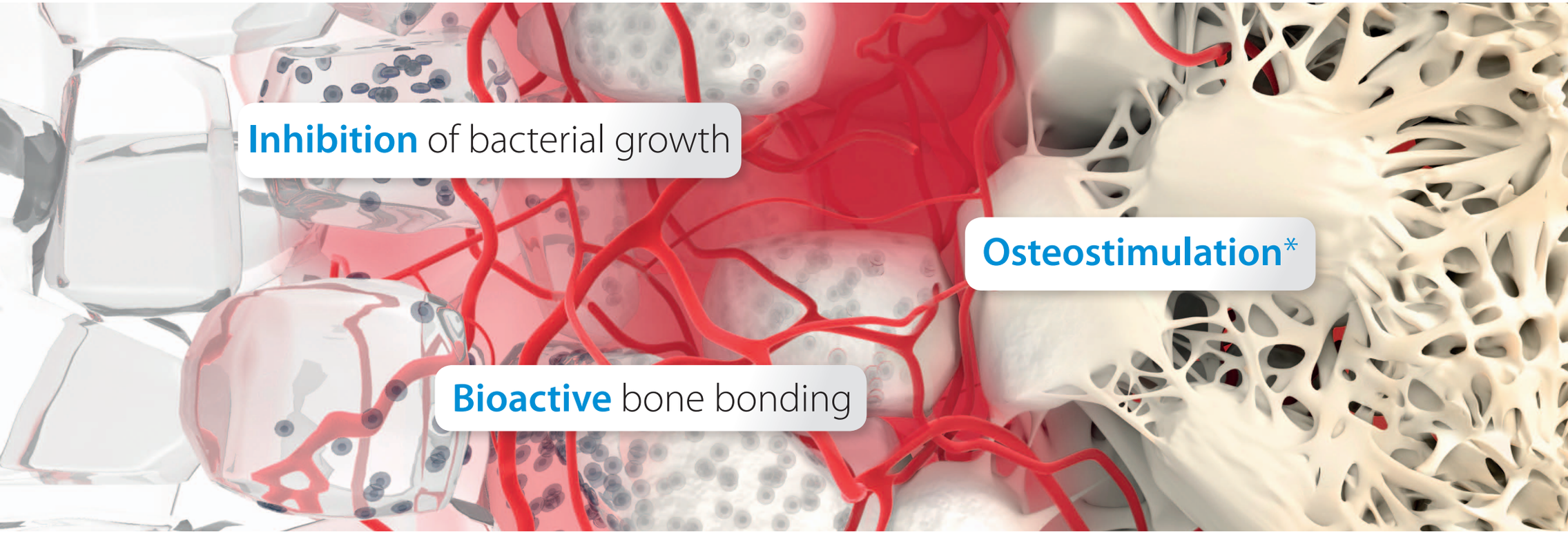
BonAlive® granules

Clinical Cases | *ENT & CMF*



*Non-osteoinduction

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BonAlive® granules mechanism of action

BonAlive® granules is a slowly resorbable bioactive glass based biomaterial with the composition: 53% SiO_2, 23% Na_2O, 20% CaO, 4% P_2O_5

After implantation:

1 hour

Release of ions increases pH and osmotic pressure (Na, Ca, P, Si)

➡ Inhibits bacterial growth on granule surface

1 day

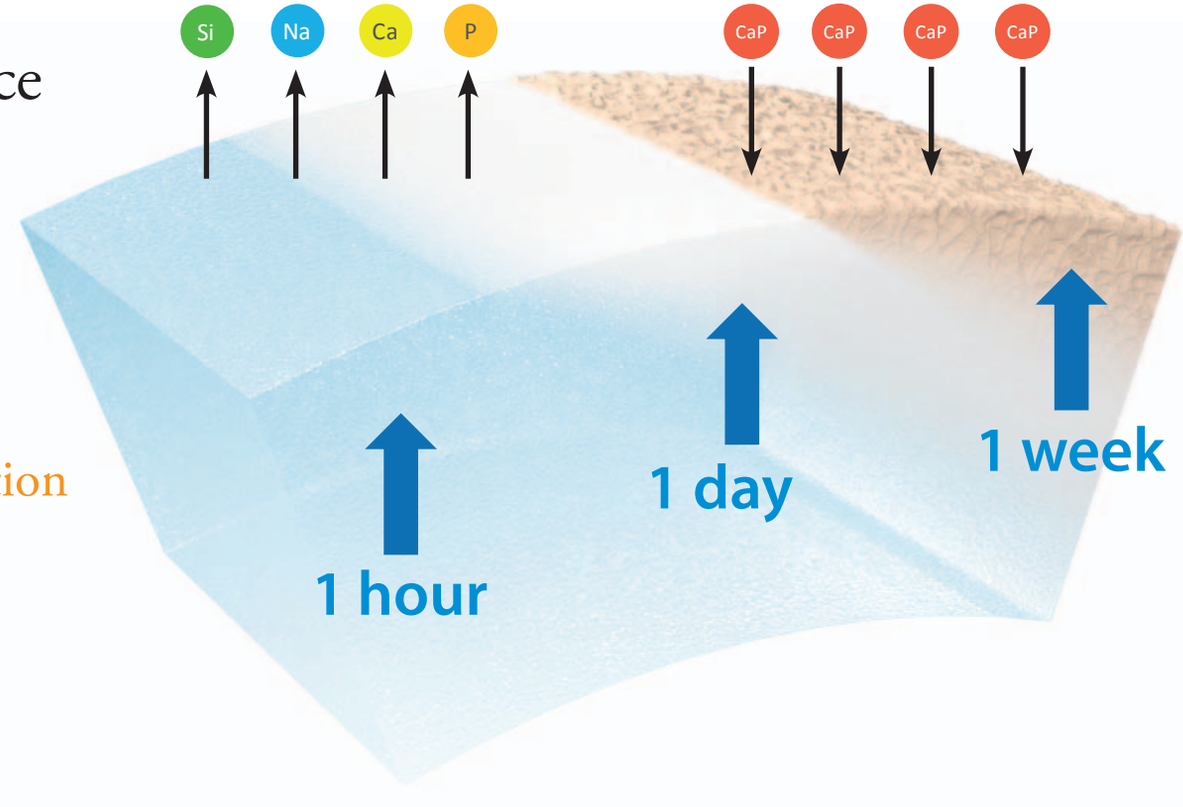
Silica gel layer forms on granule surface

