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Role of a commercially available bioactive bone graft material in the treatment of periodontal osseous defects: A randomized controlled clinical trial.

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Abstract

Bone grafts are the most used modalities of therapy for which there is histologic evidence of regeneration coronal to the base of the previous osseous defect. Bioactive glasses are used extensively in medicine and dentistry. The present study evaluated the additional efficacy of a bioactive alloplast, PerioGlas, in comparison with open flap debridement alone. 12 systemically healthy subjects were selected, each having 2 collateral sites with ≥6 mm clinical probing depth and radiographic evidence of an intrabony defect. On one side defect treatment with open flap debridement plus bioactive glass (test) and on other with open flap debridement alone (control) was performed. At baseline, 3, 6, 9 months measurements were recorded which included plaque index, gingival index, pocket probing depth, clinical attachment level, and increase in gingival recession. Standardized radiographs were used to measure defect fill and alveolar crest resorption. Data collected was put to statistical analysis. Both treatments showed no significant differences between the two groups at any point of time. However, radiographically, bioactive glass group showed significant improvement in bone in comparison to open flap debridement alone. The alloplastic bone graft material, PerioGlas, demonstrated clinical advantages beyond that achieved by debridement alone.

Keywords: *Bone grafts, Bioactive glass, Intraosseous defects*

Introduction

The pathological hallmark of periodontitis is the destruction of the supporting structures of the teeth involved and loss of clinical attachment. Different types of regenerative approaches have been utilized in the past to regenerate periodontal tissues and treat periodontal disease. At present, bone replacement grafts are the only modality of therapy for which there is histologic evidence along with guided tissue regeneration for regeneration of new attachment composed of new bone, cementum, and periodontal ligament coronal to the base of the previous osseous defect. This has not been observed with other forms of regenerative periodontal therapy, which attempt to eliminate bony defects without a bone replacement graft material (1).

The bioactive glasses have been used extensively in medicine and have been applied to dental field for the treatment of bone defects, ridge preservation and periodontal osseous defects. Bioactive ceramics have been used clinically to repair bone defects owing to their biological affinity to living bone, i.e. the capability of direct bonding to living bone, their so-called bioactivity (2). During periodontal therapy, deep intraosseous defects represent a major challenge for the clinician, often requiring access by flap surgery alone or in association with bone-regenerative procedures. This study was designed to evaluate

the additional efficacy of a bioactive alloplast (PerioGlas) in comparison to open flap debridement alone.

Methods

12 subjects aged between 20-65 were selected for the study taking following criteria in consideration:

Inclusion criteria:

1.Two or more sites showing periodontal osseous defects in different quadrants with probing depth ≥ 6mm.

2, No medical problems that contraindicated routine periodontal surgery.

3. Patients who had not taken antibiotics within 6 months of initial examination.

4. No periodontal surgery in the areas to be treated within the last 12 months.

5. No known allergy to materials and drugs used or prescribed in this study, including silica products.

Exclusion criteria:

1. Subject has a medical condition or therapeutic regimen that would decrease the probability of soft tissue and bone healing.

2. Pregnant patients.

3. Smokers.

4. Patients with previously implanted materials, natural or synthetic and physical barriers in the selected defects.

5. Patients who did not show any improvement in oral hygiene after phase I therapy.

6. Patients who did not accept the terms and conditions of the study.

Methodology

All participants, following an initial examination and treatment planning appointment, were given detailed instructions in plaque control measures, and were then subjected to full mouth scaling and root planing. A Split mouth model was employed in this study. Two of the bilateral defects were randomly selected as Site A - test (open flap debridement with PerioGlas) or Site B - control (open flap debridement only). Postoperatively, subjects were prescribed antibiotic 100mg Doxycycline, and analgesic Ibuprorufen 400mg. Patients were instructed to rinse with 10 ml of 0.2% chlorhexidine gluconate twice daily. The following parameters were recorded at baseline, 3 months, 6 months and 9 months. A. Plaque

