EUROPEAN ENDODONTIC JOURNAL

ORIGINAL ARTICLE

# Anesthetic Efficacy, Injection Pain and Pulse-rate Effect of Needle-free Injection in Pulpal Anesthesia of Maxillary Premolars with Irreversible Pulpitis: Randomised Clinical Study

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## ABSTRACT

**Objective:** This study aims to compare the pain perception associated with the needle-free system (Comfort-In™) and the standard needle injection method during root canal treatments in adults.

**Methods:** Forty-four maxillary premolar teeth of the patients that applied to university for treatment and needed endodontic treatment were included in the study. Patients were anesthetized with two different injection methods; needle-free injection and conventional dental injection. In both groups, oxygen saturation and pulse measurements of the patients were recorded at 30-second intervals for 2 minutes before anesthesia and 4 minutes after anesthesia. Pain during the injection and opening of the access cavity preparation was recorded according to Visual Analog Scale (VAS). The data were analyzed according to a statistical program.

**Results:** In this study, a significant difference was found between the groups in terms of pain during anesthesia administration and the access cavity preparation ($p<0.001$). There were no significant differences in terms of gender and age ($p>0.05$). There was no significant difference between the groups in terms of oxygen saturation and pulse values before and after treatment ($p>0.05$).

**Conclusion:** Needle-free injection makes the treatment more comfortable for patients with injection fear and anxiety, making the procedure easier for the physician and the patient.

**Keywords:** Comfort-in, dental anesthesia, endodontic treatment, intraoperative pain, irreversible pulpitis, needle-free injection

## HIGHLIGHTS

- The needle-free injection method causes less pain during anesthesia administration compared to the conventional injection method.
- The needle-free injection method can make the treatment more comfortable for patients by reducing pain during anesthesia administration and make them more motivated for treatment.
- Pain felt during cavity preparation was significantly lower in the needle-free injection group.

**Please cite this article as:**
Sağlam H, Karataş E. Anesthetic Efficacy, Injection Pain and Pulse-rate Effect of Needle-free Injection in Pulpal Anesthesia of Maxillary Premolars with Irreversible Pulpitis: Randomised Clinical Study. Eur Endod J 2025; 10: 181-7

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**Received :** December 19, 2024,
**Revised :** January 04, 2025,
**Accepted :** January 06, 2025

**Published online:** May 09, 2025
DOI 10.14744/eej.2025.26566



## INTRODUCTION

Dental procedures requiring anesthesia often pose a challenge in dental practice due to patients' fears of needle-related pain (1, 2). Needle-related pain typically occurs during the anesthesia phase of dental procedures. This pain-related fear can cause dental anxiety. Dental anxiety is an important cause of avoidance or postponement of dental treatments among patients, with some patients even developing dental phobia (3). According to previous study by Ocak et al (4), seeing the needle during a local anesthesia procedure can heighten a patient's fear of the injection more than fear of the treatment itself. Although this anxiety is generally more prevalent among pediatric patients, it

can also be common among adult patients and may complicate treatment. Therefore, dentists strive to minimize the pain associated with dental injections (5).

During a conventional dental injection, both the penetration of the needle and the administration of the anesthetic solution into the tissue can cause pain (6). In addition, dental patients may experience pain during intraoperative procedures when adequate anesthesia is not provided. For these reasons, several techniques have been developed with the aim of providing painless anesthesia. These include needle-free injections, topical anesthesia, precooling the injection area, or applying pressure in the injection area (7). The needle-free injection technique delivers the anesthetic solution to the tissues under pressure due to a spring coupled to an apparatus within the system (8–11).

Comfort-in (Mika Medical, Busan, Korea) is a new needle-free injection device that has been found to have similar efficacy to conventional dental anesthesia (12, 13). It is well-known that different anesthesia injection techniques can lead to an increase in pulse rate (14). Injection-related pain associated with the needle-free device during anesthesia administration and the effect of the technique when using the device on pulse rate and oxygen saturation levels have not yet been studied. Therefore, the aim of the present study was to evaluate the level of injection pain during anesthesia administration using the needle-free injection system, as well as changes in pulse rate and variations in oxygen saturation following administration. The null hypothesis was that there would be no difference between needle-free and conventional injection methods regarding efficacy, injection pain, pulse rate, and oxygen saturation levels.

