Original Article

# The effect of bioactive glass-based, bioceramic based and epoxy amine resin based root canal sealers on post-obturation pain: A double blinded randomized controlled trial

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## Abstract

**Aim:** The aim of this study was to compare the effect of two calcium silicate-based and an epoxy resin-based root canal sealers on postoperative pain and analgesic intake following single-visit root canal treatment.

**Materials and Method:** Ninety patients with at least one first or second molar tooth diagnosed as symptomatic irreversible pulpitis and symptomatic apical periodontitis were selected and allocated into three groups (n=30) according to the sealer used. Root canals were prepared using Protaper Gold instruments (Dentsply Sirona) in a crown down technique and irrigated with 2.5% NaOCl (Calyx, India) and saline solution. Root canal filling was then accomplished with a single cone obturation technique and treated in a single visit by the same endodontist. Patients were told to use a Visual Analog Scale (VAS) to rate their postoperative pain severity as none, minimal, moderate, or severe after 6 h, 24 h, 48 h, 5 days and 7 days following obturation using the appropriate sealers. The need for analgesic intake was also recorded. The data were statistically analyzed.

**Results:** Results showed a significant difference among the studied groups. Bio-C Sealer Ion+ reported the least pain score followed by Nishika Canal Sealer BG and AH plus sealer at all the time intervals recorded. The intergroup analysis, revealed was a significant difference in postoperative pain at 6 h ($p=0.000$) and 24 h ($p = 0.028$), but not at 48 h, 5 day or 7 days ($P > 0.05$). VAS ratings for all the three groups decreased over time. Also, there were significant differences between the means of analgesic intake among 3 groups ($p=0.022$). Analgesic intake in group BIO-C Sealer Ion+ is significantly lesser than AH Plus and Nishika Canal Sealer BG group.

**Conclusion:** Calcium silicate-based sealer (Nishika Canal Sealer BG and Bio-C Sealer Ion+) resulted in significantly lower levels of pain as compared to epoxy resin-based sealer (AH Plus) at 6h and 24-h interval, there was no significant difference in postoperative pain occurrence at 48-h, 5 day and 7-day period. The analgesic intake in Bio-C Sealer Ion+ group is significantly lesser than Nishika Canal Sealer BG and AH Plus group.

**Keywords:** Bioactive glass-based sealer; bioceramic-based sealer; epoxy resin-based sealer; postoperative pain; single-visit root canal treatment

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## INTRODUCTION

To preserve a sufficient biological environment for physiological recovery, the aim of endodontic therapy is to remove both necrotic and healthy pulp tissue.[1] An efficient obturation must provide a satisfactory apical



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seal to prevent entry of microorganisms and subsequent failure of treatment.[2] Root canal sealers are applied as a thin, sticky paste during obturation. They have lubricating and luting properties, stop coronal leakage, seal the apex from periapical tissue fluids, and encapsulate any leftover bacteria in the canal, all of which help to lessen bacterial contamination.[3]

The frequency of endodontic postoperative pain varies from 3% to 65%, making it one of the most common side effects of root canal therapy.[4] The process of postoperative pain is intricate and multifaceted, impacted by factors that are intrinsic to the patient (e.g., age, gender, arch, tooth vitality, and use of analgesics), to the tooth that has to be treated (preoperative pain, occlusal contacts, tooth type, and history of emergency endodontic treatments), and to the procedure.[1,5,6] Among the procedural factors, extrusion or leakage of endodontic sealer through the apical foramen or lateral canal may elicit inflammation, tissue degeneration, and the development of postoperative discomfort.[4]

Endodontic sealers may be broadly categorized based on their chemical constitution into zinc oxide eugenol-based, salicylate, glass ionomer, silicone, $Ca(OH)_2$-based, epoxy resin-based, calcium silicate-based (MTA and bioceramic), and methacrylate resin sealer systems. Studies have reported conflicting results regarding postoperative pain following obturation with different sealers.

