



bonalive

Smart Healing™

Literature references
Electronic

Bonalive is a smart biomaterials company, transforming healthcare at the intersection of biology and technology. With over 30 years of clinical history, and one of the most evidence-based technologies in the industry, we are re-imagining a smarter future for healthcare.

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ELECTRONIC REFERENCE LIST

Preclinical and clinical research publications are an authoritative and valuable resource for healthcare professionals interested in Bonalive technologies and their use.

The electronic reference list also contains:

- a link to each article's abstract
- surgeons' video presentations of their research

BIOACTIVE GLASS TECHNOLOGY

At the core of our technology is S53P4 bioactive glass – a smart biomaterial consisting solely of elements that exist naturally in the human body.

Characterized by its ability to firmly attach to living tissue and chemically bond with surrounding bone, S53P4 bioactive glass naturally facilitates the formation of new bone. Thus, it is a unique material for filling defects and replacing damaged bone tissue because S53P4 bioactive glass functions as naturally as your biology.

Smart Healing™ solutions are osteostimulative (non-osteoinductive) and come with a range of benefits for filling, reconstructing and regenerating bone defects as well as for filling bone cavities, voids and gaps in both adult and pediatric patients.

THE LEVEL OF EVIDENCE IN CLINICAL STUDIES

The Level of Clinical Evidence provides a guide to describe the strength of the results measured in a clinical trial or research study. It is developed from USPSTF and Oxford (UK) CEBM Levels of Evidence.^[1]

Type of evidence	Level of evidence
Data derived from meta-analyses or systematic reviews of randomized studies or multiple randomized trials.	L1a
Data derived from at least one well-designed randomized trial.	L1b
Data derived from at least one well-designed non-randomized trial (e.g. cohort studies, case-control studies) or from at least one low-quality randomized trial.	L2
Data derived from case reports or low-quality non-randomized trials.	L3
Data derived from expert opinions without explicit clinical appraisal.	L4

According to this hierarchy, we provide the following list of level L1a, L1b and L2 clinical research publications to support the use of our products.

^[1] Burns PB, Rohrich RJ, Chung KC. The levels of evidence and their role in evidence-based medicine. *Plast reconstr surg.* 2011;128(1):305-10.

THE LEVEL OF EVIDENCE IN CLINICAL STUDIES

L1A LEVEL OF EVIDENCE CLINICAL STUDIES

Bone infection surgery

- **Clinical applications of Bioactive glass S53P4 in bone infections: a systematic review.**
Bigoni M, Turati M, Zanchi N, Lombardo AS, Graci J, Omeljaniuk RJ, Zatti G, Gaddi D.
Eur Rev Med Pharmacol Sci. 2019;23(2 Suppl):240-51.^[2]
- **Clinical application of antimicrobial bone graft substitute in osteomyelitis treatment: A systematic review of different bone graft substitutes available in clinical treatment of osteomyelitis.**
van Vugt T, Geurts J, Arts J. Biomed Res Int. 2016;2016:6984656.^[2]

Trauma surgery

- **Autologous versus synthetic bone grafts for the surgical management of tibial plateau fractures: a systematic review and meta-analysis of randomized controlled trials.**
Cooper G, Kennedy M, Jamal B, Shields D. Bone Jt Open 2022 Mar;3(3):218-228.

L1B LEVEL OF EVIDENCE CLINICAL STUDIES

Trauma surgery

- **Bioactive glass granules: a suitable bone substitute material in the operative treatment of depressed lateral tibial plateau fractures: a prospective, randomized 1 year follow-up study.**
Heikkilä JT, Kukkonen J, Aho AJ, Moisander S, Kyyrönen T, Mattila K.
J Mater Sci: Mater Med. 2011;22(4):1073-80.^[3]
- **Bioactive glass S53P4 and autograft bone in treatment of depressed tibial plateau fractures. A prospective randomized 11-year follow-up.**
Pernaa K, Koski I, Mattila K, Gullichsen E, Heikkilä J, Aho A, Lindfors N.
J Long Term Eff Med Impl. 2011;21(2):139-48.^[3]

