PLATELET-RICH FIBRIN VS INTRA-MARROW PENETRATION IN THE TREATMENT OF HUMAN PERIODONTAL INTRA-BONY DEFECTS: A CLINICAL AND RADIOGRAPHIC COMPARATIVE STUDY

DISSERTATION

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BABU BANARASI DAS UNIVERSITY,

LUCKNOW, UTTAR PRADESH

In the partial fulfilment of the requirements for the degree

of

MASTER OF DENTAL SURGERY

In

PERIODONTOLOGY

By

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Under the guidance of

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "**PLATELET-RICH FIBRIN VS INTRA-MARROW PENETRATION IN THE TREATMENT OF HUMAN PERIODONTAL INTRA-BONY DEFECTS: A CLINICAL AND RADIOGRAPHIC COMPARATIVE STUDY.**" is a bonafide and genuine research work carried out by me under the guidance of **Dr. MONA SHARMA,** Professor and Head, Department of Periodontology,Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 15/02/2023

Place: LUCKNOW

15/02/23

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CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **"PLATELET-RICH FIBRIN VS INTRA-MARROW PENETRATION IN THE TREATMENT OF HUMAN PERIODONTAL INTRA-BONY DEFECTS: A CLINICAL AND RADIOGRAPHIC COMPARATIVE STUDY."** is a bonafide work done by **Dr. SNIGDHA BISWAS**, under my direct supervision and guidance in partial fulfilment of the requirement for the degree of MDS in Periodontology.

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Dr. SNIGDHA BISWAS

DEDICATED TO
MY PARENTS
and
MY SISTER

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Dr. SNIGDHA BISWAS

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LIST OF ABBREVIATIONS

OFD	Open Flap Debridement
PRF	Platelet Rich Fibrin
IMP	Intra Marrow Penetration
IBD	Intra Bony Defect
RCT	Randomized controlled trial
rDD	Radiographic Defect Depth
PPD	Pocket probing depth
PPDR	Pocket probing depth Reduction
CAL	Clinical Attachment Level
CALG	Clinical Attachment Level Gain
BG	Bone Gain
BL	Bone Loss
RVG	Radiovisiography
IOPAR	Intraoral periapical radiographs

Objective: To assess the pocket probing depth (PPD), Clinical attachment level (CAL)& bone gain (IOPA with Grid) following periodontal surgery alone (OFD), periodontal surgery with PRF & periodontal surgery with IMP (Intra Marrow penetration) in the treatment of intra bony defects for 3 months and 6 months of follow-up.

Materials and Methods:30intrabony defects in patients suffering with chronic periodontitis were randomly divided into three different groups and treated as group 1 (OFD alone), group 2 (OFD + PRF), or group 3 (OFD +IMP). At baseline, 3 months and 6 months after surgery, clinical measures including Pocket Probing Depth (PPD) and Clinical Attachment Level (CAL) were evaluated. At 3 and 6 months following surgery, radiographic data including bone defect fill (BG), were measured.

Results: Intragroup comparisons showed consistently significant improvements in all the clinical and radiographic parameters in the three groups at 6 months postsurgery. Compared to baseline, in group 1,the mean PPDR at 3 months and 6 months was 3.00±1.059 mm (45%), 4.10±1.19 mm (60%) respectively. And mean CALG was 2.70±1.34 mm (43%), 4.00±1.41 mm (64%).In group 2, the PD decreased to3.80±1.22 mm (47%), 5.40±2.11 mm (67%) and mean CALG was 4.00±1.69 mm (55%), 5.60±2.27 mm (77%). and in group 3, the mean PPDRwas3.30±1.10 mm (45%) and 4.40±1.07 mm (62%) respectively and mean CALG at 3 months was 3.00±1.17 mm (45%), The bone fill percentages in group 1after 3 months and 6 months were(32.00 ± 10.50% and 51.08 ± 14.03%), group 2 (42.21 ±11.56% and 57.08 ± 16.61%) and group 3 (25.97 ± 6.34 and 66.80 ± 12.11%) were observed at 3 and 6 months postsurgery.

Conclusions: Though all the procedures are capable to improve clinical and radiographic parameters in treating intrabony defects, PRF yielded better treatment outcomes in periodontal tissue healing and improvements of clinical and radiographic parameters at 3 months. But at 6 months IMP demonstrated significantly and comparatively higher bone gain in radiographic parameters. Thus, long term clinical study with larger sample size needs to be carried out to further explore the role of intramarrow penetration, PRF in the management of periodontal intrabony defects due to periodontitis.

Periodontitis is an inflammatory disease of the periodontium leading to breakdown of gingival and/or periodontal structure. It is one of the most prevalent disease worldwide. Periodontitis causes inflammation and destruction of supporting alveolar bone and periodontal ligament. In addition to diminishing height, periodontal disease modifies the morphologic characteristics of bone. It causes many types of bone loss[1].Alveolar bone height and density are maintained by an equilibrium and controlled by regional and systemic interactions between bone formation and bone resorption[2,3]. Bone resorption outpaces bone creation when inflammation extends to the alveolar bone, which results in a loss of bone height and bone density[4].Due to the prevalence of intrabony defects in periodontitis, there is a great deal of interest in methods that can transform them into shallow probing sites that are simple to maintain and less susceptible to disease progression.

The expected outcome of periodontal therapy is Repair or Regeneration[5].The primary goal of the regenerative periodontal therapy is to completely restore the tooth's supporting apparatus, characterized by the formation of new cementum with inserting collagen fibers, new periodontal ligament and alveolar bone[6]. The ultimate goals of treating periodontal illnesses include regeneration of the periodontal tissues and a return to a clinically healthy status.[7]

Several treatment modalities have been advocated to ensure outcome in which regeneration of these lost structures can occur. Among the various surgical techniques, to achieve the ideal biologic conditions for periodontal regeneration, open flap debridement or access flap surgery was among the earliest and reliable procedure used and has been shown to result in successful treatment of intra bony defects[8]. However, Standard OFD cannot be used to regenerate the tissues lost to periodontal disease[9]. Although the documented clinical outcomes of OFD have a range, there is always room for improvement in terms of predictability when treating intra bony lesions with open flap debridement[10]. One of the main difficulties impeding the success of periodontal regeneration methods is the junctional epithelium's downgrowth along the denuded root surface[11].

Other regenerative therapies include use of biomedical mediators ie growth factors, bone graft, barrier membranes and other molecules which are believed to play a role in the growth of periodontal cells[12].

Amongst an array of materials available, the most popular platelet concentrate in fibrin technology is platelet-rich fibrin (PRF), a fibrin matrixcontaining cells, growth factors, and platelet cytokines. PRF stimulates the growth of osteoblasts but inhibits the growth of oral epithelial cells[13].

PRF(Platelet Rich fibrin) is promising treatment since platelets are a natural source of growth factors, which help in the healing and regeneration of periodontal lesions and does not induce an inflammatory reaction at the graft site[14]. The PRF membrane's elasticity, flexibility, and strength are all a result of this three-dimensional arrangement[15,16] that forms a scaffold from where the growth factors are released for more than 7 days[17] (Liang chen et al. 2021)[4].Due to the PRF's strong fibrin matrix, it takes longer for the host to absorb it, which causes a slower, prolonged release of platelet- and leukocyte-derived growth factors into the wound region (Dohan et al. 2006)[14].Growth factors are consistently released from PRF membrane for at least 1 week and as long as 28 days[18]. Leucocytes and fibrin in platelet concentrates play important roles in addition to platelets which help to regulate the immune system and have anti-infectious properties[9].As whole, PRF possesses physical and biochemical qualities that make it appealing for use in periodontal wound healing. For these reasons, the present study evaluated PRF as a potential regenerative agent for periodontal intrabony defects.

Several authors have also advocated the use of intra marrow penetration, also known as decortication, as a means to improve the local blood vessel and progenitor cell supply and, consequently, the outcomes of surgical procedures used to treat intra bony defects[19] (Crea A et al. 2014).

INTRA MARROW PENETRATION (IMP) as a procedure is incorporated in the regenerative treatment modality of intrabony defects where intentionally holes are drilled through the cortical into the cancellous bone[20]. Since degradation of the cortical bone must occur before access to the bone-forming components is acquired, the cortical bone plate may constitute a temporary barrier to the entry of desirable cell and tissue components from the endosteal compartment. In order to achieve a satisfactory outcome, perforations or removal of the cortical bone plate may be advantageous.An additional justification for perforating the cortical bone would be to encourage bleeding and blood clot formationby releasing all the factors required for wound healing, which has been considered crucial for directed bone regeneration[21] (Lundgren et al. 2000).

In the present study, intrabony defects were treated by Periodontal Flap procedure alone(OFD), Flap along with PRF and Flap along with IMP. The treatment outcomes were assessed and compared in the 3 different Groups in terms of reduction in Pocket Probing Depth(PPDR), Gain in Clinical Attachment Level (CALG)& Bone Gain (BG).

AIM:

To assess the efficiency of OFD, OFD along with PRF (Platelet-Rich Fibrin) and OFD along with IMP(Intra Marrow penetration) in the treatment of intra bony defects.

OBJETIVES:

1. To assess clinical (Pocket Probing Depth, Clinical Attachment Level) and radiographic parameters (Bone Gain) in OFD.
2. To assess clinical (Pocket Probing Depth, Clinical Attachment Level) and radiographic parameters (Bone Gain) in OFD along with PRF.
3. To assess clinical (Pocket Probing Depth, Clinical Attachment Level) and radiographic parameters (Bone Gain) in OFD along with IMP.
4. To compare the same in all the 3 groups.

1. **ZEINA MAJZOUB, MARIO BERENGO, ROBERTO GIARDINO, NICOLÒ NICOLI ALDINI, AND GIAMPIERO CORDIOLI (1999)[22]** performed a pilot study to evaluate the effect of intra marrow penetration on the rate of bone neogenesis in protected spaces created on the calvarial bone using occlusive titanium domes in 16 adult white rabbits. Within the limits of this study, the results demonstrate that intra marrow penetration accelerates initial bone neogenesis and results in increased bone fill and density, suggesting that its use can be beneficial in bone regenerative procedures.

2. **MANOJKUMAR THORAT, A R PRADEEP, BORSE PALLAVI (2011)[23],**conducted a study to evaluate the effectiveness of PRF in treatment of periodontal intra-bony defects. Thirty-two intra-bony defects (one site/patient) were treated either with autologous PRF or a conventional open flap debridement alone. The study revealed a significant reduction in probing pocket depth (PPD)and Clinical Attachment Level (CAL) gain and greater intra-bony defects fill occurred at sites treated with PRF.

3. **Y-C CHANG, J H ZHAO (2011)[24]** conducted a study regarding PRF and its Regenerative property and evaluation of bony defects repair after PRF application. In this study, PRF application exhibited the radiographic defects filled in grafted teeth. In these cases, the reduction in pocket depth was found after PRF application.

4. **LI QI et al in (2013)[14]** conducted a study to determine the usefulness of PRF as a bioactive scaffold for periodontal regeneration and alveolar bone augmentation and both in vitro and clinical studies indicate the benefit of PRF for bone regenerative procedures lies in its combined competency as a cell proliferation, migration and wound healing agent together. This study concluded that PRF contains a number of attributes ideally suited for its use as a scaffold for alveolar ridge augmentation and bone healing.

5. **CREA et al (2013)[19]** performed a study to assess the effect of the addition of IMP to OFD during the treatment of intrabony defects in chronic periodontitis patients. 42 chronic periodontitis patients, each contributing a 2-, 3- or 2-3-wall intrabony defectwere treated in this study. They have concluded that addition of IMP to an OFD procedure used to treat intrabony defects results in statistically and clinically significant enhancement of both clinical and radiographic outcomes.

6. **LIANG CHEN, YI DING, GUOPING CHENG, SHU MENG (2021)[26]** performed a systemic review and meta-analysis to discuss the use of platelet rich fibrin in the treatment of Periodontal Intrabony Defects. Out of 391 scientific papers, 78 from PubMed database of last 5 years, 18 meta-analysis were found suitable as per the inclusion criteria. Full text was retrieved and review was done and this data was then synthesized. It was concluded that OFD combined with PRF significantly better than OFD alone in reduction of PPD and bone fill % changes in intrabony defects by showing good promising results. PRF seems to promote to promote early wound healing and proved to have a good prospect for its use as healing aid in various aspects of the dentistry.

7. **AGARWAL M, AGARWAL V (2014)[27]** conducted a review to describe PRF and its applications in dentistry. It was concluded that the use of PRF as an adjunct in wound healing and periodontal regeneration has shown promising results. Also, in addition to clinical trials, histopathological studies are also required to learn about the nature of the newly formed tissue in the defect and to understand the biology, efficacy and mode of action of PRF more effectively.

8. **KUMAR V R et al (2015)[28]** presented a review in PRF concept and on its potential clinical benefits, it shows that PRF being the more recent of the Platelet Derivatives is safer and simpler than the previous PRP concentrates. The healing and regenerative properties of the PRF are attributed to its basic fibrin composition. This autologous fibrin matrix has the ability to release cytokines over a period of 7-11 days along with the slower release of growth factors, which helps in periodontal regeneration.

9. **GAURESH KUMAR PATEL, SHEELA KUMAR GUJJARI, VEERENDRA KUMAR S.C (2017)[29]** conducted a study comparing two group (open flap debridement and platelet rich fibrin respectively) aimed to evaluate the effectiveness of Platelet Rich Fibrin (PRF) in Regeneration of Intra bony Defects. In conclusion they have mentioned that use of platelet rich fibrin showed a definite clinical and radiographic evidence of regeneration along with satisfactory healing but a larger sample size is need to be use in future studies to further support the outcome of this study.

10. **HUSSEIN IBRAHIM SAUDI, SHEREEN ABD EL-MOULA ALI AND AHMED MOHAMED EL GHAYSH (2017)[20]**, conducted a study to examine the validity of IMP with OFD in the treatment of human periodontal intra bony defects. They concluded that all the clinical and radiographic parameters improved significantly.

11. **SUNIL PARAMEL MOHAN, NALLUSAMY JAISHANGAR, SANDHA DEVY, ANJHANA NARAYANAN, DEEPTHI CHERIAN, SANUPA SETHU MADHAVAN (2019)[30]** presented a review in PRF concept and it concluded that PRF, a new generation of platelet concentrate, is a novel step in regenerative periodontal treatment with simplified processing and without biochemical medication. Apart from its application in dentistry, PRF is also been used in various medical fields: orthopedic and plastic surgery.

12. **ASHISH MATHUR, VIVEK KUMAR BAINS, VIVEK GUPTA, RAJESH JHINGRAN, G. P. SINGH (2019)[31]** conducted a study was to compare clinically and radiographically the efficacy of autologous platelet rich fi brin (PRF) and autogenous bone graft (ABG) obtained using intraoral periapical radiographs [IOPA] with grid and orthopantomogram [OPG] in the treatment of intra bony periodontal defects. Thirty-eight intra bony defects (IBDs) were treated with either open flap debridement (OFD) with PRF or OFD with ABG. The results of the study demonstrates that the use of autologous PRF and autogenous ABG were effective in the treatment of three wall IBD

with an uneventful healing of the sites. Also conclude that long term, multi-centered randomized, controlled clinical trials are further required.

13. **JANA MILUTINOVIC, MIRJANA POPOVSKA, BILJANA RUSEVSKA, MILAN NACEVSKI, STEFAN ANASTASOVSKI, MARIJA IVANOVSKA-STOJANOSKA (2020)**[32] conducted a study to investigate the effectiveness of PRF in the treatment of intra bony defects in chronic periodontitis patients. They concluded that additional use of PRF demonstrated better parameters than OFD alone.

14. **VIPIN BHARTI, PUNEET KAMAL NAGI, MANPREET SINGH (2021)**[33], carried out a study to compare the clinical and radiographic efficacy of platelet rich fibrin with and without intra marrow penetration in the treatment of intra bony defects. They concluded that the combination of intra marrow penetration and PRF demonstrated better results in probing pocket depth reduction, clinical attachment level gain and linear bone fill as compared to PRF alone in the treatment of periodontal intra bony defects. In this study, no complication was reported with intra marrow penetration. They also concluded that further study needs to be conducted t to further explore the role of intra marrow penetration in the management of periodontal intra bony defects.

15. **MIRON RJ et Al (2021)**[34]**,** conducted a study aims to compare the treatment outcomes of periodontal intra bony defects by using platelet-rich fibrin (PRF) with other commonly utilized modalities. From 551 articles, 27 RCTs, this study showed that the use of PRF in conjunction with OFD statistically significantly improved PD, CAL, and RBF values, yielding to comparable outcomes to OFD/Bone Grafts.

16. **THUY ANH VU PHAM (2021)**[35] performed a study comparing periodontal regeneration methods for the treatment of intrabony defects in the PRF, GTR, OFD groups. 30intrabony defects were treated in this study. They had concluded that PRF significantly improved clinical and radiographic parameters better than GTR and OFD

groups. Also confirms that PRF can replace GTR in the treatment of intrabony defects in periodontology.

17. **KOMAL DEEP WALIA, SPHOORTHI ANUP BELLUDI, NEHA PRADHAN, VIPIN JAIN, SHARAZ SHAIK (2022)[36],** conducted a study to compare two groups (open flap debridement and Platelet-rich fibrin matrix respectively) aimed to evaluate PRFM regenerative ability in human periodontal intra bony defects. And the result showed that PRFM can be a clinically significant periodontal regenerative material in the treatment of vertical intraosseous defects.

