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Research Article

Comparison between the Effect of Adding XP-Endo Finisher to the Irrigation Protocol Versus the Conventional Irrigation Technique on Post-Operative Pain in Necrotic Teeth: (A Randomized Controlled Trial)

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Abstract

Objective: The aim of the study was to assess the effect of applying XP-Endo Finisher to the irrigation protocol versus the conventional irrigation method on the post-operative pain in necrotic teeth.

Method: Thirty-four patients diagnosed with asymptomatic mandibular premolar tooth, were enrolled in this study. Patients were randomly assigned into two equal groups of 17 patients each. For both groups, endodontic treatment was performed in a single visit with using ProTaper Next rotary system and 2.5% sodium hypochlorite irrigant for chemo-mechanical preparation. In the first group, root canals were irrigated with side vented needle between each consequent file then final irrigation was performed with XP- Endo Finisher. The second group was irrigated only by side vented needle through the whole root canal treatment procedure. Then, canals were dried and obturated by modified single cone technique with resin-based sealer. Post-operative pain and swelling were assessed using a four-point verbal rating scale (VRS) before going to bed on the day of treatment, then on waking up, and before bedtime each day for the following 5 days. Also, the need for analgesic and/or systemic antibiotics were recorded. All demographic data and VRS scores were collected from the patients and statistically analyzed using the Statistical Package for Social Sciences (SPSS) version 21.

Results: The results showed that there was no statistically significant difference between both groups regarding any of the assessed outcomes.

Conclusion: Within the limitations of this study, it could be concluded that applying the XP-Endo Finisher to the conventional irrigation protocol had no influence on post-operative pain and swelling.

Keywords: Conventional Irrigation; Post-operative Pain; Swelling; XP- Endo Finisher

Abbreviations

VRS: Verbal Rating Scale; NaOCl: Sodium Hypochlorite; SPSS: Statistical Package for Social Science

Materials and Methods

Postoperative pain can be defined as any degree of pain that occurs after the initiation of root canal treatment causing disturbance to the patient's life style. Patients measure the dentists' knowledge and experience by the presence or absence of such pain [1]. Occurrence of postoperative pain is thought to be a consequence of pushing debris, dentine chips, micro-organisms, pulpal remnants or irrigating solution into the periapical tissues during chemo-mechanical preparation. Thus, all endodontic treatment procedures can develop this dilemma [2,3].

Performing sufficient irrigation is considered a crucial step in the chemo-mechanical preparation of root canals. Side vented needle presented high efficiency as well as low risk of irrigant extrusion to the periapical region. However, it showed a limited ability of irrigant exchange, and thereby difficulty in the debris removal form the apical part of the root canal [4].

With time, new irrigant agitation techniques and devices are being introduced aiming to enhance the apical cleaning. XP- Endo Finisher was introduced by FKG Swiss Endo in 2015, it was claimed that its use after any root canal instrumentation can accomplish an improved cleaning effect. It was introduced as being highly flexible with the ability to expand its reach 6 mm or 100 fold of an

equivalent sized file. Also, it contacts and scrapes the dentinal wall without altering the original canal shape [5].

Thus, the purpose of the study was to assess the effect of adding XP-Endo Finisher to the irrigation protocol.

The null hypothesis was that there would be no statistically significant difference between adding XP-Endo Finisher to the irrigation protocol and using the conventional irrigation protocol on the post-operative pain and swelling in necrotic teeth.

Subjects and methods

Thirty- four patients with non-contributory medical history presented to the endodontic department, Faculty of dentistry, Cairo University between January 2017 and March 2018 were selected. All selected teeth were single-rooted, mandibular premolars that were asymptomatic Inclusion criteria was no preoperative pain or swelling, no acute endodontic or periodontal abscess, no previous endodontic treatment. All pulps were necrotic and did not respond to cold testing, with or without periapical radiolucency. All patients were aged between 18 and 55 years, had no systemic diseases or allergies to local anesthetic agents. Patients taking analgesic, anti-inflammatory or antibiotic medications during 14 days prior to the beginning of treatment were also excluded. All patients were informed that they were to be included in a clinical trial and their consent was obtained.

