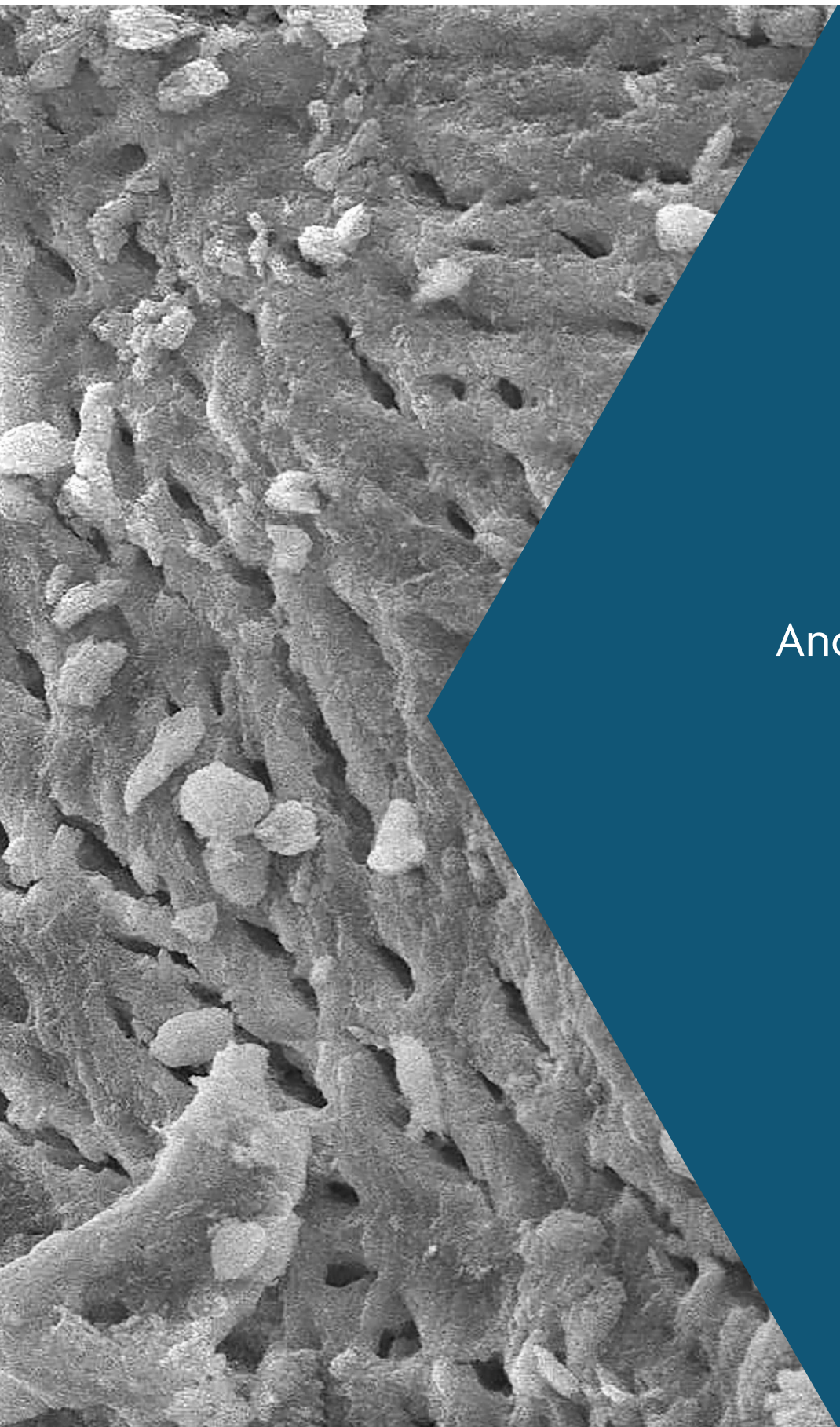
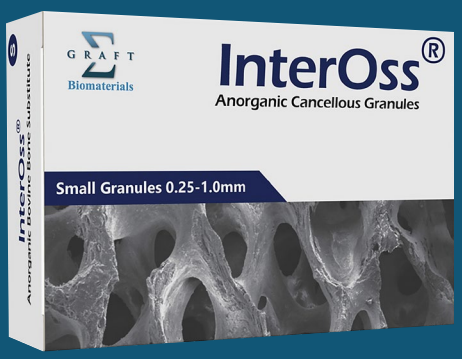
SigmaGraft

SCIENCE THAT NURTURES WELLNESS



InterOss®

Anorganic Cancellous Bone Granules



GRAFT BIOMATERIALS

InterOss®

Anorganic Cancellous Bone Granules

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.

