



Evaluation of Postoperative Flare Up After Root Canal Retreatment Using Different Irrigation Methods (Randomized Clinical Trial)

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Abstract

Removal of infected substances and avoidance of further intraoperative/postoperative infection are crucial for successful RCT. Failure of RCT can be because of infected substances inside the root canal or at extra-radicular areas. The aim of the study was to evaluate the degree of postoperative pain in patients with root canal retreatment in mandibular first premolar teeth at 6, 12, 24, 48 and 72 hours, time interval after using different irrigation activation techniques in single-visit endodontic treatment. The participants included in this study were recruited from the out-patient clinic in the endodontic department, Faculty of Oral and Dental Medicine, Future University in Egypt. The operator was a master's degree candidate in the Endodontics department. Endodontic treatment was performed on the same dental units and X-ray machine as the rest of the dental operations. The trial took one year from 2021 to 2022. Within the control group, 5 out of 26 patients (19.2%) had no pain, 8 patients (30.8%) had mild pain and 13 patients (50%) had moderate pain. Within the endo ultra group, 7 out of 26 patients (26.9%) had no pain, 14 patients (53.8%) had mild pain and 5 patients (19.2%) had moderate pain. Within the eddy group, 7 out of 26 patients (26.9%) had no pain, 13 patients (50%) had mild pain and 6 patients (23.1%) had moderate pain. There was no significant difference between the three groups ($p = 0.146$). The incidence and intensity of post-operative pain decreased with time regardless the final irrigation protocol used.

Keywords: Postoperative Flare Up, Root Canal Retreatment, Incidence.

Full length article *Corresponding Author, e-mail: 20183232@fue.edu.eg

1. Introduction

The primary objective of endodontic treatment is to eradicate the bacterial accumulation or decrease it to prevent re-infection. Endodontic treatment usually fails when treatment falls short of acceptable standards [1-2]. Root canal treatment has a high success rate but failures occasionally occur. In this context, non-surgical root canal retreatment is considered the first treatment option. The favorable outcome of retreatment depends on the complete elimination of the previous root-filling material that may harbor bacteria and its by-products [3]. Non-surgical root canal retreatment aims to eradicate old root canal filling, correct mechanical failures, and treat missed canals. This helps the clinicians to reshape, disinfect and obturate the canals. The success rate of non-surgical retreatment is high when the guidelines for case selection are respected besides using the most suitable materials, techniques and technologies [4]. Pain after RCT is one of the most common complications of endodontic treatment. Postoperative pain from RCT may occur between 3% to 50% of cases. Mild

postoperative pain is not rare even when endodontic treatment follows established protocols. A flareup, here, refers to intense pain and/or swelling of the facial soft tissues and the oral mucosa in the area of endodontically treated tooth after initiation of endodontic treatment. The clinical symptoms (pain on biting, chewing or isolated) are so strongly expressed that the patient needs to visit the clinic sooner than scheduled. After endodontic treatment, a flareup often manifests as pain of varying intensity with or without swelling. A flareup can occur within a few hours or a few days post RCT. The pain may be a periapical inflammatory response to one or more of the following factors: instrumentation/mechanical, the introduction of medications/chemical injury, apical extrusion of debris into the periapical tissues and psychological influences [5]. In fact, the most effective procedure in endodontic treatment is root canal irrigation; due to its various functions. First, it has an antimicrobial effect as well as a washing effect. Second, it acts as a coolant for the file and dentin and decreases the friction between them.

Irrigation is also the only approach to those areas not touched by mechanical preparation in the root canal system. Conventional manual irrigation with a syringe and needle remains a widely accepted technique in RCT. However, this method has been shown to be incapable of reaching areas that are difficult to access such as the apical and isthmus regions. Thus, different irrigation agitation techniques have been proposed to improve the efficacy of irrigation solutions within the root canal system. These techniques include the agitation of irrigation solutions with gutta-percha cones, lasers, brushes and sonic and ultrasonic devices. Passive ultrasonic irrigation (PUI) was introduced to increase the effectiveness of canal disinfection by agitating an irrigation solution previously placed inside the canal. An ultrasonic tip is activated in the canal up to the working length and moves passively. With its acoustic streaming and cavitation effects, the PUI method was reported to clean more debris from the canal [6]. The aim of the study was to evaluate the need and rate of analgesic and antibiotic intake in patients with root canal retreatment in mandibular first molar teeth after using different irrigation activation techniques.