➡ CaP precipitates to surface

1 week

CaP crystallizes to natural HA

➡ Bonds to bone and promotes osteointegration



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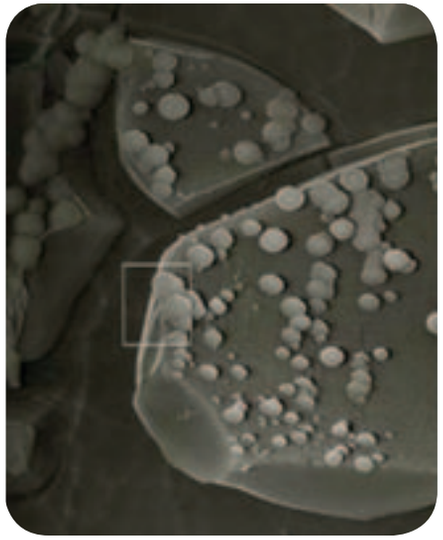
Bone formation with BonAlive® granules

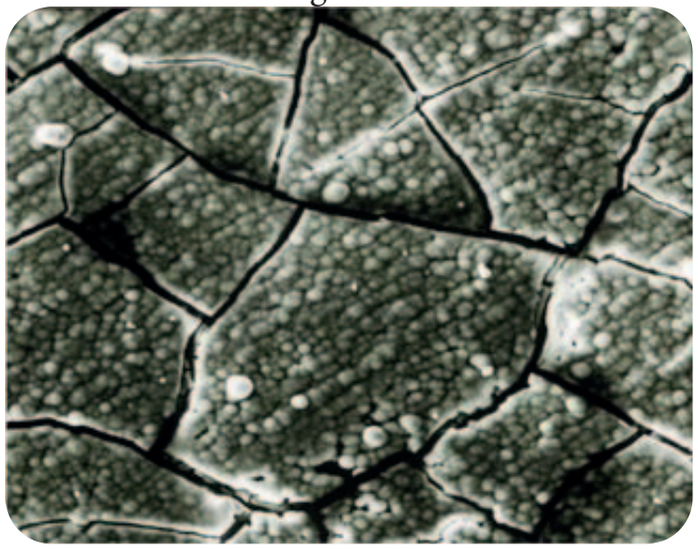
(Scanning electron microscopy images)

Hydroxyapatite starts to form on surface



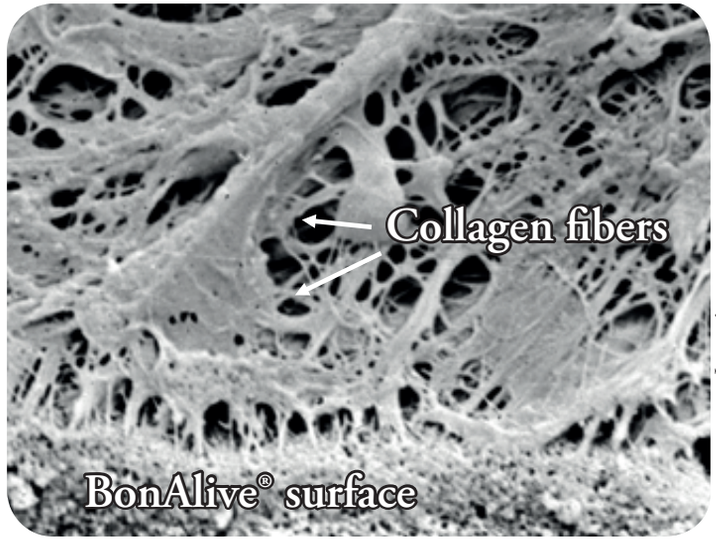
1 day

Hydroxyapatite covers BonAlive® granules surface



1 week

BonAlive® granules bonds to bone and stimulates new bone formation (osteostimulation*)



6-12 weeks

Basis for osteostimulation*

Osteostimulation* signifies that BonAlive® granules has the capacity to:

1) stimulate the recruitment and differentiation of osteoblasts
2) activate osteoblasts to produce new bone
3) activate specific osteoblast genes as a response to ion dissolution from the material

The bioactive glass surface is not only conductive but also osteoproductive in promoting migration, replication, and differentiation of osteogenic cells and their matrix production. *(Virolainen et al. 1997)*

*Non-osteoinduction

A unique feature of BonAlive® granules:

Inhibits Bacterial Growth

A total of 29 aerobic and 17 anaerobic clinically important bacterial species tested.
Results show clear inhibition towards all tested species.

