

Original Research

Clinical Outcome Evaluation of The Effectiveness of Calcium Hydroxide as A Root Canal Sealer Constituent

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Abstract

Background: The objective of this study was to evaluate the clinical outcomes of using calcium hydroxide-containing sealer (Sealapex) compared to zinc oxide eugenol (ZOE) sealer in single-visit root canal treatments.

Methods: This cross-sectional observational study was conducted at different private clinics, Dhaka, Bangladesh during the period from January 2018 to December 2018. A total of 60 permanent teeth with periradicular pathosis were selected and randomly assigned into two groups. Group 1 (ZOE group) comprised 30 teeth treated with a ZOE sealer, while Group 2 (Sealapex group) included 30 teeth treated with a calcium hydroxide-containing sealer. Clinical evaluations were performed at 3 months and 12 months post-treatment, with patient complaints recorded and analyzed using SPSS version 22 and Microsoft Excel.

Results: Group 2 had a higher proportion of younger participants (40.00% aged 11-20) compared to Group 1 (26.67%). Group 1 had more males (66.67%) compared to Group 2 (56.67%). Trauma was the leading etiological factor in both groups. Maxillary teeth were more frequently affected, with 56.67% in Group 1 and 63.33% in Group 2. Pre-operative pain was higher in Group 2 (90.00%) compared to Group 1 (76.67%). At the 3-month follow-up, percussion pain was more prevalent in Group 1 (76.67%) than in Group 2 (46.67%, $p = 0.016$). By the 12-month follow-up, percussion pain persisted in 13.33% of Group 1 but was absent in Group 2. Group 2 achieved a 100.00% success rate, significantly higher than Group 1's 86.67% ($p = 0.038$).

Conclusion: The use of calcium hydroxide-containing sealer (Sealapex) in single-visit root canal treatments resulted in superior clinical outcomes compared to zinc oxide eugenol sealer. These findings suggest that calcium hydroxide-containing sealers offer better pain management and higher long-term success rates, making them a more effective alternative for endodontic treatments. Further research is recommended to confirm these results in broader clinical settings.

Introduction

Endodontic treatment, commonly known as root canal therapy, aims to eliminate infection from the root canal system and prevent future microbial invasion. This treatment is crucial in saving teeth that would otherwise be lost to decay or trauma, thereby preserving the patient's natural dentition and function. The primary objectives of endodontic treatment are thorough debridement, disinfection

of the root canal system, and obturation to seal the canal space completely^{1,2}. The success of endodontic treatment largely depends on the elimination of pathogens and the effective sealing of the canal to prevent reinfection. This involves the use of various chemical agents and materials to ensure a sterile environment and a hermetic seal, which are essential for the long-term success

of the treatment³. Root canal sealers play a pivotal role in achieving these goals by filling the irregularities between the root canal walls and the core filling material, such as gutta-percha. The key functions of sealers include providing a tight seal to prevent microleakage, being biocompatible to promote healing of periapical tissues, possessing antibacterial properties to eliminate residual bacteria, and being radiopaque to allow for radiographic detection of the fill⁴. Various materials are employed as root canal sealers, each with unique properties and advantages. Commonly used sealers include zinc oxide-eugenol, which is known for its good sealing properties and ease of handling; glass ionomer, which offers chemical adhesion to dentin and fluoride release; epoxy resins, which provide excellent sealing and durability; and calcium hydroxide-based sealers, which are valued for their antibacterial effects and promotion of tissue healing⁵. Calcium hydroxide ($\text{Ca}(\text{OH})_2$) is widely used in dentistry due to its high pH, which provides an antibacterial environment and stimulates hard tissue formation. It is used in various forms, including as a root canal sealer constituent, for its therapeutic benefits⁶. The antibacterial effect of calcium hydroxide is attributed to its high pH, which inactivates many bacterial species, making it effective in reducing bacterial load in the root canal⁷. Additionally, calcium hydroxide promotes the formation of mineralized tissue, aiding in the healing of periapical lesions⁸. It is well-tolerated by the periapical tissues, reducing the risk of adverse reactions, thus underscoring its biocompatibility⁹. However, calcium hydroxide-based sealers face challenges regarding their sealing ability and solubility over time. While effective initially, their sealing ability may diminish due to solubility in tissue fluids, potentially compromising the long-term seal of the root canal filling¹⁰. The literature provides a wealth of studies on the properties and effectiveness of calcium hydroxide-based sealers. Desai and Chandler provide a comprehensive review of the physical properties, biocompatibility, leakage, adhesion, solubility, antibacterial properties, and periapical healing effects of calcium hydroxide-based sealers¹¹. Their findings highlight the varied physical and biological properties of these sealers and the need for further research to establish their tissue healing properties. The antibacterial properties of calcium

