CERAMENT® G
with Gentamicin

KEY CLINICAL DATA OVERVIEW

The CERAMENT® platform is supported by over 240 publications and abstracts. This document provides an overview of the key clinical and safety data.

CERAMENT HAS BEEN USED IN

70,000 PATIENTS

OVER 240+ PUBLICATIONS AND ABSTRACTS

Bone Remodeling

LEVEL 1 CLINICAL STUDY AGAINST GOLD STANDARD AUTOGRAFT

Title: Autologous Iliac Bone Graft Compared with Biphasic Hydroxyapatite and Calcium Sulfate Cement for the Treatment of Bone Defects in Tibial Plateau Fractures – A Prospective, Randomized, Open-Label, Multicenter Study*

Authors: Hofmann et al.

Publication: The Journal of Bone And Joint Surgery (American) (2020)

About the Study: This non-inferiority study compared CERAMENT® BONE VOID FILLER to autograft in acute traumatic fractures of the proximal tibia. The study also compared bone remodeling and patient-reported outcome measures between the two treatment groups.

*This study featured CERAMENT® BONE VOID FILLER.

RESULTS:

- CERAMENT is as good as autograft
- Proven bone remodeling
- Less post-op pain compared to autograft
- Less blood loss compared to autograft
- Trend towards shorter duration of surgery

Disclaimer: CERAMENT BVF is not registered in Canada.

Antibiotic Elution

2 KEY STUDIES | 33 PATIENTS

1. Title: Pharmacokinetics of Gentamicin Eluted from a Regenerating Bone Graft Substitute - In Vitro and Clinical Release Studies

Authors: Stravinskas et al.

Publication: Bone & Joint Research (2016)

About the Study: This study compares the elution of gentamicin from CERAMENT® G in vitro with elution and efficacy in clinical applications. The results showed that the elution pattern in vitro was comparable to that seen in patient studies.

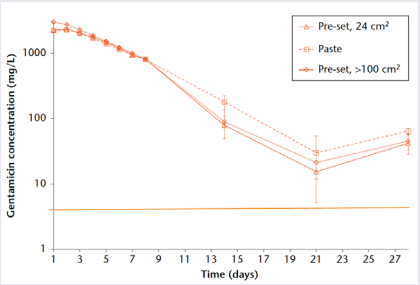


Fig. 1) Gentamicin concentration over time shows consistent elution above the minimum inhibitory concentration for 28 days and features a high initial burst and does not differ depending on surface area.

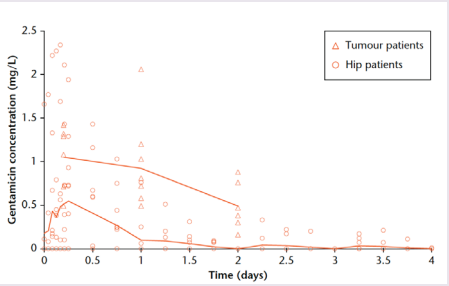


Fig. 2) Gentamicin levels in serum from tumour and hip patients for the first two days post-operatively. Local levels of gentamicin are 1000 times higher than systemic levels.

RESULTS:

- High initial burst of gentamicin above 2000 mg/L
- Elution for up to 28 days
- Antibiotic elution is not surface dependent
- Low serum concentrations well below toxic threshold of 10mg/L

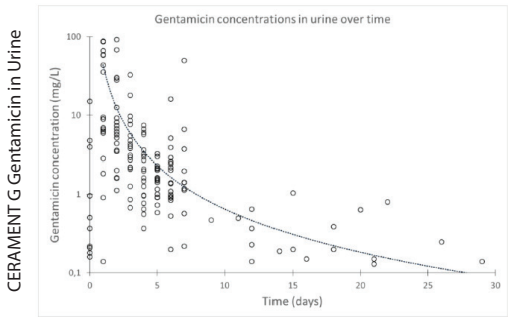
Antibiotic Elution Cont.

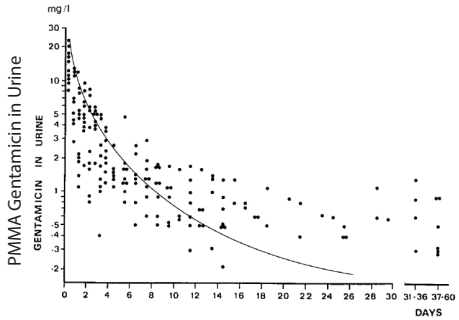
2. Title: Antibiotic Containing Bone Substitute in Major Hip Surgery: A Long Term Gentamicin Elution Study

Authors: Stravinskas et al.

Publication: Bone & Joint Research (2018)

About the Study: Examines the antibiotic elution of CERAMENT® G in patients over a 30-day follow-up period. Also compares the pharmacokinetics of CERAMENT® G to gentamicin containing PMMA bone cement used in primary total hip arthroplasty.





RESULTS:

- CERAMENT® has higher initial elution than PMMA (see graphs on the left)
- All of CERAMENT®'s antibiotic is released
- Low serum concentrations well below toxic threshold of 10mg/L

Osteomyelitis

3 KEY STUDIES | 163 PATIENTS

1. Title: Mid- to long-term results of single-stage surgery for patients with chronic osteomyelitis using a bioabsorbable gentamicin-loaded ceramic carrier

Authors: McNally et al.

Publication: The Bone & Joint Journal (2022)

About the Study: This paper analysed the same first 100 patients that are in the paper below. The patients had chronic osteomyelitis and were treated by surgery, implantation of CERAMENT® G and systemic antibiotics, followed up for an average of 6.05 years.