2. Materials and Methods

2.1. Trial design

The trial design of this study was a double blinded parallel randomized clinical trial design. This design is one of the simplest and most powerful tools in clinical research.

2. Ethical considerations

The protocol and the template informed consent forms were approved by research ethics committee (REC-FODM) (FUE.REC code (8)/2-2020) (Appendix 1 & 2) with respect to scientific content and compliance with applicable research and human subject's regulations. The treatment procedures, aim of the study, possible side effects, and treatment alternatives were thoroughly explained to all the participants. Participants were asked to follow the general instructions and to sign a site-specific printed informed consent (Arabic language and English versions) (Appendix 3), that explains the aim of the study and obligates the patient to fill a pain diary (appendix 4) at pre-treatment and 6, 12, 24, 48 and 72 hours and 1 week post-operatively then to return the pain diary to the operator.

2.3. Participants

2.3.1. Sample size

Based on a previous study by Dönmez Özkan et al., 2019 (70) the outcome variable was postoperative pain assessed by Visual analogue Scale. The samples were divided into 3 groups. A total sample size of 60 was (20 per group) was sufficient to detect an effect size of 0.2, a power of 80%, and a significance level of 5%. The number was increased to a sample size of 66 to allow for using non-parametric distribution of the outcome variable. Further increase of 25% to allow for least frequently used (LFU), so a total sample size of 78 (26 per group) was needed to compensate for possible losses during follow up.

2.4. Eligibility criteria

2.4.1. Inclusion criteria

- Medically free patients with no systemic disease: (American Society of Anesthesiologists / (ASA Class I or II).
- Age range is between 18 to 50 years.
- No sex predilection.
- Patients who can understand visual analogue scale (VAS).
- Positive patient's acceptance for participating in the study.
- Patients able to sign informed consent.
- Mandibular first premolar teeth with previous endodontic treatment.
- Improper coronal seal of restoration (broken crown or filling).
- Previous endodontically treated teeth (Underextended root canal filling).
- No periapical pathosis.

2.4.2. Exclusion criteria

- Root canals with an immature open apex.
- Non restorable crown, root caries & resorption.
- Patients who were preoperatively using any form of medication, such as analgesics or non-steroidal or steroidal anti-inflammatory treatments.
- Patients with any systemic condition that is uncontrolled.

2.5. Intraoral clinical examination

It was done where the suspected tooth was examined as follows:

2.5.1. Visual examinations

The suspected tooth was examined using a diagnostic-instruments (Mirror and Probe) aided by dental unit light to detect any swelling, or sinus tract associated with the problematic tooth.

2.5.2. Palpation

Firm digital pressure was applied to the mucosa covering the roots and the apices. The index finger was used to press the mucosa against the underlying cortical bone, in which no pain was achieved on pressure.

2.5.3. The percussion tests

The percussion test was performed by tapping the tooth crown with the end of the mirror handle vertically & horizontally. The contralateral tooth was tested first as control. The test was negative with no painful response.

2.5.4. Periodontal examination

Probing depth of the included teeth were measured using a periodontal probe parallel to the tooth's long axis and around all four sides of the tooth. Teeth with a probing depth more than 5mm on more than one surface of the tooth axial walls were excluded. The degree of tooth mobility was determined. To record the tooth mobility pressure was applied using two mirror handles in buccolingual direction.

- Teeth with more than grade 1 mobility were excluded.
- Pregnant patient or allergic to material used.
- Periodontally affected with grade 2 or 3 mobility.

- No possible restorability.
- Abnormal anatomy and calcified canals.
- Pocket more than 5 mm.
- Uncooperative patients.

2.6. Setting and location

The participants included in this study were recruited from the out-patient clinic in the endodontic department, Faculty of Oral and Dental Medicine, Future University in Egypt. The operator was a master's degree candidate in the Endodontics department. Endodontic treatment was performed on the same dental units and X-ray machine as the rest of the dental operations. The trial took one year from 2021 to 2022.

Dental units: Sirona C8 dental unit.

X-ray machine: Sirona (Dentsply, Sirona, USA).

X-ray sensor: NanoPix sensor (Eighteeth, China).

2.7. Randomization

Three stages are required to complete the randomization process:

2.7.1. Sequence generation

A random sequence was computer made by assistant supervisor using computer software (<http://www.random.org/>). The randomization table consisted of 3 columns: one for the control group (A), NaviTip with double sideport irrigation tip and other for the intervention groups (B), ultrasonic activation using Endo Ultra and (C), sonic activation using EDDY sonic activator.

