median 20.5 for delayed group compared with 28.0 for two stage, p=0.011). There were significantly more complications (Table 4) in the two-stage group when compared using the chi-squared test.

## Discussion

The management of PJI is often time-consuming and associated with costly use of hospital and surgeon resources. [19, 20] Treatment ranges from long-term antibiotic suppression, debridement with prosthetic retention, resection arthroplasty, one- or two-stage reimplantation or arthrodesis. In terms of patient satisfaction and long-term functional

outcomes, eradication of infection and re-implantation is desirable. [21, 22] Contemporary literature remains divided as to the best method for re-implantation with advocates of both one- and two-stage techniques.

Many authors have reported successful eradication rates of 90% or better. [7-13, 23] A recognized, successful system with long-term reproducible results is the PROSTALAC system (DePUY, Warsaw, Indiana). The authors believe that the success is due to the ability of the articulating spacer to promote improved joint function and early mobilisation, maintenance of leg length and retention of tissue planes, whilst the cement mantle permits local delivery of antibiotics.[23] This system is not readily available for clinical use in all countries, including countries in the European Union (EU). In proposing the CUMARS construct, we feel that this has the same theoretical advantages as the PROSTALAC system but in contrast, it uses components that many surgeons are familiar with and which are readily available. Data from this single-centre retrospective analysis of 76 cases with a minimum of two-year follow-up demonstrates comparable results with those reported in the literature for both one- and two-stage reconstruction. [11, 23-26] In a recent meta-analysis, Beswick et al [24] reported no difference in eradication rates when comparing one- and two-stage reconstructions. This, combined with less patient morbidity [27, 28] and lower resource costs [19, 20] makes the option of one-stage reconstruction an attractive one in cases where that is possible. Initially designed as the first of a two-stage reconstruction, the results of the CUMARS construct have been encouraging; with eradication rates that are comparable to other reported methods, and a construct that is well tolerated by patients. A common clinic scenario is that of a well-functioning articulating spacer, no evidence of infection and a reluctance to accept the need for second stage re-implantation. In this setting the current practice of this unit is often to delay the

second stage until there is a decline in function and/or radiological failure, particularly for lower demand or high-risk patients. As reported in this series the CUMARS spacer has continued to function effectively out to 12 years.

Whilst the comparative data on delayed two-stage and two-stage reconstruction presented in the secondary analysis of this study is encouraging, it is difficult to draw a meaningful conclusion given the limitations. The dataset is relatively small, and by necessity, only those patients who continue to have a well-functioning CUMARS remain in the delayed group, thereby creating a clear selection bias.

What remains to be seen is the effect on long-term implant fixation of the addition of significant concentrations of antibiotic to the cement mantle. Dunne *et al* have reported that *in vitro*, following the addition of gentamicin powder to acrylic bone cement in concentrations of 1-4g per 40g cement powder, there is a mean reduction in compressive and bending strengths of up to 18% plus a reduction in fatigue performance when compared with unloaded cement. [29] At present the effect on long-term fixation of antibiotic loaded acrylic cement *in vivo* is not known and requires further study. This unknown variable, in addition to the current CUMARS technique that promotes macrointerlock of cement with bone but not micro-interlock may compromise the long-term survivorship of the CUMARS.

The results presented here are from a heterogeneous group of patients, in whom an evolving technique was used. It reports the "learning curve" with this technique, which as a result was subject to change. This has produced some findings that are distorted by bias.

Not least of these is the complication rate seen in the two groups – those that have proceeded to second stage and those that have not (the delayed second stage group). The complication rate for the former group was significantly higher, but this is most likely due to

selection bias. In several cases the second stage procedure went ahead earlier than planned because of the occurrence of a complication in the interval between the first and second stages. Those patients who had a complication were therefore more likely to have a second stage procedure, whereas only successful, well-functioning implants remained in the delayed second stage group of patients.

