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The effect of premixed bio-ceramic sealer versus standard sealer on post-obturation pain after single-visit endodontic therapy: a randomized clinical trial

Showq A. Salem [1 *], Nora Agila [2], Ali Ashames Ali [3]
[1, 2] Conservative and Endodontic Department, Faculty of Dentistry, Sirte University, Sirte, Libya
[3] Department of Dental Technology, Higher Institute of Medical Sciences and Technology, Bani Walid, Libya

تأثير لاصق البيوسيراميك المسبق الخلط مقارنة بلّاصق القياسي على الألم ما بعد علاج الجذور في جلسة واحدة: تجربة سريرية عشوائية

شوق عوض سالم [1*]، نورا عقيلة [2]، علي الشامس علي [3]
[2،1] قسم العلاج التحفظي وعلاج الجذور، كلية طب الاسنان، جامعة سرت، سرت، ليبيا
[3] قسم تقنية الاسنان، المعهد العالي للعلوم والتقنيات الطبية، بني وليد، ليبيا

[*]Corresponding author: showq.awad@su.edu.ly

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Abstract

Background: Postoperative pain frequently occurs following root canal treatment and is influenced by variables including pulp status, periapical condition, and the materials used for obturation. However, the specific impact of sealer type on post-obturation discomfort in vital mandibular premolars without periapical lesions has not been clearly established.

Aim: This study aims to compare post-obturation pain following single-visit endodontic therapy using a bioceramic sealer versus AH Plus sealer in vital mandibular premolars tooth requiring of endodontic therapy without periapical pathosis.

Materials and Methods: Forty vital mandibular premolars tooth (single root/canal) with Symptomatic Irreversible Pulpitis (SIP) were randomly allocated (1:1) to receive obturation using either a Bio-C sealer or an AH Plus sealer. All teeth were endodontically treated in a single visit utilized standardized instrumentation, irrigation, and obturation techniques. Post-obturation pain was documented with a 10-point Visual Analogue Scales (VAS) at 6, 24, 48, and 72 hours. Outcome data were statistically analyzed at a significance level of $p<0.05$.

Results: The tested groups demonstrated a significant reduction in postoperative pain over time ($p < 0.001$). Pain was maximised at 6 hours (1.55±0.51 for AH Plus, 1.50±0.51 for Bio-C sealer) and subsequently declined after 24 hours (1.46 ± 1.96 for AH Plus, 1.21 ± 2.09 for Bio-C sealer), with no discomfort reported at 72 hours (0.00±0.00 for both sealers). There were no statistically significant differences identified between the groups at 6, 24 and 72 hours ($p > 0.05$). At 48 hours, AH plus group exhibited statistically significant higher pain scores (0.54 ± 0.96) than Bio-C group (0.03 ± 0.02) ($P > 0.05$). Overall, the Bio-C group reported lower pain scores throughout the observation period.

Conclusion: The sealers evaluated in this study produced comparable levels of post-obturation pain, with no observable differences in either the intensity or incidence of pain experienced following single-visit treatments. This randomised clinical trial demonstrated that the pain intensity post-obturation starting from 6 hours and declined rapidly with time, irrespective to the type of sealer used.

Keywords: Bioceramic sealer, Postoperative pain, Single-visit endodontics, Visual Analogue Scale, Randomized clinical trial.

