Master of Medicine

Randomized clinical trial to evaluate the efficacy of porcine and bovine collagen membranes

Graduate School
of University of Ulsan

Department of Medicine
Hoon-Je Chang

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Supervisor: Kang-Min Ahn, DDS, MSD, PhD

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Hoon-Je Chang

Department of Medicine
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This certifies that the master thesis
of Hoon-Je Chang is approved.

Jee-Ho Lee
Committee Chair Dr.

Kang-Min Ahn
Committee Member Dr.

Hyun-Suk Cha
Committee Member Dr.

Department of Medicine
University of Ulsan, Korea
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English abstract

Randomized clinical trial to evaluate the efficacy of porcine and bovine collagen membranes

Hoon-Je Chang, D.D.S

Directed by Kang-Min Ahn, D.D.S., M.S.D., PhD

Department of Dentistry, Graduate school of Medicine, University of Ulsan

Introduction

Collagen membranes are one of the most popularly used membranes for guided bone regeneration (GBR) because there is no need for removal and it shows lower rate of patient morbidity. It is less likely to be exposed and presents stable results even after partial exposure. The sources of the collagen membrane are porcine, bovine and equine. The efficacies of those collagen membrane are well studied, however, randomized clinical trial is scarce. The purpose of this study was to compare the efficacy of collagen membrane from bovine and porcine in oral and maxillofacial pathologic lesions.

Patient & Methods

Patients who needed bone graft due to jaw bone defect such as nasopalatine cyst and periapical cyst were included in this study. Patients whose bone defects underwent primary closure were included. Patients with uncontrolled metabolic disease, history of bone target agent infusion and pregnant woman were excluded. Heavy smokers and those who received radiation therapy at the treatment site were also unable to participate the study. A total of 12 patients were selected and was required to visit 5 times at minimum. Conebeam computed tomography (CBCT), digital model scanning data were acquired at visits 1, 3, and 5. Panoramic views were taken, and adverse reaction evaluation were performed at each visit. Clinical photos were taken at visits 2, 3, 4, and 5. Porcine bone was grafted and bovine and porcine membranes were randomly allocated for each patients. The

evaluation methods were clinical, radiological and 3-dimesional model scanning for volume change and efficacy of collagen membranes. Clinical evaluation included presence of inflammation, infection, presence of dehiscence, and foreign body reaction. The treatment area which contained the defect sites were selected and manually manipulated for CBCT analysis. The grafted volume was measured by connecting the outermost border of bone graft in each CBCT layer containing the defect. Trabecular thickness which stands for bone regeneration were measured in the CBCT scan. Pores that are enclosed from all sides and pores connected to the external structure were respectively measured as closed and open pores. The volume of pores was measured as a percentage of the total volume. Soft tissue volume change was evaluated by comparing the data of the plaster models acquired at visit 1 and 5. Model scanning was performed by an intraoral scanner (Medit i500 oral scanner, MegaGen, Korea) and compared by a 3-dimensional analysis software (Geomagic Control X, 3D Systems, Cary, NC, USA).

Results

The gender ratio was 9:3 for males and females, with an age distribution ranging from 24 to 73 years. Periapical cysts (n=10) were the most dominant histopathological result composing 83% of the total group followed by nasopalatine cyst (n=2). No signs of infection or inflammation were presented during follow-up periods. There was no statistical difference between the porcine and bovine membrane groups ($p>0.05$ on the student's t-test and Mann-Whitney u-test) from the CBCT data. In the analysis of soft tissue volume in superimposition with 3D models, decreasing and no changing results were 5 cases each, and increasing results were 2 cases.

Conclusion

The results of GBR and soft tissue volume maintenance in the porcine and bovine membrane group showed no significant difference in clinical and radiologic analysis. Therefore, the bovine and porcine membranes used in the study showed no significant difference in clinical application.

Keywords: collagen membrane, guided bone regeneration, bone graft, CBCT, superimposition,

degradation

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Introduction

A barrier membrane is an essential element in implementing guided bone regeneration (GBR) in oral and maxillofacial surgery such as dental implant, cyst, and benign tumor.[1-3] For successful GBR, it is necessary to create a sealed space using a barrier membrane and induce bone formation cells into the space to promote bone regeneration.[4] In an experiment by Dahlin et al.[5] bone defects were formed through the buccal and lingual sides of both mandibular angles of rats. It was found that complete bone regeneration occurred only when the barrier membrane was used, and the defect was filled only with soft tissue when the barrier membrane was not used. In clinical use, Buser et al.[6-8] established the surgical protocol. He used Gore-Tex barrier membranes and autogenous bone grafts, which were the gold-standard membranes at the time.

To properly act as a barrier membrane, it should have five characteristics, which are biocompatibility, space-making, cell occlusiveness, tissue integration, and clinical manageability.[9] The type of barrier membranes can be largely divided into non-resorbable and resorbable membranes, and each has its advantages and disadvantages. Non-resorbable barrier membranes include expanded polytetrafluoroethylene(ePTFE), dense polytetrafluoroethylene(dPTFE), titanium mesh, etc.[10] The advantages are excellent space formation and maintenance, stable bone formation. The duration of the barrier function could be adjusted by the operation's decision. Since it has been used clinically for a long time, there is an appropriate surgical protocol, and the results can be predictable. However, the downside is that it can be exposed during the healing process, which affects bone regeneration and it requires second surgery for removal.[11]

For types of resorbable barrier membranes, collagen membranes, allogeneic dermis, and membranes made of synthetic polymers can be considered.[10] Collagen material appears to be a good choice for the resorbable GBR barrier because it shows biocompatible and clinical features.[12] Resorbable membranes do not require removal, reduce the likelihood of exposure, and contribute to a comparatively lower level of patient discomfort. The surgical technique can be considered simple, but

the disadvantage is that the functional period of the membrane cannot be adjusted, and occasionally leads to direct contact with the implant.[9, 10] In addition, space maintenance ability is poor and anchoring materials such as screws are needed in unfavorable defects. Micromovement of membranes can make grafting material unstable and hinder the formation of blood clots.[13] Resorbable membranes show stable results in alveolar bone defects such as fenestration or dehiscence, but may not be an ideal material to use on defects that need severe vertical bone graft or major bone defects.[14]

Collagen Membrane 2® (Dentium, Korea) (CM2) derived from bovine skin has been known to be maintained for a relatively long time in the body and is easy to manipulate and apply. Although, the physical properties are soft, it is quite tough and could induce extensive bone regeneration if used with fixing pins. Therefore, it is considered to be easily used in the elderly or patients with systemic diseases. Another advantage is that it has relatively good maneuverability and high degradation stability when implanted in vivo. Bio-gide® (Geistlich, Switzerland) (BG) made from porcine skin is one of the most used collagen membranes for GBR. Due to its stable results, it is usually considered the golden standard of collagen membranes in small defects or areas where space maintenance is not important.[11]

The purpose of this study was to compare the efficacy between bovine and porcine collagen membranes by evaluating barrier function of the resorbable membranes in clinical, radiological, and 3-dimensial (3D) analysis.

Patients and Methods

The study protocol was reviewed and approved by the institutional review board (IRB) of the Asan Medical Center, Seoul, Korea (IRB approval No. 2022-1114). This work was supported by the Korea Medical Device Development Fund grant funded by the Korea government (the Ministry of Science and ICT, the Ministry of Trade, Industry and Energy, the Ministry of Health & Welfare, the Ministry of Food and Drug Safety) (Project Number:RS-2022-00140935).

1. Patient screening and schedule

Patients who have bone defects in the jaw bones were potential targets for this study. Only defects that could be primarily closed were considered to satisfy the criteria. A total of 12 patients were satisfied the inclusion criteria. Patients with factors that could affect normal healing were excluded (Table 1).

CM2, a bovine derived collagen membrane was used in the case group, while BG, a porcine derived collagen membrane was applied in the control group. Patients were required to visit the hospital 5 times (Table 2). Screening and evaluation of enrollment, clinical and radiologic examination on conebeam computed tomography (CBCT) and panoramic view was performed at the first visit. Alginate (Aroma fine plus, GC corporation, Japan) impression and pouring with yellow stone (New plastone II, GC corporation, Japan) was done, and digital model scanning was implemented by an intraoral scanner (Medit i500 oral scanner, MegaGen, Korea).

Surgery was performed at the second visit. Xenograft porcine bone material (Osteon Xeno, Dentium, Korea) was used regardless of the control and case group and the particle size was 1.0mm~2.00mm. As assigned in the randomized table, BG and CM2 were applied to the control and case groups respectively.

Antibiotics and analgesics were used for approximately 5 to 14 days for infection control and pain relief. Stitch out was done at visit 3 which was about 2 weeks after the surgery and CBCT was taken to evaluate the postsurgical state. Visit 4 was set in 2 to 4 months post surgically and photos were taken. The final visit was scheduled at 3 to 7 months post surgically and clinical, radiological examination including CBCT, panoramic views, and impression scanning was done.

2. Procedure of application of resorbable membrane

The amount of bone graft material needed for the defect was evaluated with the data obtained from the first visit. Incision, dissection, and removal of inflammatory and granulation tissues were done regularly before GBR. Xenograft was performed at the defect after surgical removal of

lesions. In order to inhibit soft tissue growth toward the grafted bone material and for GBR, a collagen membrane was applied to cover the surface of the bone graft material. Primary closure was done to prevent exposure and leakage of bone graft materials.

3. Soft tissue volume analysis

During visits 1, 3, and 5, alginate impressions and yellow stone models were obtained from the patients. The plaster model data acquired from visit 3 was excluded due to the presence of postoperative swelling in many cases. Digital model scanning was done and the obtained standard tessellation language (STL) files were analyzed using 3D analysis software (Geomagic Control X, 3D Systems, Cary, NC, USA). After loading two STL files and performing initial alignment, a best-fit alignment was conducted. The 3D comparison was visualized using a color difference map, specifying a range of ±1mm (15 color segments) and a tolerance range of ±0.3mm (green). Based on the color difference map, measurements within the ±0.3mm range were categorized as "No change," those exceeding +0.3mm or beyond the 1mm criterion were labeled as "Increase," and measurements falling below -0.3mm or beneath the -1mm criterion were classified as "Decrease."

4. Histopathological result

During surgery, pathological tissues were collected from each patient and submitted to the Department of Pathology at our institute for analysis. The attained tissue was fixed by 10% formalin and stained with hematoxylin and eosin(H&E). The diagnosis was confirmed by the pathologist at our hospital.

5. Statistical analysis

The CBCT data was analyzed by Nrecon software program (Micro Photonics Inc., USA, Ver 1.7.0.4, Bruker-CT) for quantitative data acquisition for each patient's visits 1, 3, and 5. The images were reconstructed with a resolution of 559x559 pixels. The treatment area which contained the defect

site was selected and manually manipulated for CBCT analysis. The grafted bone volume was measured by connecting the outermost border of the graft material in each CBCT layer containing the defect. Each layer was combined and the total volume was calculated. Trabecular thickness was defined as the average of uninterrupted lengths of the bone graft. Pores that are enclosed from all sides and pores connected to the external structure were respectively measured as closed and open pores. The volume of pores was measured as a percentage of the total volume. SPSS statistical software (release 21.0, IBM, Chicago, IL, USA) was used to evaluate the degree of bone formation from visits 3 and 5. Student's t-test and Mann-Whitney u-test were performed to compare the differences between the measurements of the two groups.

Results

1. Demographic characteristics

The gender ratio was 9:3 for males and females, with ages ranging from 24 to 73 years. The average age was 43 (±15) years. The distribution was generally similar by different age groups (Table. 3).

2. Histopathologic results

Periapical cysts(n=8) accounted for ten cases of the total group, followed by two cases of nasopalatine duct cysts. Characteristic pathological findings were observed in the case and control group (Fig.1, 2).

