



Periodontal Regeneration of Intra Bony Defects using Demineralized Bone Matrix (ColoCast)[®] alone and in Conjunction with β Tricalcium Phosphate (R.T.R)[®] : A Randomized Controlled Clinical Trial

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Abstract

Aim: Aim of the present study was clinical and radiographic evaluation and comparison of the efficacy of periodontal regeneration of intrabony defects using demineralized bone matrix (ColoCast[®]) alone and in conjunction with beta tri calcium phosphate (R.T.R[®]).

Materials and Methods: A total of 45 intrabony defects were treated in 28 patients. Defects were randomly divided by using lot technique into group I (n=15; ColoCast[®]), group II (n=15; ColoCast[®] + R.T.R[®]) and group III (n=15; OFD). Clinical parameters included of plaque index, gingival index, probing depth (PD), clinical attachment level (CAL), gingival recession (GR), and cemento enamel junction from a fixed reference point (acrylic stent). Radiographic parameters included radiographic defect depth, radiographic defect fill, percentage defect fill and radiographic bone density analysis. Radiographs were recorded and analyzed using radiovisiography (RVG) and film grid. All the parameters were recorded at baseline, 3, 6 and 9 months visits.

Results: The mean PD reduction, gain in CAL, mean GR, reduction in mean radiographic defect depth and mean percentage defect fill was 3.87mm, 2.87mm, 0.33mm, 2.73mm and 27.8% respectively in group I at 9 months. The mean probing depth reduction, gain in clinical attachment level, mean gingival recession, reduction in mean radiographic defect depth and mean percentage defect fill was 5.20mm, 4.60mm, 0.33mm, 4.33mm and 30.7% respectively in group II at 9 months. The mean PD reduction, gain in CAL, mean GR, reduction in mean radiographic defect depth and mean percentage defect fill was 2.93mm, 2.73mm, 0.47mm, 3.07mm and 26.3% respectively in group III at 9 months.

Conclusion: Within the limits of the present study, it can be concluded that regenerative periodontal surgery with both demineralized bone matrix (ColoCast[®]) alone and in conjunction with beta tri calcium phosphate (R.T.R[®]) resulted significant clinical improvements in intrabony defects when compared to open flap debridement alone, as evidenced by reduction in probing depths and gain in clinical attachment level and satisfactory defect fill. Improvement of clinical and radiographic parameters at sites treated with ColoCast[®] + R.T.R[®] were better compared to that of sites treated with ColoCast[®] alone and OFD.

Keywords: Intrabony Defects, Open flap debridement, ColoCast[®], R.T.R[®], Film Grid, Density analysis

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Introduction

Periodontitis is a bacterially induced inflammatory disease of the supporting tissues of the teeth.^[1] The consequence of periodontitis is commonly the formation of intrabony defects. Vertical defects are more amenable for regenerative procedures.^[2] Periodontal regeneration remains a fundamental therapeutic goal for the preservation of teeth through the restoration of health, function, and esthetics of the periodontium.^[3] Several treatment procedures have shown histologic proof of principle that the periodontal ligament apparatus can be regenerated in human studies.^[4] Several materials have been introduced as bone grafts, i.e., autografts, allografts, xenografts and alloplastic grafts. These grafts contribute to new bone formation through osteogenic, osteoconductive or osteoinductive mechanisms.^[5]

Xenografts used in the treatment of intrabony defects can be both bovine bone and natural coral.^[6] DBM (demineralized bone matrix) is considered as a good osteoinductor in bone grafting biomaterials. DBM can be produced through decalcification of cortical bone in order

to reduce the potential for infection and immunogenic host response. Thus, DBM can be more osteoinductive than standard mineralized allograft.^[7]

Over the years beta tri calcium phosphate has been successfully used in the treatment of periodontal osseous defects. Beta-tricalcium phosphate (β -TCP) is one popular choice among alloplastic grafts. Biodegradable TCP has been associated with the repair of lost periodontium. There is also evidence that it possesses the potential to inhibit osseous resorption. Beta-TCP has also been shown to be resorbable and simultaneously capable of supporting new bone formation both in animal models and in human trials.^[8]

To the best of our knowledge there is no study comparing the

regenerative potential of demineralized bone matrix (ColoCast®) (Figure 1) alone and in conjunction with beta tri calcium phosphate (R.T.R®) (figure 2) in the treatment of periodontal intrabony defects. Therefore this study was aimed to evaluate clinically and radiographically the regenerative potential of demineralized bone matrix (ColoCast®) in the treatment of periodontal intrabony defects, regenerative potential of demineralized bone matrix (ColoCast®) and beta TCP (R.T.R®) in the treatment of periodontal intrabony defects and to compare the regenerative potential of demineralized bone matrix (ColoCast®) alone and in conjunction with beta (R.T.R®) with that of open flap debridement in the treatment of periodontal intrabony defects.



Figure. 1: ® Bone Graf: Colocast T



Figure. 2: R.t.r® Bone Graft

Material And Methods

Source of data

Patients who visited to the Department of Periodontology, RajaRajeswari Dental College and Hospital, Bangalore were included in the study and the study was approved by the Ethical committee of Rajarajeswari dental college and hospital.

Method of collection of data

A total of 45 randomly selected intrabony periodontal defects in the localized or generalized periodontitis patients between the age group of 20-50 years are selected for the study and grouped as follow:

Group I – 15 intrabony defects treated using ColoCast®.

Group II – 15 intrabony defects treated using ColoCast® and R.T.R® bone graft.

Group III – 15 intrabony defects treated using open flap debridement.

Inclusion criteria are 1) Presence of intrabony defect with probing depth > 6mm, with radiographic evidence. 2) Systemically healthy patients. 3) Patients who had not taken any medication within last 6 months which may alter the periodontal status. 4) Patients with no history of allergy to materials and drugs used or prescribed in this study. Exclusion criteria 1) Smokers. 2) Pregnant and lactating mothers. 3) Patients who have undergone periodontal treatment within a period of 1 year. 4) Patients with plaque index > 1 and who don't follow oral hygiene instructions after phase I therapy. 5) Patients who did not accept terms and conditions of the study.

Clinical Parameters recorded were Probing depth (PD) - was measured from fixed reference point to base of the pocket. Clinical attachment

level (CAL) - was measured from CEJ to the base of the pocket. Gingival recession (GR) - measured from fixed reference point to gingival margin. The following calculations were made from the radiographs:

1. Amount of defect fill = Initial defect depth – defect depth at recalled time interval.
2. Percentage (%) of defect fill = Amount of defect fill /baseline defect depth x 100.
3. Radiographic density changes in the defects were assessed using Kodak Densitometric Software.

