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Evaluation of Postoperative Pain Intensity Following the Use of Three Different Canal Preparation Systems: A Randomized Clinical Trial

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Abstract

Objective: The objective of this study was to compare the intensity of postoperative pain after Hand Protaper preparation, Wave One Gold and a HyFlex EDM instrument.

Materials and Methods: Thirty patient were randomly divided into three groups. Endodontic treatment was performed for premolar and molar root canals, and they were filled with gutta-percha and an epoxy resin-based root canal sealer using a lateral condensation technique. Teeth were restored using a resin composite material. A single operator performed the treatments in a single visit for asymptomatic molars, and the patients were asked to record their pain severity during a 12, 24, 36, and 72 h follow-up period using a visual analog scale (VAS). One-way ANOVA and Tukey's multiple comparison test were used for statistical comparisons.

Results: Up to 12 hours, postoperative pain was significantly higher in the group treated by HyFlex EDM ($p < 0.01$). No differences were seen from 36 hours to 7 days.

Conclusion: For all three techniques, higher pain intensity was seen at 12 hours and then the pain steadily decreased. No significant difference was noted in quality of life, suggesting the filling systems or techniques has a similar effect.

Keywords: Asymptomatic molars; Endodontic treatment; Postoperative pain; Wave One Gold; Hyflex EDM; Hand Protaper.

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Introduction

Postoperative pain, which is a complex and multi-factorial process, may develop even following an ideal root canal treatment. During root canal preparation, apical extrusion of debris, irrigants, and/or bacteria can occur, potentially leading to such complications as post operative pain, flare-ups, or even treatment failure [1]. Apical extrusion has been reported as the main cause of pain after completion of endodontic treatment [2]. Which factors increase the number of extruded debris remains controversial; studies have demonstrated associations with the type of file motion, to working length, cross-section, tip, taper, flexibility, heat treatment, and number of files used [2]. During canal instrumentation, dentine chips, pulp tissue fragments, necrotic tissue, bacteria, and intracranial irritants may frequently be extruded into the apical foramen, causing post-operative pain. Additionally, it has been proposed that the reciprocating motion itself may contribute to the packing of the debris into the irregularities of the root canal space, raising the possibility of post-operative discomfort. Employing nickel–titanium (NiTi) shaping instruments in rotary or reciprocating motion reduces cycle fatigue and improves root canal centering ability. Because varying amounts of irritants are extruded from the root canal area, different nickel–titanium (Ni-Ti)

rotational systems may produce varied patterns of neurogenic inflammatory response in the periodontal ligament [3]. There are numerous potential causes of post endodontic discomfort. During chemo mechanical preparation, the extrusion of pulp tissue, microbes, and irrigants to the periapical tissues may result in inflammation. In recent years, numerous systems with novel designs have been introduced because of significant advancements in rotating instrumentation and metallurgy. Despite, all preparation methods and tools currently in use are still connected to some degree of extrusion of debris, which can result in post endodontic discomfort [4]. Frequency of postoperative endodontic pain is common, with a reported frequency ranging between 25% and 40%. The HyFlex EDM (Coltene/Whaledent, Switzerland) NiTi GPF is a GPF file system produced using an innovative manufacturing process called Electrical Discharge Machine with a controlled memory (CM) wire. In EDM, instead of conventional grinding, electric discharges are used to shape the file via melting and vaporization of the material [5]. This method creates a cratered surface, which further increases the file's fatigue resistance and lifetime. The HyFlex EDM GPF consists of a single file with a tip size of 10 and a 5% taper. The cross-section of the HyFlex EDM GPF varies along its length, being quadratic at the tip, trapezoidal in the middle, and triangular at the shaft. The flexibility of the HyFlex EDM GPF confers this instrument the ability to maintain the apical canal curvature despite its greater taper [6]. Protaper (Universal) files are shaped as convex, triangular, and cross-sectional, with a guiding tip, and a factually variable helical angle and slope. Initially, hand-used files with Universal design were a revolutionary advancement in endodontics but mechanical preparations became faster with rotary instruments, and it is easier to maintain original anatomy, centered position, and taper of the root canals [6]. Thus, improved and better forms of biomechanical preparation are being developed, which include the coronal to apical approach techniques, having advantages such as less debris extrusion and elimination of coronal interferences. Protaper rotary system was started with Protaper Universal, then improved to Protaper Gold and one of the recent refinements is Protaper Next files with M-wire technology, imparting improved flexibility and less cyclic fatigue Both Protaper Universal and Protaper Gold have the same convex triangular cross-sections, but Protaper Next have off-centered, rectangular cross-sections. The purpose of the present study was to evaluate the incidence, intensity and prediction of postoperative pain after glide path preparation performed with Hand Protaper instruments, Wave One Gold and a HyFlex EDM [7].

