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ORIGINAL RESEARCH

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Effectiveness of a needle-free local anesthetic technique compared to the traditional syringe technique for the restoration of young permanent molars: a single-blind randomized clinical trial

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Abstract

The sensation of pain can elevate anxiety levels, establishing a cyclical pattern that may result in the avoidance or premature termination of dental procedures. Previous endeavors employing various methods and products have produced varied outcomes. Jet injection systems, employing high pressure and velocity to deliver anesthesia without needles, offer a non-invasive option for local anesthesia administration. To assess and measure pain perception levels in a pediatric population during the restoration of young permanent teeth, comparing a needle-free injection system with the traditional dental needle method. Sixty participants with young permanent first molars requiring indirect pulp capping were enrolled, all under the care of a single operator. A simple randomization method was employed, utilizing sequentially numbered, opaque, sealed envelopes to allocate participants into two intervention groups: Group 1 and Group 2. Group 1 received traditional needle syringe anesthesia, while Group 2 received the needle-less injection system, Injex (INJEX Pharma AG, Germany). Following topical anesthesia application, local anesthesia was administered, and indirect pulp capping was performed. The Face, Legs, Activity, Cry, Consolability Scale (FLACC), Wong-Baker Scale, Time of local anesthesia (LA) Administration, Frankl Behavior Rating Scale (FBRS), and Pulse rate were evaluated and recorded at various intervals. The needle-less injection system required approximately 26.2 seconds for anesthesia administration, significantly less time than the traditional syringe ($p < 0.001$). FBRS score analysis revealed no significant differences between groups at all intervals. FLACC score analysis during anesthesia administration indicated lower scores in the needle-free injection group ($p < 0.001$). Evaluation of Wong Baker Scale (WBS) scores showed higher values in the traditional syringe needle group ($p < 0.05$). Using the Injex system presents a promising alternative for dental anesthesia administration, enhancing patient comfort and alleviating fear associated with traditional injections.

Keywords

Injex; Needle-free injection; Local anesthesia; Needleless anesthesia; Pain

1. Introduction

Fear and anxiety in dental patients are interconnected with the actual sensation of pain. Individuals with anxiety often have lower pain thresholds, making them more sensitive to pain during dental procedures [1]. Contrarily, the experience of pain can escalate anxiety levels, creating a cyclical relationship that may lead to the avoidance or premature discontinuation of dental treatment [2]. Inadequate pain management can provoke negative responses and fear in children, posing a challenge for dentists striving to instill a positive attitude in pediatric patients. As a result, the major goal for every pediatric dentist is to provide minimal distress and pain during treatment for young patients [2]. Administering a local anesthetic (LA) solution is the traditional method used to relieve dental discomfort in children [3].

Although this method successfully removes pain during the procedure, anxiety and hostile conduct continue to be significant issues for many children before and after the administration of anesthesia [3, 4]. The traditional syringe method induces discomfort during both the puncture and injection stages, contributing to patient apprehension [5]. Patients un-

dergoing the traditional syringe method may associate it with pain, potentially leading to heightened anxiety levels and an overall negative experience. Other factors exacerbating pain and discomfort levels in such patients include improper handling of the syringe—such as applying excessive pressure on the plunger or rapidly injecting large volumes of anesthetic solution [6]. These factors highlight the crucial need for proper training and incorporation of techniques for syringe handling to minimize patient discomfort.

Several products and techniques have been previously attempted, resulting in varied outcomes. For instance, precooling the injection site could reduce the sensation of injection. Applying vibration to the injection site before and during the procedure helps distract the patient, thus reducing the perception of pain. Computer-controlled systems enable more precise and controlled injection rates, minimizing discomfort during the process [7]. Jet injection systems in dentistry represent an innovative and less intimidating method of delivering local anesthesia, aiming to alleviate fear associated with traditional injections. This device utilizes a mechanical energy source to provide pressure, allowing a controlled flow of anesthetic to penetrate the soft tissues. It is believed to provide advantages compared to standard infiltration methods due to its ability to rapidly induce numbness in soft tissues, precise delivery of the anesthetic dosage, and high level of acceptability among patients who are afraid of needles [8, 9]. Jet injection systems offer a non-invasive alternative for delivering local anesthesia, eliminating the need for a sharp needle. Patients experiencing needle phobia or anxiety related to dental procedures could benefit greatly from such systems [9]. The lack of a needle for administration contributes to a favorable psychological result [10]. This device has the capability to guide the anesthetic solution *via* a tiny opening that is seven times smaller than the tiniest needle currently accessible in the globe. The device is capable of delivering quantities of 0.01–1 cm^3 at a pressure of 2000 psi using intradermal, subcutaneous, and intramuscular routes. This feature enhances the effectiveness of anesthesia and is especially well-suited for nasopalatine and larger palatine injections. In addition, mechanical adjustments enable customization of the depth of penetration [11]. The expedited onset of anesthetic has the potential to decrease the total duration of dental treatments [12]. Prior application of a topical anesthetic gel to the injection site could enhance the comfort level of patients undergoing the jet injection system, as it numbs the area completely. Evaluating such newer techniques and incorporating the most effective ones in pediatric dentistry is crucial for treating children with dental phobia [13]. Various dental jet injectors [5, 14, 15] are now employed in dentistry for the purpose of delivering local anesthetic.

