Journal of Lasers in Medical Sciences

J Lasers Med Sci. 2025;16:e13

Original Article

http://journals.sbmu.ac.ir/jlms

doi 10.34172/jlms.2025.13

Evaluation of LLLT Along With Minimally Invasive Flaps in Regeneration of Periodontal Intrabony Defects: A Randomized Controlled Clinical Trial

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Received: May 24, 2024
Accepted: April 8, 2025
ePublished: May 24, 2025

Abstract

Introduction: The current study aims at evaluating the effectiveness of low level laser therapy (LLLT) in intra-bony defect regeneration by comparing the clinical parameters between periodontitis patients with intra-bony defects treated with simplified papilla preservation flap (SPPF) alone and SPPF with the adjunctive use of LLLT.

Methods: The current study is a randomized controlled clinical trial involving 64 patients/sites, 32 sites treated with SPPF – control group and 32 sites treated with SPPF and adjunctive use of LLLT (SPPF + LLLT) – test group. Clinical parameters such as probing pocket depth (PPD), clinical attachment level (CAL), position of gingival margin (PGM), radiographic intra-bony defect depth (R-IBD), full mouth plaque score (FMPS), and full mouth bleeding score (FMBS) were evaluated at baseline, 6 months, and one year post-surgery. Radiographic defect depths were assessed at baseline and one year post-surgery. The results were statistically analyzed.

Results: There was a statistically significant reduction in the PPD, CAL, PGM, and radiographic defect depth in the test group at the 6 months and one year post-surgery when compared with the control group ($P<0.05$). In addition, the total number of sites with PPD more than 4 mm was reduced significantly in the test group when compared to the control group at 6 months and one year.

Conclusion: The current study reports a significant improvement in PPD and radiographic intrabony defect fill in periodontitis patients treated with adjunctive LLLT supplementing SPPF. The article evaluates the adjunctive usage of LLLT in periodontal regeneration. The results reiterate the synergistic role of LLLT with periodontal surgical therapy for accelerated regenerative outcomes.

Keywords: Low level laser therapy, Minimally invasive surgical techniques, Periodontal surgery, Wound healing

Introduction

Periodontal regeneration is the ultimate goal of any periodontal therapy. Over several decades in the past, multiple techniques have been equipped in promoting a holistic regeneration of periodontium.[1] Owing to the recent technological advances, a plethora of macro, cellular and molecular approaches have been proposed, involving various directions and principles towards regeneration.[2]

Successful periodontal regeneration of a compromised periodontium involves multifaceted aspects, right from the access flap, placement of scaffold, and stimulation of the inherent potential of the native bone to regenerate.[1,2] An exacerbated focus has been laid on the development and evaluation of the efficacy of scaffolds in recent decades. In contrast, being most evaluated five decades back, the invention and evaluation of flap techniques have come down in the past two decades.[3]

There is much evidence supporting the fact that an appropriate flap technique could partly/ completely aid in regeneration by itself depending on the dimensions of the defect. Among the multiplicity of flap techniques being proposed, flaps preserving the interdental papilla, such as modified papilla preservation flap (MPPF) and simplified papilla preservation flap (SPPF), are reported to be more reliable and more amenable in terms of regeneration.[4]

SPPF is one of the minimally invasive surgical techniques (MIST) proposed for the access and treatment of intrabony defects with advantages like preservation of supracrestal soft tissues, achievement of primary wound closure, accelerated clot stabilization, and minimal invasiveness.[4] Various pieces of literature evidence have revealed an escalated periodontal regeneration and wound healing in SPPF compared to conventional flap techniques. However, there is no evidence to stamp a clinical recommendation in this aspect.[4,5]

Moving to the literature evidence supporting another important aspect of regeneration, that is, the stimulation of the inherent potential of periodontal tissues to regenerate, researchers have considered the role of LASER in this

Please cite this article as follows: PSG P, Sanjeev K, Subramanian S, Thanigaimalai A, Appukuttan D. Evaluation of LLLT along with minimally invasive flaps in regeneration of periodontal intrabony defects: a randomized controlled clinical trial. *J Lasers Med Sci.* 2025;16:e13. doi:10.34172/jlms.2025.13.

