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Effect of an Experimental Resin-based Sealer (Resil) and AH-26 on Postoperative Pain: A Randomized Controlled Clinical Trial

Nazanin Zargar [a], Hengameh Ashraf [a], Saeede Zadsirjan [b], Farhood Najafi [c], Siavash Jafari Semnani [d], Omid Dianat [e], Pegah Mehrabinia [d*]

[a] Department of Endodontic, School of Dentistry, Shahid Beheshti University of Medical Sciences, Tehran, Iran; [b] Iranian Centre for Endodontic Research, Research Institute for Dental Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran; [c] Department of Resin and Additives, Institute for Color Science and Technology, Tehran, Iran; [d] Department of Endodontics, Shahed University of Medical Sciences, Tehran, Iran; [e] Endodontic Division, Department of Advanced Oral Sciences and Therapeutics, School of Dentistry, University of Maryland, Baltimore, MD, USA & Private Practice, Irvine Endodontics, Irvine, California , USA

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**Corresponding author*: Pegah Mehrabinia, Department of Endodontics, Shahed University of Medical Sciences, Tehran, Iran.

E-mail: Dr.PMehrabinia.dds.msc@gmail.com

Introduction: One of the most common problems in endodontic treatments is post-treatment pain, and sealers might be one of the factors influencing the degree of pain following root canal therapy. The purpose of this study is to compare pain following endodontic treatment using an AH-26 resin sealer against the Resil experimental sealer in mandibular molars with irreversible pulpitis. **Materials and Methods:** One hundred patients with irreversible pulpitis in the mandibular first or second molar were randomly divided into two groups (n=50) based on the type of sealer applied. Two postgraduate students with at least five years of experience treated all patients. All patients had a single root canal treatment. Postoperative pain scores and analgesic consumption were assessed after 6, 12, 24, and 48 hours and 3, 4, 5, 6, and 7 days after the treatment. The data were statistically analyzed by Fisher's exact or Chi-Square test (to compare the distribution of qualitative variables in two groups), repeated measures ANOVA (to compare changes in pain intensity over time in two groups), Boneferronie (for pairwise comparisons), Friedman, Wilcoxon and Mann-Whitney tests (for assessment of the changes in pain scores over time). The generalized estimating equations (GEE) were used for assessing time and group effects. **Results:** There was no significant difference in postoperative pain between groups at any of the time points studied (P>0.05), and also for patient analgesic consumption between groups (P>0.05). Both groups recorded the maximum pain levels in the first 6 hours. For each subsequent day postoperatively, the odds ratio (OR) of not using analgesics was 2.078. **Conclusion:** Resil and AH-26 perform similarly in terms of the occurrence and intensity of postoperative pain in mandibular molar teeth with irreversible pulpitis.

Keywords: AH-26; Endodontic Treatment; Endodontic Sealers; Resil

Introduction

Postoperative pain, defined as an unpleasant sensation for the patient after beginning root canal therapy, is one of the most common complications in endodontic treatment, with prevalence ranging from 3 to 58 percent in various studies [1-3]. Some factors such as age, gender, molars, mandibular teeth, preoperative pain, and periapical radiolucency, as well as some intraoperative factors such as prophylactic analgesics, number of visits, long-acting anesthesia, working length determination method (radiography or apex locator), instrumentation system, laser, occlusal reduction, may impress pain perception following endodontic therapy [4, 5]. Knowing these factors allows the dentist to choose techniques and materials that cause less pain [6].

The type of sealer applied impacts the intensity of pain felt following root canal therapy [7]. Sealers in the root canal communicate with periodontal tissues through the apical and accessory foramen and can affect the healing process in the periodontium [8]. Therefore, sealers can be expected to stimulate an inflammatory response and activate sensory neurons [9-11], which causes postoperative pain [12]. The AH-26 sealer with epoxy resin base (Dentsply, Tulsa Dental, Tulsa, OK, USA) is one of the

most widely used sealer among dentists [13, 14], which Schroder introduced as a canal filler [15]. This sealer is in the form of powder and liquid, with the powder containing bismuth oxide and hexamethylenetetramine (HMT) and the liquid (resin) containing bisphenol-a-diglycidyl ether [16]. HMT is decomposed in an aqueous solution or acidic media once these two components are mixed to create ammonia and formaldehyde [16]. This sealer has excellent flow and working time, as well as low solubility, and it efficiently adheres to the dentin wall [17-19]. The most crucial problem with the AH-26 sealer is shrinkage [20]. This sealer can also show cytotoxic effects due to formaldehyde production [21].

