Section: Research Paper

A comparative evaluation of an Irradiated allograft with an alloplast in the treatment of periodontal intrabony defects: A clinical & radiological study

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ABSTRACT

Introduction: To compare the effectiveness of an Alloplast (Bioactive glass) and an Irradiated Bone Allograft (Rocky Mountain) as a graft material in Periodontal intrabony defects, clinically and radiologically.

Materials and Method: 20 intrabony defects were treated with either an alloplast (Perioglass) or an irradiated allograft (Rocky Mountain). Clinical parameters recorded at baseline and at 6 months post-operative include plaque index, modified gingival index, sulcus bleeding index, probing pocket depth, gingival recession and clinical attachment level.

Statistical analysis: All the descriptive data that include mean and standard deviation were determined. The data derived for each group was analyzed by paired and unpaired‘t’test. For all tests, a p value of <0.05 was considered significant and p value of <0.001 was considered highly significant.

Results: Mean PD reduction and CAL gain in the allograft group (3.20 ± 0.91 mm and 3.20 ± 0.91 mm) were not statistically different than the allopast group (2.90 ± 0.73 mm and3.10 ± 0.87 mm).

Conclusions: Within the limitation of the study, both the groups showed a significant improvement in clinical parameters from baseline to 6 months post-operative. Also, there was a comparable improvement in defect fill and defect depth at 6 months.

INTRODUCTION

The goal of periodontal therapy is to provide the patients with a dentition that functions in health and comfort for the remainder of their lives. Ideally, periodontal therapy should resolve inflammation, arrest progression of disease,maximize patient comfort,maintain aesthetics and regenerate lost periodontal support[1].

Periodontal regeneration is defined histologically as regeneration of the tooth’s supporting tissues, including alveolar bone, periodontal ligament and cementum over a previously diseased root surface[2]. Great strides are being made to achieve this goal using bone grafts and various other regenerative procedures[3].

Bioactive glass is a non-resorbable material whose medical use evolved 25 years ago due to its reported advantages of forming a strong bond with living tissues, both bone and soft connective tissue and with a modulus of elasticity similar to that of bone[4].

Alloplasts are osteoconductive; i.e., they act as a scaffold and support new bone growth. But, they neither generate new bone nor induce new bone formation. Later, studies reported that the ceramic alloplast, bioactive glass, in addition to being osteoconductive, bonds directly to bone tissue[5].

The first demonstration of matrix induced bone formation was by Urist in 1965 in a report describing specific preparations of allogenic bone matrix implanted in muscle[6].

Allografts can be obtained from tissue banks. These banks supply a wide range of allograft bones, including cortical bone allografts,massive bone allografts and milled bone[7]. However, the use of allograft material carries with it the risk of transfer of disease from donor to recipient. The risk may be in the form of bacteria, viruses or prions. In an effort to eliminate tissue contamination, many methods are used such as donor screening, aseptic surgical techniques during retrieval, processing and storage of the tissue[8,9]. Following tissue processing, many banks consider it essential for bone allografts to be terminally sterilized using gamma irradiation sources from Cobalt 60[10].

One such newer allograft material is Irradiated cancellous bone, manufactured by Rocky Mountain Tissue Bank, Denver, marketed as Rocky Mountain®. This is trabecular allograft which is obtained from the spinal column and is treated with between 2.5-3.8 megarads of radiation.

Therefore, the present study was conducted to compare the new material; irradiated cancellous allograft with bioactive glass in the treatment of intraosseous, vertical periodontal defects, judged over a period of six months and to evaluate the amount of hard tissue fill obtained.

MATERIALS AND METHOD

PATIENT POPULATION

The present clinical study included 10 subjects (6 males, 4 females) in the age range of 30-46 years, who reported to the Department of Periodontics, Pacific Dental College and Hospital, Debari, Udaipur with generalized chronic periodontitis.

Each patient selected for the study satisfied the following criteria**:** 1.Systemically healthy subjects. 2.Patients who had paired vertical osseous defects both present either in the maxilla or in the mandible with a probing pocket depth $\geq$ 5 mm exhibiting clinical and radiographic evidence of intrabony or furcation defects. 3. Patients who have not taken antibiotics within 6 months of initial examination and who do not require antibiotic premedication for any systemic condition. 4. No drug allergy.

