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Postoperative Pain Evaluation After Single Visit Endodontic Retreatment Using XP Endo Shaper and ProTaper Retreatment Rotary Systems: A Randomized Clinical Trial

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ORIGINAL STUDY

Postoperative Pain Evaluation After Single Visit Endodontic Retreatment Using XP-endo Shaper and Protaper Retreatment Rotary Systems: A Randomized Clinical Trial

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Abstract

Purpose: To evaluate endodontic retreatment outcome using XP-endo shaper and ProTaper retreatment files by recording postoperative pain. **Patients and methods:** Twenty eight cases aged 15−40 years old were divided randomly into two groups (14 cases each). Group I (XP-endo shaper group); Old Gutta Percha in this group was removed by XP-endo shaper file used in the following sequence as DR1 (15 mm length, orifice opener), XP-endo Shaper (size/taper 30/0.04) and XP-endo Finisher R (size/taper 30/0.00). Group II (ProTaper Retreatment group): The Old Gutta Percha in this group were removed by ProTaper rotary retreatment system as follows: D1 within the coronal third, D2 within the middle, then reach the full working length by D3. Irrigation protocol was done using 2.6% NaOCl solution using a 31-G Navi-Tip needle during changing the files. Then, using 5 mL of 17% EDTA solution for 1 min, and finally rinsed with 5 mL of distilled water. Enlargement of the apical portion was done by F4 protaper rotary file. The treatment outcome was evaluated clinically through pain recording using VAS (Visual Analogue Scale) at 24 h and 1 week). **Results:** The result showed no statistically significant differences between median pain scores in the two groups after 24 h as well as 1 week. **Conclusion:** It could be concluded that the XP-endo shaper retreatment file is a reliable approach in root filling removal showing mild postoperative pain values.

Keywords: Postoperative pain, Retreatment, XP-endo shaper

1. Introduction

Elimination of apical periodontitis is the main aim of root canal treatment by achieving effective disinfecting of the canal by complete cleaning and shaping and perfect sealing of the root canal system. The success of endodontic therapy depends on complete bacterial disinfection from the root canal. Irrigation and mechanical preparation have a main role in reducing the number of bacteria within the root canal system [1].

With all the recent advances in endodontic treatment, studies showed that some cases present periradicular radiolucency due to endodontic infection as a result of the persistence of bacteria and infection inside the root canal. In the majority of failed endo-treated teeth, and with the increased interest in preserving the tooth structure, nonsurgical retreatment has been the first choice. The main steps of retreatment are complete removal of previous root filling materials which may be covering necrotic tissues or bacteria causing the persistent infection and proper mechanical preparation of the canal by reaching the correct working length [2,3].

Many techniques and devices have been introduced for the removal of Gutta-Percha including hand file, engine-driven rotary file, solvent, and ultrasonic instrument are helpful ways for removing Gutta-Percha [4]. Although the removal of Gutta-Percha can be challenging and time-consuming, the literature showed that none of the techniques can remove the old filling material completely from the canal. Ni−Ti rotary systems have been used to do

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endodontic retreatment, new systems were introduced specifically for retreatment purposes [5,6].

ProTaper Universal retreatment system (Dentsply Maillefer, Ballaigues, Switzerland) was introduced consisting of three files which are D1, D2, and D3 having different tapers and tip diameters. These instruments have a convex triangular cross-section. Each file works on one-third of the canal. They also have a specific flute design and motion which pull the gutta perchae toward the flutes till reaching the canal orifice [7].

Recently, new instruments have been introduced with changes in the cross-section design and modern Ni–Ti alloys [8]. XP-endo Shaper is a new instrument that was introduced for root canal preparation [5]. This instrument is made from a proprietary alloy which is MaxWire, Martensite-Austenite Electropolish - flex [FKG Dentaire] with a tip size of 27 and a 0.01 taper at room temperature but it expands to a tip size of 30 and a 0.04 taper at body temperature regarding the anatomy of the canal. The instrument design and its properties make it to make effective debridement with fewer untouched canal walls. XP-endo Shaper has a good shaping ability and is effective in reducing bacterial count within the root canal [2].

Postoperative pain is one of the complications of endodontic treatment. More studies were done reporting the incidence of postoperative pain [9–11]. The prevalence of postoperative pain is increased with insufficient root canal filling, complications with the irrigation process, and tooth with periapical pathosis [12]. The most important reason for postoperative endodontic pain is the extrusion of infected debris like dentin chips, bacteria, and irrigating solution from the periapical foramen. This debris spread in the periradicular tissues and might lead to acute inflammation. The postoperative pain might be a high or low response according to the size of damage within the periapical tissues [13,14].

