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Postoperative Pain and Flare-Up Incidence Following Preparation with Rotary ProTaper and Single-File Reciprocating Systems: A Randomized Clinical Trial

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Objectives Techniques used in root canal treatment (RCT) can cause postoperative pain. This clinical trial study aimed to compare the degree of postoperative pain following RCT using ProTaper Next rotary files and VDW reciprocating single-file systems.
Methods Initially, a pilot study involving 10 patients in each group was performed to determine the final sample size. Sixty molars with irreversible pulpitis were randomly prepared using the Reciproc or ProTaper system. Postoperative pain severity was assessed using the Visual Analog Scale (VAS), categorizing pain level as no pain, mild, moderate, or severe before and immediately after treatment, as well as at 2, 6, 12, 24, and 48 hours postoperatively. Pain scores were analyzed using the Mann-Whitney U test to compare the two groups, and the impact of various factors on predicting postoperative pain incidence was assessed using PLUM ordinal regression ($P < 0.05$). The non-parametric Friedman test was used to evaluate differences in means before and after treatment.
Results No significant differences were observed in pain score classifications between the Reciproc and ProTaper preparation systems before treatment, immediately after treatment, and at 2, 6, 12, 24, and 48 hours postoperatively. However, pain severity scores reported for the ProTaper system were slightly higher than those for Reciproc, with the difference becoming more noticeable 24 hours after treatment. None of the studied factors significantly predicted postoperative pain incidence.
Conclusion Within the study's limitations and despite the absence of significant differences, using the single-file Reciproc system for tooth preparation appeared to yield slightly more favorable outcomes in alleviating postoperative pain of RCTs.
Keywords Postoperative pain; Rotary ProTaper system; Endodontic Treatment; Nickel-Titanium Instruments

Introduction

Despite the availability of new rotary systems and advanced root canal treatment (RCT) techniques, inter-appointment flare-ups remain a significant challenge for dentists. The flare-up, characterized by postoperative discomfort, including pain and swelling, necessitates unplanned appointments for immediate treatment. [1]

One of the most common endodontic complications is postoperative pain, with an incidence ranging from 1.4% to 16% and potentially reaching 50% in certain cases. [2-4] Flare-ups are typically multifactorial and can be triggered by various factors, including endodontic infection and microbiological, chemical, mechanical, and treatment-related variables. [2] Microbial factors contributing to flare-ups may be linked to factors such as residual caries, inadequate coronal sealing, insufficient chemo-mechanical preparation, and the absence of intra-canal medication between sessions. [5-7] Chemical factors, such as intracanal medications, irrigation solutions, and sealers, can lead to inflammation and irritation of the peri-radicular tissues if they come into contact with them. The intensity of the inflammatory response depends on the amount of chemicals released. [8] Mechanical factors during endodontic treatment can also contribute to the flare-up mechanism by pushing debris, necrotic pulp tissue, solutions, and bacteria into the periapical tissues, causing inflammation, postoperative pain, and hindering peri-radicular tissue healing. [9, 10]

An instrumentation technique should aim to minimize damage to peri-radicular tissues, reduce debris extrusion, and reach the apical third as smoothly as possible to reduce postoperative pain. According to the existing literature on postoperative pain, both rotary and reciprocating instrumentation kinematics can yield positive or negative outcomes.

The ProTaper Next® system (Dentsply Sirona©, Ballaigues, Switzerland) is a well-known continuous rotating instrumentation system made of M-wire nickel-titanium (NiTi), which has higher flexibility and wear resistance compared to traditional NiTi, according to the manufacturer. [11, 12] Another system, Reciproc Blue® (VDW©, Munich, Germany), is a heat-treated reciprocating single-file system with the same design as its predecessor, Reciproc, but with improved fatigue resistance and flexibility due to the use of Blue wire. [13]

Several factors causing postoperative pain in endodontics can be controlled and are related to the dental practitioner and procedural steps used. Factors such as canal cleaning and preparation, type of the file used (hand or rotary files), and dentist's dexterity can be controlled to prevent postoperative pain. [14] In many new NiTi rotary systems compared to K-files, there is a reduction in the seepage of debris from the apical foramen due to the rotational movements of files and copious irrigation, resulting in decreased postoperative pain. [15] However, despite sterilization, rotary files may still retain some debris. [16] Therefore, to enhance the infection control and facilitate

RCT while reducing the procedure time, new systems like Reciproc and WaveOne have been introduced based on a single-file technique, utilizing a new NiTi alloy called M-wire. However, research in this area is still ongoing.

