

Contact:

Hub Biotech Co., Ltd.

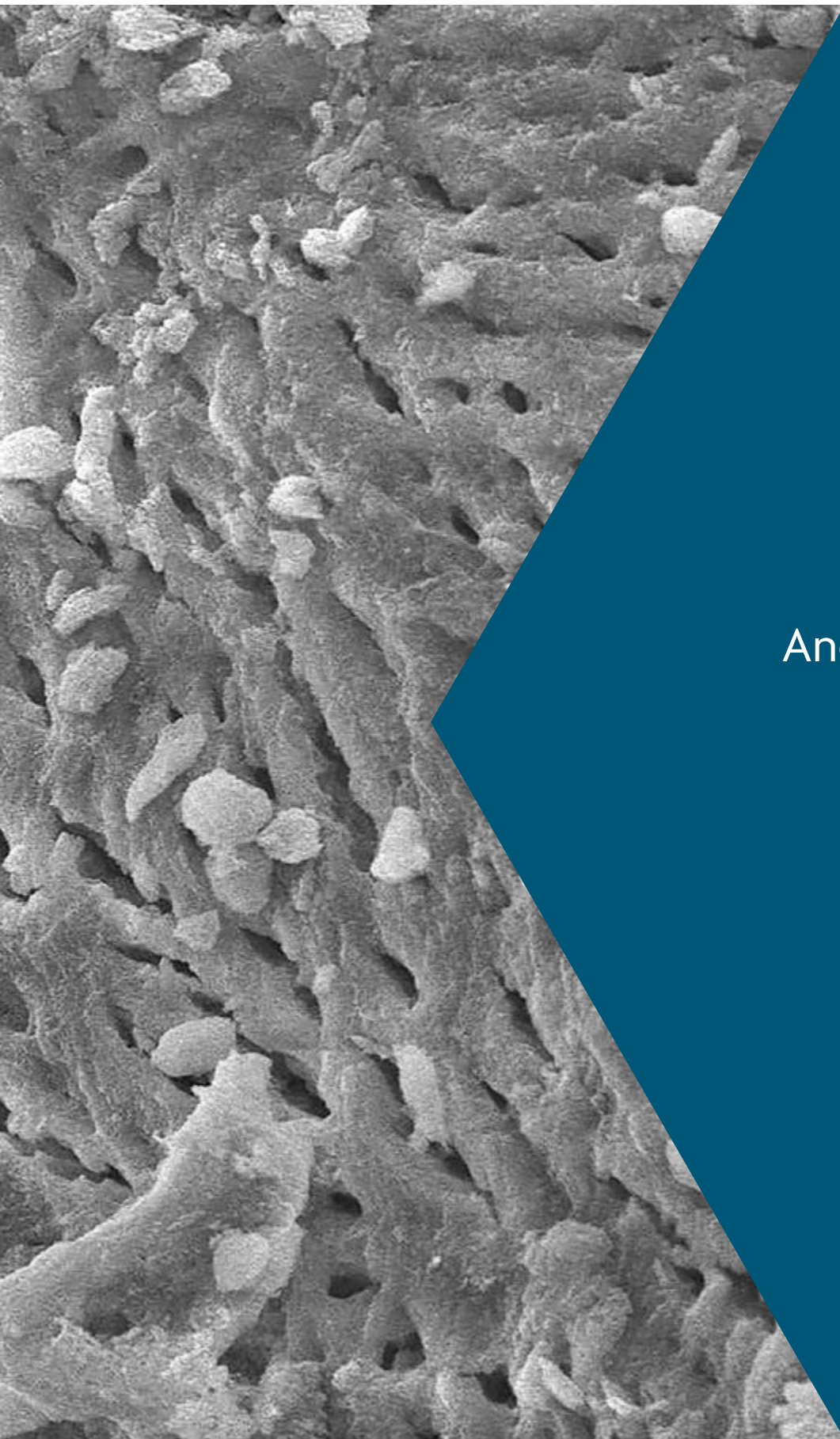
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SCIENCE THAT NURTURES WELLNESS

Made by  **SigmaGraft**



InterOss[®]

Anorganic Cancellous
Bone Granules



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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 of 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

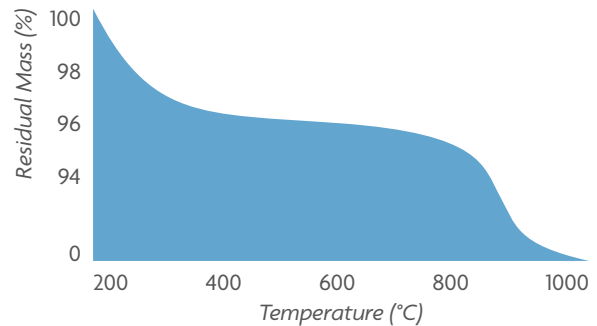
Small Granules (0.25 - 1.0 mm)

| VIAL | Volume | Weight | SYRINGE | Volume |
|---------|---------|--------|----------|---------|
| IOSG025 | 0.54 cc | 0.25 g | IOSGS025 | 0.25 cc |
| IOSG050 | 1.08 cc | 0.5 g | IOSGS050 | 0.5 cc |
| IOSG100 | 2.16 cc | 1.0 g | IOSGS100 | 1.0 cc |
| IOSG200 | 4.32 cc | 2.0 g | | |