This clinical, experimental, prospective study was carried out in the OPD of Department of Periodontology, Babu Banarasi Das College of Dental Sciences (BBDCODS), Lucknow. Patients were selected based upon the following inclusion and exclusion criteria.

Inclusion criteria-

1. Patient suffering from chronic periodontitis with pocket probing depth ≥5 mm.
2. Patient with radiographic evidence of intrabony defects.
3. Systemically healthy patients.
4. Patient with no contraindication to local anesthetics and periodontal surgery.
5. Patients having sufficient platelet count for platelet rich fibrin preparation.
6. Patients, who showed acceptable oral hygiene during pre-surgical (phase I therapy) and are cooperative.

Exclusion Criteria-

1. Patients with systemic disease that affects periodontal treatment outcome
2. Smokers and Tobacco chewers
3. Pregnant and lactating women
4. Patients who have used antibiotics in last 3 months.

ARMAMENTARIUM*:*

1. Mouth mirrors,

2. UNC-15 Probe (Hu-Friedy)

3.Tweezer

4. Explorer

5. syringe 3 ml and 5 ml

6.Surgical blade no. 15, 12

7. BP Blade handle.

8. Local anesthetic agent 2% lignocaine

9. A set of surgical curettes (Gracey's Hu-Friedy)

10. Periosteal elevator (Hu-Friedy)

11. Plain Test Tubes for PRF preparation.

12. PRF (Platelet Rich fibrin)

13. Gauge.

14. Cumine scaler and condenser

15.Adamstissue holding forceps

16. Castroviejo scissors, needle and holder

17. Sutures (3-0)

18. Laboratory centrifuge (Forco scientific UdyogPvt.Ltd)™

19. Coe-pack dressing (GC AMERICA INC) ™

20. Round Carbide bur (1 mm diameter).

21. Micromotor.

Study Design:

This clinical, experimental, prospective randomized controlled study was conducted in the Department of Periodontology of Babu BanarasiDas College OfDental Sciences (BBDCODS), Babu Banarasi Das University (BBDU), LUCKNOW, UTTAR PRADESH, after taking the Institutional Ethical Clearance.

The treatment procedure was fully explained to the patients and a duly signed consent form was taken from all the patients before initiating the treatment. 30 sites fulfilling the inclusion and exclusion criteria were selected and all the sites were then distributed randomly into three groups viz. Group I, Group II and Group III.

1. Group I: The treatment done was Open Flap Debridement (OFD) alone;
2. Group II: The treatment done was Open Flap Debridement (OFD), along with PRF placed in the intra bony defect.
3. Group III: The treatment done was Open Flap Debridement (OFD) in combination with Intra Marrow Penetration (IMP) in the intra bony defect.

At baseline, after phase I therapy, the following clinical and radiographic parameters were assessed:

a) Pocket Probing Depth (PPD)
b) Clinical Attachment Level (CAL)
c) Intra bony defect viewed with the help of IOPA with grid by paralleling cone technique.

RVG Imaging:

An IOPA image was captured with paralleling technique (owing to its reproducibility) using *Unicorn RVG sensor, Geno-ray Portable Xray unit X-II, XCP RVG-sensor positioner, and a grid.*

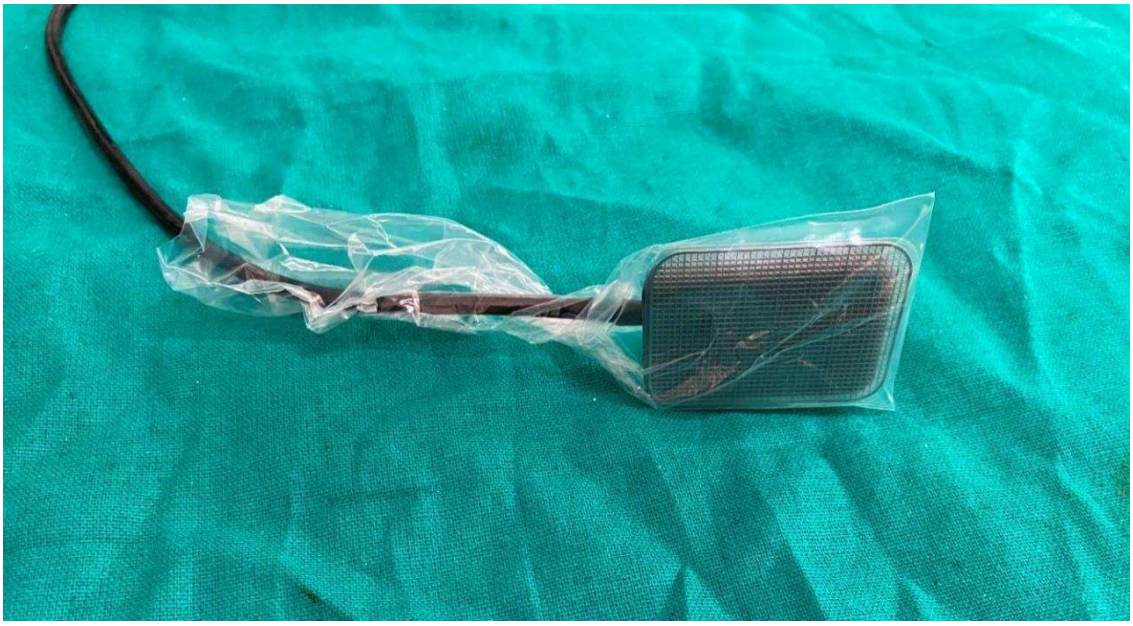


FIGURE 1: RVG sensor with GRID

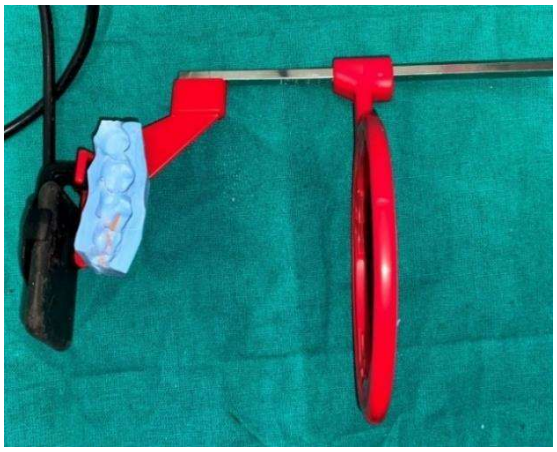


FIGURE 2: Model analysis for paralleling technique

FIGURE 3: IOPA Radiograph

PLATE NO: 1

Patients were told a pre-procedural rinse with 10 ml of 0.2% chlorhexidine gluconate solutions. Surgical procedures were performed under aseptic conditions.

The operative sites were anesthetized with a solution of 2% lignocaine containing adrenaline at a concentration of 1:100000. After administration of local anesthesia, a sulcular incision was given and a full thickness mucoperiosteal flap was elevated on both facial and lingual side. Proper care was taken to preserve as much interproximal soft tissue as possible. The osseous defects were then thoroughly debrided using hand instrumentation with curettes and scalers. Surgical areas were then irrigated with sterile saline and betadine solution and was carefully inspected to ensure the debridement completion.

In Group I, flaps were repositioned and sutured with 3-0 silk sutures using an interrupted sutures followed by Periodontal dressing.

In Group II, after thorough debridement at the surgical site, 10 ml of intravenous blood was drawn by venipuncturing the subject's antecubital vein from the cubital fossa. The blood was collected in 10-mL sterilized glass tubes, not containing any anti-coagulating agent. The PRF was prepared following the protocol developed by Choukrounet al.[45], The blood containing tubes was immediately **centrifuged (at 3000 rpm for 10 minutes)** using the centrifuge (Forco Scientific Udyogpvt.Ltd)^{TM} .Thecentrifuged blood mass due to differential densities separated in three fractions. (FIG 4)

- Top layer- acellular platelet poor plasma (PPP)
- Middle layer- Platelet rich fibrin (PRF)
- Bottom layer- Red blood corpuscles (RBC layer)

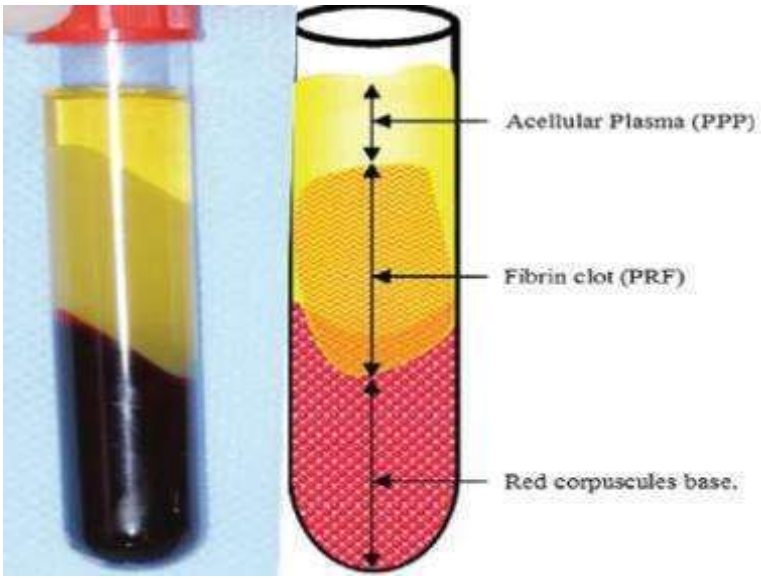


FIGURE 4 : Structure of PRF

The **Structured PRF** can be easily separated from the lower red corpuscle base (preserving a small RBC layer) using sterile tweezers and scissors just after the removal of 2-3 ml of top acellular plasma and then transferred on to sterile gauze and used immediately.

The retrieved PRF was cut into two parts, one part was compressed between two gauze pieces in order to convert it to a consistent membrane which was placed in the intra bony defect area and other part used to cover the defect site.
And the flaps were repositioned at the original level and sutured with 3-0 silk sutures using interrupted technique. And the surgical sites were protected by applying periodontal dressing.

In Group II, the intrabony defect walls were penetrated using a round carbide bur(1 mm diameter) to open up the marrow spaces, multiple perforations were done to obtain bleeding from spongiosa.

Now the flaps were repositioned and sutured with 3-0 silk sutures using an interrupted technique followed by Periodontal Dressings.

Antibiotics and analgesics were prescribed for all three groups. And the patients were asked to report after 7-10 days for suture removal, dressing removal and examination. Patients in all the 3 Groups were instructed for Oral Hygiene measures & were recalled further for clinical and radiographic re-evaluation at 3 months and 6 months post operatively.

At the end of the study, the entire data thus collected was subjected to suitable statistical analysis and interpretation for final results.

