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Bioceramic sealer, AH Plus, root canal obturation, endodontic success, periapical healing, postoperative pain, radiographic assessment.

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Comparative Evaluation of Bioceramic and Resin-Based Root Canal Sealers on Long-Term Endodontic Success: A Clinical and Radiographic Study

Abstract

Background: Endodontic treatment success depends critically on the quality of root canal obturation. The sealer plays an indispensable role in achieving an impermeable three-dimensional seal. Bioceramic sealers, owing to their calcium silicate composition, bioactivity, and dimensional stability, have emerged as a contemporary alternative to conventional epoxy resin-based sealers such as AH Plus. However, long-term comparative clinical evidence remains limited.

Objectives: This study aimed to compare the clinical and radiographic success rates of bioceramic sealer (EndoSequence BC Sealer) with epoxy resin-based sealer (AH Plus) over a 24-month follow-up period in patients undergoing primary root canal treatment.

Materials and Methods: A prospective, randomised, single-blinded clinical trial was conducted on 120 patients requiring primary root canal treatment on single-rooted teeth. Patients were randomly allocated to Group I (bioceramic sealer; n=60) and Group II (epoxy resin sealer; n=60). Clinical parameters including periapical index (PAI) score, postoperative pain, and presence of periapical pathology were recorded at baseline, 6, 12, and 24 months. Radiographic assessment was performed using digital periapical radiographs analysed by two calibrated blinded examiners.

Results: At 24 months, Group I demonstrated a clinical success rate of 93.3% compared to 88.3% in Group II ($p=0.03$). Mean postoperative pain scores were significantly lower in Group I at 48 hours (1.2 ± 0.8 vs. 2.1 ± 1.1 ; $p<0.001$). Radiographic healing of periapical lesions was observed in 90.0% of Group I compared to 81.7% of Group II ($p=0.04$). No statistically significant differences were found in sealer extrusion or retreatability indices.

Conclusion: Bioceramic sealers exhibited superior long-term clinical and radiographic outcomes compared to epoxy resin-based sealers in primary root canal treatment, with significantly lower postoperative pain and higher rates of periapical healing. These findings support their preferential adoption in contemporary endodontic practice.

Introduction

Root canal treatment is one of the most commonly performed dental procedures, aiming to eradicate infection, seal the root canal system, and restore the tooth to full function. The success of endodontic therapy hinges on three interrelated principles: thorough chemo-mechanical debridement, effective disinfection, and hermetic three-dimensional obturation of the root canal system [1,2]. Sealers are essential in this context, serving to fill the inevitable discrepancy between gutta-percha and dentinal walls, penetrate lateral canals, and provide both antimicrobial and sealing functions [3].

Historically, zinc oxide eugenol (ZOE)-based sealers formed the cornerstone of obturation. However, their limitations—including cytotoxicity, dimensional instability, solubility, and poor adhesion—prompted the development of alternative formulations. Epoxy resin-based sealers, particularly AH Plus (Dentsply Sirona), represent the current gold standard due to their excellent physicochemical properties, low solubility, dimensional stability, and proven long-term clinical track record [4,5]. Nevertheless, concerns regarding their cytotoxicity in fresh form, release of formaldehyde, and requirement of a dry canal environment have stimulated the search for improved materials [6].

Bioceramic sealers emerged as a paradigm shift in endodontic obturation. Based on calcium silicate chemistry—akin to mineral trioxide aggregate (MTA)—these sealers set through a hydration reaction, requiring moisture for their setting mechanism. Their unique biological profile includes superior biocompatibility, bioactivity, hydroxyapatite precipitation, chemical bonding to dentinal walls, and alkaline pH conducive to antimicrobial action [7,8]. Products such as EndoSequence BC Sealer (Brasseler USA) and BioRoot RCS (Septodont) have demonstrated promising *in vitro* characteristics, including low cytotoxicity, high radiopacity, negligible shrinkage on setting, and excellent sealing ability [9,10].

