Original Article

Novabone™ dental putty as a potential regenerative material for treating horizontal defects in chronic periodontitis patients.

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ABSTRACT

Introduction: Periodontitis is a multifactorial disease, which, when not adequately treated, is followed with progressive attachment loss which leads to tooth mobility and eventually tooth loss. Periodontal regenerative surgery aims to regenerate and reconstruct the lost periodontal tissue. Regeneration with novabone putty has shown to be effective in reducing probing pocket depth, gain in clinical attachment level and increase in horizontal bone level.

Aim: This interventional clinical trial was to evaluate the osseous regenerative potential of a calcium phosphosilicate bioactive glass NOVABONE TM in the treatment of horizontal bone defects.

Materials and method: A total of 20 sites with horizontal bone defect was treated with open flap debridement with intra marrow penetration and novabone putty.

Statistical analysis: Plaque index, gingival index and radiographic determination were analysed by paired t test. Probing pocket depth and clinical attachment levels were analysed by Wilcoxon Signed Ranks Test.

Result: There was significant reduction seen in plaque index, gingival index, probing pocket depth and radiographic crestal level when compared between baseline and 12 months respectively (2.48 ± 0.44, 2.92 ± 0.39, 6.80 ± 0.89, 8.29 ± 0.87) and (1.89 ± 0.42, 1.92± 0.51, 3.00± 0.67, 5.48 ± 0.89) and significant gain in clinical attachment level from 4.40 ± 0.96 to 1.20 ± 0.91.

Conclusion: The present study showed novabone putty significantly improved the clinical parameters in horizontal bone defects.

Keywords: Periodontitis, osteoconduction, regeneration, novabone putty, horizontal alveolar bone loss.

INTRODUCTION

Periodontitis is a multifactorial disease, which, when not adequately treated, is followed by progressive attachment loss which leads to tooth mobility and eventually tooth loss. If managed appropriately, involving a systematic and thorough control of the periodontal inflammation, periodontally affected teeth can be retained for long-term, at limited costs, even in cases where bone loss (BL) is advanced. Alteration and elimination of microbial aetiology and containing risk factors determines the goal of periodontal therapy which ultimately leads to preservation of dentition in a state of health, comfort and function with appropriate aesthetics.1 It also aims at regeneration of periodontal attachment apparatus which is lost, whenever indicated, thereby restoring the lost function and structure of tissues.

The end result of periodontal regenerative therapies are the alveolar bone repair and new cementum formation with collagen fibres inserted onto the root surfaces which were involved by the periodontal disease.2 The progression of periodontal disease can be halted by the conventional treatment modalities like scaling and root planing which have been proven to be effective. Elimination of pocket depths and regeneration of new attachment apparatus leading to the periodontal unit reconstruction within the existing normal physiological limits remains to be the aim of periodontal surgery, in particular regenerative periodontal surgery.

Literature states that the treatment modalities for vertical bone loss is around 96.8 % in spite of its prevalence being as less as 7.8%. Whereas horizontal bone loss with a maximum prevalence of 92.2% gets very little attention with treatment modalities being 3.2% only.3

The treatment option for horizontal defects remains to be the open flap debridement. Of lately there has been a quest among the periodontists to explore horizontal defect regeneration with the advent of various biomaterials and biologic approaches.

Regenerative therapy is attempted commonly by the use of various bone grafts. Calcium phosphosilicate bioactive glass, developed by Hench and West in the late 1960s, because of its reported advantages of forming a strong bond with living tissues both bone and soft tissue and its modulus of elasticity being similar to that of bone has gained a place as a good periodontic regenerative material .4,5

The good handling, homeostatic and osteoconductive properties of NovaBoneTM putty makes it one of the promising newer bone graft material. The other property of the graft to act as an epithelial barrier, retarding the epithelial down growth, obliviates the use an additional membrane.4

NovaBoneTM is a commercially available bioactive glass intended for filling surgical or traumatic bone gaps.4 Its composition is 45% silica dioxide, 45% sodium oxide, 5% calcium, and 5% phosphate.5 NovaBoneTM, a second-generation NovaBoneTM product, has two components: a slowly absorbing, melt-derived calcium phosphosilicate bioglass and a more rapidly absorbed solution-gelation calcium phosphosilicate component. The latter is more rapidly absorbed, leaving more space for bone infiltration in the interstices between the more slowly absorbed melt-derived component. 6 NovaBoneTM thus acts as a scaffold for the ingrowth of new bone and is substantially resorbed within 6 months.

