

## EVALUATION OF POST OPERATIVE PAIN AFTER OBTURATION USING TWO DIFFERENT TYPES OF SEALER: A RANDOMIZED CLINICAL TRIAL

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**Objective:** This study aims to assess the impact of bioceramic and resin based sealers on postendodontic pain after endodontic treatment performed in single visit.

**Methods:** In this study, forty patients in need of endodontic therapy were chosen. single visit endodontic treatment was done for the patients but obturated using two different types of sealers: in Group 1: AH Plus sealer was used and in Group 2: EndoSequence BC sealer Hiflow was used. Post endodontic pain was measured for 12,24,48 and 72 hours postoperatively.

**Results:** Both sealer groups' post-endodontic pain levels did not significantly differ from one another.

**Conclusions:** Both AH Plus and Endosequence BC sealer Hiflow perform similarly in terms of the incidence and severity of postoperative pain in teeth with symptomatic irreversible pulpitis (SIP). Endodontics performed in a single visit can utilise any type of both sealers without worrying about pain following obturation.

**Keywords:** EndoSequence BC sealer Hiflow, AH plus, postoperative pain, visual analogue scale

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**Conflicts of interest:**

The authors declare no conflicts of interest

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## ÉVALUATION DE LA DOULEUR POST-OPÉRATOIRE APRÈS OBTURATION À L'AIDE DE DEUX TYPES DIFFÉRENTS DE SCELLANT : UN ESSAI CLINIQUE RANDOMISÉ

**Objectif:** Cette étude vise à évaluer l'impact des scellants biocéramiques et à base de résine sur la douleur post-endodontique après un traitement endodontique réalisé en une seule visite.

**Méthodes:** Quarante patients nécessitant un traitement endodontique ont été choisis. un traitement endodontique en une seule visite a été effectué pour les patients mais obturés à l'aide de deux types différents de scellants : dans le groupe 1 : le scellant AH Plus a été utilisé et dans le groupe 2 : le scellant EndoSequence BC Hiflow a été utilisé. La douleur post-endodontique a été mesurée pendant 12, 24, 48 et 72 heures après l'opération.

**Résultats:** Les niveaux de douleur post-endodontique des deux groupes de scellants ne différaient pas significativement les uns des autres.

**Conclusions:** Les scellants AH Plus et Endosequence BC Hiflow fonctionnent de manière similaire en termes d'incidence et de gravité de la douleur postopératoire dans les dents avec pulpite irréversible symptomatique (SIP). L'endodontie réalisée en une seule visite peut utiliser n'importe quel type de scellant sans se soucier de la douleur après l'obturation.

**Mots clés:** EndoSequence BC sealer Hiflow, AH plus, douleur postopératoire, échelle visuelle analogique

## Introduction

One of the most frequent side effects of endodontic therapy is pain, which is defined as “an unpleasant psychological and sensory experience associated with or suggested by actual or probable tissue injury” [1]. It is multifactorial and influenced by host response, infection, physical injury, working length accuracy, apical foramen enlargement, number of visits, analgesic consumption, gender, filling technique, kinematics, bacterial extrusion and type of sealer used during obturation [2-5]. The postoperative pain prevalence is 3-58% after endodontic treatment [6] and is significantly higher (6%) in mandibular molars than in maxillary molars (2.2%) [7].

Symptomatic irreversible pulpitis is the most common endodontic disease and is characterized by sharp pain due to stimulus or lingering spontaneous pain with thermal changes due to inflamed vital pulp [8].

Endodontic treatment consists of three important steps: access cavity, mechanical preparation and obturation. The obturation phase consists of two important components: a gutta percha cone and sealer. Owing to the importance of sealers many studies have been carried out to evaluate the impact of sealers on pain following endodontic treatment.

Many types of sealers have been introduced to the market for obturation, but recent innovations have led clinicians to use resin and bioceramic sealers owing to their advantages. Resin sealers are classified as methacrylate-based or epoxy resin-based sealers. Epoxy resin-based sealers are commonly used because of their micro-retention to dentin in the root canal, good apical seal, and low solubility. The original formula is modified and commonly used [9]. The reactive epoxide ring, that polymerizes these rings, is an epoxy resin-based sealers characteristic. AH Plus (Dentsply, De Trey GmbH, Konstanz, Germany) resin sealer is the gold standard.

