Clinical Evaluation of a Bioactive Glass in the Treatment of Periodontal Osseous Defects

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Abstract

Background

PerioGlas is an alloplastic bone graft material which is used for the treatment of intrabony defects. Among the alloplastic synthetic bone grafts, bioactive glass is an osteoconductive and osteostimulative graft material which enhances bone formation in regenerative procedures.

Method

Efficacy of bioactive glass (PerioGlas) was assessed in 30 patients for the treatment of periodontal osseous defects and was compared to open flap debridement alone.

Results

Statistically significant improvements were demonstrated at 6 months post treatment in all the parameters studied. Mean probing depth reduction, clinical attachment level, radiographic bone fill were 4.27mm, 5.87mm, 3.27mm respectively for test sites and 4.43mm, 5.67mm, 2.25mm respectively for control sites at 6 months.

Conclusions

The results of the present study show that bioactive glass improves the healing outcomes regarding probing depth reduction, osseous defect fill, and gain in clinical attachment.

Introduction

The complete and predictable restoration of the periodontium following trauma or infection remains a critical objective in periodontics[1]. Grafts are used to provide a scaffold for bone regeneration, resolve bony defects resulting from periodontal disease[2]. Different types of bone grafts used to restore the lost periodontal attachment apparatus have showed varying degree of success[3]. On a histologic basis alloplasts act almost exclusively as biologic fillers inducing little bone fill and very limited periodontal regeneration[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[5,6].

Bioactive glass (PerioGlas - NovaBone) is a 45S5 bioglass composed of silicon oxide 45%, sodium oxide 24.5%, and calcium oxide 24.5%, phosphorus pentoxide 6% with particle size of 90- 700 μm. It has a good clinical manageability, haemostatic properties, and is not only osteoconductive, but also may act as a barrier retarding epithelial downgrowth[6]. It has the ability to bond to both hard and soft tissue, a property rarely found in other alloplasts. The basis of the bonding property of bioactive glasses is their chemical reactivity with body (tissue) fluids. A series of chemical reactions occurs, which results in the formation of hydroxyapatite layer to which bone can bond[7]. Sites implanted with bioactive glass show significantly less junctional epithelium migration, stopping at the level of material and bone formation around the particles[8]. Bioactive glass has also been used in the treatment of conductive deafness and alveolar ridge resorption in humans[9].

The purpose of this study was to evaluate the efficacy of bioactive glass as a bone graft in the treatment of osseous defects, over open flap debridement both clinically as well as radiographically.

Materials and Method

Patient selection

30 subjects (18 males and 12 females) were selected randomly for the study from those

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attending the Out Patient Department of Periodontics at D.A.V. Centenary Dental College and Hospital, Yamuna Nagar India. A complete clinical examination that included radiographs was performed. Thorough medical and dental histories were obtained. The nature of study was explained to the patients, and informed consent was obtained. The study was approved by University's Institutional Review Board.

Inclusion Criteria[3]

Patients diagnosed as suffering from moderate to advanced periodontitis, in age group between 35 to 55 years were selected for the study. Patients with an inter-proximal probing depth [3] 6 mm with radiographic evidence of bone loss of at least 3 mm from the alveolar crest to the base of defect were included. Only patients, who showed compliance with the maintenance program and recall appointments were selected.

Exclusion Criteria[10]

Patients suffering from systemic diseases, with previously implanted natural or synthetic materials in the selected defects and pregnant or lactating females were excluded from the study.

Intial Therapy and Measurements

At the first appointment scaling and root planning was performed and oral hygiene instructions were given. Occlusal adjustment was performed if trauma from occlusion was diagnosed. Prior to surgery, a customized acrylic stent was fabricated for each patient and stored on the study cast to distortion. The stent was grooved in an occlusal apical direction with a tapered bur so that the periodontal probe (UNC-15 Hufriedy, USA) was returned to the same position for each successive measurement[11].

The following clinical parameters were recorded at baseline, at 3 months and 6 months post-operatively.

1. Plaque index
2. Gingival index
3. Pocket depth
4. Clinical attachment level

Using the apical margin of the customized acrylic stent as the fixed reference point the following measurements were made at the proximal line angle of the tooth with the associated bony defect. Fixed reference point was used for better reproducibility. All clinical measurements were made by one examiner, using a periodontal probe. Only one site representing the deepest point of the defect was included and following measurements were made:-

1. Fixed Reference Point (FRP) to the Base of Pocket (BP)
2. Fixed reference point to the Gingival Margin (GM)
3. Fixed reference point to the Cemento-Enamel Junction (CEJ)

The following calculations were made :

1. Pocket Depth = (FRP to BP) - (FRP to GM)
2. Clinical attachment level = (FRP to BP) - (FRP to CEJ)

Measurements were made pre-operatively and post-operatively for test sites at baseline, 3 months and 6 months and for control sites at baseline and 6 months.

