PERI-IMPLANT MUCOSITIS TERAPY WITH DIOD LASER TERAPY AS A COADYUVANT TREATMENT VS CONVENTIONAL TREATMENT ONLY IN SMOKERS: a prospective Randomized control clinical trial

Universidad Europea Valencia

Máster Oficial en Implantología Oral Avanzada

Autor: Davide Frongia

Tutora: Rebecca Sanchez Martos

ABSTRACT

Introduction: Peri-implant mucositis presents a significant challenge due to inflammation around implants, especially for smokers with compromised health. Technological advancements, particularly diode laser therapy, offer promising solutions by targeting specific tissues to reduce inflammation and enhance circulation, minimizing patient discomfort.

The **objective** of this study was to evaluate the efficacy of laser therapy as an adjunct to conventional treatment for peri-implant mucositis.**Materials and Methods**: Following CONSORT 2010 guidelines, 60 patients from the Advanced Oral Implantology program at Universidad Europea de Valencia Clinic underwent non-surgical treatment. The test group received both conventional and photothermal therapy using the Fox®III diode laser, while the control group received only conventional therapy. Treatment efficacy was assessed over six months through comprehensive peri-implant evaluations.

Results and Discussion:Results indicate that both groups experienced reductions in probing depth after one month, with the TEST group demonstrating superior efficacy, particularly from three to six months. Fluctuations in bleeding on probing (BOP) were observed, with the TEST group showing a more pronounced reduction over time. However, no significant differences were observed between groups from three to six months, suggesting a plateau effect. Both groups exhibited significant improvements in plaque index initially, although a regression was noted in the TEST group at three months. Significant decreases in Periotron values were observed in both groups post-intervention, indicating comparable efficacy in reducing gingival fluid flow.**Conclusion**:Laser therapy, showed promising effects on periodontal health parameters, notably in reducing probing depth and BOP. Further research is needed to explore long-term impacts and mechanisms of action.

1.INTRODUCTION

Nowadays more and more implants are being placed into patients mouths, although not always this implants stay in a optimal state of health, and among most common complication we can find mucositis or inflammation around the implant.(1) Perimplant mucositis is an inflammatory condition that affects the soft tissues surrounding dental implants, such as the gums and alveolar bone. It is similar to gingivitis in natural teeth, but instead of affecting the teeth, peri-implant mucositis occurs around the dental implants. It is characterized by inflammation of the peri-implant mucosa, which can manifest as redness, bleeding on gentle probing, swelling and sensitivity in the area around the implant.(2) Smokers are at increased risk of developing peri-implant mucositis for several reasons:
It poses severe threats to oral health by compromising blood circulation, immune response, and cellular function. This is due to chemicals produced tobacco combustión such as alquiltrans and nicotine, producing constriction of small blood vessels, diminishing supply to oral tissues and hindering the body's ability to combat inflammation. This weakened immune system makes smokers more susceptible to infections and chronic inflammation, such as mucosal and peri-implant inflammations.(3) Additionally, tobacco disrupts the normal functioning of cells responsible for repairing and maintaining oral tissues, impeding the natural healing process. Smoke also delays the crucial healing process after dental implant placement, raising the likelihood of loosing the implant before integration. Quitting smoking is vital for preserving optimal oral health and supporting the success of implant placement since the elimination of the risk factors from smoke optimized the probability of a successful and stable rehabilitation and thus reducing greatly the risk of developing peri-implant mucositis and improve overall oral health.(4)
Technology comes to help when treatment of this pathologies presents The diodelaser is a relatively new system which is being used in dentistry to treat a variety of oral conditions, including peri-implant mucositis. This technique uses a device that emits coherent and focused light of a specific wavelength, interacting in a controlled manner withbiological tissues.(5)
In the context of peri-implant mucositis, the diode laser seems to improve the condition by reducing inflammation, decontaminating the area, stimulating blood circulation and

