INTERSPACE® PRE-FORMED SPACER SYSTEM LITERATURE REVIEW

In September 2020, a systematic review of globally accumulated literature was conducted showcasing positive clinical evidence for the routine use of InterSpace.

The following compilation of papers highlights those clinical publications from the systematic review along with many relevant papers to the effective use for the InterSpace family of products.

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Exactech®

Release of Gentamicin and Vancomycin from Temporary Human Hip Spacers in Two-Stage Revision of Infected Arthroplasty

Bertazzoni Minelli E, Benini A, Magnan B, Bartolozzi P.

J Antimicrob Chemother. 2004 Feb;53(2):329-34. Epub 2003 Dec 19.

ABSTRACT – AIM

Evaluation of the delivery of gentamicin and vancomycin from polymethylmethacrylate (PMMA) spacers before and after implantation for the treatment of total hip replacement infections.

METHODS

Twenty industrially produced spacers containing gentamicin (1.9%) were utilized. Vancomycin (2.5%) immersed in phosphate buffer at 37 degrees C for 10 days. Antibiotic concentrations were determined by fluorescence polarization immunoassay.

RESULTS: Gentamicin and vancomycin were still present in all the spacers removed from the patients. The release of gentamicin alone and in combination with vancomycin was in the range 0.05%-0.4% of the initial amount present, whereas the release of vancomycin was in the range 0.8%-3.3%. The release kinetics showed a similar pattern for both drugs. After a high initial release of drug, a reduced, but constant, elution was observed over the next few days.

CONCLUSIONS: The delivery of gentamicin and vancomycin from PMMA cement was high initially, with sustained release over several months. Incorporation of vancomycin into the surface of the spacers permitted spacers to be prepared with multiple antibiotics present and without adversely affecting the release kinetics of the agents. The gentamicin-vancomycin combination shows potential for the treatment of infection following total hip replacement in specific patients.

KEY QUOTE

"The superficial application of vancomycin using the 'surface drill hole' technique eliminates the problem of interference between release of gentamicin and vancomycin from PMMA cement. Moreover, the concentrations of gentamicin (1.9%) and superficial vancomycin (2.5%) enabled us to obtain an optimal ratio (1:1) in this elution system." (p. 332)

Exactech Literature # 002I

Drainage and Serum Levels of Antibiotics Following Temporary Spacer Implants in Two-Stage Revision Surgery

Bertazzoni Minelli E, Benini A, Magnan B, Bartolozzi P.

Proceedings of the 24th meeting of the European Bone and Joint Infection Society. 2005; Lubiana.

INTRODUCTION

Polymethylmethacrylate (PMMA) cements impregnated with aminoglycosides and/or vancomycin are currently utilized as local antibiotic carriers in orthopaedic prosthetic infections.

AIM

The local and systemic release of gentamicin from temporary spacers loaded with 2.5% gentamicin (Spacer-G®) was studied in patients undergoing two-stage revision surgery.

KEY QUOTE

"We found that the maximal drug release from spacers occurs within the first few days and that explanted spacers are able to release bioactive antibiotics 3-6 months after implantation." (Results)

Exactech Literature # 001I

Pre-Formed Articulating Knee Spacer in Two-Stage Revision for the Infected Total Knee Arthroplasty

Pitto RP, Castelli CC, Ferrari R, Munro J.

Int Orthop. 2005 Oct;29(5):305-8. Epub 2005 Aug 5.

ABSTRACT

We performed a prospective study to assess safety and effectiveness of a pre-formed articulating spacer made of gentamicin-impregnated acrylic cement in the management of infected total knee arthroplasty. Twenty-one consecutive patients with unilateral deep infection were treated by two-stage revision in two centres. Two patients were excluded, and 19 patients remained available for assessment. The mean implantation time of the spacer was 12 weeks. The rehabilitation programme between stages consisted in early range of motion exercises and partial weight bearing. Mean follow-up after removal of the spacer and insertion of the final prosthesis was 24 (range, 12-43) months. No patient had recurrence of infection at the latest follow-up. The mean Knee Society functional score during spacer management was rated 75 points and was rated 84 points at the latest follow-up. No device-related complication was observed.

KEY QUOTE

"Unfortunately, cement spacers moulded in the operating theatre do not have reproducible mechanical characteristics, and there is a potential risk fracture of the components… Scott used a spacer prosthesis in combination with antibiotic-impregnated cement chains. A major drawback of the spacer prosthesis is the presence of hardware, which could theoretically favour bacterial adhesion." (Discussion)

Exactech Literature # 003I

Strategies and Results of Two-Stage Treatment for the Infected THA and TKA

Meani E, Castelli C.

Poster presented at the American Academy of Orthopaedic Surgeons Meeting; 2006 March 22-26; Chicago, IL.

KEY QUOTE

TKA block spacer disadvantages "Stage 1: pain, difficult mobility, knee instability and bone loss. Stage 2: scar formation, shortening of the extensor mechanism, retraction of the joint capsule and ligaments and more constrained implant."

Exactech Literature # 005I

Measurements of In Vivo Intra-Articular Gentamicin Levels from Antibiotic Loaded Articulating Spacers in Revision Total Knee Replacement

Mutimer J, Gillespie G, Lovering AM, Porteous AJ. Knee.

