[Absorbable Collagen Membrane for Dental Surgery]

OssGuide

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Contents

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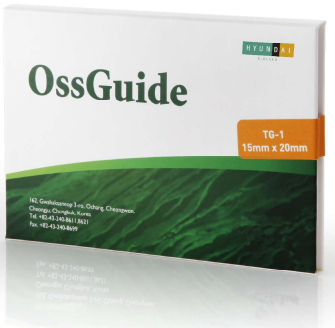
Ⅰ. OssGuide Product Description

- Product Name: OssGuide
- Description: Absorbable collagen membrane
- Intended use: The dental device used for guided tissue regeneration procedures in periodontal defects.
- Shelf-life: 36 months
- Characteristics of the product

  OssGuide is made of pure type I collagen derived from porcine pericardium to minimize antigenicity. It helps regeneration of periodontal tissue.
- Order information

Model	Width x Length(mm)
TG-1	15 x 20 ㎜
TG-2	20 x 30 ㎜
TG-3	30 x 40 ㎜



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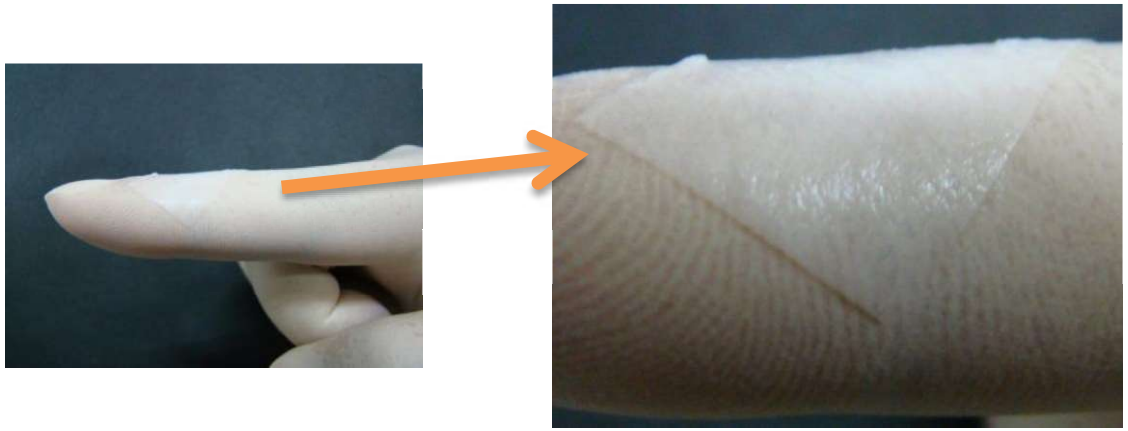
- **Characteristics of the product**
  - Natural collagen structure.
  - Good adaptation to various shapes of any defect.
  - High tear resistance in oral surgery.
  - Good handling properties and Easy to cut or shape.
  - Excellent assistance for fast blood supply to the defect.
  - Prolonged barrier function of 3~5 months.
  - Fast hydration, It can be used with no hydration.
  - No need of distinction, either side can be placed against the defect.



1. Biocompatible and safe
2. Integrates with tissues
3. Cell occlusivity
4. Good handling

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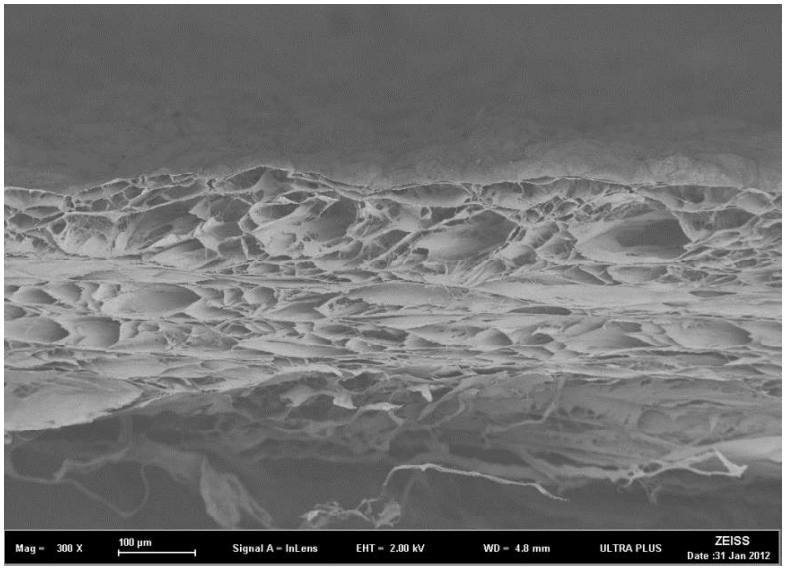
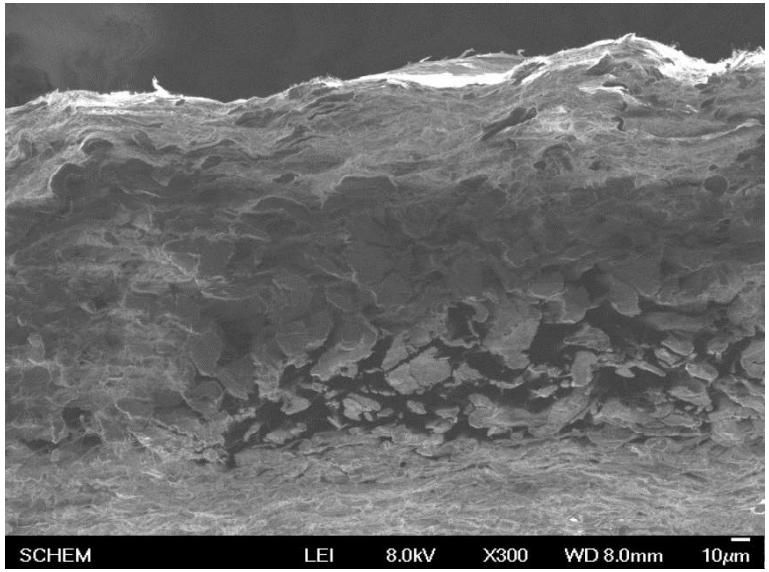
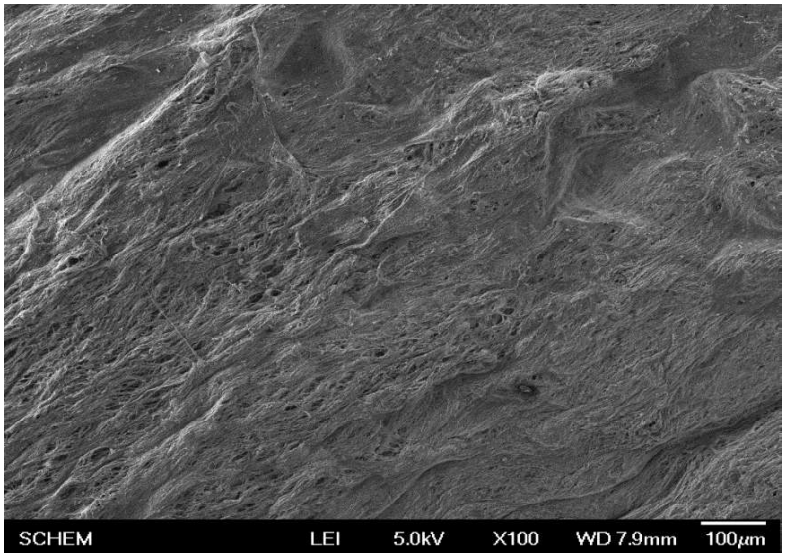
Micro pore structure (SEM)