Indications for Use

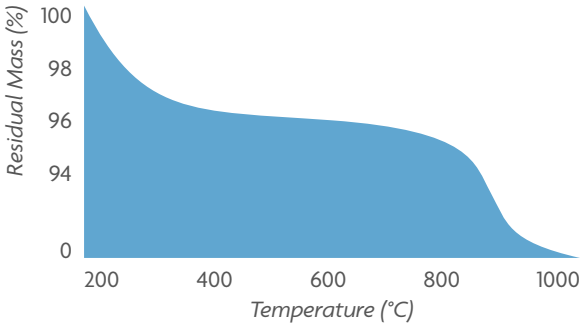
InterOss® is recommended for:

- 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)

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

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

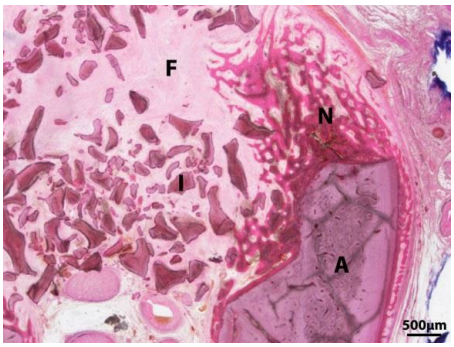
SYRINGE	Volume
IOLGS050	0.5 cc
IOLGS100	1.0 cc

Features & Benefits (cont'd)

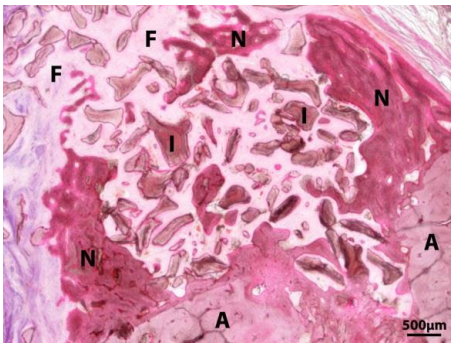
Osteoconductive

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.

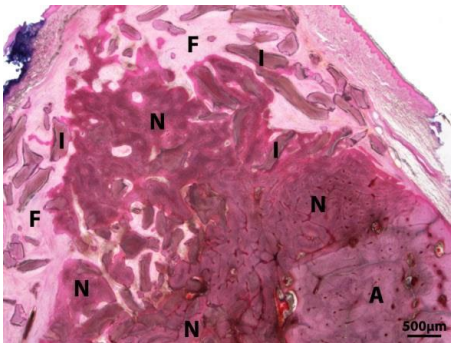
At 4 weeks:
Residual material with some woven bone formation (N) was observed.



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.



A Comparison Study with Bio-Oss®

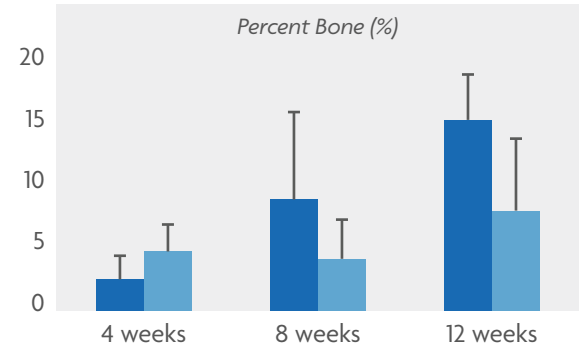


Figure 1, Histomorphometry
Percent Bone by Area (BA/DA)

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 Bio-Oss® (3.58% and 7.54%, respectively).

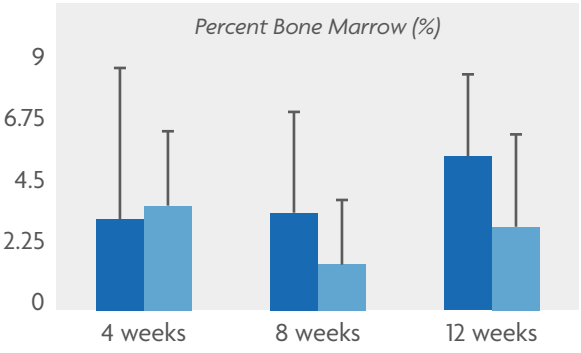


Figure 2, Histomorphometry
Percent Residual Graft by Area (GA/DA)

Overall, both InterOss®and Bio-Oss® 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 Bio-Oss®.

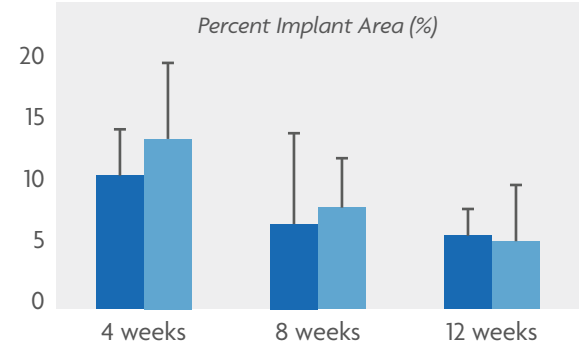
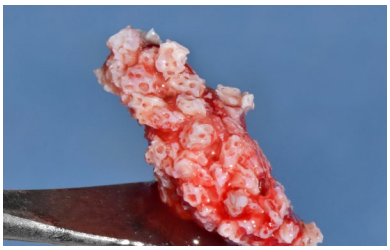


Figure 3, Histomorphometry
Bone Formation Density (BA/BMA)

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.