aspect. LASER, which stands for light amplification by stimulated emission of radiation, is one modality which has extensively been evaluated, and varying results have been obtained. A variant of dental lasers, that is, low level laser therapy (LLLT), often referred to as "LASER Biostimulation", has been reported to produce various cellular and metabolic changes such as exuberant division, multiplication, proliferation, and migration of fibroblast leading to rapid matrix production and wound healing.[6] They are also reported to induce a higher proliferation rate pertaining to human periodontal ligament stem cells.[7] In addition, they have been reported to elevate the bone formation markers such as bone morphogenetic protein (BMP), alkaline phosphatase (ALP), and osteocalcin and promote the level of growth factors such as platelet derived growth factor, vascular endothelial growth factor, and transforming growth factor.[6,7,8]

The adjunctive usage of LLLT in synergy with periodontal surgical/non–surgical has been researched extensively in both in vitro (cellular level) and clinical levels.[9,10] However, the majority of the studies are not standardized; that is, a wide heterogeneity is seen in terms of defect standardization and laser power settings (Watts and joules). Thus the pieces of evidence are not standard enough to be conclusive of the facts. Considering this, the current study aims to evaluate the effectiveness of LLLT in intra-bony defect regeneration by comparing the clinical and radiographic parameters between periodontitis patients with intra-bony defects treated with SPPF alone and SPPF with adjunctive use of LLLT.

Methods

Experimental Design

The current study is a randomized controlled clinical trial (RCCT) evaluating the efficacy of adjunctive use of LLLT in patients with intra-bony defects. The study was carried out involving the outpatients from the Department of Periodontology, SRM Dental College, Ramapuram, Chennai, Tamilnadu, India. There were two study groups; the first one, that is, the control group involved only SPPF in the management of intra-bony defects, and the second one, that is, the test group involved SPPF with the adjunctive use of LLLT in the management of intra-bony defects. The study duration spans from December 2021 to July 2023. The study was conducted with Institutional ethical approval (SRMDC/IRB/2019/PhD/No.118), registered in the clinical trial registry, (CTRI/2022/07/044413) and it was undertaken following the norms of the Declaration of Helsinki. Informed consent was obtained from all the study participants.

Study Population

Periodontitis patients with probing pocket depth (PPD) > 4 mm, Clinical attachment level (CAL) > 2 mm, and two- or three-wall intra-bony defects with defect depth > 2 mm were included. Tobacco users and patients with full mouth plaque score (FMPS) and full mouth bleeding score (FMBS) > 20% after phase I periodontal therapy, malalignment of teeth, para-functional habits, restorations and root canal treatment involving the tooth of the selected site, systemic illnesses altering the course of periodontal disease, chemotherapy, and radiation therapy were excluded.

After thorough examination, 64 patients having 64 sites with intra-bony defects were recruited, with 32 sites being treated with SPPF only (control group) and 32 sites treated with SPPF with adjunctive application of LLLT (test group) (Figure 1). This sample size was derived based on the results of a research study by AboElsaad et al with 90% power and 5% alpha error.[11]

Calibration, Randomization and Blinding

Randomization

The patients were randomized by means of simple random sampling, with the help of the shuffled deck of cards. The patients falling in even numbers were assigned to the test group and odd numbers were assigned to the control group.

Blinding

The examiners S1 and S2 were blinded to the study group allotment. The patients were also blinded to the groups. The patients in the control group received Sham LLLT where the laser tip was just placed in the position and not activated. However, the operator S3 could not be blinded to the study protocol. Hence, the current study is a double-blinded clinical trial.

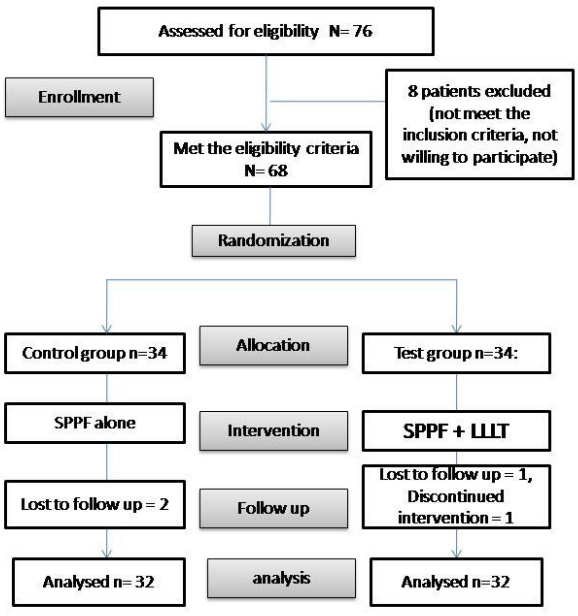

Figure 1. Consort Flowchart of the Study

Calibration

A single calibrated examiner S1 evaluated all the preoperative and postoperative clinical parameter findings. Examiner S2 evaluated all the radiographic findings. The intra-examiner calibration was done by examining 10 patients twice within 24 hrs. The statistical values were close to one at the 95% level. A single operator S3 performed all the surgical procedures.