The management of carious lesions in permanent teeth involves restoration, and anesthesia is necessary to alleviate pain in treating deep carious lesions [16]. Therefore, the primary objective of the study was to compare the difference in pain perception levels experienced when using a needle-less injection system versus the traditional system (syringe needle method) in the pediatric population during the restoration of young permanent teeth.

2. Materials and methods

2.1 Study design

The current study was a randomized, single-blinded, controlled trial. The study design adhered to the guidelines established by the Consolidated Standards of Reporting Trials (CONSORT). Fig. 1 illustrates the schematic portrayal of the research design.

2.2 Sample size calculation

The sample size was established using the provided technique, considering a mean difference of 1.2 in the Face, Legs, Activity, Cry, Consolability ratings and a combined standard deviation of 1.89, which were obtained from a previous study [17].

$$Sample\ size\ (n) = 2{S_p}^2 \left[Z_{(1-\alpha/2)} + Z_{1-\beta}\right]^2 2/{\mu_d}^2$$

$${S_p}^2 = ({S_1}^2 + {S_2}^2)/2$$

Where,

$Z_{(1-\alpha/2)}$ = 1.96 for 95% confidence interval;

$Z_{1-\beta}$ = 0.84 for 80% power;

S_1 = 1.32 (standard deviation in computer-controlled injection group);

S_2 = 1.43 (standard deviation in traditional syringe group);

μ_d = 1.2 (difference in mean FLACC scores between two groups).

After replacing these numbers, the resulting sample size was 21. However, an extra 20% of the expected sample size was included to compensate for probable sampling loss. As a result, the ultimate sample size comprised a total of 30 participants in each group.

2.3 Study population

Based on the inclusion and exclusion criteria outlined below, a total of 60 participants requiring indirect pulp capping in young permanent first molars were recruited for the study.

2.4 Participant selection

2.4.1 Inclusion criteria

The initial screening process involved evaluating children between the ages of 7 and 14 at the outpatient section of the pediatric dental department, College of Dentistry at Jazan University in Saudi Arabia. The inclusion criteria consisted of choosing children who demonstrated total well-being, encompassing both full physical and mental health, and had no complex medical background. The research selected children who had positive or clearly positive conduct according to Wright's adaptation of the Frankl behavior Rating Scale (FBRS) at the initial assessment and intra-oral periapical radiographs. Another essential need was the existence of a profound carious lesion in the young permanent first molar, necessitating indirect pulp capping. All parents of the participants submitted written

