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The use of acellular allogenic dermal matrix in soft tissue management around the implants

Min-Jeong Kwoen[1], Sang-Yun Kim[1], Yong-Hoon Choi[2], Young-Kyun Kim[1,3]

Departments of [1]Oral and Maxillofacial Surgery, [2]Conservative Dentistry, Section of Dentistry, Seoul National University Bundang Hospital, Seongnam, [3]Department of Dentistry & Dental Research Institute, School of Dentistry, Seoul National University, Seoul, Korea

Purpose: The purpose of this study was to introduce various strategies to deal with soft tissue using an acellular allogenic dermal matrix and to evaluate postoperative complications and implant prognosis (success rate, survival rate, failure, and marginal bone loss).

Materials and Methods: This retrospective study investigated 28 patients who had intraoral surgery using an acellular allogenic dermal matrix (Megaderm, L & C BIO Inc, Seoul, Korea) from May 2013 to December 2017. Vestibuloplasty, increasing keratinized mucosa, soft tissue augmentation, and barrier membrane for bone graft were used as surgical methods in 32 cases. Megaderm was applied to nine cases for barrier membrane after guided bone regeneration and 22 cases for soft tissue treatment. One case was used for bone graft and soft tissue treatment. A total of 48 implants were placed.

Results: Among the 48 implants, 25 were counted to measure the success rate because more than a year has passed since the placement of prosthetic devices, and radiographic examination was performed. Three implants had peri-implantitis and was classified as failures. Of the 25 implants, 22 (88%) were successful. As none of implants were removed from the placement site, the survival rate was 100%.

Conclusions: Megaderm is a biocompatible material which maintains its collagen structure after the manufacturing process. As a result, it acts as a membrane and graft soft tissue material properly in the intraoral environment. (JOURNAL OF DENTAL IMPLANT RESEARCH 2019;38(1):6-12)

Key Words: Implant, Bone graft, Soft tissue augmentation, Megaderm

INTRODUCTION

In the edentulous area, as the alveolar bone continues to be absorbed over time, the bone mass becomes insufficient and the soft tissue condition becomes poor, which often hinders functional and aesthetic restoration of implants. Therefore, various treatments have been attempted to restore bone and soft tissue defects[1-3].

Various bone graft materials, including autogenous bone, have been developed and used in clinical practice to repair hard tissue defects, and various complicated procedures have been applied. In addition, soft tissue defects other than hard tissue and related problems cause many problems in implant treatment. However, only few kinds of biomaterials are available for soft tissue treatment, and studies on related procedures or clinical results are insufficient compared with hard tissue-related studies. The surrounding soft tissues are likely to be recessed after the implant surgery, and various problems arise, such as lack of the keratinized mucosa (which helps maintain the implant prosthesis) and shallowing depth of the oral vestibule[4,5].

The authors performed various treatments to improve the hard tissue and soft tissue conditions surrounding the

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Correspondence to: Young-Kyun Kim, https://orcid.org/0000-0002-7268-3870
Department of Oral and Maxillofacial Surgery, Section of Dentistry, Seoul National University Bundang Hospital, 82 Gumi-ro 173beon-gil, Bundang-gu, Seongnam 13620, Korea. Tel: +82-31-787-7541, Fax: +82-31-787-4068, E-mail: kyk0505@snubh.org

implant using Megaderm (L & C BIO Inc, Seoul Korea), which consists of an acellular allogenic dermal matrix (ADDM). The mainly used treatments include shielding as barrier membrane for guided bone regeneration (GBR), oral vestibuloplasty, creating keratinized mucosa, and soft tissue augmentation. The purpose of this study was to introduce various treatment methods using Megaderm and to evaluate postoperative complications and implant prognosis.