It was reported that different methods of mechanical preparation or file systems according to different designs and tapers might control postoperative pain; this study aimed to evaluate endodontic retreatment outcomes using XP-endo shaper and ProTaper retreatment files by recording postoperative pain. The null hypothesis, there is no difference between the effect of XP-endo shaper and ProTaper retreatment rotary systems on postoperative pain.

2. Patients and methods

2.1. Study design

The study was designed as a randomized controlled clinical trial with an allocation ratio of 1:1, analyzed, and interpreted according to the Consolidated Standards of Reporting Trials (CONSORT 2010) checklist of information [15]. This study was conducted in the clinic of the Endodontic Department, Faculty of Dental Medicine for Girls, Al-Azhar University.

Ethical approval for the human research was obtained by guidelines from the Research Ethics Committee (REC) of the Faculty of Dental Medicine for Girls, Al-Azhar University with the code number: REC-EN-22-04. All patients read and accepted an informed consent form with details about the study along with the benefits and risks of the therapy.

To practice evidence-based dentistry in failed endodontic treatment era, the clinical question in this study was addressed in terms of the PICO question which involves 4 elements:]problem (P), intervention (I), comparison (C), and outcome (O)[as following:

P (Problem): Failed endodontically treated teeth.

I (Intervention): Root canal retreatment.

C (Comparison): XP-endo shaper file compared with protaper retreatment files.

O (Outcome): pain recording using Visual Analogue Scale (VAS) at 24 h and 1 week after the treatment.

2.2. Sample size calculation

This sample size was calculated at 80% power of the study and 95% confidence level.

By the following equation:

$$n = (Z\alpha/2 + Z\beta)^2 * pq \;/\; (d^2)$$

[16].

$$Pq = P1\,(1 - p1) + p2\,(1 - p2)/2$$

Where P1 is the proportion of absence of pain in the studied group (85%) and P2 is the proportion of absence of pain in the control group (62%) from previous research [13,17].

- Z (1-α) = s the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96).
- Z (1- β) = Zβ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84).
- d is the difference in the absence of pain between groups which is assumed to be 22%.

Accordingly $n = 14.40$. So we selected 14 patients for each group.

A total of 28patients participated in this study who met the criteria of selection [18].

2.3. Patients' selection

A total of 28 patients were selected for this study after clinical and radiographic examinations from cases that were referred to the Endodontic clinic. The inclusion criteria were the patient has a noncontributory medical history, patients are 15–40 years old, failed endodontic cases with inadequate root canal filling, single-rooted teeth with type I root canal system and the selected root canals have a periapical radiolucency with diameter up to 5 mm. The exclusion criteria were the cases representing acute clinical complaints such as Tenderness to percussion, tenderness to palpation of the adjacent area, sinus tract, and presence of swelling in the adjacent area. Tooth mobility, root fracture, and pregnant women are also excluded.

Complete history and clinical examination were done for the selected case. Intraoral radiograph for initial endodontic treatment to show the quality of the root canal filling, periodontal tissues, and possible success of retreatment and adequate construction afterward. A preoperative periapical radiograph had been taken for each selected tooth using a digital radiography system (Vistascan Dental Perio, Dürr Dental AG, Bietigheim, Germany) to evaluate the quality of the root canal obturation, periapical radiolucency and evaluation of the coronal restoration.

2.4. Treatment protocol

The 28 cases were divided randomly into two groups (14 cases each): Group I (XP-endo shaper group) and Group II (ProTaper Retreatment group).

Strict infection control protocol was performed throughout the whole procedure [1]. A rubber dam was applied on the assigned tooth to obtain proper isolation. Removal of coronal restoration was done and the coronal access was reassessed using round bur and fine tapered stone.