2009 Jan;16(1):39-41. Epub 2008 Sep 10.

ABSTRACT

Previous in vitro studies have found high levels of antibiotic release in the days immediately following implantation of antibiotic loaded articulating spacers. However there are relatively few data describing the elution profile beyond this immediate period. This study was designed to measure if gentamicin levels continue to be clinically therapeutic after an extended period following in vivo implantation. Twelve patients received a gentamicin loaded articulating spacer between a 1st and 2nd stage revision total knee arthroplasty. At the 2nd stage procedure synovial fluid and blood samples were collected and assayed for the presence of gentamicin. The second stage revision occurred at a median of 99 days following spacer insertion. The median intra-articular gentamicin levels were 0.46 mg/L (0.24 to 2.36 mg/L) which would be considered therapeutic. There were no cases of reinfection. In this study, preformed articulating spacers containing gentamicin provided therapeutic concentrations in the synovial fluid surrounding the joint throughout the period of implantation. These data confirm the observations from in vitro studies, where a prolonged elution profile was observed for such spacers.

KEY QUOTE

"In this study, preformed articulating spacers containing gentamicin provided therapeutic concentrations in the synovial fluid surrounding the joint throughout the period of implantation."

Exactech Literature # 012I

Aseptic Versus Septic Total Hip Arthroplasty Revision: Comparing the Results

Romano CL, Romano D, Logoluso N, Meani E.

Poster presented at the 76th Annual American Academy of Orthopaedic Surgeons Meeting; 2009 Feb 25-28; Las Vegas, NV.

INTRODUCTION

Two-stage re-implantation using an interval spacer of antibiotic-impregnated bone cement is a well-established and accepted method of treatment for chronic infection of total hip prosthesis with eradication rates exceeding 90 percent in most series.

However, little data is currently available on medium-term results and functional outcome of two-stage revision surgery for chronically infected hip prosthesis compared to aseptic one-stage revision. Preformed articulating antibiotic-loaded spacers provide predictable mechanical resistance and antibiotic elution rates while long step spacers allow the surgeon to overcome the frequent proximal bone loss at the femoral level.

The purpose of this study was to evaluate the medium-term results of aseptic versus two-stage septic hip revision, performed according to a standardized and reproducible treatment protocol.

KEY QUOTE

"Two-stage revisions for infected hip prosthesis using a pre-formed antibiotic-loaded cement spacer (InterSpace Hip) and uncemented revision prosthesis offers medium-term success rates equivalent to one-stage non-infected revisions." (Conclusion)

Exactech Literature # 009I

Treatment of Glenohumeral Sepsis with a Commercially Produced Antibiotic-Impregnated Cement Spacer

Coffey MJ, Ely EE, Crosby LA.

J Shoulder Elbow Surg. 2010 Apr 13. [Epub ahead of print]

ABSTRACT – BACKGROUND

We report our experience in treating infected shoulder arthroplasty and primary shoulder sepsis using a commercially produced antibiotic-impregnated cement spacer.

MATERIALS AND METHODS: We treated 16 shoulders in 15 patients for infected arthroplasty or osteomyelitis of the proximal humerus with irrigation and débridement, hardware removal, or humeral head resection, or both, and placement of an interval articulating hemiarthroplasty with a commercially made gentamicin-impregnated cement spacer.

RESULTS: Mean follow-up was 20.5 months after spacer placement. At the time of débridement, 12 shoulders had positive cultures; the most common organisms were methicillin-resistant Staphylococcus aureus (n = 3) and S. epidermidis (n = 3). Twelve patients underwent revision. Four refused revision and have retained antibiotic spacers. White blood cell counts returned to within normal ranges in all patients at the time of revision, the erythrocyte sedimentation rate in 5 of 12 patients, C-reactive protein in 8 of 12 patients, and interleukin-6 in 9 of 11 patients. Mean visual analog pain scale score decreased from 8.4 before spacer placement to 0.5 at the final follow-up. Active forward flexion increased from a mean of 65 degrees to 110 degrees , and active external rotation from -5 degrees to 20 degrees. Mean University of California Los Angeles (UCLA) Shoulder Rating Scale score increased from 7 to 26, Simple Shoulder Test (SST) from 1.2 to 6.6, American Shoulder and Elbow Surgeons (ASES) Standardized Shoulder Assessment Form score from 16 to 74, and Constant score from 16 to 57. There was no recurrence of infection.

CONCLUSIONS: Treatment of glenohumeral sepsis with a commercially produced antibiotic-impregnated cement spacer appears to be an effective treatment modality, and serum interleukin-6 level appears to be useful in the evaluation of shoulder infection.

KEY QUOTE

"A commercially produced spacer may be as effective in controlling infection as an intra-operatively crafted spacer because it allows for a more predictable level of antibiotic elution, eliminates the operating room time required for crafting the spacer on the back table, has a smooth articular surface, and may allow better shoulder function than intra-operatively produce spacer implants." (Conclusions p. 5)

Preformed Gentamicin Spacers in Two-Stage Revision Hip Arthroplasty: Functional Results and Complications

Pattyn C, De Geest T, Ackerman P, Audenaert E.

Int Orthop. 2010 Nov 30. [Epub ahead of print]

ABSTRACT

Two-stage revisions with antibiotic-loaded spacers have gained popularity for treating infected hip joint arthroplasties. The aim of this prospective study was to assess patient functionality between stages and treatment impact on duration of hospital stay and to describe related complications. Sixty-one consecutive patients with infected hip arthroplasties underwent two stage revision with preformed spacer implantation. Mean Harris Hip and Merle d'Aubigné scores between the two stages were 39.9 and 7.6, respectively. Forty-six patients (75.4%) were able to leave hospital between stages. Spacer dislocation occurred in 16.4%. No cases of spacer breakage were noted. Preformed cement spacers provide acceptable functional outcome between revision hip arthroplasty stages and facilitate the surgical procedure without increasing mechanical complication rates.

