

Comparative Evaluation of Open Flap Debridement Alone and In Combination with Bone Graft in the Treatment of Vertical Bony Defects in Periodontitis

Subedi G,¹ Rijal AH,² Lamichhane S,² Humagain M²

¹Department of Periodontology and Oral Implantology,

Nobel Medical College Teaching Hospital,
Biratnagar, Morang, Nepal.

²Department of Periodontology and Oral Implantology,

Dhulikhel Hospital, Kathmandu University Hospital
Kathmandu University School of Medical Sciences,
Dhulikhel, Kavre, Nepal.

Corresponding Author

Gitanjali Subedi

Department of Periodontology and Oral Implantology,

Nobel Medical College Teaching Hospital,

Biratnagar, Morang, Nepal.

E-mail: sgeetu1995@gmail.com

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ABSTRACT

Background

Regeneration of lost periodontium is the ultimate goal of periodontal therapy. Regenerative periodontal therapy aims to improve the regeneration of lost periodontal tissue by using various kinds of bone grafts, membranes, growth factors or combination thereof.

Objective

To compare open flap debridement alone and in combination with alloplastic bone graft (Biphasic calcium phosphate) for the treatment of vertical bony defects in periodontitis.

Method

A total of 24 patients with vertical bony defects > 3 mm were selected for the study. The study design was randomized controlled clinical trial. The study participants were assigned into 2 groups: Group A receiving open flap debridement only (n = 12) and Group B receiving open flap debridement along with biphasic calcium phosphate (n = 12). Simple random sampling technique was employed. The primary outcome measures were changes in Probing Pocket Depth, Clinical Attachment Loss and Radiographic Defect Depth, from baseline to 3 and 6 months after surgery. Secondary clinical outcomes included Plaque Index, Gingival Index and Gingival Recession, which were also assessed at baseline, and 3 and 6 months after surgery.

Result

No statistically significant difference was noted between the groups in terms of clinical parameters (P-value > 0.005 for all parameters). However, there was a statistically significant increase in the radiographic defect fill in group B in 6 months, as compared to group A (P-value < 0.001 at 95% confidence intervals).

Conclusion

The present study failed to demonstrate any superior clinical outcomes for Group B compared to Group A in terms of clinical parameters but radiographs revealed superior results in favor of group B. Hence, biphasic calcium phosphate can be considered as a potential periodontal regenerative material for the treatment of vertical bony defects in periodontitis.

KEY WORDS

Biphasic calcium phosphate, Periodontitis, Periodontal regeneration, Radiographic defect depth, Vertical bony defect

INTRODUCTION

A periodontal disease initiates and propagates through a dysbiotic plaque biofilm which then interacts with the host immune defense systems, leading to inflammation and disease.¹ Until the affected tooth is extracted or microbial biofilm is therapeutically removed, the pathophysiological state of disease remains through the periods of activity and quiescence. The main objective of periodontal therapy is to regenerate the destroyed periodontal tissues including apposition of new cementum and insertion of new periodontal ligament fibers along with alveolar bone defect filling.² Vertical bony defects of varying morphology may have a varying regenerative potential depending on the extent of source of the cells from periodontium.³

During periodontal therapy, deep vertical defects possess a greater difficulty for a periodontal surgeon, requiring access by flap surgery alone or in combination with the bone regenerative procedures. The therapeutic concepts have shifted from resection to regeneration, which have significantly impacted the practice of periodontology.⁴ Open Flap Debridement (OFD) is a procedure in which root surfaces and supporting alveolar bone are exposed to gain proper access for root surface instrumentation. It has shown successful results in the treatment of vertical defects.⁵

Alloplasts are biocompatible material, capable of filling the intra-bony defects, in addition to providing defects fillers of variable biologic activity.⁶ Among various biomaterials used as alloplasts, tricalcium phosphate and hydroxyapatite (HA) are most common. Nery et al., first used the term Biphasic Calcium Phosphate (BCP), to describe bio-ceramic consisting of mixture of β -tricalcium phosphate (β -TCP) HA.⁷ The main purpose of the combination is to take advantage of rapid resorption of β -TCP and the inert scaffold of dense HA.

