Palatal Wound Healing Evaluation After Application of Platelet Rich Fibrin Versus 0.2% Hyaluronic Acid Dressings (Randomized Controlled Clinical Trial)

Methodology

Date: 12/5/2020

Sample selection and assignment:

Thirty patients (16 females and 14 males) who were candidates for free gingival grafting surgery participated in this prospective clinical trial.

The subject were recruited consecutively from the outpatient clinic of Oral Medicine, Periodontology, oral Diagnosis and Radiology Department, Faculty of Dentistry, Ain Shams University .The purpose of the study was explained to all patients and an informed consent was signed before the conduction of the study. The proposal was presented to the faculty of Dentistry Ain Shams University Research Ethics committee and was approved before starting the research with number (566). Also the study was registered in clinical trial registration site (NCT).

Patient selection:

Inclusion Criteria:

- Patients who were indicated for soft tissue augmentation with free gingival graft for mucogingival surgery or for implant therapy.

- Age range (20-50) years.
- Good patient compliance with the plaque control instructions following initial therapy.

Exclusion criteria:

- Presence of systemic diseases which could influence the outcome of the therapy. (***American Society of Anesthesiologists I; ASA I***)
- Smoker patients.
- Pregnant and lactating females.
- Vulnerable group of patients (prisoners, handicapped, decisionally impaired individuals).

Grouping Criteria:

The study consisted of three groups; the number of patient in each group was determined by sample size calculation based upon the results of ***Yildirim et al. 2017***. Using alpha level of 0.05 (5%) and β level of 0.20 (20%) i.e. power = 80%; the estimated minimum required sample size was approximately 10 cases in each group. Patients were randomly selected using computer generated randomization (www.randomizer.org). Allocation concealment was achieved using a sealed coded opaque envelope containing treatment of the subject

Group I(10 patients):

Patients received platelet rich fibrin as a palatal dressing after free gingival graft harvesting.

Group II(10 patients):

Patients received hyaluronic acid* gel 3-4 times per day as a palatal dressing after free gingival graft harvesting.

Group III(10 patients) (Control group) :

Patients received gel foam as a palatal dressing after free gingival graft harvesting

*Gengiegel 0.2% oral gel 20ml Riceerfarma Milano Italy.

III- Assessments:

1-Clinical parameters:

- **Subjective assessment**

-Patients were asked to assess their pain sensation and bleeding at 1st, 3rd, 7th 14th, 21stand 30th days using the visual analogue scale (VAS). The visual analogue scale score by Price et al 1983 for pain ranged from 0 (no pain) to 10 (severe pain), while bleeding wasscored as 0(not present) and 1(present) (***Price et al.1983***).

- **Objective assessment**

-The Healing index scale by ***Landry et al.1988*** was used to assess the palatal wound healing, where in this index tissue color, response to palpation, presence of granulation tissue presence of suppuration and epithelization of the incision margin were recorded.

-The color of the palatal mucosa was assessed by comparing it to the adjacent and opposite side by taking pictures and using the image J program at 3rd,7th, 14th, 21st and30th days (***Pei-Nan et al.2012***).

- The thickness of the palatal mucosa was measured preoperative and 4 weeks postoperative by a graduated periodontal probe.

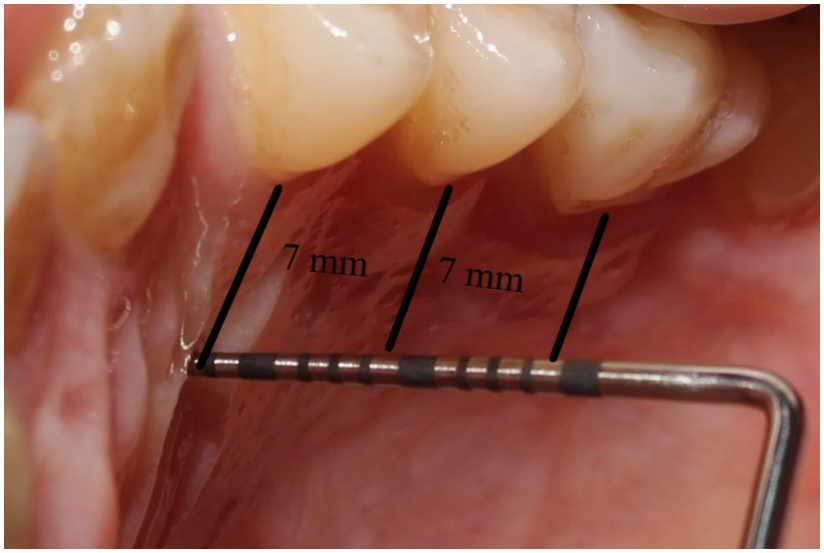

Fig (1): Palatal thickness measurements at 3 different points the middle of 1st, 2nd premolar and 1st molar 7mm from the gingival margin

IV-Surgical protocol:

A) Pre surgical procedures

Scaling and root planning was done; oral hygiene instructions was given to the patient to follow them.

B) Surgical procedures

Group 1:

1. Anesthesia (Articaine HCL 4% containing epinephrine at a concentration of 1:100,000)[†] was administrated at to the palate where a free gingival graft was harvested.
2. Just prior to surgery a 10 ml intravenous blood was obtained from the median antecubital vein of the patient in order to be divided into two 5 ml glass tubes[‡] without additives to be [§]centrifuged immediately at 2700 revolutions per minute for 12 minutes or in one 10 ml glass test tube without additives were centrifuged immediately at 3000 revolutions per minute for 10 minutes at room temperature.