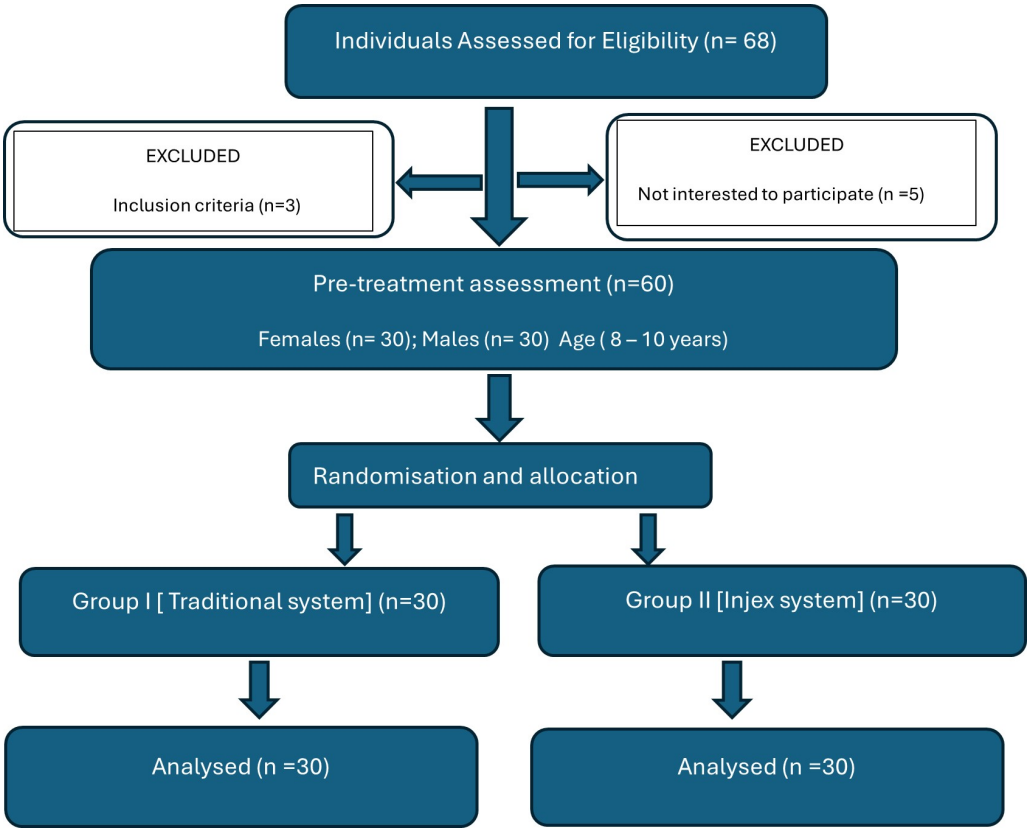

FIGURE 1. Schematic representation of the study design (CONSORT).

informed permission and stated their desire to participate in the experiment.

2.4.2 Exclusion criteria

The study excluded children who were under the age of seven, those who showed symptoms of irreversible pulpitis and dentoalveolar abscess, children who displayed negative or definitely negative behavior according to Wright's modification of the FBRS during the initial examination, and children who had medical or mental impairments.

2.5 Randomization and allocation concealment

Children were allocated into one of the following two groups using a simple randomization method with a random number table, employing the sequentially numbered, opaque, sealed envelopes method of allocation concealment.

2.5.1 Group I

All of the participants in this group received anesthesia through the traditional system (needle syringe system) (Fig. 2).

2.5.2 Group II

The individuals participating in the present group received anesthesia utilizing needleless injection technology, namely the Injex (INJEX Pharma AG, Germany) (Fig. 3). The INJEX system comprises multiple components, such as disposable ampoule, an adaptor and an activating device. Prior to each usage, the injector must undergo an activating procedure. This

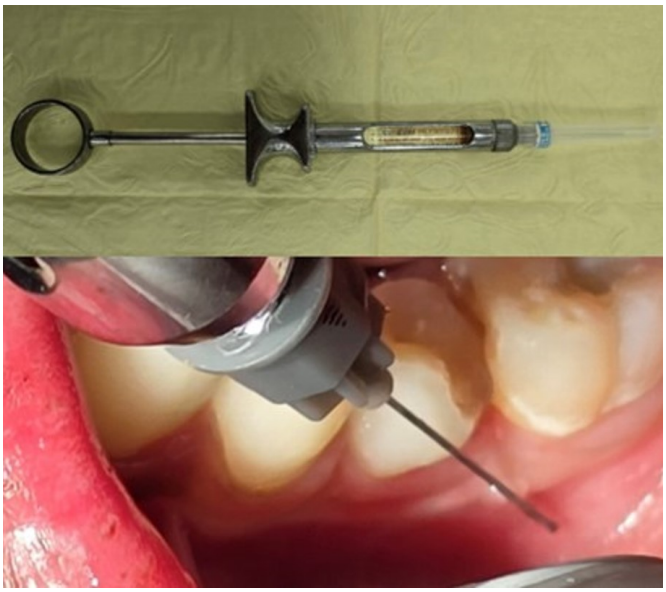

FIGURE 2. Traditional system (needle syringe system).

involves inserting the assembled components into the activating device and closing it, which activates a lever mechanism. This mechanism compresses the spring within the injector, allowing it to be activated [18]. After being prepared, the injector is firmly placed on the mucosa, and a quick press on the trigger administers anesthesia. The injection is provided at a standardized pressure of 3000 psi, delivering the medicine into the tissue at a penetration ranging from 5 to 8 millimeters.