minimizing patient discomfort. Laser therapy emerges as a potential and innovative option for addressing various oral health conditions, however, its effectiveness is contingent upon factors such as the severity of the condition and the expertise of the practitioner. The application of laser therapy in dentistry has shown promise in treating conditions like periodontal disease and peri-implantitis. Laser devices are designed to target specific tissues, promoting precision and minimizing damage to surrounding areas. While it can offer advantages such as reduced discomfort and faster healing, its success may vary depending on the specific case and the skill of the dentist administering the treatment. Moreover, therapy's efficacy is often observed in conjunction with traditional treatments, highlighting the importance of a comprehensive approach. The severity of the oral health issue, patient characteristics, and the practitioner's experience all play pivotal roles in determining the appropriateness and success of laser therapy as part of a tailored treatment plan. As research and technology continue to advance, laser therapy may increasingly become a valuable tool in the dental arsenal, but careful consideration and individualized assessment remain crucial in determining its optimal application.(6)

1.1.OBJECTIVE

The objective of this study was to evaluate the effects of laser therapy on peri-implant health parameters, specifically focusing on probing depth, bleeding on probing, plaque index, and Periotron values. The study aimed to compare these outcomes between a TEST group receiving laser therapy and a CONTROL group, assessing the potential efficacy of laser therapy as a coadjutant treatment for peri implant mucositis.

2.MATERIALS AND METHODS

2.1.ETHICS

This protocol received approval from the Clinical Research cs Committee of the ClínicoSan Carlos Hospital in Madrid and the Research Ethics Committee of the European University. CIPI/21/88

2.2. STUDY POPULATION

2.2.1 Reference Population

The reference population was formed based on consecutive recruitment of patients attending the Advanced Oral Implantology Master's program at the European University of

Valencia (UEV) between January 2021 and June 2023. All these patients were offered participation in the study and underwent a brief screening to determine if they met the inclusion criteria.

2.2.2.Inclusion Criteria:

- Patients who smoke aged 18 years and above.

- Single or multiple fixed posterior implant-supported rehabilitation.

- Established diagnosis of mucositis according to the latest consensus from the 2017 World Workshop on Periodontology.

2.2.3.Exclusion Criteria

Patients with systemic diseases affecting immune levels (e.g., HIV) or autoimmune conditions impacting the oral cavity (such as pemphigus, pemphigoid, lichen planus, and lupus).

- Chronic consumption (2 weeks or more) of non-steroidal anti-inflammatory drugs affecting periodontal status.

- Systemic antibiotic therapy within the 6 months prior to the start of the study.

- Non-surgical peri-implant treatment within the last 6 months or surgical treatment within the last 12 months before the study's commencement.

- Use of bisphosphonates at any point in their life or calcium supplements.

- Patients who have undergone radiation therapy in the head and neck area.

2.3.Eligeble population

Patients meeting the criteria received study information, including its purpose, risks, and benefits, through two documents: one explaining the study and their involvement, and an informed consent form they signed before the study (see annexes).

2.3.1Study Population

The eligible patients who agreed to participate in the study and signed informed consents constituted our study population. This population was divided into three groups based on the non-surgical therapy used for mucositis treatment.

Therefore, we distinguished between:

- Control Group (CG):

- Received conventional non-surgical treatment for peri-implant mucositis as described by

Renvert et al. in 2008 (7).

- Test Group (TG):

 - Received non-surgical treatment for peri-implant mucositis as described by Renvert et al. in 2008 (7), along with high and low-intensity photothermal therapy using the Fox® III diode laser (A.R.C. Laser GmbH, Nürnberg, Germany).

The entire study population received non-surgical treatment for peri-implant mucositis and had follow-up visits. The clinical phase took place at the Dental University Clinic of the European University of Valencia (UEV).

2.4.METHOD

The methodology of this research study was drafted based on the CONSORT 2010 Statement, designed for standardizing randomized parallel-group clinical trials.

2.4.1.STUDY TYPE

A six months prospective randomized controlled clinical trial was conducted.

2.5.INFORMED CONSENT

Patients received clear and detailed information from the investigators (DF)(RS) about the study's objectives and characteristics to participate voluntarily. They were provided with an informed consent form which they signed before the study.

2.6.STUDY DESIGN

2.6.1EXMINER CALIBRATION

The study was conducted by an examiners (DF) y (RS) trained and calibrated beforehand. Calibration involved training for diagnostic criteria using photos and an expert (RS) for categorical variables and calibration for quantitative variables based on 10 patients. The pilot study showed high agreement (98%) in measurements, ensuring reliability. In this new study, the same calibrated investigators (RS and DF) collected and recorded the same variables and indices.

