Original Article

DOI: 10.7860/JCDR/2024/64742.18950

Dentistry Section

A Randomised Split-Mouth Clinical Trial to Assess the Efficacy of OroQuiver: An Affordable Vibrotactile Device for Dental Injections

RAVINDRA REDDY[1], VARSHA HARIDAS UPADYA[2], JOYCE PASCALIA SEQUEIRA[3], JAGADISH CHANDRA[4]

ABSTRACT

Introduction: Injection pain is a common concern among patients, including those receiving dental injections. Local Anaesthesia (LA) is a crucial procedure in dentistry to ensure painless treatment. Vibration stimuli have shown promise in raising the pain threshold, managing orofacial pain, musculoskeletal pain, and relieving dental pain. However, many vibrotactile devices available in the market are not affordable for common dentists.

Aim: To compare pain perception in patients undergoing bilateral extractions using OroQuiver-assisted LA administration versus conventional LA administration.

Materials and Methods: A randomised split-mouth clinical trial was conducted with 17 patients undergoing simultaneous bilateral extractions. LA was administered with and without OroQuiver on the right and left-sides, respectively. Pain assessment was performed using Wong Baker's Facial Rating Scale and a questionnaire sheet comparing patient comfort following LA administration on both sides.

Results: There was a significant difference in the Visual Analog Scale (VAS) score for pain experienced during LA injections using the vibrotactile device (4.29±1.1) compared to the conventional method (7.2±1.5). None of the patients reported discomfort with the device. The device reduced anxiety towards dental injections in 14 patients, and 16 patients indicated they would recommend the device to others.

Conclusion: OroQuiver effectively reduced injection-related pain regardless of the type of nerve block administered. It is a cost-effective, easily maneuverable, feasible, sterilisable, and reusable device that effectively reduces LA injection-related pain.

Keywords: Injection pain, Local anaesthesia, Nerve block, Vibration analgesia

INTRODUCTION

Local Anaesthesia (LA) is commonly used in dentistry to ensure painless treatment for patients. One of the main causes of anxiety related to injectable LA administration is the fear of observing and feeling the needle piercing and the resulting swelling of the soft tissues [1]. Therefore, there have been ongoing efforts in dentistry to develop techniques and devices to reduce injection pain [2].

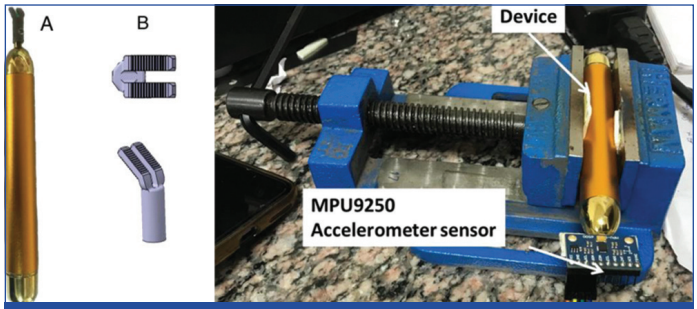
Various pain control techniques have been introduced over time, including LA sprays, gels, smaller diameter needles, ice packs, icing sprays, audio analgesia, 'talkesthesia,' hand holding, iontophoresis, and all have been implicated in reducing pain during injections [3]. Vibration stimuli have also been found to be effective in raising the pain threshold, relieving dental pain, managing chronic orofacial pain, and treating acute or chronic musculoskeletal pain. The analgesic effect of vibration is based on the Gate control theory of pain proposed by Melzack and Wall, which suggests that α-β nerve fibers stimulate inhibitory interneurons in the spinal cord [3,4].

In dental practice, where a significant portion of the brain's somatosensory cortex is dedicated to sensory inputs from the oral cavity, the use of vibration to control injection pain can be particularly valuable [3-5]. While there are a few vibrotactile devices or systems available on the market to control injection pain, they are often not affordable for many dentists. In an effort to provide a more accessible and affordable solution, the OroQuiver vibrotactile device was designed. This device is based on existing models in the market and has been specifically created to help dentists control pain associated with LA administration. OroQuiver is a pioneering solution to the challenge of managing injection pain, as it is easily maneuverable, feasible, sterilisable, and reusable. The study aimed to test the alternate hypothesis that there is a significant difference in pain scores between anaesthetic injections administered with OroQuiver compared to those without OroQuiver.

About OroQuiver-Intraoral vibrotactile device:

The OroQuiver device consists of a round aluminium body with a removable sterilisable tip made of industrial PEEK. It is equipped with a switch located at the bottom and powered by two double A batteries [Table/Fig-1]. This device offers a cost-effective alternative to topical LA products and overcomes the challenges associated with them, such as delayed onset of action, bitter taste, burning sensation, and rare adverse effects [6].

