Spine Fusion Surgery

bonalive

Smart Healing™

Together with medical professionals we create Smart Healing™ – a better future for healthcare and smarter solution for spine and neurosurgery.

Contents

Bonalive is an ISO 13485:2016 certified, Class III medical device company.

Bonalive® putty is CE marked medical device.

Bonalive is committed to the promise of Smart Healing™. Through Smart Healing™ we sustainably improve the anatomical and functional healing of the spine – supporting healthy bone formation and reliable fusions in patients.

Smart Healing™

Patients with a compromized spine require special attention due to a complex anatomy and risks for devastating pain. We provide Smart Healing™, which means we focus on solutions that restore the function of the spine by supporting the patient's own biological healing processes.

The long-term use of our Bonalive® products has proven their clinical safety and efficacy without disturbing the normal growth of bone. The world needs solutions that are smarter and more sustainable for all patients worldwide.

About us Bonalive is a smart biomaterials company, transforming healthcare at the intersection of biology and technology. With over 20 years of clinical history, and one of the most evidence-based technologies in the industry, we are re-imagining a smarter future for healthcare. Bonalive is a medical device Class III certified company.

Bonalive® putty

A highly moldable, easy-to-apply bone regeneration technology that naturally stimulates bone formation.

Bonalive® putty is an optimized bone graft substitute for spine and neurosurgery. The putty is a sterile ready-to-use paste that can be used without mixing or preparation. The putty consists of S53P4 bioactive glass in addition to a synthetic binder, i.e. a blend of polyethylene glycols (PEGs) and glycerol. The binder allows the putty to stay in place during surgery.

Bonalive® putty is frequently combined with autologous bone in spine fusion procedures as a volume expander.

Bonalive® putty | Adult patient | Pediatric patient

INDICATIONS FOR USE

- Bony voids and gaps

INTENDED USE

- Filling, reconstruction and regeneration of bone defects

PROPERTIES

- Osteoconductive
- Osteostimulative*

COMPOSITION

- 53% SiO_2
- 23% Na_2O
- 20% CaO
- 4% P_2O_5
- Polyethylene glycols (PEGs) and glycerol

Bonalive® putty
For spine surgery.

Unit size	Ref. no.
1 cc prefilled applicator	16110
2.5 cc prefilled applicator	16120
5 cc prefilled applicator	16130
10 cc prefilled applicator	16140

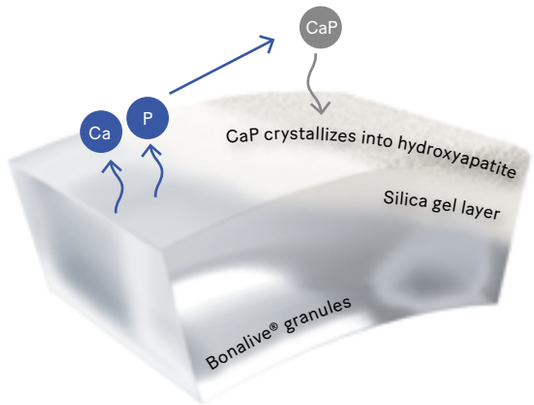
Bonalive® putty MIS
For minimally invasive surgery, especially hard to reach areas.

Unit size	Ref. no.
1 x 5 cc prefilled cartridge with dispenser	18100
1 x 5 cc prefilled cartridge	18131

Our technology

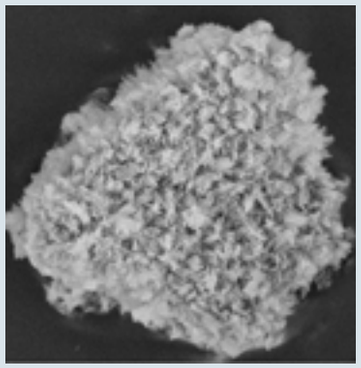
Bone regeneration and remodeling

Bonalive® S53P4 bioactive glass is osteoconductive and also osteoproductive in the promotion, migration, replication and differentiation of osteogenic cells and their matrix production.*

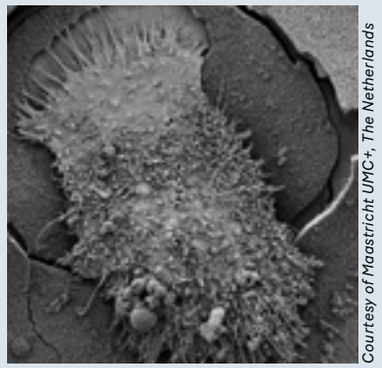


When the bioactive glass is placed into the bony area it reacts with body fluids and ions are released from the glass surface. These surface reactions develop a silica gel layer on the bioactive glass that attracts CaP to crystallize into natural hydroxyapatite.

Once the hydroxyapatite layer is formed the bioactive glass interacts with biological entities, i.e. blood proteins and growth factors. Following this interactive, osteoconductive and osteostimulative process, new bone grows onto and between the bioactive glass structures.

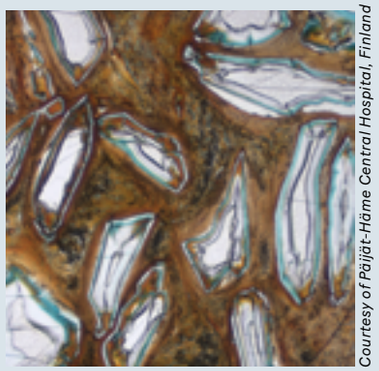


Natural hydroxyapatite layer formed on bioactive glass granule 72 hours after exposure to an aqueous solution.



Courtesy of Maastricht UMC+, The Netherlands

The SEM (scanning electronic microscopy) image shows the osteoclast activity on the surface of the Bioactive glass.



Courtesy of Päijät-Häme Central Hospital, Finland

Histological image 3 months after Bonalive® granules implantation (human biopsy).

* Virolainen et al. 1997. Histomorphometric and molecular biologic comparison of bioactive glass granules and autogenous bone grafts in augmentation of bone defect healing.

