A Comparative Evaluation of Biphasic Calcium Phosphate Material and Bioglass in the Treatment of Periodontal Osseous Defects: A Clinical and Radiological Study

Nymphea Pandit, BDS, MDS; Rajan Gupta, BDS, MDS; Sachin Gupta, BDS, MDS

Abstract

Aim: The aim of this study was to evaluate the efficacy of biphasic calcium phosphate (ossifi®) and bioactive glass in the treatment of periodontal osseous defects clinically and radiographically and compare them with open-flap debridement.

Methods and Materials: A total of 45 sites in two test groups (test 1, ossifi; test 2, bioactive glass) and a control group (open-flap debridement), in 35 patients, were selected in this study conducted at the department of Periodontics and Oral Implantology, D.A.V.(C) Dental College, Yamuna Nagar, India. Clinical parameters like plaque index, gingival index, pocket depth, and clinical attachment level were recorded at the baseline and at three months and six months postoperatively. Radiological parameters like the amount of defect resolution and the percentage of defect resolution were recorded at the baseline and at three months and six months postoperatively.

Results: Statistically significant difference in mean values of the plaque index, gingival index, pocket depth reduction, clinical attachment level, gain amount of defect resolution, and percentage of defect resolution were observed in all the groups at subsequent time periods.

Conclusion: Both test groups showed significant improvement over the control in both the clinical and radiological parameters.

Clinical Significance: A greater percentage of defect resolution was noticed in test 1 as compared to test 2, followed by the control.

Keywords: Biphasic calcium phosphate material (ossifi®), scaling, root planing, periodontal therapy/surgery, bioactive glass, bone regeneration

Introduction

Periodontal therapy involves two primary components. First is the elimination of the periodontal infection by eliminating the pathogenic periodontal microflora, which induces substantial favorable clinical changes in the periodontium. However, the anatomic defect resulting from active periodontitis still persists and is represented clinically by loss of clinical attachment, increased probing depth, and radiographic bone loss. The substantial efforts made to alter this defect represent the second component of periodontal therapy.[1]

The use of bone grafts to promote periodontal regeneration during periodontal surgery has been the subject of multiple recent reviews. Mellonig and Brunsvold have shown more regeneration in sites where a graft material was used versus nongrafted controls.[2]

The ideal graft material remains to be found. Such a material would induce osteogenesis and cementogenesis that would result in the regeneration of a new periodontal attachment complex at a more coronal level. It would be biocompatible, noncarcinogenic, nontoxic, and nonantigenic. It also would be easily obtainable, would be relatively inexpensive, and would not cause the patient or the surgeon unnecessary inconvenience.[3] In search of such a material, autografts, allografts, and alloplastic materials have been tried. Autografts would fulfill almost all the requirements except the morbidity with a second surgical site. Allografts are associated with cross infection and disease transmission.

An inorganic synthetic material would fulfill the criteria of an ideal graft material. The development of a biphasic calcium phosphate (i.e., a combination of hydroxyapatite and β-tricalcium phosphate) ceramic has an advantage that it controls the resorbability of material and maintains its osteoconductive property.[4]

Bioactive glass, which is a type of alloplastic graft, has the property to promote adsorption and concentration of proteins utilized by osteoblasts to form a mineralized extracellular matrix and, thus, promote osteogenesis by allowing rapid formation of bone.

Methods and Materials

A total of 45 sites in two test groups (test 1, ossifi; test 2, bioactive glass) and a control group (open-flap debridement), in 35 patients in the age group between 20 and 60 years, were selected. These patients were suffering from moderate to advanced periodontitis with radiographic evidence of a periodontal osseous defect greater than 3 mm. The study was conducted in the Department of Periodontics and Oral Implantology, D.A.V (C) Dental College and Hospital, Yamunanagar, India. The procedure was explained to the patients and informed consent was signed by them. The ethics committee of KU University of Haryana approved the study protocol.The exclusion criteria included any systemic health, which precludes smoking, pregnancy, lactating females, teeth with inadequate endodontic treatments, grade III mobile teeth, and teeth with overhanging margin restorations.

