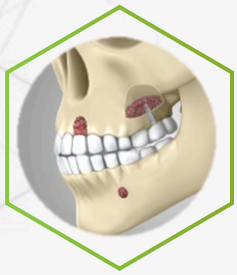
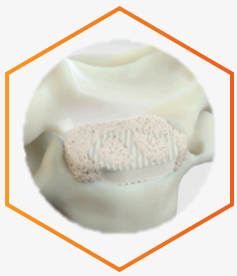
NORAKER®

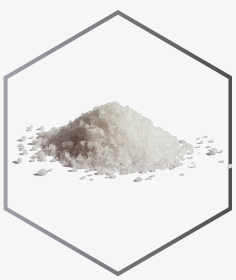
THE BIOGLASS® COMPANY

CLINICAL SUMMARY

BIOGLASS BONE REGENERATION SOLUTIONS







1-NORA-Clinical compilation-EN-1.0 07/2023

This document presents clinical data with some publications and patient cases.

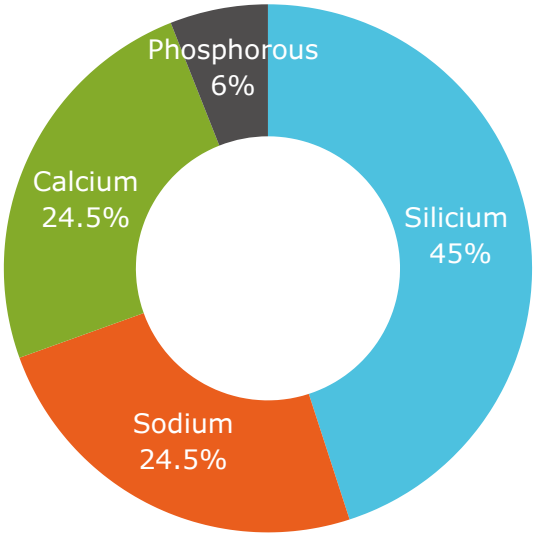
To note, cases reports were not subjected to clinical investigation protocols and are not sufficient proof to validate performance and safety of the device.

Please, consult our clinical studies.

BIOACTIVE GLASS

The bone substitute is made of Bioactive Glass 45S5, a revolutionary ceramic, composed of minerals naturally present in the human body.

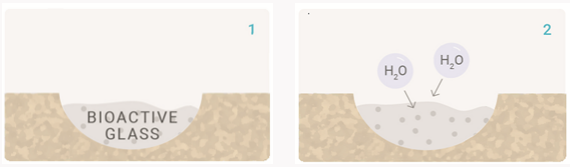
COMPOSITION



- Osteoconductive
- Improves the bone regeneration: natural matrix for cells to attach, differentiate and make new bone:
  - Bone Bonding
  - Soft tissue bonding
- 100 % synthetic
- Bioabsorbable
- Excellent biocompatibility

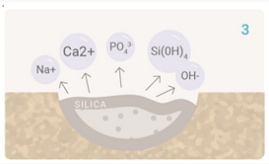
MECHANISM OF ACTION

1. Implantation of bioactive glass in a bone defect.
2. Rapid exchange of Na^+ and / or Ca^{2+} cations with H^+ of the solution, creating silanol (Si-OH) bonds at the glass surface: $SiO{-}Na^+ + H_2O \rightarrow Si{-}OH + Na^+_{(aq)} + HO^-$



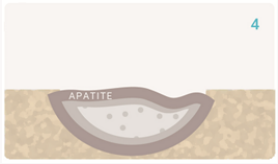
3. The pH of the solution increases and a silica-rich region forms near the surface of the glass. The high local pH drives the silica-glass network through HO^-, breaking the Si-O-Si bonds. The soluble silica is lost as $Si(OH)_4$ in the solution, leaving more than SiOH (silanols) at the glass / solution interface:

$$Si - O - Si + H_2O \rightarrow Si - OH + HO - Si$$



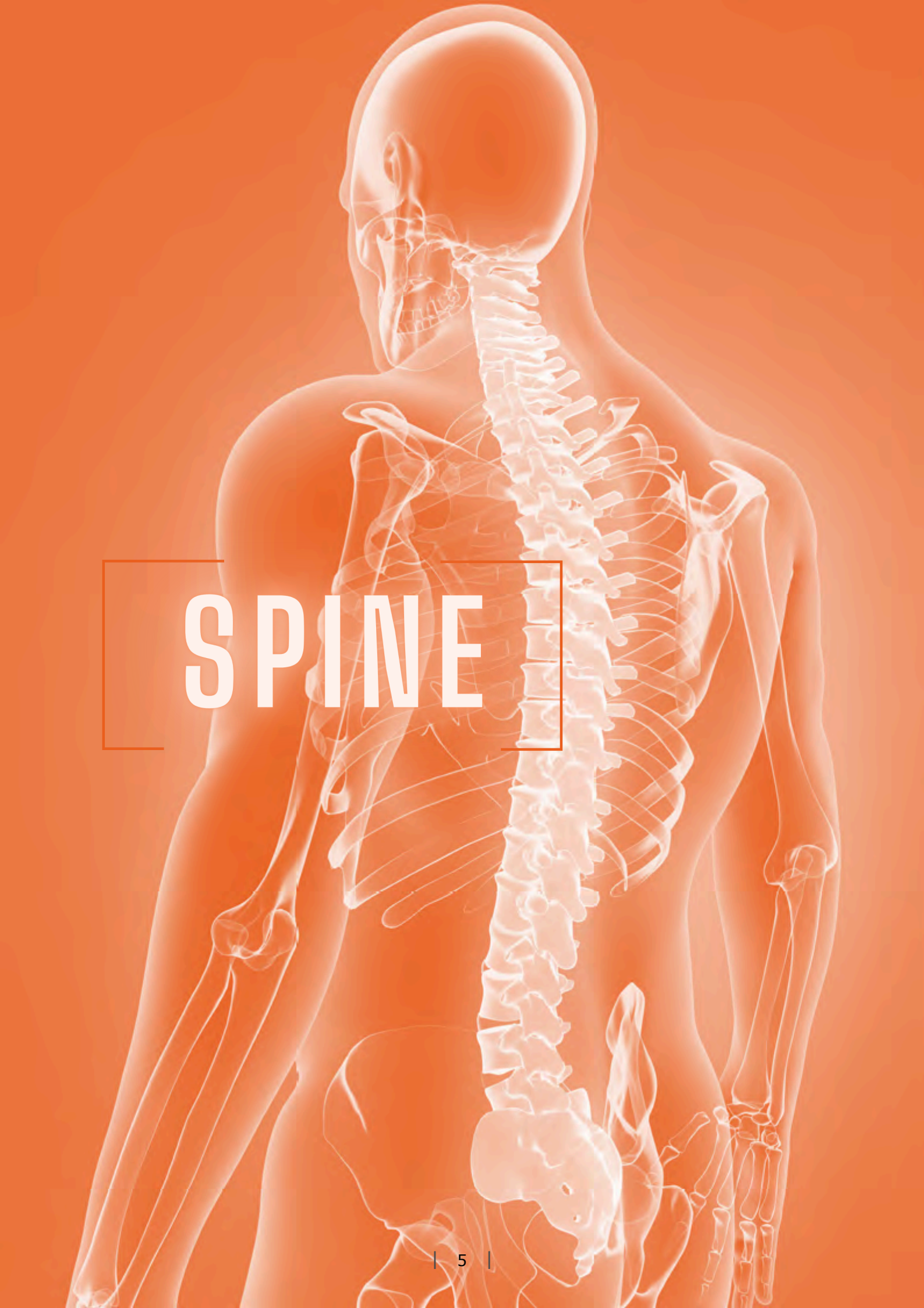
Then condensation of the Si-OH groups near the glass surface will allow to repolymerize the silica-rich layer.

4. Migration of Ca^{2+} and PO_4^{3-} groups to the surface through the silica-rich layer and from the solution, thereby forming a film rich in amorphous calcium phosphate on the silica-rich layer. Finally, the incorporation of hydroxyls and carbonates in the solution and the crystallization of the calcium phosphate film will produce a carbonate hydroxy-apatite (CHA) layer. Therefore, this layer of hydroxyapatite formed is recognized as atural bone. This apatite will bind to native bone and soft tissues and release calcium and silicon ions, which promote bone formation by serving as a support for bone reconstruction (osteoconduction).



5-6. Following these reactions, bone growth continues, and bioactive glass continues to degrade and serves as a scaffold for bone regeneration.

SUMMARY



SPINE

Cervical or lumbar pain, also defined respectively as low back or neck pain, is the most common health problem among older adults that results in pain and disability. Low back or neck pain is sometimes associated with disc degeneration and injury occurring in the lumbar or cervical spine (the thoracic spine is less affected) or deformity (Frost et al., 2019; Nemani et al., 2016; Zhu et al., 2022). These pains could be associate with other symptoms as deformity, neurologic signs, radiculopathy, disability, mechanical instability, stiffness, sagittal and coronal imbalance, claudication, myelopathy etc. (Cho et al., 2014; Nemani et al., 2016; Passias et al., 2015; Vercoulen et al., 2021; Wewel et al., 2019; Zhu et al., 2022).

Various pathologies associated with these symptoms are diagnosed, such as degenerative disc disease (lumbar and cervical), vertebral spinal stenosis, spondylolisthesis, scoliosis (idiopathic adolescent or adult), cervical spondylosis myelopathy. Currently, the non-operative, also called conservative treatment is the first-line approach, for patients without severe neurologic deficits or the unique approach for contraindicated surgery patient.

When conservative treatment fails, that is to say when there are progressive and important neurological deficit, unacceptable deformity causing cosmetic or respiratory problems (scoliosis deformity), severe disability, and pain unresponsiveness to treatment after several months: surgery is indicated and necessary (Boer et al., 2021; Heemskerk et al., 2021; Olgun & Yazici, 2013; Ozyemisci Taskiran, 2020; Zigler et al., 2018). The goals of surgical treatment include improvement of the regional back or neck pain, correction of deformity and achievement of a balanced spine, prevent further deterioration of the curve (prevent progression of the disease) decompression of the neural elements, and spinal stabilization with solid bony fusion while avoiding complications. Major surgical procedures can be combined: arthrodesis (osteosynthesis +/- bone graft) and osteosynthesis alone.

Common options for bone grafting include: autograft; allograft; Bone morphogenetic protein and synthetic materials (Katsuura et al., 2020). Of all the grafts available clinically, autologous bone is still considered the absolute reference because all the properties necessary for bone regeneration in terms of osteoconduction, osteoinduction and osteogenesis are combined (Wang & Yeung, 2017).

However, the disadvantages of autografting have been widely reported: morbidity of the site of collection (risk of infection, complication, pain), a limited volume of available material as well as a prolonged operating time. For these reasons, health professionals will use other bone substitutes (HAS_2013; Wang & Yeung, 2017). The most common options for replacing autograft are: allografts; xenografts and synthetic bone substitutes. These alternatives eliminate the second operative site due to autologous sample. Regarding allografts and xenografts, they are not exempt from viral contamination and immune reaction and with a minimal risk of transmission of a pathogen (Ameri et al., 2009; Crawford et al., 2013; Delécrin et al., 2000; Ilharreborde et al., 2008). Synthetic bone substitutes allow a biocompatibility with no risk of contamination and an availability in quantity.

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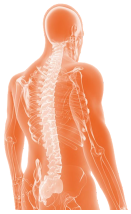

Safety & efficacy of stand-alone bioactive glass Injectable Putty or Granules in posterior vertebral fusion

Publication - 2023

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https://www.mdpi.com/2227-9067/10/2/398

INDICATION – Spine deformity: Adolescent idiopathic and non-idiopathic scoliosis

SURGERY – Stand-alone GlassBone Injectable Putty (IP) or Granules Granules in posterior vertebral fusion

METHOD

- Retrospective and monocentric study – 43 children and adolescents.
- Objective: Evaluate and compare the post-operative safety and efficacity of GlassBone IP and Granules in posterior thoracolumbar spinal fusion.
- Design: GlassBone IP was applied to the spine after facetectomies for 25 patients and GlassBone Granules for 18 patients.
- Primary endpoint assessment: the occurrence of anomalies and/or complications at each postoperative visit (15 days, 6 months and 2 years).
- Follow-up: 24 months.

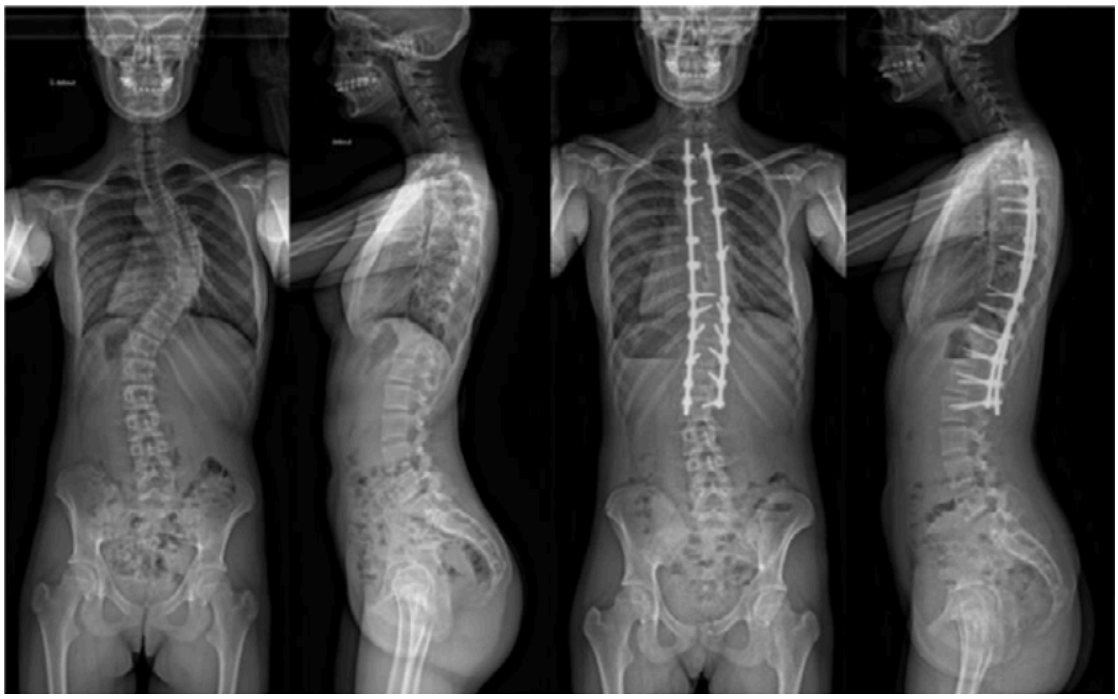
RESULTS

Performance – 100% bony fusion and the Cobb angle measurements reflected a significant reduction in spinal deformity.

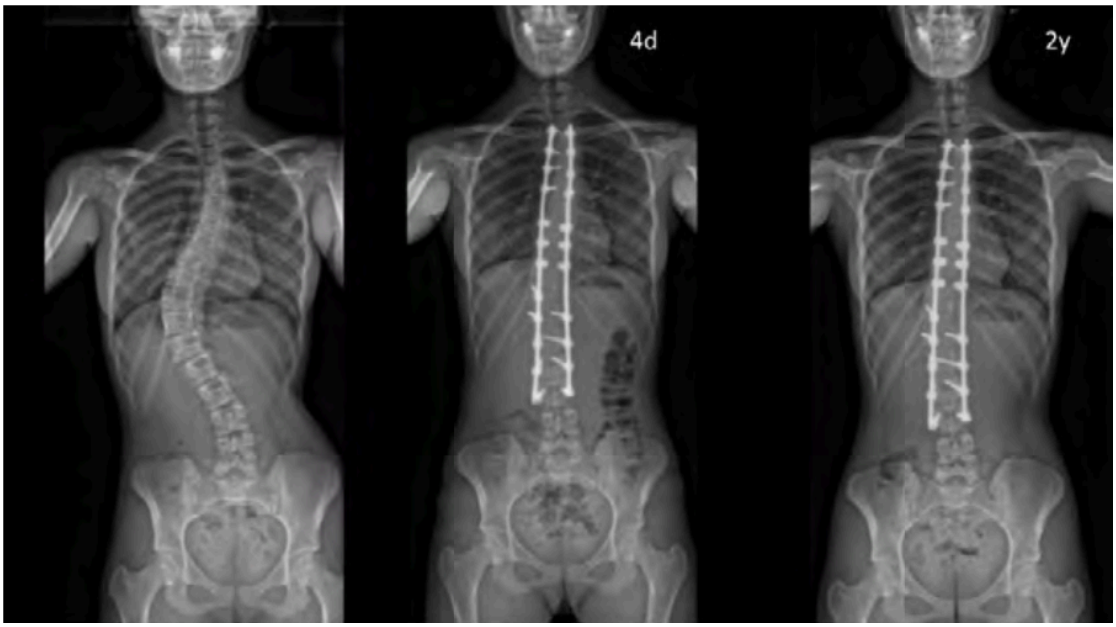
Benefits – The bone harvested from the facetectomies, and the spinous processes was not used for additional grafts.

Safety – There were 3 early postoperative complications (2 surgical site infection treated with revision and 1 extended stay in the intensive care unit) and 1 case of late mechanical complications (proximal junctional kyphosis) requiring removal of the instrumentation at 24 months.

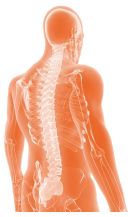
CONCLUSION – This study showed that the massive use of bioactive glass in posterior fusion, when combined with proper surgical planning, hardware placement and correction, is effective in providing good clinical and radiological outcomes. The performance and safety of Glassbone (Granules and IP) are demonstrated.



Pre-and post-operative full-spine coronal and sagittal X-rays illustrating a typical long construct for posterior fusion to correct a deformity



Pre- and post-operative full-spine coronal X-rays (1st erect and 2y po) illustrating the proper stabilisation of the main curve (<10◦) without any screw loosening. (4d: Day 4 after surgery; 2y: 2 years after surgery)



Bioactive glass grants equivalent fusion compared to autologous iliac crest bone for ALIF: a within-patient comparative study

Publication - 2021

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https://jeo-esska.springeropen.com/articles/10.1186/s40634-022-00496-6

INDICATIONS - Degenerative disc disease, spondylolisthesis, and stenosis

SURGERY - Single-level (L5-S1) or two-level (L5-S1 and L4-L5) ALIF, with or without posterior instrumentation

METHOD

- Retrospective study – 40 patients (58 levels)
- Objective: To compare the fusion rates between GlassBone Injectable Putty (IP) and autologous bone.
- Intra-patient comparative design: use of bipartite cage, with one chamber filled with GlassBone IP, and the other with autologous iliac crest bone.
- Primary endpoint assessment: Bridwell classification on CT scan at 12 months.
- Follow-up: 15 ± 5 months.

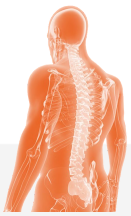
RESULTS

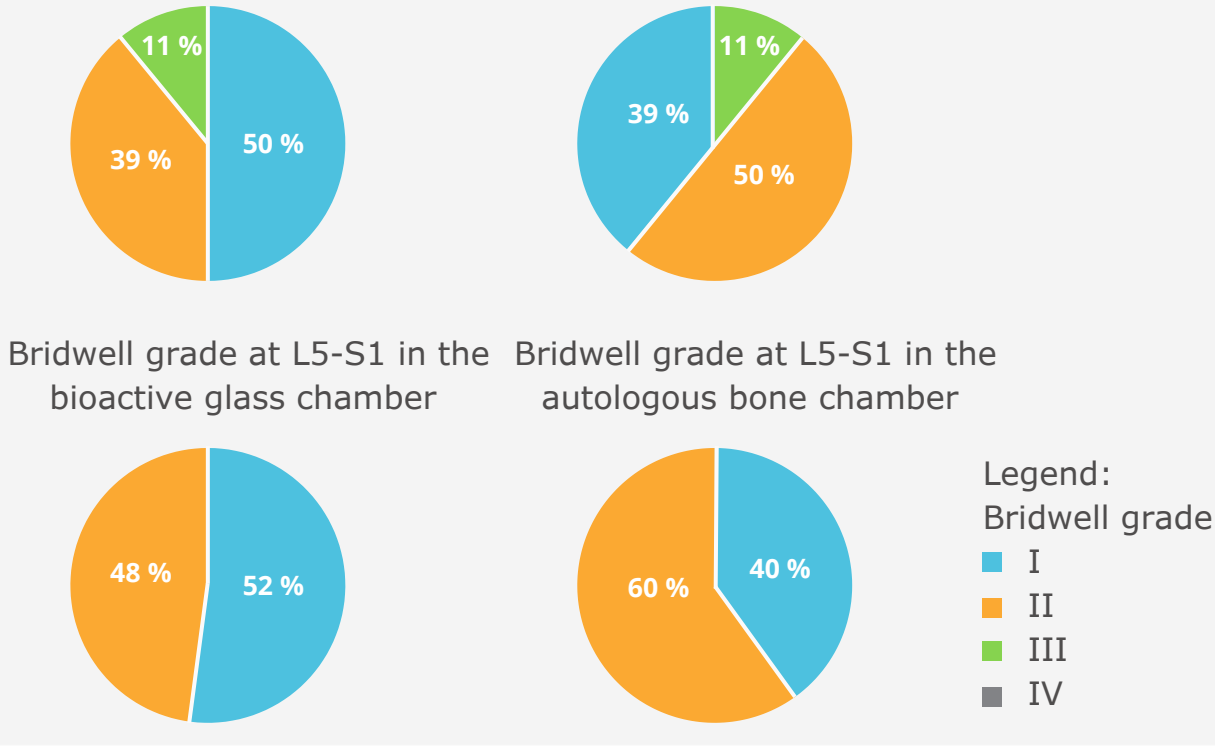
Performance – A satisfactory fusion rate (Bridwell grade I and II) was observed at 56 levels (97%) in chambers with bioactive glass and in chambers with autologous bone. About the proportion of chambers assessed as Bridwell grade I or Bridwell grade II, there was no significant difference between both of the graft materials.

Benefits – A clinical improvement concerning the disability, the physical and mental quality of life, the lower back pain, and the leg pain, was measured. With the use of GlassBone IP, there is a reduction of donor site morbidity.

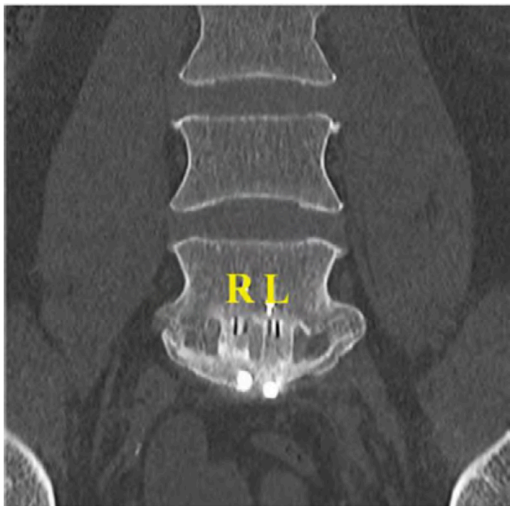
Safety – There were two early postoperative complications (5%); one hematoma and one radiculopathy.

CONCLUSION – Fusion rates within-patient were equivalent for GlassBone IP compared to autologous bone. GlassBone IP can be used as a substitute to autograft in patients undergoing ALIF. The performances and safety of Glassbone IP are demonstrated.

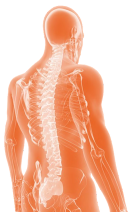




Bar chart presenting the Bridwell grades in the chambers filled with bioactive glass and autologous bone, at L4-L5 and L5-S1



Frontal CT scan of a patient with fusion of Bridwell grade I1 in both the chamber filled with bioactive glass (R) and the chamber filled with autologous bone (L) in both the chamber filled with bioactive glass (R) and the chamber filled with autologous bone (L)in both the chamber filled with bioactive glass (R) and the chamber filled with autologous bone (L)



Clinical and radiographic evaluation of bioactive glass in posterior cervical & lumbar spinal fusion

Publication - 2019

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https://link.springer.com/article/10.1007/s00590-019-02477-5

INDICATION - Degenerative diseases, trauma, or spinal deformities in the lumbar or cervical spine

SURGERY - Posterior spinal fusion with bioactive glass

METHOD

- Retrospective study – 30 patients.
- Objective: Evaluate if 45S5 bioactive glass (GlassBone Granules) could be an alternative to autogenous bone with comparable fusion rates than the other bone substitutes for any indication in spine fusion.
- Primary endpoint assessment: Fusion evaluation at 12 months with X-rays.
- Follow-up: 12 months.

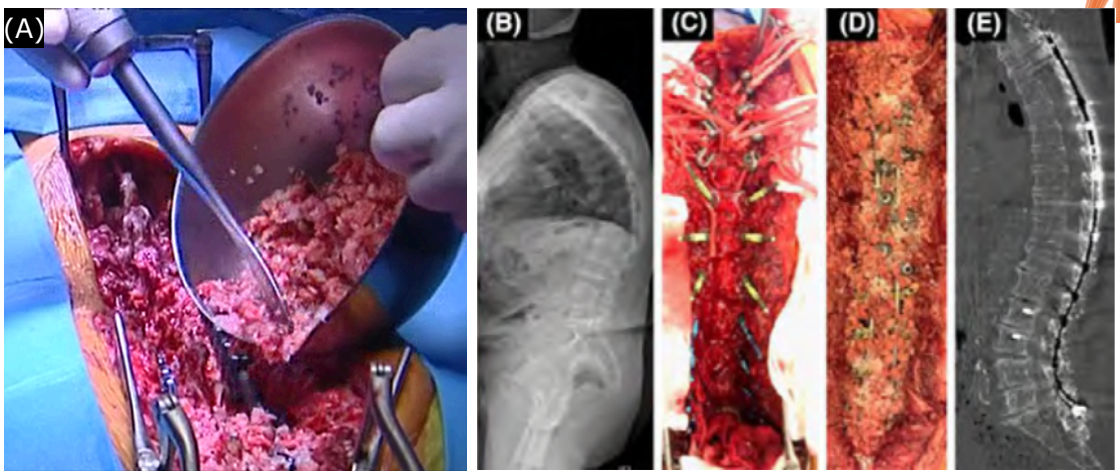
RESULTS

Performance – 100% patients had an acquired fusion in cervical pathologies. 82% patients had an acquired fusion, 11% had an in-progress fusion and 7% had pseudarthrosis in lumbar, thoracic, and sacral surgery.

Benefits – A clinical improvement concerning the pain with a reduction of 60% at 1 year post-op. The mean pre-operative VAS score was 7.5, and the mean postoperative score was 3. With the use of GlassBone Granules, there is a no donor site morbidity.

Safety – After surgery, four complications were reported: 1 mechanical complication (3.8%), 3 infections after surgery (staphylococcus, 10%). There are no serious adverse events relating specifically to the use of 45S5 bioactive glass. These four patients were re-operated successfully (graft consolidation and patient recovery).

CONCLUSION – This retrospective study suggest that the 45S5 bioactive glass may be an interesting alternative option to autologous graft, in terms of safety and bone fusion efficiency. The performance and safety of GlassBone Granules were confirmed.