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
- Microporosity facilitates proliferation of osteoblasts
- Macroporosity allows vascularization and plays important role in the osteoconductivity

Large Granules (1.0 - 2.0 mm)

| VIAL | Volume | Weight | SYRINGE | Volume |
|---------|--------|--------|----------|--------|
| IOLG050 | 2.0 cc | 0.5 g | IOLGS050 | 0.5 cc |
| IOLG100 | 4.0 cc | 1.0 g | IOLGS100 | 1.0 cc |
| IOLG200 | 8.0 cc | 2.0 g | | |

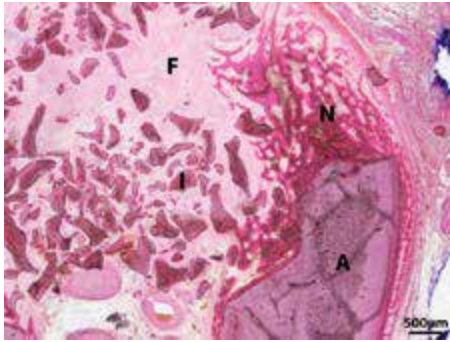
Features & Benefits (cont'd)

Osteoconductive

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

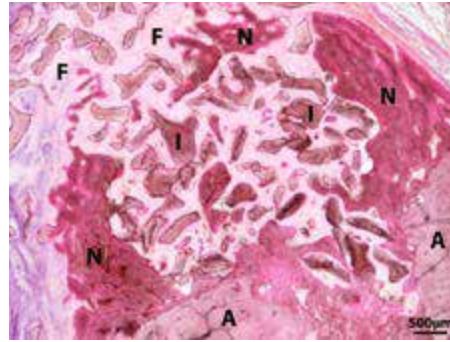
At 4 weeks:

Residual material with some woven bone formation (N) was observed.



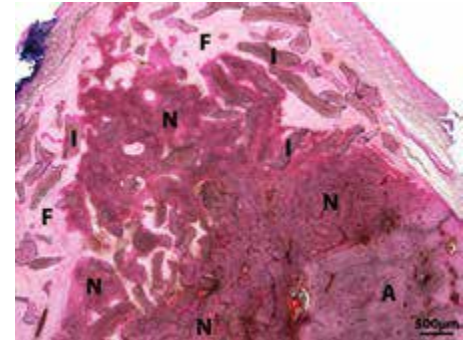
At 8 weeks:

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®

■ InterOss® ■ Bio-Oss®

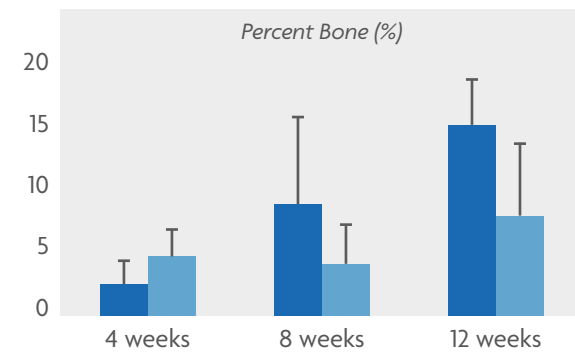


Figure 1, Histomorphometry
Percent Bone by Area (BA/DA)

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).

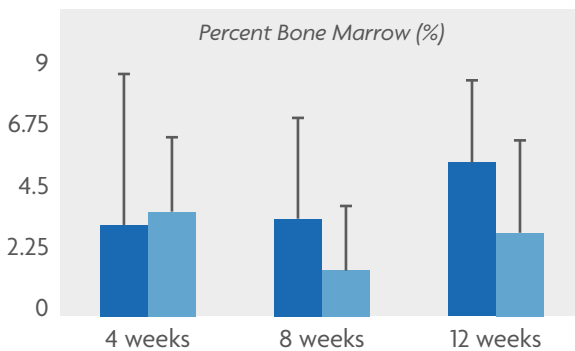


Figure 2, Histomorphometry
Percent Residual Graft by Area (GA/DA)

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®.

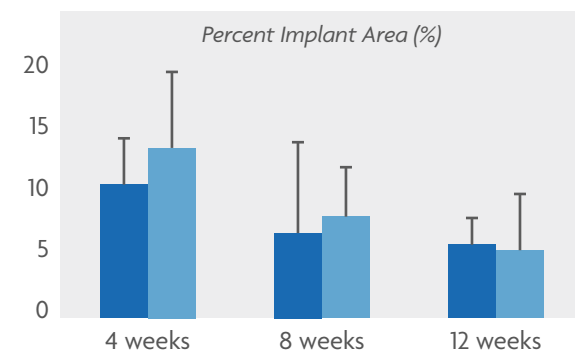
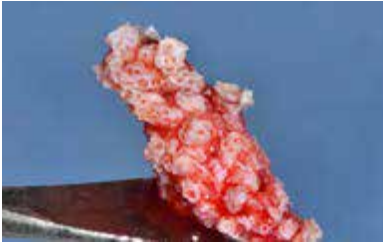


Figure 3, Histomorphometry
Bone Formation Density (BA/BMA)

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.