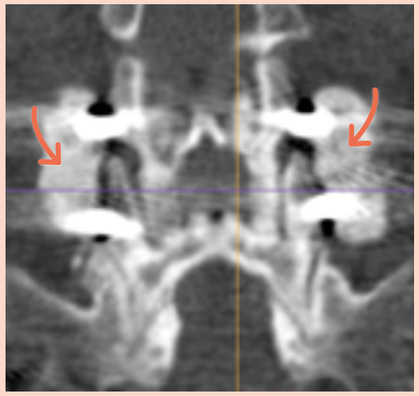
Visualization of the healing process

The radiopaque feature of Bonalive® putty enables significant benefits, both for patients and medical professionals.

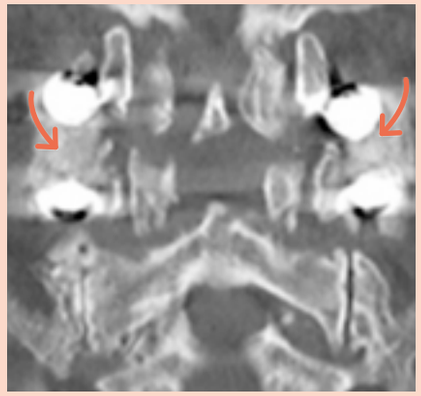
Bonalive® putty can be visualized perioperatively and postoperatively, allowing for post-operative evaluation of the healing process without the need for further surgical intervention.

Bonalive® putty

Post-op CT (coronal)



6-month post-op CT (coronal)



Courtesy of Brisbane Private Hospital, Australia

Areas of use

Long term clinical experience has been gained in several application areas in spine surgery.

Cervical fusion

Anterior cervical discectomy and fusion (ACDF) is surgery to decompress the neural structures due to a herniated disc or osteophytes. An incision is made in the anterior part of the neck to gain access to the disc space. The disc is removed, and a cage with bone graft is inserted to fuse the vertebrae after decompression. An anterior plate fixation may also be used to provide additional support.

A posterior approach is used in degenerative and trauma cases. This technique allows a wide decompression and stabilization of the spine using lateral mass screws and rods. Anterior and posterior approaches can be combined in complex pathology.

Interbody fusion

In combination with pedicle screw fixation, a cage can be placed in the disc space through a posterior or lateral approach. The cage provides load sharing and containment of the bone graft that facilitates a bony fusion. An anterior approach can be used in the low segments of the lumbar spine with anterior fixation of the cage allowing a stand-alone construct.

Posterolateral thoraco-lumbar fusion

In conditions involving a vertebral slip, spinal stenosis or compression of the nerve roots, a posterior approach to the thoracolumbar spine can be used. This involves a posterior approach to the spine, detaching the paravertebral muscles, decompressing the spine and performing a fusion of the vertebraes.

Transpedicular screws are used with rods to stabilize the segments and bone graft material is placed over the transverse processes laterally on the vertebrae. The procedure can be combined with an intervertebral fusion.

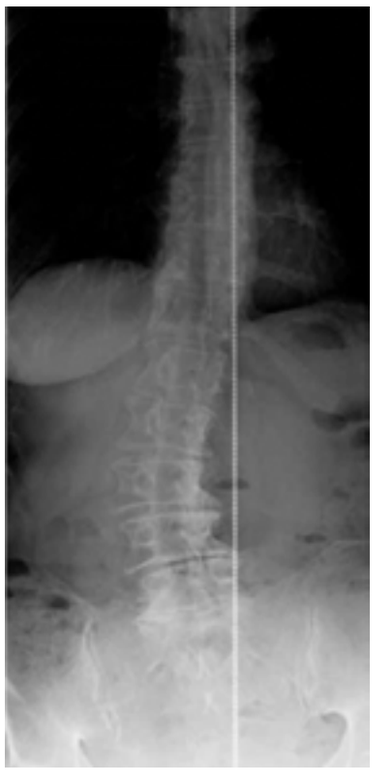
Spinal deformity surgery

Deformities of the spine are in most cases non-progressive; however, in some patients, scoliosis and kyphosis continue to progress slowly throughout life. This can result in cosmetic issues, functional issues and occasionally painful and sometimes dangerous curvatures that must be addressed through spine stabilization surgery.

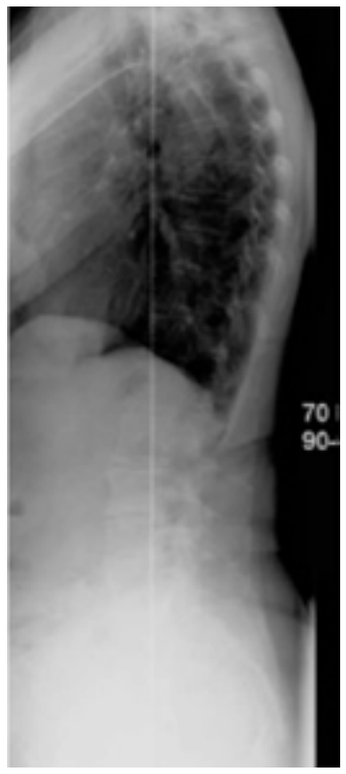
In this type of surgery transpedicular fixation and osteotomies are performed in order to achieve correction of the curvatures of the spine. Intervertebral cages may be used for additional correction and load sharing of the construct. Various types of bone grafts may be used depending on the construct and the age of the patient.

Surgical techniques may vary according to the hospital protocols.

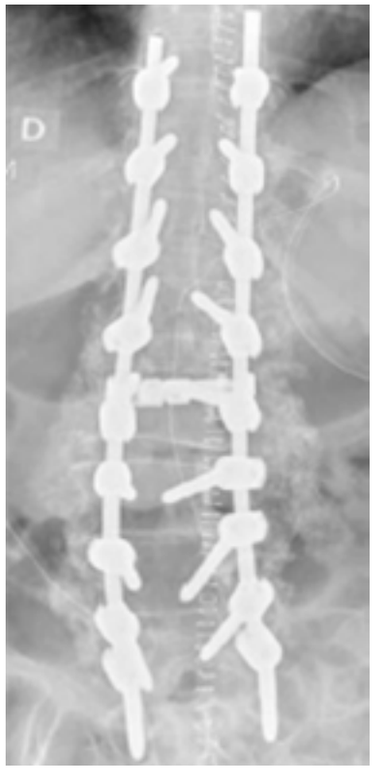
Posterolateral fusion in a degenerative scoliosis patient