PLATE NO: 2

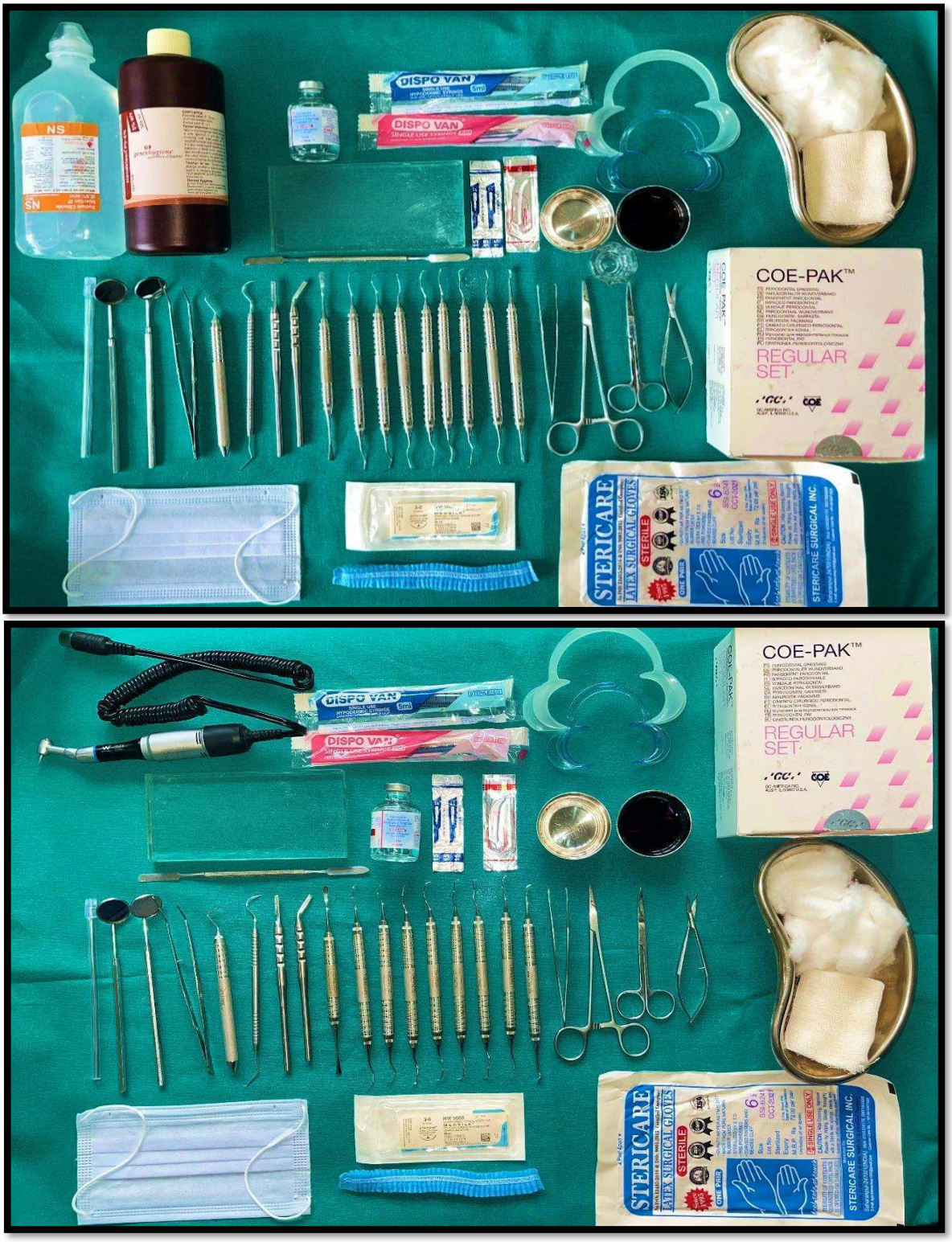


FIGURE 5: ARMAMENTARIUM FOR SURGICAL PROCEDURE

PLATE NO: 3

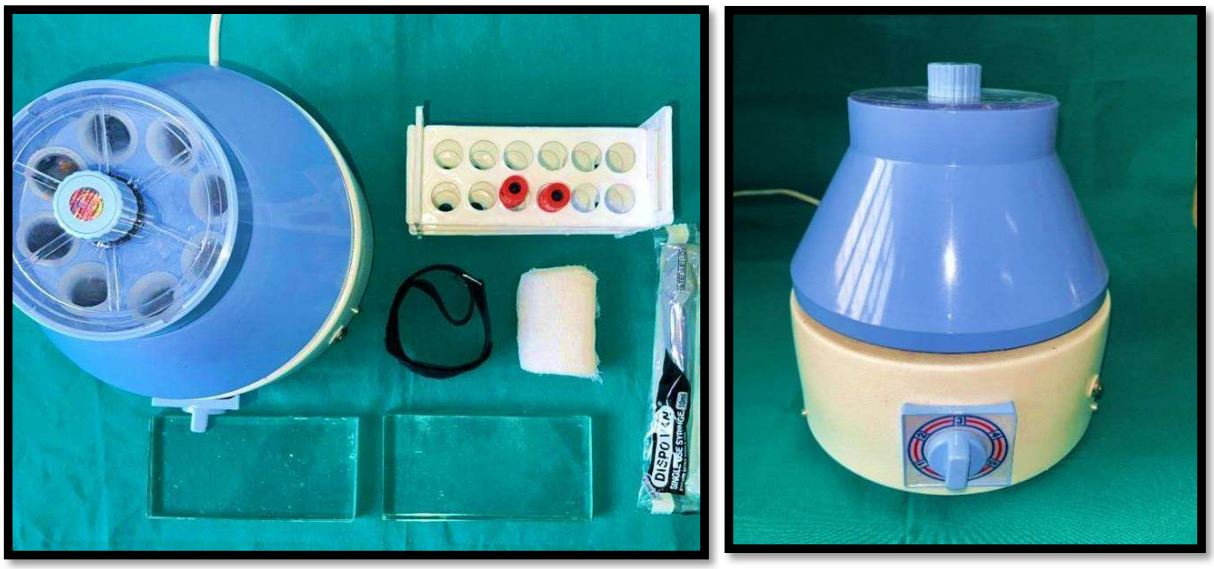


FIGURE 6: ARMAMENTARIUM FOR OBTAINING PRF

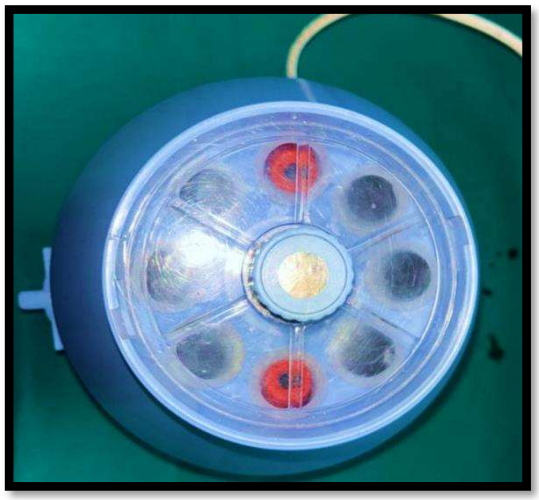
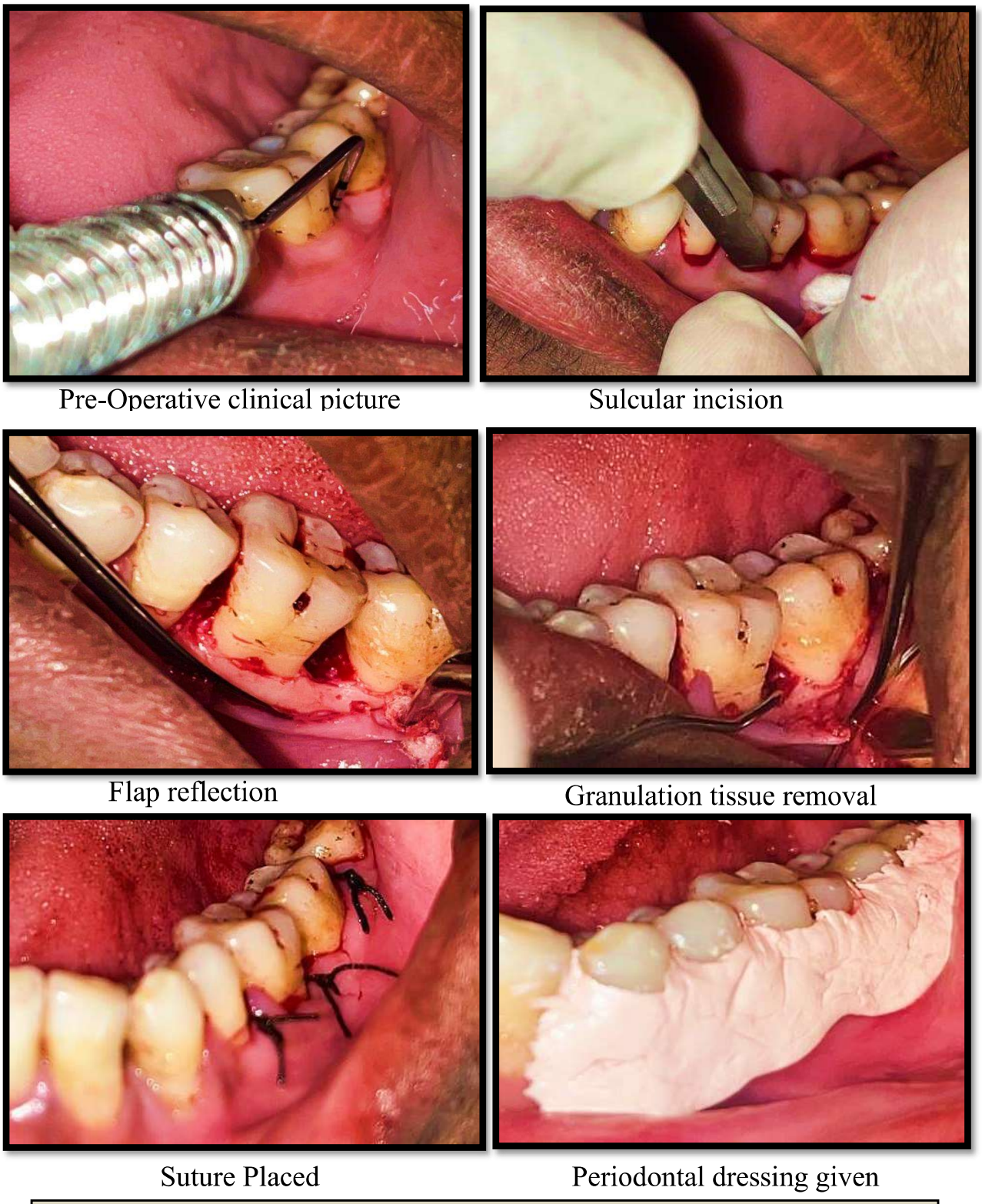


FIGURE 7: LABORATORY CENTRIFUGE MACHINE

FIGURE 8: ROUND CARBIDE BUR FOR IMP

PLATE NO: 4



Pre-Operative clinical picture

Sulcular incision

Flap reflection

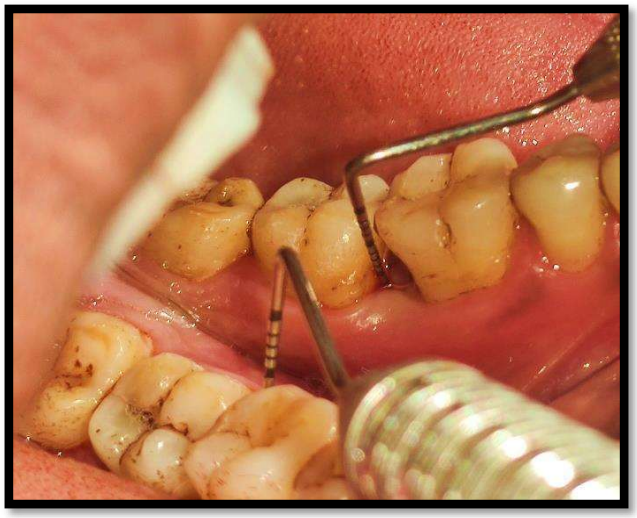
Granulation tissue removal

Suture Placed

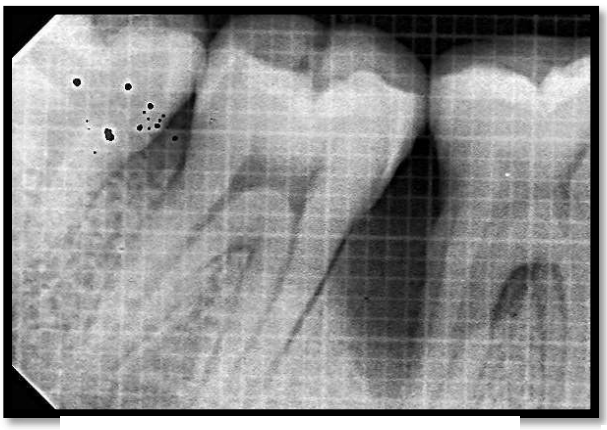
Periodontal dressing given

FIGURE 9: SURGICAL PROCEDURE: GROUP I (OFD GROUP)

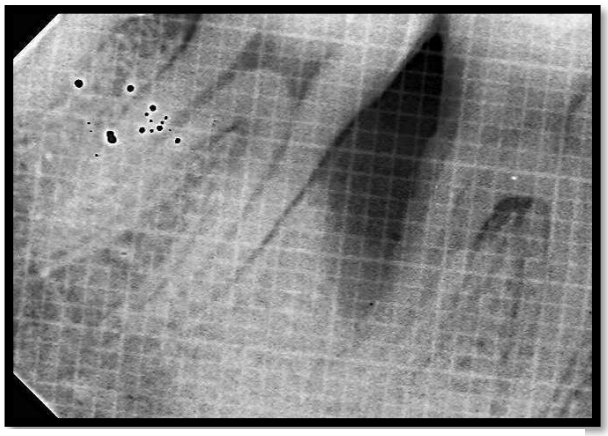
PLATE NO: 5



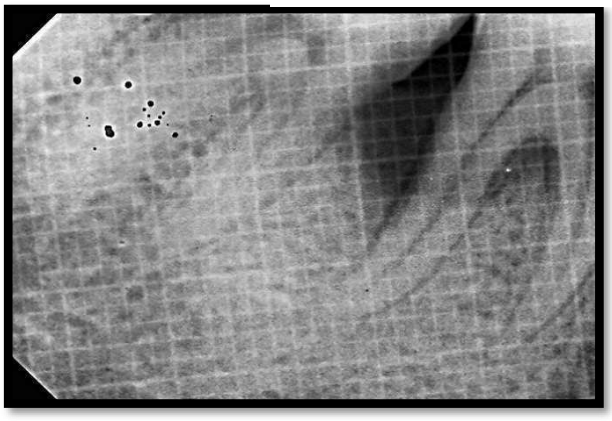
Post operative clinical picture



Baseline radiograph



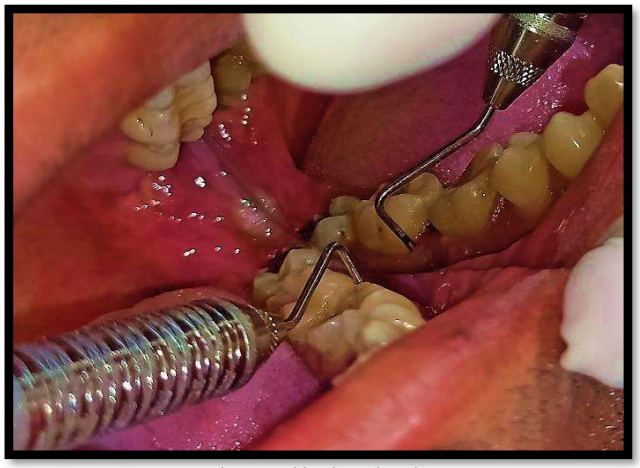
3 months follow up radiograph



6 months follow up radiograph

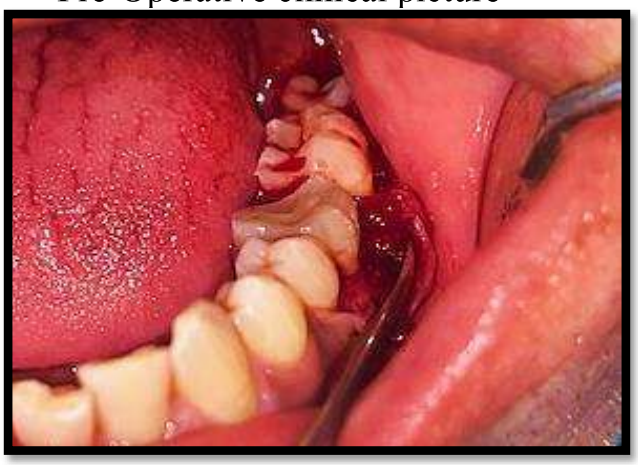
FIGURE 10: RADIOGRAPHIC IMAGES OF DEFECT IN GROUP I

PLATE NO: 6



Pre-Operative clinical picture

Sulcular incision



Flap reflection

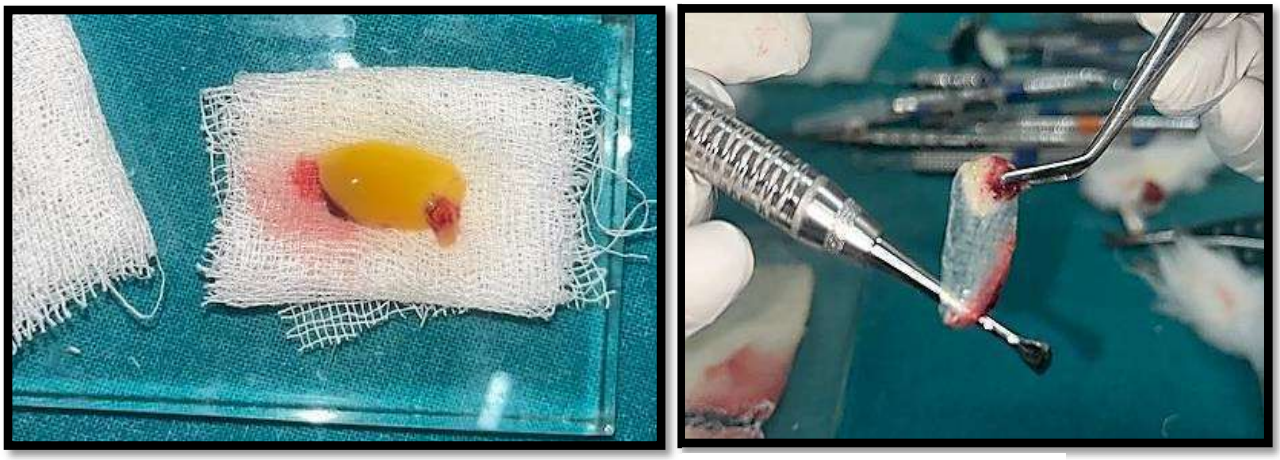
Blood withdrawal

Blood collection

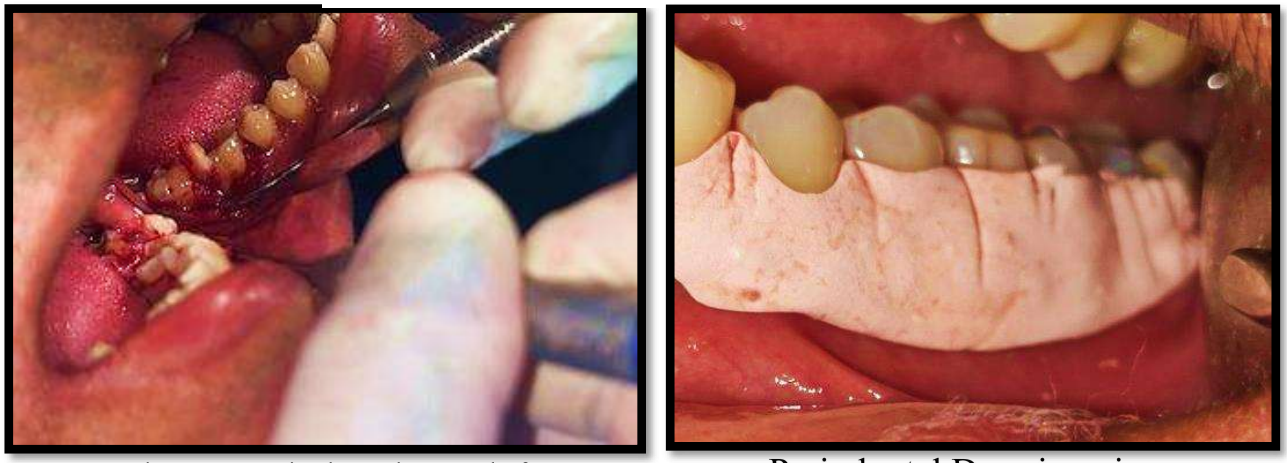
PRF

FIGURE 11: SURGICAL PROCEDURE: GROUP II (OFD + PRF GROUP)

PLATE NO: 7

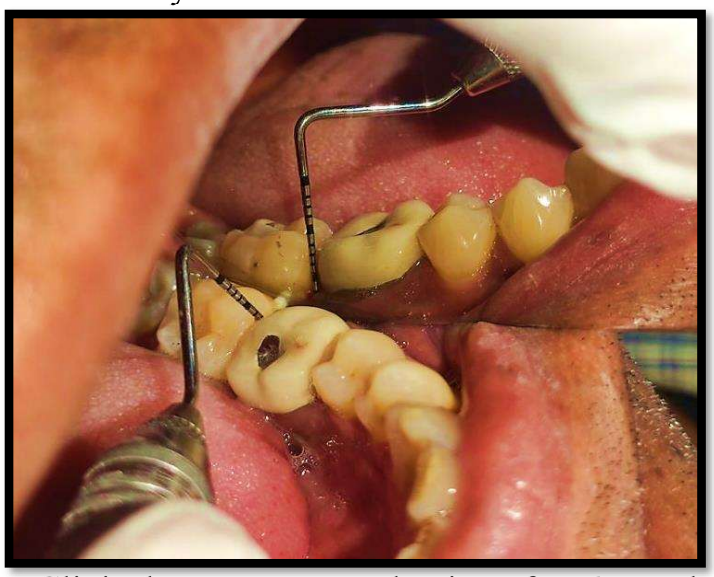


Platelet Rich Fibrin (PRF)



PRF placement in intrabony defects

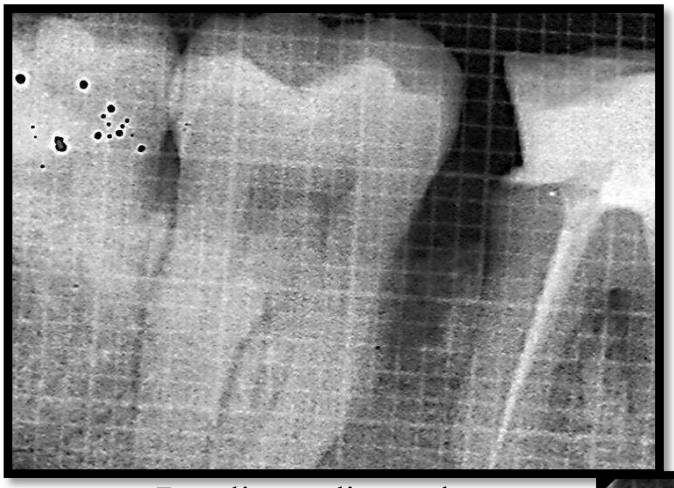
Periodontal Dressing given



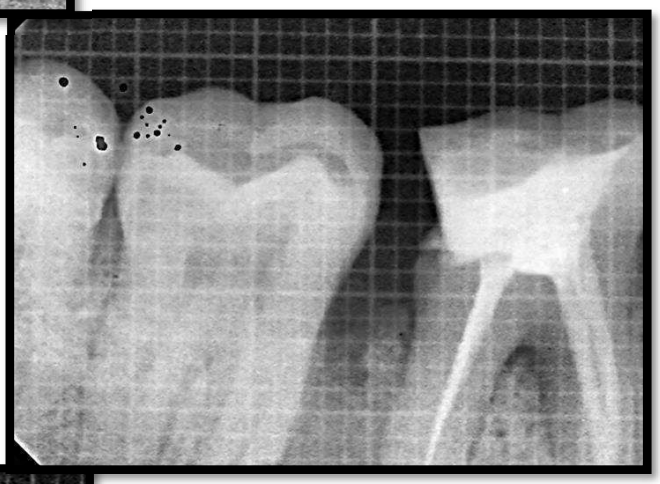
Clinical parameters evaluation after 6 months

