EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS – A SPLIT MOUTH STUDY

A Dissertation submitted in
partial fulfillment of the requirements
for the degree of

MASTER OF DENTAL SURGERY

BRANCH – II
PERIODONTOLOGY

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY
Chennai – 600 032

2016 - 2019

CERTIFICATE BY THE GUIDE

This is to certify that **Dr.S.RUBINE**, Post Graduate student (2016–2019) in the Department of Periodontology, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003 has done this dissertation titled **"EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS –A SPLIT MOUTH STUDY"** under my direct guidance and supervision in partial fulfillment of the regulations laid down by **Tamil Nadu Dr. M.G.R. Medical University**, Chennai – 600 032 for **M.D.S.,** (Branch – II) **Periodontology** degree examination.

Dr. JAISHREE TUKARAM KSHIRSAGAR, M.D.S.,

Professor and Guide

Department of Periodontology

TAMIL NADU GOVERNMENT DENTAL COLLEGE AND HOSPITAL

CHENNAI – 600 003

ENDORSEMENT BY HEAD OF THE DEPARTMENT / HEAD OF THE INSTITUTION

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Dr. K. MALATHI, M.D.S.,
PROFESSOR & H.O.D.,
Department of Periodontology.

Dr. G. VIMALA, M.D.S.,
Principal,
TNGDC&H

TAMIL NADU GOVERNMENT DENTAL COLLEGE AND HOSPITAL
CHENNAI – 600 003

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TITLE OF STUDY	EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS –A SPLIT MOUTH STUDY
PLACE OF STUDY	TAMIL NADU GOVERNMENT DENTAL COLLEGE AND HOSPITAL, CHENNAI – 600 003.
DURATION OF THE COURSE	3 YEARS
NAME OF THE GUIDE	Dr. JAISHREE TUKARAM KSHIRSAGAR, M.D.S
HEAD OF THE DEPARTMENT	Dr. K. MALATHI, M.D.S

I hereby declare that this dissertation titled **"EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS –A SPLIT MOUTH STUDY"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. JAISHREE TUKARAM KSHIRSAGAR, M.D.S., Professor and Guide,** Department of Periodontology, Tamil Nadu Government Dental College and Hospital, Chennai -600003.

Dr. JAISHREE TUKARAM KSHIRSAGAR, M.D.S
Guide

Dr. G. VIMALA, M.D.S
Principal

Dr. S.RUBINE
Student

TAMIL NADU GOVERNMENT DENTAL COLLEGE AND HOSPITAL
CHENNAI – 600 003

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A special mention of thanks to all of my study subjects for their very kind cooperation throughout my study.

Last, but not the least, I thank **GOD ALMIGHTY** for his blessings.

TRIPARTITE AGREEMENT

This agreement herein after the "Agreement" is entered into on this day -------- between the Tamil Nadu Government Dental College and Hospital represented by its **Principal** having address at Tamil Nadu Government Dental College and Hospital, Chennai – 600 003, (hereafter referred to as, 'the college')

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Dr. S.RUBINE, aged 27 years currently studying as **Post Graduate student** in Department of Periodontology, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003 (herein after referred to as the 'PG student and Principal Investigator'),

And

Mrs. Dr. JAISHREE TUKARAM KSHIRSAGAR, M.D.S., aged 49 years working as **Professor** in Department of Periodontology at the Tamil Nadu Government Dental College and Hospital, Chennai – 600 003 (hereafter referred to as 'Co-investigator'),

Whereas the PG student as part of her curriculum undertakes this research on **"EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS – A SPLIT MOUTH STUDY"** for which purpose the Co – investigator and the college shall provide the requisite infrastructure based on availability and also provide facility to the PG student as to the extent possible as a Principal Investigator

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Student Guide

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1.

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TELEPHONE : 044-253403343
FAX: 044- 25300681

Ref No: R. C. NO: 0420/DE/2017 date : 15/05/2017
Sub: IEC review of the research proposals,

Title of the work: EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS – A SPLIT MOUTH STUDY

Investigator: DR. S. RUBINE,
II YEAR MDS

Department : DEPARTMENT OF PERIODONTICS,
TAMIL NADU GOVT. DENTAL COLLEGE & HOSPITAL,CHENNAI-3.

Thank you for submitting your research proposal , which was considered at the Institutional Ethics Committee meeting held on the 27/02/2017, at TN Govt. Dental College. The documents related to the study referred above were discussed and reviewed. The decision of the members of the committee , the secretary and the Chairperson IEC of TN Govt. Dental College is here under:

Approved	Approved and advised to proceed with the study
Approved with suggestions	----------

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CERTIFICATE

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ABSTRACT

BACKGROUND: Modern day periodontics aims at maintaining the health of teeth and their supporting structures with the main goal of controlling the infection and regenerating the lost supporting structures. Bovine porous bone mineral is a Xenograft and they induce bone formation through osteoinductive property. One of the recent approaches is to enhance the bone graft healing by growth factors. Concentrated growth factor (CGF), an advanced second generation platelet concentrate is a rich autologous source of various growth factors and leukocytes and has a strong potential to influence the cellular mechanisms responsible for periodontal regeneration.

AIM: Aim of the present study is to evaluate, the effectiveness of Concentrated growth factor in combination with Bovine porous bone mineral as compared to Bovine porous bone mineral alone in the treatment of periodontal intrabony defects.

MATERIALS AND METHODS: A total number of 20 intrabony defects in 10 systemically healthy patients were selected randomly for the purpose of the study. After the Phase-I therapy, the defects were equally divided into two groups and treated with concentrated growth factor and bovine porous bone mineral and bovine porous bone mineral alone. Clinical parameters such as plaque index (PI), gingival bleeding index (GBI), probing pocket depth (PPD), and clinical attachment level (CAL) were recorded at baseline, 6 months and 1 year post-operatively. In both the groups, radiographic analysis was performed at baseline, 6 months and 1 year post operatively.

RESULTS: Significant reduction in the mean probing depth and gain in clinical attachment level was observed in CGF=BPBM and BPBM groups as compared to baseline but there was no significant difference between the two groups at 6 months ($p=0.655$ and $p=0.250$ respectively) and 1 year ($p=0.247$ and $p=0.70$ respectively). Radiographically, bone fill%, bone crest change% and defect resolution% was significantly higher in CGF=BPBM group than BPBM group at the end of 6 months ($p=0.005$, $p=0.02$, $p=0.019$ respectively) and at 1 year ($p=0.000$, $p=0.007$, $p=0.001$ respectively).

CONCLUSION: Within the limits of the present study, it can be concluded that both the modalities of treatment were efficient in improving the clinical as well as radiographic parameters. The addition of concentrated growth factor to bovine porous bone mineral has demonstrated significantly successful and promising results. Thus in future, clinical trials with larger sample size may be employed to further explore the potential benefits of CGF as a grafting material.

KEY WORDS: Concentrated growth factor, Bovine porous bone mineral, Intra bony defect, Periodontal Regeneration.

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LIST OF ABBREVIATIONS

ABBM	Anorganic bovine bone mineral
AC	Alveolar crest
BCC	Bone crest change
BDGF	Brain derived growth factor
BF	Bone fill
BG	Bone graft
BMP	Bone morphogenic protein
BMSC	Bone marrow stromal cells
BP	Base of the pocket
BPBM	Bovine porous bone mineral
CAF	Coronally advanced flap
CAL	Clinical attachment level
CD	Cluster of differentiation
CEJ	Cemento enamel junction
CF	Correction factor
CGF	Concentrated growth factor
DBM	Demineralised bone matrix
DD	Defect depth
DFDBA	Demineralized freeze-dried bone allograft
DR	Defect resolution
EGF	Epithelial growth factor
FGF	Fibroblast growth factor
GBI	Gingival bleeding index
GM	Gingival margin
GR	Gingival recession

GTR	Guided tissue regeneration
HA	Hydroxyapatite
hPDLC	Human periodontal ligament cells
IGF	Insulin-like growth factor
KGW	Keratinised gingival width
LBG	Linear bone growth
MRC	Mean root coverage
OFD	Open flap debridement
PDGF	Platelet-derived growth factor
PDL	Periodontal ligament
PI	Plaque index
PPD	Periodontal probing depth
PRF	Platelet rich fibrin
PRP	Platelet rich plasma
RA	Root apex
RBC	Red blood cells
RP	Reference point
SCAP	Stem cells of the apical papilla
SD	Standard deviation
SPSS	Statistical Package for Social Science
TGF	Transforming growth factor
TNF	Tumour necrosis factor
UNC	University of north carolina
VEGF	Vascular endothelial growth factor

INTRODUCTION

Regeneration is one of the most dominant objectives of today's rehabilitation therapies. The goals of periodontal therapy is not only to arrest disease progression but also regeneration of structures lost due to disease[1].

The aims of periodontal regeneration are to obtain: (i) gain in the periodontal attachment and bone level of a periodontally compromised tooth; (ii) a decrease in pocket depth; and (iii) no, or a minimal gingival recession[2].

Tissue loss due to periodontal disease is typically treated by using various regenerative procedures, including bone grafts, guided tissue regeneration (GTR) and growth factors, to regenerate the tooth's supporting tissues[3].

An ideal graft material is the one that is osteoinductive, easy to manipulate, absorbable, abundant and easily available. Bovine porous bone mineral (Bio-Oss Collagen) is one of the material used in periodontal regeneration. It is prepared by protein extraction of bovine bone which is similar in structure to human cancellous bone and has the ability to enhance bone formation[4].

Platelets are the major resource of autogenous growth factors which are the first cells to reach a wound site to initiate the healing process[5].

Platelets are known to release high quantities of growth factors such as Platelet-derived growth factor (PDGF), Transforming growth factor-β1 (TGF-β1) and β2 (TGF-β2), Fibroblast growth factor (FGF), Vascular endothelial growth factor (VEGF), and Insulin-like growth factor (IGF)

These growth factors are deposited in the extracellular matrix and are released during matrix degradation and they act as a part of a complex network of signals with mutual effects during tissue remodeling and regeneration[6].

Concentrated growth factor is an advanced 2nd generation platelet concentrate (Sacco in 2006). It is a fibrin rich organic matrix which contains growth factors, platelets, leukocytes and CD34+ stem cells which help in regenerating process[7].

Difference in centrifugation speeds of CGF permit the isolation of a much larger and denser fibrin matrix richer in growth factors than typically found in PRP or PRF.

It improves wound stability, which is essential for the establishment of a new connective tissue attachment to a root surface. It also provides a scaffold supporting cytokine attachment and cellular migration[8].

There are only limited studies available regarding the use of CGF in combination with various bone graft materials in periodontal regeneration.

The purpose of this study is to evaluate the beneficial role of CGF mixed with bone graft to accelerate bone formation in the healing of intrabony defect areas.

AIM AND OBJECTIVES

AIM:

- The aim of this study is to evaluate the effectiveness of concentrated growth factor in combination with Bovine porous bone mineral as compared to Bovine porous bone mineral alone in the treatment of periodontal intrabony defects.

OBJECTIVES:

The objectives of the study are:

- To **clinically** evaluate and compare the use of concentrated growth factors in conjugation with bovine porous bone mineral and bovine porous bone mineral alone in the management of intrabony defects.
- To **radiographically** compare and assess the regeneration of lost alveolar bone by the use of concentrated growth factors in conjugation with bovine porous bone mineral and bovine porous bone mineral alone in the management of intrabony defects.

REVIEW OF LITERATURE

Periodontitis is an inflammatory disease that leads to the loss of tooth supporting tissues. Tissue loss caused by periodontal disease is typically managed by various regenerative procedures.[9]

Regeneration is the natural renewal of a structure, produced by growth and differentiation of new cells and intercellular substances to form new tissues or parts. Regeneration occurs through growth from the same type of tissue that has been destroyed or from its precursor **(Melcher 1976)** [10].

Periodontal regeneration is defined histologically as regeneration of the tooth's supporting tissues, including alveolar bone, cementum and periodontal ligament over the diseased root surface[11].

Periodontal-regeneration is performed to improve the long-term clinical outcomes of periodontally compromised teeth presenting with deep pockets and reduced periodontal support.[12]

The ultimate goal of periodontal therapy is to regenerate periodontal tissues lost due to periodontitis. For this purpose bone grafts and guided tissue regeneration (GTR) membranes or their combinations have been used. [12,13]

Bone grafts are widely used to promote bone formation and periodontal regeneration. Bone grafts and their substitutes provide a structural framework for clot development, maturation and remodeling that supports bone formation in osseous defects.[14]

BONE GRAFTS:

Ideal characteristics of a bone graft are: should be non-toxic, nonantigenic, resistant to infection, not leading to root resorption or ankylosis, strong and resilient, easily adaptable, readily and sufficiently available, requires minimal surgical procedure, stimulate new attachment and be able to trigger osteogenesis, cementogenesis and formation of a functional periodontal ligament.[15]

For any graft material to be considered as a successful regenerative material, it should have clear histological, clinical and radiographic evidence of the following criteria:[16]

1. Biologic acceptability: the graft should not have any side effects or cause any unwanted tissue reaction.

2. Resorbability: the graft should resorb slowly and be replaced by the patient's own bone.

3. Regeneration: the graft should have evidence of regenerative ability with formation of new bone, cementum and periodontal ligament fibers.

4. Defect fill: the graft should have evidence of bone fill.

5. Stability: the outcome of the treatment should be stable at reevaluation visits.

A wide range of graft materials have been applied, including autografts, allografts, xenografts, and synthetic materials.[17]

Xenografts are obtained from vital tissues of cow or coral. Bio-Oss is a bovine bone that is processed by complete removal of the organic components.[18]

Bovine Porous Bone Mineral: (BIO OSS)

- Ideal environment for new bone formation
- Excellent handling properties
- Excellent osseointegration
- Highly hydrophilic

The unique micro- and macropore structure of Bio-Oss is an important factor contributing to high Hydrophilicity. The micropores ensure the high capillary action, and consequently the fast liquid uptake in Bio-Oss. The interconnected macropores allow blood cells and proteins to enter into the Bio-Oss particles enabling effective osseointegration of Bio-Oss particles.[19]

Bio-Oss undergoes a low heat (300˚C) chemical extraction process by which all organic components are removed, but maintains the natural architecture of bone **(Gross 1997)**.[21]

When evaluating parameters such as inner surface area, porosity, crystallite size, and calcium to phosphorous ratio, Bio-Oss most closely resembles human cancellous bone as compared to DFDBA and synthetic hydroxyapatite **(Giovanoli 1994[22], Valdre et al. 1995[23])**.

Bio-Oss was evaluated by **Chen et al. 1996**[24], with regards to its osteogenic potential and was found to support bone ingrowth when implanted into the muscle of rabbits.

With regards to graft activity following placement, **Thaller et al. (1994)**[25], found that Bio-Oss resorbed and underwent normal physiologic bone remodeling in the rabbit calvarial model.

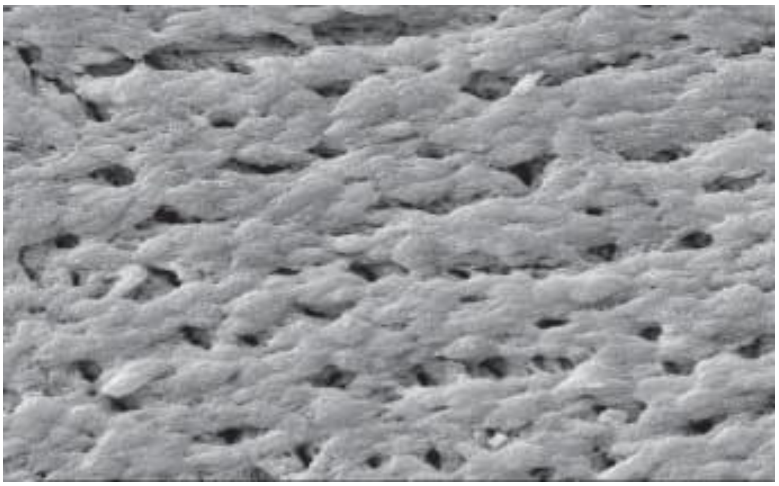


Figure 1: *Micro structure of bone graft (The micropores that ensure the high capillary action, and consequently the fast liquid uptake in Bio-Oss)*

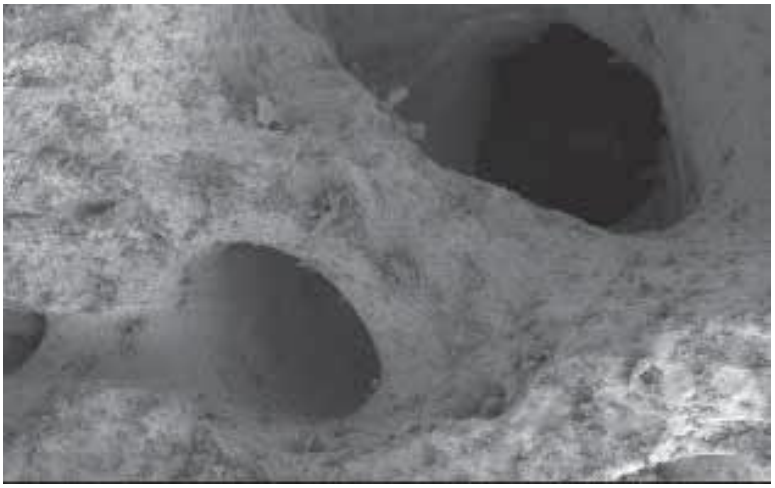


Figure 2: *Micro structure of bone graft (The interconnected macropores that allow blood cells, osteoblasts, osteoclasts and proteins to enter into the Bio-Oss particles enabling effective osseointegration of Bio-Oss particles)*

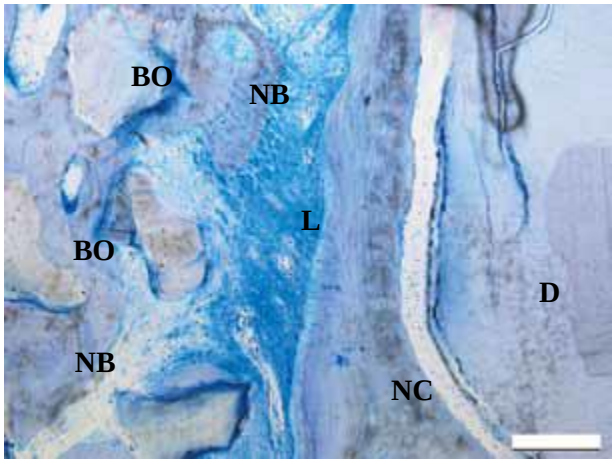
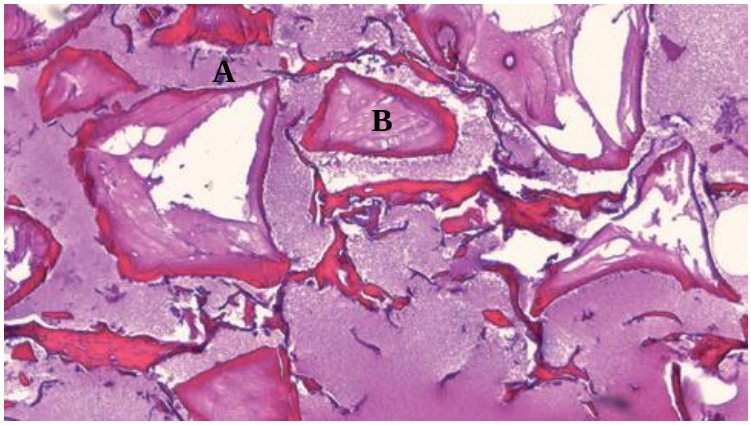


Figure 3: *Histological section of newly formed bone (The histologic assessment demonstrates the presence of new periodontal ligament, cementum, and bone. The newly formed woven bone can be observed maturting into bone trabeculae completely surrounding Bio-Oss particles. BO=Bio-Oss; NB=new bone L=ligament; NC=new cementum; OC=old cementum; D=dentin)*[20]



A - Blood serum components

B - Geistlich Bio-Oss®

Figure 4: *Histological section of bone matrix (A provisional matrix consisting of blood serum components surrounds Geistlich Bio-Oss®. Protein deposits are found between the biomaterial particles. The Geistlich Bio-Oss® pores are filled with serum proteins and serve as a reservoir for growth factors.)*

Clergeau et al. (1996)[26] obtained biopsies from intrabony defects in humans treated with Bio-Oss plus collagen. The specimens, when analysed with the electron microscope, demonstrated vascular channels co-existing with osteoclastic lacunae at the surface and many areas of bone apposition.