MATERIALS AND METHODS

This study retrospectively evaluated patients for whom Megaderm was used for implant treatment between May 2013 and December 2017. This study was conducted under the approval of the Bioethics Review Committee of Seoul National University Bundang Hospital (B-1807-478-101). The medical records and radiographs were reviewed retrospectively, and care was taken to ensure that no personal information or facial features were exposed. The treatments used were classified into the following four methods:

1. Barrier membrane for GBR (Fig. 1)
2. Increasing keratinized mucosa (Fig. 2)
3. Vestibuloplasty (Fig. 3)
4. Soft tissue augmentation (Fig. 4)

Twenty-eight patients, consisting of 9 men and 19 women, were included in this study. Their ages ranged from 22 to 75 years, with a mean age of 52.3 years. Thirty-two surgical sites were made. Megaderm was applied to 9 cases for barrier membrane after GBR and 22 cases for soft tissue treatment. In 1 case, Megaderm was used for bone graft and soft tissue treatment. A total of 48 implants were implanted in 14 anterior regions

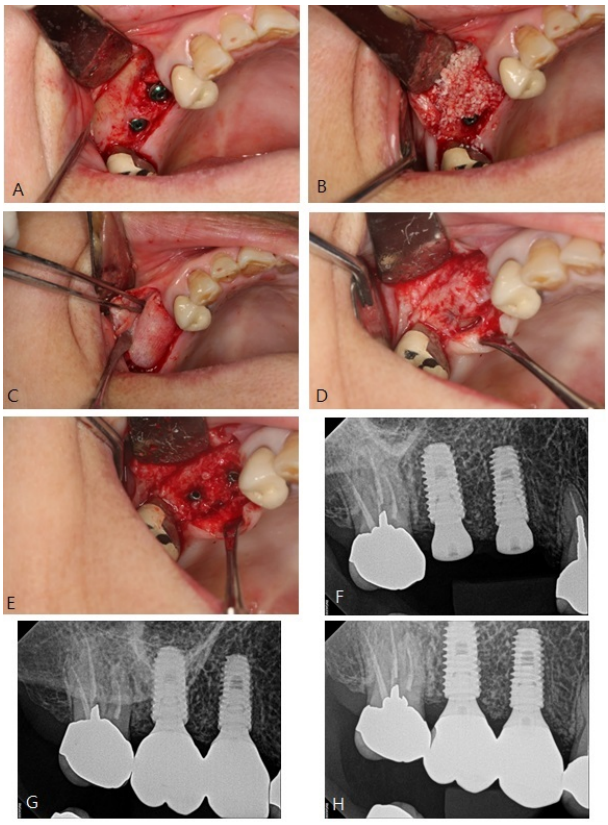

Fig. 1. Barrier membrane for GBR. (A) Concave appearance of the buccal alveolar ridge. (B) A 0.25-cc DO bone graft. (C) Megaderm application. (D, E) At 4.5 months after first surgery, newly formed bone could be observed above the implant fixture. (F) Second implant surgery: healing abutment connection. (G) Three months after prosthetic loading. (H) Nine months after prosthetic loading.