Osteogenesis

Osseous Defect
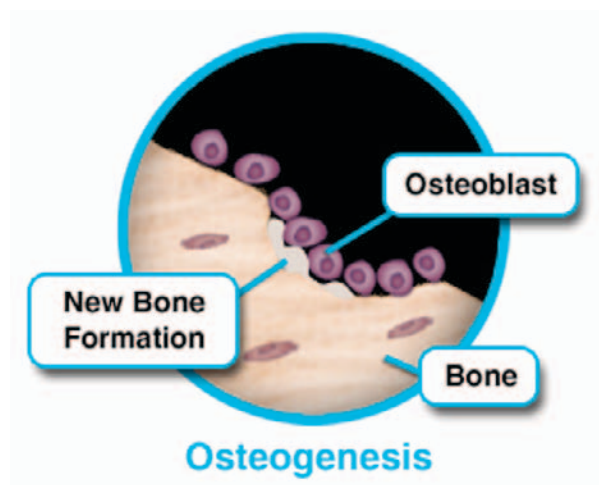
The initial preparation phase of the treatment consisted of oral hygiene instructions, scaling and root planing, and occlusal therapy as needed. Reevaluation four weeks after completion of the initial therapy confirmed that an acceptable level of plaque control was maintained by the patients and provided the presurgical soft tissue measurements.

Customized acrylic occlusal stents were prepared to provide reproducible testing points and insertion axes.

Clinical parameters like plaque index, gingival index, pocket depth, and clinical attachment level were recorded at the baseline and at three months and six months postoperatively. Intraoral periapical radiographs with a millimeter grid were used for evaluation of the amount of defect resolution and the percentage of defect resolution at three months and six months postoperatively.

The surgical procedure was performed under aseptic conditions. The area selected for surgery was anesthetized using lignocaine with adrenaline injection I.P. Intrasulcular incisions were given with reflection of full thickness flaps to retain as much soft tissue as possible in order to obtain primary closure. Osseous defects were completely debrided of granulation tissues and root surface deposits. The control sites were then sutured with interrupted sutures using 3-0 Mersilk suture. In the test sites in both test groups, small increments of graft material were added, starting from the bottom of the defect and adapted well to its configuration. The flap was then repositioned at the original level and closed with interrupted direct loop sutures using 3-0 Mersilk sutures. Care was taken to achieve a tension-free primary closure of the flap on suturing. Applying a periodontal dressing protected the surgical site. All the subjects were given both verbal and written instructions as a part of the postoperative regimen. After 7 to 10 days of dressing, sutures and any plaque present in the area were removed.

Results

Data were analyzed statistically by paired sample *t*-test.

The mean plaque index difference from the baseline to three months and six months was found to be 1.02±0.60 and 1.33±0.58 respectively for the control, 1.51±0.61 and 1.83±0.45 respectively for test 1, and 0.78±0.41 and 0.99±0.40 respectively

for test 2. The mean plaque index difference was found to be statistically significant (Table 1).

The mean gingival index difference from baseline to three months and six months was found to be 1.03±0.58 and 1.25±0.67 respectively for the control, 1.45±0.28 and 1.70±0.30 respectively for test 1, and 0.82±0.37 and 1.00±0.37 respectively for test 2. The mean gingival index difference was found to be statistically significant (Table 2).

The mean pocket depth difference from the baseline to three months and six months was found to be 2.86±0.83 and 3.60±0.50 respectively for the control, 3.40±1.12 and 4.13±0.83 respectively for test 1, and 2.80±0.67 and 4.00±1.06 respectively for test 2. The mean pocket depth difference was found to be statistically significant.

On intergroup comparison, at three months, the mean pocket depth difference between the control and test 1 (0.73±1.38), between the control and test 2 (1.33±1.04), and between test 1 and test 2 (2.06±1.75) were significant. At six months, the mean pocket depth difference between the control and test 1 (0.73±1.03), between the control and test 2 (0.86±1.12), and between test 1and test 2 (1.60±1.12) were significant (Table 3, Figure 1).

