



# Postoperative pain of minimally invasive root canal treatment: a randomized clinical trial

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## Abstract

This randomized clinical trial compared postoperative pain between a minimally invasive (MP) and conventional root canal treatment protocol (CP). A total of 170 mature permanent teeth (either with vital or necrotic pulp), were randomly assigned into two groups. In the CP group, ProTaper Gold (Dentsply Sirona, Ballaigues, Switzerland) and a continuous wave of condensation technique were used, whereas, in the MP group, TruNatomy (Dentsply Sirona), ultrasonic-assisted irrigation (UI), calcium hydroxide, and a sealer-based obturation technique were used. Patients recorded preoperative and postoperative pain using a 0–10 numerical rating scale (NRS) at 4 h, 1, 2, 3, 4, 5, 6, and 7 days after instrumentation and 1 day after canal obturation, respectively. There were no significant differences in pain intensity at any time points assessed between the two groups ( $p > 0.05$ ). The occurrence of moderate/intense pain after instrumentation was significantly associated with preoperative periapical index (PAI) ( $p = 0.017$ ) and NRS scores ( $p < 0.001$ ). Preoperative pulp status ( $p = 0.009$ ) and NRS score ( $p = 0.006$ ) were identified as significant factors in the occurrence of moderate/intense pain after obturation. Instrumentation unequivocally reduced pain severity for both groups. The post-endodontic pain associated with the use of MP, combined with UI, Ca(OH)<sub>2</sub>, and calcium-silicate cement, did not differ from that of CP. Preoperative pain score, PAI, and preoperative pulp status were determined to be prognostic factors for postoperative pain.

**Keywords** Postoperative pain · Minimally invasive endodontics · Canal preparation · Canal obturation

## Introduction

Patients experiencing endodontic pain visit dental practices, and root canal treatment (RCT) consistently reduces pain prevalence [1]. However, post-preparation pain in nonsurgical endodontic treatment is a common complication, with the highest incidence occurring within the first 24 h [1, 2]. Factors contributing to this pain include mechanical preparation and obturation beyond the apex, bacteria not eliminated during primary disinfection, and the extrusion of irrigants

beyond the apex [3]. In particular, the techniques used in RCT may influence the severity of post-operative pain [4–7].

Recently, the concept of minimally invasive endodontics, which focuses on maintaining structural dentin and tooth integrity, has been suggested [8–10]. Applying the minimally invasive concept to root canal preparation aims to retain more dentin in the pericervical region and includes the usage of low-tapered instruments for shaping [11]. TruNatomy (TN) rotary system (Dentsply Sirona, Ballaigues, Switzerland) has been developed to achieve this goal, with a set of instruments made of a maximum fluted diameter of 0.8-mm nickel-titanium (Ni–Ti) wire [10]. However, conservative canal preparation might compromise the cleanness of root canal systems [12, 13]. While Silva et al. [10] suggested that TN and ProTaper Gold (PTG) systems (Dentsply Sirona) were similar in terms of untouched canal walls and remaining dentin thickness, they also observed a slight difference in the percentage of dentin removal at the coronal third. Consequently, the primary concern of minimal canal enlargement is its potential impact on untouched bacterial biofilm [14]. To reduce the risk of remaining biofilm, ultrasonic-assisted

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irrigation (UI) and the use of intracanal medication such as calcium hydroxide (CH) are recommended [6, 13, 15].

Despite the interest in minimally invasive endodontics, there are no clinical studies evaluating the effectiveness of this technique on pain. Therefore, the aim of this randomized prospective clinical trial was to compare the occurrence and intensity of postoperative pain after two distinct RCT protocols: (1) conventional treatment protocol (CP) using PTG systems and continuous wave of condensation techniques (CWC) and (2) minimally invasive treatment protocol (MP) using TN rotary system and sealer-based obturation (SBO).

## Materials and methods

This randomized controlled parallel clinical trial was designed to compare the post-endodontic pain and treatment outcome between minimally invasive and conventional RCT. The study was approved by the Institutional Review Board of Yonsei University Dental Hospital (no. 2-2020-0003) and registered at the Clinical Research Information Service (CRIS, no. KCT0005351: 25/08/2020). We enrolled systematically healthy patients aged 18–82 years between April 2020 and March 2021. All patients were given written informed consent papers that explained the study and required them to sign to participate.

