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Original Article

Assessment of Pain Perception and Soft Tissue Reaction after Local Anesthetic Injection Using Needleless versus Needle Systems: Randomized Clinical Trial

Ayatallah ElSayed Bassiouny[1] , Manal A. ElSayed[1] , Rasha A. Ragab[1]

Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University.

Email: ayatallah_elsayed@dentistry.cu.edu.eg

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Abstract

Aim: The aim was to assess the impact of needleless injection (comfort in jet) on pain perception and its influence on the nearby oral mucosa and soft tissue, in comparison to the traditional needle injection technique during local anesthesia administration in children undergoing dental extraction.

Methodology: A total of 60 children aged 6 to 8 undergo dental extraction for at least one tooth. These children were randomly divided into two equal groups: intervention (needleless injection) or control group (needle injection). The primary outcome was to assess the self-perception of pain during injection. While secondary outcomes were assessing the child behavior using modified venham picture test scale, anesthesia onset and duration, anesthesia action, and effectiveness of anesthesia (pain during extraction) by using the face pain scale reversed.

Results: Face pain scale revised were similar, despite the potential soft tissue reactions from needleless injection. Post-extraction anxiety levels were comparable, but children showed higher acceptance rates and shorter anesthesia durations and a faster onset with needleless injection. However, needleless injection led to higher anxiety levels during extraction differing significantly between the groups.

Conclusion: This study highlights the potential benefits and considerations associated with needleless injection in pediatric dental settings. While needleless injection showed advantages such as higher acceptance rates and quicker onset of anesthesia, it also presented challenges including soft tissue changes and increased anxiety levels. The findings underscore the need for further research and careful consideration of needleless injection techniques in pediatric dentistry.

Keywords: Needleless ; Jet injection; local anesthesia; deciduous teeth; child behavior

Introduction

Pain, fear, and anxiety are related to dental anesthesia, especially in children. In fact, conventional anesthetic delivery systems can be a causative factor of these problems. That's why manufacturers always try to deliver the local anesthetic delivery systems with a better experience for the patient. Recent techniques have been developed to reduce the pain sensation from the needle. Other methods have been created to inject the anesthetic solution without a needle. (**Elicherla et al., 2021)**.

Local anesthetic injections are a common method for pain management, but anxiety and negative reactions can still occur. Despite the effectiveness of needles, some patients may avoid dental care due to discomfort. Traditional needle systems can cause pain, hematoma formation, and burning sensations. Needle fractures and soft tissue trauma during insertion can lead to conditions like recurrent aphthous stomatitis or gingival laceration (**Angelo and Polyvios, 2018).**

Needleless systems are considered a valuable alternative to conventional needle systems, which represent a shift in local anesthetic administration, as they solve multiple problems caused by the conventional needle system. Examples of needleless anesthetic systems include electronic dental anesthesia, computer-controlled local anesthesia delivery (CCLAD) systems (wand system and comfort control syringe), vibrotactile devices, and jet injectors. Despite the cost of these needleless systems and the slight, sudden pain the patient can feel, they can provide a better experience for the child because, in the absence of a needle, some of the aforementioned complications are eliminated **(Alameeri et al., 2022).**

Based on the concepts of pressure dynamics, jet injections are typically well-received by patients since they lessen their fear of needles. During numerous dental operations, a needleless jet injector promises to be a sustainable method of pain management **(Hameed et al. 2021)**.

The objective of the current study was to compare the effects of needleless injection (comfort in jet) and traditional needle injection technique on pain perception and its influence on the surrounding oral mucosa and soft tissue during the administration of local anesthesia in children undergoing dental extractions.

Subjects and Methods

Study design:

A double blinded randomized clinical trial with a parallel group, two-tail, superiority frame with a ratio of 1:1. Clinical trial took place between the date October 2022 to May 2023.

