"COMPARATIVE EVALUATION OF PHOTOBIOMODULATORY EFFECT OF 660NM AND 970NM DIODE LASER ON POST-OPERATIVE PAIN MANAGEMENT IN SINGLE VISIT ENDODONTIC TREATMENT – A RANDOMIZED CONTROL TRIAL"

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LIST OF ABBREVIATIONS

NiTi	Nickel – Titanium
NaOCl	Sodium Hypochlorite
K file	Kerr file
EDTA	Ethylenediamine Tetracetic acid
PBM	Photobiomodulation
#10	Tip diameter – 0.10mm
#15	Tip diameter – 0.15mm
mm	Millimeter
%	Percentage
i.e	That is
ISO	International Organization for Standardization
LLLT	Low Level Laser Therapy
GP	Gutta percha
PP	Paper point
EAL	Electronic Apex Locater
WL	Working length
M	Male

F	Female
VAS	Visual Analogue Scale
Post op	Post-operative
min	minutes
hrs	hours
yrs	years
<	Less than
>	Greater than
=	Equal to
Fig.	figure
vs.	versus
RVG	Radiovisiography

ABSTRACT

Title: *Comparative Evaluation of Photobiomodulatory Effect of 660 nm and 970 nm Diode Laser on Postoperative Pain Management in Single-Visit Endodontic Treatment – A Randomized Control Trial*

Background: Postoperative pain remains a frequent concern in endodontic therapy, often affecting patient comfort and satisfaction. Photobiomodulation using low-level laser therapy (LLLT) has emerged as a promising non-pharmacological alternative to conventional analgesics. However, the efficacy of different laser wavelengths in reducing postoperative pain remains underexplored.

Aim: The present study aimed to evaluate and compare the photobiomodulatory effects of 660 nm and 970 nm diode lasers on the management of postoperative pain following single-visit endodontic treatment.

Methodology: A randomized controlled trial was conducted involving 81 patients requiring root canal treatment in maxillary first premolars. Patients were randomly divided into three groups (n=27 each): Group A (control – no laser), Group B (660 nm diode laser), and Group C (970 nm diode laser). All patients underwent standardized single-visit root canal treatment. Laser irradiation was applied immediately post-treatment in Groups B and C. Postoperative pain was assessed using the Visual Analogue Scale (VAS) at 6, 24, 48, and 72 hours. Statistical analysis was performed using Kruskal-Wallis ANOVA, Mann-Whitney U, Friedman's ANOVA, and Wilcoxon tests.

Results: All groups demonstrated a statistically significant reduction in pain over time ($p<0.05$). Intergroup analysis revealed significantly lower VAS scores in Group C (970 nm) compared to Group A at all time intervals and compared to Group B at 6 and 24 hours ($p<0.05$). Group B also showed significantly lower VAS scores than Group A during the early postoperative period.

Conclusion: The 970 nm diode laser demonstrated superior efficacy in reducing postoperative endodontic pain compared to the 660 nm wavelength. Photobiomodulation using diode lasers can be considered an effective adjunct for postoperative pain management in endodontic practice.

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INTRODUCTION

"Pain is inevitable, but suffering is optional."

Even though the concept of single visit endodontics has existed since the 1800s(1), it has gained increased popularity in the last couple of decades due to advancements in endodontic techniques and technology. While it offers the advantage of reduced appointments, a major concern remains the incidence of post-endodontic pain (PEP), which significantly affects both patient satisfaction and clinical outcomes(2). Studies by Gupta et al. and Bhagwat S et al. report postoperative pain in 32.35% and between 24%–60% of patients, respectively(3,4). Post endodontic pain (PEP) control measures are vital components of endodontia treatment, ensuring optimal patient comfort, accelerated healing, and long-term treatment success.(5) Despite advancements in root canal therapy techniques, managing post-treatment discomfort remains a challenge.(3) Postoperative endodontic pain has a multifactorial etiology, resulting in acute inflammation mainly due to inflammatory mediators produced due to chemical, mechanical, or microbial injuries to the pulp & periapical tissues.(6)

The primary choices for managing post-treatment pain typically revolve around different prescription drugs like non-steroidal-anti-inflammatory drugs(NSAID), steroid-based anti-inflammatories (corticosteroids), analgesics like acetaminophen (paracetamol), and opioid-based pain relievers.(7)

However, these drugs present side effects and contraindications. NSAIDs increase cardio-vascular and renal failure risk and are contraindicated throughout pregnancy(8). Gastropathy related to NSAID is encountered very frequently.(9)

As an alternative, Photobiomodulation (PBM) initially known as LLLT has gained recognition as a non-invasive and effective method for pain reduction and accelerated healing in dental procedures.(10,11) Photobiomodulation (PBM), was discovered in 1967 by Hungarian physician and surgeon Professor Endre Mester at Semmelweis Medical University in Budapest while working on cancer cells where the tissue injuries demonstrated accelerated healing in the laser-treated group.(12)

Photobiomodulation gained recognition in medicine during the 1970s and 1980s.(13) Following this, dentists began using near-red and near-infrared lasers in various procedures. Diode lasers, particularly those operating at 660 nm and 970 nm, have gained popularity in endodontics due to their ability to enhance cellular metabolism, reduce inflammation, and modulate pain perception.(14)

Photobiomodulation has shown a comparable effect over NSAIDs in pain management as per studies done by Nunens et al(15) & Nabi et al.(16) While photobiomodulation can be done in the 600nm - 1000nm wavelength range previous studies have been done with 970 ± 15 nm by Arsaln et al.(17) and Yildiz et al(18), with 808 nm wavelength by Asnaashari et al(19), Lopes et al.(20) & with 640nm wavelength by Nabi et al.(16), in root canal treatment and re-treatment cases.

While a variety of dental lasers exist which include , Er,Cr: YSGG -780 nm, CO_2 - 10,600 nm, Er: YAG - 2940 nm and Nd: YAG - 1064 nm —many are limited by shallow tissue penetration, making them more suitable for surgical applications rather than PBM.(21,22) In contrast, diode lasers offer deeper penetration and are preferred for photobiomodulatory use. (10)

Specific laser parameters, including wavelength, power, duration, and frequency, may result in varying degrees of pain reduction, and some wavelengths

may be better than others at controlling post-operative pain.(23) According to the literature, there is no evidence on which wavelength of the Diode laser is more efficient & safer way of decreasing post-operative pain for patients who require endodontic therapy.(14) While both wavelengths have demonstrated promising results in pain management, their comparative effectiveness after single-visit endodontic treatment remains unclear. Randomized Controlled rials (RCTs) are considered the gold standard for effective research interventions, as the process of randomization helps eliminate many of the biases associated with other research designs. Therefore, this study aims to evaluate the photobiomodulation effect with 660nm and 970nm in the management of postoperative pain in patients who have been diagnosed with asymptomatic irreversible pulpitis after single-visit endodontics.

AIMS AND OBJECTIVES

STUDY AIM

To evaluate and compare the photobiomodulatory effect of 660nm and 970nm Diode laser on post-operative pain management in single visit endodontic treatment –A Randomized control trial.

STUDY OBJECTIVES

- To assess and conduct an intragroup comparison of the intensity & incidence of post-operative pain at 6, 24, 48 and 72 hours using Visual analogue scale without performing photobiomodulation.
- To assess and conduct an intragroup comparison of the intensity & incidence of post-operative pain at 6, 24, 48 and 72 hours using Visual analogue Scale after performing photobiomodulation at 660nm wavelength.
- To assess and conduct an intragroup comparison of the intensity & incidence of postoperative pain at 6, 24, 48, and 72 hours using a Visual Analogue Scale after performing photobiomodulation at 970nm wavelength.
- To assess and conduct an inter-group comparison of the intensity & incidence of postoperative pain at 6, 24, 48, and 72 hours using a Visual Analogue Scale after performing photobiomodulation at 660nm and 970nm wavelengths.
- To assess and compare how age and sex are associated with the groups using 660nm and 970nm wavelength of Diode laser.

RESEARCH HYPOTHESIS

NULL HYPOTHESIS

There is no difference in postoperative pain management using 660nm & 970nm wavelength diode lasers in single-visit endodontic treatment.

ALTERNATE HYPOTHESIS

There is a difference in postoperative pain management using 660nm & 970nm wavelength diode lasers in single-visit endodontic treatment.

REVIEW OF LITERATURE

1. A comprehensive systematic review was performed for assessing the rendition of PBM on postoperative endodontic pain. The authors analysed nine clinical trials involving human subjects where PBM was used after root canal therapy. Databases such as PubMed, Scopus, and Cochrane were searched for clinical trials using PBM to manage post-endodontic pain. Studies reported pain scores using standard tools like the VAS. It was seen that PBM significantly reduced postoperative pain in most studies, especially within the first 72 hours. It was found to be a safe, effective, and non-invasive approach. However, further studies are needed to standardize laser parameters and protocols.(24)
2. A comprehensive systematic review and meta-analysis was performed for assessing the rendition of laser therapy on postoperative pain and outcomes in endodontic retreatment cases. This study systematically analysed three clinical trials from multiple databases assessing laser applications—particularly PBM (PBM)—during or after endodontic retreatment. Pain scores and treatment success were compared between laser and non-laser groups. The analysis included trials with clear methodologies and standardized pain assessment tools like the VAS. The meta-analysis revealed that laser therapy, especially PBM, significantly reduced postoperative pain in endodontic retreatment cases. It also showed improved patient comfort and reduced need for analgesics, reinforcing the role of lasers as an effective adjunct in retreatment protocols. (25)
3. A study was done to assess the impact of laser PBM on postoperative pain after SVE treatment in 5–9-year-old children with acute irreversible pulpitis in primary molars. One group received PBM therapy using a diode laser at continuous mode with a wavelength of 808nm with an 8mm tip in contact mode

and spot size 0.8 cm2 immediately after endodontic treatment, while the control group utilized a blue LED wavelength of 420-480 nm with an exposure time of 15s. Pain levels were measured using the VAS at 4, 12, and 24 hours after treatment. The results indicated that PBM significantly reduced postoperative pain at all measured time intervals, with the treatment group reporting less pain in comparison to the control. The study supports the use of PBM as an effective, non-invasive approach for managing pain after endodontic therapy in pediatric patients.(26)

4. A randomized control trial was done to examine the impact of PBM on postoperative pain after primary endodontic treatment in molars diagnosed with symptomatic apical periodontitis. The study involved patients undergoing single-visit root canal treatment for molars diagnosed with symptomatic apical periodontitis. A low-level diode laser (used for PBM) was applied postoperatively. Pain was measured at multiple intervals using a VAS, and outcomes were compared to a non-laser control group. The study found that PBM significantly reduced postoperative pain, particularly within the first 24–48hours. It concluded that PBM is a safe and effective adjunct to conventional endodontic therapy in managing pain associated with apical periodontitis.(27)
5. A comprehensive systematic review was performed evaluating laser PBM on postoperative pain in endodontics. The authors reviewed sixteen clinical studies that assessed the application of PBM in endodontic procedures, focusing on postoperative pain management. Studies were selected based on their design (randomized controlled trials, clinical trials), and pain outcomes were measured using validated instruments like the VAS and numeric rating scales. A meta-analysis was conducted to aggregate data across studies. The systematic review found that PBM significantly reduced postoperative pain following endodontic

treatments. The authors highlighted PBM as an effective and non-invasive adjunct to conventional pain management techniques, supporting its use in enhancing patient recovery after endodontic procedures.(28)

6. A study was to done to determine the impact of PBM (PBM) using infrared laser source of gallium and aluminium arsenide (GaA1As) during root canal treatment on oral health-related quality of life (OHRQoL). This study included patients undergoing root canal treatment, with one group receiving PBM using the low-level laser with a wavelength of 660 ± 10 nm during the procedure, while the control group received no laser therapy. OHRQoL was measured using the OHIP-14 questionnaire, assessing factors like pain, discomfort, and overall health-related quality of life. The outcomes were assessed at baseline, immediately after treatment, and at 1-week follow-up. The study found that PBM significantly improved the OHRQoL scores in the treatment group, particularly in terms of reducing pain and discomfort post-treatment. The authors concluded that PBM is a beneficial adjunct in root canal therapy, enhancing patient comfort and improving overall quality of life during the recovery period.(29)
7. A study was done to determine the effectiveness of PBM (PBM) therapy in reducing postoperative pain after root canal treatment in 90 systemically healthy patients aged 20–50 years, each presenting with symptomatic irreversible pulpitis in mandibular molars. All patients underwent single-visit root canal treatment, which included shaping by Reciproc system, accompanied by irrigation using 2.5% sodium hypochlorite and 17% EDTA. obturation was done with gutta-percha and AH Plus sealer using the lateral compaction technique. After obturation and restoration Patients were divided into 2 groups of PBM 940 nm diode laser and Placebo. Pain levels were self-reported by

patients at 6, 12, 24, 48, and 72 hours postoperatively using a VAS. The PBM group consistently reported significantly lower pain scores at 6, 12, and 24hours post-treatment compared to the placebo group. It was concluded that PBM therapy using a 940 nm diode laser effectively reduces postoperative pain in patients undergoing single-visit root canal treatment for symptomatic irreversible pulpitis, particularly within the first 24 hours. This non-pharmacological approach can serve as a valuable adjunct in endodontic pain management strategies.(30)

8. A study was done that to determine the impact of LLLT in postoperative pain management following single-visit root canal retreatment of mandibular molars. This randomized controlled clinical trial included 36 subject requiring retreatment of symptomatic first or second mandibular molars with periapical index scores of 2 or 3. Patients were randomly assigned to two groups: first group was LLLT group which received LLLT using 980 nm diode laser at 6.89 W/cm2 energy density, 0.5 W power and tip diameter of 10mm immediately after root canal retreatment second group was Sham group which underwent a simulated laser treatment without actual irradiation. Postoperative pain levels were recorded at 4, 8, 12, and 24 hours, and on days 2, 3, and 7 using a VAS. The results indicated that the LLLT group experienced significantly lower pain intensity at the 4-hour mark compared to the sham group ($p = .016$). However, no significant differences in pain levels were observed between the groups at subsequent time points. The study concluded that LLLT effectively reduces postoperative pain at 4 hours following single-visit root canal retreatment of mandibular molars.(31)