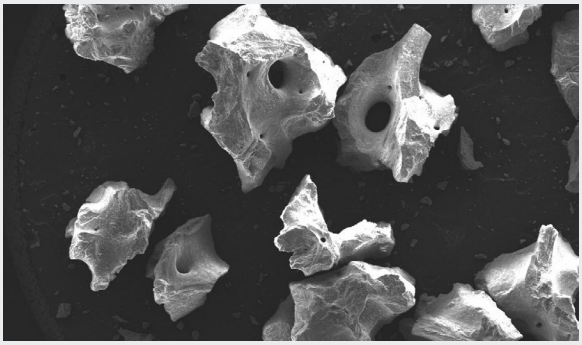
Application

- 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

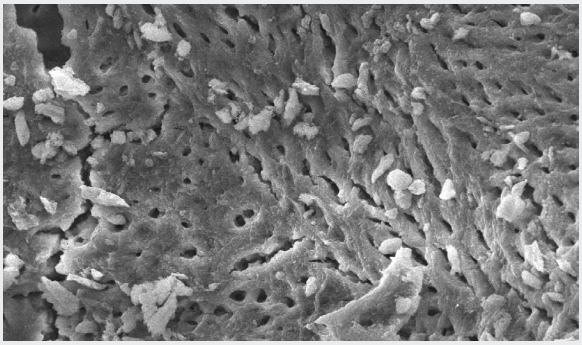
Properties

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.

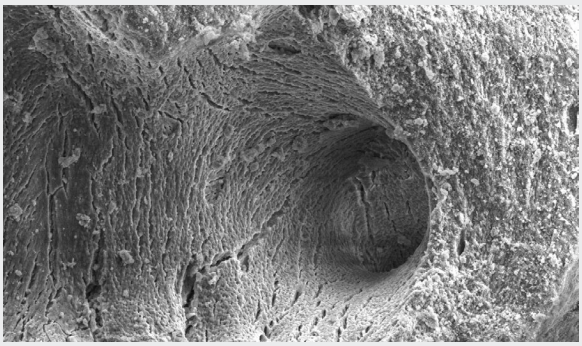
The existence of mesopores and micropores in the granules increases the inner surface area enhancing osteoconduction thus encouraging bone growth inside the pores.



1 mm



10 µm



100 µm

Alveolar ridge augmentation through guided bone regeneration

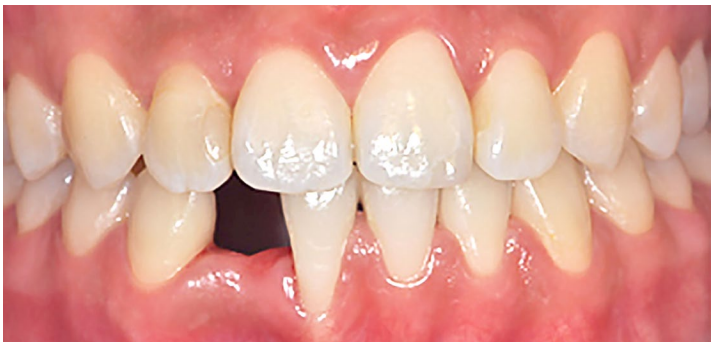
Dr. Byung Do Ham
Kainos Dental Clinic
South Korea

Objective

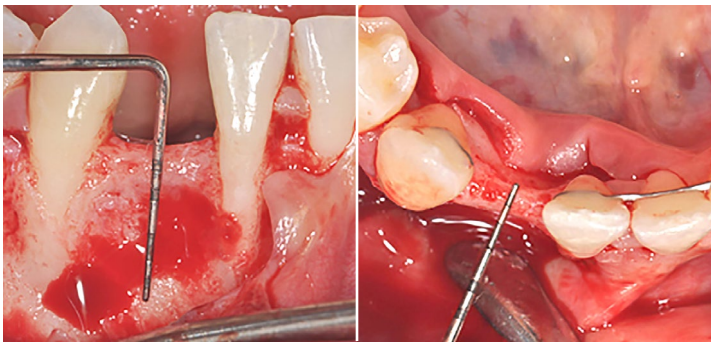
Patient was missing tooth number 42. It was determined that the missing tooth should be restored byimplant restoration.

Conclusion

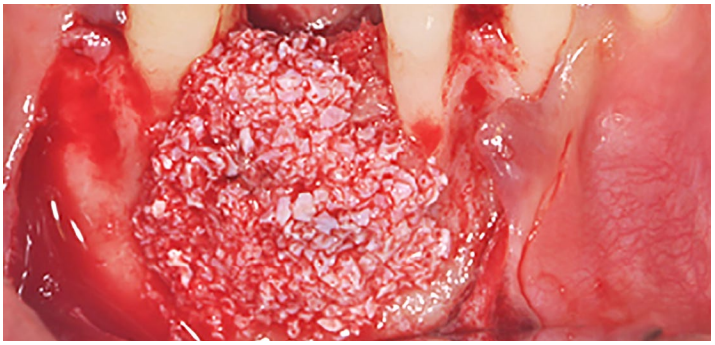
InterOss® actively induced new bone formation, and implant placement surgery was successful. Decalcified section showed a trabecular bony network with thick osteophyte formation.



