Evaluation of the injection pain with the use of DentalVibe injection system during supraperiosteal anaesthesia in children: a randomised clinical trial

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Purpose. The purpose of this study was to compare the use of a traditional syringe (TS) and the DentalVibe (DV) Injection Comfort System on the pain of needle insertion and injection of supraperiosteal (SP) anaesthesia into the mandibles and maxillas of children aged 6–12 years.

Methods. The study was a randomised, controlled, crossover clinical trial, comprising 60 children requiring an operative procedure with SP anaesthesia on both their mandibular and maxillary molars, bilaterally. One of the molars was treated with a TS, and the contralateral tooth was treated with the DV for both arches. On each visit, subjective and objective pain was evaluated using the Wong-Baker FACES Pain Rating Scale and the Face, Leg, Activity, Cry, Consolability Scale. Patients were asked which technique they preferred. The data were analysed using Wilcoxon signed-rank test, Spearman’s correlation test, and Mann–Whitney U-test.

Results. No statistically significant differences were noted between TS and DV for pain during injection and needle insertion for supraperiosteal anaesthesia in either the maxillary and mandibular operative procedures.

Conclusions. Children experienced similar pain during SP anaesthesia administered with a TS and the DV, regardless of gender and jaw differences. DV was less preferred over the traditional procedure in children.

Introduction

Several methods are available for dental pain control using local anaesthetics, which vary according to the site of anaesthetic deposition relative to the area of the operative procedure. One of the most common techniques is to anaesthetise individual teeth or a circumscribed portion of the mandible or maxilla by infiltration, also known as supraperiosteal anaesthesia¹. Infiltration anaesthesia, which is usually considered as an atraumatic method of pain control, is used in dentistry due to the ease of implementation and very high success rate³. This technique offers pain-free treatment, comfort, and cooperation for the patient and improved performance by the practitioner, but the application of a local anaesthesia paradoxically causes injection pain and anxiety². Some studies have reported that infiltration anaesthesia is a less painful injection method when compared with palatal injections, nerve blocks, or periodontal ligament injections³, but it is not a pain-free injection. Moreover, Yassen et al. reported that mandibular infiltration anaesthesia was not significantly less painful than a mandibular block⁴.

Injection pain in paediatric patients may have long-term negative consequences, such as fear and anxiety, causing a negative influence on the behaviour, comfort, and cooperation of the child during subsequent dental treatments⁵. Thus, a number of methods have been suggested to minimise the injection pain of local anaesthesia, including prior application of a topical anaesthetic, the use of lidocaine patches, warming and buffering the anaesthetic agents, performing electronic dental anaesthesia, and using a computer-controlled local anaesthesia delivery system (CCDS)¹,⁶. The application of topical anaesthesia or the use of lidocaine patches still do
not provide a completely painless injection. Some authors have also reported that CCDS reduces the injection pain\textsuperscript{7}, whereas other studies did not find a reduction in pain when comparing the CCDS with the traditional injection\textsuperscript{8}.

The vibration stimulus, which is based on the gate control theory, is one of the newly introduced procedures for reducing injection pain\textsuperscript{9}. The gate control theory of pain, proposed by Melzack and Wall, holds that physical pain is not a direct outcome of activation of pain receptor neurons; rather, its perception is modulated by the interactions between different neurons\textsuperscript{10}. The activity generated by myelinated primary afferent fibres (the A\textsubscript{beta} fibres) inhibits the transmission of activity in small unmyelinated primary afferent pain fibres (the C fibres) via inhibitory circuits in the dorsal horn. Therefore, stimulating the larger diameter A\textsubscript{beta} fibres by application of pressure or vibration can interrupt nociceptive signals, thereby ‘closing the gate’ and reducing the perception of pain\textsuperscript{11}. In this regard, the positive effects of vibratory stimulation on pain reduction have been reported in both clinical and experimental settings\textsuperscript{12-16}.

Vibrational stimuli are easily administered in the orofacial region and can be used to increase the pain threshold. Nanitsos et al. researched the effect of vibrations on pain during local anaesthesia injections\textsuperscript{12}. Their results indicated that injections with vibration resulted in decreased pain and lower pain ratings when compared to injections with no vibration stimulus.

