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Efficacy of Calcium Phosphate Composite Bone Graft in Treatment of Periodontal Intrabony Defects: Clinico-radiographic Study

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ABSTRACT

Introduction: Regeneration of periodontium is always difficult to achieve regardless of all advancement. In an attempt to refine, various materials have been tried and tested. The present study was carried out to evaluate regenerative potential of easy-graft CRYSTAL in intrabony defects, clinically, and radiographically.

Methods: This randomised split-mouth study was conducted at Rungta College of Dental Sciences and Research from 2015 October to 2016 October. Intrabony pockets more than 5 mm and radiographic evidence of vertical bone loss were selected from 15 patients having two sites each. The chosen sites were randomly divided into test sites: open flap debridement (OFD) with easy-graft CRYSTAL and control sites (OFD). The clinical parameters evaluated were Plaque Index, Gingival Index, Probing Pocket Depth, Relative Attachment Level, and Gingival Recession at baseline, three months, and six months postoperatively. Radiographic parameters recorded were Defect Fill and Percentage of Defect Fill at baseline, three months, and six months. Data were analysed in SPSS v.20.

Results: At six months, improved clinical and radiographic values were obtained compared to baseline. The plaque and gingival index showed statistically significant reduction. Both groups showed statistically significant reduction in mean probing pocket depth and gain in relative attachment level. Mean gingival recession score was increased in both the group but was not significant. There was significant increase in Defect Fill and Percentage of Defect fill in both groups with better bone fill in test group.

Conclusion: Easy-graft CRYSTAL is a potential regenerative material for the treatment of periodontal intrabony defects.

Keywords: Bone grafts; bone substitute; osseous defects; periodontal regeneration; periodontitis.

INTRODUCTION

Destructive periodontal disease is characterised by loss of alveolar bone support and is considered the anatomical sequel to apical spread of periodontitis.[1] Intrabony defects (IBDs) formed in periodontitis provide shelter to pathogenic microorganisms and worsen prognosis. Elimination of IBDs during periodontal treatment is vital for resolution of infection, chronic inflammation, and regeneration.[2,3] Regeneration is reconstitution of lost or injured part.[4] Periodontal regeneration involves development of new cementum with collagen fibers and bone, involving formation of three tissues.[3,5]

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Different bone grafts are used in periodontal therapy to regenerate bone and filling of IBDs, such as autogenous, allogeneic, and alloplast. Alloplasts are biocompatible alternatives to autografts, allografts, and xenografts and are capable of filling IBD in addition to providing defect fillers of variable biological activity.[6] They are also surgically convenient, osteoinductive or osteoconductive, of unlimited availability, and predictably promote regeneration.[7]

Biphasic calcium phosphate (BCP) ceramic [easy-graft CRYSTAL] comprising of hydroxyapatite (HA) and β-tricalcium phosphate (β-TCP) is an alloplast that resembles inorganic phase of human bone. HA withhold its form and structure thus maintaining space, while β-TCP stimulates new bone formation by dematerialising into calcium and phosphate ions.[8,9] Present study was aimed to evaluate the regenerative capability of easy-graft CRYSTAL in IBDs clinic-radiographically.

METHODS

The study was designed as a randomised split-mouth interventional study comparing the effectiveness of a bone

graft for treatment of periodontal IBDs. The study was carried out from October 2015 to October 2016 at Rungta College of Dental Sciences and Research. Ethical approval was provided by the ethical committee of the institution (RCDSR/IEC/MDS/2014/14). Informed consent (written and verbal) was acquired from all the patients before the commencement of the study.

