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RESEARCH ARTICLE

A COMPARATIVE CLINICAL AND RADIOLOGICAL STUDY USING BIOGRAFT-HABG ACTIVE AND BIOGRAFT –CPC.

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Abstract

Background and objectives: This clinical study was carried out on 20 systemically healthy subjects to evaluate and compare, clinically and radiographically, the efficacy of Bioactive composite granule (Biograft-HABG Active) and Calcium phosphate cement (Biograft-CPC) in the treatment of periodontal endosseous defects clinically and radiographically and compare them.

Methodology: 20 intrabony defects present in 20 patients, who fulfilled the inclusion and exclusion criteria were selected and divided into two groups. Group I received bioactive composite granule, Group II received calcium phosphate cement. Clinical and radiological parameters such as Plaque Index (PI), Gingival Index (GI), Probing Pocket Depth (PPD), Clinical Attachment Level (CAL), Gingival recession (GR) and Depth of the bone defect (BL) were assessed at baseline 3, 6 and 9 months post operatively. The results were averaged for each clinical and radiological parameter at baseline, 3 months, 6 months and 9 months.

Results: Statistically significant difference in mean values of the plaque index, gingival index, pocket depth reduction, clinical attachment level, gain amount of defect resolution were observed in both the groups at subsequent time periods.

Conclusion: Clinical and radiographic assessments reveal that both bone graft materials were efficacious in the treatment of periodontal endosseous defects and have nearly comparable effects. However, long-term, multicenter randomized, controlled clinical trials will be required to discern the definite clinical and radiographic effects of these graft materials and to arrive at an explicit conclusion.

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Introduction:-

Periodontitis, evoked by the bacterial biofilm (dental plaque) that forms around teeth, progressively destroys the periodontal tissue supporting the teeth, including the periodontal ligament, cementum, alveolar bone and gingiva (Darout et al, 2014). It is characterized by the presence of gingival inflammation, periodontal pocket formation, and loss of connective tissue attachment and alveolar bone around the affected teeth (Hanna et al, 2004). Several

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therapeutic modalities have been considered to arrest the disease progression and to regenerate the lost tissue. Periodontal surgical procedures have focused on the elimination of hard and soft tissue defects (i.e., probing depths and osseous defects) by regenerating new attachment (Froum et al, 1998). Reconstructive modalities that appear to have merit and have demonstrated significant gain of clinical attachment include: surgical debridement with adjunctive root surface or wound conditioning, implantation of bone, bone derivatives and substitutes, and placement of barrier membranes for guided tissue regeneration (Becker et al 1999).

One of the best approaches to achieve periodontal regeneration is the use of bone replacement graft techniques, which are based on the concept of filling the infrabony defects with a number of grafting materials, including autografts, xenografts and alloplastic materials (Kasaj et al 2008). The objectives of periodontal bone grafts are: probing depth reduction, clinical attachment gain, bone fill of the osseous defect and regeneration of new bone, cementum and periodontal ligament.

Alloplasts are synthetic bone substitutes that are readily available and also eliminate the need for a patient donor site. BIOGRAFT -CPC is an osteostimulative and osteoconductive bioactive device used for grafting osseous defects. BIOGRAFT - HABG ACTIVE (Bioactive composite granule) are bioactive glasses composed of SiO_2 , CaO , Na_2O , P_2O_5 and bond to bone through the development of a surface layer of carbonated hydroxyapatite. It is thought that the bioactive properties guide and promote osteogenesis, allowing rapid and quick formation of new bone.

A paucity of studies comparing the effects of Bioactive composite granule (BIOGRAFT-HABG ACTIVE) with Calcium phosphate cement (BIOGRAFT - CPC) was noted, thus, this study was designed to evaluate and compare, clinically and radiographically, the efficacy of bioactive composite granule versus calcium phosphate cement in the treatment of periodontal endosseous defects.

Aims And Objectives:-

1. To evaluate clinically, the efficacy of Bioactive composite granule (BIOGRAFT -HABG Active) and Calcium phosphate cement (BIOGRAFT -CPC) in the treatment of periodontal endosseous defects.
2. To evaluate radiographically, the efficacy of Bioactive composite granule (BIOGRAFT -HABG Active) and Calcium phosphate cement (BIOGRAFT -CPC) in the treatment of periodontal endosseous defects.
3. To compare clinically and radiographically, the efficacy of Bioactive composite granule (BIOGRAFT-HABG ACTIVE) and Calcium phosphate cement (BIOGRAFT -CPC) in the treatment of periodontal endosseous defects.