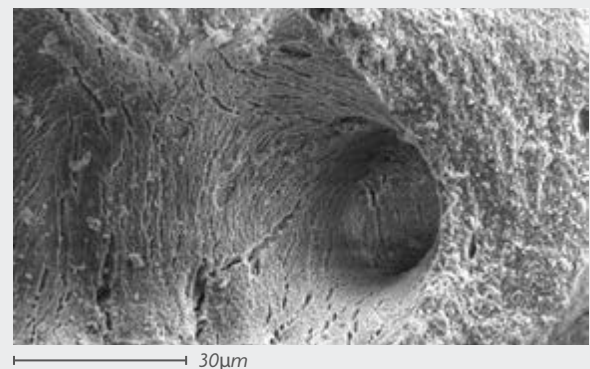
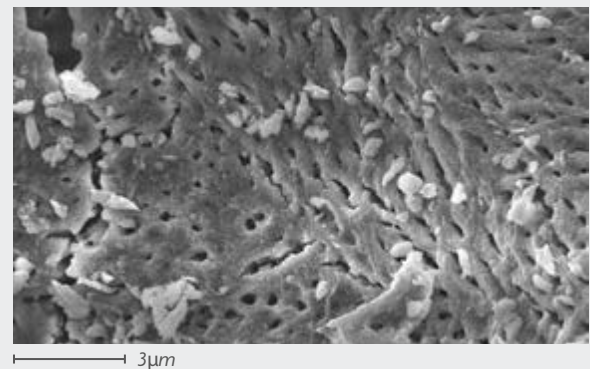
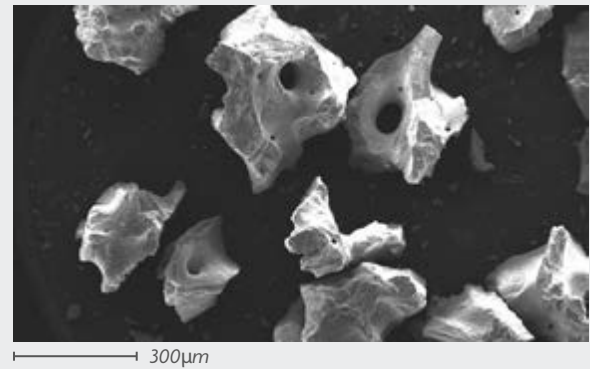
Application

- InterOss® can be administered to the surgical site after hydration using a surgical curette 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 osseointegration 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.



Alveolar ridge augmentation through guided bone regeneration

Dr. Byung Do Ham
Kainos Dental Clinic
South Korea

Objective

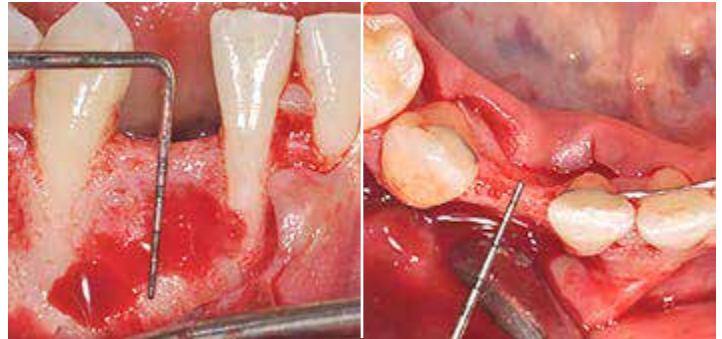
Patient was missing tooth number 42. It was determined that the missing tooth should be restored by implant restoration.

Conclusion

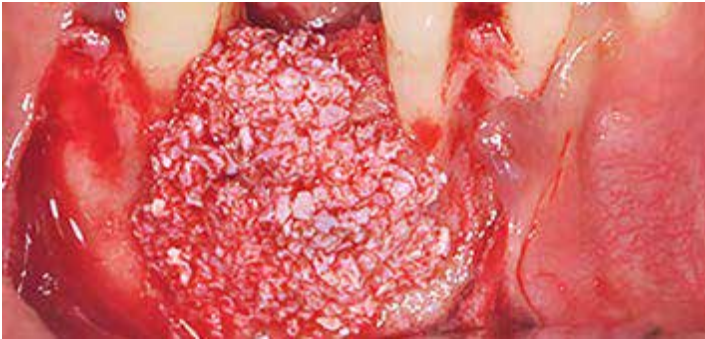
InterOss® actively induced new bone formation, and implant placement surgery was successful. Decalcified section showed a trabecular bony network with thick osteophyte formation.



Pre-operative view.