KEY QUOTE

"Preformed cement spacers provide acceptable functional outcome between revision hip arthroplasty stages and facilitate the surgical procedure without increasing mechanical complication rates." (Abstract)

"An important finding in our series was the absence of spacer fractures." (Discussion)

Exactech Literature # 014I

Two-Stage Revision of Hip Prosthesis Infection Using a Hip Spacer with Stabilising Proximal Cementation

Gil Gonzalez S, Marqués López F, Rigol Ramon P, Mestre Cortadellas C, Cáceres Palou E, León García A.

Hip Int. 2010;20 Suppl 7:S128-34. doi: 10.5301/HIP.2010.1374. Epub 2010 May 27.

ABSTRACT

Two-stage revision hip arthroplasty for infection using an antibiotic-loaded cement spacer has been used frequently with good results. However, spacer instability is also frequent. Proximal cementation of the spacer could avoid spacer dislocation. We retrospectively assessed 35 patients in whom a 2-stage revision hip arthroplasty for infection was carried out using an antibiotic-loaded cement spacer with gentamicin (Spacer-G) in which the spacer was proximally cemented in 16 patients. The mean follow-up was 32 months.

We assessed spacer stability and infection elimination. There were 8 spacer dislocations (22.9%), 5 in hips without proximal cementation and 2 in hips with proximal cementation ($p>0.05$). There was no fracture in any hip. Reinfection occurred in 5 hips (14.3%), in 3 with the same microorganism, while 2 had a different microorganism. Our results indicate that the proximal cementation of the spacer prevents its dislocation. Infection was eliminated in 86% of the hips.

Two-Stage Hip Revision in Periprosthetic Infection: Results of 41 Cases

Pignatti G, Nitta S, Rani N, Dallari D, Sabbioni G, Stagni C, Giunti A.

Open Orthop J. 2010 Jun 11;4:193-200. doi: 10.2174/1874325001004010193.

ABSTRACT

BACKGROUND: two-stage revision is considered the best treatment approach for the eradication of chronic joint infection. We report the outcome of 41 consecutive patients with infected hip prostheses, treated between 2000 and 2005, with two-stage revision using an antibiotic-loaded cement spacer.

METHODS: Patients underwent a treatment protocol which included clinical and radiographic evaluation, laboratory investigations, hip aspiration, 99mTc-MDP and 99mTc-leukocyte-labeled scintigraphy and intraoperative assessment. All patients were diagnosed with a late chronic infection and classified as B-host according to the Cierny-Mader classification system. 9 patients out of 41 (22%) required a second interim treatment period, with exchange of the spacer. The proportion of methicillin-resistant Staphylococcus was similar between the one-spacer group and two-spacer group (28% vs 33%), whereas the proportion of patients with three or more risk factors was significantly higher in the two-spacer group than in the one-spacer group (28% vs 55%, respectively).

RESULTS: Forty patients had final reimplantation, one patient had a resection arthroplasty. At an average follow-up of 5.3 years no recurrence of infection occurred. The average post-operative Harris hip score improved from 41 to 80.

CONCLUSIONS: In the treatment of two-stage revision arthroplasty the adherence to the protocol proved to be effective for infection eradication and final reimplantation.

Two-Stage Revision Surgery with Preformed Spacers and Cementless Implants for Septic Hip Arthritis: A Prospective, Non-Randomized Cohort Study

Romano CL, Romano D, Meani E, Logoluso N, Drago L. .

BMC Infect Dis. 2011 May16;11(1):129.

ABSTRACT

Outcome data on two-stage revision surgery for deep infection after septic hip arthritis are limited and inconsistent. This study presents the medium-term results of a new, standardized two-stage arthroplasty with preformed hip spacers and cementless implants in a consecutive series of adult patients with septic arthritis of the hip treated according to a same protocol.

KEY QUOTES

"The most relevant clinical advantage of using an antibiotic-loaded spacer is that it helps to maintain joint space and minimizes the risk of large limb shortening, while local antibiotic delivery prevents bacterial re-colonization of the implant. Furthermore, preformed antibiotic-loaded spacers offer off-the-shelf availability, a standardized and reproducible technique, known mechanical resistance predictable antibiotic release and shorter operating time, being available in short and long stemmed shapes that can be chosen intraoperatively based on femoral bone loss." (Discussion)

"Satisfactory outcomes can be obtained with two-stage revision hip arthroplasty using preformed spacers and cementless implants for prosthetic hip joint infections of various etiologies." (Conclusion)

Exactech Literature # 015I

The Use of a Preformed Spacer in Two-Stage Revision of Infected Hip Arthroplasties

D'Angelo F, Negri L, Binda T, Zatti G, Cherubino P.

Musculoskelet Surg. 2011 Aug;95(2):115-20. doi: 10.1007/s12306-011-0128-5. Epub 2011 Apr 9.

ABSTRACT

Two-stage revision with the use of an antibiotic-loaded cement spacer has spread widely as a successful treatment for THA infection. Between 1999 and 2008, 28 patients with infected THA were treated with two-stage implant revision using a preformed spacer. The spacer was left in situ for 5.5 months (range 1-13 months), and the patients were allowed to walk with partial weight bearing. At a mean follow-up of 53 months (range 18-106 months), recurrence of infection was observed in only one patient. Complications were observed in five patients: three spacer dislocations, one distal femoral fracture occurred during stem removal, and one femoral artery pseudo-aneurysm.

