

Effect of Simultaneous Working Length Control During Root Canal Preparation Versus Electronic Apex Locator on Postoperative Pain in Teeth with Symptomatic Irreversible Pulpitis (A Randomized Clinical Trial)

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Received: October 04, 2021

Published: November 18, 2021

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Abstract

Aim: The aim of this study was to evaluate the effect of simultaneous length control during root canal preparation on postoperative pain compared with separate working length determination by electronic apex locator.

Methodology: One hundred and twenty-four patients, with symptomatic irreversible pulpitis related to their mandibular premolars, were randomly divided into 2 groups (n = 62), a control group (separate length determination and root canal preparation) and an intervention group (simultaneous length control during root canal preparation). All teeth were treated in single visit using ProTaper Next rotary file system. All demographic data, VAS scores, and the analgesic intake during 7 days after the procedure were collected from patients and statistically analyzed.

Results: Patients in the intervention group showed statistically significant lower postoperative pain incidence and intensity on the first, third and fifth days than did the control group ($P < 0.05$). There also was a significant reduction of postoperative analgesic intake in the intervention group compared to the control group ($p < 0.001$).

Conclusion: Simultaneous length control during root canal preparation as a nonpharmacologic strategy for reducing postoperative pain is a beneficial technique for preventing postoperative pain.

Keywords: Endodontic Treatment; Postoperative Pain; Root Canal Treatment; Separate Working Length Control; Simultaneous Working Length Control; Working Length Determination

Introduction

Postoperative pain is a common complication of endodontic treatment, with an incidence ranging from 3%–58% [1]. Many factors can induce postoperative pain, including mechanical, chemical, and/or microbial insult of the pulp or periradicular tissues. Irritation of periradicular tissues during root canal treatment causes an acute inflammatory reaction, which leads to release of chemical mediators and changes in local adaptation and periapical tissue pressure [2].

One of the iatrogenic factors causing the postoperative pain after endodontic treatment is incorrect measurement of working

length (WL) of the root canal [3]. Therefore, it seems favorable to accurately measure and maintain the WL during root canal preparation to avoid preparations ending in the periapical tissues [4]. The radiographic method was the method used for many years to determine the working length until the electrical method was introduced [5]. The radiographic method has some disadvantages as it exposes the patient to radiation, it is time consuming, and it causes loss of buccolingual dimension as a result of projection of a three-dimensional object in a two-dimensional radiograph. An alternative to the radiographic method for WL determination was the electrical method [5]. Root ZX (J Morita, Tokyo, Japan) is a third-generation electronic apex locator (EAL). It is considered the gold

standard EAL due to its proven accuracy even in presence of different electrolytes in the canal and under different clinical conditions [6,7].

When using conventional electronic apex locators, maintenance of WL is achieved manually by observing the stopper and coronal reference points. Unfortunately, the rubber stopper could deviate during canal preparation with subsequent loss of WL. Endodontic motors with integrated apex locators offer a solution to the described problem as they have been developed with the intention of making root canal treatment easier and faster [8], [9]. These devices aim to continuously monitor and control the apical limit all the way through the mechanical preparation of the root canals and have an auto apical reverse (AAR) function that stops and reverse the rotation when the file tip reaches the predetermined apical limit of the preparation. This property would allow for simultaneous control of the WL throughout the mechanical preparation of the root canal which in turn could reduce both postoperative pain incidence and intensity.

Only one study evaluated the effect of simultaneous length control during root canal preparation on post-operative pain [10]. It was reported that, Simultaneous length control during root canal preparation resulted in lower postoperative pain levels on all days; only the differences on day 1 were statistically significant due to the small sample size of the study. Therefore, the author recommended the need for further clinical trials with larger sample size to detect the difference between the groups.

Thus, the aim of our study was to evaluate the effect of simultaneous length control during root canal preparation in patients with symptomatic irreversible pulpitis related to their mandibular premolars, compared with separate length determination and root canal preparation on postoperative pain and number of analgesics taken.