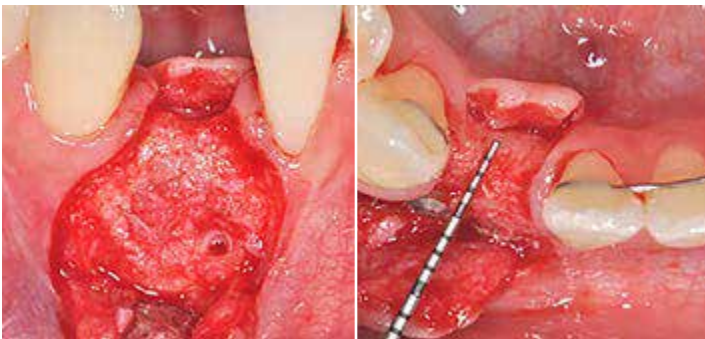
A view of the bone defect.



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.



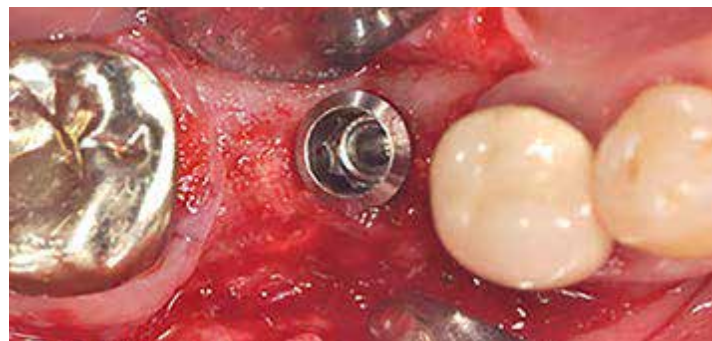
Pre-operative X-ray.



InterOss® placement.



Post-operative X-ray at 4 months.



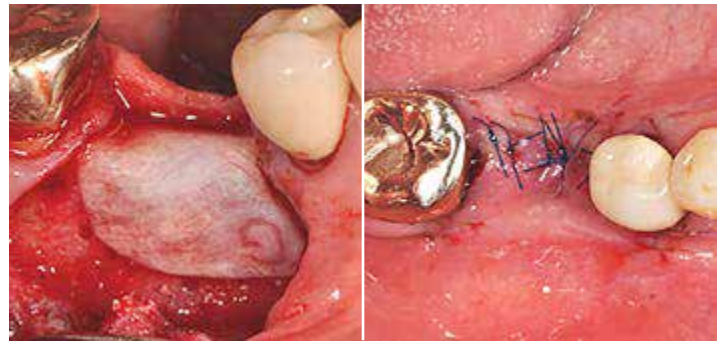
Implant placement.

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.



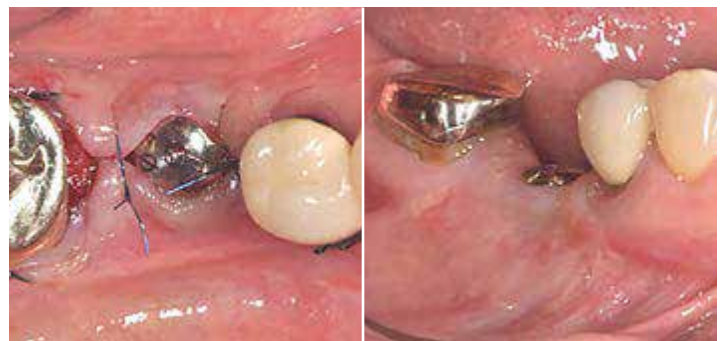
A view of the bone defect.



Membrane placement and immediate post-operative view.



View at re-entry.



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

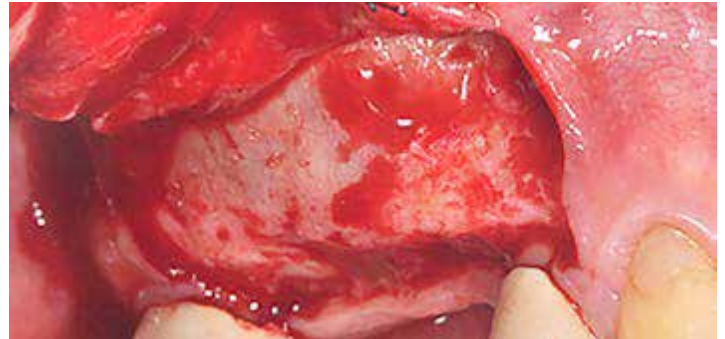
Patient suffered from missing tooth number 15 and 16.
It was determined sinus augmentation was necessary for implant placement surgery.

Conclusion

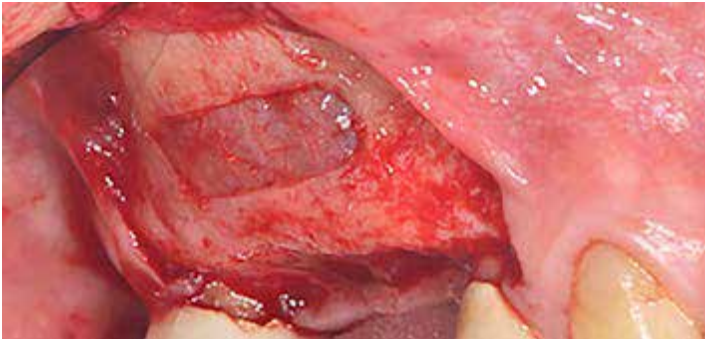
Decalcified section showed active new bone deposition on the xenogeneic graft bone (InterOss®). This graft lesion was clearly competent with favorable bony remodeling, still undergoing further new bone deposition.



