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Clinical and Radiographic Evaluation of Demineralized Bone Matrix – Xenograft (Osseograft) and Collagen Membrane (Healiguide) in the Treatment of Intraosseous Defects in Chronic Periodontitis: A Randomized Controlled Trial

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ABSTRACT

Background: At present, it is unknown to what extent this combination of DMBM-X and type-I collagen may additionally enhance the clinical outcome of the therapy compared with treatment with DMBM-X alone. Aim of the study was to compare clinically and radiographically the treatment of deep intra-bony defects with a demineralized bone matrix-Xenograft (DMBM-X) alone or DMBM-X in combination with type I collagen membrane as a GTR.

Methods: 25 intrabony defects in ten patients were divided into Group A (Test) and Group B (Control). The Group A sites were debrided and grafted with DMBM-X and type-I collagen membrane. The Group B sites were debrided and grafted with DMBM-X alone. Probing depth, Relative attachment level and gingival margin position were recorded at baseline, 3, 6 and 9 months. Standardized radiographs were also documented at these intervals.

Results: On completion of 9 months, the mean percentage of probing depth reduction and relative attachment level gain achieved was 67.39 versus 43.32; and 55.63 versus 30.71 in the Group A and Group B sites respectively which was statistically significant (P<0.005*). Gingival recession was seen to be non-significant when compared between the experimental and control sites.

Conclusion: Overall, both therapies led to significant improvements of the investigated parameters. The combination of DMBM-X and type-I collagen membrane as GTR was more effective in terms of improving clinical parameters than DMBM-X alone.

Keywords: Demineralized bone matrix – Xenograft; bone graft material; type-I collagen membrane; Guided tissue regeneration; intrabony defect; periodontal regeneration.

INTRODUCTION

Regenerative periodontal therapy comprises procedures which are specially designed to restore those parts of the tooth-supporting apparatus which have been lost due to periodontitis.

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Periodontal regeneration has been reported following a variety of surgical approaches involving root surface biomodification, often combined with coronally advanced flap procedures, the placement of bone grafts or bone substitutes and organic or synthetic barrier membranes.[1, 2]

Bovine-derived, hydroxyapatite bone replacement grafts, act as an osteoconductive scaffold due to their porosity and have a mineral content comparable to that of human bone, allowing them to integrate with host bone. They have been used with success for the treatment of intrabony defects.[3] However; controversy still remains as to whether periodontal regeneration at a coronal level is achieved or whether primarily a long junctional epithelium (repair) occurs as found with flap debridement surgery alone.

Use of barrier membranes for guided tissue regeneration (GTR) allows selective cellular repopulation of the root surface during periodontal regenerative attempts.[3]Absorbable collagen barriers have proven to achieve better probing depth reduction (PPD), clinical attachment level (CAL) gain, and defect fill than open flap debridement and were equally successful in comparative studies with non-resorbable membranes and also it avoids second surgery for the removal of the non-resorbable membrane.[4]

However, at present, it is unknown to what extent this combination of Demineralized bone matrix – Xenograft (DMBM-X) and type-I collagen may additionally enhance the clinical outcome of the therapy compared with treatment with DMBM-X alone. Thus the study aimed to compare clinically and radiographically the treatment of intra-bony defects with a DMBM-X for the treatment of osseous defects alone or DMBM-X in combination with type I collagen membrane as GTR.

MATERIAL AND METHODS

It is a randomized controlled clinical study in which ten patients who reported to the outpatient Department of Periodontics, M.S. Ramaiah Dental College and Hospital, Bangalore with following inclusion and exclusion criteria were considered.

Inclusion criteria:

1. Patients aged between 20 - 45 years.
2. Periodontal pocket with probing depth ≥6mm and CAL of ≥4 mm.
3. Radiographic evidence of infrabony osseous defects.
4. Patients who have not undergone any type of regenerative periodontal therapy 6 months prior to the initial examination.
5. Patients without any systemic problems.

Exclusion criteria:

1. Pregnant or lactating patients.
2. Medically compromised patients
3. Patients who are allergic to materials used in this study.
4. Smokers.

