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Original Article

Dentistry Section

Clinical and Radiographical Evaluation of Bovine Derived Xenograft without or with Calcium Sulphate Hemihydrate in the Treatment of Intrabony Defects in Chronic Periodontitis: A RCT

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ABSTRACT

Introduction: Intrabony periodontal defects respond well to regenerative periodontal therapy. Numerous grafts and non graft materials are available for regeneration. Careful use of nonallogenic bone graft could enhance radiographic defect fill.

Aim: To compare the clinical and radiographical evaluation of bovine derived xenograft (Osseograft™) alone versus a combination of bovine derived xenograft and calcium sulphate hemihydrate (Osseomold™) in the treatment of intrabony defects in chronic periodontitis.

Materials and Methods: A prospective, single blinded randomised clinical trial was conducted in the department of Periodontics, Nair Hospital Dental College, Mumbai, India (December 2017-August 2019). A total of 42 patients presenting with 43 intrabony defects were randomly assigned to Control Group (CG) (n=21) or Test Group (TG) (n=22). Clinical parameters {Probing Pocket Depth (PPD) and Clinical Attachment Level (CAL)} were assessed at baseline (M0), one month (M1), three months (M3) and six months (M6) and radiographic parameters {Bone Fill (BF)} were measured using Intraoral Periapical Radiograph (IOPA) at baseline (M0) and six months (M6). Two patients (three defects) were lost to follow-up. Descriptive and inferential statistical analyses were performed, results on continuous measurements were presented on Mean±SD. Statistical software IBM SPSS statistics 20.0. Level of significance was fixed at p=0.05. Student's t-test was used to find the significant difference between and within the groups. Repeated measures Analysis of variance (ANOVA) was used to find the significance of study parameters within the group (at different time intervals).

Results: PPD was lowest at six months for TG (3.95±0.61) and CG (3.30±0.66) and it gradually improved from baseline to six-months (p<0.001 for both TG and CG). CAL gain was highest at six-months for TG (4.4±0.50) and CG (3.65±0.75) (p<0.001). Significant reduction in Radiographic Defect Depth (RDD) was noted in both the groups (CG: 6.65±1.08 at M0 and 4.92±1.00 at M6 (p<0.001); TG: 7.06±0.96 at M0 and 5.14±0.77 at M6) (p<0.001). Intergroup analysis was statistically significant for clinical parameters with greater improvement seen in CG control group {PPD and CAL at M3 and M6 (p<0.001)} and statistically insignificant for radiographic parameters (p>0.5). BF was higher at M6 in TG (1.87) as compared to CG (1.72), which was statistically insignificant.

Conclusion: Both treatments were clinically effective showing a significant improvement in clinical and radiographic parameters and there was significant difference between the two groups-clinically in terms of reduction in PPD and CAL gain at three months and six months with greater improvement seen in CG as compared to TG, with no difference radiographically. Further studies are needed to show the stability over time of the present results.

Keywords: Bone fill, Bone grafts, Periodontal disease, Putty-like graft, Regenerative therapy

INTRODUCTION

Intrabony periodontal defects compromise the teeth of their support and present a clinical challenge in the treatment process [1]. The management of such defects ranges from non surgical mechanical debridement to regenerative therapy. During regenerative periodontal therapy, using a xenograft as a grafting material within periodontal defects when indicated is usually used and nicely documented [2]. A xenograft (heterograft) is a graft acquired from some other species which includes bovine, equine, or coral [3,4]. Such materials, once obtained are processed to remove cells, organic, and proteinaceous materials, thus leaving behind an inert absorbable bone scaffolding that is reported to assists in revascularisation, osteoblast migration, and new bone formation [5-8]. Various studies in humans and animals have shown that anorganic bovine derived bone shows osteoconductive property and facilitates new bone formation [9,10]. It contains growth factors that might facilitate the induction of new bone [11]. Previous case reports have shown uneventful recuperation and minimal inflammatory reaction following the use of bovine-derived bone [8,12-14]. On the other hand, calcium sulphate hemihydrate, an alloplastic graft material has the greatest usefulness as bone graft extenders. They are not better clinically than other graft materials, but because they are easily available, very economic and offer better handling characteristics, they are commonly used [15].