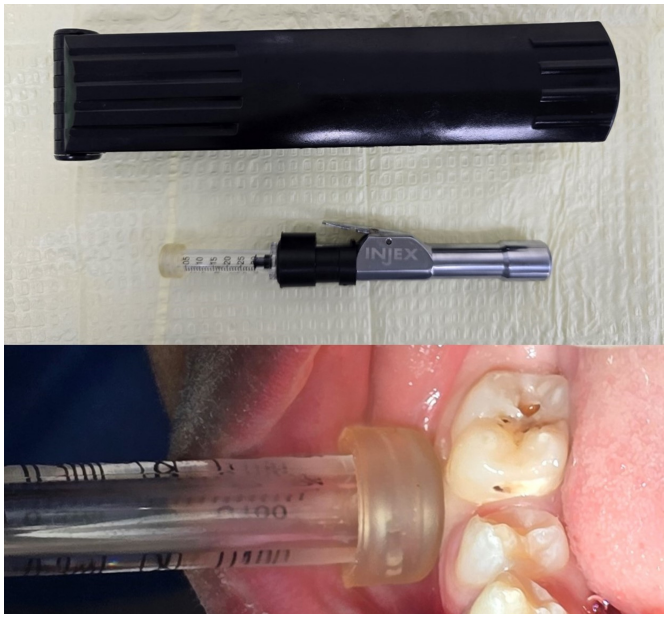

FIGURE 3. Injex system (needleless system).

2.6 Intervention procedure

In order to eliminate any potential bias caused by different operators, a solitary operator oversaw the complete anesthetic process for all subjects in the experiment. The participants were introduced to and provided with explanations of all pertinent therapy equipment and protocols using the "tell-show-do" method. The injection method was well explained using suitable euphemistic language. The injection site was cleansed with sterile dry gauze before the injection was administered. Then, a little amount of topical anesthetic (Benzocaine 20%, Lakewood, NJ, USA) was applied and kept in place for at least one minute. After applying topical anesthetic, the participant received local anesthesia according to their allocated group. Following a typical three-minute waiting period for the anesthetic to have an effect, Indirect pulp capping procedure was completed (Dental caries was removed using a round diamond bur number "6" (Mani, Inc., a company based in Tochigi, Japan). The procedure was performed using a high-speed air-rotor handpiece. The procedure involved the removal of soft and mushy diseased dentin using a sharp spoon excavator, while ensuring the preservation of the hard-affected dentin).

2.7 Outcomes

The key outcomes, including the FLACC Scale [19, 20] and the Wong-Baker Faces Rating Pain Scale (WBS) [21], were measured by a single investigator. Another examiner assessed the secondary results, which encompassed the duration of anesthetic administration, the FBRS [22], and pulse rate.

2.7.1 Primary outcomes

2.7.1.1 Face, legs, activity, cry, consolability scale

While administering local anesthetic, the FLACC scale was used as a reliable method for objectively assessing pain. This scale measures the intensity of pain by examining five distinct behavioral characteristics. Facial expressions, such as grimacing and frowning, are monitored in order to ascertain the existence of pain. Leg motions or tension are analyzed to identify indications of agitation or stress. Activity entails evaluating the entire physical mobility of an individual, which includes observing signs of restlessness or an unwillingness to stay motionless. Verbal manifestations of anguish, such as sobbing or vocalizations, are also considered. Consolability evaluates an individual's capacity to offer comfort or consolation. According to a scale that ranges from 0 to 2, a score is awarded to each category. A score of 0 indicates that there is no pain or discomfort at all, while a score of 2 indicates that there is the greatest amount of pain or distress. The FLACC score is determined by adding together the results from each category, resulting in a total score that can range from 0 to 10. A reduction in the score correlates to reduced levels of pain intensity, whilst higher values reflect heightened levels of pain severity [19, 20].

2.7.1.2 Wong-baker scale

The current research utilized the WBS as the method for subjective pain assessment. This scale consists of 6 distinct face expressions, each with a numerical value between 0 and 10, which indicates the intensity of pain felt. Pain levels are classified according to the scale's scores: a score of 0 to 4 shows mild pain, 4 to 6 signifies moderate pain, 6 to 8 represents severe pain, and 8 to 10 displays unbearable agony. Both groups of children were directed to evaluate the level of their pain at four particular time intervals using the Wong-Baker Faces Scale (WBS): prior to the injection, immediately following the injection, during the therapy, and after the treatment [21].

2.7.2 Secondary outcome

2.7.2.1 Duration of delivering LA

There was a recording made of the time duration in which the LA solution was delivered. A timer was used by a third researcher to monitor the amount of time that elapsed between the delivery of the local anesthetic and the removal of the traditional/INJEX device from the mouth of the participant.

2.7.2.2 Frankl behavior rating scale (FBRS)

Wright's adaptation of the FBRS was used to assess a child's behavior at various stages throughout the course of dental procedures. The FBRS scale is widely recognized for its systematic approach to evaluating a child's cooperation and response during dental treatments. The child's conduct was assessed during several phases of the dental procedure, which included intra oral examination, taking X-rays, applying topical anesthetic (referred to as "before" values), administering LA, and the process of restoring the teeth (referred as "after" values) [22].