## MATERIALS AND METHODS

### Ethical Approval and Patient Selection

Ethics committee approval for the study was received from Atatürk University, Faculty of Dentistry Ethics Committee (no: 06/2023, date: 22.06.2023. The experimental design followed the Preferred Reporting Items for Randomized Trials in Endodontics 2020 guidelines. The study was conducted in accordance with the Declaration of Helsinki. A flow chart of the experimental protocol is shown in Figure 1. A pilot study including 5 patients per group (needle-free and conventional injection) was conducted to calculate the required sample size. A power analysis was conducted using GPower program (Franz Faul, University of Kiel, Germany) based on the data obtained from the pilot study. The analysis revealed that 6 participants were sufficient per group (α=0.05, power=0.95, effect size=2.21). A total of 44 patients were included to the study to increase the power. The patients were randomly selected from those who attended dental clinic for endodontic treatment. An informed consent form was obtained from all the patients before the procedure.

### Inclusion Criteria

Patients aged between 18 and 60 years.

- Upper premolar teeth with vital pulp (vitality was tested by using cold test).
- Preoperative spontaneous pain level higher than 50 mm according to a visual analog scale (VAS) with 100 mm.

### Exclusion Criteria

- Teeth with periapical lesion.
- Teeth having previous root canal treatments.
- Teeth with more than 50% crown damage.
- Patients having any systemic disease.
- Patients with an allergic condition.
- Patients with alcohol and drug addiction.
- Pregnancy.

### Anesthesia Application Protocol and Groups

In this study, two different methods (needle-free injection and conventional injection) were used for anesthesia administration. According to the method of anesthesia administration, the patients were divided into two groups with the aid of a randomization program (www.randomizer.org).

**Needle-free Injection Group:** Using the needle-free system [Comfort-in (Mika Medical, Busan, Korea)], the anesthesia solution was injected into the apical part of the relevant tooth through a silicone cap designed to avoid damaging the soft tissue (Figs. 2, 3). Prior to injecting the anesthetic solution, the patients were advised not to be alarmed by the sound they would hear during the injection. In total, 1 ml of anesthesia solution was injected in four parts (0.1, 0.3, 0.3, and 0.3 ml) using the needle-free injection system.

**Conventional Injection Group:** Traditional infiltration anesthesia using a 30-gauge needle was performed by injecting 1 ml of anesthetic solution into the apical part of the relevant tooth. To ensure standardization, the total injection time was 1 minute in both groups. In both groups, 1 ml of articaine hydrochloride (2%) with 1:100.000 epinephrine (Ultracain; PharmaVision, Istanbul, Turkey) was used. All the procedures were performed by a single clinician in both groups.

### Measurement of Anesthetic Efficacy, Injection Pain, Pulse Rate, and Oxygen Saturation Levels

In both patient groups, oxygen saturation and pulse measurements were recorded at 30-second intervals for 2 minutes before and 4 minutes after anesthesia application using a pulse oximeter (Oncomed Pulse Oximeter Finger Type Pulse Oxygen 6007; Istanbul Reidan, Istanbul, Turkey). Injection-related pain was recorded using a 100 mm VAS. The patients were asked to mark their pain level between 0 and 100 on the 100 mm VAS.

After the administration of anesthesia, endodontic access cavities were prepared for each patient after a 4-minute latency period. The pain level during the preparation of the access cavity was also recorded using VAS. In case of the anesthesia applied during the procedure was insufficient, it was planned to apply additional anesthesia and record the current anesthesia as "failed".

All root canal treatments and coronal restorations were completed in the same visit.

### Statistical Analysis

All the statistical analyses were performed using IBM SPSS Statistics for Windows, Version 20 (IBM Corp, Armonk, NY, USA) at a significance level of 5% (p=0.05). A chi-square test was used

