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Comparison of post-operative pain intensity following root canal preparation using WaveOne gold and JIZAI file system - A randomized controlled clinical trial

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Abstract:
Managing acute post-operative pain in symptomatic irreversible pulpitis remains a significant clinical challenge during single-visit endodontics. Therefore, it is of interest to compare the post-operative pain following single-visit root canal treatment using WaveOne Gold and JIZAI systems in patients with symptomatic irreversible pulpitis. Both systems effectively reduced post-operative pain. The JIZAI system showed significantly lower pain at 12 hours, with no differences at subsequent time points. Thus, data shows an early post-operative pain benefit with JIZAI, though further studies are needed.

Keywords: Post-operative pain, root canal treatment (RCT), WaveOne gold, JIZAI, reciprocating files, rotary instrumentation, symptomatic irreversible pulpitis

Background:
The advancement of nickel–titanium (NiTi) instrumentation, irrigation protocols, and obturation has significantly improved root canal treatment (RCT); however, post-operative pain remains one of the most common adverse outcomes. Reported incidence ranges from 3% to over 50%, with pain typically peaking within the first 24 hours before gradually declining, making its management an important indicator of treatment success and patient satisfaction **[1, 2]**. Post-operative pain is multifactorial, resulting from microbial, mechanical, chemical, and host-related factors. Apical extrusion of microorganisms, dentinal debris, necrotic tissue remnants, and irrigants during instrumentation can induce an inflammatory response, while preoperative pain is considered one of the strongest predictors of post-operative discomfort **[3, 4]**. The extent of apical debris extrusion varies according to instrument design, taper, cross-sectional geometry, alloy, number of instruments, and instrumentation kinematics. Greater extrusion is associated with increased post-operative pain, highlighting the importance of instrumentation systems that minimize debris extrusion while maintaining shaping efficiency **[5]**. WaveOne Gold is a heat-treated single-file reciprocating NiTi system designed to improve flexibility and fatigue resistance, whereas the JIZAI file system is a newer heat-treated continuous rotary NiTi system with enhanced flexibility, canal-centering ability, and cutting efficiency. Although laboratory studies have demonstrated favorable shaping characteristics of the JIZAI system, clinical evidence regarding its effect on post-operative pain remains limited **[6]**. Clinical trials comparing reciprocating and continuous rotary instrumentation have reported conflicting results regarding post-operative pain. Most evidence suggests that any differences are primarily observed during the early post-operative period and may be influenced by debris extrusion, irrigation protocols, working length control, and patient-related factors rather than instrumentation kinematics alone **[7]**. Therefore, it is of interest to report the post-operative pain following single-visit root canal treatment using WaveOne Gold and JIZAI instrumentation systems in patients with symptomatic irreversible pulpitis.

Materials and Methods:
Study design:
This is a prospective, parallel-arm, randomized controlled clinical trial. This study was designed and reported following the Consolidated Standards of Reporting Trials (CONSORT 2010) statement for randomized clinical trials.

Ethical approval and trial setting:
The study protocol was approved by the Institutional Ethics Committee of Approval No. IEC/P-554/2024. The study was performed in compliance with the Declaration of Helsinki and informed consent was signed by all participants prior to enrollment in the study. This trial was registered after it was conducted in the Thai Clinical Trials Registry (TCTR) (Registration No. TCTR20260527007).

Sample size calculation:
The sample size was calculated using the formula for comparison of two independent means based on post-operative pain scores reported in previous randomized clinical trials.

$$N = (Z_{\alpha/2} - Z_{1-\beta})\ 2 \times (\sigma_1^2 + \sigma_2^2)\ /\ d2$$

Where
[1] $Z_{\alpha/2} = 1.96$ (95% confidence interval)
[2] $Z_{1-\beta} = 0.84$ (80% study power)
[3] $\sigma_1 = 0.59$
[4] $\sigma_2 = 1.05$
[5] Expected mean difference (d) = 0.65

The calculated sample size was 26.92 participants per group, which was rounded to 27 participants for each group. Therefore, a total sample of 54 participants was included.

Participant recruitment:
Patients with a need of primary root canal treatment were consecutively screened in the outpatient Department of Conservative Dentistry and Endodontics from 1 April 2024 to 15 January 2026.