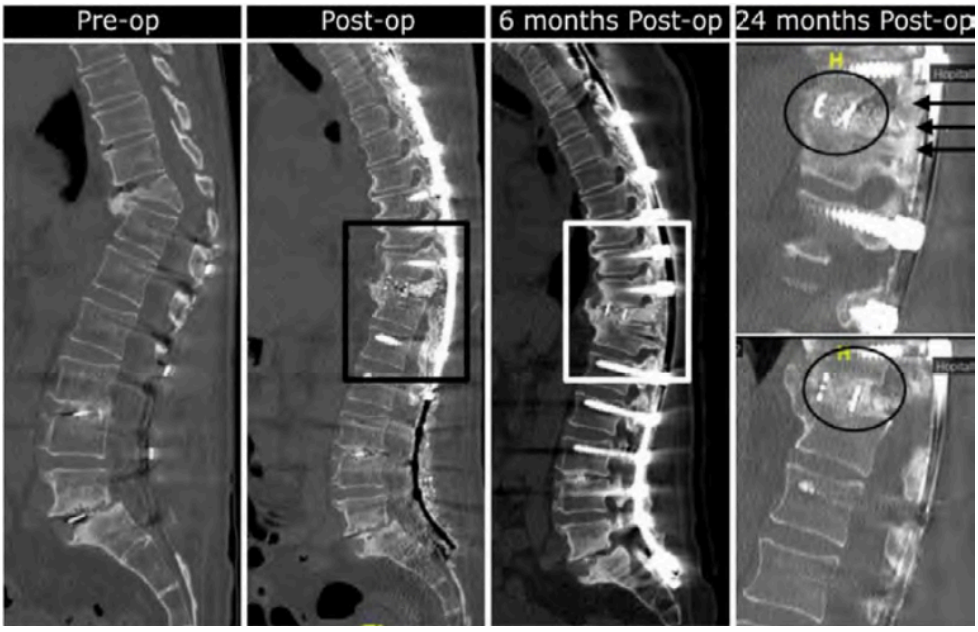
(A) Mix of GlassBone with local autologous bone and saline serum place on the decorticated posterior elements of the spine along the construct from T3 to pelvis

(B) Pre-operation X-ray

(C) Positioning of the instrumentation

(D) Composite placed between facets and lamina

(E) Postoperation X-ray



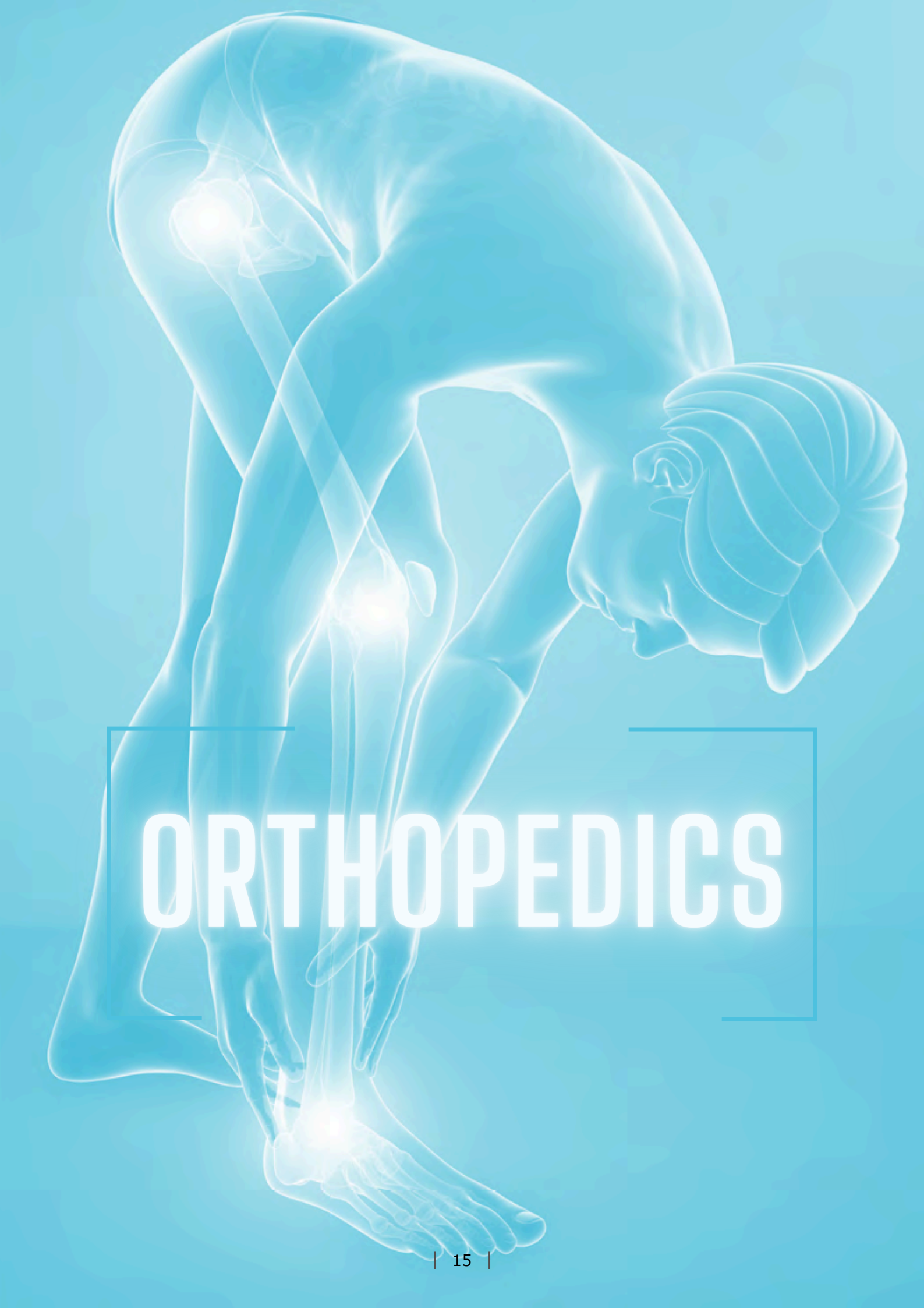
Patient was operated by VCR (vertebral column resection) to treat PJK (proximal junctional kyphosis). The granules are visible immediately after surgery along the instrumentation. At 2 years after surgery, a bone bridging is clearly visible inside the vertebral cage and through the disc space

SPINE

ORTHOPEDICS

CRANIO MAXILLO FACIAL - EAR NOSE THROAT

DENTAL



ORTHOPEDICS

Orthopedic surgeries are performed daily to repair bone tissue due to traumatic injuries, disease as ntumors, deformity, and degeneration. It is intended to correct the osteoarticular deformations and to treat the painful joints/defect mainly due to the cysts, the tumors of the limbs and, finally, to correct the after-effects of the traumatisms (Andreasson et al., 2020; D'Elia et al., 2010; Dhanakodi et al., 2019; Dragosloveanu et al., 2020; Ferguson et al., 2019; Gaiarsa et al., 2019; Heikkila et al., 2011; Lindfors et al., 2009; Lindfors et al., 2010; Loveland et al., 2021; Pan et al., 2018; Pernaa et al., 2011; Shrouder-Henry et al., 2019; Thordarson & Kuehn, 2003; Wang & Yeung, 2017; Zhao et al., 2020) with or without infections.

Bone is one of the most common organs affected by metastases. Metastatic bone disease (MBD) can be caused by different primary tumors, with the highest prevalence being from breast and prostate cancer (Phull et al., 2021; Sebghati et al., 2021). Also, bone loss can be caused by the presence of a cyst or bone tumour that enlarge over time, resulting in thinning of the bone. Cysts are described as cavities filled with a benign fluid. Usually, these cysts are reported in the metaphyseal regions of long bones (50-70%) and 85% of unicameral bone cysts occur almost exclusively in children and adolescents (Dong et al., 2020; Noordin et al. 2018).

The treatment of tumors, cysts or even treatment-resistant infections often requires removing bone fragments that are too large for the natural self-repair process to be effective. Currently recommended treatment options include:

- curettage and bone-grafting
- intralesional injections with corticosteroids, bone marrow, demineralized bone matrix
- or bone ceramic filling, PMMA bone cement, decompression, not filling
- internal fixation
- and also combinations of these (Dong et al., 2020; Deventer et al., 2021; Gava & Engel, 2021).

After a fracture, the dead bone must be resorbed, and the new bone reformed. Bone resorption is performed mainly by osteoclasts and new bone formation is performed by osteoblasts. Osteoblasts line the outer surface of bones and are also present in most bone cavities. These cells secrete a very strong protein matrix, consisting mainly of collagen fibres. The matrix is then mineralized, and the osteoblasts become osteocytes. Blood vessels containing mineral elements are key contributors to the process of osteogenesis. Most bone fractures occur as a result of inconvenient or incompetent bone regeneration.

But sometimes segmental bone fractures did not repair instinctively and require orthopedic
operation (Ansari, 2019). Depending on the case, a repair of the fracture (osteosynthesis) by nail, plate, screw will be carried out with or without graft. In some cases (complex fracture of the elderly, risk of bone necrosis of the head, etc.) replacement by partial or total shoulder prosthesis will be chosen (Marongiu et al., 2020; Martin et al., 2021).

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The impact of bone graft type used to fill bone defects in patients undergoing ACL reconstruction with bone–patellar tendon–bone autograft

Publication - 2023

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https://link.springer.com/article/10.1007/s00590-023-03624-9

INDICATION - Anterior cruciate ligament (ACL) injuries

SURGERY - Anterior cruciate ligament (ACL) reconstruction with bone–patellar tendon–bone (BPTB) autograft

METHOD

- Prospective study (2018 – 2020) – 102 patients.
- Objective: Investigate the influence of these bone graft types on kneeling and knee functional outcomes.
- Three groups: GlassBone Injectable Putty (36 patients), Collapat II (34 patients) and Osteopure (32 patients).
- Follow-up: 24 months.

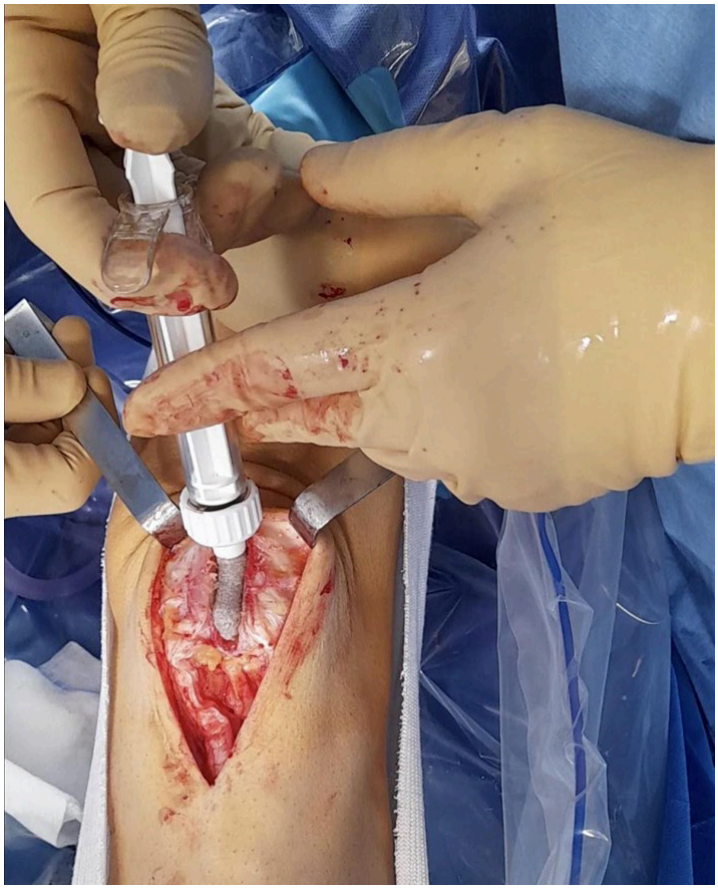
RESULTS

Performance – No defect's sensation and 100% filling.

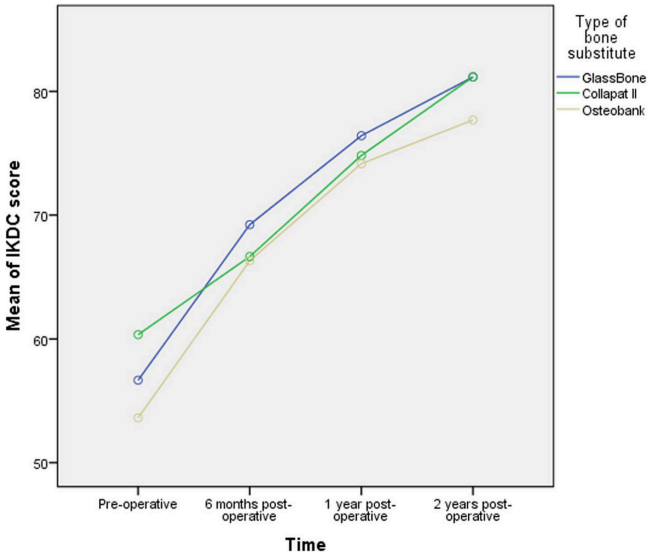
Benefits – No harvest bone graft site. In terms of Kneeling pain, the percentage of GlassBone and Collapat patients' who kneel with ease were much higher than that of Osteopure patients (77.78%, 76.5% vs 65.6%, respectively). There was no difference in anterior knee pain between the groups.

Safety – No postoperative complication and no patellar fracture were observed with GlassBone Injectable Putty.

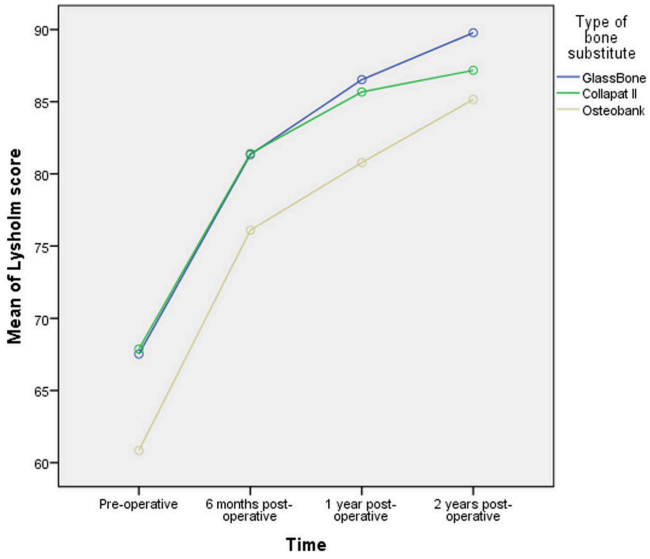
CONCLUSION – The use of GlassBone and Collapat II bone substitutes reduced the incidence of kneeling pain compared to Osteopure. There was no influence of the bone substitute type on the functional outcome of the knee or on the anterior knee pain at two years of follow. So the performance and safety of GlassBone Injectable Putty are demonstrated.



Intra-operative photograph showing the patellar defect being filled with GlassBone allograft



Evolution of the IKDC score over time



Evolution of the Lysholm score over time

Is a Bioceramic Glass Bone Graft Superior to Spongious Allografts in Femoral and Tibial Benign Bone Lesions?

Publication - 2022

Gökhan İlyas[1], Ahmet Kaya[2], Mustafa İncesu[2]

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https://tepecikdergisi.com/jvi.aspx?pdir=terh&plng=eng&un=TERH-76402

INDICATION - Benign bone lesions – Long bone

SURGERY - Grafting for benign bone lesions in the long bones carrying lower extremity

METHOD

- Retrospective study (2007 – 2013) – 47 patients.
- Objective: Compare the clinical and radiological results of bioceramic glass graft (GlassBone Granules) and human induced cancellous allograft.
- Two groups: Spongious allograft (29) and Bioceramic glass bone graft (18).
- Primary endpoint assessment: Evaluation of the bone consolidation.
- Follow-up: 16,5 months.

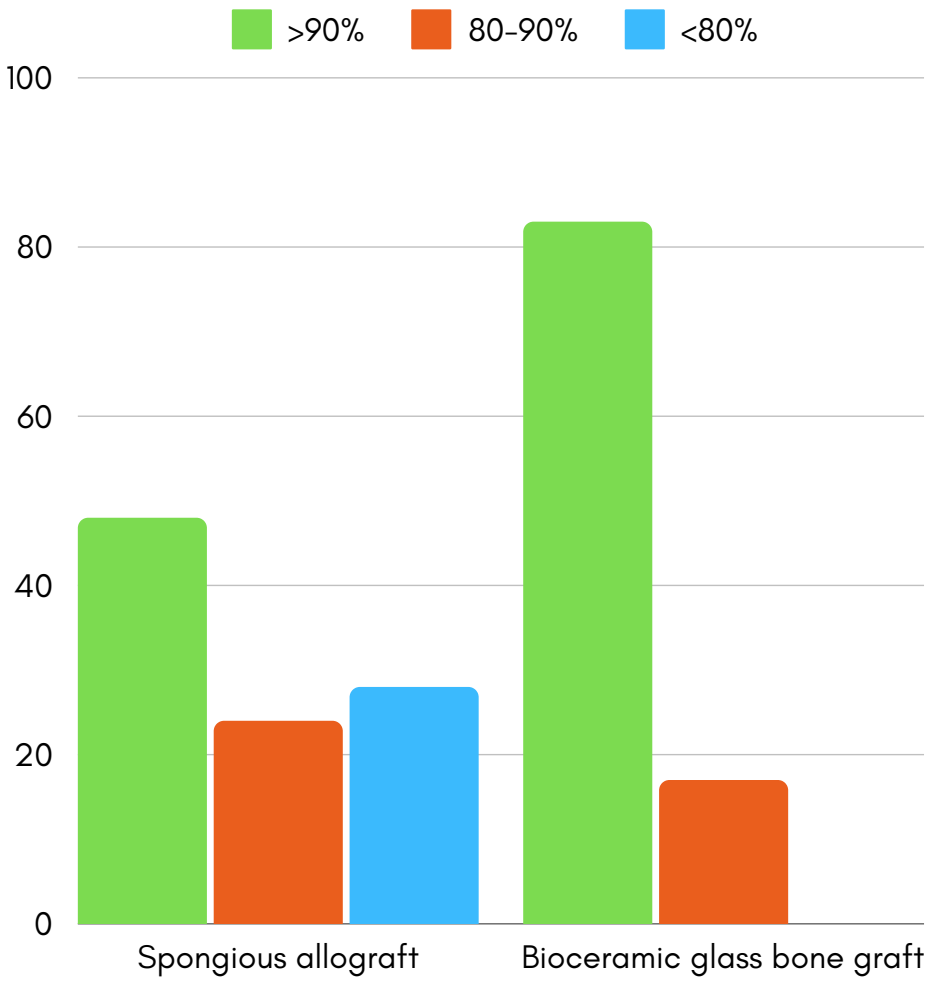
RESULTS

Performance – Bioceramic glass bone grafts performed significantly better (p=0.002) than spongy grafts, showing a consolidation ratio of 93.78% compared to 82.58%. Consolidation success rates were highest in patients with fibrous dysplasia (96.75%) and simple bone cysts (95%).

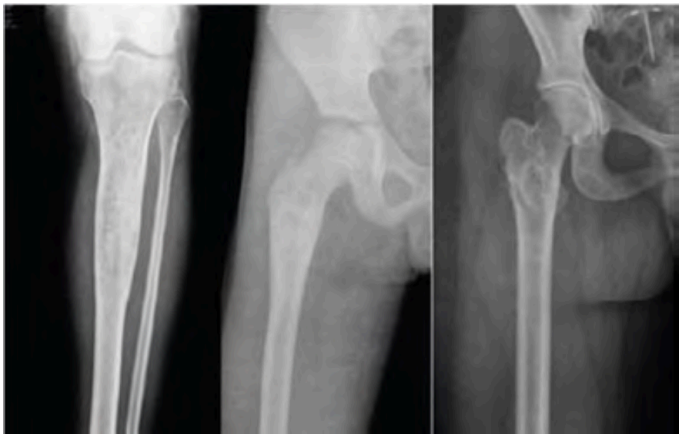
Benefits – No harvest bone graft site. In both the spongious graft and bioceramic glass bone graft groups, there were minimal differences in average pain scores and lower extremity function scores at the end of the follow-up period. The pain scores were 1.07±0.96 and 1.0±0.84, respectively, with no significant difference. Similarly, the lower extremity function scores were 93.75±3.67% and 94.51±3%, respectively.

Safety – No adverse event reported in this study.

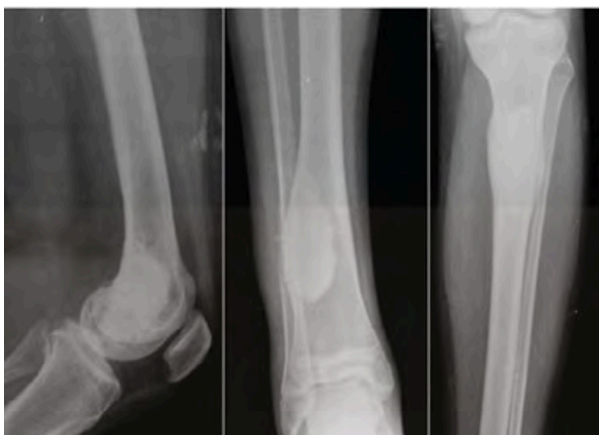
CONCLUSION – GlassBone Granules, exhibit superior radiological outcomes and comparable clinical efficacy to spongious allografts. Notably, they demonstrate statistically significant radiological consolidation success, particularly beneficial for benign aggressive tumors like fibrous dysplasia. So the performance and safety of GlassBone Granules are demonstrated.



Consolidation range by graft materials



Spongious allograft samples



Bioceramic bone graft samples

A large osteoid osteoma of trapezium: a regenerative approach and a review of literature

Publication - 2022

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https://www.sciencedirect.com/science/article/pii/S2589514122000639

INDICATION - Hand osteoid osteoma, with a sclerotic nidus and cortical reaction (tumor)

SURGERY - A large (1.3 cm) osteoid osteoma of the trapezium treated surgically with resection, curettage and filling with bioactive glass (granules and putty)

METHOD

- Case report - A 19-year-old man.
- Objective: Evaluate the performance and safety of GlassBone in the treatment of a rare case of a large (1.3 cm) osteoid osteoma of the trapezium.
- Follow-up: 12 months.

RESULTS

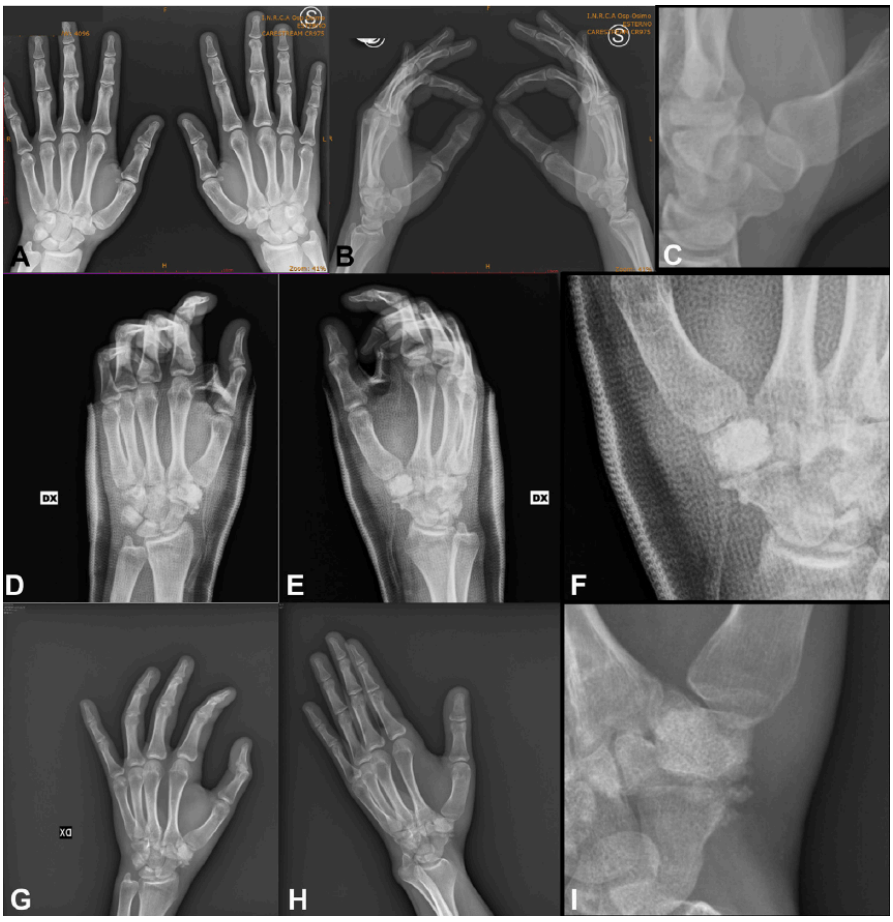
Performance – At 1 month, the trapezium density is similar to that of the normal bone and at 12 months the appearance of the trapezius is similar to that of a normal trapezius in terms of density and joint relationships with the other carpals and there is no recurrence of the disease.

Benefits – No harvest bone graft site to avoid donor morbidity in such a young patient. Improvement in VAS, Pinch test and Kapanji scores at 30 and 60 days after surgery.

Safety – No adverse event reported in this case.

CONCLUSION – Osteoid osteoma should be suspected when a patient presents with long-lasting wrist pain with unclear diagnosis, associated with radial side tenderness surrounding the thumb, night pain responsive to NSAIDs, and negative x-rays. The best treatment is the curettage of the osteoid osteoma, avoiding trapeziectomy if the carpometacarpal joint is not involved. If the lesion is larger in size, bone grafting, bone substitutes, or bioglass can be useful. So the performance and safety of GlassBone Granules and Putty are demonstrated.

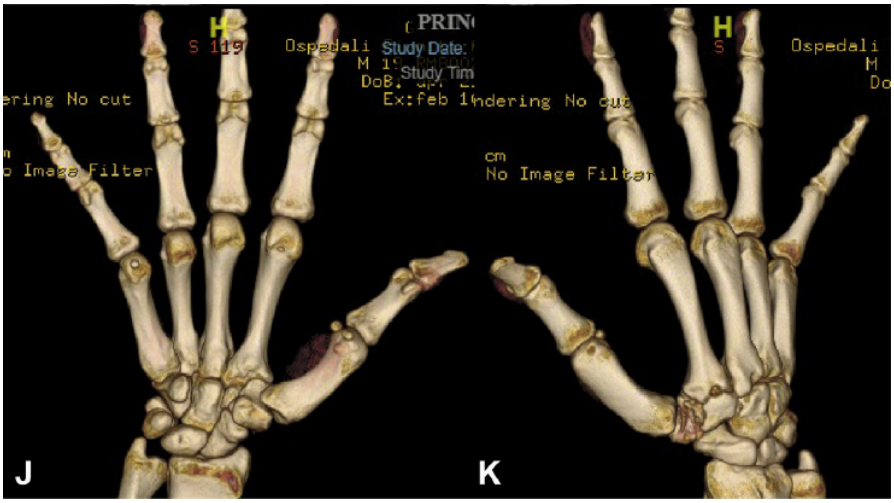
X-ray examinations from months before and after surgery and at 30 days of follow-up.



(A) Anteroposterior view showing the standard trapezium;
(B) Okay sign view showing the normal trapezium;
(C) Magnified view of the trapezium;
(D) Anteroposterior view showing the trapezium filled with bioglass;
(E) Oblique view showing the trapezium filled with bioglass;
(F) Magnified view of the trapezium;
(G) Anteroposterior view showing the trapezium filled with bioglass;
(H) Oblique view showing the trapezium filled with bioglass;
(I) Magnified view of the trapezium;

(A-C) Radiographs before surgery. The trapezium is quite similar in both hands, both in the anteroposterior and lateral view.
(D-F) Radiographs at the end of the surgery with the cast including metacarpo phalangeal joint. A hyperintense image of the trapezium is due to the active bioglass applied in the bone cavity.
(G-I) Thirty days after surgery. The trapezium density is similar to that of the normal bone, demonstrating how bioglass is going to integrate. Note that some parts of the active bioglass outside the trapezium will be absorbed in the following months.

X-ray examinations at 12 months follow-up.



(J) One-year follow-up (front view). The appearance of the trapezius is similar to that of a normal trapezius in terms of density and joint relationships with the other carpals.
(K) One-year follow-up (lateral view). The appearance of the trapezius is similar to that of a normal trapezius in terms of density and joint relationships with the other carpals.