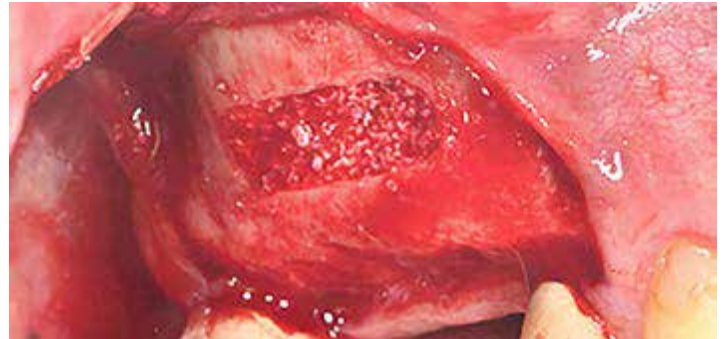
Pre-operative X-ray and view.



Exposure of the defect site.



Sinus cavity exposure.



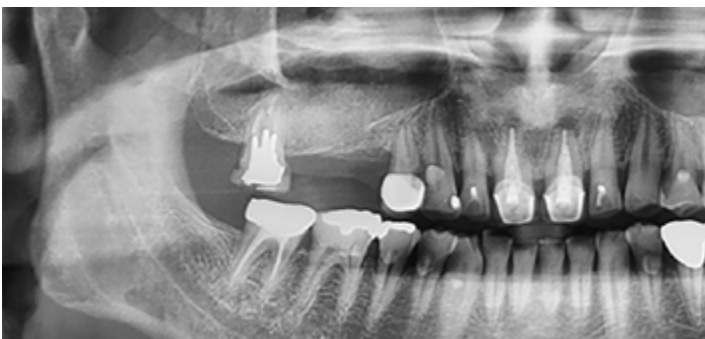
InterOss® placement.



Membrane placement.



Immediate post-operative view.



Post-operative X-ray at 1 week.



Post-operative X-ray at 7 months.

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InterOss[®] Collagen

Anorganic Bone-Collagen
Composite



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InterOss® Collagen

Anorganic Bone-Collagen Composite



InterOss® Collagen is anorganic hydroxyapatite-collagen composite for use in periodontal, oral, and maxillofacial surgery. It is a combination of 90% bovine granules and 10% collagen fibers molded into a block and plug form.

InterOss® granules exhibits a natural mineralized bone structure, similar to human bone, and provides an osteoconductive environment for the ingrowth of the adjacent viable bone. Its excellent porosity allows the grafting material to act as a conduit for the exchange of body fluids and growth factors while allowing cells to guide bone formation. Highly purified collagen facilitates the adaptation of the these granules to the defect site, bringing about exceptional handling and ease of use.

Indications for Use

InterOss® Collagen is indicated for the filling of extraction sockets to enhance the preservation of the alveolar ridge. The product is recommended for:

- Filling of extraction sockets to enhance preservation of alveolar ridge
- Filling of periodontal defects in conjunction with products intended for guided tissue regeneration (GTR) and guided bone regeneration (GBR)

Features & Benefits

Slow Degradation Time

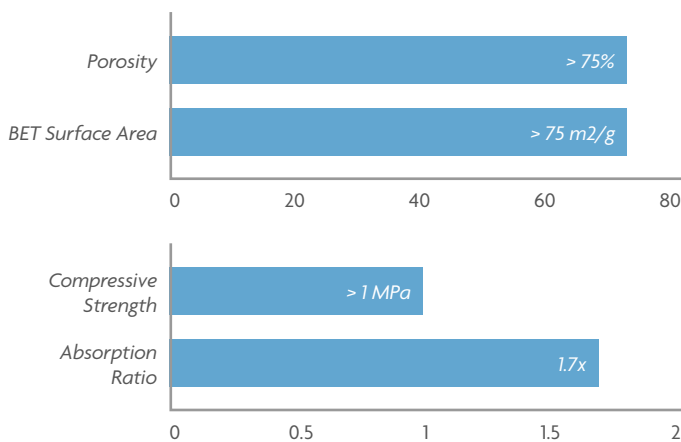
The collagen-hydroxyapatite composite is substantially resorbed by 12 weeks in a canine model with less than 10% article remained at the defect site.

Easy Handling & Application

Superior absorption properties allowing easier handling and trimming.

Adaptable Shape

Cuboid and cylindrical shaped structure allows it to adapt to the defect site when wet.

