Comparison of postoperative pain after the use of different nickel-titanium instrumentation systems: A randomized clinical trial

Purpose
Postoperative pain is a common complication in endodontics contributed by multiple etiological factors, which consist canal preparation instruments and kinematics. The aim of this randomized clinical trial compare the postoperative pain in terms of intensity and incidence after the use of different nickel-titanium (NiTi) file systems.

Patients and Methods
In this randomized clinical trial (NCT03791762), a total of 150 patients were root canal treated by 2 experienced endodontists according to a standardised protocol. The subjects were randomly assigned to 1 of the 3 groups according to preparation instrument used: ProTaper Next (Dentsply Sirona, Ballaigues, Switzerland), Reciproc Blue (VDW, Munich, Germany) and WaveOne Gold (Dentsply Sirona). Following preparation the teeth underwent standardized root canal treatment procedures in a single visit. The patients were contacted to gather information about the incidence of pain and intensity at 6th, 12th, 18th, 24th, 48th, and 72nd hours postoperatively. The data were analysed using chi-square, one-way analysis of variance and post hoc Tukey tests and logistic regression analysis with 5% significance threshold.

Results
No significant difference was found among preparation groups in relation to the intensity of postoperative pain. The incidence of postoperative pain was significantly linked with the preoperative pain presence with odds ratio values ranging between 2.06 and 4.08 irrespective of the preparation technique (P<0.05).

Conclusion
The effects of reciprocating and the continuous rotary systems on the intensity and incidence of postoperative pain were found to be similar.

Keywords: Endodontic treatment, WaveOne Gold, postoperative pain, ProTaper Next, Reciproc Blue

Introduction
Postoperative pain after endodontic treatment is an undesirable condition that leads to distress for both the clinician and the patient (1). Frequency of postoperative endodontic pain is common, with a reported frequency ranging between 25% and 40% (2). Postoperative pain, which is a complex and multifactorial process, may develop even following an ideal root canal treatment (3). Several etiologic factors are considered as predictive factors, including pulpal and periradicular status, sinus tracts, systemic steroid therapy, preoperative swelling, the presence and incidence of preoperative pain (4, 5). When encountered with these predictive factors, clinicians take preoperative and perioperative measures to manage postoperative pain. These management strategies may include pre and postoperative use of pharma-
cologic agents such as the use of antihistamines, paracetamol, non-steroidal anti-inflammatory drugs (NSAI) and nonpharmacologic methods that can be used to adapt treatment procedures such as occlusal reduction, canal preparation technique, the use of intracanal medications (6-8). Root canal preparation is emphasized as an important factor to achieve thorough disinfection along with high volume of irrigation (7).

Standard root canal preparation has been carried out with the use of different instruments and kinematics. Rapid technological advances in the endodontic instrumentation systems introduce new design concepts with the claim of easier and faster preparations that preserve the original canal shape with considerably less iatrogenic error (9, 10). The manufacturers also claim to achieve more favorable treatment outcome with less postoperative pain rate. ProTaper Next (PTN) (Dentsply, Sirona) is a popular continuous rotating instrumentation system which is manufactured from M-wire nickel-titanium (NiTi) showing enhanced flexibility and fatigue resistance over conventional NiTi (11). WaveOne Gold (WOG) (Dentsply, Sirona) is a reciprocating instrument manufactured via a special thermomechanical treatment termed as Gold treatment. WaveOne Gold instruments show novel parallelogram cross-sectional shape with 2 cutting edges, and consist of 4 instruments as 21/06 (small), 25/07 (primary), 35/06 (medium) and 45/05 (large) (12). The Reciproc Blue (RB) (VDW, Munich, Germany), another thermally treated reciprocating single-file system with a design identical to that of its predecessor, the Reciproc with the advancement of Blue wire providing increased fatigue resistance and flexibility (13, 14). These novel thermally treated systems have design modifications such as changing tapers, different cross-sections, variable helicoidal angles that have been associated with postoperative pain by affecting the amount of extruded debris (15-18).

