

Guided bone regeneration using two types of non-resorbable barrier membranes

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Abstract (J Korean Assoc Oral Maxillofac Surg 2010;36:275-9)

Introduction: Guided bone regeneration (GBR) is a common procedure for the treatment of bone defects and bone augmentation. The non-resorbable barriers are well-documented barriers for GBR because of their stability and malleability. However, few GBR studies have focused on the different types of non-resorbable barriers. Therefore, this study examined the clinical results of different non-resorbable barriers for GBR; expanded polytetrafluoroethylene (e-PTFE) (TR-Gore Tex, Flagstaff, AZ, USA), and high-density polytetrafluoroethylene (d-PTFE) (Cytoplast membrane, Oraltronic, Bremen, Germany).

Materials and Methods: The analysis was performed on patients treated with GBR and implant placement from January 2007 to October 2007 in the department of the Seoul National University Bundang Hospital. The patients were divided into two groups based on the type of non-resorbable barrier used, and the amount of bone regeneration, marginal bone resorption after prosthetics, implant survival rate and surgical complication in both groups were evaluated.

Results: The implants in both groups showed high survival rates, and the implant-supported prostheses functioned stably during the follow-up period. During the second surgery of the implant, all horizontal defects were filled with new bone, and there was no significant difference in the amount of vertical bone defect.

Conclusion: In bone defect areas, GBR with non-resorbable barriers can produce favorable results with adequate postoperative management. There was no significant difference in bone regeneration between e-PTFE and d-PTFE.

Key words: Guided bone regeneration (GBR), Expanded polytetrafluoroethylene (e-PTFE), High-density polytetrafluoroethylene (d-PTFE), Non-resorbable barrier membrane

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1. Introduction

Guided bone regeneration (GBR) has been used commonly in clinics to resolve anatomical problems such as inadequate bone quality at the implant site, insufficient residual bone quantity, etc. Barrier membranes have been used widely because they protect the adjacent soft tissues from cells impeding bone formation¹ and have the advantage of improving the mechanical stability of the graft materials and reducing micro-mobility². Barrier membranes could be classified broadly as non-resorbable membranes and absorbable membranes. Thought non-resorbable membranes require a second surgery, they have advantage that the space could be maintained and

the regenerated underlying tissues could be evaluated³. Therefore, non-resorbable membranes have been used widely in clinics.

Non-resorbable membranes can be divided into expanded-polytetrafluoroethylene (e-PTFE) and high-density polytetrafluoroethylene (d-PTFE) according to the structure. Among porous membranes, the Gore-Tex membrane (W. L. Gore & Associates, Flagstaff, AZ, USA) is e-PTFE, which allows nutrients to be supplied through multiple pores. Although it can allow the invasion of bacteria when the membrane is exposed to the oral cavity, it has been used as the standard in research conducted on non-resorbable membranes, and its effectiveness has been proven.

Some authors report that the d-PTFE completely blocks the penetration of food and bacteria, and thus even if it is exposed to the oral cavity, the d-PTFE membranes exert good guided tissue regeneration (GTR) effects^{4,6}. Numerous studies have compared the efficacy of absorbable membranes and non-resorbable membranes. However, very few studies have compared the clinical effects of non-resorbable membranes with

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different structures⁷⁻⁹.

In this study, the clinical outcome of GBR using the non-resorbable TR-Gore-Tex (e-PTFE) (Augmentation material, Flagstaff, AZ, USA) was compared to that of Cytoplast (d-PTFE) (Oraltronics, Bremen, Germany).

II . Materials and Methods

1. Subjects

The subjects were patients who underwent simultaneous GBR using non-resorbable membranes and implant placement performed by the same oral and maxillofacial surgeon at the Bundang Seoul National University Dental Clinic from January 2007 to October 2007. The subjects were patients who had dehiscence and/or circumferential defects around implant after implant placement. Smoking history was not assessed, and patients with uncontrolled systemic diseases were excluded from this study.

Of the 14 patients, 10 were male and 4 were female. The patient age ranged from 26 years to 68 years, and the average age was 47.9 years.

