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ORIGINAL RESEARCH

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The effect of a needle-free injection system on dental injection pain in children: a randomised cross-over clinical trial

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Abstract

Background: This study aimed to compare pain perception and behavioral responses in pediatric patients during dental injections using needle-free (NF) or traditional injection methods (TMs) over two consecutive dental visits. **Methods**: This randomized, clinical crossover study involved 28 children aged 6 to 12 years who exhibited positive or absolute positive behavior according to the Frankl Behavior Scale and required dental anesthesia for bilateral operative procedures on their primary maxillary molars. The children were randomly assigned to receive both the NF and TM injections, for a total of 56 injections. Patients who underwent filling or pulpotomy treatment on a primary maxillary molar received anesthesia with both techniques at a one-week interval. At each visit and after the administration of anesthesia, the patients' pain levels were assessed using the Wong-Baker Faces Pain Rating Scale (Wong-Baker) and the Face, Legs, Activity, Cry, Consolability scale. The data were recorded, and statistical analyses were performed using paired *t*-tests or Wilcoxon nonparametric tests and Chi-square tests. Statistical significance was defined as a $p \leq 0.05$. **Results**: There was no significant difference between the NF system and the TM according to the Wong-Baker scores. However, there were significant differences in the amount of anesthetic solution and duration of the analgesic effect between the first and second visits for both injection methods, respectively ($p = 0.003$ for NF-TM and $p < 0.0001$ for the TM-NF groups). **Conclusions**: In this study, the NF system and the TM exhibited similar results when evaluated using different pain scales. However, the NF injection system may be a promising approach when working with uncooperative children. **Clinical Trial Registration**: ClinicalTrials.gov PRS ID: NCT06541925.

Keywords

Children; Comfort-in system; Needle injection; Needle-free injection; Pain

1. Introduction

Pain is a complex and multidimensional construct that involves sensory, emotional and cognitive processes. One of the most important aspects of child behavior management is pain control [1], and the most common method used to achieve pain control during dental procedures is the use of local anesthetics (LA) [2]. However, in dentistry, injecting local anesthesia is an anxiety-provoking procedure for both children and adult patients [3]. Understanding changes in pain-related behaviors between consecutive dental visits will help in planning and scheduling treatment procedures, as well as managing children in the dental clinic [4].

A number of methods and techniques have been proposed to minimize or reduce pain caused by the infiltration of LA agents. These methods include the application of topical anesthesia [5], pre-cooling the injection site [6] and applying pressure to the injection site [7]. Other techniques involve using lasers as a pretreatment method [8], buffering LA [9] and employing tactile stimulations [10]. Additional approaches include distraction techniques [11], computerized injection systems [12] and modern devices such as VibraJect [13], DentalVibe [14] or Aculief [15]. These methods have been the subject of trials to help alleviate the fears of pediatric patients; however, none of them have gained universal acceptance, and more situations and techniques need to be evaluated to improve stress management among patients in dental settings [13].

During the administration of a LA injection, an anxious patient may experience more severe and prolonged pain than a less anxious one [16]. From a visual and psychological perspective, the dental syringe is seen as a threatening instrument, especially by children [17]. The fear of pain caused by the needle has often been reported to be the most anxiety-provoking stimulus for children with dental anxiety [18]. Thus, a needle-free (NF) injection system can provide a higher level

of comfort by eliminating the puncture and injection phase, and it has emerged as a novel alternative to traditional needle-based techniques [19]. A recent dental device that administers local anesthesia using an NF injection technique is the Comfort-in™ system. This patented device uses a liquid jet system to rapidly inject the anesthetic solution from a 0.15-mm hole at high pressure [19]. Using this NF local anesthesia system in dentistry can help treat needle-phobic patients. However, to our knowledge, few studies have evaluated the efficacy of this new injection technique in the primary molars of children [20–23]. We believe pediatric patients are the target group for whom pain control should be adequately addressed. Therefore, the current study was designed to compare pediatric patients' pain perception during dental injections using the NF injection system with the traditional injection method (TM). In addition, secondary outcomes, including the dosage of LA used and the duration of the analgesia effect, were assessed. The expectation and hypothesis tested were that the NF method would result in a less painful injection and require a lower amount of LA solution during the dental procedure.

2. Materials and methods

2.1 Study design

This crossover, randomized clinical trial followed the Consolidated Standards of Reporting Trials (CONSORT) [24] guidelines. It was conducted at Marmara University, School of Dentistry, Department of Pediatric Dentistry clinics from January 2018 to January 2019. The study meets the standards established by the World Health Organization and the International Committee of Medical Journal Editors. The research protocol was reviewed and approved by the Clinical Research Ethics Committee of Marmara University Faculty of Medicine (number: 09.2017.280).

2.2 Study population

The minimum required sample size was determined based on a previous study [23] with a power of 0.90, a margin of error of 0.05, and an effect size of 0.68. Using G*Power (Ver: 3.1.9.4, Heinrich Heine University, Düsseldorf, Germany) software, it was determined that 25 participants were needed. To account for potential data loss during the study, 28 participants (10% more) aged 6 to 12 years of both genders who met the criteria were recruited for the study.

The inclusion criteria were children:

1. in good general health with no history of allergic reactions, as confirmed by a written history,
2. aged 6 to 12 years, who were in the mixed dentition stage,
3. not currently taking any analgesics or sedatives that would alter their pain perception,
4. with no prior experience of local anesthesia administration,
5. displaying either "positive" or "definitely positive" behavior based on the Frankl Behavior Scale (FBS),
6. requiring treatment for both maxillary primary molars with comparable operative challenges.

The exclusion criteria were:

1. the presence of any medical or developmental conditions,
2. a history of chronic disease,
3. a "negative" or "definitely negative" behavior rating on the FBS,
4. the presence of inflammation at the injection site.

2.3 Procedure

The study was conducted by two experienced pediatric dentists. One dentist provided all explanations, communicated with the children, administered the anesthesia, and performed the treatment (FE). Both dentists (FE and MSP) observed and assessed the children's pain perception during the anesthesia procedure. Parental consent was obtained before the procedure to ensure ethical guidelines were followed.

In this study's crossover design, children underwent both types of local anesthesia injections before undergoing filling or pulpotomy treatments on their maxillary primary molars. The treatments were conducted in two separate appointments, with a one-week interval between procedures. During the first appointment, the side of the dental arch (right or left) for the initial anesthesia administration was randomly determined, as well as the selection of the injection method (NF or TM). Each participant's administration type and sequence were randomly assigned using a coin toss (with block randomization). All maxillary primary molars included in the study had similar carious structures and were categorized as dentin caries. Therefore, the decision to proceed with a restorative filling or pulpotomy treatment was made during the dental procedure and based on clinical findings. After the administration of anesthesia at each visit, the patients' pain levels were assessed using the Wong-Baker Faces Pain Rating scale (Wong-Baker) and the Face, Legs, Activity, Cry, Consolability (FLACC) scale. All dental instruments were presented using the "tell-show-do" technique. A total of 56 procedures were conducted and categorized into two groups based on the anesthesia technique. Fig. 1 shows the CONSORT flow diagram of the study. To avoid the influence of positive or negative memories, none of the children had prior experience with local dental anesthesia.

