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LITERATURE

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Content

THE LEVEL OF EVIDENCE

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

[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.
[2] Review article
[3] Publications are from the same clinical study
[4] Publications are from the same clinical study

L1a Level of Evidence Clinical Studies

- 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] [Open access]
- 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] [Open access]

L1b Level of Evidence Clinical Studies

- The effect of bioactive glasses on spinal fusion: A cross-disciplinary systematic review and meta-analysis of the preclinical and clinical data.
  Cottrill E., Pennington Z., Lankipalle N., Ehresman J., Valencia C., Schilling A., Feghali J., Perdomo-Pantoja A., Theodore N., Sciubba D., Witham T. Journal of Clinical Neuroscience 2020;78:34-46. [2]
- 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]
- 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 A. J Biomed Mater Res. 2010(a);94B(1):157-64. [4]
- Bioactive glass and autogenous bone as bone graft substitutes in benign bone tumors.
  Lindfors NC, Heikkilä JT, Koski I, Mattila K, Aho A. J Biomed Mater Res. 2009;90(1):131-6. [4]
- Long-term evaluation of blood silicon and ostecalcin in operatively treated patients with benign bone tumors using bioactive glass and autogenous bone.
  Lindfors NC, Heikkilä JT, Aho A. J Biomed Mater Res 2008;87(1):73-6. [4]

L2 Level of Evidence Clinical Studies

- Efficacy and safety of bioactive glass S53P4 as a treatment for diabetic foot ostemyelitis.
  De Giglio R., Di Vieste G., Mondello T., Balduzzi G., Masserini B., Formenti I., Lodigiani S., Pallavicini D., Pintaudi B., Mazzone A. The Journal of Foot and Ankle Surgery. 2020. Doi: https://doi.org/10.1053/j.jfas.2020.06.029.
- The role of bioactive glass in the management of chronic osteomyelitis: a systematic review of literature and current evidence.
  Tanwar Y, Ferreira N. Infect Dis (Lond). 2020 Apr;52(4):219-26.[2]
- Mastoid obliteration with synthetic materials: a review of the literature.
  Skoulakis C, Koltsidopoulos P, Iyer A, Kontorinis G. The Journal of International Advanced Otology. 2019;15(3):400-4.[2]
- Treatment of cavitary bone defects in chronic osteomyelitis: Bioactive glass S53P4 vs. calcium sulphate antibiotic beads.
  Ferrando A, Part J, Baeza J. J. Bone Jt. Infect. 2017;2(4):194-201.

- Bioactive glass obliteration of the mastoid significantly improves surgical outcome in non-cholesteatomatous chronic otitis media patients.
  Vos J, de Vey Mestdagh P, Colnot D, Borggreven P, Orelio C, Quak J. Eur Arch Otorhinolaryngol. 2017;274(12):4121-6.
- Bioactive glass for long bone infection: a systematic review.
  Aurégan JC, Bégué T. Injury, Int. J. Care Injured. 2015;46(8):3-7.[2]
- Clinical applications of S53P4 bioactive glass in bone healing and osteomyelitic treatment:
  A literature review.
  van Gestel NA, Geurts J, Hulsen DJ, van Rietbergen B, Hofmann S, Arts JJ. Biomed Res Int. 2015;2015: 684826.[2]
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- A comparative study of the use of bioactive glass S53P4 and antibiotic-loaded calcium based bone substitutes in the treatment of chronic osteomyelitis: a retrospective comparative study.
  Romano CL, Logoluso N, Meani E, Romano D, De Vecchi E, Vassena C, Drago L.
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Primary stability of a press-fit cup in combination with impaction grafting in an acetabular defect model.
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Grønseth T, Vestby L, Nesse L, von Unge M, Silvola J. Upsala journal of medical sciences. 2020;152(3):217-225

Imaging studies of bacterial biofilms on cochlear implants - Bioactive glass (BAG) inhibits mature biofilm.
Kirchhoff L, Arweiler-Harbeck D, Arnolds J, Hussain T, Hansen S, Bertram R, Buer J, Lang S, Steinmann J, Höing B. PLoS ONE 2020;15(2):e0229198.

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Moreno M, Butini M, Maiolo E, Sessa L, Trampuz A. Colloids and Surfaces B: Biointerfaces. 2020;189:110853.

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Sarin J, Hiltunen M, Hupa L, Pulkkinen J, Vallittu PK. Biomed Mater Eng. 2016;27:425-36.

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Varila L, Fagerlund S, Lehtonen T, Tuominen J, Hupa L. J Europ Cer Soc. 2012;32:2757-63.

