

# Evaluation of the Injection Pain with the Use of Vibraject during Local Anesthesia Injection for Children: A Randomized Clinical Trial

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## ABSTRACT

**Aim:** To compare the outcomes of the conventional syringe and the outcomes of the vibraject-assisted injection (VAI) in terms of the pain of the needle insertion during various intraoral injections of local anesthesia in children aged 6–9 years.

**Materials and methods:** A total number of 75 children aged 6–9 years were selected from patients visiting the pediatric dental clinic at Damascus University. The children were assigned into three equal groups (25 children each) according to the type of intraoral injection needed for the treatment: Group I: received upper buccal infiltrations (UBI), Group II: received posterior palatal infiltrations (PPI), and Group III: received inferior alveolar nerve block (IANB). This study was conducted considering the split-mouth design. Each child was subjected to both anesthetic injections: the conventional and the vibration-assisted in two separate dental visits 2 weeks apart. At each clinic visit, subjective and objective pain levels were assessed using the visual analog scale (VAS) and Face, Leg, Activity, Cry, Consolability (FLACC) scale.

**Results:** Children who received local anesthesia using the Vibraject method had lower VAS and FLACC scores than those who received local anesthesia using the conventional method.

**Conclusion:** Vibraject was more effective in reducing the pain with local anesthetic injection compared to the conventional injection technique in clinical dental procedures for children.

**Clinical significance:** In a pediatric dental clinic, pain management is considered a pillar that influences actions. Using the VAI may achieve the ease, cooperation, and compliance during the dental care session.

**Keywords:** Local anesthesia, Oral injection, Pediatric dentistry.

*The Journal of Contemporary Dental Practice* (2022): 10.5005/jp-journals-10024-3383

## INTRODUCTION

Significant association is observed between pain during the most recent dental visit of children and poor oral health-related quality of life.<sup>1</sup>

Injections are the major reason for pain during routine dental treatment for children. Thus, dentists are advised to minimize the experience of pain and discomfort by using all available measures to perform pain-free and effective dental injections.<sup>2</sup>

Paradoxically, the primary goal of local anesthesia injections is to relieve pain in a specific region, while the actual process of administering the anesthetic drug is anxiety-inducing and painful due to the stimulation caused by needle insertion and injection of the anesthetic solution.<sup>3</sup>

Therefore, a successful pain management during those critical moments of needle insertion and anesthetic solution injection is crucial for achieving the ease, cooperation, and compliance during the dental care session itself.<sup>4</sup>

Several approaches are suggested for reducing the pain associated with local anesthetic injections, including the use of topical analgesics,<sup>5</sup> buffering and warming the local anesthetic solutions,<sup>6</sup> the use of enhanced syringes with fine needles, and injection site precooling.<sup>7</sup>

Even though these techniques have been documented in numerous studies, no definitive painless injection technique has yet been identified.

Vibratory stimulation is one of the nonpharmacological pain-relieving procedures used during a local anesthetic injection.

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**How to cite this article:** Albouni MA, Kouchaji C, Al-Akkad M, *et al.* Evaluation of the Injection Pain with the Use of Vibraject during Local Anesthesia Injection for Children: A Randomized Clinical Trial. *J Contemp Dent Pract* 2022;23(7):749–754.

**Source of support:** Nil

**Conflict of interest:** None

The concept of vibration is based on the gate control theory, which states that vibration acts as a counter-stimulation to the injection site.<sup>8</sup>

Melzack and Wall proposed the “Gate Control” theory in 1965, which helped to develop our perception of pain transmission. According to the theory, the application of non-noxious stimuli will reduce pain (like using appropriate pressure or vibration).<sup>9</sup> It also argues that non-noxious stimuli will reduce pain sensitivity by stimulating nerve fibers with a larger diameter.<sup>10</sup>

In clinical practice, vibration sensations not only decrease pain perception but also increase the pain threshold. The sensory signals from the oral cavity occupy more than a third of the brain's somatosensory cortex while operating in the highly sensitive oral cavity.<sup>11</sup>

