RESEARCH PAPER

Efficacy of a vibrating Facial-T-Massager as an Adjunct to Topical Anesthesia in reducing Intraoral Injection Pain in Children: A Pilot Trial.

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ABSTRACT

Background: Local anesthesia injections are a primary source of dental anxiety and behavioral distress in pediatric patients. This 3-arm parallel pilot randomized controlled trial aimed to evaluate and compare the clinical feasibility, self-reported pain, behavioral distress, and physiological anxiety of 20% benzocaine gel alone, an intraoral vibrating T-Massager alone, and a combination of both modalities during local anesthesia administration in children.

Methods: Twenty-one healthy children aged 5–12 years requiring local anesthesia were randomly allocated into three equal groups (n = 7 per arm): Group A (20% Benzocaine gel), Group B (vibrating T-Massager), or Group C (Benzocaine + T-Massager). Pain and behavior were evaluated subjectively using the Wong-Baker FACES Pain Rating Scale and objectively via the FLACC scale. Physiological anxiety was measured via pulse rate fluctuations from baseline to the time of injection (Δ pulse). The data were analyzed using non-parametric Kruskal-Wallis tests (alpha = 0.05).

Results: The protocols demonstrated excellent clinical feasibility with zero adverse events. No statistically significant differences were observed among the groups for self-reported pain (p = 0.511) or behavioral distress (p = 0.399). However, Group B (T-Massager alone) demonstrated the lowest objective behavioral distress (Median FLACC = 2.0) and profound stabilization of pulse rate (Δ Pulse = +1.1 +\- 12.3 BPM) compared to Group A (Δ Pulse= +11.0 +\- 19.1 BPM). Group C (Combination) did not show a synergistic effect (Median FLACC = 5.0; Δ Pulse = +5.4 BPM).

Conclusion: Utilizing an intraoral T-Massager is a highly feasible, safe, and promising non-pharmacological approach to reduce injection distress in pediatric patients.

Keywords: Children; Local Anesthesia; Gate Control Theory; Vibration; Behavior Management;

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INTRODUCTION

Management of dental pain and anxiety in children remains one of the most critical challenges in pediatric dentistry [1]. Local anesthesia (LA) is the cornerstone of pain-free dental practice;nonetheless, the administration of local anesthesia via intraoral injection itself is frequently reported as the most terrifying and painful experience by children [2]. At times, acute injection pain can trigger immediate uncooperative behavior in the chair and may foster long-term dental phobias that continue into adulthood [3]. In this regard, the selection of an effective topical anesthetic and an efficient LA administration technique that minimizes mucosal penetration-related distress is paramount to ensuring successful pediatric behavior management and clinical outcomes.Traditionally, topical anesthetic gels, particularly 20% benzocaine, have been widely used to anesthetize the surface of oral mucosa prior to needle insertion. While benzocaine is topically effective at a depth of 2 to 3 mm, its efficacy is limited to the superficial layers and does not reduce the deeper pressure-related discomfort caused by deposition of local anesthetic solution [4]. Furthermore, the delayed onset of surface anesthesia requiring 1 to 2 minutes of mucosal contact coupled with bitter taste can sometimes induce aversion in highly sensitive children.

To overcome these limitations, physical distraction techniques have gained considerable attention [5]. The most notable and popular among these is the application of external high-frequency vibration at the injection site, which is based on a neurophysiological rationale rooted in Melzack and Wall's Gate Control Theory of Pain [6]. According to this theory, the transmission of noxious stimuli can be modulated by peripheral sensory inputs. High-frequency vibration selectively stimulates fast-conducting, myelinated Aβ nerve fibers, which carry tactile perception. The rapid activation of these tactile nerve fibers stimulates inhibitory neurons within the dorsal horn of the spinal cord, effectively "closing the gate" and