index – Silness & Loe, 1964 (3). B. Gingival index – Loe & Silness, 1963 (4). C. Probing pocket depth - measured from the crest of the gingival margin to the base of the pocket. D. Clinical attachment level – Measured from cementoenamel junction to the base of pocket. E. Recession – Measured from the fixed reference point to the gingival margin. F. Standardised radiographs of the experimental and control sites were taken using a paralleling technique with a film holder. This was taken to measure the bone fill and the alveolar crest resorption. Soft Tissue Parameters using the apical margin of the customized acrylic stent as the fixed reference point (FRP), measurements were made at the proximal line angle of the tooth with the associated bony defect. Only one site representing the same deepest point of the defect was included. The following measurements were recorded for test and control teeth by a single investigator using a Williams graduated periodontal probe. 1 Stent (FRP) to Cementoenamel junction (CEJ) 2 Stent (FRP) to gingival margin (GM) 3 Stent (FRP) to base of the pocket (BOP) The following calculations were made from the clinical measurements recorded: 1 Pocket Depth = (FRP to BOP) - (FRP to GM) 2 Clinical attachment level = (FRP to BOP) - (FRP to CEJ) 3 Increase in gingival recession = (FRP to GM at recall interval) - (FRP to GM at baseline). These measurements were made at baseline, 3 months, 6 months and 9 months. Radiographic / hard tissue parameters: Standardized intra oral periapical radiographs of each defect site using paralleling cone technique with film holders (XCP kit) and a millimeter grid (X-ray mesh) were taken, preoperatively and post-operatively at 3 months, 6 months and 9 months.

Radiographic Assessment

Radiographic evaluation was performed on an X-ray viewer. Bone defect depth was measured preoperatively and post-operatively at 3 months, 6 months and 9 months as the distance from the alveolar crest to the base of the bone defect.

The Base of defect (BOD) was defined as the most coronal point where the periodontal ligament space showed continuous width. (5) The alveolar crest (AC) level was taken as the crossing of the alveolar crest with the root surface. (5) If several bony contours could be identified, the most apical that crossed the root was defined as BOD and the most coronal as the AC. (6) The following calculations were made from the radiographs: Amount of defect fill = Initial defect depth – defect depth at recalled time interval. Percentage (%) of defect fill = Amount of defect fill / baseline defect depth x 100. These measurements were made at baseline, 3 months, 6 months, and 9 months.

Statistical analysis

The collected data were then subjected to statistical analysis. The Mann-Whitney U test was used to compare the results between site A (test) and site B (control) groups. The Wilcoxon sign rank sum test was used to compare the results between the various time intervals.

Results

The plaque index, gingival index, probing depth showed no statistical difference between any of the test and control sites at any point of time. Similarly, clinical attachment level and gingival recession (Table 1) showed no statistical difference between any of the test and control.

Table 1: Comparison of PD, CAL, and Increase in gingival recession between test site (Site A) and Control (Site B) at baseline, 6 and 9 months.

	Site	N	Mean	Standard Deviation	Z test
PD Baseline	A B	12 12	8.500 8.250	1.412 1.581	0.1070 P=0.914 NS
PD 6 months	A B	12 12	4.500 5.600	0.925 1.598	1.3610 P=0.174 NS
PD 9 months	A B	12 12	4.250 5.123	1.035 1.356	1.351 P=1.35 NS
CAL Baseline	A B	12 12	7.628 7.367	2.669 2.389	0.0540 P=0.957 NS
CAL 6 months	A B	12 12	4.875 6.975	2.900 1.725	1.2720 P=0.204 NS
CAL 9 months	A B	12 12	4.562 6.398	3.295 1.725	1.1703 P=0.242 NS
Increase in gingival recession in 6 months	A B	12 12	0.542 1.002	0.534 0.536	1.72 P=0.263 NS
Increase in gingival recession in 9 months.	A B	12 12	0.548 0.974	0.534 0.640	1.20 P=0.328 NS

N: Number of subjects

Mean and Standard Deviation Measurements are in millimetres.

NS: Non-significant.