Pre-surgical Protocol/Measurements

The patients recruited for the study, irrespective of their groups, underwent routine phase I periodontal therapy. After 4 weeks of scaling and root surface debridement, the patients exhibiting FMPS and FMBS < 20% were evaluated with the following clinical parameters:

1. FMPS[12]
2. FMBS[13]
3. PPD
4. Relative CAL
5. Position of gingival margin (PGM)
6. Intra-surgical measurement of intrabony defect (intrasurgical IBD)
7. Radiographic intra-bony defect depth measurement (R-IBD). The standardization of radiographs was done. The paralleling cone technique was used along with positioning frames for reproducibility.

After recording the findings, the patients were further advanced for the surgical phase.

Surgical Protocol

Following Local anesthesia, the SPPF was elevated, and open flap debridement and granulation tissue removal were done.[14] Following this, the flaps were approximated, and vertical internal mattress sutures along with the simple interrupted sutures for the papilla were done in the control group. The control procedure was identical to the test procedure, except for the application of LLLT after the debridement and before suturing.

Laser Energy Settings

LLLT was done in the intrabony defects of the test group, after defect debridement, using an 810 nm diode laser delivering 2/4/8 J/m^2 energy density at 0.4 W with its tip kept in non-contact mode approximately 5mm away from the defect. Following the application of LLLT, the flaps were approximated and vertical internal mattress sutures along with the simple interrupted sutures for the papilla were done (Figure 2).

Intra-surgical Measurement

Before the application of LASER and after the defect debridement, the intrasurgical measurement of IBD was evaluated. The depth was measured from the highest point of the alveolar bone until the base of the defect.

Post-surgical Protocol

After surgery, 0.2% chlorhexidine mouth rinse was advised to be used to support plaque control. In addition, professional plaque removal for every 2 weeks, up to the sixth week, was done. All the patients were asked to report thereafter, on the 3rd, 7th and 14th day post-surgery. The sutures were removed on the 14th day. All the clinical parameters evaluated pre-surgically were re-evaluated at 6 months and one year post-surgery. The radiographic bone fill was evaluated after one year (Figure 3).

Statistical Analysis

All the results were further statistically evaluated. The intergroup comparison was done with the Mann-Whitney U test. The intragroup comparison of parameters was done with the student t-test. A *P* value less than 0.05 was considered to be statistically significant. All the statistical analyses were done with SPSS software version 22.

Results

The current study aimed to evaluate the effectiveness of LLLT in intra-bony defect regeneration, by comparing the clinical and radiographic parameters between the control group and the test group. The demographic variables such as age and gender did not vary significantly between the groups ($P > 0.05$). The baseline clinical parameters and radiological parameters did not differ significantly between the groups. This indicates a precise randomization of defect characteristics between the groups (Table 1).

Table 2 shows the comparison of clinical parameters between the control group and the test group 6 months post-surgery. The FMPS and bleeding scores were similar between the groups, indicating that both the groups were

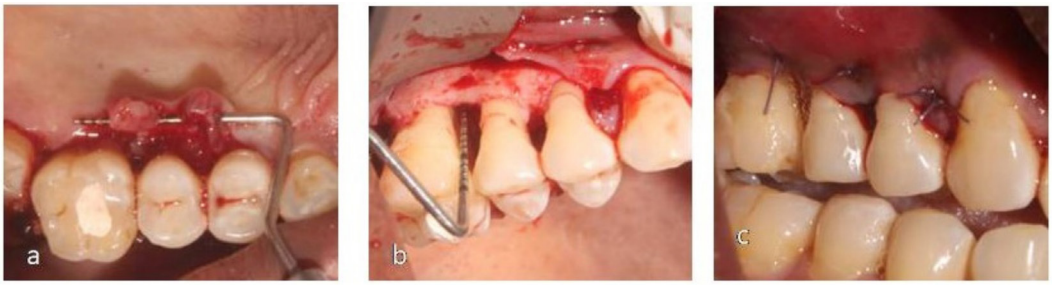

Figure 2. (a) Elevation of simplified papilla preservation flap. (b) Visualization of the 3-wall intrabony defect. (c) Internal vertical mattress sutures placed

