

Research Article

## Evaluation of the effects of an alloplastic bioactive graft material in the treatment of periodontal osseous defects: A Clinical Study

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### Abstract

#### **Background**

*Bioactive synthetic materials are commonly used graft materials for various intrabony human defects and have shown the potential to enhance bone formation. The purpose of this study was to evaluate the efficacy of a bioactive synthetic graft material in the treatment of intrabony periodontal defects.*

#### **Materials and Methods**

*Fourteen intrabony defects in twelve systemically healthy subjects having moderate to severe chronic periodontitis were evaluated after bone grafting with bioactive ceramic filler for 6 months. Clinical and radiographic evaluations were made at baseline, at 3- and 6-months following surgery.*

**Results**

Mean radiographic defect fill of 68.76% was observed in 6 months, which was statistically significant. A statistically significant relative attachment level gain of  $2.91 \pm 1.18$  mm and probing pocket depth reduction of  $4.27 \pm 1.16$  mm was recorded at the end of the study. A significant decrease in mobility and gingival index was observed.

**Conclusions**

Bioactive glass is an efficacious treatment option for the reconstruction of intrabony periodontal defects as it led to statistically significant improvements in the clinical and radiographic parameters.

**Keywords:** Bioactive glass, intrabony defects, periodontitis, regeneration

**Introduction**

Periodontal disease is the most common worldwide affliction. It is characterized by the formation of gingival inflammation, periodontal pocket, clinical attachment loss and /or tooth mobility when there is excessive bone loss. The main goal of periodontal treatment is to prevent further attachment loss and predictably restore the periodontal supporting structures that were lost because of the disease or trauma in a way that the architecture and function of the lost structures can be re-established.(1) Functional reconstruction requires periodontal regeneration, which aims at the restoration of lost periodontium or supporting tissues and includes the formation of new alveolar bone, new cementum and new periodontal ligament.(2) Current literature suggests that only guided tissue regeneration and osseous grafting have resulted in successful periodontal regeneration.(3) The efforts to obtain optimal regeneration of the periodontium has resulted in many clinical trials and studies which included the utilization of autologous, allogenic, and alloplastic implants in the treatment of periodontal osseous defects.(4) Drawbacks of autografts and allografts ha lead to the development of various alloplastic materials. Among alloplastic graft materials, bioactive ceramics is a group of osteoconductive materials including Hydroxyapatite, Flouroapatite, Bioactive glass and Tricalcium phosphate. The Discovery of bioceramics was made in 1969 by a ceramic engineer Lary.(5) Bioactive glass is a ceramic composed principally of SiO<sub>2</sub>. The original composition of bioactive glass approved by FDA, designated 45S5 was, 45 mol% of SiO<sub>2</sub>, 26.9 mol% CaO, 24.4 mol% Na<sub>2</sub>O, 2.5 mol% P<sub>2</sub>O<sub>5</sub>. This material can bond to bone through the development of a surface layer of carbonated hydroxyapatite, *in situ*. The calcium phosphate layer is thought to promote adsorption and concentration of osteoblast derived protein necessary for mineralization of extracellular matrix.(6) In the present study, an effort has been made to evaluate the



efficacy of a commercially available bioactive synthetic graft, in the treatment of intrabony periodontal osseous defects.

## Materials and Methods

### Material

Novabone Dental Putty was used as the material for study. It is a premixed composite of bioactive calcium-phospho-silicate particulate which is composed solely of elements that exist naturally in normal bone (Ca, P, Na, Si, O) and an absorbable binder which is a combination of polyethylene glycol and glycerin. The material requires no mixing or preparation before application. This nonhardening putty is ready to use and is to be applied directly to the intended graft site.

### Study method

#### Patient selection

12 systemically healthy subjects suffering from moderate to severe chronic periodontitis, aging between 35-60 years, having radiographic evidence of one or more vertical defects (two or three walled) and probing pocket depth of 6 mm or more at the experimental site were enrolled.

Patients who were suffering from any medical condition or were on a therapeutic regimen that could decrease the probability of soft tissue or bone healing, pregnant or lactating women, teeth with furcation involvement, nonvital or endodontically treated teeth, third molars, one walled defects, patients with parafunctional habits i.e., bruxism and who had periodontal surgery in last 6 months, allergic to tetracycline, chlorhexidine were excluded.