2.7.2. Allocation concealment

The computer-generated randomized sequence was kept with assistant supervisor only, hence the operator wasn't aware of which group the patient will be enrolled into.

2.7.3. Implementation

Following local anesthesia, access cavity preparation and the working length determination. If the patient was considered eligible, they were given a number from 1 to 78, the operator contacts the assistant supervisor over the phone to know which group this number was assigned to (control and experimental groups).

2.7.4. Blinding

The study was double blinded where the participants unaware of the assigned treatment and the statistician was uninformed of the participants intervention during the outcome assessment phase.

2.8. Statistical analysis

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests and showed parametric (normal) distribution. The mean and standard deviation values were calculated for each group in each test (Pain Evaluation and Bacterial count). Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. Friedman test was used to test the difference between more than two groups in related samples while Wilcoxon test was used to test the difference

between two groups in related samples. Mann-Whitney U test was used to compare the difference between two groups in non-related samples for Pain evaluation. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM@SPSS® Statistics Version 20 for Windows.

3. Results

The mean and standard deviation values of age were 29.9 (3.7) years in the control group, 29.5 (3.3) years in the endo ultra group and 30 (2.7) years in the eddy group. There was no significant difference between the three groups ($p = 0.884$) (Table 1). Within the control group, 13 out of 26 patients (50%) were males and 13 patients (50%) were females. Within the endo ultra group, 14 out of 26 patients (53.8%) were males and 12 patients (46.2%) were females. Within the eddy group, 15 out of 26 patients (57.7%) were males and 11 patients (42.3%) were females. There was no significant difference between the three groups ($p = 0.958$) (Table 2).

3.1. Incidence of preoperative pain categories

Within each group, all 26 patients (100%) had no preoperative pain (Table 3).

3.2. Incidence of pain categories at 6 hours postoperatively

Within the control group, 5 out of 26 patients (19.2%) had no pain, 8 patients (30.8%) had mild pain and 13 patients (50%) had moderate pain. Within the endo ultra group, 7 out of 26 patients (26.9%) had no pain, 14 patients (53.8%) had mild pain and 5 patients (19.2%) had moderate pain. Within the eddy group, 7 out of 26 patients (26.9%) had no pain, 13 patients (50%) had mild pain and 6 patients (23.1%) had moderate pain. There was no significant difference between the three groups ($p = 0.146$) (Table 4).

3.3. Incidence of pain categories at 12 hours postoperatively

Within the control group, 5 out of 26 patients (19.2%) had no pain, 18 patients (69.2%) had mild pain and 3 patients (11.5%) had moderate pain. Within the endo ultra group, 8 out of 26 patients (30.8%) had no pain, 17 patients (65.4%) had mild pain and 1 patient (3.8%) had moderate pain. Within the eddy group, 9 out of 26 patients (34.6%) had no pain, 15 patients (57.7%) had mild pain and 2 patients (7.7%) had moderate pain (Table 5). There was no significant difference between the three groups ($p = 0.656$) (Table 6).

4. Discussion

One of the primary objectives of root canal filling is to seal the canal system completely in such a way as to prevent the penetration of tissue liquid, bacteria, and/or their products into the canal and to avoid reinfection after cleaning and shaping [7]. The major factor associated with endodontic failure are persistence of microbial infection in the root canal system and/or the periradicular area [8]. The main cause of postoperative pain is associated with inflammation in the periradicular tissues caused by irritants extruded from the root canal during re-treatment. Irritation can be of biological (microorganisms) or non-biological (chemical or mechanical) origin [9]. The present study was designed as a double-blinded parallel randomized clinical trial (RCT).

RCT is considered the gold standard and the most reliable type of studies that uses primary data generated in the clinical environment [10]. The goal of randomization is to produce comparable groups in terms of general participants' characteristics, such as age, gender and other factors that affect the probable course the disease would take. In this way, the three groups were as similar as possible at the start of the study. thus, eliminating the bias that would result from differences between the tested groups that may affect the relation between the interventions and outcomes [11]. In the present study, 78 patients were included to undergo endodontic retreatment. All the baseline characteristics (age & gender), and the clinical preoperative findings (palpation, percussion and pain) were balanced between the three groups, because the random sequence generation and allocation concealment were successful ensuring similar distribution of both known and unknown factors that may influence the study results [12]. Several studies have shown that age and gender have no significant effect on pain. Therefore, in the current study, patients from both genders in the age range from 20 to 50 years were included in this study [13]. The incidence of postoperative pain was higher in younger participants and the flare up rarely occur in older patients due to narrowing of the diameter of root canal therefore less debris extruded below the root apex [14]. None of the patients included had systemic disorders or had been administrated analgesics or antibiotics during the last 12 hours preoperatively. This was done to eliminate any causes of pain or drug interaction that may affect the degree of pain after agitation of irrigation [15]. Nonsurgical retreatment teeth were incorporated in the

