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Periodontal healing in intrabony defects treated with demineralized freeze-dried bone allografts in conjunction with ePTFE membranes*

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I. INTRODUCTION

One goal of periodontal therapy is regeneration of periodontal tissues lost due to periodontal diseases. Various studies have shown that new attachment could be achieved by excluding gingival epithelium and connective tissue and allowing cells from periodontal ligaments to populate the wound during healing[1~6]. This principle has been termed guided tissue regeneration(GTR). A number of studies, however, have suggested that guided tissue regeneration procedures without bone grafting would result in new cementum formation and connective tissue attachment but no new bone formation.

Clinical studies using decalcified freeze-dried bone allografts(DFDBA) have shown marked attachment gain and new bone formation. Histologic observations by Bowers et al.[7, 8] have suggested that DFDBA could induce new connective tissue attachment and new bone formation. It may be speculated that by combining the use of DFDBA and barrier membranes could enhance the predictability of therapeutic outcomes as well as the amount of new bone formation. Various studies have been conducted based on these premises.

Schallhorn & McClain[9] have reported promising clinical results for the combined use of GTR and various bone graft materials compared to the procedures without bone grafting.

Combined use of ePTFE and porous hydroxyapatite in furcation defects have shown greater bone formation compared to the therapy with ePTFE alone[10]. Combined use of DFDBA and ePTFE in furcation defects and intrabony defects have also shown good clinical results, while a study done on class II furcation defects has found no significant difference between the combined therapy and the bone grafting alone [11~13].

Various methods to assess bone regeneration in periodontal defects have been suggested,

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including radiographic evaluations, re-entry operations and histologic observations, but clinical applications of these methods have been difficult. In this study, probing bone level assessment method has been used to evaluate bone regeneration 6 months after the combined therapy of DFDBA and ePTFE barrier membranes in human intrabony defects.

II. MATERIALS AND METHODS

A. Subject Selection

Thirty six intrabony defects from 36 patients, 17 males and 19 females, ranging in age from 27 to 55(mean of 40.9±8.1), who had been diagnosed as having chronic periodontitis were selected after informed consent.

Criteria for the selection of the subjects include no history of systemic disease, and no drug therapies in the last 12 months. After the patients had received oral hygiene instruction and root planing, those defects that displayed more than 6mm of probing depths, and more than 4mm of probing bone level with plaque index score of 0, had been selected. Twelve defects(one defect per one person) received periodontal flap surgery alone as the control(GFS), 12 defects received ePTFE membranes, and 12 defects received ePTFE membrane and demineralized freeze-dried bone allografts(GTR+DFDBA).

B. Surgical Treatments and Maintenances

After anesthesia, sulcular incisions were given and full thickness flaps were raised. Removal of granulation tissue was followed by root planing, and the flaps were sutured. For those defects with ePTFE membranes*, a close adaptation of the membranes 3mm apically over the edge of the defects were checked. For those defects with the membranes and DFDBA, the allografts were positioned to fill the defects first and the membranes were positioned and sutured in place. No perioodntal dressings were given. The patients were instructed to avoid mechanical oral hygiene measures for 6 weeks, and rinse with 0.5% chlorhexidine[@] three times daily. Tetracycline HCl 250mg q.i.d. for 7 days were prescribed. Sutures were removed after 3 weeks. The barrier membranes were removed 5 weeks postsurgery. All subjects received oral hygiene procedures at 3, 4 and 5 weeks postsurgery.

