## Journal of Clinical Periodontology

# Polymer-assisted regeneration therapy with Atrisorb<sup>®</sup> barriers in human periodontal intrabony defects

Hou L-T, Yan J-J, Tsai AY-M, Lao C-S, Lin S-J, Liu C-M: Polymer-assisted regeneration therapy with Atrisorb<sup>®</sup> barriers in human periodontal intrabony defects. J Clin Periodontol 2004; 31: 68–74. © Blackwell Munksgaard, 2004.

#### Abstract

**Aim:** This study compared clinical results of 40 periodontal osseous defects treated by two types of absorbable barrier materials.

Material and Methods: Thirty patients (23 males and seven females) suffering from moderate to advanced periodontitis (with comparable osseous defects) were randomly assigned to receive either Atrisorb<sup>®</sup> barrier (n = 22; group A) or Resolut XT<sup>®</sup> barrier (n = 18; group B) therapy. Periodontal phase I treatment and oral hygiene instruction were performed before periodontal surgery. Papillary preservation, partial thickness flap, citric acid root conditioning, and decortication procedures were applied during the operation. Bone defects were filled with demineralized freeze-dried bone allograft and minocycline mixture (4:1 ratio). Postoperative care included 0.10% chlorhexidine rinse daily and antibiotic medication for 2 weeks. Clinical assessments including probing depth (PD), clinical attachment level (CAL), gingival recession (GR), plaque index (PII), gingival index (GI), and radiographic examinations were taken at the baseline, preoperatively and at 3 and 6 months after regenerative surgery. **Results:** Six months following therapy, both Atrisorb<sup>®</sup> and Resolut XT<sup>®</sup> groups had achieved comparable clinical improvement in pocket reduction (3.9 versus 4.4 mm), attachment tissue gain (clinical attachment gain; 3.5 versus 3.6 mm), and reduction in the GI and in the PII. Within-group comparisons showed significant attachment gain and pocket reduction between baseline data and those at both 3 and 6 months

postoperatively (p < 0.01). There were no statistically significant differences in any measured data between groups A and B.

**Conclusions:** The results of this study indicate that a comparable and favorable regeneration of periodontal defects can be achieved with both  $Atrisorb^{(i)}$  and  $Resolut XT^{(i)}$  barriers. Further long-term study and histologic observations of tissue healing are needed to evaluate whether  $Atrisorb^{(i)}$  is promising for clinical use.

## Lein-Tuan Hou<sup>1</sup>, Ji-Jong Yan<sup>1</sup>, Alex Yi.-Min Tsai<sup>1,2</sup>, Chia.-Shih Lao<sup>1</sup>, Shih.-Jung Lin<sup>1</sup> and Cheing-Meei Liu<sup>1</sup>

<sup>1</sup>Department of Periodontology, Graduate Institute of Clinical Dentistry, National Taiwan University Hospital, National Taiwan University, Taipei, Taiwan; <sup>2</sup>Department of Periodontology and Implant Dentistry, School of Dental Medicine, Harvard University, Boston, MA, USA

Key words: demineralized freeze-dried bone allograft; guided tissue regeneration; periodontal osseous defect; polylactide polymer: root conditioning

Accepted for publication 5 February 2003

The processes of periodontal wound healing after conventional periodontal therapy only provide periodontal repair and usually result in long junctional epithelial attachment and/or connective tissue adhesion instead of new attachment (Takata 1994). In order to achieve true periodontal regeneration, the concept of a membrane barrier, which excludes apical epithelial cell migration of gingiva and provides an isolated osseous defect for ingrowth of the periodontal ligament, osteoblasts, and cementoblasts, was developed. Guided tissue regeneration (GTR) was first introduced in 1982 by Nyman et al. (1982), who successfully used a Millipore membrane to aid in the regeneration of lost periodontal tissues caused by periodontitis. This technique was further defined by Gottlow et al. (1986). Cumulative evidence indicates that periodontal attachment gain was more evident in defects treated with GTR than those treated with a conventional flap and/or conventional flap treatment combined with bone grafts (Blumenthal & Steinberg 1990, Blumenthal 1993, Mattson et al. 1995, Laurell et al. 1998).

Barrier membranes, in the early stages of GTR, such as those made from

Gore-Tex (expanded polytetrafluoroethylene, W. L. Gore and Associates Inc., Flagstaff, AZ, USA) and TefGen (dense-polytetrafluoroethylene, TefGen-GD Inc., Sacramento, CA, USA), belong to the first generation of GTR membranes, which are characterized by being non-absorbable. Second-generation absorbable membranes are believed to be superior to first-generation ones due to the fact that second-stage membrane retrieval can be omitted, and complications of barrier exposure are usually minimal because the exposed barriers are spontaneously absorbed (Gottlow et al. 1993, Caffesse et al. 1994, Wang et al. 1994, Polson et al. 1995a, b, c, Wang & MacNeil 1998). In addition, several studies have shown that compared with non-absorbable GTR membranes, absorbable ones seem to produce better clinical results both in animal and human clinical trials. (Yaffe & Shoshan 1987, Blumenthal & Steinberg 1990, Blumenthal 1993, Caffesse et al. 1994, Mattson et al. 1995, O'Brien et al. 1995, Laurell et al. 1998). Thus, the use of absorbable membranes is currently a popularly selected option for periodontal regeneration.

