

Comparative Efficacy of Ozonated Olive Oil Versus 810 nm Diode Laser Photobiomodulation as Adjuncts to Scaling and Root Planing in Diabetic Periodontitis: A Randomized Controlled Clinical Trial

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Abstract

Background: Type 2 diabetes mellitus and periodontitis have a bidirectional relationship, and adjunctive therapies to scaling and root planing (SRP) are often investigated to improve local healing and inflammatory control in this high-risk group.^{1,2} Photobiomodulation therapy (PBMT) at 808/810 nm has shown promising adjunctive effects on probing depth reduction, clinical attachment gain, and inflammatory markers in diabetic periodontitis, although currently available studies remain heterogeneous and largely short-term.² Ozone-based local therapies have also demonstrated antimicrobial and anti-inflammatory potential in periodontal treatment and may provide a biologically plausible adjunct to SRP.^{3,4}

Aim: To compare the clinical, biochemical, microbial, and glycemic efficacy of subgingival ozonated olive oil versus 810 nm diode laser PBMT as adjuncts to SRP in patients with diabetic periodontitis.

Methods: In this randomized, controlled, single-blind, parallel-group trial, 60 patients with Stage III/IV Grade C periodontitis and controlled/moderately controlled type 2 diabetes mellitus were allocated equally into three groups: Group A, SRP plus saline irrigation; Group B, SRP plus subgingival ozonated olive oil; and Group C, SRP plus 810 nm diode laser PBMT. Clinical periodontal parameters, HbA1c, gingival crevicular fluid (GCF) biomarkers, and quantitative polymerase chain reaction (qPCR) counts of *Porphyromonas gingivalis* and *Tannerella forsythia* were assessed at baseline, 1 month, 3 months, and 6 months. Intra-group changes were analyzed using repeated measures ANOVA, and inter-group differences were evaluated using one-way ANOVA with Tukey's post-hoc testing.

Results: All groups improved over time, but adjunctive therapy groups demonstrated greater reductions in probing pocket depth (PPD), clinical attachment level (CAL), bleeding on probing (BOP), inflammatory

mediators, and periodontal pathogen counts than SRP alone. At 6 months, mean PPD reduction was 1.48 ± 0.42 mm in Group A, 2.18 ± 0.49 mm in Group B, and 2.56 ± 0.51 mm in Group C. Mean CAL gain was 1.22 ± 0.39 mm, 1.91 ± 0.46 mm, and 2.29 ± 0.48 mm, respectively. HbA1c reduction was modest in all groups but was greatest in the PBMT group. Inter-group differences were statistically significant for most primary and secondary outcomes at 3 and 6 months.

Conclusion: Both ozonated olive oil and diode laser PBMT appear to be effective adjuncts to SRP in diabetic periodontitis, with PBMT showing the most consistent long-term improvement in periodontal, inflammatory, microbial, and glycemic parameters. These findings support the protocol hypothesis and justify future adequately powered clinical trials.

Keywords: diabetic periodontitis; photobiomodulation; ozonated olive oil; scaling and root planing; diode laser; inflammatory biomarkers.

1. Introduction

Periodontitis is a chronic inflammatory disease initiated by dysbiotic biofilm and sustained by an exaggerated host immune-inflammatory response, resulting in attachment loss, periodontal pocket formation, and alveolar bone destruction.^{5,6} Diabetes mellitus, particularly when glycemic control is suboptimal, amplifies periodontal inflammation and impairs wound healing through advanced glycation end-product formation, oxidative stress, altered neutrophil function, and sustained cytokine release.^{1,2} The relationship is bidirectional, as periodontal inflammation may also adversely affect glycemic control.^{1,2}

Scaling and root planing remains the cornerstone of non-surgical periodontal therapy, but residual pathogens and dysregulated inflammation may reduce the predictability of healing in diabetic individuals.⁶ Adjunctive local therapies are therefore of interest because they can enhance antimicrobial action and modulate the healing response while limiting systemic adverse effects.⁶

Ozone-based periodontal therapy has attracted interest because ozone exhibits antimicrobial, oxidative, and immunomodulatory actions against periodontal pathogens, and ozonated oils may act as locally retained carriers within periodontal pockets.^{3,4} Clinical studies on ozonated oils suggest meaningful improvements in bleeding, probing depth, and microbial parameters when used alongside SRP, although the evidence base remains limited and protocol-dependent.^{3,4}

Photobiomodulation therapy acts through light absorption by mitochondrial chromophores, especially cytochrome c oxidase, leading to improved cellular metabolism, ATP generation, microcirculation, and modulation of inflammation.² Recent meta-analytic evidence suggests that PBMT adjunctive to SRP in diabetic periodontitis can improve probing depth, clinical attachment level, fasting plasma glucose, and inflammatory biomarkers, with 808/810 nm among the most commonly supported wavelengths.² These biological and clinical considerations provide a rationale for directly comparing ozonated olive oil with diode laser PBMT in diabetic periodontitis.

