waldent

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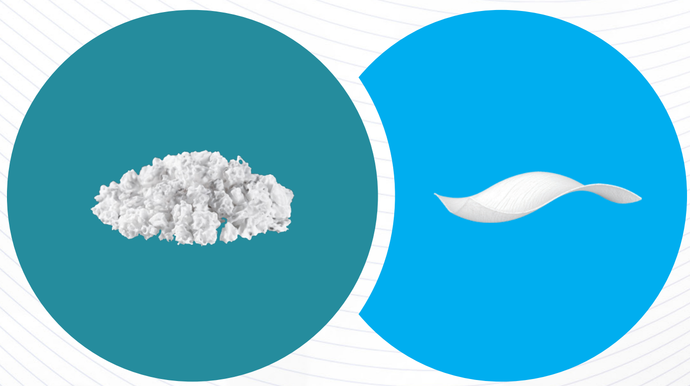
DENTAL TISSUE REGENERATION SOLUTION

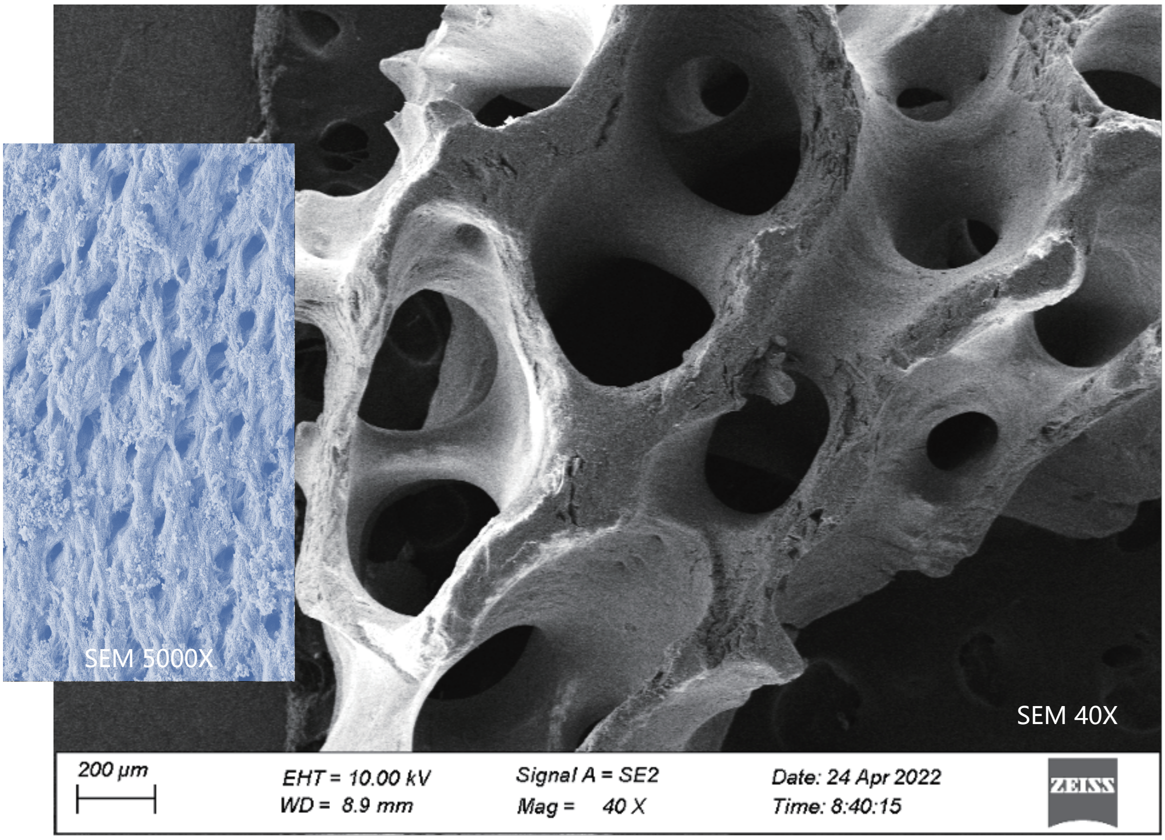
Bonabone™ Bonamem™



natrual bone graft collagen membrane

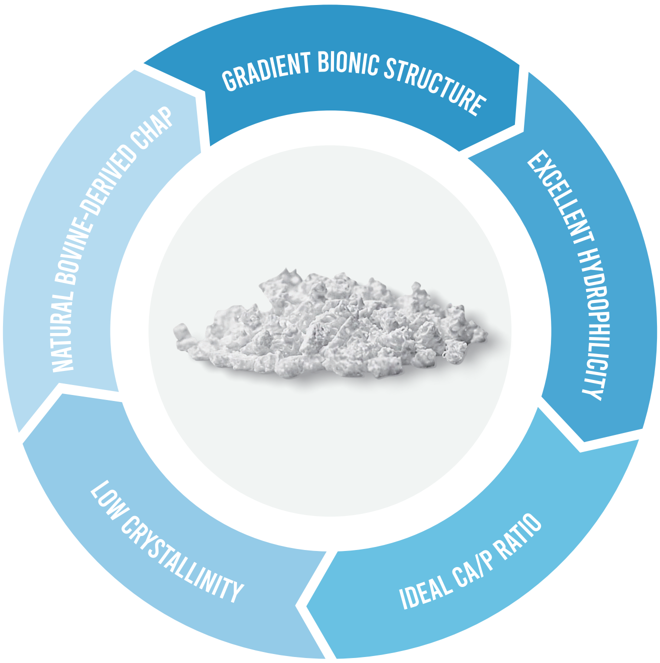
Bonabone™

NEXTGEN CHAP



Bonabone™ is a natural bone grafting material made from traceable bovine cancellous bone. Its component is Carbonated hydroxyapatite (CHAp). It is manufactured by adopting a unique multi-step temperature controlled (low-temperature) calcination and special degreasing and deproteinization purification technologies. There are no residues of chemical substances or organic substances. Compared with bone grafting material calcined at high temperature, it has better biocompatibility, ensuring the safety of clinical use.

Bonabone™ retains the carbonate substitution of natural cancellous bone, the crystal structure with low crystallinity, as well as the macroscopic and microscopic porous interconnected structures with gradients. Its metabolic process is close to the metabolic pattern of the human bone matrix. It enables human osteoclasts to absorb Bonabone™ particles while maintaining the physiological spatial structure, thus achieving predictable physiological bone reconstruction, reducing long-term bone resorption and providing a better choice for clinical practice.