C. Clinical Recordings

Recordings for probing depths, attachment level, gingival recession, and probing bone level were made after initial oral hygiene instructions, and scaling was performed. At 3 weeks, 5 weeks and 3 months postsurgery, plaque index, gingival index and gingival recession were assessed. At 6 months postsurgery, all of the clinical recordings from

*Gore-Tex Periodontal Material, WL Gore & Associates, Inc., Flagstaff, AZ.
[@] Dembone, Pacific Tissue Bank, Los Angeles, CA.
Gore-Tex Suture, CV-5, WL Gore & Associates, Inc., Flagstaff, AZ.
Hexamedin, Chlorhexidine digluconate, 0.5%, Bukwang Pharmaceutical Co., Korea

the first sessions were repeated. Probing depth was measured at 6 sites(mesiobuccal, midbuccal, distobuccal, distolingual, midlingual and mesiolingual) for each tooth using Marquis color-coded probes to the nearest mm. Gingival recession from CEJ and probing depth were added to estimate loss of attachment. Probing bone level measurements were made under infiltration anesthesia at the same 6 sites for each tooth as pocket depths measurements, forcing the probe apically until the probe contacted alveolar bone. Gingival recession from CEJ to the gingival margin was recorded at the 6 sites. At the time of the surgery, mesial and distal intrabony defects were characterized by measuring the distances from bone crests to the fundus of the defects at 4 sites(buccal, lingual, mesio/disto-buccal, mesio/disto-lingual), and by measuring the widths of the defects from the crest of the defects to the root surfaces. Angle of the defects were assessed using the central fossa of the corresponding tooth as the reference.

D. Statistical analysis

Means and standard deviations of pocket depths, loss of attachment, probing bone levels and gingival recessions were calculated. Differences made in each procedure were assessed using Wilcox sign rank sum test, and the comparisons between the control and each experimental group were performed with Mann-Whitney U test.

III. RESULTS

All surgical sites healed without signs of clinical infection. Membrane exposure occurred in 9 cases in the GTR and GTR+DFDBA group.

Mean averages of presurgery probing depth in the GFS,GTR and GTR+DFDBA groups were 6.9± 1.1, 7.4± 1.2, 7.0± 2.0mm, respectively. 3 patients in GFS and GTR groups and 2 patients in GTR+DFDBA groups were smokers.

In the GFS and GTR groups 8 patients were female respectively while 4 patients in GTR+DFDBA were female.

Defect characteristics are shown in Table 2. No statistically significant difference was seen among the control and experimental groups in the clinical parameters.

Healing in all cases was uneventful (membrane exposure occurred in 9 cases in GTR+DFDBA groups respectively).

Pre-intrasurgery defect characteristics, including probing depth, clinical attachment level, probing bone level, gingival recession, tooth surfaces, depth and width of intrabony defect, were similar for all treatments.

Significant probing depth reduction were observed for all treatments(GFS : 3.4±1.3mm, GTR : 4.3±1.3mm, and GTR + DFDBA : 3.4±2.1mm)(Table 3).

Significant clinical attachment gain were observed for all treatments(GFS : 2.0±1.2mm, GTR : 3.1±1.5mm, and GTR+ DFDBA : 2.4±1.9mm)(Table 4).

In comparisons between treatment, no significant differences were observed in probing depth and clinical attachment level reduction.

All but the GFS treatment exhibited a significant probing bone level gain(GTR : 4.2±2.2mm, GTR+DFDBA : 2.6±1.6mm , GFS:1.3±2.0mm)(Table 5).

Table 1 Patient characteristics and distribution among treatments

	n	male/female	mean age (years)	age range (years)	smoker/non smoker
GFS	12	4/8		27-53	3/9
GTR	12	5/7		32-46	3/9
GTR+DFDBA	12	8/4		33-55	2/10
Total	36	17/19		27-55	8/29

Table 2 Characterization of intrabony defects

Dfect Characteristics	Treatment	Mean±STD
Crestal involvement (degrees)	GFS	148.3±58.6
	GTR	158.4±34.5
	GTR+DFDBA	120.6±31.3
Depths of intrabony defects(mm)	GFS	5.8±1.7
	GTR	5.3±2.5
	GTR+DFDBA	4.7±2.3
Widths of intrabony defects(mm)	GFS	3.3±1.0
	GTR	3.2±1.1
	GTR+DFDBA	3.5±0.6

Table 3 Probing Depth(mm)

	after scaling	post-op 6 mo.	change
	Mean SD	Mean SD	Mean SD
GFS	6.9±1.1	3.5±1.0	3.4±1.3**
GTR	7.4±1.2	3.2±0.7	4.3±1.3**
GTR+DFDBA	7.0±2.0	3.6±1.5	3.4±2.1**

