

Title of Article- Comparative Evaluation of Novabone Putty In Combination With Platelet Rich Fibrin (PRF) And Platelet Rich Fibrin (PRF) Alone In The Treatment of Human Infrabony Defects– A Randomized Clinical Trial

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Trial Registration: *Clinical trial registration REF/2019/07/027264*

Abstract--- *Periodontitis is chronic inflammatory disease leads to loss of supporting structures of the teeth results in exfoliation of teeth.(1, 2) Treatment of these periodontal condition is mandatory. Previously, decreasing the disease advancement considered as utmost treatment protocol by preserving the lost periodontal structures.(3,4)*

Keywords--- *Infrabony defects, Novabone putty, Platelet rich fibrin, Periodontal regeneration*

I INTRODUCTION:

Deep periodontal defects cause difficulty in eliminating disease tissue. To eliminate, it may require periodontal surgery also for regeneration of lost periodontal tissues. Diversity found in bonegraft materials such as autografts, allografts, xenografts, and synthetic materials.^(5,6) Alloplast characterized as they are synthetically originate, harmless and inorganic substitute. Alloplast does not require second surgical.^(7,8) These bonegraft regenerate periodontal tissues through osteoinductive or osteoconductive pathways.

Previously, Bioactive glasses used as alloplast materials for periodontal regeneration.^(9,10) NovaBone Dental putty (Calcium phosphosilicate putty) is a new, next generation calcium phosphosilicate(CPS) bone graft material. It is premixed made up of bioactive calcium phosphosilicate particulate along with absorbable binder. It consist of polyethylene glycol (PEG)and glycerin. It is delivered in ready to use form which is available in single use syringe and allows holding the material easily. ⁽¹¹⁻¹⁴⁾

Fibrin products extensively used in dentistry as treatment modality which imitates the natural coagulation cascade in which fibrinogen converts to fibrin through activation of thrombin.⁽¹⁵⁾ This network fibrin helps to

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coaggregate platelets at the injury site, where formation of platelet plug occur to achieve hemostasis. And also it release growth factors and cytokines to initiate healing.^(16,17)

Choukroun's given Platelet Rich Fibrin contains concentrated platelet.⁽¹⁸⁾ It consist of glycanic chains, cytokines and structural glycoproteins. PRF is rich in leukocyte.⁽¹⁹⁻²¹⁾ During formation and centrifugation process it forms 3 layers in test tube: Platelet poor plasma (PPP) at the topmost portion , PRF clot found in centre, and Red blood cells (RBC) at the base of test tube. After completion of centrifugation process get removed out serum into fibrin membrane.⁽²²⁾ It is 3D membrane which consist of platelets and growth factors.^(23,24) It is autologous, easy to handle and safe for treatment protocol.⁽²⁵⁾ It has potential to release variety of growth factors at healing site for longer period.^(27,28) PRF has potential to release some growth factors at equal concentration for a period of seven days.⁽²⁹⁾

Thus, the aim of present randomized parallel clinical trial is whether combination of Novabone Putty with PRF and PRF alone effective in the treatment of human infrabony defects ?

II OBJECTIVES :

- To determine the efficacy of Novabone Putty in combination with platelet rich fibrin with respect to CAL gain, PPD reduction and radiographic bone fill in infrabony defects.
- To determine the efficacy of PRF in terms of CAL gain, PPD reduction and radiographic bone fill.
- To compare the efficacy of Novabone Putty in combination with PRF and PRF alone and in terms of gain in CAL, decrease in PPD and radiographic bone fill in infra-bony defects.

III STUDY POPULATION

24 patients having moderate to advanced chronic periodontitis with clinical and radiographic findings of angular defects will be chosen from the outpatient Department Of Periodontics, Sharad Pawar Dental College, Sawangi (Meghe), Wardha using following criteria.

IV INCLUSION CRITERIA:

- Patient should not be systemically comprimised.
- Presence of minimum 1 or 2 interproximal infrabony osseous defect with PPD \geq 5 mm and CAL \geq 5 mm following initial therapy and which are radiographically noticeable.
- Depth of intraosseous defect component \geq 3 mm by clinical and radiographic means, which will be accepted through intrasurgical measurement
- A radiographically determined defect base should be minimum of 3 mm above terminal end portion of root of tooth.
- Presence of minimum \geq 2 mm zone of keratinized gingiva surrounds the test teeth which allows full soft tissue coverage at defect site.

V EXCLUSION CRITERIA:

- Presence of localized aggressive periodontitis.
- Patients with poor oral hygiene care (Plaque Index >1)
- Patient who smokes (with recent history of smoking more than 10 cigarettes /day) or who consume any type of tobacco products.
- Study tooth with improper endodontic / restorative therapy.
- Study tooth with mobility exceeding grade II and exhibiting a class III or class IV furcation defect.
- Previous History of periodontal surgery in selected quadrant selected for study purpose.
- Pregnant females or lactating mothers.
- Clinically determined and/or radiographic examined untreated acute infection present at selected area.
- Presence of apical pathology, cemental pearls, root irregularities and fracture which causes difficulty in removal through odontoplasty process, untreated decayed tooth at cementoenamel junction or at root surface.

