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Research Article

Influence of Apical Patency Concept Upon Postoperative Pain Following Single Session Primary Root Canal Treatment in Molars with Pulpal Disease

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Abstract

This clinical investigation examined the effect of implementing the apical patency concept on postoperative pain following root canal treatment in a single session approach for molars with irreversible pulpal pathology and healthy periodontium. Thirty-two patients, ranging in age from 18 to 60 years, were divided into two groups: group I with implementation of the apical patency concept and group II without implementation of the apical patency concept. The primary end measure was postoperative pain, which was quantified using the Visual Analogue Scale (VAS) at four, six, twelve, twenty-four, and forty-eight hours after root canal procedure. Consumption of analgesics was a side effect. Pain alleviation occurred more rapidly in group I than in group II. The two groups did not differ statistically substantially in terms of analgesic pill intake (P-value = 0.654). Maintaining apical patency during a single session of root canal therapy is associated with decreased postoperative discomfort.

Keywords: Postoperative Pain; Single Session; Root Canal Treatment; Pulpal Diseases; Patency

Introduction

Pain is an unpleasant sensory or emotional sensation that comes because of tissue injury, either actual or potential [1]. Pain is a disguised blessing since it alerts us that something is amiss and demands attention. Regrettably, postoperative discomfort is a frequent adverse effect of endodontic therapy, occurring at a rate of between 3 and 58% [2].

The endodontic preparation phase's primary objectives are to generate a canal geometry favorable to sealing and a biological environment conductive to healing. Managing the apical control zone is one of the most challenging elements of non-surgical root canal treatment. The apical termination point of root canal preparation and obturation has long been a topic of dispute in endodontics [3]. Schilder [4]. said in 1974 that all instrumentation must be limited to the root canal, a position later rejected by Bellamy [5]. Access to the apical foramen should be established mechanically, but the apical foramen should be kept as small and debris-free as feasible biologically [6]. This divisive topic resulted in the formation of the notion of apical patency. Numerous definitions, concepts, and approaches relating to patency are accessible [7]. The American Association of Endodontists (AAE) defines "patency" as a technique for preventing debris from entering the apical region of the root canal by recapitulating through the physiological foramen with a fine file [8]. According to a 1997 survey of 53 dental schools in the United States, 53% of institutions teach their students the concept of apical patency [9].

Buchanan proposed apical patency, as opposed to apical blockage, as a means of safely managing root canals that are significantly curved. According to him, a patency file is a small flexible K-file that can be passively stretched beyond the root canal's physiologic terminus without increasing it [10]. When the apical patency idea is utilized, numerous procedural errors such as apical blockage, ledging, and perforation, as well as apical transportation, are reduced [11]. Ruddle further proposes gently and passively pushing file #10 past the apical foramen during initial root canal scouting to allow the irrigating solution to reach the root canal's apical end and circulate through the ramifications, assuring the elimination of germs, endotoxins, and debris [12]. The apical part of the root canal might be viewed as a critical niche not just for microorganisms and the host immune system, but also for endodontists [13]. Cohen and Burns estimate that the cemental canal contains adequate space to contain 80,000 streptococci in necrotic pulp canal space [14].

Numerous studies examined the apical patency concept's effect on molars with asymptomatic apical periodontitis and postopera-

tive pain [15-17]. To our knowledge, no study has examined the effect of apical patency on postoperative pain when inflammation is contained inside the pulp canal space. The purpose of this study is to determine the effect of implementing the apical patency concept on postoperative pain in molars with pulpal disease following one visit root canal therapy. The null hypothesis is that postoperative pain in molars with pulpal disease is identical regardless of whether apical patency is maintained or not following single visit root canal therapy.

Methods

The Faculty of Dentistry at Cairo University-Ethics Egypt's Committee approved this clinical investigation, which was done in conformity with the Helsinki Declaration conditions (29-9-21). (29-9-21). Additionally, the trial was registered on clinicaltrials.gov with the registration number of (ID: NCT05170477). An informed consent form comprises information about the study's purpose, the sequence of steps, the benefits, and the dangers. To preserve the privacy of participants, all data was securely stored in closed files in places with restricted access after they agreed to participate in the study.