Several studies have recently been conducted to look at the impact of vibration on pain during local anesthesia injections, but the findings are mixed. Vibraject is a battery-operated, compact vibratory system with an adapter that straps on to a regular dental syringe and produces high-frequency vibrations on the needle to suppress pain sensation during local anesthetic injections.<sup>12</sup>

If effective, this device may be a nonpharmacological, time-saving technique for improving the experience of children obtaining local anesthetic during dental procedures.<sup>13</sup>

Therefore, the purpose of this study is to compare the outcomes of the conventional syringe and the outcomes of the VAI in terms of the pain of the needle insertion during various intraoral injections of local anesthesia in children aged 6–9 years.

## MATERIALS AND METHODS

### Study Design

This study was conducted as a prospective randomized controlled trial. The informed consent was taken from parents or legal guardians before the procedures were carried out.

### Subjects

A total number of 75 consecutive children aged 6–9 years were recruited from the children visiting the Pediatric Dental Clinic, Faculty of Dentistry, Damascus University between April 2020 and May 2021 (Flowchart 1).

The children were assigned into three equal groups (25 children each) according to the site of intraoral injection needed for their treatment:

- Group I: Children underwent upper posterior buccal infiltration
- Group II: Children underwent posterior palatal infiltration
- Group III: Children underwent inferior alveolar nerve block

### Inclusion and Exclusion Criteria

Children who needed symmetric dental treatment and aged 6–9 years were included. On the other hand, children with acute or chronic inflammation or abscesses at the injection site or with previous traumatic painful dental experiences were excluded. Children who had taken any sedative or analgesic drugs in the past 24 hours of the dental visit were also excluded.

### Preanesthetic Procedures

The Frankel Scale was used to assess the patient's behavior before the procedure (which separates observed behaviors into four categories ranging from definitely negative to definitely positive).<sup>14</sup> After a brief description of the procedures and a warning about the possibility of future outcomes, each child's parents or guardians signed an informed consent document. Before the inspection and taking of dental and medical histories, the child was advised to sit comfortably in the dental chair and gain trust.

### Anesthetic Technique Designing

This study was done with the split-mouth design in mind. In two separate dental visits, each child received all anesthetic injections; traditional injections and vibration-assisted injections. The time

between the two visits was set at 1–2 weeks depending on each case. The order in which local anesthesia was administered, whether vibration aided or traditional, was chosen at random.

To see whether the vibratory system (Vibraject; Vibraject® MiltexInc LLC., York, PA, USA) was used on the first visit, the operator chose from an opaque bag one of two cards with the letter V or C printed on them (denoting vibration-assisted or conventional). We considered the child's main complaint when deciding which side to inject first (right or left). All topical anesthetic injections were administered by the same dentist to control operator-related variables such as gender, technical experience, and previous experience.

### Injection Technique

Topical anesthetic gel (20% benzocaine) was used for all children before local anesthesia administration. It was applied for 1 min on a previously dried mucosal surface before both anesthesia techniques. The same volume of local anesthesia (lidocaine HCl, 2% and epinephrine 1:10,000) was administered slowly to each child using one of the two injections, taking into account anatomical landmarks. A 27-gauge needle was chosen for all dental injections to simplify the protocol, as this needle size is commonly used in typical dental practice and as clinical studies show that there is no difference in perceived pain between 30-gauge needles (small gauge), 27-gauge needles (medium profile), and 25-gauge needles (large gauge).<sup>15</sup>

The VibraJect was chosen as the vibrator because it is a simple battery-operated device that easily clamps on to a syringe and requires little change from conventional injection (CI) techniques. In addition, it is relatively inexpensive compared to other vibration devices (e.g., DentalVibe).

### Pain Measuring Tool Used in This Study

The pain levels were assessed immediately after the injection. The VAS ranges across a continuum from none to an extreme amount of pain. The scale is scored in a range of 0–10, with 0 representing no pain and 10 worst pain.<sup>16</sup> After a brief description, each child was asked to rate the actual pain he or she felt during local anesthesia administration using the VAS. The child was asked to place a mark on the scale line where he or she thought it best reflected his or her level of pain.