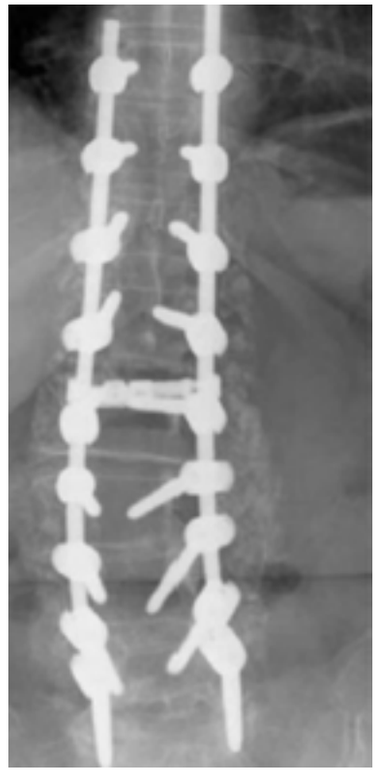
Pre-op X-ray (AP)



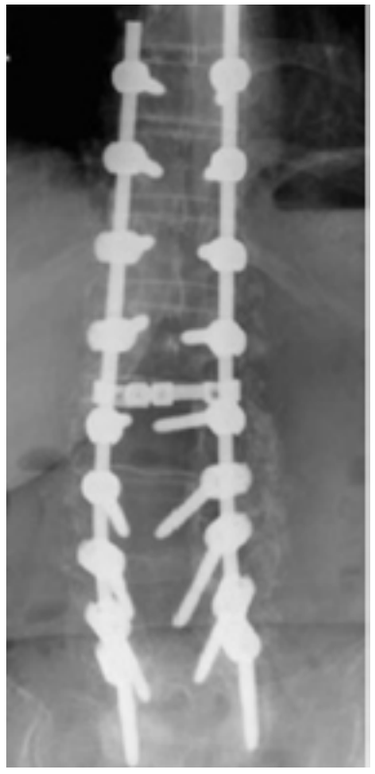
Pre-op X-ray (sagittal)



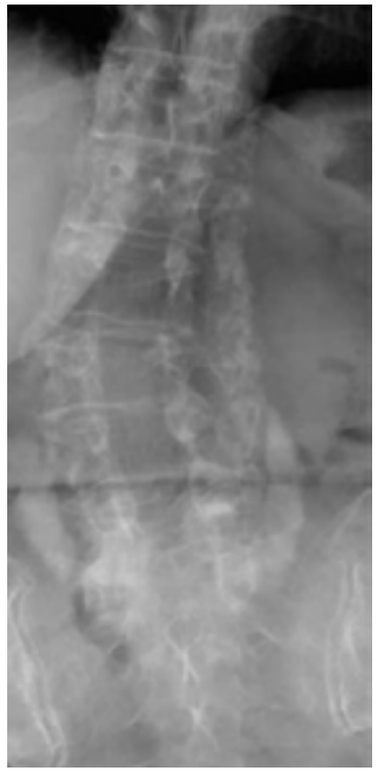
3-day post-op X-ray (AP)



3-month post-op X-ray (AP)



12-month post-op X-ray (AP)



20-month post-op X-ray (AP)

Bonalive® putty

Adult patient

PATIENT

66-year-old patient with a degenerative scoliosis Cobb's degrees 22. Low back pain, radicular symptoms to left L4 dermatome. VAS Pain 8–9/10.

Lumbar MRI showed advanced lumbar degeneration and right convex scoliosis. Left-sided L3/L4 foraminal compression of the nerve roots.

OPERATION

Decompressive laminectomy L2–L5. Two osteotomies. Transpedicular fusion Th10–S1. Posterolateral fusion using autograft and Bonalive® putty as a bone graft expander.

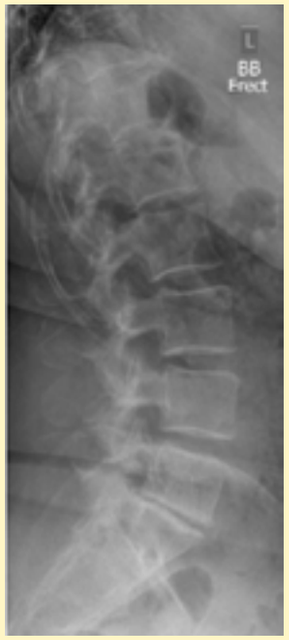
CLINICAL OUTCOME

Intraoperative O-arm® images showed that the instrumentation was placed correctly. Recovered well until 6 months postoperatively, whereafter the patient had kyphotic change in posture.

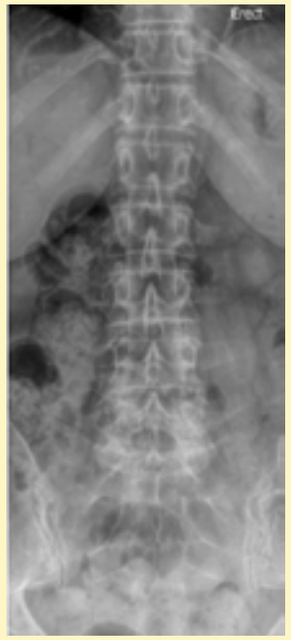
At the one-year follow up the bony fusion was well developed. Removal of the hardware was performed at 20 months post-op, however a pseudoarthrosis was suspected at L5/S1. Re-operation at this level is planned.