METHODS

This was a Randomized Controlled Clinical Trial (RCT), carried out in the Department of Periodontics, Dhulikhel Hospital. The study period was from December, 2022 – July, 2024. Ethical clearance was obtained from the Institutional Review Committee (IRC) of Kathmandu University School of Medical Sciences (Approval no. 211/22). Informed consent was taken from all the participants prior to the study. Sample size was determined based on mean difference method using data derived from similar study.⁸ Calculated sample size was 24, 12 on each group.

Systemically healthy patients above the age of 18 years with the presence of one or two radiographically detectable interproximal vertical bony defects with Probing Pocket Depth (PPD) ≥ 5 mm, after completion of phase I therapy were recruited for the study.⁸ Participants with radiographic evidence of vertical bone loss of at least ≥ 3

mm at baseline were selected. Patients with the history of periodontal treatment in past six months, patients undergoing orthodontic treatment and teeth exceeding class II mobility were excluded from the study.

Four weeks after the completion of phase I therapy, re-evaluation was done for the assessment of specific sites and to determine the eligibility of patient previously planned to be included in the study. A randomization was done using computer generated numbers to equally divide 24 patients into two groups (12 on each group): Group A (treated with OFD only) and Group B (treated with OFD along with BCP). Clinical parameters like Plaque Index (PI), Gingival Index (GI), PPD, Gingival Recession (GR), Clinical Attachment Loss (CAL) and radiographic parameters like Radiographic Defect Depth (RDD) were recorded at baseline (prior to surgery), 3 and 6 months after the surgery. Clinical and radiographic measurements were performed by a sole trained examiner to eliminate any bias. Clinical parameters were assessed with University of North Carolina – 15 (UNC-15) probe and recorded to the nearest millimeter (mm). Grooves created on the acrylic stent were used as a fixed reference point. For measurement of RDD, distance between CEJ to alveolar crest (AC), CEJ to the base of the defect (BD) and AC to BD was measured using intra-oral periapical radiography (IOPAR), using long cone paralleling technique. The linear radiographic bone fill (RBF) was measured after subtracting CEJ-BD (at baseline) and CEJ – BD (at 3 and 6 months).

In Group A, only OFD was performed, whereas in Group B, BCP (Osteon™ II) of particle size 0.2-0.5 mm and volume 0.25 CC was placed after performing OFD. Patients were kept under regular supportive periodontal therapy and recalled again after 3- and 6- months post-surgery, for recording both the clinical and radiographic parameters. No sub-gingival instrumentation was attempted till 3 months of follow up. The recall appointments consisted of reinforcement in oral hygiene measures and professional supragingival tooth cleaning.

All the clinical and radiographic data were recorded in a case proforma. All the data were entered and coded in Microsoft excel. The data were then transferred to Statistical Package for Social Sciences (SPSS) 21.0 premium version (IBM SPSS Inc.), for further analysis. The measurements for each group were averaged (means $\pm$ standard error). The net difference between each pair of measurements (pre and postoperative) were calculated, followed by computation of the difference between treatment groups. An independent t-test was used to compare the intergroup measurements of PPD, CAL, GR, PI, GI and RDD between the two study groups at baseline, 3 months, and 6 months. The level of significance was set at a P-value ≤ 0.05 .

RESULTS

A total of 24 patients were included in the study, out of which 14 were male (8 in Group A and 6 in Group B) and 10

were female (4 in Group A and 6 in Group B). The mean age group of the participants in Group A was 43.17 ± 13.044 and 46.25 ± 8.792 in Group B.

Plaque Index (PI)

Comparison of PI scores at baseline and different time intervals between the two groups shows no statistically significant differences between mean PI scores of two groups at subsequent follow up visits (Table 1).

Table 1. Inter-group comparison of PI at baseline, 3 months and 6 months

PI score	Group A (Mean±SD)	Group B (Mean±SD)	Mean difference	95% CI of mean diff.	
				Lower	Upper
Baseline	0.96±0.88	0.96±0.97	0.044	-0.07	0.168
3 months	0.86±0.16	0.90±0.14	0.045	-0.18	0.27
6 months	0.78±0.61	0.82±0.16	0.04	-0.20	0.36

Gingival Index (GI)

Comparison of GI scores at baseline and different time intervals between the two groups shows no statistically significant differences between mean GI scores of two groups at subsequent follow up visits (Table 2).