Owing to the enhanced handling properties of calcium sulphate hemihydrate, a combination of xenogenic bone and an alloplast such as calcium sulphate hemihydrate could be potentially advantageous and hence the purpose of this study was to compare and evaluate, clinically and radiographically the BF of human intrabony periodontal defects grafted with bovine derived xenograft (Osseograft™) alone versus a combination of bovine derived xenograft and calcium sulphate hemihydrate (Osseomold™).

MATERIALS AND METHODS

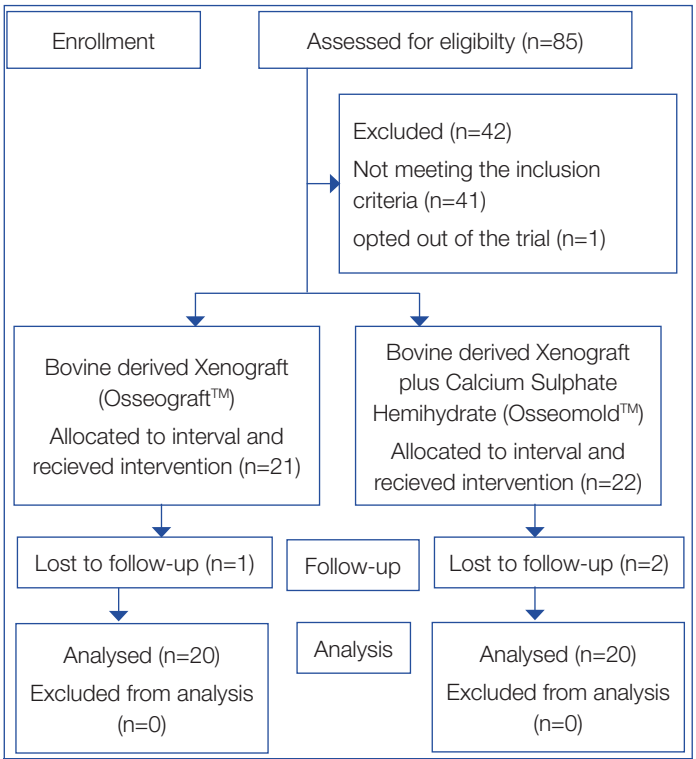
A prospective, single blinded randomised clinical trial was conducted in the Department of Periodontics, Nair Hospital Dental College, Mumbai, India for a period of one year and nine months from

December 2017 to August 2019 with a six month follow-up, which focused on the treatment of human intrabony defects. Prior clearance was obtained from the Institutional Ethical Committee (EC/PG-08 PERIO/2017). The study was registered on Clinical Trails Registry under the reference: CTRI/2018/01/011245. All patients were selected and treated in the Department of Periodontology, Nair hospital Dental College, India. Informed consent was obtained from all individual participants included in the study for participation and use of clinical images.

Inclusion criteria: Patients diagnosed with chronic periodontitis of age 20 to 55 years with three walled intrabony defects (defect depth ≥3 mm) with good oral hygiene after phase I periodontal therapy, in good systemic health and those willing to give written informed consent were included in the study.

Exclusion criteria: Patients with one or two walled osseous defects, compromised immune system or systemic disorders, with known allergy to the drugs used in the study or former/current smokers were excluded from the study.

Sample size selection: A total of 85 intrabony defects were examined between December 2017 and January 2019. After clinical and radiographic examinations, 42 patients (with a total of 43 intrabony defects) were selected based on inclusion and exclusion criteria. Two patients (3 intrabony defects) were lost to follow-up. Out of 40 defects, twenty-six (26) were on the mesial side (65%) and fourteen (14) were on the distal side (35%). Twenty-one (21) were of right side (52.5%) and nineteen (19) were of left side (47.5%) [Table/Fig-1].



[Table/Fig-1]: Intrabony-defect accountability diagram.
n: Intrabony defects

Before beginning of the study, a computer assisted randomisation programme was used which divided the participants into two groups, using Microsoft excel. As the study was single blinded, the participants remained unaware of the intervention type (Osseograft™) or Osseomold™) throughout the study. The statistical unit for the randomisation was the lesion, i.e., the intrabony defect. The intrabony defects were treated by the same investigator following the randomisation list. The patients were included and treated from December 2017 until August 2019 with a six-month follow-up after surgery.

After obtaining a signed informed consent, the CG was treated with bovine derived xenograft with type I collagen (Osseograft™) and the TG was treated with a combination of bovine derived xenograft and calcium sulphate hemihydrate (Osseomold™).