2.7.2.3 Pulse rate

A pulse oximeter (Beurer PO 40, Great Britain, UK) was used to monitor the pulse rate. This approach was used because of the potential correlation between anxiety or stress and an elevated pulse rate. Anxiety levels were evaluated by measuring pulse rate. Physiological measurements were gathered expeditiously. Data was collected within a 15-minute period prior to the administration of LA in order to capture any

changes that occurred during this time. The mean was then calculated based on this data. In addition, pulse rate measurements were taken separately during the LA injection and the 1-minute interval following the injection. The average values during the injection and after the injection were calculated.

These secondary outcomes were measured by a third party not involved in the study, who was blinded to the anesthesia procedure protocol.

2.8 Statistical analysis

The statistical analysis was carried out using SPSS 17 software for Windows (SPSS Inc., Chicago, IL, USA). The distribution of participants based on age, gender, and accompanying person was analyzed using the Chi-square test. Inter-group comparisons were conducted using the unpaired *t*-test and Mann-Whitney test. Intra-group comparisons were performed using the paired *t*-test and Wilcoxon signed-rank test.

3. Results

Table 1 provides a detailed breakdown of the distribution of participants between the traditional system (needle syringe system) and INJEX system (needleless injection system) groups, categorized by the age and gender of the participants. The administration time for LA was approximately 26.2 seconds for the needle-free injection system, whereas the traditional syringe method required more time. The noted time difference demonstrated a highly significant statistical significance ($p < 0.001$). Comparing the observed pulse rates before and one minute after LA administration revealed no significant difference. Although no significant difference was observed during other time intervals, a statistically significant distinction between the two groups was noted for pulse rate during anesthesia, with a higher pulse rate reported in the traditional syringe group (103.46 ± 13.55) (refer to Table 2).

Analysis of the FBRS scores revealed no significant difference for all three time periods—before ($p = 0.45$), during ($p = 0.054$), and after anesthesia ($p = 0.311$). However, FLACC score analysis during the time of LA administration exhibited a statistically significant difference ($p < 0.001$) between the two groups, with lower scores observed for those in the needle-free injection group. Assessment of WBS scores indicated statistically significant differences between the groups before the procedure ($p < 0.001$), immediately after the injection ($p < 0.001$), during the treatment ($p < 0.001$), and at the end of the treatment ($p < 0.001$), with higher values observed in the traditional syringe needle group (refer to Table 3).

Intra-group comparison of pulse rate, FBRS and WBS revealed significant differences between the two intervention groups at all measured time periods ($p < 0.05$). The only exception was the WBS score, which exhibited no significant difference ($p = 0.16$) when comparing the score immediately after injection to that during the treatment (refer to Table 4).

Comparison of all the outcomes based on the arch treated demonstrated statistically significant differences in the analysis of the FBRS scores during anesthesia ($p < 0.001$) and WBS scores during ($p < 0.001$) and at the end of treatment ($p < 0.01$), with higher scores observed for the interventions in the mandibular arch (refer to Tables 5 and 6).

4. Discussion

Dental fear and anxiety pose significant challenges in pediatric dentistry [23]. It is a common reason why individuals, especially children, avoid dental treatment, which can lead to deteriorating oral health over time [24]. Dental fear and anxiety in children have a complex and multifactorial origin [25], with one factor being fear of anesthesia and pain during its delivery. Managing pain in pediatric dental care is crucial

TABLE 1. Participants distribution according to age and gender.

SI. no	Parameters	Traditional system N (%)	INJEX system N (%)
	Age		
1	8–9 years	20 (66.7)	12 (40)
	9–10/11 years	10 (33.3)	18 (60)
	Gender		
2	Male	14 (46.7)	21 (70)
	Female	16 (53.3)	9 (30)

TABLE 2. Comparison of various parameters (metric data) during local anesthesia administration.

SI. no	Parameters	Traditional system (Mean ± SD)	INJEX system (Mean ± SD)	*p* value
1	Time needed for delivering LA (in seconds)	50.36 ± 4.80	26.20 ± 3.64	0.001***
	Pulse rate			
2	Before anesthesia	92.45 ± 10.57	93.93 ± 7.25	0.530
	During anesthesia	103.46 ± 13.55	88.66 ± 7.22	0.020*
	1 min after LA administration	99.13 ± 11.95	96.70 ± 6.13	0.326

*Independent t test; *Significant < 0.05; ***Significant < 0.001; LA: Local Anesthesia; SD: Standard Deviation.*

TABLE 3. Comparison of different parameters (ordinal data) when administering local anesthesia.