As for objective assessment, the FLAAC scale was used because of its reliability in measuring pain levels in children who have difficulties in expressing extreme pain.

The FLACC scale is a measurement used to assess pain in children. The scale is scored in a range of 0–10 with 0 representing no pain. The scale has five criteria, which are each assigned a score of 0, 1, or 2.

### Variables Studied and Statistical Analysis

The determination of that each group should have a minimum of 25 subjects is based on power analysis and sample size calculation. The site of injection, the type of injection, and the pain score were recorded for each child. Mann–Whitney and Kruskal–Wallis tests were used. Data were analyzed by the SPSS statistical package version 20 (SPSS, Inc., Chicago, IL, USA).

## RESULTS

About 75 children, consisting of 38 girls (50.7%) and 37 boys (49.3%), aged from 6 to 10 years, were included in this study. Both injection

Flowchart 1: CONSORT flow diagram

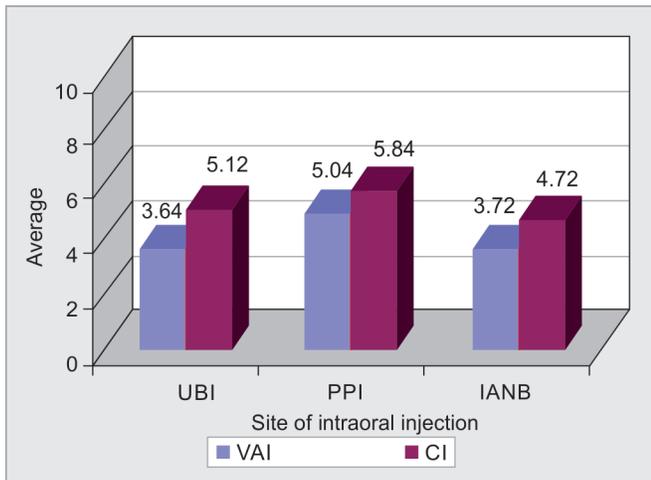
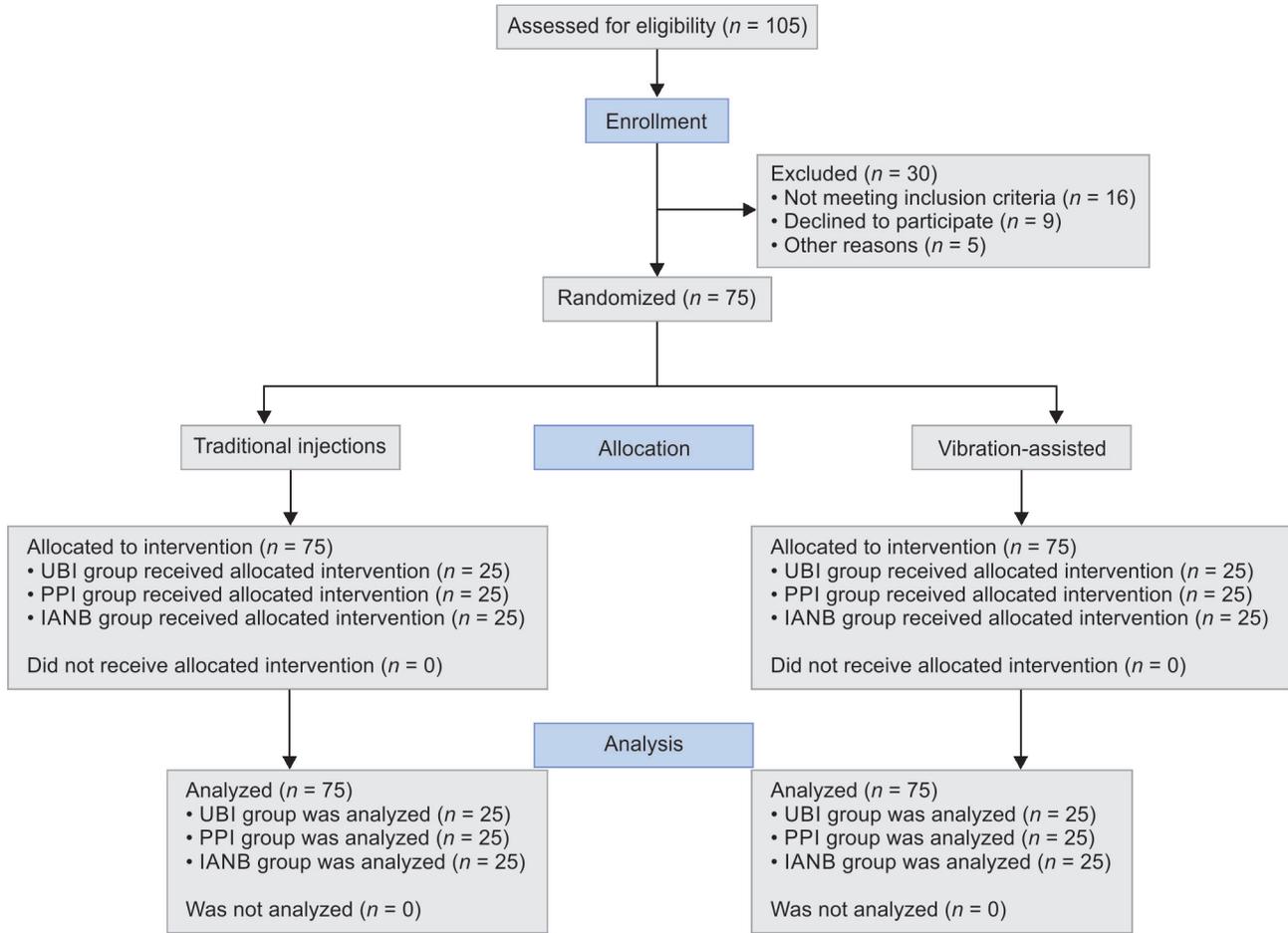