Eligibility criteria

Inclusive criteria

- Patients range in age from 18 to 60 years.
- The study comprised both males and females.
- Each patient was in good health without systemic disorders.
- The offending tooth was a molar that required primary root canal therapy due to pulpal problems.
- Each patient receives a single molar treatment.
- Each and every patient signed a document requesting informed consent.

Exclusive criteria

- Any previous attempt of root canal therapy on the offending tooth.
- On the troublesome tooth, clinical or radiographic signs of periapical pathosis.
- Patients received a systemic antibiotic in the preceding month.
- Twelve hours before therapy, the patient was given an analgesic.
- The errant molar has a mobility score of no more than two.
- Infringing molar with less than a 4mm pocket depth.
- 7.Molars that are still in their infancy.
- Pain that is not associated with the teeth.
- Patients who require several teeth endodontic therapy.

Sample size and grouping

The primary outcome of this power analysis was pain (Visual Analogue Scale). Yaylali., *et al*. findings were used to estimate the effect sizes w1 = (0.72) and w2 = (0.86). [17]. The minimal expected sample size was 27 persons, assuming a 5% alpha () and a 20% beta () level, i.e., power = 80%. The sample size will be expanded to 32 to account for a 15% dropout rate (16 per group). G*Power Version 3.1.9.2 was used to calculate the sample size.

In the diagnostic records, demographic information such as age, sex, address, phone number, and medical and dental history were entered. The patient's major complaint was elicited directly. To arrive at a probable diagnosis, a complete dental history was gathered.

Cavities, fractures, and changes in the color of the diseased tooth's clinical crown were visually assessed. Additionally, periradicular examinations and thermometric examinations of the pulpal neural element were done utilizing cold and hot sensibility tests. A periapical digital scan was used to assess the problematic molar and its attachment device (ATECO sensor, Kaso group, England).

Clinical procedures

Regardless of the group, all patients were treated in a single session by the same operator. Octocaine 2 percent with epinephrine 1: 100,000 was utilized to anaesthetize all molars, either by infiltration in the case of maxillary molars or by inferior alveolar nerve block in the case of mandibular molars (Lidocaine HCl, Novocol Pharmaceutical, Ontario, Canada) (Lidocaine HCl, Novocol Pharmaceutical, Ontario, Canada). A rubber dam was built, and substantial caries reduction was achieved prior to access being opened with the Endo access bur, confirming the initial clinical diagnosis. A further intraligamental anesthetic method was performed for those who reported pain during access opening. The mechanical glide path was constructed by reciprocating a revolving Ni-Ti Proglider file (DENTSPLY MAILLEFER, Baillagues, Switzerland), followed by

early coronal flaring with Gates Glidden drill #3 in a brushing motion away from the hazardous zone. A supplemental intrapulpal or pressure anesthetic was provided for any patient feeling pain during root canal scouting. To increase the efficiency of the electronic apex locator Root ZX II (J. Morita Mfg. Corp, Kyoto, Japan) when determining the working length with a manual patency stainless-steel K-file #10, root canals were irrigated with 2.5 percent sodium hypochlorite NaOCl (Clorox; Egyptian Company for household bleach, Egypt) delivered via a 30 Gauge safety Steri Irrigation Tip (DiaDent Group International, To assure patency, the patency file was advanced at the "apex" point or "beginning of the red zone" on EAL and then retracted at the "end of green zone," with the working length set to 0.5 mm short of the anatomic apex or end of the green zone. The working length was radiographically validated using digital radiography.

Patients grouping

Apical patency group: (GP I)

Between the beginning of the preparation phase and the end of the sealing phase in this group, a stainless-steel K-file #10 is advanced a hundredth of a millimeter beyond the anatomic apex to maintain apical patency. The K-file is advanced until the start of the red zone is visible on the Root ZX II apex locator's LCD and then withdrawn. This procedure is repeated for each file used to shape the root canals.