Inclusion criteria:
Participants fulfilling all of the following criteria were included:

[1] Age between 18 and 65 years.
[2] American Society of Anesthesiologists (ASA) physical status I or II.
[3] Permanent maxillary or mandibular teeth diagnosed with symptomatic irreversible pulpitis.
[4] Positive response to pulp sensibility testing.
[5] Mature root apex.
[6] Teeth indicated for primary nonsurgical root canal treatment.
[7] Absence of radiographic evidence of apical periodontitis.
[8] Ability to understand the Numerical Rating Scale (NRS).
[9] Provision of written informed consent.

Exclusion criteria:
Patients presenting with any of the following conditions were excluded:

[1] Previously initiated or completed root canal treatment.
[2] Pulp necrosis.
[3] Acute apical abscess or chronic apical abscess.
[4] Presence of sinus tract.
[5] Open apex.
[6] Internal or external root resorption.
[7] Root fracture or cracked tooth syndrome.
[8] Calcified canals.
[9] Complex canal anatomy unsuitable for standardized instrumentation.
[10] Advanced periodontal disease.
[11] Non-restorable teeth.
[12] Pregnancy or lactation.
[13] Known allergy to local anesthetics or ibuprofen.
[14] Intake of analgesics or anti-inflammatory medications within 24 hours before treatment.
[15] Immunocompromised conditions or systemic diseases influencing pain perception or wound healing.

Randomization and allocation concealment:
Once eligible and baseline assessment completed, participants were randomly assigned to one of two intervention groups, 1:1 allocation ratio. Randomization was achieved by a computer-generated random sequence generated by a person not involved with patient recruitment, treatment, or outcome assessment. The envelopes were sequentially numbered and opaque and sealed. The sequence of intervention was opened during access cavity preparation just before instrumentation, and an envelope was opened for each treatment **Figure 1**.

Blinding:
Since the instrumentation systems were obviously different, they did not permit operator blinding. However, the level of blinding was maintained: Participants were blinded to the allocated intervention. The investigator who assessed the post-operative pain and performed the statistical analysis was blinded all along the study. Therefore, the study employed a single operator, assessor-blinded randomized controlled design

Baseline assessment:
Prior to a treatment, a comprehensive clinical examination was carried out.
The following information was noted:
[1] Age
[2] Sex
[3] Medical history
[4] Dental history
[5] Tooth type
[6] Clinical diagnosis
[7] Preoperative pain intensity

Where indicated, cold testing and electric pulp testing confirmed the vitality of the pulp. Clinical evaluation carried out in terms of percussion and palpation tenderness. The digital radiographs taken preoperatively were standardised by the paralleling technique to ensure canal anatomy, root development and absence of periapical pathology. The pain level was measured before surgery on an 11-point Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst possible pain).

Intervention groups:
Group I: WaveOne gold group (N = 27):
The WaveOne Gold Primary file (25/.07) (Dentsply Sirona) was used for root canal preparation in reciprocating motion as per manufacturer's instructions till the full working length was reached.

Group II: JIZAI rotary group (n = 27):
Using the manufacturers recommended instrumentation sequence, root canal preparation was made with the JIZAI rotary nickel–titanium (NiTi) file system (MANI Inc., Tochigi, Japan) with continuous rotary motion until the desired working length was reached.

Clinical procedure:
The procedures were carried out by one highly experienced pedodontist under uniform conditions. Teeth were isolated with a rubber dam after administration of 2% lignocaine with 1:80,000 epinephrine and conventional access cavities were prepared. The working length was determined with an electronic apex locator and verified radiographically. Canal preparation was done using the instrumentation system according to the manufacturer's instructions with a torque controlled endodontic motor before preparing a glide path for the #15 K-file. Only one patient was treated with each of the instruments.

Irrigation protocol:
The harvesting and irrigation methods were standardized in both groups. At the time of instrumentation, canals were flushed with 2.5% sodium hypochlorite using a 30-gauge side-vented needle that was placed 1–2 mm short of the working length. The

final irrigation solution was 5 mL of 17% EDTA for 1 minute followed by 5 mL of sterile saline and then canals dried with sterile paper points.

Obturation:
Obturations of root canals were performed using AH Plus sealer and gutta-percha with the use of cold lateral compaction technique during the same appointment. Post-operative radiographs were used to determine the quality of obturation and access cavities were provisionally filled with reinforced zinc oxide–eugenol cement.

Post-operative instructions:
Patients were informed that mild pain may occur following surgery. Analgesic consumption was recorded and Ibuprofen 400 mg was given only as a rescue drug when the pain became intolerable. The subjects were asked to report any heavy pain, swelling, or other severe complications after surgery.