Study settings:

The present study was a diagnostic accuracy study conducted in the Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University, Egypt. The study protocol was registered on the clinical trial website (http://www.clinicaltrial.com.gov) with protocol ID: NCT05334433

Sample size calculation:

A previous study by **Menaka et al. (2020)** revealed that the pain percentage with needle injections was 75%, whereas with needleless injections it was 40%. With a statistical power of 80% and a significance level of 5%, a sample size of 30 participants was required for each group. The sample size calculation was based on comparing the occurrence of pain at the injection site during anesthesia using the needle injection technique versus the needleless system during dental procedures in children. The sample size calculation was conducted using PS: Power and Sample Size Calculation Software Version 3.0.11 for MS Windows.

Eligibility criteria:

Inclusion Criteria

- Children between the ages of 6 to 8.
- Children attending for the first time.
- Children who are apparently medically fit.
- Children with any tooth indicated for extraction (loose tooth or remaining root

Exclusion Criteria:

- Children who struggle with behavioral control (uncooperative).
- Parental rejection of participation.

Subject Selection

60 participants who met the inclusion and exclusion criteria were enrolled from the outpatient clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University. The participants were randomly assigned to the intervention or control group. Simple randomization was accomplished using a random number mobile application where each patient tapped on the application's random button appearing on the screen which automatically runs a selection of a number. The application settings was set to give out numbers from 1 to 60 without repeating the display of any of the numbers upon each use. Each number was assigned to a group in an encrypted list using Microsoft excel. The excel sheet was stored and encrypted by the main supervisor.

Informed Consent and Assent:

Study's objectives and methodology were discussed with the eligible participating children's legal guardians, who were asked to sign an informed consent form after being fully informed of all details, including benefits of the study. They also received full descriptive information sheets outlining the trial's major components (aim, treatment, harms, and possible side-effects). Arabic translations of all information sheets and consent forms were provided. The participating child's verbal assent was obtained orally when he is engaged in choosing the picture in the modified venham scale and answering some questions.

Clinical Procedure:

1. The patient is asked to tap on the mobile "random number application" generate button appearing on the screen which automatically runs a selection of a number. Then the operator sees that number whether it is in group A (needleless) or group B (needle)
2. The **child behavior** was scored for the 1st time as a baseline data using Modified venham picture test **figure (2)**.
3. **Child preparation:** The patient was then prepared for treatment after psychological management and tell show and do techniques. In any particular technique, the child was prepared for the injection of the anesthetic agent either with needle or needleless technique using simple language. However, we showed the patient the needleless injection device and described the

device to the child as "it is a pistol-like device to kill the caries" and then the child was asked to listen to the pop sound emitted by the device so as not to get surprised and scared later during application.

4. **Topical anesthesia**: The child's eyes were obscured by the palm of the principal investigator while the patient was asked to widely open his/her mouth. The child was told that the topical gel "it is a jelly that we used to put to make the caries eats it and sleep" then the child was asked to smell the topical anesthetic gel and say what fruit it smelled like. A piece of cotton was used to dry the injection site before applying a 20% benzocaine topical anesthetic gel for 1-2 minutes.
5. **Anesthetic preparation:** Either the anesthetic carpule was loaded into the metal syringe with a 30-gauge sided beveled ultra-short needle, or the comfort in needleless injection device as shown in **figure(1)** was prepared for use by the principal investigator.
6. Following the administration of anesthesia, the patient was asked about **self-perception of pain during injection** whether they accepted the procedure and their answers by Yes/No were recorded. Subsequently, the **child's behavior** was assessed for a second time using the Modified Venham Picture Test was recorded.
7. The patient was asked if there were any changes felt at the anesthetic site, enlargement of lips, as a subjective sign of successful infiltration. At that time the **onset** was calculated**.**
8. **Soft tissue** was examined for any change in color, swelling, laceration.
9. Finally, after tooth extraction the **child behaviour** was scored for the 3rd time using Modified venham picture test
10. The child remained in the dental unit for observation of the wound and bleeding, while also monitoring the **duration of the anesthesia** until all sensation subsided, using a stopwatch