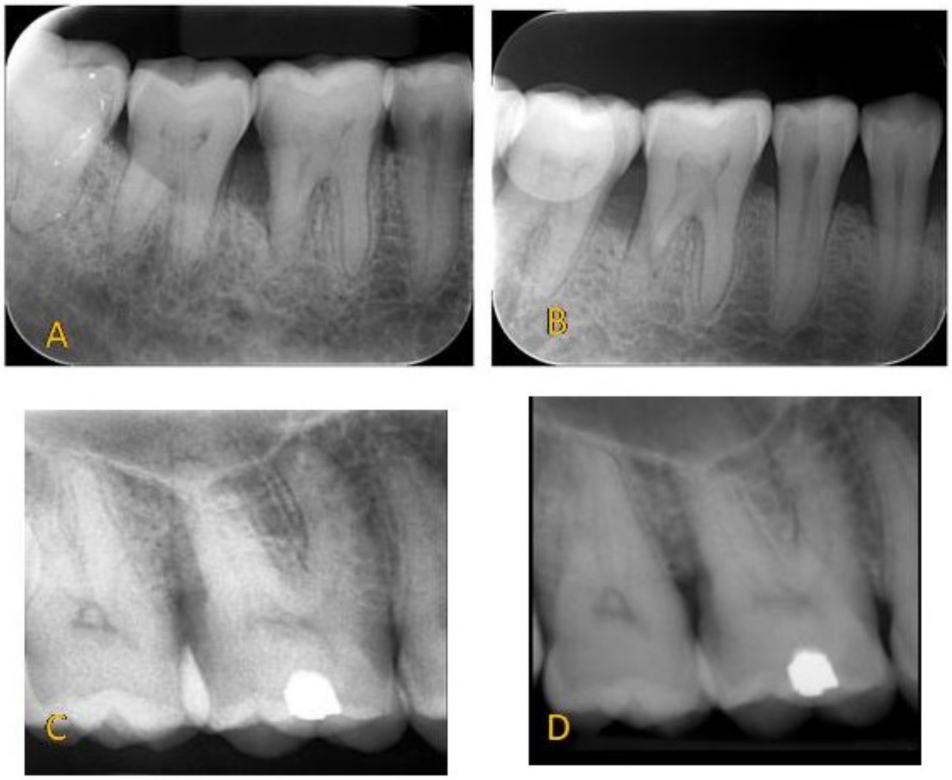

Figure 3. (A) Pre-treatment radiograph, control group. (B) Post-treatment radiograph, control group. (C) Pre-treatment radiograph, test group. (D) Post-treatment radiograph, test group

Table 1. Intergroup comparison of clinical parameters at baseline

Clinical Parameter	Control Group	Test Group	*P* Value*
FMPS	19.18 ± 0.20	18.20 ± 1.10	0.60
FMBS	18.20 ± 0.40	18.60 ± 0.40	0.66
PPD	7.46 ± 1.28	7.82 ± 0.38	0.70
CAL	8.86 ± 0.12	8.90 ± 0.40	0.68
PGM	1.40 ± 0.20	1.38 ± 0.10	0.76
R-IBD	5.50 ± 2.50	5.89 ± 2.60	0.66

FMPS, Full mouth plaque score; FMBS, Full mouth bleeding score; PPD, Probing pocket depth; CAL, Clinical attachment level; PGM, Position of the gingival margin; R-IBD, Radiographic intrabony defect depth.
* *P* value ≤ 0.05 and statistically significant.