The mean HHS increased from 43 points (range 13-77) to 82 points (range 35-96). Though small prospective studies are reported in literature, good eradication rate and good functional outcomes encourage for the use of an antibiotic-loaded cement spacer. The industrial production ensures procedure standardization, well-defined physical and chemical properties to the device and eliminates time necessary to intraoperatory manufacturing.

Pre-Formed Articulating Knee Spacers in Two-Stage Total Knee Revision Arthroplasty

Wan Z, Karim A, Momaya A, Incavo SJ, Mathis KB. .

J Arthroplasty. 2012 Sep;27(8):1469-73. doi: 10.1016/j.arth.2012.01.027. Epub 2012 Mar 14. Erratum in: J Arthroplasty. 2012 Dec;27(10):1879.

ABSTRACT

Two-stage revision arthroplasty using articulating spacers for the treatment of infected total knee arthroplasty (TKA) is a successful management technique. Our purpose was to report our results using preformed, commercially available articulating spacers made of gentamicin-impregnated cement. Thirty-three patients with infected primary or revision TKAs were treated with these spacers using a 2-stage revision technique. In most cases, the spacers were modified intraoperatively by adding a stem of reinforced antibiotic-impregnated acrylic cement. Successful eradication was achieved in 30 of 33 cases at a minimum 2-year follow-up interval. Two patients required a second spacer before successful revision TKA. No spacer fractures or dislocations occurred in this series. No adverse soft tissue effects were noted from the use of this type of articulating spacer.

Two-Stage Cementless Revision of Late Total Hip Arthroplasty Infection Using a Premanufactured Spacer

Neumann DR, Hofstaedter T, List C, Dorn U.

J Arthroplasty. 2012 Aug;27(7):1397-401. doi: 10.1016/j.arth.2011.10.022. Epub 2011 Dec 16.

ABSTRACT

We observed 44 patients with 2-stage revisions for septic hip prostheses. We used a uniform protocol consisting of the implantation of a preformed spacer (interval 12-26 weeks), specific systemic antibiotic therapies, and cementless total hip arthroplasty at time of reimplantation. The minimum follow-up was 36 months (mean, 67 months; range, 36-120 months). During the spacer period, we observed 4 dislocations and 2 fractures leading to a resection arthroplasty interval before reimplantation in 5 cases. In one patient, reinfection was diagnosed 12 months after reimplantation. The Harris hip score increased from a preoperative mean of 39 to 90 at a mean follow-up of 67 months after reimplantation.

Pre-Formed Antibiotic-Loaded Cement Spacers for Two-Stage Revision of Infected Total Hip Arthroplasty. Long-Term Results

Romanò CL, Romanò D, Albisetti A, Meani E.

Hip Int. 2012 Jul-Aug;22 Suppl 8:S46-53. doi: 10.5301/HIP.2012.9570.

ABSTRACT

Two-stage revision is the most widely accepted and performed intervention for chronically infected hip prosthesis and different interim spacers have been proposed. In recent years, antibiotic-loaded preformed spacers have become available on the market. The aim of this retrospective study was to assess the long-term results of two-stage revision with preformed spacers and uncemented hip prosthesis for the treatment of septic hip prosthesis. From 2000 to 2010, 183 consecutive patients underwent two-stage revision of septic hip prosthesis, with a same protocol, including preformed antibiotic-loaded cement spacer and a cementless modular hip revision prosthesis and four to six weeks antibiotic administration. Clinical and radiologic assessment at a minimum follow-up of two years was performed. At a minimum two years follow-up, 10 patients (5.4%) had had an infection recurrence, four (2.2%) an aseptic loosening and four more required partial revision of the modular components of the prosthesis, because of hip instability/dislocation; 21 patients died or were lost to follow-up. Considering all the reasons for revision, survivorship at eleven years was 93.9%. Harris Hip Score improved from 29.1 ± 14.6 pre-operatively to 41.1 ± 15.9 after spacer implant and 81.7 ± 17.6 after hip revision. The main complications after spacer implant included: spacer dislocation (16.4%), intra-operative femoral fractures (2.7%), and thromboembolism (2.1%). Complications after hip revision were: instability/dislocation (4,3%), intra-operative femoral fractures (1.6%), and thromboembolism (3.3%). Two-stage revision of septic hip prosthesis with preformed antibiotic-loaded spacers and cementless hip prosthesis provides satisfactory long-term results, with reduced complications.

Does a Prefabricated Gentamicin-Impregnated, Load-Bearing Spacer Control Periprosthetic Hip Infection?

Degen RM, Davey JR, Davey JR, Howard JL, McCalden RW, Naudie DD.

Clin Orthop Relat Res. 2012 Oct;470(10):2724-9. doi: 10.1007/s11999-012-2350-3.

ABSTRACT

INTRODUCTION: Treating deep infection following THA has been a challenge. While the standard treatment has remained a two-stage revision, spacer designs, incorporated antibiotics, and concentrations have varied. Since control of infection may relate to choice and concentration of antibiotics, it is important to report rates of control from various spacers.

QUESTIONS/PURPOSES: We therefore determined (1) the rate of infection control and (2) complications associated with a prefabricated, load-bearing, gentamicin-impregnated hip spacer in treating periprosthetic infections of the hip.

