

Original Article

Clinical comparison of periodontal pack with and without L-PRF on post-operative pain after surgical gingival depigmentation: A Randomized Clinical Trial

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Abstract

Aim: The aim of the study was to evaluate the effect of platelet rich fibrin on post-operative pain after surgical depigmentation. **Methodology:** Twenty-four patients with gingival pigmentation were recruited and randomly assigned to control group; non-eugenol periodontal pack only, or to test group; L-PRF with periodontal pack. Gingival depigmentation was done using a combination of scalpel and bur techniques and both groups were covered using periodontal pack. Post-operative pain was measured using visual analogue scale (VAS) was tested and compared. **Results:** In the control group, 100% of the patients reported pain ranging from moderate to distressing pain after the 5th day while in the test group 8.3% reported very mild pain after the 5th day. **Conclusion:** Using PRF after gingival depigmentation results in decreased post-operative pain when compared to using periodontal packs alone.

I. INTRODUCTION:

An attractive smile begins with a healthy and highly aesthetic appearance of the gingiva. It greatly affects the confidence of an individual. A pigmented gingiva especially with a high smile line is not a medical condition but is not acceptable by modern beauty standards. The pigmentation of the gingiva could be physiological or pathological (Dummett and Barens, 1971).

Normal colour of the gingiva is mainly due to the melanin pigment produced by melanocytes present in the basal and supra-basal layer of the epithelium, excessive melanocytic activity leads to hyper pigmentation (Dummett, 1985). There are

multiple techniques for depigmentation including bur abrasion, surgical stripping and laser. The bur abrasion technique has drawbacks including post-operative pain, bleeding, placement of periodontal pack and exposure of the alveolar bone (Alasmari, 2018).

The periodontal pack protects the wound from mechanical injury, stability of the blood clot that promotes better wound healing, more patient comfort, prevents post-operative bleeding and infection (Harpenan, 2003). However, there is a debate with regards to its effect on wound healing as well as increased plaque accumulation (Kakar et al., 2018)

Platelet Rich Fibrin (PRF) was first used by Choukroun et al in 2001 in dentistry which is a new generation of platelet concentrates. PRF consists of an autologous leukocyte-platelet-rich fibrin matrix, composed of a tetra molecular structure, with cytokines, platelets and stem cells within it, which acts as a biodegradable scaffold that favours the development of micro vascularization and is able to guide epithelial cell migration to its surface (Dohan et al., 2006)

PRF has the property of acting as a scaffold to deliver cells crucial for regeneration along with constant release of growth factors that allows for accelerated wound healing. It has a strong fibrin matrix with good mechanical properties along with slow remodelling which is similar to a blood clot (Wu et al., 2012). Structural stability and ease of handling as well as its homogenous form are what makes it different from a blood clot (Simonpieri et al., 2012).

The study was designed to evaluate the effect of L-PRF in regards to post-operative pain following surgical gingival depigmentation procedure.

MATERIALS AND METHODS

Study design:

The study was done as a randomized controlled clinical trial, parallel, two arms, and superiority trial with 1:1 allocation ratio. The study was reviewed and approved by the Ethics Committee of Scientific Research - faculty of Dentistry – Cairo University code 4420.

Study outcomes:

Pain was recorded using visual analogue scale (VAS) measurement (Freyd, 1923). The participants were instructed to record their pain on a scale of 0-10 with 0 being no pain and 10 being unbearable pain at 1,3 and 5 days post-operative. The questionnaire was collected from the patients on the fifth day post-operatively.

Study settings:

The study recruitment was from the outpatient dental clinics of the Oral medicine and Periodontology department in the Faculty of Dentistry of Cairo University and the Oral medicine and Periodontology department in the Faculty of Dentistry of MSA University. The surgical procedures were done in the postgraduate periodontology clinics in Faculty of Dentistry of Cairo University and periodontology clinics in Faculty of Dentistry of MSA University.

