



Laterally closed tunnel technique with and without adjunctive photobiomodulation therapy for the management of isolated gingival recession—a randomized controlled assessor-blinded clinical trial

Vamsi Lavu^{1,2} · Norbert Gutknecht³ · Amrutha Vasudevan² · Balaji S.K² · Ralf-Dieter Hilgers⁴ · Rene Franzen⁵

Received: 21 May 2021 / Accepted: 2 September 2021 / Published online: 20 September 2021
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Abstract

The objective of this prospective randomized controlled single-center clinical trial was to prove the efficacy of adjunctive photobiomodulation in improving selected outcomes following the use of laterally closed tunnel technique for the management of isolated gingival recession. Nineteen participants (with isolated gingival recession) each treated by laterally closed tunnel technique were randomized to either add on treatment with control (sham laser application) or test group (photobiomodulation with 660 nm diode, 3.5 J/cm² per point of application). The primary outcome variable was change in recession depth and secondary variables included recession width, width of keratinized gingiva, periodontal biotype, and VAS score for pain assessment and EHS index for early wound healing assessment. Analysis was performed using a linear mixed effects model. There were no significant differences in the gingival recession depth ($p=0.8324$) and recession width ($p=0.969$) at 3-month follow-up. The VAS scores were significantly lower for the test (laterally closed tunnel technique + photobiomodulation) group as compared to control (laterally closed tunnel technique + sham laser) over time ($p < 0.0001$) as well as per site ($p=0.0006$). The Early Wound Healing Index scores were significantly higher in the test (laterally closed tunnel technique + photobiomodulation) group as compared to control (laterally closed tunnel technique + sham laser) group ($p < 0.0001$). The adjunctive use of photobiomodulation did not show a better outcome concerning recession depth but appears to provide faster healing of the surgical wounds and better patient comfort. The result needs further evaluation in particular with respect to long-term effect and due to limitation in sample size. Clinical Trial Registry of India: CTRI/2019/11/022012.

Keywords Photobiomodulation · Laterally closed tunnel technique · Recession coverage · Recession depth · Patient-related outcome measures

Introduction

Gingival recession is clinically manifested by an apical displacement of the gingival tissues, leading to root surface exposure. It is a concern for both patients and clinician for several reasons such as aesthetics, root hypersensitivity, erosion, and root caries [1].

The primary indication to treat isolated recession is to increase soft tissue thickness and stability to facilitate plaque control and prevent further periodontal inflammation and breakdown or root caries [1]. Achieving predictable coverage of gingival recessions still represents a challenge for the clinician due to difficulties in managing the soft tissues and poorer wound healing related to factors such as the large avascular surface, blood supply, differences in recession depth and position of the teeth [2].

✉ Vamsi Lavu
vamsi.aachen@gmail.com

¹ RWTH International Academy GmBh, Aachen, Germany

² Sri Ramachandra Institute of Higher Education and Research, Chennai, India

³ Clinic for Conservative Dentistry, Periodontology and Preventive Dentistry, University Hospital Aachen, RWTH Aachen University, Aachen, Germany

⁴ Institut Für Medizinische Statistik, RWTH Aachen University, Aachen, Germany

⁵ RWTH International Academy GmBh, Aachen, Germany

Coronally advanced flap (CAF), although a gold standard, is technique sensitive, has limitations due to placement of vertical incisions, difficulty in maintaining papilla integrity thereby compromising blood supply and may result in decreased vestibular depth and flap dehiscence due to increased flap tension [3]. A novel minimally invasive surgical approach laterally closed tunnel (LCT) has been recently introduced for the management of isolated gingival recession [4]. The laterally closed tunnel technique is a minimally invasive procedure which ensures predictability by tunneling, and mobilization of flap for graft coverage [4].

