

Bone cavity filling in the treatment of chronic osteomyelitis

For complete instructions for use, see Bonalive® granules package insert.

Background

Chronic osteomyelitis is an inflammatory process of the bone, which often requires prolonged antibiotic therapy and surgical debridement. Currently, in standard treatment, the 1st surgical procedure involving the debridement of the infected and necrotic bone leaves a "dead space" in the bone. The dead space is then typically filled with nondegradable (PMMA) antibiotic releasing beads or spacers, which are left in the cavity for 6-8 weeks. In a 2nd surgical procedure the non-degradable beads are removed and the "dead space" is filled with a bone graft.

Introduction to Bonalive® granules

Bonalive® granules is a fully synthetic biomaterial that can be used in septic surgery to regenerate bone without the application of local antibiotics, given its intrinsic antibacterial properties. The 20-year history of using Bonalive® granules in septic bone surgery in the frontal sinus¹ and mastoid areas² was reinforced in 2011 by the approval of the official indication for Bonalive® granules: Bone cavity filling in the treatment of chronic osteomyelitis in orthopaedics and traumatology. The clinical problem that Bonalive® granules can solve is the regeneration of bone in anatomical areas that have undergone radical debridement due to a chronic infection in bone, in a one-stage procedure. The simultaneous capacity of Bonalive® granules to regenerate bone and prevent bacterial growth is provided by the unique osteostimulative*^{3,4} and bacterial growth inhibiting^{5,6} capacity of the biomaterial. Bonalive® granules have been proven to effectively inhibit bacterial growth of more than 50 clinical relevant bacterial species with a broad spectrum effect on both gram positive and negative bacteria and towards Methicillin resistant bacteria, e.g. MRSA or MRSE.

Clinical evidence

These unique features have been clinically proven to be both safe and effective in healing septic bone conditions^{7,8,9}. The use of Bonalive® granules has also been proven to decrease both the average number of postoperative hospital days by 30% and wound complication rates by 80% in patients compared to two competing synthetic biomaterials that were used as carriers for antibiotics¹⁰. Bonalive® granules is the first biomaterial in the world that can be safely used in septic bone surgery, without containing antibiotics¹⁰. The efficacy has been proven in an 11-patient retrospective study⁷, 27-patient prospective study¹⁰ and further in a recent 120-patient retrospective study¹¹.

- 1 Bonalive® granules can be safely used in a one-stage procedure in cases where complete debridement of the necrotic tissues can be performed. In cases where complete debridement is difficult to perform, it is recommended to perform a two-stage procedure.
- 2 Bony walls are needed in the defect to enable effective 1) containment and 2) access to the osteogenic cells for the promotion of osteogenesis.
- 3 Bonalive® granules can be used in the presence of gram positive or negative bacteria and in mixed floras; given its wide spectrum anti-bacterial activity and mechanism of action, Bonalive® granules can also be used in cases in which the pathogen has not been identified pre-operatively.
- 4 The bone cavity needs to be completely filled with Bonalive® granules. Incomplete filling of the defect can lead to bacterial growth in the hematoma that is formed in the dead space. It is important to remember that the surface of Bonalive® granules can prevent bacterial growth, but the granules cannot impact or eradicate bacterial growth in necrotic tissues or dead space with haematoma. Therefore the radical debridement of the wound area is very important. Also proper closing of the wound after implantation of Bonalive® granules is essential.
- 5 In case there is a need to accelerate osteogenesis, e.g. as in non-unions, segmental resections, Masquelet, large cortical resections, it is recommend to mix Bonalive® granules with autograft to accelerate the new bone formation. It is worthwhile to recognize that this will however decrease the capacity of the diluted graft to inhibit the bacterial growth.
- 6 Bonalive® granules has only a local bacterial growth inhibiting effect, hence systemic antibiotics should always be given according to normal clinical practice.

Following steps are required for a good application performance, accurate obliteration and to initiate the bioactive reaction:

- Fill the defect completely with Bonalive® granules.
- Do not overfill the defect, as Bonalive® granules does not shrink or expand.
- Bonalive® granules is non-hardening, i.e. it does not set.
- Avoid dropping Bonalive® granules outside the bone defect. Misplaced granules must be removed.
- Prevention of movement and migration of Bonalive® granules is essential for proper bone formation.
- Immobilize the granules with e.g. periosteum or collagen membrane, when necessary.
- Avoid direct contact of Bonalive® granules with skin by adequate closure of the defect.
- Ensure that excess fluid is post-operatively properly drained from the surgical area.

References

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