PPD, RAL and gingival margin position were recorded using a University of North Carolina Periodontal Probe (UNC) 15 probe at baseline, 3, 6 and 9 months postoperatively (Figure: 1-4). To ensure accuracy and reproducibility of PPD and RALs, occlusal stents were used and recorded to the nearest millimetre.[5]

Radiographic Measurements:

All of the 25 intrabony defects (10 patients) selected for the study were subjected to conventional IOPA radiography using long cone paralleling technique with identical exposure parameters were used at all examinations. Radiographs were taken at baseline, 3, 6 and 9 months postoperatively.

The amount of bone fill was assessed on conventional IOPA radiographs using grid and AUTOCAD 2009 software for digital images. The following parameters were estimated

Distance from CEJ to the bottom of the bony intrabony defect (BD), representing the radiographic bone level (RBL). The BD was defined as the most coronal point where the periodontal ligament space showed a continuous width.[6]

The percentage of bone fill was calculated by the formula: [6]

$$\textbf{Percentage of bone fill} = \frac{(RBL_{baseline}) - (RBL_{12})}{(RBL_{baseline})} X100$$

Fig 1: Recording of probing pocket depth by using stent in group A at baseline.

Fig 2: Recording of probing pocket depth by using stent in group B at baseline.

Fig 3: Recording of probing pocket depth by using stent in group A at 9th month.

Fig 4: Recording of probing pocket depth by using stent in group B at 9th month.

Fig 5: Defect depth measurement using grid in group A at baseline.

Fig 6: Defect depth measurement in group A at 9 months.

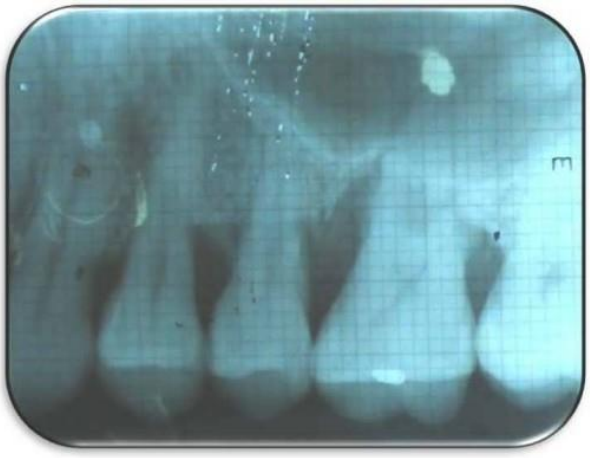
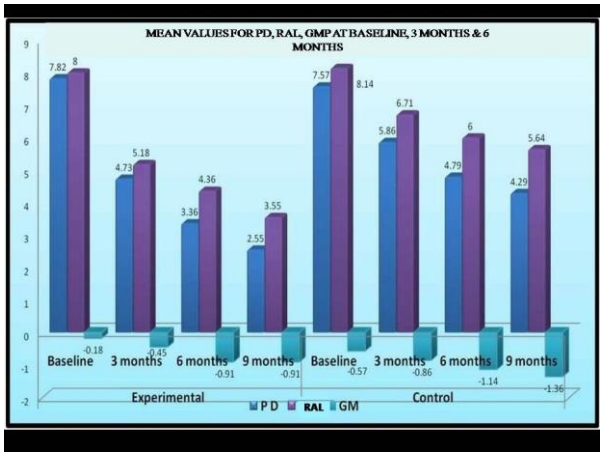
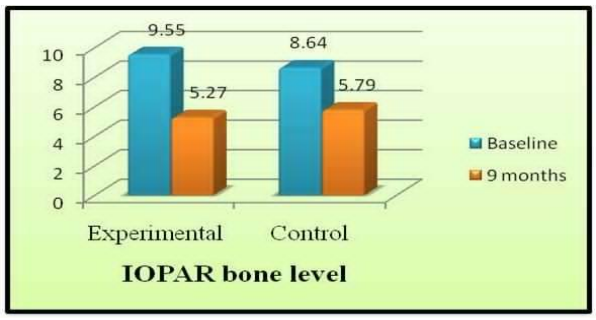


Fig 7: Defect depth measurement in group B at baseline.

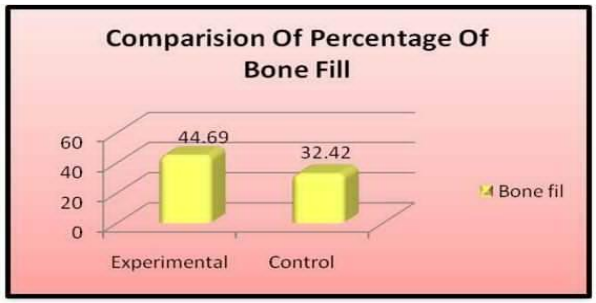
Fig 8: Defect depth measurement in group B at 9 months



Graph I: Comparison of mean probing pocket depth, relative attachment level and gingival margin level measurements between group A and group B at different follow up intervals.



