Comparison of Clinical Outcomes Following Guided Tissue Regeneration Treatment with a Polylactic Acid Barrier or a Collagen Membrane

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This prospective, randomized, controlled clinical trial compared the clinical outcomes for a polylactic acid barrier versus a collagen membrane in conjunction with guided tissue regeneration (GTR). Thirty patients with chronic periodontitis and at least one intrabony defect of a minimum 4 mm were enrolled. Following full-mouth scaling, GTR using a collagen membrane or a polylactic acid barrier was performed at one site in each patient. At 1 week before and 6 months after surgery, probing pocket depth (PPD), clinical attachment level (CAL), marginal tissue recession, and bone fill were assessed. A significant reduction in PPD (2.50 ± 1.35 mm for the polylactic acid barrier and 2.60 ± 1.08 mm for the collagen membrane) was obtained, in addition to gains in CAL (2.40 ± 1.17 mm for the polylactic acid barrier and 2.60 ± 1.26 mm for the collagen membrane) and bone fill (0.33 ± 1.89 mm for polylactic acid barrier and 2.57 ± 1.64 mm for collagen membrane), for each group compared to baseline. Significantly, the results from 6 months after surgery showed that there was greater bone fill when the collagen membrane was used compared to the polylactic acid barrier. (Int J Periodontics Restorative Dent 2010;30:173–179.)

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It is possible to encourage regeneration of a new connective tissue attachment to a denuded root surface by allowing selective coronal regrowth of the periodontal ligament cells while excluding the gingival tissues from contact with the root during wound healing.[1] This procedure is called guided tissue regeneration (GTR) and is accomplished by periodontal flap surgery, which includes the placement of a barrier membrane between the gingival and the root surfaces.[2,3]

Numerous studies have proven the effectiveness of using collagen membranes in GTR therapy.[4–8] The reasons for selecting collagen as a barrier membrane[9] include the following: *(1)* collagen is the major extracellular macromolecule of the periodontal connective tissues and is physiologically metabolized by these tissues, *(2)* collagen is chemotactic for fibroblasts, and *(3)* collagen membrane acts as a barrier against migrating epithelial cells. Collagen membranes (BioMend, Sulzer Calcitek) have the capacity to support regeneration of periodontal tissue, and eventually the collagen membrane is

either incorporated within the healing tissues or degraded during the healing process.[5]

A bioabsorbable polylactic acid barrier, Atrisorb (Atrix Laboratories), has also been used for GTR treatment and has produced successful clinical outcomes.[10] It is a gel polymer of 37% poly(DL-lactide) and 63% *N*-methyl-2-pyrrolidone. Owing to the product's flowability, Atrisorb is often used along with space filler in clinical applications. Animal studies have shown it to have good tissue response, biocompatibility, and safety.[10,11] In the area of clinical application, Atrisorb has been shown to lead to good bone fill and clinical attachment gain in patients with periodontitis and Class II furcation involvement.[10,12–14]

The purpose of this clinical trial was to compare the therapeutic outcomes of GTR using either the polylactic acid barrier (Atrisorb) or the collagen membrane (BioMend). This will provide scientific evidence for clinicians that will help them select the appropriate membrane for use in periodontal treatment.

Method and materials

Subject selection

Thirty participants (age: 33 to 63 years) with chronic periodontitis were recruited from the periodontics section of Taipei Veterans General Hospital. Inclusion criteria consisted of: *(1)* radiographic evidence of at least one intraosseous bony defect of a minimum 4 mm in the mandibular posterior teeth, with the defect's probing pocket depth (PPD) being at least 6 mm; *(2)* no systemic disease present that might affect periodontal healing; *(3)* no periodontal surgery in the previous 12 months; and *(4)* no use of antibiotics or steroids for least 6 months prior to this study. This research proposal was approved through the Institutional Review Board of Taipei Veterans General Hospital. Each participant was informed about the purpose and procedures of the study as well as the possible risks associated with it. Written informed consent was obtained.