One of the newly developed dental devices for producing vibration during the injection of local anaesthesia is the DentalVibe (DV), a wireless, rechargeable, and hand-held injection system that reportedly delivers soothing, pulsed percussive vibration by gently tapping the surrounding mucosa of the injection site while also illuminating the injection area. The device also has an attachment for retracting the lip or cheek\textsuperscript{13}. Some studies reported in the literature have stated that DV lowered the pain experienced by adults during the administration of a local anaesthetic\textsuperscript{14,15}. Ching et al.\textsuperscript{16} reported that DV significantly reduced pain during local anaesthesia injection in adolescents when compared to a conventional approach. No study, however, has yet compared DV and conventional methods during local infiltration injection in younger age groups.

The purpose of this prospective, randomised clinical study was to compare the injection pain of local infiltration anaesthesia administered by DV injection and TS injection to both the mandible and the maxilla in children aged 6–12 years.

**Material and methods**

The protocol of this study was approved by the Ethics Committee of Kocaeli University (KOU KAEK#196/2014), and written consent was obtained from both parents and patients before every treatment. Based on the data from a previous study\textsuperscript{16}, a minimum sample size of 58 subjects was calculated using the G*Power software program (version 3.1.9.2; power 0.95, $\alpha = 0.05, \beta = 0.05$). Therefore, taking into account the possible requirements for additional anaesthesia or other events, in total sixty children (29 boys and 31 girls), who were receiving dental treatment in a paediatric dental clinic, were selected based on a need for infiltration anaesthesia for operative procedures on the bilateral primary molars in both the maxillary and the mandibular arches (a total of four cavities per patient). One patient was excluded from the study because he presented with varicella during the course of the appointments.

The inclusion criteria were as follows: 6–12 years of age, no medically or developmentally compromising conditions, and having positive or definitely positive behaviour during preoperative behavioural assessments according to the Frankl Scale (which separates observed behaviours into four categories ranging from definitely negative to definitely positive)\textsuperscript{17}. The exclusion criteria were as follows: the presence of medically or developmentally compromising conditions, a history of chronic disease, the current use of medication that contraindicated the use of local anaesthetic, having active sites of pathosis in the area of injection that could affect...
anaesthetic assessment, and having negative or definitely negative behaviour during preoperative behavioural assessments according to the Frankl Scale.

The ‘tell-show-do’ technique was used for all patients. Reframing techniques (e.g., using euphemistic phrases such as ‘putting the tooth to sleep’) were used to describe the injection to all the children. No child needed a sedative or other pharmacological therapy prior to receiving dental treatment.

This randomised and controlled study was conducted as a split-mouth design. Operative procedures were performed on both the left and right maxillary and the mandibular teeth of each patient with SP anaesthesia using two different anaesthesia systems [TS or DV (BING Innovations, Boca Raton, FL, USA)] with an interval of 5 days between procedures. The administration of local anaesthesia in the maxilla or mandible and the injection technique used in the first procedure in a patient were chosen randomly using R 2.11.1 software (R Foundation for Statistical Computing, Vienna, Austria). Randomisation and allocation of the groups were carried out by only a person who did not perform the injection or evaluation of the pain. In total, 118 injections in the maxilla (59 with DV, 59 with TS) and 118 injections in the mandible (59 with DV and 59 with TS) were administered (Fig. 1).

Before initiating all treatments, the site of the injection was dried and a topical anaesthetic (Hurricane, Beutlich, Waukegan, IL, USA) was applied with a cotton tip applicator for 60 s. For all injections, 1 mL of articaine hydrochloride with 1/100,000 epinephrine (Ultracaine D-S forte, Hoechst Canada Inc., Montreal, QC, Canada) was injected using a 27G dental needle.

A demonstration of DV was performed by putting into direct contact with the children’s nails before applying the device intraorally. In both TS and DV groups, the DV device was placed on the oral mucosa to enclose the injection site before administering local anaesthesia. Potential subject-expectancy effects and pressure from the placement of the DV were controlled for by placing the device near the injection area for all injections; however, it was not turned on for the TS group. Although blinded conditions could not be performed exactly because of the noise of the device, it was used as a retractor in the same manner as a dental mirror (Fig. 2).

