치의학박사 학위논문

Clinical efficiency of novel collagen membrane derived from porcine pericardium; randomized double-blind clinical study

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2018년 8월

서울대학교 대학원
치의과학과 치주과학 전공
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Abstract

Clinical efficiency of novel collagen membrane derived from porcine pericardium; randomized double-blind clinical study

Hyeyoon Chang

Program in Periodontology, Department of Dental Science
Graduate School, Seoul National University

(Directed by Professor Sungtae Kim, D.D.S., Ph.D.)

Purpose The aim of this study was to radiographically and clinically compare dimensional alterations during ridge preservation using two extracellular matrix (ECM) membranes.

Methods A widely used ECM membrane (Bio-Gide®) and newly developed ECM membrane (Lyso-Gide®) were applied during the ridge preservation procedure in control and test groups, respectively. Cone-beam computed tomography (CBCT) scans were taken at surgery day and 6 months after the ridge preservation procedure. Alginate impressions were obtained at 1 week and 6 months after the ridge preservation procedure. Results were statistically analyzed using the *independent t-test* and the *nonparametric Whitney U test*.

Results Change of extraction socket dimension from master casts showed no significant difference between two ECM membranes. Likewise, differences of width, height and quantity of bone tissue from CBCT scans showed no significant difference. The mean VAS of characteristics of test group was shown higher than that of control group.

Conclusions Newly developed ECM membrane in ridge preservation procedure showed comparable clinical/ radiographical result to widely used ECM membrane.

Keywords: 3-D imaging, Alveolar bone grafting, Bone regeneration, Cone-Beam Computed Tomography, Membranes, Tooth socket

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Introduction

After tooth extraction, various events for remodeling soft and hard tissue are initiated, such as (a) formation and maturation of a blood clot, (b) infiltration of fibroblast to replace the coagulum, and eventually (c) establishment of a provisional matrix that allowed for bone tissue formation.

[1-3] The alveolar ridge is dependent on teeth, its volume and shape is determined by the form of the teeth.[4] Therefore, tooth extraction leads to reduced alveolar ridge contour. The resorption processes responsible for dimensional changes following tooth extraction have been assessed in previous studies.[3-5]

Clinically, most of the resorption occurs during the first 3 months of healing, and this results in the buccolingual dimension of the alveolar ridge being reduced by approximately 50%.[6] Araujo et al. reported that buccal wall reduction was more pronounced than that of the lingual wall because buccal bone is bundle bone that loses its function after tooth extraction and is resorbed by osteoclasts.[4] The possible consequences of these hard-tissue alterations may significantly limit implant placement if additional bone grafting is not performed, and impair the aesthetic outcome for a prosthesis due to horizontal or vertical ridge deficiencies.

Ridge preservation techniques are designed to minimize dimensional changes of the edentulous ridge after tooth loss. Various surgical techniques involving different choices of bone graft, barrier membrane, and soft tissue have been evaluated. However, none of the tested treatments completely preserved the buccal bone plate after tooth loss.[7-9] However, placing biomaterials in the extraction sockets promoted bone remodeling and partially compensated the ridge resorption in an animal model.[10] A technique involving both bone grafting and a resorbable membrane showed the most favorable results, with implant placement being possible at 4–6 months after ridge preservation.[11,12]

Covering the extraction socket with a free gingival graft or membrane may

reduce the postoperative external contour shrinkage.[13] Using manufactured barrier membrane is more convenient than using a soft-tissue graft because a donor site is not required. The use of occlusal membrane for a ridge preservation procedure also prevents particle loss and the migration of epithelial and connective tissue cells from adjacent areas into the defect area.[14]

The ideal barrier membrane would exhibit characteristics that include biocompatibility, dimensional stability, tissue integration at the defect site, and a barrier function preventing soft-tissue ingrowth.[15] Barrier membranes can be classified into two categories, non-resorbable and resorbable membranes. The non-resorbable membranes for guided bone regeneration procedure (GBR) are polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), and titanium, which are suitable for maintaining space for bone formation.[16,17] However, these membranes require another surgical approach to remove them and they have a higher risk of exposure to the oral environment, thus increasing the risk of secondary infection which can interrupt bone regeneration.[17,18]

To avoid some complications of non-resorbable membranes, resorbable membranes were developed.[19,20] Recently, many options have been introduced to the market and resorbable membranes can now be manufactured from natural or synthetic. They don't need another surgical procedure and they can induce good tissue integration with lower risk of membrane exposure.[21] Although different non-resorbable and resorbable membranes have been developed and their use extensively studied, there is still the need to develop a better membrane for clinical use.