Materials and Methods

The applicable institutional review boards\ethical committees (IRBs\ECs) Cairo university approved this randomized prospective clinical trial. The study protocol was recorded in www.ClinicalTrials.gov databases, with the NCT number (NCT/03899129). The required minimum sample size was calculated using the G*Power v.3.1.9.2 program (Heinrich Heine, Düsseldorf University, Düsseldorf, Germany) according to the data of a previous study [10]. A

total sample size of 114 participants (57 participants per group) was sufficient to detect an effect size of 0.53, a power of 80% and a significance level of 5%. This number was increased to 124 cases (62 cases in each group) to compensate for possible losses during follow up.

The patients were recruited from the outpatient clinic of the Endodontic Department, Faculty of Dentistry, Cairo University for root canal treatment. Only patients who had mandibular first or second premolar teeth diagnosed with symptomatic irreversible pulpitis were included. The diagnosis of symptomatic irreversible pulpitis was based on the history of the chief complaint, clinical and radiographic examinations. Thermal test (EndoIce; Coltene/Whaledent Inc, Altstätten, Switzerland) was performed to determine the pulp sensibility and symptomatic irreversible diagnosis was defined as spontaneous pain and lingering response to thermal stimuli. The diagnostic findings obtained by cold test were checked by comparison with the adjacent tooth with a vital pulp. Additional identifiers for this diagnosis were that after exposing the pulp, profuse bleeding of the pulp having a thick consistency and an inability to achieve hemostasis within 2-3 minutes. Inclusion and exclusion criteria are listed in table 1. All participants were informed accordingly and signed a written informed consent form. A pain scale chart (Visual Analogue Scale VAS) [11] was given to the participant who was taught how to record the pain level before treatment. All patients received single-visit root canal treatment.

Inclusion criteria	Exclusion criteria
Age between (20-50) years old. Systemically- healthy patients (ASA I). Mandibular premolar teeth with: <ul style="list-style-type: none"> • Symptomatic irreversible pulpitis. • Single root canal. • Straight root canal. 	Mandibular premolars with necrotic pulp, tenderness to percussion or palpation or fistula. Patients having teeth with any of the following radiographic findings: <ul style="list-style-type: none"> • Periapical radiolucency. • Internal or external resorption. • Open apices. • Root canal obliteration, perforation. • Previous root canal treatment. Pregnant women and patients with pacemakers were excluded from the study.

Table 1: Eligibility criteria of the present study.

Treatment procedures

Inferior alveolar nerve block anesthesia (4% Articaine hydrochloride with 1:100.000 adrenalin, Art Pharma for pharmaceutical industries, 6th October city, Egypt) was performed. Intra-pulpal injection was the supplemental anesthesia of choice when needed. Then, the related tooth was isolated with rubber dam. An access cavity was performed with a high-speed handpiece using round bur and Endo-Z bur. Irrigation with 2.6% sodium hypochlorite (Clorox, Household Cleaning Products, Egypt) was performed using a 27-gauge side-vented needle fit and disposable plastic syringe. The canals were explored with #15 and #20 stainless steel hand K- files (MANI, INC. Industrial Park, Utsunomiya, Tochigi, Japan) using a watch winding motion. In the presence of NaOCl, the coronal portion of each canal has been flared using size #17/04 X1 ProTaper Next (PTN) NiTi rotary file (Dentsply Maillefer, Ballaigues, Switzerland) in a brushing motion. Each root canal was then irrigated using 2.6% NaOCl and excess irrigant was removed with cotton pellets without drying the canal. Thereafter, participants were randomly allocated to a group using a computer algorithm program (<http://random.org>) (n = 62).

