



## ROCKY MOUNTAIN TISSUE BANK (RMTBTM) - IRRADIATED ALLOGENIC BONE GRAFT IN THE MANAGEMENT OF INTRABONY DEFECTS IN CHRONIC PERIODONTITIS PATIENTS: A PILOT CLINICAL TRIAL.

### Dental Science

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### ABSTRACT

**AIM:** To evaluate clinically and radiographically the efficacy of irradiated allogenic bone graft (RMTB™) in the treatment of Intrabony defects post surgically over a 9-month period.

**MATERIALS AND METHODS:** After initial periodontal therapy, patients with moderate to severe chronic periodontitis underwent surgical open flap surgery during which bone defects were filled with RMTB™ in 10 intrabony defects. Clinical parameters and standardized radiographic data were collected at baseline and 9 months post-operatively. Primary outcomes measures included (1) radiographic bone fill using Intra oral periapical radiograph (IOPA) and Radiovisiography (RVG) as measured from the Cemento-enamel junction (CEJ) to base of bony defect (2) change in clinical attachment level (CAL) and (3) change in Probing pocket depth (PPD).

**RESULTS:** At 9 months evaluation satisfactory healing with the mean reduction in PPD was found to be  $4.1 \pm 0.61$ , the mean gain in CAL was  $3.8 \pm 0.42$ , percentage gain in bone fill using IOPA and RVG was found to be 37.79% and 44.06% respectively.

**CONCLUSION:** In the surgical management of periodontal intrabony defects, RMTB™ elicited in statistically significant PPD reduction, CAL gain, and better intrabony defect fill 9 months postoperatively.

### KEYWORDS

Intrabony defects, Chronic Periodontitis, Regenerative therapy, RMTB™

### INTRODUCTION:

Periodontal tissues represent a peculiar system in the human body where epithelial, hard and soft connective tissues come together to form a junction. This junction, which is a complex structure, referred to as the dentogingival junction and the maintenance of the integrity of this junction is crucial for preservation of underlying bone, cementum and periodontal ligament<sup>1</sup>. Lamentably, the structure of this junction is lost with chronic inflammation associated with periodontal diseases resulting in alveolar bone loss. However angular or vertical bone loss adjacent to root frequently occurs resulting in the areas that are difficult to access for root debridement and maintenance of effective plaque control as a consequence of disease process.

Contemporary periodontal therapy is directed towards controlling the infection and regenerating lost supporting structures.<sup>2</sup> The goal of regenerative therapy is to restore the lost tissue with a functional attachment apparatus by recreating the junctional epithelium at cemento-enamel junction by regeneration of lost periodontium resulting in embedding of newly established periodontal ligament fibres in newly organised cementum and alveolar bone.

Two main treatment modalities, bone grafting and guided tissue regeneration<sup>3</sup> have been proposed in literature and clinically evaluated for regeneration in human intrabony defects.

RMTB™ used in this study is an irradiated cancellous freeze-dried bone allograft (FDBA) procured aseptically from the spinal column. Among all available allograft, irradiated bone is more like autogenous bone in terms of demonstrating rapid replacement and consistent establishment of a reasonable ratio of new bone which is economic and has less morbidity that is associated with autogenous graft material.<sup>4,5</sup>

**AIM:** To evaluate clinically and radiographically the efficacy of RMTB™ in the treatment of human intrabony defects post surgically over a 9-month period.

**MATERIALS AND METHODS:** Power analysis for the present study using nMaster-software. The present single arm study comprised of a total of 10 sites in 6 patients in age range 30–45 years affected with

moderate to severe chronic periodontitis with intrabony defects and was initiated after ethical approval from Institutional Ethics Committee. The trial was registered with the Clinical Trial Registry-India. Involvement of human subjects in this work was in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). All the surgical procedures were carried out after obtaining the written informed consent from the study participants.

**Study population:** All the patients included in the study were systemically healthy with moderate to severe chronic periodontitis with deep inter-proximal, intrabony periodontal defects with radiographic defects > 3mm of 2-wall, 3-wall or combination defects and probing pocket depth > 5mm.

Patients with previous history of periodontal treatment or antibiotic therapy in the past 6 months, history of known systemic/infectious diseases, allergies or pregnant/lactating women, 1 wall defects were excluded from the study.

All the patients underwent preliminary preparation including supra and sub-gingival scaling, root planing, and occlusal adjustments 4–6 weeks before surgery.

**Clinical and radiographic assessment:** Performed at baseline and 9 months following therapy. Clinical parameters were measured and noted by an examiner using custom-made occlusal acrylic stents to standardize the probing measurements with UNC15-periodontal probe (Figure 1a). The clinical parameters recorded included: plaque-index (PI)<sup>6</sup>, gingival-index (GI)<sup>7</sup>, PPD and CAL.

