"EFFECT OF 0.2% CHITOSAN AND 970nm DIODE LASER DISINFECTION ON POST-OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC THERAPY: A RANDOMIZED CLINICAL TRIAL."

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LIST OF ABBREVIATIONS

SR.NO	ABBREVIATIONS	FULL FORM
1.	NaOCl	Sodium Hypochlorite
2.	CHX	Chlorhexidine
3.	EDTA	Ethylene Diamine Tetra-Acetic Acid
4.	BMP	Biomechanical Preparation
5.	RCT	Root Canal Treatment
6.	SVE	Single Visit Endodontics
7.	LAI	Laser activated irrigation
8.	POP	Post Operative Pain
9.	NSAIDs	Non- Steroidal Anti-Inflammatory Drugs
10.	IOPA	Intraoral Periapical Radiograph
11.	+	Plus
12.	WL	Working Length
13.	ANOVA	Analysis of Variance
14.	SD	Standard Deviation
15.	n	Number of specimens
16.	p-value	Probability of obtaining a test statistic at least as extreme as the one that was actually observed

17.	<	Less than
18.	>	Greater than
19.	µm	Micrometers
20.	kHz	Kilohertz
21.	&	And
22.	w/v	Weight per Volume
23.	J	Joule
24.	W/cm2	Watts per square centimeter (power density)
25.	ml	Milliliter
26.	mm	Millimeter
27.	i.e.	That is
28.	SE	Standard error

ABSTRACT

AIM: To clinically Assess and Compare the effect of 0.2% Chitosan and 970nm Diode Laser disinfection on Post-Operative Pain after Single Visit Endodontic therapy.

MATERIAL AND METHODS: Hundred patients requiring endodontic treatment on permanent mandibular premolars based on defined inclusion and exclusion criteria were selected. The procedure was explained in the patient's native language and written informed consent was obtained. Pulp sensibility was assessed using an electric pulp tester and single clinician performed all treatments to ensure consistency. Patients were randomly allocated into three groups (n=30) using a computer-generated randomization sequence prior to intervention.

After administration of local anesthesia (2% Lignocaine with 1:100,000 Adrenaline) and rubber dam isolation, access preparation and working length determination was performed using an electronic apex locator. Cleaning and shaping was done using ProTaper Universal NiTi rotary instruments up to F3. The groups were divided according to the final disinfection protocol:

- **Group 1 (Control):** 5 ml 3% NaOCl + 5 ml 17% EDTA, conventional irrigation (3 mins)
- **Group 2:** 5 ml 3% NaOCl + 5 ml 0.2% Chitosan, conventional irrigation (2 mins)
- **Group 3:** 5 ml 3% NaOCl + 5 ml 17% EDTA with 970-nm Diode laser disinfection

Laser irradiation (970 nm Diode laser) was performed in four 10-second cycles using a 200-μm optical fiber with parameters standardized for power and duration. Canals were dried and obturated using single cone obturation technique with AH Plus sealer and ProTaper-matched gutta-percha points followed by post-endodontic restoration.

Postoperative pain was recorded at 6, 24, 48, and 72 hours using a validated Visual Analogue Scale (VAS). Patients were instructed to take rescue analgesics (Ibuprofen, 600mg) only if severe pain occurs, after notifying the clinician.

RESULTS: A total of hundred patients were distributed into three groups, At 6 hours, the Diode Laser group (Group 3) reported significantly lower pain scores (mean = 2.1) compared to both NaOCl + EDTA (Group 1, mean = 2.8) and Chitosan (Group 2, mean = 2.9) ($p = 0.014$). This trend continued at 24 hours with the Diode Laser group maintaining lower pain scores (mean = 1.2) significantly different from Group 1 ($p = 0.034$) though not statistically different from Group 2. By 48 and 72 hours, pain levels continued to decline across all groups with no statistically significant differences observed between them.

The overall percentage of pain reduction from 6 to 72 hours was highest in the Diode Laser group (95.24%) followed by Chitosan (89.66%) and NaOCl + EDTA (78.57%).

No significant differences in gender ($p = 0.873$) or mean age ($p = 0.626$) among them, ensuring comparability across groups. Pain scores were recorded at 6, 24, 48, and 72 hours post-treatment using the Visual Analogue Scale (VAS). All groups exhibited a significant decrease in pain over time ($p < 0.0001$, Friedman's ANOVA) indicating the effectiveness of each intervention in postoperative pain management.

CONCLUSION: All three irrigation protocols were effective in reducing postoperative pain over time. Diode laser disinfection demonstrated the most rapid and significant pain reduction specially within the first 24 hours. Chitosan also showed favorable outcomes with greater pain reduction than NaOCl + EDTA though not statistically significant. Both Diode laser and Chitosan can be considered promising alternatives to conventional irrigation methods for enhancing patient comfort after endodontic treatment.

KEYWORDS: Single Visit Endodontics, Chitosan, Diode laser, Visual Analogue Scale, Post Operative Pain

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INTRODUCTION

Post operative pain (POP) related to single visit endodontic (SVE) procedures is an important consideration for clinicians and patients, affecting overall treatment satisfaction and clinical outcomes. Effective management of post-operative pain impacts patient comfort and treatment outcomes. [1]

Following endodontic therapy, reports indicate that POP may occur in 3 to 58% of cases and may affect up to 12% of patients within 24 to 48 hours after the procedure, as measured by a Visual Analog Scale (VAS).[2] Rate of discomfort reported after undergoing single-visit root canal therapy varies widely, ranging from 25% to 40% within the first 24 to 48 hours, with some studies reporting even higher rates (Elmallawany et al). [3] This pain is typically transient, peaking within the first 24 hours and gradually subsiding within 3 to 7 days (Sathorn et al., 2008). [4] Issues such as over-instrumentation, improper shaping, or inadequate irrigation can compromise the effectiveness of antimicrobial measures during the RCT.[5] Throughout the biomechanical preparation phase of root canals, material with both organic as well as inorganic components is left along the canal walls. This amorphous structure is known as the smear layer.[6] While mechanical instrumentation is a major factor in facilitating permeation of irrigants to the apex region and ensuring effective canal filling, it is insufficient on its own to manage the complex structure of the anatomy of the canal.[7]

Mechanical instruments are required to allow irrigants to reach into the apical area and, hence, to enable proper root filling. However, they are insufficient for handling the intricacies of the root canal system, leaving up to 60% of root canal walls unexposed to mechanical shaping (Peters et al. 2001, Paque et al. 2010). [8]

Additionally, endodontic instrumentation can sometimes leave a residual smear layer with their cutting action (McComb & Smith 1975). [9] This can create debris comprising of hard tissue, which may aggregate within canal complexities.[10]

The smear layer produced during instrumentation can act as a reservoir for microbial colonization, invariably affecting the post-operative pain. [11] Thus, irrigating solutions play an important role in eliminating smear layer, cleansing the canal system by washing out debris that remains un-instrumented by mechanical preparation. The ability for removal of the microbes and smear layer is strongly affected by both the chemical characteristics of the irrigant and the technique used for its application. [12,13]

In endodontics, the most commonly used irrigant is Sodium hypochlorite (NaOCl) by majority of the dentists. It's deemed as the gold standard among endodontic irrigants. These may be attributed to its antimicrobial characteristic and capability to disintegrate organic tissue. However, it doesn't come without its drawbacks. There is some concern due to its cytotoxicity to periapical tissues. Some studies even suggest that it may harm the micromechanical properties of dentin, such as hardness and elasticity.[14] NaOCl can cause inflammation if it reaches the periapical area, often leading to postoperative pain. [12,14]

Another significant drawback of NaOCl is its incapacity to eliminate smear layer effectively. Furthermore, it fails to affect the inorganic fraction of the smear layer; hence, it is used in accessory with a decalcifying agent. A chelating agent like EDTA is often suggested as an additional step to help remove the smear layer. EDTA is generally utilized at 10-17% concentrations, and in order to enhance its chelating activity, its pH is usually increased from an acidic 4 to up to a slightly alkaline 8 pH.[15] Additionally, EDTA which is a chelating agent is extensively used by dentists. [16] It

has been shown to lack a significant antimicrobial effect which is important for reducing POP since microorganisms are the primary cause linked with it. Hence, the search for solutions with improved biocompatibility and antimicrobial properties is still going on.

A new chelating agent, Chitosan, has attracted interest of dental researchers. It is a polysaccharide obtained from chitin and is biocompatible as opposed to EDTA, an artificial substance. In addition, it has antimicrobial properties, leading to less inflammation due to bacteria, and in fact, has anti-inflammatory effects (Zhang et al., 2020). [17] This also prevents the periapical tissues from being harmed. Chitin is a made up of N-acetyl glucosamine and one of the most prevalent polysaccharides found in nature. It is naturally produced in our bodies in the partial breakdown of chitin.[18] The high biocompatibility, biodegradable, bioadhesive, and non-toxic nature of Chitosan has been proved in previous studies. [19] Moreover, Chitosan is not new to the dentistry field, and it has been used as a medicine as an antibacterial, excipient, and healing accelerator. [20] Though the exact mechanism is still unknown, the best theory for the action of the cationic biopolymer is that it induces the covalent remineralization of demineralized dentin structure and binds Chitosan to dentin. The theory is supported by the fact that Chitosan's functional phosphate groups can form strong bonds with calcium ions, creating a conducive environment enucleation of crystal and forming creation of calcium and phosphate layer. Additionally, Silva et al. suggested that a 0.2% Chitosan exhibited comparable efficacy to higher concentrations of EDTA (15%) in eliminating inorganic smear. [21] Futhermore, previous research has shown that postoperative pain intensity was significantly lower with Chitosan nanoparticles [22]

The most common technique for irrigation in endodontics is with a syringe and a needle. [15] However, research has demonstrated that the infiltration of fluid is limited, especially in apical regions [24,25,26]. To alleviate this problem, several apparatus and methods for activating irrigants have been suggested to enhance irrigant delivery within the canal system (Gu et al. 2009). [27] A relatively recent technique, LAI has proved to be effective, and has been studied by multiple groups (Blanken & Verdaasdonk 2007, George & Walsh 2008 and George et al. 2008). [28,29,30]

With lasers, complete canal sterilization is actually possible due to its far reach (>1000 μm into the dentin).[31] The use of lasers in endodontics seems to be promising; they have found to be incredibly efficient in sterilization of canals, removing debris along with blocking the dental tubules in the canal walls.[31] In particular, irradiation with Diode laser has proven to disinfect the deep radicular dentin better than existing alternatives. [32] In addition, it also eliminates *Escherichia Faecalis* and *Enterococcus coli* thus increasing the efficacy of endodontic therapy.[33]

Hence, to summarize lasers as a technique for irrigation in endodontics, it has an advantage over other disinfection methods as it removes the smear layer, reduces bacterial load and causes a reduction in post-operative pain. [34,35] The mode of action of laser irradiation is via photothermal action. [36]

Diode lasers operating at various wavelengths, such as 970 nm and 808 nm, have been engineered for use in endodontic procedures. They are used in conjunction with optical fibres that have a diameter of 200μm. This allows their usage in all canals irrespective of shapes, sizes and curvatures, thus allowing for disinfection better than existing techniques like syringes and needles. [37]

Despite the well-documented effects of NaOCl, Chitosan, and Diode lasers in endodontics, there is limited clinical evidence comparing their impact on POP following SVE canal therapy. By analysing these three modalities separately, this research seeks to optimize pain management strategies in endodontic practice while assessing the potential benefits of biocompatible irrigants and laser therapy over conventional NaOCl irrigation.

Hence, keeping the essence of these principles in mind, this study is designed to analyse the effect of 0.2% Chitosan, 970nm Diode laser and NaOCl + EDTA disinfection on post-operative pain after single visit endodontics.

AIMS AND OBJECTIVES

STUDY AIM

- To clinically Assess and Compare the effect of 0.2% Chitosan and 970nm Diode Laser disinfection on Post-Operative Pain after Single Visit Endodontic therapy.