FIGURE 12: SURGICAL PROCEDURE: GROUP II

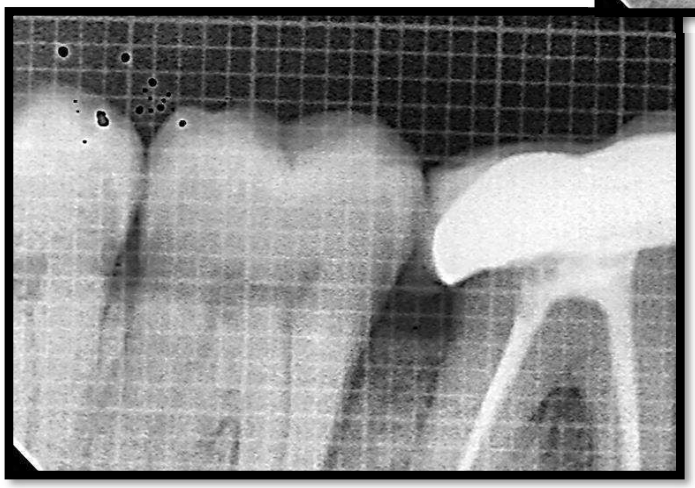
PLATE NO: 8



Baseline radiograph



3 months follow up radiograph

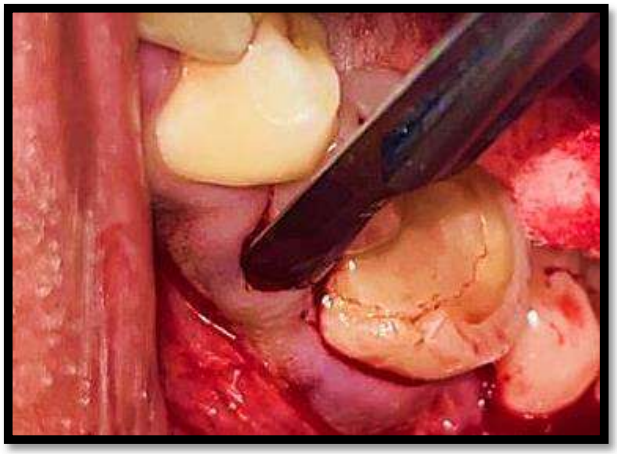


6 months follow up radiograph

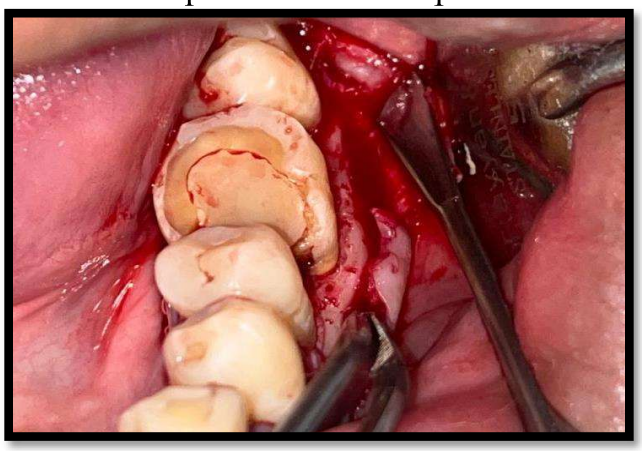
FIGURE 13: RADIOGRAPHIC IMAGES OF DEFECT IN GROUP II

PLATE NO: 9

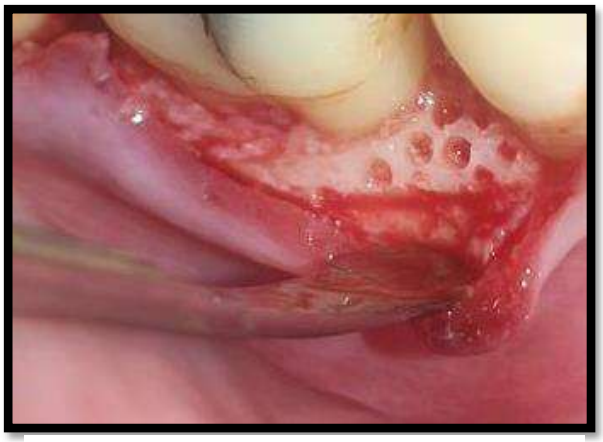
Pre-Operative clinical picture



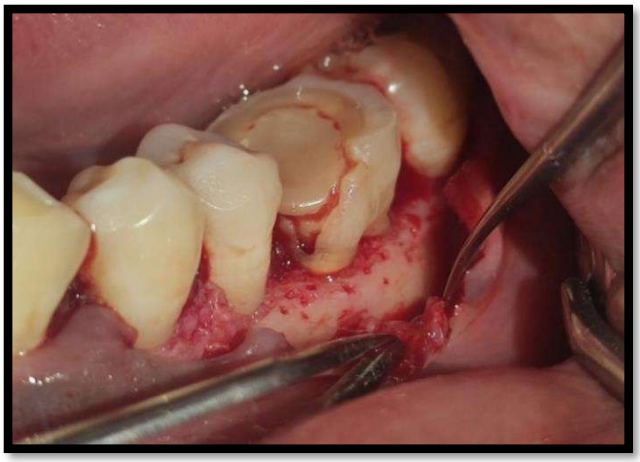
Sulcular incision



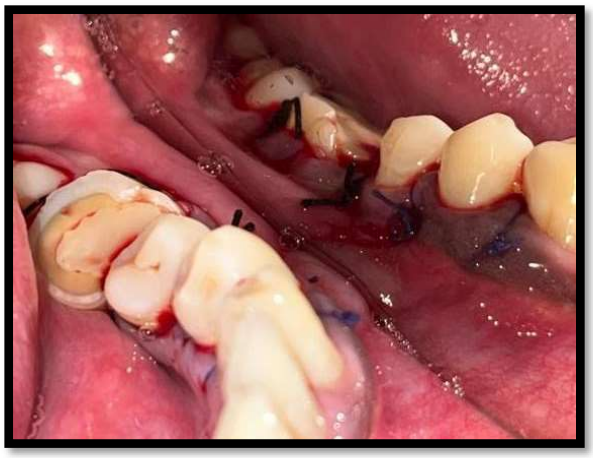
Flap Reflection



Intra Marrow Penetration



IMP in intrabony defects

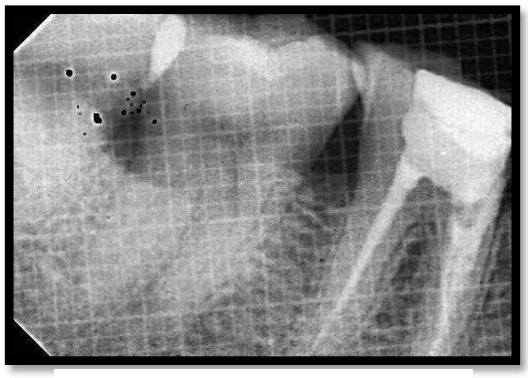


Suture placed

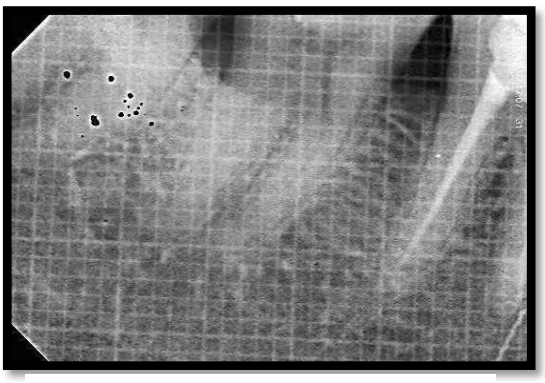
FIGURE 14: SURGICAL PROCEDURE: GROUP III (OFD + IMP)

PLATE NO: 10

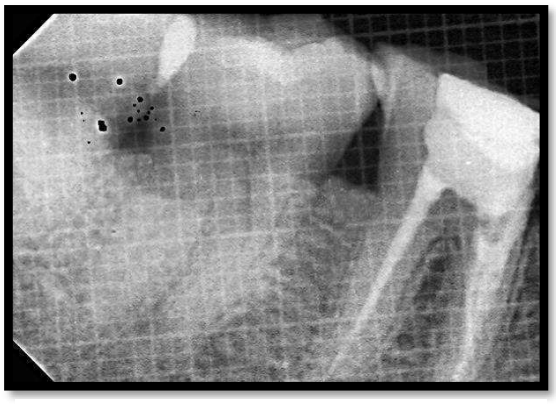
6 months follow up postsurgery



Baseline radiograph



3 months follow up



6 months follow up radiograph

FIGURE 15: RADIOGRAPHIC IMAGES OF DEFECT IN GROUP III

STATISTICAL ANALYSIS

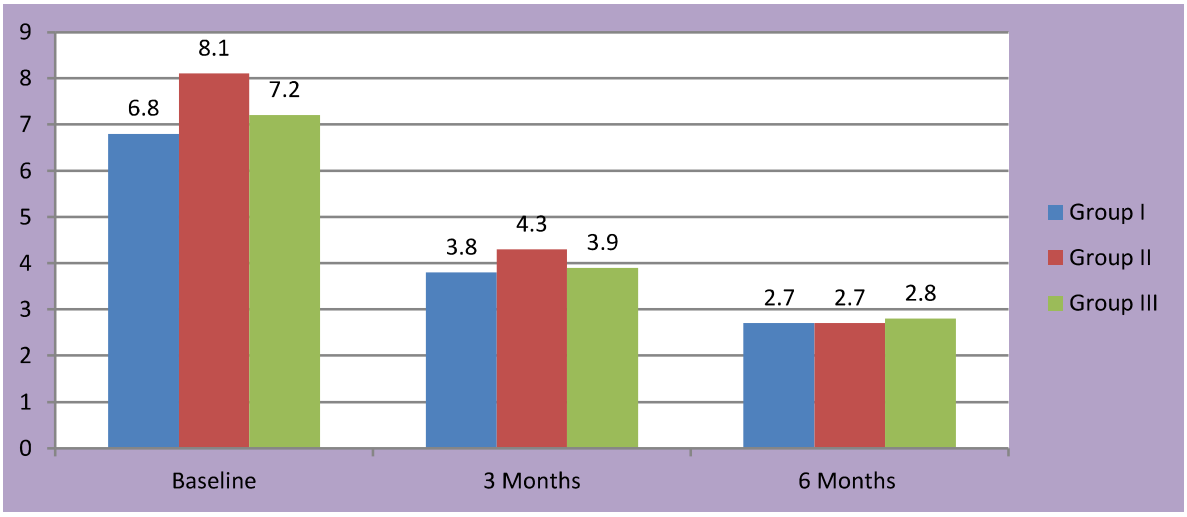
The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 19.0 Version. The descriptive statistics included mean, standard deviation .The intragroup comparison for the different time intervals was done using Repeated Measures ANOVA and paired t test to find the difference between the individual time intervals The level of the significance for the present study was fixed at 5%.

The intergroup comparison for the difference of mean scores between the independent groups was done using the One Way ANOVA followed by post hoc analysis

The Shapiro–Wilk test was used to investigate the distribution of the data and Levene's test to explore the homogeneity of the variables. The data were found to be homogeneous and normally distributed. Mean and standard deviation (SD) were computed for each variable

TABLE 1: INTERGROUP COMPARISON OF PPD BETWEEN THE GROUPS

	Baseline (mm)	3 Months (mm)	6 Months (mm)	Mean Change at 3 Months(mm)	Mean Change at 6 Months(mm)	Percentage Change at 3 Months(%)	Percentage Change at 6 Months(%)
Group I	6.80±1.47	3.80±1.22	2.70±0.67	3.00±1.05	4.10±1.19	44.45±13.24	59.96±7.80
Group II	8.10±2.33	4.30±1.41	2.70±0.49	3.80±1.22	5.40±2.11	46.70±6.47	65.25±7.53
Group III	7.20±1.93	3.90±1.10	2.80±1.03	3.30±1.05	4.40±1.07	45.62±7.19	61.56±6.52



GRAPH - 1

In Group I, the mean PPD at baseline was 6.80±1.47, at 3 months it was 3.80±1.22 and at 6 months it was 2.70±0.67. The mean reduction in PPD at 3 months was 3.00±1.05 (45%), at the 6 months was 4.10±1.19 (60%).

In Group II, The PPD at baseline was 8.10±2.33, at 3 months it had reduced to 4.30±1.41and at 6 months it was 2.70±0.49. The mean reduction in PPD at 3 months was 3.80±1.22 (47%), at 6 months was 5.40±2.11 (65%).

In Group III, The PPD at baseline was 7.20±1.93 at the 3 months was 3.90±1.10 and at 6 months the mean PPD was 2.80±1.03. The mean reduction at 3 months was 3.30±1.05(45%), at the 6 months was 4.40±1.07(62%).

TABLE 2: INTERGROUP –POST HOC ANALYSIS

	Intergroup Comparison		P value	Significance
At 3 Months	Group I	Group II	0.600	Non-Significant
	Group I	Group III	0.783	Non-Significant
	Group II	Group III	0.802	Non-Significant
	Intergroup Comparison		P value	Significance
At 6 Months	Group I	Group II	0.117	Non-Significant
	Group I	Group III	0.629	Non-Significant
	Group II	Group III	0.269	Non-Significant

P value<0.05, statistically significant

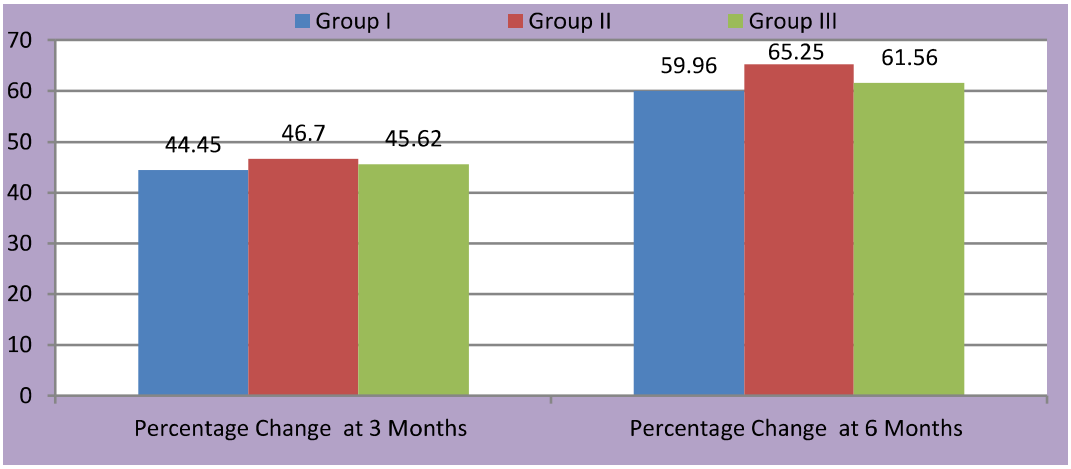
One Way ANOVA and post hoc analysis

When a comparison was made between group I and group II, P value was 0.600 (non-significant) at 3 months and 0.117(non-significant) at 6 months

On comparing group II and group III, the difference was non-significant for both at 3 months and 6 months. the P value was 0.783 at 3 months and 0.629 at 6 months.

Lastly, on comparing group II and group III, the P value was 0.802 at 3 months and 0.269 at 6 months. both the value was again non-significant.

Hence the intergroup comparison of percentage change in the PPD from baseline at 3 months and 6 months between Group I and Group II, Group I and Group III, Group II and Group III was statistically non-significant



GRAPH - 2

TABLE3: INTRAGROUP COMPARISON OF PPD BETWEEN BASELINE AND 3 MONTHS, BASELINE AND 6 MONTHS IN THREE GROUPS

	Baseline (mm)	3 Months (mm)	6 Months (mm)	Baseline-3 Months	Baseline-6 Months
Group I	6.80±1.47	3.80±1.22	2.70±0.67	0.001 (Sig)	0.001 (Sig)
Group II	8.10±2.33	4.30±1.41	2.70±0.49	0.001 (Sig)	0.001 (Sig)
Group III	7.20±1.93	3.90±1.10	2.80±1.03	0.001 (Sig)	0.001 (Sig)

P value<0.05, considered to be statistically significant.