The mean clinical attachment level difference from the baseline to three months and six months was found to be 3.00±1.00 and 3.73±0.70 respectively for the control, 3.40±1.12 and 4.26±0.79 respectively for test 1, and 2.20±0.67 and 3.06±1.27 respectively for test 2. The mean clinical attachment level difference was found to be statistically significant.

On intergroup comparison, at three months, the mean clinical attachment level difference between the control and test 1 (0.93±1.57), between the control and test 2 (2.20±1.20), and between test 1 and test 2 (3.13±1.88) were significant. At six months, the mean clinical attachment level difference between the control and test 1 (1.06±1.09), between the control and test 2 (2.06±1.27), and between test 1 and test 2 (3.13±1.50) were significant (Table 4, Figure 2).

The mean defect resolution difference from the baseline to three months and six months was found to be 4.80±1.81 and 4.23±1.67 respectively for the control, 2.70±0.70 and

Table 1. Comparison of plaque index at different observation periods in different groups.

Group	Observation Period	Mean ± S.D.	Comparison	Mean ± S.D.	t value	p value
Control	Baseline	1.75 ± 0.57				
	3 months	0.72 ± 0.24	BL vs 3M	1.02 ± 0.60	6.52	0.000
	6 months	0.41 ± 0.15	BL vs 6M	1.33 ± 0.58	8.79	0.000
			3M vs 6M	0.31 ± 0.16	7.15	0.000
Test 1	Baseline	2.25 ± 0.39				
	3 months	0.73 ± 0.20	BL vs 3M	1.51 ± 0.61	9.5	0.000
	6 months	0.42 ± 0.10	BL vs 6M	1.83 ± 0.45	15.5	0.000
			3M vs 6M	0.32 ± 0.21	5.8	0.000
Test 2	Baseline	2.07 ± 0.45				
	3 months	1.28 ± 0.24	BL vs 3M	0.78 ± 0.41	7.4	0.000
	6 months	1.08 ± 0.27	BL vs 6M	0.99 ± 0.40	9.4	0.000
			3M vs 6M	0.20 ± 0.15	5.2	0.000

Table 2. Comparison of gingival index at different observation periods in different groups.

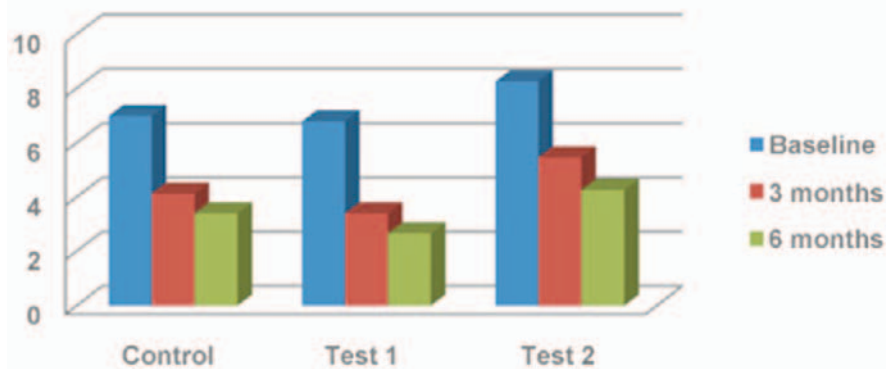| Group	Observation Period	Mean ± S.D.	Comparison	Mean ± S.D.	t value	p value
Control	Baseline	1.56 ± 0.65				
	3 months	0.53 ± 0.20	BL vs 3M	1.03 ± 0.58	6.84	0.000
	6 months	0.31 ± 0.17	BL vs 6M	1.25 ± 0.67	7.25	0.000
			3M vs 6M	0.22 ± 0.17	5.02	0.000
Test 1	Baseline	1.98 ± 0.24				
	3 months	0.53 ± 0.22	BL vs 3M	1.45 ± 0.28	20.07	0.000
	6 months	0.28 ± 0.12	BL vs 6M	1.70 ± 0.30	21.74	0.000
			3M vs 6M	0.25 ± 0.18	5.42	0.000
Test 2	Baseline	1.89 ± 0.31				
	3 months	1.07 ± 0.27	BL vs 3M	0.82 ± 0.37	8.50	0.000
	6 months	0.88 ± 0.24	BL vs 6M	1.00 ± 0.37	0.00	0.000
			3M vs 6M	0.18 ± 0.17	4.10	0.001

2.10±1.05 respectively for test 1, and 2.70±0.64 and 1.96±0.54 respectively for test 2. The mean defect resolution difference was found to be statistically significant.