METHODS: We retrospectively reviewed 33 patients with periprosthetic THA infections treated with a prefabricated, partial load-bearing, gentamicin-impregnated hemiarthroplasty spacer. Thirty of the 33 patients underwent second stage reimplantation after a mean 15 weeks. We collected patient demographic data, laboratory values, infecting organism, size of spacer mold, antibiotic selection, complications, and infection control rates from two academic centers. Recurrent infection at last follow-up was determined by the presence of physical symptoms or signs or elevated serologic tests. The minimum follow-up was 24 months (mean, 43 months; range, 24-70 months).

RESULTS: Twenty-eight of the 30 patients who underwent reimplantation remained infection-free at last follow-up: one patient became reinfected with a different organism secondary to wound problems; one became reinfected with the same organism, but was restaged with the mold used in this study, reimplanted, and subsequently remained free of infection. Two of the 33 patients had persistently elevated inflammatory markers at the completion of their first stage and were restaged with this mold; both underwent reimplantation and remained free of infection at latest follow-up. One of the 33 patients was satisfied and ambulatory with their spacer mold. There were no major complications.

CONCLUSION: Our data supported the use of a partial load-bearing, gentamicin-impregnated hemiarthroplasty spacer in treating deep periprosthetic THA infections.

Low-Dose Gentamicin-Loaded Spacers are Effective for Two-Stage Revision

Romano CI, Drago L, Logoluso N.

Proceedings from Musculoskeletal Infection Society. 2013 July 30

ABSTRACT

Peri-prosthetic infection is among the most common reason for revision in the United States and in Europe. Two-stage revision with antibiotic-loaded spacers is the gold standard with an eradication rate greater than 90 percent. High antibiotic concentration (greater than 2 percent) and the association of more than one antibiotic in the spacer are proposed by different authors in a limited series of patients.

MATERIALS AND METHODS: A systematic review of published papers on two-stage revisions of infected total hip and knee arthroplasties treated with the routine use of an industrial low-dose (1.9 percent) gentamicin-loaded, preformed spacer has been performed. This systematic review evaluated the hypothesis: are high antibiotic concentrations and antibiotic associations necessary for interim spacers in routine two-stage revision surgery? Papers that were included were published in peer-reviewed journals from the years 1995 to 2013 and reported an infection eradication rate of two-stage hip or knee joint prosthesis with the use of an industrial, preformed low-dosegentamicin spacer (Spacer G or Spacer K, Tecres SpA, Italy. InterSpace® Hip or InterSpace Knee, Exactech, Inc. USA). The systematic review excluded case reports, clinical series with less than 10 patients, duplicate studies and mean follow-up less than 24 months. RESULTS: Twenty-four papers were retrieved, 10 of which met the inclusion criteria, yielding a total of 491 spacers implanted in10 centers (seven in Europe, two in North America and one in Oceania). Nineteen patients (3.9 percent) had an infection recurrence/persistence that required a spacer exchange or are section arthroplasty. Twenty-five of the 480 patients (5.2 percent) that underwent the second stage procedure had an infection recurrence/persistence at an average follow-up of 46 months.

KEY QUOTES

"This systematic review provides evidence in favor of the routine use of an industrially, preformed spacer loaded with a standardized, relatively low concentration of gentamicin,[and] that in different centers, showed an average infection eradication rate of 96.1 percent at spacer removal and 94.8percent at the latest follow-up after re-implantation. The systematic review does not support the hypothesis that the antibiotic associations or antibiotic concentrations higher than1.9 percent are routinely needed for spacers used in two stage revision surgery."

Two-Stage Treatment of Infected Total Knee Arthroplasty: Two to Thirteen Year Experience Using an Articulating Pre-Formed Spacer

Castelli CC, Gotti V, Ferrari R.

Int Orthop. 2014 Feb;38(2):405-12. doi: 10.1007/s00264-013-2241-6. Epub 2014 Jan 26.

ABSTRACT

PURPOSE: Infection following knee replacement is an important cause of failure despite rigorous prophylaxis antibiotic protocols. The two-stage reimplantation procedure is considered the gold standard for treatment of subacute and chronic deep periprosthetic infections. The purpose of this study was to determine whether or not a preformed articulated spacer would allow comparable eradication of infection equal to rates reported in published studies and to see whether there is a resulting improvement in postoperative function with an acceptable quality of life, reducing postoperative pain and limiting surgical complications, thus simplifying the second stage of the procedure.

METHODS: We retrospectively reviewed 50 patients with infected TKA who underwent a two-stage exchange arthroplasty using an articulating preformed spacer. The device, designed like an ultracongruent condylar knee prosthesis, is composed of acrylic cement impregnated with antibiotic, with tested and standardised mechanical properties and antibiotic content and release mechanism.

RESULTS: The median follow-up period was seven (two to 13) years. Two-stage exchange arthroplasty was successful in controlling the infection in 92% of patients; 64% of patients where women, and median patient age was 68 (54-80) years. Median implantation time of the preformed spacer was 16 (four to 60) weeks; 4% of infections were delayed, and 96% were late. Forty-six percent were caused by coagulase-negative Staphylococcus (CoNS). Mean Knee Society Score (KSS) was 35.38 (clinical) and 37.96 (function) on presentation; it improved to a mean of 72.92 (clinical) and 76.04 (function) after the first stage and to a mean of 75.38 (clinical) and 80.58 (function) at the final review. Bone loss was unchanged between stages, and range of motion remained unchanged or improved after definitive reimplantation.

CONCLUSION: The use of preformed articulated knee spacer during a two stage technique for infected TKA improves patient QOL between stages and increases patient compliance and cooperation, reducing social costs.

