GRAFT BIOMATERIALS SigmaGraft

InterOss®

Anorganic Cancellous Bone Granules

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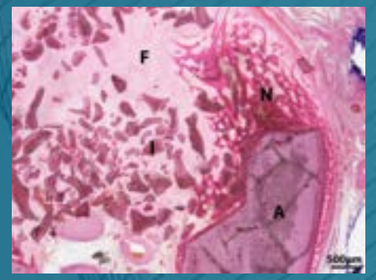
InterOss® is a natural hydroxyapatite bone grafting material for use in dentistry. Made from a proven multi-step purification process which leaves only a bone composition, it is a highly purified osteoconductive material for bone regeneration.

Having an interconnected network of macro and micro pores and large inner surface areas that provides an ideal environment for cell attachment, InterOss® is chemically and structurally comparable to mineralized human bone. It is available in sterilized granule form and is dedicated for single uses.

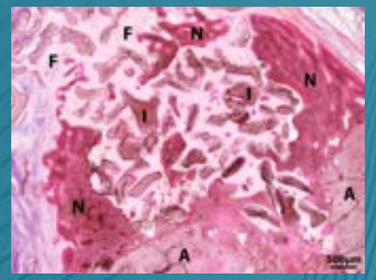
Osteoconductive

A preclinical trial was conducted to treat 54 mandibular critical-sized alveolar ridge defects in 27 canines. The study confirmed InterOss®' osteoconductivitiy as it was clinically and histologically successful in forming new bone.

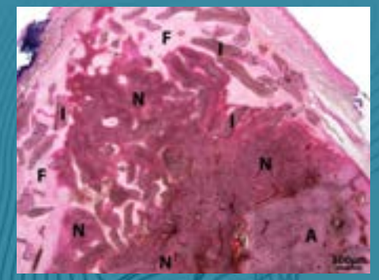
At 4 weeks:
Residual material with some woven bone formation (N) was observed.



At 8 weeks:
A significant amount of new bone formation (N) was observed.



At 12 weeks:
A mixture of mature and woven bone formation (N) was observed.



Indications for Use

InterOss® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge including the filling of extraction sockets
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Elevation of the maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for guided tissue regeneration (GTR) and guided bone regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for guided bone regeneration (GBR)

Available in the following options

Small Granules (0.25 - 1.0 mm)

VIAL	Volume	Weight
IOSG025	0.54 cc	0.25 g
IOSG050	1.08 cc	0.5 g
IOSG100	2.16 cc	1.0 g
IOSG200	4.32 cc	2.0 g

SYRINGE	Volume
IOSGS025	0.25 cc
IOSGS050	0.5 cc
IOSGS100	1.0 cc

Large Granules (1.0 - 2.0 mm)

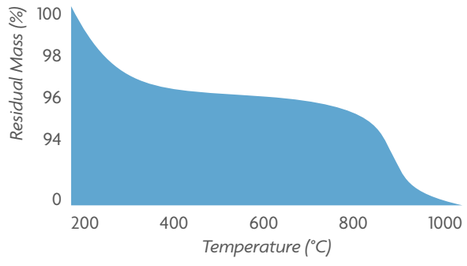
VIAL	Volume	Weight
IOLG050	2.0 cc	0.5 g
IOLG100	4.0 cc	1.0 g
IOLG200	8.0 cc	2.0 g

SYRINGE	Volume
IOLGS050	0.5 cc
IOLGS100	1.0 cc

Features & Benefits

Biocompatible

Highly purified bone mineral resulting from a long annealing process. A plateau region observed in the Thermogravimetric Analysis curve below shows extremely low residual organic substances.



Micro & Macro Porous

- Porosity enhances osteogenesis and promotes attachment and proliferation of bone forming cells
- Micropososity facilitates proliferation of osteoblasts
- Macroporosity allows vascularization and plays important role in the osteoconductivity

A Comparison Study with Bio-Oss®

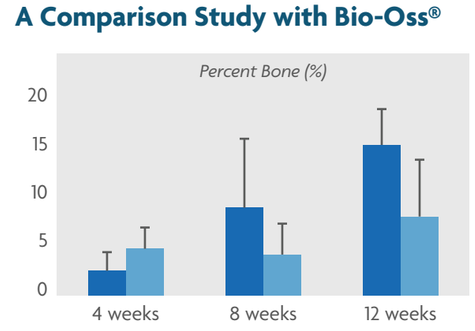


Figure 1, Histomorphometry
Percent Bone by Area (BA/DA)

While not statistically different, on average InterOss® had more than twice the mean amount of bone present at 8 and 12 weeks (8.88% and 14.76%, respectively) as compared to Product B (3.58% and 7.54%, respectively).