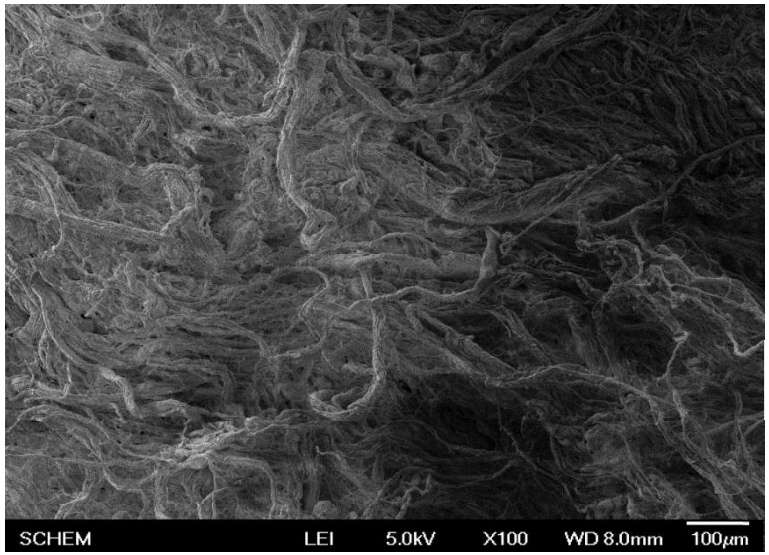
The cross-section (OssGuide)



The cross-section (A product)



The plain (OssGuide)



The plain (A product)

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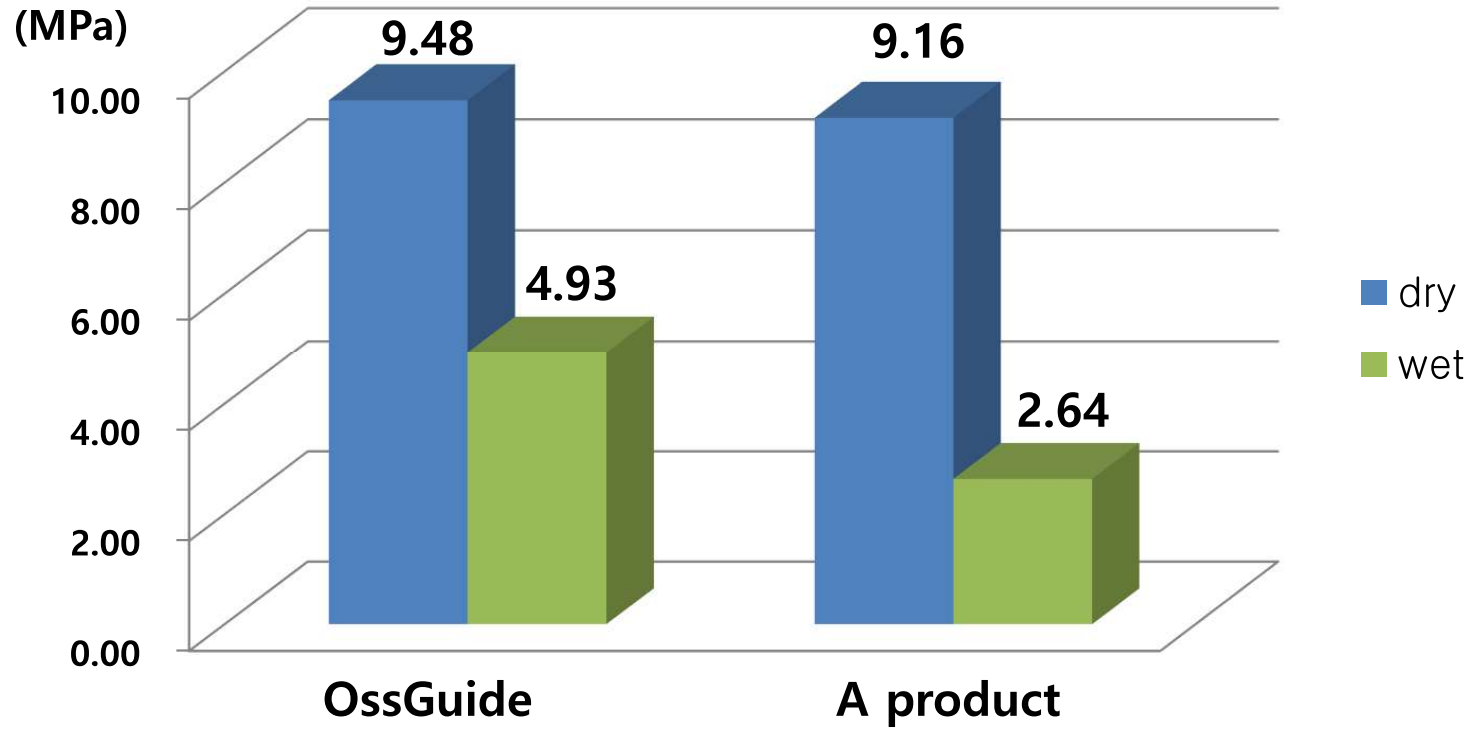
The comparison of Tensile strength



- OssGuide has a higher tensile strength than similar products, therefore providing high tear resistance in oral surgery.
- It has good handling properties.

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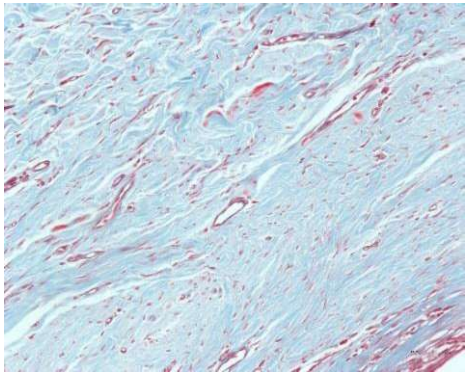
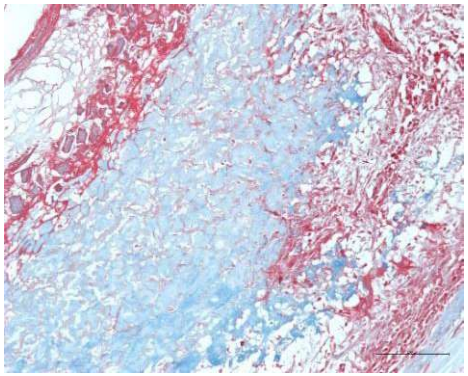
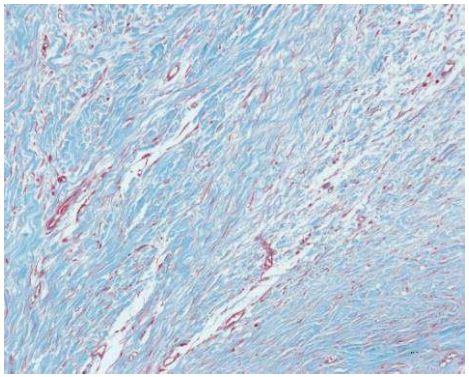
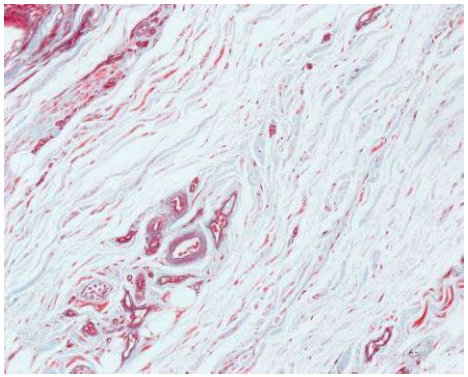
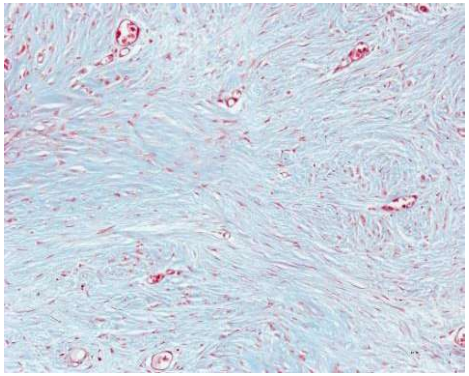
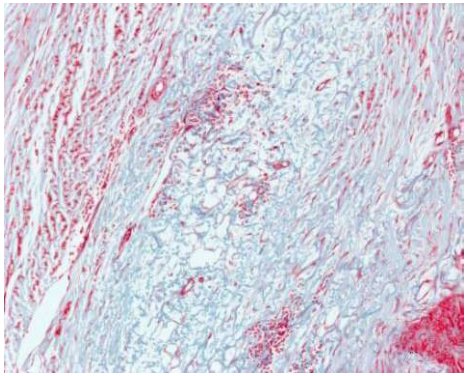
Ⅱ. OssGuide Animal Study 1