9. This study highlights the distinct biological responses triggered by 660 nm (red) and 980 nm (near-infrared) light in PBM therapy. Using cultured keratinocytes and fibroblasts, researchers found that both wavelengths enhance metabolic activity and ATP production, but through different pathways and durations. The 980 nm wavelength produced a quick, yet short-lived ATP increase, whereas 660 nm led to a longer-lasting effect, sustained for up to 24 hours. The extended response to 660 nm was linked to increased COX-1 expression, pointing to a cytochrome c oxidase (CCO)-mediated mechanism. In contrast, the effects of 980 nm seem to involve alternative pathways such as calcium signalling, TRP channels, and water absorption. Interestingly, using both wavelengths together did not enhance outcomes compared to individual treatments. These results emphasize the need for wavelength-specific approaches in PBM and suggest that 660 nm may be more suitable for long-term therapeutic benefits. The findings offer valuable insights for refining PBM treatment protocols and improving clinical outcomes.(32)
10. A systematic review was conducted to evaluate the effect of LLLT on postoperative pain following endodontic procedures. They analysed randomized clinical trials comparing LLLT with placebo treatments after primary root canal therapy, retreatment, and periapical surgery. The review included 12 studies, with most reporting significantly reduced postoperative pain at various time intervals post-treatment. However, the evidence quality was rated as low to very low, attributed to factors like lack of standardization in laser parameters and concomitant medication use. The authors concluded that while LLLT shows promise in reducing postoperative pain, further research with standardized protocols is needed to confirm its efficacy.(14)

11. A study was conducted to check the effect PBM on postoperative symptoms in teeth with asymptomatic apical periodontitis treated with foraminal enlargement. It included patients with asymptomatic apical periodontitis undergoing single-visit endodontic treatment. One group received PBM therapy using infrared laser source of gallium and aluminium arsenide (GaA1As) with a wavelength of 660±10nm postoperatively, while the control group did not receive any laser treatment. Postoperative pain and tenderness were evaluated using VAS scores and clinical examinations were done 6, 12, and 24 hours after treatment. The study found that PBM significantly reduced postoperative pain and tenderness, particularly in the first 24 hours after treatment. The authors concluded that PBM is an effective non-pharmacological adjunct in managing postoperative symptoms in cases involving asymptomatic apical periodontitis, especially after foramina enlargement procedures(33)
12. A randomized clinical trial was carried to compare the effectiveness of PBM therapy (PBMT) and ibuprofen in controlling postoperative pain after endodontic treatment. Seventy patients diagnosed with symptomatic irreversible pulpitis were enrolled in the study and underwent single-sitting endodontic therapy. Post-treatment, participants were randomly assigned to two groups: one receiving two doses of 600 mg ibuprofen within a 12-hour interval, and the other undergoing PBMT using AsGaAl infrared laser of 808nm at 100mW for 25s immediately after the procedure. Pain levels were assessed at 6-, 12-, 24-, and 72-hours post-treatment using numerical and VRS. The results indicated that PBMT provided superior pain relief compared to ibuprofen at 6, 12, and 24 hours, with no significant difference observed at the 72-hour mark due to its actions Such effects include the elimination of pain-inducing substances through enhanced local blood flow, suppression of inflammatory mediator production,

activation of cellular respiration, and the release of neurotransmitters into the affected tissues. The study concluded that PBMT is efficient in decreasing postoperative pain within the first 24 hours following endodontic treatment.(15)

13. A comprehensive systematic review was performed to analyse the efficiency of LLLT in managing postoperative pain following endodontic therapy and re-treatment (RCR). The review analysed seven randomized controlled trials—five focusing on RCT and two on RCR—comparing LLLT with placebo, blank, or ibuprofen treatments. The studies utilized diode and indium-gallium-aluminium lasers, evaluating outcomes such as pain prevalence, intensity, and analgesic consumption. Three studies reported a significant reduction in pain prevalence post-treatment with LLLT. While pain intensity results varied across different time points, most studies observed lower pain levels in the LLLT group. Additionally, two out of three studies assessing analgesic use found notable benefits with LLLT. The authors concluded that LLLT shows promise for postoperative pain control in endodontic therapies but emphasized the necessity for additional high-quality clinical trials to definitively confirm its effectiveness.(34)

14. A study was conducted to check the effect of low level laser therapy (LLLT) using 808 nm wavelength diode laser at a power of 100 mW with a fiber diameter of 600μm on postoperative endodontic pain in patients with symptomatic irreversible pulpitis, focusing on different irradiation sites. Patients were randomly assigned to receive LLLT at different irradiation sites—either intraoral, extra oral, or both—after endodontic treatment. Pain levels were assessed using the VAS at various time intervals postoperatively. It was found that LLLT significantly reduced postoperative pain, especially when applied

both intraorally and extraorally. The study supports the use of LLLT as a safe and effective adjunct for managing pain in acute endodontic cases.(35)

15. A systematic review was done to explore PBM effects utilizing different wavelengths of 904nm, 830nm, 685 nm, 660 nm on post-surgical dental pain, aiming to evaluate its clinical usefulness in reducing discomfort after invasive procedures. This systematic review included 10 randomized control trials done on patients undergoing various oral surgical procedures. PBM was applied postoperatively using the low-level laser, and pain levels were monitored over time using standardized tools like the VAS. The outcomes were compared to a control group receiving no laser therapy. The results showed that PBM significantly decreased pain intensity and improved patient comfort in the early postoperative period. The authors concluded that PBM is a non-invasive, effective, and safe technique for managing post-surgical dental pain.(36)
16. A randomized control trial was conducted to investigate the effect of PBM on pain following endodontic therapy. This clinical trial involved patients who underwent routine endodontic procedures. After treatment, one group received PBM using an indium-gallium-aluminium laser with a wavelength of 808nm and 0.0283 cm2 spot size, while one of group did not receive laser treatment. Pain levels were assessed at 6, 12, 24, and 48 hours post-treatment using the VAS. The study found that PBM significantly reduced postoperative pain, with the treatment group reporting less discomfort at all time intervals compared to the control. The authors concluded that PBM is an effective, non-invasive therapy for pain management following endodontic treatment, improving patient recovery without the need for pharmacological interventions.(20)

17. A study was conducted to assess the effectiveness of preoperative ibuprofen and LLLT in managing postoperative pain following single-visit endodontic procedures was conducted. 120 patients were randomly allocated into 4groups ; group A received 400mg Ibuprofen orally before the treatment, group B underwent LLLT with a wavelength of 905 nm AT 50Hz for 3 minutes post-procedure, targeting the periapical region on both buccal and lingual aspects. , group C received both preoperative ibuprofen and post-procedure LLLT; group D served as the control group, receiving neither ibuprofen nor LLLT. Pain levels were assessed immediately after treatment and at 4, 8, 12, 24, and 48 hours postoperatively using the Heft Parker pain survey. Results indicated that all treatment groups experienced significant pain reduction postoperatively. Ibuprofen alone was particularly effective at the 4 and 8-hour marks. Notably, the combination of ibuprofen and LLLT (Group C) resulted in the most substantial reduction in postoperative pain across all time intervals. The study concluded that LLLT can serve as an effective alternative to NSAIDs for controlling post-endodontic pain, potentially mitigating the adverse effects associated with these drugs.(16)

18. A study was conducted to examine the impact of LLLT on pain after single visit endodontic therapy in mandibular molars diagnosed with symptomatic apical periodontitis. 42 patients meeting specific inclusion criteria underwent root canal treatment using reciprocating instruments and were randomly assigned to one of three groups. First group was control group which received no laser , second was placebo which underwent mock laser therapy without actual irradiation and third group was LLLT group which received a 970 nm diode laser on apex of roots for 30 secs postoperatively. Postoperative pain levels were recorded on the 1st, 3rd, 5th, 7th, and 30th days using a VAS. The results

demonstrated that the LLLT group experienced significantly lower pain levels on the 1st and 3rd days compared to the control and placebo groups ($P < .05$). However, no significant differences were observed among the groups regarding postoperative percussion pain levels. The study concluded that LLLT can be beneficial in reducing postoperative pain in endodontic procedures.(18)

19. A study was conducted in vivo and in vitro to examine the effects of PBM using multiple wavelengths on oxidative stress. In vitro, polymorphonuclear neutrophils (PMN), granulocytes and keratinocytes were exposed to 800 nm, 660 nm, and 970 nm laser light, both before and after oxidative stress induction. In vivo, patients suffering from oral mucositis(OM) caused by chemotherapy or radiotherapy were treated with PBM using these wavelengths. The study utilized standard reactive oxygen species (ROS) detection methods and a genetically encoded roGFP2-Orp1 sensor for dynamic redox imaging. The findings revealed that increased ROS production was seen before or after an oxidative stimulus at 660 nm when applied, at 970nm there was moderate antioxidant activity and 800 nm laser and combined wavelength led to significant reductions in ROS levels in both cell types. The study concluded that PBM's effects on oxidative stress vary based on the wavelength used, suggesting the potential for developing multiwavelength clinical protocols.(37)
20. This study explores the effects of 808-nm wavelength diode laser on mitochondrial function. It challenges the conventional belief that high-fluence laser therapy impairs cellular activity, showing instead that a fluence of 64 J/cm^2 at 1 W enhances mitochondrial performance. Using mitochondria from bovine liver, researchers observed increased oxygen consumption and activation of complexes III and IV in the electron transport chain, leading to greater ATP synthesis. Complexes I, II, and cytochrome c were unaffected. The flat-top

beam's uniform energy distribution is credited for preventing the uneven irradiation typical of Gaussian beams, thereby minimizing overstimulation or inhibition. These findings question the biphasic dose-response theory and indicate that, when applied evenly, high-fluence PBM can be both safe and therapeutically beneficial in mitochondrial and energy-related cellular treatments.(38)

MATERIALS AND METHODS

This study titled –"Comparative evaluation of photobiomodulatory effect of 660nm and 970nm diode laser on post-operative pain management in single visit endodontic treatment – A Randomized clinical control trial" was conducted at the Department of Conservative Dentistry and Endodontics, KAHER's KLE V.K. Institute of Dental Sciences, Belagavi, Karnataka, with approval of Research and Ethical Committee of KLE University's V K Institute of Dental Sciences. With reference number 1636 dated 08.04.2025, and with the CTRI number CTRI/2025/02/080023.

MATERIALS USED: -

- 2% Local anesthesia lignocaine 1:1,00,000 adrenaline (ICPA), 15%EDTA gel (Avue Gel), 5% w/v Povidine Iodine (Sun Pharma Ind), Hydrogen Peroxide 30% w/v (Thermo Fisher Scientific Pvt.. Ltd.), Sodium Thiosulphate (Ranbaxy Ltd.), Saline: 0.9% w/v (AH Ltd. Ind), NaOCl 3% (Vishal Dentocar Ltd) Di sodium edetate solution 17% (Canalarge), RVG (Dentsply Sirona), Sterile cotton, Paper points (DiaDent MMPP), Guttapercha (25/6 NeoEndo Flex compatible GP points), AH-Plus® Sealer (Dentsply, Germany), Tab Ibuprofen 400mg (Abbott India.)
- The DG-16 probe (GDC®, India), the mouth mirror (GDC®, India), the rubber dam kit (Hygienic kit , Coltene, Swetzerland), electric pulp vitality tester (Parkell Inc, New York), Single use saliva ejector; Airotor (NSK Pana-Air, Tokyo, Japan); spoon excavator (GDC®, India), Disposable syringes (Unolock India); Mini Endo-block (Dentsply-Maillefer, Switzerland); Endomotor X-SmartTM (Dentsply, Switzerland), Apex locator (E pex, Eighteeth,

Changzhou, China)

- Endo access diamond point (Dentsply Maillefer, Switzerland); Endo-Z bur (Dentsply-Maillefer, Switzerland); Stainless-steel K-files #10, #15, (Mani Inc, Japan) ; Neoendo Flex rotary file (Orikam, India) and compatible GP points (Diadent, Korea)
- SiroLaser Blue with 8mm Multitip (Dentsply Sirona, New York, USA),

METHODOLOGY

Adhering to the stated inclusion and exclusion conditions 81 patients in need of endodontic therapy concerning maxillary 1st premolar teeth, diagnosed as asymptomatic irreversible pulpitis were selected from the normal patient population of the Department of Endodontics and Conservative Dentistry, the KLE VKIDS Belagavi. A signed informed consent was received from each patient post-procedure was explained in their native language.

INCLUSION CRITERIA: -

Patients in need of root canal therapy for their 2 rooted maxillary premolar teeth, identified clinically with pulp sensitivity tests as asymptomatic irreversible pulpitis, patients aged between 18 and 50 years, having an insignificant past medical history, without any pre-operative pain, and sufficient coronal structure for isolation.

EXCLUSION CRITERIA: -

A. PATIENT-SPECIFIC:

Patients who declined their consent, individuals with immunocompromised states, pregnancy, any systemic diseases, patients receiving antibiotic treatment within the last three months, patients who have used analgesic medications within the last

seven days, patients with lignocaine allergies adrenaline concentration of 1:1,00,000, Ibuprofen-allergic patients, as well as those in need of root canal therapy for two or more teeth on the ipsilateral side.

B. SPECIFIC TO DIAGNOSIS:

Teeth having diagnosis of apical periodontitis, acute periapical abscess, teeth whose diameter of periapical radiolucency is > 0.5cm (5mm), teeth where the canal is being drained of inflammatory exudate, painful teeth without a sinus canal for drainage, cases involving retreatment, Dilacerated teeth, teeth with grade III mobility or severe periodontitis.

C. TOOTH SPECIFIC:

Teeth with internal and external resorption, an immature apex, and calcified canals, with two root canals and one apical foramen at the end, Teeth with such canals were not accepted. If a 10 K-file moved very slowly, a 20 K-file extending readily (apical gauging), severe labially or lingually incorrectly positioned teeth that make it challenging to gain straight-line access were also excluded.

DETAILS OF THE PROCEDURES CONDUCTED IN THE RESEARCH –

81 patients requiring endodontic treatment on permanent maxillary first premolars were chosen on predefined inclusion and exclusion criteria. The operative process was described to each patient in their native tongue, and documented informed consent was taken prior to treatment. Pulp-Sensibility was assessed using an electric pulp tester (Parkell) and a cold test with Endo-Frost spray (Coltene).

All evaluations and treatments were carried out by a single clinician to minimize operator-related variability. A computer-generated randomization sequence,

provided by statistician independent of the study, was used to allocate patients to the intervention groups after eligibility screening and recruitment.

Following consent, local anaesthesia (2% lignocaine with 1:100,000 parts epinephrine) was injected. Tooth isolation was done using a rubber-dam (Coltene Hygienic Kit), after which the crown was cleaned with pumice and rinsed with normal saline. Disinfection was performed using 30% H_2O_2 and five percent, applied for 60 sec. Sodium thiosulphate was then used to neutralize the iodine.