### Patient selection

The inclusion criteria were as follows: Healthy individuals (age  $\geq 18$ ) and mature permanent teeth that need RCT, either with vital or necrotic pulp. The exclusion criteria were as follows: previously initiated or treated teeth, teeth associated with periodontal pocket extending beyond the apical third of the root, patients who took analgesics within 24 h before the treatment, patients who were disabled for proper communication, and teeth with canals that cannot negotiate within 2 mm of the radiographic apex.

### Sample-size determination and randomization

This clinical trial was designed to evaluate two key outcomes: Short-term postoperative pain, the results of which are reported in this study, and long-term success rates of the respective treatment procedures, to be compared later. Both outcomes were considered when calculating the sample size, with the larger of the two results being selected as the definitive sample size. The required sample size for comparing postoperative pain between the two groups was calculated using G\*Power 3.1 software (Franz Faul, University of Kiel, Germany) with a significance level of 5%, a statistical power of 80%, and an effect size of 0.5. The sample size calculation for comparing success rates was based on the outcome of a

previous clinical trial on nonsurgical RCT [16]. According to Kim et al. [17], the success rates for the continuous wave of condensation technique with a resin-based sealer and the sealer-based obturation technique with a calcium silicate sealer were reported as 92.3 and 94.3%, respectively, using loose criteria. This study was designed as an equivalence trial, with an equivalence limit of 10%, a significance level of 5%, and a power of 90%. Based on these parameters, the required number of cases in each group was determined to be 75. Considering a dropout rate of 20%, the final estimated sample size was 180 cases.

The study employed a rigorous process to maintain impartiality. An unbiased assistant, unaware of the study's objectives, generated a set of random numbers using the Sealed Envelope website (<https://www.sealedenvelope.com/>) with a 1:1 allocation ratio and employing random block sizes of 6. To ensure absolute secrecy, the resulting list was securely stored in a locked file cabinet and remained confidential. It was only unveiled by the impartial assistant after participant inclusion in the study but before the intervention phase. Each participant received an enrollment number based on the random list, determining their assignment to either the CP or MP treatment group in accordance with the established protocol.

### Preoperative clinical and radiographic evaluation

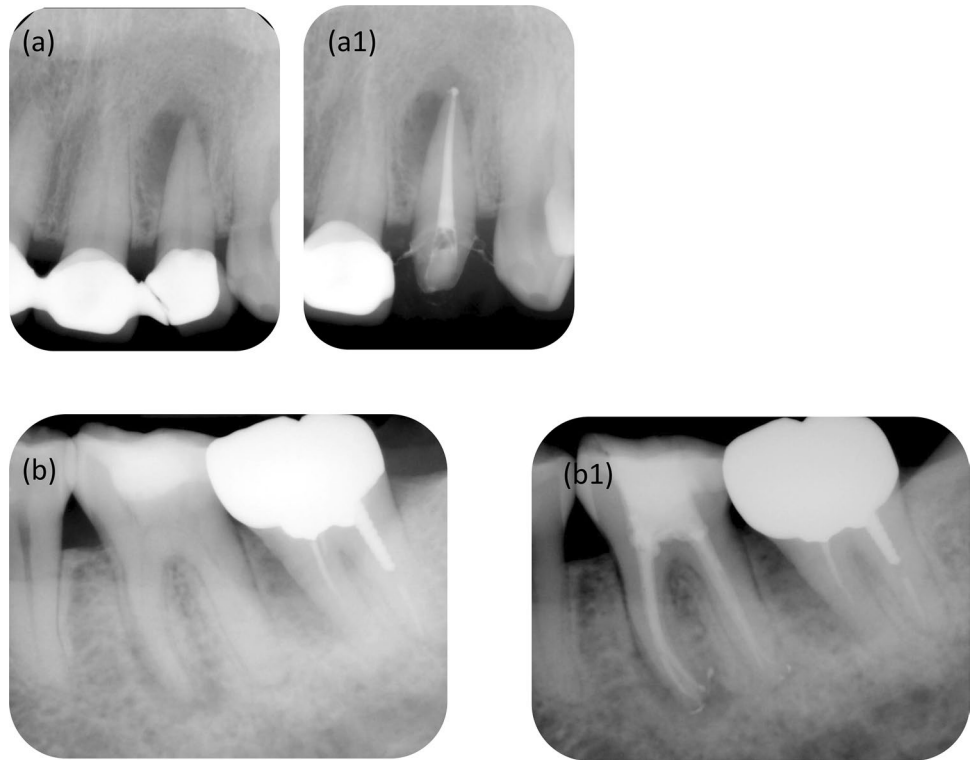
Before beginning treatment, each tooth was examined both clinically and radiographically. Percussion tests and periodontal probing were carried out, and the presence of sinus tracts was also recorded. The pulp sensibility testing including cold and electric pulp tests confirmed the need for RCT. Detecting bleeding in the pulp chamber was essential for diagnosing a vital pulp. If no vital tissue was present within the pulp chamber, it was considered necrotic. The periapical index (PAI) score was recorded [18] and dichotomized into healthy (PAI scores of 1–2) and unhealthy (PAI scores of 3–5) periapical statuses.

