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Dentistry Section

Comparison of Ultrasonic and Laser-activated Continuous Chelation Irrigation on Postoperative Pain after Primary Endodontic Therapy: A Randomised Controlled Trial

VINAYA PISAL[1], DEEBAH CHOUDHARY[2], AJAY SINGH RAO[3], NIMISHA SHAH[4], DEVASHREE DARAK[5], CHANDNI SHAH[6], SEJAL DODAL[7], RUTVI KARANDE[8]

ABSTRACT

Introduction: Irrigation solutions are used to flush away debris, remove the smear layer, and disinfect the non instrumented areas of the root canal system. To enhance root canal disinfection, various irrigation and activation techniques have been advocated. To the authors knowledge, limited research has been conducted on the clinical efficacy of various irrigants with regard to Postoperative Pain (PP). Therefore, to fill this gap, the present study was conducted.

Aim: To evaluate PP after initial endodontic treatment in symptomatic teeth when continuous chelation irrigation is activated ultrasonically versus when laser irradiation is performed.

Materials and Methods: A single-blinded randomised controlled trial was conducted in the Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, Vadodara, Gujarat, India, from October 2023 to October 2024. A total of 36 patients with symptomatic teeth requiring root canal treatment were included in the study. A preoperative Visual Analogue Scale (VAS) score was recorded for all subjects, after which they were divided into two groups. In Group A, ultrasonic activation of the continuous chelation irrigation was used, and in Group B, laser irradiation after irrigation (continuous chelation irrigation) using a 980 nm diode laser in pulsed mode was used. Postoperative VAS levels (1-10) were recorded at 6, 24, and 48 hours after therapy. Pain levels and incidence were analysed using an independent two-sample t-test and presented as means with standard deviations, with statistical significance set at $p<0.05$.

Results: Preoperative pain levels were higher in Group A, though the difference was not statistically significant ($p=0.164$). PP was notably higher in Group A at 6 hours but became comparable between groups at later time points. Within-group comparisons showed a gradual reduction in pain over time, with significant differences observed between preoperative and postoperative values ($p<0.001$) in both groups. Pain categorisation analysis revealed no significant difference between groups, and no patients reported severe pain at 24 and 48 hours.

Conclusion: The results indicate no significant difference when a continuous chelation protocol {2.5% Sodium Hypochlorite (NaOCl) and 9% 1-hydroxyethylidene-1,1-bisphosphonate (HEBP)} is used as the final irrigant, in combination with either ultrasonic activation or laser irradiation, in symptomatic irreversible teeth. To fully understand the exact mechanism underlying these activation systems, more clinical research is necessary.

Keywords: Apical periodontitis, Diode laser, Etidronate, Sodium hypochlorite, Ultrasonic activation

INTRODUCTION

One common short-term side-effect of endodontic therapy is postoperative discomfort. Typically, this pain emerges approximately 24 hours post-treatment [1,2] and generally diminishes within a 48-hour timeframe [3]. However, in certain cases, it can persist intensely for several days. Between 3% and 58% of patients experience PP, which concerns both patients and endodontists [4].

Research utilising micro-Computed Tomography (CT) imaging has demonstrated that a significant portion, ranging from 9.6% to 48%, of the primary root canal walls remain unprepared following instrumentation [5-8]. The cutting action of endodontic instruments also produces hard tissue debris and a smear layer on the canal walls, which can lead to irregularities in the canal. For these reasons, irrigation solutions are essential to flush away debris, eliminate the smear layer, and further disinfect the non instrumented areas of the root canals [6]. To enhance root canal disinfection, various irrigation and activation techniques have been advocated.

Sodium Hypochlorite (NaOCl) is the most commonly used irrigant due to its strength against bacteria and biofilms and its capacity to degrade organic tissue [9]. Nevertheless, NaOCl is cytotoxic to periapical tissues [10], and when extruded, it may result in an inflammatory response [11]. NaOCl may not always completely eradicate bacteria in canal complexities, such as isthmuses and dentinal tubules, because of its limited penetrating capabilities brought on by insufficient irrigation dynamics. Demineralising agents are therefore advised to be used alongside the irrigant solutions. Previous research has shown that opening tubules may promote disinfection by allowing sodium hypochlorite to enter dentinal tubules [12].