Procedure

All subjects were explained about the need and objectives of the study. Only those subjects who agreed to participate in the study are included after obtaining an informed consent. Each patient underwent scaling & root planing, oral hygiene instructions, and occlusal adjustment where indicated. Only when the patient demonstrated adequate plaque control, surgery was performed. Prior to surgery, a customized acrylic stent was fabricated. The stent was grooved in an occlusal apical direction with a tapered bur to make a fixed reference point (FRP). Measurements for clinical parameters are recorded from the fixed reference point (stent). All measurements were recorded by a single investigator. The following measurements were recorded for test and control teeth using a Williams graduated periodontal probe.

1. Stent to cemento-enamel junction (CEJ)
2. Stent to gingival margin (GM)
3. Stent to base of the pocket (BOP).

Standardized radiographs of the defect sites will be taken using radiovisiography (RVG) and Film Grid.

Surgical Procedure

The surgical procedures were performed under local anesthesia of 2% lignocaine containing adrenaline at a concentration of 1: 80,000. Buccal and lingual / palatal sulcular incisions were placed using Bard Parker handle with no^[12]. surgical blade & interdental incisions were placed using no^[15]. surgical blade and mucoperiosteal flap was reflected. Care was exercised to preserve as much interproximal soft tissue as possible. After reflection of flap and exposure of osseous defect, a thorough surgical degranulation of the infected tissue from the osseous defect and thorough root planing was done with curettes.(Figure 3) The defects were randomly assigned to group I or Group II or Group III and treated with ColoCast® with R.T.R® graft or ColoCast® and with open flap debridement alone respectively. Antibiotics (Amoxicillin 500mg, every 8 hours for 5 days), analgesics (Imol/Dicloamol every 8 hours for 3 days), 0.2% chlorhexidine gluconate rinses (every 12 hours for 2 weeks) were prescribed. Post-surgical instructions were given to the patients.

Post Surgical Procedures

One week following surgery, the periodontal dressing and sutures were removed and the area was irrigated thoroughly with normal saline. Any signs of swelling, infection, flap displacement, haematoma

and necrosis were noted and if needed periodontal dressing were reapplied for another week. Symptoms regarding discomfort, pain and sensitivity were asked to the patient. Patients were recalled 3 months, 6 months and 9 months post-surgery and at each visit, oral hygiene instructions were re-enforced and scaling was done if necessary. Postoperative patient evaluation was done clinically and radiographically at 3 months, 6 months and 9 months.

Statistical Analysis

Data was expressed as mean \pm standard deviation of the parameters evaluated. In all the groups, clinical and radiographic parameters were recorded at baseline, 3, 6 and 9 months post operatively. Comparisons were made within each group between baseline, 3, 6 and 9 months evaluation using the one-way analysis of variance (ANOVA) followed by Student -T test.

1. Intragroup comparisons were done using paired Kruskal Wallis and ANOVA
2. Intergroup analysis i.e change in PPD, CAL, REC and Radiographic bone fill were compared between the test and control group using unpaired t test
- b. Indices were compared using repeated measure one way Analysis of Variance (ANOVA) test from baseline and at different time intervals.

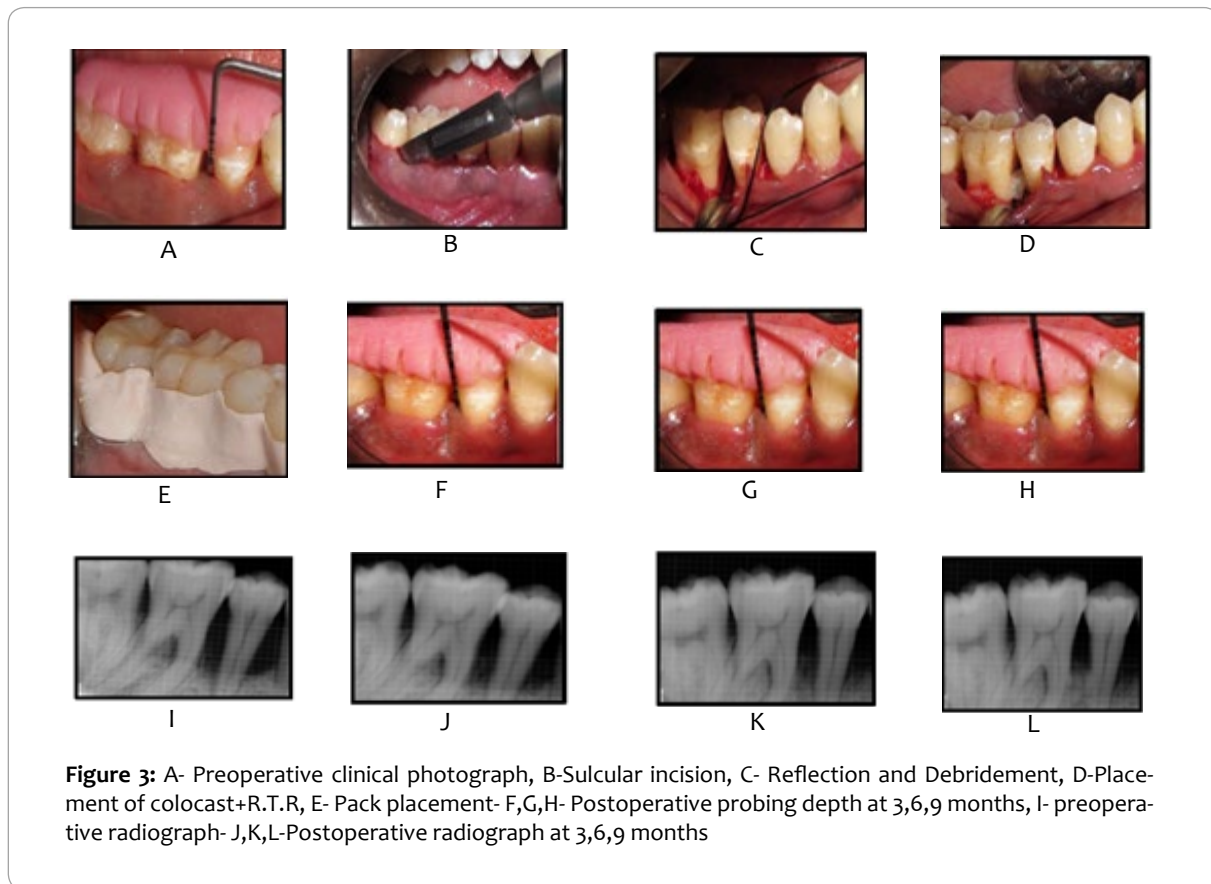


Figure 3: A- Preoperative clinical photograph, B-Sulcular incision, C- Reflection and Debridement, D-Place-ment of colocast+R.T.R, E- Pack placement- F,G,H- Postoperative probing depth at 3,6,9 months, I- preoperative radiograph- J,K,L-Postoperative radiograph at 3,6,9 months

Results

Age distribution of the participants are reflected in the table A, and the table B shows the gender distribution of the patients that were included in the study, male (n=15) and female (n=13).

