A Comparative Evaluation of SYBOGRAF ® Plus with PRF as compared to PRF Alone in the treatment of Intra bony Defect - A Clinico-Radiographic Study

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Abstract

Background: Periodontitis is a multifactorial diseases resulting in inflammation within supporting tissue of the teeth, progressive attachment and bone loss. The objective of periodontal therapy is to control inflammation and to reduce pocket depths and associated bone defects.

Aim: The aim of the present study was to assess the efficacy and compare the SYBOGRAF® Plus with PRF and PRF alone graft in the treatment of intra-bony defects in chronic periodontitis.

Materials and Methods: A total 20 intra-bony defects were selected from patients with chronic periodontitis and divided into three groups Group I Open flap debridement with SYBOGRAF® PLUS with PRF and Group II Open flap debridement with PRF alone. Before taking the clinical parameters, all the patients underwent oral prophylaxis and then recordings were taken at baseline, 3 months and 6 months for Plaque Index, Gingival Index, Pocket Probing depth, Relative Attachment Level and Bone Fill radiographically.

Results: The results of the present study showed significant difference in both the groups in inter-group and intra-group analysis except in GI from baseline to 6 months.

Conclusion: The overall efficacy in the treatment of chronic periodontitis in terms of clinical parameters (Plaque Index, Gingival Index, Pocket Probing Depth and Relative Attachment Level) and Radiographic parameter (Bone Fill) were shown by Group I (SYBOGRAF ® Plus with PRF) more significant as compared to Group II (PRF alone)

Keywords: Periodontitis; Periodontal therapy; SYBOGRAF® Plus, PRF; Intra-bony defects

INTRODUCTION

Chronic periodontitis is a polymicrobial, complex multifactorial inflammatory disease characterized by presence of gingival inflammation; periodontal pocket formation that affects the supporting structures of the teeth including periodontium.[1] The objective of periodontal therapy is to eliminate the inflammatory process, helps in stoppage of the progression of periodontal disease and contributes in the regeneration of the lost functional attachment. Bone grafts, soft-tissue grafts, guided tissue regeneration, and a combination of all helps in periodontal regeneration.[2] A wide array of bone graft substitute such as autogenous, allogenic and alloplastic materials are available today and have shown to produce greater clinical bone defect fill than flap debridement alone.[3]

The most extensively researched material used in periodontal defects is hydroxyapatite (HA) which is a biocompatible material, non-toxic, osteo-conductive, and osteo-phillic material which have close structural and chemical resemblance to bone mineral.[4] SYBOGRAF®Plus is a synthetic nanocryatalline hydroxyapatite and β tricalcium-phosphate and it is bio-resorbable with a high porosity and is osteoconductive.[5] PRF is prepared by immediate centrifugation of whole blood collected without anticoagulant or gelifying agents and polymerizes slowly leading to flexible and elastic matrix capable of supporting cytokine enmeshment and cellular migration. Platelet-rich-derived fibrin clot formation stimulates collagen synthesis in the periodontium that accelerates wound closure and mucosal healing and effectively promotes wound healing at sites of injury in periodontal tissue.[6]

Hence, the present clinical study was aimed to evaluate the clinical and radiographic outcome of the effect of SYBOGRAF®Plus bone graft along with PRF and PRF alone in the treatment of intra-bony periodontal defects.

MATERIALS AND METHODS

Twenty intrabony defect sites were selected from patients with chronic periodontitis from the out-patient department (OPD) of Department of Periodontology and Implantology, Dasmesh Institute of Research and Dental Sciences, Faridkot, Punjab. The subjects were selected randomly with no discrimination of sex, caste, religion and socioeconomic status. A complete dental & medical history was obtained and thorough clinical & radiological examination was done. Blood investigations such as complete blood count, bleeding time (BT), clotting time (CT) and tests for viral markers (Hepatitis B & C, HIV) were done. The research protocol was initially submitted to the institutional Ethical committee. After ethical approval, all subjects were verbally informed and written informed consent was taken for participation in the study.

The intrabony defect sites in the selected patients was randomly and equally divided into three groups –

Group I: Open Flap Debridement (OFD) with hydroxyapatite with β- tricalcium phosphate (SYBOGRAF®Plus) with PRF.

Group II: Open Flap Debridement (OFD) with PRF alone.