Non-apical patency group: (GP II)

Apical patency was used in this group only during working length determination using an electronic apex finder, and no patency files were used to maintain a patent and debris-free apical foramen following working length correction.

In all groups, the root canals were formed using the ProTaper Next rotary Ni-Ti files (DENTSPLY MAILLEFER, Baillagues, Switzerland). Root canal preparation was performed using X3, X4, or X5 files, depending on the root canal's first clinical apical width. Canals were chemically cleansed with 2ml 2.5 percent NaOCl between each rotary filing, regardless of group. Irrigant was injected at a distance of 3mm coronal to anatomic apex, keeping in mind that the needle would not be connected to the canal wall. To remove the smear layer, 1 minute of 17 percent EDTA was retained inside the root canals after they were properly formed. 2ml/canal irrigation at the conclusion The EndoActivator device (Dentsply Tulsa Dental, Tulsa, OK) was utilized to agitate 2.5 percent NaOCl hydrodynamically using red tips #25/04 inserted, and the root canals were then dried using paper points. The root canals were sealed utilizing the cold lateral compaction technique with an epoxy resin-based sealer (AH plus). An intraradicular fiber post was employed, and to prepare them for zirconia crowns, a coronal dual cure composite restoration was used. Finally, occlusion was evaluated and adjusted. All patients were prescribed 400 mg ibuprofen every six hours if they experienced substantial postoperative discomfort. All participants were instructed to call for emergency treatment if they had substantial postoperative pain that was not relieved by medications.

Patient questionnaire

All participants calibrated their preoperative pain intensity using the Visual Analogue Scale (VAS) in order to get training on quantifying their postoperative pain at four time points following root canal treatment: 6 hours, 12 hours, 24 hours, and 48 hours. The pain VAS is a continuous scale comprised of a 100-mm-long horizontal line. The VAS is founded on the concepts of "no pain" (a value of 0) and "pain as bad as it possible can be" (score of 1). (100 points). The pain VAS's cut points are as follows: no pain (0-4 mm), mild pain (5-44 mm), moderate pain (45-74 mm), and severe pain (75-100 mm) [27]. The VAS for pain was completed by the patients. Six hours, twelve hours, twenty-four hours, and forty-eight hours following treatment, patients were told to place a mark perpendicular to the pain VAS line at the location that best indicated their pain level. To get the patients' pain scores, the distance between the 0 (no pain) anchor and the patients' marks on the 100-mm line was measured with a ruler [28].

Statistical analysis

Normality tests were used to determine the normality of numerical data (Kolmogorov-Smirnov and Shapiro-Wilk tests). The distribution of age data was normal (parametric); however the distribution of pain scores was non-normal (non-parametric). The mean, standard deviation (SD), median, and range values were used to present the data. The student's t-test was used to compare the age values of the two groups when using parametric data. The student's t-test was used to compare the age values of the two groups when using parametric data. The Mann-Whitney U test was used to compare the two groups with non-parametric data. To analyze changes within each group, Friedman's test was performed. When Friedman's test was determined to be significant, Dunn's test

was used to make pair-wise comparisons.

The researchers conducted a multivariate regression analysis to identify significant determinants of post-operative discomfort. Frequencies and percentages were used to present qualitative data. To compare qualitative data between groups, the Chi-square test was performed. P 0.05 was chosen as the criterion of significance. IBM SPSS Statistics for Windows, Version 23.0, was used to conduct the statistical analysis. IBM Corporation, Armonk, New York.

Results

Base line data

All patients who took part in the current investigation were included in the follow-up (Figure 1). There was no statistically significant difference in mean age between the two groups. There was no statistically significant difference in the gender, arch, or diagnostic distributions between the two groups. (Table 1).

