



A Comparative Evaluation of the Effect of Root canal Preparation by Wave One and Neolix on Post - Operative Pain in Mandibular Premolars with Acute Irreversible Pulpitis: A Blinded Randomized Clinical Trial study

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Abstract

Introduction: Many instrumentation techniques have been innovated unfortunately, all of them associated with debris extrusion which was attempted one important cause for post-endodontic pain. The study was designed to compare the influence of two different kinematics rotary nickel-titanium instrumentation systems, full rotation single file (Neolix) versus reciprocation single file (WaveOne) on postoperative pain (incidence, degree and duration) after single visit endodontic treatment in single rooted mandibular premolars with acute irreversible pulpitis.

Materials and Methods: Forty four patients with symptomatic irreversible pulpitis in their mandibular premolars were randomly allocated to two groups underwent root canal preparation using (Neolix) and (WaveOne) files. Patients were asked to rate their pain level on a number rating scale (NRS) postoperatively after 6,12,24,48 hours. Mann- whitney U test and Chi square test were used to compare the outcome between the two groups.

Results: Results showed that there was no statistical difference between the two groups regarding demographic data except gender, prevalence of post- operative pain. Also, there was statistically significant difference in postoperative pain reduction between the two groups at 12 hours ($p = 0.4$).

Conclusion: Within the limitation of this study it was concluded that both files are reliable method for root canal preparation having a normal range of postoperative pain.

Keywords: Irreversible Pulpitis; Numerical Rating Scale; Postoperative Pain; Reciprocation; Root Canal treatment; Rotation

Abbreviations

EDTA: Ethylenediaminetetraacetic Acid; NRS: Numerical Rating Scale.

Introduction

Endodontic post-operative pain is a real challenge for the endodontist as it can have detrimental effect on the individual's quality of life. It is defined as any degree of pain that occurs after endodontic treatment [1]. Flare-up is a phenomenon known in literature which defined by the development of pain, swelling or both a few hours or days after the endodontic treatment [2]. Meanwhile post endodontic pain is reported by 25%-40% of patients irrespective of pulp and periradicular status [3-5].

According to the systematic review of Pak and White [6], the prevalence of pain in the first 24 hours is 40%, falling to 11% after 7 days. Since post-operative endodontic pain is considered to be multifactorial, [6] the most common factors influencing the occurrence of this pain may be due to over or under instrumentation, apical extrusion of intra canal dressing, infected dentinal debris and irrigant, hyper occlusion, missed canals, presence of periapical pathosis with preoperative pain [7].

During the chemo -mechanical preparation of the root canals, apical extrusion of root canal debris including dentin chips, pulp tissue, micro-organisms and irrigants that exacerbate an inflammatory response leading to pain with an incidence ranges from 1.4%-16% according to the literature and this includes both hand

and rotary instrumentation [8]. The amount of extruded debris differs depending on instrument design and technique of instrumentation [9].

However; new advances are present nowadays in kinematics of canal shaping either rotation or reciprocation movement of files systems, where many studies have assessed the properties of instruments in invitro studies [10-12].

One of the most popular reciprocating systems used nowadays is the Wave One, where the system consist of single file for full length canal preparation with the advantage of using new metallurgy of M-wire with thermal treatment which improving strength, resistance to cyclic fatigue and less incidence to fracture, its cutting design and its motion allows it to go through the canal in less preparation time by 40% as claimed by manufacturer compared to traditional rotary techniques in continuous motion with maintaining the canal shape which favorable for the dentists to save time and cost with decrease of debris extrusion that considered the main advantage of this system. It also has other unique property as its sterile file used for single use to prevent the cross infection. And about the single file full rotation systems the Neolix file which considered innovative one which made from CM wire with electric discharge machining which produces more flexible file with specifically hard and naturally rough surface, these features allow the file to be flexible with resistance to fatigue with possibility to precurving the file in difficult canal access as claimed by manufacturer.