Table 2. Inter-group comparison of GI at baseline, 3 months and 6 months

GI score	Group A (Mean±SD)	Group B (Mean±SD)	Mean difference	95% CI of mean diff.	
				Lower	Upper
Baseline	1.017±0.037	0.92±0.12	0.097	0.010	0.184
3 months	0.96±0.079	0.81±0.17	0.145	0.046	0.243
6 months	0.83±0.125	0.60±0.17	0.235	0.134	0.335

Probing Pocket Depth (PPD)

The difference in mean values of PPD of both the treatment groups were compared to test statistical significance. The difference was not statistically significant (Table 3).

Table 3. Probing Pocket Depth (PPD)

PPD	Group A (Mean±SD)	Group B (Mean±SD)	Mean difference	95% CI of mean diff.	
				Lower	Upper
Baseline	7.17±0.93	7.75±1.35	0.583	-1.682	0.516
3 months	5.75±0.17	5.83±0.93	0.083	-0.917	0.750
6 months	3.42±0.66	3.33±0.65	0.083	-0.341	0.508

Clinical Attachment Loss (CAL)

Comparison of CAL scores at baseline and different time intervals between the two groups shows no statistically significant differences between mean CAL scores of two groups at subsequent follow up visits (Table 4).

Table 4. Clinical Attachment Loss (CAL)

CAL	Group A (Mean±SD)	Group B (Mean±SD)	Mean difference	95% CI of mean diff.	
				Lower	Upper
Baseline	8.00 ± 1.595	8.75 ± 1.712	0.75	-2.466	0.966
3 months	6.67 ± 1.303	7.25 ± 1.603	0.583	-2.054	0.887
6 months	4.92 ± 1.67	5.0 ± 1.75	0.083	-1.603	1.436

Gingival Recession (GR)

The difference in mean GR values of both the treatment groups were compared to test statistical significance. At 3 months and 6 months follow up, there was an increase in the values of GR in both the groups with no statistically significant differences between the groups (Table 5).

Table 5. Inter-group comparison of GR at baseline, 3 months and 6 months

GR	Group A (Mean±SD)	Group B (Mean±SD)	Mean difference	95% CI of mean diff.	
				Lower	Upper
Baseline	0.83±1.03	1.0±1.206	0.167	-1.210	0.877
3 months	0.92±0.996	1.42±1.165	0.500	-1.567	0.567
6 months	1.50±1.446	1.67±1.303	0.167	-1.403	1.070

Radiographic Defect Depth (RDD)

Comparison of RDD scores at baseline and different time intervals between the two groups shows statistically significant differences between mean RDD scores of two groups at subsequent follow up visits with a p-value < 0.05 (Table 6).

Table 6. Inter-group comparison of RDD at baseline, 3 months and 6 months

GR	Group A (Mean±SD)	Group B (Mean±SD)	Mean difference	95% CI of mean diff.	
				Lower	Upper
Baseline	7.84±1.37	8.40±1.72	0.56	-1.9	0.81
3 months	7.64±1.36	5.45±1.87	2.19	0.80	3.58
6 months	7.33±1.34	4.48±1.81	2.853	1.57	4.13

*Statistically significant

DISCUSSIONS

Regenerating the lost tooth supporting tissues such as periodontal ligament, cementum and the alveolar bone, caused by the infectious disease process is the most favorable result of the periodontal therapy.^{9,10} From a biologic point of view, autogenous bone grafts have always been considered a gold standard bone graft material. Considering the advantages like handling characteristics, their easy availability in various sizes, the lack of morbidity that can result from harvesting autogenous bone and no risk for disease transmission, alloplastic bone grafting materials

have been shown to result in positive clinical outcomes for PPD reduction, CAL gain and fill of the defects.¹¹

In the present study, we focused on a BCP alloplastic bone grafting material, namely OSTEONTM II, containing 70% HA and 30% β -TCP. Both are biologically compatible and have been used in the treatment of periodontal osseous defects.¹²⁻¹⁶ Since these two materials alone could not yield the expected outcomes, the development of a 2-phased BCP made it possible to control the of the material and at the same time maintain its osteoconductive property.¹⁷