GROUP	AGE			TOTAL
	20-29 YEARS	30-39 YEARS	40-49 YEARS	
GROUP I	2	3	3	8
GROUP II	4	4	2	10
GROUP III	3	4	3	10
TOTAL	0	11	8	28

Table A: Age distribution of the participants in different groups

GROUP	AGE		TOTAL
	MALES	FEMALES	
GROUP I	4	4	8
GROUP II	6	4	10
GROUP III	5	5	10
TOTAL	15	13	28

Table B: Gender distribution of the participants in different groups

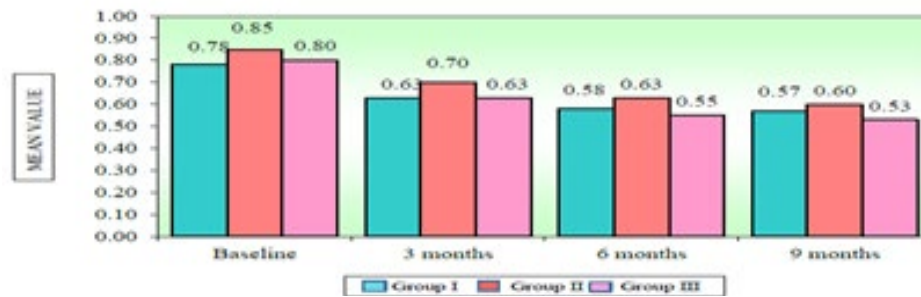
The intergroup comparison of group I (ColoCast®), group II (ColoCast® + R.T.R®), and group III (OFD) with respect to plaque index (PI) scores at different time intervals from baseline to 3 month, 6 month and 9 month were assessed by Wilcoxon matched pair test (Table 1 & Graph 1). The intra group comparison with respect to PI, at different time intervals was carried out by using Kruskal Wallis ANOVA test (Ta-

ble 1 & Graph 2). The mean plaque index scores at baseline was 0.78 ± 0.40 , 0.85 ± 0.32 and 0.80 ± 0.38 and was reduced to 0.57 ± 0.22 , 0.60 ± 0.18 and 0.53 ± 0.19 at the end of 9 months in group I, II and III respectively. The plaque index results showed improvement at all time intervals of all the three groups (19.15%, 25.53%, 27.66% in group I, 17.65%, 25.49% and 29.41% in group II and 20.83%, 31.25%, 33.33% in group III at 3, 6 and 9 months respectively).

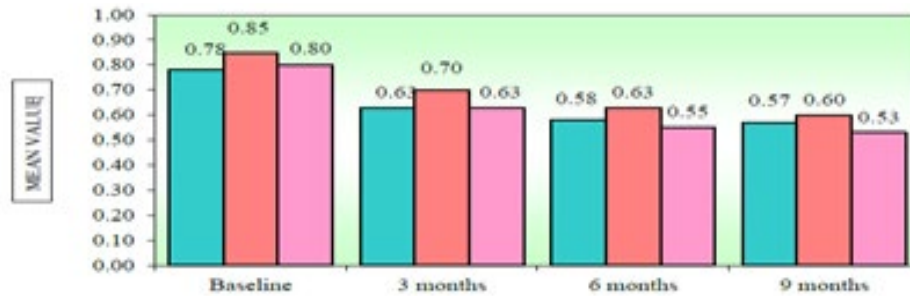
Groups	Baseline		3 Months		6 Months		9 Months		Changes from baseline to					
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	3Months		8Months		9Months	
Groups									Mean	SD	Mean	SD	Mean	SD
GROUP I	0.78	0.40	0.63	0.27	0.58	0.22	0.57	0.22	0.15	0.18	0.20	0.27	0.22	0.27
GROUP II	0.85	0.32	0.70	0.19	0.63	0.16	0.63	0.18	0.15	0.21	0.22	0.27	0.25	0.27
GROUP III	0.80	0.38	0.63	0.27	0.55	0.17	0.53	0.19	0.17	0.24	0.25	0.31	0.27	0.35
% change in group I									19.15%# p=0.0179*		25.53%# p=0.0179*		27.66%# p=0.0177*	
% change in group II									17.65%# p=0.0284*		25.49%# p=0.0144*		29.41%# p=0.0087*	
% change in group III									20.83%# p=0.0277*		31.25%# p=0.117*		33.33%# p=0.0077*	
p-value	0.8910		0.7520		0.5380		0.7160		0.9850		0.8940		0.8340	
GROUP I vs GROUP II	p=0.6632		p=0.5338		p=0.6187		p=0.789		p=0.9174		p=0.7089		p=0.5897	
GROUP II vs GROUP III	p=0.9174		1.0000		p=0.6632		p=0.7244		p=0.9339		p=0.6936		p=0.7716	
GROUP I vs GROUP III	p=0.7244		p=0.5338		p=0.2902		p=0.4429		p=0.8846		p=0.9835		p=0.7400	

*p<0.05, #applied Wilcoxon matched pairs test

Table 1: Comparison of three study groups (i, ii, iii) with respect to plaque index scores at baseline, 3, 6 and 9 months time intervals by kruskal wallis anova.



Graph 1: Intergroup comparison of three study groups (i, ii, iii) with respect to plaque index scores at baseline, 3, 6 and 9 months' time points



Graph 2: Intragroup comparison of three study groups (i, ii, iii) with respect to plaque index scores at baseline, 3, 6 and 9 months' time points

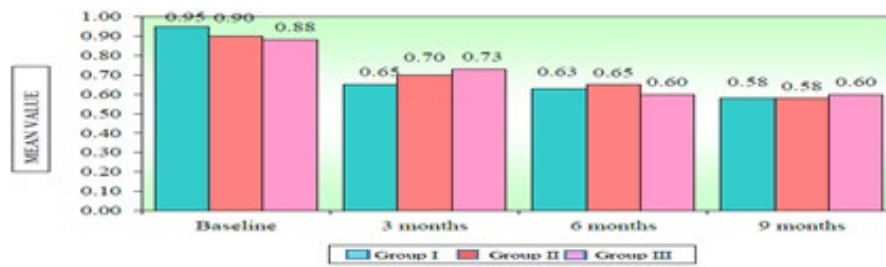
The intergroup comparison of group I (ColoCast®), group II (ColoCast® + R.T.R®), and group III (OFD) with respect to gingival index (GI) scores at different time intervals from baseline to 3 month, 6 month and 9 month were assessed by Wilcoxon matched pair test (Table 2 & Graph 3). The intra group comparison with respect to GI, at different time intervals was carried out by using Kruskal Wallis ANOVA test (Ta-

ble 2 & Graph 4). The mean gingival index scores at baseline was 0.95 ± 0.42 , 0.90 ± 0.35 and 0.88 ± 0.36 and was reduced to 0.58 ± 0.20 , 0.58 ± 0.18 and 0.60 ± 0.18 at the end of 9 months in group I, II and III respectively. The gingival index results showed improvement at all time intervals of all the three groups (31.58%, 33.33% and 38.60% in group I, 22.22%, 27.78% and 35.19% in group II and 16.98%, 32.08% and 32.08% in group III at 3, 6 and 9 months respectively).