2.3.1 Injection with the NF system

The Comfort-in™ anesthesia device (needle-free injection device, Mika Medical Global Co, Busan, Korea) (Fig. 2) was the NF system used in this study. This system has a micro-hole (0.15 mm) that injects an anesthetic solution under the mucosa. The pressure can be controlled according to the dose of the drug to be used, thereby reducing the pain that may occur with traditional needles. Before the injection, the children were introduced to the popping sound of the device to prevent reflex reactions and were told it would feel like a gentle pinch to their gum. The NF injection device was prepared following the manufacturer's instructions [19]. It was placed in full contact with the buccal gingiva, and a pre-measured dose of 0.1 mL was administered to the buccal region for topical use by pressing the top of the device. After 10–15 seconds, the procedure was repeated using a drawn dose of 0.3 mL. Five minutes after the treatment began, the children were instructed to raise their hand if they felt any pain during the procedure. Each time the child expressed pain, an additional 0.3 mL of

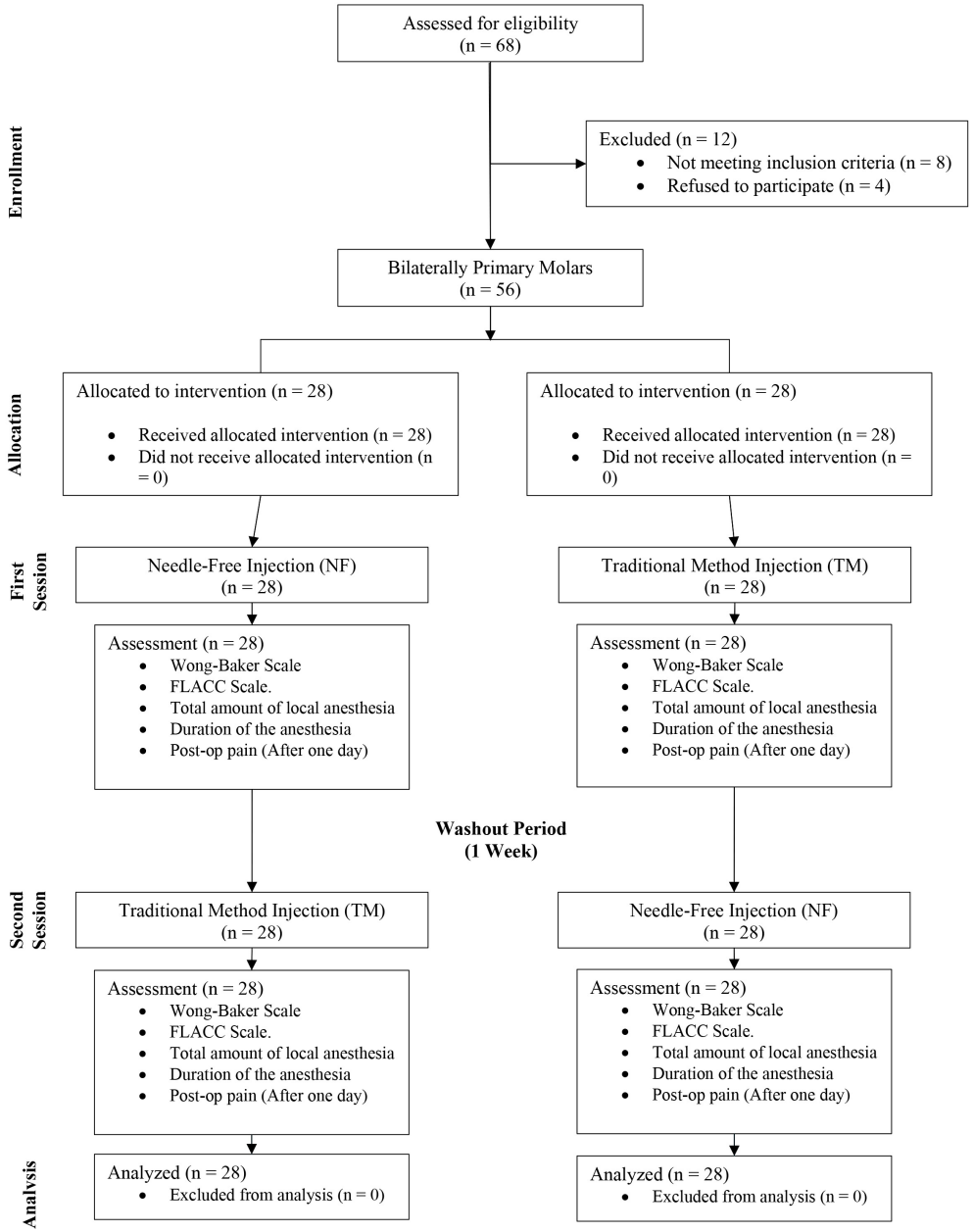

FIGURE 1. Consolidated standards of reporting trials flow diagram. FLACC: Face, Legs, Activity, Cry, Consolability.

FIGURE 2. Comfort-in injection system and its intraoral application.

anesthetic solution was administered according to the same protocol until a sufficient anesthetic effect was achieved. The final amount of anesthetic solution was recorded in milliliters (mLs). Precautions were taken to prevent tissue ballooning. After the treatment, the duration of the analgesic effect (in minutes) was recorded by monitoring the time from the administration of anesthesia until the sensation of numbness in the patient had subsided. The presence of postoperative pain was assessed via a phone call one day after the procedure, during which pain was evaluated verbally as either present or absent.

2.3.2 Injection using the TM

The TM was administered using a traditional syringe on the opposite side of the dental arch. The injection site was dried with a cotton-tip applicator, and topical anesthetic spray (batch number: 8699844510046, Lidocaine 10%, Vemcain, Tekirdag, Turkey) was applied to the area with a cotton-tip for 1–2 minutes. A traditional injection was then given using a 27-gauge, 40-mm disposable syringe with a needle (batch number: 8699931753479, Genject, İstanbul, Turkey). The penetration depth was only a few millimeters, and 0.3 mL of anesthetic solution was administered. After 5 minutes, the treatment began, and the children were instructed to raise their hand if they felt pain during the procedure. Each time a child expressed pain, an additional 0.3 mL of anesthetic solution was administered according to the same protocol until a sufficient anesthetic effect was achieved. The final amount of anesthetic solution was recorded in mLs. Precautions were taken to prevent tissue ballooning. After the treatment, the duration of the analgesic effect (in minutes) was recorded by monitoring the time from the administration of anesthesia until the sensation of numbness had subsided. The presence of postoperative pain was assessed through a phone call one day after the procedure, during which the pain was evaluated verbally as either present or absent.