Access cavity preparation was carried out using Endo Access and Endo-Z burs (Dentsply Maillefer). Canal patency was confirmed with a #10K-file (Mani Inc., Japan), and the glide-path was established with a #15 K-file. WL determination was performed with an electronic-apex-locator (E-Pex, Eighteeth).

The teeth were prepared with Neoendo Flex rotary files (Orikam,India) in accordance with the manufacturer's guidelines at 350 RPM and 1.5 N Torque. Following the Specifications given by the manufacturer, biomechanical preparation was done maintaining an apical width of 0.25mm and 6% taper for uniformity.

The cavity was flushed with 2ml of 3% NaOCl, in between instrumentation. Following shaping, the root-canal was rinsed with 5mL of 3%NaOCl succeeded by rinsing with saline and flushing with 5mL of 17%EDTA in each canal, followed with irrigation with 3 ml saline and dried with the help of sterile paper point after completion of procedure.

After the master cone was positioned it was confirmed with RVG, patients of three groups underwent single cone obturation using Neoendo Flex compatible GP points(25/6; Diadent, Korea), with resin-based-sealer (AH Plus). Obturated was done in the same visit. After obturation, permanent post-endodontic restoration with

composite was done and a radiograph was obtained. Patients were segregated into 3 separate categories (n = 27).

Group A: No exposure with any wavelength of diode laser.

Group B: Exposed with Diode laser at wavelength 660nm for 120 secs at 0.1W giving the energy of 12 J. The 8mm Multitip in contact mode with continuous wave (CW) mode at 2 points both palatally and buccally over the apical region of the tooth (either side of tooth apex, 3mm from gingival crest on mesial & distal side)

Group C: Exposed with Diode laser at wavelength 970nm for 60secs at 0.2W giving the energy of 12 J. The 8mm Multitip was used in contact mode with continuous wave (CW) mode at 2 points each buccally and palatally over the apical region of the tooth (either side of tooth apex, 3mm from gingival crest on mesial & distal side).

Visual Analogue Scale (VAS) grading standards were taught to the patients.

No pain(0) - Treated tooth appeared normal, and patients reported absence of pain.

Mild pain(1-3) - Pain was noticeable yet not distressing

Moderate pain (4-7) - Pain was uncomfortable yet tolerable

Severe- pain (8-10)- Pain was hard to endure

Post-treatment, the patients were provided with a VAS form (Annexure VII) with them to record their pain levels at 6, 24, 48, and 72hrs following the procedure. The patient received frequent reminders telephonically to record their pain levels and to submit the completed VAS form. If an analgesic was used, the dosage was noted at

that specific moment. If the recommended medication was insufficient to relieve the pain, patients were instructed to get in contact with the treating doctor.

For the statistical analysis, SPSS software (version 20) was utilized

The following methods were used to compare VAS scores: the Mann-Whitney-U test was used for pair wise comparison of three groups at different time points. VAS scores between groups; the Kruskal-Wallis ANOVA test was used to compare three groups with VAS scores at different time points; the Chi-square test was used to explore the relationship between age and sex with VAS scores.

The VAS scores were compared using the following techniques: Three groups were compared pairwise at various intervals in time with the Mann-Whitney U test. VAS scores amongst groups; three groups. VAS scores at numerous time points were analyzed using the Kruskal-Wallis ANOVA test; the relation between age, sex and VAS scores was investigated using the Chi-square test.

THE STUDY DESIGN

81 patients requiring endodontic treatment in the maxillary 1st premolar teeth and fulfilling the inclusion criteria were selected for the study.

↓

The procedure was explained to the patient in his/her own language and a written informed consent was obtained

↓

An electric pulp-testing device (Parkell) was used to assess pulp vitality of the included teeth

↓

A single clinician evaluated all the patients, using radiographic and clinical findings, followed by treatment of all cases. This pocess was performed to eliminate interpersonal variability in the treatment between clinicians

↓

Exclusion criteria was strictly maintained and confounding variables were taken care by random allocation using computer generated table of random numbers.

After obtaining written consent from the patient, local anesthesia (2% lignocaine 1:1,00,000 adrenaline) was administered and rubber dam applied on tooth for isolation.

After isolation, tooth crown was cleaned with pumice and rinsed with normal saline

The tooth was then disinfected with 30% hydrogen peroxide and 5% iodine tincture for 60 seconds each using sterile cotton rolls and cotton pellets. The iodine was later inactivated by sodium thiosulphate[10].

After disinfection procedure, access cavity preparation was done and canal patency was checked by #10 K-file.

Glide path was created by # 15 k file

Teeth were instrumented with NEOENDO rotary files according to the manufacturer's instructions

The canals of all the teeth during preparation were irrigated with 3% NaOCl and 17% EDTA

1) After access: cavity flooded with 3% NaOCl for 2 mins[11]

2) Between instrumentation: 2 mL of 3% NaOCl per canal

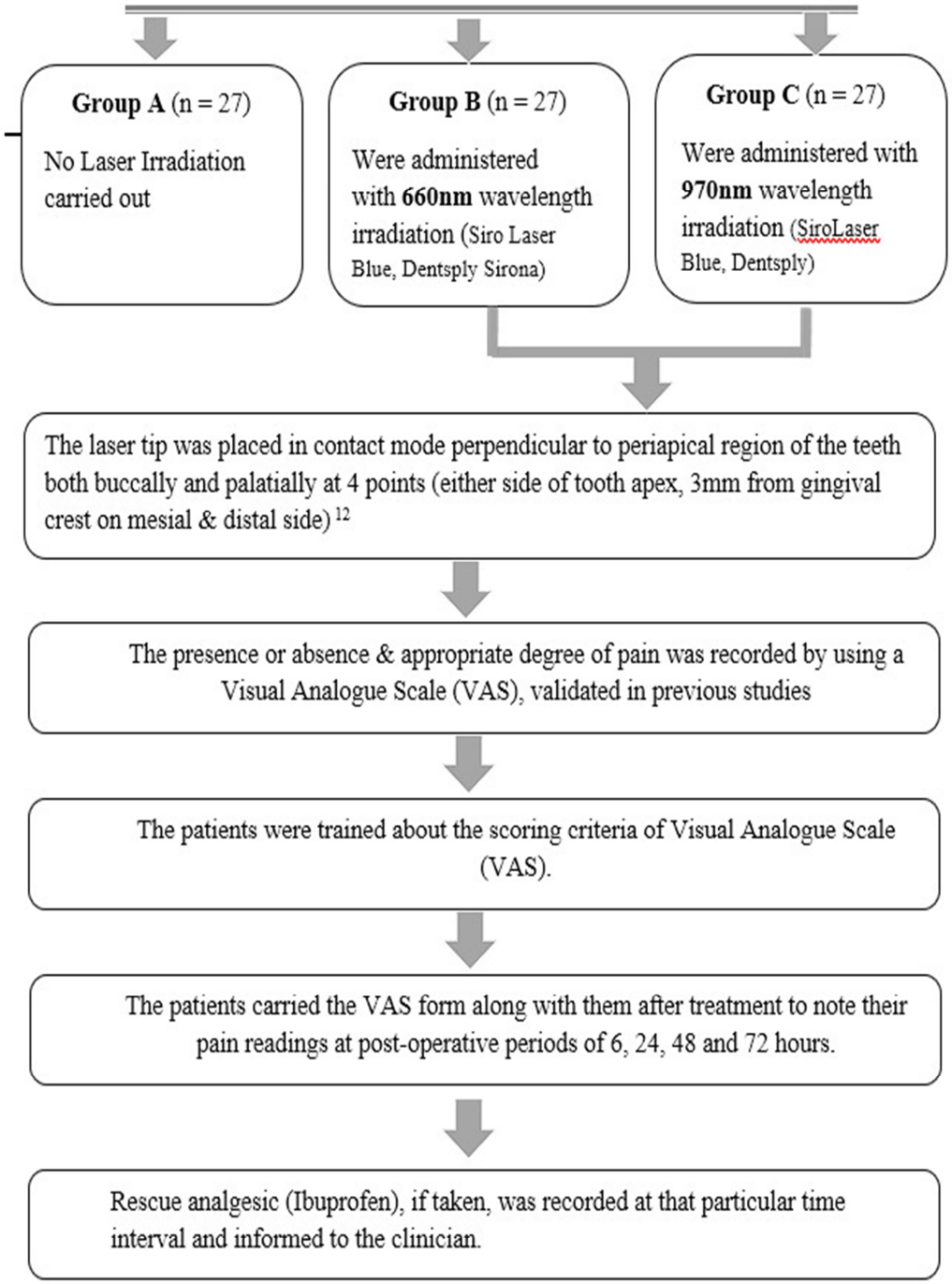
3) After shaping: 5 mL of 3% NaOCl followed by 5 mL of 17% EDTA per canal.

4) At completion of preparation, the canals will be irrigated with 3 ml of normal saline and dried with sterile paper points .

All canals were shaped & obturated with NEOENDO matching gutta-percha points and AH Plus sealer in a single-visit and coronal sealing was performed with composite followed by final radiograph.

For standardization purposes apical diameter of 0.25mm and 6% taper was maintained.

81 patients were randomly divided into three groups (Group A, Group B & Group C) of 27 each and irradiation was performed immediately after the endodontic treatment in group B & C.


Group A (n = 27)
No Laser Irradiation carried out
Group B (n = 27)
Were administered with **660nm** wavelength irradiation (Siro Laser Blue, Dentsply Sirona)
Group C (n = 27)
Were administered with **970nm** wavelength irradiation (SiroLaser Blue, Dentsply)
The laser tip was placed in contact mode perpendicular to periapical region of the teeth both buccally and palatially at 4 points (either side of tooth apex, 3mm from gingival crest on mesial & distal side) [12]
The presence or absence & appropriate degree of pain was recorded by using a Visual Analogue Scale (VAS), validated in previous studies
The patients were trained about the scoring criteria of Visual Analogue Scale (VAS).
The patients carried the VAS form along with them after treatment to note their pain readings at post-operative periods of 6, 24, 48 and 72 hours.
Rescue analgesic (Ibuprofen), if taken, was recorded at that particular time interval and informed to the clinician.

PHOTOGRAPHS

Fig.1 Diagnostic Instruments

Fig.2 LA and rubber dam armamentarium

Fig 3 Administration of LA

Fig.4 Rubber Dam Isolation

Fig.5 Material for Sterilization Protocol

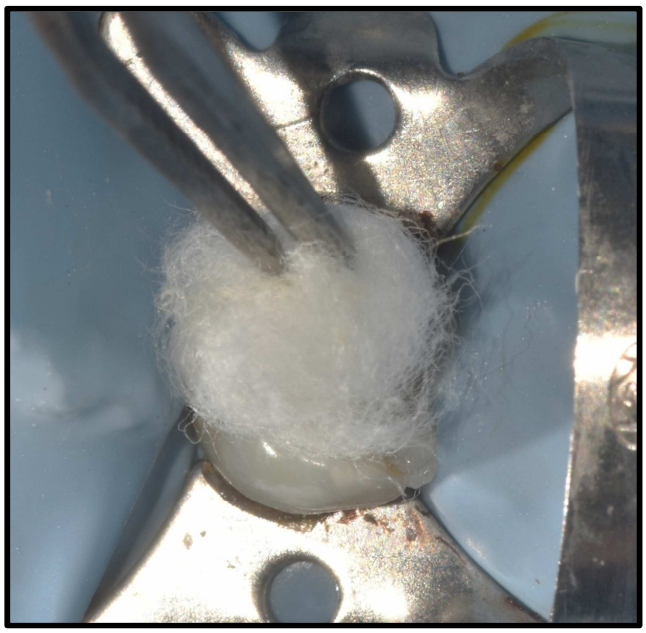


Fig.6 Sterilization Protocol; Step 1 - 30% Hydrogen Peroxide

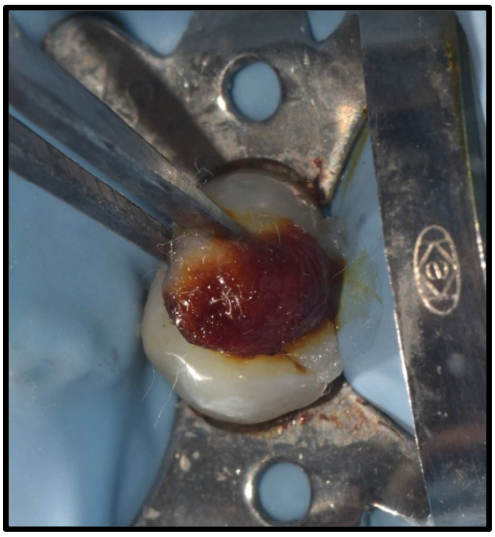


Fig 7.Sterilization Protocol;
Step 2 - 5% Povidine Iodine

Fig 8. Sterilization Protocol;
Step 3– Sodium Thiosulphate

Fig. 9 Access cavity preparation armamentarium

Fig.10 Prepared Access Cavity (Group A)