Clinical Measurements

All measurements were performed by the primary investigator. The following clinical parameters were recorded:

1. Plaque Index (PI) [16] (Turesky S, Gilmore ND and Glickman I. modification of Quigley-Hein PI 1970): Using chewable plaque disclosing tablets (At baseline, one month, three months and six months).
2. Gingival Index (GI) [17] (Loe H, 1967): Measured at baseline, one month, three months and six months.

   The following clinical parameters were measured using specially fabricated acrylic stent and a Hu-Friedy UNC-15 periodontal probe. This was done to facilitate reproduction of direction and angulation of probe placement at the periodic recordings, thereby ensuring standardisation of preoperative and postoperative comparisons (Isidor F et al., 1984) [18].
3. Probing Pocket Depth (PPD): from gingival margin to the bottom of the pocket, measured at six points around the tooth. (At baseline, three, six months post surgery).
4. Clinical Attachment Level (CAL): from Cemento-Enamel Junction (CEJ) to the base of the sulcus, measured at six points around the tooth. (At baseline, three, six months post surgery).

Radiographical Measurements

The following radiographical parameters were recorded:

IOPA radiographs of the selected sites were taken using long cone paralleling technique. RDD was calculated from the CEJ to the base of the defect at baseline and six month follow-up. BF was evaluated by comparing the preoperative depth of the defect with the postoperative depth of the defect, determined by using CEJ as the fixed reference point. Amount of radiographic BF is calculated as the difference in the distance from CEJ to base of the defect at baseline and at six months post surgery.

Surgical Protocol

After rinsing with 0.2% chlorhexidine gluconate (Hexidine, ICPA, India) for 30 seconds, local anaesthesia was administered using infiltration/nerve block technique. Intrasulcular incisions were performed with no. 15 blade to raise an envelope full thickness muco-periosteal flap in the region of the osseous defect. Granulation tissue was debrided, root surfaces were thoroughly scaled and planed with manual instrumentation (Hu-Friedy Gracey curettes). The surgical site was regularly rinsed with normal saline. Depending on the group, the defect was filled either with Osseograft™ or Osseomold™. Interrupted loop sutures were placed to obtain primary closure of the interdental papilla using 3-0 black braided non resorbable silk suture material. Non eugenol based periodontal dressing (Coe-Pak) was placed over the surgical area.

Postoperative Instructions and Care

Patients were advised not to eat or drink anything hot or to brush after surgery. They were advised to eat soft non-spicy food only for a week. One week after the surgery, patients were asked to use a soft bristle toothbrush. After two weeks, they could go back to normal brushing habits.

The following medications were prescribed:

- Doxycycline Hydrochloride 200 mg once daily for first day followed by 100 mg once daily for six days.

- Tablet Ibuprofen (400 mg) and Paracetamol (500 mg) thrice daily for three days.
- 10 mL of 0.2% chlorhexidine rinses twice daily for seven days.

The sutures were removed after seven days. Patients were seen every two weeks in the first month and once a month thereafter to monitor the surgical site and perform supra gingival scaling, if necessary. Oral hygiene instructions were reinforced.

Patients were evaluated clinically at one, three and six months and radiographically six months postoperatively. Clinical and radiographic measurements were repeated for both TG and CG, similar to the previous pre surgical measurement procedure.

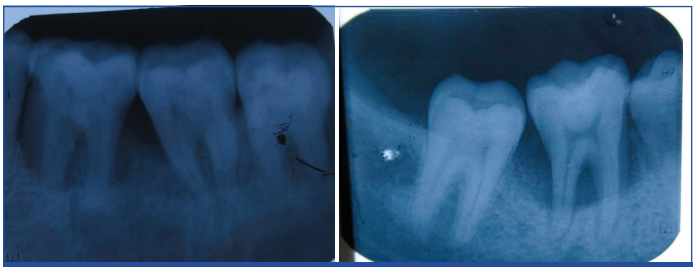
STATISTICAL ANALYSIS

Descriptive and inferential statistical analyses were carried out in the present study. Results on continuous measurements were presented on Mean±SD. Level of significance was fixed at p≤0.05 and any value less than or equal to 0.05 was considered to be statistically significant. Student's t-tests (two tailed, paired and unpaired) were used to find the significance of study parameters on continuous scale between and within the groups. One-way and two-way Repeated measures Analysis of variance (ANOVA) was used to find the significance of study parameters within the group (at different time intervals). The Statistical software IBM SPSS statistics 20.0 (IBM Corporation, Armonk, NY, USA) was used for the analysis of the data and Microsoft Word and Excel were used to generate graphs, tables etc.