Most collagen membranes currently available in the dental clinic are made with type I and type III collagen derived from porcine or bovine collagen. Collagen is accepted as a safe material and also has a nontoxic degradation product. However, its resorption time is uncontrolled. Ensuring the proper time for resorption of the barrier membrane is also important, since resorption before new bone formation would cause loss of dimensional stability, dissipation of bone substitute, and impaired healing of the defect site, while delayed resorption would also cause nonideal healing due to the remaining nonfunctional barrier membrane.[22] Therefore, cross-linking agents are used in commercial collagen membranes to delay resorption time, such as 1-ethyl-3-(3-dimethylaminopropyl) carbodiimide (EDC), glutaraldehyde, and formalin.[23] Chemically cross-linked collagen membrane seems to be safe and effective for controlling the resorption time of collagen membrane.[22] However, it is also known that certain cross-linking chemical agents can induce unwanted inflammation and foreign-body reactions.[24] Moreover, cross-linked membranes can delay revascularization. Therefore, as long as the resorption time could be controlled, a membrane without a chemical cross-linking agent could lead more favorable healing.

The traditional method of membrane production involves the extraction of collagen and reconstruction by cross-linking the agent with the mold. This method, however, has the possibility of destroying native tissue construction and requires the cross-linking agent. A new extracellular matrix (ECM)-based resorbable membrane (Lyso-Gide®, Oscotec, Sungnam, South Korea) was recently introduced. This membrane is derived using an acellular method based on porcine pericardium. The main concept of this membrane was

keeping the tissue structure as well as being useful for tissue regeneration.[23]

Porcine pericardium is adaptable to acellular processes. Because raw porcine pericardium is very thin (<0.3 mm) and has a low cell density, making it ideal for acellular processes. The structure of lyophilized acellular porcine pericardium is bilayer structure and it is particularly suitable for the GBR: the upper layer is very thin (<0.1 mm), has a high density, and can act as a barrier to tissue invasion, while the bottom layer (>0.2 mm) has a micropore structure and can provide spaces for osteoblast homing. This membrane has a natural cross-linking structure, which avoids the need for any additional cross-linking process.[23]

The aim of this study was to radiographically and clinically compare the dimensional alterations of alveolar ridge preservation between using two ECM membranes. A widely used ECM membrane (Bio-Gide®, Geistlich Biomaterials, Wolhusen, Switzerland) and newly developed ECM membrane treated with acellular lypophilized porcine pericardium (Lyso-Gide®) were applied during the ridge preservation procedure in control and test groups, respectively.

Material and Methods

Study design

This study was prospective, double-blind, controlled, randomized clinical investigation consistent with the Helsinki Protocol. The study protocol was approved by the Institutional Review Board at Seoul National University Dental Hospital (**approval no. CGE14001**) and registered as a clinical trial (http://cris.nih.go.kr, **approval no. KCT0001815**). The Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting a clinical trial were followed. Informed consent was obtained from all patients prior to the commencement of the study. Block randomization with numbered containers was used to randomly assign treatment protocols.

Participants

Sixty-six patients who were visited to the Department of Periodontology or the Department of Oral and Maxillofacial Surgery, Seoul National University Dental Hospital, Seoul, South Korea for the treatment of tooth extraction were enrolled in the study. Patients were recruited between April 2015 and September 2016. Twenty-two patients dropped out during screening and two patients dropped out during the follow-up period (Figure 1).

Ridge preservation was performed on 42 patients (22 males and 20 females with a mean age of 60.3 years and an age range of 41–78 years). The patients were randomly divided into the control group (n=21) and the test group (n=21). Their general characteristics are listed in Table 1. Only

patients older than 20 years were included in this study. The indications for tooth extraction included dental caries, tooth fracture, and chronic periodontitis (loss of clinical attachment of more than 5 mm or degree-3 mobility).

The following exclusion criteria were applied:

1. Uncontrolled hypertension or diabetes mellitus.
2. History of malignant bone tumor.
3. Severe cardiovascular disease, respiratory disease, kidney disease, liver disease, digestive disease, blood disease, nerve disease, or mental disease.
4. Hyperthyroidism or hypothyroidism.
5. History of drug allergy.
6. Severe depression or anxiety disorder.
7. Alcohol abuse within the previous year.
8. Considered inappropriate by the researchers.

Treatment

All of the ridge preservation procedures were performed by four periodontists. This study was designed to have high reproducibility, and so the four examiners were trained for at least 10 hours, practicing the procedure under the same conditions. The tooth was carefully removed, and the inner granulation tissue was carefully eliminated with curettes. In both groups, deproteinized bovine bone mineral collagen (Bio-Oss Collagen®, Geistlich Biomaterials) was placed in the fresh socket without flap elevation:

two ECM membranes were applied in the test and control groups, respectively, in a double-blind manner. The membrane was stabilized with sutures (4-0 Vicryl, Ethicon, NJ, USA). Antibiotic coverage using amoxicillin or cefdinir was prescribed for 5 days. The sutures were removed after 7~10 days, and signs of complications were checked (Figure 2). Cone-beam computed tomography (CBCT) scans (Dinnova 3, HDX Corporation, Seoul, South Korea) were obtained (scan time of 7 s at 120 kV and 10 mA) before surgery, on the day of surgery, and 6 months after the ridge preservation procedure.

