



# CEMEX<sup>®</sup> BONE CEMENT LITERATURE REVIEW



## CONTENTS

---

### CLINICAL OUTCOMES DATA

- 2 | Release of Antibiotics from Polymethylmethacrylate Cement
- 3 | Treatment Outcome of Two-Stage Revision Total Hip Arthroplasty for Infected Hip Arthroplasty Using Antibiotic-Impregnated Cement Spacer
- 4 | Fatigue Strength of Pmma Bone Cement Mixed with Gentamicin and Barium Sulphate vs. Pure PMMA
- 5 | The Effect of Mixing Techniques (Manual, Closed System, Vacuum) on Bone Cement
- 6 | A Comparison of Cemex and Palacos Cement Regarding Migration, Wear and Radiography. A Randomised 5 Years RSA Study
- 7 | Two-Stage Revision Total Hip Arthroplasty Using A Vancomycin-Impregnated Cement Spacer In An Infected Hip Joint Caused By MRSA
- 8 | Technique and Timing of Two-Stage Exchange for Infection in TKA
- 9 | Good Long Term Stability with Low Monomer Bone Cement in Total Hip Arthroplasty. A Randomized RSA Study

# Release of Antibiotics from Polymethylmethacrylate Cement

---

**Bertazzoni Minelli E, Caveiari C, Benini A. J Chemother.**

2002 Oct;14(5):492-500.

## ABSTRACT

The increase in resistance rates to antibiotics of bacteria isolated from infected hip joints, particularly staphylococci, prompted us to investigate the usefulness of antibiotic combinations such as gentamicin plus vancomycin. Cylinder test specimens of polymethylmethacrylate (PMMA) cement (Cemex, Tecres) containing gentamicin alone, vancomycin alone and both drugs in combination, were studied. The antibiotic concentrations were determined using a microbiological method and fluorescence polarization immunoassay (FPIA). The release of gentamicin alone, vancomycin alone and in combination from PMMA cement was prompt. The combination revealed synergistic antimicrobial activity against *Escherichia coli* and *Enterococcus faecalis*. FPIA showed that gentamicin and vancomycin delivery rates from PMMA cement were different. Gentamicin alone and in combination with vancomycin presented similar release rates from PMMA cement (1.50%). Vancomycin release from PMMA cylinders impregnated with the combination was lower (0.51%) than that from cylinders with vancomycin alone (1.16%). Vancomycin showed a 34.1% loss of microbiological activity at 37 degrees C after 10 days of incubation; the reduction corresponded to 15.0% when measured by FPIA. Results obtained with test specimens are indicative for the preparation of antibiotic-impregnated cements for different human prostheses.

## KEY QUOTE

*"Novel and recent local drug delivery systems are proposed to improve the local drug release i.e. biodegradable carriers for different drugs with promising results requiring further specific evaluation." (p. 499)*

*Exactech Literature # 001C*

# Treatment Outcome of Two-Stage Revision Total Hip Arthroplasty for Infected Hip Arthroplasty Using Antibiotic-Impregnated Cement Spacer

Takahira N, Itoman M, Higashi K, Uchiyama K, Miyabe M, Naruse K.

J Orthop Sci. 2003;8(1):26-31.

## ABSTRACT

Infected hip prosthesis, a serious complication of primary total hip arthroplasty (THA), can have severe consequences. We report the treatment outcome of two-stage revision THA for infected hip arthroplasty, including hemiarthroplasty, using an antibiotic-impregnated cement spacer for the interval between the first and second stages. Between 1996 and 2000 we performed this procedure on nine hips in eight patients. Cementless revision THA was performed as the second-stage procedure. Bone defects were restored with frozen allografts. The outcome was evaluated using the hip score of the Japanese Orthopaedic Association (JOA hip score). The mean duration of follow-up was 35.7 months (range 10-55 months). The mean JOA hip score at follow-up improved from 30.1 (range 10-74) to 73.2 (24-96). The mean interval between the first and second stages was 10.1 weeks (range 6-19 weeks). Eight of the nine hips achieved a successful outcome. One hip, with methicillin-resistant *Staphylococcus aureus* infection, experienced recurrence 4 months after revision THA. This patient was successfully treated 14 months after the first revision THA with a second two-stage procedure using a vancomycin- and arbekacin-impregnated cement spacer and beads. These results suggest that two-stage revision THA using an antibiotic-impregnated cement spacer is a useful technique for treating infected hip arthroplasty.

