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Three Dimensional Radiographic Bone Fill Evaluation Using Octacalcium Phosphate-Coated Deproteinized Bovine Bone Material (Ti-Oss Bone Graft) and Demineralized Freeze Dried Bone Allograft (DFDBA) in Three Walled Defects

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Abstract

Introduction: The aim of the present study was to evaluate and compare the defect resolution and the amount of bone fill in three wall intra bony defects treated by Open Flap Debridement (OFD) with octacalcium phosphate-coated deproteinized bovine bone material (Ti-oss) and DFDBA bone graft in regeneration of human intra bony defects using CBCT.

Materials and Methods: A total of 20 defects in systemically healthy subjects diagnosed with moderate to advanced Generalized Chronic Periodontitis (GCP) were treated with OFD with octacalcium phosphate-coated deproteinized bovine bone material (Ti-oss Group A) and demineralized freeze dried bone allograft (DFDBA-Group B). Clinical and radiographic parameters were assessed preoperatively and at 3 months and 6 months postoperatively. Data thus obtained was subjected to statistical analysis.

Results: Significant improvement seen in PPD and RAL from baseline to 6 months for both the groups. However, on intergroup comparison, there were no statistical significant differences observed. The radiographic parameters also showed statistically significant improvement from baseline to 6 months for both the groups & significant improvement was seen in bone density at 6 month in (Ti-oss group A) but no significant difference was observed when compared between the test and control groups at all-time points.

Conclusion: Within the limitation of current study, it can be concluded that Ti-oss did not shows any improvement in the clinical and radiographic parameters over DFDBA except in bone density in the treatment of intra bony defects.

Keywords: Ti-oss; Demineralized freeze dried bone allograft; Intra bony defect; Periodontitis

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Introduction

Regeneration of lost structure has become the primary therapeutic goal in Periodontology over past several decades [1]. The objective of periodontal regenerative therapy is to reconstitute the bone, cementum and periodontal ligament on previously diseased root surface [2]. Angular bone loss adjacent to roots results in areas that are difficult for access and maintenance of effective plaque control [3]. Various materials such as auto genous grafts, allografts xenografts, alloplasts have been aimed in the treatment of intra bony defect.

To achieve regeneration, a number of surgical procedures like open flap procedures (e.g. modified Widman flap) alone or with bone grafts such as auto genous bone, allografts like Demineralized Freeze-Dried Bone Allograft (DFDBA), Freeze-Dried Bone Allograft (FDBA), various bone substitutes and Guided Tissue Regeneration (GTR) are employed [4].

New Gold standard in Xenograft, Macro pore Octacalcium Phosphate Coated Deproteinized Bovine Bone (Ti-oss) developed by Dr. Kim Sung O in Korea, has both osseo-conductive and osseo-inductive properties. Ti-oss is made from 100% bovine cancellous bone substitute. The high osteo conductivity of graft bone materials promotes the new bone formation by helping the in growth of

Figure 1a: PPD and RAL at baseline.

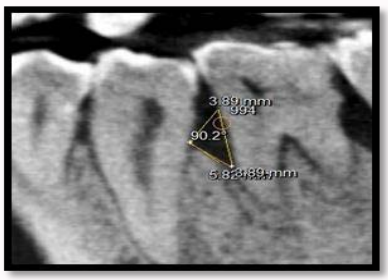

Figure 1b: Bone Defect Area at baseline = 7.56mm^2.

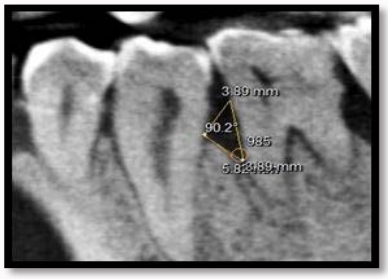

Figure 1c: Bone Density most apical portion of the defect at baseline.

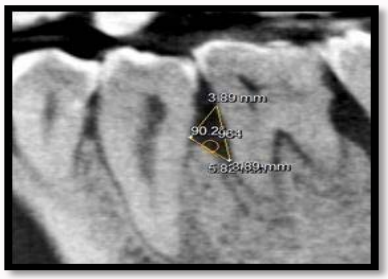

Figure 1d: Bone density halfway between the base of defect & alveolar crest, at baseline.