On intergroup comparison, at three months, the mean defect resolution difference between the control and test 1 (2.03±1.66) and between the control and test 2 (1.40±1.54) were significant, but between test 1 and test 2 (0.63±.78) it was not significant. At six months, the mean defect resolution difference between the control and test 1 (2.06±1.64) and between the control and test 2 (1.56±1.52) were significant, but between test 1and test 2 (0.50±1.66) it was not significant (Table 5, Figure 3).

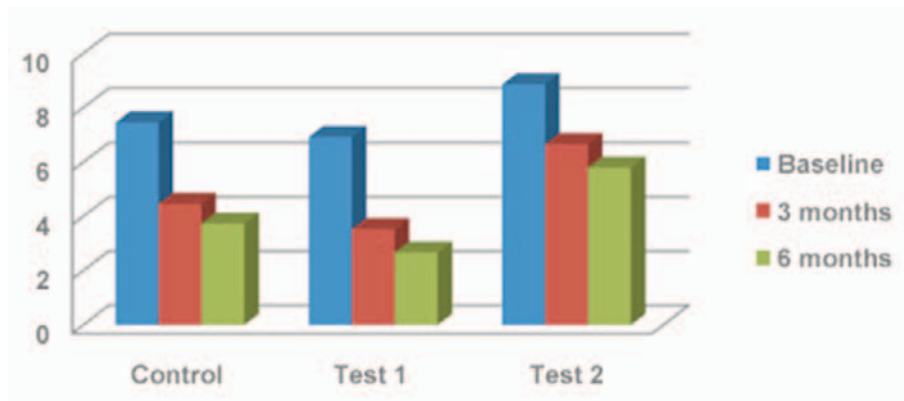**Table 3. Intergroup comparison of pocket depth at different observation periods.**

Observation Period	Group	Mean ± S.D.	Comparison	Mean ± S.D.	t value	p value
Baseline	Control	7.00 ± 0.65	Control vs Test 1	0.20 ± 1.08	0.71	0.486
	Test 1	6.80 ± 0.77	Test 1 vs Test 2	1.46 ± 1.80	3.14	0.007
	Test 2	8.26 ± 1.53	Control vs Test 2	1.26 ± 1.38	3.53	0.003
3 months	Control	4.13 ± 0.74	Control vs Test 1	0.73 ± 1.38	2.04	0.045
	Test 1	3.40 ± 1.05	Test 1 vs Test 2	2.06 ± 1.75	4.57	0.000
	Test 2	5.46 ± 1.24	Control vs Test 2	1.33 ± 1.04	4.93	0.000
6 months	Control	3.40 ± 0.50	Control vs Test 1	0.73 ± 1.03	2.75	0.16
	Test 1	2.66 ± 0.72	Test 1 vs Test 2	1.60 ± 1.12	5.52	0.000
	Test 2	4.26 ± 1.23	Control vs Test 2	0.86 ± 1.12	2.98	0.010

Figure 1. Intergroup comparison of pocket depth.