Fig. 1: Average of VAS score values according to local anesthesia injection method and site of intraoral injection variables

methods CI and VAI allowed the completion of 150 local anesthesia procedures.

The mean value of VAS by using the conventional syringe was 5.12 in group I upper posterior buccal infiltration (UBI) subjects, 5.84 in group II posterior palatal infiltration (PPI) subjects, and 4.72 in group III inferior alveolar nerve block (IANB) subjects (Fig. 1).

Meanwhile, the mean value of VAS by using a VibraJect-assisted syringe was 3.64 in group I UPI subjects, 5.04 in group II PPI subjects, and 3.72 in group III IANB subjects.

On comparing the difference in VAS by using the conventional syringe and the VibraJect-assisted syringe, a significant difference was detected in Groups I, II, and III ( $p$ -value = 0.000, 0.001, and 0.000, respectively) with VAS being higher by using conventional syringe than the VibraJect-assisted syringe. Table 1 shows descriptive statistics and Mann–Whitney  $U$  Test results of the VAS pain score values in the VAI and CI groups according to the site of intraoral injection variable.

Similarly, in the FLACC scale, the responses that indicate “mild” and “moderate” pain levels were higher in the VAI method, whereas the “severe pain” response was higher in the CI method compared with the VAI (Fig. 2).

Table 2 shows mean ranks and Mann–Whitney  $U$  Test results of the FLACC degree frequencies in the VAI and CI groups, according to site of intraoral injection variable.

The data from VAS and FLACC scales indicated that the posterior palatal infiltration injection produced a higher pain response than the other two injections (Figs 3 and 4).