STUDY OBJECTIVES

- To assess the effect of 0.2% Chitosan disinfection on post operative pain after single visit endodontics using Visual Analogue Scale
- To assess the effect of 970nm Diode Laser disinfection on post operative pain after single visit endodontics using Visual Analogue Scale
- To compare the effect of 0.2% Chitosan and 970nm Diode Laser disinfection on post operative pain after Single Visit Endodontics using Visual Analogue Scale

RESEARCH HYPOTHESIS

NULL HYPOTHESIS

There is no difference of 0.2% Chitosan and 970nm Diode laser disinfection on Post-Operative Pain after Single Visit Endodontic therapy

ALTERNATE HYPOTHESIS

There is a difference of 0.2% Chitosan and 970nm Diode laser disinfection on Post-Operative Pain after Single Visit Endodontic therapy

REVIEW OF LITERATURE

1. A systematic review was done to evaluate effectiveness of irrigant activation method in reducing postoperative pain. The review demonstrated that sonic, ultrasonic, LAI, and EndoVac significantly outperformed needle irrigation in pain management. Manual dynamic irrigation was effective in eliminating the vapor lock by improving irrigant flow but, due to its piston-like motion, posed a risk of apical extrusion of irrigants, which may cause chemical irritation and increase postoperative discomfort. EndoVac, a negative pressure irrigation system, proved more effective than conventional syringe irrigation. Overall, activation techniques enhanced irrigant penetration with reduction in microbial load, and contributed to better pain management. [14]

2. A randomized clinical trial study performed done to evaluate the impact of a 980 laser in root canal disinfection in 30 patients with asymptomatic apical periodontitis. Patients were divided into a laser irradiation group and a placebo group. The laser group showed a statistical eradication in *E. faecalis*, and while both groups experienced bacterial reduction post-treatment, the laser-treated group demonstrated significantly better healing in the periapical area over 12 months. This enhanced outcome is likely due to the Diode laser's deeper infiltration into dentinal tubules beyond the reach of conventional irrigants which allows it to effectively target resistant bacteria like *E. faecalis*. Its photothermal action disrupts bacterial cell walls and enhances disinfection, while its biostimulatory effects promote microcirculation and tissue regeneration, contributing to improved long-term healing. The study suggested that the laser enhances bacterial reduction before biomechanical preparation

and improves long-term healing, though it provides no additional benefit during retreatment. [37]

3. A study previously done to examine the antimicrobial efffect of Chitosan and laser in disinfecting infected primary molars. 64 molars had been divided into four groups: NaOCl, 0.2% Chitosan, Diode laser and a Chitosan-laser combination. All groups significantly reduced *E. faecalis* counts, but there was no significant difference between NaOCl and Diode laser, nor between Diode laser and Chitosan-laser. The study suggested that Chitosan and Diode laser could be potential alternatives to NaOCl for endodontic canal disinfection as Chitosan a natural biopolymer disrupts bacterial cell membranes, while the Diode laser enhances disinfection through deep dentinal penetration and photothermal effects. Their combined biocompatibility, low cytotoxicity, and effectiveness against *E. faecalis* support their suitability in managing infections. [38]

4. A study was done tocompare the effect of CUI and LAI on POP in necrotic mandibular molars. Forty patients underwent endodontic treatment in a single visitusing a standardized protocol and were randomly divided into conventional syringe irrigation or CUI groups. Each group was categorized into laser and non-laser subgroups. Postoperative pain was assessed at multiple time points using a visual analog scale. The lowest pain scores wwas recorded in the CUI with Diode-laser group, which also exhibited the highest bacterial reduction. The study concluded that combining ultrasonic irrigation with Diode laser enhances root canal disinfection and minimizes postoperative pain. This outcome is attributed to the synergistic effect of ultrasonic activation, which enhances irrigant flow and disrupts biofilms, and the Diode laser, which

penetrates dentinal tubules to thermally eliminate residual bacteria. Combined, they improve disinfection and reduce inflammation, leading to less postoperative pain. [3]

5. A study had been conducted to assess the antibacterial effect of 0.2% Chitosan and 3% Sodiium Hypochlorite, and 2% CHX against *E. faecalis*, independently and with Diode laser activation. Seventy-two extracted teeth were inoculated with *E. faecalis* for 7 days and treated with different irrigation solutions. The highest bacterial reduction was observed in the CHX-laser combination group, followed by NaOCl and Chitosan. The study found that Diode laser activation enhanced the antimicrobial properties of all irrigants, with laser-treated groups showing significantly fewer bacterial colonies. This enhancement is likely due to the laser's photothermal effect, which increases the temperature within the canal, thereby boosting the efficacy of irrigants by improving their penetration into dentinal tubules and disrupting bacterial biofilms more effectively. The results support the use of laser-activated irrigation as an adjunct to conventional disinfectants for improved root canal sterilization. [39]

6. A study conducted to examine the outcome of 980-nm Diode after chemo-mechanical preparation on postoperative pain in two-visit RCT. Sixty patients were randomly divided into a laser and non-laser group. The control group received standard irrigation with NaOCl, EDTA, and distilled water, while the laser group underwent additional laser irradiation after the final rinse. Pain levels were recorded at 8 h, 24 h, 48 h, and 7 days using a visual analog scale. The laser group reported significantly lower pain levels, especially in single-rooted teeth with periapical lesions. This pain reduction is attributed to the Diode laser's photothermal and biostimulatory effects, which enhance bacterial

elimination, reduce inflammatory mediators, and promote healing by improving blood flow and cellular repair. The study concluded that Diode laser application effectively reduces postoperative pain and enhances treatment outcomes. [2]

7. A systematic review was done to assess various irrigation activation techniques on postoperative pain. Studies up to March 2021 were analyzed, focusing on sonic, ultrasonic, laser-activated, and manual dynamic irrigation. The review confirmed that activation techniques significantly reduced postoperative pain by improving debris and bacterial removal. This is primarily due to improved irrigant penetration into complex canal anatomies and disruption of biofilms, which conventional syringe irrigation may not achieve effectively. Manual dynamic agitation was effective but carried a risk of apical extrusion. EndoVac, a negative pressure system, showed superior outcomes in minimizing postoperative discomfort. The study highlighted the importance of advanced activation techniques in improving patient comfort and clinical success. [13]

8. A randomized clinical study was conducted to compare PUI and laser disinfection for postoperative pain reduction in 44 patients with non-vital single-rooted teeth. Patients were randomized into two groups: one received ultrasonic irrigation with NaOCl, while the other underwent laser disinfection using an 810-nm Diode laser. Pain levels were assessed at 6, 24, and 48 hours, as well as 7 days post-treatment. While no significant difference in pain reduction was observed, laser disinfection provided slightly better early postoperative pain relief. This early relief is likely due to the Diode laser's photothermal and biostimulatory effects, which enhance bacterial elimination, reduce inflammation, and promote faster tissue response. The study concluded

that both PUI and laser disinfection were effective, with minimal differences in patient outcomes.[40]

9. A study had been previously conducted to assess the antimicrobial efficiency of nano Chitosan, CHX, and NaOCl in necrotic mandibular premolars. Sixty patients were assigned to four irrigant groups: 3% CNPs, 2% CHX, CHX-CNP combination, and 5.25% NaOCl. Pre- and post-instrumentation bacterial samples were cultured, and pain levels were recorded. CNPs and CHX-CNPs were significantly more effective against anaerobic bacteria than NaOCl and CHX alone. This is likely due to CNPs' deep tubule penetration and membrane-disrupting action, with CHX-CNPs offering a synergistic effect. Postoperative pain was also lower in the CNP groups, possibly due to their biocompatibility and anti-inflammatory properties. The study suggested that nano Chitosan could serve as an effective biocompatible alternative to conventional irrigants. [41]

10. A randomized clinical trial was done for comparing postoperative pain after primary RCT using ultrasonically activated irrigation and laser-activated irrigation. Fifty-six patients with asymptomatic teeth were treated and assigned to either UAI or LAI groups. Postoperative pain was recorded at 6, 24, 48, and 72 hours using a visual analog scale. The UAI group experienced significantly higher pain at 6 hours compared to LAI ($P < 0.05$), but no significant difference was observed at later time intervals. The short-term advantage of LAI may be due to its photothermal and anti-inflammatory effects, which reduce bacterial load and early inflammation more effectively, resulting in quicker initial pain relief. The study concluded that both techniques resulted in minimal pain, with LAI showing a short-term advantage. [42]

11. A study was done to assess root temperature changes in lower incisors using 810nm Diode laser at various power levels and exposure times. Sixty extracted teeth were divided into groups based on laser power (1.05 W, 1.5 W, and 1.95 W) and exposure times (20 s and 60 s). A thermocouple recorded temperature rise at the apical and middle root regions. All power settings remained below a 7°C increase, ensuring safety. The highest temperature increase was recorded in the apical region at 1.95 W for 60 s. The study concluded that Diode laser application is safe for root canal disinfection within tested parameters. [43]

12. A study was conducted to asses the effect of intracanal Diode-laser irradiation on perception of pain in mandibular molars with symptomatic apical periodontitis. Fourteen patients underwent single-visit root canal treatment, and a 970 ± 15 nm Diode laser was used at a maximum power of 14 W after final irrigation. Pain levels were recorded during laser application and postoperatively at days 1, 3, 5, 7, and 30 using a visual analog scale (VAS). Although 78% of patients experienced pain during laser application, multiple linear regression analysis showed that age, gender, tooth type, and pulp status were not significant predictors of intraoperative pain. The study concluded that preoperative patient factors do not significantly predict intraoperative pain during Diode laser application in root canals, suggesting that intraoperative discomfort is more likely related to laser parameters or individual pain thresholds. [44]

13. A study was done to evaluate the chelation efficiency and eradication of smear of 3 final irrigation solutions used in root canal treatment. Forty-five teeth were instrumented using rotary files and randomly divided into three groups based on the final irrigation solution: 17% ethylenediaminetetraacetic acid (EDTA),

0.2% Chitosan, and 10% trisodium citrate. Each group was further subdivided based on application time (1 min, 5 min, and 24 h). Flame atomic absorption spectrometry (FAAS) was used to quantify chelated calcium ions, while scanning electron microscopy (SEM) analyzed smear layer removal at the coronal, middle, and apical levels of the root canal. The study found no significant difference between EDTA and Chitosan in chelation efficiency and smear layer removal, likely due to their strong calcium-binding capabilities—EDTA through chemical chelation and Chitosan via its amino and hydroxyl groups. Trisodium citrate showed superior performance due to its high ionic strength and effective calcium-binding properties. Chelator application should not exceed 5 minutes to avoid dentin erosion, and 0.2% Chitosan is recommended as a natural, biocompatible alternative to EDTA, remaining effective even after 24 hours. [16]

14. A systematic review was conducted on POP following endodontic treatment, evaluating predictors, risk factors, and pain management strategies. They found that POP ranged from 2% to 69.3%, primarily due to microbial factors. No statistical difference was found between singleand multiple-visit treatments as both, when properly performed, achieve comparable disinfection and healing outcomes, pain being more influenced by infection severity and patient-specific factors. Pain was generally mild to moderate, even in well-executed procedures. Advancements in endodontic techniques, irrigants, and obturation methods have contributed to pain reduction. The study concluded that flexible, severity-based drug regimens and modern techniques improve postoperative pain management in endodontics. [45]

15. A study was done to compare the antimicrobial effect and structural effects of 808nm and 970nm Diode-lasers on E. faecalis biofilms. Thirteen single-rooted teeth were sectioned into 100 dentin blocks, inoculated with E. faecalis, and incubated for 5 days. Samples were divided into ten groups based on different laser-irradiation settings and irrigants (NaOCl, CHX). Bacterial reduction was measured using spectrophotometry, and ultrastructural dentin changes were analyzed with SEM. The 970 nm laser altered the organic matrix, while the 808 nm laser caused intertubular dentin erosion—both due to thermal effects on dentin. Although laser irradiation alone did not significantly improve antibacterial efficacy compared to conventional irrigants, its combination with NaOCl led to greater dentin erosion due to synergistic thermal and chemical interactions. [46]

16. An study was done to assess the effect of various modalities of activation of irrigant for debris removal in simulated root canal irregularities. Twenty-five straight human canine roots were embedded in resin, sectioned, and instrumented before testing six irrigation techniques: conventional needle irrigation, manual dynamic irrigation, passive ultrasonic irrigation, Er:YAG laser with plain fiber, Er:YAG laser with PIPS and a 980-nm Diode laser. Debris removal efficacy was assessed using non-parametric statistical tests. The Er:YAG laser achieved the highest debris removal, followed by PUI and MDI, while conventional irrigation was the least effective. The study concluded that laser activation significantly enhances debris removal in endodontic procedures. [47]

17. A study was done to investigate cavitation formation using near-infrared Diode lasers (940 nm and 980 nm) in aqueous solutions. A 200 mm fiber optic was used to deliver laser energy into capillary tubes, and cavitation was observed microscopically. The first phase identified laser parameters that induced cavitation within 5 seconds, while the second phase compared cavitation effects in different fluids including distilled water, tap water, degassed water, ozonated water and 3%-6% hydrogen peroxide. Results showed that both lasers successfully induced cavitation, with laser power being a more significant factor than pulse frequency. The study concluded that laser-induced cavitation can enhance debridement in endodontic irrigation.[48]

18. A study was done to assess the release of calcium ion and efficacy of eradication of smear layer removal of various root canal chelators. Forty-two maxillary central incisors were instrumented and irrigated with 15% EDTA, 10% citric acid, 10% sodium citrate, apple vinegar, 5% acetic acid, 5% malic acid, and NaOCl. Calcium ion concentration was analyzed using flame atomic absorption spectrometry, and smear layer removal was assessed using SEM. Results explained that 15% EDTA had the of calcium ion, followed by 10% citric acid, with both solutions being the most effective in smear layer removal. The study concluded that EDTA and citric acid remain the gold standard for effective chelation in endodontics. [49]

19. A systematic review was done on POP comparing single- vs. multiple-visit endodontic treatments. POP ranged from 3% to 58%, but significant heterogeneity across studies made meta-analysis difficult. Findings indicated no clear advantage of single-visit over multiple-visit treatments regarding pain and flare-up rates. The review emphasized that preoperative pain, periapical

status, and instrumentation technique were more critical factors influencing pain than the number of visits. [4]

20. A prospective study involving 100 patient assessing outcomes of single multiple-visit root endodontic treatment. POP levels, assessed using a VAS, were comparable between both groups across all time intervals. However, a higher percentage of healed cases was observed in single-visit group. This superior healing could be attributed to fewer chances of inter-appointment contamination and the uninterrupted progression of periapical tissue repair. The findings highlight that while both treatment protocols are effective in managing postoperative pain, single-visit RCT may offer improved healing and clinical efficiency, making it a preferable option in suitable cases based on patient condition and operator judgment. [50]

MATERIALS AND METHODOLOGY

STUDY DESIGN:

A Randomized Clinical Trial

SOURCE OF DATA

- Study titled - "Effect Of 0.2% Chitosan And 970nm Diode Laser Disinfection on Post-Operative Pain after Single Visit Endodontic Therapy: A Randomized Clinical Trial" was carried out Department of Conservative Dentistry and Endodontics, KLE VK Institute of Dental Sciences, KAHER Belagavi, Karnataka, with the approval of research and ethical committee of KLE VK Institute of Dental Sciences with reference number REF/2025/04/103803, and with the CTRI number CTRI/2025/04/084995.

