COMPARATIVE EVALUATION OF DEMINERALIZED FREEZE-DRIED BONE ALLOGRAFT WITH AND WITHOUT CONCENTRATED GROWTH FACTORS MEMBRANE IN THE TREATMENT OF PERIODONTAL INTRABONY DEFECTS: A CLINICO-RADIOGRAPHIC STUDY.

Dissertation submitted to

Maharashtra University of Health Sciences, Nashik

in the Partial Fulfillment of Regulations

for the award of the Degree of

MDS

IN

PERIODONTICS

BRANCH II

2022

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LIST OF ABBREVIATION

SR NO	SHORT FORM	LONG FORM
1	PPD	Probing pocket depth
2	CAL	Clinical attachment level
3	AAP	American Academy of Periodontology
4	GTR	Guided Tissue Regeneration
5	TGFB 1	Transforming growth factors Beta 1
6	PDGF	Platelet-derived growth factors
7	EGF	Epethelial growth factors
8	IGF-1	Insulin Growth Factors
9	VEGF	Vascular endothelial growth factors
10	GF	Growth Factor
11	CGF	Concentrated Growth Factors
12	DFDBA	Decalcified freeze dried bone allograft
13	BMP	Bone morphogenic proteins
14	2D	Two Dimensional
15	3D	Three Dimensional
16	CBCT	Cone beam computed tomography
17	CGFM	Concentrated growth factor membrane
18	ES	Effective size
19	PI	Plaque index
20	GI	Gingival index
21	UNC-15	University of North Carolina-15
22	FGM	Free gingival margin
23	REC	RECESSION
24	CEJ	Cemento enamel junction
25	AC	Alveolar crest
26	BD	Bone defect depth
27	MD	Mesiodistal
28	BL	Buccolingual
29	HCL	Hydrochloride
30	RPM	Rotation per minute
31	RBC	Red blood cell
32	FOV	Field of view

33	DBM	Demineralized bone matrix
34	HPO	Human periosteal cells
35	ALP	Alkaline phosphatase
36	EMD	Enamel matrix derivative
37	FDBA	Freeze dried bone allograft
38	CT	Computed tomography
39	PD	Probing Depth
40	AM	Amnion Membrane
41	PRF	Platelet rich factor
42	PRP	Platelet rich plasma
43	CM	Chorion Membrane
44	PPD	Probing pocket depth
45	PPP	Platelet-poor plasma
46	AGF	Acelleuar Fibrin Glue
47	BPBM	Bovine porous bone mineral
48	ISQ	Implant stability quotient
49	TCP+HA	Tricalcium phosphate –hydroxyapatite bone graft
50	BOP	Bleeding on probing
51	MDI	Modified gingival index
52	RAL	Relative attachment level
53	PDL	Periodontal ligament
54	DD	Defect depth
55	BG	Bioactive Glass
56	IBD	Intrabony Periodontal defect
57	BI	Bleedind index
58	CBVT	Cone beam volumetric tomography
59	RVG	Radiovisiography
60	IOR	Intraoral radiography
61	HS	Highly significant
62	NS	Not Significant
63	S	Significant
64	SD	Standard deviation

INTRODUCTION

Periodontal diseases are multifactorial infections caused by a variety of bacteria that link with host tissues and cells, releasing wide range of inflammatory cytokines, chemokines, and mediators, some of which cause destruction of periodontal structures like tooth supporting tissues, bone, and periodontal ligament. The presence of complex bacterial biofilm that occupies the sulcular area/zone between the surface of the tooth and the gingival edge through specific attachment, interactions and accumulation owing to structural or anatomical changes in the sulcus is the cause for the onset of disease (i.e. attachment loss and pocket formation)[1].

Following the analysis and consensus conclusion of an International Workshop held in November 2017, a new classification of periodontal diseases and disorders was

announced in 2018[2]. The new classification, which includes the concept of staging, allows for a multidimensional picture of periodontitis, encompassing severity, tooth loss owing to periodontitis, and the complexity of managing a patient's periodontal and total oral rehabilitation needs.

Stage I periodontitis (mild disease): Individual will have probing pocket depth (PPD) ≤ 4mm, CAL ≤ 1-2mm, with mild horizontal bone loss, requiring only non-surgical therapy. There will be no post- treatment loss of teeth, indicating good prognosis and requires only maintenance.

Stage II periodontitis (moderate disease): Individual will have PPD ≤ 5mm, CAL ≤ 3-4mm, with horizontal bone loss, and can be managed by non-surgical or surgical therapy. There will be no post-treatment loss of teeth, indicating good prognosis and requires only maintenance.

Stage III periodontitis (severe disease): Individual will have PPD ≥ 6mm, CAL ≥ 5mm, with presence of either vertical bone loss or class II or III furcation involvement. This would necessarily require periodontal regenerative procedure. There is the possibility loss of 0-4 teeth. Also, the requirement of complex treatment and/or restorative may increase. The need of multi-specialty treatment approach also involve, which makes overall fair prognosis and should be kept on maintenance therapy.

Stage IV periodontitis (very severe disease): Individual will have PPD ≥ 6mm, CAL ≥ 5mm, with presence of either/ or both angular bone loss and/or class II or III furcation involvement. Less than twenty teeth may be present and potential of loss of five or more

teeth. It may require periodontal regenerative surgery, including hard and soft tissue augmentation therapy to aid in implant therapy. Also, the requirement of very complex treatment and/or restorative therapy may increase. The need of multi-specialty treatment approach also involves which leads to overall questionable prognosis and should be kept on maintenance therapy[2].

An intrabony defect, according to the American Academy of Periodontology's (AAP) glossary of terms, is defined as a "periodontal defect within the bone surrounded by one, two or three bony walls or a combination ofthese"[3].

Goldman and **Cohen's** criteria are commonly used to classify intrabony defects[4].

- One-wall intrabony defects: defects limited by one osseous wall and the toothsurface;
- Two-wall intrabony defects: defects limited by two osseous walls and the tooth surface; and
- Three-wall intrabony defects: defects limited by three osseous walls and the tooth surface.

Treatment of periodontal intrabony defects is a main therapeutic goal of periodontal treatment[5].The treatment of intrabony defect aids in the removal of subgingival biofilm and calculus as well as the establishment of an architecture that allows for effective plaque management and thereby avoids future attachment loss[6].In the course of periodontal history, various techniques have been put forward and promoted to treat intrabony defect. Although periodontal regenerative therapy showed a high degree

of increase in clinical attachment, decreased pocket probing depth, increase in radiographic bone height, and overall improvement in periodontal health[5].The ability to regenerate intrabony defect in a expected manner led to the invention of the concept of guided tissue regeneration (GTR), which suggested placement of a barrier membrane between the flap and graft material to prevent both gingival connective tissue and gingival epithelial cells from repopulating the defective bony surface during healing and allow cells from the periodontal ligament or the alveolar bone marrow to recolonise the wound area, thus inducing the formation of new cementum and a new connective tissue attachment. The necessity to exclude both the epithelial and connective tissue cells of the gingiva from the lesion area led to development and application of GTR membranes[6].

Periodontal regeneration has been proven to be efficient in the treatment of one-, two-, and three- wall intrabony defects, as well as combinations thereof, ranging from deep to shallow and broad to narrow[6]. In periodontal regenerative therapy morphology of defect play an important role in healing of intrabony defect. **Perichard** in 1957 reported that three-walled bony defects are seen in combination with one and two bony walls and that only a small percentage are classic three-walled bony defects. Shallow three-walled bony defects may be located in many areas, but only the deep defects are good candidates for bone regeneration[7]. **Chodrotf** and **Ammons** in 1984 presented some interesting findings regarding three walled bony defects. Their findings revealed that deeper defects demonstrate mere bone fill and also greater residual probing depths[8]. Periodontal regeneration using a variety of regenerative materials, including barrier membranes, grafts, active biological substances, and combinations of these, showed considerable

clinical improvements in intrabony defect, far above what could be obtained with only debridement[6].

Platelets have been proven to produce several growth factors that help with tissue regeneration. Platelets contain high amounts of growth factors, like transforming growth factor B-1 (TGFB 1), platelet-derived growth factor (PDGF), epithelial growth factor (EGF), insulin growth factor I (IGF-I), and vascular endothelial growth factors (VEGF), that also stimulate cellular proliferation and up regulate angiogenesis in order to accelerate bone graft healing over the bony defect[9].

The concentrated growth factor (CGF), which is the third generation of platelet concentrate product was first developed by **Sacco et al** in 2006, is a recently derived platelet concentrate. Due to variation in centrifugation protocol i.e. in the range of 2400-2700, the fibrin matrix becomes larger, denser, and more abundant of growth factors (GF) as compared to PRF. According to professor Rodella decreased viscosity, increased adhesive strength, higher amount of growth factors & increased tensile strength are the properties of CGF. So, to enhance soft tissue healing CGF can be used as amembrane[10].

Bone replacement grafts are a group of materials used for periodontal regeneration. One of the properties of an ideal bone replacement graft is it should have ability to stimulate osteogenesis[11]. However, most of them have been shown to work on the principles of osteoinduction and/or osteoconduction. Autografts, allografts, xenograft and alloplasts are commonly used bone graft materials, but amongst these only autogeneous bone grafts are actually osteogenic. Autografts harvested from cancellous

bone may contain viable cells forming fresh bone when implanted in a periodontal intrabony defect. However autografts are often criticized because of need for a second surgical site, absence of enough donor tissue or size of the bony defect. Pioneering work by **Urist** and **Strates** in 1960's demonstrated that demineralised bone has osteoinductive ability by stimulating bone formation in extraskeletal sites, and that, the osteoinductive ability of Demineralized freeze-dried bone allograft (DFDBA) is linked to the quantity of bone morphogenetic proteins (BMPs) that remain after demineralization processing has been completed[12]. The use of DFDBA has attracted a lot of interest during the last thirty years as one such material which may be capable of promoting regeneration of the attachment apparatus[11].

There are various methods for evaluation of new attachment and periodontal reconstruction. Evaluation of regenerative procedure is essential for the assessment of existing modalities, new modalities and also for the comparison of different methods of therapy. Histology, direct measurement of bone, periodontal probing and radiographic analysis are the approaches used for assessment for regenerative procedures. The most often used examination method is periodontal probing to measure the clinical consequences of regenerative procedures. Another assessment method for regeneration is the clinical attachment level measurements, relative to a landmark, such as the cementoenamel junction, a restoration, occlusal surface, or stent. Comparison of consecutive investigations allows the clinician or clinical researcher to find out whether particular regenerative technique shows improvement or not[13].

Histological examination of a sample of the graft is not a favored procedure owing to its intrusive process. Radiographs are frequently used to determine the degree and form of alveolar bone loss that impacts periodontal treatment planning. Conventional radiographs provide two dimensional (2D) radiographs that are inadequate for the recognition of intra-bony alveolar defect morphology. This is due to obstruction of spongious bone changes by cortical plate. So, three dimensional (3D) imaging is required for mapping of alveolar defects. Additionally, Cone beam computed tomography (CBCT) was suggestively more precise than digital intraoral radiographs when direct surgical measurements served as the gold standard for the assessment of intra-bony defects regenerative treatment outcomes. CBCT provides accurate measurements that are almost equivalent to direct surgical measurements thus replacing the surgical re-entry procedure[14].CBCT comprises a conically shaped X-ray source, focused at a region of interest, which sensitizes a 2-dimensional grid of image detectors. CBCT provides a number of advantages, including the capacity to observe structures in all three orthogonal planes and the removal of distortions[15].

So far, the literature search did not reveal any clinical study that has been carried out solely to check the efficacy of DFDBA along with Concentrated growth factor membrane (CGFM) in the intrabony defects. The preliminary results with DFDBA and CGFM when used individually appear to be satisfying in terms of regeneration of the periodontal structures, and so, it was felt that more research into this material in the therapy of intrabony defects is required. Also, CBCT is one of the latest methods of assessment of periodontal regeneration and there are very few studies that have used

CBCT for assessment of regeneration using CGFM. So, the present study was planned to evaluate and compare the efficacy of DFDBA alone and when used with CGFM in the treatment of intrabony defects clinically and radiographically by CBCT.

AIM AND OBJECTIVES

The study was aimed to evaluate and compare the efficacy of DFDBA alone and in combination with CGFM in the treatment of periodontal intrabony defects, clinically and radiographically by CBCT.

Also, attached to this aim were certain objectives:

1. To evaluate the efficacy of DFDBA alone in the treatment of periodontal intrabony defects clinically and radiographically by CBCT.

2. To evaluate the efficacy of DFDBA in combination with CGFM in the treatment of periodontal intrabony defects clinically and radiographically by CBCT.

3. To compare the efficacy of DFDBA alone and DFDBA in combination with CGFM in the treatment of periodontal intrabony defects clinically and

radiographically by CBCT.

4. To evaluate and compare the changes between the groups in Clinical attachment level and Periodontal pocket depth at baseline 3 months and 6 months.

5. To evaluate Bone Defect height, Bone defect width, Bone defect depth, and Bone defect volume at baseline and at 6 months radiographically using CBCT.

REVIEW OF LITERATURE

The goal of periodontal surgical techniques has been to regenerate hard and soft tissue deficiencies (such as probing depths and osseous deformities). This regeneration should ideally include new bone, cementum and periodontal ligament attachments to restore what has been lost owing to periodontal disease. A number of materials and regeneration methods have been used to achieve these goals. Bone grafts and bone replacement materials are used in several periodontal surgeries. The key to tissue regeneration is to trigger a series of healing activities that, when properly coordinated, can result in the production of fully integrated tissue. Like other treatments, it is not a cure for all individuals affected with periodontitis, however research has provided enough data to support the use of regenerative treatments in periodontology. Better understanding of the physiologic features of platelets in wound healing has led to greater therapeutic use

in various forms with variable results during the last two decades. Third generation platelet concentrate Concentrated growth factor membrane (CGFM), had shown beneficial results in terms of periodontal regeneration. Hence the efficacy of CGFM in combination with DFDBA graft was evaluated in this trial. The assessment of regeneration also presents a challenge. Radiographs give detailed information about the periodontium, but radiographs give a two-dimensional representation of three-dimensional structures and their limitations are well known. Complex anatomic structure, such as cortical plates of teeth may be superimposed on the region of interest. Furthermore, radiography cannot reveal the specific shape of periodontal defects such as hemiseptal defects, intrabony defects, or furcation involvements. 3D image analysis using CBCT was introduced and employed in this study to overcome the basic problems of traditional radiography.

For the ease of understanding, the review of literature has been segregated into four parts:

1. Review of studies on Bone grafts.
2. Review of studies on Concentrated growth factor membrane (CGFM).
3. Review of studies on the combination therapy (Bone graft +GTR).
4. Review of studies on the methods of analysis of regeneration.

1. Review of studies on Bone grafts.

Quintero G et al. (1982)[16] examined DFDBA's osteogenic potential in the therapy of periodontal osseous defect in a 6-month clinical trial. A total of 27 osseous defect were treated with cortical bone acquired from a human donor within 24 hours of death under sterile conditions, decalcified, freeze-dried, crushed, and sieved to particle sizes of 250 to 500 μm in 11 patients with one-, two-, or three-wall morphology. Clinical record measures were taken with a stent and graduated periodontal probing before surgery, during surgery, and at re-entry, and were complemented with radiographs and pictures after pre-surgery. The average bone fill of a one-wall, two-wall, and three-wall defect was 61 percent, 62 percent, and 73 percent, respectively. All osseous defects had a combined mean regeneration of 2.4 mm, or 65% defect fill. The authors concluded that the DFDBA has the ability of an osseous grafting material in treatment of periodontal osseous defect.

Fucini SE et al (1993)[17] suggested that the efficacy of periodontal grafting techniques might be improved by employing different DFDBA particle sizes, and evaluated the bony defect resolution obtained in 11 patients with intrabony defects using two distinct DFDBA particle size ranges. DFDBA graft material was produced from cortical bone of a single donor and processed into different particle sizes in 11 patients with paired interproximal intrabony defect. An electronic constant-force probe was used for initial soft and hard tissue measurements before the periodontal flap surgery and at re-entry after 6 months. Bony defect fill average was 1.66 mm seen with the big particle size group and 1.32 mm in the small particle size group, although the difference between the

groups was not seen statistically significant. As a result, particle size selection is a personal choice and is determined by the clinician's preference based on handling qualities.

Reynolds MA et al. (1996)[18] The fate of DFDBA employed for intrabony defect regeneration was studied histologically, and the new attachment apparatus creation, including component tissues, was compared to the presence or lack of residual graft material. To investigate the involvement of DFDBA in the creation of new attachment apparatus, histologic data from previous research was acquired. Intrabony abnormalities affecting 32 teeth in 12 individuals were treated with and without DFDBA and were late suggested for extraction in the current study. At 6 months, the teeth were extracted in their entirety and histologically examined. In histologic sections from 12 individuals with 32 grafted defects, residual DFDBA particles were found in 72 percent of the grafted lesions. The presence of DFDBA particles within the new viable bone was obvious. To examine the quantity of regeneration in relation to the presence or absence of residual graft material, data was taken from 14 sites (5 patients) treated with DFDBA graft material. Within-subject comparisons revealed that defects harbouring residual graft particles had considerably more new attachment apparatus creation, including new bone, cementum, and associated periodontal ligament. The nature of the new attachment apparatus and component tissues did not appear to differ, but the degree of production did. As a result, the study implies that inflammation and graft containment may be major determinants of DFDBA's destiny and regenerative response.

Zhang M et al. (1997)[19] agreed that the osteoinductive capability of demineralized bone matrix (DBM) is an important issue to evaluate before clinical application, thus they conducted an in vivo and in vitro investigation to develop a quantitative method for assessing DBM's osteoinductive potential. DBM was implanted into intramuscular and subcutaneous locations in 8-10 week old athymic mice for in vivo and in vitro testing. DBM was received from fourteen cadaveric donors. For the in vivo assay, 82 athymic mice (2 implants in one mouse) were employed, which were then euthanized at the specified time period. The calcium content of explants was measured and as an indicator of new bone growth, the difference in "weight percent calcium" in the explant against "weight percent calcium" in the implanted material is represented as a percentage change. DBM had a calcium level of 0.5 ± 0.048 weight % before implantation. Muscle implantation yielded a higher calcium content increase than subcutaneous implantation. Between weeks 1 to 4, there was no statistical difference in the weight of explanted and implanted material; but, by week 5, the explant weight began to rise. In the in vivo assay, week 4 was identified as the best time for explantation since appropriate calcium levels had been established and an increase in a linear pattern had been detected after 5 weeks. Dose response curves with DBM disclosed that the 20 mg dose produced the most activity. Human periosteal (HPO) cells were selected for the DBM in vitro bioassay. The activity of the enzyme alkaline phosphatase (ALP) was thought to be an indicator of osteoblast induction, reaching its peak on 5^{th} day of DBM therapy. The dose response studies for the in vitro assay revealed that amounts ranging from 5 to 10 mg DBM provided the highest levels of alkaline phosphatase in cell extracts. A liner correlation

(R2 = 0.7397) was found between both the in vivo calcium remineralization assay and the in vitro alkaline phosphatase assay of DBM osteoinductivity. As a result, it is possible that the in vitro assay may be a better substitute for the in vivo assay in determining DBM's osteoinductive ability.

Grunisky BS et al. (2004)[20] In a study, compared the use of combination of DFDBA and Enamel matrix derivative (EMD) [EMD + DFDBA] with EMD alone in the therapy of human intrabony abnormalities. A total of forty patients were chosen, with 67 intrabony defects of less than 3 mm. The EMD was used alone on 20 patients with 34 sites, and EMD and DFDBA were used together on 20 patients with 33 sites. At baseline and 6 months after re-entry surgery, the UNC 15 probe was used to take all clinical soft and hard tissue measurements. PD, CAL, and recession (REC) are soft tissue parameters, while defect depth, alveolar crestal resorption, and defect wall morphology are hard tissue metrics. He found that soft tissue recovery was excellent in both groups, with no problems. The locations treated with EMD alone had a probing depth reduction of 4.0 ± 0.3 mm and gain in CAL 3.2 ± 0.3 mm. The sites that received combination therapy had a PD reduction of 3.6 ± 0.2 mm and a CAL gain of 3.0 ± 0.3 mm. Both therapy groups showed considerable improvement in soft tissue measurements at 6 months, although the difference between both the groups was not seen statistically significant. The EMD + DFDBA group had a mean bone fill of 74.9%, while the EMD alone group had a mean bone fill of 55.3%. When compared to EMD alone, the combined therapy resulted in a 50 percent to 90 percent increase in bone fill. As a result, using EMD in conjunction with DFDBA may improve hard tissue characteristics.

Gajiwala AL et al. (2006)[21] evaluated the osteogenic potential of DFDBA in the therapy of human periapical osseous lesions associated with devitalized teeth using clinical and radiographic methods. Tata Memorial Hospital Tissue Bank was the first in India to prepare the DFDBA in-house. DFDBA was implanted in periapical osseous deficiencies in 10 healthy patients after periapical lesions associated with devitalized teeth were removed. All of the patients had clinical and radiographic measurements taken. The osseous fill of the radiolucent periapical defects was assessed with IOPA before and after surgery. Any of the patients who received treatment showed no evidence of post-operative infection or problems. At the 6-month mark, all of the patients had experienced a significant reduction in mobility grades, and 9 of the 10 patients had experienced more than 50% mineralization of periapical osseous defects, which was validated radiographically by evidence of normal bone trabeculae. The results show that DFDBA is a low-cost, biocompatible material with osteogenic ability that can be used to cure osseous abnormalities.

Wood RA et al. (2012)[12] compared the proportion of new bone development in the healing of non-molar extraction sockets grafted with freeze dried bone allograft (FDBA) to DFDBA for ridge preservation in a histological investigation and also compared changes in dimensions of ridge i.e. height & width by using these 2 allograft materials. A maximum of forty individuals were split into 2 groups of twenty, each with FDBA or DFDBA extraction sockets. Bone graft material came from a single donor, pulverised to a particle size of 250–750 m, and DFDBA demineralized to residual calcium of 3.3 percent. The sole difference between the two materials was the percent calcification of

the resultant bone graft. At 19 weeks after grafting, a trephine drill was utilised to take a core biopsy out of each transplanted area. A total of 32 biopsies (16 from each group) were histologically evaluated to assess the percentage of viable bone, residual graft particles, connective tissue, and other non-bone components. When comparing changes in alveolar ridge dimensions and percentage CT/other between groups, there were no significant differences. DFDBA-treated sites had a considerably higher proportion of vital bone (38.42%) than FDBA-treated sites (24.63%) and a lower percentage of residual graft particles (8.88%) than FDBA-treated sites (25.42%). This study was the first to compare the healing of ridge preservation with DFDBA with FDBA in humans, and it found that DFDBA resulted in much more fresh bone production and less residual graft particles than FDBA.

Ogihara S et al. (2014)[22] conducted a study to verify the relative potency of EMD/FDBA aganist EMD/DFDBA in therapy of infrabony defect. A total of 69 patients with no more than one intrabony defect were randomly categorized into three groups: EMD/FDBA (EF), EMD/DFDBA (ED), or EMD alone (E), with no defects in all three groups (n=23). Minocycline (10 mg/ml) was added to the FDBA or DFDBA-containing composite graft material. Clinical measurements were taken at the start, one year, and three years thereafter. From baseline, all groups a significant reduction in PD and an increase in CAL was seen. At one year and three years, the EF and ED groups outperformed the control group in terms of treatment outcomes. At one year and three years, there were no statistically significant differences between the EF and ED groups. In addition, all of the groups had substantial radiographic Bone Gain at baseline, but there were no statistically

significant variations between the groups between 1 and 3 years. When compared to the E group alone, both the EF and ED groups improved soft tissue after 1 and 3 years. As a result, it is clear that when paired with EMD, both graft materials improve soft tissue and hard tissue, and are a better option for treating deep intrabony abnormalities.