Statistical Analysis:

Data were statistically described in terms of mean ± standard deviation (± SD), median and range, or frequencies (number of cases) and percentages when appropriate. A comparison of categorical variables between the study groups was done using the Chi-square test for independent samples. Sample size calculation was done using PS Power and Sample Size Calculations software, version 3.0.11 for MS Windows (William D. Dupont and Walton D., Vanderbilt University, Nashville, Tennessee, USA). Two-sided p-value less than 0.05 were considered statistically significant. All statistical calculations were done using computer program.

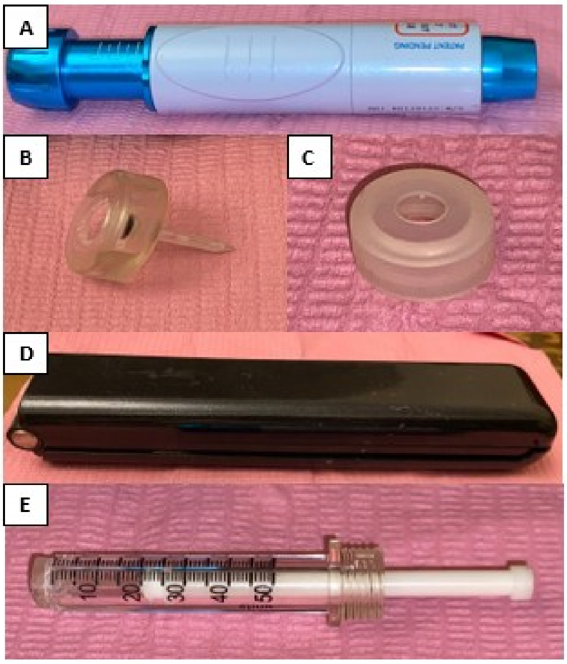

Figure (1): Showing components of comfort-in system; (A) main body (injector), (B) T-adapter, (C) cap-01, (D) pressure box, (E) nozzle (spring)

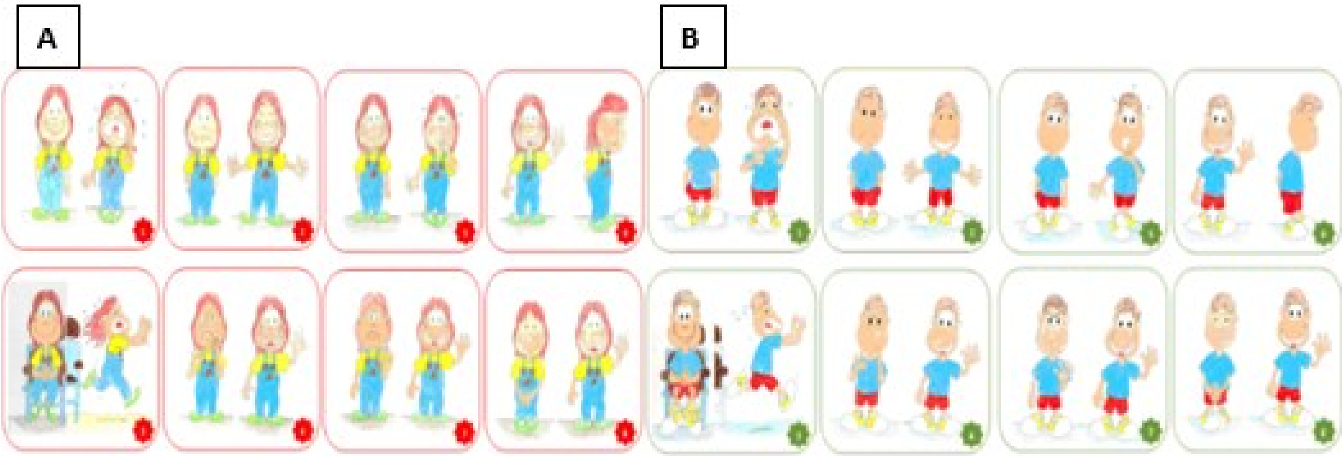

Figure (2): Showing modified venham picture test (mVPT)