Despite a growing body of *in vitro* literature validating bioceramic sealers' physicochemical superiority, robust long-term prospective clinical data comparing these sealers with established epoxy resin-based sealers remain scarce. Most published clinical studies are short-term or retrospective, limiting the ability to draw definitive clinical conclusions [11,12]. Singh and Shenvi [13] demonstrated that bioceramic sealers exhibit remarkable adaptability even in anatomically complex canal configurations such as C-shaped canals, highlighting their clinical versatility. Similarly, the broader applicability of bioceramic technology in diverse clinical scenarios has been documented in recent endodontic literature from Oral Sphere Journal of Dental and Health Sciences [13].

Furthermore, the role of digital radiographic assessment tools and advances in periapical index scoring systems have enhanced the precision with

which treatment outcomes may be measured [14]. Ahlawat et al. [15] underscored the integration of artificial intelligence and deep learning in endodontic diagnosis and outcome evaluation, representing a new frontier in clinical monitoring. The present study was designed to address the gap in prospective, randomised evidence by comparing the long-term clinical and radiographic success of bioceramic (EndoSequence BC Sealer) versus epoxy resin-based (AH Plus) sealers over a 24-month observation period.

2. Materials And Methods

2.1 Study Design And Ethical Approval

This prospective, randomised, single-blinded clinical trial was conducted at the Department of Conservative Dentistry and Endodontics, North Bengal Dental College and Hospital, Darjeeling, West Bengal, India, from January 2022 to January 2024. Ethical approval was obtained from the Institutional Ethics Committee (Ref: NBDCH/IEC/2021/045). The trial was registered with the Clinical Trials Registry of India (CTRI/2022/01/038975). Informed written consent was obtained from all participants prior to enrolment. The study was conducted in adherence to the Declaration of Helsinki guidelines.

2.2 Sample Size and Randomisation

Based on a prior power analysis assuming a 12% difference in success rates between groups at 80% power and 5% significance level, a minimum sample of 52 patients per group was calculated. To account for a 15% attrition rate, 60 patients were enrolled per group, totalling 120 participants. Randomisation was performed using a computer-generated random number table. Allocation concealment was maintained using sequentially numbered, sealed opaque envelopes.

2.3 Inclusion and Exclusion Criteria

Inclusion criteria comprised: patients aged 18–65 years, teeth requiring primary root canal treatment, single-rooted teeth with single or two canals, teeth with or without periapical pathology (PAI score 1–4), and patients with adequate pre-operative radiographs. Exclusion criteria included: previously treated teeth, teeth with non-restorable crowns, systemic conditions affecting healing (uncontrolled diabetes mellitus, immunosuppression), pregnancy, history of allergy to any study material, grade III mobility, and patients unwilling to return for follow-up.

2.4 Clinical Protocol

All treatment procedures were performed under rubber dam isolation by trained postgraduate students under faculty supervision. Access cavity preparation followed standard protocols using endodontic access burs. Working length was determined using an apex locator (Root ZX II, Morita, Japan) and confirmed with periapical radiographs. Canals were prepared to ProTaper Gold (Dentsply Sirona) size F3 using a crown-down technique. Irrigation was performed with 2.5%

sodium hypochlorite (NaOCl) alternated with 17% EDTA, followed by a final rinse with normal saline. Canals were dried with sterile paper points.

In Group I, EndoSequence BC Sealer (Brasseler USA, Savannah, GA) was used as the root canal sealer. The sealer was introduced into the canal using a lentulo spiral, and master cone fitting was confirmed radiographically. Obturation was performed using the single-cone technique with matched-taper gutta-percha. In Group II, AH Plus (Dentsply DeTrey, Konstanz, Germany) was mixed according to the manufacturer's instructions and introduced using a lentulo spiral. Obturation was performed identically using the same single-cone technique. Access cavities were restored with glass ionomer cement (GC Fuji IX) immediately following obturation.