Atrisorb<sup>®</sup> (DL-lactide polymer, Atrix Laboratories Inc., Ft. Collins, CO, USA). a new absorbable barrier membrane, was introduced in 1996, and has been proposed to achieve a similar periodontal regeneration (Rosen & Reynolds 1999, Jepsen et al. 2000). It is composed of 37% of a liquid polymer of lactic acid that is dissolved in 63% N-methyl-2pyrrolidone (NMP). Atrisorb<sup>®</sup> membranes have been shown to have good tissue response, biocompatibility, and safety in animal studies (Bogle et al. 1997, Coonts et al. 1998). Polson et al. (1995b) demonstrated that application of an Atrisorb<sup>®</sup> membrane to the molars of dogs with Degree II furcation involvement achieved 77% new periodontal regeneration after 1 year. With regard to its application in humans, it was reported that Atrisorb<sup>®</sup> membranes showed good bone filling and clinical attachment gain (CAG) in patients with periodontitis and Degree II furcation involvement (Polson et al. 1995a, c, Garrett et al. 1997, Rosen et al. 1998, Rosen & Reynolds 1999). However, reports of its application in periodontal intrabony defects are limited (Rosen et al. 2000). Furthermore, no comparable clinical studies between Atrisorb<sup>®</sup> barriers and other absorbable membranes used in the treatment of intra-

## Material and Methods Patient population

Thirty patients (23 males and seven females) from the Periodontal Outpatient Clinic of National Taiwan University Hospital were selected. These patients had moderate-to-severe periodontitis, were aged 30-55 years, and had received no periodontal therapies within the previous 6 months. They were randomly assigned to receive either the Atrisorb<sup>®</sup> or the Resolut XT<sup>®</sup> (polylactic and polyglycolic acid copolymer; W. L. Gore and Associates Inc.) barriers for GTR procedures. There were 40 intrabony defects with two to three bony walls ± Degree II furca involvement; 22 defect sites were in the Atrisorb<sup>®</sup> group (group A), and 18 sites in the Resolut XT<sup>®</sup> group (group B). The unequal number of defects was caused by the fact that six and four patients had two similar osseous defects in the Atrisorb<sup>®</sup> and Resolut XT<sup>®</sup> groups, respectively. There were no three or greater number of osseous defects present in our treated patients. All patients were free of smoking habits, diabetes mellitus, hypertension, heart diseases, and other systemic diseases. Before periodontal treatments, all patients were scheduled for oral hygiene care training, including video instruction in the Bass toothbrushing method (Bass 1954), flossing, and interdental brushing technique. All patients then received phase I periodontal therapy including scaling/ root planing, correction of defective restorations or carious lesions, and institution of a plaque control regime (hygienic phase) before and after periodontal surgery. After phase I therapy, only patients with a plaque control record  $\leq 15\%$  (O'leary score) and teeth that met the predetermined criteria (described later) were accepted for periodontal regeneration surgery.

#### Criteria of tooth selection

All studied teeth had to be vital with no endodontic problems like root resorp-

tion, apical periodontitis, or periapical cyst. They had to have at least 1 mm of keratinized gingival width (KGW) surrounding the tooth. After phase I periodontal treatment, the tooth was treated with occlusal adjustment if signs and symptoms of occlusal trauma were noted. Teeth to be included in the regenerative therapy had to have mobility of no greater than grade II according to Miller's classification (Miller 1943). Teeth, indeed, with grade II mobility received temporal splinting and occlusal adjustment before surgery. Third molars were excluded from this study. Premolars and molars were not to have Degree III furcation involvement according to Lindhe et al.'s classification (Nyman & Lindhe 1983). Teeth with probing depth (PD)  $\geq 5 \,\text{mm}$  and signs of intrabony resorption radiographically, and a depth of intrabony defect  $\geq 3 \text{ mm}$  with the remaining two to three walls detected during flap operation were included in this study. Teeth with either circumferential osseous defects or Degree II furca involvement fitting the criteria mentioned above were also included. There were only one to two narrow circumferential osseous defects (2-3 mm wide and  $\geq 3 \text{ mm}$  in depth at the orifice of defects) present at the premolar areas in both treatment groups. Finally, three Degree II furcation involvements were found in the Atrisorb<sup>®</sup> group and two similar lesions were noted in the Resolut XT<sup>®</sup> group.

## **Clinical measurements**

A Hu-Friedy periodontal probe (University of Michigan with William's marking) was used for measuring the periodontal PD, gingival recession (GR), and clinical attachment level (CAL). Six sites were measured per tooth, namely the mesial, middle, and distal sides of the facial and lingual (palatal) aspects. KGW was also measured in millimeters. In addition, the plaque index (PII, Silness & Loe 1964) and gingival index (GI, Loe & Silness 1963) were recorded. All clinical parameters were recorded before and after phase I treatment, and again at 3 and 6 months postoperatively. Although six sites were measured for PD, CAL, and GR, only tooth sites selected for GTR were included for analysis. The analysis involved one PD, two CAL, and one GR score per site. PII and GI data were derived from the average of the clinical recordings of the tooth selected for surgical treatment.