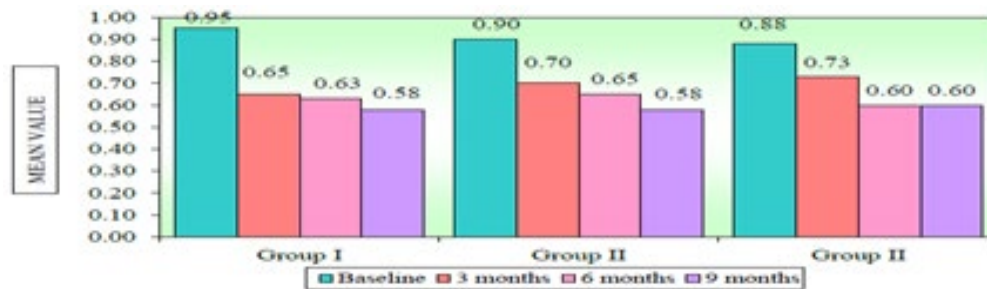
Groups	Baseline		3Months		6Months		9Months		Changes from baseline to					
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	3Months		6Months		9Months	
									Mean	SD	Mean	SD	Mean	SD
GROUP I	0.95	0.42	0.65	0.16	0.63	0.16	0.58	0.20	0.30	0.37	0.32	0.41	0.37	0.43
GROUP II	0.90	0.35	0.70	0.27	0.65	0.16	0.58	0.18	0.20	0.25	0.25	0.27	0.32	0.29
GROUP III	0.88	0.36	0.73	0.20	0.60	0.16	0.60	0.18	0.15	0.26	0.28	0.34	0.28	0.33
% change in group I									31.58% p=0.125*		33.33%# p=0.080*		38.60%# p=0.0519	
% change in group II									22.22%# p=0.152*		27.78%# p=0.0077#		35.19%# p=0.0077*	
% change in group III									16.98%# p=0.0093*		32.08%# p=0.0033*		32.08%# p=0.0087*	
H-value	0.0740		1.4440		1.0270		0.0920		1.4800		0.0290		0.1670	
p-value	0.9640		0.4860		0.5980		0.9550		0.4770		0.9850		0.9200	
GROUP I vs GROUP II	p=0.9504		p=0.8519		p=0.7716		p=0.9504		p=0.4937		p=0.8519		p=0.9174	
GROUP II vs GROUP III	p=0.8035		p=0.2809		p=0.5615		p=0.8519		p=0.2717		p=0.9835		p=0.7089	
GROUP I vs GROUP III	p=0.8519		p=0.4307		p=0.3837		p=0.7875		p=0.6041		p=0.9339		p=0.7716	

*p<0.05, # applied Wilcoxon matched pairs test

Table 2: Comparison of three study groups (i, ii, iii) with respect to gingival index scores at baseline, 3, 6 and 9 months' time points by kruskal wallis anova



Graph 3: Intergroup comparison of three study groups (i, ii, iii) with respect to gingival index scores at baseline, 3, 6 and 9 Months' time points



Graph 4: Intragroup comparison of three study groups (i, ii, iii) with respect to gingival index scores at baseline, 3, 6 and 9 Months' time points

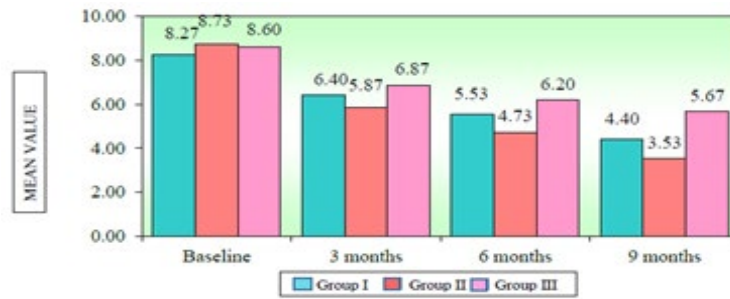
Groups	Baseline		3Months		6Months		9Months		Changes from baseline to					
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	3Months		6Months		9Months	
GROUP I	8.27	1.58	6.40	0.74	5.53	0.64	4.40	0.83	1.87	0.99	2.73	1.44	3.87	1.51
GROUP II	8.73	1.10	5.87	0.99	4.73	0.70	3.53	0.52	2.87	0.92	4.00	1.07	5.20	1.08
GROUP III	8.60	1.06	6.87	0.64	6.20	0.77	5.67	0.72	1.73	0.70	2.40	0.83	2.93	0.96
% change in group I									22.58%# p=0.0001*		33.06%# p=0.0001*		46.77%# p=0.0001*	
% change in group II									32.82%# p=0.0001*		45.80%# p=0.0001*		49.54%# p=0.0001*	
% change in group III									20.16%# p=0.0001*		27.91%# p=0.0001*		34.11%# p=0.0001*	
F-value	0.5395		5.8276		16.1266		35.0903		7.4609		8.2323		13.3886	
p-value	0.5870		0.0058*		0.0001*		0.0001*		0.0017*		0.0010*		0.0001*	
GROUP I vs GROUP II	p=0.9504		p=0.8519		p=0.7716		p=0.9504		p=0.4937		p=0.8519		p=0.9174	
GROUP II vs GROUP III	p=0.8035		p=0.2809		p=0.5615		p=0.8519		p=0.2717		p=0.9835		p=0.7089	
GROUP I vs GROUP III	p=0.8519		p=0.4307		p=0.3837		p=0.7875		p=0.6041		p=0.9339		p=0.7716	

*p<0.05, # applied paired test

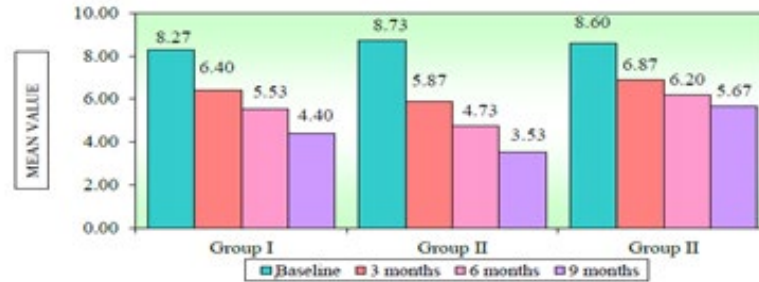
Table 3: Comparison of three study groups (i, ii, iii) with respect to probing depth scores at baseline, 3, 6 and 9 months time points by one way anova

The intergroup comparison of group I (ColoCast®), group II (ColoCast® + R.T.R®), and group III (OFD) with respect to probing pocket depth (PPD) scores at different time intervals from baseline to 3 month, 6 month and 9 month were assessed by paired t test (Table 3 & Graph 5). The intragroup comparison with respect to PPD, at different time intervals was carried out by using ANOVA test (Table 3 & Graph 6). The

PPD scores at baseline was 8.27 ± 1.58, 8.73 ± 1.10 and 8.60 ± 1.06 and was reduced to 4.40 ± 0.83, 3.53 ± 0.52 and 5.67 ± 0.72 at the end of 9 months in group I, II and III respectively. The probing pocket depth scores showed significant improvement at all time intervals in all the three groups (22.58%, 33.06% and 46.77% in group I, 32.82%, 45.80% and 59.54% in group II and 20.16%, 27.91% and 34.11% in group III at 3, 6 and 9 months respectively).