### Treatment protocol

Treatments were performed at a single center by 10 operators: 3 professors and 7 well-trained residents in the Department of Conservative Dentistry under dental operating microscopes (OPMI pico; Carl Zeiss, Göttingen, Germany). All treatments were performed under rubber dam isolation, and finished in two or more visits. The concentration of sodium hypochlorite (NaOCl) used in the treatment was 2.5% and that of ethylenediamine tetraacetic acid (EDTA) was 18%.

In the CP group (Fig. 1), on the first visit, an access cavity was formed using high-speed burs under local anesthesia (infiltration and/or block anesthesia). Canal length

**Fig. 1** Conventional treatment group: **a** preoperative radiograph of maxillary lateral incisor with apical periodontitis **a1** postoperative radiograph **b** preoperative radiograph of a mandibular first molar tooth with apical periodontitis **b1** postoperative radiograph



was measured using electronic apex locators (DentaPort Root zx II, Morita, Irvine, USA), and then a periapical radiograph was taken with initial apical file insertion. Pulp extirpation and canal shaping were simultaneously performed using a rotary Ni–Ti file system (ProTaper Gold, Dentsply Sirona, Ballaigues, Switzerland). During the canal shaping process, canal irrigation with NaOCl was performed using a 30-gauge notched-tip needle (Sungshim Medical Co., Bucheon-si, Korea). The root canal preparation was completed using a PTG F2 instrument in curved canals and a PTG F3 instrument in straight canals. After canal shaping, the canals were soaked with NaOCl for 5 min.

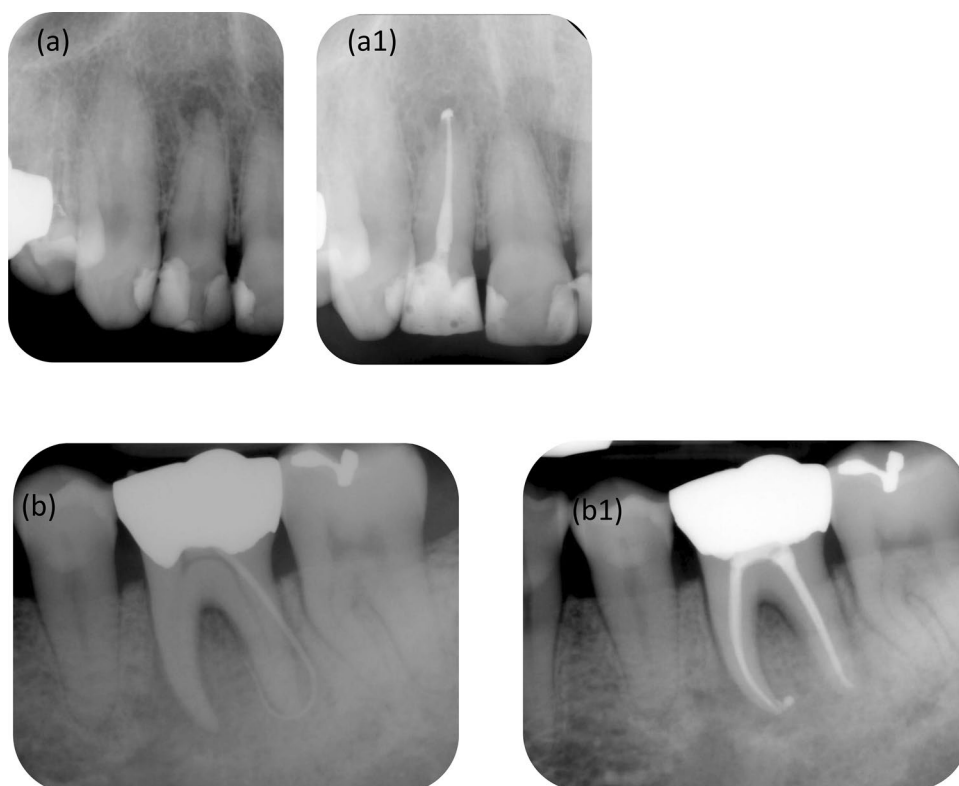
During the obturation visit, each canal was re-instrumented with the previous final instrument and irrigated with 1 mL of EDTA, followed by 3 mL of NaOCl. Appropriately sized gutta-percha cones were adapted to the root canals and checked with a periapical radiograph. Then, canals were soaked with NaOCl for 15 s, and the irrigant was replaced. To ensure an equal final irrigation time in both groups, the process was repeated three times. Canals were dried with paper points, and CWC was performed. Gutta-percha cones were coated using AH Plus sealer (Dentsply Sirona) and inserted into the prepared root canals. A heated plugger (SuperEndo Alpha 2, B & L Biotech, Ansan, Korea) that could penetrate 4 or 5 mm short of the working length was inserted into the canal to cut and compact the master cone. Backfilling of the canal was performed using a