Table (1): Anxiety level score according to the modified VPT

Score	Anxiety level
0	Anxiety free
1-3	Low anxiety level
4-6	Intermediate anxiety level
7-8	High anxiety level

Results:

1. Self-perception of Pain during Injection:

An overall acceptance of the injection method (where yes is positive and patient is accepting the procedure and no is negative) between both groups showed a statistically insignificant at p = 0.197; however, the number of cases accepting the needleless injection (n=26) (43.33%) is greater than those who accepted needle anesthesia (n=22) (36.67%) as shown in table (2)

2. Onset of Local Anesthesia (Seconds):

The onset of local anesthesia was 27.97 (13.61) seconds in needleless injection, and 112.9 (20.11) seconds in needle injection, with statistically significant between both groups (P=0.001) as shown in table (3).

3. Anesthesia Duration (Minutes):

The duration of local anesthesia was 30.20 (19.07) minutes in needleless injection, and of 118.7 (12.17) minutes in needle injection, with statistically significant between both groups (P=0.001) as shown in table (4).

4. Soft Tissue reaction:

Soft tissue reactions took place in the needleless injection group illustrated in the form of bleeding (n=1), laceration (n=11), both bleeding and laceration (n= 17), and no change(n=1) while in needle injections showed no soft tissue reactions at all in all participants (n=30). Statistically significant difference between both groups at p=0.001 as shown in Table (5)

5. Effectiveness of Anesthesia (Pain During Extraction):

The Face pain scale Revised ("0" = "no pain" and "10" = "very much pain") showed no statistical difference between both types of injections used at p = 0.0615. as shown in Table (6)

6. Child Behavior: (mVPT)

Table (7) showed that there is a statistical significance difference in child behavior between 2 groups only before anesthesia injection, as p-value =0.0416 by performing non-parametric (Mann-Whitney) test. Also by checking the significance level within each study group separately with non-parametric (Friedman) test, it revealed that the statistical significance difference between child behavior before injection, during injection and also during extraction only found in the needleless group, P-value= 0.003.

Table (2): Frequencies of self-perception of pain during injection of needle and needleless injection groups

Patient Acceptance (Binary;Yes/No)	Intervention		
	Needle Injection	**Needleless Injection**	**Total**
No	8 (13.33%)	4 (6.67%)	12 (20%)
Yes	22 (36.67%)	26 (43.33%)	48 (80%)
Total	30 (50%)	30 (50%)	60 (100%)
Pearson chi2(1) = 1.667			p = 0.197

Table (3): Mean of anesthesia onset (in seconds) of needle and needleless injection groups

Two-sample t-test with unequal variances						
Intervention	**Number of patients**	**Mean (seconds)**	**Std. dev.**	**95% conf. interval**		
Needle Injection	30	112.9	20.11	105.4	120.4	
Needleless Injection	30	27.97	13.61	22.88	33.05	p=0.001
Diff		84.97		76.06	93.87	

Table (4): Mean of anesthesia duration (in minutes) needle and needleless injection

Two-sample t test with unequal variances						
Group	**Number of Patients**	**Mean (minutes)**	**Std. dev.**	**95% conf. interval**		
Needle Injection	30	118.7	12.17	114.1	123.2	
Needleless Injection	30	30.20	19.07	23.08	37.32	p=0.001
diff		88.47		80.17	96.77	

Table (5): Frequencies of soft tissue reaction among needle and needleless injection groups

	Intervention	
soft tissue reaction	**Needle Injection**	**Needleless Injection**
No Change	30	1
Bleeding	0	1
Laceration	0	11
Bleeding and laceration	0	17
Total	30	30
Pearson chi2(3) =56.129		p=0.001