- Chitosan (0.2% Solution) was prepared at the KLE College of Pharmacy, KAHER, Belagavi, Karnataka.

- Permanent mandibular premolar teeth requiring endodontic therapy were selected from the regular pool of patients presenting to the Department of Conservative Dentistry and Endodontics, KLE VK Institute of Dental Sciences, KAHER Belagavi, Karnataka

SAMPLE SIZE ESTIMATION:

The sample size was determined using the formula with a 95% confidence interval and 80% power.$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (SD_1{}^2 + SD_2{}^2)}{(\bar{x}_1 - \bar{x}_2)^2}$

SD_1 : Standard Deviation in the 1st group
SD_2 : Standard Deviation in the 2nd group
$\bar{x}_1$: Mean of 1st group
$\bar{x}_2$: Mean of 2nd group
α : Significant level
$1 - \beta$: Power

Estimated sample size for each group, *n = 30*

Considering 10% drop out rate, the total sample size of the study was rounded off to 100, at a power of 0.90 with 0.6% Type I error.

INCLUSION CRITERIA

- Patients in need of endodontic treatment of mandibular premolar teeth which have single root canal diagnosed as asymptomatic irreversible pulpitis using pulp sensibility tests.
- Patient aged between 18 and 55 years
- Patients with no significant medical history
- Teeth with no history of pre-operative discomfort
- Teeth with adequate sufficient coronal form to ascertain proper isolation

EXCLUSION CRITERIA

- Patients that decline consent for endodontic treatment
- Patients that are pregnant or have an immuno-compromised condition/disease
- Patients on have undergone any antibiotic therapy in the previous 3 month
- Patients who have used analgesic medications within the last seven days
- Patients that have an allergy to local anaesthetic agent (Lignocaine with 1:100,000 concentration adrenaline)
- Patients that are indicated for endodontic therapy on more than one teeth the same side of the arch.

SPECIFIC TO DIAGNOSIS

- Teeth diagnosed with acute apical periodontitis
- Teeth diagnosed with acute periapical abscess
- Symptomatic teeth diagnosed with pulpal necrosis without absence of any sinus tract
- Cases requiring non-surgical endodontic retreatment
- Teeth exhibiting >grade II mobility.

TOOTH SPECIFIC

- Teeth presenting with immature apex, calcified canals, internal and external resorption.
- Teeth with severe labial or lingual malposition, making straight-line access difficult
- Dilacerated teeth

MATERIALS USED FOR STUDY

- Local anaesthetic agent - 2% Lignocaine 1:100,000 adrenaline (INDOCO-REMEDIES LTD, MUMBAI, INDIA)
- Povidine Iodine 5% w/v (SUN PHARMACEUTICAL, MUMBAI, INDIA)
- Hydrogen Peroxide 30% w/v (THERMOFISHER SCIENTIFIC PVT.LTD, MUMBAI, INDIA)
- Sodium Thiosulphate (RANBAXY FINE CHEMICALS LIMITED, PUNE, INDIA)
- Root Canal Irrigants
    1. 3% Sodium Hypochlorite (VISHAL DENTOCARE, AHMEDABAD)
    2. 17% Ethylenediamine tetra-acetic acid (CANALARGE, AMMDENT, MOHALI)
    3. 0.2% Chitosan (SIGMA ALDRICH, BANGALORE)
- Paper Points (DIADENT GROUP INTERNATIONAL, KOREA)
- Saline Solution (ULTRA QUALITY PHARMACEUTICALS, HANAN, KARNATAKA)
- AH Plus Sealer (DENTSPLY, GERMANY)
- GP Points (DIADENT GROUP INTERNATIONAL, KOREA)
- Tetric-N-ceram (IVOCLAR VIVADENT, ZURICH)

ARMAMENTARIUM:

- Airotor (PANA AIR, NSK, JAPAN)
- Electric pulp sensibility tester (PARKELL DIGITEST, EDGEWOOD, USA)
- Relax Mouth mirror (HAHNENKRATT, KÖNIGSBACH-STEIN, GERMANY)
- Rubber DAM KIT (HYGIENIC KIT, COLTENE, ALTSTÄTTEN, SWITZERLAND)
- Probe (GDC, INDIA)
- Tweezer (GDC, INDIA)
- DG-16 probe (GDC, INDIA)
- RadioVisioGraphy (DENTSPLY SIRONA, SWITZERLAND)
- Spoon Excavator (GDC, INDIA)
- Disposable Syringes (UNOLOCK, INDIA)
- Disposable Saliva Ejector (EKO DENTAL, KANPUR, INDIA)
- Airotor (NSK PANA AIR, TOKYO, JAPAN)
- EndoAccess Bur (DENTSPLY MAILLEFER, SWITZERLAND)
- EndoZ Bur (DENTSPLY MAILLEFER, SWITZERLAND)
- Endogauge (DENTSPLY MAILLEFER, SWITZERLAND)
- #10 K- File (MANI INC, JAPAN)
- Apex locator (EPEX PRO, EIGHTEETH, CHANGZHOU, CHINA)
- ProTaper Universal NiTi Files (DENTSPLY MAILLEFER, SWITZERLAND)
- Endomotor (X SMART, DENTSPLY, SWITZERLAND)

- 2.5 ml – 27gauge Syringes (DISPOVAN, Hindustan Syringes & Medical Devices Ltd, NEW DELHI, INDIA)
- 30 Gauge Side Vented Needle (NEOENDO, ORIKAM, GURGAON, INDIA)
- Ultrasonic Unit (EIGHTEETH, CHANGZHOU, CHINA)
- SIROLASE BLUE (DENSPLY SIRONA, NEW YORK, USA)
- 200-µm optical fiber tip (DENSPLY SIRONA, NEW YORK, USA)

Preparation of Study materials:

Preparation of 0.2% Chitosan irrigant-

0.2g of Chitosan was mixed with 100 ml of 1% acetic acid and stirred continuously for 2hrs using a magnetic stirrer.

METHODOLOGY: -

According on the specific inclusion as well exclusion criteria 100 patients requiring endodontic therapy with respect to mandibular premolar teeth, diagnosed as asymptomatic irreversible pulpitis were chosen from the pool of patients visiting of Department of Endodontics and Conservative Dentistry, KLE V K Institute of Dental Sciences, KLE Academy of Higher Education & Research (KAHER), Belagavi, Karnataka. A duly signed informed consent agreement was collected from patient after being informed about the procedure in his or her native tongue.

Pulp sensibility was assessed using an electric pulp testing device (EPT). The same clinician diagnosed all patients with the help of radiographic as well as clinical findings. This helped to ensure that all the patients received the same level of care, hence minimizing any differences in treatment between clinicians. Randomization was done using computer-generated randomization which was obtained using table

of randomly generated numbers. Once the patients were evaluated for eligibility and enrolled, the intervention was randomly assigned before starting the treatment.

Local anaesthesia (2% lignocaine with 1: 100,000 adrenaline) was applied. For isolation, rubber dam (Hygienic Kit, Coltene) was placed. The isolated tooth was then disinfected for 60 seconds each with a 30% w/v hydrogen peroxide and 5% w/v Povidine-iodine solution, Sodium thiosulphate was applied which subsequently rendered the iodine inactive.

Following endodontic access preparation WL was established using an apex locater (E pex, Eighteeth). The BMP was done with using of ProTaper Universal (Dentsply) rotary instruments, reaching F3 size. All enrolled patients were allocated into 3 distinct groups in accordance to the final irrigation performed followed (n=30): one control group and two experimental.

Group 1: 5 ml 3% NaOCl + 5ml 17% EDTA Conventional Irrigation for 3 minutes

Group 2: 5ml 3% NaOCl + 5ml 0.2% Chitosan Conventional Irrigation for 2 minutes

Group 3: 5ml 3% NaOCl and 5ml 17% EDTA + 970nm Diode Laser Disinfection

Final irrigation was completed following the respective irrigation protocols for each group and using paper points, the canals were dried.

A 970-nm Diode laser was used to perform Diode laser irradiation (SIROLASE, DENSPLY SIRONA) with an attached 200-µm optical fiber tip. Diode laser irrigation was performed in pulsed mode, with each cycle delivering 2.4 W of power and totaling 12 J of energy. Each cycle consisted of a 10s irradiation period succeeded by a 10-second pause, with 4 repetations in each canal. This protocol resulted in a power density of 3823 W/cm² at a 50 Hz. The tip of the Diode Laser was placed 1–2 mm from the apical terminus. A helical motion was used with the tip from the apex to the coronal part at a pace of 2 mm per second, lightly in contact with the dentinal walls, following recommended clinical guidelines

Obturation was completed with Single Cone Technique using an AH Plus Sealer (Dentsply) and ProTaper Universal matching size of Gutta Percha Points. Excess Gutta-percha beyond the orifice level was seared off using a heated plugger and post-endodontic restoration will be placed. Pain was assessed based on its presence or absence and was recorded by using a VAS as mentioned in studies. After the obturation procedure, the VAS form was provided to the patient and were instructed on how to use it for assessment of pain. The patient was explained and trained after the treatment about the scoring criteria on the scale and were given the form to record the pain levels at 6 h, 24 h, 48 h and 72 h postoperatively. The patients were advised to take rescue analgesic of Ibuprofen 600 mg, only if experiencing severe pain, after informing the operator.

STATISTICAL ANALYSIS:

1. **Kolmogorov-Smirnov Test and Shapiro-Wilk Test:** This test is used to assess the normality of the data distribution. The results of these tests guided the selection of parametric/non-parametric methods in the subsequent analyses.
2. **Chi-Square Test:** This test was employed to evaluate the correlation between variables across the different groups. The test evaluated the presence of statistically significant differences in proportions or frequencies across the study groups.
3. **One-Way ANOVA or Friedman's Test:** Depending on data distribution, either a one-way ANOVA or Friedman test was used to assess pain scale values across groups over time, followed by Dunn's post hoc test for pairwise comparisons.

Study design

Hundred patients (including 10% dropout) requiring endodontic treatment in the mandibular premolar teeth and fulfilling the inclusion and exclusion 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 was used to assess pulp vitality

↓

A single clinician evaluated all patients, using radiographic and clinical findings, followed by treatment of all cases

