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Original Article

# Comparative Evaluation of Postoperative Pain After Root Canal Preparation with Rotary (Hyflex EDM) vs Reciprocating (Reciproc VDW) System in Molar Teeth: A Randomized Controlled Trial

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## ABSTRACT

***Objective:*** To evaluate and compare postoperative pain experienced by patients undergoing root canal treatment using continuous rotation (Hyflex EDM) vs reciprocating (Reciproc) instrumentation systems.
***Study Design:*** Randomized controlled trial (NCT06779565).
***Place and Duration of Study:*** 21 Military Dental Centre, Quetta, Pakistan, from Aug 2024 to Jan 2025.
***Methodology:*** Patients were randomly divided into two groups to receive root canal therapy using either the Reciproc or Hyflex EDM instrument systems. The therapy was carried out over two sessions, and postoperative pain was measured using the Numerical Rating Scale (NRS) at intervals of 6-, 12-, 18-, 24-, 48-, and 72-hours after treatment. Post-operative swelling was recorded using a modified Gabka and Matsumura Scale.
***Results:*** Group-A (Hyflex EDM) and Group-B (Reciproc) had the same distribution of gender, pulp vitality, and tooth type. The mean numerical rating scale score was significantly higher in Group-B compared to Group-A at all-time points ($p < 0.05$). Except for 48 hours during the first visit, Group B's mean swelling was significantly higher than Group-A's at 6-, 12-, 18-, and 24-hour periods. On the contrary, a significant difference was observed at the second visit after 6 hours ($p = 0.041$).
***Conclusion:***
The Hyflex EDM system significantly reduces postoperative pain after endodontic therapy compared to the Reciproc system.

**Keywords:** Hyflex EDM, Numerical Rating Score, Postoperative Pain, Reciproc, Root Canal Treatment

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## INTRODUCTION

Postoperative pain is a common, distressing and unpredictable complication after a root canal treatment and the degree of pain varies considerably according to procedural and patient-related factors. Discomfort after endodontic therapy occurs in as many as 60% of patients which would make it a high clinical concern world-wide.[1] The etiology of post-treatment pain is multifactorial, including microbial contamination, mechanical injury of periapical tissues, chemical irritation, and extrusion of debris beyond the apex. These causes may lead to the development of an inflammatory process in the periapical region, causing pain that influences patient satisfaction and treatment success.[2]

Al Omari *et al.,* implicated that the linear and rough design of manual K-files is responsible for an increased debris extrusion and is in turn more painful after the operation.[3] On the contrary Puleio *et al.,* suggested that other rotary and reciprocating nickel-titanium systems (Hyflex EDM and Reciproc) have shown better results in reducing debris extrusion because of low-torque design with a debris flushing ability and consistent canal shapes, which lead to no apical blockages.[4] Necrotic pulp remnants, microorganisms, dentinal debris, and chemical irritants can be extruded, causing acute inflammation and pain.[5] A recent clinical trial in Pakistan showed that 58.7% of the patients were experiencing mild to moderate pain within 24 hours after RCT, which highlights local contribution to the issue.[6] Furthermore, international studies from India, Iran, and Italy have also reported postoperative pain rates ranging between 52% and 70% related to the instrumentation technique and patient factors.[7,8,9] Moreover, Ahmad *et al.,* also identified that the utilization of effective irrigation methods coupled with rotary and reciprocating single-file systems improves their efficiency in eliminating postoperative symptoms, with combined incidence rates for pooled pain varying between 18% and 38% based on the utilized system.[10]

Although the use of such modern instrumentation systems is increasing, the association

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of their design characteristics with the amount of debris that is extruded during root canal treatment and the subsequent incident postoperative pain has yet to be adequately examined. Moreover, there is limited evidence regarding the comparison of postoperative pain following use of Hyflex EDM and Reciproc instruments; especially randomized clinical trials. The objective of this study is to assess and compare the incidence and severity of postoperative pain after root canal treatment in two common instrumentation systems (Hyflex EDM and Reciproc).

## METHODOLOGY

This parallel-group randomized controlled study used a 1:1 allocation ratio and was conducted in 21 Military Dental Centre, Quetta, Pakistan, from August 2024 to January 2025. The study was registered in clinicaltrials.gov with an RCT Identification no. NCT06779565. Sample size was computed by using the WHO sample size calculator at 95% confidence level, 80% power, and α = 0.05. Incidence of postoperative pain at 48 hours was 35.7% for the reciprocating system and 3.4% for the rotary system according to Gençoğlu *et al*.[2] This would provide a minimum sample size of 23 patients in each group. To account for potential dropouts, the actual sample size was determined as 37 patients in each group.