3. Clinical and radiologic results

All 12 participants in the study exhibited lesions and bone defects in the maxilla. Cyst enucleation and bone graft with collagen membranes were done by buccal and palatal approaches in eight and four patients respectively. There were no postoperative issues in ten patients. However, one

complication occurred in both the case group and the control group. In the case group, a fistula persisted three months post-surgery, leading to the eventual extraction of the affected tooth. In the control group, an excessive gingival recession occurred, exposing the palatal root. Nevertheless, in both cases, the underlying bone remained intact and was included in the analysis. Clinical and CT images for each patient were reviewed (Fig.3-14).

4. Result of model scanning and superimposition

Results showed that in a total of 5 cases, there was a "decrease" in soft tissue volume, "no change" in 5 cases, and an "increase" in 2 cases. The two cases where there was an increase in soft tissue volume were both associated with lesions in the palatal region. Among the cases with decrease, one was related to tooth extraction, while the remaining four were associated with bone dehiscence. The color difference maps of soft tissue volume change for each patient are illustrated in Figure 15.

5. Statistical result

To examine whether there were significant differences between the experimental and control groups in terms of changes and outcomes between visits 3 and 5, a student's t-test was conducted. However, all p-values were higher than 0.05, leading to the rejection of the hypothesis that there is a difference between the experimental and control groups. Regarding the impact of defect size on the trends between visits 3 and 5, significant results were observed in bone volume change and trabecular thickness (Table 4). The results of the Mann-Whitney u-test were consistent with those of the student’s t-test (Table 5). Measurements of the average defect volumes by each group are represented in Table 6.

Discussion

CM2 used in this study showed stable results compared to BG in clinical, radiologic, and 3D

analysis. This is can be considered as a consistent result with the previous studies of porcine and bovine collagen membranes.[15, 16] Our study design implies objectivity because it was a randomized prospective study. The surgical protocol presented by Buser et al.[6-8] has been regarded as a standard protocol for GBR and has clinical significance. In addition to the surgical protocol, the operator's factors and the patient's factors should also be considered. The skill of the practitioner and the selection of appropriate techniques and materials are very critical.[17] As for the factors of the patient, consideration of the condition of the patient's bone defect, periodontitis, thickness and condition of the mucous membrane, and awareness of systemic diseases that can affect bone metabolism or healing process is important.[18] However, in this study, we tried to evaluate the clinical significance of the membrane itself rather than focusing on these factors. To control the patient factor as much as possible, patients who met the inclusion criteria were selected. Furthermore, to minimize potential variations in results based on anatomical characteristics, only patients with lesions in the maxilla were selected.

Collagen membrane is a resorbable barrier membrane and is currently widely used. Collagen membranes can be produced from variant sources such as porcine, bovine, equine, and human origin tissues. Type 1 and type 3 collagens are derived from tendons, dermis, or skin from each source.[19] CM2 was derived from type 1 collagen and showed advantages in tear resistance and maneuverability. Easy to apply and low dehiscence rates lowered patient discomfort in our study. Advantages of using a collagen membrane include biocompatibility, stable absorption, and chemotaxis to fibroblasts to induce primary healing and stabilize wound healing.[20, 21] They are sometimes considered to have more potential in healing and regenerating bones than non-resorbable membranes in wounds.[15] Collagen membranes share the general disadvantages of resorbable membranes and products that are newly produced are considering these facts for improvements of quality.[22] The first use of collagen membranes was reported in the 1990s, with the recommendation of use with fixation devices in particular defects where the membrane might collapse.[23] Successful studies of the application of resorbable membranes were continuously reported in GBR of implant defects.[24] Although the results

were not precise, we were able to conduct a qualitative assessment by utilizing a 3D scanner, which distinguishes our study from previous research.

Ideally, the collagen membrane should perform its role until the internal bone reaches an optimal state of healing. However, premature absorption may hinder its effectiveness.[11] Therefore, the slow progression of collagen membrane degradation can be considered advantageous for defects that need sufficient time to heal.[16] It is crucial to ensure that non-osteogenic cells such as epithelial cells do not infiltrate the bone defect and that factors related to bone formation such as osteo-progenitor cells have sufficient time to undergo osteogenesis.[25, 26] The native collagen membrane is characterized by the preservation of the biological features of the extracted tissue during its use. It typically offers advantages such as good tear resistance and maneuverability.[15] However, it exhibits a relatively rapid degradation, which may not provide sufficient time for adequate bone formation.[27] Cross-linked collagen membrane is produced by subjecting raw materials extracted from living tissues to physical and chemical treatments. Utilizing a cross-linked collagen membrane offers advantages such as establishing a membrane with increased surface area and thickness.[28, 29] These aspects significantly slow down the degradation rate compared to native collagen membranes. However, a disadvantage is that during the absorption process, there is a possibility of triggering inflammatory reactions or foreign body reactions.[12] In studies comparing these two types of collagen membranes, it was reported that there was no significant difference in osteogenic capabilities between the two products.[30, 31] On the other hand, some studies explain the cross-linked collagen membrane has a significantly higher capacity in supporting soft tissue healing.[32, 33] The cross-linked membrane has the potential to reduce bone graft resorption, as its degradation begins after implantation. Some studies suggest for required barrier function duration of one month per millimeter of bone regeneration.[34] Using a cross-linked collagen membrane can be the solution to quick degradation problems with enhanced material characteristics.[35, 36] Until now, various studies have compared products of different cross-linked collagens with BG, and this study can be considered within the same context. The distinctive aspect of this research lies in the comparison with a product called CM2 which has not been compared before.

CM2 achieves cross-linking through chemical treatment, and unlike BG, it can be used without differentiation on both sides. When using 50U/ml of collagenase, CM2 exhibits superior degradation stability with a higher residue after degradation per hour. The BG is a porcine derived type I and type III collagen membrane. It is a non-cross-linked collagen membrane with one cell-non-permeable layer and one cell-permeable layer. It is known to work as a barrier for 12~24 weeks, and from many studies, it has shown great performance.[37, 38] While BG serves as a non-cross-linked barrier for a short time of up to 16 weeks, CM2 functions as a barrier for over 24 weeks. In our study, based on analyzed bone formation data, it appears to show similar results on both collagen membranes. The results of both the student's t-test and Mann-Whitney u-test indicated no significant differences in the outcomes between the case and control groups. Therefore, it can be concluded that there is no remarkable difference in bone formation based on the type of collagen membrane used.

The development of periapical cysts related to apical periodontitis is associated with inflammatory and bone resorption markers.[39] There is currently no study that has yielded results indicating variations in bone defects based on the type of cysts. However, when it comes to the size of bone defects, if the defect area is larger than $1cm^3$, complete bone regeneration does not occur spontaneously regardless of the duration of observation. Therefore, it can be inferred that without GBR, achieving complete bone regeneration may be challenging and is likely not to occur.[40-42]

Significant differences in values were observed at visits 3 and 5 based on the size of the defect, showing consistent results across both statistical methods. GBR occurs when the barrier membrane remains intact and well-maintained, regardless of the size of the defect.[43] However, in the case of the collagen membrane used in the study, maintaining a stable position becomes challenging with larger defect sizes. A larger defect size decreases the stability due to the increased micromovement of the collagen barrier. There are differences observed in both bone volume and the thickness of trabecular bone. However, there is not a substantial variance in porosity, suggesting that the overall bone regeneration is not significantly compromised.[44] Therefore, there was a small decrease in bone formation, but the overall GBR process was not hindered.

The results of the comparison with means of defect volume value indicated that there was no significant correlation between changes in soft tissue volume and the size of the defect. Even with smaller bone defects, a decrease in soft tissue volume occurred, and conversely, larger bone defects did not consistently result in a decrease or similarity in soft tissue volume. All patients who exhibited an increase in soft tissue volume received the surgery by palatal approach. While two additional patients underwent a palatal approach, one showed bone dehiscence, and the other had a relatively small lesion size. Due to the absence of splint treatment for wound protection and postoperative swelling control, gravitational forces continued to act on the bone graft material and collagen membrane, resulting in an unexpected increase in soft tissue volume in the palatal area.[45)]

All patients who showed a decrease in soft tissue volume shared a commonality of having bone dehiscence (control group). In the case group, the extraction case because of a fistula was the only case that showed a soft tissue volume decrease. In cases where bone dehiscence is present, the prognosis is not as favorable for bone regeneration compared to fenestration. In cases of bone defects such as bone dehiscence, the stability of the barrier membrane may be more compromised compared to fenestration.[46)] However, successful GBR was reported in studies with buccal dehiscence in implants.[47, 48)] Regarding implants, it seems to have little relation to the type of bone defect.[49)] In a study on GBR with implants, it has been reported that there is no significant difference in attachment level or probing depth from the time of prosthesis placement to the most recent follow-up.[50)] While this demonstrates the long-term stability of GBR when successfully executed, it does not explain post-surgical bone contraction in the defect area immediately after the surgery. In our study, although bone regeneration occurred successfully in cases with dehiscence, a reduction in the volume of soft tissue was observed. This could be due to the vulnerability of soft tissue contraction in the absence of underlying bone. Additionally, considering the difference in soft tissue attachment on teeth and implants, such results were understandable.

The limitation of this study is the inadequate evaluation of the collagen membrane itself. To thoroughly assess the superiority of the collagen membrane, it would be necessary to evaluate not

only its osteogenic capabilities but also the properties of its composition. A more comprehensive study could have been achieved by directly examining the extent of bone formation and the degradation of the collagen membrane if harvesting tissues at the 6-month postoperative state was possible. This direct assessment would have allowed for a more accurate prediction of the degree of bone formation within the defect, considering the degradation of the collagen membrane. Another limitation of this study is the small sample size. Conducted as a preliminary study in clinical research, the limited sample size remains a point that could be improved. Some yellow stone casts did not show the surgical area sufficiently because of impression errors. Additionally, since different individuals took the impressions each time, precise comparison was challenging. Therefore, only a visual assessment was made with no further 3D statistical analysis. Finally, considering that results may be influenced by the condition of the bone defect, a more reliable dataset could have been obtained by either limiting the cases to those without dehiscence or by specifying and comparing cases with either palatal or buccal lesions.

Conclusion

In this study, there are no significant differences in clinical, radiological, and 3D results in the bovine collagen membrane and porcine collagen membrane groups. For soft tissue volume, defect configuration was found to have a greater influence than the size of the defect or the type of collagen membrane used. Therefore, the bovine and porcine membranes used in the study showed no significant difference in clinical application.

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dehiscences and fenestrations: a systematic review. Clinical oral implants research. 2009;20:113-23.