Comparison of the Results of Glassbone and Tricalcium Phosphate Graft Used in Bone Tumors

Publication - 2021

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INDICATION - Benign bone tumours (simple bone cysts and aneurysmal bone cysts)

SURGERY - Grafting with GlassBone Granules or Tricalcium phosphate after curettage and cauterization

METHOD

- Retrospective study – 41 patients.
- Objective: Compare clinically and radiologically results of bioactive glass graft (GlassBone Granules) and tricalcium phosphate grafts used in benign bone cysts.
- Patients were treated between either glass graft or tricalcium phosphate graft between 2013-2015.
- Primary endpoint assessment: Evaluation of the graft consolidation evaluated radiologically with X-rays.
- Follow-up: 54 months.

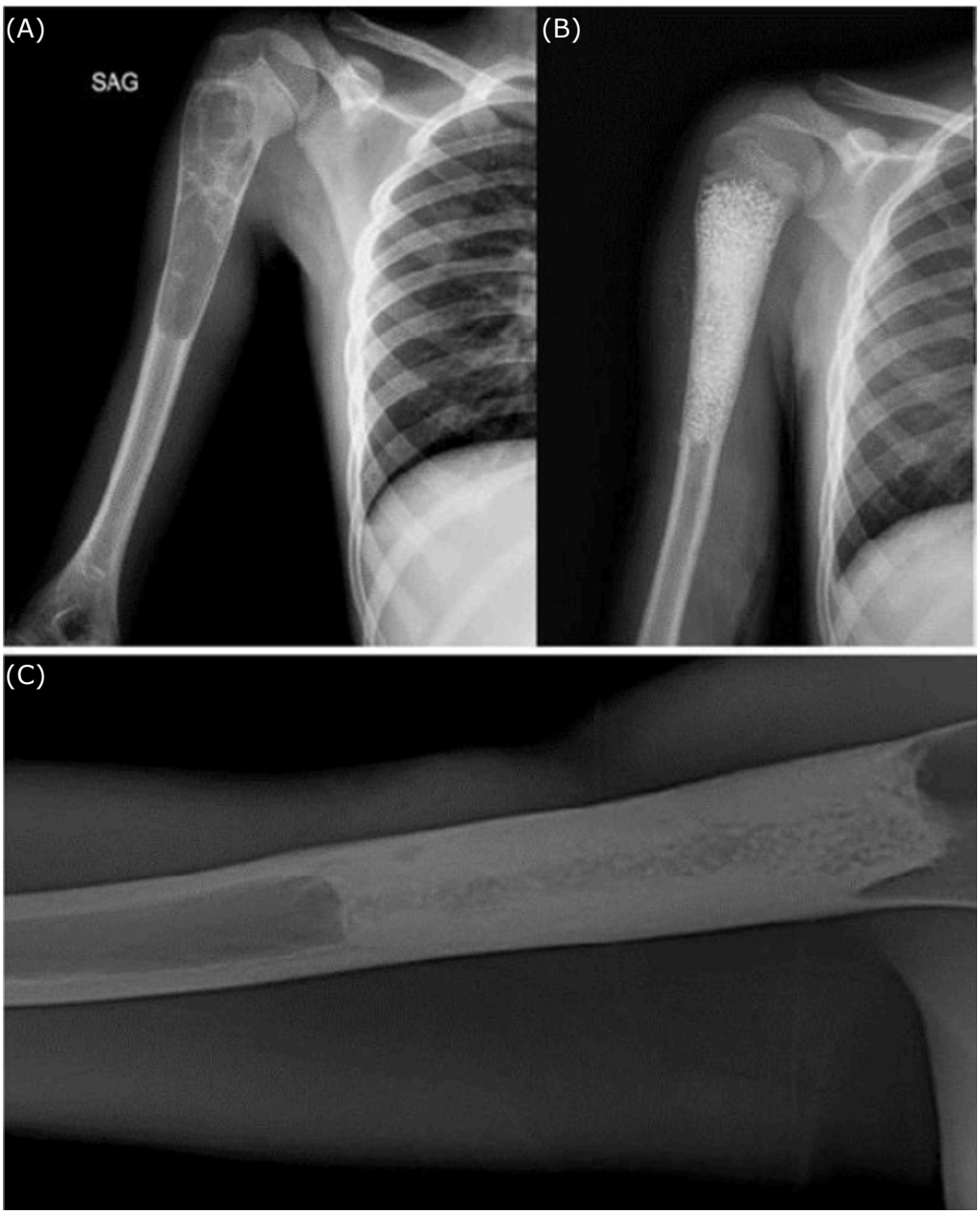
RESULTS

Performance – Patient treated with GlassBone achieved bone healing (100% consolidation) between 14 and 16 months (faster than patient treated with tricalcium phosphate).

Benefits – No harvest bone graft site.

Safety – For GlassBone group: there were 9.09% that had residual cyst (treated in revision surgery with the same graft). No infection. For TCP group: 5.26% had infection and 5.26% had residual cyst (treated in revision surgery with the same graft).

CONCLUSION – In the treatment of benign bone tumors GlassBone Granules can be used as an alternative to tricalcium phosphate grafts. It is noticed that patients treated with GlassBone Granules showed a faster rate of fusion radiologically. The safety and performance of GlassBone Granules are demonstrated.



Allograft Prosthesis Composite (APC) located proximal to the right humerus in a 14-year-old male patient.

(A) Direct radiograph of a lobulated septal cystic lesion extending from the proximal humerus to the diaphysis;

(B) Post-operative radiograph after curettage + allograft (bioglass graft);

(C) Postoperative 10th month radiograph; graft fusion is seen.

Three-dimensional printed titanium pseudo-prosthesis for the treatment of a tumoral bone defect

Publication - 2021

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https://www.jsesreviewsreportstech.org/article/S2666-6391(21)00086-9/fulltext

INDICATION - Tumoral bone defect

SURGERY - Reconstruction of a large bone defect after a wide resection in the middle third of the left clavicle with lytic lesion (tumor)

METHOD

- Case study - A 37-year-old man with Langerhans cell histiocytosis (LCH).
- Objective: Evaluate the performance and safety of GlassBone Injectable Putty in the treatment of bone tumor in adults.
- Follow-up: 24 months.

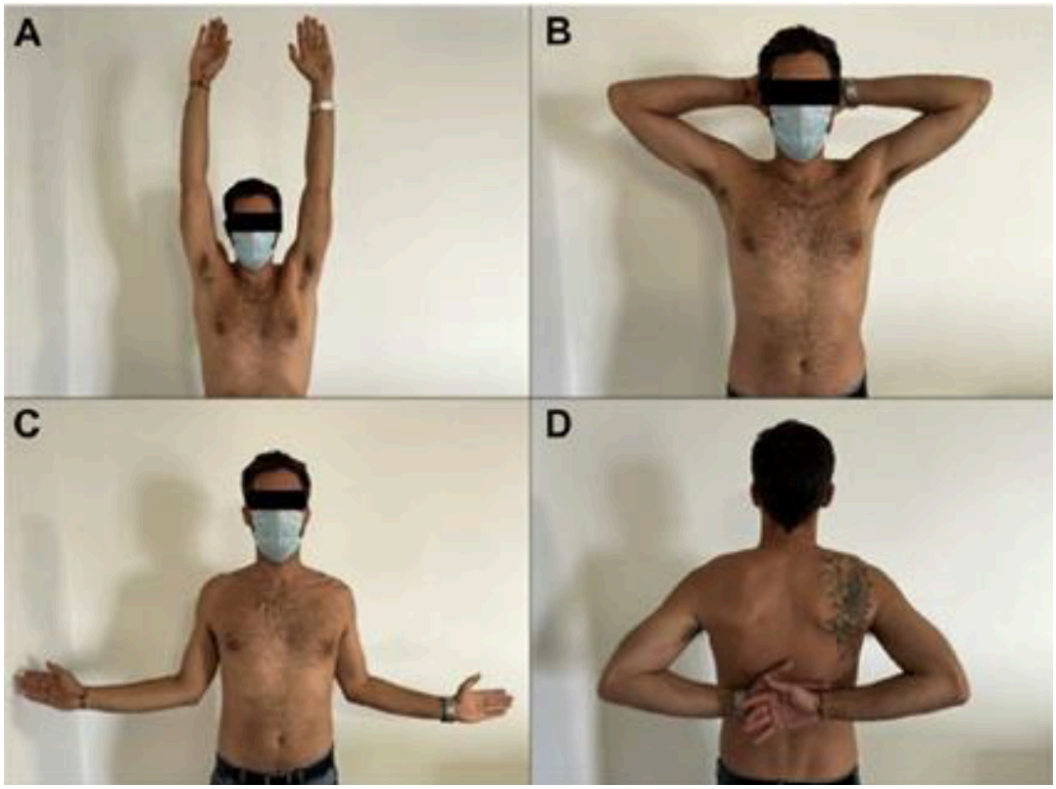
RESULTS

Performance – Complete range of motion of the left shoulder and normal life without any type of functional limitation at 24 months.

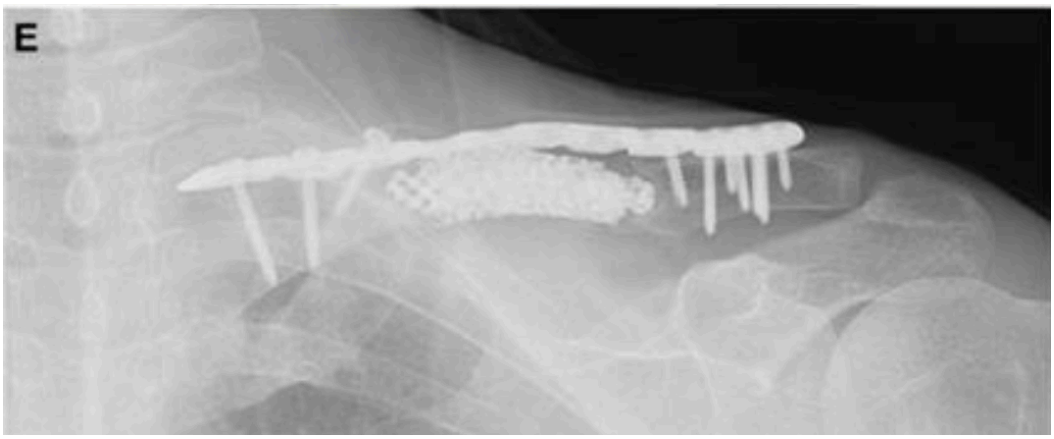
Benefits – No harvest bone graft site.

Safety – No complications were reported. No pain on palpation or mobilization at 3 months after surgery.

CONCLUSION – The results of this case study show that performance and safety of GlassBone Injectable Putty are confirmed.



(A-D) Two years after surgery, the patient had a complete range of motion of the left shoulder



(E) The follow-up X-ray 2 years after surgery

Adamantinome case on a 7-years-old patient

White Paper - 2019

Dr Bernard Fraisse

CHRU Rennes, France

ORTHOPEDICS

INDICATION - Tibial bone tumor

SURGERY - Induced membrane technique (Masquelet technique) with 50% cancellous bone autograft and 50% GlassBone Granules

METHOD

- Case study - A 7-year-old patient.
- Objective: Evaluate the performance and safety of GlassBone Granules in the treatment of bone tumor in children.
- Follow-up: 36 months.

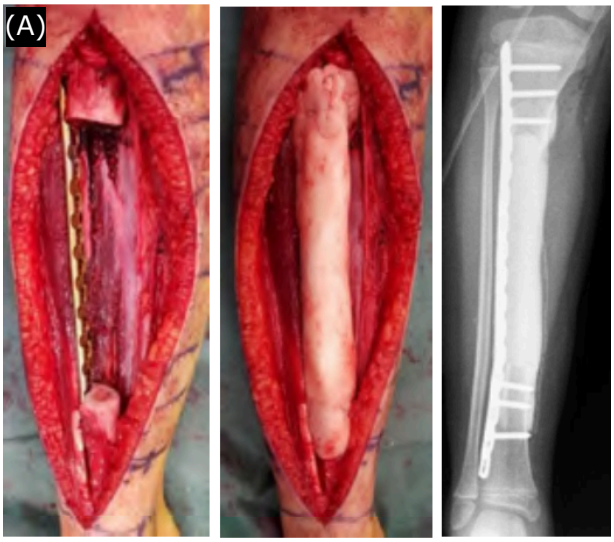
RESULTS

Performance – Demonstrated consolidation at 2 years.

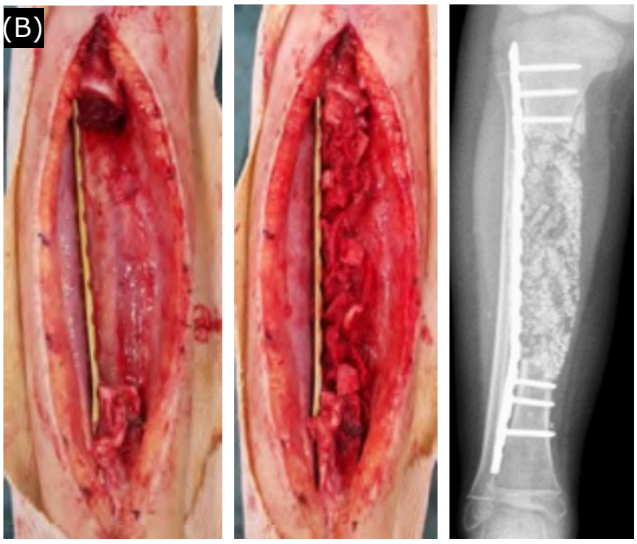
Benefits – Reduced quantity of cancellous bone autograft.

Safety – At 6 months, the plate was broken and replaced, but this happens almost every time a resection of this importance is performed. No complications were reported.

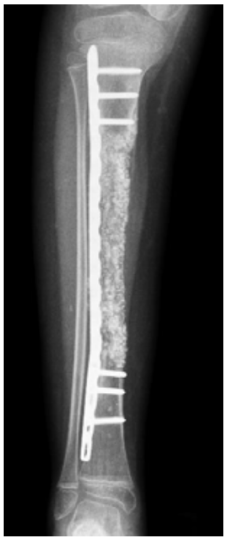
CONCLUSION – The results of this case study show that performance and safety of GlassBone Granules are confirmed.



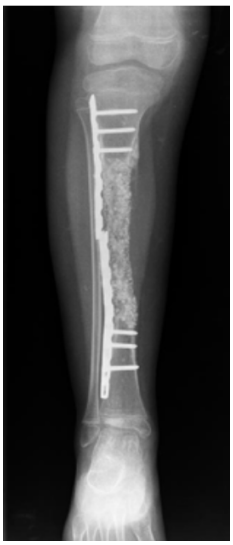
(A) First time: insertion of bone cement spacer into the bone defect after a resection of 16cm



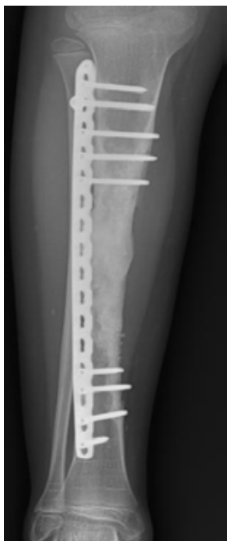
(B) Second time (6 weeks postoperative): spacer is replaced by 50% of cancellous bone autograft and 50% of GlassBone Granules



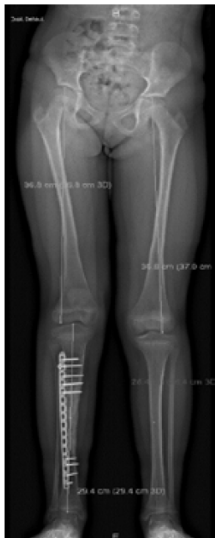
5 months postop



6 months postop



24 months postop



36 months postop

Chronic Tibial Osteomyelitis, use of Bioactive Glass as an alternative of treatment

Publication - 2022

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https://pubmed.ncbi.nlm.nih.gov/35451257/

INDICATION - Chronic tibial osteomyelitis type IV B (classification Cierny-Mader)

SURGERY - Extensive debridement followed by the application of PMMA impregnated with amikacin. In second time, an osteoclysis system with vancomycin irrigation and autologous fibular graft with bioactive glass were applied

METHOD

- Case study - A 42-year-old man.
- Objective: Evaluate the performance and safety of GlassBone Granules in the treatment of osteomyelitis in adults.
- Follow-up: 12 months.

RESULTS

Performance – At 1 month, radiographic control showed no signs of instability of the osteosynthesis material and osseointegration of the fibula into the tibia. At 12 months, the patient recovery of 90% of the function of the affected limb.

Benefits – No harvest bone graft site. At 3 months, the patient was already walking without support.

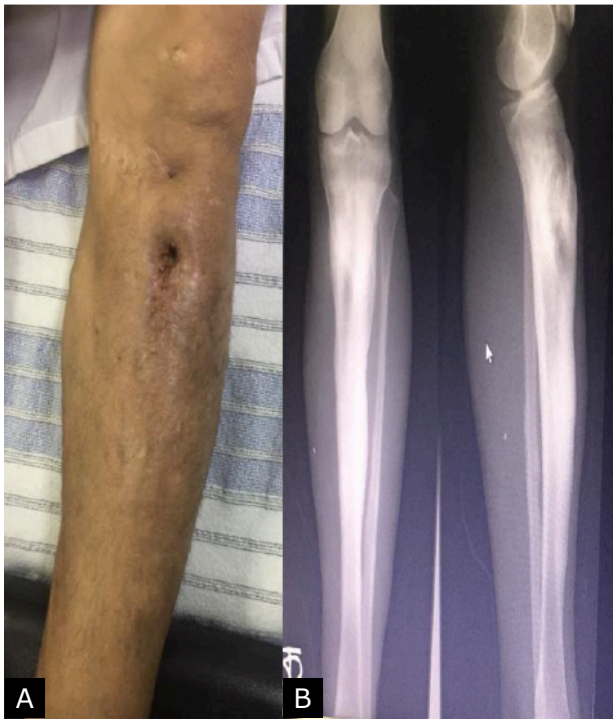
Safety – No adverse event reported in this study. At 1 month, clean healed surgical wounds with no evidence of infection and at 3 months, normal laboratory tests. At 12 months, no signs of infection.

CONCLUSION – In this case, the surgical management in two time, the use of medication, bone graft and the use of bioactive glass, achieved a complete eradication of the infection and favorable clinical evolution with optimal functional recovery of affected limb. So the safety and performance of GlassBone Granules are confirmed.

BEFORE SURGERY

(A) Fistulas in the proximal metaphyseal region

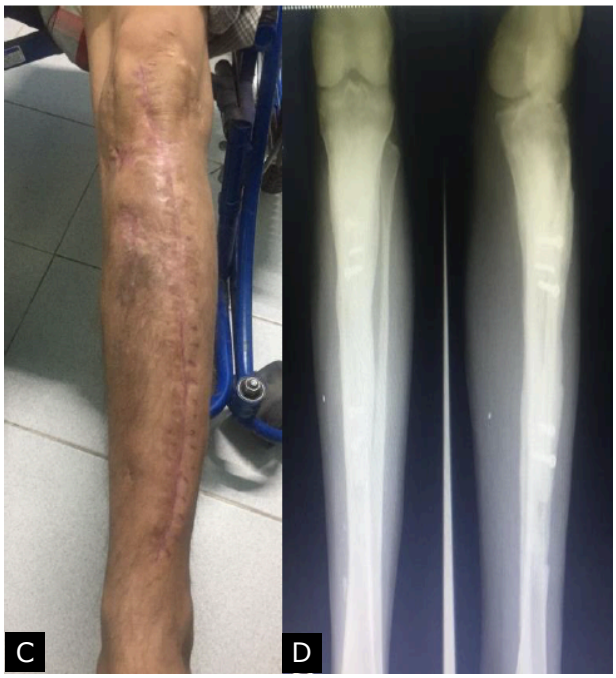
(B) AP and lateral radiography of the left tibia, lytic area in the tibial metaphyseal region and anterior bone condensation up to the distal diphyseal region



AFTER SURGERY

(C) Closure of fistulas and surgical wound without evidence of exudates

(D) Bone osseointegration of the fibula in the tibia



Saving the lower limb with GlassBONE - Successful surgical revision of pseudarthrosis after infected open proximal tibia fracture type IIIC with bioactive glass grafting

Publication - 2021

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https://pubmed.ncbi.nlm.nih.gov/33426259/

INDICATION - Open proximal tibia fracture, type IIIC

SURGERY - Masquelet therapy followed by GlassBone Granules grafting

METHOD

- Case report - A 51-year-old man.
- Objective: Show the results with the use of bioactive glass in the management of bone defect due to trauma.
- Follow-up: 24 months.

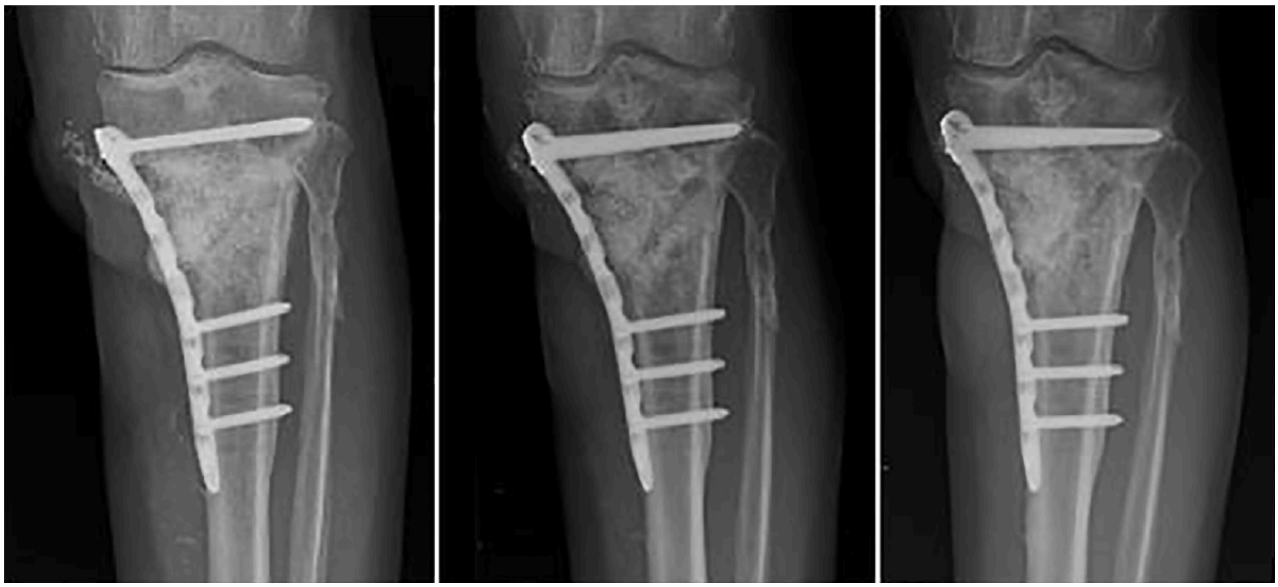
RESULTS

Performance – At 10 months, bone consolidation was found and there was no deformity of axe nor signs of material loosening. At 24 months, transformation of GlassBone Granules into bone and perfect bone consolidation were visible.

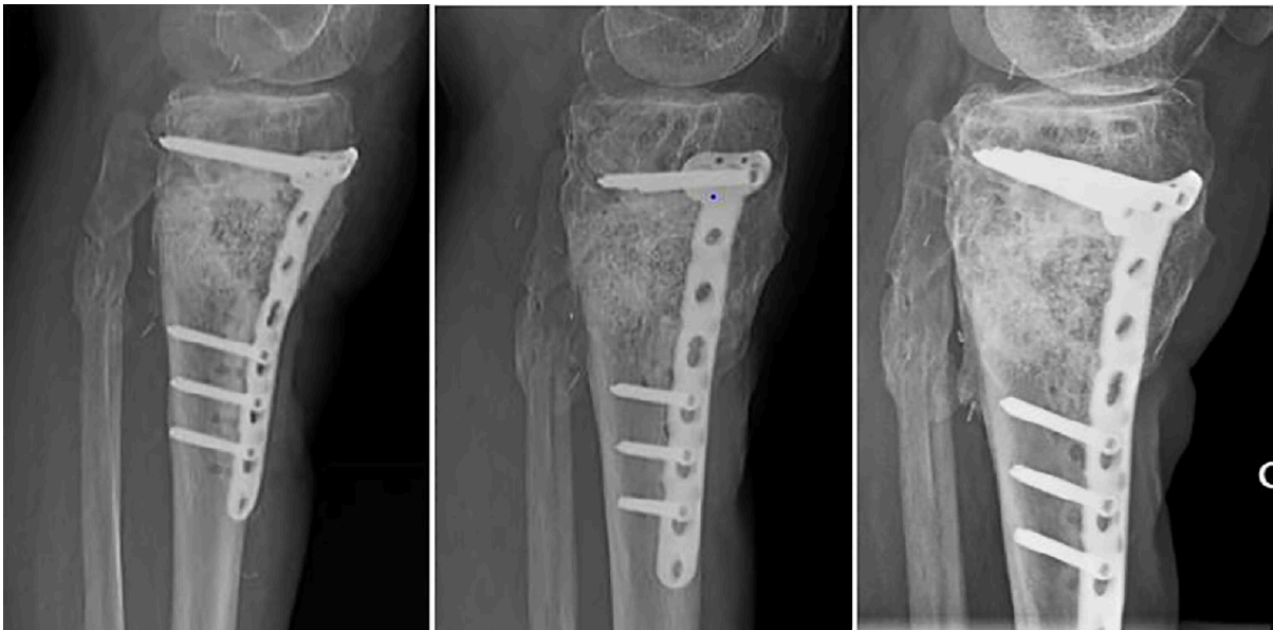
Benefits – No harvest bone graft site. At 24 months, pain does not restrict the patient's daily life activities, no limping and walking was possible without crutches (walking distance limited).

Safety – No complications or signs of infection were noted.

CONCLUSION – GlassBone Granules has proven to be an effective bone substitute even in difficult grafting conditions, including multiple surgical revisions for bone nonunion and infection. At the end of 2 years and 3 months of follow-up, the patient reported no pain, and had no signs of infection. Bone union and full weight bearing was achieved. So the performance and safety of GlassBone Granules are demonstrated.



Antero-posterior view of left leg at 1 month, 6 months and 24 months postoperatively



Lateral view of leg at 1 month, 6 months and 24 months postoperatively

A case report of upper limb loss of substance: Use of functional gracilis free flap, brachioradialis transposition and bioglass for bone regeneration

Publication - 2022

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https://pubmed.ncbi.nlm.nih.gov/35141388/

INDICATION - Complex upper limb loss of substance (trauma) with ulnar pseudoarthrosis

SURGERY - Use of functional gracilis free flap, brachioradialis transposition and bioglass for bone regeneration with Masquelet procedure

METHOD

- Case report - A 27-year-old man presented as victim of car and motorcycle collision with injury to the distal third of the right forearm.
- Objective: Evaluate the performance and safety of GlassBone Granules in a complex reconstruction with loss of substance including nerve, bone, tendons and vascular defects.
- Follow-up: 36 mois.

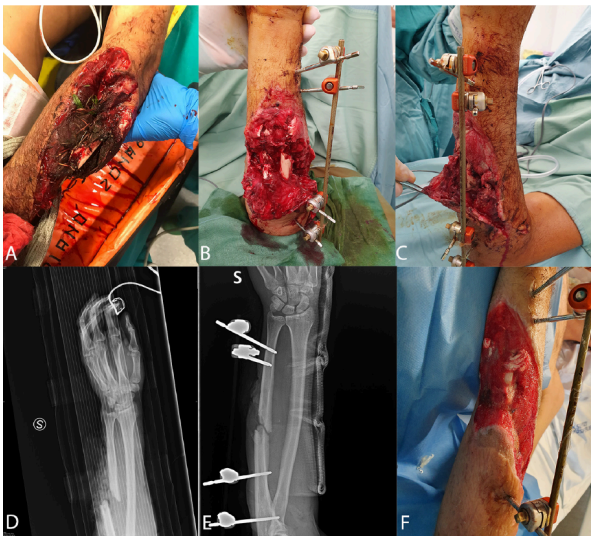
RESULTS

Performance – At 3 and 5 months, we observed satisfactory outcomes in the injury site. At 18 months, hand movement was partially retrieved with ability to undergo normal daily activities without heavy limitation.