thermoplastic injection technique using SuperEndo Beta 2 (B & L Biotech).

In the MP group (Fig. 2), access opening, canal length measurement, and radiography were performed using the same protocol as the CP group. For canal shaping, a TN prime shaping file was used in curved canals, and a medium file was used in straight canals. At the end of the treatment, the irrigant was activated by applying ultrasonic vibration for 15 s (Endosonic Blue, Maruchi, Wonju, Korea). After drying the canals, premixed syringe-type  $\text{Ca}(\text{OH})_2$  (Cleanical, Maruchi) was placed into the canal. Subsequently, the paste was evenly placed on the canal wall using a gutta-percha that was slightly smaller than the shaped root canal.

On the obturation visit,  $\text{Ca}(\text{OH})_2$  was removed using the previous final instrument, and irrigation using 1 mL of EDTA and 3 mL of NaOCl was performed. The gutta-percha master cone fit was verified with a periapical radiograph. Passive UI was performed with NaOCl for 15 s in each canal, and this procedure was repeated three times consecutively. After canal drying, SBO was used for the obturation. Calcium silicate-based sealer (Endoseal TCS, Maruchi, Wonju, Korea) was dispensed into the middle third of the canal using a 24-gauge needle tip, and a matching-taper single gutta-percha cone (DiaDent, Cheongjusi, Korea) was inserted into the canal up to the working length. A heated plugger was used to sear the gutta-percha point at the orifice level. Obtura S-Kondenser (Obtura Spartan, Earth City, MO) was used to vertically compact the gutta-percha.

**Fig. 2** Minimally invasive group: **a** preoperative radiograph of maxillary lateral incisor with apical periodontitis **a1** postoperative radiograph **b** preoperative radiograph of a mandibular first molar tooth with a sinus tract **b1** postoperative radiograph



At the end of the first visit for both groups, an analgesic (ibuprofen 200 mg tablets) was prescribed, and patients were instructed to intake them in case of significant pain.

### Preoperative and Postoperative pain assessment

Before the administration of local anesthesia at the first visit, patients were asked to record the preoperative pain using a 0–10 numerical rating scale (NRS). Along with the numeric ratings, a modified Wong-Baker FACES scale was presented to the patients to help them in scoring the pain: no pain (0), mild pain (1–2), moderate to severe pain (3–6), very severe pain (7–9), and worst pain possible (10). After the treatment on the first visit, each patient received a pain diary to write down their pain level using the same scale at the following time points: 4 h, 1, 2, 3, 4, 5, 6, and 7 days after instrumentation. Patients were also requested to record the date and time of their analgesic intake in the diary. For the assessment of pain after canal obturation, each patient received a phone call and was asked to report their pain score 1 day after treatment.