#### Periodontal surgery and postoperative care

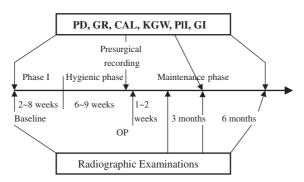
The GTR membranes used in the periodontal surgery were randomly assigned to be the Atrisorb<sup>®</sup> (group A) or Resolut XT<sup>®</sup> (group B) groups. All examinations including periodontal recording, periodontal surgery, postoperative care, and follow-up observations were performed by the same periodontist. The two groups were treated in the same way, using saturated citric acid for root conditioning and applying a demineralized freeze-dried bone allograft (DFDBA) into the osseous defect. An intracrevicular incision was used together with the papillary preservation technique. A vertical incision was made at least one tooth away from the tooth to be treated in order to release the tension of the flap and to achieve primary closure of the wound. After root planing, root conditioning of the diseased tooth surfaces was routinely performed by applying saturated citric acid (pH 1) for 3 min to enhance colonization of fibroblasts on root surfaces during the healing phase (Ririe et al. 1980, Daly 1982, Polson et al. 1984). After debridement of the bony defects, penetration of the osseous defect walls was made to promote the in-growth of osteoblasts into the osseous defect (Schallhorn & McClain 1988; Rosen & Reynolds 1999). DFDBA was soaked in normal saline solution, dried, and then mixed with Minocin<sup>®</sup> (Lederle Pharmaceutical, Pear River, NY, USA) (Minocycline HCl) in the proportion of 4:1. This mixture was then placed and condensed into debrided osseous defects and was covered with an Atrisorb<sup>®</sup> barrier using an in situ method. In the Resolut XT<sup>®</sup>treated group, flaps and osseous defects were similarly prepared before the placement of DFDBA and the barrier

membrane. However, a sling suture was used to stabilize the Resolut XT<sup>®</sup> membrane. In both treatment groups, the GTR barriers extended 3 mm beyond the margin of the osseous defects and were ultimately covered by flap. The vertical mat-tress suture method was used to obtain primary closure of the wound (Hallmon 1996, Tseng et al. 1997, Huang et al. 1999). The surgical site was dressed with a periodontal pack for 1–3 weeks.

After GTR surgery, daily 200 mg Minocin<sup>®</sup> was prescribed for 2 weeks, and patients were instructed to rinse their mouths with 0.1% chlorhexidine for 6–8 weeks. Brushing and flossing were prohibited, at least, at surgical sites for 8 weeks. Postoperative examinations were performed weekly in the first month, and biweekly in the second and third months. After 3 months, patients were recalled every 2–3 months for periodontal maintenance care. The time schedules for recording various clinical examinations and treatments are listed in Fig. 1.

#### Statistical analysis

The means and standard deviations of PD, CAL, and GR at the baseline and at various periods after periodontal treatment were calculated. Analysis of variance (ANOVA) was used to analyze measurements of clinical parameters including PD, CAL, and GR. Withingroup comparisons of these data were analyzed by paired t-tests, and t-tests were used in the comparison between groups. Non-parametric data such as GI and PII were analyzed using the Wilcoxon matched-pairs signed-rank test. The percentage of membrane exposure was compared and analyzed by  $\chi^2$  and tested by z-test.



*Fig. 1.* Time course of various recordings and treatments in the present study. PD = probing depth; GR = gingival recession; GI = gingival index; PII = plaque index; CAL = clinical attachment level; KGW = keratinized gingival width; OP = operation.

#### Results

#### GI and PII indices

The results showed significant improvements in the clinical periodontal indices for both treatment groups (Table 1). When comparing the baseline with either the end of phase I to the 3- or 6-month postoperative GI, the Atrisorb<sup>®</sup> barrier group showed  $0.3 \pm 0.5$ ,  $1.3 \pm 0.6$ , and  $1.7\pm0.5$  reductions, while the Resolut XT<sup>®</sup> group displayed  $0.4 \pm 0.5$ , 1.3+0.6, and 1.6+0.7 reductions, respectively. Similarly, with regard to the reduction in PII at the end of phase I, and at 3 and 6 months postoperatively, the Atrisorb<sup>®</sup> group achieved  $0.8\pm0.6$ ,  $1.2\pm0.7$ , and  $1.4\pm0.7$ , while the Resolut  $XT^{\mathbb{R}}$  group achieved  $0.8 \pm 0.7$ ,  $1.0\pm0.6$ , and  $1.1\pm0.7$ , respectively. Although there was a tendency for a gradual reduction in GI and PII preoperatively (after phase I therapy) and at 3 and 6 months postoperatively, changes for both the GI and PlI in each group were statistically significant with respect to the observation periods (Table 1). As to changes of GR relative to the baseline data, both the Atrisorb® and Resolut XT<sup>®</sup> groups showed a small, comparable increase (0.3-0.8 mm) at 3 and 6 months after surgery. Meanwhile, both groups also exhibited a slight reduction in the KGW within the course of the observation (data not shown).

