Advice sheet for Surgeons and Radiologists

Radiographic appearance of CERAMENT™
The structure and function of CERAMENT™

CERAMENT™ is an osteoconductive bone graft substitute which consists of hydroxyapatite (HA) particles, calcium sulfate (CaS) crystals and a liquid. CERAMENT™ G contains gentamicin and CERAMENT™ V contains vancomycin.

Turnover of CERAMENT™

After CERAMENT™ has been injected into a bone void, tissue fluids fill microporous channels in the material, and both passive dissolution and active resorption of the CaS begins, leaving behind a HA scaffold for colonization by osteoblasts and formation of new bone. The remodeling process of CERAMENT™ starts immediately after implantation and continues over several months. This process of dissolution and simultaneous bone formation is unique to the material. Bone remodeling is not uniform in all cases and this may lead to difficulty in assessing progress on radiographs. The aim of this guidance document is to describe the different radiological patterns of bone remodeling seen after implantation of CERAMENT™ products.

Pattern of remodeling of CERAMENT™

Analysing the radiographs of the first 100 patients treated for chronic osteomyelitis at the Nuffield Orthopaedic Centre, Oxford University Hospitals, Oxford, UK with CERAMENT™ G, we were able to distinguish at least four distinct patterns of remodeling of CERAMENT™. These patterns can often be found at specific time intervals and may occur alone or in combination.

These signs might cause some concern in the clinic, but should be thought of as stages in the process of degradation of CERAMENT™ G and the generation of new bone. None of the signs imply cessation of remodeling, a failure of the bone graft substitute or an indication for revision surgery.
Pattern A - Direct transition into bone structure

**Case details:** 54 year old male presenting after a puncture wound to the right heel 25 years ago and subsequent chronic osteomyelitis. In a one-stage approach, the soft tissue and the bone were debrided and the void filled with 20mL CERAMENT™G. No external or internal fixation was used. Each of the five intra-operative bone samples were positive for Achromobacter species.

**FIGURE 1:** Pre-operative radiographs. Note the osteolysis of the calcaneus.

**FIGURE 2:** Post-operative radiographs. After debridement, the contained void was completely filled with CERAMENT™G. It can be seen that the CERAMENT™G has a very distinct edge and it is clearly distinguished from the surrounding bone.

**FIGURE 3:** Follow-up radiograph at 3 months. The dense aspect of CERAMENT™G has changed to a blurry, milky appearance. Some leakage of CERAMENT™G into the soft tissue is seen at the plantar surface of the calcaneus.
Pattern A - Direct transition into bone structure

**FIGURE 3 CONT:** Follow-up radiograph at 6 months. The leakage into the soft tissue is gradually resorbed. The remodeling process of CERAMENT™ is continuing.

**FIGURE 4:** Follow-up radiograph at 12 months. A trabecular structure becomes visible in the former bone void. CERAMENT™ in the soft tissue has been completely resorbed.
**Pattern B - “Marble” sign**

**Case details:** 33 year old male presenting with a haematogenous Brodie’s abscess of the left femoral neck. After debridement, the bone void was filled with 20mL CERAMENT™G.

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**FIGURE 5:** Post-operative radiographs. After debridement, the contained void was completely filled with CERAMENT™G.

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**FIGURE 6:** Follow-up radiograph at 5 weeks. Resorption of CERAMENT™G has begun. The CERAMENT™G remnants form two compact looking structures, like marbles (“marble” sign).

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**FIGURE 7:** Follow-up radiograph at 3 months. The “marble” sign has disappeared and bone remodeling is seen in the periphery of the residual material.
Pattern B - “Marble" sign

**FIGURE 8:** Follow-up radiograph at 6 months: Progressive bone formation can be noted.

**FIGURE 9:** Follow-up radiograph at 12 months: The bone remodeling continues.

**FIGURE 10:** Follow-up radiograph at 16 months: Complete bone remodeling is seen.
Pattern C - “Halo” sign

Case details: 56 year old male presenting with chronic osteomyelitis after ORIF of an ankle fracture. Persistent discharge for 3 years despite local excision, VAC therapy, fasciocutaneous flap and prolonged antibiotics.