Selected species are listed below:

Aerobic species	Growth inhibition
Gram positive	
S. epidermidis	Effective
S. aureus	Effective
E. faecalis	Effective
S. pneumoniae	Effective

Munukka et al. 2008

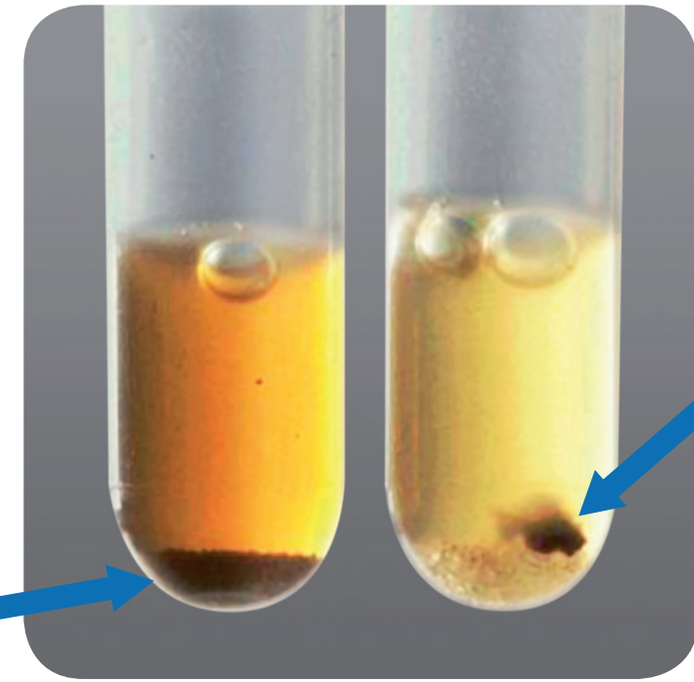
Anaerobic species	Growth inhibition
C. difficile	Effective
B. adolescentis	Effective
E. lentum	Effective
P. gingivalis	Effective
P. acnes	Effective
P. anaerobius	Effective

Leppäranta et al. 2008

Aerobic species	Growth inhibition
Gram negative	
E. coli	Effective
P. aeruginosa	Effective
K. pneumoniae	Effective
H. influenzae	Effective

Munukka et al. 2008

Test with pigmented *P. gingivalis*



Bactericidal effects of bioactive glasses on clinically important aerobic bacteria.
Munukka E, Leppäranta O, Korkeamäki M, Vaahtio M, Peltola T, Zhang D, et al. J Mater Sci: Mater Med. 2008;19:27-32.
Antibacterial effect of bioactive glasses on clinically important anaerobic bacteria in vitro.
Leppäranta O, Vaahtio M, Peltola T, Zhang D, Hupa L, Ylänen H, et al. J Mater Sci: Mater Med. 2008;19:547-551.
Comparison of antibacterial effect on three bioactive glasses.
Zhang D, Munukka E, Leppäranta O, Hupa L, Ylänen H, Salonen J, et al. Key Engineering Materials. 2006;309-311:345-348.
Interactions between bioactive glass and periodontal pathogens.
Stoor P, Kirstilä V, Söderling E, Kangasniemi I, Herbst K, Yli-Urpo A. Microbial Ecology in health and Disease,1996;9:109-114.
Interactions between the frontal sinusitis-associated pathogen Heamophilus Influenzae and the bioactive glass S53P4.
Stoor P, Söderling E, Andersson OH, Yli-Urpo A. Bioceramics. 1995;8:253-258.