Photobiomodulation involve the use of lasers of visible or near infrared wavelengths (660–980 nm) at low power (0.05–0.5 W) on the tissues to enhance wound healing and/or pain relief [5]. Lasers have been used as adjuncts in root coverage procedures for several purposes such as donor site-palatal wound healing [6], biomodulation at recipient site for enhancing healing [7], and graft de-epithelialization [8]. In addition, photobiomodulation has been used an adjunct with Emdogain to enhance periodontal regeneration [9]. A systematic review by Al-Shibani et al. [10] showed that PBMT was effective in improving certain clinical parameters such as tissue thickness, post-operative discomfort, remaining wound area, and patient-related outcomes such as visual analogue score at follow-up. However due to the low number of included clinical studies, the authors reported more controlled trials needs to be performed to assess the healing outcomes.

We conducted a prospective randomized controlled single-center clinical trial to prove the efficacy of adjunctive photobiomodulation compared to sham laser in improving clinical parameters and patient-reported outcome measures following the use of laterally closed tunnel technique for the management of isolated gingival recession.

Materials and methods

A single-center prospective blinded randomized controlled clinical trial with two arm parallel group design to proof a superiority hypothesis was conducted. Patients visiting the out-patient Department of Periodontology & Implantology, Faculty of Dental Sciences, Sri Ramachandra Institute of Higher Education and Research (SRIHER), Chennai, India, fulfilling specific inclusion and exclusion criteria were enrolled in the study after obtaining informed consent. The study was approved by the Institutional Ethics Committee of Sri Ramachandra Institute of Higher Education and Research (IEC/19/APR/150/21) and was registered in the Clinical Trial Registry of India (Ref No: CTRI/2019/11/022012).

Inclusion and exclusion criteria

Patients with an age between 20 and 45 years, presence of isolated (single tooth) Cairo's RT1 (RT1-gingival recession with no loss of interproximal attachment) [11] maxillary/mandibular isolated gingival recessions, full mouth visible plaque score [12] and Bleeding score [13] of < 20%, and no medication known to interfere with periodontal tissue health/healing (steroids, calcium channel blockers, anti-epileptic agents, immune-suppressants, non-smoker (= never smoker), or former smoker (= does not smoke now and has not smoked at all for a minimum of the last 12 consecutive months)) are eligible to participate to the trial. The exclusion criteria were multiple adjacent gingival recessions, lingual recession in the selected teeth, current smokers, systemic chronic conditions known to be associated with periodontitis or with changes in systemic inflammation, pregnant or lactating mothers, presence of malocclusion/patients with orthodontic therapy in progress, and previous history of periodontal disease/surgical periodontal therapy.

Randomization and blinding

A randomization list was prepared, using the Big Stick algorithm with a maximal tolerated imbalance of 4 and an intended 1:1 allocation ratio at the Department of Medical Statistics, RWTH Aachen University and send to Dr. SKB. Sealed opaque envelopes were prepared accordingly by a co-investigator (Dr. SKB), who was not involved in the conduct of the study, in particular patient enrolment. The envelopes numbered from 1 to 38 are collected in a box. Patient enrolment was done by another investigator (Dr. AV), who also draws the next envelop from the box. The envelope is handed over to the surgeon Dr. VL, who opened the envelope prior to start of the surgery and applied the method indicated by the paper in the envelope.

To maintain assessor blinding the primary endpoint variable was measured by Dr. AV, who was unaware of the allocated treatment. Further to maintain blinding of most personnel involved in the trial as well as the patients, a sham laser application was applied in the control group, with the light guide being placed in the same application points and time periods as in the control group but without the laser being activated.

Surgical procedure

All surgical procedures were performed by the same operator (Dr. VL) with a longstanding clinical experience (10 years) in periodontal plastic surgery. After oral prophylaxis, under local anesthesia, root planning with curettes

and root conditioning with 5% tetracycline hydrochloride of the exposed root surfaces were performed. Laterally closed tunnel technique (LCT) was performed as described by Sculean and Allen [4] for both groups (Figs. 1, 2, 3 and 4).