The device utilises a standardised vibration frequency of 35-50 MHz, based on the literature for vibration analgesia, which provides optimal and effective analgesia for injection pain [7]. It was carefully calibrated for consistent, reliable, and optimal vibration analgesia for injection pain at the Yenepoya incubation center. The device has a maximum amplitude of 0.11 mm and a frequency of 47 Hz, measured using the MPU9250 sensor connected to Arduino via I2S communication with a female jumper cable [Table/Fig-2]. The sensor is attached to the tip



[Table/Fig-1]: A) OroQuiver; B) Tip design.
[Table/Fig-2]: Frequency calibration of OroQuiver. (Images from left to right)

of the device to measure the corresponding readings in PLX DAQ software via a serial monitor.

MATERIALS AND METHODS

The study was designed as a randomised split-mouth controlled trial to evaluate the effectiveness of the OroQuiver vibrotactile device in reducing injection pain during bilateral tooth extractions. CONSORT reporting guidelines [8] were followed, and the study was conducted at the Department of Oral and Maxillofacial Surgery, Yenepoya Dental College, Mangaluru, Karnataka, India, from March 2022 to November 2022. The study was registered under the Clinical Trial Registry of India (CTRI) with the number CTRI/2023/08/056188. Ethical approval for the study was obtained from the Institutional Ethics Committee (IEC) with the approval number YEC2/1121. The OroQuiver vibrotactile device was patented at the Yenepoya Incubation Centre, Yenepoya (Deemed to be University), with the patent number 202241072004. Ethical considerations were strictly followed, and informed consent was obtained from all participating patients after explaining the purpose of the study.

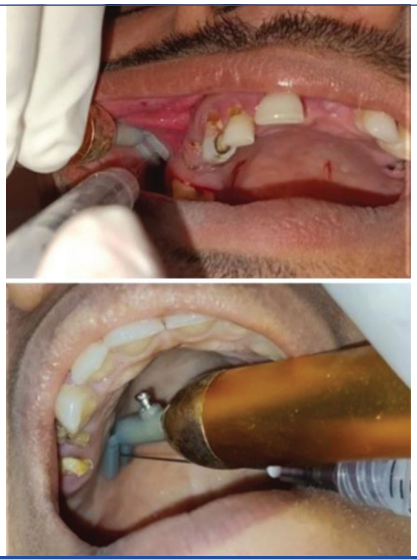
Sample size calculation: With a 95% confidence level and 18% relative precision [3], and a standard deviation of 2.04, the total sample size was calculated as 17.

Inclusion criteria: The inclusion criteria for this study were patients aged 15 years or older requiring bilateral extraction of similar teeth with the same nerve blocks on either side.

Exclusion criteria: Those patients with missing contralateral teeth for extraction, those with mental disabilities, and individuals with any mucosal abnormalities at the site of local anaesthesia administration were excluded from the study.

Procedure

The study employed a split-mouth design, where local anaesthesia injections were administered without using the device on the left-side and with stimulation using the vibrotactile device (OroQuiver) on the right-side. The device was placed at the site of injection and switched on 10 seconds prior to the procedure. The needle was inserted between the vibrating prongs of the tip [Table/Fig-3]. The trial was conducted in an unmasked manner because the nature of the investigated device made it impossible to blind the patients, operator, and outcomes assessor for the study.



[Table/Fig-3]: Maxillary nerve blocks using OroQuiver.

Bilateral extractions were performed on the same day. Local anaesthesia was administered using Lignocaine hydrochloride 2% with 1 in 80,000 adrenaline (Xicaine, ICPA Health Products Ltd.) through a 26-gauge needle by the same oral and maxillofacial surgeon for all nerve blocks. The injection rate on both sides was maintained at 1 mL/minute, and no topical anaesthesia was used.

Before conducting the main study, a pilot study was conducted on five patients using the device as recommended by the ethics committee. The pilot study yielded positive results, which encouraged the continuation of the study. The results were recorded by an independent observer using a questionnaire designed by one of the authors. The questionnaire was validated by two maxillofacial surgeons and one general dentist who were not connected to the study. The primary outcome variable was the pain experienced by the patient right after local anaesthesia injection. This was assessed through a self-reported pain measure using a Visual Analog Scale (VAS). The VAS incorporated a Numeric Rating Scale ranging from 0 to 10, where 0 signified no pain and 10 indicated the most severe pain possible. Additional questions related to the patient's overall experience with the device were included in the questionnaire [Table/Fig-4].