Graph 5: Intergroup comparison of three study groups (i, ii, iii) with respect to probing pocket depth scores at baseline, 3, 6 and 9 months time points



Graph 6: Intragroup comparison of three study groups (i, ii, iii) with respect to probing pocket depth scores at baseline, 3, 6 and 9 months time points

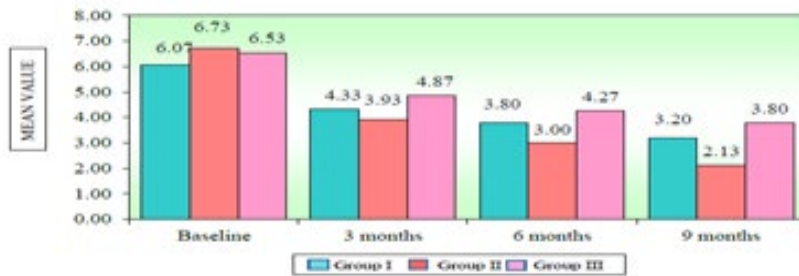
The intergroup comparison of group I (ColoCast®), group II (ColoCast® + R.T.R®), and group III (OFD) with respect to clinical attachment level (CAL) scores at different time intervals from baseline to 3 month, 6 month and 9 month were assessed by paired t test (Table 4 & Graph 7). The intragroup comparison with respect to CAL, at different time intervals was carried out by using ANOVA test (Table 4 & Graph

8). The CAL scores at baseline was 6.07 ± 1.53 , 6.73 ± 1.10 and 6.53 ± 1.19 and was reduced to 3.20 ± 0.68 , 2.13 ± 0.74 and 3.80 ± 0.77 at the end of 9 months in group I, II and III respectively. The clinical attachment level scores showed significant improvement at all time intervals of all the three groups (28.57%, 37.36% and 47.25% in group I, 41.58%, 55.45% and 68.32% in group II and 25.51%, 34.69% and 41.84% in group III at 3, 6 and 9 months respectively).

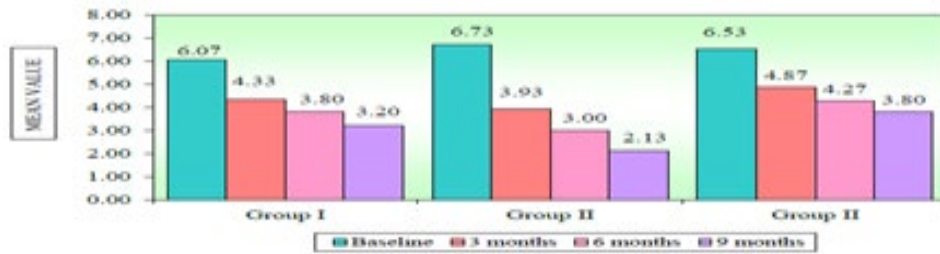
Groups	Baseline		3Months		6Months		9Months		Changes from baseline to					
									3Months		6Months		9Months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
GROUP I	6.07	1.53	4.33	0.90	3.80	0.94	3.20	0.68	1.73	0.96	2.27	1.39	2.87	1.51
GROUP II	6.73	1.10	3.93	1.10	3.00	0.76	2.13	0.74	2.80	0.94	3.73	1.03	4.60	0.83
GROUP III	6.53	1.19	4.87	0.64	4.27	0.80	3.80	0.77	1.73	0.82	2.27	0.88	2.73	0.96
% change in group I									22.58%# p=0.0001*		33.06%# p=0.0001*		46.77%# p=0.0001*	
% change in group II									32.82%# p=0.0001*		45.80%# p=0.0001*		49.54%# p=0.0001*	
% change in group III									20.16%# p=0.0001*		27.91%# p=0.0001*		34.11%# p=0.0001*	
F-value	1.0594		4.0628		8.8136		19.9213		7.3500		8.5556		12.1422	
p-value	0.3557		0.0244*		0.0006*		0.0001*		0.0018*		0.0008*		0.0001*	
GROUP I vs GROUP II	p=0.3409		p=0.4497		p=0.0320*		p=0.0009*		p=0.0071*		p=0.0026*		p=0.0006*	
GROUP II vs GROUP III	p=0.5855		p=0.2473		p=0.2879		p=0.0756		p=0.9781		p=0.9999		p=0.9468	
GROUP I vs GROUP III	p=0.9053		p=0.0187*		p=0.0006*		p=0.0001*		p=0.0041*		p=0.0026*		p=0.0003*	

*p<0.05, # applied paired t test

Table 4: Comparison of three study groups (i, ii, iii) with respect to clinical attachment level at baseline, 3, 6 and 9 months time points by one way anova



Graph 7: Intergroup comparison of three study groups (i, ii, iii) with respect to clinical attachment level scores at baseline, 3, 6 and 9 months time points



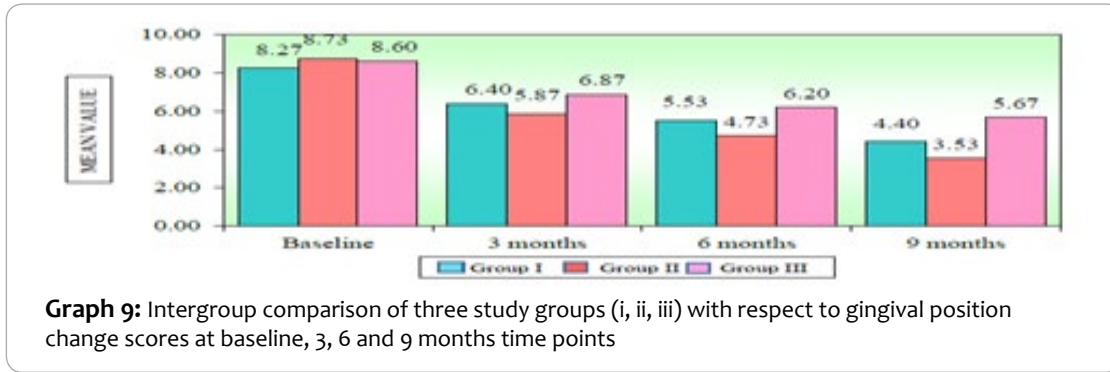
Graph 8: Intragroup comparison of three study groups (i, ii, iii) with respect to clinical attachment level scores at baseline, 3, 6 and 9 months time points

The intergroup comparison of group I (ColoCast®), group II (ColoCast® + R.T.R®), and group III (OFD) with respect to gingival position changes (GR) scores at different time intervals from baseline to 3 month, 6 month and 9 month were assessed by paired t test (Table 5 & Graph 9). The intra group comparison with respect to GR, at different time intervals was carried out by using ANOVA test (Table 5 & Graph 10).