Debris extrusion is an inevitable complication during the cleaning and shaping procedures, both with manual stainless steel and nickel-titanium rotary instrumentation techniques (15, 19). The instrument kinematics have been improved to minimize the amount of extruded debris during preparation, while conflicting findings have been reported regarding the amount of extruded debris by instruments with continuous rotation or reciprocation in the literature. Several clinical studies compared reciprocating and rotating systems and linked instrument kinematics with the postoperative pain (16, 17, 20-22). A meta-analysis concluded that preparation with rotary instrumentation was linked with a lower pain incidence compared to the preparation with reciprocating instruments in single visit cases (18). According to our literature review, the effect of root canal preparation using Reciproc Blue and WaveOne Gold on the incidence and intensity of postoperative pain has not yet been compared by a randomised controlled clinical trial. This study aimed to compare the postoperative pain after use of PTN, RB or WOG. The null hypothesis was established as no significant difference was expected in the term of the intensity and incidence of postoperative endodontic pain after root canal preparation using any of the 3 instruments.

**Patients and methods**

*Ethical board approval and selection of participants*

Study protocol was approved by local university clinical searches ethical board (KAEG/389) and also registered in ClinicalTrials.gov (NCT03791762). A priori sample size calculation was performed using a computational software (G*Power, G*Power 3.1 for Macintosh, Heinrich-Heine, Düsseldorf, Germany) F test family based on the effect size of a previous study (21). Based on a type I error of .05 and a power of 80%, a minimum sample size of 39 would be required to detect differences among groups. Fifty patients per group were included to the study due to a possible dropout rate of 10% (n = 50). Patients with systemic diseases, apical abscess or multiple teeth requiring treatment, showing signs of systemic infection, currently taking medications until 7 days prior to the procedure (analgesic, anti-inflammatory drugs, antibiotics or corticosteroids), or having a drug allergy were excluded from the study (Figure 1). Subjects were informed about the study protocol and signed informed consent forms before treatment. The study included teeth diagnosed with symptomatic/asymptomatic irreversible pulpitis or symptomatic/asymptomatic apical periodontitis. The clinical diagnosis of symptomatic irreversible pulpitis was based on positive pulp sensibility test result, presence of spontaneous pain, lingering provoked pain longer than 30 seconds, and deep caries, extensive restorations or fractures exposing the pulp. The clinical diagnosis of asymptomatic irreversible pulpitis was based on the absence of clinical symptoms and presence of a deep carious lesion that will eventually result in a large pulp exposure following removal. Symptomatic apical periodontitis was diagnosed according to the presence of painful response to biting / percussion / palpation, spontaneous pain and periradicular radiographical features varying from a normal periapical structures to a periapical radiolucency, whereas asymptomatic apical periodontitis was diagnosed according to the absence of clinical symptoms, responsiveness to pulp sensibility tests and the presence of a periapical radiolucency. Thermal and electric pulp tests were performed to determine pulp sensibility. Preoperative periapical radiographs were taken with a digital radiography system (Sirona Vario DG, Bensheim, Germany). Two independent blinded endodontists analysed clinical and radiological data sheets, which was obtained and filled for each subject. A third opinion of an endodontist was obtained when conflicts arose. Table 1 provides a summary of the baseline demographic and clinical properties of the study groups.

![Figure 1. Flow diagram CONSORT for randomised clinical trials.](image-url)
Table 1: Baseline demographic and clinical features of the patients in the study groups.

| Baseline demographic and clinical features | ProTaper Next, n(%) (n=50) | Reciproc Blue, n(%) (n=50) | WaveOne Gold, n(%) (n=50) | Total, n(%) (n=150) |
|-------------------------------------------|-----------------------------|-----------------------------|---------------------------|----------------------|
| Female                                    | 26 (31.3)                   | 27 (31.3)                   | 31 (37.4)                 | 84                   |
| Male                                      | 24 (36.3)                   | 23 (34.8)                   | 19 (28.9)                 | 66                   |
| Vital                                     | 36 (30.7)                   | 42 (35.89)                  | 39 (33.4)                 | 117                  |
| Nonvital                                  | 14 (42.4)                   | 8 (24.2)                    | 11 (33.4)                 | 33                   |
| Incisor Teeth                             | 5 (27.7)                    | 7 (38.8)                    | 6 (33.5)                  | 18                   |
| Premolar Teeth                            | 12 (31.6)                   | 14 (36.8)                   | 12 (31.6)                 | 38                   |
| Molar Teeth                               | 33 (35.1)                   | 29 (30.8)                   | 32 (34.1)                 | 94                   |
| Frequency of preoperative pain            | 39 (78)                     | 35 (70)                     | 42 (84)                   | 116                  |