Graph II: Changes in IOPAR bone level at baseline and 9 months in group A and group B.



Graph III: Comparison of percentage of bone fill at baseline and 9 months in IOPA in group A and group B.

The pre-and post-operative radiographs were analysed by the same examiner. The percentage of bone fill was calculated for both groups IOPAR's (Figure: 5 - 8).

Pre-surgical procedures:

After obtaining the ethical clearance, initial examination and treatment planning, patients were given detailed instructions in self-performed plaque control measures and were subjected to phase I periodontal therapy. Selective grinding in cases with traumatic occlusion was considered. 4-6 weeks after phase I therapy the patients were subjected to surgical procedure. 11 sites were taken in Group A, 14 sites were taken in Group B.

Surgical procedure:

The patient was made to rinse with 0.2% Chlorhexidine digluconate mouth rinse for 30 seconds prior to the surgery. After anaesthetizing the area with 2% lignocaine with adrenaline (1: 80000) solution, a full-thickness mucoperiosteal flap was raised to provide access to the intrabony defect and surrounding alveolar bone.

Table I: Comparison of mean probing pocket depth measurements between group A and group B at different follow up intervals. **Significant (S) – p <0.05 Non significant (NS) – p > 0.05.

Visit	Group	Mean ± SD	F	Mean difference	'p' value	
BASELINE	Control	7.57±1.342	0.000	0.25	0.651	
	Experimental	7.82±1.328		0.25	0.651	(NS)
3 MONTHS	Control	5.86 ±1.610	2.903	-1.13	0.049**	(S)
	Experimental	4.73±0.905		-1.13	0.038**	
6 MONTHS	Control	4.79±1.369	0.002	-1.42	0.012**	
	Experimental	3.36±1.206		-1.42	0.011**	
9 MONTHS	Control	4.29±1.383	0.033	-1.74	0.003**	
	Experimental	2.55±1.128		-1.74	0.002**	

**Significant (S) – p <0.05 Non significant (NS) – p > 0.05.

Table II: Comparison of mean relative attachment level measurements between group A and group B at different follow up intervals. **Significant (S) – p <0.05 Non significant (NS) – p > 0.05.

Visit	Group	Mean ± SD	F	Mean difference	'p' value	
BASELINE	Control	8.14±1.562	0.422	-0.14	0.825	
	Experimental	8±1.612		-0.14	0.826	(NS)
3 MONTHS	Control	6.71±1.541	1.048	-1.53	0.010**	(S)
	Experimental	5.18±1.079		-1.53	0.008**	
6 MONTHS	Control	6±1.414	0.784	-1.64	0.015**	
	Experimental	4.36±1.690		1.64	0.018**	
9 MONTHS	Control	5.64±1.499	0.269	-2.10	0.003**	
	Experimental	3.55±1.1695		-2.10	0.004**	

**Significant (S) – p <0.05 Non significant (NS) – p > 0.05

The defect was cleared of granulation tissue and the exposed root surface thoroughly planed to a smooth, hard surface. In group A, following presuturing, the DMBM-X was mixed with saline to a homogenous mixture and delivered into the vertical defect in small increments to the level of the remaining bony walls of the defect. Now the trimmed GTR was placed to cover 3-5 mm past the osseous defect margin. In group B, the defects were filled with only DMBM-X alone.

Flaps were then repositioned and secured in place using braided silk and interrupted sutures were placed. The surgical areas were protected with a non-eugenol dressing (Coe-pak). Patients were prescribed systemic doxycycline HCL 200 mg for the first day followed by 100 mg/day for another six days along with a combination of Ibuprofen 400 mg and Paracetamol 325 mg given twice daily for three days. Post-operative instructions were given to patients, and they were instructed to report after 24 hours of surgery and then after ten days. On the tenth day following surgery, the dressing and sutures were removed. Symptoms regarding discomfort, swelling, pain and sensitivity were asked of the patient. Any sign of swelling, infection, hematoma or necrosis was noted, and if needed, the dressing was again replaced for another one week.

