

GENTAMICIN ANTIBIOTIC ELUTING BONE GRAFT SUBSTITUTE PROMOTES AND PROTECTS BONE HEALING

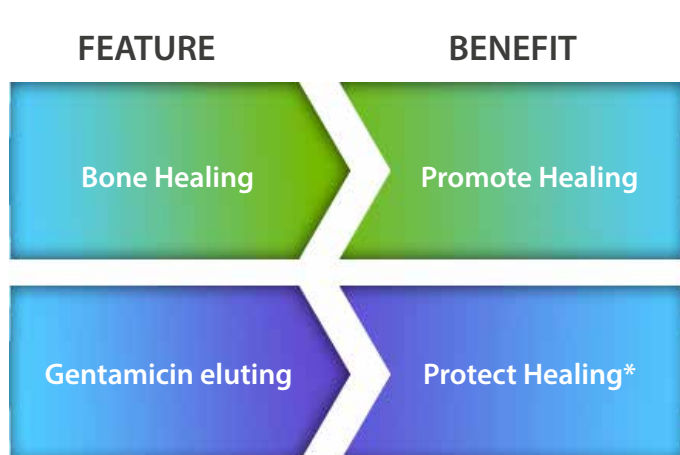
The first CE-marked injectable ceramic bone graft substitute - containing an antibiotic which protects bone healing.

- A resorbable ceramic bone graft substitute intended to fill bone gaps and voids to promote bone healing
- To provide a void/gap filler that can augment hardware and bone alignment during surgical procedures
- The elution and local delivery of gentamicin is intended to prevent colonization of gentamicin sensitive microorganisms to protect bone healing



Benefits

EASY TO USE



* By preventing colonization of gentamicin sensitive micro organisms

Material Composition

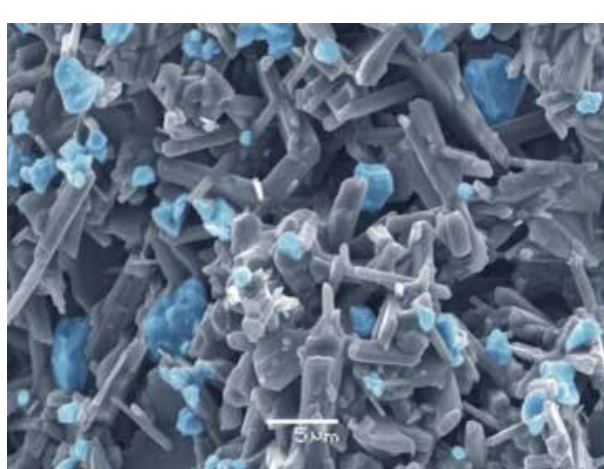
Powder phase

- Hydroxyapatite (HA) for long term support and bone remodeling
- Calcium sulfate hemihydrate (CaS) for short term strength (resorbs within 6 to 12 months¹)

Liquid phase

Sodium Chloride 9mg/mL
10mL paste contains 175mg gentamicin

¹Osteotomy of Distal Radius Fracture Malunion Using a Fast Remodeling Bone Substitute Consisting of Calcium Sulphate and Calcium Phosphate. Abramo A. et al. J Biomed Mater Res Part B: Appl Biomater 92B: 281–286, 2010 and DO 0037. Data on file, BONESUPPORT, Sweden



Clinical results

A Prospective Evaluation of CERAMENT™|G Bone Void Filler with Gentamicin in the Treatment of Chronic Osteomyelitis with Cavitory Defects.

Oxford Bone and joint Infection Congress (OBIC) 3rd to 4th April 2014

MA McNally, JY Ferguson, R Giordmaina, M Sutherland, D Stubbs, A Woodhouse
Bone Infection Unit, Nuffield Orthopaedic Centre Oxford University Hospitals

Early Clinical Results

n = 41

Safety:

- No adverse reactions
- No renal complications
- No allergic response
- No toxicity

Overview of Early Results

- Mean follow up 8.8 months (3-12 months)
- No recurrence of infection
- No toxicity
- 2.4% wound leakage (ooze)
- 2.5% fracture (n = 1) humerus at 4 weeks
- ~80% good bone ingrowth at 6 months

Overview of Radiological Results

n = 30 at 6 months:

All patients experienced bone ingrowth:

- 21 complete filling with bone = 78%
- 9 partial filling with bone = 22%
- 2 observed material 'migration'/'leakage'

Patient: 71 year old female

Cierny-Mader IIIB, Tibia

This extensive infection on the medial side of the tibia followed internal fixation of a fracture with a plate. Plate removal did not resolve the infection and the patient presented with a 16cm skin ulcer over the medial tibial border with exposed bone and discharge of pus. MRI confirmed CM Stage III osteomyelitis.

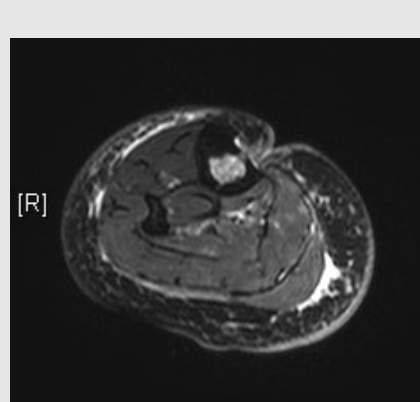


Figure 1 & 2: MRI scan confirmed CM stage III osteomyelitis.



Figure 3: radiograph.

At operation, a large area of cortex was removed from the medial tibia and the infected medullary bone removed. The defect was filled with 20mls of CERAMENT™|G and a Gracilis muscle flap applied. An external fixator was used to allow full weight-bearing without fracture risk.



Immediately post operative: CERAMENT™|G is clearly seen filling the bone void, an external fixator has been applied.