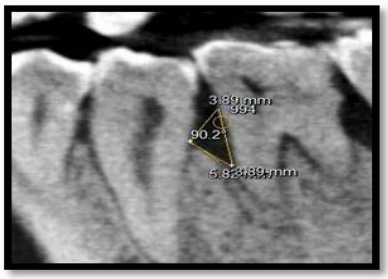

Figure 1e: Bone Density placed just below the alveolar crest in lateral aspect of defect at baseline.

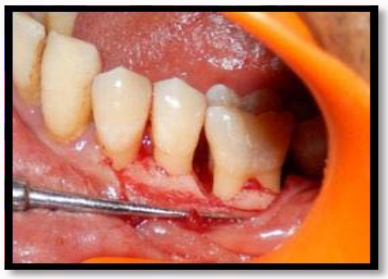

Figure 1f: Defect debrided.

osteogenic cell and micro vessels. Innovative pulverizing technique allows multi porous structure, maximizing blood vessel in growth.

This study is an effort to research and explore the outcome of radiographic bone fill using octacalcium phosphate-coated deproteinized bovine bone material (ti-oss bone graft) & DFDBA in human intra bony three wall defects clinically and radio graphically using CBCT to measure changes in bone density in Gray values after 6 months post treatment.

Clinical Presentation

A clinical and radiographic study was carried out to assess the efficacy of Octacalcium Phosphate-Coated Deproteinized Bovine Bone Material (Ti-Oss bone graft group A) and Demineralized Freeze Dried Bone Allograft (DFDBA) (Group B) in the treatment of human intra bony defects. Patients were selected from Out Patient Department (OPD) of Periodontology, Subharti Dental College and Hospital, Meerut, Uttar Pradesh.

A total of 20 defects in systemically healthy and compliant subjects diagnosed with moderate to advanced Generalized Chronic Periodontitis (GCP) aged between 20-55 years showing clinical and radiographic evidence of angular defects in relation to mandibular premolars and molars were selected for the study and randomly divided into 2 groups.

The patients selected were explained about the treatment procedure and the associated risks and benefits and their written consent was obtained.

Group A: 10 Intra bony defects were subjected to OFD with octacalcium phosphate-coated deproteinized bovine bone material (Ti-oss) bone graft particle size = (0.2 mm to 1.0 mm).

Group B: 10 Intra bony defects were subjected to OFD with DFDBA (300 µm to 500 µm).

The following recordings were made in the proforma (annexure) designed for the study:

1. Medical history, dental history and personal history

2. Clinical examination of the dentition

3. CBCT to assess area of the defect and bone density at baseline & after 6 months.

All clinical parameters i.e. GI [5], PI [6], OHIS [7], PPD, RAL were recorded preoperatively (baseline) and postoperatively at 3 months and 6 months.

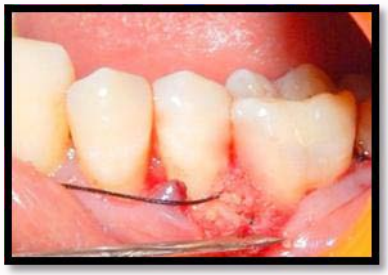

Figure 2a: Graft placed (Ti-oss).

Figure 2d: PPD and RAL at 6 months.

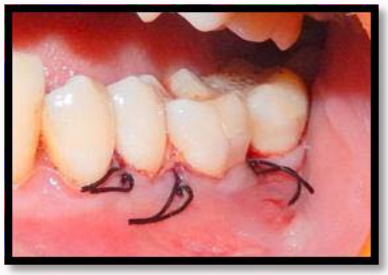

Figure 2b: Suturing done.

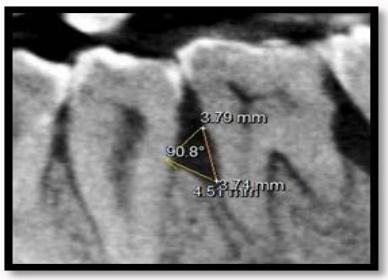

Figure 2e: Bone Defect Area at 6 months= 7.08 mm^2.

Figure 2c: PPD and RAL at 3 months.

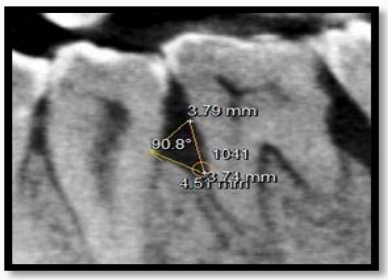

Figure 2f: Bone Density most apical portion of the defect at 6 months.