Both the NF and TM anesthesia techniques were performed with 4% articaine hydrochloride and 1:100,000 epinephrine (Ultracaine D-S; Hoechst Canada Inc., Montreal, QC, Canada) as the anesthetic agent. When administering local anesthesia in children, the maximum dose of local anesthesia was calculated using weight-based dosing to minimize the risk of systemic toxicity.

2.3.3 The Wong-Baker assessment

Pain levels were subjectively assessed using the Wong-Baker scale [25], which evaluates the unpleasantness or emotional aspect of a child's pain experience. The scale includes a series of cartoon faces displaying different expressions, from smiling/laughing to crying, and each child is asked to choose the face that best represents their level of discomfort. Each face is assigned a numerical value from 0 (smiling, "no hurt") to 5 (crying/screaming, "hurts the most"). This scale was carefully explained to the children beforehand. Immediately following each injection, the children were asked to rate the pain they experienced using the Wong-Baker scale.

2.3.4 The FLACC assessment

Pain level was also evaluated using the FLACC scale [26]. This assesses five categories: face, legs, activity, cry and consolability. Each category is scored as 0, 1 or 2, resulting in a total score ranging from a minimum of 0 to a maximum of 10. Based on this scale, 0 indicates quiet and relaxed (no pain), 1–3 signifies mild discomfort or pain, 4–6 represents moderate pain and 7–10 indicates severe pain.

2.4 Data collection

A structured form was designed to collect information regarding the patient's age, gender, injected tooth number, type of dental treatment (filling or pulpotomy), the total amount of LA used, the duration of the analgesia effect, the postoperative pain (after one day), the Wong-Baker score after injection, and the FLACC score during injection.

2.5 Statistical analysis

The data were analyzed using SPSS software (2024 trial version, IBM SPSS Statistics, Armonk, NY, USA). Paired *t*-tests or Wilcoxon nonparametric tests were used to compare data within groups over the two time periods based on whether the data was normally distributed. The Chi-square test was used to compare discrete random variables. Spearman's Rho correlation coefficient was used to find relationships between continuous variables. A p-value ≤ 0.05 was considered statistically significant.

3. Results

A total of 28 children, 18 girls (64.3%) and ten boys (35.7%), aged between 6–12 years participated in the study. The mean age was 8.07 years, with a standard deviation of 1.41 years. At the end of this study, a total of 56 injections were administered to 28 children, with 28 NF injections and 28 TM injections.

In the study, when the distributions of the parameters (gender, type of dental treatment, type of teeth and postoperative pain) were evaluated according to the type of injection technique, we found no statistically significant difference between the groups (Table 1).

The group that received the NF system on the first visit and the TM on the second is designated as the NF-TM group, while those who received the TM on the first visit and the NF system on the second is referred to as the TM-NF group. As shown in Table 2, the Wong-Baker scores in the NF-TM group were 4.44 ± 3.28 and 1.55 ± 0.88, respectively. In contrast, in the TM-NF group, the Wong-Baker scores were 1.68 ± 1.91 and 2.52 ± 2.56, respectively. In both cases, regardless of the method of anesthesia applied first, no significant difference was found between the groups. For the FLACC scores, a significant difference was observed in the TM-NF group ($p = 0.025$), while for the NF-TM group, no significant difference was observed ($p = 0.141$). There were significant differences in the amount of anesthetic solution and the duration of the analgesia effect between the first and second visits for both injection methods, respectively ($p = 0.003$ for NF-TM and $p < 0.0001$ for the TM-NF groups). The anesthetic solution used for the first NF injection visit was 0.91 ± 0.48 mL. For the second NF injection visit, it was 0.65 ± 0.30 mL. These amounts were statistically lower than the anesthetic solution needed for the TM injections during both visits. In the first

TABLE 1. Distribution of injection techniques based on evaluation parameters.

Variables	Needle Free (NF) n	Traditional Method (TM) n	Total	*p*
Gender				
Girl	18	18	36	1.000
Boy	10	10	20	
Type of dental treatment				
Filling	22	14	36	0.051
Pulpotomy	6	14	20	
Type of teeth injected				
1st primary molar	12	7	19	0.259
2nd primary molar	16	21	37	
Post-op pain (after one day)				
Pain	5	7	12	0.746
No pain	23	21	44	

The Chi-square test (χ^2-test) was also used to compare discrete random variables.

TABLE 2. Comparison of the 1st visit and 2nd visit measurements for continuous random variables in needle free-traditional method and traditional method-needle free.

	1st visit	2nd visit	*p*
Wong-Baker (WB) Scores			
Needle Free-Traditional Method	4.44 ± 3.28	1.55 ± 0.88	0.056
Traditional Method-Needle Free	1.68 ± 1.91	2.52 ± 2.56	0.119
FLAAC			
Needle Free-Traditional Method	0.78 ± 1.09	0.11 ± 0.33	0.141
Traditional Method-Needle Free	0.21 ± 0.41	0.68 ± 0.67	**0.025**
Amount of Anesthetic Solution (mL)			
Needle Free-Traditional Method	0.91 ± 0.48	1.62 ± 0.38	**0.003**
Traditional Method-Needle Free	1.37 ± 0.42	0.65 ± 0.30	<**0.0001**
Duration of the Analgesia Effect (min)			
Needle Free-Traditional Method	85.00 ± 39.05	130.00 ± 50.74	**0.001**
Traditional Method-Needle Free	140.00 ± 59.97	90.26 ± 43.25	<**0.001**

Paired t-test was used.
Values with a p-value ≤ 0.05 are presented in bold.
Needle Free-Traditional Method group: 1st visit Needle Free and 2nd visit Traditional Method was used of injection.
Traditional Method-Needle Free group: 1st visit Traditional Method and 2nd visit Needle Free was used of injection.
FLACC: Face, Legs, Activity, Cry, Consolability.

visit, the mean duration of the analgesia effect in the NF group was 85.00 ± 39.05 min, whereas in the second visit, it was 90.26 ± 43.25 min. In the TM group, the mean anesthesia duration for the first and second visits was 140.00 ± 59.97 min and 130.00 ± 50.74 min, respectively. Regardless of the visit in which it was first applied, the duration of the analgesia effect in the NF group was significantly shorter than in the TM group ($p < 0.001$).