The main component of animal-derived bone substitutes is hydroxyapatite, which is similar to human bone. It is the core of the success of oral guided bone regeneration (GBR) surgery and bone grafting surgeries caused by various bone defects.

An excellent animal-derived bone substitute should provide a morphological structure that can effectively guide the attachment of osteoblasts and a crystal structure that can be effectively metabolized by osteoclasts[8]. It should also provide the ability to maintain a spatial structure that is balanced with the bone remodeling process to meet the predictable bone reconstruction requirements and offer stable and outstanding clinical expected benefits.

During the natural bone remodeling process in the human body, there is an ion substitution phenomenon in hydroxyapatite. For example, carbonate ions (CO_3^{2-}) replace some phosphate ions (PO-), resulting in subtle changes in its crystal structure [9]. This endows bone substitutes with a carbonated crystal structure with unique biological properties - they are more easily and safely recognized by the human body and have better biological activity and solubility. Moreover, the crystal structure with low crystallinity that mimics natural bone enables osteoclasts to effectively carry out physiological metabolism, rather than just simple structural conduction and new bone deposition [10].

An ideal animal bone substitute should possess the following characteristics

Biocompatibility: The components are safe, and the body does not produce rejection reactions.
Bionic Structure: It has a natural spatial morphological structure similar to human cancellous bone, enhancing the bone conduction effect.
Component Similarity: It mimics the crystal structure of human bone and the Ca/P ratio, increasing the physiological substitution rate.
Space Maintenance: The particle structure is stable, effectively maintaining the height and width of the defect area.
Operational Convenience: The porous interconnected structure facilitates blood clotting into masses, and the implant is stable without displacement.

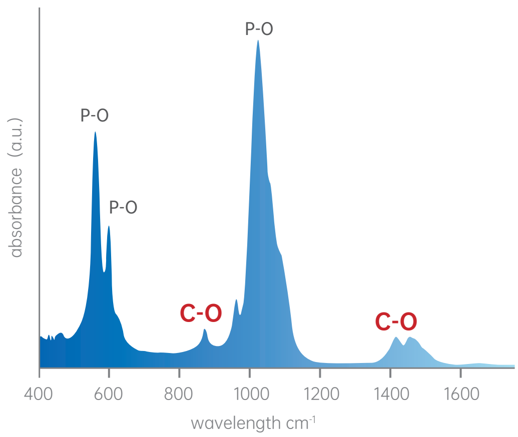
SIZE AND TYPE

Vial Small particles size is 0.25mm - 1mm
Large particles size is 1mm - 2mm

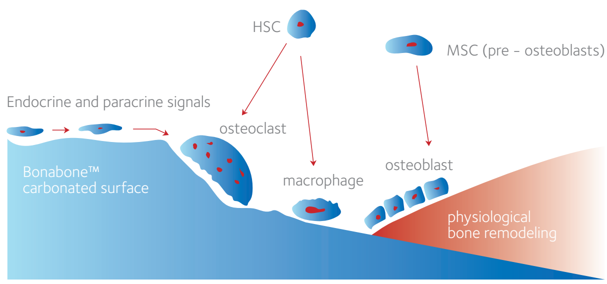
Syringe The patented 30°bending design
Small particles size 0.25mm - 1mm

NATURAL BOVINE-DERIVED CHAP

There exists a carbonate substitution structure accounting for 4-8wt.% in human bone. After special calcination treatment, the bovine cancellous bone selected for Bonabone™ retains the A/B dual-type carbonate substitution structure (there are characteristic absorption waves of carbonate ions near 878cm^{-1} and 1455cm^{-1} in the IR spectrum absorption). Among them, the A-type carbonate substitution structure has higher stability and lower solubility, while the crystal structure substituted by the B-type carbonate is more easily dissolved and metabolized [9,11,12]. This crystal structure with dual-type carbonate substitution enables Bonabone™ to provide a suitable metabolic environment and physical support for the growth of new bone during the process of bone remodeling. It ensures that the rates of bone resorption and reconstruction are the same, maintaining a good balance between bone formation and bone substitution. [13,14]



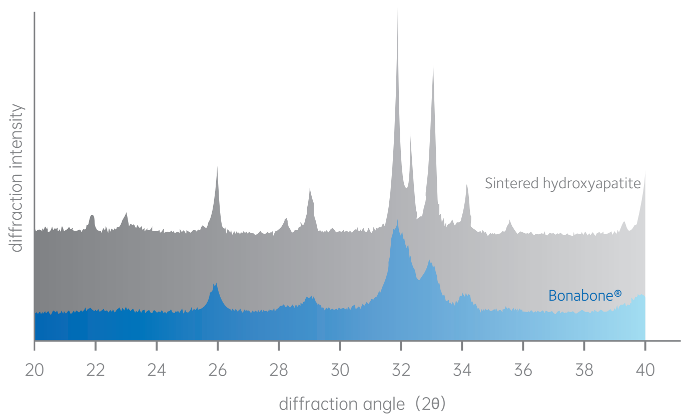
A/B dual-type carbonated hydroxyl structure
(There are characteristic absorption waves of carbonate ions in the IR spectrum absorption at 878cm^{-1} and 1455cm^{-1})



Osteoclasts are believed to be able to modify the surface of bone grafts, thereby altering the response of osteoblasts.
Carbonated hydroxyapatite has the potential to stimulate local osteoblasts to upregulate the expression of bone-related genes. [13]

LOW CRYSTALLINITY

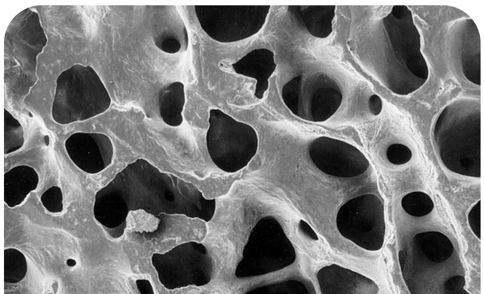
X-ray diffraction measurement shows that Bonabone™ has a diffraction angle with a low peak similar to that of human bone. In contrast, the animal-derived bone particles after high-temperature calcination exhibit a sharp peak diffraction angle due to the change in the mineral phase structure.
The multi-step temperature-controlled (low-temperature) processing technology ensures that Bonabone™ retains a crystal structure with low crystallinity (55% - 70%), which is similar to that of natural bone [15] (50% - 60%). As a result, it has better biocompatibility and metabolic absorbability, and is more conducive to the physiological reconstruction of new bone.