Outcome assessment:
Primary outcome:
The study's main outcome was post-operative pain intensity assessed on the 11-point Numerical Rating Scale (NRS). Participants self-assessed pain scores at: 12 hours, 24 hours, 48 hours and 72 hours after treatment. Participants were provided with written pain diaries and a blinded investigator made standardized telephone prompts to enhance compliance.

Secondary outcomes:
Secondary outcome measures were:
[1] Number of tablets of rescue analgesics used.
[2] Severe post-operative pain (unscheduled emergency visit).

Statistical analysis:
IBM SPSS Statistics Version 27.0 was used for statistical analysis. Results are graphed as the mean ± standard deviation (SD) or frequency (%). The Shapiro–Wilk test was used for the assessment of normality. A two-sample t-test was used to compare baseline characteristics and post-operative pain scores, and a chi-square test was used to analyze categorical variables. Using repeated-measures ANOVA with Pillai's Trace, the changes in pain throughout the study were assessed, while homogeneity of variances was examined with Levene's test. Partial eta squared (η^2) was used as an expression of effect sizes. A two-tailed p value <0.05 was considered statistically significant.

Results:
The baseline demographic and clinical characteristics of the participants are presented in (**Table 1**). The mean age was 35.00 ± 10.31 years in the WaveOne Gold group and 37.74 ± 6.57 years in the JIZAI group, with no significant difference (p = 0.250). The WaveOne Gold group included 17 males (63.0%) and 10 females (37.0%), whereas the JIZAI group included 16 males (59.3%) and 11 females (40.7%), with no significant difference in sex distribution (p > 0.05). The mean baseline pain score (NRS) was 5.33 ± 1.66 in the WaveOne Gold group and 5.41 ± 2.15 in the JIZAI group (p = 0.880). Post-operative pain scores at 12, 24, 48, and 72 hours are summarized in (**Table 2**). At 12 hours, the mean pain score was 3.41 ± 1.39 in the WaveOne Gold group and 2.44 ± 1.58 in the JIZAI group, with a statistically significant difference (p = 0.021). At 24 hours, the mean pain scores were 1.67 ± 0.88 and 1.19 ± 1.08, respectively (p = 0.077). At 48 hours, the corresponding values were 0.48 ± 0.58 and 0.30 ± 0.47 (p = 0.201). At 72 hours, all participants in both groups reported an NRS score of 0, and no statistical comparison was performed. Repeated-measures ANOVA demonstrated a significant main effect of time (Pillai's Trace = 0.891; F (3,50) = 135.658; p < 0.001; partial η^2 = 0.891) and a significant time × group interaction (Pillai's Trace = 0.192; F(3,50) = 3.953; p = 0.013; partial η^2 = 0.192) (**Table 3**). Levene's test showed no significant differences in variance for baseline pain (p = 0.126), 12-hour pain (p = 0.252), or 24-hour pain (p = 0.913). A significant result was observed at 48 hours (p = 0.029) (**Table 4**). Post-operative pain scores over time are illustrated in **Figure 2**.

Table 1: Baseline demographic and clinical characteristics of study participants

Variable	WaveOne Gold (n=27)	JIZAI (n=27)	p value
Age (years), Mean ± SD	35.00 ± 10.31	37.74 ± 6.57	0.250
Male, n (%)	17 (63.0)	16 (59.3)	0.780*
Female, n (%)	10 (37.0)	11 (40.7)	
Preoperative pain (NRS), Mean ± SD	5.33 ± 1.66	5.41 ± 2.15	0.880

**Chi-square test.*

Table 2: Comparison of post-operative pain scores across both groups

Time Interval	WaveOne Gold (Mean ± SD)	JIZAI (Mean ± SD)	p value
Baseline	5.33 ± 1.66	5.41 ± 2.15	0.880
12 hours	3.41 ± 1.39	2.44 ± 1.58	**0.021**
24 hours	1.67 ± 0.88	1.19 ± 1.08	0.077
48 hours	0.48 ± 0.58	0.30 ± 0.47	0.201
72 hours	0.00 ± 0.00	0.00 ± 0.00	N/A

Table 3: Repeated-measures ANOVA for post-operative pain

Effect	Pillai's Trace	F (df)	p value	Partial η^2
Time	0.891	135.658 (3,50)	<0.001	0.891
Time × Group	0.192	3.953 (3,50)	0.013	0.192

