

POST-OPERATIVE PAIN EVALUATION AFTER USING DIFFERENT SINGLE-FILE ROOT CANAL PREPARATION SYSTEM: A RANDOMIZED CLINICAL STUDY

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Abstract

Aims: Clinically assess post-operative pain following root canal preparation using various single-file systems. **Material and Methods:** For this study, thirty patients between the ages of 20 and 40 who needed a routine root canal treatment for a tooth with a single root canal were chosen. Cases were randomly divided into three equal groups (n = 10). Group 1: Hyflex EDM; Group 2: XP-endo Shaper; and Group 3: Primary Wave One Gold. Root canal treatment was done, and the postoperative pain severity was evaluated using a Visual Analogue Scale (VAS) at 24, 72 hours, and 7 days after treatment. **Results:** When compared to the Hyflex EDM and Wave One Gold groups, the incidence of postoperative pain was greater in the XP-endo Shaper group, but without statistically significant differences. In all groups, the incidence of reported postoperative pain decreased with time. **Conclusions:** The use of different tested root canal instruments has no significant impact on postoperative pain. All groups experienced a progressive decrease in postoperative pain intensity.

Keywords: Hyflex/EDM, Post-Operative Pain, Wave One Gold, XP-Endo Shaper.

1. INTRODUCTION

One of the factors influencing individuals after having root canal treatment is postoperative pain. Most of the time, it returns to the extrusion of dental debris, pulp tissue, bacteria, and irrigating solutions through the apical foramen, aggravating the inflammatory reaction [1].

Debris extrusion is influenced by a number of variables, including irrigation protocol [2], instrumentation method, final apical size [3], time required for root canal instrumentation [4], and instrument design [5]. All instrumentation approaches ultimately lead to some degree of apical ejection of dental debris, regardless of how much care is taken to limit preparation to the apical endpoint. However, some rotating techniques are said to limit debris ejection more than others [6].

The single-file preparation concept has the advantages of decreasing instrument fatigue, working time, cross-contamination between patients, and cost compared to multiple-file rotary systems. Hyflex EDM, XP-endo Shaper and Wave One Gold are new single-file systems with great flexibility, cutting efficiency, and high resistance to cyclic fatigue [7].

Hyflex EDM, which works in continuous rotation, is produced using controlled memory wire (CM-wire) that has undergone electrical discharge machining (EDM) to increase cutting efficiency and provide greater fracture resistance [8].

The instrument's cross-section changes shape over its entire working length, ranging from two trapezoidal halves at its base to an almost triangular portion at its coronal ends and a rectangular section at its apex. This is supposed to improve the file's fracture resistance [9].

XP-endo Shaper is a rotary NiTi snake-shaped instrument that works on continuous rotation. It is made of a unique alloy called Max Wire.

When the file is cooled, it has a unique tip with an ISO diameter of 15, and its initial taper in the martensitic phase (M-phase) is 0.01.

When exposed to 35°C, it gradually develops a minimal canal preparation of 30/.04 [10]. According to the manufacturer, this file may have the ability to shrink and extend within the canal, allowing it to reach spaces that traditional files cannot [11].

The post-manufacturing heating procedure used to create Wave One Gold instruments resulted in a file with super elastic metal characteristics [12]. This treatment increases the file's strength and flexibility while also providing the characteristic gold finish [13].

There are only one or two contact points between the Wave One Gold files and the dentin at any given cross section due to the parallelogram's off-center cross-section [12] and it is operated in reciprocating motion.

There are insufficient clinical studies comparing the efficacy of these single-file systems on post-operative pain, therefore this study was conducted.

The Hyflex/EDM, Wave One Gold, and XP-endo shaper systems will all experience postoperative pain at around the same rates, according to the null hypothesis.

2. MATERIALS AND METHODS

This clinical study was registered at ClinicalTrials.gov (ID: NCT06207019) and approved by the Research Ethics Committee (#R-END-1-20-5). Patients were told of the study's goal, and their consents were obtained in accordance with the standards of human research.

Trial Design

This study was designed as a prospective, parallel, randomised clinical trial with a 1:1:1 allocation ratio. The study followed the Preferred Reporting Items for Randomised Trials in Endodontics CONSORT guideline (Fig. 1).

The sample size was calculated using data from a prior study.⁸ A total sample size of 30 patients provided 84% power and a significance level of 5%. G Power version 3 was used to calculate the sample size.

Patient Selection

Thirty patients between the ages of 20 and 40 who needed routine root canal treatment were chosen for this study.