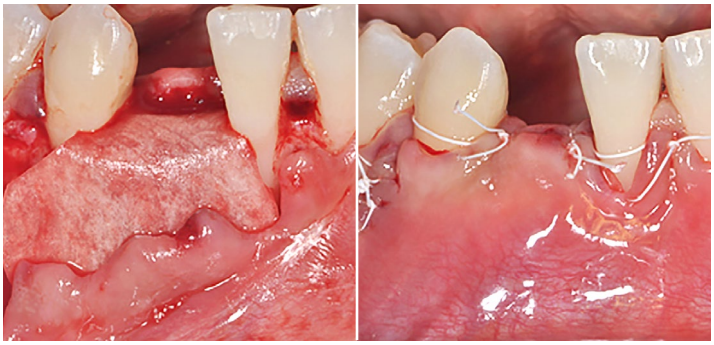
Pre-operative view.



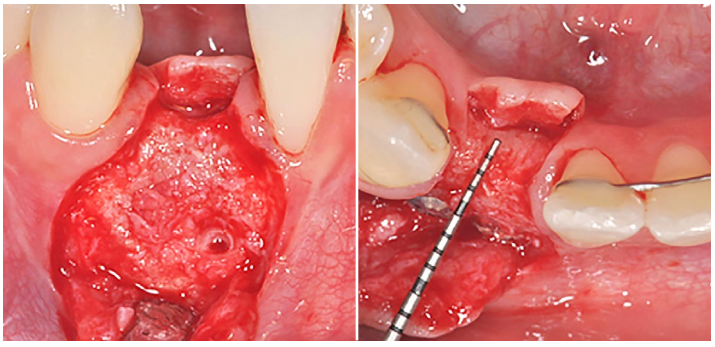
A view of the bone defect.



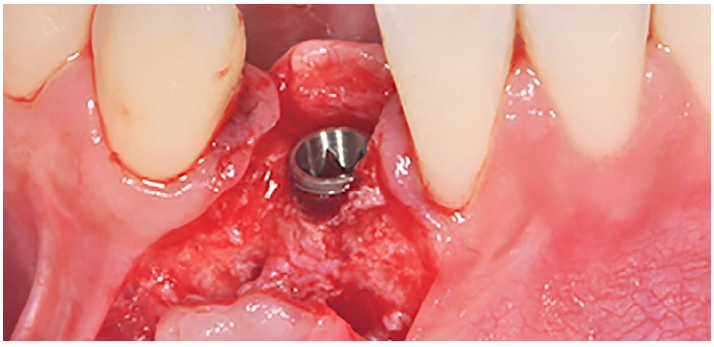
InterOss® placement.



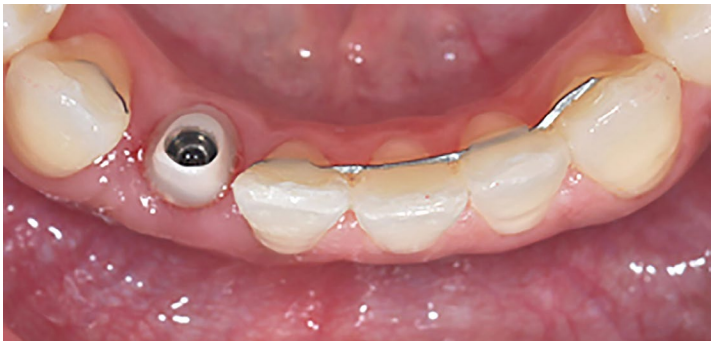
Membrane placement and immediate post-operative view.



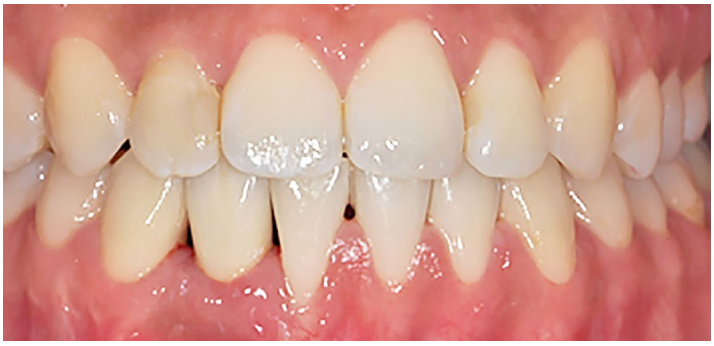
Post-operative view at 5 months.



Implant placement.



Post-operative view at 10 months.



Post-operative view at 10 months with crown installed.