Bioceramic-based sealers in endodontics have only been available for the last three decades and are composed of calcium phosphates, calcium silicates, zirconia, hydroxyapatite, glass ceramics, bioactive glass, and alumina. According to previous studies these sealers are biocompatible, non-resorbable, highly antibacterial and adhesive to dentinal walls [10].

Endosequence BC sealer (Brasseler, Savannah, GA, USA) is one of the oldest bioceramic sealers introduced to the market. Endosequence BC sealer HiFlow (Brasseler, Savannah, GA, USA) is a bioceramic sealer with the same composition as the Endosequence BC sealer which is calcium silicates, zirconium oxide, calcium phosphate, calcium hydroxide, filler, and thickening agents, except for a higher zirconium dioxide percentage and a lower percentage of calcium ions modifying the radio-opacity of the material, decreasing the viscosity and enhancing the flow with heat [11]. The manufacturer recommends its use in warm vertical compaction technique.

Bio ceramic sealers have been claimed to cause less postoperative pain than resin sealers due to their shorter setting time. Studies have validated this claim, as reactive oxygen species (ROS) formation during the time needed during the setting of resin sealer may cause pain due to unpolymerized components [12].

Since measuring pain is difficult due to the fact that it is extremely subjective and greatly influenced by the patient's emotional state, various techniques have been developed including the Verbal Descriptor Scale (VDS) pain thermometer, Numeric Rating Scale (NRS) and visual analogue scale (VAS) which is recorded by a single handwritten mark at each location along a 10-cm line, representing a continuum between the two ends of the scale: “worst pain” is situated on the right end (10 cm), and “no pain” is located at the left end (0 cm) of the scale. These are self-reported assessments of symptoms. Ten

Measurements from the scale's left end (starting point) to the patients' marks were recorded in centimetres and interpreted as pain level. These values can be used to compare pain between patients with similar conditions or to track the progression of pain for a patient [13].

Considering previous studies and the importance of obturation components in postoperative pain, this study was designed and executed for the evaluation of the impact of using two different sealers during obturation on postoperative pain with adoption of the null hypothesis assuming that following endodontic treatment, there is no difference in post-operative pain between resin and bioceramic sealers.

## Materials and Methods

The research ethics committee, British University in Egypt, Faculty of Dentistry approved the protocol of the trial with an approval code (21-036), It was carried out in accordance with the ethical standards established by the 1964 Helsinki Declaration, in addition this clinical trial and the format of the informed consent were registered in [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (ClinicalTrials.gov Identifier: NCT05728783) and submitted in compliance with CONSORT clinical trial guidelines.

### Sample size calculation

Using an alpha ( $\alpha$ ) level of 0.05 and a beta ( $\beta$ ) level of 0.85, the sample size based on previous research was determined using G power (3.1.9.4) software. Forty participants (n=40) were included in the sample [14].

### Patient Selection

Patients requiring root canal treatment of one multirrooted tooth diagnosed with Symptomatic Irreversible Pulpitis (SIP) were included. Confirmation of the Diagnosis was based on digital radiography and clinical examination. Patients aged from 18–40 years, who presented with a multiple-rooted mandibular

molar with SIP were included. Patients requiring endodontic therapy were selected from the Hospital of the British University in Egypt over a period of 6-months extending from February to August 2023. According to a set of inclusion and exclusion criteria, all patients who met the inclusion criteria were invited to participate in the study. All patients received oral and written information regarding the study and signed an informed consent form. Patients were also asked to mark their pre-operative pain score before starting treatment. Patients who scored between 5-10 were included in the trial [15].

**Inclusion criteria:**

- The age of the patients ranged from 18 to 40.

- Patients whose teeth have been diagnosed with SIP.
- A normal periapical condition on radiography, or one with little to no periodontal ligament (PDL) space widening, confirming the normal periapical state.
- Restorable teeth
- Periodontally free teeth.

**Exclusion criteria:**

- Non-restorable teeth
- Patients with poor health whose systemic complications could change the course of treatment
- Teeth with immature roots.
- Teeth with periapical lesions or apical periodontitis.
- teeth with Necrotic pulp
- Teeth requiring numerous visits for treatment

**Patient allocation and randomization**

The participants were randomly allocated into two equal groups, using computer-generated randomization. In an opaque envelope the sequential numbers generated were placed, prior to the intervention each participant was asked to choose an envelope to identify the intervention group to which they were assigned, 45 patients were diagnosed but 40 patients were included in the study according to the calculated sample size (n=40) as shown in the consort flow chart Figure 1.