Each patient was prescribed with analgesics and antibiotics after surgery. All patients were instructed to discontinue tooth brushing and avoid trauma at the surgical site for 4 weeks. A 60-s rinse with 0.12% CHX will be prescribed 3 times/day for first 4 weeks. Sutures were removed after 10 days in the palatal site and after 3 weeks if necessary, at the surgical site. Four weeks after surgery, patients were instructed to resume mechanical tooth cleaning with a soft toothbrush and received a professional oral cleaning. Patients were recalled at 3, 7, 10, 14 days, 1, 3, and 6 months for professional oral hygiene and review for which they were notified through phone calls prior to the date of the visit.

Photobiomodulation protocol for test group (modified from Dias SB et al. 2015) [6]

The photo biomodulation was performed with a 660 nm diode laser (DuoLase, Medsol India Pvt Ltd) with 50mw output power and a light guide tip with a beam diameter of 3 mm and area of 0.07 cm², when used in contact with the tissue. A total energy density of 17.5 J/cm² was achieved with irradiation at five different points [5 s at each point] in the wound area with energy density at each point being 3.5 J/cm². The light guide was kept perpendicular to the tissue in light contact with the wound site. The abovementioned protocol was performed at both the palatal wound (donor) site and surgical (recipient) site. The photobiomodulation therapy was done on day of surgery (baseline), third day, seventh day and tenth day post-surgery (Fig. 1). The sham laser application was done on the abovementioned days for the control group (Fig. 2).



Fig. 1 Sample case for test group (laterally closed tunnel technique + photobiomodulation) for recession management in upper left second premolar. **a** Pre-operative RT I recession. **b** De-epithelialization at tooth margin. **c, d** Tunneling with Sculean-Aroca Instruments.

e Connective tissue graft from palate. **f** Graft placement in recipient site. **g** Graft stabilization and suturing. **h** Photobiomodulation at palatal site. **i** Photobiomodulation at surgical site



Fig. 2 Sample case for control group (laterally closed tunnel technique + sham laser application) for recession management in lower anterior. **a** Pre-operative RT 1 recession. **b** De-epithelialization at tooth margin. **c, d** Tunneling with Sculean-Aroca Instruments. **e** Con-

nective tissue graft from palate. **f** Graft placement in recipient site. **g** Graft stabilization and suturing. **h** Sham laser application at palatal site. **i** Sham laser application at surgical site



Fig. 3 Sample case of test group for recession management in upper left second premolar. **a** Pre-operative RT 1 recession. **b** 3 months post-operative at same site