Alveolar ridge augmentation through guided bone regeneration

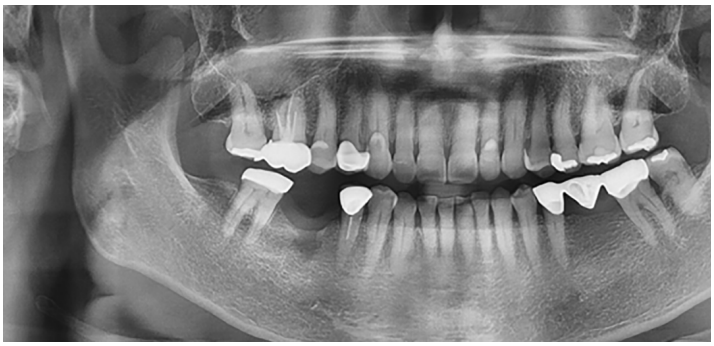
Dr. Byung Do Ham
Kainos Dental Clinic
South Korea

Objective

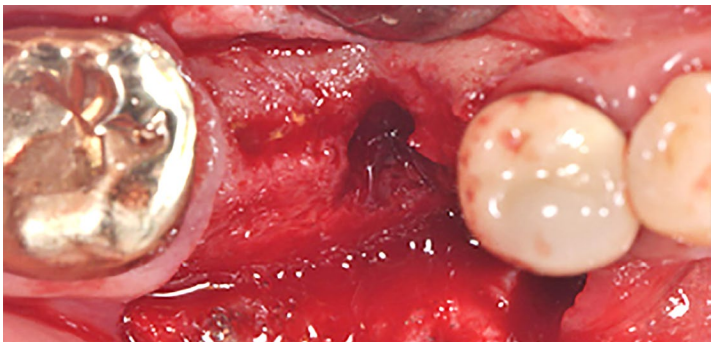
Patient was missing tooth number 46. It was determined that ridge augmentation was needed for implant placement.

Conclusion

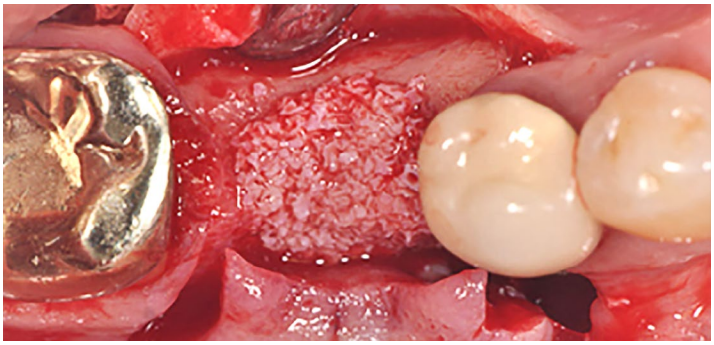
After 5 months of healing, implant placement surgery was performed and successful. Decalcified section showed active new bone formation on InterOss®. As InterOss® gradually resorbed, it subsequently induced osteogenic effect for excellent bone formation.



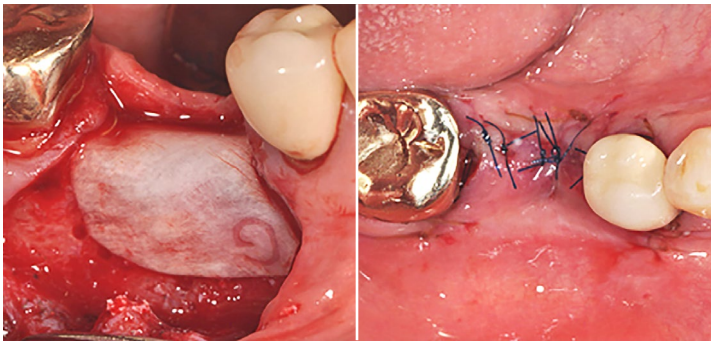
Pre-operative X-ray.



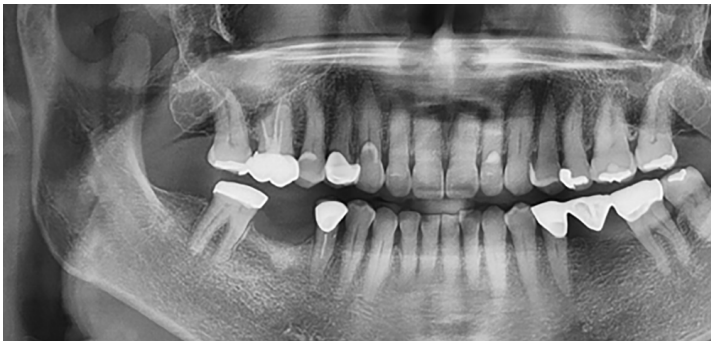
A view of the bone defect.