When the first and second visits were evaluated, the Wong-Baker and FLACC scores were higher in the NF group compared to the TM group in both visits (Figs. 3,4). Additionally, the amount of anesthetic solution and duration of the analgesia effect were lower in the NF group compared to the TM group in both visits (Figs. 5,6).

The effects of gender differences on the Wong-Baker and FLACC scores for NF and TM injections administered in different sequences over two sessions were also evaluated. In our analysis, we found no significant differences between the groups (Table 3). We also evaluated the effect of the type and sequence of restorations (filling-filling, filling-pulpotomy, pulpotomy-filling) on the Wong-Baker and FLACC scores for NF and TM injections administered in different sequences over

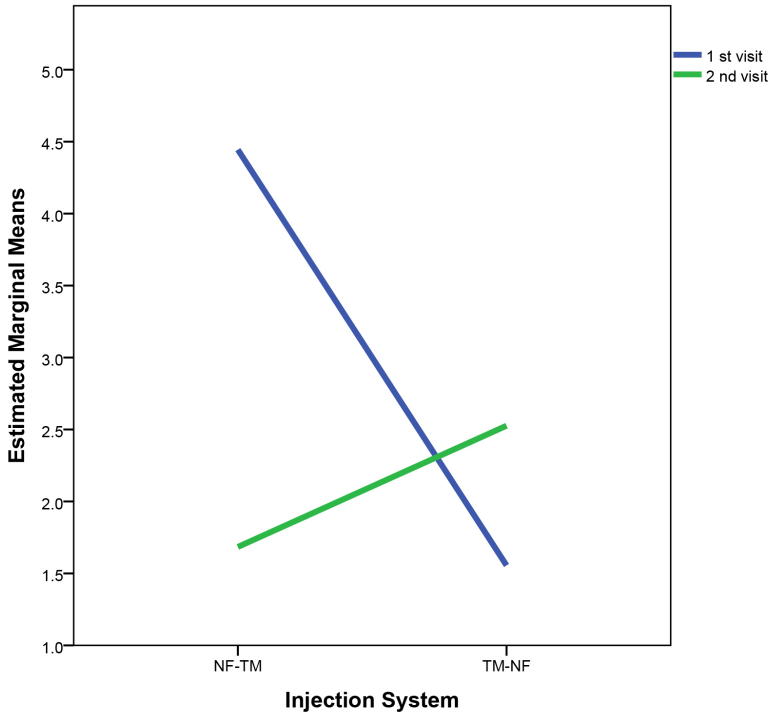

FIGURE 3. Changes in Wong-Baker scores for Needle Free (NF) and Traditional Method (TM) injection methods between the 1st and 2nd visits. The blue line represents the 1st visit, while the green line represents the 2nd visit. NF-TM represents: 1st visit Needle Free and 2nd visit Traditional Method. TM-NF represents: 1st visit Traditional Method and 2nd visit Needle Free.

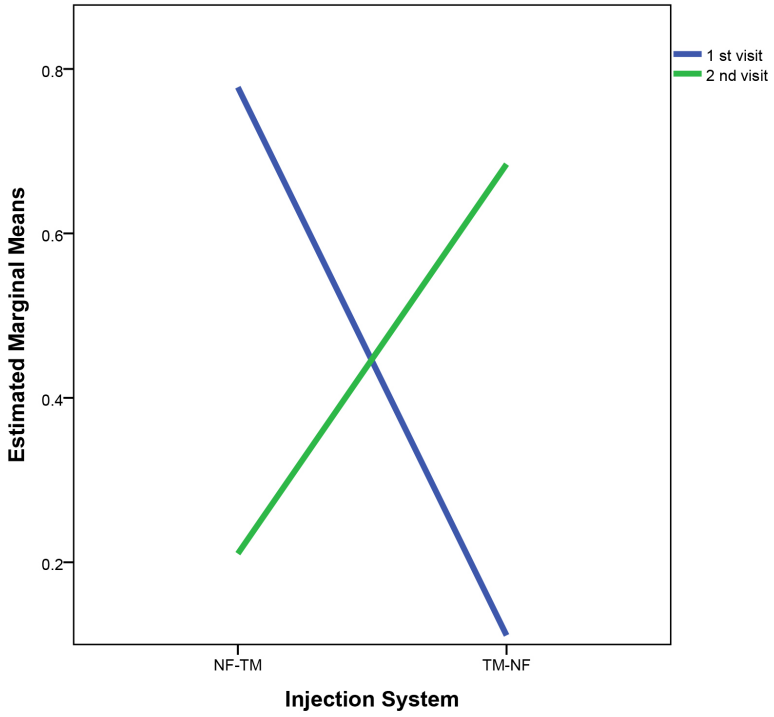

FIGURE 4. Changes in FLACC scores for Needle Free and Traditional Method injections between the 1st and 2nd visits. The blue line represents the 1st visit, while the green line represents the 2nd visit. NF-TM represents: 1st visit Needle Free and 2nd visit Traditional Method. TM-NF represents: 1st visit Traditional Method and 2nd visit Needle Free. NF: Needle Free; TM: Traditional Method.

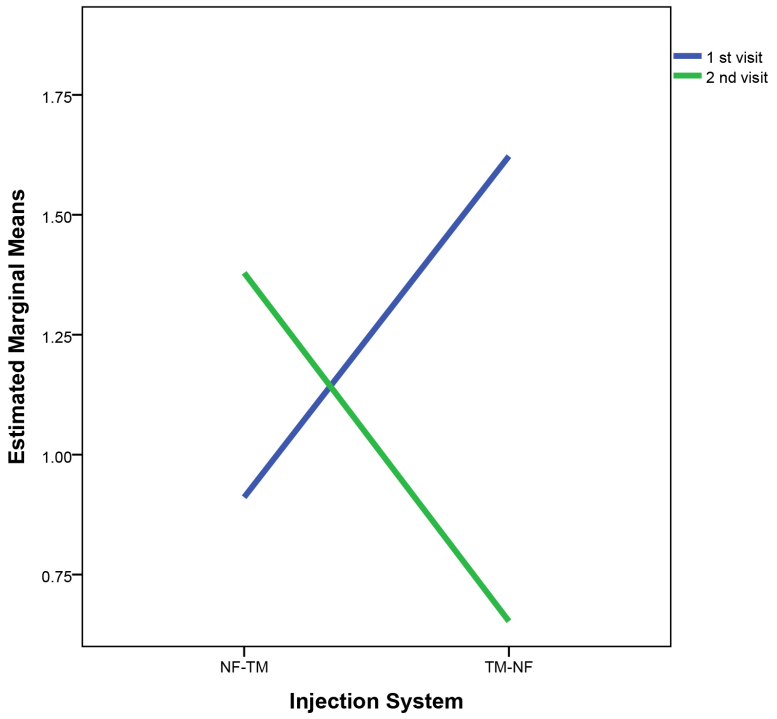

FIGURE 5. Changes in amount of anesthetic solution (mL) for needle free and traditional method injections between the 1st and 2nd visits. The blue line represents the 1st visit, while the green line represents the 2nd visit. NF-TM represents: 1st visit Needle Free and 2nd visit Traditional Method. TM-NF represents: 1st visit Traditional Method and 2nd visit Needle Free. NF: Needle Free; TM: Traditional Method.