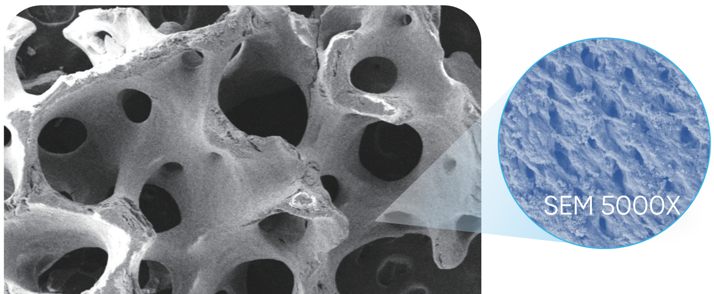


GRADIENT BIONIC STRUCTURE

Bonabone™ retains the natural morphological structure of bovine cancellous bone and has an internally interconnected porous structure that mimics human bone. After effectively removing organic substances such as lipids, it provides a gradient distribution, including the reasonable retention of nanopores, microscopic pores, and macroscopic pores. This enables Bonabone™ to quickly adsorb blood. After being implanted into the defect site and forming a blood clot, it can stably form a mass without loosening and supports the ingrowth of early angiogenesis. In addition, the rough surface of Bonabone™ (see the microscopic structure under a 5kx electron microscope) is conducive to the attachment of osteoblasts and osteoclasts. The nanoscale rough structure has been proven to promote the differentiation of stem cells into osteoblasts [17], thus creating favorable conditions for the growth and differentiation of new bone cells.

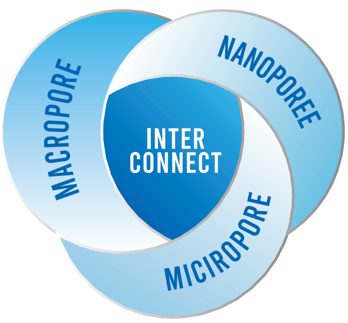
The surface morphological structure that mimics human bone


Human Bone SEM 50X

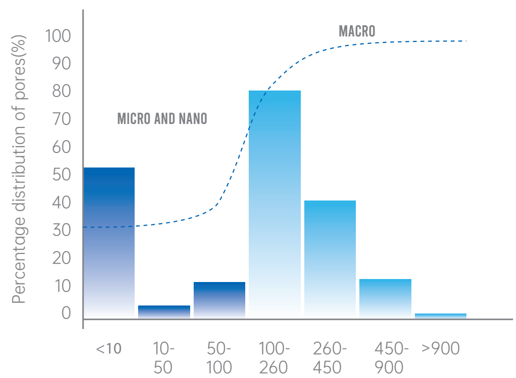


Bonebone™ SEM 50X

particle size(0.25 - 1.0mm), the porosity is 80%
particle size (1.0 - 2.0mm), the porosity is 90%.



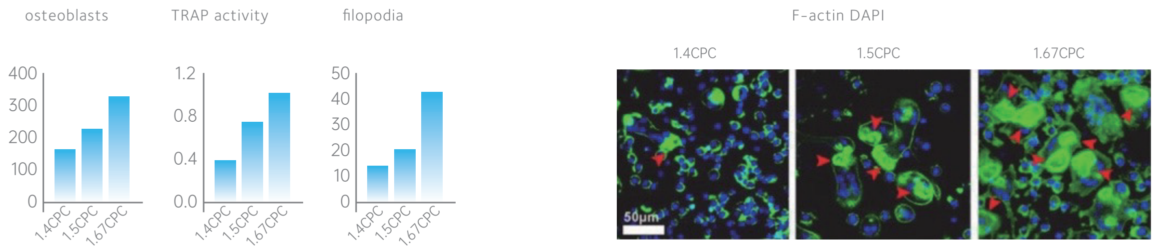
Macropores > 95μm: Channels for early angiogenesis and bone reconstruction.
Micropores 1 - 10μm Anchoring and proliferation of osteoblasts, and adsorption of nutrients.
Nanopores < 150nm The mechanical structure of bone morphology, enhancing the adhesion of particles.



Pore size distribution

RATIO OF CA/P

Under physiological conditions, the Ca/P ratio of natural bone is approximately 1.67. When the Ca/P ratio of a bone substitute is close to that of natural bone, it can provide stable crystal characteristics, making it easier for human osteoblasts and osteoclasts to recognize and adhere to its surface, secrete extracellular matrix, and promote the metabolism of the bone substitute and the formation of new bone [18]. The Ca/P ratio of Bonabone™ is approximately 1.66 to 1.67. Therefore, it has excellent biocompatibility and absorbability in the physiological environment within the body, which is more conducive to the growth and remodeling of new bone.

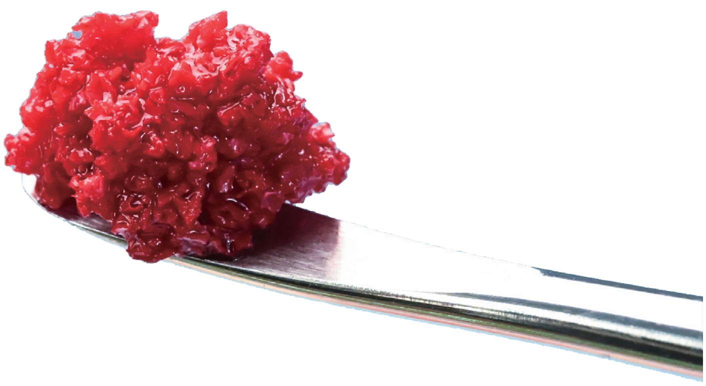


The differences in the osteogenic effects of bone substitute materials with different Ca/P ratios