Radiographic-Assessment and Measurements

Radiographic evaluation was done at baseline, 3 month and 6 month for test sites and at baseline and 6 months for control sites. Intra oral periapical radiographs were taken with millimeter grid (X-ray-Mesh Meyer-Haake) superimposed on the radiographic film (Fig 1c, 1d). Distance and angulations of the radiographic source and beam were standardized by fabrication of radiographic bite blocks for each experimental site using impression material and film holders.

Bone defect depth was measured as the distance from the alveolar crest to the base of the bone defect. Amount of defect fill was calculated as the difference between initial and post-surgical defect depth; thereafter percentage of defect fill was calculated.

Surgical Procedure[12]

Under aseptic conditions, the area was anaesthetized using Lignocaine with Adrenaline injection and Intracrevicular incisions were given to raise mucoperiosteal flap both buccally and lingually including one tooth mesial and

distal of the tooth/teeth associated with the osseous defect. Vertical incision was used wherever necessary. Care was exercised to avoid flap perforation or loss of papilla to ensure coverage and containment of the graft post-surgically. All granulation tissue and islands of calculus were removed. Gentle root planning of exposed root surfaces was performed. Osteoplasty of any bony ledges was done to ensure abutting of papilla and tension free primary closure of flap. After cleaning, the surgical area was irrigated with sterile saline. The control sites were then sutured with interrupted direct loop sutures using 3-0 silk suture.

In the test sites small increments of graft material were added. PerioGlas was prepared by emptying particulate into a sterile dappen dish and adding 4 to 6 drops of saline until the mixture was paste like in consistency. Working time was approximately 2-3 minutes[11]. Graft was condensed using an amalgam condenser, to adapt the particles to the configuration of defect till the defect was completely filled (fig 1a, 1b). The soft tissue flap was then repositioned at the original level and closed with interrupted direct loop sutures. Surgical site was protected by applying a periodontal dressing.

All subjects received instructions to rinse with 0.2% chlorhexidine gluconate solution twice daily for 14 days and to refrain from all mechanical plaque control in and around the surgical area for 2 weeks. Tetracycline was prescribed to the patient on a regimen of 250 mg four times a day for 14 days and a non-steroidal anti inflammatory agent for next 6 days. After 1 week, dressing, sutures and any plaque present in the area was removed[10].

Patients were recalled again at 14 days and 30 days for additional follow up and plaque control and were instructed to clean the teeth in the surgical area with a soft toothbrush. Thereafter, recall appointments were scheduled at 1 month, 3 months and 6 months post surgically for tissue evaluation, plaque debridement, oral hygiene review, radiographic evaluation and recording of clinical parameters. Neither probing nor subgingival instrumentation was carried out during first 3 months after surgery.

Data Analysis

A total of 30 periodontal osseous defects were treated, 15 test sites & 15 control sites. Mean values and standard deviations were calculated for each variable. The paired student t-test was utilized to evaluate and establish differences between baseline and post surgical measurements within a group. The unpaired student t-test was utilized to evaluate and establish differences between two groups (test Vs control) at baseline and 6 months post-operatively.

Results

Graft material demonstrated cohesiveness which facilitated accuracy of placement and, it adapted to the respective osseous defect. Postoperative healing was uneventful.

Plaque Index

There was no statistically significant difference in mean values of plaque index at baseline ($p=0.563$) and 6 months ($p=0.383$) between test and control groups. There was no statistically significant difference ($p=0.255$) in mean change in plaque index at 6 months between test sites (1.00 + 0.44) and control sites (0.99 + 0.23) (Table-1).

Gingival Index

There was no statistically significant difference in mean values of gingival index at baseline ($p=0.319$) between test and control groups. Difference in mean values of gingival index at 6 months between test and control groups was statistically significant ($p=0.009$). There was no statistically significant difference ($p=0.288$) in mean change in gingival index at 6 months between test sites (1.00 + 0.37) and control sites (0.85 + 0.28) (Table-1).