In control group

The WL was determined using Root ZX according to the manufacturer's instructions. A size #15 K-file attached to the apex locator was slowly introduced into a root canal. When the 0.5mm bar was reached, the rubber stopper was positioned to the coronal reference point (flattened buccal or lingual cusp) and the file was removed from the canal, and the length was measured and recorded to the nearest 0.01 mm then it was verified with a working length radiograph. Measurements were considered valid if the measurement remained stable for at least 5 seconds. Three measurements were made for each tooth and an average of these measurements has been recorded as the estimated working length.

In the intervention group

E-CONNECT S endomotor with integrated apex locator (Eighteenth Medical Technology Co., Ltd, China) was used. The file electrode that is built into the handpiece was latched onto the rotary NiTi PROTAPER NEXT X1 #17/04 file and the lip hook was attached to the patient's lip. The file rotated automatically when it entered the canal. The motor was set to apical auto reverse (AAR) mode so, it automatically stopped rotating at the level 0.5 on its display when the apical constriction was reached. Once the apical

constriction was reached by the first rotary file as indicated by the EAL, the rotary motor was stopped. At this point, the silicon stopper has been positioned to the coronal reference point, and the length was measured and recorded and verified with a working length radiograph.

After WL determination, all teeth in both groups were instrumented by a crown-down preparation technique using PROTAPER NEXT rotary files in a brushing motion with E-CONNECT S endomotor motor. Preparation starts by using the X1 #17/04 file till full WL followed by X2 #25/06, X3 #30/07 and was finished with file X4 #40/06. All files have been rotated at speed of 350 rpm and 4Ncm torque [12]. Canals were irrigated with 3 ml 2.6% sodium hypochlorite solution between each two successive instruments followed by saline solution and final wash with 1ml 17% EDTA solution (Prevest DenPro Limited, India) for 1minute. Then, the canal was dried using paper points. Matching ProTaper NEXT X4 gutta percha point (Dentsply Maillefer, Ballaigues, Switzerland) was put in the canal and periapical radiograph was taken for both groups to ensure proper fit and length. In both groups, the canals were dried with sterile paper points and obturated using modified single cone obturation technique. Spreaders of suitable size were selected and used to allow space for auxiliary cones, together with a resin-based root canal sealer (Meta Adseal, Meta Biomed Co. Ltd, Korea). The cavity was sealed with temporary filling (MD-Temp, Meta Biomed Co. Ltd, Korea).

Postoperative radiographs were taken following the completion of treatment. At the end of the visit, patients were asked to fill the VAS at 1, 3, 5, 7-day intervals. The operator kept in contact with the patients by the phone for reminding and assuring accurate readings. The patients were instructed to take mild analgesic Ibuprofen (400 mg) only when they encountered severe pain as previously suggested [13] and instructed to record the number of tablets, when taken. The patients were recalled after 1 week for follow-up and referral to restorative clinic of Faculty of Dentistry, Cairo University for permanent restoration. All clinical procedures and measurements were performed and recorded by the same operator.

Statistical analysis

All the data was collected and tabulated by Microsoft Office 2016 (Excel). The following variables were recorded: age; gender; tooth number; preoperative pain on the VAS; postoperative pain level on days 1, 3, 5, and 7; and analgesic intake after the procedure

to compare both pain intensity and incidence between the two groups. Continuous data were tested for normality using Shapiro Wilk and Kolmogorov Smirnov tests. Mean and standard deviation values were used for data presentation. Comparisons between the two groups were done using Chi² test when comparing for the incidence of studied parameters and Mann-Whitney test for analysis of severity of postoperative pain. The significance level was set at (P ≤ 0.05). All statistical analyses were performed using IBM SPSS Statistics software (version 22.0; SPSS Inc., Chicago, IL, USA).