hydroxide-based sealers have been evaluated extensively, with studies demonstrating their effectiveness in reducing bacterial load and promoting a sterile environment within the root canal¹². Biocompatibility is a critical factor in the success of endodontic treatments, and calcium hydroxide-based sealers have been shown to be biocompatible and to promote healing of periapical tissues. Zmener et al. evaluated the biocompatibility of two calcium hydroxide-based sealers in rat subcutaneous tissue and observed varying degrees of tissue reaction over time¹³. Their study suggests that while these sealers are generally biocompatible, more extensive studies are necessary to fully understand their long-term effects. Furthermore, the sealing ability of calcium hydroxide-based sealers is crucial for preventing microleakage and ensuring the longevity of the root canal treatment. Studies by Zmener and Barnett et al have assessed the sealing properties of calcium hydroxide-based sealers, showing that while these sealers provide an initial effective seal, their performance may decline over time due to solubility issues^{10,14}. Despite these challenges, the use of calcium hydroxide-based sealers remains prevalent in endodontics due to their therapeutic benefits. Their antibacterial properties, ability to promote tissue healing, and biocompatibility make them a valuable component of root canal treatments. However, further research is needed to address the challenges related to their long-term sealing ability and solubility to ensure the best clinical outcomes for patients.

Methods

This cross-sectional observational study was conducted at different private clinics, Dhaka, Bangladesh during the period from January 2018 to December 2018. A total of 60 permanent teeth were selected from patients purposively chosen from the outpatient department. These patients had teeth with periradicular pathosis and were randomly assigned into two groups, with 30 patients in each group. Group 1 (ZOE group) consisted of patients treated with single-visit root canal therapy and obturated with a zinc oxide eugenol sealer. Group 2 ($\text{Ca}(\text{OH})_2$ group) included patients treated with single-visit root canal therapy and obturated with a calcium hydroxide-containing

sealer (Sealapex). All patients were recalled for clinical evaluation on days 2 and 7 after the completion of treatment. Clinical evaluations of patients were conducted at 3 months and 12 months post-treatment. Patient complaints were recorded in a data sheet during these follow-up visits. The collected data were analyzed using standard statistical methods with SPSS version 22 software and Microsoft Excel.

Results

Table 1: Distribution of demographic characteristics among the participants (N=60)

Baseline	Group 1 (n=30)	Group 2 (n=30)
	n (%)	n (%)
Age		
11-20	8 (26.67)	12 (40.00)
21-30	14 (46.67)	11 (36.67)
31-40	5 (16.67)	5 (16.67)
41-50	3 (10.00)	1 (3.33)
51-60	0 (0.00)	1 (3.33)
Gender		
Male	20 (66.67)	17 (56.67)
Female	10 (33.33)	13 (43.33)

In Group 1, 26.67% of the participants were aged 11-20 years, 46.67% were aged 21-30 years, 16.67% were aged 31-40 years, 10.00% were aged 41-50 years, and none were aged 51-60 years. In contrast, Group 2 had 40.00% of participants aged 11-20 years, 36.67% aged 21-30 years, 16.67% aged 31-40 years, 3.33% aged 41-50 years, and 3.33% aged 51-60 years. Regarding gender distribution, Group 1 had 66.67% male and 33.33% female participants, while Group 2 had 56.67% male and 43.33% female participants.

In Group 1 (ZOE group), the primary etiological factor was trauma, affecting 70.00% of the participants. This was followed by caries, which was responsible for 13.33% of cases, and leaking restorations, which accounted for 10.00%. Occlusal trauma and other factors each affected 3.33% of the participants in this group. In Group 2 (Ca(OH)₂ group), trauma was also the leading etiological factor, affecting 60.00% of participants. Caries accounted for 20.00% of the cases, while leaking restorations were responsible for 13.33%.

Similar to Group 1, occlusal trauma and other factors each affected 3.33% of the participants in Group 2.

Table 2: Distribution of etiological factors among the participants (N=60)

Etiological factors	Group 1 (n=30)	Group 2 (n=30)
	n (%)	n (%)
Trauma	21 (70.00)	18 (60.00)
Leaking restoration	3 (10.00)	4 (13.33)
Caries	4 (13.33)	6 (20.00)
Occlusal trauma	1 (3.33)	1 (3.33)
Others	1 (3.33)	1 (3.33)

Table 3: Distribution of type of tooth affected among the participants (N=60)

Type of tooth	Group 1 (n=30)	Group 2 (n=30)
	n (%)	n (%)
Maxillary	17 (56.67)	19 (63.33)
Mandibular	13 (43.33)	11 (36.67)

In Group 1 (ZOE group), 56.67% of the affected teeth were maxillary, while 43.33% were mandibular. In Group 2 (Ca(OH)₂ group), the proportion of maxillary teeth affected was slightly higher at 63.33%, with mandibular teeth comprising 36.67% of the cases.