Evaluation of dimensional changes

Master casts of each patient were made with dental stone (GC Fujirock EP, GC Corporation, Tokyo, Japan) utilizing alginate impressions at 1 week and 6 months after the ridge preservation procedure. Computer-aided design software (DentalCAD, EGS, Lazzaro, Italy) and an optical scanner (DScan version 1.1, EGS) were used to scan the casts.

The 1-week cast scans were matched with the corresponding 6-month cast scans using digital imaging software (Polyworks®, InnovMetric, Quebec, Canada). The different scans were superimposed while using adjacent teeth as references to ensure precise alignment. A region of interest (ROI) was set in the scan of the 1-week cast from the upper middle of the gingiva to the mucogingival junction. The average surface vector was calculated for the ROI, and then the ROI was projected onto a plane perpendicular to the average surface vector. The projected area was projected onto the scans of

the 1-week and 6-month casts. Volumetric measurements were performed in the ROI and the projected area. The volumetric change was divided by the area of the projection and quantified as the displacement between the surfaces (Figure 3).

Quantity of bone tissue

Two CBCT raw scans obtained on the day of surgery and 6 months after the ridge preservation procedure were merged and then resliced at a resolution of 0.3 mm using a software program (OnDemand3D^{TM}, Cybermed, Daejeon, South Korea). The segmentation range of the two data was set to be equal. The three-dimensional shape of the ridge preservation site was developed and the quantity of bone tissue was measured using the OnDemand3D^{TM} program. The quantity of the initial total graft (Q2) was measured in a CBCT scan obtained on the day of surgery (V2). The program could evaluate the volume with setting HU (Hounsfield Unit) of area of interest. The quantity of mineralized new bone and residual graft (Q6) was also measure during CBCT at 6 months after the ridge preservation procedure (V6). The performance of a membrane as a barrier was quantified as Q6/Q2′100 (Figure 4).

Width and height changes

Changes in the width and height at the center of the extraction socket

were evaluated in merged axial and sagittal views of V2 and V6 CBCT images using the OnDemand3D^{TM} program (Figure5,6).

Assessment of membrane characteristics

Operators assessed characteristics of this membrane with the aid of a visual analogue scale (VAS) immediately after ridge preservation procedure. The VAS comprised a horizontal continuous numeric range, with a value of 0 indicating negative value (on the left side) to a value of 10 indicating positive value (on the right side). The questions about characteristics included the followings:

1) Is it easy to trim into proper form of membrane?

2) Is it easy to manipulate for covering the defect?

3) Does it have proper resistance to tearing?

4) Is membrane easy to prevent bone particle dissipation?

5) Is it easy to maintain the membrane at suture?

Data analysis

A power calculation before the study commenced revealed that a sample size of 23 was needed to detect a 6 mm^3 of difference in ridge volume of after 6 months, assuming a maximum standard deviation of 7.68mm^3 with

80% power and 0.05 cutoff for significance and increasing the sample size by 10% due to drop-out.

The primary outcome variables were dimensional changes in the residual ridge and quantity of bone tissue. The secondary outcome variables were changes in width and height and VAS scale.

The height conformed to a normal distribution (*Shapiro-Wilk test*, $p>0.05$), while the distributions of the dimensional change in the residual ridge, quantity of bone tissue, width and VAS measures did not (*Shapiro-Wilk test*, $p<0.05$). The gender, jaw position, and right/left proportions in the treatment and control groups were compared using the *Pearson chi-square test*.

Due to the characteristics of the distributions, the *independent t-test* was applied to compare differences in age and height according to the treatment and control groups, while the *nonparametric Whitney U test* was used to compare the difference in dimensional changes in the residual ridge, the quantity of mineralized tissue, width, and the VAS. SPSS (version 23.0, SPSS, Chicago, IL, USA) was used for the analysis procedure.

Results

Evaluation of dimensional changes

The results for the dimensional changes in master casts are displayed in Table 2. The mean dimensional difference between the 1-week and 6-month casts was –0.98 mm in the test group and –1.01 mm in the control group ($p \geq 0.05$). The cast volume was lower at 6 months than at 1 week in both the test and control groups.

Quantity of bone tissue in CBCT

The results for the normalized quantity of bone tissue (Q6/Q2) in CBCT data are presented in Table 2. The mean percentage was 91.6% in the test group and 91.5% in the control group ($p \geq 0.05$). The quantity of bone tissue was less at 6 months than at 1 week in both the test and control groups.

Changes in width and height in CBCT

The changes in the width in the center of the extraction socket in CBCT data are displayed in Table 2. The mean difference in width between the V2 and V6 images was –1.7 mm in the test group and –2.1 mm in the control group ($p \geq 0.05$).

The changes in the height of the extraction socket in CBCT data are listed in Table 2. The mean difference in height between the V2 and V6 images was –2.1 mm in the test group and –2.2 mm in the control group ($p \geq 0.05$).