Radiographic measurements

Radiographic bone fill (RBF) (%) after 6 months was then calculated by using the formula by Eickholz et al. [8]

Changes in bone density (Gray values) after the bone fill were recorded at 6 month compared from baseline. Four Standard Region of Interest (ROIs) were selected for each defect [9]. Mean value of 3 points was taken.

Case Management

Local anesthesia (2% lidocaine, epinephrine 1:100,000) was injected in the site of surgery. Crevicular incision was given in the sextant of the defect, and a mucoperiosteal flap was raised. The area was degranulated, curetted and irrigation was done with diluted betadine solution (Figures 1a-1f). Defect was isolated, and the graft was moistened in patient's own blood and placed in small increments in the defect and condensed until the defect was filled. Before graft placement, presuturing was performed (Figure 2a, 2b). Periodontal pack placed over the sutures.

Postoperative instructions given and medication that included analgesics (Ibuprofen 400 mg after every 8 h) and antibiotics (Amoxicillin 500 mg every 6 h) for 5 postoperative days were advised to the patient.

The clinical parameters were recorded at baseline (Figure 1a) postoperatively at 3 months (Figure 2c) and at 6 months (Figure 2d). The Radiographic parameters were recorded at baseline (Figures 1b-1e) and at 6 months (Figures 2e-2h) and oral hygiene instructions reinforced at every visit.

Statistical analysis

The data regarding the clinical and radiographic parameters for both the treatment groups recorded at baseline, 3 months and 6 months was tabulated and subjected to statistical analysis. Student's paired t-test was applied for intra-group analysis, and Student's unpaired t-test was applied for the inter-group analysis.

$P<0.05$ indicated significant difference between the group means at 5% level of significance. The following conclusions were considered:

1. If calculated value was more than the tabulated value, then $P<0.05$ that is a significant difference was observed

2. If calculated value was less than tabulated value, then $P>0.05$ that is no significant difference was observed between groups at 5% level of significance.

Clinical Outcomes

Current research demonstrated a mean difference of GI from

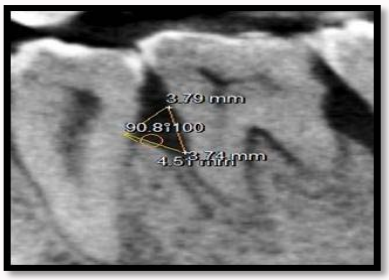

Figure 2g: Bone Density halfway between the base of defect & alveolar crest, at 6 months.

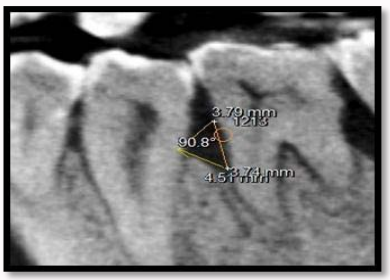

Figure 2h: Bone Density placed just below the alveolar crest in lateral aspect of defect at 6 months.

baseline to 3 months as (P=0.0042). The decrease in the GI from baseline to 6 month was calculated as mean difference of (P=0.2103). Also the change in the GI from 3 months to 6 month was (P=0.0004) for Ti-oss and (P=0.0144) which is significant from baseline to 3 months, (P=0.1131), (P=0.4241) respectively for DFDBA which was statistically insignificant (Table 1). Inter-group comparison was also non-significant at all-time intervals (Table 2).

In the present research, difference in the oral hygiene status from baseline to 3 months to 6 months, respectively, and from 3 months to 6 months were not statistically significant (Table 1). Similarly, inter-group comparison (Table 2) at all-time points was also not statistically significant. This suggests that oral hygiene was maintained optimally well throughout the period of study.

On application of paired t test for Ti-oss, the mean difference in PI at different time interval from baseline to 3 month was statistically not significant (P=0.1506). The value of decrease in the PI from 3 to 6 month as mean difference which was statistically non-significant (P=0.0584). However, the change in the PI from baseline to 6 month was statistically significant (P=0.0008). For DFDBA mean difference from baseline to 3 months (P=0.6086), 3 to 6 months (P=0.0540) was statistically non-significant, from baseline to 6 month (P=0.0158) was statistically significant (Table 1). While the result were non-significant at all-time interval on inter-group comparison (Table 2). This was achieved by the reinforcement of plaque control measures and oral hygiene maintenance instructions at various recall periods.