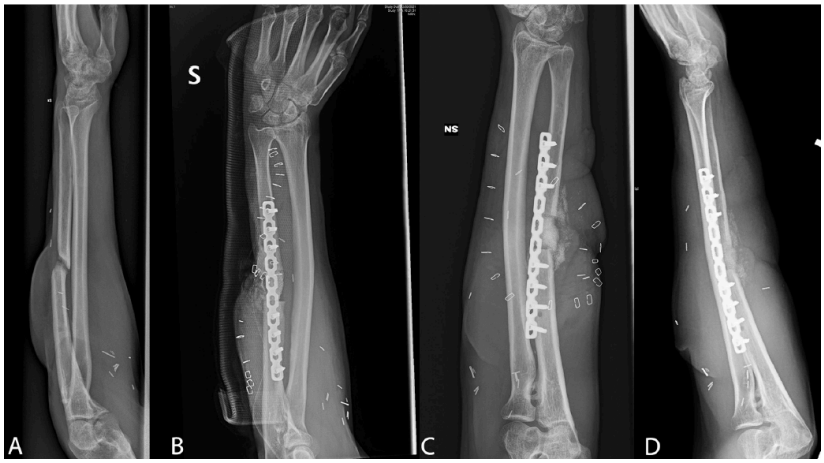
Benefits – No iliac crest graft site to avoid ulterior donor site damage for the patient who already undergone to multiple operations. Wound healing occurred following 18 months of surgery.

Safety – No adverse event reported in this study.

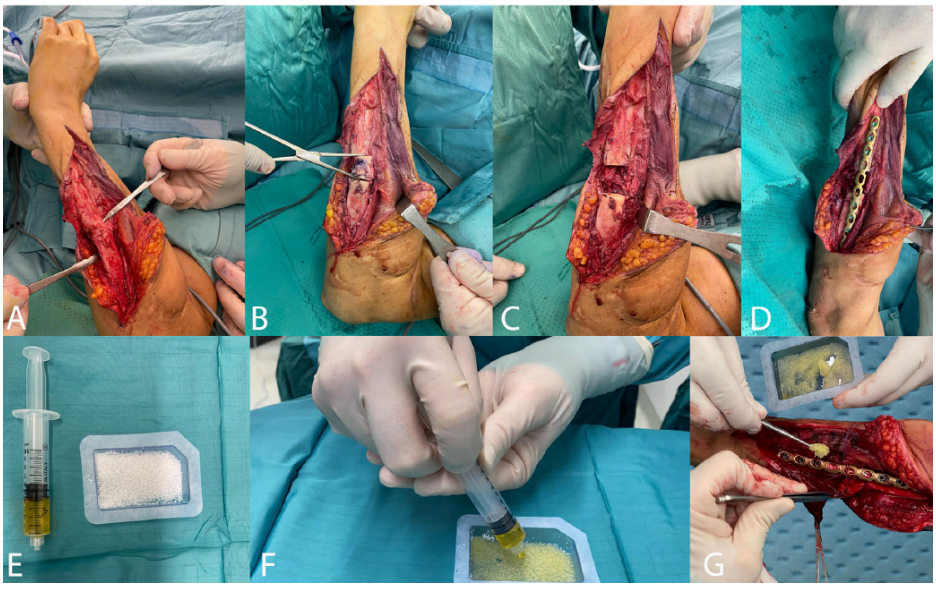
CONCLUSION – The gracilis free flap may be considered as an ideal therapeutic option for reconstruction of upper limb lesions involving multiple tissue damage with loss of hand extension in view of its composite characteristics aforementioned as well as its ability to be innervated by a single motor nerve and tendon. Furthermore, bone grafts may be avoided by using Bioglass, a valuable material for small extra-articular bone gaps. So the safety and performance of GlassBone Granules are demonstrated.



Clinical presentation of 27-year-old trauma of forearm and emergency room treatment of the ulnar bone and tissue damage



Pseudoarthrosis of ulnar fracture after six months and radiographic follow-up after bioglass treatment



Bioglass procedure for treatment of ulnar pseudoarthrosis

Treatment of high-energy tibial open fracture: a case report

White paper - 2018

Dr. David Alonso Alvarez
Dr. Victor Folgueras Henriksen

Hospital Valle Del Nalon. Asturias

ORTHOPEDICS

INDICATION - Osteomyelitis

SURGERY - Open tibial shaft fracture with subacute osteomyelitis

METHOD

- Case study - A 43-year-old man.
- Objective: Evaluate the performance and safety of GlassBone Granules in the treatment of osteomyelitis in adults.
- Follow-up: 6 months.

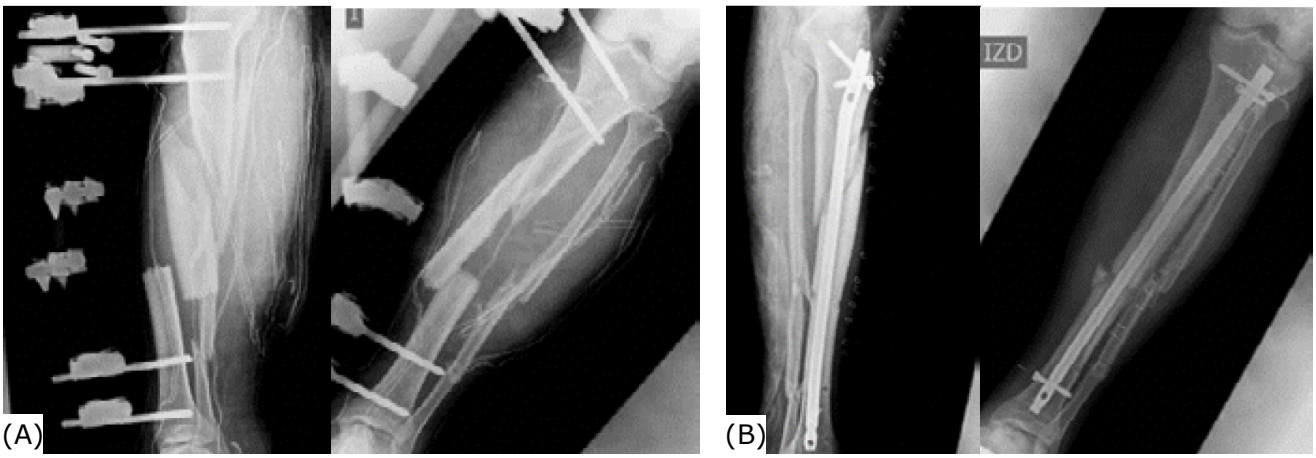
RESULTS

Performance – At 6 months, the external fixators were removed, demonstrating primary consolidation of the bone.

Benefits – Reduced quantity of cancellous bone autograft.

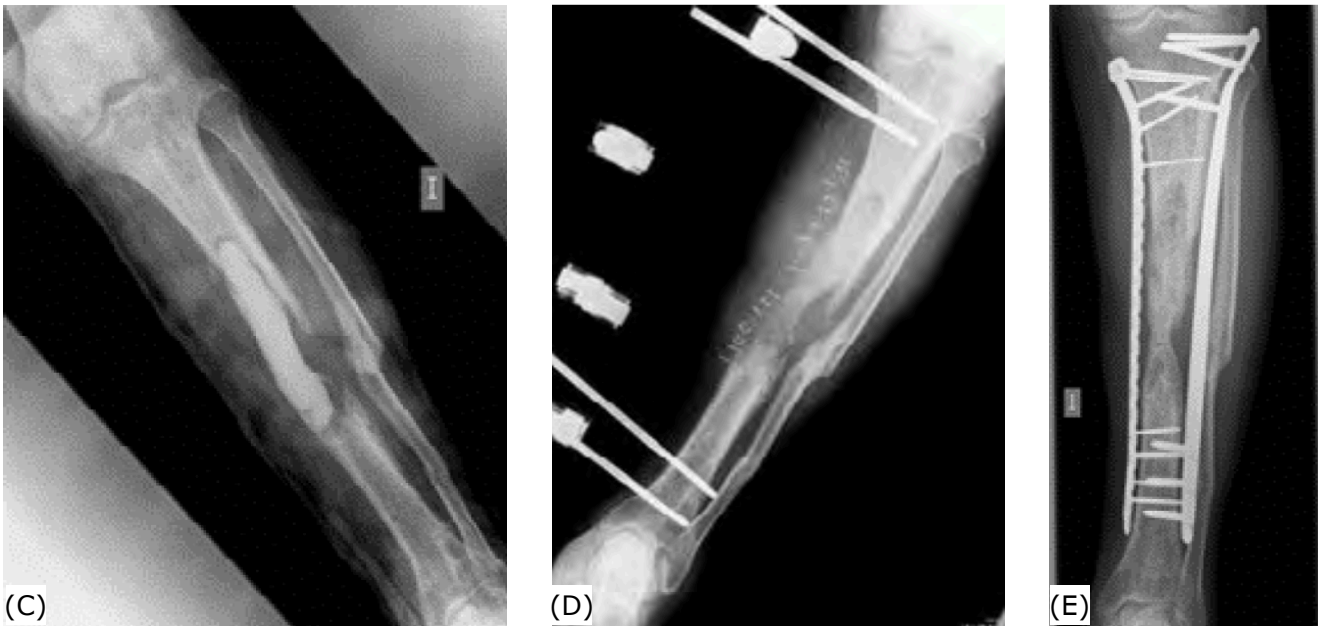
Safety – No adverse event reported in this case.

CONCLUSION – The safety and performance of GlassBone Granules are demonstrated.



(A) Open fracture

(B) Intramedullary nail



(C) Resection and obliteration of necrosis area with PMMA spacer of gentamicin.

(D) Defect's filling with autologous bone and GlassBone Granules and stabilization with external fixers

(E) Consolidation at 6 months

GlassBone (Noraker) in foot surgery : Case report

White paper - 2017

INDICATION - Torsion torque osteoarthritis

SURGERY - Arthrodesis

METHOD

- Case study - A 63-year-old man.
- Objective: Evaluate the performance and safety of GlassBone Granules in the treatment of osteomyelitis in adults.
- Follow-up: 6 months.

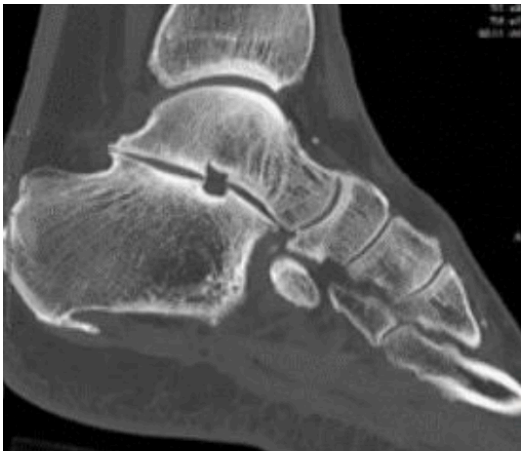
RESULTS

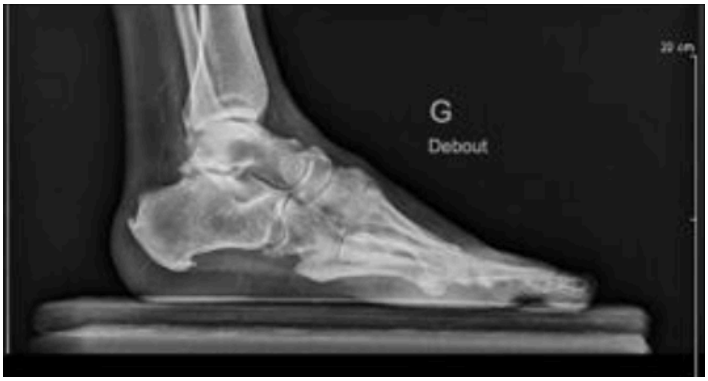
Performance – At 6 months the patient was consolidated.

Benefits – No bone harvesting at the iliac crest which reduces morbidity.

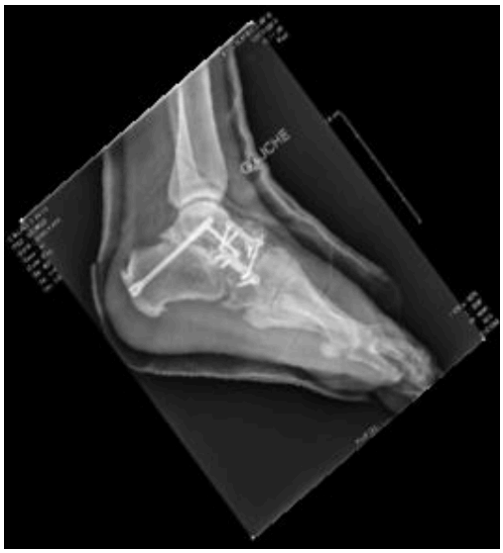
Safety – No adverse event reported in this case.

CONCLUSION – The safety and performance of GlassBone Granules are demonstrated.

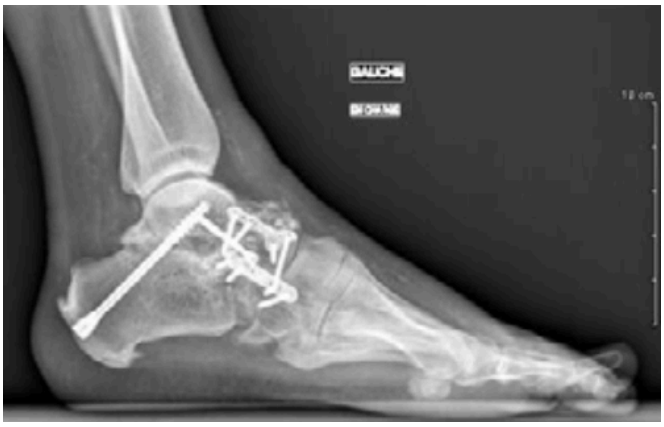




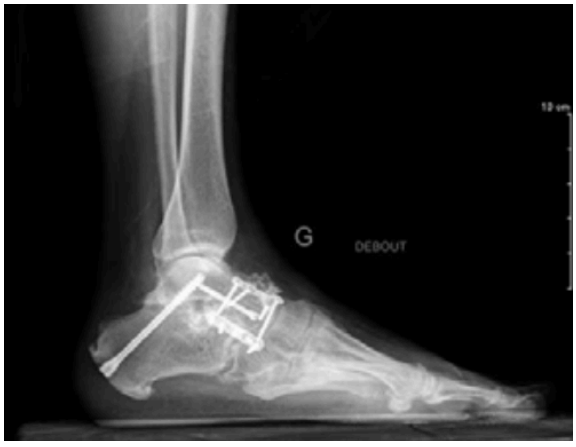
Preoperative X-rays



Immediate post-op.



3 months post-op.



6 months post-op.

Treatment of osteomyelitis of the 5th metatarsal phalanx with bioglass

White paper - 2023

Tor Vergata Hospital (Rome, Italy)

INDICATION - Osteomyelitis

SURGERY - Osteotomy, revascularization and surgical decontamination

METHOD

- Case report - A 83-year-old diabetic woman (type II diabetes for over 20 years).
- Objective: Evaluate the absence of infection after filling with GlassBone Injectable Putty (IP) in the treatment of osteomyelitis of the 5th metatarsal phalanx of the right foot.
- Follow-up: 3 months.

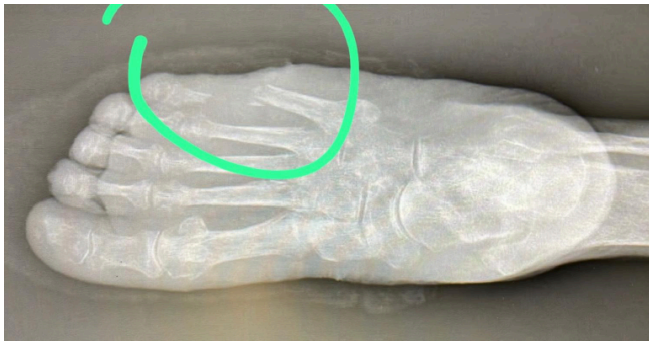
RESULTS

Performance – Osteomyelitis cooled down in 3 weeks and was completely cured by the 10th week following bioglass implantation.

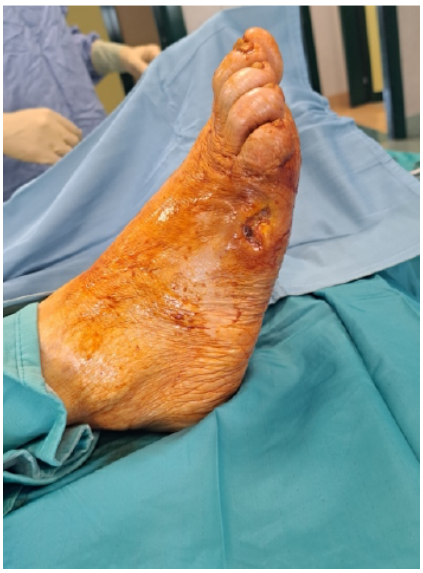
Benefits – No ulcer recurrence and were able to walk regularly.

Safety – No complication reported in this case.

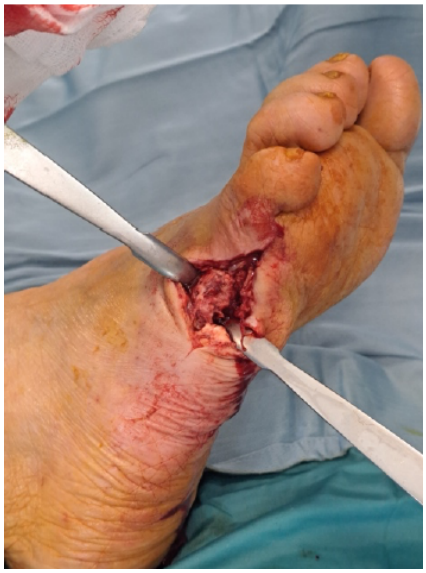
CONCLUSION – The purpose of using bioglass in the diabetic foot is the elimination of osteomyelitis.



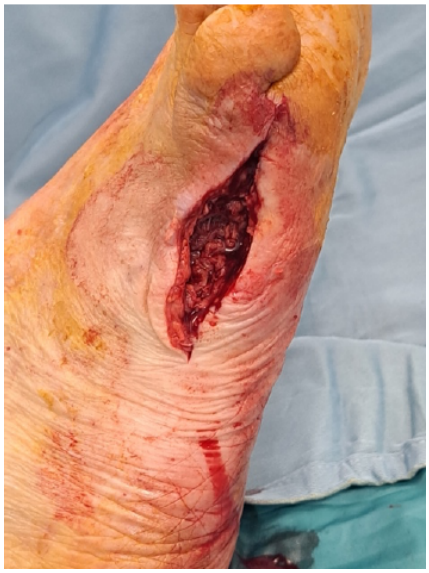
Before surgery



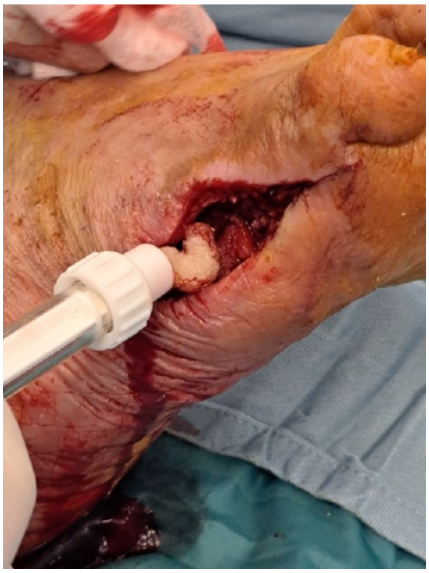
Dehisced wound
before 2nd surgery



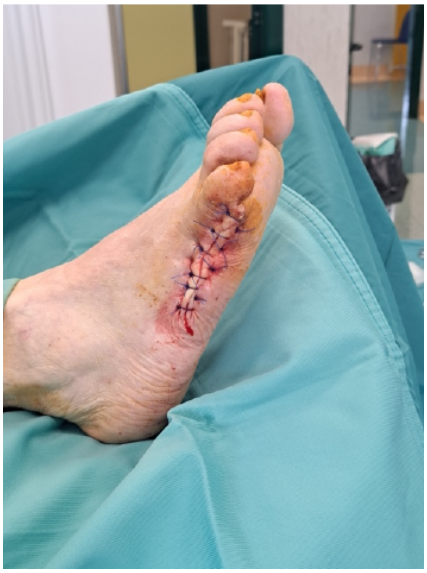
Beginning 2nd surgery



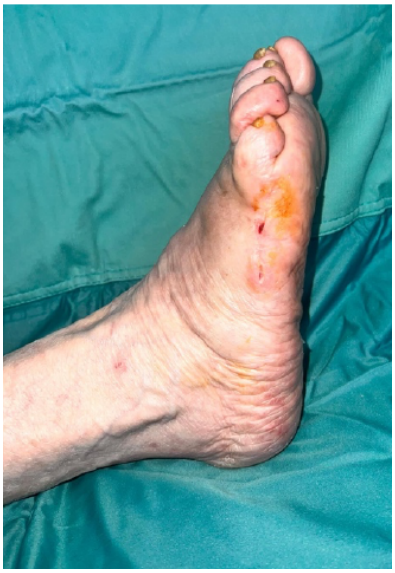
During 2nd surgery



Application of GlassBone IP



Sutured wound



Healed foot

Treatment of osteomyelitis of the big toe with bioglass

White paper - 2023

Tiberia Hospital (Rome, Italy)

INDICATION - Osteomyelitis

SURGERY - Osteotomy, revascularization and surgical decontamination

METHOD

- Case report - A 70-year-old diabetic woman.
- Objective: Evaluate the absence of infection after filling with GlassBone Granules in the treatment of osteomyelitis of the big toe.
- Follow-up: 45 days.

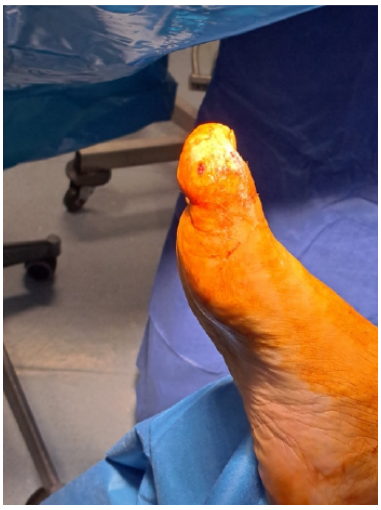
RESULTS

Performance – After 45 days a control x-ray was carried out and there was clinical evidence of healing with closure of the ulcerative frame work and complete regression of the signs of inflammation of the big toe.

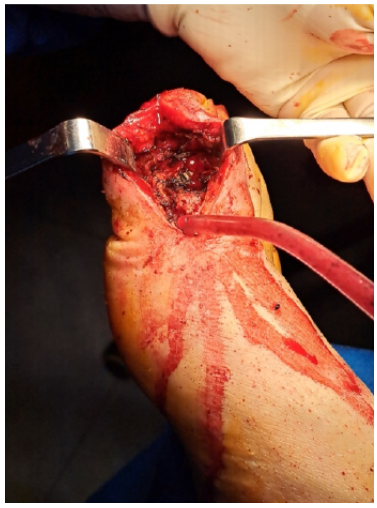
Benefits – Healing progressed well after a few weeks.

Safety – No complication reported in this case.

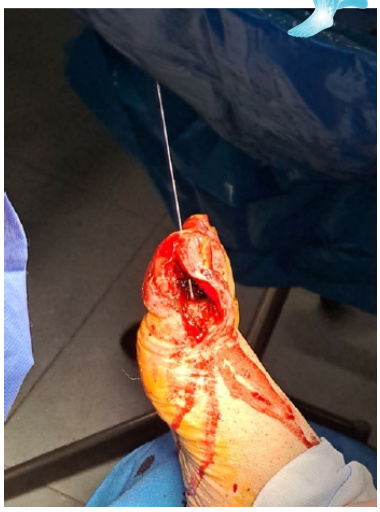
CONCLUSION – The purpose of using bioglass in the diabetic foot is the elimination of osteomyelitis.