※ Comparison of Collagen resorption *(Dog model, GBR, College of Dentistry, Yonsei University)*

	OssGuide	A product
4weeks		
8weeks		
12weeks		

- After applying the same **bone graft materials** to both groups, each membrane was applied. Histological analyses were performed after different healing periods : 4, 8 and 12 weeks.
  (by Masson'strichrome staining, Collagen in blue)
- **It was observed during whole periods that Collagen of OssGuide was more slowly absorbed than A product.**
- 12weeks) Collagen fibers of A product became thinned and shortened, in contrast with OssGuide
- ***The slow degradation of OssGuide enables the long barrier function, therefor, helping the formation of the new bone.***

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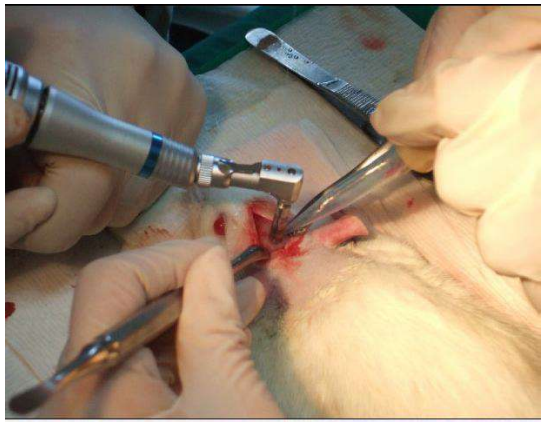
※ Comparison of efficacy study with A product

- Calvarial defect(6mm) on rat's head



1) Divided 30 rats into 3 groups. (i) negative control group without any treatment, (ii) experimental group, with OssGuide, (iii) positive control group, with A product
2) Created 6mm-diameter defect in the middle of head by electric drill with 6mm diameter trephine bur.
3) The collagen membranes(8mm Dia.) were implanted to the defects.
4) Periosteum was sutured with absorbable silk sutures and the skin was sutured with E-Z clip.
5) After the surgery, macroscopy and cranial biopsy were conducted in 2, 4, 8, 12 weeks.
6) Evaluated the barrier function by comparing the biodegradability and the rate of bone regeneration of each group.

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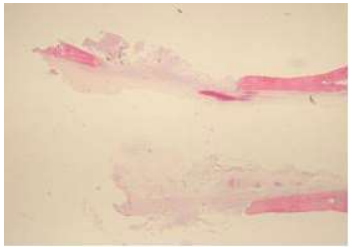
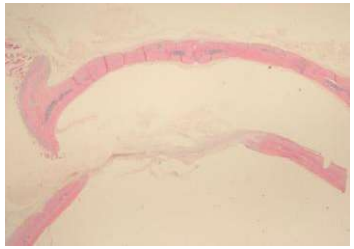
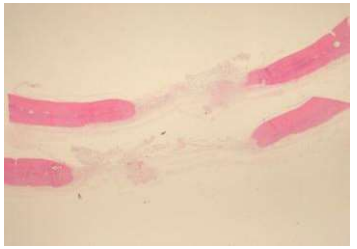
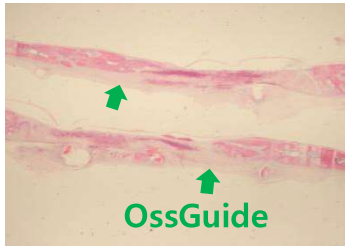
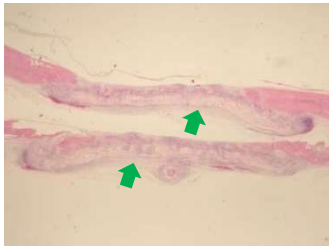
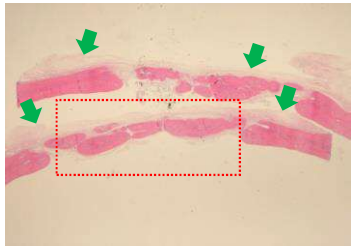
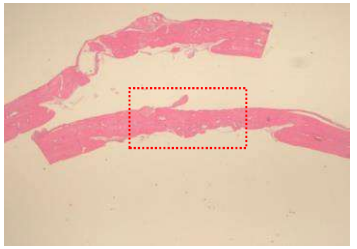
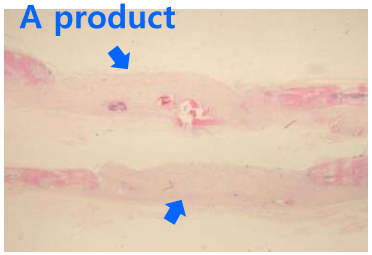
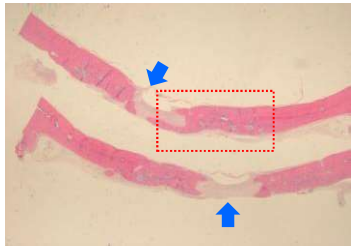
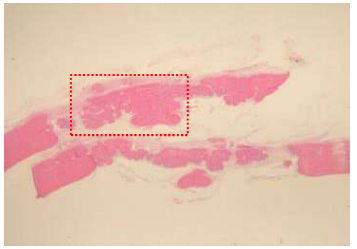
Ⅱ. OssGuide Animal Study 2 (Rat, Calvarial defect model)