The diagnosis of patients with chronic periodontitis was made on the basis of clinical and radiographic criteria proposed by the 1999 International World Workshop for Classification of Periodontal Diseases and Conditions.[10] Fifteen patients with a sum of 30 intrabony periodontal defects were selected after completion of Phase I therapy. The study group included seven female and eight male patients with age range from 25-55 years with a mean age of 43 years. The defects were randomly divided using a closed envelope method into two groups according to the type of treatment rendered to them by using split-mouth design.[11] Control sites included 15 surgical sites treated with open flap debridement (OFD) alone. Test sites included 15 surgical sites treated with Calcium Phosphate ceramic (GUIDOR easy-graft CRYSTAL, Sunstar Suisse SA, Etoy, Switzerland) and OFD.

Easy-graft CRYSTAL is a biphasic synthetic bone replacement graft, having granule size of 0.45–1 mm. It hardens in situ consisting of microporous compound particles of 60% hydroxyapatite (HA) and 40% beta tricalcium phosphate (β-TCP). Each particle of the bone graft is covered by a 10 µm layer of polylactic-co-glycolic acid (PLGA). The bone substitute is available as loose particles which are mixed with a biolinker (N-methyl-2-pyrrolidone solution). This biolinker is flushed out by the natural blood flow once grafted into the defect resulting into hardening of biomaterial into a solid bone-substitute scaffold.[12]

The inclusion criteria were: patients with chronic periodontitis with probing pocket depth (PPD) ≥ 5mm after phase I therapy; patients with at least two IBDs (two-wall or three-wall) one in each quadrant or contra lateral side of same arch with radiographical evidence of vertical bone loss at affected site; systemically healthy patients with no contraindication to periodontal surgery; patients who have not received any type of periodontal therapy for the past six months; patients who were non-smokers; and patients not undertaking any drugs which caused immunosuppression or gingival enlargement. The exclusion criteria were: patients allergic to medications; patients who were pregnant or lactating; patients using tobacco in any form; and patients showing dissatisfactory oral hygiene maintenance during pre-surgical period.

Four weeks after completion of phase I therapy, periodontal re-evaluation was carried out to substantiate the competence of the sites selected for the study. The clinical measurements included were: Plaque Index (PI, Silness and Loe, 1964),[13] Gingival Index (GI, Loe and Silness, 1963),[13] PPD, which was measured from gingival margin to base of the periodontal pocket.[14] Relative attachment level (RAL), recorded as distance from the marking on the stent to base of the defect recorded with the help of University of North Carolina (UNC) 15 (Hu-Friedy) probe.[14] Gingival recession recorded with the help of UNC 15 probe as a distance from the marking on the stent to the gingival margin.[15] Radiographic evaluation by intraoral periapical radiograph using radiovisuography employing long cone paralleling technique.[16,17] The area of defect on the radiograph was measured according to the landmarks described by Eickholz et al.[17] The area has been calculated as following: cementoenamel junction (CEJ)-BD = distance from CEJ to base of defect; CEJ-AC = distance from CEJ to alveolar crest, H = length of the perpendicular from the vertex opposite the base of the triangle, Area of the defect A = ½ × CEJ-BD × H. All the clinical parameters and radiographic parameters were evaluated preoperatively at baseline and postoperatively at three months and six months.

Surgical procedure: The extra oral surface of the patient was swabbed with 5% povidone iodine solution and patient was advised preprocedural rinsing with 10 ml of 0.2% chlorhexidine digluconate solution. Local anaesthetic solution (2% Xylocaine Hydrochloride, epinephrine 1:80,000) was injected to obtain anaesthesia in the area of intention. After achieving adequate anaesthesia, crevicular incision was given using Bard Parker handle with blade no. 15 in the sextant of the defect. A full thickness mucoperiosteal flap was reflected with periosteal elevator carefully to preserve interdental papillary tissue as much as possible. The area was debrided, thorough root planing, and irrigation was done with 0.9% normal saline solution. Intrasurgical measurements such as CEJ-BD and CEJ-AC were made. Presuturing was done at defect site and was kept loose. Then pack of bone graft was opened and biolinker was poured into the syringe of graft material by pulling out the rear plunger. The plunger was then placed back in the syringe and moved back and forth for complete wetting of graft particles with biolinker to get the putty form. Spared biolinker was removed by pushing the graft in the front of the syringe after pulling out the front plunger. Graft was applied directly to the defect from the syringe. The material was moldable and sets only when it comes in contact with blood or body fluids. Proper condensation of the graft into the defect was done. Then the flaps were approximated by suturing over the defect site and adjacent areas. The procedure similar to test site was repeated for the controlled site except for graft placement.