Fig.11 Cleaning and shaping armamentarium and materials

Fig.12 Materials for Irrigation

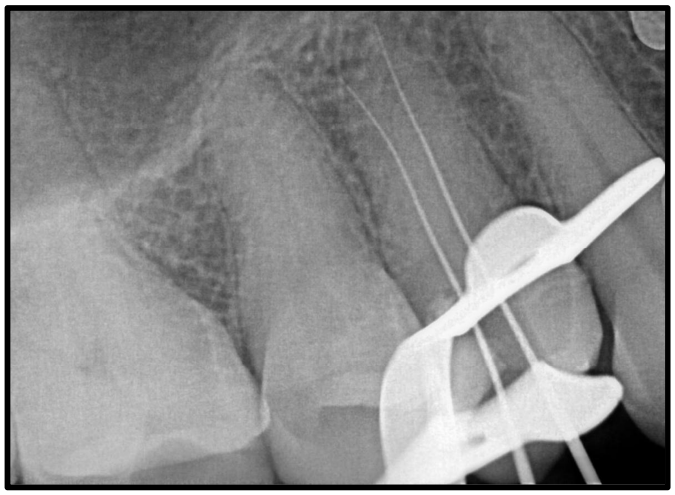


Fig.13 Working Length Radiographic Confirmation

Fig.14 Obturation materials and armamentarium

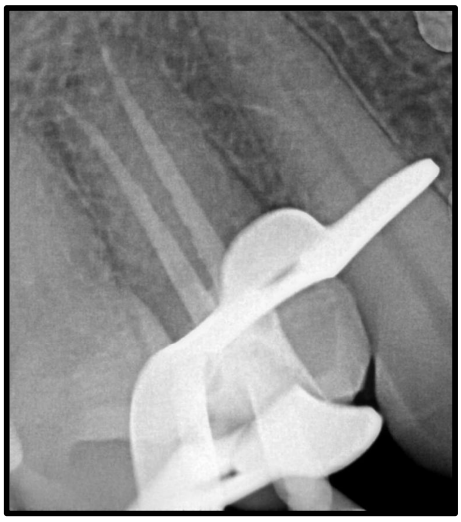


Fig.15 Master cone RVG with corresponding gutta-percha points

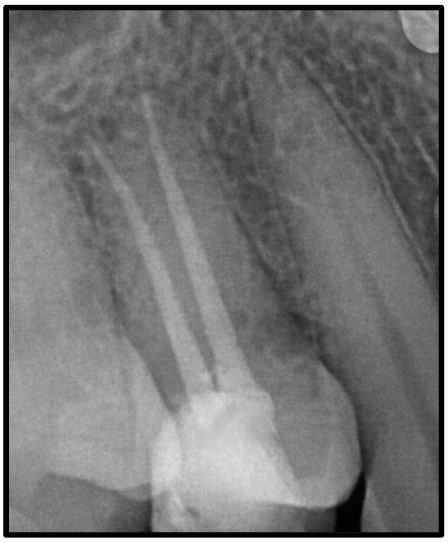


Fig.16 Post Obturation RVG

Group B

Fig 17. Prepared Access Cavity

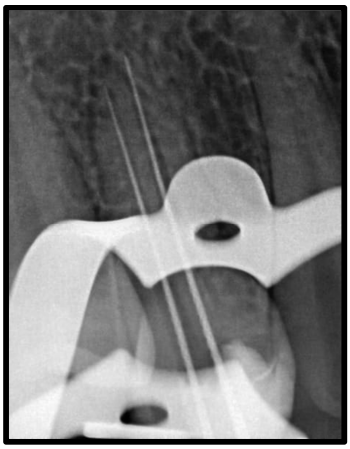


Fig.18 Working Length Radiographic Confirmation

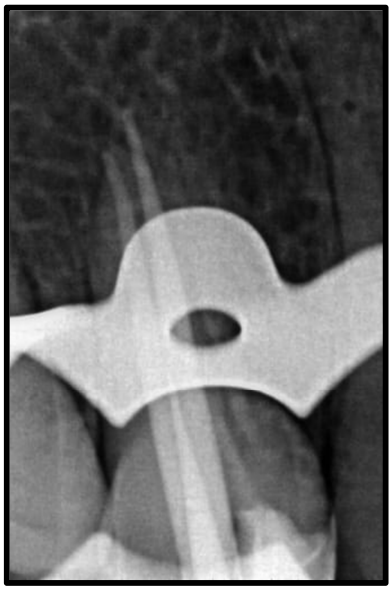


Fig.19 Master cone IOPAR with corresponding gutta-percha points

Fig.20 Post Obturation RVG

Fig 21 Laser parameters setting at 660nm

Fig 22.Photobiomodulation done on buccal surface using 660nm diode laser

Fig 23.Photobiomodulation done on palatal surface using 660 nm diode laser

Group C

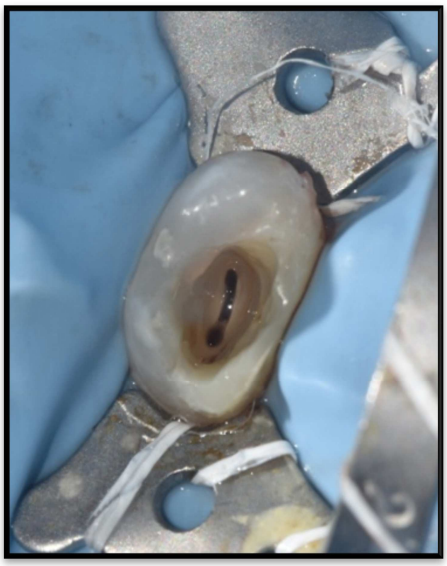


Fig 24. Prepared Access Cavity

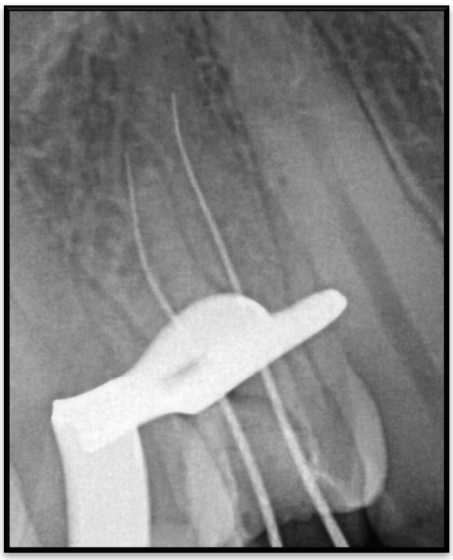


Fig.25 Working Length Radiographic Confirmation

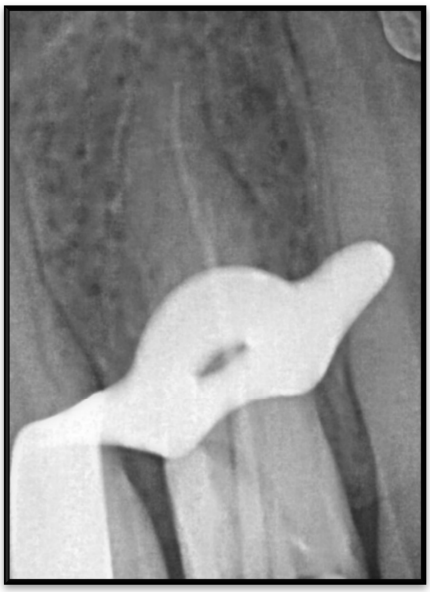


Fig.26 Master cone IOPAR with corresponding gutta-percha points

Fig.27 Post obturation RVG

Fig 28 Laser parameters at 970 nm settings

Fig 29 .Photobiomodulation done on buccal surface using 660nm diode laser

Fig 30.Photobiomodulation done on palatal surface using 660nm diode laser

RESULTS

Table 1: Group A

Patient	Sex	Age	6hrs	24hrs	48hrs	72hrs
A1	M	41	4	1	0	0
A2	M	36	1	1	0	0
A3	F	25	6	3	1	1
A4	M	35	1	0	0	0
A5	F	26	5	2	1	0
A6	F	35	0	0	0	0
A7	F	33	3	2	0	0
A8	F	34	1	1	1	0
A9	M	35	4	1	0	0
A10	F	30	1	1	0	0
A11	M	34	5	2	1	0
A12	F	29	4	1	0	0
A13	F	35	2	1	0	0
A14	M	48	4	1	0	0
A15	M	46	2	1	1	0
A16	F	34	1	1	0	1
A17	F	30	4	1	0	0
A18	F	28	5	2	0	1
A19	F	22	1	0	0	0
A20	M	32	3	1	1	1
A21	F	27	0	0	0	0
A22	F	40	2	2	2	0
A23	F	32	1	1	0	0
A24	F	36	4	2	0	0
A25	F	29	2	1	1	0
A26	F	28	0	0	0	0
A27	F	37	1	1	0	0

Table 2 - Group B

Patient	Sex	Age	6hrs	24hrs	48hrs	72hrs
B1	F	42	2	1	0	0
B2	M	32	0	0	0	0
B3	M	30	1	0	0	0
B4	M	38	2	1	0	0
B5	M	35	1	0	0	0
B6	F	26	0	0	0	0
B7	M	31	3	1	0	0
B8	F	45	1	1	0	0
B9	F	25	2	0	0	0
B10	F	28	1	1	0	0
B11	F	20	0	0	0	0
B12	F	39	1	0	0	0
B13	M	37	1	1	0	0
B14	F	27	0	0	0	0
B15	F	35	1	0	0	0
B16	M	20	4	2	0	0
B17	M	26	1	0	0	0
B18	F	21	0	0	0	0
B19	F	24	4	3	0	0
B20	F	24	0	0	0	0
B21	F	35	1	0	0	0
B22	F	33	1	1	0	0
B23	F	26	4	1	0	0
B24	F	32	1	1	0	0
B25	F	25	0	0	0	0
B26	F	26	2	1	0	0
B27	F	25	0	0	0	0

Table 3 - Group C

Patient	sex	age	6hrs	24hrs	48hrs	72hrs
C1	F	21	1	0	0	0
C2	F	36	0	0	0	0
C3	M	25	2	0	0	0
C4	F	25	1	1	0	0
C5	M	26	1	0	0	0
C6	M	35	0	0	0	0
C7	M	33	0	0	0	0
C8	F	24	0	0	0	0
C9	F	35	1	0	0	0
C10	M	33	1	1	0	0
C11	F	34	0	0	0	0
C12	M	29	1	0	0	0
C13	M	36	0	0	0	0
C14	M	48	0	0	0	0
C15	F	45	1	0	0	0
C16	F	44	4	2	0	0
C17	F	33	1	0	0	0
C18	F	25	0	0	0	0
C19	M	22	0	0	0	0
C20	F	42	0	0	0	0
C21	F	23	1	0	0	0
C22	M	33	1	1	0	0
C23	M	32	4	1	0	0
C24	F	50	1	1	0	0
C25	F	29	0	0	0	0
C26	F	40	2	1	0	0
C27	M	34	0	0	0	0

Table 4: Comparison of three groups with gender distribution

Group	Male	%	Female	%	Total
Group A	9	32.14	19	67.85	28
Group B	9	32.14	19	67.85	28
Group C	12	42.85	16	57.14	28
Total	30	35.71	54	64.28	84
Chi-square=1.1770, p=0.5551					

Figure 31: Comparison of three groups with gender distribution

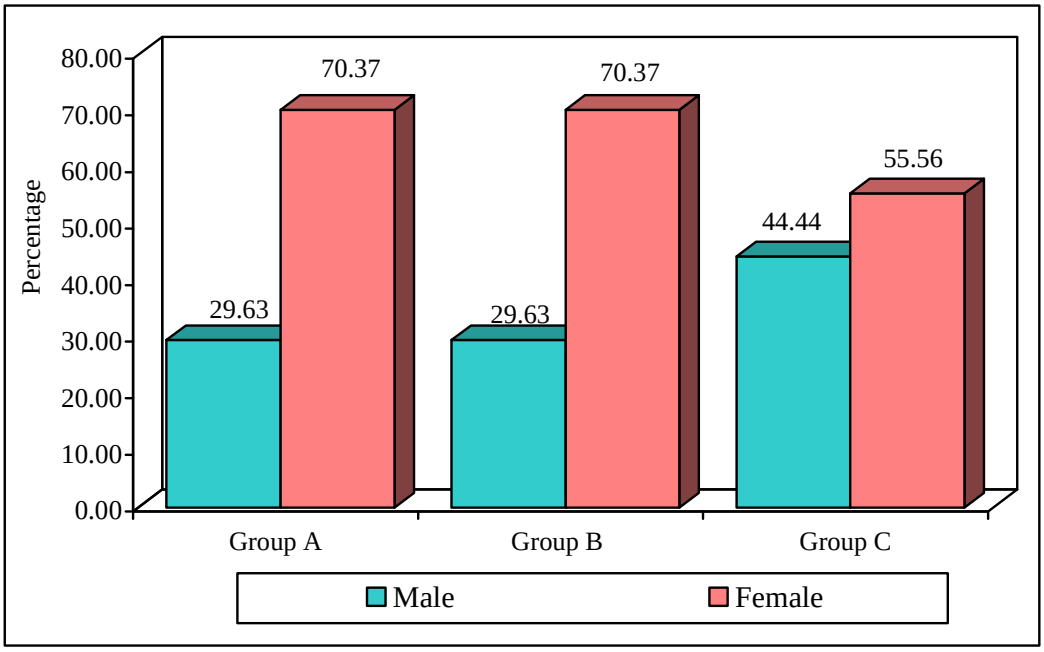


Table 5: Comparison of three groups with mean age by one way ANOVA

Group	Mean	Std.Dev.
Group A	33.22	5.98
Group B	29.89	6.68
Group C	33.04	7.98
Total	32.05	7.02
F-value	1.9718	
p-value	0.1461	

Figure 32: Comparison of three groups with mean age

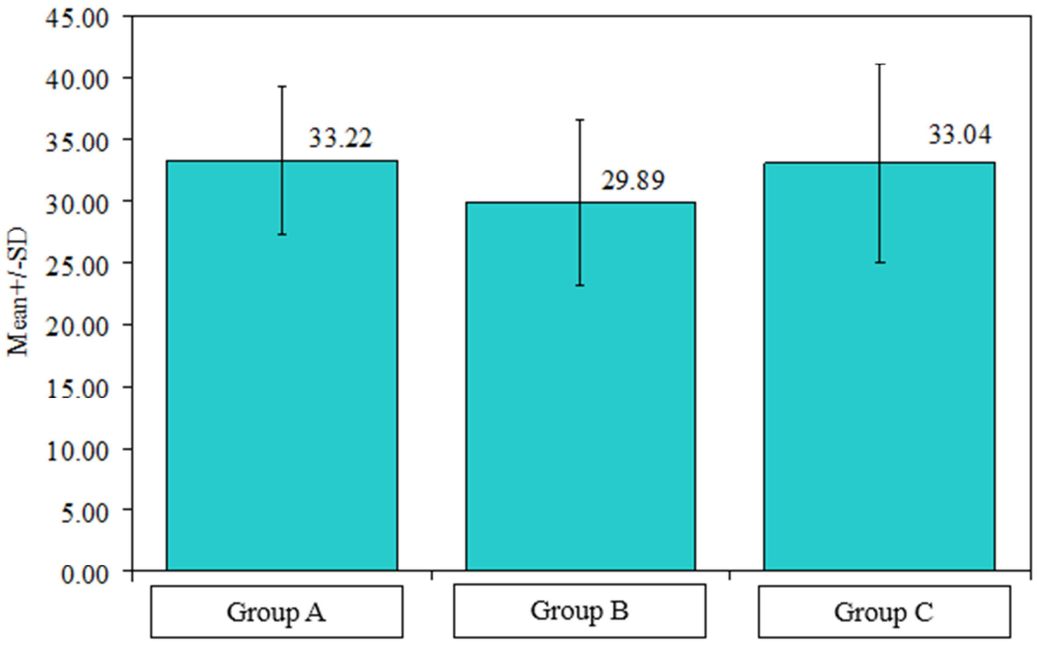


Table 4, Figure 21 and Table 5, Figure 22 shows the demographic profile of the participants by showing age and gender wise distribution of patients in 3 groups namely Group A, Group B, and Group C.