EXCELLENT HYDROPHILICITY

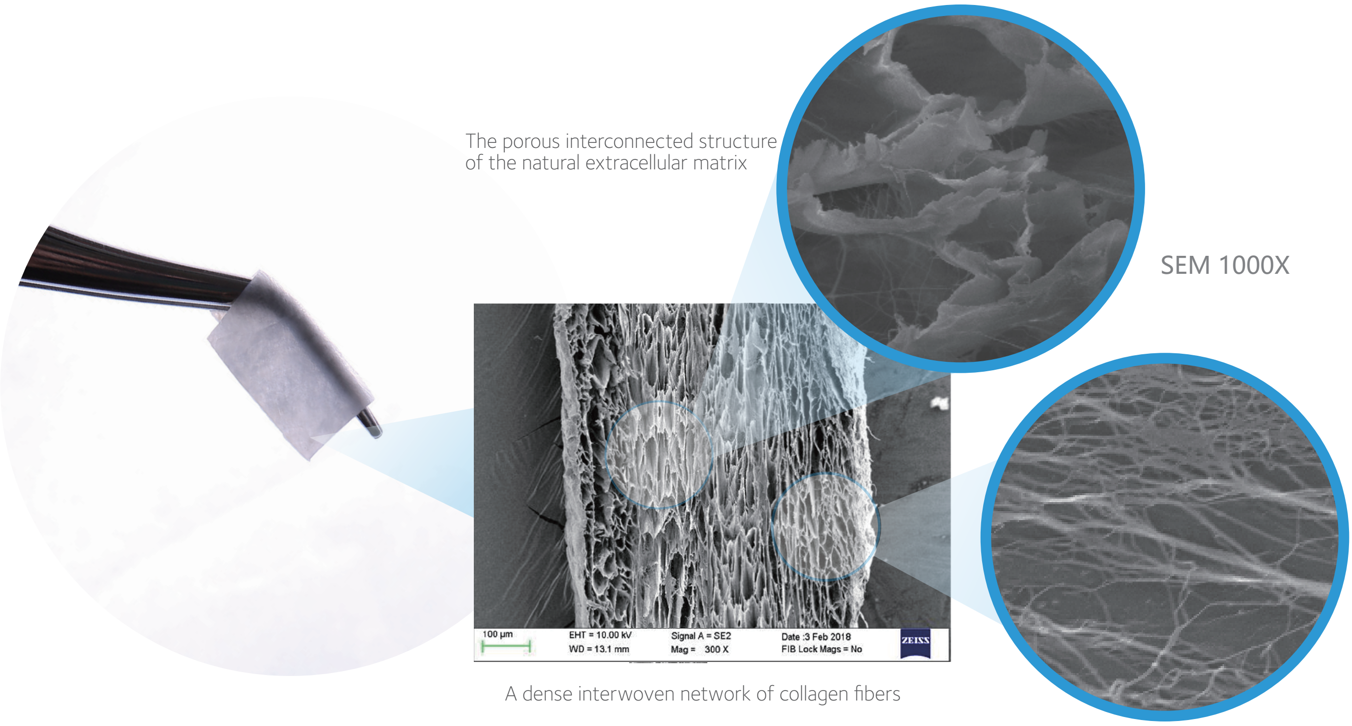
The Bonabone™ particles have high wettability and a high specific surface area (>85m²/g). When they come into contact with blood, they can rapidly adsorb the blood and form a stable mass, effectively enhancing the bone conduction ability.

Its gradient porous interconnected structure endows Bonabone™ with extremely high surface energy and excellent siphoning ability, enabling it to quickly adsorb a large amount of blood and nutrients. The microscopic nanoporous structure retained in Bonabone™ makes the bone powder particles adhere to each other. After being implanted into the defect site, they can form a stable mass without loosening.



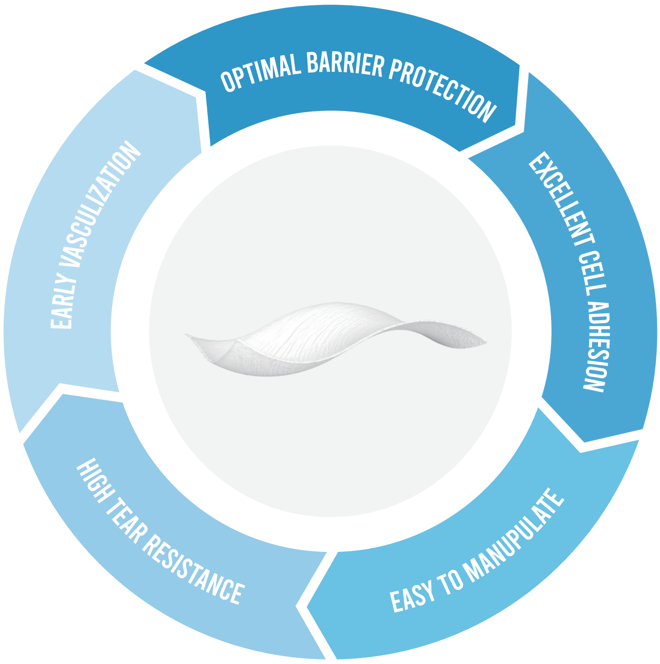
Bonamem™ collagen membrane

NATURAL PERICARDIUM



*The picture is sourced from the Medical Device Testing Center of Peking University School and Hospital of Stomatology.

Bonamem™ is derived from natural porcine pericardium membrane. Using the decellularization process, it retains a complete three-dimensional porous structure of collagen and contains functional components such as growth factors and adhesion proteins. Since the pericardium membrane must withstand the pressure of the heart muscles, fix the heart, and limit excessive expansion of the heart, it has extremely strong mechanical properties, as well as good softness, conformability, and hydrophilicity. It has good stability, which is beneficial for operation. Meanwhile, it also has a suitable degradation period of 3 to 6 months. Rich in bioactive substances, it can stimulate cellular responses and promote and induce tissue repair and regeneration. With a high porosity of 80%, it can achieve early vascularization and simultaneously promote the formation of new bone beneath the membrane. It is currently an extracellular matrix membrane with a relatively high cost-performance ratio.



Bonamem™ collagen membrane

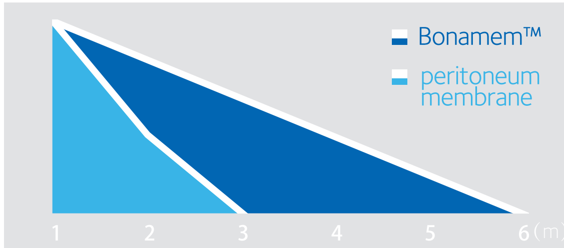
In oral surgical procedures, absorbable barrier membranes have become a routine approach for guided tissue regeneration (GTR), guided bone regeneration (GBR), the treatment of periodontal and peri-implant bone defects, as well as bone augmentation procedures carried out before or simultaneously with implant placement, due to their good biocompatibility and tissue integration ability [1,2]. Among them, decellularized extracellular matrix (ECM) membranes, because of their intact structure and the characteristic of being rich in bioactive functional components, can not only block the migration of non-relevant regenerative cells to the defect site, allowing regenerative cells to proliferate in the filled defect area [3], maintain the space for new bone formation, but also induce tissue regeneration and promote vascularization and the formation of new bone.