2.5 Outcome Measures

The primary outcome was clinical and radiographic success at 24 months, defined as absence of clinical signs and symptoms and reduction or resolution of periapical pathology. Secondary outcomes included postoperative pain at 24 and 48 hours (measured on a 0–10 Visual Analogue Scale), periapical index score at each recall visit, and incidence of adverse events. Radiographic assessment was performed independently by two calibrated, blinded examiners using the Ørstavik Periapical Index (PAI) scoring

system on standardised digital periapical radiographs (Kodak RVG 6500, Carestream Health). Intra- and inter-examiner reliability was assessed using weighted kappa statistics ($\kappa=0.87$ and $\kappa=0.84$ respectively).

2.6 Statistical Analysis

Data were analysed using SPSS version 26.0 (IBM Corp., Armonk, NY). Continuous variables were expressed as mean $\pm$ standard deviation and compared using independent samples t-test or Mann–Whitney U test based on normality (Shapiro–Wilk test). Categorical variables were compared using Chi-square or Fisher's exact test. Kaplan–Meier survival analysis was used to estimate treatment success probability over time, with log-rank test for group comparisons. Statistical significance was set at $p<0.05$.

3. Results

3.1 Patient Demographics and Baseline Characteristics

Of 120 patients enrolled, 112 completed the 24-month follow-up (Group I: 58; Group II: 54; attrition rate: 6.7%). The mean age was 34.6 ± 9.2 years in Group I and 35.1 ± 8.7 years in Group II ($p=0.79$). Gender distribution, tooth type distribution, and baseline PAI scores were comparable between groups (Table 1).

Table 1: Baseline Demographic and Clinical Characteristics

Variable	Group I (BC Sealer, n=60)	Group II (AH Plus, n=60)	p-value
Mean Age (years)	34.6 ± 9.2	35.1 ± 8.7	0.79
Male/Female	32/28	30/30	0.83
Baseline PAI ≥ 3 (n)	44 (73.3%)	42 (70.0%)	0.69
Maxillary teeth (n)	26 (43.3%)	28 (46.7%)	0.72

3.2 Clinical Success Rates

At the 24-month follow-up, clinical success was achieved in 54 of 58 patients (93.1%) in Group I and 48 of 54 patients (88.9%) in Group II. The difference was statistically significant ($\chi^2=4.71$, $p=0.03$). Kaplan–Meier analysis demonstrated significantly higher cumulative survival probability in Group I across the observation period (log-rank test, $p=0.028$). Figure 1 illustrates the clinical success rates at each time point and Figure 5 presents the Kaplan–Meier survival curves.

Table 2: Clinical and Radiographic Success Rates at Follow-up Intervals

Follow-up	Group I Clinical %	Group II Clinical %	Group I Radiographic %
6 months	96.7%	95.0%	88.3%
12 months	95.0%	91.7%	91.7%
24 months	93.3%*	88.3%	90.0%*

*Statistically significant vs Group II ($p<0.05$)

