



Original Research Article

To evaluate whether maintenance of apical patency has an effect on post-operative pain in symptomatic irreversible pulpitis cases: An in vivo study

Mansi Punjabi¹, Sonal Mukhraiya^{1*}, Apoorva Sharma¹, Rohit Kochhar¹, Manju Kumari¹

¹Dept. of Conservative Dentistry and Endodontics, Atal Bihari Vajpayee Medical University, Lucknow, Uttar Pradesh, India

Abstract

Background: Apical patency refers to the controlled extension of a small, flexible file slightly beyond the apical foramen to prevent debris accumulation and apical blockage during root canal preparation. Its role in influencing postoperative pain remains controversial.

Aim & Objective: To evaluate whether maintaining apical patency affects postoperative pain in patients with symptomatic irreversible pulpitis.

Materials and Methods: This prospective, randomized clinical study was conducted on 30 patients with single-rooted teeth diagnosed with symptomatic irreversible pulpitis. Patients were randomly assigned into two groups: Group A (patency, n=15), where a #10 K-file was extended 1 mm beyond the working length to maintain apical patency; and Group B (non-patency, n=15), where instrumentation was confined to the working length. Postoperative pain was assessed using a Visual Analog Scale (VAS) at baseline, 24 hours, and 48 hours. Data were analyzed using independent t-tests and one-way ANOVA, with a significance level set at $p \leq 0.05$.

Results: Both groups demonstrated significant pain reduction over time ($p=0.001$). However, pain scores were significantly lower in the patency group compared with the non-patency group at 24 hours ($p=0.002$) and 48 hours ($p=0.001$).

Conclusion: Maintaining apical patency does not increase postoperative pain; instead, it is associated with a greater reduction in pain compared to non-patency.

Keywords: Apical patency; Root canal treatment; Symptomatic irreversible pulpitis; Postoperative pain.

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1. Introduction

1.1. Rationale

Root canal therapy might be confusing at times because of the difficult operation and post-surgical discomfort. This has sparked studies on postoperative pain and successfully aiding the process.^{1,2}

Operative complications including apical transportations, ledges, and perforations may result from the closure of the root canal in the apical area by dental hard and soft tissue debris. Additionally, this debris could include bacteria that can sustain or cause periradicular pathology.³⁻⁶ Therefore, in order to address these problems, Buchanan had proposed the idea of "apical patency" which involves

repeatedly extending a small, flexible file past the apical foramen to render the foramen patent.⁷

Apical patency is a preparation technique that entails recapitulating through the apical constriction using a fine file to keep the apical portion of the root canal clear of debris, according to the "American Association of Endodontists" Glossary of Endodontic Terms.⁸ Size 10 K-files are most frequently used to increase the apical foramen^{7,9} and prevent the apical binding.

Additional benefits of this procedure include decreased risk of length loss, decreased incidence of canal transportation and other mishaps like ledges, effective irrigation in the apical third of the canal, preservation of the apical anatomy, and enhanced tactile perception during apical shaping.^{7,10}

*Corresponding author: Sonal Mukhraiya
Email: mukhraiya01@gmail.com

In endodontics, the idea of apical patency is a contentious topic. Some writers have argued for halting instrumentation at the apical constriction¹¹ short of the radiographic apex, while others have supported the apical patency filing.

1.2. Statement of hypothesis

Null Hypothesis (H₀): Maintaining apical patency does not significantly affect post-operative pain in symptomatic irreversible pulpitis cases.

2. Objectives

1. To assess how preserving apical patency affects post-operative pain in patients who have irreversible pulpitis symptoms.
2. To assess the degree of post-operative discomfort at 24 and 48 hours in patients treated with and without apical patency.
3. To use the Visual Analog Scale (VAS) to evaluate the statistical significance of pain decrease between the two groups.

3. Materials and Methods

3.1. Subjects and methods

The study was conducted in the Department of Conservative Dentistry and Endodontics at ITS Dental College, Greater Noida in the duration from September 2023 to November 2023. This study was carried out with the Ethics Committee of Clinical Research's clearance (Ref No. IEC/Cons/11/24)

3.2. Sample size determination

To ensure meaningful and reliable results, we calculated the required sample size based on previous research in this area. Using a power analysis with 80% power and a 5% significance level ($\alpha = 0.05$), we determined that a minimum of 30 participants (15 per group) would be needed to detect significant differences in post-operative pain outcomes.

3.3. Study design

This prospective, randomized clinical study (CTRI/2024/12/078598) was conducted in the Department of Conservative Dentistry and Endodontics, ITS Dental College, Greater Noida, between September and November 2023.