#### Changes in CAL and PD

Both treatment modalities demonstrated significant improvements in CAL and PD chronologically (Table 2). When the PD at 3 and 6 months postoperatively were compared with those after phase I treatment, the Atrisorb<sup>®</sup> group had mean pocket reductions of  $3.4 \pm 1.7$ and  $3.9 \pm 1.8$  mm, while those of the Resolut XT<sup>®</sup> group had decreased by  $4.3 \pm 1.6$  and  $4.4 \pm 1.4$  mm, respectively. Similar changes were noted in mean CAL. Improvements in CAL of  $2.9 \pm 1.6$  and  $3.5 \pm 1.6$  mm were found in the Atrisorb<sup>®</sup> group, while those of  $3.6\pm2.0$  and  $3.6\pm2.2$  mm were noted in the Resolut XT<sup>®</sup> group, respectively (Table 2). Generally, within-group comparisons for both treatment modalities showed statistical significance with regard to changes in PD and CAL among the baseline, preoperative, and 3 and 6 months after surgery. There was a marked reduction in PD and improvement in CAL during the observation periods (Table 2). However, there were

Table 1. Comparisons of clinical parameters (PII, GI, and GR) among different time points of both treatment groups	clinical paramete	ers (Pll, Gl,	and GR) amonį	g different tim	e points of bot	n treatment gro	sdn					
		IId	п			GI	I			GR	R	
	baseline	Ι	3m	6m	baseline	Ι	3m	6m	baseline	Ι	3m	6m
Resolut XT <sup>®</sup> , $N = 18$ mean diff. p-value Atrisorb <sup>®</sup> , $N = 22$ mean diff. p-value	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{c} 0.3\pm0.7\\ 1\pm0.7\\ 0.001\\ 0.0\pm0.0\\ \pm4\pm0.7\\ <0.001 \end{array}$	$2.3 \pm 0.5 -0.4; -0.4; p = 0$ $2.2 \pm 0.4; -0.3; -0.3; p = 0.4; p = 0.6; -0.3;$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{ccc} 0.6 \pm 0.6 \\ 0.6 & -1.6 \pm \\ 0.1 & p < 0. \\ 0.6 \pm 0.6 \\ -1.7 \\ 0.1 & p < 0. \end{array}$	$\begin{array}{c} 0.4\pm 0.7\\ \pm 0.7\\ 001\\ 0.2\pm 0.4\\ \pm 0.5\\ 001 \end{array}$	$1.4 \pm 1.1 \\ 0.6 \pm 0.6 \pm 0.6 \pm 0.19 \pm 14 \\ 1.9 \pm 14 \\ 0.5 \pm 0.5 \pm$	$\begin{array}{ccc} 2.0 \pm 1.2 \\ \pm 0.7 & 0.7 \pm \\ 0.002 & p = \\ 2.4 \pm 1.8 \\ \pm 0.9 & 0.5 \pm \\ 0.07 & p = 0 \end{array}$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	2.8±1.3 ±1.1 .005 2.7±2.1 ±1.0 .148
• • • • • • • • • • • • • • • • • • • •				•			•••••••••••••••••••••••••••••••••••••••		•	:	· · · · · · · · · · · · · · · · · · ·	

I = after phase I, 3m = 3 months, 6m = 6 months; data are expressed as mean  $\pm$  standard deviation. Mean change differences are calculated between each two time points: baseline - I, I - 3 m and I - 6 m; statistically significant difference of all parameters within group (p < 0.01) and not between groups (p > 0.01). Pll: plaque index; Gl: gingival index; GR: gingival recession.

Table 2. Comparisons of clinical parameters (PD and CAL) among different observation periods of both treatment groups

			PD			0	CAL	
	baseline	I	3m	6m	baseline	I	3m	6m
Resolut XT <sup>®</sup> $(N = 18)$ mean diff.	8.1±1.2 -0	$7.2 \pm 1.3$ - 0.9 ± 1.0	$2.9\pm1.1$ - 4.3 ± 1.6	$-4.4\pm1.4$ 2.8±0.5	$9.5 \pm 1.8$ $-0.3 \pm 1.0$ n = 0.336	<b>9.2</b> ±2.0	$5.6\pm1.7$ $-3.6\pm2.0$ $-3.6$	$5.6\pm1.4$ $-3.6\pm2.2$
Atrisorb ( $N = 22$ ) mean diff. <i>p</i> -value	$8.4\pm 1.4$ -1 -1 -1 -1	$6.9 \pm 1.8$	p < 0.001 - 3.4 ± 1.7 p < 0.001		$10.2 \pm 2.1 \\ -0.9 \pm 1.6 \\ p = 0.013$	<b>9.3</b> ±2.3	$6.4 \pm 2.6$	p < 0.001 5.8±2.5 - 3.5±1.6 p < 0.001
I = after phase I, $3m = 3$ months, $6m = 6$ months; data are expressed as mean $\pm$ standard deviation; significant difference of all parameters at $p < 0.01$ . Mean change differences are calculated between each	is, $6m = 6$ months; $6m = 6$	data are expressed :	as mean $\pm$ standard c	leviation; significant differenc	e of all parameters at $p < 0.0$	)1. Mean change	differences are calculat	ed between each

not between groups (p > 0.01); PD (mm): probing depth; CAL: clinical 6m. Statistically significant difference of all parameters within group (p < 0.01) and two time points: baseline -I, I - 3m and I attachment level

significant differences observed no among the between-group comparisons.