### Statistical analysis

Statistical analyses were conducted using R version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria) and Statistical Package for the Social Sciences software version

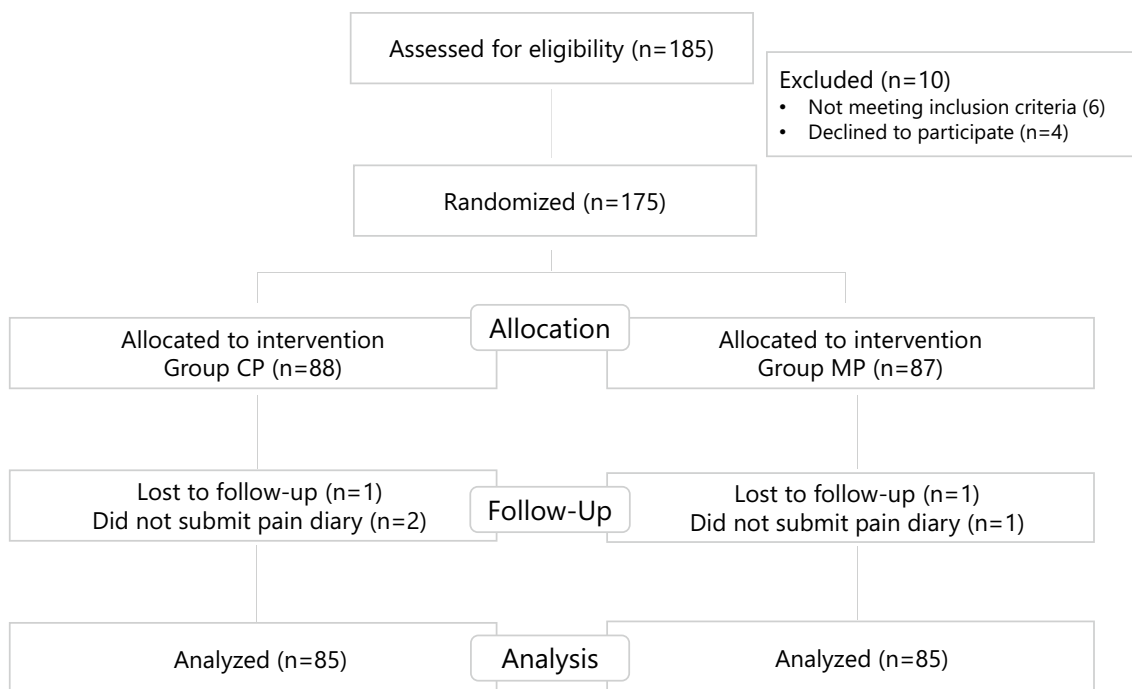
26 (IBM Corp., Armonk, NY, USA). The level of significance was set at 0.05.

*t*-tests, chi-squared tests, or Fischer's exact tests were used to evaluate the data related to the baseline characteristics of the included study participants and the analgesic intake ratio. Repeated measures analysis of variance (RM-ANOVA) followed by Tukey's post-hoc test was performed to compare NRS scores among all time points for each treatment group. Mann–Whitney *u*-test was used to compare postoperative pain at each time interval between the two groups.

The highest score among the NRS recorded at 8 post-instrumentation time points for each patient was selected and then dichotomized into absent/mild (responses lower than 3) and moderate/intense (responses 3 or higher). The post-obturation pain score was dichotomized in the same way as mentioned above. All variables were analyzed using multivariate logistic regression analysis, followed by a stepwise method to investigate the factors associated with moderate / intense pain after instrumentation and obturation.

### Results

Of the 173 participants (185 teeth) assessed for eligibility, 163 (170 teeth) were included in the analysis (Fig. 3). The demographic characteristics did not show any significant difference between the two treatment groups except for mean



**Fig. 3** Flow chart of allocation of the patients

age and the presence of a sinus tract (Table 1). One hundred thirty-three teeth (78.2%) were treated in 2 visits to complete the RCT. There was no difference between the two groups in the number of visits required to complete the treatment ( $p=0.182$ ). All cases demonstrated adequate root canal filling levels, with the gutta-percha cone positioned 0–2 mm within the canal from the radiographic apex; however, a significant difference in sealer extrusion rates was observed ( $p=0.017$ , Table 1).

The results of RM-ANOVA demonstrated that there were significant differences in pain intensity among different time points in both groups ( $p < 0.001$ ). The NRS scores gradually decreased over time after instrumentation showing a significant reduction from 2 days after instrumentation and increased significantly after obturation in both groups ( $p < 0.05$ , Table 2). However, there were no significant differences in pain intensity at any evaluated time points between the CP and MP groups ( $p > 0.05$ , Table 2). Thirty-one out of 170 (11/85 in the CP group and 20/85 in the MP group) patients took the analgesic; there was no significant difference in analgesic intake between the groups ( $p > 0.05$ ).

