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ORIGINAL ARTICLE

Assessment of clinical efficacy of 445 nm Diode laser as an adjunct to Kirkland flap surgery in the management of periodontitis – a split mouth randomized clinical trial

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Abstract
Aim of this study is to assess the clinical efficacy of 445 nm Diode laser as an adjunct to Kirkland flap surgery in management of periodontitis. Type of study is a Split mouth clinical trial in which a total of 13 patients were recruited based on specific inclusion and exclusion criteria. In each participant, random allocation of selected sites into test and control in contralateral quadrants was done. Clinical parameters such as probing depth and clinical attachment loss was measured in control and test sites using occlusal stents. Flap surgery was carried out 6 weeks after phase I therapy and the selected contralateral sites with a probing depth of > 5mm were subjected to surgical therapy. In a test quadrant, 445 nm diode laser with a power of 0.8 W, CW mode, 320 µm fiber, in non-contact mode was used as an adjunct to flap surgery. Primary outcome variable assessed was change in PPD between baseline, pre-operative, 1-, 3- and 6-months post-surgery. Secondary outcomes variables assessed were Clinical attachment loss at baseline, pre-operative, 1, 3 and 6 months, visual analog scale at days 3 and 7 and patient satisfaction index at day 7 post surgery. Surgery for the second site (Test/control) in the contralateral quadrants was performed 1 week after the first surgery. A higher reduction in probing depth and gain in CAL was observed in test site at 1, 3 and 6 months follow up amongst all the included participants. VAS score was lower at the test site as compared to the control sites. PSI scores were similar in both the sites. The adjunctive use of 445nm diode laser to surgical periodontal therapy contributed to improved short term clinical outcomes as assessed at the end of 6 months post- surgery. VAS score indicative of post -surgical discomfort were also lower for the laser treated sites. Hence adjunctive use of laser (445 nm wavelength) can be recommended for achieving more predictable clinical outcomes.

Keywords 445 nm wavelength · Laser – tissue interaction · Periodontal pocket · Surgical periodontal therapy

Introduction

Periodontitis is a chronic inflammatory condition characterized by progressive destruction of the supporting tissues of the teeth. It is multifactorial in nature, marked by complex interactions between pathogenic microorganisms and the host immune system along with genetic and environmental influences [1]. A dysbiotic oral microbiome is the primary etiological factor that triggers a cascade of inflammatory events ultimately resulting in tissue destruction [2]. The clinical manifestations of periodontal disease include bleeding on probing, increase in probing pocket depth (PPD) and clinical attachment level (CAL), tooth mobility, tooth loss and radiographic bone loss [3]. The primary goals of periodontal therapy are to preserve, improve, and maintain the natural dentition, dental implants, periodontal and peri-implant tissues to achieve health, comfort, esthetics and

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function [4]. Non-surgical periodontal therapy comprising of scaling and root planing (SRP) remains the gold standard therapeutic modality and results in mechanical debridement of pathogenic plaque and calculus. However, SRP alone may not result in total elimination of the pathogenic biofilm [5]. As the plethora of periodontal micro-organisms are tissue invading in nature, the mere removal of the biofilm from the tooth surface would not suffice hence there is a need for an adjunct therapy to target these tissue invading bacteria [1]. This can be achieved by various treatment modalities such as systemic anti microbial therapy, systemic host modulation, local drug delivery, surgical periodontal therapy, lasers, photo dynamic therapy [1].

Lasers, represents a form of non-ionising electromagnetic radiation with proven anti-bactericidal activity, haemostatic effect and supports wound healing [6]. These properties render the use of Lasers as a viable adjunct in periodontal tissue management. Periodontal pocket reduction can be predictably achieved by using lasers along with conventional therapy [7]. Diode lasers have been used effectively in the management of periodontitis. Their wavelengths exhibit strong absorption in darkly pigmented bacteria, leading to a direct, amplified impact on the red and orange complex bacteria associated with periodontitis [8]. Laser assisted Phase I therapy aids in the debridement of the infected periodontal pocket. The usage of lasers has no detrimental effect on the healthy tissues beneath the non-healing granulation layer, thereby significantly resulting in removal of the "bio burden" and better healing outcomes [9].

A few clinical trials have been conducted on the use of Diode laser as an adjunct to periodontal surgery. These trials have reported improved clinical outcomes following laser assisted periodontal therapy. In a randomized clinical trial by Lobo TM et al [10],the authors reported that diode laser with the wavelength of 940nm provided additional benefits to open flap debridement in terms of decreased gingival index scores and a greater reduction in gingival inflammation in the laser treated test group. Another clinical trial by Agarwal P et al [11]' the authors reported that diode laser with the wavelength of 810nm provided additional benefits to Modified Widman flap surgery in terms of clinical parameters like probing depth and clinical attachment loss. Jonnalagadda BD et al [12] have shown in their study that flap surgery with adjunctive use of 810nm diode laser presented comparable results with periodontal flap surgery alone in terms of clinical parameters such as probing depth, clinical attachment level, plaque index and gingival index over a 6-month period. Janani K et al [7] reported the use of a 970 nm diode laser as an adjunct to Kirkland flap surgery resulted in greater reduction in clinical parameters assessed as compared with Kirkland flap surgery alone.In the recent past, a diode laser system emitting a wavelength of 445 nm, belonging to the visible spectrum was developed for dental soft tissue surgery. As the literature pertaining to the clinical efficacy of 445nm Diode laser as an adjunct to periodontal flap surgery is sparse, the objective of the present study was to evaluate the clinical efficacy of 445nm diode laser as an adjunct to Kirkland flap surgery versus Kirkland flap surgery alone in the surgical management of periodontitis by a split mouth clinical trial design.