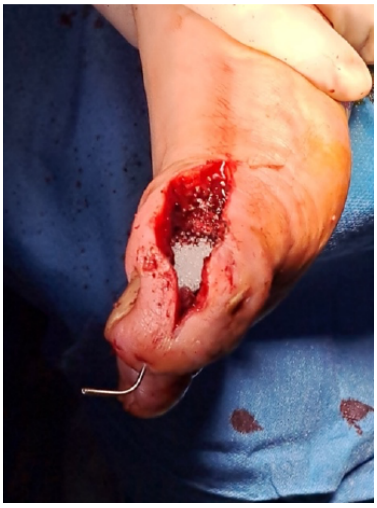
Lesion before surgery



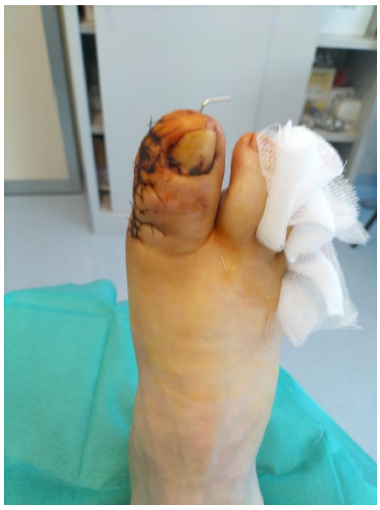
Complete sequestrectomy



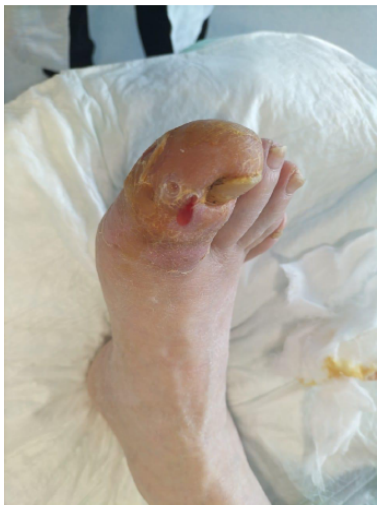
Insertion of Kirscher wire



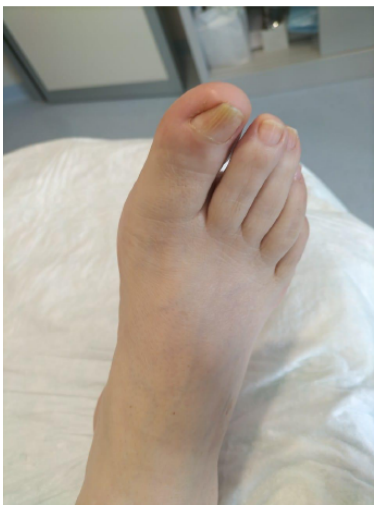
GlassBone Granules



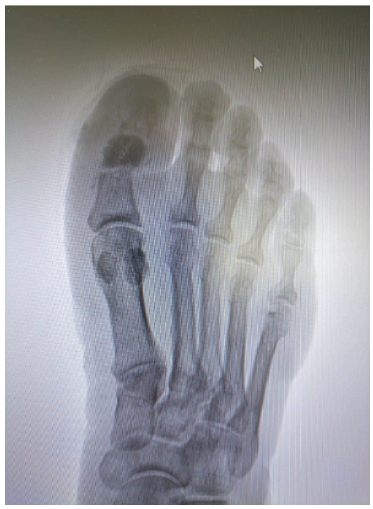
Removal of Kirscher wire

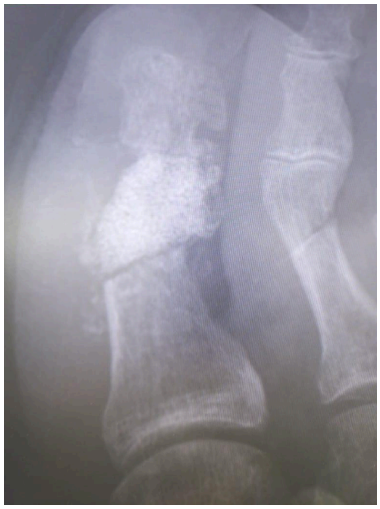


Healing after a few weeks



Fully healed foot at 45 days





45 days after surgery showing the GlassBone Granules

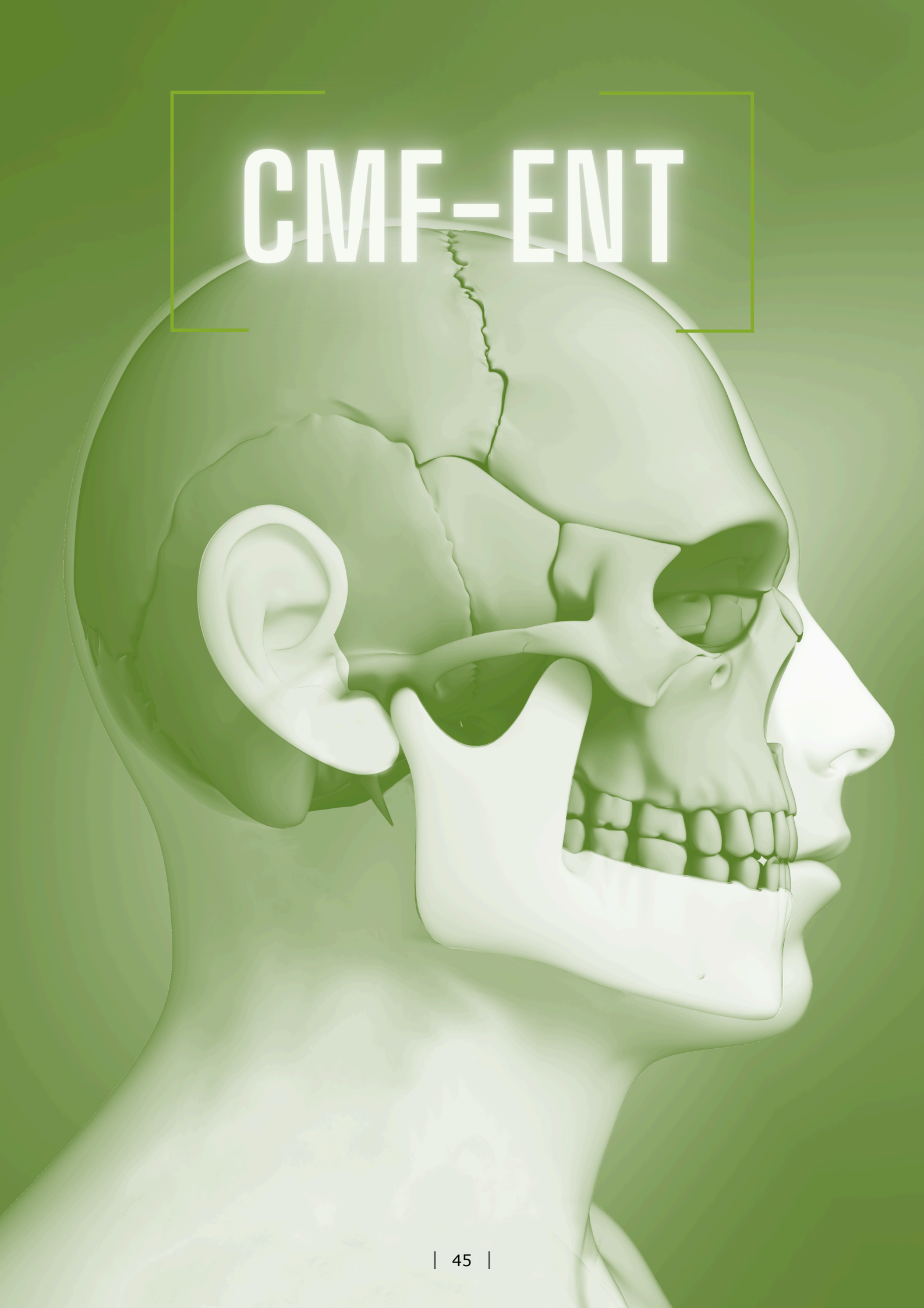
SPINE

ORTHOPEDICS

CRANIO MAXILLO FACIAL - EAR NOSE THROAT

DENTAL

CMF-ENT



Cranio-maxillofacial surgery includes orthognathic surgery (jaw size or positioning anomalies), stomatology (tumors and cysts, implantology, etc.), cranial and facial malformations and facial traumatology in both children and adults, although tumor types, biological behavior and oncological management vary between the two populations (Wasserzug et al., 2018). It aims to treat trauma to the skull and face, often involving soft or hard tissue lesions with distinct developmental origins, cellular properties and healing outcomes.

Craniofacial reconstruction aims to restore facial function, form and aesthetics, taking into account craniofacial growth (Teven et al., 2015). Cranial bone grafts are used to treat a variety of post-traumatic defects such as orbital fractures, post-resection defects due to bone tumors, congenital anomalies and aesthetic reasons. For small mandibular defects and alveolar clefts, different graft materials are used, such as iliac bone splinters, cranial bone splinters or synthetic materials. Large mandibular defects often require vascularized bone flaps containing free flaps for reconstruction. Despite rigid internal fixation, three-dimensional stability can be compromised, especially if the defect between bone segments is large, leading to proliferation of fibrous rather than bony tissue along the osteotomy (Çelik. 2018).

An acute otitis media is an infection of the middle ear. Cholesteatoma is the most serious form chronic otitis media characterized by the production of skin that will invade the middle ear or mastoid (Yew et al., 2012). It is classified as a benign tumor due to its variable clinical expression, frequent superinfection, tendency to recurrence, and high risk of potentially serious complications such as erosion of adjacent structures, hearing loss, and others. Sometimes, antibiotics are enough to clear the infection (Mendlovic et al., 2021; Minovi & Dazert, 2014). But to completely remove the cholesteatoma or when conservative treatments have failed, otologic surgery is the treatment of choice to create a dry and safe cavity without recurrence (Hamed et al., 2016).

The surgical management can be classified into two main techniques canal wall down mastoidectomy (CWDM) and canal wall up mastoidectomy (CWUM) (Alves et al., 2016; Mendlovic et al., 2021).

Mosher, in 1911, started the idea of mastoid obliteration to promote healing of a mastoidectomy defect. He described an obliteration technique using a superiorly based postauricular soft tissue flap, which was failed. These findings encouraged surgeons to associate other filler materials inside the bowl (Mosher, 1911).

Palva (Palva & Mäkinen, 1979) modified and popularized the technique, further adding to it the use of bone chips and bone pate in combination with an anteriorly based musculoperiosteal flap.

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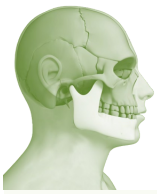

Allograft bone vs. bioactive glass in rehabilitation of canal wall-down surgery

Publication - 2021

Maxime Fieux[1,2,3], Romain Tournegros[1], Ruben Hermann[2,4], & Stéphane Tringali [1,2,3]

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2 Université de Lyon, Université de Lyon 1, 69003 Lyon, France
3 UMR 5305, Laboratoire de Biologie Tissulaire et d'Ingénierie Thérapeutique, Institut de Biologie et Chimie des Protéines, CNRS/Université Claude Bernard Lyon 1, 7 Passage du Vercors, 69367 Lyon Cedex 07, France
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https://doi.org/10.1038/s41598-023-44901-1

INDICATION - Cholesteatoma

SURGERY - Mastoid and epitympanic obliteration in Canal Wall Down Tympanomastoidectomy with Reconstruction (CWDTwR)

METHOD

- Retrospective study (July 2010 - January 2019) – 32 patients.
- Objective: Compare the efficacy of CWDTwR with allograft or GlassBone Injectable Putty (IP) for mastoid filling in rehabilitation of radical cavities.
- Comparative design: 17 patients with GlassBone IP (BG), and 15 patients with cancellous bone dust (AG).
- Primary endpoint assessment: The absence of new surgery at 18 months from all causes (persistent otorrhea or the presence of a residual cholesteatoma on MRI).
- Follow-up: 18 months.

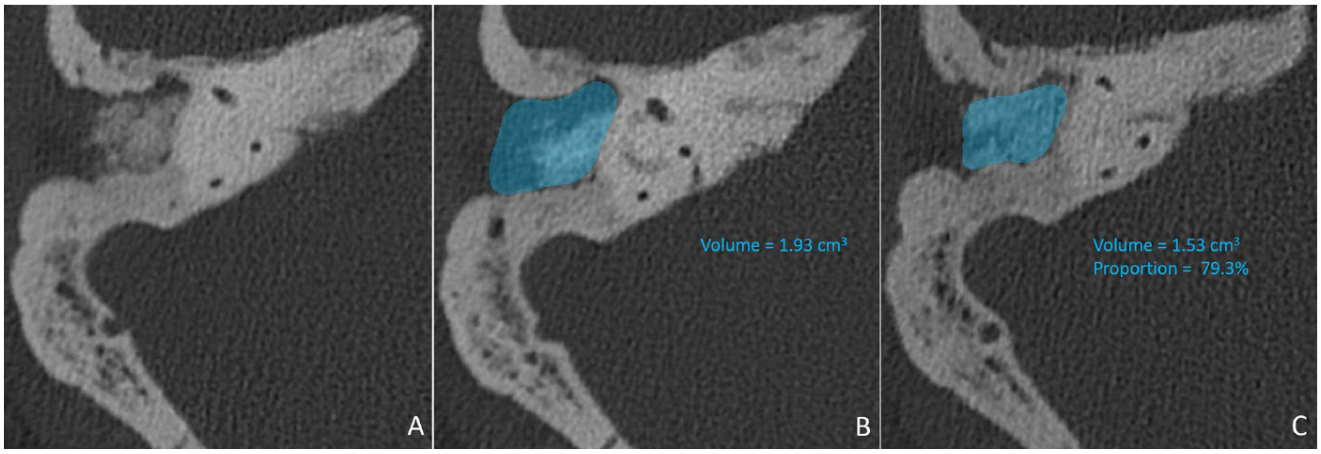
RESULTS

Performance – At 18 months, 53.3% of the patients in the AB group presented with recurrent otorrhea versus 5.9% of patients in the BG group (p=0.005).

Benefits – Both groups showed no difference in the recurrence rate. There was a significant difference in patient's satisfaction at 18 months: 88.2% were satisfied (no otorrhea, no residual cholesteatoma, no revision surgery needed, good aquatic tolerance) in the GlassBone IP group, whereas it was only 33.3% in the allograft group.

Safety – At 18 months, 78% of symptomatic patients had undergone revision surgery : 40% in the AB group and 5.9% in the BG group (p=0.033).

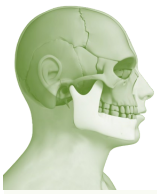
CONCLUSION – Canal wall-down mastoidectomy rehabilitation with BG mastoid obliteration can significantly improve the quality of life of patients who undergo multiple operations without increasing risk of recurrent or residual cholesteatoma, provided that the surgical technique is perfectly mastered. Performance and safety are demonstrated.



(A) Postoperative right ear high-resolution computed tomography (HRCT) scan of the temporal bone at 18 months postoperation to show how volumetric measurements were performed. HRCT images were reconstructed for each ear in the plane of the lateral semicircular canal.

(B) Mastoid volume assessment at baseline (18 months postoperation, blue). IntelliSpace Portal software (Medisys, Philips Research, Suresnes, France) was used for the 3D semiautomated quantitative assessment of volume. It was segmented in 3D by using an interactive mouse “click and drag” function within the lesion on HRCT axial slices, after which a 3D segmentation mask was generated and edited in the same way for all slices. With the 3D segmentation mask and the image matrix dimensions and slice thickness, the software calculated the volume (in cm3).

(C) Mastoid obliteration volume assessment at 18 months postoperation (blue). The same software (Intellispace portal) was used for 3D semiautomated quantitative assessment of mastoid obliteration volume.



Transcanal Endoscopic Ear Surgery for Epitympanic Cholesteatoma With Obliteration Using Bioglass

Publication - 2021

Stephane Ayache, MD[1]

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https://onlinelibrary.wiley.com/doi/10.1002/lary.29710

INDICATION - Cholesteatoma

SURGERY - Epitympanic obliteration during TEES

METHOD

- Case report – 1 adult patient.
- Objective: Present the results of one patient operated with TEES, using GlassBone Injectable Putty (IP) for the epitympanic obliteration.
- Primary endpoint assessment: MRI at 12 months.
- Follow-up: 12 months.

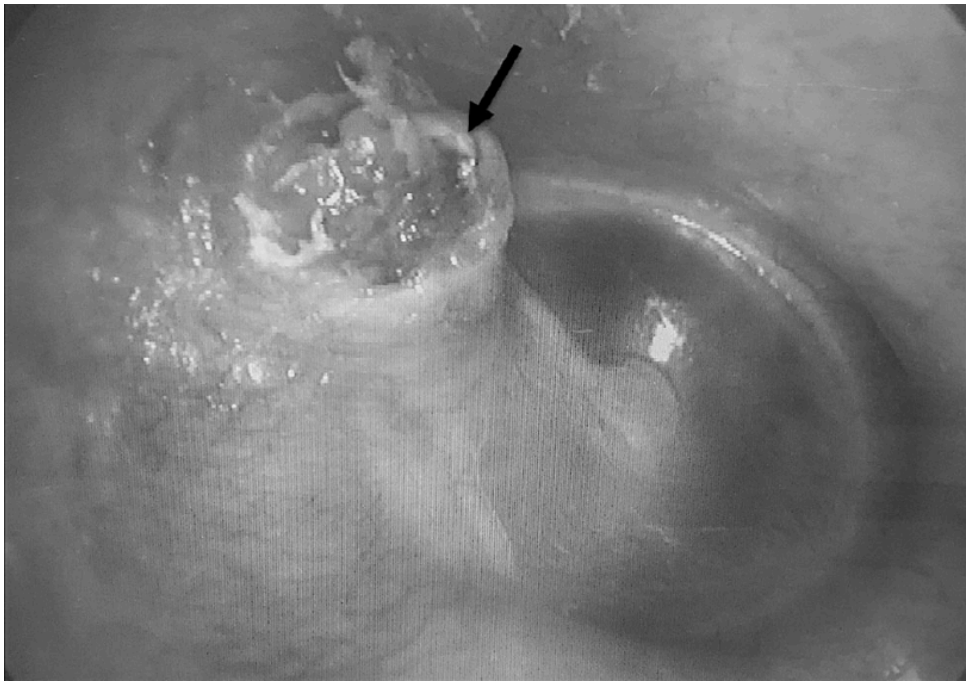
RESULTS

Performance – A total epitympanic obliteration has been done with GlassBone IP: 100% filled. The healing of EAC was complete at 12 months, without stenosis and without leakage of GlassBone IP.

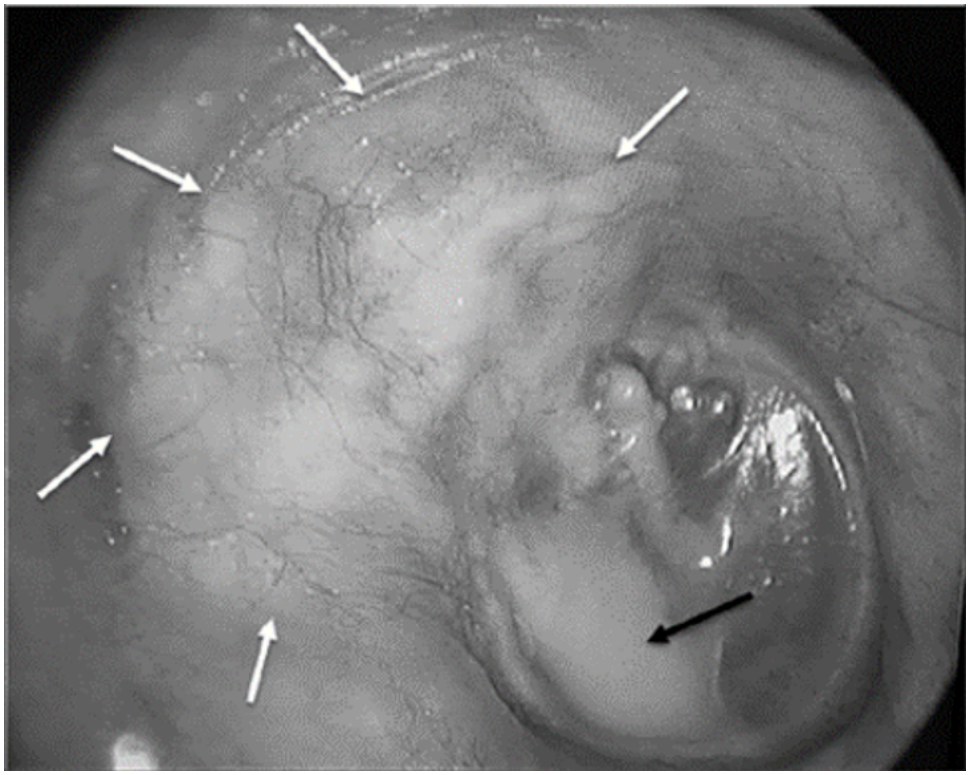
Benefits – On the 1-year post-operative MRI, there was no sign of recurrence or residual cholesteatoma.

Safety – There were no pre- or post-operative complications.

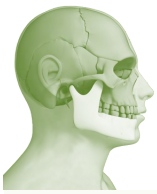
CONCLUSION – GlassBone IP was used successfully in this case report of an epitympanic obliteration during TEES, with no recidivism at 1 year. GlassBone IP seems to be a good option for cholesteatoma treatment.



Preoperative otoscopic examination (black arrow: pars flaccida cholesteatoma)



Postoperative otoscopic examination after 1 year (white arrows: margins of the epitympanic obliteration, black arrow: ossiculoplasty using cartilage)



Mastoid obliteration with bone substitute in the management of cholesteatoma in children

Thesis - 2021

Nakhleh, L., et al.

Hôpital Robert Debré - Paris (France)

INDICATION - Cholesteatoma

SURGERY - Mastoid and epitympanic obliteration

METHOD

- Retrospective study – 55 pediatric patients.
- Objective: Assess the tolerance and early performance (and functional results) of GlassBone Injectable Putty (IP) in mastoid and epitympanic obliteration when managing paediatric cholesteatoma.
- Three groups: Open technique rehabilitation (n=17), a canal-wall-down "on demand" mastoidectomy (n=17) or a canal-wall-up mastoidectomy technique (n=21).
- Follow-up: 27 months.

RESULTS

Performance – The overall technique's success rate was 87% (48/55). Bioactive glass is associated with the lowest failure rate (10% with S53P4 and 5.3% with 45S5) vs 25% with others bones substitutes. The probability at 18 months of being free from recurrent cholesteatoma was 94.25% and the probability at 12 months of being free from residual cholesteatoma was 72%. All patients had at least 12 months postoperative otoscopic follow-up and only 3 (5.45%) presented a recurrent cholesteatoma.

Benefits – No harvest graft site.

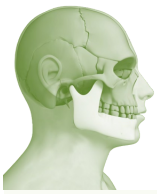
Safety – No adverse event reported.

CONCLUSION – The use of Glassbone Injectable Putty in these 3 types of mastoidectomies improve the hearing of patients. Technics with the use of bone substitute reduce the recurrence and residual rate of cholesteatoma. The perforance and safety were confirmed.

Postoperative otoscopic examination after 1 year (white arrows: margins of the epitympanic obliteration, black arrow: ossiculoplasty using cartilage).

Depending on the bone substitute			
BS 1	0% (0/5)		100%
BS 2	29% (2/7)		71%
BS 3	44% (4/9)		53%
BS 4	33% (5/15)		52%
p-value	*0,41*		*0,38*

Results of univariate analysis exploring factors influencing the occurrence of recurrent or residual cholesteatoma of the obliteration technique in children (Fisher's Test)
BS1 : Allograft and xenograft - BS2 : Two-phase ceramics
BS3 : BAG 45S5 - BS4 : BAG S53P4



Tolerance and safety of 45S5 bioactive glass used in obliteration procedures during middle ear surgery: Preliminary results

Publication - 2020
Nasser Al Tamami [a], Naif Bawazeer [b], Maxime Fieux [a], Sandra Zaouche [a], Stéphane Tringali [a]

a Department of Otolaryngology, and Otoneurosurgery, Centre Hospitalier Lyon Sud, Hospices Civils de Lyon, 165 Chemin du Grand Revoyet, 69310 Lyon, Pierre-Bénite, France
b Department of Otolaryngology-Head & Neck Surgery, Umm Al-Qura University, Makkah, Saudi Arabia

https://www.sciencedirect.com/science/article/pii/S0196070920302337

INDICATION - Cholesteatoma

SURGERY - Mastoid and epitympanic obliteration

METHOD

- Retrospective study – 42 patients.
- Objective: Evaluate the tolerance and safety of 45S5 bioactive glass as a filing bone-synthetic material by clinical, audiological, and radiological examinations.
- Follow-up: 12 months.

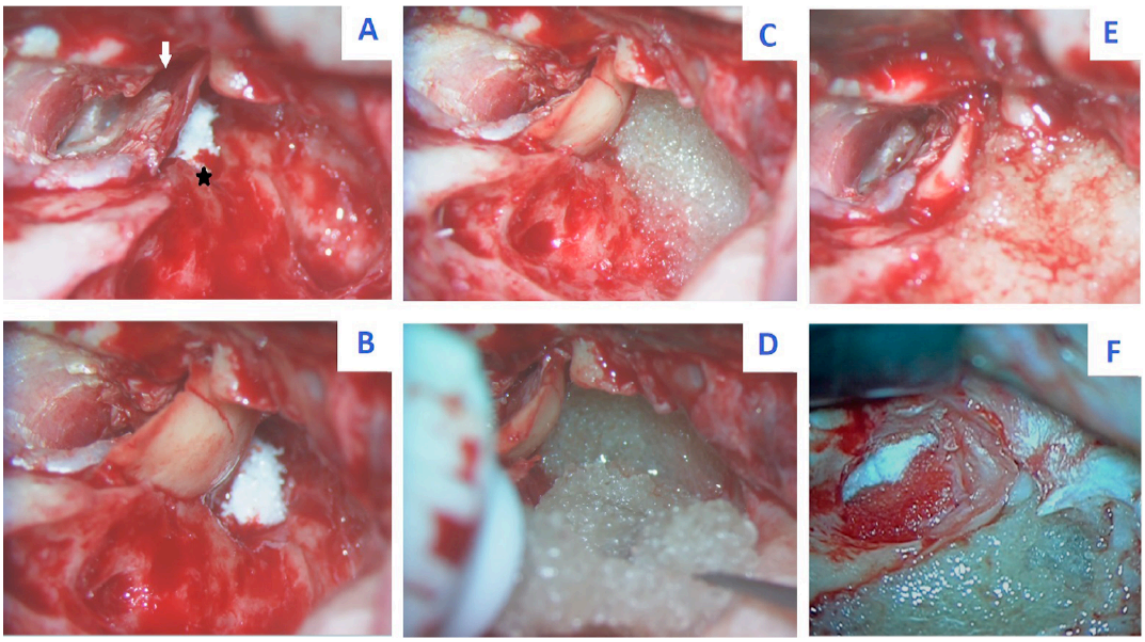
RESULTS

Performance – All CT scans (35 patients) showed satisfactory filled mastoid and epitympanic cavity, without migration of bioactive glass material in the middle ear. All MRIs (42 patients) revealed no sign of enclosing cholesteatoma within the obliterated cavities or residual disease.

Benefits – No bone harvesting.

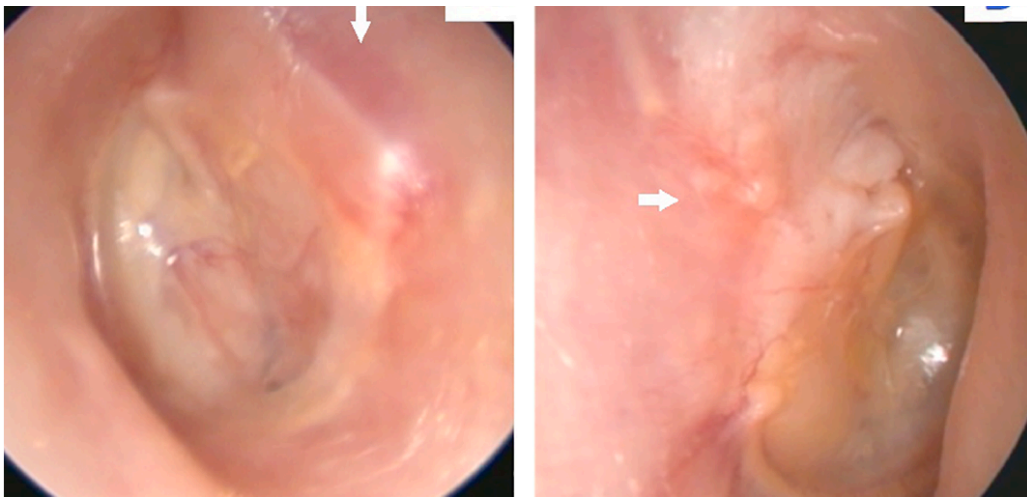
Safety – At 1 year, 2 patients had recurrent otorrhea (meningocele reparation with GlassBone) and MRI revealed 2 patients with inflammation around the obliterated material (4.76%). There is 0% of major complication (facial nerf palsy, skull base osteitis or fistulae with CSF leak.

CONCLUSION – Mastoid and epitympanic obliterations with 45S5 bioactive glass seem to be a tolerable and safe option in cholesteatoma surgery with favorable outcomes similar to other member of bioactive glass especially the S53P4.



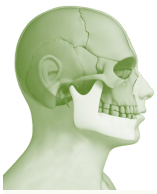
Intraoperative surgical steps for middle ear reconstruction, mastoid and epitympanic cavity obliterations using 45S5 Bioactive Glass after aggressive primary cholesteatoma surgery with complete posterior was erosion in a left ear.
A: Attic reconstruction with a cartilage (white arrow) and Gelfoam (black star) was used to support the tympanic membrane graft and to separate the attic from the tympanic cavity to prevent any particles of Bioactive Glass migration after obliteration.
B: A large cartilage graft with a perichondrium were positioned to reconstruct the posterior canal wall.
C: Epitympanic cavity obliteration using 45S5 Bioactive Glass, it is essential to carefully obliterate the supratubal recess.
D: Mastoid cavity obliteration, regular compression of the material with a sterile gauze is important to avoid dead space.
E: Final aspect of the reconstructed ear canal and the obliterated mastoid cavity.
F: After clearing the surgical site and a pope ear wick was inserted before suturing.

LEFT EAR



RIGHT EAR

Otoscopic examinations after 1-year postoperative showing the result of obliteration using 45S5 Bioactive Glass. Note the reconstructed attic with a cartilage (white arrow)



Bioglass 45S5, a relevant alternative to autogenous harvesting for secondary alveolar bone grafts in clefts?