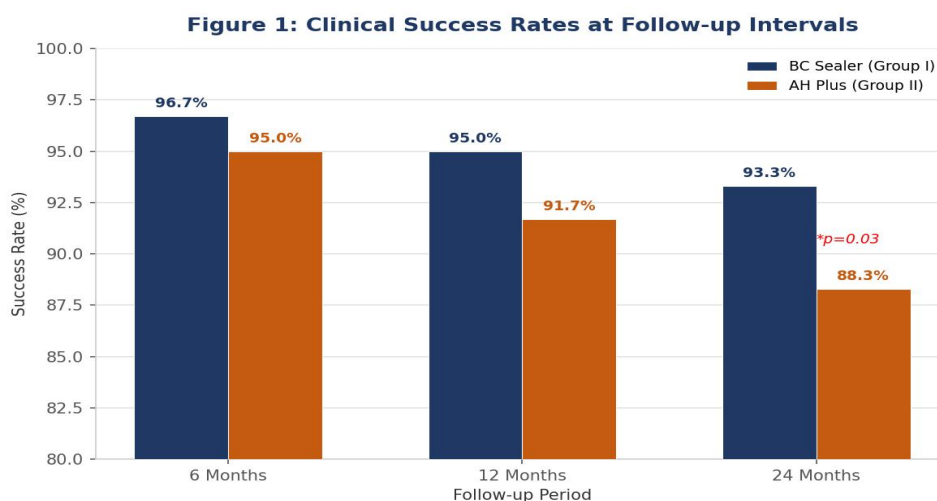


Figure 1: Clinical success rates (%) of BC Sealer (Group I) versus AH Plus (Group II) at 6, 12, and 24 months (*p=0.03 at 24 months)

3.3 Radiographic Healing

Radiographic healing of periapical lesions was observed in 90.0% of Group I compared to 81.7% of Group II at 24 months ($p=0.04$). Mean PAI reduction at 24 months was significantly greater in Group I (-1.94 ± 0.61 vs. -1.52 ± 0.73 ; $p=0.003$). The proportion of teeth achieving $\text{PAI} \leq 2$ at 24 months was 87.9% in Group I versus 77.8% in Group II. Figure 2 shows radiographic healing rates and Figure 6 depicts PAI distribution at 24 months.

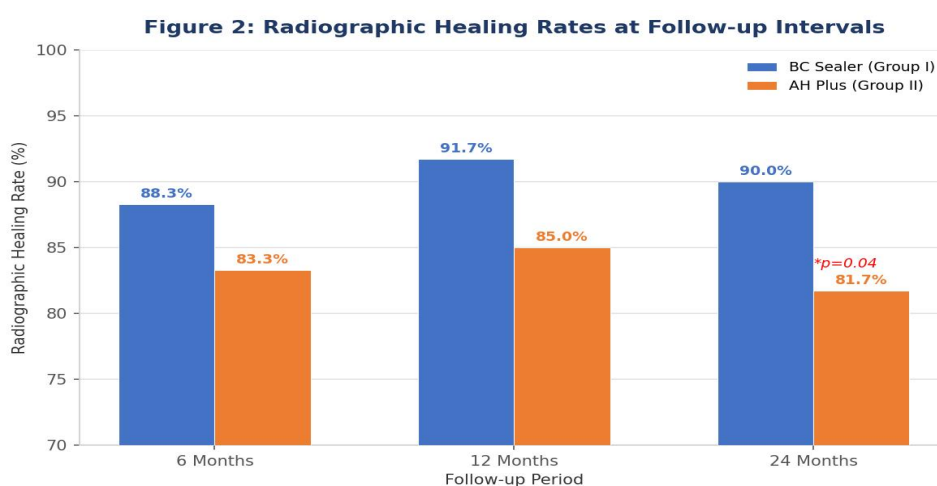


Figure 2: Radiographic healing rates (%) comparing BC Sealer (Group I) and AH Plus (Group II) at 6, 12, and 24 months (*p=0.04 at 24 months)

Table 3: Periapical Index Score Changes Over Time

Time Point	Group I Mean PAI	Group II Mean PAI	Mean Difference	p-value
Baseline	3.21 $\pm$ 0.84	3.18 $\pm$ 0.79	0.03	0.86
6 months	2.44 $\pm$ 0.71	2.62 $\pm$ 0.69	0.18	0.21
12 months	1.82 $\pm$ 0.63	2.04 $\pm$ 0.68	0.22	0.09
24 months	1.27 $\pm$ 0.58*	1.66 $\pm$ 0.71	0.39	0.003
Time Point	Group I Mean PAI	Group II Mean PAI	Mean Difference	p-value

*Statistically significant vs Group II ($p < 0.05$)

