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Original Article

EFFECT OF BUZZY SYSTEM (VIBRATING DEVICE) COMPARED TO TOPICAL ANAESTHESIA ON PAIN REDUCTION DURING INJECTION OF INFILTRATION ANAESTHESIA IN CHILDREN: A RANDOMIZED CLINICAL TRIAL

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Abstract

Aim: The present study aimed to evaluate the effectiveness of the buzzy system (vibrating device) compared to topical anaesthesia on pain reduction during the injection of maxillary buccal infiltration anaesthesia in children.

Subjects and methods: Seventy children aged 5-8 years with decayed maxillary primary molars were randomly assigned into two equal groups. Group A received maxillary buccal infiltration anaesthesia using the buzzy device, while group B received maxillary buccal infiltration anaesthesia using topical anaesthetic gel (20% benzocaine). Pain perception during local anaesthesia injection was assessed using Wong-Baker Faces Scale (WBFS) for subjective pain evaluation. The Face, Legs, Arms, Crying, and Consolability (FLACC) scale was also used for objective pain evaluation. All obtained results were statistically analysed.

Results: The evaluation of pain scores during local anaesthesia (LA) injection showed no statistically significant difference between both experimental groups. No correlation was detected between pain scores and age or gender.

Conclusion: The buzzy device is a successful tool that is equally effective to the topical anaesthetic gel in terms of pain control during maxillary buccal infiltration anaesthesia in children aged 5-8 years.

Keywords: : Local anaesthesia, buzzy, vibration, maxillary infiltration

I. INTRODUCTION

Routine medical and dental procedures are a leading cause of acute pain in children, second to disease and injury. Inadequate management of pain during these procedures can pose challenges in behaviour guidance, leading to longer treatment times and uneasiness when treating children ***(Randall et al., 2020)*.**

Local anaesthetics have been widely used to prevent and control procedural pain in children and adults. However, the delivery process can be distressing due to needle insertion and

injection, potentially leading to adverse emotional and cognitive responses, avoidance of future dental care, and needle phobia ***(Mohamed et al., 2023)***.

Recently, there has been an introduction of the idea of using vibration stimuli to alleviate dental pain associated with needle injections. According to the gate control theory, applying pressure and vibration can close the neural gate, thereby reducing the perception of pain and itchiness. As the brain can only process one sensation from a specific area at a given moment, extra oral vibration has been employed to divert attention away from any discomfort caused by anaesthetic injections ***(Nuvvula et al., 2021; Reddy et al., 2024)***.

The buzzy device is an innovative vibrotactile device comprised of a vibrating motor and an ice pack, cleverly designed to resemble a honeybee. This unique design makes it particularly appealing to children. By combining the effects of ice and vibration, the device effectively distracts children from the needle insertion and subsequent pain ***(Sahithi et al., 2021)***.

There is an insufficient number of clinical trials conducted on the effectiveness and acceptance of the buzzy device in pediatric patients aged 5-8 years. The lack of trials makes it difficult to validate the effectiveness and applicability of this method. However, by exploring this new non-pharmacological approach to achieving painless local anaesthesia and evaluating its clinical adequacy, we can improve the quality of care in pediatric dentistry.

Accordingly, the present study was designed to compare the effect of extraoral vibration introduced by the buzzy device to the effect of topical anaesthesia in terms of pain perception during conventional local infiltration anaesthesia in children aged 5-8 years.

II. SUBJECTS AND METHODS

The study was designed to be a parallel randomized controlled trial with an allocation ratio of 1:1.

Participants were randomly allocated into two equal groups. Group (A): children who received extraoral vibration using the buzzy device. Group (B): children who received topical anaesthetic gel.

A computer-generated random sequence was created using the true random number service available online at (www.random.org). Sequentially numbered, opaque, sealed envelopes were used to conceal the allocation sequence from the principal investigator. Blinding of the operator and the participants was not feasible due to the obvious differences between the techniques employed. However, the statistician was blinded.