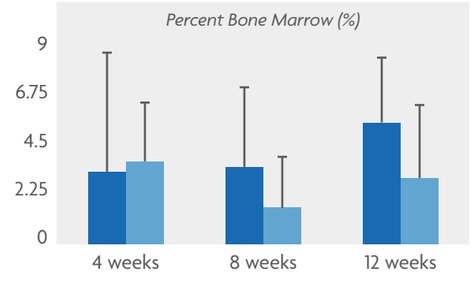


Figure 2, Histomorphometry
Percent Residual Graft by Area (GA/DA)

Overall, both InterOss®and Product B were very similar throughout the study; no statistical differences in percent residual graft were observed between the two treatment groups. At 12 weeks, the values were 5.78% ffl 2.83 for InterOss® and 5.73 ffl 4.43 for Product B.

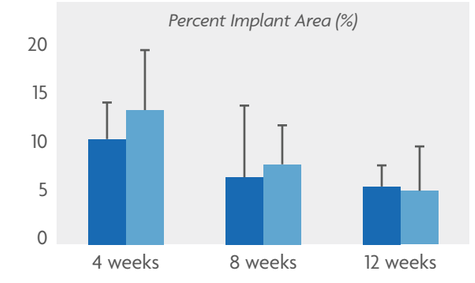


Figure 3, Histomorphometry
Bone Formation Density (BA/BMA)

Bone formation density is the ratio of newly formed bone to newly formed bone marrow area and can be used to understand bone formation densities.

Application & Handling

Hydration

InterOss® can be hydrated in blood or sterile saline solution.

Wound Closure

Ensure that the grafted site is securely closed with the soft tissue free of tension.

Healing Time and Re-entry

Healing time depends on the patient, nature and the size of the defect site and thus must be determined by the clinician based on the initial diagnosis. For a safe re-entry, it is recommended to let the surgical site heal for at least six months to ensure the graft material has been integrated properly.

For Use with Allograft

The long-term stability of InterOss® coupled with the biological potential of allograft may yield enhanced bone regeneration.

For Use with Autologous Bone

InterOss® helps achieve a natural biological activity due to the osteoinductivity and osteogenesis of autologous bone which in turn may encourage faster regeneration.

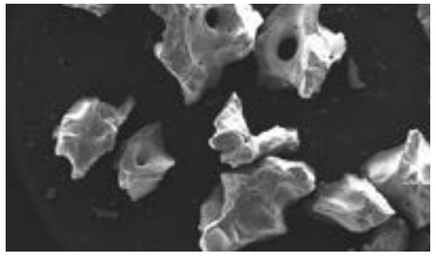
Application

- InterOss® can be adminstered to the surgical site after hydration using a surgical currette or periosteal elevator.
- For maximum results, the graft material should make sufficient contact with the bleeding bone surface to facilitate ingrowth of new blood vessels and bone forming cells.
- A resorbable membrane should be used in conjunction with the graft material by placing over it to minimize particulate migration

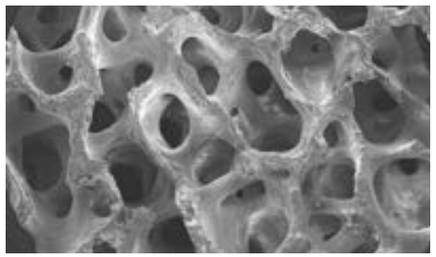
Properties

Attribute	Description
Composition	Calcium phosphate (100% pure hydroxyapatite, mineral phase)
Integration time	6 - 9 months (depending on defect)
Storage temperature	59 - 77 °F / 15 - 25 °C
Degradation profile	Bovine hydroxyapatite provides osteoconductive surface enabling a slow degradation and enhanced osseo-integration of particles into a new bone.

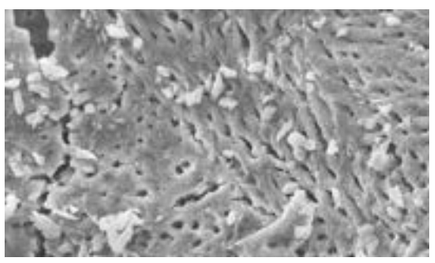
The existence of mesopores and micropores in the granules increases the inner surface area enhancing osteoconduction thus encouraging bone growth inside the pores.