This research demonstrates a decrease in pocket probing depth from baseline to 3 months and 3 to 6 months and baseline to 6 months highly statistically significant (P=0.0000), for Ti-oss and (P=0.0032) respectively, for DFDBA which was found to be statistically significant (Table 1). However, the result was non-significant at all-time intervals on inter-group comparison (Table 2).

Similar observations were seen for RAL which demonstrates a mean difference of baseline to 3 months and baseline to 6 months for Ti-oss (P=0.0002), (P=0.0000) and P=(0.0004), P=(0.0000) for DFDBA at baseline to 3 months and 6 months, respectively, which was statistically significant but the mean difference between 3 to 6 months was statistically non-significant for Ti-oss P=(0.0811) whereas for DFDBA significant at 3 to 6 months (Table 1). Inter-group comparison was also non-significant at all-time points (P>0.05) (Table 2).

The observation of the study shows a decrease in the area of the defect from baseline to 6 months, respectively, in both the groups and was found to be statistically significant. Furthermore, the difference from baseline to 6 months was statistically significant in both the groups (Table 1) but inter-group comparison was statistically insignificant (Table 2) (P>0.05).

An increase in the radiographic bone density for Ti-oss at baseline to 6 months. The mean deference in the BDF of the defect from baseline to 6 months as calculated by applying paired t test, which was highly statistically significant (P=0.0003). For DFDBA (P=0.0002). The scores were found not to be statistically significant at the end of 6 months between test & control groups (P>0.05), whereas BDF & BDF% scores were found to be statistically significant at the end of 6 months between test & control groups (p<0.05).

Discussion

This research was a comparative evaluation of Ti-oss and DFDBA in the treatment of intra bony defects. Periodic oral prophylaxis was performed so as to avoid formation of plaque, calculus deposits and

Table 1: Intra group comparison for different parameters (P values) at different pair of time-intervals.

S. NO.	PARAMETERS	GROUP A			GROUP B		
		0-3	0-6	6-Mar	0-3	0-6	6-Mar
1	GINGIVAL INDEX	0.0042* P<0.05 (SIG.)	0.0004* P<0.05 (SIG.)	0.2103* P<0.05 (SIG.)	0.0144* P<0.05 (SIG.)	0.1131** P>0.05)N.S.	0.4241** P>0.05) N.S.
2	PLAQUE INDEX	0.1506** P>0.05) N.S.	0.0008* P<0.05 (SIG.)	0.0584** P>0.05) N.S.	0.6086** P>0.05)N.S.	0.0158* P<0.05 (SIG.)	0.0540** P>0.05) N.S.
3	OHIS SCORES	0.6078** P>0.05) N.S.	0.3542** P>0.05)N.S.	0.1708** P>0.05) N.S.	0.6788** P>0.05)N.S.	0.9329** P>0.05)N.S.	0.7478** P>0.05)N.S.
4	PPD	0.0001* P<0.05 (SIG.)	0.0000* P<0.05 (SIG.)	0.0095* P<0.05 (SIG.)	0.0002* P<0.05 (SIG.)	0.0000* P<0.05 (SIG.)	0.0032* P<0.05 (SIG.)
5	RAL	0.0002* P<0.05 (SIG.)	0.0000* P<0.05 (SIG.)	0.0811** P>0.05) N.S.	0.0004* P<0.05 (SIG.)	0.0000* P<0.05 (SIG.)	0.0095* P<0.05 (SIG.)
6	AREA	----	0.0029* P<0.05 (SIG.)	-------	-----	0.0027* P<0.05 (SIG.)	------
7	BONE DENSITY	----	0.0003* P<0.05 (SIG.)	----	----	0.0002* P<0.05 (SIG.)	----

**shows no significant difference at 0.05 level of significance (p>0.05)
*shows a significant difference at 0.05 level of significance (p<0.05)

Table 2: Inter group comparison for different parameters between group A & group B at baseline, after 3 months & after 6 months.