Pregnant and lactating women and patients with any type of habits were excluded.

A comprehensive medical and dental history was recorded. Patients were then given an explanation of the study and an informed consent was obtained. Patients were advised blood investigations, which included fasting blood sugar level, hemoglobin percent, bleeding time and clotting time.

INITIAL THERAPY AND MEASUREMENTS

Initial therapy consisted of scaling and root planing and oral hygiene instructions. This Phase-I therapy was re-evaluated after 3-4 weeks to see whether the level of plaque control by the subject is maintained. If acceptable, baseline examination was performed which included the recording of following parameters:

Ancillary parameters like Turesky Gilmore Glickman modification of Quigley Hein Plaque index[11], Modified Gingival index[12], Sulcus Bleeding index[13], Clinical soft tissue parameters

like Gingival recession, Probing pocket depth and Clinical attachment level. Radiographs were taken using the long cone paralleling angle technique.

Prior to surgery, a customized acrylic stent incorporating a metal wire on the occlusal surface of the teeth was fabricated for each patient and stored on the study cast to minimize distortion[14]. The stent was grooved in an occluso-apical direction with a tapered bur so that a William's Periodontal probe was returned to the same position for successive measurements. This stent served as a guide for clinical and radiographic measurements. All measurements were recorded by a single investigator.

SURGICAL THERAPY

One to 3 months following cause-related therapy, surgery was performed. All periodontal surgical procedures were performed under aseptic conditions. Standardized surgical procedure for the test and the control sites were performed as follows-

Surgical area was anaesthetized and sulcular incisions were placed, aimed at preserving as much interproximal tissue as possible and mucoperiosteal flaps were raised on the buccal and lingual/palatal aspects of the alveolar process upto at least two teeth on either side of the osseous defect.Meticulous defect debridement and root planing were carried out to remove subgingival plaque, calculus, diseased granulation tissue and pocket epithelium. Selection of sites as test or control was made at the time of surgical procedure using a toss of a coin. Following open flap debridement, the test site was treated with Rocky Mountain® (Picture1) and the control site with Perioglas® (Picture 2).

Picture 1: Test Site- Placement Of Rocky Mountain®

Picture 2: Control Site- Placement Of Perioglass®

The graft was carried directly to the site with a sterile instrument and condensed into the defect. Overfilling of the defect was avoided. Figure of eight sutures using 3-0 silk suture material were placed. The sutures were removed one-week post surgery.

POST-OPERATIVE CARE

All patients were prescribed Amoxicillin 500 mg thrice daily for 5 days and a non-steroidal anti-inflammatory agent, Ketorolac, thrice daily for 5 days.0.2% chlorhexidinegluconate rinse twice daily for a period of 2 weeks was also adviced.

POST-TREATMENT EVALUATION

All subjects were placed on a regular maintenance schedule following surgery.

Plaque Index and Modified Gingival Index were measured at 3 and 6 months according to the study design. Sulcus Bleeding Index, Gingival Recession and Probing Attachment Level were measured at 6 months post surgery.

Radiographic examination was done at 6 months, similar to that at the time of baseline examination, using paralleling angle technique and the same operator.

Radiographic interpretation was done using two techniques.

In the first technique, the radiographic image was analyzed digitally, using a software, Pixcavator 6.0. Using this software, the defect area was outlined at baseline and the 6^{th}month revaluation, taking the CEJ as the Fixed Reference Point. The number of pixels in this object were considered for calculation. Bone fill was obtained by subtracting the number of pixels inside the object at baseline and at the end of 6^{th} month.

Percentage bone fill was calculated using the formula,

Percentage Bone Fill= Postoperative defect size×100/ Preoperative defect size

In the second technique, the distance between the Fixed Reference Point (providedby the stainless steel wire incorporated in the stent) to the base of the defect was measured. These measurements were performed at baseline and at the 6^{th} month re-evaluation. The difference between the two values was used for obtaining the defect fill.