Clinical periodontal examinations

One week before surgery and 6 months after surgery, clinical parameters including Plaque Index (PI),[15] Gingival Index (GI),[16] PPD, clinical attachment level (CAL), and recession were recorded. The deepest point of each defect was located and this was used as the site for measurements. An individual tray with a 1-mm-deep groove was used to align a periodontal probe (Hu-Friedy) and ensure accurate measurement. The same periodontal probe was used for all measurements, which were recorded to the nearest millimeter. PPD was measured from the gingival margin to the tip of the probe. Recession was measured from the cementoenamel junction (CEJ) to the gingival margin. The difference from PPD to recession was calculated as the CAL. Intra-examiner variability was assessed by repeated measurements.

Surgical procedures

After initial periodontal treatments that included plaque control, scaling, and root planing, two groups of 10 participants each were randomly assigned to receive GTR with Atrisorb or GTR with BioMend. The remaining 10 patients received flap surgery only without any GTR membrane or grafting material and served as controls. All examinations and treatments were performed by the same investigator.

The selected area was anesthetized with 0.2% Xylestesin-S (Showa Yakuhis Kakon) containing 1/50,000 (0.1 mg/5 mL) epinephrine. After a full-thickness mucoperiosteal flap had been raised, scaling and root planing were performed. In the Atrisorb group, the defects were first filled with demineralized freeze-dried bone allograft (Pacific Coast Tissue Bank). Atrisorb was then applied to cover the defects and extend 3 to 4 mm beyond the defects. Sterile saline was used to facilitate hardening of the barrier. Flaps were positioned coronally to cover the barrier and secured in place with polyglycolic acid suturing material (Unik Surgical Sutures Manufacturing) using modified vertical mattress sutures. A periosteal releasing incision was made to achieve tension-free primary closure whenever necessary. For the BioMend group, all the procedures were the same, except that BioMend membranes were used and kept in place with sling sutures.

Oral analgesics (diclofenac 25 mg as necessary) and antibiotics (amoxicillin 500 mg) every 8 hours for 7 days were also prescribed. Patients were instructed to use a cotton tip with

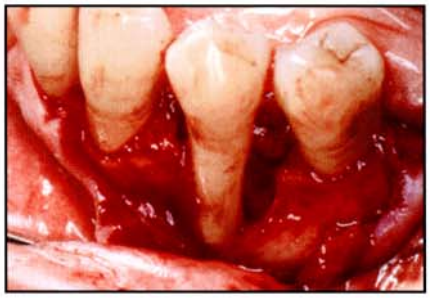

Fig 1a *Two-walled (distal and lingual walls) defect.*

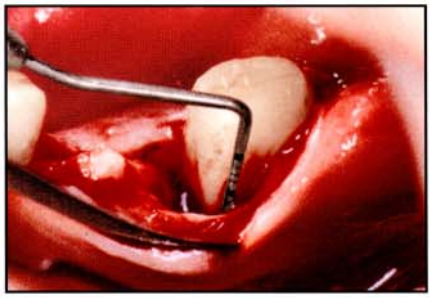

Fig 1b *Three-walled (buccal, mesial, and lingual walls) defect.*

Fig 1c *Circumferential bony defect.*

0.12% chlorhexidine twice a day in the area that had been operated on and were told not to floss the GTR area for 6 weeks.

Radiographic evaluation

With the aid of an individual tray, standardized radiographs were taken 1 week before and 6 months after surgery. For the purpose of analysis, the films were scanned and digitalized using a scanner (Microtek Scanmaker 4700 at 3,000 dpi). Linear measurements were made using analytical software (Emago, version 3.42). The distances from the CEJ to the bottom of the defect and from the CEJ to the bone crest were measured. The differences were calculated as the height of bone fill and the crestal bone resorption.

