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ORIGINAL RESEARCH

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# The effectiveness of a needle-free system in reducing injection pain during palatal infiltrative anesthesia in children: a randomized clinical study

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## Abstract

**Background**: Dental palatal infiltrative injection challenges tolerance in pediatric patients. The study aimed to evaluate the pain and effectiveness of the Comfort-In™ injection compared to dental needle injection using palatal infiltrative anesthesia to extract upper permanent first molars in children. **Methods**: This randomized, parallel-arm, prospective clinical trial was conducted in children aged 7 to 14 years who required the extraction of upper permanent first molars. Fifty participants were randomized into two groups: the Comfort-In™ and the dental needle injection group. Pain acceptance was evaluated during the palatal infiltrative anesthesia using the Wong-Baker FACES Pain Rating Scale (WBFPRS) and the Face, Leg, Activity, Cry, Consolability (FLACC) Scale. Extra-dose requirements were assessed in both groups. Data were analyzed using version 4.4.1 of the R programming language, and the significance level was set at $p < 0.05$. **Results**: The WBFPRS was evaluated for pain acceptance, and a statistically significant difference was found, with the Comfort-In™ injection group demonstrating better pain acceptance compared to the dental needle injection group ($p = 0.003$). There was no statistical difference between the Comfort-In™ injection system and the dental needle injection in FLACC scores ($p = 0.05$) and the extra-dose requirements ($p = 0.05$). In the multiple regression for FLACC, the dental needle method increased scores ($\beta \pm$ SE (Standard Error) $= 0.53 \pm 0.20$; $p = 0.012$). In the ordinal logistic regression for WBFPRS, it also yielded higher scores ($\beta \pm$ SE $= 3.27 \pm 0.73$; $p < 0.001$). **Conclusions**: Dental needle injection anesthesia was associated with more pain during palatal anesthesia than Comfort-In™ injection method. Although Comfort-In™ injection system generally provided adequate anesthesia, it required an extra dose in some cases. Nevertheless, due to its lower pain perception and needle-free application, the Comfort-In™ injection system is recommended as a suitable alternative for palatal anesthesia in pediatric patients. **Clinical Trial Registration**: ClinicalTrials.gov: NCT06606587 (Retrospective registration).

## Keywords

Comfort-In™; Dental anxiety; Needle-free injection; Palatal infiltrative anesthesia

## 1. Introduction

Pain is an unpleasant sensation originating from any part of the body [1]. Every dentist strives to deliver painless dental treatments with minimal discomfort for their patients [2]. Local anesthesia has been the cornerstone of these materials since its introduction. Local anesthesia blocks pain sensations by a topical or injected drug into a part of the body without affecting the level of consciousness. One of the critical factors affecting success in dentistry, especially in pediatric dentistry, is pain control. Pain during dental procedures is one of the main factors that cause permanent and profound effects on the child's behavior [3, 4]. In pediatric patients, injection pain can have long-term negative consequences such as fear and anxiety, and subsequently harm the child's behavior, comfort, and cooperation during dental treatments [5]. Preventing pain creates a positive and trusting relationship between the pediatric dentist and the child, reducing the child's anxiety and fear. It also helps develop a positive attitude towards future dental treatments [6].

Pain during local anesthetic administration may arise from mechanical trauma caused by needle insertion, the sudden separation of tissues by the anesthetic solution, or the rapid injection of the anesthetic agent. Palatal infiltration anesthesia is a frequently used local anesthesia technique applied to the palatal region in procedures that include the palatal region, such as single-tooth extraction, matrix band, and rubber dam applications. Palatal infiltration anesthesia is an excruciating


  

and traumatic local anesthesia method for both children and adults due to the presence of thick keratinized tissue in the palatal region [7]. Given the concerns surrounding needle phobia and needle-stick injuries, there is an increasing need for alternative methods that eliminate the use of needles.

Hingson and Hughes invented a new injection method based on a different principle that eliminated the use of needles [8]. This technique was called pressure injection or jet injection. Needle-free injection systems operate via a mechanism fundamentally different from traditional needle-based methods, employing high-pressure, high-velocity fluid jets to deliver anesthetic solution into oral tissues [9]. These devices use a pressurized mechanism—such as a spring or compressed gas—to force anesthetic through a micro-orifice, creating a focused, high-speed liquid stream capable of penetrating mucosal barriers without a needle [10]. By precisely controlling both pressure and velocity, the jet ensures effective delivery directly into the gingiva or soft tissue. This needle-free approach aims to reduce pain and anxiety associated with needle injections, which is particularly advantageous in pediatric dentistry and has been shown to improve patient acceptance and comfort [11]. A study found that the application of a needle-free system during Palatal Infiltrative Anesthesia (PIA) ensured a decrease in pain perception in children [12].

Palatal anesthesia is crucial for upper molar extractions but presents tolerance difficulties for pediatric patients. This study, therefore, aimed to compare the pain acceptance associated with palatal infiltration anesthesia administered via dental needle injection and the Comfort-In™ injection system, a needle-free alternative, in pediatric patients undergoing maxillary permanent molar extraction. Additionally, the study assessed the anesthesia effectiveness of both methods.

## 2. Materials and methods

### 2.1 Study type and sample size

The local clinical research ethics committee approved this prospective, clinical, randomized study (Approval number: 22-KAEK-060). The clinical trial number is NCT06606587 at the ClinicalTrials.gov website. This study was conducted between January 2023 and December 2023.