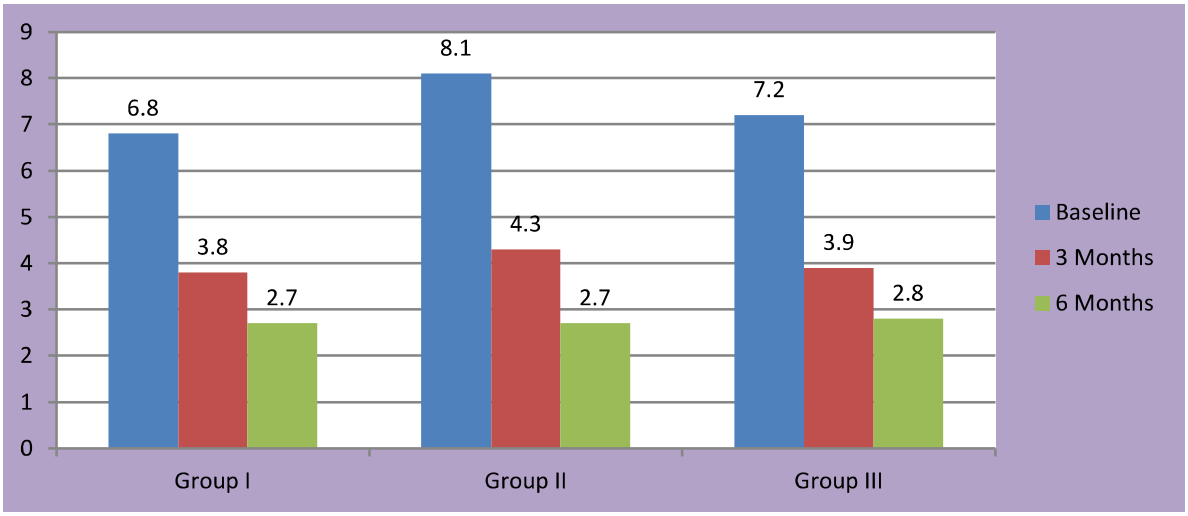
Repeated Measures ANOVA and Paired t test

Intragroup comparison showed a significant reduction in PPD in all the 3 groups.

In the Group I, The mean PPD at the baseline was 6.80±1.47, at 3 months it was 3.80±1.22 and at 6 months the mean PPD was 2.70±0.67. The reduction in the PPD at 3 months and 6 months was statistically significant (p=0.001).

In the Group II, The PPD at the baseline was 8.10±2.33, at the 3 months was 4.30±1.41and at 6 months the mean PPD was 2.70±0.49.The reduction in the PPD at 3 months and 6 months was statistically significant (p=0.001).

In the Group III, The PPD at the baseline was 7.20±1.93 at the 3 months was 3.90±1.10 and at 6 months the mean PPD was 2.80±1.03.The reduction in the PPD at 3 months and 6 months was statistically significant (p=0.001).



GRAPH - 3

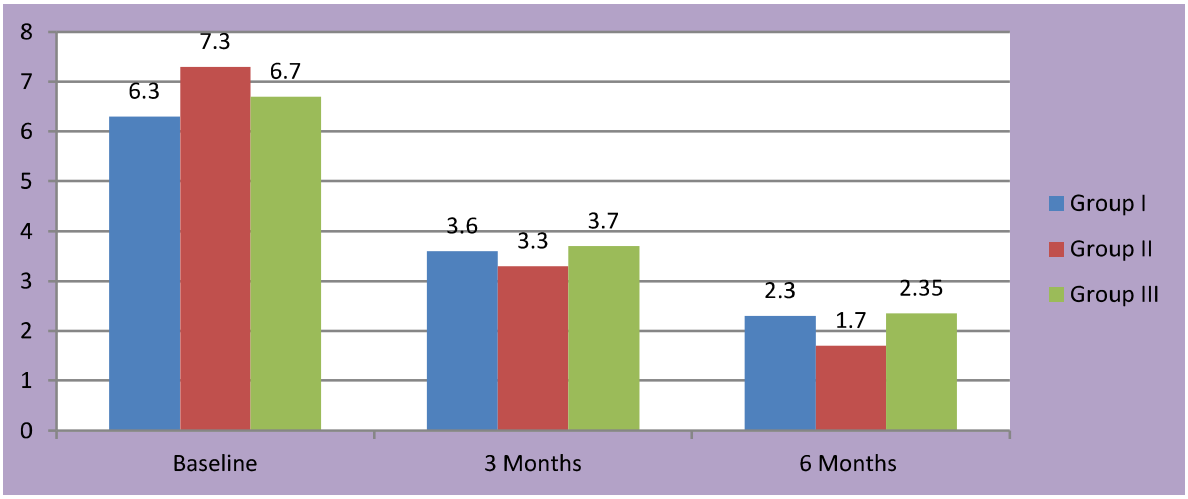
TABLE4: INTERGROUP COMPARIOSN OF CAL BETWEEN THE GROUPS

	Baseline (mm)	3 Months (mm)	6 Months (mm)	Mean Change at 3 Months (mm)	Mean Change at 6 Months (mm)	Percentage Change at 3 Months(%)	Percentage Change at 6 Months(%)
Group I	6.30±1.41	3.60±1.19	2.30±0.67	2.70±1.34	4.00±1.41	42.84±16.79	63.49±10.80
Group II	7.30±2.58	3.30±1.41	1.70±0.67	4.00±1.69	5.60±2.27	54.42±8.32	76.57±10.44
Group III	6.70±2.05	3.70±1.31	2.35±0.99	3.00±1.17	4.35±1.31	44.77±10.69	64.23±8.56

In Group I, the mean CAL at baseline was 6.30±1.41, at 3 months there was a gain in CAL and was noted as3.60±1.19and at 6 months it was 2.30±0.67. The mean reduction in CAL at 3 months was 2.70±1.34 (43%), at 6 months it was 4.00±1.41(64%).

In the Group II, mean CAL at baseline was 7.30±2.58, at 3 months it was 3.30±1.41and at 6 months the mean CAL was 1.70±0.67.A steady gain in CAL was noted from baseline to 6 months. The mean reduction from the baseline at the 3 months was 4.00±1.69(55%), at the 6 months was 5.60±2.27. In percentage there was an improvement of upto 77% in CAL.

In the Group III, The CAL at baseline was 6.70±2.05at 3 months it was 3.70±1.31and at 6 months the mean CAL was 2.35±0.99. The mean reduction at the 3 months was 3.00±1.17(45%), at the 6 months was 4.35±1.31 (64%).



GRAPH - 4

TABLE5: INTERGROUP –POST HOC ANALYSIS

	Intergroup Comparison		P value	Significance
At 3 Months	Group I	Group II	0.043	Significant
	Group I	Group III	0.790	Non-Significant
	Group II	Group III	0.012	Significant
	Intergroup Comparison		P value	Significance
At 6 Months	Group I	Group II	0.036	Significant
	Group I	Group III	0.285	Non-Significant
	Group II	Group III	0.021	Significant

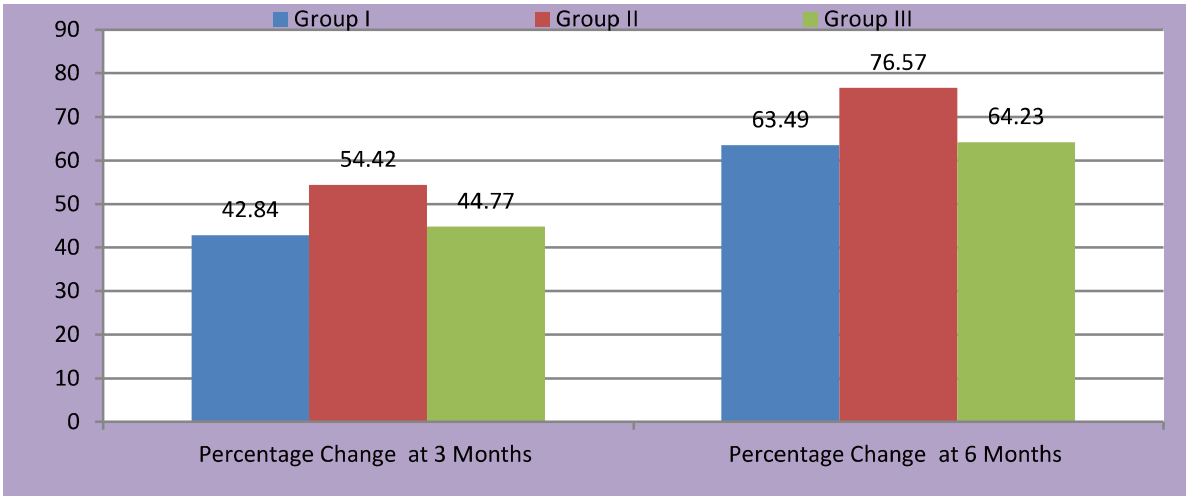
P value<0.05, statistically significant

One Way ANOVA and post hoc analysis

When a comparison was made between group I and group II, significant CAL reduction has seen in group II compare to group I. At 3 months P value was 0.043 (significant) and at 6 months P value was 0.036, the P value difference between both the groups was statistically significant.

On comparing, group I and group III, the difference was non-significant for both at 3 months and 6 months. the P value was 0.790 at 3 months and 0.285 at 6 months, that was statistically non-significant.Lastly, on comparing group II and group III, the P value was 0.012 at 3 months and 0.021 at 6 months. The P value difference between both the groups was statistically significant.

Hence the intergroup comparison of percentage reduction in the CAL from baseline at 3 months and 6 months was significant between Group I and Group II and Group II and Group III.



GRAPH - 5

TABLE 6: INTRAGROUP COMPARISON OF CAL BETWEEN BASELINE AND 3 MONTHS, BASELINE AND 6 MONTHS IN THREE GROUPS

	Baseline (mm)	3 Months (mm)	6 Months (mm)	Baseline-3 Months	Baseline-6 Months
Group I	6.30±1.41	3.60±1.19	2.30±0.67	0.001 (Sig)	0.001 (Sig)
Group II	7.30±2.58	3.30±1.41	1.70±0.67	0.001 (Sig)	0.001 (Sig)
Group III	6.70±2.05	3.70±1.31	2.35±0.99	0.001 (Sig)	0.001 (Sig)

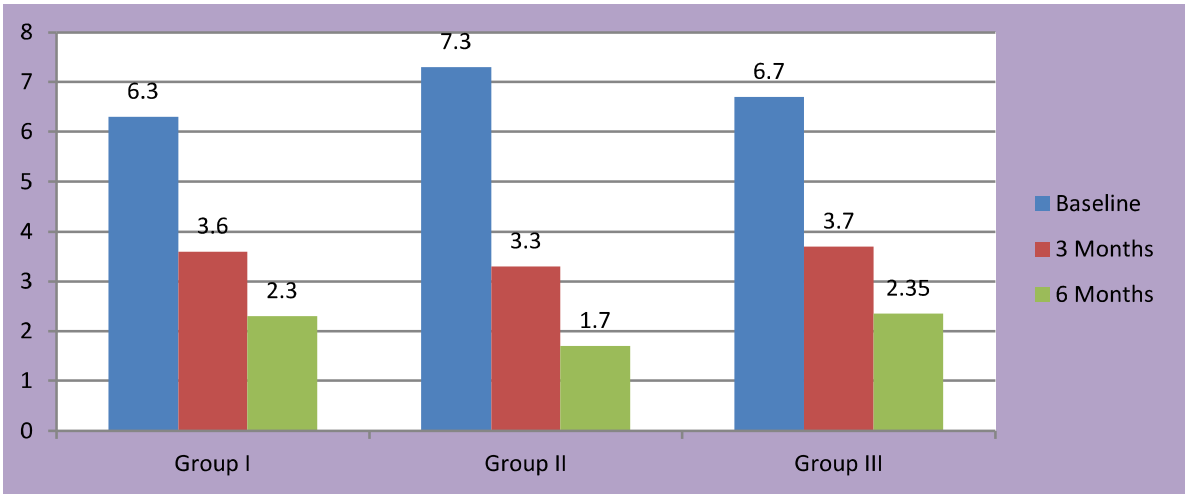
P value<0.05, statistically significant.

Repeated Measures ANOVA and Paired t test

In the Group I, The mean CAL at the baseline was 6.30±1.41, at the 3 months was 3.60±1.19and at 6 months the mean CAL was 2.30±0.67. The reduction in the CAL at 3 months and 6 months was statistically significant (p=0.001).

In the Group II, The CAL at the baseline was 7.30±2.58, at the 3 months was 3.30±1.41and at 6 months the mean CAL was 1.70±0.67. The reduction in the CAL at 3 months and 6 months was statistically significant (p=0.001).

In the Group III, The CAL at the baseline was 6.70±2.05at the 3 months was 3.70±1.31and at 6 months the mean CAL was 2.35±0.99. The reduction in the CAL at 3 months and 6 months was statistically significant (p=0.001).



GRAPH - 6

TABLE7: INTERGROUP COMPARIOSN OF BONE DEFECT BETWEEN THE GROUPS

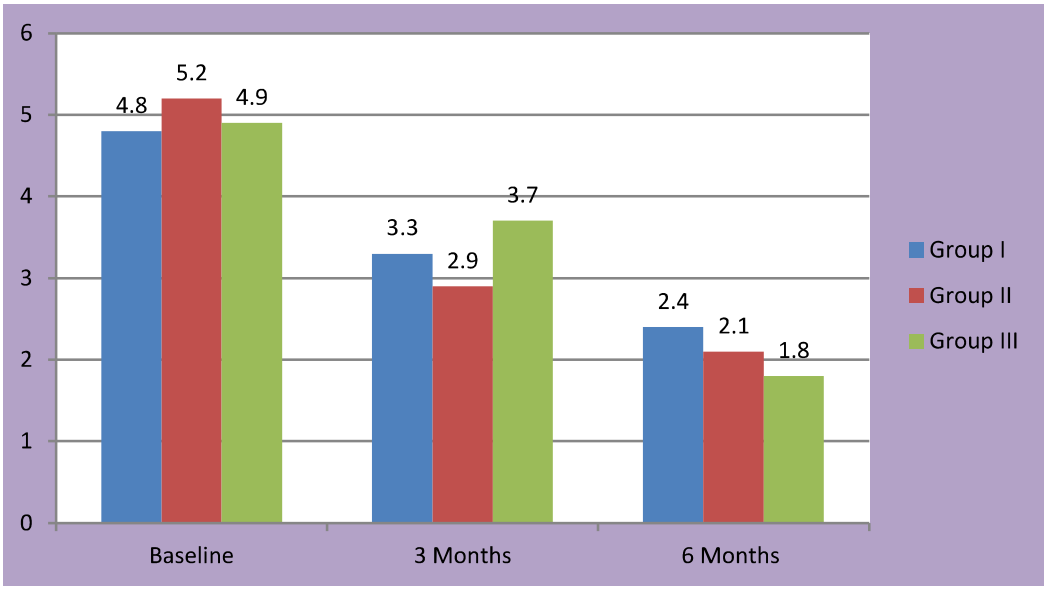
	Baseline (mm)	3 Months (mm)	6 Months (mm)	Mean Bone Gain at 3 Months (mm)	Mean Bone Gain at 6 Months (mm)	Percentage Bone Gain at 3 Months(%)	Percentage Bone Gain at 6 Months(%)
Group I	4.80±1.47	3.30±1.25	2.40±1.17	1.50±0.52	2.40±0.69	32.00 ±10.50	51.08±14.03
Group II	5.20±1.61	2.90±0.73	2.10±0.73	2.30±1.15	3.10±1.59	42.21 ±11.56	57.30±16.61
Group III	4.90±2.07	3.70±1.82	1.80±1.47	1.20±0.42	3.10±0.87	25.97±6.34	66.80±12.11
						0.003	0.045

P value<0.05, statistically significant.

In the Group I, the mean bone defect at baseline was 4.80±1.47, at 3 months it was 3.30±1.25 and at 6 months was 2.40±1.17. The mean bone gain at the 3 months was 1.50±0.52(32%) and at the 6 months was 2.40±0.69(51%).

In the Group II, bone defect at the baseline was 5.20±1.61, at3 months it was 2.90±0.73and at 6 months was 2.10±0.73. The mean bone gain at 3 months was 2.30±1.15(42%), at the 6 months was 3.10±1.59(57%).

In the Group III,mean bone defect at baseline was 4.90±2.07, at 3 months it was 3.70±1.82and at 6 months was 1.80±1.47. The mean bone gain at the 3 months was 1.20±0.42(26%), at the 6 months was 3.10±0.87(67%).



GRAPH - 7

TABLE8: INTERGROUP –POST HOC ANALYSIS

	Intergroup Comparison		P value	Significance
At 3 Months	Group I	Group II	0.027	Significant
	Group I	Group III	0.178	Non-Significant
	Group II	Group III	0.001	Significant
	Intergroup Comparison		P value	Significance
At 6 Months	Group I	Group II	0.341	Non-Significant
	Group I	Group III	0.021	Significant
	Group II	Group III	0.112	Non-Significant

P value<0.05, considered to be statistically significant.

One Way ANOVA and post hoc analysis

On comparing, between group I and group II, significant bone gain has seen in group II. At 3 months P value was 0.027, that was significantandat 6 months P value was 0.341, which was statistically non-significant.