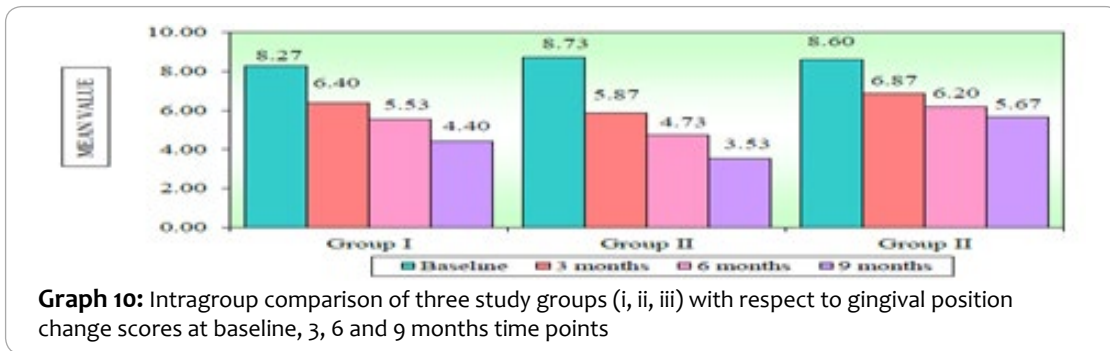
The GR scores at baseline was 4.07 ± 0.80 , 3.93 ± 0.80 and 4.00 ± 0.85 and was reduced to 3.73 ± 0.96 , 3.60 ± 0.91 and 3.53 ± 0.74 at the end of 9 months in group I, II and III respectively. The GR scores showed improvement at all time intervals of all the three groups (6.56%, 9.84% and 8.20% in group I, 6.78%, 8.47% and 8.47% in group II and 5.00%, 8.33% and 11.67% in group III at 3, 6 and 9 months respectively).

Groups	Baseline (in mm)		3 months (in mm)		6 months (in mm)		9 months (in mm)		Changes from baseline to					
									3 months		6 months		9 months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group I	4.07	0.80	3.80	0.86	3.67	0.90	3.73	0.96	0.27	0.46	0.40	0.51	0.33	0.49
Group II	3.93	0.80	3.67	0.82	3.60	0.83	3.60	0.91	0.27	0.46	0.33	0.49	0.33	0.49
Group III	4.00	0.85	3.80	0.86	3.67	0.90	3.53	0.74	0.20	0.41	0.33	0.49	0.47	0.52
% of change in group I									6.56%#, p=0.0406*		9.84%#, p=0.0406*		8.20%#, p=0.0824	
% of change in group II									6.78%#, p=0.0086*		8.47%#, p=0.0192*		8.47%#, p=0.0192*	
% of change in group III									5.00%#, p=0.0192*		8.33%#, p=0.0192*		11.67%#, p=0.0035*	
P-value	0.9046		0.8838		0.9715		0.8175		0.8935		0.9133		0.7005	
Group I vs Group II	p=0.8955		p=0.9029		p=0.9764		p=0.9090		p=0.9999		p=0.9278		1.0000	
Group II vs Group III	p=0.9728		p=0.9999		p=0.9999		p=0.8074		p=0.9111		p=0.9278		p=0.7450	
Group I vs Group III	p=0.9728		p=0.9029		p=0.9764		p=0.9764		p=0.9111		p=0.9999		p=0.7450	

Table 5: comparison of three study groups (i, ii, iii) with respect to gingival position changes scores at baseline, 3, 6 and 9 months time points by one way anova



Graph 9: Intergroup comparison of three study groups (i, ii, iii) with respect to gingival position change scores at baseline, 3, 6 and 9 months time points



Graph 10: Intragroup comparison of three study groups (i, ii, iii) with respect to gingival position change scores at baseline, 3, 6 and 9 months time points

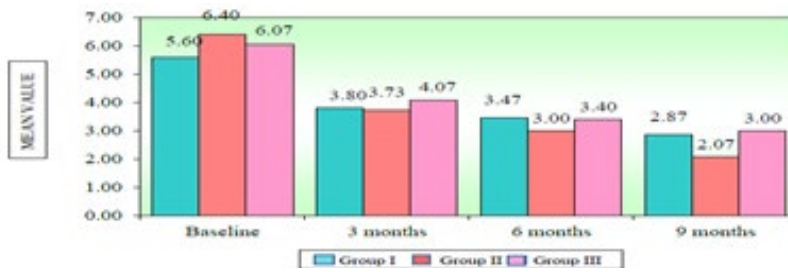
The intergroup comparison of group I (ColoCast®), group II (ColoCast® + R.T.R®), and group III (OFD) with respect to radiographic defect depth (RDD) scores at different time intervals from baseline to 3 month, 6 month and 9 month were assessed by paired t test (Table 6 & Graph 11). The intra group comparison with respect to RDD, at different time intervals was carried out by using ANOVA test (Table

6 & Graph 12). The RDD scores at baseline was 5.60 ± 1.24 , 6.40 ± 1.18 and 6.07 ± 1.03 and was reduced to 2.87 ± 0.52 , 2.07 ± 0.80 and 3.00 ± 0.38 at the end of 9 months in group I, II and III respectively. The RDD scores showed significant improvement at all time intervals in all the three groups (32.14%, 38.10% and 48.81% in group I, 41.67%, 53.13% and 67.71% in group II and 32.97%, 43.96% and 50.55% in group III at 3, 6 and 9 months respectively).

