Periodontal bone regeneration in intrabony defects using osteoconductive bone graft versus combination of osteoconductive and osteostimulative bone graft: A comparative study

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ABSTRACT

Background: Bone loss is one of the hallmarks of periodontitis. Hence, a major focus of research into periodontal regeneration has concentrated on the initiation of Osteogenesis. Osteoinduction requires the differentiation of mesenchymal cells into osteoblasts with subsequent formation of new bone. The present study has been carried out to evaluate periodontal bone regeneration in intrabony defects using osteostimulative oleaginous calcium hydroxide suspension Osteora® (Metacura, Germany) in combination with osteoconductive bone graft Ossifi™ (Equinox Medical Technologies, Holland).

Materials and Methods: A total of 22 sites in patients within the age range of 25-50 years, with intrabony defects were selected and divided into two groups (Group A and Group B) by using the split-mouth design technique. All the selected sites were assessed with the clinical parameters such as - Plaque Index, Gingival Index, Sulcus Bleeding Index, Periodontal Probing Depth, Clinical Attachment Level, Gingival Recession and radiographic parameter to assess the amount of Defect Fill. Mann-Whitey U-test and Wilcoxon Signed Rank Test has been used to find the significance of study parameters on continuous scale for the comparison between the mesial and distal bone levels. P < 0.05 was considered to be statistically significant.

Results: Osteora® in combination with osteoconductive Ossifi™ showed better regenerative potential and more significant amount of bone fill in periodontal intrabony defects than when Ossifi™ was used alone (P = 0.039).

Conclusion: Osteora® can be used as an adjunct to osteoconductive bone grafts, as an osteostimulating agent in the treatment of periodontal intrabony defects.

Key Words: Bone substitutes, calcium hydroxide, osteogenesis, periodontal bone loss, periodontal regeneration

INTRODUCTION

Since antiquity, bone has been known to have a remarkable potential for repair and regeneration. The ultimate goal of periodontal therapy is the regeneration of periodontal supporting tissues that have been lost as a consequence of periodontitis. The key to tissue regeneration is to stimulate a cascade of healing events which, if coordinated, can result in completion of integrated tissue formation. The various treatment modalities include the use of autografts, allografts and alloplastic materials. Bone grafting is a dynamic process, it is a unique scientific endeavor employed to incorporate four desired properties-Osteogenesis, Osteoinduction, Osteoconduction and Osteointegration. The development of a new generation of totally synthetic, biologically active bone graft substitutes is beginning to make progress.
in clinical testing, incorporating one or more of these properties.

Recent studies\(^1\)\(^-\)\(^5\) have suggested a substantial role of an oily calcium hydroxide suspension on bone regeneration in periodontal osseous defects. It has been considered to have osteostimulative effect on periodontal bone regeneration. The osteostimulative effect is considered to be biologic and seems to rely on factors such as the deposit action of calcium hydroxide (sustaining bone metabolism in a constant mild, alkali environment), the stimulation of the angiogenetic bone growth and possibly the concentration of the growth factors next to the defect wall. The calcium powder and oily phase of the claw oil that is added to Osteora® provide for a gradual, hours-long rise in the alkalinization in the tissue to a pH value of around 10.5. This brings about, on one hand, the differentiation and the growth of both osteoblasts and fibroblasts, thereby enhancing bone regeneration.

On the other hand, the alkaline milieu arrests the growth of microorganisms of oral flora. It has a depot effect and hence calcium hydroxide is released through the oil only at phase limits. On this account the compound is known to have a long bacteriostatic effect. The new calcium hydroxide is released at a rate at which the oily phase is resorbed by the body. The calcium hydroxide for this part enhances and stimulates osteoinduction. It has proven to reduce the inflammation in the operated site, thus enhancing the wound healing. Histological and radiological analysis\(^2\)\(^,\)\(^3\)\(^,\)\(^6\) both in animals and humans, suggest a certain amount of regeneration in periodontal defects.

Osteora® is considered as an effective tool for appositional bone induction, one that could be deployed quickly, safely and with success in the areas of craniofacial and periodontal surgery and implantology.

However, certain clinical studies reveal consistency of Osteora® as one of the practical drawbacks of the material when used alone. Its low consistency cannot ensure a sufficient stability of the mucoperiosteal flap, especially in one-wall and circular defects. This leads to a frequent collapse of the mucoperiosteal flap and reduction of the space necessary for the regeneration process.\(^7\)

To overcome such inconveniences, the combination of the Osteora® with a bone replacement material could offer a convenient solution. Thereby, the chemical and biological properties of Osteora® could be combined with the mechanical properties of the bone replacement material. Thus, in this study a combination of biphasic beta-tricalcium phosphate (β-TCP)-Hydroxyapatite with Osteora® is used.