Post-operative care: After the surgical procedure, analgesic drugs (Paracetamol 325 mg, Diclofenac potassium 50 mg, twice a day) and antibiotics (Amoxicillin 500 mg thrice a day) was prescribed for five days post-operatively. Routine post-surgical instructions were advised to all the subjects. The patients were again instructed to rinse with 0.2% chlorhexidine mouthwash

for two times a day for one week. They were refrained from brushing on surgical site for seven days.

Post-operative recall visits: Patients of both the groups were recalled after one week post-operative for removal of sutures. Recall appointments were made after three months and six months post-surgery, and the clinical and radiographic parameters were recorded. Oral hygiene instructions were reinforced at each recall visits.

Data of differences between Test group and Control group and differences between baseline to different time intervals was subjected to statistical analysis. The statistical software used in the analysis was IBM SPSS Statistics for Windows, version 20 (IBM Corp., Armonk, N.Y., USA). Statistical analysis was carried out for all the groups in this study. The statistical tests used for the analysis of the result were: Student's paired-t test to compare the post treatment changes with baseline (Intra-group) and Student's unpaired-t test to compare post-treatment changes between test and control groups. A probability P value of P<0.05 was considered for statistical significant.

RESULTS

All the patients completed the study. Primary closure was achieved in both the groups. There was no statistical significant difference observed in terms of defect depth and number of walls in both the groups preoperatively.

All clinical parameter changes are summarised in Table 1, Table 2. There was a statistical significant reduction in plaque and gingival index from baseline to six months as presented in Table 1. This reduction was followed by clinical parameters (PPD and RAL, P <0.001). For Test group, greater statistically significant reduction was observed as compared to control group (Table 2). Gingival recession (GR) was observed in both the groups. It was statistically significant at six months when compared to baseline however no statistically significant difference was observed between the groups (Table 2). Regarding radiographic parameters, test group conduced a significantly greater Defect Fill (DF) and % Defect Fill (%DF) as compared to control group (P <0.05, Table 3).

Table 1: Comparison of oral hygiene status using plaque index and gingival index.

Clinical parameter	Baseline	Three months	P value (baseline to three months)	Six months	P value (baseline to six months)
PI	1.83±0.51	1.42±0.38	P <0.001	1.37±0.34	P <0.001
GI	2.07±0.46	1.34±0.40	P <0.001	1.26±0.39	P <0.001

Table 2: Intergroup comparison of clinical parameters.

Clinical parameter	Group	Baseline	Three months	P value (baseline to three months)	Six months	P value (baseline to six months)
PPD	Control	7.06±1.90	6.26±1.79	P <0.001	3.60±0.91	P <0.001
	Test	8.86±1.72	6.40±1.18		2.40±0.50	
RAL	Control	13.46±1.88	12.26±1.66	P <0.001	9.46±1.30	P <0.001
	Test	14.33±1.80	11.93±1.43		7.40±1.29	
GR	Control	6.40±1.05	6.53±0.99	P >0.05	7.13±0.91	P >0.05
	Test	6.20±0.86	6.40±0.82		6.93±0.59	

Table 3: Intergroup comparison of radiographic parameters.

Radiographic parameter	Group	Baseline - three months	P value	Baseline - six months	P value
DF	Control	15.43±7.31	P <0.05	32.16±12.31	P <0.05
	Test	34.71±13.68		58.84±16.10	
% DF	Control	17.46±6.18	P <0.05	36.13±8.78	P <0.05
	Test	38.26±11.43		65.80±10.73	

Table 4: Statistical significance comparison for intragroup.

