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Comparative evaluation of two intracanal medicaments on post-operative pain following root canal treatment

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Abstract:
Post-operative pain is an inevitable aftermath of the nonsurgical root canal treatment that can be influenced by the type of intracanal medicament. Therefore, it is of interest to compare the effect of calcium hydroxide and Bio-C Temp on post-operative pain in 30 patients that underwent non-surgical root canal treatment divided into 2 equal groups. Pain was assessed using the visual analog scale at 24, 48 and 72 hours and 7 days post-operatively. Secondary outcomes included analgesic consumption, time to first analgesic dose, flare-ups, swelling and percussion tenderness. Thus, both medicaments reduced post-operative pain, but Bio-C Temp showed better pain control, lower analgesic use and delayed first analgesic intake than calcium hydroxide.

Keywords: Intracanal medicament, post-operative pain, root canal treatment (RCT)

Background:
Post-operative discomfort is a frequently observed finding following Endodontic treatment and can affect the patient's post-treatment experience **[1, 2]**. Although modern-day procedures are typically performed to thoroughly debride and disinfect the root canal system, pain can develop during the early healing period due to transient inflammation of the periapical tissues **[3]**. This response can be predisposed by various factors including the preoperative status of the pulp and periapical tissues, microbial load, instrumentation, extrusion of debris or irrigant beyond the apical foramen and individual inflammatory response **[4]**. Therefore, the control over residual intracanal organisms and the prevention of periapical irritation are crucial to achieve predictable post-treatment comfort **[5]**. The intracanal medicament between the treatment appointments can offer an additional opportunity for microbial control after mechanical preparation and irrigation **[6]**. Calcium hydroxide has been widely advocated for this indication due to the potential antimicrobial effects of a strongly alkaline environment prepared by this material **[7]**. At the same time, there are reports on the presence of microorganisms resistant to the action of calcium hydroxide and clinical outcomes of its use for the treatment of the root canal system remained controversial with mixed evidence on its impact on post-treatment discomfort **[8]**. Therefore, an interest in alternative medicaments that could offer sufficient disinfection while possessing favorable properties for the periapical tissues has emerged. Bio-C Temp is a premixed bio ceramic intracanal medicament introduced for the application between the appointments **[9]**. Its calcium-based composition, alkaline environment and potential for calcium-ion release can potentially contribute to antimicrobial and bioactive properties in the treated area **[10]**. Apart from the handling simplicity due to the premixed nature of the material, its interactions with the biological environment were also considered beneficial. However, the evidence on the biological effects of this material comes primarily from laboratory studies, while the clinical benefits, including the effects on post-treatment discomfort, are difficult to estimate **[11]**. Therefore, it is of interest to evaluate the clinical evidence on the effects of these medicaments on the post-treatment experience in patients following root canal treatment.

Materials and Methods:
Study design and participants:
A prospective, parallel-group clinical study was designed to compare the effect of two intracanal medicaments, calcium hydroxide and Bio-C Temp, on post-operative pain following nonsurgical endodontic. The study comprised patients aged 18–40 years who required primary nonsurgical root canal treatment. All eligible participants were informed about the study protocol and written informed consent was obtained before treatment.

Case selection:
Patients were included if they were aged 18–40 years, required primary nonsurgical root canal treatment and presented with permanent teeth diagnosed with symptomatic or asymptomatic irreversible pulpitis or pulp necrosis associated with apical periodontitis requiring intracanal medication. Only restorable teeth with a favorable prognosis were included. Patients were

required to provide written informed consent and comply with the scheduled follow-up visits. Patients were excluded if they were pregnant or lactating, had systemic conditions that could influence pain perception or wound healing, including uncontrolled diabetes mellitus or immunocompromised conditions, or had received corticosteroids, antibiotics, analgesics, or immunosuppressive medications within the preceding week. Patients with known allergy or hypersensitivity to any study medication or treatment material were also excluded. Teeth with root fractures, internal or external resorption, periodontal pockets greater than 5 mm, advanced periodontal disease, or previously completed root canal treatment were excluded.

