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Assessment of Post-operative Pain after using EdgeFile X7 and Protaper Next Rotary Systems in Patients with Symptomatic Pulpitis in Mandibular Molars: A Randomized Controlled Clinical Trial

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Abstract

AIM: The aim of the study was to evaluate the incidence of post-operative pain and analgesics intake after single-visit endodontic treatment using Edge File X7 and ProTaper Next (PTN) rotary files in mandibular molars having symptomatic pulpitis.

METHODS: The study included 60 patients complaining of symptomatic pulpitis in mandibular molar teeth. After confirming the diagnosis clinically and radiographically, patients were assigned into two equal groups; Group (I): Instrumentation was done with Edge File X7 (EF) rotary files and Group (II): Instrumentation was done with PTN rotary files. The patients underwent standardized single visit endodontic treatment procedures using 2.5% sodium hypochlorite for irrigation. Modified visual analogue scale was used to access pain preoperatively, and then postoperatively after 6, 12, 24, 48, and 72 h. An analgesic (ibuprofen 400 mg) was prescribed to the patient who suffered from persistent pain. The incidence and/or number of analgesic tablets intake were recorded. Data of pain score were compared using Mann–Whitney U test for intergroup comparisons and Freidman's test followed by Dunn's *post hoc* test for intragroup comparisons.

RESULTS: No statistically significant difference was detected between EF and PTN groups regarding the incidence and intensity of pain at different time intervals ($p > 0.05$). There was a significant reduction in the mean VAS score through the follow-up periods in both groups ($p < 0.001$). The incidence of analgesic intake was not significant in both groups.

CONCLUSION: The incidence of post-operative pain and the analgesic intake in terms of frequency and quantity were found to be similar with both rotary systems for all the post-operative time points.

Introduction

Post-operative pain is the sensation of discomfort that occurs after endodontic intervention. The incidence of post-operative pain is reported to be 25–40% irrespective of pulp and periradicular condition [1]. It has been reported that pain prevalence declined from 40% in the first 48 h after treatment to 11% 7 days post-treatment [2]. Endodontic post-operative pain mechanisms are complex and multifactorial that includes host-dependent factors such as host immunity and history of preoperative pain as well as operator-dependent factors such as mechanical, chemical, or bacterial injury that occurs during endodontic treatment. The extrusion of infected debris as dentin chips, microorganisms, and pulpal tissue remnants to the periradicular area has been considered the main cause of developing of post-operative pain whose intensity is directly proportional to the intensity of the tissue injury [3].

All of the preparation techniques available are associated with certain degree of debris extrusion [4]. Nevertheless, instrumentation technique, instrument design, taper, and tip size have an impact on the amount of debris extruded. It has been reported manual instrumentation cause more debris extrusion that rotary NiTi systems [5].

Major advances in the manufacturing of rotary instruments and metallurgy have introduced various systems with novel designs over the past years. The ProTaper Next (PTN) (DentsplyMaillefer, Ballaigues, Switzerland) system is a member of the fifth generation of NiTi files. It is manufactured with M-Wire; a nickel-titanium alloy fabricated using a thermal treatment process [6]. PTN operates in continuous rotary motion, and designed to operate with the center of rotation positioned off-center, to produce a mechanical wave of motion that moves through the working part of the instrument, thereby reducing the engagement of the file to the dentin. The manufacturer stated that the offset design of this instrument enhances the debris removal and flexibility of the file [7].

EdgeFile X7 instruments (EF) (Edge Endo; Albuquerque, New Mexico, United States) have

triangular cross-sections with constant 0.04 taper and variable helical angle. They are manufactured by a process called FireWire, which comprises a combination of treatment and cryogenic applications that enhanced the file flexibility and resistance and reduced the shape memory effect of NiTi instruments [8].