Camargo PM et al (2000)[27]conducted a controlled re-entry study on the effectiveness of bovine porous bone mineral used in combination with a collagen membrane of porcine origin in the treatment of intrabony defects in humans. Surgical reentry of the treated defects revealed a significantly greater amount of defect fill in favour of experimental sites (differences of 2.67±0.91 mm on buccal and 2.54±0.87 mm on lingual measurements. The results of this study shows that clinical resolution of intrabony defects can be attained using a combination of bovine porous bone mineral.

Sculean A et al (2003)[28] compared the combination of bovine-derived xenograft with a bioresorbable collagen membrane to access flap surgery in deep intra bony defect cases. In 1 year, statistically higher PD reductions (p=40.05) and CAL gains (p=0.001) were found in test group than the control one. In the test group all sites (100%) gained minimum of 3 mm of CAL. In the control group no CAL gain was seen in four sites (29%), at six sites (43%) the CAL gain was of 2 mm. A CAL gain of 3 mm or more was noted in four defects (29%). Thus treatment with bovine derived xenograft and collagen membrane resulted in significantly higher CAL gains than treatment with access flap surgery.

Andreas Stavropoulos (2005)[29]: in a five-year study of guided tissue regeneration in combination with deproteinized bovine bone (Bio-Oss) in the treatment of intrabony periodontal defects, the results of GTR with bioabsorbable membranes in combination with Bio-Oss in the treatment of periodontal intrabony

defects showed highly significant improvements in the parameters PD and CAL and are basically stable on a long-term basis.

Galindo-Moreno et al (2014)[30] found a correlation between CD44 expression and number of vessels in Anorganic bovine bone particles (ABB). Osteopontin expression was identified on the interstitial boundary of bone with ABB particles and within the osteocyte lacunae and bone canaliculi. CD44-positive cells were seen inside ABB particles after 6 months of graft maturation.

PLATELETS & PLATELET CONCENTRATES:

Platelets arise from cytoplasmic fragmentation of the megakaryocyte in bone marrow and have a lifespan of about 7 to 10 days.[31] The platelets are responsible for hemostasis and are a natural source of growth factors and various cytokines.

Ross et al [32] in ***1974*** found the regenerative potential of platelets and their role in wound healing. The alpha granules are the storage granules of the growth factors; they contain pre-packaged growth factors in an incomplete and therefore bio-inactive form. The growth factors proven to be contained in these granules are the three isomers of platelet-derived growth factor (PDGF-AA, PDGF-BB and PDGF-AB), the two isomers of transforming growth factor beta (TGF-β1 and TGF-β2), vascular endothelial growth factor (VEGF), and epithelial growth factor (EGF). The alpha granules are also rich in the cell adhesion molecule vitronectin, which is required for osteoconduction and osseointegration.[33]

PLATELET CONCENTRATES:

Since 1990, medical science has recognized several components in blood, which are a part of the natural healing process, and when added to wounded tissues or surgical sites, have the potential to accelerate wound healing.

Fabbro et al in 2011 [34] summarized the role of platelet concentrates as:

1. Augmentation of tissue healing: By increased proliferation of connective tissue progenitor cells that stimulate fibroblast and osteoblast activity and enhance osteogenesis.[35]

2. Anti-microbial activity: Against various bacterial species involved in oral infections**.**

3. Modification of host defence mechanism: By delivering signaling peptides that attract macrophages.[36]

4. Modification of immune reaction: By releasing leukocytes that synthesize interleukins.[37]

FIBRIN GLUE

Fibrin glue was first described in 1970 and is formed by polymerizing fibrinogen with thrombin and calcium, is a biomaterial that was developed in response to the search for improved haemostatic agents and surgical adhesives at bleeding sites ***(Gibble & Ness 1990).*** Thus the fibrin adhesives paved the way for the present day platelet concentrates.

PLATELET RICH PLASMA

The first generation platelet concentrate, which consists of a limited volume of plasma enriched with platelets obtained from the patient, was called platelet rich plasma (PRP). PRP contains growth factors such as PDGF and TGF-β that aids in regeneration. If a normal human blood clot contains 5% platelets, according to ***Sunitha et al*** [38],a PRP blood clot contains 95% platelets.

Creeper et al [39] in an in-vitro study reported that there was proliferation of PDL and osteoblastic cells under the influence of PRP. Although PRP contains various growth factors, their release in wound site tends to be rapid and occurs over extremely limited time. Also, complex process involving the use of bovine thrombin and other biochemical agents has limited the benefits of platelet rich plasma.[40]

PLATELET RICH FIBRIN

Platelet-rich fibrin represents a new step in the platelet gel therapeutic concept with simplified processing minus artificial biochemical modification. Platelet rich fibrin is a second and latest generation platelet concentrate, developed in France in 2001 by ***Choukroun et al***. It is a reservoir of autologous growth factor which attempts to accumulate platelets and cytokines in a physiologic fibrin clot. PRF contains 97% of platelets and >50% of leukocytes in a specific three dimensional distribution. It consists of an intimate assembly of cytokines, glycanic chains and structural glycoproteins enmeshed within a slowly polymerized fibrin network.[37]

DIFFERENCE BETWEEN PRP & PRF

PRP	**PRF**
Sudden fibrin polymerization	Slow and natural polymerization
Strong thrombin concentration	Weak thrombin concentration
Rigid network	Fine, flexible fibrin network
Condensed tetramolecular or bilateral junction	Connected trimolecular or equilateral junctions

Fast elimination of incorporated platelets and cytokines in fibrin clot	Glycosaminoglycans like heparin, hyaluronic acid enmeshed, therefore strong affinity for platelets and cytokines

CONCENTRATED GROWTH FACTOR:

Concentrated growth factor is an advanced 2nd generation platelet concentrate (**Sacco in 2006**). In dentistry, many researches of growth factors related to bone regeneration techniques recognised that the prime tissue regenerative stimulus are present amongst the autologous growth factors, which have clinically proven to induce regeneration and tissue healing.

PREPARATION:

CGF is an autologous preparation withdrawn from venous blood collected in sterile Vacuette tubes without anticoagulant solutions. The tubes are then centrifuged (Medifuge, Silfradent, Sofia, Italy) with one step centrifugation protocol: 30sec - acceleration, 2min - 2700 rpm, 4min - 2400 rpm, 4min - 2700 rpm, 3min - 3000 rpm, 36sec – deceleration and stop. Thus 4 different phases of CGF are obtained:

PHASES OF CGF:

1. Superior phase – Serum
2. Interim phase – Fibrin buffy coat
3. Liquid phase – Growth factors
4. Lower phase – Red blood cells

Phase 1:

Superior phase is constituted by Serum. It is a clear straw coloured fluid and is the lightest and most liquid part of blood. It consists of 92% of water and 7% of other concentrates which includes proteins, glucides, amino acids, lipids, enzymes, hormones and inorganic electrolytes. It is used to secure the bleeding capillaries, wash the surgical site, coat and protect the regenerated portions.

Phase 2:

The interim phase is a fibrin buffy coat which is a polymerised fibrin block with 3 dimensional polymer networks of fibrinogen molecules and interwoven fibres united to form a single phase in the form of gel. When seen under electron microscope this layer is composed of thick and thin fibrillar elements. During polymerisation reaction the diameter of fibres increases in size until end of the reaction. During polymerisation it enables for volume growth of chains in all directions. The fibrin blocks are of higher quality as it contains high concentration of fibrinogen, factor XIII and thrombin. Factor XIIIa, which is activated by thrombin stabilizes the fibrin clot and secures it from plasmin degradation, contributing in higher fibrin tensile strength and stability and prolong the duration of growth factor activity, which is conducive for growth factor synergy & promotes cell proliferation and osteogenic differentiation.[8] It is used as an autologous membrane support, filling material as a whole or mixed with bone particles in the defects.

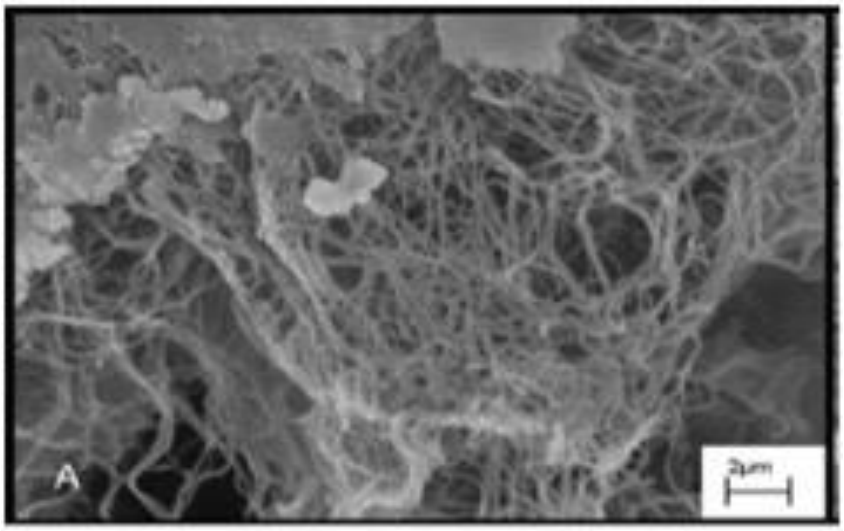


Figure 5: *Electon microscopic structure of fibrin matrix of CGF (shows CGF fibrin network constituted by thick & thin fibrillar elements)*

Phase 3:

Liquid phase consists of growth factors, white blood cells and stem cells. These stem cells are capable of differentiating into their specialized cell types. This phase is mixed with autologous bone graft to acquire high performance activated graft.

Phase 4:

Lower phase is a dark reddish dense gel. It contains high concentration of red blood cells and also few white cells, platelets and clotting factors. This phase is used in pure form or mixed with bone grafts to fill large cavities.

MECHANISM:

CGF delivers various growth factors such as Platelet-derived growth factor (PDGF), Transforming growth factor-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.[41] A vitro study has demonstrated

that growth factors like TNF-α and BDGF had a fast kinetic release from the concentrate and reached its maximum accumulation in 1st and 3rd day respectively. Similarly PDGF-AB, TGF- β1 and IGF-I had a constant kinetic release and attained its maximum in 3rd and 6th day respectively. VEGF and BMP-2 showed a slow kinetic release and reached its maximum in 8th day. These growth factors primarily play a role in osteoblast proliferation and differentiation.[42]

CGF functions by degranulation of the alpha granules in platelets that consists of growth factors which play an important role in early wound healing.[43] The biphasic platelets in CGF hastened by thrombin, influences the release of growth factors and other substances which improves the wound-healing process by increasing cellular proliferation, matrix formation, osteoid production, connective tissue healing, angiogenesis and collagen synthesis.

FUNCTIONS:

CGF is a fibrin tissue adhesive possessing haemostatic and tissue sealing properties. It accelerates wound healing and enhances osteogenesis. The CGF promotes the wound stability, which is vital for the establishment of a new connective tissue attachment to a root surface. It also delivers a scaffold supporting cytokine attachment and cellular migration and functions as a carrier for growth factors. It is an potent surgical haemostatic agent, induces epithelial, endothelial and epidermal regeneration and decreases dermal scarring. Possess antimicrobial effect as it contains high concentration of leukocytes. Possess anti-angiogenic property on chronic non healing wounds.

APPLICATIONS:

CGF has broad range of healing property in patients undergoing cosmetic surgeries. The treatment is evidently successful in all aspects of facial aesthetics such as Mesotherapy as well as non-surgical facial augmentation, lips enhancement and lip line coutour, treating smile lines, the forehead, cheeks, neck décolletage, and other unwanted folds and wrinkles on the face in indistinguishable to dermal fillers. However attaining natural results not involving the injection of foreign chemical substances into the skin is the most important part in this therapy.

In dentistry CGF is used to:

- To fill extraction sockets **(Tadic et al 2014)**[44]
- To fill the cavity after cystectomy **(Mirkovic et al 2015)**[45]
- In sinus lift procedure **(Kim et al 2014)**[46]
- Can be used alone in Recession coverage **(Dogan et al 2015)**[47]
- With autologous bone particles or biomaterials in bone defects **(Gheno et al 2014)**[48]
- In implants to accelerate bone integration **(Yang LM et al 2015)**[49]

STUDIES:

Piemontese et al (2008)[50] conducted a randomized, double-masked, clinical trial to compare platelet-rich plasma (PRP) combined with a demineralized freeze-dried bone allograft (DFDBA) to DFDBA mixed with a saline solution in the treatment of human intrabony defects in 60 systemically healthy patients. Clinical and radiographic measurements were recorded at baseline and at the 12-month evaluation. Treatment with a combination of PRP and DFDBA resulted in significantly greater clinical improvement in intrabony periodontal defects compared to DFDBA with

saline. No statistically significant differences were seen in the hard tissue response between the two treatment groups, which confirmed that PRP had no effect on hard tissue fill or gain in new hard tissue formation.

Manmeet Kaur et al (2010)[51] compared the efficacy of platelet rich plasma (PRP) associated with bioactive glass (BG) and BG alone in the treatment of periodontal intrabony defects. At 6 months after treatment, the PRP/BG group presented a mean PPD reduction of 3.4±1.4 mm, CAL mean gain of 4.3±1.3 mm, and defect fill of 3.5±1.0 mm. The BG group presented a mean PPD reduction of 2.6±1.1 mm, mean CAL gain of 3.3±1.3 mm, and defect fill of 3.1±1.2mm. Both treatment modalities resulted in significant PPD reduction, CAL gain and defect fill. The combination of PRP with a BG graft material appeared to add some benefits to the improvement of the clinical parameters in the treatment of intrabony defects.

Pradeep et al [52] in **2011** in their clinical trial compared autologous platelet rich fibrin to open flap debridement alone in treatment of 3-wall intrabony defects in chronic periodontitis patients. The mean reduction in probing depth recorded in test group (4.55 ± 1.87 mm) was greater than control group (3.21 ± 1.64 mm) while mean PAL gain recorded was also greater in test group (3.31 ± 1.76 mm) compared to controls (2.77 ± 1.44 mm). Moreover, significantly greater percentage of mean bone fill was seen in the test group (48.26 ± 5.72 %) compared to control (1.80 ± 1.56 %).

Thorat et al [53] in **2011** performed a controlled clinical trial in order to estimate the clinical effects of autologous PRF in treatment of intra-bony defects**.** All the clinical parameters and radiographic parameters reported greater improvement with the use of PRF. Significant reductions in probing depth, CAL gain and greater intrabony defect fill was observed.

Lekovic et al [54] in **2012** compared PRF and bovine porous bone mineral versus PRF alone in the treatment of intrabony periodontal defects. The results of this study indicated that PRF had the ability to augment the effects of PRF in reducing pocket depth, improving clinical attachment levels and promoting defect fill.

Pradeep et al [55] in **2012** combined porous hydroxyapatite graft with platelet rich fibrin in management of intrabony defects in chronic periodontitis patients to explore the additional effectiveness of autologous PRF with bone graft material. On evaluation HA addition to PRF increased the regenerative effects than observed with PRF alone.

Borsani et al (2015)[56] conducted a study to assess the biological rationale for the use of CGF, by evaluating blood cell localization, the *in vitro* cumulative release of seven growth factors (PDGF-AB, VEGF, TNF-α, TGF-β1, BDNF, BMP-2 and IGF-1), it's *in vitro* effects on cell proliferation and its mechanical behaviour. The results indicated that platelets and leukocytes were present in a very thin space called "buffy coat", localized between the white and red part of CGF. Each growth factor appraised, had a specific kinetic release with a great variability among subjects. The *in vitro* cell proliferation was excited. CGF showed an "apparent plasticity" and its mechanical response was determined by fibrin network structure. These findings support the CGF's clinical use and will allow us to better interpret and refine the clinical outcomes.

Bozkurt Dogan et al (2015)[47] studied the clinical effect of concentrated growth factor (CGF) in combination with coronally advanced flap (CAF) compared to CAF alone for the treatment of multiple adjacent gingival recessions(GRs) in 20 patients with Miller's class I and class II recession. The results obtained were mean root coverage (MRC) of 82.06% and 86.67%, complete root coverage (CRC) of

45.8% (27/59) and 56.7% (34/60) for CAF and CAF + CGF, respectively at 6th month. This study suggests that use of CGF + CAF may improve the success of GRs since there is a significant increase in KGW and GT.

Chandradas ND et al 2016[57] evaluated the efficacy of platelet rich fibrin (PRF) with or without bone graft [demineralized bone matrix (DBM) graft] in the treatment of intrabony defects based on clinical and radiographic parameters in 36 patients. Results showed that the mean reduction of PD and gain in RAL were greater in group A (4.25 ± 1.48, 3.92 ± 0.90) and group B (3.82 ± 0.75, 3.27 ± 0.65) than control (3.00 ± 1.21, 2.25 ± 0.62). Furthermore, statistically significant improvement in LBG and %BF was found in group A (3.47 ± 0.53, 61.53 ± 4.54) compared to group B (2.55 ± 0.61, 49.60 ± 14.08) and group C (1.21 ± 0.80, 24.69 ± 15.59). The study showed that PRF enhances clinical and radiological parameters compared to OFD alone in intrabony defects. Addition of DBM increases the effects of PRF in RAL gain and radiographic defect fill.

J.Qiao (2016)[58] investigated the effect of CGFs on proliferation and alkaline phosphatase (ALP) activity of human periodontal ligament cells (hPDLCs) in vitro. As bone homeostasis was fundamentally controlled by Wnt-mediated signals, they investigated Wnt3a expression of hPDLCs after treatment of CGFs. Results revealed that CGFs significantly promoted the proliferation and ALP activity of hPDLCs, and the effects seem more stimulatory compared to rhPDGF-AB and rhTGF-β1 combination. This was the first report Wnt3a expression by hPDLCs after treated by CGFs. This indicated the participation of Wnt/β-catenin signaling in CGFs inducing cell proliferation and differentiation in early phase.

Pirpir et al (2017)[59] evaluated the effectiveness of concentrated growth factor on osseointegration in twelve patients in maxillary anterior region. The mean ISQ

values recorded were 79.40 ± 2.604 in the study group and 73.50 ± 5.226 in the control group at 1st week, 78.60 ± 3.136 in the study group and 73.45 ± 5.680 in the control group at 4th week. The differences between the two groups were seemed to be statistically significant ($p < 0.05$). The results showed that the concentrated growth factor had positive effects on implant stabilization. The ISQ measurements at week 1 and week 4 were markedly higher in the study group. Application of this material seems to promote osseointegration.

Xia Chen et al (2018)[60] studied the effect of Concentrated Growth Factor (CGF) on the Promotion of Osteogenesis in Bone Marrow Stromal Cells (BMSC) *in vivo.* This study demonstrated that CGF not only promotes the superior osteoinductive activity of BMSCs to enhance bone formation, but also outperforms collagen in stimulating angiogenesis. This study concluded that CGF is an excellent cell growth factor biomaterial. Combined with BMSCs, it had a strongly positive effect on both osteogenesis and angiogenesis, making it a very promising material for bone regeneration.

Shebin Hong et al (2018)[61]: In a Comparative Evaluation of Concentrated Growth Factor and Platelet-rich Fibrin on the Proliferation, Migration, and Differentiation of Human Stem Cells of the Apical Papilla. The objective of this study was to assess their effects on the proliferation, migration, and differentiation of human stem cells of the apical papilla (SCAPs). From the results obtained they concluded that both CGF and PRF can stimulate the proliferation, migration, and differentiation of SCAPs. CGF may be a potential alternative in regenerative endodontics.