PATIENT QUESTIONNAIRE

1. Rate the pain experienced by you during injection on both sides

Right side (Oroquiver vibrotactile device)

Left side

2. Did you experience any discomfort with the Oroquiver vibrotactile device during injection?

A. Yes

B. No

3. Did the Oroquiver vibrotactile device reduce your anxiety towards dental injections?

A. Yes

B. No

4. Do you want to get dental injections in the future using the Oroquiver vibrotactile device?

A. Yes

B. No

[Table/Fig: 4]: Patient questionnaire.

STATISTICAL ANALYSIS

Descriptive statistics and inferential analyses, specifically the paired t-test/Wilcoxon signed-rank test, were used for the statistical analysis. The International Business Management (IBM) Statistical Package for Social Sciences (SPSS) Statistics version 21.0 software was utilised for the analysis. The level of significance was set at $p<0.05$.

RESULTS

In this study, a total of 17 patients participated, with a mean age of 36.41 years (standard deviation: 17.19). Among the participants, seven patients (41.2%) were male, and 10 patients (58.8%) were female.

The mean VAS score for the vibrotactile device was 4.29, with a standard deviation of 1.1. In comparison, the mean VAS score for the conventional method was 7.2, with a standard deviation of 1.5 [Table/Fig-5]. The independent sample t-test comparing the VAS scores of both groups showed statistical significance ($p=0.047$) [Table/Fig-6]. These results indicate that the use of the vibrotactile device during local anaesthesia injections significantly reduced the pain experienced by patients.

	VAS (Vibrotactile Group)	VAS (Conventional Group)
Mean	4.29411	7.20588
Median	4	7
Mode	3	6.5
SD	1.10518	1.51028

[Table/Fig-5]: Mean, median, mode, and standard deviation of Visual Analog Scale scores for pain between two groups.

		t	p-value	95% confidence interval of the difference	
				Lower	Upper
VAS	Equal variances assumed	-6.704	**0.047**	-3.91154	-2.08846

[Table/Fig-6]: Independent sample t-test comparing the VAS of both groups.

The effectiveness of anaesthesia with the vibrotactile device versus the conventional method was evaluated for different nerve blocks [Table/Fig-7]. For the PSA nerve block, the vibrotactile device demonstrated a mean anaesthesia score of 4.2, which was lower than the conventional method's mean score of 6.2. Similarly, in the infraorbital nerve block, the vibrotactile device yielded a mean score of 4.125, while the conventional method scored 7.875. The results were consistent across the greater palatine and incisive nerve blocks, where the vibrotactile device outperformed the conventional method in achieving anaesthesia. For lingual infiltration, the vibrotactile device again showed superior results, with a mean score of 5 compared to the conventional method's mean score of 7.

Nerve block	Mean score (Vibrotactile)	Mean score (Conventional)	Standard deviation (Vibrotactile)	Standard deviation (Conventional)
PSA	4.2	6.2	1.92	1.92
Infra orbital	4.125	7.875	1.24	1.64
Greater palatine	4.23	7.38	1.42	1.45
Incisive	4	6.75	0.81	0.5
Lingual infiltration	5	7	0.81	0

[Table/Fig-7]: Comparison of mean, median, mode, and standard deviation of the VAS scores between the two groups for individual nerve blocks and infiltration.

In the questionnaire, none of the patients reported any discomfort when the device was used. The device reduced anxiety towards dental injections in 14 patients, and 16 patients responded that they would want to receive injections in the future using the vibrotactile device. Overall, the data suggests that the vibrotactile device offers better anaesthesia outcomes across various nerve blocks, making it a promising option for maxillofacial procedures. Additionally, the standard deviations were relatively low, indicating consistent anaesthesia results for each method.

DISCUSSION

Effective pain management during Local Anaesthesia (LA) is crucial in dental procedures, as the fear of dental pain can lead to patients avoiding or canceling appointments [9]. Dental anxiety is often associated with previous traumatic or painful dental experiences involving LA and tooth extraction. To address this issue, various strategies have been developed to reduce pain and improve the overall dental experience [10]. Extensive literature exists on different techniques for pain management during LA injections, highlighting the significance of this research area [10].

The application of topical anesthetics is commonly used to alleviate pain during needle insertion by numbing the surface area. However, the effectiveness of these anesthetics in completely eliminating pain during injection depends on factors such as the type and amount of LA used, injection rate, and the dentist's expertise. Additionally, topical anesthetics have limited penetration into deep tissues, making them less effective at deeper levels [11]. As a result, alternative techniques like TENS and Wand have been developed to address this limitation. TENS stimulates large-diameter nerve fibers, which have a lower threshold of response to electrical activity compared to smaller fibers. This mechanism effectively reduces pain by closing the central gating mechanism to small-diameter nerve transmission [11].