الملخص

يُعدّ الألم ما بعد العلاج أحد أكثر المؤشرات السريرية شيوعًا بعد علاج جذور الأسنان، ويتأثر بعوامل متعددة تشمل التشخيص اللُّبي، حالة النسج حول الذروة، وإجراءات التحضير والري والحشو. ولا يزال تأثير نوع لاصق الجذر في الأسنان الحيوية الخالية من الآفات حول الذروة غير محسوم بشكل واضح. تهدف هذه الدراسة السريرية العشوائية إلى مقارنة شدة الألم بعد العلاج في جلسة واحدة باستخدام لاصق البيوسيراميك المسبق الخلط مقابل لاصق إيبوكسي راتنجي تقليدي (AH Plus) في ضواحك سفلية حيوية مصابة بالتهاب لبّي غير عكوس. شملت الدراسة أربعين مريضًا (سن واحد لكل مشارك) ممن انطبقت عليهم معايير الاختيار، وتم توزيعهم عشوائيًا إلى مجموعتين متساويتين. نُفِّذت جميع العلاجات وفق بروتوكول سريري موحّد يشمل التحضير الآلي، والري، وتقنية التكثيف الحراري الرأسي للحشو. جرى تسجيل مستوى الألم باستخدام مقياس VAS عند 6، 24، 48، و72 ساعة بعد العلاج. أظهرت النتائج انخفاضًا تدريجيًا وذا دلالة إحصائية في شدة الألم لدى المجموعتين بمرور الوقت، حيث وصلت أعلى قيمة للألم عند 6 ساعات، تلتها استجابة تحسنية واضحة بعد 24 ساعة، وصولًا إلى غياب الألم تمامًا عند 72 ساعة. لم تُسجَّل فروق ذات دلالة إحصائية بين اللاصقين في معظم الفترات، باستثناء فترة 48 ساعة التي أظهرت فيها مجموعة الـ AH Plus مستويات ألم أعلى بشكل ملحوظ مقارنة بلاصق البيوسيراميك.

الخلاصة: أظهرت االلّاصقات المستخدمة نتائج سريرية متقاربة فيما يتعلق بحدوث وشدة الألم بعد علاج العصب في جلسة واحدة. تُشير هذه الدراسة السريرية العشوائية إلى أن شدة الألم بعد العلاج يبلغ ذروته خلال الساعات الأولى ثم يتراجع بسرعة مع الوقت بغض النظر عن نوع اللاصق المستخدم.

الكلمات المفتاحية: لاصق البيوسيراميك، الم ما بعد العلاج، علاج عصب في جلسة واحدة، مقياس التناظر البصري، تجربة سريرية عشوائية.

1. Introduction

Postoperative pain is among the most frequently patient-reported outcomes after endodontics therapy, with prevalence rates recoded among 3% and 58% across clinical studies [1, 2]. The occurrence and severity of post-treatment pain are influenced by several biological and procedural factors, including pulpal diagnosis, periapical status, canal preparation, irrigant extrusion, sealer extrusion, and obturation technique [3, 4]. Although vital teeth without periapical pathology generally have a more predictable healing process, patients may still experience postoperative discomfort due to mechanical irritation, chemical insult, or transient periradicular inflammation.

Root canal sealers can affect periodontal tissue across the apical foramina, accessary canals, thereby interfering with the healing capacity of periodontal area. Focal inflammation induced by these sealers can result in post-obteuration discomfort, and the intensity of such inflammatory reactions is influenced by factors including sealer composition [5, 6]. Multiple studies have demonstrated that bioceramic materials enhance the effectiveness of endodontic treatment. These components contribute to bioceramic sealers' resistance to leakage and biological compatibility. Additionally, bioceramic materials liberate substances with biological effect that induce intra-tubular bio-mineralisation in pre-osteoblasts and encourage odontoblastic differentiation, further improving endodontic outcomes [7, 8]. A resin sealers, such as AH Plus, are primarily composed of epoxy resins, filler particles, and amine hardeners. They have been widely recognized as the standard due to their dimensional stability, limited solubility, and sealing efficacy [9]. However, numerous studies have demonstrated that resin sealers can release cytotoxic by-products, including un-polymerised monomers and bisphenol-A diglycidyl ether. These by-products may induce oxidative stress and inflammatory responses in periapical cells [10, 11]. These effects contributed to post-obturation pain and delayed periapical healing [12, 13]. To mitigate this issue, bioceramic sealers have been recently developed with a reduced cytotoxic compound content compared to resin-based alternatives. Bioceramic sealers, predominantly consisting of calcium silicates, zirconium oxide, calcium phosphates, alumina, and bioactive glass, demonstrate exceptional biocompatibility, bioactivity, antibacterial properties, and the ability to form hydroxyapatite at the dentin interface [14, 15]. Their alkaline pH and mineralising potential may contribute to reducing periapical inflammation, particularly in cases with minimal pre-existing tissue irritation. While the use of calcium silicate-based sealers is gaining traction among clinicians, their efficacy in alleviating pain following non-surgical endodontic therapy remains inconclusive. Therefore, this randomised clinical study assesses post-obturation pain following single-visit endodontic therapy of vital first- or second-mandibular premolar teeth without periapical lesions. The study compares AH Plus sealer and Bio-C sealer under fully standardised instrumentation and obturation protocols, with eliminating variations in pulp status, periapical status, and tooth type. The study offers a focused assessment of the impact of sealers composition on early post-obturation pain.