Forabosco, *et al (2018)*[62] conducted a clinical study was to examine the effect of concentrated growth factors matrix (CGFm) on implant survival rate in augmented sinuses; the secondary aim was to evaluate the effect of CGFm on sinus augmentation

postoperative morbidity in fifty patients. Of these, 25 patients (control-group) received a corticocancellous xenograft. The other 25 patients (test group) received a mixture of 70% CGF matrix and 30% corticocancellous xenograft. Results showed 96.4% survival rate was described in the test group (with CGFm) and a 96.1% survival rate in the control group (without CGFm). No statistically significant differences were observed between the survival rates of the two groups after 1 year. This study concluded that the mixture of CGFm (70%) with xenograft (30%) is an alternative to xenograft material alone and is a predictable procedure resulting in less postoperative morbidity in sinus augmentation.

MATERIALS AND METHOD

SOURCE OF DATA:

The study population will be selected from the outpatient sections of the Department of Periodontics, TNGDC and Hospital, Chennai.

INCLUSION CRITERIA:

1. Patients within the age group 20 - 60 years of either gender
2. Patients with probing depth ≥ 5mm following Phase-I therapy
3. Radiographic evidence of vertical / angular bone loss bilaterally.
4. Systemically healthy patients
5. Patients willing for voluntary participation & have signed informed consent

EXCLUSION CRITERIA:

1. Patients showing poor oral hygiene maintenance after Phase-I therapy
2. Patients with known systemic diseases/ metabolic disorders
3. Patients under any medication
4. Patients using tobacco or tobacco related products
5. Pregnant / Lactating women
6. Patients with any known allergies

SUBJECTS:

A total of 10 patients diagnosed as chronic periodontitis or aggressive periodontitis with clinical and radiographic evidence of vertical / angular bone loss

bilaterally, indicated for regenerative periodontal surgery and Group A and Group B were randomly assigned

Group A: Receiving Concentrated growth factor with Bovine porous bone mineral

Group B: Receiving Bovine porous bone mineral alone

STUDY DESIGN:

In this clinical study the participants were recruited prospectively.

SEX: Either sex

STUDY PROTOCOL:

1. Patient selection as per the inclusion & exclusion criteria.
2. Purpose of the study explained to the subjects. (Annexure 1 & 2)
3. Medical history and informed consent obtained. (Annexure 3 & 4)
4. Complete periodontal examination using a mouth mirror and UNC15 periodontal probe under artificial light
5. Intra-oral evaluation and periodontal examination - Clinical periodontal parameters namely, Plaque index, Gingival Bleeding Index, Probing Pocket Depth and Clinical Attachment Level
6. Radiographic evaluation- Orthopantamogram, Intraoral periapical radiograph
7. Phase I therapy and re-evaluation of clinical parameters after 4 weeks.
8. Surgical procedure- Regenerative therapy in bilateral defect sites using CGF combined with bone graft and bone graft alone respectively
9. Post-operative care.
10. Clinical and Radiographic re-evaluations at the end of 6 and 12 months.

PRE-OPERATIVE CLINICAL ASSESSMENT

CLINICAL PARAMETERS

Using proforma (Annexure-5) case history was taken and following clinical parameters were evaluated at baseline and post surgically at 6 and 12 months:

1. Plaque index (PI)

2. Gingival bleeding index (GBI)

3.Probing Pocket Depth (PPD): Measured with customized acrylic stent and UNC-15 probe

4. Clinical attachment level (CAL)

1. PLAQUE INDEX (Silness and Loe 1967)[63]

All teeth were examined at 4 sites each (disto-facial, facial, mesio-facial lingual / palatal) and were scored as follows :

Criteria for Scoring:

Score 0 : No plaque

Score 1: Plaque not visible to the naked eye, detected only by running the explorer or by using a disclosing agent

Score 2: Thin to moderate accumulation of soft deposits within the gingival pocket or on tooth and gingival margin, visible to the naked eye

Score 3: Abundance of soft matter within gingival pocket and/or on tooth surface and margin, inter-dental area stuffed with soft debris

Calculation:

Plaque index per tooth = Total score / 4

$$\text{Plaque index per individual} = \frac{\text{Total PI per tooth}}{\text{Total number of teeth examined}}$$

Interpretation:

Score 0	Excellent oral hygiene
0.1 to 0.9	Good oral hygiene
1.0 to 1.9	Fair oral hygiene
2.0 to 3.0	Poor oral hygiene

2. GINGIVAL BLEEDING INDEX: (Ainamo & Bay 1975)[64]

Starting distobuccally, the probe was inserted slightly into the sulcus and run to the buccal and mesial surfaces of every tooth at an angle of about 45°. This was repeated for all teeth present. Probing was similarly carried out at palatal/lingual sites. Any gingival units that exhibited bleeding were recorded. The total number of bleeding sites per tooth was thus recorded for every tooth except the third molar.

Criteria for Scoring:

Positive score (1) - Presence of bleeding within 30 seconds

Negative score (0) - Absence of bleeding

$$\%\text{ of bleeding sites} = \frac{\text{Total number of positive score x 100}}{\text{Total number of surfaces of all teeth}}$$

STENT PREPARATION

Acrylic occlusal stents were fabricated over the study models. Self cure acrylic was used for this purpose. The stent covered the occlusal and coronal 1/ 3rd of the labial and lingual surfaces of the teeth. Vertical grooves were given to guide the probe placement in the same plane and direction repeatedly during measurements to avoid any variation. The recordings were made using a UNC 15 periodontal probe.

3. PROBING POCKET DEPTH (PPD)[65]

A customized acrylic stent was prepared and stored in the cast itself. The base of the stent served as a reference point (RP) to take the measurements. Probing depth was calculated by measuring the distance from a fixed reference point on the stent to the base of the pocket (BP) along the groove using a UNC-15 periodontal probe and subtracting it by the distance from the fixed reference point to the gingival margin (GM).

4. CLINICAL ATTACHMENT LEVEL (CAL)[65]

Clinical attachment level was calculated by measuring the distance from a fixed reference point on the stent to the base of the pocket (BP) along the groove using a UNC-15 periodontal probe and subtracting it by the distance from the fixed reference point to the cemento enamel junction (CEJ)

RADIOGRAPHIC PARAMETERS

Intraoral periapical radiographs were taken with radiographic grid for each site using long cone paralleling technique and XCP holders at baseline and post surgically at6 months and 1 year.

All radiographs were digitalized using digital camera and transferred to the computer as JPEG image. To measure the linear radiographic defect depth (DD) in

millimetre (mm), **ImageJ** software designed for image analysis by **National Institute of Health (NIH)** was used.

The following anatomical landmarks of the intrabony defect were identified on the radiograph images based on the criteria set by ***Bjorn et al*** [66] and ***by Schei et al*** [67]***:***

1. CEJ: The cemento-enamel junction of the tooth with the intrabony defect.

2. AC: The most coronal position of the alveolar bone crest of the intrabony defect when it touches the root surface of the adjacent tooth before treatment. (The top of the crest)

3. BD: The most apical extension of the intrabony defect where the periodontal ligament space still retained its normal width before treatment. (The bottom of the defect)

If restorations were present, the apical margin of the restoration was used to replace the CEJ as a fixed reference point.

The following linear measurements were made[68,69]

1. CEJ to bottom of the defect **(CEJ to BD) =** Defect Depth (DD)

2. CEJ to most coronal extent of the alveolar crest **(CEJ to AC)**

3. Depth of the intrabony defect at baseline = **(CEJ to BD) - (CEJ to AC)**

4. **CORRECTION FACTOR (CF):** In order to estimate distortion between the consequent radiographs, an anatomically non-variable distance i.e., the root length [distance from the CEJ to the root apex (CEJ to RA)] was measured on all the radiographs. The correction factor (CF) was calculated as follows[69]

$$\textbf{Correction Factor} = \frac{\textbf{CEJ to RA (baseline)}}{\textbf{CEJ to RA (post-op)}}$$

In cases where it was not possible to measure the root length, the crown length was measured. (Distance from the cusp tip to the CEJ).

5. Bone fill (BF) = CEJ to BD (baseline) - [CEJ to BD (post op) x CF]

6. Bone fill percentage **(BF %) = Bone fill x 100**

Defect Depth (at baseline)

7. Bone crest change (BCC) = CEJ to AC (baseline) - [CEJ to AC (post op) x CF]

8. Bone crest change percentage **(BCC%) = Bone Crest Change x 100**

CEJ to AC (baseline)

If the results were negative, this means that a process of bone resorption had occurred.[69]

9. Amount of original defect resolution (DR) = Bone fill (BF) - bone crest change (BCC)

10. Percentage (%) of original defect resolution **(DR%) = Defect Resolution x 100**

Depth of intrabony defect (BL)

All the above mentioned observations were recorded and subjected to statistical analysis.

ARMAMENTARIUM:

FOR CLINICAL EXAMINATION:

1. Patient drape
2. Mouth mirror
3. UNC 15 probe
4. Kidney tray
5. Cotton roll

6. Sterilized disposable gloves, head cap, facemask
7. Customized acrylic stents
8. Intraoral periapical radiograph film
9. Radiographic grid.

FOR PHASE I THERAPY:

1. Patient drape
2. Mouth mirror
3. UNC 15 probe
4. Kidney tray
5. Cotton rolls
6. Saline
7. Gauze
8. Sterilized disposable gloves, head cap, facemask
9. Sterile disposable syringes
10. Ultrasonic scaler
11. Local anaesthetic solution (2% lignocaine hydrochloride with adrenaline 1:80000)
12. Gracey Curettes

FOR SURGICAL PHASE:

1. Patient drape
2. Mouth mirror
3. UNC 15 probe
4. Dental tweezers
5. Sterile surgical gloves

6. Disposable facemask
7. Local anaesthetic solution (2% lignocaine hydrochloride with adrenaline 1:80000)
8. Sterilised disposable syringes
9. Bard parker blade no 15 and 15C
10. Bard parker blade handle straight and contra-angled
11. Periosteal elevator
12. A set of Gracey's curettes
13. Schlugler and Sugarman bone files
14. Straight and Curved scissors
15. Saline
16. Gauze
17. Dapen dish
18. Bovine porous bone mineral
19. Suture material 3-0 black silk braided
20. Needle holder
21. Cement spatula and Glass slab
22. Periodontal dressing (Coe pacTM)

FOR CGF PREPARATION AND COLLECTION:

1. Sterile cotton and surgical spirit
2. Sterile disposable syringe (9 ml)
3. Tourniquet
4. Sterile 10 ml test tubes
5. Centrifuge
6. Dental tweezers

METHOD:

PRESURGICAL PROCEDURES AND INVESTIGATIONS:

- Clinical case history record and clinical photographs of the site of interest.
- Clinical probing pocket depth was assessed with customized acrylic stents to help reproducibility of probe placement
- Intraoral periapical radiographs using long cone paralleling technique and radiographic grid.
- Phase I therapy, that included oral hygiene instructions, scaling and root planing using hand and ultrasonic instruments, were performed. Adjunctive chemical plaque control in the form of chlorhexidine mouthwash 0.12% twice daily was advised.
- Routine haematological investigations was performed

SURGICAL PROCEDURE:

Intra-oral antisepsis and extra-oral antisepsis were performed with 0.2% chlorhexidine digluconate rinse and 5% povidone iodine solution respectively. The surgical site was anaesthetized with 2% Lignocaine HCl with adrenaline (1:80,000) using block or infiltration techniques. Then crevicular incisions were made using Bard Parker blade No.15 on the facial and lingual/palatal surfaces, extending to one tooth on either side of the defect.

A full thickness mucoperiosteal flap was carefully reflected using the periosteal elevator. After flap reflection and exposure of the osseous defect, a thorough debridement of soft and hard tissue was done using the area specific Gracey curettes. Debridement was followed by copious irrigation with 0.9% normal saline. Presuturing was done prior to placement of bone graft.

In Group A, the defect was filled with a combination of Bovine porous bone mineral (BPBM) and Concentrated growth factors (CGF).

In Group B, the defect was filled with Bovine porous bone mineral (BPBM) mixed with saline.

CGF PREPARATION: [59]

CGF was produced as follows: 9 ml of blood was drawn in sterile test tubes without anticoagulant solutions. These tubes were then immediately centrifuged using a program with the following characteristics: 30 seconds acceleration, 2400 - 2700 rpm for 12 minutes and 36 seconds deceleration and stop. At the end of the process, four blood fractions were created: A superior phase represented by the serum (blood plasma without fibrinogen and coagulation factors, platelet poor plasma, PPP); an interim phase represented by a very large and dense polymerized fibrin block containing the CGFs; third layer containing white blood cells and stem cells; and the lower RBC layer. The fibrin block (interim phase) and RBC layer (lower phase) beneath it was cut into pieces of 1~2 mm, and mixed with Bovine porous bone mineral granules at a relative volume of 1:1 and homogenized.

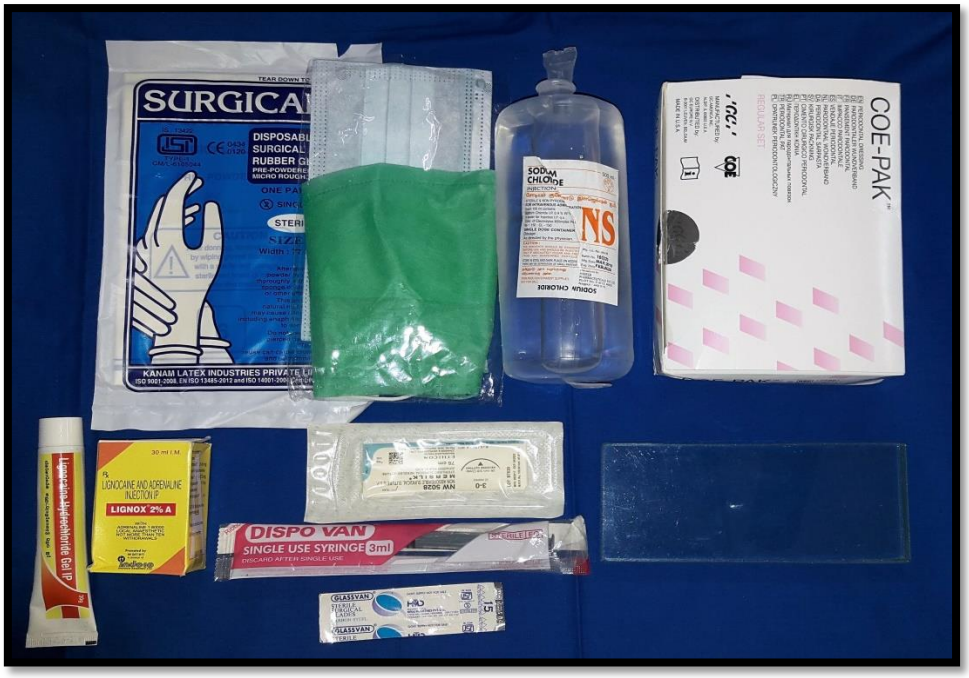
The mixture was then placed into the osseous defect with light pressure and filled upto the most coronal level of osseous defect. The mucoperiosteal flaps were then repositioned and secured using 3-0 black braided silk sutures. Periodontal dressing (Coe-pacTM) was placed.

POST OPERATIVE INSTRUCTIONS

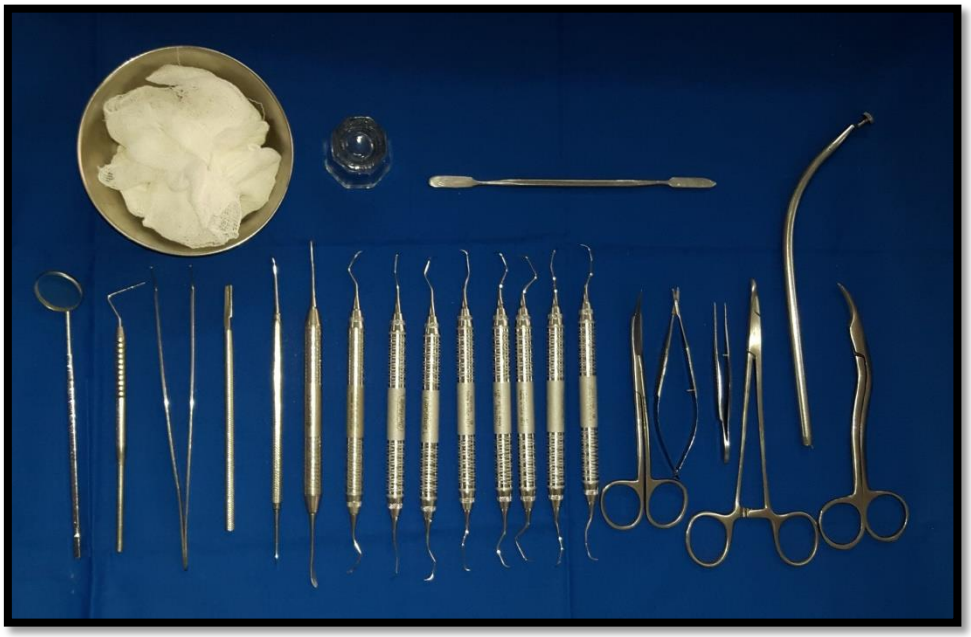
- Suitable antibiotics and analgesics were prescribed.

- The patient was instructed to continue regular home hygiene care, except in the operated area, in which tooth brushing was discontinued for 14 days after surgery and plaque control was maintained by means of gentle topical applications of cotton swabs saturated with 0.12% chlorhexidine gluconate twice a day. Gentle tooth brushing with an extra soft-bristle toothbrush (Postsurgical toothbrush) using Charter's method was then initiated after 14 days.
- Periodontal dressings and sutures were removed 14 days after surgery

Photograph 1A: SURGICAL ARMAMENTARIUM



Photograph 1B: SURGICAL ARMAMENTARIUM

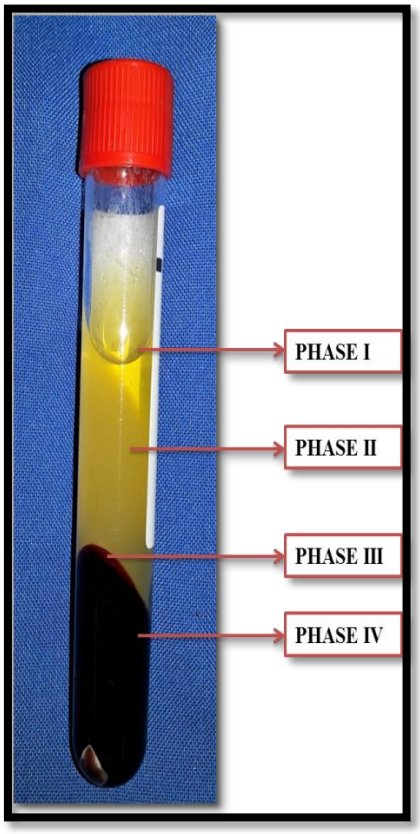


Photograph 2: ARMAMENTARIUM FOR CGF PREPARATION

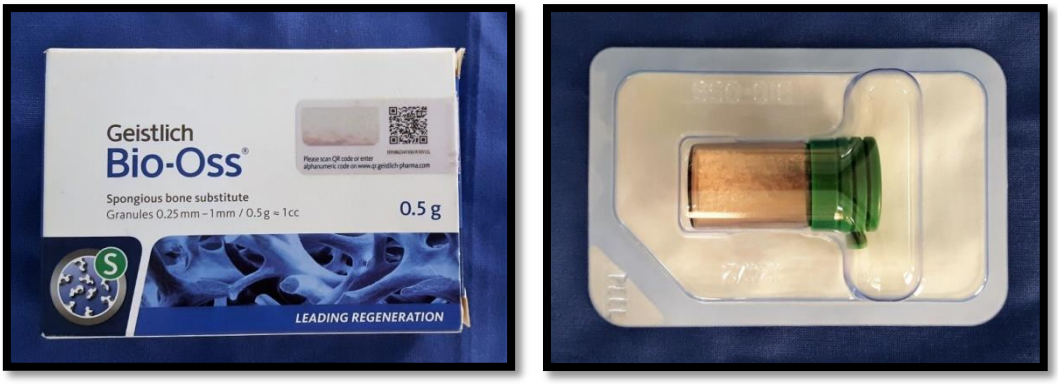
Photograph 3: COLLECTION OF BLOOD SAMPLE