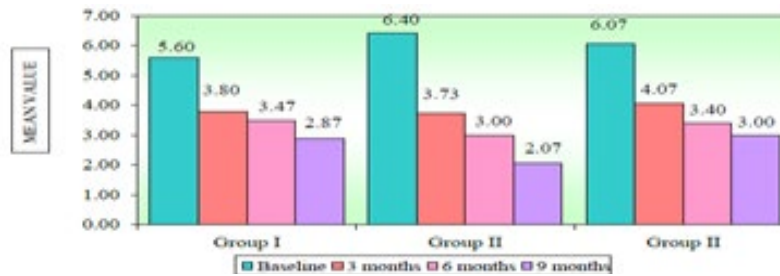
Groups	Baseline (in mm)		3 months (in mm)		6 months (in mm)		9 months (in mm)		Changes from baseline to					
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	3 months		6 months		9 months	
									Mean	SD	Mean	SD	Mean	SD
Group I	5.60	1.24	3.80	0.77	3.47	0.99	2.87	0.52	1.80	1.08	2.13	1.25	2.73	1.16
Group II	6.40	1.18	3.73	1.03	3.00	0.76	2.07	0.80	2.67	1.23	3.40	1.35	4.33	1.18
Group III	6.07	1.03	4.07	0.80	3.40	0.63	3.00	0.38	2.00	1.13	2.67	1.05	3.07	1.16
% of change in group I									32.14%#, p=0.0001*		38.10%#, p=0.0001*		48.81%#, p=0.0001*	
% of change in group II									41.67%#, p=0.0001*		53.13%#, p=0.0001*		67.71%#, p=0.0001*	
% of change in group III									32.97%#, p=0.0001*		43.96%#, p=0.0001*		50.55%#, p=0.0001*	
F-value	1.8124	0.6074	1.4683	10.9455	2.3278	4.0660	7.8485							
P-value	0.1758	0.5495	0.2419	0.0001*	0.1100	0.0243*	0.0013*							
Group I vs Group II	p=0.1527	p=0.9764	p=0.2636	p=0.0018*	p=0.1107	p=0.0187*	p=0.0016*							
Group II vs Group III	p=0.5161	p=0.6848	p=0.9723	p=0.8112	p=0.8833	p=0.4624	p=0.7160							
Group I vs Group III	p=0.7115	p=0.5553	p=0.3720	p=0.0004*	p=0.2633	p=0.2388	p=0.0133*							

*p<0.05, #applied paired t test

Table 6: Comparison of three study groups (i, ii, iii) with respect to radiographic defect depth scores at baseline, 3, 6 and 9 months time points by one way anova



Graph 11: Intergroup comparison of three study groups (i, ii, iii) with respect to radiographic defect depth scores at baseline, 3, 6 and 9 months time points



Graph 12: Intragroup comparison of three study groups (i, ii, iii) with respect to radiographic defect depth scores at baseline, 3, 6 and 9 months time points

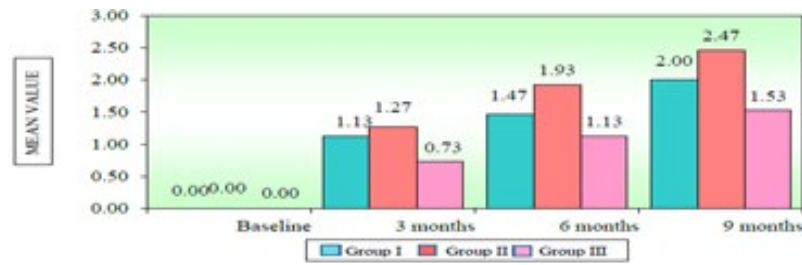
The intergroup comparison of group I (ColoCast®), group II (ColoCast® + R.T.R®), and group III (OFD) with respect to radiographic defect fill (RDF) scores at different time intervals from baseline to 3 month, 6 month and 9 month were assessed by paired t test (Table 7 & Graph

13). The intra group comparison with respect to RDF, at different time intervals was carried out by using ANOVA test (Table 7 & Graph 14). The RDF scores increased to 2.00 ± 0.65 , 2.47 ± 0.64 and 1.53 ± 0.64 at the end of 9 months in group I, II and III respectively.

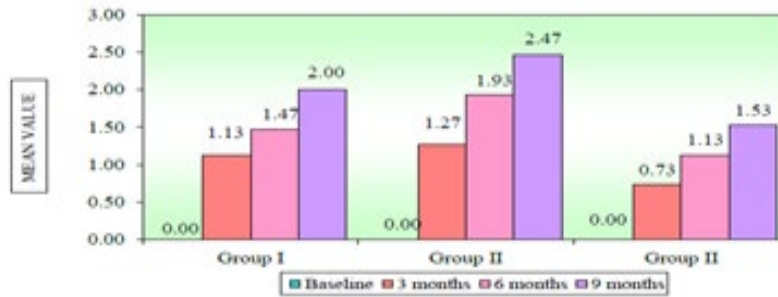
Groups	Baseline (in mm)		3 months (in mm)		6 months (in mm)		9 months (in mm)		Changes from baseline to					
									3 months		6 months		9 months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group I	0.00	0.00	1.13	0.52	1.47	0.64	2.00	0.65	1.13	0.52	1.47	0.64	2.00	0.65
Group II	0.00	0.00	1.27	0.59	1.93	0.59	2.47	0.64	1.27	0.59	1.93	0.59	2.47	0.64
Group III	0.00	0.00	0.73	0.59	1.13	0.52	1.53	0.64	0.73	0.59	1.13	0.52	1.53	0.64
% of change in group I									100.00%#, p=0.0001*		100.00%#, p=0.0001*		100.00%#, p=0.0001*	
% of change in group II									100.00%#, p=0.0001*		100.00%#, p=0.0001*		100.00%#, p=0.0001*	
% of change in group III									100.00%#, p=0.0001*		100.00%#, p=0.0001*		100.00%#, p=0.0001*	
F-value	0.0000		3.5686		7.0648		7.8550		3.5686		7.0648		7.8550	
P-value	1.0000		0.0370		0.0023*		0.0013*		0.0370*		0.0023*		0.0013*	
Group I vs Group II	P=1.0000		p=0.7981		p=0.0860		p=0.1293		p=0.7981		p=0.0860		p=0.1293	
Group II vs Group III	P=1.0000		p=0.1443		p=0.2746		p=0.1293		p=0.1443		p=0.2746		p=0.1293	
Group I vs Group III	P=1.0000		p=0.0365		p=0.0017*		p=0.0009*		p=0.0365*		p=0.0017*		p=0.0009*	

*p<0.05, #applied paired t test

Table 7: Comparison of three study groups (i, ii, iii) with respect to radiographic defect fill scores at baseline, 3, 6 and 9 months time points by one way anova



Graph 13: Intergroup comparison of three study groups (i, ii, iii) with respect to radiographic defect fill scores at baseline, 3, 6 and 9 months time points



Graph 14: Intragroup comparison of three study groups (i, ii, iii) with respect to radiographic defect fill scores at baseline, 3, 6 and 9 months time points

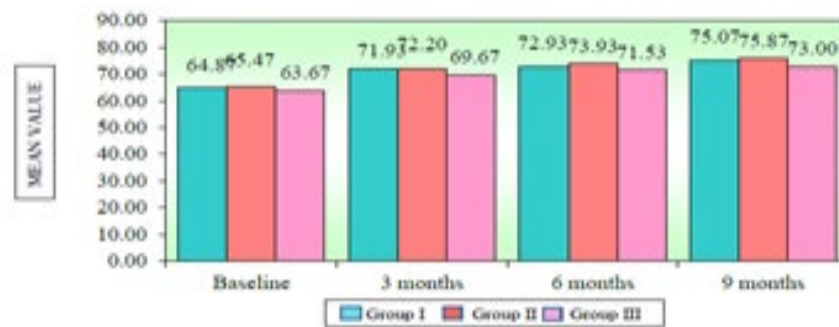
The intergroup comparison of group I (ColoCast®), group II (ColoCast® + R.T.R®), and group III (OFD) with respect to radiographic bone density (RBD) scores at different time intervals from baseline to 3 month, 6 month and 9 month were assessed by paired t test (Table 8 & Graph 15). The intra group comparison with respect to RBD, at different time intervals was carried out by using ANOVA test (Table 8