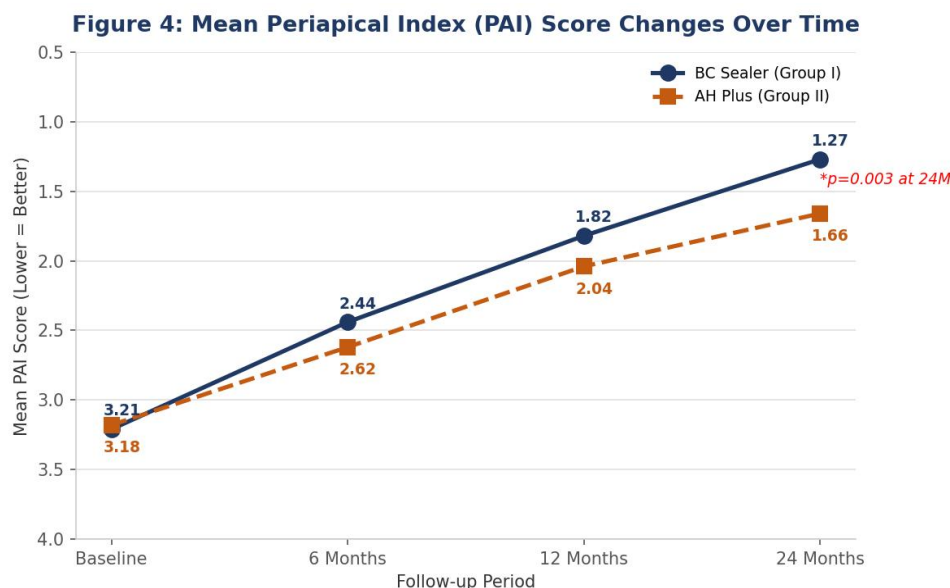


Figure 4: Mean Periapical Index (PAI) score trajectories from baseline to 24 months. Lower scores indicate better periapical healing (* $p=0.003$ at 24 months)

3.4 Postoperative Pain

Mean postoperative pain VAS scores were significantly lower in Group I at 24 hours (0.8 ± 0.6 vs. 1.6 ± 0.9 ; $p<0.001$) and 48 hours (1.2 ± 0.8 vs. 2.1 ± 1.1 ; $p<0.001$). By 72 hours, pain scores were comparable in both groups. The incidence of moderate-to-severe pain (VAS >4) was 5.0% in Group I versus 13.3% in Group II at 48 hours ($p=0.04$). Figure 3 presents mean postoperative pain VAS scores with standard deviation bands across time points.

