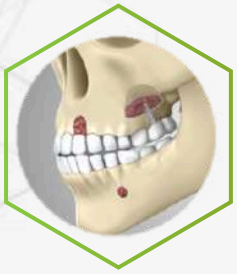
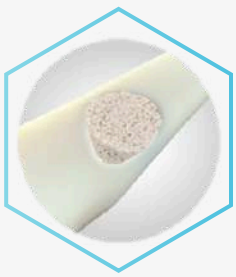
NORAKER®

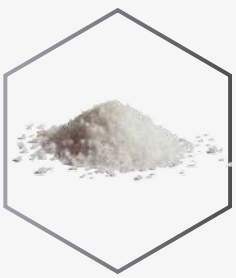
THE BIOGLASS® COMPANY

CLINICAL SUMMARY

BIOGLASS BONE REGENERATION SOLUTIONS







1-NORA-Clinical summary-Dental-EN-1.0 07/2023

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

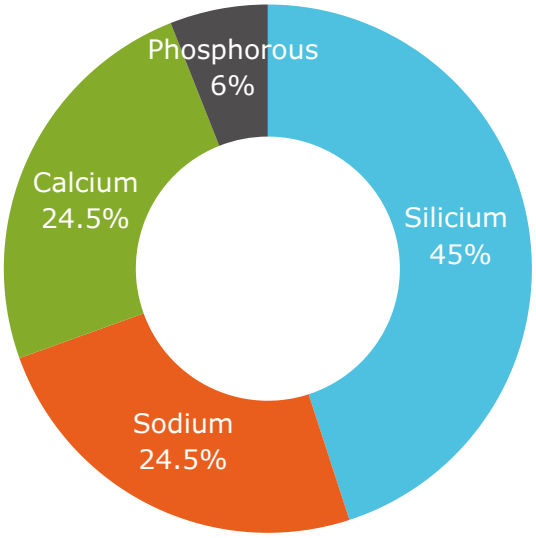
To note, cases reports were not subjected to clinical investigation protocols and are not sufficient proof to validate performance and safety of the device.

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.

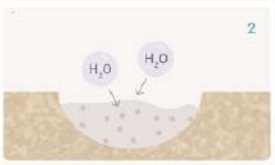
COMPOSITION



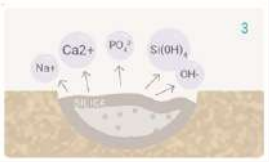
- Osteoconductive
- Improves the bone regeneration: natural matrix for cells to attach, differentiate and make new bone:
  - Bone Bonding
  - Soft tissue bonding
- 100 % synthetic
- Bioabsorbable
- Excellent biocompatibility

MECHANISM OF ACTION

1. Implantation of bioactive glass in a bone defect.



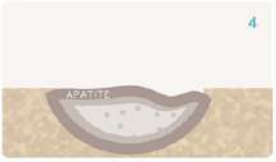
2. Rapid exchange of Na^+ and / or Ca^{2+} cations with H^+ of the solution, creating silanol (Si-OH) bonds at the glass surface: $SiO–Na^+ + H_2O \rightarrow Si\text{-}OH + Na^+_{(aq)} + HO^-$



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.