2.6.2.Randomization and Allocation Concealment

SPSS® Statistics for 1:1 randomization of study groupswas used , stratified by smoking status, a key factor in peri-implant mucositis risk. Sixty patients were divided into 10 blocks of 6 cells each, assigning them interventions through a numerical sequence. Results were sealed in

opaque envelopes for disclosure during treatment visits by RS.

2.6.3.secuence of the study

1) Selection Visit:

At the initial meeting, study's purpose was explained by the autors (DF) (RS), conducted an inclusion questionnaire, and performed a periodontal screening. Patients meeting the criteria were briefed on the study specifics and provided an informed consent form. They completed a questionnaire on demographics, socioeconomics, medical history(medication, allergy, age, systemic disease) and oral health. Smoking habits were categorized(amount, type and frequency), and an intraoral exam was conducted to determine the peri-implant condition. Patients were informed about potential risks and benefits, particularly regarding diode laser use, highlighting its clinical benefits in reducing bleeding, plaque, and probing depth.

2) Baseline Visit

All study participants had peri-implant crevicular fluid sampled using absorbent paper strips (Periopaper® Harco, Irvine, CA) to record immunological variables. Data was recorded in the data collection sheet.

Following data recording, non-surgical peri-implant mucositis treatment per Renvert et al.'s 2008 protocol (7) was administered to all participants, involving:

- Mechanical debridement using Teflon curettes (Implant Deplaquers®, KerrHawe SA, Bioggio, Switzerland) and Teflon PH1 ultrasonic tips (Acteon Satelec®, Acteon Médico-Dental Ibérica SAU, Barcelona, Spain).Peri-implant irrigation with 0.12% chlorhexidine + 0.05% CPC (Perio-Aid Tratamiento®,Dentaid, Barcelona, Spain).

- Oral hygiene instructions emphasizing the modified Bass brushing technique and use of interproximal hygiene aids like dental floss and interdental brushes.

Following phototherapy was applied with the laser "The Fox III Diode Laser", a medical device designed for dental applications, distributed by SWEDEN & MARTINA®. It is manufactured by A.R.C. Laser GmbH in Nuremberg, Germany, and distributed by MEDITERRANEA S.L in Padua, Italy.

2.6.4.Diode Laser Application Protocol Used in the Study:

The diode laser was administered by operators (DF)(RS) following the specified protocol:

Technical Specifications:

- Test Group ➜ Diode laser photothermal therapy.

  - High-intensity therapy: 1 W power, 50 Hz 0 Hz, ton=10 ms, toff=10 ms for 30s per surface. Optical fiber tip of 300 μm.

1. High-Intensity Photothermal Therapy:

  - The 300 μm optical fiber tip was inserted parallel to the longitudinal axis of the implant, 1 mm above the base of the sulcus.

  - Upward and downward movements were performed while traversing the sulcus in the mesio-distal direction for 30 seconds.

2. Low-Intensity Photothermal Therapy:

  - Maintaining the 1cm handpiece in contact with the gingival margin, the operator passed it over the buccal and palatal-lingual surfaces of the affected implants for 30 seconds per surface.

3) 6-Week Reassessment Visit:

After 6 weeks of treatment, a comprehensive peri-implant assessment was conducted, along with a new peri-implant crevicular fluid sample, following the established protocol from the baseline visit.

4) 3-Month Reassessment Visit:

At the 3-month mark post-treatment, another thorough assessment of the peri-implantcondition was performed, maintaining the protocol established during the baseline visit.

5) 6-Month Reassessment Visit:

After 6 months from the treatment, a comprehensive reassessment of the peri-implant condition was conducted, following the baseline visit's established protocol.

2.6.7.RESPONSE VARIABLES

1) Plaque Index Variable:

  - Plaque Index (Sillness and Löe, 1964):

    - Code 0: No plaque accumulation on the gingival margin.

    - Code 1: Thin plaque film adhering to the free gingival margin and adjacent area, detectable by probing or staining.

