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ORIGINAL RESEARCH

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The effects of virtual reality and external cooling and vibration (Buzzy®) on dental anxiety and pain during inferior alveolar nerve block in children: a randomized clinical trial

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Abstract

Background: To compare the effectiveness of virtual reality (VR) and external cooling and vibration distraction techniques on dental anxiety and pain in children during inferior alveolar nerve block (IANB). **Methods**: In this randomized controlled parallel arm trial, 120 children aged 6 to 12 years requiring IANB were included and randomly assigned into one of three groups: Group I: VR eyeglasses, Group II: Buzzy® device and Group III: Control (conventional behavior management technique). Dental anxiety levels were measured by the heart rate (HR) and oxygen saturation level (SpO_2) before, during, and after the IANB procedure. Pain perception was assessed using the Face, Legs, Activity, Cry, Consolability (FLACC) Scale, Wong Baker Faces Scale (WBS) and Visual Analog Scale (VAS). **Results**: A significant increase in HR was observed in all groups during the IANB procedure ($p < 0.05$). Group II (Buzzy® device) showed the lowest FLACC scores, followed by Group I (VR eyeglasses) and Group III (Control), with statistically significant differences among groups ($p < 0.05$). However, no significant differences were found between the groups in terms of WBS and VAS scores ($p > 0.05$). **Conclusions**: Although neither VR eyeglasses nor the Buzzy® device significantly reduced physiological indicators of dental anxiety during IANB, both techniques were effective in lowering pain levels compared to conventional behavior management techniques. **Clinical Trial Registration**: The study protocol was retrospectively registered at www.clinicaltrials.gov (ID: NCT06788301).

Keywords

Dental anxiety; Distraction; Local anesthesia; Pain; Pediatric dentistry

1. Introduction

The International Association for the study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage” [1]. During dental procedures, inadequate pain control can lead to significant physical and psychological consequences [2]. In pediatric dentistry, local anesthesia is routinely employed to manage pain. However, local anesthetic administration remains one of the most painful, fear and anxiety-inducing procedures in pediatric dentistry [3, 4]. Beyond procedural factors, children’s dental anxiety is also affected by broader psychosocial and familial factors—particularly parental dental anxiety. Recent studies have demonstrated a strong association between parental anxiety and children’s fear of dental procedure. For instance, a cross-sectional study by Šimunović *et al.* [5] reported a significant correlation between children’s dental fear and parental dental anxiety across various European populations, underscoring the impact of parental attitudes on children’s clinical responses. Given these considerations, various techniques have been explored to minimize pain and anxiety during local anesthesia administration.

Effective pain management is essential to successful behavior modification in pediatric patient during dental appointments. Numerous behavioral management techniques have been developed, encompassing both pharmacological and non-pharmacological approaches. Among the non-pharmacological strategies recommended by the American Academy of Pediatric Dentistry is distraction, a widely used method for alleviating dental anxiety [6]. Distraction techniques help reduce pain, anxiety and fear during painful medical procedures by diverting their attention from unpleasant or noxious stimuli [7, 8]. These methods are generally considered safe, cost-effective, and beneficial for improving the overall quality of pediatric dental care [9].

Distraction can be categorized into active or passive form. Active distraction involves the child’s direct engagement, such as with interactive toys, virtual reality (VR), breath control or guided imagery and relaxation. In contrast, passive dis-

traction does not require active participation and may rely on listening to music or watching television [10]. An effective distractor should engage multiple sensory modalities, including visual, auditory and kinesthetic, as well as active emotional involvement to capture child's attention and reduce dental anxiety [11]. A novel approach in the medical field, VR distraction is described as "a human-computer interface that enables the user to interact dynamically with the computer-generated environment", which is intended to support patient behavior management. By immersing the child in a virtual world, they are distracted from real world that could cause a negative attitude during dental procedures [7, 12]. VR distraction incorporates multiple senses—visual, audio and kinesthetic—and is believed to be more effective than traditional distraction methods due to its immersive nature. The use of the occlusive headsets that project visual content directly in front of the user's eyes can block out real-world sensory input (visual, auditory or both), depending on the model used [7]. Previous studies have shown that VR distraction is a promising and effective method for reducing both anxiety and pain in pediatric patients undergoing dental and medical procedures [8, 10–14].

