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Postoperative Pain Control and Early Periapical Healing following Use of Two Calcium Hydroxide-based Sealers: A Randomized Study.

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Abstract

Aim: To compare postoperative pain, tenderness, swelling and early periapical healing following root canal treatment using two calcium hydroxide-based sealers.

Materials and Methods: Forty patients requiring endodontic treatment in anterior teeth and premolars diagnosed with acute irreversible pulpitis with asymptomatic apical periodontitis were randomly divided into two groups (n = 20 each). Following standardized cleaning and shaping, obturation was performed using gutta-percha with one of the two calcium hydroxide-based sealers. Postoperative pain was assessed using a visual analog scale and tenderness and swelling were clinically evaluated at 48 hours, 1 week, 4 weeks and 6 weeks. Radiographic evaluation of periapical changes was performed preoperatively and at 6 weeks.

Results: Both materials demonstrated satisfactory clinical and radiographic performance. One group showed comparatively lower incidence and severity of postoperative pain and tenderness at 48 hours and 1 week. Swelling was minimal in both groups. Radiographic assessment at 6 weeks revealed reduction in periodontal ligament widening and early signs of periapical healing.

Conclusion: Both calcium hydroxide-based sealers were clinically effective, with better early postoperative comfort observed in Calapex group.

Keywords: Post operative, pulpitis, tenderness, swelling

INTRODUCTION

The primary objective of endodontic therapy is elimination of microorganisms from the root canal system and prevention of reinfection, thereby allowing periapical healing [1]. Successful obturation requires a sealer that provides an adequate seal, biocompatibility, dimensional stability and antimicrobial activity [2]. Postoperative pain is one of the most significant concerns following root canal therapy and may result from mechanical irritation, microbial extrusion, chemical irritation from irrigants or sealers, or host inflammatory response [3,4]. The incidence of postendodontic pain has been reported to range between 3% and 58%, with the highest frequency within the first 48 hours [5,6]. Calcium hydroxide-containing sealers have been widely used because of their high pH, antibacterial activity and ability to stimulate mineralized tissue formation [7,8]. Hydroxyl ion release leads to inactivation of bacterial endotoxins and promotes periapical repair [9]. Sealapex (Kerr) is a well-documented calcium hydroxide-based sealer with established biocompatibility and bioactivity [10,11]. Calapex (Prevest DenPro Limited) is a non-eugenol based calcium hydroxide polymeric bioceramic root canal sealer formulated to provide enhanced flow and sealing properties. Several studies have emphasized that the biological properties of sealers influence postoperative inflammation and healing [12,13]. However, limited clinical evidence exists comparing different calcium hydroxide-containing sealers with respect to postoperative pain, swelling and early periapical healing. Therefore, the present study aimed to compare Sealapex and Calapex in terms of postoperative pain, tenderness, swelling at 48 hours, 1 week, 4 weeks, and 6 weeks, along with radiographic periapical changes at 6 weeks.

MATERIALS AND METHODS

Study Design and Ethical Approval

This randomized controlled clinical study was conducted in the Department of Conservative Dentistry and Endodontics after obtaining approval from the Institutional Ethical Committee. Written informed consent was obtained from all participants prior to inclusion in the study.Sample size was calculated based on previous studies evaluating postoperative pain in endodontic treatment, considering 80% power and 5% significance level. A minimum of 18 patients per group was required; therefore, 20 patients were included in each group to compensate for potential dropouts, resulting in a total sample size of 40 teeth.Patients aged between 18 and 50 years reporting with pain in anterior teeth or premolars were screened.

Inclusion Criteria

- Single-rooted anterior teeth and premolars
- Diagnosis of acute irreversible pulpitis
- Associated asymptomatic apical periodontitis (radiographic widening of periodontal ligament space or periapical radiolucency)
- Teeth with fully formed apices
- Patients in good systemic health

Exclusion Criteria

- Acute apical abscess or sinus tract
- Previously endodontically treated teeth
- Teeth with root resorption or calcified canals
- Medically compromised patients
- Pregnant or lactating women
- Patients on antibiotics or analgesics within 48 hours prior to treatment.