Statistical analysis

Baseline values for PI, GI, and the depth of the intrabony defects were compared among the three groups using the Kruskal-Wallis test. Age, PPD, CAL, recession, and the width and crestal bone level of the intrabony defects were compared among the three groups using one-way analysis of variance. Within-group comparison of measurements at 1 week before and 6 months after surgery was carried out using the Wilcoxon signed ranks test for PI and GI and a paired *t* test for PPD, CAL, recession, bone fill, and crestal bone resorption. Statistical analysis was performed using a computer program (SPSS 8.0, SPSS Inc). Any P value < .05 was considered to be statistically significant.

Results

No significant differences in age, sex, or the distribution of the defects in premolars or molars were found among the three groups. The types of defects present in this study are shown in Fig 1. Table 1 summarizes the periodontal status for all treatment groups at 1 week before surgery. No statistically significant differences were observed for PI, GI, PPD, CAL, recession, and bone width and crestal bone level of the intrabony defects among

Table 1 Periodontal status 1 week before surgery (mean ± SD)

	Atrisorb	BioMend	Control	*P*
PI	0.60 ± 0.70	0.60 ± 0.52	0.40 ± 0.52	.683
GI	0.30 ± 0.48	0.50 ± 0.53	0.20 ± 0.42	.362
PPD (mm)	6.50 ± 1.90	6.30 ± 1.25	5.40 ± 1.08	.215
CAL (mm)	7.80 ± 2.10	7.80 ± 1.03	7.80 ± 1.40	1.000
Recession (mm)	-1.30 ± 1.89	-1.50 ± 1.78	-2.40 ± 1.08	.288
Defect type				
Two- or three-walled	0	1	4	
Circumferential	10	9	6	
Width of defect (mm)	4.00 ± 1.49	3.90 ± 1.29	3.40 ± 1.17	.561
Depth of defect (mm)	6.00 ± 2.45	6.40 ± 1.43	4.00 ± 1.24	.012*
Crestal bone level (mm)	3.40 ± 1.50	3.60 ± 2.07	5.30 ± 2.00	.061

*Statistically significant ($P < .05$).

Table 2 Clinical measurements at 1 week before and 6 months after surgery (mean ± SD)

	Atrisorb	BioMend	Control
PPD (mm)			
Before surgery	6.50 ± 1.90*	6.30 ± 1.25*	5.40 ± 1.08*
After surgery	4.00 ± 1.76*	3.70 ± 1.50*	3.20 ± 1.03*
Reduction	2.50 ± 1.35	2.60 ± 1.08	2.20 ± 1.14
CAL (mm)			
Before surgery	7.80 ± 2.10*	7.80 ± 1.03*	7.80 ± 1.40*
After surgery	5.40 ± 2.50*	5.20 ± 1.69*	6.00 ± 1.33*
Gain	2.40 ± 1.17	2.60 ± 1.26	1.80 ± 0.92
Recession (mm)			
Before surgery	−1.30 ± 1.89	−1.50 ± 1.78	−2.40 ± 1.08*
After surgery	−1.30 ± 2.41	−1.50 ± 1.72	−2.80 ± 0.92*
Increase	0.00 ± 1.63	0.00 ± 0.67	0.40 ± 0.52

*Statistically significant change ($P < .05$).

the three groups. However, the depth of the intrabony defect was significantly different: 6.00 ± 2.45 mm for the Atrisorb group, 6.40 ± 1.43 mm for the BioMend group, and 4.00 ± 1.24 mm for control group ($P < .05$). Nine barriers became exposed 1 week postoperatively in the Atrisorb group (90%) and three were exposed in the BioMend group (30%).

A statistically significant treatment effect was observed in the three groups in terms of PPD and CAL ($P < .05$; Table 2). No significant difference was detected when the clinical results of the three groups were compared. The level of recession remained the same before and after surgery in the GTR groups but increased slightly in the control group ($P < .05$; Table 2).