The present clinical study was carried out with an aim to evaluate periodontal bone regeneration in the intrabony component of periodontal osseous defects through pH-guided osteostimulation using oleaginous calcium hydroxide suspension-Osteora® in combination with osteoconductive bone graft – Ossift™. The objectives of this study were to assess the clinical efficacy of Osteora® in combination with Ossift™ on various clinical parameters and to assess the amount of defect fill with Osteora® in combination with Ossift™ on radiographic parameter.

**MATERIALS AND METHODS**

**Sample selection**

The present study was carried out as per the Helsinki declaration (1964) with the ethical clearance from the institution. The patients were selected from the out-patient Department of Periodontology and Oral Implantology, M.M College of Dental Sciences, M.M. University, Mullana, Ambala, India.

This was an experimental study. Both males/females between the age groups of 25-60 years were a part of the study. Co-operative and motivated patients with no contraindication to periodontal surgery and local anesthesia, having no known allergies to the products being used and absence of any relevant medical condition were selected. Smokers, alcoholics, pregnant/nursing women were not a part of the study. Periodontal sites with periodontal probing depth >5 mm with radiographic evidence of vertical/angular bone loss were chosen. Grade-III mobile teeth were not a part of the study.\(^8\)\(^,\)\(^9\)

**Study materials**

Osteora® (osteostimulative) — is an oleaginous calcium hydroxide suspension, available in a creamy consistency with a periodontal regenerative action. The CE-certified class-III medical product is gamma sterilized and supplied in a ready-to-use 1 g syringe with an injection cannula. The product is manufactured by Metacura, Germany.

Ossift™ (osteoconductive) — is a porous, biphasic β TCP-Hydroxyapatite bone graft material with 0.5cc granules having a particle size of 0.25-1 mm.
The product is manufactured by Equinox Medical Technologies, Holland.

**Study design**

A total of 22 sites were selected. These were divided according to split-mouth designs into two groups—Group A and Group B according to the treatment modality received.

Group A: Sites in which flap debridement was followed by the placement of Ossifi™.

Group B: Sites in which flap debridement was followed by the placement of mixture of Osteora® and Ossifi™.

All the selected patients of both groups were subjected to pre-surgical, clinical and radiographic interpretation.

**Pre-surgical protocol**

Pre-treatment record included a detailed medical and dental history, followed by thorough clinical examination. Study casts were made. Clinical photograph and radiographs were taken. Essential laboratory investigations were carried out.

Clinical parameters assessed at baseline (before the periodontal surgery) and at different intervals (3 and 6 months):

- Plaque index, Gingival index, Sulcus bleeding index,
- Probing Pocket Depth (PPD), clinical attachment level (CAL), gingival recession (GR).

**Fabrication of the stent**

Customized occlusal stents were fabricated with cold-cure acrylic resin on a cast model to compare pre- and post-surgical measurements with a standard reference point. A guide plane in the form of a groove was made on the stent in relation to each involved tooth to guide the periodontal probe into the defect[10]. To assess the tissue changes reproducibly, measurements were taken using a UNC-15 probe to measure PPD, CAL and also to determine defect characteristics.

**Radiographic assessment**

All the intra-oral peri-apical radiographs taken at baseline (pre-operatively) and 6 months (post-operatively) were subjected to digital assessment. They were scanned using a HP scanjet G3010 with a scanning resolution of 600 dpi. The scanned images were then stored in JPEG format. These were then transferred and digitized using Radiovisiography (Suni Imaging Microsystems Inc. Suni Ray 6840 Via Del Ora Suite). For measurement, calibrated measurement tool was used. The cemento-enamel junction (CEJ), the base of the defect and the crest of alveolar bone were located on the image. A line was drawn from CEJ to the base of the defect. The length of the line was displayed on the image. The software then displayed the distance between these two points. The same procedure was then repeated to obtain the distance between CEJ and alveolar crest. Subtracting the two measurements, the depth of the osseous defect was obtained. The total bone fill was measured subtracting the depth of the osseous defect at 6 months from the baseline measurement [Figure 1].

- a. Distance from CEJ to the base of defect (pre-operatively)
  - a1. Distance from CEJ to the base of the defect (6 months post-operatively)
- b. Distance from the CEJ to the alveolar crest (pre-operatively)
  - b1. Distance from the CEJ to the alveolar crest (6 months post-operatively)
- c. Defect depth (pre-operatively) = (a − b)
  - c1. Defect depth (6 months post-operatively) = a1 − b1
- d. Amount of defect fill = c − c1.