Sali DD. (2016)[23] examined the potency of Amnion membrane (AM) in combination with DFDBA in the treatment of periodontal intrabony defects. 10 individuals with bilateral similar intrabony defects were included in the study and the defects were randomly categories into 2 groups 10 defects in each group. In control group DFDBA was placed and in test group DFDBA and AM was placed in the defects. Clinical and radiographic parameters were evaluated at baseline 3, 6, 9 and at 12 months post-operatively. Both the groups showed significant improvement from baseline, but there was no significant difference was seen between both the groups suggesting that there was no beneficial effect of AM on DFDBA.

Agarwal A et al. (2016)[24] did a study to see if PRF had the ability to regenerate periodontal tissues. The goal of the study was to test the additive effects of PRF and DFDBA in the treatment of periodontal intrabony defects in a randomised, split mouth clinical experiment. The study included a total of 60 interproximal intrabony defects in 30 non-smoker healthy participants with chronic periodontitis. They were assigned to one of two groups: PRF/DFDBA or DFDBA/saline. At baseline and at 12 month clinical and radiographic measurements were taken. When the baseline and 12-month outcomes were compared, it was discovered that both treatment modalities resulted in significant changes in all clinical and radiographic parameters. However, the PRP/DFDBA group showed

statistically significant improvements in PD, CAL, REC, bone fill and defect resolution when compared to the DFDBA/saline group. The findings of this study show that combining PRF with DFDBA is more successful than using DFDBA alone to address infrabony periodontal problems.

Pajnigara NG et al. (2017)[25] evaluated volumetric changes to assess the regenerative efficacy of DFDBA with and without Amion membrane (AM) in Grade II furcation defects both clinically and radiographically using CBCT. A total of 20 patients exhibiting at least 1 pair of bilateral Grade II furcation defects were randomly assigned to Group I (DFDBA) and Group II (DFDBA + AM). All the clinical parameters such as PPD, CAL, GR, and horizontal PD were recorded at baseline, 3 months, and 6 months. Radiographic assessment included measurements of the defect height, width, depth, and volume at baseline and 6 months postoperatively. On statistical analysis, defects treated with DFDBA + AM resulted in significant improvement in clinical and radiographic parameters when compared with DFDBA alone. The study suggests combination therapy of DFDBA in conjunction with membrane (AM) results in greater the reduction in defect volume indicating greater amount of healed regenerated tissue.

Shah K et al.(2018)[11] evaluated volumetric changes to assess the regenerative efficacy of DFDBA with and without Chorion membrane (CM) in Grade II furcation defects both clinically and radiographically using CBCT. A total of 20 patients exhibiting at least 1 pair of bilateral Grade II furcation defects were randomly assigned to Group I (DFDBA) and Group II (DFDBA + CM). All the clinical parameters such as PPD, CAL, GR, and horizontal PD were recorded at baseline, 3 months, and 6 months. Radiographic

assessment included measurements of the defect height, width, depth, and volume at baseline and 6 months postoperatively. On statistical analysis, defects treated with DFDBA + CM resulted in significant improvement in clinical and radiographic parameters when compared with DFDBA alone. The study suggests combination therapy of DFDBA in conjunction with CM results in greater the reduction in defect volume indicating greater amount of healed regenerated tissue.

Kothiwale S et al. (**2019)**[26] to evaluate and compare the effectiveness of demineralized freeze dried blockgraft and freeze dried block graft with chorion membrane (CM) as barrier membrane. Nine systemically healthy patients (6 mens, 3 womens) with radiographic evidence of angular bone defects in maxillary or mandibular molar tooth with PPD more than 6 mm were included in the study. In 9 patients, from each patients 2 sites from posterior region were randomly divided into group 1 (FDBA plus CM) and group 2 (DFDBA plus CM). After completion of debridement, during periodontal surgery with a sterile divider measurement of defects were carried out and block graft was contoured accurately for adjustment to the defect site. The graft on defect site was covered with CM entirely in both the groups. Clinical parameters PI, GI, PPD and CAL and radiographs were measured at baseline and at 12 month. At 12 month of periodontal surgery both the groups shows similar results in terms of clinical parameters and radiographs.

Saini K A et al.(2020)[27] did a study to examine the effect of decortications with grafting

DFDBA in the treatment of intrabony defect. Total Forty defects in forty individuals were randomly categories into test and control group. In test group before placing DFDBA decortications was done after reflecting the flap in intrabony site, whereas in control group only graft was placed without decortications on site. Clinical measures PPD, CAL, and bone fill were evaluated at baseline, 6 months, and 9 months after surgery. Both the groups had better clinical outcome from baseline but the results after 9 months showed that PPD and CAL gain in test site was significantly better than the control group. Similarly, the radiographic measures showed better percentage bone fill and linear growth in test group compared to control group concluding that decortications at the defect site increases the healing ability and has a benefit on grafting.

2. Review of studies on CGFM.

Sohn DS in 2009[10] did a case report in which he explained 3 cases, first case was of replacement of missing teeth along with sinus augmentation. In that case after the elevation of the sinus membrane, a piece of CGF was placed under the raised sinus membrane whereas after placement of an implant and bone graft the other was used as a barrier membrane over the graft after preparing 2 pieces of CGF. Desired sinus augmentation was achieved with the use of CGF alone. The second case was a male patient with severe alveolar bone resorption. The defect was filled with a mixture of CGF and allograft over which the CGF barrier membrane was used. It was found that there was a reduction of pocket by 5mm. Third case presented with a complaint of missing teeth. Implants were placed at the site with grafting of bone which was mixed with CGF

and covered by concentrated growth factor as a barrier membrane Implants were exposed after 12 weeks which showed an excellent bone gain. The results say that growth factors play a major role in the regeneration and/or repair of injured tissue. Blood platelets and plasma contains a massive amount of growth factors. Hence it can be concluded that CGF can be used as a substitute for bone for regeneration which is inexpensive and can be easily prepared. It can also be used in sinus augmentation and can be used to reduce healing time and post-operative pain and discomfort.

Rodella LF et al (2011)[28] did a study to examine the presence of some important growth factors (TGF-b1 and VEGF) involved in tissue regeneration and measure their levels in PPP and RBC layers. From the six individuals' venous blood is collected and immediately centrifuged to form CGF. SEM analysis of CGF revealed that the fibrin network is made up of thin and thick fibrillar elements. Multiple platelet cell essentials were found trapped within the fibrin network, forming a cell aggregate. Immunostaining in both fractions that is CGF and RBC layer suggestive of TGF-b1 and VEGF expression. The quantitative analyses using integrated optical dentistry measurements revealed a similar level of TGF-b1 and VEGF in the CGF and RBC layers. The immune histochemical method was used to assess CD34 positive cells, and the findings revealed the presence of CD34 positive cells in CGF and RBC layers. Hence it was concluded that TGF-B1 and VEGF are found in both the CGF and RBC layers, implying that a better procedure could optimize the number of growth factors in the CGF layer, or that the RBC layer could be used instead of the CGF layer in clinical applications. Furthermore, the presence of CD34 positive cells within the CGF network may prompt further research

into their clinical implications.

Dong-Seok Sohn [29]did a case report in the year **2015** to discuss how to prepare and use CGF, as well as clinical examples that support their use. They performed simple and predictable ridge and sinus augmentation techniques using CGF membrane and growth factor enriched bone graft matrix. Case report 1: Comparison of Collagen Membrane and CGF Membrane. The patient wanted implant-supported fixed restoration for replacement of missing teeth 7, 8, 9, 10. Along with implant placement bone graft mixed in exudate released from CGF placed which was covered by collagen membrane on the right side whereas 2 CGF membranes on the left side. After a 6-month healing period, on surgical re-entry both augmented sites displayed favorable ridge augmentation. Bone biopsy was performed with the help of a 2mm diameter trephine bur for comparison between collagen membrane and CGF membrane. On H&E examination under light microscope bone, both specimens show good fresh bone formation along with the mineral allograft with no signs of inflammation.

Case 2: A 45-year-old patient required three-dimensional ridge augmentation. On radiographic and clinical examinations, it was found that the right mandibular edentulous ridge had severe vertical and horizontal ridge resorption and the left mandibular edentulous ridge had severe horizontal ridge deficiency. It was done using sticky bone which was prepared by mixing Acellular Fibrin Glue (AFG) and bone particulate and waiting for 5-10 min for polymerization. On the right side ridge after implant placement, the exposed area was packed with sticky bone and covered by collagen membrane whereas on the left side ridge the exposed implant area was covered by particulate graft,

and over that titanium mesh and CGF membranes were placed. Favorable ridge augmentation was found on the right and left sides. In the third case, the CGF membranes were used in the upper right region for sinus augmentation. This case report concluded that CGF and sticky bone can be helpful in surgeries of edentulous alveolar ridge reconstruction.

Qiao et al (2016)[30] did a study to examine the role of CGF in periodontal intrabony defect. 17 patients having PPD of ≥6 mm and radiographic evidence with more than 3 mm of intrabony defect were selected for the study. In total 31 defects were randomly categorised as 15 defects in test group and 16 in control group. During the surgery, CGF and Bovine porous bone mineral particles (BPBM) were inserted in test group defect site where as in control group site only BPBM was placed. Clinical parameters plaque index, bleeding index, PD, REC and CAL and radiographic parameters were measured before surgery and after 1 year of treatment. And also content of CGF was evaluated in comparison to platelet poor plasma. There was no significant result seen between both the groups but the data showed favorable outcome from test group than control and also the levels of various growth factors in CGFs were seen higher than that in platelet poor plasma with significant p value <0.001.

Pirpir C et al. (2017)[31] did a study to examine the effect of CGF membrane on implant stability and osseointegration. Total of 40 implants were placed in 12 patients having edentulous maxillary front region were selected for study .In study group 20 implant prepared site walls were filled with CGF membranes before implant insertion and in control group 20 conventional implant was placed. The implant stability quotient (ISQ)

scores of the implants were evaluated immediately after insertion of implant, at the 1st and at the 4th week after the insertion. In study group implants ISQ value at different time duration was significantly higher than the control group. The data suggest that CGF strengthen the implants by increasing its stability and also favors osseointegration.

Bernardi S et al. in (2017)[32] performed a study to investigate the histological aspects of a CGF membrane. 2 CGF blocks were prepared from blood. Haematoxylin-eosin and Azan Mallory staining were done with both samples. The morphological characteristics of CGF clots were highlighted in histological slides which show a membrane made up of three concentric layers. The first layer is distinguished by a network of plasmatic proteins containing cells devoid of nuclei and resembling erythrocytes. These cells appear directed towards the second layer. The second layer shows more cellular elements are entrapped by the fibrin network and there are circular bodies-blue stained – that are probably collagen fibers entrapping other corpuscular elements. The third layer was stained blue which indicated collagen fibers presence and it appears to have a larger network as compared to the second layer. Furthermore, there are corpuscular elements in the network with the absence of a nucleus and are smaller than red blood cells, such as platelets. The CGF on histological analysis shows entrapped platelets, leukocytes, and consequently growth factors that provide a scaffold for migration of cells like fibroblast and endothelial cells involved in angiogenesis and tissue remodeling.

Xu Y et al. (2019)[33] examined the effects of CGF in combination with bone graft substitute and CGF alone in the treatment of intrabony defects. Total 120 one walled intrabony defects were randomly categories into 4 groups. In group 1 only open flap

debridement was done, in group 2, after debridement CGF was placed, in group 3 bone graft Bio-Oss was placed and in group 4 CGF plus Bio-Oss was placed. Clinical measures were evaluated at baseline, 6 and 12 months after surgery. After 12 months, the results of clinical measures in group 3 and 4 were significantly better than group 1 and 2. The author concluded that the addition of CGF with bone graft (Bio-oss) significantly improves the bone regenerative ability of bone graft.

Amr A. Ellithy et.al. 2021[9], clinically evaluated and compared the potency of PRF and CGF with synthetic bone graft material β-tri calcium phosphate and hydroxyapatite bone graft (β-TCP+HA) in the treatment of periodontal intrabony defects. 20 individuals with intrabony defect were included in study and were randomly divided into CGF+ (β-TCP+HA) (group I) and PRF+ (β-TCP+HA) (group II). Clinical parameters PI, BOP, PPD, and CAL were assessed at baseline, 3 month and after 6 month of surgery and CBCT parameters bone level and bone density were measured at baseline and at 6 months post-operatively. Both groups exhibited significant results in clinical measures after 3 and 6 months post-surgical in comparison to baseline. In addition, CBCT examination of radiographic data revealed substantial improvements in bone growth and density in both groups. In group I the decrease in Vertical Depth of defect (VD) was seen statistically significant in comparison with group II at 6 month post-operatively. In comparison to PRF and bone graft, the author found that adding CGF to bone graft improved clinical and radiographic results.

Vaid T et al 2021[34] did a study to compare the combination effect of DFDBA and CGF with only CGF in the treatment of intrabony defect. Total 10 individuals with 2 comparable bilateral intrabony defects were included in the study. Each pair of defects was randomly treated by DFDBA + CGF or CGF alone. Clinical measures PI, modified gingival index (MDI), PPD, and relative attachment level (RAL) were evaluated at baseline 3 months and 6 months and also radiographic measures before surgery and after 6 months were evaluated. In both the group the clinical measures showed better results after 6 month from baseline but there was no significant difference seen between both the groups. From the results the author concluded that the addition of DFDBA to CGF has no additional benefit.

3. Review of studies of Guided tissue regeneration.

Nyman S et al. (1982)[35]undertook a study to check whether new cementum and attachment would form during wound healing if periodontal ligament (PDL) cells were given precedence to repopulate the wound area close to the root that had been surgically deprived of its PDL and cementum layer. The study experiment was conducted on three adult monkeys wherein a Millipore filter was placed on maxillary lateral incisors and mandibular canines. After the reflection of mucoperiosteal flap and removal of approximal levels of alveolar bone, notches were prepared along root surface for demarcation and Millipore membrane was placed. After repositioning the flap, the jaws were removed after 6 months for histological sections. On the curetted root surfaces of all specimens, new cementum with collagen fibres was detected, and the newly created

cementum was thicker in the apical section than at the coronal level. Connective tissue adhesion to the root surface without evidence of cementum production or fibrous attachment was common in the coronal stage of the healing process. The limited ability of bone cells to enter the incision adjacent to the roots can thus explain the considerable cementum production, including fibrous attachment and absence of symptoms of ankylosis found in the current material. The findings show that the PDL cells' ability to repopulate the curetted root surfaces was aided by the design of the surgically treated wound and the ability of the PDL cells.

Bansal et al. (2013)[36] clinically evaluated and compared the potency of autologous PRF with DFDBA and only DFDBA in the treatment of periodontal intrabony defects. Ten patients having bilateral intrabony defect and having PPD of at least 6 mm were selected for the study. Defect sites were randomly divided intoGroup I and Group II. In Group I DFDBA Graft was placed at defect site were as in Group II DFDBA plus PRF is placed. Clinical parameters PPD, REC, and CAL were measured at baseline, 3 months and after 6 months of surgery and radiographic pararmeter were measured at baseline and at 6 months post-operatively. Both groups showed similar results in clinical parameters and radiographically. But, there was a significantly greater PPD reduction and CAL gain when PRF was placed with DFDBA. Authors indicated that a combination of PRF and DFDBA demonstrated better results in PPD reduction and CAL gain as compared to DFDBA alone in the treatment of periodontal intrabony defects.

Kher VK et al.(2013)[37] compared the effectiveness of collagen membrane with and without DFDBA in the treatment of infrabony defects.20 periodontal intrabony defects in

16 systemically healthy patients were randomly categorized equally into test and control group. In control group a bioabsorbable collagen (type I and III) membrane of porcine origin, was placed while in the test group combination of a bioabsorbable collagen and DFDBA was placed. Selection criteria of patient was at least presence of greater than 5 mm clinical PPD at the selected site and depth of intrabony defect ≥ 3 mm as appraised by clinical and radiographic measurements. At baseline, 3 month and at 6 month post surgery clinical parameters were measured which include plaque index, papillary bleeding index, and PPD, gingival recession, CAL and radiographic defect depth (DD) were measured only at baseline and at 6 month. After 6 month of surgery, there was significant difference seen in PPD reduction in the test group which was greater in comparison to the control group. Similarly, Radiographic DD reduction was greater in the test group as compared to control group. GTR application with bioabsorbable collagen membrane and DFDBA showed better results than bioabsorbable collagen membrane alone in periodontal intrabony defect.

Shah R et al 2014[38] provided a case study to highlight the utility and promise of DFDBA in the treatment of ridge preservation when combined with human CM. Due to a failed endodontic treatment, a 22-year-old male patient with a history of root canal treatment and Grade II mobility underwent tooth extraction. GTR used DFDBA in concert with the human CM to manage a missing buccal wall of socket discovered after extraction. The soft tissue appeared healthy at 6 months, however there was a modest reduction in tissue height (0.36 mm) and tissue width (2.04 mm). When compared to pre-operative gingiva thickness (0.93 mm), there was an increase in post-operative gingiva thickness (0.93 mm)

(0.76 mm).On post-operative radiographic assessment, there was no loss of bone height. The instance shows that using DFDBA in conjunction with human CM was helpful in reducing soft/hard tissue loss while also allowing for some tissue growth.

Agarwal P et al 2016[39] compared the effectiveness of PRP with and without DFDBAin the treatment of infrabony defects.28 periodontal intrabony defects in 10 systemically healthy patients were randomly categorized into 3 groups 10 sites were treated with PRP alone (test group A), 9 sites combination therapy of PRP + DFDBA (test group B) and 9 sites with OFD alone (control group C). Clinical parameters included PI, GI, PD, and CAL, and radiographic parameters were measured at baseline and 12 months postoperatively. Mean PD reduction and CAL gain were greater in test group A and in test group B than the control group C.The amount of defect depth reduction and defect resolution treated with PRP alone group were significantly less than PRP + DFDBA. The results pertaining to these parameters were significantly better than the control group.

Bodhare et al. (2019)[40] did a study to examine and compare the combination of Bioactive Glass (BG) with PRF and only PRF in the treatment of periodontal intrabony defect. Total 20 chronic periodontitis individuals having at least one pair of bilateral intrabony defect were selected for study. 40 sites from 20 individuals were equally divided into 2 groups. Group 1 was treated with a combination of BG and PRF and group 2 were treated with BG only. Clinical parameters were evaluated at baseline 3 months and 6 months and radiographic measures were evaluated at baseline and at 6 months. After 6 months both the groups showed significant PPD reduction whereas the CAL gain and bone fill in group 1 was more than group 2. Authors concluded that the combination

of BG and PRF was more effective in the therapy outcome in intrabony defect.

Lei L et al 2020[41] conducted a study to compare the level of growth factors releasing from A-PRF and CGF, and to evaluate their clinical efficacy in the regenerative management of intrabony defects. Thirty-two blood samples were collected from 8 healthy donors and assessed for PDGF-AB, VEGF, BMP-2 and TGF-β1 release at indicated times. In addition, the clinical records of forty-five patients (15 per group) who had undergone guided tissue regeneration (GTR) with or without A-PRF/CGF were retrieved. Clinical parameters were evaluated at baseline, 3 and 6 months after the surgery and radiographs were evaluated at baseline and at 6 months. After the 6 months of evaluation it was found that A-PRF had a looser fibrin network than the CGF but presented larger amounts of growth factors with a more sustained release period. Although there was no difference in PPD reduction, CAL gain, RBL height change and defect filling (%) between A-PRF and CGF group, both achieved a more favorable clinical result in IC height reduction and defect filling (%) than the control. A-PRF and CGF have the ability to stimulate a continual and steady release of total growth factors over a 14-day period. A-PRF and CGF show a similar effectiveness in periodontal bone regeneration with a potential benefit of improving GTR outcomes in IBD treatment.

Liu K et al in **2021**[42] checked the regenerative effect of GTR by using Bovine porous bone mineral (BPBM), and PRF in intrabony defects. Total 65 intrabony defects of 14 individuals were selected and equally categories into 2 groups test and control. Test group received BPBM and PRF in liquid form whereas the Control group received only PRF. Clinical parameters PD, CAL, Bleeding index were measured at baseline, 6, 12,

and 24 months and radiographs were evaluated at baseline, 12 and 24 month after the surgery. PD was seen significantly less in test group than in control group after 12 and 24 months of surgery. Similarly CAL gain results in test group were better in control group at 6 months. It was concluded that the GTR combination of BPBM-PRF complex has better clinical outcomes than PRF alone.

4. Review of studies on the methods of analysis of regeneration.

Misch KA et al (2006)[43] compared CBCT measures of periodontal abnormalities to traditional techniques. On the mandibles of dry skulls, artificial osseous deformities were generated. An electronic calliper was employed as a standard reference for CBCT scanning, periapical radiography, and direct measurements using a periodontal probe. There were no significant differences in linear measures for any faults between bone sounds, radiography, and CBCT. When comparing isolated interproximal measures with a probe with a calliper (P 0.001), there was a significant difference, but not when comparing CBCT or radiography. Directly or with CBCT, all bone abnormalities were visible and quantified. Buccal and lingual deficiencies, on the other hand, could not be measured with radiography. All three techniques are effective in detecting interproximal periodontal abnormalities. The three-dimensional capacity of CBCT provides a substantial advantage over radiography since all abnormalities may be spotted and measured.

Grimard BA et al (2009)[44] analyzed the difference between the measures obtained from

digital intraoral radiographs and cone-beam volumetric tomography (CBVT) images to direct surgical measures for the assessment of regenerative therapy effect. For 35 intrabony deficiencies, digital intraoral radiographs and CBVT pictures were collected before to first bone grafting and after 6 months of surgery. A periodontal probe was used to measure the defects after they had been debrided. Measurements were taken on radiographs and CBVT pictures in the same way, and the results were compared to the direct surgical measures. CBVT had a good correlation with surgical measures, although intraoral radiographs had a less correlation. Intraoral radiograph measurements were significantly less accurate than CBVT for all parameters studied, and surgical values were underestimated by 0.6 2.3mm to 1.5 2.3mm. Between CBVT and surgical measurements, there was no substantial difference in the distance from the cementoenamel junction to the alveolar crest, defect fill, or defect resolution. CBVT was substantially more precise and accurate than intraoral radiography when compared to direct surgical measurements. According to the findings, CBVT may be able to replace surgical reentry as a method of evaluating regenerative therapy effect.

de Faria Vasconcelos et al (2012)[45] by comparing linear measures of the height, depth, and breadth of the defects, as well as recognizing combined bone defects in tomographic images, researchers examined periapical radiographs with CBCT in diagnosing and localising alveolar bone loss. The images were from a separate database of individuals who had been referred for periodontal examination. There were 51 sites in study showing both horizontal and vertical bone loss, analysed by three experienced examiners. The findings revealed that there were no statistically significant differences in the detection of

the pattern of bone loss between the imaging modalities. When the distance between the cement-enamel junction and the alveolar crest (CEJ-AC) was measured, however, there were variations between the two approaches. The two approaches detect the height of the alveolar bone crest differently, although the depth and breadth of bone abnormalities are identical. The only technology that allowed for a thorough examination of the buccal and lingual/palatal surfaces, as well as greater visibility of the defect's morphology, was CBCT.