#### Clinical parameters

The graft material was assessed based on evaluation of certain selected clinical parameters, soft and hard tissue measurements of the experimental defect. The clinical parameters i.e., Probing pocket depth, Relative attachment level, Gingival recession, Mobility, Plaque index, Gingival index and Radiographic parameters (depth of intrabony defect) were recorded by a single investigator just before surgery as baseline data, and they were re-evaluated at 3 and 6 months post-surgery.



Probing pocket depth was measured as the distance from the gingival margin to the base of the pocket using the University of North Carolina probe. Relative attachment level and the gingival recession was measured with the same periodontal probe from a reference notch on a vacuum formed acrylic stent.

To facilitate serial radiographic comparisons, intraoral periapical radiographs with attached X-ray grid, standardized using the paralleling technique were utilized. The grid was calibrated in millimeters, which could be counted to measure the osseous defect fill on the radiograph.

### **Study protocol**

After completing oral prophylaxis, subjects were re-evaluated after 4 weeks. The subjects showing acceptable oral hygiene were selected for the study and signed written consents were obtained from the patients.

### **Surgical protocol**

Surgical procedure was performed under local anesthesia. It included intrasulcular incisions, full-thickness flap elevation, meticulous debridement and root planing, endosseous defect filling with bioactive glass, flap repositioning. Suturing was done with interrupted 3-0 silk sutures. The periodontal dressing was placed. Routine Postoperative instructions were given to all the subjects.

Antibiotics Doxycycline Hyclate (100 mg every 12 hours on the day of surgery and every 24 hours for subsequent 7 days) were prescribed and Chlorhexidine mouth rinse (0.12%) twice daily for 14 days. Subjects were recalled after 7 days for suture removal. Scaling and root planning, motivation, and oral hygiene instructions were reinforced at 1, 3 and 6 months recall visits. Clinical and radiographic parameters were re-evaluated at 3 and 6 months post-surgery.

### **Statistical analysis**

The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 16.0 for Windows). All quantitative variables were estimated using measures of central location (mean) and measures of dispersion (standard deviation and standard error). For time-related comparison, a Paired *t*-test was applied. All statistical tests were two-sided and performed at a significance level of  $\alpha=0.05$ .



### Results

Twelve patients in the age group 30-65 years had participated in this study. Fourteen intrabony defects were treated with Novabone Dental Putty. All the treated sites resulted in uneventful healing. No complications such as allergic reaction, abscesses, or infections were observed throughout the study period, in any of the patients.

Statistically, a significant mean radiographic osseous defect fill of 68.76% was observed from baseline to 6 months (Table 1). About 85% of the intrabony defects studied, had a defect fill of equal to or more than 50%, whereas 15% of the defects had less than 50% defect fill at the end of 6 months (Table 2).

Sr No.	Radiographic Parameter	Percentage Mean Change	Significance
1.	RD1-RD2	32.76	HS(Highly significant)
2.	RD1-RD3	68.76	S(Significant)
3.	RD2-RD3	48.09	NS(Non Significant)

**Table 1:** Mean percentage change in radiographic osseous defect measurements at different periods of observation

RD1-RD2 ( % Change from baseline to 3 months)

RD1-RD3 ( % Change from baseline to 6 months)

RD2- RD3 ( % Change from 3 months to 6 months)

	> 50 % fill	<50% % fill
No. Of Defect	12	2
% of defects	85	15

**Table 2:** Showing 50% or Greater Fill

To analyze the association of radiographic osseous defect fills to initial radiographic osseous defect depth, the defects were categorized into two groups for descriptive purposes: Group I: Defects with baseline radiographic depth less than or equal to 3 mm. (n=7), Group II; Defects with baseline radiographic depth of defect more than 3 mm.(n=7)



In a group, I radiographic osseous defect fill of 79.19% was observed from baseline to 6 months, which was statistically significant (Table 3). In this group, all the defects had 50% or greater radiographic osseous defect fill after 6 months. Group II had a radiographic osseous defect fill of 62.3% over 6 months (Table 3). Intergroup comparisons revealed that the difference in radiographic osseous defect fill was statistically significant for a group I as compared to group II.