“BEST” for bone regeneration

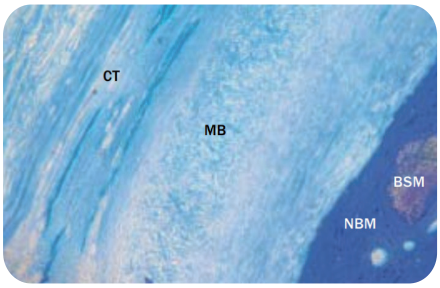
Biological compatibility- prevents adverse reactions with surrounding tissues and organisms
Ease of handling- Easy to trim before place over defects and can be repositioned as wanted
Selective penetration- preventing unwanted epithelial cells ingrowth while allowing osteoblasts to increase
Space maintenance- Provides space for a stable clot, allowing bone regeneration, high tear resistance, less prone to breakage in the presence of tension
Tissue integration- facilitates nesting with surrounding tissue and to allow gradual integration of collagen fibers at a max. 6 month degradation

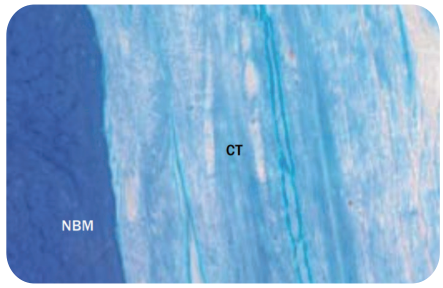
OPTIMAL BARRIER PROTECTION

The special natural collagenous structure of the pericardium endows Bonamem™ with special toughness, multi - directional tear resistance and tensile strength, as well as a barrier protection period of up to 6 - 8 weeks.



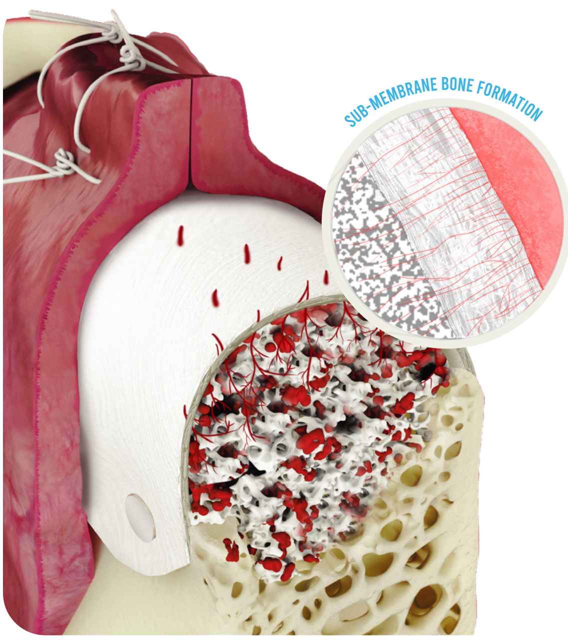
Comparison of the protection periods [5]

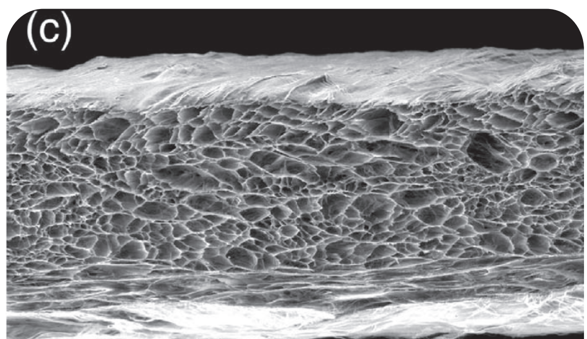




Assessment of the biocompatibility and biodegradability of natural porcine pericardium membranes in beagle dogs. The tissue sections 12 weeks after surgery (as shown in the above figures) show that there are still residual porcine pericardium fibers in the experimental group (the upper - left figure). In the control group (the upper - right figure), the degradation is complete, and the new bone is covered by the periosteum and soft tissues [6].

EARLY VASCULARIZATION





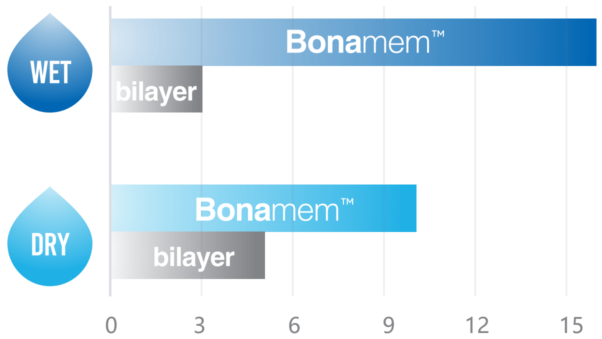
(c) cross-section of Bonamem™

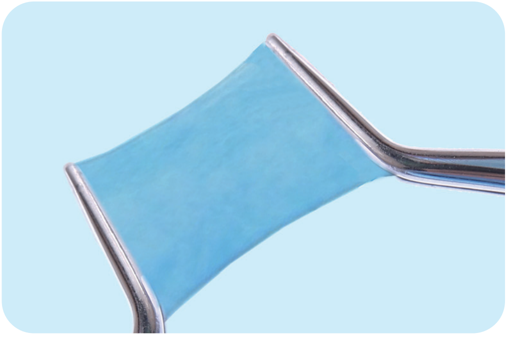
(ESEM) images of acellular porcine pericardium (APP) at 300x magnification[7]

Early vascularization: The porosity is as high as 80%, which can ensure sufficient blood supply in the bone grafting area. This allows bone formation-related proteins, osteogenic factors, and nutrients to pass through smoothly, deposit in the bone grafting area, and exert their functions, thus accelerating the repair of bone tissue.

HIGH TEAR RESISTANCE

Bonamem™ can be applied both under dry and wet conditions. Under dry conditions, the relative strength of Bonamem ™ enables the membrane to be smoothly placed vertically in the area filled with bone graft. Meanwhile, Bonamem™ has excellent hydrophilicity. After being infiltrated with normal saline or blood, it can quickly become soft and acquire good adhesiveness, allowing it to adhere well to the wound surface. At the same time, it also enables easy secondary placement and repositioning.





The picture above shows the tensile force test conducted at the Medical Device Testing Center of Peking University School of Stomatology. The results show that the tensile strength of Bonamem™ in the dry state is 9.95±3.38MPa, which is twice that of the double-layer membrane in the same state. In the wet state, the tensile strength is 15.51±1.37MPa, which is three times that of the bilayer membrane in the same state.

EASY TO MANIPULATE

Bonamem™ has no distinguishable front or back side and can be applied both under dry and wet conditions. With a thickness of only 0.2 to 0.3 mm, it is still very convenient to operate even when the soft tissue is thin.