A total of 81 participants were included in the study. In Group A a total of 27 participants were included where 8 participants (29.63%) were males and 19 participants (70.37%) were females. In Group B, a total of 27 participants were included where 8 participants (29.63%) were males and 19 participants (70.37%) were females. In Group C a total of 27 participants were included from which 12 participants (44.44%) were males and 15 participants (55.56%) were females. Thus, all 28 male participants and 53 female participants were included in the study. The chi-square value was 1.7770 and the 'p' value was 0.5551 ($p<0.05$) which was non-significant indicating equal gender distribution of participants in all the 3 groups.

The mean age of Group A was 33.22 ± 5.98, mean age of Group B was 29.89±6.68 and the mean age of Group C was 33.04±7.98. The mean age group of the study was 32.05±7.02. By one-way ANOVA test, F value = 1.9718 and p value = 0.1461 which was non-significant indicating equal age distribution of participants in all the 3 groups.

Table 6: Comparison of three groups with VAS scores at different treatment time points by Kruskal Wallis ANOVA

Time points	Group A			Group B			Group C			H-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank	Mean	SD	Mean rank		
6hrs	2.5	1.8	54.0	1.3	1.3	38.3	0.9	1.1	30.7	14.9530	0.0010*
24hrs	1.1	0.8	54.7	0.6	0.8	37.9	0.3	0.5	30.4	18.2720	0.0001*
48hrs	0.3	0.6	48.0	0.1	0.3	39.0	0.0	0.0	36.0	11.8000	0.0030*
72hrs	0.1	0.4	45.0	0.0	0.0	39.0	0.0	0.0	39.0	8.3120	0.0160*
6hrs to 24hrs	1.4	1.3	49.2	0.7	0.8	39.0	0.6	0.8	34.9	6.1240	0.0470*
6hrs to 48hrs	2.1	1.7	50.9	1.2	1.1	39.7	0.9	1.1	32.4	9.2720	0.0100*
6hrs to 72 hrs	2.3	1.7	53.0	1.3	1.3	38.8	0.9	1.1	31.2	12.9620	0.0020*

*$p<0.05$

Intergroup comparison of Mean rank of VAS scores was compared for 3 groups by Kruskal Wallis ANOVA test. At 6 hrs, in Group A VAS was 54.0, in Group B VAS was 38.3 and in Group C VAS was 30.7 showing the lowest pain score value in Group C with a highly statistically significant p-value = 0.0010. Similarly, at 24 hrs VAS scores in Group A were 54.7, in Group B were 37.9 and in Group C were 30.4 showing the lowest pain scores value in Group C with a very highly statistically significant p-value = 0.0001. The pain scores at 48 hrs in Group A were 48, in Group B was 39, and in Group C was 36 showing the lowest pain score value in Group C with a highly statistically significant p-value = 0.003**.** The pain scores at 72 hrs in

Group A were 45, in Group B was 39, and in Group C was 39 showing the lowest pain score value in Group C with a highly statistically significant p-value = 0.016**.**

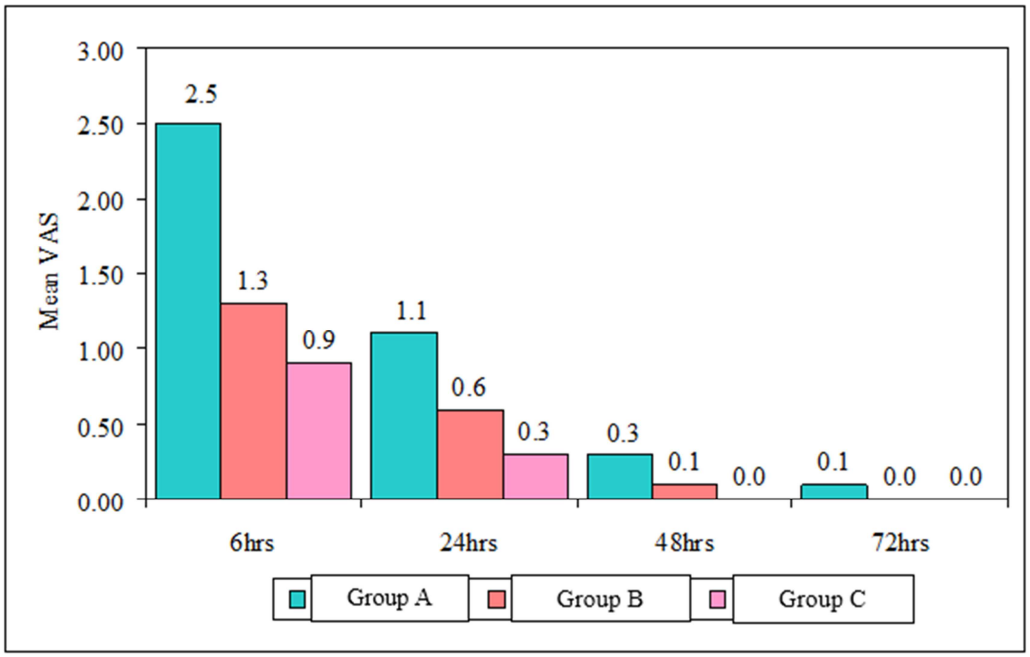
Comparison of pain scores at 6hrs to 24 hrs in Group A, Group B, and Group C, was 49.2, 39 and 34.9 respectively. The difference among them was statistically significant with a p-value of 0.0470. Similarly, the comparison of pain scores at 6hrs to 48hrs in Group A is 50.9, in Group B is 39.7, and in Group C is 32.4 with a statistically significant p-value of 0.0100. Whereas the Comparison of pain scores in Group A Group B and Group C were 53.0, 38.8, and 31.2 respectively with a statistically significant p-value of 0.0020.

Table 7: Pair-wise comparison of three groups with VAS scores at different treatment time points by Mann-Whitney U test

	Group A vs Group B		**Group A vs Group C**		**Group B vs Group C**	
Time points	**Z-value**	**p-value**	**Z-value**	**p-value**	**Z-value**	**p-value**
6hrs	2.5431	0.0110*	3.5119	0.0004*	1.2888	0.1975
24hrs	2.6296	0.0085*	3.7368	0.0002*	1.1850	0.2360
48hrs	1.4099	0.1586	1.8597	0.0629	0.4584	0.6466
72hrs	0.9255	0.3547	0.9255	0.3547	-0.0086	0.9931
6hrs to 24hrs	1.6521	0.0985	2.1365	0.0326*	0.7006	0.4835
6hrs to 48hrs	1.8857	0.0593	2.7247	0.0064*	1.2542	0.2098
6hrs to 72hrs	2.3095	0.0209*	3.2783	0.0010*	1.2888	0.1975

*$p<0.05$

Figure 33: Comparison of three groups with VAS scores at different treatment time points



Pairwise comparison of three groups having VAS by Mann Whitney U test at 6 hrs of Group A in comparison to Group B gave a statistically significant 'p' value of 0.011. For Group A compared to Group C a very highly statistically significant p-value of 0.0004 was obtained. The difference in VAS for Group B in compared to Group C was found to be statistically non-significant with a p-value of 0.1975. At 24 hrs Group A in compared to Group B gave a statistically significant 'p' value of 0.0085. For Group A in comparison to Group C, a very highly statistically significant p-value of 0.0002 was obtained whereas the difference in VAS for Group B vs Group C was found to be statistically non-significant with a p-value of 0.2360. At 48 hrs Group A in comparison Group B gave a statistically non-significant with a 'p' value of 0.1586. For Group A vs Group C, a statistically non-significant p-value of 0.0629 was obtained and the difference in VAS for Group B vs Group C was found to be statistically non-significant with a p-value of 0.6466. At 72 hrs Group A in

comparison to Group B gave a statistically non-significant with a 'p' value of 0.3547. For Group A vs Group C, a statistically non-significant p-value of 0.3547 was obtained and the difference in VAS for Group B vs Group C was found to be statistically non-significant with a p-value of 0.9931.

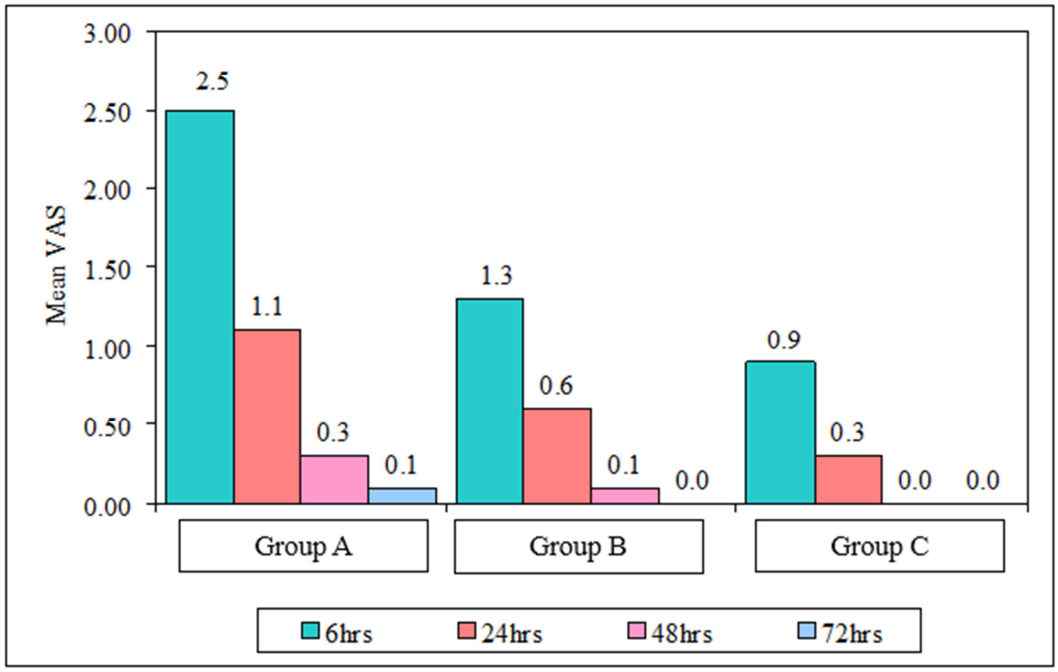
Pair-wise analogy of pain scores at 6hrs to 24 hrs in Group A vs Group B showed statistically non-significant results with a 'p' value of 0.0985. The comparison between Group A in compare to Group C was found to be statistically significant with p value of 0.0326. The difference in VAS at 6-24hrs for Group B in compare to Group C was found to be statistically non-significant with p-value of 0.4835. Pair-wise analogy of pain scores at 6hrs to 48 hrs in Group A in compare to Group B showed statistically non-significant results with a 'p' value of 0.0593. The comparison between Group A in compare to Group C was found to be statistically significant with p value of 0.0064. The difference in VAS at 6-24hrs for Group B in compare to Group C was found to be statistically non-significant with p-value of 0.2098. Whereas Pair-wise analogy of pain scores at 6hrs to 72 hrs in Group A in compare to Group B showed statistically significant results with a 'p' value of 0.0209. The comparison between Group A in compare to Group C was found to be statistically significant with p value of 0.0010. The difference in VAS at 6-24hrs for Group B in compare to Group C was observed to be statistically non-significant with p-value of 0.1975.

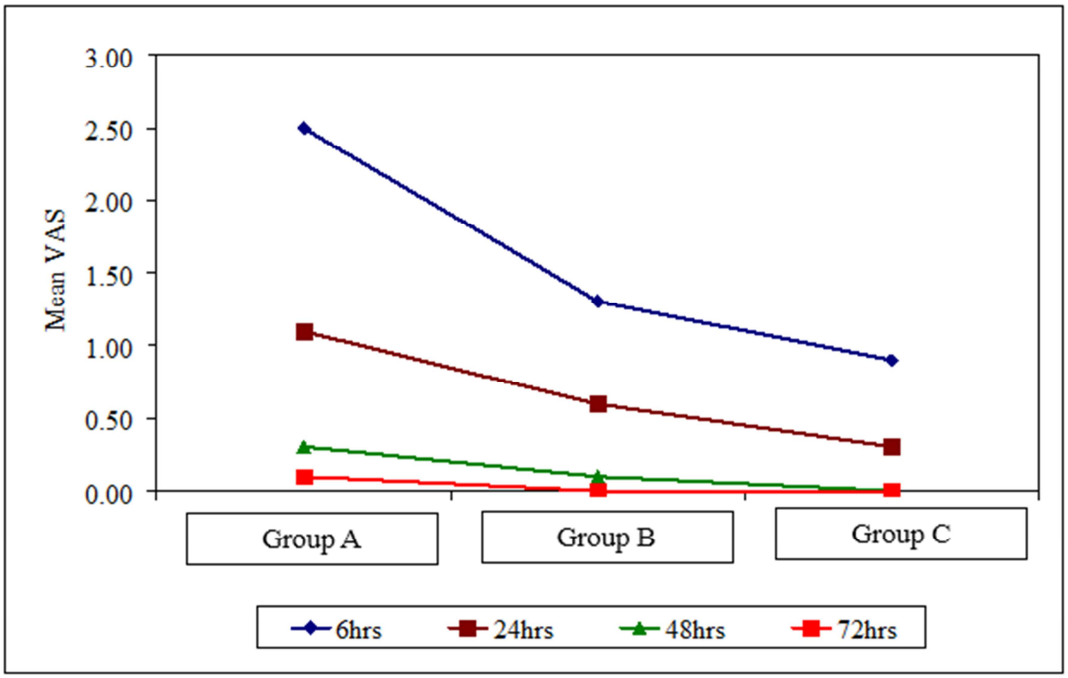
Table 8: Comparison of different treatment time points with VAS scores in three groups by Friedman's ANOVA and Wilcoxon matched pairs test

Groups	Changes from	Mean change	% of change	Z-value	P-value	Friedman ANOVA	P-value
Group A	**6hrs -24hrs**	1.4	55.22	3.6214	0.0003*	58.4619	0.0001*
	6hrs -48hrs	2.1	86.57	4.1069	0.0001*		
	6hrs -72hrs	2.3	94.03	4.1973	0.0001*		
Group B	**6hrs -24hrs**	0.7	55.88	3.2958	0.0010*	48.3061	0.0001*
	6hrs -48hrs	1.2	94.12	3.8230	0.0001*		
	6hrs -72hrs	1.3	100.00	3.8230	0.0001*		
Group C	**6hrs -24hrs**	0.6	65.22	2.9341	0.0033*	37.2616	0.0001*
	6hrs -48hrs	0.9	100.00	3.4078	0.0007*		
	6hrs -72hrs	0.9	100.00	3.4078	0.0007*		

*$p<0.05$

Figure 34: Comparison of different treatment time points with VAS scores in three groups





Intragroup comparison of VAS in 3 groups was done by Friedman's ANOVA and Wilcoxon matched pairs test. In Group A the changes from 6hrs – 24 hrs were perceived to be very highly statistically significant p=0.0003. Changes from 6 to 48 hrs were also found to be very highly statistically significant p=0.0001. The changes from 6 to 72 hrs were found to be very highly statistically significant p=0.0001. Overall, the intragroup comparison in Group A was very highly statistically significant with p = 0.0001. And In Group B the changes from 6hrs – 24 hrs were found to be very highly statistically significant p=0.0001. Changes from 6 to 48 hrs were also found to be very highly statistically significant p=0.0001. The changes from 6 to 72 hrs were found to be very highly statistically significant p=0.0001. Overall, the intragroup comparison in Group B was very highly statistically significant with p = 0.0001. Similarly In Group C the changes from 6hrs – 24 hrs were found to be very highly statistically significant p=0.0033. Changes from 6 to 48 hrs were also found to be very highly statistically significant p=0.0007. The changes from 6 to 72 hrs were perceived to be very highly statistically significant p=0.0007. Overall, the intragroup comparison in Group B was very highly statistically significant with p = 0.0001.