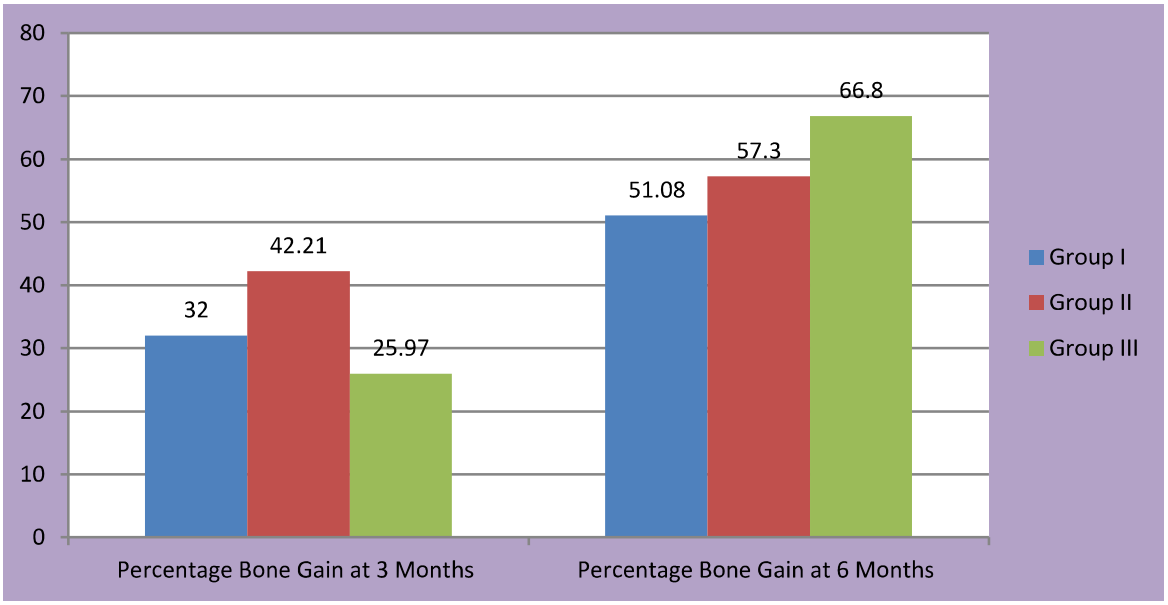
On comparing, group I and group III, the difference was non-significant at 3 months. The P value was 0.178 at 3 months.

At 6 months, the P value was 0.021, that was statistically significant.

Lastly, on comparing group II and group III, the P value was 0.001. The P value difference between both the groups was statistically significant at 3 months.

At 6 months, the P value was 0.112, which was statistically non-significant.

Hence, by statistical analysis, at 3 months the bone gain was significantly higher in the Group II as compared to Group I and Group III.At 6 months the bone gain was significantly higher in the Group III as compared to Group I.



GRAPH - 8

TABLE 9: INTRAGROUP COMPARISON OF BONE DEFECT BETWEEN BASELINE AND 3 MONTHS, BASELINE AND 6 MONTHS IN THREE GROUPS

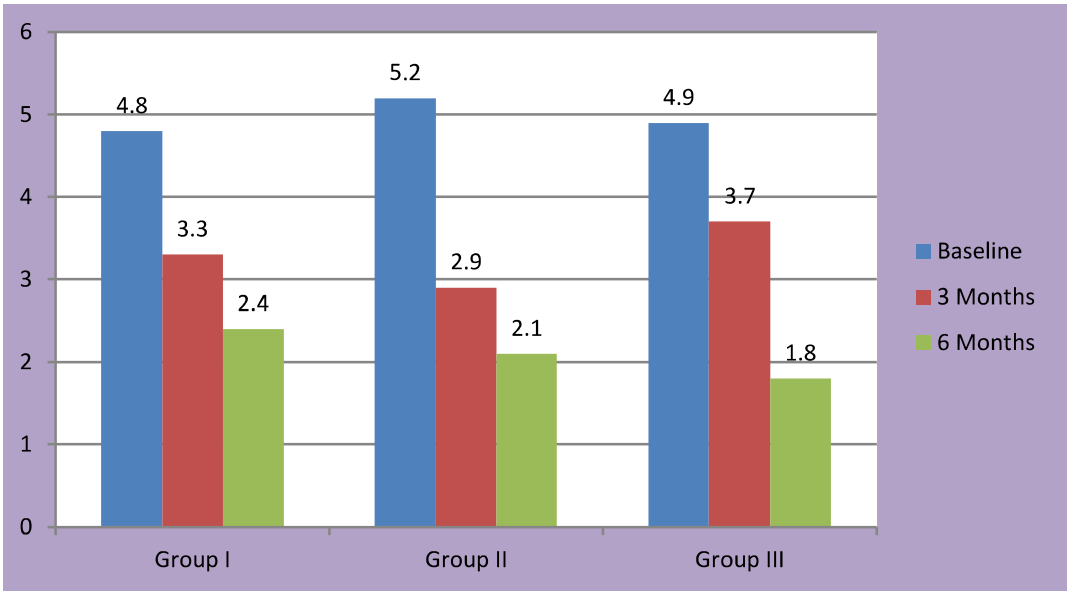
	Baseline (mm)	3 Months (mm)	6 Months (mm)	Baseline-3 Months	Baseline-6 Months
Group I	4.80±1.47	3.30±1.25	2.40±1.17	0.001 (Sig)	0.001 (Sig)
Group II	5.20±1.61	2.90±0.73	2.10±0.73	0.001 (Sig)	0.001 (Sig)
Group III	4.90±2.07	3.70±1.82	1.80±1.47	0.001 (Sig)	0.001 (Sig)

Repeated Measures ANOVA and Paired t test

In the Group I, the mean bone defect at the baseline was 4.80±1.47, at the 3 months was 3.30±1.25 and at 6 months was 2.40±1.17. The bone gain at 3 months and 6 months was statistically significant (p=0.001).

In the Group II, the bone defect at the baseline was 5.20±1.61, at the 3 months was 2.90±0.73and at 6 months was 2.10±0.73. The bone gain at 3 months and 6 months was statistically significant (p=0.001).

In the Group III, the mean bone defect at baseline was 4.90±2.07at the 3 months was 3.70±1.82and at 6 months was 1.80±1.47. The bone gain at 3 months and 6 months was statistically significant (p=0.001).



GRAPH - 9

Periodontitis is a highly prevalent progressive disease that results in inflammation within the supporting tissues of the teeth, advancing loss of attachment, and decreased bone density[1]. Alveolar bone height and density are maintained by an equilibrium and are regulated by local and systemic interactions between bone formation and bone resorption[2,3]. When inflammation affects the alveolar bone, bone resorption outpaces bone formation, which causes a reduction in bone height and bone density[4]. Either resective[37] or regenerative[29,30] techniques can be used to preserve shallow probing sites and significantly slow the advancement of periodontal disease.

Periodontal therapy works toward controlling disease activity and regeneration of periodontal structures. The primary goal of this therapy is to arrest the progression of periodontal disease and to maintain a healthy natural dentition and comfortable function.[38] Periodontal therapy has evolved noticeably since 1957 when Prichard first focused attention on the morphology and the treatment of intrabony pocket.[39] Periodontal intrabony defects, also known as vertical defects, are the anatomical consequences of periodontitis and are commonly linked to periodontal pockets.[40]

Although, periodontal regeneration is still an elusive goal, different studies have shown improved clinical parameters using various surgical techniques or graft materials alone or in combination.

Among all the surgical techniques used to achieve the ideal biological conditions required for periodontal regeneration, access flap surgery (OFD) was considered as the earliest and successful procedures used and has been shown to have favorable results in the treatment of intra bony defects (Caffesse, Sweeney and Smith 1986)[8]. Although, the reported clinical outcomes of OFD may vary and there is always an opportunity to improve the predictability of Open flap debridement in the treatment of intra bony defects (Graziani et al. 2012)[10]. Standard OFD cannot be used to regenerate the tissues lost to periodontal disease[9] (Dohan Ehrenfest D.M 2008). One of the main difficulties impeding the success of periodontal regeneration methods is the junctional epithelium's downgrowth along the denuded root surface[41] (Raja VS et al. 2008).

Observations from animal and human histological studies have demonstrated that healing following conventional periodontal therapy is primarily characterised by repair, in which a long epithelial attachment is formed along the majority of the previously exposed and instrumented root surface, while in some cases, limited amounts of periodontal regeneration may be seen at the apical aspects of the defects. Periodontal regeneration in this context implies that CAL gain is accomplished through the formation of new cementum with functionally oriented inserting collagen fibres on the previously exposed/affected portion of the root. At the same time, formation of alveolar bone and the establishment of a periodontal ligament (PDL) is taking place. Reformation of only a portion of the periodontium (e.g. new cementum and PDL) is referred to as reconstruction[49].

Graziani et al. in 2012[10] did a systematic meta analytic study on conservative surgery (surgical procedure without regenerative approach). The evidence from 734 defects were gathered and it showed that the teeth treated by this approach had a short term (12 months) tooth retention. Evidence for a longer term of follow up was limited to restricted number of studies. The authors concluded that whenever a viable therapeutic option of doing regenerative treatment in intrabony defects is feasible (depending upon the type and accessibility of defects), regeneration should be planned.

Despite the publication of several systematic reviews and meta-analysis evaluating regenerative therapy in the treatment of intrabony defects (Trombelli et al. 2002, Needleman et al. 2005, Esposito et al. 2009), a systematic assessment of the clinical performance of Conservative Surgery is still lacking. Therefore, this study was conducted to see the efficacy of OFD/PRF/IMP in the intrabony defects and to compare these three groups. This information could be valuable for clinicians as all of this three is a technique with a favourable cost–benefit ratio commonly used in clinical practice.

One of the key steps necessary before bone production is angiogenesis, a multistep process. New blood arteries are essential because they feed the transplanted location with osteoprogenitor cells and supply the nutrients needed for bone formation.[42] After the flap is reflected, angiogenesis typically starts from the blood vessels already there, which may become exposed to the grafted location. This causes harm to the blood

vessels that continue from the flap into the bone surface. It may only take tearing of the vasculature to start the biological process of bone healing. [S. A. Danesh-Sani 2016][43].

However, by using a bioabsorbable substance to act as a barrier between the gingival tissue and the tooth surface and selectively repopulating root sites that had previously been exposed to periodontal disease, periodontal ligament cells are able to acquire a new connective tissue attachment[44] [Elkhatat et al 2017].

There are various regenerative materials available in the market today ie biological mediators, including as growth factors, bone grafts, barrier membranes, and other chemicals. In light of collagen's capacity for regenerative activity during periodontal procedures, we chose PRF membrane, which aids in the repopulation of Periodontal Ligament (PDL) cells.

Choukroun et al. (2001)[45] in France developed Platelet-Rich Fibrin, a second-generation platelet concentrate and an autogenous living biomaterial. As platelets are a rich source of PDGF (platelet-derived growth factor)-AA/AB/BB, TGF (transforming growth factor), IGF (insulin-like growth factor)-I, EGF (epidermal growth factor) (EGF), VEGF (vascular endothelial growth factor) and PDAF (platelet-derived angiogenesis factor), autologous platelet concentrates have attracted the interest of researchers and clinicians as a way to accelerate and enhance wound healing. According to Dohan et al. (2006)[14], the main differences between PRF and other platelet concentrates such as PRP (first generation platelet concentrate) are that PRF does not require the use of an anticlotting or gellifying agent, that the naturally forming PRF clot has a dense and complex 3 dimentional fibrin structure, and it concentrates both platelets and leukocytes. Natural blood clotting differs from PRF in that the latter is easier to manage and implant since it is more uniform, stable, and easy to handle[46]. The fibrin network is architecturally composed of equilateral junctions (linked trimolecularly), which promote the enmeshing of cytokines and cellular movement. The PRF membrane's elasticity, flexibility, and strength are all a result of this three-dimensional arrangement[47]. The advantages of using PRF as a bioactive substitute include reduced technical competence requirements, minimum biochemical alteration, cost effectiveness, enhanced integration

of circulating cytokines in the fibrin meshes, and gradual polymerization, which promotes structural integrity and healing[30]. [paramelmohan et al 2019]

Leucocytes and fibrin in platelet concentrates play important roles in addition to platelets. leucocytes help to regulate the immune system and have anti-infectious properties[9]. Its biologic characteristics are negatively affected by the leukocytes present, and bacterial contamination develops during storage[13] (Jana Milutinovic et al. 2020). By utilising its angiogenesis property, PRF decreases the volume of bone substitute and enhances revascularization. After application, PRF does not disappear right away; instead, the solid fibrin matrix slowly undergoes a process resembling that of a blood clot[8] (Caffesse, Sweeney and Smith 1986). Overall, PRF possesses physical and biochemical qualities that make it appealing for use in periodontal wound healing, and for these reasons it was examined as a potential regenerative agent for periodontal intrabony defects in the current investigation.

The PRF membrane was chosen over the GTR membrane[35] because of membrane exposure, a common problem with GTR, occurs with a prevalence of 50–100%, and bacterial contamination as a result has a detrimental effect on the regenerative outcomes. Erythema, edema, suppuration, sloughing, and post-operative discomfort are some additional GTR side effects that have been recorded (Murphy 1995).

There were no unexpected patient experiences, infections, or adverse tissue reactions during the surgery or at the post-operative consultations. The overlying flap tolerated the graft materials well in the PRF group, the healing over the materials appeared outstanding. In comparison to the OFD group, the post-operative inflammation was seen to be reduced in the PRF group. No metrics were employed to evaluate the differences in the early healing between the 3 groups; this was just a clinical observation. However, this observation might be the result of PRF acting as an immune regulatory node because to its capacity to reduce inflammation retroactively.

The reduction of inflammation and post-operative infections observed at surgical sites when PRF is used as a surgical additive may be explained by the presence of leukocytes, inflammatory retro-control cytokines (particularly IL-4), chemotactic

properties of cytokines like IL-1, IL-6, and TNF-, as well as their capacity to facilitate access to the injured site (neovascularization) (Dohan et al. 2006)[14]

Patients in all the 3 groups depicted good oral hygiene levels. The PPD showed no statistically significant differences at baseline and at 6 months between all the 3 groups, though it as significant in intragroup comparison. And the CALG showed statistically significant differences in Group II (OFD +PRF) between the groups both at 3 months and at 6 months.

The extraordinarily high density of fibrin fibres found in the PRF for PRF group, which adds additional stability to the wound and encourages quick neo-angiogenesis, may be the cause of the result disparities between the OFD and PRF groups (Choukroun et al. 2006)[45]. These improvements may also be attributed to increased levels of several platelet- and leukocyte-derived polypeptide growth factors that are continuously secreted in the surgical wound[14] (Dohan et al. 2006). In the present study clinical (PPD, CAL, BG) and radiographic (CEJ-C and CEJ-A) parameters were evaluated at baseline, at 3 months and at 6 months.

A number of authors have promoted the use of intramarrow penetration (IMP), also known as decortication, as a way to enhance the supply of progenitor cells and blood vessels in the area and subsequently, the effectiveness of surgical methods used to cure intrabony defects[23]. The biologic rationale for decorticating bone is to cause bleeding that submerges the defect in blood. As the clot organizes, it releases cytokines and growth factors to attract progenitor cells, osteoblasts, and blood vessels, intramarrow penetration (IMP), a procedure which involves either purposeful drilling holes through the cortical bone into the cancellous bone or exposing the cancellous bone by removing the cortical bone.

Beginning in the 1970s and 1980s, a number of writers reported the clinical use of IMP in conjunction with regenerative periodontal surgical procedures; specifically, IMP has been utilised in OFD, bone grafting, and GTR operations used to correct intra bony abnormalities[19]. [crea et al 2013]

After careful debridement, decortication of the defect walls with a round carbide bur improved the clinical and radiographic results of OFD; more specifically, the addition of IMP led to greater clinical (CBL) and radiographic (rDD) bone fill, which was significant in both clinically and statistically terms. Based on these clinical and radiographic results, IMP considerably improves the bone regeneration associated with OFD[19]. (crea et al 2013)

This study was designed to compare and evaluate the clinical and radiographic outcomes of three groups in the treatment of periodontal intra bony defects. As previously mentioned, three groups were formed to evaluate the parameters. The data gathered from these evaluations was then collated, tabulated, and statistically analysed to produce the following results:

The outcomes of this clinical trial suggest that three of the treatment groups treated with OFD alone or OFD+PRF or OFD+IMP showed a significant improvement in both clinical and radiographical parameters from baseline to6 months and good healing up to 14 days postsurgery. Regarding intergroup comparisons, the group II treated with OFD + PRF showed the greatest improvements in both clinical and radiographic parameters at 3 months, followed by the group III treated with OFD + IMP. The least amount of improvement was found in the group I treated with OFD alone. But at 6 months group III treated with OFD+IMP showed the greatest improvements in radiographic parameters, followed by the group II and group I respectively.

In OFD group, the mean PPDR at 3 months and 6 months was 3.00±1.059 mm (45%), 4.10±1.19 mm (60%) respectively. And mean CALG was 2.70±1.34 mm (43%), 4.00±1.41 mm (64%). A previously conducted study by Patel GK et al. 2017 evaluated and compared 2 groups i.e OFD alone and OFD+PRF and showed a mean PPDR and mean CALG in the range of 2.4±0.69 mm and 2.1±0.46 mm respectively in OFD group. These results were in accordance to our study results for PPDR and CALG. Mild differences can be attributed to surgeon's skill, baseline site characteristics, and surgical technique used. (Table 1,4).