## DISCUSSION

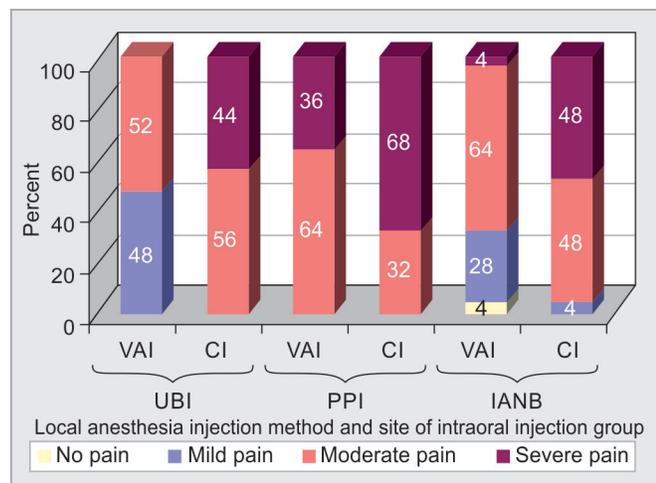
The results of our study show that the use of the VibraJect-assisted syringe significantly reduces the sensation of pain in children in all the groups.

## Pain during Local Anesthesia Injection

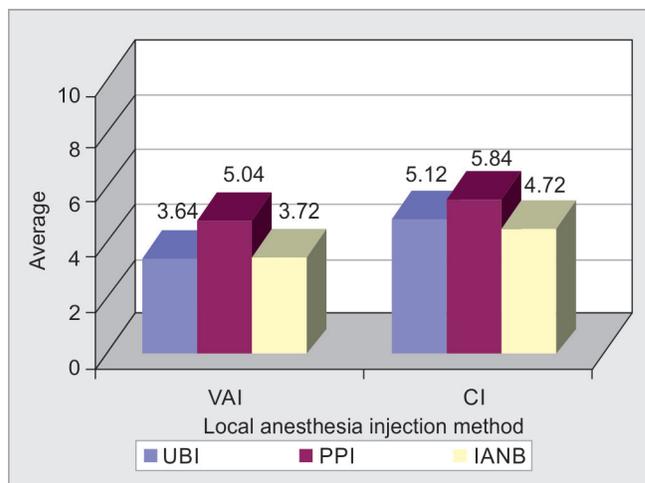
**Table 1:** The VAS pain score values in the VAI and CI groups according to site of intraoral injection variable

Site of intraoral injection	Local anesthesia injection method	N	Mean	Std. deviation	Minimum	Maximum	Mean difference	U value	p-value	Significant diff.?
UBI group	VAI	25	3.64	0.81	2	5	-1.48	57.0	0.000	YES
	CI	25	5.12	0.67	4	6				
PPI group	VAI	25	5.04	0.84	4	7	-0.80	154.0	0.001	YES
	CI	25	5.84	0.69	5	7				
IANB group	VAI	25	3.72	0.68	2	5	-1.00	102.0	0.000	YES
	CI	25	4.72	0.68	3	6				

UPI, upper posterior buccal infiltration; PPI, posterior palatal infiltration; IANB, inferior alveolar nerve block



**Fig. 2:** Percent of FLACC degree during anesthesia observation results according to gender, local anesthesia injection method, and site of intraoral injection group



**Fig. 3:** Average of VAS pain values according to site of intraoral injection and local anesthesia injection method variables

**Table 2:** Mean ranks and Mann–Whitney U test of FLACC degree frequencies between VAI and CI groups according to site of intraoral injection variable

Site of intra-oral injection	Local anesthesia injection method	N	Mean rank	U value	p-value	Significant diff.?
UBI group	VAI	25	16.64	91.0	0.000	YES
	CI	25	34.36			
PPI group	VAI	25	21.50	212.5	0.025	YES
	CI	25	29.50			
IANB group	VAI	25	18.38	134.5	0.000	YES
	CI	25	32.62			

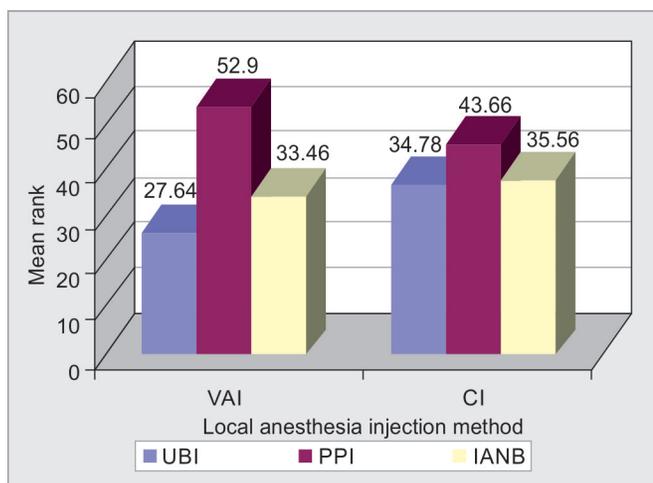
UBI, upper posterior buccal infiltration; PPI, posterior palatal infiltration; IANB, inferior alveolar nerve block

