

# CERAMENT®

## Overview of Key Clinical Evidence



### Introduction

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**CERAMENT®** is a synthetic bone graft substitute that consists of a powder component comprising 40% hydroxyapatite (HA) and 60% calcium sulfate (CaS), and a liquid component, which are mixed to form a paste that can be injected, molded, sets within 15 minutes and is then drillable<sup>1</sup>.

The CERAMENT product portfolio consists of CERAMENT® BONE VOID FILLER, CERAMENT® G with gentamicin and CERAMENT® V with vancomycin.

All CERAMENT products are used to fill bone gaps or voids. The type and ratio of HA and CaS in CERAMENT gives it unique material properties, including the ability to remodel into host bone within 6-12 months, and the addition of gentamicin in CERAMENT G and vancomycin in CERAMENT V prevents colonisation by gentamicin- or vancomycin-sensitive microorganisms, to protect bone healing.

CERAMENT has been used to treat more than 50,000 patients, and has over 160 publications confirming safety and efficacy. The CERAMENT portfolio has the largest amount of pre-clinical and clinical data of any bone substitute on the market, and the only level 1 randomised controlled trial (RCT) study with Patient Reported Outcome Measures (PROMS).

This summary document outlines the key clinical papers for CERAMENT.

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<sup>1</sup> Note: All CERAMENT products are injectable, but only CERAMENT BONE VOID FILLER and CERAMENT V are moldable, and only CERAMENT BONE VOID FILLER and CERAMENT G are drillable.

## Osteomyelitis

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- Mifsud & McNally. (2019) 'Local delivery of antimicrobials in the treatment of bone infections.' *Orthopaedics and Trauma*. 33:3. *Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals, UK.*

Review of the use of ceramic bone substitutes in osteomyelitis and infected non-unions, and the protocol used at the Oxford Bone Infection Unit, UK.

*'the only study investigating... **CERAMENT G showed the lowest infection recurrence rate of 4%.** Eighty of the 100 cases in this large study were patients with poor Cierny & Mader host status, and Type 3 and 4 chronic osteomyelitis, infected non-union and concomitant septic arthritis. Despite the significant comorbidities that would normally predict a high recurrence rate, the recurrence rate was one of the lowest.'*

- Ferguson et al. (2019) 'Radiographic and histological analysis of a synthetic bone graft substitute eluting gentamicin in the treatment of chronic osteomyelitis.' *Journal of Bone and Joint Infection*. 4(2):76-84. *Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals, UK.*

Patients with chronic osteomyelitis, treated by surgery, implantation of CERAMENT G and systemic antibiotics. 138 of these patients had minimum one-year follow up (mean 1.7 years), and their radiographs were assessed to determine bone remodeling. 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'.

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

*'Radiographic evidence of bone defect healing was good, with almost a quarter of cases demonstrating full void-filling at final follow-up (24.6%). In contrast another study examining void-filling with a pure CS carrier in osteomyelitis demonstrated...complete filling in only 4.4%'*

- McNally et al. (2016) 'Single-stage treatment of chronic osteomyelitis with a new absorbable, gentamicin-loaded, calcium sulphate/hydroxyapatite biocomposite – A prospective series of 100 cases.' Bone & Joint Journal. 98-B:1289–96. *Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals, UK.*

Patients with chronic osteomyelitis, treated by surgery, implantation of CERAMENT G and systemic antibiotics, followed up for a mean of 19.5 months (12-34).

**100** patients

**96%** infection eradication

**3%** fracture rate

## Health Economic Data

- Ferguson et al. (2019) 'The financial burden of treating osteomyelitis in the UK.' Orthopaedic Proceedings. 101-B:14:65. *Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals, UK.*

**575** patients treated by a MDT in Oxford vs. **24,408** patients treated in the rest of England

**42.3%** reduction in length of stay

**58%** reduction in readmissions

**7%** reduction in all hospital attendances

**48%** reduction in all A&E attendances  
MDT patients also had lower amputation rates, and significantly better survival rates

The largest analysis of hospital episode statistics for NHS England carried out for a bone graft substitute to date.