RESULTS

A total of 10 paired osseous defects were treated. All treated sites showed uneventful healing. A statistically significant reduction in Plaque index, Sulcus bleeding index and Modified gingival index measurements was found at 6 months post surgery, however intergroup comparisons did not reveal any significant differences.(Table-I). Both, test and control sites showed statistically significant reduction in PD and CAL comparing from baseline to 6 months postoperative. (Table-II).However, there were no inter-group differences seen. (Table-II).Gingival recession measurements were not significantly different for both the groups (Table-II). Table III shows changes in the defect bone fill for both the groups. The test sites showed a 57.91% of defect fill while the control sites showed a 57.55% defect fill. On comparing statistically, no significant difference was found (p= 0.961) (Table- III)

The mean defect depth improved significantly at 6 months from baseline for both the test and the control groups (Table- III). However, the difference between both the groups was statistically non-significant at 6 months (p= 0.849) (Table- III)

Table I:Changes in plaque index, sulcus bleeding index & modified gingival index (mean ± standard deviation)

	TEST GROUP	CONTROL GROUP	p VALUE
PLAQUE INDEX			
BASELINE	1.832 ± 0.715	1.831 ± 0.718	0.5†
6 MONTHS	0.785 ± 0.314	0.765 ± 0.321	0.435†
p VALUE	0.000*	0.000*	
SULCUS BLEEDING INDEX			
BASELINE	1.465 ± 0.525	1.468 ± 0.456	0.659†
6 MONTHS	0.132 ± 0.203	0.131 ± 0.198	0.662†
p VALUE	0.000*	0.000*	

MODIFIED GINGIVAL INDEX			
BASELINE	1.687 ± 0.562	1.688 ± 0.532	0.734†
6 MONTHS	0.843 ± 0.314	0.795 ± 0.390	0.825†
p VALUE	0.000*	0.000*	

*** Significant**

† Not Significant

Table II: Changes in probing depth, clinical attachment level and gingival recession (in mm; mean ± standard deviation)

	TEST GROUP	CONTROL GROUP	p VALUE
PROBING DEPTH			
BASELINE	7.5 ± 1.08	7.5 ± 0.81	1.00†
6 MONTHS	4.3 ± 0.82	4.6 ± 0.84	0.431†
p VALUE	0.000*	0.000*	
MEAN REDUCTION	3.20 ± 0.91	2.90 ± 0.73	
CLINICAL ATTACHMENT LEVEL			
BASELINE	7.90 ± 1.2	7.80 ± 0.7	0.836†
6 MONTHS	4.7 ± 0.94	4.7 ± 0.72	0.806†
p VALUE	0.000*	0.000*	
MEAN GAIN	3.2 ±0.91	3.1 ± 0.87	
GINGIVAL RECESSION			
BASELINE	0.4 ± 0.51	0.3 ± 0.48	0.438†
6 MONTHS	0.5 ± 0.52	0.4 ± 0.51	1.00†
p VALUE	0.426†	0.449†	
INCREASE IN RECESSION AT 6 MONTHS	0.1 ± 0.31	0.1 ± 0.32	

† Not Significant

Table III: Changes in bone fill (in pixels; mean ± standard deviation) and defect depth (in mm; mean ± standard deviation)

	TEST GROUP	CONTROL GROUP	p VALUE
BONE LEVEL			
BASELINE	37069.3 ± 3104.26	37061.3 ± 2641.33	0.526†
6 MONTHS	21408.4 ± 3652.62	21478.9 ± 3356.84	0.961†
p VALUE	0.001*	0.001*	
BONE FILL AT 6 MONTHS	15660.9 ± 3965.08	15582.1 ± 3191.09	
% BONE FILL	57.91	57.55	
DEFECT DEPTH			
BASELINE	14.89 ± 0.96	14.85 ± 0.92	
6 MONTHS	11.27 ± 1.04	11.30 ± 0.93	0.635†
p VALUE	0.000*	0.000*	0.849†
REDUCTION AT 6 MONTHS	3.62 ±0.85	3.55 ± 0.77	

*** Significant**

† Not Significant

DISCUSSION

The present study was undertaken to evaluate the amount of hard tissue fill obtained using bioactive glass and irradiated allograft as bone graft materials. Significant improvement in clinical and radiological parameters was found, both at control and experimental sites. In Bioactive glass, the silica rich layer has a negatively charged surface. This increases the electrostatic charges so that water is absorbed quickly and hydrogen bonding occurs between water molecules and hydroxyl group and silanol. This hydrostatic attraction gives bioglass a cohesiveness, which when in contact with blood is prevented from migrating from surgical site. The active, hydrated calcium phosphate layer at surface of glass particles mediates connection with bone and cementum[15].

