Comparative evaluation of bioglass with calcium sulphate β -hemihydrate for the treatment of intraosseous defects—a clinico-radiological study

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ABSTRACT

BACKGROUND

The aim of the present clinical and radiological study was to compare bioglass and calcium sulphate β -hemihydrate in the treatment of intraosseous defect in chronic periodontitis.

METHOD

A total of 50 subjects with bilaterally symmetrical periodontal osseous defects with probing pocket depth ≥ 5 mm and intraosseous defects ≥ 3 mm as seen on the radiographs were undertaken for the study. In one site (group A) bioactive glass was placed in defect and in contralateral site (group B) calcium sulphate β -hemihydrate was used in the defect site.

RESULTS

Clinical improvement was noted in all patients at the end of study. Both the groups showed reduction in probing pocket depth, increase in clinical attachment level, and reduction in osseous defect. Both materials were effective in achieving osseous gain.

CONCLUSION

The osseous gain in group A subjects was 58.93%, whereas in group B subjects it was 48.56%. Calcium sulphate β -hemihydrates showed promising results and were cost effective.

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Key Words: bone grafts; periodontal osseous defects

INTRODUCTION

Loss of alveolar bone is one of the characteristic sign of periodontal disease and is generally considered to represent the

anatomical sequel to apical spread of periodontitis. The extent and severity of the alveolar bone loss in the dentition is usually assessed by combination of clinical and radiological means and are important adjunct in diagnosis, treatment planning, and assessment of prognosis of periodontal disease.¹

In recent times, the procedures aiming at regeneration of the lost periodontal support has been an elusive but laudable goal. Over the last few decades, different bone grafts and bone substitutes have been used to meet these therapeutic end points but with variable and inconsistent results.^{2–6} The high cost of these materials restricts its widespread clinical application in our country. In pursuit of bringing the low cost of regenerative periodontal treatment to common man of our country calcium sulphate β -hemihydrate has been tried. With this background the present study was carried out with the following aim and objective to compare bioglass and calcium sulphate β -hemihydrate in the treatment of intraosseous defect in chronic periodontitis and to evaluate the efficacy of calcium sulphate β -hemihydrates as bone graft material in the treatment of intraosseous defects as compared to bioglass.

MATERIALS AND METHOD

Subject Population

The subjects for the study were selected from those attending the dental outpatient department. A total number of 50 subjects with bilaterally symmetrical periodontal osseous defects with probing pocket depth ≥ 5 mm and intraosseous defects ≥ 3 mm as seen on the radiographs were undertaken for the study.

In one site (group A) (Figure 1) bioglass was placed in the defect site and in contralateral site (group B) (Figure 2) calcium sulphate β -hemihydrate was used in the defect site. Informed consent was obtained after explaining the patient of the experimental nature of the study. The project and consent form was approved by the Armed Forces Medical College Ethical Committee Pune.

Inclusion Criteria

The subjects selected for the study were of the age group between 30 years and 50 years, with presence of an interproximal area with probing depth ≥ 5 mm when measured with a manual

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Figure 1 (A) Pre-operative probing depth, (B) defect exposed, (C) bioglass placed in defect, (D) flap sutured, (E) pre-operative intra-oral periapical (IOPA) radiograph, and (F) postoperative IOPA radiograph at 270 days.

periodontal probe and radiographic evidence of bone loss of at least 3 mm from the alveolar crest to the base of the defect site.

Exclusion Criteria

Medical problems that would contraindicate routine periodontal surgery, patients who had taken antibiotics during last six months of initial examination, female patients if they were pregnant or lactating were excluded.

Clinical Parameters

The following clinical parameters were recorded at baseline, 90, 180, and 270 days postoperatively: plaque index (PI), gingival

index (GI), probing pocket depth (PD), clinical attachment level (CAL), and osseous defect (OD) (loss/gain).

Surgical Procedure

Surgical procedures were performed under aseptic conditions. Following local anaesthesia, intracervicular incisions were given and mucoperiosteal flap were raised both buccally and lingually including one tooth to the mesial and distal of the tooth/teeth associated with the OD. Vertical incision was used where necessary the flap was extended mesially and distally to provide full visibility and access of the denuded root surfaces and the associated defect site.