Information related to dietary status, oral hygiene care, systemic background, gingival and periodontal condition details will be documented precisely in charts. Clinical evaluation of patients will be done through mouth mirror and William's graduated periodontal probe in good illumination.

VI INITIAL THERAPY:

In first visit, full mouth scaling will be undertaken followed by root planing under local anesthesia if required.⁽³⁰⁾ Coronoplasty will be carried out and oral hygiene instructions will be given to patient. Plaque control measures will be repeated until plaque score will be ≤ 1 . After initial therapy, periodontal evaluation will be carried out once in 2 week.

The information about the need of study will be clarified and signed informed consent will be taken from patients. Study protocol will be first approved by Ethical committee of DMIMS (IEC/2018-19/7493), Sawangi (Meghe), Wardha.

For the Standardization of probe angulations and accurate position, custom made occlusal acrylic stent will be made. Alginate impression will be taken for cast model preparation on which occlusal stent will be fabricated through use of acrylic material. Stent should cover the occlusal surface of test tooth and extend to minimum one adjacent tooth and covers the coronal third of teeth. A reference point (slot) will be marked on the stent at the deepest site of involved tooth to facilitate reproducible periodontal probe positions. The apical margin will be linear and served as a fixed reference point.

VII STUDY DESIGN:

After initial therapy 24 patients who are systemically healthy will be selected. It is double blinded study. Before undergoing surgical treatment, the chosen infrabony defects were allocated randomly. Groups will be divided into

test and control which consist 12 defects in each. The test group will be treated by combination of Novabone Putty and platelet rich fibrin (PRF), while the control group will be treated by platelet rich fibrin (PRF) alone.

VIII CLINICAL MEASUREMENTS:

Clinical measurements like Plaque index, Papillary bleeding index, Probing pocket depth, Relative attachment level and Relative gingival marginal level will be recorded at the day of surgery & postoperatively at 3 and 6 months. Primary outcomes will be radiographic bone fill and Secondary outcomes will be PI, PBI, CAL gain, PPD reduction. Also, periodontal charting on specially designed form, intraoral periapical radiographs and intraoral clinical photographs will be obtained.

Oral health status of patient will be examined by using plaque index which will represent the accumulation of plaque present above the gingival margin of teeth. Gingival inflammation will be measured through Papillary bleeding index.

VIII.I. Indices

- Plaque Index (PI) (Turesky – Gillmore –Glickman Modification of Quigley-Hein 1970)³¹
- Papillary Bleeding Index (Muhlemann H.R 1977)³²

VIII.II. Probing Measurements:

Both treatment groups will be recorded to measure probing pocket depth (PPD), relative clinical attachment level (R-CAL), relative gingival marginal level (RGML at six site of the selected defect: mesiobuccal, mesiolingual, midmesial of one tooth, and distobuccal, distolingual, middistal of adjacent tooth. Only one deepest measurement per defect will be taken into consideration for calculation of the result through UNC-15 calibrated periodontal probe. These clinical parameters will be measured at the day of surgery, post operatively at 3 & 6 months.

The UNC-15 probe will be placed in the slot made on the acrylic stent and tip at the gingival marginal level and the measurement will be determined upto lower border of stent as relative gingival margin level (RGML). Placement of probe will be placed at the base of the pocket and the distance upto the lowest border of stent will be considered as a relative attachment level (RAL). Probing pocket depth will be measured from base of the pocket upto gingival margin (PPD).

The width of keratinized gingiva will be recorded by measuring the sulcular depth and attached gingiva (from mucogingival junction upto free gingival groove) through UNC-15 calibrated Periodontal Probe. All the probing measurements will record at baseline, after 3 and 6 months of surgery.

VIII.III. Radiographic analysis:

Intra oral periapical radiograph (IOPA) xray will be choosen of selected area. The x-ray taken through by parallel technique with long cone at day of surgery and 6 month post surgical period. Radiographic measurements will be taken through a film mounted with grid scale. On grid scale, lines are at intervals of 1mm and bold lines at 5 mm.

Distance of CEJ upto base of defect will be obtained through radiographic measurement with use of developed IOPA.

$$\%BF = \frac{\text{CEJ to base of defect(Baseline)} - \text{CEJ to base of defect(6 months)}}{\text{Original defect depth (Crest of the bone to base of defect)}} \times 100$$

IX SURGICAL PROCEDURE:

Before surgical treatment, patients will be advised to swish with 0.2 % chlorhexidine gluconate mouthwash for about 1-2 minute. Under all aseptic precaution and condition, nerve block will be given with local anaesthetic solution of 2% xylocaine⁽³³⁾ containing 1:1,00,000 epinephrine.

IX.I. Flap Design (Incisions):

Use of Bard-Parker number 12 or 15 surgical blades to achieve predictable reflection of defect site. For reflection of flap intracrevicular incision given on buccal and lingual aspects. To achieve primary wound closure and to preserve complete interdental papillae, the incisions should be given as far interproximally as possible. To achieve added exposure, vertical releasing incisions will be placed on a adjacent tooth.