Pocket Depth

The mean pocket depth at baseline was 8.27 + 1.5 whereas mean values after 3 months and 6 months post-operatively were 5.47 + 1.24 and 4.27 + 1.27 respectively for test sites. The mean pocket depth at baseline was 7.73 + 1.90 whereas mean value after 6 months postoperative was 4.43 + 1.74 for control sites. For test sites, the mean difference of pocket depth at 3 months and 6 months from baseline was 2.80 + 0.67 and 4.00 + 1.20 respectively which was statistically

significant (p=0) both at 3 and 6 months. For control sites, the mean difference of pocket depth at 6 months from baseline was 3.30 + 0.79 which was statistically significant (p=0).

There was no statistically significant difference in mean values of pocket depth at baseline (p=0.405) and 6 months (p=0.199) between test and control group. The mean change in pocket depth at 6 months between test sites (4.27 + 1.20) and control sites (3.30 + 0.79) was statistically significant (p=0.002) (Table-1).

Clinical Attachment Level

The mean clinical attachment level at baseline was 8.87 + 1.35 whereas mean values after 3 months and 6 months post-operatively were 6.67 + 1.29 and 5.87 + 1.44 respectively for test sites. The mean clinical attachment level at baseline was 7.80 + 1.82 whereas mean value after 6 months postoperative was 5.67 + 1.49 for control sites. For test sites, the mean difference of clinical attachment level at 3 months and 6 months from baseline was 2.20 + 0.67 and 3.00 + 1.30 respectively which was statistically significant (p=0) both at 3 and 6 months. For control sites, the mean difference of clinical attachment level at 6 months from baseline was 2.13 + 0.83 which was statistically significant (p=0).

There was no statistically significant difference in mean values of clinical attachment level at baseline (p=0.079) and 6 months (p=0.540) between test and control groups. The mean change in clinical attachment level at 6 months between test sites (3.00 + 1.30) and control sites (2.13 + 0.83) was statistically significant (p=0.001) (Table-1).

Amount of Defectfill

The mean baseline osseous defect depth was 5.23 + 1.42 for test sites and 3.93 + 1.09 for control sites.

The mean amount of defect fill from baseline to 3 month and 6 months post surgery were 2.47 + 1.35 and 3.27 + 1.26 respectively for test sites. The mean amount of defect fill from baseline to 6 month post surgery was 2.25 + 0.96 for control sites. For test sites, the mean difference of amount of defect fill at 3 month & 6 month from baseline was 3.13 + 0.76 and 1.97 + 0.48 which was statistically significant (p=0). For control sites, the mean difference of amount of defect fill at 6 months from baseline was 1.68 + 0.71 which was statistically significant (p=0). There was statistically significant difference in mean values of defect fill at baseline (p=0.009) and 6 months (p=0.002) between test and control groups.

There was no statistically significant difference (p=0.767) in mean change in amount of defect fill at 6 months between test sites (1.97 + 0.48) & control sites (1.68 + 0.71) (Table-1).

Percentage of Defectfill

The mean percentage of defect fill from baseline to 3 months and 6 months post surgery was 44.92 + 14.0 and 61.27 + 9.42 respectively for test sites. The mean percentage of defect fill from baseline to 6 months post surgery was 43.20 + 16.7 for control sites. There was statistically significant difference (p=0.008) in mean change in percentage of defect fill at 6 months between test sites (61.27 + 9.42) & control sites (43.20 + 16.7).

Discussion

PerioGlas being alloplastic in nature it doesn't increase the patient morbidity and doesn't require second surgical site as in case of autografts. PerioGlas is osteoconductive which undergoes surface biomodification when implanted in the bony defect, due to which, there is incorporation of local proteins into newly formed crystalline hydroxycarbonateapatite layer. Other key feature is osteostimulation in which bone forms through out a defect simultaneously not just from the margins and ion release capability of PerioGlas increases the cellular activity of osteoblasts. When implanted in periodontal osseous defects, bioactive glass (PerioGlas) acts as a haemostatic agent, is not washed out of the site and forms a cohesive mass when mixed with saline/blood. This hydroxylcarbonateapatite layer is negatively charged and due to increase in electrostatic charges, water is absorbed over it quickly. Hydrogen bonding occurs between the water molecule and the hydroxyl groups of the silanol. This hydrostatic attraction gives bioactive glass cohesiveness that when in contact with blood is prevented from migrating from the surgical site[13,14]. Bioactive glass contributed to an

increase in wound stability and prevented collapse of the flap. Wikesjo UME et al[15] concluded that outcome of any type of regenerative procedure is strongly dependent upon the available space under mucoperiosteal flap and stability of wound.