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Table 1. Criteria of the study

Inclusion	Exclusion
1. Over 20 years old	1. Pregnant women
2. Those who need bone graft due to severe bone defect/ chronic periodontitis/ cyst or tumor removal	2. Patients with uncontrolled metabolic disease (diabetes mellitus, hypertension, etc.)
3. When primary closure is possible	3. Patients who have been continuously administered drugs that can affect bone metabolism for more
4. Those who have agreed to participate voluntarily in written consent	4. Patients with uncontrolled gingivitis, periodontitis, or dental caries
5. Those who are willing to comply with the follow-up period and instructions	5. Patients who have received radiation therapy in the treatment area
	6. Patients with uncontrolled hemorrhagic disease requiring anticoagulant therapy
	7. Those who smoke more than 1 pack (20 cigarettes) per day

Table 2. Visit schedule

Visit	1	2	3	4	5
Follow up period after membrane application	-	0	2(±1) weeks	3(±1) months	5(±2) months
Panoramic view	√	√	√	√	√
CBCT	√		√		√
Clinical photo		√	√	√	√
Digital model scanning	√		√		√
Adverse reaction evaluation	√	√	√	√	√

Table 3. Age distribution

Age	n
20~29	2
30~39	3
40~49	3
50~59	2
60~69	1
70~79	1

Table 4. Difference between case and control group (by student's t-test)

Number of patients	case (n=6)	control (n=6)	p-value*	p-value**
BV change (mean (SD))	46.47 (46.85)	16.68 (14.80)	0.168	0.0123
TbTh change (mean (SD))	68.04 (103.06)	72.98 (67.89)	0.924	0.0136
Po(cl) change (mean (SD))	178.19 (392.12)	-23.49 (69.01)	0.243	0.4282
Po(op) change (mean (SD))	163.57 (456.90)	0.50 (113.34)	0.416	0.4056
Po(tot) change (mean (SD))	165.14 (459.05)	0.09 (112.20)	0.412	0.4044

$p<0.05$ was considered statistically significant, BV: Bone Volume (mm^3), TbTh: Trabecular Thickness (mm), Po(cl): Closed porosity (%), Po(op): Open porosity (%), Po(tot): Total porosity (%), *: (between groups), **: (between visit 3 &5 considering the defect area)

Table 5. Difference between case and control group (by Mann-Whitney u-test)

Number of patients	case (n=6)	control (n=6)	p-value*	p-value**
BV change (mean (SD))	24.42 [13.58, 86.69]	20.53 [8.74, 24.31]	0.423	0.0024
TbTh change (mean (SD))	36.33 [4.62, 88.79]	97.15 [18.04, 124.08]	0.631	0.021
Po(cl) change (mean (SD))	101.45 [-87.24, 115.49]	-32.15 [-75.49, 16.66]	0.361	0.7002
Po(op) change (mean (SD))	-12.71 [-50.17, 46.37]	-43.43 [-57.28, 2.35]	0.631	0.6772
Po(tot) change (mean (SD))	-13.25 [-48.64, 47.05]	-43.47 [-56.95, 2.39]	0.631	0.6772

$p<0.05$ was considered statistically significant, *: (between groups), **: (between visit 3 &5 considering the defect area)

Table 6. Average measurements of defect volumes *(Unit: mm^3)*

Soft tissue volume	Case group defect volume	Control group defect volume	Total group defect volume
Increase	1946	0	1946
No change	1780	922	1437
Decrease	272	2472	2033

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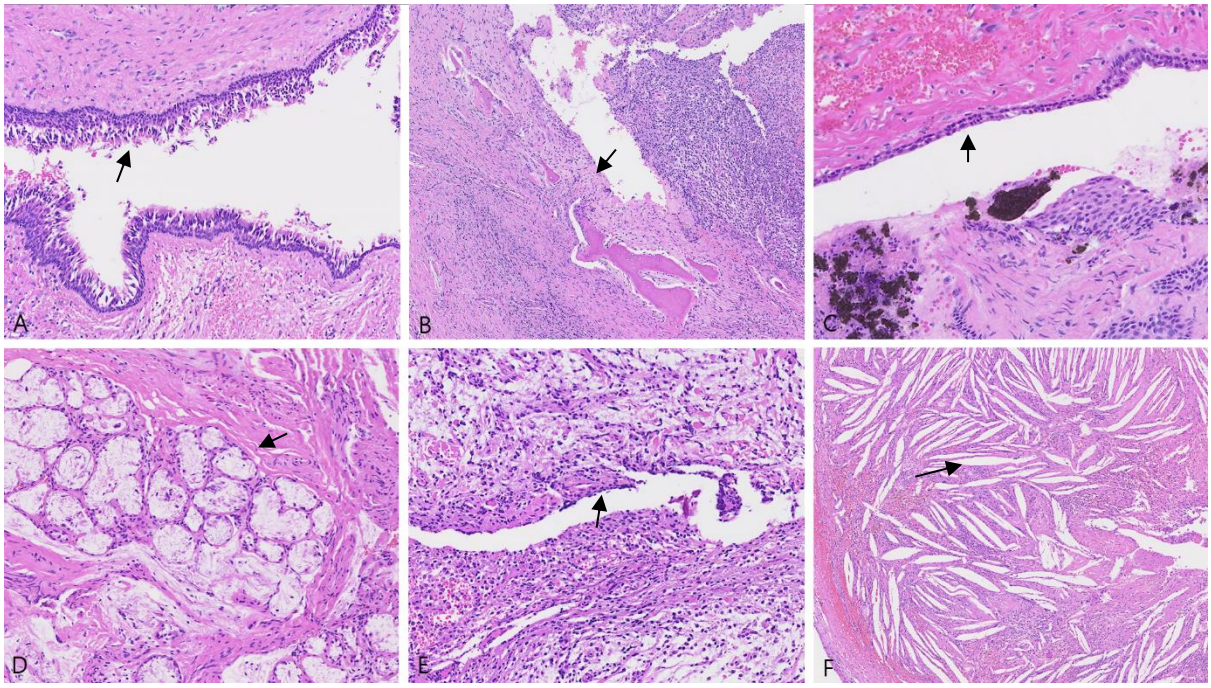

Figure 1. Histologic results of the case group (H&E staining, x40, x100, and x200). (A) Nasopalatine duct cyst lined by stratified squamous epithelium and cilia (arrow). (B) Periapical cyst with bone tissue (arrow). (C) Periapical cyst with non-keratinized stratified squamous epithelium (arrow). (D) Nasopalatine duct cyst with nerve tissue (arrow). (E) Periapical cyst with non-keratinized stratified squamous epithelium (arrow). (F) Periapical cyst with cholesterol clefts (arrow).

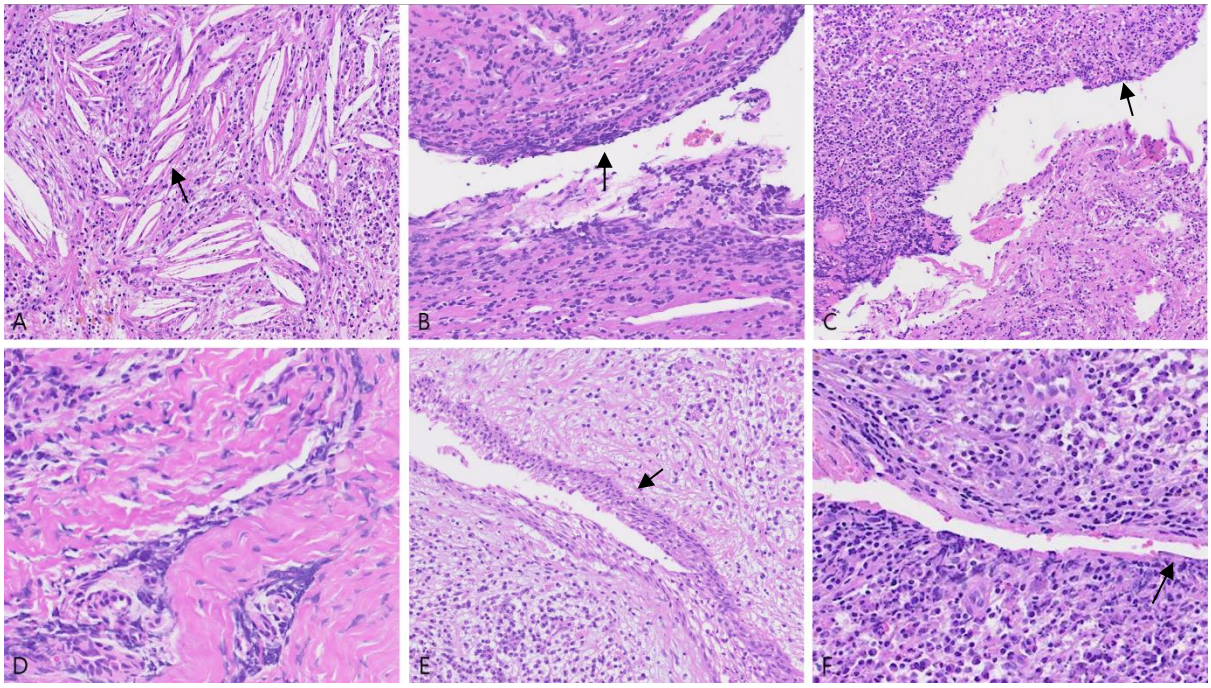

Figure 2. Histologic results of the control group (H&E staining, x 40, x100, and x200). (A) Periapical cyst with cholesterol clefts (arrow). (B) Periapical cyst with non-keratinized stratified squamous epithelium (arrow). (C) Periapical cyst with a thin layer of Stratified squamous epithelium (arrow). (D) Periapical cyst with no typical features. (E) Periapical cyst with a thick layer of stratified squamous epithelium (arrow). (F) Periapical cyst with non-keratinized stratified squamous epithelium (arrow).

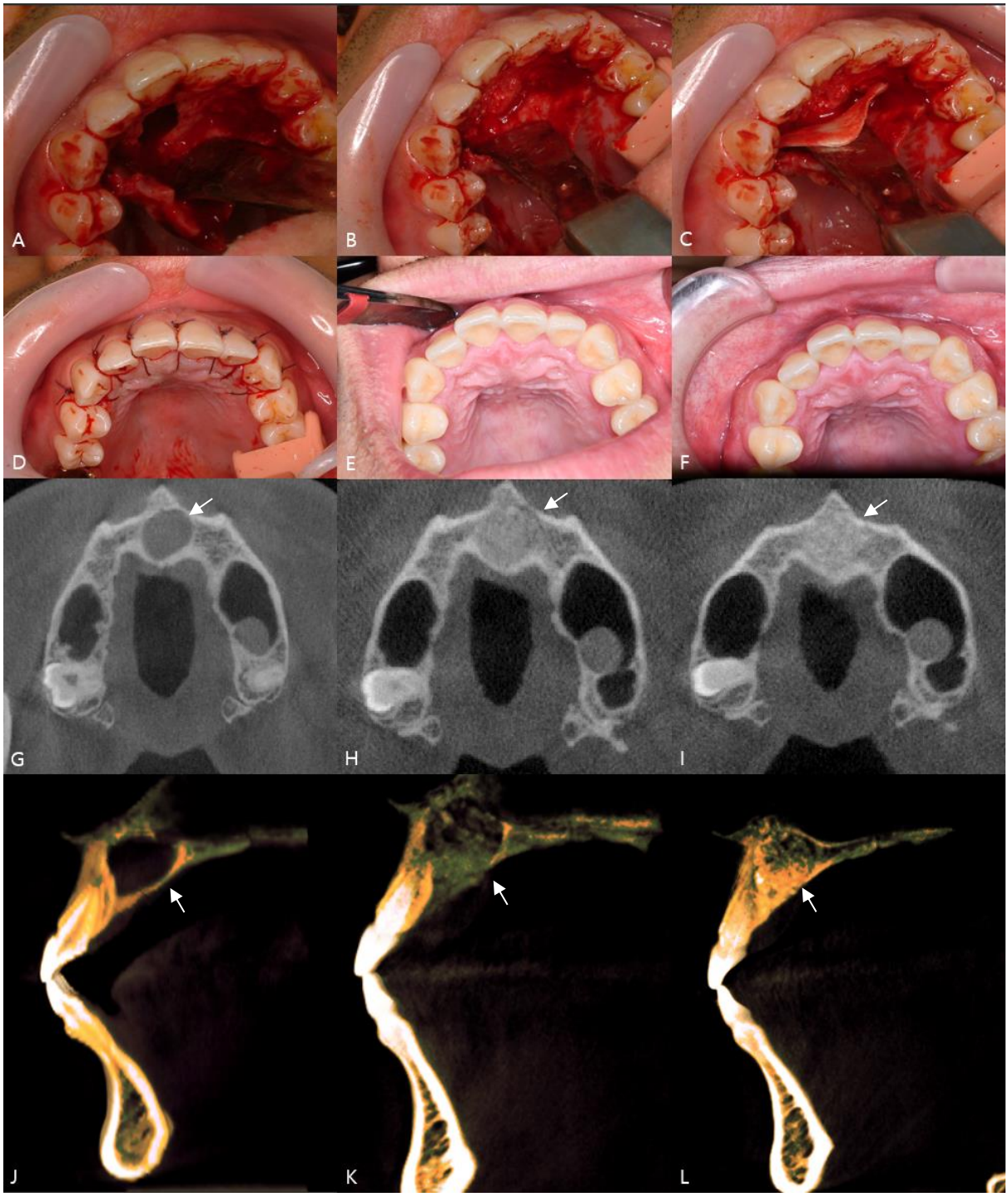

Figure 3. Collagen membrane 2 applied patient (Case 1). (A) Bone defect at the palatal side of #11, 21. (B) Bovine derived bone grafted in the bone defect area. (C) Collagen membrane application (case group). (D) Primary closure of the defect. (E) Clinical view of post-op 3 months. (F) Clinical view of post-op 7 months. (G) Axial CBCT view of initial status. (H) Axial CBCT view of post-op 1 week. (I) Axial CBCT view of post-op 7 months. (J) Sagittal CBCT view of initial status. (K) Sagittal CBCT view of post-op 1 week. (L) Sagittal CBCT view of post-op 7 months.