Parameter		Baseline - three months	Baseline - six months
PPD	Control	0.001	0.001
	Test	0.001	0.001
RAL	Control	0.001	0.001
	Test	0.001	0.001
GR	Control	0.164	0.001
	Test	0.062	0.001
DF	Control	0.001	0.001
	Test	0.001	0.001
% DF	Control	0.001	0.001
	Test	0.001	0.001

The clinical and radiographic pictures are depicted in the Figures 1 to 14.

Figure 1: Material used: easy graft CRYSTAL.

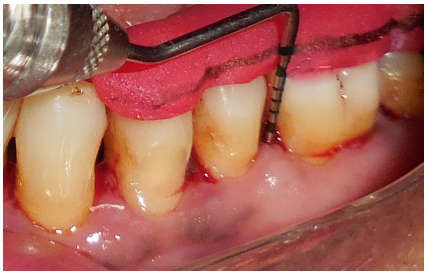

Figure 2: Preoperative probing at test site irt 36.

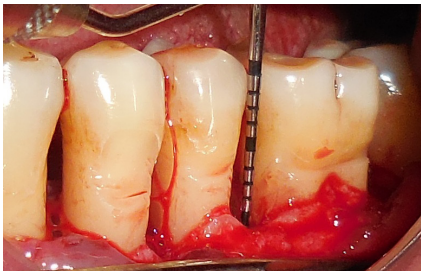

Figure 3: Intraoperative probing at test site irt 36.

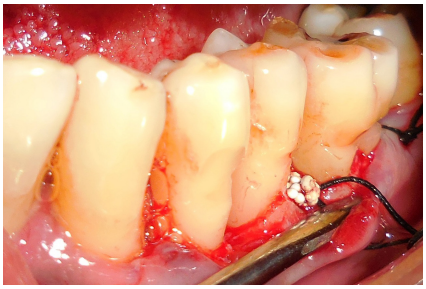

Figure 4: easy graft CRYSTAL placed into the defect.

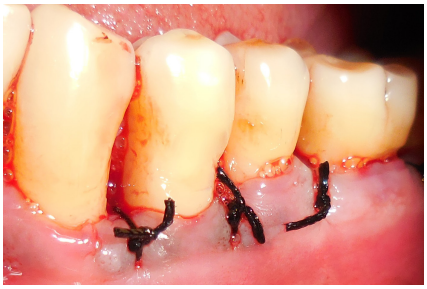

Figure 5: Suture placed at defect site irt 36.

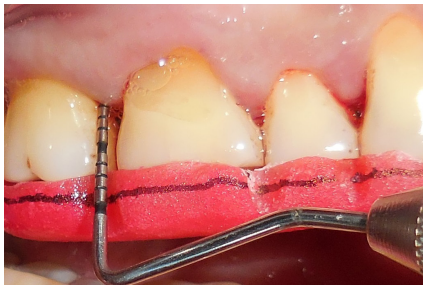

Figure 6: Preoperative probing at control site irt 17.

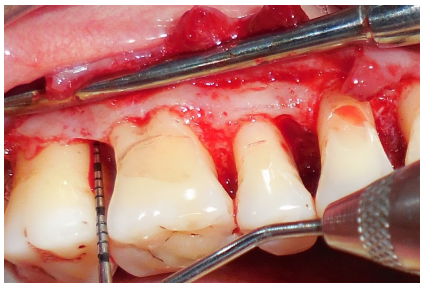

Figure 7: Intraoperative probing at control site irt 17.