All procedures performed in this study were carried out according to the ethical principles described in the Declaration of Helsinki. Patients and their parents were informed about the study, and informed consent was obtained before treatment and the study was executed following the Consolidated Standards of Reporting Trials (CONSORT) Statement 2010 guidelines [13]. The required number of participants was obtained after power analysis based on data from a previously conducted study on the subject (alpha ($\alpha$) = 0.05, beta ($\beta$) = 0.05 and power = 0.95). It was found that at least 50 people should be included in the study [12].

### 2.2 Patient selection and randomization

This study included 50 children aged 7–14 years who presented to the dentistry clinic with their parents/guardians. Participants were required to have an indication for the extraction of maxillary permanent first molars under palatal infiltration anesthesia and to provide informed consent for the procedure (Fig. 1).

Included in this study were children with presence of a maxillary first permanent molar with an indication for extraction; absence of ankylosis, root resorption exceeding one-half of the root length, severe structural loss, root canal calcification precluding endodontic treatment, vertical root fracture, or extensive furcation lesions; systemically healthy status; and a behavioral rating of 2, 3, or 4 on the Frankl scale [14]. The primary indications for extraction included extensive dental caries, orthodontic treatment planning, and periapical or periodontal infections affecting the maxillary first permanent molars. Frankl behavior rating scale (FBRS) scores were rating 2 (negative), 3 (positive) and 4 (definitely positive). Exclusion criteria included a Frankl score of 1, known allergy to local anesthetic agents, presence of acute infection, refusal to participate in the study, medical or developmental disorders, pathological conditions in the anesthesia area, developmental tooth defects, and limited mouth opening.

Participants meeting the inclusion criteria were randomly assigned to one of the two groups: Group 1 (Comfort-In™ injection group) and Group 2 (Dental needle injection group). To ensure randomization, two sealed envelopes, each containing one of the anesthesia methods, were prepared. One envelope contained “Group 1” and the other contained “Group 2”. Each participant selected an envelope, determining their assigned anesthesia technique. In Group 1, palatal anesthesia was administered using the Comfort-In™ injection system, while in Group 2, a dental needle injection was used. To prevent any interference with pain perception, topical anesthetics were not applied before the injections [15]. The procedure was performed by only one dentist.

### 2.3 Comfort-In™ injection group

In the experimental group, palatal infiltrative anesthesia for maxillary first permanent molars was administered using the Comfort-In™ injection system (Mika Medical, Busan, Korea). A total of 25 patients were included in this group. Before administering anesthesia, the child was prepared using the tell-show-do behavioral guidance technique.

The Comfort-In™ injection system utilizes a pressurized spring mechanism and a yellow silicone cap to facilitate proper positioning on periodontal tissues during jet injection. The injection was administered 5 mm below the palatal gingival margin line, close to the free gingiva, and at a vertical angle (Figs. 2,3). A total of 0.3 cc of anesthetic solution was delivered by pressing the jet injection system button. The local anesthetic used was 1 mL of Articaine Hydrochloride (3F250A, Ultracaine D-S forte, Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, HE, Germany) with 1:100,000 epinephrine (Figs. 2,3).

After the injection, a 2-minute waiting period was observed to allow for intraosseous anesthetic diffusion. The Comfort-In™ injection system is an intraosseous anesthesia technique, and since its effect becomes evident within a short period, a waiting time of 2 minutes was established [16]. The decision to administer an additional dose was specifically determined during clinical evaluations based on the patient’s sensitivity or pain response upon gingival probing at the palatinal gingiva.