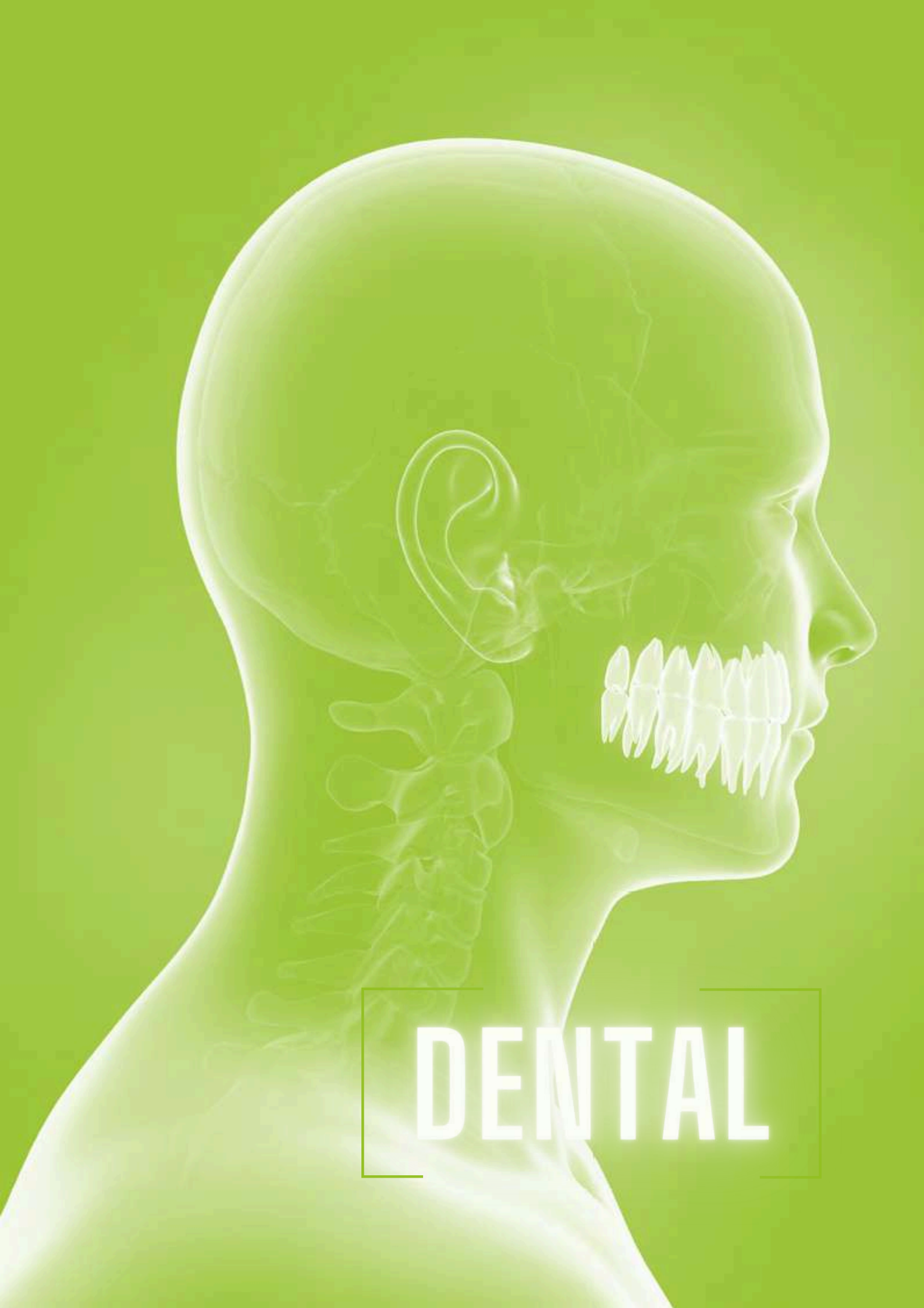
4. Migration of Ca^{2+} and PO_4^{3-} groups to the surface through the silica-rich layer and from the solution, thereby forming a film rich in amorphous calcium phosphate on the silica-rich layer. Finally, the incorporation of hydroxyls and carbonates in the solution and the crystallization of the calcium 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.

DENTAL

ActivIoss®
Bioactive Bone Substitute

DENTAL


DENTAL

STATE OF THE ART

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).