The radiographic parameter recorded at baseline included radiographic defect depth (RDD) measured on an IOPA obtained by long cone paralleling technique which involved the assistance from a film-holding device (Figure 2a) and on a RVG Kodak 6100 operated at 60Kvp and 7Ma 0.25 seconds radiation-time (Figure 3a).

Following radiographical parameters were assessed: Measurement of percentage of bone fill using IOPA from baseline to 9 months,

measurements of percentage of bone fill using RVG from baseline to 9 months and comparative evaluation of percentage bone fill between IOPA & RVG from baseline to 9 months. The following landmarks were considered for recording radiographic parameters at baseline and 9 months post surgery: Distance from CEJ to base of the defect at baseline, distance from CEJ to base of the defect at 9 months, distance from alveolar crest to base of the defect at baseline, distance from alveolar crest to base of the defect at 9 months. All radiographic measurements of standardized image size were transferred into Digimiser image analysis software which was then transferred to master chart.

**Surgical Procedure:** Under adequate local anaesthesia, in selected sites (Figure 1b) full-thickness muco-periosteal flap was reflected to gain access for the defect debridement (Figure 1c, 1d). The defect site was exposed and complete debridement of granulation tissue, root planing and irrigation with normal saline was done. The RMTB™ bone graft material placement was done as per manufacturer's instruction (Figure 4). The graft material was placed into the defect and condensed using plastic filling instrument till the level of the alveolar crest or the remaining osseous walls (Figure 1e 1f). Flaps were approximated using vertical mattress sutures at defect site and remaining sites with interrupted sutures (Figure 1g) and protected using a non-eugenol periodontal dressing (Figure 1h). Patients were explained of postsurgical instructions, and medications were prescribed including antibiotics and anti-inflammatory drugs. Sutures were removed after 10 days (Figure 1i).

The patients were re-evaluated clinically and radiographically for 9 months (Figure 1j, 2b, 3b). During the first 2 months of postsurgical follow-up, the patients were reviewed every 3 weeks and after 2 months, patients were recalled once in two month for oral hygiene maintenance.

**STATISTICAL ANALYSIS:** The collected data were analysed using IBM.SPSS statistics software 23.0. Paired sample t-test was utilised to find the significant difference between the bivariate samples in paired groups with p value of 0.05 was considered as significant.

**RESULTS:** All the selected patients were assessed for 9 months follow up without any dropout. Wound healing was uneventful with no signs of complication or infection in all the participants. Satisfactory oral hygiene was exhibited by all patients throughout the study period. Table 1 summarizes the clinical and radiographic parameters for the participants at baseline. Table 2 summarizes the intragroup comparison of clinical and radiographic parameters for the participants from baseline to 9 months (Figure 5). The RMTB™ group exhibited a mean PPD reduction of  $4.10 \pm 0.60$  mm ( $p < 0.05$ ), and a gain in the mean CAL of  $3.8 \pm 0.42$  mm ( $p < 0.05$ ) at 9 months postoperatively. At 9 months, the mean reduction in RDD observed in the RMTB group was  $1.92 \pm 0.38$  mm using IOPA and  $2.48 \pm 0.43$  using RVG which was statistically significant ( $p < 0.05$ ).

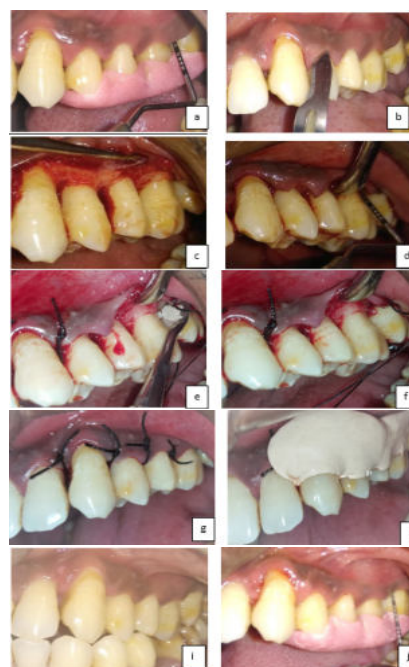
**Table 1: Baseline characteristics of study participants (Mean±SD)**

OFD + RMTB™ (n=10)	
Male/female	7/3
Age (years)	31.3±2.83
PI (score)	2.17±0.37
GI (score)	2.12±0.26
PPD(mm)	7.4±1.17
CAL(mm)	5.2±1.03
RDD (mm) (IOPA)	4.45±0.74
RDD (mm) (RVG)	4.90±0.77

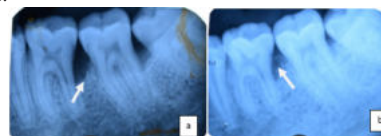
**Table 2: Intra- group comparison of clinical and radiographical parameters in OFD + RMTB group.**