Till now, limited evidence is available in literature on EdgeFile X7 rotary system and its effect on post-operative pain. The aim of the present study was to evaluate the incidence and intensity of post-operative pain after single-visit endodontic treatment using EFand PTNrotary systems in a randomized clinical trial (RCTs). The null hypothesis was that there would be no significant difference between the tested groups.

Materials and Methods

Sample size

Ethical board approval was given by the university clinical research ethical committee FUE. REC (28/11-2020). By adopting an alpha (α) level of 0.05 (5%), a beta (β) level of 0.20 (20%), that is, power=80% and an effect size (d) of (0.826) calculated based on the results of a previous study Kherlakian *et al.* (2016) [6]; the predicted sample size (n) was a total of (48) cases. Sample size was increased by (25%) to compensate for possible dropouts during follow-up intervals to be (60) cases.

Patient selection criteria

Mandibular molar teeth of systematically healthy patients and were diagnosed with symptomatic pulpitis were included in the study. Symptomatic pulpitis was diagnosed clinically based on positive response to pulp sensibility test, the presence of spontaneous provoked pain that lasted longer than 30 s.

Exclusion criteria included the following: (1) Patients incapable of providing informed consent or under the age of 18, (2) patients who developed allergies to local anesthetic agents or administered medications 7 days before the procedure, (3) teeth diagnosed with acute or chronic apical abscesses, and (4) teeth with roots having internal or external resorption. All participants were informed about the study and signed an informed written consent before starting the treatment.

A list for random participant assignment was generated by randomization software as they were recruited. The randomization was carried out by an operator not involved in the study.

Thermal and electric pulp tests (Parkell, NY, USA) were performed to test the pulp sensibility, and the pulp status was detected after access cavity preparation according to the presence or absence of bleeding. Periapical radiographs were taken using a digital radiologic system (Sirona Vario DG, Bensheim, Germany). Clinical and radiographic data for each patient were recorded on and analyzed by two blinded examiners who were experienced endodontists.

Pain measurement

The patients were asked to record the level of felt pain. Modified visual analogue scale (VAS) was used to record pre- and post-treatment pain. The VAS is a 10 cm straight line numbered from 0 to 10 at each centimeter. The patients scored their pain level to one of four categories as: 1, None (0); 2, mild (1–3); 3, moderate (4–6); and 4, severe (7–10) (Jalalzadeh *et al.*, 2010).

Clinical steps

Local anesthesia using inferior alveolar nerve block technique of 1.8 ml of 2% Mepivacaine HCl_3 with 1:100,000 epinephrine (Mepecaine-L, Alexandria Company for Pharmaceuticals and Chemical Industries, Egypt) using a 27-G needle was administered to all patients.

Confirmation of profound anesthesia was carried out by applying cold testing. Then, a rubber dam was placed to isolate the tooth being treated. Following preparation of the access cavity, each patient was randomly assigned to one of the two experimental groups by choosing a sealed envelope containing the group name. The root canals patency was checked using stainless steel K files #10 (MANI, INC., Industrial Park, Utsunomiya, Tochigi, Japan.), and then the working length was determined using electronic apex locator (J Morita Corp, Osaka, Japan) and confirmed using a periapical radiograph.

Group (I) (n = 30): Mechanical preparation was carried out using EdgeFileX7 (EF) rotary files(Edge Endo; Albuquerque, New Mexico, United States) (size17, taper 0.4, then 20, taper 0.4, size 25, taper 0.4, 30, and taper 0.4). When required, distal root canals were enlarged up to size 35 and 40 (taper 0.4). Files were operatedat300 rpm/3Ncm.

Group(II) (n = 30): Mechanical preparation was carried out using PTN rotary instruments (Dentsply Sirona, Ballaigues, Switzerland) (X1: size17, taper 0.4 and X2: size 25, taper 0.6, X3: size30, and taper 0.7). When required, distal root canals were enlarged up to the X4 (size 40, taper 0.6). The instruments were operated to the full working length passively using an endodontic motor (X-Smart, Dentsply Sirona) at 300 rpm/20 Ncm. When resistance was felt the instrument was withdrawn, the canal was recapitulated with size 10 K-files.