A novel resin sealer named Resil (Endodontic Department, Dental School, Shahid Beheshti University of Medical Sciences, Tehran, Iran) including calcium tungstate, zirconium oxide, Aerosol, bismuth oxide, titanium oxide, hexamine, and an epoxy resin was investigated. The results of these studies showed that Resil has a shorter setting time [22] and less cytotoxicity [23] compared to AH-26 sealer and is not significantly different from AH-26in terms of radiopacity, film thickness, and solubility [22]. Furthermore, compared to the AH-26 and AH-Plus sealers, this sealer demonstrated more significant antibacterial activity before and after setting [24]. As we know, sealer is an essential substance in endodontics treatment. However, the impact of this sealer on postoperative pain and comparing it to AH-26 has never been investigated. Since Resil sealer has demonstrated desirable laboratory characteristics, as well as the role of sealer in causing pain after treatment and the lack of conclusive evidence in this regard, the goal of this study was to compare the occurrence and intensity of postoperative pain following single-visit root canal treatment with Resil sealer *versus* AH-26 resin sealer in mandibular molars with irreversible pulpitis.

The following null hypotheses were evaluated in this study: *1)* There is no difference between two experimental groups in terms of frequency or degree of post-treatment endodontic pain. *2)* The consumption of the analgesics in the experimental groups after single-visit root canal therapy would be the same.

Materials and Methods

This controlled, double-blind, parallel-group, randomized clinical trial that was conducted with the approval of the Ethics Committee of the Shahid Beheshti University of Medical Science (Grant No.: IR.SBMU.DRC.1400.088), registered online (www.irct.ir, identification No.: IRCT20150720023253N5), and reported following the CONSORT clinical trial guidelines (Figure1). Assuming a first type error of the test α=0.05 and a second type error of the test β=0.2 (power=80%) and extracting the mean values of μ1=0.1 and μ2=0.4 and standard deviation σ2=0.6 and σ1=0.4 for the pain intensity variable from the study of Lopes *et al.* [25], the number of samples were calculated: 50 in each group, totaling 100.

Patients were selected from those referred to the School of Dentistry, Shahid Beheshti University of Medical Sciences from May 2021 to July 2022 who have mandibular first or second molars with irreversible pulpitis. The clinical diagnosis of irreversible pulpitis was based on clinical tests, including a positive response to electric pulp test (The Elements Diagnosis Units, SybroneEndo, Glendora, CA), moderate to severe responses to cold test (Roeko Endo-Frost; Roeko Langenau, Germany) (Visual analog scale (VAS)=40-100) and prolonged responses to cold test. The irreversible pulpitis was confirmed by the absence of hemostasis within 5-10 min after pulp exposure [26].

The Corah dental anxiety form (CDAS) published in 1969 proved to be a valuable and reliable indicator in clinical trials and was used to assess preoperative anxiety [27, 28]. Preoperative pain (using a cold test), access cavity preparation pain (AP), filling pain (FP) (VAS from 0 to 100), as well as supplementary infiltration anesthesia (ISA), periodontal ligament supplemental anesthesia (LSA), preparation duration (PD), and overall treatment duration (OTD) were all recorded for each patient. Inclusion and exclusion criteria are listed in Table 1. An informed written consent was obtained before recruitment.

Treatment procedures

All treatments were carried out by two postgraduate students with a minimum of 5 years of clinical experience. For patients meeting the inclusion criteria, the inferior alveolar nerve block anesthesia was first administrated using 2% lidocaine with epinephrine 1:80000 (Darou Pakhsh, Tehran, Iran) [29]. Tooth anesthesia was assessed following the response to the cold test. If the response was positive, supplementary anesthesia was applied and recorded. In the case of a negative response, the corresponding tooth was isolated with a rubber dam, then caries and prior restorations were removed with a high-speed diamond bur and water cooling. Vitality or pulp necrosis was confirmed after observing bleeding (or lack of bleeding) in the pulp chamber.

Teeth with irreversible pulpitis and the absence of periapical pathosis were confirmed radiographically and clinically, as well as the lack of hemostasis within 5-10 min after pulp exposure [26].