Assessment of membrane characteristics

The mean VAS of characteristics of membrane were shown in Table 3.

1) Trimability

The mean VAS of this question was 9.2 for test group and 8.1 for control group. Test group is easier to fabricate the proper membrane form in significant difference.

2) Manipulation

The mean VAS of this question was 8.9 for test group and 7.1 for control group. Test group is easier to manipulate for covering the defect in significant difference.

3) Resistance to tearing

The mean VAS of this question was 9.2 for test group and 8.1 for control group. Test group is stronger resistance of tearing in significant difference.

4) Preventing bone particle dissipation

The mean VAS of this question was 8.9 for test group and 7.9 for control group. Test group is easier to maintain the bone particle in significant difference.

5) Convenience for suturing

The mean VAS of this question was 9.0 for test group and 8.1 for control group. Test group is easier to maintain the membrane at suture in significant difference.

Discussion

Ridge preservation using bone graft and resorbable membrane has been shown to improve the ridge height and width dimensions relative to tooth extraction alone.[14] The present randomized controlled trial compared the effectiveness of using two different membranes for ridge preservation. Neither of the membranes could prevent ridge resorption entirely after tooth loss. This investigation found no significant differences in changes in the volume, width, or height of the extraction socket.

There have been usually three ways to measure ridge dimension after the ridge preservation procedure. As a first method, the horizontal ridge width and the vertical ridge height were measured with a standardized periodontal probe at the alveolar crest directly. The custom-made template was used to specify the reference point.[7,25,26] The first method was prone to inaccurate measurement and tissue damage. To overcome this issue, the first method was commonly combined with other methods.[25,26] The second method of measurement was using a cast model. Base model was scanned and matched with the corresponding scan of the post-surgery casts using digital imaging software. Cross-section of the buccolingual measurement was then compared with each other.[25,27] If there was a change in volume of the healed ridge, it was indicated with blue polyvinyl siloxane stent.[28] The third method was taking the CBCT. In most previous studies, patient-specific radiographic stents were fabricated on diagnostic casts. Radiopaque markers served as references on the CBCT images at the coronal, buccal, and lingual aspects of the treated site to allow for standardization of the measurements of the alveolar ridge. Buccal plate thickness, ridge width and height were

evaluated in CBCT image.[26,29,30]

Most previous studies have evaluated ridge alteration in two dimensions, the present study approached evaluation of the ridge in three dimensions by superimposing data obtained through both CBCT and a 3D scanner. While linearly measured outcomes are valuable, volumetric measurements could show more detailed and accurate understanding of the important anatomic changes that occur following both tooth removal and subsequent ridge preservation procedures.

CBCT provides high-quality images with a lower radiation dose than CT. Furthermore, CBCT is a non-destructive method that can measure the surgical site 3-dimensionally without re-entry. Not only hard tissue but soft tissue could be measured in CBCT image. New program which was used in this study can superimpose and analyze the CBCT image. This program would be useful even without any reference guide. Furthermore, this program could be the new methodology of recognizing the volume using the HU of bone.

In this study, the applied technique of 3D scanner showed a high reproducibility and an excellent accuracy for measuring volume changes with a measurement error below 10 mm.[13,31] This method offers advantages including its noninvasive character, absence of radiation and the fact that it can easily be applied. But in using 3D scanner, there was one shortcoming of the technique since optical scans were performed on study casts. The accuracy of the method is highly influenced by the accuracy of the impressions and the casts. Alginate impressions were taken in this study for efficiency reasons, but it is clearly less precise than rubber impression. If

digital imaging software data can be obtained directly from patient with oral scanner, the degree of error would be reduced and be more convenient.

The volumetric changes of the extraction sockets in the master casts did not differ significantly between the test and control groups. This indicates that using either type of membrane in ridge preservation was similarly helpful in preventing collapse of the socket volume. Both membranes seemed to last long enough to prevent dissipation of bone graft particles and soft-tissue growth into the extraction socket. The decrease in bone quantity in the study cast and CBCT from week 1 to 6 months was similar in the test and control groups, furthermore the decrease was consistent with the results of previous studies.[13,32]

Newly developed ECM membrane from porcine pericardium is comparable to the most commonly used membrane, and has the advantage of being inexpensive and not requiring a cross-linking agent. In addition, higher tensile strength was shown in this membrane compared with commercial natural collagen membrane (control group). High tensile strength is an important function because it allows membrane stabilization with sutures.[23] Clinically, when the clinician chooses the membrane for their surgery, ability and the characteristics of the membranes are also an important factor of consideration. The clinicians assessed that the membrane characteristics (operability/ trimability/ durability) were similar in the control and test groups. It was evaluated through questionnaire with VAS score. The ease of use was slightly better in the test group. However, there was one case of dropout during follow-up in the test group that was due to the membrane not being secured in the extraction socket. Another case of dropout was due

to the presence of a retained root, therefore re-entry was needed.