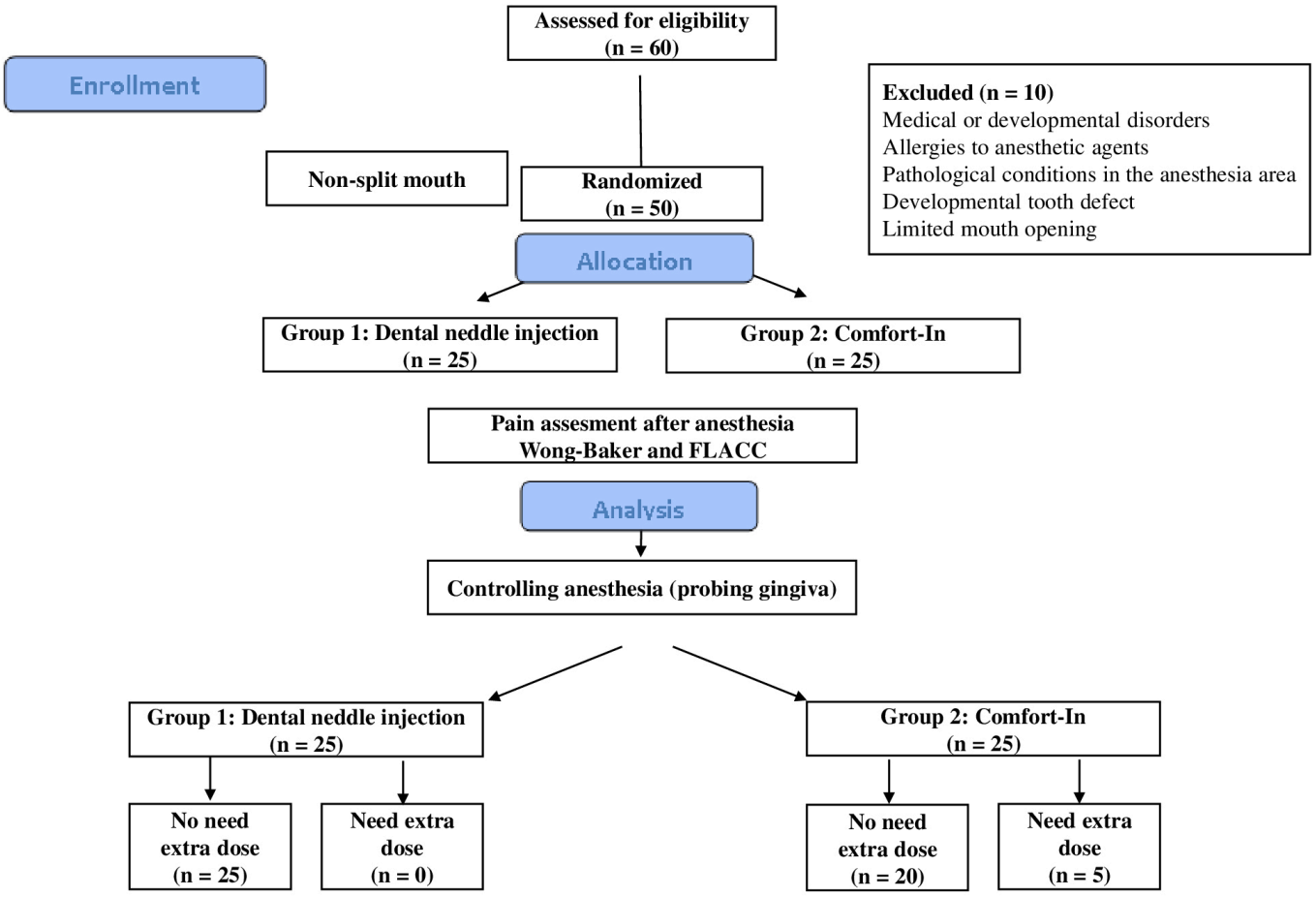


**FIGURE 1. Participant CONSORT Statement flow diagram.** FLACC: Face, Leg, Activity, Cry, Consolability.

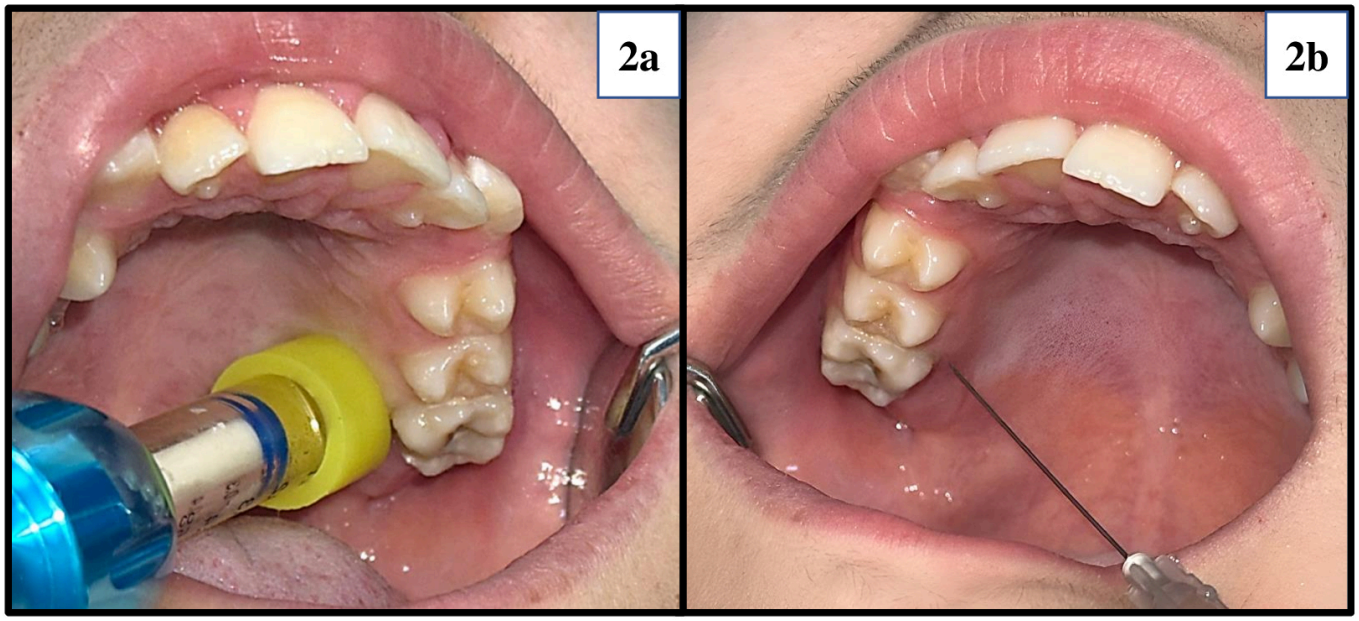


**FIGURE 2. Application of the two injection methods.** (a) Application of Comfort-In™ injection system. (b) Application of dental needle.