**Inclusion Criteria:** Patients 18-50 years of age with no systemic disease or medical history and diagnosed with irreversible pulpitis in molar teeth in either arch. On a radiograph, a normal periapical region or enlarged periodontal ligament space without signs of a periapical abscess.

**Exclusion Criteria:** Patients diagnosed with internal ankylosis, internal or external resorption, underlying systemic disease, severe malocclusion, rotated teeth, periodontal scoring index less than 3, apical radiolucency with signs of abscess, tooth malposition, history of dental trauma, pregnancy and severe anxiety before and during the endodontic procedure.

Patients who had received any analgesic drug in the last 12 hours before treatment were excluded from the study to preclude the possibility of confounding effects on postoperative pain appreciation. Radiographic inclusion requirements were presence of visibly enlarged periodontal ligament (PDL) space—i.e., PDL space ≥ twice normal width—on periapical radiographs obtained with paralleling technique. Radiographs were read by two calibrated endodontists separately. The Ethical Committee of 21 Military Dental Centre (MDC) Quetta, Pakistan reviewed the study design and approved it vide letter no. (001/Mil/Trg/01/13 Aug 2024). The patients were randomly divided into two groups based on the file system. Group-A (patients treated using the Hyflex EDM rotary file system) and Group-B (patients treated using the Reciproc reciprocating file system) were allocated to participants via a computer-generated randomization method. The allocation was done by a different individual not involved in the root canal treatment to eliminate selection bias. Each participant received a sealed envelope with details regarding the instrumentation system used in their case. The principal operator, who was not a part of the randomization process, used the specific file system to perform the endodontic therapy on each patient.

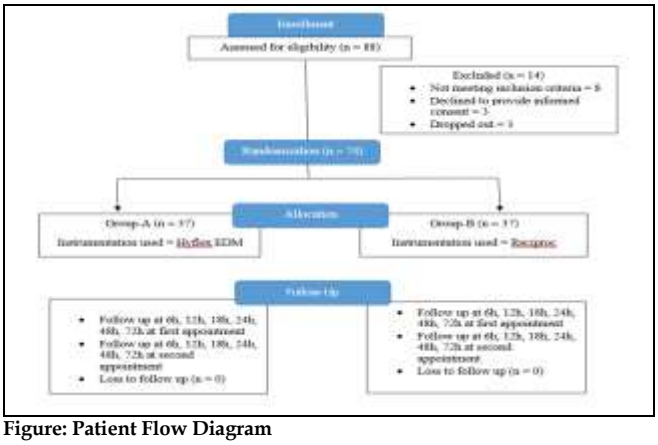


**Figure: Patient Flow Diagram**

The procedure was completed in two sittings by the same operator. Local anesthesia was administered using 2% lignocaine (Septodont, France) with 1;100,000 epinephrine. The endodontic procedure began with rubber dam isolation and access cavity preparation using 3.5x magnification loupes (Brilliance, PRC). The initial working length was estimated with an electronic apex locator (Dentaport, J Morita, Tokyo, Japan) and 0.5mm short of the radiographic apex was set as the working length, which was confirmed by two different angled periapical radiographs.

Canal shaping during the endodontic procedure was done with either Hyflex EDM (Coltene, Switzerland) rotary files or Reciproc (VDW, Germany) reciprocating files, following the manufacturer's instructions. The Hyflex EDM usage protocol followed the sequence; Orifice Opener, glide path file, and Hyflex OneFile in sequence of the working length. The evaluation of canal preparation was done with a manual K file (size #20), and if it did not fit snugly, the

Hyflex Finisher was used, and the process was repeated. In the Reciproc group, the canal prep began with a glide path with a 10k manual file, and after negotiating the canal with a 15k file, Reciproc R25 was used as one file system to prepare the canals. Throughout the canal preparation procedure, lubrication was done using EDTA (Cerkamed, Finland) and recapitulation using a 10K file. The irrigation was done with a 27-G Side-vented needle (Trunatomy, Sirona), and NaOCl was used at 2.5% concentration for disinfection.