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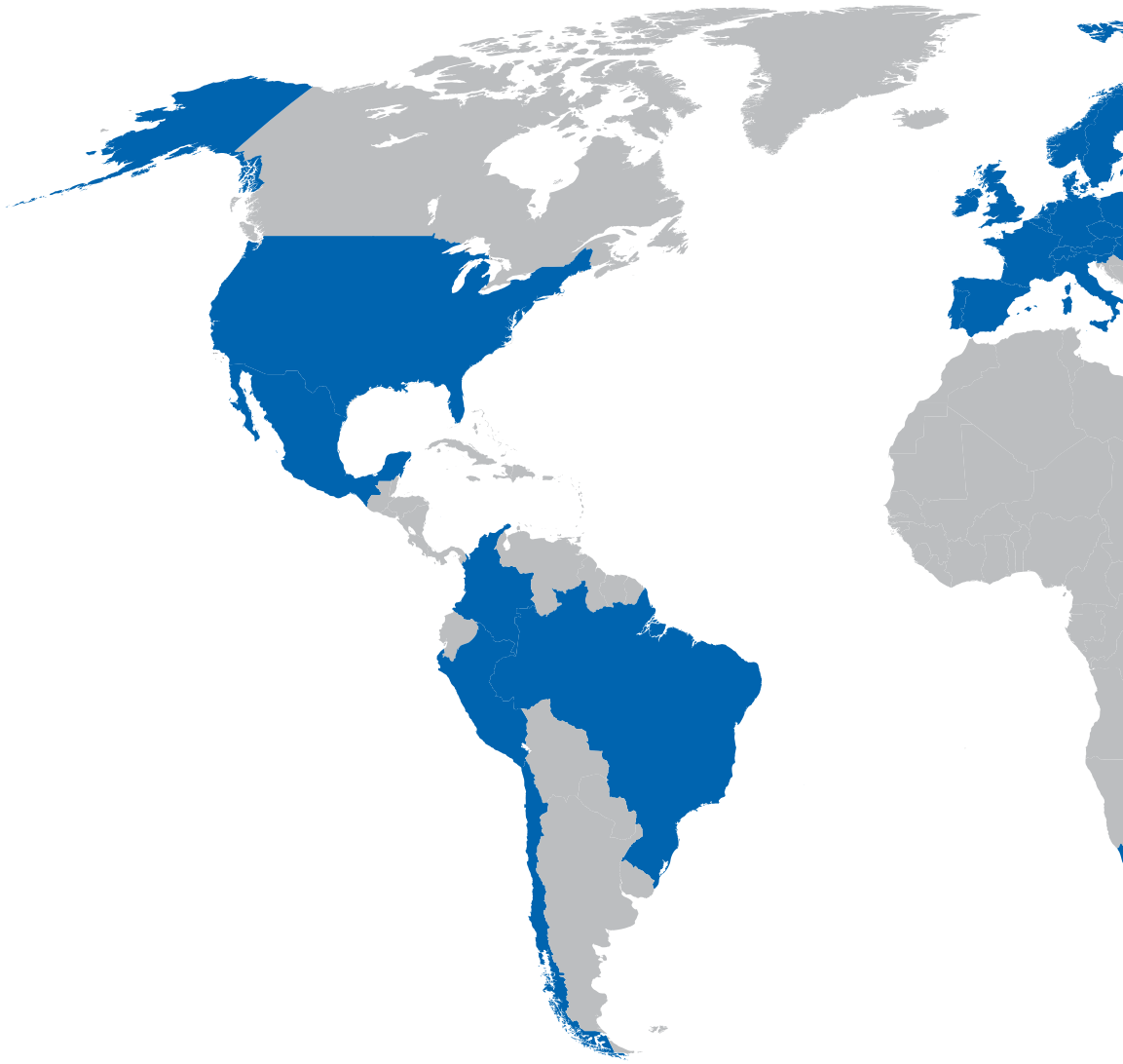
Bonalive Biomaterials Ltd

Manufacturer

In the late 1960s an associate professor called Larry Hench travelled to an Army Materials Conference in Sagamore, New York, and seated himself next to a Vietnam veteran. Their discussions lead into the topic of bone recovery and methods of replacing bone with a man-made material that the body would not reject. The 45S5 Hench glass was soon born. The glass had tissue regenerative properties and bonded tightly to bone while being slowly biodegraded in the body.



bonalive

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A couple of decades after, in the 1980's, the story of the Hench glass and its composition was still puzzling university researchers in this field at Turku, Finland. What would happen if the composition were different, would it bring the same advantages or even new ones? Soon many different new bioactive glass compositions were developed and among them was the formulation S53P4 bioactive glass.

Today the story continues – the S53P4 bioactive glass is manufactured and provided worldwide by Bonalive Biomaterials Ltd in Turku Finland, the birth city of the technology.

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See trimedortho.com/patents for all patent information.

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