Pain scores (VAS) and Comparison between the two groups

There was no statistically significant difference in pain scores between the two groups pre- and post-operatively (P-value = 0.570, Effect size = 0.201) and (P-value = 0.113, Effect size = 0.583), respectively (P-value = 0.570, Effect size = 0.201). After 12 and 24 hours, Group I had a statistically significant lower pain score than Group II (P-value 0.001, Effect size = 1.694) and (P-value 0.001, Effect size = 2.242), respectively (P-value 0.001, Effect size = 1.694). After 48 hours, no statistically significant differences were seen between the two groups (P-value = 0.239, effect size = 0.436). (Table 2).

Pain scores (VAS) and changes within each group

In Group I, there was a statistically significant change in pain scores over time (P-value 0.001, Effect size = 0.66). After six hours, there was no statistically significant change in pain scores, followed by a statistically significant decrease in median pain scores between six and twelve hours and between twelve and twenty-four hours, according to pair-wise comparisons between time periods. Between 24 and 48 hours, there was no statistically significant difference in pain levels.

The change in pain scores over time was statistically significant in Group II (P-value 0.001, effect size = 0.472). According to pair-wise comparisons between time periods, there was a statistically significant increase in pain levels after six hours and from six to 12 hours, followed by a decrease in median pain ratings from 12 to 24 hours and from 24 to 48 hours. (Figure 2 and Table 3).

Analgesics intake

The two groups did not differ statistically substantially in terms of analgesic pill intake (P-value = 0.654, effect size = 1.615). (Table 4, Figure 3).

Significant predictors of post-operative pain

The dependent variables in a multivariate regression model were pain levels six, twelve, twenty-four-, and forty-eight-hours following surgery. Group and diagnosis were independent variables. The model took gender, age, arch, and pre-operative pain into account. At all follow-up dates, the results indicated that group had a statistically significant effect on post-operative pain (regardless of diagnosis). At all-time points of follow-up, diagnosis (irrespective of group) had a statistically significant effect on postoperative discomfort. The highest pain scores in group I were associated with pulp necrosis diagnosed between 6 and 12 hours. After six hours, patients diagnosed with symptomatic irreversible pulpitis and those diagnosed with pulp necrosis after 12, 24, and 48 hours had the highest levels of discomfort in group II. (Table 5).

Discussion

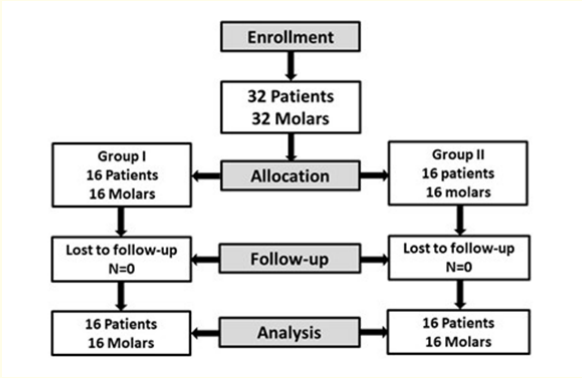

Figure 1: CONSORT 2010 flow diagram of the study.

	Group I (n = 16)	Group II (n = 38)	*P*-value
Age (Years)			
Mean (SD)	39 (12)	41.3 (12.2)	0.592
Gender [n (%)]			0.723
Male	8 (50%)	9 (56.2%)	
Female	8 (50%)	7 (43.8%)	
Arch [n (%)]			0.723
Mandibular	9 (56.2%)	8 (50%)	
Maxillary	7 (43.8%)	8 (50%)	
Diagnosis [n (%)]			1
Asymptomatic irreversible pulpitis	5 (31.2%)	4 (25%)	
Symptomatic irreversible pulpitis	8 (50%)	8 (50%)	
Pulp necrosis	3 (18.8%)	4 (25%)	

Table 1: Mean, standard deviation (SD), frequencies (n), percentages and results of Student's t-test, Chi-square test and Fisher's Exact test for comparisons between base line characteristics in the two groups.

*: Significant at P ≤ 0.05.