**Treatment Protocol**

The treatment was performed at the endodontic clinic in the hospital in the Faculty of Dentistry, British University in Egypt by an experi-

**CONSORT Flow Diagram**

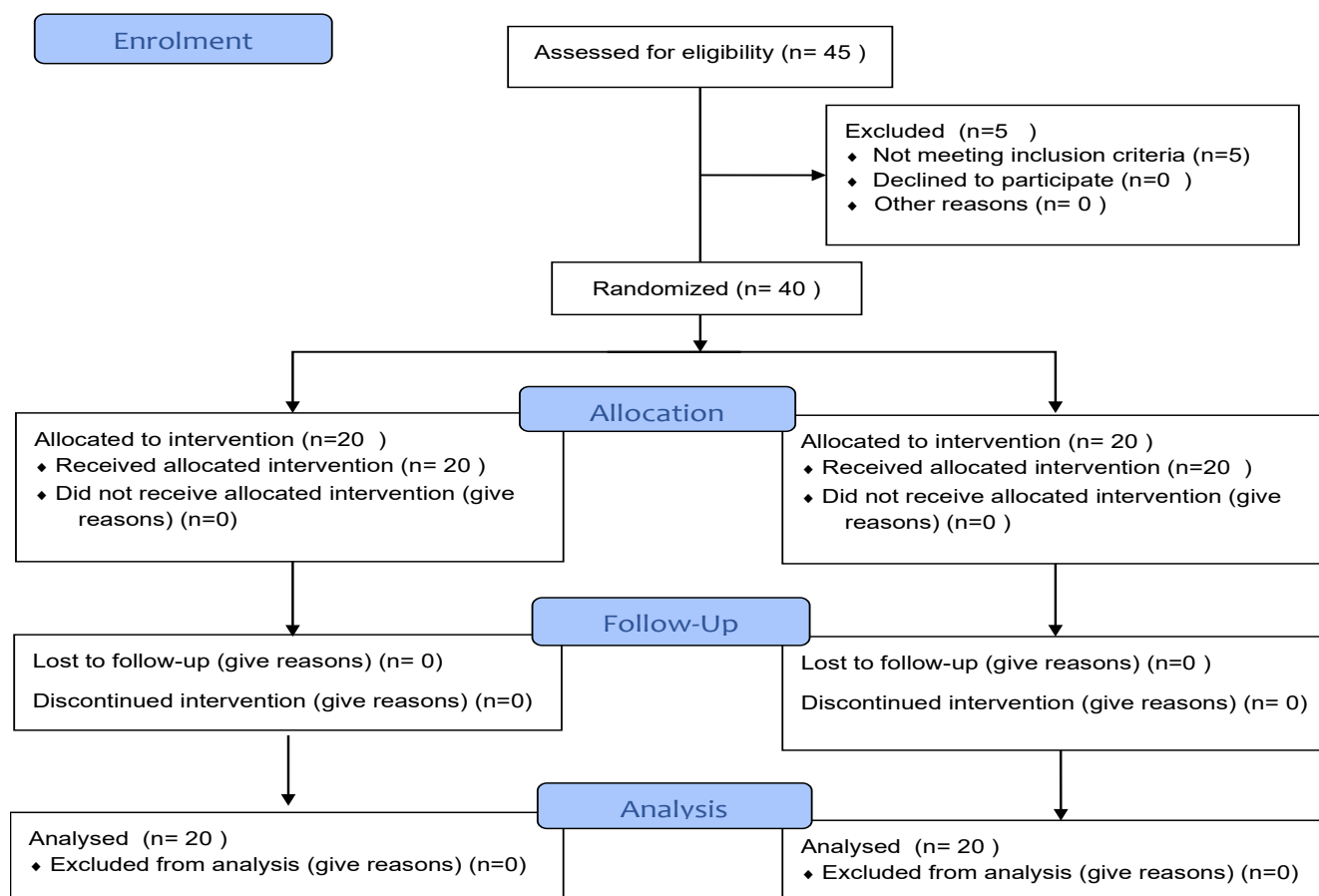


Figure 1. illustrating consort flow diagram.