Given the impact of instrument control and prevention of debris passage through the apical foramen during root canal preparation on reducing postoperative pain and flare-up incidence, it is possible that the use of newer canal preparation systems, such as Single-File Endo (Reciproc), could help control these factors and reduce postoperative pain incidence. [17]

Movement dynamics may influence the degree of debris extrusion from the root canal. Therefore, in this study, two widely used instrument groups were selected that employ rotational and reciprocal motion. The null hypothesis of the study was that postoperative pain following preparation with these two systems would not differ from baseline.

Methods and Materials

This in clinical trial study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran (ethical code: IR.SBMU.RIPF.RIC.1394.78).

A pilot study involving 10 patients in each group demonstrated a success rate of 80%, assuming an alpha error of 0.05, beta error of 0.2, and coefficient Z (critical value) of 1.96. To allow for a stratified randomization procedure, 30 patients were required in each group, resulting in a total of 60 patients. [18] The sample size was calculated using the following formula:

$n= (Z1-\alpha/+ Z1-\beta)2 (\sigma12+ \sigma22) / (\mu1 - \mu2)2$

Patients from the pilot study were included in the final sample.

Randomization

Using a stratified randomization design, patients were stratified into two groups: the Reciproc group and the ProTaper group. An assistant who was blinded to the purpose of the study and was unaware of the nature and purpose of the study generated a list of random numbers using a computer algorithm from a website (https://www.sealedenvelope.com/) with an allocation ratio of 1:1 and created random blocks of size 4. The researcher (undergraduate student) was unaware of the coding details. The operator (post graduate student) was aware of the rotary system used only after preparing the access cavity and was unaware of the study objectives. [19]

After obtaining written informed consent from patients referred to the endodontics department of the dentistry school at Shahid Beheshti University of Medical Sciences, 100 patients with irreversible pulpitis were initially selected. However, 40 patients were subsequently excluded for non-referral or not meeting the inclusion criteria and the study finally included 60 permanent molar teeth. Patients meeting the following inclusion criteria entered the randomization process: aged 20-50 years, good general health condition, positive response to the electric pulp test (EPT) and prolonged positive response to cold testing, first or second molar teeth with symptomatic irreversible pulpitis due to deep decay during caries removal, healthy periapical tissue confirmed by radiography and clinical examination without percussion sensitivity, and absence of allergies to substances and drugs used during RCT and local anesthesia.

Exclusion criteria were systemic diseases, pregnancy, calcifications, internal or external resorption, previous endodontic treatment, sinus tracts, periapical lesions, periapical abscess or cellulitis, percussion sensitivity, and recent use of opioids, corticosteroids, or nonsteroidal anti-inflammatory drugs (NSAIDs) within the preceding 24 hours.

The clinician and patient were blinded, and patient assignment to the groups was conducted by a second person. An electric pulp test (Coxo, China) and Endo-Ice (Coltene/Whaledent, Langenau, Germany) were used to perform a diagnosis of pulpal status before providing anesthesia to the teeth.

The teeth were anesthetized with 2% lidocaine containing 1:80 000 epinephrine (Daroupakhsh, Iran) using buccal infiltration for maxillary molars and inferior alveolar nerve block for mandibular molars. Rubber dams (Sanctuary, Malaysia) were used for isolation, and access cavities were prepared using diamond cylindrical burs in a high-speed handpiece (NSK, Japan). The working lengths (WLs) of the canals were measured using an electronic apex locator (Root ZX; J. Morita, Tokyo, Japan); and subsequently confirmed radiographically. The instrumentation sequence for each group followed the manufacturer's protocol.