SP anaesthesia was administered as follows: after stretching the mucosa of the injection region with the comfort tips of the DV, the needle penetrated the mucobuccal fold between the two tips of the device and was inserted to the depth of the apices of the buccal roots of the teeth. A small amount of solution was injected into the superficial mucosa; after a few seconds, the needle was slowly advanced 1–2 mm and, after a negative aspiration, another small amount of solution was deposited. In the TS group, SP injections were administered using only TS. In the DV group, the DV was turned on to stimulate the area of needle penetration. After 5 s of vibration, the needle was inserted. The DV continued vibrating during needle insertion and anaesthetic injection. All dental injections were administered by the same operator, who already had 2 months of experience using the DV. During the study, both injection techniques were evaluated by a single rater, who was an experienced paediatric dentist and did not perform the treatment. Unfortunately, blindness of the observer was not achieved because of the vibration noise of the DV. Wearing headphones was considered for creating blinded conditions, but this was not feasible because the pain ratings required hearing as well as visual observation.

Both subjective and objective evaluations were performed to measure the pain of each child in this study. The objective assessment was performed by observing the patients’ behaviour using the Face, Leg, Activity, Cry, Consolability Scale (FLACC Scale) during the anaesthetic injection and needle insertion\(^{18}\). The scale comprised the following parameters: (1) Face, (2) Legs, (3) Activity, (4) Cry, and (5) Consolability. Each of the five categories is scored from 0 to 2, which results in a minimum score of 0 and maximum of 10. According to this scale: 0 = relaxed and comfortable (no pain), 1–3 = mild discomfort, 4–6 = moderate pain, and 7–10 = severe discomfort or pain. Behavioural parameters were recorded.
The subjective evaluation was obtained using the Wong-Baker FACES pain rating scale (PRS) \(^{19}\). The PRS consists of a set of cartoon faces with varying facial expressions, ranging from a smile/laughter to tears, and each child was asked to select the facial expression that best represented their discomfort. Each face has a numerical value ranging from 0 (smiling face, ‘no hurt’) to 5 (crying/screaming face, ‘hurts worst’). The same investigator who evaluated the injection techniques explained the Wong-Baker FACES Scale to the children and their parents, and each child was trained to use the scale by first
modelling and then asking each participant to ‘think of the last time she/he felt something painful’ and to select the facial expression that best represented his/her experience of discomfort. As the patient group consisted of Turkish children only, the investigator did not encounter any difficulties in explaining the scale. Immediately after the anaesthesia injection, the patients were asked to use the PRS to indicate how they felt during needle insertion and solution injection. Needle insertion was defined as ‘the first time he/she felt discomfort’ and solution deposition as ‘a later time he/she felt discomfort’ during injection. These data were then recorded.

After injections for the bilateral teeth in maxilla and mandible, all patients were asked to indicate their preference of injection type (TS or DV injection). These data were recorded.

The injections in both sides of the maxilla or mandible in the first ten patients were video-taped to establish reliability of the rater. These videotapes were evaluated 3 weeks after the treatments. The reliability of the rater was established in two ways. First, the rater’s evaluations on the scales were compared to his evaluations of videotapes, to establish intra-rater reliability. Second, another rater, who was an experienced paediatric dentist, evaluated the videotapes and these evaluations were then compared to the main rater’s evaluations to establish inter-rater reliability.

Statistical analysis was then performed using a commercially available software program (SPSS 20.00; SPSS, Chicago, IL, USA) to compare the measurements of both scales. Spearman’s rho (ρ) test was used to establish intra-rater reliability. Inter-rater agreement was assessed using Kappa (κ) test, with values >0.81, 0.80–0.61, 0.60–0.41, 0.40–0.21, and <0.20 denoting perfect, substantial, moderate, fair, and slight agreement, respectively. The differences between groups were evaluated using Spearman’s correlation test and Mann–Whitney U-test and Wilcoxon t-test. Gender differences were examined by analysing the data with Monte Carlo chi-square and Fisher’s exact tests; the level of significance was set at P < 0.05.

Results

Sixty children, consisting of 31 girls (51.7%) and 29 boys (48.3%), aged from 6 to 12 years (7.31 ± 1.35), were included in this study. Both injection methods (TS and DV) allowed completion of 236 local infiltration anaesthesia procedures in a total of 59 patients. None of the patients showed any adverse reactions to the treatment. Intra- and inter-rater reliabilities were established as ρ = 0.832, which indicated high reliability for intra-rater reliability, and κ = 0.90, which means perfect inter-rater reliability from the observations, according to the video-taped data.

Most of the pain scores were low according to PRS and FLACC Scale in this study. The median values of the pain scores did not exceed 2 indicating ‘mild pain’ according to FLACC Scale and ‘little bit’ according to PRS. Most of the pain ratings provided by children (PRS) and dentist (FLACC Scale) showed significant correlation, with P values of <0.01 (Table 1).