Radiographic Parameter	Group	Mean % File	Standard Deviation
RD1-RD3	Group I	79.9%	16.16
	Group II	62.3%	16.01

**Table 3:** Summary of mean percentage radiographic osseous defect fill after 6 months in group I and group II.

A statistically significant probing pocket depth reduction of  $4.27 \pm 1.16$  mm was recorded after 6 months, ( $P < 0.001$ ). A mean relative attachment level gain of  $2.91 \pm 1.18$  mm was observed at the end of the study period, which was statistically significant. A statistically significant ( $P = 0.003$ ) decrease of  $0.74 \pm 0.72$  was observed in the mean mobility score from baseline to 6 months. A decrease of the score by  $0.52 \pm 0.36$  in the gingival index over 6 months was observed which was statistically significant ( $P = 0.003$ ). An increase in the gingival recession had also been observed.

## Discussion

Bone grafting is the most common form of regenerative therapy and is usually essential for restoring all types of periodontal supporting tissues.(5) For some years, so-called bioactive glass products have been available for the treatment of intrabony defects.(7) Bioactive glass has good manageability, hemostatic, and osteoconductive properties and it may also act as a barrier retarding epithelial down growth.(8-13) Widespread use, popularity among the clinicians and manufacturer's claims made us interested to study this particular material. The present study has evaluated the efficacy of bioactive synthetic graft material (Novabone Dental Putty) in the treatment of intrabony periodontal osseous defects.

The amount of mean radiographic osseous defect fill was measured to be 68.76% after 6 months, which was statistically significant ( $P < 0.001$ ). These findings are by studies of Mengel, *et al.*,(14) Froum, *et al.*,(15) and Lovelace, *et al.*,(16) who showed a mean bone fill of 65.0%, 62.0% and 61.8% respectively



in the bioactive glass treated sites. Park, *et al.*,(17) reported that a similar mean bone fill was observed in the intrabony defects which were treated with bioactive glass.

Group I (Subjects with initial radiographic osseous defect measurement equal to 3 mm) had a mean percentage radiographic osseous defect fill of 79.19% and Group II (subjects having initial radiographic osseous defect measurement more than 3 mm) showed 53.33% osseous defect fill. These findings are strikingly different from as reported by Rummelhart JM, Mellonig, *et al.*,(18) who had stated that greater regeneration is anticipated in deeper defects. In our study, Group II had lesser osseous defect fill as compared to group I, despite having greater initial radiographic osseous defect depth. This could be attributed to a variety of factors that can affect the outcome of regenerative periodontal therapy like defect characteristics (no. of walls, circumference, depth of the defect, the width of the defect), mobility, wound stability, plaque index, operator's technique and host factors, etc. Amongst all the defects, about 85% had a fill of equal to or greater than 50%, whereas 15% of the defects had a defect fill of less than 50%.

It is difficult to compare measurements of osseous defect fill in the present study with previous studies because of the mode of measurement. In the majority of earlier studies, re-entry measurements were made whereas only radiographic interpretation was used in this study. The re-entry procedure was not performed because it causes a degree of ethical concern and is usually not accepted by the patient. Furthermore, during the second surgery, the new connective tissue attachment may be disturbed and replaced by long junctional epithelium. Also, the problem of loss of crestal alveolar bone following the second intervention remains unresolved. (5) Histology is the ultimate standard to assess periodontal regeneration but cannot be performed due to ethical concerns as the tooth is needed to be sacrificed. Previous literature suggests that osseous defect fill is ranged between 10-30% for open flap debridement procedures, (19) whereas with the use of Novabone Dental Putty in the present study, 68.76% defect fill was recorded which was statistically significant.

A statistically significant mean probing pocket depth reduction of  $4.27 \pm 1.16$  mm was observed from baseline to 6 months. This reduction in probing pocket depth can be attributed to soft and hard tissue improvements following the resolution of inflammation and the osteogenic potential of the bone graft material used in the study. Our results are in agreement to the previous studies of Froum, *et al.*,(15) Lovelace, *et al.*,(16) Mengel, *et al.*(7) who had reported 4.26 mm, 3.07 mm, 3.8 mm reduction in probing pocket depth respectively over 6 months in sites treated with bioactive glass. Other studies by Ong, *et al.*,(20) Park, *et al.*,(17) Zamet, *et al.*,(21) have also demonstrated statistically significant reductions in probing pocket depth over 6 months in bioactive glass treated sites.