Irradiated allograft used in our study is non-demineralised and non-freeze dried. It is osteo-conductive in nature. The manufacturers claim that it provides a dense scaffold over which the osteoblast can grow and bone formation takes place.

Comparison of the plaque index, gingival index and the sulcus bleeding index between the test and control group at baseline and at 6 months post-surgery, revealed no significant differences. However, there was a significant improvement in the parameters at 6 months post-surgery when compared to baseline in both the groups. Comparison of these parameters showed that there was a good maintenance of oral hygiene throughout the study period. Good plaque control has been cited as an important factor in treatment outcome.

All soft tissue measurements were made using a William's graduated periodontal probe and a customized acrylic stent with a guiding groove to maintain a consistency in the angulation and location of the instrument.

Pocket depth resolution is not only a desirable outcome of periodontal regenerative procedures, but, may also be the most important parameter in patient care for the clinician, since it directly impacts one's ability to instrument a treated area during maintenance appointments[16]**.** Both the treatment modalities resulted in a significant reduction in pocket depth and clinical attachment gain.

In this study, mean reduction in pocket depth for the control group from baseline to 6 months was 2.90 ± 0.73 mm, which was statistically highly significant (p=0.000). The results of this study are similar to the findings of Froum et al (1998)[17]who reported a probing pocket depth reduction of 4.26 mm at the end of a 12 month post operative follow up. In the test group, mean reduction in pocket depth 6 months post surgery was 3.20 ± 0.73 mm, which was also statistically highly significant (p=0.000). These results are similar to the findings of Mellonig et al (1984)[18]who demonstrated reduction in pocket depth with the use of an allograft as a graft material.

On comparing mean reduction in pocket depth between the two groups at 6 months post-surgery, the result was statistically not significant (p= 0.431).

A statistically significant improvement in the clinical attachment level was found in the test (p=0.000) and control group (p=0.000) on comparing from baseline to 6 months.

On comparison between the two groups at 6 months post-surgery, mean gain in clinical attachment level was statistically not significant (p= 0.806). Results of this study are similar to those found by Lovelace et al (1998)[19]. Bowen et al (1989)[20]also reported a similar clinical attachment level gain while comparing demineralised freeze dried bone allograft to Hydroxyapetite.

Results of our study showed a bone fill of 57.91% in test site and 57.55% in control site at the end of the 6 month revaluation period. These findings are in accordance with a similar study conducted by Lovelace et al[19] who found a mean bone fill of 61.8% in bioactive glass group compared to 62.5% bone fill in demineralised freeze dried bone allograft treated sites, which were not significant.

On comparing the Vertical Distance (Fixed reference point- Base of defect) in individual groups, there was a statistically significant difference at 6 months compared to baseline values (p= 0.001). Comparing between the two groups, the difference was statistically non significant (p= 0.849).

The results of the study suggest that Irradiated Allograft as well as Bioactive Glass are effective in improving the clinical and radiologic parameters when used as bone graft materials in the treatment of periodontal intrabony defects and have comparable clinical outcomes.

CONCLUSION

In this study, clinical outcome observed with the use of an Irradiated Allograft (Rocky Mountain) and Bioactive glass (Perioglas) as the bone graft material showed enhancement of clinical measurements of periodontal osseous defects. It is suggested that Irradiated Allograft (Rocky Mountain) or Bioactive glass (Perioglas) is useful for better clinical outcome in treating periodontal osseous defects.

Further long-term studies should be carried out comparing the use of Irradiated Allograft (Rocky Mountain) and Bioactive glass (Perioglas) in the treatment of periodontal osseous defects.

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