A power analysis was designed to have adequate power to apply a two-sided statistical test of the null hypothesis that there is no difference would be found in pain perception during local anaesthesia injection using the buzzy device in comparison to the topical anaesthetic gel. By adopting an alpha level of (0.05) a beta of (0.2) i.e. power=80% and an effect size (d) of (0.680) calculated based on the results of a pilot study; the predicted sample size (n) was a total of (70) cases (i.e. 35 cases per group). Sample size calculation was performed using G*Power version 3.1.9.78[1]. The pilot study included a total of ten patients who were recruited and randomly allocated into two experimental groups. The pilot study followed the same protocol, methods, and statistical analysis as the main study.

A total of 70 patients aged from 5 to 8 years were selected from the outpatient clinic in The Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University. All patients had decayed maxillary primary molars.

[1] Faul, Franz, et al. "G* Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences." *Behavior research methods* 39.2 (2007): 175-191.

Inclusion criteria included children of both genders classified as positive or definitely positive based on Frankl behavior rating scale, children attending for their first dental visit and requiring maxillary buccal infiltration anaesthesia.

Children with neurological or psychological disorders, or patients representing with acute signs and symptoms requiring emergency treatment or those whose parents refused to participate were excluded from the study.

The principal investigator introduced the clinical trial to the legal guardian of each participating child in a clear language and explained the main aspects of the trial including the aim, treatment, benefits, and possible side effects. The legal guardians signed an Arabic informed consent form, and a verbal assent was obtained orally from each participating child.

Diagnostic procedures:

Extra-oral examination, intra-oral examination and radiographic examination were carried out by the principal investigator to assess each patient's dental status. All diagnostic and clinical findings were documented by the principal investigator in a patient assessment chart.

Intraoperative procedures:

A) First visit:

1. The child was escorted to the operating room and seated on the dental chair.
2. Preoperative behaviour management was accomplished through non-pharmacological techniques such as tell-show-do, voice control and positive reinforcement.
3. The principal investigator performed an introductory treatment for each child according to the child's dental needs such as pits and fissure sealing and topical fluoride application.
4. At the end of the first visit, the principal investigator provided the patient and the legal guardians with oral hygiene instructions, motivation, and dietary advice.

B) Second visit:

1. In group (A), children were given a chance for 5 minutes to play with the device, turn it on and sense the vibrations on their hands before placing the device over their cheek ***(Hegde et al., 2019)***.
2. The vibrating device (figure 1), without the ice packs, was held extra-orally against the zygomatic arch above the site of anaesthesia injection by the assistance of the parent.
3. The device was switched on for 60 seconds before the injection and switched off after the completion of the injection ***(Alhareky et al., 2021)***.
4. The needle was inserted into the mucobuccal fold approximately 1-2 mm in depth, and then gradually advanced towards the target area.
5. In group (B), the injection site was dried with one side of a cotton-tipped applicator.
6. A thin layer of 20% benzocaine topical anaesthetic gel was applied for 1-2 minutes using the other side of the applicator ***(Mohamed et al., 2023)***.
7. Local anaesthesia was delivered using the same technique and the same anaesthetic agent.
8. For both groups, once the principal investigator confirmed the success of local anaesthesia, an experienced intern dentist performed the treatment recommended for each patient according to the patient's dental needs listed in the assessment chart.

Assessment of the outcomes:

During injection, a video was recorded for each child using the camera of an iPhone 7 and all videos were assessed by an external evaluator (the assistant supervisor) using the behavioural FLACC scale ***(Alhareky et al., 2021)***.

Immediately after LA injection, the child was provided with an explanation of the WBFS, and then asked to select the face that best corresponded to his/her level of pain during the injection process ***(Reddy et al., 2024)***.

III. RESULTS

Categorical data were presented as frequency and percentage values and were analyzed using Fisher's exact test. Numerical data were presented as mean, standard deviation (SD), median and interquartile range (IQR) values. They were explored for normality by checking the data distribution using Shapiro-Wilk test. Age data were normally distributed and were analyzed using independent t-test. Other data were non-parametric and were analyzed using Mann-Whitney U test. Correlations were analyzed using Spearman's rank order correlation coefficient. The significance level was set at $p<0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.3.1 for Windows[2].

