

TEMPORAL CHANGES IN CLINICAL RESPONSES OF HUMAN PERIODONTAL DEFECTS TREATED WITH OPEN FLAP DEBRIDEMENT OR BIOACTIVE GLASS OVER 6-12 MONTH HEALING PERIOD

S. Froum^{1,2} and M. Weinberg²

¹ New York University College of Dentistry, Department of Implant Dentistry, 345 E. 24th Street, New York, NY. ²Department of Surgical Sciences (Periodontics).

ABSTRACT

The purpose of the present investigation was to clinically evaluate over a 6-12 month postsurgical period changes in the healing response of human intraosseous defects treated with open flap debridement with and without Bioglass® implantation. Patients were chosen for this study if they had at least 2 sites with attachment loss of ≥ 6 mm and radiographic evidence of intraosseous defects. Clinical measurements (probing depths (PD), attachment level (AL), and gingival recession (Rec) were recorded at baseline (day of the surgery), 6 and 12 months. The test defects were implanted with bioactive glass. The other sites served as unimplanted controls. At 1 year, significantly greater ($P=0.0430$) mean probing depth reduction was noted in the bioactive glass group (3.42 mm) compared to the control (4.31 mm). Attachment level gain was significantly improved ($P=0.0016$) in the bioactive glass sites (2.96 mm) compared to the control sites (1.48 mm). There was significantly less ($P=0.0190$) gingival recession in the bioactive glass sites (1.36 mm) compared to the control sites (1.90 mm). In conclusion, bioactive glass showed significant improvement in clinical parameters compared to open flap debridement alone. Moreover, changes in clinical parameters (PD reduction and AL gain) recorded 6 months postsurgery remained stable at the 12-month evaluation. Changes in Rec recorded at 12 months were significantly greater ($P=0.0104$) than the 6 month values in both treatment groups.

KEY WORDS: bioactive glass; periodontal diseases/surgery; periodontal diseases/treatment; open flap debridement, Bioglass®

INTRODUCTION

The ultimate goal of periodontal therapy is focused on the elimination of hard and soft tissue defects (e.g., probing depths and osseous defects) by regenerating new attachment. This new attachment ideally consists of new bone, cementum, and attached periodontal ligament to replace that which was lost due to periodontal disease. Methods to evaluate the clinical results of various therapies has focused on measuring clinical parameters of probing depth (PD), attachment levels (AL) and gingival recession (Rec) prior to and at various postsurgical time intervals. Traditionally reevaluation measurements take place 6 or 12 months postsurgery. However, the difference between the 6 and 12-month results has rarely been tested. A variety of materials and procedures have been utilized to obtain periodontal regeneration including use of bone grafts and bone replacement materials. Recently there has been renewed interest in evaluating alloplasts as bone substitute materials in the treatment of intraosseous defects. One such material, which has shown positive clinical results, is bioactive glass.

Bioglass® (Perioglas®, Block Drug Inc., Jersey City, NJ) is a bioactive glass that demonstrates osteoconduction by having a bioactive surface that is colonized by osteogenic stem cells⁷ and the ability to bond to soft tissue and bone.²⁻⁴ New attachment has been shown in both animal⁷ and human studies^{5,6} comparing Bioglass® and other ceramics to open flap debridement.

The purpose of the present investigation was to clinically evaluate over a 6-12 month postsurgical period changes in the healing response of human intraosseous defects treated with open flap debridement with and without Bioglass® implantation.

MATERIAL AND METHODS

Sixteen systemically healthy patients, 8 males and 8 females, with an average age of 43 years were selected for this study. Each patient had localized moderate to severe periodontitis with two or more sites in different quadrants with attachment loss ≥ 6 mm. These sites exhibited clinical and radiographic evidence of intraosseous defects. The patients had not taken antibiotics within 6 months of the start of the study and were not allergic to any medications used in this study.

Each patient had undergone cause-related therapy at least 1 to 3 months prior to enrollment in the study. This consisted of oral hygiene instruction, scaling and root planing and occlusal therapy where indicated. Prior to surgery, a customized acrylic stent was fabricated for each patient. The stent was grooved in an occlusal apical direction with a bur so that a number 50 silver point was returned to the same position for each successive measurement. Soft and hard tissue measurements were recorded from a fixed reference point (stent) to the nearest 0.01 mm using a digital Boley gauge, silver point, and locking pliers.

The following clinical measurements were recorded at baseline (just prior to surgery), 6 months, and 12 months after surgery: probing depth (PD), attachment level (AL), and gingival recession (Rec). Six and 12-month clinical changes from baseline measurements were compared to each other to evaluate changes during this time period.

SURGICAL PROTOCOL

Sites were selected by the flip of a coin and designated as test (t) or control (c). Following administration of local anesthesia, buccal and lingual intrasulcular incisions were made and full thickness flaps were elevated. After debridement of the osseous defect, the root surfaces were scaled and root planed. Wherever there was no observable intramarrow bleeding, small penetrations through the bony walls were made with a $\frac{1}{2}$ round bur or curet tip. The control sites were then sutured with interrupted sutures. The test sites were treated in the same manner. However, following debridement of the root and bone defect, the bioactive glass was implanted to fill the defects to the most coronal level of the osseous walls.

All patients received systemic tetracycline HCl 1 gm/day for 14 days postsurgery and were instructed to rinse with 0.12% chlorhexidine gluconate twice daily until the sutures were removed 1 week later. Patients were seen for periodontal supportive therapy at the surgical sites weekly for 6 weeks then monthly for the next 10½ months.