Photograph 4: MEDIFUGE CENTRIFUGE FOR CGF PREPARATION

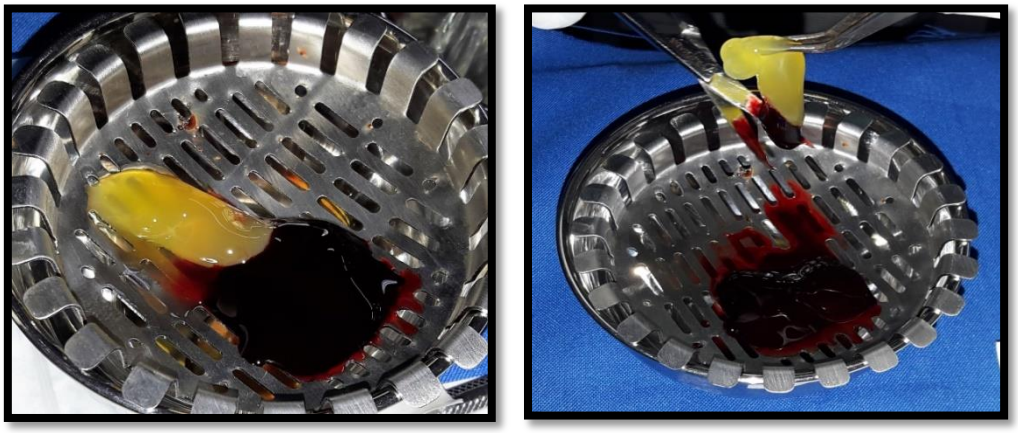
Photograph 5: PHASES OF CGF



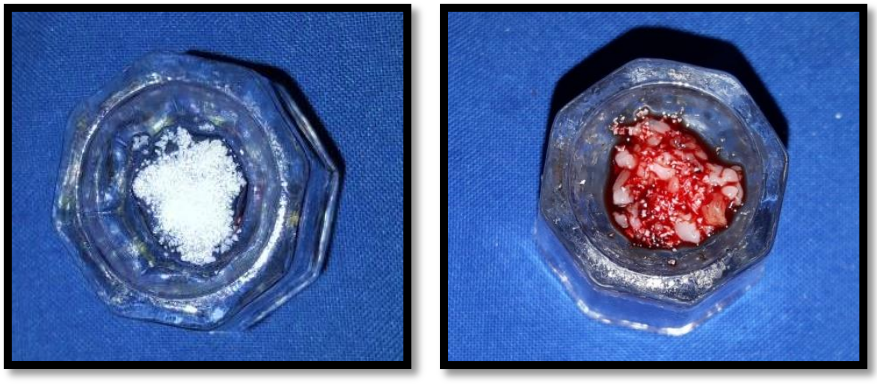
Photograph 6: BOVINE POROUS BONE MINERAL (BIO-OSS®)



Photograph 7: SEPARATION OF PHASE 2 & PHASE 3 OF CGF

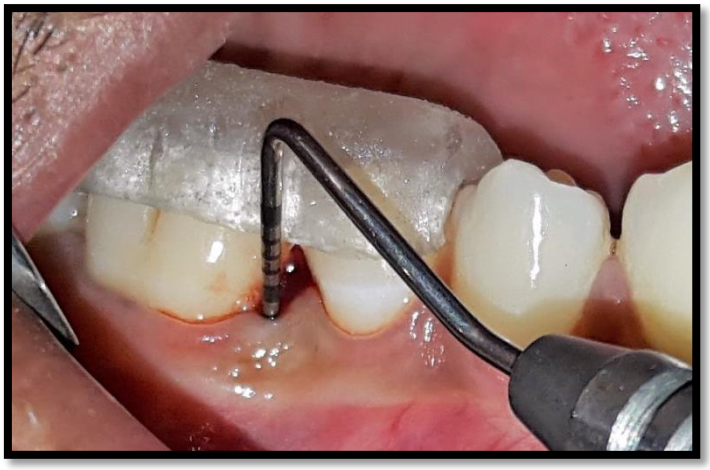


Photograph 8: HOMOGENISED MIXTURE OF CGF AND BIO-OSS®

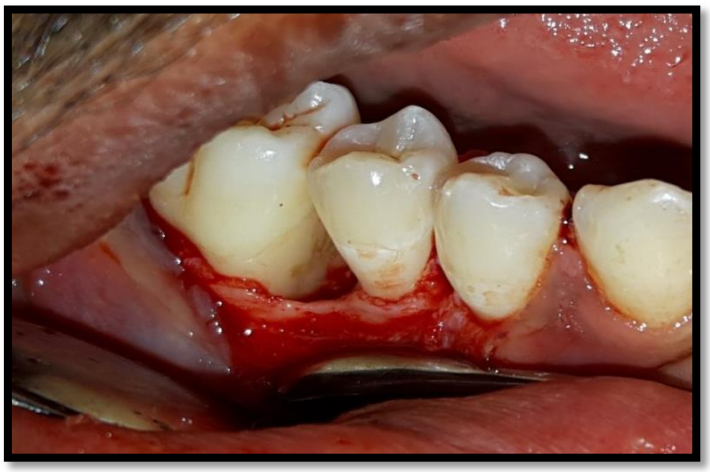


GROUP A

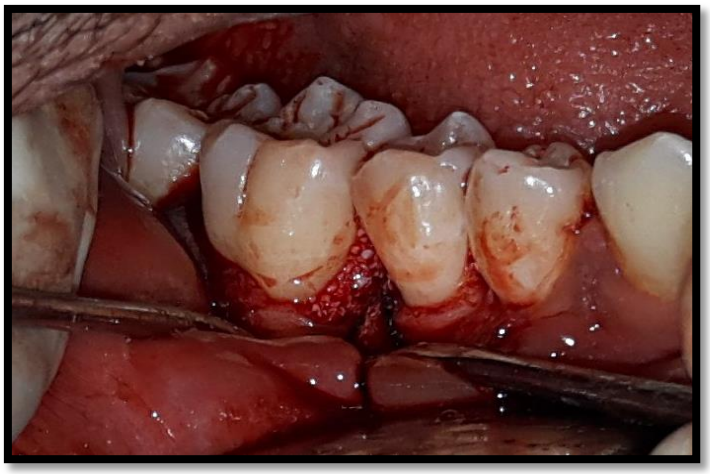
Photograph 9: PREOPERATIVE VIEW



Photograph 10: INTRABONY DEFECT EXPOSURE

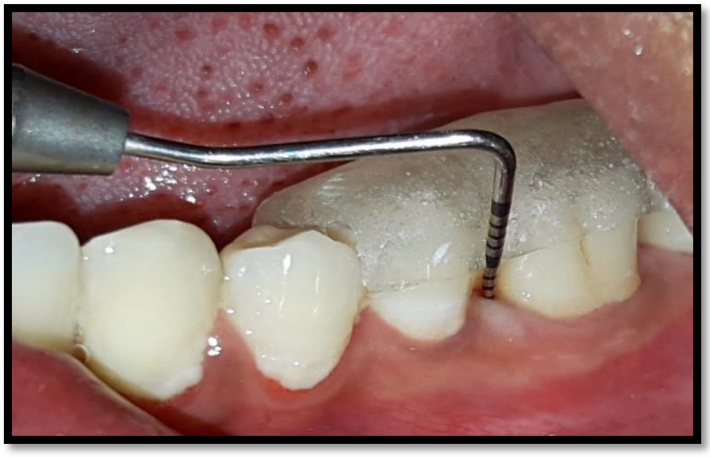


Photograph 11: PLACEMENT OF CGF + BIO-OSS MIXTURE

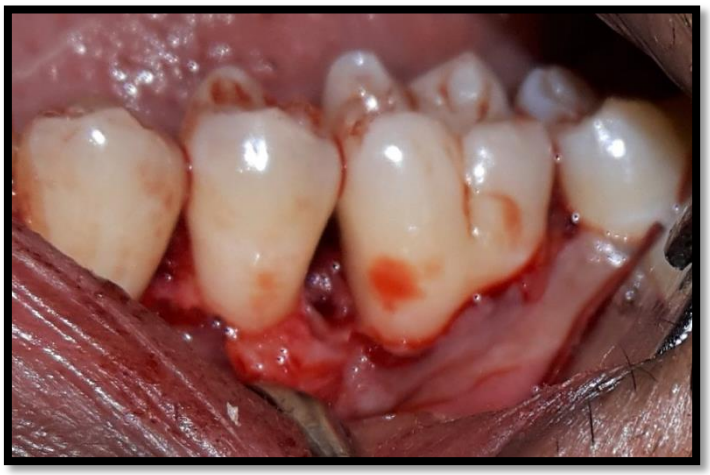


GROUP B

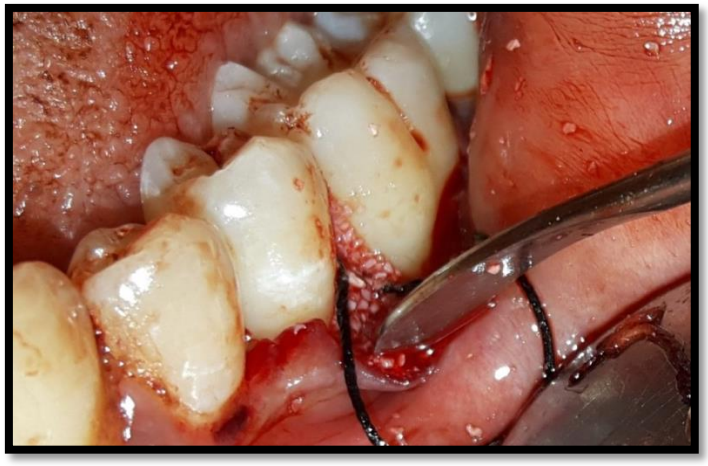
Photograph 12: PREOPERATIVE VIEW



Photograph 13: INTRABONY DEFECT EXPOSURE

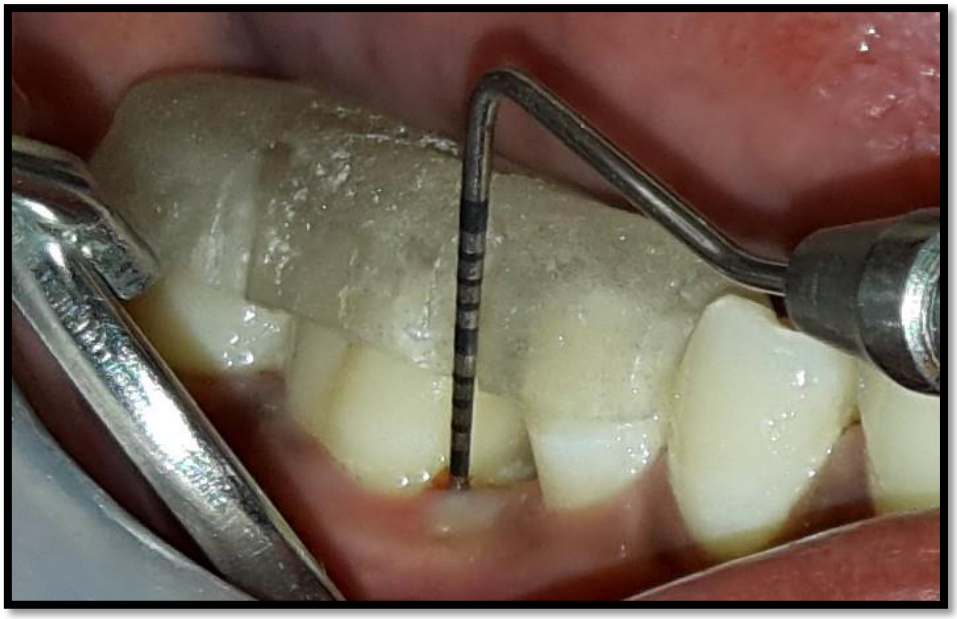


Photograph 14: PLACEMENT OF BIO-OSS + 0.9% SALINE MIXTURE



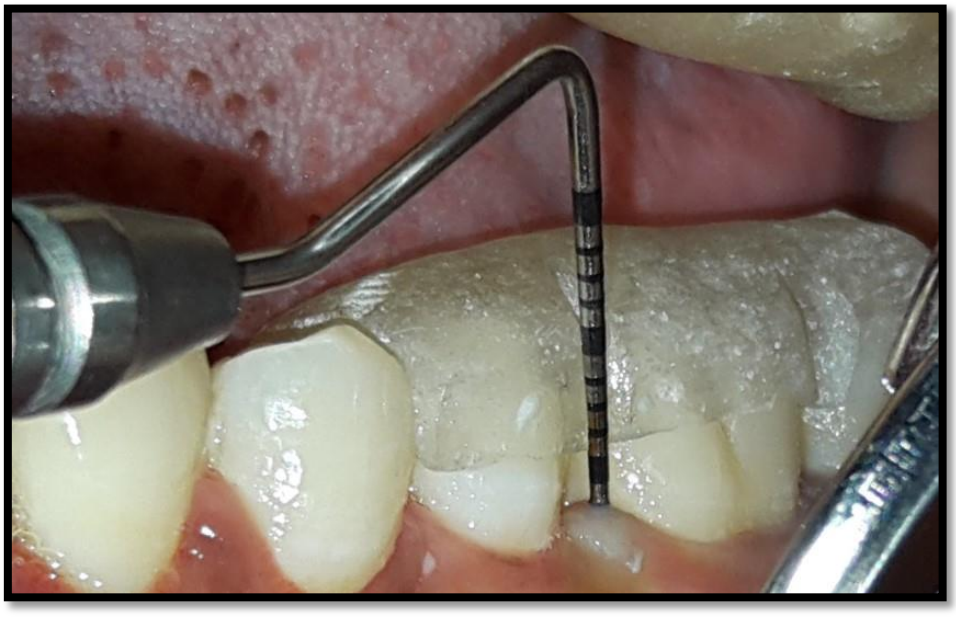
Photograph 15:

6 MONTHS POST OPERATIVE VIEW - GROUP A



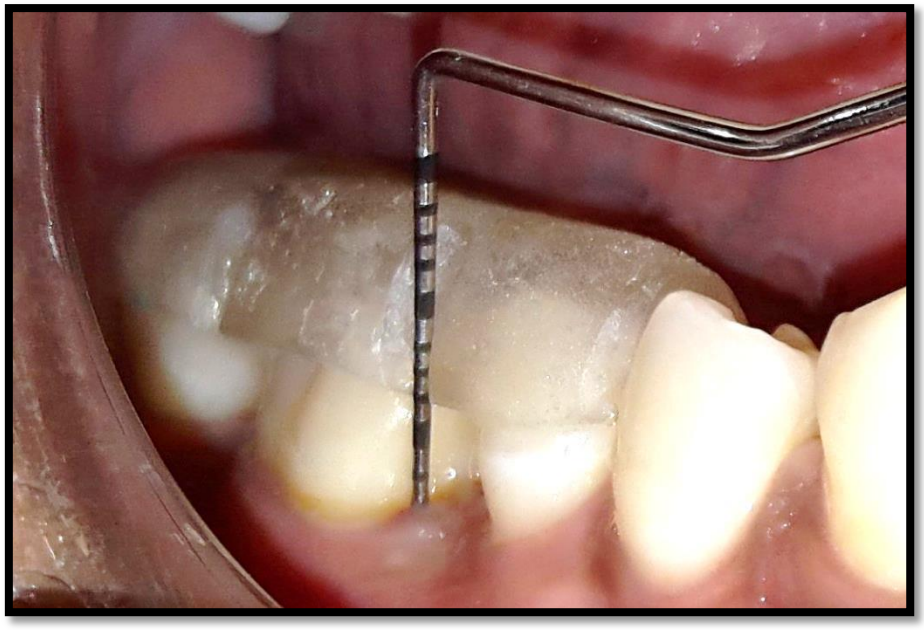
Photograph 16:

6 MONTHS POST OPERATIVE VIEW - GROUP B



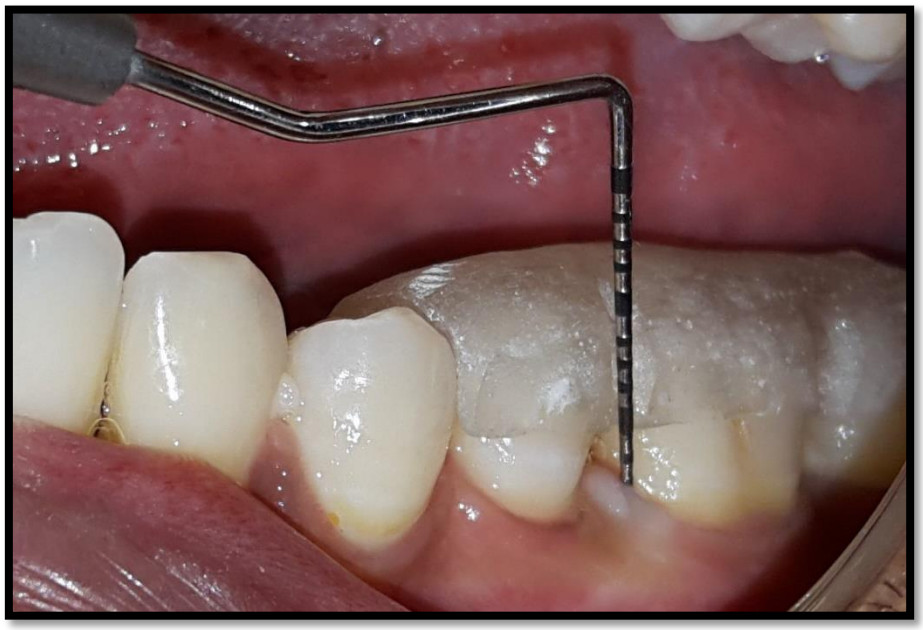
Photograph 17:

1 YEAR POSTOPERATIVE VIEW - GROUP A

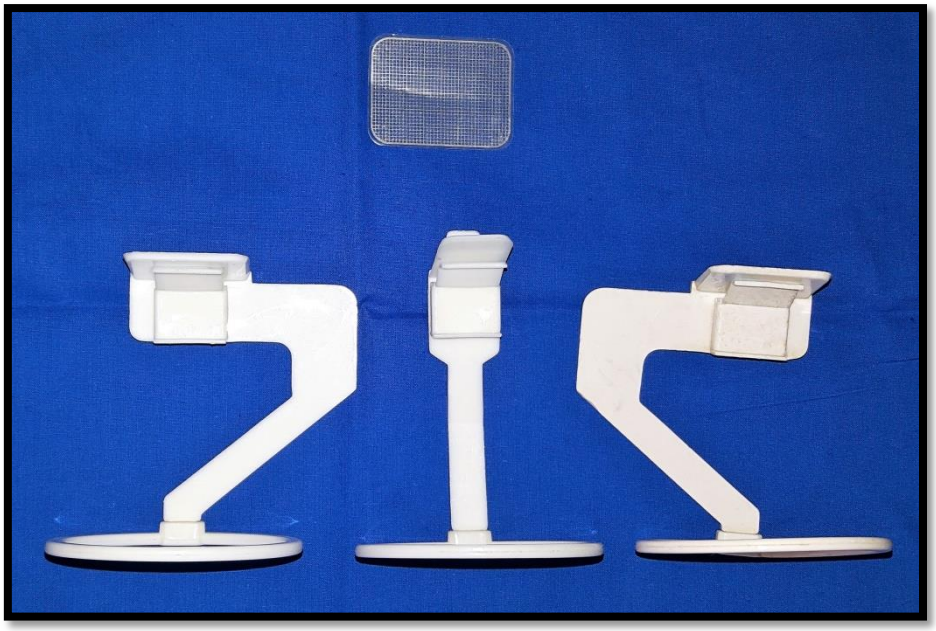


Photograph 18:

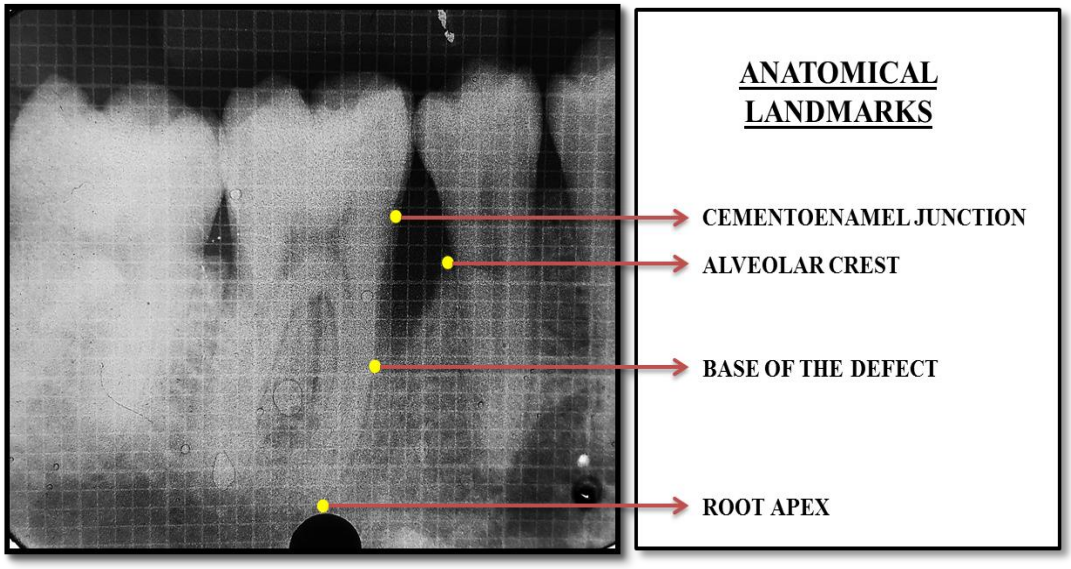
1 YEAR POSTOPERATIVE VIEW - GROUP B



Photograph 19: XCP HOLDERS AND IOPA GRID

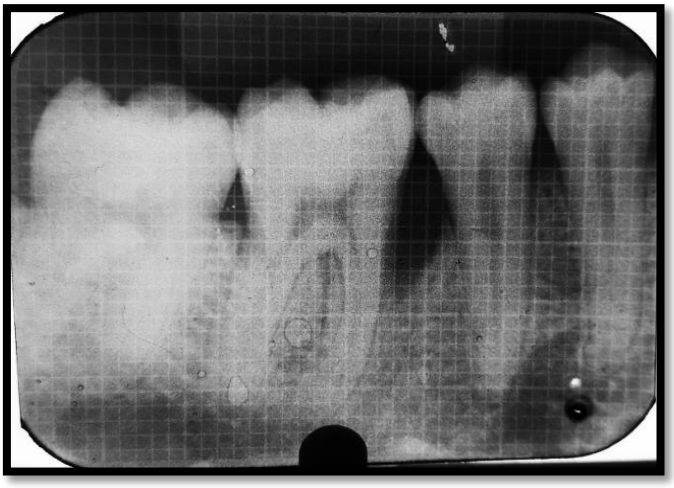


Photograph 20: MARKING OF RADIOGRAPHIC LANDMARKS

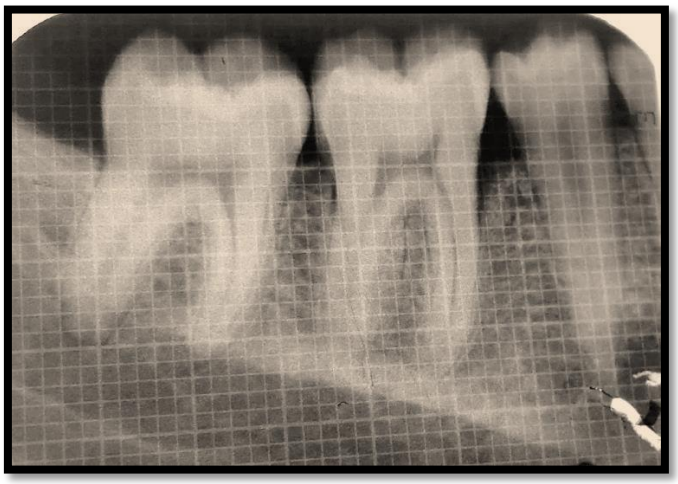


GROUP A

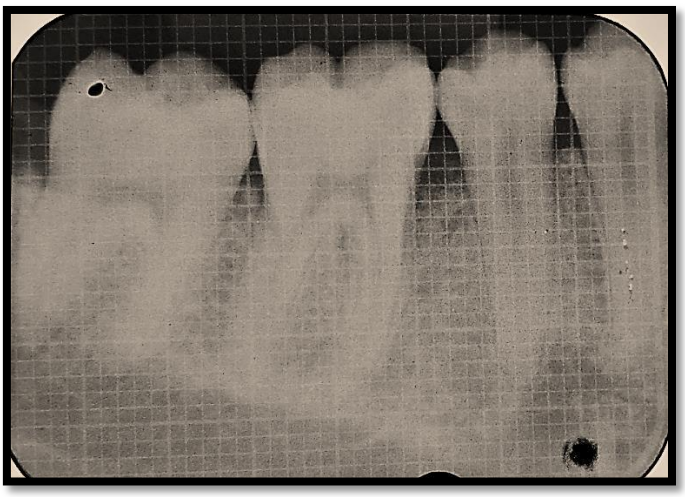
Photograph 21A: PREOPERATIVE IOPA



Photograph 21B: 6 MONTHS POSTOPERATIVE IOPA

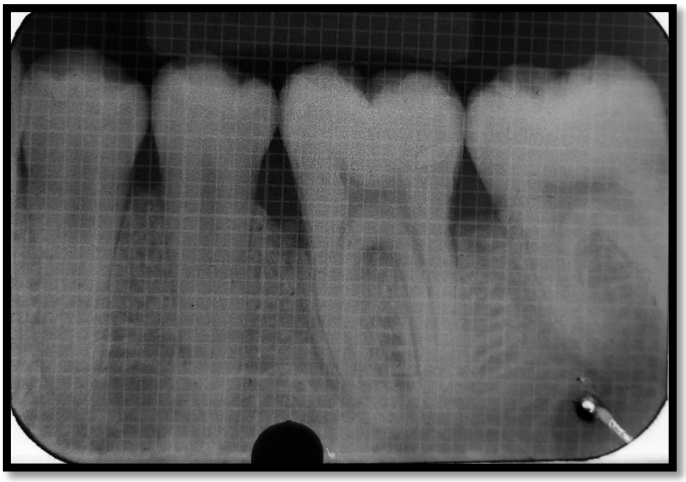


Photograph 21C: 1 YEAR POSTOPERATIVE IOPA

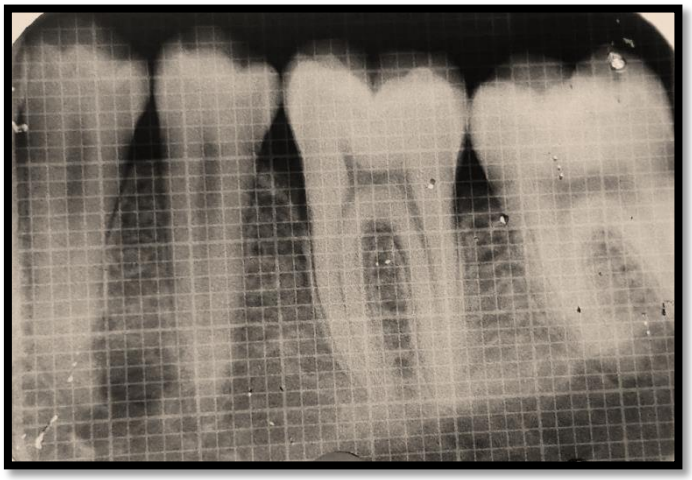


GROUP B

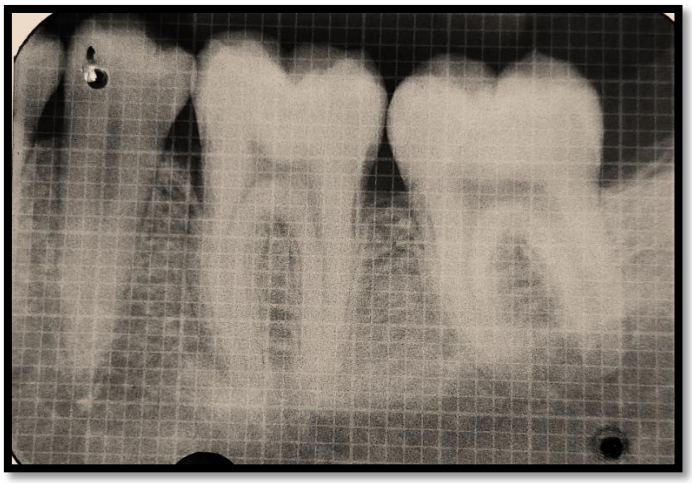
Photograph 22A: PREOPERATIVE IOPA



Photograph 22B: 6 MONTHS POSTOPERATIVE IOPA

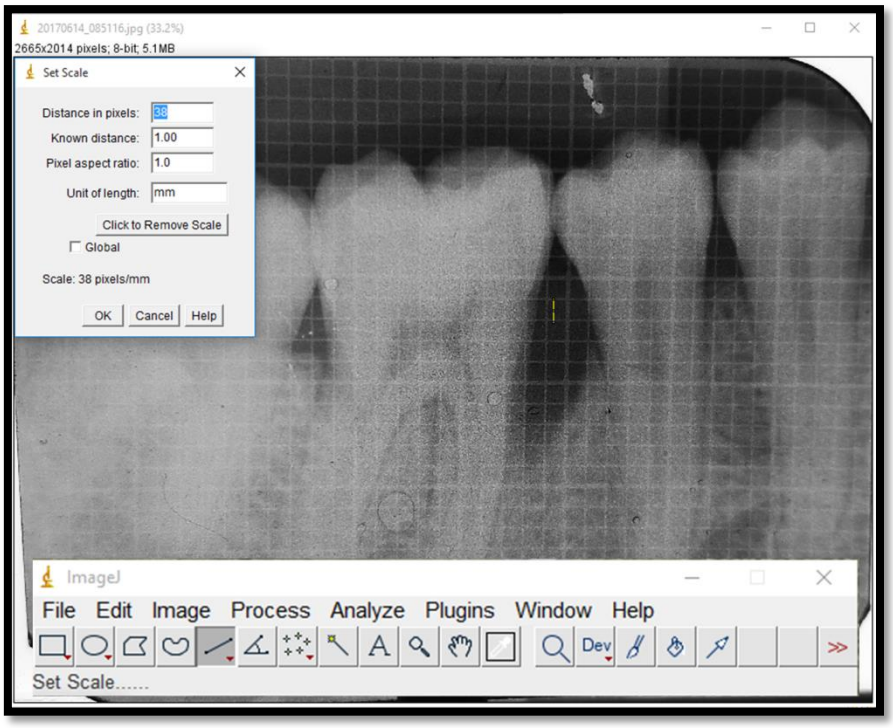


Photograph 22C: 1 YEAR POSTOPERATIVE IOPA

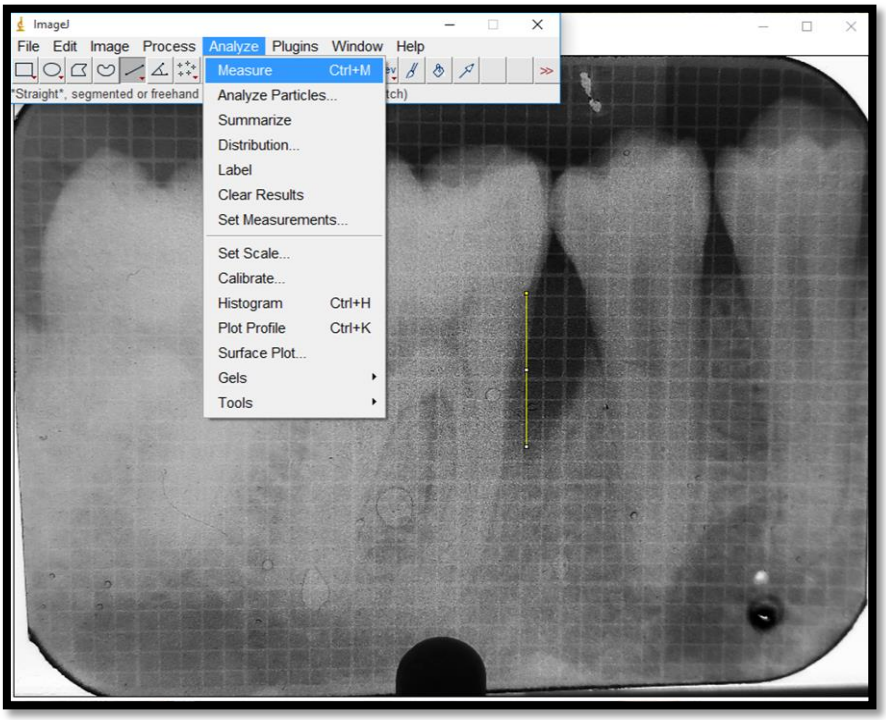


ANALYSIS OF RADIOGRAPHIC IMAGE WITH IMAGEJ SOFTWARE

Photograph 23A: SETTING SCALE OF 1mm PER RADIOGRAPHIC GRID



Photograph 23B: MEASUREMENT OF DEFECT



STATISTICAL ANALYSIS

Statistical Analysis was carried out using Statistical software **SPSS** (Statistical Package for Social Science) **Version 16** (IBM Corp, Chicago, IL, USA).

Quantitative data was assessed for normality using **Shapiro Wilk's Test**.

Intra group comparisons for parametric data (Plaque index, Gingival bleeding index, Periodontal probing depth and Clinical attachment level) between baseline, 6 months, 1 year was carried out using **Repeated Measures ANOVA**.

Intra group comparisons for parametric data (Bone Fill%, Bone crest change%, and Defect resolution%) between 6 months and 1 year was conducted using **Paired Sample t Test**.

Intergroup comparison of all the parametric data was carried out using **Independent Sample t Test**.

P ≤0.05 was evaluated as significant in the present study.

REPEATED MEASURES ANOVA

$$\mathrm{SS}_{\text{total}} = \sum_{i-1}^{a}\sum_{j-1}^{n_i}\sum_{k-1}^{t} Y_{ijk}^2 - Nt\overline{y}_{...}^2$$

$$\mathrm{SS}_{\text{treat}} = t\sum_{i-1}^{a} n_i \overline{y}_{i..}^2 - Nt\overline{y}_{...}^2$$

$$\mathrm{SS}_{\text{error(a)}} = t\sum_{i-1}^{a}\sum_{j-1}^{n_i} \overline{y}_{ij.}^2 - t\sum_{i-1}^{a} n_i \overline{y}_{i..}^2$$

$$\mathrm{SS}_{\text{time}} = N\sum_{k-1}^{t} \overline{y}_{..k}^2 - Nt\overline{y}_{...}^2$$

$$\mathrm{SS}_{\text{treat x time}} = \sum_{i-1}^{a}\sum_{k-1}^{t} n_i \overline{y}_{i.k}^2 - Nt\overline{y}_{...}^2 - \mathrm{SS}_{\text{treat}} - \mathrm{SS}_{\text{time}}$$

PAIRED SAMPLE t TEST FORMULA

$$t = \frac{\Sigma d}{\sqrt{\frac{n(\Sigma d^2) - (\Sigma d)^2}{n-1}}}$$

INDEPENDENT SAMPLE t TEST FORMULA:

$$t = \frac{\overline{X}_1 - \overline{X}_2}{\sqrt{\left(\frac{(N_1 - 1)s_1^2 + (N_2 - 1)s_2^2}{N_1 + N_2 - 2}\right)\left(\frac{1}{N_1} + \frac{1}{N_2}\right)}}$$

p value:

The **p value** or calculated probability was the estimated probability of rejecting the null hypothesis (H_0) of a study question when that hypothesis was true. The smaller the p-value, the more significant the result was said to be. In this study all the p-values are two tailed and confidence intervals were calculated at the 95% level. Differences between the two populations were considered significant when $p \leq 0.05$.

RESULTS

The present study was carried out with the aim to evaluate, the effectiveness of concentrated growth factor in combination with Bovine porous bone mineral as compared to Bovine porous bone mineral alone in the treatment of periodontal intrabony defects both clinically and radiographically. All the patients who were enrolled in the study returned for scheduled maintenance visits. A total of 10 patients and 20 sites exhibiting radiographic vertical / angular osseous defects within the age group of 20-60 years were selected for the study. The final results and statistical analysis was done for a total of 20 sites, 10 sites in each group.

In Group A, the defect was filled with a combination of Bovine porous bone mineral (BPBM) and Concentrated growth factors (CGF).

In Group B, the defect was filled with Bovine porous bone mineral (BPBM) mixed with saline.

All patients showed good compliance and healing period was uneventful for both the groups, without any signs of infections and complications, indicating biocompatibility of both grafting modalities. The observations and results of various parameters are summarized in the tables and figures. Master chart observations of clinical parameters are listed in table 1 and 2 with mean ± SD values and intragroup and intergroup comparisons in table 5, 6 and 7 respectively. Master chart observations of radiographic parameters are listed in table 3 and their mean ± SD, correction factor values, intragroup and intergroup comparisons are listed in table 4, 8 and 9 respectively. Figures 6,7,8,9,10 and figures 11,12,13,14 diagrammatically represent clinical and radiographic parameters respectively in both the groups.

CLINICAL PARAMETERS

1. Plaque Index

Intragroup comparison

The mean plaque index score at baseline was 2.30±0.39, at 6 months was 0.88±0.27 and at 1 year was 0.47±0.12. The mean reduction in plaque index from baseline to 6 months was 1.42±0.10 and from 6 months to 1 year was 0.41±0.06 which was statistically significant (p=0.000) at both time intervals.

2. Gingival Bleeding Index

Intragroup comparison

The mean gingival bleeding index percentage value was 76.83±6.55, at 6 months was 21.02±6.58 and at 1 year was 9.74±2.17. The mean reduction in gingival bleeding index score from baseline to 6 months was 55.81±1.84 and from 6 months to 1 year was 11.28±1.51 which was statistically significant (p=0.000) at both time intervals.

3. Probing pocket depth

Intragroup comparison

Group A: The mean pocket depth at baseline was 8.0±2.05, at 6 months was 3.6±1.35 and at 1 year was 2.2±0.91. The mean reduction in pocket depth from baseline to 6 months was 4.4±0.31 with p=0.000 and from 6 months to 1 year was 1.4±0.26 with p=0.002 which was statistically significant.

Group B: The mean pocket depth at baseline was7.0±1.83, at 6 months was 3.9±1.60 and at 1 year was 2.7±0.95. The mean reduction in pocket depth from baseline

to 6 months was 3.1±0.18 with p=0.000 and from 6 months to 1 year was 1.2±0.25 with p=0.003 which was statistically significant.

Intergroup comparison

The mean difference in pocket depth between Group A and Group B at baseline was 0.27, at 6 months was 0.66 and at 1 year was 0.25 which were statistically non-significant (p=0.265, p=0.655 and p=0.247 respectively).

4. Clinical Attachment level

Intragroup comparison

Group A: The mean clinical attachment level at baseline was 8.9±2.08, at 6 months was 4.9±1.96 and at 1 year was 3.5±1.72. The mean reduction in attachment level from baseline to 6 months was 4.0±0.39 with p=0.000 and from 6 months to 1 year was 1.4±0.27 with p=0.002 which was statistically significant.

Group B: The mean clinical attachment level at baseline was 8.3±1.95, at 6 months was 6.0±2.16 and at 1 year was 4.9±1.52. The mean reduction in attachment level from baseline to 6 months was 2.3±0.26 with p=0.000 and from 6 months to 1 year was 1.1±0.28 with p=0.01 which was statistically significant.

Intergroup comparison

The mean difference in pocket depth between Group A and Group B at baseline was 0.60, at 6 months was -1.1 and at 1 year was -1.4 which were statistically non-significant (p=0.514, p=0.250 and p=0.70 respectively).