Table 3 shows the results of the multivariate logistic regression analysis on the occurrence of moderate/intense pain (NRS  $\geq 3$ ) after the instrumentation and obturation, respectively. Moderate/intense pain after the instrumentation was significantly associated with a preoperative PAI score of 2 or less (odd ratio [OR] = 2.54,  $p = 0.017$ ) and pain (OR = 1.37,  $p < 0.001$ ); the other factors were not related. The preoperative NRS score (OR = 1.26,  $P = 0.006$ ) and

preoperative pulp status (vital pulp) (OR = 4.43,  $p = 0.009$ ) were significant factors in the occurrence of moderate/intense post-obturation pain. The marginal effect plot for each logistic regression model on the postoperative pain is presented in Fig. 4. A higher preoperative NRS was associated with an increased probability of postoperative pain in both instrumentation and obturation procedures. A PAI score less than 3 and preoperative vital pulp status were related to higher probabilities of post-instrumentation pain and post-obturation pain, respectively.

## Discussion

This study aimed to evaluate the postoperative pain associated with MP combined with UI, Ca(OH)<sub>2</sub>, and calcium-silicate cement, compared with the conventional RCT protocol. While the MP technique has recently garnered significant interest [8, 9], there are limited clinical studies on MP, making this study particularly meaningful.

In this study, the two groups underwent different cleaning, shaping, and obturation protocols. Several studies have shown that post-treatment pain levels can vary depending on the instrumentation system used [19–21]. Regarding cleaning and shaping protocols, TN was used as the instrumentation system in the MP group. UI and Ca(OH)<sub>2</sub> were exclusively used in the MP group because the primary concern of minimal canal enlargement is its potential impact on untouched bacterial biofilm [14]. The UI system we used was

**Table 1** Baseline demographic and clinical features distribution of patients

Factors	CP (N=85)	MP (N=85)	p
Age	46.6 ± 17.6	52.5 ± 18.3	0.034*
Gender			1.000
Female	49 (57.6%)	49 (57.6%)	
Male	36 (42.4%)	36 (42.4%)	
Location			1.000
Maxilla	48 (56.5%)	49 (57.6%)	
Mandible	37 (43.5%)	36 (42.4%)	
Tooth			0.366
Anterior	17 (20.0%)	16 (18.8%)	
Premolar	18 (21.2%)	26 (30.6%)	
Molar	50 (58.8%)	43 (50.6%)	
Preoperative pain (NRS)	1.8 ± 2.5	2.2 ± 2.8	0.310
Pain on percussion			1.000
No	47 (55.3%)	47 (55.3%)	
Yes	38 (44.7%)	38 (45.2%)	
Pulp status			0.758
vital	37 (43.5%)	40 (47.1%)	
Necrosis	48 (56.5%)	45 (52.9%)	
Sinus tract			0.009*
Absence	66 (77.6%)	79 (92.9%)	
Presence	19 (22.4%)	6 (7.1%)	
PAI index			0.124
≤ 2	34 (40.0%)	45 (52.9%)	
≥ 3	51 (60.0%)	40 (47.1%)	
Sealer extrusion			0.017*
No	46 (54.1%)	62 (72.9%)	
Yes	39 (45.9%)	23 (27.1%)	

\* Statistically significant ( $p < 0.05$ ) by *t*-tests, chi-square tests, or Fisher's exact tests

**Table 2** Pain intensity (NRS) during treatment procedures for the CP and MP groups

Group	CP	MP	$p^a$
Time-point	(Mean ± SD)	(Mean ± SD)	
Preoperative pain	1.84 ± 2.50 <sup>a</sup>	2.25 ± 2.77 <sup>a</sup>	0.510
4 h after instrumentation	1.41 ± 1.49 <sup>a</sup>	1.95 ± 1.91 <sup>a</sup>	0.051
Day 1	1.24 ± 1.32 <sup>a</sup>	1.70 ± 1.97 <sup>a</sup>	0.267
Day 2	0.93 ± 1.17 <sup>bc</sup>	1.18 ± 1.47 <sup>b</sup>	0.428
Day 3	0.67 ± 0.97 <sup>d</sup>	0.94 ± 1.36 <sup>c</sup>	0.320
Day 4	0.61 ± 0.94 <sup>de</sup>	0.66 ± 1.18 <sup>d</sup>	0.765
Day 5	0.47 ± 0.91 <sup>def</sup>	0.42 ± 0.94 <sup>e</sup>	0.685
Day 6	0.44 ± 0.84 <sup>ef</sup>	0.42 ± 0.97 <sup>e</sup>	0.640
Day 7	0.34 ± 0.75 <sup>f</sup>	0.41 ± 1.10 <sup>e</sup>	0.680
Post-obturation	1.23 ± 1.66 <sup>ab</sup>	1.04 ± 1.61 <sup>b</sup>	0.372