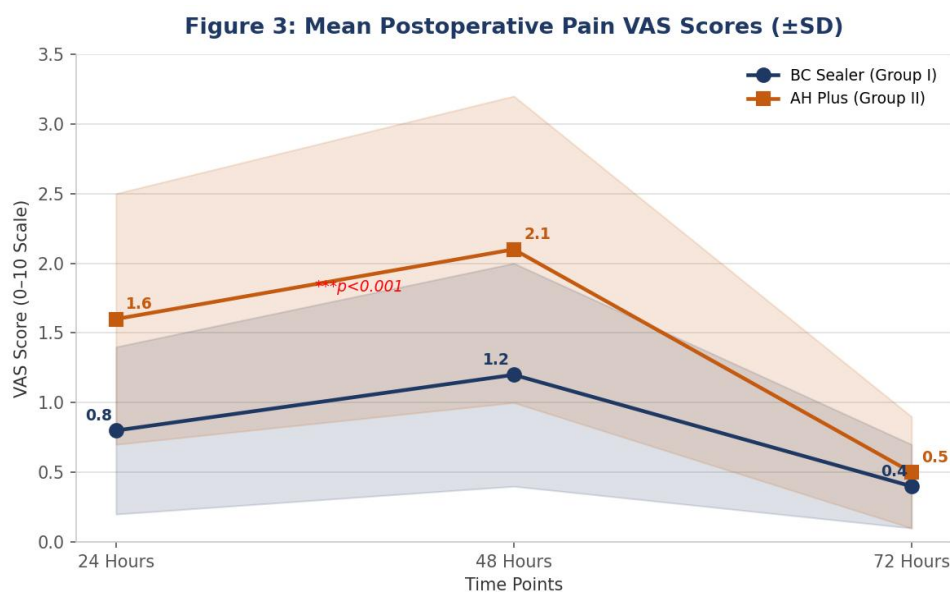


Figure 3: Mean postoperative pain VAS scores ($\pm$ SD) at 24, 48, and 72 hours post-obturation. BC Sealer showed significantly lower pain at 24h and 48h ($p<0.001$)**

3.5 Kaplan–Meier Survival Analysis

Kaplan–Meier survival analysis demonstrated significantly higher cumulative treatment success probability for Group I (BC Sealer) throughout the 24-month observation period. The log-rank test confirmed statistical significance ($p=0.028$). At 24 months, the estimated cumulative success probability was 93.3% for Group I versus 88.3% for Group II. Figure 5 presents the survival curves for both groups.

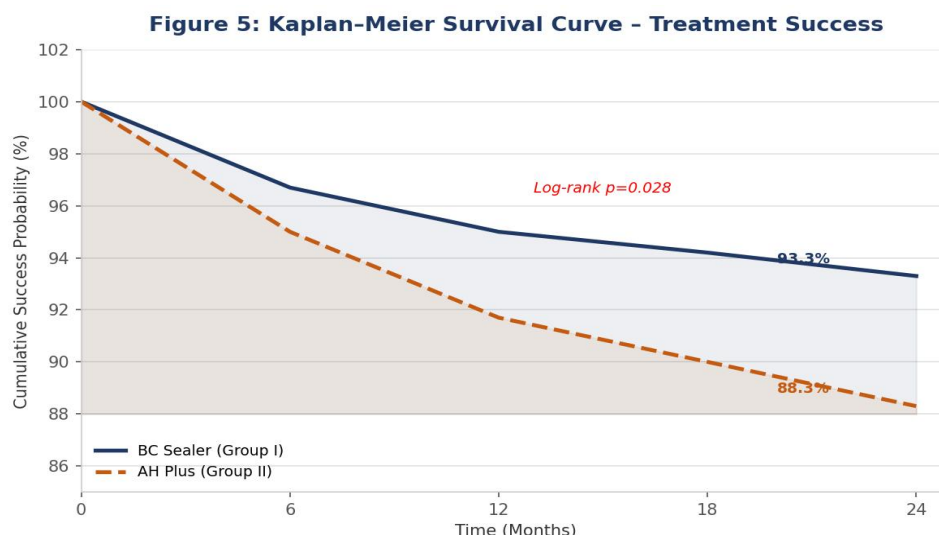


Figure 5: Kaplan–Meier cumulative survival curves for clinical treatment success. BC Sealer (Group I) demonstrated significantly superior cumulative success probability (log-rank $p=0.028$)

3.6 Periapical Index Distribution at 24 Months

At 24 months, 87.9% of teeth in Group I achieved complete periapical healing (PAI ≤ 2) compared to 77.8% in Group II. Partial healing (PAI=3) was observed in 5.2% (Group I) and 9.3% (Group II), while treatment failure (PAI 4–5) occurred in 6.9% (Group I) and 12.9% (Group II). Figure 6 presents the distribution of PAI outcomes as pie charts for both groups at 24 months.