Inclusion Criteria: Age group - 25-65 years, radiographic evidence of vertical bone loss, Probing depth (PD) equal to or greater than 5 mm.

Exclusion criteria: Teeth with grade II and grade III mobility, Patient with any medications that may affect platelet count or function.

MATERIALS

SYBOGRAF®Plus: Osteoconductive bone graft which mainly composed of 90% nanocrystalline hydroxyapatite 10% β-tricalcium phosphate crystal. The particle size of bone graft ranges 250-550 microns. It is manufactured by Eucare Pharmaceuticals Pvt. Ltd. India

Platelet Rich Fibrins (PRF): The PRF was prepared according to the Choukroun et al. at 3000 revolution per minute for 10 minutes.

OCCLUSAL STENT PREPARTION

Occlusal stents were used for standardization for probing depth.

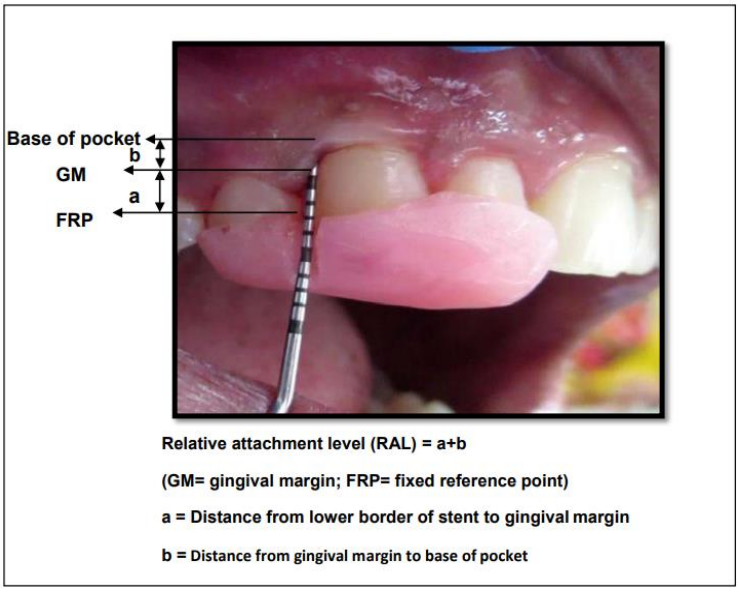

Figure 1 - Measurement of Relative Attachment Level (RAL) Using an Occlusal Stent

The clinical parameters taken as follows:

1. **Plaque Index (PI)**[7]
2. **Gingival Index (GI)**[8]
3. **Probing Pocket Depth (PPD)**
4. **Relative Attachment Level (RAL)**

Radiographic Examination

I) Bone Defect

STATISTICAL ANALYSIS

The recorded data was compiled & subject to statistical analysis using the **SPSS statistical software 19.0 Version**. The intragroup comparison for the different time intervals was doing using **paired t test** to find the difference between the individual time intervals. The intergroup comparison was done using the **One Way ANOVA**. The level of the significance for the present study was fixed at <0.05.

RESULTS

The present study was undertaken to clinically compare the efficacy of bone grafts with PRF and PRF alone in the treatment of periodontal intraosseous defects. Twenty intra-bony defects were selected and divided randomly into three groups. In Group I patient treated with OFD with SYBOGRAF®Plus with PRF and in Group II patients were treated OFD with PRF alone. Clinical and radiographic measurements were recorded at baseline, at 3 months and 6 month post operatively.

Intra-Group Comparison of Clinical and Radiographic Parameters

In Group I and In Group II the mean change in PI, GI, probing depth, RAL and bone fill from baseline to 3 months & 6 months and from 3 months to 6 months found to be significant (p=0.001).

Inter-Group Comparison of Clinical and Radiographic Parameters

1. Plaque Index (PI)

The mean difference of plaque index score l between the Group I and Group II from baseline to 3 months and 6 months was found to be statistically non-significant and in between 3 months and 6 months (p=0.009) was statistically significant. (Table 1).

