Study Protocol

Evaluation of effectiveness of Platelet Rich Fibrin Matrix (PRFM) membrane and Platelet Rich Fibrin (PRF) membrane using Vestibular Incision Subperiosteal Tunnel Access (VISTA) Approach technique for the Treatment of Multiple Gingival Recession Defects in Humans – A Study Protocol

Abstract:

Background: To evaluate the effectiveness of Platelet Rich Fibrin Matrix (PRFM) membrane and Platelet Rich Fibrin (PRF) membrane using Vestibular Incision Subperiosteal Tunnel Access (VISTA) Approach method for the management of multiple gingival recession (GR) defects in humans.

Methodology: 20 subjects with gingival recession will be enrolled. 10 patient will be randomly allotted to test group (PRFM membrane) or control group (PRF membrame). Primary outcome will be gain in root coverage (RC) and secondary outcome will be Plaque index (PI), Papillary bleeding index (PBI), probing pocket depth (PPD), relative attachment level (RAL), relative gingival margin level (RGML), recession depth (RD), gingival thickness (GT) and width of keratinized gingiva (WKG). Clinical evaluation will be performed at 3 & 6 months of therapy.

Expected results: When all the parameters will be compared at 6 months post-operatively to baseline data, both the treatment group (test and control) will be expected to show significant gain in RC, RAL gain, PPD reduction, decrease in RD, increase in GT and WKG. PRFM membrane will result in significant gain in RC, RAL gain, PPD reduction, and decrease in reduction depth, increase in GT and WKG at 6 months when compared to PRF membrane.

Conclusion: PRFM membrane will be effectual in management of gingival recession. PRFM membrane is expected to have significantly greater outcome as compared to PRF membrane group.

Keywords: Gingival Recession, Vestibular Incision Subperiosteal Tunnel Access, Platelet Rich Fibrin Matrix membrane, Platelet Rich Fibrin membrane.

Introduction:

In routine dental practice, gingival recession (GR) defects are frequently encountered and presents persistent challenges for their management owing to increasing awareness of patient that cause substantial functional and esthetic concern. “GR is defined as the displacement of marginal tissue apical to the cementoenamel junction (CEJ)”.[1] Root coverage procedures are indicated to correct the areas of localized or generalized soft-tissue recession. [2] The treatment of GR is a common request in daily periodontal practice mostly due to esthetic reasons. [3] Recession defects can be isolated or multiple. First line of treatment includes removal of etiological factors followed by surgical correction.[4] Several periodontal plastic surgical procedures have been documented for Miller’s Classes I and II recession defects and negotiate patient’s discomfort due to hypersensitivity, food lodgement, fear of tooth loss,

etc.[5] Evidence echoes that coronally advanced flap (CAF) based techniques are regarded as reliable method for complete root coverage (CRC) while managing isolated GR defect. A primary goal of periodontal therapy is to reduce PPD to limit the risk of local infection. [6] However, there is consistent lack of evidence for coverage of multiple recession defects (MRD).[7]

The surgical treatment for MRD include connective tissue graft,[8] guided tissue regeneration membrane,[9] enamel matrix derivative,[10] acellular dermal matrix allograft,[11] and platelet-rich fibrin (PRF) [7] membrane.

Vestibular Incision Subperiosteal Tunnel Access (VISTA) is a recent, minimally invasive approach used for the management of both multiple and isolated contiguous recession defects.[12] This method is characteristically distinct in that it allows more access in the vestibule and a single vestibular incision can provide access to an entire region. This permits visualization of root and bone morphology or any dehiscence. Additionally, the delicate margin of gingiva has a reduced possibility of trauma, since the line of incision is away from the area of defect, decreasing the invasiveness of the procedure. Treatment with GR defects with VISTA, in conjunction with several bone grafts, leads to gain in tissue thickness along with RC over the exposed root surfaces.