Material and Methods

A total of 30 patients were selected from the outpatients of our Dental Clinic. patients were selected with Asymptomatic non-vital lower first molars with three separate canals and without periapical lesion and patients with medically compromised patients were excluded The study included teeth diagnosed with symptomatic/asymptomatic irreversible pulpitis or apical periodontitis was diagnosed according to the absence of clinical symptoms, responsiveness to pulp sensibility tests and the presence of a periapical radiolucency The clinical diagnosis of symptomatic irreversible

pulpitis was based on positive pulp sensibility test result, extensive restorations or fractures exposing the pulp and x-ray. Symptomatic apical periodontitis was diagnosed according to the presence of painful response to biting / percussion / palpation, spontaneous pain and peri - radicular radio graphical features varying from a normal periapical structure to a periapical radiolucency, whereas asymptomatic apical periodontitis. Other Exclusion criteria were the following: patients younger than 18 years, patients with vertical root fractures, excessive periodontal disease, teeth that need periodontal surgery prior to coronal restorations due to marginal deficiency. Inclusion criteria for patients were as follows: age between 18-45 years, both males and females, medically-free patients, mandibular posterior teeth (premolars and/ or molars) with vital or non-vital pulp without periapical pathosis, symptomatic or asymptomatic cases, and positive patients' acceptance for participation in the study.

Grouping the samples

Group I: Hand Protaper (n=10)- After preparing the glide path with 15 k file, the coronal portion of canals were prepared using hand Protaper SX, S1, S2 (shaping files), F1–F5 (finishing files) within 0.25 tip size and 8% taper. and obturated by AH Plus Sealer.

Group 2: HyFlex EDM (n=10) teeth and obturated by AH Plus Sealer.

Group3: (n=10) prepared by Wave One Gold and obturated by AH Plus Sealer., the root canals were prepared with primary Wave One Gold file (0.25 tip size and 7%taper) till full working length.

Teeth were prepared by Pro Taper, Wave One Gold, HyFlex EDM according to manufacture instructions. The master apical file and irrigation was done between each file using plastic syringe with side perforated 27-G needle containing 2.5% sodium hypochlorite and another one containing 17% EDTA solution. Master apical file was done by 35 size k file. After instrumentation each canal was flushed with saline and then dried by paper point. All teeth obturation was made by lateral condensation technique where AH plus sealer was introduced using Lentulo spiral and master cone was introduced, and the accessory cones were added after it. In Group 3, WaveOne (Dentsply Maillefer) was used for cleaning and shaping root canals. Each tooth was prepared at 0.5 mm from the apex. Primary (red; size 25, 0.08) or large (black; size 40, 0.08) files were used according to root canal diameter. Irrigation and final irrigation were performed using protocols like those used in patients in groups 1, 2 and 3. The single-cone technique was used to introduce to seal the root canal by means of a matching gutta-percha cone (Wave-One) in brushing motion. Accessory gutta-percha cones [25] were used if needed employing the non-compaction method Coronal restorations were performed using total-etch adhesive system (Single Bond, 3M Espe), according to the manufacturer's instructions. Root canal orifices were sealed using a flowable composite resin (Filtek Ultimate Flowable, 3M Espe) as the base material. Remaining coronal restorations were performed using composite resin (Filtek Ultimate, 3M Espe) restoration performing fixed restoration depending on the prosthetic plan.

Post-clinical procedures

Patients are asked to evaluate the pain level & although the patients are not prescribed an analgesics, they can take if needed. Assessment of post-operative pain by using The Visual Analogue Scale (VAS) described by Pinkham et al. The VAS consists of a list of adjectives describing different levels of pain intensity with scores assigned to each of the levels of pain intensity (Table 1). The (VDS) was translated into Colloquial Arabic.

Table 1. Description of levels of pain intensity.