13 weeks: A reaction can be seen throughout the material.



28 weeks: Signs of bone remodeling can be seen.



44 weeks: There is almost no visible material and there is evidence of organized trabecular bone.

Publications

- The 4th Oxford Bone Infection Conference; Abstract 2014: A Prospective Evaluation of CERAMENT™|G bone void filler with Gentamicin in the treatment of chronic Osteomyelitis with cavitory defects. MA McNally, JY Ferguson, R Giordmaina, M Sutherland, D Stubbs, A Woodhouse
- Use of CERAMENT™ as a BONE VOID FILLER in Complex Foot and Ankle Reconstruction. DiDomenico LA Presented at: AOFAS Annual Meeting (2013) <http://www.ankleandfootcare.com/posters/cerament.pdf>
- 14th European Congress of Trauma and Emergency Surgery (ECTES), May 4th to 7th 2013, Lyon France. Abstract: The injectable biphasic calcium sulphate/hydroxyapatite bone substitute CERAMENT™ possesses reliable remodeling activity in metaphyseal fracture defects. T. Nusselt MD, A Hofmann, MD, PhD & P.M. Rommens, MD, PhD
- 8th World Congress of Combined Orthopaedic Societies (CORS) 13th to 16th October 2013, Venice Italy. Five-year follow-up of patients treated with radius osteotomy and biphasic resorbable bone substitute. M. Landgren, P. Kopylov, A. Abramo, M. Geijer, M. Tägil
- EBJS 2012, Antibiotic elution and bone remodelling with a novel bone substitute impregnated with gentamicin. F Lindberg
- Antibiotic-containing Bioceramics Can Provide Safe and Effective Treatment in Bone and Joint Infections. Gunnar Kahlmeter and Lars Lidgren. <http://www.touchmusculoskeletal.com/journals/editions/european-musculoskeletal-review-volume-7-issue-3-autumn-2012>
- GRIBOI 2012, Release of gentamicin from a ceramic bone substitute. V Sandell, E Lidén
- GRIBOI 2012, Mechanical properties ceramic bone substitute loaded with gentamicin. C Ehrenborg, V Sandell, E Lidén
- Bioceramic vertebral augmentation with a calcium sulphate/hydroxyapatite composite (CERAMENT™ SPINE SUPPORT) in vertebral compression fractures due to osteoporosis. Michael Reuschmann, Thomas Vogl, Akhil Rehmayed, Robert Pflugmacher, Thomas Werba, Sven Schmidt, Johannes Hierholzer. Eur Spine J DOI 10.1007/s00586-010-1279-z. Published online <http://www.springerlink.com/content/n7x28826418r1524/>
- Bone Healing in Vertebroplasty; H. Paul Hatten, Jr., M.D. Indian River Radiology, Vero Beach, Florida Society of Interventional Radiology (SIR) 35th Annual Scientific Meeting March 13-18 2010 Tampa FL USA. Poster presentation abstract 262. <http://download.journals.elsevierhealth.com/pdfs/journals/1051-0443/PIIS1051044309011981.pdf>
- Clinical Presentation: Metatarsal Delayed Union Management in a Diabetic Patient with CERAMENT™|BONE VOID FILLER. Dr J Karr. The Journal of Diabetic Foot Complications 2010, Volume 2, Issue 3, No. 3, Pages 65-68. http://jdfc.org/wp-content/uploads/2010/11/v2-i4-a1_Metatarsal_Delayed_Union.pdf
- Bone substitute as an on-lay graft on rat tibia. Truedsson A, Wang J-S, Lindberg P, Gordh M, Sunzel B, Warfvinge G. Clin. Oral Impl. Res. 21, 2010; 424–429. <http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0501.2009.01875.x/abstract>
- Osteotomy Of Distal Radius Fracture Malunion Using a Fast Remodelling Bone Substitute Consisting of Calcium Sulphate and Calcium Phosphate. Abramo A, Geijer M, Kopylov P, Tägil M. J. of Biomed Materials Research (B) Nov 2009 281-286. <http://onlinelibrary.wiley.com/doi/10.1002/jbm.b.31524/abstract>
- Cancellous Bone Defect Healing with a novel Bi-Phasic Calcium Sulphate-Hydroxyapatite Composite Injectable Bone Substitute. Voor MJ, Burden RL, Borden J, Nilsson M. Poster presentation ORS New Orleans 2009
- Biomechanics and bone integration on injectable calcium sulphate and hydroxyapatite in large bone defect in rat. Wang J-S, Zhang M, McCarthy I, Tanner KE and Lidgren L. Poster presentation at ORS, Chicago 2006. <http://cms.proximedia.com/files/23170/MediaArchive/cerament/cerament>
- Biodegradation and biocompatibility of a calcium sulphate-hydroxyapatite bone substitute. Nilsson M, Wang J-S, Wielanek L, Tanner KE and Lidgren L. J Bone Joint Surg [Br] 2004; 86-B:120-125. <http://web.jbjs.org.uk/cgi/reprint/86-B/1/120.pdf>
- Resorption and bone ingrowth of injectable bone substitute: a comparative study in rabbit. Wang J-S, Nilsson M, McCarthy I, Tanner KE and Lidgren L. Oral presentation at EORS, Helsinki 2003.
- Biodegradation and biocompatibility of a calcium sulphate with hydroxyapatite bone substitute. Wang J-S, Nilsson M, Wielanek L, Tanner KE and Lidgren L. Poster presentation at ORS, Tampa 2002.

Links



CERAMENT™|BONE VOID FILLER
iPAD Bone Healing App
Android Bone Healing App



CERAMENT™|BONE VOID FILLER
Indications App

www.bonesupport.com