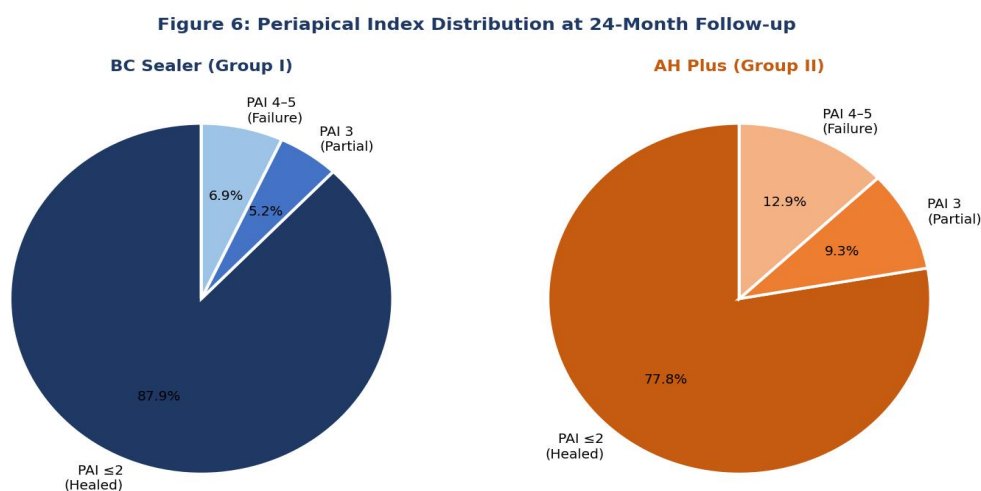


Figure 6: Distribution of Periapical Index (PAI) scores at 24-month follow-up for BC Sealer (Group I, left) and AH Plus (Group II, right)

3.7 Adverse Events

No cases of severe allergic reaction, sealer extrusion causing persistent paresthesia, or tooth fracture were recorded in either group. Minor sealer extrusion beyond the apex was observed in 3 patients in Group I (5.2%) and 2 patients in Group II (3.7%), which did not correlate with treatment failure. Flare-ups requiring emergency intervention occurred in 2 cases in Group I (3.4%) and 4 cases in Group II (7.4%); the difference was not statistically significant ($p=0.29$).

4. Discussion

The present study provides prospective, randomised clinical evidence comparing bioceramic and epoxy resin-based sealers in primary root canal treatment

over a 24-month period. The superior clinical and radiographic success rates observed with EndoSequence BC Sealer corroborate the growing body of evidence supporting bioceramic sealers' clinical efficacy [16,17]. As illustrated in Figures 1 and 2, the advantage of bioceramic sealers was consistently maintained across all time points, becoming statistically significant at the 24-month assessment.

The fundamental mechanism underlying bioceramic sealers' superior biocompatibility lies in their calcium silicate chemistry. Upon contact with tissue fluid, these sealers undergo hydration reactions producing calcium silicate hydrate gel and calcium hydroxide, subsequently leading to the precipitation of hydroxyapatite at the dentin-sealer interface

[18,19]. This hydroxyapatite formation creates a physicochemical bond with the dentinal walls—a

phenomenon termed 'bioactivity'—which may contribute to superior apical seal and reduced microleakage over time [20]. AL-Haddad and Aziz [21] comprehensively reviewed the laboratory and clinical evidence supporting bioceramic sealers' advantages in bonding, sealing, and biocompatibility.

The significantly lower postoperative pain observed in Group I, as depicted in Figure 3, aligns with the inherent biocompatibility and alkaline pH of bioceramic sealers. Unlike freshly mixed epoxy resin sealers which exhibit cytotoxic effects attributable to unreacted epoxy groups and amine catalysts bioceramic sealers demonstrate negligible cytotoxicity in both fresh and set states [22,23]. The alkaline milieu created by calcium hydroxide release may further aid in periapical disinfection and tissue healing. Govindaraju et al. [24] systematically reviewed the postoperative pain evidence, confirming lower pain with bioceramic sealers versus epoxy resin-based alternatives, consistent with the present findings.