Clinical procedure:
All participants underwent standardized nonsurgical root canal treatment under local anesthesia. Following administration of topical anesthetic gel (Lox 2%; Neon Laboratories Ltd., India), local anesthesia was achieved using 2% lidocaine with 1:100,000 epinephrine (Lignox® 2% A; Warren Pharmaceuticals Pvt. Ltd. India). The teeth were isolated using a rubber dam and conventional endodontic access cavities were prepared using sterile diamond burs under copious water cooling. The working length was determined using an electronic apex locator and subsequently confirmed using digital radiography. Biomechanical preparation was performed using the ProTaper Gold rotary file system (Dentsply Sirona Endodontics, Switzerland) with an endodontic motor according to the manufacturer's recommendations. The canals were generally prepared to a final apical size of F2 (25/0.08 taper), unless anatomical considerations required modification of the final preparation size. During instrumentation, the root canals were intermittently irrigated with 3% sodium hypochlorite using a sterile side-vented irrigation needle. Following completion of biomechanical preparation, a final rinse with 17% ethylenediaminetetraacetic acid was performed for 1 minute to facilitate smear-layer removal. This was followed by a final rinse with sterile saline. The root canals were then dried with sterile paper points.

Intracanal medicaments:
Following canal preparation and drying, participants were allocated to one of two treatment groups according to the intracanal medicament used.

Group I—calcium hydroxide:
The canals were medicated with calcium hydroxide paste (RC Cal; Prime Dental Products Pvt. Ltd., Mumbai, India). The medicament was introduced into the prepared canal using a Lentulo spiral and distributed to achieve adequate canal filling.

Group II—bio-C temp:
The canals were medicated with Bio-C Temp, a ready-to-use calcium silicate-based bio ceramic intracanal medicament. The material was delivered according to the manufacturer's recommended technique using the supplied delivery system and placed throughout the prepared canal. Following placement of the assigned intracanal medicament, the access cavities were sealed with a temporary restorative material to prevent coronal leakage. The patients were recalled for subsequent treatment and clinical evaluation according to the study protocol. At the second visit, scheduled 7 days after the initial treatment, the temporary restoration and intracanal medicament were removed using copious irrigation with sodium hypochlorite and 17% EDTA. The canals were dried with sterile paper points and obturated with gutta-percha and sealer using the cold lateral condensation technique. The access cavities were subsequently restored with resin composite and patients were recalled for post-operative evaluation.

Post-operative pain assessment:
Post-operative pain intensity was evaluated using a 100-mm visual analog scale (VAS), ranging from 0 (no pain) to 100 (worst imaginable pain). Participants were asked to record their pain scores at 24, 48 and 72 hours and 7 days following treatment. Standardized instructions were provided to ensure consistent recording of pain scores.

Analgesic consumption:
Participants were provided with a standardized analgesic for use when required and were instructed to record the time at which the first dose was taken and the total number of doses consumed during the follow-up period. The time to first analgesic intake and cumulative analgesic consumption were subsequently recorded for each participant.

Evaluation of post-operative complications:
The occurrence of interappointment flare-up, post-operative swelling and percussion tenderness was assessed during the follow-up period. Flare-up was recorded when a patient developed acute pain and/or swelling requiring an unscheduled clinical intervention. Post-operative swelling was recorded based on its clinical presence or absence, while percussion tenderness was assessed clinically and documented at the predetermined follow-up intervals.

Statistical analysis:
Data were analysed using IBM SPSS Statistics version 24. Results were expressed as mean ± SD or frequencies and percentages, with $p < 0.05$ considered statistically significant.