DISCUSSION

The twenty-first century has endorsed many remarkable advancements in the field of endodontics transforming the way root canal treatments are performed.(39) These advancements include digital radiography, motor-driven root canal preparation systems, ultrasonics, and lasers. These key developments over the last couple of decades have increased the efficiency of clinicians in performing the procedures faster, with more precision, leading to improved patient outcomes thus improving the quality and demand for single-visit endodontia.(40)

Endodontic treatment procedures or non-surgical endodontic treatment are done to alleviate pain and irradicate infection from the teeth. A painful tooth might lower one's quality of life.(41) Post-operative pain development is a common complication that can occur immediately post endodontic therapy and can last up to 3 days post-treatment.(42) Post-operative endodontic pain has been reported to be 1.9%-48%(3) . The severity and duration of pain can vary depending on several factors, including the extrusion of debris at the apex, over-instrumentation or over-preparation of apical areas, pulp tissue remnants, extrusion of irrigants, and obturating materials, microbiological remnants(43).

The conventional endodontic treatment supported multiple visit endodontics for high clinical success rates(44). However postoperative sequelae and healing outcomes do not show a significant difference between one-visit and two-visit treatment procedures.(45) A similar outcome was also concluded by Mergoni et al. 2022,(46) and the comprehensive systematic review by Wong et al. 2014. (44) Molendar et al. concluded that there was no significant difference in terms of healing results between one-visit and multiple-visit endodontic treatment(47).

Inflammatory mediators such as prostaglandins, leukotrienes, bradykinin, and serotonin are released in response to pain, which activate pain-sensing nociceptors.(48) This leads to increased sensitivity and pain through both local and systemic mechanisms. Notably, prostaglandins are key contributors to the development of pulpal and periradicular inflammation, playing a significant role in the underlying pathology of endodontic disease.(49)

For reliving the post-endodontic pain the primary choices typically revolve around different prescription drugs like non-steroidal-anti-inflammatory drugs (NSAID), steroid-based anti-inflammatories (corticosteroids), analgesics like acetaminophen (paracetamol), and opioid-based pain relievers(7,50).

Despite NSAIDs' effectiveness in pain management and reduction of inflammation, extensive research and literature show their side effects, specific limitations, and risks which include increased cardiovascular risk, renal toxicity, drug hypersensitivity, decreased fertility, gastric ulceration, etc.(47) Additionally, the usage of corticosteroids and opioid analgesics also have adverse effects.(8)

An alternative for the management of pain can be photobiomodulation therapy (PBM). (11,27,51). PBM therapy has been in use in dentistry since the 1970s(52). With growing interest in non-pharmacological and minimally invasive adjuncts for pain control, photobiomodulation (PBM) using LLLT has emerged as a promising modality(14).

The therapeutic applications of LLLT are guided by three main principles: reducing inflammation and edema in chronic conditions, promoting wound healing, and managing neurological disorders and neuropathic pain.(53)

Arndt-Schultz's law states that “small doses stimulate, moderate doses inhibit, and large doses can be harmful”. In PBM, Subcellular chromophores mostly in the mitochondria absorb low-level radiation, which causes cellular activity.(54,55)

The key mechanism involves the absorption of light by cytochrome-c-oxidase (CCO), an enzyme within the mitochondria, which enhances ATP synthesis and boosts oxygen utilization. This triggers the release of nitric oxide (NO), initiates secondary messenger cascades, and stimulates the activation of transcription and growth factors.(56) As photon absorption increases, cellular metabolism is stimulated up to a point, beyond which the effects diminish and may become inhibitory or damaging. Randa Zein et al. stated that properly dosed photobiomodulation (PBM) can enhance periradicular healing after root canal treatment by promoting wound healing, collagen synthesis, vascularization, and enzyme production, supporting overall tissue repair and regeneration(19,55).

The pain-relieving effects of PBM are attributed to multiple mechanisms. These include reduced levels of inflammatory mediators such as prostaglandins, interleukin-1β, TNF-alpha, and substance P; inhibition of nociceptor activity; enhanced lymphatic drainage; and increased histamine release. LLLT also boosts the production of anti-inflammatory agents like PGI2, beta-endorphins, enkephalins, and ACTH, while modulating immune responses through elevated immunoglobulin and lymphokines.(31,57) Additionally, it inhibits pro-inflammatory neurotransmitters and the COX-2 pathway, and alters cell membrane permeability to calcium, sodium, and potassium ions. Together, these effects contribute to its analgesic and anti-inflammatory actions.(58) (17,18,59)

Despite growing evidence of its effectiveness in pain management, photobiomodulation (PBM) lacks universal acceptance due to variability in light sources.(60) Various parameters noted are wavelengths (600–1100 nm), power-density measured in mW/cm^2, and the energy-density measured in J/cm^2 across studies.(37) The power-density and resulting cellular effects can vary significantly depending on the specific area exposed to the photon beam, and specific wavelengths produce distinct biological effects and identify optimal parameters for achieving the best therapeutic outcomes in each condition.(11,55)

Determining the most effective wavelength for therapeutic use remains a debated topic, with ongoing research and assessment continuing to explore this area.(60–62) Therefore, a prospective randomized controlled trial aimed to compare the photobiomodulatory effects of 660nm and 970nm diode lasers on post-operative pain management in single-visit endodontic treatment was conducted.

This research also investigated the association of characteristics such as age and sex on post-operative pain within the groups.

In this study, participants were chosen from the regular patient base reporting to the Department of Conservative Dentistry and Endodontics at KAHER's KLE V.K. Institute of Dental Sciences, Belagavi. A total of 81 patients diagnosed with asymptomatic irreversible pulpitis in maxillary first premolars and requiring endodontic therapy were selected by a single practitioner. Case selection was based on thorough clinical and radiographic assessment aligned with predefined inclusion and exclusion criteria.

Statistical Analysis

$p1$: Percentage of change in the 1st group= 0.429

$p2$: Percentage of change in the 2nd group= 0.086

d : Risk difference $p1 - p2$ = 0.343

α: Level of significance = 5%

1 – β: Power = 85%

Formula $n = \frac{2(pq)(Z\alpha+Z\beta)(d)2}{(d)^2}$

Where, p =$\frac{p1+p2}{2}$, q = 1- p

Estimated sample size for each group = 27

The total sample size was 81

Considering 10 % dropouts in each group,

n = 30 in each group

The clinical trial's reliability and validity were assessed with a 10% dropout rate, as a higher rate could potentially impact the study's effectiveness and would also help avoid attrition bias.(63)

The condition of the teeth was standardized to minimize the effect of confounders.(31) An age range of 18 to 50 years old was considered for this investigation. As the connection between a dentist and a patient is fundamentally a contract, it follows that only those who are at least 18 years old are eligible to sign a doctor-patient agreement and provide consent for medical treatment.(53) Additionally, individuals over 50 were not considered, as studies indicate that up to 90% of this population exhibit some degree of root canal calcification.(64,65)

Maxillary premolars with two roots or two canals and straight root anatomy were selected for this study to minimize frictional stress and torque exerted by the

endodontic file.(66) This selection also helps reduce the apically directed force required to reach the working length(WL), thereby decreasing the risk of inadvertent debris extrusion. Teeth in which a #20 K-file easily reached the working length or a #10 K-file was difficult to advance were excluded to ensure consistency in canal anatomy. To eliminate variability in clinical technique, all procedures were performed by a single clinician(67).

Based on Glennon et al.'s findings that preoperative pain significantly affects postoperative outcomes, the study focused on teeth with asymptomatic irreversible pulpitis or vital teeth undergoing treatment for prosthetic reasons(68). Teeth with adequate coronal structure were included to ensure proper isolation, while asymptomatic non-vital teeth were excluded due to their association with increased postoperative discomfort.

Additionally, patients with multiple ipsilateral teeth requiring root canal treatment were excluded to avoid confusion in pain perception and potential false positives(69). Teeth with chronic apical periodontitis, necrotic pulps, symptomatic acute conditions, or those previously treated with intracanal medicaments—such as retreatment cases and weeping canals—were also excluded due to their higher risk of postoperative pain. Furthermore, periapical radiolucencies greater than 5 mm in diameter were excluded, as Glennon et al. reported a correlation with increased postoperative pain(68).

This study excluded patients who were taking antibiotics that might indicate a weak immune system or an underlying illness.(70) It also excluded those taking painkillers, as these could affect pain levels and lead to inaccurate VAS (Visual Analogue Scale) scores. Additionally, patients using steroids were not included

because steroids can significantly reduce the amount and severity of pain after treatment.(71)

Apical-patency was maintained by gently passing a small #10 K-file through the canal without binding or widening the apical foramen, helping to prevent postoperative pain.

WL was determined using an apex locator and confirmed with a radiograph, as the European Endodontic Society recommends this combined method for greater accuracy.(72) Torabinejad et al. found that unintentional overextension of a #15 K-file does not impact the incidence of postoperative pain.(73)The irrigants for this study was 3%NaOCl, 17%EDTA, 0.9% normal saline according to the following protocol.

Following Ruddle's technique, a push-pull motion with #15 stainless steel K-files (Mani Inc., Japan) was used to establish the working length and complete the glide path. This approach helps minimize treatment-related pain by reducing debris extrusion beyond the apex and aiding its suspension in the irrigant.(74)

The root canals were prepared with Neoendo Flex. The teeth were instrumented with Neoendo Flex (orikam, India) files according to the manufacturer's instructions operating at 350 RPM and 1.5 Ncm Torque.(75) NeoEndo Flex files have undergone gold thermal treatment, enhancing their flexibility and cutting efficiency, which are critical factors in successful root canal procedures.(76) Following the Specifications given by the manufacturer, biomechanical preparation was done maintaining an apical diameter of 0.25mm and 6% taper for uniformity purposes.

Between each file during instrumentation, 2 mL of 3% NaOCl was used to irrigate the canal. Following shaping, for final irrigation 5 mL of 3% NaOCl was used followed by rinsing with saline and flushing with 5 mL of 17% EDTA in each canal, To neutralise any remaining irrigants, a final irrigation was carried out using 0.9% normal saline and dried with help of sterilized Paper point after completion of the procedure.

Following the placement of a master cone and confirmation with RVG, patients of three groups underwent single cone obturation using Neoendo Flex compatible GP points, with AH plus sealer. AH plus sealer was used as Several studies have considered it to be the gold-standard for sealer, due to its resorption resistance and dimensional stability.(77)The canals were obturated in a single visit. After obturation, permanent restoration with bulk fill composite was obtained to obtain a good-quality coronal seal thereby to avoid coronal microleakage(78). A radiograph was taken postoperatively.

A table of random numbers was used to randomly allocate the confounding variables of age and sex. The table of random no helps eliminate selection bias and enhances randomization improving the validity of the results.(79) There were three groups of patients each consisting of 27 patients.

Patients of Group A being the control group were not exposed to any wavelength of a diode laser. The patients belonging to Group B (Fig. 21)were exposed to Diode Laser at a wavelength of 660nm for 120 secs at 0.1W giving the energy of 12 J per tooth. The Multitip of 8mm diameter (beam area 0.5 cm^2) was used in contact mode with continuous wave mode at 2 points each buccally(Fig 22) and palatally (Fig 23) thereby delivering an energy of 3J per site over 30 seconds.(15) In Group C(Fig 28) the patients were exposed to Diode laser at a

wavelength 970nm for 60secs at 0.2W giving the energy of 12 J per site. The Multitip of 8mm diameter (beam area 0.5 cm^2) was used in contact mode with continuous at 2 points each buccally(Fig 29) and palatally(Fig 30) thereby delivering a total energy of 3J per site over 15 seconds.

LLLT or photobiomodulation can be conducted using wavelengths in between 600nm -1100nm.(10)This range of wavelength can be divided into two groups; 660nm wavelength near-red light and 970 nm wavelength near infrared light(15). Studies by Nabi et al.,(16) 2018, Shah et al. (2021) have shown 660nm to be effective in postendodontic pain management. On the contrary studies by Asnaashari et al.(19) (2017), Lopes et al.(2019)(20) showed 970nm wavelength to be more effective in postendodontic pain management. 660nm and 970nm being the most common wavelength being used for photobiomodulation therapy were the chosen wavelength for the study.(11)

Jenkins and Carroll (2011)(80) emphasized that key treatment parameters—such as the beam spot size at the target(cm^2), irradiance at the target(mW/cm^2), exposure-time (seconds), number of irradiation-points, total area treated(cm^2), and the number and frequency of treatment sessions—significantly influence the total energy delivered, thereby affecting clinical outcome and to successfully elicit biological responses.(31)

The laser light is transmitted via a laser tip or multitip. The multitip follows the principle of Transmission emission mode (TEM).(22) In TEM the energy is not meant to cut or ablate, but rather to be absorbed by cells and deeper tissues to stimulate repair. The Flat-top headpiece of multitip uses internal optics (e.g., prisms and lenses) to flatten the beam profile and maintain a uniform, collimated spot size,

ensuring consistent energy delivery this explains the use of multitip which is 8mm in diameter and giving out the beam spot size at the target area to be 0.5cm.(60)

The laser was used in contact mode which is needed to ensure full contact with dental structures to minimize the loss of energy.(81) (Low-level laser therapy in dentistry; DCNA 2004).