The binder is absorbed to permit tissue infiltration between the bioglass particles on implantation. During the healing process the new bone tissue replaces the particles which are absorbed slowly. This osteostimulation results in new bone formation throughout the

grafted site at rates faster than those seen with other synthetic graft materials.7

Literature regarding the use of NovaBoneTM putty in periodontal regenerative approaches in the management of horizontal defects were lacking. The aim of this interventional clinical trial was to evaluate the osseous regenerative potential of a calcium phosphosilicate bioactive glass - NovaBone TM in the treatment of horizontal bone defects.

Materials and methods

Patients visiting the Department of Periodontics, Vydehi Institute of Dental Sciences and Research Centre, Bangalore were selected based on the following inclusion criteria: age group between 20-60 years, systemically healthy patients with chronic periodontitis clinically diagnosed based on American Academy Periodontology (1999) classification having clinical attachment loss (CAL) ≥ 3mm in 30% of the sites and probing pocket depth (PPD) ≥ 5 mm with at least 6 teeth, presence of horizontal bone loss ≥ 6mm measuring from cementoenamel junction (CEJ) radiographically. Patients were excluded if medically compromised, teeth with grade III mobility, patients who underwent periodontal surgery in the last 1year, smokers, pregnant and lactating women. The study was approved by the institutional ethical committee (204/2019).

Study design

A total of 20 sites with horizontal bone defects in 5 patients satisfying the above mentioned criteria were included in the study. The nature of the study, the need for surgery and the outcome of it was explained to the patients, following which a verbal and written consent was obtained. The sample size was calculated based on data from previous literature using software SPSS 23.0 version.

Clinical parameters

A single examiner performed all the investigations required and all the parameters were noted at baseline and 12 months. Parameters noted were gingival index (GI) (Loe & Silness, 1963)8 plaque index (PI) (Silness & Loe, 1964)9, probing pocket depth and clinical attachment level the measurements were made using surgical stent (Figure A) for reproducibility.

Radiographic assessment

Radiographic evaluation was carried out using Radiovisiography (RVG) taken at baseline and 12 months. RVG was obtained in a standardised exposure set up. RVG SOPIX2 ACE and CARESTREAM CS2100 X-ray unit operated at 60 Kvp and 7mA with a radiation exposure of 0.250 milliseconds. The sensor was covered with plastic sleeves and for each patient a new plastic cover was used hence ensuring optimum hygiene. The system we used in our study contained a charged coupled device or CCD sensor. RVG was obtained at baseline and 12 months follow up visit. To standardise the measurement the initial reference point was taken from Cementoenamel junction (CEJ) up to the crest of alveolar bone (CAB). A line is drawn from the CEJ of one tooth to the CEJ of adjacent tooth, the same way another parallel line is drawn from CAB joining adjacent 2 teeth. The midpoint from the CEJ line to the midpoint of CAB line is taken (Figure F). After obtaining the baseline and 12 months post-operative images (Figure G), the images was transferred into Digimizer image analysis software and all the images were resized to width of 600 pixels and height of 400 pixels which standardize the image size and the measurements were obtained and transferred to the master chart.

Presurgical therapy

Full mouth scaling and root planing was done.

Oral hygiene instructions were given. Patients were recalled after 8 weeks for revaluation. Sites demonstrating >6mm of probing pocket depth during follow up after phase I therapy were considered for surgical management.