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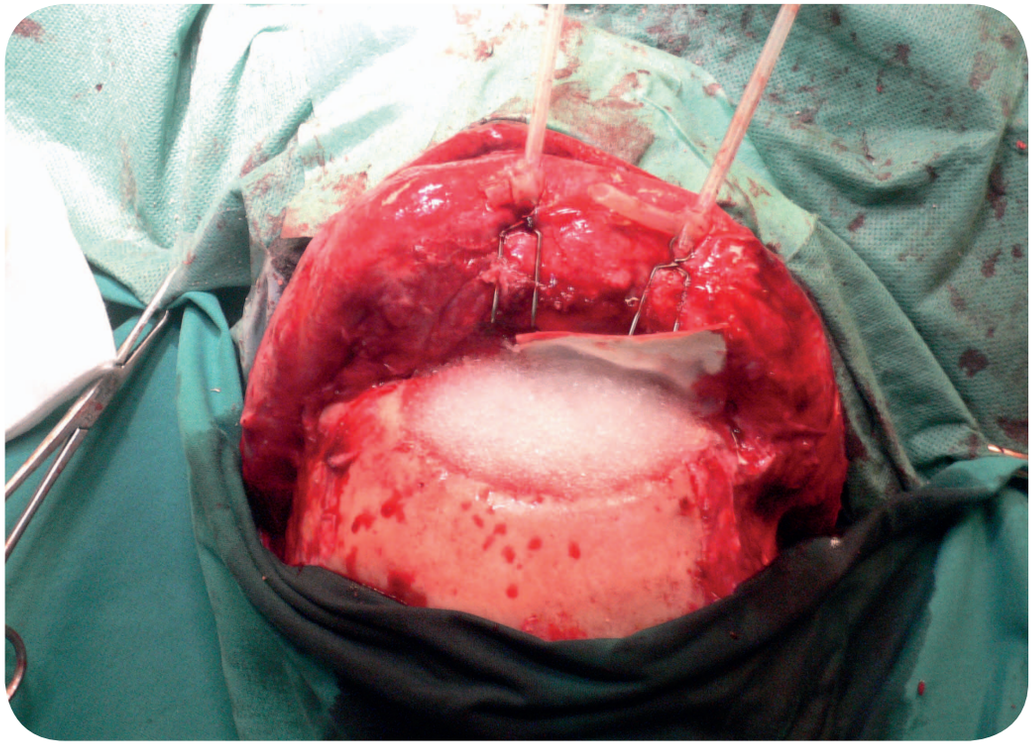
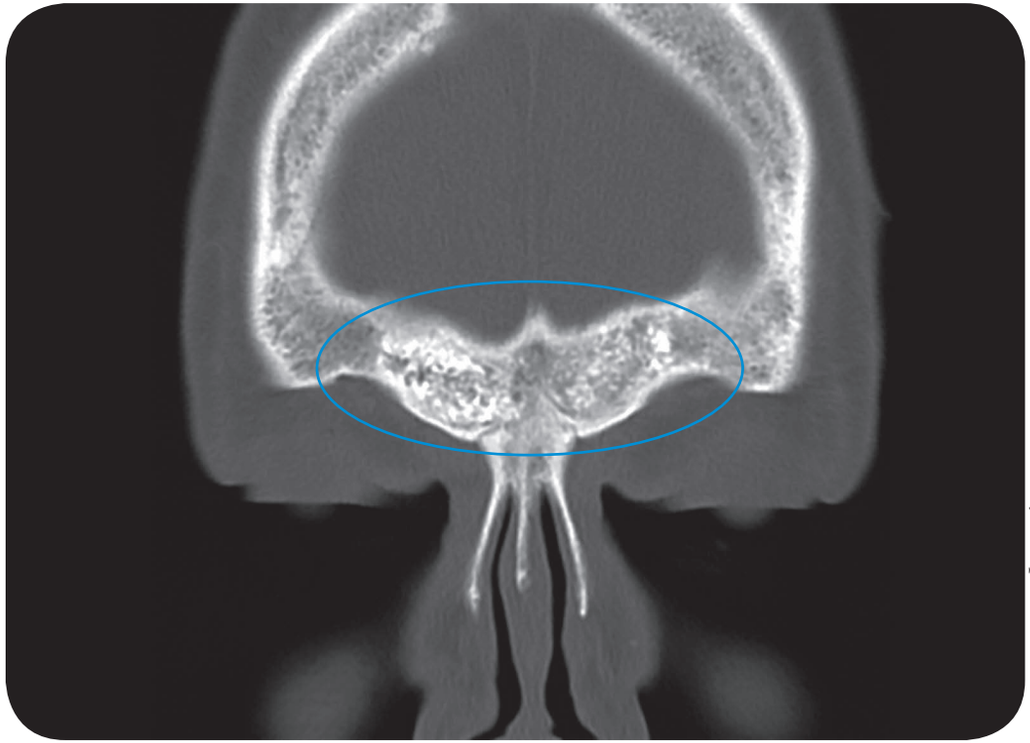
Frontal sinus obliteration

BonAlive® granules has been successfully used for 20 years for frontal sinus obliteration in patients suffering from chronic frontal sinuitis. Healing of the frontal sinus area is promoted by the bacterial growth inhibition and osteostimulative* features of the BonAlive® granules.

**non-osteoinductive*



Clinical image of obliteration with 30 cc (0.5-0.8 mm) BonAlive® granules

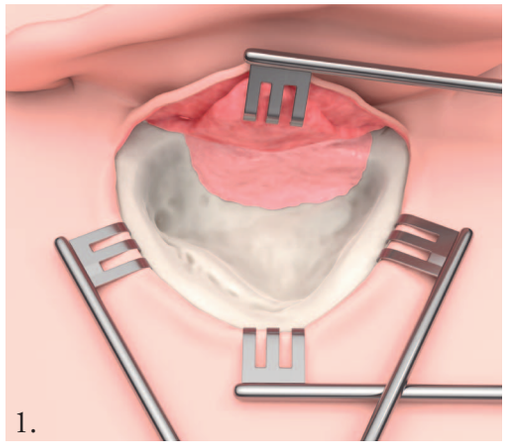


Post-op CT illustrating the implanted BonAlive® granules

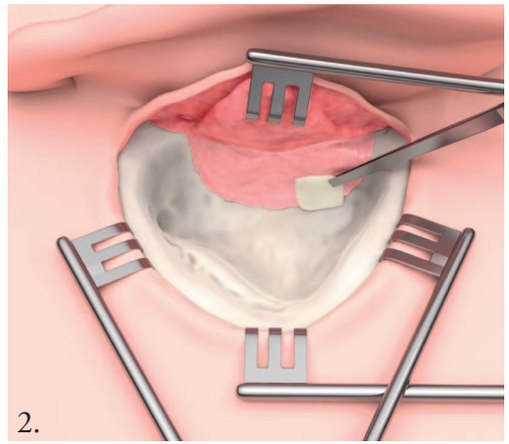
1. Long-term microscopic and tissue analytical findings for 2 frontal sinus obliteration materials. Peltola M, Aitasalo K, Aho AJ, Tirri T, Suonpää J. J Oral Maxillofac Surg. 2008;66(8):1699-1707.
2. Long-term tissue reactions of three biomaterials in craniofacial surgery. Peltola M, Aitasalo K, Tirri T, Rekola J, Puntala A. Key Engineering Materials. 2008;361-363:1343-1346.
3. Bioactive glass hydroxyapatite in fronto-orbital defect reconstruction. Aitasalo K, Peltola M. Plast Reconstr Surg. 2007;120(7):1963-72.
4. Bioactive glass S53P4 in frontal sinus obliteration: A long-term clinical experience. Peltola M, Aitasalo K, Suonpää J, Varpula M, Yli-Urpo A. Head and Neck. 2006;28(9):834-841.
5. Bioactive glass S53P4 in frontal sinus obliteration. A 9-year experience. Aitasalo K, Peltola M, Suonpää J, Yli-Urpo A. Key Engineering Materials. 2001;192-195:877-880.
6. Obliteration of the frontal sinus cavity with bioactive glass. Peltola M, Suonpää J, Aitasalo K, Varpula M, Yli-Urpo M, Happonen R. Head and Neck. 1998;20(4):315-319.
7. Behaviour of bioactive glass (S53P4) in human frontal sinus obliteration. Aitasalo K, Suonpää J, Peltola M, Yli-Urpo A. Bioceramics. 1997;10:429-432.
8. Obliteration of frontal sinuses with bioactive glass after chronic suppurative sinusitis. One year follow up. Aitasalo K, Peltola M, Suonpää J, Yli-Urpo A, Andersson Ö, Varpula M, et al. Bioceramics. 1994;7:409-414.

Mastoid obliteration with BonAlive® granules

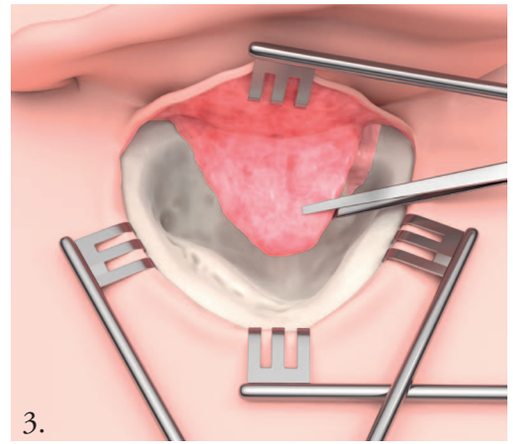
Elevation of the mastoid cavity skin to form new skin for the posterior canal wall



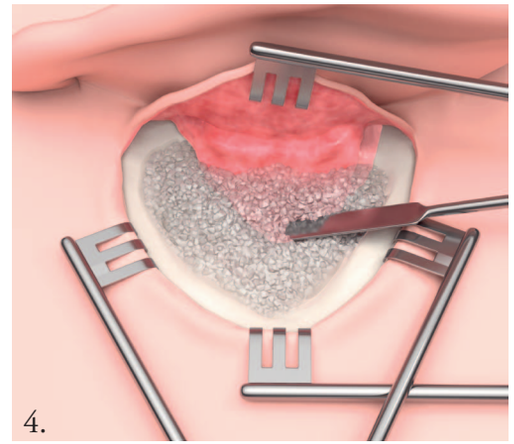
Applying a piece of cartilage on the bottom of the cavity along the skin



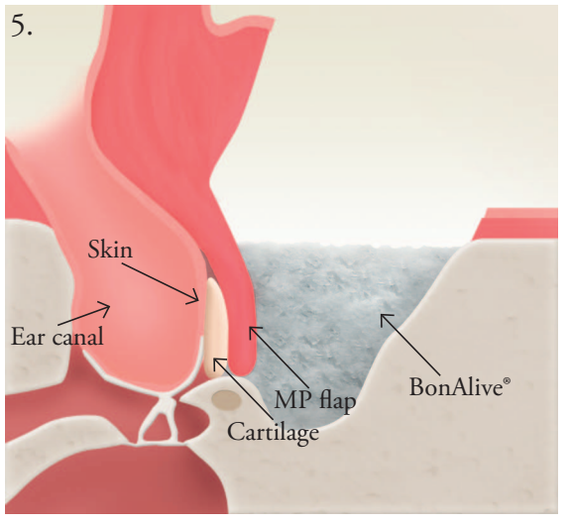
Reconstruction of the canal wall with a Palva type flap (MP-flap)



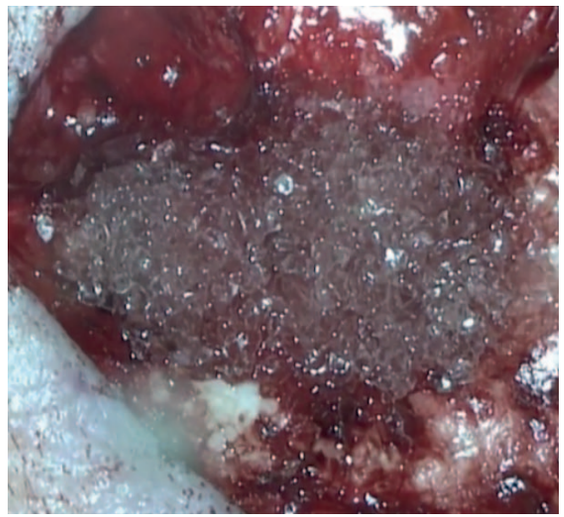
Obliteration of the cavity with BonAlive® bioactive glass



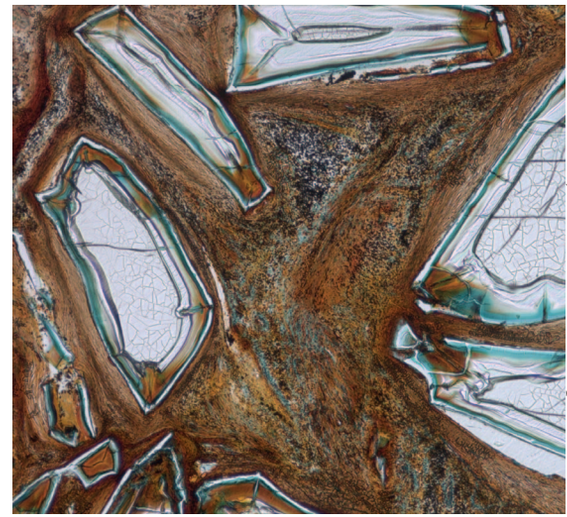
Lateral view of the reconstructed posterior wall of the ear canal and obliterated cavity