A) Participants flow diagram (Figure 2)

B) Demographic data of study sample (Table 1)

C) Pain perception during LA injection: The mean ± SD of pain scores using the WBFS was 1.37±2.10 for group A and 2.63±3.90 for groups B, as presented in figure (3), with no statistically significant difference between both groups (p=0.675).

While the mean ± SD of pain scores using the FLACC scale was 3.20±2.91for group A and 3.17±3.58 for groups B, as presented in figure (4), with no statistically significant difference between both groups (p=0.630).

D) Association of pain perception with gender (Figures 5,6): Within both experimental groups, there was no significant association between pain and gender (p>0.05).

E) Association of pain perception with age: All correlations were not statistically significant (p>0.05).

F) Association between the pain scales: For group A, there was a moderate positive correlation between WBFS and FLACC scale that was statistically significant (rs=0.432, p=0.010). While for group B and overall, the correlation was strong (rs>0.5, p<0.001).

Figure (1): Vibrating body of the buzzy device.

[2]R Core Team (2023). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.

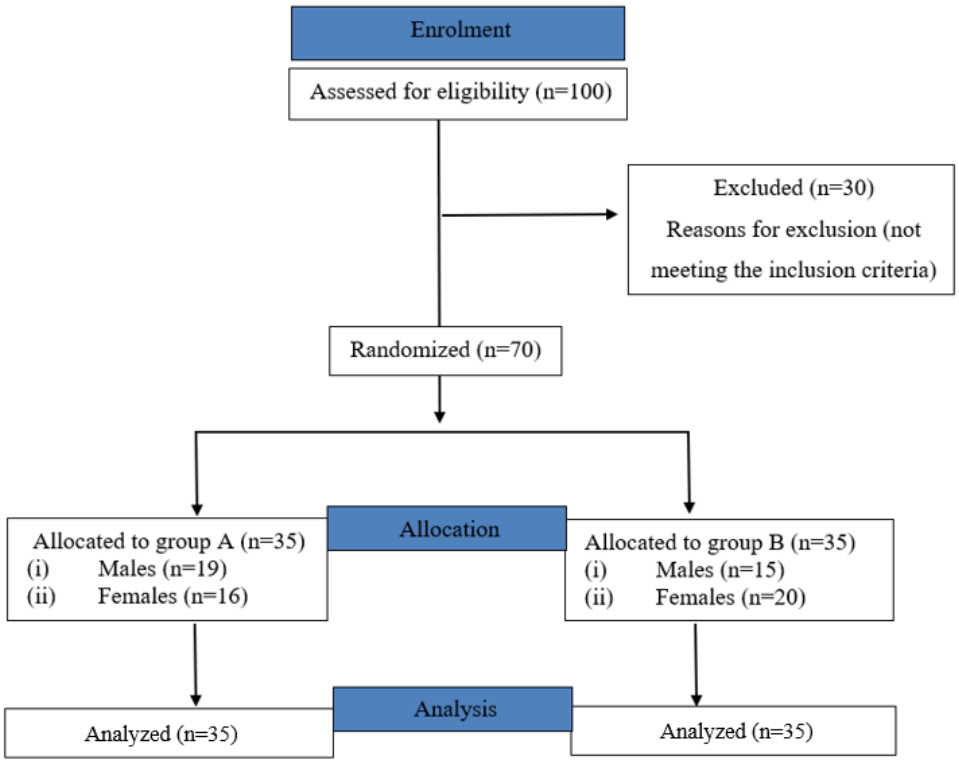

Figure (2): Participants flow diagram

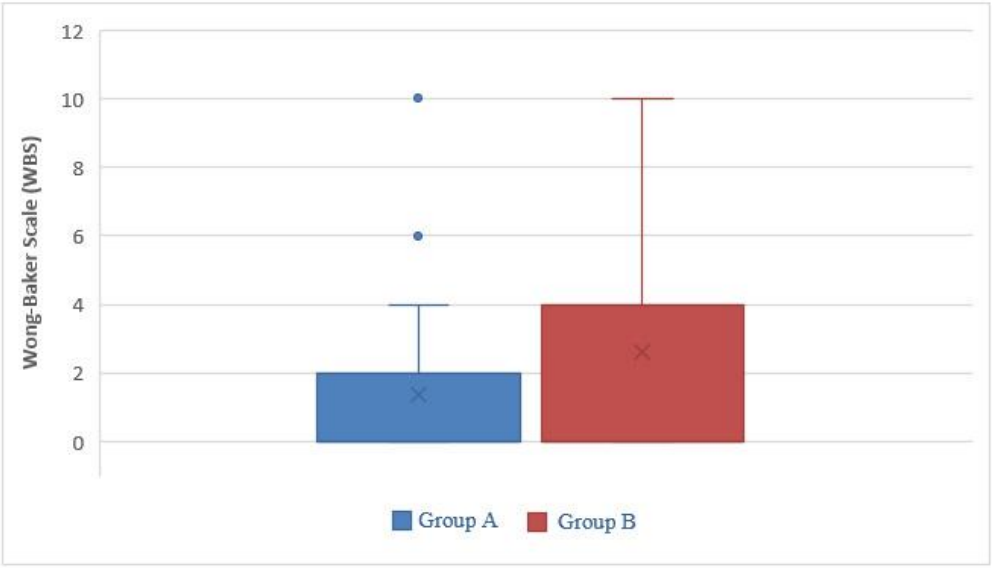

Figure (3): Box plot showing WBFS values for different groups

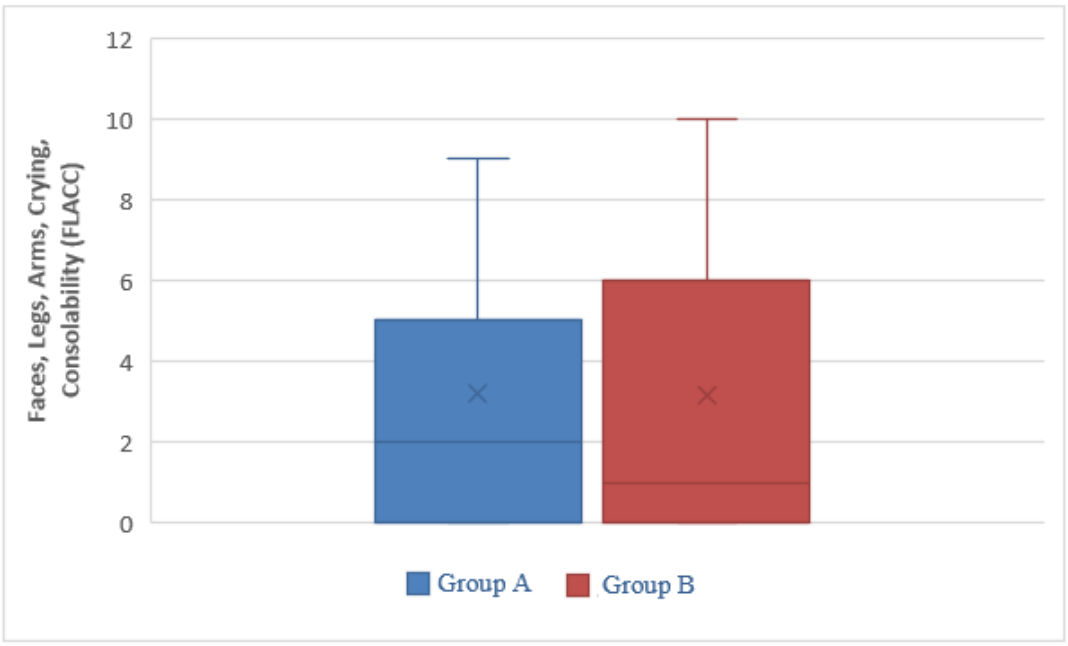

Figure (4): Box plot showing FLACC scale values for different group

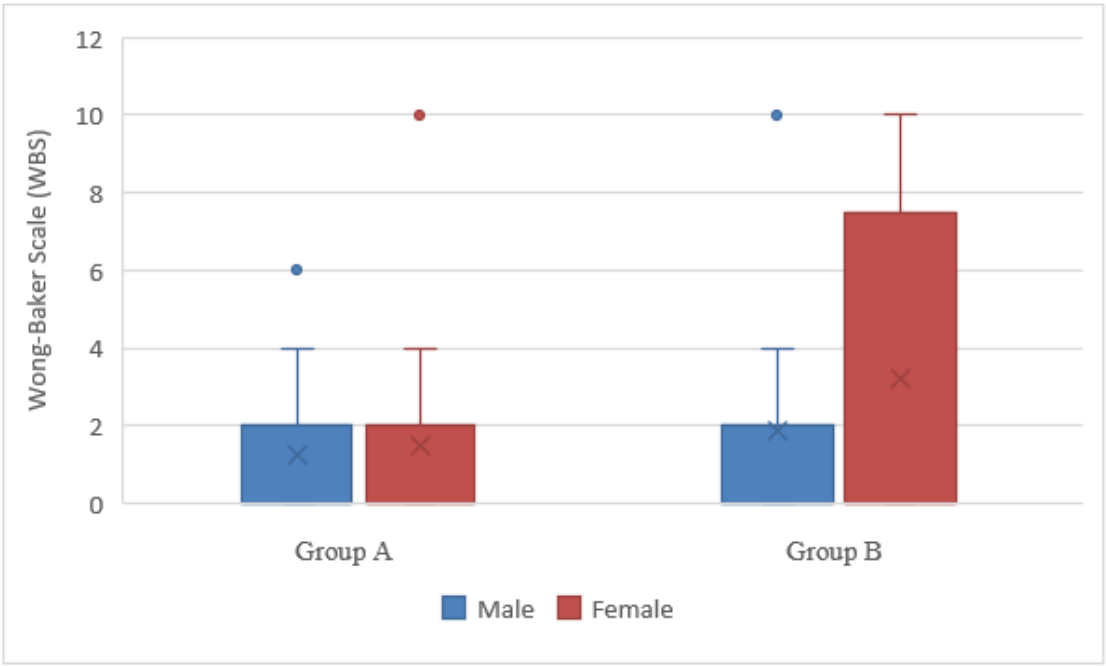

Figure (5): Box plot showing the association between WBFS and gender

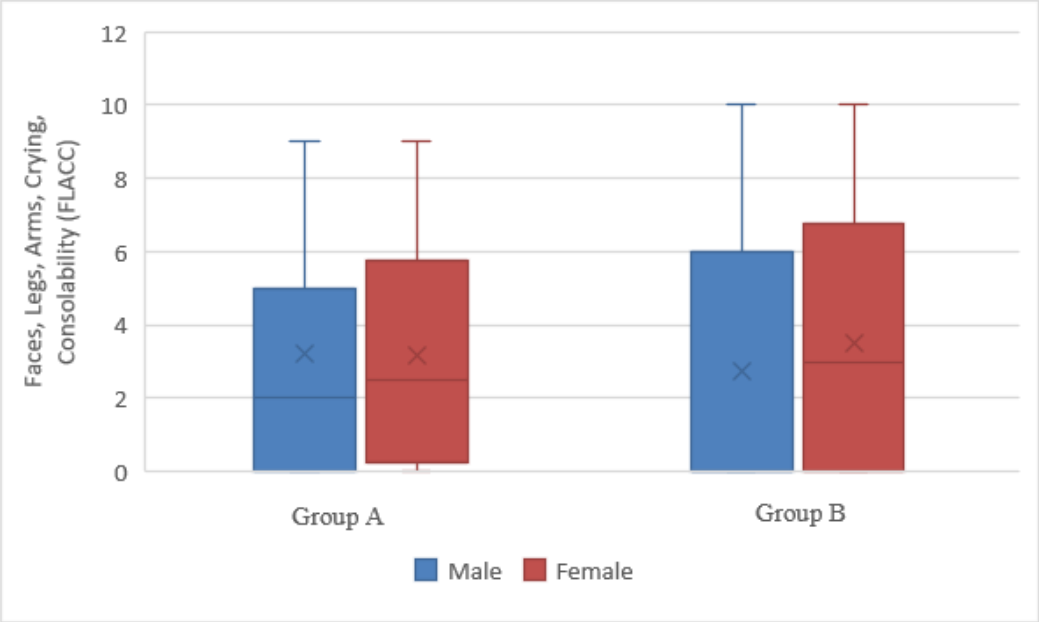