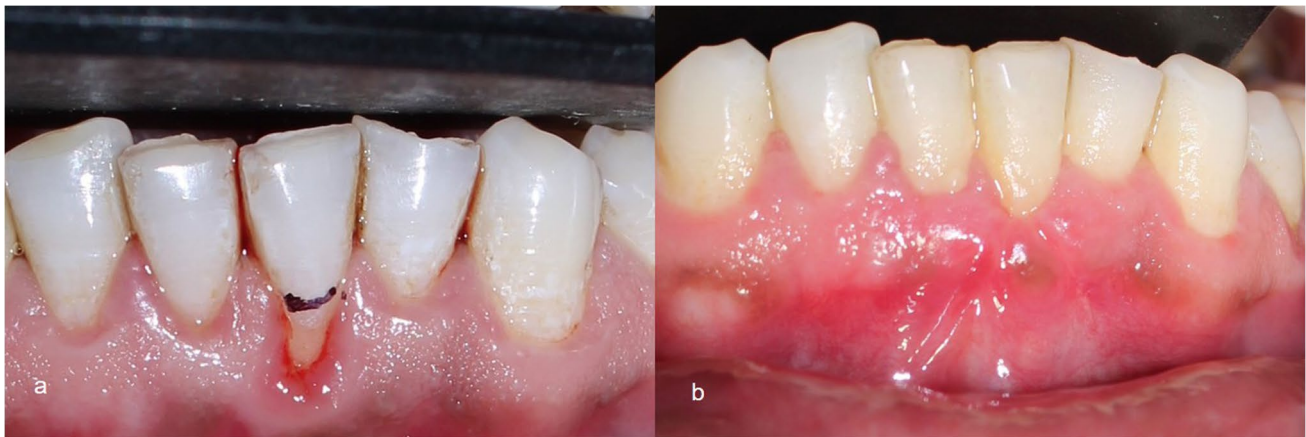


Fig. 4 Sample case of control group for recession management in lower anterior. **a** Pre-operative RT 1 recession. **b** 3 months post-operative at same site

Outcome variables assessed

The clinical measurements were taken at the facial aspect of the selected tooth before surgery (baseline) and at pre-determined post-operative time points (1 month and 3 months post surgery). The measurements were taken by an investigator blinded to the allocation who was calibrated prior to the start of the study. Gingival recession depth (RD), Gingival recession width (RW), Probing depth (PD), Clinical attachment level (CAL), Width of the keratinized gingiva (WKT) and periodontal biotype were assessed at baseline and post-operative time points.

The Primary outcome variable is change of recession depth after 6 month from baseline. Secondary outcome variables include recession depth, complete root coverage, increase in width of keratinized tissue, periodontal biotype [14], Visual Analogue Scale [15], and Early Wound Healing Index score [16].

Deviation from protocol

All patients randomized to the control group could be analyzed with the data obtained at the 3 month post-operative visit. However, in the test group, 4 patients who were prepared and posted for surgery did not report due to the Covid 19 pandemic situation and hence no surgery could be carried out. Further 1 patient was lost to follow up after receiving the surgery before the 3-month visit, because, the patient had moved to another city and could not come for further follow-up visits. As the 4 patients did not receive any treatment and the one dropout patient did not provide any post randomization data, the patients were excluded from the full analysis set. In addition, due to limitation of the Covid 19 pandemic situation, follow-up period has to be reduced to 3 month instead of the initially planned 6 months.

Statistical analysis

The sample size was calculated based on the findings of Francetti et al. [3] who observed mean residual recession depth at 6-month follow-up in the control group of 1.15 and in the test group of 0.44 with a common standard deviation of 0.62 resulting in an effect size of 1.145. Thus a reduced effect size of 1 was assessed as clinically meaningful effect. To proof this difference at the two-sided 5% significance level with a power of 80% using a t-test 17 patients per group are necessary (calculation nQuery 7.0, procedure MTT0). To allow for a rather high dropout rate of 10%, the total sample size of 38 patients was necessary, i.e., 19/group.

Statistical analysis was done with SAS statistical software version 9.4. Data for primary and secondary outcome parameter were described by mean values, standard deviations, frequencies and percentages. The primary endpoint change in recession depth was analyzed by fitting an ANCOVA model to the data of recession depth at 3 month, with group effect treatment and the covariable baseline recession depth. In a sensitivity analysis a linear mixed effects model was fitted to the data with random intercept and time to model the recession depth progress over time to study the effect of additional variables on the primary and secondary endpoints. Width of the keratinized gingiva (WOKG), recession width, VAS pain score, Early Wound Healing score, periodontal biotype, and complete root coverage were described by percentage. Appropriate linear contrast added to the fitted model was used to analyze further research questions. The analysis was based on the intention to treat population. The significance level was set to 5%.

Results

Demographic data of the study population and baseline parameters

A total of 38 subjects, 19 randomized to either the control group or test group, were enrolled in the trial. All control patients completed the 3-month follow-ups; however, only 14 participants of the test group completed follow-up. Details for non-participation are given in the section “[Deviation from protocol](#)” above and consort flow diagram (Fig. 5). Table 1 summarizes the demographic data of the study population and baseline clinical parameters and the participants were found to be matched for the baseline variables.