Patients were randomly assigned into two groups (n = 20 each) using computer-generated randomization. Allocation concealment was maintained using sealed opaque envelopes opened at the time of obturation. **Group I:**Sealapex (Kerr,Calcium hydroxide-based Sealer), **Group II:**Calapex (Prevest Denpro, Calcium hydroxide-based Sealer).

Clinical Procedure

All treatments were performed by a single experienced operator to eliminate inter-operator variability. Local anesthesia was administered using 2% lignocaine with 1:100,000 adrenaline. Rubber dam isolation was performed for all teeth to ensure aseptic conditions. Standard access cavity preparation was performed using sterile round and Endo access burs under water coolant. Complete caries removal was ensured before entry into the pulp chamber.Working length was determined using an electronic apex locator (J-Morita) and confirmed radiographically using #15 K-file. Canals were prepared using rotary nickel–titanium instruments (Rotoflex Gold, Prevest Denpro Limited) with a crown-down technique. Irrigation protocol included2.5% sodium hypochlorite after each instrument, 17% EDTA for 1 minute for smear layer removal, Final rinse with saline. Canals were dried using sterile absorbent paper points. Obturation was performed in the same visit using lateral condensation technique with standardized gutta-percha cones and the allocated calcium

hydroxide-based sealer. Excess gutta-percha was removed using a heated instrument, and vertical compaction was performed. Post-obturation radiographs were taken to verify the quality of obturation. The access cavity was sealed with temporary restorative material. Patients were prescribed analgesics (ibuprofen 400 mg) only if required and instructed to record consumption.Patients were recalled at:48 hours,1 week, 4 weeks and 6 weeks. Evaluation was performed by a blinded examiner.Pain intensity was recorded using a 10-point Visual Analog Scale (VAS):0 = No pain, 1–3 = Mild pain, 4–6 = Moderate pain, 7–10 = Severe pain.

Tenderness on Percussion

Assessed using vertical percussion with mirror handle and recorded as:

- Present
- Absent

Swelling

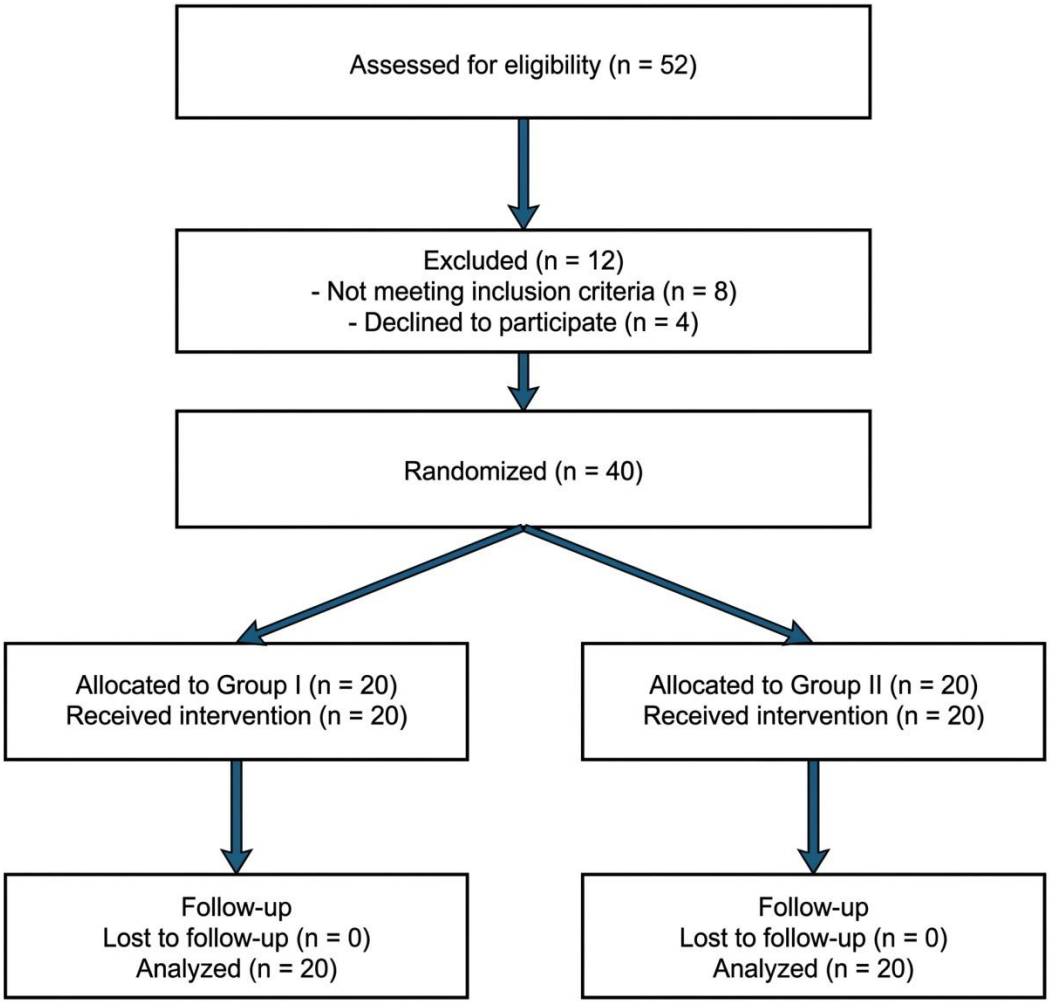
Clinical examination for soft tissue swelling intraorally and extraorally. Recorded as present or absent.

Radiographic Evaluation

Standardized digital periapical radiographs were taken preoperatively and at 6 weeks using paralleling technique with positioners to ensure reproducibility.Radiographs were evaluated for:Periodontal ligament space widening, Size of periapical radiolucency, Re-establishment of lamina dura. Periapical changes were scored using a modified Periapical Index (PAI). Two blinded evaluators independently assessed the radiographs, and disagreements were resolved by consensus.

Statistical Analysis

Data were analyzed using SPSS software version 31.Mean VAS scores were compared using Independent t-test.Incidence of tenderness and swelling were analyzed using Fisher's exact test.Intragroup comparisons across time intervals were analyzed using repeated measures ANOVA.Significance level was set at $p < 0.05$.



RESULTS

A total of 40 patients were included in the study and completed the 6-week follow-up period. No dropouts were reported. The two groups were comparable with respect to age, gender distribution, and type of tooth ($p > 0.05$).

Postoperative Pain (VAS Scores)

The highest incidence and intensity of postoperative pain were observed at 48 hours in both groups.At 48 hours, mild pain (VAS 1–3) was reported in 5 patients (25%) in Group I and 3 patients (15%) in Group II. Moderate pain (VAS 4–6) was observed in 2 patients (10%) in Group I and 1 patient (5%) in Group II. No patient reported severe pain. The mean VAS score was higher in Group I compared to Group II, and the difference was statistically significant ($p < 0.05$). At 1 week, pain intensity decreased markedly in both groups. Mild pain persisted in 2 patients (10%) in Group I and 1 patient (5%) in Group II. No moderate or severe pain was recorded. The difference between groups was not statistically significant ($p > 0.05$). At 4 weeks and 6 weeks, none of the patients in either group reported pain (VAS = 0).

Tenderness on Percussion

At 48 hours, tenderness on percussion was observed in 4 patients (20%) in Group I and 2 patients (10%) in Group II. The difference was not statistically significant ($p > 0.05$). At 1 week, tenderness reduced substantially and was present in 1 patient (5%) in Group I and none in Group II. At 4 and 6 weeks, no tenderness was observed in either group.