Courtesy of Turku University Hospital, Finland

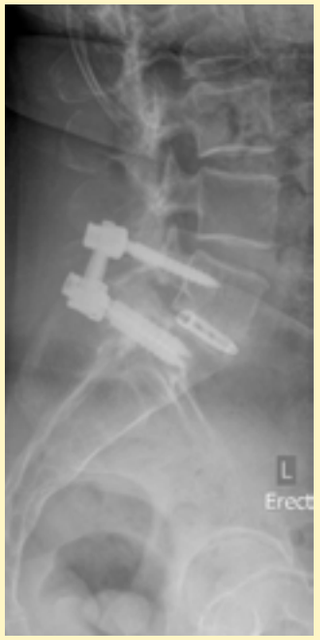
Left L5–S1 transforaminal lumbar interbody fusion



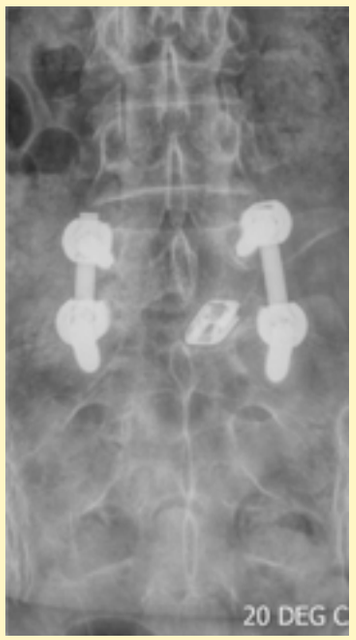
Pre-op x-ray (lateral)



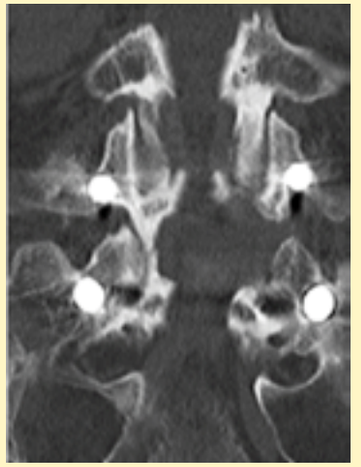
Pre-op x-ray (AP)



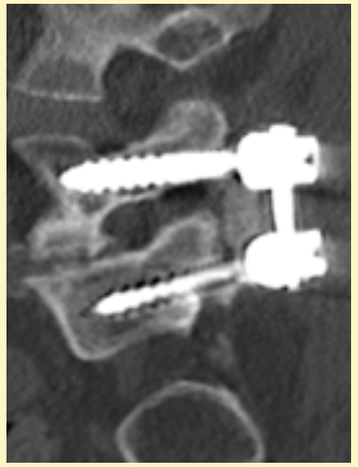
6 months post-op x-ray (lateral)



6 months post-op x-ray (AP)



6 months post-op CT (coronal)



6 months post-op CT (sagittal)

Bonalive® putty

Adult patient

PATIENT

56-year-old female, non-smoker.

Presented to the clinic with severe back pain and left sciatica. L5–S1 disc degeneration.

OPERATION

Left L5–S1 transforaminal lumbar Interbody fusion with Bonalive® putty.

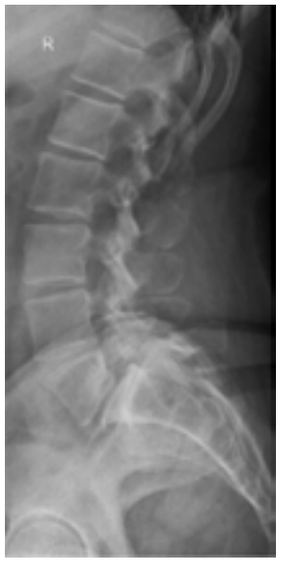
Very narrow disc. Some L5 foraminal and S1 lateral recess stenosis. Suggestion of bony defect in L5 body. Appearances of haemangioma. Core biopsies taken.

CLINICAL OUTCOME

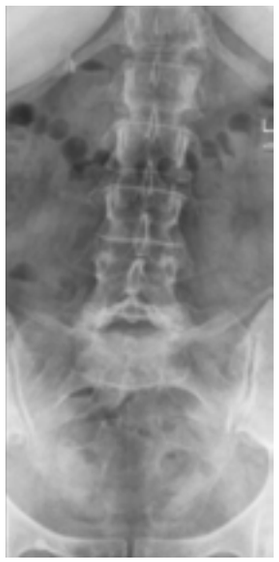
6 months after fusion her leg pain is gone and only minimal back pain remains.

Courtesy of Brisbane Private Hospital, Australia

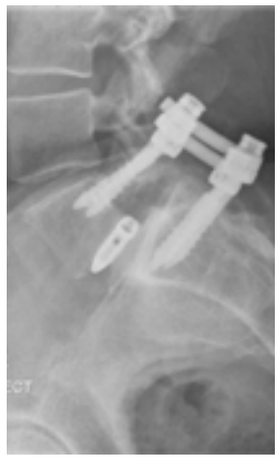
Posterolateral fusion in a grade 2 spondylolisthesis using a minimally invasive technique



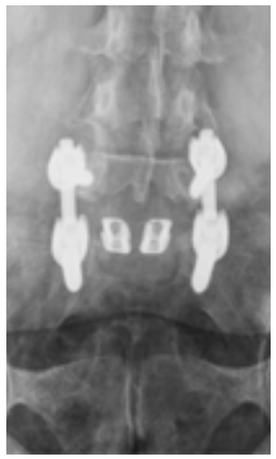
Pre-op x-ray (lateral)



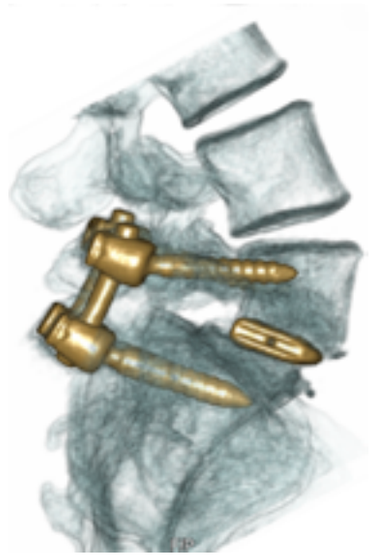
Pre-op x-ray (AP)



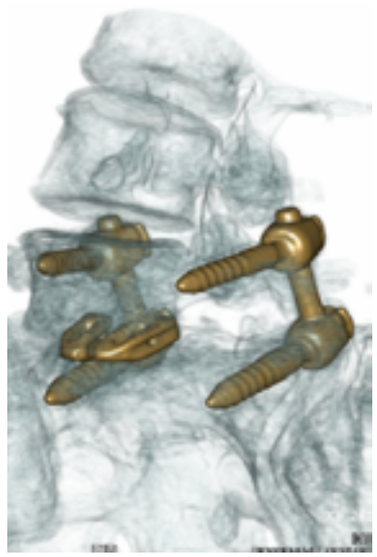
6 months post-op x-ray (lateral)