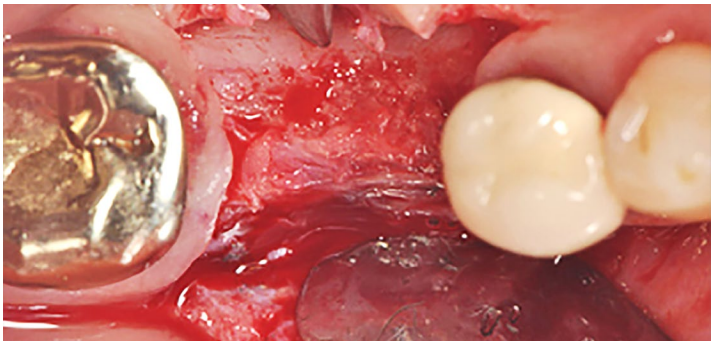
InterOss® placement.



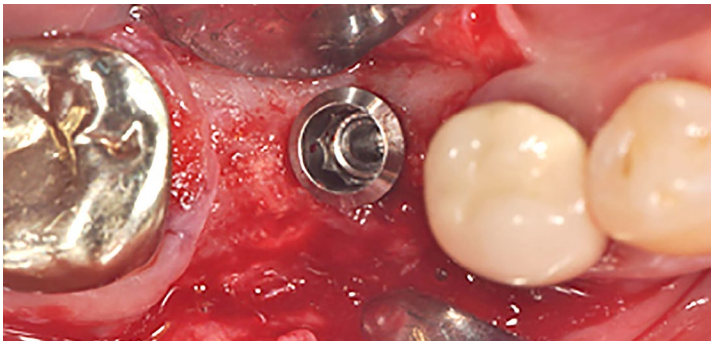
Membrane placement and immediate post-operative view.



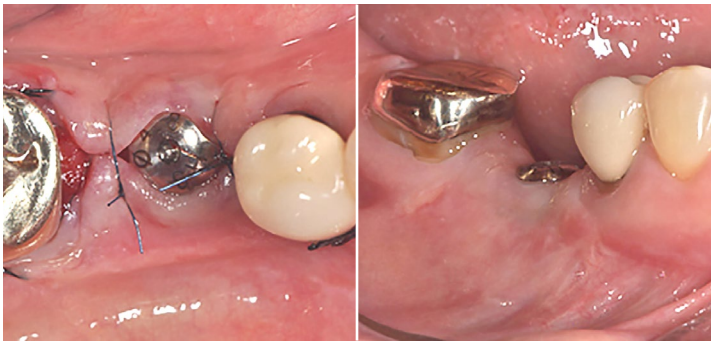
Post-operative X-ray at 4 months.



View at re-entry.



Implant placement.



Immediate post-loading view and 4 weeks after.

Vertical ridge augmentation through sinus floor elevation

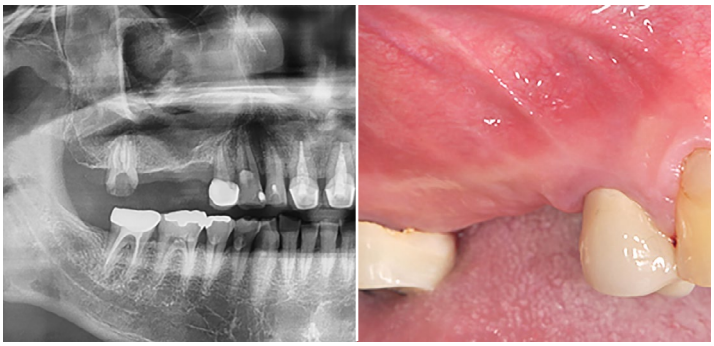
Dr. Byung Do Ham
Kainos Dental Clinic
South Korea

Objective

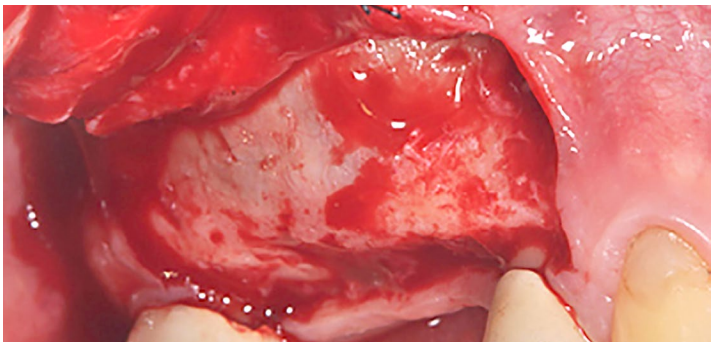
Patient suffered from missing tooth number 15 and 16.
It was determined sinus augmentation was necessary for implant placement surgery.