Results

Eight patients were lost during follow-up (4 patients from the control group and 4 patients from the simultaneous length control during root canal preparation group) figure 1. No statistically significant differences were found between the groups in terms of demographic data (age, gender, tooth number) (P > .05) Table 2. Pre-operative and postoperative pain levels according to the groups are shown in table 2. According to the statistical analysis, no statistically significant difference was found between the groups in terms of preoperative pain (P > .05). However, the simultaneous length control during root canal preparation group had lower postoperative pain intensity on day 1, 3 and 5 than did the control group (P < .05). No statistically significant differences were found between the groups in terms of postoperative pain intensity on day 7 (P > .05). The simultaneous length control during root canal preparation group had lower postoperative pain incidence on day 1 and 3 than did the control group (P < .05). No statistically significant differences were found between the groups in terms of postoperative pain incidence on day 5 and 7 (P > .05).

	Control n = 58	Intervention n = 58	P-value
Gender [n (%)]			
Female	23(39.7%)	24(41.4%)	0.85
Male	35(60.3%)	34(58.6%)	
Age (Mean ± SD)	32.9 ± 6.25	31.67 ± 6.39	0.28
Tooth type			
Mandibular 1 st premolar N(%)	26(44.8%)	27 (46.5%)	0.9
Mandibular 2 nd premolar N(%)	32(55.2 %)	31 (53.5%)	

Table 2: Demographic data of both groups.

In control group, 22 patients (37.9%) needed analgesics due to the presence of moderate to severe post-operative pain. While in intervention group, only 5 patients (8.6%) needed analgesic. There was a statistically significant difference between the two groups in terms of postoperative analgesic intake (p < 0.001).

	Control n = 58	Intervention n = 58	P value
Pre-operative	95 ± 4.9	96.12 ± 4.5	0.2
First day	33.18 ± 37.11	9.8 ± 18.7	<0.001
Third day	12.9 ± 19.34	1.6 ± 7.5	<0.001
Fifth day	1.93 ± 6.4	0.00 ± 0.00	0.023
Seventh day	0.00 ± 0.00	0.00 ± 0.00	1

Table 3: Mean, Standard deviation values of pain intensity of both groups.

		Control n = 58	Intervention n = 58	P-value
Pre-operative	No pain	0(0%)	0(0%)	1
	Mild pain	0(0%)	0(0%)	
	Moderate	0(0%)	0(0%)	
	Severe	58(100%)	58(100%)	
First day	No pain	26(44.8%)	42(72.4%)	0.002
	Mild	2(3.4%)	2(3.4%)	
	Moderate	11(19%)	11 (19%)	
	Severe	19(32.8%)	3(5.2%)	
Third day	No pain	38(65.5%)	55(94.8%)	<0.001
	Mild	0(0%)	0(0%)	
	Moderate	17(29.3%)	3(5.2%)	
	Severe	3(5.2%)	0(0%)	
Fifth	No pain	53(91.4%)	58(100%)	0.07
	Mild	1(1.7%)	0(0%)	
	Moderate	4(6.9%)	0(0%)	
	Severe	0(0%)	0(0%)	
Seventh	No pain	58(100%)	58(100%)	1
	Mild	0(0%)	0(0%)	
	Moderate	0(0%)	0(0%)	
	Sever	0(0%)	0(0%)	

Table 4: Pain Incidence at different pain categories of the two groups.