2. Material and methods

2.1. Design of study and ethical consideration

The study was conducted as a randomized clinical trial with 2 parallel groups, allocated (1:1) to receive obturation utilized either AH Plus or Bio-C sealer to compare post-obturation discomfort following single-visit endodontic therapy. The trial protocol was approved by the Human Ethics Committee at Sirte University, Libya, under an assigned approval number (S.U.2025.3). All eligible patients provided written informed consent before inclusion. Estimation of sample size in accordance with data of prior study was conducted utilized G Power (3.1.9.4) software. It considered an error of alpha = 0.05 and a power of 0.85, and indicated a required sample size of 20 in each group. Assuming possible loss, 40 patients were enrolled in the study [16].

2.2. Sample selection

Patients aged 18–45 years requiring endodontic therapy for one first or second mandibular premolar tooth (single root/canal) with Symptomatic Irreversible Pulpitis (SIP) were enrolled. Diagnosis was confirmed through clinical examination and digital radiography. Forty patients (one tooth per patient) were selected from a private dental clinic in Sirte, Libya. All individuals meeting the inclusion and exclusion criteria were invited to patient. Pre-operative pain scores were recorded, and only patients with scores between 5 and 10 were involved in the study [17].

Inclusion criteria

- Patients aged 18–45 years.
- Vital premolar tooth diagnosed with symptomatic irreversible pulpitis (SIP)
- No periapical radiolucency (PAI = 1)
- Restorable tooth with complete root formation
- Ability to understand and record VAS scores

Exclusion criteria

- Necrotic pulp or any periapical lesion
- Facial swelling, sinus tract, or systemic infection
- Pregnant or medically compromised patients
- Previous endodontic treatment on the same tooth
- Teeth have calcified canals, open apices, resorption, or fractures

2.3. Randomisation and allocation concealment

Patients were randomly dividing to 2 groups utilized computer-generated randomisation. Allocation was concealed in numbered opaque envelopes, and each participant selected an envelope to determine group assignment. The trail flowchart is presented in Figure 1.

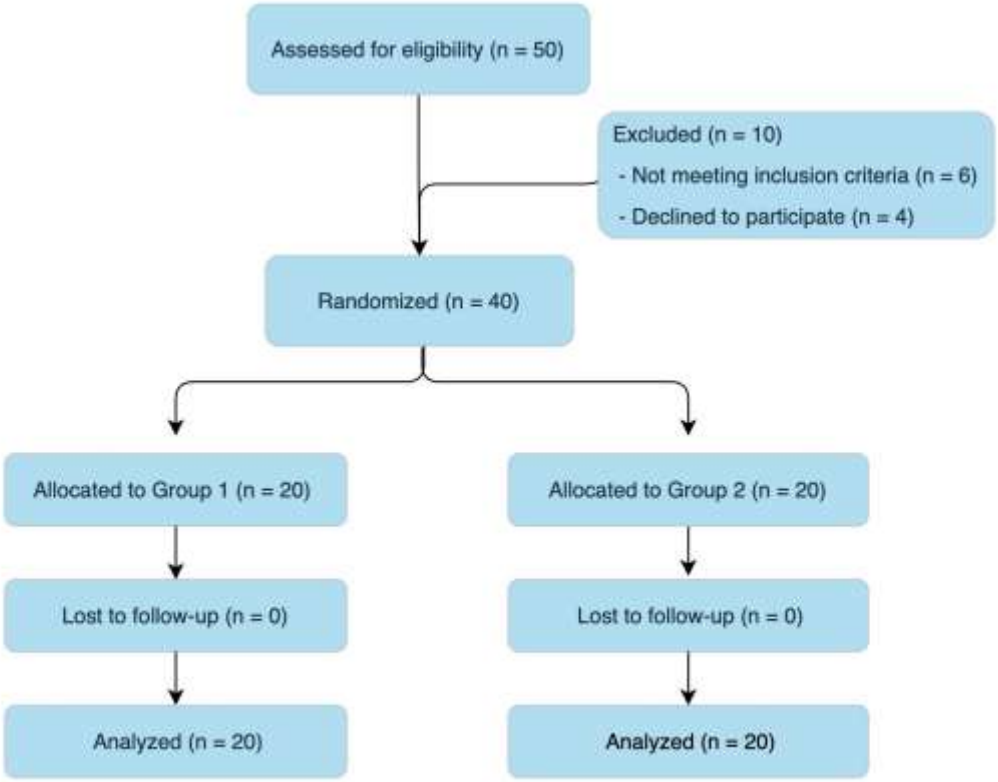

Figure 1: Flow chart of patient enrollment.