Several researchers have recommended the combination of Ethylenediaminetetraacetic Acid (EDTA) and hypochlorite for smear layer removal, noting that this mixture is more effective in disinfection than NaOCl alone [13,14]. This led to the development of the sequential chelation protocol, in which NaOCl and EDTA are used successively to irrigate root canals, resulting in complete demineralisation of the superficial intertubular (0.5-1 µm) and dentinal walls (up to 20 µm) [15]. To address challenges associated with sequential chelation, the continuous chelation approach was introduced, in which NaOCl is combined with a soft chelator, 1-hydroxyethylidene-1,1-bisphosphonate (HEBP), to create an improved irrigation solution. The proteolytic and antimicrobial efficiency of NaOCl relies on freely retained chlorine ions, whereas

HEBP, a calcium sequestrant, prevents the accumulation of dentinal debris and the smear layer [15].

Studies have also explored the use of 980 nm diode lasers as an adjunct to irrigation, demonstrating effective root canal disinfection. Diode lasers with wavelengths of 810, 940, and 980 nm have significant water transmission capacity, enabling them to penetrate dentinal tubules and enhance bactericidal effects. Laser-induced optical cavitation generates vapor bubbles that expand and collapse at the fiber tip within the irrigant [16]. Smaller secondary bubbles undergo acoustic streaming as they propagate through the canal, occurring within the microsecond range and facilitating rapid liquid movement [16-19]. However, limited research has been conducted on its clinical efficacy concerning PP. Thus, this clinical study aimed to assess PP using ultrasonic activation and laser irradiation alongside irrigation with a 2.5% NaOCl and 9% HEBP mixed solution in cases of symptomatic irreversible pulpitis.

MATERIALS AND METHODS

The present single-blinded randomised controlled trial was conducted in the Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, Vadodara, Gujarat, India, from October 2023 to October 2024. The clinical trial was written according to the Preferred Reporting Items for Randomised Trials in Endodontics (PRIRATE) 2020 guidelines [20]. The study was conducted in accordance with ethical standards of the Declaration of Helsinki (1964), and the research protocol was approved by the Institute Ethics Committee (SV1EdON/Dent/SRP/oct/23/22) and registered with the Clinical Trials Registry–India (CTRI/2024/05/067190).

Inclusion and Exclusion criteria: The inclusion criteria included healthy patients {American Society of Anaesthesiologists (ASA) Class I} aged 18-60 years with maxillary or mandibular teeth diagnosed with symptomatic irreversible pulpitis with or without periapical pathology or radiographic rarefaction. Teeth with open apices, resorption, calcified pulp chambers and canals, or root canal curvature greater than 20 degrees were excluded, as were patients who had taken analgesics within 12 hours before the intervention, previously treated teeth, periodontally compromised teeth, and flare-ups during root canal therapy.

Sample size calculation: Based on the study by Kaplan et al., with pain as the primary parameter, using a 5% alpha error, 80% power, and an effect size of 0.2 [19]. Calculations for alpha = 0.05 and power = 80%:

$$N = \frac{2(Z_{1-\frac{\alpha}{2*k}} + Z_{1-\beta})^2 \sigma^2}{d^2}$$

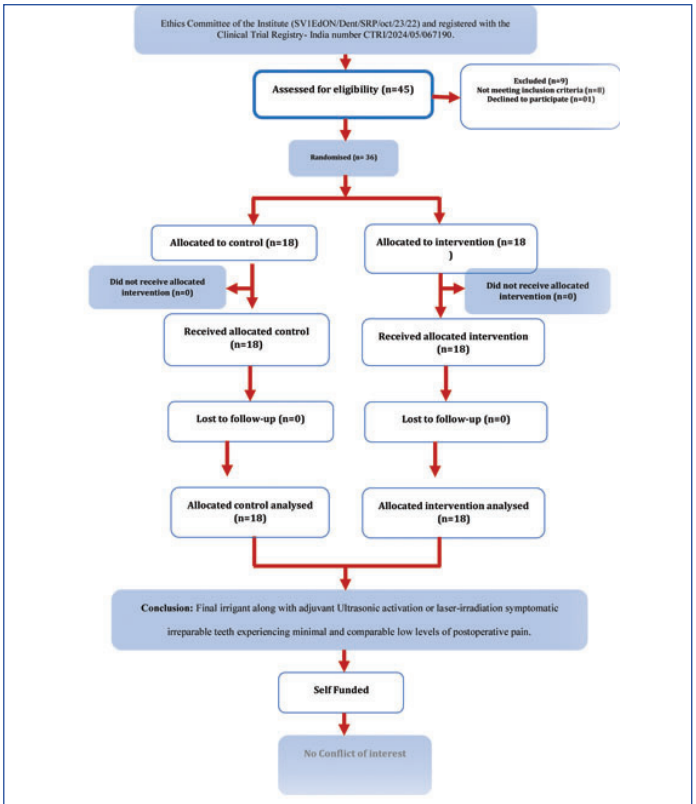
This calculated sample size was 15; as the present study was a follow-up study, allowing for a 20% dropout, an additional three samples were included in each group. Therefore, the final sample size per group was 18, for a total of 36 samples.

The patients were allocated into two groups by computer randomisation based on irrigation regimen, with an allocation ratio of 1:1 (n=18 per group) [Table/Fig-1].

Study Procedure

The preoperative pain score for all patients was recorded using the Visual Analogue Scale (VAS) before the procedure began. The VAS consisted of a 100-mm line, with endpoints representing no pain (0) and the worst possible pain (10); pain categories were defined as mild (1-3), moderate (4-6), and severe (7-10).

During the first visit, the teeth were anaesthetised with 2% lidocaine hydrochloride (Xylocaine, ICPA) with epinephrine 1:100,000. An access opening was created, and root canal patency was established using a 10 K-file (Dentsply Maillefer, Switzerland). The working length was determined with an apex locator (J Morita Root ZX II) and verified radiographically, set 0.5 mm short of the apex.



[Table/Fig-1]: PRIRATE flowchart.

Irrigation was performed using a 27-gauge side-vented needle (Vista Dental Products, USA), positioned 1 mm short of the working length. Throughout mechanical preparation, saline and 2.5% NaOCl were used intermittently for irrigation. The final rinse involved a continuous chelation irrigant solution prepared by mixing 10 mL of 2.5% NaOCl with 9% HEBP irrigant and one capsule of etidronate (Dual Rinse HEDP) containing 0.9 g of etidronate powder.

Group A: Final irrigation was performed with 2.5% NaOCl and 9% HEBP, followed by ultrasonic activation for 20 seconds, repeated three times. Before each activation, a fresh solution was flushed into the canal. A total of 10 mL of irrigant was used, followed by a final flush of 5 mL of normal saline for 1 minute. The canals were dried with paper points, and the access cavity was sealed with Cavit-G.

Group B: Final irrigation used the continuous chelation irrigant solution, followed by laser irradiation using a Biolase Epic X dental diode laser. The laser was delivered via a 200-µm optical fibre connected to a 980 nm diode laser, delivering 2.4 W output power and 12 J energy per cycle. Each cycle consisted of 10 seconds of irradiation followed by a 10-second pause, performed four times. The optical fibre tip (25 mm) was placed at the working length, and the canal was gradually heated from the apex to the coronal third with a circling motion at a speed of 2 mm/s. A final rinse of 5 mL of normal saline was performed for 1 minute, after which the access cavity was sealed with Cavit-G.

All patients were asked to rate postoperative pain using the VAS, and a follow-up appointment was scheduled for four to five days later. During the second visit, root canal obturation was completed with gutta-percha and AH Plus sealer (Dentsply Maillefer, Switzerland). Permanent coronal restorations were placed using core build-up or composite resin (3M Filtek P60; 3M ESPE). Postoperative pain was assessed via telephone at 6, 12, 24, and 48 hours post-treatment using the VAS to evaluate pain levels over time.