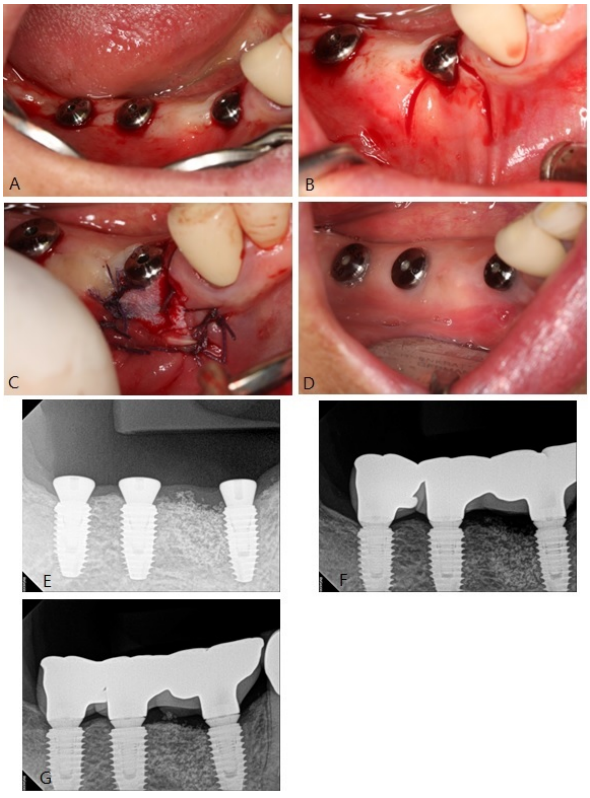

Fig. 2. Procedure to create a keratinized mucosa around the implant abutment. (A) Lack of keratinized gingiva; small amount of white portion. (B) Sulcular and bilateral releasing incisions were made. A partial-thickness flap was elevated for an apically positioned flap. (C) Megaderm application. (D) Appearance at 2.5 months after implant placement. (E) Periapical radiograph after second surgery. (F) Periapical radiograph 5 months after prosthetic loading. (G) Periapical radiograph 1 year after prosthetic loading.

(29.16%), 15 premolar regions (31.25%), and 19 posterior regions (39.58%).

Among 23 cases of soft tissue treatment, 3 were treated for vestibuloplasty; 2, for Increasing keratinized gingiva; and 18, for soft tissue augmentation (Table 1). The follow-up examination period after the restoration of prosthetic devices until the final visit date was 0 to 53 months (mean, 16 months).

The implant success criteria were based on the following criteria mentioned by Esposito et al.: 1) no mobility, 2) marginal bone loss on radiographic evaluation of <1.5 mm during the first year of function and <0.2 mm per year, 3) no pain or abnormal sensation, and 4) peri-implant probing shows a firm osseointegration of the implant without bleeding on probing (BOP)[6]. The survival rate was based on maintaining the function of the final observation. The implants were considered to have no problems when they were not followed up after the prosthesis was installed[7].

The amount of marginal bone resorption was based on radiographs taken immediately after restoration of the implant prosthesis. During the first year of prosthesis and at the last follow-up observation, periapical radiographs were taken and the mean mesiodistal height of the alveolar bone was calculated and measured. Patients were ex-