In the field of dentistry a recently developed growth factor delivery system is autologous platelet rich fibrin matrix (PRFM). PRFM has dense concentration of platelets as compared to normal human blood clot. The alpha granules of these growth factors (GF) affect the cells and formation of these tissues involved in the healing of wound. The regeneration of bone and soft tissue has shown an immense potential role in regenerative therapy due to its robust release of GF which are also pivotal components of wound healing process through signaling transduction mechanism.[13] Carroll et al. in 2005 had revealed, in vitro, that the viable platelets in PRFM released six GF mainly epidermal growth factor (EGF), vascular endothelial growth factor (VEGF),platelet-derived growth factor (PDGF), fibroblast growth factor (FGF) in around the same concentration for the seven days duration.[14]

PRF membrane is a fibrin 3-D polymerized matrix in which leukocytes platelet, circulating stem cells, cytokines, and GF are confined and it will help as a resorbable membrane. Hence, it can be used as regenerative therapy in periodontal patients [15]. PRF membrane placement in GR defects can be utilized to establish the function of the properties of the labial gingiva of maxillary and mandibular teeth and re-establishing the integrity & continuity of the zone of KG. Beneficial effects of PRF have been studied in various surgical procedures like sinus floor augmentation during implant placement in multiple gingival recessions with coronally displaced flap and in facial plastic surgical procedures. [16] Jankovic et al[17] conducted a randomized controlled trial and stated that the use of PRF membrane in management of GR provided satisfactory clinical outcomes, and accelerate healing of wound and reduces discomfort of patient in comparison with CTG treated GR defects. Martinez-Zapata et al [18] in their systematic review stated that autologous plasma rich in platelets enhanced GR.

Therefore, the aim of parallel randomized clinical trial is to know if there is root coverage (RC), gains in clinical attachment level (CAL), gingival thickness (GT) & improve width of the keratinized gingiva (WKG) using Platelet rich fibrin matrix (PRFM) membrane in Miller Class I and II multiple gingival recession defect in humans.

Objectives:

1. To evaluate the effectiveness of PRFM membrane using VISTA technique with respect to RC, gains in CAL, GT and improvement in the WKG.
2. To evaluate the effectiveness of (PRF) membrane using VISTA technique in terms of RC, gains in CAL, GT and improvement in the WKG.
3. To compare the effectiveness of PRFM membrane with that of PRF membrane using VISTA technique in terms of RC, gains in CAL, GT and improvement in the WKG.

Material and Methods:

20 subjects with labial or buccal GR defects will be chosen from the outpatient Department of Periodontics, Sharad Pawar Dental College, Sawangi (Meghe), Wardha using following criteria:

Inclusion Criteria:

1. Presence of multiple GR (>1) on the labial or buccal surfaces of the teeth having Miller's Class I or II defects either in maxilla or mandible
2. Presence of ≥ 2 mm GR depth
3. Intraoral periapical radiographic evidence of sufficient interdental bone (the distance between the crestal bone and CEJ as ≤ 2mm).
4. Presence of adequate WKG.

Exclusion Criteria:

1. Patients using tobacco products and smokers.
2. Un-cooperative subjects.
3. Subjects with unsatisfactory oral hygiene after nonsurgical therapy and showing plaque score ≥1.
4. History of periodontal surgical treatment in quadrant selected for the study.
5. Pregnant lady or lactating mother.
6. Presence of badly caries teeth
7. Presence of mobile teeth.

Study Design:

Twenty patients, each with minimum 2 adjacent GR defects will be selected for the study. It is a double-blinded study. Prior to surgery selected patients will be randomly assigned to either PRFM membrane group or PRF membrane, each group will be consisting 10 patients respectively.

Initial Therapy:

Each patient will undergo scaling and root planning along with polishing. They will also receive oral hygiene instructions. Coronoplasty and recontouring of teeth will be performed wherever needed. Patient will be demonstrated to use Modified Stillman's brushing technique to reduce the brushing injury. Oral hygiene instructions will be given till the patients attain plaque score of ≤ 1. The patient's plaque control and tissue response will be re-evaluated 6 weeks later. [19] If the patient's oral hygiene is not maintained then the patient will not be included in the study. The information about the purpose of study will be given to patient and informed consent will be signed from patient.

Study protocol was accepted by Ethical Committee of Datta Meghe Institute of Medical Sciences, Sawangi(M), Wardha.