After confirming the diagnosis clinically and radiographically. Treatment of all the participants was performed in a single-visit as follows. Teeth were anaesthetized using local infiltration technique by Mepivacaine HCI 4% and Adrenaline 1:100,000. After endodontic access cavity preparation was preformed, the tooth was properly isolated with rubber dam (Dental Dam, Sanctuary Dental, UK). The patency of the canal was confirmed with stainless steel hand instrument # 15 or 20 K files (DENTSPLY, Tulsa Dental, DENTSPLY Maillefer, TN, USA). Working length was determined using an electronic apex locator (Root ZX, J.Morita USA, Irvine, CA) and confirmed radiographically. Mechanical preparation of root-canals was performed by crown-down technique using ProTaper Next (Protaper Next, Dentsply Maillefer, Ballaigues, Switzerland), attached to an endodontic motor (X-Smart, Dentsply, Maillefer, USA) with adjusted torque of 2 N.cm and speed 300 rpm according to the manufacturer's instructions. The canals were prepared to X4 with tip size. 40 and taper 6%.

During the instrumentation procedures, the canals were thoroughly irrigated using 3 ml syringe gauge 30 (S-S disposable syringe, SUNG SHIM medical Co.Korea) of 2.5% Sodium hypochlorite (Clorox®, Household Cleaning Products of Egypt, Egypt) by side vented needle (ENDO-TOP. IRRIGATION NEEDLES, Poland) between every subsequent instrument.

For the experimental group

XP-Endo Finisher was used after the last instrument in preparation at 800 rpm and torque set to 1 Ncm according to the manufacturing instruction in a vertical motion for 1 minute.

The canals were finally flushed with saline then dried with sterile paper points (Meta Biomed Co. Ltd, Korea) corresponding to the same size of the master cone. Master cone fit radiograph to the same size as the master apical files, was taken to insure proper length and preparation.

The canals were obturated using modified single cone technique by master cone fitting, and then a spreader was used to allow space for auxiliary cones (Meta Biomed Co. Ltd, Korea) using resin-based root canal sealer (ADSEAL, META BIOMED CO., LTD, Korea). After obturation, a cotton pellet was placed in the pulp chamber and the access cavity was sealed with temporary filling material (MD-TEMP, META BIOMED CO., LTD. Chungbuuk, Korea). Post-operative radiograph was taken after complete root canal treatment. Postoperative instructions were given to the patient, Ibuprofen 200 mg tablets (Brufen, Abbot, Egypt.) was prescribed (one tablet every 4 to 6 hours if needed). The patient was instructed to contact the operator, in case of swelling to assess the severity of the swelling and to determine the need of systemic antibiotics or drainage.

All participants received a questionnaire for the evaluation of pain using VRS (0: no pain; 1: mild pain, 2: moderate pain and 3: severe pain) in the following intervals: before going to bed on the day of treatment, then on arising, and before bedtime each day for the following 5 days. The number of ibuprofen tablets taken by the patient from time 0 to the 5th day and presence or absence of swelling were recorded as well. Finally, the patient was instructed to return after 5 days to complete the treatment procedures.

Statistical analysis

Data management and statistical analysis were performed using the Statistical Package for Social Sciences (SPSS) vs. 21.

Numerical data were summarized using means and standard deviations or medians and ranges. Categorical data were summarized as percentages.

Comparisons between the two groups with respect to normally distributed numeric variables were done using the T-test. None normally distributed numeric variables were compared by Mann-Whitney test. Comparisons over time regarding numeric variables were done by Friedman test and pairwise difference were detected by the Wilcoxon rank test.

For categorical variables, differences were analyzed with Chi square (χ^2) test when appropriate. Adjustments of P- value were done using the Bonferroni method for multiple testing. All P-values are two-sided. P-values ≤0.05 were considered significant

Results

Of the 200 patients enrolled participants assessed for eligibility, 34 participants were included in the study and randomly distributed between the two groups. 17 patients in each group. The flow of participants is represented in consort flow diagram (Figure 1).

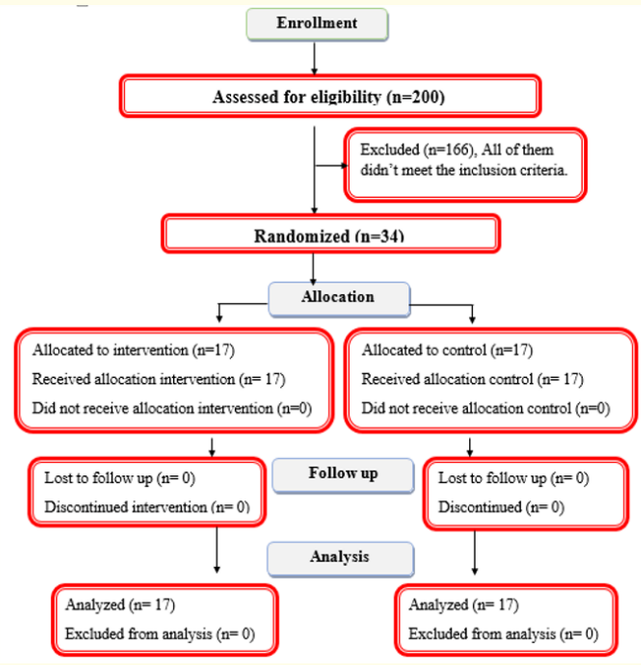

Figure 1: Consort flow diagram.