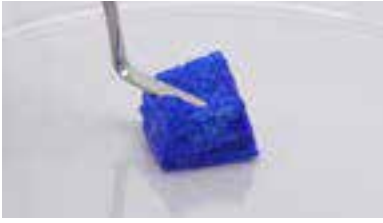


Available in the following options

| PLUG | Size | Weight |
|----------|-----------|--------|
| IOC-P150 | 6 x 10 mm | 150 mg |
| IOC-P250 | 8 x 10 mm | 250 mg |

| BLOCK | Size | Weight |
|---------|----------------|--------|
| IOC-50 | 6 x 6 x 3 mm | 50 mg |
| IOC-100 | 6 x 6 x 6 mm | 100 mg |
| IOC-250 | 7 x 8 x 9 mm | 250 mg |
| IOC-350 | 8 x 9 x 10 mm | 350 mg |
| IOC-500 | 9 x 10 x 12 mm | 500 mg |

Application & Handling



Hydration

InterOss® Collagen 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® Collagen coupled with the biological potential of allograft may yield enhanced bone regeneration.

For Use with Autologous Bone

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

Application

- InterOss® Collagen can be trimmed to the desired dimensions both in a dry state or after hydration using forceps and a pair of scissors.
- 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

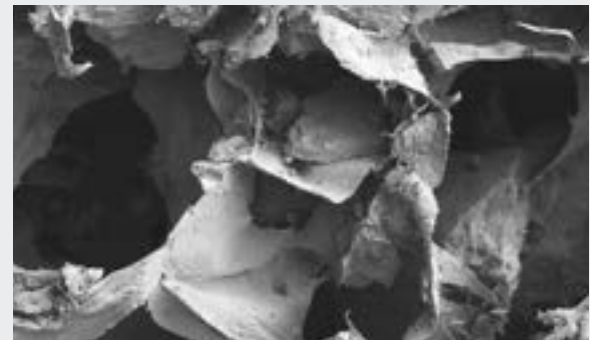
Properties

| Attribute | Description |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| Composition | 90% Calcium phosphate (100% pure hydroxyapatite, mineral phase) 10% Type I Collagen |
| Integration time | 6 - 9 months (depending on defect) |
| Storage temperature | 59 - 86 °F / 15 - 30 °C |
| Degradation profile | Bovine hydroxyapatite enclosed within a collagenous matrix enables slower degradation and enhanced osseo-integration of particles into a new bone. |

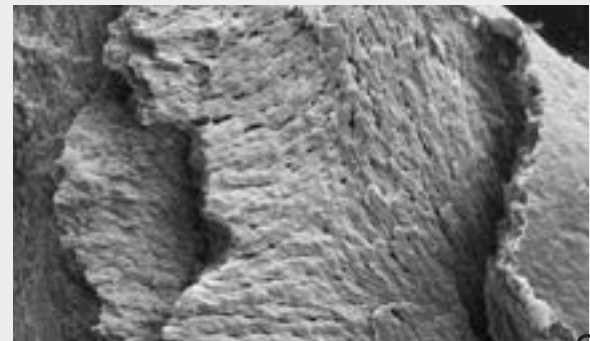
Its multi-porous matrix helps facilitate nutrient exchange and the development of nerve and blood vessel, allowing the formation of dense bone structure.



1 mm



200 μm



20 μm

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Objective

To minimize soft tissue shrinkage and the amount of bone graft used during the implant, socket grafting was indicated, and densely packed InterOss® Collagen blocks can fulfill these goals. The open wound can then be covered by a couple layers of InterCollagen® Guide.

Conclusion

The extraction socket was successfully maintained by this simple procedure, reducing patient's morbidity by minimizing the extent of surgery at the time of implant placement. Chronic fistula should not pose any trouble as long as it does not have an active infection.



Post-operative view.



Post-extraction view.



InterOss® Collagen placement.



Immediate post-operative view.



Post-operative view at 4 months.



View at re-entry.



Implant placement.



Immediate post-loading view.

Objective

To minimize soft tissue shrinkage and the amount of bone graft used during the implant, socket grafting was indicated, and densely packed InterOss® Collagen blocks can fulfill these goals. The open wound can then be covered by a couple layers of InterCollagen® Guide.

Conclusion

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Post-operative view.



Post-extraction view.



InterOss® Collagen placement.



Immediate post-operative view.



Post-operative view at 4 months.



View at re-entry.



InterOss® and implant placement.



Immediate post-loading view.

Ankylosed tooth extraction and socket preservation

Dr. Yong Dae Kwon
Kyung Hee University, School of Dentistry
South Korea

Objective

Maintaining the form of the socket post-extraction was necessary as the #11 tooth had been traumatized and internal resorption was seen in the long-term follow-up.

Conclusion

Two InterOss® Collagen blocks were inserted and an InterCollagen® Guide was applied to cover them. Although a chronic fistula was seen, a socket graft procedure can be performed as long as no acute inflammation nor suppuration were identified. The blocks were firm enough to maintain the socket form and were easy to handle and trim with a scalpel.



Pre-operative X-ray.



Chronic fistula detected near the affected tooth.



Extraction of ankylosed tooth.



Post-extraction view.



InterOss® Collagen placement.