**Statistical analysis**

Descriptive statistical analysis was carried out in the present study. Results on continuous measurements were presented on mean ± standard deviation (min-max) deviation. Mann-Whitney U-test and Wilcoxon Signed Rank Test has been used to find the significance of study parameters on continuous scale for the comparison between the mesial and distal...

![Figure 1: Arithmetic determinations based on radiographic measurements by using radiovisiography](image-url)
bone levels. Results with $P < 0.05$ were considered as statistically significant in this study.

**RESULTS**

All the selected sites were assessed with the clinical parameters such as - Plaque Index, Gingival Index, Sulcus Bleeding Index, PPD, CAL, GR and radiographic parameter to assess the Amount of Defect Fill. The results are shown in Table 1.

**Clinical observations**

On comparison between the Group A and Group B, the mean difference for all the above mentioned clinical parameters were statistically not-significant ($P > 0.05$) at baseline, 3 months and 6 months.

**Radiographic defect fill**

On comparison between Group A and Group B, the mean difference for amount of defect fill at 6 months was 0.92 with $z = 2.06$, which was statistically significant ($P < 0.05$). [Figures 2-6]

**DISCUSSION**

In the present study, a split-mouth design technique was employed so as to exclude the influence of patient specific characteristics[^11] and thereby facilitate a direct comparison between both groups in the same individual under similar environmental conditions.

Modified flap operation (Kirkland flap)^[12]^ is basically an access flap for proper root debridement. Bone regeneration in intrabony defects, which is one of the major advantages of this technique, was considered in this study. 24% ethylenediaminetetraacetic acid (EDTA)[^13,14] has been considered to be effective in hard tissue formation and periodontal regeneration. Hence, in this study root biomodification with 24% EDTA at neutral pH was carried out.

True regeneration of tissues can be determined only by means of histologic and radiographic parameters. Radiographic assessment is a reliable method for evaluating the changes in the alveolar bone. Defect

### Table 1: Mean difference of various clinical and radiographic parameters between group A and group B at different time intervals

| Index | Baseline | 3 months | 6 months |
|-------|----------|----------|----------|
|       | Mean difference | Z value | P value | Mean difference | Z value | P value | Mean difference | Z value | P value |
| PI    | 0.03     | 0.98     | 0.32 (NS) | 0.13     | 2.35     | 0.01* (S) | 0.02     | 0.38     | 0.69 (NS) |
| GI    | 0.04     | 1.19     | 0.23 (NS) | 0.10     | 1.53     | 0.12 (NS) | 0.00     | 0.09     | 0.92 (NS) |
| SBI   | 0.32     | 1.41     | 0.15 (NS) | 0.31     | 1.56     | 0.11 (NS) | 0.31     | 1.46     | 0.14 (NS) |
| PPD   | 0.03     | 0.06     | 0.94 (NS) | 0.31     | 0.66     | 0.50 (NS) | 0.86     | 0.70     | 0.47 (NS) |
| CAL   | 0.24     | 0.24     | 0.80 (NS) | 0.12     | 0.00     | 1.00 (NS) | 0.39     | 0.84     | 0.39 (NS) |
| GR    | 0.54     | 1.31     | 0.18 (NS) | 0.00     | 0.16     | 0.86 (NS) | 0.32     | 0.49     | 0.62 (NS) |
| RDF   | –        | –        | –        | 0.92     | 2.06     | 0.039* (S) |

*Significant. GI: Gingival index; CAL: Clinical attachment level; NS: Not significant; SBI: Sulcus bleeding index; GR: Gingival recession; PI: Plaque index; PPD: Probing pocket depth; RDF: Radiographic amount of defect fill

![Figure 2: Group A: Baseline (pre-operatively)](image)

![Figure 3: Group A: Post-operatively at 6 months](image)
fill with new bone formation is a desirable outcome of any regenerative procedure. Hence, in this study, the radiographic parameters were taken to assess the amount of defect fill. The various clinical parameters that were considered in this study were Plaque index, Gingival index, Sulcus bleeding index, PPD, CAL, GR for the soft-tissue assessment to evaluate the clinical outcome of regenerative periodontal therapy following the use of Ossifi™ and Osteora®.