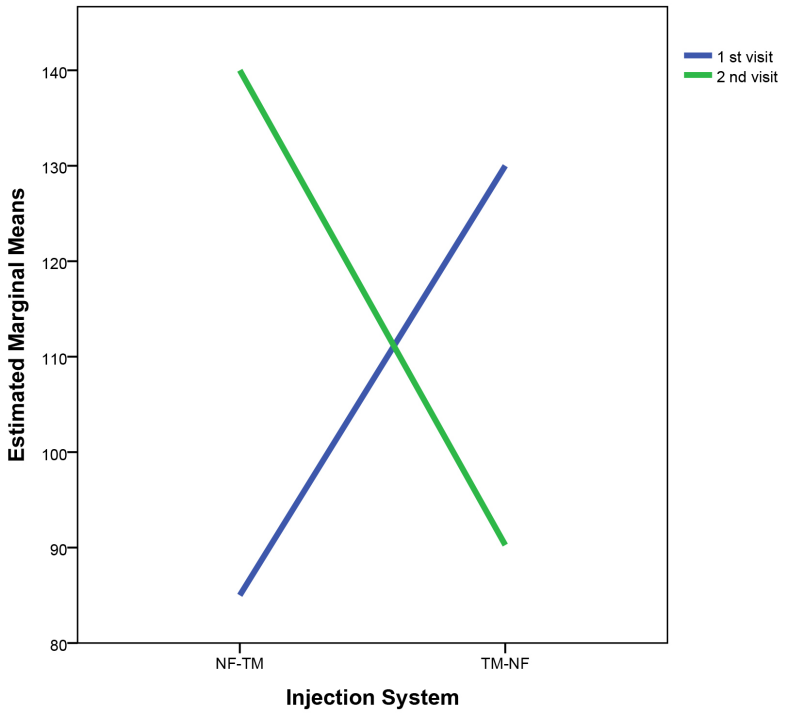

FIGURE 6. Changes in duration of the analgesia effect (min) for needle free and traditional method injections between the 1st and 2nd visits. The blue line represents the 1st visit, while the green line represents the 2nd visit. NF-TM represents: 1st visit Needle Free and 2nd visit Traditional Method. TM-NF represents: 1st visit Traditional Method and 2nd visit Needle Free. NF: Needle Free; TM: Traditional Method.

TABLE 3. Wong-Baker and FLACC scores in Needle Free-Traditional Method and Traditional Method-Needle Free groups based on gender.

Gender	Needle Free-Traditional Method Group		*p*	Gender	Traditional Method-Needle Free Group		*p*
	1st visit Needle Free	2nd visit Traditional Method			1st visit Traditional Method	2nd visit Needle Free	
Wong-Baker							
Girl, N = 6	4.1, (1.500–8.500)	2, (0–2.000)	0.141	Girl, N = 12	2, (0.500–2.000)	1, (0–3.500)	0.558
Boy, N = 3	4.1, (2.000–4.000)	2, (2.0–2.000)	0.180	Boy, N = 7	0, (0–4.000)	2, (2.000–4.000)	0.059
FLACC							
Girl, N = 6	0, (0–1.500)	0, (0–0.250)	0.414	Girl, N = 12	0, (0–0)	0.5, (0–1.000)	0.053
Boy, N = 3	1, (0–1.000)	0, (0–0)	0.180	Boy, N = 7	0, (0–1.000)	1, (0–1.000)	0.317

Wilcoxon nonparametric test was used.
Needle Free-Traditional Method group: 1st visit Needle Free and 2nd visit Traditional Method was used for injection.
Traditional Method-Needle Free group: 1st visit Traditional Method and 2nd visit Needle Free was used for injection.
The values are presented as Median, (Inter Quartile Range).
FLACC: Face, Legs, Activity, Cry, Consolability.

two sessions. Our results found no significant differences between the groups (Table 4).

Whether the type and sequence of different restorations administered in different sequences over two sessions with NF and TM injections resulted in any differences in the amount of anesthetic solution used is shown in Table 5. There was a significant difference in the amount of anesthetic solution used in the TM-NF group, the group that received fillings in both the first and second sessions, and the group that received pulpotomy in the first session and a filling in the second session. A significantly lower amount of anesthetic solution was used with the NF injection system in both groups (Table 5).

According to the Spearman's Rho correlation coefficient test, no correlation was found between age and Wong-Baker scores, FLACC scores, or the amount of anesthetic solution administered ($p = 0.830$, $p = 0.436$ and $p = 0.976$, respectively). Similarly, no correlation was found between Wong-Baker scores and the amount of anesthetic solution administered ($p = 0.537$) and Wong-Baker scores and the duration of the analgesia effect ($p = 0.468$). However, a negative correlation was found between the FLACC score and the amount of anesthetic solution ($p = 0.033$). Moreover, a positive correlation was found between the FLACC scores and Wong-Baker scores and between the dosage administered and the duration of the analgesia effect ($p < 0.001$, $p = 0.009$, respectively).

4. Discussion

This study compared an NF injection system (Comfort-in™) with the traditional syringe injection technique in terms of pain during buccal infiltration injections for the treatment of maxillary primary molars in pediatric patients. Few studies have compared pain perception between TMs and NF injection systems (such as Comfort-in) during primary molar treatment in children [20, 22, 23]. Moreover, this is the first crossover clinical trial to assess both TMs and NF injection systems (Comfort-in) in terms of measuring the amount of anesthetic solution needed for painless treatment in primary molars, evaluating postoperative pain one day after the procedure, and measuring the duration of anesthesia within the same study design.