study as it poses a challenge to the dentist since postoperative pain is highly encountered after endodontic retreatment. All retreatment techniques showed extruding a certain quantity of debris through the apex [16]. The incidence of post-operative pain to be 63.8% for vital cases, 38.5% for necrotic cases and 48.8% for retreatment cases. This could be attributed to the fact that removing root canal filling materials cause extrusion of debris and other material through of the apex. Depending on the amount of damage caused to the periapical tissues, higher or lower levels of postoperative pain can be provoked [17]. Mandibular first premolars were selected in this study because post endodontic pain was previously reported higher in lower posterior teeth than that in upper anterior teeth [18]. Also, mandibular premolar teeth were chosen for this PP study as many variables in the root canal morphology of these teeth [6]. Postoperative pain was found to be significantly higher in the mandible compared to the maxilla because the mandible has a dense trabecular pattern, thus there is reduced blood flow and more localization of infection and inflammation, which might delay healing [19]. In the current study, treatment was completed in a single visit which show several advantages as it takes less time, cost-effective, prevent RC contamination and/or bacterial regrowth, less stressful to patient regarding anaesthesia, and instrumentation related to treatment [20]. On the other hand, there was A systematic review concluded that patients undergoing a single visit may experience a slightly higher frequency of swelling and are significantly more likely to take painkillers [21].

Table 1: Mean, standard deviation, median, minimum and maximum values and the result of ANOVA test for comparison of age between the three groups.

	Control	Endo Ultra	Eddy	<i>p</i> - value
Mean	29.9	29.5	30	0.884
SD	3.7	3.3	2.7	
Median	30	30	30	
Min	22	23	25	
Max	35	35	35	

Table 2: Frequencies (N), percentages (%) and the results of Chi square test for comparison of gender distribution between the three groups.

	Control		Endo ultra		Eddy		<i>p</i> - value
	N	%	N	%	N	%	
Males	13	50%	14	53.8%	15	57.7%	0.958
Females	13	50%	12	46.2%	11	42.3%	

Table 3: Frequencies (N), percentages (%) of preoperative pain categories in the three groups.

	Control		Endo ultra		Eddy		p - value
	N	%	N	%	N	%	
No Pain	26	100%	26	100%	26	100.0%	NA
Mild	0	0%	0	0%	0	0%	
Moderate	0	0%	0	0%	0	0%	
Severe	0	0%	0	0%	0	0%	

Table 4: Frequencies (N), percentages (%) and the result of Fisher’s exact test for comparison of incidence of pain categories at 6 hours postoperatively between the three groups.

	Control		Endo ultra		Eddy		p - value
	N	%	N	%	N	%	
No Pain	5	19.2%	7	26.9%	7	26.9%	0.146
Mild	8	30.8%	14	53.8%	13	50%	
Moderate	13	50%	5	19.2%	6	23.1%	
Severe	0	0%	0	0.0%	0	0%	

Table 5: frequencies (N), percentages (%) and the results of Fisher exact test for comparison of incidence of pain categories at 12 hours postoperatively between the three groups.

	Control		Endo ultra		Eddy	
	N	%	N	%	N	%
No Pain	5	19.2%	8	30.8%	9	34.6%
Mild	18	69.2%	17	65.4%	15	57.7%
Moderate	3	11.5%	1	3.8%	2	7.7%
Severe	0	0%	0	0%	0	0%

Table 6: Results of pairwise comparisons using McNemar test with Bonferroni correction.

Time intervals	p-value
Preoperative - 24 hours	<0.001*
Preoperative - 48 hours	<0.001*
24 hours - 48 hours	0.315
24 hours - 72 hours	<0.001*
48 hours - 72 hours	<0.001*

*Significant at $p < 0.05$.

5. Conclusions

Machine-assisted irrigation agitation devices are promising & reliable method as a final step of irrigation protocol. It helps successfully in decrease of post-operative pain after root canal retreatment in permanent mandibular first premolar teeth.

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