Results:
A total of 30 patients were included in the study, with 15 patients per group. Postoperative pain scores decreased progressively over the 7-day follow-up period in both groups. However, the Bio-C Temp group demonstrated significantly lower VAS scores than the calcium hydroxide group at 24 hours (31.40 ± 7.15 vs. 42.67 ± 8.21; $p = 0.001$), 48 hours (21.87 ± 6.32 vs. 31.20 ± 7.46; $p = 0.002$), 72 hours (13.47 ± 5.21 vs. 20.53 ± 6.18; $p = 0.003$), and 7 days (4.20 ± 2.51 vs. 7.73 ± 3.84; $p = 0.006$) **(Table 1)**. These findings indicate significantly lower postoperative pain scores in the Bio-C Temp group throughout the observation

period. Regarding analgesic-related outcomes, fewer patients in the Bio-C Temp group required analgesics (40.0%) than in the calcium hydroxide group (73.3%); however, this difference was not statistically significant (p = 0.070). The mean number of analgesic doses was significantly lower in the Bio-C Temp group (1.27 ± 0.88) than in the calcium hydroxide group (2.47 ± 1.06; p = 0.003). Furthermore, the time to first analgesic intake was significantly longer in the Bio-C Temp group (13.67 ± 4.16 hours) than in the calcium hydroxide group (8.13 ± 3.24 hours; p = 0.001) **(Table 2)**. These results suggest reduced analgesic requirements and a delayed need for pain relief among patients receiving Bio-C Temp. The incidence of postoperative complications was also lower in the Bio-C Temp group. Interappointment flare-ups and postoperative swelling occurred in 6.7% of patients in the Bio-C Temp group compared with 20.0% in the calcium hydroxide group (p = 0.283 for both outcomes). Similarly, percussion tenderness was observed in 20.0% of patients in the Bio-C Temp group and 40.0% in the calcium hydroxide group (p = 0.427) **(Table 3)**. Although these findings favoured Bio-C Temp, none of the differences was statistically significant. Overall, both intracanal medicaments were associated with a progressive reduction in postoperative pain. However, Bio-C Temp demonstrated significantly better outcomes in terms of pain scores, total analgesic consumption, and time to first analgesic intake. Although postoperative complications were less frequent in the Bio-C Temp group, larger studies are required to establish whether these differences are statistically and clinically meaningful.

Table 1: Comparison of post-operative pain scores between the study groups

Follow-up period	Group I (Mean ± SD)	Group II (Mean ± SD)	*p*-value
24 hours	42.67 ± 8.21	31.40 ± 7.15	0.001
48 hours	31.20 ± 7.46	21.87 ± 6.32	0.002
72 hours	20.53 ± 6.18	13.47 ± 5.21	0.003
7 days	7.73 ± 3.84	4.20 ± 2.51	0.006

Table 2: Comparison of analgesic-related outcomes

Outcome	Group I	Group II	*p*-value
Patients requiring analgesics, n (%)	11 (73.3)	6 (40.0)	0.070
Total analgesic doses, mean ± SD	2.47 ± 1.06	1.27 ± 0.88	0.003
Time to first analgesic intake (hours), mean ± SD	8.13 ± 3.24	13.67 ± 4.16	0.001

Table 3: Comparison of post-operative complications

Clinical outcome	Group I	Group II	*p*-value
Interappointment flare-up, n (%)	3 (20.0)	1 (6.7)	0.283
Post-operative swelling, n (%)	3 (20.0)	1 (6.7)	0.283
Percussion tenderness, n (%)	6 (40.0)	3 (20.0)	0.427

Discussion:

Post-operative pain is an important clinical concern following nonsurgical root canal treatment and may influence patient comfort and satisfaction with endodontic therapy. Oguntebi *et al.* reported that the incidence of post-operative pain following root canal treatment ranges from 1.4% to 16% **[12]**. Its occurrence is influenced by several factors, including preoperative pulpal and periapical status, microbial load, instrumentation and irrigation procedures, extrusion of debris into the Periradicular tissues and the host inflammatory response. Extrusion of infected debris has been identified as an important cause of periapical inflammation and post-operative pain, which may manifest as an endodontic flare-up **[13]**. Although the precise etiology of flare-ups is not always clear, changes in periapical tissue pressure, the number and virulence of endodontic microorganisms and local environmental conditions have been proposed as contributing factors **[14]**. In our study, both calcium hydroxide and Bio-C Temp resulted in a gradual decrease of post-operative pain during the 7-day follow-up period. Interestingly, patients that received Bio-C Temp presented with lower VAS scores at all measurement points, especially within the first 72 hours, indicating a more advantageous post-operative pain profile. The higher pain scores observed among patients that received calcium hydroxide in the early post-operative days are most likely explained by the different biological and antimicrobial properties of both medicaments. Calcium hydroxide has been widely used as an intracanal medicament due to its high pH level and antimicrobial properties that are well-established **[15]**. However, the antimicrobial efficacy may be compromised due to the variability of the microbial content of the root canal system and the tolerance of microorganisms to the alkaline pH. Hence, persistent microbial irritation or the host's inflammatory mediators may be responsible for post-operative pain despite chemomechanical instrumentation. Bio-C Temp is a premixed, calcium silicate-based bioceramic intracanal medicament that creates an alkaline environment in the root canal by releasing calcium ions with antimicrobial effects **[16]**. The sustained release of calcium ions and the biocompatible nature of calcium silicates may have resulted in a favorable periapical environment and less post-operative pain **[17-19]**. Our findings are consistent with Chauhan *et al.* **[20]**, who compared post-operative pain following the use of Bio-C Temp, calcium hydroxide, and Odontopaste. Thakur *et al.* **[21]** and Bhawalkar *et al.* **[22]** also investigated postoperative pain associated with different intracanal medicaments, highlighting the importance of medicament selection in postoperative pain management. These studies provide additional context for interpreting our findings, although differences in study design and materials should be considered. Furthermore, Hegde *et al.* **[23]**, in their systematic review and meta-analysis, evaluated the effects of calcium hydroxide and other intracanal medicaments on postoperative pain, providing broader evidence for comparing pain outcomes associated with different medicaments. These studies highlight the importance of intracanal medicament selection in postoperative pain management. The lower VAS scores observed in our study with Bio-C Temp may be explained by the physicochemical and biological differences in comparison with traditional calcium hydroxide. However, this observation should be considered with caution as our study did not directly evaluate the antimicrobial or anti-inflammatory potential of both medicaments. An important observation from our study is the difference in the requirements for analgesics with the use of different intracanal medicaments. Patients that received Bio-C Temp consumed fewer doses of analgesic and needed a longer

time to take the first dose in comparison with patients that received calcium hydroxide. This observation reinforces the findings of our study on the VAS scores since the difference between the groups was not only on a subjective scale but also objective in terms of analgesic requirements. A lower incidence of interappointment flare-up, post-operative swelling and percussion tenderness was also observed among patients that received Bio-C Temp in comparison with those that received calcium hydroxide. However, the difference was not statistically significant, potentially due to the small sample size of our study. As such, although the findings suggest that Bio-C Temp potentially reduces the risk of post-operative complications, the results should be considered with caution. The reduction of pain experienced by the participants in both groups was comparable with the typical clinical progression of post-endodontic discomfort, which is less noticeable after the first post-treatment week. The treatment protocol used in our study was standardized in terms of instrumentation, irrigation techniques, the time of intracanal medicament and obturation technique to reduce the variability between the groups. In summary, both calcium hydroxide and Bio-C Temp were associated with a reduction of post-operative pain following nonsurgical root canal treatment. However, Bio-C Temp was associated with lower post-operative pain scores, reduced analgesic requirements and a later time to the first dose of analgesia within the limitations of this study compared with calcium hydroxide, whereas the differences in the incidence of post-operative complications were not statistically significant.

Conclusion:

Both calcium hydroxide and Bio-C Temp were effective in preventing post-operative pain. However, Bio-C Temp showed less post-operative discomfort, reduced analgesic consumption and delayed first analgesic intake. Adverse effects were also less frequent, although not statistically significant. Further studies with larger samples and longer follow-up are needed to confirm these findings.

Advancement to knowledge:

The study provides clinical evidence that Bio-C Temp may be more effective than calcium hydroxide in reducing post-operative pain and analgesic consumption following root canal treatment. It also highlights the potential of bioceramic-based medicaments to improve patient comfort and reduce the need for post-operative analgesics.

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