Benign bone tumor surgery

- **Biodegradable biomaterials in orthopedic surgery: a narrative review of the current evidence.**
Raitio A, Saarinen A, Sinikumpu J-J, Helenius I. Scandinavian Journal of Surgery 2024,113(1):62-70.
- **Allograft versus bioactive glass (BG-S53P4) in pediatric benign bone lesions: a randomized clinical trial.**
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- **A prospective randomized 14-year follow-up study of bioactive glass and autogenous bone as bone graft substitutes in benign bone tumours.**
Lindfors NC, Koski I, Heikkilä JT, Mattila K, Aho AJ. J Biomed Mater Res. 2010(a);94B(1):157-64.^[4]

^[2] Review article

^[3] Publications are from the same clinical study

^[4] Publications are from the same clinical study

- **Bioactive glass and autogenous bone as bone graft substitutes in benign tumors.**
Lindfors NC, Heikkilä JT, Koski I, Mattila K, Aho AJ. J Biomed Mater Res 2009;90(1):131-6.^[4]
- **Long-term evaluation of blood silicon and osteocalcin in operatively treated patients with benign bone tumors using bioactive glass and autogenous bone.**
Lindfors NC, Heikkilä JT, Aho AJ. J Biomed Mater Res 2008;87(1):73-6.^[4]

Spine Surgery

- **The effect of bioactive glasses on spinal fusion: a cross-disciplinary systematic review and meta-analysis of the preclinical and clinical data.**
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- **Dead space management strategies in the treatment of chronic osteomyelitis: a retrospective review.**
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- **The role of bioceramics in the management of osteomyelitic voids.**
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- **Clinical applications of S53P4 bioactive glass in bone healing and osteomyelitic treatment: A literature review.**
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THE LEVEL OF EVIDENCE IN CLINICAL STUDIES

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- **Enchondromas of the Hand: Curettage With Autogenous Bone vs. Bioactive Glass S53P4 for Void Augmentation.**
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CLINICAL STUDIES

Trauma



Autologous versus synthetic bone grafts for the surgical management of tibial plateau fractures: a systematic review and meta-analysis of randomized controlled trials.

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Benign bone tumor



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Allograft versus bioactive glass (BG-S53P4) in pediatric benign bone lesions: a randomized clinical trial.
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CLINICAL STUDIES

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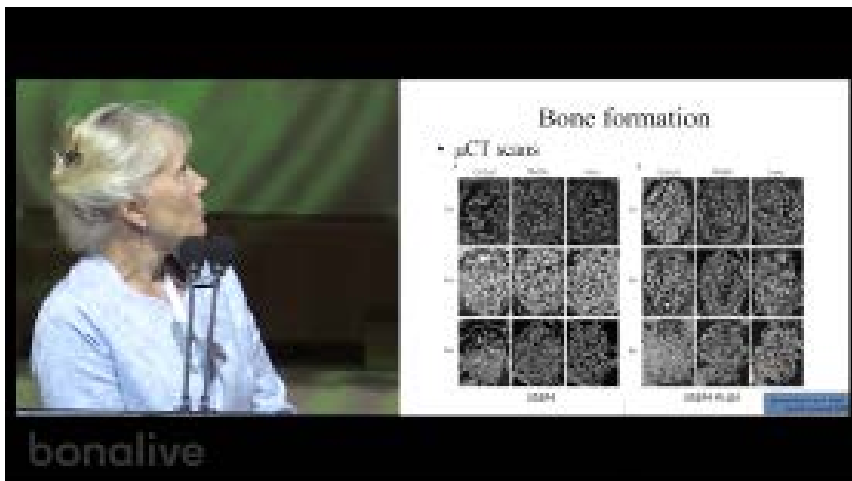
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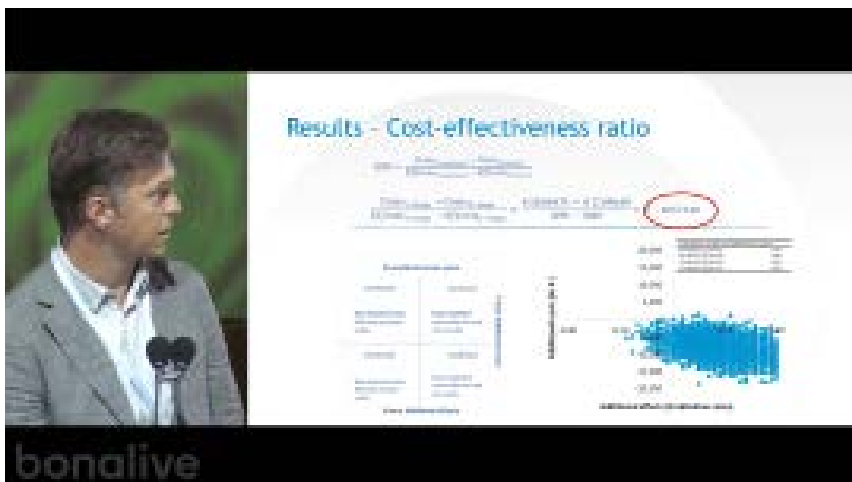
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Assoc. Prof. Nina Lindfors