There was statistically significant difference in the mean plaque index and gingival index at 6 months post-operatively from baseline in both control and test groups. Ong MA et al[16] evaluated bioactive glass alloplast in treating periodontal osseous defects and found no significant difference in plaque and gingival index from baseline to 12 months post-surgically.

The mean pocket depth reduction from baseline to 3 and 6 months post-surgery was 2.8mm and 4.0mm respectively for test group and was 3.30mm at 6 months post surgery for control group, which were statistically significant for both the groups. This finding is in agreement with the results of study by Sculean et al[3] who reported a mean pocket depth of 3.8mm at 1 year post surgery after treatment with bioactive glass. The mean change in pocket depth from baseline to 6 month post surgery was statistically significantly (0.002) greater in test sites (4.0mm) compared to control sites (3.30mm).

The mean attachment gain from baseline to 3 and 6 months post-surgery was 2.20mm and 3.00mm for test group and was 2.13mm at 6 months post surgery for control group, which were statistically significant for both the groups. There was a statistically significant clinical attachment gain from baseline to 6 months in test sites (3.00mm) compared to the control sites (2.13mm). These findings are in accordance with findings of Park JS et al[17]. The mean change in clinical attachment level from baseline to 6 month post surgery was statistically significantly (0.001) greater in test sites (3.00mm) compared to control sites (2.13).

The mean amount of defect fill from baseline to 3 and 6 months was 2.47mm and 3.27mm respectively for test groups and was 2.25mm at 6 months post surgery for control group which were statistically significant. The mean percentage of defect fill from baseline to 3 and 6 months post-surgery was 44.92% and 61.27% respectively for test group, and 43.20% for control group which was statistically significant. The mean change in percentage of defect fill from baseline to 6 months was significantly greater in test group (61.27%) compared to control group (43.20%).

The results of the present study are consistent with Garett's assessment that "In controlled clinical trials treating furcation defects and intraosseous defects non-absorbable and absorbable synthetic graft materials have consistently demonstrated clinical advantages beyond that achieved by debridement alone".[4] Schepers E et al[18] also reported effective bone regeneration using bioactive glass in extraction sockets, periodontal defects and apical resection sites.

Histological study ,a gold standard for assessment for regenerative procedure was not done because of ethical considerations. Based on the results of the present clinical investigation further histological and long term studies are warranted.

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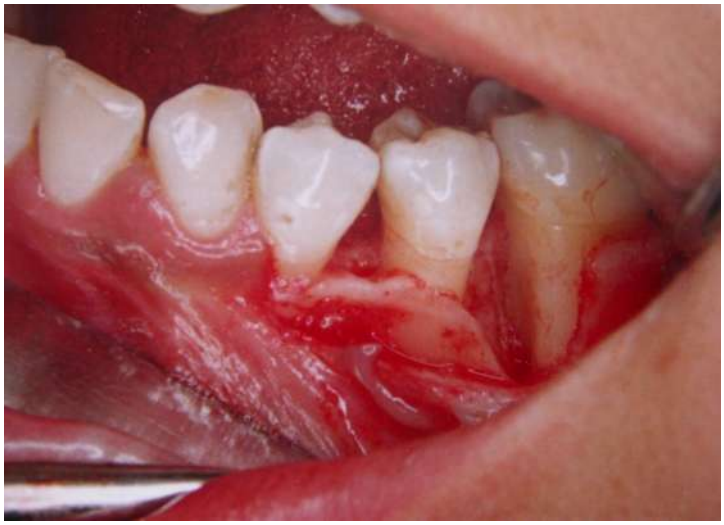

Fig 1a Two-wall periodontal osseous defect on the mesial of the mandibular first molar after debridement