Small uppercase letters denote significant differences according to time point within each treatment group

<sup>a</sup> $p$ -value by Mann–Whitney *U* test between two groups at each time point

the Endosonic Blue, which comprises a portable ultrasonic device and a size 15, 0.02-tapered Ni–Ti file. The Ni–Ti file can enter within 2 mm of the apex of a minimally prepared root canal. Currently, there is no standardized protocol for UI, and the duration and number of cycles for UI vary. In this study, we applied ultrasonic vibration for 15 s per cycle, with a total of three cycles per visit. The effectiveness of Ca(OH)<sub>2</sub> in eliminating bacteria from human root canals was not well-established [22]. However, a recent study showed that teeth treated with Ca(OH)<sub>2</sub> as the intracanal medication exhibit a greater reduction of mean lipopolysaccharide, regardless of the irrigant solution used [23].

The main focus of minimally invasive endodontics is root canal preparation. Consequently, we could not find an optimal obturation method for minimally prepared canals in the existing literature. When a TN Prime shaping file is used as the final instrument in curved canals, it can sometimes be challenging to insert a metal plugger into the root canal to a depth that is 4–5 mm shorter than the working length. Therefore, we employed a sealer-based obturation method in the MP group.

All instrumentation techniques result in debris extrusion [24, 25], possibly one of the main causes of postoperative pain [26]. TN has been reported to produce relatively small amounts of apically extruded debris [25, 27], and recent systematic reviews showed that both UI and Ca(OH)<sub>2</sub> reduced postoperative pain [6, 7]. However, the results of this study suggested that the intensity of post-instrumentation pain in the MP group did not differ from those of the CP group at any assessed time points.

Yu et al. [28] suggested that sealer extrusion was associated with higher levels of postoperative pain, and the sealer extrusion occurred more frequently in the CP group in this study (Table 1). However, the post-obturation pain in this study was not different between the two groups. Yu et al. [28] also showed that the two obturation techniques, which were similar in design in this study, had no differences in postoperative pain. In addition, other investigations comparing AH Plus and calcium silicate-based sealer showed that there was no difference in post-obturation pain, which is similar to the results of this study [17, 28, 29].

In addition to the direct comparison of NRS reported by patients, other pain assessment analyses were performed to find better patient satisfaction regarding pain management. In this study, NRS = 3 was set as the threshold, as it represents the baseline score for moderate pain that distracts patients from their daily lives and necessitates analgesics. To analyze the occurrence of moderate/intense pain after the instrumentation, we used the highest pain scores rather than the average values of the measured numbers. The highest pain scores better represent the pain intensity, and the effect of analgesics can also be minimized. The moderate/intense pain after instrumentation was significantly associated with