Assoc. Prof. Lindfors presents some promising new results of applying bioactive glass to stimulate new bone growth.

Video (13:29)

Article Polymer-coated bioactive glass S53P4 increases VEGF and TNF expression in an induced membrane model in vivo. Björkenheim R, Strömberg G, Pajarinen J, Ainola M, Uppstu P, Hupa L, Böhling TO, Lindfors NC. 2017.



S53P4 bioactive glass – a highly cost-effective solution

MD Dr. Jan Geurts

MD Dr. Geurts shares an eye-opening study of the cost-savings a 1-step compared to a 2-step procedure might imply when treating infected bone.

Video (8:42)

EXTRA MATERIALS



The role of S53P4 bioactive glass in septic non-union surgery

Dr. Martin Glombitza

Dr. Glombitza shares his experiences of treating septic non-unions with bioactive glass.

Video (10:58)

Article The use of bioactive glass S53P4 as bone graft substitute in the treatment of chronic osteomyelitis and Infected non-unions – a retrospective study of 50 patients. Al Malat TA, Glombitza M, Dahmen J, Hax P-M, Eva Steinhausen E. 2018.



Antibacterial bioactive glass, S53P4, for chronic bone infections – a multinational study

Assoc. Prof. Nina Lindfors

Assoc. Prof. Lindfors presents results from the multinational study using S53P4 for the resolution of bone infections and dead space management.

Video (23:59)

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EXTRA MATERIALS



What is the role of S53P4 bioactive glass in diabetic foot treatment?

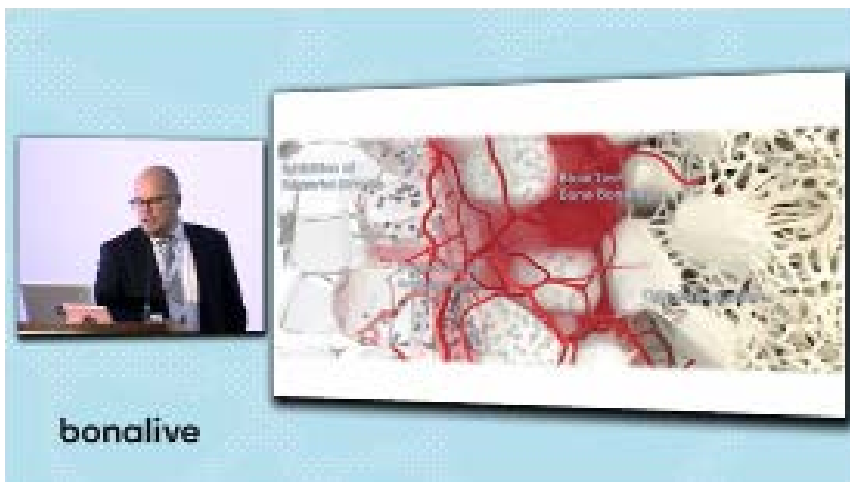
Dr. Roberto De Gigilio

Dr. De Gigilio talks about his experiences from using bioactive glass in the treatment of chronic osteomyelitis for

patients with diabetes mellitus. Dr. De Gigilio is a diabetologist and talks about the promising results of his research, where bioactive glass S53P4 has been compared with current standard of care in treating diabetic foot complications.

Video (6:26)

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S53P4 bioactive glass putty in MIS spine surgery

Adjunct Prof. Janek Frantzén

Adjunct Prof. Janek Frantzén shares his experience of using S53P4 bioactive glass putty in minimal invasive spine surgery.

Video (12:42)

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