Inclusion Criteria

- Teeth with a single root canal with nearly the same apical diameter (#15)
- Vital pulp exposures due to caries or trauma with asymptomatic pulpitis
- Asymptomatic non-vital teeth that require root canal therapy
- Non-vital teeth with a sinus tract
- Restorable teeth

Exclusion Criteria

- Patients with immune deficiencies or systemic illnesses
- Pregnant women
- Cases of re-treatment
- Presence of root resorption
- Teeth with anatomic variations
- A cute periapical abscess cases with pus discharge
- A patient who has several teeth that need to be treated in order to eliminate the likelihood of pain referral
- Periodontal diseases
- Patients on analgesics, anti-inflammatory drugs, sedatives, or antibiotics seven days before therapy



CONSORT 2010 Flow Diagram

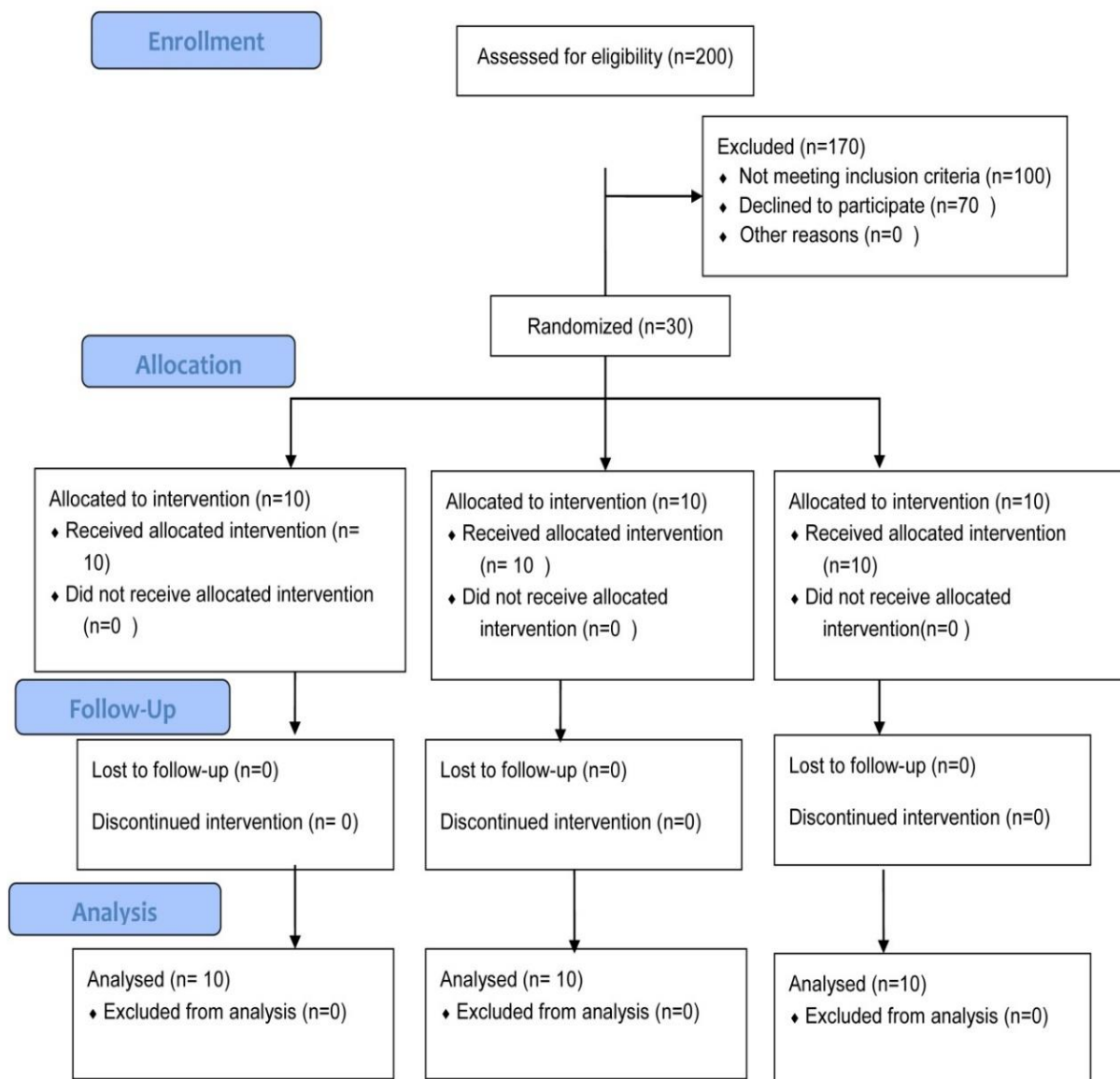


Figure 1: CONSORT Flow Diagram

Treatment Protocol

Anaesthesia was administered using 4% articaine and 1:100.000 epinephrine¹. The tooth indicated for root canal therapy was isolated with a rubber dam, and an access cavity was made. Working length (WL) was measured using an apex locator² and then confirmed by two blinded operators by taking a digital radiograph using an initial apical file size of 15.