The root canal length was determined using an apex locator (Root ZX II; J Morita, Kyoto, Japan) and K-file number 8 or 10 (Dentsply Sirona, Ballaigues, Switzerland) and confirmed with periapical radiography. During the operation, apical patency was established and maintained with K-file number 10 [26]. The pain level experienced through the access cavity preparation and filling as well as preparation and overall treatment duration were also recorded. Canal preparation was performed using ProTaper

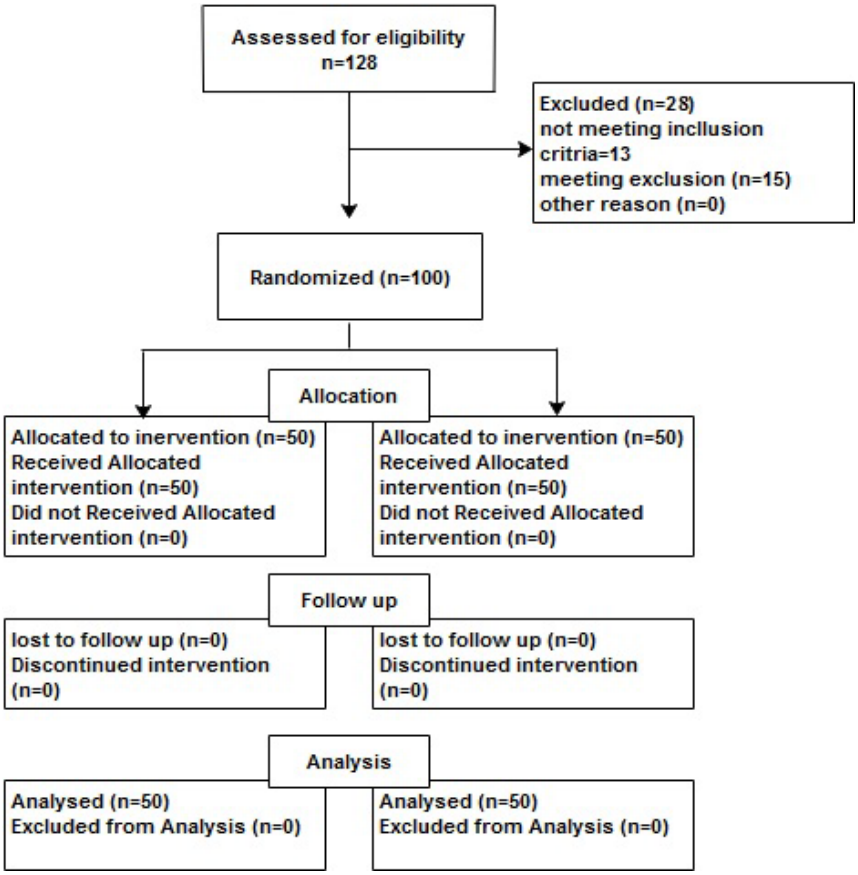

Figure 1. Flow diagram of Consort's checklist

Universal rotary system (Dentsply, Maillefer, Ballaigues, Switzerland). A S1 file was inserted into the canal with a brushing motion, 3 mm short of the predicted working length, followed by a SX file inserted into the canal with a brushing stroke two-thirds of its blade length, followed by S1, S2, and F1 files to the working length. The canal was then evaluated using an ISO #20 file. The preparation would be complete if it fits tightly at the apex, but if the ISO #20 file did not fit adequately at the apex, the instrumentation would be continued using the F2 file, and the canal would be examined with the ISO #25 file. Instrumentation is deemed accomplished if the file fits perfectly at the apex; otherwise, it is resumed with a F3 file [30]. Patients with a final apical size more than 25 in mesial canals and 40 in distal canals were excluded.

During instrumentation, irrigation was performed using 10 mL of 5.25 percent sodium hypochlorite (Morvabon, Tehran, Iran) applied with a side-vent closed-end 30-gauge needle (Endo Needle, M3, China) 1.5 mm shorter than the working length and moderate pressure (between each file 1-2 mL of irrigation solution was used). The canals were then flushed with 3 mL of 17% EDTA, 3 mL of 5.25% sodium hypochlorite, and 2 mL of serum before being dried with a sterile paper point [26]. Teeth with canals did not dry up, were excluded from the study.

Blinding and allocation concealment

Patients were randomly allocated into two groups using Permuted Block Randomization (based on the type of sealer used):

Group 1: patients with irreversible pulpitis and treated with AH-26 sealer

Group 2: patients with irreversible pulpitis and treated with Resil experimental sealer

To avoid bias, the allocation was disguised in opaque letters unsealed just before obturation by an irresponsible person in the treatment procedure. Before obturation, the operator was informed about the type of sealer applied.