Conclusion

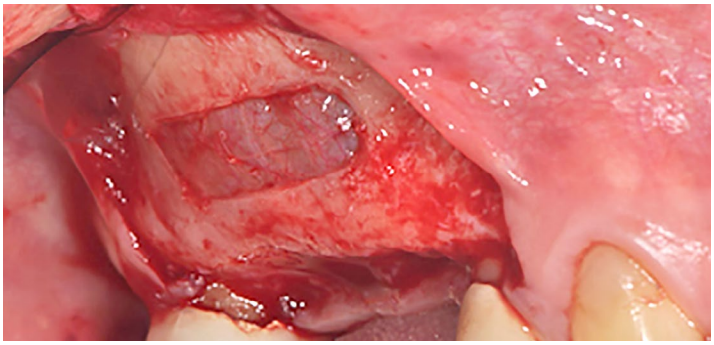
Decalcified section showed active new bone deposition on the xenogeneic graft bone (InterOss®). This graft lesion was clearly competent with favorable bony remodeling, still undergoing further new bone deposition.



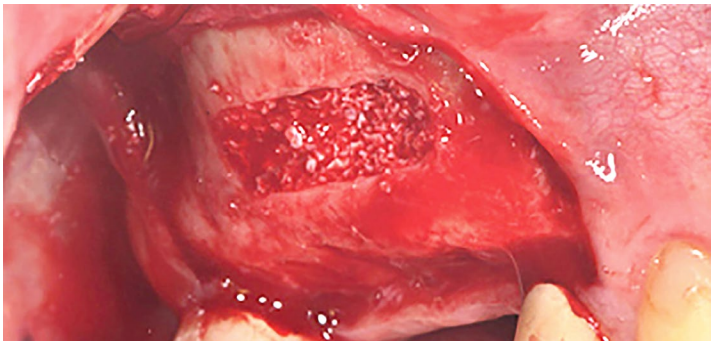
Pre-operative X-ray and view.



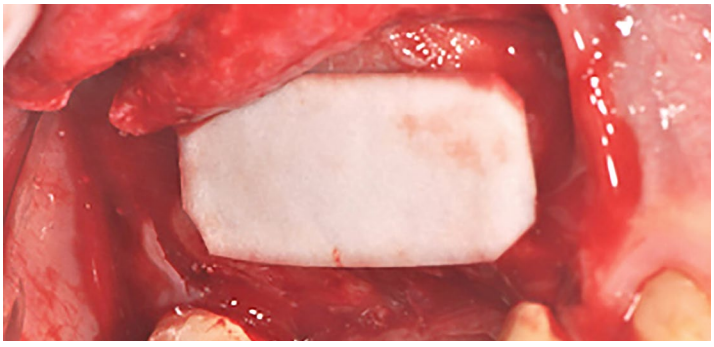
Exposure of the defect site.



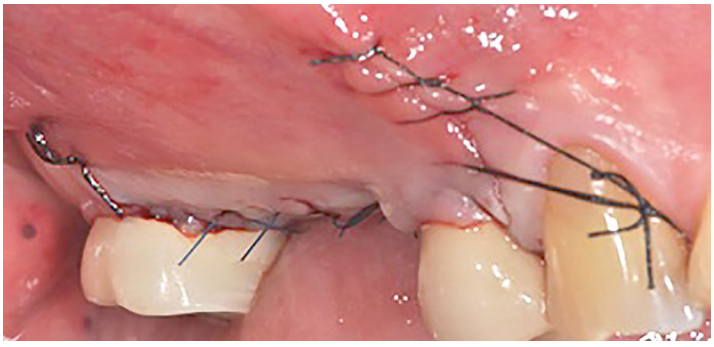
Sinus cavity exposure.



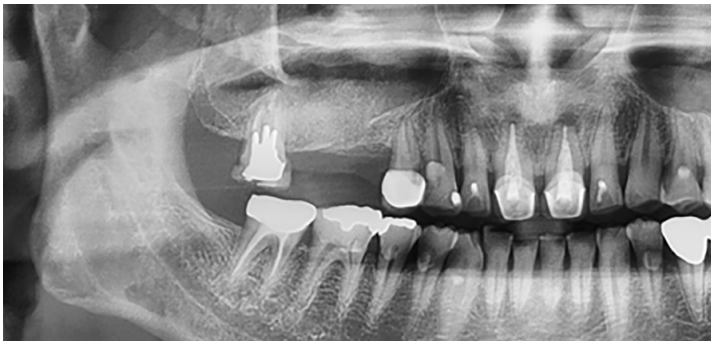
InterOss® placement.



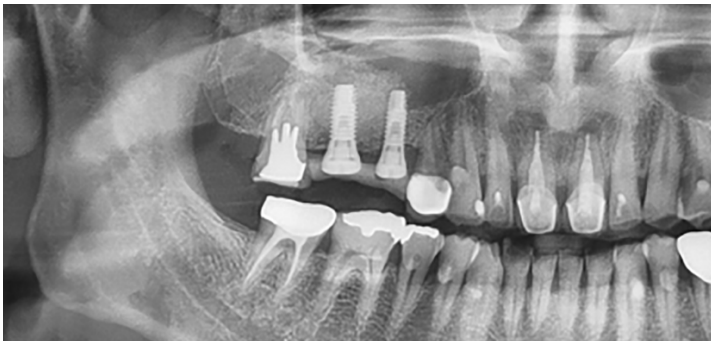
Membrane placement.