**significant changes from the baseline ($p<0.01$)

Table 4 Attachment level(mm)

	after scaling	post-op 6 mo.	change
	Mean SD	Mean SD	Mean SD
GFS	7.4±1.2	5.4±1.5	2.0±1.2**
GTR	7.7±1.5	4.6±1.6	3.1±1.5**
GTR+DFDBA	8.2±2.3	5.8±2.2	2.4±1.9**

**significant changes from the baseline($p<0.01$)

Table 5 Probing bone level(mm)

	after scaling	post-op 6 mo.	changes
	Mean SD	Mean SD	Mean SD
GFS	8.8±1.6	7.6±2.1	1.3±2.0**
GTR	9.1±1.6	5.5±1.8	4.2±2.2**
GTR+DFDBA	9.5±2.2	6.9±2.1	2.6±1.6**

**significant changes from the baseline (p<0.01)
significant differences between treatment methods(p<0.01)

Table 6 Gingival Recession(mm)

	after scaling	post-op 6 mo.	changes
	Mean SD	Mean SD	Mean SD
GFS	0.3±0.7	2.0 ± 0.9	1.7±0.8**
GTR	0.4±0.8	1.5 ± 0.3	1.1±1.4**
GTR+DFDBA	1.1±1.5	2.3± 1.3	1.2±1.7**

**significant changes from the baseline(p<0.01)

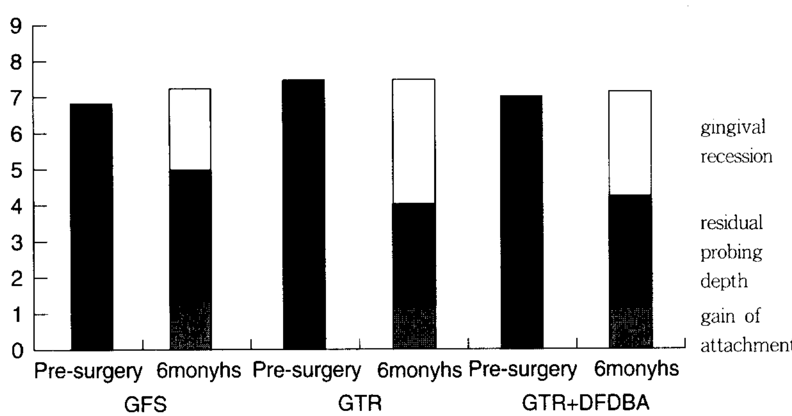

Figure 1 soft tissue measurements ; control and experimental groups showed signficant improvements from the pre-surgey recordings

In comparisons between treatments, GFS exhibited a smaller gain. All but the GFS treament exhibited a no significant gingival recession(GTR : 1.1±1.4mm, and GTR+DFDBA : 1.2±1.7mm). In comparisons between treatments, no significant differences were observed(Table 6).

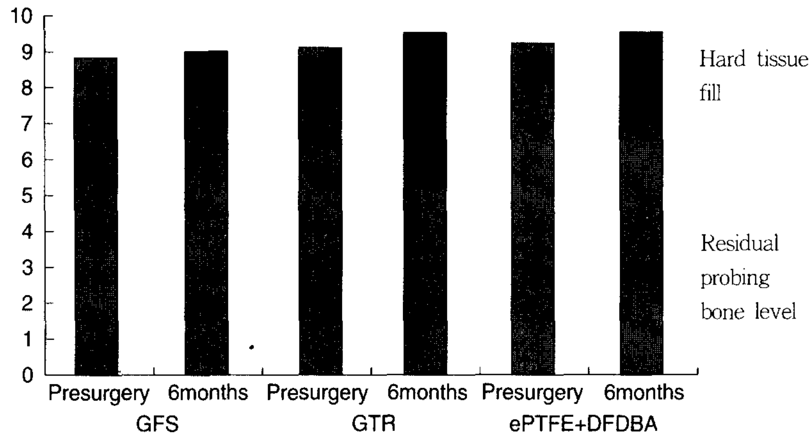

Figure 2 Hard tissue measurements : Two treatment modalities of experimental groups were effective in tissue changes compared to the control