The statistician who was blinded to the study procedure generates a random sequence for each block using Excel software (Microsoft Corporation, Redmond, WA, USA). Twenty-five blocks of four were produced. Following the random sequence, a nurse places the sealer and VAS charts in identical opaque bags labeled for each block and opened only after chemo-mechanical preparation and before obturation.

A single standard gutta-percha cone (Gapadent, Incheon, Korea) was fitted to each root canal, and its location was evaluated using a periapical radiograph [26]. The specified sealer was placed into the dried canals according to each group utilizing the master

gutta-percha cone coating technique. All canals were then obturated using the cold lateral condensation technique.

As an interim restoration, the coronal access cavity was filled with GIC glass ionomer (Fuji IX; GC, Tokyo, Japan). Teeth were permanently restored within two weeks after treatment.

Ibuprofen 400 mg (Gelofen; Jabberebne Hayyan, Tehran, Iran) was prescribed, and patients were advised to use it only in severe pain [31]. Patients who needed to take antibiotics were excluded from the study.

Post-operative pain evaluation

Visual analog scale was used for recording pain levels. Following treatments, patients were given two forms. The earliest form used VAS to record pain levels, with 0 indicating "no pain" and 100 indicating "unbearable pain." The second form was related to the frequency of analgesic medication use and consisted of a table with three options:

No pain or pain that does not require analgesic, 1: Moderate pain that is adequately managed by analgesics and does not interfere with daily activities or sleep, 2: Impaired daily activities result from intense pain that cannot be managed with analgesics [26].

Participants were instructed to fill out these two forms after 6,12, 24, and 48 h following treatment, as well as on the third, fourth, fifth, sixth, and seventh days; also, they were questioned over the phone and their VAS scores were recorded. Patients were instructed to call if they experienced severely uncomfortable.

Statistical analysis

Normality distribution of the quantitative variables were assessed using the Shapiro-Wilk test. Therefore, the equality of the distribution of background variables in two groups were checked using the Fisher exact test or Chi-Square test. If the data distribution is normal, repeated Measures ANOVA was used to compare the changes in pain intensity over time in two groups. Pairwise comparisons were performed using the Bonferroni method. Otherwise, Friedman, Wilcoxon, and Mann-Whitney tests were used. Generalized linear models or generalized estimating equations (GEE) were used to compare the difference between two groups over time. All statistical analyses were performed using SPSS statistics software (version 22.0; SPSS Inc., Chicago, IL, USA) (α=0.05).

Result

There were 128 eligible patients. Twenty-eight patients were excluded from this number. 13 for poor oral hygiene, and 15 refused to participate. Figure 1 includes Consort's checklist. According to Table 2, there were no significant differences between the AH-26 and Resil groups in terms of gender, first and second mandibular molar, pre-operative VAS, access cavity preparation pain (AP), filling pain (FP), anxiety score, supplementary infiltration anesthesia (ISA), periodontal ligament supplemental anesthesia (LSA), preparation duration (PD), and overall treatment duration (OTD). Additionally, VAS scores at 6, 12, 24, and 48 h showed no significant differences between the two groups (Table 3). In Resil group, the VAS score was 10 and 20 only in two patients with zero in all the other cases on 3rd day. However, in AH26 group, the mentioned value equaled zero in all cases (n=50) during the same time period. Nevertheless, there was no significant difference between the two groups (P=0.155) according to Mann-Whitney test. On the other days tested (4, 5, 6, 7), the VAS scores were zero in all cases of the stated groups; and thus, no analysis was performed.

The analgesic consumption scale shown in Table 4 was also Figure 2 illustrates an inverse association between average VAS not significantly different at 6, 12, 24, and 48 h, and on the third, fourth, fifth, sixth, and seventh days post-treatment.and time in the two groups, AH-26 and Resil. The average VAS reached zero on the third day for the AH-26 group and on the fourth day for the Resil group. Statistical analysis using GEE revealed no significant difference in pain reduction between the two groups (P=0.557); however, pain significantly decreased over time, with B=-11.031 indicating an average reduction of 11 units per day.