Materials and Methods:-

Subjects and study groups:-

A randomized, longitudinal interventional study involving a total of 20 systemically healthy subjects, contributing to a total of 20 surgical sites was designed and conducted on a study population selected from the subjects visiting the out-patient section of the Department of Periodontics, D A Pandu Memorial R V Dental College, Bangalore. The ethical clearance for the study was obtained from the ethical committee and review board of the institution.

Patients aged between 25-55 years, who were systemically healthy and had no contraindications for periodontal therapy met the inclusion criteria. A patient was not considered eligible if gingival index score was >2.1 .

Two and combined 3-wall intrabony periodontal defects with a probing pocket depth (PPD) ≥ 5 mm, radiographic defect depth ≥ 3 mm were included in the study.

The 20 surgical sites were identified and were randomly divided into 2 groups; Group I and Group II.

The groups were:-

Group I (n=10): Those to be treated with Bioactive composite granule (BIOGRAFT-HABG ACTIVE).

Group II (n=10): Those to be treated with Calcium phosphate cement (BIOGRAFT -CPC).

Clinical and Radiographic Assessments:-

Oral hygiene status was assessed using Plaque Index (Sillness and Loe (1964)) and Gingival index (Loe and Sillness (1963)). Probing pocket depth (PPD), clinical attachment level (CAL), and marginal recession (GR) were measured to the nearest millimeter with a calibrated periodontal probe using an occlusal stent as a reference point for probe

placement. Occlusal stents for positioning measuring probes were fabricated with cold-cured acrylic resin on a cast model obtained from an alginate impression. Measurements were recorded from:

- ☐ Stent to cemento-enamel junction
- ☐ Stent to gingival margin
- ☐ Stent to deepest probing depth at test sites

Surgical Procedure:-

After local anesthesia, an intrasulcular incision aiming to preserve the papillae was performed. Mucoperiosteal buccal and lingual access flaps were then reflected. Granulation tissue adherent to the alveolar bone was removed to provide full access and visibility to the root surfaces. Any subgingival calculus was removed gently by using hand instruments. Defects in group I received Bioactive composite granule (BIOGRAFT-HABG ACTIVE) and defects in group II patients received Calcium phosphate cement (BIOGRAFT -CPC). Finally, the flaps were replaced and sutured appropriately with a 3-0 silk material using interdental suture technique. After a healing period of 10 days, the sutures were removed.

Postoperative Care:-

All patients received systemic antibiotic therapy for a period of 5 days postoperatively (amoxicillin 500 mg three times per day for 5 days). In addition, all patients were advised to avoid tooth brushing and hard chewing in the surgical areas and to rinse twice daily with a 0.2% solution of chlorhexidinedigluconate for 2 weeks. Recall appointments were scheduled every second week during the first 2 months after the surgical procedure, and all patients were recalled once a month for the remaining observation period.

Post-Surgical Evaluation and Review:-

Gingival Index (GI) and Plaque Index (PI) were re-evaluated at 3 months, 6 months and 9 months. Probing Pocket Depth (PPD), Clinical Attachment Level (CAL), Gingival Recession (GR) were also re-evaluated at 3 months, 6 months and 9 months using the previously used acrylic stents to provide a reproducible insertion axis. Depth of the defect was re-assessed at 3 months, 6 months and 9 months using digital radiography.

Results:-

Statistical test used included Kruskal Wallis test and Student unpaired t-test.

Clinical evaluation of post-surgical healing revealed a good soft tissue response to the combinations with no adverse complications. Both groups presented similar baseline characteristics in terms of PPD, GR, CAL, plaque index, gingival index.

All patients maintained a good level of oral hygiene and gingival status throughout the recall periods. Intergroup differences were found to be insignificant ($P > 0.05$) in terms of plaque index and gingival index (Table I and Table II).

At 9 months, all the groups presented a significant improvement in terms of PPD reduction and CAL gain (Table III and Table IV). The intergroup differences were found to be significant (Table III and Table IV). Gingival recession levels had also improved, however, the difference was not statistically significant (Table V).

Evaluation of the hard tissue findings indicated that all treatment modalities resulted in bone gain at 9 months in both groups (Table VI).

Discussion:-

The results of the present study show that treatment of intrabony defects with Bioactive composite granule (BIOGRAFT-HABG ACTIVE) / Calcium phosphate cement (BIOGRAFT -CPC) leads to significant PPD reduction, attachment, and radiographic bone gain compared to baseline values. Statistically significant differences in all of the investigated parameters were found between the treatments. Being alloplastic in nature, these graft materials do not increase the patient morbidity and do not require a second surgical site as in the case of autografts.