Group Assignment and Randomization

Based on the root canal preparation system, cases were randomly divided into three equal groups (n = 10) using the computer random allocation programme³, and the sequentially numbered opaque sealed envelope (SNOSE) approach was used to conceal information from the operator as follows:

- Group 1: Hyflex EDM One File (25/) with variable taper was used in continuous rotation at 500 rpm and 2.5 Ncm in a circumferential brushing action in the coronal and middle thirds, then in a pecking action for three to five cycles until the WL was reached [15].
- Group 2: The XP-endo Shaper⁴ (30/0.01) was used in rotation mode at 800 rpm and 1.0 Ncm torque [16]. Long, gentle strokes with amplitudes of 3–4 mm were used to go down to adjusted WL in three to five cycles. After it reached the WL over the adjusted WL, it was subjected to five more up-and-down motions [17].
- Group 3: Primary Wave One Gold⁵ (25/07) was applied three times in a reciprocating motion; a gradual in-and-out pecking movement was utilized as directed by the manufacturer till the WL was reached.

Each root canal was irrigated with a total volume equal to 10 mL of a 2.5% NaOCl solution throughout instrumentation. Irrigation was done using disposable syringes with a side-vented needle placed 2 mm shorter than the WL into the canal, followed by 1 mL of 17% EDTA for 1 minute. Finally, the root canals were rinsed with 5 mL of distilled water before being dried with a sterile paper point.

At the same visit, obturation was done with the lateral compaction technique using gutta-percha cones and adseal resin-based sealer, and then composite resin was used as the final restoration.

Postoperative Pain Evaluation

Postoperative pain assessment was done by an independent evaluator with no knowledge of the group under investigation. The Visual Analogue Scale (VAS) was employed [18].

Patients could put a mark anywhere on the VAS sheet with values ranging from 0 to 100 mm [19].

- Score 0: No pain (between 0 and 4 mm) the tooth after treatment felt normal, and no discomfort was reported by the patients.
- Score 1: Recognizable, mild pain (between 5 and 44 mm), not requiring analgesics.
- Score 2: Moderate pain (between 45 and 74 mm) that is uncomfortable but bearable (when analgesics were taken, the pain was successfully reduced).
- Score 3: Severe pain (between 75 and 100 mm) painful to endure (pain was not relieved by taking analgesics).

The patients in this study were not aware of the preparation system used during treatment. Following treatment, three readings were taken at 24, 72, and 7 days [20]. Each patient carried a VAS form, and reminder calls were made to record pain levels and return the form filled out completely. Only when necessary, each patient received Ibuprofen 600 mg on prescription for pain management [21].

Statistical Analysis

The Kruskal-Wallis test was used to compare the rates of postoperative discomfort after collecting, tabulating, and analyzing the data. Pairwise comparisons between groups were done using the Mann-Whitney U test, and the Wilcoxon Signed Ranks Test was used for intragroup comparison. All statistical testing was done with SPSS 20+, and results were considered significant when the P value was less than 0.05.

3. RESULTS

A comparison of post-operative pain across three separate testing groups at each time period revealed no significant difference (P-value = 0.613, =0.681, =1.000) at 24, 72 hours, and 7 days, respectively. No statistically significant difference was found between the three examined groups when post-operative pain was compared among them, independent of the time intervals (P-value =0.600) [Table I]. On comparing post-operative pain among the three time periods in each group, it was shown that post-operative pain decreased over time in all groups, which was represented by an increasing number of cases recording a score 0 (representing no pain) and a decreasing number of cases recording scores 1 and 2 by time, as shown in Table II.