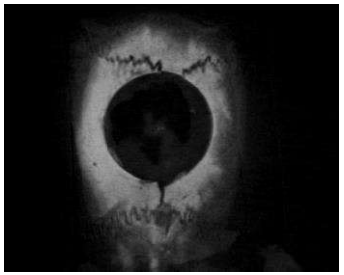
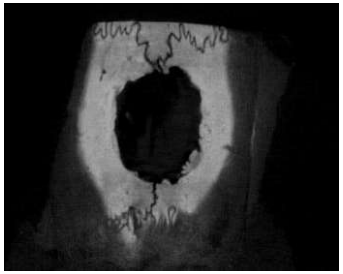
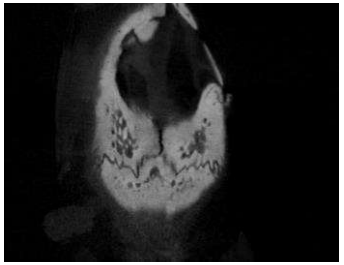
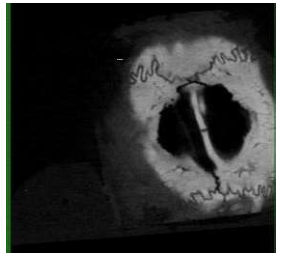
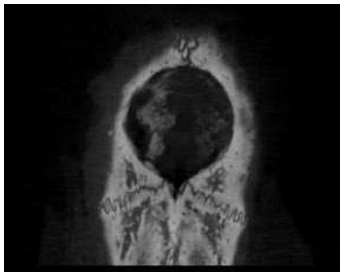
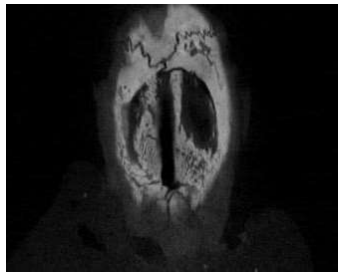
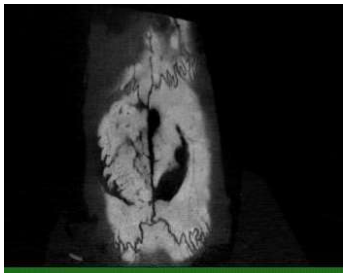
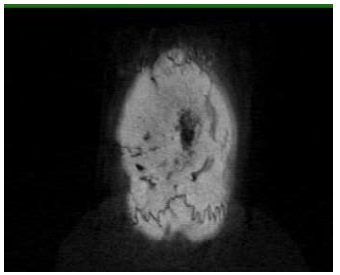
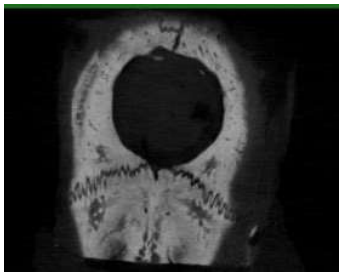
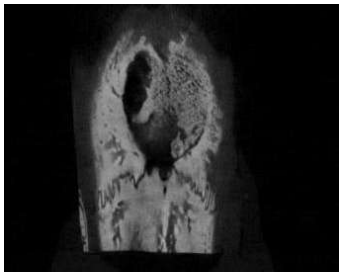
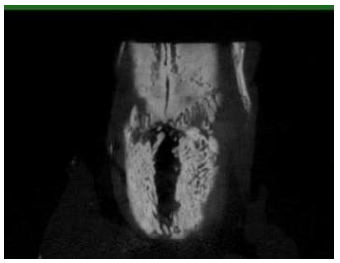
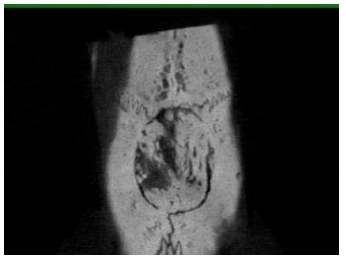
- ***Histology findings (2 tissue specimens in each slide, H&E staining, x 12.5)***

구분	2 weeks	4 weeks	8 weeks	12 weeks
Negative Control Group	 No or minimal bone regeneration, severe inflammatory reaction.	 Inflammatory reactions intensified.	 Inflammatory reaction was in progress.	 Bone healing was in partial progress sides of defect with residue inflammatory reaction.
Experimental group OssGuide®	 Membrane: dyed part	 Bone regeneration was active than other groups.	 Overall bone regeneration was observed.	 Complete bone regeneration was observed. Membrane biodegradation
Positive Control group	 Membrane: dyed part	 The start of biodegradation was observed.	 A bone healing was in partial progress sides of defect.	

Bone regeneration site

Ⅱ. OssGuide Animal Study 2 (Rat, Calvarial defect model)

- *Micro-CT analysis*

구분	2 weeks	4 weeks	8 weeks	12 weeks
Negative Control Group	 No or minimal bone regeneration.	 No or minimal bone regeneration.	 No or minimal bone regeneration.	 Bone healing was in partial progress sides of defect.
Experimental group OssGuide®	 Slightly increasing volume of bone.	 New bone formation in half area of cranial defect were observed.	 Significantly increasing new bone were observed	 Formation of new bone was observed in hole area of cranial defects
Positive Control group	 No or minimal bone regeneration.	 New bone formation in half area of cranial defect were observed.	 Significantly increasing new bone were observed	 Formation of new bone was observed in hole area of cranial defects

Comparison of bone volume(BV) and tabecular number (Tb.N) for rat calvarial defect model

Group	BV/TV (trabecullae volume / total volume) [1]			
	2 weeks	4 weeks	8 weeks	12 weeks
Negative Control	0.975 ± 0.096	10.05 ± 1.026	20.2 ± 1.732	21.12 ± 0.976
OssGuide	**0.924 ± 0.135**	**37.01 ± 1.88**	**51.64 ± 0.331**	**93.15 ± 0.411**
Positive control	11.457 ± 0.108	16.84 ± 0.939	48.42 ± 0.504	80.41 ± 1.194

Group	Tb.N (number of trabecullae, higher value means stronger bone intensity) [2]			
	2 weeks	4 weeks	8 weeks	12 weeks
Negative Control	0.068 ± 0.032	0.76 ± 0.125	0.77 ± 0.094	0.85 ± 0.035
OssGuide	**0.544 ± 0.059**	**1.12 ± 0.028**	**1.17 ± 0.060**	**1.68 ± 0.039**
Positive control	0.067 ± 0.009	0.60 ± 0.019	0.95 ± 0.062	1.50 ± 0.020

- ✓ **BV – Negative control group : up to 80.41 / OssGuide group : up to 93.15**
- ✓ **Bone intensity – positive control : up to 1.50 / OssGuide group : up to 1.68**
- ✓ **OssGuide demonstrated significantly better bone healing effects than negative control group and indicated the equivalence level with positive control group.**

1) BV/TV : Bone volume / Total volume, Trabecular bone volume

2) Tb.N : Trabecular bone number, The higher the value, the stronger the bone strength.

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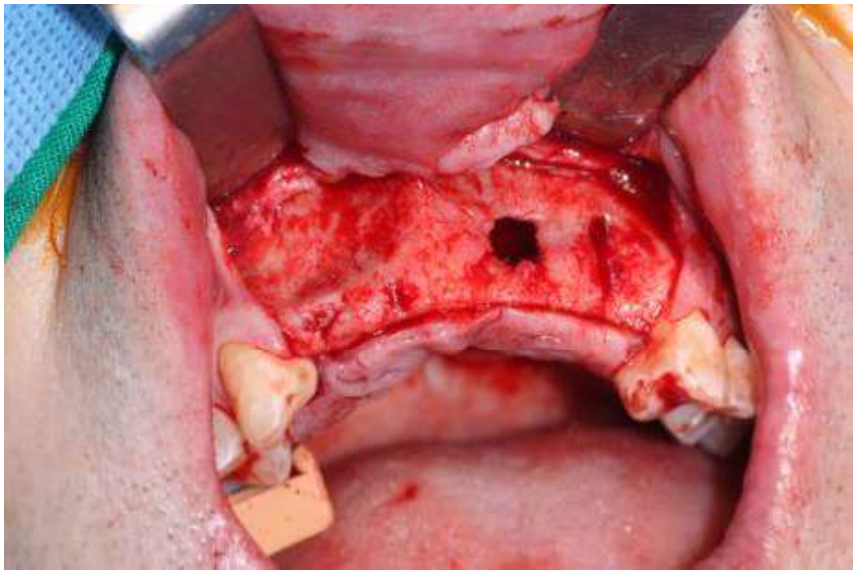
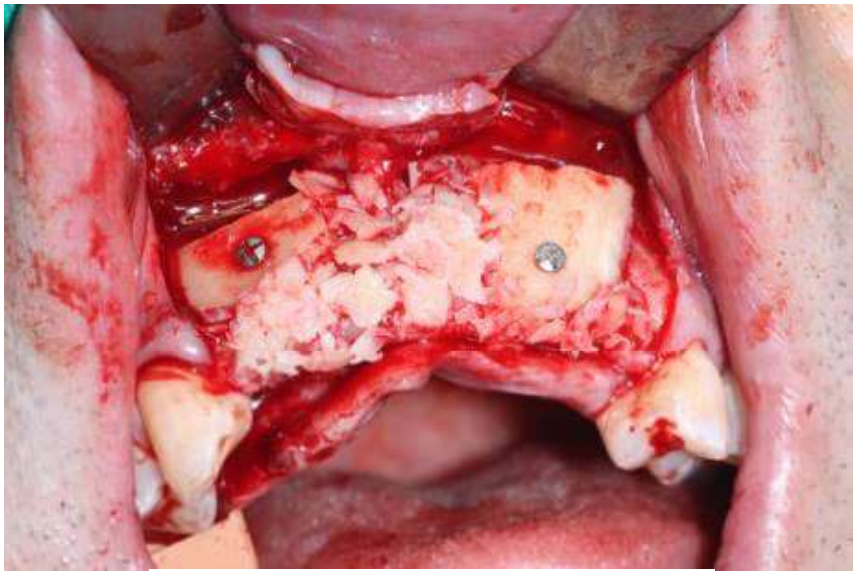
▪ Conclusion