Time	Group I(n = 16)		Group II(n = 38)		P-value	Effect size (d)
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
Pre-operative	36.5 (0-97)	44 (44.3)	28 (0-97)	40.9 (42.7)	0.570	0.201
6 hours	31 (0-80)	31.6 (25.8)	38.5 (20-79)	47.4 (20.7)	0.113	0.583
12 hours	19 (0-2)	19.9 (17.2)	50.5 (21-95)	53.5 (25.9)	<0.001*	1.694
24 hours	3 (0-13)	4.6 (5)	22.8 (0-51)	26.4 (16.2)	<0.001*	2.242
48 hours	0 (0-.0)	0 (0)	0 (0-4)	0.8 (1.4)	0.239	0.436

Table 2: Descriptive statistics and results of Mann-Whitney U test for comparison between pain (VAS) scores in the two groups.

*: Significant at P ≤ 0.05.

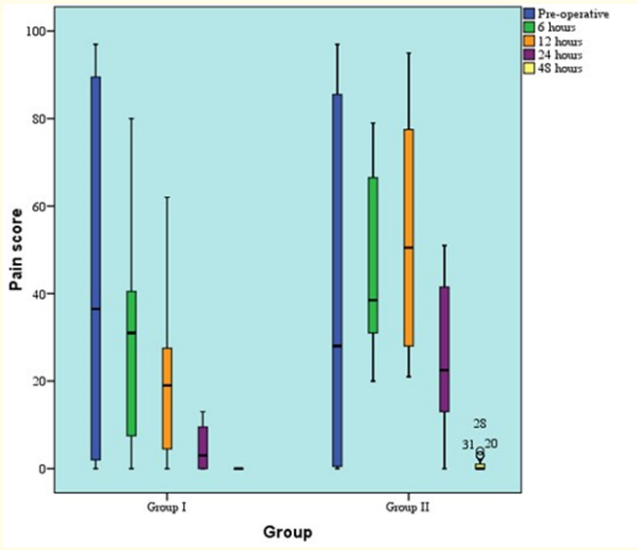

Figure 2: Box plot representing median and range values for pain scores in the two groups (Circles represent outliers).

Time	Group I (n = 16)		Group II (n = 38)	
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)
Pre-operative	36.5 (0-97) [A]	44 (44.3)	28 (0-97) [C]	40.9 (42.7)
6 hours	31 (0-80) [A]	31.6 (25.8)	38.5 (20-79) [B]	47.4 (20.7)
12 hours	19 (0-2) [B]	19.9 (17.2)	50.5 (21-95) [A]	53.5 (25.9)
24 hours	3 (0-13) [C]	4.6 (5)	22.8 (0-51) [C]	26.4 (16.2)
48 hours	0 (0-.0) [C]	0 (0)	0 (0-4) [D]	0.8 (1.4)
P-value	<0.001*		<0.001*	
Effect size (*w*)	0.66		0.472	

Table 3: Descriptive statistics and results of Friedman's test for comparison between pain scores at different times within each group.

*: Significant at P ≤ 0.05, Different superscripts in the same column indicate statistically significant changes by time.

Analgesic	Group I (n = 16)		Group II (n = 16)		*P*-value	*Effect size (OR)*
	n	%	n	%		
Intake	2	12.5	4	25	0.654	1.615
No intake	14	87.5	12	75		

Table 4: Descriptive statistics and results of Fisher's Exact test for comparison between intake of analgesic tablets in the two groups.

*: Significant at P ≤ 0.05.

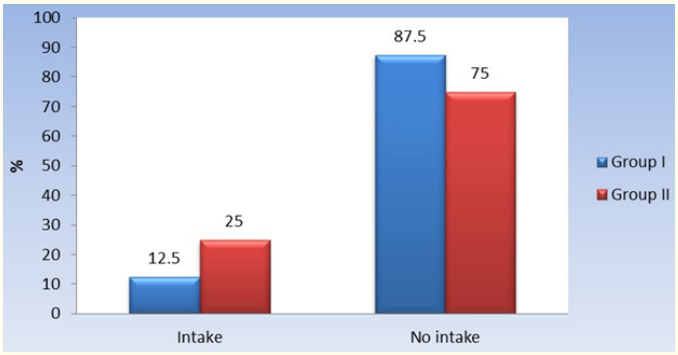

Figure 3: Bar chart representing percentage intake of analgesic tablets in the two groups.