RESULTS

Summary of mean soft tissue measurements at baseline, 6 and 12 months postsurgery

(Table 1)

Table 1: Summary of LS-Mean Soft Tissue Measurements at Baseline, 6 and 12 Months

Clinical Parameter	Post-Surg				ANOVA P-Value
	Control		Test		
	LS-Meant† (n=23 defects)	SE	LS-Meant† (n=27 defects)	SE	
Initial Pocket Depth (PD)	7.31	0.37	7.85	0.37	0.2815
6-Month Change in PD	3.14	0.29	4.03	0.30	0.0276†
12-Month Change in PD	3.42	0.32	4.31	0.33	0.0430 †
6-Month Clinical Attachment Level (CAL)	1.36	0.26	2.92	0.26	0.0001†
12-Month Clinical Attachment Level	1.48	0.33	2.96	0.33	0.0016†
6-Month Change in Remssion	1.63	0.16	0.96	0.16	0.0029 †
12-Month Change in Remssion	1.90	0.17	1.36	0.17	0.0190 †

†Statistically significant differences were detected in the means between the control and test treatment groups using a 2-group randomized block analysis of variance with subjects considered as randomized blocks.

‡The LS-means are means which have been weighted to account for the variable number of defects assessed in the control or test quadrants in each subject.

A 2-group randomized block analysis of variance (ANOVA) with patients considered as randomized blocks was used to compare mean change from baseline per individual site in soft tissue measurements. A comparison was made between the debridement and bioactive glass treatments of probing depth, clinical attachment level and recession. For each outcome measurement, least-squares (LS) means, standard errors (SE), and 95% confidence intervals (CI) were estimated for change from baseline at each postsurgery observation time.

There was a statistically significant ($P = 0.0276$) mean reduction in probing depths at the test sites (4.03 mm) compared to the control sites (3.14 mm) at 6 months post-op. There was a significant ($P=0.0001$) attachment level gain in the test sites (2.92 mm) compared to the control sites (1.36 mm). The mean change in gingival recession from baseline to 6 months postsurgery was significantly lower ($P=0.0029$) in the test sites (0.96 mm) compared to the control sites (1.63 mm).

There was a statistically significant ($P = 0.0430$) mean reduction in probing depths at the test sites (4.31 mm) compared to the control sites (3.42 mm) at 12 months post-op. There was a significant ($P=0.0016$) attachment level gain in the test sites (2.96 mm) compared to the control sites (1.48 mm). The mean change in gingival recession from baseline to 12 months was statistically lower ($P=0.0190$) in the test sites (1.36 mm) compared to the control sites (1.90 mm).

Comparison of the 6 and 12 month post surgical results (Table 2)

Table 2: Comparison of Probing Depth, Attachment Level and Gingival Recession Changes at 6 and 12 Months Post-Surgery Repeated Measures ANOVA Results

Parameter	Time ¹	Time *Trt .Group Interaction ²	Treatment Group ³
Pocket Depth	0.1855	0.9873	0.0197†
Clinical	0.7198	0.8262	0.0001†
Attachment Level			
Recession	0.0104 †	0.5863	0.0027†

†Statistically significant differences were detected using a repeated measures analysis of variance.

¹This is a test for a difference in the change from baseline from six, to twelve months.

²This is a test to see if the time effect (from 6 to 12-months) is the same for the two treatments, control and test

³This is a test to see if the two treatments have an effect on the mean change from baseline.

Repeated measures ANOVA, with the patient again considered as a randomized block and observation time post surgery considered as a repeated factor was used to determine if differences in change from baseline existed between the 6-month and 12 month results. Also, a test was done to see if a time effect, if any between the 6 month and 12 month values, differed between the two treatment groups.

There were no significant time and treatment group interactions for pocket depth, clinical attachment level, or recession indicating that the temporal effects, if any, were the same in the two treatment groups. A significant time effect was found for the changes from baseline in recession between the 6 month and 12 month data ($p=0.0104$) with more recession at 12 months versus at 6 months in both treatment groups. There were no significant differences found between the 6 month and 12 month mean changes from baseline in probing depth ($P=0.1855$). There was no time effect found.

DISCUSSION

The present study compared clinical parameter probing depths, gingival recession and attachment level following open debridement with and without implantation of a bioactive glass. The findings that the bioactive glass treated sites showed significantly more probing depth reduction and attachment level gain than the open debridement treated sites is in agreement with Ong et al.⁶ However, the magnitude of change in both the test and control treated sites was greater in this study. This may have been attributed to differences in patient population, defect morphology, or plaque control. In fact clinical changes in both PD reduction and AL gain has been shown to correlate with plaque control.¹

The results of the present study also show that the clinical improvement in PD and AL is maintained over a 6 to 12 month period. This is consistent with the finding of Low et al.⁵ who showed that PD reduction and AL gain was stable over a 24 month period following use of bioactive glass to treat periodontal osseous defects in 12 patients. Implications of these results are that soft tissue changes following open flap debridement with or without Bioglass® implants maybe evaluated 6 months postsurgery. However, statistically significant changes do take place in gingival recession from 6 to 12 months postsurgery with more recession at 12 months. The question of whether new histological attachment and/or bone fill can be assessed at this time period remains to be answered. Moreover, the reasons for changes in recession and whether these changes will continue to show significance after 1 year must also be further studied.

Conclusions that can be gleaned from these studies include the fact that the improvement in clinical parameters following open flap debridement with the use of a bioactive glass are significantly enhanced over open flap debridement alone. Moreover, clinical improvements in PD and AL gain when evaluated 6 months postsurgery are stable for at least an additional 6 months if low plaque levels are maintained.

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