The files were used for a single use following the manufacturer's instructions. The canals were irrigated using 2.5% sodium hypochlorite with a disposable side vented 30-gauge needle tips (NaviTip, Ultradent, South Jordan, UT, USA) plastic syringe.

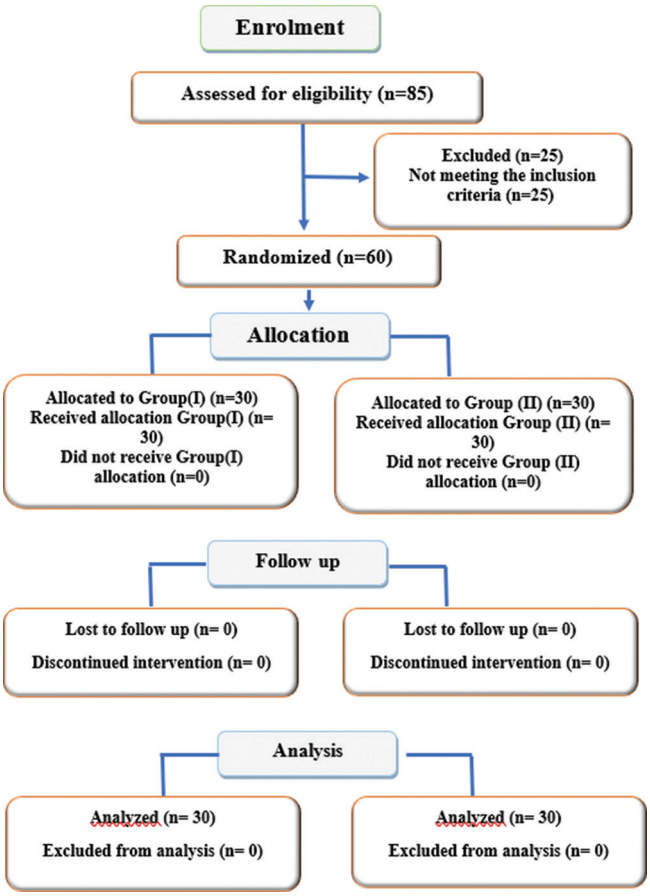

Figure 1: Flow diagram consort for randomized clinical trial

Then, canals were flushed for 1 min with 3 ml of 17% EDTA, followed by 2.5 ml distilled water and 2.5 ml of 5.25% NaOCl, respectively, as a final irrigants. A final rinse of 1 ml 95% ethanol was used before obturation, then root canals were dried with sterile paper points and obturation was completed using modified single cone technique using gutta-percha matching the size of the master file and AdSeal resin-based root canal sealer (AdSeal, META BIOMED CO., LTD, Korea). Periapical radiographs were taken to confirm the master cone fitting and to check the quality of obturation. Access cavities were sealed with Temporary restoration (Cavit G, 3M ESPE DentalMedizin GmbH Co, Seafeld, Germany).

Post-operative pain assessment

The patients were notified about the possible development of pain and given the VAS forms to record the pain level. Ibuprofen 400 mg was prescribed to patients to be taken only when needed. The VAS scores were recorded at 6, 12, 24, 48, and 72 h as well as the analgesic intake.

Table 1: Summary statistics for demographic data

Parameter	File type		p-value
	Edge file	ProTaper next	
Sex			
Male			
n	14	12	1 ns
%	46.7%	40.0%	
Female			
n	16	18	
%	53.3%	60.0%	
Treated tooth			
First molar			
n	22	24	1 ns
%	73.3%	80.0%	
Second molar			
n	8	6	
%	26.7%	20.0%	
Age			
Mean ± SD	33.80 ± 6.88	33.20 ± 6.28	0.805 ns

ns; significant ($p > 0.05$).