According to FLACC Scale data, the number of ‘no pain’ responses was higher in the DV group than in the TS group for needle insertion in the maxilla (DV:22/TS:19) and anaesthetic injection in the mandible (DV:20/TS:18). In contrast, the number of ‘no pain’ responses was smaller in the DV group than in the TS group for needle insertion in the mandible (DV:15/TS:19) and anaesthetic injection in the maxilla (DV:20/TS:21). The number of ‘severe discomfort or pain or both’ responses was higher in the TS group than in the DV group for both procedures in the maxilla (TS:2/DV:1 for needle insertion, TS:3/DV:1 for anaesthetic injection) and in the mandible (TS:5/DV:1 for needle insertion, TS:4/DV:2 for anaesthetic injection). The results were not statistically significant during needle insertion and anaesthetic injection in both the maxilla and the mandible, according to the Wilcoxon signed-rank test (P > 0.05) (Table 2).

The PRS data indicated that the number of ‘no hurt’ responses was equal in both the DV and the TS groups for needle insertion (DV/TS: 19), whereas the number of ‘no hurt’ responses was higher in the TS group for...
anaesthetic injection (TS:13/DV:10) in the maxilla. In the mandible, the number of ‘no hurt’ responses was higher in the DV group for both procedures (DV:18/TS:16 for needle insertion, DV:12/TS:11 for anaesthetic injection). The number of ‘hurts worst’ responses was smaller only in the DV group for needle insertion (DV:4/6) in the maxilla. The results were not statistically significant between groups during needle insertion and anaesthetic injection for both the maxilla and the mandible, according to the Wilcoxon signed-rank test ($P > 0.05$) (Table 3).

The Mann–Whitney $U$-test revealed no significant effect of gender in either the DV or the TS groups during needle insertion and anaesthetic injection for both the maxilla and the mandible, according to FLACC Scale and PRS ($P > 0.05$). Moreover, there was no correlation between age and both techniques for maxilla and mandible according to Spearman’s correlation ($P > 0.05$).

Most patients in this study preferred the use of TS during local anaesthesia administration. In total, 41 of 59 subjects preferred TS for the maxilla, whereas 38 preferred TS for the mandible. A total of 36 subjects chose TS after the first bilateral injections, whereas 43 subjects chose TS after the second bilateral injections. No significant difference was noted between the subjects who received DV first or second (chi-square test, $P > 0.05$). No significant gender difference was observed in terms of preference (chi-square test, $P > 0.05$) (Table 4).

**Discussion**

This study revealed that vibration applied using the DV did not decrease the injection pain associated with supraperiosteal anaesthesia for both the maxilla and the mandible, taking into account the age, gender, and the scale used in children aged 6–12 years.

Management of the pain induced by administering local anaesthesia is one of the most important aspects of patient care, especially in paediatric dentistry. A painful injection may cause paediatric patients to become more likely to avoid future dental care when...
compared with adults. Therefore, various strategies, devices, or techniques have been developed to reduce or remove injection pain. Utilisation of a vibration stimulus is a newly introduced method for decreasing the sensation of local anaesthesia injection pain. In a previous study, Hutchins et al. reported that the vibration stimulus might be an effective procedure for reducing the pain of dental local anaesthesia injections.

Several vibrotactile devices exist which produce vibrations to reduce injection pain, including the VibraJect, DV, Syringe Micro Vibrator, and Accupal. The VibraJect is a device that snaps onto the needle. Previous studies on the VibraJect by Yoshikawa et al., Roebel et al., and Saijo et al. found no significant pain reduction when compared to a conventional local anaesthesia injection technique. These authors concluded that the possible reason was that the vibrations were extremely small and did not activate the large nerve fibres in that area in many individuals. The authors also stated that the design of the device was an important factor in pain perception for applying local anaesthesia.

Table 2. FLACC Scale pain scores during needle insertion and anaesthetic injection (n = 59).

<table>
<thead>
<tr>
<th>No pain (Max/Mand)</th>
<th>Mild pain (Max/Mand)</th>
<th>Moderate pain (Max/Mand)</th>
<th>Severe pain (Max/Mand)</th>
<th>P values (Max/Mand)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle insertion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DV 22/15</td>
<td>28/33</td>
<td>8/10</td>
<td>1/1</td>
<td>0.878/0.477</td>
</tr>
<tr>
<td>TS 19/19</td>
<td>29/28</td>
<td>9/7</td>
<td>2/5</td>
<td></td>
</tr>
<tr>
<td>Anaesthetic injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DV 20/20</td>
<td>28/30</td>
<td>10/7</td>
<td>1/2</td>
<td>0.489/0.365</td>
</tr>
<tr>
<td>TS 21/18</td>
<td>25/29</td>
<td>10/8</td>
<td>3/4</td>
<td></td>
</tr>
</tbody>
</table>

No significant difference between groups (P > 0.05).