Pahwa et al. (2014)[46] compared the diagnostic values of RVG and CT images in comparison with direct surgical measurements for the determination of periodontal bone loss. Fifteen patients including10 female and 5 male with the age range 20 to 54 years participated in the study. The inclusion criteria were generalized moderate to severe CP patients and at minimum one inter proximal site with a minimum of 3 mm of CAL. Each defect was the unit of analysis in the present study. Total 31 angular defects were selected for direct measurements using a periodontal probe during surgery. At the beginning of the study, the patients were subjected to a baseline examination during which the PPD and CAL were assessed. RVG and CT images were taken preoperatively. Similar measures were evaluated on RVG and CT and compared with the direct surgical measures. Measurements included determination of alveolar bone level that is, CEJ-BD and CEJ-AC. Infrabony component was measured by subtracting CEJ-AC from CEJ-BD. Intra class correlation of CT scan was maximum with the smallest length of 95% confidence interval. The CT scan revealed the highest level of agreement with the surgical value. CT scan outperformed RVG in assessing osseous abnormalities, resulting in more accurate

and therapeutically usable pictures of osseous defects that were closer towards the gold standard.

Banodkar A et al (2015)[47] by evaluating CBCT measures of alveolar bone abnormalities induced by periodontal disease to actual surgical measurements, they were able to determine the precision of CBCT measurements. The research comprised a total of a hundred periodontal bone abnormalities in 15 individuals with periodontitis who were planned for flap surgery. Prior to anaesthesia, a CBCT of the region to be operated on was obtained on the day of operation. A reamer and a digital vernier calliper were used to take clinical measures of the periodontal defect after the flap was reflected. The defect depth was calculated as the distance between the CEJ and the alveolar crest in the case of horizontal defects. The defect depth was calculated as the distance between the CEJ and the defect's base in the case of angular defects. Clinical measures and CBCT measures showed similar trends. The measures collected during surgery were compared to the CBCT measurements and statistical analysis was performed using the Pearson's correlation test. Overall, the surgical and CBCT data had a very good correlation of 0.988. When it came to defect types, horizontal defects had a greater correlation than vertical defects. CBCT is a very important technique in periodontal diagnostic and therapy evaluation because it is very accurate in measuring periodontal abnormalities.

Chhabra A et al (2016)[48] conducted a prospective cross sectional study to determine the accuracy of CBCT in quantifying intra-osseous periodontal bone defects. 5 patients with intra-bony defects were selected and 10 defects were assessed. A total of 60 measurements were performed. Periapical radiographs and Cone beam CT scan images

were obtained. Height and depth of each defects was measured using appropriate software. Direct measurements were done during surgical interventions using a periodontal probe and were considered the standard reference. Measurements made by all three modalities were compared to each other. Linear measurements for all defects revealed no statistical differences between CBCT and direct intra-surgical measurements with respect to the height as well as the depth of the defect. There wasa significant difference when comparing peri-apical radiographs to the other two methods. IOPA measurements were only 74.3% accurate as compared to the standard intra-surgical whereas the CBCT measurements were 86.5%. All three modalities proved to be useful for identifying interproximal periodontal defect but CBCT took the lead with better accuracy in reproducing the clinical measurement of intra-bony periodontal bone defects and better visualization of the extent of the defect.

Guo YJ et al (2016)[49] assessed periodontal bone loss in CBCT images by 6 site method. Total 150 measuring points in 11 molars and 14 premolars from 6 patients i.e. 2 males and 4 females were included. Prior to periodontal surgery CBCT images of the teeth were acquired. Four observers evaluated the distances between CEJ-BD at the mesio–buccal, mid-buccal, disto-buccal, mesio-lingual/palatal, midlingual/palatal and disto–lingual/palatal sites in CBCT images. Direct surgical measurements of the six sites were obtained during periodontal surgeries. Difference between the values of distances measured in the CBCT images and direct surgical measurements were checked. Interobserver and intraobserver differences were tested. Results showed that no statistically significant difference was found between the surgical and CBCT

measurements. Diagnostic similarity rates of four observers were 86.7%, 87.3%, 88.7% and 88.0%, respectively. The interobserver and intraobserver variances were not statistically significant. Study concluded that the six-site measuring method implicated in study may be a useful 3-dimensional method for evaluation of periodontal defect.

Suphanantachat S et al. (2017)[50] evaluatedand compared clinical values by CBCT and conventional intraoral radiography (IOR) in IBD assessment. The study included 25 patients suffering from periodontitis and presented at least two IBDs. All patients received clinical periodontal examination, IOR and CBCT. Three periodontists checked periodontal diagnosis and prognosis of each tooth. For teeth with presence of infrabony defects, the number of defect walls was determined. IOR and CBCT assessment was compared. There were total 666 teeth and 123 infrabony defects. The overall value similarity between IOR and CBCT for periodontal diagnosis, prognosis, infrabony defect type and infrabony defect treatment were 79.3%, 69.5%, 44.7% and 64.2%, respectively. Diagnosis, prognosis and the number of infrabony defect walls were underestimated by IOR at 16.4%, 24% and 37.4%, respectively. CBCT showed admirable interexaminer agreement and greater percentage of complete agreement among examiners than IOR for all assessments. IOR underrated the severity and prognosis of periodontal disease. CBCT was finer to IOR for valuation of infrabony defect morphology and treatment. The study concluded that CBCT provides excellent agreement among examiners on IBD assessment and hence is a reliable method to measure them.

Pajnigara N et al. (2017)[51] evaluated the dimensions of 200 Grade II furcation defects clinically (pre-and post-surgery), intra-surgically, and by CBCT (pre and post-surgery) in

forty patients, diagnosed with chronic periodontitis. After the pre surgical clinical and CBCT measurements, DFDBA was placed in the furcation defect. Six months later, these defects were evaluated by recording measurements clinically, i.e., post-surgery clinical measurements and also post-surgery CBCT measurements (40 defects each). Pre-surgery clinical measurements (vertical 6.15 ± 1.71 mm and horizontal 3.05 ± 0.84 mm) and CBCT measurements (vertical 7.69 ± 1.67 mm and horizontal 4.62 ± 0.77 mm) underestimated intra-surgery measurements (vertical 8.025 ± 1.67 mm and horizontal 4.82 ± 0.67 mm) in both vertical and horizontal aspects, and the difference was statistically not significant. Further, post-surgery clinical measurements (vertical 2.9 ± 0.74 mm and horizontal 1.52 ± 0.59 mm) underestimated CBCT measurements (vertical 3.67 ± 1.17 mm and horizontal 2.45 ±0.48 mm). The difference between pre-surgery clinical – pre-surgery CBCT ($p< 0.0001$, 95% CI) versus post-surgery clinical – post-surgery CBCT ($p< 0.0001$, 95% CI) values in both vertical and horizontal aspects was statistically significant. It was concluded that the use of CBCT appears to be prudent for accurate diagnosis of furcation defects in advanced periodontal diseases.

Zang W et al. (2018)[52] compared and correlated accuracy of molar furcation assessment via three different evaluation methods i.e., clinical detection, intraoral radiography and CBCT images. Total eighty-three patients having chronic periodontitis with an existing CBCT scans were included. Furcation involvement was assessed on maxillary and mandibular first molars. Furcation involvement on buccal and palatal/lingual sites were evaluated by using Periodontal charts (modified Glickman‘s classification), intraoral (periapical and/or bitewing) radiographs (recorded as presence or absence) and axial CBCT sections. Significant correlation ($p < 0.05$) was found between clinical detection

and intraoral radiography, clinical detection and CBCT, as well as intraoral radiography and CBCT at all the measured sites. While, CBCT exhibited higher correlation with clinical detection relative to intraoral radiography, especially at distal palatal side of maxillary first molar and n addition, CBCT provided more accurate assessment of bone loss measurement up to 2 decimals in millimeters, The study thus validated the use of CBCT as a valuable tool in assessing molar furcation defects in addition to clinical detection and intra-oral radiographs.

MATERIALS AND METHODS

The present study was undertaken to evaluate and compare DFDBA plus CGFM and DFDBA alone in treatment of intrabony defects. The evaluation was done clinically and radiographically using CBCT.

The study was initiated after the clearance from the Institutional Ethics Committee of our institute. A special proforma was designed so as to have systematic and methodological recording of observation and information. This included a detailed case history, clinical examination, radiographic evaluation, periodontal indices and written consent of the patient.

Sample Size Calculation

Sample size is determined considering mean difference in bone defect volume as

the mean outcome measure. Following assumptions were made from the study by **Shah et al 2018**, in which the authors evaluated the efficacy of Chorion Membrane as an adjunct to DFDBA for the treatment of Grade II furcation defects in moderate to severe periodontitis patientsclinically and radiographically. The proposed study used CGFM as an adjunct to DFDBA in patients with moderate to severe periodontitis having periodontal intrabony defect. In the present split mouth study design two treatments were randomly assigned to each side in the same patient. The data on mean difference of parameter (Bone defect volume) between baseline to 6 month for control and test groups, was considered for estimating the effect size (ES).

For the proposed study, an ES estimate of 4.54 was considered, which resulted in a sample of 30 defects. This sample size has provided the desired effect with 95% confidence and 80% power.

The formula for estimating the sample size was: $n = \frac{(Z\alpha+Z\beta)\ 2}{(\mu1-\mu2)2}$

Where Zα & Zβ are the standard normal values corresponding to specified α & β errors μ1 & μ2 are respective population means in two groups.

S = combined SD from 2 samples

And $S=\sqrt{(n1-1)s1\ 2+(n2-1)s22(n1+n2-2)}$

S12 and S2 2 two samples variances

Sample size: So the required Sample size was 24 intrabony defects per group

Assuming 20% loses to follow up in 6 months.

Effective sample size was n = 30 per group.

Therefore, total sample size of the study was 60 intrabony defects including both the groups.

Total 10 (3 males and 7 females) systemically healthy patients between the age ranges of 20 to 60 years having Chronic periodontitis with atleast one pair of bilateral vertical defects were recruited. Thus a total of 30 pairs of bilateral intrabony defects were included in the present study. The selected sites were randomly assigned to one of the two groups using computer generated random numbers at the time of surgery. Group I was Control Group (DFDBA) and Group II was Test Group (DFDBA + CGFM). Each patient was explained about the details of the procedure and an informed consent was obtained prior to participation.

INCLUSION CRITERIA

- Patients with age group 30 to 50 years.
- Patients with severe periodontitis as assessed by probing pocket depth (PPD) ≥ 5mm and clinical attachment level (CAL) ≥ 4mm exhibiting bilateral intrabony defects.
- Patients with no systemic diseases.

EXCLUSION CRITERIA

- Patients with history of systemic diseases, allergies or drug usage.
- Patients who have undergone periodontal treatment in previous 6 months.
- Pregnant and lactating females.

WITHDRAWAL CRITERIA

- Patients not willing to participate in the study.
- Patients wanting to leave the study at any point during the study.

Clinical Procedure

Presurgical hygiene therapy

Each patient was subjected to presurgical hygiene therapy consisting of a session of oral hygiene instructions, scaling and root planing and occlusal adjustment as needed. Six weeks after the initial therapy the patients were re-evaluated to assess the plaque control and overall oral hygiene. On the day of the surgical procedure, prior to surgery, recording of clinical data was carried out by the same examiner in all the patients. For evaluation of oral hygiene and gingival health, PI and GI were obtained at baseline, 3 months and 6 months.

A. Plaque index (Silness and Loe 1964)

It was examined in the scoring units of teeth: distofacial, facial, mesiofacial and lingual surfaces. A mouth mirror and dental explorer were used to assess plaque index.

Scoring Criteria:

Score	**Criteria**
0	No plaque
1	A flim of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen only by running a probe across the tooth surface.
2	Moderate accumulation of soft deposits within the gingival pocket,on the gingival margin and/or adjacent tooth surface, which can be seen by the naked eye.
3	Abundance of soft matter within the gingival pocket and/or on the gingival margin and adjacent tooth surface.

Calculation:

A plaque index per person was obtained by adding all of the plaque scores and dividing by the number of surfaces examined.

$$\textbf{Plaque Index (PI)} = \frac{\textbf{Total plaque score}}{\textbf{No of surfaces examined}}$$

Interpretation

Excellent	**0**
Good	0.1-0.9
Fair	1.0-1.9
Poor	2.0-3.0

B. Gingival Index (Loe and Silness, 1963)

The severity of gingivitis was scored on mesial, distal, buccal and palatal/lingual surfaces.

The teeth selected as the index teeth were-

16 - Maxillary Right First Molar

12 - Maxillary Right Lateral Incisor

24 - Maxillary Left First Premolar

36 - Maxillary Left First Molar

32 - Mandibular Left Lateral Incisor

44 - Maxillary Right First Premolar

Score Criteria

0	Absence of gingival inflammation/normal gingiva.
1	Mild inflammation, slight change in colour, slight oedema, no bleeding on probing.
2	Moderate inflammation, moderate glazing, redness, oedema, hypertrophy, bleeding on probing.
3	Severe inflammation, marked redness and hypertrophy, ulceration, tendency to spontaneous bleeding.

The scores of all the surfaces were added and divided by number of surfaces examined which provided the gingival index score per person.

$$\textbf{Gingival Index (GI)} = \frac{\textbf{Total GI scores per tooth}}{\textbf{No. of surfaces}}$$

Gingival scores	**Condition**
0.1-1.0	Mild gingivitis
1.1-2.0	Moderate gingivitis
2.1-3.0	Severe gingivitis

After the hygiene phase of therapy, soft tissue measurements were determined to the nearest millimeter mark by using UNC15 (University of North Carolina 15)

periodontal probe from the cementoenamel junction (CEJ) to free gingival margin (FGM) and from the CEJ to the base of periodontal pocket. Probing pocket depth (PPD), Gingival Recession (REC) and Clinical attachment level (CAL) were also recorded. Custom made occlusal acrylic stents were used to standardize the probe angulation and position. Occlusal stents were fabricated with cold cured acrylic resin on a cast model obtained from an alginate impression. The occlusal stents covered the occlusal surface of the tooth being treated and occlusal surfaces of at least one tooth in mesial and distal directions. Stents also extended apically on the buccal and lingual surfaces so as to cover the coronal third of the teeth. A groove (guide plane) was made on the stent in relation to each involved tooth to guide the periodontal probe while taking measurements. This technique provided fixed angulations for measurements at each site.

CBCT analysis

CBCT measurements were taken for each Group i.e. the Test and the Control group at baseline and at 6 months. The CBCT analysis included the measurement of bone defect height (CEJ –BD), bone defect depth (AC-BD) and the mesiodistal (MD) bone defect width and buccolingual (BL) width.

Surgical Armamentarium

Instruments were arranged in a definite order on a sterilized drape placed on a surgical trolley. All equipments were autoclaved and kept within easy reach of the operating and the assisting surgeons.

The surgical armamentarium consisted of:

- Mouth mirror.
- UNC-15 probe.
- Straight probe.
- Explorer number 23 and number 17.
- Tweezer.
- Disposable gloves.
- Disposable face masks.
- Disposable syringe – 5ml and 2ml.
- Local anesthetic (2% Lignocaine HCl with adrenaline 1:200000).
- Bard parker handles.
- No 11, 12, and 15 blades.
- Periosteal elevator (24G Hu-Friedy, USA).
- Gracey curettes.
- Scissors – straight and curved.
- Tissue forceps.
- Needle holder.
- Mersilk suture material.
- Cotton swabs.
- Kidney tray with saline and irrigation syringe.
- Dappen dish.
- Coe – pak.

- Normal saline.
- Denatured spirit.
- 0.2 % Chlorhexidine gluconate.

Material used in periodontal regeneration

DFDBA was procured from the Tissue Bank of TATA Memorial Hospital and Research Centre, Mumbai. It comprises of cortical bone which is harvested in a sterile manner within 12 hours of death of the donor.

DFDBA primarily works through both the principles of osteoconduction and osteoinduction. On demineralization, the crude particles of the DFDBA graft may expose/ activate the bone inductive proteins, such as BMPs located within the matrix that aids in mesenchymal cell migration and osteogenesis when implanted into the bony defects. Occasionally, the part of graft does not activate bone growth thereby serving as a scaffold for the natural bone to grow in and then eventually gets resorbed and replaced by new bone. The particle size used in this study was 500-1040 μm.

Concentrated growth factor (CGF) was developed by Sacco in 2006. CGF is produced by centrifuging blood samples similar to PRF. Nevertheless, the different centrifugation speed permits the isolation of a much larger, denser and richer in growth factors in the fibrin matrix.PRF has been used in different clinical applications as engineering tissue nevertheless CGF seems to have a better regenerative capacity and versatility, as reported for sinus and alveolar ridge augmentation.

Clinical research reported remarkable gains in clinical attachment levels using DFDBA in human intrabony lesions. CGFM is newly introduced Platelet concentrate in the field of Periodontology and there is paucity of literature available on its use as a regenerative material in periodontal regeneration. So, it was felt necessary to conduct clinical trial and evaluate its efficacy of this autologous membrane and its combination with DFDBA in the treatment of periodontal intrabony defect.

Surgical procedure

After baseline examinations, the patients entered into the surgical phase of the regenerative therapy. Local anaesthesia for the respective sites was obtained with 2% Lignocaine HCl with adrenaline (1:200000). After adequate anaesthesia the surgical procedure was initiated.

Incision

Intrasulcular incision extending atleast one tooth mesial and distal to the treatment site were made to release full thickness mucoperiosteal flaps. It was attempted to preserve the interdental papilla wherever possible.

Reflection of Flap

A full thickness mucoperiosteal flap was reflected to gain access for the defect debridement. All granulation tissue from the bony wall of the defects was removed with the help of curettes. The root surfaces were scaled and planed using hand instruments.

Preparation of CGFM

The CGF was prepared according to the protocol given by Sacco et al. Intravenous blood was collected in two 10 mL sterile tubes without anticoagulants. These tubes were then immediately centrifuged in the following way: 30" acceleration, 2' 2,700 rpm, 4' 2,400 rpm, 4' 2,700 rpm, 3' 3,000 rpm, and 36" deceleration in a special machine (R-4C, REMI, Mumbai, India). Three blood fractions form at the end of the process. (1) Poor plasma at the top; (2) Fibrin-rich gel with CGF and aggregated platelets; (3) Red blood cell (RBC) layer at the bottom. After removal of PPP, CGF was separated from the RBC layer while keeping a small RBC layer attached as it contains some amountof growth factors, and it was taken out with the help of a tweezer and scissor. The membrane was formed from the CGF layer by squeezing it.

Placement of Graft Material andPlacement of Graft Material and CGFM

For Test group, DFDBA graft was placed in small increments in defect site and a CGFM was placed in the defect site covering the graft. Immediately after placing the CGFM the reflected flap was repositioned and secured with interrupted sutures (3-0 Mersilk suture). Periodontal dressing was placed. For Control group, the sites received the same treatment without placement of the CGFM.

Post-surgical care

Patients were placed on antibiotics Capsules Amoxicillin trihydrate 500 mg 3 times a day for five days. Analgesics (Tablet of Acelofenac 100 mg and Paracetamol 325

mg) were prescribed for postsurgical discomfort. Sutures and Coe pak were removed after seven days.

Post surgical evaluation

The patients were evaluated clinically at 3 and 6 months by CBCT at 6 months intervals. Using UNC-15 periodontal probe the measurements of CAL, and PPD were taken similar to the pre procedures.

CBCT Measurements

All the sites in both Test and Control groups were subjected to CBCT assessment. The Orthophos® XG 3D manufactured by Sirona Dental Systems GmbH, Germany using 3Diagnosys 4.2 Imaging software was used for the CBCT assessment. Patient was asked to remove all metal objects and wear a lead apron. The patient was asked to bite gently and naturally on the bite block without joining the incisors. The upper incisors centered with the bite block. The patient was adjusted using two positional laser beams-

- The mid-sagittal positioning laser beam
- The 3D field of view (FOV) positioning laser beam

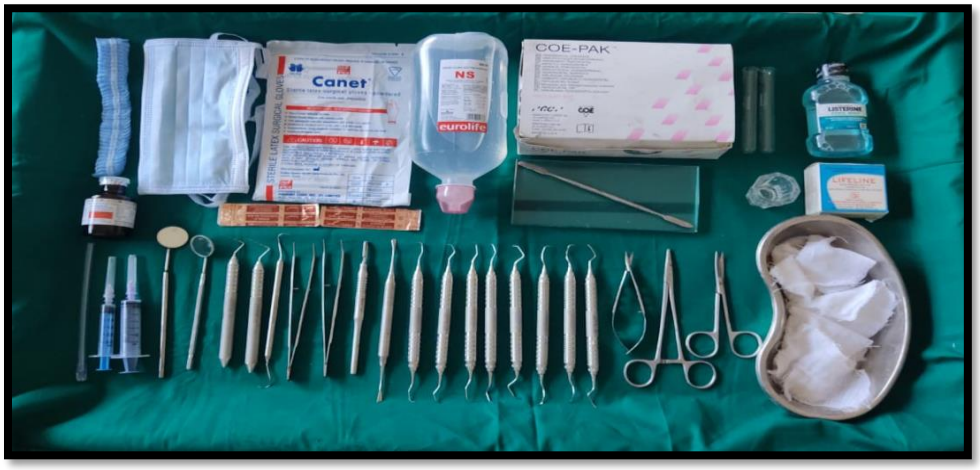
The digital readout was seen on the computer screen.

All the sites in both Test and Control groups were subjected to CBCT assessment at baseline and 6 months postoperatively. The parameters which were measured on CBCT included included CEJ-BD, the depth of the defect (AC-BD) and the MD width sagittal view of the intrabony defect. Additionally, the BL width of the defect was

measured on the axial plane of the CBCT. When the BL width of the defect was measured, the innermost and the most coronal point for the buccal and lingual alveolar crest was chosen on the axial plane, and the horizontal distance of two points were measured.

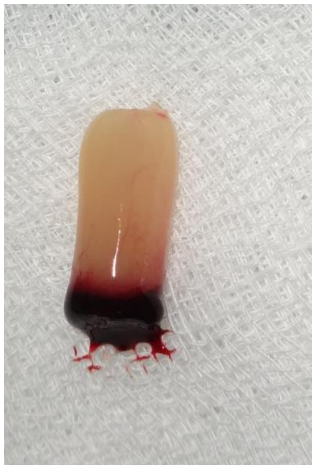
The linear measurements of CEJ to AC and CEJ to BD for each technique were used to determine IBD depth reduction. The Bone fill was calculated by subtracting CEJ to BD at 6 month from CEJ to BD at baseline. With the bone defect depth (d), bone defect width (MD) and BL width the total volume of the bone defect was calculated.

