

BONESUPPORT™'s CERAMENT™ | G Highly Effective Adjunct in the Single Stage Surgical Management of Chronic Osteomyelitis

[Single stage surgical procedure achieves 96% infection eradication rate](#)

Lund, Sweden, 1 September 2016 – BONESUPPORT AB, an emerging leader in innovative injectable bioresorbable bone graft substitute products to treat bone voids caused by trauma, infection, disease or related surgery, today announced the publication of a paper in *The Bone and Joint Journal: Single-stage treatment of chronic osteomyelitis with a new absorbable gentamicin-loaded, calcium sulphate/hydroxyapatite biocomposite - A prospective series of 100 cases.* McNally et al, *The Bone and Joint Journal*, 2016, Vol. 98-B, No. 9, p1289-96.

The paper provides 12-34 month follow up data from the first 100 patients in a prospective study evaluating CERAMENT™ G for dead space (void) management in patients with chronic osteomyelitis (bone infection) using a single stage surgical procedure. These data showed that this approach, augmented by the use of CERAMENT™ G, was highly effective, delivering a 96% prevention of infection recurrence rate, a 3.0% fracture rate and a total wound leakage rate of 6.0%. This is significantly lower than published results with alternative bone graft substitutes that deliver antibiotics locally.

These results highlight the essential properties of CERAMENT™ G in the management of chronic osteomyelitis. The very encouraging infection recurrence prevention rate is supported by CERAMENT™ G's attractive local delivery properties, which enable it to provide an initial targeted ultra-high concentration of gentamicin into the bone defect and then a longer sustainable dose above the minimal inhibitory concentration (MIC) of the bacteria that initially caused the osteomyelitis. This unique antibiotic-eluting profile helps protect the bone healing process and promote bone remodeling.

The bone healing and bone remodeling properties of CERAMENT™ G, when combined with gentamicin, make it an ideal solution for dead space management in patients with chronic osteomyelitis. It is able to fill the void completely due to its injectability and to provide initial structural stability due to its self-setting properties.

The use of CERAMENT™ G to deliver gentamicin locally could play an important role in improving antibiotic stewardship in hospitals by increasing compliance and reducing the need for patients with chronic osteomyelitis to receive long term systemic antibiotics.

[Mr Martin McNally, Consultant Bone Infection and Limb Reconstruction Surgeon at Oxford University Hospitals \(Oxford, UK\) and lead author of the paper said, "The results that we have achieved with the single stage surgical procedure using CERAMENT™ G for the dead space management of patients with chronic osteomyelitis are a significant improvement on past experience. These results reflect CERAMENT™ G's unique local antibiotic delivery profile and its attractive bone remodeling capabilities. We are increasingly using CERAMENT™ G in the treatment of patients with chronic osteomyelitis and infected fractures. It allows a more patient-friendly treatment, preventing repeated operations and recurrent infections. We expect it to become the mainstay of our dead space management, given the major clinical and health economic benefits that it supports."](#)

The paper covers the first 100 patients in a prospective cohort study utilising CERAMENT™ G for dead space management in a single stage surgical procedure for chronic osteomyelitis. The mean duration

of chronic osteomyelitis in this patient group was 10.4 years (0.5 to 68 years). All surgeries were performed by two surgeons and were completed in a single operative session. All patients were given similar systemic antibiotic therapy and rehabilitation. Patients were followed up for at least 12 months (mean 19.5 months, range 12 -34 months) with infection recurrence, fracture rate and wound leakage rate as the primary outcome measure. The study showed that the single stage surgical procedure with CERAMENT™ G, was highly effective delivering a 96% infection recurrence prevention rate, a 3.0% fracture rate and a total wound leakage rate of 6.0%.

Richard Davies, CEO of BONESUPPORT said, “The results that have been published today highlight the clear clinical benefits with CERAMENT™ G’s ability to deliver sustained bactericidal levels of gentamicin locally to support the eradication of underlying infections in patients with chronic osteomyelitis. By using CERAMENT™ G in a single stage procedure to help patients with chronic osteomyelitis return to a normal life, we can deliver significant health economic benefits to payors who are struggling to contain the significant and growing costs of treating severely debilitating bone infection.”

Reference

1. McNally et al, *The Bone and Joint Journal*, 2016, Vol. 98-B, No. 9, p1289-96.

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Notes to Editor

About BONESUPPORT™

BONESUPPORT AB has developed CERAMENT™ as an innovative range of radiopaque injectable osteoconductive bioceramic products that have a proven ability to heal defects by remodeling to host bone in six to twelve months. Our products are effective in treating patients with fractures and bone voids caused by trauma, infection, disease or related surgery. Our lead product, CERAMENT™ |BONE VOID FILLER (BVF) addresses important issues facing health care providers, such as avoiding hospital readmissions and revision surgery that result from failed bone healing and infection caused by residual bone voids. CERAMENT™ |BVF is commercially available in the U.S., EU, S.E. Asia and the Middle East.

CERAMENT™'s distinctive properties as a drug eluting material have been validated in clinical practice by CERAMENT™ |G and CERAMENT™ V, the first CE-marked injectable antibiotic eluting bone graft substitutes. These products provide local sustained delivery of gentamicin and vancomycin, respectively. The local delivery feature enables an initial high concentration of antibiotics to the bone defect and then a longer sustainable dose above the minimal inhibitory concentration (MIC) to protect bone healing and promote bone remodeling.

CERAMENT™ |G and CERAMENT™ V have demonstrated good results in patients with problematic bone infections including osteomyelitis. They are also used prophylactically in patients who are at risk for developing infection. CERAMENT™ |G and CERAMENT™ V are available in the EU.

BONESUPPORT AB was founded in 1999 by Prof. Lars Lidgren, an internationally respected scientist who has been the President of various musculoskeletal societies. BONESUPPORT’s mission is to bring people with bone and joint diseases back to an active life. The company is based in Lund, Sweden.

PRESS RELEASE



BONESUPPORT™ is a registered trademark.

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