Figure (6): Bar chart showing the association FLACC scale and gender

Table (1): Intergroup comparisons and summary statistics for demographic data

Parameter			Buzzy	Control	p-value
Gender	**Male**	**n**	19	15	**0.339ns**
		%	54.3%	42.9%	
	Female	**n**	16	20	
		%	45.7%	57.1%	
Age (years)	**Mean±SD**		6.63±1.93	6.16±1.91	**0.309ns**

IV. DISCUSSION

Local anaesthetic injections are traditionally and commonly used to alleviate pain during dental procedures for children ***(Chavhan et al., 2020)***. However, the pain experienced during injections can affect their coping abilities in future visits. Thus, alternative and less painful approaches to local anaesthetic administration are being explored to improve pain management and reduce injection pain ***(Eicher et al., 2021)***.

The present study involved children within the age group of 5–8 years because this particular age range has been proposed as the starting point for the manifestation of cognitive development which is important to develop the ability to cooperate and self-report pain ***(Suohu et al., 2020)***.

All children participating in this study were chosen with no prior dental experience to exclude the influence of any previous negative dental experience on the child's attitude ***(Marković-Đurić et al., 2015; Vafaei et al., 2019)***.

Children with any neurological or psychological disorders were excluded to avoid the effect of any medications that would alter their pain perception ***(Aminah et al., 2017).***

A first dental visit was scheduled for all participants to develop trust between the child and the principal investigator, familiarize the child with the dental setting, verify the eligibility criteria and ensure accurate sample selection ***(Mika et al., 2018; Kharouba et al., 2023).***

