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RANDOMIZED CONTROL TRIAL

Effect of the DentalVibe Injection System on Pain During Local Anesthesia Injections In Adolescent Patients

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Abstract: Purpose: The purpose of this study was to compare the pain rating scale measurements from an exposure group (injections with the aid of DentalVibe Injection Comfort System) and control group (traditional injection without the aid of the DentalVibe) in adolescent patients using self-reported pain during administration of local anesthetic injections. Methods: This was a randomized, controlled study. Subjects consisted of 36 10- to 17-year-old patients who required dental treatment on both sides of the maxilla or mandible. All subjects received a conventional injection (control) and an injection using DentalVibe (experimental). A pain rating for each injection was obtained from subjects using the Wong-Baker FACES Pain Rating Scale. Results: Statistical analysis using a Wilcoxon signed rank test found a significant reduction in pain ratings for injections with the DentalVibe when compared to control injections. There was a positive correlation between the pain rating for control injection and the difference between the two types of injection, indicating that subjects who reported a higher pain score with the control injection had a greater reduction when DentalVibe was used. Conclusion: When compared to a conventional approach, DentalVibe significantly lowered self-reported pain during local anesthesia injection for adolescent subjects in this study. (Pediat Dent 2014;36:51-5) Received September 18, 2012 / Last Revision January 4, 2013 / Accepted January 4, 2013

KEYWORDS: LOCAL ANESTHESIA, PAIN, INJECTIONS

Dental procedures are associated with pain and discomfort, which is considered one of the main reasons for dental fear and anxiety, with possible severe consequences for the individual's future dental health. When children experience pain during dental treatment, they may exhibit greater behavioral problems at subsequent visits, resulting in greater need for behavior guidance. Injection of local anesthetic is among the most feared and anxiety-producing procedures during dental intervention and may cause subsequent unfavorable behavior. It is the dental procedure that produces the greatest negative response in children. Of even greater concern is the fact that children who experience discomfort may avoid necessary dental care and may be more likely to avoid future care as adults.

As control of pain and anxiety is one of the most important aspects in administration of local anesthetic in dental practice, numerous methods have been developed to address the discomfort associated with dental injections. Psychological techniques, such as distraction with audiovisual glasses, have been used successfully to reduce the pain associated with injections. Another study has shown that precooling of the soft tissues of an injection site can minimize the discomfort and anxiety associated with the injection procedure.

One of the injection systems developed to minimize pain and discomfort during local anesthesia injection is the Wand system, a computer-automated injection system that provides a precise injection flow rate. In previous studies with children, divergent results were found. Studies have shown lower pain ratings for injections with the Wand vs injections with a conventional syringe, while another study reported lower pain ratings upon deposition of the anesthetic solution using the Wand system but similar pain ratings for needle insertion. Other studies reported no difference between the two injection methods. Distraction and counterstimulation, as well as vibration stimuli, have been found to be effective in reducing a pain reaction induced by injection of local anesthetic agents.

The "gate control" theory of Melzack and Wall, proposed in 1965, suggests that the pain experience can be reduced by activating nerve fibers that conduct non-noxious stimuli. This theory proposed that the spinal cord contains a neurologically "gate" that either blocks pain signals or permits them to travel up the spinohalamic tract to the brain. Stimulation of the larger diameter fibers through touch signal mechanoreceptors (eg, massage techniques, rubbing, pressure, ice packs, acupuncture, or vibration) causes a release of inhibitory neurons, preventing the activation of projection neurons at the synaptic junction in the dorsal horn of the spinal cord, resulting in a closure of the gate to the sensation of pain.

The effects of vibration on pain have been reported in both clinical and experimental settings.

Lundeberg et al. reported reduction of pain during vibratory stimulation in patients suffering acute or chronic musculoskeletal pain of different origins. In the orofacial region, vibration stimuli have been used to raise the pain threshold, to relieve pain of dental origin, whether pulpal, periodontal, or postsurgical, and to help manage acute or chronic musculoskeletal pain. A study investigating the effect of vibration on pain during local anesthesia injections found that, compared to no vibration-stimulus injections, injections with vibration resulted in less pain and lower pain ratings.

Numerous methods have been developed to cause stimulation of the mechanoreceptors during delivery of dental injections in order to reduce pain during injections. The use of vibration stimuli during injections has included a personal massager, a vibrating syringe attachment, or a vibrating swab for topical anesthetic application. Use of the Vibraject, a small device attached to a traditional dental syringe to transfer a vibrating stimulus to the needle, did not result in a significant
decrease in pain scores at needle insertion or anesthetic injection.

A newly marketed technology, the DentalVibe, is a cordless, rechargeable, handheld device that delivers pulsed, percussive micro-oscillations to the site where an injection is being administered. The device is attractive because it requires no modification to the traditional anesthetic protocol, including injection technique, patient positioning, and time involved. If effective, the device may represent a time-efficient, nonpharmacological technique to improve the experience of patients receiving local anesthetic during dental procedures. To the best of our knowledge, no study has been published on the effectiveness of the DentalVibe.

Therefore, the purpose of this study was to compare the pain rating scale measurements from an exposure group (injections with the aid of DentalVibe Injection Comfort System) and control group (traditional injection without the aid of the DentalVibe) in adolescent patients using self-reported pain during administration of local anesthetic infiltration injections. We hypothesized that the amount of discomfort experienced with the use of the DentalVibe injection comfort system during intra-oral injections would be less than traditional intra-oral injections of local anesthetics in the adolescent patient.

**Methods**

This investigation involved a randomized, controlled, split-mouth study of adolescents receiving local anesthesia for routine dental treatment. The study procedure was approved by the Institutional Review Board at Tufts Medical Center and Tufts University Health Sciences Campus, Boston, Mass, and informed consent was obtained from each subject's parent or legal guardian.

The study compared the pain rating scale measurements from an exposure group (injections with the aid of DentalVibe Injection Comfort System) and control group (traditional injection without the aid of the DentalVibe). The study was performed according to a split-mouth design, with both types of injections given to all subjects. A sample size calculation was performed using nQuery Advisor 7.0 software (Statistical Solutions, Inc, Saugus, Mass., USA). Assuming a mean difference of 3.0 between groups, and a standard deviation of 3.0, a sample size of n=36 was adequate to achieve a type I error rate of α (alpha) = five percent and a power over 99 percent.

**Subjects.** A total of 36 healthy and cooperative subjects were selected from patients attending the clinic in the Department of Pediatric Dentistry, Tufts University School of Dental Medicine. Subjects were selected on the basis of planned dental treatment that necessitated local anesthesia administration by infiltration injections for dental treatment in both sides of the maxilla or mandible. The inclusion criteria were: 10 to 17 years old; no medically or developmentally compromising conditions; English speaking; and in need of dental treatment requiring bilateral local anesthesia via infiltration injections in the posterior region of the mouth. The exclusion criteria were: presence of medically or developmentally compromising conditions (e.g., autism, cerebral palsy, moderate/severe asthma); history of chronic disease (e.g., seizure disorder, cardiac disorder, hematological disorder, endocrine disorder, liver disease, renal disease); and currently taking medication which contraindicated the use of local anesthetic.

**Procedure.** Subjects were randomly assigned, using R 2.11.1 software (R Foundation for Statistical Computing, Vienna, Austria), to receive the injection according to the traditional technique (control) at one visit, while the DentalVibe (BING Innovations, Boca Raton, Fla., USA) was used for the other injection (experimental). Prior to all injections, topical anesthesia gel containing 20 percent benzocaine (Centrix, Shelton, Conn., USA) was placed on dried soft tissue in the area of the injection site for two minutes. For all injection procedures, local infiltration with a 30-gauge extra-short needle with two percent lidocaine containing 1:100,000 epinephrine (Novocain, Cambridge, Ontario, Canada) was used to anesthetize patients. Each subject received 0.85 ml of the anesthetic solution, which was delivered at a constant rate over 30 to 40 seconds. All injections were timed and performed by one operator using standardized techniques in order to control for operator-related variables such as previous experience and technical expertise.

During the anesthesia injection, the control injection was administered using the traditional method. To control for potential subject-expectancy effects and pressure from placement of the DentalVibe, it was placed near the injection site for all injections; however, it was not turned on for the control injections. The DentalVibe comfort tip was used as a retractor in the same manner as a dental mirror. The comfort tip prongs were positioned on the soft tissue in the area of the injection, and the lip was retracted with the same strength as with a dental mirror.

When the experimental injections were administered, all procedures were identical, except for the fact that the DentalVibe was turned on to stimulate the area of intended needle penetration. After five seconds of vibration, the needle was inserted close to one of the prongs on the comfort tip. The DentalVibe continued vibration during needle insertion and anesthetic delivery. After the anesthetic was delivered, the needle was removed, followed by removal of the DentalVibe.

**Pain assessment.** Immediately after each injection, subjects were asked to rate the amount of discomfort experienced during the injection from 1 to 10, with 1 being no pain and 10 being worst pain, using the Wong Baker FACES Pain Rating Scale in Figure 1.

![Figure 1. Wong Baker FACES Pain Rating Scale.](image-url)
After administration of the standardized amount of anesthesia and the completion of the pain assessment, additional anesthesia was provided, if necessary. The amount of additional anesthetic and route of administration was determined and administered by the dentist completing the dental treatment.

Statistical analysis. Statistical analyses were performed using the Wilcoxon signed rank test, Spearman correlation, and Mann-Whitney U test. All analyses were conducted using SAS 9.1 software (SAS Institute Inc., Cary, N.C., USA). The five percent level of significance was adopted (i.e., a P-value of <.05 was considered statistically significant).

Results
This study included a total of 36 10- to 17-year-old subjects (median age=14 years old)—15 males and 21 females. Nineteen subjects had the first injection with the traditional technique (control), and 17 subjects had the first injection with the DentalVibe. The difference in reported pain ratings (difference—pain rating from control injection minus pain rating with the DentalVibe), with positive values indicating greater pain during the control injection. Thirty subjects (~83 percent) found the injection with the DentalVibe to be less painful than the injection with the traditional technique, while three (~eight percent) found the injection with the DentalVibe to be more painful than the control injection (Figure 2). Three of the 36 subjects (~eight percent) found the two techniques to be equally painful. The subjects who found the injection with the DentalVibe to be more painful than the control injection had low pain ratings (0 or 1) with the control injection.

Interestingly, 17 subjects (~47 percent) reported no pain with the DentalVibe injection (pain rating=0). In comparison, only three subjects (~eight percent) felt no pain with the conventional injection, and one of these three subjects also felt no pain with the DentalVibe. Pain during infiltration injection was eliminated in a total of 16 subjects (~44 percent) with the use of the DentalVibe when compared to the traditional technique.

Using the Wilcoxon signed rank test, the data showed there was a statistically significant difference in the self-reported pain using the Wong-Baker FACES pain scale between the two types of injections (P<.001). Pain ratings after the control injection were significantly higher (median=3, interquartile range=2.5, range=0 to 8) than the DentalVibe injection (median=1, interquartile range=2, range=0-5). The median "difference" (pain rating with control injection minus pain rating with DentalVibe injection) was 2, with an interquartile range of 3 and ranging from ~4 to 8.

There was a positive correlation between pain rating after the control injection and the difference (Spearman's correlation coefficient=0.79, P<.001), indicating subjects who reported higher pain rating with the control injection had a greater reduction in pain rating when DentalVibe was used during the injection (Figure 3). There was no statistically significant correlation between age and difference in pain rating (Spearman's correlation coefficient=0.023, P=.89).

The Mann-Whitney U test, used to determine whether there was a statistically significant association between difference in pain ratings and gender or sequencing of the injections, found no significant effect for either (P=.64 and P=.27, respectively).

Discussion
This study applied the gate control theory of pain modulation to determine whether large A-beta nerve fiber input from a vibration stimulus would inhibit smaller fiber A-delta and C fiber (nociceptive) input from an intraoral infiltration injection. The study revealed that vibration applied using the DentalVibe decreased pain associated with a local anesthetic injection delivered via infiltration. Most subjects (83 percent) found the injection with the DentalVibe to be less painful than the injection with the traditional technique, while approximately eight percent found the injection with the DentalVibe to be more painful than the control injection. Subjects in the DentalVibe group had significantly lower pain scores than those in the control group.

These results agree with the findings of Nanitsos et al., who found that adult subjects in the vibration group exhibited
significantly less pain during local anesthesia injections vs. the control group. This agreement may be attributed to the larger area of stimulus in the two techniques. By contrast, use of the Vibraject, a vibrating attachment for a traditional syringe, did not reduce the subjects’ pain. The possible reason may be that the vibrations were extremely small and did not activate the large nerve fibers in that area for many individuals.

A correlation was observed between the pain rating with the control injections and the difference between the control and the DenalVibe injections. There was a higher reduction of perceived pain with the DentalVibe in subjects with a higher pain response during the control injection. This was in agreement with the findings of Palm, Kirkegaard, and Poulsen, who investigated the effect of pain during mandibular block injections using the Wand. Their study found that there was a significantly greater reduction in perceived pain with the Wand in patients with a higher pain perception during traditional injection. As the level of dental anxiety may have a strong influence on an individual’s reaction, knowledge of each patient’s level of dental anxiety may help tailor treatment to the patient’s needs.

Three of the subjects reported the infiltration injection with the DentalVibe to be more painful than the control injection. Interestingly, all of these subjects reported low pain ratings (0 or 1) with the control injection. This could be attributed to the fact that individuals were uncomfortable with the vibration sensation experienced with the DentalVibe and reported this discomfort as a higher pain rating. A previous study using vibration during local anesthesia also reported that, although most subjects in the study reported less pain, a minority (19 percent) experienced more pain when vibration was used.

Efforts were used to minimize differences between the two procedures, such as timing each injection, placing the DentalVibe near the injection site for all injections, having the same experienced operator perform all the injections, and using topical anesthesia before all injections to minimize pain during needle insertion. As the anatomical location of an injection is an important determinant of pediatric pain reaction, this study evaluated injections administered in the posterior areas only. A limitation to this study is that patients could not be blinded due to inherent physical vibrational stimulation experienced with the DentalVibe. On the other hand, while the DentalVibe was only turned on for those in the experimental group, it was not always used for all patients, including those in the control group. Further research is needed to evaluate the effect of the DentalVibe in children and adolescents. The study also found that children and adolescents experienced more pain when vibration was used.

Conclusion
Based on the study’s results, the following conclusion can be made:

1. Use of the DentalVibe injection system significantly reduced pain associated with infiltration injection of local anesthesia in an adolescent population.

Acknowledgments
This study was supported by DHHS-HRSA grant no. D84HP19955. The authors wish to thank Dr. Catherine DeFuria for her assistance in preparing this manuscript.

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