The percent contributions of clinical attachment changes in the Atrisorb<sup>®</sup> and Resolut XT® groups are shown in Table 3. In the Atrisorb<sup>®</sup> group, more than 72% and 90% treated sites had a CAG of  $\ge 2 \text{ mm}$  at 3 and 6 months after surgery, respectively. Comparable CAG was also obtainable in the Resolut XT® group for the same periods. The percentages of CAG of  $\geq 4 \text{ mm} (40-55\%)$ were similar in both treatment groups for the 3- and 6-month periods.

#### Early membrane exposure and CAG

The rate of early membrane exposure was lower in the Atrisorb<sup>®</sup> group (23%)than in the Resolut XT<sup>®</sup> group (39%) in the present study (Table 4). Comparisons of membrane exposure rate between groups were not statistically significant (p = 0.279). CAG in sites with membrane exposure in the Atrisorb<sup>®</sup> group was  $4.0 \pm 1.6$  mm, while it was  $4.7 \pm 2.0$  mm in the Resolut XT<sup>®</sup> group. The effect of early membrane exposure on the results of CAG was also not statistically significant according to both within-group (p = 0.465) and between-group (p = 0.413) comparisons (Table 4).

### Discussion

This study evaluated the application of a new-generation GTR material, Atrisorb<sup>®</sup>, for the treatment of human periodontal intrabony defects. The 6-month results showed an obvious reduction in probing pocket depth and an increment in CAG at treated sites. There were also overt decreases of GI and PII indices in the Atrisorb<sup>®</sup> group during the observation periods of this study. Improvements in these clinical parameters were comparable to those obtained with the use of the Resolut  $XT^{\mathbb{R}}$ .

It has been demonstrated that Resolut XT<sup>®</sup> membranes show good clinical results in the treatment of intrabony defects of periodontitis. In a recent report (Cortellini et al. 1996), it was demonstrated that the GTR procedure, regardless of using absorbable or non-absorbable membranes, resulted in better clinical results 12 months postoperatively when compared with the flap control group. Similar findings were reported by Becker et al. (1996) in the treatment of 30 teeth with

Clinical attach. (CA)	At	risorb <sup>®</sup> group $(n = 2)$	22)	Resolut $XT^{\textcircled{R}}$ group $(n = 18)$		
	baseline – I	I - 3m	I-6m	baseline – I	I - 3m	I-6m
Loss (mm)						
≥4	1 (4.6%)	0 (0%)	0	0	0	0
2-3.99	0 (0%)	0	0	0	0	1 (5.6%)
1-1.99	1 (4.6%)	0	0	2 (11.1%)	0	0
>0-0.99	0 (0%)	0	0	0	0	0
0	0	5 (22.7%)	0	0	12 (66 %)	1 (1.6 %)
Gain (mm)						
>0-0.99	0	0	0	0	0	0
1-1.99	8 (36.4%)	6 (27.3%)	2 (9.1%)	2 (11.1%)	0	2 (11.1%)
2-3.99	6 (27.3%)	7 (31.8%)	9 (40.9%)	2 (11.1%)	9 (50.0%)	5 (27.8%)
≥4	1 (4.6%)	9 (40.9%)	11 (50.0%)	0	8 (44.4%)	10 (55.6%)
Loss≥2 mm	1 (4.5%)	0	0	0	0	1 (5.6%)
Gain≥2 mm	7 (31.8%)	16 (72.7%)	20 (90.9%)	2 (11.1%)	17 (94.4%)	15 (83.3%)

Table 3. Numbers of sites and percent distribution of clinical attachment changes in both treatment modalities during various observation periods

I = after phase I; 3m = 3 months, 6m = 6 months; baseline -I = CA level after phase I treatment; I-3m or I-6m = CA levels at 3 or 6 months after GTR surgery compared with those after phase I treatment. Data are results expressed as defect-site numbers and percentage of CA changes at indicated ranges in both Atrisorb<sup>®</sup>- and Resolut XT<sup>®</sup>-treated groups.

Table 4. Effects of early membrane exposure on the results of clinical attachment gain

	ŀ	Atrisorb <sup>®</sup> $(n = 22)$			Resolut	$\mathrm{XT}^{\mathbb{R}}$ ( <i>n</i> = 18)	
		within-group			within-group		between-group*
	non-exp.	exp.	<i>p</i> -value	non-exp	exp.	<i>p</i> -value	<i>p</i> -value
number CAG	17 (77%) 3.4±1.5	5 (23%) 4.0±1.6	0.465	11 (61%) 2.9±2.1	7 (39%) 4.7 ± 2.0	0.09	0.279 0.413

Data are expressed as mean  $\pm$  standard deviation. Exp.: membrane exposure; CAG: clinical attachment gain; (·): percentage of membrane exposure. Comparison of membrane exposure rate between groups is not statistically significant (p = 0.279). Similar result is found in the comparison of CAG within membrane exposure category (p = 0.413).

\*Indicates comparison between group within membrane exposure category.

intrabony defects using Resolut XT<sup>®</sup> membranes. In the present study, our data indicate that applications of both Resolut XT<sup>®</sup> and Atrisorb<sup>®</sup> resulted in similar clinical improvements with regard to changes in PD and CAL throughout the 6-month observation period. Radiographic examinations also showed a comparable amount of bone filling for both treatment modalities.