In group A, the vibrating body of the buzzy device was used without including the ice packs because the level of discomfort experienced from direct ice contact is highly subjective and varies over time ***(Hameed et al., 2018).*** Additionally, the application of ice packs may not be well-tolerated, especially among young anxious patients ***(Subramaniam and Ghai, 2021).*** Children were given the chance to interact with the device in order to become acquainted with it and to eliminate any anxious or hesitating feelings ***(Hegde et al., 2019).***

In group B, topical anaesthesia was the comparator of choice because it is the most commonly performed procedure before the administration of *LA* ***(Shilpapriya et al., 2015).*** Topical anaesthesia was used in the form of a flavoured gel to improve drug localization, increase control over systemic drug absorption, enhance bioavailability, reduce dosage, and improve acceptability among children ***(Srivastava and Tandon, 2020).***

Maxillary buccal infiltration anaesthesia was the anaesthetic technique of choice because this technique is believed to be the least painful, making it more easily accepted by children. Further, this technique is considered relatively straight forward for dental practitioners which ensures minimal variations in its implementation ***(Jain et al., 2021).***

All dental procedures were performed by a single operator (the principal investigator) using standardized armamentarium and techniques to exclude any performance bias and to regulate the variables related to the operator, including prior experience and technical proficiency ***(Subramaniam and Ghai, 2021).***