Materials and methods

Patient recruitment

This Randomized split mouth clinical trial was carried out at the Department of Periodontology and Implantology of Sri Ramachandra Institute of Higher Education and Research, Chennai within the time period of January 2022- December 2022. Six months follow up was completed by June 2023. The ethics approval for the conduct of the trial was obtained from the Institutional Ethics Committee, Sri Ramachandra Institute of Higher Education and Research (IEC/22/FEB/169/10). Registration was done in the Clinical Trial Registry of India (CTRI/2022/10/046490). Each patient was informed about the possible risks of the study and a written informed consent was acquired from all the patients in accordance with the Declaration of the World Medical Association 1975 in Helsinki, revised in 2000.

The inclusion criteria were as follows:

- Individuals between 18–50 years of age.
- Both genders (Male/ female)
- Patients having moderate to severe chronic periodontitis with contralateral sites having PPD and CAL ≥ 5mm, 6 weeks after completion of phase 1 therapy (scaling and root planing)
- Radiographic evidence of horizontal bone loss at the selected sites
- Systemically healthy individuals.

Exclusion Criteria:

- Smokers
- tobacco chewers
- Pregnant women
- lactating mothers
- Immunocompromised patients
- Patient undergoing orthodontic treatment
- Patients with previous history of periodontal treatment were excluded from the study.

In the first phase of the study, 100 patients were enrolled from the Department of Periodontology. After screening, 55 patients were excluded for the following reasons: did not

meet the inclusion and exclusion criteria ($n=45$), declined to participate ($n=30$), did not report for further management—were lost during the first visit ($n=2$). Finally, a total of 13 patients (5 male & 8 females) were enrolled for the study (Fig. 1). The clinical trial was conducted from January 2022 to April 2023 in agreement with the CONSORT guidelines.

Clinical examination

A full-mouth periodontal evaluation was performed in all patients. Probing pocket depth (PPD) and Clinical Attachment Level (CAL) were measured at six sites per tooth. Probing pocket depth can be assessed by gently inserting a graduated UNC 15 periodontal probe until resistance is