SI. no	Parameters	Traditional system (Median (Q1, Q3))	INJEX system (Median (Q1, Q3))	*p* value
1	FBRS			
	Before administration of anesthesia	3 (3, 4)	3 (3.5, 4)	0.450
	During administration of anesthesia	2.5 (2, 3)	3 (2, 3)	0.054
	Following administration of anesthesia	3 (3, 3)	3 (3, 3)	0.311
2	FLACC Scale	4.5 (2, 5)	1 (0, 3)	0.001***
3	WBS			
	Prior to the procedure	1 (0, 2)	0 (0, 0)	0.001***
	Instantly after administration of anesthesia	4 (2, 6)	2 (0, 2)	0.001***
	During the procedure	3 (2, 6)	0 (0, 0)	0.001***
	Upon completion of the procedure	2 (2, 4)	0 (0, 0)	0.001***

*Mann Whitney U test; ***Significant < 0.001. FBRS: Frankl Behavior Rating Scale; FLACC: Face, Legs, Activity, Cry, Consolability Scale; WBS: Wong-Baker scale.*

TABLE 4. Intra group comparison of pulse rate, Frankl behavior rating scale and Wong Baker Scale at different time periods.

SI. no	Parameters	Groups	Comparisons	*p* value
1	Pulse Rate	Traditional system	Prior administration versus during administration of anesthesia	0.001***
			Prior administration versus after administration of anesthesia	0.001**
			During administration versus after administration of anesthesia	0.001***
		INJEX system	Prior administration versus during administration of anesthesia	0.001***
			Prior administration versus after administration of anesthesia	0.020*
			During administration versus after administration of anesthesia	0.030
2	FBRS	Traditional system	Prior administration versus during administration of anesthesia	0.001***
			Prior administration versus after administration of anesthesia	0.001***
			During administration versus after administration of anesthesia	0.001***
		INJEX system	Prior administration versus during administration of anesthesia	0.001***
			Prior administration versus after administration of anesthesia	0.020*
			During administration versus after administration of anesthesia	0.001***
3	WBS	Traditional system	Prior versus right after injection	0.001***
			Prior versus during the therapy	0.010**
			Prior versus at the end of the therapy	0.001***
			Right away after injection versus during the therapy	0.160
			Right away after injection versus at the end of therapy	0.007**
			During the therapy versus at the end of therapy	0.010*
		INJEX system	Prior versus right after injection	0.001***
			Prior versus during the therapy	0.001***
			Prior versus at the end of the therapy	0.001***
			Right away after injection versus during the therapy	0.010*
			Right away after injection versus at the end of therapy	0.001***
			During the therapy versus at the end of therapy	0.020*

*Paired t test and Wilcoxon signed-rank test; *Significant < 0.05, **Significant < 0.01, ***Significant < 0.001. FBRS: Frankel Behaviour Rating scale; WBS: Wong-Baker scale.*

TABLE 5. Comparison of various parameters during INJJEX administration in relation to arches.

SI. No	Parameters	Mandibular Arch (Mean ± SD) (Median (Q1, Q3))	Maxillary Arch (Mean ± SD) (Median (Q1, Q3))	*p* value
1	Time needed for delivering LA (in seconds)	27.0 ± 3.74	25.4 ± 3.48	0.235
2	FBRS			
	Before administration of anesthesia	4 (3, 4)	3 (3, 4)	0.292
	During administration of anesthesia	3 (3, 4)	2 (2, 2)	0.001***
	Following administration of anesthesia	3 (3, 4)	3 (3, 3)	0.056
3	FLACC Scale	1 (0, 3.5)	1 (0, 2)	0.528
4	WBS			
	Prior to the procedure	0 (0, 0)	0 (0, 0)	NA
	Instantly after administration of anesthesia	2 (0, 2)	0 (0, 2)	0.435
	During the procedure	6 (5, 8)	2 (0, 2)	0.001***
	Upon completion of the procedure	4 (2, 4)	2 (1, 2)	0.008**

*Wilcoxon signed-rank test. ** significant < 0.01, ***Significant < 0.001 level. FBRS: Frankl Behavior Rating Scale; FLACC: Face, Legs, Activity, Cry, Consolability Scale; WBS: Wong-Baker scale; SD: Standard Deviation; LA: local Anesthesia; NA: Not applicable.*

TABLE 6. Comparison of various parameters during traditional LA administration in relation to arches.