The outcome of 575 patients with osteomyelitis treated in a multi-disciplinary team (MDT) service (orthopaedics, plastics and microbiology) with CERAMENT G as part of their treatment were compared to 24,408 patients with osteomyelitis treated in the rest of England (between 2013-2017). Patient were followed for 24 months after surgery.

The results showed that the cost and time for treating patients in a MDT setting were lower, equating to a potential saving of £7.42 million per year and an additional 15,508 bed days per year.

## Fracture related infection

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- Drampalos et al. (2020) 'Augmented debridement for implant related chronic osteomyelitis with an absorbable, gentamycin loaded calcium sulfate/hydroxyapatite biocomposite.' *Journal of Orthopaedics*. 17:173-179. Orthoplastic Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, UK.

Patients with implant-related chronic osteomyelitis, treated by removal of metalwork, debridement and augmentation with CERAMENT G.

**51** patients

**92.3%** infection eradication

**8/9** infected non-unions healed

**0** fractures

'bone remodeling in all patients'

## Trauma

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- Hofmann et al. (2019) 'Autologous iliac bone graft compared with biphasic hydroxyapatite and calcium sulfate cement for the treatment of bone defects in tibial plateau fractures.' *Journal of Bone and Joint Surgery*. Published online December 6, 2019 ahead of print. DOI: *Journal of Bone & Joint Surgery American*;00:1-15.

Randomised controlled trial comparing autologous bone to CERAMENT BONE VOID FILLER (CBVF) in the treatment of tibial plateau fractures. Bone remodeling, Patient Reported Outcome Measures (PROMS), blood loss, length of stay and surgery time were measured.

**135** patients from 20 hospitals in Germany

CERAMENT proven to remodel into bone as well as the 'gold standard' autograft

CERAMENT had less post-operative pain, less blood loss and a trend towards shorter surgery

- Jahangir et al. (2019) 'The use of adjuvant local antibiotic hydroxyapatite bio-composite in the management of open Gustilo-Anderson type IIIB fractures. A prospective review.' *Journal of Orthopaedics*. 16:278–282. *Orthoplastic Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, UK.*

**51** patients

**0%** deep infections

**84%** primary union rate

**98.1%** limb salvage

51 patients with type IIIB open tibial fractures, treated by a single-stage 'fix-and-flap' procedure with CERAMENT G followed up until fracture union and wound healing (mean 39 months).

- Aljawadi et al. (2020) 'Adjuvant local antibiotic hydroxyapatite bio-composite in the management of open Gustilo Anderson IIIB fractures. Prospective review of 80 Patients from the Manchester Orthoplastic Unit.' *Journal of Orthopaedics*. 18:261-266. *Orthoplastic Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, UK.*

**80** patients

**1.25%** infection rate

**96.1%** fracture union

**96.25%** limb salvage rate

80 patients with type IIIB open tibial fractures, treated by a single-stage 'fix-and-flap' procedure with CERAMENT G followed up until wound healing and union (mean 22 months).

## Diabetic foot infection and Charcot Neuroarthropathy

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- Niazi et al. (2019) 'Adjuvant antibiotic loaded bio composite in the management of diabetic foot osteomyelitis – A multicentre study.' *The Foot*. 39:22-27. *Orthoplastic Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, UK.*

**70** patients

**90%** infection eradication

**12** week mean time to ulcer healing

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).

*'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.'*

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- Drampalos et al. (2017) 'Single stage treatment of diabetic calcaneal osteomyelitis with an absorbable gentamicin-loaded calcium sulphate/hydroxyapatite biocomposite: The Silo technique.' *The Foot*. 34:40-44. Orthoplastic Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, UK.

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).

**12 patients**

**100% infection eradication**

**0 fractures**

## Bone tumors

- Horstmann et al. (2018) 'Early clinical and radiological experience with a ceramic bone graft substitute in the treatment of benign and borderline bone lesions.' *Scientific reports*. 8:15384. *Musculoskeletal Tumor Section, Department of Orthopedic Surgery, Rigshospitalet, University of Copenhagen, Denmark.*

Patients with benign bone lesions, treated by curettage and filling with CERAMENT BONE VOID FILLER or CERAMENT G. 28 patients had comparative X-rays post-operatively and at 12 months, which were assessed for bone remodeling.