In PRF group, the mean PPDR at 3 months and 6 months was found to be 3.80±1.22 mm (47%), 5.40±2.11 mm (67%) and mean CALG was 4.00±1.69 mm (55%), 5.60±2.27 mm (77%). Our results are in agreement with the findings of Patel et al. (2017),3 who conducted a survey of 13 patients with 26 bilateral defects (13 per group), randomized as either PRF or OFD alone, and found that at 6, 9, and 12 months, the clinical parameters of the PRF group significantly outperformed those of the OFD group. The improvements in PD in our study were almost the same at 6 and 12 months postsurgery. The PPDR values were in accordance, but CALG was lower than our study. The use of PRF membrane in Group II may have contributed to the increase in CAL. After surgery, gingival recession in Group II stayed stable while it considerably increased in Groups I and III. The attainment of decreased gingival recession at 6 months following surgery due to the use of PRF membrane may account for the considerable CAL gain seen in Group II. (Table 1,4).

In Group III (IMP group), mean PPDR at 3 months and 6 months was 3.30±1.10 mm (45%) and 4.40±1.07 mm (62%) respectively and mean CALG at 3 months was 3.00±1.17 mm (45%), at the 6 months was 4.35±1.31 mm (64%). This results are in agreement of the findings of a study by Saudi HI et al. 2017 compared OFD to OFD + IMP, showed a mean PPDR and CALG and bone gain in OFD + IMP group in the range of 3.6 ± 1.57 mm and 3.7 ± 1.4 mm. and mean CALG was 2.8 ± 1.5 mm , 3.6 ± 1.57 mm. the mean bone gain at 3 months and 6 months was these results were lower as compared to our study results.

Radiographic assessment was recorded by the IOPA (RVG along with Grid). This technology offers increased precision, lower radiation doses, and lower costs. significant changes in the level of bone were observed after 3 months in the PRF treated sites and after 6 months bone gain was higher in the IMP treated sites. Similar significant defect resolution in IBDs that had received PRF treatment was reported by Throat et al.[23] and Sharma and Pradeep[48].

In the Group I, mean reduction in defect depth after 3 months and 6 months was 2.30±1.15 mm (42%), at the 6 months was 3.10±1.59 mm (57%). In Group II, the mean bone gain at the 3 months was 2.30±1.15 mm (26%), at the 6 months was 3.10±1.59

mm (57%). And in Group III, the mean bone gain at the 3 months was 1.20±0.42 mm (26%), at the 6 months was 3.10±0.87 mm (67%). (table 7).

The intergroup comparison of percentage change in the PPD from baseline at 3 months and 6 months between Group I,Group II and Group III was statistically non-significant. But all three groups showed a statistically significant reduction in PPD from baseline individually in intragroup comparison. On intergroup comparison, a steady gain in CAL was seen in Group II as compared to Group 1 and group III at all time intervals.The value was statistically significant.

In Radiographic evaluation, the intragroup comparison, all 3 groups were showing statistically significant reduction in defect depth measurements.

However, when the results of the three groups were compared, group II showed superior outcomes than group I and group III at the three-month mark following surgery. And six months following surgery, group III had more favourable outcomes. Statistics-wise, the results were noteworthy. Significantly, there was a 67% increase in mean defect resolution from baseline to six months.

Regarding group II, Our findings concur with those of Patel et al. (2017)29, who studied 13 patients with 26 bilateral defects (13 per group), randomly assigned to receive either PRF or OFD alone, and found that the PRF group demonstrated significant improvements in clinical parameters over the OFD group at 6, 9, and 12 months. At six months after surgery, the improvements in the clinical and radiographic measures (PPD, CAL, and BG) in our research were nearly identical.

Previously, PRF was evaluated as sole grafting material and results showed significant improvements in clinical parameters over 3 and 6 months duration[46].

Probing depth reduction in present study at end of 6 months are in accordance other studies reporting probing depth reduction of 4.56 ± 0.37mm in test sites compared to 3.56± 0.27mm[12].

This is in line with research that found that locations treated with PRF had a probing depth reduction of 4.55 ± 1.87 mm after 6 months[43].These results are in accordance with **yaseminsezgin et al** in 2017 and also Several studies[17,18,23,24,25,26,27]who have examined the suitability of autologous PRF for treatment of human intra-bony defects and revealed that PRF improves clinical[15] and radiographical[17,18,23,24,25,33]parameters and reported similar statistically significant reduction in clinical attachment level in intrabony defects using PRF.

Regarding group III, our results agree with the first study of IMP by De Carvalhoet et al.(2000)[44], who investigated the impact of bed preparation on the integration of autogenous bone grafts in dogs' mandibles using three distinct types of receptor beds: cortical, perforated, and decorticated. According to histological findings, the perforated and decorticated groups were the ones where the autogenous bone grafts were most thoroughly incorporated into the receptor bed. Cortical group participants showed the worst outcomes. These findings may be explained by the beginning of local tissue repair, the release of osteoprogenitor cells (signalling and angiogenesis), and the action of osteoinductive agents as vascularity peaked following injury to the bone tissues, which was followed by high tissue turnover that is functionally normal[23].

Our study supports a study published in 2014[9], Crea A et al. examined the clinical (PPD, CAL, and BOP) and radiographic (defect depth and width) effects of adding IMP to an OFD technique used to correct intrabony defects in patients with moderate to severe chronic periodontitis. Results were in agreement with our findings and shown a considerable improvement in the test group's clinical and radiographic outcomes.

In 2017 Saudi HI et al[10] conducted a study to examine the validity of IMP with OFD in the treatment of human periodontal intra bony defects. They concluded that all the clinical and radiographic parameters improved significantly. Results were in agreement with our findings and shown that the addition of IMP to an OFD procedure used to treat Intrabony defects could result in significant improvement of clinical outcomes in well maintained patient.

Platelet Rich Fibrin has recently been studied by Bharti V et al in 2021 in the treatment of intra-bony defects with and without intra-marrow penetrating. They have concluded that the combination of intra marrow penetration and PRF demonstrated better results in probing pocket depth reduction, clinical attachment level gain and linear bone fill as compared to PRF alone in the treatment of periodontal intra bony defects, such finding support our study[23].

In contrast, our findings differ with those of Lundrgen., et al. (2000), who examined the effect of donor bone decortication on directed bone augmentation in rabbits. The use of an animal model rather than humans in our study, as well as the different design of the titanium cylinders used in their research compared to the animal studies mentioned above, may help to explain why decortication of the donor bone did not result in more bone formation beyond the skeletal envelop or increasing density than the control group, according to the authors[45].

The above randomized clinical trial (RCT) was designed to investigate treatment of periodontal intra bony defects with Periodontal flap surgery (OFD) alone in one group, PRF in second and IMP in third group. To our knowledge, this is the first RCT which compare these three groups to assess the regeneration of periodontium to restore lost form, function and esthetics and to compare the clinical and radiographic effect of the addition of PRF and IMP to OFD during the treatment of intra bony defects in chronic periodontitis patients.

In our study, the combination of intramarrow penetration with OFD and PRF with OFD demonstrated better results in clinical as well as radiographic parameters than control roup (OFD alone). Future longterm clinical studies with larger sample size should be carried out to further explore the role of intramarrow penetration, PRF in the management of periodontal intrabony defects due to periodontitis.

As far as our knowledge, this study is the first prospective, randomized, double-masked, controlled clinical trial reported to date that assesses the clinical and radiographic outcomes of different surgical treatments, including OFD, PRF, and IMP, for intrabony defects caused by periodontitis.

In conclusion, all treatment modalities improved clinical and radiographic outcomes however our findings strongly suggest that adjunctive use of platelet rich fibrin showed a definite clinical and radiographic evidence of regeneration along with satisfactory healing. But IMP provided more radiographic improvement with time. Our study also confirms the excellent properties of PRF for periodontal wound healing. PRF is a simple, easy, and inexpensive biomaterial compared with bone grafts [37] making its use suitable for the treatment of intrabony defects due to periodontitis, which has a high prevalence in developing countries.

Therefore, IMP alone can be used as a promising treatment protocol in the surgical treatment of intrabony defects as it adds minimal time and cost-effective protocol.

However, long-term randomized controlled clinical trials with larger sample sizes and/or specific defect morphology types and longer follow-up periods are needed to support the outcome of this study.

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ANNEXURE - 1

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Platelet-Rich Fibrin vs Intra-Marrow Penetration in the Treatment of Human Periodontal Intra-Bony Defects: A Clinical and Radiographic Comparative Study"** submitted by **Dr Snigdha Biswas** Post graduate student from the **Department of Periodontology** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **11th October 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

ANNEXURE – II

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 12 **BBDCODS/04/2022**

Title of the Project: Platelet-Rich Fibrin vs Intra-Marrow Penetration in the Treatment of Human Periodontal Intra-Bony Defects: A Clinical and Radiographic Comparative Study.

Principal Investigator: Dr Snigdha Biswas **Department:** Periodontology

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Snigdha Biswas,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. Puneet Ahuja)
Principal
BBDCODS

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road Lucknow 226028

ANNEXURE – III

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow –226028 (INDIA)

Consent Form(English)

Title of the Study:

Platelet-Rich Fibrin Vs Intra-Marrow Penetration in The Treatment of Human Periodontal Intra-Bony Defects: A Clinical And Radiographic Comparative Study.

Study Number……..
Subject's Full Name…….
Date of Birth/Age……
Address of the Subject…….
Phone no. and e-mail address……
Qualification……
Occupation: Student/Self Employed/Service/Housewife/Other
(Please tick as appropriate)
Annual income of the Subject……
Name and of the nominees(s)and his relation to the subject..... (For the purpose of Compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated ……..for the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I permit the use of stored sample(tooth/tissue/blood) for future research. **Yes[] No[] NotApplicable[]**
6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature(or Thumb impression)of the Subject/Legally Acceptable Representative:……..

Signatory's Name……. Date…….

Signature of the Investigator…… Date……..

Study Investigator's Name..... Date……..

Signature of the witness…… Date……..

Name of the witness……

Received a signed copy of the PID and duly filled consent form

Signature/thumb impression of the subject or legally Date…

ANNEXURE – IV

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

अध्ययन का शीर्षक:

प्लेटलेट-रिच फाइब्रिन बनाम इंट्रा-मज्जा प्रवेश मानव पीरियोडॉन्टल इंट्रा-बोनी दोषों के उपचार में: एक नैदानिक और रेडियोग्राफिक तुलनात्मक अध्ययन।

स्टडी नंबर.....

विषय का पूरा नाम .....

जन्म तिथि/आयु .....

विषय का पता.....

फोन नंबर। और ई-मेल पता .....

योग्यता .....

व्यवसाय: छात्र / स्वरोजगार / सेवा / गृहिणी /

अन्य (कृपया उपयुक्त के रूप में टिक करें)

विषय की वार्षिक आय.....

नाम और नामांकित व्यक्ति (ओं) और विषय से उसका संबंध ..... (के उद्देश्य के लिए

मुकदमे से संबंधित मौत के मामले में मुआवजा)।

1. मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक . को पढ़ और समझ लिया है .....उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।

2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।

3. मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी। इसके संबंध में आयोजित किया जा सकता है, भले ही मैं परीक्षण से हट जाऊं। हालांकि, मैं समझता हूं कि तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में मेरी पहचान प्रकट नहीं की जाएगी।

4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।

5. मैं भविष्य के शोध के लिए संग्रहीत नमूने (दांत/ऊतक/रक्त) के उपयोग की अनुमति देता हूं। हाँ नही [ ]
लागू नहीं [ ]

6. मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। मुझे जटिलताओं और दुष्प्रभावों के बारे में समझाया गया है, यदि कोई हो, और उन्हें पूरी तरह से समझ लिया है। मैंने प्रतिभागी/स्वयंसेवक के मुझे दिए गए सूचना दस्तावेज को भी पढ़ और समझ लिया है।

विषय/कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान):.....

हस्ताक्षरकर्ता का नाम..... तारीख .....।

अन्वेषक के हस्ताक्षर ..... तारीख.....

अध्ययन अन्वेषक का नाम ..... तारीख.....

गवाह के हस्ताक्षर..... तारीख.....

गवाह का नाम .....

पीआईडी की एक हस्ताक्षरित प्रति और विधिवत भरे हुए सहमति फॉर्म विषय के हस्ताक्षर/अंगूठे का निशान या कानूनी रूप से दिनांक.....

ANNEXURE – V

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)
BBD Green City, Faizabad Road, Lucknow–226028 (INDIA)

Guidelines for Devising a Participant / Legally Acceptable Representative Information Document (PID)in English

1. Study Title

Platelet-Rich Fibrin Vs Intra-Marrow Penetration in the Treatment of Human Periodontal Intra-Bony Defects: A Clinical and Radiographic Comparative Study.

2. Invitation Paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

The aim of the study is to assess the pocket probing depth, Clinical attachment level & bone gain (IOPA with Grid) following periodontal surgery alone, periodontal surgery with PRF & periodontal surgery with IMP (Intra Marrow penetration) in the treatment of intra bony defects.

4. Why have I been chosen?

You are chosen as you fulfill the criteria of the study.

5. Do I have to take part?

It is upto you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still are free to withdrawal any time and without giving a reason.

6. What will happen to me if I take part?

Periodontal Flap surgery will be done in areas fulfilling the criteria. In one group, only periodontal flap surgery will be done. In second group, blood will be drawn intravenously to prepare the PRF, that will be placed and work as autologous graft. In the third group, Intra-marrow penetration will be done using carbide burs. As a volunteer, your responsibility will be to arrive on time and follow the postoperative instructions.

7. What do I have to do?

There will be certain changes in the dietary intake with few other precautionary measures, and you will be expected to follow that.

8. What is the procedure that is being tested?

The procedure that is being tested is a comparison between debridement, PRF and Intra marrow penetration in the treatment of intra-bony defects. These will be done in the course of periodontal flap surgery.

9. What are the interventions for the study?

Pre-Surgical: IOPA with grid will be obtained before starting the procedure.

Surgical: site will be prepared under 2% lignocaine with adrenaline and full thickness flap will be raised. Post-Surgical: medications will be prescribed such as: antibiotics, NSAIDS

10. What are the side effects of taking part?

There are no known side effects of taking part in the study. If the patient feels any discomfort post surgery then they have to immediately contact the doctor.

11. What are the possible disadvantages and risks of taking part?

There are no reported risks or disadvantages of taking part in the study.

12. What are the possible benefits of taking part?

By taking this study you will be receiving a better treatment option. The main benefits will be bone gain and the gain in Probing Pocket Depth and Clinical Attachment Level in intra bony defects.

13. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the research being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your researcher /investigator will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study finishes/stops before the stipulated time, this should b eexplained to the patients.

15. What if something goes wrong?

Volunteers will be taken care of by the doctors expertising in the field at BBDCODS OPD.

16. Will my taking part in this study be kept confidential?

Your name, address or any personal or other information will not be shared outside the BBDCODS.

17. What will happen to the results of the research study?

Identity of the participants will not be disclosed in any result/reports/publications

18. Who is organizing the research?

Study is organized by the researchers

19. Will the results of the study be made available after study is over?

If the patient wishes, result of the study will be made available to him/her.

20. Who has reviewed the study?

The HOD/IRC/IEC of the institution has reviewed and approved the study.

21. Contact for further information

Dr. SNIGDHA BISWAS

Department of Periodontology.

Babu Banarsi Das College Of Dental

Sciences.Lucknow- 226028

Contact number:

7005367949

Dr. MONA SHARMA

(HOD)

Department of Periodontology.

Babu Banarsi Das College of Dental

Sciences.Lucknow- 226028

Contact number: 9984110444

SignatureofPI……

Name……..

Date……

Annexure - VI

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University, Lucknow)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

प्रतिभागीकेलिएसूचनापत्र

1.अध्ययन शीर्षक

प्लेटलेट-रिच फाइब्रिन बनाम इंट्रा-मज्जा प्रवेश मानव पीरियोडॉन्टल इंट्रा-बोनी दोषों के उपचार में: एक नैदानिक और रेडियोग्राफिक तुलनात्मक अध्ययन।

2.निमंत्रण अनुच्छेद

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि शोध क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो मित्रों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक/पारिवारिक चिकित्सक के साथ इस पर चर्चा करें। हमसे पूछें कि क्या कुछ ऐसा है जो स्पष्ट नहीं है या यदि आप अधिक जानकारी चाहते हैं। यह तय करने के लिए समय निकालें कि आप भाग लेना चाहते हैं या नहीं।

3. अध्ययन का उद्देश्य क्या है ?

अध्ययन का उद्देश्य केवल पीरियोडॉन्टल सर्जरी के बाद पॉकेट प्रोबिंग डेप्थ, क्लिनिकल अटैचमेंट लेवल और बोन गेन (आईओपीए विद ग्रिड), पीआरएफ के साथ पीरियोडॉन्टल सर्जरी और इंट्रा बोनी डिफेक्ट के इलाज में आईएमपी (इंट्रा मैरो पेनेट्रेशन) के साथ पीरियोडोंटल सर्जरी का आकलन करना है।

4. मुझेइसअध्ययनकेलिएक्योंचुनागयाहै?

आपको चुना जाता है क्योंकि आप अध्ययन के मानदंडों को पूरा करते हैं।

5. क्याइसमेंमुझेभागलेनाचाहिए ?