- Code 2: Moderate accumulation of soft deposits within the gingival sulcus or on the gingival margin, visible to the naked eye.

- Code 3: Abundance of soft, thick material, 1-2 mm deep from the gingival sulcus onto the gingival margin and adjacent dental surface.

2) Sulcus Bleeding Index Variable:

- Sulcus Bleeding Index (Mombelli 1987):

- Grade 0: No bleeding on probing around the implant's gingival margin.

- Grade 1: Isolated bleeding points.

- Grade 2: Blood forms a confluent line on the gingival margin.

- Grade 3: Abundant bleeding or hemorrhage

3) Probing Depth Variables:

- Probing Depth: Distance from the gingival margin to the base of the periodontal pocket.

- Each implant assessed in 6 areas: disto-buccal, buccal, mesio-buccal, mesio-palatal, palatal, and disto-palatal.

- Periodontal probing pressure: 0.25 N using a Colorvue UNC12 periodontal probe (Hu-Friedy, Leimen, Germany).

6) Immunological Variable:

- Peri-implant crevicular fluid (PICF) Samples:

- PICF samples were collected from the mesio-buccal implant sulcus using absorbent paper strips (Periopaper® Harco, Irvine, CA).

- PICF volume calculation: Measured using Periotron 8000®, calibrated with physiological serum. The readings were recorded in periotron units.

2.6.8.Statistical Analysis

2.6.9.Sample Size Calculation:

Using SPSS Statistics 21.00 and referencing a prior pilot study, the required sample size was determined. For a 95% power and 0.05 alpha risk to detect a probing depth difference, 60 patients per study group were needed after incorporating a 20% dropout buffer.

2.6.10.Data Analysis:

- Implants were the analyzed units.

- Descriptive statistics were computed for clinical and immunological variables.

- Normality was assessed via Kolmogorov-Smirnov tests.

- Homogeneity was tested using t-tests and chi-square tests for respective variables.

- Comparison between groups utilized chi-square tests for categorical variables and t-tests for quantitative variables, with significance set at $p < 0.05$.

3.RESULTADOS

TABLE 1.1 PPD mm ± Standard Deviation(SD)

GRUPO	BASELINE	1 MONTH	3 MONTH	6 MOTN
TEST	3.62 ± 01.5	de 2,91 ± 0.22*	3.08 ± 0.16*	3.05 ± 0.25*
CONTROL	3.26±0.19	2.93 ± 0.28	de 3.07 ± 0.16	3.24 ± 0.24**

In the case of the CONTROL group, the average change in probing depth one month after the initial measurement is -0.33 ± 0.10 mm, which represents a 10.12% reduction compared to the initial average value. From one month to three months, there is a change of 0.14 ± 0.10 mm, which represents a 4.78% increase compared to the average value at one month. From three months to six months, there is a change of 0.18 ± 0.09 mm, which represents a 5.86% increase compared to the average value at three months, as shown in Figure1.

In the case of the TEST group, the average change in probing depth one month after the initial measurement is -0.72 ± 0.24 mm, which represents a 19.83% reduction compared to the initial average value. From one month to three months, there is a change of 0.17 ± 0.12 mm, which represents a 5.81% increase compared to the average value at one month. From three months to six months, there is a change of 0.03 ± 0.012 mm, which represents a 0.65% increase compared to the average value at three months, as shown in Figure1.

In the first month, a p-value of 0.004* (less than 0.05) indicates significant differences between the probing depth changes of the two groups, with the control group showing a significantly greater change.

From one to three months, a p-value of 0.639* (greater than 0.05) indicates no significant differences between the groups in this period.

From three to six months, a p-value of 0.032 *(less than 0.05) indicates significant differences between the groups, with the TEST group showing a significantly greater change.