enced endodontist (Primary Investigator). Single-visit endodontic treatment was performed to reduce the number of procedures and possible impact of intracanal medication. Tooth was locally anesthetised before treatment using inferior alveolar nerve block with Local anesthesia of 1.8ml of 4%Articaine HCl with epinephrine 1:100,000(INIBSA S, Barcelona, Spain)

The entire procedure was performed under rubber dam (Hygienic,Akron,OH) isolation. The WL was established using Root ZX II apex locator (J Morita, Kyoto, Japan) with #10 or larger K-files (Mani, Japan) and confirmed on the radiograph. For creating the glide path #10 and #15 manual files (Mani, Japan) were used and ProTaper Gold system (Dentsply Maillefer) was used for canal shaping according to the manufacturer's recommendations using NSK Endo-mate DT endodontic motor (Dentsply Maillefer). patency was checked using file #10 after each file. 2 mL 5.25% sodium hypochlorite (NaOCl) was used for canal irrigation using side vented needles 30-Gauge tips (Fanta, China) after each file. The apical foramen's size determined the size of the master apical file, which ranged from F3 to F4., master cone check was done using 2-dimensional digital radiograph.

The root canals of the patients in group 1 were obturated and sealed using gutta-percha and an epoxy resin-based sealer (AH Plus) (Dentsply Maillefer). The root canals of group 2 were obturated and sealed with bioceramic Endo sequence BC sealer Hiflow (Brasseler, Savannah, GA, USA) and gutta-percha. The choice of the material was random according to the envelop and the

patient was not aware of the treatment they received, while the operator could not be blinded due to the dissimilarities in appearance of the obturation materials. As instructed by the manufacturer, the root canal sealers were mixed and introduced into the canals.

After drying with paper points, in group 1 an even ratio of 1:1 from the base and catalyst of the AH plus was manually mixed on a paper pad with a spatula and introduced into the canal on the master cone. In group 2, the sealer's introduction to the canal was through intracanal tip from the sealer syringe, followed by the master cone. After the master gutta percha cone was checked and the accurate sizes of the fitting pluggers to be used in the vertical compaction was chosen allowing depth of the first plugger to reach the last apical 5 mm, the canals were obturated by warm -vertical condensation technique using the gutta smart cordless obturation system (Dentsply Maillefer) in the two groups. As recommended by the manufacturers 180°C was the heated plugger's temperature for AH Plus group while 150°C was the heated plugger's temperature for Endosequence BC sealer Hiflow group. An Intermediate Restorative Material (Cavit™,3M) was used to seal the coronal cavity.

#### Assessment of postoperative pain

The primary outcome of this study was pain following obturation. A visual analogue scale (VAS) (Figure 2) was handed to each patient to document the level of pain at 12, 24, 48, and 72 hours after treatment. Participants were asked to indicate on a line of 100 mm how much pain they felt following obturation, split into ten equal segments, ranging

from 0 (no pain) to 100 (extreme pain). The participant's pain was defined as the difference between "no pain" and the mark. the patients were contacted four times in a row, and the recorded pain scores were obtained. To ensure accurate pain assessment and prevent their exclusion and replacement from the group, they were asked to report whether they had taken painkillers postoperatively.

#### Statistical Analysis

Frequency and percentage numbers were used to display both ordinal and categorical data. The chi-square test was used to analyse categorical data. The mean and standard deviation figures were used to present numerical data. The Shapiro-Wilk test analysis was performed to determine their normality. Using an independent t-test, parametric data (age and obturation time) were examined. Ordinal and non-parametric numerical data were analysed using Friedman's test followed by the Nemenyi post hoc test for intragroup comparisons, and the Mann-Whitney U test for intergroup comparisons. Using Spearman's rank order correlation coefficient, correlations were examined. For every test, the significance threshold was set at  $p < 0.05$ . R statistical analysis software, version 4.3.1 for Windows1, was used to conduct the statistical analysis. (R Core Team (2023). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria)

#### Results

##### I- Demographic data

Intergroup comparisons and summary statistics for demographic data and baseline characteristics are presented in table 1.

The study concluded 45 patients for diagnosis but was conducted on 40 cases that were randomly and equally allocated to each of the studied groups (i.e., 20 cases each).