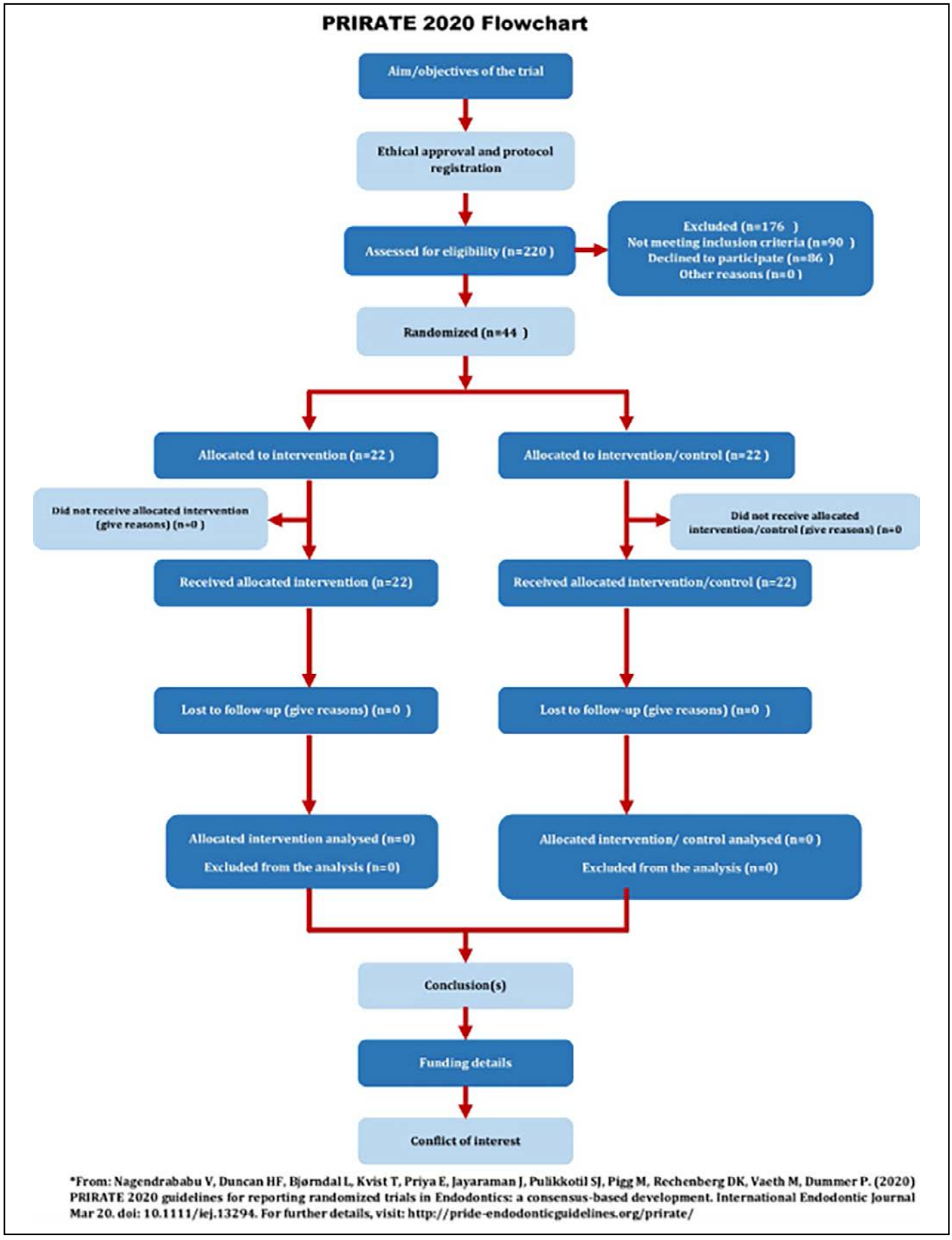


**Figure 1.** Experimental flowchart.


**Figure 2.** Comfort-in system

to analyze nominal data (gender and tooth number). The normality and homogeneity of the numeric data were analyzed using Shapiro–Wilk and one-way ANOVA (Analysis of Variance) tests. As the data were normally distributed, injection and pain values during cavity preparation were compared between the groups using an independent samples t-test. A repeated measures ANOVA test was used to analyze the oxygen saturation and pulse rate data at different measurement times.

## RESULTS

In total, 44 patients (29 females and 15 males) were included in the study. Detailed patient demographic data are shown in Table 1. There was no statistically significant difference between the groups in terms of mean age, gender, and tooth number distribution (p>0.05).

**Figure 3.** Application of needle-free system

The pulse rate and oxygen saturation levels are shown in Figures 4 and 5. In the needle-free injection group, following the administration of anesthesia, a transient slight decrease in pulse rate was detected, which returned to normal by the 180$^{th}$ second. In the conventional injection group, there was a slight increase in pulse rate following anesthesia administration, with the pulse rate returning to normal by the 240$^{th}$ second. There was no statistically significant difference between the groups in pulse rate or oxygen saturation levels at any of the measurement times before or after anesthesia administration (p>0.05). Information on the measured injection and pain levels during cavity preparation is provided in Table 2. The needle-free injection technique resulted in significantly less pain compared to the conventional injection technique. The mean injection pain level in the conventional injection group was significantly higher in the needle-free group (p<0.001). There was also a statistically significant difference between the groups in terms of pain levels during cavity preparation, with mean pain levels of 13.52±10.63 in the infiltration group and 1.43±4.32 in the needle-free group (p<0.001).