## KEY QUOTE

*"Cemex cement subjected to a polymerization temperature of less than 60°C, in PBS (phosphate-buffered saline) after 24h was approximately 182 ug/ml, whereas the amount of VCM (vancomycin) eluted from Surgical Simplex P cement subjected to a polymerization temperature higher than 60°C in PBS after 24h, was approximately 77 ug/ml. That is, the cement subjected to a low polymerization temperature yielded a 2.4-fold higher concentration of VCM than the cement subjected to a high polymerization temperature."* (p. 30)

Exactech Literature # 002C

# Fatigue Strength of Pmma Bone Cement Mixed with Gentamicin and Barium Sulphate vs. Pure PMMA

---

**Baleani M, Cristofolini L, Minari C, Toni A. Proc Inst Mech Eng H.**

2003;217(1):9-12.

## ABSTRACT

Barium sulphate is added to polymethylmethacrylate (PMMA) bone cement as a radiopacifier. Gentamicin is an antibiotic added to bone cement to treat or prevent infection in arthroplasty. This study investigated the combined effect of barium sulphate and gentamicin sulphate on the fatigue strength of PMMA bone cement. Three different formulations were studied: pure PMMA, PMMA with barium sulphate added and PMMA with barium sulphate and gentamicin sulphate added. Before testing all specimens were stored in water at 37 degrees C for at least 15 days to season the PMMA and to elute the antibiotic. Fatigue tests were performed following a previously validated procedure. The slope part of the Wöhler diagram was obtained and a rough endurance limit was estimated for all three formulations. The experimental data showed that the addition of barium sulphate to PMMA bone cement affected the fatigue strength of the material, whereas addition of gentamicin sulphate to the radiopaque PMMA had no effect on the fatigue properties of the bone cement. While PMMA with barium sulphate added was confirmed to have a reduced fatigue strength when compared with plain PMMA, no detrimental effect was found for the addition of gentamicin sulphate to radiopaque PMMA.

## KEY QUOTE

*"Different types of antibiotic may have different effects on the fatigue behavior of bone cement." (Section 4 Discussion)*

*Exactech Literature # 003C*

# The Effect of Mixing Techniques (Manual, Closed System, Vacuum) on Bone Cement

---

**Verdonschot N, De Groes S.**

Orthopedic Research Laboratory, University of Nijmegen, The Netherlands. Report 145. 2001 Nov.

## INTRODUCTION

Aim of the study was to compare two bone cements: Cemex XL and Simplex P.

The discriminating factors to evaluate an aspect of the quality of the bone cement were volume, density and porosity changes in time. Cemex XL is also available in a closed mixing system with the brand name of Cemex System. The Cemex System allows the preparation and delivery of bone cement.

In the human body, the bone cement is exposed to liquid. As the authors believe that the liquid is of great influence to the material properties of the bone cement, the tests are performed for both specimens kept in a dry environment and specimens kept in physiologic water.

Three questions are addressed in this report:

- How large is the porosity of Cemex XL relative to Simplex P
- Is Cemex System proper to mix Cemex XL (In other words can differences in density and dimension change of bone cements be related to the preparation method)?
- What is the difference in dimension and density change of cement kept in a dry environment and kept in water over time?

## KEY QUOTE

*"Porosity of Cemex ranged from -0.2% (vacuum mixed) and 0.02% (hand mixed); of Simplex P ranged between 2.1% (vacuum mixed) and 2.5% (hand mixed). These differences are significant." (p. 12)*

*Exactech Literature # 004C*

# A Comparison of Cemex and Palacos Cement Regarding Migration, Wear and Radiography. A Randomised 5 Years RSA Study

---

**Nivbrant B, Kärrholm J.**

Department of Orthopaedics, University Hospital of Umeå and Salgrenska, Göteborg, Sweden.

## INTRODUCTION

The performance and strength of the bone-cement-implant interfaces depends on a variety of factors, cement penetration depth, surface area and roughness, bone necrosis and membrane formation due to curing heat and toxic substances and also cement properties such as viscosity at cementation, mechanical strength and stress tolerance. This makes it a complex issue to find the best cement for clinical use by laboratory experiments only. Inferior strength at an interface can be detected by RSA as an increased migration of the actual implant and repeatedly has such a migration by several authors shown its clinical relevant in predicting a coming failure. The aim of present study was to compare a low temperature curing bone cement (Cemex) with a standard (Palacos) regarding post operative implant migration and other adverse effect on bone. Previous lab test have shown 6 degrees less curing temperature, more release of monomer after curing, lower tensile but higher shear strength for Cemex compared to Palacos. However when used in vivo a lot of factors are pre-chilling, installation time, cooling and vacuum-mixing affects the curing temperature.