STATISTICAL ANALYSIS

The data were entered into Microsoft Excel (Version 13). Statistical analysis was performed using IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows, Version 23 (IBM Corp.). For continuous variables, the mean and standard deviation were

calculated; for categorical variables, frequencies and percentages were calculated. Between-group comparisons were made using independent samples t-tests. All statistical tests were performed at a 90% confidence level, and p<0.05 was considered statistically significant.

RESULTS

Random allocation of the sample was conducted using computer-generated methods. Preoperative pain levels were higher in Group A (t=0.793) but not statistically significant (p=0.434). Mean pain values were slightly higher for Group A at 6 and 12 hours, with similar values at 24 and 48 hours. Postoperative evaluations showed a higher pain score in Group A at 6 hours, but the difference was non significant (p=0.164). Pain levels decreased for both groups at 12, 24, and 48 hours, with no statistically significant differences [Table/Fig-2].

Parameters	Group A (Ultrasonic group)		Group B (Laser group)		t value	p-value
	n	Mean±SD	n	Mean±SD		
Age (in years)	18	39.94±12.86	18	38.89±10.7	0.268	0.791
Preoperative	18	6.56±1.5	18	6.11±1.84	0.793	0.434
6 hours	18	4.56±1.62	18	3.78±1.67	1.422	0.164
12 hours	18	2.33±1.46	18	1.83±1.1	1.164	0.253
24 hours	18	0.56±0.71	18	0.5±0.71	0.236	0.815
48 hours	18	0.22±0.43	18	0.22±0.55	0	1
6 hours pain difference	18	2±1.33	18	2.33±0.97	-0.86	0.396
12 hours pain difference	18	4.22±1.59	18	4.28±1.41	-0.111	0.912
24 hours pain difference	18	6±1.61	18	5.61±1.75	0.693	0.493
48 hours pain difference	18	6.33±1.46	18	5.89±1.88	0.794	0.432

[Table/Fig-2]: Intergroup comparison of preoperative parameters.
Independent t-test, p<0.05: significant

In a paired t-test assessing preoperative and Postoperative Pain (PP) values, Group A exhibited higher preoperative mean values compared to those recorded at 6, 12, 24, and 48 hours post-surgery. In contrast, Group B demonstrated lower preoperative mean values. Within-group analysis highlighted a steady decline in mean pain values, signifying a substantial increase in the pain difference and t values. In Group A, the difference between preoperative and six hours postoperative pain yielded a t value of 6.39, whereas the difference between preoperative and 48 hours postoperative pain yielded a t value of 18.47. Group B displayed similar trends [Table/Fig-3].

Groups	Mean±SD		Mean±SD	t value	p-value
Group A (Ultrasonic group)	Preop (6.56±1.5)	6 hours	4.56±1.62	6.39	<0.001
		12 hours	2.33±1.46	11.25	<0.001
		24 hours	0.56±0.71	15.82	<0.001
		48 hours	0.22±0.43	18.47	<0.001
	6 hours (4.56±1.62)	12 hours	2.33±1.46	9.40	<0.001
		24 hours	0.56±0.71	10.32	<0.001
		48 hours	0.22±0.43	10.72	<0.001
	12 hours (2.33±1.46)	24 hours	0.56±0.71	5.58	<0.001
		48 hours	0.22±0.43	6.01	<0.001
	24 hours (0.56±0.71)	48 hours	0.22±0.43	2.38	0.029
Group B (Laser group)	Preop (6.11±1.84)	6 hours	3.78±1.67	10.20	<0.001
		12 Hours	1.83±1.1	12.91	<0.001
		24 Hours	0.5±0.71	13.58	<0.001
		48 Hours	0.22±0.55	13.32	<0.001
	6 hours (3.78±1.67)	12 Hours	1.83±1.1	7.10	<0.001
		24 Hours	0.5±0.71	9.11	<0.001
		48 Hours	0.22±0.55	9.13	<0.001
	12 hours (1.83±1.1)	24 Hours	0.5±0.71	7.38	<0.001
		48 Hours	0.22±0.55	6.99	<0.001
	24 hours (0.5±0.71)	48 Hours	0.22±0.55	2.56	0.02

[Table/Fig-3]: Intragroup comparison of ultrasonic group and laser irradiation group.