↓

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

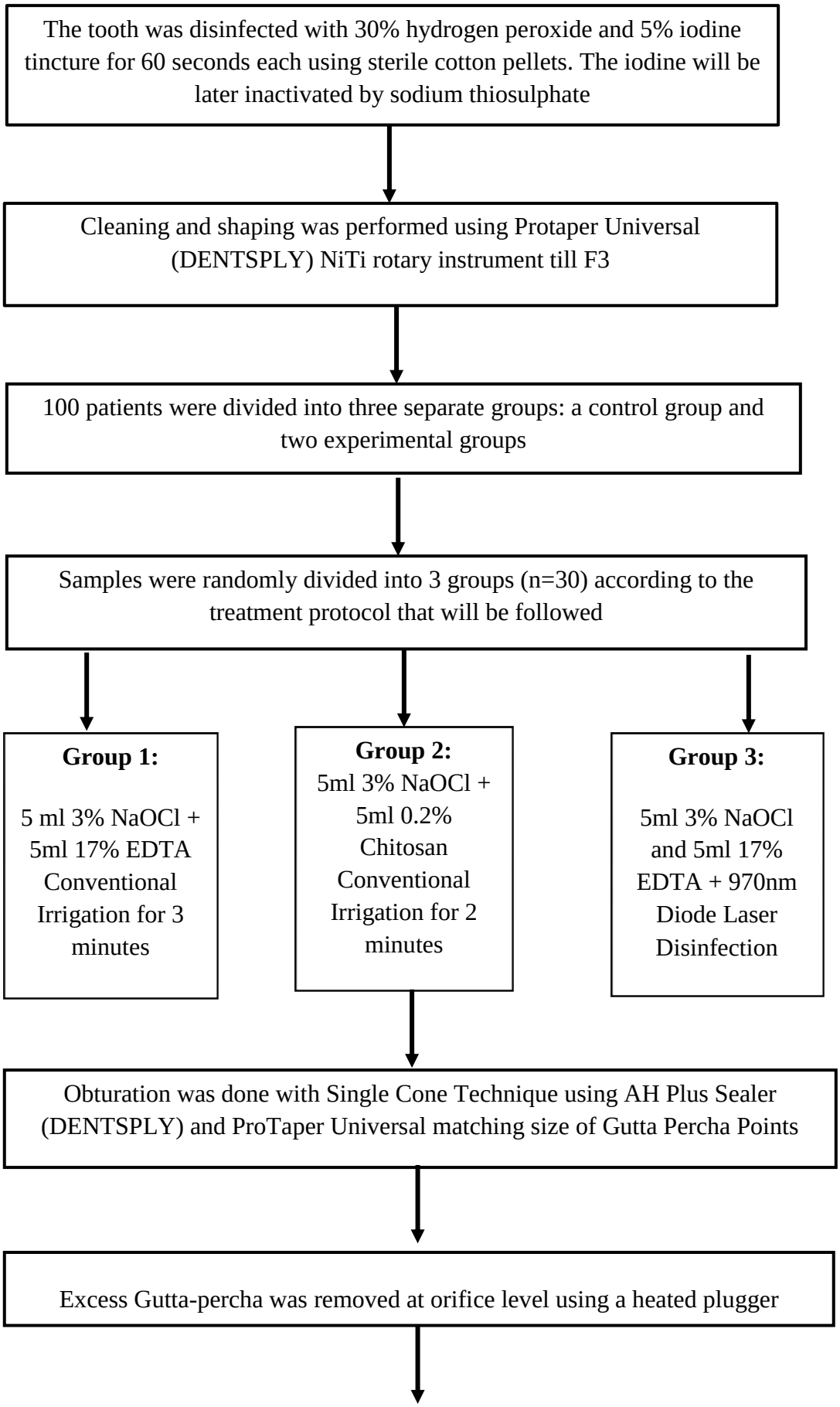
↓

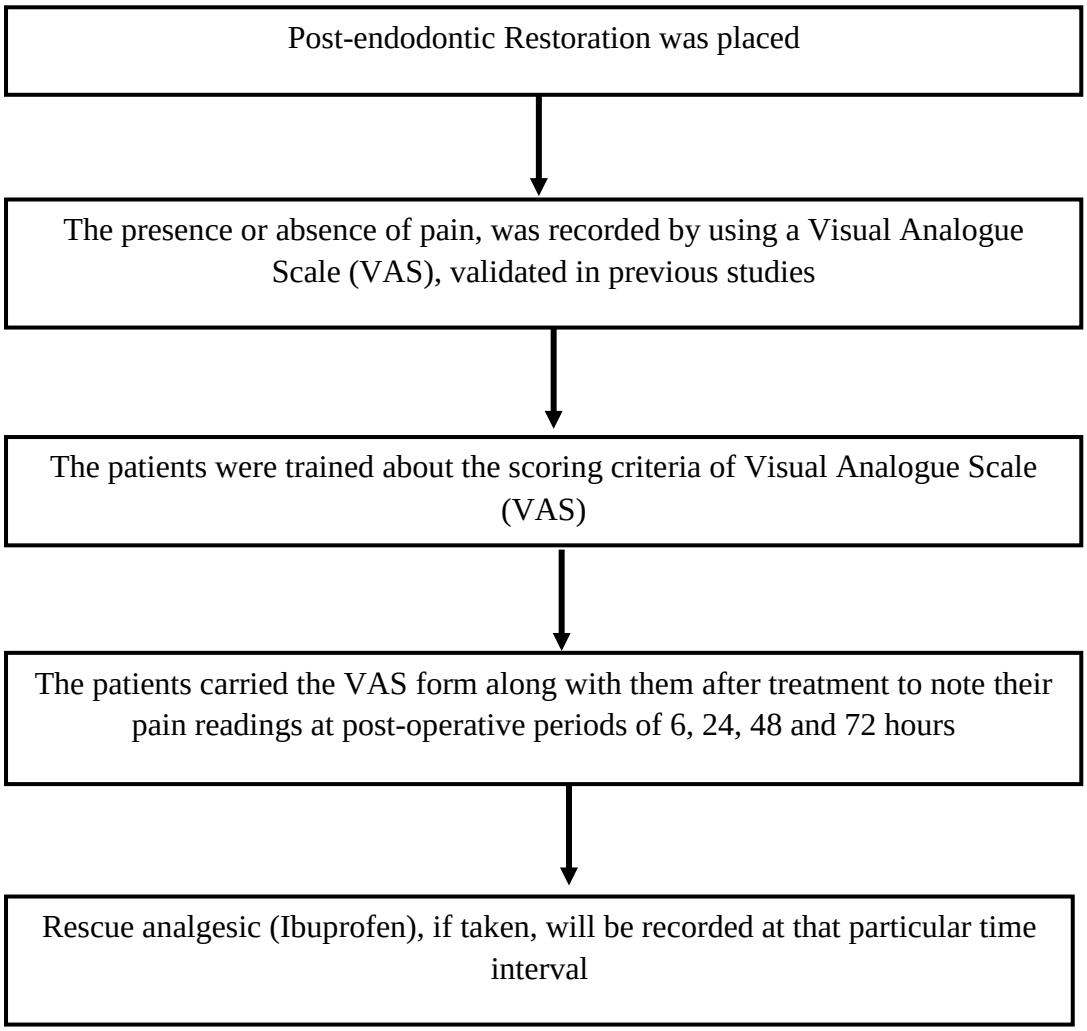
Local anaesthesia (2% lignocaine 1:80,000 adrenaline) was administered and rubber dam applied on tooth for isolation

↓

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

↓


The tooth was disinfected with 30% hydrogen peroxide and 5% iodine tincture for 60 seconds each using sterile cotton pellets. The iodine will be later inactivated by sodium thiosulphate
Cleaning and shaping was performed using Protaper Universal (DENTSPLY) NiTi rotary instrument till F3
100 patients were divided into three separate groups: a control group and two experimental groups
Samples were randomly divided into 3 groups (n=30) according to the treatment protocol that will be followed
Group 1:
5 ml 3% NaOCl + 5ml 17% EDTA Conventional Irrigation for 3 minutes
Group 2:
5ml 3% NaOCl + 5ml 0.2% Chitosan Conventional Irrigation for 2 minutes
Group 3:
5ml 3% NaOCl and 5ml 17% EDTA + 970nm Diode Laser Disinfection
Obturation was done with Single Cone Technique using AH Plus Sealer (DENTSPLY) and ProTaper Universal matching size of Gutta Percha Points
Excess Gutta-percha was removed at orifice level using a heated plugger


Post-endodontic Restoration was placed
The presence or absence 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, will be recorded at that particular time interval

PICTURES

Fig.1 Diagnostic Instruments

Fig.2 LA and rubber dam armamentarium

Fig 3 Administration of LA

Fig.4 Material for sterilization protocol

Fig 5. Sterilization Protocol; Step 1 - 30% Hydrogen Peroxide

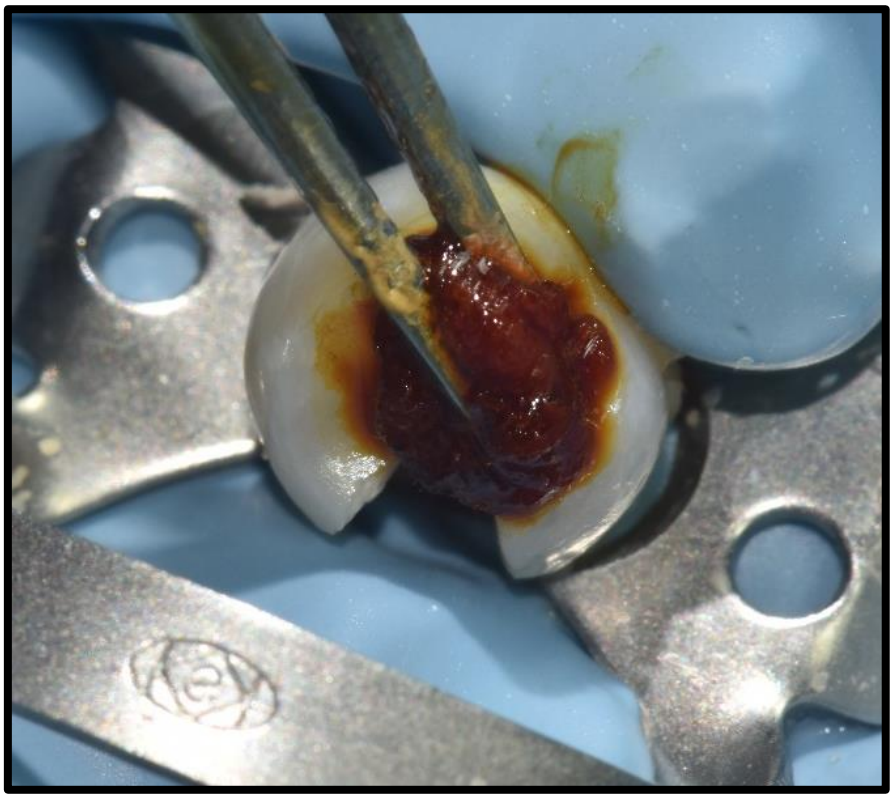


Fig 6. Sterilization Protocol; Step 2 - 5% Povidine Iodine

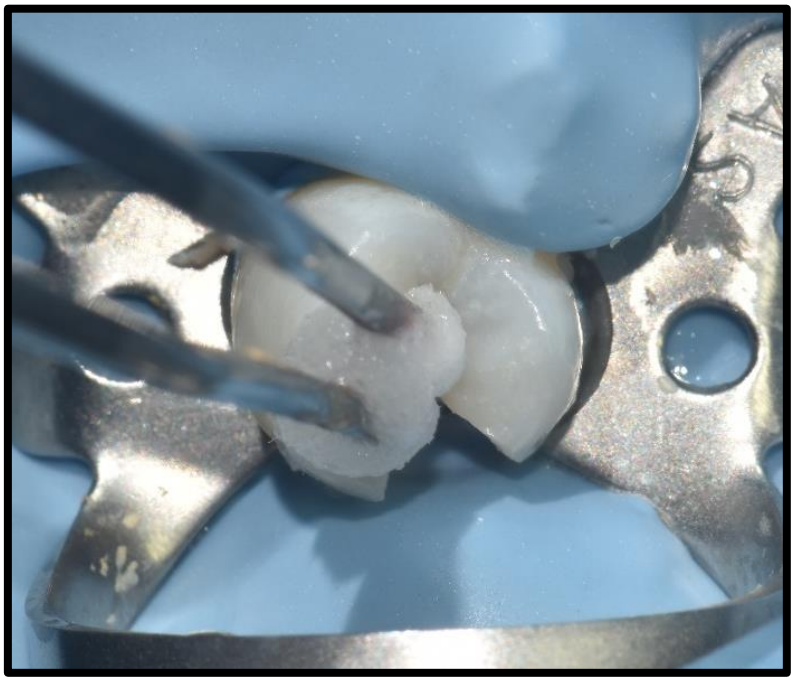


Fig 7. Sterilization Protocol; Step 3 – Sodium Thiosulphate

Fig. 8. Access cavity preparation armamentarium

Fig. 9 Access cavity preparation armamentarium

Fig. 10 Working Length Determination

Fig.11 Cleaning and shaping armamentarium

Fig 12. Armamentarium for disinfection

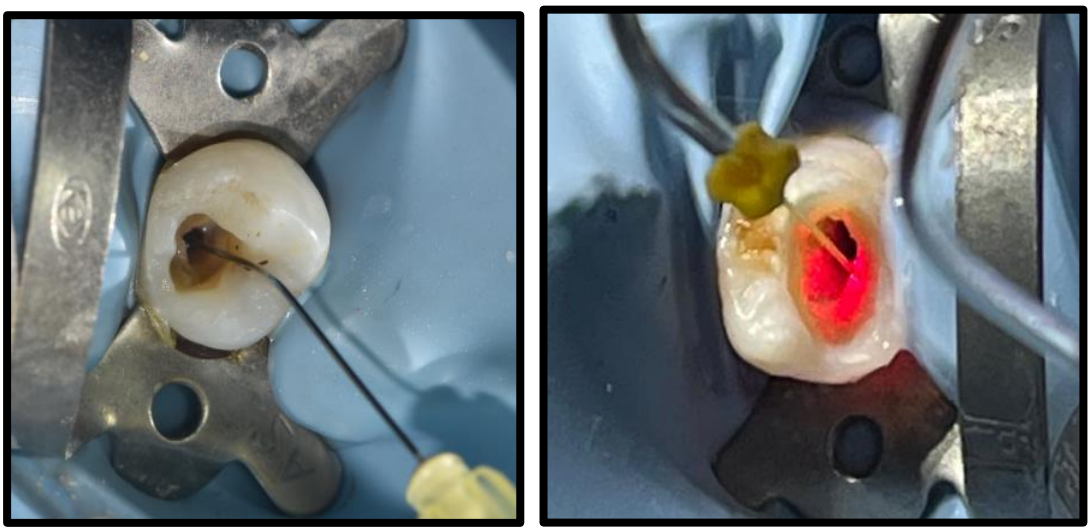


Fig 13. Irrigation with side vented needle and 970nm Diode Laser

Fig 14. Armamentarium for Obturation

Fig 15. Master Cone Selection

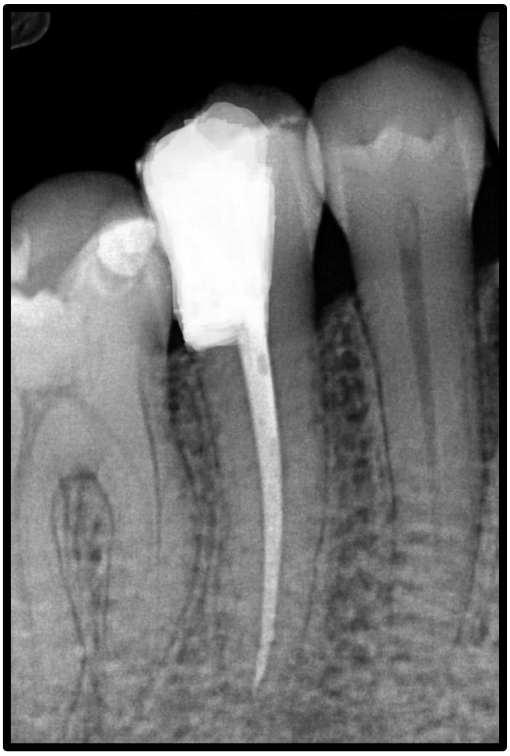


Fig 16. Obturation and post endodontic restoration

RESULTS

Table 1: VAS scores for patients in Group 1 (NaOCl + EDTA)

Group 1						
Name	**Sex**	**Age**	**6 hrs**	**24 hrs**	**48 hrs**	**72 hrs**
A1	F	19	0	1	0	5
A2	M	36	2	4	4	4
A3	F	39	4	2	0	0
A4	M	43	3	2	2	0
A5	F	37	4	1	0	0
A6	M	35	3	2	2	0
A7	M	51	2	2	0	0
A8	F	27	2	0	0	0
A9	M	34	4	2	0	0
A10	F	53	1	0	0	0
A11	F	25	4	2	4	2
A12	M	48	4	3	1	0
A13	M	36	4	2	1	0
A14	F	28	3	2	2	0
A15	F	31	4	2	0	0
A16	F	51	3	1	0	2
A17	M	24	2	0	1	0
A18	F	31	3	1	0	1
A19	M	28	2	3	1	0
A20	M	27	3	1	0	0
A21	F	32	2	2	0	0
A22	F	30	4	3	2	1
A23	F	24	3	2	0	0
A24	F	28	2	3	1	1
A25	M	53	2	2	1	0
A26	F	26	5	3	2	1
A27	M	34	3	2	2	0
A28	F	49	2	2	0	0
A29	F	24	2	1	0	0
A30	F	28	1	0	0	0

POP was assessed in all three groups at periods of 6 hours, 12 hours, 24 hours, and 72 hours using VAS to evaluate pain level following single-visit endodontic therapy.