OFD + RMTB GROUP (n=10)			
Parameters	Baseline	9 months	p value
PI(score)	2.17±0.37	0.78±0.13	<b>0.0005*</b>
GI(score)	2.12±0.26	0.85±0.18	<b>0.0005*</b>
PPD(mm)	7.4±1.17	3.3 ± 0.85	<b>0.0005*</b>
CAL(mm)	5.2±1.03	1.4 ±1.07	<b>0.0005*</b>
RDD (mm) ( IOPA)	4.4c5±0.74	2.5±0.68	<b>0.0005*</b>
RDD (mm) (RVG)	4.90±0.77	2.42±0.74	

\* p value  $\leq 0.05$  using Paired t test within the study group (Baseline – 9 months)



**Figure 1:** Surgical protocol for RMTBTM group (a) Baseline clinical measurement. PPD of 9 mm (b) Crevicular incision (c) & (d) Full-thickness flap elevated with a defect depth of 5 mm with 26 distally. (e) & (f) RMTBTM graft placement with intra-bony defect with 26 and condensation following thorough debridement and presuturing. (g) Flap repositioning to preoperative level. (h) Periodontal dressing given (i) 10 days postoperative (j) Postoperative PPD of the treated site after 9 months.



**Figure 2:** (a) Preoperative IOPA (b) Post operative 9 months IOPA

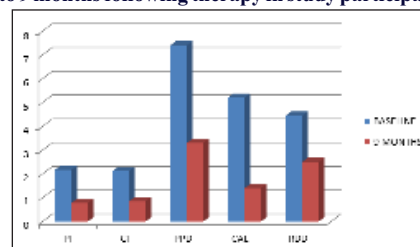


**Figure 3:** (a) Preoperative RVG (b) Post operative 9 months RVG



**Figure 4:** Rocky Mountain Tissue Bank (RMTBTM) bone graft

**Figure 5:** Changes in clinical and radiographic parameters from baseline to 9 months following therapy in study participants.



\* p value  $\leq 0.05$  using Paired t test within the study group (Baseline – 9 months)

## DISCUSSION:

The present study was performed from April 2019 to December 2019 with a nine-month observation period. This study did not have non graft sites as a control because numerous studies have shown statistically significant results in favor of bone replacement.<sup>4</sup> The purpose of this study was to test the efficacy of a bone replacement graft without inclusion of a control site is based on the findings of the systematic review by Reynold et al, showed that the use of bone replacement grafts were associated with significant reduction in PPD and CAL gain when compared to open flap debridement alone.<sup>4</sup>

The study conducted by Mellonig et al also supports the purpose of this study of using cancellous allogenic bone grafts in osseous defects for gaining bone fill and not using any control for comparative analysis.<sup>5</sup>

PI was recorded at baseline and 9 months post operatively as a method to assess the oral hygiene status of the patient which was similar to comparative study by Rummelhart et al between FDBA and DFDBA.<sup>9</sup> From baseline to 9 months, there was a statistically significant reduction in PI ( $1.38 \pm 0.24$ ) within the study group.

The findings of this study were similar to study done by Mellonig et al, where out of 97 grafted sites, 39 sites showed greater than 50% bone regeneration thereby proving the efficacy of Freeze-dried bone allograft (FDBA) as a regenerative material.<sup>8</sup>

Meticulous oral hygiene instructions were given to the patients in the present study, as osseous grafting procedures have shown to be clinically successful when encompassed in a compendious care program based on successful daily plaque control by the patient and a professionally organized supportive periodontal program.

There was a statistically significant reduction in GI scores from baseline to 9 months ( $1.27 \pm 0.15$ ), which was similar to a study done by Borghetti A et al where periodontal intraosseous defects were treated by cryopreserved cancellous bone allografts.<sup>10</sup>

Periodontal pocket is considered as pathognomic sign of periodontal disease, whereas the PPD is considered as the tool for evaluating the success of periodontal therapy. CAL is the therapeutic modality which has become widely accepted as one of the primary clinical end points of regenerative attempts around natural teeth because it is specific to periodontitis.<sup>11</sup>

PPD and CAL were recorded using customized acrylic stents with vertical grooves as it provided guidance and stability for maintaining the direction of probe insertion and for standardizing the measurements in follow up visits. This method of assessment is based on the study done by Isidor F et al on the effects of periodontal treatment on clinical parameters.<sup>12</sup>

PPD reduction ( $4.1 \pm 0.61$ ) and the gain in CAL ( $3.8 \pm 0.42$ ) was statistically significant from baseline to 9 months which were similar to the study by Browning E S et al where the author had used mineralized bone allograft in treatment of periodontal osseous defects.<sup>13</sup>

All the patients showed good compliance and the healing was uneventful at the surgical sites. Signs and symptoms of inflammation and any other post operative complications was not evident. In all patients, oral hygiene maintenance was found to be satisfactory at each recall visit.