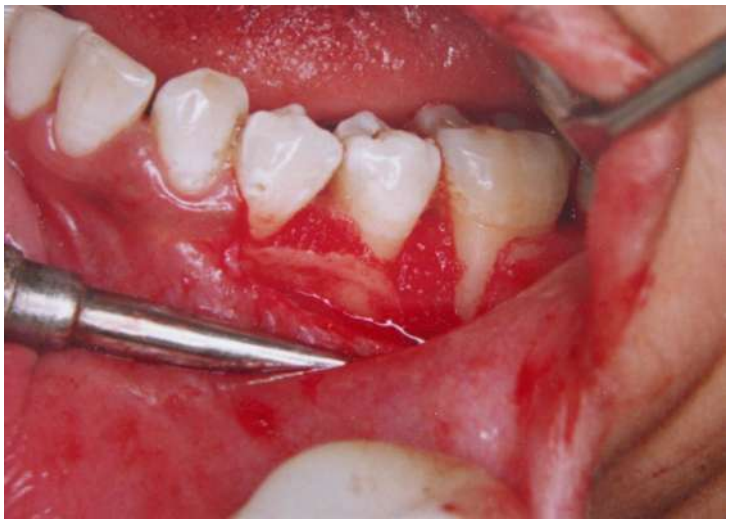

Fig 1b PerioGlas packed into periodontal osseous defect

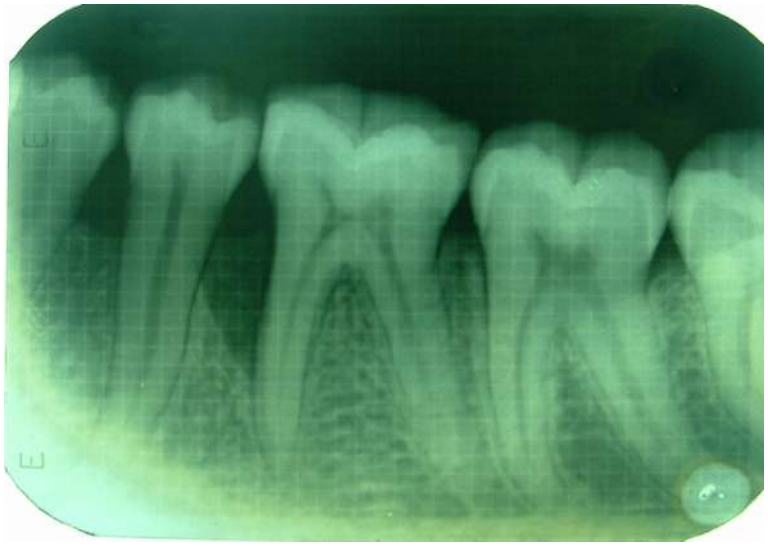

Fig 1c Preoperative radiograph demonstrates periodontal osseous defect on the mesial of mandibular first molar

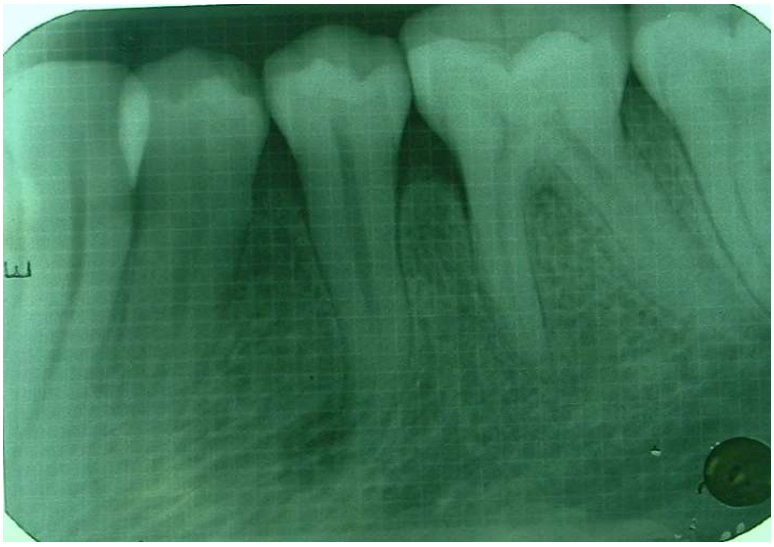

Fig 1f Post-operative radiograph after 6 months

Table 1 : Comparison of Mean Change in Investigated Parameters at 6 Months Between Test and Control Group

	TEST	CONTROL	P-VALUE
PLAQUE INDEX	1.00 ± 0.44	0.99 ± 0.23	0.255
GINGIVAL INDEX	1.00 ± 0.37	0.85 ± 0.28	0.288
POCKET DEPTH	4.00 ± 1.20	3.30 ± 0.79	0.002
CLINICAL ATTACHMENT LEVEL	3.00 ± 1.30	2.13 ± 0.83	0.001
DEFECT FILL	1.97 ± 0.48	1.68 ± 0.71	0.767