Clinical picture illustrating an obliterated mastoid cavity



3-month post-op histology from a mastoid cavity that has been obliterated with BonAlive® granules



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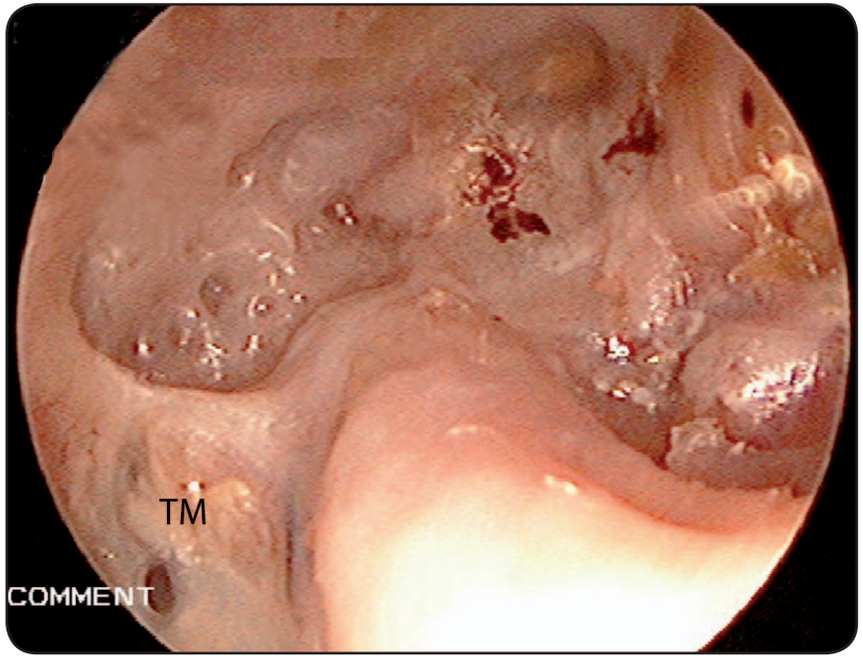
Related articles:
1. Bioactive glass S53P4 in mastoid obliteration surgery for chronic otitis media and cerebrospinal fluid leakage. Sarin J, Grénman R, Aitasalo K, Pulkkinen J. Annals of Otology, Rhinology & Laryngology. 2012;121:563-569.
2. Mastoidectomy Cavity Obliteration with Bioactive Glass: A Pilot Study. Silvola J. Otolaryngology - Head and Neck Surgery. 2011;145(2):P96-P97.
3. Bioactive glass S53P4 in the filling of cavities in the mastoid cell area in surgery for chronic otitis media. Stoor P, Pulkkinen J, Grénman R. Annals of Otology, Rhinology & Laryngology. 2010;119(6):377-382.

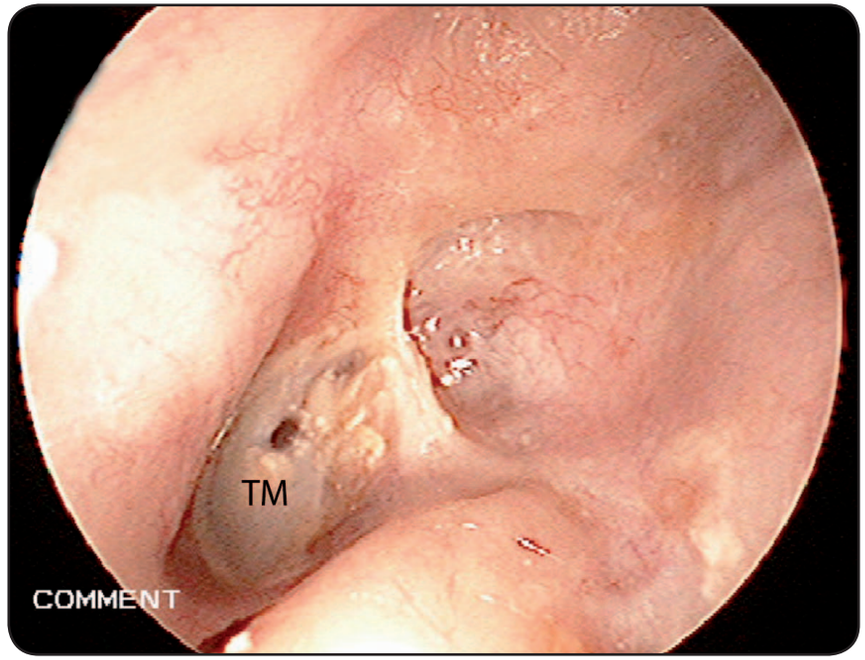
BonAlive® granules in obliteration of an old radical mastoid cavity

Patient: 60-year old female
Operation: Radical mastoidectomy in 1975 due to cholesteatoma (right ear). Revision in 1999 due to repeted otorrhea, otalgia and cleaning problems. Obliteration using BonAlive® granules (4 cc; 0.5-0.8 mm) in 2007.
Outcome: The ear has been problem free and dry since the operation and the ear canal has sustained its natural form.

Pre-op status



3-year post-op image



Source: Päijät-Häme Central Hospital, Finland

Filling a follicular cyst cavity in the mandible

Patient: Female born 1979
Operation: May 2009, 6 cc of BonAlive® granules (0.5-0.8 mm) was used to fill the defect

X-ray image showing the cyst with total lack of posterior bone support for the second molar

Surgical removal of the wisdom tooth and the cyst (20*15*30 mm). Nervus alveolaris inferior was exposed (6 mm) and covered with a collagen membrane. The second molar was saved.

