CERAMENT®
BONE VOID FILLER

KEY CLINICAL EVIDENCE

CERAMENT® BONE VOID FILLER is a radiopaque, injectable, moldable and drillable synthetic bone graft, uniquely formulated to completely resorb and remodel into bone within 6-12 months.

The CERAMENT technology is anchored by robust clinical evidence across all study levels, supporting safety and efficacy within a variety of applications.

Strong clinical data provides more confidence for successful clinical outcomes.

CERAMENT HAS BEEN USED IN

55,000+ PATIENTS | **OVER 160 PUBLICATIONS**

Bone Remodeling Evidence in Trauma

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.

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

Foot & Ankle and Trauma Evidence

1. Title: Displaced Intra-Articular Calcaneal Fractures Treated with Open Reduction and Internal Fixation and Bone Void Filling with CERAMENT: A Series of 18 Patients

Authors: Papadia et al

Publication: Archives of Trauma (2018)

About the Study: This study evaluates the effect of CERAMENT in internal fixation of calcaneal fractures. The records of 18 patients (20 fractures) with calcaneal fractures type Sanders III and IV treated with internal fixation plus CERAMENT were reviewed. Radiographs were evaluated using different measurements and clinical outcomes were evaluated using the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale.

RESULTS:

- At 12 months, 20 fractures were available for radiographic follow-up examination
- CERAMENT completely resorbed in all fractures on radiograph at 12 months
- In 6 fractures, there was no decrease in Bohler's angle, a slight reduction (< or equal to 5 degrees) in 6 fractures, and in 8 fractures Bohler's angle was >5 degrees. There were 2 calcaneal collapses where the Bohler's angle was >5 degrees.
- The average AOFAS score was 89.8 (68-99) at 1 year follow-up and indicated an excellent outcome in 11 fractures, a good outcome in 8, and a fair outcome in 1 fracture
- The study team concluded "the study results support the use of CERAMENT in displaced intra-articular calcaneal fractures"

Additional Trauma Evidence

2 KEY STUDIES

1. Title: Augmentation of tibial plateau fractures with an injectable bone substitute: CERAMENT. Three year follow-up from a prospective study.

Authors: lundusi et al.

Publication: BMC Musculoskeletal Disorders (2015)

About the Study: 3-year prospective study of proximal tibial fractures needing both internal fixation and grafting, with CERAMENT used as an alternative to autologous or allograft bone, to determine if it aids in supporting initial reduction and preserving alignment until fracture healing.

RESULTS:

- Loss of fracture reduction average 1.18mm (< 2mm = satisfactory)
- CERAMENT resorption complete in all cases after an average 5 months (3-8 months)
- Mean Rasmussen score 26.5 – all patients in the good or excellent categories

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2. Title: Osteotomy of distal radius fracture malunion using a fast remodeling bone substitute consisting of calcium sulphate and calcium phosphate

Authors: Abramo et al.

Publication: Journal of Biomedical Materials Research. Part B, Applied Biomaterials (2010)

About the Study: 15 consecutive patients with malunion after distal radius fracture underwent an osteotomy. A fragment specific fixation system was used for fixation and CERAMENT as a bone graft substitute. Clinical follow-ups were performed at 2 weeks, 7 weeks, 3 months, and 1 year. Follow-ups included clinical examination, blood samples, radiographic examination, and the DASH form

RESULTS:

- Grip strength increased from 61 (range 28-93)% of the contralateral hand to 85 (range 58-109)%, $p<0.001$
- DASH scores decreased from 37 (22-61) to 24 (2-49), $p=0.003$
- Radiographically all osteotomies healed. An increase of ulnar variance was noted during healing from 1.8 mm immediately post operatively to 2.6 mm at final follow up
- CERAMENT was replaced by bone, but a minor loss of the achieved radiographic correction was noted in some patients during osteotomy healing. A more rigid fixation may improve the radiographic outcome

Orthopedic-Oncology Evidence

Title: Complete twelve month bone remodeling with a bi-phasic injectable bone substitute in benign bone tumors: a prospective pilot study

Authors: Kaczmarczyk et al.

Publication: BMC Musculoskeletal Disorders (2015)

About the Study: 14 patients with benign bone tumors were treated by minimal invasive intervention with CERAMENT, with the purpose of avoiding open surgery with bone grafting. There were 3 solid bone tumors, while 11 lesions were bone cysts (8 unicameral and 3 post-traumatic). Defects were treated by either minimally invasive surgery (solid tumors) or percutaneous injection (cysts) and followed clinically and radiologically for 12 months. CT scans were performed after 12 months to confirm bone remodeling of the CERAMENT.

RESULTS:

- At surgery, the defects were completely or partially filled with median 18 mL of CERAMENT (range 5-28)
- At 12 months, there was full resolution (Neer Classification grade I) in 11 patients, partial resolution (Neer II) in 2 patients, and in 1 patient the cyst persisted (Neer III)
- No lesions required revision surgery during the observation period

Pediatric Evidence

Title: Percutaneous cyst aspiration with injection of two different bioabsorbable bone cements in treatment of simple bone cyst.

Authors: Dong et al.

Publication: Journal of Children's Orthopaedics (2020)

About the Study: Level III Study to compare outcomes of 38 patients (aged 2-37 years; mean age 12.4) treated with one of two different bioresorbable bone graft substitutes (CERAMENT BVF/G and ChronOS) that were used in minimally invasive treatment concept of percutaneous cyst aspiration, lavage, and intralesional injection. Retrospective collection and analysis of the data of patients who had undergone a percutaneous treatment of active simple bone cysts.

RESULTS:

- CERAMENT had a better resorption rate than ChronOS
- CERAMENT was resorbed in 100% of cases at the end of follow-up, whereas ChronOS was resorbed in 76% of cases
- Overall complication rate (recurrence, refracture and infection) was clearly but not significantly lower in the CERAMENT group
- Recurrence rate was less in the CERAMENT group than the ChronOS group
- The cysts treated with CERAMENT healed earlier compared to those treated with ChronOS

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