Supportive periodontal therapy was provided weekly during the first month, followed by monthly maintenance recall till the end of the study period. Patients were re-examined again at the end of 3rd, 6th and 9th month postoperatively and all the above clinical and radiographic measurements were repeated.

Statistical analysis:

The data were analysed using the SPSS - software 20.00 program (SPSS Inc., Chicago, IL, USA). Student 't' test, One-way analyses of variance (ANOVA) and Chi-square test were used to evaluate the statistical differences between and within the groups.

RESULTS

All patients showed good compliance. The healing period was uneventful in both groups. This showed the biocompatibility of the DMBM-X when used alone or in combination with type-I collagen membrane as GTR.

Changes in PPD measurements (Table I & Graph I)

The mean PPD (mm) in Group A was 7.82 ± 1.32 at baseline and 2.55 ± 1.12 at 9th month. The changes in PPD when compared to baseline were statistically significant at 3rd, 6th and 9th months. In Group B was 7.57 ± 1.34 at baseline and 4.29 ± 1.38 at 9th months. The changes in PPD when compared to baseline were statistically significant at 3rd, 6th and 9th months. The mean percentage of PPD reduction in Group A at 3rd, 6th and 9th months was 39.51%, 57.03% and 67.39% respectively and 22.58%, 36.72% and 43.32% in Group B at 3rd, 6th and 9th months respectively. The mean PPD measurements between groups were not statistically significant at baseline and but greater PPD reduction in Group A than Group B, which was statistically significant at 3rd 6th and 9th month.

Changes in RAL measurements (Table II & Graph I)

The mean RAL (mm) in Group A was 8.00 ± 1.61 at baseline and 3.55 ± 1.69 at nine months. The changes in RAL, when compared to baseline, were significant at 3, 6 and 9 months postoperatively. The mean RAL (mm) in Group B was 8.14 ± 1.56 at baseline and 5.64 ± 1.49 at nine months. The changes in RAL, when compared to baseline, were significant at 3, 6 and 9 months postoperatively. The mean RAL measurements did not defer significantly between groups at baseline, but there was a statistically significant greater gain in Group A than Group B at 3rd, 6th and 9th month. The mean percentage of RAL gain in Group A at 3, 6 and 9 months was 35.25%, 45.5% and 55.62% respectively, Group B achieved a gain of 17.56%, 26.28% and 30.71 % at 3, 6 and 9 months respectively.

Changes in gingival margin position (Graph I)

The mean gingival margin level (mm) in Group A was -0.18±0.603 at baseline and -0.91 ± 1.044 at 9 months. There was no statistically significant difference between baseline and 9 months. The mean gingival margin level (mm) in Group B was -0.57 ± 1.016 at baseline and -1.36 ± 0.842 at 9 months. There was no statistically significant difference between baseline and 9 months.

Changes in the IOPAR bone level measurements (Graph II & Graph III): The mean radiographic bone level in mm was 9.55 ± 2.38 at baseline and 5.27 ± 1.42 at 9th month in the Group A and 8.64 ± 2.02 at baseline and 5.79 ± 1.62 at 9th month in the Group B. There was a statistically significant difference in the radiographic bone level within the groups when compared from baseline to 9th month. The mean percentage of bone fill in the Group B obtained was 32.42% whereas the percentage of bone fill in Group A was 44.69% which is 12% more than Group B.

DISCUSSION

Bone replacement grafts (BRG), such as autografts, allografts, xenografts, and alloplasts are the most widely used therapeutic strategies for the correction of periodontal osseous defects. The results of meta-analysis with respect to intrabony defects support the following conclusion: bone grafts increase the bone level, reduce crestal bone loss, increase CAL, and reduce PPD when compared to open flap debridement procedures.[7]

GTR is based on the principle of guiding various periodontal tissue components to the defect area during healing following periodontal surgery. GTR is consistently more effective than open flap debridement in relation to reduced PPD and gain of

CAL in the treatment of intrabony and furcation defects. No substantial differences were detected among barrier types.[4, 8]

A common problem with GTR is the lack of bone formation and its contribution to the functional stability of the tooth. Only narrow intrabony or moat defects have depicted the relative frequency of bone apposition accompanying the GTR technique. BRG has had the problem of epithelial proliferation attenuating the extent of cementogenesis in the defect. Although an array of combinations of regenerative techniques is feasible, only selective combination approaches have been reported in human studies.[8]