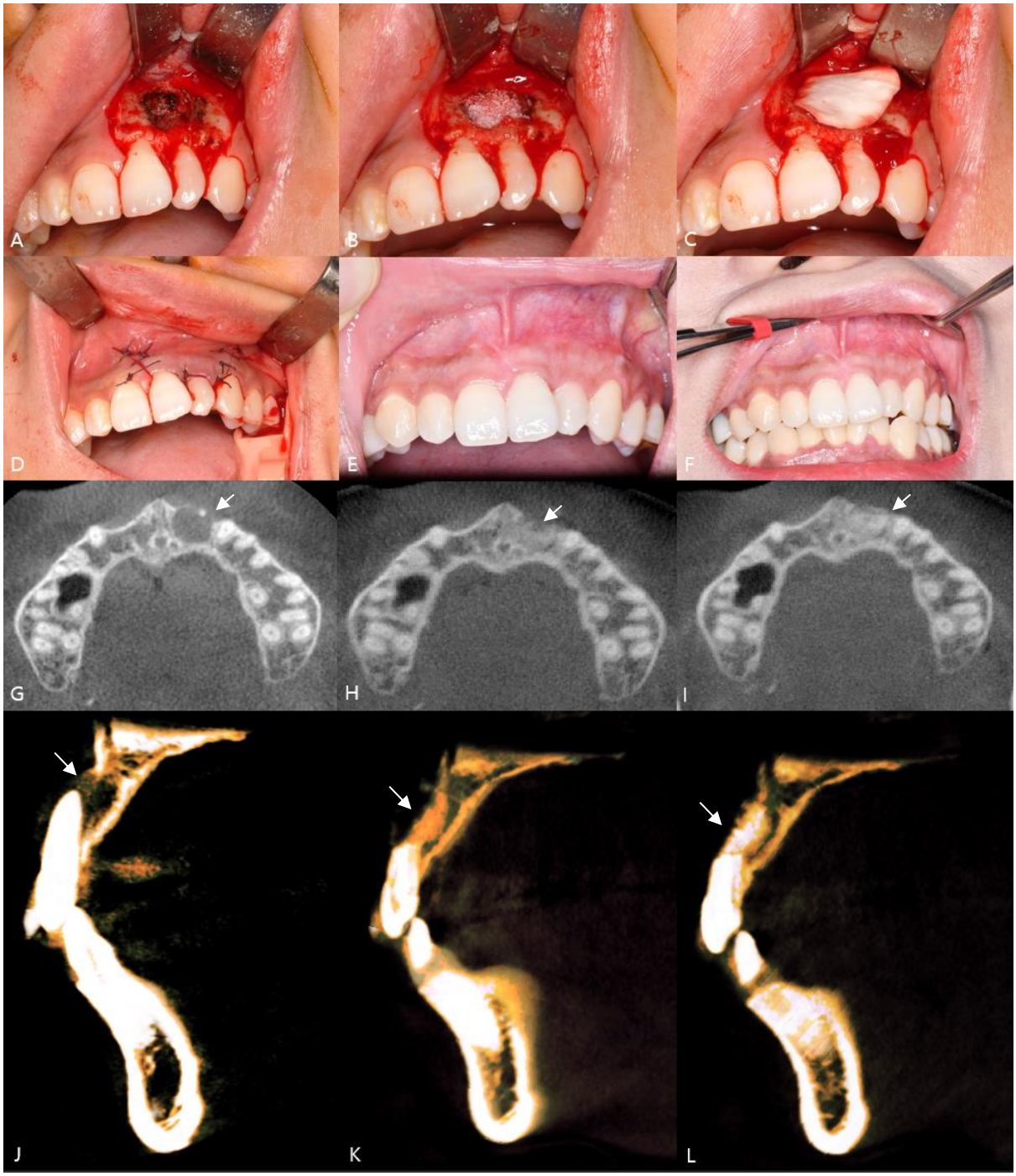

Figure 4. Collagen membrane 2 applied patient (Case 2). (A) Defect at the buccal side of #21, 22. (B) Bovine derived bone grafted in the bone defect area. (C) Collagen membrane application (case group). (D) Primary closure of the defect. (E) Clinical view of post-op 3 months. (F) Clinical view of post-op 6 months. (G) Axial CBCT view of initial status. (H) Axial CBCT view of post-op 1 week. (I) Axial CBCT view of post-op 6 months. (J) Sagittal CBCT view of initial status. (K) Sagittal CBCT view of post-op 1 week. (L) Sagittal CBCT view of post-op 6 months.

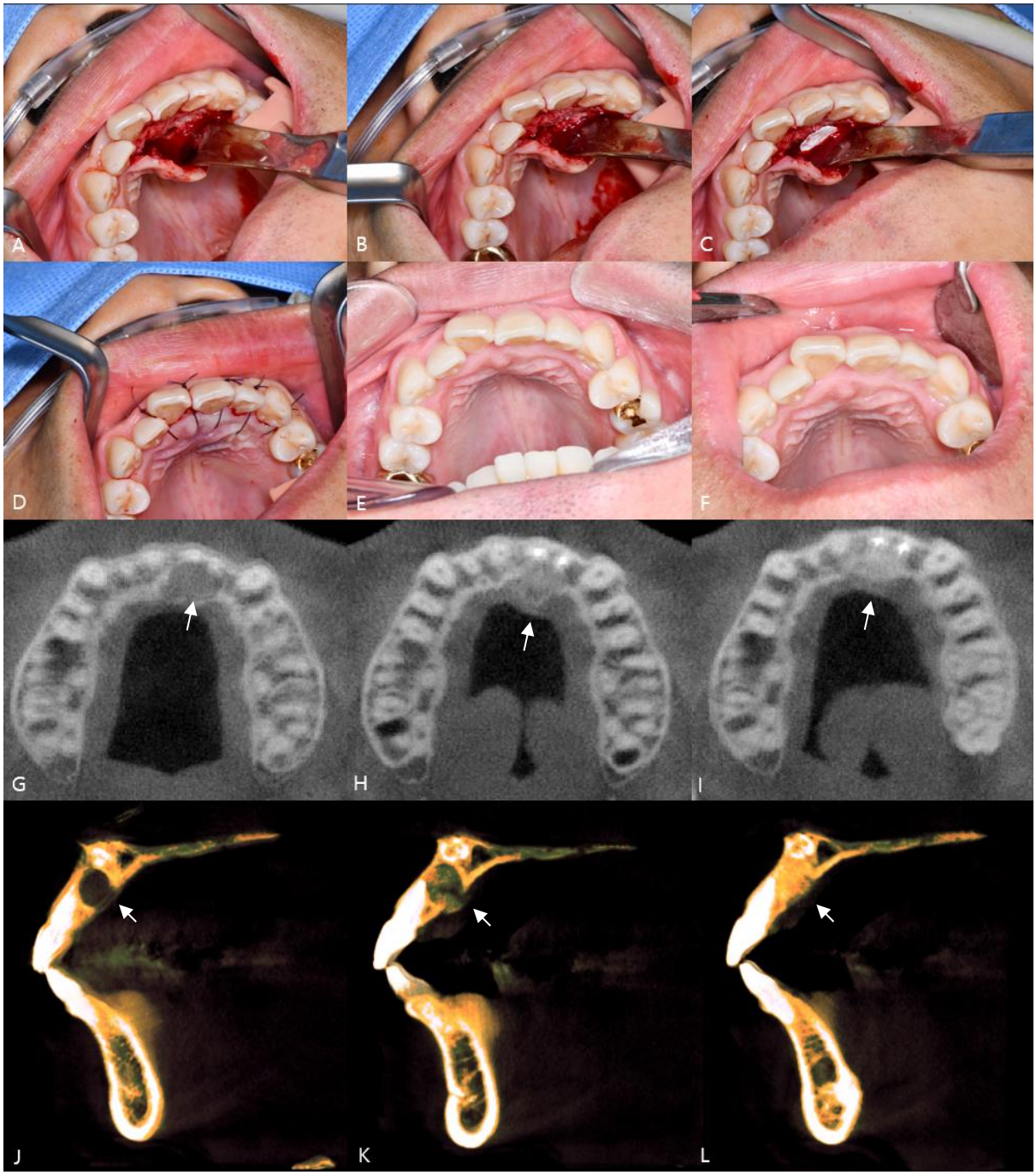

Figure 5. Collagen membrane 2 applied patient (Case 3). (A) Defect at the palatal side of #21, 22. (B~L) The description is consistent with the previous figure.