INSTRUMENTATION



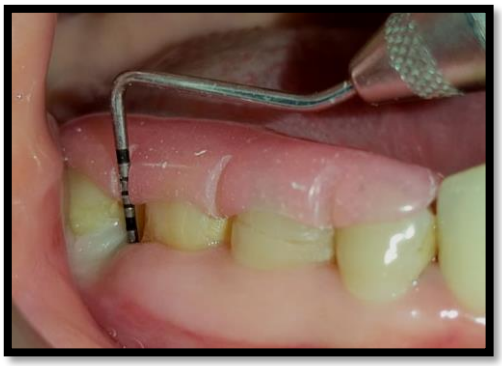
Surgical Armamentarium

Demineralized Freeze-Dried Bone Allograft (DFDBA)

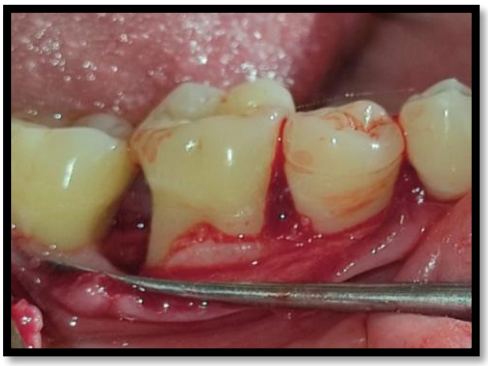


Concentrated growth factor membrane (CGFM)

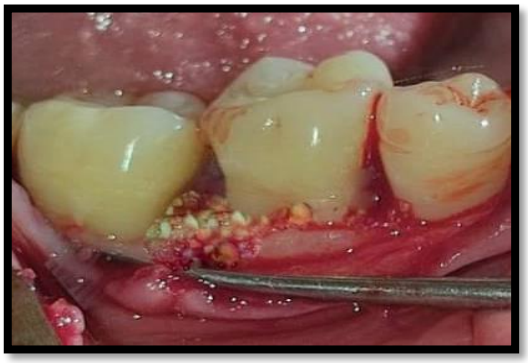
SURGICAL PROTOCOL FOR DEMINERALIZED FREEZE- DRIED BONE ALLOGRAFT



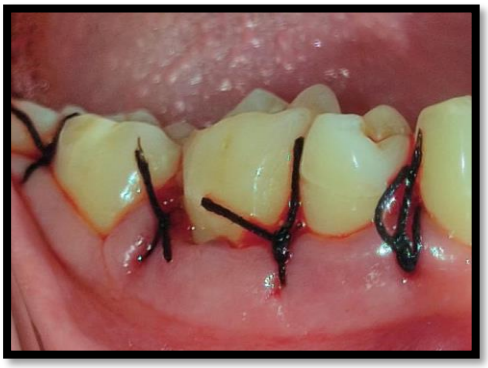
Pre-operative Photograph



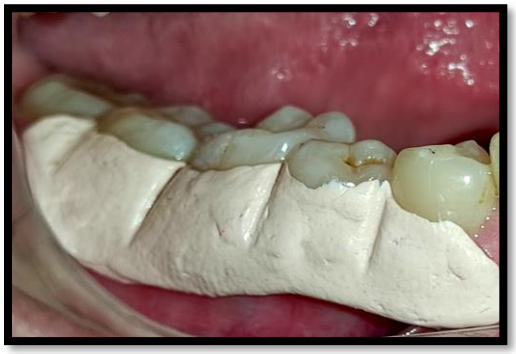
Control Site



Placement of DFDBA

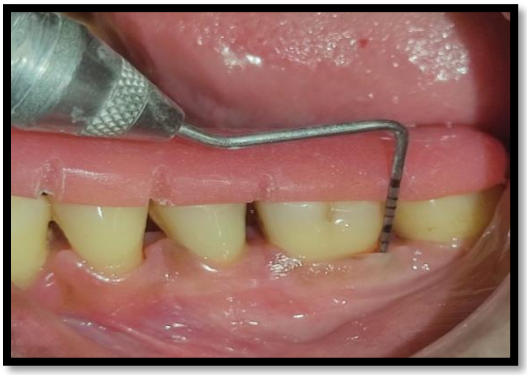


Sutured flap

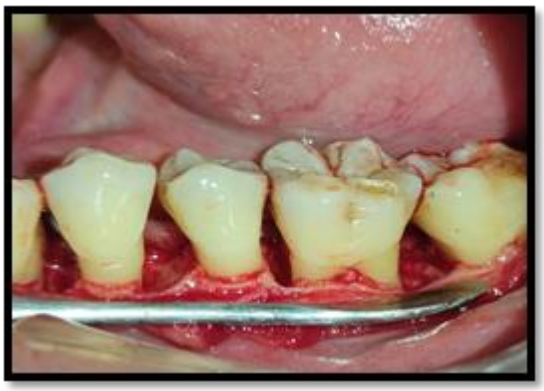


Periodontal Dressing Placed

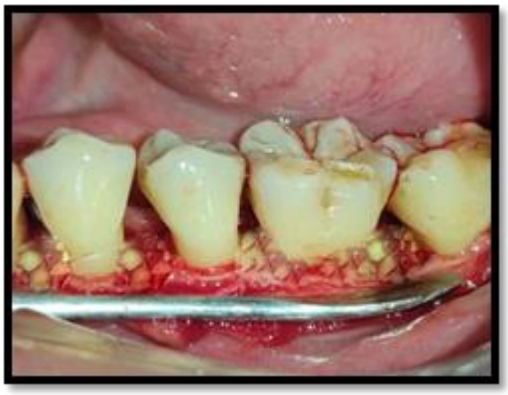
SURGICAL PROTOCOL FOR DEMINERALIZED FREEZE- DRIED BONE ALLOGRAFT PLUS CONCENTRATED GROWTH FACTOR MEMBRANE



Pre-operative Photograph

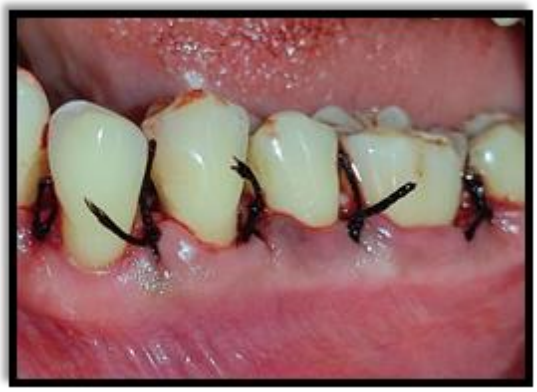


Test site

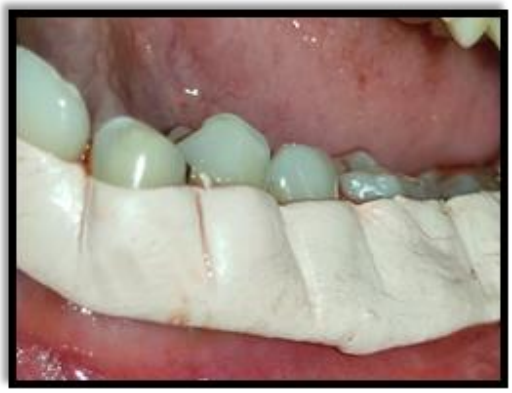


Placement of DFDBA

Placement of CGFM

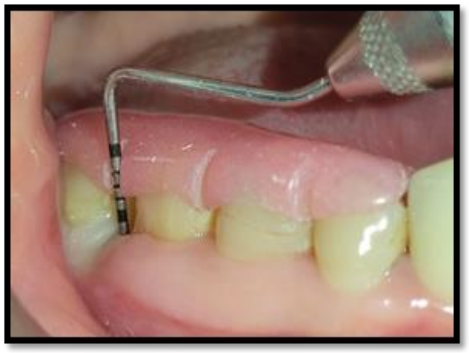


Sutured flap

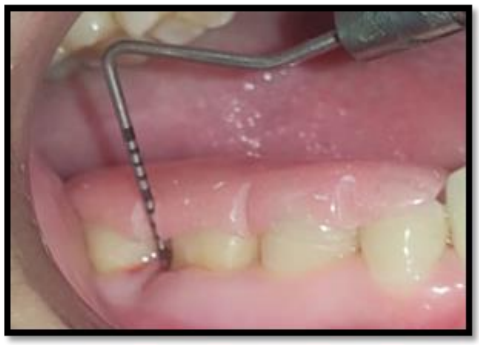


Periodontal Dressing Placed

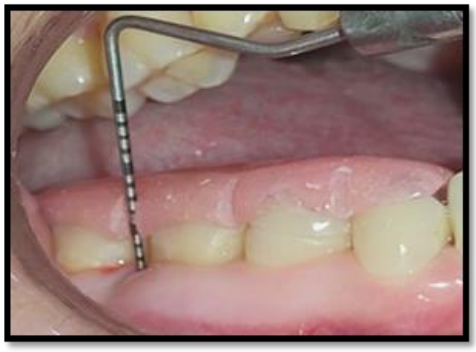
RECALL FOR DFDBA



Baseline

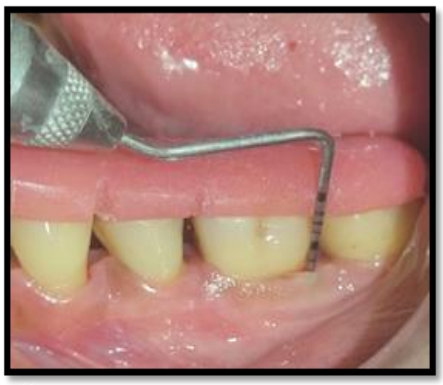


3 months

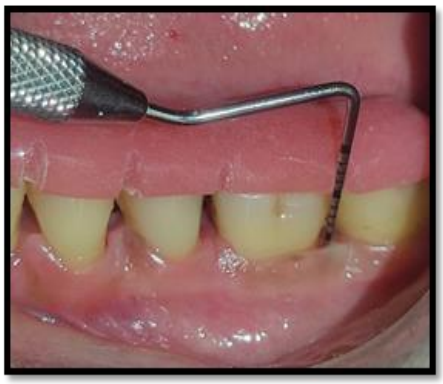


6 months

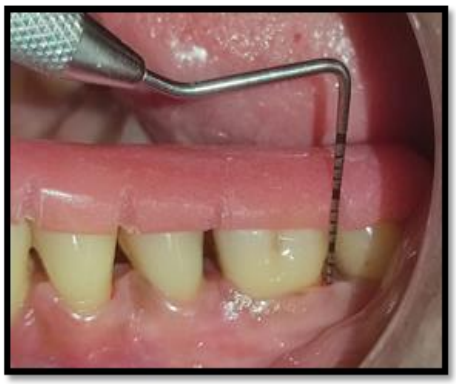
RECALL FOR DFDBA + CGFM



Baseline

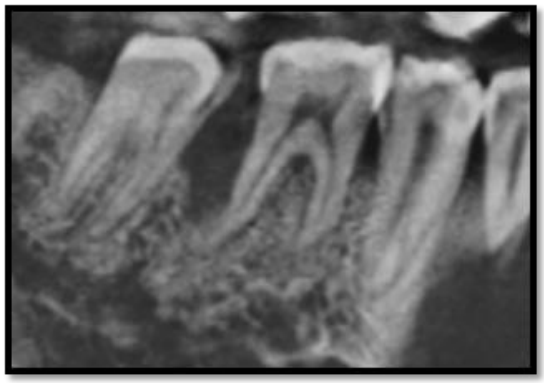


3 months

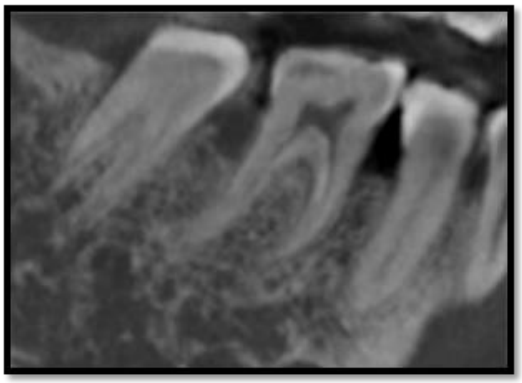


6 months

CBCT PARAMETERS FOR DFDBA

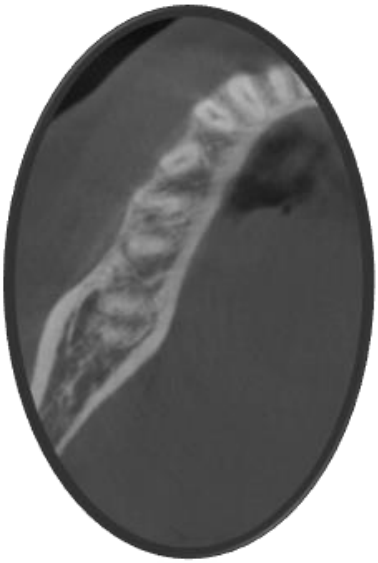


Baseline



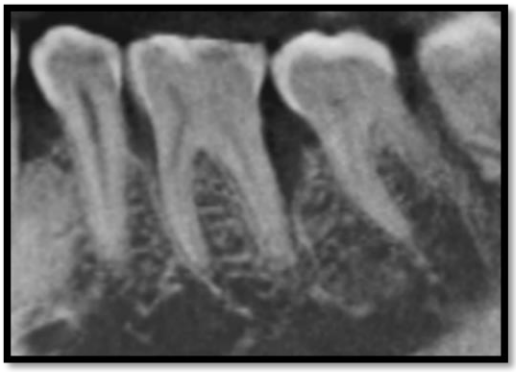
6 months

Baseline

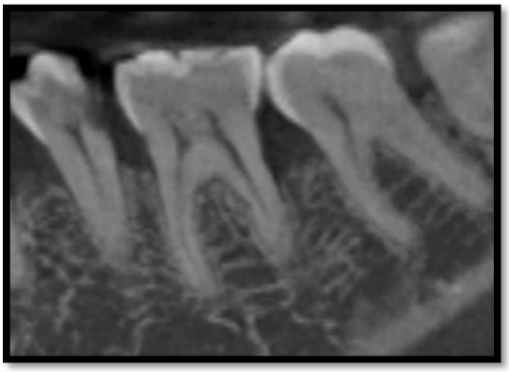


6 months

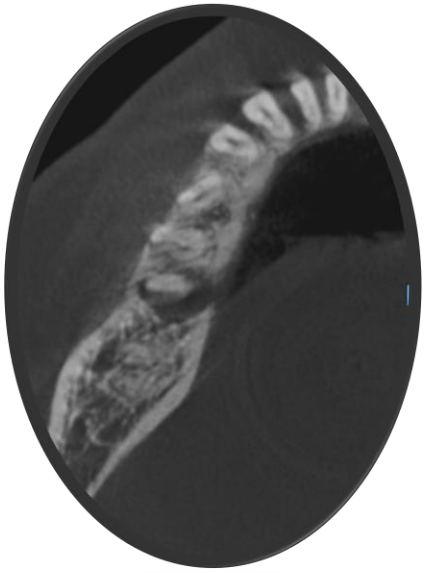
CBCT PARAMETERS FOR DFDBA + CGFM



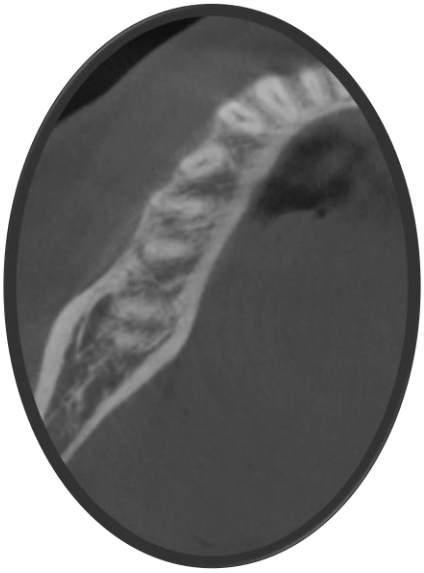
Baseline



6 months



Baseline



6 months

RESULTS

The present study was conducted in Department of Periodontology with an aim to evaluate and compare DFDBA plus CGFM and DFDBA alone in treatment of intrabony defects, clinically and radiographically by CBCT.

At baseline the clinical parameters assessed were PI, GI, PPD, CAL, Gingival recession and the intrabony defect parameters such as CEJ- BD, CEJ-AC, AC-BD, BL width, MD width were evaluated by CBCT for both the groups. PI, GI, PPD, CAL, GR were measured at all recall visits (3 and 6 months). Change in CEJ-BD (bone fill), CEJ-AC (alveolar crest resorption), AC-BD (Defect Depth), MD (Mesio-distal), and BL (Bucco-lingual) width was evaluated at baseline and 6 months by CBCT.

Statistical Methods:

Clinical parameters were summarized in terms of mean and standard deviation at each time point i.e. 3 and 6 months, post-operatively and radiographic evaluation will be performed at 6 months post-operatively by CBCT. Clinical results were evaluated using mean and standard deviation at baseline, 3 and 6 months post-operatively by Plaque Index, Gingival Index, Probing Pocket Depth (PPD), Clinical Attachment Level (CAL) and Gingival Recession (GR). Radiographic evaluation of intrabony defects was summarized in terms of mean and standard deviation for two groups at each time point. Further, the comparison of clinical and radiographic parameters across time points in each group was performed using repeated measure analysis of variance. Also the comparison between two groups for clinical and radiographic parameter was performed using independent t-test. Further, pair wise comparison for clinical and radiographic parameter between two time points in two groups was performed using Tukey's test.

All the analyses were performed using SPSS Ver. 26.0 (IBM Corp USA), and the statistical significance was evaluated at 5% level.

During the course of study, wound healing was uneventful in both the groups, without any signs of infections or complications. There was no untoward local and systemic reaction, indicating the biocompatibility of the DFDBA as well as CGFM.

In general, patients showed good oral hygiene through the complete duration of the study. Baseline full mouth PI was 2.83 ± 0.46 while at 3 months, it decreased to 2.20 ± 0.45 and at 6 months, the mean PI score was 1.54 ± 0.37. The difference in PI scores

when compared with baseline measurements versus 3 months, showed statistically significant decrease in PI score ($p<0.0001$). At 6 months post-surgical measurements showed statistically significant decrease ($p<0.001$) when compared to baseline, also, the reduction of PI score from 3 months to 6 months was statistically significant ($p<0.0001$). **(Table 1, 2)**

The mean GI score dropped from 1.75 ± 0.36 at baseline to 1.25 ± 0.24 at 3 months and to 0.95 ± 0.19 at 6 months. GI scores when compared with baseline to 3 months showed statistically significant decrease ($p<0.0001$) and also when compared at 6 months, the difference was statistically significant ($p<0.0001$). The mean decrease in GI score from 3 months to 6 months was also statistically significant ($p<0.0001$). **(Table 3, 4)**

Baseline clinical characteristics

Baseline mean PPD in Group I was 9.56 ± 0.81 mm and in Group II was 9.40 ± 0.62 mm. The baseline mean CAL for Group I was 7.97 ± 0.96 mm and in Group II was 7.83 ± 0.65 mm. At baseline, no statistically significant differences in any of the clinical parameters were observed between the Test and Control groups, indicating that the patient and defect selection was appropriate and devoid of any bias.

Clinical outcomes at 3 and 6 Months

Probing pocket depth (PPD)

In Group I, the mean PPD at baseline was 9.56 ± 0.81 mm and that at 3 months

was 3.8 ± 0.48 mm and in Group II, the mean PPD at baseline was 9.40 ± 0.62 mm and that at 3 months was 3.1 ± 0.48 mm. At 3 months, the mean PPD reduction was 5.76 ± 0.93 mm for Group I and 6.3 ± 0.65 mm for Group II. There was a statistically significant reduction in PPD for Group I as well as Group II at 3 months compared to baseline ($p<0.0001$).

In the Group I, the mean PPD at baseline was 9.56 ± 0.81 mm and that at 6 months was 2.87 ± 0.57 mm and in Group II the mean PPD at baseline was 9.40 ± 0.62 mm and that at 6 months was 2.4 ± 0.50 mm. At 6 months, the mean PPD reduction was 6.7 ± 0.87 mm for Group I and 7 ± 0.74 mm for Group II. There was statistically significant reduction in PPD for Group I and Group II at 6 months when compared to baseline ($p<0.0001$). There was no statistically significant reduction in PPD at 3 months ($p=0.208$) and 6 months ($p=0.210$) in Group II when compared to Group I. **(Table 5, 6, 7)**

Clinical attachment level (CAL)

In Group I, the mean CAL at baseline was 7.97 ± 0.96 mm and that at 3 months was 4.13 ± 0.35mm. The mean CAL at baseline in Group II was 7.83 ± 0.65 mm and that at 3 months was 3.47 ± 0.57 mm. A mean CAL gain of 3.83 ± 0.117 mm was observed in Group I and Group II exhibited a mean CAL gain of 4.3 ± 0.85 mm. Both groups exhibited a statistically significant increase in CAL gains at the end of 3 months ($p<0.0001$).

In Group I, the mean CAL at baseline was 7.97 ± 0.96 mm and that at 6 months

was 3.77 ± 0.77 mm. Group II showed a mean baseline CAL of 7.83 ± 0.65 mm and at 6 months, it was 3.13 ± 0.57 mm. The mean CAL gain at 6 months in Group I was 4.2 ± 1.29 mm and in Group II was 4.7 ± 0.79 mm. There was statistically significant CAL gain for Group I and Group II at 6 months when compared to baseline ($p<0.0001$). There was a statistically significant CAL gain at 3 months in Group II when compared to Group I ($p=0.012$). **(Table 8, 9, 10)**

Gingival recession (GR)

In Group I, the mean gingival recession at baseline was -1.6 ± 0.56 mm and that at 3 months was 0.33 ± 0.55 mm. The mean gingival recession at baseline in Group II was -1.57 ± 0.68 mm and that at 3 months was 3.37 ± 0.61 mm. A mean increase in gingival recession of 1.93 ± 0.82 mm was observed in Group I and Group II exhibited a mean increase in gingival recession of 1.94 ± 0.98 mm. Both, Group I and Group II exhibited a statistically significant increase in gingival recession ($p<0.05$) at the end of 3 months.