Study eligibility criteria:

Inclusion criteria:

- Ages 18-40 years old
- Systemically healthy
- Mild to moderate gingival pigmentations
- Gingival and plaque index <1
- Good oral hygiene
- Thick gingival biotypes
- Keratinized gingiva >2mm

Exclusion criteria:

- Smokers
 - Taking any medications that could affect healing
 - Previous depigmentation procedures
 - Pregnant or lactating females
 - Previous periodontal surgery within 6 months before the start of the trial
- Sample size:

Based on the study of Chhina et al. in 2019, the VAS was checked at 1st, and 7th day postoperatively. On the 1st day, 2.5 ± 0.515 of patients reported pain and 0.7 was the clinical most important difference based on expert opinion (Chhina et al., 2019), Using power 80% and p value: 0.05 as significance level, the number of patients that were enrolled to the study were 10 in each group with 20% more allocated to overcome dropouts, accordingly the number was 12 in each group with 24 patients in the study. Sample size calculation was achieved using Independent T test.

Randomization and allocation concealment:

The randomization was done using computer generated randomization (random.org) used for the patient's division into two groups from 1 to 12 randomly and equally assigned to both groups. Patients were sequentially numbered and a central telephone was used to inform the operator of the allocation of the patients to either group after re-evaluation post non-surgical periodontal therapy was performed and signed written consent was obtained. Due to the nature of the procedure only the statistician was blinded.

Pre surgical protocol

After taking a thorough medical and dental history as well as clinical examination from all the potential study subjects to confirm their eligibility to enter the study, the eligible patients were sat down to an interview to explain the procedure and its objectives, the follow-up periods, post-operative complications and its treatment. All eligible patients received non-surgical periodontal therapy (supra and subgingival scaling) followed by adequate oral hygiene measures and then re-evaluated after 6 weeks for their compliance and oral hygiene status.

Surgical protocol:

Depigmentation procedure:

The area of melanin hyperpigmentation (area of interest) was marked using a surgical marker. The perioral skin was disinfected using Iodopovidone 10% and the participants were asked to rinse with chlorhexidine gluconate mouthwash 0.12% for one minute. Local infiltration was done using local anaesthetic solution.

Surgical de-epithelization of the gingiva was performed using diamond flame/football stones with feather-like brushing strokes under copious irrigation. The procedure was carried out until the underlying soft connective tissue is exposed. The bur abrasion

was done sparing the gingival margins, interdental papilla and any deep areas of pigmentation which were depigmented using a surgical blade no.15 in strokes in one direction till all the visible pigmentations were removed. Then, the area was mopped with a wet gauze to stop the bleeding. Once the bleeding has stopped, the periodontal pack was applied. Standard skin preparation was carried out by 10% Iodopovidone 10% solution.

Intervention for Control group (Group A):

Non-eugenol periodontal pack was immediately placed after surgical depigmentation. Equal lengths of the paste and catalyst were pressed out of the two tubes and were quickly mixed together with tongue blade until blended. The tongue blade was used to pick up the paste and place in water for 1 minute. The paste was picked up with wet gloves. One U-Strip was placed starting from the most distal extension of one side extending to the other side applied on the facial surface of the wound and the teeth. Pressing labially and interproximal with the hands was done to adapt the dressing around the gingival surface and interproximal areas to gain retention and create festooning.

Intervention for test group (Group B):

Before the administration of anaesthesia two test tubes of 5 ml blood samples were withdrawn from the patient. The tubes were placed in a centrifuge machine and were balanced with two test tubes containing water. The centrifuge machine was set at 2800 rpm for 12 minutes. The prepared PRF was picked up using long and slender tissue forceps then the upper most layer/part containing acellular plasma and bottom layer containing the red thrombus (fraction of red blood cells) was cut off by scissors and discarded leaving the middle layer which is the L-PRF. The gel was compressed between two saline-soaked sterile gauze pieces to obtain PRF membrane. The membrane was then adapted on the surgical site and the excess was trimmed off. The PRF was

stabilized in place by crisscross sutures using 5-0 resorbable vicryl sutures. Then the periodontal pack dressing was placed in the same manner as the control group.

Post-surgical protocol:

Immediate post-operative instructions:

Immediately post-operative, Paracetamol 500 mg was prescribed to the patients as an analgesic. The patients were also instructed to avoid consuming any hot food or drink the day of the surgery and not to bite any food but cut it to small pieces by hand to avoid dislodgment of the periodontal dressing material or any irritation to the surgical area. They were also instructed to abstain from brushing their upper arch for the first three days to avoid dislodgment of the periodontal pack till the fifth day post-operatively to avoid any trauma to the surgical site. Chlorhexidine 0.12% mouthwash was prescribed twice daily for 5 days to compensate for the lack of tooth brushing during that period.

Recall appointments (T1, T2, T3 and T4):

T1: On the 1st day post-operative, the patients were contacted via telephone call and asked to rate their pain and to fill a VAS pain score chart (Freyd, 1923) that was given to them.

T2: On the 3rd day post-operative, the patients were recalled to the clinic to remove the periodontal pack and the sutures. They were also asked to rate the pain on the VAS chart (Freyd, 1923).

T3: On the 5th day post-operative, the patients were recalled to the dental clinic to record their pain on a VAS chart healing index score

Data analysis and statistical method:

Data presented as mean, standard deviation (SD) and 95% confidence interval. Data explored for normality using Shapiro-Wilk test. Age data showed normal distribution while all other data showed a non-normal distribution. Independent t-test used to compare between tested groups for mean age. Mann

Whitney test used to compare between the tested groups. Friedmann test was used for comparison between tested periods for each group followed by multiple comparison with Dunn Bonferroni. The significance level was set at $p < 0.05$. Statistical analysis was performed with IBM® SPSS®.

III. RESULTS

Study patients:

All the demographic data including the gender, age, medical history, marital status and occupation are shown in table (1). Twenty-four medically free patients were enrolled and electronically randomized and allocated to either group. 12 patients were assigned to the control group and 12 in the intervention group. The mean age of the patients was 22.5 ± 4.46 years in the control group and 21.92 ± 3.03 in the intervention group with no statistical significance between them. There were no dropouts and the data of all patients were evaluated in the statistical analysis

Pain (VAS):

The pain score evaluation was done using VAS during the 1st, 3rd and 5th days post-operatively. The pain score showed statistical significance between the two groups with the control group exhibiting higher pain levels during all 5 days especially during the first day post-operatively.

Control group: the pain score was reported to be the worst (distressing pain, Score 5-6) on the first day by 7 patients and moderate pain (Score 2-4) by 5 patients. The pain showed slight decrease in intensity on the 3rd and 5th days (score 2-4) by 10 patients but remained consistent at distressing for the entire duration for 2 patients.

Intervention group: on the first day only 4 patients reported very mild pain (Score 1-2) which decreased to only one patient reporting pain (score 1) during the 3rd and 5th days.



Figure (1): pre-operative clinical pictures of the patient with the extension of the gingival pigmentation on the attached gingiva from the pre-molar region of the right side to the pre-molar region of the left side



Figure (2): pre-operative pictures with cheek retractors. The pictures show the extension of the gingival pigmentations including both the attached gingiva and the alveolar mucosa. (a): showing pigmentation extension from a frontal view (b) &(c): showing the proximal extension of the pigmented area



Figure (3): (a): surgical depigmentation using a diamond/football shaped diamond stone. (b): de-epithelized gingiva of the upper right side. (c): de-epithelized gingiva of upper arch.



Figure (4): (a): the periodontal pack used. (b): final position of the periodontal pack

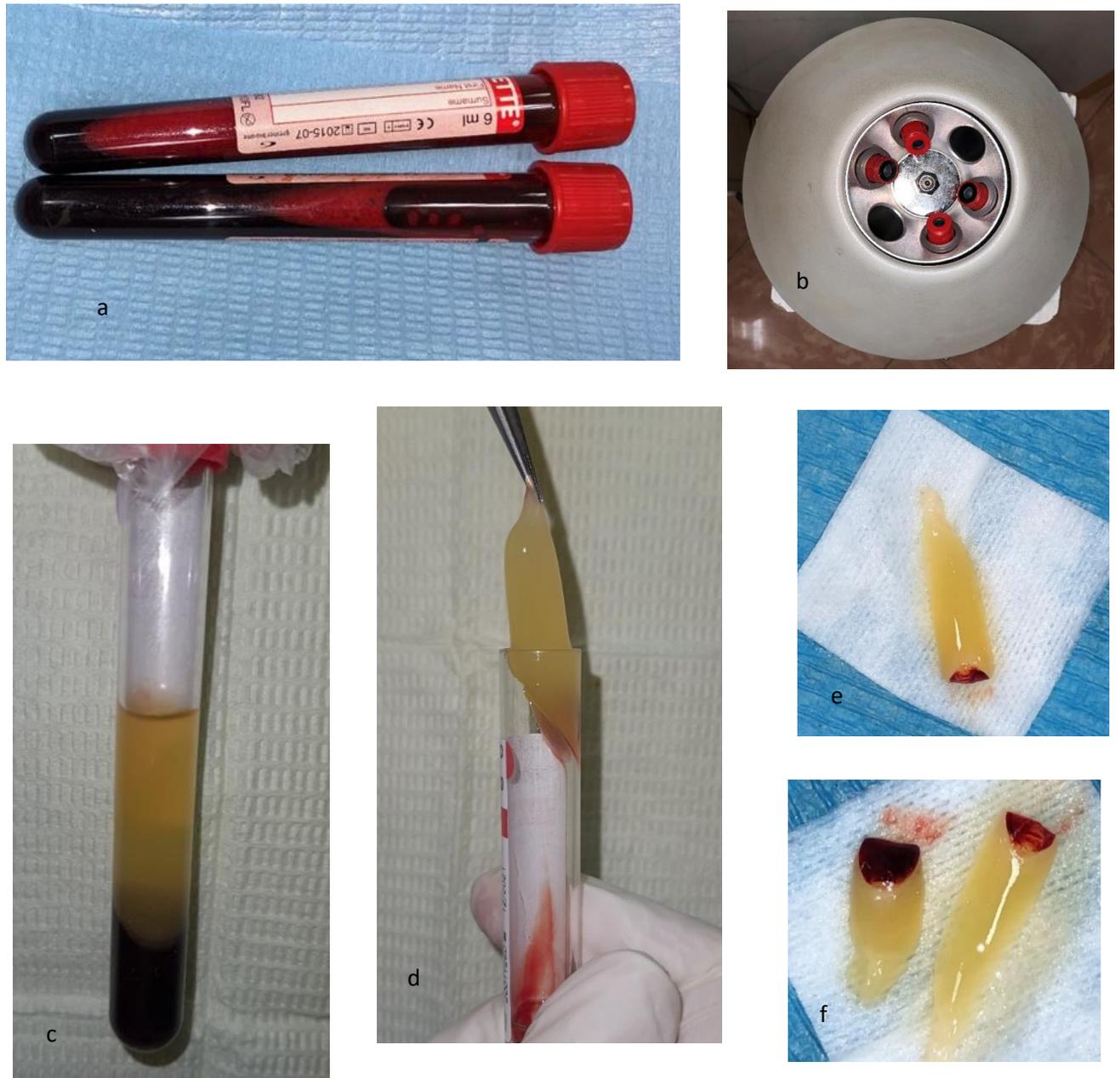


Figure (5): (a): the collected blood samples. (b): the placement of the test tubes in the centrifuge. (c): the tube after centrifuging with 3 layers of PRF. (d): the final Platelet Rich Fibrin clot. (e) & (f): PRF clot before pressing them between 2 sterile gauze pieces to create a PRF membrane.



a



b

Figure (6): (a): placement and adaptation of the PRF membrane using crisscross sutures. (b): final placement of the periodontal pack over the PRF

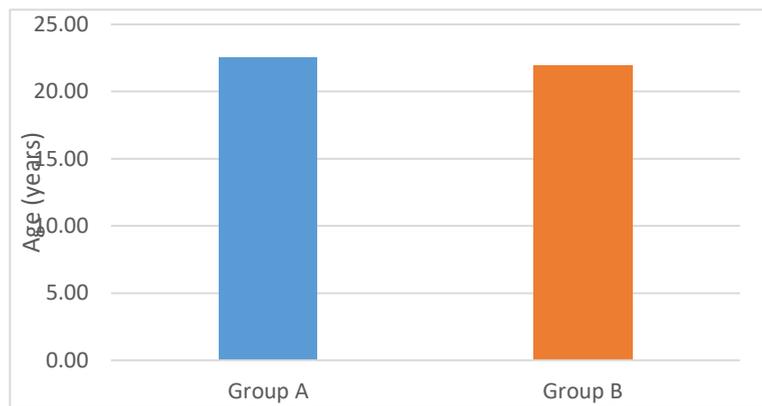
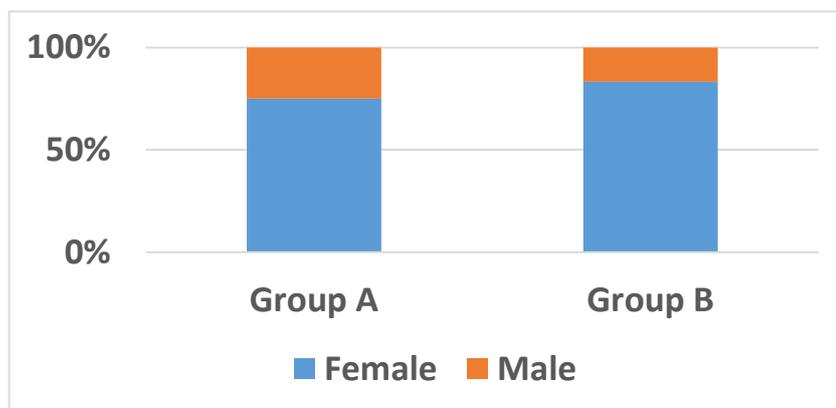


Figure (7): a: clinical picture of control group 3 days post-operative showing incomplete healing and bleeding from the surgical site. b: clinical picture of test group 3 days postoperative showing partial wound healing in the surgical site with minimal bleeding. c: Clinical picture of control group 5 days postoperative showing partial wound healing with areas of bleeding. d: clinical picture of test group 5 days postoperative showing wound healing with no bleeding sites.

Table 1: Demographic data of the patients

		Group A (Control)	Group B (Intervention)	p-value
Age [Mean (SD)]		22.5(4.46)	21.92(3.03)	0.712 NS
Gender [N (%)]	Female	9(75)	10(83.3)	0.615 NS
	Male	3(25)	2(16.7)	

NS=non-significant

**Figure (8):** Bar chart showing mean age for tested groups.**Figure (9):** Stacked bar chart showing gender distribution for tested groups.**Table 2 :** Mean, standard deviation (SD), 95% CI (confidence interval), of VAS score for different tested groups.

	Group A (Control)				Group B (Intervention)				p-value
	Mean	SD	Lower 95% CI	Upper 95% CI	Mean	SD	Lower 95% CI	Upper 95% CI	
VAS Day 1	4.3	1.2	3.6	5.1	0.4	0.7	-0.0	0.8	<0.001*

Day 3	3.6	1.2	2.8	4.4	0.1	0.3	-0.1	0.3	<0.001*
Day 5	3.3	1.2	2.5	4.0	0.1	0.3	-0.1	0.3	<0.001*
p-vale	0.001*				0.018*				

*=Significant

Different superscript letter within each column indicates significant difference at $p < 0.05$ (Adjusted Dunn Bonferroni)

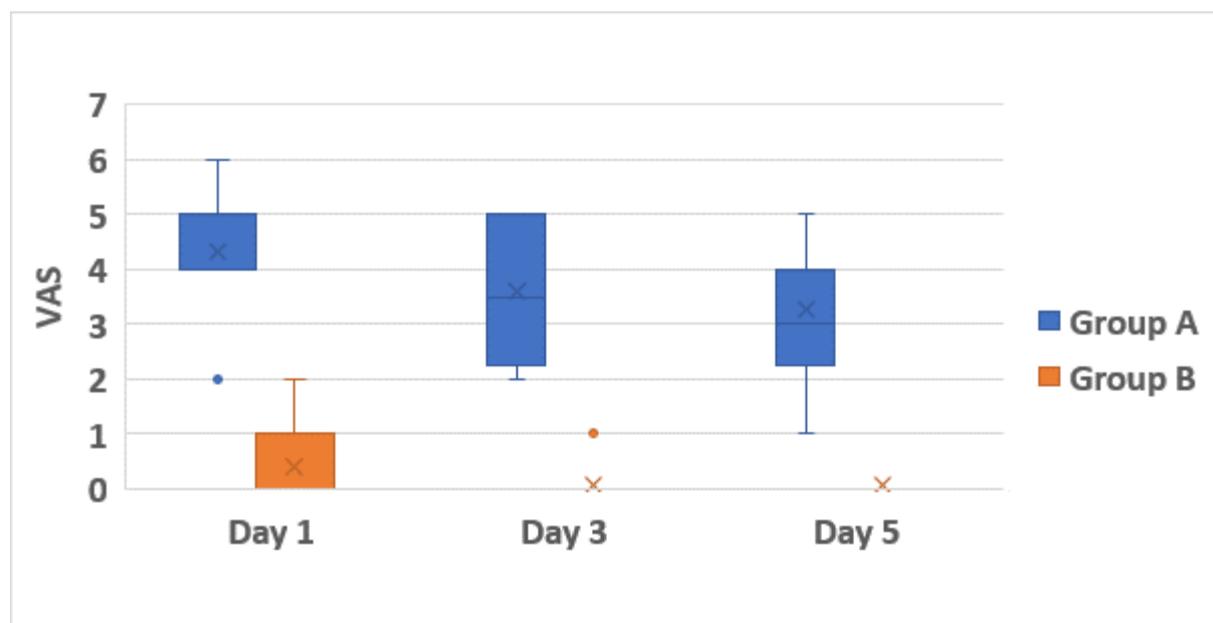


Figure (10): Box plot showing VAS data for tested groups.

IV. DISCUSSION:

Aesthetics have become an integral part of dentistry nowadays with a remarkable increase in the demand for aesthetics procedures. Dentists are now required to achieve and maintain pristine aesthetics as well as addressing the biological and functional aspects in every procedure performed (Humagain, Nayak and Uppoor, 2009).

Melanin, the most common endogenous pigment, is the main cause for physiological gingival pigmentation. This condition is attributed to an increased deposition of melanin granules in the supra-basal and basal cell layers of the gingival epithelium. With regards to gingival pigmentation, it is presented as a diffuse light brown to black discoloured patches or strands involving the gingival

margin and/or attached gingiva and may even extend to the alveolar mucosa (Nagati *et al.*, 2017). Even though pigmentation of the gingiva is not considered as a medical condition but when coupled with a gummy smile or high smile line it represents an aesthetically non-acceptable condition by many people (Murthy, Kaur and Das, 2012).

The combined use of bur abrasion and scalpel techniques was chosen in the current study due to the numerous advantages of both techniques which include: the ease of execution, no need for special equipment, time efficient, fast wound healing, low recurrence rates and economic compared to other techniques. However, both of these methods have drawbacks like increased post-operative pain and bleeding as well as needing the use of

periodontal pack post-operatively (Suchetha *et al.*, 2018; Gul *et al.*, 2019).

After gingival depigmentation procedures; an exposed connective tissue wound is created. To cover this wound with a periodontal dressing or not is an ongoing debate. The use of non-eugenol periodontal pack was the material of choices and its efficacy was supported by multiple studies proving that it is one of the most biocompatible dressings that has adequate mechanical, physical and therapeutic properties (Kathariya, Jain and Jadhav, 2015; Bezawada *et al.*, 2020; Baghani and Kadkhodazadeh, 2013). The periodontal dressing was removed after 5 days post-operative to avoid delayed healing and increased infection rates due to plaque accumulation around the dressing which are associated by leaving it for long periods of time (Kathariya, Jain and Jadhav, 2015).

For the test group, Leukocyte rich platelet rich fibrin (L-PRF) showed superior results to the control group with a statistical significant difference in VAS scores.

The pain scores were reported on the 1st day by 33.3% of patients in the test group with mild pain (scores 1-2) while 100% of the control group reported moderate to distressing pain (scores 2-6). On the 3rd and 5th days all patients in the test group were pain free except one

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which reported mild pain (score 1), while 100% of the patients in the control still reported moderate to distressing pain. These results are similar to the results in 2019 by Dahiya and co-workers who reported 41.7% patients described moderate pain in PRF group on the 3rd day post-operative whereas in non-eugenol periodontal dressing group 83.3% patients complained of severe pain. On the 5th day, 100% patients in PRF group reported no pain, while moderate pain was seen in all 100% patients in non-eugenol periodontal dressing group. This could be attributed to the high concentrations of the growth factors delivered by the PRF that allows for faster wound healing, maturation and sealing (Bansal *et al.*, 2016; Debnath and Chatterjee, 2018; Dahiya *et al.*, 2019).

V. Conclusion:

Within the limitations of this study, we could conclude the following:

- Using PRF after surgical depigmentation has resulted in significant decrease in postoperative pain when compared to using periodontal pack alone.

VI. Recommendations:

Similar RCT studies should be done but with a larger sample size.

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