2.5. Removal of obturation material

2.5.1. Group I (XP-endo shaper group)

Old Gutta Percha of the teeth in this group was removed using the XP-endo shaper file. According to the manufacturer, it was used in the following sequence as DR1 (15 mm length, orifice opener) at 800–1000 rpm and 1.5 Ncm torque, XP-endo Shaper (size/taper 30/0.04) rotating at 1000 rpm, 1 Ncm and XP-endo Finisher R (size/taper 30/0.00) at 800–1000 rpm, 1 Ncm. Gently engaged DR1 into obturation material to make 3–4 mm a start point for XP-endo Shaper. Pecking motion was used until the tip of XP-endo Shaper engaged into Gutta Percha. Gentle pressure was done on the XP-endo Shaper to allow it to go down into the root canal till reaching the full working length. Gutta Percha solvent was added (2 mm of D-Limonene based Gutta Percha Solvent, Carvene). XP-endo Shaper was used for 10–15 with additional long gentle strokes to working length and the canal was irrigated to remove the debris. The working length was fixed on the XP-endo Finisher R and slowly threaded inside the canal. XP-endo Finisher R was used for 1 min, in slow and gentle movements to reach the full working length [8].

2.5.2. Group II (protaper retreatment group)

In this group, filling material was removed by Protaper rotary retreatment files. D1 was used for initial penetration in the coronal third, then D2 in the middle third of the canal, and D3 to the full working length. These instruments were activated by an electric motor at 500 rpm speed and 3 N/cm torque, with brushing motion [19].

The irrigation protocol was the same in all tested groups. 2.6% NaOCl solution (Alex. Detergents and Chemical Co., Egypt) was used by a 31-G Navi-Tip double-sided port needle (Navi-Tip, Ultra-dent product, South Jourdan, UT) between each instrument change, after that 5 mL 17% EDTA solution for 1 min, and 5 mL of distilled water as a final rinse.

Enlargement of the apical portion was done by F4 protaper rotary file. Canals were dried using paper points of comparable size to the master cone and obturated using the Modified single-cone technique. The master cone was the #F4 gutta-percha cone (Dentsply Maillefer, Ballaigues, Switzerland). Cone fitness was evaluated by radiograph. A size #25 spreader was used to allow space for auxiliary cones size #25 to fill the canals. All canals were sealed with ADSEAL resin-based sealer (Meta Biomed Co, Cheongju, Korea) which was homogeneously mixed. Excess gutta percha was cut off with the aid of a heated plugger till the level of the orifice. After obturation, a postoperative periapical radiograph was done for each patient. Then, each tooth received a permanent filling of a composite resin restoration.

2.6. Pain evaluation

A visual analog scale (VAS) was done for the assessment of pain. VAS is a line marked as 1–10. Pain level is categorized as no pain (0), mild pain

(1–3), moderate pain (4–6), and severe pain (7–10). The patient took the scale and was told how to fillit. The patient recorded his pain at 24 h and 1 week. Ibuprofen (400 mg) was prescribed postoperatively in case of intolerable pain [20].

2.7. Statistical analysis

Pain (VAS) scores data showed nonnormal (nonparametric) distribution. Data were presented as median, range, mean, and standard deviation (SD) values. Mann–Whitney *U* test was used to compare the two groups. Wilcoxon signed-rank test was used to study the changes within the group. 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.

3. Results

3.1. Pain (VAS) scores: Table 1 Fig. 1

3.1.1. Comparison between the groups

After 24 h and 1 week; There was no statistically significant difference between median pain scores in the two groups (*P* value = 0.505, Effect size = 0.227) and (*P* value = 0.578, Effect size = 0.113), respectively.

3.1.2. Changes within each group

In both study groups; there was a statistically significant decrease in the median pain scores after one week (*P* value = 0.016, Effect size = 0.644) and (*P* value = 0.041, Effect size = 0.545), respectively.

3.2. Intake of analgesics

After 24 h; two cases in each group had analgesics while after one week none of the cases had analgesics.

4. Discussion

Retreatment of previously treated root canals is the first choice for the management of insufficient root canal treatment Arora and Joshi, Angerame and colleagues [17,21]. Remnants of necrotic tissues and bacterial infection in the root canal is the known cause of common inflammatory lesions which may lead to periapical inflammation or cysts. For successful endodontic treatment and restoring periapical health, the clinician should do the best during chemo-mechanical preparation remove all the infected tissues, and make good seal to the canal Angerame and colleagues [21].

This study was performed to evaluate endodontic retreatment outcomes using XP-endo shaper and ProTaper retreatment files by recording postoperative pain.

All cases were selected with single root and type I root canal systems. This type was with no morphologic variation which could affect the outcome Angerame and colleagues [21].

Successful endodontic treatment is achieved by the elimination of the bacterial count within the canal so that a good infection control protocol was applied Siqueira and Rocas [1].