In Group I, the mean gingival recession at baseline was -1.6 ± 0.56 mm and that at 6 months was 0.90 ± 0.76 mm. Group II showed a mean baseline gingival recession of -1.57 ± 0.68 mm and at 6 months, it was 0.73 ± 0.64 mm. The mean increase of gingival recession at 6 months in Group I was 2.50 ± 0.97 mm and in Group II was 2.3 ± 0.75 mm. There was statistically significant increase in gingival recession for Group I ($p<0.0001$) and Group II ($p<0.0001$) at 6 months when compared to baseline. There was

statistically significant increase in gingival recession in Group I when compared to Group II at 3 months (p=0.0570). There was a statistically insignificant increase in gingival recession in Group II at 3 months and 6 month when compared to Group I. **(Table 11, 12, 13)**

CBCT analysis of intrabony defect parameters

CEJ-BD (Height of Intrabony Defect)

The mean CEJ-BD at baseline for Group I was 10.01 ± 0.8 mm and for Group II it was 9.69± 0.58 mm. At 6 months, the mean CEJ-BD for Group I was 7.46 ± 0.84 mm, showing a mean reduction in CEJ-BD. The difference in the measurement values of CEJ –BD at baseline and 6 month denotes the bone fill. So bone fill of 2.55± 0.96mm was noted after 6 months for Group I. The mean CEJ-BD at 6 months for Group II was 5.67± 0.91 mm thus exhibiting a reduction in CEJ-BD and giving a bone fill of 4.02± 0.81 mm. There was a highly significant bonefill in both the groups (p<0.0001). When the reduction in CEJ-BD at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was statistically significant (p=0.0001).**(Table 14, 15, 16, 17)**

CEJ-AC (Level of Alveolar Crest)

The mean CEJ-AC at baseline for Group I was 3.50± 0.50mm and for Group II it was 3.75 ± 0.46 mm. The difference in the measurement values of CEJ –AC at baseline

and 6 month denotes the change in level of alveolar crest. At 6 months, the mean CEJ-AC for Group I was 3.60 ± 0.49 mm, showing a mean increase in CEJ-AC (alveolar crest resorbtion) of 0.10 ± 0.04 mm. The mean CEJ-AC at 6 months for Group II was 3.87 ± 0.54 mm thus exhibiting an increase in CEJ-AC (alveolar crest resorbtion) of 0.12 ± 0.19 mm. There was a significant alveolar crest resorbtion in both the groups (p=0.045). When alveolar crest resorbtion was compared between Group I and Group II it was insignificant. **(Table 14, 15, 16, 17)**

AC-BD Defect Depth

The mean defect depth (AC-BD) at baseline for Group I was 6.52± 0.85mm and for Group II it was 5.94± 0.65mm. The difference in the measurement values of AC-BD at baseline and 6 month denotes the reduction indepth of defect. At 6 months, the mean defect depth (AC-BD) for Group I was 3.86± 1.04mm, showing a mean reduction in defect depth (AC-BD) of 2.65± 0.97mm. The mean defect depth at 6 months for Group II was 1.80± 0.73mm thus exhibiting a reduction in defect depth of 4.14± 0.76mm. There was a highly significant defect depth reduction in both the groups (p<0.0001). When the reduction in defect depth at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was highly statistically significant (P<0.0001). **(Table 14, 15, 16, 17)**

MD (Mesiodistal) Width

The mean MD dimension at baseline for Group I was 2.94 ± 0.43 mm and for Group II it was 2.95 ± 0.39 mm. At 6 months, the mean MD dimension for Group I was 2.24 ± 0.34 mm, showing a mean reduction in MD dimension of 0.70 ± 0.16 mm. The mean MD dimension at 6 months for Group II was 1.92 ± 0.30 mm thus exhibiting a reduction in MD dimension of 1.03 ± 0.29 mm. There was a highly significant MD dimension reduction in both the groups ($p<0.0001$). When the reduction at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was statistically significant ($P<0.0007$). **(Table 14, 15, 16, 17)**

BL (Bucco-lingual) Width

The mean BL dimension at baseline for Group I was 4.88 ± 0.95 mm and for Group II it was 4.99 ± 1.0 mm. At 6 months, the mean BL dimension for Group I was 3.30 ± 0.78 mm, showing a mean reduction in BL dimension of 1.58 ± 0.74 mm. The mean BL dimension at 6 months for Group II was 3.20 ± 0.74 mm thus exhibiting a reduction in BL dimension of 1.78 ± 0.66 mm. There was a highly significant BL dimension reduction in both the groups ($p<0.0001$). When the reduction at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was statistically insignificant ($P=0.274$). **(Table 14, 15, 16, 17)**

Volume (Defect volume) mm^3

The mean volume at baseline for Group I was 93.32 ± 25.52 mm^3 and for Group II it was 87.70 ± 27.55 mm^3. At 6 months, the mean volume for Group I was 28.08 ± 9.71 mm^3, showing a mean reduction in volume of 65.24 ± 23.83 mm^3. The mean volume at 6 months for Group II was 10.98 ± 5.28 mm^3 thus exhibiting a reduction in volume of 76.72 ± 26.26 mm^3. There was a highly significant volume reduction in both the groups ($p<0.0001$). When the reduction at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was statistically insignificant (P=0.081). **(Table 14, 15, 16, 17)**

DISCUSSION

Periodontitis is an infectious condition that destroys the tooth attachment apparatus, leading to progressive attachment loss and eventual loss of teeth if left untreated. The ultimate goal of periodontal treatment is to regenerate the periodontium that has been lost. Regeneration is defined as the reproduction or rebuilding of a lost or wounded component of the body in such a way that the architecture and functioning of the lost or damaged tissues are fully restored. Periodontal regenerative therapy attempts to restore lost periodontal structures and functional attachment through the regeneration of cementum, periodontal ligament, and alveolar bone[53].

Periodontal regenerative procedures include soft tissue grafts, bone replacement grafts, root biomodifications, guided tissue regeneration, and combinations thereof, for

osseous, furcation and recession defects. Numerous different graft materials, such as autogenous, allogeneic, xenogeneic bone substitutes, and alloplasts, are widely used in periodontal regenerative therapy to boost the restoration or reconstitution of tissues destroyed by inflammatory periodontal disease, either alone or in combination with membrane barriers[5].The rationale behind the use of bone graft is to take advantage of innate capabilities of such materials, namely osteoconduction, osteoinduction and osteogenesis, which are induced by transplanted cells that can differentiate into osteoblasts.. But amongst the bone grafts only autogeneous bone grafts are actually osteogenic, however autogeneous grafts are often criticized because of need for a second surgical site and there may be insufficient quantities of autogenous bone for grafting large or multiple defects[16]. Allograft like FDBA and DFDBA has been successfully used to regenerate bone. However, while both provide an osteoconductive scaffold, DFDBA also provides the osteoinductive factor[21]. Through multiple animal tests, **Urist** and colleagues demonstrated that demineralizing a cortical bone transplant causes new bone growth and considerably increases its osteogenic potential[54]. The induction of new bone is mediated by bone morphogenetic proteins (BMPs) found in DFDBA. BMP-4, BMP-2, and BMP-7 have all been found in DFDBA extracts and have been proved to be osteoinductive proteins. The BMPs trapped by minerals are exposed during the demineralization process, and the amount of BMP exposed is related to the degree of demineralization. Another factor to take into consideration while using DFDBA is the size of the bone particles. The maximal osteoinductive potential is seen in bone particles with a diameter of 550–710 microns. This particle size allowed for simple clinical

handling while avoiding the macrophage reaction and resorption which is evident with particle sizes smaller than 125 micron[21]. The particle size used in our study was 500-1040 microns.

The foundation for the development of the guided tissue regeneration principle was informed by the realization that the periodontal ligament is of central importance to the regenerative processes of the tooth-attachment apparatus. The principle of GTR is based on exclusion of gingival connective tissue cells from the wound area and to prevent the epithelial downgrowth and allow cells with regenerative potential to enter into the wound site first[53]. Thus, placement of a barrier membrane would ensure that the detached root becomes repopulated with cells from PDL capable of forming bone, PDL and cementum. An alternative explanation is that the membrane provides sufficient space for optimal wound stability, an essential requisite for periodontal regeneration to occur [55]. The introduction of resorbable barrier membranes, the second generation barrier membranes against non-resorbable membrane, has come up due to the need for second surgical procedure to remove the barrier membrane. In this study a resorbable CGFM has been used.

Concentrated growth factors membrane (CGFM) is a modified form of PRF prepared by repeatedly switching the centrifugation speed and are characterized as a relatively rigid fibrin clot. The unique fibrin network micro-structure of CGFM is a complex tridimensional architecture constituted by thin and thick fibrillar elements. CGFM releases numerous growth factors such as Platelet-derived growth factor (PDGF), Transforming growthfactor-β1 (TGF-β1) and β2 (TGF-β2), Fibroblast growth factor

(FGF), Vascular endothelial growth factor (VEGF), Brain-derived growth factor (BDGF) and Insulin-like growth factor (IGF) which stimulate cell proliferation, matrix remodelling and angiogenesis[34]. Improved CGF procedure might upgrade the amount of growth factors in the CGF layer. Adding to this, the presence of CD34 positive cells, within the CGFM network, may contribute to potential analysis of their clinical implications[28].

Research has demonstrated that growth factors such as TNF-α and BDGFshowed fast kinetic release from the concentrate and reached its peak accumulation in1st and 3rd day respectively. Likewise, PDGF-AB, TGF- β1 and IGF-I had continuouskinetic release and come to its greatest on 3rd and 6th day whereas VEGF and BMP-2had slow kinetic release and reaches its peak level on 8th day. These growth factors play a major role in proliferation and differentiation of osteoblasts. CGF also has important role in early wound healing by degranulation of the alpha granules in platelets that contain growth factors. In CGF the biphasic platelets are accelerated by thrombin, initiates the release of growth factors and other substances. These substances induce cellular proliferation, matrix formation, osteoid production, connective tissue healing, angiogenesis and collagen synthesis, thus enhancing the wound-healing process. The wound stability is improved by CGF, which is necessary for the formation of a new connective tissue attachment to a root surface. It also offers a scaffold that facilitates cytokine attachment and cellular migration. One of important factor is due to high concentration of leukocytes in CGF have antimicrobial effect. It has anti-angiogenic property on chronic non healing wounds[55].

Studies in the literature have suggested the effectiveness of CGFM and DFDBA used individually for periodontal regeneration. However, there is paucity in literature evaluating the effectiveness of the use of CGFM as a barrier in the treatment of periodontal intrabony defects. Hence, through this study we would like to evaluate and demonstrate the superior qualities of CGFM as a physical barrier in combination with DFDBA in bringing about regeneration of the bone.

The present study was a split mouth randomised controlled clinical trial aimed to evaluate the efficacy of DFDBA alone and combined therapy of DFDBA plus CGFM in the treatment of human periodontal intrabony defects. 10 patients (3 males and 7 females) with age ranges of 20 to 60 years with 30 bilateral intrabony defects who met the inclusion criteria were recruited and randomly assigned to each treatment sequence. Group I or a Control Group was treated with DFDBA alone and Group II or a Test Group was treated with DFDBA + CGFM. A split-mouth design was employed because it allows the comparison of outcome between the treatments. It has the ability to greatly facilitate the interpretation of trials by minimizing the effects of inter-patient variability.

At baseline, no significant differences in any of the investigated parameters were observed between Group I and Group II indicating that the randomization process was effective. One defect was treated with DFDBA alone and other with DFDBA + CGFM. The clinical and CBCT parameters in the study were evaluated until 6 months as the dimensional alteration of the periodontal tissues after periodontal therapy occurs within

the first 6 months.

Each patient participating in the study showed good oral hygiene level and a healthy clinical gingival condition throughout the duration of study. The PI score was low at the end of six months. This was the result of repeated oral hygiene instructions given to the patients throughout the study period. Plaque control is essential for the long term stability of clinical outcomes. Bacterial plaque is a major and important factor in the etiology of periodontal destruction and successful therapy depends upon its removal subsequent to treatment. Reduction in PI was statistically significant at the end of 6 months. The result of the study showed that there was significant reduction in the mean PI score from baseline to 3 and 6 months. These results are in accordance with the study done by **Vaid T et al. (2021)[34]**. The GI was significantly improved from baseline to 3 and 6 months, similar results were found by **Bodhare et al(2019)[40].** The improved gingival and plaque index scores suggested that there was increased level of oral health awareness among the patients and a good maintenance of oral hygiene by them throughout the study period.

The pathognomonic sign of periodontal disease is periodontal pocket and reduction in Probing pocket depth (PPD) is one of the prerequisites for successful periodontal treatment.

In the present study the Control Group, the mean PPD at baseline was 9.56 ± 0.81 mm and that at 3 months was 3.8 ± 0.48 mm and in Test Group, the mean PPD at baseline was 9.40 ± 0.62 mm and that at 3 months was 3.1 ± 0.48 mm. At 3 months, the

mean PPD reduction was 5.76 ± 0.93 mm for Control Group and 6.3 ± 0.65 mm for Test Group. There was a significant reduction in PPD for Test Group as well as Control Group at 3 months compared to baseline but this difference between two groups was insignificant.

At 6 months, the mean PPD reduction was 6.7 ± 0.87 mm for Control Group and 7 ± 0.74 mm for Test Group. But the difference when compared between Test Group and Control Group at 6 month was statistically insignificant. These results can be explained on the basis of observation of **Lindhe et al.**[57] where the authors opined that all surgical procedures result in a reduction in PPD with higher reduction occurring at initially deeper sites. In the present study, test group showed more reduction in PPD, probably showing the additive effect of CGFM when compared to control group. These results were similar to those reported by **Vaid T et al. (2021)**[34] who compared CGF + DFDBA with CGF alone in the treatment of intrabony defects. The author found that there was a significant reduction in PPD at 3 and 6 month in both the groups from baseline, but the reduction being more significant in the test group as compared to control group. **Kher V K et al. (2013)**[37] compared the effectiveness of collagen membrane with and without DFDBA in the treatment of intrabony defects.They observed the mean PPD of 4.06 ± 0.38 mmfor the test group and 3.2 ± 0.74 mm for the control group at 6 month from baseline which indicate significantly greater reduction in mean PPD seen in the test group as compared with the control group. The resemblance in the findings of both the previous studies suggest that the addition of DFDBA in combination with a barrier is advantageous to barrier (DFDBA graft) alone GTR technique. In **2016 Qiao et al.**[32] did a study to

compare the effect of CGF + BPBM and BPBM alone in the treatment of intrabony defect for 1 year. They found that the mean PD at 1 year decreased significantly in both groups (decrease of 4.2 ± 1.3 mm and 3.0 ± 1.6 mm, respt) compared with the baseline data and the decrease of mean PD in the CGFs + BPBM group was significantly greater than that of the BPBM group. The mean reduction in PPD after treatment can be associated to the reduced gingival inflammation and shrinkage of pocket wall.

Clinical attachment level (CAL) is most commonly used clinical parameter to evaluate the changes in periodontal status after regenerative treatment. Clinical attachment level was measured using a customized acrylic stent. The groove was fabricated in the stent in order to duplicate the placement of the probe both apicocoronally and mesiodistally at the end of 3 and 6 months, to minimize the error in post-operative measurements. In Group I, the mean CAL at baseline was 7.97 ± 0.96 mm and that at 3 months was 4.13 ± 0.35mm. The mean CAL at baseline in Group II was 7.83 ± 0.65 mm and that at 3 months was 3.47 ± 0.57 mm. A mean CAL gain of 3.83 ± 0.12 mm was observed in Group I and Group II exhibited a mean CAL gain of 4.3 ± 0.85 mm. Both groups exhibited a statistically significant increase in CAL gains at the end of 3 months. The mean CAL gain at 6 months in Group I was 4.2 ± 1.29 mm and in Group II was 4.7 ± 0.79 mm. There was significant CAL gain for Group I and Group II at 6 months when compared to baseline. There was a significant CAL gain at 3 months in Group II when compared to Group I.

These results are in accordance with **Bansal et al. (2013)[36]** who reported the mean CAL gain at of 3.4 ± 0.6 mm in test group (DFDBA + PRF) and 2.3 ± 0.69 mm in control

group (DFDBA) at6 months. Also there was significant CAL gain for test group and control group at 6 months when compared to baseline and a significant CAL gain at 3 months and 6 months in test group when compared to control group. Similar results were found with **Liu K** et **al. (2021)**[42] who reported significant CAL gain of mm in test group (BPBM + PRF) compared to in the control group (PRF) at 6 month interval. It was 2.9 ± 0.4 mm in test group and 2.0 ± 0.9 mm in control group at 6 month. The difference in the findings from the above mentioned studies with the present study might be because of selection of deeper defects in present study which leads to greater gain in CAL**.** Similar results have been reported by **Cortellini and Tonetti**[58] who concluded that in deeper defects (4mm or more), a greater CAL gain is achieved.

Study by **Agrawal A et al (2016)**[24] also noted statistically significant CAL gain in sites with placement of PRF+DFDBA as compared to sites with DFDBA alone. The significant CAL gain seen in test group might have been the result of true periodontal regeneration via new attachment in the case of PRF.

Qiao et al. (2016)[32] investigated and compared the effects of CGF+ BPBM and BPBM alone in treatment of intrabony defects. They found significantly greater CAL gain in sites treated with CGF + BPBM (3.7 ± 1.3 mm) as compared to sites treated with BPBM alone (2.4 ± 1.1mm) after 1 year. The greater amount of CAL gain in the present study from above mentioned study might be because of DFDBA graft material used in the present study, which has both osteoconductive and osteoinductive factor inducing the differentiation of host mesenchymal cells into osteoblasts whereas the BPBM graft lack the osteoinductive ability. **Xu Y et al. (2019)**[33] did a study to examined the effects of

CGF in combination with bone graft substitute and CGF alone in the treatment of intrabony defect. They reported that bone graft group (bone graft + CGF and bone graft alone) had significantly more CAL gain than in OFD and CGF alone group. **Amr A. Ellithy et.al. in 2021[9]** compared the effect of CGF + bone graft (HA + β TCP) and PRF + bone graft (HA + β TCP) in treatment of intrabony defects in chronic periodontitis patients. They reported that there was significant CAL gain in both the groups at 3 and 6 month interval compared to baseline. In addition on comparison for CAL at 3 and 6 months interval, there was a statistically significant difference in favor of CGF + bone graft compared to PRF + bone graft. And also reported that the gain in CAL more in CGF group might be because of high content of growth factors in CGF.

In the present study at 6 months, the mean increase in gingival recession was 2.3 ± 0.75 mm in the Test Group and 2.5 ± 0.97 mm in the Control Group.A statistically significant increase in gingival recession was found in both the groups at 6 months as compared to baseline. These results are nearly similar to **Agrawal P et al. (2016)[39]** who compared the effect of PRF alone with OFD and PRF + DFDBA group. The increase in GR at 12 months in PRP group was 2.04 ± 1.15mm and PRF + DFDBA group was 1.45 ± 2.08mm and it was more in OFD group 3.31±0.54 mm. In present study increase in GR was observed to the limited extent in both groups. This can be due to maintenance of flap in a high and stable position enhances neoangiogenesis, reduces the necrosis and shrinkage of the flap, and, thus, guarantees maximal root covering by remodeling and stabilization of the gingival flap in the highest possible covering position.

Assessing new bone formation is frequently used as a primary parameter for regenerative therapy. Recording alveolar bone changes radiographically following regenerative procedures is a non-invasive painless alternative to surgical re-entry procedure. The minimum time required for bone changes to be evident on radiograph is 6-month. **De Faria Vasconcelos et al. (2012)**[45]compared periapical radiographs with CBCT imaging in detecting and localizing alveolar bone loss. The authors concluded that CBCT offers improved visualization of the morphology of the defect. CBCT allowed for an analysis of the buccal and lingual/palatal surfaces and an improved visualization of the morphology of the defect. **Grimard et al. (2009)**[44] compared direct clinical, periapical radiograph, and CBCT measurement techniques for assessing bone level changes following regenerative periodontal therapy in 35 intrabony defects. Authors found that overall; CBCT was significantly more precise and accurate than periapical radiographs and concluded that CBCT may obviate surgical reentry as a technique for assessing regenerative therapy outcomes. **Suphanantachat S et al (2017)**[50]evaluated and compared clinical values by CBCT and conventional intraoral radiography (IOR) in IBD assessment. The study included 25 patients suffering from periodontitis and presented at least two IBDs. The authors concluded that compared to CBCT, IOR assessment tended to underestimate the periodontal disease severity and prognosis. CBCT was superior to IOR for evaluation of infrabony defect morphology and was beneficial for treatment decision that involved periodontal regeneration and tooth extraction. **Pajnigara N et al. (2017)**[51] evaluated the dimensions of 200 Grade II furcation defects clinically (pre-and post-surgery), intra-surgically, and by CBCT (pre and post-surgery) in forty chronic periodontitis patients. The author suggested that the use of CBCT in advanced periodontal disease diagnosis appears to be more informative and precise. A

comprehensive assessment of furcation involvement is possible with CBCT and also to optimize treatment decisions. And the findings of study indicate towards a better insight of details in periodontal osseous defects. Considering above mentioned trials we have preferably followed the CBCT measurements for the interpretation of results.

Evaluation of hard tissue changes including height of defect, defect depth, mesiodistal and buccolingual width was done by CBCT at baseline and at 6 months post operatively.

In the present study, the reduction in the CEJ-BD distance signifies bone fill. The mean CEJ-BD at baseline for Group I was 10.01 ± 0.8 mm and for Group II it was 9.69 ± 0.58 mm. At 6 months, the mean CEJ-BD for Group I was 7.46 ± 0.84 mm, for Group II was 5.67± 0.91 mm the difference in the measurement values of CEJ–BD at baseline and 6 month denotes the bone fill. So bone fill of 2.55 ± 0.96 mm was noted in Group I and 4.02 ± 0.81 mm for Group II. There was a highly significant bone fill seen in both the groups. When the reduction in CEJ-BD at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was statistically significant, suggesting that more bone fill must have form in group II.

In the present study the change of distance CEJ-AC denotes change in the level of alveolar crest (crest resorption). The mean change in CEJ-AC at 6 months for Group I and Group II was 0.10 ± 0.04 mm 0.12 ± 0.19 mm (respt). There was a significant alveolar crest resorption in both the groups was noted. When alveolar crest resorbtion was compared between Group I and Group II it was insignificant.

These results are in accordance with to **Bodhare et al. (2019)[40]** where authors have found that CEJ to BD reduction of 2.49± 0.99 for PRF group and 3.30 ± 1.10 for PRF + Bone graft group. The Bone fill was significantly higher for PRF + Bone graft group when compared to PRF group. Also there was increase in the mean value of level of alveolar crest (CEJ-AC) at 6 month. The mean value at 6 month showed a significant increase of 0.13 ± 0.22 and 0.33 ± 0.37 mm in PRF + Bone graft and PRF group respectively compared to baseline, exhibiting alveolar crest resorption.

These results were nearly similar to **Qiao et al. (2016)[32]** and they reported that CEJ to BD reduction of 2.1 ± 1.5 for Bone graft (BPBM) group and 3.3 ± 1.5 for bone graft + CGF group. And also alveolar crest reduction of 0.8 ± 0.5 and 0.5 ± 0.3 in control and test group was seen after 1 year. The author concluded from result that test group showed more improved result which was better than control group but not statistically significant bone fill.

In **2016 Agrawal A et al.[24]** evaluated the bone fill on intra-oral standardized radiographduring the treatment of intrabony defects. They found that the bone fill in PRF + DFDBA group was higher (3.50 ± 0.67mm) compared to DFDBA group (2.49 ± 0.64mm) at 12 month from baseline. And they also reported that alveolar crest resorption in both the groups, it was -0.23 ± 0.25 mm in PRF + DFDBA group and – 0.26 ± 0.25 in DFDBA group.The results of the test group are more in above mentioned studies proves the beneficiary effect of PRF and CGF on bone graft.

In the present study the difference in the measurement values of AC-BD at

baseline and 6 month denotes the reduction indepth of defect. The mean defect depth (AC-BD) at baseline for Group I was 6.52± 0.85mm and for Group II it was 5.94± 0.65mm.At 6 months, the mean defect depth (AC-BD) for Group I was 3.86± 1.04mm, showing a mean reduction in defect depth (AC-BD) of 2.65± 0.97mm. The mean defect depth at 6 months for Group II was 1.80± 0.73mm thus exhibiting a reduction in defect depth of 4.14± 0.76mm. There was a highly significant defect depth reduction in both the groups. When the reduction in defect depth at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was highly statistically significant.

Bodhare et al(2019)[40] reoported a highly significant defect depth reduction of 3.51 ± 1.17mm and 2.56 ± 0.95 mm for test group and control group respectively. When compared between the two groups it was significantly higher in test group as compared to control group.

Similar results were seen in **Kher V K et al (2013)[37]** who reported significant defect depth reduction in test group (2.4 ± 0.51) compared to control group (1.60 ± 0.51) after 6 month of surgery. The difference in results value from the present study can be attributed to the use of digital radiograph which being 2D evaluation imaging technique whereas in the present study the evaluation was carried out by CBCT which is 3D technique which known to be more precise in such evaluation.

In 2016 Agrawal A et al[24] in radiographic study where defect depth reduction at 12 months was higher in test group compared to control group. It was 3.73 ± 0.63mm in test group and 2.75 ± 0.57mm in control group. Study done by **Qiao et al. (2016)[32]** reported more favorable reduction in defect depth in test group compared to control group at 12 month interval. It was 3.8 ± 1.5 mm in test group and 2.8 ± 0.57 mm in control group. Although, the **above** mentioned studies were also evaluated in 2D imaging technique but had a follow up of 12 month, which must have favor the gradual improvement in bone regeneration which leads to higher value of defect depth reduction.