Industrially Prefabricated Cement Spacers: Do Vancomycin- and Gentamicin-impregnated Spacers Offer Any Advantage?

Corona PS, Barro V, Mendez M, Cáceres E, Flores X.

Clin Orthop Relat Res. 2014 Mar;472(3):923-32. doi: 10.1007/s11999-013-3342-7. Epub 2013 Oct 19. Erratum in: Clin Orthop Relat Res. 2014 Feb;472(2):771.

ABSTRACT

BACKGROUND: Industrially preformed antibiotic-loaded cement spacers are useful to facilitate the second stage of two-stage exchange arthroplasty for infected THAs and TKAs. However, whether gentamicin alone or a combination of antibiotics (such as vancomycin and gentamicin) is more effective is not known.

QUESTIONS/PURPOSES: We therefore sought to compare industrially prefabricated spacers containing either gentamicin or gentamicin and vancomycin with respect to (1) infection control, (2) complications, and (3) quality of life, pain, and patient satisfaction.

METHODS: We performed a review of 51 patients with chronic infections treated at one center using either gentamicin or vancomycin and gentamicin-prefabricated spacers. The former were used exclusively from January 2006 until May 2009, and the latter from June 2009 until July 2011, and there was no overlap. We collected data on demographics, immunologic status (McPherson classification), prosthetic joint infection location, type of prosthesis, microbiologic results, and time between stages. We evaluated the primary outcome of infection control or recurrence after at least 12 months follow-up. We also recorded complications. Each patient completed a quality-of-life survey, VAS, and a self-administered satisfaction scale.

RESULTS: The overall infection control rate was 83% after a mean follow-up of 35 months (range, 12.4-64.7 months). There were no differences between gentamicin and vancomycin and gentamicin spacers in terms of infection eradication (80 % versus 85 %, respectively; p = 0.73), nor in terms of complications, quality of life, pain, or satisfaction scores.

CONCLUSIONS: Prefabricated, antibiotic-loaded cement spacers has been proven effective for infection control in TKAs and THAs but with the numbers available, we did not find any differences between a gentamicin or vancomycin and gentamicin-prefabricated spacer, and therefore, we are unable to validate the superiority of the combination of vancomycin and gentamicin over gentamicin alone. Because of the higher costs involved with vancomycin and gentamicin spacers, and the potential risks of unselective use of vancomycin, further comparative studies are necessary to evaluate their role in the treatment of infected THAs or TKAs.

Antibiotic-Loaded Spacer for Two-Stage Revision of Infected Total Knee Arthroplasty

Vecchini E, Micheloni GM, Perusi F, Scaglia M, Maluta T, Lavini F, Bondi M, Dall'Oca C, Magnan B.

J Knee Surg. 2017 Mar;30(3):231-237. doi: 10.1055/s-0036-1584190. Epub 2016 May 20.

ABSTRACT

Infection of total knee arthroplasty (TKA) is a challenge in orthopedic surgery. In literature TKA infection is classified according to the time after surgery: acute postoperative; late chronic; acute hematogenous; positive intraoperative microbiological growth. The purpose of this study is to present the results of the use of a preformed antibiotic-loaded spacer in TKA infections, treated by a two-stage revision procedure. A series of 19 consecutive patients (20 knees) with a diagnosis of infected TKA were treated from January 2003 to February 2012. Two-stage reimplantation protocols were completed only in 16 patients and these data were included in the study. We lost three patients at follow-up. An antibiotic-loaded preformed articulating polymethylmethacrylate spacer was applied. Patients were observed 1, 3, and 6 months postoperatively and then yearly for clinical and radiographic examination. The mean American Knee Society Score improved from 68.4 preoperatively (range, from 34 to 108) to 112.7 at final follow-up (range, from 49 to 180). The pain was evaluated as part of clinical score. It improved from an average of 19.3 preoperatively (range, from 10 to 30) to 34.3 at final follow-up (range, from 10 to 50). The average range of motion improved from 40.1 degrees (range, from 6 to 90 degrees) to 79.3 degrees (range, from 45 to 125 degrees). The use of the spacer allows obtaining a reduction of pain, an improvement of quality of life in the period of time between the two surgical stages and an easier reimplantation of TKA.

The Influence of a Failed Irrigation and Debridement on the Outcomes of a Subsequent Two-Stage Revision Knee Arthroplasty

Nodzo SR, Boyle KK, Nocon AA, Henry MW, Mayman DJ, Westrich GH.

J Arthroplasty. 2017 Aug;32(8):2508-2512. doi: 10.1016/j.arth.2017.03.026. Epub 2017 Mar 22.

ABSTRACT

BACKGROUND: Previous work has suggested a failed irrigation and debridement (I&D) before a 2-stage exchange negatively impacts the outcome of the subsequent 2-stage revision.

METHODS: This was a retrospective review of 132 patients who underwent a 2-stage exchange without prior I&D (2-Stage), and 45 patients had a failed I&D before their 2-stage exchange (I&D+2Stage) between April 2009 and April 2015. Charts were reviewed for patient demographics, presenting inflammatory laboratory values, type of antibiotic spacer used, surgical details, microbiology data, length of postoperative antibiotic treatment, and reoperation. A logistic regression was used to assess the association between I&D and reoperation.

RESULTS: The I&D+2Stage group had an 82.2% success rate, and the 2-Stage group had an 82.5% success rate (P = .95). The odds of reoperation for infection with the use of greater than 2 grams of vancomycin was 0.33 (P = .01, 95% confidence interval 0.14-0.79) as compared with having less than 2 grams of vancomycin in the construct. Spacer type, having a prior I&D to the 2-stage procedure, being infected with an antibiotic resistant organism, total grams of aminoglycoside were not associated with a risk of failure.