S.NO.	PARAMETERS	AT BASE LINE	AFTER 3 MONTH	AFTER 6 MONTHS
1	GINGIVAL INDEX	0.3353**P>0.05)N.S.	0.5594** P>0.05)N.S.	0.1636** P>0.05)N.S.
2	PLAQUE INDEX	0.5173** P>0.05)N.S.	0.6266** P>0.05)N.S.	0.8476** P>0.05)N.S.
3	OHIS SCORES	0.9750** P>0.05)N.S.	0.4283** P>0.05)N.S.	0.4406** P>0.05)N.S.
4	PPD	0.3430** P>0.05)N.S.	0.2800** P>0.05)N.S.	0.6511** P>0.05)N.S.
5	RAL	0.6332** P>0.05)N.S.	1** P>0.05)N.S.	0.8191** P>0.05)N.S.
6	AREA	0.2157** P>0.05)N.S.	------	0.3227** P>0.05)N.S.
7	BONE DENSITY	0.6611** P>0.05)N.S.	------	0.6268** P>0.05)N.S.

**shows no significant difference at .05 level of significance (p>0.05)

debris on the grafted site as they could hamper the final outcome.

Results are in slight contrast with the observations reported by Oreamuno et al. [10] who reported significant reduction in the mean plaque score but the decrease was statistically insignificant from baseline to 6 months. However, in the present research there was a slight change of 1.05 ± 0.70 in the mean plaque score from baseline to 6 months but this was also statistically insignificant.

BRG when used alone to treat intra bony defects showed an approximate bone fill of 60% to 65%. Although an improvement occurs, a residual defect usually exists. Rummelhart et al. [11] also reported a mean osseous repair of 59% with use of DFDBA and 66% with FDBA. Quintero et al. [12] also reported a mean osseous regeneration for all defects as 2.4 mm, representing a 65% mean bone-fill of the original defect. The findings demonstrated that DFDBA has potential as an osseous grafting material in periodontal therapy. However, in the present research mean difference bone density fill 92.72 and radiographic bone density fill % of 11.81% (p=0.0001).

Richardson et al. [13] compared the bovine derived xenograft (BDX) Bio-Oss to DFDBA. BDX group showed statistically significant improvement as compared to DFDBA (P<0.05). Osseous measurements at 6 month re-entry showed bone fill of 2.4 mm (46.8%) for the DFDBA group and 3.0 mm (55.8%) for the BDX group. Defect resolution was 59.4% for the DFDBA group and 77.6% for the BDX groups. Combination ABM/P-15 grafts demonstrated significantly better mean defect fill of 2.8 ± 1.2 mm (72.3%) *vs.* a mean defect fill of 2.0 ± 1.4 mm (51.4%) for defects treated with DFDBA and a mean defect fill of 1.5 ± 1.3 mm (40.3%) for defects treated with OFD (P<0.005) [14]. The results of the above studies [13,14] were comparable to the present research in which use of graft showed a bone fill of 26.04 ± 12.86% in control group and 22.98 ± 15.64% in test group in a time span of 6 months as evaluated by using CBCT (P<0.05). Ti-oss show statistically significant improvement as compared to DFDBA (P<0.05).

To the best of our knowledge, this is the 1st study to report the use of octacalcium phosphate-coated deproteinized bovine bone material (Ti-oss) bone graft in the treatment of intra bony defects in humans. Hence, a direct comparison with other studies was not possible. While monitoring changes in clinical and radiographic parameters with other studies, (Ti-oss) showed a significant improvement in soft and hard tissue regeneration also radiographic Bone Density Fill % (BDF %) was 22.76% in test group A (Ti-oss) as compared to control group B (DFDBA) radiographic BDF % was 10.95%. The amount of defect fill in mm, percent defect fill and bone density fill were significantly improved at 6 month as compared to baseline.

Conclusion

Both treatment modalities demonstrated a significant improvement in the probing depth, RAL and radiographic area of the defect and bone density fill at 6 months post-surgery. Octacalcium phosphate-coated deproteinized bovine bone material (Ti-oss) bone graft showed superior results regarding radiographic bone fill and radiographic bone density fill % than DFDBA.

Summary

Why is this case new information?	It is 1st research reporting the use of Octacalcium phosphate-coated deproteinized bovine bone material (Ti-oss) in the treatment of intrabony defect to evaluate radiographic bone density fill.
What are the keys to successful management of this case?	Proper surgical technique, aseptic conditions, postoperative care, and follow-up are the keys to successful management of this case.
What are the primary limitations to success in this case?	Histological analyses have not been performed.

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