**TABLE 1.** Distribution of patients according to age, gender, and tooth number

| | Conventional injection | Needle-free | p |
|---|---|---|---|
| n | 22 | 22 | |
| Mean age | 35.9±10.6 | 38.6 ±12.3 | 0.456 |
| Gender | | | 0.169 |
| Female | 16 | 13 | |
| Male | 6 | 9 | |
| Tooth number | | | 0.865 |
| #14 | 5 | 5 | |
| #15 | 6 | 7 | |
| #24 | 3 | 4 | |
| #25 | 8 | 6 | |

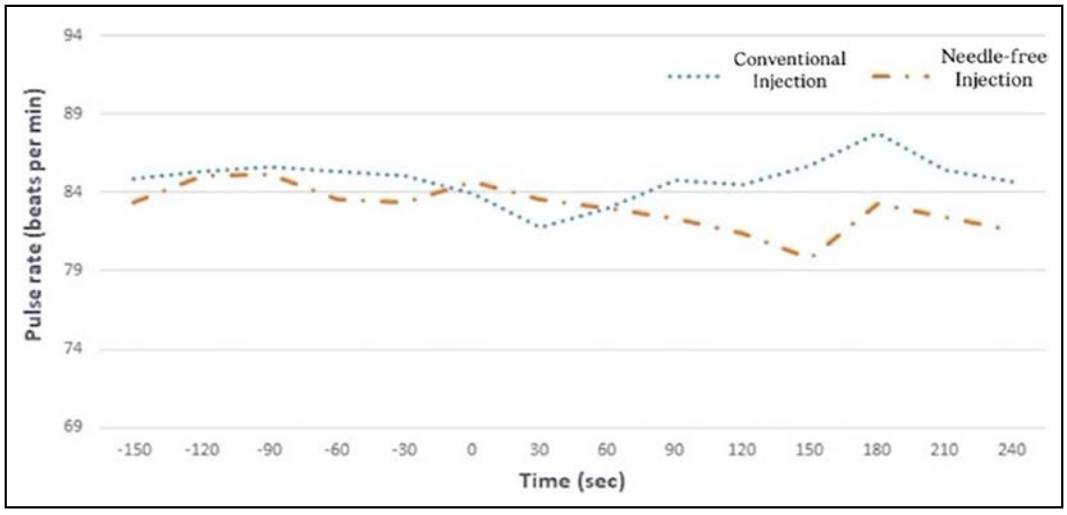


**Figure 4.** Pulse rate change of groups according to time

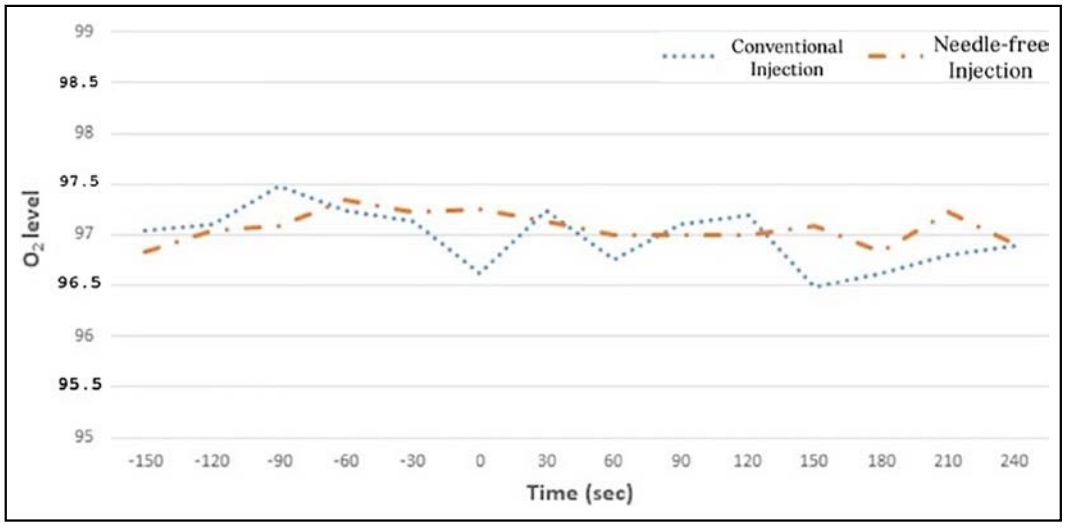


**Figure 5.** Oxygen level change of groups according to time

## DISCUSSION

Preoperative pain, anxiety regarding anesthesia administration, and apprehension about intraoperative pain may lead patients to delay their treatment, potentially resulting in tooth loss. The necessity for local anesthesia in dentistry should be determined on a case-by-case basis. In instances where local anesthesia is deemed necessary, appropriate measures should be taken to minimize patient discomfort (15). Injections should be avoided in cases where anesthesia is not required (teeth with lesions, devital teeth, and routine checks). In procedures that may not require anesthesia, starting the procedure without anesthesia, in line with the patients' consent, and applying it if necessary, can make patients feel more comfortable about the treatment.

Topical anesthesia serves as an adjunctive method employed in conjunction with conventional dental injections to mitigate needle penetration sensation in patients exhibiting needle phobia. Nevertheless, as the patient may remain cognizant of the needle's presence, this approach may not fully resolve such phobia. Furthermore, the efficacy of a local anesthetic solution applied to the cutaneous surface is limited, as it impedes the distribution of solution from the dermal layers to the stratum corneum (16).

Needle-free injection systems, such as Comfort-in, developed for this purpose, aim to mitigate the pain associated with needle penetration and provide a more comfortable treatment experience for patients. In the present study, the efficacy of the conventional injection method and the needle-free system was compared for pulpal anesthesia of maxillary premolars, with a focus on pain during the injection and the effects on pulse rates and oxygen saturation levels. The results indicated that both the levels of injection pain and pain during cavity preparation were significantly lower in the needle-free injection group compared to the conventional injection group. Therefore, the null hypothesis was rejected.

**TABLE 2.** Pain levels experienced during the administration of anesthesia and cavity preparation according to the groups (Mean±standard deviation)

| | Conventional injection method | Needle-free injection method | p |
|---|---|---|---|