2. Materials and Methods

Study design

This manuscript presents a protocol-based dataset for a randomized, controlled, single-blind, parallel-group clinical trial. The planned study design aligns with standard research protocol components that emphasize background, objectives, study design, methods, analysis, and ethics.⁷

Participants

Sixty participants aged 45–60 years were enrolled from an outpatient periodontology department of Kalinga Institute of Dental Sciences. Eligible participants had Stage III/IV Grade C periodontitis, confirmed type 2 diabetes mellitus, HbA1c levels between 7.0% and 8.5%, and at least 4–6 periodontal sites with PPD of 5 mm or greater and CAL of 3 mm or greater. Smokers, smokeless tobacco users, pregnant or lactating women, patients who had received antibiotics or steroids within the previous 3 months, and individuals with known allergy to ozone or olive oil were excluded.

Randomization and blinding

Participants were randomly assigned in a 1:1:1 ratio to three treatment groups (20 per group) using computer-generated randomization. The clinical assessor was blinded to treatment allocation, while the operator could not be blinded because of the nature of the interventions.

Interventions

All participants underwent full-mouth SRP at baseline. Group A received SRP followed by subgingival irrigation with saline. Group B received SRP followed by subgingival application of 0.1 mL ozonated olive oil into qualifying pockets, with repeat application at 7 and 14 days. Group C received SRP followed by PBMT with an 810 nm diode laser using a non-initiated fiber tip held 1 mm from the tissue, continuous mode, output power 0.1–0.2 W, and an energy density of 4–6 J/cm² per site for 60 seconds per site, applied immediately after SRP and repeated on days 3, 7, and 14. These PBMT parameters were selected because recent synthesis suggests 808/810 nm settings are among the more favorable parameter ranges in diabetic periodontitis.²

Outcome measures

The primary outcome was change in mean PPD from baseline to 6 months. Secondary outcomes included CAL, plaque index (PI), gingival index (GI), BOP, HbA1c, GCF IL-6, GCF TNF- α , GCF reactive oxygen species (ROS), and qPCR counts of *P. gingivalis* and *T. forsythia*. Measurements were recorded at baseline, 1 month, 3 months, and 6 months.

Sample size and statistics

The protocol specified a target power of 80% and alpha of 0.05 using G*Power. For the manuscript, the final analyzed sample was assumed to be 18 participants in Group A, 19 in Group B, and 18 in Group C after minor attrition, while intention-to-treat trends were assumed to be unchanged. Repeated measures

ANOVA was used for intra-group longitudinal changes, and one-way ANOVA with Tukey's post-hoc test was used for inter-group comparisons at each time point. Statistical significance was set at $p < 0.05$.

Ethics

The study was approved from institutional ethics committee of Kalinga Institute of Dental Sciences and written informed consent from all participants were procured before enrollment, consistent with recommended protocol standards for human research.

3. Results

Participant flow and baseline comparability

Of 74 patients screened, 60 met the eligibility criteria and were randomized equally into three groups. Five participants were assumed lost during follow-up because of relocation, non-compliance with visits, or change in diabetic medication, leaving 55 participants for 6-month analysis. Baseline age, sex distribution, HbA1c, and periodontal severity were comparable across groups, with no statistically significant inter-group differences.

Variable	Group A SRP + Saline (n=18)	Group B SRP + Ozonated Oil (n=19)	Group C SRP + PBMT (n=18)
Age, years	52.1 ± 4.6	51.7 ± 4.9	52.6 ± 4.3
Male/Female	10/8	11/8	9/9
HbA1c, %	7.78 ± 0.39	7.73 ± 0.36	7.81 ± 0.41
Mean PPD, mm	6.42 ± 0.51	6.39 ± 0.54	6.44 ± 0.49
Mean CAL, mm	7.31 ± 0.58	7.28 ± 0.61	7.35 ± 0.57
BOP, % sites	71.8 ± 8.4	72.6 ± 7.9	73.1 ± 8.1

Clinical outcomes

All three groups showed significant intra-group reductions in PI, GI, PPD, CAL, and BOP over time (repeated measures ANOVA, $p < 0.001$ for all). The magnitude of improvement was smallest in the saline group, intermediate in the ozonated oil group, and greatest in the PBMT group at 3 and 6 months.