2.4. Root canal procedure

Under a rubber dam, single-visit endodontic treatment was performed by one experienced endodontist for standardisation. Local anesthesia utilized 4% Articaine (Septanest, Septodont) was administered by inferior alveolar nerve block. Coronal access cavities were performed for all teeth. Working length (WL) was estimated utilized an apex locator with a sterile K file #15 (Mani, Japan) and confirmed radiographically. Instrumentation was performed utilized the ProTaper Gold system (Dentsply Maillefer) in accordance with the manufacturer's guidelines with NSK endodontic motor (Dentsply Maillefer). A size 10 K-File was utilized to assess apical canal patency by entering it to 0.5 mm longer than WL following every file [18]. The apical foramen's size estimated the master apical file size, which varied between F3 and F4. A standardised irrigation regimen was used for all teeth, 2 mL 5.25% NaOCl after each file during instrumentation. Last irrigation with 5 ml 17% EDTA and 5 ml 5.25% NaOCl was carried out for 1 minute per canal. Irrigation was delivered utilized a 30-gauge side-vented irrigate needle with 20 mL total volume of NaOCl irrigant per canal. The appropriate master cone was selected utilized a two-dimensional digital radiograph. All canals were dried by utilizing sterile paper points. Participants were randomly divided into 2 groups in accordance the type of obturation material.

Group 1: AH Plus sealer (Dentsply Maillefer).

Group 2: Bioceramic-based sealer (Bio-C sealer, Angelus, Brazil)

The obturation material was selected at random from the envelope. Patients were blinded to the treatment received, while operator blinding was not feasible due to differences in sealer handling. Endodontic sealers were prepared and introduced as recommended by the manufacturers. In group 1, an equal 1:1 ratio of AH Plus base and catalyst was manually mixed and applied to the gutta-percha master cones, which were then placed in the prepared canals. In group 2, an intra-canal tip was utilized to apply Bio-C sealer into the middle part of the canal, then placement of the master cone. Following verifying the fit of the master gutta-percha and selecting appropriate pluggers for the warm vertical compaction method, obturation was performed with the gutta smart cordless obturation device in both groups. A coronal seal was established with a universal bonding agent and resin composite.

2.5. Postoperative pain assessment

A 0–10 visual analogue scale (VAS) was utilized to assess post-obturation discomfort, where 0 mean no pain while 10 mean extreme pain. Each patient documented the pain intensity at 6, 24, 48, and 72 hours following root canal obturation using the VAS card. Levels of pain were categorized as follows: None (VAS 0) – asymptomatic; Mild (VAS 1-3) – slight pain, no analgesics required; Moderate (VAS 4-6) – discomfort requiring analgesics; Severe (VAS 7-10) pain disturbing normal activity or sleep, with minimal or no effect from analgesics. Any value of 1 or higher was considered indicative of postoperative pain. Patients were also asked to report any use of analgesics postoperatively to ensure accurate pain assessment.

2.6. Statistical analysis

The statistical evaluation involved the use of frequency and percentage distributions for presenting ordinal and categorical data. The chi-square test was employed to analyze categorical variables. For continuous data, results were expressed as mean values associated with standard deviations (SD). The assumption of normality was tested utilized the Shapiro-Wilk test. Parametric data, such as age, was analyzed using an independent t-test. For ordinal and non-parametric numerical variables, Friedman's test was utilized, followed by the Nemenyi post hoc test and the Mann-Whitney U test for intragroup and intergroup comparisons respectively. Associations between variables were assessed using Spearman's rank-order correlation coefficient. $p<0.05$ was set as significant level within all tests. All analyses were conducted utilized R statistical software version 4.5.1 for Windows (R Core Team, 2025),