Group 1

Canals were prepared with Reciproc Blue files (25/0.08) using the VDW Endo motor (VDW, Munich, Germany) in the RECIPROCALL mode, employing a pecking motion until reaching the WL. For wide canals, a 40/0.06 file was used, while for the narrow canals, a 25/0.06 file was used.

Group 2

Canals were prepared with ProTaper Next files (X1 and X2) using the VDW Endo motor in full rotational mode at 350 rpm and 2 N.cm torque.

Canal patency was obtained throughout the procedure by inserting a #10 K-type file (Mani, Japan) 1 mm beyond the WL after each instrument change. Each canal was irrigated with 5 mL of 2.5% NaOCl, followed by 5 mL of 17% ethylenediaminetetraacetic acid (EDTA) solution, with a final rinse using 5 mL of normal saline. Canals were then dried with paper points (Meta Biomed, Korea) and filled with gutta-percha (Meta Biomed, Korea) and AH26 sealer (Dentsply Maillefer, USA) using the warm vertical condensation technique. Teeth were temporarily sealed

with Cavit (3M ESPE, Germany), and patients were instructed to take 400 mg of ibuprofen as needed for pain relief. [20]

Pain severity scores were determined using the Heft-Parker Visual Analog Scale (HP-VAS). This scale is a 170-mm line that has been divided into different pain groups. Different signs on the line indicate specific severities of pain. The absence of pain is indicated by zero. Mild pain covers a range from 0 to 54 mm, moderate pain is located from 54 to 114 mm, and severe pain covers from 114 to 170 mm. Patients were directed to rate their pain intensity on the VAS at 6, 12, 24, 48, and 72 hours after endodontic treatment.

Statistical Analysis

The data were analyzed using the Mann-Whitney U test between the two groups, and the effects of different factors on predicting postoperative pain incidence were determined using PLUM ordinal regression ($P < 0.05$). Since the means before and after treatment significantly differed, the non-parametric Friedman test was used.

Results

This study included 60 permanent molar teeth in patients who were in good health and presented with one molar tooth requiring endodontic treatment due to symptomatic irreversible pulpitis. The patients had a mean age of 37.7 ± 10.9 years, ranging from 20 to 50 years. The mean ages of patients in the Reciproc and ProTaper groups were 38.2 ± 9.8 and 37.2 ± 12.0 years, respectively. Table 1 displays the gender distribution, type of anesthetic agent used, periapical status, pulpal status, tooth type, analgesic use, and the number of root canals in each tooth in the two groups. Figure 1 illustrates the progress of patients at each stage of the clinical trial, following the CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Table 1-Frequency of variables among the study groups

Preparation type system		protaper	Reciproc
Sex	Male	46.7%	16.7%
	Female	53.3%	83.3%
Anesthesia	Lidocaine	100%	100%
Periapical status	Non	100%	100%
	Mild	0%	0%
	Moderate	0%	0%
	Severe	0%	0%
Pulpal status	Irreversible pulpitis	100%	100%
	necrotic	0%	0%
Tooth location	Maxillary molars	50%	66.7%
	Mandibular molars	50%	33.3%
Analgesic consumption	Yes	23.3%	26.7%
	No	76.7%	73.3%
2 or 3 canal	3 canal	75.9%	82.1%
	2 canal	24.1%	17.9%

The results of PLUM regression analysis indicated that none of the variables, including sex, intervention, pain immediately after treatment, and pain at 2 and 6 hours after treatment, had a significant effect on pain intensity.

The chi-square test did not reveal any significant differences in the doses of analgesics ($P = 0.771$) or the number of root canals ($P = 0.563$) between the two groups.

The results of the non-parametric Mann-Whitney U test showed no significant differences in pain severity scores between the two groups before RCT ($P = 0.172$), immediately after treatment ($P = 0.891$), and at 2 hours ($P = 0.683$), 6 hours ($P = 0.990$), 12 hours ($P = 0.435$), 24 hours ($P = 0.134$), and 48 hours ($P = 0.364$) postoperatively.