Treatment procedures

Root canal treatments were performed by 2 endodontists between June 2018 and December 2018. All treatments were completed in a single visit. The patients were trained about the use of visual analogue scale (VAS) forms. Treatment preparation included the administration of 2.0 mL local anesthesia 4% articaine with adrenaline 1:100.000, which might be followed by an additional 2.0 mL carpule of 4% articaine use when necessary. Before treatment 1 of the 3 sealed envelope, which was written the experimental group name was selected by a third person, who was not involved in the study and kept sealed until root canal preparation phase. Traditional endodontic access cavities were prepared. Glide path was created with stainless steel #8, 10, 15 K-files with push and pull motion at apical direction. Working length (WL) was determined using a 10 K-file and electronic apex locator (Root ZX Mini, Morita, Kyoto, Japan) and periapical radiography (Sirona Vario DG, Bensheim, Germany). Then, the envelope was opened and the subject was assigned to 1 of the 3 preparation groups according to the root canal instrumentation system as RB, WOG and PTN. All instrumentation procedures were performed according to the manufacturers’ instructions. Patients did not know which experimental group they were assigned to.

Group RB. In the Reciproc Blue group, instrument selection was performed based on the dimensions of root canals (23). If a 30 K-file was passively introduced into the root canals up to WL, this root canal was considered as large and R50 (50.05) instrument was selected. When a 30 K-file failed to reach the WL and a 20 K-file was introduced into the WL, the root canal was considered as medium and R40 (40.06) instrument was selected. When a 20 K-file failed to reach the WL, this canal was considered as narrow and R25 (25.08) instrument was selected. Three pecking motion with 3 mm amplitude followed by removal and cleaning of the instrument was performed until the established WL was achieved. The instruments were operated with Reciproc ALL mode of the same apex locator integrated endomotor (VDW Gold, Munich, Germany).

Group WOG. In the WaveOne Gold group, the Small file (20.07) was used to prepare the root canals if a 25 K-file failed to reach the WL. When a 25 K-file was passively introduced to the WL, the Primary file (25.07) was selected for preparation. When a 25 K-file was passively introduced to the WL, the Medium file (35.06) was selected. When a 35 K-file was passively introduced to the WL, the Large file (45.05) was selected. Three pecking motions with 3 mm amplitude followed by removal and cleaning of the instrument was performed until the established WL was achieved. The instruments were operated with WaveOne ALL mode of the same apex locator integrated endomotor (VDW Gold, Munich, Germany).

During preparation of each canal was flushed with 10 mL of 5.25% NaOCl with a 30-G needle syringe. Patency of the apical foramen was maintained during all the techniques by introducing a #10 K-type file (Dentsply Sirona) to a point 0.5 mm beyond the working at each instrument change. After preparation, final irrigation of each root canal included flushing with 5 mL of 17% EDTA, 2.5 mL distilled water and 2.5 mL of 5.25% NaOCl, respectively. Then, the canals were dried with sterile paper points. Root canal obturation was performed by cold lateral compaction technique using epoxy resin sealer (AH Plus Jet, Dentsply Sirona, Ballaigues, Switzerland) and gutta-percha. Coronal restorations were performed with composite resin filling material (Gradia Direct, GC Dental, Tokyo, Japan). After treatment, the patients were recommended to take 600 mg ibuprofen only if necessary and record their analgesic intake. Then the patients were discharged with VAS forms. No prescription was prepared for any medication. Following 3 days, the patients were contacted via telephone for the record of their postoperative pain scores, 6th, 12th, 18th, 24th, 48th, and 72nd hour VAS scores.