RADIOGRAPHIC PARAMETERS

1. Bone Fill

Intragroup comparison

Group A: The mean bone fill at 6 months was 4.52±2.01 and at 1 year was 6.71±1.77. The mean difference in bone fill from 6 months to 1 year was 2.20 which was statistically significant (p = 0.000).

Group B: The mean bone fill at 6 months was 2.33±1.11 and at 1 year was 4.16±1.37. The mean difference in bone fill from 6 months to 1 year was 1.83 which was statistically significant (p = 0.001).

Intergroup comparison

At 6 months mean difference in bone fill between group A and group B was 2.19 which was statistically significant (p=0.007). At 1 year mean difference in bone fill between group A and group B was 2.56 which was statistically significant (p=0.002).

2. Bone Fill %

Intragroup comparison

Group A: The mean bone fill percentage at 6 months was 41.46±15.79 and at 1 year was 62.92±11.38. The mean difference in bone fill from 6 months to 1 year was 2.14 which was statistically significant (p = 0.001).

Group B: The mean bone fill percentage at 6 months was 23.16±9.26 and at 1 year was 41.52±8.97. The mean difference in bone fill from 6 months to 1 year was 1.83 which was statistically significant (p = 0.001).

Intergroup comparison

At 6 months mean difference in bone fill percentage between group A and group B was 18.30 which was statistically significant (p=0.005). At 1 year mean difference in bone fill between group A and group B was 21.40 which was statistically significant (p=0.000).

3.Bone crest change

Intragroup comparison

Group A: The mean bone crest change at 6 months was 0.98±0.57 and at 1 year was 1.79±0.77. The mean difference in bone fill from 6 months to 1 year was 0.82 which was statistically significant (p = 0.000).

Group B: The mean bone crest change at 6 months was 0.54 ± 0.29 and at 1 year was 1.11 ± 0.40. The mean difference in bone fill from 6 months to 1 year was 0.57 which was statistically significant (p = 0.001).

Intergroup comparison

At 6 months mean difference in bone crest change between group A and group B was 0.44 which was statistically significant (p=0.043). At 1 year mean difference in bone fill between group A and group B was 0.69 which was statistically significant (p=0.022).

4.Bone Crest change %

Intragroup comparison

Group A: The mean bone crest change percentage at 6 months was 27.39±14.90 and at 1 year was 50.64±16.68. The mean difference in bone fill from 6 months to 1 year was 2.32 which was statistically significant (p = 0.000).

Group B: The mean bone crest change percentage at 6 months was 14.08±7.14 and at 1 year was 30.03±13.53. The mean difference in bone fill from 6 months to 1 year was 1.59 which was statistically significant (p = 0.002).

Intergroup comparison

At 6 months mean difference in bone crest change percentage between group A and group B was 13.31 which was statistically significant (p=0.02). At 1 year mean difference in bone fill between group A and group B was 20.61 which was statistically significant (p=0.007).

5.Defect resolution:

Intragroup comparison

Group A: The mean defect resolution at 6 months was 3.53±1.76 and at 1 year was 4.92±1.39. The mean difference in bone fill from 6 months to 1 year was 1.385 which was statistically significant (p = 0.002).

Group B: The mean defect resolution at 6 months was 1.79±1.10 and at 1 year was 3.05±1.56. The mean difference in bone fill from 6 months to 1 year was 1.25 which was statistically significant (p = 0.009).

Intergroup comparison

At 6 months mean difference in defect resolution between group A and group B was 1.74 which was statistically significant (p=0.016). At 1 year mean difference in bone fill between group A and group B was 1.86 which was statistically significant (p=0.011).

6.Defect resolution %

Intragroup comparison

Group A: The mean defect resolution percentage at 6 months was 47.76±19.12 and at 1 year was 68.80±9.05. The mean difference in bone fill from 6 months to 1 year was 2.10 which was statistically significant (p = 0.004).

Group B: The mean defect resolution percentage at 6 months was 28.31±14.31 and at 1 year was 47.61±14.96. The mean difference in bone fill from 6 months to 1 year was 1.93 which was statistically significant (p = 0.009).

Intergroup comparison

At 6 months mean difference in defect resolution percentage between group A and group B was 19.44 which was statistically significant (p=0.019). At 1 year mean difference in bone fill between group A and group B was 21.20 which was statistically significant (p=0.001).

TABLES

TABLE 1:

MASTER CHART 1: PLAQUE INDEX AND GINGIVAL BLEEDING INDEX

S.NO	AGE (years)	SEX (M/F)	BASELINE		6 MONTHS		1 YEAR	
			PI	GBI%	PI	GBI%	PI	GBI%
1	31	F	2.8	81.7	1.0	26.9	26.9	26.9
2	33	M	2.6	79.3	0.8	21.7	21.7	21.7
3	22	M	2.1	75.9	0.7	15.8	15.8	15.8
4	22	M	2.1	75.9	0.7	15.8	15.8	15.8
5	29	F	1.9	64.1	0.6	20.3	20.3	20.3
6	48	M	2.0	83.4	1.2	27.1	27.1	27.1
7	31	F	2.8	81.7	1.0	17.6	17.6	17.6
8	32	F	1.7	72.5	0.5	14.2	14.2	14.2
9	59	F	2.6	84.2	1.4	34.5	34.5	34.5
10	33	M	2.4	69.6	0.9	16.3	16.3	16.3

TABLE 2:

MASTER CHART 2: CLINICAL PARAMETERS

S.NO	GROUP A						GROUP B					
	Baseline (mm)		6 months (mm)		1 year (mm)		Baseline (mm)		6 months (mm)		1 year (mm)	
	PPD	CAL	PPD	CAL	PPD	CAL	PPD	CAL	PPD	CAL	PPD	CAL
1	7	8	3	4	2	3	6	7	4	6	3	5
2	10	11	4	5	3	4	9	10	5	7	3	5
3	8	8	3	3	2	2	6	7	3	4	2	3
4	9	9	4	4	2	2	6	7	3	4	2	3
5	7	7	3	4	1	2	5	7	2	4	2	4
6	6	7	3	4	2	3	8	10	5	8	3	6
7	9	11	4	6	3	5	9	11	5	8	3	6
8	5	7	2	5	2	5	6	7	3	5	2	5
9	7	8	3	4	1	2	5	6	2	4	2	4
10	12	13	7	10	4	7	10	11	7	10	5	8

TABLE 3A:

MASTER CHART 3: RADIOGRAPHIC PARAMETERS

S.NO	GROUP A								
	BASELINE (mm)			6 MONTHS (mm)			1 YEAR (mm)		
	CEJ – BD	CEJ-AC	AC – BD	CEJ - BD	CEJ-AC	AC - BD	CEJ - BD	CEJ-AC	AC-BD
1	10.455	2.870	7.585	5.014	2.092	2.922	3.329	1.528	1.801
2	12.869	3.936	8.933	6.173	2.374	3.799	4.105	1.371	2.734
3	12.10	3.789	8.311	5.213	2.001	3.212	2.361	0.594	1.767
4	10.211	1.810	8.401	5.332	1.736	3.596	3.632	1.245	2.387
5	9.517	2.604	6.913	7.894	1.928	5.966	3.341	1.395	1.946
6	8.506	2.638	5.868	4.721	1.742	2.979	3.152	1.183	1.969
7	12.275	4.729	7.546	6.547	3.964	2.583	5.051	2.857	2.194
8	8.273	4.283	3.99	6.931	3.617	3.314	5.274	3.242	2.032
9	8.493	3.371	5.122	5.326	2.507	2.819	2.870	1.431	1.439
10	13.871	5.692	8.179	10.204	4.714	5.49	7.150	3.301	3.849

TABLE 3B:

MASTER CHART 4: RADIOGRAPHIC PARAMETERS

S.NO	GROUP B								
	BASELINE (mm)			6 MONTHS (mm)			1 YEAR (mm)		
	CEJ - BD	CEJ- AC	AC- BD	CEJ - BD	CEJ- AC	AC- BD	CEJ - BD	CEJ- AC	AC- BD
1	9.406	3.471	5.935	7.856	3.293	4.563	5.016	2.965	2.051
2	12.523	3.682	8.841	8.442	3.051	5.391	5.984	2.293	3.691
3	7.816	3.00	4.816	4.845	2.542	2.303	3.896	1.529	2.367
4	7.421	3.320	4.101	5.274	2.475	2.799	4.425	1.454	2.971
5	8.602	3.742	4.86	7.422	3.351	4.071	5.959	3.021	2.938
6	12.395	3.550	8.845	10.482	3.341	7.141	6.880	3.205	3.675
7	12.429	4.928	7.501	8.026	4.397	3.629	6.891	3.902	2.989
8	8.031	4.052	3.979	7.710	3.660	4.05	6.590	3.215	3.375
9	8.021	3.609	4.412	6.392	2.914	3.478	4.539	2.431	2.108
10	12.994	5.037	7.957	11.321	4.582	6.739	9.016	3.910	5.106

TABLE 4:

CORRECTION FACTOR (CF) CALCULATION FOR RADIOGRAPHIC PARAMETERS

GROUP A						
S.NO	CEJ – RA		CF 6	CEJ – RA		CF 1
	BASELINE	6 MONTHS		BASELINE	1 YEAR	
1	18.62	16.94	0.91	18.62	16.20	0.87
2	17.95	20.64	1.15	17.95	18.67	1.04
3	18.5	15.73	0.85	18.5	16.84	0.91
4	17.97	17.43	0.97	17.97	17.07	0.95
5	17.6	17.78	1.01	17.6	17.6	1
6	16.84	13.81	0.82	16.84	17.85	1.06
7	18.23	18.96	1.04	18.23	20.42	1.12
8	18.48	17.74	0.96	18.48	16.45	0.89
9	16.73	18.90	1.13	16.73	15.39	0.92
10	18.47	15.88	0.86	18.47	17.92	0.97
GROUP B						
S.NO	CEJ – RA		CF 6	CEJ – RA		CF 1
	BASELINE	6 MONTHS		BASELINE	1 YEAR	
1	18.25	19.16	1.05	18.25	17.16	0.94
2	17.64	19.76	1.12	17.64	18.52	1.05
3	17.93	17.21	0.96	17.93	20.26	1.13
4	16.97	17.99	1.06	16.97	16.29	0.96
5	18.24	18.60	1.02	18.24	17.15	0.94
6	17.35	15.96	0.92	17.35	16.14	0.93
7	17.89	17.53	0.98	17.89	18.96	1.06
8	16.72	14.04	0.84	16.72	15.55	0.93
9	18.58	18.95	1.02	18.58	16.54	0.89
10	17.79	16.19	0.91	17.79	17.61	0.99

TABLE 5A:

PLAQUE INDEX AND GINGIVAL BLEEDING INDEX

PARAMETER	(MEAN ±SD)		
	BASELINE	6 MONTHS	1 YEAR
PI	2.30±0.39	0.88±0.27	0.47±0.12
GBI	76.83±6.54	21.02±6.57	9.74±2.17

TABLE 5B:

PROBING DEPTH & CLINICAL ATTACHMENT LEVEL:

GROUP A			
PARAMETERS	(Mean ±SD)		
	BASELINE	6 MONTHS	1 YEAR
PPD	8.0 ± 2.05	3.6 ± 1.35	2.2 ± 0.92
CAL	8.9 ± 2.08	4.9 ± 1.97	3.5 ± 1.72
GROUP B			
PARAMETERS	(Mean ±SD)		
	BASELINE	6 MONTHS	1 YEAR
PPD	7.0 ± 1.83	3.9 ± 1.60	2.7 ± 0.95
CAL	8.3 ± 1.94	6.0 ± 2.16	4.9 ± 1.52

TABLE 6A: INTRAGROUP COMPARISON:

PLAQUE INDEX & GINGIVAL BLEEDING INDEX:

TIME INTERVAL	PLAQUE INDEX		GINGIVAL BLEEDING INDEX	
	Mean difference	P value	Mean difference	P value
Baseline - 6 months	1.42	0.000*	55.81	0.000*
6 months - 1 year	0.41	0.000*	11.28	0.000*

TABLE 6B: PERIODONTAL PROBING DEPTH

TIME INTERVAL	GROUP A		GROUP B	
	Mean difference	P value	Mean difference	P value
Baseline - 6 months	4.40	0.000*	3.10	0.000*
6 months - 1 year	1.40	0.002*	1.20	0.003*

TABLE 6C: CLINICAL ATTACHMENT LEVEL

TIME INTERVAL	GROUP A		GROUP B	
	Mean difference	P value	Mean difference	P value
Baseline - 6 months	4.00	0.000*	2.30	0.000*
6 months - 1 year	1.40	0.002*	1.10	0.010*

*Statistically significant ($p<0.05$)

Repeated measures ANOVA for intra group comparison

TABLE 7: INTERGROUP COMPARISON

CLINICAL PARAMETERS:

PARAMETER	TIME FRAME	Mean Difference (Group A Vs Group B)	p value
Periodontal probing depth (PPD)	Baseline	1.0	0.26
	6 months	-0.3	0.65
	1 year	-0.5	0.25
Clinical attachment level (CAL)	Baseline	0.6	0.51
	6 months	-1.1	0.25
	1 year	-1.4	0.07

Independent sample t test for intergroup comparisons.

Statistically non-significant (p>0. 05)

TABLE 8: INTRAGROUP COMPARISONS

RADIOGRAPHIC PARAMETERS

GROUP A			
PARAMETERS	**(Mean ±SD)**		**p value**
	6 MONTHS	**1 YEAR**	
Bone fill (BF)	4.52 ± 2.01	6.71 ± 1.77	0.000*
Bone fill percentage (BF%)	41.46 ± 15.79	62.92 ± 11.38	0.001*
Bone crest change (BCC)	0.98 ± 0.57	1.79 ± 0.77	0.000*
Bone crest change percentage (BCC%)	27.39 ± 14.90	50.64 ± 16.68	0.000*
Defect resolution (DR)	3.53 ± 1.76	4.92 ± 1.39	0.002*
Defect resolution percentage (DR%)	47.76 ± 19.12	68.80 ± 9.05	0.004*
GROUP B			
PARAMETERS	**(Mean ±SD)**		**p value**
	6 MONTHS	**1 YEAR**	
Bone fill (BF)	2.23 ± 1.11	4.16 ± 1.37	0.001*
Bone fill percentage (BF%)	23.16 ± 9.26	41.52 ± 8.97	0.001*
Bone crest change (BCC)	0.54 ± 0.29	1.11 ± 0.40	0.001*
Bone crest change percentage (BCC%)	14.08 ± 7.14	30.03 ± 13.53	0.002*
Defect resolution (DR)	1.79 ± 1.10	3.05 ±1.56	0.009*
Defect resolution percentage (DR%)	28.31 ± 14.31	47.61 ± 14.96	0.009*

*Statistically significant ($p<0.05$)

Paired sample t test for intragroup comparisons

TABLE 9: INTERGROUP COMPARISONS

RADIOGRAPHIC PARAMETERS

PARAMETER	TIME FRAME	Mean Difference (Group A Vs group B)	p value
Bone fill (BF)	6 months	2.19	0.007*
	1 year	2.56	0.002*
Bone fill percentage (BF%)	6 months	18.29	0.005*
	1 year	21.40	0.000*
Bone crest change (BCC)	6 months	0.44	0.043*
	1 year	0.69	0.022*
Bone crest change percentage (BCC%)	6 months	13.31	0.020*
	1 year	20.61	0.007*
Defect resolution (DR)	6 months	1.74	0.016*
	1 year	1.86	0.011*
Defect resolution percentage (DR%)	6 months	19.44	0.019*
	1 year	21.20	0.001*

*Statistically significant ($p<0.05$)

Independent sample t test for intergroup comparisons

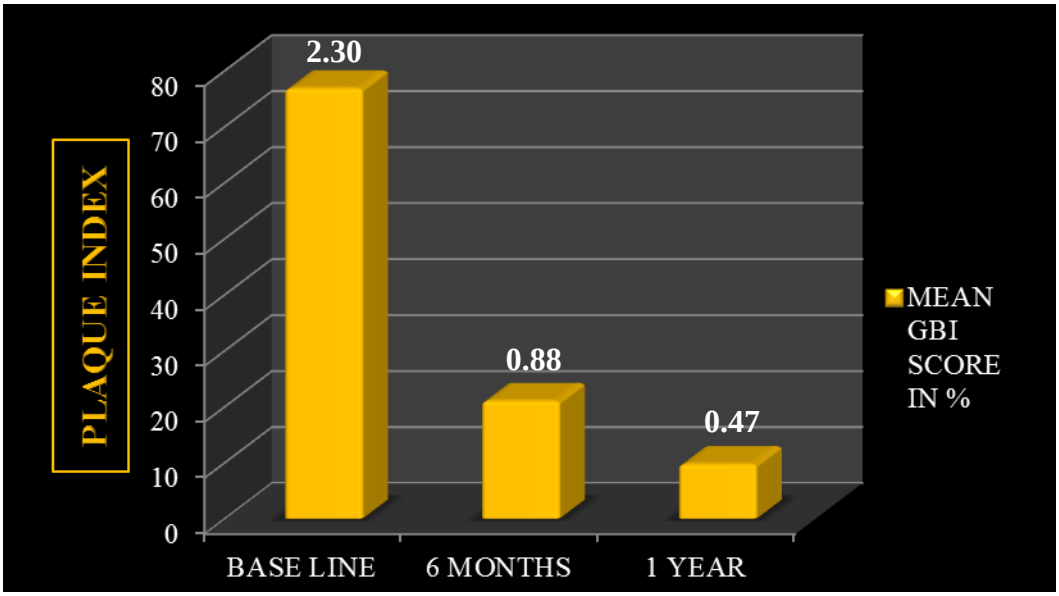


Figure 6: Comparison of mean score in Plaque index (PI) at Baseline, 6 months and 1 year

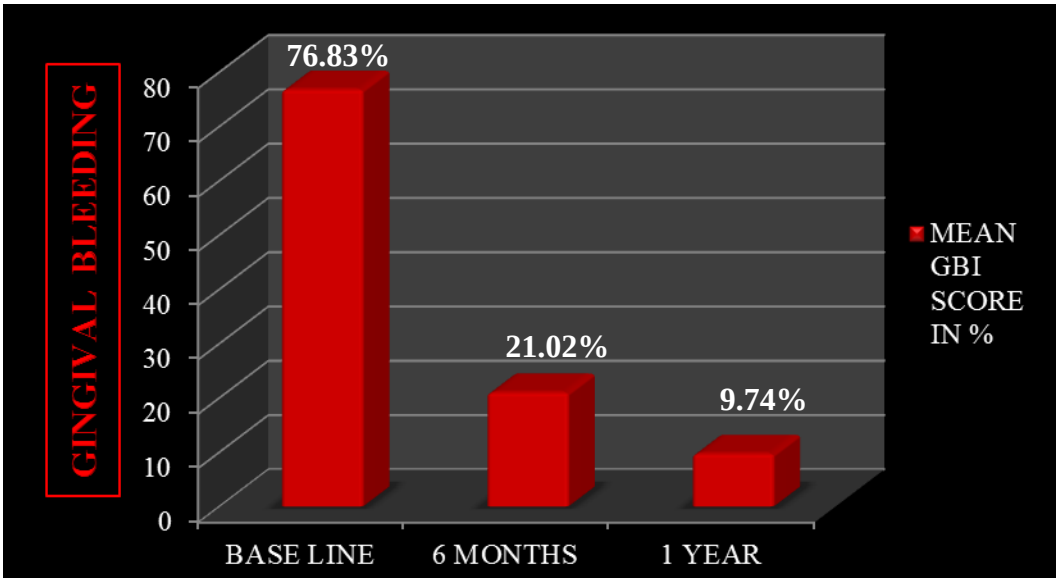


Figure 7: Comparison of mean score in Gingival bleeding index at Baseline, 6 months and 1 year