Clinical Measurements

Clinical records like (PI), (PBI), (PPD), (RAL), (RGML), (RD), WKG and GT will be noted at the day of surgery, three and six months after surgery. Primary outcome will be gain in RC and secondary outcome will be PI, PBI, PPD, RAL, RGML, RD, GT and WKG.

A. Indices:

Patient's gingival status and oral hygiene will be evaluated at the day of surgical procedure 3 and 6 months.

1. Plaque Index will be measured using Turesky - Gilmore - Glickman Modification of Quigley-Hein 1970 [20]
2. Papillary Bleeding Index will be measured using Muhlemann H.R 1977 [21]

B. Probing Measurements:

The clinical parameters will be measured for evaluation of the results are the PPD, RAL, [22] RGML, RD, WKG and GT which will be recorded using a UNC-15 probe. To assimilate the clinical parameters, acrylic stents will be made on patient's casts. An acrylic stent covering the occlusal surfaces of test tooth will be used as reference point. To extend periodontal probe to the deepest area of defect, it inserted at an angle. With the help of burs, longitudinal grooves will be made on the stent which will be used as guide for periodontal probe. GT will be calculated 3 mm below the margin of gingiva, under topical anesthesia with the help of endodontic reamer and rubber stopper. RD will be calculated from cement-enamel junction to the margin of gingiva. WKG will be achieved by calculating the sulcular depth plus the attached gingiva by UNC-15 Probe. These clinical measurements will be noted on the treated areas at the day of surgery, 3 and 6 months.

Preparation of PRFM membrane:

Ten milliliter of blood sample will be collected from antecubital vein by venipuncture within 1 min from the participants for the preparation of PRFM. The samples will be immediately transferred within 30 s in the Meresis PRFM kit (*R-4C, REMI Laboratory Instruments, Mumbai, India) and placed in the centrifugation machine. It will be centrifuged at rpm of 3000 for 10 min using single-spin centrifugation. Following centrifugation, the PRFM clot will be obtained. [23] The clot will be transferred to PRFM box and compressed to obtain PRF membranes.

Preparation of PRF membrane:

10mL of blood sample will be withdrawn from antecubital vein with the help of 24-gauge needle. In 10 ml glass test tubes the blood samples will be collected and immediately centrifuged at 2,700 rpm for 12 minutes by using a table centrifuge machine. The fibrin clot formed in the middle part of the tube will be taken, and the remnants of red blood cells will be discarded. The clot will be shifted to the PRF box and pressed so that PRF membranes can be obtained.

Surgical Procedure for Test group:

Prior to the therapy, the patients will be explained to rinse the mouth with (0.2 %) Chlorhexidine gluconate for 1 minute. The surgical procedure accentuated infection control

and complete asepsis. After induction of 2% local anaesthesia, the exposed root surfaces will be carefully cleaned with ultrasonic instruments followed by curettes. Under local anaesthesia, full thickness 8–10 mm vertical incision will be given in the vestibule mesial or distal to the surgical site treated. This incision will not extended up to gingival margin and served as door for extension of subperiosteal tunnel. This tunnel exposes the osseous plate and extending by Orbans knife up to one or two teeth beyond the recession site undergoing surgical correction. Moreover, the subperiosteal tunnel will be extended into interpapillary region without piercing the papillary tip. Slow apical movement of knife through papillary region commute to the vestibular tunnel and allow the coronal movement of mucogingival complex covering the MRDs. This subperiosteal tunnel will be repositioned coronally and adapted passively to CEJ covering the recession defects. Coronal anchored sutures will be placed engaging the 2–3 mm apical gingival margin of individual tooth using 4-0 non-absorbable silk suture. The suture will be secured with the help of composite resin button to prevent apical relapse of the gingival margin, at the midcoronal point of the facial aspect of each tooth. Once coronal stabilization will be achieved, freshly prepared PRFM membrane will be inserted through the tunnel using the small periosteal elevator and spread it uniformly on recession defects. After complete and proper adaptation of the membrane the vertical incision will be sutured for the primary closure. Complete surgical site will be covered with Coe-pack. [24]

Surgical procedure for Control group:

The surgical method for the control site will be similar to the method of test site except only PRF membrane will be placed over the sites with exposed root surfaces.