2. Methods

This study was conducted prospectively after obtaining IRB approval from the Bundang Seoul National University Hospital (B-0808-060-102). Patients were divided into two groups according to the type of membrane used i.e. e-PTFE or d-PTFE. The patients were assigned randomly to either the e-PTFE group or the d-PTFE group according to the order of the surgery. The effect of each barrier membrane was assessed by measuring the amount of the bone defect at the time of the GBR and second surgery after GBR. In all cases, the implants were placed simultaneously, and submerged-type implants were used. The total number of implants placed was 21; 11 patients in the e-PTFE group and the 10 patients in the d-PTFE group received implants. Allogenic bones (Orthoblast II, Isotis OrthoBiologics, California, USA) were used as the graft materials. After performing the bone graft, more than 2 mm of the margin of the bone defect area was covered with a barrier membrane. All barrier membranes were removed after 6-8 weeks. The mean follow-up period after functional loading was 13 months.

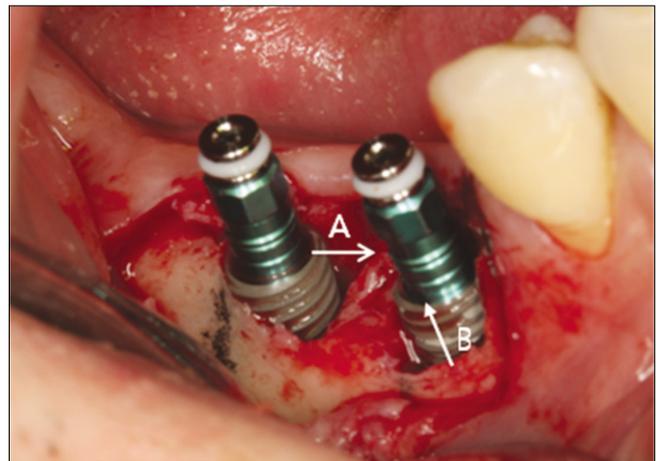
3. Measurement of bony defects

The amount of the bony defects around implants was determined by measuring the horizontal and vertical bone defects

using a periodontal probe from the mesial, distal, buccal, and lingual sides and calculating the mean of these measurements (unit: millimeter). At the time of the second surgery, the amount of the bone defect around implant was measured using the same method. The ratio of the bone defect area remaining at the time of the second surgery to the initial bone defect area was calculated (bone defect after GBR, primary defect \times 100), and the ratios of the two groups were compared.(Fig. 1)

4. Measurement of marginal bone loss

At the last follow up, radiographs were taken, and the resorption rate of the marginal bone of the implant was evaluated. To determine the amount of marginal bone loss, the distance was measured from the area of the implant shoulder to the area where radiographic radiolucency was observed on periapical radiographs taken using the paralleling technique; the mean value was then calculated. On the radiograph, the height of each fixture was measured, and by considering the magnification rate, the amount of marginal bone loss was calculated.



(A: Horizontal defect, B: Vertical defect)

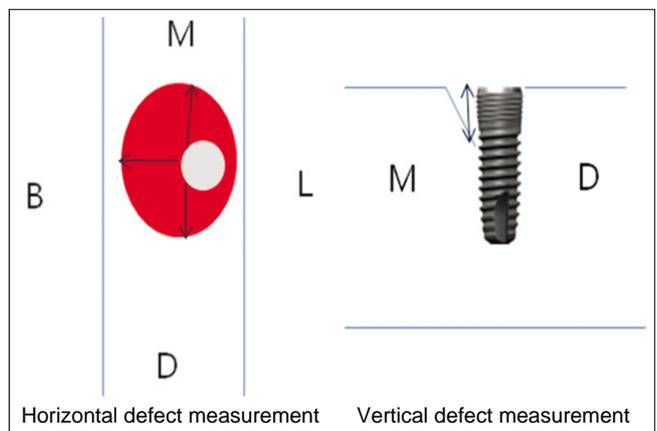


Fig. 1. Measurement of peri-implant bony defect.

5. Statistics

The mean and standard deviation of all the values were calculated. The bone defect amount and the amount of marginal bone loss of the two groups were compared by the Mann-Whitney U test using the SPSS program Ver. 12 for Windows (SPSS, Inc., Chicago, IL, USA). Differences were considered statistically significant for $P < 0.05$.