Statistical analysis

Categorical data were presented as frequencies (n) and percentages (%) and were analyzed using Fisher's exact test. Numerical data were represented as mean and standard deviation (SD) values. Shapiro–Wilk's test was used to test for normality. Parametric data of age was compared using independent t-test. Ordinal data of pain score were compared using Mann–Whitney U test for intergroup comparisons and Freidman's test followed by Dunn's *post hoc* test for intragroup comparisons. The significance level was set at $p \leq 0.05$ for all tests.

Results

The clinical trial was conducted on 60 patients that were randomly and equally allocated to each of the studied groups (Figure 1). No patient was assigned for an emergency appointment due to flare-up. Summary of demographic data is presented in Table 1. Analysis showed that the demographic data in terms of gender, age group, preoperative pain, and tooth type were equally distributed among the experimental groups ($p > 0.05$).

The mean pre-operative and post-operative pain scores are presented in Figure 2. The mean pre-operative scores for PTN and EF groups were 9 and 8.93, respectively, with no significant difference between the groups ($p > 0.05$). Inter and intragroup comparisons of pain score at different follow-up intervals are presented in Table 2. There was no significant difference between both groups at different intervals ($p > 0.05$). In both groups, there was a significant decrease of pain scores starting from value measured preoperatively to value found 72 h post-operatively ($p < 0.001$). No significant difference was detected between both groups regarding post-operative analgesic intake as presented in Table 3 ($p > 0.05$).

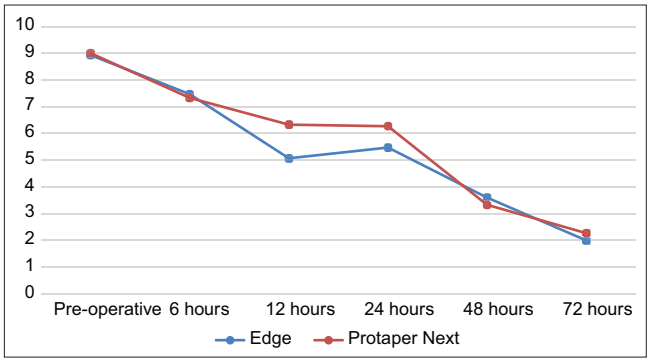

Figure 2: Line chart showing average pain score

Discussion

The aim of this study was to compare the incidence and intensity of post-operative pain following endodontic treatment using rotary PTN and EF rotary instruments. The results of the study showed no significant differences between both groups; thus, the null hypothesis was accepted.

Table 2: Mean and SD values for pain score

Parameter	Pain score (Mean ± SD)		p-value
	Edge file	Protaper next	
Pre-operative	8.93 ± 0.88^{A}	9.00 ± 0.85^{A}	0.935 ns
After 6 h	7.47 ± 2.00^{AB}	7.33 ± 2.02^{AB}	0.870 ns
After 12 h	5.07 ± 1.91^{BC}	6.33 ± 2.38^{BC}	0.126 ns
After 24 h	5.47 ± 2.13^{BC}	6.27 ± 2.34^{BC}	0.250 ns
After 48 h	3.60 ± 2.16^{CD}	3.33 ± 2.47^{CD}	0.539 ns
After 72 h	2.00 ± 1.60^{D}	2.27 ± 1.91^{D}	0.713 ns

Means with different superscript letters in the same vertical column are statistically significantly different; ns; significant (p>0.05). SD: Standard deviation.

Multiple factors have an impact on the post-operative pain sensation, that is, patient, tooth, and operator, causing the clinical study on post-operative pain to be challenging [9]. This study was designed as RCTs as the RCTs show the highest level of evidence within the hierarchy of evidence and its results can be used reliably as a basis for clinical practice. The three elements of randomization (sequence generation, allocation concealment, and implementation) were performed to ensure that all participants have the same chance to be enrolled in any of the study groups.