3.4. Inclusion criteria

1. Patients aged ≥ 18 years.
2. Single-rooted permanent teeth with a confirmed diagnosis of symptomatic irreversible pulpitis.
3. Positive response to pulp vitality tests with prolonged pain.
4. Absence of periapical radiolucency on periapical radiographs.

3.5. Exclusion criteria

1. Teeth with periapical lesions or root resorption.
2. Previously root canal-treated or retreatment cases.
3. Severely mutilated, fractured, or ankylosed teeth.
4. Patients with systemic conditions compromising immunity.
5. Pregnant or lactating women.
6. Patients who had taken antibiotics, steroids, or analgesics within one month prior to treatment.
7. Patients with parafunctional habits such as bruxism.

3.6. Treatment protocol

All included teeth were treated in multiple visits. This was done to allow intracanal medicament placement and pain assessment at recall before obturation.

The patients visiting the Department of Conservative Dentistry and Endodontics were assessed for inclusion and exclusion criteria. The selected patients were explained about the aims and design of the study. A consent form was duly signed by all the patients.

3.7. Study variables

3.7.1. Primary outcome

The primary outcome of this study was post-operative pain intensity, measured using the Visual Analog Scale (VAS). Pain was assessed at three time intervals: pre-operatively, 24 hours, and 48 hours post-treatment.

3.7.2. Exposure

The main exposure variable was maintenance of apical patency during root canal instrumentation:

1. Patency Group (Group A): Apical patency was maintained using a size 10 K-file extended 1 mm beyond the working length.
2. Non-Patency Group (Group B): Apical patency was not maintained; instrumentation was restricted to the working length.

3.7.3. Predictors

Key predictors included:

1. Treatment group (patency vs. non-patency)
2. Time of evaluation (pre-operative, 24 hours, 48 hours)

3.8. Potential confounders

1. The study minimized confounding through:
 - a. Randomization of participants
 - b. Standardized treatment procedures
 - c. Blinding of participants to their group allocation
2. However, potential confounders may include:
 - a. Individual pain threshold
 - b. Patient anxiety

- c. Degree of canal curvature or complexity
- d. Type of tooth treated (though only single-rooted teeth were included)

3.9. Effect modifiers

No effect modifiers were specifically evaluated. However, patient-related variables such as age, gender, or pre-operative pain levels could act as potential modifiers and should be explored in larger studies.

3.10. Diagnostic criteria

Participants were selected based on a clinical diagnosis of symptomatic irreversible pulpitis in single-rooted teeth. Diagnostic criteria included:

1. Prolonged response to thermal stimuli
2. Spontaneous pain
3. Positive pulp vitality testing
4. Absence of periapical radiolucency (to rule out necrosis or chronic periapical infection)

3.11. Data sources/Measurement

1. Post-operative pain was the primary outcome, assessed using a 10-point Visual Analog Scale (VAS) at three time points: pre-operatively, 24 hours, and 48 hours post-treatment. Pain data were self-reported by patients.
2. Apical patency was the exposure variable. In Group A (patency), a size #10 K-file was passed 1 mm beyond the working length. In Group B (non-patency), instrumentation was confined to the working length. Patency was confirmed using an apex locator and radiographs.
3. All procedures were performed by the same operator using standardized methods and instruments, ensuring comparability of measurements across both groups.

3.12. Randomization and group allocation

Each eligible patient was randomly assigned to one of two groups using a computer-generated randomization system:

Group A (Patency Group, n=15): Underwent root canal treatment with apical patency maintained using a size #10 K-file.

Group B (Non-Patency Group, n=15): Underwent the same treatment, but without maintaining apical patency.

To minimize bias, patients were unaware of their assigned group, ensuring that their pain reporting remained unbiased.