Analysis of the primary outcome variable (recession depth at 3 months)

The remaining mean recession depth at 3-month follow-up in the control group amounts to 0.632 (SD 0.895 mm) compared to 0.571 (SD 0.646) mm in the PBMT group and was

not statistically significantly different ($F=0.84$, $ndf\ 1$, $ddf\ 30$, $p=0.3654$) using the preplanned ANCOVA model (Supplementary Table 1, 2).

A linear mixed effects model was used to account for possible confounders (age, gender, baseline recession depth, time, and group). It was inferred from the analysis that apart from time ($p < 0.0001$) no factor modified the results for recession depth. The time effect describes a significant overall change in recession depth from baseline to 3-month follow-up across the groups. Of particular interest is the “interaction group by time” which states, that the changes from baseline to 3 months does not significantly differs between the treatment groups ($p=0.1755$) (Supplementary Table 3).

Analysis of the secondary outcome variable (recession width after 3 month)

The mean recession width after 3 months amounts in the control 0.632 (SD 0.89 mm compared to 0.643 (SD 0.745) mm in the PBMT group. The linear mixed effects model

Fig. 5 CONSORT flow diagram for the study

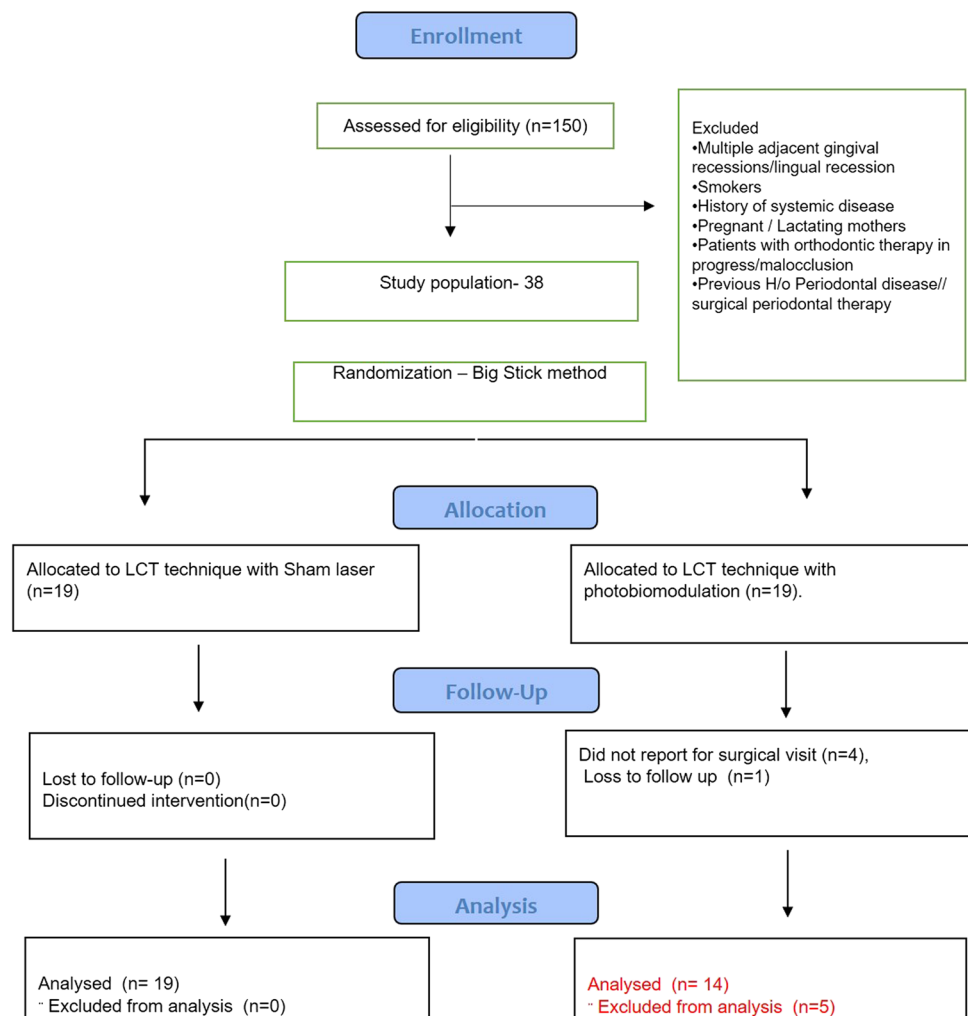


Table 1 Demographic data and baseline clinical parameters of study population

S.No	Category	Control intervention group (LCT+Sham)	Test intervention group (LCT+PBMT)
1	Number (<i>N</i>)	19	14
2	Age (mean ± SD) (years)	31.68 ± 6.20	31.21 ± 8.15
3	Male/female	11/8	9/5
4	Pre-operative recession depth (mm) (mean ± SD)	2.36 ± 1.01	2.71 ± 0.82
5	Pre op recession width (mm) (mean ± SD)	3.05 ± 0.62	3.35 ± 0.63
6	Pre-operative periodontal biotype (thin/thick)	13/6	9/5
7	Pre op width of keratinized gingiva (mm)	1.94 ± 1.35	2.28 ± 1.04
8	Oral Hygiene Index score	0.92 ± 0.88	0.77 ± 0.82

accounting for age, gender, baseline width, time and group showed a significant overall change in recession width from baseline to 3-month follow-up across the groups ($p < 0.0001$), but no significant influence of the other variables on recession width could be determined. In addition, no significant difference in recession width between the treatment groups ($p = 0.2478$) nor change over time between the treatment groups ($p = 0.4001$) could be detected (Supplementary Table 4).