It can be concluded that a ridge preservation procedure using a bone graft and resorbable membrane is effective at decreasing dimensional changes of the edentulous ridge. However, no differences between two different resorbable membranes were found in this study.

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Tables

Table 1 General characteristics of subjects

	Test group Mean (SD)	Control group Mean (SD)	*P-value*	
N	21	21		
Age (years)[a)]	60.0 (10.0)	60.5(11.6)	0.876	NS
Gender, N(%)[b)]			0.382	NS
Male	11(55.0)	9 (45.0)		
Female	10(45.5)	12(54.5)		
Jaw position, N(%)[b)]			0.123	NS
Upper	8(38.1)	13(61.9)		
Lower	13(61.9)	8(38.1)		
Right/Left, N(%)[b)]			0.204	NS
Right	10(62.5)	6(37.5)		
Left	11(42.3)	15(57.7)		

[a)] Using *parametric independent t-test*; [b)] Using the *chi-square test*

Table 2 Clinical and radiographic dimensional change

	Test group Mean (SD)	Control group Mean (SD)	Total Mean (SD)	*P-value*[a)]
Dimensional changes[b)]				
1-week-cast (mm^3)	860.1(401.6)	933.1(639.4)	896.6(528.7)	0.850
6-month-cast (mm^3)	790.2(356.4)	876.3(642.7)	833.3(515.1)	0.660
Surface vector (mm^2)	73.4(45.2)	72.1(57.6)	72.8(51.1)	0.811
Change (mm^3/mm^2)	-0.98(1.48)	-1.01(1.67)	0.99(1.55)	0.970
Quantity of bone tissue in CBCT[b)]				
Surgery day	224.2(153.9)	217.4(111.9)	220.8(133.0)	0.811
6 month	207.1(150.9)	201.7(107.8)	204.4(129.6)	0.734
Change (%)	91.6(8.3)	91.5(6.1)	91.6(7.2)	0.890
Width[b)]				
Surgery day	10.0(1.6)	10.4(2.5)	10.2(2.1)	0.715
6 month	8.3(1.6)	8.4(2.1)	8.3(1.9)	0.715
Change (mm)	-1.7(0.8)	-2.1(1.5)	-1.9(1.2)	0.633
Height[a)]				
Surgery day	8.3(2.0)	9.1(2.1)	8.7(2.0)	0.213
6 month	6.2(1.7)	6.9(1.7)	6.6(1.7)	0.172
Change (mm)	-2.1(1.1)	-2.2(1.4)	-2.1(1.2)	0.894

[a)] Using *parametric independent t-test*; [b)] Using *nonparametric Whitney U test*

Table 3 VAS scale[a)]

	Test group Mean (SD)	Control group Mean (SD)	Total Mean (SD)	*P-value*[a)]
VAS 1	9.2(1.1)	8.1(1.5)	8.6(1.4)	**0.005**
VAS 2	8.9(1.3)	7.1(1.7)	8.0(1.7)	**0.001**
VAS 3	9.2(0.8)	8.1(1.5)	8.7(1.3)	**0.015**
VAS 4	8.9(1.3)	7.9(1.4)	8.4(1.4)	**0.012**
VAS 5	9.0(1.2)	8.1(1.1)	8.5(1.2)	**0.012**