The current study examined the effect of implementing the apical patency concept on the incidence and intensity of postoperative pain, as well as the frequency of analgesic consumption. Following primary root canal treatment in a single session, molars with irreversible pulpal pathosis and a healthy periodontium received specific attention. The current study involved only patients with pulpal abnormalities to determine the effect of the apical patency concept on the healthy periodontium's postoperative discomfort. Numerous studies have demonstrated that employing the apical patency concept significantly reduces postoperative discomfort in individuals with asymptomatic apical periodontitis of pulpal origin [15,17]. Our study included patients with pulp necrosis and healthy periodontium because the primary preoperative inclusion

Source of variation	Dependent variable	Type III Sum of Squares	df	Mean Square	F-value	P-value	Effect size (Partial eta squared)
Group	6 hours	303.7	1	303.7	8.612	0.008*	0.281
	12 hours	7398.6	1	7398.6	89.028	<0.001*	0.802
	24 hours	3949.2	1	3949.2	74.279	<0.001*	0.771
	48 hours	6.8	1	6.8	92.281	<0.001*	0.807
Diagnosis	6 hours	5250.1	2	2625.1	74.443	<0.001*	0.871
	12 hours	10832.8	2	5416.4	65.176	<0.001*	0.856
	24 hours	1751.1	2	875.5	16.468	<0.001*	0.6
	48 hours	8.7	2	4.3	58.633	<0.001*	0.842
Group x Diagnosis	6 hours	6022	2	3011	85.388	<0.001*	0.886
	12 hours	186	2	93	1.119	0.344	0.092
	24 hours	853	2	426.5	8.022	0.002*	0.422
	48 hours	9.9	2	5	67.326	<0.001*	0.86

Table 5: Multivariate regression analysis results for significant predictors of post-operative pain adjusted for gender, age, arch and pre-operative pain.

df: degrees of freedom = (n-1), *: Significant at P ≤ 0.05.

criterion was healthy periodontium. A single-session therapy is a reasonable option for molars with pulp necrosis [18].

A flare-up is defined as the recurrence or onset of preoperative pain and/or swelling following endodontic treatment that impairs the patient's quality of life and necessitates an unscheduled appointment, whereas postoperative pain is defined as any intensity of pain that occurs following the initiation of endodontic treatment [19]. Prior to surgery, patients calibrated their pain intensity using a visual analogue scale [20-22] to calibrate their postoperative pain and examine the effect of preoperative pain on postoperative pain. We analyzed the incidence and severity of pain at four time points within 48 hours of root canal therapy, as several studies have demonstrated that this is the period during which postoperative pain is at its greatest [23-25]. According to one study, if a patient remains symptom-free 24 hours after obturation, it is improbable that symptoms will develop in the 60 days following obturation [26]. The current study concentrated exclusively on molars due to past studies indicating that root canal treatment increased the degree of pain in molars [27]. To exclude the operator as a factor affecting postoperative discomfort and to overcome the problems associated with molars and finish the treatment in a single session, all treatments were conducted by the same clinician with over 18 years of endodontic experience [28].

To provide the highest level of precision, the working length was calculated using a combination of electronic and radiographic methods [29]. The computerized apex finder provides doctors with the most effective approach for administering and maintaining apical patency with the least amount of periodontal stress [30]. The Root ZX apex locator was utilized as the benchmark for all other apex locators [31]. Due to the presence of a minor apical constriction at this point, the working length was decreased by 0.5mm from the anatomic/radiographic apex [32,33]. When the electronic and radiographic readings did not agree, we used the electronic measurement [34].