To reduce pain during injection procedures, external cooling and vibration application to the injection site is an alternative method. Having applied cold stimuli to the injection site prior to local anesthesia administration is a simple, physiologically effective, and cost-free method [15]. Additionally, vibration is one of the oldest and most widely used technique for minimizing discomfort in children during local anesthesia administration [16]. Recently, a simple, easy-to-use, non-invasive, cost-effective, and reusable device, Buzzy® (MMJ Labs, Atlanta, GA, USA), has been developed to manage pain in children undergoing needle-related procedures. The Buzzy® device combines cold and vibration to mitigate pain perception during needle-related procedures in children [17]. The Buzzy® device is placed it extra-orally over the area targeted for anesthesia before injection. It is considered a non-invasive, child-friendly, and cost-effective device that can reduce the perception of pain by distracting children from the noxious stimulus [18]. The rationale for combining cold and vibration is that pain is a psychological phenomenon that depends on the patient's perception and level of the attention. The vibrating feature of the Buzzy® device is believed to create a distracting environment, which allows the analgesia to be delivered by causing the brain cells to relay the vibrations. By adding a cold application, the pain pathway's perception of signals is further confused, allowing for a "masking effect of pain" [18–20]. Systematic reviews have shown that children's perceptions of pain during the administration of local anesthesia can be effectively reduced by using external cooling and vibration application [16].

While a range of distraction techniques has been evaluated in pediatric populations to reduce anxiety and pain during both dental and medical procedures [8, 10–15, 20]. However, information regarding the effectiveness of external cooling and vibration application on dental anxiety and pain as compared to VR distraction remain limited. Therefore, this study aimed to compare the effect of VR distraction and external cooling and vibration application on dental anxiety and pain in children during local anesthesia administration.

2. Materials and methods

2.1 Study design and sample size

This study was designed as a three-arm parallel randomized controlled trial (RCT) to compare the effects of virtual reality, external cooling, and vibration on dental anxiety and pain during inferior alveolar nerve block (IANB) in children aged 6 to 12 years old. This study was conducted at the Department of Pediatric Dentistry, Faculty of Dentistry, Pamukkale University, between July 2022 and April 2023. Ethical approval was obtained from the Ethics Committee of the Faculty of Medicine, Pamukkale University (No. 03; 08 February 2022), and all procedures were carried out in accordance with the ethical standards outlined in the Declaration of Helsinki. The study protocol was retrospectively registered at www.clinicaltrials.gov (ID: NCT06788301). The trial was designed and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Fig. 1) [21].

The sample size was determined using G*Power 3.1. software (University of Kiel, Kiel, SH, Germany) with a significance level of 5%, a power of 95% and an effect size of 0.721 [10]. Power analysis indicated that a minimum pf 33 participants per group was required. The final sample size included 120 children, who were randomly assigned to one of the three groups: Group I: VR eyeglasses group, Group II: Buzzy® device group and Group III: control group. A table of random numbers was generated using the website www.randomizer.org to randomly allocate the 120 participants into three groups of 40 each. Group assignment was further determined using a lottery method. Allocation concealment sequentially numbered, opaque, sealed envelopes. To ensure allocation concealment, the investigator (AİA) was blinded until the IANB was administered.

2.2 Eligibility criteria

Patients who attended the pediatric dental clinic were selected as participants based on the following inclusion and exclusion criteria:

2.2.1 Inclusion criteria

- Children aged 6 to 12 years, without any systemic disease and physical and/or mental disorders.
- Children whose behavior was rated as "positive" or "definitely positive" according to the Frankl Behavior Scale (FBS).
- Children with no known allergy to any medication or local anesthetic.
- Children with a mandibular primary/permanent molar requiring dental treatment under an IANB.
- Children with no previous experience of local anesthesia.

2.2.2 Exclusion criteria

- Children with systemic disease or neurological behaviour disorders.
- Children whose behavior was rated "negative" or "definitely negative" according to the FBS.