III . Results

Postsurgical complications developed in five cases in the first group, which were treated using TR-Gore-Tex, and in six cases of the second group, which were treated with Cytoplast. (Table 1) The most common complications were wound dehiscence, and in one case of the first group, ecchymosis developed in association with wound dehiscence. All complications were treated with dressings and other conservative methods, and after the removal of the barrier membrane, good healing was observed. The average healing period after the first surgery was 3.7 months, and all prostheses were restored with single non-splinted crowns.

The average amount of horizontal and vertical bone defect around implant fixture at the time of the first surgery are shown in Table 2. With regard to the amount of the bone defect, a statistically significant difference between the two groups was not detected.

The amount of bone defect were measured during the second surgery after GBR. All horizontal areas were filled with new bones, and the average vertical bone defect was 1.21 ± 0.45 mm for the e-PTFE group, and 1.87 ± 1.2 mm for the d-PTFE group. A statistically significant difference between the two groups was not detected. (Table 3, $P > 0.05$) The ratio of the size of the residual bone defect after GBR to the size of the initial bone defect was measured. The results showed that the ratio for the e-PTFE group was 6.63%, and the ratio for the the d-PTFE group was 11.25%; the difference between the two groups was not statistically significant. (Table 3) The marginal bone loss after functional loading was compared, and a significant difference between the two groups was not observed. (Table 4, $P > 0.05$)

IV . Discussion

The use of a barrier membrane for the regeneration of bones and tissues is a widely known procedure. In 1989, Dahlin *et al.*⁶ reported that in the cases in which e-PTFE was used to treat dehiscence defects around titanium implants, significant

Table 1. Postoperative complications

| Complications | Group 1 | Group 2 |
|-----------------------------|---------|---------|
| Wound dehiscence | 4 | 6 |
| Wound dehiscence+Ecchymosis | 1 | 0 |

Table 2. Primary bone defects (Mean (SD))

| | Group 1 | Group 2 |
|-----------------------------|-------------|------------|
| Vertical bone defect (mm) | 2.29 (4.54) | 3.24 (4.9) |
| Horizontal bone defect (mm) | 2.36 (0.8) | 1.4 (0.84) |

Table 3. Vertical bone defect after GBR on second surgery (Mean (SD)) and comparison of bone defects after GBR to primary bone defects

| Vertical bone defect (mm) | Group 1 | Group 2 | Sig. ¹ |
|--------------------------------|-------------|------------|-------------------|
| | 1.21 (0.45) | 1.87 (1.2) | * ² |
| Bone defect ratio ³ | 6.63% | 11.25% | |

(¹: significance of Mann-Whitney test, ²: $P > 0.05$, ³: bone defect after GBR /primary defect $\times 100$, GBR: guided bone regeneration)

Table 4. Bone loss after the functioning of the prosthesis (Mean (SD))

| | Group 1 | Group 2 | Sig. ¹ |
|------------------------------|------------|------------|-------------------|
| Bone loss (mm) | 0.9 (0.07) | 0.7 (0.05) | * ² |
| F/U period (post-prosthetic) | 12 M | 7 M | |

(¹: significance of Mann-Whitney test, ²: $P > 0.05$, M: months)

bone regeneration was achieved in comparison with the cases in which the membrane was not used. And they reported that the barrier membranes provided an appropriate environment for the growth of blood vessel and bone formation cells originating from the adjacent bone marrow. In addition, the experimental studies showing that GBR using various absorbable and non-resorbable membranes accelerated the attachment of initial osteoblasts have been reported^{10,11}.

A barrier membrane should satisfy the following conditions: tissue adhesion without morbidity, block of soft tissue ingrowth, clinical ease of use, space maintenance, and biocompatibility. Considering the above five conditions may be of help when selecting a barrier membrane¹².

Non-resorbable membranes have the disadvantage that they must be removed by a second surgery, and can be exposed to oral cavity because of incomplete coverage or gingival recession during the healing processes. Nonetheless, the use of non-resorbable membranes has the advantage that the evaluation of

the regenerated underlying tissue is possible, and the efficacy of the use of these membranes has been proven, as they have been widely used for a long time¹²⁻¹⁴.