According to the results in Figure 3, the average VAS in the group of women reached zero on the third day and males on the fourth day. Furthermore, the pain decrease is identical in both groups. Women's pain decreased extremely quickly over time; despite having higher pain intensity than males, their pain reduction was faster (P=0.028).

The average VAS in tooth number 6 on the third day and tooth number 7 on the fourth day reached zero. Furthermore, the pain decrease is identical in both groups (Figure 4). Analgesic usage frequency was 81% (405) for no use, 16.4% (82) for moderate use, and 2.6% (13) for high use. For valid results, the two higher usage codes were combined, resulting in a binary variable of zero (no analgesic use) and one (analgesic use), with 81% (405) for no use and 19% (95) for use. Generalized estimating equations (GEE) analysis showed the group effect was insignificant (P=0.194), but time was significant (P=0.000). The coefficient B=0.732 with Exp (B)=2.078 (95% confidence intervals (CI): 1.491-2.898) indicates that for each additional day post-treatment, the odds of not requiring analgesics increased by a factor of 2.078.

Discussion

This randomized, double-blind, controlled, and prospective clinical trial aimed to evaluate the occurrence and severity of postoperative pain and analgesic consumption after endodontic treatment of AH-26 and Resil sealers used in root canal treatment.

The multifactorial nature of pain etiology, influenced by factors such as age, gender, pulp and periradicular condition, type of tooth, sinus tract, and preoperative pain, it is difficult todescribe the occurrence of pain after treatment to a specific factor. The treatment process depends on preparation and protocols [32]. The groups in the current study were similar in terms of baseline factors and have no significant differences, and the treatment methods as well as pulp and periapical conditions have been standardized.

The subjectivity of judgment is a fundamental challenge while investigating pain. Each person's pain threshold is unique and heavily influenced by their cultural, psychological, and economic circumstances. It is essential to create a questionnaire to ensure that participants understand the questions and that the assessors can easily analyze them. Each participant was given a thorough explanation of the study's objective and methodology. The visual analog scale has been utilized as a pain evaluation tool in several investigations of post-endodontic pain [33-35].

In the present study, root canal treatment similar to the studies conducted by Graunaite *et al.* [8] and Gondim *et al.* [36]. Was performed in one visit. This strategy reduced the possibility of

Table 1. Inclusion/exclusion criteria of the patients

Inclusion Criteria	Exclusion Criteria
-Participants between 18-60 years old **-Good oral hygiene.** **-Patients had not used any analgesic in last 7 days.** **-Patients had not used any antibiotic in last 7 days.** **-Prolonged positive response to cold test (EndoIce; Coltene/ Whaledent Inc, Cuyahoga Falls, OH, USA) and electric pulp tester (Parkell, NY, USA).** **-Patients diagnosed with asymptomatic irreversible pulpitis caused by deep carious lesion on the mandibular first or second molar teeth.** **-The presence of profusely pulp bleeding with a thick consistency, -which is exposed during caries removing.** **-Patients who had healthy periapical tissues (confirmed with periapical radiography).**	-Patients who refuse to participate this study. -Medically compromised patients (with immunosuppressive/systemic diseases, patients on medications). -Symptomatic or nonvital teeth. The presence of advanced periodontal disease (probing depth>3 mm). -The presence of open apex, presence of calcification, presence of resorption. -Patients who had multiple teeth requiring endodontic treatment. -Patients with allergic sensitivity to materials that should be used during the root canal treatment. -Patients who had systemic or allergic sensitivity for the NSAIDs. -Pregnant patients and patients in lactation period. -Overfilling (extrusion of the gutta-percha or sealer beyond the radiographic apex) or short filling (>2 mm short from the radiographic apex). -The teeth with extensive coronal destruction that need a core build-up. -Patients who received intra-pulpal supplementary anesthesia. -Apical preparation size other than 25 in mesial canals and other than 40 in distal canals.