Fig 2a (left) *Representative radiograph at 1 week before surgery in the Atrisorb group.*

Fig 2b (right) *Representative radiograph at 6 months after surgery in the Atrisorb group.*

Fig 3a (left) *Representative radiograph at 1 week before surgery in the BioMend group.*

Fig 3b (right) *Representative radiograph at 6 months after surgery in the BioMend group.*

Radiographic differences between measurements at baseline and at 6 months after surgery were observed in all groups (Figs 2 and 3). The amount of bone fill was greater in the BioMend group (2.57 ± 1.64 mm) than in the Atrisorb group (0.33 ± 1.89 mm) and the control group (1.05 ± 0.77 mm) ($P < .05$). However, a similar amount of crestal bone resorption was noted 6 months after surgery in all three groups (0.41 ± 0.95 mm, 0.92 ± 1.54 mm, and 0.70 ± 0.84 mm, respectively).

Discussion

The purpose of this clinical trial was to compare the therapeutic outcomes of GTR using Atrisorb and BioMend. Chen et al[17] have demonstrated that the addition of demineralized freeze-dried bone allografts to BioMend appears to add no further extra benefit versus GTR with BioMend alone. Because a space filler is always used along with the Atrisorb, demineralized freeze-dried bone allografts were used for both GTR groups in the present study. Subjects in both groups achieved significant reductions in PPD and gains in CAL and bone fill.

The polylactic polymer chains in Atrisorb are cleaved by hydrolysis to form monomeric acids and eliminated from the body through the Krebs cycle as carbon dioxide and water. Previous studies[10,12,13,18,19] have shown a 2.2- to 4.7-mm PPD reduction, a 1.7- to 3.7-mm CAL gain, and –0.4 to 0.3 mm of gingival recession. The variation is explicable owing to the inclusion of furcation defects,[19] different bovine bone mineral grafting materials with different observation times,[18] and the presence of Class II furcation defects.[10,12,13]

Collagen membranes have the capacity to partially prevent epithelial apical migration and to support new connective tissue attachment formation when used in periodontal defects in dogs.[5,7] It is believed that the collagen membrane is either incorporated into the healing connective tissues or is degraded by macrophages after 6 to 8 weeks. In sites treated with the collagen membrane, the results for PPD and CAL in the present study are in agreement with a previous study.[20] A comparison of the literature[17,21] on collagen membranes used for the treatment of intrabony defects in humans shows a 2.84- to 3.4-mm PPD reduction and 1.67- to 2.3-mm CAL gain. A deeper defect[17] and different ways of evaluating bone fill (using reentry surgery and a less crosslinked collagen membrane[21]) may have influenced the results.

The results obtained 6 months after surgery showed greater bone fill with the use of BioMend (2.57 ± 1.64 mm) than with Atrisorb (0.33 ± 1.89 mm). The bone fill seen in the BioMend group is in agreement with previous studies.[21,22] In comparison to previous studies, the use of different kinds of collagen membrane[4,20,23] and anorganic bovine bone[23] may have influenced the results. There is a lack of information on bone fill after GTR with Atrisorb in the periodontal literature. Further studies are needed to characterize the healing that takes place within the hard tissues.

In the present study, 90% of the membranes were exposed after GTR treatment with Atrisorb, compared to 30% in the BioMend group. The frequency of exposure of BioMend membranes was lower than that previously reported for collagen membranes.[21,22] The higher incidence of membrane exposure in the Atrisorb group when compared to the BioMend group might be a result of the difficulty controlling thickness as well as the extensiveness of the circumferential lesions. Previous studies have reported exposures of 87%[24] and 63%[25] for GTR-treated interproximal osseous defects using an expanded polytetrafluoroethylene membrane. A negative correlation between membrane exposure and the amount of newly growing tissue noted on membrane removal has been reported previously.[26] Furthermore, the amount of newly growing tissue at the time of membrane removal is not necessarily related to the clinical attachment gain after GTR.[25] However, a significantly greater recession is noted after GTR when membranes are exposed during the process.[25,27–30]

Guided tissue regeneration with Atrisorb or BioMend or a flap operation only all resulted in a similar level of PPD reduction and attachment gain after surgery. GTR tended to result in less recession. Additionally, greater bone fill was obtained when BioMend was used versus Atrisorb or performance of the flap operation only.

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