In patients undergoing root canal preparation with the Reciproc system, the mean pain scores before treatment, immediately after treatment, and at 2-, 6-, 12-, 24-, and 48-hour postoperative intervals were 1.43 ± 0.82, 1.8 ± 0.81, 2.1 ± 0.71, 2.5 ± 0.86, 2.3 ± 1.18, 1.83 ± 0.99, and 1.57 ± 0.86, respectively. The non-parametric Friedman test demonstrated significant changes in pain severity during the evaluated time intervals in the Reciproc group ($P < 0.001$). The pain variable was compared in pairs with the gender and time variables.

In the ProTaper group, the mean pain scores before treatment, immediately after treatment, and at 2-, 6-, 12-, 24-, and 48-hour postoperative intervals were 1.17 ± 0.46, 1.77 ± 0.77, 2.2 ± 0.71, 2.5 ± 0.73, 2.5 ± 1.1, 2.17 ± 0.91, and 1.77 ± 0.82, respectively. The non-parametric Friedman test showed significant changes in pain severity

during the evaluated time intervals in the ProTaper group (P < 0.001).

The chi-square test was used to compare the frequencies of pain severity scores in all patients undergoing root canal preparation with the Reciproc and ProTaper systems. The results showed no significant differences in pain severity scores before treatment (P = 0.481), immediately after treatment (P = 0.987), and at 2 hours (P = 0.661), 6 hours (P = 0.500), 24 hours (P = 0.143), and 48 hours (P = 0.681) postoperatively between the two root canal preparation systems. However, significant differences were observed at the 12-hour postoperative interval (Figures 1-5; P < 0.001).

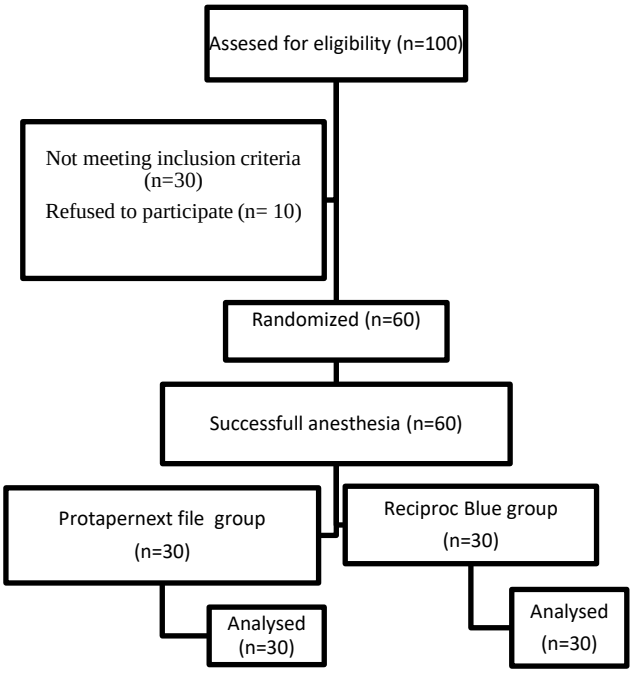
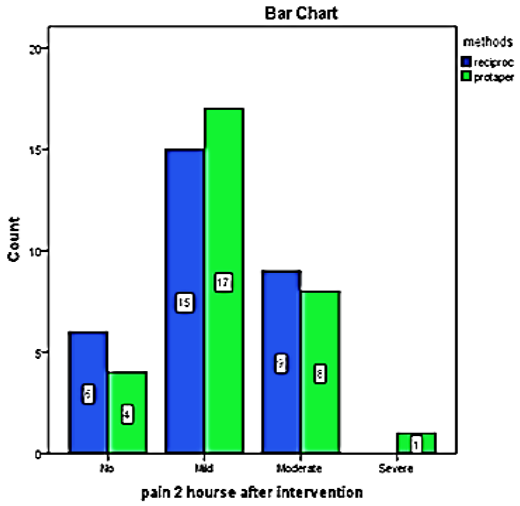
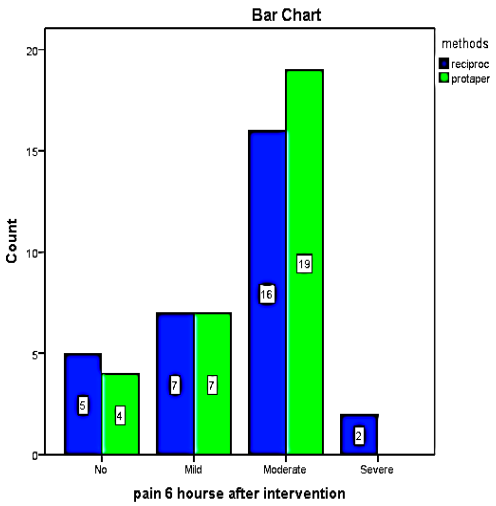