구분	**Efficacy study for barrier function** (rat calvarial defects model)
Negative Control	Inflammatory reaction on bone defects was observed. bone regeneration was slower than other groups.
OssGuide	After 12 weeks after the surgery, membrane biodegradation began. OssGuide demonstrated the significant effect for the bone regeneration.
Positive Control	At 4 weeks after the surgery, membrane biodegradation began. Positive control group demonstrated good bone healing effects

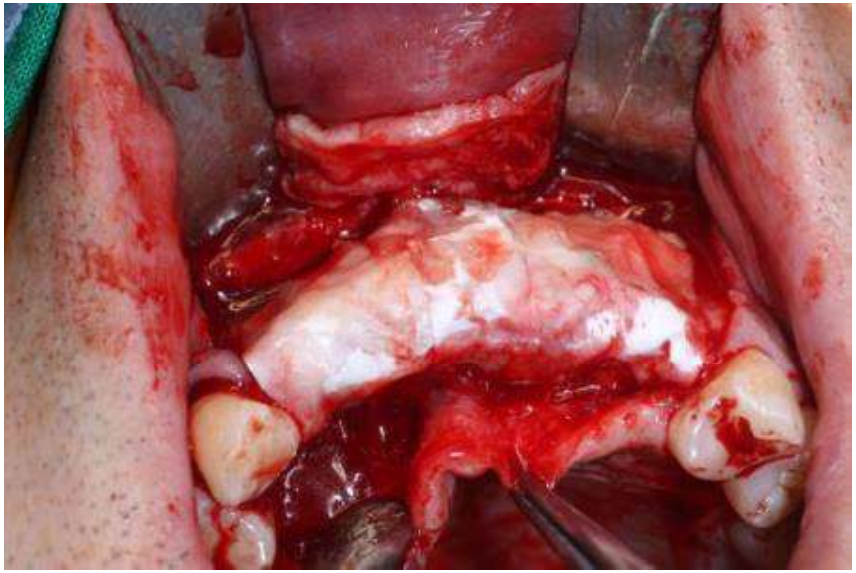
Ⅲ. OssGuide Clinical Case #1



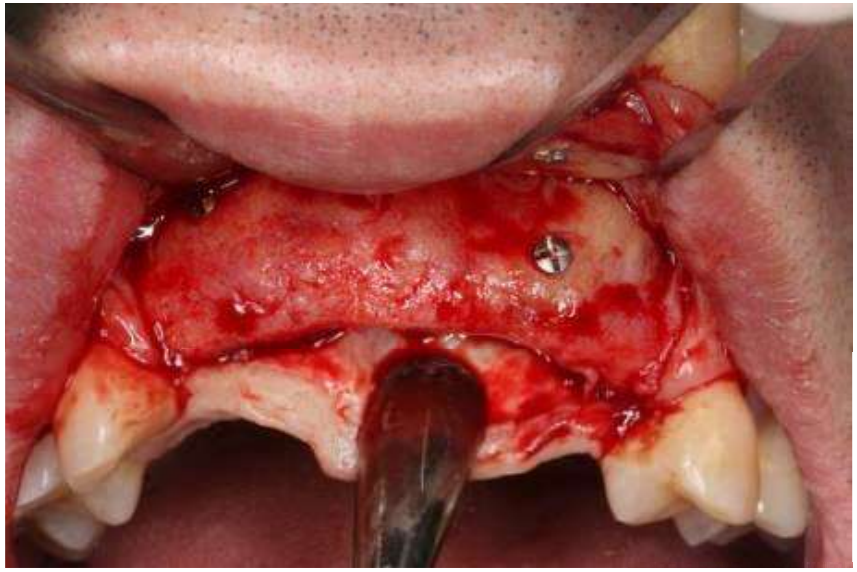
Before Application



Application of Bone graft



Application of OssGuide



After 4 months

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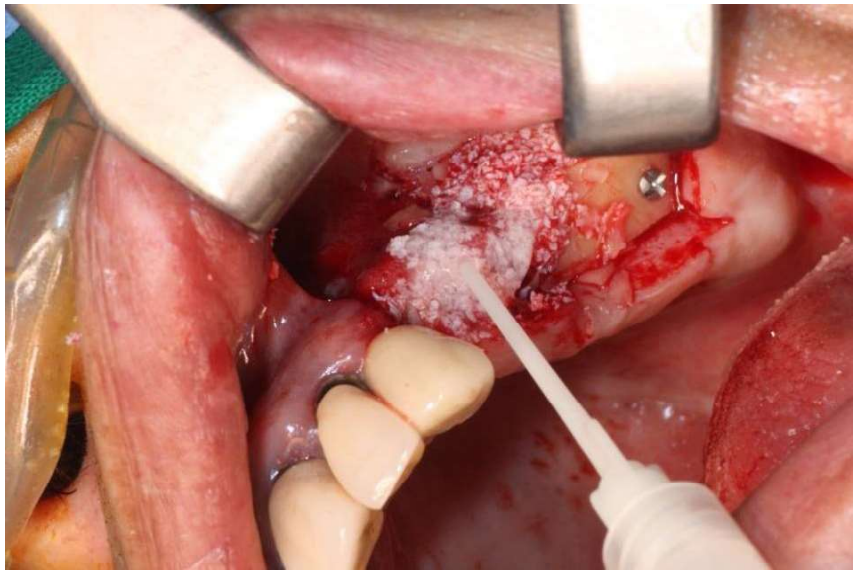
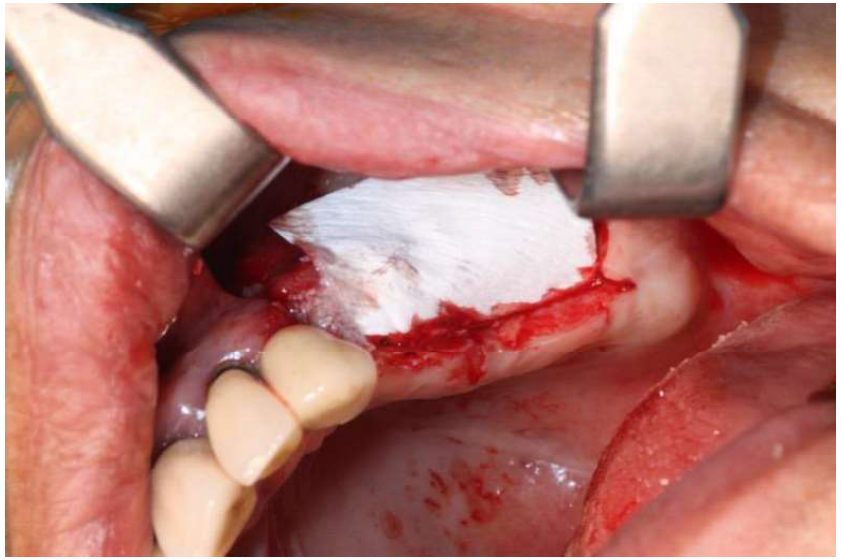
Ⅲ. OssGuide Clinical Case #2