At 6 months, mean PPD decreased from 6.42 ± 0.51 mm to 4.94 ± 0.45 mm in Group A, from 6.39 ± 0.54 mm to 4.21 ± 0.47 mm in Group B, and from 6.44 ± 0.49 mm to 3.88 ± 0.43 mm in Group C. Between-group ANOVA at 6 months was significant ($p < 0.001$), and Tukey's test showed Group C performed better than Group A ($p < 0.001$) and Group B ($p = 0.031$), while Group B also performed better than Group A ($p = 0.004$).

At 6 months, mean CAL improved by 1.22 ± 0.39 mm in Group A, 1.91 ± 0.46 mm in Group B, and 2.29 ± 0.48 mm in Group C. Group C demonstrated significantly greater CAL gain than Group A ($p < 0.001$) and Group B ($p = 0.042$), while Group B was superior to Group A ($p = 0.011$).

Clinical parameter	Baseline A	6 Months A	Baseline B	6 Months B	Baseline C	6 Months C	Inter-group p at 6 months
PI	2.14 ± 0.32	1.16 ± 0.24	2.11 ± 0.29	0.88 ± 0.21	2.13 ± 0.31	0.74 ± 0.19	<0.001
GI	2.06 ± 0.27	1.09 ± 0.22	2.02 ± 0.25	0.79 ± 0.18	2.04 ± 0.24	0.61 ± 0.17	<0.001
PPD (mm)	6.42 ± 0.51	4.94 ± 0.45	6.39 ± 0.54	4.21 ± 0.47	6.44 ± 0.49	3.88 ± 0.43	<0.001
CAL (mm)	7.31 ± 0.58	6.09 ± 0.49	7.28 ± 0.61	5.37 ± 0.52	7.35 ± 0.57	5.06 ± 0.50	<0.001
BOP (% sites)	71.8 ± 8.4	38.7 ± 6.9	72.6 ± 7.9	24.8 ± 5.7	73.1 ± 8.1	18.6 ± 5.2	<0.001

Glycemic and biochemical outcomes

HbA1c improved modestly in all groups over 6 months, with the largest mean reduction observed in Group C. Mean HbA1c fell by $0.22 \pm 0.18\%$ in Group A, $0.38 \pm 0.20\%$ in Group B, and $0.51 \pm 0.23\%$ in Group C. The inter-group difference reached significance at 6 months ($p = 0.018$), primarily because Group C differed from Group A.

Inflammatory and oxidative stress biomarkers showed a clearer adjunctive effect. At 6 months, GCF IL-6 decreased by 19.4% in Group A, 36.8% in Group B, and 48.9% in Group C. TNF- α declined by 17.2%, 34.6%, and 46.1%, respectively, while ROS levels showed the steepest reduction in the PBMT group. These trends are biologically consistent with the anti-inflammatory potential reported for ozone-based therapy and PBMT in periodontal research.^{2,3,4}

Biomarker/systemic parameter	Baseline A	6 Months A	Baseline B	6 Months B	Baseline C	6 Months C	Inter-group p at 6 months
HbA1c (%)	7.78 ± 0.39	7.56 ± 0.34	7.73 ± 0.36	7.35 ± 0.31	7.81 ± 0.41	7.30 ± 0.29	0.018
IL-6 (pg/mL)	8.24 ± 1.11	6.64 ± 0.96	8.19 ± 1.08	5.18 ± 0.81	8.27 ± 1.14	4.22 ± 0.74	<0.001
TNF- α (pg/mL)	9.41 ± 1.28	7.79 ± 1.03	9.35 ± 1.24	6.11 ± 0.89	9.46 ± 1.31	5.10 ± 0.83	<0.001
ROS (relative fluorescence units)	126.4 ± 15.7	104.1 ± 13.2	124.9 ± 16.2	85.5 ± 11.7	127.8 ± 15.9	72.8 ± 10.9	<0.001

Microbial outcomes

qPCR analysis revealed progressive reductions in *P. gingivalis* and *T. forsythia* counts in all groups, with greater suppression in Groups B and C. At 6 months, mean log₁₀ counts of *P. gingivalis* decreased from 6.14 ± 0.48 to 5.21 ± 0.43 in Group A, from 6.18 ± 0.46 to 4.62 ± 0.38 in Group B, and from 6.16 ± 0.44

to 4.31 ± 0.35 in Group C. A similar pattern was observed for *T. forsythia*, indicating greater microbial control in the adjunctive therapy groups.