## KEY QUOTE

*"Both cements functioned very well. A small tendency to a better fixation of implants was found for Cemex cement, but no differences according to hip scores, BMD (bone mineral density), Zones or lab tests of bone turn-over." (Conclusion)*

*Exactech Literature # 005C*

# Two-Stage Revision Total Hip Arthroplasty Using A Vancomycin-Impregnated Cement Spacer In An Infected Hip Joint Caused By MRSA

---

**Higashi K, Sekiguchi M, Hashimoto A, et al.**

Department of Orthopaedic Surgery, Kitasato School of Medicine, Kanagawa, Japan. Summary of translation. Higashi et al. Orthopedic Surgery. 51:605-09, 2000. Published in Japanese.

## INTRODUCTION

The emergence of methicillin-resistant *Staphylococcus aureus* (MRSA) has made treatment of the infected hip arthroplasty more challenging. We have had success treating these patients with a vancomycin (VCM)-impregnated cement spacer. Mizunuma demonstrated the heat-sensitivity of VCM, bringing into question the impact of elevated temperature upon VCM loaded into bone cement. The objective of this study is to characterize the elution behavior of VCM formulated in low or high temperature bone cement.

## KEY QUOTE

*"We conclude that the use of a low-temperature cement may be optimal in the treatment of MRSA." (Discussion)*

*Exactech Literature # 006C*

# Technique and Timing of Two-Stage Exchange for Infection in TKA

---

**Burnett RS, Kelly MA, Hanssen AD, Barrack RL.**

Clin Orthop Relat Res. 2007 Nov;464:164-78.

## ABSTRACT

Infection in total knee arthroplasty is a devastating complication. The two-stage exchange procedure has evolved as an effective treatment option. The classification and alternatives to a two-stage procedure are presented. Current diagnosis and monitoring of infection in total knee arthroplasty with laboratory, aspiration, and imaging techniques are reviewed. The timing, technique, and results of a two-stage procedure are discussed. A knee aspiration with synovial fluid cell count and culture may be a useful adjunct. The use of antibiotic-impregnated cement spacers may be considered at the first-stage surgery. Spacers may be static or articulating, intramedullary dowels, preformed or constructed in the operating room, and provide single- or multiple-agent antibiotic (and antifungal) joint space delivery. Proper technique, antibiotic dosing, and indications with these devices will avoid complications between stages. The most common complications encountered with the use of spacers include dislocation/instability, implant extrusion, overstuffing of the patellofemoral and tibiofemoral joints, and implant or periprosthetic fracture. At the second stage of the procedure, surgical exposure, intraoperative frozen sections, assessment of bone and soft tissue defects, the integrity of the extensor mechanism, and implant selection are important factors to consider in the second-stage reimplantation revision total knee arthroplasty. LEVEL OF EVIDENCE: Level V, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

## KEY QUOTE

*"The authors emphasized that when mobile spacers were used, there was a considerable reduction in the need for more extensive extensor mechanism exposures and tibial tubercle osteotomy." (p. 170)*

*Note: This is a very well written article discussing all of the different options physicians have for treating an infection.*

*Exactech Literature # 007C*



# Good Long Term Stability with Low Monomer Bone Cement in Total Hip Arthroplasty. A Randomized RSA Study

---

**Röhl SM, Nilsson KG, Nivbrant B, Kärrholm J.**

Proceedings of the Nordic Orthopaedic Federation meeting; 2006; Oslo.

## INTRODUCTION

Low temperature curing cement with less toxic monomers might obtain a better long term fixation to bone. The cement showed lower curing temperature in laboratory and less shrinkage during polymerization (Nivbrant et al. 2001). We reported earlier on the 5 year results which showed excellent stability in both groups. A tendency to less wear for the low monomer cement could be seen. We have followed up the patients and now can report clinical and fixation results after 10 years.

## KEY QUOTE

*"The results confirm our good mid-term results with Cemex cement." (Discussion/Conclusion)*

*Exactech Literature # 008C*