| Injection pain | 26.81±17.85 | 3.13±4.08 | **<0.001** |
| Cavity preparation | 13.52±10.63 | 1.43±4.32 | **<0.001** |

A previous study (17) compared the effectiveness of needle-free and infiltration anesthesia techniques during the restoration of maxillary first molars with medium-depth class 1 caries, and found no significant between-group difference in pain during the administration of anethesia. The difference in the findings of this study versus those of the present one could be attributed to different tooth groups and, therefore, different bone tissue volumes in the area to be anesthetized. In addition, the different dental treatments (pulpectomy and class I restoration) performed in the two studies may explain the difference in pain sensation results. Altan et al. (13) compared pain perceptions associated with a needle-free and standard injection system in pulpotomy procedures in a pediatric population. The authors reported that the needle-free group experienced less injection pain than the standard injection group, with a statistically significant difference. Similarly, Ocak et al. (4) showed that the administration of an anesthetic solution using a needle-free injection system (Injex; Rösch AG Medizintechnik Germany) caused less pain than the standard injection approach. This finding is in accordance with that of the present study, although the patient populations and treatments were different.

The fact that the needle-free system does not have a visible needle tip may have reduced patients' anxiety and therefore reduced their perceptions of pain. The lack of needle penetration may also have caused less pain to be felt. Hameed et al. (18) compared the effectiveness of needle-free injection and conventional injection techniques for maxillary anterior and premolar teeth with symptomatic irreversible pulpitis. The authors found that the level of pain felt with the conventional injection technique was higher than that felt with the needle-free injection technique. Similarly, in the present study, the needle-free injection system caused significantly less pain than the conventional injection system. This may be attributed to pharmacokinetic dynamics that occur during tissue diffusion after an anesthetic injection. A needle-free injection deposits the entire solution in a fraction of a second and provides a high concentration of anesthetic at the one time, allowing for a higher rate of diffusion (19). Makade et al. (20) compared a pressurized injection system and a conventional injection system in terms of anesthesia effectiveness in dental restorative procedures among adult patients. The authors reported that patients found pressurized anesthesia less comfortable than the conventional method but that it caused significantly less pain and fear during anesthesia ($p<0.001$).