CONCLUSION: Success rates between the I&D+2Stage group and the 2-Stage group were similar. The use of greater than 2 grams of vancomycin in the spacer construct decreased the odds of reoperation. I&D before a 2-stage exchange may not negatively influence the outcomes of a subsequent 2-stage revision procedure and requires further investigation.

Acetabular Spacers in Two-Stage Hip Revision: Is It Worth It? A Single-Centre Retrospective Study

Burastero G, Basso M, Carrega G, Cavagnaro L, Chiarlone F, Salomone C, Papa G, Felli L.

Hip Int. 2017 Mar 31;27(2):187-192. doi: 10.5301/hipint.5000446. Epub 2016 Nov 25.

ABSTRACT

PURPOSE: The aim of this work is to evaluate an acetabular antibiotic loaded bone cement spacer in 2-stage revision surgery as a potential approach able to reduce complications during the inter-stage period (i.e. dislocation, acetabular wear), as well as simplify 2-stage hip revision surgery and improve hip biomechanics.

METHODS: We performed a retrospective comparative study and evaluated clinical, radiological and surgical data of 71 patients affected by periprosthetic hip infection who were treated with 2-stage exchange. 31 patients were treated using an acetabular spacer in addition to the femoral (group A) while 40 underwent a standard revision surgery (femoral spacer only, group B).

RESULTS: Mean time of surgery for the first stage was 148 ± 59 minutes and 142 ± 45 minutes for group A and B respectively; we noted a statistically significant reduction (26 min, p = 0.015) in the same parameter for the second stage (83 ± 35 minutes for group A and 109 ± 36 minutes for group B). We observed the following interstage complications: 5 femoral spacer dislocations (1 for group A and 4 for group B); 1 spacer fracture (group B), 1 spacer fracture (group A), 2 periprosthetic fractures (group B) and 2 patients with acetabular spacer instability (group B). Additionally, we observed a significant improvement in leg length restoration for group A (p = 0.03).

CONCLUSIONS: Our data show that the acetabular spacer technique is able to reduce the interstage complication rate and allow improved hip biomechanics restoration.

Two-Stage Revision for Infected Shoulder Arthroplasty

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J Shoulder Elbow Surg. 2017 Jun;26(6):939-947. doi: 10.1016/j.jse.2016.09.056. Epub 2016 Nov 22.

ABSTRACT

BACKGROUND: Periprosthetic shoulder infections (PSIs) are challenging to treat and often result in significant patient morbidity. Without a standardized treatment protocol, PSIs are often managed similarly to periprosthetic hip and knee infections. Because 2-stage revision is the gold standard for treating periprosthetic hip and knee infections, we performed a case series and literature review to determine its effectiveness in PSIs.

METHODS: We identified 19 patients (14 men) from our institution who were treated with a 2-stage revision after presenting with a PSI. Mean patient age was 63 ± 9 years, and average body mass index was 30.8 ± 5.8. The average time from the index arthroplasty to treatment was 40 months, 8 of 13 positive cultures were Propionibacterium acnes, and 9 of 19 patients had multiple shoulder operations before presenting with infection. Minimum follow-up for all patients was 2 years.

RESULTS: After a mean follow-up of 63 months (range, 25-184 months), 15 of 19 patients in our study were successfully treated for PSI. Average postoperative American Shoulder and Elbow Surgeons (ASES) Shoulder Assessment score was 69 (range, 32-98) and average postoperative forward elevation was significantly increased from 58° to 119° ($P < .001$). The incidence of recurrent infection was 26%. The rate of noninfection complications was 16%, for a total complication rate of 42%.

CONCLUSION: In patients with PSIs, especially those with intractable, chronic infections, a 2-stage revision represents a viable treatment option for eradicating infection and restoring function. However, it is important to recognize the risk of recurrent infection and postoperative complications in this challenging patient population.

Clinical Results and Complications of a Two-Stage Procedure in Hip Infection Using Preformed Antibiotic-Loaded Cement Spacers

Garcia-Oltra E, Garcia S, Bosch J, Combalia A, Soriano A, Bori G.

Acta Orthop Belg. 2019 Dec;85(4):516-524.

ABSTRACT

Antibiotic-loaded cement spacers are used in two- stage hip replacement. The aim of our study was to compare our results using a Spacer-G with previous results reported in the literature. From June 2002 to April 2010, all patients treated with a two-stage revision were retrospectively reviewed. On the basis of the results of the first-stage procedure, 52 patients underwent the second stage, six developed a dislocation, in eight the spacer was maintained, and five patients developed an acute infection of the spacer or the infection was not resolved. With regard to the second-stage procedure the revision was successful in 44 patients, a re-infection developed in four patients and the definitive prosthesis presented a mechanical complication in four more.

The literature results reported that 97.5% of the spacers were reimplanted, although 12.09% of them developed a dislocation. Surgeons must assess several aspects so as to avoid mechanical complications like dislocation and re-infections during the two stages of the procedure.

Cement Pedestal Spacer Technique for Infected Two-Stage Revision Knee Arthroplasty: Description and Comparison of Complications

Akhtar A, Mitchell C, Assis C, Iranpour F, Kropelnicki A, Strachan R.

Indian J Orthop. 2019 Nov-Dec;53(6):695-699. doi: 10.4103/ortho.IJOrtho_90_19.