Table 2: Intergroup Comparison of Percentage bone fill between Test Site (Site A) and Control Site (Site B) at 3, 6 and 9 months.

Time Interval	Site	N	Mean	Standard Deviation	Z Test
At 3 months	A B	12 12	31.76 13.60	20.88 15.25	1.962 P=0.05 S
At 6 months	A B	12 12	46.33 28.58	15.27 12.72	1.98 P=0.049 S
At 9 months	A B	12 12	55.17 38.22	15.90 15.78	2.01 P=0.046 S

Mean and Standard Deviation are in percentage, S: Significant.

Discussion

Alveolar bone destruction is one of the characteristic signs of destructive periodontal disease and is generally considered to represent the anatomical sequela to the apical spread of periodontitis. (7) To be considered as a regenerative modality, a material or technique must histologically demonstrate that bone, cementum and a functional periodontal ligament can be formed on a previously diseased root surface. Bone grafts and their synthetic substitutes have been used, as an attempt to gain this therapeutic endpoint. (8) This study compared the soft tissue and hard tissue changes with the use of flap debridement along with alloplastic bone graft material, PerioGlas, versus that of open flap debridement alone in periodontal intrabony osseous defects. Twelve systemically healthy patients were selected with as per desired selection criteria (9). To nullify the subject differences, bilateral defects in the same patient were chosen and randomly divided into test and control. The plaque and gingival indices showed non-significant differences between the test and control groups. The results could be due to the lack of improvement in home care. This is similar to the findings of Zamet et al. (10) who observed no significant change in plaque index or gingival index 12-months postsurgery compared to baseline. An overall improvement in the probing depth and attachment level was noted in both test and control groups. The probing depth in test and control group at any time interval showed no statistical difference which is consistent with the findings of Froum et al. (11). The increase in gingival recession showed no statistical difference between test and control sites at any time interval. The increase in gingival recession between various time intervals was significant in test group. Park et al. (9) and Lovelace et al. (12) showed lesser recession values, probably due to the fact that these studies were of shorter duration (6 months). While measuring all the soft tissue parameters a fixed reference point at the apical edge of the custom-made acrylic stent was used. Clark et al. (13) have reported that the measurements using a stent appear to be better than the measurements made using cemento-enamel

junction as the reference point. However, Trevor Watts (14) examined the possible sources of error with regard to probing measurement reliability with and without stent. He reported that the stent made little difference to overall reproducibly of probing depths, though it appears to reduce variation in different areas. Healing of the bone defect was a combination of bone fill and alveolar crest resorption. The percentage of bone fill was significant at 3, 6 and 9 months. At the test site the values obtained at various intervals are statistically significant. The results of the present study are in general agreement with the findings of Zamet et al. (10) in their clinical comparison of intrabony defects treated with bioactive glass or open flap debridement. The conclusion that bioactive glass treated sites showed a greater trend to improvement compared to open flap debridement treated sites is consistent with the findings of the present study.

A change of the alveolar bone level was detected radiographically using consecutive radiographs. Projection geometry of serial radiographs should be standardized to minimize measurement errors. A source of error is caused by different angulations between the central beam related to the film holder and the film while relation between teeth and film is fixed. (15, 16) Prefabricated film holders like what was used in this study may provide projection standardization to a certain degree. The selection of the appropriate imaging technique cannot overcome the fundamental limitations of intraoral radiography, even when the images are of high quality. The use of radio-opaque or transparent millimeter grids, does not improve the measurement accuracy. (17) Grids like the one used in this study may facilitate the measurement process, but they do not account for magnification or distortion. 1The treatment success reported in various studies may differ which is likely to be in part to the varying morphology of initial defects.

Conclusion

Within the limits of this study, it may be concluded that sites treated with bioactive glass showed significant improvement in bone fill over the sites treated with open flap debridement alone. Both groups showed significant improvements at the various time intervals. Moreover, bioactive glass was well tolerated by the gingival tissues. However, further studies with a larger sample size are required to clarify the beneficial effects of bioactive glass in treating periodontal osseous defects.

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