Few studies focused on the clinical outcomes [10-12], like the post-operative pain which considered one of the important concerns after endodontic treatment in in vivo studies especially within the first 24 hours but; unfortaually an extensive literature search demonstrated that few studies till date have evaluated the post-operative pain after instrumentation of root canals with single -reciprocating files versus single rotation file.

Materials and Methods

Ethics

The protocol of this randomized clinical trial was approved by the institutional review boards/ethical committees (IRBs/ECs) of the Faculty of Dentistry, Cairo University. The clinical trial was registered on www.clinicaltrials.gov (Code: NCT02940405).

Selection of subjects

All included patients signed an informed consent after the explanation of the involved procedures and the possible risks. The patients were recruited from the outpatient clinic of the Department of Endodontics from November 2016 to May 2017. Interventions were done by a master's degree student in the Department of Endodontics.

Sample size

The sample size was calculated considering that a minimal clinical difference in the pain between the two groups will be clinically relevant. Using the power of 80%, a level of significance of 5%. 17 patients per group would be necessary. The number was increased to 20 to allow for losses during follow up and again to 22 per group to correct for non-parametric usage. Sample size was calculated using G*power program (university of Dusseldorf, Dusseldorf, Germany).

Inclusion and exclusion criteria

Forty four adult patients with a diagnosis of irreversible pulpitis in a mandibular premolar tooth were invited to participate in this study. All patients (males and females) were 20-35 years old; in good health (ASA class I); with a history of preoperative sharp, moderate or severe pain; with normal periapical radiographic appearance or slight widening in lamina dura; and able to understand the use of pain scales. Patient exclusion criteria included those teeth with positive percussion test, teeth had history of necrosis with or without apical pathosis, and teeth had sinus tract or fistula extra oral or intraoral. Patients had active pain in more than one premolar in the same side or who had taken analgesics in the 12 hours preceding the preparation, pregnant or mentally retarded patients and teeth with grade 2 or 3 mobility. Diagnostic criteria for symptomatic irreversible pulpitis was confirmed by a chief complaint of spontaneous pain, then the patient marked his pain level as moderate to severe pain on the NRS scale [13], more objective confirmation was done by ethyl chloride spray (Ethyl chloride spray; Walter Ritter GmbH, Germany), as lingering moderate to severe painful response to cold testing (> 10 s).

Randomization, allocation concealment and blinding

To randomize the participants, a table of random numbers from 1 to 44 distributed into two groups was generated using a computer

program (www.random.org) and table was kept with the assistant supervisor. The patients were blinded. After the subject was confirmed to be enrolled in the trial, the investigator gave a phone call to the co-supervisor who allocated the patient either to the intervention or the control group according to the generated random sequence. The investigator was the one responsible for performing the whole procedure, assessing the outcomes from the patients and recording any abnormal findings such as mishaps or side effects.

Clinical Procedures

After patients were confirmed eligible and signed the informed consent, they were asked to mark their preoperative pain level on the NRS. According to the randomization sequence, each patient received two IANB injections of either anesthetic solution (2% mepivacaine hydrochloride with 1:100,000 epinephrine) (Carpule Mepecaine -L, (Alexandria Company for pharmaceuticals and chemical industries) using a side loading aspirating syringe and 27-gauge long needle (Neopoint; Servoprax GmbH, Germany). At 15-minutes post injection, once lip numbness occurred, the patient received inferior alveolar nerve block injections. Access cavity was performed using round bur size 4 and endo-z bur (Dentsply Maillefer, Ballaigues, Switzerland), the tooth was then isolated using rubber dam to prevent introduction of saliva and bacteria from the oral cavity. The patency of the canal was checked with K- file size 15 taper 0.02 (Mani Inc., Tochigikan, Japan) and extirpation of pulp was done with H-file size 15 taper 0.02 (Mani Inc., Tochigikan, Japan). An electronic apex locator (Root ZX, Morita Corporation, Kyoto, Japan) was used to determine working length which confirmed radiographically to be adjusted 1mm shorter than the root apex. The patients were classified into two groups, Group A: mechanical preparation was done by large reciprocating WaveOne (WaveOne DENTSPLY Maillefer, Ballaigues, Switzerland.) single file size 40 taper 8% in a reciprocating slow in and out pecking motion to full working length with preprogrammed motor (X. Smart plus Dentsply Maillefer, USA.) with reducing hand piece 6:1 more anti-clockwise angle than clock wise one. Group B: mechanical preparation was done by single large full rotation Neolix file (Neolix SAS, France) size 40 taper 4% with slow in and out pecking motion to the full working length with the same motor speed 300-500 rpm and torque 1.5 N.cm. Both files were used according to the manufacturing instructions, each file used only once. The file flutes were cleaned after three pecks and irrigation was done by 3 ml 2.5% sodium hypochlorite by a 27-G side-vented needle (Endo-Top; CerKamed, Poland). To remove the smear layer, final irrigation was done with 5 ml of 2.5% sodium hypochlorite followed by sterile