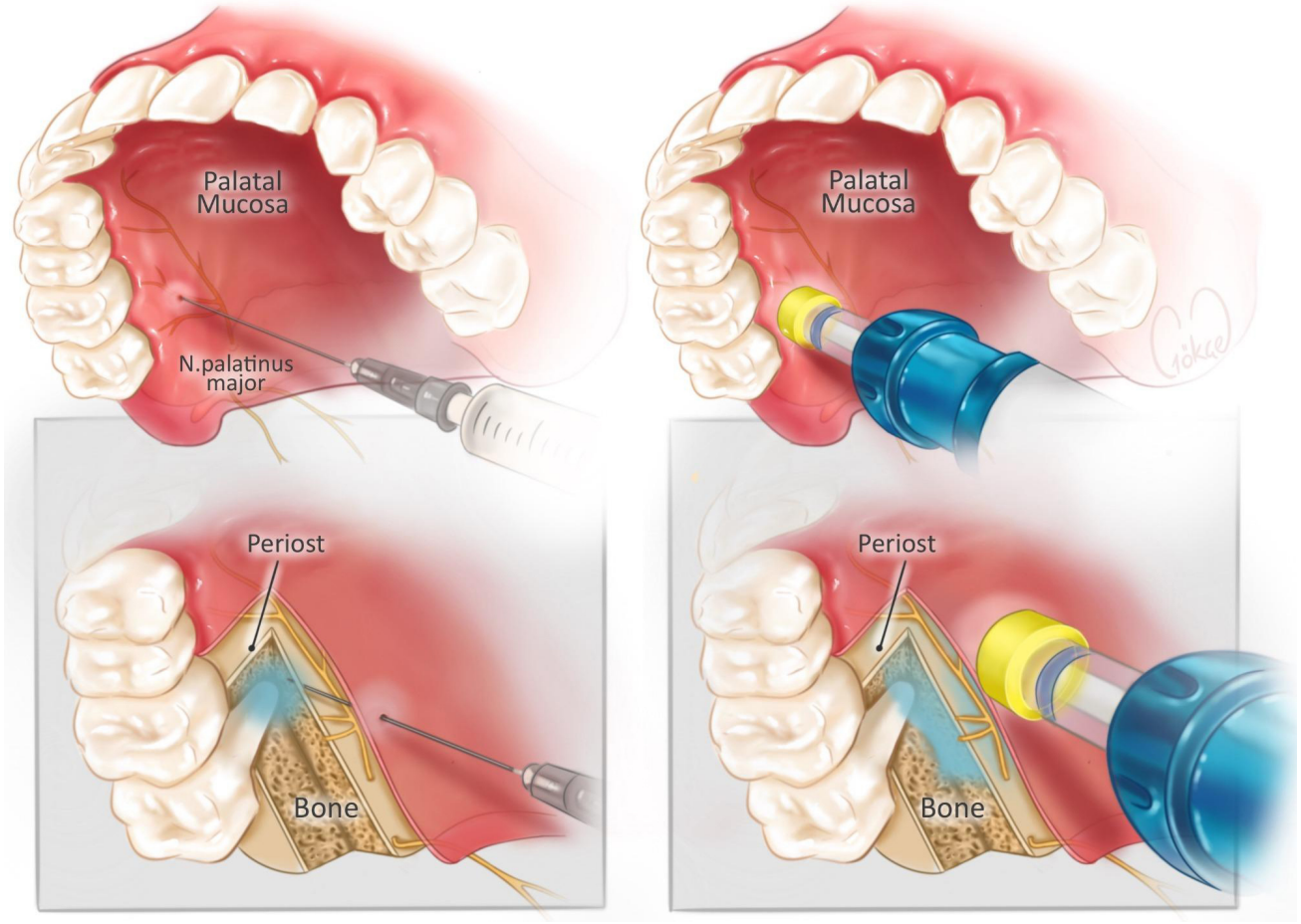


**FIGURE 3. Diagrammatic presentation of Comfort-In™ injection system and dental needle injection during palatal anesthesia.**

To assess the adequacy of palatal anesthesia, a periodontal probe was gently inserted into the palatal mucosa at the anesthesia site, and the child's response was monitored. If the patient reported no pain or discomfort during probing, the anesthesia was considered sufficient. If any discomfort was noted, an extra dose of anesthesia was administered before proceeding.

Once palatal anesthesia was confirmed to be sufficient, buccal infiltration anesthesia was performed using a dental needle syringe. Following successful anesthesia, the tooth was extracted.

## 2.4 Dental injection group

In this group, palatal anesthesia was administered using the dental needle injection technique. A total of 25 patients were included in this group. The injection site was located approximately 5 mm below the palatal gingival margin, on the attached gingiva, and the needle was inserted at a 45-degree angle (Figs. 2,3). Before administering anesthesia, the child was prepared using the tell-show-do behavioral guidance technique.

Following needle insertion, bone contact was established and then withdrawn by 3–5 mm, at which point 0.3 cc of anesthetic solution was slowly deposited. The local anesthetic agent used was 1 mL of Articaine Hydrochloride (3F250A, Ultracaine D-S forte, Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, HE, Germany) with 1:100,000 epinephrine, administered with a 27G dental needle (Figs. 2,3).

After the injection, a waiting period of five minutes was allowed to ensure the anesthetic had taken full effect. The adequacy of palatal anesthesia was assessed clinically by gently probing the gingiva and observing the patient's response to pain or sensitivity. If no discomfort was noted, the anesthesia was considered sufficient. However, in cases where the response indicated inadequate anesthesia, an additional dose of local anesthetic was administered using the conventional dental needle technique. This supplementary injection was intended to alleviate any remaining discomfort and was interpreted as a sign of failure in the initial palatal infiltration. Once adequate palatal anesthesia was confirmed, buccal infiltration anesthesia was delivered with a dental needle syringe, and the tooth was extracted under effective local anesthesia.

## 2.5 Pain assessment

Pain perception was assessed using both subjective and objective measures immediately after palatal anesthesia. For subjective evaluation, the Wong-Baker FACES Pain Rating Scale (WBFPRS) [17] was used, allowing patients to self-report their pain levels. For objective assessment, the Face, Legs, Activity, Cry, Consolability (FLACC) Scale [18] was utilized.