After determining the working length, the duration of instrumentation and irrigation was also recorded. If the patients experienced pain, they were prescribed 400 mg ibuprofen as escape medicine. The Numeric Rating Scale (NRS) was used to record the pain at 6-, 12-, 18-, 24-, and 48-hour intervals using phone check-ins, followed by check-ins every 24 hours until the pain was relieved. At the second appointment, the temporary restoration was removed, and the canal irrigation was repeated using 17% EDTA before obturating with conform fit gutta-percha cones using SureSeal bioceramic sealer (SureEndo, Korea) employing the hydraulic condensation technique. Postoperative swelling was evaluated based on clinical assessment at 6-, 12-, 24-, and 48-hours after the treatment was completed. Swelling was recorded using a modified Gabka and Matsumura Scale (0–3) where Grade 0 = No swelling, Grade 1 = Mild localized swelling, Grade 2 = Moderate swelling beyond the surgical site, and Grade 3 = Severe swelling extending to adjacent anatomical regions.

Data was analyzed using statistical package for social sciences (IBM SPSS) version 23. Descriptive statistics were computed for all variables of interest. Mean and standard deviation (SD) were given for age. Frequencies and percentages were computed for categorical variables such as gender, type of tooth, and pulp vitality status, to determine whether or not the groups are comparable at baseline.

Shapiro–Wilk test was used to check normality of continuous variables. Variable of age showed normal distribution, while Numerical Rating Scale (NRS) scores and swelling score were non-normally distributed. The Mann–Whitney U test was used to find differences between NRS and swelling scores postoperatively between the two groups (Hyflex EDM and Reciproc) at different time intervals. The data record for these variables is represented with median and IQR. In all the comparisons, a *p*-value of ≤0.05 was deemed statistically significant.

## RESULTS

A total of 74 patients were included in the study, with 37 in Group-A and 37 in Group-B. Patients in Group-A and Group-B had mean ages of 48.51±13.62 years and 45.81±9.24 years, respectively. Both groups had the same distribution of genders i.e., 18(48.65%) male and 19(51.35%) female, pulp vitality 9(24.32%), and tooth type including 19(51.35%) molars and 18(48.65%) premolars. There were no signs of systemic illness in the patients.

At each time point, Group-B (Reciproc) had significantly higher NRS scores than Group-A (Hyflex EDM). The median (IQR) pain score was 2.7 (0.2) in Group-B vs 1.9 (0.2) in Group-A at 6 hours ($p$<0.001). The same trends were noted at 12 hours [1.9 (0.3) vs. 0.9 (0.6), $p$<0.001], 18 hours [1.7 (0.2) vs. 0.5 (0.3), $p$<0.001], and 24 hours [1.3 (0.2) vs. 0.3 (0.2), $p$<0.001]. At 48 hours, pain had decreased in both groups but was still significantly higher in Group-B [0.6 (0.3) vs. 0.0 (0), $p$<0.001]. Patients treated with the Hyflex EDM system had lower levels of postoperative pain compared to those who were treated with Reciproc system at all-time points; greatest difference being first 24 hours (Table-I).

**Table-I: Median Postoperative Pain Scores (NRS) of Group-A and Group-B at different intervals following the First Endodontic Visit (n=74)**

| Time Period | Groups | | *p*-value |
|---|---|---|---|
| | Group-A n=37 | Group-B n=37 | |
| Prior to taking medicine after treatment Median (IQR) | 0.1 (0.2) | 0.2 (0.1) | 0.019 |
| After 6 hours Median (IQR) | 1.9 (0.2) | 2.7 (0.2) | <0.001 |
| After 12 hours Median (IQR) | 0.9 (0.6) | 1.9 (0.3) | <0.001 |
| After 18 hours Median (IQR) | 0.5 (0.3) | 1.7 (0.2) | <0.001 |
| After 24 hours Median (IQR) | 0.3 (0.2) | 1.3 (0.2) | <0.001 |
| After 48 hours Median (IQR) | 0 (0) | 0.6 (0.3) | <0.001 |

**Table-II: Median postoperative pain scores (NRS) of Group-A and Group-B at different intervals following the Second Endodontic Visit (n=74)**

| Time Period | Groups | | *p*-value |
|---|---|---|---|
| | Group-A n=37 | Group-B n=37 | |
| Prior to taking medicine after treatment Median (IQR) | 0 (0) | 0.2 (0) | <0.001 |
| After 6 hours Median (IQR) | 1 (0.4) | 2.1 (0.4) | <0.001 |
| After 12 hours Median (IQR) | 0 (0.1) | 0.7 (0.2) | <0.001 |
| After 18 hours Median (IQR) | 0 (0) | 0.3 (0.2) | <0.001 |
| After 24 hours Median (IQR) | 0 (0) | 0.1 (0.2) | <0.001 |
| After 48 hours Median (IQR) | 0 (0) | 0 (0) | 0.006 |