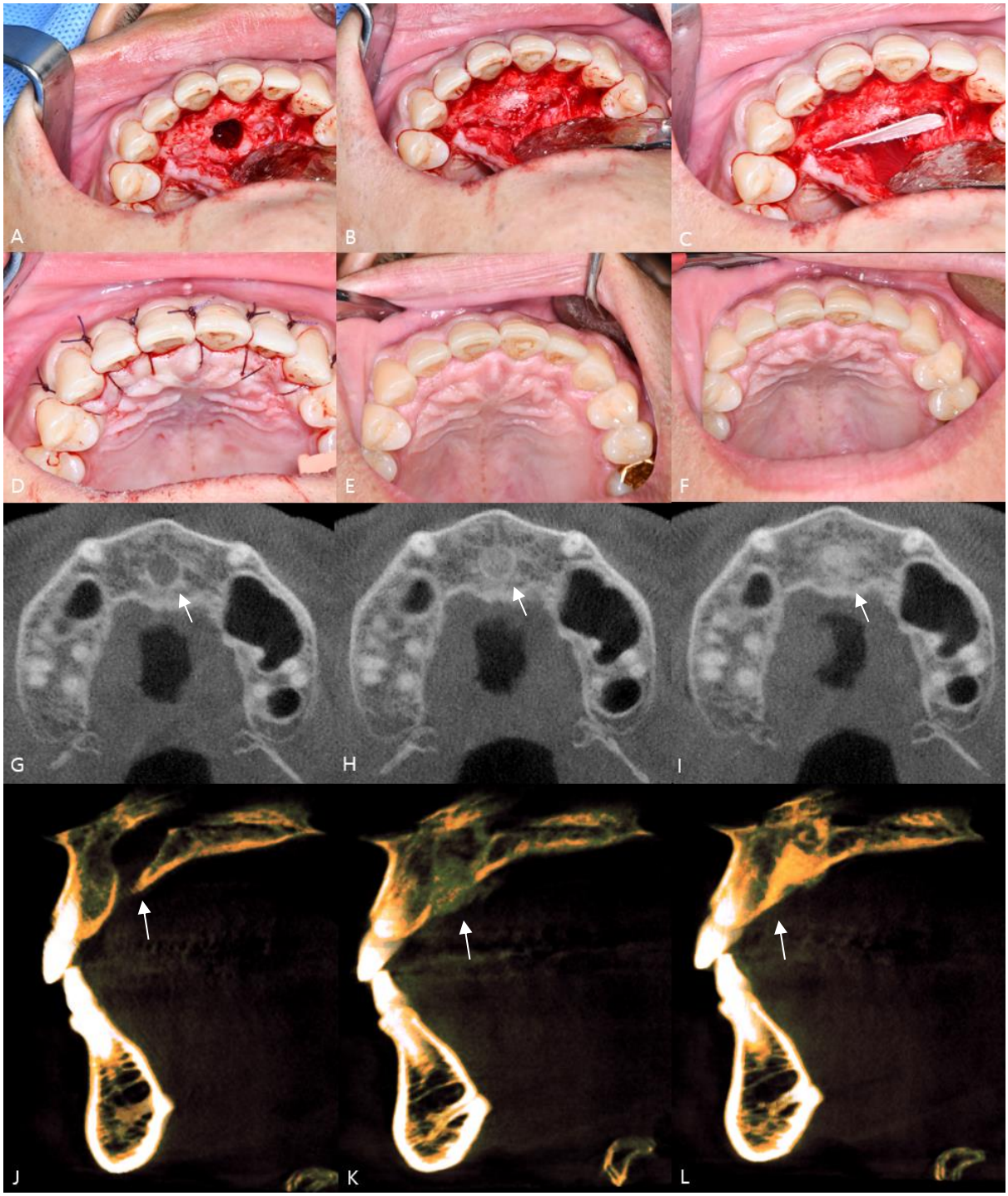

Figure 6. Collagen membrane 2 applied patient (Case 4). (A) Defect at the palatal side of #11, 21. (B~L) The description is consistent with Figure 4.

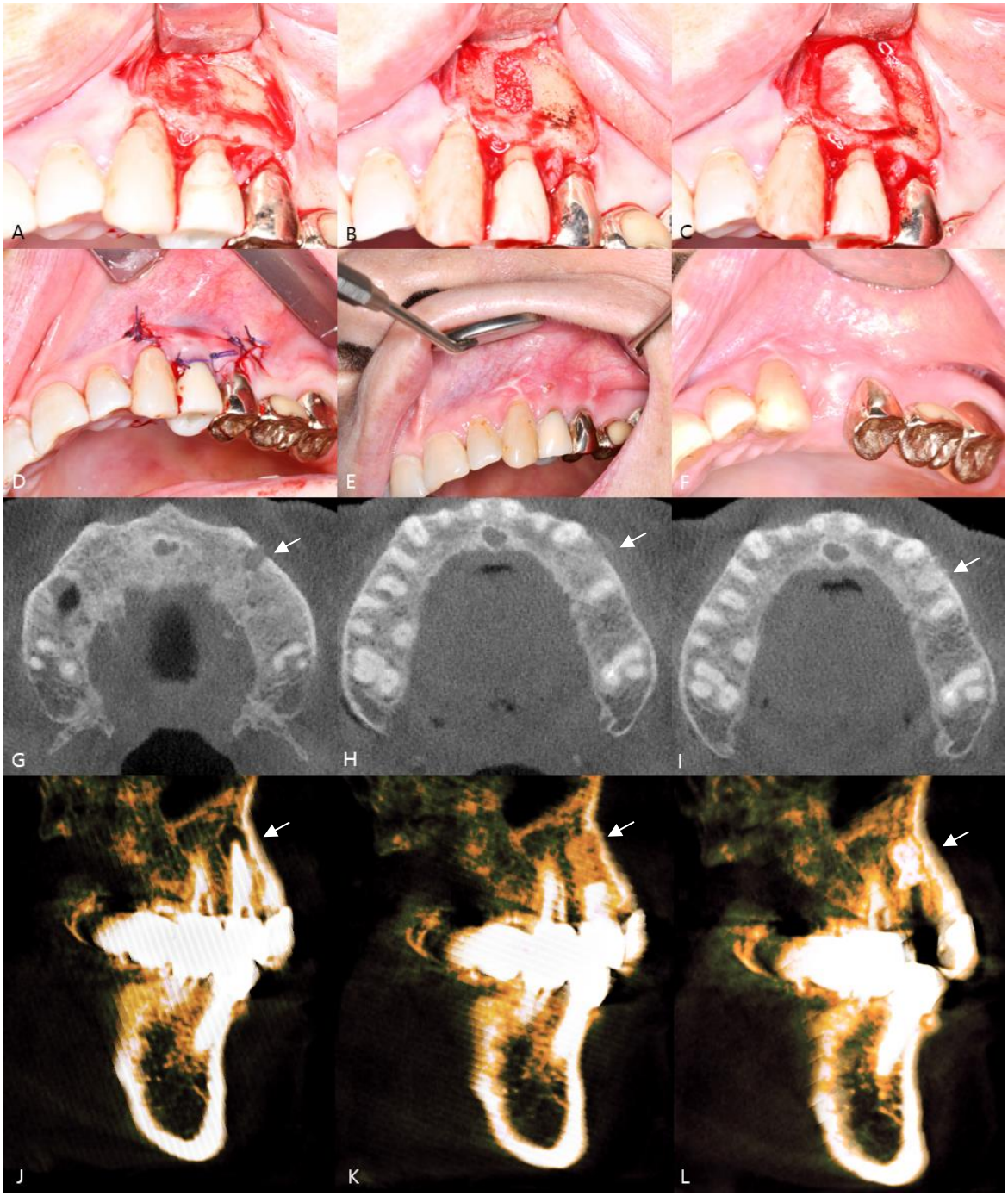

Figure 7. Collagen membrane 2 applied patient (Case 5). (A) Defect at the buccal side of #24. (B) Bovine derived bone grafted in the bone defect area. (C) Collagen membrane application (case group). (D) Primary closure of the defect. (E) Clinical view of post-op 3 months, showing a fistula. Extraction performed. (F) Clinical view of post-op 6 months. (G) Axial CBCT view of initial status. (H) Axial CBCT view of post-op 1 week. (I) Axial CBCT view of post-op 6 months. (J) Sagittal CBCT view of initial status. (K) Sagittal CBCT view of post-op 1 week. (L) Sagittal CBCT view of post-op 6 months.

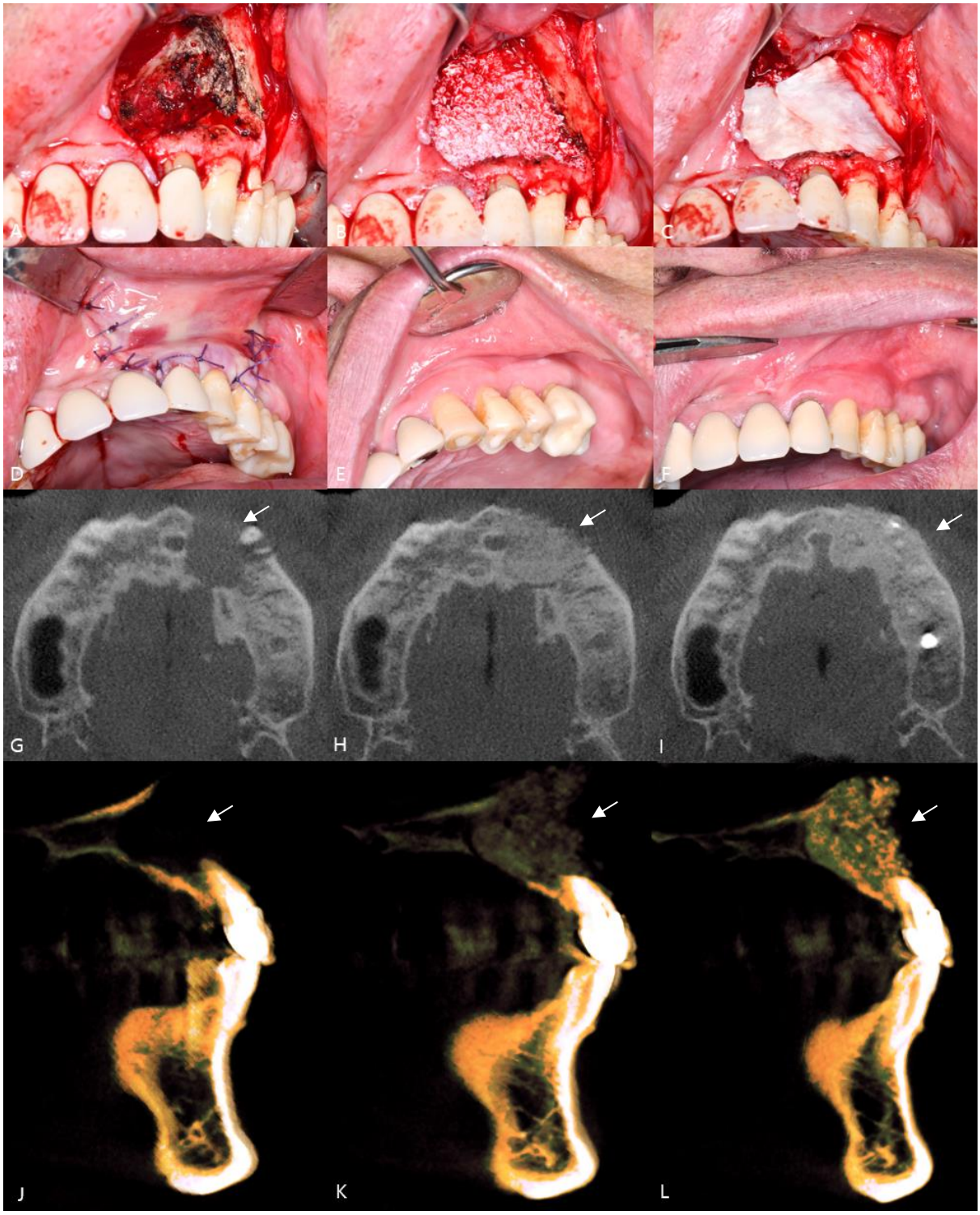

Figure 8. Collagen membrane 2 applied patient (Case 6). (A) Defect at the buccal side of #21~12. (B~L) The description is consistent with Figure 4.