Table 4. Intergroup comparison of clinical attachment level at different observation periods.
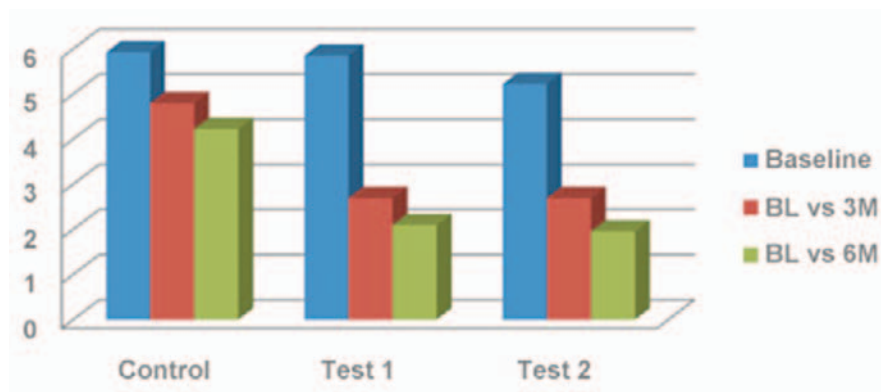
Observation Period	Group	Mean ± S.D.	Comparison	Mean ± S.D.	t value	p value
Baseline	Control	7.46 ± 1.06	Control vs Test 1	0.53 ± 1.55	1.33	0.205
	Test 1	6.93 ± 0.79	Test 1 vs Test 2	1.93 ± 1.86	4.00	0.001
	Test 2	8.86 ± 1.35	Control vs Test 2	1.40 ± 1.50	3.60	0.003
3 months	Control	4.46 ± 0.91	Control vs Test 1	0.93 ± 1.57	2.28	0.038
	Test 1	3.53 ± 1.12	Test 1 vs Test 2	3.13 ± 1.88	6.43	0.000
	Test 2	6.66 ± 1.29	Control vs Test 2	2.20 ± 1.20	7.05	0.000
6 months	Control	3.73 ± 0.70	Control vs Test 1	1.06 ± 1.09	3.75	0.002
	Test 1	2.66 ± 0.72	Test 1 vs Test 2	3.13 ± 1.50	8.06	0.000
	Test 2	5.80 ± 1.26	Control vs Test 2	2.06 ± 1.27	6.25	0.000

Figure 2. Intergroup comparison of clinical attachment level.

Table 5. Comparison of defect resolution at different observation periods in different groups.

| Group	Observation Period	Mean ± S.D.	Comparison	Mean ± S.D.	*t* value	*p* value
Control	Baseline	5.93 ± 1.75				
	3 months	1.13 ± 0.71	BL vs 3M	4.80 ± 1.81	10.26	0.000
	6 months	1.70 ± 0.70	BL vs 6M	4.23 ± 1.67	9.76	0.000
			3M vs 6M	0.56 ± 0.37	5.90	0.000
Test 1	Baseline	5.86 ± 1.59				
	3 months	3.16 ± 1.27	BL vs 3M	2.70 ± 0.70	14.89	0.000
	6 months	3.76 ± 1.33	BL vs 6M	2.10 ± 1.05	7.70	0.000
			3M vs 6M	0.60 ± 0.57	4.05	0.001
Test 2	Baseline	5.23 ± 1.42				
	3 months	2.53 ± 1.31	BL vs 3M	2.70 ± 0.64	16.10	0.000
	6 months	3.26 ± 1.29	BL vs 6M	1.96 ± 0.54	13.85	0.000
			3M vs 6M	0.73 ± 0.41	6.81	0.000

Figure 3. Intergroup comparison of defect resolution.

Table 6. Intergroup comparison of percentage of defect resolution at different observation periods.