saline and 3 ml of 17% EDTA solution (Calix E; Dharma Research, Florida, USA) for 1 minute. Final rinse was done with saline. Master cone-fit radiograph was done with the corresponding size cones. The canals were then dried with paper points and obturated using a modified single-cone technique using matched-size gutta-percha points (Meta Biomed Co., Ltd, Chungbuuk, Korea) and a resin-based sealer (Adseal, Meta Biomed Co., Ltd, Chungbuuk, Korea). Finally, a cotton pellet placed in the pulp chamber and the access cavity sealed with temporary filling (Cavit 3M ESPE, GERMANY). At the end of the visit, participants were asked to record their pain intensity (using NRS) after 6, 12, 24, 48 h and to return the pain diary back to the investigator.

Pain assessment and outcomes

Pain was measured using an 11-point NRS where the endpoints are the extremes of no pain and worst pain. Pain intensity was assigned into one of four pain categories: none (0); mild (1-3); moderate (4-6); and severe (7-10) and the time points are 6, 12, 24, 48 hours, (Preoperative assessment of pain were also included). The outcome was postoperative pain (incidence, degree and duration) after single visit endodontic treatment.

Statistical Analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS), version 21 (IL SPSS, Inc, IBM Corporation, Chicago, USA). Numerical data were described as mean and standard deviation or median and range. Categorical data were described as numbers and percentages. Data were explored for normality using Kolmogorov-Smirnov test and Shapiro-Wilk test. Comparisons between two groups for normally distributed numeric variables were done using the Student's t-test, while for non-normally distributed numeric variables by Mann-Whitney test. Comparisons between categorical variables were performed using the Chi square test. A p-value less than 0.05 was considered statistically significant. All tests were two tailed.

Results and Discussion

Results

Of the 60 enrolled participants assessed for eligibility, 44 participants were included in the study and were randomly distributed between two groups, 22 patients in each group. The trial design followed the CONSORT 2010. The flow of the participants throughout the study is presented in (Figure 1). There was no significant difference found between the two groups regarding age, tooth type distribution and preoperative pain ($p > 0.05$) but there was sig-

nificant difference regarding gender. Baseline demographic data is presented in (Table 1).

Age	Group A		Group B		P Value
Median	29		29		0.822
Minimum	21		20		
Maximum	35		35		
	No.	Percentage	No.	Percentage	P Value
1st Premolar	6	27.3%	11	50.0%	0.122
2nd Premolar	16	72.7%	11	50.0%	
Median NRS	8	7	0.40		
Minimum	4	4			
Maximum	10	10			

Table 1: Median, minimum, maximum values and results of Mann-Whitney U test for comparison of age, tooth type and preoperative pain between the two groups (Group A: WaveOne file, Group B: Neolix file)

	Group A		Group B		P Value
	No.	Percentage	No.	Percentage	P Value
Male	6	27.3%	1	4.5%	0.039*
Female	16	72.7%	21	95.5%	

Table 2: Frequencies, percentages (%) and results of Chi square test for comparison of gender distribution between the two groups (Group A: Wave One file, Group B: Neolix file).