There was no significant difference in the categorisation of pain as mild, moderate, or severe between Group A and Group B (p=0.591). At six hours postoperatively, distributions of pain categories did not differ significantly between groups. None of the patients in either group had severe pain at 24 and 48 hours [Table/Fig-4].

DISCUSSION

Postoperative Pain (PP) after Root Canal Treatment (RCT) is typically influenced by microorganisms, with root canal preparation and iatrogenic factors such as instrumentation and irrigants also playing significant roles [21]. These preparation challenges can result in inadequate antimicrobial disinfection during biomechanical procedures, underscoring the importance of confining all treatments within the canals to minimise PP risk [22].

Parameters	Categories	n	Group		Chi-square	p-value
			Group A n (%)	Group B n (%)		
Preop category of pain	Mild	1	0	1 (5.6)	1.053	0.591
	Moderate	19	10 (55.6)	9 (50)		
	Severe	16	8 (44.4)	8 (44.4)		
6 hours category of pain	Mild	13	5 (27.8)	8 (44.4)	1.874	0.392
	Moderate	22	12 (66.7)	10 (55.6)		
	Severe	1	1 (5.6)	0		
12 hours category of pain	Mild	31	14 (77.8)	17 (94.4)	2.09	0.148
	Moderate	5	4 (22.2)	1 (5.6)		
	Severe	0	0	0		
24-hour category of pain	Mild	36	18 (100)	18 (100)		
	Moderate	0	0	0		
	Severe	0	0	0		
48 hours category of pain	Mild	36	18 (100)	18 (100)		
	Moderate	0	0	0		
	Severe	0	0	0		

[Table/Fig-4]: Categorical variables of pain in Group A (Ultrasonic) and Group B (laser irradiation) group.
*Chi-square test, **p-value <0.05 significant

The present study employed a combination of periapical radiographs and apex locators to enhance the accuracy of working length measurements. Despite comprehensive root canal cleaning and shaping, some patients still reported PP, potentially influenced by individual pain sensitivity. Ultrasonics improve the antibacterial and tissue-dissolving efficacy of irrigants [15], which is why they are considered the standard protocol in conjunction with irrigants.

The study population consisted of healthy individuals without systemic complications to reduce PP risks. Teeth diagnosed with symptomatic irreversible pulpitis, with or without periapical pathology or radiographic rarefaction, were included to assess pain intensity reduction. Patients prone to exaggerated pain responses were

excluded to prevent external pain influences on the operated tooth. In prior research, PP was evaluated in both necrotic and retreatment cases treated in a single visit. These studies found that PP severity has a multifactorial etiology, with both single- and multiple-visit approaches showing similar PP incidences and periapical healing outcomes [23-25]. In alignment with other studies, the present research employed a two-visit RCT protocol [26]. While most studies focus on PP in asymptomatic irreversible pulpitis cases, this study specifically examined symptomatic irreversible pulpitis to assess PP reduction [1,3,4].

The PP measurement can be conducted using various scales and methods. The present study utilised the VAS, which ranges from 0 to 10, ensuring accurate, comprehensible, and valid assessments. Prior endodontic studies have frequently relied on the VAS for PP evaluation [27]. To guarantee precision in PP recordings, participants received a thorough explanation of the scale before the treatment commenced.

Diode lasers are widely used in endodontics for canal disinfection due to their affordability, ease of application, versatility, and compact design [19]. While numerous studies have examined diode lasers' effectiveness in reducing PP, the precise mechanism remains debated. Some early research suggests that diode lasers may alleviate chronic pain via anti-inflammatory effects [22,23], while other studies attribute pain reduction to the lasers' potent antibacterial properties [12]. Consequently, diode lasers were integrated into the treatment of symptomatic irreversible pulpitis following initial traditional irrigation.