Surgical protocol

All the surgeries were done by a single examiner. The selected patients were subjected to the following surgical protocol. The operated site was anaesthetised with 2% local anaesthesia with 1:200000 adrenaline. No 15 blade was used to give crevicular incision and full thickness mucoperiosteal flap was reflected and the defect was debrided to remove granulation tissue using area specific Hu-Friedy Gracey curettes. Saline irrigation was done. Contrangled micromotor handpiece and a round carbide bur of 1 mm diameter was used to make intra marrow penetration in the interdental area (Figure B). The required amount of NovaBone putty was taken and placed in the defect area (Figure C). Vertical mattress sutures were placed using 3-0 silk suture (Figure D). Periodontal dressing was placed and post-operative instructions were given.

Post-operative care

All the patients were prescribed cap amoxicillin 500mg thrice daily for 5 days and combination of Tab Diclofenac Sodium 50mg with Tab Paracetamol 325mg twice daily for 3 days 0.2% chlorhexidine gluconate oral rinse was given twice daily for 15 days. Patients reported for suture removal post 10 days. All the patients were recalled once in every two months intervals up to 12 months for plaque removal and reinforcement of oral hygiene instructions.

Statistical analysis

Statistical analysis was done using a SPSS software 23.0 version. The analyses values were represented by mean and standard deviation. Parameters were analysed at baseline and 12 months. Plaque index, gingival index and radiographic determination were analysed by paired t test. Probing pocket depth and clinical attachment levels were analysed by Wilcoxon Signed Rank Test.

Results

A total of 20 sites of horizontal bone loss were treated with NovaBoneTM putty. All treated sites showed uneventful healing.

All parameters were assessed at baseline and 12 months. There was statistically significant reduction in plaque and gingival index from baseline to 12 months with P value <0.001. There was a reduction in probing pocket depth from baseline to 12 months and the difference was statistically significant. A great gain in clinical attachment level was found from baseline to 12 months, which was statistically significant. There was statistically significant gain in the defect fill from baseline to 12 months with P value <0.001 (Table I).

DISCUSSION

Destruction of bone, periodontal ligament and cementum are the end result of Periodontal diseases. Hence regeneration of these lost tissues remains to be the ultimate goal of periodontal therapy.10 In spite of numerous treatment modalities available currently, we clinicians continue to seek for regenerative therapies that are less technique sensitive and leads to faster tissue regeneration.

Horizontal bone loss remains to be the most commonly encountered clinical situation whose regeneration poses a major challenge to the periodontists.

Nova Bone TM putty is a new next generation calcium phosphosillicate bone graft material built from a bioactive glass

platform with additives. The major advantage of this material is its improved handling and efficacy besides being osteostimulative and osteoconductive,[11] hence in this present study this material was used to evaluate its regenerative potential in horizontal bone defects.

Our findings were similar to the clinical and radiographic findings observed by Rosamma et al[12] where the efficacy of autologous platelet rich fibrin in horizontal alveolar bony defect was evaluated. Our clinical results were in accordance to the few previous studies which aimed at regenerating horizontal bone loss.[13,14,15,16]

In this study intra marrow penetration was done in the interdental area with round carbide bur mainly to enhance bone regeneration capacity. This procedure was done to expose cancellous bone which indeed cause bleeding, through which regenerative cells, bone morphogenetic proteins and growth factors can readily interact with the artificial bone graft material and accelerate the new bone formation process.[17,18] Crea et al. evaluated the efficacy of intramarrow penetration along with open flap debridement which resulted with gain in clinical attachment level, reduction in probing depth and bone fill seen in radiographic assessment.[19]

As digital radiographs are more accurate in measurements than conventional radiographs while measuring alveolar bone loss,[20,21] here we used RVG for a more accurate pre and post radiographic comparison.

The limitation of the present study was that it had only one group in contrast to other studies, hence necessitating future studies with a comparative group with standard protocols. The other limitation of this study included assessment of periodontal regeneration using only clinical and radiographic parameters. True periodontal regeneration can only be assessed in histological sections.[22,23] Due to ethical reasons it could not be done in the present study.