CLINICAL CASE

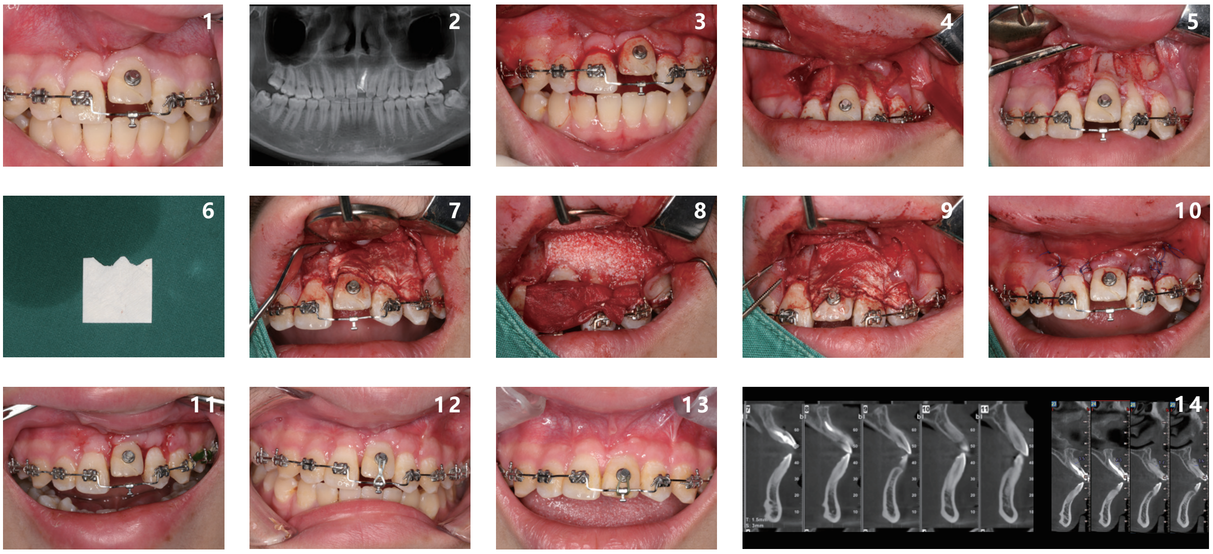
21 CORTICOTOMY-ASSISTED BONE GRAFTING

Case Overview

Patient: Male, 18 years old. The left upper anterior tooth suffered a trauma several months ago. After undergoing root canal treatment, orthodontic movement of the affected tooth is planned followed by crown restoration. Currently, corticotomy is required to assist with orthodontic movement, so the patient came to our department for treatment today.
Intraoral examination: A resin filling can be seen at the incisal edge of tooth 21. The fracture end is located above the gingiva, and the percussion test is negative (-).
Imaging examination: There is a high-density shadow in the pulp cavity of tooth 21. The root canal is properly filled, and there is no obvious abnormality around the root apex.
Diagnosis: 1. Tooth #21 trauma; 2. Malocclusion.

Treatment Plan

1.OHI   2.#21Corticotomy-assisted orthodontic surgery with bone grafting   3. Regular follow-up



1-2. In the preoperative intraoral photograph, a resin filling can be seen at the incisal edge of tooth 21. The fracture end is located above the gingiva, and the percussion test is negative (-). In the preoperative imaging, there is a high-density shadow in the pulp cavity. The root canal is properly filled, and there is no obvious abnormality around the root apex.
3-5. Incise the gingiva, reflect a full-thickness flap, and perform corticotomy with an ultrasonic bone knife.
6-7. Trim and fix the Bonamem™.
8-10. Implant Bonabone™ bovine bone graft between teeth 21 and 22, cover with Bonamem™ and then suture.
11-13. In the postoperative intraoral photographs taken at 2 weeks, 1 month, and 2 months, the soft tissue is seen to heal well.
14. The CBCT images before and 2 months after the operation show the changes in the hard tissue.

Conclusion

In this case, covering with Bonamem™ provides good spatial stability for the bone graft, which is beneficial for the formation of new bone and promotes the healing of soft tissue. Corticotomy accelerates orthodontic tooth movement, can significantly speed up the orthodontic tooth movement, and shorten the orthodontic treatment time. It also increases the local alveolar ridge bone volume during the operation, reducing orthodontic risks. The treatment effect is relatively satisfactory.

CLINICAL CASE

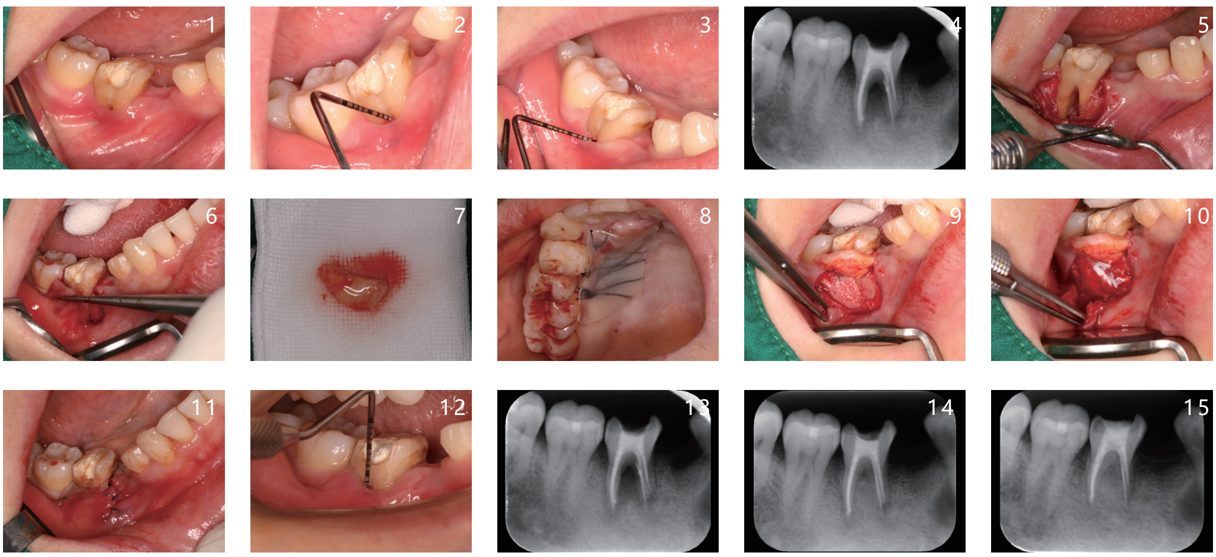
46 COMBINED TREATMENT FOR SEVERE SOFT AND HARD TISSUE DEFECTS

Case Overview

Patient: Female, 30 years old. There has been recurrent swelling and pain in the lower right area. Root canal treatment of the relevant tooth was completed one month ago, so she came to our department for treatment.
Intraoral examination: Tooth 46 is in a prepared state with a filling on the buccal - occlusal surface. There is gingival recession on the buccal side of tooth 46, exposure of the furcation area, and enamel pearls can be seen in the furcation area. The probing depth in the furcation area exceeds 5mm, and the horizontal probing depth exceeds 4mm. The buccal soft tissue is thin, the keratinized gingiva is narrow, and the frenum is attached too high.
Diagnosis: Combined periodontal - endodontic lesion of tooth 46 (root canal treatment already completed), mucogingival abnormality.