0	1	2	3	4	5
No Pain	Slight Pain	Moderate Pain	Strong Pain	Severe Pain	Maximum Pain

0= no pain

1= moderate pain relieved by analgesics

2= slight pain/discomfort

3= moderate pain not completely relieved by analgesics

4= severe pain not completely relieved by analgesics

5= severe pain/swelling not relieved by analgesics and required an unscheduled visit

Statistical Analysis

The data collected was statistically analyzed using statistical software. Kruskal Wallis ANOVA non-parametric test was carried out to determine the comparison between the three groups at different time intervals and Mann Whitney U test was used to do the intra group comparison at significant difference of p- value <0.05

Results

Statistical analysis indicated significant difference in pain intensity between 6, 12, 24, 36, and 72 hours and 7 days among the groups (P = 0.001). When pairwise comparisons of 6-, 12-, 18-, and 24-hour pain intensity values were compared, Group 3 (WaveOne) group presented the highest pain intensity values, followed by patients treated using Group 2 (P = 0.001) and One Shape (P = 0.001). Pain intensity values for patients treated using group 1 (P < 0.01) were significantly higher than those of patients treated using One Wave (P = 0.001). None of the patients reported any postoperative pain at 1-week follow-up. Two patients from the HyFlex EDM, three patients from the One Wave, and six patients from the hand protaper group used analgesics (naproxen sodium) to reduce the pain which represents the number of debris extruded and the actual instrumentation time (in seconds) for all groups. There was no significant difference between the HyFlex EDM and One Wave groups (p > 0.05), Again, there was no significant difference between all (p > 0.05) after 1 week. The highest mean value of pain score was found in Hand Protaper have the least mean value of pain scores was found in (HyFlex EDM) (p =0.33 ± 0.32).

Table 1. Mean preoperative and six postoperative VAS scores with median, minimum and maximum values of NRS scores and standard deviation (SD) at different time points in the tested groups.

Group	Time	Mean ± SD	Range (Min-Max)
Hand Protaper	Pre-op	2.42 ± 1.20	1 - 5
	12h	3.00 ± 0.72	1 - 4
	24h	1.20 ± 0.98	0 - 3
	36h	1.00 ± 0.30	0 - 1
Wave One Gold	Pre-op	2.10 ± 1.20	1 - 5
	12h	1.30 ± 0.40	3 - 4
	24h	1.00 ± 0.25	0 - 3
	36h	0.10 ± 0.00	0 - 1
HyFlex EDM	Pre-op	2.25 ± 0.30	1 - 5
	12h	0.42 ± 0.00	0 - 2

	24h	0.11 ± 0.00	0 - 1
	36h	0.01 ± 0.00	0 - 1
All Groups	1 Week	0.00 ± 0.00	0 - 0

Table 2. Protaper hand and Wave One Gold.

Group	Times	SD	P-VALUE
Hand Protaper	12 hr	0.72	0.33
	24 hr	0.98	
	36 hr	0.30	
Wave One Gold	12 hr	0.40	
	24 hr	0.25	
	36 hr	0.00	

Table 3. Protaper hand and HyFlex EDM.

Group	Times	SD	P-VALUE
Hand Protaper	12 hr	0.72	0.272
	24 hr	0.98	
	36 hr	0.30	
HyFlex EDM	12 hr	0.42	
	24 hr	0.11	
	36 hr	0.00	

Discussion

Persistent pain after root canal treatment is a common occurrence, with a frequency of 5.4%. It can be classified as either or both odontogenic and non-odontogenic in etiology [9]. While odontogenic origin might be the root canal-treated tooth or the adjacent tooth, non-odontogenic origin was shown to be temporo-mandibular disorder pain or dentoalveolar pain disorder [10]. To eliminate the risk of persistent pain, which would affect the results of this study, follow-ups were continued up to 1 month to ascertain the complete relief of pain. Several factors such as age, gender, pulpal and periradicular status, tooth type, preoperative pain, and technical aspects affect postoperative dental pain. Of these factors, only technical aspects, including instrumentation technique, file characteristics, and irrigation and obturation protocols could be controlled by the clinician. These technical aspects, also referred to as operator-dependent factors, are the main causes of non-biologic (chemical and mechanical) or biologic (bacterial) injuries during root canal preparation [11]. Therefore, in the present study, to limit the effect of variables in the procedure and prevent unwanted interaction with the apical tissues, no chemical solvents were used during the removal of the previous root canal filling. Although pain is subjective, biological and clinical factors are often responsible for its initiation [12]. In our study, the total amount of medication intake did not differ between the three instrumentation motions. However, there were some conflicting studies in the 24-hour. Various instrumentation systems were associated with some degree of postoperative pain [13]. Three clinical trials reported similarity regarding the intensity of postoperative pain between regarding the intensity of postoperative pain between Hand protaper file groups; WaveOne and HyFlex EDM. Some studies have concluded that variables such as gender, age, tooth type and preoperative pain are significant factors for the development of postoperative