Table 3. Wong-Baker FACES Pain Rating Scale scores during needle insertion and anaesthetic injection (n = 59).

<table>
<thead>
<tr>
<th>No Hurt (Max/Mand)</th>
<th>Little Bit (Max/Mand)</th>
<th>Little More (Max/Mand)</th>
<th>Even More (Max/Mand)</th>
<th>Whole lot (Max/Mand)</th>
<th>Hurts worst (Max/Mand)</th>
<th>P values Max/Mand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle insertion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DV 19/18</td>
<td>16/15</td>
<td>10/9</td>
<td>7/6</td>
<td>3/3</td>
<td>4/8</td>
<td>0.860/0.803</td>
</tr>
<tr>
<td>TS 19/16</td>
<td>13/16</td>
<td>15/9</td>
<td>4/8</td>
<td>2/4</td>
<td>6/6</td>
<td></td>
</tr>
<tr>
<td>Anaesthetic injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DV 10/12</td>
<td>18/12</td>
<td>11/16</td>
<td>11/6</td>
<td>4/7</td>
<td>5/6</td>
<td>0.424/0.321</td>
</tr>
<tr>
<td>TS 13/11</td>
<td>14/14</td>
<td>14/14</td>
<td>10/10</td>
<td>5/4</td>
<td>3/4</td>
<td></td>
</tr>
</tbody>
</table>

No significant difference between groups (P > 0.05).

Table 4. Preferences of subjects according to order of the techniques, jaws, and gender (n = 59).

<table>
<thead>
<tr>
<th>Maxilla</th>
<th>Mandible</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>TS (Girls/Boys)</td>
<td>DV (Girls/Boys)</td>
<td>TS (Girls/Boys)</td>
</tr>
<tr>
<td>First Bilateral Injections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First TS 9/8</td>
<td>4/3</td>
<td>8/6</td>
</tr>
<tr>
<td>First DV 1/2</td>
<td>4/2</td>
<td>2/0</td>
</tr>
<tr>
<td>Second Bilateral Injections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First TS 5/4</td>
<td>1/1</td>
<td>7/9</td>
</tr>
<tr>
<td>First DV 5/7</td>
<td>2/1</td>
<td>2/4</td>
</tr>
</tbody>
</table>

No significant difference between groups (P > 0.05).
VibraJect needle was connected to the device while in use for injection, the vibration stimuli could complicate the injection process. Additionally, the presentation of the device with a needle could be frightening for paediatric patients. In contrast, the DV looks like a dental mirror and has a toy head that comes in different animal shapes, so it can be applied comfortably, especially in paediatric patients\(^{14}\). Furthermore, the DV gives practitioners the ability to hide the syringe from children easily and to manipulate the needle safely during injection. These advantages made the DV our device of choice for producing vibration during the administration of local anaesthesia injection in this study.

Measuring the pain of children is a difficult and complex process, because of their limited experiences, cognitive level, and a still-growing capacity for expressions and vocabulary\(^{26}\). The PRS, developed with the intent of subjective evaluation, has adequate psychometric properties and is easy to use. Although subjective measurement is generally considered the gold standard when assessing pain\(^{27}\), Zarbock\(^{26}\) stated that subjective evaluation may not always provide real results because younger children have insufficient cognitive development for understanding pain scales. The FLACC Scale has been shown to have excellent validity and reliability for pain assessment in young or cognitively intact children for objective evaluation\(^{18,28}\). Merkel \textit{et al.}\(^{28}\) reported that the FLACC Scale is very reliable and valid for quantifying pain in children who have difficulties expressing severe pain. In this study, the subjective and objective pain of children was assessed using PRS and FLACC Scale to obtain a greater reality in the results, by benefiting from the advantages of both scales.