The patients in group B (Neolix) showed higher pain scores than in group A (WaveOne) only at 12 hours postoperatively (statistical difference) (Table 3).

Group		Group A	Group B	P -Value
Pain intensity				
Preoperative	Median Range	8 4 - 10	7 4 -10	0.40
6 h	Median Range	4 0 - 8	5 0 -10	0.184
12 h	Median Range	3 0 - 6	4.5 0 - 8	0.04*
24 h	Median Range	2 0 - 3	2 0 - 4	0.662
48 h	Median Range	0 0-1	0 0 - 3	0.609

Table 3: Median and range values of preoperative pain Postoperative pain intensity at different time intervals, and calculated p-value in the two groups.

Discussion

The Neolix file is a new file in the market with no enough studies in literature evaluating its action and its effect on the postoperative pain. It was used in this study as intervention owing to its new properties and its innovative technology in metallurgy that aids in its cutting efficiency. The WaveOne file was used as comparator because of its unique kinematics, shaping ability of the root canals. Many studies had evaluated its effect on postoperative pain and debris extrusion but still there was a debate.

It is difficult to determine causative factor of the pain after endodontic treatment that may include preoperative factors and intraoperative mechanical factors such as extrusion of debris, over instrumentation, faulty application of rubber dam clamp and irrigant extrusion [14], that's why high amount of care was exhibited in this study to reduce all possible preoperative and intra operative pain factors.

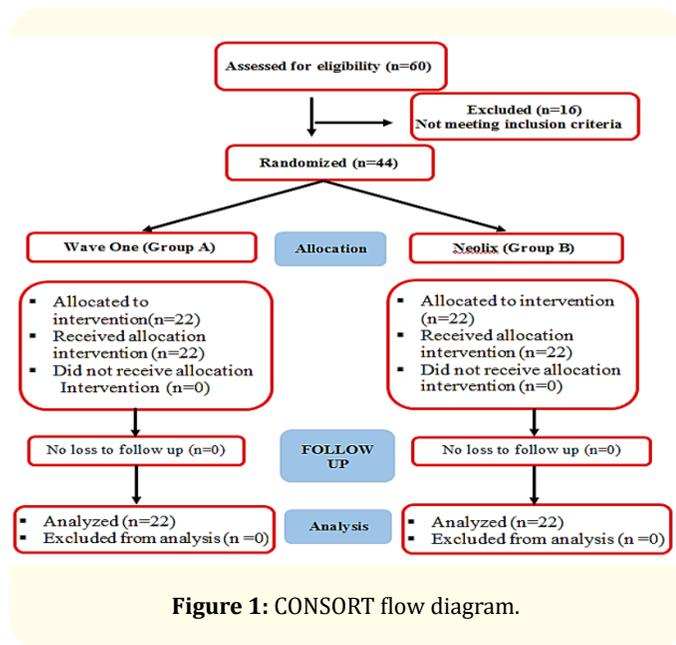


Figure 1: CONSORT flow diagram.

Regarding the baseline data there was no statistically significant difference between the two groups in the mean age values, tooth type distribution and preoperative pain (Table 1).

Regarding the gender there was statistically significant difference between the two groups (Table 2).

In the present study, patients with a non-contributing history, who did not take analgesic medication during the preceding 12 h before treatment, were included to avoid any drug interaction and to prevent any variable from influencing the results of the study. Mandibular posterior teeth were selected as post endodontic pain is significantly higher in these teeth [15]. It has been reported by Yesilsoy, *et al.* [16] that more pain was felt in mandibular teeth (42%) than in maxillary teeth (26%). Mandibular premolars with single root and single root canal were chosen to standardize the number of the prepared canals and to evaluate the pain with minimal variables. Analysis of patient's age, tooth type, and baseline pain score showed that their equal distribution between the 2 groups. But there was a significant difference in gender distribution where the number of females was significantly more in Neolix group. This might have effect on the outcome records of postoperative pain between the two groups. It was proved that women were significantly more likely to anticipate higher pain and unpleasantness levels than men [17]. Pain recording and evaluation is difficult as it depends upon the patient's threshold level which differs from one patient to another. The numerical rating scale was used in this study to evaluate the postoperative pain as it is considered the most valid scale in recording the pain intensity in humans when compared to other ways [13].