REFERENCES

Guillaume, B. (2017). Filling bone defects with beta-TCP in maxillofacial surgery: A review. Morphologie, 101(334), 113-119. https://doi.org/10.1016/j.morpho.2017.05.002

Liu, C. C., Solderer, A., Heumann, C., Attin, T., & Schmidlin, P. R. (2021). Tricalcium phosphate (-containing) biomaterials in the treatment of periodontal infra-bony defects: A systematic review and meta-analysis. J Dent, 114, 103812. https://doi.org/10.1016/j.jdent.2021.103812

Stahli, A., Strauss, F. J., & Gruber, R. (2018). The use of platelet-rich plasma to enhance the outcomes of implant therapy: A systematic review. Clin Oral Implants Res, 29 Suppl 18(Suppl Suppl 18), 20-36. https://doi.org/10.1111/clr.13296

Suárez-López Del Amo, F., & Monje, A. (2022). Efficacy of biologics for alveolar ridge preservation/reconstruction and implant site development: An American Academy of Periodontology best evidence systematic review. J Periodontol, 93(12), 1827-1847. https://doi.org/10.1002/jper.22-0069

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

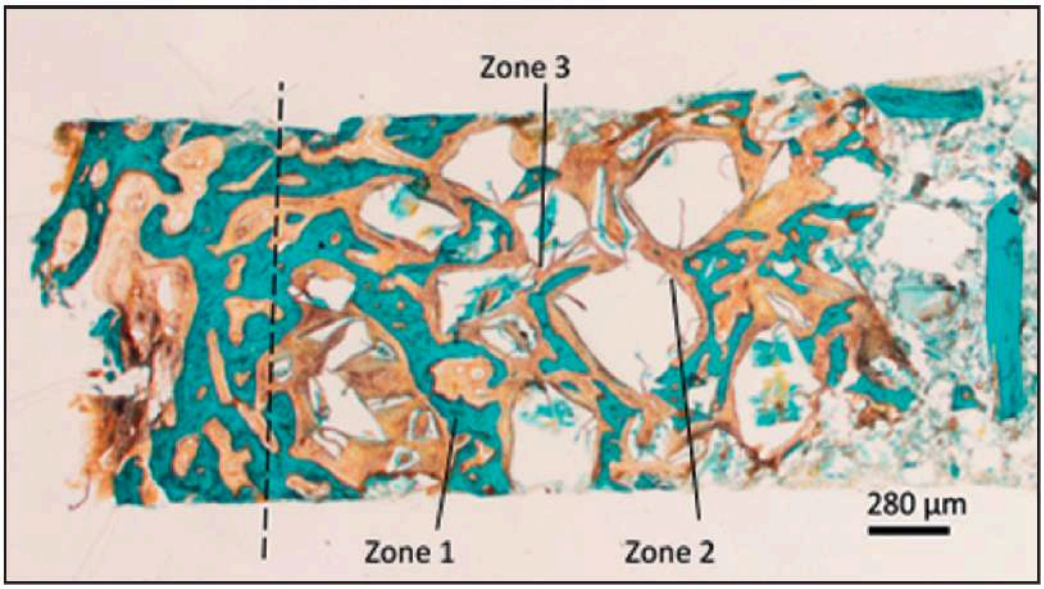
Performance – On average, osseointegration was validated at 6 months (1-stage) and 11 months (2-stage). Implant success rates were 98.8% (1 failure) for the group with immediate abutment placement, and 95.2% (1 failure) for 1-stage surgery but with deferred abutment placement. For 2-stage surgery, the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

Benefits – No harvesting bone graft site.