Observation Period	Group	Mean ± S.D.	Comparison	Mean ± S.D.	t value	p value
3 months	Control	19.87 ± 12.90	Control vs Test 1	34.05 ± 15.12	8.70	0.000
	Test 1	55.93 ± 10.90	Test 1 vs Test 2	9.01 ± 17.12	2.00	0.601
	Test 2	44.92 ± 15.35	Control vs Test 2	25.04 ± 19.38	5.00	0.000
6 months	Control	29.45 ± 11.35	Control vs Test 1	37.56 ± 14.28	10.18	0.000
	Test 1	67.01 ± 8.86	Test 1 vs Test 2	5.74 ± 3.33	1.72	0.107
	Test 2	61.26 ± 10.83	Control vs Test 2	31.81 ± 4.05	7.66	0.000
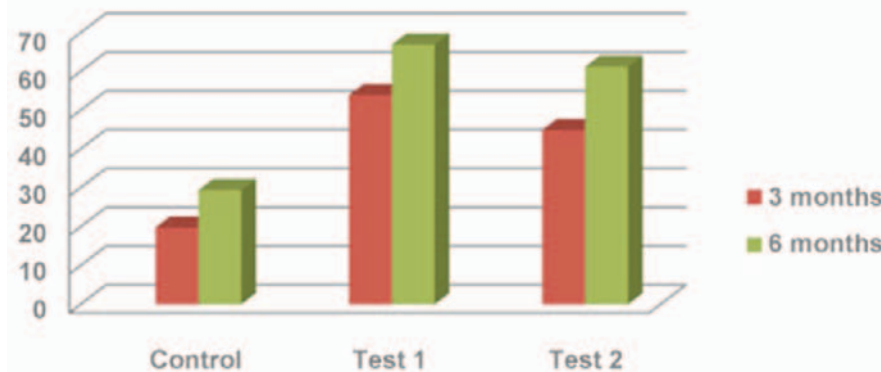
Figure 4. Intergroup comparison of percentage defect resolution.

The mean percentage of defect resolution from the baseline to three months and six months postsurgery was 53.93±10.90 and 67.01±8.86 respectively for test group 1, 44.92±15.35 and 61.26±10.83 respectively for test group 2, and 19.87±12.90 and 29.45±11.35 respectively for the control.

On intergroup comparison, at three months, the mean percentage of defect resolution difference between the control and test 1 (34.05±15.12) and between the control and test 2 (25.04±19.38) were significant, but between test 1 and test 2 (9.01±17.12) it was not significant. At six months, the mean percentage of defect resolution between the control and test 1 (37.56±14.28) and between the control and test 2 (31.81±4.15) were significant, but between test 1 and test 2 (5.74±3.33) it was not significant (Table 6, Figure 4).

Discussion

The present study was designed to evaluate clinically the efficacy of biphasic calcium phosphate (ossifi®) and bioactive glass in the treatment of periodontal osseous defects as compared with open-flap debridement. Being alloplastic in nature, these graft materials do not increase the patient morbidity and do not require a second surgical site as in the case of autografts.

Approximately 60% of the bone graft substitutes currently available involve ceramics, either alone or in combination with another material. These include calcium sulfate, bioactive glass, and calcium phosphate. The use of ceramics, especially calcium phosphates, is driven in part because of the fact that the primary inorganic component of bone is calcium hydroxyapatite, a subset of the calcium phosphate group. In addition, calcium phosphates are osteoconductive, osteointegrative (the newly formed mineralized tissue forms intimate bonds with the implant material), and, in some cases, osteoinductive. They often require high temperatures for scaffold formation and have brittle properties; therefore, they are frequently combined with other materials to form a composite. Bioactive glass (bioglass) is a biologically active silicate-based glass. Its high modulus and brittle nature

Pocket Depth Reduction
Pre-op Probe Depth
Post-op Probe Depth
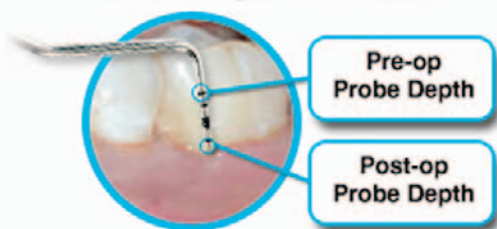
make its applications limited, but it has been used in combination with polymethylmethacrylate to form bioactive bone cement and with metal implants as a coating to form a calcium-deficient carbonated calcium phosphate layer. This layer facilitates the chemical bonding of the implant to surrounding bone.[5]

ossifi is a synthesized combination of hydroxyapatite and β-tricalcium phosphate in a 70/30 ratio and has calcium phosphate in its purest form. It has a bioceramic matrix that is extremely biocompatible and highly osteoconductive. Bioactive glass particulate composed of SiO_2 45%, NaO 24.5%, CaO 24.5%, and P_2O_5 6% by weight is osteoconductive in nature as a surface biomodification occurs when it is implanted in the bony defect. Due to the modified surface, local proteins are incorporated into the newly formed crystalline hydroxycarbonateapatite layer. Another key feature is osteostimulation, in which bone forms throughout a defect simultaneously, not just from the margins; the ion release capability of this material also increases the cellular activity of osteoblasts.[4]