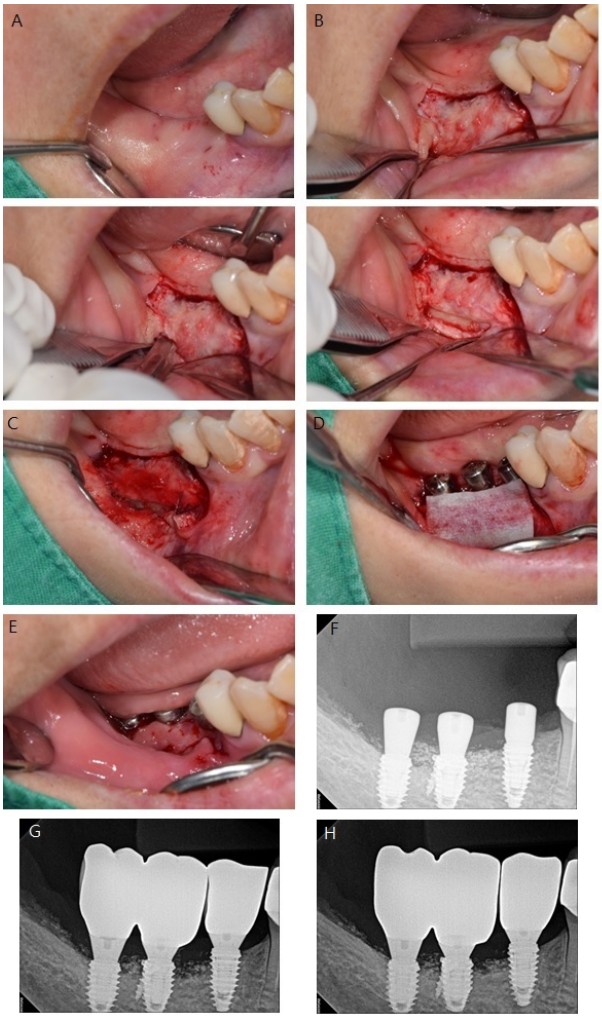

Fig. 3. Fenestration technique for vestibular deepening during the second implant surgery. (A) Shallow vestibule. (B) Crestal incision and partial thickness flap. (C, D) Fenestration procedure: A 2-mm excision of the periosteum was performed at the vestibular area. (E) Suture fixation for vestibular deepening. (F) Periapical radiograph after the second surgery. (G) Periapical radiograph 7 months after prosthetic loading. (H) Periapical radiograph 11 months after prosthetic loading.

Table 1. Types of soft tissue treatment

Soft tissue treatment	No.	%
Vestibuloplasty	3	13.04
Increasing keratinized gingiva	2	8.69
Soft tissue augmentation	18	78.26

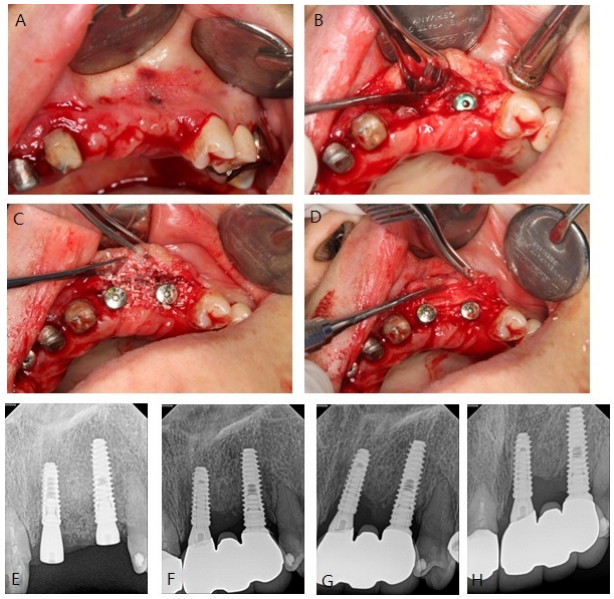

Fig. 4. Soft tissue augmentation during the second implant surgery. (A) Implant fixture thread exposed on the buccal side. (B) Elevated full-thickness mucoperiosteal flap. (C) Bone graft applied around the exposed implant thread. (D) Megaderm applied for soft tissue augmentation. (E) Periapical radiograph after the second implant surgery. (F) Periapical radiograph 8 months after prosthetic loading. Marginal bone loss can be observed. (G) Periapical radiograph 1 year 1 month after prosthetic loading. (H) Periapical radiograph 2 years 2 months after prosthetic loading.

cluded if they did not undergo follow-up or radiographic examination.

RESULTS

1. Complications

Complications occurred in 6 of the 32 cases of Megaderm application as follows: peri-implantitis in 2 cases, peri-implant mucositis in 1 case, prosthetic problem such as screw loosening in 1 case, and wound dehiscence and Megaderm exposure in 2 cases. Peri-implantitis cases had significant marginal bone loss. An implant was observed to have mobility after 6 months of prosthesis installation. Periapical radiographs and peri-implant probing showed intact bone-implant relationship, so we made a diagnosis as screw loosening (Table 2).

2. Marginal bone loss

In 25 implants, more than a year has passed since the placement of prosthetic devices and radiographic examination was performed with continuous follow-up. The mean resorption after 1 year was 0.58 mm, and the mean resorption over the total observation time was 0.53 mm at the last appointment.

Of the 48 implants, none was removed or reimplanted until the final follow-up, and 100% survival rate was achieved.

The success rate was evaluated on the basis of the success and failure criteria of the implant by Esposito et al. In the first year of implantation, loss of marginal bone of ≥1.5 mm occurred in three implants affected by peri-implantitis and was classified as failure. Of the 25 implants, 22 (88%) were successful (Table 3).