IV. DISCUSSION

The principle of guided tissue regeneration is based on selective growth of cells necessary for the regeneration of periodontal tissue. Expanded polytetrafluoroethylene(ePTFE) barrier membranes have been studied extensively, and have been proven to promote new attachment and bone formation and to possess biological compatibility. Various studies have been conducted using ePTFE barrier membranes on intrabony and furcation defects,[1, 11, 15]and they have shown regeneration of periodontal tissues.

Decalcified freeze-dried bone allografts are the most widely used bone graft materials today, and they are known to possess definite osseogenic potentials. Clinical studies using DFDBA have suggested bone regeneration and new attachment[16~18], and histologic observations made 6 months after DFDBA implantations have shown new bone formations and new attachments[7, 8]. In periodontal defects, especially furcation defects, ePTFE therapy has been reported to result in new attachments. However, new bone formations have been limited in those reports. Based on these results, it has been speculated that the efficacy of periodontal therapy could be enhanced if ePTFE, which could exclude gingival epithelium and connective tissue elements from the wound, and bone graft materials which could induce bone formation were combined. Numerous studies have been conducted based on this expectation[11, 12, 13, 19].

Bone graft materials used in a combined therapy along with barrier membranes could not only induce bone formation, but also act as space-maker, clot-stabilizer, and provider for the matrix upon which the cells could be allowed to differentiate into osteoblasts.

In this study, regeneration of alveolar bone has been assessed using probing bone level measurements. This method is easier to apply clinically and consistently to large number of patients, compared to re-entry operations or histologic observations.

The three modalities of therapy used in this experiment all showed significant reductions in probing depth, and the largest reductions in probing depth belonged to ePTFE group.

Attachment gain was also significant in all three groups, but only ePTFE group, not ePTFE+DFDBA group, has shown significant difference compared to the control group. These may be due to the largest reductions in probing depths shown by e-PTFE group, and a possibility for DFDBA to delay connective tissue attachment during the early healing phase.

No significant differences have been found between the ePTFE therapy and the combined approach, in accordance with the results from similar studies[9, 13].

All three groups have shown significant changes in probing bone level. The significant change shown by the control group has suggested that some bone regeneration could be expected from flap surgery alone. However, both test groups showed significantly larger changes in probing bone level compared to the control. No significant differences were found between the two test groups.

Studies comparing e-PTFE therapy and the combined therapy of ePTFE+DFDBA have shown conflicting results. Andregg et al.[11] has reported significantly more bone formations for the combined approach, while Schallhorn & McClain[9] have found no significant differences. In this investigation, ePTFE group has shown greater changes in probing bone level rather than ePTFE+DFDBA group, although the differences were not significant. Percentages of the changes in probing bone levels to the initial levels have shown 37.6% for the membrane group and 31.8% for the combined therapy, also in favor of ePTFE therapy. The deeper probing bone level for ePTFE group might have resulted in more bone formation for this particular group. It could be also speculated that space-making and clot stabilization could be adaquately provided by ePTFE alone in intrabony cases, while in furcation defects, such as the ones used in Andregg's study[11] bone graft materials might play more prominent roles.

There is also a possibility that bone graft materials themselves may prevent the coronal migration of cells that could promote periodontal regeneration, as Stahl[19] and Hwang[20] had suggested. Therefore, whether to use bone graft materials in guided tissue regeneration should be decided according to the pattern and the extent of the defect.

Gingival recession has increased significantly after 6 months in all groups, but there were no significant differences between the control and the test groups.

In summary, the sole use of ePTFE had resulted in more changes in probing depths compared to flap surgery alone or the combined therapy of GTR+DFDBA, while in attachment level, GTR group showed higher gains than the control and GTR+DFDBA group although the difference was not significant. Probing bone level showed significant differences from the control for both ePTFE-only and GTR+DFDBA groups, but no significant differences were found between the test groups. The use of ePTFE membranes does not seem to affect the gingival recession any more than the control group.

