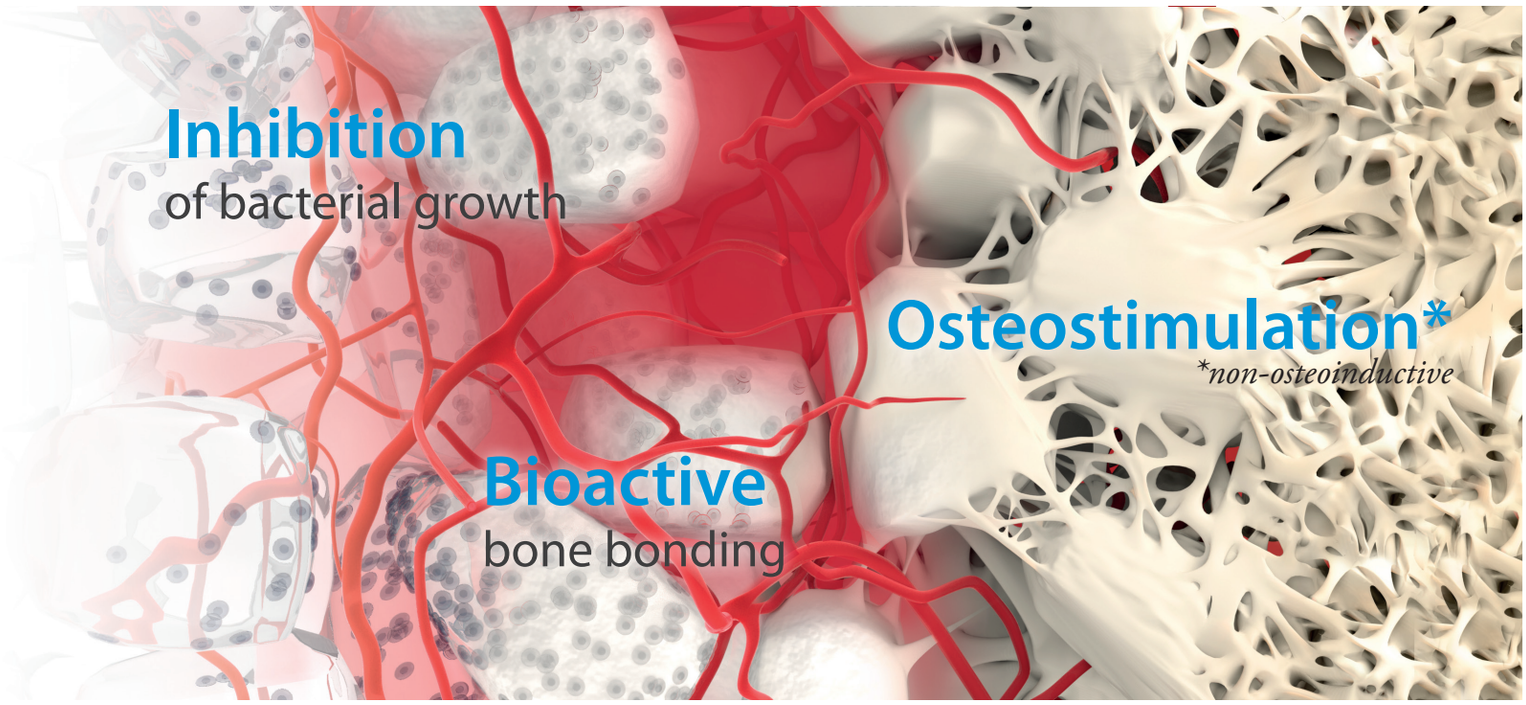
BonAlive®
granules



BonAlive® for use in:

- *Mastoid obliteration*
- *Frontal sinus obliteration*
- *Cranio-maxillofacial bone cavity filling*

BonAlive®
BIOMATERIALS LTD

BonAlive® in cranio-maxillofacial (CMF) surgery

The use of BonAlive® has provided successful and reliable long-term clinical outcomes in frontal sinus surgery, mastoid cavity obliteration and repair of skull base defect[1-3].