SI. No	Parameters	Mandibular Arch (Mean ± SD) (Median (Q1, Q3))	Maxillary Arch (Mean ± SD) (Median (Q1, Q3))	*p* value
1	Time needed for delivering LA (in seconds)	51.06 ± 4.6	49.66 ± 5.2	0.442
2	FBRS			
	Before administration of anesthesia	3 (3, 4)	3 (3, 4)	0.479
	During administration of anesthesia	3 (2, 3)	2 (2, 3)	0.670
	Following administration of anesthesia	3 (3, 3)	3 (3, 3)	0.736
3	FLACC Scale	5 (4, 6.5)	4 (1, 5.5)	0.194
4	WBS			
	Prior to the procedure	0 (0, 2)	2 (0, 2)	0.232
	Instantly after administration of anesthesia	4 (2, 6)	4 (3, 6)	0.672
	During the procedure	0 (0, 0)	0 (0, 0)	0.571
	Upon completion of the procedure	0 (0, 0)	0 (0, 0)	1.000

Mann Whitney U test and independent t test. FBRS: Frankl Behavior Rating Scale; FLACC: Face, Legs, Activity, Cry, Consolability Scale; WBS: Wong-Baker scale; SD: Standard Deviation; LA: Local Anesthesia.

for addressing anxiety, as pain induction often exacerbates pain perception. The decision to use local anesthesia in dental practice depends on the clinical context and should aim to minimize pain sensation, as pain experienced during dental anesthesia can negatively impact the patient. Despite advancements in local anesthesia formulations and administration methods, traditional cartridge syringes remain the predominant choice globally [26].

Since the 1970s, jet injectors designed for dental use have been consistently employed, demonstrating successful anesthesia of the target tissue, and contributing to enhanced patient comfort during dental procedures [27]. While jet injections are effective for a range of dental procedures, their suitability may vary depending on the specific case and the type of dental work being performed. Factors such as cost and availability of jet injection systems may influence their adoption in dental clinics, and these considerations should be taken into account in the decision-making process [14].

Numerous studies examining the use of needle-free devices on both adult and child patients have been conducted and investigated, with particular emphasis on assessing the effectiveness of the device employed [5, 8, 12, 14, 27–33]. This needleless technique for delivering anesthetic provides several advantages, such as painless injection, minimal tissue harm, quicker administration, and enhanced drug absorption into the tissues in comparison to conventional needle delivery [14]. The results of these studies have consistently shown varying percentages of participants achieving satisfactory anesthesia, ranging from approximately 50% to around 90% [18].

Saravia *et al.* [30], in their study comparing the impact

of needle-free devices and traditional injections in children aged between 7 and 14 years, found no fear of needles among participants. Facial expressions concerning pain were evaluated, and children were asked to provide subjective perceptions of the dentist and dental restorative treatment. The study results showed no significant differences between the two injection methods in terms of the assessed parameters [30]. Both subjective and objective signs were considered in our study to gain a comprehensive understanding of both patient and observer perspectives on intervention strategies. Together, these provided an overall view of the feasibility and acceptability of the needle-free injection technique.

Brunton *et al.* [31] assessed the impact of needle-free injection techniques for dental extractions and found that patients experienced significantly less disturbance with the traditional needle injector during local anesthesia compared to the INJEX system. Additionally, pain scores were higher for the INJEX method of LA administration during extraction. Notably, a higher percentage of patients required additional anesthesia when the INJEX system was used [31]. However, the current study demonstrated minimal scores for both subjective and objective assessments in the INJEX group, indicating that the needle-free injection system was more effective compared to the traditional syringe technique. However, the validity of this result is related to case selection because the participants in our study underwent only indirect pulp capping compared to the previously mentioned study, which involved tooth extractions.

Makade *et al.* [27] conducted a similar study on the efficacy of jet injectors compared to traditional syringes in adults requiring restorative management. Their findings indicated that adults preferred jet injectors, as they offered better comfort and less pain and anxiety compared to traditional syringes [27]. Similarly, a study by Shankar *et al.* [32] concluded lower scores based on the Visual Analog Scale and Verbal Rating Scale for adult patients undergoing periodontal surgery [32]. The present study also showed similar results due to lower subjective and objective measures towards needle-free injection systems.

The beneficial influence of the painless system on children's behavior, as found in our study, was evident in the Frankl rankings. At first, the majority of children in both groups were rated positively. However, only the children in the INJEX group consistently displayed positive behaviour throughout the whole procedure. This might be due to the visual appeal of the injector, which captivated the attention of youngsters. The handpieces of these devices feature a distinct design that may be more easily embraced by young children, in contrast to conventional syringes. When comparing the needle-free injection (Comfort-In^{TM}) technology to traditional dental injections, Oliveira *et al.* [8] found no difference in pain perception.