Apical patency implementation is a long-standing riddle in endodontics [3]. Numerous publications embrace this concept for safe non-surgical root canal therapy from a mechanical aspect [5,10,12]. According to the researchers, patency already exists in vital pulps since contact is limited to the patent foramen, and patency also exists in apical periodontitis of pulpal origin because the clear foramen is the only route for bacteria and microbial byproducts to exit [7]. The authors that support the concept of apical patency suggest that debris should be removed from the apical foramen to allow irrigant to access the cemental canal and improve the quality of chemical disinfection [6]. Numerous additional authors, in their own words, refute the notion of apical patency [4,35]. According to the authors of this study, following the apical patency concept is critical for preventing different disasters that could arise when attempting to cure apical obstruction in highly curved canals away from the preoperative pulpal and periapical conditions [10]. That is why we limited our analysis to molars with irreversible pulpal pathosis and an otherwise healthy periodontium.

To prevent debris extrusion and apical translocation, we used a stainless-steel K-file #10 in a watch winding movement to maintain apical patency in the apical patency group [36]. Cailleteau and Mullany [9] discovered that 24 of the 53 dental colleges in the United States teach some concept of a patency file; 42 percent teach the use of the #10 file, 33% the #15 file, and 25% the #20 file. One study discovered a 56.6 percent increase in the chance of apical transfer when file #20 was used to maintain apical patency [37].

The basic demographic characteristics of the two groups did not differ statistically significantly, showing that demographic considerations are not a factor in postoperative pain. Similarly, there was no statistically significant difference in clinical diagnosis or preoperative median pain levels between the two groups. In accordance with Abdulrab., *et al*. [38], the current investigation discovered no statistically significant difference in postoperative pain after six hours between the two groups, regardless of other factors [17,38]. After six hours and from six to 12 hours, the non-patency group exhibited a statistically significant increase in median pain levels, which could be due to the accumulation of severe anaerobic gram-negative bacteria often isolated from teeth with irreversible pulpal pathosis. These microbes produce endotoxins that can cause injury to the periodontium, leading in pulpal apical periodontitis [39].

Between six and twelve hours, as well as between twelve and twenty-four hours, the Patency group demonstrated a statistically significant decrease in median pain levels. After 12 and 24 hours, the patency group had statistically lower pain scores than the non-patency group, refusing the null hypothesis of the current study because implementation of the apical patency concept resulted in a faster reduction of postoperative pain. These findings may be explained by decreased bacterial loads and endotoxins in the ce-

mental canal, the most frequently seen site of postoperative pain [13,40]. Additionally, our agitation of the irrigant with the acoustic EndoActivator may have contributed to the patency group's reduction in median pain levels. Maintaining apical patency has been demonstrated to increase irrigant penetration into the apical third of the root canal when used in conjunction with passive sonic agitation, resulting in enhanced root canal disinfection and a drop in postoperative median pain scores [41,42]. Intriguingly, the non-patency group demonstrated a statistically significant decrease in median pain scores from 12 to 24 hours as well as 24 to 48 hours, which could be attributed to the immune system's success in removing the pathogenic effect of endotoxins via increased expression of anti-inflammatory cytokines involved in healing mediation [43].

Both group and preoperative diagnosis had statistically significant influence on postoperative pain throughout follow-up periods. The Patency group had the greatest pain scores after six and twelve hours with molars diagnosed as having pulp necrosis, which could be attributable to the extrusion of contaminated debris beyond the apical foramen [44]. Additionally, the patency group had the highest pain levels after 24 hours with molars identified with symptomatic irreversible pulpitis, which could be attributed to the occurrence of past pain [15]. and central sensitization and/or deafferentation events [45].

After six hours in the non-patency group, molars diagnosed with symptomatic irreversible pulpitis experienced the most pain, while molars diagnosed with pulp necrosis experienced the most agony after 12 and 24 hours. These data imply that in the absence of apical patency, bacteria and bacterial byproducts released from an infected cemental canal may prolong the duration of postoperative pain more than central sensitization and/or deafferentation.

There was no statistically significant difference in analgesic consumption between the two groups, indicating that both therapies were well tolerated clinically.

Conclusions

Maintaining apical patency during single-session root canal treatment is associated with decreased postoperative discomfort, within the limits of this study.

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