Studies have focused on the regenerative potential of NovaBone™ putty in intrabony defects[24] and furcation area.[25] Materials like PRF[12] and enamel matrix proteins16 have also been tried in the regeneration of horizontal alveolar bone loss. There is no study done till date to the best of our knowledge to check the evaluation of regenerative potential of NovaBone™ putty in horizontal alveolar bone defect, hence making this study a novel treatment option and also increasing its research potential in this area.

Conclusion

Treatment modalities in horizontal defect is minimal and the present study has shown that novabone putty significantly improved the clinical and radiographic parameters in horizontal bone defects within the limitations, hence further studies including larger sample size are recommended.

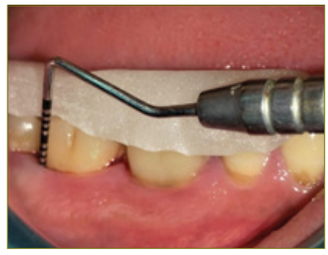
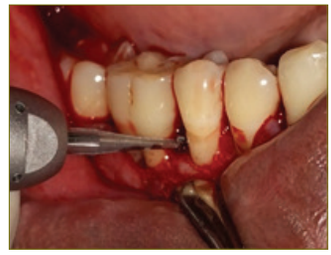


Figure-A



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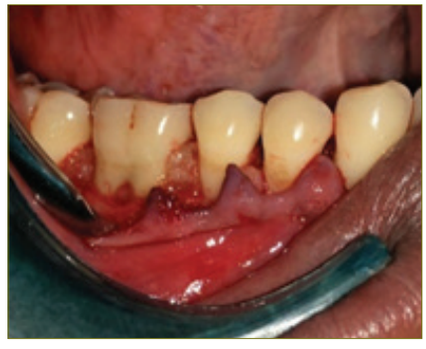
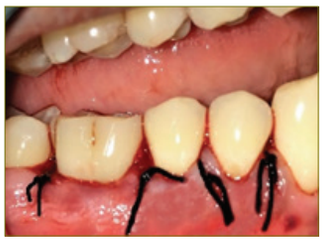


Figure-C



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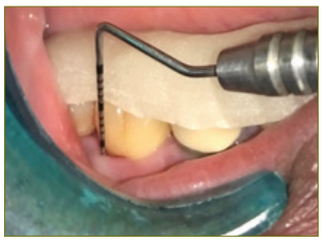

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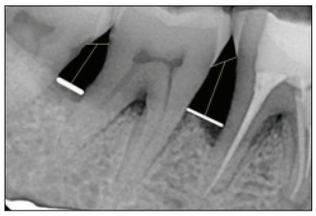

Figure-F

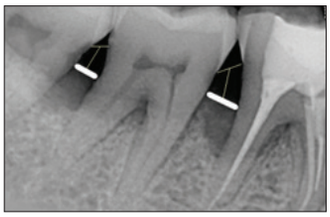

Figure-G

FIGURE LEGENDS

FIGURE A: Probing depth at baseline.

FIGURE B: Intramarrow penetration

FIGURE C: Placement of novabone putty

FIGURE D : Sutures placed

FIGURE E :12 Months revaluation

FIGURE F : Baseline RVG

FIGURE G : Post 12 months RVG

PARAMETERS	BASELINE	12 MONTHS	n	P VALUE
Plaque index	2.48 ± 0.44	1.89 ± 0.42	20	<0.001
Gingival index	2.92 ± 0.39	1.92± 0.51	20	<0.001
Probing pocket depth mm	6.80 ± 0.89	3.00± 0.67	20	<0.004
Clinical attachment level mm	4.40 ± 0.96	1.20 ± 0.91	20	<0.004
Radiographic crestal level mm	8.29 ± 0.87	5.48 ± 0.89	20	<0.001

Table 1 : Comparison of clinical and radiographic parameter at baseline and 12 months

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