Our study found that the INJEX system demonstrated more efficacy in the maxillary arch compared to the mandibular arch. In many cases, an extra dose of anesthetic was necessary for the mandibular arch to attain the same level of efficiency. The discrepancy might be ascribed to the permeable structure of the maxilla, facilitating the infiltration of the anesthetic solution in comparison to the mandible. Additionally, the maxilla attains skeletal maturity in late adolescent period [34]. In research conducted by Arapostathis *et al.* [14], it was shown that out of 87 treatment performed on children utilizing the INJEX system, an additional injection was required to reach the required degree of anesthesia in 80.5% of instances [14]. The WBS and FLACC ratings demonstrated that the INJEX group had lower levels of pain in comparison to the Traditional group, namely at scores of 2 and 1, respectively. Nevertheless, it is important to mention that the majority of children experienced surprise and panic due to the abrupt force and popping noise associated with jet injection, which they may have mistakenly perceived as pain.

The notable feature of this investigation is the meticulous use of equivalent gauge needles for both INJEX and traditional methods, which enhanced the reliability of the data provided. An important strength of the study is in the utilization of widely accepted pain scales, which allow for precise and reliable assessments of pain from both objective and subjective perspectives. Furthermore, the investigation was carried out by a specialist, guaranteeing uniformity in operational effectiveness. The delivery part of the INJEX system is angled at 45° with the gingiva to provide appropriate placement, in comparison to conventional pressure anesthetic systems. As a consequence, this leads to a simpler and more effective management, direct touch with the gums, little force used, and no bad taste or leaking. Nevertheless, it is crucial to acknowledge that the INJEX system does incur a greater expense in comparison to conventional needles. Administering medicine with a needle necessitates a cautious and watchful approach owing to its inherent dangers and possibility for injury. Adhering to appropriate needle handling practices, including maintaining the right angle, is essential to prevent inflicting significant harm. In contrast, needleless administration utilizes pressure to minimize the necessity for these measures [33].

5. Strengths and limitations

Although this study is one of the few that has examined the use of needle-free injection technique in children to compare pain levels with the traditional syringe technique, a limitation is that the participants were not evenly distributed across the different age groups, genders, and treatment approaches. However, the findings of the current study unequivocally indicate that the utilization of the INJEX system leads to reduced pain and discomfort ratings and is favored by the participants. Needle-free systems provide several significant benefits, such as their high speed and user-friendly nature, low or nonexistent discomfort, less tissue damage, accelerated medication absorption at the injection site, and avoidance of the hazards associated with needlestick incidents and post-operative problems. Nevertheless, there are a few drawbacks linked to the utilization of needle-free jet injections, such as the abrupt loudness generated during administration, elevated expenses, pressure feeling during anesthesia delivery, and the potential for hematomas. Additional study is necessary to assess the efficacy of inducing anesthesia in both the upper and lower dental arches, utilizing a larger sample size and employing a split-mouth experimental approach.

6. Conclusions

Based on the study's results, the following conclusions were drawn:

1. The INJEX or needle-free injection system proved to be effective compared to the traditional dental needle method in achieving anesthesia for restoring young permanent molars.

2. Pain perception levels were lower with the needle-free injection system compared to the traditional dental needle method, and patient cooperation during the operative procedure was higher with INJEX.

3. When comparing the effectiveness of achieving anesthesia in the maxilla and mandible, the needle-free injection system was particularly effective in the maxilla compared to the mandibular region during the restoration of permanent molars.

Therefore, the needle-free jet injection system offers a promising alternative for administering dental anesthesia, as it has the potential to enhance patient comfort and diminish the fear associated with traditional injections. Depending on the system's effectiveness, patient preferences, and the specific requirements of dental procedures, dentists may choose to incorporate this system into their practice.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

NHA, PCM and SV—designed the research study; wrote the manuscript; supervised all steps of the research. NHA, PCM, AAHA, BHAM, SAA and SV—performed the research. SP, AHMG, HTM, RHK, LYM and MBH—provided help and advice for the research. PCM and SV—analyzed the data. SP, AAHA, BHAM, SAA, AHMG, HTM, RHK, LYM and MBH—reviewed and edited 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

Prior to initiation of the study, an informed ethical consent and assent was obtained from the parents of all the children who had enrolled for the study. This study was conducted in accordance with Standing committee for scientific research, Jazan University, Jazan, Saudi Arabia (HAPO-10-Z-001) and approved by the Institutional Review Board, Jazan university under the reference number (Vide no REC-44/11/692. The prospective study was registered in the clinical trials registry with ref no NCT06448507.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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