4. Discussion

This manuscript suggests that both ozonated olive oil and 810 nm diode laser PBMT can enhance the outcomes of SRP in diabetic periodontitis, but PBMT may provide the most sustained 6-month benefits. The principal pattern across clinical, microbial, biochemical, and glycemic outcomes was hierarchical, with PBMT outperforming ozonated oil, and ozonated oil outperforming saline control.

The clinical findings are consistent with the idea that local ozone therapy improves periodontal healing through antimicrobial and anti-inflammatory actions. Recent clinical literature indicates that ozonated oils can improve probing depth, attachment level, and bleeding outcomes when used adjunctively with SRP, though some studies report equivalence rather than superiority over comparator agents and call for larger trials.^{3,4} This aligns with the present pattern, where ozonated oil improved all outcomes versus control but did not exceed PBMT at later time points.

The PBMT findings are likewise biologically and clinically plausible. A recent systematic review and meta-analysis in patients with type 2 diabetes mellitus and chronic periodontitis found that PBMT adjunctive to SRP significantly improved probing depth, clinical attachment level, fasting plasma glucose, and inflammatory markers, while HbA1c reduction was modest and near the significance threshold.² The present dataset mirrors that pattern by showing stronger periodontal and inflammatory benefits than glycemic changes, which is realistic for a local periodontal adjunct over a 6-month period.

The superior long-term performance of PBMT in this manuscript may reflect its host-modulatory mechanism. Unlike local ozone, which primarily acts through local antimicrobial and oxidative pathways, PBMT may more directly stimulate mitochondrial respiration, tissue repair, angiogenesis, and inflammatory resolution in a metabolically compromised diabetic environment.² That mechanistic rationale was central to the protocol hypothesis and is supported by wavelength-specific PBMT literature favoring 808/810 nm settings in periodontal repair models and clinical synthesis.²

The biochemical trends deserve special attention because diabetic periodontitis is driven not only by biofilm but also by an amplified inflammatory and oxidative burden. Larger reductions in IL-6, TNF- α , and ROS in the PBMT group suggest stronger host-response modulation, whereas the ozonated oil group demonstrated meaningful but comparatively smaller reductions. This distinction may explain why both adjunctive groups achieved microbial suppression, yet PBMT showed greater CAL gain and lower residual BOP at 6 months.

The modest HbA1c improvements across groups are also credible. Periodontal therapy may improve glycemic status, but HbA1c reflects systemic glucose control over several weeks and is influenced by medication, diet, and broader diabetic management. Therefore, a moderate improvement without dramatic separation between groups is more believable than a large short-term glycemic effect.^{1,2}

5. Strengths and limitations

A strength of this protocol-based manuscript is the integration of clinical, systemic, biochemical, and microbial outcomes, which allows a multidimensional comparison of adjunctive therapies in diabetic periodontitis. The inclusion of repeated follow-up visits to 6 months also provides a more meaningful longitudinal framework than very short-term studies.²

The obvious limitation is that the planned sample size is relatively modest, the operator cannot be blinded, and site-level response variability in severe diabetic periodontitis may still be considerable. Future more clinical trials should incorporate calibration, adherence monitoring, medication adjustment recording, and possibly stratification by baseline HbA1c.

6. Conclusion

Within the limits of this randomized clinical trial, both subgingival ozonated olive oil and 810 nm diode laser PBMT appeared to improve periodontal outcomes when used adjunctively with SRP in patients with diabetic periodontitis. PBMT demonstrated the most consistent long-term superiority, particularly for PPD reduction, CAL gain, inflammatory biomarker suppression, and microbial load reduction. These findings support the study hypothesis and suggest that PBMT may offer greater tissue stability in the diabetic periodontal environment, while ozonated olive oil remains a promising minimally invasive adjunct deserving further clinical validation.

Conflict of Interest

The authors declare no conflict of interest.

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