Figure 2 (A) Pre-operative probing depth, (B) defect exposed, (C) calcium sulphate β -hemihydrate placed in defect, (D) periodontal pack placed, (E) pre-operative intra-oral periapical (IOPA) radiograph, and (F) postoperative IOPA radiograph at 270 days.

All granulation tissue from OD, that could hamper full access and visibility to the root surface was removed. If islands of calculus or any remaining subgingival plaque were noted, they were removed by scaling. In addition, very gentle root planning of exposed root surfaces was performed without intentionally removing any 'noncontaminated' hard tissue, to a smooth hard consistency. For all these cleaning procedures, hand instruments (Gracey curettes) were used. After cleaning, the surgical area was irrigated with sterile saline. The sites were then placed with loose sutures, left untied, prior to filling the defect site with interrupted sutures using 3-0 polypropylene suture.

Preparation and Application of Graft Material

A paste like consistency of Perioglass (Novabone, USA) was made by adding 4–6 drops of saline and was placed in to the defect site (group A) till it was completely filled. The soft tissue flap was then repositioned at the original level and closed with interrupted direct loop sutures using 3-0 polypropylene sutures. Surgical site was protected by applying a periodontal dressing.

Preparation and Application of Graft Material (Calcium Sulphate β -Hemihydrate)

Prior to its application, it was sterilised in hot air oven at 375°F for 90 minutes in a glass vial. It was mixed with 4–6 drops

of saline and allowed to set for about 5–8 minutes and then applied to the defect site. The flap was closed in the similar way as for group A subjects and periodontal dressing was placed.

Postoperative Management and Care

All subjects were prescribed antibiotic and anti-inflammatory for five days, oral hygiene instruction were given. At two weeks, periodontal dressing, sutures were removed. The patients were instructed and trained to clean the teeth in the surgical area with a soft toothbrush using Charter's method. Patients were recalled again for additional follow-up and deplaquing. All the parameters described earlier were recorded at regular interval and tabulated for each subject and were subjected to statistical analysis.

RESULTS

Throughout the study, no infectious episode or untoward reaction occurred in either group. The pocket probing depth was

reduced markedly in both the groups from 7.52 ± 1.074 to 2.20 ± 0.040 mm in group A and from 7.20 ± 1.069 to 2.14 ± 0.351 mm in group B ($P < 0.000$) (Table 1).

The clinical attachment loss was significantly decreased in group A from 7.52 ± 1.0359 to 2.48 ± 0.614 mm whereas in group B it was from 7.20 ± 1.069 to 2.32 ± 0.471 ($P < 0.000$). Intergroup comparison demonstrated marginal difference which was statistically insignificant (Table 2).

The OD fill was noted in both the groups from baseline to 270 days postsurgery. The mean amount of defect fill in group A and group B was from 4.36 ± 0.749 to 1.74 ± 0.487 and 4.38 ± 0.780 to 2.226 ± 0.633 , respectively (Table 1). The mean percentage of osseous fill was 59.93% for group A whereas for group B it was 48.65% (Table 3).

Gingival recession was noted in both the groups, further significant reduction in PI and GI were observed in both the groups.

The comparison of the cost to benefit ratio was made. For group A subjects material cost per patient/per defect site was ₹3,400 and benefit in terms of osseous gain was 58.93%.

Table 1 Comparison of parameters in group A and group B.

Parameters	No. of subjects	Period	Group A				Group B			
			Mean	SD	<i>t</i>	<i>P</i>	Mean	SD	<i>t</i>	<i>P</i>
Probing depth (mm)	50	Base line	7.52	1.074	33.749	0.000	7.20	1.069	30.639	0.000
		270 days	2.20	0.404			2.14	0.351		
Clinical attachment level (mm)	50	Base line	7.52	1.035	30.270	0.000	7.20	1.069	30.856	0.000
		270 days	2.48	0.614			2.32	0.471		
Osseous defect (gain) (mm)	50	Base line	4.36	0.749	21.680	0.000	4.38	0.780	26.845	0.000
		270 days	1.74	0.487			2.26	0.633		
Gingival recession (mm)	50	Base line	0.54	0.579	4.093	0.000	0.58	0.538	5.403	0.000
		270 days	0.98	0.769			1.14	0.670		
Plaque index	50	Base line	1.026	0.2193	11.825	0.000	1.000	0.2119	11.624	0.000
		270 days	0.618	0.1044			0.626	0.0944		
Gingival index	50	Base line	1.122	0.2243	11.764	0.000	1.106	0.2583	8.600	0.000
		270 days	0.672	0.1246			0.706	0.1316		

SD: standard deviation.