Statistical analysis

Distribution of possible confounding factors such as gender (female/male), age, pulp sensibility (nonvital/vital), tooth type (incisor/premolar/molar), and preoperative pain (present/absent) among groups were tested with chi-square test. Distribution of postoperative VAS scores was tested for
normality and confirmed normal distribution. Prior to treatment, the patients were instructed how to complete a visual analogue scale (VAS) to determine their preoperative and postoperative pain scores. The VAS forms included a 10 cm straight horizontal line numbered at each centimetre from 0 to 10. The beginning of the line was defined as ‘0=no pain’ and the ending was defined as ‘10=the most severe pain experienced’. Scores of postoperative pain intensity were analysed with by one-way analysis of variance and post-hoc Tukey tests. Then a logistic regression analysis was performed to assess the importance of the preparation group and confounding variables for the prediction of postoperative pain. Model fit was assessed with Hosmer-Lemeshow goodness of fit statistics. SPSS software (v.18.0; IBM, Chicago, IL, USA) was used to analyze all statistical analyses.

Results

A total of 150 patients were enrolled but one patient of each group was excluded because they could not be contacted for follow-up. None of the patients applied with the complaint of inter-appointment flare-up. Five patients in the PTN group (2 paracetamol intake for 3 patients and 1 NSAI intake for 3), one patient in the RB group (1 NSAI) and four patients in the WOG group (1 NSAI) reported analgesic intake for 3 patients. In the PTN group, one patient reported analgesic intake for 3 patients and 1 NSAI. The frequency of patients reporting postoperative endodontic pain in each experimental group was presented in Table 2.

Table 2 presents the logistic regression analysis results at each time intervals. Hosmer-Lemeshow tests showed good level of fit for all time intervals. Only the presence of preoperative pain variable showed significant influence on the presence of postoperative pain during the first 24 hours (P<0.05). Root canal preparation method was not a significant predictive factor at all time intervals. When the subjects had preoperative endodontic pain they tend to report more pain (P<0.05) with odd ratio values varied between 2.06 and 4.08 irrespective of the preparation system.

Discussion

The use of reciprocating instruments was correlated with increased postoperative pain incidence compared to continuous rotation in parallel to greater amount of apically extruded debris (18, 22, 24, 25). However, the effect of instrument kinematics on the amount of extruded debris is not evidenced in the presence of the various conflicting results caused by the use of different instruments varying with cutting efficacy, alloy type, cross-sectional shape, number of files used, pitch design and taper (22). As an attempt to standardize the instrument related factors, an in vitro study compared the debris extruded during reciprocation and continuous rotation using the same instrument and reported that the continuous rotation caused significantly greater amount of extruded debris, while another study also standardized the instrument and reported similarity between reciprocation and continuous rotation (25-27). Well designed randomized clinical trials are warranted to evaluate the effect of different instrumentation systems on postoperative pain since in vitro results may not apply to clinical situations. Therefore, the aim of this prospective clinical trial was to compare the incidence and intensity of postoperative pain after the use of different NiTi instrumentation systems. Since the results of the study revealed similarity among RB, WOG and PTN; the null hypothesis was not rejected.

Various instrumentation systems were associated with the same degree of postoperative pain (16, 20, 21, 26-28). Two clinical trials reported similarity regarding the intensity of postoperative pain between OneShape and reciprocating single file groups; WaveOne and Reciproc (29, 30). Creation of glide path with reciprocating or rotating instruments caused similar degree of postoperative pain (31). Another randomized trial reported that the use of PTN or Reciproc exerted a similar impact on quality of life (32). The results of the present study showed that no significant difference was observed in the incidence of postoperative pain after use of PTN, RB, and WOG. These results are in accordance with those clinical trials, however the compared instruments were different apart from the comparison of reciprocation and rotation motions (18, 22, 28). The differences might stem from methodological differences, including subject number and randomization, the use of different irrigation agents
Table 3: Odd ratios, 95% confidence intervals (CI) and associated p values for logistic regression models of the data of the postoperative pain incidence for each measurement intervals.