Table (6): Frequencies of effectiveness of anesthesia (pain during extraction) among needle and needleless injection groups

Intervention	Face Pain Scale Revised (0-10)								Total
	0	1	2	3	4	6	8	10	
Needle Injection	14 (46.67%)	1 (3.33%)	8 (26.67%)	2 (6.67%)	3 (10%)	1 (3.33%)	1 (3.33%)	0 (0%)	30 (50%)
Needleless Injection	6 (20%)	4 (13.33%)	9 (30%)	2 (6.67%)	4 (13.33%)	1 (3.33%)	2 (6.67%)	2 (6.67%)	30 (50%)

Table (7): The child behavior among needle and needleless injection groups in different time intervals during the dental visit

Child behavior	Needle group (Mean Rank)	Needleless group (Mean Rank)	P-Value
Before Anesthesia Injection	2.02	2.42	**0.0416***
During Anesthesia Injection	1.93	1.75	**0.946**
During Extraction	2.05	1.83	**0.738**
P-Value	**0.786**	**0.003***	

***Significance level (p-value=or <0.05**

Discussion:

The child's response to dental treatment is a complex process that is influenced by several factors, including the child's age, temperament, anxiety levels, parental anxiety, and previous dental experiences **(San et al., 2014).** Pain perception during treatment is determined by both physical and psychological factors **(Farooq et al., 2019).** In very young children, the appearance of dental equipment, drug sprays' smell and taste, vibrations, pressure, breathing difficulties, and limited mouth opening can also cause significant discomfort during treatment.

Dental injection with a needle is a major contributor to dental anxiety and fear in patients. The majority of children showed needle phobia, ranged from 20–50% **.** As a result, approximately 5% to 15% of the population avoids dental treatments due to needle-phobia anxiety which could contribute to those who require more complex treatments. Additionally, their oral health may be in a more precarious state due to the delay in seeking treatment, leading to further complications and consequences **(Altan et al., 2021).**

Dental extractions can be a challenging and stressful experience for children, especially when it involves the administration of local anesthesia. Traditionally, dental local anesthesia for children has been administered via needles, which can be intimidating and painful for them. However, recent advancements in technology have enabled the use of needleless local anesthesia devices, which have been shown to be less painful and more comfortable **(Townsend and Wells, 2019)**. The current randomized controlled trial aimed to evaluate the post-operative pain and soft tissue reaction of needleless anesthetic technique versus needle anesthetic technique for tooth extraction in a group of children**.**

The current study is a randomized controlled clinical trial designed**.** In the hierarchy of evidence, the greatest level of evidence regarding the primary study design are randomized controlled trials. The fundamental advantage of randomization is that it eliminates possible biases. In the current RCT, simple randomization was performed using a mobile application which automatically runs a selection of non-repeated numbers (1-60), then each number represented by a group on Microsoft excel. A split mouth design was avoided to obviate any bias that could be reported by the child during measuring pain scores due to previous dental experience. Moreover, both the outcome assessor (co-supervisor) and the biostatistician were blind to the study groups to avoid reporting bias.

Furthermore, all participants underwent a preliminary diagnostic visit, without any dental procedures, to manage their anxiety and exclude uncooperative children or those with general phobia that could have impacted the accuracy of our pain and anxiety measurements during the subsequent visit, where they received anesthesia and underwent tooth extraction.

It has been proposed that needle-less jet injection be used instead of conventional needle injection. With the help of a small aperture and a compressed spring or gas, a small volume of medicine can be driven quickly and forcefully through it to create a liquid jet that can penetrate tissue. This is the basic principle of jet injectors. The primary benefit of not having a needle is that it eliminates pain and injection-related anxiety **(Schoppink and Rivas, 2022)**.