pain. These findings are in accordance with the literature that reported that greater postoperative pain incidence is significantly linked with the presence of preoperative pain [14]. Today, preoperative pain is considered as a significant factor for the prediction of postoperative pain. Therefore, patients whose chief complaint is endodontic pain could be warned about probable postoperative pain and possible need for analgesic intake. In the present study subjective nature of the pain evaluation method could be considered as a limitation. The visual analogue scale was used to assess pain levels as it is a basic method with greater reliability, validity and sensitivity than descriptive scales [15]. Pain was followed up to 72 hours after the completion of root canal treatment as the incidence and intensity of pain were the greatest in the first 24 hours and then decreased substantially after 48 hours. As the follow up period of postoperative pain included the first 48 to 72 hours after treatment in several clinical studies [16]. Another limitation was the inability of blinding the operators regarding the groups; however, assignment of the patients to the experiment groups was performed after working length determination just prior to the root canal preparation step to minimize a possible selection bias. The systems associated with the most Apical extrusion has been reported as the main cause of pain after endodontic treatment. Debris extrusion was those that required longer instrumentation times, indicating a possible correlation - as demonstrated by simple linear regression - that the longer the instrumentation time, the greater the number of debris extruded [16]. Likewise, Dincer et al. [17] demonstrated that the Protaper system extruded more debris and required longer instrumentation times compared to the WOG system, as did Ehsani et al. [18], who observed greater extrusion of debris with those systems in which instrumentation took longer. The authors believe this might be explained because using a greater number of files naturally requires a longer instrumentation time, which means more time spent cutting dentin and, consequently, greater formation of debris, which may eventually be extruded through the apex. Thus, when working with this type of system, the use of irrigation protocols capable of removing debris from the canal isthmus is paramount. However, when the reciprocating systems included in this study were compared to the other system (which, although rotary, is also a single-file system), the number of extruded debris was found to be similar. Gummadi et al. [19] observed greater debris extrusion with the WaveOne system when compared to the One Shape single-file rotary system; however, they analyzed the first generation of this reciprocating system, while the present study used the later WaveOne Gold iteration. The findings of this experiment demonstrate that instrumentation kinematics play a relevant role the number of debris extruded, but that even rotary systems which employ a single file to simplify preparation reduce the risk of debris extrusion compared to multiple-file systems. This can be explained by the fact that using a greater number of instruments can generate a greater number of debris. Despite being mentioned by other authors such as Amaral et al [20]. as a possible interfering factor in the extrusion of debris, instrument taper was not relevant in the present study. In our experiment, #25 rotary instruments but with smaller tapers generated more debris

than reciprocating instruments with the same diameter but a relatively larger taper, a finding also reported by Dincer et al. [22]. The systems evaluated in this study all have different cross-sections, but again, this was not a determining factor in the amount of debris extrusion observed. Among the rotary systems analyzed, PTN uses an M-Wire alloy, while the HCM system employs a memory NiTi wire and would thus theoretically be capable of greater canal-centering ability, with less deviation, thus allowing more conservative preparations. Nevertheless, this potential advantage was not associated with any difference in the number of debris extruded through the apical foramen of curved canals between the two systems. The greater flexibility of these systems is probably associated with greater canal-centering ability but has no bearing on the number of debris extruded through the apical foramen. The extrusion of micro-organisms, material and dentinal debris may cause periapical inflammation. Caviedes-Bucheli et al. [21] evaluated the expression of substance P along with calcium gene related p. Manual protaper techniques compared to instrumentation procedures that include a rotating force, push-and-pull canal enlargement actions, such as filing, generate a greater number of apical debris. This led to the formation of a hypothesis that engine-driven rotary devices using the balanced force technique would generate less debris than hand-filing operations, hence lowering the risk of periradicular tissue irritation and postoperative sequelae [22]. Similar studies show that using the rotation technique for canal preparation causes less post-treatment pain than K-files [23]. However, Kashefinejad et al. [24] discovered that all patients included in the study were successfully treated in a single visit. Therefore, the findings of the present study cannot be applied or interpreted for multiple-visit treatments, which warrants for further randomized clinical trials.

Conclusion

Within the parameters and limitations of this randomized clinical trial, the following conclusions can be drawn. The intensity of post-operative pain varied between the three groups tested. No significant difference was noted between the parameters of quality of life assessed, suggesting the filing systems or techniques had a similar effect.

Conflicts of interest

The author declares that there is no competing interest.

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