3. Results

3.1. Demographic data

All 40 patients returned their VAS cards after 72 hours and completed the study. Overall, 15were male and 25 were female patients, with ages ranging from18 to 45 years were enrolled. Both groups were comparable in terms of age and gender, and the patients' demographic profiles did not differ significantly (Table 1). Therefore, the potential influence of demographic factors was considered negligible. Of the 50 patients initially diagnosed, 40 were included and randomly assigned to two equal groups (20 per group). Group 1 consisted of 8 males and 12 females, while group 2 included 7 were males and 13 were females. The mean age in the AH Plus group was 29.25 ± 8.89 years, and in the Bio-C sealer group, it was 31.35 ± 8.87 years. There were no notable variation between the groups in terms of gender (p=0.743) or age (p=0.46).

Table 1: Demographic data and baseline characteristics, including intergroup comparisons

Parameter		Group 1 AH plus Sealer	Group 2 Bio-C Sealer	p-value
Gender [n(%)]	Male	8 (40.00%)	7 (35.00%)	0.743 ns
	Female	12 (60.00%)	13 (65.00%)	
Age (Mean±SD) (years)		29.25± 8.89	31.35 ± 8.87	0.46 ns

*; significant ($p<0.05$) ns; non-significant ($p>0.05$)

3.2. Pain assessment

3.2.1. Mean and standard deviation (SD) for VAS

Data for mean and standard deviation for visual analogue scale were recorded, statistically analyzed and provided in Table (2) and Figure. (2) for inter, intragroup comparisons of postoperative pain for the both sealers.

***A-Inter-group comparisons**:*

There were no notable differences between AH Plus and Bio-C Sealer groups at 6, 24, and 72-hours intervals. However, at 48-hours interval the AH Plus Sealer group exhibited significantly higher VAS pain scores. The

maximum score of post-obturation pain was recorded at 6 hours post-procedure, with pain severity declining significantly in both groups after 24 hours (P < 0.05). (Figure 2)

B-Intra group comparisons:

1. ***AH plus:***

Measurements taken at distinct periods revealed a significant difference (p<0.001). The greatest value was observed at the 6-hours (1.55 ± 0.51), followed by 24 hours measurement (1.46 ± 1.96), then 48 hours (0.54 ± 0.96), with the minimum score recorded at 72 hours (0.00 ± 0.00). Post hoc pairwise comparisons confirmed that the 6-hours values were significantly higher than those obtained from any other time points (p<0.001). Additionally, the values recorded at 24 and 48 hours were significantly higher than those at 72 hours (p<0.001). (Figure 2)

2. ***Bio-C sealer****:*

The data collected at distinct periods revealed a significant difference (p<0.001). The highest value was recorded at the 6-hours (1.50 ± 0.51), followed by the 24-hours measurement (1.21 ± 2.09), then 48-hours (0.03 ± 0.02), and finally, the minimum score observed at 72 hours (0.00 ± 0.00). Post hoc pairwise comparisons confirmed that the values at 6 hours were significantly higher than those recorded from any other time (p<0.001). Additionally, the results revealed that values at 24 hours were substantial higher than those recorded at both 48 and 72 hours (p<0.001). (Figure 2)

Table 2: Mean and standard deviation (SD) for VAS. Inter, intragroup comparisons,

Time	VAS (Mean±SD)		p-value
	AH plus Sealer	Bio-C Sealer	
6 hours	1.55±0.51 ^{A}	1.50±0.51 ^{A}	0.766 ns
24 hours	1.46 ± 1.96 ^{B}	1.21 ± 2.09 ^{B}	0.70 ns
48 hours	0.54 ± 0.96 ^{B}	0.03 ± 0.02 ^{C}	0.028*
72 hours	0.00±0.00 ^{C}	0.00±0.00 ^{C}	NA
P-value	<0.001*	<0.001*	

NA: Not Applicable, Values with different superscript letters within the same vertical column are significantly different *; significant (p<0.05) ns; non-significant (p>0.05)