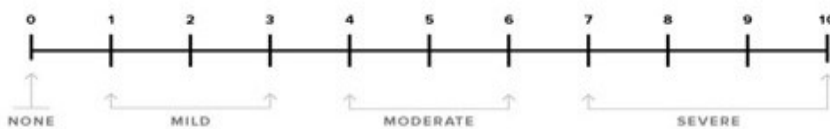


Figure 2. Visual Analogue Scale

In both groups, there were 10 males and 10 females. The mean age of the cases in AH plus was (30.40±6.71) while in Endosequence BC sealer Hiflow group it was (27.90±7.72) years. There was no significant difference between either groups regarding gender (p=1) and age (p=0.281).

### Pain assessment

#### Mean and standard deviation (SD) for VAS

Inter, intragroup comparisons, are presented in table 2 and figure 3

##### A-Inter group comparisons:

Upon comparing the groups, the results showed no significant differences thorough the 12, 24 and 72 hours intervals while there was a significant difference in the 48 hours intervals results of higher values with AH plus sealer.

##### B-Intra group comparisons:

###### • AH plus:

The values obtained at various intervals showed a significant difference (p<0.001). the 12-hour measurement yielded the highest value (1.50±0.51), followed by 24 hours (0.60±0.50), then 48 hours (0.40±0.50), while the lowest value was found at 72 hours (0.00±0.00). Values assessed at 12 hours were significantly greater than values measured at other times, according to post hoc pairwise comparisons (p<0.001). Furthermore, they demonstrated that values obtained after 24 and 48 hours were significantly greater than values obtained after 72 hours (p<0.001).

###### • Endosequence BC sealer Hiflow :

The values obtained at various intervals showed a significant difference (p<0.001). the 12-hours measurement yielded the highest value (1.55±0.51), followed by 24 hours (0.60±0.50), then 48 and 72 hours (0.00±0.00). Values assessed at 12 hours were significantly greater than values measured at other times, according to post hoc pairwise comparisons (p<0.001). Furthermore,

Table 1: Intergroup comparisons and summary statistics for demographic data and baseline characteristics

Parameter	AH plus	Endosequence BC sealer Hiflow	p-value
Gender [n (%)]	Male	10 (50.00%)	1ns
	Female	10 (50.00%)	
Age (Mean±SD) (years)	30.40±6.71	27.90±7.72	0.281ns

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

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

Time	VAS (Mean±SD)		p-value
	AH plus	Endosequence BC sealer Hiflow	
12 hours	1.50±0.51 <sup>A</sup>	1.55±0.51 <sup>A</sup>	0.766ns
24 hours	0.60±0.50 <sup>B</sup>	0.60±0.50 <sup>B</sup>	1ns
48 hours	0.40±0.50 <sup>B</sup>	0.00±0.00 <sup>C</sup>	0.002*
72 hours	0.00±0.00 <sup>C</sup>	0.00±0.00 <sup>C</sup>	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)

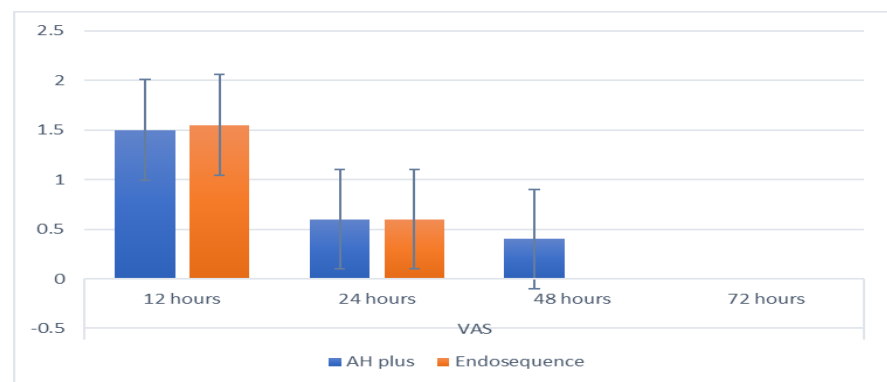


Figure 3: Bar chart showing mean and standard deviation values of VAS for different groups.

they demonstrated that values obtained after 24 hours were substantially greater than those obtained after 48 and 72 hours (p<0.001).

#### Frequencies, and percentages for VAS

Inter, intragroup comparisons, are presented in table 3 and figure 4

##### A-Intergroup comparisons:

Upon comparing the groups, the results showed no significant differences thorough the 12, 24 and 72 hours intervals while there was a significant difference in the 48 hours intervals results of higher pain incidence in the AH plus sealer.