This RCT was designed to compare the treatment outcomes of OFD alone and in combination with BCP in the treatment of vertical bony defects in periodontitis. The principles of cautious soft tissue handling, wound stability and infection control were highlighted in the treatment protocol. None of the participants under study experienced any post-operative complications or uneventful healing, which with the studies previously performed by Shiraji et al. and Jasser et al.^{18,19}

In the present study, Bone graft group (Group B) did not exhibit additional benefits in terms of PPD reduction and clinical attachment level gain, as compared to the OFD group (Group A), which was in accordance with other studies done by Gojkov-Vukelic et al. and Shirakata et al.^{11,20} However, a number of studies demonstrated a greater reduction in PPD and a greater gain in clinical attachment level with BCP as compared to OFD alone.^{18,19} The possible explanation for the lack of significant differences in terms of clinical parameters between the two groups might be the fact that most of the defects were narrow 3-walled, contained intra-bony defects, in which periodontal healing potentially resulted in complete clinical repair with or without periodontal regenerative therapy.²¹ Different methods used for patients and material selection, measurements, surgical techniques and defect characteristics might also have played the role.

On the other hand, GR was observed to have increased following surgery in both the groups. Similar changes were observed in the study done by Shirakata et al. and Bhatnagar et al.^{11,22} In terms of RDD, there was statistically significant bone fill in both the groups at 3 months and 6 months, when comparison was done from the baseline. The results were in agreement with the findings suggested by the previous studies performed by Yukna et al., Bhatnagar et al. and Kaushick et al.^{16,22,23}

Although a statistically significant difference was observed in the radiographic parameters, no statistically significant inter-group differences were detected in the clinical parameters, including PPD and CAL. This discrepancy may be attributed to the different aspects of periodontal healing assessed by these parameters. Radiographic measurements primarily reflect changes in mineralized tissue and may be more sensitive to changes in osseous defect fill. In contrast, PPD and CAL are influenced by several factors, including

gingival margin position, inflammation, probing force, probe angulation, and anatomical characteristics of the periodontal defect. Furthermore, radiographic evidence of bone fill does not necessarily correspond directly to the formation of new periodontal attachment.²² Also un-resorbed dense BCP particles can cause radiopacity on 2D radiographs, simulating bone fill without the true histologic attachment.

It is well known that PPD reduction, CAL gain or defect filling does not necessarily represent periodontal regeneration. Thus, the clinical findings following surgical procedure with BCP might need to be validated by histologic evidence. These could confirm that the radiographic bone fill and clinical parameters indicating periodontal regeneration correspond to the resorption of BCP and its effects on osteoconductive activity. BCP was tolerated well and did not elicit consequent adverse reactions, such as infection, swelling, or suppuration and material exposure. However, it should be kept in mind that caution is needed for clinical use in periodontal defects. Considering the properties of this material, it also might be used in other situations, such as bone filling of extraction sockets, ridge augmentation, sinus floor augmentation, and peri-implant defects.

Limitations of the study include limited sample size and lack of 3-dimensional (3D) radiographic evaluation with Cone-Beam Computed Tomography (CBCT). Since complete periodontal regeneration necessitates long-term follow-up and the study has only monitored the patients for six months, long-term follow-up is necessary to assess the durability of the regenerative process. Histologic verification could have given the better picture of the type of regeneration that has occurred, which could not be done due to ethical reasons.

Although results of the present study demonstrates that the use of alloplasts was effective in the treatment of two or three walled vertical defects with an uneventful healing of the sites, our results are based on single-centered study with a small sample size. Future research is needed, including histologic evaluation of defects treated with and alloplast to determine if periodontal regeneration is obtained.

CONCLUSION

According to the results obtained from the present study, it is appropriate to conclude that BCP appears to be a promising novel material for the treatment of vertical bony defects in periodontitis, yielding superior outcomes as compared to conventional OFD, in terms of bone defect fill radiographically and comparable results in terms of the clinical parameters. Future studies with more critically fabricated protocols and larger sample size are warranted to further investigate the prospective of BCP as a periodontal regenerative material.

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