Following the injection procedure, we assessed the **patients' overall self-perception** of pain during the injection using a simple "Yes/No" question, as outlined in the study by **Menaka et al. (2020)**. Our findings illustrated that the overall difference in patient acceptance of the injection method between the two groups was statistically insignificant; however, the number of cases accepting the needleless injection (n = 26; 43.33%) was greater than the number of cases accepting needle anesthesia (n = 22; 36.67%) as shown in Table (2). The jet injector's higher initial local anesthetic concentration accelerates diffusion, aiding in anesthetizing soft tissues effectively **(Oliveira et al., 2019)**

Regarding **the anesthesia onset**, a stopwatch was used. After comparing the time, it took for local anesthesia to take effect between the needleless and needle injection methods, a statistically significant difference was observed with a p-value of less than 0.001. The needle injection group had a mean onset time of 112.9 (20.11) seconds, while the needleless injection group had a significantly shorter mean onset time of 27.97 (13.61) seconds as shown in Table (3). Our findings are consistent with previous studies that have demonstrated the effectiveness of needleless injections in accelerating the onset of anesthesia, with an average time of 14.3 seconds for needleless injections compared to 43.9 seconds for needle injections (p-value < 0.001) **(Lee et al., 2020; Kim et al., 2019)**. This can be explained by the fact that anesthesia delivered by jet injection infiltrates the tissue in tiny droplet form better taken up by the myelin sheath of the supplying nerves. (**Gazal et al., 2015; Bortoluzzi et al., 2018).**

Our results showed a statistically significant difference between the two groups in terms of **the anesthesia's duration** effect. Compared to traditional anesthesia, which had a mean value of 118.7 (12.17) minutes, needleless injection had a shorter duration effect, with a mean value of 30.20 (19.07) minutes as shown in Table (4). Additionally, some studies have evaluated the duration of anesthesia following needle- and needleless injections in young patients. In contrast to needle injections, the average anesthetic duration with needleless injections was much longer (77.5 minutes for needleless injections vs. 52.3 minutes for needle injections, p-value< 0.001) **(Lee et al., 2020).** One reason for this may be related to the way that needle-free injection systems deliver the anesthetic solution. In the current study, the children remained seated and monitored by the principal investigator until the complete wear off of the anesthesia was observed and noted by the patient. This method ensured accurate measurement of the duration of anesthesia and allowed for appropriate monitoring of the children during the postoperative period. Besides, the greater initial concentration of local anesthetic deposited by the jet injector at one time creates a higher concentration gradient for diffusion and faster diffusion rate of anesthetic solution upon jet injection, accompanied by the unhindered flow of these liposoluble molecules in the direction of the epineurium's nerve fascicles (**Gazal et al., 2015; Bortoluzzi et al., 2018).**

Soft tissue reactions frequently occur following local anesthesia during dental procedures and can manifest as pain, numbness, swelling, laceration, or tissue sloughing at the injection site **(Parate and Mohod, 2022).** Since the presence of bleeding, lacerations, and soft tissue changes are contributing factors that might affect the overall acceptance of the patients, we decided to measure those factors too in this study as a soft tissue reaction assessment. Although these reactions are usually self-limiting and resolve without complications, the swelling may cause parental anxiety. These responses can be restricted or prevented by utilizing the needle at a 45-degree angle **(Gao Q et al.,2021).** Unfortunately, children may develop a negative dental attitude towards future visits due to the unpleasant memory of this experience **(Bagattoni et al., 2020).** Soft tissue was examined for any changes in color, swelling, laceration. Adjacent mucosa was visually examined for any soft tissue changes at the site of injection, such as the appearance of ulcers or changes in color. Results show there was a statistically significant difference between the two groups (p-value<0.001). Only one participant in the group receiving needleless injections (n=1) did not experience any soft tissue alterations, compared to all individuals in the group receiving traditional injections (n=30). In the needleless injection group, there were additional soft tissue reactions, such as bleeding (n = 1), laceration (n = 11), and bleeding with laceration (n = 17) as shown in Table (5). This might be because of the collision between the perpendicular stream and its backflow in perpendicular Needle free injection. These results did not meet those of **Ocak et al.'s 2020 and Mohamed et al. 2023,** who found only 7.1% of participants experienced bleeding at the injection site, with no statistically significant difference between the two groups and it was observed that no participant reported any hematoma, swelling at the injection site, or stinging sensation in the needleless injection group. This unmatching results between our findings and the findings of earlier studies may be due to the difference in soft tissue assessment parameters between the studies. Another rationale can be ascribed to the Comfort-in needleless syringe application approach, which requires the device to be left in place after injection while exerting light pressure and massaging to stop bleeding. In addition, the various needleless injector designs may be responsible for the variations in the needleless stream's characteristics and, consequently, the tissue reaction, such as driving pressure and its impact on penetration depth and the risk of harming vascular systems **(Barolet and Benohanian, 2018).**