In the present study the mean Mesiodistal Width (MD) dimension at baseline for Group I was 2.94 ± 0.43 mm and for Group II it was 2.95 ± 0.39 mm. At 6 months, the mean MD dimension for Group I was 2.24 ± 0.34 mm, showing a mean reduction in MD dimension of 0.70 ± 0.16 mm. The mean MD dimension at 6 months for Group II was 1.92 ± 0.30 mm thus exhibiting a reduction in MD dimension of 1.03 ± 0.29 mm. There was a highly significant MD dimension reduction in both the groups . When the reduction at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was statistically significant.

In the present study the mean Buccolingual Width (BL) dimension at baseline for Group I was 4.88 ± 0.95 mm and for Group II it was 4.99 ± 1.2 mm. At 6 months, the mean BL dimension for Group I was 3.30 ± 0.78 mm, showing a mean reduction in BL dimension of 1.58 ± 0.74 mm. The mean BL dimension at 6 months for Group II was 3.20 ± 0.74 mm thus exhibiting a reduction in BL dimension of 1.78 ± 0.66 mm. There was a highly significant BL dimension reduction in both the groups. When the reduction

at 6 months was compared between the two groups it was higher in Group II as compared to Group I and was statistically insignificant

Similar results were in accordance with **Bodhare et al (2019)[40]**who found that there was a highly significant MD dimension reduction of bone defect in Group 1 (Bioactive Glass (BG) + PRF) and Group 2 (without PRF). When the reduction at 6 months was compared between the two groups it was significantly higher in Group 1 as compared to Group 2. Similarly they found more BL dimension reduction of bone defect in Group 1 (Bioactive Glass (BG) + PRF) and Group 2 (without PRF) at 6 months from baseline.

Study done by Amr A. Ellithy et.al. in 2021[9] who comapared compared the effect of CGF + bone graft (HA + β TCP) and PRF + bone graft (HA + β TCP) reported no significant difference change in the width of MD dimension in both the groups from baseline to 6 month but the change in MD dimension when compared in both groups it was more in group I. The explanation for these favorable results of CGF treated group which showed better and rapid increase in bone formation and bone mineral density may be due to the effect of CGF when mixed with bone graft material that gave sticky bone graft enriched with growth factors that didn't migrate during healing period.

Fei Li et al.[59] found that CBCT could provide relatively accurate measurements of MD width of the defect and the BL width of the defect which periapical radiograph could not show. **Vasconcelos K De Faria et al**[45] compared periapical radiographs with CBCT in detecting and localizing alveolar bone loss. The authors concluded that CBCT

offers improved visualization of the morphology of the defect. CBCT allowed for an analysis of the buccal and lingual/palatal surfaces and an improved visualization of the morphology of the defect. We are also in agreement that CBCT allows better visualization of defect and helps in better preoperative decision making for treatment. Evaluation by CBCT in the present study showed that reduction in MD and BL was more in Group II as compared to Group 1.

In the present study the mean volume at baseline for Group I was 93.32 ± 25.52 mm^3 and for Group II it was 87.70 ± 27.55 mm^3. At 6 months, the mean volume for Group I was 28.08 ± 9.71 mm^3, showing a mean reduction in volume of 65.24 ± 23.83 mm^3. The mean volume at 6 months for Group II was 10.98 ± 5.28 mm^3 thus exhibiting a reduction in volume of 76.72 ± 26.26 mm^3. There was a highly significant volume reduction in both the groups.

It is first time the change in volume of defect in periododntal intrabony defect is evaluated. The results are in accordance with study recently done by **Shah et al. (2019)**[11]who have evaluated the efficacy of CM with DFDBA over DFDBA alone in grade II furcation defect. The authors found statistically significant reduction in defect volume in the test site as against control site when evaluated by using CBCT**.** Similarly, **Pajnigara NG et al. (2017)**[25] evaluated volumetric changes to assess the regenerative efficacy of DFDBA with and without Amion membrane (AM) in Grade II furcation defects both clinically and radiographically using CBCT. The study suggests combination therapy of DFDBA in conjunction with membrane (AM) results in greater the reduction in defect volume indicating greater amount of healed regenerated tissue.

From the study it is confirmed that DFDBA when used alone and in combination with CGFM can result in periodontal regeneration in intrabony defect. Also the combination of CGFM and DFDBA has more beneficial effect on hard tissue parameters as well as on soft tissue parameters.

Like the previously mentioned studies CBCT analysis enabled us to assess bone fill and the volumetric healing characteristics to a certain extent and also helped in analyzing regeneration radiographically with relatively less invasion.

The following limitations were observed in the present study:

1. The sample size in the present study was limited to 30 bilateral intrabony defects. A larger sample size would be desirable so as to substantiate the results.
2. Evaluation of radiographic parameter at 6 months may be speculated as too early for a final evaluation of bone fill in intrabony defects.Therefore, long term analysis is needed to determine the stability of the results and to improve the radiographic assessment of the results.
3. Ethical constraints as well as relative invasiveness restricted the assessment of bone fill by surgical re-entry as well as histologically.

CONCLUSION

The present randomized controlled clinical and CBCT study was undertaken to compare the effectiveness of DFDBA plus CGFM and DFDBA alone in the treatment of periodontal intrabony defects.10 systemically healthy subjects with 30 bilateral intrabony defects were selected for the study. Baseline measurements included PI, GI, PPD, CAL, GR and bone defect height, depth and width (MD and BL) by CBCT. At the time of surgery, defects were randomly assigned to either Group I i.e. Control group (DFDBA) or Group II i.e. Test group (DFDBA + CGFM). PI, GI, PPD, CAL and GR were assessed at 3 and 6 months while the CBCT analysis was done at 6 months.

During the course of study, healing was uneventful in both Group I and Group II, without any signs of infection or complications. There was no untoward local and

systemic reaction indicating the biocompatibility of the materials used. No clinical evidence of undesirable, immune response was detected and no evidence of tissue reaction was seen. The reductions in Plaque index and Gingival index indicated satisfactory maintenance of oral hygiene by patients throughout the study period. PPD reduction and CAL gain in Group II was significantly greater than in Group I at 6 months. The mean bone height, width and depth reduction in Group II was statistically significantly greater than in Group I at 6 month evaluation. Also, there was higher reduction in volume of defect in Group II as compared to Group I at 6 month evaluation.

From the analysis of results, following conclusions were drawn:

1. DFDBA + CGFM resulted in statistically significant reductions of PPD at 3 months and 6 months, compared to DFDBA alone.

2. DFDBA + CGFM showed statistically significant CAL gain at 3 months compared to DFDBA alone.

3. DFDBA + CGFM showed significantly better results in terms of reduction in bone defect height, depth and width at 6 months, compared to DFDBA alone.

4. DFDBA + CGFM showed significantly better results in terms of reduction of bone defect volume at 6 months, compared to DFDBA alone.

In conclusion, within the limits of the present study, both the treatment groups resulted in significant periodontal regeneration as assessed by clinical and radiographic parameters, but use of DFDBA + CGFM could be more beneficial in achieving better results in terms of periodontal regeneration.

Attempting to identify the most accurate method for evaluating hard tissue changes after periodontal therapy is an important task. To date, re-entry procedure appears to be the gold standard and, while no single method can produce similar information consistently. The images obtained by CBCT, combined with clinical measurements, will definitely increase our ability to determine the treatment outcome without the use of re-entry procedure.

It should be noted that the differences in healing patterns, microbial pathogens, study designs, patient population, measurement techniques and human defect variations make it difficult to compare clinical results. Also, different methods like clinical, histological and radiographic evaluations have been used in various studies for assessing the outcomes of treatments. This could be some of the reasons for variations observed amongst clinical trials. Further studies that exploit properties of CGFM in the field of periodontal regeneration and tissue engineering are encouraged.

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TABLES

Table 1: Mean Values of Plaque Index among the Study Population

	Baseline	**3 month**	**6 month**
Mean	2.83	2.20	1.54
SD	0.46	0.45	0.37

Table 2: Comparison of Plaque Index at Different Time Intervals

Comparison	**Mean difference**	**p-value***	**Significance**
Baseline Vs 3 month	0.633	<0.0001	**HS**
Baseline Vs 6 month	1.288	<0.0001	**HS**
3 month Vs 6 month	0.655	<0.0001	**HS**

(HS: Highly significant)

Table 3: Mean values of Gingival Index among the Study Population

	Baseline	**3 month**	**6 month**
Mean	1.75	1.25	0.95
SD	0.36	0.24	0.19

Table 4: Comparison of Gingival Index at Different Time Intervals

Comparison	**Mean difference**	**p-value***	**Significance**
Baseline Vs 3 month	0.493	<0.0001	**HS**
Baseline Vs 6 month	0.801	<0.0001	**HS**
3 month Vs 6 month	0.308	<0.0001	**HS**

(HS: Highly significant)

Table 5: Mean values of PPD (in mm) among the Study Population

	Group I	**Group II**	**p-value***
Baseline	9.56 ± 0.81	9.4 ± 0.62	0.378(NS)
3 Month	3.80 ± 0.48	3.10 ± 0.48	<0.0001**(HS**)
6 Month	2.87 ± 0.57	2.40 ± 0.50	0.001(S)

(HS: Highly significant, S: Significant, NS: Non significant)

Table 6: Comparison of reduction of PPD (in mm) in study groups at Different Time Intervals

	Group I		**Group II**	
Comparison	**Mean difference**	**p-value***	**Mean difference**	**p-value***
Baseline Vs 3month	5.76	<0.0001**(HS)**	6.30	<0.0001**(HS)**
Baseline Vs 6 month	6.70	<0.0001**(HS)**	7.0	<0.0001(**HS**)
3 month Vs 6 month	0.93	<0.0001**(HS)**	0.70	<0.0001(**HS)**

(HS: Highly significant, S: Significant)

Table 7: Comparison of reduction of PPD (in mm) among the study groups at Different Time Intervals

Comparison	Group I	Group II	p-value*
Baseline Vs 3 month	5.76 ± 0.93	6.3 ± 0.65	0.20 (NS)
Baseline Vs 6 month	6.70 ± 0.87	7.0 ± 0.74	0.21 (NS)
3 month Vs 6 month	0.93 ± 0.69	0.7 ± 0.70	0.18 (NS)

(NS: Non significant)

Table 8: Mean values of CAL (in mm) among the Study Population

	Group I	Group II	p-value*
Baseline	7.97 ± 0.96	7.83 ± 0.65	0.53 (NS)
3month	4.13 ± 0.35	3.47 ± 0.57	<0.0001 **(HS)**
6month	3.77 ± 0.77	3.13 ± 0.57	0.001 (S)

(HS: Highly significant, S: Significant, NS: Non significant)

Table 9: Comparison of CAL gain (in mm) in study groups at Different Time Intervals

Comparison	Group I		Group II	
	Mean difference	**p-value***	**Mean difference**	**p-value***
Baseline Vs 3 month	3.83	<0.0001 **(HS)**	4.36	<0.0001 **(HS)**
Baseline Vs 6 month	4.20	<0.0001 **(HS)**	4.70	<0.0001 **(HS)**
3 month Vs 6 month	0.36	<0.0001 **(HS)**	0.33	<0.0001 **(HS)**

(HS: Highly significant)

Table 10: Comparison of CAL gain (in mm) among the study groups at Different Time Intervals

Comparison	Group-I	Group -II	p-value*
Baseline Vs 3 month	3.83 ± 0.12	4.36 ± 0.85	0.012 **(S)**
Baseline Vs 6 month	4.20 ± 1.29	4.70 ± 0.79	0.078 (NS)
3 month Vs 6 month	0.36 ± 0.66	0.33 ± 0.47	0.082 (NS)

(NS: Non significant, S: Significant)

Table 11: Mean values of Gingival Recession (in mm) among the Study Population

	Group I	Group II	p-value*
Baseline	-160 ± 0.56	-1.57 ± 0.68	0.837 (NS)
3Month	0.33 ± 0.55	0.37 ± 0.61	0.825 (NS)
6Month	0.90 ± 0.76	0.73 ± 0.64	0.362 (NS)

(NS: Non significant)

Table 12: Comparison of Gingival Recession (in mm) in study groups at Different Time Intervals

Comparison	Group I		Group II	
	Mean difference	**p-value***	**Mean difference**	**p-value***
Baseline Vs 3 month	1.93	<0.0001 **(HS)**	1.94	<0.0001 **(HS)**
Baseline Vs 6 month	2.50	<0.0001 **(HS)**	2.30	<0.0001 **(HS)**
3 month Vs 6 month	0.56	<0.0001 **(HS)**	0.36	<0.0001 **(HS)**

(HS: Highly significant)

Table 13: Comparison of Gingival Recession (in mm) among the study groups atDifferent Time Intervals

Comparison	Group-I	Group -II	p-value*
Baseline Vs 3 month	1.93 ± 0.82	1.94 ± 0.98	0.99 (NS)
Baseline Vs 6 month	2.50 ± 0.97	2.30 ± 0.75	0.37 (NS)
3 month Vs 6 month	0.56 ± 0.72	0.36 ± 0.66	0.27 (NS)

(NS: Non - Significant)

Table 14: Mean values of different parameters by CBCT at Baseline

CBCT Parameters	Baseline				p-value*
	Group I		Group II		
	Mean	SD	Mean	SD	
CEJ-BD (mm)	10.01	0.80	9.69	0.58	0.079 (NS)
CEJ-AC (mm)	3.50	0.50	3.75	0.46	0.044 **(S)**
AC-BD (mm)	6.52	0.85	5.94	0.65	0.004 **(S)**
MD (mm)	2.94	0.43	2.95	0.39	0.899 (NS)
BL (mm)	4.88	0.95	4.99	1.20	0.712 (NS)
Volume (mm^3)	93.32	25.52	87.70	27.55	0.416 (NS)

(NS: Non significant, S: Significant)

Table 15: Mean values of different parameters by CBCT at 6 months

CBCT Parameters	6 Months				p-value*
	Group I		Group II		
	Mean	SD	Mean	SD	
CEJ-BD (mm)	7.46	0.84	5.67	0.91	< 0.0001 **(HS)**
CEJ-AC (mm)	3.60	0.49	3.87	0.54	0.045 **(S)**
AC-BD (mm)	3.86	1.04	1.80	0.73	< 0.0001 **(HS)**
MD (mm)	2.24	0.34	1.92	0.30	< 0.0001 **(HS)**
BL (mm)	3.30	0.78	3.20	0.74	0.625 (NS)
Volume (mm^3)	28.08	9.71	10.98	5.28	< 0.0001 **(HS)**

(HS: Highly Significant: S: Significant;NS: Non significant)

Table 16:Comparison of CBCT parameter between two time intervals in control group

CBCT Parameter	Group I		p-value*
	Mean	SD	
CEJ-BD (mm)			
Baseline	10.01	0.80	< 0.0001 **(HS)**
6 month	7.46	0.84	
CEJ-AC (mm)			
Baseline	3.50	0.50	< 0.0001 **(HS)**
6 month	3.60	0.49	
AC-BD (mm)			
Baseline	6.52	0.85	< 0.0001 **(HS)**
6 month	3.86	1.04	
MD (mm)			
Baseline	2.94	0.43	< 0.0001 **(HS)**
6 month	2.24	0.34	
BL (mm)			
Baseline	4.88	0.95	< 0.0001 **(HS)**
6 month	3.30	0.78	
Volume (mm^3)			
Baseline	93.32	25.52	< 0.0001 **(HS)**
6 month	28.08	9.71	

(S: Significant)

Table 17: Comparison of CBCT parameter between two time intervals in test group

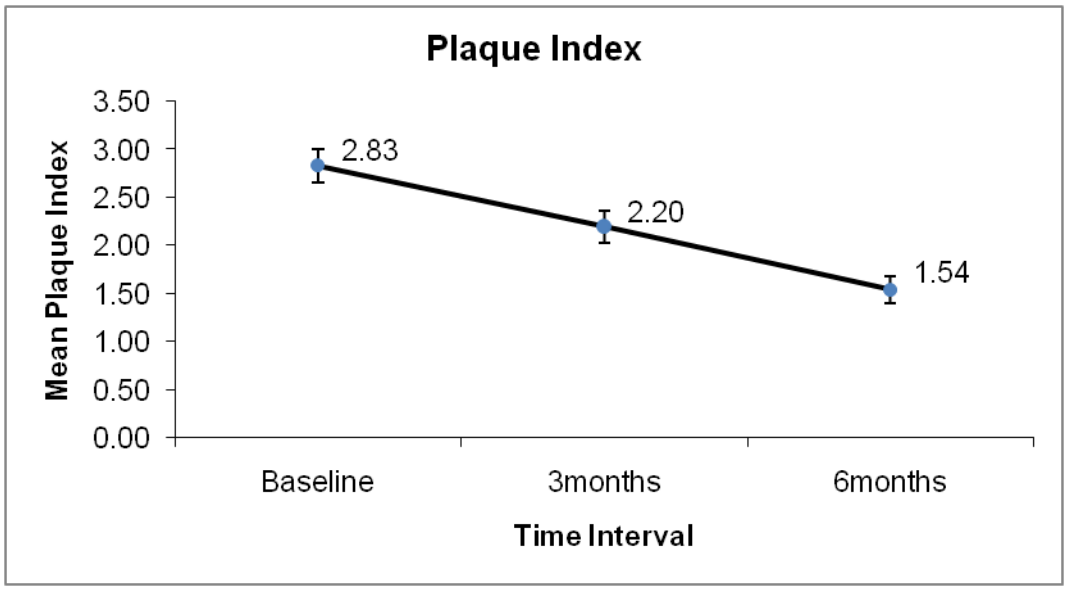
CBCT Parameter	Group-II		p-value*
	Mean	**SD**	
CEJ-BD (mm)			
Baseline	9.69	0.58	< 0.0001 **(HS)**
6 month	5.67	0.91	
CEJ-AC (mm)			
Baseline	3.75	0.46	0.003 **(S)**
6 month	3.87	0.54	
AC-BD (mm)			
Baseline	5.94	0.65	< 0.0001 **(HS)**
6 month	1.80	0.73	
MD (mm)			
Baseline	2.95	0.39	< 0.0001 **(HS)**
6 month	1.92	0.30	
BL (mm)			
Baseline	4.99	1.20	< 0.0001 **(HS)**
6 month	3.20	0.74	
Volume (mm^3)			
Baseline	87.70	27.55	< 0.0001 **(HS)**
6 month	10.98	5.28	

(HS: Significant)

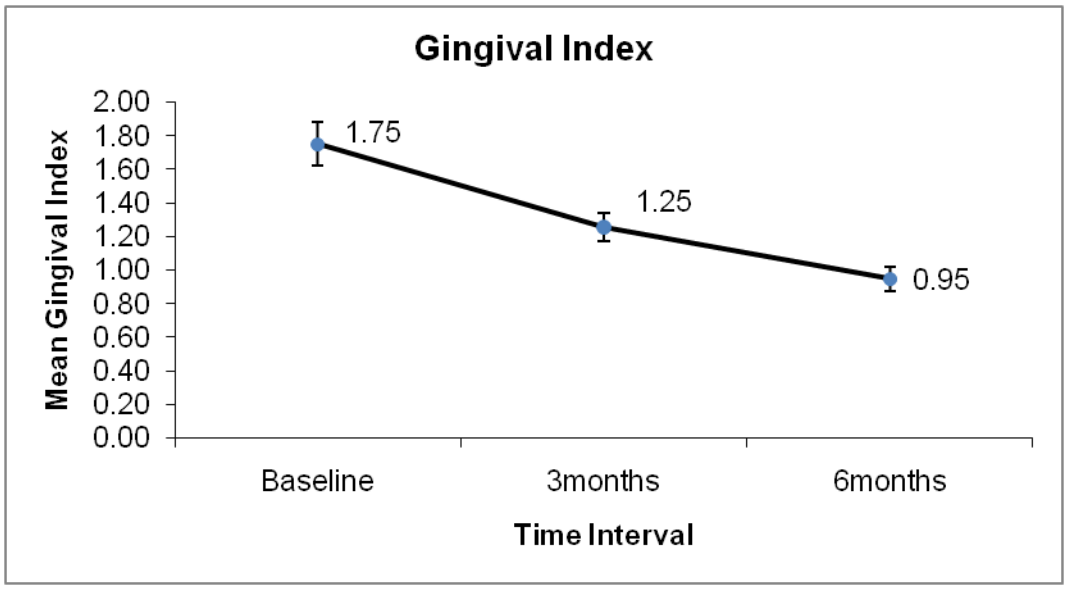
Table 18: Comparison of difference between baseline and 6 months for CBCT parameter in two groups

CBCT Parameter	Group I		Group II		P-value*
	Mean	SD	Mean	SD	
CEJ-BD (mm)	2.55	0.96	4.02	0.81	< 0.0001 **(HS)**
CEJ-AC (mm)	-0.10	0.04	-0.12	0.19	0.664 (NS)
AC-BD (mm)	2.65	0.97	4.14	0.76	< 0.0001 **(HS)**
MD (mm)	0.70	0.16	1.03	0.29	< 0.0001 **(HS)**
BL (mm)	1.58	0.74	1.78	0.66	0.274 (NS)
Volume (mm^3)	65.24	23.83	76.72	26.26	0.081 (NS)

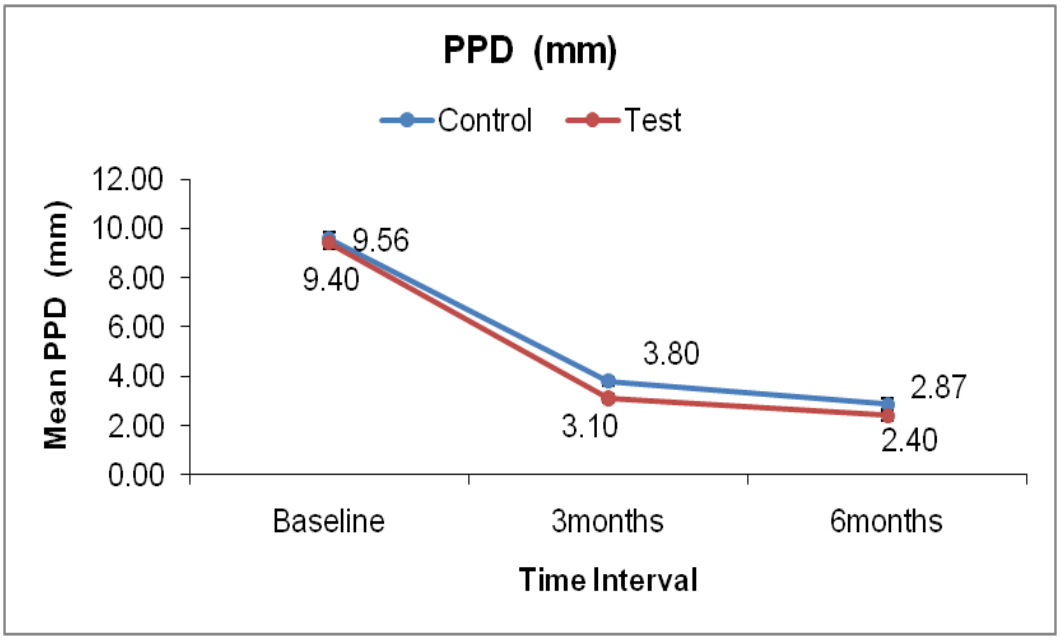
(HS: Highly Significant, NS: Not Significant)