The composition of the sealer is crucial and could have an impact on how intense the inflammatory response is in the apical region. In dentistry, AH Plus sealer is currently recommended due to its biocompatibility.[7] It is a bisphenol epoxy resin-based sealer made of calcium tungstate, silicone oil, silica dibenzyl diamine, zirconium oxide, tricyclodecane diamine, and iron oxide pigments.[8] Due to its superior physicochemical characteristics, it is regarded as the gold standard among endodontic sealers and was, therefore, assessed in the current study.

Lately, a two-paste bioactive glass-based Nishika Canal Sealer BG (J. Morita, Japan) has been introduced in the market for the purpose of endodontic treatment. It is composed of bismuth subcarbonate, fatty acid, calcium silicate glass, silicon dioxide, purified water, magnesium oxide, and silicon dioxide. Numerous advantageous qualities, including biocompatibility, sealing ability, physicochemical stability, and removability, are exhibited by this sealer.[9]

Latest of all, a hydraulic calcium silicate-based Bio-C Sealer Ion$^+$ (Angelus, Londrina, Brazil) has been released. It is eugenol free and resin free, with improved biocompatibility and alkalinization capacity.[10]

Literature is meager on these newly introduced sealers and no study has evaluated postoperative pain occurrence after obturation with these novel sealers in patients with symptomatic irreversible pulpitis and apical periodontitis. Assessing and comparing the frequency of discomfort following root canal obturation with Nishika Canal Sealer BG, AH Plus, and Bio-C Sealer Ion$^+$ was the purpose of this double-blinded randomized clinical trial.

The null hypothesis stated that following obturation using bioceramic-based, bioactive glass-based, and epoxy amine resin-based root canal sealer, there would be no difference in the postoperative pain levels between patients with symptomatic irreversible pulpitis and symptomatic apical periodontitis.

## MATERIALS AND METHODS

### Study design

Under protocol number ITSCDSR/IIEC/RP/2022/015, a prospective, single-centered, double-blind, randomized controlled clinical trial was planned and carried out in compliance with ethical standards following an independent assessment and approval by the Institution's Ethics Committee.

The CONSORT criteria were adhered to and the study protocol was registered under Registration Number CTRI/2023/03/050501 with the Clinical Trials Registry-India. Before their enrollment in the trial, each patient provided their informed consent.

Sample size calculations were made using a reference to the formula that can be found in the that can be found in the following article (pages 3–4; section 3.1 test for equality).[11] It was established that the sample size needed for the study was at least 27 people per group with 95% power and $\alpha = 0.05$. Thirty people per group were recruited with a 10% attrition loss in mind.

The following formula was applied to determine the sample size:

$$n = \frac{(Z\alpha/2 + Z\beta)^2 \times (p1[1-p1] + p2[1-p2])}{(p1-p2)^2}$$

The notation for the formulae is:

$n$ = sample size of groups

$Z\alpha/2$ = critical value of the normal distribution at $\alpha/2$

$Z\beta$ = critical value of the normal distribution at $\beta$

$p1$ and $p2$ = expected sample proportions of two groups

Power = 95%.

Patients were recruited based on the following selection criteria:

- The inclusion criteria for patient selection were as follows:
  - Good oral hygiene
  - Individuals in the age range of 18–50
  - Individuals who have not used antibiotics or analgesics in the previous 7 days
  - Extended positive reaction to cold and electric pulp tester
  - Individuals with mandibular first or second molar teeth diagnosed with symptomatic irreversible pulpitis and symptomatic apical periodontitis
  - Pulp exposed during caries removal bleeding profusely with a thick consistency
  - Patients with healthy periapical tissues.

- Among the study's exclusion criteria were:
  - Patients who decline to take part in the research
  - Patients with impaired immune systems or systemic disorders, as well as those on medication
  - Presence of advanced periodontal disease (probing depth >4 mm)
  - The presence of calcification, open apex, and resorption
  - Individuals who are allergic to substances used in the root canal procedure, including local anesthetics
  - Individuals with systemic sensitivity or allergies to nonsteroidal anti-inflammatory drug
  - Patients who are nursing or who are pregnant
  - >2 mm of short filling from the radiographic apex or overfilling (the sealer or Gutta-percha [GP] expanding past the radiographic apex)
  - Teeth that require a core buildup due to significant coronal damage.