& Graph 16). The RBD scores at baseline was 64.87 ± 2.85 , 65.47 ± 3.11 and 63.67 ± 3.85 and was increased to 75.07 ± 1.28 , 75.87 ± 2.42 and 73.00 ± 2.88 at the end of 9 months in group I, II and III respectively. The RBD scores showed improvement at all time intervals of all the three groups (10.89%, 12.44% and 15.72% in group I, 10.29%, 12.93% and 15.89% in group II and 9.42%, 12.36% and 14.66% in group III at 3, 6 and 9 months respectively).

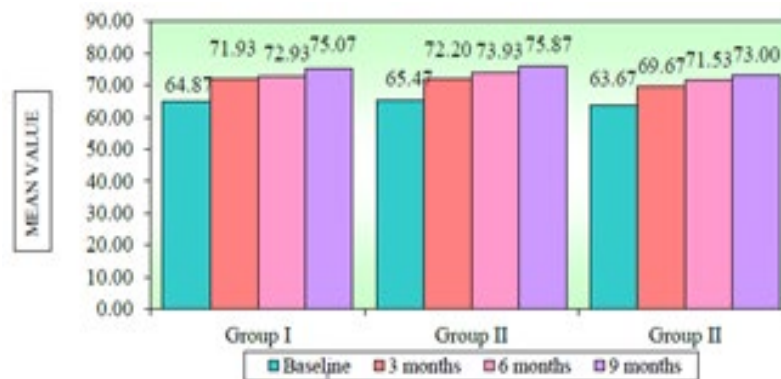
Groups	Baseline		3 months		6 months		9 months		Changes from baseline to					
									3 months		6 months		9 months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group I	64.87	2.85	71.93	1.87	72.93	1.75	75.07	1.28	7.07	3.43	8.07	3.15	10.20	3.82
Group II	65.47	3.11	72.20	2.18	73.93	2.31	75.87	2.42	6.73	3.08	8.47	3.23	10.40	4.22
Group III	63.67	3.85	69.67	3.72	71.53	2.85	73.00	2.88	6.00	3.40	7.87	3.04	9.33	2.92
% of change in group I									10.89%#, p=0.0001*		12.44%#, p=0.0001*		15.72%#, p=0.0001*	
% of change in group II									10.29%#, p=0.0001*		12.93%#, p=0.0001*		15.89%#, p=0.0001*	
% of change in group III									9.42%#, p=0.0001*		12.36%#, p=0.0001*		14.66%#, p=0.0001*	
F-value	1.1585		3.9551		3.9534		6.2471		0.4079		0.1419		0.3533	
P-value	0.3238		0.0267		0.0267*		0.0042*		0.6676		0.8681		0.7045	
Group I vs Group II	p=0.8726		p=0.9609		p=0.4797		p=0.6086		p=0.9590		p=0.9353		p=0.9880	
Group II vs Group III	p=0.5832		p=0.0684		p=0.2434		p=0.0457*		p=0.6541		p=0.9835		p=0.7977	
Group I vs Group III	p=0.3038		p=0.0371		p=0.0208*		p=0.0040*		p=0.8172		p=0.8606		p=0.7109	

*p<0.05. #applied paired t test

Table 8: Comparison of three study groups (i, ii, iii) with respect to radiographic bone density scores at baseline, 3, 6 and 9 Months time points by one way anova



Graph 15: Intergroup comparison of three study groups (i, ii, iii) with respect to radiographic bone density scores at baseline, 3, 6 and 9 months time points



Graph 16: Intragroup comparison of three study groups (i, ii, iii) with respect to radiographic bone density scores at baseline, 3, 6 and 9 months time points

Discussion

Periodontal disease involves a major part of global problems of oral diseases. Use of specific biomaterials was more effective than open flap debridement (OFD) in improving attachment levels in periodontal defects^[9]. Bone grafting is the most common form of regenerative therapy and has been used for almost 100 years in attempts to stimulate healing of bony defects. Linhart and colleagues¹⁰ concluded that calcium phosphate cement represents a good alternative to autogenous bone transplantation, especially in elderly patients when tri-calcium phosphate was compared with inorganic bovine bone in dogs with mandibular defects, tri calcium phosphate showed significantly greater bone formation at 12 and 24 months and better resorption than inorganic bovine bone.

In a study published in 2008 by Dori F, at 1 year after therapy, the sites treated with platelet rich plasma and β -TCP using GTR showed a reduction in mean PD from 9.1 ± 0.6 mm to 3.3 ± 0.5 mm ($P < 0.001$) and a change in mean CAL from 10.1 ± 1.3 mm to 5.7 ± 1.1 mm.¹¹ Studies on animal have revealed, bovine bone granules possess better osteoconductive potential than bioglass crystal and hydroxyapatite when tested in on rabbits in New Zealand.¹² Pure phase beta-tricalcium phosphate is fully resorbed and replaced by vital bone over six months' time as shown histologically in animal studies, where bovine derived grafts are not^[13]. Graft replacement ensures the regenerated bone will be able to remodel according to the stresses placed upon it in the future. This non-immunogenic and resorbable material provides the

basis for complete, predictable, and reproducible bone regeneration. For these reasons, pure phase β -TCP is an ideal bone augmentation material as has been shown in multiple publications^[14,15].

The in vitro study demonstrated that β -TCP granules scaffolds with sizes of 1 mm and 1– 2.5 mm can improve the proliferation of BMSCs and promote the expression of osteogenic genes and osteogenesis-related proteins.¹⁶ From the outcome of the study, it could be interpreted that ColoCast® +R.T.R® when compared to ColoCast® alone and OFD showed a statistically significant difference in clinical / radiological outcome. There was notably significant reduction in PPD, CAL gain and increase in radiographic bone fill when intragroup comparison was done in all the three groups.

Conclusion

Within the limits of the present study, it can be concluded that regenerative periodontal surgery with both demineralized bone matrix (ColoCast)® alone and in conjunction with beta tri calcium phosphate (R.T.R)® resulted significant clinical improvements in intrabony defects when compared to open flap debridement alone, as evidenced by reduction in probing depths and gain in clinical attachment level and satisfactory defect fill. Improvement of clinical and radiographic parameters at sites treated with ColoCast® + R.T.R® were better compared to that of sites treated with ColoCast® alone and OFD.

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