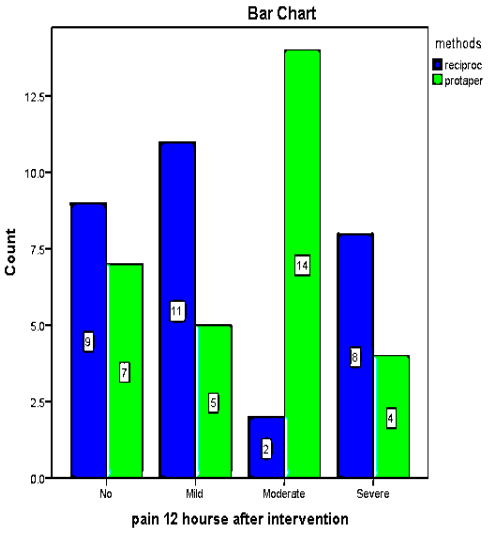
Figure1: Flow diagram of the progress of the patients at each stage of the clinical trial, according to CONSORT.



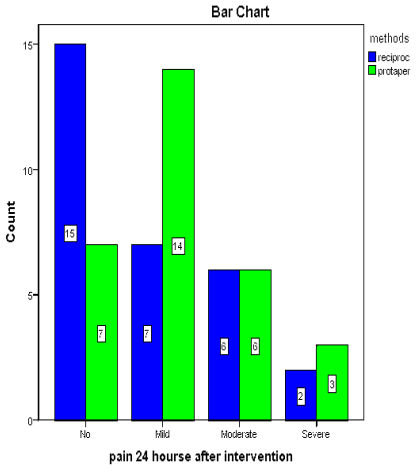
Graph 1: frequencies of pain severity scores 2-hour after root treatment in all the patients and in preparation with the two Reciproc and ProTaper systems



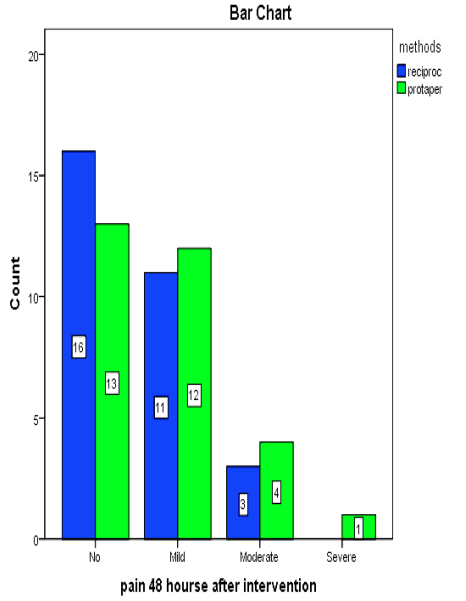
Graph 2: frequencies of pain severity scores 6-hour after root treatment in all the patients and in preparation with the two Reciproc and ProTaper systems