Treatment Plan

Guided tissue regeneration with connective tissue grafting



1 - 4. Preoperative intraoral photographs and X - ray films of tooth 46 show severe alveolar bone resorption in the furcation area, mild alveolar bone resorption on the proximal surface, and proper filling in the root canal.
5. A full - thickness flap of tooth 46 was reflected, and the enamel pearls were debrided and ground away. Complete alveolar bone resorption in the furcation area was visible.
6 - 8. The Bonamem™ was trimmed and fixed, and relaxation incisions were made on the buccal side of tooth 46. A subepithelial connective tissue flap was harvested from the palate and set aside. The palatal side was sutured with Bonasil™ and covered with Bona-aid™.
9 - 11. The connective tissue flap was suspended and sutured on the buccal side of tooth 46. Bonabone™ bone graft mixed with autologous blood was implanted in the bone defect of the furcation area. After covering with Bonamem™, it was sutured with Bonasil™4-0 nylon suture.
12. Two weeks after the operation, the furcation area was completely covered by soft tissue. The probing depth was 3mm seven months after the operation.
13 - 15. X - ray films before the operation, six weeks after the operation, and seven months after the operation show that the transplanted bone particles are stable. The bone in the furcation area is completely filled, and there is no shadow in the furcation area.

Conclusion

In this case of guided tissue regeneration (GTR), Bonamem™ plays a complete barrier role. With the support of the bone graft, it effectively guides the colonization, differentiation, and remodeling of periodontal tissue cells. Eventually, it repairs the damaged furcation lesion, eliminates the originally existing furcation lesion structure, and effectively reduces the depth of the periodontal pocket.

CLINICAL CASE

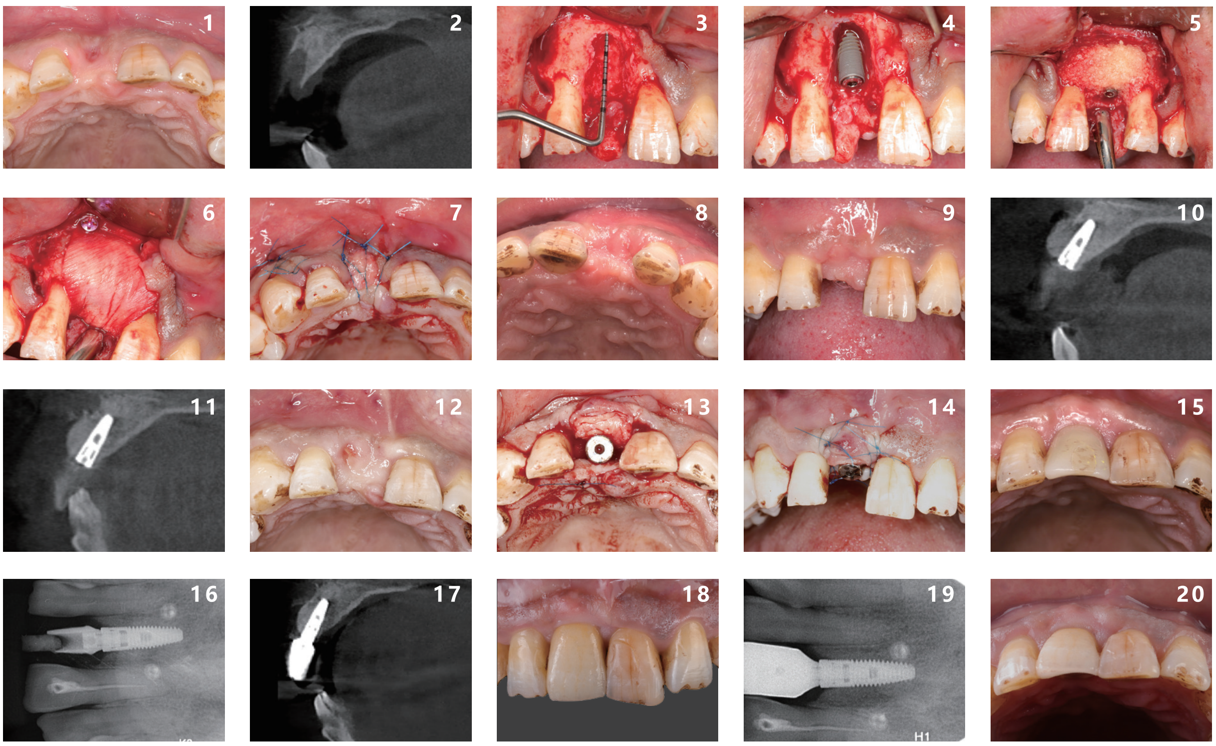
EARLY-STAGE IMPLANT PLACEMENT WITH HORIZONTAL AND VERTICAL GBR

Case Overview

Patient: A 45 - year - old male with a demand for anterior tooth restoration due to tooth loss.
Current medical history: The patient had an anterior tooth extracted due to looseness one and a half months ago. The tooth loss affects his appearance, leading to the request for restoration.
Past medical history: The patient is in good health.
Intraoral examination: Tooth 11 is missing, with labial soft tissue collapse. CT scan shows that the labial bone plate has a defect of approximately 10mm.
Clinical diagnosis: Missing tooth 11.

Treatment Plan

11 Early stage implantation, simultaneous horizontal and vertical bone augmentation with freeze-dried bone allograft (FDBA), fixation of Bonamem™ using the sausage technique with membrane tacks, and coverage of the wound with VIP—CT soft tissue.



1 - 2. Preoperative intraoral photographs and CT images.
3. Gingival flap reflection, measure the bone wall defect with a periodontal probe.
4. After implant placement, the implant threads are exposed.
5. Perform guided bone regeneration (GBR) at the exposed part of the implant, ensuring that the bone graft completely covers the bone defect area.
6. Fix Bonamem™ with membrane tacks.
7 - 9. Intraoral photographs after the operation and six months post - operation.
10 - 11. Immediate post - operation implant images and cone - beam computed tomography (CBCT) images six months after the operation.
12. Second-stage implant procedure.
13 - 14. VIP CT and connective tissue graft (CTG).
15 - 16. Temporary restoration for seven months after the operation.
17 - 18. CT re - examination 12 months after the operation and the recovery of the intraoral soft tissue contour.
19 - 20. Re - examination one year after the operation and replacement of the final restoration.