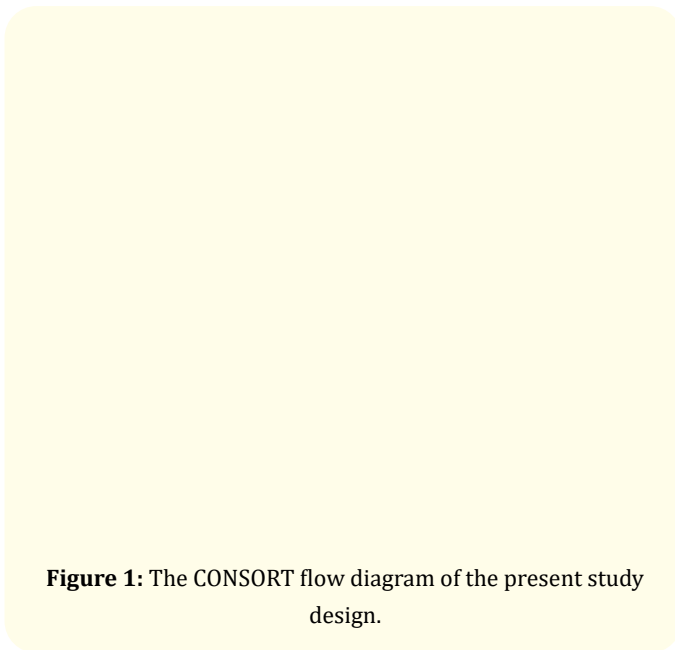


Figure 1: The CONSORT flow diagram of the present study design.

Figure 2: Line chart representing the changes in the intensity of pain at different time intervals for each group.

Discussion

The present study was conducted as a parallel, randomized clinical trial on 124 participants with teeth with symptomatic irreversible pulpitis following the CONSORT 2010 statement [14,15]. The aim of the present study was to evaluate the effect of simultaneous length control during root canal preparation on post-operative pain compared with separate length determination and root canal preparation as only one study was published concerning this matter [10].

Patients with symptomatic irreversible pulpitis related to their mandibular premolars and indicated for endodontic treatment were selected for the present study. These cases showed significantly higher incidence of postoperative pain compared to asymptomatic teeth [16] as presence of preoperative pain has been cited as predictive factor in the incidence of postoperative endodontic pain [17]. Postoperative pain was also found to be significantly higher in the mandible compared to the maxilla [17,18] 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 [18].

Single rooted teeth were selected for evaluating the postoperative pain to minimize the risk of iatrogenic errors due to missed canals or complicated root canal anatomy. Mandibular premolars with single, straight canals, and normal peri-apical radiographic appearance were included since it has been reported that the existence of peri-apical radiolucency of different sizes can affect postoperative pain [19].

In the current study, treatment was completed in a single visit which has several advantages including reduction in the number of appointments and treatment cost, familiarity with internal root canal anatomy, avoidance of inter-appointment contamination and bacterial regrowth which result in pain and reinfection of the canals as a sequence of bacterial ingress from a leaky temporary restoration [20,21].

Cervical preflaring of the root canals was done first before the electronic working length measurement in both groups. Preflaring of the root canals allows working length files to reach the apical foramen more consistently, which in turn increases the efficacy of apex locator and more accurate measurements [22-24].

In the control group, The WL was determined using Root ZX (J Morita, Tokyo, Japan). Root ZX has been proven to be accurate in determining the distance between the file tip and the apical constriction. Therefore, it is considered the gold standard in endodontic practice [7].

The mechanical preparation of the teeth, in both groups, was done using ProTaper Next rotary file system (PTN) as its offset design along with its swaggering motion in the canal could enhance the auguring of debris out of the canal coronally rather in the apical direction [25,26]. Thus, causing lesser postoperative pain [27].

In the present study, a standardized irrigation protocol involved using 3 ml of 2.6% sodium hypochlorite solution between each two successive instruments as proven to be less cytotoxic than 5.25% sodium hypochlorite solution [28] with the same antimicrobial effect [29]. The combination of sodium hypochlorite followed by final wash of EDTA solution after being separated with saline solution was used in previous studies [30,31] to remove both the organic and inorganic parts of the smear layer.

Obturation of the canals was done using modified single cone technique with the matching ProTaper Next gutta percha cones that proved to have the most gutta-percha-filled areas and least sealer-filled areas and voids compared to other types [32].

In our study, postoperative analgesics were only prescribed on-demand and not a regular prescription of medication since it would influence the outcome measures of the study. This recommendation is consistent with previous study [10]. Since the objective was primarily to assess postoperative pain after root canal

treatment, patients were advised to take analgesics only in the case of severe pain.