Relative attachment level gain of  $2.91 \pm 1.18$  mm was statistically significant from baseline to 6 months. This gain in attachment level can be attributed to periodontal regeneration, long junctional epithelium formation and/or soft tissue healing at the base of the pocket. These findings are by the studies of Lovelace, *et al.*, (16) Froum, *et al.*, (15) who reported approximately similar mean attachment level gain of  $2.27 \pm 0.8$  mm and 2.96 mm respectively in the sites treated with bioactive glass. Mengel, (14) Park, *et al.*, (17) Singh, *et al.*, (5) also reported that the sites treated with bioactive glass have shown a statistically significant gain of attachment levels 6 months post-surgery.

A statistically significant decrease in mobility scores was recorded and the decrease patterns seemed to be a reflection of a decrease of the inflammatory state, formation of new fibrous attachment and alveolar bone in the grafted sites. This decrease may also be attributed to mechanical support provided by the graft material. These findings are following the studies of Froum, *et al.*, (15) Meffert, *et al.*, (22) who reported a decrease in mobility in the teeth which were treated with bioactive glass.

An increase in a gingival recession may be attributed to the shrinkage of gingival tissues with the resolution of inflammation. These findings are consistent with Froum, *et al.*, (15) Mengel, *et al.*, (8) Sculean, *et al.*, (14) who reported an increase of 1.29 mm, 1.20 mm, 1.28 mm in gingival recession respectively after 6 months of the implantation of graft material. The plaque index was monitored throughout the study period and a non-significant change was observed. This variable is dependent on the patient's compliance and his/her efficacy to maintain oral hygiene. As the subjects were on continuous periodic recall, constant motivation, education and oral hygiene instruction revision have led to almost similar plaque scores at all the periods of observation, which have negated the possibility of the elucidation of the effect of this variable on regeneration. Similarly, non-significant changes in plaque scores have also been reported in previous studies. (14,23) A statistically significant improvement in the gingival index may be attributed to the resolution of inflammation and return of the gingival tissues from a diseased state to health. These findings are in accordance with that of Park, *et al.*, (17) Sculean, *et al.*, (8) Demir, *et al.*, (24)

The results of this study demonstrate that treatment of intrabony periodontal osseous defects with Novabone Dental Putty (A bioactive glass synthetic graft) has led to clinically and statistically significant probing depth reduction, relative attachment level gain and radiographic osseous defect fill.

The primary advantage of bioactive glasses is their rapid rate of surface reaction which leads to fast tissue bonding. (25) The silica-rich layer has a negatively charged surface. This increases the electrostatic charges enough so that water is absorbed quickly. Hydrogen bonding occurs between a water molecule and the hydroxyl groups of the silanol which gives bioactive glass cohesiveness. (26) The negatively



charged surface of HCA layer attracts proteins such as growth factors and fibrin which act like an “organic glue” attracting osteoblastic stem cells to the layer which differentiate into osteoblasts and produce bone. Collagen attaches to the surface and embeds into the HCA layer. Apical migration of the junctional epithelium is indirectly inhibited by the extension of the collagen up to the junctional epithelium.(27) Bioactive glass can promote cementum repair.

The results of this study demonstrate that treatment of intrabony periodontal osseous defects with Novabone Dental Putty has led to statistically significant probing depth reduction, relative attachment level gain and radiographic osseous defect fill.

## Conclusion

Novabone Dental Putty resulted in statistically significant improvements in radiographic osseous defect measurements and clinical parameters. It was very well tolerated by the subjects. No adverse effects such as periodontal abscess, inflammation and/or allergic reaction in the treated surgical sites were reported. Although the clinical parameters i.e., probing pocket depth reduction, clinical attachment level gain and radiographic evidence of bone fill are proved to be consistent with the successful regenerative therapy, but these findings cannot be directly extrapolated as an outcome of periodontal regeneration, as these are not supported by histologic evidence. So future studies with more critically designed protocols, larger sample size and inclusion of histologic evidence as a criterion for periodontal regeneration, are warranted to further explore the potential of the Novabone Dental Putty as a periodontal regenerative material.

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