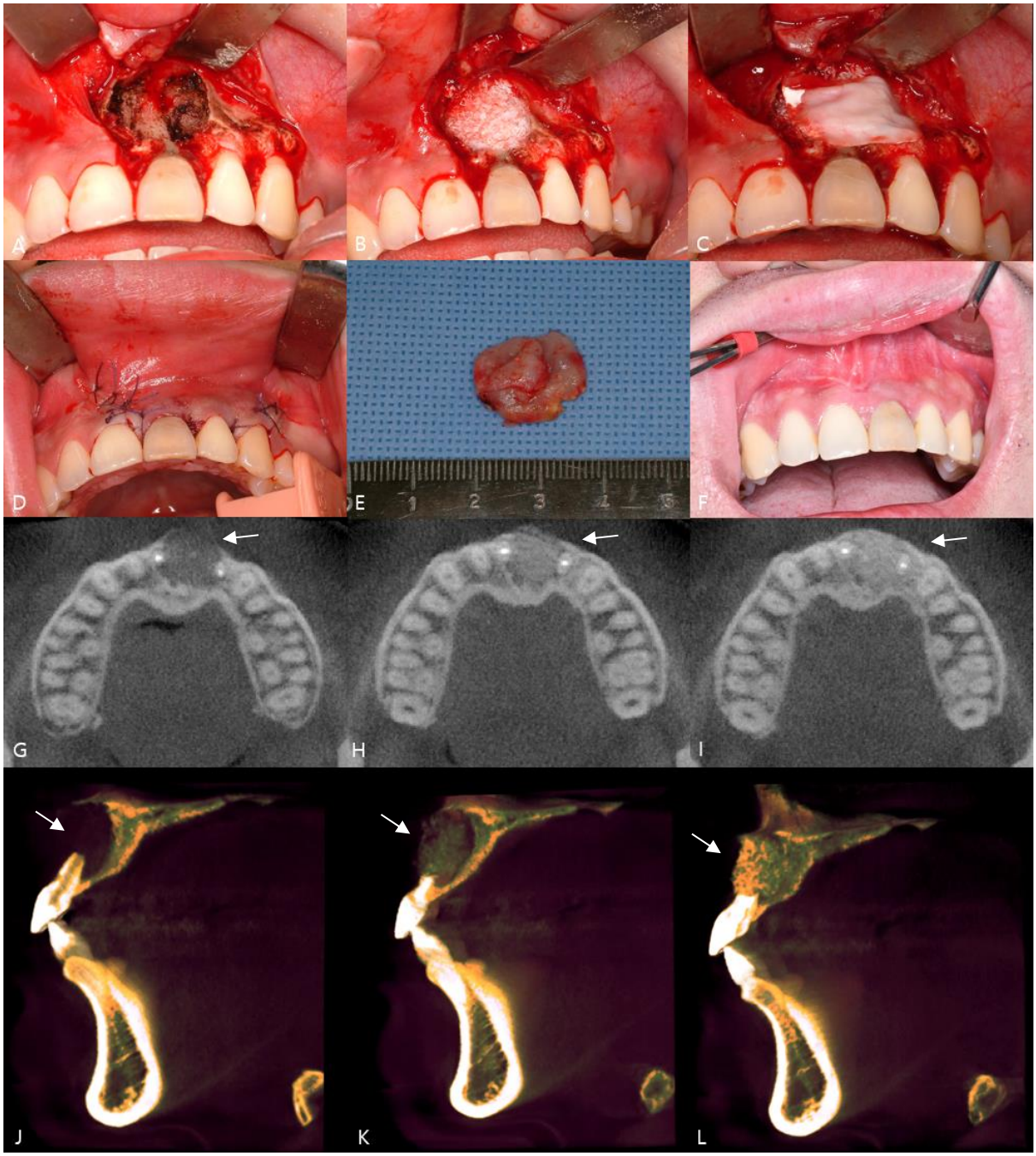

Figure 9. Bio-gide applied patient (Case 1). (A) Defect at the buccal side of #21, 22. (B) Bovine derived bone grafted in the bone defect area. (C) Collagen membrane application (control group). (D) Primary closure of the defect. (E) An enucleated periapical cyst (F) Clinical view of post-op 6 months. (G) Axial CBCT view of initial status. (H) Axial CBCT view of post-op 1 week. (I) Axial CBCT view of post-op 6 months. (J) Sagittal CBCT view of initial status. (K) Sagittal CBCT view of post-op 1 week. (L) Sagittal CBCT view of post-op 6 months.

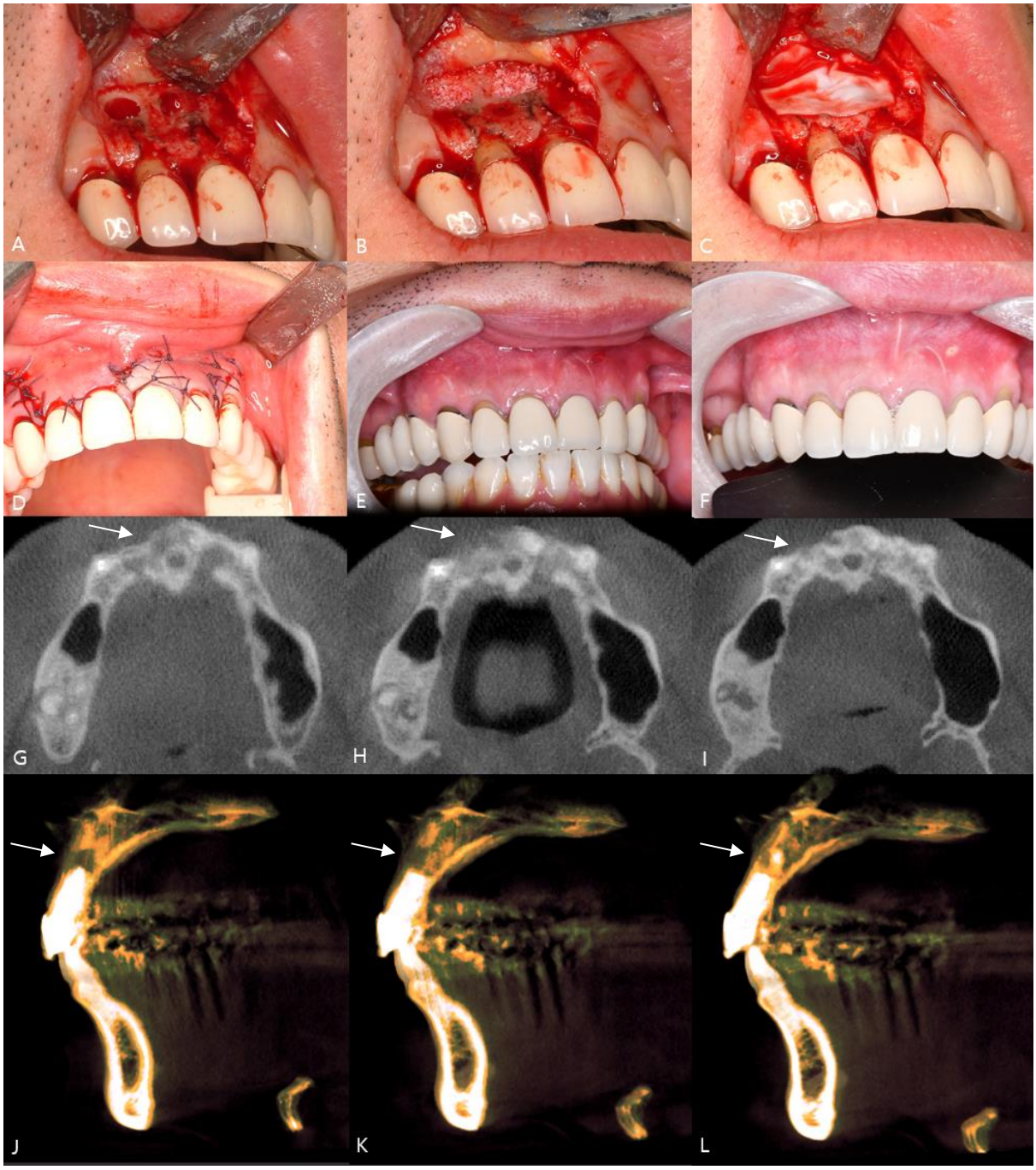

Figure 10. Bio-gide applied patient (Case 2). (A) Defect at the buccal side of #11, 12. (B) Bovine derived bone grafted in the bone defect area. (C) Collagen membrane application (control group). (D) Primary closure of the defect. (E) Clinical view of post-op 3 months (F) Clinical view of post-op 6 months. (G) Axial CBCT view of initial status. (H) Axial CBCT view of post-op 1 week. (I) Axial CBCT view of post-op 6 months. (J) Sagittal CBCT view of initial status. (K) Sagittal CBCT view of post-op 1 week. (L) Sagittal CBCT view of post-op 6 months.

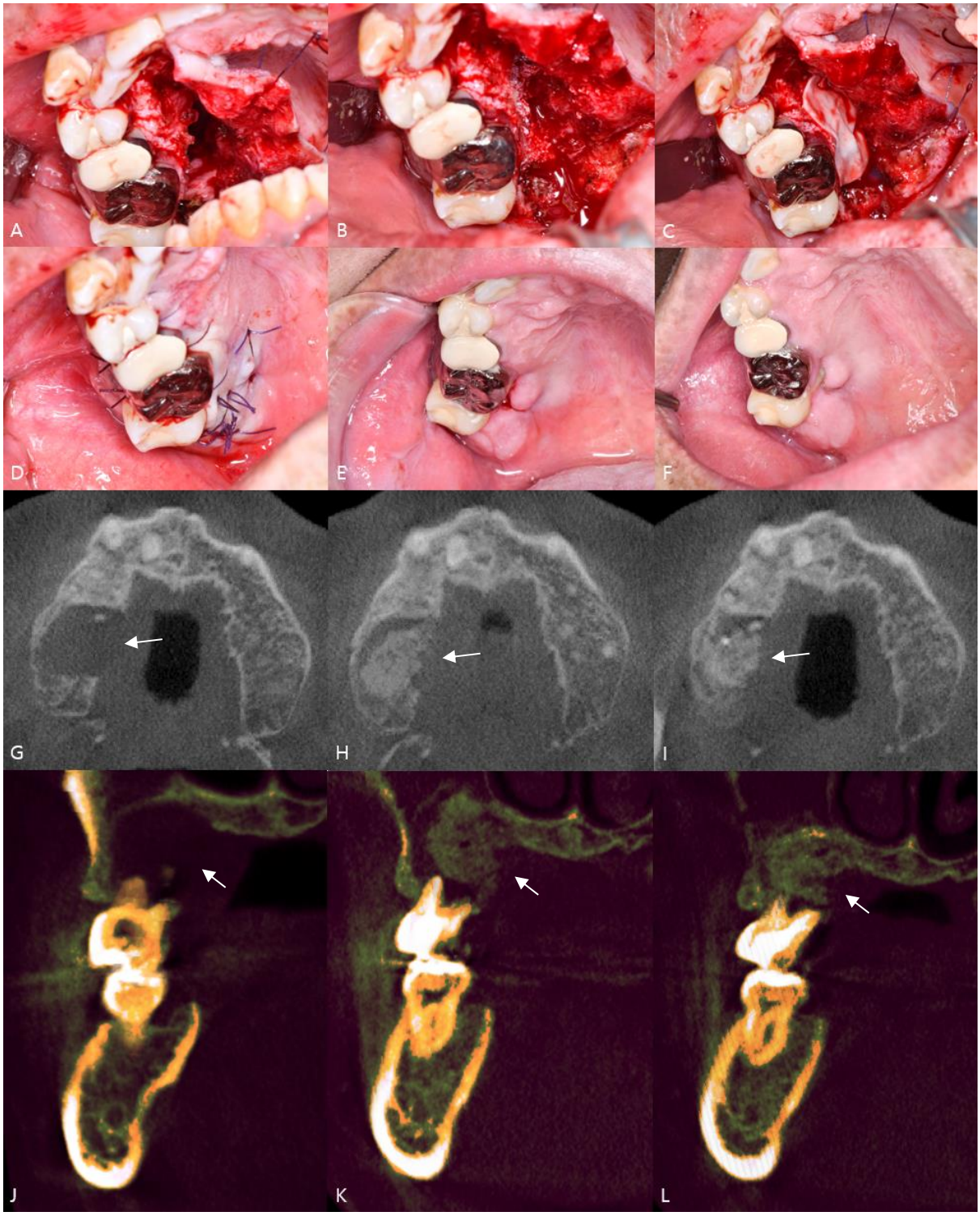

Figure 11. Bio-gide applied patient (Case 3). (A) Defect at the palatal side of #16, 17 (B~L). The description is consistent with Figure 10.