There have only been a few reports about the application of Atrisorb<sup>®</sup> membranes for the treatment of human intrabony periodontal osseous defects (Rosen & Reynolds 1999), although pilot and multicenter studies of class II furcation lesions indicated favorable outcomes (Polson et al. 1995a, b, c). The results of our Atrisorb<sup>®</sup> application for human intrabony defects displayed a good reduction in PDs and favorable CAG  $(2.9 \pm 1.6 \text{ and } 3.5 \pm 1.6 \text{ mm}, \text{ re-}$ spectively). The amount of improvement in PD and CAL of the present study reached those of a recent report using Resolut XT<sup>®</sup> membranes (Becker et al. 1996). Recent application of Atrisorb<sup>®</sup> in buccal dehiscence and

fenestration defects in dental implants was reported to produce good results in both animals and human beings (Jepsen et al. 2000, Pereira et al. 2000). Although there are few reports in the literature, this limited evidence suggests that Atrisorb<sup>®</sup> is a valuable material suitable for use in GTR or GBR procedures. In addition, the present study also illustrates an equivalent CAG in the Atrisorb<sup>®</sup>- compared with the Resolut XT<sup>®</sup>-treated group.

Attempting to regenerate the periodontal tissues lost during periodontal disease by the GTR procedure is the prevailing technique in clinical practice over the last two decades (Nyman et al. 1982, Gottlow et al. 1993, Laurell et al. 1998). Favorable clinical and histologic results have been documented (Stahl et al. 1990, Cortellini et al. 1993, Garrett et al. 1997). However, the efficacy of GTR in the treatment of periodontal infrabony defects measured against open flap debridement (OPD) has been questioned. This report disclosed that the mean difference between test (GTR) and control (OPD) was only 1.1 mm, while that of GTR+bone substitutes was 1.25 mm. The benefit of inclusion of DFDBA in GTR procedures is still controversial in literature. Although good CAG in both groups was obtained at 6 months in the present study, one can only speculate as to what portion of regeneration was contributed either by GTR membrane or DFDBA, since there was no non-membrane group (OPD) and no membrane-only group as a basis of comparison. Also, limited data and sample size in our current study did not provide evidence to confirm that the interaction of membranes and DFDBA was the same for Atrisorb<sup>®</sup> and Resolut XT<sup>®</sup> membranes. Further long-term and histologic studies including a larger sample population of split-mouth design, and comparisons between OPD and membrane-only groups are still necessary to evaluate these issues and the nature of the healing processes in both treatment modalities.

Random assignment of either treatment to the patients in this study resulted in an unequal number of sites being assigned to each treatment group. This was due to the fact that some patients in both treatment groups had two defects. The unequal number of defects was caused by the fact that six and four patients had two similar osseous defects in the Atrisorb® and Resolut XT<sup>®</sup> groups, respectively. There were no three or greater number of bony defects in any patients of both treatment groups. Another reason for this was that some osseous defects did not fit the criteria of either defect depth  $\geq$  3 mm or two- to three-wall defects observed during surgery, and were thus excluded from the study. Owing to the inclusion of some non-independent treated sites (for example, two intrabony defects within patients), a stringent choice of 0.01 as a significance level was thus made to increase the statistical confidence level.

The rationale for including occlusal adjustment and/or temporary splinting in this study was that some treated teeth were associated with occlusal interferences, while others showed excessive tooth mobility ( $\leq$  grade II) based on the criteria of Millers classification. Teeth might also shift in position after splinting, and thus, occlusal adjustment was necessary to prevent excessive stress or loading on the treated teeth for patient comfort. In the present study, only a few teeth, two in the Atrisorb® and one in the Resolut XT<sup>®</sup> group, had grade II tooth mobility and thus received splinting/occlusal adjustment. Owing to the small number with this condition in both groups, they were not specially considered in statistical analysis.

The membrane exposure rate of Atrisorb<sup>®</sup> in situ in the present study was still a common phenomenon (23%) when compared with that of early application (Polson et al. 1995a, b). The exposure rates when using Atrisorb<sup>®</sup> (in situ) were lower than those of Resolut-XT<sup>®</sup> membranes (23%) versus 39%). However, this difference was not statistically significant. Membrane exposure rates of Resolut XT<sup>®</sup> application in this study were comparable to the data of recent studies (Becker et al. 1996, Cortellini et al. 1996). It is interesting to note that early membrane exposure of both barriers did not seem to affect the outcome of CAG in this study. Similar observations were also found in studies by Becker et al. (1996) and Caffesse et al. (1997). The reasons for this conflict need to be further investigated.

With respect to the malleability of using Atrisorb<sup>®</sup> in situ, we found that it was critical to control the delivered volume and flow initially, which might cause membrane folding and overspreading, resulting in an uneven thickness of membranes. Thick Atrisorb® membrane application could create flap tension, which might then jeopardize the initial wound healing of the flap and result in membrane exposure. In order to obtain an even-thickness barrier when using Atrisorb<sup>®</sup> in situ, the following precautions should be followed: (1) Before applying the Atrisorb<sup>®</sup> liquid, the operator must ensure a hemostatic surgical site, and must isolate the site from saliva contact. (2) The position of the patient's head should be properly adjusted so that the orifice of the osseous defect is horizontally positioned to prevent the overflow of Atrisorb<sup>®</sup> liquid. (3) Atrisorb liquid must be applied in small increments each time and gradually polymerized by an evenwater aerosol spray. When one is familiar with the techniques of handling Atrisorb<sup>®</sup> in situ, the use of this material can result in an easy and time-saving GTR procedure.