In the present study, patients also found the needle-free injection less painful and less frightening. However, in the present study, electrical pulp test evaluation was not performed to measure the effectiveness of pulpal anesthesia. Instead, the time between opening the endodontic access cavity and entering the canal orifices was determined as "pain during cavity preparation" and accepted as a measure of the effectiveness of pulpal anesthesia. The results of the present study showed that cavity pain was significantly lower in the needle-free injection group. In addition, sufficient depth of anesthesia for the treatment was obtained in the needle-free group.

In terms of anesthesia effectiveness, a previous study showed that the need for additional anesthesia was much higher after needle-free injection than conventional anesthesia (21). Another study demonstrated that 3% mepivacaine administration using the needle-free injection technique could not achieve pulpal anesthesia (22). Makade et al. (20) reported that additional anesthesia was more likely to be required when using conventional needle anesthesia than when using a needle-free system. In the current study, there was no need for additional anesthesia using either anesthesia method. Differences in the requirement for additional anesthesia may be attributed to the different age groups of the patients in the studies, the technical sensitivity of the needle-free injection systems used, and the different dental treatments administered.

In the present study, although there was a slight change in pulse rate after the administration of anesthesia in the needle-free and conventional injection groups, the rate returned to normal after 180 and 240 seconds, respectively, and no statistically significant between-group difference in pulse rate or oxygen saturation was found. Similarly, Silvestre et al. (23) found no significant changes in pulse rate and oxygen saturation values recorded at three time intervals during tooth extraction after injection of an anesthetic solution containing mepivacaine. However, regardless of the method of anesthesia, Bible et al. (24) noted that lidocaine plus epinephrine increased pulse rates, in addition to systolic and diastolic blood pressure rates, during dental procedures.

Needle injections are among the major factors that trigger dental treatment-related anxiety and fear (8). The lower pain perception in the needle-free injection group in the present study supports this finding. However, there was no significant between-group difference in oxygen saturation and pulse rate values in the present study. Accordingly, it can be concluded that the injection method has no effect on pulse rate and oxygen saturation. Based on a review of the literature comparing different needle-free injection and conventional injection systems, there is no clear consensus. Although the traditional injection technique provides the motor and sensory blockage required for treatment, the fear of needles is always ignored (11). However, needle-free injection systems are not generally preferred by dentists due to their bulky nature high-precision application requirement, and longer time as compared with conventional injection systems. In the present study, there was no significant difference between groups in average pulse rates and oxygen saturation levels. This finding may indicate that the needle-free injection technique can be used safely for dental anesthesia.

The present study has some limitations. First, we did not assess the patients' anxiety and fear levels regarding injections before assigning them to the different groups. However, standardization of each variable is impossible in clinical studies. To the best of knowledge, needle-free injection systems have been studied mostly in children (11, 13) and in studies examining endodontic treatments, focusing on topics such as anesthesia effectiveness (4, 25), patient preference (12, 25), and acceptability (20). Thus, the pulse rate and oxygen saturation data in the current study cannot be directly compared with those obtained in studies involving other needle-free injection methods. This

can be considered a limitation of the present study. Another limitation may be the absence of procedures requiring deeper and longer anesthesia, as all the patients in the present study required pulpal anesthesia only for maxillary premolars. Since the VAS scale, which is a subjective scale, was used for pain values, differences in pain between patients may have caused the standard deviation to be high as shown in Table 2. This can be considered as a limitation of the current study.

## CONCLUSION

Within the limitations of this study, a needle-free injection system provides lower levels of injection pain and higher pulpal anesthesia efficacy compared to a conventional injection method. The type of injection technique does not affect pulse rate or oxygen saturation levels. Therefore, using a needle-free injection system could be beneficial for patients with anxiety or fears about dental injections, providing a more comfortable treatment experience.

### Disclosures

**Ethics Committee Approval:** The study was approved by the Atatürk University Faculty of Dentistry Ethics Committee (no: 06/2023, date: 22/06/2023).

**Authorship Contributions:** Concept – E.K.; Design – E.K.; Supervision – E.K.; Funding – E.K., H.S.; Materials – H.S.; Data collection and/or processing – H.S.; Data analysis and/or interpretation – E.K.; Literature search – H.S.; Writing – H.S.; Critical review – E.K., H.S.

**Conflict of Interest:** All authors declared no conflict of interest.

**Use of AI for Writing Assistance:** The authors declared that artificial intelligence-supported technologies were not used in the production of this study.

**Financial Disclosure:** The authors declared that all funding was provided by the authors.

**Peer-review:** Externally peer-reviewed.

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