In this study the pain intensity was recorded preoperatively as base line data and postoperatively at different time intervals. 6 hours was chosen as it is the time that the effect of anesthetic solution will start to fade [18]. 12, 24, 48 hours were chosen as it was proven that most of postoperative pain occurred between these time intervals [5,19].

The results of the study showed significant difference in postoperative pain intensity between the 2 groups. Only at 12 hours interval where the Neolix group showed higher pain scores. Although the Neolix groups also recorded higher pain score than WaveOne at 6 hours but the difference was not significant. This might be due to large number of females in this group. It was stated by several researches [20-23] that the postoperative endodontic pain is expressed more in female patients when compared to male patients.

During the root canal treatment by rotary Ni-Ti instruments there is still a degree of apical debris extrusion accompanying different kinematics. This results in activation of numerous types of inflammatory cells and mediators and pain initiation [24-26].

There is a debate concerning the effect of different kinematics on amount of apical debris extrusion during endodontic treatment. Yan Lu, *et al.* [43] stated that WaveOne file is better in squeezing the debris into the flutes then carrying them out of the orifice leading to less apical extrusion of debris and less postoperative pain. He proved that WaveOne single reciprocating file resulted in less apical extrusion than continuous rotation motion using BLX files. This was in agreement with several studies that proved that WaveOne reciprocating file extruded less debris than full rotation files such as Protaper Universal [28], BioRace [29], Protaper Next and Twisted files especially when used at smaller size [30]. These results were consistent with a study done by Ehsani, *et al.* [31] who proved that Neolix file extruded more debris than WaveOne file. Subsequently other studies [32-34] claimed that reciprocating files resulted in less postoperative pain than continuous rotation files. On the other hand, in spite of the few studies in literature concerning the effect of Neolix file on debris extrusion and postoperative pain Goerig, *et al.* [35] claimed that full rotary motion tends to direct debris towards the orifice avoiding its extrusion apically. Others [36,37] approved the concept of continuous rotation rotary file extruded less debris than single reciprocating file system.

Two systematic reviews done by Ahn, *et al.* [38] and Caviedes, *et al.* [39] revealed that most of the included studies concluded that the amount of debris extrusion and subsequently pro-inflammatory mediators that are released causing postoperative pain are more with reciprocation files than with continuous files rotating ones. Nekoofar, *et al.* [40] and Pasqualini, *et al.*, [41] also proved that WaveOne file resulted in more postoperative pain than other full rotation files. Others believed that there was no significant difference between reciprocation files and continuous rotation files concerning the debris extrusion [42-44] and postoperative pain [45].

These contradicting findings might be explained by difference in the designs of the investigation.

In the present study there was a significant decrease in pain at all postoperative intervals compared to preoperative pain scores. This was accordance to several studies [20,46] showing successfully treated cases. This was due to the high standard of care followed during cases involved in this study.

Postoperatively higher pain scores were recorded at 6 and 12 hours with no significant difference between the 2 intervals. This was agreement with several studies [32-34] where patients re-

corded higher pain scores at 6 and 12 hours postoperatively. This is explained to be due to the initiation of tissue inflammation response resulting from debris extrusion and stimulation of nociceptors of c-fibers found in the periodontal ligaments that was stated to reach its maximum level at 12 hours postoperatively [42,47]. There was a going on significant decrease in pain scores at 24 and 48 hours compared to each other and to all other tested intervals. This might be explained due to subsiding of inflammatory response and the ongoing process of normal healing [24,48].

According to the systematic review of Pak and White [8] the prevalence of pain in the first postoperative 24 hours is 40% falling gradually to reach 11% after 7 days.

Conclusion

Within the limitation of this study it was concluded that both files are reliable method for root canal preparation having a normal range of postoperative pain.

Conflict of Interest

The authors deny any conflicts of interest in this study.

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