**FIGURE 11:** Pre-operative radiographs. Note the sclerotic and osteolytic bone of the distal tibia.

**FIGURE 12:** Post-operative radiographs. After excision of necrotic bone, the bone void was completely filled with CERAMENT™G. The distinct edge of the material is visible.

**FIGURE 13:** Follow-up radiograph at 9 weeks. Resorption of CERAMENT™G has progressed to a great amount. The previous distinct edge has disappeared and has been replaced by a radiopaque ring. This radiographic finding was named “halo” sign. The ring forms in the bone adjacent to the CERAMENT™G, indicating a zone of high bone remodeling activity. The centre of the void is radiolucent and therefore might appear ‘empty’.
Pattern C - “Halo” sign

**FIGURE 14:** Follow-up T2 MRI at 12 weeks. T2 MRI was carried out to analyse the structures inside the bone void at 3 months. In contrast to the radiographs, the void does not appear empty in the T2 MRI, but filled with a liquefied substance, containing solid particles throughout.

**FIGURE 15:** Follow-up radiograph at 7 months, showing progression of bone remodeling.

**FIGURE 16:** Follow-up T2 MRI at 12 months, showing bone remodeling throughout CERAMENT™G, including the formation of cortical bone at the bone window created during surgery.
Pattern D - “Puddle” sign

Case details: 83 year old male patient with a history of chronic osteomyelitis for 60 years with a draining sinus. A gentamicin sensitive S. aureus was detected in four of four bone samples.

FIGURE 17: Pre-operative radiographs: Note the three osteolytic lesions of the distal tibia.

FIGURE 18: Post-operative radiographs: The osteomyelitic cavity was excised with a bone burr and the void filled with 20mL of CERAMENT™G.

FIGURE 19: Follow-up radiographs at 5 weeks: Resorption of CERAMENT™G has started and a “halo” sign appears in the bone adjacent to the material.
**Pattern D - “Puddle” sign**

**FIGURE 20:** Follow-up radiographs at 10 weeks: The resorption of CERAMENT™ continues. Note the “marble” sign in combination with the “halo” sign.

**FIGURE 21:** Follow-up radiographs at 4 months. The “marble” sign has disappeared, the bone graft substitute settles in the distal part of the cavity due to gravity and forms a “puddle” sign. This occurs over several weeks. It should be noted that the CERAMENT™ is not liquid. The radiographs are taken with the patient supine and the material does not flow into the posterior part of the cavity.

**FIGURE 22:** Follow-up radiographs at 6 months: The combination of the “puddle” and “halo” signs is clearly visible.
Pattern D - “Puddle” sign

FIGURE 23: Follow-up radiographs at 12 months: Compared to the previous radiographs, the ventral cortical bone in front of the bone void has become thicker and stronger. There is increased density with trabecular figures visible in the cavity which were not present at 4 months after surgery. The “puddle” sign has not changed.

FIGURE 24: Follow-up radiographs at 16 months: The “halo” sign becomes less prominent.

FIGURE 25: Follow-up radiographs at 22 months: The “puddle” sign is still visible after almost 2 years but continued bone remodeling can be seen and the patient is clinically well and mobilizing.
Conclusion

**CERAMENT™** is remodeled over many months. This process will be determined by the surrounding bone quality and the mechanical loading of the material. It is likely that remodeling will continue until the bone has produced sufficient new bone to cope with the loads placed across the defect (Wolff’s Law). The x-ray appearances described above are stages in the process from initial defect filling to restoration of bony integrity.

Literature


2. **CERAMENT™** G Product Data Sheet, BONESUPPORT AB PR-0283-02EN.