3.2.BLEEDING ON PROBING

TABLE 2.1BOP %(SD%)

GROUP	BASELINE	1 MONTH	3 MONTH	6 MONTH
TEST	60%(10%)	3.5%(2%)*	7%(3%)*	18%(0.6%)*
CONTROL	63%(9%)	30% (5%)**	42%(4.5%)**	54%(6.5%)**

TABLE 2.2 BoP Variations relative to initial situation

GROUP	BOP 1 Months	BOP3 months	BOP 6 months
TEST	- 94.21%(-1.14±0.19)	+6.61%(0.08± 0.05)	+ 19.01%(0.23± 0.10)
CONTROL	- 52.76%(0.67±0,16)	+ 18.90%(0,24 ± 0.09)	+ 18.90%(0.24 ± 0.13)

The p-values of the test statistics for the TEST group are all less than 0.05*, indicating that the changes in bleeding intensity between each time point in the study are significant.

In the first month, a p-value of less than 0.001 *(less than 0.05) indicates significant differences in probing depth changes between the groups, with the control group showing a significantly greater change in bleeding intensity, shown in Figure2.

From one to three months, a p-value of 0.002 *(less than 0.05) indicates significant differences between the groups, with the TEST group showing a significantly greater change in bleeding intensity.

From three to six months, a p-value of 0.835* (greater than 0.05) indicates no significant differences in bleeding intensity changes between the groups in this period

3.3.Plaque index

Table2.3 Plaque index %(SD%)

GROUP	BASELINE	1 MONTH	3 MONTH	6 MONTH
TEST	55.5% ± 8%	15% ± 4.5%.	25.5% ± 4.5%	43% ± 3.5%.*
CONTROL	52% ± 6%.	32% ± 4.5%.	42% ± 5%	is 43% ± 4%.**

For the TEST group, the average change in plaque one month after the initial measurement is -40.5% ± 9.5%, which represents a 72.97% decrease from the initial average value. From one month to three months, there is a change of 10.5% ± 2.5%, which represents a 70.00% increase from the average value at one month. From three months to six months, there is a change of 0.5% ± 5%, which represents a 1.96% increase from the average value at three months, as shown in Figure3.

In the TEST group, p-values are less than 0.05* for the periods from baseline to one month and from three to six months, indicating significant changes during these times. However, the p-value for changes between three and six months is 0.228, which is not significant.

In the CONTROL group, p-values are less than 0.05** for the periods from baseline to one month and from one to three months, indicating significant changes. However, the p-value for changes between three and six months is 0.913, which is not significant.

3.4.Periotron VALUES

Table2.4 Periotron Values and their variation (Figure1.)

GROUP	BASELINE	1 MONTH	VARIATION
TEST	108.37 ± 14.65	70.97 ± 11.01	-37.40 ± 14.03*
CONTROL	97.00 ± 12.09	75.60 ± 11.42	-21.40 ± 9.73**

In the case of the CONTROL group, the value of the test statistic is less than 0.001**, which is less than 0.05. Therefore, we find evidence to say that there has been a significant decrease in the Periotron values in the CONTROL group. The same is true for the TEST group*.

The p-value of the t-test statistic is 0.054, which is greater than 0.05. Therefore, we do not find statistical evidence to say that the changes in Periotron values between the two groups are significantly different.

4.1.DISCUSSION

The present study aimed to evaluate the efficacy of a particular intervention on periodontal health parameters, including probing depth, bleeding on probing (BOP), plaque index, and Periotron values. The results revealed noteworthy findings regarding the effects of the intervention on these parameters over a period of six months.

The use of the FOX III 980 nm diode laser in the treatment of peri-implant mucositis has demonstrated promising results in terms of reducing inflammation and promoting healing. Our findings are consistent with previous studies that have highlighted the efficacy of diode lasers in periodontal therapy.

For instance, Schwarz et al.(8) demonstrated that the application of diode lasers in the management of peri-implantitis led to significant improvements in clinical parameters, such as probing depth reduction and clinical attachment level gain. Similarly, Wawrzyk A,et al(9). found that diode lasers provided effective bacterial reduction and improved clinical outcomes in the treatment of peri-implant diseases.