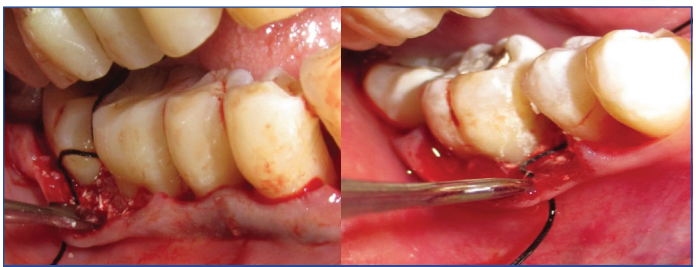
RESULTS

The surgical procedures and evaluation of various clinical and radiographic parameters are depicted in [Table/Fig-2-7]. There were 18 females and 22 males in the study population aged between 23 to 55 years (mean age of 35 years).

[Table/Fig-2]: Baseline PPD using specially fabricated acrylic stent and a Hu-Friedy UNC-15 periodontal probe in CG and TG.



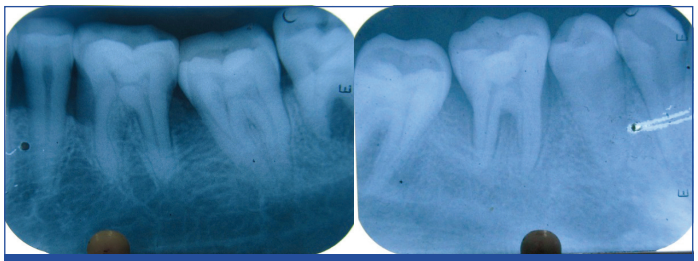
[Table/Fig-3]: Baseline radiograph using long cone paralleling angle technique and a paralleling device in CG and TG.



[Table/Fig-4]: After thorough debridement, intrabony defect filled with bone grafts-Osseograft™ in CG and Osseomold™ in TG.

[Table/Fig-5]: A three-months postoperative Probing Pocket Depth (PPD) using specially fabricated acrylic stent and a Hu-Friedy UNC-15 periodontal probe in Control Group (CG) and Test Group (TG).

[Table/Fig-6]: A six-months postoperative Probing Pocket Depth (PPD) using specially fabricated acrylic stent and a Hu-Friedy UNC-15 periodontal probe in Control Group (CG) and Test Group (TG).



[Table/Fig-7]: A six-month radiograph using long cone paralleling angle technique and a paralleling device in Control Group (CG) and Test Group (TG).

Clinical Measurements

1. Plaque Index (PI)

Intergroup analysis: The intergroup analysis as shown in [Table/Fig-8] was statistically insignificant at baseline (p=0.582), one month (p=0.886), three months (p= 0.288) and six months postoperative (p=0.066).

Plaque Index (PI)		N	Mean	Std. Deviation	t value	p-value
Baseline	CG	20	1.3160	0.21197	0.556	0.582
	TG	20	1.3515	0.19137		
1 month	CG	20	0.9680	0.19322	0.144	0.886
	TG	20	0.9560	0.31784		
3 months	CG	20	0.7860	0.16181	1.078	0.288
	TG	20	0.7400	0.10110		
6 months	CG	20	0.7060	0.16155	1.892	0.066
	TG	20	0.6185	0.12922		

[Table/Fig-8]: Comparison of Plaque Index (PI) values in terms of {Mean (SD)} at different time intervals between both the groups using unpaired t-test.

Intragroup analysis: The mean PI score for patients in CG was 1.31 at baseline, 0.97 at one month, 0.786 at three months and 0.706, six months postoperative [Table/Fig-9]. The mean PI score for patient in the TG was 1.35 at baseline, 0.96 at one month, 0.74 at three months and 0.62 at six months postoperative and the difference was found to be statistically significant compared to baseline in individual groups (p<0.001) [Table/Fig-9].

2. Gingival Index (GI)

Intergroup analysis: The intergroup analysis as shown in [Table/Fig-10] was statistically insignificant at baseline (p=0.595), one month (p=0.404), three months (p=0.197) and six months postoperative (p=0.129).