Among the non-steroidal anti-inflammatory drugs, Ibuprofen was selected in previous studies [33,34]. It is proved to be effective for treating acute pain and inflammation related to endodontic treatment, rapidly absorbed, and metabolized by the liver [35].

In the present study, the baseline characteristics including age, gender and tooth type showed no significant difference between the two groups implying successful randomization which assumes similar distribution of factors and minimizing any potential effects of these parameters on the results of the present study.

The results of this study showed that, the intervention group (Simultaneous working length control during root canal preparation) revealed statistically significant lower postoperative pain intensity on the first, third and fifth days than did the control group. It also showed a significant increase in the percentage of cases that reported some pain relief in the intervention group compared to the control group on the first day postoperatively. On the other hand, there was a significant increase in the percentage of cases that reported some pain relief in the control group compared to the intervention group on the 3rd, 5th, and 7th days. This can be explained by the higher number of patients who experienced pain in the control group compared to the intervention group.

The results of the present study are in accordance with the results by Arslan., *et al.* who found that simultaneous length control during root canal preparation group resulted in lower postoperative pain levels on all days compared with the control group; only the differences on day 1 were statistically significant [10]. The author assumed that, this may be due to the small sample size of his study. The results of our study also come in agreement with a previous study [36] which concluded that, the possibility of performing mechanical instrumentation with an endomotor with integrated EAL eliminates the need to stop during the root canal preparation to measure and confirm the WL and allows monitoring the file position and confining the preparation to the canal system.

In the control group, the WL was obtained in the early stages of the root canal preparation using Root ZX and files were calibrated by the visual method, by using a clinical ruler and rubber stoppers. However, the visual method is subjected to procedural errors such

as inaccurate identification of the length, lack of parallelism when measuring the file, and rubber stopper movements [37]. Moreover, it has been proved that WL can vary across different stages of the chemo-mechanical preparation mainly due to straightening of the root canal during instrumentation [22,38-40]. Loss of the working length (WL) can lead to instrumentation beyond the predefined apical limit of the preparation [41]. Some studies showed that this kind of over instrumentation can adversely affect the outcome of the endodontic treatment [41-43]. Furthermore, all endodontic instruments produce apical extrusion of debris, even when the preparation is kept within the confines of the root canal [44]. Consequently, preparations ending in the periapical tissue will produce a greater amount of debris extrusion that could elicit a neurogenic inflammatory response resulting from an irritation of the periodontal ligament with subsequent postoperative symptomatic apical periodontitis [45,46].

Therefore, it seems reasonable that controlling the WL simultaneously during root canal preparation to avoid preparations ending in the periapical tissue would significantly decrease the postoperative pain which was proven in the intervention group. Moreover, the incorporation of EALs into integrated endodontic motors improves the efficiency of shaping procedures by dispensing the need of calibrating the files [47-51].

By searching the recent available literature, the study by Arslan., *et al.* was the only study comparing the effects of simultaneous length control during root canal preparation and separate length determination and root canal preparation on postoperative pain [10]. Thus, a direct comparison cannot be done with the findings of other studies.

Conclusion

Within the limitations of the present study, it could be concluded that simultaneous length control during root canal preparation aids decreasing postoperative pain intensity and incidence and has a significant effect on reduction of postoperative analgesic intake. Using simultaneous length control during canal preparation made the single visit endodontic treatment faster and easier which helped both the operator and the patient.

Recommendations

Within the limitations of this study, it could be recommended that further clinical trials are needed to investigate the effects

of simultaneous length control during root canal preparation on teeth with other pulpal and periradicular conditions, such as necrotic pulp and acute apical abscess. It would be of much interest to evaluate the effect of simultaneous length control during root canal preparation of molar teeth, with their more complicated anatomy.

Conflict of Interest Statement

The authors have stated explicitly that there are no conflicts of interest in connection with this article. This research is self-funded.

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Volume 5 Issue 12 December 2021

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