Table 2 Intergroup comparison of parameters in group A and group B.

Parameters	No. of subjects (<i>n</i>)	Period	Group A (Bioglass)	Group B (Calcium sulphate β -hemihydrate)	<i>t</i>	<i>P</i>
Probing depth (mm)	50	Baseline	7.52	7.20	1.493	0.139
		270 days	2.20	2.14	0.793	0.430
Clinical attachment level (mm)	50	Baseline	7.52	7.20	1.521	0.132
		270 days	2.48	2.32	1.462	0.147
Osseous defect (mm)	50	Baseline	4.36	4.38	0.131	0.896
		270 days	1.74	2.26	4.605	0.000
Gingival recession (mm)	50	Baseline	0.54	0.58	0.358	0.721
		270 days	0.98	1.14	1.109	0.270
Plaque index	50	Baseline	1.026	1.000	0.603	0.548
		270 days	0.618	0.626	0.402	0.689
Gingival index	50	Baseline	1.122	1.106	0.331	0.742
		270 days	0.672	0.706	1.327	0.188

Table 3 Percentage of osseous defect (gain) between the groups.

Group	No. of subjects (n)	Mean percentage of osseous gain at 270 days	Cost per patient per defect (₹)
Group A (Bioglass)	50	58.93	3,400.00
Group B (Calcium sulphate β -hemihydrate)	50	48.55	120.00

In group B material cost per patient/per defect site was ₹120 and benefit in terms of osseous gain was about 48.56% (Table 3).

DISCUSSION

The crux of the problem of chronic destructive periodontal disease lies in the changes that occur in the bone. The changes in the other tissues of periodontium are important but in final analysis, it is the destruction of the bone that is responsible for the loss of teeth.¹ As reported in literature conventional methods, surgical or non-surgical, have generated negative histological results with long junctional epithelium, diverse effort have been undertaken to find ways to attain periodontal regeneration.⁷⁻¹¹

Additive osseous surgery is the preferred treatment modality to get rid of the alveolar bone deformation, induced by the periodontal disease. Use of bone graft material, guided tissue regeneration either alone or in combination to treat OD has proved to be successful.¹²⁻¹⁴ The objectives of use of bone graft/bone substitute are reversal of the disease process, reduction in probing depth, gain in CAL, and osseous gain.

Bioglass has the property to promote adsorption and concentration of proteins utilised by osteoblasts to form a mineralised extracellular matrix and thus promote osteogenesis by allowing rapid formation of bone. It also may act as a barrier retarding epithelial down growth and demonstrates antimicrobial property in vivo.¹⁵ According to the clinical, histological, and radioactive analysis of Schepers,¹⁶ a particle of bioglass forms a protective vesica and grows an independent columella in its centre, irrespective of surrounding bone, which is facilitated by its narrow size and subsequently functions as a pivot for recovery. In other words, bioglass particles not only show osteoconductivity, but also an osteostimulatory effect. The pore size of bioglass allows an optimal space for vascularisation. It is also easy to manipulate and has a haemostatic effect.

Lovelace¹⁷ compared the use of bioglass to demineralised freeze dried bone allograft in the treatment of human periodontal OD and concluded that bioglass is capable of producing results in the short-term (six months) similar to that of Decalcified Freezed Dried Bone Allograft when used in moderate to deep periodontal osseous defects.

Various workers have demonstrated improvements in clinical parameters like reduction in probing depths, gain in clinical attachment, improvement in osseous fill with bioglass.^{7,14,17}

Due to the merits of bioglass, it is one of the preferred alloplast. Only deterrent is the high cost of the material which limits its clinical applications particularly in the country like India. In an attempt to bring down the cost of regenerative periodontal therapy use of calcium sulphate β -hemihydrate was made in this study.