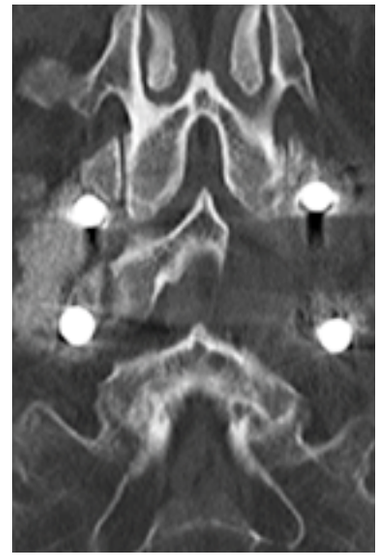
6 months post-op x-ray (AP)



6 months post-op CT (3D)



6 months post-op CT (3D)



6 months post-op CT

Bonalive® putty

Adult patient

PATIENT

73-year-old female. She had a fall and presented right leg pain from the lateral thigh down to the knee. Scans revealed marked degeneration of L2–3 and L3–4 and a disc bulge at L2–3 which was irritating the right L3 nerve root. Left L4–5 foraminal stenosis.

She went through conservative treatment such as rehabilitation and injections prior to undertaking surgery.

OPERATION

Left L5/S1 transforaminal lumbar interbody fusion with Bonalive® putty.

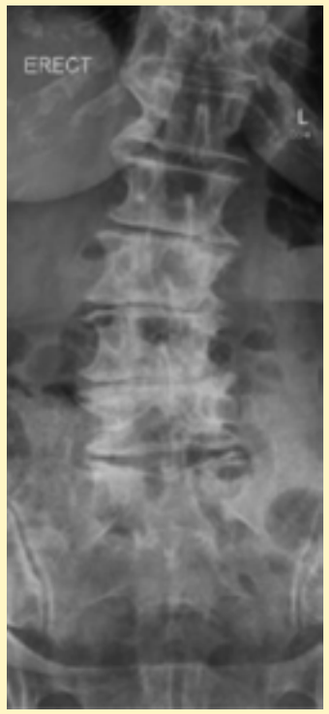
Very compressed left L4 nerve root from thickened facet capsule and facet cyst. Uncomplicated.

CLINICAL OUTCOME

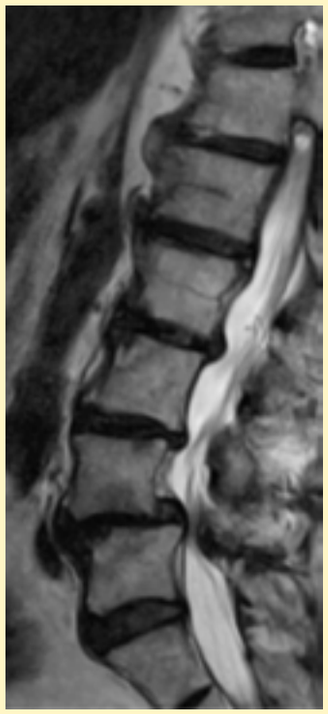
Scan was taken at 6 months post-op. Her nerve pain has improved but unfortunately her foot drop has failed to resolve.

Courtesy of Brisbane Private Hospital, Australia

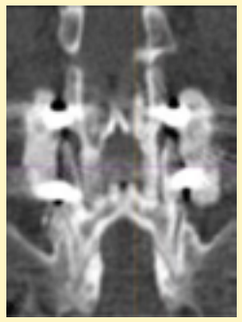
Spine fusion with a medial approach



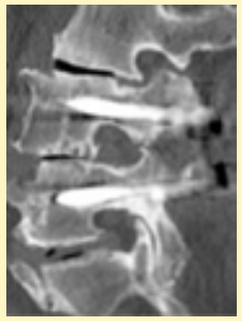
Pre-op X-ray (AP)



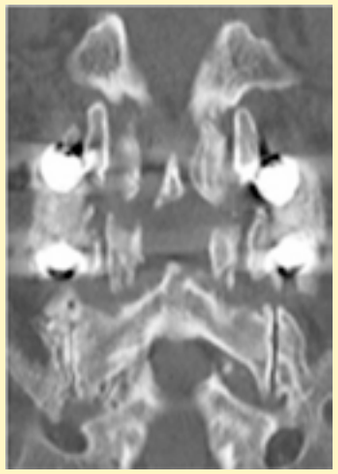
Pre-op MRI T2 (sagittal)



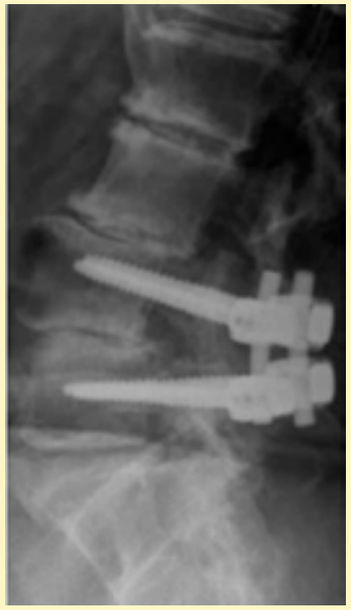
Post-op CT (coronal)



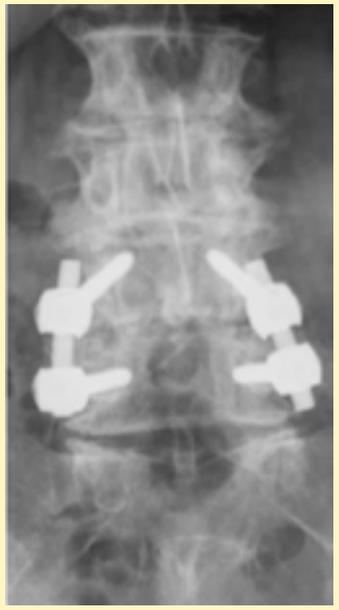
Post-op CT (sagittal)



6-month post-op CT (coronal)



6-month post-op X-ray (lateral)



6-month post-op X-ray (AP)

Bonalive® putty

Adult patient

PATIENT

82-year-old patient with deteriorating back and leg pain and with difficulty in walking.

Symptoms suggestive of neurogenic claudication. The patient received temporary relief with an epidural steroid injection.