[a)] Using *nonparametric Whitney U test*

Figures

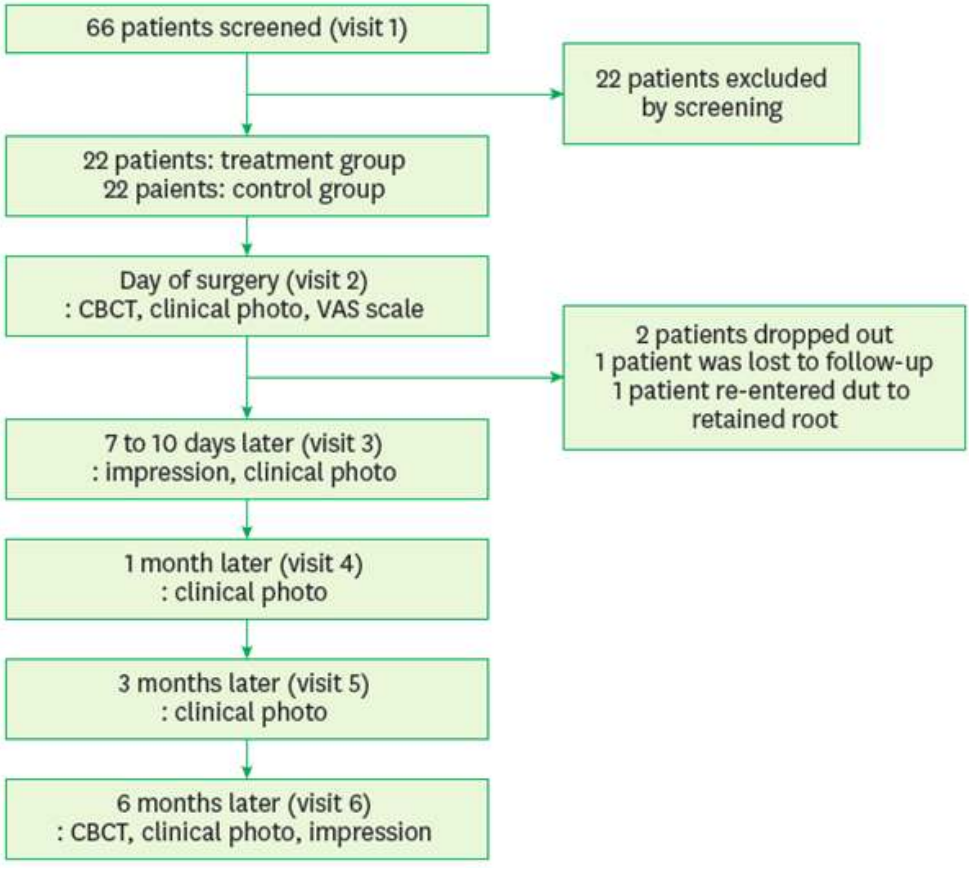

Figure 1. Flowchart of the RCT procedure

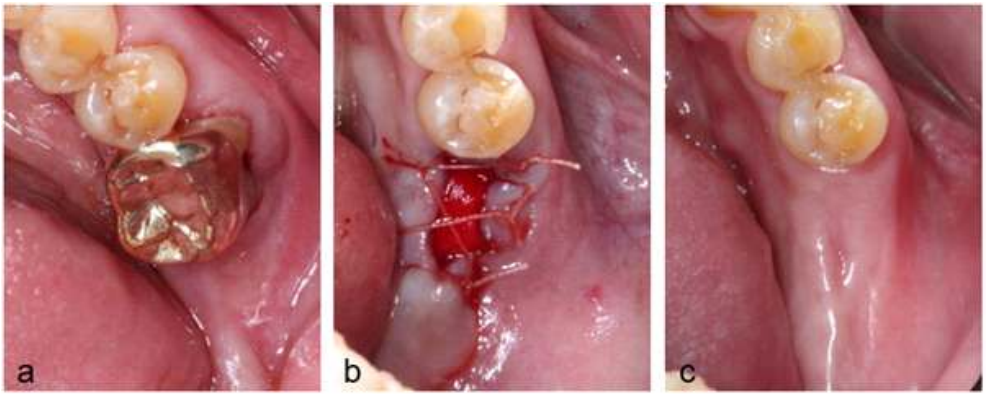

Figure 2. Clinical photograph illustrating an extraction site in posterior mandible (a) Before extraction (b) After ridge preservation procedure (c) At 6-month f/u

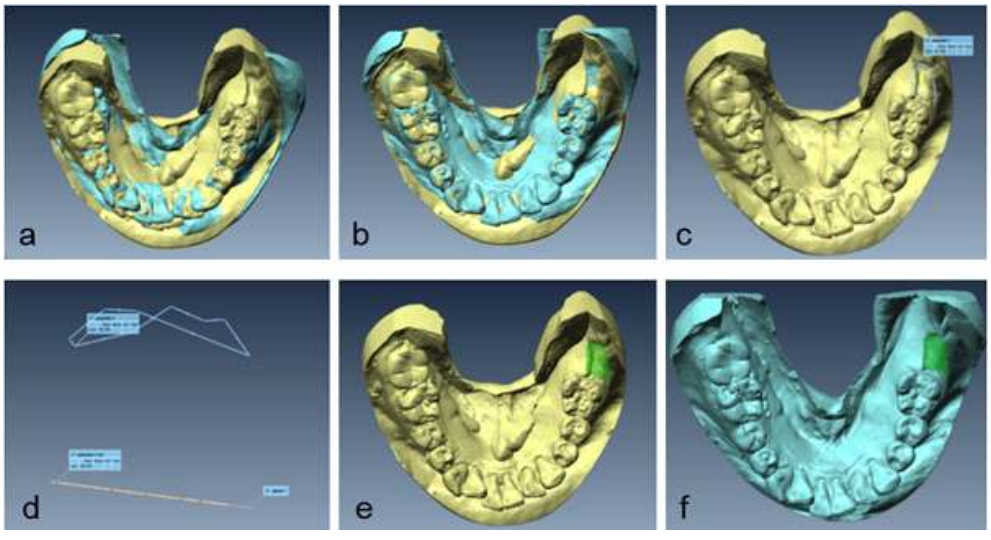

Figure 3. Polyworks® (a) Before superimposing (b) After superimposing, adjacent teeth were used as reference points (c) Designated area; from middle top of gingiva to MGJ (d) Vector was projected from designated tri-dimensional area (e) Volume from the vector at 1-week model could be measured. (f) Volume from the vector at 6-month model could be measured. Measured volume was divided by the vector area. (mm^3/mm^2)