Intragroup analysis: The median GI score for patients in CG was 1.4 at baseline, 0.84 at one month, 0.57 at three months and

Time interval	N	Mean		Std. Deviation		Wilk's Lambda value		p-value
		CG	TG	CG	TG	CG	TG	
Baseline	20	1.3160	1.3515	0.21197	0.19137	40.658	57.991	<0.001**
1 month	20	0.9680	0.9560	0.19322	0.31784			
3 months	20	0.7860	0.7400	0.16181	0.10110			
6 months	20	0.7060	0.6185	0.16155	0.12922			

[Table/Fig-9]: Intragroup analysis of PI using repeated measures ANOVA test.
*p<0.05 (significant), **p<0.001 (Highly significant)

Gingival Index (GI)		N	Mean	Std. Deviation	t value	p-value
Baseline	CG	20	1.4260	0.18955	0.536	0.595
	TG	20	1.4620	0.23332		
1 month	CG	20	0.8425	0.23943	0.844	0.404
	TG	20	0.9035	0.21741		
3 months	CG	20	0.5710	0.30255	1.312	0.197
	TG	20	0.6775	0.20068		
6 months	CG	20	0.4375	0.25856	1.553	0.129
	TG	20	0.5450	0.17028		

[Table/Fig-10]: Comparison of Gingival Index (GI) values in terms of {Mean (SD)} at different time intervals between both the groups using unpaired t test, and in individual groups using repeated measures ANOVA.

0.44 six months postoperative [Table/Fig-11]. The mean GI score for patient in TG was 1.5 at baseline, 0.90 at one month, 0.68 at three months and 0.55 six months postoperative [Table/Fig-11]. The difference was found to be statistically significant compared to baseline in individual groups (p<0.001).

Time interval	N	Mean		Std. Deviation		Wilk's Lambda value		p-value
		CG	TG	CG	TG	CG	TG	
Baseline	20	1.4260	1.4620	0.18955	0.23332	60.321	99.924	<0.001**
1 month	20	0.8425	0.9035	0.23943	0.21741			
3 months	20	0.5710	0.6775	0.30255	0.20068			
6 months	20	0.4375	0.5450	0.25856	0.17028			

[Table/Fig-11]: Intragroup analysis of GI using Repeated measures ANOVA test.
**p<0.001 (Highly significant)

3. Probing Pocket Depth (in mm)

Intergroup analysis: The intergroup analysis as shown in [Table/Fig-12], was statistically significant at three months (p<0.001) and six months postoperative (p=0.002) indicating a greater reduction in pocket depth in CG at M3 and M6 as compared to TG.

Pocket probing depth		N	Mean	Std. Deviation	t value	p-value
Baseline	CG	20	8.30	1.081	1.640	0.109
	TG	20	8.85	1.040		
3 months	CG	20	4.30	0.657	3.894	<0.001**
	TG	20	5.45	1.146		
6 months	CG	20	3.30	0.657	3.255	0.002*
	TG	20	3.95	0.605		

[Table/Fig-12]: Comparison of Pocket probing depth values in terms of (Mean and SD) at different time intervals between both the groups using unpaired t-test, and in individual groups using repeated measures ANOVA.
*p<0.05 (Significant), **p<0.001 (Highly significant)

Intragroup analysis: The mean PPD (in mm) for patient in CG was 8.30 mm at baseline, 4.30 mm at three months and 3.30 mm at six months postoperative [Table/Fig-13].

The mean PPD (in mm) for patient in TG was 8.85 mm at baseline, 5.45 mm at three months and 3.95 mm at six months postoperative [Table/Fig-13]. The difference was found to be statistically significant compared to baseline in individual groups (p<0.001).

Time interval	N	Mean		Std. Deviation		Wilk's Lambda value		p-value
		CG	TG	CG	TG	CG	TG	
Baseline	20	8.30	8.85	1.081	1.040	228.214	285.119	<0.001**
3 months	20	4.30	5.45	0.657	1.146			
6 months	20	3.30	3.95	0.657	0.605			

[Table/Fig-13]: Intragroup analysis of PPD using Repeated measures ANOVA test.
**p<0.001 (Highly significant)

4. Clinical Attachment Level (in mm)

Intergroup analysis: The intergroup analysis as shown in [Table/Fig-14], was statistically significant at three months (p<0.001) and six months postoperative (p<0.001) indicating a greater CAL gain in CG at M3 and M6 as compared to TG.