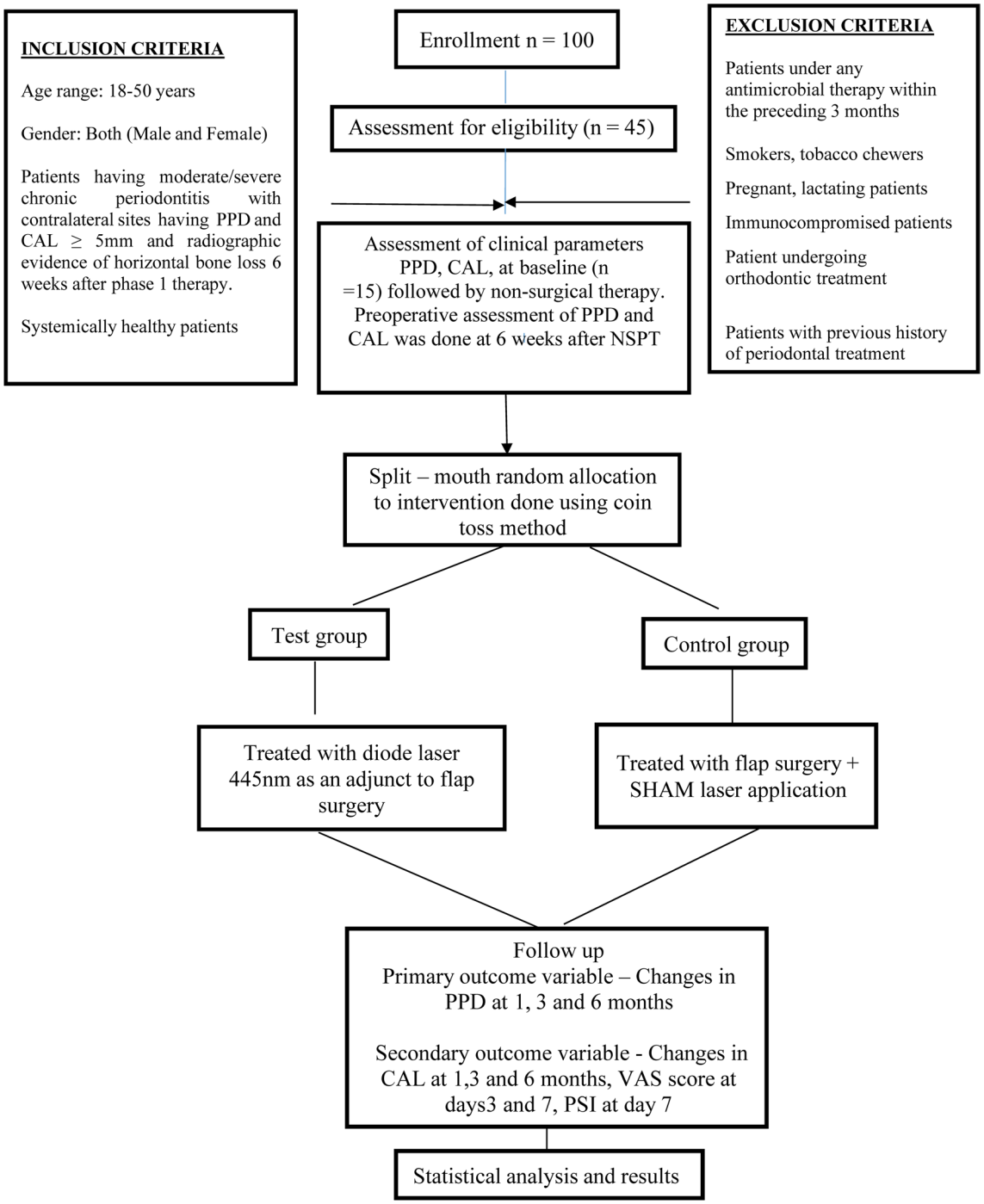


Fig. 1 CONSORT flow diagram of the study

encountered at the base of the sulcus. The depth from the free gingival margin to the base of the sulcus was measured in millimeters at six sites around the tooth at baseline,. pre-operative (six weeks after phase 1 therapy), 1, 3 and 6 months post-operative [13]. Clinical attachment level (CAL) is calculated from a fixed reference point (cementoenamel junction), and it is measured by calculating the distance from the CEJ to the base of the pocket at baseline, pre-operative (six weeks after phase 1 therapy), 1, 3 and 6 months follow up [14]. A custom stent was prepared and seated occlusally at the test and control sites to standardize the angulation of the probe at baseline, pre-operative and follow up visits. Patient reported outcomes measures such as visual analog scale and patient satisfaction index were assessed in this trial. Visual Analog Scale Score (VAS) is used to assess the patient discomfort, wherein the score is determined by the patient choosing a continuum between "No pain" and "worst pain", providing a range of scores from 0–10 [15]. A higher score indicates greater pain levels and the VAS scores were assessed at day 3 and day 7 post surgery. The Patient Satisfaction Index (PSI) recorded on day 7 was used to describe self-evaluation of the outcome, and a response of 1 or 2 was considered to indicate a satisfying outcome whereas 3 or 4 indicated a dissatisfied outcome [16].

Randomization to treatment

Randomization of the intervention in the selected sites from the contra lateral quadrants, in each patient was performed by simple randomization method using coin toss method. Kirkland flap with adjunctive use of 445 nm diode laser was the intervention in the test sites whereas Kirkland flap surgery with sham application of the 445 nm diode laser was performed in the control quadrant. The participants were blinded for the intervention and hence were not aware of the nature of laser application.

Surgical procedure

Six weeks after completion of phase 1 therapy, the pre-operative clinical parameters were recorded by a single operator (VV). The allocated surgical / laser intervention was carried out by the same operator (VL) for all patients. A 7 day interval was provided between the test (Kirkland flap + 445nm diode laser) and control (Kirkland flap + SHAM laser) interventions for each patient. In the test site after proper isolation of the surgical field, the operative sites were anesthetized using 2% lidocaine hydrochloride with adrenaline (1:200,000) and kirkland flap surgery was performed. In brief, crevicular incisions were made using Bard-Parker No. 15 blade on the facial and lingual/palatal surfaces of the involved area (Fig. 3a, b). A full-thickness mucoperiosteal flap involving 3–4 teeth at Test/ control sites was reflected using a periosteal elevator taking care to preserve the maximum amount of gingival connective tissue in the flap exposing the root upto 2mm of alveolar bone (Fig. 3c). After root exposure, open flap debridement was done. The root surfaces were planed and the flap trimmed to remove granulation tissue tags and minimize bleeding (Fig. 3d). A 445 nm wavelength was selected in the SiroLaser Blue unit and was used as an adjunct to flap surgery at the test sites (Fig. 2 a, b). The 445 nm laser was used with a power setting of 0.8 W, continuous wave mode of operation, with a 320 µ fiber tip in contact mode to remove the entire visible epithelium