Self-report pain assessment is considered the gold standard for pain evaluation. Thus, the WBFS was used in this study for its wide acceptance, common usage, simplicity and reproducibility among children as young as three years ***(Nagarwal et al., 2023).*** The WBFS was used in black and white format, to maintain its validity and accuracy ***(Clegg et al., 2022).***

However, subjective evaluation of pain by patients can potentially impact the accuracy of the findings in certain situations such as when dealing with pre-verbal, non-verbal, cognitively impaired, or very young children ***(Trottier et al., 2022).*** Therefore, both subjective and objective evaluation methods were employed to ensure the reliability of the results ***(Elbay et al., 2016).*** The FLACC scale was used as a behavioural observational tool for pain assessment due to its demonstrated interrater reliability, internal consistency and ability to accurately measure pain levels ***(Nagarwal et al., 2022).***

All participants were aged from 5 to 8 years. The mean age in the test group was (6.63±1.93) years and (6.16±1.91) years in the control group with no significant difference between both experimental groups, which was in agreement with ***Subramaniam & Ghai, 2021.***

Regarding the gender distribution, the total number of males was 34 participants (48.5%) while the total number of females was 36 participants (51.5%), with no statistically significant difference between both groups. This was in accordance with ***Mohamed et al., 2023*** and suggests the absence of specific gender predilection.