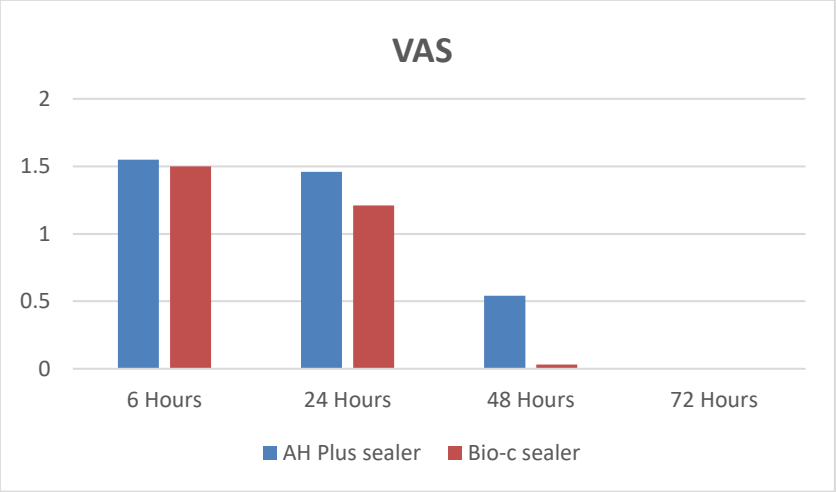

Figure 2: Bar chart showing mean and standard deviation values of VAS for different groups

3.2.2. Frequencies and percentages for VAS

Data for frequencies and percentages for visual analogue scale were recorded, statistically analyzed and presented in Table (3) for inter, intragroup comparisons of postoperative pain for the both sealers.

A-Intergroup comparisons:

A comparison among the groups revealed no notable differences at the 6, 24, and 72-hour time points. Whereas a significant difference was detected at the 48-hours, where the AH Plus group demonstrated a higher incidence of pain.

B-Intragroup comparisons:

1. ***AH plus:***

A significant variation was found among the values recorded at the distinct periods ($p < 0.001$). Post hoc analysis revealed that the 6-hours value differed significantly from all other time points ($p < 0.001$), and that the 24- and 48-hour measurements differed significantly from the 72-hours measurement ($p < 0.001$)

2. ***Bio-C sealer :***

The measurements recorded at the different time intervals demonstrated a significant variation ($p < 0.001$). Post hoc analysis revealed that the value recorded at 6 hours differed significantly from all other time points ($p < 0.001$). In addition, measurements recorded at 24 hours were significantly different ($p<0.001$) from those recorded at 48 and 72 hour time points.

Table 3: Frequencies and percentages for VAS**.** Inter, intragroup comparisons,

Times	Scores	n(%)		p-value
		Group 1 AH Plus	Group 2 Bio-C Sealer	
6 hours	(0)	0 (0.00%) ^{A}	0 (0.00%) ^{A}	0.766 ns
	(1)	7 (35 %)	8 (40 %)	
	(2)	13 (65 %)	12 (60 %)	
24 hours	(0)	9 (45 %) ^{B}	10 (50 %) ^{B}	0.70 ns
	(1)	11 (55 %)	10 (50 %)	
	(2)	0 (0.00%)	0 (0.00%)	
48 hours	(0)	12 (60 %) ^{B}	18 (90 %) ^{C}	0.028*
	(1)	8 (40 %)	2 (10 %)	
	(2)	0 (0.00%)	0 (0.00%)	
72 hours	(0)	20 (100.00%) ^{C}	20 (100.00%) ^{C}	NA
	(1)	0 (0.00%)	0 (0.00%)	

NA: Not Applicable, Values with different superscript letters within the same vertical column are significantly different *; significant ($p<0.05$) ns; non-significant ($p>0.05$)

4. Discussion

The current randomised, controlled, and prospective clinical study examined the appearance of post-obturation discomfort following single-visit endodontic therapy of first or second mandibular premolar teeth with symptomatic irreversible pulpitis, using either an AH Plus sealer (as a control) or a Bio-C bioceramic sealer. Post-obturation pain is a frequent side effect associated with endodontic therapy. It is challenging to pinpoint the exact cause of post-obturation pain as it can be influenced by various factors, including periradicular and pulpal status, age, gender, type of tooth, pre-endodontic treatment pain, and procedural factors such as cleaning and shaping technique, irrigation, and obturation technique [1,19, 20]. The initiation of post-obturation pain can often be linked to biological (microorganisms) or non-biological (mechanical or chemical) influences [19]. Researches have indicated that post-obturation pain may impact as many as 69% of patients [2, 21, 22]. Post endodontic pain typically arises from acute inflammation affecting the periradicular tissues. It typically manifests a few hours following the endodontic therapy and may be influenced by various factors [23]. Understanding the underlying causes of this pain is crucial, as implementing suitable preventive strategies can greatly minimize the occurrence