Fig. 2 **a, b** 445 nm SIRO blue laser with power settings

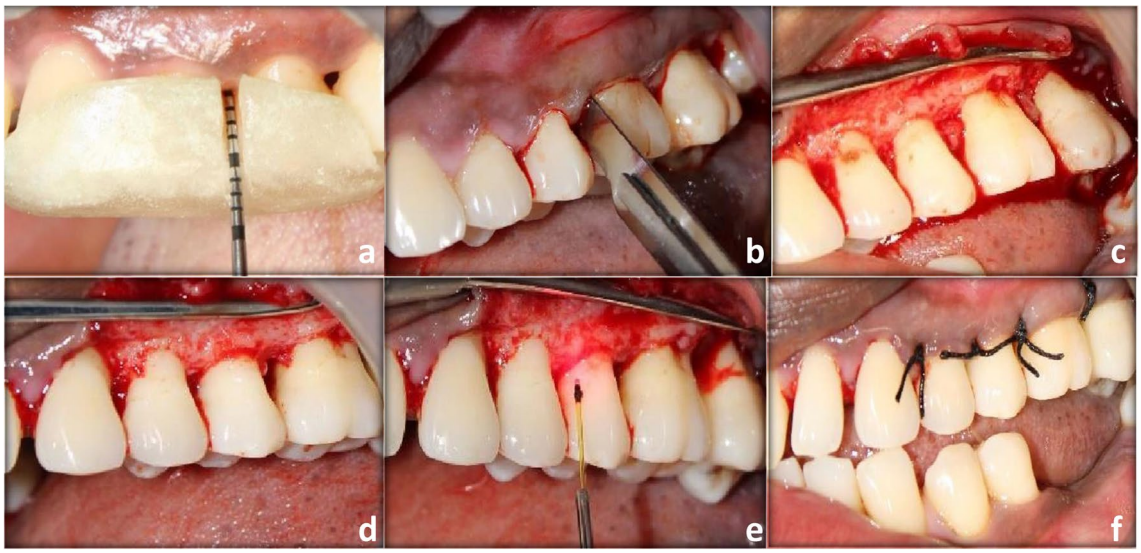


Fig. 3 **a-f** Represents clinical pictures of the procedure at the test site (Kirkland flap surgery with adjunctive use of 445 nm diode laser). **a** Pre-operative probing depth value with UNC 15 probe and occlusal stent, **b** Crevicular incision using Bard parker no.15 blade, **c** Full thickness mucoperiosteal flap elevated, **d** Open flap debridement done, **e** Application of Diode laser with wavelength of 445 nm, 0.8w, continuous mode, **f** Flaps approximated and sutured with 3–0 black silk suture

in the inner side of the flap by placing the fiber optic tip at a 45 degree angle to the inner aspect of the flap (Fig. 3e). Horizontal overlapping strokes in parallel paths were used on the inner lining of both facial and palatal/lingual flaps from the free gingival margin to the bottom of the apical aspect of the flap for about 10 s in relation to each tooth. The fiber tip was inspected frequently, and any accumulated tissue and debris was wiped off with gauze soaked in saline. The duration of treatment session lasted around 60–80 s. The fiber was also used to clean any granulation tissue in the interdental area between the teeth. Following this, the sites were irrigated with normal saline, a high-volume suction apparatus was additionally used to clear the field, and the flaps were approximated (Fig. 3f).

One week later, Kirkland flap surgery was performed in the control site with Sham application of the laser. The Sham application involved use of the laser without activating it and performing a sham motion at the control site during the surgery. The mucoperiosteal flap was approximated at the test and control sites using 3–0 black silk sutures thereby achieving primary wound closure (Fig. 4a-f).

Post operative care and follow—up

On the first day following surgery, the patients were instructed to avoid chewing on the operated side and analgesics were prescribed. Patients were advised to rinse the mouth daily with a solution of 0.2% chlorhexidine digluconate for 7 days. All patients were placed on a strict maintenance schedule following surgery. Recall appointments were scheduled once in the 1st, 3rd and 6th month. At every recall appointment, oral hygiene was evaluated and reinforced.

Outcome variables assessed

The primary outcome variable assessed in the study was Probing pocket dept and the secondary outcomes variables were Clinical attachment level, Visual analog scale scores, patient satisfaction index scores. PPD, CAL were assessed in the 1st, 3rd and 6th month follow up time points. Patient related outcome measures such as VAS scores were evaluated at day 3 and day 7 post surgery. PSI score was evaluated at day 7 post surgery. All parameters (outcome variables) were assessed at baseline, pre and post operative by the same investigator (VV).

Statistical analysis

According to the power analysis, a sample size of 26 quadrants in 13 patients was determined to have 95% statistical power [7]. Any one site of the patient was set as a test unit for statistical analysis and evaluation. The data collected was not normally distributed, hence non parametric analysis was performed for both between and within sites (Test and control sites) comparison. The difference in the clinical parameters over time between test and control sites was assessed by Mann–Whitney U test. Wilcoxons Signed Rank test was used for testing the significance of changes in the clinical parameters and VAS scores within the Test and Control sites (intragroup comparison).