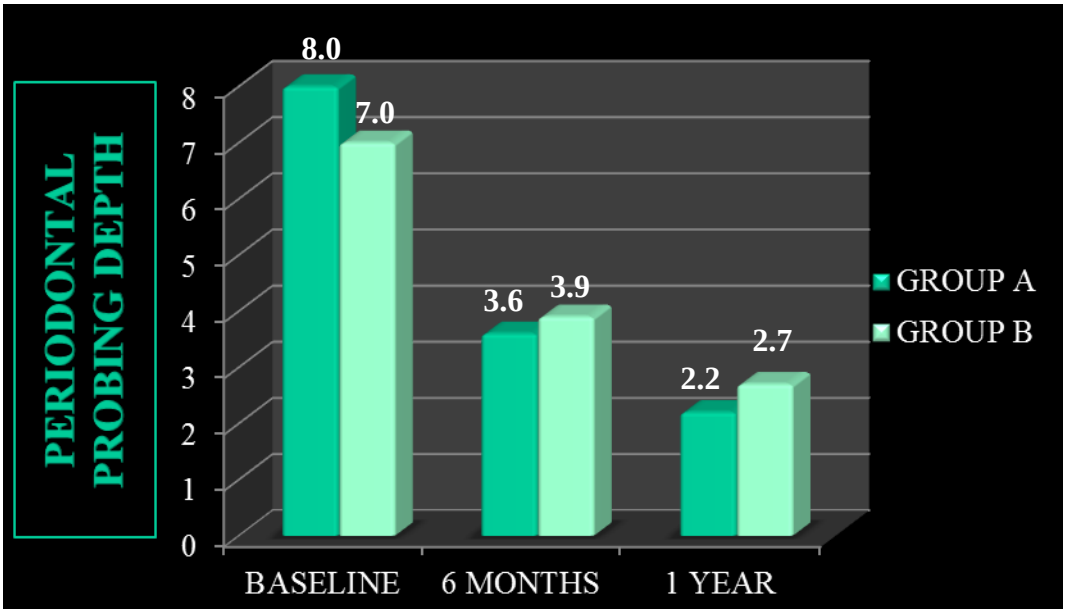


Figure 8: Comparison of Probing pocket depth (mm) between Group A and Group B

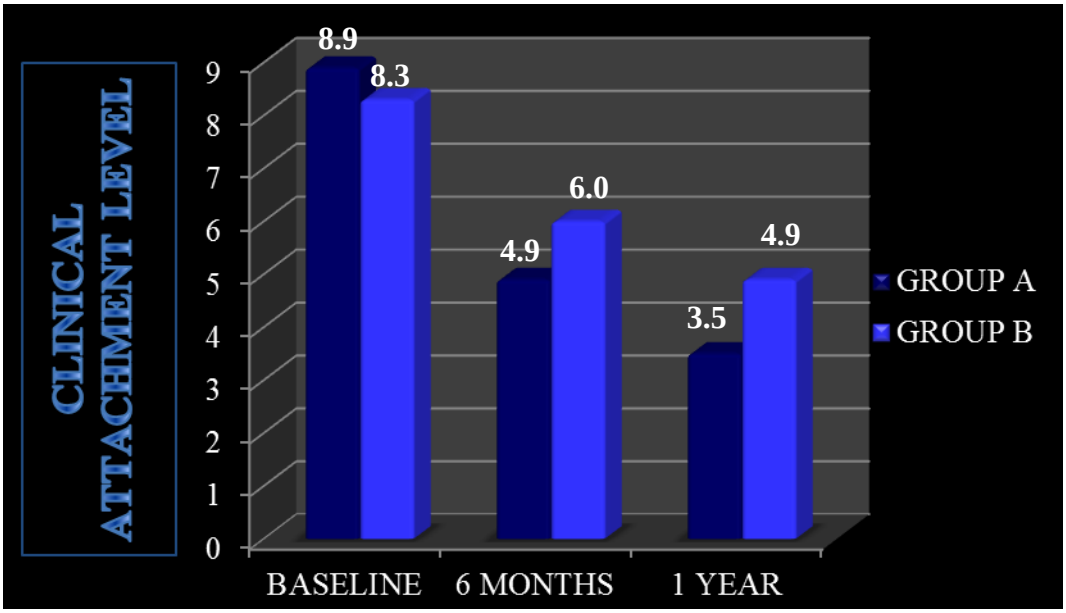


Figure 9: Comparison of Clinical attachment level (mm) between Group A and Group B

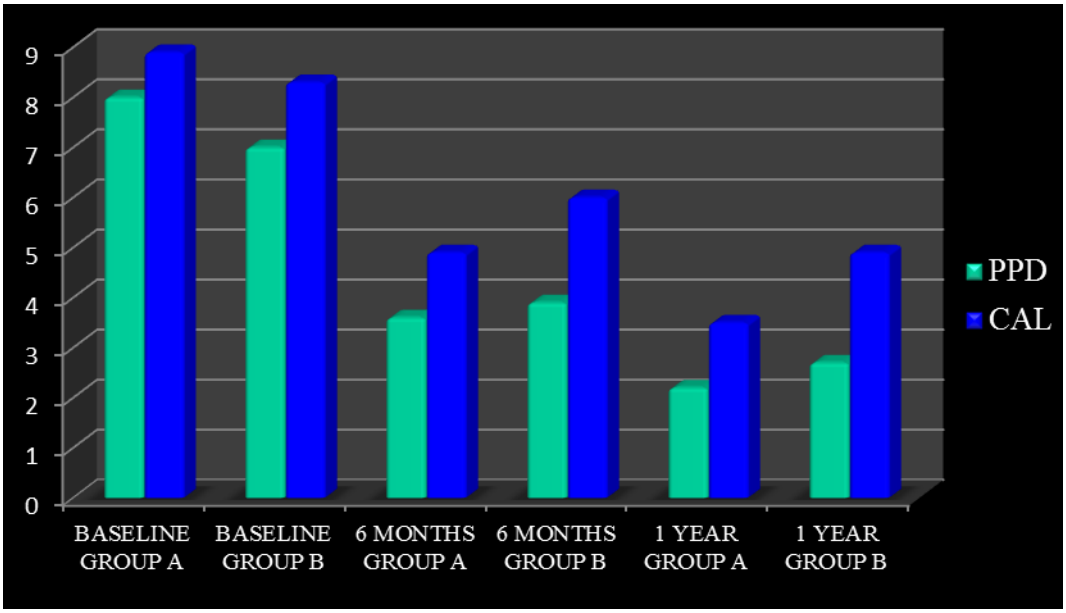


Figure 10: Comparison of Clinical parameters

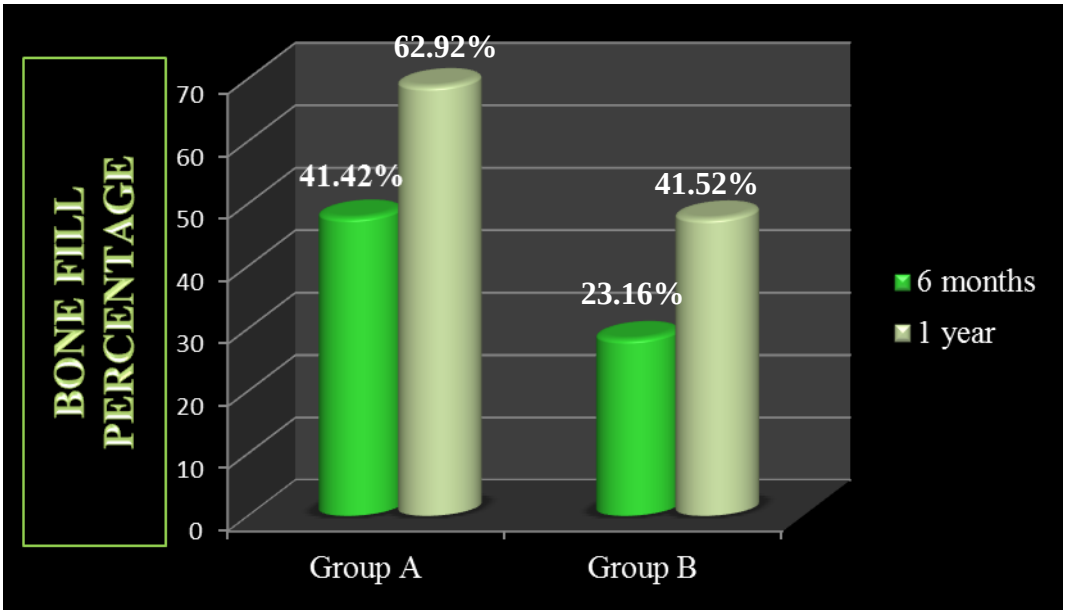


Figure 11: Comparison of Bone fill percentage between Group A and Group B

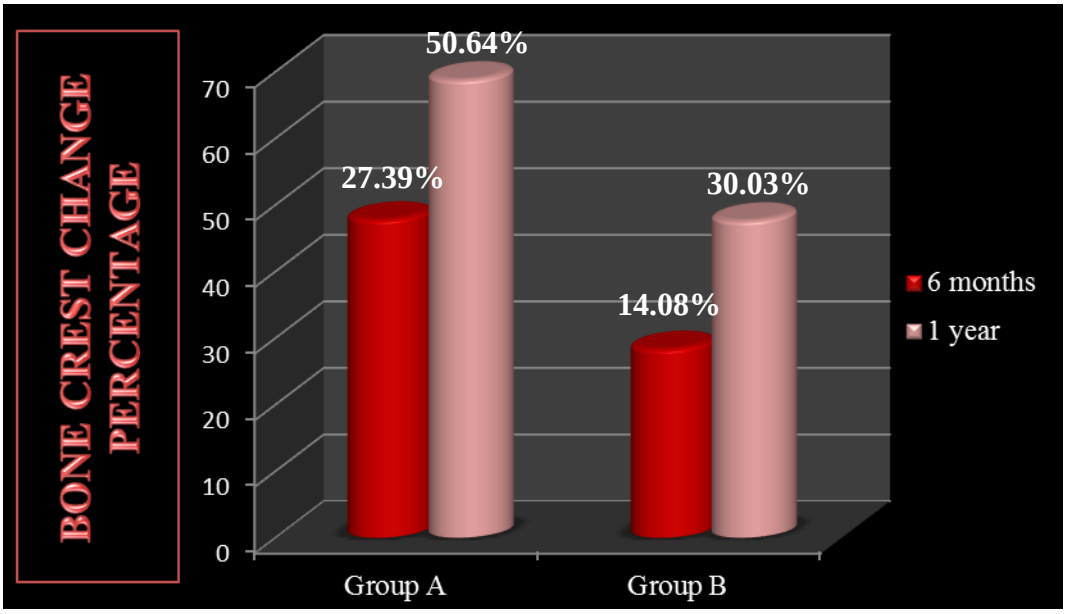


Figure 12: Comparison of Bone crest change percentage between Group A and Group B

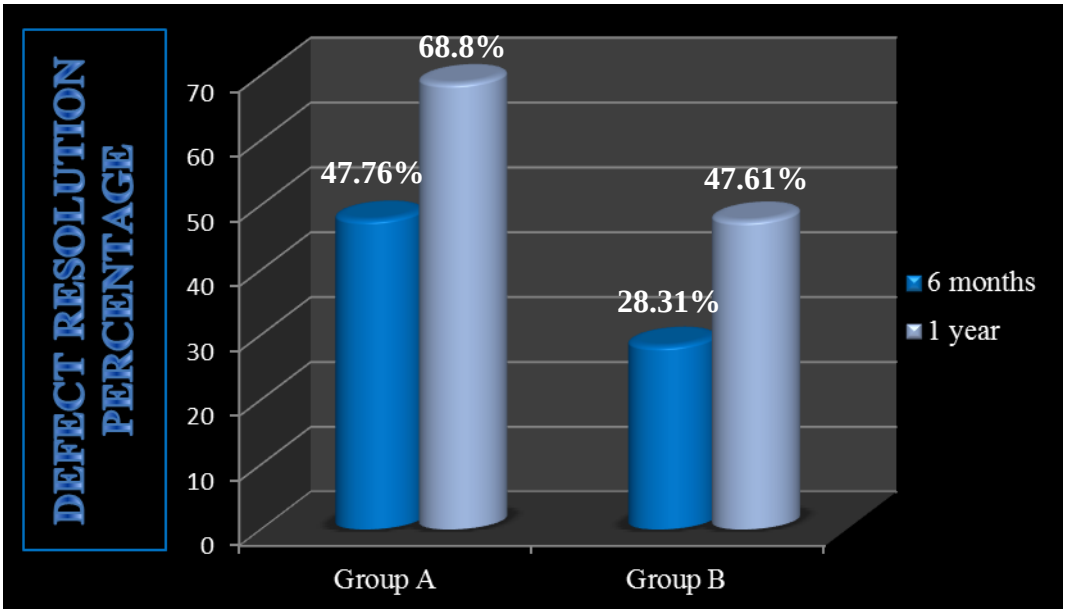


Figure 13: Comparison of Defect resolution percentage between Group A and Group B

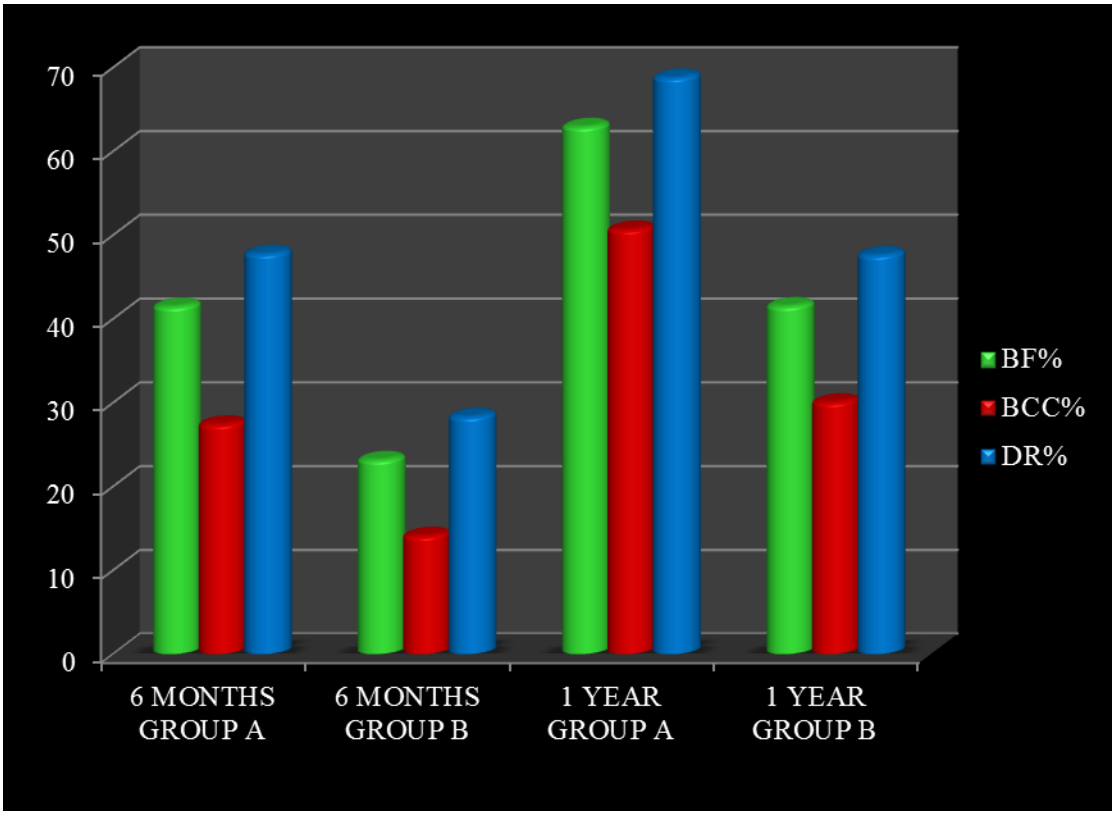


Figure 14: Comparison of Radiographic parameters

DISCUSSION

The last two decades of periodontal therapy has perceived a significant progress in various aspects. A complete shift of resective pocket eradicative procedures to techniques and methods aimed at regeneration and conservation of the periodontium has been obtained. Bone being the crux of periodontal disease has evidently received lot of attention.[70]

A wide array of new materials has been used for promoting periodontal regeneration in intraosseous defects. The bone replacement grafts provide regeneration through conductive or inductive processes and in combination with growth factors, have the potential to optimize the outcome of periodontal regeneration.[51] Till date no graft material has been proven as a gold standard in the treatment of intrabony defects. However in a systematic review ***Trombelli et al***[71] have concluded that the use of specific biomaterials/bone grafts was more effective than open flap debridement in improving attachment levels in intraosseous defects.

In the present study Bovine porous bone mineral (Geistlich Bio-Oss®) was the graft material used. Like in earlier studies[72] bovine porous bone mineral exhibited favourable handling properties such as:

1. Ease of delivery to the site,
2. Ease of condensing the material into the defect,
3. Ability of the material to demonstrate an adhesion once placed in the defect, even with significant haemorrhage of the wound site, providing a stable graft.

Polypeptide growth factors are one of the fundamental elements in tissue engineering, which have shown an important role in the growth and differentiation of

cells involved in periodontal wound healing.[73,74] Platelets, a major resource of autogenous growth factors, are among the first cells to reach a wound site and initiate the healing process.

Platelet-rich plasma (PRP) was the first generation of platelet gel used in periodontal regeneration therapy.[35,75,76,77] While the potential benefits of this procedure have been critiqued, many of the discrepancies are likely more related to the lack of suitable methodological standardization and definition of the different PRP preparations than to any functional inadequacies, as the protocols and biological and surgical techniques used in the administration of the PRPs differ widely between study groups.[78,79]

Platelet-rich fibrin (PRF), the second generation of platelet concentrate products, exhibits the same properties as PRP with the advantages of osteogenicity, a simple preparation process and a lack of bovine thrombin and anticoagulants, as it is produced from autologous blood.[31,37,80]

Unlike PRF, CGF use variable rpm from 2400-3000 rpm to separate cells in the venous blood, therefore, results in fibrin rich blocks that are much larger, denser and richer in growth factors than common PRF. This shows superior regenerative capacity and higher versatility when using the fibrin rich block. According to **Rodella**[8], CGF shows higher tensile strength, more growth factors, higher viscosity and higher adhesive strength than PRF. So surgeons can use CGF as barrier membrane to accelerate soft tissue healing or be mixed with bone graft to accelerate bone and soft tissue regeneration.

One major criterion for periodontal regeneration is the maintenance of a wound space for the periodontal ligament cells to migrate into. For growth factors to exert their potential, they require a medium that can provide this space, and thus cell

induction and differentiation can be obtained. ***Marx et al***[35] demonstrated a 1.62 to 2.16 fold increase in bone maturation using autologous platelet preparation in combination with a bone graft compared to bone graft alone in large human mandibular defects. However, only one study has focused on the application of CGF in combination with bone graft till date, evaluating the treatment outcomes in intra-bony defects.[92]

The present study was designed to evaluate the effectiveness of CGF with a BG when compared to BG alone. For this purpose, a total of 20 sites in 10 patients were taken in a split mouth design for the study.

Only 3-wall and combined intrabony defects were selected because the number of remaining bony walls were found to be correlated positively with regeneration potential in grafting procedures.[81,82] In addition, 3-wall defects provide the best spatial relationship for defect bridging by vascular and cellular elements from the periodontal ligament and adjacent osseous wall.[83]

Defect morphology plays a vital role in healing after periodontal-regenerative treatment of intrabony defects. This was demonstrated in studies showing that the depth of the intrabony component of the defect influenced the amount of clinical attachment and bone gained at 1 year: the deeper the defect, the greater was the amount of clinical improvement.[84-88] However, in a multicenter controlled study, it was demonstrated that deep and shallow defects have the 'same potential' for regeneration.[89]

The uneventful healing and the lack of adverse reactions post-operatively suggested that BG and CGF used were tolerated well and in line with observation from previous studies that failed to show any foreign body reaction during initial healing and thereafter in the 6-month and 1 year evaluation period.[27,28,59,62]

On evaluating the clinical parameters, mean plaque score and gingival bleeding score were 2.30 & 76.83% respectively. The plaque index and the gingival bleeding index showed statistically significant difference 6 months (0.88 & 21.02%) and 1 year (0.47 & 9.74) with p=0.000 respectively. These results were in accordance with the studies by **Yukna et al** [90] and **Srikanth et al**[91] who observed that patients undergoing periodontal therapy try to maintain optimal oral hygiene.