Clinical attachment level		N	Mean	Std. Deviation	t value	p-value
Baseline	CG	20	8.90	1.071	0.477	0.636
	TG	20	8.75	0.910		
3 months	CG	20	4.65	0.745	4.210	<0.001**
	TG	20	5.60	0.681		
6 months	CG	20	3.65	0.745	3.732	<0.001**
	TG	20	4.40	0.503		

[Table/Fig-14]: Comparison of Clinical Attachment Level (CAL) values in terms of {Mean (SD)} at different time intervals between both the groups using unpaired t-test, and in individual groups using repeated measures ANOVA.
**p<0.001 - Highly significant

Intragroup analysis: The mean patient CAL (in mm) in CG was 8.90 at baseline, 4.65 at three months and 3.65 at six months [Table/Fig-15]. The mean patient CAL (in mm) in TG was 8.75 at baseline, 5.60 at thee months and 4.40 at six months [Table/Fig-15]. The difference was found to be statistically significant compared to baseline in individual groups (p<0.001).

Time interval	N	Mean		Std. Deviation		Wilk's Lambda value		p-value
		CG	TG	CG	TG	CG	TG	
Baseline	20	8.90	8.75	1.071	0.910	195.483	273.254	<0.001**
3 months	20	4.65	5.60	0.745	0.681			
6 months	20	3.65	4.40	0.745	0.503			

[Table/Fig-15]: Intragroup analysis of CAL using Repeated measures ANOVA test.
**p<0.001 - Highly significant

Radiographical Measurements

Radiographic Defect Depth (RDD): (in mm)

Intergroup analysis of Radiographic depth of the defect showed no significant difference between CG and TG at baseline and six months [Table/Fig-16].

Radiographic depth of the defect		N	Mean	Std. Deviation	t-value	p-value
Baseline	CG	20	6.645	1.0802	1.267	0.213
	TG	20	7.055	0.9627		
6 months	CG	20	4.925	1.0073	0.759	0.453
	TG	20	5.140	0.7694		

[Table/Fig-16]: Comparison of Radiographic depth of the defect in terms of {Mean (SD)} at different time intervals between both the groups using unpaired t test, and in individual groups using paired t- test.

Intragroup analysis: Significant reduction in RDD was noted in both the groups (CG: 6.65±1.08 at M0 and 4.92±1.00 at M6; TG: 7.06±0.96 at M0 and 5.14±0.77 at M6). Intergroup analysis showed statistically insignificant difference between the two groups [Table/Fig-17].

Radiographic Bone Fill (BF): (in mm)

Intergroup analysis was not statistically significant. BF was higher (statistically insignificant) at M6 in TG (1.87) as compared to CG (1.72)

Time Interval	N	Mean		Std. Deviation		t value		p-value
		CG	TG	CG	TG	CG	TG	
Baseline	20	6.645	7.055	1.0802	0.9627	8.795	9.975	<0.001**
6 months	20	4.925	5.140	1.0073	0.7694			

[Table/Fig-17]: Intragroup analysis paired t test.
**p<0.001 - Highly significant

[Table/Fig-18]. Thus, there was no significant difference for the measures at baseline between the TG and the CG for all measures except PPD AND CAL at three months and six months (p<0.001).

Radiographic bone fill		N	Mean	Std. Deviation	t value	p-value
Baseline-6 months	CG	20	1.720	0.8746	0.524	0.603
	TG	20	1.870	0.9348		

[Table/Fig-18]: Comparison of Radiographic Bone Fill (BF) (Baseline - 6 months) in terms of {Mean (SD)} among both the groups using unpaired t-test.

Follow-up

There were no major complications encountered throughout the study. The graft was well tolerated by all the study participants with minimal postoperative discomfort. Two patients (three intrabony defects) were lost to follow-up during the study period.

DISCUSSION

In the present study, 40 intrabony defects were included and based on the results, both treatment modalities showed better clinical results at M6 compared to M0 with respect to PPD, CAL, (measured using a graduated UNC-15 periodontal probe and a customised acrylic stent), RDD and BF. CAL gain and PPD reduction was greater in TG at M3 and M6 as compared to CG. Radiographic parameters showed similar improvements in both the groups. Human clinical study done by Yukna RA where coralline calcium carbonate was evaluated against open flap debridement as a bone replacement graft material demonstrated significantly better BF in periodontal intrabony defects compared to control [19]. Scabbia A and Trombelli L conducted a parallel-group randomised clinical trial to compare equine xenograft to bovine derived xenograft. Although intragroup analysis showed significant improvements, no statistical difference was found for PPD, CAL gain and defect depth gain [20]. All clinical parameters of the current study showed statistically significant improvements for both groups with results comparable to the mentioned studies.

The GI and PI indicate the oral hygiene maintained by the patient thus affecting the gingival health and final outcome of regenerative therapy [17,18]. There was a statistically significant improvement seen in plaque scores and gingival scores in both TG and CG (p<0.001). There was no statistical difference (p<0.05) between the two groups for PI and GI. For PPD and CAL gain, in both the groups, statistically significant difference was observed. Effect of treatment on PPD and CAL was statistically significant after three and six months (p<0.001). Reduction in PPD was found to be higher in TG as compared to CG, which was statistically significant. Gain in CAL was higher in TG as compared to CG and significant at three months and six months (p<0.001).

The RDD was less in TG as compared to CG after six months. However, the difference of Radiographic depth of defect in two groups was statistically not significant when observed from baseline. The mean BF (Depth of the defect at baseline to depth of the defect at six months) in CG was 1.72 and in TG was 1.87. On comparison the difference was not statistically significant. Numerous clinical studies have demonstrated BF and resolution of the defect through re-entry and direct clinical measurement after six months [21-24].

Yamada S et al., conducted an experimental animal model trial to evaluate periodontal regeneration where xenogenic bone graft was used with or without a collagen membrane. After eight weeks when the animals were sacrificed, histological analysis revealed de novo formation of cementum and periodontal ligament fibers indicating regeneration [25]. Vouros I et al., in a clinical and radiographical study concluded that the use of Bovine Bone Material (BBM) provided better BF as compared to access flap alone [22]. Similar clinical findings were observed in previous studies by Richardson CR et al., and Walters SP et al., where radiographic assessment was made at six months and later after grafting intrabony defects with bovine derived bone, with or without GTR and improvement in clinical parameters such as PPD reduction, clinical attachment gains, and BF. The results were found to be stable over five years [26,27]. This is evident by a clinical trial conducted by Stavropoulos A and Karring T where BBM was used in the treatment of periodontal intrabony defects and stable outcomes in clinical and radiographic parameters were obtained for six years [28]. The clinical and radiographic findings of the current study are in accordance with the studies conducted by Yukna RA; Scabbia A and Trombelli L; Vouros I et al., and Yamada S et al., [19,20,22,25].

Limitation(s)

The main limitation of the present study was in the design; due to practical reasons, only one non-blinded investigator performed all the measurements. The study was conducted for a period of six months. There is a need for studies with a protocol longer than six months in order to evaluate the long-term stability of both the treatments. Paired or split mouth design would have excluded the influence of patients' specific characteristics and facilitated the interpretation of the study by minimising the effects of inter-patient variability. The current study used conventional radiographs to assess the BF which has its obvious disadvantages. Instead use of Digital Subtraction Radiography (DSR) or advanced technology such as Computer-Assisted Densitometric Image Analysis (CADIA) could have been used. According to the study protocol, there was no surgical re-entry at six months that could confirm the bone regeneration; only classic clinical and radiographic measurements which only evaluated the clinical effects of both treatments were performed. Histologic sections provide the best evidence for regeneration, however are subject to ethical clearance. In order to avoid re-entry, Cone Beam Computed Tomography (CBCT) could have been considered. Unfortunately, due to higher radiation dosage compared to IOPA and economic constraints, it was not preferred.

CONCLUSION(S)

The present randomised controlled clinical trial, comparing the effects of the combination of bovine derived xenograft and calcium sulphate hemihydrate (Osseomold™) versus bovine derived xenograft alone (Osseograft™) on the surgical treatment of human intra-bony defects, showed that both treatments were successful in improving clinical and radiographic measurements, with statistically significant improvement in PPD and CAL in treatment group at third and six months; however, as there was no histologic analysis, the amount of real regeneration could not be analysed. No statistically significant difference was noted radiographically in both the groups. Further studies are needed to show the stability over time of the present results.

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