## Conclusions

In our 6-month study comparing Atrisorb<sup>®</sup> with Resolut XT<sup>®</sup> membranes in treating periodontal intrabony osseous defects in situ, Atrisorb<sup>®</sup> demonstrated comparable and effective results with regard to CAG and reduction in PD. Atrisorb<sup>®</sup> also showed a tendency for lower GI and less GR than did Resolut XT<sup>®</sup>. These data indicate that Atrisorb<sup>®</sup>, a new bio-absorbable GTR barrier, is a suitable material for clinical use in GTR. However, its advantages and long-term effectiveness need to be further investigated.

## Acknowledgments

This study was supported by National Science Council of the Taiwan under Grants NSC-90-2314-B-002-346 and NTUH-91A04.

#### References

- Bass, C. C. (1954) An effective method of personal oral hygiene. Part II. Journal of the Louisiana State Medical Society 106, 100–105.
- Becker, W., Becker, B. E., Mellonig, J., Caffesse, R. G., Warrer, K., Caton, J. G. &

- Blumenthal, N. M. (1993) A clinical comparison of collagen membranes with e-PTFE membranes in the treatment of human mandibular buccal class II furcation defects. *Journal of Periodontology* 64, 925–933.
- Blumenthal, N. M. & Steinberg, J. (1990) The use of collagen membrane barriers in conjunction with combined demineralized bone– collagen gel implants in human intrabony defects. *Journal of Periodontology* 61, 319–327.
- Bogle, G., Garrett, S., Stoller, N. H., Swanbom, D. D., Fulfs, J. C., Rodgers, P. W., Whitman, S. L., Dunn, R. L., Southard, G. L. & Polson, A. M. (1997) Periodontal regeneration in naturally occurring class II furcation defects in beagle dogs after guided tissue regeneration with bioabsorbable barriers. *Journal of Periodontology* 68, 536–544.
- Caffesse, R. G., Mota, L. F., Quinones, C. R. & Morrison, E. C. (1997) Clinical comparison of resorbable and non-resorbable barriers for quided tissue regeneration. *Journal of Clinical Periodontology* 24, 747–752.
- Caffesse, R. G., Nasjleti, C. E., Morrison, E. C. & Sanchez, R. (1994) Guided tissue regeneration: comparison of bioabsorbable membranes. Histological and histometric study in dogs. *Journal of Periodontology* 65, 583–591.
- Coonts, B. A., Whitman, S. L., O'Donnell, M., Polson, A. M., Bogle, G., Garrett, S., Swanbom, D. D., Fulfs, J. C., Rodgers, P. W., Southard, G. L. & Dunn, R. L. (1998) Biodegradation and biocompatibility of a guided tissue regeneration barriers formed from a liquid polymer material. *Journal of Biomedical Material Research* 42, 303–311.
- Cortellini, P., Clauser, C. & Pini Prato, G. (1993) Histologic assessment of new attachment following the treatment of a human buccal recession by means of a guided tissue regeneration procedure. *Journal of Periodontology* 64, 387–391.
- Cortellini, P., Pini Prato, G. & Tonetti, M. S. (1996) Periodontal regeneration of human intrabony defects with bioresorbable membranes. *Journal of Periodontology* 67, 217–223.
- Daly, C. G. (1982) Antibacterial effect of citric acid treatment of periodontally diseased root surface in vitro. *Journal of Clinical Periodontology* 9, 386–392.
- Garrett, S., Polson, A. P. & Stoller, N. H. (1997) Comparison of a bioabsorbable guided tissue regeneration barrier to a non-absorbable barrier in treating human class II furcation defects. A multi-center parallel design randomized single-blind trial. *Journal of Periodontology* 68, 667–675.
- Gottlow, J., Nyman, S., Lindhe, J., Karring, T. & Wennstrom, J. (1986) New attachment formation in the human periodontium by guided tissue regeneration. Case reports.

Journal of Clinical Periodontology 13, 604–616.