In laboratory settings, laser irradiation demonstrated a significant bacterial burden reduction of 99.5% in infected root canals [5]. This result was supported by researchers [2], who found no detectable bacteria post-irradiation. Experimental studies have shown that 980 nm diode laser irradiation surpasses both traditional irrigation and Ultrasonic-Activated Irrigation (UAI) in effectively removing debris from both synthetic and natural canal complexities [13-16].

Existing literature suggests that diode lasers primarily rely on heat for their antibacterial effects [19]. Similar to previous studies [24], this research employed pulsed intra-canal laser irradiation with circular movements to minimise dentin heating and prevent damage to surrounding periodontal tissue. No adverse thermal effects were identified during laser irradiation in this study.

The role of age in PP has yielded conflicting findings in past research [2,21]. Ali SG et al., suggested that age may influence PP, whereas Arias A et al., found no significant age-related effect [2,21]. To ensure statistical consistency, patients were randomly assigned to laser and control groups, eliminating potential age and gender-related differences that could impact results.

Genc Sen O and Kaya M (2019) reported that PP typically peaks within the first two to three days before gradually declining [24]. Similarly, the present study found that PP was most prevalent six hours post-treatment and progressively decreased thereafter. Notably, PP levels in the laser group were significantly lower than those in the control group at the six-hour mark. This finding aligns with prior research, which demonstrated reduced PP in laser-treated groups during single-visit RCTs [26,27]. Pain intensity is often linked to analgesic use. In this study, patients experiencing substantial pain were instructed to take ibuprofen, with a recommended dosage of 600 mg for severe pain due to its dose-dependent effect lasting approximately eight hours. To maintain the integrity of PP assessment at the six-hour post-treatment interval, patients who consumed analgesics within eight hours of treatment were excluded from the study.

The present research has contributed to clinicians' understanding regarding the compatibility of various irrigant activation systems with continuous chelation irrigants (2.5% NaOCl + 9% HEBP). Additionally, ultrasonic activation was observed to require shorter clinical time compared to laser irradiation, which served as a secondary outcome.

Limitation(s)

Randomised clinical studies are influenced by various standardisation criteria, such as treatment protocols and case selection. A primary limitation of the present study is the inherently subjective nature of pain perception. PP may also be affected by factors such as tissue damage during anaesthesia or rubber dam placement, patient comfort, and anxiety levels before and during RCT. Furthermore, the inability to quantify the reduced microbial load in treated teeth limits the evaluation of diode lasers' antibacterial efficacy. Additionally, given that both groups utilised adjunctive interventions to enhance procedural outcomes, future research should consider incorporating a control (placebo) group for comparison.

CONCLUSION(S)

The present randomised clinical trial demonstrated that employing a continuous irrigation protocol (i.e., 2.5% NaOCl and 9% HEBP) alongside adjuvant activation systems effectively reduces PP. Postoperatively, at six and 12 hours, patients experienced moderate pain, which was ultimately alleviated at 24 and 48 hours. Following treatment, there was minimal pain associated with either ultrasonic activation or laser irradiation. Furthermore, there were no adverse effects linked to either activation strategy, and both performed well in conjunction with HEBP and NaOCl. To fully understand the precise mechanisms underlying these activation systems, additional clinical research is required.

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PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Student, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara, Gujarat, India.
2. Reader, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara, Gujarat, India.
3. Professor, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara, Gujarat, India.
4. Professor and Head, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara, Gujarat, India.
5. Postgraduate Student, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara, Gujarat, India.
6. Postgraduate Student, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara, Gujarat, India.
7. Postgraduate Student, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara, Gujarat, India.
8. Postgraduate Student, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara, Gujarat, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Deebah Choudhary,
Reader, Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College and Hospital, A Constitute Institute of Sumandeep Vidyapeeth (Deemed to be University), Vadodara-391760, Gujarat, India.
E-mail: deebahchoudhary@yahoo.co.in

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