Base line data

Age, gender and presence of periapical lesions distribution had no statistically significant difference between the two groups.

Outcome data

Post-operative pain:

There was no statistically significant difference between both groups in all time intervals, they were more than 0.05 detailed clearly in table 1.

- **The Need for analgesics was reported:** In group A, 3 out of 17 patients (17.6%) needed analgesics and 14 patients (82.4%) did not, while in group B, 6 patients (35.3%) needed analgesic and 11 patients did not. There was no statistically significant difference between the two groups (P = 0.244).
- **The number of analgesics intake:** In group A, the median and range values of the number of analgesic tablets taken were 0 (0-8), while in group B they were 0 (0-13). There was no

	At bedtime on the day of treatment				Rising on the first day				Rising on the first day			
	A		B		A		B		A		B	
	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%
No Pain	12	70.6%	12	70.6%	13	76.5%	12	70.6%	15	88.2%	12	70.6%
Mild	5	29.4%	3	17.6%	4	23.5%	2	11.8%	1	5.9%	2	11.8%
Moderate	0	0.0%	1	5.9%	0	0.0%	3	17.6%	0	0.0%	2	11.8%
Severe	0	0.0%	1	5.9%	13	76.5%	12	70.6%	1	5.9%	1	5.9%
P- Value	= 0.475				= 0.157				= 0.446			

	Second day				Third day				Fourth day				Fifth day			
	A		B		A		B		A		B		A		B	
	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%
No Pain	15	88.2%	12	70.6%	16	94.1%	13	76.5%	16	94.1%	14	82.4%	17	100.0%	16	94.1%
Mild	1	5.9%	3	17.6%	0	0.0%	2	11.8%	0	0.0%	3	17.6%	0	0.0%	1	5.9%
Moderate	0	0.0%	2	11.8%	1	5.9%	2	11.8%	1	5.9%	0	0.0%	0	0%	0	0%
Severe	1	5.9%	0	0.0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
P- Value	= 0.228				= 0.267				= 0.127				= 0.310			

Table 1: Frequencies, percentages and results of Chi square test for comparison of pain categories after treatment between the 2 groups.

statistically significant difference in the number of analgesic tablets taken by the two groups. (P = 0.233)

- **Swelling incidence:** In group A, 1 out of 17 patients (5.9%) reported swelling, while in group B, 2 out of 17 patients (11.8%) reported swelling. There was no statistically significant difference between the two groups. (P = 0.545).
- **Need for antibiotic:** In both groups no patients needed antibiotics. There was no statistically significant difference between the two groups (P = 1).

Discussion

Judging an endodontic therapy as successful, not only depends on its efficacy and appropriate completion, but also on giving the patient a minimal level of discomfort. Thus, every effort is directed towards providing the patient with the best root canal treatment with minimal or no postoperative pain. Post-operative pain depends on a number of preoperative factors, including age, gender, tooth type and severity of preoperative pain [6,7], as well as intra-operative factors such as missed canals, inappropriate instrumentation, extrusion of irrigation solutions or intra-canal dressing and apical extrusion of debris [3].

The present study was designed as a prospective double-blinded parallel randomized clinical trial as it is considered the gold standard and the most reliable type of studies [8]. The three elements of randomization (sequence generation, allocation concealment and implementation) guarantee that all participants have equal chance to be enrolled in any of the study groups. This pattern is the most suitable way to assure balance of the anonymous prognostic factors in the participants between the two groups thus, eliminating the selection or allocation bias [9,10]. Moreover, the exclusion criteria were set such that there are no additional factors that may influence the pain that results from endodontic therapy.

Since post-operative pain is significantly higher in mandibular posterior teeth, mandibular premolars were chosen for our study [9]. It has been reported that more pain is felt in mandibular teeth (42%) than in maxillary teeth (26%) because the mandible has a dense trabecular pattern, with reduced blood flow and more localization of infection and inflammation causing delayed healing [9]. Moreover, mandibular premolar teeth are accounted for a higher rate of post-operative emergencies as pain or swelling due to the diversity in their root canal configuration [11]. Consequently, mandibular premolars with single root canals were selected to eradicate such variable which might affect the study outcome.