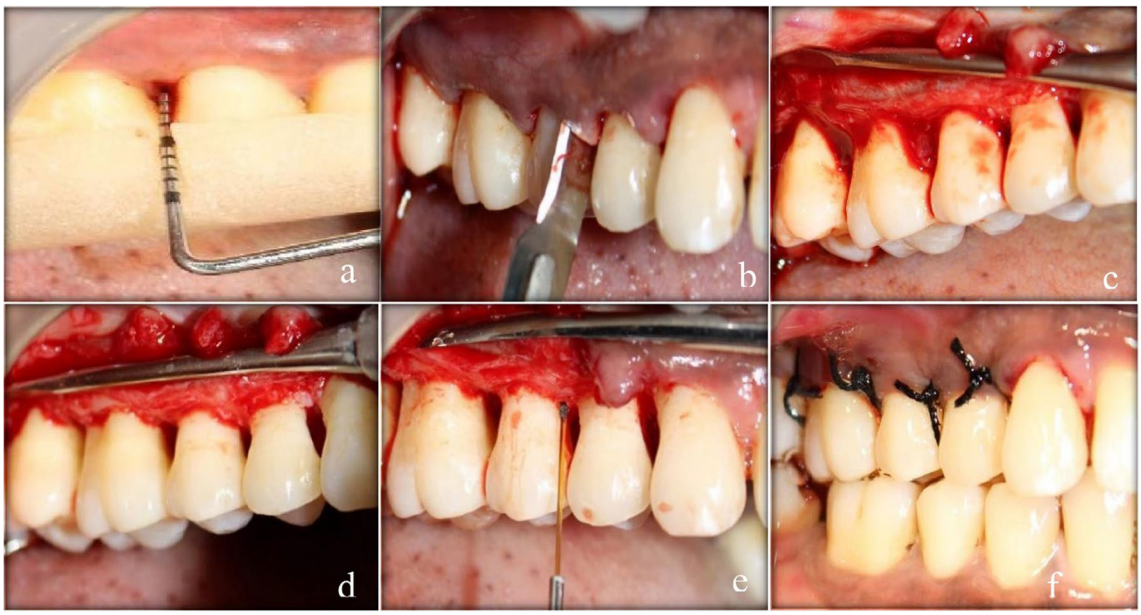


Fig. 4 **a-f** Represents clinical pictures of the procedure at the control site (Kirkland flap surgery with Sham laser application). **a** Pre-operative probing depth with UNC 15 probe and occlusal stent, **b** Crevicular incision using Bard parker no.15 blade, **c** Full thickness mucoperiosteal flap elevated, **d** Open flap debridement done, **e** Treated with Sham laser – placement of 445 nm diode laser without activation, **f** Flaps approximated and sutured with 3–0 black silk suture

Table 1 Demographic data of study participants

SI.NO	Variables	N	Distribution		*P* value
1	Age (mean ± std.deviation)	13	41.77 ± 13.461		NA
2	Gender (Male/Female)	13	(5/8)		NA
3	PPD – P (mm) (mean ± std. deviation)	13	Test site	Controlsite	0.785
			5.08 ± 0.760	5.08 ± 0.954	
4	CAL – P (mm) (mean ± std. deviation)	13	5.15 ± 0.555	5.15 ± 0.555	1.000

**PPD-P* Probing Pocket Depth pre-operative, *CAL-P* Clinical Attachment Level pre-operative

Results

Thirteen patients, with a mean age 41.77 years, were enrolled in the clinical trial. The data analysis was performed for all the 13 participants who attended the baseline, pre-operative examination, treatment and follow-up appointments at the first, third and sixth month. The study had a split mouth design and hence at pre-operative examination, no significant differences were evident between the sites for the parameters assessed (Table 1).

Comparison of outcome variable assessed between test and control sites

The mean values of the Probing Pocket Depth assessed at the post operative time points for test and control sites

Table 2 Comparisons of Probing Pocket Depth (PPD) values between test and control sites at Pre-operative (PPD-P), 1 month, 3 months and 6 months assessed using Mann–Whitney U test

	Group	N	Mean	Std. Deviation	*P* value
PPD-P	Test	13	5.13	.743	1.000
	Control	13	5.13	.915	
PPD—1 month	Test	13	2.69	.630	0.040*
	Control	13	3.38	.961	
PPD—3 month	Test	13	2.00	.000	0.000*
	Control	13	2.64	.505	
PPD—6 month	Test	13	1.91	.302	0.438
	Control	13	2.09	.701	

* $p \leq 0.05$ – Statistically significant

are summarized in (Table 2). The mean PPD values at 1 month (2.69 ± 0.630 mm), 3 months (2.00 ± 0.000 mm) and 6 months (1.91 ± 0.302 mm) in the test site were lower as compared to the control site at 1 month (3.38 ± 0.961 mm), 3 months (2.60 ± 0.516 mm) and 6 months (2.09 ± 0.701 mm). A significance reduction in the PPD values was observed in the test sites at 1 month ($p = 0.040$), 3 months ($p = 0.000$) and 6 months ($p = 0.438$) as compared to control sites.