Table 2. Frequency of variables in the studied subjects in two groups

Variables		AH-26	Resil	*P*-value
Gender	**Male**	31 (62.0%)	19 (30.8%)	0.683
	Female	29 (58.0%)	21 (42.0%)	
Tooth number	**6**	33 (66.0%)	25 (56.0%)	0.305
	7	17 (34.0%)	22 (43.0%)	
Age		39.0 (11.30)	28.58 (12.25)	0.859
Preoperative VAS		59.0 (12.83)	60.80 (12.59)	0.724
Anxiety score		10.30 (3.97)	10.40 (3.93)	0.900
AP		0.72 (1.40)	0.34 (0.85)	0.109
FP		1.16 (2.22)	1.16 (2.23)	1.000
ISA		0.20 (0.57)	0.18 (0.52)	0.855
PD		27.70 (4.97)	28.50 (8.16)	0.555
OTD		60.50 (7.50)	58.00 (12.57)	0.230
LSA		0.08 (027)	0.06 (0.24)	0.699

AP: Access cavity preparation pain; FP: Filling pain; ISA: Supplementary infiltration anesthesia; PD: Preparation duration; OTD: Overall treatment duration; LSA: Periodontal ligament supplemental anesthesia

Table 3. VAS measurements in different time points in two groups

Variables	Time	AH-26	Resil	*P*-value
Mean (SD)	**6 Hours**	21.00 (18.10)	18.00 (19.68)	0.430
	12 Hours	10.20 (13.01)	8.80 (13.19)	0.594
	24 Hours	6.80 (9.78)	4.60 (9.08)	0.274
	48 Hours	3.80 (8.30)	1.60 (3.70)	0.092

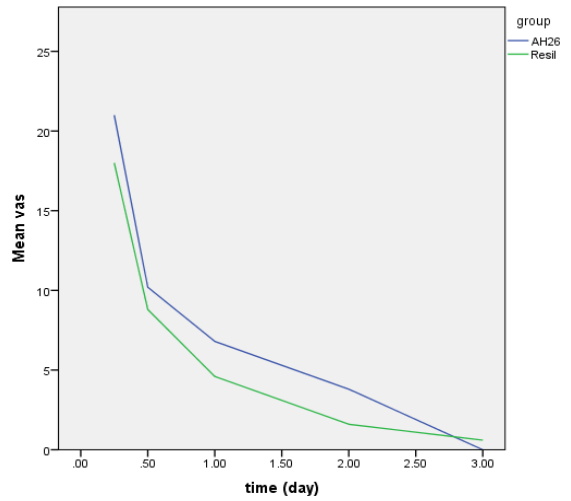

Figure 2. Association of VAS average and time according to the groups

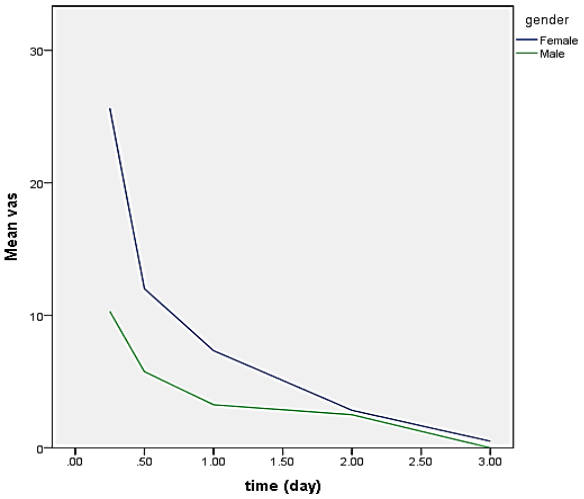

Figure 3. Association of VAS average and time according to gender

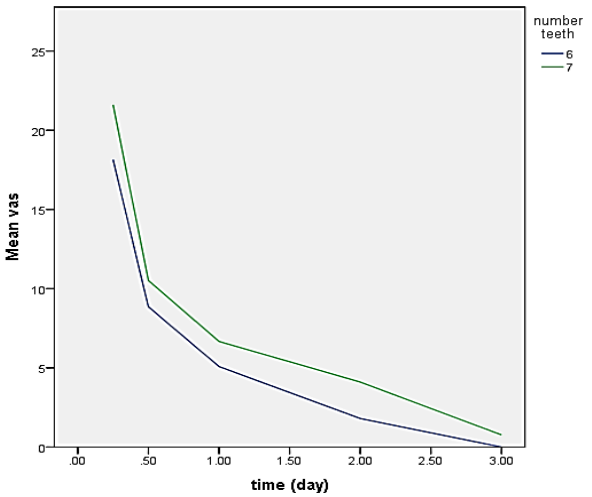

Figure 4. Association of VAS average and time according to tooth number

post-treatment pain triggers (treatment procedures and intracanal medicaments). The patient was eliminated from the trial if one-session root canal treatment was not conducted for various reasons.

In this study we aimed to minimize the factors which influence postoperative pain. One of the factors influencing postoperative pain is preoperative pain. Patients with emergency pain were excluded from this trial, and there was no significant difference in pretreatment pain between the two groups.