Table 2: VAS scores for patients for Group 2 (0.2% Chitosan)

Group 2						
Name	Sex	Age	6 hrs	24 hrs	48 hrs	72 hrs
B1	F	45	2	1	0	0
B2	M	53	3	2	0	0
B3	F	38	6	0	0	2
B4	F	46	3	1	0	0
B5	M	55	3	3	1	0
B6	F	34	4	3	3	0
B7	M	42	2	0	0	0
B8	F	36	0	0	0	0
B9	M	27	6	3	2	0
B10	M	26	2	2	1	0
B11	M	33	1	1	0	0
B12	F	45	3	0	0	0
B13	F	16	3	2	0	0
B14	F	37	2	0	0	0
B15	M	34	4	2	1	0
B16	F	47	3	2	1	1
B17	M	21	5	3	2	0
B18	F	34	2	0	0	1
B19	F	38	3	2	0	0
B20	F	56	2	2	0	0
B21	F	43	3	2	1	1
B22	M	37	4	2	0	0
B23	M	28	2	0	0	0
B24	F	32	2	2	1	1
B25	M	18	3	2	0	0
B26	F	24	2	3	2	1
B27	F	24	3	2	0	0
B28	F	35	4	2	0	0
B29	F	34	3	2	0	1
B30	M	44	3	1	0	0

Table 3: VAS scores for patients for Group 3 (970nm Diode Laser)

Group 3						
Name	Sex	Age	6 hrs	24 hrs	48 hrs	72 hrs
C1	M	43	0	0	0	0
C2	F	32	3	1	1	0
C3	F	47	2	0	0	0
C4	M	38	3	0	0	0
C5	F	55	0	0	0	0
C6	F	45	2	2	1	0
C7	F	40	4	2	0	0
C8	F	47	2	2	0	0
C9	M	16	3	2	1	0
C10	F	15	4	2	0	1
C11	F	37	2	1	1	0
C12	M	22	2	3	2	0
C13	M	24	0	0	0	0
C14	F	65	2	0	0	0
C15	M	27	2	1	1	0
C16	F	37	1	1	0	0
C17	M	17	4	2	0	0
C18	F	28	2	1	1	0
C19	F	40	3	1	0	0
C20	M	64	2	2	0	1
C21	M	50	1	0	0	0
C22	F	44	2	3	1	0
C23	M	40	3	2	0	0
C24	M	16	2	1	0	0
C25	M	53	3	1	0	0
C26	M	21	2	3	0	0
C27	M	40	1	2	0	0
C28	F	29	0	0	0	0
C29	F	58	3	2	0	0
C30	F	28	2	0	0	0

Table 4: Comparison of Group 1 (NaOCl + EDTA), Group 2 (0.2% Chitosan) and Group 3 (970nm Diode Laser) with pain scores at different treatment time points by Kruskal Wallis ANOVA

Time points	Group 1 (NaOCl + EDTA)				Group 2 (0.2% Chitosan)				Group 3 (970nm Diode Laser)				H-value	p-value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR	Mean	SD	Median	IQR		
6 hrs	2.8	1.1	3.0	2.0	2.9	1.3	3.0	1.0	2.1	1.1	2.0	1.0	8.5171	**0.0141***
24 hrs	1.8	0.9	2.0	1.0	1.6	1.0	2.0	1.0	1.2	1.0	1.0	2.0	4.9705	0.0833
48 hrs	0.9	1.2	0.0	2.0	0.5	0.8	0.0	1.0	0.3	0.5	0.0	1.0	4.1635	0.1247
72 hrs	0.6	1.2	0.0	1.0	0.3	0.5	0.0	0.0	0.1	0.3	0.0	0.0	4.8206	0.0898

*$p<0.05$

Pairwise Comparisons (Mann-Whitney U Test)

The Group 3 (970nm Diode laser) exhibited significantly lower POP (mean = 2.1) as opposed to NaOCl + EDTA (mean = 2.8) and the Chitosan group (mean = 2.9). At the 6-hour mark, a statistically meaningful variation in pain levels was recorded in the groups (p = **0.0141**), Diode laser showing the most rapid pain relief. By 24 hours, pain levels had decreased across all groups, though not statistically significant (p = 0.0833). Pain reduction continued at 48 and 72 hours, with the Diode laser group consistently reporting the lowest scores.

Table 5: Pair wise comparison of Group 1 (NaOCl + EDTA), Group 2 (0.2% Chitosan) and Group 3 (970nm Diode Laser) with pain scores at different treatment time stamps by Mann-Whitney U test

Time points	Groups	Mean	SD	Median	Mean rank	Mean rank	Z-value	p-value
6 hrs	Group 1	2.8	1.1	3.0	30.4			
	Group 2	2.9	1.3	3.0	30.6	447.5	-0.0296	0.9764
	Group 1	2.8	1.1	3.0	35.9			
	Group 3	2.1	1.1	2.0	25.1	288.0	2.3877	**0.0170***
	Group 2	2.9	1.3	3.0	36.0			
	Group 3	2.1	1.1	2.0	25.0	285.0	2.4320	**0.0150***
24 hrs	Group 1	1.8	0.9	2.0	32.2			
	Group 2	1.6	1.0	2.0	28.8	398.0	0.7614	0.4464
	Group 1	1.8	0.9	2.0	35.3			
	Group 3	1.2	1.0	1.0	25.7	306.0	2.1216	**0.0339***
	Group 2	1.6	1.0	2.0	33.3			
	Group 3	1.2	1.0	1.0	27.7	366.0	1.2345	0.2170
48 hrs	Group 1	0.9	1.2	0.0	32.9			
	Group 2	0.5	0.8	0.0	28.1	377.0	1.0719	0.2838
	Group 1	0.9	1.2	0.0	34.4			
	Group 3	0.3	0.5	0.0	26.6	334.0	1.7076	0.0877
	Group 2	0.5	0.8	0.0	31.9			
	Group 3	0.3	0.5	0.0	29.1	408.5	0.6062	0.5444
72 hrs	Group 1	0.6	1.2	0.0	31.4			
	Group 2	0.3	0.5	0.0	29.6	424.0	0.3770	0.7062
	Group 1	0.6	1.2	0.0	33.6			
	Group 3	0.1	0.3	0.0	27.4	356.0	1.3823	0.1669
	Group 2	0.3	0.5	0.0	33.0			
	Group 3	0.1	0.3	0.0	28.0	374.0	1.1162	0.2643

*$p<0.05$

Results demonstrated a reduction in POP among the Diode laser group in relation to the others two groups, particularly at 6-hour mark. This early pain reduction is critical as it influences patient comfort and reduces the need for after treatment analgesics. The statistical results displayed that the Diode laser group (mean pain score = 2.1) had substantially reduced pain levels in contrast to the NaOCl +

EDTA (mean = 2.8) and the Chitosan group (mean = 2.9) (p = 0.0141). Pairwise comparisons further confirmed that the Diode laser group exhibited substantially reduced pain when compared to NaOCl + EDTA group (p = 0.0170) and the Chitosan group (p = 0.0150) at 6 hours. At 24 hours, while pain levels continued to decrease in all groups, statistical significance was solely observed between the Diode laser and NaOCl + EDTA groups (p = 0.0339), with the laser group maintaining the lowest pain levels (mean = 1.2). Yet, no significant statistical variations were observed were observed between Chitosan and NaOCl + EDTA at any stage. By 48 and 72 hours, pain had reduced significantly in all groups, and the differences did not reach statistical significance though the Diode laser group continued to show the lowest pain scores.

Graph 1: Comparison of Group 1 (NaOCl + EDTA), Group 2 (0.2% Chitosan) and Group 3 (970nm Diode Laser) with pain scores

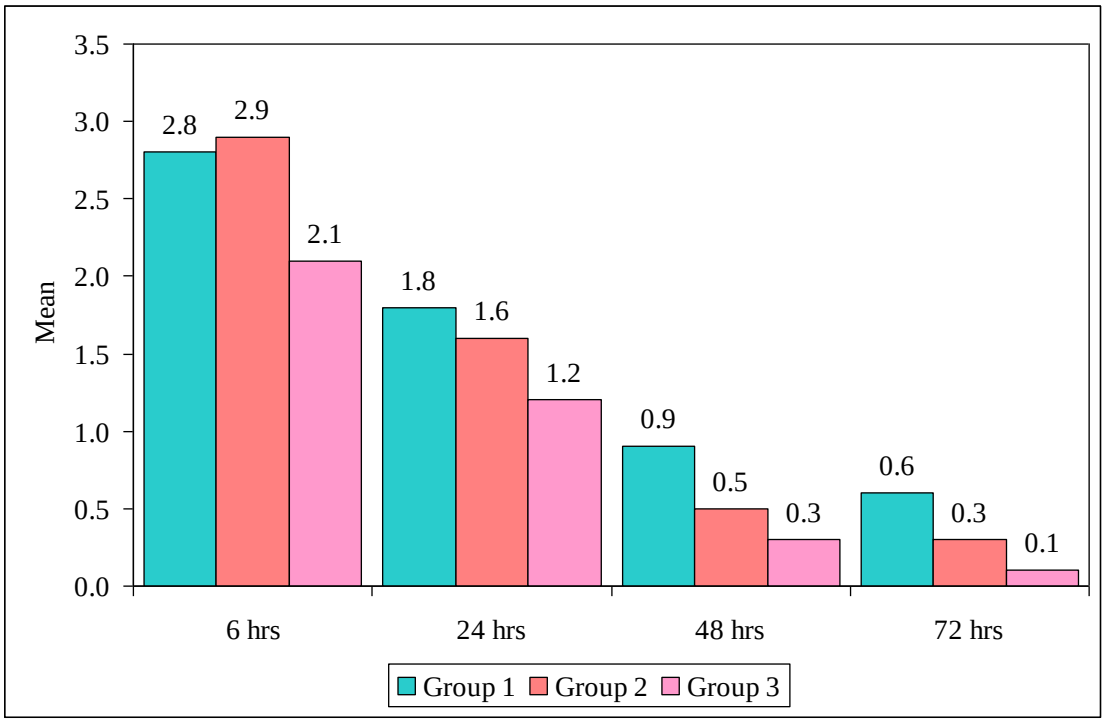


Table 6: Comparison of different treatment time points with pain scores in Group 1 (NaOCl + EDTA), Group 2 (0.2% Chitosan) and Group 3 (970nm Diode Laser) by Friedman's ANOVA followed by Wilcoxon matched pairs test

Group	Time points	Mean	SD	Median	% of change (6hrs to)	Z-value	p-value	Friedman test	p-value
Group 1 (NaOCl + EDTA)	6 hrs	2.8	1.1	3.0	-	-	-		
	24 hrs	1.8	0.9	2.0	35.71	3.4037	**0.0007***	54.7671	0.0001*
	48 hrs	0.9	1.2	0.0	67.86	4.3266	**0.0001***		
	72 hrs	0.6	1.2	0.0	78.57	3.9800	**0.0001***		
Group 2 (0.2% Chitosa)	6 hrs	2.9	1.3	3.0	-	-	-		
	24 hrs	1.6	1.0	2.0	44.83	4.1143	**0.0001***	70.284	0.0001*
	48 hrs	0.5	0.8	0.0	82.76	4.6226	**0.0001***		
	72 hrs	0.3	0.5	0.0	89.66	4.7030	**0.0001***		
Group 3 (970 nm Diode Laser)	6 hrs	2.1	1.1	2.0	-	-	-		
	24 hrs	1.2	1.0	1.0	42.86	3.2628	0.0011	60.722	0.0001*
	48 hrs	0.3	0.5	0.0	85.71	4.3724	**0.0001***		
	72 hrs	0.1	0.3	0.0	95.24	4.4573	**0.0001***		

*$p<0.05$

This compares % of reduction of pain at various time periods among the 3 groups

The statistical analysis revealed a significant pain reduction is seen over time within each group ($p < 0.0001$). Among the three groups, the Diode laser group (Group 3) exhibited the highest percentage of pain reduction (95.24%) from 6 to 72 hours, followed by the Chitosan group (Group 2) with an 89.66% reduction, and the NaOCl + EDTA group (Group 1) with a 78.57% reduction. These findings indicate that while all three disinfection methods effectively reduced post-operative pain, Diode laser disinfection resulted in the most substantial pain relief over time.