Table 4: Levene's Test for Equality of Variances

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Variable	Levine Statistic	p value
Baseline pain	2.413	0.126
12-hour pain	1.340	0.252
24-hour pain	0.012	0.913
48-hour pain	5.016	0.029

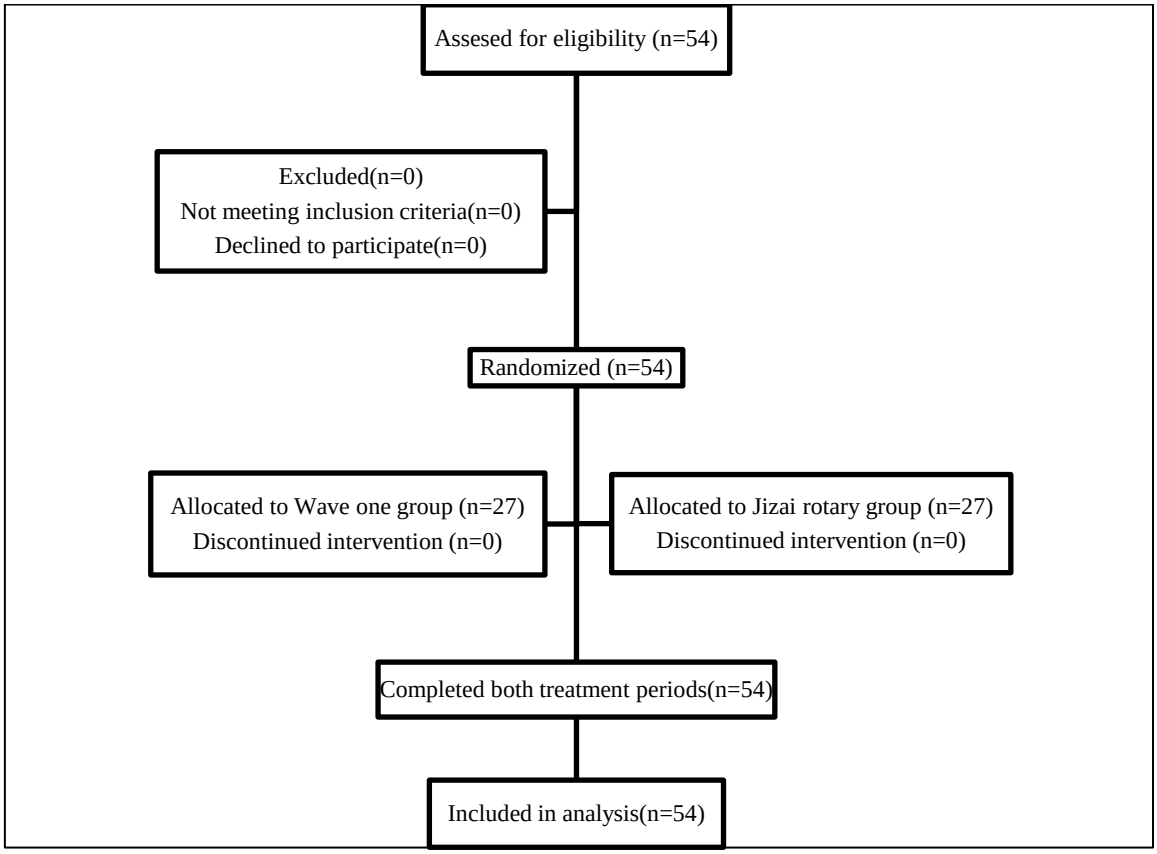


Figure 1: CONSORT flow diagram of the study

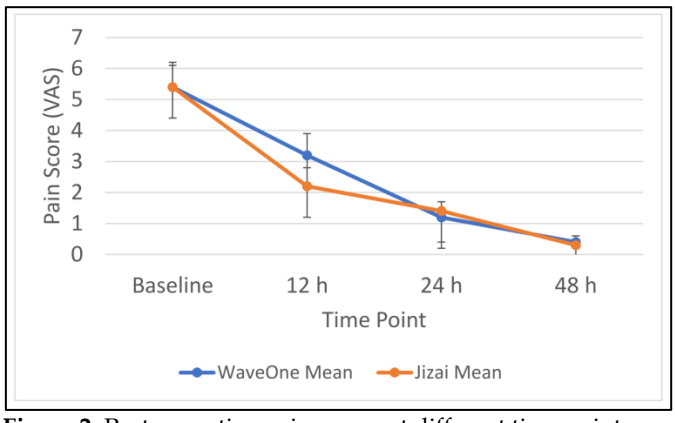


Figure 2: Post-operative pain scores at different time points

Discussion:

The present study advances current knowledge by providing clinical evidence on the effect of two different instrumentation kinematics, specifically the WaveOne Gold reciprocating system and the JIZAI continuous rotary system, on post-operative pain in patients with symptomatic irreversible pulpitis. The findings demonstrate that the JIZAI system was associated with significantly lower pain intensity during the early post-operative period at 12 hours, while no significant difference was observed between the systems at 24 and 48 hours. This finding adds to the existing evidence by suggesting that the choice of instrumentation system may influence early post-operative pain, although this effect appears to diminish with time. The present study also provides clinical data on the relatively newer JIZAI system in comparison with the widely used WaveOne Gold system under a standardized single-visit treatment protocol. Post-operative pain remains one of the most important patient-reported outcomes after nonsurgical root canal treatment despite advances in nickel–titanium (NiTi) instrumentation. Previous systematic reviews have reported post-operative pain in 3–58% of patients, with the highest intensity occurring during the first 24 hours before gradually subsiding. The temporal pain pattern observed in the present study is consistent with these findings, as pain peaked at 12 hours and progressively decreased thereafter **[1–3]**. Successful randomization was confirmed by the comparable baseline demographic characteristics and preoperative pain scores between the groups. Since preoperative

pain is considered one of the strongest predictors of post-operative pain, the similarity at baseline reduces the likelihood that patient-related factors influenced the observed outcomes **[4]**. Furthermore, the significant reduction in pain over time in both groups supports previous evidence that effective chemomechanical preparation and obturation result in rapid resolution of post-operative symptoms regardless of the instrumentation technique used **[5, 6]**. The most clinically relevant finding was the significantly lower pain intensity observed with the JIZAI system at 12 hours. This difference may be explained by reduced apical extrusion of dentinal debris during continuous rotary instrumentation. Reciprocating systems have been suggested to produce a piston-like effect that may extrude greater amounts of debris beyond the apical foramen, resulting in an enhanced inflammatory response and increased early post-operative pain. Additionally, the heat-treated alloy, improved flexibility, and optimized cross-sectional design of the JIZAI system may contribute to better canal centering and reduced mechanical irritation of the periapical tissues **[7–9]**. The present findings are consistent with previous randomized clinical trials reporting lower early post-operative pain with continuous rotary instrumentation, although differences between instrumentation systems diminish over time **[10].** Similarly, systematic reviews have concluded that while instrumentation kinematics may influence immediate post-operative discomfort, the overall quality of evidence remains limited because of variations in tooth type, pulpal diagnosis, irrigation protocols, obturation techniques, and pain assessment methods across studies **[11–21]**. In the present study, these potential confounding factors were minimized by using a standardized treatment protocol, a single experienced operator, identical irrigation and obturation procedures, and consistent working length determination, thereby strengthening the internal validity of the findings. Although the reduction in pain at 12 hours was modest, it may still be clinically meaningful by improving patient comfort during the period when post-operative symptoms are most intense. Reduced early pain may decrease anxiety, analgesic consumption, and unscheduled emergency visits while maintaining effective root canal preparation. This study has certain limitations. It was conducted at a single center with a relatively small sample size, limiting the generalizability of the findings. Pain assessment relied on subjective patient-reported scores, and psychological factors that may influence pain perception were not evaluated. Future multicenter randomized controlled trials with larger sample sizes, longer follow-up, and assessment of analgesic consumption and patient-reported quality-of-life outcomes are recommended to validate these findings.

Conclusion:
Both WaveOne Gold and JIZAI systems effectively reduced post-operative pain. The JIZAI system produced significantly lower pain at 12 hours, but no differences were observed thereafter. Larger multicenter randomized controlled trials are required to confirm these findings.

Data availability statement:
The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Author contributions:
All authors contributed substantially to study conception, design, data collection, statistical analysis, manuscript preparation, and final approval of the submitted manuscript.

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Institutional Ethics Committee NIMS University Jaipur, Rajasthan Approval No IEC/P-554/2024

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Thai Clinical Trials Registry (TCTR) (Registration No TCTR20260527007)

Consent:
Informed consent was signed by all participants prior to enrollment in the study

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