Swelling

Mild localized swelling was reported in 1 patient (5%) in Group I and none in Group II at 48 hours. No cases of diffuse swelling or flare-up were observed. Swelling resolved completely by 1 week in all cases. No swelling was recorded at 4 or 6 weeks in either group.

Radiographic Evaluation of Periapical Changes

Preoperative radiographs showed widening of periodontal ligament space and/or small periapical radiolucency in all cases.

At 6 weeks, radiographic assessment revealed reduction in periodontal ligament widening in 14 cases (70%) in Group I (Sealapex) and 15 cases (75%) in Group II (Calapex). A decrease in the size of periapical radiolucency was observed in 12 cases (60%) in Group I and 14 cases (70%) in Group II. Early reformation of lamina dura was noted in 6 cases (30%) in Group I and 8 cases (40%) in Group II. No case demonstrated increase in radiolucency or worsening of periapical condition.There was no statistically significant difference between the two groups in terms of radiographic healing at 6 weeks ($p > 0.05$).

Overall Findings

Both calcium hydroxide-based sealers demonstrated satisfactory clinical and radiographic performance. Group II showed comparatively lower early postoperative pain and tenderness, while radiographic healing at 6 weeks was favorable and comparable in both groups.

Table 1. Comparison of Mean VAS Scores

Time Interval	Group I (Sealapex) (Mean ± SD)	Group II (Calapex) (Mean ± SD)	p-value
48 hours	1.65 ± 1.21	0.95 ± 0.88	0.041*
1 week	0.25 ± 0.44	0.10 ± 0.30	0.289
4 weeks	0	0	—
6 weeks	0	0	—

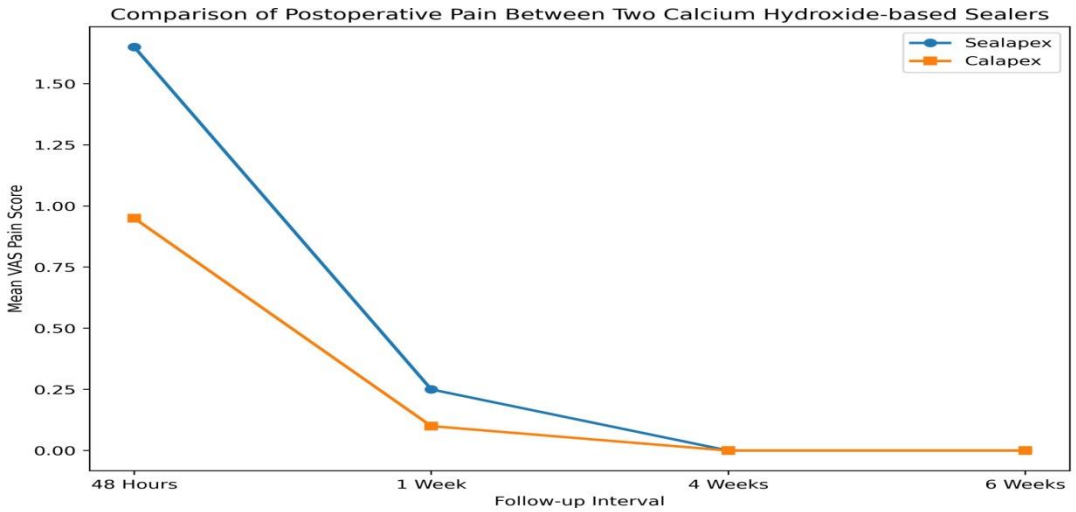
*Statistically significant ($p < 0.05$)

Table 2. Incidence of Tenderness

Time Interval	Group I (Sealapex)	Group II (Calapex)	p-value
48 hours	4 (20%)	2 (10%)	0.376
1 week	1 (5%)	0	0.311
4 weeks	0	0	—
6 weeks	0	0	—