The complications were themselves drivers for change in the evolution of the technique described above. In our early experience with the CUMARS, we had a relatively high rate of dislocations and periprosthetic fracture, which we felt was likely due to the combination of a poorly fixed, rotationally unstable implant in bone made weak by infection, previous implant loosening and, of course, patient age. Whereas our initial concern was to avoid rigid fixation of the CUMARS, to prevent extraction problems at the second stage, it soon became apparent that extraction was not difficult but the loosely fixed femoral component may be contributing to periprosthetic fractures. We therefore changed the technique, to improve femoral fixation and, as a result, the torsional stability of the CUMARS. Our second common complication that frequently necessitated an early second stage revision was dislocation of the hip. Again, we felt that poorly fixed implants may contribute to this complication, but in addition to improving implant fixation we have also changed to use of larger diameter bearings for our CUMARS and, in some cases with absent abductors, to the use of constrained acetabular components.

The current body of evidence regarding the treatment of PJI is based primarily on analyses of longitudinal studies and case series of differing techniques. The study presented here is subject to the same limitations as those from other centres but we believe it validates the use of the CUMARS technique as an effective first stage articulating spacer, which in conjunction with best practice systemic treatments, delivers comparable eradication rates

and improved patient outcomes. Longer term follow-up is necessary to fully evaluate this technique but early results are promising.

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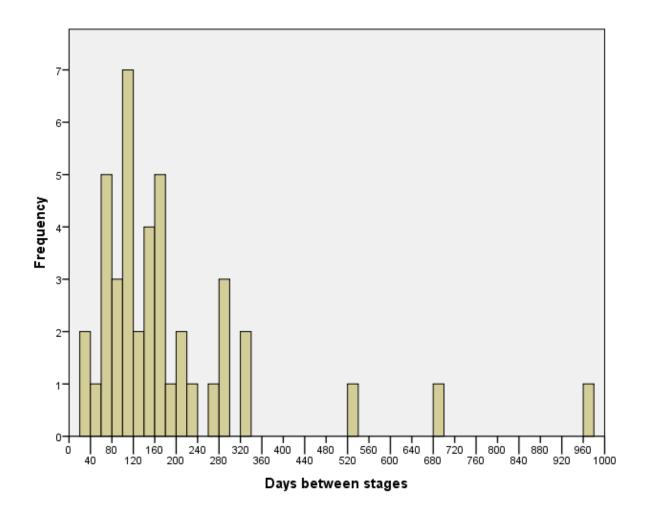
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**Figure 1.** Exeter Universal stem coated in Palacos R acrylic cement prior to insertion into the prepared femoral canal as used in the "temporary spacer" technique. The cement coated implant is pushed into the femoral canal and the cement allowed to polymerise before reduction of the hip.



Figure 2: Days between stages for those patients proceeding to second stage



Reason for Revision	n
Infected THR (Primary or Revision)	67
Infected internal fixation device	4
Infected Hemiarthroplasty	3
Native hip septic arthritis	2

Table 1. Reason for revision.

Infecting Organism	n	%
No Growth	7	9.1
Staphylococcus aureus	16	20.7
Staphylococcus epidermidis	15	19.5
Coagulase Negative Staphylococcus	15	19.5
Streptococcus	8	10.4
Escherichia coli	4	5.2
MRSA	3	3.9
Pseudomonas	2	2.6
Enterococcus faecalis	2	2.6
Clostridium	1	1.3
Mixed	1	1.3
Listeria	1	1.3
Morganella	1	1.3
Propionibacterium	1	1.3

Table 2: Summary of microorganisms identified on intra-operative specimens

Complication	Occurrence		Requiring Unplanned Revision		Technique
	n	%	n	%	
Dislocation	8	10.5%	4	5.3%	1 long-term spacer
Periprosthetic fracture	6	7.9%	4*	5.3%	All temporary spacers
HO/Hardware irritation	2	2.6%	2	2.6%	Temporary spacers
Death	1	1.3%			Temporary spacer
Overall	17	22.4%	10	13.2%	

Table 3: Summary of complications, excluding failure of eradication.

<sup>\*</sup>The remaining 2 periprosthetic fractures were identified intra-operatively during second stage reconstruction and treated at that time.

Complication	Delayed two- stage	Two-stage
Dislocation	2	6
Periprosthetic fracture		6
HO/hardware irritation		2
Death	1	
Overall (%)	3 (8.8%)	14 (33.3%)

Table 4: Comparison of complication frequency by group