Conclusion

1. For the timing of implantation, when the soft tissue can be closed, early stage implantation can be chosen for anterior teeth.
2. For cases with large bone defects undergoing guided bone regeneration (GBR), it is advisable to choose long - acting membranes, such as the absorbable Bonamem™.
3. Cover the implant thread surface with autologous bone chips or FDBA, and perform excessive bone grafting on the labial side.

CLINICAL CASE

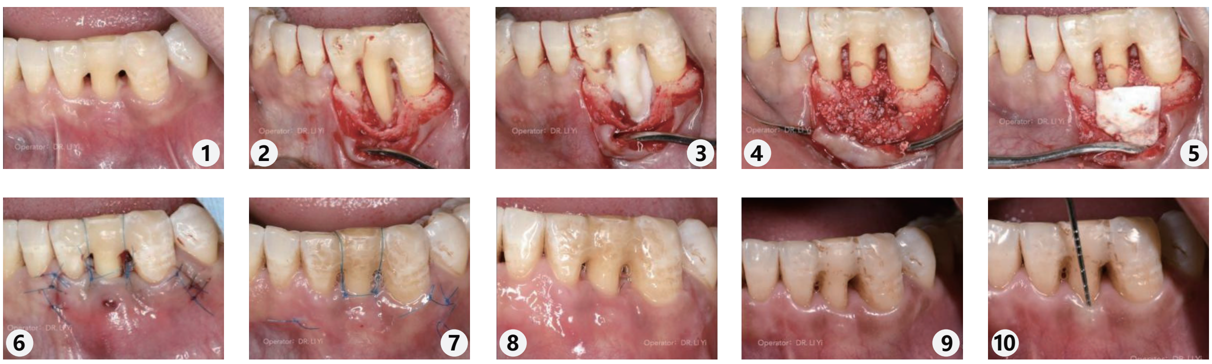
GUIDED TISSUE REGENERATION FOR MANDIBULAR ANTERIOR TEETH WITH A POOR PROGNOSIS

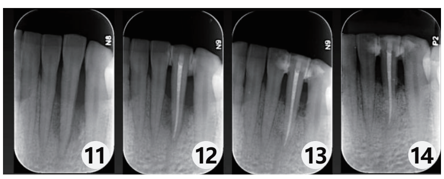
Case Overview

Patient: A 25 year old male presented with complaints of gingival bleeding, swelling of the gingiva around mandibular anterior teeth, and tooth mobility.
Intraoral examination: Poor oral hygiene with a large amount of dental plaque and soft debris. The gingiva is generally red and mildly swollen. The bleeding index (BI) is 2 - 3, and the probing depth (PD) is 3 - 6mm throughout the mouth. Tooth 32 has a mobility of grade II+ and gingival swelling. A fistula can be seen on the labial side. The response to cold test is dull. The PD values (from mesial to distal on the labial side) are 4mm, 10mm, 3mm, and (from mesial to distal on the lingual side) are 4mm, 3mm, 4mm.
Imaging examination: Periapical radiograph shows vertical alveolar bone resorption from the mesial to distal of tooth 32, reaching the root apex.
Diagnoses: 1. Chronic periodontitis; 2. Combined periodontal - endodontic lesion of tooth 32.

Treatment Plan

Periodontal basic therapy
Root canal treatment (RCT) for tooth 32 + periodontal splint fixation
Guided tissue regeneration (GTR) procedure for tooth 32
Periodontal maintenance





1 - 2. Incisions were made including intrasulcular incisions, papilla - preserving incisions, and mesial - distal vertical releasing incisions for teeth 31 - 33. A full - thickness labial flap was reflected. Thorough debridement was carried out to remove the inflammatory granulation tissue. Mixed bone pockets with 1 - 2 walls on the labial, mesial and distal sides of tooth 32 were found, extending to the root apex. The lingual bone wall was relatively intact.
3 - 4. Root planing was performed, and the root surface was treated with EDTA for 2 minutes. Bonabone™ and injectable platelet - rich fibrin (iPRF) were implanted into the bone pockets.
5 - 6. Bonamem™ (natural porcine pericardium membrane) was covered. The gingival flap was relaxed, repositioned coronally, and the wound was closed with suspension and interrupted sutures to ensure precise alignment of the incisions.
7 - 8. Reexamination two weeks after the operation showed that the wound achieved first - intention healing, and no incision dehiscence was observed.
9 - 10. Reexamination six months after the operation showed that the gingiva around tooth 32 was pink in color and firm in texture. The PD values (from mesial to distal on the labial side) were 2mm, 1mm, 3mm, and (from mesial to distal on the lingual side) were 3mm, 2mm, 3mm.
11 - 12. Periapical radiographs of tooth 32 before treatment; periapical radiograph of tooth 32 three months after root canal treatment.
13 - 14. Immediate periapical radiograph of tooth 32 after GTR; periapical radiograph of tooth 32 six months after GTR.

Conclusion

1. In this case, there are severe bone defects on the buccal, mesial and distal sides of tooth 32. However, the periodontal bone around the mesial and distal adjacent teeth and the lingual bone wall of the affected tooth are still intact. This situation is favorable for the stability of the bone grafting material in the GTR (guided tissue regeneration) procedure and the effect of tissue regeneration, which is also one of the reasons why the surgeon chose to try the GTR procedure for this case.
2. When performing the GTR procedure on a tooth with a relatively severe degree of bone destruction, various details should be considered to increase the success rate of tissue regeneration after the operation: A. Design the incisions reasonably; B. The barrier membrane should be made of materials with good biocompatibility, strong tissue binding ability and fast vascularization, such as Bonamem™; C. For severe and complex bone defects, the space maintenance ability and duration of the barrier membrane are of great importance.

	small size	15 x 18mm / 16 x 19mm
	medium size	15 x 25mm / 16 x 26mm
	big size	25 x 25mm / 26 x 26mm
	large size	29 x 40mm
	**vial**	
	0.25-1mm(particle)	0.25g、0.5g、1.0g、2.0g
	1-2mm(particle)	0.5g、1.0g、2.0g
	syringe	
	0.25-1mm(particle)	0.15g、0.25g

Specifications are subject to change without any notice.
Some products listed in this catalog are not available for sales in all markets due to pending regulatory clearance.
Please contact the local sales representative for current products availability.

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