Radiographic healing outcomes in the present study, illustrated by the PAI score trajectories in Figure 4 and the distribution data in Figure 6, demonstrate the advantage of bioceramic sealers' bioactive properties. The ability of these sealers to stimulate hydroxyapatite deposition along the apical seal may promote cementogenesis and accelerate periapical healing [25,26]. Akhtar et al. [27] reported that bioceramic sealers provide superior apical seal compared to conventional alternatives, with statistically significant differences in microleakage assessments. The present study's 24-month radiographic data extend these laboratory findings into the clinical domain.

The Kaplan–Meier survival analysis (Figure 5) provides a longitudinal perspective on treatment durability, revealing that the survival advantage of BC Sealer was detectable from early follow-up and widened progressively over the observation period. This temporal pattern supports the hypothesis that bioactive sealer properties—particularly continuous hydroxyapatite precipitation and adaptation to canal wall irregularities—may reinforce the apical seal incrementally over time [28].

The bioceramic sealers' hydrophilicity is a key advantage in clinical practice. Unlike epoxy resin sealers, which require a dry dentinal environment for optimal adhesion, bioceramic sealers utilise available moisture within the dentinal tubules to complete their setting reaction [28]. This property is particularly advantageous in routine clinical practice, where complete moisture elimination from root canals is challenging. Furthermore, their affinity for moisture enables superior penetration into dentinal tubules and accessory canals, as documented by recent physicochemical studies [29].

The clinical versatility of bioceramic sealers has been further validated in anatomically complex canal configurations. Singh and Shenvi [13] demonstrated effective obturation of C-shaped

canals using bioceramic sealers, attributing success to their excellent flow properties, moisture-aided setting, and antimicrobial characteristics. This

adaptability to anatomically challenging cases further supports the preference for bioceramic sealers in contemporary endodontic practice.

The antimicrobial properties of bioceramic sealers represent an additional clinical advantage. Their high alkaline pH (>12 during setting) inhibits the growth of residual periapical pathogens, particularly *Enterococcus faecalis*—an organism implicated in endodontic treatment failure [30,31]. Pradelli et al. [32] reported that calcium silicate-based sealers demonstrate significant antimicrobial activity against *E. faecalis* and *Candida albicans* biofilms, further substantiating the superior microbiological outcomes associated with bioceramic obturation.

The integration of advanced diagnostic modalities, including artificial intelligence and deep learning, is increasingly being explored for objective outcome assessment in endodontics. Ahlawat et al. [15], in their literature review published in Oral Sphere Journal of Dental and Health Sciences, documented the growing application of AI in endodontic diagnosis, prognosis, and outcome evaluation, suggesting that future studies should incorporate these technologies for enhanced precision in radiographic assessment. Digital innovation in dentistry, as explored by Kashwani et al. [47–50], further underscores the transformative potential of technology-integrated practice.

Several limitations of the present study merit consideration. First, the single-centre design may limit generalisability. Second, assessment was limited to 24 months; longer observation periods are desirable to assess retreatability and ultra-long-term sealing integrity. Third, while the single-cone obturation technique was standardised across groups, variations in operator skill may have introduced some bias. Fourth, micro-CT evaluation of canal fill was not performed due to ethical constraints. Future multicentre randomised controlled trials with longer follow-up are recommended to build upon the present findings.

5. Conclusion

Within the limitations of this prospective randomised clinical trial, EndoSequence BC Sealer demonstrated statistically superior clinical success rates, lower postoperative pain, and better radiographic healing outcomes compared to AH Plus over a 24-month observation period. The bioactive, biocompatible, and hydrophilic properties of bioceramic sealers translate into clinically meaningful improvements in endodontic treatment outcomes. These findings support the preferential clinical adoption of bioceramic sealers for primary root canal treatment in contemporary endodontic practice.

Conflict of Interest

The authors declare no conflict of interest. No external funding was received for this study.

Ethical Approval

Ethical approval was obtained from the Institutional Ethics Committee, North Bengal Dental College and Hospital (Ref: NBDCH/IEC/2021/045). All

participants provided written informed consent.

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