According to current guidelines, irradiance should be kept below 0.75W/cm² when using near-infrared (NIR) sources in photobiomodulation and below 0.3 W/cm² for sources in the 600–700 nm wavelength range to ensure safe therapeutic levels.(55,82) With 660nm wavelength, the Power irradiance at the target used was 0.1W/cm² with a total exposure time of 120 seconds and with 970nm wavelength, the Power irradiance at the target used was 0.2W/cm² with a total exposure time of 60 seconds.

Energy (Joules) = Power (Watts) × Time (seconds)

Roscoe–Bunsen's law of reciprocity states that “the most important parameter in PBM is the total quantity of photons absorbed by the target cells, and it is not important how quickly or how slowly these photons are delivered using the same spot size”(81). Among energy, time, and power, the most important parameter for photon delivery is energy, and hence the energy delivery while using both wavelengths has been kept at 12J.

In this study, postoperative pain was assessed using the 10cm VAS, a widely accepted and patient-friendly tool in dental research. Pain levels were recorded at 6, 24, 48, and 72 hours after endodontic treatment. The 6-hour mark was chosen as the earliest time point due to the possible extended effect of local anaesthesia, which can

last up to 6 hours in some cases. The 12-hour interval was omitted to avoid inconvenience in contacting patients. Pain scores were categorized as follows:

- **No pain (0):** Tooth felt normal with no reported discomfort.
- **Mild pain (1–3):** Noticeable but not distressing pain.
- **Moderate pain (4–7):** Uncomfortable yet tolerable pain.
- **Severe pain (8–10):** Intense, difficult-to-endure pain.

All scores were recorded, tabulated, and analysed statistically.

In table 4 groups A and B had the same gender distribution—29.63% male and 70.37% female—while Group C consisted of 44.44% males and 55.56% females. Overall, the study comprised 28 males and 53 females. Statistical analysis showed no significant difference in gender distribution among the groups (chi-square = 1.7770, $p = 0.5551$).

The mean ages (Fig 32, Table 5) were 33.22 ± 5.98 years for Group A, 29.89 ± 6.68 years for Group B, and 33.04 ± 7.98 years for Group C, with an overall mean age of 32.05 ± 7.02 years. One-way ANOVA revealed no significant difference in age distribution across the groups ($F = 1.9718$, $p = 0.1461$), indicating a balanced demographic distribution in terms of both age and gender.

In Intragroup VAS Comparison Friedman's ANOVA and Wilcoxon matched pairs test revealed very highly significant reductions in pain over time within all three groups across all time points.(6-24hrs 6-48hrs 6- 72hrs) with p=0.0001. Pairwise VAS comparisons were done using the Mann-Whitney U test (Table 7). Group C consistently showed significantly lower pain compared to Group A in early postoperative periods (6–24 hrs.) p = 0.0004 and p = 0.0002 at 6hrs and 24 hrs.

respectively, while differences between Group B and C were not significant p = 0.1975 and p = 0.2360 at 6hrs and 24 hrs. respectively. Suggesting Group C was more effective in reducing pain. This result is in accordance with Mahta Fazlyab(31) and authors. where the energy delivered using both wavelengths was 12J which explains the No significant difference between pain management with 990nm and 660nm wavelength however as scattering is wavelength dependent with shorter wavelengths undergoing more intense scattering than longer Wavelengths depth of penetration of 970nm Wavelength increases and it showed better results.(53)

VAS Pain Score Comparison was done with Kruskal-Wallis ANOVA (Table 6). Where Group C consistently demonstrated the lowest postoperative pain scores at 6hrs, 24hrs and 48hrs intervals, with statistically significant differences (p = 0.0010) in comparison to Group B and Group A, indicating superior pain relief. Followed by Group C, Group B showed a significant reduction in comparison to Group A at all the time intervals. This finding aligns with the Roscoe–Bunsen law of reciprocity, which states that "the total number of photons absorbed by target cells is the key factor in photobiomodulation (PBM)". Although both setups deliver the same energy (12 J), the 970 nm wavelength emits a greater number of photons. Both the 660 nm and 970 nm diode lasers significantly reduced post-operative pain compared to the control group. However, the 970 nm laser demonstrated a slightly stronger and more prolonged analgesic effect than the 660 nm laser, leading to the rejection of the null hypothesis.

However, a major challenge in pain management research lies in the subjective nature of pain perception, which varies considerably among individuals. Pain is not solely a physiological response but is also modulated by a range of psychological factors.(83) According to Turk and Melzack (1992), the perceived

intensity of pain is influenced by the patient's interpretation, anticipated duration, environmental context, as well as their attitudes, beliefs, and expectations.(84)

The multitip diode laser system provides safe, controlled, and effective photobiomodulation without harmful localized heating, making it a reliable non-pharmacological tool for post-endodontic pain management(85). However, some of the patients experienced certain heating when multitip was used in contact mode hence future studies should explore optimal exposure times and wavelength-specific protocols for improved clinical outcomes.

Both 660 nm and 970 nm diode lasers demonstrate potential for integration into endodontic practice to enhance patient comfort. However, the 970 nm diode laser appears to offer superior early postoperative pain relief, making it a preferable option for optimizing clinical outcomes. Further clinical trials and research are warranted to standardize protocols for photobiomodulation therapy (PBMT) in endodontics.

CONCLUSION

Within the limitations of the present research, it can be concluded that:

1. Diode laser therapy (660 nm and 970 nm) is a clinically effective alternative to analgesics for post-endodontic pain management, reducing reliance on pharmacological interventions.
2. Although 660nm and 970nm wavelengths both were equally effective in reducing postoperative pain but 970nm diode laser showed the greatest reduction in pain and for a longer time.

SUMMARY

Pain after endodontic treatment is the biggest fear of an endodontist and is a common complication, which affects approximately 3-58% of patients. The etiology of postoperative endodontic pain is multifactorial, generally induced by inflammatory mediators produced due to chemical, mechanical, or microbial injuries to the pulp & periapical tissues that result in acute inflammation.

While analgesic remains a popular form of therapy, lasers can be proposed as an alternate yet competent form of pain management due to their evident side effects. Low-level laser therapy (LLLT) or Photobiomodulation has shown a comparable effect over NSAIDs in pain management as per studies.

Photobiomodulation can be done in the 600nm - 1000nm wavelength range previous studies have been done with 970 ± 15 nm & a few studies with 640nm wavelength in root canal treatment and re-treatment cases.

Different laser parameters such as wavelength, power, duration, and frequency could provide different reduction in pain intensity results and certain wavelengths can be more effective than others in managing post-operative pain. According to the literature, there is no evidence for a standardized wavelength of the Diode laser for reduction of post-operative pain for patients who require endodontic treatment. Hence the present study was designed to evaluate and compare the efficacy of photobiomodulatory effect with 660nm and 970nm wavelength of diode lasers in single visit endodontic treatment.

Eighty-one patients presenting with asymptomatic irreversible pulpitis in maxillary first premolars and meeting the defined inclusion and exclusion criteria were selected from the routine patient flow at the Department of Conservative

Dentistry and Endodontics, KAHER's KLE V.K. Institute of Dental Sciences, Belagavi, for endodontic therapy. They were randomly divided into three groups:

1. Group 'A' (control): consisted of 27 patients who did not receive PBM irradiation.
2. Group 'B' consisted of 27 patients who received PBM with 660 nm wavelength at 0.1W for 120 seconds with 12 J of energy at the apical region of teeth at 4 points buccally and palatally.(Fig 21)
3. Group 'C' consisted of 27 patients who received PBM with 970 nm wavelength at 0.2W for 60 seconds with 12 J of energy at the apical region of teeth at 4 points buccally and palatally.(Fig 28)

This was done after standard root canal therapy and obturation in a single appointment.

Pain levels were recorded using the Visual Analog Scale (VAS) at 6, 24, 48, and 72 hours post-treatment. Statistical analysis included Friedman's ANOVA, Mann-Whitney U, Kruskal-Wallis ANOVA, and Wilcoxon tests. Results showed that all three groups experienced a significant decrease in pain over time, but Group C (970 nm) consistently reported the lowest pain levels, particularly within the first 24 hours, followed by Group B (660 nm). Group A (no laser) recorded the highest pain scores at all intervals. While both PBMT groups outperformed the control, the 970 nm wavelength proved slightly more effective, possibly due to its deeper tissue penetration and reduced photon scattering compared to 660 nm.

The study emphasizes that the analgesic effects of PBMT are achieved through mechanisms such as enhanced ATP production, modulation of inflammatory mediators, and improved cellular metabolism. The 970 nm wavelength, due to its

better penetration depth, may activate mitochondrial and inflammatory responses more effectively than the shorter 660 nm wavelength.

Though both lasers showed clinical promise, the findings favored the 970 nm diode laser for superior pain relief. The null hypothesis—stating no difference between the two wavelengths—was rejected. However, this study acknowledges limitations including the subjective nature of pain and the potential variability in laser-tissue interaction. Further research is recommended to refine PBMT protocols and validate its widespread use in endodontics.

In conclusion, the study demonstrates that both 660 nm and 970 nm diode lasers are effective adjuncts for post-endodontic pain management, offering a viable, non-pharmacological alternative to traditional analgesics. The 970 nm wavelength diode laser appears to provide superior early pain relief, making it a more favourable choice for clinical implementation in single-visit endodontics.

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ANNEXURE – I – ETHICAL APPROVAL CERTIFICATE

Research and Ethics Committee
KLE VK INSTITUTE OF DENTAL SCIENCES
A Constituent Unit of KLE Academy of Higher Education & Research
Accredited 'A' Grade by NAAC | Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State
☎: 0831-2470362 | Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 | E-mail:principal@kledental-bgm.edu.in

Sl. No. : 1636

CERTIFICATE

This is to Certify that the synopsis titled

Comparative Evaluation of Photobiomodulatory effect of 660nm and 970nm Diode Laser on Post-Operative pain management in single visit endodontic treatment - A randomized Control trial *Submitted by*

Dr. IE0222005 *P. G. Student /*

Staff, Guided by _____ *from Department of*

Conservative Dentistry and Endodontics *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 8/11/25

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE – II – BIOSTATISTICS CLEARANCE LETTER

KLE
VISHWANATH KATTI
INSTITUTE OF DENTAL SCIENCES,
(Constituent college of K.L.E. University, Belgaum)
J.N.M.C. Campus, Nehru Nagar Belagavi -590010 Karnataka, India.
Conservative Dentistry and Endodontics

KLE UNIVERSITY
EMPOWERING PROFESSIONALS

BIOSTATISTICS CLEARANCE CERTIFICATE

This is to certify that the Biostatistics art of Dissertation/ Research work of IE0222005 **Postgraduate student** under the guidance of **Professor and Head of the Department, Department of Conservative Dentistry and Endodontics** entitled **"COMPARATIVE EVALUATION OF PHOTOBIOMODULATORY EFFECT OF 660nm and 970nm DIODE LASER ON POST-OPERATIVE PAIN MANAGEMENT IN SINGLE VISIT ENDODONTIC TREATMENT – A RANDOMIZED CONTROL TRIAL"** has been done under my guidance and considered satisfactory.

Place: Belagavi
Date: 08.04.25

Name and signature of Biostatistician
Dr. S. B. Javali. Ph.D.
Professor In Statistics
Department of Community Medicine
JGM KLE International Medical Programme
BELAGAVI-590010.

ANNEXURE – III – PLAGIARISM CERTIFICATE

Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences

A Constituent Unit of KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi - 590 010, Karnataka State

Accredited 'A+' Grade by NAAC (3rd Cycle) Placed in Category 'A' by MHRD (GoI)

☎: 0831-2470362
FAX: 0831-2470640

Web: http://www.kledental-bgm.edu.in
E-mail:principal@kledental-bgm.edu.in

Date : 18/04/2025 Serial No. : 421

PLAGIARISM CHECK REPORT

Name of the Applicant : IE0222005
UG / PG / Ph.D / Staff : PG
Batch & Year : 2022 - 2025
Department : Department of Conservative and Endodontics Dentistry.

The soft copy of Research Work / Manuscript by . IE0222005 .... entitled
" Comparative evaluation of photobiomodulatory effect of 660nm and 970 nm diode laser on post-operative pain management in single visit endodontic treatment - A randomised control trial "
under the guidance of ... .has been submitted for

Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of 6 %, which is **within / not within** the acceptable limits of 10% as per the UGC guidelines.

18/4/2025

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE – IV - CTRI REGISTRATION CERTIFICATE

Clinical Trials Registry - India (ICMR-NIMS)

Welcome: PRIYANKAR ROY [KLE VK Institute of Dental Sciences] 17/04/2025 Main Page | Change Password | Website Home Page | Logout

Trial Clarification/Modification | Registered Trials | Edit Profile

SOP to be followed for field unlocking in registered trials

For site addition/deletion - Please upload EC/DCGI approval of additional site or site deletion under Ethics Approval - this field is permanently unlocked and revert by mail for site unlocking. Please also mention the list of new site PI in the mail. For those sites which have not received EC approval, please mark a copy of the mail to the PI requesting a confirmation email to this email ID regarding their participation in trial.

For new contact person (Overall trial PI/Scientific/public query) - Please indicate new person, mark a copy of the mail to concerned person and request mail confirmation of responsibility

For Intervention/comparator agent/ inclusion & exclusion criteria, sample size, scientific title primary and secondary outcome, please specify changes (in a tabular format) and confirm if EC approval has been received for the same, if applicable, and upload in EC section which is permanently unlocked.

Registered Trials

Total Number of Registered Trials=2

CTRI Reg. Date	CTRI Reg. No	Reference No.	Type of Trial	DCGI Clearance	EC Clearance	Recruitment Status India	Modification	Details
27/11/2024	CTRI/2024/11/077388	REF/2024/05/084526	Interventional	Not Applicable	Approved	Completed	Click	Click to View Details
07/02/2025	CTRI/2025/02/080023	REF/2023/08/072444	Interventional	Not Applicable	Approved	Completed	Click	Click to View Details

ANNEXURE V - INFORMED CONSENT FORM FOR

CLINICAL TRIAL

This Informed Consent form is for adults between 18-64 years receiving treatment from the department of Conservative Dentistry and Endodontics, KLE VK Institute of dental sciences, Nehru Nagar, Belagavi.