To the best of our knowledge, other studies examining VibraJect in children have been studied without considering the injection site, which gave us the advantage of assessing the pain felt during injection with and without vibration at three different injection sites UPI, PPI, and IANB in children.

Our results are consistent with Chaudhry et al. who also evaluated the effectiveness of VibraJect for pain relief from local anesthetic injections in 20 children aged between 8 and 14 years.<sup>14</sup> In addition, Chandrasekaran et al. reported that VibraJect significantly reduced pain under local anesthesia in 37 adults above 18 years of age.<sup>17</sup> The age limit in our study ranged from 6 to 9 years,

as it is the most common age range for children attending the University of Damascus Pediatric Dental Clinic. Furthermore, this age-group was adequate for explaining the pain scale to children and for obtaining reliable scores from them. Vibration on pain during local anesthesia injections discovered that, as compared to traditional injections, vibration injections caused less pain and a lower pain rating.<sup>18</sup>

In a study by Tandon et al., the results were in the favor of our study. Local anesthetic injection along with mucosal vibration resulted in significantly less pain in comparison with the injections without the use of mucosal vibration in 30 children aged between



**Fig. 4:** Mean ranks of FLACC degree during anesthesia according to site of intraoral injection and local anesthesia injection method variables

6 and 11 years. Pain was scaled using sound, eye, and motor scale and facial pain rating after administration of injection.<sup>19</sup>

On the other hand, the results of a pilot study by Saijo et al. were in contrast to ours. No statistically significant decrease in pain scores was found at needle insertion nor at anesthetic injection. The study concluded that the clinical efficacy of VibraJect is controversial. Nevertheless, this may be explained by the small size of sample of only 10 participants.<sup>20</sup>

A single-blind randomized controlled study performed by Roeber et al. examined 90 children receiving local anesthesia for routine restorative procedures. They also disagreed with our results. One possible explanation for this disagreement is that Roeber et al. did not compare the injection of VibraJect to the CI in the same patient.<sup>21</sup>

Garewal et al. evaluated the efficacy of five different adjunctive aids of local anesthesia in reducing pain and anxiety in pediatric patients of the 6–8 years of age group. A total of 90 child dental patients were allocated in six groups. One group as control, plus five groups corresponding to the adjunctive aids: topical gel, audio, audiovisual, transcutaneous electric nerve stimulation, and VibraJect. Physiological parameters, psychological parameters, and pain assessment were recorded. Transcutaneous electric nerve stimulation and VibraJect groups showed maximum reduction in pain.<sup>22</sup>

In the current study, the palatal injection was the most painful. This was in agreement with the results of Badcock et al.<sup>23</sup> Although they are painful and poorly tolerated by patients, palatal injections are still needed, as dictated by the anatomical description of palatal sensory innervations, to anesthetize palatal soft tissues whenever a procedure may involve their manipulation.

VibraJect was effective in reducing pain with local anesthetic injection compared to the CI technique in clinical dental procedures in children. It may be a promising method for relieving the pain of local dental anesthetic injections in children.

There are two limitations in this study that could be addressed in future research. Both are related to the sample selection. First, the study focused only on the children aged 6–9 years. Second, the children seeking treatment at Damascus University are usually from the same socio-economic status.

## CONCLUSION

VibraJect is a safe and effective nonpharmacological way to reduce the pain experienced with injection of local anesthetics during clinical dental treatment of children compared to traditional injection techniques. It allows a more convenient dental experience for the children.

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