The WBFPRS is a visual analog scale that features a series of

facial expressions ranging from a smiling face to a crying face, each corresponding to a numerical value between 0 and 10. A score of 0 represents "no pain" while a score of 10 indicates "hurts worst". Patients were asked to identify the face that best represented their pain at that moment.

The FLACC behavior scale is an observational pain assessment tool that evaluates five behavioral parameters:

1. Facial expression,
2. Leg movement,
3. Activity level,
4. Crying,
5. Consolability.

Each parameter is scored on a scale from 0 to 2, with a total possible score ranging from 0 to 10. According to the FLACC behavior scale:

- 0 points indicate no pain,
- 1–3 points indicate mild pain,
- 4–6 points indicate moderate pain and discomfort,
- 7–10 points indicate severe pain and distress.

To ensure standardized evaluations, all injections were administered by a single researcher experienced in Comfort-In™ injection. Additionally, all injections were recorded on video for later assessment. The FLACC behavior scale scores were assigned by two pediatric dentists (BA, HA), who reviewed the video recordings to assess interobserver reliability. Meanwhile, WBFPR scores were obtained directly from the patients immediately after anesthesia.

## 2.6 Statistical analysis

Data were analyzed using version 4.4.1 of the R programming language. Normality was assessed using the Kolmogorov Smirnov test. Numerical data were represented as mean ± standard deviation and median (minimum–maximum), while categorical data were represented as frequency and percentage.

Spearman's rho ($\rho$) test was used to establish intra-rater reliability. Inter-rater agreement was assessed using the Kappa ($\kappa$) test, with values >0.81, 0.80–0.61, 0.60–0.41, 0.40–0.21, and <0.20 denoting perfect, substantial, moderate, fair, and slight agreement, respectively.

The differences between groups were evaluated using the Spearman's correlation test, Mann-Whitney U-test, and Wilcoxon *t*-test. The significance level was set at $p < 0.05$.

Multiple linear regression and multiple ordinal logistic regression were used to model the effects of age, gender, Frankl behavior scale scores, and anesthesia methods (Comfort-In™/Dental needle) on the scores of the FLACC behavior scale and WBFPRS, respectively.

## 3. Results

Fifty children, 23 boys and 27 girls, aged 7 to 14 (10.4 ± 2.11), were included in this study. Table 1 shows the frequency and percentage of tooth number, gender, Frankl behavior scale, and anesthesia success rate that were evaluated for this study. Frankl behavior scale scores in children were negative, positive, and definitely positive (38%, 28%, and 34%). While dental needle was applied more to tooth number 16, Comfort-In™ was applied more to tooth number 26.

Table 2 compares the objective and subjective pain scores during the Comfort-In™ injection and Dental needle methods of anesthesia. In our study, the mean WBFPRS scores marked during Comfort-In™ injection were 1.04 ± 1.54; the mean WBFPRS scores marked during dental needle injections were 4.24 ± 2.85. There was a statistical difference in pain during the application of anesthesia by WBFPRS scores ($p = 0.003$) (Table 2). The WBFPRS scores were high; the maximum score was "hurts even more" in the Dental Injection group. According to WBFPRS scores, the "no pain" responses were the highest in the Comfort-In™ injection group (Table 2). In the WBFPRS, none of the children (regardless of gender) in the Comfort-In™ injection group selected the higher pain categories hurts even more, hurts a whole lot, or hurts worst, whereas these ratings were more frequently observed in the dental needle injection group.

**TABLE 1. The descriptive values for tooth number, gender, Frankl Behavior Scale, and Pain after anesthesia.**

| | Comfort-In™ Injection Frequency (%) | Dental Needle Frequency (%) | Total Frequency | % | *p*-value* |
|---|---|---|---|---|---|
| Tooth Number | | | | | |
| Right Upper Molar | 9 (18%) | 13 (26%) | 22 | 44 | 0.25 |
| Left Upper Molar | 16 (32%) | 12 (24%) | 28 | 56 | |
| Sex | | | | | |
| Boy | 16 (32%) | 7 (14%) | 23 | 46 | 0.01 |
| Girl | 9 (18%) | 18 (36%) | 27 | 54 | |
| Frankl Behavior Scale Scores | | | | | |
| Negative | 10 (20%) | 9 (18%) | 19 | 38 | 0.78 |
| Positive | 7 (14%) | 7 (14%) | 14 | 28 | |
| Definitely Positive | 8 (16%) | 9 (18%) | 17 | 34 | |
| Anesthesia** | | | | | |
| Needs an extra dose | 5 (20%) | 0 (0%) | 5 | 10 | 0.05 |

*: *Pearson's Chi Squared Test;* **: *Extra dose of Palatal Anesthesia.*

**TABLE 2. Distribution of pain scores of the Wong-Baker FACES Pain Rating Scale and FLACC behavior scale during injection.**