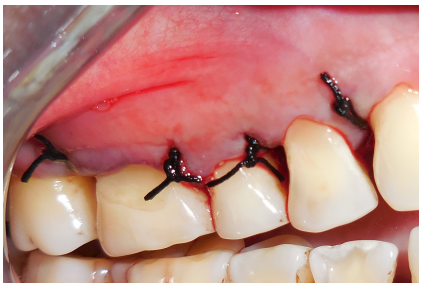

Figure 8: Suture placed at defect site irt 17.

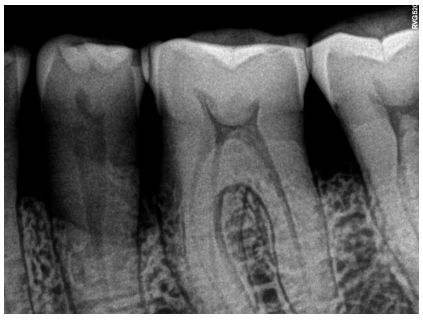

Figure 9: Preoperative IOPA irt 36 (test site).

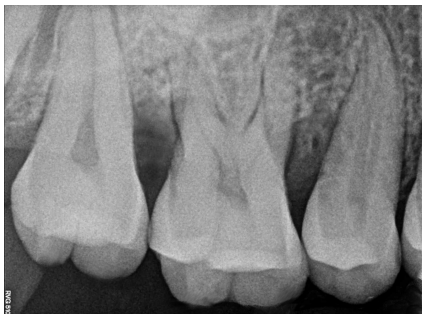

Figure 10: Preoperative IOPA irt 17 (control site).

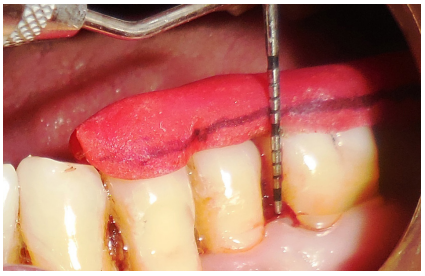

Figure 11: Post-operative probing at test site irt 36 after six months.

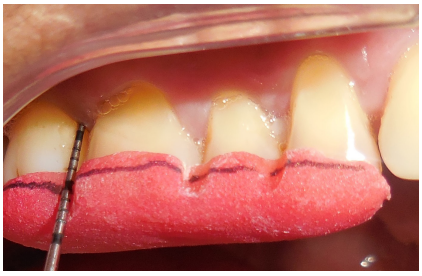

Figure 12: Post-operative probing at control site irt 17 after six months.

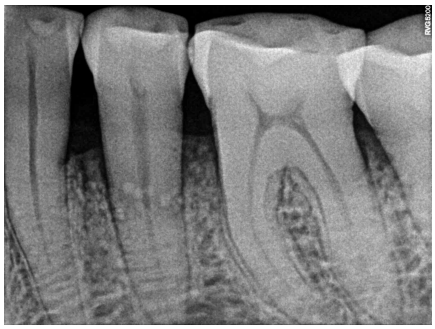

Figure 13: Post-operative IOPA irt 36 (test site) after six months.

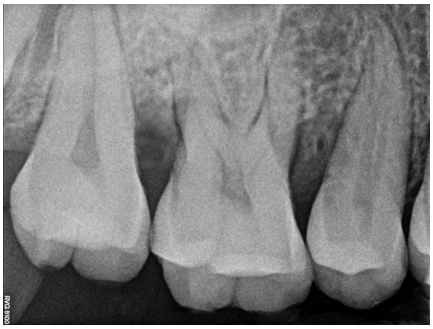

Figure 14: Post-operative IOPA irt 17 (control site) after six months.