Analysis of width of keratinized gingiva (WOKG)

The mean width of keratinized gingiva at 3-month follow-up in the PBMT was 4.42 (SD 1.22) mm compared 3.632 (SD 1.342) mm in the control group. The linear mixed effects model was used to account for possible confounders (age, gender, baseline recession width, time and group). It can be inferred from the analysis that apart from time ($p < 0.0001$), by means of a significant overall change in width of keratinized gingiva from baseline to 3-month follow-up within the groups, no significant influence of the other variables on width of keratinized gingiva could be determined (Supplementary Table 5). In addition, no significant difference in width of keratinized gingiva between the treatment groups ($p = 0.4367$) nor change over time between the treatment groups ($p = 0.1478$) could be detected (Supplementary Table 5).

Analysis of VAS score

The mean VAS—as patient reported outcome measure—appears to be lower on the surgical site compared to the palatal site to each of the time points with a lower VAS scores in the PBMT group as compared to the control group (Table 2).

The corresponding linear mixed effects model shows a significant difference over time ($p < 0.0001$), between sites ($p = 0.0006$), treatment groups ($p < 0.0001$) as well as the interaction of group by time ($p < 0.0001$) and group by site

($p = 0.0043$) (Supplementary Table 6). Considering the model base least square means shows, that.

- Overall, the control group shows significant higher VAS score than the PBMT group.
- VAS score decreases linearly over time.
- Mean VAS scores for the surgical site was significantly lower than the palatal site.
- The VAS score decreases faster in the PBMT group than in the control group.
- In the PBMT group, the VAS scores appear to be similar between surgical and palatal sites, whereas in the control group, the difference between surgical and palatal sites appears to be larger (Supplementary Tables 7–11).