The mean values of the Clinical Attachment Level for test and control sites at different time points assessed are summarised in (Table 3). The mean CAL values at 1 month (3.77 ± 1.013 mm), 3 months (3.27 ± 1.009 mm) and 6 months (3.27 ± 1.009) were lower in test sites as compared to control sites at 1 month (4.69 ± 0.751 mm), 3 months (3.91 ± 0.944 mm) and 6 months (3.91 ± 0.944) indicating higher gain in CAL in test sites as compared to control sites. A significant CAL gain was noted in the test site at 1 month follow up ($p = 0.014$) as compared to control sites. No significant difference in CAL scores was observed between test and control sites at 3 months and 6 months follow up.

Table 4 summarizes the mean Visual Analog Scale scores on day 3 and day 7 for test and control sites. The mean VAS score on day 3 and day 7 for test sites were lower (1.53 ± 0.990 and 0.07 ± 0.258) as compared to control sites on day 3 and day 7 (1.87 ± 0.990 and 0.20 ± 0.414) respectively. No significant difference in VAS score was observed between test and control sites on days 3 ($p = 0.429$) and day 7 ($p = 0.291$).

Table 5 summarizes the mean PSI score assessed on day 7 post surgery for test sites (1.93 ± 0.258) and control sites (1.73 ± 0.458). No statistically significant difference was observed between PSI scores at test and control sites on day 7 ($p = 0.152$).

Table 3 Comparisons of clinical attachment level scores between test and control sites at Pre-operative (CAL-P), 1 month, 3 months and 6 months assessed using Mann–Whitney U test

	Group	N	Mean	Std. Deviation	*P* value
CAL-P	Test	13	5.20	.561	1.000
	Control	13	5.20	.561	
CAL—1 month	Test	13	3.77	1.013	0.014*
	Control	13	4.69	.751	
CAL—3 month	Test	13	3.27	1.009	0.142
	Control	13	3.91	.944	
CAL—6 month	Test	13	3.27	1.009	0.142
	Control	13	3.91	.944	

*$p \leq 0.05$ – Statistically significant

Table 4 Comparisons of visual analogue scale scores between test and control site at days 3 and 7 assessed using Mann–Whitney U test

	Group	N	Mean	Std. Deviation	*P* value
VAS—day 3	Test	13	1.53	.990	0.429
	Control	13	1.87	.990	
VAS—day 7	Test	13	.07	.258	0.291
	Control	13	.20	.414	

Intragroup comparison of outcome variable assessed in test sites (Kirkland flap with adjunctive use of 445nm Diode laser)

Supplementary Table (1–3) summarize the difference in mean values of PPD and CAL between pre-operative, 1 month, 3 months and 6 months post operative and VAS score on day 3 and day 7 in test sites post surgery. A significant reduction in PPD and gain in CAL was noted between pre-operative and 1 month, 3 months, 6 months post operative for PPD and CAL values ($p \leq 0.05$) and a significant reduction in VAS score was also evident ($p \leq 0.05$).

Intragroup comparison of outcome variable assessed in control sites (Kirkland flap with Sham laser application)

Supplementary Table (4–6) summarize the difference in mean values of PPD and CAL between pre-operative, 1 month, 3 months and 6 months post operative and VAS score on day 3 and day 7 for control sites post-surgery. A significant reduction in PPD and gain in CAL was noted between pre-operative and 1 month, 3 months, 6 months post operative for PPD and CAL values ($p \leq 0.05$). In addition, the VAS scores were also found to be reduced significantly ($p \leq 0.05$).

Discussion

Periodontal therapy aims to prevent disease, reduce the rate of disease progression, restore lost periodontal tissues, and maintain the therapeutic goals that have been met [17]. Mechanical debridement of the soft and hard tissues eliminates the pocket epithelium and results in healing by

Table 5 Comparisons of patient satisfaction index score between test and control sites at day 7 assessed using Mann- Whitney U test

	Group	N	Mean	Std. Deviation	*P* value
PSI—day 7	Test	13	1.93	.258	0.152
	Control	13	1.73	.458	

the formation of long junctional epithelium [18]. The main drawback of mechanical debridement is the inability to reach the bottom of deep periodontal pockets wherein the pathogenic microorganisms invading the tissues continue to thrive [19]. In the recent past, considerable research has been done on the use of laser therapy as an alternative or an adjunct to traditional mechanical procedures for the management of periodontal and peri-implant diseases. This approach has shown that lasers aid in sculpting the gingiva and slows down the epithelial migration thereby promoting the growth of new connective tissue attachment. In addition, the flexible optical fibres allow for easy maneuverability and adaptation to the tooth anatomy, resulting in disruption of the subgingival biofilm with greater accuracy [20].

This split-mouth clinical trial compared the clinical efficacy of Kirkland flap surgery alone versus Kirkland flap surgery with adjunctive use of 445nm Diode laser in patients with generalized chronic periodontitis. The study observations revealed, that both treatments enhanced the clinical outcomes, however, the use of 445nm diode laser as an adjunct to Kirkland flap surgery yielded a significant improvement in PPD, CAL, VAS score and PSI scores as compared with Kirkland flap surgery alone at one, three and six months of follow-up visit. The split mouth clinical trial design was chosen in order to eliminate confounding variables related to age, gender, oral hygiene maintenance, differences in the rate of wound healing, patient compliance and regular follow-up.