Table I: Post-operative Pain Numbers and Score Percentages of the Three Examined Groups, Regardless of Time Intervals, with Statistical Analysis

Pain score	Groups						Kruskal- Wallis Test	
	Group 1		Group 2		Group 3		X ²	P-value
	N	%	N	%	N	%		
0	16	53.33	12	40.00	15	50.00	1.021	0.600
1	10	33.33	13	43.33	11	36.67		
2	4	13.33	5	16.67	4	13.33		
Median	0		1		0.5			

Table II: The number and percentage of cases in each examined group that recorded various scores of post-operative discomfort at different time periods, as well as their statistical analysis

Groups	Pain	Time						Kruskal-Wallis Test		Wilcoxon Signed Ranks Test		
		24 Hours		72 Hours		7 days		X ²	P-value	24-72	24-7D	72-7D
		N	%	N	%	N	%					
Group 1	0	2	20	5	50	9	90	10.003	0.007*	0.025*	0.015*	0.059
	1	5	50	4	40	1	10					
	2	3	30	1	10	0	0					
	Median	1		0.5		0						
Group 2	0	0	0	3	30	9	90	16.815	<0.001*	0.034*	0.004*	0.020*
	1	6	60	6	60	1	10					
	2	4	40	1	10	0	0					
	Median	1		1		0						
Group 3	0	1	10	5	50	9	90	12.54	<0.002*	0.014*	0.005*	0.059
	1	6	60	4	40	1	10					
	2	3	30	1	10	0	0					
	Median	1		0.5		0						

* Significant (p<0.05)

4. DISCUSSION

Single-file techniques for root canal preparation have become available with the differences in design, cross-sections, taper, motion, metallurgy, manufacturing process, and various application techniques, with different amounts of debris pushed into the periapical tissue [4]. Consequently, it has become more challenging to ascertain whether or not attributes translate into enhanced clinical performance [22].

The selection of these three file systems was based these novel on their enhanced features and performance after undergoing thermomechanical treatment [23],[24],[25]. Only single root canal teeth with similar anatomy were incorporated in this study to reduce the potential for iatrogenic mistakes caused by missed or complex root canal anatomy [26],[27]. Poor shaping capabilities of single-file systems in broader canals may compromise disinfection [27]; thus, the teeth were selected based on a maximum apical diameter of 15 K-file.

Postoperative pain may be influenced by a number of variables, such as age, sex, pulpal and periradicular state, preoperative pain, tooth type, and technical considerations. The operator has control over just the technical aspects of these factors, including irrigation, instrumentation, and obturation methods [28]. Inflammation and post-operative discomfort can develop from shaping and cleaning operations that drive dentin chips, bacteria, pulpal fragments, irrigating fluids, or necrotic material into the periapical area

[29]. Therefore, it was important to assess how the three tested files affected postoperative pain.

Pain might begin a few hours to a few days after a root canal procedure, requiring emergency visits [30]; for this reason, postoperative pain was monitored for one week in this study. Several scales and techniques have been tried to evaluate postoperative pain since it is so difficult to measure subjective variables [31]. Since patient reports are considered the gold standard for pain evaluation, the VAS (100 mm) scale was employed to quantify postoperative pain in a range from 0 to 100 [31]. This scale, which has been frequently utilized in earlier research evaluating post-operative pain following RCT [19],[32],[33], was proven to be a very reliable tool by Bijur et al. [34] for evaluating acute pain in adults. In comparison to other ordinal scales, the VAS was shown by Garra et al. [35] to be both more informative and reasonably responsive to changes in pain.

Because preoperative discomfort is a strong indicator of postoperative pain, asymptomatic teeth were chosen for the study. Also, teeth with non-vital pulps associated with sinus tract were included in this study as they are least likely to be painful after treatment and can be treated in a single appointment [36].

Furthermore, to ensure that the pain caused by endodontic therapy was not affected by any other sources of pain or drug interactions, only individuals without a relevant medical history and those who had not previously used analgesic medications were included in this study [37].

The diameter of the apical foramen, the volume and type of irrigant solution, and other variables that potentially influence the amount of debris extrusion were standardized across all groups. Moreover, a side-vented irrigation needle was used in the present study as it is closed apically, thus decreasing the likelihood of irrigant apical extrusion, allowing it to reflux, and increasing coronal displacement of debris while preventing irrigant expression into periapical tissue accidentally [38].

Endodontic treatment delivered in a single visit has a number of benefits over several visits, including patient and operator convenience, less chance of bacterial leaking between sessions, and reduced cost [39]. Therefore, taking into account the benefits indicated earlier, root canal treatment procedures in the current study were finished in a single appointment.

Because Alonso-Ezpeleta et al. [40] reported less discomfort after the cold lateral compaction obturation method compared to the thermal obturation method, this technique was adopted in the current study. As sealing ability is of the utmost importance in sealers' selection, resin-based sealer (adseal) was used in this study due to its hermetic sealing ability [41]. Composite resin was used as the final restoration after the completion of the obturation procedure to prevent coronal leakage, which would allow bacteria and their byproducts to enter the obturated root canals and jeopardize the outcome of endodontic therapy [42].