Endodontic treatment was performed in a single visit to avoid root canal recontamination and/or bacterial regrowth that can occur with prolonged treatment, subsequently preventing the pain occurrence in accordance with Kerekes*., et al.* Sivakumar*., et al*. [12,13]. In addition, multiple systematic reviews and meta-analyses showed that after single visit endodontic treatment, patients experienced a significant lower pain frequency than those who received multiple-visit endodontic treatment [14-16].

In our study, the working length was determined by Root ZX electronic apex locator, because of its high accuracy which has been confirmed in previous *in vitro* and *in vivo* studies [13], then confirmed by the radiograph. The procedure ensures confinement of the instruments within the root canal system, reducing post-operative pain and flare-up [13].

2.5% sodium hypochlorite (NaOCl) was used as an irrigant between each subsequent instrument because of its efficacy in reducing the intracanal microbiota and maintaining an extraordinary tissue dissolution capacity with lower cytotoxic action than 5.25% NaOCl [17].

Rotary instrumentation technique was selected for mechanical preparation of the root canals owing to its superiority in causing less post-operative pain than manual or hybrid techniques [18]. The engine-driven techniques were proved to extrude less amounts of debris and irrigants apically, as the rotatory motion tends to direct the debris toward the orifice and avoid its compaction apically [19]. Thus, reducing the incidence of postoperative inflammation and pain. ProTaper Next files were utilized as they show the least amount of apical debris extrusion [20-22], high durability and resistance to fracture together with giving maximum safety during the canal preparation [21].

30-gauge side vented needles were introduced 1 mm short of the working length. Agitating the needle manually between 1 and 3 mm in vertical strokes [22] has a reducing effect on irrigant and debris extrusion into the periapical tissues [4], which is responsible for periapical inflammation, post-operative pain and delayed healing [23].

VRSs was considered as a pain-scale because of its ease in administration, understanding and scoring. Since, it has faces as well as verbal adjectives to explain different levels of pain severity, its

application with patients is considered better than other scoring systems [24]. Moreover, this scale does not stand in need for the patients to be literate and provide an advantage for patients who have problems with written language [25].

Nowadays, NSAIDs are considered one of the most recommended classes of pain relievers in dentistry, displaying minimal side effects [26,27]. However, it is not recommended to prescribe regular usage of medication after single-visit root canal treatment rather, they should be administered on demand [28]. Thereby, Ibuprofen 200 mg was prescribed as an analgesic in case of pain incidence. The methodological steps of this study were executed in such a way to induce the least post-operative pain to patients in order to precisely investigate the effect of adding XP-Endo Finisher to the irrigation protocol on post-operative pain and swelling.

In our study, analyses of patients' gender and age showed similar distribution between the two groups, which indicated adequate randomization of the subjects. Thus, the contribution of these factors to the incidence of post-operative pain was not significant, in accordance with, Imura., *et al.* [29] and Alves., *et al* [30].

Although there was no statistically significant difference detected between the two groups regarding the incidence and severity of post-operative pain and swelling, the XP-Endo Finisher group (Group A) showed lower incidence of pain and swelling, lower need for analgesics intake as well as lower number of tablets intake. This may be attributed to its highly flexible proprietary alloy together with the small core size and zero taper which allowed it to expand its reach while rotating [5]. This unusual property promoted the agitation of the irrigant solution allowing the disruption of the accumulated hard tissue and its removal by the final flushing action of the needle in accordance with Leoni., *et al* [31]. XP-Endo Finisher showed high ability in reaching the inaccessible and untouched canal areas, thereby, providing improved cleaning and superior removal of smear layer and bacterial biofilms, in accordance with Živković., *et al.* [32], Bao., *et al* [33], Liviac., *et al.* [34] and El Naghy., *et al* [35]. On top of that Alves., *et al* [36] and Azim., *et al* [37] demonstrated that it shows high efficiency in reducing bacterial counts and disinfection.

The overall incidence of post-operative pain gives the single visit Endodontics the privilege as it is considered a safe way for treatment of asymptomatic teeth with necrotic pulp without the fear of severe post-operative complications, in accordance with Al-Negrish., *et al.* [38]; Risso*., et al.* [39]; Kalhoro and Mirza [40], Rao., *et al* [41].

Conclusion

Within the limitations of this study, it could be concluded that.

Adding the XP-Endo Finisher to the conventional irrigation protocol in a single visit endodontic treatment had no negative influence post-operative pain and swelling.

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