It has been reported that depending on the wavelength emitted and the type of target tissue, different lasers have varying depths of tissue penetration and have multiple applications in periodontal therapy [21]. The Diode laser beam has a bactericidal effect and aids in sulcular debridement and soft tissue curettage with no impact on dental hard tissues when used correctly. In addition, it causes blood vessels to thermocoagulate, giving rise to its hemostatic effects. Diode laser radiation exhibits greater absorption and less penetration than Nd:YAG (Neodymium- doped yttrium aluminum garnet) laser, especially in highly vascular tissues [22]. In order to overcome effects of insufficient primary absorption, a diode laser system emitting light at a wavelength of 445 nm was introduced [23].The 445-nm diode laser has a higher absorption coefficient for collagen, haemoglobin, and melanin than the infrared wavelengths [23]. As a result, 445-nm diode laser systems appear to have excellent absorption properties in biological tissue and could therefore be very advantageous in periodontal surgical applications as well [23]. Due to its higher level of absorption, maximum coagulation with a limited depth of penetration during surgical incisions can be expected and is advantageous in surgical therapy.

Studies have evaluated the efficacy of different wavelengths of diode laser (810nm, 940nm, 970nm) as an adjunct to open flap debridement [7, 9]. Three different laser wavelengths have been used in continuous wave mode with predominantly 300 and 320 µm tips [9] being utilized for curettage and the removal of pocket epithelium. Power setting in the above-mentioned studies range between 1.5 W to 2.5W [7, 12]. The time duration of irradiation in above mentioned studies varied between 10 seconds to 60 seconds [7–9] applied continuously with one study using the laser in an intermittent mode (30 seconds irradiation followed by 10 seconds pause) [12]. In the present study, a new wavelength (445nm) was used for the removal of pocket epithelium and granulation tissue. The laser operating parameters used in this study were 320 µm tip, 0.8 W, continuous mode of operation with exposure time of 10 seconds in relation to each tooth. The tip diameter used in this study (320 µm) was the same as in the above-mentioned literature [7–9].

The 445 nm wavelength demonstrates close to 100 times more absorption in the chromophores namely melanin and hemoglobin as compared to 810nm, 940nm and 970nm [24]. Hence, the same clinical efficacy (granulation tissue removal) can be achieved when using 445nm wavelength even at lower power setting. The lower power also enables, better thermal relaxation for the chosen laser wavelength (445nm). The time duration of laser irradiation used in the present study (10 seconds per tooth) was similar to the parameters mentioned in the literature [7, 9]. Since each quadrant treated with the laser as adjunct to flap involved between 3 to 6 teeth, the total irradiation time ranged between 30 to 60 seconds which was within the time range mentioned in the literature [7, 9].

Periodontal probing depth reduction and Clinical Attachment Level gain represents two important clinical periodontal parameters which are used widely for assessing and comparing therapeutic outcomes [25]. Several clinical trials have investigated the clinical effects of diode laser as an adjunct to surgical therapy in the treatment of periodontitis. Research by Sopi M et al [26] in 2020, Janani K et al [7] in 2018, Petrovic MS et al [27] in 2017 evaluated the clinical efficacy of 980nm Diode Laser as adjunct to periodontal flap surgery. The authors reported that sites treated with laser (980nm wavelength) as adjunct to flap surgery demonstrated a higher decrease in PPD as compared to control sites at 3 months. There are controversial results in the literature regarding the additional benefits of lasers when compared with conventional treatment. Gokhale K et al [1] 2012, Kolamala N et al [28] 2021 reported contradictory findings with same laser wavelength (980nm), wherein no significant difference in PPD was observed between laser treated sites and control sites. Similar research by Agarwal A et al [29] in 2021, Lobo T et al [10] in 2017 and Suprit S et al [30] in 2016 on the efficacy of use of 940nm diode laser as an adjunct to flap surgery for the management of periodontitis revealed a significant improvement in PPD scores in test

sites on intergroup comparisons at 3 and 6 months. In addition, authors like Kemal U et al [31] in 2014, Sanz – Moliner D et al [9] in 2013 using 810nm wavelength reported significant reduction in PPD as a result of laser treatment at 6 months. In the present study, the mean PPD values at 1 month (2.69 ± 0.630 mm), 3 month (2.00 ± 0.000 mm) and six months (1.91 ± 0.302 mm) in laser treated test sites were significantly lower as compared to control (sham laser) sites (3.38 ± 0.961 mm), 3 month (2.64 ± 0.505 mm) and 6 months (2.09 ± 0.701 mm).

The observations of the present study with regards to PPD reduction are in agreement with the afore-mentioned studies [1, 8, 9, 19, 21, 25, 26]. In the present study, the greater reduction in levels of PPD in the sites treated by Kirkland flap with adjunctive diode laser use (445 nm wavelength) as compared with conventional Kirkland flap surgery group can be attributed to better absorption in hemoglobin by the 445 nm wavelength which resulted in effective de-epithelization of the pockets and granulation tissue removal.