OPERATION

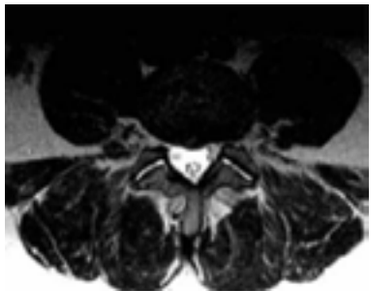
L4/L5 posterolateral instrumented fusion with Bonalive® putty and decompressive laminectomy.

CLINICAL OUTCOME

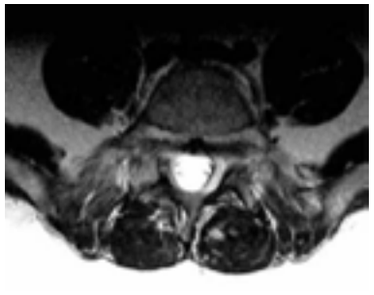
Resolution of leg pain and significant improvement in walking tolerance. Mild ongoing low back pain. Subjectively very satisfied.

Courtesy of Brisbane Private Hospital, Australia

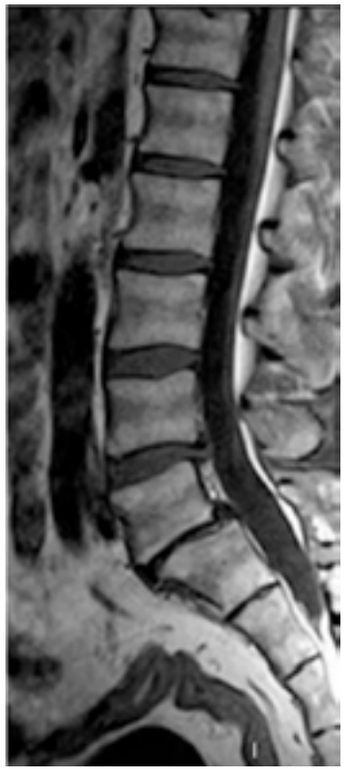
Open posterolateral fusion



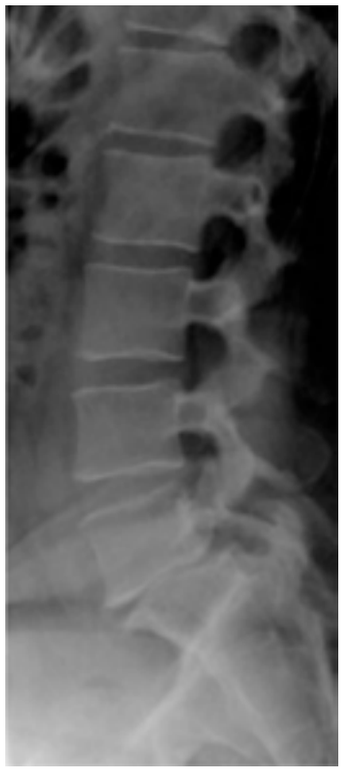
Pre-op MRI T2 (axial L4/L5)



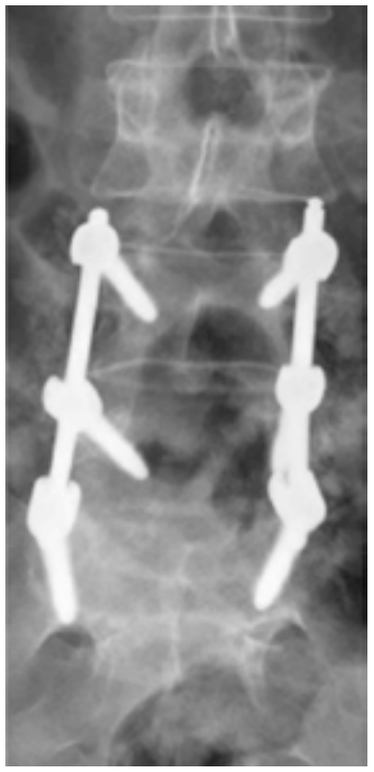
Pre-op MRI T2 (axial L5/S1)



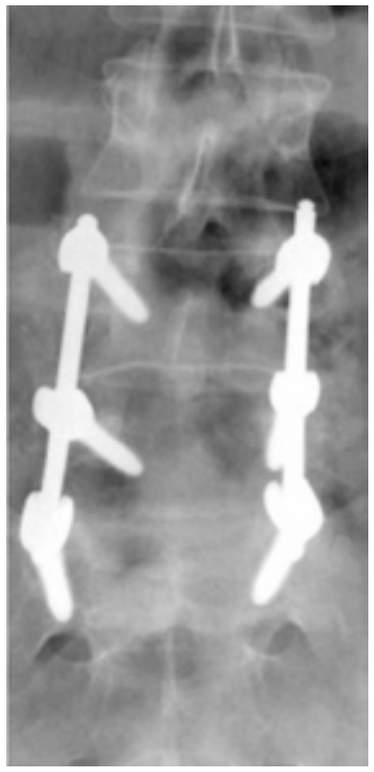
Pre-op MRI T1 (sagittal)



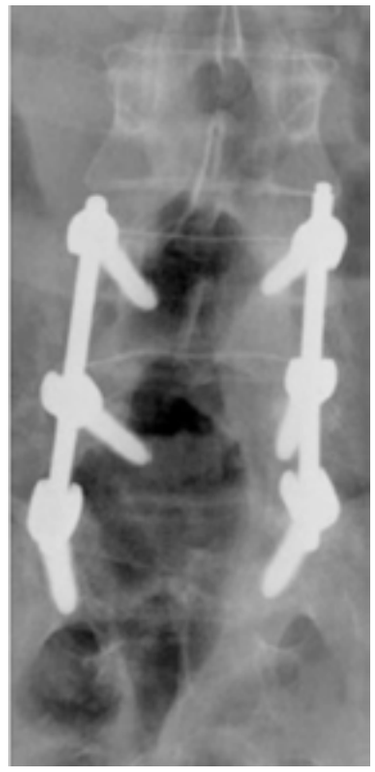
Pre-op X-ray (lateral)



3-day post-op X-ray (AP)



3-month post-op X-ray (AP)



12-month post-op X-ray (AP)

Bonalive® putty

Adult patient

PATIENT

44-year-old patient suffering from low back pain for 2.5 years. Increasing radicular pain to the right leg for more than one year before surgery.