Approximately 60% of the bone graft substitutes currently available involve ceramics, either alone or in combination with another material. These include calcium sulphate, bioactive glass, and calcium phosphate. The use of ceramics, especially calcium phosphates, is driven in part because of the fact that the primary inorganic

component of bone is calcium hydroxyapatite, a subset of the calcium phosphate group. In addition, calcium phosphates are osteoconductive, osteointegrative (the newly formed mineralized tissue forms intimate bonds with the implant material), and, in some cases, osteoinductive. They often require high temperatures for scaffold formation and have brittle properties; therefore, they are frequently combined with other materials to form a composite. They may be porous or non-porous. Calcium phosphate compounds, currently most widely used in periodontal surgery are hydroxyapatite (HA) and tricalcium phosphate (TCP) (Pandit et al, 2010).

Bioactive glasses are composed of bone silicon dioxide (46 mole %), sodium oxide (24.4 mole %), calcium oxide (26 mole %), and phosphorous pentoxide (6 mole %) and bond to bone through the development of a surface layer of carbonated hydroxyapatite. It is thought that the bioactive properties guide and promote osteogenesis, allowing rapid and quick formation of new bone. Fetner et al in 1994 suggested that these materials have properties of superior manageability, hemostatic effects, and osteoconductive properties (Fetner 1994).

In a study by Lindhe et al, it was shown that, surgical procedures would induce loss of attachment if done in pockets shallower than 4.2mm (Lindhe et al, 1982). Hence, probing depth greater than 5mm was considered for the study. Laurell et al, in his study, has shown that, to benefit from regenerative procedures, depth of defect should be at least 3-4 mm (Laurell et al, 1998).

Probing Pocket Depth (PPD), Clinical Attachment Level (CAL) and Gingival Recession (GR) were assessed using a UNC 15 probe positioned along the grooves on a customized acrylic stent which was fabricated for each patient for providing a reproducible insertion axis for the probe. Similar technique has been adopted in other studies (Sharma, 2011; Subbaiah 2011, Sollazzo et al 2010).

Preoperative and postoperative comparability of probing measurements that do not use this standardized method may be open to question (Carranza, 2006). The depth of the angular bone loss was assessed to the closest 0.5 mm on the intraoral periapical radiograph taken using the paralleling cone technique with the radiographic grid in position which allowed for standardization. Other studies have also used this technique for assessment of bone defect and bone fill (Subbaiah, 2011; Cardaropoli, 2002).

The results of the study showed a statistically significant decrease in the plaque index and gingival index from baseline to 3 months, baseline to 6 months and at the end of 9 months in Group I as well as in Group II which is in accordance with the study conducted by Stein et al who used biphasic calcium composite grafting material in the treatment of human periodontal intrabony defects. However, no statistically significant difference was recorded between the two groups suggesting that all patients were very well motivated and there was a good maintenance of oral hygiene throughout the study in both the groups.

There was a statistically significant reduction in mean values of pocket depth and clinical attachment level at three months and six months in the two groups. These findings are in agreement with the results of Froum and Gupta (Froum et al 1998).

The mean amount of defect resolution from the baseline to three months and six months in all the groups was statistically significant. The mean percentage of defect resolution at three months and six months in the two groups was statistically significant. These results were in accordance with the study conducted by Meffert and Pepelassi.

Group I

Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Figure 6



Figure 1& 2:- Pre-Operative Clinical And Radiographic Examination

Figure 3 & 4:- Intraoperative View Of Defect, Graft Placement (Biograft Habg)

Figure 5:- Post- Suturing

Figure 6:- Periodontal Dressing Placed

Figure 7



Figure 8



Figure 7 & 8:- Clinical and radiographic evaluation at 9 months.

Group II

Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Table I:- Comparison Of Mean PI Scores Between Two Study Groups At Different Time Intervals

Time	Group	N	Mean	SD	Mean Diff	t	P-value
Baseline	BCG Group	10	1.56	0.14	0.06	0.896	0.38
	CPC Group	10	1.50	0.16			
3 Months	BCG Group	10	1.32	0.12	0.00	0.001	1.00
	CPC Group	10	1.32	0.14			
6 Months	BCG Group	10	1.19	0.09	-0.01	-0.287	0.78
	CPC Group	10	1.20	0.07			
9 Months	BCG Group	10	1.03	0.02	0.00	-0.29	0.77
	CPC Group	10	1.03	0.02			

denotes significant difference (P value <0.05)

Table II:- Comparison Of Mean GI Scores Between Two Study Groups At Different Time Intervals.