of this troubling and clinically unfavorable complication. Key factors influencing post-obturation pain include the number of treatment visits [21], the choice of irrigation used [24], the cleaning and shaping technique [25], the occlusal adjustment [26], and the type of obturation material have all been observed to be correlated with post-obturation discomfort following endodontic therapy [27]. Additionally, the extrusion of sealer during obturation procedure has been reported to cause cytotoxic effects on periapical tissues, resulting in periapical inflammation, necrosis, and pain [28]. The chemical component of endodontic sealers is crucial in influencing the degree of tissue reaction [29]. To attain the highest level of standardization, only mandibular premolar teeth exhibiting a straight, single-root, single-canal configuration were included in the sample collection.. This tooth category exhibits simpler anatomy, fewer confounding mechanical variables, and minimal baseline inflammation, allowing for a more precise assessment of the biological impact of sealer type alone. While the sealer chemistry may influence biological behavior, postoperative pain may be more susceptible to other factors such as pulpal status, apical pathology, and technical standardization. For that reason, this trial exclusively included vital teeth that had been diagnosed with symptomatic irreversible pulpitis. To enhance standardization among the specimens, the study used the same instrumentation systems, same irrigation protocol and same obturation technique. A single-visit treatment was conducted to diminish the number of visit for treatment and remove any possibility influence of intra-canal medicament.on post-obturation discomfort. Among the various root canal obturation methods, the warm vertical compaction technique is commonly favored by endodontists [30]. This approach provides closer adaptation to the wall of root canals with minimal gaps and reduced radiographic translucencies. [30, 31, 32]. The endodontic sealers are typically categorized in accordance their content, involving resin, calcium hydroxide, mineral trioxide aggregate, and glass ionomer. AH Plus, a resin sealer, is widely regarded as the gold standard due to its superior physicochemical properties, though it lacks bioactivity [33, 34]. Consequently, alternative endodontic sealers, particularly bioceramic sealers, have garnered significant attention in recent years due to their numerous merits, including enhanced bioactivity for periapical healing and biocompatibility [35]. Previous studies have shown that bioceramic sealers have better biological, physical and chemical properties than conventional sealers [36], as evidenced by a retrospective analysis which demonstrated a total success rate of 90.9%.[37]. Bio-C. Sealer is a pre-mixed, ready-to-use bioceramic sealer that includes a composition of calcium silicates, calcium oxide, calcium aluminate, iron oxide, zirconium oxide, silicon dioxide, and a dispersing agent in its composition. The manufacturer states that this sealer possesses bioactivity and biocompatibility [38]. Pain severity was examined utilized the Visual Analogue Scale (VAS), chosen for its straightforward application, ease of patient communication, and proven reliability in pain evaluation [39].

The findings of this study demonstrated that pain scores at 6, 24, and 72 hours did not differ significant between the AH Plus Sealer and Bio-C Sealer groups. Our results revealed that the bioceramic sealer consistently demonstrated lower pain values than the resin-based sealer at all tested intervals. Both groups exhibited a rapid decline in pain after 24 hours, with minimal discomfort by 48 hours. These findings align with many recent clinical studies, such as Elemam et al. [40],who recorded that the Bio-C and AH Plus sealers did not differ significant in post-obturation pain at different intervals, despite varying obturation techniques and the pulpal state of the tested teeth, which were diagnosed as asymptomatic apical periodontitis. The findings of this study were in full agreement with those of Graunaite et al. [41] and Troiano et al. [42], who investigated how bioceramic and AH Plus sealers influence the occurrence and severity of post-obturation pain. Their findings indicated that both types of sealers performed similarly when efforts were made to minimize other treatment-related irritants. Additionally, the systematic review conducted by Jamali et al. [43] revealed that bioceramic and resin sealers demonstrate similar trends in both the frequency and severity of pain following obturation. Their findings highlight comparable effects of these sealers on the intensity and incidence of post- obturation discomfort. Our results showed a significant difference between the Bio-C and AH Plus sealers at 48-hours, with higher values for the AH plus sealer. This was in full agreement with Alsayed Amin et al. [44], who found no significant differences at 24 and 72 hours, but a significant difference between AH Plus sealer and bioceramic sealer at 48 hours when both were used with an identical warm vertical compaction technique. The bioceramic sealer group consistently exhibited lower pain values than the resin-based sealer group at all measured interval. This difference could be linked to the unique biological behavior of the sealer. Resin sealers, such as AH Plus, can release unreacted monomers and bisphenol-A diglycidyl ether, which are associated with oxidative stress and inflammatory responses in periapical tissues [10, 15]. In contrast, bioceramic sealers demonstrate superior biocompatibility and bioactivity due to their calcium silicate composition, elevated pH, and capacity to induce hydroxyapatite deposition [14, 45]. However, most clinical studies, including the present trial, indicate minimal or no difference in patient-reported pain, suggesting that when instrumentation, irrigation, and obturation are standardised, sealer selection may have a limited effect on short-term pain outcomes. The low pain levels observed in both groups may also be attributed to the clinical model employed. Vital teeth without periapical radiolucency generally present with lower baseline inflammation, reduced microbial load, and a decreased risk of apical extrusion, all of which are factors known to