Publication - 2024

Emmanuelle F. Verdier [1], Apolline L. Salloux [2], Olivier M. Azzis [1], Ronan M. Lebullenger [3], Tiphaine A. Davit-Béal [2], Damien Y. Brézulier [2,3]

1 CHU Rennes, Université de Rennes, Service de Chirurgie Pédiatrique, France
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https://doi.org/10.1016/j.jcms.2023.12.005

INDICATION - Cleft lip and palate

SURGERY - Gingivoperiosteoplasty by Secondary Alveolar Bone Grafting (SABG)

METHOD

- Retrospective study – 102 grafts (79 paediatric patients)
- Objective: Evaluate the success rate of SABG with the addition of GlassBone Granules.
- Primary endpoint assessment: maxillary CBCT at 1 year.
- Follow-up: 12 months.

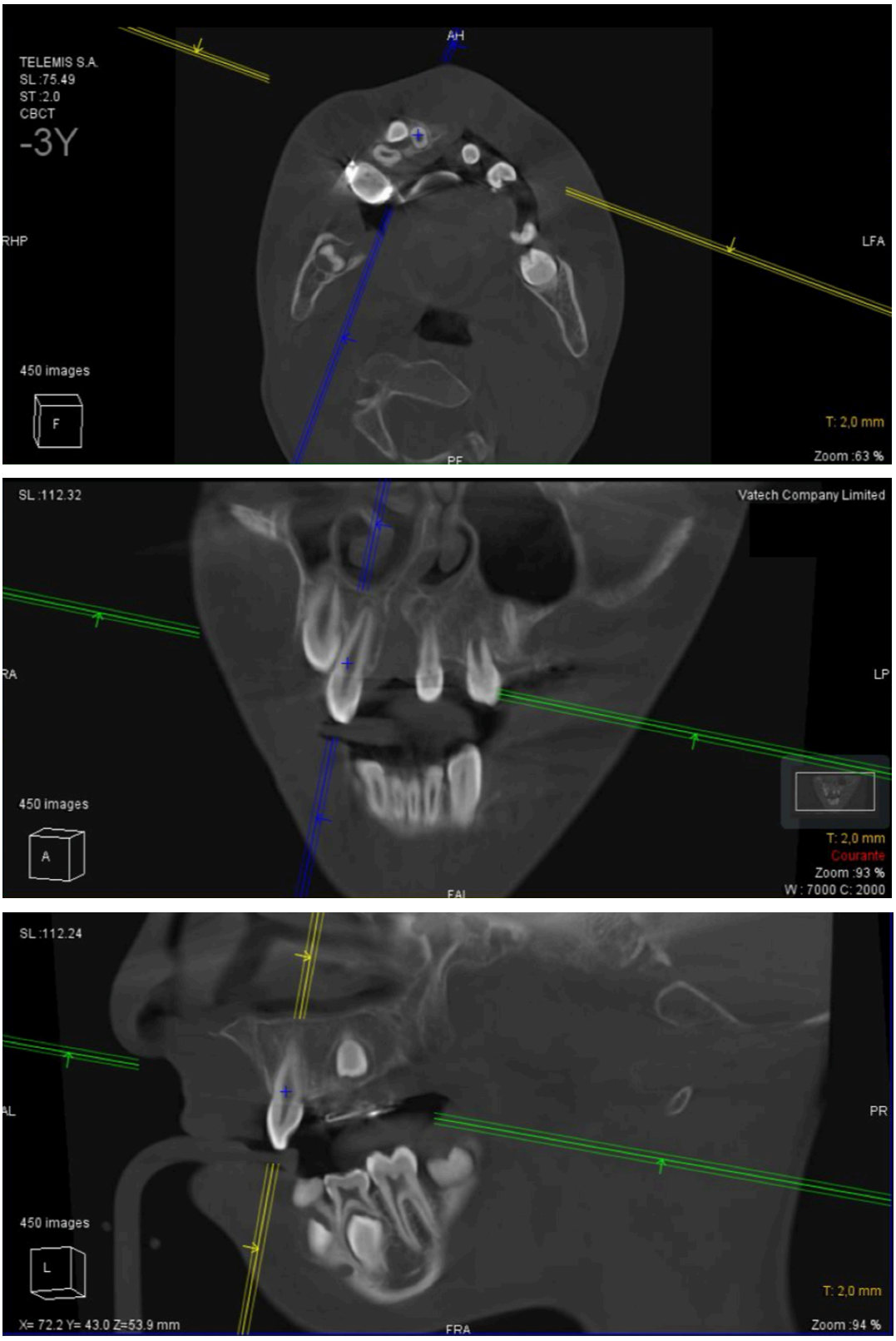
RESULTS

Performance – The radiographic success rate was about 80.4% (82/102) at 1 year. A success was characterized by the detection of bone (completely filling the area or not) in a number greater than or equal to 3 out of 6 sites that were evaluated.

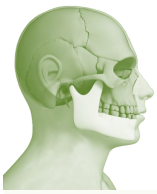
Benefits – GlassBone Granules is associated with an absence of donor site harvesting, and so an absence of associated morbidity. On top of that, this substitute is available in an unlimited quantity compared to autologous bone graft. It also allows teeth eruption and movements through the graft without any particular complication.

Safety – Complications: 3 post-operative infections (2.9%).

CONCLUSION – GlassBone Granules presents good performance and safety outcomes, while allowing teeth movements, so it can be an alternative to autologous bone graft.



Positioning of 2-mm-thick CBCT slices in vertical and horizontal dimensions



Cone Beam-CT-Based bone volume assessments of alveolar synthetic bone graft GlassBone in cleft lip and palate patients

Publication - 2023

Philip-Alliez C.[1,2], Fievet L.[3], Serratrice N.[4], Seiler M.[1], Le Gall M.[1], Charavet C.[5,6,7], Catherine J. H.[8]

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2 UMR-T24 Ifsttar Aix-Marseille Universite/Université Gustave Eiffel, Marseille, France
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4 Department of Neurosurgery, La Timone Hospital (Assistance Publique - Hopitaux de Marseille), Marseille, France
5 Departement d'Orthodontie, Faculte de Chirurgie Dentaire, Universite Cote d'Azur, Nice, France
6 Unite d'Orthodontie, Institut de Medecine Bucco-Dentaire, CHU de Nice, Nice, France
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https://doi.org/10.1007/s12663-023-02056-6

INDICATION - Clefts of the lip and palate (CLP)

SURGERY - Gingivoperiosteoplasty by Secondary Alveolar Bone Grafting (SABG)

METHOD

- Retrospective study – 19 grafts (17 paediatric patients).
- Objective: Evaluate the success rate of SABG with the addition of GlassBone Granules.
- Primary endpoint assessment: to evaluate the reduction of the cleft volume via CBCT and panoramic radiographs at 1 year.
- Follow-up: 12 months.

RESULTS

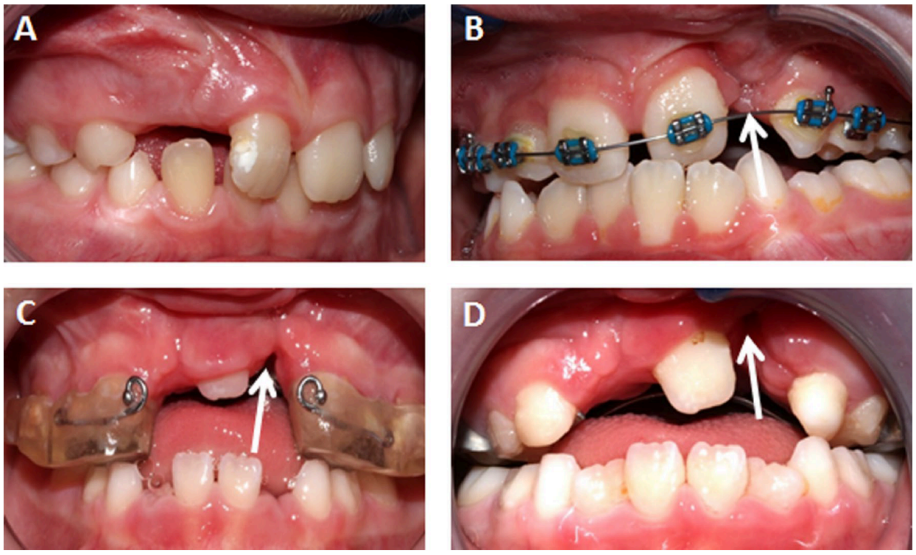
Performance – The surgical success rate was about 68% (13/19), defined as A and C scores according to the Chelsea's classification. The mean filling of the cleft was about 57.6 ± 27.7% at 1 year, corresponding to a mean remaining cleft about 42.4 ± 27.7% of its initial volume, which is a significant relative reduction.

Benefits – GlassBone Granules is associated with an absence of donor site harvesting, and an absence of associated morbidity. On top of that, this substitute is available in an unlimited quantity compared to autologous bone graft. Its use simplifies the surgical process and is associated with a reduction in surgical time, pain, and duration of school exclusion.

Safety – Complications: 7 patients with unsatisfactory gingival scar (37%), 5 absences of germs' evolution through the graft (27%), 2 recurrences of oro-nasal fistula (10.5%). No complications with GlassBone Granules were noted.

CONCLUSION – GlassBone Granules presents good performance and safety outcomes providing satisfactory clinical and radiological results; it represents a convincing alternative to autologous bone graft. Its use might be particularly accurate in cases of small clefts, bilateral clefts, and dental agenesis with poor prognosis for grafting.

Endobuccal pictures



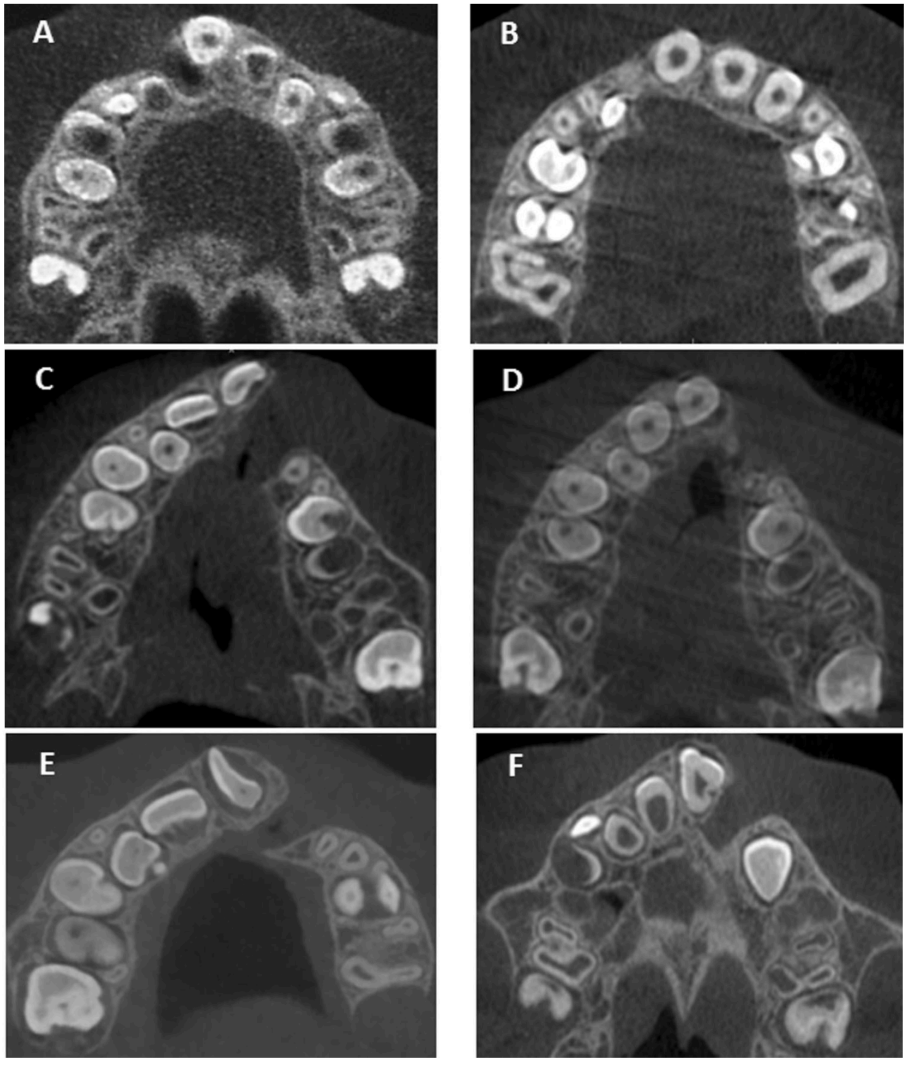
(A) Satisfactory gingival scar after bone graft

(B) Unsatisfactory scar (arrows)

(C) Satisfactory scar on the right side, unsatisfactory scar on the left side (arrow) with a significant gingival retraction

(D) A recurrence of the oro-nasal fistula in a patient with a bilateral CLP

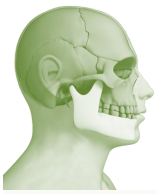
Cone beam-CT, axial thin sections, bony window



Patient #1:
(A) Preoperative
(B) Postoperative satisfactory result

Patient #7:
(C) Preoperative
(D) Postoperative insufficient result

Patient #11:
(E) Preoperative
(F) Postoperative failure



The use of GlassBone vs autogenous bone graft for alveolar reconstruction in cleft surgery

Thesis - 2022

Tewfik K., Giampaoli G., Peta C., Burlini D.

Pediatric Maxillofacial Unit - Children's Hospital of Brescia (Italy) 14th International Cleft Congress (CLEFT 2022)

https://www.sciencedirect.com/science/article/abs/pii/S101051821830581X

INDICATION - Alveolar cleft defect

SURGERY - Reconstruction of an alveolar cleft defect with GlassBone Granules

METHOD

- Cohort study - 6 children.
- Objective: Compare the use of autogenous iliac bone graft (Group A) with the use of GlassBone 45S5 Bioactive Glass Synthetic Bone Substitute (Group B).
- Follow-up: 6 months.

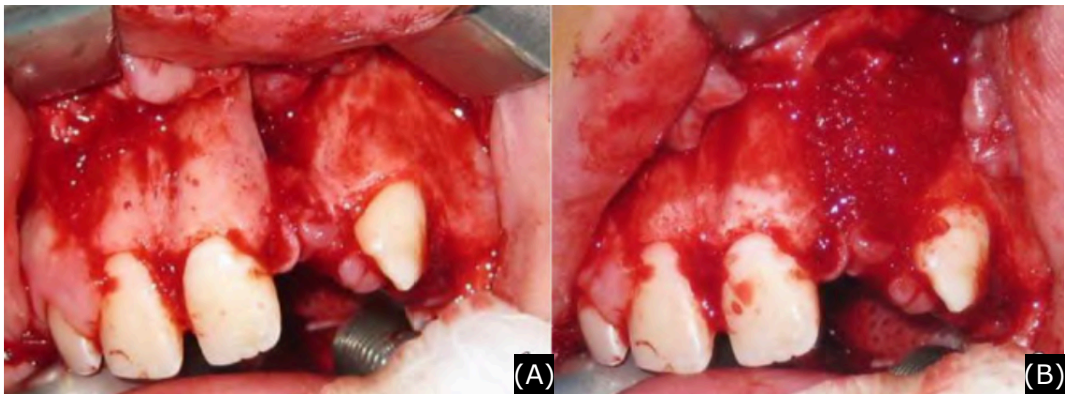
RESULTS

Performance – Adequate ossification of the maxillary alveolar ridge for both techniques.

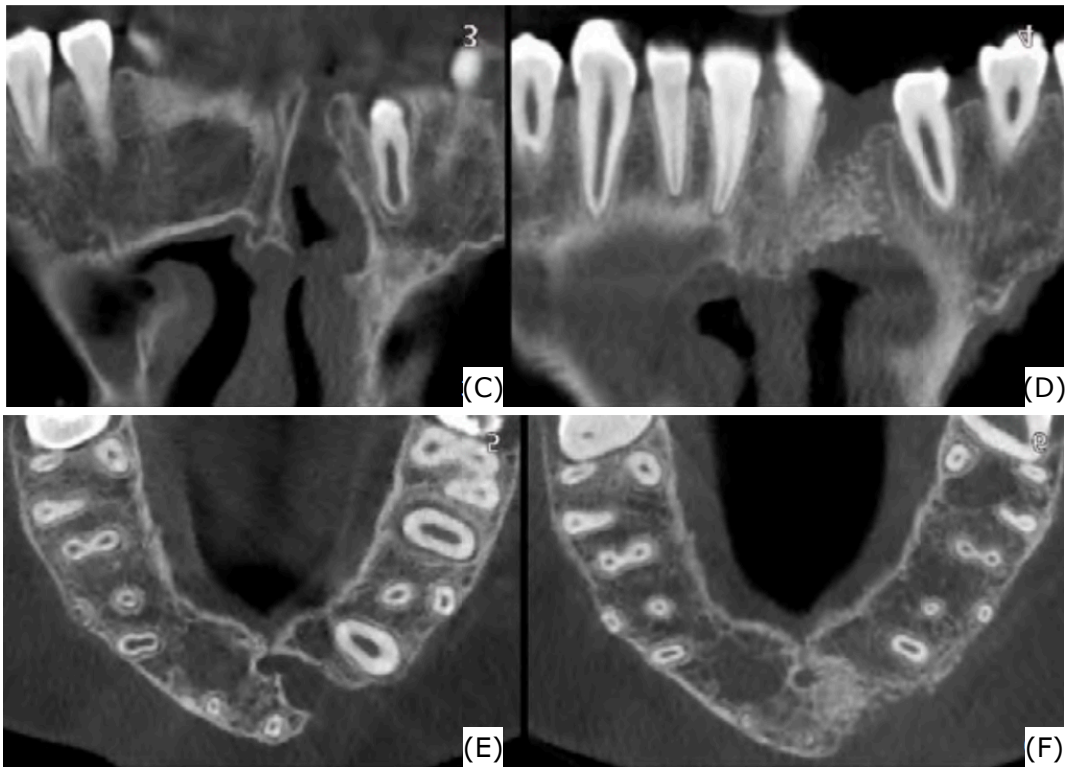
Benefits – No harvest bone graft site.

Safety – A higher level of pain (Median of Visual Analogue Scale VAS = 4,6) was reported by the Group A patients compared to the Group B (VAS = 1,6) during the first postoperative day.

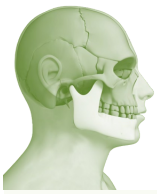
CONCLUSION – In the cohort, the use of GlassBone has provided similar results as traditional iliac bone graft, showing an uneventful postoperative course, less postoperative pain, and consistent bone regeneration 6 months after surgery. The safety and performance of GlassBone Granules are demonstrated.



Intraoperative aspect of a left alveolar cleft defect in a 11 years old child (Figure A) grafted with GlassBone (Figure B)



Cone Beam CT scan of the upper alveolar ridge before (Figure C and D) and at 6-month follow-up after grafting with GlassBone (Figure E and F)



Bioactive glass 45S5 ceramic for alveolar cleft reconstruction

Publication - 2018

Nicolas Graillon[a], Nathalie Degardin[b], Jean Marc Foletti[c,d], Magali Seiler[e], Marine Alessandrini[f], Audrey Gallucci[a]

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b Department of Pediatric Plastic Surgery, Public Assistance Hospital of Marseille, University Hospital Center Timone, France
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d Department of Maxillofacial Surgery, Public Assistance Hospital of Marseille, University Hospital Center Nord, Marseille, France
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https://www.sciencedirect.com/science/article/abs/pii/S101051821830581X

INDICATION - Cleft lip and palate

SURGERY - Alveolar cleft reconstruction with GlassBone Granules

METHOD

- Prospective study (2011-2015) - 58 children (3-15 years old).
- Objective: Evaluate the 45S5 bioactive glass versus iliac crest bone harvesting.
- Follow-up: 12 months.

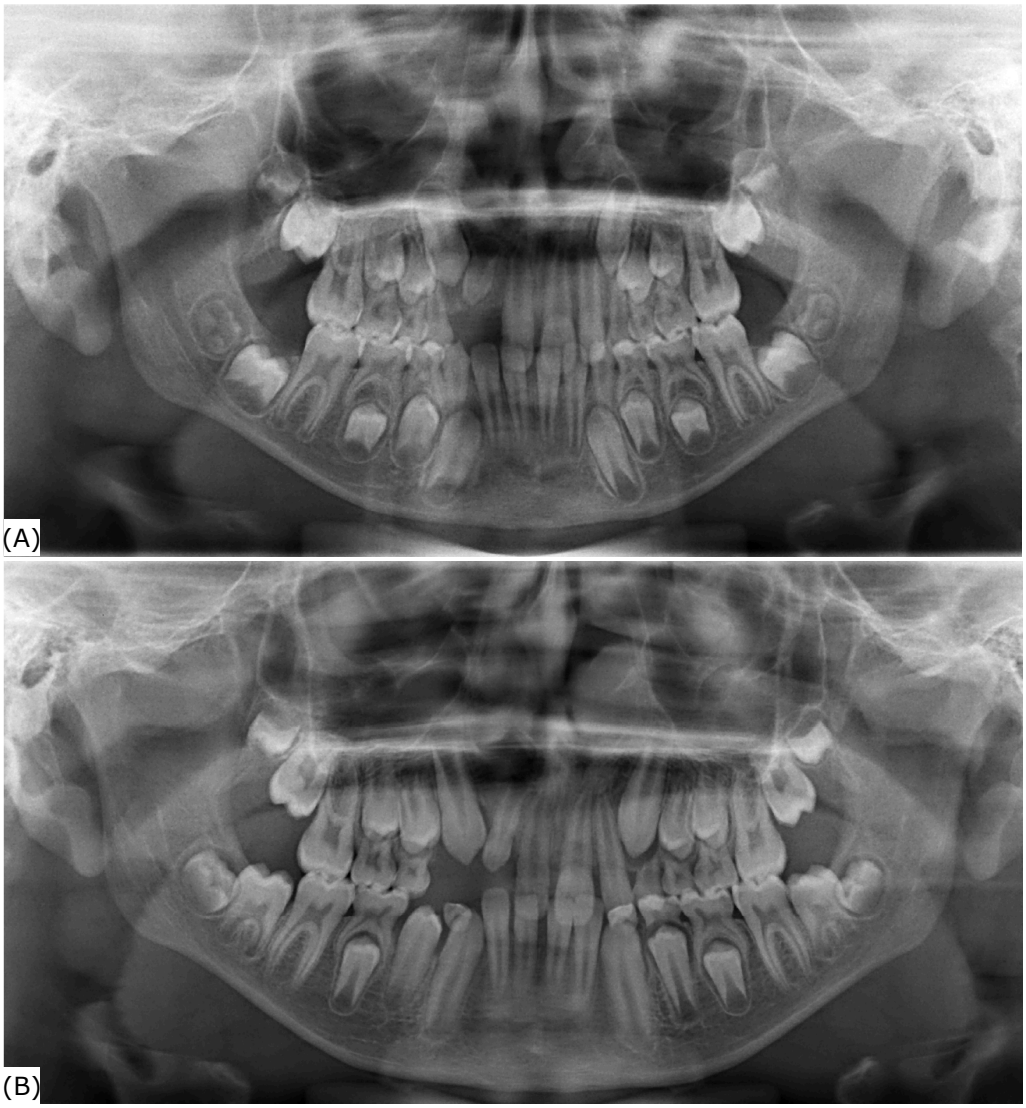
RESULTS

Performance – Bone continuity was achieved in 37/55 cases (63.8%). In the subgroup of 25 patients with isolated unilateral cleft without dental agenesis, 80% had bone continuity after 12 months.

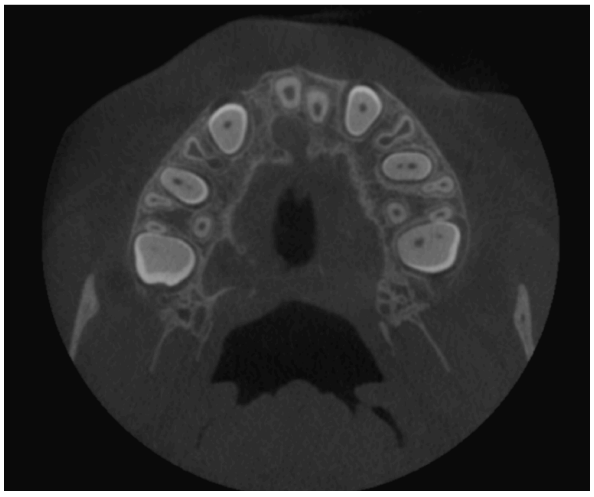
Benefits – No harvest bone graft site.

Safety – Among the 58 patients, 2 (3,4%) have delayed wound healing (one local site intervention, other with an exteriorization of graft and complete loss), 6 (10,3%) had recurrent alveolar fistula and 1 (1,7%) had a reopening of the cleft after maxillary expansion.

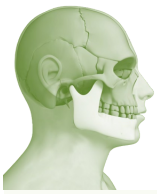
CONCLUSION – The use of GlassBone in alveolar grafts simplifies the surgery procedure and the postoperative management, and ensures satisfactory mucosal healing, tooth eruption and bone continuity in two thirds of the followed grafts. The safety and performance of GlassBone Granules are demonstrated.



Dental panoramic view – preoperative (A) and at 1 year (B) – showing the evolution of the lateral incisor and the canine through the right alveolar bone graft with GlassBone



Maxillary CBCT 1 year after the right alveolar bone grafting using GlassBon showing an alveolar bone continuity



Interest of Glassbone® in cleft lip and palate surgery

Poster - 2016

A. Frapsauce[1], C. Luans[1], O.Azziz[2], V.Gicquel[1]

1 Service Pharmacie, Centre Hospitalier Universitaire de Rennes
2 Service Chirurgie Pédiatrique, Centre Hospitalier Universitaire de Rennes

https://doi.org/10.1016/j.phclin.2016.10.023

INDICATION - Cleft lip and palate

SURGERY - Reconstructive surgery. Comparison with the reference technique using autologous bone graft harvesting

METHOD

- Retrospective study - 26 children since July 2015.
- Objective: Evaluate the medico-economic value of GlassBone Granules.
- Follow-up: 18 months.

RESULTS

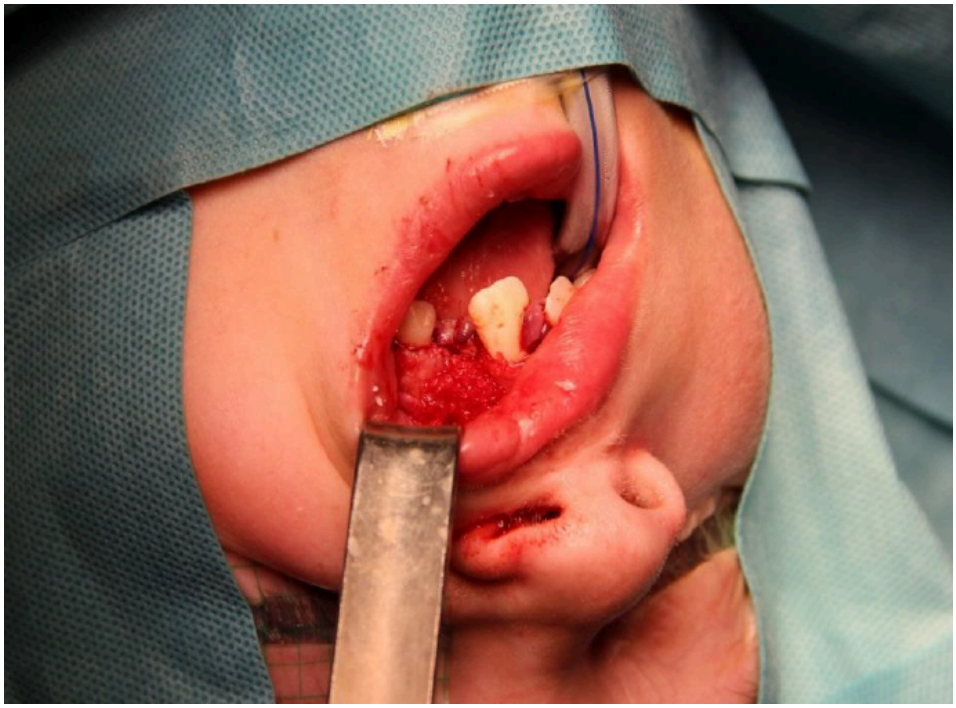
Performance – Reduction of surgery time compared to autologous bone grafting. Easy handling and positioning of the material.