Time	Group	N	Mean	SD	Mean Diff	t	P-value
Baseline	BCG Group	10	1.77	0.36	0.00	0.001	1.00
	CPC Group	10	1.77	0.43			
3 Months	BCG Group	10	1.30	0.11	-0.02	-0.314	0.76
	CPC Group	10	1.32	0.11			
6 Months	BCG Group	10	1.16	0.07	-0.02	-0.570	0.58
	CPC Group	10	1.18	0.08			
9 Months	BCG Group	10	0.83	0.21	0.00	-0.010	0.99
	CPC Group	10	0.83	0.21			

*denotes significant difference (P value <0.05)

Table III:- Comparison Of Mean PPD Scores Between Two Study Groups At Different Time Intervals

Time	Group	N	Mean	SD	Mean Diff	t	P-value
Baseline	BCG Group	10	9.22	1.00	0.36	0.891	0.38
	CPC Group	10	8.86	0.79			
3 Months	BCG Group	10	5.95	0.59	0.08	0.323	0.75
	CPC Group	10	5.87	0.51			
6 Months	BCG Group	10	4.97	0.45	0.05	0.270	0.79
	CPC Group	10	4.92	0.37			
9 Months	BCG Group	10	4.26	0.30	0.12	1.134	0.27
	CPC Group	10	4.14	0.14			

*denotes significant difference (P value <0.05)

Table IV:- Comparison Of Mean RAL Scores Between Study Groups At Different Time Intervals Using Student Unpaired 't' Test

Time	Group	N	Mean	SD	Mean Diff	t	P-value
Baseline	BCG Group	10	10.12	0.54	0.04	0.155	0.88
	CPC Group	10	10.08	0.61			
3 Months	BCG Group	10	7.07	0.42	0.14	0.607	0.55
	CPC Group	10	6.93	0.60			
6 Months	BCG Group	10	5.39	0.41	0.11	0.567	0.58
	CPC Group	10	5.28	0.46			
9 Months	BCG Group	10	4.37	0.28	0.05	0.470	0.64
	CPC Group	10	4.32	0.19			

*denotes significant difference (P value <0.05)

Table V:- Comparison Of Mean GR Scores Between Two Study Groups At Different Time Intervals.

Time	Group	N	Mean	SD	Mean Diff	t	P-value
Baseline	BCG Group	10	1.67	0.13	0.03	0.485	0.63
	CPC Group	10	1.64	0.14			
3 Months	BCG Group	10	2.05	0.16	-0.06	-0.845	0.41
	CPC Group	10	2.11	0.16			
6 Months	BCG Group	10	1.81	0.13	-0.01	-0.172	0.87
	CPC Group	10	1.82	0.13			
9 Months	BCG Group	10	1.70	0.14	-0.10	-1.732	0.10
	CPC Group	10	1.80	0.12			

*denotes significant difference (P value <0.05).

Table VI:- Comparison Of Mean Depth Of The Defect As Measured In IOPAR Within Subjects At Different Time Intervals In Two Study Groups.

Study Groups	Time	N	Mean	SD	Greenhouse-Geisser		Diff	P-Value
					F	P-Value		
BCG Group	BL	10	11.35	0.93	556.642	<0.001*	I Vs II, III, IV	<0.001*
	3 Months	10	8.07	0.73			II Vs III	<0.001*
	6 Months	10	6.07	0.41			II Vs IV	<0.001*
	9 Months	10	4.19	0.39			III Vs IV	<0.001*
CPC Group	BL	10	10.94	1.15	375.542	<0.001*	I Vs II, III, IV	<0.001*
	3 Months	10	7.15	1.16			II Vs III	<0.001*
	6 Months	10	5.40	0.67			II Vs IV	<0.001*
	9 Months	10	4.14	0.54			III Vs IV	<0.001*

*denotes significant difference (P value <0.05).

Conclusion:-

Clinical and radiographic assessment reveal that treatment with bioactive composite granule and calcium phosphate cement both are efficacious in the treatment of periodontal endosseous defects. These two appear to have nearly comparable effects, treatment with both bioactive composite granule and calcium phosphate cement improve the healing outcomes regarding probing depth reduction, CAL gain, and bone fill. However, long-term, randomized, controlled clinical trial and histomorphometric studies employing a greater number of patients will be needed to arrive at a definitive conclusion.

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