After being given a number, each patient was instructed to select a sealed envelope containing a sheet of paper bearing the group name. The patients were randomized to one of the three groups at random, per the text written on the piece of paper.

- Group 1: AH Plus group (Dentsply Maillefer, Ballaigues, Switzerland)
  - Following the sealing of the root canals with AH Plus sealer using a single-cone method.
- Group 2: Nishika Canal Sealer BG (J. Morita, Japan)
  - Following the sealing of the root canals with Nishika Canal Sealer BG using a single-cone method.
- Group 3: Bio-C Sealer Ion$^+$ (Angelus, Londrina, Brazil)
  - Following the sealing of the root canals with Bio-C Sealer Ion$^+$ sealer using a single-cone method.

The patient and the observer were double-blinded to prevent bias in the Visual Analog Scale (VAS).

After recording the preoperative pain levels, a local anesthesia injection of 1.8 mL of 2% lidocaine (Ultracaine D-S Forte) containing 1:80,000 epinephrine for local anesthesia (inferior alveolar nerve block for mandibular molars) was administered. The depth of anesthesia was checked twice with an electric pulp tester in 15-min intervals. Isolation of the tooth was done using a rubber dam (GDC, UK), and any breach was secured with a gingival dam (Prevest DenPro, India) using a light cure unit followed by occlusal reduction to bring the tooth out of occlusion. Using sterile burs to prepare the access cavity and a broach to remove the pulp tissue, a #10 K file (Dentsply Maillefer, Ballaigues, Switzerland) and an electronic apex locator (DentaPort ZX, J Morita Corp.) were used to build a glide path. Cleaning and shaping of the canals were done in continuous rotary motion with ProTaper Rotary Instrument till size F2 (25/0.08) under copious irrigation with 2.5% NaOCl (Calyx, India), placing the needle short of the WL. Using 10 K-file, apical patency was preserved.

Following root canal preparation, an Irrisafe ultrasonic 20.00 tip (Satelec, Merignac, France) was used to ultrasonically activate 3 mL of fresh NaOCl at 50% power of the Acteon Satelec ultrasonic unit. The tip was positioned 3 mm from the WL. This procedure was carried out three times, requiring 20 s for each activation. Then, 17% EDTA was gently delivered to 1 mm from the WL as a final irrigant and maintained intracanally for 1 min. Sterilized paper tips were then used to dry the root canals. After applying the mixed sealer to the master GP cone, the canal was sealed using the single-cone obturation method.

To avoid further discomfort, the occlusion and proximal integrity were thoroughly evaluated once treatment was finished, and the access cavity was restored with temporary restoration (Cavit-G, 3M). Patients were informed before being discharged to complete the pain questionnaire after 6, 24, 48 h, 5 days, and 7 days, as well as to contact at the appointed time. Patients were given a VAS ruler with nonnumeric signs, while the operator kept a ruler with numbers that matched the nonnumeric signals. The operator then linked the patient's VAS pain signs with the corresponding scores from 0 to 10. Patients were instructed to keep track of the amount of analgesics they

used, if any, to lessen their postoperative pain. To track their analgesic usage, the patients were directed to use 400 mg of ibuprofen (Brufen; Abbott) if the pain became intolerable.