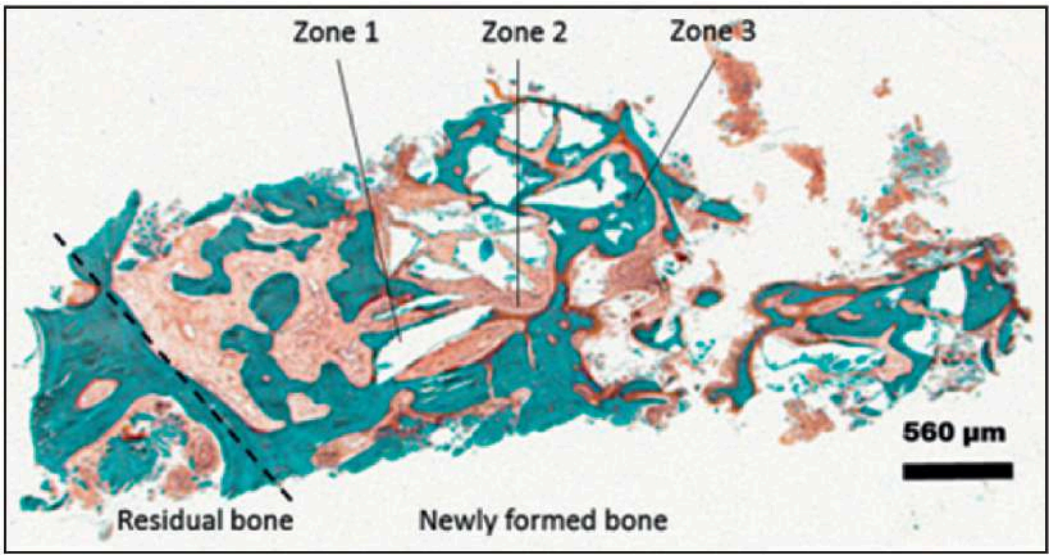
Safety – No particular intraoperative complications were observed. Post-operative follow-up was normal, with no inflammation abnormalities. Some rare pains, usual for this type of surgery, were controlled with medication.

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.

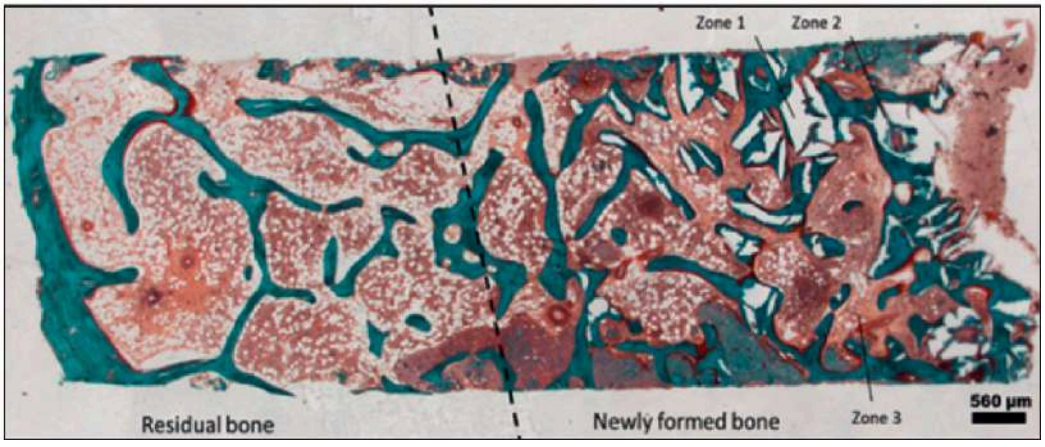
DENTAL



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

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.

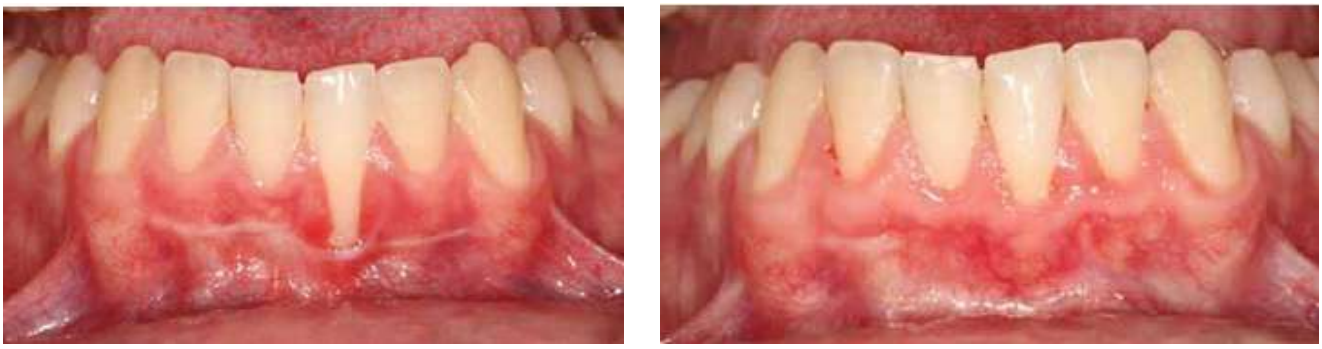
Benefits – No harvesting bone graft site.