**B-Intragroup comparisons:**• **AH plus:**

The values obtained at various intervals showed a significant difference ( $p < 0.001$ ). Post hoc pairwise comparisons showed value measured at 12 hours to be significantly different from values measured at other intervals ( $p < 0.001$ ). In addition, they showed values measured at 24 hours and 48 hours to be significantly different from value measured at 72 hours ( $p < 0.001$ ). Values assessed at 12 hours were considerably different from values measured at other intervals ( $p < 0.001$ ), according to post hoc pairwise comparisons. Furthermore, they demonstrated that the values obtained after 24 and 48 hours differed significantly from the values obtained after 72 hours ( $p < 0.001$ ).

• **Endosequence BC sealer Hiflow:**

The values obtained at various intervals showed a significant difference ( $p < 0.001$ ). Values assessed at 12 hours were considerably different from values measured at other intervals ( $p < 0.001$ ), according to post hoc pairwise comparisons. Furthermore, they demonstrated that values obtained after 24 hours differed considerably ( $p < 0.001$ ) from those obtained after 48 and 72 hours.

**Obturation time**

Intergroup comparisons and mean and standard deviation (SD) for obturation time (mm:ss.ms) are presented in table 4 and figure 5

AH plus (00:07:50±00:00:10.76) had a higher value than Endosequence (00:07:43.5±00:00:15.82) nonetheless, the difference ( $p = 0.137$ ) did not reach statistical significance.

**Discussion**

This clinical trial was conducted to evaluate the postoperative pain in mandibular molars with symptomatic irreversible pulpitis after endodontic treatment and obturation using two different types of sealers.

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

Time	Score	n (%)		p-value
		AH plus	Endosequence BC sealer Hiflow	
12 hours	(0)	0 (0.00%) <sup>A</sup>	0 (0.00%) <sup>A</sup>	0.766ns
	(1)	10 (50.00%)	9 (45.00%)	
	(2)	10 (50.00%)	11 (55.00%)	
24 hours	(0)	8 (40.00%) <sup>B</sup>	8 (40.00%) <sup>B</sup>	1ns
	(1)	12 (60.00%)	12 (60.00%)	
	(2)	0 (0.00%)	0 (0.00%)	
48 hours	(0)	12 (60.00%) <sup>B</sup>	20 (100.00%) <sup>C</sup>	0.002*
	(1)	8 (40.00%)	0 (0.00%)	
	(2)	0 (0.00%)	0 (0.00%)	
72 hours	(0)	20 (100.00%) <sup>C</sup>	20 (100.00%) <sup>C</sup>	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 ( $p > 0.05$ )

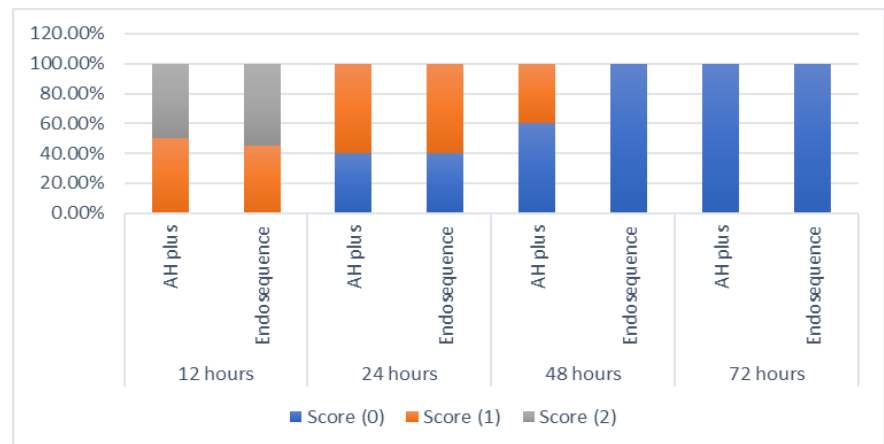


Figure 4. Stacked bar chart showing distribution of VAS scores.

