



EVALUATION OF POSTOPERATIVE PAIN AFTER USING XP-ENDO SHAPER AND F-ONE BLUE FILES

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ABSTRACT

Objectives: This study was aimed to evaluate the effect of XP-endo shaper file and F-One blue files on the degree of the experienced postoperative pain. **Subjects and Methods:** Twenty male patients complaining of acute pulpitis without apical periodontitis related to the mandibular molars were divided into 2 groups: group 1: treated with XP-endo shaper and group 2: treated with F-One file. The postoperative pain scores were recorded at 6,24,48,72h and 7days using the modified verbal descriptor scale. Mann-Whitney U test was used to compare between the two groups. Dunn's test was used for pair-wise comparisons when Friedman's test is significant. The significance level was set at $P \leq 0.05$. **Results:** There was no statistically significant difference between the two groups at different time intervals except at 48h in which the F-One showed statistically significant lower mean pain scores than the XP-endo shaper file. **Conclusions:** Both XP-endo shaper and F-One blue files showed nearly the same amount of postoperative pain over time.

KEYWORDS: F-One blue, Root canal preparation, Rotary Ni-Ti files, Postoperative pain, XP-endo shaper.

INTRODUCTION

Postoperative pain is considered one of the most commonly occurring complication after root canal preparation ⁽¹⁾. In the literature, it has been reported that the incidence of the postoperative pain to be between 1.5% and 53% and it may last from few hours to many days after root canal treatment ^(2,3). Several reasons may contribute to the development of the postoperative pain such as irrigant and debris extrusion, presence of periapical pathosis, or mechanical injuries to the periapical tissues that stimulate the release of some cell mediators that result in inflammatory response ^(4,5). Unfortunately, all instrumentation techniques and instruments are associated with debris and irrigant extrusion which is inevitable ⁽⁶⁾.

In the past few years, with the advancement in the instrument designs and metallurgy, many files emerged in the dental market which showed promising results and unique designs. One of these are the XP-endo shaper file (FKG, La Chaux-de-Fonds, Switzerland) is made of MaxWire alloy with a tip diameter #30 and a core taper of 1% ⁽⁷⁾. The alloy has an unusual transition temperature which according to the manufacturer, allows the file to expand when it is subjected to body temperature and this expansion appears in the form of a "snake-like" shape ^(8,9,10). F-One blue file (FANTA dental materials, Xuhui District, Shanghai, China) is another example, which has a unique design feature. It is a thermally treated file with tip size of #25 (4% taper) and S-shaped cross section with flat surface

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design which allow not only for reducing the blade engagement with the dentin but also reducing the stresses by clearing the debris to relieved area ⁽¹¹⁾.

Up to date, there are no research papers which compared the postoperative pain scores associated with the use of these two files. This study was aimed to evaluate the effect of XP-endo shaper file and F-One blue files on the degree of the experienced postoperative pain. The Null hypothesis was that there will be no difference in the postoperative pain between the two file systems.

SUBJECTS AND METHODS

Patient selection

This single-blind randomized clinical trial study was approved by the ethical committee (641/249), Faculty of Dental medicine, Boys' branch, Al-Azhar university. The treatment procedure and the aim of the study was thoroughly explained to all patients and written informed consent was obtained.

Twenty male patients out of a total of 93 patients aged between 20 and 25 year requiring endodontic therapy for their mandibular first molars were selected from the outpatient clinic in the faculty of dental medicine at Al-Azhar University. All patients were clinically examined and radiographically assessed. Pulp vitality testing was done using an electric pulp tester. Inclusion criteria included: male, literate patients, age range between 20-25 years old, suffering from acute pulpitis without apical periodontitis related to the first mandibular molar.

Exclusion criteria included: teeth with aberrant morphology (calcified canals, teeth showing root dilacerations, open apices, root fractures, roots curvature more than 30 degree), patients with necrotic teeth or teeth showing acute or chronic abscesses, patients with periodontal diseases, or with any systemic diseases, patients took medication 12 hours before the diagnostic visit.

Randomization, grouping and access cavity preparation

All patients were randomly placed into 2 equal groups using a research randomizer software (www.randomizer.org): **Group 1: (XP-S)** XP-endo shaper file. **Group 2: (F-One)** F-One blue file. Prior to isolation and after administration of anesthesia, rubber dam was applied, and access cavity and removal of defective restoration and remaining caries was achieved followed by restoring the missing part of the tooth with glass ionomer filling material and refinement of the access cavity was done using endo-z bur.

