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Research Article

COMPARISON OF THE EFFICACY OF INJECTABLE PLATELET RICH FIBRIN (I-PRF) AS AN ADJUNCT TO COE-PAK™ WITH COE-PAK™ ALONE ON WOUND HEALING AFTER OPEN FLAP DEBRIDEMENT IN THE TREATMENT OF STAGE III GRADE B PERIODONTITIS: A RANDOMIZED CONTROLLED TRIAL

Nawamee Phadnis, Amit Benjamin, Kahkashan Kadri and Pankti Gangar

Department of Periodontology, YMT Dental College and Hospital, Navi Mumbai

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ABSTRACT

Introduction: Recently introduced platelet concentrate, injectable platelet rich fibrin (i-PRF) has been shown to possess healing and antimicrobial properties. Coe-pak™, is a non-eugenol periodontal dressing which has been routinely used post periodontal surgeries but is devoid of any healing properties. Hence this was carried out to evaluate the efficacy of i-PRF after open flap debridement.

Objective: To compare the efficacy of i-PRF as an adjunct to Coe-pak™ with Coe-pak™ alone on wound healing after open flap debridement in periodontitis patients.

Methodology: 22 patients within the age range of 35-65 years, diagnosed with Stage III Grade B periodontitis after open flap debridement were subjected to receive either placement of Coe-pak™ alone (Group B) or i-PRF followed by Coe-pak™ (Group A). The clinical parameters assessed were Wound healing Index, Pocket probing depth and Plaque Index at baseline, 1 week and 4 weeks.

Result: On intergroup comparison, Group A showed enhanced wound healing, lower PI score and lower PPD reduction compared to group B with statistical insignificance ($p>0.05$).

Conclusion: Based on the results of the current study, it can be concluded that i-PRF has no influence on the wound healing, pocket probing depth and plaque index in a period of 4 weeks.

INTRODUCTION

Periodontitis is a multifactorial disease associated with the loss of supporting tissues around the tooth.[1] Surgical procedures used in the treatment of periodontal diseases involve surgical manipulation of the oral mucosa and the tooth supporting structures to eliminate the soft and hard tissue defects resulting from the disease process to create an environment favorable for effective plaque control.[2]

Wound healing following a flap surgery is a complex process since the mucoperiosteal flap is placed against the instrumented root surface which is avascular and devoid of its attachment apparatus. During healing, normal tissue turnover is maintained by a delicate balance of the growth factors and cytokines as they have a dual function of inflammation and tissue repair.[3] Evidence has shown presence of both growth factors and cytokines in PRF.[4] Platelet concentrates such as platelet rich plasma (PRP) and platelet rich fibrin (PRF) have been used extensively in the field of medicine, oral and maxillofacial surgery owing to its regenerative potential.[5,6] PRF described by Choukron is a second-generation platelet concentrate, containing platelets, various growth factors and cytokines in the form of fibrin membrane. [7]

Recently introduced 'injectable PRF (i-PRF)' which can be considered as a blood concentrate and not just a platelet concentrate was developed to deliver clinicians a platelet concentration in a liquid formulation with simple preparation and without biochemical handling. is considered as a blood concentrate and not just a platelet concentrate.[8,9,10] PRF helps in the healing process by actively participating in the angiogenesis process, guiding the migration of the epithelial cells to its surface helping in wound coverage, microbial inhibition and acting as an immune node by stimulating the defense mechanisms through secretion of various cytokines.[11,12,13,14] The regenerative potential of PRF has been studied to assess soft tissue wound healing ,in procedures such as management of furcation defects , root surface biomodification, and also as a wound dressing.[15,16,17,18]

Corresponding author:* **Nawamee Phadnis
Department of Periodontology, YMT Dental College and Hospital, Navi Mumbai

Periodontal dressing was first introduced by Dr. A.W Ward in 1923, who advocated the use of it following periodontal surgery.[19] Coe-Pak™ is one of the most extensively used noneugenol periodontal dressings today and can be considered as a standard to which other dressings can be compared with. It adapts closely to the teeth preventing the formation of dead space between the periodontal flap and the root surface which is one of the basic requisites of wound healing. Despite these advantages, Coe-Pak™ like other periodontal dressings does not have any wound healing properties to aid and augment the surgical wound.[20,21]

Considering the enhanced wound healing properties of i-PRF and its potential to aid in wound healing, the present study is being carried out to evaluate the efficacy of i-PRF as an adjunct to Coe-Pak™ as a periodontal dressing after open flap debridement in the treatment of Stage III Grade B Periodontitis compared to Coe-Pak™ alone as a periodontal dressing.

METHODS

In this split-mouth randomized controlled, blinded clinical trial, 22 systemically healthy patients within the age range of 35-65 years diagnosed with Stage III Grade B periodontitis (AAP 2017) were recruited from the Out Patient Department of Periodontology of a recognized dental college from June 2019 to May 2020. The study was carried out after the ethical approval from the ethical committee and review board of the institute and obtaining patients written informed consent.

Inclusion criteria: 1) Horizontal bone loss; 2) probing pocket depth of ≥5mm and ≤7mm in 4 or more sites post phase I therapy.

Exclusion criteria:1) Subjects with history of antibiotic and/or anti-inflammatory drugs within previous 3 months; 2) history of any periodontal therapy in the past 6 months; 3) systemic conditions modifying the inflammatory response; 4) smokers & tobacco chewers; 5) pregnancy or lactation

Subjects were withdrawn from the study if they failed to follow the study parameters or report for re-evaluation. Compensation for the attrition of subjects was managed by recruitment of fresh subjects.

Methods of measurements

Clinical parameters recorded were wound healing [Wound Healing Index (Lien- Hui Huang, 2005) (WHI)], Plaque index (Loe H, 1967) and Pocket Probing Depth (PPD). The measurements were carried out using a UNC-15 periodontal probe and customized acrylic stents with grooves as reference points.[22,23] The subjects were motivated, given oral hygiene instructions and then subjected to phase- I therapy in which a full-mouth scaling and root planing procedure was performed. Four weeks post phase-I therapy, a periodontal re-evaluation for PPD and Plaque Index was performed and the patients with residual pockets of ≥5mm and ≤7mm, present bilaterally were subjected to open flap debridement. It was a single blinded study with randomization being carried out using a computer-generated randomization table. Allocation of subjects into two groups either to receive Coe-Pak™ alone (Group A) or i-PRF followed by placement of Coe-Pak™ post flap surgery (Group B) was done by a third person.

Surgical procedure

Perioral scrubbing using iodine solution and presurgical rinsing with 0.12% chlorhexidine digluconate was carried out. Following administration of local anesthesia, at the selected surgical area, a horizontal incision was placed and a mucoperiosteal flap was raised. Thorough debridement of the area was carried out with the help of Gracey Curettes and ultrasonic instruments followed by approximation of the flaps using black braided silk sutures. i-PRF was prepared following the protocol developed by Choukroun et al. Just before the suturing, intravenous blood was collected from the antecubital vein and immediately centrifuged at 700 rpm for 3 minutes. The upper liquid layer was collected as i-PRF in a syringe and was dispensed along the incision lines before flap approximation in Group A. A periodontal dressing, Coe-Pak™ was adapted over the surgical area in both the groups.

1. Measurements with acrylic stent

2. Administration of local anesthesia

3.Placement of incision

4. Reflection of mucoperiosteal flap

5. i-PRF dispensed at the incision lines and flaps sutured

6. Coe-Pak™ periodontal dressing placed over the operated area

7. Wound Healing at 1 week

8. Wound Healing at 4 weeks

Figure 1 Surgical protocol for Group A

1. Measurements with acrylic stent

2. Administration of local anesthesia

3.Placement of incision

4. Reflection of mucoperiosteal flap

5. Suturing of the flaps

6.Coe-Pak™ periodontal dressing placed over the operated area

7.Wound Healing at 1 week

8. Wound Healing at 4 weeks

Figure 2 Surgical protocol for Group B

Post-operative instructions

Antibiotics and analgesics (500 mg amoxicillin and 400 mg ibuprofen, three times per day for 5 days) were prescribed along with 0.12% chlorhexidine digluconate rinses twice daily for 2 weeks. Each patient was reinforced for proper oral hygiene maintenance at 1 week and 4 weeks post-surgery. All the subjects were asked to report after 1 week for removal of the periodontal dressing and sutures and at 4 weeks for the recording the clinical parameters postoperatively.

Statistical Analyses

Sample size of 22 sites per group was determined using the mean and standard deviation values from literature keeping the power of the study as 80%, α error to be 5% and β error to be 20%. The data obtained was compiled on a MS Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond, Washington, United States) and subjected to statistical analysis using Statistical package for social sciences (SPSS v 26.0, IBM). Descriptive statistics were expressed as Mean & SD for numerical data. Normality of numerical data was checked using Shapiro-Wilk test & it was found that the data for Plaque Index, Pocket Probing Depth followed a normal curve; hence parametric tests were used for comparisons. Inter group comparison (2 groups) was done using t test. The data for Wound Healing Index did not follow a normal curve; hence non-parametric tests were used for comparisons. Inter group comparison (2 groups) was done using Mann Whitney U test. For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus power of study being 80%.

RESULTS

Twenty-two patients, 11 males and 11 females aged 35-65 years (mean 42.73) had enrolled in the study. All the procedures were carried according to the clinical protocol with uneventful healing and no intra-operative or post-operative complications seen in both the groups. Complete wound closure was observed at 4 weeks. All the patients completed the study with a 4-week follow-up with no dropouts.

Wound Healing Index

On intergroup comparison, the WHI score at 1 week and 4weeks was greater in Group B than Group A with statistically non-significant difference between the groups ($p>0.05$). (Table-1)

Table 1 Intergroup Comparison of Wound Healing Index between Group A and Group B

	Group	Mean	Std. Deviation	Median	Mann-Whitney U value	Z value	p value
1 Week	A	1.27	.456	1	220.00	-0.640	0.522#
	B	1.36	.492	1			
4 Weeks	A	1.00	.000	1	231.00	-1.000	0.317#
	B	1.05	.213	1			

= non-significant difference ($p>0.05$)

The reduction seen in the Wound Healing Index scores at from 1 week to 4 weeks in Group A (0.27) was lower as compared to Group B (0.31). The difference (0.05) seen between both the groups was statistically insignificant. (Table-2, Graph-1)

Table 2 Inter group comparison of differences in Wound Healing Index

	Group	Mean	Std. Deviation	Std. Error Mean	T value	p value
1 week-4 weeks difference	A	.27	.456	.097	-.323	.748#
	B	.32	.477	.102		

= non-significant difference ($p>0.05$)

Plaque Index

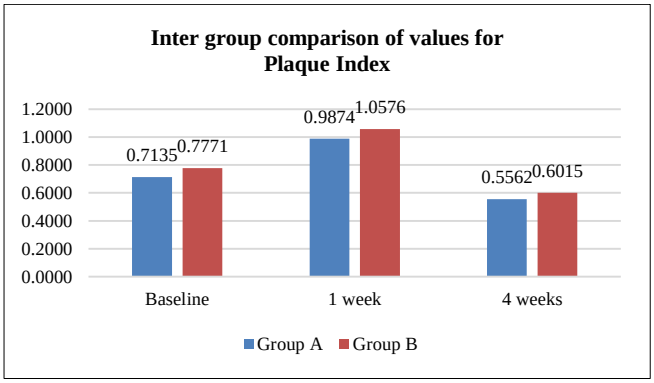
The PI scores between Group A and Group B at baseline, 1 week and 4 weeks were statistically non-significant ($p>0.05$)

(Table-3, Graph-2)

Table 3 Intergroup Comparison of Plaque Index in Group A and Group B

	Group	Mean	Std. Deviation	Std. Error Mean	T value	p value
Baseline	A	.71353	.279823	.059658	-.807	.424#
	B	.77706	.240934	.051367		
1 week	A	.98739	.221209	.047162	-1.078	.287#
	B	1.05758	.210418	.044861		
4 weeks	A	.55617	.284388	.060632	-.549	.586#
	B	.60152	.263343	.056145		

= non-significant difference (p>0.05)



Graph 2 Inter group comparison of values for Plaque Index.

The increase in plaque index scores from baseline to 1 week in group B (0.295671) was greater than group A (0.273864); the decrease in plaque index scores from 1 week to 4 weeks was greater in group B (0.471212) than group A (0.431224) and the decrease in the plaque index scores from baseline to 4 weeks was greater in group A (0.239179) was greater than group B (0.193723).

(Table-4, Graph-3)

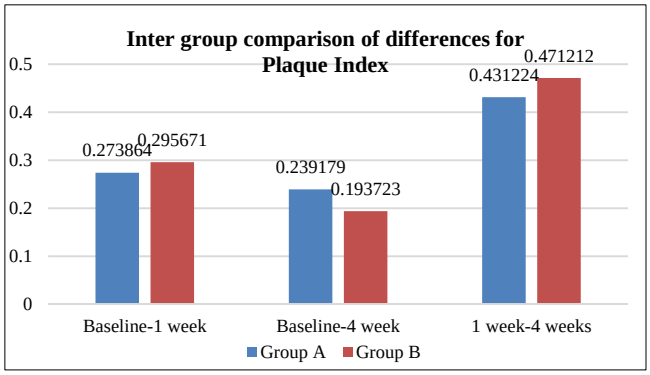
Table 4 Inter group comparison of differences in Plaque Index between Group A and Group B

	Group	Mean	Std. Deviation	Std. Error Mean	T value	p value
Baseline-1 week	A	.273864	.1843020	.0392933	-.381	.705#
	B	.295671	.1955333	.0416878		
Baseline- 4 weeks	A	.239179	.1700523	.0362553	.797	.430#
	B	.193723	.2064994	.0440258		
	Group	Mean	Std. Deviation	Std. Error Mean	T value	p value of t test
1 week – 4 weeks	A	.431224	.2396168	.0510865	-.568	.573#
	B	.471212	.2275605	.0485161		

= non-significant difference (p>0.05)

The differences seen for the values between group A and group B were statistically non-significant at between baseline, 1 week and 4 weeks (p>0.05)

(Table-4, Graph-3)



Graph 3 Inter group comparison of differences for Plaque Index

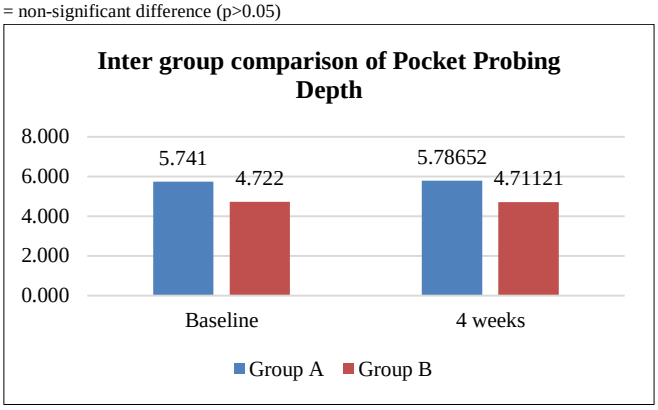
Pocket Probing Depth

On Intergroup comparison, at baseline the PPD in Group A was 5.74089 mm and Group B was 5.78652mm and at 4 weeks in Group A was 4.72194 and Group B was 4.71121. The PPD values between Group A and Group B at baseline and 4weeks were statistically non-significant (p>0.05) (Table-4, Graph 4)

Table 5 Intergroup Comparison of Pocket Probing Depth in Group A and Group B

	Group	Mean	Std. Deviation	Std. Error Mean	T value	p value
PPD baseline	A	5.74089	.215603	.045967	-.766	.448#
	B	5.78652	.177653	.037876		
PPD 4 weeks	A	4.72194	.194729	.041516	.200	.842#
	B	4.71121	.158735	.033842		

= non-significant difference (p>0.05)



Graph 4 Inter group comparison of Pocket Probing Depth

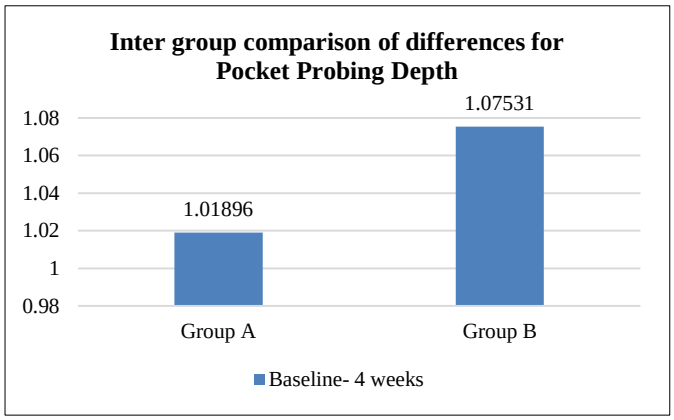
The reduction seen in the Pocket Probing Depth at from baseline to 4 weeks in Group A (1.01896 mm) was lower as compared to Group B (1.07531). The difference seen between both the groups at 4 weeks was statistically insignificant (p>0.05).

(Table-6, Graph-5)

Table 6 Inter group comparison of differences for Pocket Probing Depth

	Group	Mean	Std. Deviation	Std. Error Mean	T value	p value
PPD Baseline-4 weeks difference	A	1.01896	.269275	.057410	-.779	.440#
	B	1.07531	.206363	.043997		

= non-significant difference (p>0.05)



Graph 5 Inter group comparison of differences for Pocket Probing Depth

DISCUSSION

Periodontal dressings have been routinely used since its introduction in 1923 by Dr Ward to protect and stabilize the wound. Recently the application of periodontal dressings has been debated upon and its influence on the wound healing has been questioned.[24] Various studies have demonstrated that placement of periodontal dressings resulted in more plaque accumulation and increased inflammation immediately post-surgery compared to the sites with no dressing which might in turn delay wound healing. [25] Coe-Pak™ though widely used and being relatively free of cytotoxicity lacks inherent healing properties, hence the present study evaluates the clinical efficacy of i-PRF in wound healing as an adjunct to Coe-Pak™ as a periodontal dressing. In this study i-PRF was employed as it could be dispensed easily being in liquid form and due to the presence of increased concentration of growth factors necessary for wound healing. A split mouth design was adopted to reduce confounding factors such as age, genetics, environmental factors etc. that influence the wound healing.

i-PRF is a recently introduced platelet concentrate, based on the concept of lower centrifugation speed with simple preparation and easy handling. There is evidence showing presence of higher number of platelets, leukocytes, monocytes, and granulocytes in i-PRF compared to other platelet concentrates such as PRP or PRGF.[10] i-PRF has demonstrated increased as well as slow and sustained release of growth factors such as PDGF-AA, PDGF-AB, EGF, and IGF-1; induction of higher cell migration and mRNA expression of TGF-β, PDGF, and type I collagen which further enhance its regenerative properties.[26]

Coe-Pak™ possesses neither anti-inflammatory nor antibacterial properties[27]. The increased inflammatory reactions after its placement post-surgery could possibly impair the healing process.[28,29] i-PRF has shown to possess anti-inflammatory effects,[30] antimicrobial potential against various periodontal pathogens and ability to potentiate the immune mechanisms through secretion of various cytokines by the platelets and leukocytes, thus contributing to the improved wound healing.[31] Although periodontal dressings do not directly aid in wound healing they create an environment that helps in the process of healing by stabilizing the blood clot which is one of the primary requisites of healing.[32] An impairment in the adhesion of the blood clot to the root may weaken the tensile strength of the wound during early healing making the tooth-mucosal interface more susceptible to tear.[33] The presence of Coe-Pak™ helps in stabilization and retention of blood clot incorporated with the i-PRF in the initial stages of healing. The well adapted dressing also prevents the seepage of the i-PRF out of the surgical site and the bacterial ingress beneath it thus enhancing the wound healing process. i-PRF contains fibronectin, an adhesive glycoprotein that has shown improved cellular proliferation from the periodontal ligament towards the supracrestal parts and has demonstrated positive effects on root coverage when used as a root surface biomodification agent in periodontal surgery.[17,34]

In the present study, there was improvement seen in the wound healing in both the groups at 4 weeks as compared to the first week post-surgery. The gingiva appeared erythematous after removal of the Coe-Pak™ in some cases at 1 week but regained its original color at 4 weeks. Wound healing was better in Group A at both the time intervals with statistical non-significance ($p>0.05$) (Table-1). This improvement can be attributed to the presence glycoproteins, elevated concentration of various growth factors and cytokines promoting neo angiogenesis and epithelialization further enhancing the healing.[14] The improvement seen from 1 week to 4 weeks is greater in Group B with statistical insignificance ($p>0.05$) (Table 2. Graph-1) which could be attributed to the physical properties of the Coe Pak only. These results are similar to studies in which accelerated wound healing was observed over a period of 4 weeks in sites treated with PRF.[18,35] In a study by Patel GK *et al* 2017, similar improvements were seen in the wound healing using PRF for management of intrabony defects after OFD in which 100% of the test sites and 38% of the control sites showed a WHI score of 1 at 1 week.[36] When i-PRF was compared to Autologous Fibrin Glue (AFG) for palatal wound healing, AFG showed better wound healing than i-PRF which is in contrast to the present study.[37]

Oral hygiene maintenance and elimination of residual infection is strongly associated with healing of conventional periodontal surgical procedures.[38] There was an increase in the plaque index score in the first week post-surgery in both groups which can be attributed to the increased plaque accumulation beneath the periodontal dressings and the patient's inability to maintain the oral hygiene post-surgery.

There was a decrease seen in the PI at 4 weeks in both the groups at 4 weeks. The decrease in the PI score implied that there was improvement in the oral hygiene maintenance thereafter (Table -3, Graph-2). The difference between PI values at baseline and 1 week was lower than baseline and 4 weeks and higher between 1 week and 4 weeks which could be due to increase in the plaque accumulation beneath the periodontal dressing in the first week which was decreased after the removal of the periodontal dressing and improvement in the oral hygiene measures.(Table 4,Graph 3) These results are similar to results in the studies by Newman and Addy (1982) and Heaney and Appleton (1976) which there was increase in the plaque accumulation at 1 week after placement of a periodontal dressing. [39,40]

The increase in the plaque index at 1 week was greater in Group B which was statistically nonsignificant ($p>0.05$). The decrease in the PI at 4 weeks was greater in Group A with statistical insignificance ($p>0.05$) (Table 4, Graph 3), which can be attributed to variations in the dimensions of the periodontal dressing on the surgical area. The PI scores were lower in group A at all time intervals which can be attributed to the anti-microbial effects of the i-PRF. (Table-4, Graph-4)

The reduced PI at all time intervals in the Group A although statistically non-significant ($p>0.05$), can be a contributing factor for the better WHI seen in the Group A at 1 week and 4 weeks as compared to Group B. (Table 4)

The reduction in the probing depth and increase in the clinical attachment levels are the most essential outcomes of periodontal therapy. The measurement of the probing depth is influenced by various factors such as the pressure used to probe, its angulation, design etc. Hence to standardize the measurements an acrylic stent with grooves was used to fixate the location and angulation during evaluation. In the present study, there was a decrease in the probing depth in both the groups (Group A-4.72194; Group B-4.71121) at 4 weeks. (Table -5). These results are similar to findings of a study that reported a probing depth reduction of 1.77mm (buccally) and 2.03mm (lingually) at 1 month in sites treated with periodontal dressing.[41]

The amount of reduction of the PPD was greater in Group B which was statistically insignificant ($p>0.05$) which demonstrated the lack of effect of i-PRF on the PPD (Table-6, Graph-5). These results are in contrast to the findings of several studies that have demonstrated decrease in probing depth in site using PRF after open flap debridement for treatment of intrabony defects as compared to open flap debridement alone. The increase in the amount of reduction in the PPD in PRF sites might be attributed to the PRF used as a membrane which ensured its retention at the surgical site unlike i-PRF where there were chances of its seepage outside the operated area. The decrease in the PPD in these studies were greater than the present study which can be due to evaluation being carried out over a period of 6 months in those studies.

Limitations

The major limitations of the study were the short term follow up as the parameters were assessed in the initial phases of healing which might have underestimated the regenerative potential of the i-PRF in terms of healing outcome. The i-PRF availability at each site could not be quantified due to its fluid consistency. Other limitations were the lack of evaluation of the patient reported outcomes such as presence of pain, discomfort, or hypersensitivity.

Clinical significance

i-PRF being in liquid form can be easily used as adjunct to periodontal dressing to achieve increased concentration of growth factors necessary for wound healing.

CONCLUSION

This randomized controlled clinical trial assesses the wound healing after using i-PRF as an adjunct to Coe-Pak™ periodontal dressing.

The results of the study demonstrated that in spite of its scientific rationale the application of i-PRF did not enhance the wound healing over a limited time period. Further i-PRF had no influence on the plaque index, gingival thickness and pocket probing depth.

However, long term randomized clinical trials would be required to appreciate the effect of i-PRF with varying case selections to support the outcomes of this study. Future studies should include histologic & microbial evaluation to determine the role of PRF on inflammatory infiltrate and its regenerative potential for assessment of wound healing.

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