Table 2 Summary of mean values of VAS on days 3, 7, 10, and 14 for control and test groups at the surgical site and at the palate

Group	Time	Site	<i>N</i>	Mean	Standard deviation
Control	3	Surgical	19	2.737	0.653
		Palatal	19	3.211	0.855
	7	Surgical	19	1.632	0.761
		Palatal	19	2.211	0.918
	10	Surgical	19	0.421	0.607
		Palatal	19	0.947	0.780
	14	Surgical	19	0.000	0.000
		Palatal	19	0.000	0.000
Test	3	Surgical	14	1.214	0.426
		Palatal	14	1.214	0.893
	7	Surgical	14	0.071	0.267
		Palatal	14	0.214	0.579
	10	Surgical	14	0.000	0.000
		Palatal	14	0.000	0.000
	14	Surgical	14	0.000	0.000
		Palatal	14	0.000	0.000

Table 3 Summary of mean values of EHS scores on days 3, 7, 10, and 14 for control and test groups at the surgical site and at the palate

Group	Time	Site	N	Mean	Standard deviation
Control	3	Surgical	19	3.000	2.236
		Palatal	19	4.158	1.864
	7	Surgical	19	4.474	2.038
		Palatal	19	3.842	2.141
	10	Surgical	19	6.053	1.471
		Palatal	19	5.421	1.710
Test	3	Surgical	14	5.929	1.439
		Palatal	14	5.643	2.098
	7	Surgical	14	6.500	1.225
		Palatal	14	5.714	2.234
	10	Surgical	14	8.143	1.406
		Palatal	14	8.143	1.657

Analysis of Early Wound Healing score (EHS)—secondary outcome variable

The following table shows the mean EHS scores split by site, time and treatment group. A higher mean EHS scores in the PBMT group at all time points was observed as compared to the control group (Table 3).

The linear mixed effect model analysis revealed a significant difference between time ($p < 0.0001$), group ($p < 0.0001$) as well as the interaction of group by site and time ($p = 0.020$) (Supplementary Table 12).

Periodontal biotype change at 3 months post-operative for control and test groups

The graph demonstrates a change in the periodontal biotype from a predominantly thin biotype at baseline to a thick biotype at 3-month follow-up among the recession sites for the control group ($n = 19$) (Supplementary Fig. 1).

The graph demonstrates a change in the periodontal biotype from a predominantly thin biotype at baseline to a thick biotype at 3-month follow-up among the recession sites for the test group ($n = 14$) (Supplementary Fig. 2).

Complete root coverage at 3 months post-operative control and test groups

Eleven out of 19 participants (58%) exhibited complete root coverage at 3 months post-operative (Supplementary Fig. 3). Seven out of 14 participants (50%) exhibited complete root coverage at 3 months post-operative (Supplementary Fig. 4).

Discussion

Laterally closed tunnel technique (LCT) is a novel technique proposed by Sculean and Allen in 2018 [4] for the management of isolated gingival recession. The authors reported complete root coverage rates between 70 and 75% based on the type of recession in the case series published [4].

The use of connective tissue graft (CTG) is considered the gold standard for obtaining recession coverage irrespective of the technique used for recession coverage [17]. The harvesting of the connective tissue graft from the palate results in morbidity such as pain and bleeding from site and affects the patient's quality of life till healing is complete. The soft tissue healing is enhanced by means of the influence of the particular laser wavelength on the cell metabolic process by photo chemical mechanisms. Lasers with 660–980 nm have been reported to have beneficial effects for soft tissue healing [5]. The photo biomodulatory activity of low level laser therapy for recession coverage procedures and at palatal wound healing sites has been attributed to minimizing the inflammatory phase of wound healing as assessed in an animal study by Fahimipour et al. [18]. The photobiomodulation also promotes epithelial cell proliferation [19] and fibroblast proliferation and collagen deposition [20] as demonstrated in in vitro cell culture-based studies.