### Statistical analysis

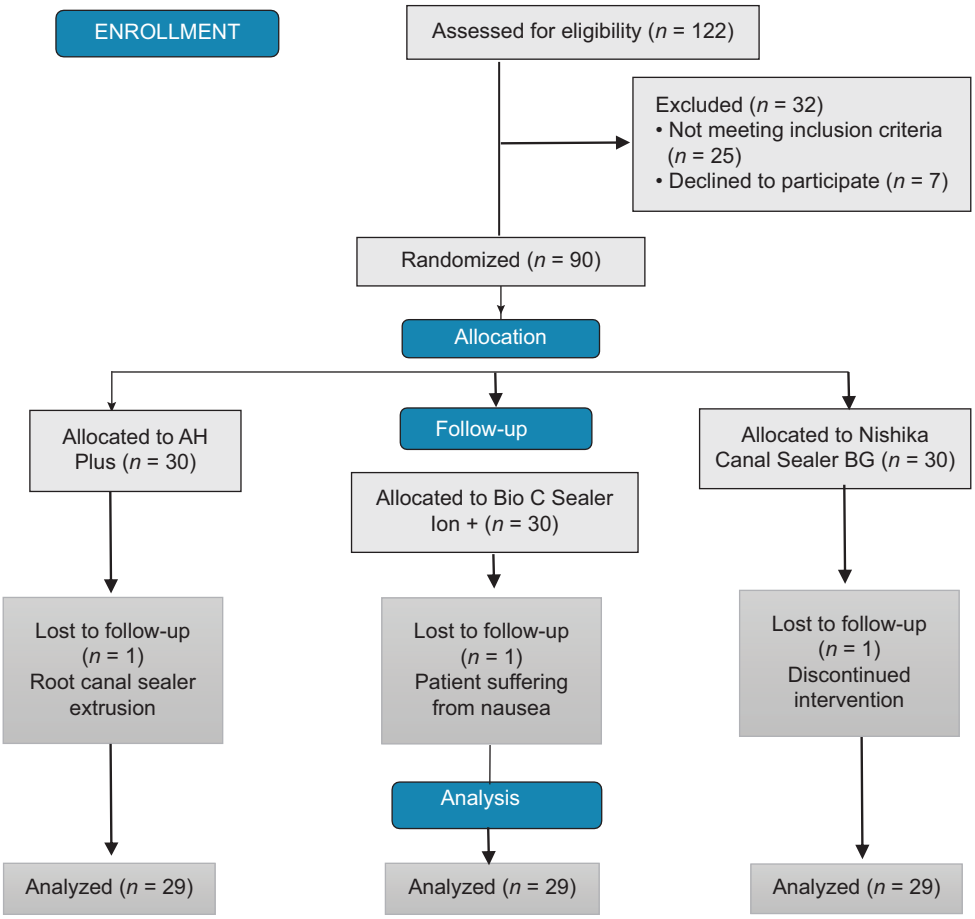
The SPSS statistics program (IBM Corp., version 24.0, Armonk, NY, USA) was used to analyze the data. The descriptive statistics mean ± standard deviation of postoperative pain was calculated. The Shapiro–Wilk test showed the data to be of nonnormal distribution, so the significance was tested by nonparametric tests. The Kruskal–Wallis test (intergroup comparison) and the Mann–Whitney *U*-test were used to assess the pain levels of the three groups. The pain intensity in the same group between the different time intervals (intragroup comparison) was tested by the Wilcoxon signed-rank test. Significant results were defined as $P < 0.05$ with a 95% confidence interval ($P < 0.05$).

## RESULTS

Flowchart 1 - CONSORT Guidelines flowchart.

A total of 122 patients were evaluated for eligibility. Thirty-two people were left out because they either refused to take part in the study or could not meet the inclusion requirements. Each group was allocated 30 patients. There was a loss to follow-up seen in each sealer group. Therefore, 29 patients were statistically evaluated for the results. Eighty-seven mandibular molars had single-visit root canal therapy. Overall pain intensity decreased postoperatively. The AH Plus group experienced more intense postoperative pain than the other two groups throughout all time intervals. The level of pain was noticeably less in the Bio-C Sealer Ion$^+$ compared to the other groups at 6, 24, and 48 h postoperatively. Bio-C Sealer Ion$^+$ showed the best results followed by Nishika Canal Sealer BG, followed by AH Plus sealer [Table 1].

At 6 h, the mean difference of pain scores between groups AH Plus versus Bio-C Sealer Ion$^+$ and Nishika Canal Sealer versus Bio-C Sealer Ion$^+$ was significant, $P < 0.05$. The mean of postoperative pain after 24 h of group Nishika Canal Sealer BG (0.30 ± 0.596) is significantly higher than Bio-C Sealer Ion$^+$ (0.10 ± 0.305). In the intragroup comparison, the mean pain score in the AH Plus and Nishika Canal Sealer BG groups was significantly different from preoperative pain – 6 h, 6 h–24 h, and 24 h–48 h. However,