The patient received physiotherapy and occupational therapy at work. Preoperatively Oswestry 30, SLR 60/80 L5 and S1 pain, instability symptoms. Sensory defect on S1 dermatome on the right side. Lumbar MRI showed an L5/S1 lytic spondylolisthesis of 8 mm, increasing in the functional X-rays. L4/L5 degeneration and a central disc herniation and fluid in the facet joints.

OPERATION

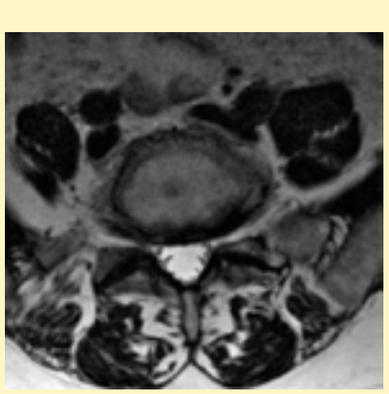
Decompressive laminectomy L5, L4–S1 transpedicular fusion. Posterolateral fusion using autograft and Bonalive® putty as a bone graft expander.

CLINICAL OUTCOME

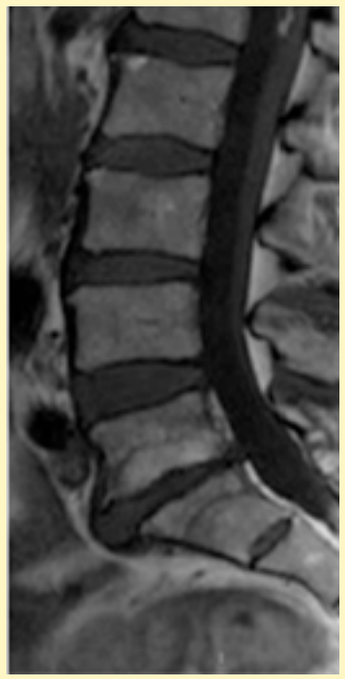
Intraoperative O-arm® images showed that the instrumentation was placed correctly. Outpatient clinic visits at 3 months and 12 months post-op. The patient returned to work 4 months post-op. At the one-year follow-up the patient was pain free and had returned to normal activities. Some numbness in right leg. No revisions, excellent outcome.

Courtesy of Turku University Hospital, Finland

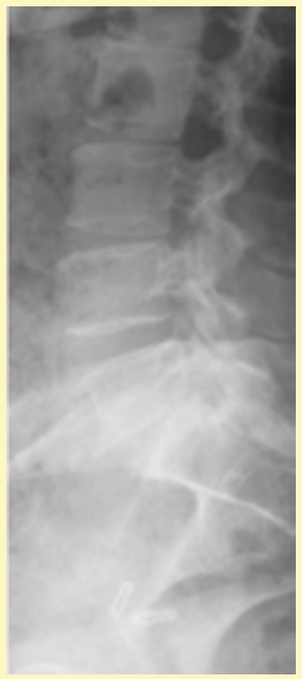
Posterolateral fusion with minimally invasive technique



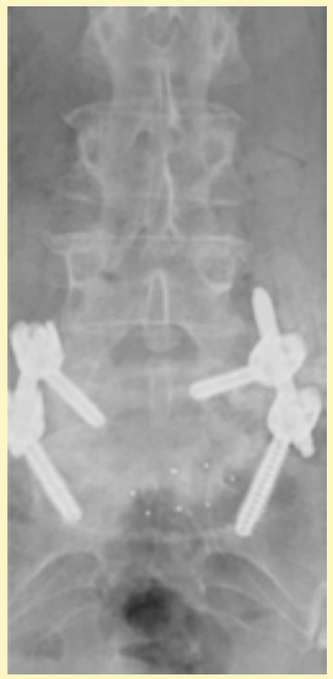
Pre-op MRI T2 axial L5/S1



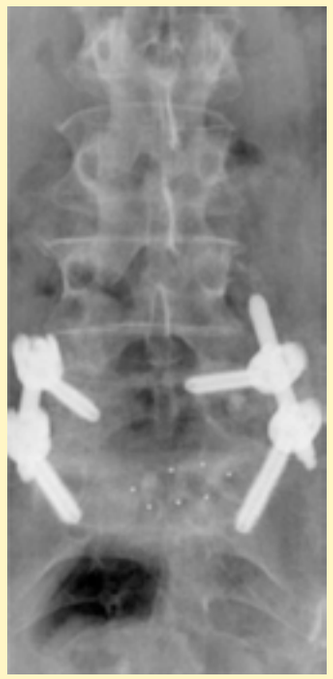
Pre-op MRI T1 (sagittal)



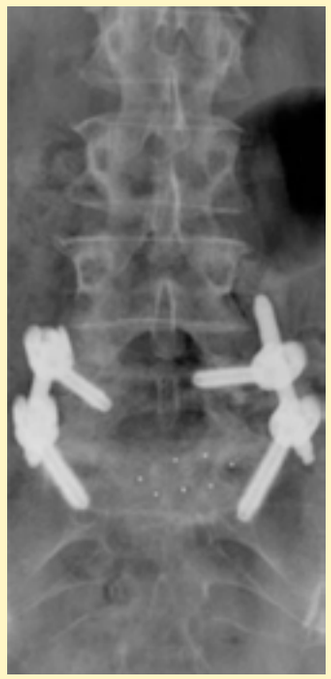
Pre-op X-ray (lateral)



3-day post-op X-ray (AP)



3-month post-op X-ray (AP)



12-month post-op X-ray (AP)

Bonalive® putty

Adult patient

PATIENT

54-year-old patient suffering from low back pain for 2 years. Worsening radicular pain in the left leg (L5). The patient received physiotherapy and changes to tasks required at the patient's place of work were made to alleviate symptoms. Preoperatively instability symptoms. Sensory defect on L5 dermatome left side. Lumbar MRI showed L5/S1 disc degeneration and Modic I changes. A small central disc herniation and fluid in the facet joints.

OPERATION

Transpedicular fusion L5/S1. Posterolateral (left) and intercorporal fusion using autograft and Bonalive® putty as bone graft expander.