| | Boys | | | Girls | | | Total | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Comfort-In™ Injection n (%) | Dental Needle n (%) | *p* | Comfort-In™ Injection n (%) | Dental Needle n (%) | *p* | Comfort-In™ Injection n (%) | Dental Needle n (%) | Test Statistics | *p*-value* |
| Wong-Baker scale scores | | | | | | | | | | |
| No Pain | 11 (91.6) | 1 (8.4) | | 5 (62.5) | 3 (37.5) | | 16 (80.0) | 4 (20.0) | | |
| Hurts Little | 1 (100.0) | 0 (0.0) | | 4 (44.4) | 5 (55.6) | | 5 (50.0) | 5 (50.0) | | |
| Hurts Little More | 4 (57.1) | 3 (42.9) | | 0 (0.0) | 2 (100.0) | | 4 (44.4) | 5 (55.6) | | |
| Hurts Even More | 0 (0.0) | 2 (100.0) | 0.021$^{Y}$ | 0 (0.0) | 5 (100.0) | 0.042$^{x}$ | 0 (0.0) | 7 (100.0) | 18.30 | 0.003$^{x}$ |
| Hurts Whole Lot | 0 (0.0) | 1 (100.0) | | 0 (0.0) | 2 (100.0) | | 0 (0.0) | 3 (100.0) | | |
| Hurts Worst | 0 | 0 | | 0 (0.0) | 1 (100.0) | | 0 (0.0) | 1 (100.0) | | |
| Mean ± SD | | | | | | | 1.04 ± 1.54 | 4.24 ± 2.85 | | |
| Median | | | | | | | 0 | 4 | | |
| FLACC scale scores | | | | | | | | | | |
| No Pain | 0 (0.0) | 1 (100.0) | | 0 (0.0) | 1 (100.0) | | 0 (0.0) | 2 (100.0) | | |
| Mild Pain | 11 (78.5) | 3 (21.5) | | 8 (50.0) | 8 (50.0) | | 19 (63.3) | 11 (36.6) | | |
| Moderate Pain | 4 (66.6) | 2 (33.4) | 0.069$^{x}$ | 1 (20.0) | 4 (80.0) | 0.143$^{x}$ | 5 (45.5) | 6 (54.5) | 7.80 | 0.05$^{x}$ |
| Severe Pain | 1 (50.0) | 1 (50.0) | | 0 (0.0) | 5 (100.0) | | 1 (14.3) | 6 (85.7) | | |
| Mean ± SD | | | | | | | 1.28 ± 0.54 | 1.78 ± 0.85 | | |
| Median | | | | | | | 1 | 2 | | |

**,$^{x}$ Pearson's Chi Squared Test; $^{Y}$ Fishers exact test; SD: Standard deviation; FLACC: Face, Legs, Activity, Cry, Consolability.*

The mean and standard deviation of FLACC behavior scale scores were 1.28 ± 0.54 in the Comfort-In™ injection group and 1.78 ± 0.85 in the Dental needle injection group (Table 2). There was no statistical difference in pain during the application of anesthesia in FLACC behavior scale scores ($p = 0.05$) (Table 2). Inter-rater reliabilities were established $\kappa = 0.820$, which means perfect inter-rater reliability from the observers, according to the FLACC behavior scale videotaped data.

In Comfort-In™ injection group, there was no statistical difference between WBFPRS scores according to the age ($p = 0.731$) (Table 3). The obtained median of age values did not show any difference ($p = 0.274$) across FLACC behavior scale groups. In Dental needle group, there was no statistical difference between Frankl behavior scale scores according to the age ($p = 0.173$) (Table 3). There was no statistical difference between WBFPRS according to the age ($p = 0.147$) (Table 3). No statistical difference was found between FLACC behavior scale scores according to age ($p = 0.093$) (Table 3). According to FLACC behavior scale scores, "mild pain" was the highest in the Comfort-In™ injection and Dental needle groups (Table 2).

In this study, the need for an additional anesthetic dose varied between the two anesthesia methods. While 80% of children (n = 20) in the Comfort-In™ injection group achieved sufficient anesthesia with a single injection, 20% (n = 5) required an extra dose. In contrast, all children in the Dental Needle group 100% (n = 25) received adequate anesthesia without the need for an extra-dose. The difference between the two groups was not statistically significant ($p = 0.05$) (Table 1).

There is no significant difference in the both methods of the Wong-Baker FACES Pain Rating Scale, FLACC behavior scale and Frankl behavior scale according to the age (Table 3).

This multiple linear regression model examines how FLACC behavior scale scores (pain level: relaxed < mild < moderate < severe) is influenced by the independent variables age, gender, Frankl behavior scale scores, and anesthesia methods (Table 4).

The Frankl behavior scale scores variable significantly reduces FLACC behavior scale scores ($p < 0.001$). The anesthesia methods variable (dental needle) significantly increases FLACC behavior scale scores ($p = 0.012$). Age and Gender variables did not have a statistically significant effect on FLACC behavior scale scores ($p > 0.05$) (Table 4).

This ordinal regression analysis evaluates the effect of age, gender, Frankl behavior scale scores, and anesthesia methods on the outcome variable WBFPRS, which represents an ordered categorical variable. Among all variables, only anesthesia methods (dental needle method) significantly increase WBFPRS scores ($p < 0.001$), indicating higher likelihood of being in a higher WBFPRS score. Age, gender, and Frankl behavior scale scores do not have a statistically significant effect on WBFPRS in this model. This suggests that the dental needle anesthesia method may be associated with higher WBFPRS scores, while other predictors are not influential (Table 4).

## 4. Discussion

Injection pain can lead to negative behavior in children, increasing the risk of avoiding essential dental treatments. Palatal infiltrative anesthesia is one of the most painful local anesthesia techniques due to the dense palatal nerve network and the firm attachment of the palatal mucosa to the periosteum [19]. This clinical trial aimed to compare the effectiveness of the needle-free Comfort-In™ injection system and dental needle injection in reducing pain during palatal infiltrative anesthesia in children. The results demonstrated that the Comfort-In™ injection system alleviated pain associated with palatal infiltrative anesthesia.