यह आपको तय करना है कि भाग लेना है या नहीं। यदि आप भाग लेने का निर्णय लेते हैं तो आपको यह सूचना पत्र अपने पास रखने के लिए दिया जाएगा और सहमति प्रपत्र पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का निर्णय लेते हैं तब भी आप किसी भी समय और बिना कोई कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6. मुझेक्याहोगायदिमैंइसअध्ययनमेंभागलेताहूं।

मानदंडों को पूरा करने वाले क्षेत्रों में पेरीओडोन्टल फ्लैप सर्जरी की जाएगी। एक ग्रुप में सिर्फ पीरियोडोंटल फ्लैप सर्जरी की जाएगी। दूसरे समूह में, पीआरएफ तैयार करने के लिए रक्त को अंतःशिरा से खींचा जाएगा, जिसे रखा जाएगा और ऑटोलॉगस ग्राफ्ट के रूप में काम करेगा। तीसरे समूह में, कार्बाइड बर्स का उपयोग करके इंट्रा-मैरो पैठ किया जाएगा। एक स्वयंसेवक के रूप में, आपकी जिम्मेदारी होगी कि आप समय पर पहुंचें और पोस्टऑपरेटिव निर्देशों का पालन करें।

7. मुझेक्याकरनाहै?

कुछ अन्य एहतियाती उपायों के साथ आहार सेवन में कुछ बदलाव होंगे, और आपसे इसका पालन करने की अपेक्षा की जाएगी

8. किसप्रक्रियाकाअध्ययनकियाजारहाहै?

जिस प्रक्रिया का परीक्षण किया जा रहा है, वह इंट्रा-बोनी दोषों के उपचार में मलबे, पीआरएफ और इंट्रा मैरो पैठ के बीच तुलना है। यह पीरियडोंटल फ्लैप सर्जरी के दौरान किया जाएगा।

9. इसशोधमेंकौनसेहस्तक्षेपदिएजाएंगे?

प्री-सर्जिकल: प्रक्रिया शुरू करने से पहले ग्रिड के साथ आईओपीए प्राप्त किया जाएगा।
सर्जिकल: साइट को एड्रेनालाईन के साथ 2% लिग्नोकेन के तहत तैयार किया जाएगा और पूरी मोटाई का फ्लैप ई उठाया जाएगा।
पोस्ट-सर्जिकल: दवाएं ई निर्धारित की जाएंगी जैसे: एंटीबायोटिक्स, एनएसएआईडीएस

10. इसअध्ययनमेंभागलेनेकेक्यादुष्प्रभावहैं ?

अध्ययनमेंभागलेनेकेकोईज्ञातदुष्प्रभावनहींहैं।अगरसर्जरीकेबादमरीजकोकोईपरेशानीमहसूसहोतीहैतोउन्हेंतुरंतडॉक्टरसे संपर्ककरनाचाहिए।

11. इसअध्ययनमेंभागलेनेकेसंभावितजोखिमऔरनुकसानक्याहै?

अध्ययनमेंभागलेनेकेकोईजोखिमयानुकसानकीसूचनानहींहै।

12. अध्ययनमेंभागलेनेकेसंभावितलाभक्याहै?

इसअध्ययनकोकरनेसेआपकोएकबेहतरउपचारविकल्पप्राप्तहोगा।मुख्यलाभहड्डीकालाभऔरइंट्राबोनीदोषोंमेंपॉकेटडेप्थ औरक्लिनिकलअटैचमेंटस्तरकीजांचमेंलाभहोगा।

13. क्याहोगायदिकोईनईजानकारीउपलब्धहोजातीहै ?

कभी-कभी एक शोध परियोजना के दौरान, अध्ययन किए जा रहे शोध के बारे में नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है, तो आपका शोधकर्ता आपको इसके बारे में बताएगा और आपसे चर्चा करेगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता/अन्वेषक आपकी निकासी की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपसे एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. क्याहोताहैजबअध्ययन / शोधपरीक्षणबंदहोजाताहै।

यदि अध्ययन निर्धारित समय से पहले समाप्त / बंद हो जाता है, तो इसे रोगियों को समझाया जाना चाहिए

15. क्याहोगाअगरकुछगलतहोजाताहै?

बीबीडीसीओडीएस ओपीडी . में क्षेत्र में विशेषज्ञता रखने वाले डॉक्टरों द्वारा स्वयंसेवकों की देखभाल की जाएगी

16. क्याइसअध्ययनमेंमेराहिस्सागोपनीयरखाजाएगा?

आपका नाम, पता या कोई व्यक्तिगत या अन्य जानकारी बीबीडीसीओडी के बाहर साझा नहीं की जाएगी।

17. अध्ययन / शोधपरीक्षणकेपरिमाणकाक्याहोगा?

किसी भी परिणाम/रिपोर्ट/प्रकाशन में प्रतिभागियों की पहचान का खुलासा नहीं किया जाएगा।

18. इसअध्ययनकोकौनआयोजितकररहाहैऔरइसपरीक्षणकेलिएधनकहांसेआएगा।

अध्ययन शोधकर्ताओं द्वारा आयोजित किया जाता है

19.क्यासेवाएंशोधखत्महोजानेकेबादउपलब्धरहेगीयानहीं?

यदि रोगी चाहे तो अध्ययन का परिणाम उसे उपलब्ध कराया जाएग

20.अध्ययनकीसमीक्षाकिसनेकीहै?

संस्थान के एचओडी/आईआरसी/आईईसी ने अध्ययन की समीक्षा की और उसे मंजूरी दी।

निम्नलोगोंसेसंपर्ककरें

21.अधिकजानकारीकेलिएसंपर्ककरें।

डॉ. स्निग्धा बिस्वास
पीरियोडोंटोलॉजी और इम्प्लांटोलॉजी विभाग।
बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज।
लखनऊ- 226028
संपर्क नंबर: 7005367949

डॉ. मोना शर्मा (विभागाध्यक्ष)
पीरियोडोंटोलॉजी और इम्प्लांटोलॉजी विभाग।
बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज।
लखनऊ- 226028
संपर्क नंबर: 9984110444

ANNEXURE VII

PATIENT PROFORMA

NAME:

OPD NUMBER:

AGE/SEX:

ADDRESS:

CHIEF COMPLAINT:

GROUP A: OFD ALONE

Clinical Parameters	At Baseline					
PPD						
CAL						

Radiographic Parameters	At Baseline					
Intra-Bony Defects						

Clinical Parameters	At 3 months					
PPD						
CAL						

Radiographic Parameters	At 3 months					
Intra-Bony Defects						

GROUP B: OFD + PRF

Clinical Parameters	At Baseline					
PPD						
CAL						

Radiographic Parameters	At Baseline					
Intra-Bony Defects						

Clinical Parameters	At 3 months					
PPD						
CAL						

Radiographic Parameters	At 3 months					
Intra-Bony Defects						

GROUP C: OFD + IMP

Clinical Parameters	At Baseline					
PPD						
CAL						

Radiographic Parameters	At Baseline					
Intra-Bony Defects						

Clinical Parameters	At 3 months					
PPD						
CAL						

Radiographic Parameters	At 3 Months					
Bone Gain						

ANNEXURE VIII

CONTROL GROUP (OPEN FLAP DEBRIDEMENT)

Patient	PPD (mm)	CAL (mm)	DD(radiographic)	BG
1				
Baseline	6	5	4	
At 3 months	4	3	3	1
At 6 months	3	2	2	2
2				
Baseline	7	6	5	
At 3 months	4	3	4	1
At 6 months	3	2	3	2
3.				
Baseline	6	7	4	
At 3 months	3	3	3	1
At 6 months	2	2	2	2
4.				
Baseline	10	9	8	
At 3 months	5	4	6	2
At 6 months	3	2	5	3
5.				
Baseline	8	7	6	
At 3 months	4	3	4	2
At 6 months	3	2	3	3
6.				
Baseline	6	5	4	
At 3 months	4	3	2	2
At 6 months	3	2	1	3
7.				
Baseline	8	7	6	
At 3 months	6	5	4	2
At 6 months	4	3	3	3
8.				
Baseline	5	4	3	
At 3 months	2	1	2	1
At 6 months	2	1	2	1
9.				
Baseline	6	7	4	
At 3 months	2	1	3	1
At 6 months	2	1	2	2
10.				
Baseline	6	6	4	
At 3 months	4	3	2	2
At 6 months	3	3	1	3

EXPERIMENTAL GROUP 1 (OPEN FLAP DEBRIDEMENT + PRF)

Patient	PPD	CAL	Defect Depth	Bone Gain
1				
Baseline	13	12	8	
At 3 months	8	7	4	4
At 6 months	3	2	2	6
2				
Baseline	10	11	5	
At 3 months	4	3	2	3
At 6 months	3	2	1	4
3.				
Baseline	7	6	3	
At 3 months	4	3	2	1
At 6 months	3	2	2	1
4.				
Baseline	10	9	7	
At 3 months	5	4	3	4
At 6 months	3	2	2	5
5.				
Baseline	8	7	6	
At 3 months	4	3	4	2
At 6 months	2	1	3	3
6.				
Baseline	5	4	3	
At 3 months	3	2	2	1
At 6 months	2	0	1	2
7.				
Baseline	8	7	6	
At 3 months	4	3	3	3
At 6 months	3	2	2	5
8.				
Baseline	7	6	5	
At 3 months	4	3	3	2
At 6 months	3	2	3	2
9.				
Baseline	6	5	4	
At 3 months	3	2	3	1
At 6 months	2	1	2	2
10.				
Baseline	7	6	5	
At 3 months	4	3	3	2
At 6 months	3	2	3	2

EXPERIMENTAL GROUP (OPEN FLAP DEBRIDEMENT + IMP))

Patient	PPD	CAL	Defect Depth	Bone Gain
1.				
Baseline	11	110	9	
At 3 months	6	6	7	5
At 6 months	5	4	4	6
2.				
Baseline	7	6	3	
At 3 months	3	2	2	1
At 6 months	2	1	1	2
3.				
Baseline	5	4	3	
At 3 months	3	2	2	1
At 6 months	2	1	1	2
4.				
Baseline	6	5	4	
At 3 months	3	2	3	1
At 6 months	2	1	1	3
5.				
Baseline	7	6	4	
At 3 months	4	3	3	1
At 6 months	3	2	1	3
6.				
Baseline	6	7	4	
At 3 months	3	2	3	1
At 6 months	2	1	1	3
7.				
Baseline	8	7	6	
At 3 months	5	4	4	2
At 6 months	3	2	2	4
8.				
Baseline	6	7	4	
At 3 months	3	4	3	1
At 6 months	2	2	1	3
9.				
Baseline	10	9	8	
At 3 months	5	4	7	1
At 6 months	4	3	5	3
10.				
Baseline	6	5	4	
At 3 months	4	3	3	1
At 6 months	3	2	1	3

ANNEXURE IX

STATISTICAL ANALYSIS

Formula used for the analysis

Mean

$$\overline{X} = \frac{\Sigma X}{N}$$

Where:

$\overline{X}$ = the data set mean

$\sum$ = the sum of

X = the scores in the distribution

N = the number of scores in the distribution

Range

$$range = X_{highest} - X_{lowest}$$

Where:

$X_{highest}$ = largest score

X_{lowest} = smallest score

Variance

$$SD^2 = \frac{\Sigma(X - \overline{X})^2}{N}$$

The simplified variance formula

$$SD^2 = \frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}$$

Where:

SD^2 = the variance

$\sum$ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

Standard Deviation (N)

$$SD = \sqrt{\frac{\Sigma(X - \overline{X})^2}{N}}$$

The simplified standard deviation formula

$$SD = \sqrt{\frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}}$$

Where:

SD = the standard deviation

$\sum$ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

The Pearson correlation

$$r = \frac{\Sigma z_X z_Y}{N}$$

Where:

r = correlation coefficient

$\sum$ = the sum of

z_X = Z score for variable X

z_Y = Z score for variable Y

$z_X z_Y$ = the cross product of Z scores

N = the number of scores

One Way ANOVA

The formula for the one-way **ANOVA***F*-test statistic is

$$F = \frac{\text{between-group variability}}{\text{within-group variability}}.$$

The between-group variability" is

$$\sum_{i=1}^{K} n_i (\bar{Y}_{i\cdot} - \bar{Y})^2 / (K-1)$$

where Y_i denotes thesample mean in the i^{th} group, n_i is the number of observations in the i^{th} group, $\bar{Y}$ denotes the overall mean of the data, and K denotes the number of groups.

The "within-group variability" is

$$\sum_{i=1}^{K} \sum_{j=1}^{n_i} (Y_{ij} - \bar{Y}_{i\cdot})^2 / (N-K),$$

where Y_{ij} is the j^{th} observation in the i^{th} out of K groups and N is the overall sample size.

Post Hoc Tukey Test

Tukey's range test, also known as the Tukey's test, Tukey method, Tukey's honest significance test, or Tukey's HSD (honestly significant difference) test,[1] is a single-step multiple comparison procedure and statistical test. It can be used on raw data

or in conjunction with an ANOVA (post-hoc analysis) to find means that are significantly different from each other. Named after John Tukey, it compares all possible pairs of means, and is based on a studentized range distribution (q) (this distribution is similar to the distribution of t from the t-test. Tukey's test compares the means of every treatment to the means of every other treatment; that is, it applies simultaneously to the set of all pairwise comparisons $\mu_i - \mu_j$ and identifies any difference between two means that is greater than the expected standard error.Tukey's test is based on a formula very similar to that of the t-test. In fact, Tukey's test is essentially a t-test, except that it corrects for family-wise error rate.

The formula for Tukey's test is:

$$q_s = \frac{Y_A - Y_B}{SE},$$

where Y_A is the larger of the two means being compared, Y_B is the smaller of the two means being compared, and SE is the standard error of the sum of the means. This q_s value can then be compared to a q value from the studentized range distribution. If the q_s value is *larger* than the critical value obtained from the distribution, the two means are said to be significantly different at level

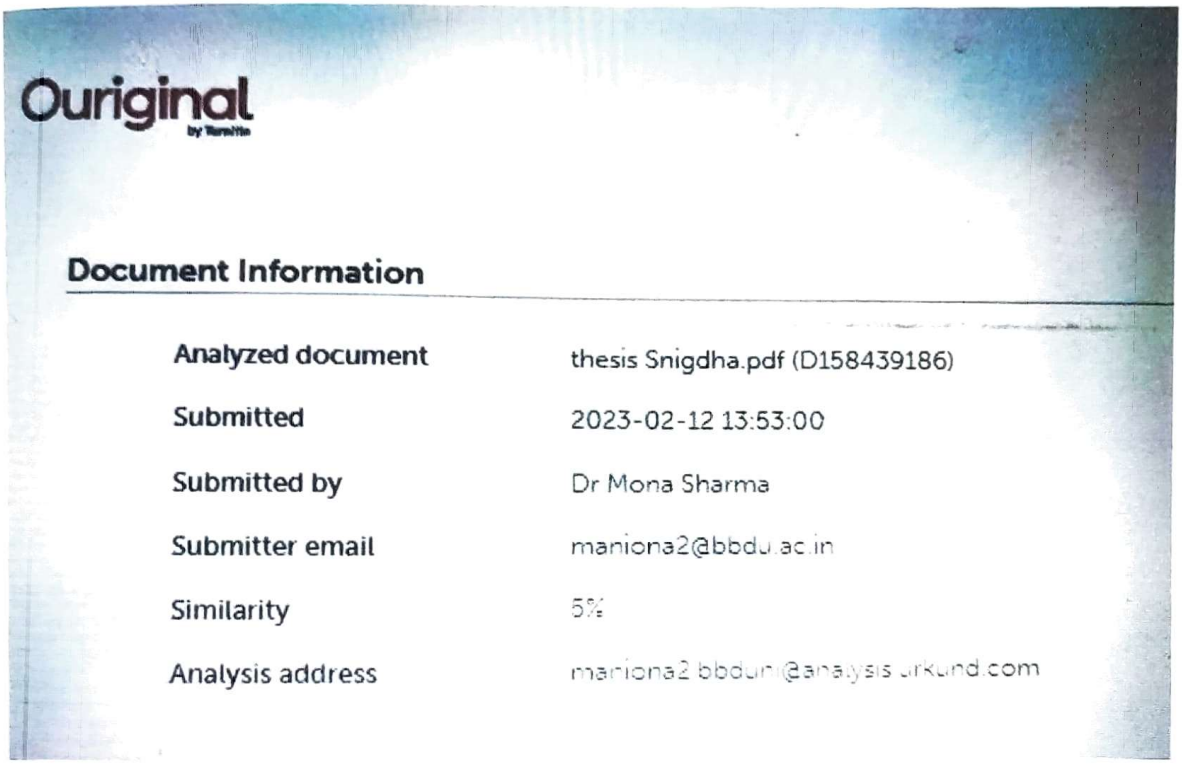
Paired t test

$$t = \frac{\bar{x} - 0}{SE(d)} = \frac{\bar{x}}{SD(x)/\sqrt{n}}$$

A paired t-test is used to compare two population means where you have two samples in which observations in one sample can be paired with observations in the other sample. Examples of where this might occur are: - Before-and-after observations on the same subjects (e.g. students' diagnostic test results before and after a particular module or course) or A comparison of two different methods of measurement or two different treatments where the measurements/treatments are applied to the same

ANNEXURE X

PLAGIARISM REPORT



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