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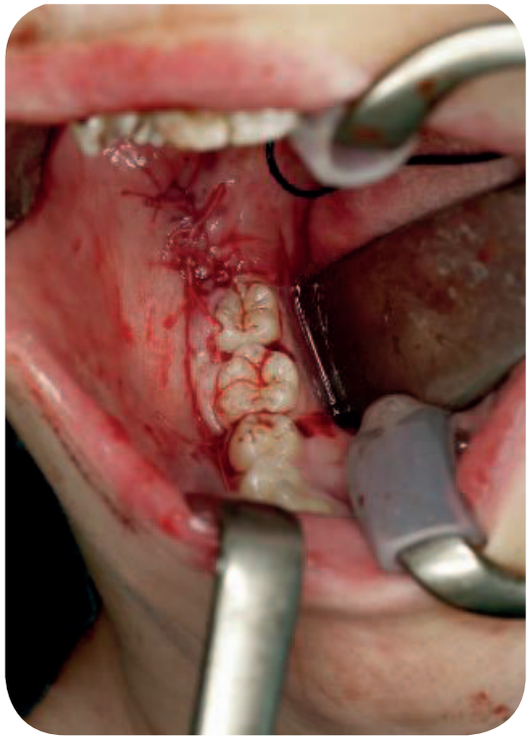
Outcome: At 18 months post-op the area had healed and the posterior bone support for the second molar has been successfully recovered



The defect was filled with 6 cc of BonAlive® granules (0.5-0.8 mm), covered with collagen membrane and the wound was closed.

Post-op x-ray image

18-month post-op x-ray image

Bilateral sagittal split osteotomy (BSSO) surgery

Patient: 45-year old female with mandibular retrognatia
Operation: March 2011, BSSO with a 10 mm mandibular advancement, 2.5 cc of BonAlive® granules (0.5-0.8 mm) was used for grafting on each side.

Pre-op x-ray, lateral view

Clinical image of defect after sagittal split osteotomy and fixation with mini plate and mono cortical screws

Filling of the osteotomy site with BonAlive® granules and application of tissue glue

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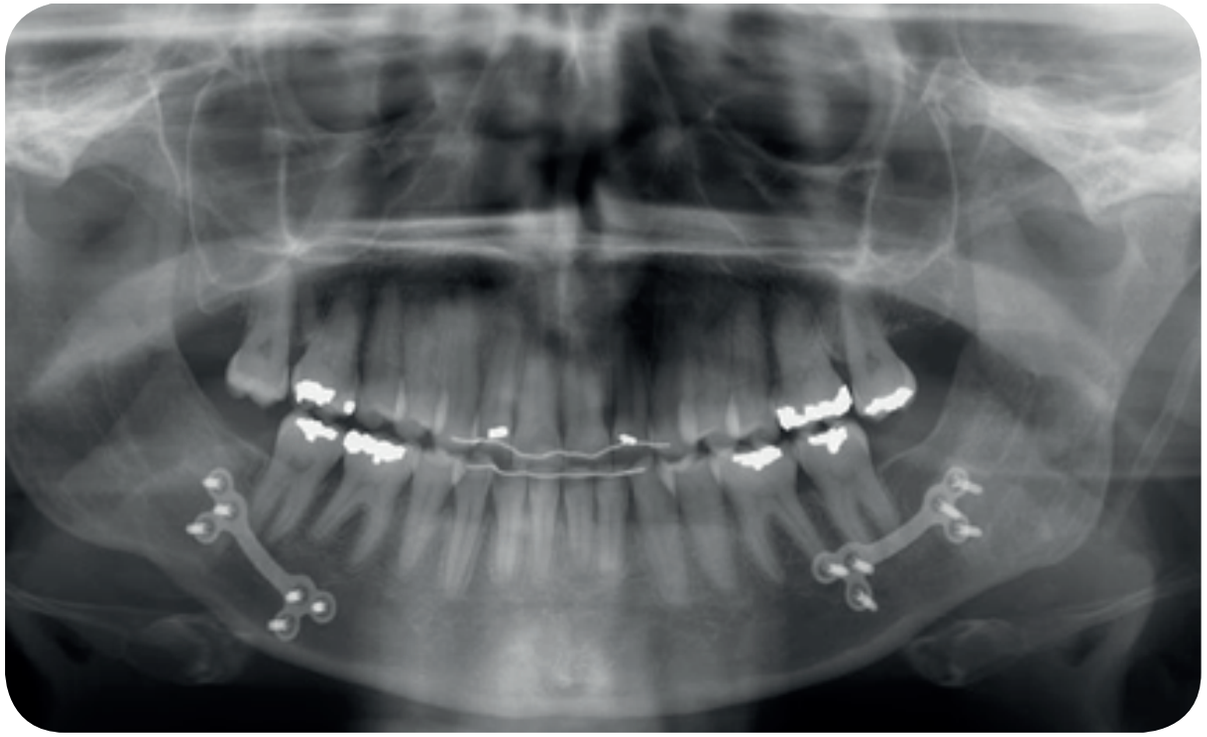
Outcome: At 12 months post-op the follow-up showed uneventful healing with a normal contour of the inferior mandible border

Immediate post-op x-ray



12-month post-op x-ray

References

The reputation of BonAlive® is built on solid clinical evidence
- *Over 20 peer-reviewed published clinical articles*
- *More than a decade of human prospective randomized clinical data*

Mechanism of action (osteostimulation*)

Osteoblast response to continuous phase macroporous scaffolds under static and dynamic culture conditions.
Meretoja VV, Malin M, Seppälä JV, Närhi TO. J Biomed Mater Res. 2008;89A(2):317-325.