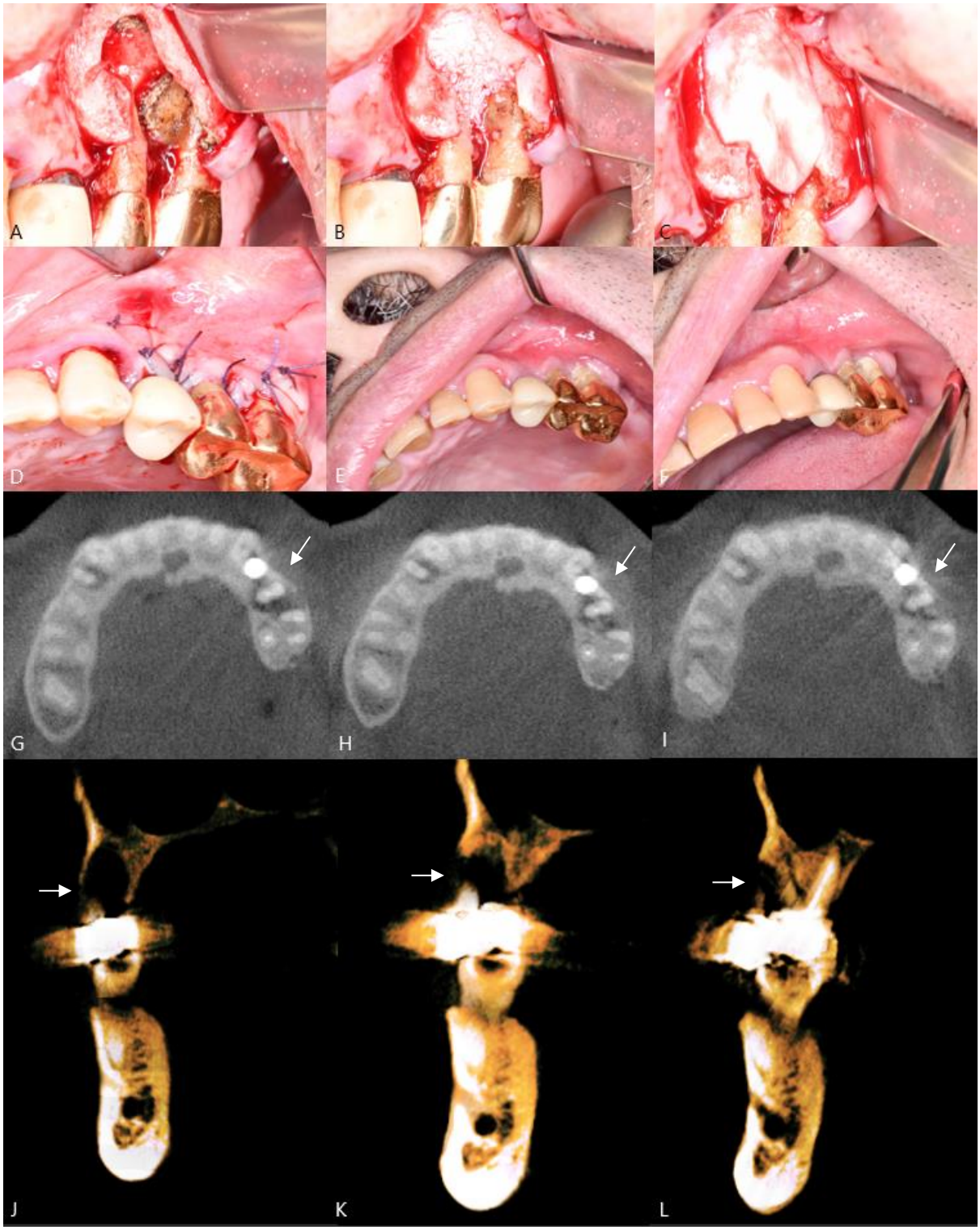

Figure 12. Bio-gide applied patient (Case 4). (A) Defect at the buccal side of #25, 27 (B~L). The description is consistent with Figure 10.

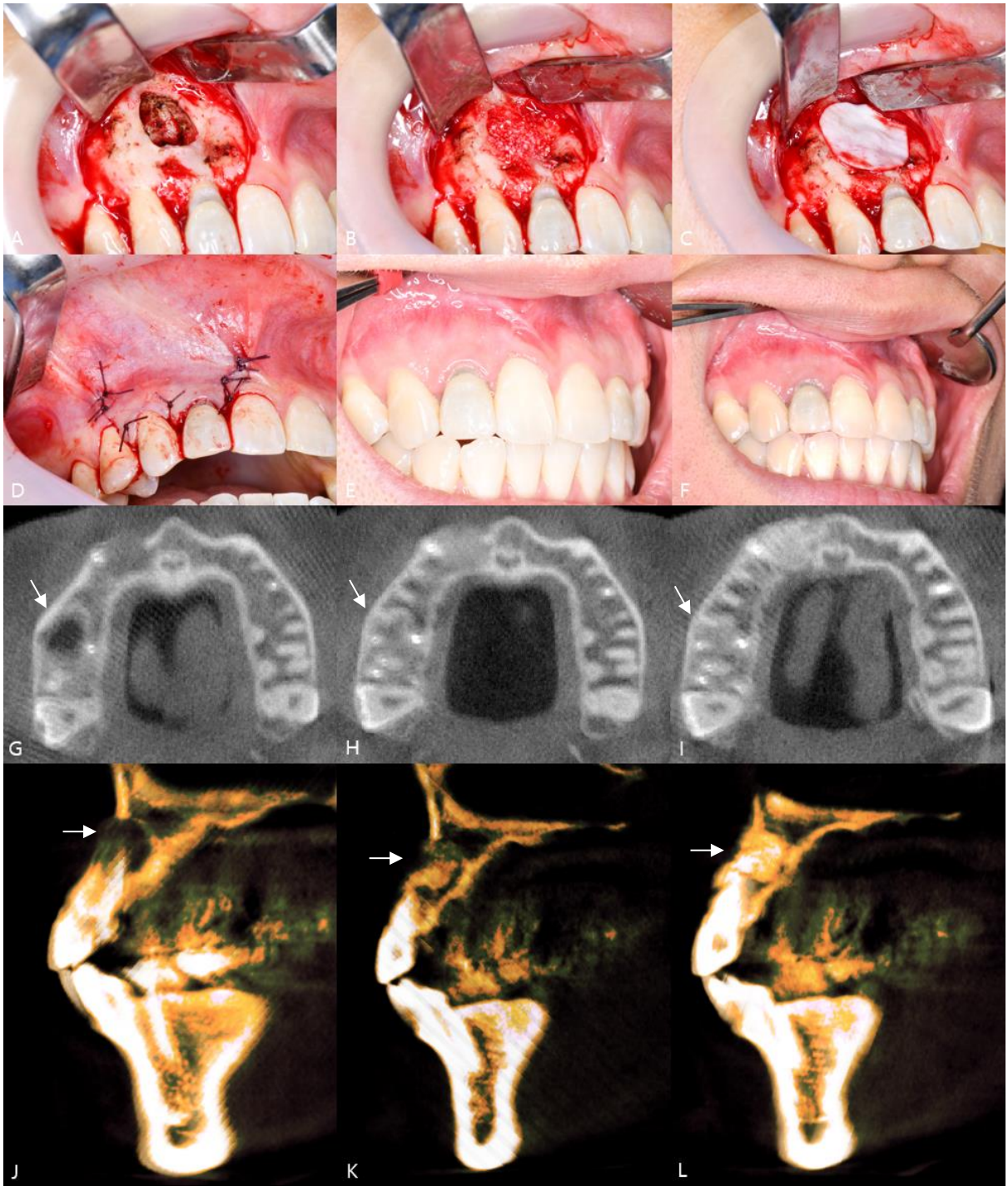

Figure 13. Bio-gide applied patient (Case 5). (A) Defect at the buccal side of #25, 27 (B~L). The description is consistent with Figure 10.

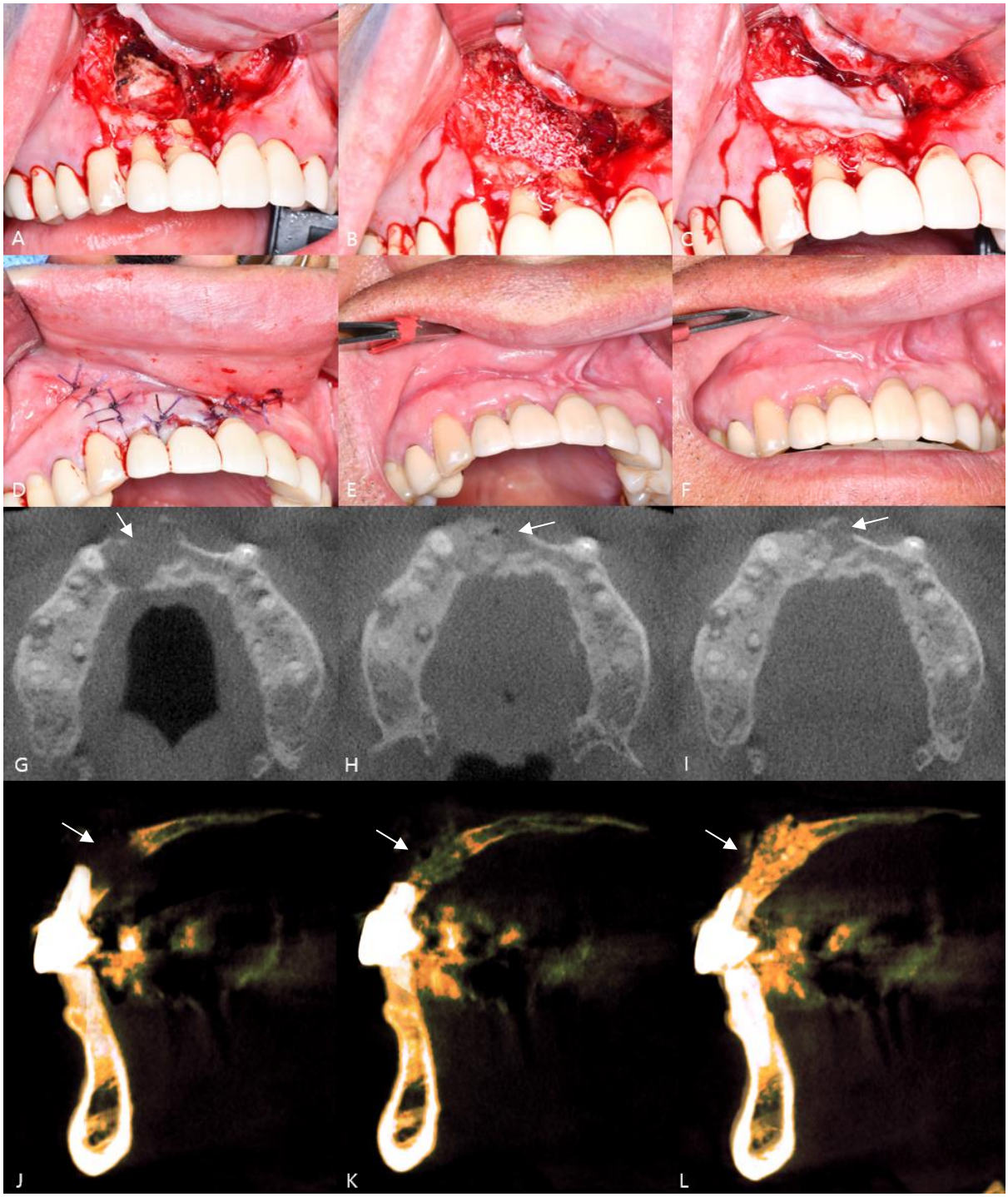

Figure 14. Bio-gide applied patient (Case 6). (A) Defect at the buccal side of #11, 12 (B~L). The description is consistent with Figure 10.