1 mm



100 µm



10 µm

Immediate Bone Grafting on a Compromised Maxillary Molar Site Restores Alveolar Ridge Width and Height

Dr. David M. Kim
Boston, MA
United States

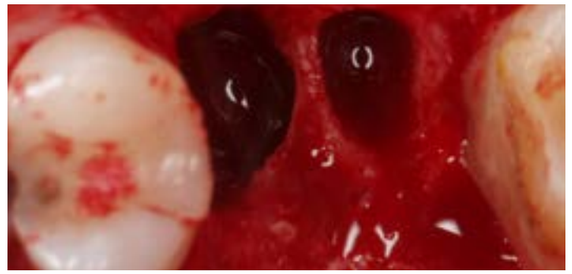
Patient History

A 38-year-old healthy female patient presented with a missing single FPD on the upper left first molar.

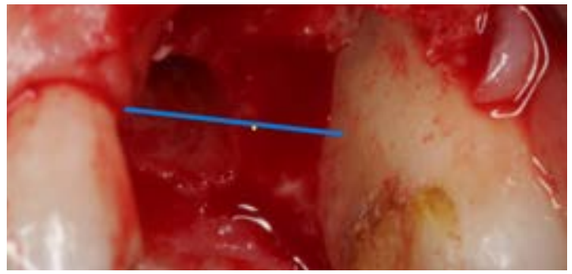
Conclusion

The tooth was extracted due to poor prognosis, and ridge preservation was performed using InterOss® and a collagen membrane. At 5 months, sufficient bone regeneration allowed implant placement. The 7-year follow-up demonstrated stable bone and healthy soft tissue, confirming long-term success of the ARP procedure.

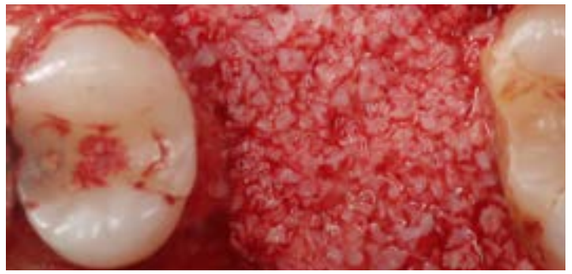
Pre-operative view.



A view of the bone defect.

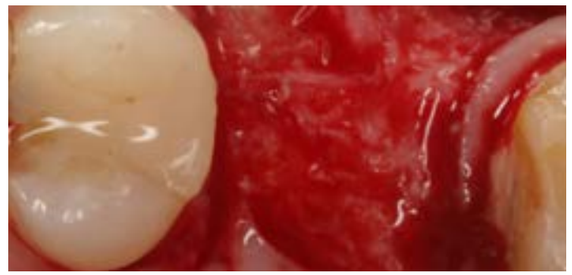


The buccal view revealed vertical bone loss.

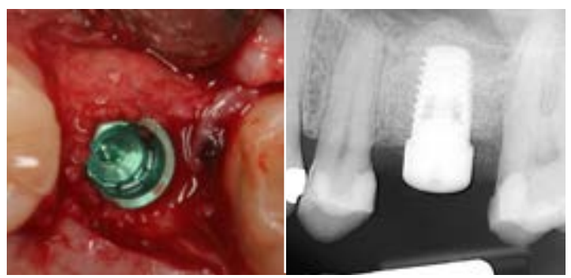


InterOss® placement.

Membrane placement and post-operative view.



Post-operative view at 5 months.



Implant placement.

Implant crown restoration.

Vertical Ridge and Sinus Augmentation in the Posterior Maxilla with InterOss

Dr. Alberto Monje
University of Michigan, United States
Universitat Internacional de Catalunya, Spain

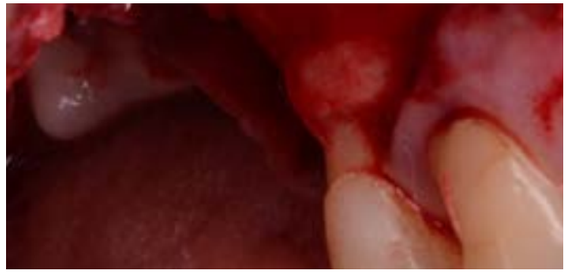
Patient History

A healthy, non-smoking, partially edentulous patient presented with a severely atrophic posterior maxilla, seeking oral rehabilitation. The patient had no significant medical history and expressed a desire for a fixed dental