**Flowchart 1:** Flow diagram of the progress of the patients at each stage of the clinical trial, according to the CONSORT guidelines

**Table 1: Comparison of mean±standard deviation of POP and analgesic intake between three groups at different time intervals**

| Pain | Groups | *n* | Mean±SD | *P*‡ | | |
|---|---|---|---|---|---|---|
| | | | | AH Plus versus Nishika | AH Plus versus Bio-C Ion+ | Nishika versus Bio-C Ion+ |
| Preoperative | AH Plus | 30 | 2.20±0.887 | 0.831 | 0.144 | 0.237 |
| | Nishika Canal | 30 | 2.13±0.973 | | | |
| | BIO-C Ion+ | 30 | 1.87±0.860 | | | |
| | *P*† | | 0.300 NS | | | |
| 6 h | AH Plus | 30 | 1.20±0.805 | 0.180 NS | 0.000** | 0.000** |
| | Nishika Canal | 30 | 0.93±0.944 | | | |
| | BIO-C Ion+ | 30 | 0.17±0.461 | | | |
| | *P*† | | 0.000** | | | |
| 24 h | AH Plus | 30 | 0.37±0.556 | 0.469 | 0.028* | 0.150 |
| | Nishika Canal | 30 | 0.30±0.596 | | | |
| | BIO-C Ion+ | 30 | 0.10±0.305 | | | |
| | *P*† | | 0.095 | | | |
| 48 h | AH Plus | 30 | 0.10±0.305 | 0.305 | 0.078 | 0.317 |
| | Nishika Canal | 30 | 0.03±0.183 | | | |
| | BIO-C Ion+ | 30 | 0 | | | |
| | *P*† | | 0.163 | | | |
| 5 days | AH Plus | 29 | 0 | 1.000 | 1.000 | 1.000 |
| | Nishika Canal | 29 | 0 | | | |
| | BIO-C Ion+ | 29 | 0 | | | |
| | *P*† | | 1.000 | | | |
| 7 days | AH Plus | 29 | 0 | 1.000 | 1.000 | 1.000 |
| | Nishika Canal | 29 | 0 | | | |
| | BIO-C Ion+ | 29 | 0 | | | |
| | *P*† | | 1.000 | | | |
| Analgesic intake | AH Plus | 29 | 0.34±0.553 | 0.515 | 0.006* | 0.024* |
| | Nishika Canal | 29 | 0.24±0.435 | | | |
| | BIO-C Ion+ | 29 | 0.03±0.186 | | | |
| | *P*† | | 0.022* | | | |

*Significant $P<0.05$, **Highly significant $P<0.01$, †Kruskal–Wallis test, ‡Mann–Whitney test, †Krushkal-Wallis test. NS: Not significant $P>0.05$, SD: Standard deviation, POP: Postoperative pain

**Table 2: Intragroup comparison of the mean of POP between two intervals of the three different sealers**

| Groups | POP after 6 h - preoperative pain | POP after 24 h - POP after 6 h | POP after 48 h - POP after 24 h | POP after 5 days - POP after 48 h | POP after 7 days - POP after 5 days |
|---|---|---|---|---|---|
| AH Plus | | | | | |
| Z | −3.999 | −4.456 | −2.530 | −1.732 | 0 |
| *P* | 0 | 0 | 0.011 | 0.083 | 1.000 |
| Nishika Canal | | | | | |
| Z | −3.813 | −3.624 | −2.530 | −1.000 | 0 |
| *P* | 0 | 0 | 0.011 | 0.317 | 1.000 |
| BIO-C Ion+ | | | | | |
| Z | −4.873 | −1.000 | −1.732 | 0 | 0 |
| *P* | 0 | 0.317 | 0.083 | 1.000 | 1.000 |

POP: Postoperative pain

the significant difference between the mean pain score in the Bio-C Sealer Ion+ group was only at preoperative – 6 h intervals [Table 2]. In addition, the means of analgesic intake in the three groups differed significantly from one another, $P = 0.022$, $P < 0.05$. The highest analgesic consumption was seen in the AH Plus group and the lowest amount was seen in the Bio-C Sealer Ion+ group [Table 1].