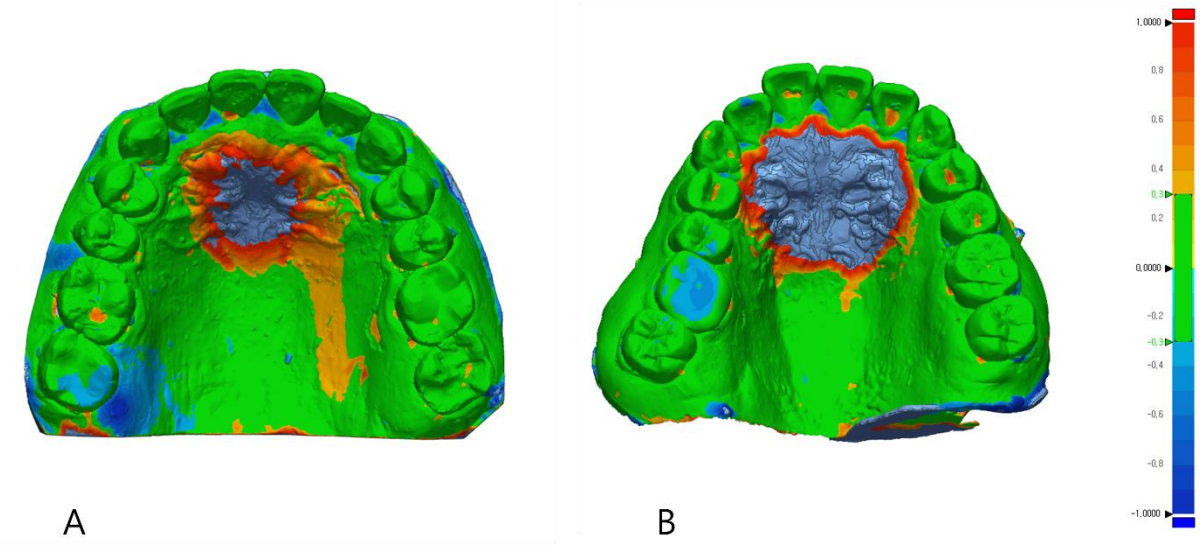

Figure 15. Soft tissue volume differences of nasopalatine cysts patients (Collagen membrane 2 applied group). (A and B) Soft tissue volume increase observed in the anterior median palatal area.

Appendix 1. Values of visits 1, 3, and 5 in case group based on CBCT indices

	variable	group	visit 1	visit 3	visit 5
Bone volume (mm^3)	BV	case 1	158.93863	2223.33731	2359.30161
Trabecular thickness (mm)	TbTh		0.73986	3.41472	3.88633
Closed porosity (%)	Po(cl)		0.00283	0.22574	0.48645
Open porosity (%)	Po(op)		71.8882	17.21142	6.82347
Total porosity (%)	Po(tot)		71.889	17.3983	7.27673
Bone volume (mm^3)	BV	case 2	481.56366	423.42064	472.76602
Trabecular thickness (mm)	TbTh		3.30571	1.99993	3.97523
Closed porosity (%)	Po(cl)		0.15792	0.2533	0.01214
Open porosity (%)	Po(op)		2.18402	25.80189	24.30384
Total porosity (%)	Po(tot)		2.33849	25.98984	24.31302
Bone volume (mm^3)	BV	case 3	892.84767	911.0967	1179.65829
Trabecular thickness (mm)	TbTh		1.88177	4.28797	3.28332
Closed porosity (%)	Po(cl)		0.57679	0.20878	0.42059
Open porosity (%)	Po(op)		12.65304	5.20906	8.53079
Total porosity (%)	Po(tot)		13.15684	5.40697	8.9155
Bone volume (mm^3)	BV	case 4	136.56174	1008.36064	1203.60693
Trabecular thickness (mm)	TbTh		0.88246	3.54467	5.63093
Closed porosity (%)	Po(cl)		0	0.12234	0.01561
Open porosity (%)	Po(op)		66.29736	15.91429	12.7924
Total porosity (%)	Po(tot)		66.29736	16.01716	12.80602
Bone volume (mm^3)	BV	case 5	61.82166	271.69025	560.85069
Trabecular thickness (mm)	TbTh		1.51905	4.97792	5.05533
Closed porosity (%)	Po(cl)		0.02766	0	0.01565
Open porosity (%)	Po(op)		10.90616	0.24996	2.97512
Total porosity (%)	Po(tot)		10.9308	0.24996	2.9903
Bone volume (mm^3)	BV	case 6	89.91695	1668.52451	3433.15903
Trabecular thickness (mm)	TbTh		0.72375	1.08709	3.89945
Closed porosity (%)	Po(cl)		0	0.07494	0.71675
Open porosity (%)	Po(op)		83.72265	56.14161	7.39043
Total porosity (%)	Po(tot)		83.72265	56.17448	8.054

Appendix 2. Values of visits 1, 3, and 5 in control group based on CBCT indices

	variable	group	visit 1	visit 3	visit 5
Bone volume (mm^3)	BV	control 1	656.00586	1919.96273	2408.85844
Trabecular thickness (mm)	TbTh		1.17367	1.94229	4.6184
Closed porosity (%)	Po(cl)		0.01149	0.22569	0.2726
Open porosity (%)	Po(op)		74.51441	34.94437	14.89232
Total porosity (%)	Po(tot)		74.51734	35.09119	15.12433
Bone volume (mm^3)	BV	control 2	298.73009	299.54652	281.11956
Trabecular thickness (mm)	TbTh		3.30193	3.45605	2.80084
Closed porosity (%)	Po(cl)		0.19337	0.03568	0.03721
Open porosity (%)	Po(op)		2.79671	2.69156	8.6505
Total porosity (%)	Po(tot)		2.98467	2.72628	8.68449
Bone volume (mm^3)	BV	control 3	165.51859	2616.63289	3527.66702
Trabecular thickness (mm)	TbTh		1.96694	2.50932	2.48766
Closed porosity (%)	Po(cl)		0.08817	0.12089	0.21622
Open porosity (%)	Po(op)		96.00391	38.32971	43.35155
Total porosity (%)	Po(tot)		96.00743	38.40427	43.47403
Bone volume (mm^3)	BV	control 4	547.92461	573.26924	689.12443
Trabecular thickness (mm)	TbTh		3.76683	2.20169	4.96671
Closed porosity (%)	Po(cl)		0.01643	0.04303	0.00065
Open porosity (%)	Po(op)		4.01254	20.83977	2.6548
Total porosity (%)	Po(tot)		4.0283	20.87383	2.65543
Bone volume (mm^3)	BV	control 5	794.56968	955.44423	1002.46005
Trabecular thickness (mm)	TbTh		1.98748	2.00881	4.41072
Closed porosity (%)	Po(cl)		0.13034	0.27827	0.08743
Open porosity (%)	Po(op)		21.62305	37.65942	16.20994
Total porosity (%)	Po(tot)		21.72521	37.8329	16.2832
Bone volume (mm^3)	BV	control 6	282.41472	1400.9656	1693.04359
Trabecular thickness (mm)	TbTh		1.15788	2.41115	4.21323
Closed porosity (%)	Po(cl)		0.00478	0.14674	0.03259
Open porosity (%)	Po(op)		77.39244	32.01669	22.44217
Total porosity (%)	Po(tot)		77.39352	32.11645	22.46744

국문 요약

돼지와 소에서 추출된 교원질 차폐막의 효과를 평가하기위한 무작위 임상시험

장훈제

지도교수 안강민

울산대학교 대학원 의학과 치의학전공

개요

교원질 차폐막은 제거가 필요 없어 환자 건강에 미치는 영향이 낮고 안정적인 결과를 보이기 때문에 골유도재생에 많이 사용되는 막 중 하나이다. 교원질 차폐막은 노출될 가능성이 적고, 부분적 노출이 되더라도 안정적인 결과를 나타낸다. 교원질 차폐막은 소, 돼지, 말에서 유래된다. 이러한 차폐막의 효용성은 연구가 잘 되어있지만, 무작위 임상시험은 그 수가 적다. 본 연구의 목적은 구강악안면외과 영역의 임상에서 소 및 돼지 유래의 교원질 차폐막 간의 효과를 비교하는 것이었습니다.

재료 및 방법

비구개낭이나 치근당낭과 같이 악골의 결손부에 골 이식이 필요한 환자가 대상이었다. 연조직으로 완전히 피개가 가능한 결손만 고려되었다. 조절되지 않는 대사질환, 골조직에 영향을 미치는 약물을 주사 맞은 이력이 있는 환자, 또는 임산부는 제외되었다. 흡연량이 많은 환자 및 치료 부위에서 방사선 치료를 받은 환자는 연구에 제외되었다. 총 12 명의 환자가 선정되었으며 최소 5 회 방문해야 했다. 방문 1, 3 및 5 에서 콘빔 컴퓨터 단층촬영, 디지털 모델 스캐닝 자료를 획득했다. 매 방문 마다 파노라마 사진 촬영 및 부작용 평가가 이루어졌다. 방문 2, 3, 4 및 5 에서 임상 사진이 촬영되었다. 돼지 유래의 골이 이식되었고, 무작위로 배정된 소 및 돼지 유래의 차폐막이 환자에게 적용되었다. 골 부피 평가 및 차폐막의 효용성 평가를 위하여 임상적, 방사선학적, 그리고 3 차우너 분석이 시행되었다. 임상적으로 수술부위의 염증, 감염, 창상열개, 그리고 이물질 반응이 있는지 평가되었다. 콘빔 컴퓨터 단층촬영에서 결손부위를 포함한 치료 영역이 수동으로 설정되었다. 결손 부위를 포함하는 각 단층에서 골이식의 가장 바깥쪽 테두리를 연결하여 이식된 골의 부피를 측정했다. 소주골 두께는 골

이식의 연속된 길이의 평균으로 정의하였다. 모든 측면에서 둘러싸인 기공과 외부 구조에 연결된 기공은 각각 폐쇄된 모공과 개방된 모공으로 측정하였다. 모든 모공의 부피는 전체 부피의 백분율로 측정하였다. 연조직 평가는 방문 1 과 3 에서 얻은 석고 모형의 정보를 비교하여 분석되었다. 모형 스캐닝은 구강내 스캐너(Medit i500 oral scanner, 메가젠, 한국)으로 시행되고 3 차원 프로그램(Geomagic Control X, 3D Systems, 미국)으로 분석되었다.

결과

성비는 남녀 각각 9:3 이었으며, 나이는 24 세에서 73 세까지 분포되었다. 평균 연령은 43 세였다. 치근단낭(8 명) 은 총 모집단의 83%를 구성하는 가장 우세한 조직병리학적 결과였고, 비구개낭의 결과는 두 명이었다. 추적관찰 기간에 염증 및 감염의 소견은 관찰되지 않았다. 통계 처리한 결과 대조군과 실험군 사이에 유의한 차이는 없었다($p>0.05$, student's t-test and Mann-Whitney u-test). 3D 모델을 중첩시켜 연조직 부피를 분석하는 결과에서 각각 5 건은 감소 및 변화 없음이었고, 증가한 결과는 2 건이었다.

결론

이 연구에서 임상적 및 방사선학적 분석결과 소 유래의 교원질 차폐막과 돼지 유래의 교원질 차폐막 간의 골유도재생술 및 연조직 부피 유지 결과에서 유의할 만한 차이는 없었다. 따라서 본 연구에서 사용된 소 및 돼지 유래의 교원질 차폐막은 임상 적용에서 큰 차이를 보이지 않았다.

중심어: 교원질 차폐막, 골유도재생, 골이식, CBCT, 중첩, 분해