Benefits – No iliac bone graft site.

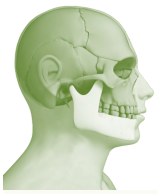
Safety – No complications were noted.

CONCLUSION – GlassBone has benefits, not only by shortening surgery, but also by reducing postoperative complications and pain, as analgesia is a complex subject to treat in pediatrics. This bioceramic allows the early discharge of the child and therefore reduces hospitalization costs. A collection of long-term data would be necessary to confirm the clinical efficacy of this bone substitute.

Mixing GlassBone Granules with the patient's blood



Intraoperative placement of GlassBone bone substitute



GlassBone® for secondary alveolar bone grafting in clefts, an alternative to autologous iliac crest graft

Thesis - 2015

M. Seiller [a]

a AP-HM La Timone – Pediatric Plastic Surgery department

INDICATION - Cleft lip and palate

SURGERY - Gingivoperiosteoplasty by Secondary Alveolar Bone Grafting (SABG)

METHOD

- Retrospective study - 40 children.
- Objective: Evaluate the performance and safety of GlassBone Granules in the treatment of cleft lip and palate in children compared to the gold standard (iliac bone graft).
- Follow-up: 36 months.

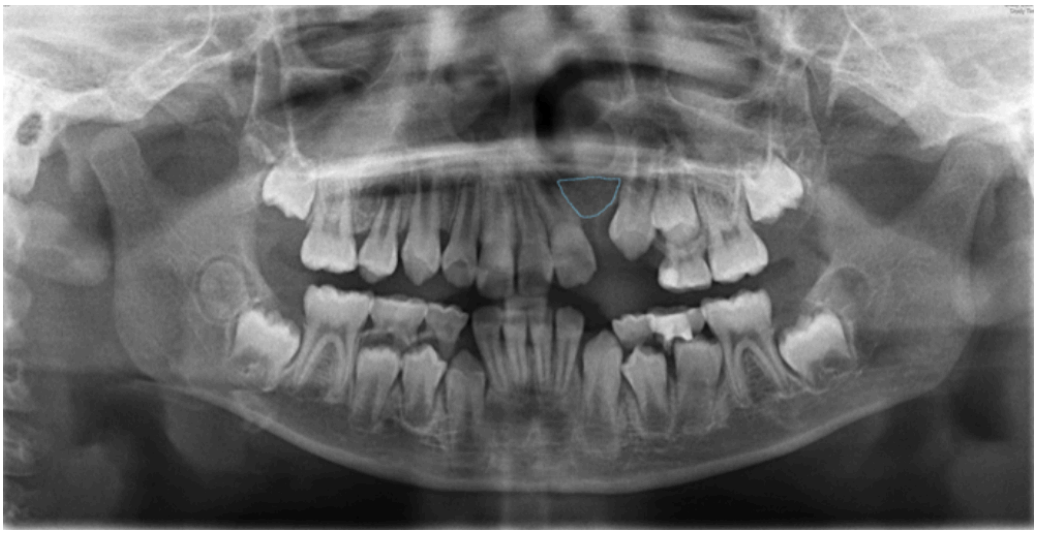
RESULTS

Performance – The SABG with GlassBone Granules was evaluated as a success on the radiological assessment at 1 year, as it was classified as a grade I according to Bergland's classification. The continuity of the alveolar arch was observed, with a net filling of the cleft. The grafted bone allowed the dental germs movements, in favor of an eruption.

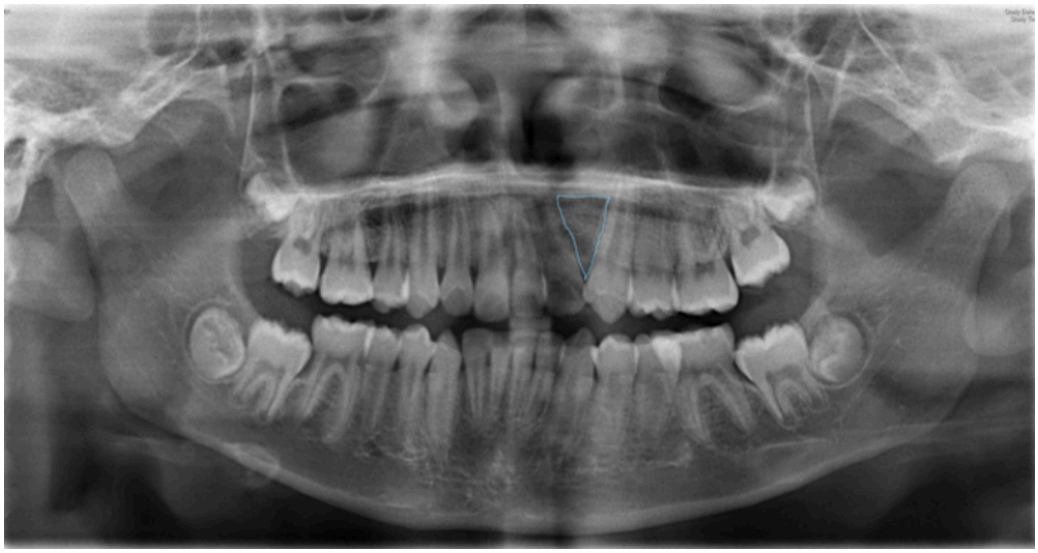
Benefits – GlassBone Granules is associated with an absence of donor site harvesting, and so an absence of associated morbidity. On top of that, its use simplifies the surgical process and is associated with a reduction in surgical time, pain, and duration of hospitalization, sport and school exclusion.

Safety – No complications or adverse events have been reported.

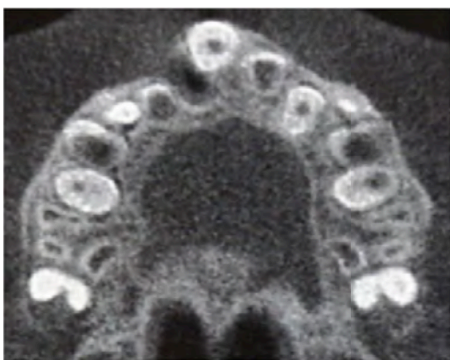
CONCLUSION – Since 2011, the Pediatric Plastic Surgery Department of La Timone Hospital in Marseille has replaced the iliac bone graft used during secondary alveolar bone grafting with a 100% synthetic bone substitute belonging to the family of bioactive ceramics (Glassbone®) with favorable results. The safety and performance of GlassBone Granules are demonstrated.



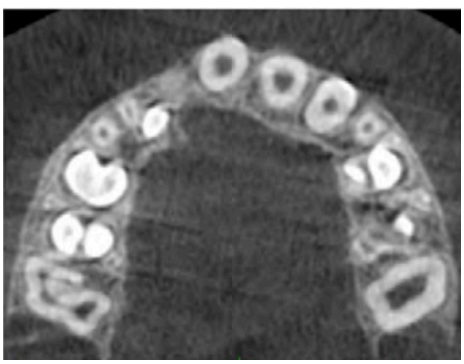
Orthopantomogram before GOA with GlassBone Granules reveals Bergland or Chelsea grade II



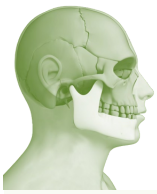
Post-operative orthopantomogram at 1 year reveals Bergland grade I or A according to Chelsea score



Preoperative axial slice at the apical third



Postoperative axial view at the apical third (1 year)



Assessment of the sticky bone preparation of bioactive bone glass in grafting critical-sized surgical bony defects

Publication - 2021

Hesham Elsayed El-Hawary* and Mohamed Shawky**

* Associate Professor, Oral and Maxillofacial Surgery Department, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt.
** Instructor, Oral and Maxillofacial Surgery Department, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt.

https://www.researchgate.net/publication/353009192

INDICATION - Cystic lesions

SURGERY - Filling critically sized surgical bony defects after enucleation of cystic bony lesions

METHOD

- Randomized clinical controlled trial - 24 patients (22-45 years-old).
- Cystic lesions exceeding 2 x 2 cm were enucleated, and the defect was obliterated with bioactive bone glass particles in group 1 and bioactive glass sticky bone in group 2.
- Objective: Assess the osteoinductive potential of bioactive bone glass in the form of sticky bone in critical-sized surgical bony defects.
- Follow-up: 6 months.

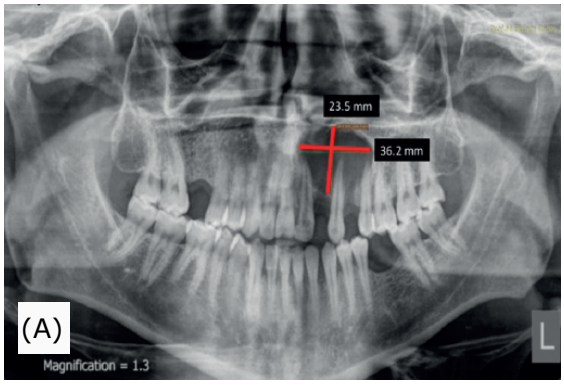
RESULTS

Performance – In group 1, the percentage of decrease in the bone density during the first three months is higher in group 1 than group 2 that was then increased by nearly the same percentage at the six months interval although statistically there is no significant difference between the two groups throughout the study period. The defects were completely filling in the 2 groups without loss of substitute.

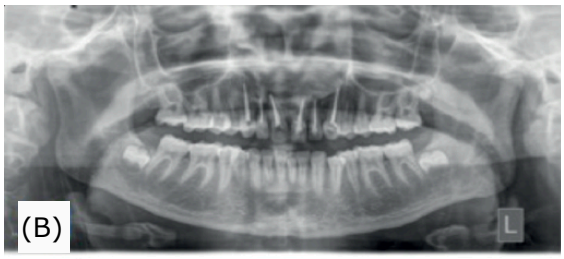
Benefits – No harvest graft site and no residual disease reported.

Safety – No postoperative infection, nor wound dehiscence or graft rejection throughout the healing phase.

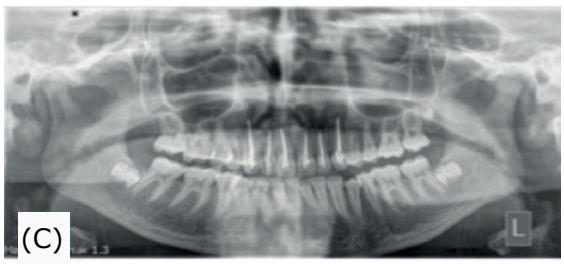
CONCLUSION – The bioactive glass prepared as the sticky bone has better intraoperative handling and workability, better soft tissue reaction during the healing period and higher bone density values of the grafted defects than when used solely although it hasn't any radiographic statistically significant results regarding the studied parameters. The safety and performance of GlassBone Granules are demonstrated.



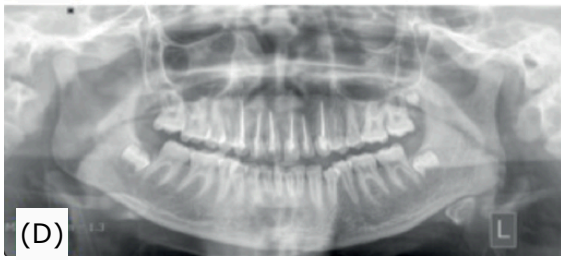
(A) Preoperative Orthopantomogram with the measurements of the cystic cavity



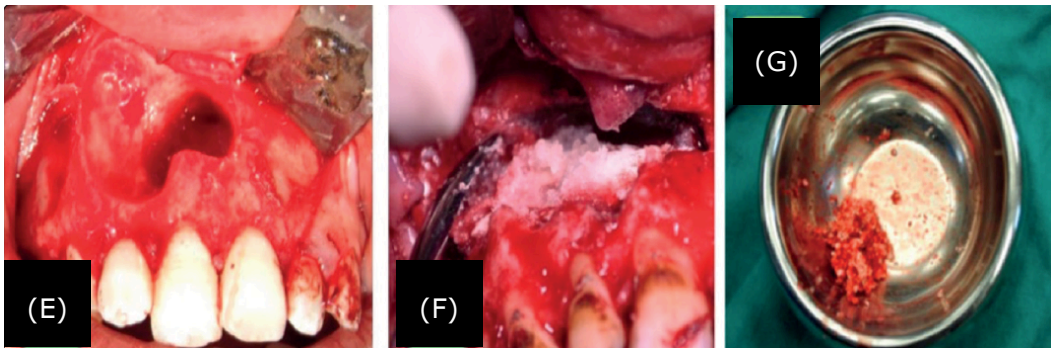
(B) Immediate Postoperative Orthopantomogram (Group 2)



(C) 3 months Postoperative Orthopantomogram (Group 2)

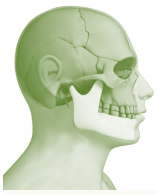


(D) 6 months postoperative orthopantomogram (Group 2)



(E) Clinical photograph of the resulted surgical defect after cyst enucleation, (F) Clinical photograph of filling the resulted surgical defect with Bioactive bone glass (Group 1)

(G) Clinical photograph showing the Bioactive glass sticky bone prior to its use in filling the resulted surgical defect (Group 2)



The gingivo periosto plastic surgery with osseous substitute: Technique and first results

Publication - 2015

S. Adam [c], H.D. Sama [a,c], N. Dégardin [b], A. Gallucci [c], V. Bellot-Samson [c,d], J. Bardot [c]

a Chirurgie maxillo-faciale et plastique de la face, CHU Sylvanus Olympio, Tokoin-Lome´, Togo
b Service d'anesthésie réanimation, CHU Sylvanus Olympio, 08 BP 8146, Tokoin-Lome´, Togo
c Service de chirurgie plastique pédiatrique, CHU Timone - Enfants, boulevard Jean-Moulin, 13385 Marseille, France
d Chirurgie maxillo-faciale et stomatologie, CHU Timone - Adultes, boulevard Jean-Moulin, 13385 Marseille, France

https://www.sciencedirect.com/science/article/abs/pii/S0294126015000850

INDICATION - Alveolar crack

SURGERY - Gingivo periosto plastic (GPP) surgery with osseous substitute type glass by bone transplant at infantile plastic surgery service of Timone

METHOD

- Retrospective study - 23 children (16 boys and 7 girls).
- Objective: Evaluate the performance and safety of GlassBone Granules in the treatment of alveolar crack in children.
- Follow-up: 18 months.

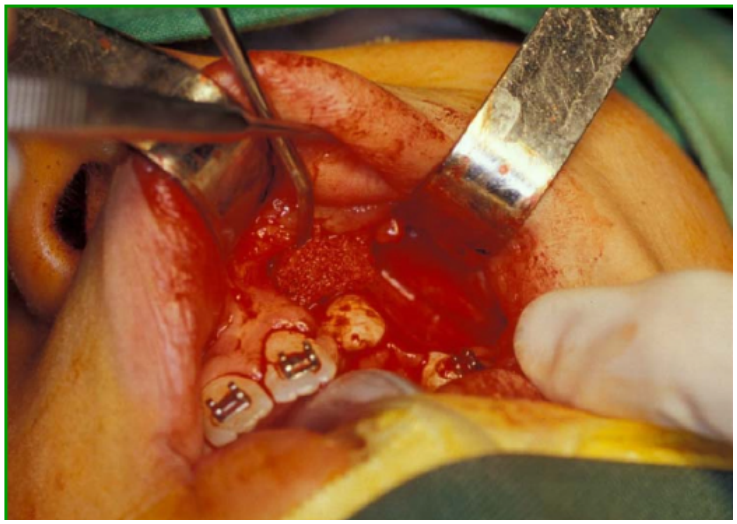
RESULTS

Performance – The bone substitute was well tolerated at the surgical site.

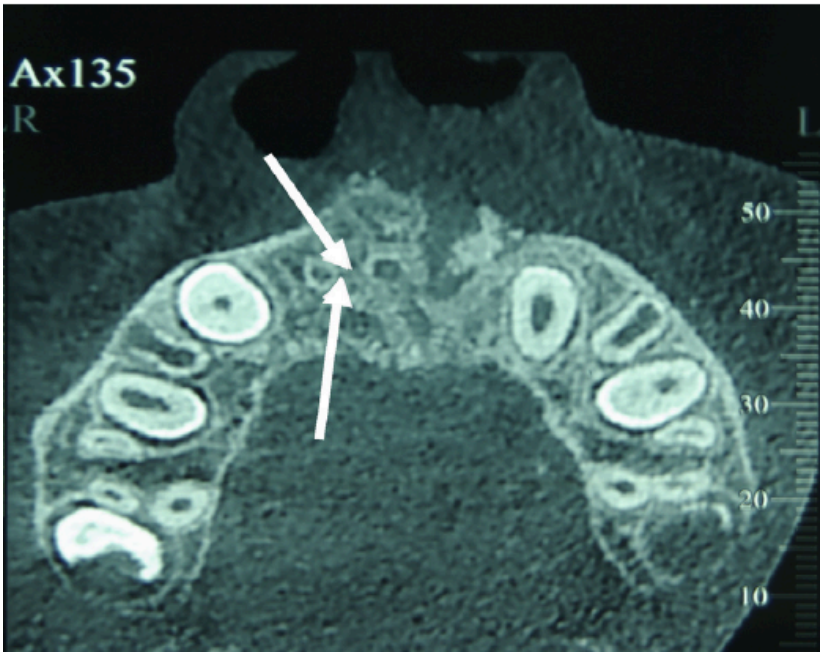
Benefits – Less morbidity of the operating site.

Safety – No suture release nor surgical site infection and inflammatory phenomen were noted. Only 4 cases out of 23 developed mucosal fissures. Bleeding at 2 days post-operatively due to patient neglect of instructions.

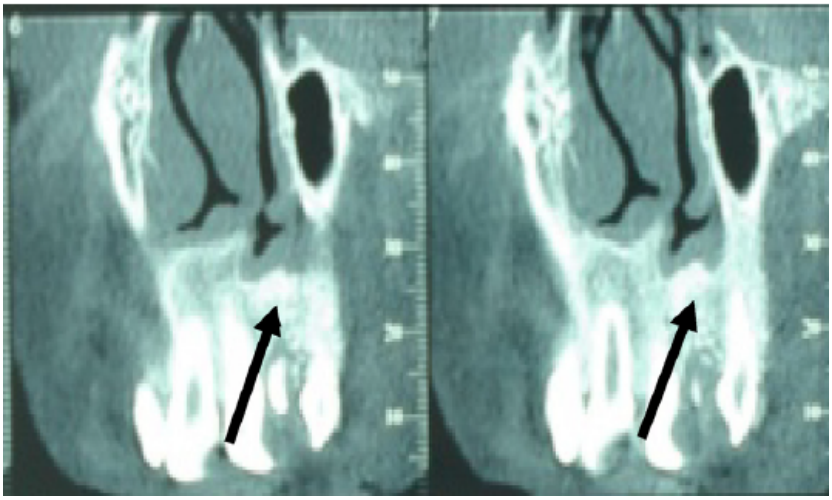
CONCLUSION – GPP with GlassBone is a simple, reliable and reproducible technique, with promising results. The reduced morbidity of the bone graft harvesting site, the affordable purchase cost of GlassBone and the simplicity of the surgical procedure are all advantages for the adoption of this technique. The safety and performance of GlassBone Granules are demonstrated.



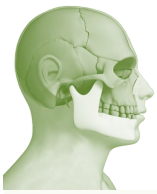
Intraoperative placement of GlassBone bone substitute



CT scan of the bone and dental environment at 3 months postoperatively after GPP with GlassBone



New Tom CT appearance of the bone and dental environment at 3 months postoperatively after GPP with GlassBone



Effectiveness of bovine derived xenograft versus bioactive glass with periodontally accelerated osteogenic orthodontics in adults

Publication - 2017

Maha A Bahammam [1]

1 Department of Periodontology, Faculty of Dentistry, King Abdulaziz University, 21589, Kingdom of Saudi Arabia

https://doi.org/10.1186%2Fs12903-016-0321-x

INDICATION - Reconstruction: periodontal osseous defects*

SURGERY - Periodontally accelerated osteogenic orthodontics (PAOO)

METHOD

- Prospective study - 33 patients (20 women, 13 men).
- Objective: Compare the effectiveness of a bovine-derived xenograft with that of bioactive glass when combined with Periodontally accelerated osteogenic orthodontics (PAOO) for the treatment of adult patients with moderate crowding of the teeth.
- Three groups: Group 1 underwent a modified corticotomy technique on the labial side only, whereas group 2 was treated with the same technique combined with (PAOO) using a bovine-derived xenograft and group 3 was treated in the same way but combining PAOO with GlassBone Granules.
- Follow-up: 9 months.

RESULTS

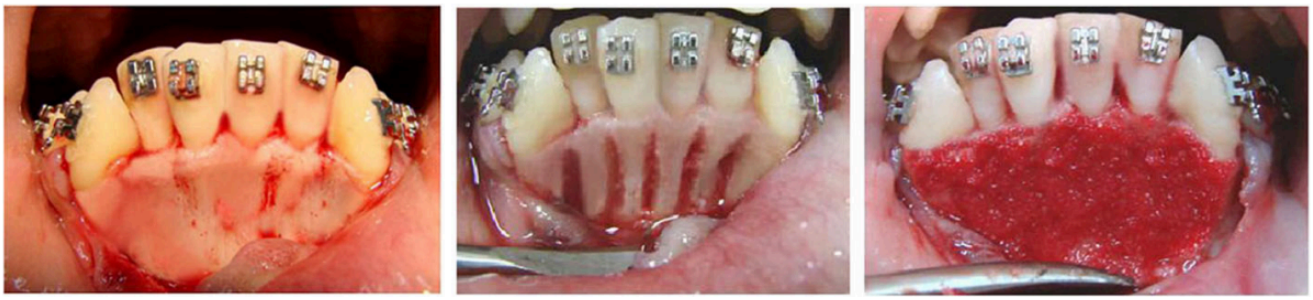
Performance – Reconstruction: The bone density percentage increase to 80.12% from the start of the treatment to 9 months postoperatively. A decrease in the probing depth from 1.56 mm on the day of the surgery to 1.19 mm 9 months postoperatively. This diminution reflects bone augmentation.

Benefits – No harvest graft site.

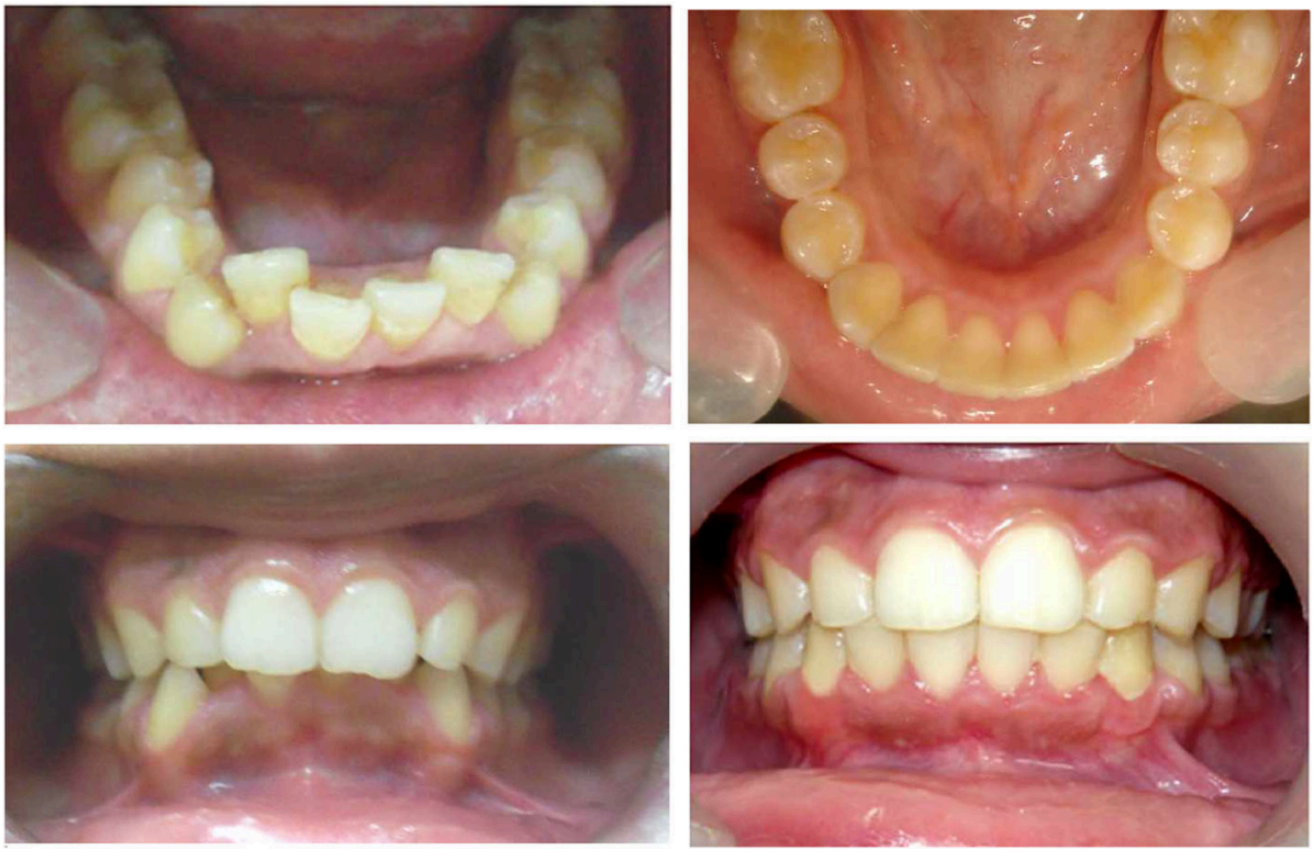
Safety – No adverse event reported in this study. The interdental papillae were well preserved, there was no loss of tooth vitality, and there was no evidence of significant apical root resorption at any time interval.

CONCLUSION – At the end of the study period, there was a significantly greater increase in bone density in the two groups that had been treated with bone grafting when compared with the group 1. The safety and performance were demonstrated.

*This indication can also be found in the dental section.



Surgical procedures



Occlusal and frontal Pre and post treatment intraoral pictures

Quantitative modifications of the periodontal support by mineralized periodontal reinforcement with the bone substitute Glassbone Injectable Putty, with or without orthodontic treatment

White paper - 2020

Straub B.[a]

a Hospital Practitioner Exclusive Periodontology at the Stomatology Department Hospices Civils de Lyon

INDICATION - Periodontal reinforcement*

SURGERY - Periodontal bone regeneration surgery

METHOD

- Prospective study - 31 patients (24 women and 7 men).
- Objective: The aim of this study is to confirm the safety and performances of GlassBone Injectable Putty (IP) under its normal conditions of use.
- Follow-up: no follow-up.

RESULTS

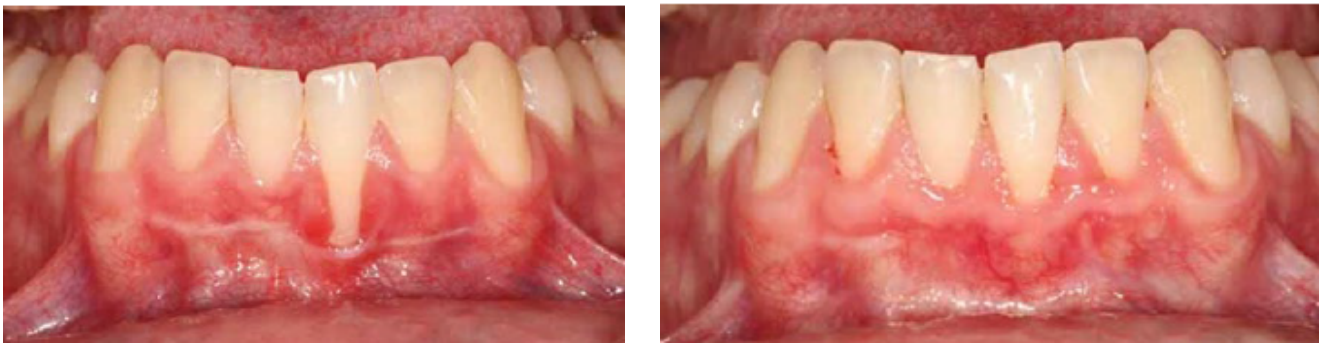
Performance – All periodontal phenotypes increased from II to I according to the classification of Seibert and Lindhe, a thick and flat periodontium. For all patients (100%), a resistant periodontium is visible, a pale pink colour with a peck in "orange peel" reflecting a bond between the underlying bone and the gum.