Dependent Variable	(J) GP	Mean Difference (I-J)	Std. Error	P Value	Significance
Baseline -3 Months	Gp I vs Gp II	5.93520	3.93130	0.148	Non-Significant
Baseline -6 Months	Gp I vs Gp II	9.042	2.42482	0.061	Non- Significant
3 Months -6 Month	Gp I vs Gp II	14.49418*	4.94135	0.009	Significant

Table 1: Intergroup Comparison of Plaque Index

2. Gingival Index (GI):

The mean difference of Gingival index score between the Group I and Group II from baseline to 3 months and 6 months and from 3 months to 6 months were found to be statistically non-significant. (Table 2)

Dependent Variable	(J) GP	Mean Difference (I-J)	Std. Error	P Value	Significance
Baseline -3 Months	Gp I vs Gp II	3.05459	2.88985	0.145	Non-Significant
Baseline -6 Months	Gp I vs Gp II	0.73281	3.71454	0.766	Non-Significant
3 Months -6 Months	Gp I vs Gp II	1.00907	5.80103	0.864	Non-Significant

Table 2: Intergroup Comparison of Gingival Index

3. Probing Pocket Depth (PPD)

The mean difference of probing depth between Group I and Group II from baseline to 3 months, between baseline to 6 months and in between 3 months to 6 months was found to be statistically significant (p=0.000), (p=0.001) and (p=0.023). (Table 3)

Dependent Variable	(J) GP	Mean Difference (I-J)	Std. Error	P Value	Significance
Baseline -3 Months	Gp II vs Gp III	27.61905*	4.69797	.000	Significant
Baseline -6 Months	Gp II vs Gp III	34.575*	4.52194	0.001	Significant
3 Months -6 Months	Gp II vs Gp III	19.765	6.41141	0.023	Significant

Table 3: Intergroup Comparison of Pocket Probing Depth

4. Relative Attachment Level (RAL)

The mean difference of RAL between Group I and Group II from baseline to 3 months and 6 months and from 3 months to 6 months which were found to be (p=0.001) statistically significant. (Table 4and figure 2)

Dependent Variable	(J) GP	Mean Difference (I-J)	Std. Error	P Value	Significance
Baseline -3 Months	Gp I vs Gp II	14.60867*	3.51488	0.001	Significant
Baseline -6 Months	Gp I vs Gp II	25.80713*	2.96845	0.001	Significant
3 Months -6 Months	Gp I vs Gp II	21.29984*	4.22345	0.001	Significant

Table 4: Intergroup Comparison of RAL Scores

5. Radiographic Defect Fill

The mean bone fill between Group II and Group III from baseline to 3 months, between baseline to 6 months and in between 3 months to 6 was significant (p=0.047),(p=0.003)and (p=0.010). (Table 5 and figure 3)

Dependent Variable	(J) GP	Mean Difference (I-J)	Std. Error	P Value	Significance
Baseline -3 Months	Gp I vs Gp II	14.94048*	7.01778	0.047	Significant
Baseline -6 Months	Gp I vs Gp II	14.00595*	6.77415	0.047	Significant
3 Months -6 Months	Gp II vs Gp III	30.59099*	11.67769	0.010	Significant

Table 5: Intergroup Comparison of Bone Defect Fill Scores

DISCUSSION

Periodontal regeneration can be defined as the complete restoration of the lost tissues to their original architecture and function by recapitulating the crucial wound healing events associated with their development.[10,11] Regenerative procedures is a multi-factorial process and requires certain sequence of biological events including cell adhesion, migration, multiplication and differentiation which may restore lost supporting structures of the dentition such as cementum, periodontal ligament and bone to a previously diseased root surface.[12,13]

There are various grafting materials which contribute to new bone formation through osteogenic, osteo-conductive or osteo-inductive mechanisms[14] and supports soft tissue walls of the defect which results in gain in clinical attachment level thereby facilitating regeneration of periodontal structures lost during the disease process.[15] The materials most commonly used have been autografts and allografts.[16] When bone grafting materials are implanted in the defect site then it provides structural framework for clot development, maturation and remodeling which contributes in bone formation in osseous defects.[17]In Group I, SYBOGRAF® Plus allograft has been placed in intrabony defects. Hydroxyapatite became the ceramic of choice because it produces predictable short term and long term results.[18] Advantages of nanocrystalline hydroxyapatite and synthetic tricalcium phosphate biomaterial are biocompatibility and osteo-conductibility and close contact which was used as bone tissue substitute that helps in rapid healing of critical size defects by increasing stimulation of osteoblastic activity.[19]

In group II comprised of PRF alone. Platelets isolated from peripheral blood are autologous and rich source of growth factors-PDGF, TGF- α and β, PDEGF, PDAF, FGF and IGF-1. The concentrated platelets are added to graft materials to get predictable outcome.[20]

The intra-group result of plaque index scores from baseline to 3 months, baseline to 6 months and 3 to 6 months revealed statistically significant reduction in plaque index in both groups. These results were in contrast to those obtained by **Lekovic V et al (2012)[21],** where there was no significant difference in these scores at baseline and at 6 months. The reduction of plaque and gingival scores could be attributed to the patient compliance and proper oral hygiene maintenance. The study conducted by **Bansal & Bharti (2013)[16]** found results which were not in accordance with the present study.