Graph 2: Comparison of different treatment time stamps with pain scores in Group 1 (NaOCl +EDTA, Group 2 (0.2% Chitosan) and Group 3 (970nm Diode Laser)

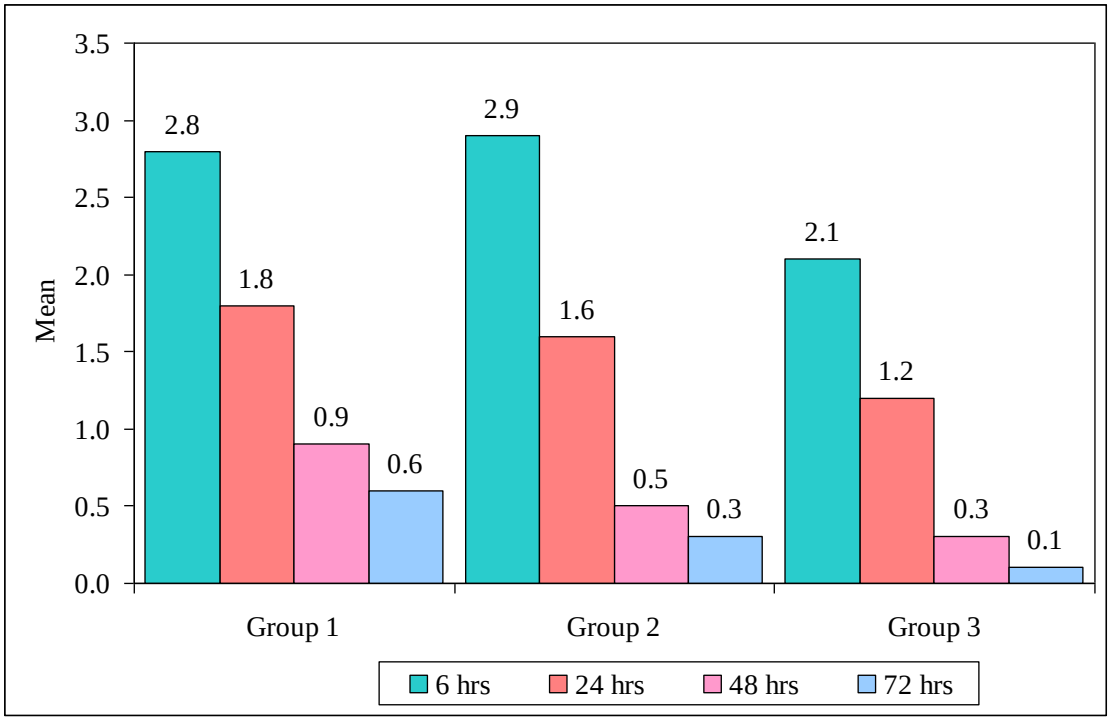


Table 7: Group 1 (NaOCl +EDTA), Group 2(0.2% Chitosan) and Group 3(970nm Diode Laser)

Group	Male	%	Female	%	Total
Group 1 (NaOCl +EDTA)	13	43.33	17	56.67	30
Group 2 (0.2% Chitosan)	12	40.00	18	60.00	30
Group 3 (970nm Diode Laser)	14	46.67	16	53.33	30
Total	39	43.33	51	56.67	90
Chi-square=0.2710, p=0.8730					

Gender Distribution (Chi-Square Test)

The gender distribution across the three groups was similar, with Group 1 (NaOCl + EDTA) consisting of 43.33% males and 56.67% females, Group 2 (Chitosan) comprising 40.00% males and 60.00% females, and Group 3 (Diode Laser) including 46.67% males and 53.33% females. The chi-square test gave a value of 0.2710 with a p-value 0.8730, not demonstrating statistical variation in gender distribution among all the groups ($p > 0.05$). This confirms that gender did not appear to be confounding factor in post-operative pain outcomes, ensuring the validity of the comparative analysis.

Graph 3: Comparison of Group 1 (NaOCl +EDTA, Group 2(0.2% Chitosan) and Group 3(970nm Diode Laser) with gender

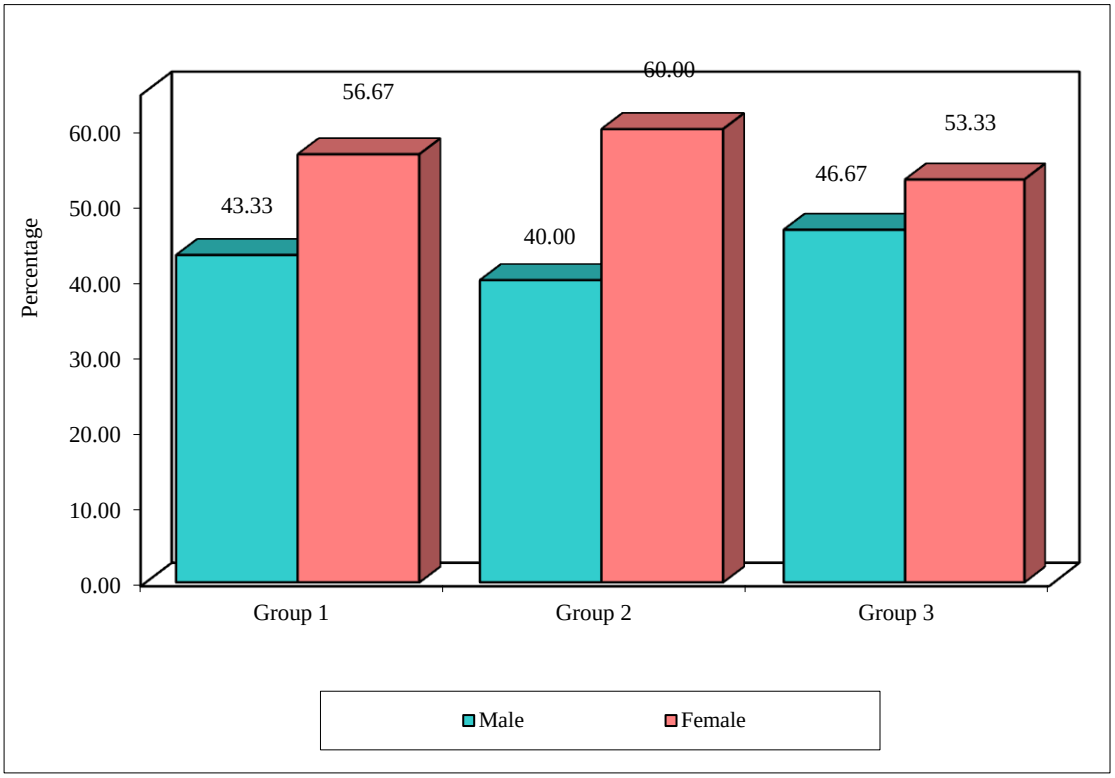
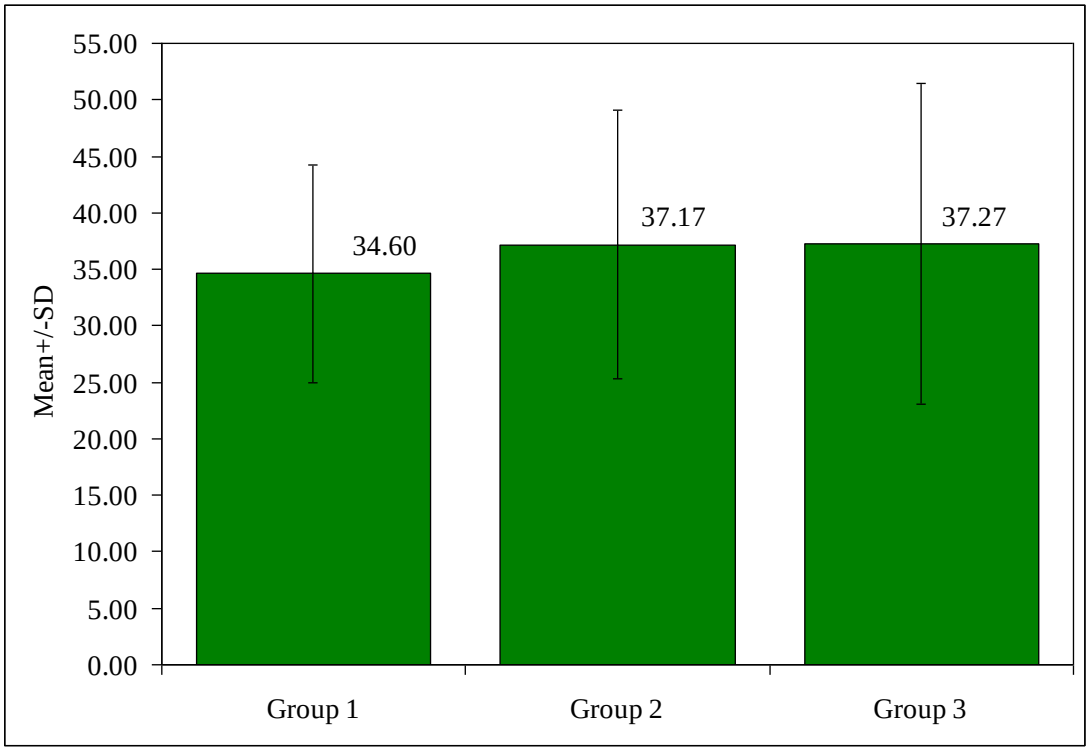


Table 8: Comparison of Group 1 (NaOCl +EDTA), Group 2 (0.2% Chitosan) and Group 3 (970nm Diode Laser) with mean age by one way ANOVA

Group	Mean	Std.Dev.	Std.Err.
Group 1	34.60	9.65	1.76
Group 2	37.17	11.89	2.17
Group 3	37.27	14.21	2.59
Total	36.34	11.99	1.26
F-value	0.4713		
p-value	0.6258		

The age of participants across three groups was comparable, with Group 1 (NaOCl + EDTA) having a mean age of 34.60 ± 9.65 years, Group 2 (Chitosan) at 37.17 ± 11.89 years, and Group 3 (Diode Laser) at 37.27 ± 14.21 years. Statistical analysis using a one-way ANOVA revealed an F-value of 0.4713 and a p-value of 0.6258, indicating that age distribution showed no significant difference among the groups ($p > 0.05$). This confirms that age did not appear to be confounding factor in the comparison of POP scores.

Graph 4: Comparison of Group 1 (NaOCl +EDTA), Group 2 (0.2% Chitosan) and Group 3 (970nm Diode Laser)



DISCUSSION

Endodontics has evolved into a specialized field dedicated to excellence in patient care by integrating historical knowledge, scientific advancements, and technological innovations. By acknowledging past achievements, we pave the way for a future of improved treatment outcomes.[51]

Endodontic treatment is commonly done in multiple visits as preferred by many clinicians, but now, the scenario is changing with the advent of single visit endodontics. Studies conducted comparing multiple visit and single visit endodontics reported statistically insignificant difference between them in regard to survival rate, post-operative pain or flare ups and long-term prognosis.[52,53]

In single visit endodontics, chemomechanical treatments ought to be finished in a single visit. By eliminating as many irritants as possible from the canal complex, the likelihood of discomfort during the inter-visit period caused by surviving microbes proliferating or increasing in virulence due to environmental changes may be reduced.[52] Studies conducted comparing multiple visit and single visit endodontics reported statistically insignificant difference between them in regard to survival rate, post-operative pain or flare ups and long-term prognosis.[53,54]

Single-visit endodontic treatment was chosen because it has comparable success rates to multiple-visit treatment while offering advantages such as shorter treatment time, reduced risks from repeated injections, and a decreased likelihood of microleakage. It was also preferred by patients as it shortened time, expense, and operative procedures. In addition to that it is more economical and time-efficient, allowing clinicians to focus on providing patients with the best endodontic care available.[55]

Post-operative pain (POP) following endodontic therapy in clinical dentistry has an impact on patient comfort and overall treatment success. Despite advancements in endodontic techniques, microbial persistence, inflammatory responses, and the limitations of conventional irrigation methods continue to contribute to post-treatment pain.[34] Post injury to the periapical area, pain mediators are secreted such as serotonin, prostaglandins, serotonin, histamine, and bradykinin at any instance during the treatment.[56]

Several risk variables are connected with POP which include gender, age, pre-operative pain, pulpal and periapical status, residual pulp remnants, extrusion of debris, use of analgesic agents and the number of treatment visits. Among these, effective sterilization of canal is imperative in reducing postoperative symptoms including localized swelling (abscess), cellulitis, and pain.[57] To achieve optimal disinfection, endodontic instrumentation combined with canal irrigation must be carried out meticulously. One critical consideration during instrumentation is the development of smear layer.

Smear layer is composed of an amorphous material (1-2 μm thick) formed during biomechanical instrumentation. McComb and Smith in 1975 first discovered the existence of a smear layer in 1975. It functions as a shield by minimizing the ability of sealants, medicament, and/or root canal irrigants from entering the dentin tubules. Hence, eliminating this layer is important for enabling the sealer to infiltrate in the dentinal tubules. [58]

NaOCl is a widely irrigant mainly due to its antimicrobial efficacy and capacity to break down organic tissue. However, it is ineffective in removing inorganic components. [59] EDTA serves as a standard chelating agent in dental

procedures due to its effectiveness in smear layer eradication and debris elimination, enhancing both sealer adhesion and the permeation of antibacterial agent deeper inside the dentinal tubules.[60] NaOCl along with EDTA is used as a dual-irrigation protocol has proven effective for thorough debridement and disinfection of the endodontic system.[34]

However, multiple studies have highlighted its potential drawbacks. One major concern is its excessive demineralization effect which can weaken dentin structure over time, making teeth more prone to fractures.[61,62] Additionally, Goel et al. (2022) noted that EDTA has limited antibacterial efficacy against certain resistant bacterial strains, including *Enterococcus faecalis*, which is a primary cause of endodontic failures and a contributing factor to post-operative pain.[39]

In addition, prolonged exposure to EDTA has proven to compromise the sealing capabilities of root canal fillings by altering the composition of dentin collagen, potentially affecting long-term treatment outcomes.[62] Another significant disadvantage (Sarkees and Al-Maarrawi 2020) is its potential cytotoxicity particularly when extruded beyond the apex, which can lead to periapical irritation along with delayed healing and periapical inflammation leading to discomfort during the immediate post-operative period.[16]

Given these limitations, Chitosan has been explored as a potential alternative due to its unique combination of antimicrobial, chelating, and biocompatible properties. Chitosan is a naturally existing homopolysaccharide extracted from Chitin. It is formed of recurring units of N-acetyl-D-glucosamine which is crosslinked together via β (1–4) linkage.