Benefits – No harvesting bone graft site.

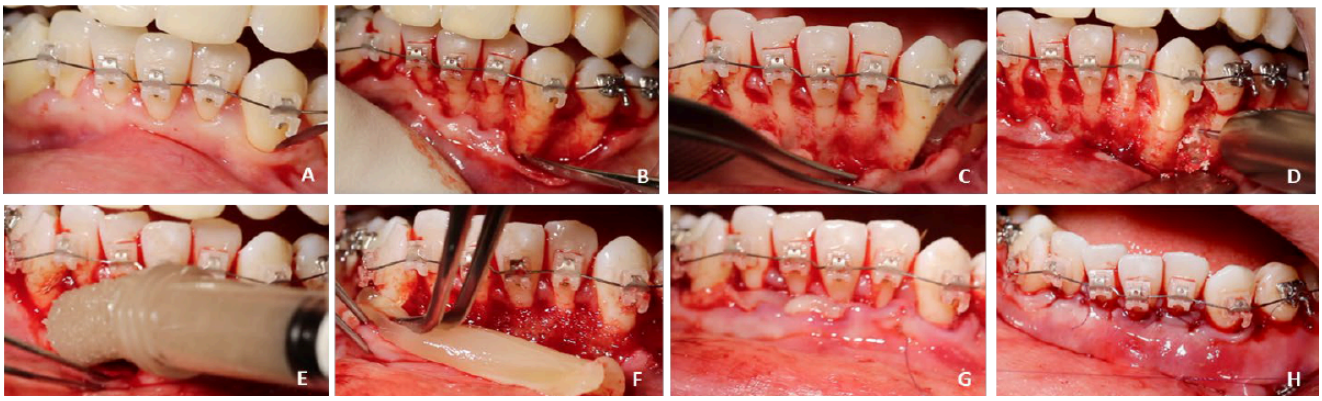
Safety – No particular complications were observed.

CONCLUSION – The technique with GlassBone IP has many advantages: an increase in the deep periodontium by gaining alveolar bone volume which leads to an improvement in the superficial periodontium and no adverse events have been occurred with a single intervention site, no palatal sampling and an aesthetic result.The safety and performance of GlassBone IP are demonstrated.

*This indication can also be found in the dental section.



Pre op and post op image
To note the increased bone volume as well as recovery from recession



Intraoperative surgical steps

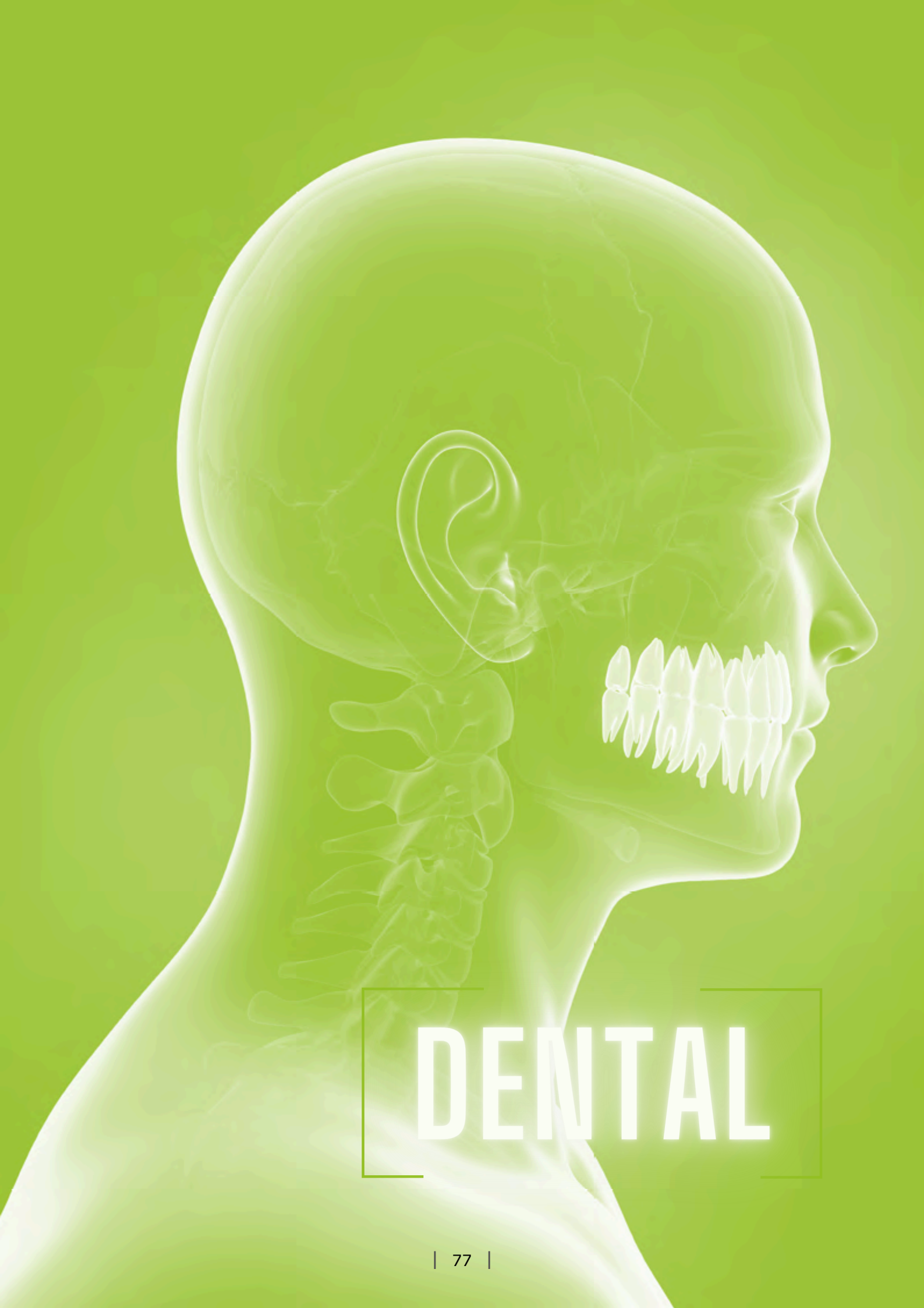
(A) Intra sulcus incision
(B) Sub-periosteum detachment
(C) Periosteum incisions to loosen the flap
(D) Cortical perforation with round bur (24 mm round without irrigation to keep bone autogenous)
(E) Filling with GlassBone IP
(F) Laying the PRP membrane
(G) Hanging sutures
(H) Sutures periosteum bottom of the vestibule

SPINE

ORTHOPEDICS

CRANIO MAXILLO FACIAL - EAR NOSE THROAT

DENTAL



DENTAL

In dental and maxillofacial surgery, the goal of bone defect repair is to recreate a suitable bony site for morphological, prosthetic, or implant-prosthetic rehabilitation. Various factors can lead to bone deficiency, including genetic factors, post-traumatic injuries, tooth extractions, infections, or iatrogenic causes. The amount of bone that needs to be reconstructed varies depending on the specific anatomical situation. The characteristics of the graft material depend on the volumes that need to be filled (e.g., alveolar area) or restored (e.g., vertical or horizontal ridge insufficiency, bone cysts, or sinus lifting) (Guillaume, 2017).

Insufficient bone volume can pose challenges in achieving ideal implant positioning and may compromise long-term peri-implant health, function, and esthetics. To address these limitations, techniques such as alveolar ridge preservation (ARP) or reconstruction (ARR) and implant site development (ISD) are employed. Horizontal and vertical alveolar ridge augmentation (ARA) and maxillary sinus floor augmentation (MSFA) are considered essential ISD interventions in modern clinical practice. These interventions, along with ARP/ARR, can be performed using various techniques and materials, each with its specific characteristics and limitations. Commonly used materials for bone augmentation in ISD and ARP include absorbable and non-absorbable barrier membranes, particulate bone replacement graft materials from different sources, and autologous bone blocks. Despite their proven success in numerous studies, all bone preservation and augmentation protocols have drawbacks and limitations, such as complications during the healing phase (e.g., infections), reduced new bone formation, and delayed healing. To overcome these limitations and increase treatment predictability, the use of biologics has been proposed (Suárez-López Del Amo & Monje, 2022).

Bone grafting is a crucial aspect of regenerative therapy, involving various materials such as autografts, allografts, xenografts, and synthetic materials (alloplasts). Synthetic materials, including calcium phosphate ceramics like hydroxyapatite (HA), tricalcium phosphates (TCP), biphasic calcium phosphates (BCP), and bio-glass (BG), have emerged as effective options for bone augmentation procedures such as sinus lifts and alveolar reconstructions (Liu, 2021). While autografts remain the gold standard due to their innate bone growth properties, they suffer from limitations such as donor site morbidity and availability issues.

Implant therapy is a reliable treatment method known for its favorable and lasting outcomes. When teeth are lost, changes occur in the alveolar process, leading to alterations in its dimensions. These dimensional changes carry significant clinical importance when devising a comprehensive treatment plan. Moreover, factors such as traumatic tooth loss during growth, prolonged edentulism, extensive bone and soft tissue resorption, can pose challenges for implant placement. As a result, implant placement often necessitates additional procedures like alveolar ridge preservation, guided bone regeneration, or sinus floor elevation (SFE) to achieve an optimal position for the prosthetic implant (Stähli, 2018).

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Is Sinusal bone augmentation using bioactive glass and bone flap repositioning

Publication - 2020

Damien CARROTTE[1], Brigitte BURT-PICHAT[2], Sébastien RIZZO[2], Georges BOIVIN[2]

1- Ancien assistant hospitalo-universitaire à la faculté de Lyon (Service de prothèse), Maîtrise de sciences biologiques et médicales, CES de prothèses scellées, DIU d'anatomie et d'implantologie orale, DU d'expertise maxillo-faciale et bucco-dentaire, Exercice privé, Villeurbanne
2- INSERM UMR 1033 « Physiopathologie, diagnostic et traitement des maladies osseuses », Université de Lyon, faculté de médecine Lyon-Est (domaine Laennec)

https://www.editionscdp.fr/revues/jpio/article/n-146

INDICATION - Sinus

SURGERY - Sinusal bone augmentation (Tatum technique) with implant placement directly during bone augmentation surgery or on a delayed basis for 6 cases with residual bone too resorbed

METHOD

- Retrospective study - 110 dental implants (52 patients).
- Objective: Evaluate the performance and safety of ActivIoss Granules in implantation after sub-sinusian bone augmentation performed by the modified Tatum technique with repositioning of the bone flap and using ActivIoss Granules bone substitute.
- Follow-up: 12-52 months.

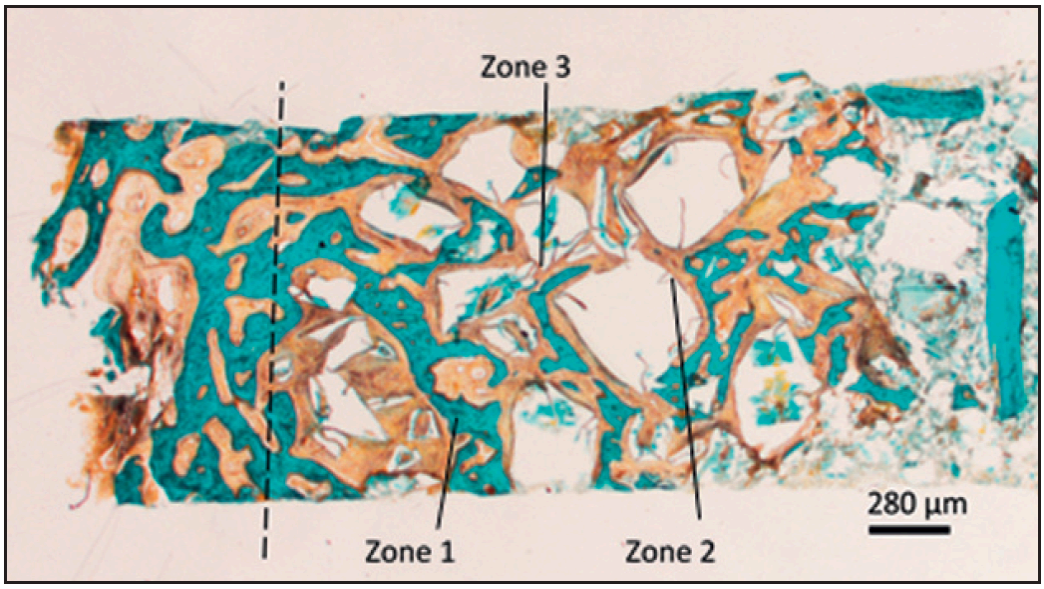
RESULTS

Performance – On average, osseointegration was validated at 6 months (1-stage) and 11 months (2-stage). Implant success rates were 98.8% (1 failure) for the group with immediate abutment placement, and 95.2% (1 failure) for 1-stage surgery but with deferred abutment placement. For 2-stage surgery, the success rate is 100%. The overall success rate is 98.2%.

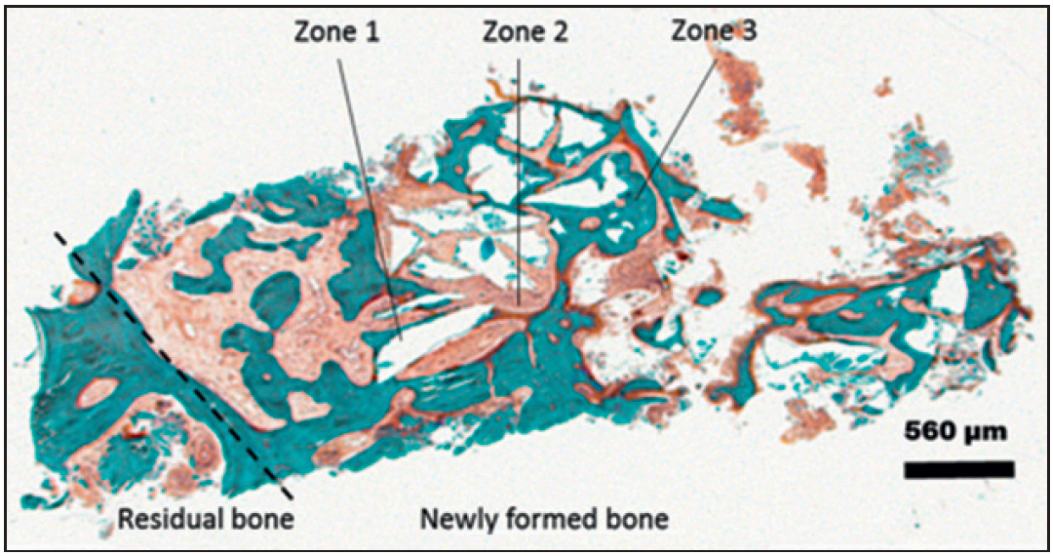
Benefits – No harvesting bone graft site.

Safety – No particular intraoperative complications were observed. Post-operative follow-up was normal, with no inflammation abnormalities. Some rare pains, usual for this type of surgery, were controlled with medication.

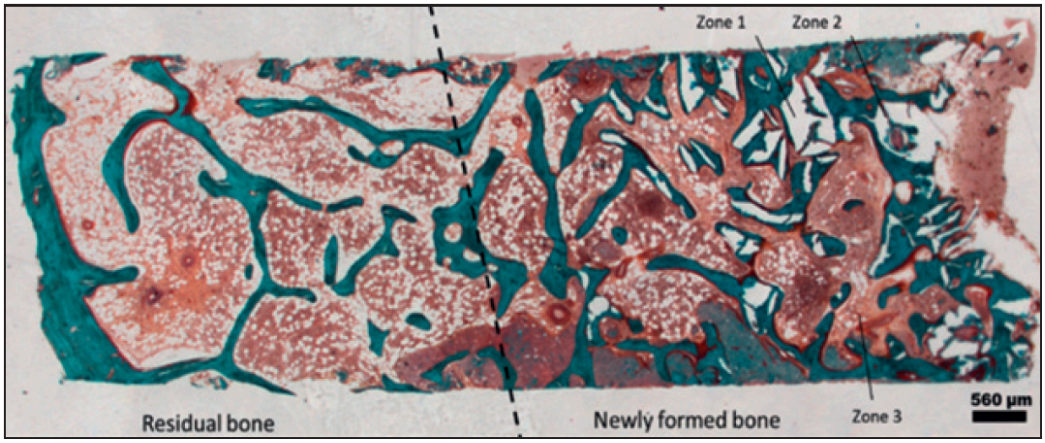
CONCLUSION – The results of this study show that the technique combining the repositioning of the bone flap, the use of bioactive glass and the immediate placement of the implant makes it possible to achieve implant success rates of over 98%, identical to the best results described. in the literature with allografts or xenografts and thus reduce the physical, temporal and economic stress of the patient. So the safety and performance of ActivIoss Granules are demonstrated.



Histology at 3 months



Histology at 6,5 months



Histology at 22 months

Quantitative modifications of the periodontal support by mineralized periodontal reinforcement with the bone substitute Glassbone Injectable Putty, with or without orthodontic treatment

White paper - 2020

Straub B.[a]

a Hospital Practitioner Exclusive Periodontology at the Stomatology Department Hospices Civils de Lyon

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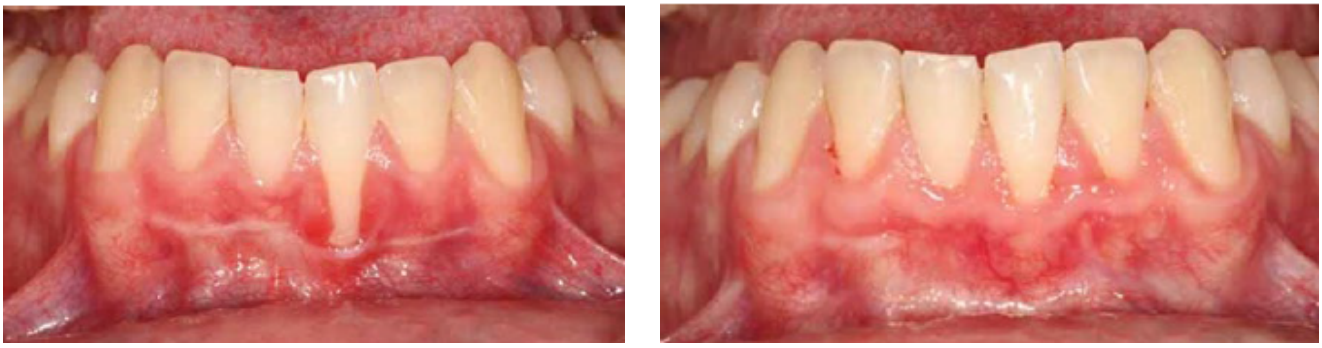

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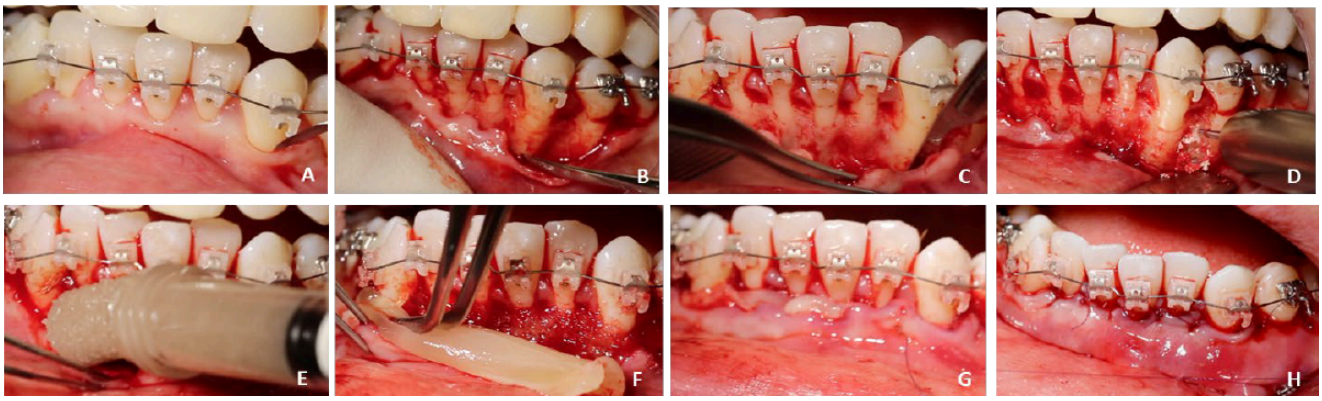

Intraoperative surgical steps

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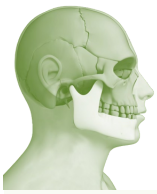


Effectiveness of bovine derived xenograft versus bioactive glass with periodontally accelerated osteogenic orthodontics in adults

Publication - 2017

Maha A Bahammam [1]

1 Department of Periodontology, Faculty of Dentistry, King Abdulaziz University, 21589, Kingdom of Saudi Arabia

https://doi.org/10.1186%2Fs12903-016-0321-x

INDICATION - Reconstruction: periodontal osseous defects*

SURGERY - Periodontally accelerated osteogenic orthodontics (PAOO)

METHOD

- Prospective study - 33 patients (20 women, 13 men).
- Objective: Compare the effectiveness of a bovine-derived xenograft with that of bioactive glass when combined with Periodontally accelerated osteogenic orthodontics (PAOO) for the treatment of adult patients with moderate crowding of the teeth.
- Three groups: Group 1 underwent a modified corticotomy technique on the labial side only, whereas group 2 was treated with the same technique combined with (PAOO) using a bovine-derived xenograft and group 3 was treated in the same way but combining PAOO with GlassBone Granules.
- Follow-up: 9 months.

RESULTS

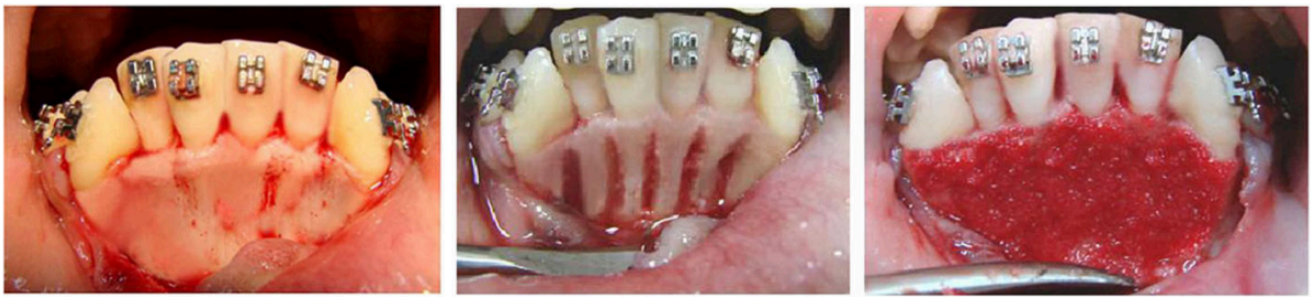
Performance – Reconstruction: The bone density percentage increase to 80.12% from the start of the treatment to 9 months postoperatively. A decrease in the probing depth from 1.56 mm on the day of the surgery to 1.19 mm 9 months postoperatively. This diminution reflects bone augmentation.

Benefits – No harvest graft site.

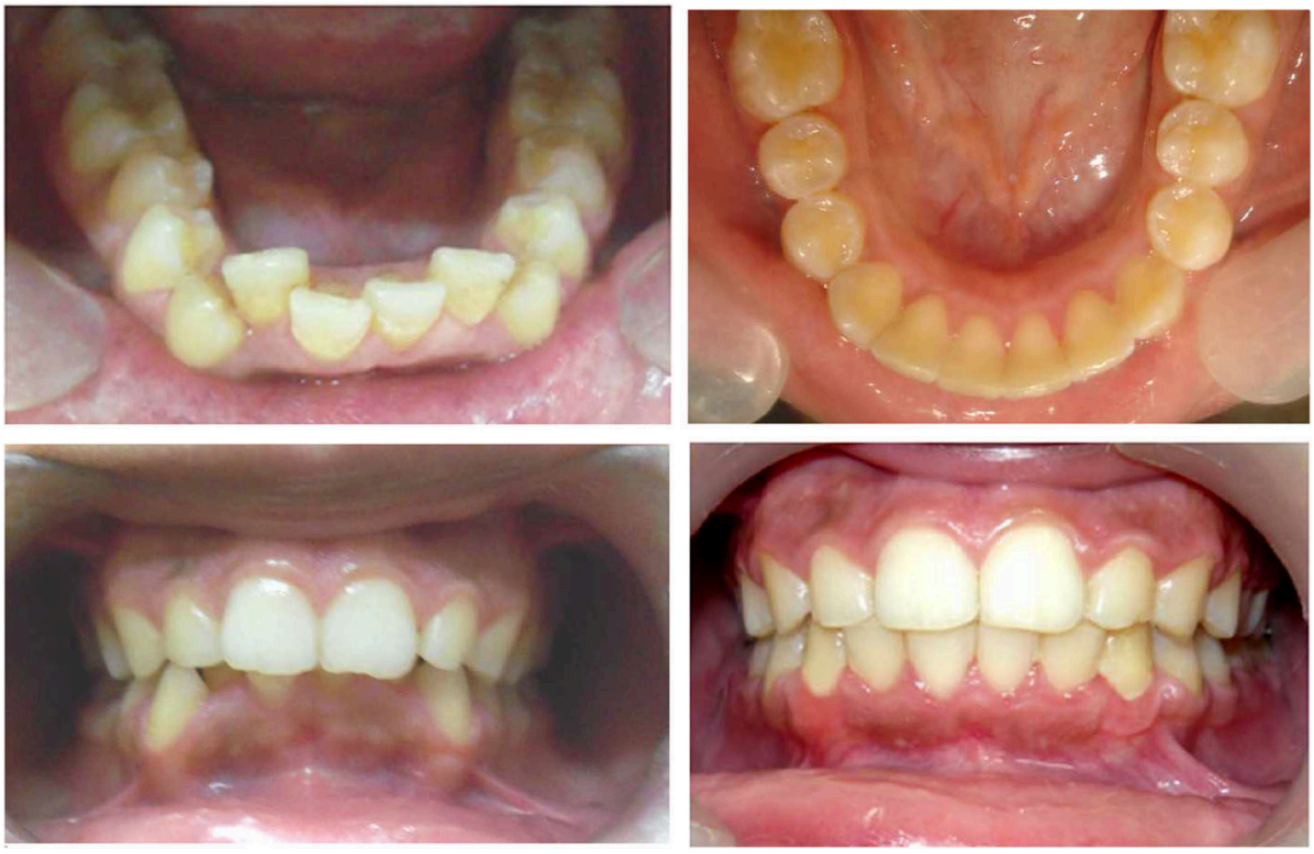
Safety – No adverse event reported in this study. The interdental papillae were well preserved, there was no loss of tooth vitality, and there was no evidence of significant apical root resorption at any time interval.

CONCLUSION – At the end of the study period, there was a significantly greater increase in bone density in the two groups that had been treated with bone grafting when compared with the group 1. The safety and performance were demonstrated.

*This indication can also be found in the CMF section.



Surgical procedures



Occlusal and frontal Pre and post treatment intraoral pictures

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