In Group 1 (ZOE group), pain was reported by 76.67% of the participants, swelling by 13.33%, tenderness on percussion by 83.33%, and the presence of a discharging sinus by 3.33%. In Group 2 (Ca(OH)₂ group), 90.00% of participants reported pain, 26.67% experienced swelling, 76.67% had tenderness on percussion, and 53.33% had a discharging sinus.

The clinical evaluation of participants at different follow-up intervals is detailed in Table 4. At the 3-month follow-up, none of the participants in either Group 1 (ZOE group) or Group 2 (Ca(OH)₂ group) reported pain or swelling. However, percussion pain was significantly more prevalent in Group 1, with 76.67% of participants experiencing this

symptom, compared to 46.67% in Group 2 ($p = 0.016$). Discharging sinus was observed in 10.00% of participants in Group 1, whereas no cases were reported in Group 2 ($p = 0.237$, not significant). At the 12-month follow-up, there were no reports of pain, swelling, or discharging sinus in either group. However, percussion pain persisted in 13.33% of participants in Group 1, while no participants in Group 2 reported this symptom ($p = 0.112$, not significant).

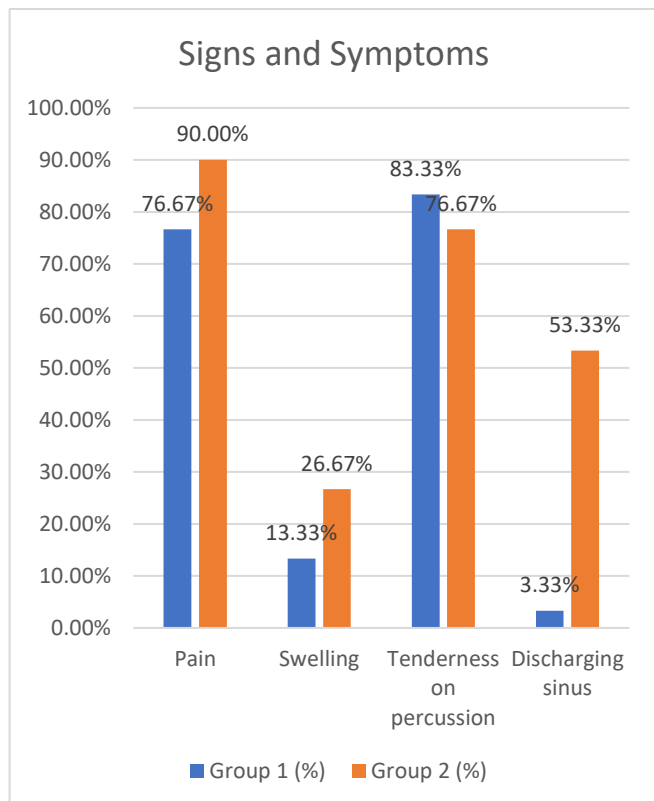


Figure 1: Distribution of patients by pre-operative signs and symptoms (n=60)

The clinical evaluation of participants at different follow-up intervals is detailed in Table 4. At the 3-month follow-up, none of the participants in either Group 1 (ZOE group) or Group 2 (Ca(OH)₂ group) reported pain or swelling. However, percussion pain was significantly more prevalent in Group 1, with 76.67% of participants experiencing this symptom, compared to 46.67% in Group 2 ($p = 0.016$). Discharging sinus was observed in 10.00% of participants in Group 1, whereas no cases were reported in Group 2 ($p = 0.237$, not significant). At the 12-month follow-up, there were no reports of pain, swelling, or discharging sinus in either group. However, percussion pain persisted in 13.33% of

participants in Group 1, while no participants in Group 2 reported this symptom ($p = 0.112$, not significant).

Table 4: Distribution of clinical evaluation of participants at different follow-ups (N=60)

Clinical Outcome	Group 1 (n=30)	Group 2 (n=30)	p-value
	n (%)	n (%)	
At 3 months			
Pain	0 (0.00)	0 (0.00)	--
Percussion pain	23 (76.67)	14 (46.67)	0.016
Swelling	0 (0.00)	0 (0.00)	--
Discharge sinus	3 (10.00)	0 (0.00)	0.237
At 12 months			
Pain	0 (0.00)	0 (0.00)	--
Percussion pain	4 (13.33)	0 (0.00)	0.112
Swelling	0 (0.00)	0 (0.00)	--
Discharging sinus	0 (0.00)	0 (0.00)	--

Table 5: Distribution of patients by final clinical outcome (N=60)

Final Outcome	Group 1 (n=30)	Group 2 (n=30)	p-value
	n (%)	n (%)	
Success	26 (86.67)	30 (100.00)	0.038
Doubtful	4 (13.33)	0 (0.00)	
Failure	0 (0.00)	0 (0.00)	

The final clinical outcomes of the participants are summarized in Table 5. In Group 1 (ZOE group), 86.67% of the participants were classified as having a successful treatment outcome, while 13.33% were categorized as doubtful, and there were no treatment failures. In contrast, Group 2 (Ca(OH)₂ group) achieved a 100.00% success rate with no doubtful or failed cases. The difference in success rates between the two groups was statistically significant ($p = 0.038$).