[†] Artinibsa 4%cartouches de 1.8ml ,inibisa dental.
[‡] Dry Vacutube, Biocon®, Brazil
[§] PRF CENTRIFUGE (Duo machine), UNSPSC code 41100000 (Ostralos Ltd, New Zealand)

3. Coagulation started immediately and three parts quickly appear in the tube: a packed red blood cell at the bottom, acellular plasma at top and the PRF clot in between.
4. The PRF clot was removed from the tube using sterile tweezers, separating it from the RBC base by using a lancet. It was compressed between two sterile glass slabs and wrapped within sterile gauze moistened with saline.
5. The thickness of the palatal tissue was measured at three different points; each point was located at the middle of 1st, 2nd premolar and 1st molar 7mm from the gingival margin.
6. Free gingival graft was harvested from the palateand its thickness was measured.
7. The PRF membrane was placed as a palatal dressing and fixed in place by X suture using 5-0 polypropylen**.

** Assut Sutures, non Absorbabale (Polypropylene) 5-0 USP, braided violet coated 3/8 rev.cutt.17mm, AM trading, Swithezland

Group 2:

1. Anesthesia (Articaine HCL 4% containing epinephrine at a concentration of 1:100,000)[††] was administrated at to the palate where a free gingival graft was harvested.
2. The thickness of the palatal tissue was measured at three different points; each point was located at the middle of 1st, 2nd premolar and 1st molar 7mm from the gingival margin.
3. Free gingival graft was harvested from the palate and its thickness was measured.
4. Gel foam was cut according to the graft's dimensions to act as a carrier for the hyaluronic acid[‡‡]that was used as a palatal dressing.
5. Gel foam was fixed in place using X suture using [§§]5-0 polypropylene.

[††]Artinibsa 4%cartouches de 1.8ml ,inibisa dental.
[‡‡]Gengiegel 0.2% oral gel 20ml Riceerfarma Milano Italy.
[§§] Assut Sutures, non Absorbabale (Polypropylene) 5-0 USP, braided violet coated 3/8 rev.cutt.17mm, AM trading, Swithezland

Group 3:

1. Anesthesia (Articaine HCL 4% containing epinephrine at a concentration of 1:100,000)*** was administrated at to the palate where a free gingival graft washarvested.
2. The thickness of the palatal tissue was measured at three different points; each point was located at the middle of 1st, 2nd premolar and 1st molar 7mm from the gingival margin.
3. Free gingival graft was harvested from the palate and its thickness was measured.
4. Gel foam was cut according to the graft's dimensions and used as a palatal dressing.
5. Gel foam was fixed in place using X suture using 5-0 polypropylene†††.

*** Artinibsa 4%cartouches de 1.8ml ,inibisa dental.

††† Assut Sutures, non Absorbabale (Polypropylene) 5-0 USP, braided violet coated 3/8 rev.cutt.17mm, AM trading, Swithezland

V-Postoperative care:

- Oral hygiene instructions was given , antibiotic (Augmentin[‡‡‡] 1 gm every 12 hours, metronidazole[§§§] 500 mg every 12 hours) , anti-inflammatory and analgesics(Brufen[****] 400 every 12 hours) was prescribed for the patient and instructed to avoid brushing at the surgical site only rinsing with hot saline mouthwash.
- Patient was recalled for assessment and follow up, sutures was removed after 1 week.

[‡‡‡] Augmentin 1gm,Medical union pharmaceuticals(MUP) Egypt under license from ,Glaxosmithkline

[§§§] Flagyl 500 mg, sanafi Aventis Egypt under license of sanafi Aventis French

[****] Brufen 400mg, Al kahira pharm. and chem..Ind.Co. under license from abbott laboratories

VI-Postoperative evaluation and assessment:

- Patients were asked to assess their pain sensation and bleeding at 1st, 3rd, 7th 14th, 21st and 30th days using the visual analogue scale (VAS). The visual analogue scale score by Price et al 1983 for pain ranged from 0 (no pain) to 10 (sever pain), while bleeding was scored as 0(not present) and 1(present).
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- The thickness of the palatal mucosa was measured preoperative and 4 weeks postoperative by a graduated periodontal probe.

IV-Statistical analysis:

Categorical data were presented as frequencies and percentages and were analyzed using chi square test. Numerical data were tested for normality using Shapiro-Wilk test and were presented as mean and standard deviation values. Parametric data were analyzed using one-way ANOVA followed by Tukey's post hoc test for intergroup comparisons and one-way repeated measures ANOVA followed by Bonferroni post hoc test for intragroup comparisons. Non-parametric data were analyzed using Kruskal-wallis test followed by pairwise comparisons utilizing Mann Whitney U test with Bonferroni correction for intergroup comparisons and Friedman's test of repeated measures followed by multiple pairwise comparisons utilizing Wilcoxon signed-rank test with Bonferroni correction for intragroup comparisons. The significance level was set at $p \leq 0.05$ within all tests. Statistical analysis was performed with IBM® SPSS® Statistics Version 26 for Windows.

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