The mean bone fill obtained in the study was 37.8% using IOPA and 44.06% using RVG which was less than that observed by Browning et al who observed 67% bone fill after a 6-month surgical reentry procedure.<sup>13</sup>

RMTB™ used in this study is an irradiated cancellous bone allograft derived from a cortical bone rather than that compared to bone allografts obtained from cancellous bone.<sup>14</sup>

The results of present study were in accordance with the literature using different autografts, allografts, and xenografts which have shown a significant bone fill, when compared to open flap debridement alone in human intrabony defects.<sup>3</sup>

Regenerative periodontal therapy for intraosseous defects is a technically demanding procedure. Selection of suitable flap design based on anatomical features of interdental space, site/architecture of

bony lesion, apt suturing technique, biological and physicochemical properties of grafted materials as well as postoperative supportive care may markedly contribute to deciding the amount of soft and hard tissue changes following surgery.<sup>3</sup>

Patient compliance with oral hygiene measures and frequent periodontal maintenance appears critical for optimal wound healing and maintenance of long-term therapeutic success following regenerative therapy.<sup>2,3</sup>

Small sample size and exclusion of control group was one of the shortcomings of the present study. Conventional radiograph was used for radiographic evaluation in the present study. Histologic examination of block sections for the presence of new attachment were not performed in this clinical study and therefore, the amount and type of regeneration occurring can only be speculative, which was the major limitation of the present study.

## CONCLUSION

Within the limitations of present study RMTB™ has proven to be a promising material for periodontal regeneration. The bone fill achieved in a short time frame by RMTB™ is highly encouraging for its use as bone augmentation material in periodontal as well as implant dentistry.

## REFERENCES

1. Zander HA, Polson AM, Heijl LC: Goals of periodontal therapy. *J Periodontol* 1976; 47:261-266.
2. Barnett JD, Mellonig JT, Gray JL, Towle HJ: Comparison of freeze-dried bone allograft and porous hydroxylapatite in human periodontal defects. *J Periodontol* 1989; 60: 231-237.
3. Kher VK, Bhongade ML, Shori TD, Kolte AP, Dharamthok SB, Shrirao TS, et al: A comparative evaluation of the effectiveness of guided tissue regeneration by using a collagen membrane with or without decalcified freeze-dried bone allograft in the treatment of infrabony defects: A clinical and radiographic study. *J Indian Soc Periodontol* 2013; 17: 484-489.
4. Mark A Reynolds, Mary Elizabeth, Aichelmann-Reidy, Grishondra L, Branch-Mays: Regeneration of periodontal Tissue: bone replacement grafts. *Dental Clinics of North America* 2010; 54: 55-71
5. Vastardis S, Yukna RA: Evaluation of allogenic bone graft substitutes for treatment of periodontal osseous defects: 6 months clinical results. *Compend contin dent* 2006; 77: 416-425
6. Turesky S, Gilmore ND, Glickman I: Reduced plaque formation by the chloromethyl analogue of vitamin C. *J Periodontol* 1970; 41: 41-43.
7. Loe H, Silness J: Periodontal disease in pregnancy, Prevalence and severity. *Acta Odontol Scand* 1963; 21: 533-551.
8. Mellonig JT: Autogenous and allogeneic bone grafts in periodontal therapy. *Crit Rev Oral Biol Med* 1992; 4:333-352.
9. Rummelhart JM, Mellonig JT, Gray JL, Towle HJ: A comparison of freeze-dried bone allograft and demineralized freeze-dried bone allograft in human periodontal osseous defects. *J Periodontol* 1989; 60: 655-63.
10. Borghetti A, Novakovitch G, Louise F, Simeone D, Fourel J: Cryopreserved cancellous bone allograft in periodontal intraosseous defects. *J Periodontol* 1993; 64: 128-132.
11. Caton JG, Greenstein G, Periodontal regeneration: current status and future direction, quintessence publishing Co Inc, Chicago 1994.
12. Isidor F, Karring T, Attström R: Reproducibility of pocket depth and attachment level measurements when using a flexible splint. *J Clin Periodontol* 1984; 11: 662-668.
13. Browning ES, Mealey BL, Mellonig JT: Evaluation of a mineralized cancellous bone allograft for the treatment of periodontal osseous defects: 6-month surgical reentry. *Int J Periodontics Restorative Dent* 2009; 29: 41-47.
14. Trombelli L, Heitz -Mayfield LJ, Needleman I, Moles D, Scabbia A: A systematic review of graft materials and biological agents for periodontal intraosseous defects. *J Clin Periodontol* 2002; 29: 117-135