Some studies have evaluated the pain upon needle insertion and solution deposition together\(^{16,24}\), and others have evaluated each pain separately in children\(^{7}\). In this study, the evaluation was performed separately. For PRS evaluation, although needle insertion was defined for the children as ‘the first time he/she felt discomfort’ and solution deposition as ‘the later time he/she felt discomfort’ during injection, this still might create a doubt whether they could discern the difference and reported pain accurately. The use of two different scales reduced this risk, as the observer rated the pain first with the FLACC Scale so as not to be biased by the children’s self-report. Eventually, the pain scores gathered from both the patients and the observer were highly concordant.

The results of this study indicated no statistically significant difference between the DV and traditional infiltration injection techniques during needle insertion and anaesthetic injection for both the maxilla and the mandible. This result was inconsistent with the studies of DiFelice \textit{et al.}\(^{15}\) and Ungor \textit{et al.}\(^{14}\), who indicated decreased pain with the use of DV. Their studies, however, utilised different local anaesthesia techniques, so comparison of the results of previous studies with those of this study may not be appropriate or feasible.

Ching \textit{et al.} compared injection pain between the DV and traditional injection and applied all local infiltration injections bilaterally for both the maxilla and the mandible\(^{16}\). These authors, however, concluded that DV significantly lowered injection pain during the delivery of local anaesthesia. This result could have arisen because their study was performed in adolescent patients, as children tend to assign higher intensity scores for pain when compared to adults and adolescents, possibly because they have fewer pain experiences to use as reference points. Another possible reason is that children may have interpreted the pressure and vibration caused by the DV as a type of pain or discomfort, which would explain why DV was found inefficient for reducing injection pain. Koyturk \textit{et al.}\(^{6}\) evaluated the injection pain of SP anaesthesia on 6- to 12-year-old children with two different techniques (conventional and The Wand) and found no significant difference in perceived pain. They reported that most of the children did not exhibit any anxiety related to local anaesthesia and concluded because the study group consisted of low-anxiety children who acted most positively and it seemed that the Wand as not a useful device. Similarly, in this study, although the DV was not found to be effective in reducing
perceived pain or disruptive pain behaviour in children, the DV may still prove beneficial for some individuals. This study performed on the children with high cooperation whose pain response scores were mostly ‘mild’ or of ‘no pain’ for both injections and might show DV as ineffective. When considering the anxiety which has high impact on the perception of pain, additional researches are needed to determine whether individual characteristics can predict who might like the DV. A previous study by Elbay et al.\textsuperscript{29} found a negative correlation between age and pain scores during inferior alveolar nerve block anaesthesia injection with DV. In contrast, there was no correlation in this study. The difference might be due to the anaesthesia technique. The injection area in the SP anaesthesia is closer to the underlying bone, so the vibration of the device would be felt further by the children, and even the age was increased, they might interpret this vibration as pain or discomfort.

In contrast to previous studies that evaluated the DV for administering local anaesthesia\textsuperscript{14,16}, this study reported that the number of patients who preferred TS injection was higher than the number that preferred DV injection. This contradiction can be explained by the possibility that children could dislike the noise and vibration of DV. Although wearing headphones would prevent the noise, it could not prevent the vibration sensation; therefore, it was considered not to be an option for creating blinded conditions.

The anatomical location for intraoral injection is recognised as one of the most important determinants causing injection pain in the clinical practice of dentistry\textsuperscript{3}. In a preliminary study, Aminadabi et al. evaluated the paediatric reaction to the pain produced by local anaesthesia injection in different intraoral regions\textsuperscript{30}. These authors found that the posterior segment of the maxilla exhibited lower pain scores when compared to the posterior segment of the mandible. This present research evaluated the injection pain on both the maxilla and the mandible separately and found no difference between both jaws, in contrast to the earlier study mentioned above.

No significant gender difference was found for either anaesthesia method in terms of pain scores during needle insertion and injection. These findings are consistent with a previous study, where boys and girls showed the same reaction while receiving local anaesthesia\textsuperscript{6}.

To the best of our knowledge, this is the first study that evaluates the effectiveness of the DV for SP anaesthesia in children aged 6–12 years for local anaesthesia administration using the SP technique. Further studies on children are recommended to confirm the accuracy of these results.

**Conclusion**

Children experienced similar levels of pain during supraperiosteal anaesthesia administered with a TS or DV, regardless of gender differences or jaw location. The children also preferred receiving anaesthesia with the traditional approach rather than the DV injection system.

**Why this paper is important to paediatric dentists**

- Paediatric dentists should be aware of the effectiveness of new injection devices designed to reduce injection pain.

**Conflict of interest**

The authors have no connection with the manufacturers of the DentalVibe Injection Comfort System.

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