V. CONCLUSION

The effects of guided tissue regeneration therapy with expanded polytetrafluoroethylene (ePTFE) barrier membrane with or without demineralized freeze-dried bone allografts were investigated. Twelve intrabony defects in 12 patients(one defect per person) were treated with periodontal flap surgery as a control (GFS), 12 introbony defect in 12 patients received e-PTFE membrane alone(GTR), and 12 defect were treated with e-PTFE membrane, and DFDBA(GTR+DFDBA). A postsurgery protocol emphasizing wound stability and infection control was used. Clinical healing was evaluated 6 months postoperatively.

For the control group (GFS), changes in probing depth, attachment level, probing bone level and gingival recession averaged 3.4±1.3mm, 2.0±1.2mm, 1.3±2.0mm, and -1.7±0.8mm, respectively, and for the GTR group, 4.3±1.3mm, 3.1±1.5mm 4.2±2.2mm and -1.1±1.4mm, respectively, and GTR+DFDBA group, 3.4±2.1mm, 2.4±1.9mm, 2.6±1.6mm and -1.2±1.7mm respectively.

Mean presurgery probing depth for GFS and GTR+DFDBA was 6.9±1.1mm, 7.4±1.2mm, 7.0±2.0mm, respectively. Significant probing depth reduction, attachment level improvement were observed in GTR and GTR+DFDBA($P<0.01$). GTR and GTR+DFDBA exhibited significantly greater improvements in probing bone level compared to GFS($P<0.001$),but no significannt difference were found between GTR and GTR+DFDBA.

Under this experiment The results suggest that GTR and GTR+DFDBA procedure compared to GFS have similar clinical results in intrabony pockets except for bone fill.

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Key words : polytetrafluoroethylene, demineralized freeze-dried bone, intrabony defect, guided tissue regeneration

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-국문 초록-

DFDBA와 e-PTFE 차단막 혼합사용이 치주골내낭 치유에 미치는 영향

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탈회냉동건조골(DFDBA)과 ePTFE막을 사용한 경우와 ePTFE만을 사용한 경우의 조직유도재생술의 효과를 관찰하였다. 12명의 환자에서 12개의 골내낭결손부(한 환자당 하나의 결손부)를 통상적인 치주수술 시행한 경우를 대조군(GFS)으로, 12명의 환자에서 12개의 결손부는 ePTFE(GTR)막 만으로, 또 다른 환자의 12개결손부는 ePTFE+DFDBA로 시행하였다.

창상안정과 감염방지를 강조한 술후계획이 사용되었다. 술후 6개월째 임상적 치유상태를 평가하였다. 대조군에서 치주낭깊이, 부착수준, 탐침골깊이, 치은퇴축의 각각의 평균치는 3.4±1.3mm 2.0±1.2mm, 1.3±2.0mm, -1.7±0.8mm, GTR군에서는 4.3±1.3mm, 3.1±1.5mm, 4.2±2.2mm, -11±1.4mm 그리고 GTR+DFDBA군에서는 3.4±2.1mm, 2.4±1.9mm, 2.6±1.6mm., -1.2±1.7mm를 보였다. 대조군과 GTR+DFDBA군의 술전 평균 치주낭깊이는 각각 6.9±1.1, 7.4±1.2, 7.0±2.0mm 였다. GTR, GTR+DFDBA군에서는 뚜렸한 치주낭감소와 부착획득을 보였다($P<0.01$).

GTR, GTR+DFDBA에서는 대조군에 비해 탐침골수준의 뚜렷한 향상을 보였으나($P<0.001$), GTR과 GTR+DFDBA사이에는 뚜렷한 차이가 없었다.

이 실험결과로 골내낭 결손부에서 GTR과 GTR+DFDBA의 사용은 골형성을 제외한 임상결과에서 대조군과 유사한 결과를 보였다.