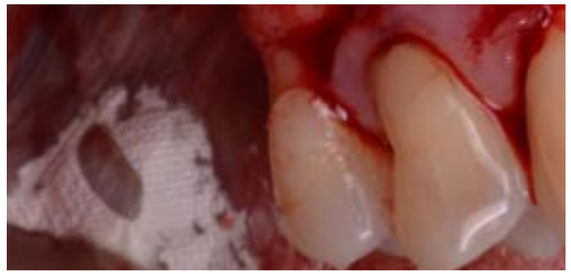
Conclusion

Sinus floor elevation and vertical ridge augmentation using InterOss and autogenous bone were performed simultaneously with the tent-pole technique. After uneventful healing, implants were placed with good stability. At 3 years, outcomes showed healthy peri-implant tissue and high patient satisfaction.

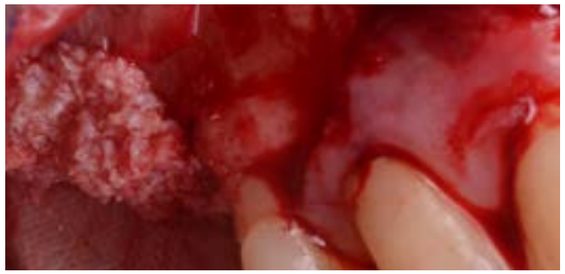
Pre-operative view.



A view of the bone defect.



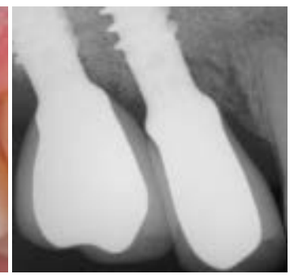
Membrane placement.



InterOss® placement.

Post-operative view.

Implant placement.



Follow-up at 3 years..

Post-operative X-ray at 3 years.

Combined Resective-reconstructive Therapy of Peri-implantitis

Dr. Riccardo di Gianfilippo
University of Michigan
United States

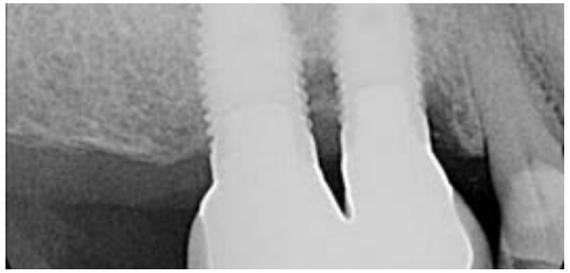
Patient History

The patient had 10 mm of peri-implant bone loss, with signs of inflammation and soft-tissue recession. They reported occasional discomfort and bleeding, with suboptimal oral hygiene and no recent trauma.

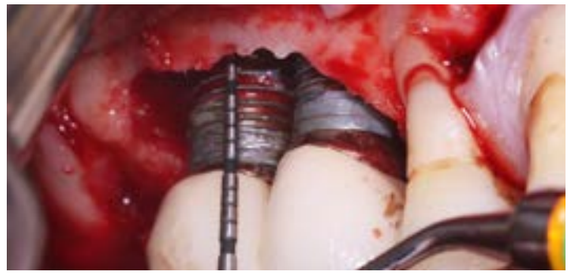
Conclusion

InterOss® was placed in a peri-implant infrabony defect and covered with a flap, without using a membrane. The material integrated well, supporting stable healing and soft-tissue closure. Its ease of use and compatibility make it a reliable option for similar cases.

Pre-operative view.



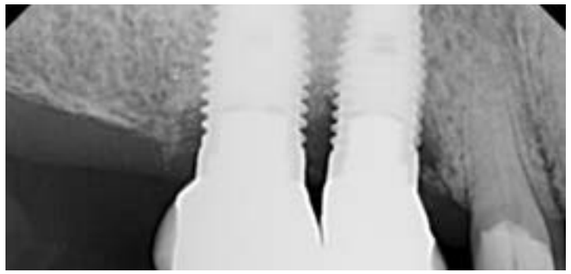
Pre-operative X-ray.



10mm peri-implant bone loss.

InterOss® placement.

Follow-up at 6 months.



X-ray at 6 months.

Gingival graft.

Follow-up at 2 weeks and 3 months after FGG.

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