CLINICAL OUTCOME

Intraoperative O-arm® images showed that the instrumentation was placed correctly. Postoperatively for one month the patient complained of left sided paresthesia and radicular pain on the left side (L5).

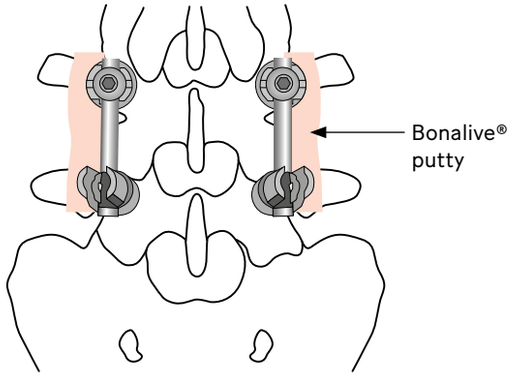
Outpatient clinic visits at 3 months and 12 months post-op. At one-year follow-up the patient had returned to full time work. No revisions, excellent outcome.

Courtesy of Turku University Hospital, Finland

Benefits of Bonalive® putty

Bonalive® putty

- 1 cc, 2.5 cc, 5 cc and 10 cc prefilled applicator
- Easy-to-use and highly moldable
- Ready-to-use and stays in place
- Radiopaque
- Osteostimulative and osteoconductive that promotes fusion
- Suitable as bone graft expander

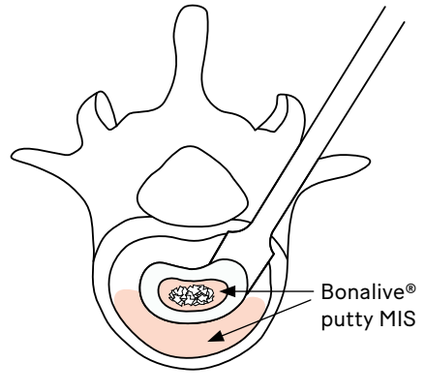


Demanding surgery requires reliable solutions. Smart Healing™ is based on evidence that spine surgeons can count on.

Our Smart Healing™ solutions support reliable fusion with an easy-to-use concept. Osteoconductive and osteostimulative putty requires no mixing, moistening or other preparation. The osteostimulative putty activates osteoblasts to produce new bone formation enabling faster recovery time and a higher quality of life for the patient.

Bonalive® putty MIS

- 5 cc highly moldable Bonalive® putty
- Controlled delivery with 0.25 cc per press cycle
- Easy access to the interbody space
- Single-use dispenser
- Pre-loaded cartridges
- Radiopaque
- Osteostimulative and osteoconductive that promotes fusion

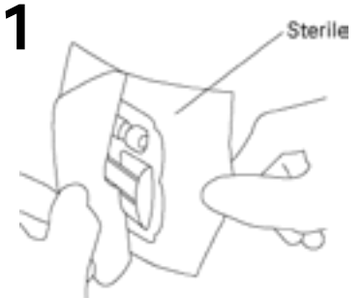


Surgical techniques may vary according to the hospital protocols.

Handling the applicator

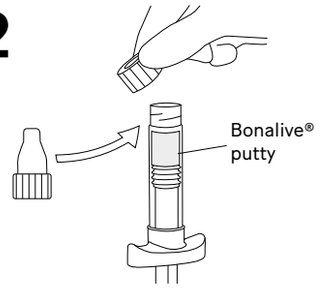
Bonalive® putty

1



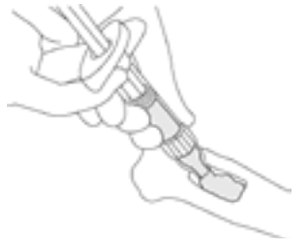
- Peel open the pouch and aseptically remove the sterile tray. Detach the applicator from the tray.

2



- Unscrew the cap. Screw tightly the nozzle onto the applicator body. Alternatively, without the nozzle, push the plunger rod to force the putty to a sterile cup and subsequently perform the implantation with a sterile instrument.

3



- Push the plunger rod to force the putty into the nozzle.
- Move the applicator to the defect site.
- Push the plunger rod to gently fill the defect with the putty.

Bonalive® putty MIS

1

- Release the dispenser plunger by lifting the black release latch and pull the plunger to its rearmost position. Keep the dispenser in the sterile area.

2

- Unscrew the cap from the cartridge end that has "wings".

3

- Attach the cartridge by screwing the cartridge firmly onto the dispenser. Unscrew the second cap from the cartridge. The Bonalive® putty MIS product is now ready for use.

4

- Gently press the dispenser trigger repeatedly to extrude Bonalive® putty MIS to fill the defect (each press gives approximately 0.25 cc).
- If more than one cartridge is needed, pull the plunger all the way back, remove the empty cartridge and add a new cartridge by repeating the steps illustrated on this page.

References

The references listed below are some examples providing an overview of our customers' experiences. New studies are frequently being reported, and an up-to-date full reference list is available on request.

CLINICAL

Novel bioactive glass putty (S53P4) as bone graft expander in minimally invasive lumbosacral interbody fusion.
Ilkka Saarenpää, Jussi Hirvonen, Jaakko Rinne, Janek Frantzén.
J Minim Invasive Spine Surg Tech. 2018;3(2):52-58.

Posterolateral spondylodesis using bioactive glass S53P4 and autogenous bone in instrumented unstable lumbar spine burst fractures. A prospective 10-year follow-up study.
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Scan J Surg. 2012;101(1):66-71.

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J Spinal Disorder Tech. 2011;24(7):455-61.

PRECLINICAL

BAG S53P4 putty as bone graft substitute – a rabbit model.
Saarenpää I, Stoor P, Frantzén J.
Biomed Glasses. 2017;3(1):30-40.

Tissue response to bioactive glass and autogenous bone in the rabbit spine.
Lindfors NC, Aho AJ. Eur Spine J. 2000;9(1):30-5.

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Lindfors NC, Tallroth K, Aho AJ.
J Biomed Mater Res. 2002;63(2):237-44.

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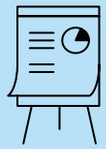
Through proactive education and engagement with our global partners, we collaborate to create a better future for healthcare.

Events



We are present at relevant medical conferences each year, where we enable peer-to-peer support and education for healthcare professionals.

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