The present study demonstrated that the use of a vibration device significantly reduced the mean VAS score for pain compared to injections without the vibration device. This reduction was observed across all types of LA administered. Overall, the mean VAS scores consistently favoured the vibrotactile device over the conventional method in all locations, except for lingual infiltration where the difference was minimal. These findings align with previous research. Hegde KM et al., conducted a study on paediatric patients aged 6-11 years, comparing an attractive device combining vibration and distraction with the conventional injection method [2]. They reported lower mean pulse rates, Face, Legs, Activity, Cry, Consolability scale (FLACC) scores, and pain ratings in the device group. It's important to note that their study used an extraoral device with vibrations applied at a distant site from the injection site, making direct comparison with the present study challenging, as the present vibrotactile device is used directly at the injection site.

Shaefer JR et al., evaluated the DentalVibe Injection Comfort System in 60 patients and found that it significantly reduced pain, discomfort, unpleasantness, and the difficulty of enduring long buccal and inferior alveolar nerve injections [12]. This aligns with the present study's findings, where the vibrotactile device consistently showed lower mean scores for pain, indicating a reduction in pain perception.

On the contrary, Erdogan O et al., observed that the DentalVibe vibratory device did not reduce perceived pain levels associated with LA infiltration in the maxillary anterior region [13]. However, their study involved dental students who were not blinded to the intervention, which may have influenced their results. In contrast, the present study aimed to minimise bias by including laypeople as participants.

In a study by Nasehi A et al., the use of a commercially available vibration device resulted in significantly lower mean VAS scores for anticipated and actual pain in all types of nerve blocks [3]. This is consistent with the present findings, where the vibrotactile device demonstrated superior mean anaesthesia scores across various nerve blocks. However, they found no significant difference in VAS scores between anticipated and actual pain for certain LA injections without the device. It's crucial to consider the specific nerve blocks and their complexities when interpreting these results.

The OroQuiver device was effective in reducing injection-related pain irrespective of the type of nerve block administered. In the patient questionnaire, no discomfort was reported by any patient, and the device reduced anxiety towards dental injections in 14 patients. Sixteen patients indicated that they would recommend this device to others.

Other popular vibrotactile devices in the market include DentalVibe and VibraJect [1]. VibraJect clips directly onto the syringe, offering the advantage of no learning curve. DentalVibe, on the other hand, applies vibration to the tissues before the needle makes contact, facilitating easier initial penetration. OroQuiver, like DentalVibe, is designed to retract the buccal or labial mucosa. It can be conveniently held and operated using the non-dominant hand, allowing the operating hand to remain free for administering injections. The vibrations massage the injection site, preventing swelling caused by the anesthetic solution and promoting quicker and more effective anaesthesia dispersion [14]. Unlike DentalVibe, OroQuiver has a sterilisable tip, making it cost-effective. While DentalVibe and VibraJect cost $995 and $299 respectively, OroQuiver was manufactured at a cost of Rs. 4000 and can be made commercially available for less than Rs. 10,000 [15,16].

Limitation(s)

Paediatric patients were not included in the study, and the effectiveness of the device for Inferior Alveolar Nerve Block (IANB) was not investigated due to potential patient discomfort from simultaneous bilateral IANB.

CONCLUSION(S)

In conclusion, the present study demonstrates that the OroQuiver vibrotactile device consistently delivers superior results in minimising pain during injection compared to the conventional method for various nerve blocks. The device is cost-effective, easy to maneuver, feasible, sterilisable, and reusable, effectively reducing pain associated with local anesthetic injections. The authors recommend future research to compare the efficacy of the device with other commercially available devices.

REFERENCES

[1] Veneva E, Cholakova R, Raycheva R, Belcheva A. Efficacy of vibrotactile device DentalVibe in reducing injection pain and anxiety during local anaesthesia in paediatric dental patients: A study protocol for a randomised controlled clinical trial. BMJ Open. 2019;9(7):e029460. Doi: 10.1136/bmjopen-2019-029460.

[2] Hegde KM, Neeraja R, Srinivasan I, Murali Krishna DR, Melwani A, Radhakrishna S. Effect of vibration during local anaesthesia administration on pain, anxiety, and behavior of pediatric patients aged 6-11 years: A crossover split-mouth study. J Dent Anaesth Pain Med. 2019;19(3):143-49. Doi: 10.17245/jdapm.2019.19.3.143.