Pain scores after the second visit showed that Group-B experienced significantly more pain at all points. 6 hours pain was 2.1 in Group-B and 1.0 in Group-A ($p$<0.001), with little pain in either group by

48 hours, though between-group differences were statistically significant. Following the second appointment, Hyflex EDM system maintained lower scores of pain compared to Reciproc system, with most differences being recorded during the early postoperative period (Table-II).

Postoperative swelling on the first visit indicated that swelling was always greater in Group-B at 6, 12, 18, and 24 hours (all $p<0.05$). At 48 hours, both groups had no swelling (p=1.00). Inflammation was greater in the Reciproc group within the first 24 hours of the initial visit, but resolved fully in both groups by 48 hours (Table-III). Swelling after the second visit indicated a highly significant difference only at 6 hours ($p=0.041$), in favor of Group-A. There was no significant swelling later in either group. Swelling after the second visit was usually minimal in both groups, with only a temporary difference at 6 hours (Table-IV).

**Table-III: Median postoperative swelling scores of Group-A and Group-B following the first endodontic visit, assessed by the modified Gabka and Matsumura scale (n=74)**

| Time Period | | Groups | | *p*-value |
|---|---|---|---|---|
| | | Group-A n=37 | Group-B n=37 | |
| After 6 hours | Median (IQR) | 1 (0) | 2 (1) | 0.011 |
| After 12 hours | Median (IQR) | 1 (1) | 1 (1) | 0.002 |
| After 18 hours | Median (IQR) | 0 (0) | 0 (1) | 0.031 |
| After 24 hours | Median (IQR) | 0 (0) | 0 (1) | 0.021 |
| After 48 hours | Median (IQR) | 0 (0) | 0 (0) | 1.00 |

**Table-IV: Median postoperative swelling scores of Group-A and Group-B following the second endodontic visit, assessed by the modified Gabka and Matsumura scale (n=74)**

| Time Period | | Groups | | *p*-value |
|---|---|---|---|---|
| | | Group-A n=37 | Group-B n=37 | |
| After 6 hours | Median (IQR) | 1 (1) | 1 (1) | 0.041 |
| After 12 hours | Median (IQR) | 0 (0) | 0 (1) | 0.442 |
| After 18 hours | Median (IQR) | 0 (0) | 0 (0) | 0.693 |
| After 24 hours | Median (IQR) | 0 (0) | 0 (0) | 0.531 |
| After 48 hours | Median (IQR) | 0 (0) | 0 (0) | 1.00 |

## DISCUSSION

The findings suggest that at all time intervals, Group-A (Hyflex EDM) reported significantly less post-operative pain and swelling as compared to Group-B (Reciproc). Mean NRS score in Group-A reached maximum at 6 hours of the procedure (1.9±0.6) and then reduced to 0 at 48 hours. In comparison, Group-B had a higher median pain score of 2.7 (IQR = 0.7) at 6 hours, which then decreased to 0.6 (SD 0.3) at 48 hours. The pattern was similar with swelling, where significantly less swelling was observed in Group-A at 6- and 12-hours ($p<0.05$), though the difference was no longer apparent by 48 hours ($p=1.00$), indicating resolution of acute inflammation.

These results are in agreement with many of the studies that have been published. Lima Neto *et al.,* performed a systematic review and meta-analysis of 11 studies and determined that rotary systems in general are related to much less postoperative pain in the first 48 hours than reciprocating systems ($p<0.05$).[11] The authors considered that this difference was due to the continuous rotation motion, which can cause less apical extrusion of debris. In agreement with this, da Silveira *et al.,* also showed in their meta-analysis that reciprocating systems had a 1.39 times increased chance of generating moderate to severe postoperative pain when compared to rotary systems ($p=0.03$), particularly during the first 24 hours.[12]