The results of the **effectiveness of anesthesia** (Pain During Extraction) in the current study by using the Face pain scale showed no statistical difference between both types of injections used at p = 0.0615. The highest percentages for the needle injection group was at scale 0 (n=14 46.67%), while the highest percentages for the needleless injection group was at scale 2 (n=9 30%) as shown in Table (6). We utilized the **Face Pain Scale - Revised (FPS-R)** to evaluate the overall pain perception during dental extraction. This scale is a modified version of the original Faces Rating Scale (FRS) and uses facial expressions to assess pain intensity in children. The FPS-R is a convenient and easy-to-use tool that does not require any equipment other than photocopied faces that lack expressive smiles or tears, which may be advantageous in clinical settings. **(Menaka, 2020)**

The child behavior between study groups in different time intervals during dental visit within each study group separately revealed a statistically significant difference between child behavior before injection, during injection, and during extraction only in the needleless group, with a P-value of 0.003, as depicted in Table (7). The data showed that child behavior before injection was recorded at 2.42, while during extraction it decreased to 1.83, indicating a higher level of comfort during the procedure compared to the Needle group. Conversely, in the needle group, the child behavior score before injection was 2.02 and slightly increased to 2.05, suggesting a lack of comfort during the procedure. Similarly, **Lee et al. (2020)** and **Sanket et al., 2020.** According to the Venham picture test, using the needleless injector resulted in decreased discomfort, with a statistically significant difference (p-value< 0.05). Moreover, according to survey results, using the needleless injector during palatal infiltration injection resulted in statistically significantly less pain than using a topical anesthetic gel (p-value = 0.05). The complexity of pain and anxiety, a multidimensional phenomenon in which biological, psychological, emotional, cultural, and environmental factors can alter how each person experiences pain and anxiety, may help to explain the contradictory results **(Pieretti et al., 2016)**.

Limitations of the study:

1- It was not the first dental visit for most of children at the age of 6-8 years

2-Parents was complaining from waiting after extraction to calculate the duration of anesthesia

3- During the administration of anesthetic solution, it was impossible to keep the children and researchers blinded to methods of administering local anesthesia

4- Limitation of the device was the T adapter which was made of plastic (can be break easily) must be inserted in different cartilages multiple times.

Conclusion:

Within the limitation of this study, we can conclude that:

1. Needleless Injection could possibly cause soft tissue changes such as bleeding and/or lacerations as a side effect.
2. Children showed no difference in post-extraction anxiety between the needleless injection group and the needle injection group, as evaluated by the mVPT scale.
3. There was a difference in overall acceptance as well as the success rate with children accepting needleless more than needle injection.
4. The duration of local anesthesia was shorter with the needleless than with the needle injection.
5. The utilization of needleless injection demonstrated a more rapid onset of anesthesia in comparison to needle injection methods.

Conflict of interest:

The authors declare no conflict of interest.

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Ethical consideration:

The study protocol was revised and agreed by the Research Ethics Committee of the Faculty of Dentistry, Cairo University, on 28-6-2022, with an approval number 3-6-22.

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