In general, the patients in this study reported extremely modest levels of discomfort; none of the patients reported severe pain or other symptoms, like swelling or paresthesia. This was accomplished by using a preparation strategy which aimed to reduce debris extrusion from the apex, which could influence the responsiveness of the periodontal ligament. This was accomplished by using electronic and radiological verification to control the working length and a side-vented irrigation needle to safely administer the irrigants to the apex [37].

Postoperative pain peaked in the first 24 hours after treatment in all study groups, with assessments of pain significantly declining at the following assessment time periods of 72 hours and 7 days. Similar results were seen in a systematic study where they found that the prevalence of pain was 40% in the first 24 hours, dropped dramatically subsequently, especially over the first 2 days, and bottomed at 11% at seven days [43]. This might be explained by the periapical area being irritated by endodontic treatment, which led to a local inflammatory reaction that subsided after the periapical area healed [44].

Furthermore, in each group, a difference with statistical significance was observed between 24 h versus 72 h and one week; this agrees with the findings of Gotler [45] and Kherlakian [46], who discovered that the pain level reported at different intervals varies statistically significantly. This may be due to post-operative pain episodes occurring on the first day following the start of root canal treatment, post-obturation, as pain episodes are typically brought on by the pressure involved in inserting root canal filling materials or due to the chemical sensitivity to the ingredients of the root canal cements or pastes. Additionally, pain in the periodontal ligaments is another adverse effect of periapical inflammation, although it is usually transitory and disappears in 48–72 hours [47].

In the current investigation, the difference in post-operative pain between the three groups was not significant at various postoperative intervals and regardless of time intervals. This difference, although not significant, could be explained by debris extrusion, which varies with the instrumentation method [28] depending on the design, metallurgy, and application methods of NiTi rotary instruments [4].

Postoperative discomfort and flare-ups have been associated with inflammation, which has been traced back to the extrusion of germs, materials, or dentin debris into the periradicular region [48]. Patients' postoperative pain levels have been found to vary depending on the instrumentation technique and instrument design rather than the total number of files [49] due to variation in the quantity of debris extrusion and neuropeptides released by C-type nerve fibers present in the periodontal ligament [48],[50].

The XP-endo shaper showed higher post-operative pain; this may be attributed to its design and operation in the canal, which may cause a more pronounced dissociation of bacterial cells from the biofilm clinging to the canal walls. This technique may, however, leave more bacteria in suspension in the liquid irrigant, where they may disperse or move outside the apical foramen during preparation [51]. Additionally, the Max-Wire alloy used in the manufacturing of this instrument allows it to change shape due to a raised

temperature inside the root canal [11]. Therefore, during preparation, the instrument could elongate, and the operator has no control over this dimensional change, which could harm the periodontal ligament (PDL) [52].

Furthermore, the 800 rpm swaggering motion of this instrument may cause turbulence in the irrigant solution, which, when combined with instrument elongation, may result in a greater apical extrusion of irrigant solution mixed with debris, resulting in more damage to the PDL and a corresponding increase in post-operative pain [53],[54]. It was determined by Caviedes et al. [52] that after root canal instrumentation, the periodontal ligament contains large concentrations of the pain-inducing substances substance P (SP) and calcitonin gene-related peptide (CGRP), which cause the occurrence of postoperative pain.

They came to the conclusion that using XP-endo shaping devices for root canal preparation causes a significant release of neuropeptides, leading to a rise in SP and CGRP levels.

Postoperative pain after using Hyflex/EDM or Wave One Gold was comparable in incidence and severity. Although it was not statistically significant, Wave One Gold showed slightly higher pain levels than Hyflex/EDM because full-sequence rotational instrumentation results in less debris extrusion beyond the apex when compared to reciprocating file systems.

Dentin chips and debris may be more efficiently transported coronally with the use of continuous rotation, which acts like a screw conveyor to lessen apical material extrusion [50]. However, according to Comparin et al. [55], postoperative pain levels for rotary and reciprocation systems were found to be comparable. Similarly, Canakçi et al. found no statistically significant difference between Hyflex/EDM and Wave One Gold in intensity postoperative pain [56].

On the contrary, one possible explanation for why there are no significant differences in post-operative pain among the three tested file systems might be the fact that the physical backpressure of the periodontal tissues may decrease extrusion in the clinical situation, allowing the periapical tissues to act as a natural barrier against debris extrusion.

5. CONCLUSION

From the current study, the following can be concluded:

- The occurrence of immediate post-operative pain was not totally eliminated by any of the evaluated single-file systems.
- The Xp-endo shaper system induces insignificantly higher post-operative pain than other tested systems.
- Postoperative pain severity decreased gradually over time in all tested groups.

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