Research comparing the level of discomfort following treatment with a Resil sealer to the gold standard of a resin sealer, AH-26, has not yet been conducted. The data indicated that the first null hypothesis cannot be rejected, consistent with prior research findings comparing two different resin sealers [12] .

In this study, the most severe postoperative pain was present in the first sixth h and gradually decreased. The visual analog scale of 6 h, 12 h, 24 h, and 48 h and on the third day was not significantly different in the studied subjects separately from the two groups. Also, after one day, the average pain decreases by 11 units, which is almost true in both groups because the interaction between group and time was insignificant (P>0.05).

The current investigation found that the sealers utilized in the trial had no significant effect on postoperative pain or analgesic consumption. However, *in vitro* investigations revealed disparities in cytotoxicity and inflammatory response among studied root canal sealers [42-46]. In addition, a previously published study showed that root canal sealers could directly activate trigeminal nociceptors, leading to a potent release of calcitonin gene-related peptide, and thus may lead to pain and neurologic inflammation [9]. However, these differences and findings do not seem to have clinical implications, as the different sealers tested did not affect postoperative pain in the present study either. This result confirms the findings of previously published studies [42-46] that found no difference in post-treatment pain when different sealers were used to fill root canals.

In the current study, 400 mg ibuprofen was prescribed and recommended for use only when needed to control pain [47]. There was no significant difference in the frequency of analgesic consumption in the first 6, 12, 24, and 48 h after treatment and on the third, fourth, fifth, sixth, and seventh days after treatment between the two experimental groups. As a result, the second null hypothesis must be accepted. Analgesic consumption analysis showed that for each day of increase in time, the odds ratio of not requiring analgesic consumption was 2.078 and this is in accordance with the several studies considering post treatment pain after different sealers use [12, 48, 49].

Future research comparing the postoperative pain conducted in multiple centers and in symptomatic patients or patients with necrotic teeth is suggested.

Table 4. Distribution of the frequency of Analgesic in different hours and days in two groups

Time/Analgesic		AH-26	Resil	P-value
6 hours	0	30 (60%)	34 (68%)	0.463
	1	12 (24%)	12 (24%)	
	2	8 (16%)	4 (8%)	
	Total	50 (100%)	50 (100%)	
12 hours	0	35 (70%)	35 (70%)	0.596
	1	14 (28%)	15 (30%)	
	2	1 (2%)	0 (0%)	
	Total	50 (100)	50 (100)	
24 hours	0	41 (82%)	43 (86%)	0.786
	1	9 (18%)	7 (14%)	
	Total	50 (100%)	50 (100%)	
48 hours	0	47 (94%)	47 (94%)	1.000
	1	3 (6%)	3 (6%)	
	Total	50 (100%)	50 (100%)	
Day 3	0	45 (90%)	48 (96%)	0.218
	1	5 (10%)	2 (4%)	
	Total	50 (100%)	50 (100%)	
Day 4	0	49 (98%)	50 (100%)	0.500
	1	1 (2%)	0 (0%)	
	Total	50 (100%)	50 (100%)	
Day 5	0	50 (100%)	50 (100%)	-
	Total	50 (100%)	50 (100%)	
Day 6	0	50 (100%)	50 (100%)	-
	Total	50 (100%)	50 (100%)	
Day 7	0	50 (100%)	50 (100%)	-
	Total	50 (100%)	50 (100%)	

0: No pain or pain that does not require analgesic, 1: Moderate pain that is adequately managed by analgesics and does not interfere with daily activities or sleep, 2: Impaired daily activities result from intense pain that cannot be managed with analgesics

Conclusion

There is no significant difference in the incidence and severity of postoperative pain and the requirement for analgesics between AH-26 and Resil root canal sealers.

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Conflict of interest

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Author contributions

Zargar N: Devised the project, the main conceptual ideas and proof outline, supervised the project, Zadsirjan S: Designed the model and the computational framework and analyzed the data, Ashraf H: Developed the theory, involved in planning, Najafi F: Designed and performed the experiments, derived the models and analyzed the data, Semnani S: Co-responding author, wrote the manuscript, Dianat O: Contributed to sample preparation, aided in interpreting the results and worked on the manuscript, Editing. Mehrabinia P: performed the measurements, Writing-original draft, Supervision. All authors discussed the results and commented on the manuscript.

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