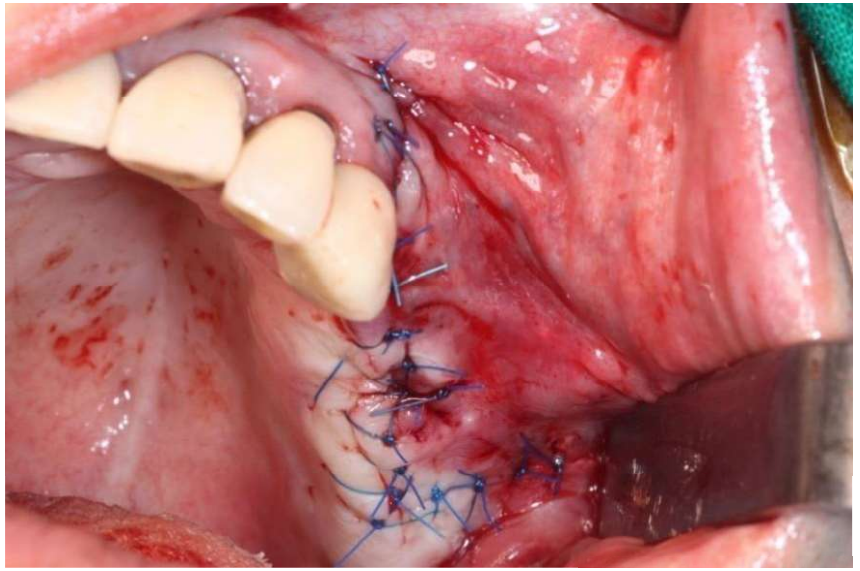
Before Application



Application of Bone graft



Application of OssGuide



Suture

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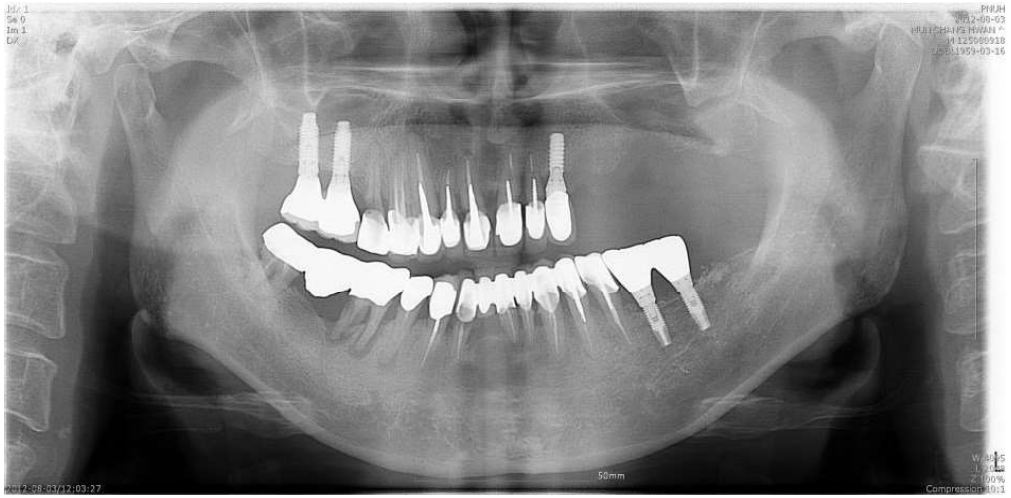
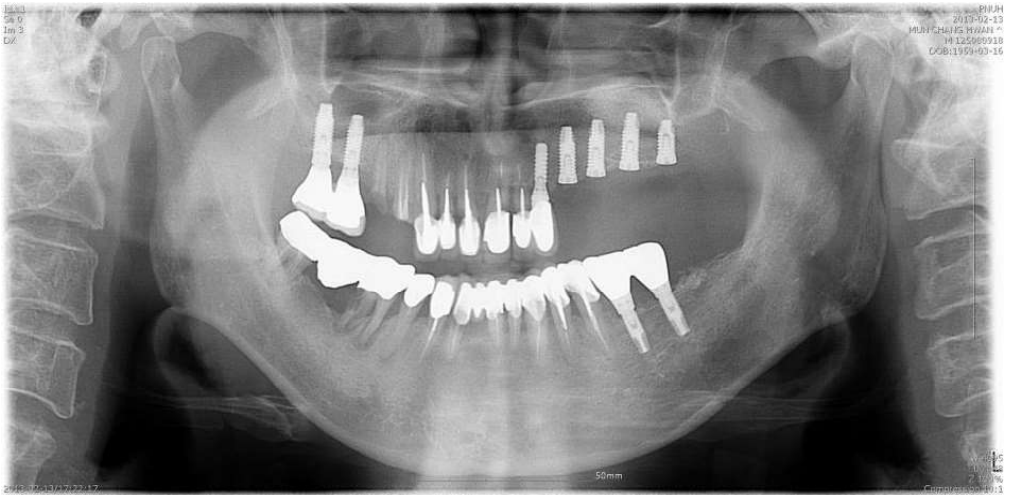
Ⅲ. OssGuide Clinical Case #2

Before operation



6 months post operation



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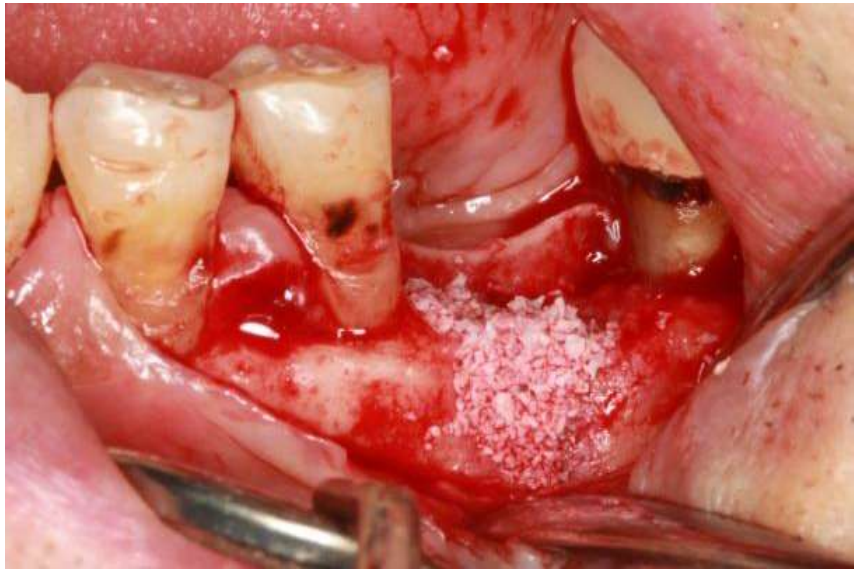
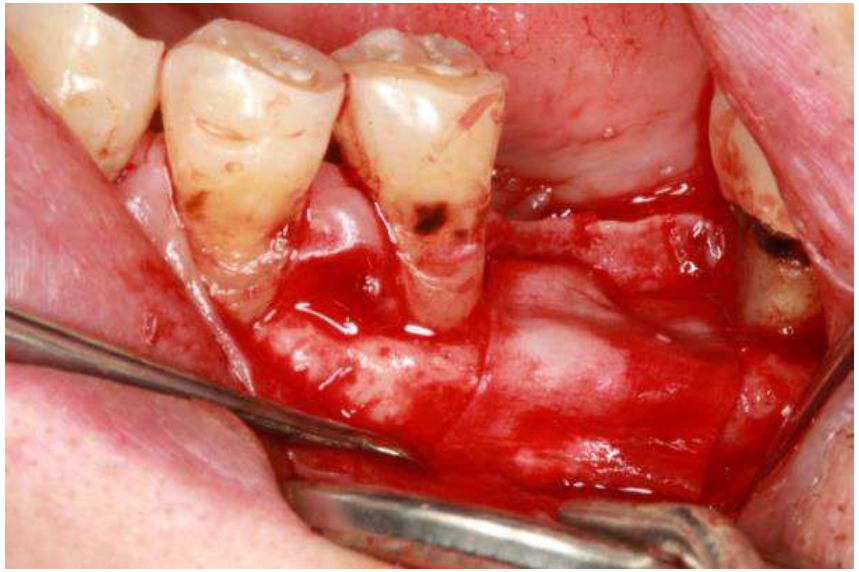
Ⅲ. OssGuide Clinical Case #3 GBR