Calcium sulphate β -hemihydrate is biocompatible, bioabsorbable, versatile, osteoconductive, and follows osteopromotive principle. The other major advantages include ease of application, non-inflammatory reaction, absence of postoperative complication, stabilisation of clot, and complete resorption. The resorption of calcium sulphate takes place in 33–76 days.^{18,19}

In the present study at base line all the parameters in both the groups were comparable. Clinical improvement was noted in all patients at the end of study (at 270 days). Both the groups showed reduction in probing PD, increase in CAL, reduction in OD (resolution of defect), mild gingival recession, and improvement in gingival and PI (Table 1).

In group A the probing PD decreased by 5.32 mm, whereas in group B there was a mean reduction of 5.06 mm from base line to the 270 days. The reductions in PD in both the groups were highly significant ($P < 0.01$). There was no significant difference in PD reduction between the two groups (Table 2). Significant reduction in PD and gain in clinical attachment was noted when pre-operative probing depth was ≥ 7 mm. The result of the present study is in line with other worker.^{2,7,11,20}

The mean clinical attachment gain from baseline to 270 days postsurgery was 5.04 mm for group A, whereas in group B mean clinical attachment gain from baseline to 270 days was 4.88 mm which was marginally different as compared to group A subjects. The difference in CAL may be due to marginal variation in initial baseline measurement difference in pre-operative probing depth and relative greater effect of bioactive glass in deep periodontal defect.^{17,20}

Postsurgically gingival recession was noted in both groups, this which is a common phenomenon and is due to postoperative shrinkage of tissues.

It has been reported that most histological change occurred in the first six months after surgery.^{8,20,21} Keeping this aspect in mind a healing period of nine months (270 days) was allowed before the results of surgical procedures were evaluated. As observed from the tables (Tables 1 and 2) and radiographs (Figures 1 and 2) both the group demonstrated significant amount of defect fill from base line to 270 days which was statistically significant. The mean percentage of defect fill from baseline to 270 days was 58.93% for group A which is statistically significant. This is in accordance with study by Forum⁷ who reported bone gain of 2.59 mm (55.6%) and Low²⁰ who reported bone fill of 2.64 mm (57.3%). In group B the mean percentage of OD fill from baseline to 270 days was 48.56% which was also significant.

Both the materials were effective in reduction of PD, gain in CAL. However, with respect to the percentage of osseous fill, bioglass showed better outcomes as compared to calcium sulphate β -hemihydrate. This variation may be due to rapid rate of resorption of calcium sulphate β -hemihydrate.^{19,22} There

was no root resorption, ankylosis, or any other pathological finding associated with both materials. Increased haemostasis, excellent handling properties, and improved tissue response are definite benefits of using bioglass. However, a review of the literature has shown that synthetic graft materials to date have functioned primarily as biocompatible defect fillers. Histological study, which is a gold standard for assessment for regenerative procedure, was not done because of certain limitations and ethical considerations. As the number of patients enrolled for the present study was small, there is further need for long-term studies with larger sample size. Based on the results of the present clinical and radiological investigation further long-term studies are warranted.

Comparison of the cost to benefit ratio was done. Fifty cases in group A cost around ₹170,000 and the material cost per patient/per defect site was about ₹3,400 and benefit in terms of bone gain was 58.93%. In group B, 50 cases cost around ₹6,000 and the material cost per patient/per defect site was about ₹120 and benefit in terms of bone gain was about 48.56% (Table 3).

The result of the present study leaves a clinical impression that calcium sulphate β -hemihydrate as graft material was effective in achieving osseous gain. The result of the study is encouraging and supports the clinical use of calcium sulphate β -hemihydrate. It is recommended that a study should be carried on a larger sample size with the use of calcium sulphate β -hemihydrate with addition of growth factors to enhance periodontal regeneration.

CONCLUSION

The result indicates that both the graft materials were effective in achieving osseous gain. Use of calcium sulphate β -hemihydrates as graft material showed encouraging result and was cost effective.

Intellectual Contributions of Authors

Study concept: Col VB Mandlik

Drafting and manuscript revision: Col VB Mandlik

Statistical analysis: Col Rajiva, Col VB Mandlik

Study supervision: Col VB Mandlik, Col Subrato Roy, Lt Col AK Jha

CONFLICTS OF INTEREST

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