The Gore-Tex membrane is composed of e-PTFE. Because of its GTR and GBR effects, Gore-Tex is used widely in clinics and its efficacy has been proven. It consists of two different micro structures. The inner intermodal distance is less than 8 μm , which blocks the migration of cells. Therefore, even if non-resorbable membrane is exposed after surgery, the blocking function can be maintained unless non-resorbable membrane is associated with infection. In addition, Gore-Tex is relatively hard, and thus it is suitable to maintain a space. The outer intermodal distance is 25 μm . The outer layer is relatively soft, and therefore easy to manipulate to adjust the shape of the bone defect. Since the Gore-Tex has many small pores, it is advantageous to attach it to tissues. It stabilizes and restricts the migration of epithelial cells.¹² Titanium-reinforced (TR) Gore-Tex membranes which contain a titanium frame inside, have the advantage of the ability to be bent into a desirable form, whose shape can be readily maintained. The multiporous PTFE (e-PTFE) structure stabilizes by attaching to the tissues; the membrane cannot be removed by pulling, and thus a second surgery must be performed. And the e-PTFE is able to supply nutrients through multiple pores but, when the membrane is exposed, the membrane can allow the invasion of bacteria. Therefore, when the membrane is early exposed to the oral cavity, the wound should be managed carefully by the use of antibiotic agent as chlorhexidine, and if inflammation occurs, e-PTFE should be removed immediately.

The Cytoplast is a d-PTFE membrane. Bacterial invasion is less frequent because the intermodal distance is less than 0.2 μm , and it is not multiporous. However, it only allows the passage of a limited supply of nutrients, so that when the Cytoplast is used, sufficient blood supply would be allowed by decortication. The Cytoplast does not have porous structure, and its attachment to tissues is weak. Thus, the Cytoplast membranes can be removed by pulling on the membrane without lifting the flap. In addition, during the early exposure of the membranes, the risk of infection is less than e-PTFE, the cost is low in comparison with the Gore-Tex membrane, and the application method is simple¹⁵⁻¹⁷.

Bartee¹⁵ reported that the use of d-PTFE is particularly useful when primary closure is impossible without tension, such as bone graft in extraction sockets, alveolar ridge preservation, large bone defects, and the placement of implants immediately after extraction. They also reported that even if the membrane is exposed, it does not affect healing. In addition, excessive releasing incision for primary closure can compromise the

blood supply and eliminate keratinized tissues, which worsens healing^{15,16}. Barber *et al.*¹⁷ reported that the use of a d-PTFE membrane, which does not require primary soft tissue coverage and can even achieve bone regeneration and soft tissue healing when membrane is exposed.

On the other hand, in animal studies that histologically evaluated the healing pattern of bone defect according to the type of membrane, it has been reported that the thickness of the fibrous tissue layer below the d-PTFE barrier membrane was relatively thin. And they mentioned the possibility of the access of cells to the bone marrow should be considered in use of d-PTFE. Also the e-PTFE directly contact with regenerated bone and was found ingrowth of bone to the inside of the membrane^{18,19}. On the other hand, Walters *et al.*²⁰ reported that in a randomized study of GBR involving 14 patients, e-PTFE membranes were not significantly different from d-PTFE membranes with regard to vertical bone regeneration and soft tissue healing.

The limitations of this study were that the type of implant was not standardized, and the number of samples was not large. All of the groups in this study showed a 100% implant survival rate during the follow-up period. The wound dehiscence was occurred, but relatively desirable bone regeneration was obtained through appropriate postsurgical maintenance, and the e-PTFE and d-PTFE did not show significant differences. In the evaluation of the marginal bone resorption performed after the placement of prosthesis, there was no significant difference between the two groups, and relatively consistent results were observed. In bone defect area, GBR with non-resorbable membrane could develop successful result with stable fixation, adequate management and sufficient healing period. Although there is no statistically significant difference between groups, we might suggest that TR-Gore-tex membrane could be more effective and useful for bone promotion.

V. Conclusion

In this study, e-PTFE and d-PTFE did not show a significant difference in bone regeneration effects. The appropriate postsurgical maintenance about wound dehiscence be done, relatively desirable bone regeneration can be obtained using non-resorbable membranes.

Disclosure

The authors claim to have no financial interest, directly or indirectly, in any entity that is commercially related to the products mentioned in this article.

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