Before Application



Application of Bone graft



OssGuide covering

Suture

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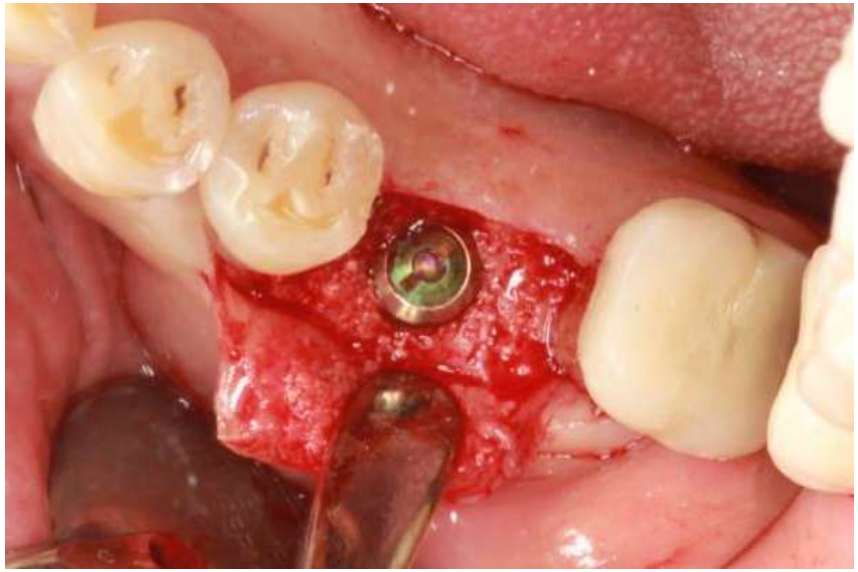
Ⅲ. OssGuide Clinical Case #3 GBR

After 4 months



Re-opening after 4 months

2nd surgery

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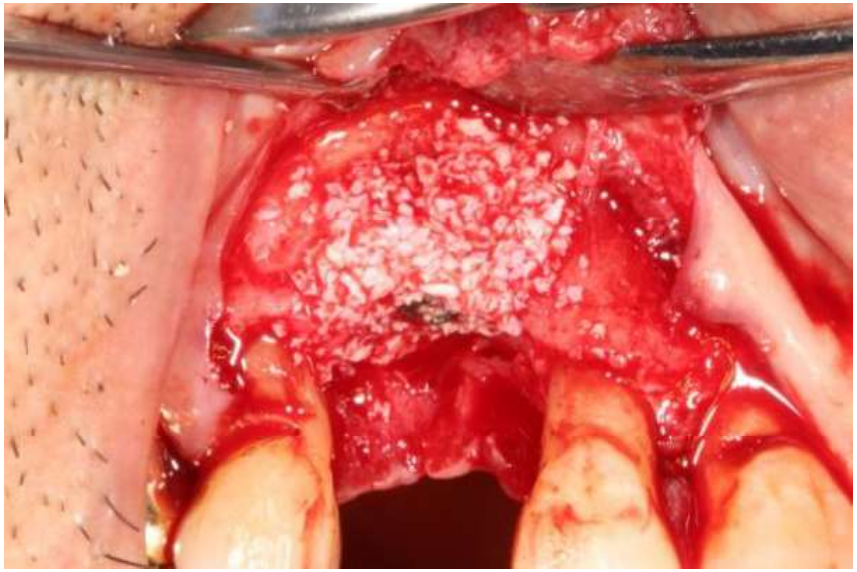
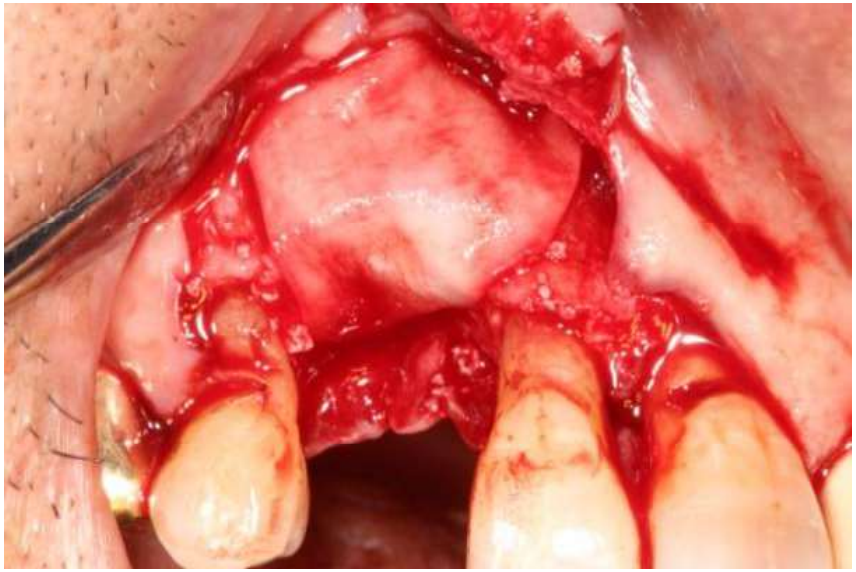
Ⅲ. OssGuide Clinical Case #4 GBR