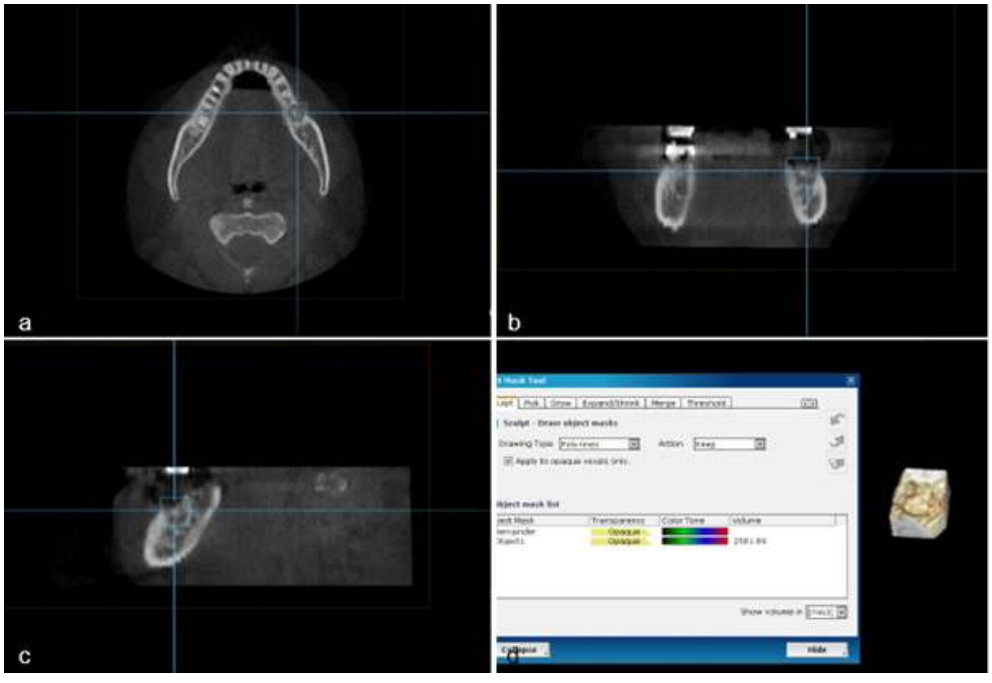

Figure 4. Quantity of bone tissue (a) Axial view (b) Coronal view (c) Sagittal view of V2 image or V6 image and specify a region of interest (d) Opaque area can be detected and volume is calculated and displayed

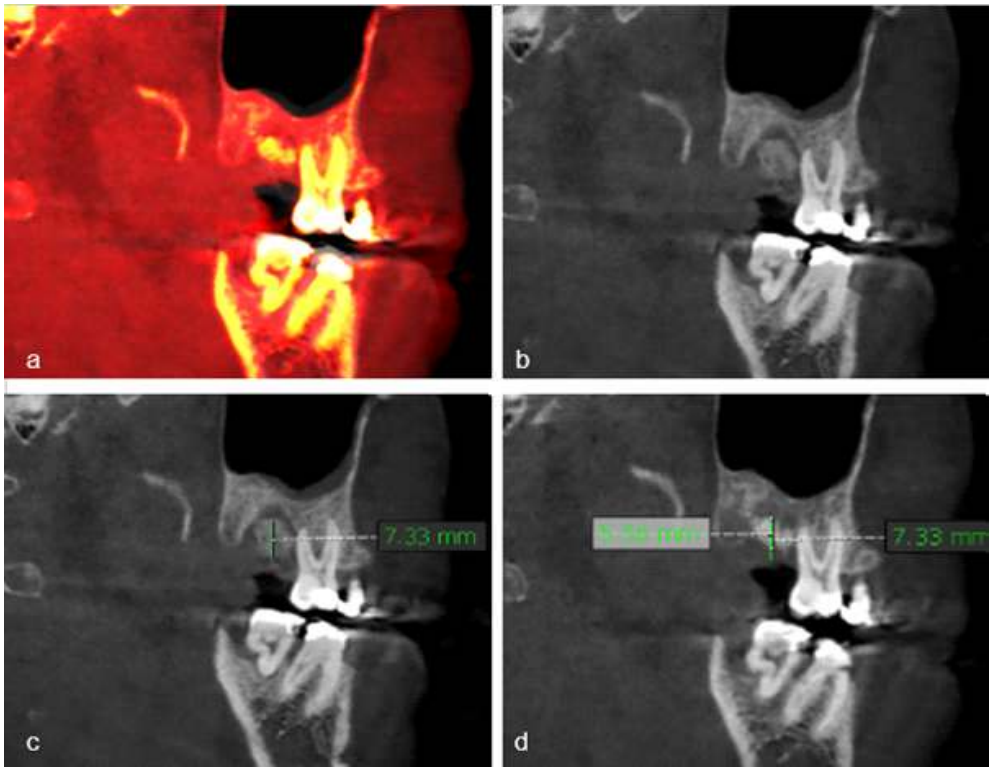

Figure 5. Change of height (a) Superimposing of V2 and V6 sagittal image (b) Displaying only V2 sagittal image of superimposing data (c) Calculating of height in V2 image (d) Calculating of height in V6 image which is same cut with V2 image