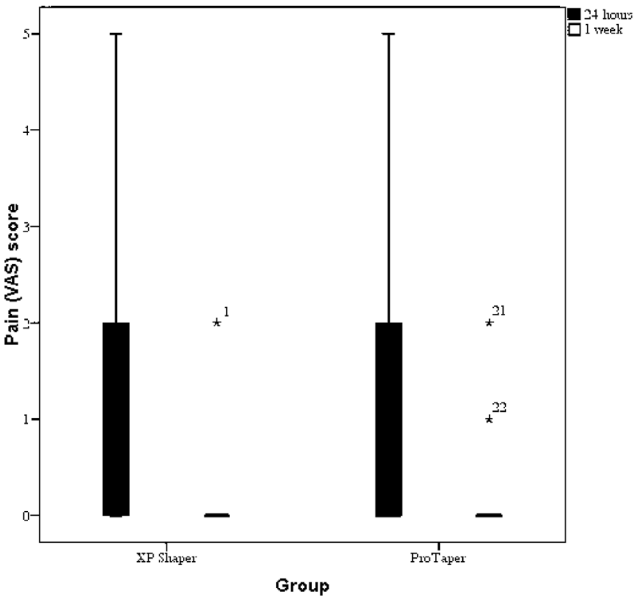

Fig. 1. Box plot representing median and range values for pain scores in the two groups (Stars represent outliers).

Table 1. Descriptive statistics and the result of Mann–Whitney U test for comparison between pains (VAS) scores in the two groups and Wilcoxon signed-rank test for the changes within each group.

Time	XP Shaper ($n = 14$)		ProTaper ($n = 14$)			
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	*P*-value	*Effect size (d)*
24 h	0.5 (0–5)	1.29 (1.64)	0 (0–5)	1 (1.66)	0.505	0.227
1 week	0 (0–2)	0.14 (0.53)	0 (0–2)	0.21 (0.58)	0.578	0.113
P- value	0.016[a]		0.041[a]			
Effect size: (d)	0.644		0.545			

[a] Significant at *P less than or equal to* 0.05.

Postoperative pain depends on factors such as age, sex, pulpal, periradicular factors, and preoperative pain [26]. The postoperative pain record which is the primary indication for the treatment prognosis was selected as an outcome of this study and measured using the VAS scale which utilizes a scale from 0 to 10 to measure the intensity of pain. Although many pain scales are used for pain assessment; VAS is valid, provides clear reliable records, and easily understand by the patient and appropriate use was observed after explanation to patients Arora and Joshi [17].

Results in the present study showed that there were no statistically significant differences between median pain scores in the two groups after 24 h as well as one week. These results might be attributed to the kinematic movement of file systems Gomes and colleagues [13].

Other studies showed that the main cause of postoperative pain is debris extrusion from the canal during the chemo-mechanical process which resulted in periapical inflammation and post-operative pain Shokraneh and colleagues, Neelakantan and Sharma [14,22].

In the present study, results showed that there was a statistically significant decrease in median pain scores after 1 week within each group. This might be attributed to that postoperative pain severity decreased after time intervals within the group due to the inflammatory response within the periapical area after the endodontic treatment. The inflammation process begins within 6 h when polymorphonuclear leukocytes go to the inflamed area and increased in count till reaching the peak at 24–48 h after releasing the inflammatory mediators Cohen [23].

These results were from previous studies that reported that postoperative pain intensity decreased after all the time intervals Gomes and colleagues, Arora and Joshi [13,17].

Also, a systematic review in 2011, showed that the postoperative pain maximum levels were achieved just after obturation. Pain scores were observed to be 40% during 24 h and decreased to 11% or less after 1 week. The same result was shown in this study Pak and White [20].

On the other hand, Ibuprofen is the analgesic of choice to relive postoperative pain which was prescribed to patients in different studies after endodontic therapy. In this study, two cases in each group had analgesics after 24 h while after one week none of the cases had analgesics.

4.1. Conclusion

Within the limitation of the study, it could be concluded that the XP-Endo Shaper retreatment system is a reliable approach in root filling removal showing mild postoperative pain values. The incidence of postoperative pain decreased gradually with time.

4.2. Recommendation

Further studies and research should be done to compare the effectiveness of XP-endo shaper retreatment files to reduce bacterial populations inside the root canal and other conventional retreatment files.

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Conflict of interest

No conflict of interest related to this study.

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