A child's response to dental treatment is complex, influenced by factors such as age, temperament, anxiety levels, parental anxiety and previous dental experiences [27]. To minimize the effects of previous negative dental experiences and varying anxiety levels, our study focused on children who had not received local anesthesia before and exhibited either "positive" or "definitely positive" behavior according to the FBS. The measurement of pain as an absolute value is challenging as it differs between individuals based on their age, developmental level, cognitive and communication skills, previous pain experiences, cultural beliefs and norms, fear and anxiety [28]. Self-reported scales are frequently used to measure pain in children. Among the various tools available to assess pediatric pain severity are facial expression drawings [20–23, 29]. The visual analog scale (VAS) is the most commonly used tool in acute pain research due to its ease of administration and validation in adults and older children [30]. However, it has been reported that only one-third of children between the ages of 5 to 14 years comprehend the VAS for pain assessment. Additionally, it has been observed that children who understand the VAS are older than those who do not, with an age difference between 5–10 years and 11–14 years [31]. In contrast, the Wong-Baker scale is effective in subjective pain assessment and can differentiate between pain and fear in school-aged children [30]. The FLACC behavioral scale includes various behavioral categories and descriptors that have been consistently linked to pain in both young and older children. It is considered reliable and sensitive for assessing procedural pain in children [32].

TABLE 4. Wong-Baker and FLACC Scores in Needle Free-Traditional Method and Traditional Method-Needle Free groups based on type of dental treatment.

Type of Dental Treatment	Needle Free-Traditional Method Group		*p*	Type of Dental Treatment	Traditional Method-Needle Free Group		*p*
	1st visit Needle Free	2nd visit Traditional Method			1st visit Traditional Method	2nd visit Needle Free	
Wong-Baker							
Filling-Filling, N = 4	7, (3.000–9.500)	2, (0.500–2.000)	0.109	Filling-Filling, N = 8	2, (0.500–2.000)	2, (0.500–5.500)	0.167
Filling-Pulpotomy, N = 3	4, (2.000–4.000)	2, (0–2.000)	0.180	Filling-Pulpotomy, N = 2	0, (0–0)	1, (0–1.000)	0.317
Pulpotomy-Filling, N = 2	1, (0–1.000)	2, (2.000–2.000)	0.317	Pulpotomy-Filling, N = 9	2, (0–3.000)	2, (0–4.000)	0.655
FLACC							
Filling-Filling, N = 4	0.5, (0–2.500)	0, (0–0)	0.180	Filling-Filling, N = 8	0, (0–0)	1, (0–1)	0.096
Filling-Pulpotomy, N = 3	1, (0–1.000)	0, (0–0)	0.180	Filling-Pulpotomy, N = 2	0, (0–0)	0.5, (0–0.500)	0.317
Pulpotomy-Filling, N = 2	0, (0–0)	0.5, (0–0.500)	0.317	Pulpotomy-Filling, N = 9	0, (0–1.000)	1, (0–1.000)	0.257

Wilcoxon nonparametric test was used.
Needle Free-Traditional Method group: 1st visit Needle Free and 2nd visit Traditional Method was used for injection.
Traditional Method-Needle Free group: 1st visit Traditional Method and 2nd visit Needle Free was used for injection.
The values are presented as Median, (Inter Quartile Range).
Filling-Filling group: 1st visit filling and 2nd visit filling restoration have been done.
Filling-Pulpotomy group: 1st visit filling and 2nd visit pulpotomy restoration have been done.
Pulpotomy-Filling group: 1st visit pulpotomy and 2nd visit filling restoration have been done.

TABLE 5. Amount of anesthetic solution (mL) in Needle Free-Traditional Method and Traditional Method-Needle Free groups based on type of dental treatment.

Type of Dental Treatment	Needle Free-Traditional Method Group		*p*	Type of Dental Treatment	Traditional Method-Needle Free Group		*p*
	1st visit Needle Free	2nd visit Traditional Method			1st visit Traditional Method	2nd visit Needle Free	
Amount of Anesthetic Solution (mL)							
Filling-Filling, N = 4	0.65, (0.325–1.125)	1.3, (1.050–1.850)	0.068	Filling-Filling, N = 8	1.1, (1.000–1.850)	0.55, (0.325–0.900)	0.012
Filling-Pulpotomy, N = 3	0.9, (0.300–0.900)	2, (1.500–2.000)	0.180	Filling-Pulpotomy, N = 2	1.4, (1.300–1.400)	1, (1.000–1.000)	0.180
Pulpotomy-Filling, N = 2	1.35, (1.200–1.350)	1.75, (1.500–1.750)	0.180	Pulpotomy-Filling, N = 9	1.5, (1.100–1.850)	0.6, (0.300–0.900)	0.008

Wilcoxon nonparametric test was used.
Needle Free-Traditional Method group: 1st visit Needle Free and 2nd visit Traditional Method was used for injection.
Traditional Method-Needle Free group: 1st visit Traditional Method and 2nd visit Needle Free was used for injection.
The values are presented as Median, (Inter Quartile Range).
Filling-filling group: 1st visit filling and 2nd visit filling restoration have been done.
Filling-Pulpotomy group: 1st visit filling and 2nd visit pulpotomy restoration have been done.
Pulpotomy-Filling group: 1st visit pulpotomy and 2nd visit filling restoration have been done.

The purpose of this study was to assess and compare pain perception rates in pediatric patients using these two scales. Specifically, we aimed to investigate whether the order of NF and TM injection administration would result in pain score changes. Using a crossover design, patients were evaluated separately based on whether they were in the NF-TM or the TM-NF group. The crossover design was preferred as it reduces subject variability and enhances biological homogeneity. We rejected our hypothesis that the NF anesthesia method would lead to lower pain experiences. However, we confirmed that lower amounts of anesthetic solution were needed during the dental procedures that used the NF anesthesia method.

A review of the literature comparing various NF systems and TMs found no consensus on the relative pain levels associated with different types of injections used for administering anesthesia. A study assessing pain during the administration of NF (Comfort-in) versus conventional anesthesia in adult patients with symptomatic irreversible pulpitis concluded that patients in the Comfort-in group reported significantly less pain during the anesthesia application compared to those in the conventional group [33]. Another clinical study evaluated the effectiveness and patient preference of an NF system versus traditional anesthesia (TA) on pain perception during palatal injection anesthesia (PIA) in children and reported significant differences between TA and the NF system based on Wong-Baker and FLACC scale scores, with the TA group experiencing significantly higher pain ratings during PIA [23]. Conversely, a 2022 study evaluated the effect of NF dental anesthesia compared to intraosseous anesthesia on injection pain for inferior alveolar nerve blocks in children aged 8 to 10 years. The study concluded that both injection methods resulted in similar pain perception during the application of local anesthesia [21]. Similarly, in another recent study, the pain perception of the NF and dental needle injection system in children requiring infiltration anesthesia was evaluated. Pain scores were assessed using the Wong-Baker scale postinjection, during treatment and posttreatment. After the study, the authors reported an average pain score of 4.128 ± 2.779 for the NF system and 3.957 ± 3.131 for the dental needle during injection, suggesting no significant difference in perceived pain between the two methods [22]. Pain perception was also evaluated in children aged 4 to 11 years undergoing filling and pulpotomy treatments using NF (Comfort-in) and traditional dental needle anesthesia. The study reported no significant difference in treatment and posttreatment Wong-Baker pain scores between the needle and NF groups for both types of treatment [20]. Similarly, in our study, we compared the pain values of NF and traditional anesthesia administered before filling and pulpotomy treatments. We found no significant difference in the Wong-Baker scores between the two groups, regardless of the order in which the anesthesia was applied.