Graph 3- frequencies of pain severity scores 12-hour after root treatment in all the patients and in preparation with the two Reciproc and ProTaper systems



Graph 4: frequencies of pain severity scores 24-hour after root treatment in all the patients and in preparation with the two Reciproc and ProTaper systems



Graph 5: frequencies of pain severity scores 48-hour after root treatment in all the patients and in preparation with the two Reciproc and ProTaper systems

Discussion

While achieving successful post-endodontic pain relief is of great importance for both patients and dentists, the exact origins of pain following RCT remain largely unaddressed. In most cases, RCT leads to a reduction in both the intensity and frequency of pain, and only a few patients report immediate post-treatment discomfort that typically resolves within the first 2 days. [21] One of the primary reasons for post-endodontic pain is the instrumentation procedure. If peri-radicular inflammation is present, it may be triggered by the extrusion of bacteria and debris during chemo-mechanical preparation, exacerbating the level of the inflammatory response. [22, 23]

The pain scales used in this study were adapted from previous studies. The current study used a number-based VAS due to its established reliability in pain assessment. Operators classified the pain intensity ratings using a range of values. [24-26]

Numerous factors can influence the perception of postoperative pain, making clinical research into its causes complex. The occurrence of postoperative pain and flare-ups has been reported in the literature to range from 2% to 58%, even though mild discomfort is expected after endodontic treatment. [27, 28] To distinguish potential postoperative pain factors from those strictly related to the instrumentation technique, teeth with necrotic pulp, symptomatic/asymptomatic apical periodontitis, or those requiring endodontic retreatment were excluded. Additionally, all teeth were treated in a single visit to eliminate the risk of intra-canal medications or other sources of pain.

The aim of this study was to evaluate the effects of root canal preparation using Reciproc and ProTaper rotary systems on pain at various preoperative and postoperative intervals. No significant differences were found in pain severity scores between the two groups before treatment, immediately after treatment, and at 2-, 6-, 24-, and 48-hour postoperative intervals following canal preparation. However, significant differences were observed 12 hours after treatment between the two systems ($P < 0.05$), with fewer patients experiencing moderate and severe pain in the Reciproc group compared to the rotary group.

According to the present research, reciprocating instrumentation resulted in slightly reduced pain incidence and duration compared to continuous rotating instrumentation. These findings are consistent with the studies conducted by Vijayran [21] and Neelakantan [29], which reported that reciprocating systems exhibited less duration and intensity of pain. This could be explained by the fact that multifile rotating systems have been shown to cause more bacterial extrusion than reciprocating motion. A randomized clinical study by Mollashahi et al [30] found that single-file reciprocating or single-file rotary instrumentation kinematics had no effect on the severity of postoperative pain. However, the results of the study by Silveira et al [31] contrasted with the present findings, as they discovered that patients treated with rotary systems experienced less postoperative pain than those treated with reciprocating systems. These discrepancies may be attributed to variations in inclusion criteria (diagnosis of irreversible pulpitis vs vital teeth), irrigating solution (chlorhexidine vs NaOCl), and reciprocating equipment kinematics. [32] Additionally, differences in instrument characteristics, such as cross-section, cutting-edge design, taper, tip type, configuration, flexibility, alloy type, number of files used, kinematics, or cutting efficacy, could account for the observed variations. [21]

The use of controlled and uniform kinematics in this study likely reduced debris extrusion or remnants, potentially lowering the incidence of postoperative pain. In conclusion, reciprocating instrumentation systems outperformed continuous instrumentation systems significantly in terms of postoperative pain incidence and the consumption (frequency and quantity) of prescribed analgesic medications at all postoperative time points. The kinematics of the instruments may be the contributing factor, although this specific explanation was not investigated in this study. Further research is needed to pinpoint the exact causes of these findings.

Conclusion

This study found no significant difference between the Reciproc and Rotary ProTaper groups in terms of postoperative pain following endodontic treatment. It appears that the instrumentation kinematics had no impact

on the intensity of postoperative pain.

Conflict of Interest

No Conflict of Interest Declared ■

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