Table 3: Association between file type and post-operative analgesic intake

Time	Post-operative analgesic intake	File type		p-value
		Edge file	ProTaper next	
Day 1	No			
	n	8	10	1 ns
	%	26.7%	33.3%	
	Yes			
	n	22	20	
	%	73.3%	66.7%	
Day 2	No			
	n	18	22	0.700 ns
	%	60.0%	73.3%	
	Yes			
	n	12	8	
	%	40.0%	26.7%	
Day 3	No			
	n	28	28	1 ns
	%	93.3%	93.3%	
	Yes			
	n	2	2	
	%	6.7%	6.7%	

Ns: Non-significant (p>0.05).

In the present study, the consistent allocation of gender, age group, tooth type, and pre-operative pain intensity was confirmed by Fisher exact test provided an even baseline, eliminating confounding variables, and allowing adequate comparison of the effect of the intervention in the two groups.

Only patients with symptomatic irreversible pulpitis were included in the study to identify the possible factors of post-operative pain from those directly related to the instrumentation technique [10] since in other pulp or periapical conditions (apical periodontitis, pulpal necrosis, or retreatment cases) pain may sustain due to a coexistent periodontal/periradicular lesion, persistent anaerobic infection or external root resorption, and thus the results of the study may be affected by other confounders.

Mild post-operative pain is often experienced following endodontic treatment. A systematic review showed that the incidence of post-operative pain reaches the peak during the first 24 h and significantly drops to 10% or less after 7 days [11]. Chemical, mechanical, and microbial injuries to periapical tissues are considered the leading causes of acute apical inflammation [12]. Infected debris extruded into the through the apex during root canal treatment causes acute inflammatory response due to alteration of the local adaptation syndrome. Extruded debris causes post-operative pain, and by far, all root canal preparation instruments and techniques show some degree of debris extrusion [13]. The NiTi instruments created an enormous development in endodontics; by reducing the debris extrusion, procedural errors, and the duration of the canal preparation [14].

Root canal treatment was completed in a single visit due to similarity of single and multiple visits regarding repair and success rate [15]. Yet, single visit treatment provides many advantages over multiple visit treatment including understanding the internal canal anatomy, reduced probability of bacterial leakage between appointments as well as patient and operator convenience [16].

Mandibular molars were selected due to higher incidence in post-operative pain (6%) compared to maxillary molars (2.2%). This is due to dense trabecular pattern of the mandible encompass reduced blood flow, causing more localization of infection and inflammation and delay the inflammation healing [17].

PTN was selected in this study as the gold standard since several studies showed promising results regarding the effect of PTN on post-operative pain [6], [18] due to its offset design. The offset design produces a mechanical wave that moves along the active part of the file minimizing the engagement between the file and dentin and enhancing auguring debris out of the canal [14].

Modified VAS model was used in the present study to assess post-operative pain (primary outcome) as it is simple tool, easy to use, and has high consistency, repeatability, and sensitive to small changes than other descriptive scales [19]. Pain assessment was recorded at 6, 12, 24, 48, and 72 h, since, pain assessment

started 6 h post-operatively to ensure complete worn off of the local anesthetic agent effect [20]. Follow-up periods were selected up to 72 h because the firing of periodontal ligament proprioceptive nerves that causes post-operative pain disappears after 24–48 h [21].

Statistical analysis revealed that there was no significant difference between PTN and EFrotary systems on the incidence of post-operative pain at all follow up intervals (6, 12, 24, 48, and 72 h).

The highest mean post-operative pain value in the study groups arose in the first 24 h, with a significant drop in the pain ratings at the consequent time points (48 and 72 h). Comparable findings were detected in a published systematic review where the pain incidence declined over the first 2 days of treatment [2]. Ng *et al.* (2004) [22] demonstrated that 40.2% of the patients developed pain 48 h following obturation, but less than 12% skillful severe pain. This could be related to the fact that preparation procedures are commonly accompanied with post-operative pain and edema initiated from an immune response to the microorganisms present in the extruded debris, irrigation material, over-instrumentation, or foreign body reactions to the obturation materials.