**Table 4: Intergroup comparisons, mean and standard deviation (SD) for obturation time (mm:ss).**

Operation time (Mean±SD) (mm:ss.ms)		p-value
AH plus	Endosequence BC sealer Hiflow	
07:50±00:10.76	07:43.5±00:15.82	0.137ns

\* significant ( $p < 0.05$ ). ns: non-significant ( $p > 0.05$ )

Post-endodontic pain is one of the most frequent complaints of patients following root canal therapy. This discomfort may affect patients' everyday activities and quality of life. Therefore, it is crucial that medical professionals handle patients' post-treatment discomfort in addition to managing pain throughout randomized controlled

trials [14]. Pain is highly subjective therefore, the methodology used for its assessment is critical [16], in this study, as well as in many other studies VAS was used for the assessment. Patients can score their pain more broadly using categories like "mild," "moderate," and "severe" on the contrary VAS is easier to use as it is a numerical rating scale allow-

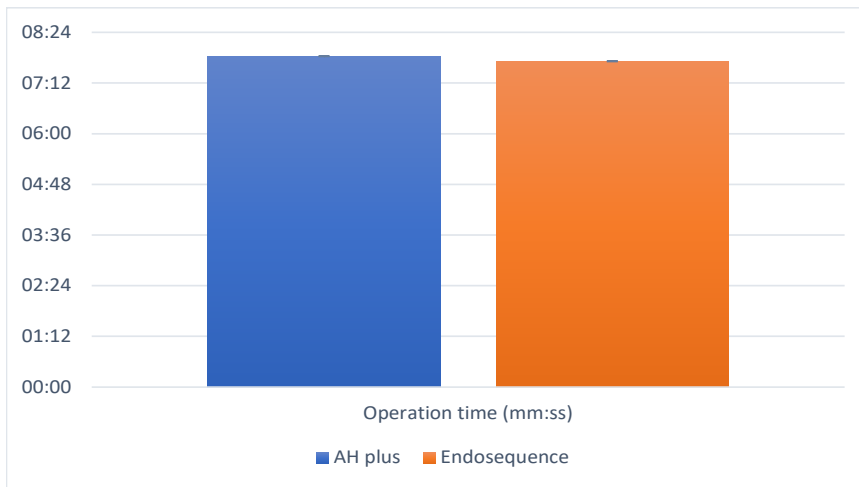


Figure 5. Bar chart showing mean and standard deviation values of obturation time (mm:ss) for different groups.

ing higher accuracy in the scores recorded by the patients.[17]. owing to the early eruption of molars and the high susceptibility to caries and pulp exposure, only multirooted teeth were chosen for this investigation. Rotary instruments, which are known to induce less postoperative pain, were used to clean the canals [18]. Single-visit root canal treatment (RCT) has become a common practice that offers several advantages, including fewer operative procedures, reduced flare-up rate, and avoidance of inter-appointment leakage risk through temporary restorations [19]. In endodontics, postoperative pain is indicative of the activation of local inflammatory response of the periapical tissues [20].

This reaction is linked to the production of biochemical mediators such reactive oxygen species (ROS) [21]. In vivo research has demonstrated a connection between oxidative stress and, more precisely, reactive oxygen species (ROS) and inflammatory pain [22, 23]. After root canal sealers were applied in vitro to human pulp cells, the amount of reactive oxygen species (ROS) produced rose four to seven times [24]. The resin-based AH Plus emits harmful monomers such bisphenol A diglycidyl ether and was mildly cytotoxic. [25]. Although noticeably less than that of AH Plus, the bioceramic sealer EndoSequence BC sealer hiflow [Brasseler, Savannah, GA USA] also showed cytotoxicity [26].

The findings of this study are consistent with those of Graunaite et al. (2018) [27], Troiano et al. (2018) and others [28], who examined the impact of bioceramic (Total Fill) and resin-based (AH Plus) root canal sealers on the incidence and severity of postoperative pain. They discovered that sealers showed comparable performance in these areas when other treatment-related irritants were reduced. Furthermore, Jamali et al. (2021) [29] found that bioceramic and resin-based root canal sealers display comparable patterns in terms of the frequency and intensity of pain post-obturation after conducting a systematic review on the impact of these materials on postoperative intensity and pain occurrence.

## Conclusion

AH Plus and Endosequence BC sealer Hiflow have similar performances in terms of the occurrence and intensity of postoperative pain in teeth with SIP without apically extruded material. Without worrying about pain following endodontic treatment either of the two sealers can be used in a single visit treatment.



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