Table 2. Postoperative complications

Complication	No.	%
None	26	81.25
Peri-implantitis	2	6.25
Peri-implant mucositis	1	3.12
Screw loosening	1	3.12
Megaderm exposure	2	6.25

DISCUSSION

ADDM has been used for soft tissue reconstruction in the medical and dental fields for many years. In the field of medicine, various reconstructive techniques such as breast reconstruction, orbital wall reconstruction, and reconstruction of necrotizing tissue due to a systemic condition have been widely used[8-10]. In the field of dentistry, it has been used to cover exposed roots at gingival recession and to reconstruct gingival tissue where keratinized gingiva is lacking vertically and horizontally etc[11-13]. ADDM has the advantage that it has a similar effect as autologous soft tissue transplantation and does not cause additional complications because it does not require secondary surgery on the donor site. Typical products that have been used for a long time include Alloderm (Lifecell Co, USA) and Surederm (Hans Biomed, Seoul Korea).

Megaderm, the ADDM used in this study, is the product of the donated human skin tissue through the AlloClean technology process. This technology was developed by L & C BIO through human tissue processing that removes cells and immune reaction factors in tissues without damaging the tissue-specific three-dimensional structure. According to the manufacturer, 1) unlike other products, the ultra-precision processing technique was used to remove the basement membrane layer, 2) the dermis removed from the basement membrane layer maximizes the infiltration of fibroblasts and new blood vessels, and 3) enough time and space can be provided for new bone formation when used as barrier membrane for GBR operation by maintaining a long barrier time.

Resorbable collagen membranes has been widely used as barrier for GBR, and clinically excellent results have

Table 3. Marginal bone loss 1 year after prosthetic loading

Bone loss (mm)	No.	%
0	22	88
0～1.5	0	0
1～2	0	0
2～3	0	0
3～4	0	0
4～5	2	8
5～6	1	4
No image	9	18.75

been published[14-16]. Megaderm has a long absorption period and acts as a collagen membrane itself, and thus can perform a barrier function to prevent soft tissues from penetrating into the bone graft material. Removal of the basement membrane layer maximizes fibroblast infiltration and neovascularization, resulting in a high rate of engraftment after transplantation, which is itself healed with keratinized gingiva[17]. It is also a biocompatible material with sufficient flexibility and hardness to support rigid anatomical structures in the mouth[18].

However, clinical studies using Megaderm have not been common in both the medical and dental fields. Currently, only articles on orbital wall and breast reconstructions are published. A study of orbital wall reconstruction compared Megaderm with absorbable mesh plates and porous polyethylene. According to Kim et al., Megaderm provided sufficient support for orbital components and performed well as a scaffold for bone tissue growth. A follow-up period of 6 months showed no complications[19]. A study of breast reconstruction compared Megaderm with the commercially available Alloderm. Lee et al. reported no statistically significant difference in clinical results between the two materials. Infection, valve necrosis, shrinkage, serous adnexal hematoma, and other complications were evaluated. The two materials showed no statistically significant differences[20].

Four complications were found in this study, namely Megaderm exposure, peri-implantitis, peri-implant mucositis, and prosthetic screw loosening. Megaderm material exposure occurred in 1 patient for whom Megaderm was used for soft tissue augmentation 4 months after bone augmentation. After confirming the stable formation of new bone, we simply removed Megaderm and waited for natural healing. No evidence of loss of bone graft material, postoperative complications, and marginal bone resorption was observed. Mehmet et al. compared the incidence of incomplete primary closure and exposure of the absorbable membrane when the GBR procedure was performed using an absorbable shielding membrane, in comparison with the case where primary closure was completely performed. As a result, no significant complications occurred when the membrane was exposed to the oral cavity, and complete absorption of the membrane was observed after 6～7 weeks despite the slight inflammation. After 7～8 weeks, normal keratinized gingiva could be observed in both the exposed and unexposed groups. This result corresponds to our stury which showed good healing after removal of the exposed Megaderm[21].