Needle-free jet injection offers several advantages over dental needle injection, including ease of use, reduced tissue trauma, faster drug absorption, and elimination of needle-stick injuries [20]. It has been successfully used in procedures such as dental fillings, pulpotomy, pulpectomy, extractions, and minor periodontal surgeries in both children and adults [21]. No studies have evaluated the effectiveness of the Comfort-In™ injection system for palatal anesthesia in permanent tooth extractions in children. Kaya and Yıldırım compared the Comfort-In™ injection system with dental needle anesthesia using 0.2 mL of Ultracaine D-S Forte (Germany) for palatal injections in primary maxillary molars [12]. They found that the needle-free jet system effectively reduced injection pain and was preferred by most children. In our study, children experienced less pain with Comfort-In™ injection than with dental needle injection for palatal anesthesia (0.3 cc Ultracaine D-S Forte, Germany) before permanent maxillary molar extraction [22].

Nogueira *et al.* [22] aimed to assess the anesthetic efficacy and pain of needle-free articaine administration compared to the conventional needle method in patients with irreversible pulpitis. Similar to our study, patients in the needle-free/Comfort-In™ injection group reported lower pain at the time of anesthesia application than patients from the conventional group. The success rate reported was for adult patient with irreversible pulpitis, which was 71.0% in the Comfort-In™ (needle-free) injection group and for the conventional needle injection group was reported as 80.6%. The study suggests that insufficient anesthesia can be attributed to several factors. First, patient anxiety and fear of anesthesia, whether with or without a needle, may lower the pain threshold, making it more susceptible to ineffective anesthesia. Second, changes in tissue pH due to inflammation typically, inflamed tissues have a more basic pH which neutralizes the anesthetic's acidic pH and can reduce the efficacy of local anesthetics. Third, individual metabolic differences and body weight can influence the amount of anesthetic available in the tissue, thereby affecting its effectiveness.

In contrast, Ocak *et al.* [21] reported that 0.3 cc buccal and 0.1 cc palatal anesthesia administered with the INJEX system resulted in higher pain and discomfort scores during extractions in adults, concluding that the jet injection method was ineffective and uncomfortable for tooth extraction. Similarly, Arapostathis *et al.* [23] found that additional anesthesia was

**TABLE 3. Comparison of Frankl Behavior Scale, Wong-Baker FACES Pain Rating Scale and FLACC behavior scale rates according to the age in Comfort-In™ injection group and dental needle group.**

| | Comfort-In™ Injection | | | | Dental Needle | | | |
|---|---|---|---|---|---|---|---|---|
| | Age (yr) Mean ± SD | Median (min–max) | Test Statistics | *p*-value* | Age (yr) Mean ± SD | Median (min–max) | Test Statistics | *p*-value* |
| Frankl Behavior Scale | | | | | | | | |
| Negative | 9.556 ± 2.297 | 9.0 (7–13) | | | 9.778 ± 1.986 | 10.0 (7–12) | | |
| Positive | 9.286 ± 1.380 | 9.0 (8–11) | 1.196 | 0.322[x] | 10.714 ± 1.890 | 11.0 (8–13) | 1.899 | 0.173[y] |
| Definitely Positive | 10.750 ± 2.053 | 11.0 (8–14) | | | 11.667 ± 2.236 | 11.0 (8–14) | | |
| Wong-Baker FACES Pain Rating Scale | | | | | | | | |
| No Pain | 9.938 ± 2.113 | 9.5 (7–13) | | | 11.500 ± 2.381 | 12.5 (8–13) | | |
| Hurts Little Bit | 10.600 ± 2.608 | 11.0 (8–14) | | | 8.800 ± 1.483 | 9.0 (7–11) | | |
| Hurts Little More | 9.500 ± 1.291 | 9.5 (8–11) | 0.318 | 0.731[y] | 11.400 ± 2.302 | 11.0 (8–14) | 6.799 | 0.147[x] |
| Hurts Even More | 0 | 0 | | | 11.143 ± 1.464 | 11.0 (10–14) | | |
| Hurts Whole Lot | 0 | 0 | | | 12.000 ± 1.732 | 11.0 (11–14) | | |
| FLACC behavior scale | | | | | | | | |
| No Pain | 0 | 0 | | | 13.500 ± 0.707 | 13.5 (13–14) | | |
| Mild Pain | 10.048 ± 2.037 | 10.0 (7–14) | 1.121 | 0.274[z] | 11.182 ± 2.183 | 11.0 (8–14) | 6.410 | 0.093[x] |
| Moderate Pain | 8.667 ± 1.528 | 9.0 (7–12) | | | 10.200 ± 1.924 | 10.5 (7–12) | | |
| Severe Pain | 0 | 0 | | | 9.571 ± 1.718 | 10.0 (7–12) | | |

**,x Kruskall Wallis H Test; [y] One Way Anova; [z] Mann Whitney U Test; FLACC: Face, Legs, Activity, Cry, Consolability; SD: Standard Deviation; min: minimum; max: maximum.*

**TABLE 4. Multiple linear regression analysis using FLACC behavior scale scores and ordinal logistic regression using Wong-Baker FACES Pain Rating Scale scores as dependent variables.**

| Comparison | $\beta \pm$ SE | 95% CI | *p*-value* |
|---|---|---|---|
| FLACC behavior scale scores | | | |
| Age | −0.04 ± 0.05 | (−0.14, 0.05) | 0.333 |
| Gender | −0.21 ± 0.20 | (−0.61, 0.19) | 0.305 |
| Frankl | −0.49 ± 0.11 | (−0.71, −0.28) | <0.001* |
| Anesthesia Methods | 0.53 ± 0.20 | (0.12, 0.93) | 0.012* |
| Wong-Baker FACES Pain Rating Scale scores | | | |
| Age | −0.02 ± 0.17 | (−0.35, 0.32) | 0.921 |
| Gender | −0.25 ± 0.73 | (−0.52, 1.06) | 0.494 |
| Frankl | 0.27 ± 0.39 | (−1.72, 1.22) | 0.732 |
| Anesthesia Methods | 3.27 ± 0.73 | (1.80, 4.74) | <0.001* |