3.13. Clinical procedure

1. Anesthesia & isolation
 - a. Local anesthesia (2% lignocaine with 1:80,000 adrenaline) was administered.

- b. Teeth were isolated using a rubber dam.
2. Access opening & Canal negotiation
 - a. Standard endodontic access cavities were prepared.
 - b. Initial canal scouting was performed with #8 and #10 K-files.
3. Working length determination
 - a. Working length was determined using an electronic apex locator and confirmed radiographically.
4. Cleaning and shaping
 - a. Rotary ProTaper files were used in a crown-down technique for canal preparation.
 - b. Irrigation was performed after each instrument with 5 ml of 3% sodium hypochlorite followed by 0.9% sterile saline.
5. Apical patency protocol
 - a. Group A (Patency): Apical patency was maintained by gently passing a #10 K-file 1 mm beyond the working length after each larger file.
 - b. Group B (Non-patency): Instrumentation was limited strictly to the working length; no file was extended beyond the apical constriction.
 - c. Any cases where accidental over-instrumentation occurred due to incorrect working length estimation were excluded.
6. Intracanal medicament & temporization
 - a. Calcium hydroxide paste was placed in all canals as an intracanal medicament.
 - b. Cavit was used for temporary sealing.
 - c. Patients were recalled after one week.
7. Recall and symptom assessment
 - a. If the patient was asymptomatic, obturation was performed at the recall visit.
 - b. If the patient reported persistent pain or symptoms, calcium hydroxide dressing was replaced and the tooth was re-temporized until the patient became symptom-free.
8. Obturation & Final restoration
 - a. Following confirmation of asymptomatic status, canals were dried with paper points.
 - b. AH Plus sealer and gutta-percha cones were used with the lateral compaction technique for obturation.

Bias- Efforts to reduce potential bias included allocation concealment through computer-generated randomization and blinding of participants to group assignment.

3.14. Statistical analysis

To ensure robust and meaningful conclusions:

1. Independent t-tests were used to compare pain levels between the two groups at different time points.
2. One-way ANOVA helped assess within-group pain reduction trends over time.

- 3. A p-value of ≤ 0.05 was considered statistically significant, meaning any differences observed had to pass a rigorous statistical threshold to be deemed valid.
- 4. Data was processed using SPSS v.24 software for accuracy and reliability.

4. Results

A total of 36 patients were screened, out of which 30 met the eligibility criteria and were randomized equally into two groups (15 in the patency group and 15 in the non-patency group). Six patients were excluded due to ineligibility or refusal to consent. No participants were lost to follow-up, and all 30 patients completed the study and were included in the final analysis (Table 1), which presents the CONSORT flow diagram of patient enrollment, randomization, allocation, and analysis.

Baseline demographic variables (age, sex, and tooth type) were comparable between the groups, with no statistically significant differences.

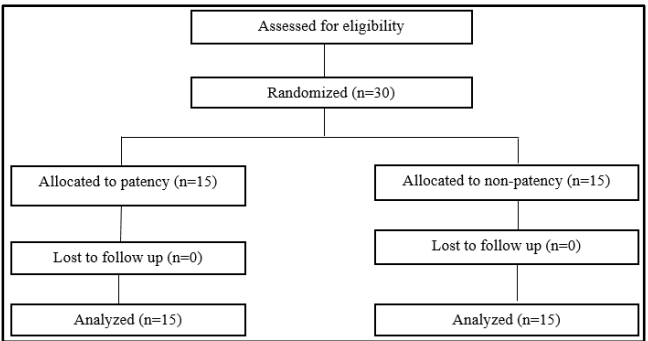


Figure 1: CONSORT flow diagram

5. Results

The present study evaluated post-operative pain levels in patients treated with and without apical patency using Visual Analogue Scale (VAS) scores recorded at different time intervals. Data were normally distributed, and statistical analysis was performed using independent t-test and one-way ANOVA.

The pre-operative VAS scores were comparable between the two groups, with no statistically significant difference (Patency: 5.60 ± 1.45 ; Non-patency: 5.73 ± 1.16 ; $p = 0.783$) (Table 1, Figure 2). This indicates that both groups were similar in terms of initial pain levels before treatment.

At 24 hours post-operatively, the patency group exhibited significantly lower VAS scores compared to the non-patency group (2.40 ± 1.12 vs. 4.13 ± 1.60 ; $p = 0.002$) (Table 2, Figure 3). This demonstrates that patients in whom apical patency was maintained experienced less post-operative pain after 24 hours.

At 48 hours post-operatively, the reduction in pain was more marked in the patency group, with mean VAS scores

significantly lower than those in the non-patency group (0.27 ± 0.70 vs. 2.13 ± 1.64 ; $p = 0.001$) (Table 3, Figure 4). This finding highlights that patency not only reduced pain earlier but also sustained the benefit over 48 hours.

Table 1: Comparison of pre-operative VAS scores between the patency and non-patency groups.

Parameter	Group	Mean	SD	P value
Pre-operative VAS Score	Patency	5.60	1.45	0.783
	Non-patency	5.73	1.16	

Table 2: Comparison of VAS scores after 24 hours between the patency and non-patency groups.