IX.II. Flap reflection:

To gain access to alveolar bone in area of bone defect, periosteal elevator (24G Hu-Friedy, USA) is used by raising the full thickness flap. A thorough debridement of defect will be carried out by removing diseased tissue from undersurface of the flap and at the same time, proper measures should be taken to prevent the flap rupturing or papillae loss.

IX.III. Debridement and root surface management:

Debridement of osseous defect will be initially done manually with scalers and curretes (Gracey cures, Hu-Friedy, USA) followed by power driven scalers. The undersurface of the flap or papillae will be debrided judiciously to prevent over trimming the flap. Root surfaces will be planned with hand instruments.

Depth of the vertical bone defects (BD) will be measured. The total osseous wall present will be recorded with UNC15 probe. All osseous defects measuring ≥ 3 mm vertically will be included in the study. Intra marrow penetration of the base of the defect through use of half round bur will ensure sufficient bleeding from the site.

IX.IV. PRF Preparation

A standard protocol will be followed for the preparation of PRF. Before the placement of PRF about 5ml blood drawn intravenously. Collection of blood will be done in sterile test tube without any added anticoagulant. After placement of test tube in centrifugation machine, centrifuged it for 10 min at 3000 rpm. This ensures fibrin clot formation at the centre of test tube. Sterile tweezers and scissors will be used to separate the PRF from red corpuscular base. It will then be compressed to squeeze out the serum and obtain a fibrin membrane.

IX.V. Procedure for test group:

Following prior isolation and achievement of haemostasis, the flap will be pre- sutured to facilitate faster flap approximation. Novabone Putty mixed with PRF will be placed into the osseous defect in test site with light pressure till it filled up to coronal most level of osseous wall by raising the flap and then PRFs will be extend over the defect as a membrane. The PRF membrane will be adapted in such a way that it covers at least 3mm beyond the osseous defect. The flap will be coronally repositioned and sutured in such a way that the flap margin will be located 1 to 2 mm coronal to CEJ, ensuring primary flap closure. A combination of vertical mattress suture and interproximal suture will be used to secure the flap in position. Slight pressure will be applied to the area with saline-soaked gauze for approximately 2 minutes, to adapt the soft tissue well to the tooth surface and eliminate any space in which a clot might form and disrupt re-attachment. This procedure will be followed by placement of a periodontal dressing.

IX.VI. Procedure for control group:

The procedure at the control site will be identical to the procedure of test site except osseous defects at control sites will be packed with Plasma rich fibrin(PRF) of the required size and other PRFs will be used to cover the defect as a membrane.

IX.VII. Post-operative care:

Post operative medications will be prescribed which includes antibiotics analgesics for 5 days. Patients will be advised to swish with 0.2% chlorhexidine mouthwash for about 6 weeks.⁽³⁴⁾ Removal of Periodontal dressing and sutures will be done at 8-10 days after the surgery. Use of tooth brushing or chewing will be not allowed for 6 weeks in the treated area. Patients will be informed to cleanse the operated area in an apico-coronal direction with cotton pellet dip in 0.12 % chlorhexidine for additional 2-3 weeks. After that oral hygiene measures like brushing and interdental cleaning aids will be reinstructed to stop use of that and also resume the use of this chlorhexidine mouthwash.

IX.VIII. Maintenance care:

Patients will be followed at 1, 3, 6 months post surgically. Oral hygiene care given to patient at every visit along with ultrasonic scaling. Care will be taken not to probe upto 6 month after surgery.

IX.IX. Re-examination:

A complete post operative evaluation will be performed at 6 months post-surgically. All clinical parameters and measurements will be re-assessed. In addition standardized radiographs will be obtained after 6 month.

IX.X. Statistical Analysis:

PBI, PI and clinical parameters like RAL, PPD, WKG and GR will be assessed by calculation of means and standard deviation (Mean \pm SD) values. Student's paired t-test will be applied to each treatment group from baseline to 6 months. Student's unpaired t test will be used for comparisons between both treatment groups at baseline level

and 6 months follow up period. If the probability value (p) > 0.05 then, difference found will be non-significant and if < 0.05, it will be considered significant.

X EXPECTED RESULTS:

Novabone Putty in combination with Platelet rich fibrin (PRF) is superior compared to Platelet rich fibrin (PRF) alone in the treatment of Human Infrabony Defects.

XI DISCUSSION:

Periodontitis is chronic inflammatory disease leads to loss of supporting structures of the teeth and resulting in exfoliation of teeth. Treatment of these periodontal condition is mandatory which includes preserving the lost periodontal structures. Deep periodontal defects cause difficulty in eliminating disease tissue and calls for the need of periodontal surgery for regeneration of lost periodontal tissues. This study will facilitate the outcomes of using Novabone Putty in combination with Platelet rich fibrin (PRF) compared to Platelet rich fibrin (PRF) alone in the treatment of Human Infrabony Defects. A number of studies related to the factors involved in this trial were reviewed ⁽³⁶⁻⁷⁵⁾.

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