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blocking the slower, unmyelinated Aδ and C nociceptive fibers that carry pain signals of the needle prick to the central nervous system [1,7]. Although commercial dental vibration devices exist, their high cost limits widespread adoption in everyday clinical practice, prompting a search for affordable alternatives, such as customized vibration devices [8]. The T-massager selected for the present study was an over-the-counter, budget-friendly, commercially available 24k Golden Beauty Bar T-Shape Device designed to produce high-frequency vibration at 10,000 times per minute to improve skin microcirculation, exercise facial muscles, eliminate excess fat and facial edema, and shape facial contours[9]. Various researchers studied different distraction aids during local anesthesia administration [10-15]. To the best of our knowledge, although individual studies have explored either topical anesthesia or mechanical vibration independently, there is a distinct lack of clinical literature directly comparing the efficacy of topical benzocaine alone against that of a T-massager, or evaluating whether their combination yields a synergistic, superior analgesic effect in children. Furthermore, establishing the operational feasibility of this new T-massager and baseline effect sizes of these protocols is a vital prerequisite before testing in large-scale clinical trials. Therefore, the purpose of this 3-arm parallel pilot randomized controlled trial was to evaluate and compare the clinical feasibility, self-reported pain perception, objective behavioral distress, and physiological anxiety with 20% benzocaine gel alone, an intraoral vibrating T-massager alone, and a combination of both modalities during local anesthesia administration in children.

MATERIALS AND METHODS

Study Design and Ethical Approval

This study was designed as a prospective, 3-armparallel pilot randomized controlled trial with a 1:1:1 allocation ratio. The clinical protocol was reviewed and approved by the Institutional Review Board and Ethics Committee (pr.69/IEC/GDCH/KDP/2025-2026). Signed written informed consent was obtained from the parents or legal guardians of all participating children, and verbal assent was obtained from the children prior to initiation of the clinical procedure. The study was conducted in strict compliance with the Declaration of Helsinki and followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The trial was registered at clinicaltrials.gov with reference number NCT0768218.

Participant Selection

A convenience sample of 21 pediatric patients was recruited from the outpatient Department of Pediatric and Preventive Dentistry.

Inclusion Criteria:

1. Healthy children aged 4 to 12 years classified as American Society of Anesthesiologists (ASA) Physical Status I.
2. Those who require local anesthesia (local infiltration) in at least one quadrant as a part of a dental procedure.
3. Children who exhibit cooperative behavior at baseline (Frankl Behavioral Rating Scale score of 3 or 4).

Exclusion Criteria:

1. Children with active oral infection or acute abscess at the injection site.
2. Children with history of systemic disease, neurological disorders, cognitive impairments, or developmental delays.
3. Those with documented hypersensitivity or allergy to local anesthetics.
4. Children with uncooperative baseline behavior (Frankl Scale score of 1 or 2).

Randomization and Blinding

The 21 participants were randomly allocated to three treatment arms (n = 7 per group) using a computer-generated randomization sequence. To ensure concealment, allocation was performed using sequentially numbered, opaque, sealed envelopes that were opened by an independent clinical assistant immediately before the procedure. Children were assigned to their respective groups as follows.

- **Group A (Control):** Topical 20% Benzocaine gel alone.
- **Group B (Experimental 1):** vibrating T-Massager.
- **Group C (Experimental 2):** Combination therapy (Topical 20% Benzocaine gel + intraoral vibrating T-Massager).

Due to the physical nature of the interventions (audible and tactile vibration), blinding of the operating clinician, evaluator, and the patient was not possible.

Clinical Protocols and Interventions

A single experienced pediatric dentist performed all clinical examinations and local-anesthesia buccal infiltration to eliminate inter-operator variability. The local anesthetic used across all groups was 2% lignocaine with 1:80,000 adrenaline administered via a standard 26-gauge dental needle.

- **Group A (Benzocaine alone):** The target mucosa was dried completely using a sterile cotton roll. A small amount of 20% benzocaine gel (Mucopain gel) was applied to the site using a cotton-tipped applicator before needle penetration.
- **Group B (T-Massager alone):** No topical gel was applied. The custom-vibrating T-Massager (RUDRESHWAR Electric Massager device) with a barrier-protected, disposable sleeve was activated and placed directly onto the mucosa adjacent to the injection site. Vibration was initiated 15 seconds prior to needle insertion and maintained continuously throughout the deposition of the local anesthetic solution.

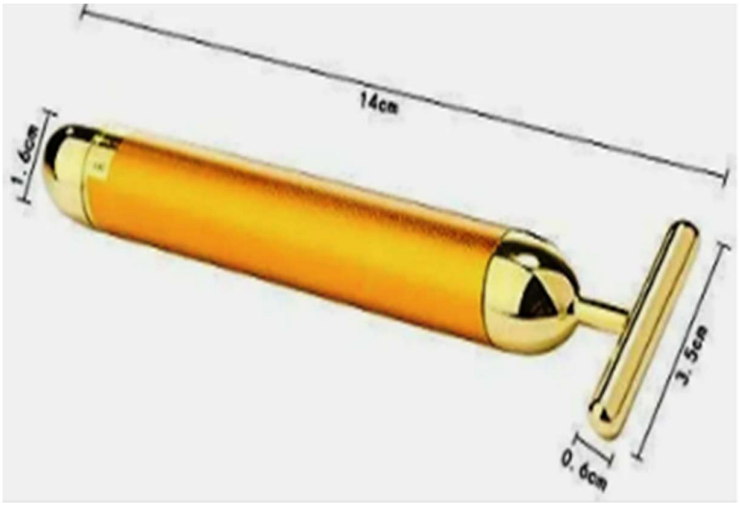

Figure-1. T-Massager (RUDRESHWAR Electric Massager device)

- **Group C (Combination):** The target mucosa was dried, and 20% benzocaine gel was applied for 60 seconds. Following gel removal, the vibrating T-Massager was placed on the site for 15 seconds prior to injection and maintained continuously during needle penetration and solution deposition.

OUTCOME PARAMETERS AND ASSESSMENT:

1. Physiological Anxiety (Pulse Rate)

The physiological anxiety was assessed by monitoring cardiovascular fluctuations usinga standard fingertip pulse oximeter that was clipped to the patient's index finger. Pulse rate (in beats per minute, BPM) was recorded at three distinct timelines:

- **Baseline (Pre):** 5 minutes prior to entering the operatory.
- **Injection (During):** At the exact moment of mucosal needle penetration and local anesthetic deposition.
- **Post-Injection (Post):** 3 minutes following syringe withdrawal.

2. Subjective Pain Perception (Self-Report)

Immediately following the completion of the local anesthesia procedure, children were shown the standardized Wong-Baker FACES Pain Rating Scale [16]. The scale consists of six continuous faces ranging from 0 (smiling face representing "No Hurt") to 10 (crying face representing "Hurts Worst"). Children were instructed to point to the face that best represented the sensation they experienced during the local anesthetic deposition.

3. Objective Behavioral Distress

A blinded independent evaluator scored the child's behavioral response using the Face, Legs, Activity, Cry, Consolability (FLACC) Behavioral Scale during LA administration [17]. The scale has five categories, each scored from 0 to 2, yielding a cumulative distress score ranging from 0 (relaxed and comfortable) to 10 (severe distress/pain behavior).

Statistical Analysis

Data management and statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for all demographic and clinical variables. Due to the small sample size (n = 7 per arm) inherent to this pilot study, normal distribution could not be safely assumed. Consequently, non-parametric tests were used for all primary and secondary outcomes to mitigate statistical distortion from potential outliers.The Kruskal-Wallis test was employed to evaluate differences across the three independent parallel arms for both ordinal behavioral data (Wong-Baker FACES and FLACC scores) and continuous physiological data (represented as Delta Pulse Rate: Pulse during Injection - Pulse Baseline). Post hoc pairwise comparisons were performed using Dunn's test with an automated Bonferroni correction to reducethe family-wise error rate. Continuous demographic variables were reported as medians with Interquartile Ranges (IQR). For all tests, the level of statistical significance was set at alpha = 0.05.

RESULTS:

Demographic Characteristics

A total of 21 pediatric patients aged 4 to 12 years successfully completed this 3-arm parallel pilot trial with no dropouts or adverse events reported. The groups were well-balanced regarding baseline characteristics with median age of 9.0 years (IQR [9.0, 11.0]) for Group A, 9.0 years (IQR [9.0, 10.0]) for Group B, and 8.0 years (IQR [6.0, 9.0]) for Group C. Gender distribution across the cohorts was 5 males and 2 females in Group A, 4 males and 3 females in Group B, and 3 males and 4 females in Group C.

Behavioral and Self-Reported Pain Outcomes

For the self-reported Wong-Baker FACES scale, Group C (Combination) exhibited the lowest median pain score of 4.0 (IQR [2.0, 8.0]), compared to median score of 6.0 in both Group A (IQR [6.0, 10.0]) and Group B (IQR [2.0, 8.0]). However, there was no statistical significance (Kruskal-Wallis H = 1.343, p = 0.511).

For objective behavioral distress evaluated with FLACC scores, Group B (T-Massager alone) demonstrated the lowest clinical distress with a median score of 2.0 (IQR [1.0, 3.5]), followed by Group A (Median: 4.0, IQR [1.0, 7.0]) and Group C (Median: 5.0, IQR [1.0, 5.0]). The inter-group variance for objective distress was not statistically significant (Kruskal-Wallis H = 1.839, p = 0.399).

Physiological Distress Outcomes

Physiological stress was evaluated by calculating the pulse rate fluctuation (Δ) from baseline to the exact moment of intraoral needle penetration withdrawal. Group B (T-Massager) demonstrated superior stabilization of pulse rate, with a low mean pulse increase of just +1.1 ± 12.3 BPM. In comparison, Group C (Combination) experienced a mean increase of +5.4 ± 14.1 BPM, while Group A (Benzocaine alone) experienced the highest mean increase in pulse rate at +11.0 ± 19.1 BPM. Due to the limited pilot sample size, the variance among these mean pulse rates did not reach statistical significance (Kruskal-Wallis H = 1.849, p = 0.397).

Table 1: Comparison of self-reported pain, behavioral distress and Δ pulse rate across three parallel arms.

Variable	Group A: Benzocaine (n=7)	Group B: T-Massager (n=7)	Group C: Combination (n=7)	H-Statistic	p-value
Wong-Baker FACES (Median [IQR])	6.0 [6.0, 10.0]	6.0 [2.0, 8.0]	4.0 [2.0, 8.0]	1.343	0.511
FLACC Score (Median [IQR])	4.0 [1.0, 7.0]	2.0 [1.0, 3.5]	5.0 [1.0, 5.0]	1.839	0.399
Pulse Rate (Δ) (Mean ± SD)	+11.0 ± 19.1	+1.1 ± 12.3	+5.4 ± 14.1	1.849	0.397

Table 2: Dunn's Post hoc pairwise comparison between groups.

Clinical variable assessed	Comparison Pair	Rank Difference	Z-Score	Raw p-value	Modified p-value (padj)
Wong-Baker FACES	Group A vs. Group B	2.36	0.71	0.478	1
	Group C vs. Group B	0.64	0.19	0.849	1
	Group A vs. Group C	1.72	0.52	0.603	1
FLACC Score	Group A vs. Group B	3.78	1.14	0.254	0.762
	Group C vs. Group B	2.85	0.86	0.39	1
	Group A vs. Group C	0.93	0.28	0.779	1
ΔPulse Rate	Group A vs. Group B	4.35	1.31	0.19	0.57
	Group C vs. Group B	3.78	1.14	0.254	0.762
	Group A vs. Group C	0.57	0.17	0.865	1

DISCUSSION

The primary objective of this parallel-group pilot randomized controlled trial was to evaluate the clinical feasibility and behavioral impact of an intraoral vibrating T-Massager, used independently or in combination with standard 20% benzocaine gel, during the administration of local anesthesia in children. While the restricted pilot sample size of each group (n = 7 per arm) inherently limits the power to achieve statistical significance (p > 0.05), a distinct clinical trend emerged that warrants critical analysis and a robust framework for future large clinical trials.

The neurophysiological foundation of utilizing a vibrating device during an intraoral injection relies heavily on Melzack and Wall's Gate Control Theory of Pain [6]. High-frequency vibration stimulates peripheral, large-diameter, myelinated A-beta tactile nerve fibers. These fibers activate inhibitory interneurons within the dorsal horn of the spinal cord, effectively "closing the gate" to the slower, unmyelinated A-delta and C fibers that transmitpain signals to the central nervous system [1,6].This mechanism has been extensively documented by researchers investigating commercial vibration systems such as DentalVibe® and VibraJect®, who demonstrated reduced pain scores with active mucosal vibration [2,5].

An interesting clinical finding in our data was that Group B (T-Massager alone) exhibited the lowest objective behavioral distress (Median FLACC = 2.0), demonstrating a nominal mean heart rate increase of only +1.1 ± 12.3

BPM from baseline to injection. In contrast, Group A (Benzocaine alone) experienced a substantial cardiovascular spike of +11.0 ± 19.1 BPM.This distinct clinical finding aligns with the findings of Banka et al. observed that children receiving vibratory stimulation experienced significantly less cardiorespiratory stress and improved subjective comfort during local anesthesia delivery compared to traditional techniques [7]. Similarly, Alam Pinjari et al. demonstrated that low-cost,modified sonic toothbrushes were highly effective in relieving injection-related pain and distress [8].Furthermore, counterstimulation via continuous mechanical pressure and vibration has been shown to provide superior competitive sensory blockade compared with topical treatments alone [18].Accordingly, thenotable difference in physiological stress suggests that the mechanical, high-frequency vibratory stimulus from the T-Massager may provide a double benefit in pediatric behavior management. It provides sensory gating that physically dulls the sharp mechanical prick of the needle tip and cognitively distractsthe child with a "buzzing" or tickling sensation on the oral mucosa, diverting the child's cognitive focus away from the syringe.As noted by Putrino et al., the physical buzz and high-frequency tactile oscillation can create an immersive sensory environment [3]. The cognitive focus on anticipating a needle prick is dominated by the novel, non-threatening tickling sensation and the ambient acoustic buzzing of the device's motor [5,19]. Nevertheless, the combination Group (Group C) did not outperform the T-Massager group regarding objective behavioral scores (Median FLACC = 5.0) orthe difference in pulse rate (+5.4 ± 14.1 BPM). From a clinical perspective, this may be attributed to sensory or over-stimulation in younger children. The simultaneous presentation of a chemically flavored topical gel (benzocaine) along with high-frequency vibrating device may induce mild sensory overload or unexpected anxiety in highly sensitive children, rather than compounding the analgesic effect.A similar trend was observed during clinical evaluation of the Buzzy® cooling-vibration device during inferior alveolar nerve blocks. The authors found that the combination tool failed to yield a statistically significant reduction in behavioral distress or heart rate compared with the conventional injection technique, emphasizing that results can vary significantly depending on child-specific coping mechanisms and sensory processing [20]. This highlights that more intervention does not necessarily lead to better pediatric behavior management, and a single, clean physical distraction, such as vibration, may be better tolerated.

LIMITATIONS:

The primary limitation of this study is the small pilot sample size (n = 7 per arm), which increased the susceptibility to Type II statistical errors and prevented the normalization of physiological data. This limitation is common in the pilot dental literature, where initial feasibility must be demonstrated before extensive trials [4]. The gender-based comparison was not made due to the equal distribution of genders in the study sample, and it was considered one of the limitations. Additionally, complete blinding of the operating clinician or the child to the vibrating intraoral device is structurally impossible, introducing a baseline expectation bias that is difficult to eliminate in physical device trials [2].However, as a pilot study, this project successfully demonstrated excellent clinical feasibility.

CONCLUSION:

The T-Massager protocol was successfully integrated into the dental chair workflow with excellent compliance across all age groups (5–12 years) and zero adverse events. Using the variance and distribution metrics obtained from this pilot study and future large clinical trials utilizing this protocol are highly justified.

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Conflict of Interest

All the authors declared no conflicts of interest.

Data availability

Data will be available from the corresponding author upon request.

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