**Statistically significant $p < 0.05$; FLACC: Face, Legs, Activity, Cry, Consolability; SE: Standard Error; CI: Confidence Interval.*

required for all extractions in the INJEX group when compared to conventional dental injections in primary tooth extractions. Belevcikli *et al.* [20] found that the Comfort-In™ injection system significantly reduced injection-related pain during the administration of local anesthesia. In our study, children experienced less pain during Comfort-In™ injection than with dental needle injection for palatal anesthesia (0.3 cc Ultracaine D-S Forte, Germany) before permanent maxillary molar extraction.

In studies conducted on children and adults using needleless injections, the percentage of patients who achieved adequate anesthesia with these devices was reported to vary between approximately 50% and 90% [23, 24]. No studies have reported using the Comfort-In™ injection system during permenant tooth extraction. The research indicates that INJEX often encounters technical challenges in palatal and lingual positioning, which can undermine its anesthetic efficacy. Ineffective anesthesia especially in posterior regions may be due to device positioning and angle differences. In our study, when the anesthesia efficacy after injection was evaluated, it was found that the dental needle injection method provided anesthesia adequate at rate of 100% and Comfort-In™ injection method at 84%; these results were found to be consistent with the literature. However, despite extra-dose rates, the Comfort-In™ injection method was still effective in reducing pain perception compared to dental needle injections. These results suggest that alternative anesthesia techniques should be considered to reduce pain.

A child's response to dental treatment is influenced by multiple factors, including age, temperament, anxiety levels, parental anxiety, and previous dental experiences. In the regression models created in our study, it was examined how the WBFPRS and FLACC behavior scale were influenced by the independent variables: age, gender, and Frankl behavior scale scores. Age and gender had no effect both on WBFPRS and FLACC behavior scale scores, in addition Frankl behavior scale scores had no effect on FLACC behavior scale. It shows that alternative techniques should be evaluated instead of anesthesia and that the Frankl behavior scale scores may be an important variable in pain management. The most effective factor in subjective pain assessment was the anesthesia method applied and that the dental needle injection caused more pain than Comfort-In™ injection system in this study.

Our study measures the pain acceptance and effectiveness of palatal anesthesia for permanent maxillary tooth extraction in children using Comfort-In™ injection. This study presents certain limitations. Firstly, the relatively small sample size and single-center design may limit the broader applicability of the results. Secondly, although validated pain assessment tools like FLACC and Wong-Baker scales were employed, pain perception remains inherently subjective and may be influenced by psychological and individual factors. Furthermore, due to the recognizable appearance and sound of the Comfort-In™ device, blinding during anesthesia administration was not possible, which could have affected patient responses. Lastly, the study specifically assessed palatal infiltrative anesthesia in maxillary permanent molars, so the outcomes may not be generalizable to other dental procedures or anatomical regions. Future research with larger, multicenter cohorts and diverse clinical conditions is needed to strengthen the evidence and guide clinical use of needle-free anesthesia methods in pediatric dentistry.

The strength of our study is that many previous studies focused only on cooperative patients whereas our study evaluated pain acceptance and effectiveness of palatal infiltrative anesthesia in both cooperative and uncooperative children. Therefore, our study provides a more comprehensive understanding of the Comfort-In™ and dental needle injection systems. Further clinical studies on jet injection systems will be valuable in optimizing treatment protocols and determining appropriate dosage ranges for different procedures. In procedures involving painful techniques such as palatal anesthesia, the Comfort-In™ injection system resulted in considerably less pain than the conventional dental syringe. It is anticipated that increasing the anesthetic dosage may help overcome the need for repeated injections. These findings can help clinicians refine anesthesia techniques and enhance patient comfort in pediatric dentistry.

## 5. Conclusions

During palatal local anesthesia application, the use of the Comfort-In™ injection system is associated with lower pain levels in children during injection. Comfort-In™ injections can be considered as an alternative method to provide painless treatment for children with high dental anxiety and needle phobia. Although there are studies investigating jet anesthesia in the literature, there is a need for studies that will provide information on the indications and contraindications of Comfort-In™ injection and palatal infiltrative anesthesia. To reduce the need for supplemental anesthetic doses as observed in our study, a higher volume than the conventional 0.3 mL could be administered. Additionally, the jet injector's nozzle design may benefit from being made smaller to enhance precision and tissue penetration.

### AVAILABILITY OF DATA AND MATERIALS

These data are available in the above database.

### AUTHOR CONTRIBUTIONS

AA and HA—designed the research study. BA—performed the research. HA, BA and AA—connected data. HA and NDŞ—analyzed data. AA, NDŞ, BA and HA—wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

### ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was conducted with the approval of the Clinical Research Ethics Committee of Tokat Gaziosmanpaşa University Dean's Office of the Faculty of Medicine (Date: 12 May 2022; Number: 22-KAEK-060). The clinical trial number is NCT06606587 at ClinicalTrials.gov website. The parents of children who accepted the experiment fully understood the experimental procedure and signed the informed consent.

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### CONFLICT OF INTEREST

The authors declare no conflict of interest.

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