The intra-group result of gingival index scores from baseline to 3 months, baseline to 6 months and 3 to 6 months revealed statistically significant reduction in gingival index in all the three groups. The study conducted by **Raghav et al. (2016)[22]** showed similar results with the present study. The gingival index in inter-group showed decrease in gingival index which was not significant.

In the present study, for both the groups, the mean difference of pocket depth reduction at 3 months and 6 months from baseline was highly significant ($p<0.001$). The study conducted by **Lekvoic et al. (2002)[21]** found statistical significant pocket depth reduction at different intervals. This reduction can be attributed to the decrease in inflammation, shrinkage of the pocket wall, change in tissue bone and placement of graft material into defect. Similar results were obtained by **Ostby N et al (2010)[23]** in their study wherein a significant pocket depth reduction was observed at 3 months, 6 months and 9 months.

The Relative Attachment Level (RAL) gain was highly significant for both the groups from baseline to 3 months and 6 months ($p<0.001$). The study conducted by **Bansal & Bharti (2013)[16]** showed significant results in RAL gain which are in accordance with study. The RAL gain can be attributed to the selection of defect, smoking, plaque control and proper surgical protocols. The studies conducted by **Demir et al. (2007)[23] and Yilmaz et al. (2010)[24]** found out non-significant result in RAL gain which are not similar to the present study.

In the present study, the mean amount of defect fill was statistically significant at 3 months from baseline among the both groups ($P<0.001$). At 6 month interval it was non-significant for group I as well as group II ($p>0.001$). These results were similar to those obtained by **Lekovic V et al (2012)[21]** where there was significantly defect fill occurs at 3 months and at 6 months ($p<0.001$).

The studies conducted by **Sharma et al. (2011)[24], Thorat et al. (2011)[25]** found similar result in accordance with the present study in terms of defect fill. The significant defect fill could be attributed to highly concentrated source of autologous platelets containing variety of biological mediators and improving handling properties of graft leading to graft stability

Overall, Group I showed higher percentage changes from baseline to 3 months and 6 months and between 3 months & 6 months in the present study.

CONCLUSION

The data from the present study suggests that treatment of intrabony defects with SYBOGRAF® Plus WITH PRF results in significant improvements of PI, PD, CAL, RAL and BD fill compared with baseline as compared to PRF alone.

Clinically, there are several factors like patient selection, defect morphology, biological and physicochemical characteristics of grafted biomaterials as well as surgical variables and post-operative maintenance may alter the extent of clinical attachment gain and bone regrowth following a grafting procedure. It is necessary to emphasize that the data generated by the present study was derived from 6 months' time period only. Hence, long tern term studies with greater sample size are required to evaluate the efficacy of the above materials in the treatment of periodontitis.

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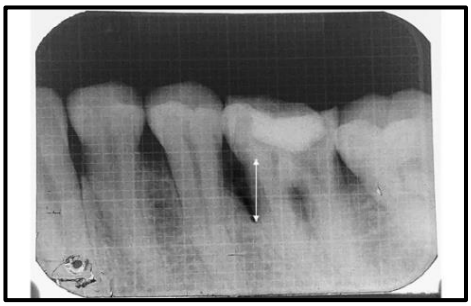
Figure 2: Group I - Clinical and Radiographic Parameters

Probing Depth And Relative Attachment Level At Baseline



Radiograph Showing Bone Defect At Baseline

Probing Depth and Relative Attachment Level at 6 Months

Radiograph Showing Bone Fill at 6 Months

Figure 3: Group II - Clinical and Radiographic Parameters

Probing Depth and Relative Attachment Level at Baseline

Radiograph Showing Bone Defect at Baseline

Probing Depth and Relative Attachment Level at 6 Months

Radiograph Showing Bone Fill at 6 Months