In this study, the majority of the reported pain scores were low as assessed by the WBFS and FLACC scale. The pain scores did not exceed a median value of 2, which indicates 'mild discomfort' according to the FLACC scale and 'hurts little bit' according to

the WBFS. This result was in agreement with ***Elbay et al., 2016*** who used the dental vibe to evaluate the effect of vibration compared to the traditional syringe on injection pain in children aged 6–12 years. This finding suggests that both experimental methods were successful in controlling pain associated with LA injection.

In terms of subjective pain assessment, the WBFS revealed that the pain scores of the test group (1.37±2.10) were lower than those of the control group (2.63±3.90) with no statistically significant difference between both groups. This finding was in line with ***Shilpapriya et al., 2015*** who used the dental vibe to test the effect of vibration compared to topical anaesthesia on pain associated with LA injection. **Shilpapriya *et al., 2015*** concluded that vibration and distraction can significantly reduce the level of self-reported procedural pain during LA injection.

While in terms of objective pain assessment, the observational FLACC scale showed that the pain scores of the test group (3.20±2.91) were almost equal to those of the control group (3.17±3.58) with no statistically significant difference between both groups. This result was in accordance with ***Elbay et al., 2016*** who concluded no statistically significant difference between vibration and the traditional syringe because patients reported comparable pain levels during LA injection with or without vibration.

Females tend to experience less pain tolerance and lower pain threshold with greater tendency to report higher pain values than males ***(Nascimento et al., 2020).*** However, the results of this study showed no statistically significant difference between males and females which was in line with ***Subramaniam & Ghai, 2021.*** This finding suggests the absence of gender bias.

In terms of correlation between the used subjective and objective pain assessment scales, the results of WBFS and FLACC scale showed strong positive correlation in both experimental groups which was statistically significant. This agreed with ***Elbay et al., 2016*** and suggests that the pain scores collected from both the patients and the external evaluator were highly consistent. The reason for this can be attributed to the fact that the specific age group included in the study sample had reached a level of cognitive development that enabled them to comprehend the pain scales and accurately express their perception of pain.

Limitations of the study

1. This study included only cooperative children. Therefore, the results of the research cannot be generally applied to children who exhibit disruptive behaviour in the dental office.
2. The study was conducted in a public hospital's outpatient clinics. Hence, the behaviour of the children receiving dental treatments in the clinic may have negatively affected the anxiety and pain perception of the study participants present in the same clinic.
3. Blinding of the principal investigator or the participants was not feasible.

V. CONCLUSION:

1. The vibrating body of the buzzy device is an attractive, child-friendly tool that shows comparable results to the topical anaesthetic gel in reducing pain perception during maxillary buccal infiltration anaesthesia in children aged 5-8 years.
2. Both subjective and objective pain assessment methods were comparable in the current study.
3. No correlation was detected between the pain scores and age or gender.

Conflict of Interest:

The authors declare no conflict of interest.

Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors

Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on: 27/09/2022, approval number: 7-9-222

Data Availability:

Data will be available upon request.

Clinical trial registration:

The protocol for this study was registered on clinicaltrials.gov, under ID: NCT05083975.

Credit statement:

Fatma Mahmoud Mohamed Mahmoud Khalil: Data curation, Writing - review & editing, Writing - original draft, Methodology, Conceptualization, Resources.

Randa Youssef Abd Al Gawad: Data curation, Conceptualization, Project administration, Supervision, Methodology, Writing - review & editing, Writing - original draft.

Shaimaa Mohamed Sabry: Methodology, Writing - original draft, Writing - review & editing, Investigation, Formal analysis, Supervision, Data curation.

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