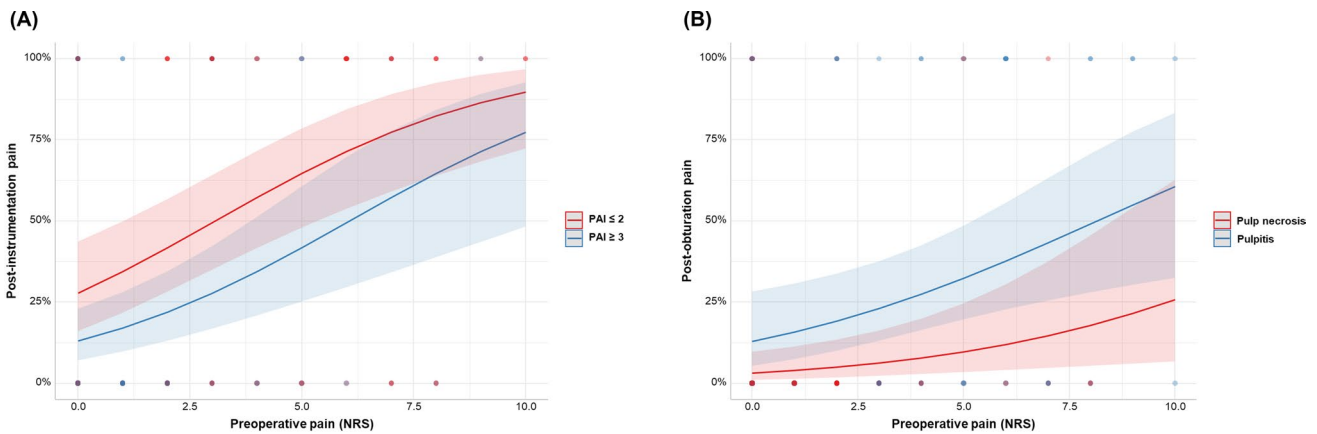
**Table 3** Results of multivariate logistic regression analysis for the effect of various factors on the occurrence of moderate/intense pain (NRS  $\geq 3$ ), (A) post-instrumentation pain; (B) post-obturation pain

Variables	OR	95% CI	<i>p</i>
<b>Sex</b>			
Female			
Male	0.55	0.25–1.18	0.134
<b>PAI Index</b>			
$\leq 2$	2.54	1.19–5.54	0.017*
$\geq 3$			
Preoperative pain (NRS)	1.37	1.19–1.58	<0.001*
Variables	OR	95% CI	<i>p</i>
<b>Age</b>			
Age	0.98	0.95–1.00	0.077
<b>Tooth</b>			
Anterior			
Premolar	6.23	0.94–124.03	0.105
Molar	2.49	0.39–48.69	0.413
Preoperative pain (NRS)	1.26	1.07–1.50	0.006*
<b>Pulp status</b>			
Vital	4.43	1.54–14.80	0.009*
Necrosis			

Pseudo- $R^2 = 0.271$ , pseudo- $R^2 = 0.338$

OR Odds ratio, CI confidence interval

\*  $p < 0.05$



**Fig. 4** Marginal effect plots for the logistic regression models and related variables. Solid lines are estimated marginal mean effect, and band-widths are 95% confidence intervals **A** Post-instrumentation pain, **B** post-obturation pain

the preoperative pain score ( $p < 0.001$ ), a finding that is consistent with those of previous studies [2, 30]. The interesting finding in the present study was that teeth with a PAI score of 2 or less have significantly more post-instrumentation pain than those with a PAI score of 3 or more ( $p < 0.033$ ). This finding is also consistent with the findings of a previous report [31]. The preoperative pain score was also a significant factor associated with moderate/intense pain after the obturation. The other significant factor on the moderate/

intense pain after the obturation was preoperative pulp status with vital pulp. Although the result was from the single-visit RCT, a similar finding was observed in the study by Segura-Egea et al. [31]. A possible explanation for this finding in our study is that patients with vital pulp reported higher preoperative pain scores. In this study, mean preoperative NRS was  $3.0 \pm 3.1$  and  $1.2 \pm 1.9$  for patients with vital and necrotic pulp, respectively ( $p < 0.001$ ). This phenomenon was also found in patients with a PAI score of 2 or less.

Severe preoperative pain can induce peripheral and central sensitization and consequently affect the intensity of post-operative pain.

The limitation of this study was that 10 clinicians performed the treatment protocols, and differences in proficiency may have affected the results. Furthermore, most clinicians were slightly more familiar with PTG than TN. However, participating clinicians have been using various Ni–Ti file systems for at least 2 years; thus, we do not believe this would have made a significant difference.

## Conclusion

Within the limitations of this study, the post-endodontic pain associated with the use of MP combined with TN, UI, Ca(OH)<sub>2</sub>, and calcium silicate-based sealer did not differ from that of CP. Teeth with a lower PAI score and a higher preoperative NRS score were more susceptible to the occurrence of moderate/intense pain after instrumentation. A higher preoperative NRS score was also found to be a significant factor in post-obturation pain. Additionally, teeth with a preoperative vital pulp exhibited a higher likelihood of experiencing post-obturation pain.

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**Data availability** The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to [restrictions e.g. their containing information that could compromise the privacy of research participants].

## Declaration

**Conflict of interest** The authors deny any conflicts of interest related to this study.

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