Table 2. Intergroup Comparison of Clinical Parameters at 6 Months

Clinical Parameter	Control Group	Test Group	*P* Value*
FMPS	15.20 ± 1.20	14.10 ± 0.20	0.68
FMBS	15.30 ± 1.70	15.10 ± 1.20	0.58
PPD	3.80 ± 0.10	3.30 ± 0.20	0.66
CAL	5.26 ± 0.20	4.10 ± 0.10	0.66
PGM	1.46 ± 0.04	1.27 ± 0.10	0.63

FMPS, Full mouth plaque score; FMBS, Full mouth bleeding score; PPD, Probing pocket depth; CAL, Clinical attachment level; PGM, Position of the gingival margin; R-IBD, Radiographic intrabony defect depth.
* *P* value ≤ 0.05 and statistically significant.

equally followed up in terms of their oral hygiene. Clinical parameters such as PPD, CAL and PGM also did not show significant differences between the groups ($P > 0.05$) (Table 2).

When evaluating the clinical parameters at one year post-surgery, PPD, CAL, and IBD showed a significant difference between the groups. The PPD was significantly lower in the test group (3.0 ± 0.04) than in the control group (4.20 ± 0.10), with a *P* value of 0.04. Similarly, CAL (3.90 ± 0.30) and PGM (1.53 ± 0.30) were also significantly lower in the test group than in the control group (CAL -5.4 ± 0.20; PGM – 1.0 ± 0.01), with *P* value < 0.05 (Table 3).

There were 15 sites in the control group and 15 sites in the test group with PPD of more than 4 mm. There were no differences in the pocket distribution at the baseline. However, at the end of 6 months post-surgery, the number of sites with PPD of more than 4 mm reduced in both of the groups. The test group (1 site reduced) showed a greater and more significant reduction than the control group (5 sites reduced) ($P = 0.0001$). Similarly, at the end of one year post-surgery, the test group did not even show one site with PPD > 4 mm; however, the control group had 5 sites and had significantly more sites with residual pockets ($P = 0.0001$) (Table 4). Thus the results indicated an accelerated regeneration seen by the inference of reduction in PPD and reduction in IBD depth radiographically at the end of 6 months and one year. This infers the efficacy of LLLT in periodontal regeneration

Table 3. Intergroup Comparison of Clinical Parameters at 1 Year

Clinical Parameter	Control Group	Test Group	*P* Value
FMPS	15.10±0.60	13.10±0.60	0.34
FMBS	16.10±0.20	15.20±0.30	0.42
PPD	4.20±0.10	3.0±0.04	0.04*
CAL	5.40±0.20	3.90±0.30	0.04*
PGM	1.52±0.30	1.0±0.01	0.05*
R-IBD	4.10±1.20	1.0±0.1	0.05*

FMPS, Full mouth plaque score; FMBS, Full mouth bleeding score; PPD, Probing pocket depth; CAL, Clinical attachment level; PGM, Position of the gingival margin; R-IBD, Radiographic intrabony defect depth.
* *P* value ≤ 0.05 and statistically significant.

when used as an adjunct during surgical procedures.

Discussion

The current study is an RCCT comparing the clinical outcomes of SPPF with or without LLLT. Both of the treatment groups were intervened with a flap technique which is minimally invasive and preserving papilla, debridement of the defect, flap approximation, and primary wound closure. The only additional intervention in the test group was the application of LLLT. However, the efficacy was evaluated for either of the treatment interventions.

The demographic variables and baseline clinical parameters did not vary significantly between the groups, indicating a uniform sample distribution between the groups. Similarly, the baseline intrabony defect depths were also similar between the groups, denoting appropriate randomization of the defects between the groups.

When evaluating the post-treatment outcomes of the current study, PPD and CAL were significantly reduced in both of the groups when compared to the baseline. This reduction is due to the efficacy of SPPF. A significant pocket reduction was noted at one year when evaluated for the management of intra-bony defect regeneration by Cortellini et al.[14] Similarly, literature evidence reported a significant reduction in PPD, and a gain in CAL at one year was reported in the group treated with SPPF (minimally invasive flap) when compared to the group treated with the extended flap technique.[4,14,15] These results provide a concordance and reiteration of the fact of significant pocket reduction in both of the groups as a result of SPPF.