Molecular basis for action of bioactive glasses as bone graft substitute.
Välimäki VV, Aro HT. Scandinavian Journal of Surgery. 2006;95(2):95-102.

Intact surface of bioactive glass S53P4 is resistant to osteoclastic activity.
Wilson T, Parikka V, Holmbom J, Ylänen H, Penttinen R. J Biomed Mater Res. 2005;77A:67-74.

Granule size and composition of bioactive glasses affect osteoconduction in rabbit.
Lindfors NC, Aho AJ. J Mater Sci: Mater Med. 2003;14:265-372.

Frontal sinus and skull bone defect obliteration with three synthetic bioactive materials. A comparative study.
Peltola M, Aitasalo KM, Suonpää JT, Yli-Urpo A, Laippala PJ, Forsback A. J Biomed Mater Res. 2003;66B:364-372.

Osteoblast differentiation of bone marrow stromal cells cultured on silica gel and sol-gel-derived titania.
Dieudonné SC, van den Dolder J, de Ruijter JE, Paldan H, Peltola T, van 't Hof MA, et al. Biomaterials. 2002;23:3041-3051.

Histomorphometric and molecular biologic comparison of bioactive glass granules and autogenous bone grafts in augmentation of bone defect healing.
Virolainen P, Heikkilä J, Yli-Urpo A, Vuorio E, Aro HT. J Biomed Mater Res. 1997;35A(1):9-17.

**non-osteoinduction*

Inhibition of bacterial growth

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Bactericidal effects of bioactive glasses on clinically important aerobic bacteria.
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Interactions between the frontal sinusitis-associated pathogen Heamophilus Influenzae and the bioactive glass S53P4.
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Frontal sinus surgery

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Behaviour of bioactive glass (S53P4) in human frontal sinus obliteration.
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Obliteration of frontal sinuses with bioactive glass after chronic suppurative sinusitis. One year follow up.
Aitasalo K, Peltola M, Suonpää J, Yli-Urpo A, Andersson Ö, Varpula M, et al. Bioceramics. 1994;7:409-414.

Mastoid surgery

Bioactive glass S53P4 in mastoid obliteration surgery for chronic otitis media and cerebrospinal fluid leakage.
Sarin J, Grénman R, Aitasalo K, Pulkkinen J. Annals of Otology, Rhinology & Laryngology. 2012;121:563-569.

Mastoidectomy Cavity Obliteration with Bioactive Glass: A Pilot Study.
Silvola JT. Otolaryngology - Head and Neck Surgery. 2011;145(2):P96-P97.

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Preclinical publications

Bioactive glass stimulates in vitro osteoblast differentiation and creates a favorable template for bone tissue formation.
Loty C, Sautier JM, Tan MT, Oboeuf M, Jallot E, Boulekbache H, et al. J Bone Miner Res. 2001;16(2):231–239.

Bioactive glass and calcium carbonate granules as filler material around titanium and bioactive glass implants in the medullar space of the rabbit tibia.
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Heikkilä JT, Salonen H, Yli-Urpo A, Aho AJ. Bioceramics. 1996;9:123-126.

Protein adsorption properties of bioactive glasses compared to their behaviour in rabbit tibia.
Brink M, Söderling E, Turunen T, Karlsson KH. Bioceramics. 1995;8:471-476.

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BonAlive® granules | Product offering

1 cc

2.5 cc

5 cc

10 cc

BonAlive® granules in small applicator

Ref. no	Granule size	Unit size
13110	0.5-0.8 mm (small)	1 cc
13120	0.5-0.8 mm (small)	2.5 cc

BonAlive® granules in large applicator

Ref. no	Granule size	Unit size
13130	0.5-0.8 mm (small)	5 cc
13140	0.5-0.8 mm (small)	10 cc

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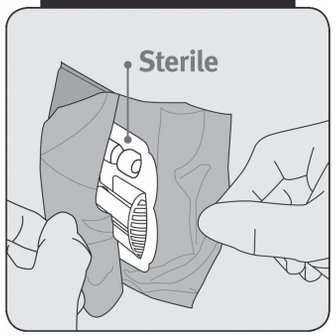
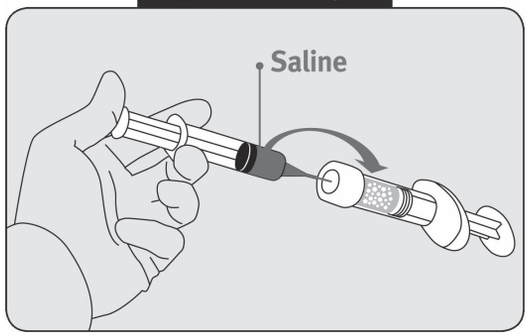
Instructions for use

Figure 1 / Step 1



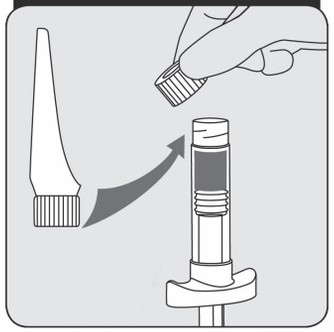
Peel open the pouch and aseptically remove the sterile tray.

Figure 2 / Step 2



Moisten the granules by injecting sterile physiological saline slowly through the cap membrane.

Figure 3 / Step 3 & 4a



Screw tightly the shovel onto the applicator body, turn the applicator to a horizontal position, and push the plunger rod to slide the moistened granules onto the shovel. Move the applicator to the defect site and implant the moistened granules from the shovel into the defect with the aid of a sterile instrument.

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