Recent studies have also used the FLACC scale to rate behavior in children during dental anesthesia administration [20, 23, 29]. In the present study, while there was no significant difference in Wong-Baker pain scores between the two groups, in the TM-NF group, FLACC scores were significantly higher during the NF anesthesia visit. This may be due to the sudden pressure and noise produced during the discharge of the Comfort-in system solution. As a result, this may have caused high scores on the FLACC test, which subjectively evaluates children's face, legs, activity, cry and consolability parameters during anesthesia.

The present study has demonstrated the efficacy of the NF injection technique, with lower amounts of anesthetic solution as a practical alternative to TM for dental treatment in children. However, the use of a reduced amount of anesthetic solution also shortens the duration of anesthesia in patients. The mean duration of anesthesia was significantly shorter with the NF system than with the TM in the present study; however, the NF technique provided an acceptable success rate. Moreover, self-inflicted injury depends on the duration of local anesthesia. The use of short-acting LA reduces the risk of lip and cheek biting, and long-acting LA are not recommended for children as the prolonged effect increases the risk of soft-tissue injury. The type of administration method affects the frequency of postprocedural adverse events, the most common of which is self-inflicted trauma. The ability of children to successfully cope with soft-tissue numbness may increase with age, resulting in reduced accidental lip/cheek injuries, even with longer-lasting soft-tissue anesthesia [34].

The effects of NF and dental needle anesthesia on pain perception and dental anxiety were compared in a study that reported similar results in both groups for "pain on postoperative 1st-day" values. In the same study, it was also reported that the level of posttreatment pain may vary depending on several factors, including the type of treatment, the extent of tissue damage, and the duration of the numbness sensation. The authors explained that Comfort-in can cause tissue injury and hemorrhage due to the high pressure during administration. However, the comparable outcomes with needle anesthesia may be attributed to children's capacity to tolerate these injuries and bleeding [22]. In the present study, and similar to the previous research, postoperative pain one day after the procedure was similar for both anesthesia methods. In another recent study, it was observed that treatment and posttreatment pain values recorded for patients undergoing filling and pulpotomy procedures exhibited no significant difference between the needle and NF groups [20]. Similarly, in our research comparing NF-TM and TM-NF groups, despite filling and pulpotomy treatments being performed in different sequences, we found no significant differences in the Wong-Baker and FLACC values.

A literature review uncovered only one study that compared the effectiveness of NF (Comfort-in) and needle injection in children undergoing filling and pulpotomy treatments, with a focus on the amount of anesthetic solution. It was reported that the application of 0.3 mL of anesthetic solution using the NF method for filling and pulpotomy was as effective as infiltrative anesthesia using TMs [20]. However, no study comparing the amount of anesthetic solution and the duration of the anesthetic effect for both injection methods was found. In the current study, the amount of anesthetic solution used in the NF-TM and TM-NF groups was comparatively evaluated during pulpotomy and filling treatments. Significantly higher amounts of solution were used when filling was performed after TM anesthesia in the first session compared to when filling was performed after NF anesthesia in the second session. Similarly, significantly higher amounts of solution were

used when a pulpotomy was performed after TM anesthesia in the first session than when filling was performed after NF anesthesia in the second session. The idea that a higher amount of solution may have been used for pulpotomy compared to filling is reasonable, given that pulpotomy treatment involves the pulp tissue. However, in both sessions where filling treatments were performed, the use of a lower dose of LA solution with NF injections compared to the TM can be explained by the mechanism of the Comfort-in system, which uses a small, high-pressure stream of anesthetic solution that penetrates the oral mucosa and delivers the solution into the underlying tissue. We believe that, with the submucosal delivery system, a lower amount of solution may be sufficient to achieve local anesthesia compared to the needle anesthesia method.

The study has limitations, including a lack of comparison between the injection systems in terms of patient preferences and the absence of physiological or biological markers to evaluate pain perception during injection. Another limitation is that it was not possible to keep the participants blinded to the method used during the local anesthesia application. Furthermore, there was a limited population in each group when assessing the effect of pain scores by gender/type of restoration or the amount of anesthetic solution used in relation to the type of restoration when evaluated according to the order of administering NF and TM injections. However, the results of this study remain significant in providing tendency and insight.

Successful anesthesia is a technique dependent on a number of factors that can be related to either the patient or the operator. The results of the present study raise questions concerning the effectiveness of the NF injection system in less cooperative children. Therefore, further research on pediatric patients with varying levels of cooperation is recommended.

5. Conclusions

Children experienced similar levels of pain with the NF system and TM. However, we also showed that the NF injection system is a promising approach to use with uncooperative children. Further research is recommended to explore the effect of the NF system on pediatric patients with varying levels of cooperation.

AVAILABILITY OF DATA AND MATERIALS

Data will be available on request.

AUTHOR CONTRIBUTIONS

FE, MSP, BK—hypothesis and experimental design. FE, MSP—performed the experiments. GNB, EGO—analysed the data. FE, BK—wrote, review and editing 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

The research protocol for the study was reviewed and approved by the Clinical Research Ethics Committee of Marmara University Faculty of Medicine (number: 09.2017.280) and registered at ClinicalTrials.gov (NCT06541925). The study was performed in accordance with the Declaration of Helsinki (1964) and detailed informed written consent form was signed by each patient's parents or guardian, who participated in this study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

[1] McDonald RE, Avery DR, Dean JA. Local anesthesia and pain control for the child and adolescent. In McDonald RE, Avery DR, Dean JA (eds.) Dentistry for the child and adolescent (p. 272). 8th edn. CV Mosby Inc.: St. Louis, MO. 2004.

[2] Bahl R. Local anesthesia in dentistry. Anesthesia Progress. 2004; 51: 138–142.

[3] Lee SH, Lee NY. An alternative local anaesthesia technique to reduce pain in paediatric patients during needle insertion. European Journal of Paediatric Dentistry. 2013; 14: 109–112.

[4] Thoppe-Dhamodhara YK, Asokan S, John BJ, Pollachi-Ramakrishnan G, Ramachandran P, Vilvanathan P. Cartridge syringe *vs* computer controlled local anesthetic delivery system: pain related behaviour over two sequential visits—a randomized controlled trial. Journal of Clinical and Experimental Dentistry. 2015; 7: 513–518.