Before Application





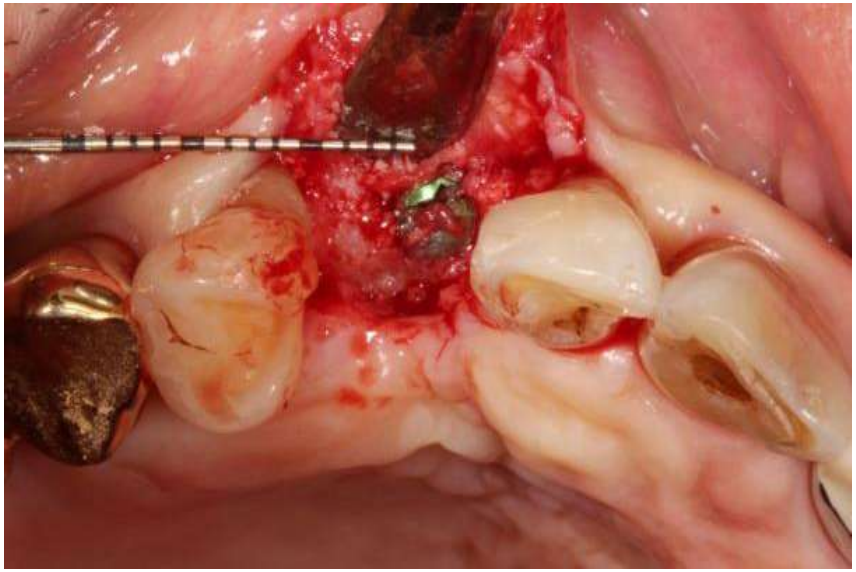
OssGuide covering

Suture

HYUNDAI BIOLAND

Ⅲ. OssGuide Clinical Case #4 GBR

After 4 months



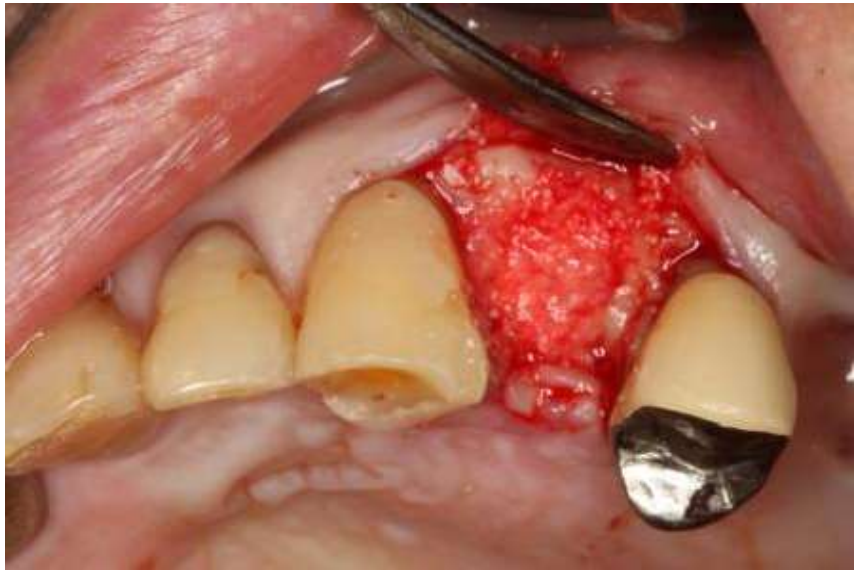
Re-opening after 4 months

2nd surgery

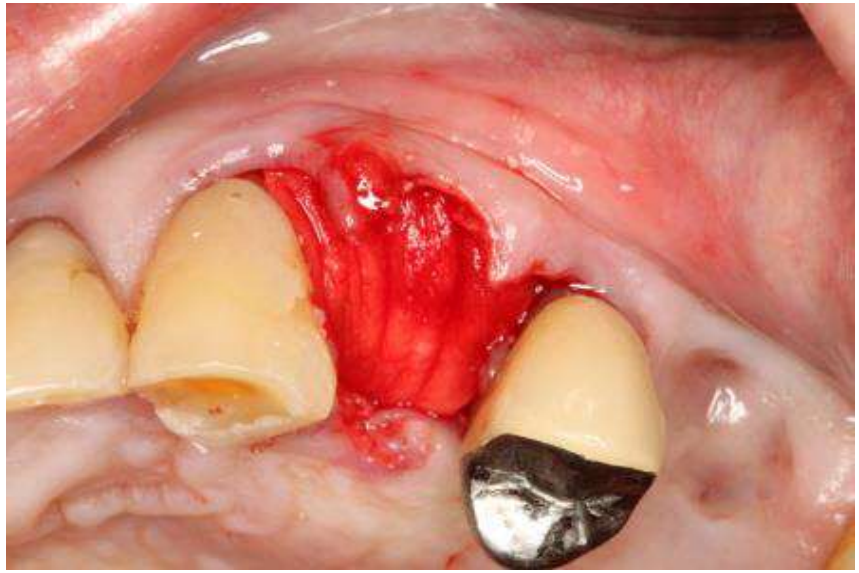
HYUNDAI BIOLAND

Ⅲ. OssGuide Clinical Case #5 Ridge preservation

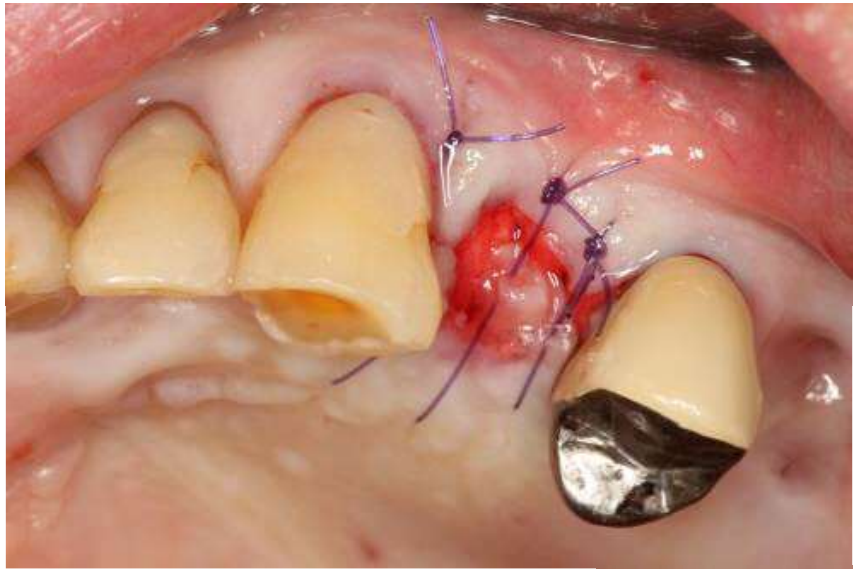
Before Application



Application of Bone graft



OssGuide covering



Suture

HYUNDAI BIOLAND

Ⅲ. OssGuide Clinical Case #5 Ridge preservation

After 4 months

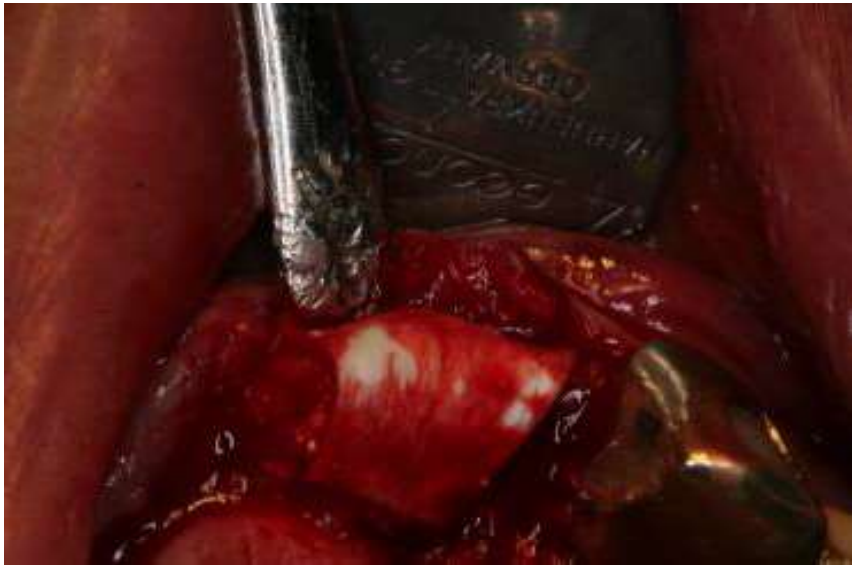
Re-opening after 4 months

2nd surgery

HYUNDAI BIOLAND

Ⅲ. OssGuide Clinical Case #6 Ridge preservation

Before Application



OssGuide covering

Suture

HYUNDAI BIOLAND

After 4 months (vestibular view)

After 4 months (occlusal view)

THANK YOU!

HYUNDAI BIOLAND