Parameter	Group	Mean	SD	P value
VAS score after 24 hours	Patency	2.40	1.12	0.002
	Non-patency	4.13	1.60	

Table 3: Comparison of VAS scores after 48 hours between the patency and non-patency groups.

Parameter	Group	Mean	SD	P value
VAS score after 48 hours	Patency	0.27	0.70	0.001
	Non-patency	2.13	1.64	

Table 4: Reduction in VAS scores in the patency group across different time intervals.

Parameter	Time	Mean	SD	P value
Reduction in VAS score in patency group	Preoperative	5.60	1.45	0.001
	24 hours	2.40	1.12	
	48 hours	0.27	0.11	

Table 5: Reduction in VAS scores in the non-patency group across different time intervals.

Parameter	Time	Mean	SD	P value
Reduction in VAS score in non-patency group	Preoperative	5.73	1.16	0.001
	24 hours	4.13	1.60	
	48 hours	2.13	1.64	

On evaluating intra-group reduction, the patency group showed a statistically significant reduction in VAS scores from the pre-operative stage to 48 hours post-operative ($5.60 \pm 1.45 \rightarrow 0.27 \pm 0.70$; $p = 0.001$) (Table 4, Figure 5). Similarly, the non-patency group also demonstrated a significant reduction in pain over the same time period ($5.73 \pm 1.16 \rightarrow 2.13 \pm 1.64$; $p = 0.001$) (Table 5, Figure 6). However, the magnitude of pain reduction was more pronounced in the patency group than in the non-patency group.

Overall, these results indicate that maintaining apical patency during endodontic treatment is associated with

significantly lower post-operative pain at both 24 and 48 hours, with a greater and faster reduction in pain compared to the non-patency approach. This trend is consistently illustrated in the comparative graphs (**Figure 2-6**), which visually depict both intergroup differences and intra-group reductions in pain scores.

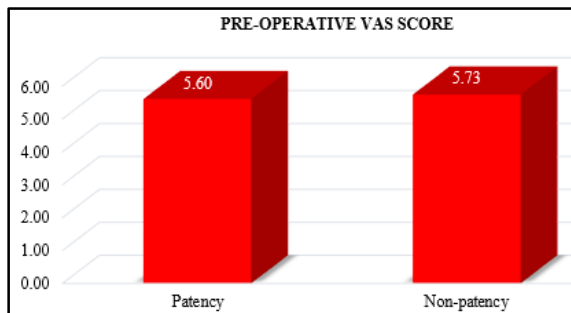


Figure 2: Bar chart depicting pre-operative VAS scores in patency and non-patency groups.

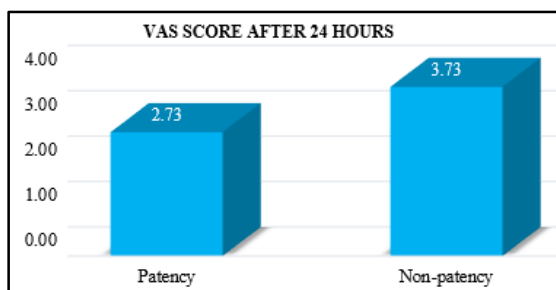


Figure 3: Bar chart comparing VAS scores at 24 hours between patency and non-patency groups.

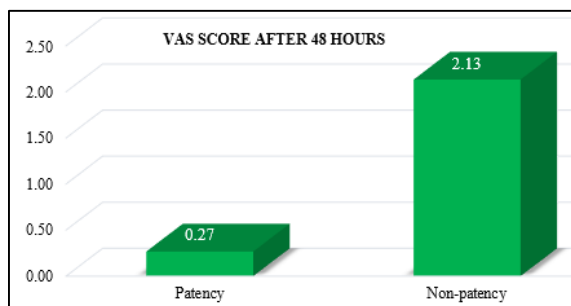


Figure 4: Bar chart comparing VAS scores at 48 hours between patency and non-patency groups.

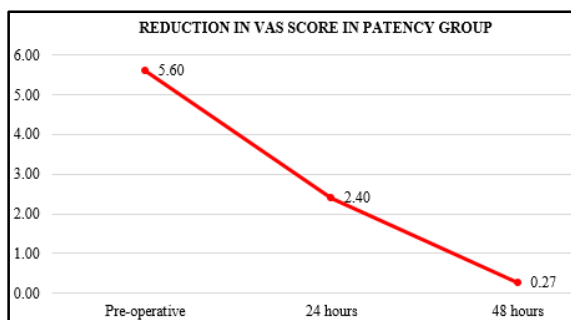


Figure 5: Line graph showing reduction in VAS scores in the patency group over time.