## DISCUSSION

The frequency and severity of postoperative discomfort are significantly influenced by the root canal sealer's composition due to the release of chemical irritants during setting that may cause local inflammation. Endodontic sealers frequently extrude, and the periradicular tissues typically tolerate this process well in small doses.[12] Extrusion-induced tissue damage results in the release of inflammatory chemical mediators, which precipitate peripheral sensitization and the initial pain experience.[13]

The bulk of research evaluating postobturation pain has been on teeth with asymptomatic apical periodontitis and irreversible pulpitis. This is the first trial where patients with apical periodontitis and symptomatic irreversible pulpitis have been treated with novel sealers in a single visit.[14] This class of patients may have the worst pain score that can be assessed in a single-visit treatment.

The purpose of this prospective, double-blind, randomized controlled experiment was to evaluate the postobturation pain as well as analgesic intake following single-visit endodontic therapy with Nishika Canal Sealer BG (bioactive glass-based sealer), Bio-C Sealer Ion$^+$ (bioceramic-based sealer), and AH Plus (epoxy resin-based sealer). Findings from the research indicate that postoperative pain in the AH Plus sealer was significantly higher and lasted for a longer duration compared to the other two sealers. The patients obturated with Bio-C Sealer Ion$^+$ experienced significantly lesser pain postoperatively ($P < 0.05$) and consumed fewer analgesics compared to patients in the AH Plus and Nishika Canal Sealer BG groups because of its composition.

A particular calcium silicate that has been modified with magnesium is present in Bio-C Sealer Ion$^+$ which enhances its biocompatibility and reduces inflammatory responses. It also exhibits excellent flow characteristics, ensuring better adaptation to the canal walls and reducing irritation to periapical tissues.[15,16] Increased flow rate and smaller particle size enable three-dimensional filling, a reduction in the proportion of voids in the apical third, and improved filling of accessory canals, irregularities, isthmuses, and dentinal tubules, thus decreasing the risk of apical extrusion and postoperative pain.[17]

Higher pain in the case of AH Plus sealer could be justified based on the cytotoxicity because it releases harmful monomers such as epoxy resin and bisphenol A diglycidyl ether.[18,19] The unpolymerized residues remain due to the formation of an oxygen inhibition layer in the mixture of the sealer. These results are in line with a related study of Drumond *et al*.[20] Along with this, the delayed setting time of AH Plus sealer which is around 7 h contributes to more frequent episodes of pain by raising biocompatibility concerns and perhaps causing the release of cytotoxic components before setting.

In the case of Nishika Canal Sealer BG, the reduced levels of postoperative pain in the first 6 h could be attributed to its relatively shorter setting time of 3 h as well as low cytotoxicity owing to its bioceramic nature.[9] This study's conclusion is consistent with one by Washio *et al*., in 2019, which concluded that a sealer based on calcium silicate exhibits exceptional biocompatibility and has the ability to mitigate patient discomfort during root canal obturation.[21]

After 48 h, there was negligible pain noted in both the sealer groups. Over time, a series of localized inflammatory events culminate, and the processes of recovery and restoration commence.[22]

The null hypothesis was rejected because patients with symptomatic apical periodontitis and symptomatic irreversible pulpitis had varying degrees of postoperative discomfort following obturation with root canal sealers based on epoxy resin, bioceramic, and bioactive glass.

This study's merits are its huge sample size, randomization, and double blinding.

The subjectivity of pain perception, which makes it a subjective experience for each person, is one of the study's primary shortcomings. Furthermore, not all population groupings could be well represented by the results.

To determine the frequency of discomfort following endodontic therapy and how it affects the quality of life associated with dental health, more research is required. To improve the statistical significance of the results, more extensive randomized clinical studies that meet the same standards as this one are also recommended.

## CONCLUSION

Within the confines of this study, bioceramic-based Bio-C Sealer Ion$^+$ caused far less postoperative discomfort following root canal therapy than epoxy resin-based AH Plus and bioactive glass-based Nishika Canal Sealer BG. Additional research is necessary to corroborate the findings of this study using alternative base endodontic sealers.

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Nil.

### Conflicts of interest
There are no conflicts of interest.

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