Published literature has reported improved short-term clinical outcomes in terms of complete root coverage and improved healing of palatal wounds following the use of adjunctive photobiomodulation. Fernandes-Dias et al. [21] reported an improved percentage of root coverage and also increased complete root coverage outcomes in the LLLT + CAF (coronally advanced flap) group as compared to the CAF group alone. Other studies have reported positive results after LLLT irradiation in semilunar coronally advanced flap procedure [22], healing wounds of palatine mucosa caused by soft tissue graft harvest [23].

In the present study, a diode laser with a wavelength of 660 nm was used with an energy density of 3.5 J/cm² per point of application with five application points at surgical site and palatal donor site each. These settings were chosen based on the data published; wherein studies have shown 3–6 J/cm² stimulated wound healing by fibroblast proliferation/collagen production and reducing edema/inflammation [24–26].

The primary outcome variable assessed in the study was residual recession depth at the 3-month follow-up visit. The follow-up period used for analysis was 3 months and not 6 months as per study protocol (due to the Covid 19 pandemic). At this short-term follow-up period of 3 months, no significant difference could be determined between the PBMT (test group—0.57 mm mean residual

recession depth) and sham laser (control—0.63 mm mean residual recession depth) groups. These observations are in contrast to the findings of Ozturan et al. [7] and Fernandes-Dias et al. [21] both of whom reported improved clinical outcomes (GRD—gingival recession depth) at 1 year and 6-month follow-up respectively. The longer follow-up periods in the abovementioned studies, could have contributed to the better outcomes due to the phenomenon of “creeping attachment” as reported by Pini Prato et al. [27] for the CAF technique.

In the present study, at 3 months post-operative, no significant differences in the mean values of the residual gingival recession width was observed between PBMT and sham laser group; however, the improvement in mean values of width of keratinized gingiva was more for the PBMT group as compared to the sham laser control. The abovementioned observations are in agreement with the meta-analysis findings of Yan et al. [28]. The increase in width of keratinized gingiva and thick periodontal biotype are important findings as these parameters influence long-term stability of the results obtained following recession coverage procedures [29].

The wound healing at Days 3, 7, 10 were analyzed by the EHS index and the Test group (LCT + PBMT) had significantly higher EHS scores as compared to control (LCT + sham laser) in both surgical site and palatal donor site. These findings are in agreement with the observations of Dias et al. [6] and da Silva Neves [30] wherein standardized photographs with proprietary imaging software was used for the analysis of the remaining wound area. In the present study, we used the EHS score which has objective criteria and scores to assess the wound healing [16].

The patient-reported outcome measures assessed in this study was the VAS score which is a measure of pain intensity, self-completed by the respondent. It is commonly used as a measure of the post-operative discomfort as felt by the patient and can be administered at different time points based on the study objectives. In the present study, VAS pain scores were reported to be significantly lower by the participants in the test group as compared to control group at both day 3 and day 7. The present study findings are in agreement with the observations of Ozcelik et al. [8] wherein the authors reported significantly lower VAS scores on day 7 post-operative for the photobiomodulation group.

The strengths of the study are the use of the Big-Stick randomization procedure which mitigates allocation (selection) bias due to less predictability. Another strength is the use of assessor blinding to mitigate detection bias, while determining the primary endpoint. On the other hand limitations of the present study include the deviation from protocol although due to unforeseen circumstances (pandemic) and the short-term follow-up period. The latter may also

influence the power of the study, while the sample size calculation was initially planned on 6 month visits.

In conclusion, within the limitations of this study, we consider the trend in the results of the study as valid, so the use of adjunctive PBMT appears to not improve the short-term (3 months) recession coverage outcomes in a significant manner but it does improve the rate of healing and patient comfort in the immediate post-operative period. Long-term recession coverage outcomes need further investigation.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s10103-021-03411-0>.

Funding The study was self funded.

Declarations

Ethics approval Approval was obtained from Institutional Ethics Committee of Sri Ramachandra Institute of Higher Education and Research, Chennai, India [IEC/19/APR/150/21].

Conflict of interest The authors declare no competing interests.

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