In another study, Gonçalves et al.(10) demonstrated that both 980-nm diode and 1064-nm Nd:YAG lasers were highly effective in decontaminating implant surfaces from Porphyromonas

gingivalis and Enterococcus faecalis, highlighting their bactericidal properties and benefits in peri-implant care. These findings collectively reinforce the therapeutic benefits of diode lasers in managing peri-implant and periodontal conditions, supporting their use as a viable intervention to enhance clinical outcomes in dental implant maintenance and periodontal therapy. While our study provides valuable insights into the use of the FOX III 980 nm diode laser for treating peri-implant mucositis, there are some limitations to consider. The sample size was relatively small, and the follow-up period was limited Additionally, the study relied on the use of the Periotron to measure gingival crevicular fluid (GCF) flow rate. While the Periotron is a widely used and accepted tool, its sensitivity and specificity can vary depending on the calibration and handling by different operators, potentially introducing variability in the results. Another limitation is the potential for measurement error and operator bias, as the Periotron requires careful handling and consistent technique to ensure accurate readings. Future studies with larger cohorts and longer follow-up periods are necessary to validate our findings and assess the long-term benefits of laser therapy in peri-implant mucositis.

Moreover, comparative studies involving other types of lasers, such as erbium-doped yttrium aluminum garnet (Er:YAG) lasers, would provide a more comprehensive understanding of the relative advantages and limitations of different laser systems in peri-implant therapy. Nevertheless, an important factor to consider in the context of peri-implant health is the influence of tobacco use on BOP. Tobacco smoking is well-documented to exacerbate periodontal disease and increase BOP due to its detrimental effects on the immune response and vascular health of the gingival tissues. In our study, the significant reduction in BOP observed in the TEST group, which are smokers, underscores the potential of diode laser to mitigate the adverse effects of smoking on periodontal health. This reduction in bleeding not only does indicates improved periodontal stability but also suggests enhanced tissue healing and inflammation control, which are crucial for the long-term success of implants in smokers. Therefore, the efficacy of diode laser therapy in reducing BOP in smokers highlights its valuable role in improving peri-implant health outcomes in this high-risk patient population

5.CONCLUSION:

The findings of this study suggest that laser therapy may have beneficial effects on periodontal health parameters, including probing depth, bleeding on probing, plaque index, and Periotron values. The TEST group exhibited superior outcomes in terms of probing depth reduction and bleeding on probing compared to the CONTROL group, particularly in the later stages of the study. Additionally, the TEST group demonstrated a more substantial reduction in plaque index compared to the CONTROL group, indicating the potential efficacy of the intervention in promoting oral hygiene practices. However, both groups exhibited comparable reductions in Periotron values, suggesting similar effects on gingival fluid flow. Further research is warranted to elucidate the long-term effects and mechanisms of action of the intervention on periodontal health outcomes.

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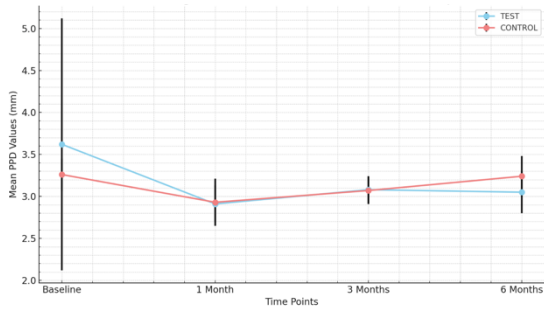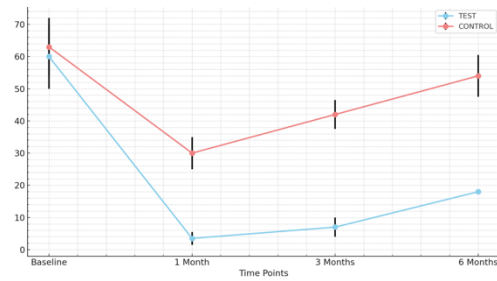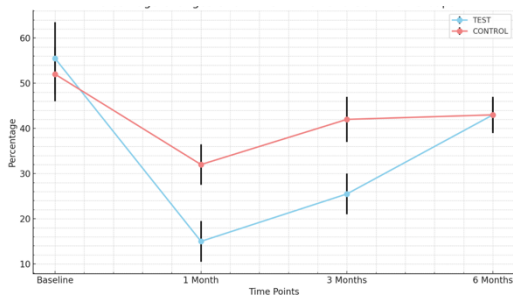
ANNEX

Figure1. PPD Change

Figure2. BOP Change

Figure3. Plaque Change

Figure4. Periotron Change