None of the patients reported an increase in pain intensity from 24 to 72 h which was in accordance with a previous study due to resolution of inflammation [17].

Acceptable results regarding post-operative pain were recorded in PTN group. This was in agreement with Kherlakian *et al.* (2016) [6] and Nabil *et al.* (2019) [18] who reported that PTN is associated with less post-operative pain than other systems specially reciprocating one.

The reduced post-operative pain reported in PTN group was attributed to its design. The off-centered rectangular cross-section and progressive taper of PTN improve the cutting efficacy of PTN, while the reduced friction between the file and dentin, providing more space for debris removal with less post-operative pain. In agreement with this explanation, Koçak *et al.* (2018) [23] reported that less post-operative pain occurred when using PTN as it showed a significant low torsional resistance and the non-cutting tip allowed each file to safely follow the anatomy of the canal. According to Yılmaz and Sa, (2015) [24], the centering ability of PTN instruments facilitate greater bacteria elimination with less post-operative pain. Another explanation of this finding was that PTN causes less post-operative pain due to its metallurgy. The presences of martensitic phase in NiTi alloy (M wire) cause less amount of apical extrusion at a similar torque than austenitic NiTi alloy. These superior properties in metallurgy ensure reduced stiffness and less restoring force that could explain the least amount of apical extrusion after instrumentation.

On controversy, Capar *et al.* (2014) [25] and Çiçek *et al.* (2017) [26] found that PTN causes more post-operative pain than other rotary systems. This was claimed to that PTN files show additional vibration during preparation that causes an adverse reaction on the periodontal ligament space causing post-operative pain.

EF rotary files showed comparable results to PTN rotary system in terms of post-operative pain. EF showed high flexibility due to the small parabolic cross-section, the surface electro-polishing, and the thermal treatment [27]. The thermal treatment results in an increased flexibility, where the file maintains the canal curvature well and causes less canal transportation. Maintaining the canal curvature has been shown to result in less iatrogenic defects and thus reduced potential to create and extrude debris and thus, lesser post-operative pain [28]. Studies showed that rotary instruments having wide cutting surfaces or radial lands are more likely to contact a large surface area of the canals walls, causing an increase in post-operative pain [29]. Furthermore, EF possesses a variable helical angle reducing the screwing in effect, Koch *et al.* [30] mentioned that instruments with constant helical angle allow the accumulation of debris, while different helical angles efficiently enhances the debris removal.

Ibuprofen (400 mg) was prescribed to be administered if the pain persisted post-operatively as it is a common side effect after the end of the treatment (3–58%) [31]. Ibuprofen is highly effective for pre- and/or post-treatment analgesia and as anti-inflammatory in acute condition [32]. An oral dose of 400 mg of Ibuprofen in tablet form is highly effective and produces a high-level relief with moderate to severe post-operative pain [31]. Regarding the analgesics intake post-operatively, there was no significant difference between both groups. It was realized that the number of analgesic tablets intake decreased with time. This may be also attributed to the resolution of inflammation resulting from pulp extirpation and instrumentation and reduction of the inflammatory mediators in the area with subsequent reduction in nociceptors stimulation and initiation of the repair process that decreased the need for analgesic intake with time [32].

It should be noted that we cannot generalize the results of this clinical study to all clinical cases, and more such studies with a larger sample size and association of more number of variables are required. Future research comparing the post-operative pain after root canal preparation experienced by asymptomatic patients is suggested.

Conclusion

Within the limitations of this study, the following conclusions were drawn:

All instrumentation techniques caused post-operative pain. Highest intensity of pain was

observed at 6 h after the treatment, after which the intensity of pain decreased in both the groups, with no pain observed at 72 h follow-up.

The incidence of post-operative pain and the analgesic medication intake in terms of all the post-operative time points.

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