Post-operative care:

After procedure, periodontal pack will be positioned on the recipient site as well as donor site. Non-steriodal anti-inflammatory Tab. Ibuprofen 325 mg + Paracetamol 400 mg, thrice a day & systemic antibiotic Capsule Amoxicillin 500 mg, thrice a day will be given for 5 days during post-surgical period. Subjects will be explained not to brush the teeth for 3 weeks post-surgery at the treated sites. All subjects will be trained to rinse with (0.2%) chlorhexidine gluconate twice daily, for 14 days.

After 7days of procedure, periodontal pack will be removed. At this time the healing is observed. After 14 days the sutures will be removed. After irrigation with saline, polishing will be done with the help of polishing paste and rubber-cup, without traumatizing the treated site. Patients will be explained to wipe the treated area with cotton dipped in (0.2%) chlorhexidine gluconate for another 7days and later brushing with Charter's method. The subjects will be recalled at one, 3 and 6 months following surgery.

Statistical Analysis:

The mean and standard deviations (Mean ± SD) measures will be recorded. Mean data will be examined by means of a standard statistical method for statistical significance. The data from the baseline to 3 and 6 months per group will be assessed by using Students paired t-test. Assessments among the treatment groups at baseline, three, & six months will be done by means of Student's unpaired t-test. If the probability [p] value is > 0.05, then the result will be non-significant, and if < 0.05, it will be considered significant.

Expected Results :

When all the parameters will be compared at 6 months post-operatively to baseline data, both the treatment group (test and control) will show significant gain in RC, RAL gain, PPD reduction, decrease in reduction depth, increase in GT and WKG. PRFM membrane will

result in significant gain in root coverage, RAL gain, PPD reduction, decrease in reduction depth, increase in GT and WKG at 6 months when compared to PRF membrane.

Discussion:

Garg et al (2017)[24] in their case series had evaluated the efficacy of VISTA with or without PRF membrane in management of multiple Classes I and III recession defects. 4 subjects with thirty & forty years of age were included in this study. In all subjects recession defects were treated using the VISTA approach with or without PRF-membrane. Clinical measurements like recession depth (RD), recession width (RW), PPD and CAL were measured at baseline & six months post-op. Class I recession defects treated with VISTA technique alone showed better result. On the other hand, subjects with Class III recession defects who were treated with VISTA + PRF-membrane revealed a better RD reduction and CAL gain in comparison to sites with VISTA only. Therefore the authors concluded that VISTA alone is a suitable procedure for the management of Class I MRDs. For Class III recession defects, inclusion of PRF-membrane gives an enhanced result in terms of RD reduction & CAL gain six months post-op.

Gil et al (2018)[25] in their study observed the relationship among initial site-specific characteristics of subjects with multiple GR & result of RC. Pre and post therapy study models of twenty-one subjects with multiple GR defects, managed with VISTA, were examined. 3-D examination of superimposed before and after surgery images was recorded. Surface and linear RC were recorded. A multistage statistical analysis was done. The mean percentages of linear (96.2±13.1% & 84.3±14.4%), root surface area coverage (92.1±12.0% and 78.6±15.7%) for Miller Class I, II and III recessions were calculated. Initial RW, Initial RD, posterior tooth type and root prominence were found to be negatively interrelated with root surface and linear area coverage while initial gingival margin thickness was found to be positively related with root surface and linear area coverage. The authors concluded the importance of negative and positive area-specific characteristics that may have efficacy in determining the RC.

Do J H (2019) [26] in his study described a minimally invasive surgical approach using the VISTA and the suture called the sub-periosteal sling (SPS) to secure the connective tissue graft (CTG) for periodontal surgery. The SPS suture involves and secure the CTG against the tooth, which reduces the risk of graft mobility. The author concluded that this technique appears to be more suitable and promising for the treatment of localized GR. Other studies on PRF were reviewed.[27-28]

Conclusion:

The combination of PRFM membrane will be effective in the treatment of GR. PRFM membrane will have significant clinical outcome as compared to GTR membrane group.

CONFLICT OF INTEREST: No

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