RESULTS:

- 100 patients
- 94% infection eradication in a single-stage surgery
- 3% fracture rate

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2. Title: Radiographic and histological analysis of a synthetic bone graft substitute eluting gentamicin in the treatment of chronic osteomyelitis

Authors: Ferguson et al.

Publication: The Journal of Bone and Joint Infection (2019)

About the Study: Patients with chronic osteomyelitis, treated by surgery, implantation of CERAMENT® G, and systemic antibiotics. 138 of these patients had minimum one-year radiographic follow-up (mean 1.7 yrs). 9 patients had subsequent surgery that allowed for histology of biopsies between 19 days – 2 years after implantation of CERAMENT® G. Histology "confirmed active remodeling of [CERAMENT® G] into...osteoid and lamellar bone."

RESULTS:

- 163 patients
- 73.8% mean void filling
- 95.7% infection eradication
- 2.5% fracture rate

Health Economic Data

1 KEY STUDY

Title: A retrospective cohort study comparing clinical outcomes and healthcare resource utilisation in patients undergoing surgery for osteomyelitis in England: a case for reorganising orthopaedic infection services

Authors: Ferguson et al.

Publication: Journal of Bone and Joint Infection (2021)

About the Study: A reduction in hospital-related costs with CERAMENT® G has been shown in the largest analysis of hospital episode statistics for NHS England carried out for a bone graft substitute to date.

The study was carried out at Oxford University Hospital, a world leader in osteomyelitis treatment and pioneer of the multi-disciplinary team (MDT) service (orthopaedics, plastics and microbiology).

In the analysis, 25,006 patients diagnosed with osteomyelitis in England between 2013 and 2017 were included. The patients treated in an MDT service with CERAMENT® G as part of their treatment were then compared to both patients treated in the top ten busiest osteomyelitis centers and those treated in the rest of England.

During the index surgery and in the 24 months after discharge, patients treated in an MDT utilized 16 fewer bed days than those in both comparative cohorts. This reduction represents a potential $10,266 in direct savings of per patient.*

RESULTS:

MDT results versus Top Ten Hospitals:

- 33.6% reduction in length of stay
- 59.5% reduction in amputation rate
- 76.5% lower mortality rate

MDT results versus Rest of England:

- 29.9% reduction in length of stay
- 49.1% reduction in amputation rate
- 79.2% lower mortality rate

*Average cost per bed day of £500; the average annual exchange rate between pound sterling and US dollars for 2020 was used (£1 = $1.2832); data sourced from the Office for National Statistics (ons.gov.uk)

Fracture Related Infection

2 KEY STUDY | 87 PATIENTS

1. Title: Augmented debridement for implant related chronic osteomyelitis with an absorbable, gentamicin loaded calcium sulfate/ hydroxyapatite biocomposite

Authors: Drampalos et al.

Publication: The Journal of Orthopaedics (2020)

About the Study: Patients with implant-related chronic osteomyelitis, treated by removal of metalwork, debridement and augmentation with CERAMENT® G and systemic antibiotics.

RESULTS:

- 52 patients
- 92.3% infection eradication
- 8/9 infected non-unions healed
- 0 fractures
- "bone remodeling in all patients"

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2. Title: Treatment of fracture-related infection of the lower extremity with antibiotic-eluting ceramic bone substitutes: case series of 35 patients and literature review

Authors: Pesch et al.

Publication: Infection (2020)

About the Study: Patients with fracture-related infections treated in either a single- or twostage protocol that included debridement and implantation of CERAMENT G, followed up for a mean of 14.9 months.

RESULTS:

- 35 patients
- 91.4% infection eradication
- No fractures

Diabetic Foot Infection and Charcot Neuroarthropathy

2 KEY STUDIES | 129 PATIENTS

1. Title: Adjuvant antibiotic loaded bio composite in the management of diabetic foot osteomyelitis - A multicentre study

Authors: Niazi et al.

Publication: The Foot (2019)

About the Study: Patients with diabetic foot ulcers and osteomyelitis, treated by surgery, CERAMENT® G and systemic antibiotics, followed up until infection eradication or ulcer healing (mean 10 months).

Author's Conclusion: "the use of adjuvant local antibiotic therapy [CERAMENT® G] can potentially decrease the risk of amputations in this vulnerable and difficult to manage group of patients."

RESULTS:

- 70 patients
- 90% infection eradication
- 12 week mean ulcer healing time

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2. Title: Single stage treatment of diabetic calcaneal osteomyelitis with an absorbable gentamicin-loaded calcium sulphate/hydroxyapatite biocomposite: The Silo technique

Authors: Drampalos et al.

Publication: The Foot (2017)

About the Study: Description of a novel bone-preserving technique for the treatment of calcaneal osteomyelitis in diabetic patients, using CERAMENT® G. Patients were followed up until ulcer healing (mean 16 weeks).

RESULTS:

- 12 patients
- 100% infection eradication
- 0 fractures

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3. Title: Limb salvage surgery in diabetic foot infection: encouraging early results with a local antibiotic carrier

Authors: Vasukutty et al.

Publication: The Diabetic Foot Journal (2022)

About the Study: Patients with diabetic foot osteomyelitis treated by debridement with or without reconstructive surgery, with CERAMENT G used to manage the dead space, followed up for a mean of 33 months.

RESULTS:

- 47 patients (48 feet)
- 94% limb salvage rate
- 88% infection control and healing

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