DISCUSSION

Regeneration of periodontal tissues is always difficult to achieve. The regeneration of periodontal defects is attempted with various biomaterials which range from bone grafts to alloplastic implants. These materials are of keen concern and demur and have displayed anecdotal levels of success.[18] Use of bone grafts resulted in a successful regeneration of periodontal defects. Several grafts are available ranging from autogenous grafts to alloplasts. Alloplasts are synthetic bone graft substitutes, which are inorganic, biocompatible materials and can be used as a feasible discretion to treat IBDs. They offer the advantages of being easily available, no second surgical site and no risk of disease transmission.[19]

Amongst the various alloplastic materials, Calcium phosphate composite, is one of the broadly used substitute for periodontal regeneration. Biphasic calcium phosphate (BCP) comprised of hydroxyapatite (HA) and β-tricalcium phosphate (β-TCP) is a bone graft substitute. It corresponds with the inorganic phase of human bone tissue. The concept of combining HA and β-TCP was developed 1980s to achieve an optimal balance between the two materials, so that the material became soluble but dissolved gradually.[20] Hydroxyapatite being insoluble helps in maintaining space through retention of its form and structure, while the β-TCP dissolves into calcium and phosphate ions stimulating new bone formation.[8] Coating the alloplastic graft granules with PLGA (a polymer used in GTR membranes) can improve the handling properties and biomechanical characteristics of the material, and produce an in-situ hardening, stable and at the same time, porous and osteoconductive bone graft substitute.[21] Since a variety of calcium phosphates are available as well as studied, clamor for a naïve material was undertaken. The quest for new material led to easy-graft CRYSTAL.

The material has been used earlier in a few studies for sinus augmentation,[12] ridge preservation,[22,23] extraction socket preservation,[21] and filling of cystic defect.[24] It has also been used in a few animal models.[20,25] Thus, this study was conducted to assess the effectiveness of easy-graft CRYSTAL in the treatment of IBDs in terms of reduction of clinical parameters like PPD, RAL, and radiographic defect fill. Since the material has not been tested before, it was compared with a negative control which was OFD.

The lessening in PI and GI score was statistically significant at three and six months when compared from baseline (Table 1). This reduction can also be co-related with reduction in PPD and gain in RAL which have helped the patients to maintain better oral hygiene. Similar results were seen in studies done by Kumar et al. (2011)[26] and Bansal et al. (2014).[19] In contrast to this, Shirakata et al. (2008)[27] has shown no significant difference between the test and control group (Table 2).

Gingival recession on the other hand was observed to have increased following surgery in both the groups. Withal, the increase was statistically non-significant on intergroup comparison. Similar changes were observed in study of Shirakata et al. (2008).[27]

There was a statistically significant rise in bone fill in both the groups when comparison was done from baseline. The results coincide with that of Yukna (1994),[28] Kaushick et al. (2011).[29] However on comparing the two groups, significant difference in mean DF and %DF was observed in favor of test group (Table 3).

Schmidlin et al.[25] have shown no degradation of graft particles, but complete bridging of defect was seen. This maintenance of shape can be accredited to the partial resorb-ability of the material as claimed by the manufacturers. However, the authors suggest that the β-TCP content of the BCP material may be steadily replaced by calcium-deficient HA. No post-operative complications were observed throughout the study.

Limitations include lack of comparison with other regenerative materials. Long term follow-up should be there to determine the stability of the regenerative procedure since complete periodontal regeneration requires long term follow up and study has followed the patients only for six months period. Less number of subjects employed. To substantiate the finding of the study, large sample size should be taken and followed for longer time duration. Histologic investigation should be employed which gives a better picture of the type of regeneration that has occurred. But because of ethical reasons, it cannot be employed.

CONCLUSION

The easy-graft CRYSTAL validated a significant improvement in Probing Pocket Depth, Relative Attachment Level and radiographic changes in the defect site at six months post-surgery. It seems a promising novel material for the treatment of intrabony defects. The study provides sufficient evidence that, easy-graft CRYSTAL is capable of producing significant and favourable result for treating periodontal intrabony defects in comparison with conventional open flap debridement procedure. Future studies with more critically fabricated protocols, larger sample size are warranted to further investigate the prospective of the easy-graft CRYSTAL as a periodontal regenerative material.

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Conflict of Interest: None.

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