The mean probing depth at baseline in group A and group B were 8.0mm and 7.0mm respectively. Significant reduction in periodontal probing depth (PPD) were observed in both group A and group B at 6 months (3.6mm and 3.9mm) and 1 year (2.2mm and 2.7mm) respectively. But the intergroup comparison showed no statistically significant difference between two groups. The reduction in pocket depth was better than a 1 year follow up study conducted by **Qiao J et al**[92] in thirty-one intrabony defects treated with CGFs + BPBM or BPBM alone which was 3.1mm and 4.5mm respectively. Similar results were obtained in a study by **Sezgin Y et al**[93] on effects of platelet-rich fibrin (PRF) on healing of intra-bony defects treated with anorganic bovine bone mineral (ABBM) in which the reduction in pocket depth in 6 months was 2.53mm and 2.86 mm respectively.

Similarly in the present study significant reduction in clinical attachment level (CAL) were observed in both group A and group B at 6 months (4.9mm and 6.0mm) and 1 year (3.5mm and 4.9mm) from baseline (8.9mm and 8.3mm) respectively. But the intergroup comparison showed no statistically significant difference between two groups. These results were in accordance with the study conducted by **Qiao J et al**[92] which was 2.4 ± 1.1 mm and 3.7 ± 1.3 mm respectively. Also the results were similar with results obtained by **Sezgin Y et al**[93] with CAL of 3.86mm and 4.46mm respectively.

When evaluating the radiographic parameters,in the present study on intragroup comparison, the bone fill percentage showed statistically significant values in group A and group B when compared at 6 months (41.46 % & 23.16%), and 1 year (62.92% & 41.52%) with p=0.001 respectively. Moreover on intergroup comparison at 6 months and one year group A was found to be statistically highly significant than group B with p=0.005 and p=0.000 respectively. The results of the present study are in accordance with previous study by **Lekovic *et al***[54] which showed a defect fill of 4.06 ± 0.87mm on buccal and 3.94 ± 0.73 on lingual sites in PRF + BPBM (Bovine porous bone mineral) compared to PRF group (2.21 ± 0.68 mm on buccal and 2.06 ± 0.64 mm on lingual sites). **Agarwal et al**[94] reported that PRF + DFDBA (demineralized freeze-dried bone allograft) showed a mean bone fill of 3.50 ± 0.67 mm compared to DFDBA (2.49 ± 0.64 mm). **Chandradas ND et al**[57] reported a bone fill% of 61.53% and 49.6% in PRF+DBM and PRF groups respectively which was in accordance with the present study.

On intragroup comparison of the bone crest change percentage showed statistically significant values in both group A and group B when compared on 6 months (27.39% & 14.08%) and 1 year (50.64% & 30.02%) with p=0.000 & 0.002 respectively. Moreover on intergroup comparison at 6 months and one year group A was found to be statistically highly significant than group B with p=0.02 and p=0.007 respectively.

When evaluating the intragroup comparison of the defect resolution percentage showed statistically significant values in both group A and group B when compared on 6 months (47.76% & 28.31%) and 1 year (68.8% & 47.61%) with p=0.004 & 0.009 respectively. Moreover on intergroup comparison at 6 months and one year

group A was found to be statistically highly significant than group B with p=0.019 and p=0.001 respectively.

In the present study CGF+BPBM group demonstrated better results in clinical and radiographic parameters than BPBM alone in the management of periodontal intrabony defects. None of the above mentioned studies discussed about bone crest change and defect resolution.[54,57,92,93,94] In the present study bone crest change and defect resolution has been calculated. This result may be attributed to the additional beneficial effects of CGF.

Although good intra-examiner reproducibility was obtained, the re-entry measurement is still the 'gold standard' to reflect actual bone change; and periapical radiography is inherently limited in its ability to evaluate true bone level. However, future long-term clinical and histological studies with larger sample size should be undertaken to determine the efficacy of bovine porous bone mineral in combination with concentrated growth factor in the treatment of intrabony defects. Thus in future, CGF may prove to be a novel adjunct to conventional regenerative methods in management of periodontal osseous defects.

SUMMARY AND CONCLUSION

The present study was conducted in order to evaluate the effectiveness of concentrated growth factor in combination with Bovine porous bone mineral as compared to Bovine porous bone mineral alone in the treatment of periodontal intrabony defects. A total of twenty defects in ten patients were selected for the study. The defects were randomly divided into two groups to receive CGF + BPBM and BPBM alone. Thus each group had ten defects. The clinical and radiographic data were assessed over a period of 6 months and 1 year and the values were subjected to statistical analysis.

The following conclusions were drawn from the study:

- Both CGF + BPBM and BPBM were well tolerated by the periodontal tissues during the course of the study.
- There was a definite improvement in the clinical and radiographic parameters in both groups, i.e. CGF + BPBM and BPBM from baseline to 6 months and 1 year.
- Radiographic evidence of bone fill, alveolar crest change and defect resolution were observed in both the groups. The difference at the end of 6 months and 1 year were statistically significant in both the groups.
- Addition of CGF revealed its beneficial effect in the combination group (CGF+BPBM) with evidence of significant increase in bone fill, alveolar crest change and defect resolution at 6 months and 1 year when compared to BPBM alone.

The outcomes of regenerative periodontal therapy are dependent on multiple factors such as patient selection, defect selection, choice of diagnostic and therapeutic

modalities and post-operative follow up period. Therefore all these factors should be taken into consideration during decision making.

Within the limits of the present study, it can be concluded that both the treatment modalities were effective in improving the clinical as well as radiographic parameters. The addition of Concentrated growth factor to Bovine porous bone mineral has demonstrated successful and promising results. Thus in future, clinical trials with larger sample size may be employed to further explore the potential benefits of CGF as a grafting material.

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ANNEXURE - 1

PARTICIPANT INFORMATION SHEET

Investigator: DR.S.RUBINE

Guide : DR.JAISHREE TUKARAM KSHIRSAGAR, MDS

Title: **EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS – A SPLIT MOUTH STUDY**

Name of the research institution: Tamil Nadu Government Dental College and Hospital, Chennai

The investigator, Dr. S.RUBINE under the guidance of Dr. JAISHREE TUKARAM KSHIRSAGAR, MDS is conducting a study as titled above with aim to do an evaluation of effectiveness of concentrated growth factor with bovine porous bone mineral as compared to bovine porous bone mineral alone in the treatment of intra bony defects

1. **Procedure: the following examinations and investigations will be done for you.**
    - Intraoral examination, Extra oral examination
    - Blood test – 7ml of blood (1 table spoon) will be drawn from your hand
    - X-ray will be taken for the diseased site with protection (lead apron , thyroid collars)
    - Model of your teeth will be prepared by taking alginate impression
    - Deposits on your teeth will be cleaned with ultrasonic scaler and hand instrument.
    - Surgery will be done in diseased site by raising the gums and cleaning the root part of the teeth with hand instruments and salt water irrigation will be done and the intended material will be placed and the gums will be repositioned and stitched with suture material.
    - Clinical evaluation will be performed at baseline, 3 months and 6 months and 9 months after the procedure and radiological evaluation will be performed at baseline, 6 months and 9 months after the procedure.

2. **Risk of participation:**
   - Patients may be allergic to LA or the material used in the study.
   - Patient may experience pain, discomfort, swelling following the procedure.
   - Patient will be exposed to radiation while taking radiographs during study.
3. **Benefits of participation:**

   Patients will be treated for improving the periodontal status and minimizing alveolar bone loss.

4. **Confidentiality :**

   The identity of the patients participating in the research will be kept confidential throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

5. **Participants right :**

   Taking part in the study is voluntary. You are free to decide whether to participate in the study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled. The results of this study will be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

6. **Compensation: Nil**

7. **Contacts:**

For queries related to the study:	**Contact details regarding rights of the participant:**
Primary Investigator: Dr.S.RUBINE PG Student Department of Periodontics Tamilnadu Govt. Dental College & Hospital Chennai- 600 003 Mobile – 9789800598	Dr. B. Saravanan, MDS,PhD, The Chairperson, Institutional Ethical committee Tamilnadu Govt. Dental College & Hospital, Chennai-600 003.

ANNEXURE - 4

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராயச்சியின் தலைப்பு

பல்வேர் பகுதி எலும்பு தேய்மானத்தில் குவிப்பு வளர்ச்சி காரணி மற்றும் மாட்டு நுண்ணிய எலும்பு தாது ஆகியவற்றை இணைத்து பயன்படுத்தி மற்றும் மாட்டு நுண்ணிய எலும்பு தாதுவை மட்டும் பயன்படுத்தி மீளுருவாக்கம் திறன் மதிப்பீடு– மனித பிரிவாய் ஆய்வு

பெயர் புறநோயாளி எண்

வயது/ பால் ஆராய்ச்சி சேர்க்கை எண்

முகவரி

தொலைபேசி

நான் …… வயது …… என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள ஒப்புதல் அளிக்கிறேன்.

கீழ்காணப்படும் நிபந்தனைகளுக்கு நான் சம்மதிக்கிறேன்.

- நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றம் செயல்முறைகள் பற்றி முழுமையாக தெரிவிக்கப்பட்டுள்ளேன்.
- நான் இந்த ஆய்வுக்காக ஈறு அறுவை சிகிச்சை செய்துகொள்ள வேண்டியதாக அறிகிறேன்.
- சிகிச்சையின்போது குவிப்பு வளர்ச்சி காரி மற்றும் மாட்டு நுண்ணிய எலும்பு தாது ஆகியவற்றை இணைத்து பயன்படுத்த சம்மதிக்கிறேன்.
- என் உடல் நலம் பாதிக்ப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்குறிகள் தென்பட்டாலோ அதற்கு சிகிச்சை பெற்றுக்கொள்வதற்கும் முழு உரிமை உள்ளதாக அறிகிறேன்.
- நான் ஏற்கனவே உட்கொண்ட மற்றும் உட்கொள்கின்ற மருந்துகளின் விபரங்களை ஆராய்ச்சியாளரிடம் தெரிவித்துள்ளேன்.
- என் மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்திக்கொள்ள சம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும் ஆராய்ச்சியாளரும் என்னுடைய விபரங்கள் அனைத்தையும் இரகசியமாக வைப்பதாக அறிகிறேன்.

……	……	……
நேயாளியின் பெயர்	கையொப்பம்	தேதி
……	……	……
ஆராய்ச்சியாளர் பெயர்	கையொப்பம்	தேதி

ANNEXURE - 2

ஆராய்ச்சி பற்றிய தகவல் படிவம்

ஆராய்ச்சி மேற்கொள்பவர் மரு.சௌ.ரூபினி

வழிநடத்துபவர் மரு.ஜெய்ஸ்ரீதுக்கஆராம் கூர்சாகர், எம்.டி.எஸ்.

ஆராய்ச்சி நிறுவனத்தின் பெயர்: தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி மற்றும் மருத்துவமனை, சென்னை.

ஆராயச்சியின் தலைப்பு

பல்வேர் பகுதி எலும்பு தேய்மானத்தில் குவிப்பு வளர்ச்சி காரணி மற்றும் மாட்டு நுண்ணிய எலும்பு தாது ஆகியவற்றை இணைத்து பயன்படுத்தி மற்றும் மாட்டு நுண்ணிய எலும்பு தாதுவை மட்டும் பயன்படுத்தி மீளுருவாக்கம் திறன் மதிப்பீடு- மனித பிரிவாய் ஆய்வு

ஆராய்ச்சியின் நோக்கம்

பல் வேர் பகுதி எலும்பு தேய்மானத்தில் குவிப்பு வளர்ச்சி காரணி மற்றும் மாட்டு நுண்ணிய எலும்பு தாது ஆகியவற்றை இணைத்து ஒருபுறம் பயன்படுத்தி மற்றும் மறுபுறம் மாட்டு நுண்ணிய எலும்பு தாதுவை மட்டும் பயன்படுத்தி மதிப்பீடுகளை அறுவை சிகிச்சைக்கு முன், 3 மாதங்களுக்கு பின், 6 மாதங்களுக்கு பின் மற்றும் 9 மாதங்களுக்கு பின் மற்றும் கதிரியக்க மதிப்பீடுகளை அறுவை சிகிச்சைக்கு முன், 6 மாதங்களுக்கு பின் மற்றும் 9 மாதங்களுக்கு பின் ஆய்வு செய்தல்.

செய்முறை

கீழ்கண்ட ஆய்வுகள் பரிசோதனைகள் உங்களுக்கு செய்யப்படும்.

- வாய் பரிசோதனை
  - உட்புறம்
  - வெளிப்புறம்
- வழக்கமான இரத்தப் பரிசோதனை
- உங்களின் கைகளிலிருந்து இரத்தப் பரிசோதனைக்காக 7மி.லி. அளவு (ஒரு மேஜைக் கரண்டி அளவு) இரத்தம் எடுக்கப்படும்.
- ஒவ்வாமை ஏற்படுகிறதா என்பதை தெரிந்துகொள்ள 0.5மி.லி 2% லிக்னோகெயின் மயக்க மருந்து உங்களின் கையில் பரிசோதனைக்காக செலுத்தப்படும். பின்பு நோயுற்ற பகுதியில் மயக்க மருந்து கொடுக்கப்படும்.
- அல்ட்ரா சோனிக் ஸ்கேலர் மற்றும் கைக்கருவிகள் பயன்படுத்தி பல் மற்றும் பல்லின் வேர் சுத்தம் செய்யப்படும். உப்புநீர் கொண்டு நோயுற்ற பகுதி சுத்தம் செய்யப்படும்.
- குவிப்பு வளர்ச்சி காரணி மற்றும் மாட்டு நுண்ணிய எலும்பு தாது ஆகியவற்றை இணைத்து பயன்படுத்தப்படும்.
- மருத்துவ மதிப்பீடு அறுவை சிகிச்சைக்கு முன், 3 மாதங்களுக்கு பின், 6 மாதங்களுக்கு பின் மற்றும் 9 மாதங்களுக்கு பின் மற்றும் கதிரியக்க மதிப்பீடு

அறுவை சிகிச்சைக்கு முன், 6 மாதங்களுக்கு பின் மற்றும் 9 மாதங்களுக்கு பின் செய்யப்படும்.

<u>பங்கேற்பதினால் வரக்கூடிய பக்க விளைவுகள்</u>

வலி, வீக்கம் மற்றும் பயன்படுத்தும் பொருட்களினால் சில நேரங்களில் ஒவ்வாமை ஏற்பட வாய்ப்புண்டு. அதற்காக தேவைப்படும் மருந்துகளும் மருத்துவமும் வழங்கப்படும்.

<u>பங்கேற்பதினால் விளையும் நன்மைகள்</u>

உங்களின் நாள்பட்ட பல் ஈறு நோய்க்கு சிகிச்சை அளிக்கப்படும்.

<u>இரகசிய காப்பு</u>

உங்களைப் பற்றிய குறிப்புகள் பிறர் அறியா வண்ணம் ஆராய்ச்சி முடியும் வரை இரகசியமாக பாதுகாக்கப்படும். அதை வெளிப்படுத்தும் நேரங்களில் எந்த தனி அடையாளங்களும் வெளிப்பட வாய்ப்பு கிடையாது.

<u>தன்னார்வ பங்கேற்பு</u>

இந்த ஆராய்ச்சியில் பங்குபெறுவது தங்களின் தனிப்பட்ட முடிவு மற்றும் இந்த ஆராய்ச்சியில் இருந்து நீங்கள் எப்போது வேண்டுமானாலும் விலகிக்கொள்ளலாம். தங்களின் இந்த திடீர் முடிவு உங்களுக்கோ அல்லது ஆராய்ச்சியாளருக்கோ எந்தவித பாதிப்பும் ஏற்படுத்தாது என்பதை தெரியப்படுத்துகிறோம்.

நோயாளியின் பெயர் **கையொப்பம்/ கைரேகை**

ஆராய்ச்சி தொடர்புடைய தகவல்களுக்கு
மரு.சௌ.ரூபினி
பட்ட மேற்படிப்பு மாணவி,
தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி
மருத்துவமனை, சென்னை-3.
செல்: 978900598

பங்கேற்பாளரின் உரிமை தொடர்புடைய தகவல்களுக்கு:
மரு.பி.சரவணன் MDS, Ph.D.,
தலைவர், நிறுவன நெறிமுறைகள் குழு,
தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி
மற்றும் மருத்துவமனை, சென்னை-3.

ANNEXURE - 3

INFORMED CONSENT FORM

EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS – A SPLIT MOUTH STUDY

Participant ID No:

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care."

_____	_____	_____
Date	Name of the participant	Signature/thumb impression Of the participant

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

_____	_____	_____
Date	Name of the witness	Signature of the interviewer
_____	_____	_____
Date	Name of the witness	Signature of the interviewer

ANNEXURE - 5

DEPARTMENT OF PERIODONTICS
TAMILNADU GOVERNMENT DENTAL COLLEGE AND HOSPITAL
CHENNAI – 600003

"EVALUATION OF EFFECTIVENESS OF CONCENTRATED GROWTH FACTOR WITH BOVINE POROUS BONE MINERAL AS COMPARED TO BOVINE POROUS BONE MINERAL ALONE IN THE TREATMENT OF INTRA BONY DEFECTS –A SPLIT MOUTH STUDY"

PROFORMA FOR TREATMENT GROUP

Date:	**O.P. No:**	**Group no:**
Name:	**Age / Sex:**	**Case no:**
Address:	**Tel no:**	**Mobile no:**
	Occupation:	**Income:**

Chief Complaint :

History of presenting illness :

Past Medical History :

Past Dental History :

Personal history:

1. **Habits:**
2. **Oral hygiene:**
3. **Menstrual history:**

Clinical Examination:

EXTRAORAL EXAMINATION:

1. **Facial symmetry**
2. **Lymph node status**

INTRA ORAL EXAMINATION:

1. **Hard tissue examination:**
2. **Gingival examination:**

Colour **Contour** **Consistency**

Position **Texture**

Bleeding on probing

Exudate

PERIODONTAL EXAMINATION:

1. PLAQUE INDEX-SILNESS&LOE (1964)

18	**17**	**16**	**15**	**14**	**13**	**12**	**11**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**
48	**47**	**46**	**45**	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**

Score:

Calculation: **Interpretation:**

2. GINGIVAL BLEEDING INDEX (AINAMO & BAY 1975)

18	**17**	**16**	**15**	**14**	**13**	**12**	**11**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**
48	**47**	**46**	**45**	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**

Score:

Calculation: **Interpretation:**

3. PROBING DEPTH (PD) & CLINICAL ATTACHMENT LEVEL (CAL) (mm)

MAXILLARY

PALATAL

CAL																
PD																
	18	**17**	**16**	**15**	**14**	**13**	**12**	**11**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**
PD																
CAL																

BUCCAL

MANDIBULAR

LINGUAL

CAL																
PD																
	18	**17**	**16**	**15**	**14**	**13**	**12**	**11**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**
PD																
CAL																

BUCCAL

4. INVESTIGATIONS:

Blood investigations:

Radiological assessment:

Others:

5. Diagnosis:

6. Prognosis:

TREATMENT:

1. EMERGENCY / PRELIMINARY:

2. PHASE I:

3. RE-EVALUATION AFTER PHASE I THERAPY:

4. CLINICAL SITE SELECTED FOR STUDY:

5. PHASE II: (SURGICAL)

6. PHASE III:

7. PHASE IV :(RE-EVALUATION)

CLINICAL EVALUATION:

Duration	SITE A		SITE B	
	PPD	CAL	PPD	CAL
Baseline				
6 months				
1 year				

RADIOGRAPHIC EVALUATION:

USING IOPA WITH GRID:

Duration	SITE A			SITE B		
	CEJ - BD	CEJ- AC	AC-BD	CEJ - BD	CEJ- AC	AC-BD
Baseline						
6 months						
1 year						

INFERENCE/RESULT:

Signature of the P.G. Student **Signature of the Guide**

Date: