Placentrex Vs Ozonated Olive Oil- a new era of healing in periodontal surgery – Original Study

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Abstract

Aim: To evaluate the clinical efficacy of placentrex and ozonated olive oil application on healing after laser depigmentation procedure.

Materials And Methods: A Split mouth study was planned with the subjects having gingival melanin hyperpigmentation in maxillary and/or mandibular arches. Each site was randomly divided into 2 groups. Laser depigmentation was performed under local anesthesia using a diode laser. After the depigmentation procedure ozonated olive oil (DENTOZONE INDIA) was applied in group 1 & Placentrex was applied in group 2. Subjects were recalled 1 week, 2 weeks, and 1 month postoperatively, and Healing Index and Visual Analog Scale for pain were recorded.

Results: There was a statistically significant reduction in VAS scores for pain and discomfort and improvement in healing in both groups after 1 week and 2 weeks. Subjects in the Placentrex group showed better healing and reduced pain after 15 days as compared to ozonated olive oil but at the end of the study period, there was no significant difference in both groups.

Conclusion: Subjects having gingival melanin hyperpigmentation would show faster healing with laser depigmentation followed by the use of Placentrex application.

Keywords: Gingival hyperpigmentation, Laser, Placentrex, Ozonated olive oil

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I. Introduction

A charismatic smile depends on the harmonious integration of the gingival and dental elements. With the growing esthetic concerns among the patients, gingival pigmentation mainly on the facial aspect of the gingiva has a psychological impact on their minds when it is visible during speech and, mastication. It is also a matter of concern for patients with gummy smiles. Gingival hyperpigmentation can be defined as a darker gingival color beyond what is normally expected.

Gingival melanin pigmentation is considered to be multifactorial, it could be physiological/pathological or exogenous/endogenous. Dummett, (1971) classified gingival pigmentation as (a) Physiologic (racial): Melanin nonhemoglobin-derived brown pigment (most common) and (b) Pathologic: may be due to druginduced such as chloroquine, quinine, and contraceptives, or smoking-associated melanosis, heavy metals, e.g., lead, bismuth, mercury, silver, and gold, and endocrine diseases such as Addison's disease.1,2

Gingival depigmentation can be considered a periodontal plastic surgical procedure or a cosmetic procedure wherein the gingival hyperpigmentation is removed or reduced by various techniques. Depigmentation is not clinically indicated but it is a treatment of choice by the patients where esthetics is concerned.3

Roshni & Nandakumar (2005) classified different gingival depigmentation methods as:

I. Methods aimed at removing the pigment layer:

- A. Surgical methods of depigmentation
- a. Scalpel surgical technique

b. Bur abrasion method

- c. Electro surgery
- d. Cryosurgery
- e. Lasers
- Neodymium: Aluminium-Yttrium-Garnet (Nd:YAG) lasers
- Erbium: YAG (Er:YAG) lasers
- Carbon Dioxide (CO2) lasers
- f. Radiosurgery
- B. Chemical methods of depigmentation using caustic chemicals- this method is not used nowadays.
- II. Methods aimed at masking the pigmented gingiva with grafts from less pigmented areas
- A. Free gingival graft.
- B. Acellular dermal matrix allograft.3

In the study, the laser was considered for the depigmentation procedure followed by the application of Placentrex and ozonated olive oil.

Laser therapy has excellent efficacy in the treatment of gingival hyperpigmentation. It is a solid-state semiconductor laser that changes electrical energy into light energy. It can be delivered through a flexible quartz fiber optic handpiece. The advantage of laser over other techniques is that it has enhanced hemostatic activity thus bloodless field allows good visibility at the surgical site. Less Postoperative complications such as less pain, bleeding, edema, infection, and impaired wound healing offers great comfort to the patients. The most commonly used lasers for gingival depigmentation are diode (980 nm) lasers, carbon dioxide (CO2, 10,600 nm) lasers, neodymium: Yttrium, aluminum, and garnet (Nd: YAG, 1,064 nm). Depigmentation was performed with short light paint brush strokes in an apicocoronal direction to remove the epithelial lining. The surgical site was wiped with gauze soaked in saline solution and the procedure was repeated till no pigments remained. Following the procedure, cyanoacrylate and vitamin E were applied on the arches' left and right sides respectively.3

In ancient times, herbal medicines extracted and purified from natural sources were considered healing agents that were further substituted for synthetic chemical drugs. But in recent years, herbal medicine emerged as an elixir for healing therapy.

The ozone gas is highly unstable. To improve the storage and stability of ozone it is better to use it with a vegetable oil suspension. An alluring and potent way to use extra virgin olive oil is in combination with ozone. The amalgamation of ozone and olive oil has synergistic therapeutic effects. Ozonated olive oil has unique therapeutic properties as a hemostatic agent, disinfectant, modulation of the inflammatory phase, stimulation of angiogenesis, and the biological and enzymatic reaction thus accelerating wound healing as well as antioxidant properties.4,5,6

The placenta is now considered a new revolution in modern medicine. The therapeutic effect of placental extract as a biogenic stimulator was first described by Russian ophthalmologist, Filatov. It has unique properties placentrex promotes fibrogenesis, neoangiogenesis, and epithelialization thus boosting the wound-healing. It accelerates cellular metabolism and activates tissue regenerative properties. The placental extract plays a beneficial role as a topical agent because of its anti-inflammatory and antiplatelet aggregation action.10,11,12

Based on magnificent properties we aimed to investigate the clinical efficacy of Placentrex gel & ozonated olive oil on healing after the laser gingival depigmentation procedure.

II. Materials And Methods

Subjects for the study were selected from the Outpatient Department, Department of Periodontology. 10 Patients with gingival hyperpigmentation ranging from 20-50 years of either sex were selected. All subjects included in the study were systemically healthy and cooperative. A signed informed consent form was taken. Exclusion criteria

- Smokers and tobacco chewers, pregnant or lactating women, or women on oral contraceptives.
- Patients undergoing orthodontic therapy.
- Patients with a history of use of medications or nutritional supplements in the past six months.

In this study, the cases were selected based on Dummett–Gupta oral pigmentation index (DOPI) (Dummett, 1971):

1.No clinical pigmentation (pink gingiva)

- 2. Mild clinical pigmentation (mild light brown color)
- 3. Moderate clinical pigmentation (medium brown or mixed pink and brown)
- 4. Heavy clinical pigmentation

Dummet proposed the Dummet Oral Pigmentation Index (DOPI) assessment:

• Score 0: Pink tissue (No clinical pigmentation)

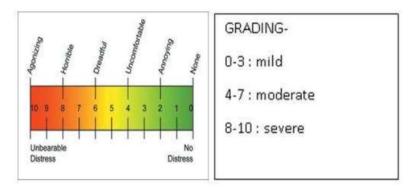
- Score 1: Mild light brown color (Mild clinical pigmentation)
- Score 2: Medium brown or blue- black tissue (Heavy clinical pigmentation)

• Score 3: Deep brown or blue- black tissue (Heavy clinical pigmentation).

The anterior labial sextant of the maxilla & mandible was divided into two halves on each side. Each site was randomly divided into 2 groups. Laser depigmentation was performed under local anesthesia using a diode laser(980 nm). After the depigmentation procedure ozonated olive oil was applied in group 1 &Placentrax was applied in group 2. Clinical parameters such as pain & wound healing were assessed after one week, two weeks, and one month.

Assessment Of Clinical Parameters (at postoperative 1 week, 2 weeks, 1 month)

- 1. Visual analog scale (VAS) ratings for pain
- 2. Healing index (Landry, Turnbull, and Howley, 1988).
- 1. Visual Analog Scale



2. Healing Index (Landry, Turnbull, And Howley, 1988)

Healing Index 1 - Very Poor:

Has 2 or more of the following:

(1) tissue color: \geq 50% of gingiva red

(2) response to palpation: bleeding

(3) granulation tissue: present

(4) incision margin: not epithelialized, with loss of epithelium beyond the incision margin

(5) suppuration present

Healing Index 2 – Poor:

(1) tissue color: \geq 50% of gingiva red

(2) response to palpation: bleeding

(3) granulation tissue: present

(4) incision margin: not epithelialized, with connective tissue exposed

Healing Index 3 – Good:

(1) tissue color: $\geq 25\%$ and < 50% of gingiva red

- (2) response to palpation: no bleeding
- (3) granulation tissue: none
- (4) incision margin: no connective tissue exposed

Healing Index 4 - Very Good:

(1) tissue color: < 25% of gingiva red

- (2) response to palpation: no bleeding
- (3) granulation tissue: none
- (4) incision margin: no connective tissue exposed

Healing Index 5 – Excellent:

(1) tissue color: all tissues pink

(2) response to palpation: no bleeding

(3) granulation tissue: none

(4) incision margin: no connective tissue exposed.

Statistical Analysis

Descriptive statistics were expressed as means and standard deviations for each group. Within-group comparison for the parametric study variables (LHI) was analyzed using Paired t-test. Between-group comparisons for the parametric study, variables were analyzed using One way ANOVA test. Post hoc comparison was done using Bonferroni correction.

Within-group comparison for the non-parametric study variables (VAS) was analyzed using Wilcoxon Signed Ranks Test.

Between-group comparisons the non-parametric variables were analyzed using Kruskal Walis ANOVA and Mann-Whitney U test.

In the above tests, a p-value less than or equal to 0.05 ($p \le 0.05$) was taken as statistically significant. All analyses were performed using SPSS software version 17.

III. Results

There was a statistically significant reduction in Visual Analog Scale scores for pain and discomfort and improvement in healing in both groups. But when a comparison was done between the 2 groups subjects in the placentrex group showed faster healing and reduced pain after 1 week as well as after 15 days compared to subjects in ozonated olive oil group. Subjects of both groups after a month showed similar healing and pain reduction.

Tables

Table no.1: Intergroup comparison of the healing index scores among the two groups

Paired T-test

Group	Oli	ve o	il	Plac	entr	ex	Mean		t -test P-Value	Inferences
Day	Mean	±	S.D	Mean	±	S.D	Difference	t -test		
Day 7	3.40	±	0.50	3.75	±	0.44	-0.35	3.199	0.005	S
Day 15	4.30	±	0.57	4.75	±	0.44	-0.45	3.943	0.001	S
Day 30	5.00	±	0.00	4.75	±	1.12	0.25	1.000	0.330	NS

p≤0.05 is statistically significant

One Way Anova

Groups	Days	N	Mean	S.D.	F	P-value	Inferences
	DAY 7	20	3.40	0.50			
Olive oil	DAY 15	20	4.30	0.57	66.673	0.000	S
	DAY 30	20	5.00	0.00			
	DAY 7	20	3.75	0.44			
<u>Placentrex</u>	DAY 15	20	4.75	0.44	12.160 0.000	S	
	DAY 30	20	4.75	1.12			

Multiple Comparisons

Dependent Variable	(I) Day	(J) Day	Mean Difference (I-J)	P-value	Inferences
Olive oil	DAY 7	DAY 15	-0.90	0.000	S
		DAY 30	-1.60	0.000	S
	DAY 15	DAY 30	-0.70	0.000	S
	DAY 7	DAY 15	-1.00	0.000	S
<u>Placentrex</u>		DAY 30	-1.00	0.000	S
	DAY 15	DAY 30	0.00	1.000	NS

Bonferroni

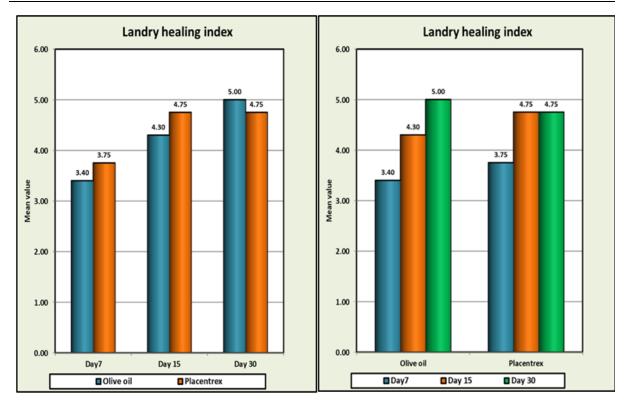


 Table no.2: Change in VAS scores (for pain) among the two groups

 Wilcoxon Signed Ranks Test

Group	Oli	ve o	il	Plac	entı	<u>ex</u>	Mean	Z	Z P-Value	Inferences
Day	Mean	±	S.D	Mean	±	S.D	Difference			
Day7	0.50	±	0.51	0.25	±	0.44	0.25	-2.236	.025	S
Day15	0.30	±	0.47	0.00	±	0.00	0.30	-2.449	.014	S
Day30	0.00	±	0.00	0.00	±	0.00	0.00	.000	1.000	NS

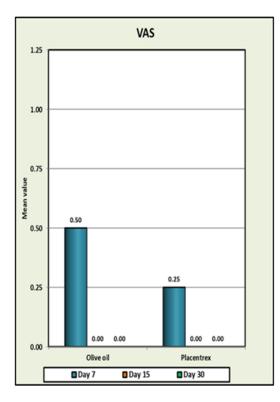
Kruskal Walis ANOVA

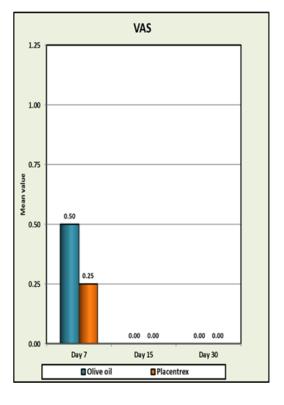
Groups	Days	N	Mean	S.D.	F	P-value	Inferences
	DAY 7	20	0.50	0.51			
Olive oil	DAY 15	20	0.30	0.47	7.848	0.001	S
	DAY 30	20	0.00	0.00			
	DAY 7	20	0.25	0.44			
Placentrex	DAY 15	20	0.00	0.00	6.333	0.003	S
	DAY 30	20	0.00	0.00			

Multiple Comparisons

Dependent Variable	(I) Day	(J) Day	Mean Difference (I-J)	P-value	Inferences
Olive oil	DAY 7	DAY 15	0.20	0.363	NS
	DAT /	DAY 30	0.50	0.001	S
	DAY 15	DAY 30	0.30	0.065	NS
	DAY 7	DAY 15	0.25	0.009	S
Placentrex		DAY 30	0.25	0.009	S
	DAY 15	DAY 30	0.00	1.000	NS

Mann-Whitney U test





Armamentarium







Case pictures CASE 1



Preoperative Intraoperative





Postoperative





Placentrex gel application

Placentrex Vs Ozonated Olive Oil- A new era of healing in periodontal surgery – Original Study





Ozonated olive oil application





Healing after 7 daysHealing after 15 days



Healing after 1 month





Preoperative



Intraoperative

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Post-operative



Placentrex application



Ozonated olive oil application



Healing after 7 days



Healing after 15 days



Healing after 1 month

IV. Discussion

Patients with excessive gingival display are more concerned and thus seek treatment. Laser is considered one of the most effective, reliable techniques for gingival depigmentation procedures. Wound Healing can be described as a body's reaction to any injury or surgical procedure for the restoration of normal function and structural integrity of the tissue.

The Placenta is a maternofetal organ that serves as a natural treasure of many biologically active components with significant healing properties. It increases healing by stimulating nervous regulation, hormonal regulation, & immune system regulation and gives resistance to the body which will help in increasing collagen synthesis. Placental Extract also helps in the activation of the clotting cascade by trauma which results in platelet activation, followed by platelet aggregation.13,14

Nicola Tesla bubbles the ozone continuously for three weeks through the oil, creating a natural gel with ozone in suspension. OLEOZON ®, The first vegetable ozonated oil registered as a medicinal product for oral

and topical therapeutic purposes by the National Center for Scientific Research in Cuba. Ozonated olive oil has unique therapeutic properties as a hemostatic agent as well as antimicrobial and antioxidant properties. Several studies have been done to check the clinical efficacy of placentrex and ozonated olive oil as wound healing agents. According to various research, it has been proved that placenta has the rich regenerative properties. In this study, sites with placentrex gel application showed faster healing compared to ozonated olive oil during the first two weeks and reduced pain and discomfort.7,8,9

However, to date, to the best of the authors' knowledge, there has been no study that has directly compared healing by placentrex gel and ozonated olive oil application after laser depigmentation techniques.

V. Conclusion

The present study showed that subjects having gingival melanin hyperpigmentation would show faster healing and reduced pain with laser depigmentation followed by the use of the application of placentrex gel as compared to ozonated olive oil. However, further long-term studies with larger sample sizes are required to reach a definitive conclusion.

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