Immediate post-operative view.



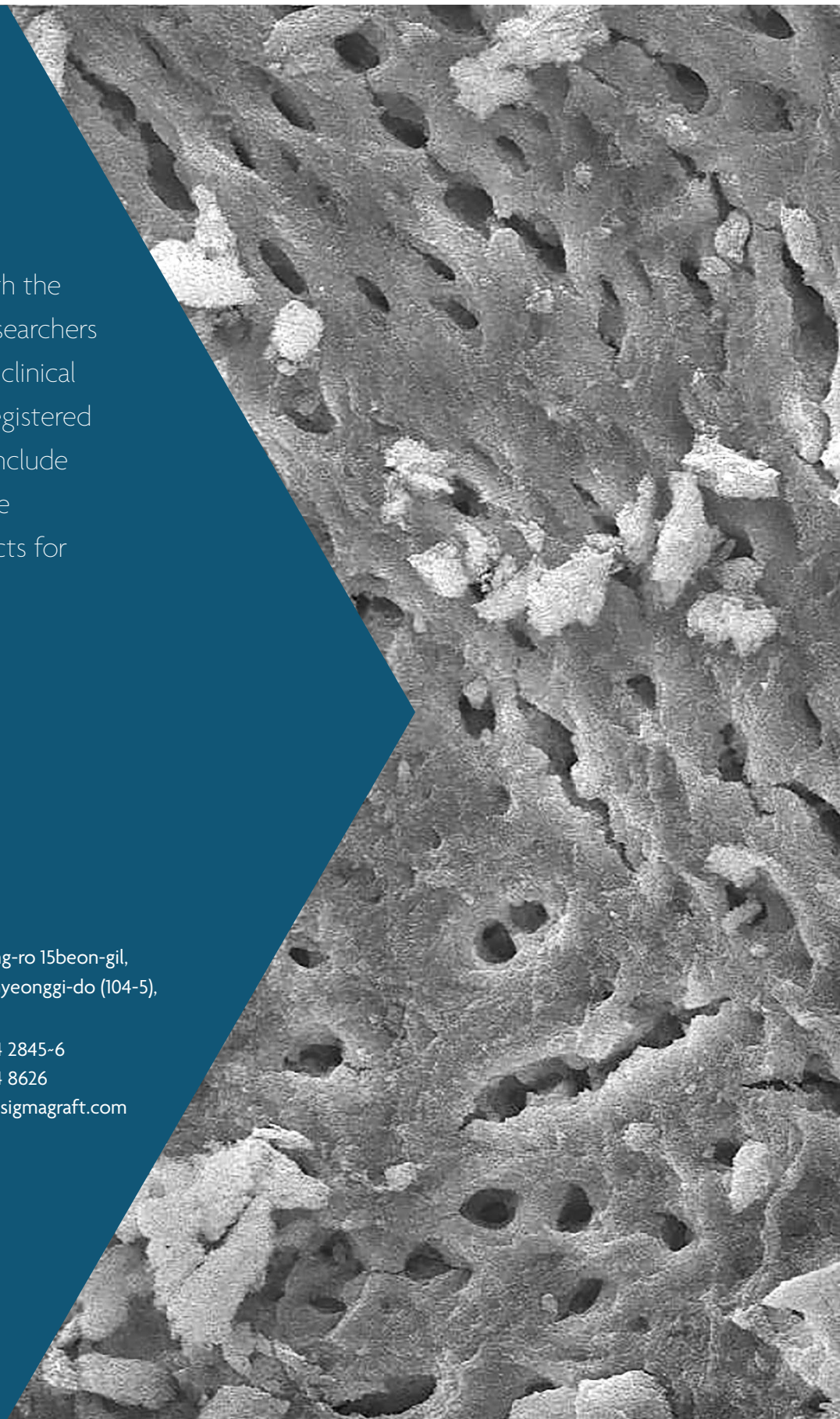
Post-operative X-ray at 1 week.



Post-operative X-ray at 7 months.

SigmaGraft

SCIENCE THAT NURTURES WELLNESS



SigmaGraft®, based in Fullerton, California, USA, collaborates with the world's leading clinicians and researchers to innovate products and build clinical experience. Our products are registered and sold worldwide, and they include bone grafting products for bone regeneration, membrane products for tissue regeneration, and more.

SigmaGraft, Inc. Headquarters
575 Sally Place
Fullerton, CA 92831
United States
www.SigmaGraft.com

USA Branch
1438 E. Valencia Dr.
Fullerton, CA 92831
United States
P: 888 499 0114 (toll free)
714 525 0114
F: 714 525 0116
E: info@sigmagraft.com

Asia Branch
13-8, Woldong-ro 15beon-gil,
Siheung-si, Gyeonggi-do (104-5),
South Korea
P: +82 31 434 2845~6
F: +82 31 434 8626
E: sgkorea@sigmagraft.com

MADE IN USA