ABSTRACT

BACKGROUND: Infection following total knee arthroplasty (TKA) is a significant complication, with an incidence of up to 2% in primary TKA and 4%-8% in revision cases. Two-stage revision is the gold standard treatment for long-lasting infections of TKA. The purpose of this study was to describe the cement pedestal spacer technique used in infected two-stage revision knee arthroplasty and compare complications against conventional fixed and mobile cement spacers.

PATIENTS AND METHODS: A retrospective review was conducted in all cases who underwent two-stage TKA revision for infection between 2009 and 2015. These cases were separated into groups depending on the cement spacer utilized (fixed, mobile nonpedestal, and mobile spacers with cement pedestal). The cement pedestal technique involves press fitting a cement cylinder into the femur before definitive spacer insertion.

RESULTS: Forty four patients underwent two-stage revision TKA. Fewest complications were observed in the pedestal group, with no spacers having subluxed/tilted. The longest follow-up was also observed in the pedestal group (mean 52.5 months). Mobile spacers with no cement pedestal displayed the highest reinfection rate (16.7%) and the greatest number of cases with complications (malalignment, subluxation, tilting, and spacer fracture). All patients in the pedestal group were ambulatory after the first-stage revision.

CONCLUSIONS: The cement pedestal technique minimizes complications by optimizing component positioning and balancing. It also safely extends the indication for an articulated spacer into a set of cases with more extensive bone loss and allows for extended monitoring of inflammatory markers.

Two-Stage Revision Shoulder Prosthesis vs. Permanent Articulating Antibiotic Spacer in the Treatment of Periprosthetic Shoulder Infections

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Orthop Traumatol Surg Res. 2019 Apr;105(2):237-240. doi: 10.1016/j.otsr.2018.10.010. Epub 2018 Nov 27.

ABSTRACT

INTRODUCTION: Periprosthetic shoulder infections (PSIs) represent a serious complication following shoulder arthroplasty. No consensus exists regarding the optimal option. We conducted a retrospective case-control study to compare the outcomes of 2-stage revision shoulder arthroplasty and those of definitive articulating antibiotic spacer implantation with regards to eradication of the infection, improvement of pain and shoulder function.

MATERIALS AND METHODS: Thirty patients treated for an infected shoulder arthroplasty were retrospectively reviewed after a mean follow-up of 8 years (range, 2-10 years). Nineteen underwent definitive articulating antibiotic spacer implantation and 11 underwent 2-stage revision arthroplasty. Mean age at surgery was 68.8 years. Assessment included Constant-Murley score, visual analog scale pain score, objective examination, patient subjective satisfaction score as well as standard radiographs.

RESULTS: At the most recent follow-up, none of the patients had clinical or radiographic signs suggesting recurrent infection. Most patients reported satisfying subjective and objective outcomes. Follow-up examination showed significant improvement of all variables compared to preoperative values ($p<0.001$). Radiographs did not show progressive radiolucent lines or change in the position of the functional spacer. No statistically significant differences were reported between the two groups concerning Constant-Murley and VAS scores, while average forward flexion and abduction were significantly higher in patients undergoing 2-stage revision surgery.

CONCLUSIONS: Both surgical procedures provided infection eradication and satisfying subjective functional outcomes. Functional results were superior in patients treated with revision shoulder prosthesis, although a higher rate of complication was reported in this cohort of patients, thus suggesting the use of permanent spacer in high-risk or low-demanding elderly patients.

Management of Infected Shoulder Arthroplasty: A Comparison of Treatment Strategies

Patrick M, Vincent HK, Farmer KW, King JJ, Struk AM, Wright TW.

J Shoulder Elbow Surg. 2019 Sep;28(9):1658-1665. doi: 10.1016/j.jse.2019.03.001. Epub 2019 Jun 14.

ABSTRACT

BACKGROUND: The study purpose was to determine whether 2-stage revision procedures result in superior outcomes and whether reverse shoulder arthroplasty produced superior outcomes to hemiarthroplasty or anatomic total shoulder arthroplasty at the time of reimplantation.

METHODS: Our prospectively collected database was retrospectively reviewed for all surgically treated infected shoulder arthroplasties between 2006 and 2014. We included 47 patients in this study: 27 underwent a 2-stage revision, and 20 were treated with an antibiotic spacer as definitive treatment. Preoperative laboratory results, intraoperative cultures and pathology findings, recurrence of infection, complications, and outcome measures were compared between treatment groups.

RESULTS: A recurrent infection developed in 3 patients in the antibiotic spacer group and 2 patients in the 2-stage revision group (P = .25). A total of 20 procedure-related complications and 11 medical complications occurred between the 2 groups; however, there was no statistically significant difference between groups. The 2-stage group had statistically significantly better Constant scores (58.1 vs. 33.3, P = .04) and elevation (94.4° vs. 48.6°, P = .02) than the antibiotic spacer group. Subanalysis of the 2-stage revision group showed that reverse total shoulder arthroplasties had statistically superior Shoulder Pain and Disability Index, Simple Shoulder Test, American Shoulder and Elbow Surgeons, University of California at Los Angeles, and Constant scores; elevation; and abduction compared with hemiarthroplasties or anatomic total shoulder arthroplasties.

CONCLUSION: Two-stage revision procedures and use of an antibiotic spacer for definitive management of periprosthetic shoulder infections appear to be similar and effective in eradicating infections. Two-stage revisions using a reverse total shoulder arthroplasty at the time of reimplantation generate superior range of motion and functional outcome scores.

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