Safety – No particular complications were observed.

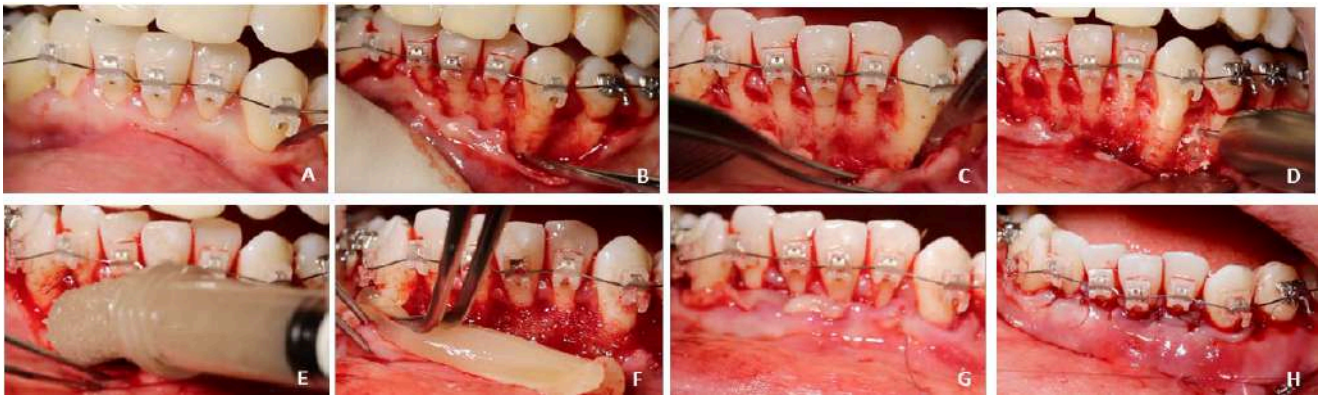
CONCLUSION – The technique with GlassBone IP has many advantages: an increase in the deep periodontium by gaining alveolar bone volume which leads to an improvement in the superficial periodontium and no adverse events have been occurred with a single intervention site, no palatal sampling and an aesthetic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

DENTAL

*This indication can also be found in the CMF 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

NORAKER®

THE BIOGLASS® COMPANY

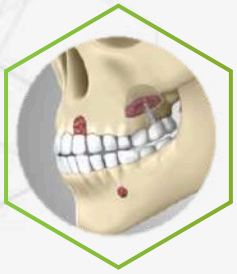
60 Av. Rockefeller
69008 Lyon
FRANCE

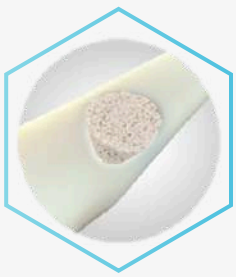
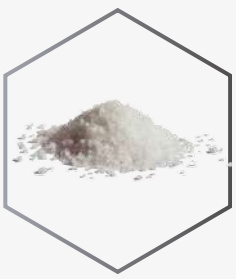
Tel: +33 (0)4 78 93 30 92
Fax: +33 (0)4 72 35 94 37

contact@noraker.com

MADE IN FRANCE





1-NORA-Clinical summary-Dental-EN-1.0 07/2023