Research has shown that Chitosan has strong chelating abilities, with its highest effectiveness observed when it's dissolved in acetic acid, which is identical to the 0.2% Chitosan utilized in this study. It exhibits chelating properties comparable to those of EDTA and citric acid., but with significantly less deleterious effects.[63]

Yadav et al. (2017) demonstrated that Chitosan exhibits strong antimicrobial activity against, *Candida albicans* and *Enterococcus faecalis* which are a broad spectrum pathogens.[64]

Kim et al. (2023) reported that Chitosan effectively penetrates dentinal tubules while maintaining high biocompatibility with periapical tissues. Chitosan induces minimal dentin demineralization compared to EDTA, making it a promising alternative for preserving tooth structure. Its natural origin and biodegradable properties also reduce the risk of cytotoxic effects, making it a safer option for root canal irrigation. Chitosan's ability to form a protective film over dentin surfaces enhances its sealing potential, reducing the likelihood of bacterial recontamination.[65]

In addition, mild chelating action and biocompatibility contribute to reduced post-operative pain by preserving dentin structure and minimizing hypersensitivity. Unlike EDTA, which aggressively demineralizes dentin, Chitosan maintains root canal integrity while effectively eliminating biofilm and smear layers. Its anti-inflammatory properties further promote faster periapical healing, alleviating discomfort in the post-operative period.[66]

Studies have shown that Chitosan nanoparticles effectively reduce microbial load while maintaining low toxicity levels, making it a safer and equally effective alternative to conventional chelating agents.[66,67] Murali et al (2017) demonstrated that the sealer penetrated to a depth of. maximum at apex with 0.2% Chitosan in

comparison to EDTA and displayed similar results at coronal as well as middle third. [68]

While chemical irrigants like NaOCl and Chitosan are effective, they have limitations in eliminating bacteria deeply embedded within dentinal tubules. This challenge has driven the exploration of advanced disinfection techniques, including laser-based methods.

Diode lasers have emerged as an innovative adjunct in endodontic disinfection due to its capacity to effectively remove bacteria and minimizing tissue damage. The 970nm Diode laser operates by emitting photothermal energy which penetrates dentinal tubules to a depth exceeding 1000μm and thereby eliminating residual bacteria that conventional irrigants may not reach, as reported by Kaplan et al. (2021).[2]

This deep penetration enhances the efficiency of root canal disinfection and disrupts biofilm formation by reduction of bacterial endotoxin release, which are key contributors to POP as noted by Pelozo et al. (2023).[37]

Additionally, the Diode laser has been reported to induce coagulation within dentinal tubules, reducing the potential for bacterial recontamination. The anti-inflammatory effects of laser irradiation also play a crucial role in modulating periapical healing as laser therapy has been found to reduce inflammatory cytokine expression which can mitigate post-operative discomfort. [69]

According to Kaplan et al. (2021), another advantage of Diode laser application is its ability to reduce extrusion of irrigant beyond the apex which is a common reason of POP in traditional irrigation techniques.[2]

There is limited literature directly comparing effects conventional irrigation with NaOCl + EDTA, Chitosan, and Diode laser when used as final irrigants.

Taking these factors into account, the goal of this study was to assess the impact of 0.2% Chitosan and 970 nm Diode laser disinfection, used in conjunction with NaOCl and EDTA, on POP following SVE.

To randomly allocate the confounding variables of age and gender a table of random numbers was used.

Sample size was calculated using the formula at 95% Confidence Interval and 80% power

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (SD_1{}^2 + SD_2{}^2)}{(\bar{x}_1 - \bar{x}_2)^2}$$

SD_1 : Standard Deviation in the 1st group

SD_2 : Standard Deviation in the 2nd group

$\bar{x}_1$: Mean of 1st group

$\bar{x}_2$: Mean of 2nd group

α : Significant level

$1 - \beta$: Power

Estimated sample size for each group, *n = 30*

Considering 10% drop out rate, the total sample size of the study was rounded off to 100, at a power of 0.90 with 0.6% Type I error.

The study evaluated the effect of three disinfection protocols: traditional NaOCl + EDTA irrigation, Chitosan-based irrigation, and Diode laser-assisted disinfection.

According to Peter et al it has been noted that 90% of people over 55 have some form of calcification in their root canals.[70] An age bracket of 18 to 55 years was chosen for this study.

After access cavity preparation, teeth where a #20 K-file reached WL without resistance or where a #10 K-file was very difficult to move, were excluded. To prevent interpersonal differences in care between clinicians, a single clinician handled every case. Glennon et al. (2021) found that pre-operative pain has a significant impact on POP.[71, 72]

The research comprised teeth with adequate coronal structure for proper isolation, excluding asymptomatic non-vital teeth due to increased POP. Patients with several ipsilateral teeth in need of endodontic therapy were excluded because of the potential false positive readings due to the inability to differentiate the pain caused by these teeth.

This study excluded teeth with chronic apical periodontitis, necrotic teeth, symptomatic acute conditions, and intracanal medicament cases like retreatment and weeping canals due to increased postoperative pain risk and a requirement of multiple visits and follow up for treatment of such conditions. [71,72,73,74] Since Glennon et al. discovered that periapical radiolucency's with a diameter more than 5 mm were related to increased post-operative pain, they were also excluded. [71]

Additional operator-dependent variables, such as chemical (irrigant extrusion) and mechanical (erroneous WL determination resulting in over-instrumentation and over-filling) injuries during root canal preparation, were addressed by measuring accurate WL using EAL and verified with an IOPA. A side-vented needle as they are designed to deliver irrigants safely and effectively while reducing the likelihood of irrigant extrusion past the apex. Lateral vents allows for a gentle and controlled flow

of irrigant solution thus promoting better cleaning and disinfection during endodontic procedures.

AH Plus continues to be the best among all endodontic sealers, was used in the present study because of its favourable properties that included excellent adhesion to root dentin low solubility, and superior radiopacity compared to other sealers.[75]

ProTaper Universal (PTU) used in this study formed from a NiTi rotary system which is developed with features including a progressive tapering and triangle cross section with convex sides.[76] Toriano et al (2019) showed that PTU has least amount of apical transportation and Toriano et al (2019) demonstrated supper centering ability when comparing the ProTaper Next file and WaveOne Gold. [77]

In Group 3, laser irradiation followed the protocol described by Soraya et al. (2024), utilizing a 970 nm Diode-laser equipped with a 200micron fiber tip. (spot size: 0.02 cm, area: 0.000314 cm^2).[78] The laser operated at "2 W output power and 12 J per cycle and it is used in pulsed mode with pulse duration of 20 μs, with 10 seconds of irradiation followed by a 10-second of pause per cycle." as per manufacturers recommendations. [79,80]

The findings of this study show notable differences in POP reduction within three disinfection protocols examined, providing valuable insights into the clinical relevance of each approach. Evaluating how different disinfection techniques impact pain levels helps in determining the most effective and patient-friendly treatment modality.

The primary outcome measure which is the POP scores was evaluated using the VAS which includes a 10 cm scale with continuous horizontal lines at each time

interval.[37] The scale is commonly ranged from 0 (left) lowest pain score to 10 (right) highest pain score.

The VAS scale when used appropriately is easy to understand by the patients and provides a valid, and clear result. This scale form was previously used in several studies to evaluate post-operative pain after endodontic therapy.[81,82,83] The existing study the clinician communicated the purpose and structure of the scale to the participants. in their native language before the treatment to confirm accurate recordings of postoperative pain.

The pain scores were recorded at times intervals of 6 hours, 24 hours, 48 hours and 72 hours following endodontic therapy with 12-hour time stamp excluded due to inconvenient patient contact. In this study, no time frame beyond 72 hours was considered, as it has been documented that regardless of the method or drug utilized, 4 days after endodontic treatments the prevalence of pain was minimal.[81,84]

Following endodontic treatment management of postoperative pain, NSAIDS including Ibuprofen (600mg) have been recommended post endodontic treatment.[85]

Numerous studies have examined the efficacy of Ibuprofen to reduce pain during root canal therapy. Because regular prescriptions could affect the study's outcome measure, it was only prescribed when necessary.[86] Patients requiring such medications were excluded, as their use could alter post-treatment pain perception. However, since these patients comprised less than 10% of the sample size, their exclusion did not impact the study's outcome. This study also eliminated patients taking antibiotics within the last 3 months that suggested immunological incompetence or a systemic illness, as well as those taking analgesics that could

provide inaccurate VAS scores because of elevated pain thresholds. Since steroids greatly lower the intensity of POP, they were also eliminated from the study. [87]

The severity of POP at 6hrs, 24hr, 48hr, and 72hr time points was assessed. The study results revealed that while all groups experienced a decline in pain over time, the rate of reduction varied substantially. After the 6h mark, pain levels differed significantly within all groups (p-value = 0.0141) [Table 4, Figure 1]

Group 3 (Diode Laser) exhibited markedly reduced pain when compared to Group 1 (NaOCl + EDTA) and 0.2% Chitosan (Group 2) at 6 hour and 24 hour mark. [Table 4]

Group 3 demonstrated the greatest percentage reduction in pain (Diode Laser) 95.24% followed by Group 2 (Chitosan) 89.66% at 72 hours.

Among the three groups, the lowest percentage of pain reduction of 78.57% was observed in Group 1 (NaOCl + EDTA) demonstrated the lowest percentage of pain reduction at 78.57% [Table 6, Figure 2]. his could be a result of EDTA's somewhat limited capibility to infiltrate the endodontic system, as suggested by Bajpe et al. (2023).[88] However, studies have shown no statistical difference in the capacity to eradicate the smear layer when comparing EDTA and Chitosan.[89,90] EDTA's limited efficacy could be due to its absence of antimicrobial activity and relatively limited biocompatibility compared to Group 2 (Chitosan).[48] In contrast, Chitosan showed a more significant reduction in POP, likely due to its strong antimicrobial activity and superior biocompatibility. [49] Its antimicrobial effect is through positively charged Chitosan binds to the phosphoryl groups on cell membranes of the bacteria. This interaction increases membrane permeability thus leading to protein leakage, disruption of cellular components, and ultimately bacterial cell lysis. [91]

Chitosan is believed to restrict bacterial growth by binding essential metallic ions, thereby reducing enzymatic activity critical for bacterial survival. [92] Its high biocompatibility and non-toxic nature may also contribute to reduced inflammation if extruded beyond the apex, further minimizing post-operative pain and promoting faster healing.[93]

The highest pain reduction was seen in Group 3 (Diode Laser). This early pain reduction is particularly relevant because the first few hours post-procedure are critical for patient comfort and analgesic dependency. The photothermal action of the Diode laser which effectively eliminates bacteria within dentinal tubules while reducing inflammation, likely contributes to this immediate pain relief.[87] Garcez et al. found there was a reduction in microbial count when Diode laser in infected root canals was performed. [94,95] Morsy et al. also stated that the reduction in POP after using Diode laser could be attributed to its strong antibacterial effect. The mechanism of includes stimulation of cell proliferation and inhibition of inflammation spreading enzymes.[87] Bjordal et al. observed that Diode laser subsides the creation of histamine, PGE2, serotonin, acetylcholine, weaken substance P production thus causing an anti-inflammatory action and invariable reducing chronic pain. [96,97]

Statistical analysis revealed significant differences in the Diode Laser group (Group 3) and both the NaOCl + EDTA (Group 1, $p = 0.0170$) and the 0.2% Chitosan group (Group 2$p = 0.0150$) [Table 5], suggesting a superior bactericidal effect and tubule sealing properties of the Diode Laser that plays a critical role in immediate pain relief.

Studies have shown that Diode laser significantly reduces POP, particularly during the initial 24 hours [Table 6], because of its penetrability which is more than

1000μm in the dentinal tubules.[2] This suggests that Diode Laser can be a preferred disinfection method in cases requiring single-visit endodontic therapy, as it ensures thorough bacterial elimination while minimizing post-treatment discomfort.

At 24,48 and 72 hours the levels of pain continued to decrease in all groups. Nevertheless, no statistically significant difference was observed. ($p = 0.0833$). However, the Diode-laser group still exhibited the lowest pain levels (mean = 1.2), in comparison to NaOCl + EDTA (mean = 1.8) and the Chitosan group (mean = 1.6). [Table 6]

When gender was considered, both male and female patients experienced similar pain ($p = 0.8730$) [Table 7] This result is consistent with those of (Albashaireh 1998, Anagha et al 2022) that found no connection between gender and pain following the endodontic procedure.[98,99]

When age was considered it was found that the degree of pain was unaffected by an individual's age ($p = 0.6258$) [Table 8]. These finding are in similar lines study published by Akram Ali et al (2016), that found no connection between the patients' self-reports of postoperative pain and sociodemographic factors such age and educational attainment.[100]

This study indicates that while traditional methods like NaOCl + EDTA remain effective, newer approaches such as Chitosan and Diode Laser may offer superior pain relief due to their antimicrobial efficiency and biocompatibility.

The differences in pain reduction also suggest that microbial elimination and tissue compatibility play key roles in post-operative recovery. The findings also reinforce the importance of selecting an irrigation or disinfection method that not only removes pathogens but also promotes patient comfort and faster recovery.