- Kotrych et al. (2018) 'Preliminary results of highly injectable bi-phasic bone substitute (CERAMENT) in the treatment of benign bone tumors and tumor-like lesions.' *Open Med*. 13: 487-492. *Department of Orthopaedics, Traumatology and Orthopaedic Oncology, Pomeranian Medical University in Szczecin, Poland.*

**33 patients**

Significant improvement in both VAS and MSTS scores

**0 recurrence/metastasis**

'new bone formation was clearly demonstrated in all cases'

Patients with benign bone lesions and tumor-like lesions, treated by curettage and filling with CERAMENT BONE VOID FILLER, followed up for a mean of 13 months. Bone remodeling, Visual Analog Scale (VAS) pain scores and musculoskeletal tumor society (MSTS) scores were measured.

- Khan et al. (2018) 'Efficacy of CERAMENT in large defects created by giant cell tumor.' *Journal of Bone and Joint Diseases*. 33(3):10-13. *Department of Orthopaedics, Hamdard Institute of Medical Sciences and Research, New Delhi, India.*

14 patients

0 infection

0 fractures

'complete bone remodeling...in 6 months in all patients'

Patients with giant cell tumor treated by curettage and filling of the defect with CERAMENT BONE VOID FILLER.

- Kaczmarczyk et al. (2015) 'Complete twelve month bone remodeling with a bi-phasic injectable bone substitute in benign bone tumors: a prospective pilot study.' BMC Musculoskeletal Disorders. 16:369. Department of Orthopedics and Traumatology, Poznań University of Medical Sciences, Poland.

14 patients

92.8% completely or partially healed

0 fractures

'A CT scan after 12 months confirmed complete radiological transformation of bone substitute into bone'

Patients with benign bone tumors, treated by minimally invasive surgery or percutaneous injection with CERAMENT BONE VOID FILLER, followed up for 12 months to assess bone remodeling and bone healing.

## Pertrochanteric hip fractures and revision hip arthroplasty

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- Stravinskas et al. (2018) 'A ceramic bone substitute containing gentamicin gives good outcome in trochanteric hip fractures treated with dynamic hip screw and in revision of total hip arthroplasty: a case series.' BMC Musculoskeletal disorders. 19:438. Lithuanian University of Health, Kaunas, Lithuania & Department of Orthopedics, Lund University Hospital, Sweden.

18 patients

No migration/loosening of implants

All trochanteric fractures healed and all hip revisions fully recovered by 3 months

Patients with trochanteric femoral fractures (N=8) or uncemented hip revisions (N=10) treated by surgery and implantation of CERAMENT G, followed up for 1 year to assess healing/implant migration and clinical outcomes. 1 trochanteric fracture patient had hardware removed after 1 year, allowing biopsies to be taken for histological analysis.

Histology showed 'viable and mature bone in all biopsies'. Bone healing was also seen on all trochanteric hip fracture X-rays, and increased bone density was seen on the hip revision X-rays where CERAMENT G was implanted.

*'Since long term fixation is dependent on the amount and quality of new bone formed around the implant, we believe that the use of [CERAMENT G] with part being replaced by ingrowing bone that surrounds the apatite may be beneficial for fracture stability and implant fixation.'*

- Logoluso et al. (2016) 'Calcium-based, antibiotic-loaded bone substitute as an implant coating: a pilot clinical study.' Journal of Bone and Joint Infection. 1: 59-64. Department of Reconstructive Surgery of Osteo-articular Infections C.R.I.O. Unit, I.R.C.C.S. Galeazzi Orthopaedic Institute, Milan, Italy & Department of Trauma and Orthopaedics, University College London Hospitals, UK.

**20** patients

**95%** infection eradication

No signs of implant loosening or subsidence in any patient

Patients with prosthetic hip (N=7) or knee (N=13) infections, treated by two-stage revision with implantation of CERAMENT G or V. Followed up for a minimum of 12 months (average 18.1 months) with assessment of clinical outcome and progression of healing and remodeling on X-rays.

If you would like more information or copies of the above clinical papers, please contact:

Name :  
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