- Gottlow, J., Laurell, L. & Rylander, H. (1993) Treatment of intrabony defects in monkeys with bioresorbable and nonresorbable GTR devices. *Journal of Dental Research* 72, 206–210.
- Hallmon, W. W. (1996) Section 12: Suture materials and methods. Periodontal literature reviews, pp. 194–196.
- Huang, K. C., Tseng, C. C., Tsai, C. C. & Chou, T. H. (1999) The application of mattress suture on regeneration surgery: technique and case report. *Chinese Journal of Periodontol*ogy 4, 73–78.
- Jepsen, S., Heinz, B., Kermanie, M. A. & Jepsen, K. (2000) Evaluation of a new bioabsorbable barrier for recession therapy: a feasibility study. *Journal of Periodontology* 71, 1433–1440.
- Laurell, L., Gottlow, J., Zybutz, M. & Persson, R. (1998) Treatment of intrabony defects by different surgical procedures. A literature review. *Journal of Periodontology* 69, 303–313.
- Löe, H. & Silness, J. (1963) Periodontal disease in pregnancy. Acta Odontologica Scandinavica 21, 533–536.
- Mattson, J. S., McLey, L. L. & Jabro, M. H. (1995) Treatment of intrabony defects with collagen membrane barriers: case reports. *Journal of Periodontal Research* 66, 635–642.
- Miller, S. C. (1943) *Textbook of periodontia*, p. 103. Philadelphia: Blankiston.
- Nyman, S. & Lindhe, J. (1983) Examination of patient with periodontal disease. In: *Textbook* of clinical periodontology, ed. Lindhe, J., pp. 298–308. Copenhagen: Munksgaard.
- Nyman, S., Lindhe, J., Karring, T. & Rylander, H. (1982) New attachment following surgical treatment of human periodontal disease. *Journal of Clinical Periodontology* 9, 290–296.
- O'Brien, W. D., Mishkin, D. J. & Engler, W. O. (1993) Guided tissue regeneration using a biodegradable barrier membrane for new attachment: A clinical, histologic, and histometric study in dogs. *International Journal of Periodontics and Restorative Dentistry* 15, 447–452.

- Pereira, S. L., Sallum, A. W., Casati, M. Z. & Caffesse, R. G. (2000) Comparison of bioabsorbable and non-resorbable membranes in the treatment of dehiscence-type defects. A histomophymetric study in dogs. *Journal of Periodontology* **71**, 1306–1314.
- Polson, A. M., Frederick, G. T., Ladenheim, S. & Hanes, P. J. (1984) The production of a root surface smear layer by instrumentation and its removal by citric acid. *Journal of Periodontology* 55, 443–446.
- Polson, A. M., Garrett, S. & Stoller, N. H. (1995a) Guided tissue regeneration in human furcation defects after using biodegradable barrier: a multicenter feasibility study. *Journal of Periodontology* **66**, 377–385.
- Polson, A. M., Southard, G. L. & Dunn, R. L. (1995b) Periodontal healing after guided tissue regeneration with Atrisorb barriers in beagle dogs. *International Journal of Periodontics and Restorative Dentistry* 15, 575–589.
- Polson, A. M., Southard, G. L., Dunn, R. L., Polson, A. P., Billen, J. R. & Laster, L. L. (1995c) Initial study of guided tissue regeneration in class II furcation defects after use of a biodegradable barrier. *International Journal of Periodontics and Restorative Dentistry* 68, 982–989.
- Ririe, C. M., Crigger, M. & Selvig, K. A. (1980) Healing of periodontal connective tissues following surgical wounding and application of citric acid in dogs. *Journal of Periodontal Research* 15, 314–327.
- Rosen, P. S. & Reynolds, M. A. (1999) Polymer-assisted regenerative therapy: case reports of 22 consecutively treated periodontal defects with a novel combined surgical approach. *Journal of Periodontology* **70**, 554–561.
- Rosen, P. S., Reynolds, M. A. & Bowers, G. M. (1998) A technique report on the in situ application of Atrisorb as a barrier for combination therapy. *International Journal* of Periodontics and Restorative Dentistry 18, 249–255.
- Rosen, P. S., Reynolds, M. A. & Bowers, G. M. (2000) The treatment of intrabony defects with bone grafts. *Periodontology 2000* 22, 88–103.

- Schallhorn, R. G. & McClain, P. (1988) Combined osseous composite grafting, root conditioning and guided tissue regeneration. *International Journal of Periodontics and Restorative Dentistry* 8, 8–31.
- Silness, P. & Löe, H. (1964) Periodontal disease in pregnancy. Acta Odontologica Scandinavica 22, 121–126.
- Stahl, S. S., Froum, S. & Tarnow, D. (1990) Human histologic responses to guided tissue regeneration techniques in intrabony lesions. Case reports on 9 sites. *Journal of Clinical Periodontology* 17, 191–198.
- Takata, T. (1994) Oral wound healing concepts in periodontology. *Current Opinion in Periodontology*, 2nd edition, pp. 119–127. Philadelphia: Current Science.
- Tseng, C. C., Yang, Y. C. & Hang, C. C. (1997) Management and prevention of early exposed membrane during guided tissue regeneration procedure. *Chinese Journal of Periodotology* 2, 225–231.
- Wang, H. L. & MacNeil, R. L. (1998) Guided tissue regeneration: absorbable barriers. *Dental Clinics of North America* 42, 505– 522.
- Wang, H. L., O'Neal, R. B., Thomas, C. L., Shyr, Y. & MacNeil, R. L. (1994) Evaluation of an absorbable collagen membrane in treating class II furcation defects. *Journal* of *Periodontology* 65, 1029–1036.
- Yaffe, A. & Shoshan, S. (1987) Re-attachment of periodontal ligament by collagen in experimentally-induced alveolar bone dehiscence in dogs. *Archives Oral Biology* 32, 69–76.

Address: Cheing-Meei Liu Department of Periodontology School of Dentistry College of Medicine National Taiwan University and NTU Hospital No. 1 Chang-Te Street Taipei 100 Taiwan Fax: +886 (2) 2383 1346 E-mail: Ithou@ha.mc.ntu.edu.tw This document is a scanned copy of a printed document. No warranty is given about the accuracy of the copy. Users should refer to the original published version of the material.