InterCollagen® Guide placement.



InterCollagen® Guide wrapped over the block.



Immediate post-operative view.

Vertical ridge augmentation through sinus floor elevation

Dr. Yong Dae Kwon
Kyung Hee University, School of Dentistry
South Korea

Objective

In order to reconstruct the missing teeth in the right posterior maxilla, a sinus lift surgery was planned via lateral window technique because of major loss of alveolar bone in the region.



Pre-operative X-ray and CBCT scan.



Exposure of the defect site.



Lateral window preparation (continued).



Exposure of the sinus cavity.



InterOss® placement.



InterCollagen® Guide placement.



Post-operative X-ray and CBCT scan.

Conclusion

A lateral window sinus lift is a safe and predictable procedure, and InterOss® is a good bone substitute with good handling. To prevent the soft tissue ingrowth to the graft, the window in the lateral wall should be covered by an InterCollagen® Guide.

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SCIENCE THAT NURTURES WELLNESS

Made by  **SigmaGraft**[®]

InterCollagen[®] Guide

Resorbable Collagen Membrane



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InterCollagen® Guide

Resorbable Collagen Membrane

InterCollagen® Guide is a porcine-derived resorbable collagen membrane intended for periodontal and/or dental surgeries. When used in conjunction with a graft material for a guided bone regeneration procedure, the membrane acts as a barrier that restricts the entry of rapidly proliferating non-osteogenic cells within the bony defect while allowing the ingrowth of slow-growing bone-forming cells. This resorbable barrier gets remodeled and/or incorporated by the host tissue.

InterCollagen® Guide's dense fibrous architecture enhances mechanical strength and increases durability, and yet it is easily sutured, highly drapable, and can be trimmed to the required size.

Indications for Use

InterCollagen® Guide, alone or in combination with suitable augmentation materials e.g. autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials, can be used in guided bone regeneration (GBR) and guided tissue regeneration (GTR) procedures as a biodegradable barrier:

- In the context of a treatment of fenestration defects
- In case of dehiscence defects
- After apicoectomy and resection or retained teeth
- In extraction sockets after tooth extractions
- In case of immediate or delayed augmentation around implants in extraction sockets

Available in the following sizes

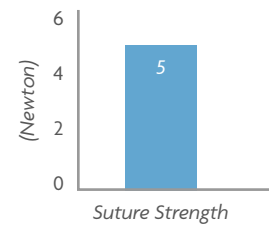
| SKU | Size |
|---------|------------|
| ICG1520 | 15 x 20 mm |
| ICG2030 | 20 x 30 mm |
| ICG3040 | 30 x 40 mm |



Features & Benefits

High Suture Strength

Despite a low thickness of 0.13 mm, the membrane retains a high suture strength of at least 5N due to minimal processing.



Slow Degradation Time

The resorbable membrane is substantially resorbed by 13 weeks in a canine model.

Easy Handling & Application

Can be easily trimmed to size in dry or wet conditions; drapable and can be pinned and sutured.

Dual Function

Bilayer structure provides dual function:

- Smooth side acts as a barrier that prevents soft tissue growth
- Open-pore structure on the rough side facilitates growth of bone forming cells, nerve, and blood vessels

Application & Handling

Hydration

InterCollagen® Guide can be hydrated in blood or sterile saline solution. It can also be applied dry, a common method used with application of the graft material in lateral augmentation of defects on the outer ridge contour. The InterCollagen® Guide can adapt to any surface contours and can be easily repositioned should the need arise.

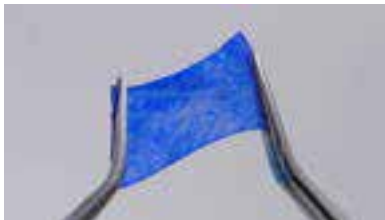


Placement

InterCollagen® Guide has a bilayer structure which provides dual function. One side has a smooth texture which acts as a barrier to prevent soft tissue growth while the other side, rougher in texture with open pores, facilitates the ingrowth of bone forming cells, nerve, and blood vessels. Although not required, it is recommended to place the smooth side towards the gingiva and the rough side towards the bone for maximum results. Trim and place InterCollagen® Guide to overlap the defect by at least 2-3 mm to prevent lateral ingrowth of gingival connective tissue.

Shaping

InterCollagen® Guide can be trimmed to the desired dimensions using a pair of scissors when needed. It could also be beneficial to use templates when trimming in order to minimize waste.



Fixation

Regardless of the direction of the stretch, InterCollagen® Guide demonstrates an exceptional tear resistance. It can be pinned, sutured, or even screwed effortlessly without rupturing. Because of this reason, additional fixation is unnecessary in most cases due to the outstanding drapability of the membrane to the bony walls.