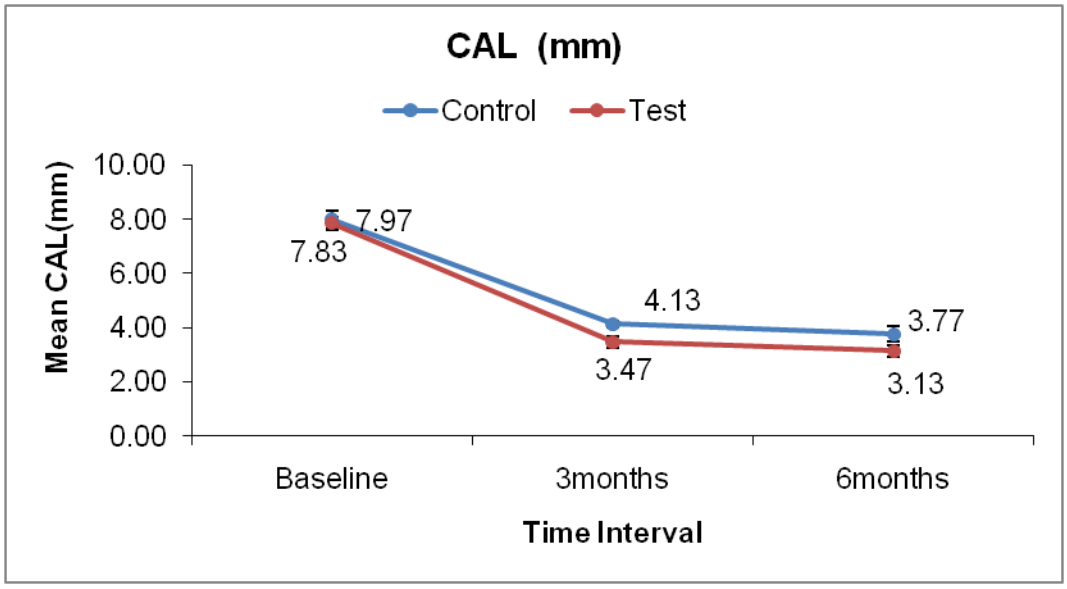
Graph 1: Line chart showing the mean plaque index at three different time point



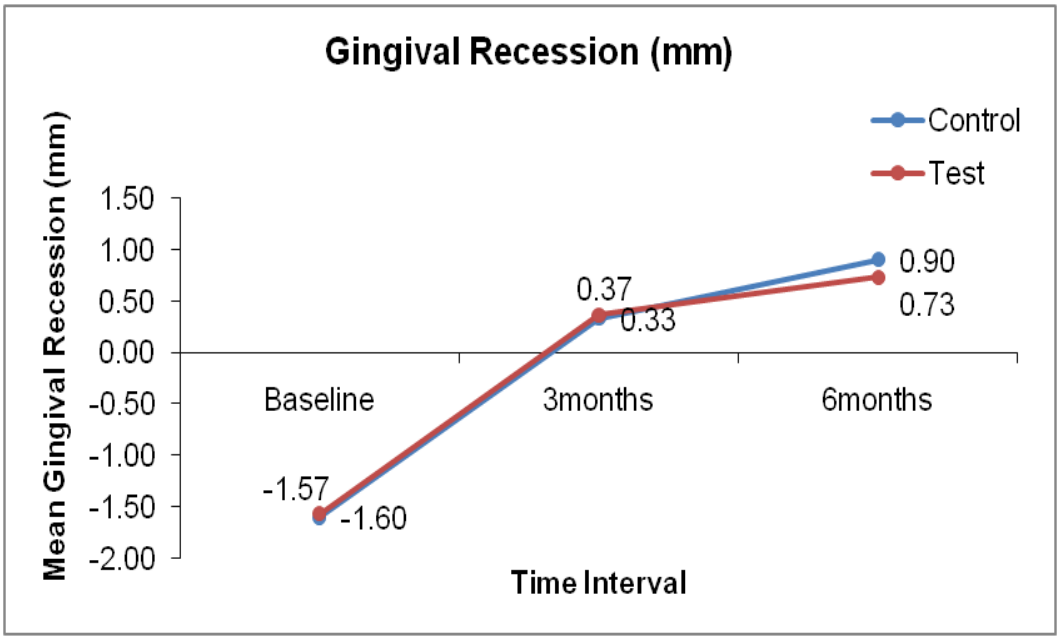
Graph 2: Line chart showing the mean gingival index at three different time point



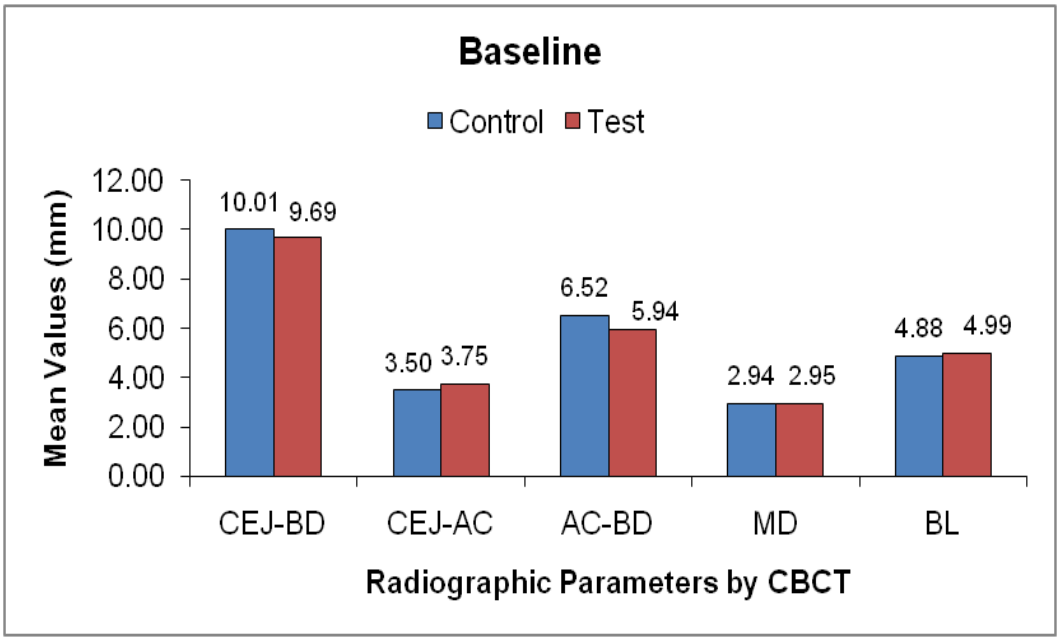
Graph 3: Line chart showing the mean PPD reduction (mm) at three different time point in two groups



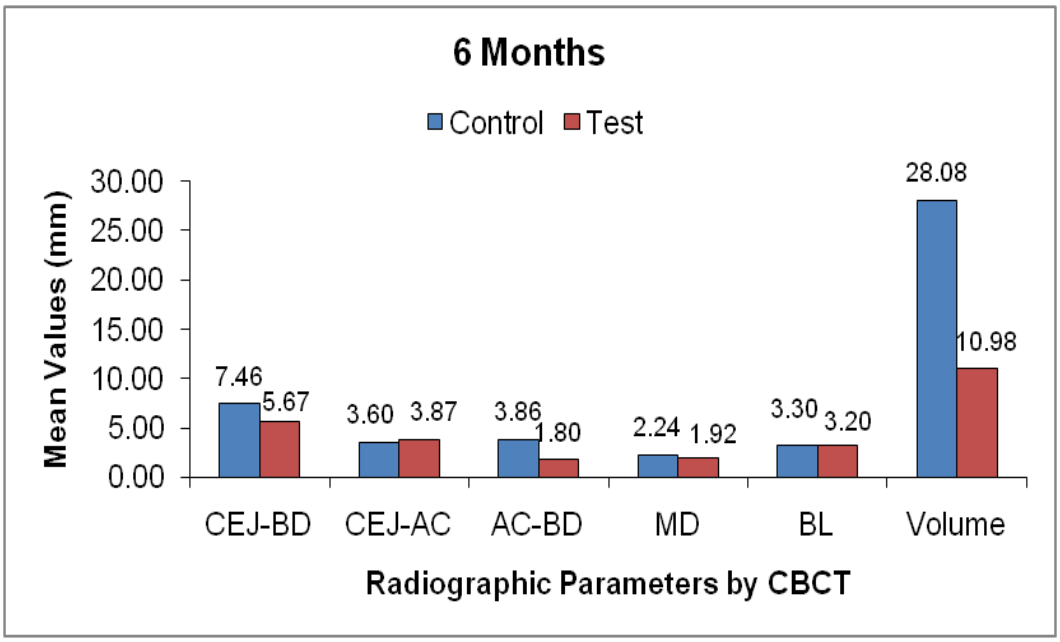
Graph 4: Line chart showing the mean CAL (mm) at three different time point in two groups



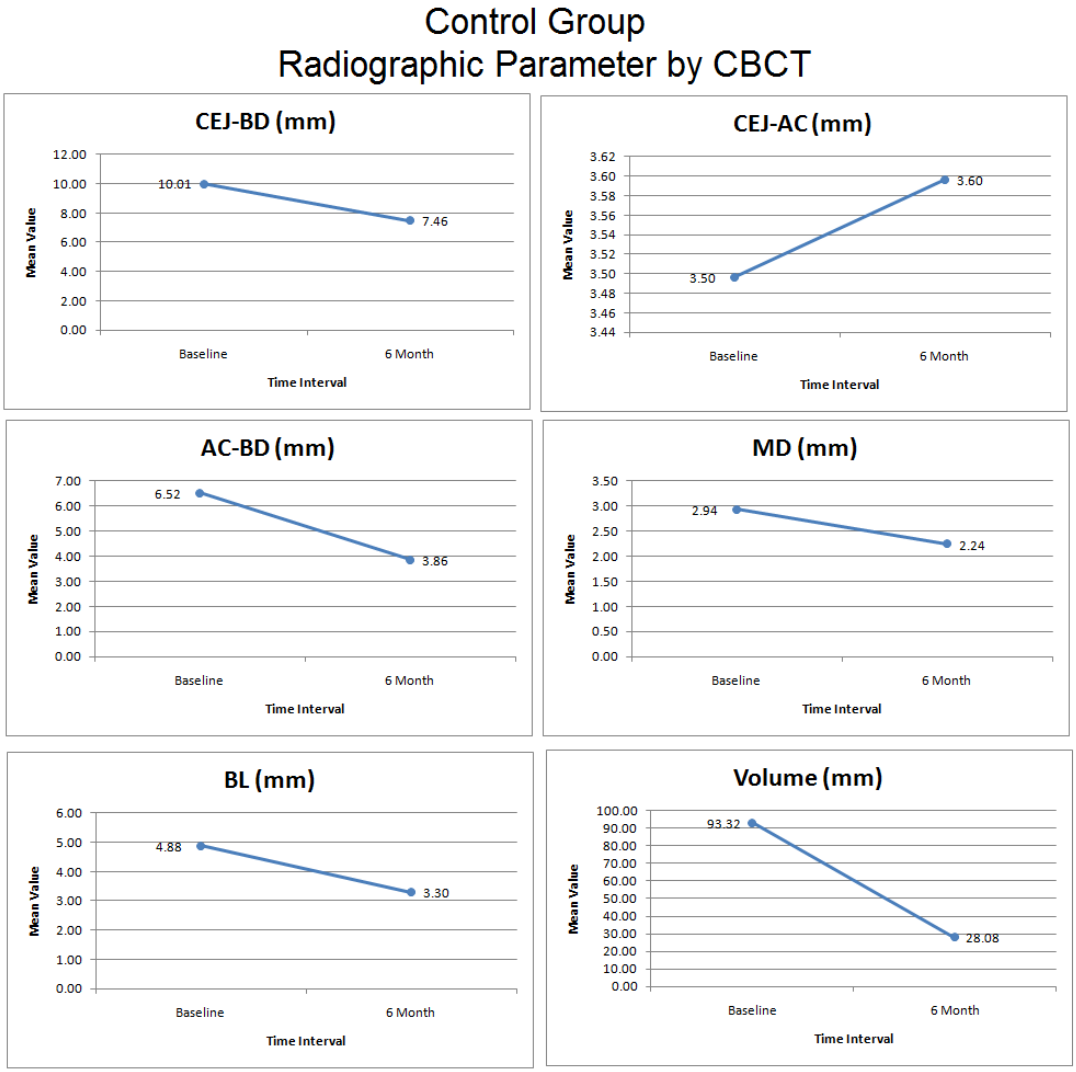
Graph 5: Line chart showing the mean gingival recession (mm) at three different time point in two groups



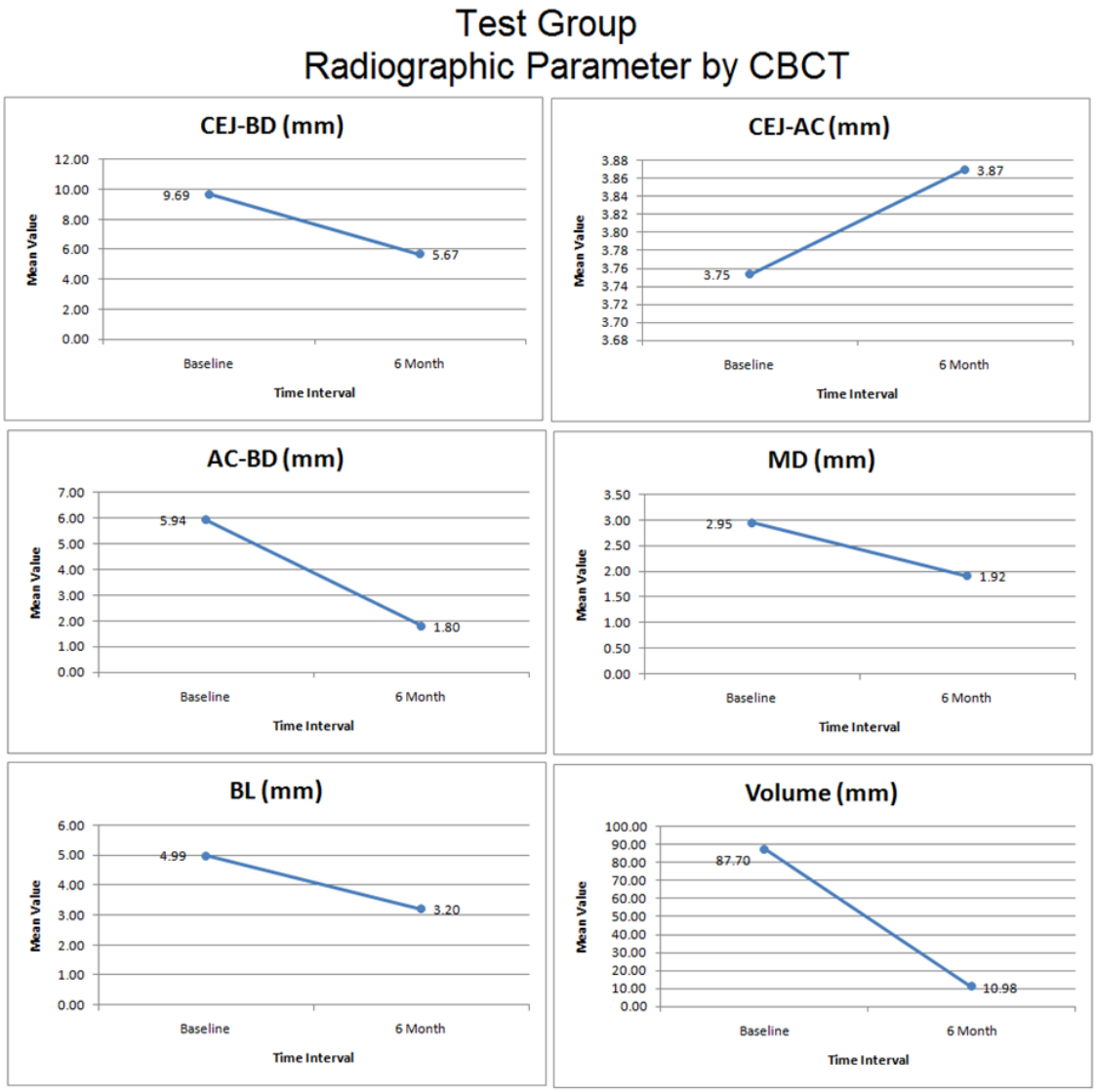
Graph 6: Bar chart showing the mean values of radiographic parameters by CBCT at baseline



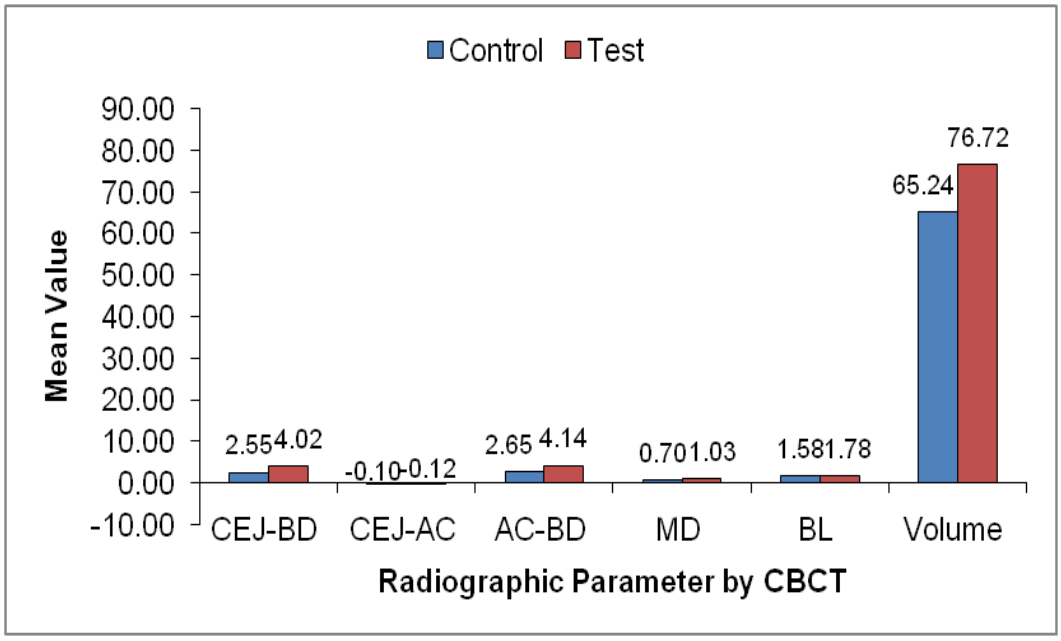
Graph 7: Bar chart showing the mean values of radiographic parameters by CBCT at 6 months



Graph 8: Line chart showing the mean values of radiographic parameters by CBCT at two different time point in control group



Graph 9: Line chart showing the mean values of radiographic parameters by CBCT at two different time point in test group



Graph 10: Bar chart showing the mean difference of radiographic parameters by CBCT in two groups

MASTER CHART

PLAQUE INDEX

SR NO	BASELINE	3 MONTH	6 MONTH
1	3	2.13	1.7
2	2.2	1.3	1.1
3	2.3	2.13	2
4	2.51	2.2	1.5
5	3.5	2	1.8
6	2.08	2.75	1.2
7	2.8	1.8	1
8	2.4	2.2	1.8
9	2.6	2.1	1.8
10	2.5	2	1.3
11	2.8	1.6	1
12	3.75	2.8	1.9
13	3.5	1.9	1.5
14	3	2.5	2
15	2.08	2.5	1.2
16	2.75	1.2	1
17	2.8	2	1.8
18	3.2	2.5	2
19	2.8	2.4	1.85
20	2.51	2.75	1.5
21	3.6	2.4	2
22	2.6	2.5	1.76
23	3.5	2.5	2.3
24	2.5	1.1	1
25	2.5	1.95	1.2
26	3.5	2.6	1.7
27	2.8	2.5	1.2
28	3.15	2.7	1.6
29	2.8	2.5	1.43
30	2.93	2.46	1.19

GINGIVAL INDEX

SR NO	BASELINE	3MONTH	6MONTH
1	2	1.3	0.7
2	2.1	1.4	0.8
3	1.4	1.08	1
4	1.6	1.4	1.2
5	1.7	1.25	1
6	1.62	1.5	1.1
7	1.2	0.9	0.8
8	1.5	1.2	1
9	2	1.5	1
10	2.3	1.8	1.2
11	1.1	1	0.8
12	2.5	1.6	1.2
13	2	1.3	1
14	1.8	1.25	0.95
15	1.6	1.3	1.1
16	1.4	0.9	0.8
17	2	1.4	0.8
18	2.3	1	0.6
19	2	1.63	1
20	1.9	1.08	1.2
21	2.1	1.51	1
22	1.95	1.5	1.2
23	1.8	1.2	0.8
24	1.1	0.95	0.85
25	1.65	1	0.9
26	1.43	1.02	0.58
27	1.66	1	0.6
28	1.33	1.2	0.9
29	1.88	1.3	1.01
30	1.5	1.17	1.3

CLINICAL PARAMETERS (BASELINE)

SR. NO.	Group I DFDBA			Group II DFDBA + CGFM		
	PPD(mm)	CAL(mm)	GR(mm)	PPD(mm)	CAL(mm)	GR(mm)
1	9	7	-2	10	8	-2
2	10	9	-1	9	8	-1
3	11	9	-2	10	8	-2
4	8	7	-1	8	7	-1
5	10	8	-2	10	8	-2
6	10	8	-2	9	8	-1
7	9	8	-1	11	9	-2
8	11	10	-1	9	7	-2
9	10	8	-2	10	7	-3
10	10	9	-1	9	8	-1
11	9	8	-1	10	8	-2
12	10	9	-1	9	8	-1
13	9	7	-2	10	8	-2
14	11	9	-2	9	7	-2
15	10	8	-2	9	7	-2
16	9	7	-2	9	8	-1
17	11	9	-2	9	8	-1
18	10	8	-2	10	8	-2
19	9	8	-1	9	8	-1
20	10	9	-1	9	7	-2
21	10	9	-1	10	9	-1
22	9	7	-2	9	9	0
23	8	7	-1	10	8	-2
24	9	6	-3	9	9	0
25	9	7	-2	10	8	-2
26	9	8	-1	10	8	-2
27	9	7	-2	9	7	-2
28	10	9	-1	9	7	-2
29	9	7	-2	9	8	-1
30	9	7	-2	9	7	-2

CLINICAL PARAMETERS (3 MONTH)

SR. NO.	Group I DFDBA			Group II DFDBA + CGFM		
	PPD(mm)	CAL(mm)	GR (mm)	PPD(mm)	CAL(mm)	GR (mm)
1	3	4	1	3	5	2
2	4	4	0	3	3	0
3	3	4	1	3	4	1
4	4	4	0	2	4	2
5	4	4	0	4	4	0
6	4	4	0	3	3	0
7	4	4	0	4	4	0
8	4	4	0	3	3	0
9	4	4	0	3	4	1
10	4	4	0	3	4	1
11	3	4	1	4	4	0
12	4	4	0	3	3	0
13	3	4	1	3	3	0
14	4	4	0	3	4	1
15	4	4	0	3	4	1
16	4	4	0	3	3	0
17	4	4	0	4	4	0
18	4	4	0	2	3	1
19	4	4	0	3	4	1
20	4	4	0	3	3	0
21	3	4	1	3	3	0
22	4	5	1	4	4	0
23	4	5	1	3	3	0
24	4	4	0	3	3	0
25	4	4	0	3	3	0
26	5	5	0	3	3	0
27	3	5	2	3	3	0
28	4	4	0	3	3	0
29	4	4	0	3	3	0
30	3	4	1	3	3	0

CLINICAL PARAMETERS (6 MONTH)