[5] Meechan JG. Effective topical anesthetic agents and techniques. Dental Clinics of North America. 2002; 46: 759–766.

[6] Amrollahi N, Rastghalam N, Faghihian R. Effect of pre-cooling on pain associated with dental injections in children: a systematic review. The Journal of Evidence-Based Dental Practice. 2021; 21: 101588.

[7] Kravitz J. The palatal press and roll anesthesia technique. Practical Procedures & Aesthetic Dentistry. 2006; 18: 242, 244–245.

[8] Uçar G, Şermet Elbay Ü, Elbay M. Effects of low level laser therapy on injection pain and anesthesia efficacy during local anesthesia in children: a randomized clinical trial. International Journal of Paediatric Dentistry. 2022; 32: 576–584.

[9] Valiulla MUE, Halli R, Khandelwal S, Mittal A, Singh A, Bhindora K. Efficacy of sodium bicarbonate-buffered local anesthetic oslution in cases requiring bilateral maxillary premolar orthodontic extraction: a comparative split-mouth study. Cureus. 2023; 15: e37934.

[10] Taddio A, Ho T, Vyas C, Thivakaran S, Jamal A, Ilersich AF, *et al*. A randomized controlled trial of clinician-led tactile stimulation to reduce pain during vaccination in infants. Clinical Pediatrics. 2014; 53: 639–644.

[11] Felemban OM, Alshamrani RM, Aljeddawi DH, Bagher SM. Effect of virtual reality distraction on pain and anxiety during infiltration anesthesia in pediatric patients: a randomized clinical trial. BMC Oral Health. 2021; 21: 321.

[12] Mittal M, Kumar A, Srivastava D, Sharma P, Sharma S. Pain perception:

computerized versus traditional local anesthesia in pediatric patients. Journal of Clinical Pediatric Dentistry. 2015; 39: 470–474.

[13] Albouni MA, Kouchaji C, Al-Akkad M, Voborna I, Mounajjed R. Evaluation of the injection pain with the use of vibraject during local anesthesia injection for children: a randomized clinical trial. The Journal of Contemporary Dental Practice. 2022; 23: 749–754.

[14] Felemban, AR Oghli, II Alsaati, LK Alattas, AM Olwi, SM Bagher. The effect of DentalVibe on pain and discomfort during local anesthesia in children: a randomized clinical trial. Quintessence International. 2021; 52: 434–443.

[15] Pushpasanthy M, Ephraim R, Ayilliath A, Dhanya KB. Effectiveness of Aculief acupressure device on pain perception during local anesthesia in children: a double-blinded study. Journal of the Indian Society of Pedodontics and Preventive Dentistry. 2023; 41: 309–315.

[16] Prabhakar AR, Marwah N, Raju OS. A comparison between audio and audiovisual distraction techniques in managing anxious pediatric dental patients. Journal of the Indian Society of Pedodontics and Preventive Dentistry. 2007; 25: 177–182.

[17] Melwani AM, Srinivasan I, Setty JV, D R MK, Pamnani SS, Lalitya D. A clinical comparative study between conventional and camouflaged syringes to evaluate behavior and anxiety in 6–11-year-old children during local anesthesia administration-a novel approach. Journal of Dental Anesthasia and Pain Medicine. 2018; 18: 35–40.

[18] Porritt J, Marshman Z, Rodd HD. Understanding children's dental anxiety and psychological approaches to its reduction. International Journal of Paediatric Dentistry. 2012; 22: 397–405.

[19] MK global. No needle for soft injection. Your best solution, Comfort-in™ needle free & easy-quick injection system. 2017. Available at: http://www.comfort-in.com/html/download/Catalogue2017.pdf (Accessed: 22 January 2017).

[20] Altan H, Belevcikli M, Coşgun A, Demir O. Comparative evaluation of pain perception with a new needle-free system and dental needle method in children: a randomized clinical trial. BMC Anesthesiology. 2021; 21: 301.

[21] Yilmaz N, Baygin O, Tüzüner T, Menteşe A, Demir S. Determination of the effect of two different methods of dental anesthesia on pain level in pediatric patients: a cross-over, randomized trial. Nigerian Journal of Clinical Practice. 2022; 25: 1853–1863.

[22] Belevcikli M, Altan H, Demir O. Effect of the new needle-free injection system on pain perception and dental anxiety during anesthesia: randomized controlled split-mouth study. Journal of Dental Anesthesia and Pain Medicine. 2023; 23: 1–8.

[23] Kaya E, Yıldırım S. Effect of a needle-free system versus traditional anesthesia on pain perception during palatal injections in children. International Journal of Paediatric Dentistry. 2023; 33: 132–140.

[24] Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Journal of Pharmacology & Pharmacotherapeutics. 2010; 1: 100–107.

[25] Wong DL, Baker CM. Pain in children: comparison of assessment scales. Pediatric Nursing. 1988; 14: 9–17.

[26] Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: a behavioral scale for scoring postoperative pain in young children. Pediatr Nursing. 1997; 23: 293–297.

[27] Klingberg G, Broberg A. Temperament and child dental fear. Pediatric Dentistry. 1998; 20: 237–243.

[28] O'Rourke D. The measurement of pain in infants, children, and adolescents: from policy to practice. Physical Therapy. 2004; 84: 560–570.

[29] Yıldırım S, Tokuç M, Aydın MN. The effect of pre-anesthesia with a needle-free system versus topical anesthesia on injection pain of the inferior alveolar nerve block: a randomized clinical trial. Clinical Oral Investigation. 2020; 24: 4355–4361.

[30] Garra G, Singer AJ, Taira BR, Chohan J, Cardoz H, Chisena E, *et al*. Validation of the Wong-Baker FACES Pain Rating Scale in pediatric emergency department patients. Academic Emergency Medicine. 2010; 17: 50–54.

[31] Shields BJ, Cohen DM, Harbeck-Weber C, Powers JD, Smith GA. Pediatric pain measurement using a visual analogue scale: a comparison of two teaching methods. Clinical Pediatrics. 2003; 42: 227–234.

[32] Crellin DJ, Harrison D, Santamaria N, Huque H, Babl FE. The Psychometric properties of the FLACC scale used to assess procedural pain. The Journal of Pain. 2018; 19: 862–872.

[33] Nogueira APA, Ferreira MC, Maia CCR, Gonçalves BLL, Filho EM, Costa CP, *et al*. Efficacy of articaine anesthesia with needle-free/Comfort-in method and conventional needle injection in dental patients with irreversible pulpitis: a randomized clinical trial. Clinical Oral Investigation. 2024; 28: 205.

[34] Council on Clinical Affairs, American Academy of Pediatric Dentistry. Guideline on use of local anesthesia for pediatric dental patients. Pediatric Dentistry. 2015; 37: 71–77.

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