Çanakçi *et al.,* in a randomized controlled trial comparing two rotary (ProTaper Universal, Mtwo) and two reciprocating (Reciproc and WaveOne) systems, published that patients with reciprocating files had significantly higher pain at 24 hours (mean VAS score of 2.35±1.02) compared to patients treated with rotary systems (mean VAS score of 1.41±0.86, $p=0.001$).[13] This trend was linked to greater extrusion of debris and the pecking action utilized during reciprocation, which potentially exacerbates periapical tissues. Ikhar *et al.,* contrasted Hyflex EDM with ProTaper Gold specifically and also found lower pain scores with Hyflex EDM (mean VAS score: 1.23 vs. 2.08, $p<0.05$), implying that the controlled memory and flexibility of the Hyflex EDM system are responsible for less periapical stress.[14] On the contrary, Reciproc VDW, with its harsh cutting motion and single-file approach, could lead to more extrusion of debris into the periapical tissue, causing inflammation and hence more pain. This action is well-documented by Uzunoğlu Özyürek *et al.*, who discovered that reciprocation systems produced significantly more apical extrusion in vitro, whether retreatment or primary treatment ($p<0.01$), supporting the clinical evidence derived from pain assessment studies.[15]

Kharouf *et al.*, determined apical debris extrusion and found that Reciproc system extruded 1.22±0.11 mg of debris, much higher than rotary systems such as Hyflex EDM (0.86±0.09 mg), which can be the reason for greater postoperative inflammation and pain in reciprocating methods.[16] Likewise, Ahmad *et al.,* in their meta-analysis of 12 studies reported that reciprocating systems extruded much more debris

than rotary files (standardized mean difference = 0.71; 95% CI: 0.49–0.93; $p<0.001$)—an extremely good predictor of why reciprocating systems should cause more postoperative pain.[17]

Clinically, Sepah *et al.*, also recorded 4.2±1.1 for pain score in patients undergoing manual instrumentation and 2.9±0.9 in rotary system-treated patients at 24 hours, which is similar to our experience where the Hyflex group consistently had lower pain at all postoperative time points.[18] In vitro findings by Abdelnaby *et al.*, concur with this trend, indicating that Hyflex EDM extruded 0.92±0.05 mg of debris versus 1.35±0.08 mg for Reciproc Blue, which testifies to the relationship between debris extrusion and postoperative pain.[19]

A local clinical study by Iqbal *et al.*, mentioned that 36% of patients in the rotary group had moderate to severe postoperative pain whereas 58% of patients had moderate to severe postoperative pain in the hand-file group ($p<0.05$), showing the better comfort offered by rotary systems.[20] In addition, Rana *et al.* established that satisfactory obturation quality was obtained in 83.3% of cases treated with rotary versus 60% in manual instrumentation, which is suggestive of more effective cleaning and fewer residual debris with rotary usage, which could result in less postoperative pain.[21]

While differences in swelling between groups became statistically non-significant after 48 hours ($p=1.00$), this most likely represents the resolution of acute inflammation over time rather than an artifact of instrumentation. The differences were most highly developed in the early postoperative period (6–12 hours), indicating that initial tissue damage and debris extrusion are the main causes of discomfort and inflammation, both of which depend on file system dynamics. Inflammation, found more often in the Reciproc group at initial postoperative time points, may be related to greater inflammatory stress on the periapical tissues from too much debris extrusion and a more vigorous cutting action. Conversely, Hyflex EDM's flexible nature and dammed-in cutting efficiency minimize dentinal wall mechanical stress, diminishing postoperative swelling.

## LIMITATIONS OF STUDY

There are various limitations that must be acknowledged despite these findings. Though the Numeric Rating Scale (NRS) was used to measure the perception of pain among the patients, subjective pain evaluation might be affected by individual pain tolerance level and psychological factors. Furthermore, this study did not take into consideration the potential influence of the operator's experience on the treatment outcomes, which could act as a confounding factor.

## CONCLUSION

This study provides compelling evidence that the type of file system used substantially influences postoperative pain and swelling in patients undergoing root canal therapy. The Hyflex EDM, a continuous rotation file system, resulted in lower pain and reduced swelling compared to the Reciproc system, which uses a reciprocating motion. These findings highlight the clinical relevance of selecting an instrumentation technique that minimizes patient discomfort, ultimately improving the overall treatment experience.

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**Authors' Contribution**

Following authors have made substantial contributions to the manuscript as under:

AA & SA: Data acquisition, data analysis, critical review, approval of the final version to be published.

AR & SZ: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

ZRS & NJ: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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