influence postoperative discomfort [1, 3]. Furthermore, premolar teeth typically have simpler anatomy compared to molars, reducing procedural complexity and the likelihood of postoperative symptoms [15]. These factors may account for the consistently low pain values across both groups.

.The findings confirm that the majority of post-obturation pain manifests within the initial 6 to 24 hours, with a substantial reduction thereafter, as previously demonstrated by Elemam et al. [40] and Alsayed Amin et al. [44]. The most intense pain following endodontic therapy typically observed within first 6 hours. This brief period of post-treatment discomfort is linked to the generation of reactive oxygen species (ROS), triggered by leakage of un-polymerized components from the endodontic sealer during its initial setting phase, which lasts roughly 24 hours. Among commonly used sealers, AH Plus and bioceramic sealers have setting times of approximately 7 hours and 4 hours, respectively [46, 47]. Calcium silicate-based sealers exhibit enhanced biocompatibility compared to the AH Plus. This superiority in biocompatibility stems from the cytotoxic effects of AH Plus, which are linked with the release of its components such as amines and epoxy resin. Subsequent researches indicated that small amounts of formaldehyde (3.9 ppm) are released immediately after mixing, attributed to the sealer's cytotoxicity. Despite these findings, laboratory assessments like filter diffusion tests and MTT assays demonstrate minimal cytotoxicity following 24 hours of mixing. Nonetheless, clinical research often contradict these in vitro observations, highlighting the complexity of translating laboratory data into predictable clinical outcomes [48, 49, 50].

Limitations and Future Directions

It is important to recognize several limitations. The study population was restricted to vital mandibular premolar teeth affected by symptomatic irreversible pulpitis, limiting the generalizability of the findings to anterior teeth, molars, or necrotic cases. Although sealer extrusion was unlikely in this tooth category, it was not assessed radiographically. Pain assessment relied on self-reported measures, introducing potential subjectivity. Additionally, operator blinding regarding sealer type was not feasible, and the same operator conducted postoperative pain assessment. Tthese factors must be taken into account when analyzing the results.

Further studies should investigate outcomes in necrotic cases or in teeth with periapical lesions, and evaluate long-term healing and radiographic outcomes. Additionally, studies should assess patient-centered outcomes, such as quality of life, and compare various bioceramic sealer formulations. Likewise, more studies are needed with larger sample size and other tooth types to reach a more definitive conclusion. Longer follow-up intervals is needed to evaluate the post-obturation discomfort of endodontic sealers.

5. **Conclusion**

The sealers evaluated in this study produced comparable levels of post-obturation pain, with no observable differences in either the intensity or incidence of pain experienced following single-visit treatments. This randomised clinical trial demonstrated that the pain intensity post obturation starting from 6 hours and declined rapidly with time, irrespective to the type of sealer used. These findings support existing evidence that both bioceramic and resin-based sealers provide similar postoperative comfort when used with modern instrumentation and obturation protocols. Further research recommended determining whether sealer type influences outcomes in necrotic, multi-rooted, or apically pathologic teeth, where biological and mechanical factors may differ.

Disclaimer

The article has not been previously presented or published, and is not part of a thesis project.

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Compliance with ethical standards

Disclosure of conflict of interest

The authors declare that they have no conflict of interest.

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