In this study, 2 cases of severe bone resorption were found in the peri-implant situation. One implant was placed on the right maxilla (#13), and 2 implants were placed on the left side (#21, 23). #21～23 implants had complications after the first operation and were accompanied by labial gumboil with implant thread exposure. #13 implant showed rapid bone loss after the second surgery. Subgingival curettage was performed to remove the inflammatory tissue from the diseased implants. The implant was cleaned with chlorhexidine solution, and minocline ointment was injected locally to the affected area along with laser treatment. Consequently, the inflammation subsided, and Megaderm was used as a membrane for GBR and soft tissue augmentation. One year after functioning of the prosthesis, the marginal bone loss was 4.88 mm. At the final visit, the marginal bone loss was 4.49 mm, the resorption progress seemed to have stopped, and bone regeneration was observed around #13 implant.

For the patient with peri-implant mucositis, Megaderm was applied to increase the amount of buccal soft tissue. We did not observe a clear pattern of marginal bone resorption, but the patient complained of gingival weakness with BOP on the mesial side of the implant. Shortage of the keratinized gingiva was identified as the direct cause. Cleaning and oral hygiene education using chlorhexidine was performed. No additional surgery was performed.

Elena et al. described peri-implantitis and peri-implant mucositis as the most common complications that can occur during implant placement. As part of the professional treatment, the surrounding implants were mechanically cleaned surgically or non-surgically. Also using ultrasonic devices, prescript antibiotics and oral cleaning agents were recommended. As criteria for clearly demonstrating the indications for surgical and non-surgical procedures have not been established yet, clinicians have to identify bone resorption patterns to choose the appropriate method[22].

In cases of screw loosening, periapical radiographs and peri-implant probing showed intact osseointegration be-

tween the bone and the implant. In this study, we solved the clinically identifiable mobility problem by restoring the prosthesis[23].

Misch et al. cited that the anatomical problems of the patient, systemic complications, and technical problems of the surgeon are the main causes of possible complications related to implant placement. Most of them can be prevented by establishing a treatment plan through thorough diagnosis before surgery, to maintain proper initial fixation with a minimally invasive method. Thus, they emphasized that when a problem occurs, clinicians should solve the cause of the problem and prescribe appropriate drug[24].

In this study, the mainly used treatments with Megaderm were shielding as a membrane for GBR, oral vestibuloplasty, creating keratinized mucosa, and soft tissue thickening. When Megaderm was used for soft tissue treatment, compared with the conventional free gingival graft, a second surgery was not required for donor tissue harvesting, so the patients do not need to feel burdened by an additional surgical site or pain. In addition, the clinician could use the desired size and shape of the product, so soft tissue treatment had relatively easy and excellent results without any complications.

As Megaderm is a recently introduced material, it is necessary to establish strong evidence through prospective studies with long-term goals to use Megaderm widely. This retrospective study could not establish a definite guideline for surgical sites and extent of bone grafting, and various surgical methods were used. In addition, as cases of Megaderm combined with autogenous soft tissue were included in this study, the good prognosis seen in this study cannot be concluded as from the effect of Megaderm only. In the future, standardized surgical procedures and protocols should be established, and prospective clinical studies will be needed to establish the criteria for systemic disease, oral hygiene management index, and surgical sites. To assess prognosis over a long period, patients should be encouraged to undergo routine follow-up. The material should also be evaluated from a critical point of view by comparing Megaderm with other soft tissue graft materials and autogenous soft tissue transplantation results.

Even though more research is needed, as healthy soft tissues of patients need not be made beneficial for transplantation, the meaning of the material called Megaderm in dentistry is highly important.

CONCLUSION

Megaderm is a biocompatible material that maintains its collagen structure after the manufacturing process. As a result, it functions properly as a shielding membrane and soft tissue graft in the oral environment. No definitive postoperative complications arising from the use of Megaderm have been reported. Megaderm can be used for various treatments such as barrier membranes for GBR, oral vestibuloplasty, increasing keratinized gingiva, and soft tissue augmentation.

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