Discussion

The present study aimed to evaluate the clinical outcomes of using calcium hydroxide-containing sealer (Sealapex) compared to zinc oxide eugenol

(ZOE) sealer in single-visit root canal treatments. The findings revealed significant differences in demographic distribution, etiological factors, pre-operative signs and symptoms, follow-up results, and final clinical outcomes between the two groups. Demographically, Group 2 (Sealapex) had a higher proportion of younger participants (40.00% aged 11-20) compared to Group 1 (ZOE) (26.67%). This aligns with previous research indicating that younger patients are more likely to undergo endodontic therapy¹⁵. The gender distribution showed more males in Group 1 (66.67%) compared to Group 2 (56.67%). This distribution is consistent with studies that suggest varying gender influences on endodontic treatment preferences¹⁶. Trauma was identified as the leading etiological factor in both groups, affecting 70.00% in Group 1 and 60.00% in Group 2. These findings are supported by literature indicating trauma as a major cause for endodontic treatment^{17,18}. The type of tooth affected was predominantly maxillary in both groups, with 56.67% in Group 1 and 63.33% in Group 2. This trend is corroborated by studies showing a higher prevalence of maxillary teeth requiring endodontic therapy^{19,20}. Pre-operatively, Group 2 exhibited higher incidences of pain (90.00%) and discharging sinus (53.33%) compared to Group 1 (76.67% and 3.33%, respectively). This aligns with research indicating that pre-operative symptoms such as pain and sinus discharge are significant predictors of postoperative outcomes^{21,22}. At the 3-month follow-up, percussion pain was more prevalent in Group 1 (76.67%) than in Group 2 (46.67%, $p = 0.016$), consistent with studies showing better short-term pain management in treatments using calcium hydroxide sealers²³. By the 12-month follow-up, percussion pain persisted in 13.33% of Group 1 but was absent in Group 2, indicating a more favorable long-term outcome for the calcium hydroxide group. The final clinical outcomes revealed a 100.00% success rate in Group 2, significantly higher than Group 1's 86.67% ($p = 0.038$). This finding is supported by several studies that demonstrate higher success rates for treatments using biocompatible and bioactive sealers like calcium hydroxide, which promote better healing and long-term stability. For instance, Zmener and Pameijer reported an 86.5% cumulative success rate over eight years for a resin-based sealer, while Kerekes and Tronstad

found a 91% success rate using a standardized endodontic technique^{24,25}. Similarly, a study comparing bioceramic and resin-based sealers showed no significant difference in success rates, underscoring the efficacy of advanced sealers in endodontic treatments²⁶. In contrast, studies using glass ionomer cement sealers reported lower success rates (78.3%) and highlighted various clinical factors influencing outcomes, such as the number of canals and preoperative symptoms²⁷. This reinforces the superior performance of calcium hydroxide-containing sealers in achieving optimal treatment results. Overall, the findings of this study underscore the clinical advantages of using calcium hydroxide-containing sealers over traditional ZOE sealers in root canal therapy. The higher success rates, better pain management, and favorable long-term outcomes associated with calcium hydroxide sealers align with existing literature and suggest their potential for improving endodontic treatment protocols. Further research is warranted to explore the underlying mechanisms and to confirm these findings across diverse populations and clinical settings.

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

Conclusion

The present study evaluated the clinical outcomes of using calcium hydroxide-containing sealer (Sealapex) compared to zinc oxide eugenol (ZOE) sealer in single-visit root canal treatments. The findings demonstrated that the calcium hydroxide-containing sealer provided superior clinical results, evidenced by lower incidences of percussion pain at both 3-month and 12-month follow-ups and a higher overall success rate. The demographic and etiological factors, along with the distribution of pre-operative signs and symptoms, highlighted the distinct advantages of Sealapex in managing endodontic cases, particularly in younger patients and those

with trauma-related etiologies. This study supports the use of calcium hydroxide-containing sealers as a more effective alternative to traditional ZOE sealers, promoting better long-term outcomes and patient satisfaction in endodontic treatments. Further research is recommended to validate these findings across broader populations and different clinical settings.

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