CONCLUSION

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

1. The 970 nm Diode laser showed a statistically significant reduction in postoperative pain at all evaluated time intervals including 6 hours ($p = 0.0170$), 24 hours ($p = 0.0339$), 48 hours and 72 hours ($p < 0.0001$ within-group analysis). These findings highlight its consistent and superior effectiveness in pain control throughout the postoperative period.

2. Irrigation with 0.2% Chitosan provided better postoperative pain relief compared to the conventional NaOCl + EDTA protocol, particularly at 24 hours where the difference was statistically significant ($p = 0.0339$). However, Chitosan was not as effective as the 970 nm Diode laser, which consistently outperformed both at 6 hours ($p = 0.0150$), and continued to show superior pain reduction throughout the 48 and 72 hour period.

3. There were no statistically significant differences in age ($p = 0.6258$) or gender distribution ($p = 0.8730$) across the groups, confirming that the observed differences in pain outcomes were not influenced by these demographic variables. Thus, the findings strongly support the clinical use of Diode laser disinfection and Chitosan irrigation for improved patient comfort, regardless of age or gender.

SUMMARY

Postoperative pain after root canal treatment is a common challenge in clinical dentistry. Even with modern techniques many patients experience discomfort within the first 24 to 48 hours. This study investigates whether newer irrigation and disinfection methods can reduce pain more effectively than the conventional Sodium hypochlorite (NaOCl) and EDTA combination.

Traditionally, NaOCl is favoured for its strong antimicrobial properties and tissue-dissolving ability but it is cytotoxic and ineffective against the inorganic smear layer. EDTA which commonly used alongside NaOCl can remove this smear layer due to its chelating properties but it lacks antibacterial action and may weaken dentin if used excessively.

These limitations have prompted exploration into safer and more biocompatible alternatives like Chitosan and advanced technologies such as laser disinfection.

Chitosan is a natural biopolymer derived from chitin, it possesses antibacterial, chelating and anti-inflammatory properties. It is biocompatible, biodegradable and has shown promising results in removing smear layers and reducing microbial load without harming periapical tissues.

On the other hand, Diode lasers have gained popularity due to their ability to penetrate deep into dentinal tubules and effectively sterilizing areas beyond the reach of conventional irrigants. The 970 nm wavelength Diode laser acts through photothermal action that disrupts bacteria while promoting tissue healing and reducing inflammation.

The study was conducted in the Department of Conservative Dentistry and Endodontics, Viswanath Katti Institute of Dental Sciences, KAHER Belagavi, Karnataka

Hundred patients requiring endodontic treatment on permanent mandibular premolars based on defined inclusion and exclusion criteria were selected. All procedures were performed by a single clinician to ensure consistency. After access cavity preparation cleaning and shaping was done using ProTaper Universal files. Patients were randomly divided into three groups (n=30) one control group an two experimental groups according to final disinfection protocol.

Group 1: 5 ml 3% NaOCl + 5ml 17% EDTA Conventional Irrigation for 3 minutes

Group 2: 5ml 3% NaOCl + 5ml 0.2% Chitosan Conventional Irrigation for 2 minutes

Group 3: 5ml 3% NaOCl and 5ml 17% EDTA + 970nm Diode Laser Disinfection

All canals were obturated using single cone technique with AH Plus sealer and corresponding gutta-percha points. Patients were trained to use the Visual Analogue Scale (VAS) to record pain at 6, 24, 48, and 72 hours post-treatment. Ibuprofen (600 mg) was prescribed as rescue medication only if severe pain occurred.

The results showed that all three protocols led to a significant decrease in pain over time. However, the Diode laser group showed the most rapid and substantial pain reduction particularly at the 6 and 24 hour marks. At 6 hours, the Diode laser group had the lowest mean pain score (2.1), significantly less than the Chitosan group (2.9) and the control group (NaOCl + EDTA) (2.8). This trend continued at 24 hours, where the laser group maintained a mean pain score of (1.2), compared to (1.6) for Chitosan and (1.8) for the control group (NaOCl + EDTA). By 48 and 72 hours, all

groups showed reduced pain levels with no statistically significant differences, but the Diode laser group consistently reported the lowest scores.

When comparing the overall percentage reduction in pain from 6 to 72 hours, the Diode laser group achieved a reduction of 95.24%, followed by 89.66% for Chitosan and 78.57% for NaOCl + EDTA. These results indicate that while all protocols are effective, Diode laser and Chitosan offer superior outcomes, particularly in the early postoperative period.

The enhanced performance of the Diode laser is likely due to its deep dentinal penetration and photothermal disinfection. The rapid relief in Group 3 (Diode laser) may be due to laser's its ability to destroy bacteria, reduce inflammatory mediators, and seal dentinal tubules. Studies have shown that Diode lasers can stimulate cellular repair and inhibit substances like prostaglandins and bradykinin, which are responsible for pain and inflammation.

Chitosan was found to be slightly less effective than the Diode laser but still performed better than the traditional protocol. Its strong antimicrobial action is due to the mechanism of positively charged molecules interacting with bacterial membranes and increasing permeability and leading to cell death. Its biocompatibility also ensures minimal periapical irritation which also contributes to reduced post operative pain. Furthermore, Chitosan's ability to bind metal ions and its mild chelating effect help eliminate the smear layer while preserving dentin structure making it a safer and equally effective alternative to EDTA.

Demographic factors like age and gender were also analyzed and no significant correlation with pain perception was found. This suggests that the

observed differences in pain levels were due to the disinfection protocols themselves and not patient-related variables.

All three disinfection protocols successfully reduced postoperative pain over time. However, the Diode laser provided the most immediate and pronounced relief, followed by Chitosan. These findings suggest that both Chitosan and Diode laser disinfection are promising additions to conventional irrigation protocols, offering better patient outcomes in terms of comfort and healing.

The study highlights the importance of selecting irrigation methods that are not only effective in microbial reduction but also safe and comfortable for the patient.

It can be concluded that:

1. The 970 nm Diode laser provided the greatest pain reduction, particularly within the first 24 hours, mostly due to deep dentin penetration and anti-inflammatory effects.

2. 0.2% Chitosan irrigation offered better postoperative pain relief than the conventional NaOCl + EDTA protocol.

3. No significant differences in age or gender across was found across groups, indicating that pain outcomes were not influenced by demographics. Thus, the findings strongly support the clinical use of Diode laser disinfection and Chitosan irrigation for improved patient comfort, regardless of age or gender.

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ANNEXURES

ANNEXURE I : ETHICAL CLEARANCE 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
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Sl. No. : 1645

CERTIFICATE

This is to Certify that the synopsis titled

Effect of 0.2% Chitosan and 970 nm Diode lasers disinfection on post-operative pain after Single visit endodontic therapy: A Randomized clinical trial.

Submitted by

Dr. REG.NO. IE0222002 *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 :

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

MEMBER SECRETARY
Research & Ethical Committee
KLEVK Institute of Dental Sciences
BELAGAVI.

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLE VK Institute of Dental Sciences
Belgaum

ANNEXURE II : BIOSTATISTIC CLEARANCE CERTIFICATE

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

BIOSTATISTICS CLEARANCE CERTIFICATE

This is to certify that the Biostatistics art of Dissertation/ Research work of REG.NO. IE0222002 **Postgraduate student** under the guidance of **Department of Conservative Dentistry and Endodontics** entitled **"EFFECT OF 0.2% CHITOSAN AND 970nm DIODE LASER DISINFECTION ON POST-OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC THERAPY: A RANDOMIZED CLINICAL 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
USM KLE International Medical Programme
BELAGAVI-590010.

ANNEXURE III : PLAGIARISM CHECK 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
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Date : 18/04/2025 Serial No. : 420

PLAGIARISM CHECK REPORT

Name of the Applicant : **REG.NO. IE0222002**
UG / PG / Ph.D / Staff : PG
Batch & Year : 2022-2025
Department : Department of Conservative and Endodontic Dentistry

The soft copy of Research Work / Manuscript by **REG.NO. IE0222002** . entitled
" Effect of 0.2% Chitosan and 970 nm Diode laser disinfection on post-operative pain after single visit endodontic therapy: A Randomised clinical 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 ……2……%, 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 : CONSENT FORM PROFORMA

K L E
VISHWANATH KATTI
INSTITUTE OF DENTAL SCIENCES,
Constituent college of
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Department of Pediatric & Preventive Dentistry

INFORMED CONSENT FORM FOR CLINICAL TRIAL
(ANNEXURE)

This Informed Consent form is for adults between 18-55 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 "EFFECT OF 0.2% CHITOSAN AND 970nm DIODE LASER DISINFECTION ON POST-OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC THERAPY: A RANDOMIZED CLINICAL TRIAL"

Name of Principal Investigator: _____

II MDS Student, Dept. of Conservative Dentistry & Endodontics KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH KLE VK INSTITUTE OF DENTAL SCIENCES, NEHRU NAGAR, BELAGAVI

Telephone number:

Name of Co-Investigator 1: _____

(Research guide) Professor, Dept. of Conservative Dentistry & Endodontics

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

KLE VK INSTITUTE OF DENTAL SCIENCES, NEHRU NAGAR, BELAGAVI Telephone number:

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 _____, a IInd year 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 EFFECT OF 0.2% CHITOSAN AND 970nm DIODE LASER DISINFECTION ON POST-OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC THERAPY. 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

Post-operative pain (PP) which causes discomfort is a frequent occurrence after root canal treatment (RCT). The cause of PP is primarily associated with the extrusion of

microorganisms and their products to the periapical area by over-instrumentation or extrusion of irrigation solutions. Chitosan is a natural polysaccharide formed by the acetylation of chitin from Crustaceans and has shown to have reduced post operative pain. Along with this, Diode laser irradiation has been shown to increase disinfection along with reduction of post-operative pain when used at a wavelength of 970nm. Hence the purpose of this study is to evaluate the effect of 0.2% Chitosan and 970nm Diode laser disinfection on Post-Operative Pain after Single Visit Endodontic therapy.

Type of Research Intervention

This research will involve intervention using 970nm Diode laser and 0.2% Chitosan irrigant.

Participant selection

All patients between the age of 18-55 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 mandibular 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 treated with 5 ml 3% NaOCl + 5ml 17% EDTA Conventional Irrigation for 3 minutes

Group II will be treated with 5ml 3% NaOCl + 5ml 0.2% Chitosan Conventional Irrigation for 2 minutes

Group III will be treated with 5ml 3% NaOCl and 5ml 17% EDTA + 970nm Diode Laser Disinfection.

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 irrigants 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.

Who to Contact

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

- Name: _____
  Address: Post graduate student, Dept of Conservative Dentistry & Endodontic Dentistry
  KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
  KLE VK INSTITUTE OF DENTAL SCIENCES, NEHRU NAGAR, BELAGAVI Telephone number: 9158336383
- Name: _____
  Address: Professor, Dept of Conservative Dentistry & Endodontic Dentistry
  KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
  KLE VK INSTITUTE OF DENTAL SCIENCES, NEHRU NAGAR, BELAGAVI Telephone number: 9448143290

This proposal has been reviewed and approved by Ethical Clearance Committee, KAHER, Belagavi, which is a committee whose task it is to make sure that research participants are protected from harm.

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___

Date __

PART III: VISUAL ANALOGUE SCALE

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

Department of Conservative Dentistry and Endodontics

PROFORMA

"EFFECT OF 0.2% CHITOSAN AND 970nm DIODE LASER DISINFECTION ON POST-OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC THERAPY: A RANDOMIZED CLINICAL TRIAL"

Patient's Name:

OPD number

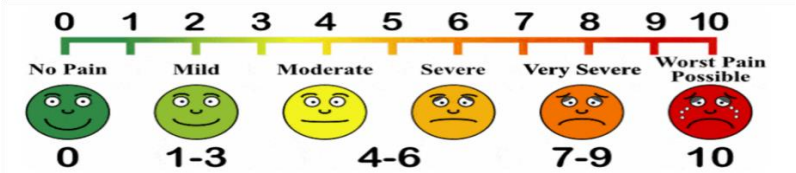
Sex:

Age:

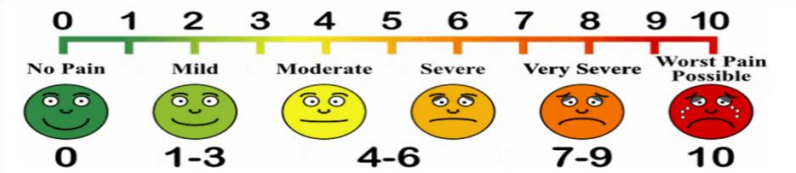
Address:

VISUAL ANALOG SCALE

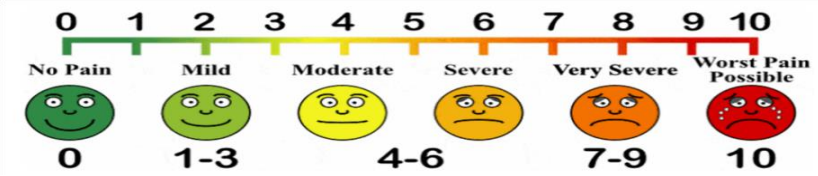
6 hours



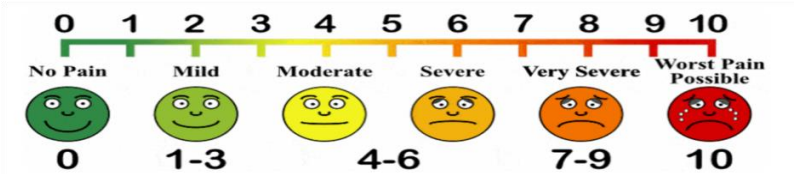
24 hours



48hours



72 hours



Medications if taken any, when _____

Signature of patients