Clinical attachment level is an important clinical parameter assessed in most studies for evaluating the effect of any intervention in periodontitis management. In the present study, the sites with ≥ 5mm pocket depth/clinical attachment loss and horizontal bone loss were treated by flap surgery. No regeneration was attempted during the procedure and hence a significant gain in CAL was not expected. The mean CAL values at 1 month (3.77 ± 1.013 mm), 3 months (3.27 ± 1.009 mm) and 6 months (3.27 ± 1.009) were lower in laser treated test sites as compared to control sites (sham laser) at 1 month (4.69 ± 0.751 mm), 3 months (3.91 ± 0.944 mm) and 6 months (3.91 ± 0.944). The above-mentioned difference in CAL was significant only at 1 month (P value = 0.014) whereas at 3 and 6 months no statistical significance could be demonstrated. Research by Sopi M et al. [26], Janani K et al. [7] and Petrovic MS et al. [27], evaluated the clinical efficacy of 980 nm Diode Laser wavelength as an adjunct to surgical periodontal therapy. The authors reported that the use of laser (980 nm wavelength) as an adjunct to flap surgery resulted in a higher CAL gain as compared to control sites at 3 months. In addition, Agarwal A et al. [29] and Lobo T et al. [10] have evaluated the efficacy of 940 nm diode laser as an adjunct to flap surgery and reported a significant gain in the CAL in laser treated sites.

The observations in our study are in consensus with the previous studies [7, 26, 27]. However, Gokhale K et al. [1] and Kolamala N et al. [28] reported contradictory findings for 980 nm wavelength, wherein no significant difference in CAL gain was observed between laser treated sites and control sites. Studies by Kemal U et al. [31] and Sanz – Moliner D et al. [9] evaluated the use of 810 nm wavelength as an adjunct to flap surgery and reported significant difference in CAL gain at 6 months in the laser treated groups. In the present study, the observed gain in CAL can be attributed to complete epithelial removal with the use of 445 nm diode laser, thereby possibly contributing to the formation of new connective tissue attachment in the diode laser assisted Kirkland flap surgery.

Patient Related Outcome Measures (PROM) has gained considerable importance in the recent past. Visual analog scale is a subjective pain assessment scale which is widely used to determine and score quantitatively, the post operative discomfort as reported by the patient [15]. In the present study, the mean VAS score at day 3 and day 7 for test sites were lower (1.53 ± 0.990 and 0.07 ± 0.258) than the control sites at day 3 and day 7 (1.87 ± 0.990 and 0.20 ± 0.414) although the difference was not statistically significant. The results of our study are in agreement with the findings of Agarwal A et al. [29] and Heidari M et al. [32] wherein the authors reported lower VAS scores in laser treated group as compared to the controls when evaluating the efficacy of 940 nm diode laser as an adjunct to flap surgery. Similar findings were also reported by Kolamala N [28] with 980 nm wavelengths when used as an adjunct in periodontal therapy at day 7.

Lasers have photobiomodulatory effect which enables faster healing when used with appropriate operating parameters. Study by Agarwal A et al. [29] evaluated the clinical effect of 940 nm diode laser as an adjunct to flap surgery on wound healing. The authors reported that the Wound Healing Index scores exhibited a significant, beneficial shift in the test group compared to the control group after one week. Similar results were reported by Jonnalagadda D et al. [12] for 810 nm and Kolamala N et al. [28] for 980 nm wavelengths when used as an adjunct to periodontal flap surgery. In the present study, the patient satisfaction with the procedure was assessed using the PS index. The PSI was first reported by Laurent et al. [33] in 2006, wherein the willingness of a patient to undergo the treatment again was evaluated. The observations of this study reported similar scores between test and control sites on day 7 ($p = 0.152$). This could be attributed to the study design which was a split mouth design with both interventions being carried out in the same individual with a time interval of one week.

A split mouth study design was chosen since there was an inherent advantage of eliminating inter-individual variations or patient-specific characteristics from the treatment effect estimates. The main limitation of this study is the small sample size. Further research with a larger sample size, comparison with an alternative wavelength at multiple intervals and long term follow up are needed.

Conclusion

To the best of our knowledge, this is the first study to evaluate the effectiveness of a 445nm diode laser as an adjunct to Kirkland flap surgery in the management of chronic

periodontitis. Within the limitations of the study, it can be concluded that the 445nm laser assisted Kirkland flap surgery provided a significant clinical benefit over short term (period of 6 months). However, further longitudinal studies are required to evaluate the efficacy of 445 nm wavelength as an adjunct to flap surgery in long term, which would provide the basis for an evidence-based surgical approach.

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Declarations

Ethics approval This study was performed in line with the principles of the Declaration of Helsinki-2013. Approval was granted by the Institutional Ethical Committee, Sri Ramachandra Institute of Higher Education and Research (Ethics No: IEC/22/FEB/169/10) and Clinical Trial Registration of India Registration was done: (CTRI Ref No: CTRI/2022/10/046490).

Consent to participate Informed consent was obtained from all the volunteers who contributed in this study.

Consent for publication Not applicable.

Competing interests The authors have no relevant financial or non-financial interests to disclose.

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