Table 3. Radiographic Healing at 6 Weeks

Radiographic Parameter	Sealapex	Calapex	p-value
PDL space reduction	70%	75%	0.723
Radiolucency reduction	60%	70%	0.512
Lamina dura reformation	30%	40%	0.502



Graph 1: Comparison of Postoperative Pain Between Two Calcium Hydroxide-based Sealers

DISCUSSION

Postoperative pain following root canal treatment remains one of the most significant clinical concerns influencing patient perception of treatment success. The present randomized clinical study evaluated the influence of two calcium hydroxide-based sealers on postoperative pain, tenderness, swelling and early periapical healing in teeth diagnosed with acute irreversible pulpitis associated with asymptomatic apical periodontitis.The highest incidence of postoperative pain was observed at 48 hours, which is consistent with previously published evidence indicating that postendodontic discomfort peaks within the first 24–48 hours and gradually subsides thereafter [5,14]. The reduction in pain over subsequent follow-up intervals observed

in both groups aligns with the biological healing response described in endodontic literature.Calcium hydroxide-based sealers are known to exert antimicrobial activity through hydroxyl ion release, resulting in bacterial cell membrane disruption and endotoxin inactivation [7,9,11]. This biological property may contribute to reduced postoperative inflammation and improved periapical tissue response. Sealapex has been extensively documented for its biocompatibility and ability to stimulate mineralized tissue formation [10,15]. Previous experimental studies have demonstrated minimal inflammatory reaction and favorable tissue repair with calcium hydroxide-containing materials [8,16].In the present study, the group receiving the second calcium hydroxide-based sealer demonstrated significantly lower mean VAS scores at 48 hours. Although the difference diminished at later intervals, the early reduction in postoperative discomfort may be attributed to improved flow characteristics and better adaptation to canal walls, potentially reducing sealer extrusion and periapical irritation. Ørstavik et al. reported that dimensional stability and sealing characteristics influence periapical tissue response [12,17], which may partially explain the early clinical differences observed.Tenderness and swelling were minimal in both groups and resolved completely within one week. The absence of flare-ups or persistent symptoms suggests adequate chemomechanical preparation and favorable biological compatibility of both materials.Radiographically, both groups demonstrated reduction in periodontal ligament widening and decrease in periapical radiolucency at 6 weeks. Although six weeks is a relatively short interval for complete radiographic healing, early reduction in radiolucency has been reported as a favorable prognostic indicator [17,18]. Estrela and Holland emphasized that calcium hydroxide materials support periapical repair by stimulating mineralization and reducing microbial load [19]. The comparable radiographic healing between groups suggests that both materials provide satisfactory biological performance.The strengths of this study include standardized clinical protocol, single-operator treatment, blinded outcome assessment and complete follow-up. However, certain limitations must be acknowledged. The follow-up period of 6 weeks may be insufficient to evaluate complete periapical healing and longer observation periods (6–12 months) would provide more definitive radiographic evidence. Additionally, cone beam computed tomography could provide more sensitive assessment of periapical healing [20].Overall, the findings indicate that while both calcium hydroxide-based sealers are clinically effective, differences in early postoperative pain control may be influenced by material properties.

CONCLUSION

Within the limitations of this randomized clinical study, the following conclusions can be drawn:Both calcium hydroxide-based sealers demonstrated satisfactory clinical performance in terms of postoperative pain, tenderness and swelling.Early postoperative pain (at 48 hours) was significantly lower in one group, indicating superior short-term patient comfort.Tenderness and swelling were minimal and resolved completely by one week in both groups.Radiographic evaluation at 6 weeks revealed favorable early periapical healing with reduction in periodontal ligament widening and radiolucency size in both groups.Both materials can be considered clinically reliable for obturation in teeth with irreversible pulpitis and asymptomatic apical periodontitis.Further long-term randomized clinical trials with larger sample sizes and extended radiographic follow-up are recommended to confirm sustained periapical healing outcomes.

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