When comparing the clinical parameters of the current study between the groups at 6 months, there was an elevated reduction of PPD, CAL and PGM seen in the test group compared to the control group. However, when comparing the clinical parameters at one year, a statistically significant reduction of PPD, CAL and PGM was seen. This reduction could be attributed to the efficacy of LLLT in pocket reduction and its clinical parameters in concordance with the existing literature. A clinical trial by AboElsaad et al has evaluated the efficacy of LLLT in the management of intrabony defects, where

Table 4. Comparison of the Number of Sites With PPD of > 4 mm

	Control Group	Test Group	*P* Value
Baseline	15	15	1.000
Six months	5	1	0.0001*
One year	5	0	0.0001*
P value	0.0001*	0.0001*	

* *P* value ≤ 0.05 and statistically significant.

they have reported a significant reduction in the clinical parameters of periodontitis. Similarly, Aena et al have reported a reduction in PPD and CAL at 9 months post-surgery in the adjunctive application of LLLT in synergy with Open flap debridement.[11,16] In addition, a significant reduction in sites with PPD > 4 mm was also seen in the SPPF + LLLT group compared to SPPF alone at both 6 months and one year post-surgery. This improvement in clinical parameters is due to the molecular effects of LLLT that include increased fibroblast differentiation, human periodontal cell proliferation, and modifying mediators like basic fibroblast growth factor.[17,18] In addition, it could also be due to the fact of wound healing phenomenon induced by LLLG such as increased granulation synthesis, enhanced neo-vascularization of tissue, increased fibroblast proliferation, maturation, attachment, and matrix synthesis.[19,20]

When evaluating the radiographic intrabony defect depth at the end of one year in the current study, a significant reduction in the intrabony defect depth was seen. This was clinically in concordance with various studies evaluating the effect of LLLT on periodontal bone regeneration, where a significant elevation in radiographic bone height was seen.[9,21] However, the majority of the trials involved LLLT as an adjunctive application to accelerate bone regeneration after the placement of bone grafts. There was only a limited piece of evidence involving the application of LLLT as a standalone therapy in regeneration with periodontal flaps. Such evidence also suggested an escalation in periodontal intrabony defect regeneration with the application of LLLT.[22,23] This could be attributed to the in vitro effects of LLLT, such as accelerated cellular differentiation, proliferation of nodule forming osteoblast, enhanced bone matrix formation, and maturation of osteoblasts. In addition, elevated ALP activity and BMPs were identified in sites irradiated with LLLT. This sums to the biological plausibility behind the accelerated bone regeneration in sites treated with LLLT.[24,25]

The above-mentioned results have reconfirmed the fact of a holistic periodontal regeneration induced by LLLT. That is, better soft tissue healing was seen in periodontal defect sites with a significant reduction of parameters such as PPD, CAL, and PGM. In addition, a profound hard tissue regeneration was reported in terms of reduction in the intrabony defect depth. Thus, a complete periodontal regeneration was obtained in sites treated with minimally

invasive flap surgery with an adjunct of LLLT in ideal defects.

The advantage of the current study is in the standardization of LASER specification and the study design. However, not evaluating the identified LASER specification with an initial in vitro evaluation on cell cultures or in vitro evaluation of biomarkers after its clinical application could be the possible limitations of the current study. This paves for the future scope in expanding the intricate knowledge on LLLT in periodontal regeneration.

Conclusion

Within the limitations, the current study reports a significant improvement of clinical and radiographic parameters of intabony defect sites in periodontitis patients treated with SPPF + LLLT (test group) compared to SPPF alone (control group). Further propagation of results with additional reiteration of biological parameters could provide definitive conclusions on the adjunctive use of LLLT in periodontal regeneration.

Authors' Contribution

Conceptualization: Prakash PSG, Kavitha Sanjeev.
Data curation: Prakash PSG, Sangeetha Subramanian.
Formal analysis: Prakash PSG, Kavitha Sanjeev.
Investigation: Prakash PSG, Sangeetha Subramanian, Devapriya Appukuttan.
Methodology: Prakash PSG, Devapriya Appukuttan.
Project administration: Prakash PSG.
Resources: Prakash PSG.
Software: Abirami Thanigaimalai.
Supervision: Kavitha Sanjeev.
Validation: Devapriya Appukuttan.
Visualization: Kavitha Sanjeev.
Writing–original draft: Prakash PSG.
Writing–review & editing: Abirami Thanigaimalai.

Competing Interests

The authors report there are no competing interests to declare.

Data Availability Statement

Data are available on request from the authors.

Ethical Approval

This study was ethically approved by the Institutional ethical committee with number SRMDC/IRB/2019/PhD/No.118.

Funding

Nil.

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