The inter-group comparisons over a period of 6 months, however, were statistically not significant for the following parameters: Mean plaque index scores, mean gingival index score, mean sulcus bleeding score, mean PPD score, mean CAL score and mean GR score. This was contrary to the study by Stratul and Sculean, which showed statistically significant higher CAL gains when oily calcium hydroxide suspension and alpha-TCP was used in comparison with alpha-TCP used alone.[15]

Furthermore, radiographic parameter was considered to assess the amount of defect fill. On comparison between the two groups, the mean amount of defect fill score was more in Group B when compared to Group A at 6 months, which was statistically significant ($P < 0.05$).

There are no known studies to the authors, which demonstrate the comparison of amount of defect fill when oily calcium hydroxide suspension is used alone versus when used in combination with osteoconductive bone-graft.

**CONCLUSION**

The overall observations that can be drawn from this study are that on comparison, Osteora® in combination with osteoconductive Ossifi™ showed better regenerative potential and more significant amount of bone fill in periodontal intrabony defects than when Ossifi™ was used alone. Hence, Osteora® can be used as an adjunct to osteoconductive bone grafts, as an osteo-stimulating agent in the treatment of periodontal intrabony defects.

However, considering the limitations of this study, further long-term clinical and histological studies with a larger sample size are needed to evaluate the regenerative potential of Osteora® in the treatment of intrabony defects.

**REFERENCES**

1. Dietz GH, Lazzerini L, Brunelli M, Stratul SI. Is Osteoinductal® an Osteostimulative bone replacement material? ZWR 2003;112:395-9.
2. Briant R. Bone regeneration through pH-guided bone stimulation with the aid of an osteoproducive short-term implant. Orale Implantologie 2004;6:8.

3. Stratul SI, Rusu D, Benta A, Willershausen B, Sculean A. 12 months clinical comparison between osteoinductal® and emdogain® for the treatment of intrabony defects. Int Poster J Dent Oral Med 2005;7: Poster 297.

4. Schwarz F, Stratul SI, Herten M, Beck B, Becker J, Sculean A. Effect of an oily calcium hydroxide suspension (Osteoinductal) on healing of intrabony periodontal defects. A pilot study in dogs. Clin Oral Investig 2006;10:29-34.

5. Stratul SI, Schwarz F, Becker J, Willershausen B, Sculean A. Healing of intrabony defects following treatment with an oily calcium hydroxide suspension (Osteoinductal). A controlled clinical study. Clin Oral Investig 2006;10:55-60.

6. Stratul S, Rusu D, Jianu R, Enache A, Ogodescu, A, Popescu MG. Densitometric evaluation of periapical bone healing using an oily Calcium hydroxide suspension. A preliminary controlled study. Int Poster J Dent Oral Med 2004;6: Poster 236.

7. Stratul SI, Willershausen B, Sculean A. Intrabony defects treated with a combination of α-tricalciumphosphate and an oily calcium hydroxide suspension-a case series. TMJ 2004;54: 410-6.

8. Wachtel H, Schenk G, Böhm S, Weng D, Zuhr O, Hürzeler MB. Microsurgical access flap and enamel matrix derivative for the treatment of periodontal intrabony defects: A controlled clinical study. J Clin Periodontol 2003;30:496-504.

9. Cortellini P, Tonetti MS. A minimally invasive surgical technique with an enamel matrix derivative in the regenerative treatment of intra-bony defects: A novel approach to limit morbidity. J Clin Periodontol 2007;34:87-93.

10. Tsao YP, Neiva R, Al-Shammari K, Oh TJ, Wang HL. Factors influencing treatment outcomes in mandibular Class II furcation defects. J Periododontol 2006;77:641-6.

11. Hujoel PP, DeRouen TA.Validity issues in split-mouth trials. J Clin Periodontol 1992;19:625-7.

12. Kirkland O. The suppurative periodontal pus pocket; its treatment by the modified flap operation. J Am Dent Assoc 1931;18:1462-70.

13. Miyaji H, Sugaya T, Miyamoto T, Kato K, Kato H. Hard tissue formation on dentin surfaces applied with recombinant human bone morphogenetic protein-2 in the connective tissue of the palate. J Periodontal Res 2002;37:204-9.

14. de Vasconcellos LM, Ricardo LH, Balducci I, de Vasconcellos LG, Carvalho YR. Histological analysis of effects of 24% EDTA gel for nonsurgical treatment of periodontal tissues. J Oral Sci 2006;48:207-14.

15. Stratul SI, Sculean A. Oily calcium hydroxide suspension and alpha-TCP in treating intrabony defects. Int Poster J Dent Oral Med 2004;6: Poster 235.

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