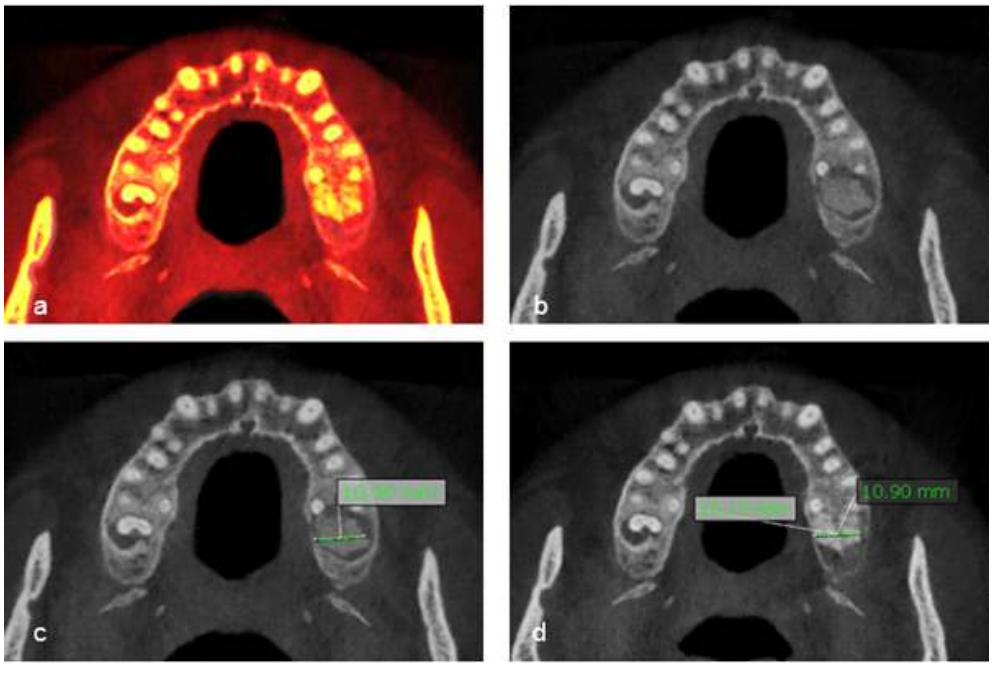

Figure 6. Change of width (a) Superimposing of V2 and V6 axial image (b) Displaying only V2 axial image of superimposing data (c) Calculating of width in V2 image (d) Calculating of width in V6 image which is same cut with V2 image

국문초록

돼지 심막에서 추출한 새로운 콜라겐 차폐막의 임상적 효율에 대한 무작위, 이중 맹검 임상 비교 연구

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이 연구의 목적은 임상적으로 널리 사용되는 차폐막 (Bio-Gide®)과 새로 개발된 차폐막 (Lyso-Gide®)의 두 가지의 세포외기질(ECM; extracellular matrix) 구조의 차폐막을 비교한다. 이 두 가지의 흡수성 차폐막을 이용하여 치조제 보존술을 시행한 후 방사선학적 및 임상적 결과를 비교하여 차폐막의 유용성에 대하여 평가한다.

치조제 보존술을 시행한 당일과 6개월 후에 콘빔형 전산화 단층촬영

(Cone-beam computed tomography scans) 을 촬영한 후 이미지를 중첩시켜 발치와의 넓이와 높이, 골이식재의 생착률을 비교한다. 또한 수술 1주일 후와 6개월 후 알지네이트 인상으로 모델을 채득하여 모델을 스캔한 이미지를 중첩시켜 치조제 부피 변화를 측정한다. 더불어 수술 당일 술자는 VAS를 이용하여 0-10까지의 점수로 차폐막의 특성을 기록한다.

콘빔형 전산화 단층촬영을 통한 이미지 비교에서 발치와 중심의 넓이와 높이, 골이식재의 생착률은 두 차폐막을 사용했을 때 유의미한 차이를 보이지 않았다. 마찬가지로 모델에서의 발치한 치조제 부피변화를 측정했을 때 양 군에서 유의미한 차이를 보이지 않았다. VAS 점수 비교에서는 실험군이 대조군에 비하여 유의미한 높은 점수를 보였다.

이 연구에서 임상적으로 널리 사용되는 차폐막 (Bio-Gide®)과 새로 개발된 차폐막 (Lyso-Gide®)의 두 가지의 세포외기질구조의 흡수성 차폐막은 임상적, 방사선학적으로 비슷한 결과를 보인다.

주요어 : 발치와, 치조제 보존술, 차폐막, 콘빔형 전산화 단층촬영, 디지털 영상 중첩

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