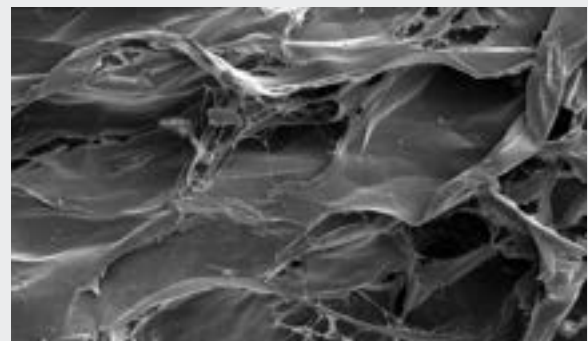
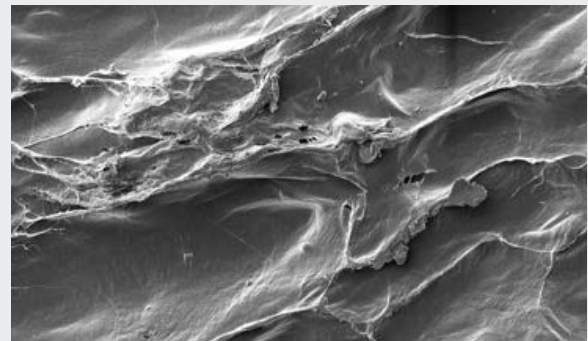
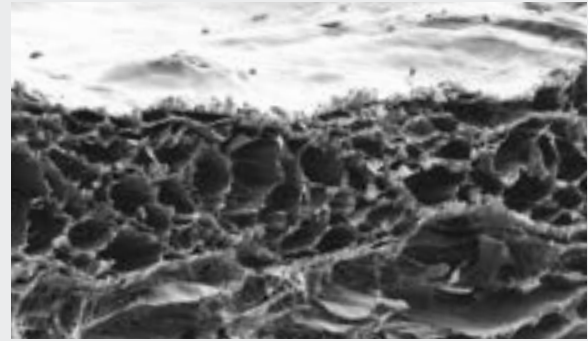
Exposure

As much as possible, avoid the exposure of InterCollagen® Guide since bacterial resorption will substantially decrease the efficacy of the membrane to act as a barrier. Should a dehiscence occur, formation of free granulation tissue usually can still help heal the wound without complications.

Properties

| Attribute | Description |
|---------------------|---------------------------------------------------------------------------------------------------|
| Source | Porcine pericardium |
| Composition | Native collagen type I and III |
| Thickness | 0.1 - 0.3 mm |
| Structure | Natural multilayered collagen structure |
| Storage temperature | 59 - 86 °F / 15 - 30 °C |
| Degradation time | 13 weeks in a canine model |
| Fixation | Generally not required due to good surface adaptation, but possible (pinning, suturing, screwing) |

The multi-scale porous structure provides favorable environment for the growth of cells and tissues and formation of extracellular matrix (ECM) while also allowing nutrient exchange and blood vessel ingrowth.



Ankylosed tooth extraction and socket preservation

Dr. Yong Dae Kwon
Kyung Hee University, School of Dentistry
South Korea

Objective

Maintaining the form of the socket post-extraction was necessary as the #11 tooth had been traumatized and internal resorption was seen in the long-term follow-up.

Conclusion

Two InterOss® Collagen blocks were inserted and an InterCollagen® Guide was applied to cover them. Although a chronic fistula was seen, a socket graft procedure can be performed as long as no acute inflammation nor suppuration were identified. The blocks were firm enough to maintain the socket form and were easy to handle and trim with a scalpel.



Pre-operative X-ray.



Chronic fistula detected near the affected tooth.



Extraction of ankylosed tooth.



Post-extraction view.



InterOss® Collagen placement.



InterCollagen® Guide placement.



InterCollagen® Guide wrapped over the block.



Immediate post-operative view.

Vertical ridge augmentation through sinus floor elevation

Dr. Yong Dae Kwon
Kyung Hee University, School of Dentistry
South Korea

Objective

In order to reconstruct the missing teeth in the right posterior maxilla, a sinus lift surgery was planned via lateral window technique because of major loss of alveolar bone in the region.



Pre-operative X-ray and CBCT scan.



Exposure of the defect site.



Lateral window preparation (continued).



Exposure of the sinus cavity.



InterOss® placement.



InterCollagen® Guide placement.



Post-operative X-ray and CBCT scan.

Conclusion

A lateral window sinus lift is a safe and predictable procedure, and InterOss® is a good bone substitute with good handling. To prevent the soft tissue ingrowth to the graft, the window in the lateral wall should be covered by an InterCollagen® Guide.

Secondary guided bone regeneration at previously grafted site

Dr. Yong Dae Kwon
Kyung Hee University, School of Dentistry
South Korea

Objective

Local inflammation and compromised healing may cause focal loss of bone graft. To repair the loss, a secondary focal bone grafting can be done.

Conclusion

To maintain the additional bone substitute on the defect area, a malleable block-type of bone graft may be a good option rather than particulate-type. Coverage with an InterCollagen® Guide membrane can reduce soft tissue ingrowth.



Post-operative view.



A view of the bone defect.



InterOss® Collagen placement.



InterCollagen® Guide placement.



Flap has been apically positioned.



Additional transpositional flap created from the palate.

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If you are interested in purchasing the products or becoming a local distributor, please contact us.