[3] Nasehi A, Bhardwaj S, Kamath AT, Gadicherla S, Pentapati KC. Clinical pain evaluation with intraoral vibration device during local anaesthetic injections. J Clin Exp Dent. 2015;7(1):e23-27. Doi: 10.4317/jced.51643.

[4] AlHareky M, AlHumaid J, Bedi S, El Tantawi M, AlGahtani M, AlYousef Y. Effect of a vibration system on pain reduction during injection of dental anaesthesia in children: A randomised clinical trial. Int J Dent. 2021;2021:8896408. Doi: 10.1155/2021/8896408.

[5] Bilsin E, Güngörmüş Z, Güngörmüş M. The efficacy of external cooling and vibration on decreasing the pain of local anaesthesia injections during dental treatment in children: A randomised controlled study. J Perianaesth Nurs. 2020;35(1):44-47. Doi: 10.1016/j.jopan.2019.06.007.

[6] Kumar M, Chawla R, Goyal M. Topical anaesthesia. J Anaesthesiol Clin Pharmacol. 2015;31(4):450-56. Doi: 10.4103/0970-9185.169049. PMID: 26702198; PMCID: PMC4676230.

[7] Subramaniam P, Ghai SK. Efficacy of an innovative device in reducing discomfort during local anaesthesia administration in children: A clinical study. Int J Clin Pediatr Dent. 2021;14(3):353-56. Doi: 10.5005/jp-journals-10005-1948.

[8] Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. BMJ. 2010:340:c332.

[9] Shahidi Bonjar AH. Syringe micro vibrator (SMV): A new device being introduced in dentistry to alleviate pain and anxiety of intraoral injections, and a comparative study with a similar device. Ann Surg Innov Res. 2011;5(1):1. Doi: 10.1186/1750-1164-5-1.

[10] Berggren U, Meynert G. Dental fear and avoidance: Causes, symptoms, and consequences. J Am Dent Assoc. 1984;109(2):247-51. Doi: 10.14219/jada.archive.1984.0328.

[11] Meechan JG, Gowans AJ, Welbury RR. The use of patient-controlled transcutaneous electronic nerve stimulation (TENS) to decrease the discomfort of regional anaesthesia in dentistry: A randomised controlled clinical trial. J Dent. 1998;26(5-6):417-20. Doi: 10.1016/s0300-5712(97)00062-6.

[12] Schaefer JR, Lee SJ, Anderson NK. A vibration device to control injection discomfort. Compend Contin Educ Dent. 2017;38(6):e5-e8. Doi: 10.1016/j.jopan.2019.06.007.

[13] Erdogan O, Sinsawat A, Pawa S, Rintanalert D, Vuddhakanok S. Utility of vibratory stimulation for reducing intraoral injection pain. Anaesth Prog. 2018;65(2):95-99. Doi: 10.2344/anpr-65-02-01

[14] Shilpapriya M, Jayanthi M, Reddy VN, Sakthivel R, Selvaraju G, Vijayakumar P. Effectiveness of new vibration delivery system on pain associated with injection of local anaesthesia in children. J Indian Soc Pedod Prev Dent. 2015;33(3):173-76.

[15] BUY DENTALVIBE: Attract more patients to your practice and make dental anxiety a thing of the past with DentalVibe; https://store.dentalvibe.com/.

[16] My Dentcart: VibraJect Injection Comfort System; https://mydentcart.com/shop/vibraject-injection-comfort-system/.

PARTICULARS OF CONTRIBUTORS:

1. Postgraduate Student, Department of Oral and Maxillofacial Surgery, Yenepoya Dental College, Mangaluru, Karnataka, India.
2. Reader, Department of Oral and Maxillofacial Surgery, Yenepoya Dental College, Mangaluru, Karnataka, India.
3. Professor, Department of Oral and Maxillofacial Surgery, Yenepoya Dental College, Mangaluru, Karnataka, India.
4. Head, Department of Oral and Maxillofacial Surgery, Yenepoya Dental College, Mangaluru, Karnataka, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Varsha Haridas Upadya,
Reader, Department of Oral and Maxillofacial Surgery, Yenepoya Dentral College, Yeepoya University, Deralakatte, Mangaluru-575018, Karnataka, India.
E-mail: varshaupadya@yenepoya.edu.in

PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Apr 20, 2023
- Manual Googling: Aug 16, 2023
- iThenticate Software: Nov 03, 2023 (6%)

ETYMOLOGY: Author Origin

EMENDATIONS: 9

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Apr 18, 2023**
Date of Peer Review: **Jul 05, 2023**
Date of Acceptance: **Nov 08, 2023**
Date of Publishing: **Jan 01, 2024**