| Time interval | Variable                                      | P value (95% CI) | Odds ratio |
|---------------|-----------------------------------------------|------------------|------------|
| 6th hour      | Group                                         |                  |            |
|               | ProTaper (reference)                          | 0.26             | -          |
|               | Reciproc Blue                                 | 0.18 (0.76-4.2)  | 1.79       |
|               | WaveOne Gold                                  | 0.86 (0.39-2.17) | 0.92       |
|               | Gender (female vs. male)                      | 0.81 (0.53-2.21) | 1.08       |
|               | Preoperative pain presence (absent vs. present)| 0.04 (1.29-6.41)| 2.29       |
|               | Vitality (nonvital vs. vital)                 | 0.18 (0.18-1.2)  | 0.47       |
| 12th hour     | Group                                         |                  |            |
|               | ProTaper (reference)                          | 0.42             | -          |
|               | Reciproc Blue                                 | 0.26 (0.09-3.75) | 1.61       |
|               | WaveOne Gold                                  | 0.93 (0.42-2.2)  | 0.96       |
|               | Gender (female vs. male)                      | 0.64 (0.42-1.7)  | 0.84       |
|               | Preoperative pain presence (absent vs. present)| 0.04 (0.8-5.1)| 2.06       |
|               | Vitality (nonvital vs. vital)                 | 0.11 (0.2-1.26)  | 0.50       |
| 18th hour     | Group                                         |                  |            |
|               | ProTaper (reference)                          | 0.49             | -          |
|               | Reciproc Blue                                 | 0.32 (0.63-3.9)  | 1.57       |
|               | WaveOne Gold                                  | 0.91 (0.4-2.2)   | 0.95       |
|               | Gender (female vs. male)                      | 0.86 (0.5-2.25)  | 1.06       |
|               | Preoperative pain presence (absent vs. present)| 0.01 (1.3-12.9)| 4.08       |
|               | Vitality (nonvital vs. vital)                 | 0.05 (0.12-1.02) | 0.35       |
| 24th hour     | Group                                         |                  |            |
|               | ProTaper (reference)                          | 0.42             | -          |
|               | Reciproc Blue                                 | 0.22 (0.6-4.7)   | 1.81       |
|               | WaveOne Gold                                  | 0.71 (0.48-2.92) | 1.18       |
|               | Gender (female vs. male)                      | 0.26 (0.7-3.52)  | 1.58       |
|               | Preoperative pain presence (absent vs. present)| 0.03 (1.06-14.0)| 3.87       |
|               | Vitality (nonvital vs. vital)                 | 0.09 (0.11-1.18) | 0.37       |
| 48th hour     | Group                                         |                  |            |
|               | ProTaper (reference)                          | 0.71             | -          |
|               | Reciproc Blue                                 | 0.59 (0.47-3.68) | 1.32       |
|               | WaveOne Gold                                  | 0.43 (0.54-4.18) | 1.50       |
|               | Gender (female vs. male)                      | 0.45 (0.57-3.36) | 1.39       |
|               | Preoperative pain presence (absent vs. present)| 0.08 (0.85-17.9)| 3.90       |
|               | Vitality (nonvital vs. vital)                 | 0.15 (0.1-1.4)   | 0.38       |
| 72nd hour     | Group                                         |                  |            |
|               | ProTaper (reference)                          | 0.43             | -          |
|               | Reciproc Blue                                 | 0.49 (0.48-4.43) | 1.47       |
|               | WaveOne Gold                                  | 0.20 (0.65-7.14) | 2.16       |
|               | Gender (female vs. male)                      | 0.70 (0.45-3.21) | 1.21       |
|               | Preoperative pain presence (absent vs. present)| 0.20 (0.58-12.9)| 2.75       |
|               | Vitality (nonvital vs. vital)                 | 0.83 (0.26-2.9)  | 0.88       |

With different volumes, variances in tooth types, the choice of blinding procedures, which pain scales were used, and varying follow-up durations.

In the present study, postoperative pain intensity was the highest in the early hours postoperative and then decreased substantially after 48 hours in all groups, which is congruent
with the existing literature (32, 33). The frequency of severe and moderate pain decreased by the time as the frequency of mild and no pain increased. Interestingly, WOG group, which showed the greatest incidence of postoperative pain among groups (n=27) also showed the greatest reduction from 55% to 10% from 6th hours to 72nd hours. In RB group least postoperative pain incidence was detected with 19 patients. It is also worth to mention that mean postoperative pain values at postoperative 6th hours were below 3 in all preparation groups. The persistence of mild pain might be related to the continuing inflammatory processes particularly in the presence of preexisting periradicular inflammation or injection wounds, pressure of the rubber dam clamp, or the discomfort due to prolonged mouth opening.