The material used in this study is DMBM-X is powdered form contains all the necessary conductive features of a carrier, and is a natural source of inductive osteogenic and chondrogenic factors such as BMPs. In addition, Demineralized bone matrix (DBM) is slowly biodegradable, non-immunogenic, easily manageable and handled product when mixed with saline.[3,9]

However, controversy still remains as to whether new attachment (regeneration) at a coronal level is achieved or whether primarily a long junctional epithelium (repair) occurs as found with flap debridement surgery alone, which led the researchers to aim towards a technique which could bring about regeneration rather than repair.[10]

Type-I collagen membrane is an extracellular macromolecule of the periodontal connective tissue and is physiologically metabolized; it is chemotactic for fibroblasts, hemostatic, a weak immunogen and a scaffold for migrating cells. The advantages of both techniques can be combined by using them together. Protection of the defect against invasion by soft tissues is achieved by using a cell-occlusive membrane. The osteoinductive substance can serve as a support for the membrane and as a solid matrix for new bone deposition. A further advantage may be the stabilization of the blood clot by this matrix.[11,12,13]

To date, there are no controlled clinical trials comparing the results of the combination of a DMBM-X and type-I collagen resorbable barrier membrane with that of a DMBM-X alone in the treatment of periodontal osseous defects. The present study is based on the study carried out by Sculean et al.[14], who treated 32 intra-bony defects, 16 defects that were treated with composite bovine-derived xenograft (BDX Coll) + collagen membrane as GTR and 16 defects treated with access flap surgery alone.

Changes in the probing depth measurements:

There was no statistical difference between the groups in baseline probing depth in this study. Group A exhibited statistically significant reductions in PPD at 3, 6 and 9 months postoperatively when compared to baseline similar results were confirmed by Sculean A et al. 2005[14] at 6th month. Group B of the present study also demonstrated statistically significant reductions in PPD at 3, 6 and 9 months postoperatively when compared to baseline; these findings are in agreement with those reported by Richardson et al.[15], Bigham[16]. There was a statistically significant greater percentage reduction in PPD in Group A compared to group B at 3 and 6 months.

Changes in the Relative attachment level

Group A exhibited statistically significant gain in RAL when compared to baseline at 3rd, 6th and 9th month similar results were confirmed by Sculean et al.[14] at 6th month. Group B demonstrated a statistically significant greater gain in RAL at 3, 6 and 9 months compared to baseline. Similar findings have been reported by Richardson et al.[15], Bigham[16]. Group A demonstrated a significantly greater gain in RAL compared to group B at 3rd 6th and 9 months postoperatively.

Changes in the gingival margin position

There was a slight recession in the gingival margin position in the Group A between the baseline and 9th month; similar was the condition in Group B. Similar results were confirmed by Sculean et al. [14].

Radiographic assessment:

Radiographic evaluation was done as per the method examined by Stavropoulos et al. [6]. In this study, there were progressive changes in the appearance of the graft material from the time of placement to 3, 6 and 9 months. There was a significant amount of bone fill in both the groups at 9th month when compared to baseline in IOPAR.

There was about 44.69% & 32.42% bone fill in the Group A and Group B respectively, the thus greater amount of bone fill is seen in the DMBM-X and GTR group than with that of a DMBM-X. No signs of root resorption were noted in any of the surgical sites.

DBM being radiolucent material and was apparent on the radiographs at all the times so that the bone filling in the defect was easy to notice at different time intervals, however, radiograph at best represents a two-dimensional picture of three-dimensional defects.[10]

CONCLUSION

There was a statistically significant reduction in probing depths & gain in clinical attachment level in the DMBM-X + type-I collagen group as well as DMBM-X alone. There was a greater percentage reduction in probing depths & gain in relative attachment level in Group A, which was statistically significant when compared to Group B. There was a greater percentage of osseous defect fill in the DMBM-X + type-I collagen (Group A) & DMBM-X alone (Group B). There was a greater percentage of osseous defect fill in Group A when compared to Group B. However, further long-term controlled studies are justified towards evaluating the adjunctive benefits of a combination of Demineralized bone matrix- Xenograft (DMBM-X) as bone graft and type-I collagen resorbable barrier membrane as GTR or while using DMBM-X bone graft alone, in the treatment of human periodontal osseous defects.

CONFLICTS OF INTEREST

The authors declare they have no potential conflict of interests regarding this article.

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