The present study evaluated post-operative pain levels in patients treated with and without apical patency using Visual

Analogue Scale (VAS) scores recorded at different time intervals. Data were normally distributed, and statistical analysis was performed using independent t-test and one-way ANOVA.

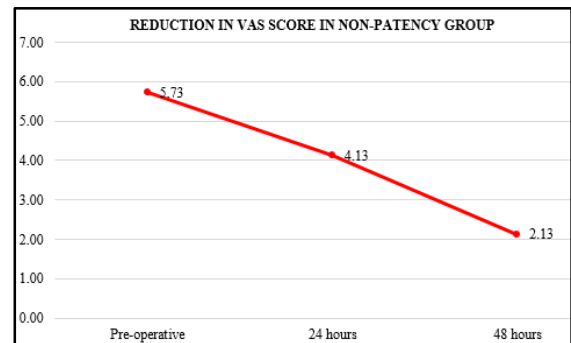


Figure 6: Line graph showing reduction in VAS scores in the non-patency group over time.

6. Discussion

The present study evaluated the effect of maintaining apical patency on postoperative pain in patients with symptomatic irreversible pulpitis. A significant reduction in pain was observed in both groups over 48 hours, with the patency group demonstrating a greater decrease compared to the non-patency group.

Our results align with the findings of Vera et al.¹² and Kamra et al.,¹³ who reported that maintaining apical patency facilitated irrigant penetration into the apical third, improving debridement and reducing postoperative pain. Similarly, Arora et al.¹⁴ observed that a higher proportion of patients in the patency group reported no pain after 24 hours compared with the non-patency group. These studies support the concept that maintaining apical patency enhances canal cleanliness and may minimize postoperative discomfort.

Conversely, Shubham et al.¹⁵ reported increased postoperative pain in the patency group, attributing it to disruption of the apical constriction and extrusion of debris into periapical tissues. Torabinejad et al.¹⁶ also highlighted that over-instrumentation may cause extrusion of filling materials and contribute to flare-ups. The discrepancy in findings may be due to differences in technique, type of file used, operator skill, and sample characteristics. In our study, only a #10 K-file was used gently for patency to minimize apical damage, which may explain the favorable outcomes.

The biological rationale for reduced pain in the patency group may be attributed to the prevention of dentin and bacterial debris accumulation at the apical foramen. Previous microbiological studies have shown that debris and bacterial remnants can sustain periapical inflammation and pain if not adequately removed.^{4,6} By maintaining apical patency, irrigants can more effectively reach the apical third, lowering microbial load and minimizing periapical inflammation.

From a clinical perspective, the findings suggest that maintaining apical patency is a safe and beneficial procedure that does not increase postoperative pain, provided it is performed carefully with small files under controlled conditions. This is consistent with systematic reviews that concluded apical patency does not adversely affect postoperative outcomes.^{2,11}

7. Limitations

The present study has some limitations. The sample size was relatively small, and only short-term pain outcomes (48 hours) were assessed. Patient-related factors such as anxiety, pain threshold, and canal anatomy were not fully controlled. Additionally, the study was restricted to single-rooted teeth; results may differ in multi-rooted teeth with complex anatomy.

8. Future Directions

Further randomized controlled trials with larger sample sizes, longer follow-up periods, and inclusion of multi-rooted teeth are recommended to validate these findings. Studies evaluating the microbiological status of canals with and without patency may also provide deeper insights into the mechanism of pain reduction.

9. Conclusion

We can conclude, given the limitations of this investigation, that postoperative discomfort is not increased by retaining apical patency. On the contrary, our research revealed that preserving apical patency led to a statistically significant decrease in postoperative pain. However, further studies can be done on a larger population with longer follow-up periods to conclude our findings.

10. Author Contribution

1. Dr. Mansi Punjabi: Methodology, Project administration, Visualization, Writing – review editing.
2. Dr. Sonal mukhraiya: Conceptualization, Data curation, Investigation, Methodology, Writing – original draft.
3. Dr. Apoorva Sharma: Supervision, Writing – review editing.
4. Dr. Rohit Kochhar: Conceptualization, Formal analysis, Methodology, Project administration, Supervision, Writing – review editing.
5. Dr. Manju Kumari: Conceptualization, Data curation, Formal analysis, Supervision, Validation, Visualization, Writing – review editing.

11. Ethical Approval

IEC/Cons/11/24

12. Source of Funding

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13. Conflict of Interest

None.

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