The *bacterial growth inhibiting*, osteoconductive and *osteostimulative** features of BonAlive® have contributed to the excellent performance in the treatment of chronically infected frontal sinuses and mastoid cavities where other materials have failed[1,3,4]. The composition of BonAlive® (S53P4) by weight is: SiO_2 53%, Na_2O 23%, CaO 20% and P_2O_5 4%.

Clinical advantages

- **Bioactive**
  Bonds effectively to surrounding bone[5]
- **Inhibits bacterial growth**
  Prevents the growth of clinically relevant bacteria[6-8]
- **Osteostimulative***
  Stimulates the growth of new bone[5,9]
- **Slowly resorbable**
  Encourages long-term bone growth[1]
- **Safe**
  Fully synthetic material

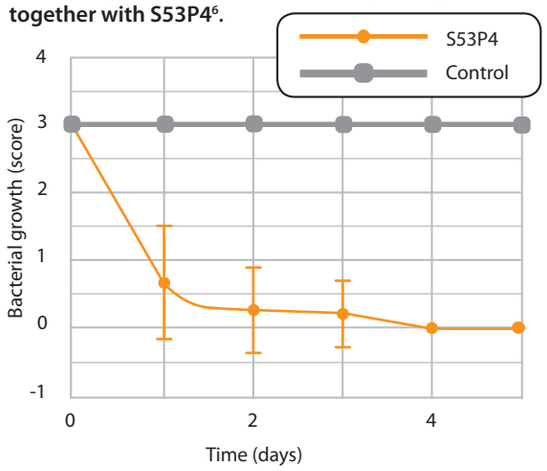
Indications

- Mastoid obliteration
- Frontal sinus obliteration
- Bone cavity filling in cranio-maxillofacial area and jaw

BonAlive® inhibits bacterial growth

BonAlive® is a bone graft substitute that *inhibits bacterial growth.* Studies have shown that the material has a bacterial growth inhibiting effect on a vast number of anaerobic and aerobic bacterial species that are related to cranio-maxillofacial (CMF) complications[6-8,10,11].

The average growth of 29 bacterial species grown together with S53P4[6].



The growth of most species was totally inhibited already at the first time point (1d). 3 = good growth (positive control), 2 = moderate growth, 1 = weak growth, 0 = no growth.

**non-osteoinductive*

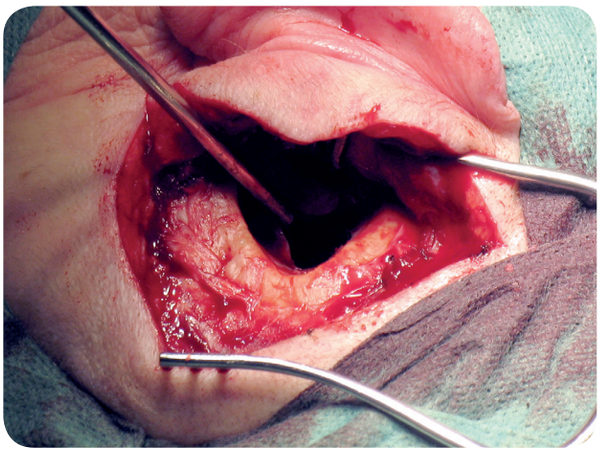
Natural bone formation with
BonAlive® granules

www.bonalive.com

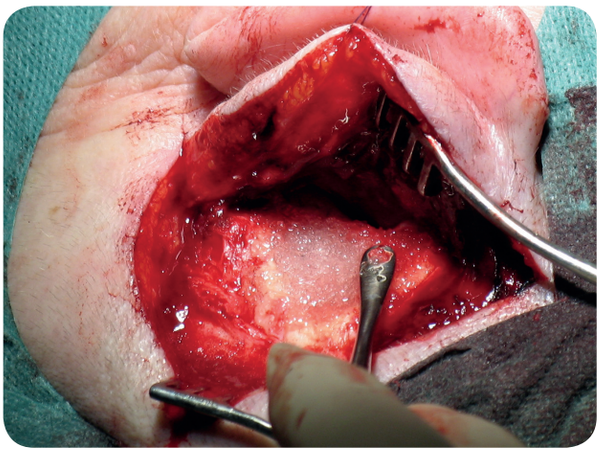
BonAlive® in mastoid obliteration[3]

The unique *bacterial growth inhibiting* feature of BonAlive® gives distinct advantages when used to obliterate discharging and chronically infected radical mastoid cavities. In addition, the *osteostimulative** property and *slow resorption* profile of BonAlive® supports new bone formation in the mastoid cavity.

**non-osteoinductive*



Old radical mastoid cavity opened with a retroauricular incision

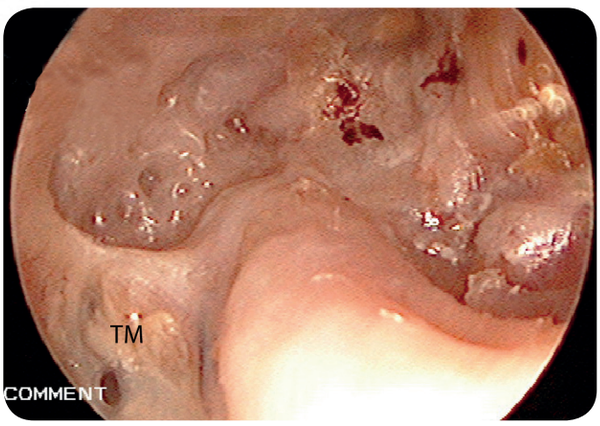


Radical mastoid cavity filled with BonAlive® granules

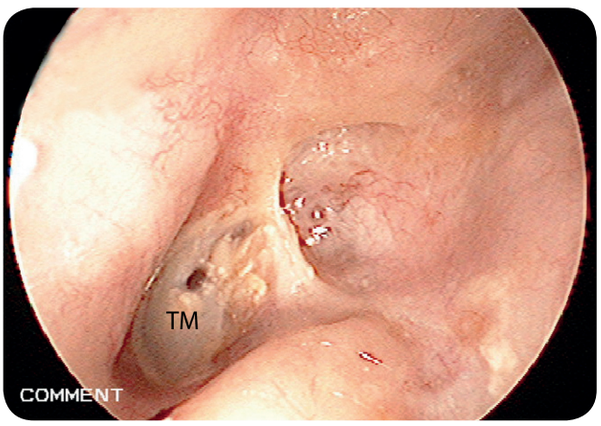
Photos © BonAlive Biomaterials Ltd

Seven patients (3 females and 4 males in an age range of 30-70 years) with radical cavities due to chronic suppurative otitis media or cholesteatoma surgery were treated by filling the cavities in the mastoid area with BonAlive® granules. The area was filled with 5 cc (0.5-0.8 mm/small size) of BonAlive® and closed with a musculoperiosteal flap and temporalis muscle fascia to keep the BonAlive® granules in position. During the follow-up periods, which ranged from 22-98 months (mean: 57 months), the radical cavity was totally eliminated in two patients and in five patients reduced to a small dry cavity. No BonAlive® -associated infections or extrusions of the material were seen.

Patient case: BonAlive® in obliteration of an old radical mastoid cavity*



Pre-op status *TM=tympanic membrane*

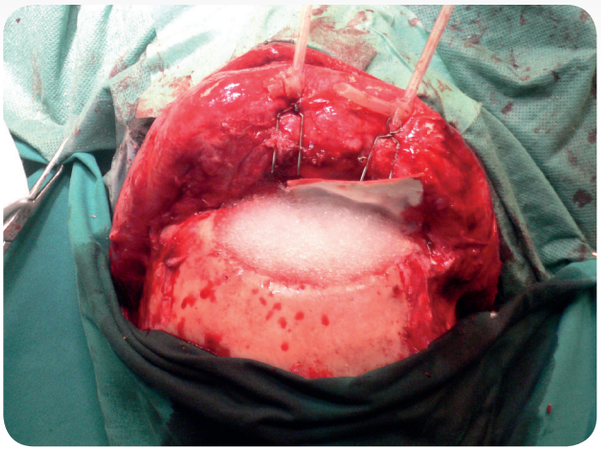


Three years post-op *TM=tympanic membrane*

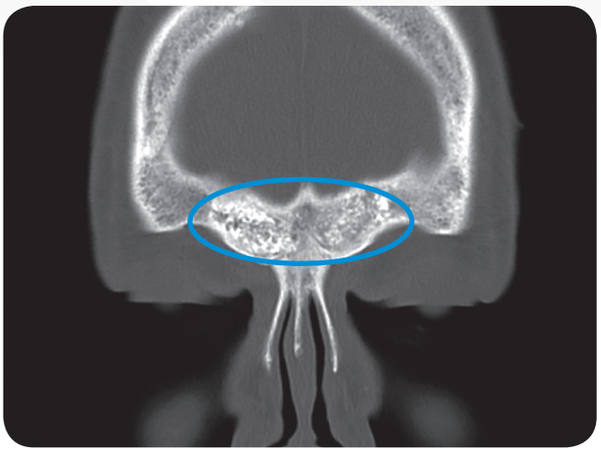
A 60 year old female patient was diagnosed with cholesteatoma in the right ear in 1975 and a radical mastoidectomy was performed. Revision surgery and obliteration with autologous bone was performed in 1999 due to repeated otorrhea, otalgia and cleaning problems. Due to continuing problems, revision surgery was performed in September 2007. The radical mastoid cavity was thoroughly cleaned by removing granulation tissue and old poorly vital bone. Skin from the large cavity was lifted from the bottom of the cavity and used for the reconstruction of the posterior wall. Bone surfaces were cleaned with a drill and laser and the musculoperiosteal flap was used to support the skin that was placed against the posterior wall of the ear canal. The mastoid cavity was obliterated using BonAlive® granules (4 cc; 0.5-0.8 mm/small size). The ear has been dry since the operation. Only a slight widening of the ear canal was observed in the three years follow-up. This was mostly due to resorption of the musculoperiosteal flap. Regular follow-up was ceased as the ear was problem free.

**Source: Päijät-Häme Central Hospital, Finland*

BonAlive® in frontal sinus obliteration[4]



Peri-op picture after obliteration



CT showing the implanted BonAlive® granules

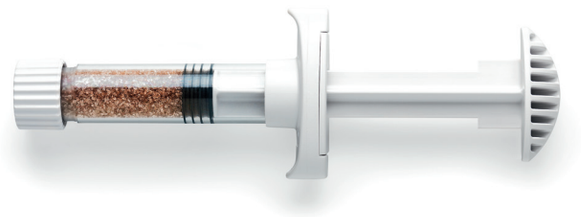
Photos are not part of the described clinical case.
Photos © Turku University Hospital, Finland

BonAlive® granules were used as an obliteration material in a series of osteoplastic frontal sinus operations on 42 patients suffering from chronic frontal sinusitis, which could not be cured with other means of treatment. Accurate obliteration of sinuses was achieved in 39 patients. Histopathologic samples harvested at 1, 5, and 10 years after obliteration revealed a healing process progressing from the fibrous tissue phase to bone formation with scattered fibrous tissue and bony obliteration maintaining BonAlive® granule remnants. Fourier-transform infrared (FTIR) studies showed that bone produced by BonAlive® is similar to natural frontal bone. Microbiological cultures obtained with histological samples revealed no growth of bacteria. BonAlive® appears to be a reliable frontal sinus obliteration material, providing favorable conditions for total bony sinus obliteration.

BonAlive® granules for cranio-maxillofacial surgery

CE 0344

Ref. no	Granule size	Package size
11110	0.5 - 0.8 mm/small	1 cc pouch
11120	0.5 - 0.8 mm/small	2 cc pouch
13130	0.5 - 0.8 mm/small	5 cc applicator
13140	0.5 - 0.8 mm/small	10 cc applicator



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