Intraosseous defects of ≥3 mm as observed radiographically and with probing depth of ≥-5 mm when observed clinically were selected. Patients with poorly controlled diabetes were excluded from the study. Diabetics with less than optimal glucose control are at increased risk for failure of regenerative procedures because of increased microbial challenge and delayed wound healing.[6] Smokers also were excluded from the study as smoking has been associated with a strong risk factor for adverse outcome of regenerative therapy.[7]

All the patients were subjected to initial preparation, which consisted of full mouth scaling and root planing. Initial preparation was done to reduce the gingival inflammation as it improved the plaque control by the patient before surgery

because postoperative gain in clinical attachment level was greater when plaque control is optimal. The same criteria were noticed by Machtei.[8] All the measurements were taken with a manual calibrated UNC-15 periodontal probe that had color coding at 5, 10, and 15 mm with markings from 0 to 15 at 1 mm intervals, which made it easier to reproduce the measurement. Before surgery, a customized acrylic stent was fabricated on the study cast for each patient. The stent was grooved in an occlusal apical direction. This was done to minimize the change in the direction of probing at subsequent recordings. Occlusion was evaluated prior to surgery and was adjusted to reduce excessive mobility, as attachment gains were greater in nonmobile teeth than mobile teeth after periodontal therapy.[9] Fleszar observed that attachment gains were greater in nonmobile teeth.[10]

The test materials were placed into the defects using standard surgical techniques of bone grafting. Overfilling of the graft material was avoided as it could interfere with proper flap closure, thereby retarding healing and possibly resulting in loss of the graft material. The flap was closed with interrupted direct loop sutures using 3-0 Mersilk sutures. The surgical site was covered with periodontal dressing for seven days.

The patients were given both verbal and written instructions. Antibiotics and analgesics were prescribed to all the patients after surgery. Patients were instructed to use 0.2% chlorhexidine gluconate mouthwash twice daily for 14 days.

There was a statistically significant reduction in mean values of pocket depth and clinical attachment level at three months and six months in all the groups. These findings are in agreement with the results of Froum[11] and Gupta.[12]

The mean amount of defect resolution from the baseline to three months and six months in all the groups was statistically significant.

The mean percentage of defect resolution at three months and six months in all the groups was statistically significant. These results were in accordance with the study conducted by Meffert[13] and Pepelassi.[14]

Although not subject to statistical analysis, from a clinical point of view, Bioglass™ helped in

hemostasis and was easier to manipulate as compared to ossifi as it forms a clump and is retained in the defect.

Conclusion

In conclusion, both biphasic calcium phosphate (ossifi®) and bioactive glass improve the healing outcomes regarding probing depth reduction, osseous defect resolution, and gain in clinical attachment as compared to open-flap debridement. Better biocompatibility, excellent handling properties, and improved tissue response to the material are the definite benefits of using ossifi and bioactive glass over the control. Both test groups showed significant improvement over the control in both the clinical and radiological parameters. Histological evaluation and long-term clinical trials are required for further study. Applying the philosophy of tissue engineering to the healing of bone, ossifi has an interconnected pore system to allow cellular proliferation and migration. It is recommended that future studies employ a greater number of patients as well as experimental studies be conducted to analyze the maximum potential of bioceramics and bioactive glass in regenerative periodontal therapy.

Clinical Significance

Calcium phosphates are the most frequently used graft materials nowadays. They circumvent most of the difficulties and limitations associated with autografts and allografts. As more materials are adapted and discovered, preexisting products are finding new applications and effectiveness in combination with newly emerging technology.

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