Kherlakian et al. (21) compared the postoperative pain following preparation with PTN, Reciproc and WaveOne instruments in 210 healthy teeth root canal treated for prosthetic rehabilitation and reported similarity between rotary and reciprocating systems in agreement with the present study also evaluating PTN with novel reciprocating instruments (21). However, apart from the different alloys Blue and Gold wire, the design of the RB is identical with Reciproc instruments, while WOG displays less taper and different cross-sectional shape from WaveOne. WaveOne instruments were reported to extrude greater amount of debris compared to WOG due to its greater taper and triangular cross-section that causes screwing effect pushing the debris apically (34). Increased flexibility of the thermally treated NiTi alloys have been indicated to lead a decreased amount of extruded debris (34). In the present study, no difference was detected between reciprocating and continuous rotation groups. In all subjects, glide path was created or followed, patency was achieved; irrigation solution, volume and technique were standardized and manufacturers’ recommendations were strictly followed during instrumentation. Along with these factors and homogenous distribution of demographic factors and preoperative pain incidence in groups might contribute to the similarity among instrumentation techniques in terms of postoperative pain occurrence and intensity.

Apical patency has been discussed due to the potential apical extrusion of infected debris risk with the assumption that it would increase postoperative pain. Two recent meta-analyses concluded that maintenance of patency does not increase postoperative pain and analgesic intake (35, 36). Based this information, apical patency was maintained in our study.

Standardization of all possible confounding variables would clarify the actual effect of the investigated variable on the postoperative pain levels. However, given the large sample size and multifactorial nature of the endodontic pain, elimination of all confounding factors would not be possible, which constitutes a major limitation. Therefore, in the present study the homogenous distributions of subject related factors such as gender, tooth type, pulp sensibility and the preoperative pain were confirmed. The effects possible confounding factors on the incidence of postoperative pain was also analysed. Some studies have concluded that variables such as gender, age, tooth type and preoperative pain are significant factors for the development of postoperative pain (4, 37). The presence of preoperative pain emerged as a significant factor for the incidence of postoperative pain apart from patient gender, tooth type and preparation group. These findings are in accordance with the previous literature that reported that greater postoperative pain incidence is significantly linked with the presence of preoperative pain (5, 38). Today, preoperative pain is considered as a significant factor for the prediction of postoperative pain (2, 3). Therefore, patients whose chief complaint is endodontic pain could be warned about probable postoperative pain and 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 (39, 40). 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 (41, 42). 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. All patients included in the study were treated in a single visit. Therefore, the findings of the present study can not be applied or interpreted for multiple-visit treatments, which warrants for further randomized clinical trials.

**Conclusion**

Within the limitations of the present randomized clinical trial, Reciproc Blue, WaveOne Gold and ProTaper Next canal preparation systems had similar postoperative pain intensity and incidence following single visit root canal treatment. The presence of preoperative pain was the most significant predictive factor for the occurrence of postoperative pain.
Ethics Committee Approval: The study protocol was approved by the university ethical board (KAET/389) and it was also registered to ClinicalTrials.gov (NCT03791762).

Informed Consent: Participants provided informed consent.

Peer-review: Externally peer-reviewed.

Author contributions: OSY, CK, HA participated in designing the study. OSY, CK, DHA participated in generating the data for the study. OSY, CK, DHA participated in creating the data for the study. OSY, CK, DHA, HA wrote the majority of the original draft of the paper. OSY, CK, DHA, HA participated in writing the paper. OSY, CK, DHA, HA have had access to all of the raw data of the study. OSY, CK, DHA, HA have reviewed the pertinent raw data on which the results and conclusions of this study are based. OSY, CK, DHA, HA have approved the final version of this paper. OSY guarantees that all individuals who meet the Journal's authorship criteria are included as authors of this paper.

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