Then canals orifices were located using size #8 K-files. Working length was determined using an electronic apex locator (Root ZX II) (Root ZX II: J.Morita Corp, Osaka, Japan) by inserting size# 8 K-file into the canal and then confirmed by radiograph. The working length was set to be 0.5mm from the apical foramen. Additionally, the canals were negotiated using file size #8 and size#10 K-files. Any molar showing canals that wouldn't allow file size#8 to reach full working length was excluded from the study. After working length determination, a glide path was established using file #15 K-file.

Cleaning and shaping procedure:

Prior to file insertion, the access cavity was filled brimful with 5.25% NaOCl (JK Dental vision, Cairo, Egypt.) using a 30-gauge side-vented endodontic needle. Preparation of the root canals was done using either one of the 2 files mounted in a 16:1 handpiece attached to a X smart endo-motor (Dentsply Maillefer, Ballaigues, Switzerland).

Group 1 (XP-S): Preparation with XP-endo shaper file

The XP-endo shaper was used at a rotational speed of 800 rpm and a torque of 1 Ncm according to manufacturers' recommendation (12) Error! Bookmark not defined.. It was used to reach the full working length with 10 strokes. After each 5 strokes, the file was withdrawn and irrigation and

patency with #15 k-file was done. After reaching the full working length, the file was activated in the canal for an additional 15 strokes to the full working length. Then irrigation and recapitulation were done with a #15K file to the working length.

Group 2 (F-One): Preparation with F-One blue file

The F-One blue file (#25 4%) was used at a rotational speed of 500 rpm and a torque of 2.5 Ncm according to manufacturers' recommendation⁽¹³⁾. Preparation in this group was divided into 3 parts: coronal, middle, and apical. After preparing each part, the file was withdrawn, followed by irrigation and recapitulation with a #15K file to the working length. Finally, in both groups, final irrigation was done using 3ml of 5.25% NaOCl and 3ml of 17% EDTA and saline as final flush. Then dryness and temporization were accomplished.

Pain assessment

Pre and Postoperative pain assessment were done using a translated modified verbal descriptor scale (VDS) translated into Arabic as described by Hagra et al,⁽¹⁴⁾. Preoperative pain assessment was done prior to root canal treatment. Each patient was given a copy of the modified VDS and instructed by a trained endodontist on how to use the modified VDS. Postoperative pain assessment was done by the patient five times: 6 hours, 24 hours, 48 hours

72 hours and 1 week.

After completion of the first visit, each patient was given 5 copies of the translated VDS and asked to spot the level of pain intensity sensed during each pain assessment interval. The pain assessment sheets were collected from each patient at the beginning of the second visit. Obturation of the root canals was completed in the second visit using cold lateral compaction technique.

Statistical analysis of the data

Mann-Whitney U test was used to compare between the two groups. Friedman's test was used to study the changes within each group. Dunn's test was used for pair-wise comparisons when Friedman's test is significant. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp. (Franz Faul, University of Kiel, Germany).

RESULTS

Table 1 summarizes the results when comparing the median pain scores between the two groups while table 2 show the results when comparing pain scores at different time intervals occurring within each group.

TABLE (1): Descriptive statistics and results of Mann-Whitney U test for comparison between pain (modified VDS) scores in the two groups:

<i>Time</i>	<i>XP (n = 10)</i>		<i>AF One Blue (n = 10)</i>		<i>P-value</i>	<i>Effect size (d)</i>
	<i>Median (Range)</i>	<i>Mean (SD)</i>	<i>Median (Range)</i>	<i>Mean (SD)</i>		
Pre-operative	4.5 (4-6)	4.8 (0.92)	4 (4-6)	4.6 (0.97)	0.543	0.238
6 hours	4 (2-8)	4.5 (1.58)	4 (3-6)	4.1 (1.2)	0.449	0.325
24 hours	3 (2-7)	3.7 (1.42)	2.5 (2-5)	2.8 (1.03)	0.088	0.78
48 hours	2 (1-8)	2.9 (2.02)	1.5 (0-2)	1.3 (0.82)	0.018*	1.099
72 hours	0.5 (0-3)	1 (1.15)	0 (0-1)	0.3 (0.48)	0.169	0.562
7 days	0 (0-1)	0.2 (0.42)	0 (0-0)	0 (0)	0.146	0.343

*: Significant at $P \leq 0.05$

TABLE (2): Descriptive statistics and results of Friedman's test for comparison between pain scores at different times within each group:

Time	XP (n=10)		AF One Blue (n=10)	
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)
Pre-operative	4.5 (4-6) ^A	4.8 (0.92)	4 (4-6) ^A	4.6 (0.97)
6 hours	4 (2-8) ^A	4.5 (1.58)	4 (3-6) ^A	4.1 (1.2)
24 hours	3 (2-7) ^B	3.7 (1.42)	2.5 (2-5) ^B	2.8 (1.03)
48 hours	2 (1-8) ^C	2.9 (2.02)	1.5 (0-2) ^C	1.3 (0.82)
72 hours	0.5 (0-3) ^D	1 (1.15)	0 (0-1) ^D	0.3 (0.48)
7 days	0 (0-1) ^D	0.2 (0.42)	0 (0-0) ^D	0 (0)
P-value	<0.001*		<0.001*	
Effect size (w)	0.776		0.946	

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

DISCUSSION

Postoperative pain is a frequent complication associated with root canal treatment, which may last from few hours to several days which can be disturbing to patients. Several reasons may contribute to the development of the postoperative pain such as microbial, chemical or mechanical injuries to the periapical tissues that stimulate the release of cell mediators that result in inflammatory response.

In this study, 20 patients were included to participate based on a pilot study conducted on four patients in each group. The pain scores after 6 hours were considered the primary outcome. The mean (SD) values for pain scores in the two groups were 4.75 (1.1) and 3 (1.2), respectively and the effect size (d) was 1.52 using Mann-Whitney U test. Using alpha (α) level of (5%) and Beta (β) level of (20%) i.e. power = (80%); the minimum estimated sample size was (9) patients per group. Sample size was increased to (10) patients per group to compensate for a drop-out rate of 10% after one week. Sample size calculation was performed using G*Power Version 3.1.9.2.

Pain assessment was carried out using the modified verbal descriptor scale (modified VDS) at different intervals: preoperatively, 6 h, 24 h, 48 h, 72 h and 1 week. This is similar to other research done in the field ⁽¹⁵⁾ to cover wide range of time intervals to reflect different possibilities of pain sensation.

The results of the present study showed that, within each instrument group, the highest pain scores were recorded after 6 hours in both groups. In both groups, the severity of pain was observed to decrease significantly between 6 hours to 72 hours. There was no significant difference between the pain scores preoperatively and after 6 hours. Furthermore, there was no significant difference in the pain score between 72 hours and 1 week.

In this study, the highest pain scores were experienced after 6h similar to other research done in the field ^(16,17,18). This is contrary to other research in which the highest postoperative pain scores were evaluated at either 12h or 24h ^(19,20). This difference is due to the fact that in the contrary research the 6h time frame was not evaluated. It is well-established that initial irritation to the periapical tissues results in intensive release of inflammatory

mediators immediately after endodontic treatment. Furthermore, in this study, the gradual decrease of the postoperative pain after 6h is similar to the vast majority of research done in the field ^(15,16).

When comparing the postoperative pain scores between the 2 instrument groups, there was no statistically difference between the pain scores at the different time intervals except at 48 hours, in which group 1 showed a statistically significant higher pain score than group 2. This is a common finding in postoperative pain studies comparing when using different instruments ^(21,22). On the other hand, there is evidence that shows no differences between the various instruments used ⁽²³⁾. This controversy can be attributed to multiple reasons: differences in methods of evaluation of pain i.e., scoring systems and evaluation times, differences in instrument design, preparation kinematics, number of files (single-files vs multiple files), type of teeth being treated (maxillary vs mandibular teeth) and preoperative condition of the pulp (vital vs necrotic).

Specifically, with regards to XP-endo shaper file, the amount of research evaluating the postoperative pain is limited ^(24,25,26,27). Furthermore, with regards to the differences between the instruments used, unlike the previous research done on the XP-endo shaper file, in the present study, the XP-endo shaper file showed more pain when compared to F-One blue file. This can be explained as the F-One blue file has a unique flat-surface design with more clearance space which may allow for debris escape coronally more than apically which may result in less apical extrusion of debris and hence, less postoperative pain comparative to the XP-endo shaper file. Moreover, the research on the apically extruded debris while using the XP-endo shaper file is limited. The results of these research are controversial, some have shown more debris when compared to other files ⁽²⁸⁾ while other have shown less ⁽²⁹⁾ or the same amount as others ⁽³⁰⁾.

CONCLUSION

Both XP-endo shaper and F-One blue files showed nearly the same amount of postoperative pain over time.

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