SR. NO.	Group I DFDBA			Group II DFDBA + CGFM		
	PPD(mm)	CAL(mm)	GR (mm)	PPD(mm)	CAL(mm)	GR (mm)
1	2	4	2	2	4	2
2	2	3	1	2	3	1
3	3	3	0	3	4	1
4	2	2	0	3	4	1
5	2	3	1	2	3	1
6	2	2	0	2	3	1
7	3	3	0	3	3	0
8	4	4	0	2	3	1
9	3	4	1	3	4	1
10	3	4	1	2	4	2
11	3	4	1	3	3	0
12	3	5	2	3	3	0
13	3	3	0	2	2	0
14	3	3	0	3	3	0
15	3	3	0	2	3	1
16	2	4	2	2	3	1
17	3	4	1	2	3	1
18	4	4	0	2	3	1
19	4	4	0	3	4	1
20	3	4	1	2	2	0
21	3	4	1	2	3	1
22	3	5	2	2	4	2
23	3	5	2	3	3	0
24	3	4	1	2	3	1
25	3	4	1	3	3	0
26	3	4	1	2	3	1
27	3	5	2	2	2	0
28	3	4	1	3	3	0
29	3	4	1	3	3	0
30	2	4	2	2	3	1

CBCT MEASUREMENTS OF INTRABONY DEFECT DIMENSION AT BASELINE

SR. NO	Group I DFDBA						Group II DFDBA + CGFM					
	CEJ -BD	CEJ - AC	AC-BC	MD	BL	VOL (mm^3)	CEJ -BD	CEJ - AC	AC -BC	MD	BL	VOL (mm^3)
1	10.7	4.8	5.9	3.2	7.6	143.488	10	3.4	6.6	3.5	7.2	166.32
2	8.4	4	4.4	3.4	6.1	91.256	8.8	3	5.8	2.5	6.2	89.9
3	9	3.4	5.6	2.4	6.8	91.392	9.4	3.6	5.8	3.5	5	101.5
4	9.6	4	5.6	2.8	5	78.4	9.8	3.9	5.9	3	7.2	127.44
5	11	3.2	7.8	3.2	4.8	119.808	10	3.5	6.5	2.6	6.5	109.85
6	9	3.6	5.4	2.4	5.8	75.168	9	3	6	2.8	6.4	107.52
7	10.4	3	7.4	3.8	4	112.48	10	3.6	6.4	2.6	6	99.84
8	9.2	2.8	6.4	2.4	3.8	58.368	9.8	3.4	6.4	3.6	5.6	129.024
9	9.5	3	6.5	2.8	5.5	100.1	8.9	3	5.9	3	4.4	77.88
10	9.5	3	6.5	2.8	5.8	105.56	10	4	6	3.4	4.9	99.96
11	10.4	3.5	6.9	3	4.9	101.43	9.3	4	5.3	2.5	4.3	56.975
12	9.6	3.2	6.4	2.3	4.4	64.768	10	4	6	2.8	5.1	85.68
13	9.8	2.5	7.3	2.6	4.9	93.002	9.4	3.8	5.6	2.8	4.6	72.128
14	10.5	3.7	6.8	3	4.3	87.72	10.2	4.8	5.4	3	5.2	84.24
15	12	4	8	3.8	4.9	148.96	9.2	3.4	5.8	2.9	6.2	104.284
16	9.9	3.8	6.1	2.8	4.8	81.984	9.6	4	5.6	3.3	3.8	70.224
17	9.9	4	5.9	2.6	4.2	64.428	8.8	3.2	5.6	2.8	3	47.04
18	10.5	3.5	7	2.4	3.8	63.84	11	3.6	7.4	2.4	2.7	47.952
19	9.1	3.4	5.7	2.8	4.8	76.608	8.8	4.9	3.9	3.2	5.4	67.392
20	10.5	3.4	7.1	3.2	4.3	97.696	10	4	6	2.8	5.2	87.36
21	10.8	3.6	7.2	3.6	4	103.68	9.6	4	5.6	2.6	4.8	69.888
22	9.8	3.5	6.3	2.8	5.4	95.256	11	3.4	7.6	2.6	5.9	116.584
23	9.8	4.2	5.6	2.8	4.4	68.992	9	3.8	5.2	3.6	5.7	106.704
24	10.2	3	7.2	3	4.8	103.68	9.6	3.6	6	2.4	2.7	38.88
25	9.9	3	6.9	2.6	5.2	93.288	10.2	4	6.2	2.5	4.8	74.4
26	12	3.8	8.2	3.2	6	157.44	9.5	3.8	5.7	3	4.8	82.08
27	10	3	7	2.8	3.4	66.64	9.6	3.5	6.1	3.4	3.8	78.812
28	9.8	4	5.8	3	4.5	78.3	10.4	4.4	6	3	4.3	77.4
29	9.4	3	6.4	2.8	3.5	62.72	9.8	4.2	5.6	2.8	3.4	53.312
30	10.2	4	6.2	3.8	4.8	113.088	10	3.8	6.2	3.6	4.5	100.44

CBCT MEASUREMENTS OF INTRABONY DEFECT DIMENSION AT 6 MONTH

SR. NO.	Group I DFDBA						Group II DFDBA + CGFM					
	CEJ -BD	CEJ-AC	AC-BC	MD	BL	VOL (mm^3)	CEJ -BD	CEJ - AC	AC-BC	MD	BL	VOL (mm^3)
1	6.8	4.9	1.9	2.2	5.4	22.572	4.9	3.5	1.4	2	4	11.2
2	7.4	4	3.4	2.4	4.5	36.72	4.2	3.1	1.1	1.6	3.8	6.688
3	5.2	3.5	1.7	1.9	4	12.92	4.7	3.1	1.6	2.6	3	12.48
4	6.2	4.1	2.1	2	3	12.6	4.5	4	0.5	1.6	4.2	3.36
5	8	3.3	4.7	2.4	3	33.84	5	3.4	1.6	2	3.6	11.52
6	7	3.7	3.3	1.8	2.5	14.85	4	2.8	1.2	2	3.4	8.16
7	7.8	3.2	4.6	2.9	2	26.68	4.8	3.7	1.1	1.6	4.5	7.92
8	7	2.9	4.1	1.8	2.8	20.664	4.4	3.4	1	2.2	3.5	7.7
9	8	3.1	4.9	2	3	29.4	4.6	3.2	1.4	2	3.2	8.96
10	7.8	3.1	4.7	2.2	3.5	36.19	6.7	4.5	2.2	2.2	3.2	15.488
11	8.4	3.6	4.8	2.3	3.4	37.536	5.7	4.2	1.5	2	3	9
12	7.3	3.3	4	1.8	4.1	29.52	6	4.2	1.8	2.2	4	15.84
13	6.8	2.6	4.2	2	3.6	30.24	6.4	3.9	2.5	2	3	15
14	6.7	3.8	2.9	2.4	2.6	18.096	6	4.8	1.2	2.2	2.8	7.392
15	6.8	4.1	2.7	2.8	3	22.68	5.7	3.5	2.2	1.8	4	15.84
16	6.3	3.9	2.4	2.2	3	15.84	5.6	4.1	1.5	2.4	2.5	9
17	6.4	4.1	2.3	2	2.8	12.88	4.8	3.3	1.5	1.6	2	4.8
18	9	3.6	5.4	1.9	2.4	24.624	6	3.7	2.3	1.4	2	6.44
19	6.8	3.5	3.3	2.2	3.8	27.588	5.6	4.9	0.7	2	3	4.2
20	7.6	3.5	4.1	2.5	2	20.5	6.5	4.2	2.3	1.7	4	15.64
21	8.4	3.7	4.7	2.9	2.8	38.164	5.4	4.2	1.2	1.4	3.5	5.88
22	7.8	3.6	4.2	2	4	33.6	6.8	3.5	3.3	1.9	4.2	26.334
23	8.4	4.3	4.1	2	3.5	28.7	6	3.9	2.1	2	3.8	15.96
24	8	3.1	4.9	2.2	3.8	40.964	5.6	4.1	1.5	1.4	1.7	3.57
25	7.5	3.2	4.3	2	3.2	27.52	7	4.3	2.7	1.7	3.2	14.688
26	8.4	3.9	4.5	2.6	3.8	44.46	6.4	3.9	2.5	2.2	2.8	15.4
27	8.4	3.1	5.3	2.2	3.5	40.81	7.2	3.6	3.6	1.8	2.2	14.256
28	7.8	4.1	3.7	2.2	3.8	30.932	6.9	4.9	2	2	3	12
29	8	3.1	4.9	2.4	2	23.52	6	4.3	1.7	1.8	2	6.12
30	7.8	4	3.8	3	4.2	47.88	6.7	3.9	2.8	2.2	3	18.48

DEPARTMENT OF PERIODONTOLOGY

Comparative evaluation of Demineralized Freeze-Dried Bone Allograft with and without Concentrated Growth Factors Membranein the treatment of periodontal intrabony defects: A clinico-radiographic study.

CASE HISTORY PROFORMA

NAME: **OPD NO.**

AGE/SEX: **DATE:**

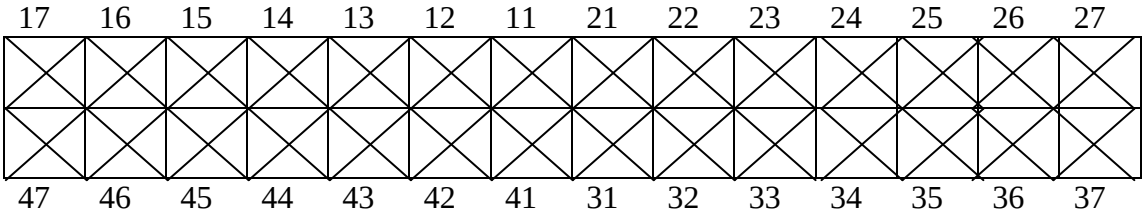
OCCUPATION: **ADDRESS:**

CHIEF PERIODONTAL COMPLAINT:

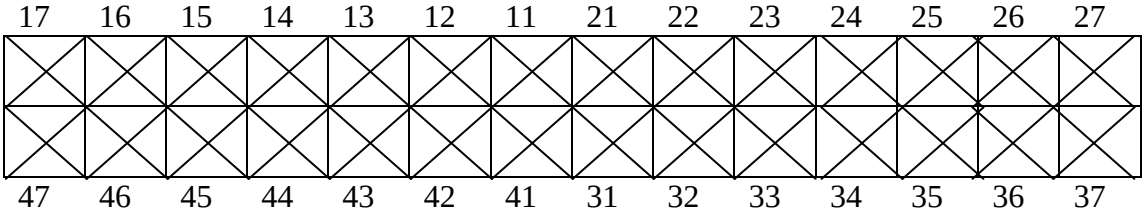
PAST DENTAL HISTORY:

PAST MEDICAL HISTORY:

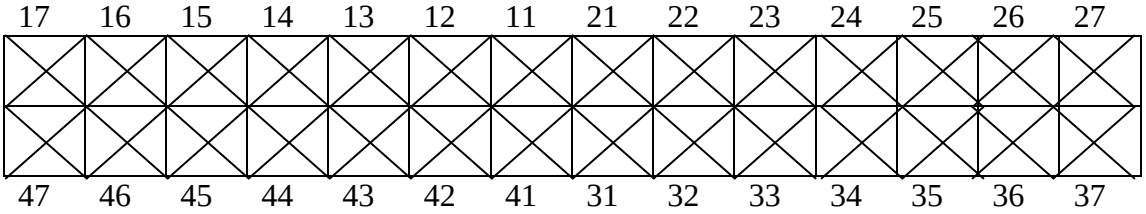
PROBING POCKET DEPTH (mm) (BASELINE):



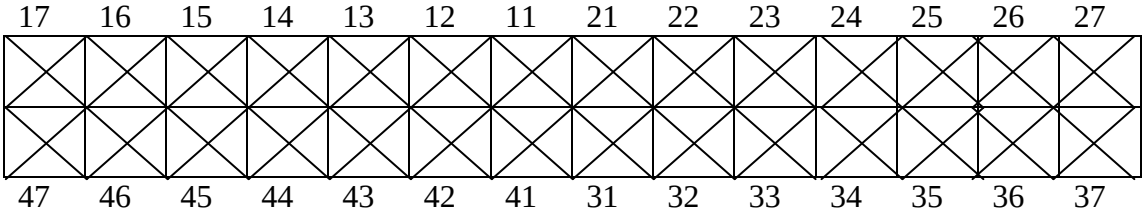
PROBING POCKET DEPTH (mm) (3 MONTHS):



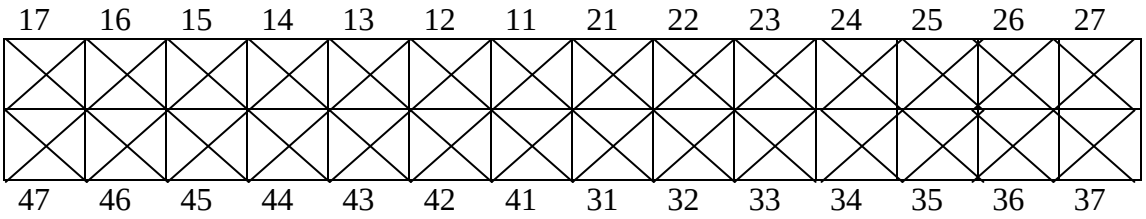
PROBING POCKET DEPTH (mm) (6 MONTHS):



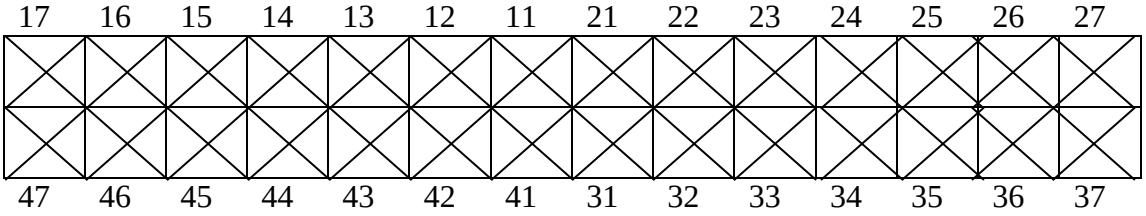
CLINICAL ATTACHMENT LEVEL (mm) (BASELINE)



CLINICAL ATTACHMENT LEVEL (mm) (3 MONTHS)

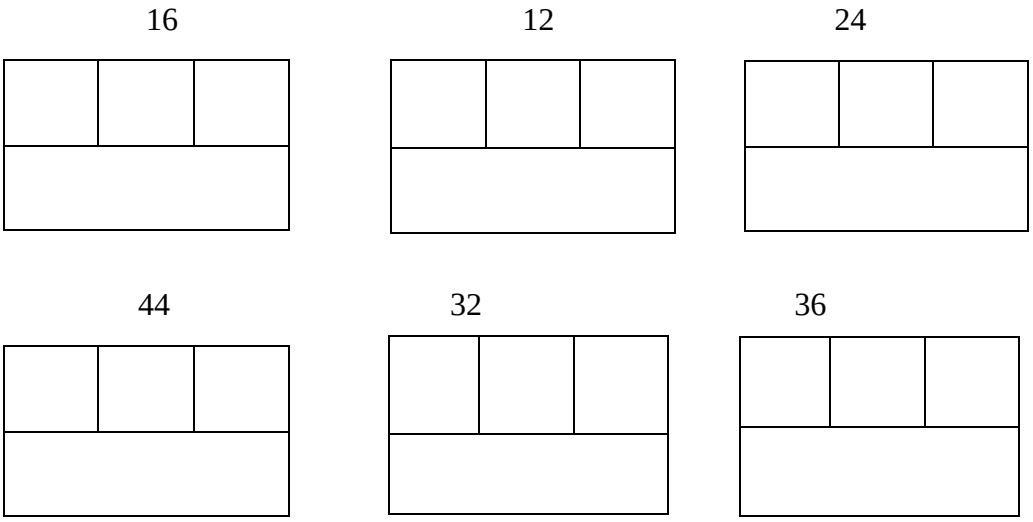


CLINICAL ATTACHMENT LEVEL (mm) (6 MONTHS)



INDICES

PLAQUE INDEX (Sillness and Loe 1964) Baseline



SCORE: Total Score of all teeth

Total number of teeth examined

PLAQUE INDEX (Sillness and Loe 1964) 3 months

16 12 24

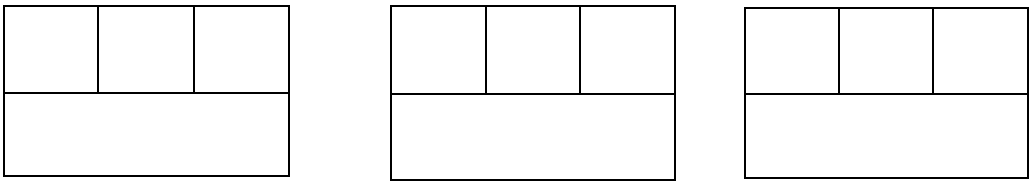
44 32 36

SCORE: Total Score of all teeth

Total number of teeth examined

PLAQUE INDEX (Sillness and Loe 1964)6 months

16 12 24



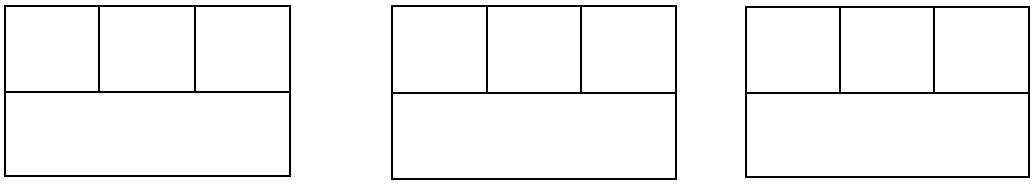
44 32 36

SCORE: Total Score of all teeth

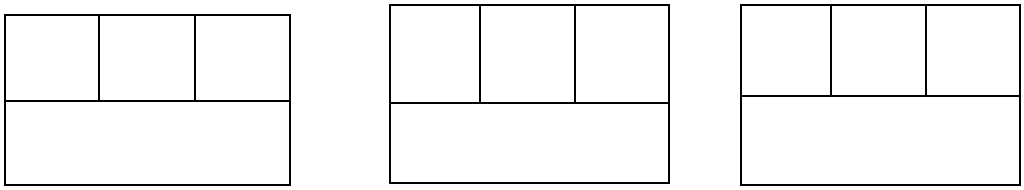
Total number of teeth examined

GINGIVAL INDEX (Loe and Sillness 1963) Baseline

16 12 24



44 32 36

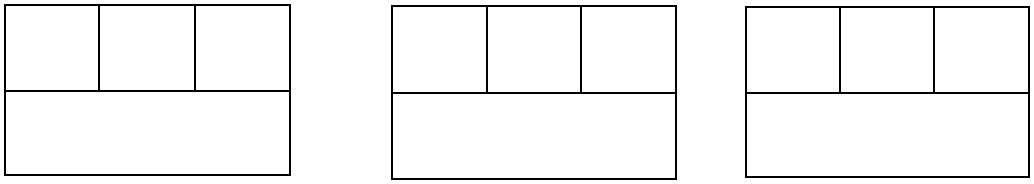


SCORE: Total Score of all teeth

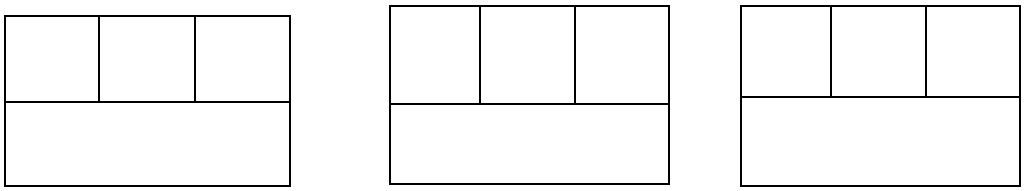
Total number of teeth examined

GINGIVAL INDEX (Loe and Sillness 1963) 3 Months

16 12 24



44 32 36

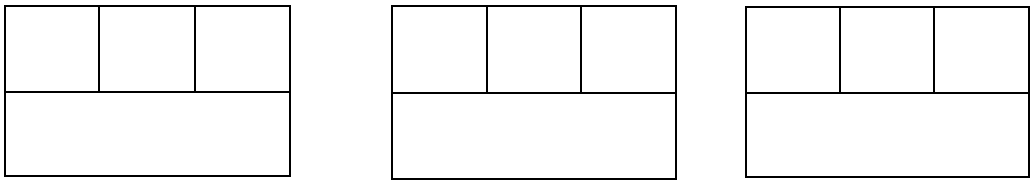


SCORE: Total Score of all teeth

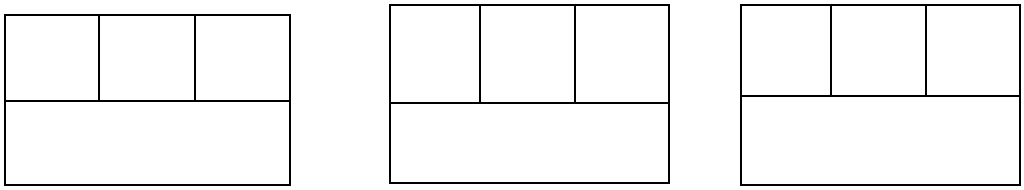
Total number of teeth examined

GINGIVAL INDEX (Loe and Sillness 1963) 6 Months

16 12 24



44 32 36



SCORE: Total Score of all teeth

Total number of teeth examined

RADIOGRAPHIC INVESTIGATION

Periodontal intrabony defect dimensions (CBCT): at baseline and 6 month

Tooth No.	Material Used	Baseline Bone Defect Height	Bone Defect Height (6 Months)	Baseline Bone Defect Width	Bone Defect Width (6 Months)	Baseline Bone Defect Depth	Bone Defect Depth (6 Months)

Tooth No.	Baseline Bone Defect Volume	Bone Defect Volume (6 Months)

(Confidential)

Informed Consent Form

"Comparative evaluation of Demineralized Freeze-Dried Bone Allograft with and without Concentrated Growth Factors Membrane in the treatment of periodontal intrabony defects: A clinico-radiographic study."

NAME: Mr./Master/Mrs./Miss._____
Resident of: _____
_____aged _____ years, exercising my free will/choice, without any pressure/lure of incentive in any form, hereby give my consent for the project to be conducted by **Dr Gopal Samarth.**

I acknowledge the receipt of "patient's information sheet", and also the doctor has informed me about this research project suitably and sufficiently to my satisfaction.
I agree to undergo this surgical periodontal treatment upon me which includes placing Demineralized freeze dried bone allograft and Concentrated Growth Factors Membrane at one Periodontal intrabony defect and only Demineralized freeze dried bone allograft at another periodontal intrabony defect in my oral cavity. I authorize placement of Bone allograft and membrane in the defects. Potential benefits, risks and complications related to the materials used in surgery have been explained to me.
I agree to let my X-rays, photographs, blood investigations, other investigations to be taken as required.

I am aware that in comparison to conventional radiographs, the CBCT scans will involve more radiation exposure but at same time it will give more details of my diseased condition thus enabling a better treatment.

I consent to the administration of anesthesia or other medications before, during or after the procedure by qualified personnel. I understand that all anesthetics or sedation medications include the very rare potential of risks or complications, such as damage to vital organs including the brain, heart, lungs, liver and kidneys; paralysis; cardiac arrest; and/or death from both known and unknown causes.

I understand that there are potential risks, complications and side effects associated with any dental procedure. Although it is impossible to list every potential risk, complication and side effect, I have been informed of some of the possible risks, complications and side effects of periodontal surgery.
I agree to take part in this project and will not mix any other projects during the period of this trial. I shall report to the dental hospital or other place where called on given appointment dates and time.

I certify that I have read or had read to me the contents of this form.

_____Date_____
Patient /legally authorized representative signature