The title of our research project is "Comparative evaluation of the efficacy of photobiomodulatory effect in post-operative pain management using 660nm & 970nm wavelength diode laser in single visit endodontic treatment – A Randomized Clinical Control trial"

Name of Principal Investigator: Dr.
MDS Student, Dept. of Conservative Dentistry & Endodontics
KLE academy of higher education and research
KLE VK Institute of dental sciences, Nehru Nagar, Belagavi

Name of Co-Investigator 1: Dr.
(Research guide)
Head of the department and Professor,
Dept. of Conservative Dentistry & Endodontics
KLE academy of higher education and research
KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi

Name of Organization: KLE Academy of Higher Education and Research
KLE VK Institute of dental sciences, Nehru nagar, Belagavi
Name of Sponsor: Self
This Informed Consent Form has three parts:
PART I: Information Sheet (to share information about the research with you)
PART II: Certificate of Consent (for signatures if you agree to take part) You will be given a copy of the full Informed Consent Form
PART III: Visual analogue scale

PART I: INFORMATION SHEET

Introduction

I am Dr. _____ postgraduate student at Department of Conservative Dentistry and Endodontics, KLE Academy of Higher Education And Research KLE VK Institute Of Dental Sciences, Nehru Nagar, Belagavi.

I am doing research on **"**Comparative evaluation of the efficacy of photobiomodulatory effect in post-operative pain management using 660nm & 970nm wavelength diode laser in single visit endodontic treatment – A Randomized Clinical Control trial". I am going to give you the information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. If you have questions later, you can ask me, the study doctor or the staff.

Purpose of the research

Postoperative pain after endodontic treatment is the biggest fear of an Endodontist and is a common complication, which affects approximately 3-58% of patients. While analgesics remain to be a popular form of therapy, but due to their evident side effects, lasers can be proposed as an alternative yet competent form of pain management. The low-level laser therapy (LLLT) or Photobiomodulation has shown a comparable effect over NSAIDs in pain management While Photobiomodulation, can be done in the 600nm - 1000nm wavelength range. Most of the previous studies have used 970nm ± 15 and only one study has used 660nm wavelength for post operative endodontic pain management. Different laser parameters such as wavelength, power, duration, and frequency could provide different reduced pain intensity results and certain wavelengths can be more effective than others in managing post operative pain. There is a lack of evidence on "which wavelength of the Diode laser is more efficient & safe way of reducing post-operative pain for patients who require endodontic treatment". Hence the purpose of this study is to evaluate and compare the efficacy of photobiomodulatory effect in post - operative pain management using 660nm & 970nm wavelength Diode lasers in single visit endodontic treatment.

Type of Research Intervention

This research will involve intervention using 660m Diode laser and 970nm Diode laser.

Participant selection

All patients between the age of 18-64 requiring root canal treatment of mandibular premolar teeth with single root canal diagnosed clinically as asymptomatic irreversible pulpitis using pulp sensitivity tests, who the Department of Conservative Dentistry and Endodontics, KLE Academy of Higher Education and Research KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi attends to for treatment to participate in the research.

Voluntary Participation

Your participation in this research is entirely voluntary. Whether you choose to participate or not, all the services you receive at this institute will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital for root canal treatment of the maxillary 1st premolar teeth. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

Patient randomization sequence will be obtained using computer generated table of random numbers. Random assignment of the patient will be completed after the patients have been assessed for the eligibility before the intervention will begin. Participants in

Group I will be given no Laser after Single Visit endodontics

Group II will be treated with 660nm diode laser after single visit endodontics
Group III will be treated with 970nm diode laser after single visit endodontics

If there is anything you are concerned about or that is bothering you about the research, please talk to me or one of the other researchers.

You will receive the treatment of your condition according to standard guidelines.

Description of the Process

In the first visit, case history will be recorded and the vitality of tooth will be assessed. A single clinician shall evaluate all patients, using radiographic and clinical findings, followed by treatment of all cases. Single visit endodontic therapy will be done and the presence or absence of pain, will be recorded by using a Visual Analogue Scale (VAS). The patient will be trained about the scoring criteria of Visual Analogue Scale (VAS) and they will carry the VAS form along with them after treatment to note their pain readings at post-operative periods of 6, 24, 48 and 72 hours. The patients will be instructed to take rescue analgesic (Ibuprofen), only if experiencing severe pain, after informing the operator

Duration

The research completes in the first visit, however the remaining treatment will be completed in the subsequent 2 visits for post endodontic prosthesis. During that time, it will be necessary for you to come to the clinic/hospital/health facility for 60 minutes.

Side Effects

There are no known/reported side effects except post-operative pain following endodontic therapy.

Risks

There is risk that the endodontic therapy itself entails. Post-operative pain may vary according to use of different irrigants and use of Diode laser therapy.

Benefits

By participating in this study, improved research on the effect of various wavelength of diode laser on post-operative pain will be assessed

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will

know what your number. It will not be shared with or given to anyone except, research committee **KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI.**

Sharing the Results

The knowledge that we get from doing this research will be shared with you before it is made widely available to the public. Confidential information will not be shared. We will share the results with scientific community through presentation in research circles and by publishing in scientific journals in order that other interested people may learn from our research.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Alternatives to participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the center/institute/hospital

PART II: CERTIFICATE OF CONSENT

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name & Signature of Participant_____

Date -

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND

Thumb print of participant

Signature of witness _____

Date _____

STATEMENT BY THE RESEARCHER/PERSON TAKING CONSENT

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Name and Signature of Researcher /person taking the consent- [redacted]

Date -

ANNEXURE – VI – CONSENT FORM

Department of Conservative Dentistry and Endodontics,

K.L.E. V.K. Institute of Dental Sciences, Belgaum

CONSENT FORM

“Comparative evaluation of the efficacy of photobiomodulatory effect in post-operative pain management using 660nm & 970nm wavelength diode laser in single visit endodontic treatment – A Randomized Clinical Control trial”

ನಾನು.....ವಯಸ್ಸಿನ ವಯಕ್ತಿಯಾಗಿದ್ದುನನಗೆ ತಿಳಿದಿರುವ ಭಾಷೆಯಲ್ಲಿಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ನನಗ

ಭಾಗವಹಿಸುವುದ್ರ ಬಗೆಿನನಗೆ ತಿಳಿಸಲಾಗಿದೆ

೧. ನಾನು ಕೆಲವು ಖಾಸಗಿ ಮಾಹಿತಿಗಳಾದ್ ಹೆಸರು ವಯಸು ಲ್ಲಂಗ ವಿಳಾಸ ಹಲ್ಲಿನತಪಾಸಣೆಯ/ ಚಿಕ್ಕತ್ಿಿಯ ಮಾಹಿತಿಯನುನ ಮತುಿಈ ಅಧಯಯನಕಾಾಗಿ ಬೊೀಕಾದ್ ಎಲಿವಿವರಣೆಗಳನುನ ಕೊಡಲು ಒಪ್ಪಿಕೊಳಳುತ್ಿಿೀನೆ.

೨. ನನನ ರೊೀಗದ್ ಪರಿಸ್ಸಿತಿಗೆಬೊೀಕಾದ್ ಚಿಕ್ಕತ್ಿಿಯ ವಿಧಾನಗಳನುನನನಗೆ ಸಂಪೂರ್ಣವಾಗಿ ತಿಳಿಸಲಾಗಿದೆ.

೩. ನನಗೆ ನೋಡುವ ಚಿಕ್ಕತ್ಿಿ ಅದ್ರಿಂದ ಉಂಟಾಗುವ ತ್ಿಿೊಂದ್ರೆ ಹಾಗೊ ಅದ್ಯಾಾಗಿ ಬೊೀಕಾಗುವ ಚಿಕ್ಕತ್ಿಿಗಳ ಬಗೆಿ ವೈೃದ್ಯರನುನ ಪರಶ್ನನಸಲು ಸಾಕಷ್ುು ಅವಕಾಶಗಳನುನ ನೋಡಲಾಗಿರುತಿದೆ.

೪. ಈ ಅಧ್ಯಯನಕಾಾಗಿ ನನನ ದ್ಂತ ವೈೃದ್ಯರು ನನನನುನ ಕರೆದಾಗಲೆಲಿ ನಾನು ಬರುವೆನೆಂದ್ು ಒಪ್ಪಿಕೊಂಡಿರುತ್ಿಿೀನೆ.

೫. ನಾನು ನನನ ದ್ಂತ ವೈೃದ್ಯರಿಗೆ ನನನ ಬಗೆಿನೋಡಿರುವ ಮಾಹಿತಿಯನುನ ಈ ಅಡ್ಾಯನದ್ ಫಲ್ತ್ಾಂಶದ್ಲ್ಲಿ ಅಳವಡಿಸ್ಸ ಪರಸು ತಿಸಲುಮನವಿ ನೋಡಿರುತ್ಿಿೀನೆ.

೬. ನಾನು ನನನ ದ್ಂತ ವೈೃದ್ಯರು ನನಗೆ ಈ ಅಧಯಯನದ್ಲ್ಲಿನೋಡುವ ಸೊಚನೆಗಳನುನ ತಪಿದೆ ಪಾಲ್ಲಸುತ್ಿಿೀನೆ.

೭. ಯಾವುದೊೀ ಕಾರಣದಿಂದಾಗಿ ನಾನು ಈ ಅಧಯಯನದ್ಲ್ಲಿಭಾಗವಹಿಸಲು ಅಸಫಲನಾದ್ರೆ/ ಅಸಫಲಳಾದ್ರೆ ಅಧಯಯನದಿಂದ್ ಹೊರಬರಲು ನನಗೆ ಅನುಮತಿ ನೋಡಲಾಗಿದೆ.

ಮೋಲಾಂಡ ಮಾಹಿತಿಯನುನ ನಾನು ಓದಿ ತಿಳಿದ್ುಕೊಂಡಿದುೀನೆ ಹಾಗೊ ನಾನು ಈ ಅರ್ಜಣಯಲ್ಲಿ ಸಹಿ ಮಾಡಿದುೀನೆ.

ದ್ಂತ ವೈೃದ್ಯ ರಹೆಸರು: ಅಭ್ಯರ್ಥಣಯ ಹೆಸರು ಮತುಿಸಹಿ

ವಿಳಾಸ:

ದ್ೂರವಾಣಿ ಸಂಖೆಯ: ದ್ಂತ ವೈೃಧಯರ ಸಹಿ:

DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDODONTICS, KLE. V.K. INSTITUTE OF DENTAL SCIENCES, BELGAUM

CONSENT FORM

"Comparative evaluation of the efficacy of photobiomodulatory effect in post-operative pain management using 660nm & 970nm wavelength diode laser in single visit endodontic treatment – A Randomized Clinical Control trial"

मी.....वय.....सहभागी

होत असलल्या वरील संशोधना बद्दल मला समजत असलल्या भाषत सर्व माहीती दिली आह.

1. मी माझी माहीती जस.की नांव वय, लिंग, पुर्व दंत उपचार महिती आणि इतर लागणारी माहीती द.य्यास तयार आह.

2. माझी दंत वैद्याकीय तपासणी करणार असल्याची मला कल्पना आह.आणि दिलली माहीती मला समजली आह.

3. मी या संशोधना बद्दल माहिती विचारु शकतो/शकत.

4. मी परिक्षणा वळी दंत वैद्याकानी दिलल्या सुचना पाळल.

5. मी दिलली माहीती आणी य.्याारा निकल वापरण्यास, मांडण्यास आणि प्रकाशीत करण्यास पुर्ण सम्मती दत आह.

6. जरी एखाद्या एजसीन.मी दिलली माहीती वापरली तरी मी कोणतीही फर मागणी करणार नाही

7. मी या संशोधनात स्वइच्छन.भाग घ.्यायाची परवानगी दत आह.

8.कोणत्याही कारणास्तव माझा सहभाग मी माघारी घऊ शकतो / शकत.

9. दंतवैद्यकान.दिलली वरील महिती मी वाचली आह.आणि ती मला समजली आह. म्हणुन मी या अर्जावर नोंदणी व स्वाक्षरी कली आह.

दंतवैद्यकाच.नांव : **पालकांची सही:**

दंतवैद्यकाची स्वाक्षरी : **स्थळ**

तारीख:

ANNEXURE – VII

'VISUAL ANALOGUE SCALE' SCORE SHEET

DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDODONTICS
K.L.E. V.K. INSTITUTE OF DENTAL SCIENCES, BELGAUM

Proforma (to be handed over to the patient)

"Comparative evaluation of the efficacy of photobiomodulatory effect in post-operative pain management using 660nm & 970nm wavelength diode laser in single visit endodontic treatment – A Randomized Clinical Control trial"

Patient's Name:

OPD number:

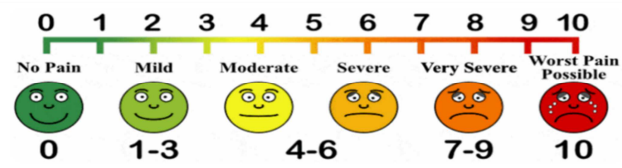
Sex:

Age:

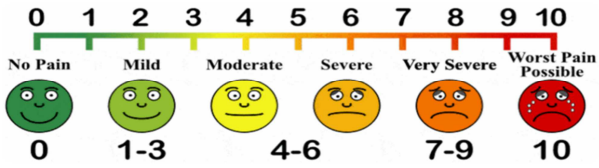
Address:

VISUAL ANALOG SCALE

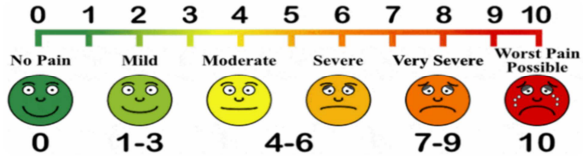
6 hours



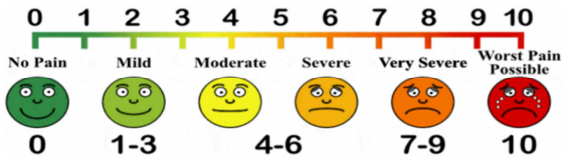
24 hours



48 hours



72 hours



Medications if taken any, when _____

Signature of patients_____