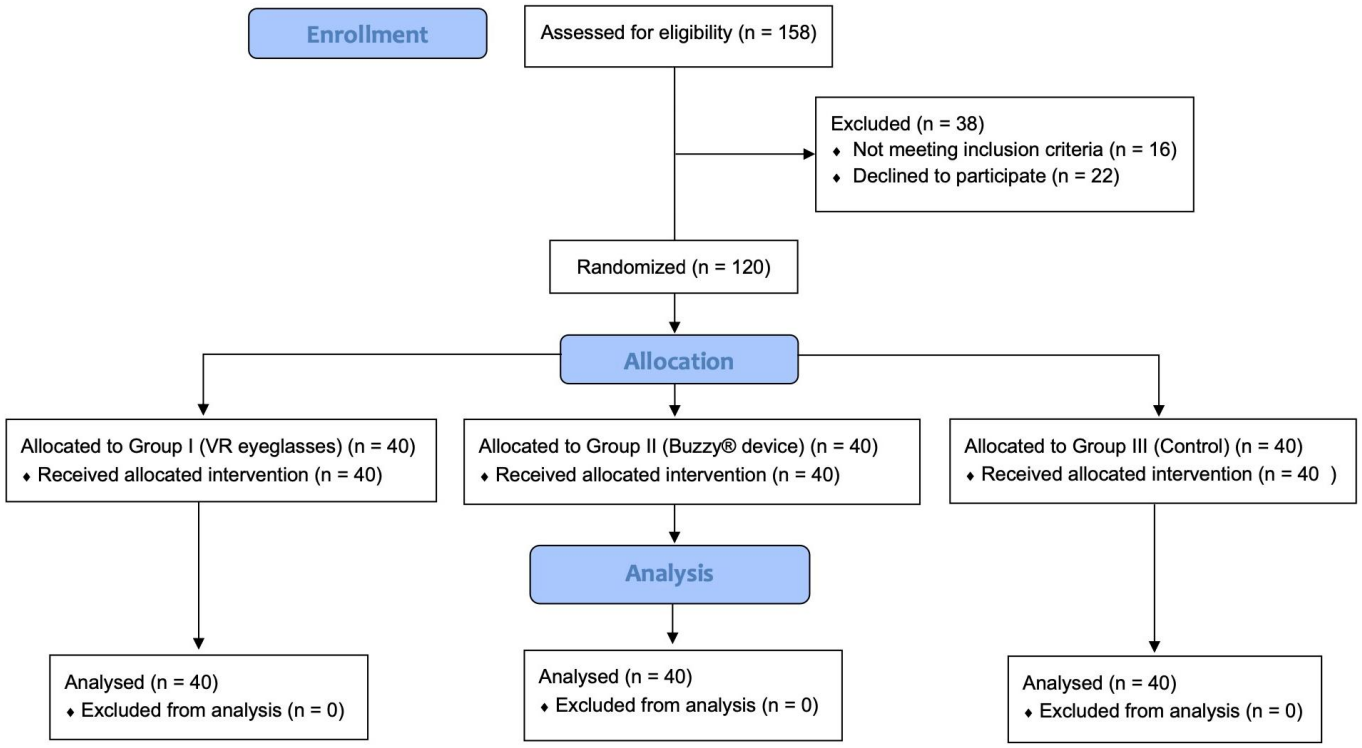

FIGURE 1. CONSORT flow diagram of participant enrollment, allocation, receipt of allocated intervention and data analysis. VR: Virtual reality.

- Children with a history of allergy to any medication or local anesthetic.
- Children with any dento-facial abnormality/syndrome that led to administration of local anesthesia difficult.
- Children with previous experience of local anesthesia or those who were non-Turkish speaking.

2.3 Study population

158 patients aged 6 to 12 who attended the Department of Pediatric Dentistry, Faculty of Dentistry, Pamukkale University were evaluated for eligibility. Of these, 142 patients met the inclusion criteria. However, 22 patients and their parents declined to participate in the study. The remaining 120 patients and their parents were informed about the study's methodology, and written informed consent was obtained from all participants. Eligible patients were randomly assigned to one of three groups based on the behavior management techniques during administration of IANB.

2.3.1 Group I: virtual reality eyeglasses group

In this group, 3D VR eyeglasses (Oculus Quest 2, Oculustm Go, Facebook Technologies, Auburn, AL, USA) were used for VR distraction (Fig. 2).

The headset and inter-pupillary distance of the VR eyeglasses were adjustable to ensure a proper fit for each user. The device completely blocked the patient's visual field and provided auditory stimulation via connection to a smartphone. Prior to the IANB procedure, the VR eyeglasses were introduced to the patient, who was then given five minutes to become familiar with the device. Age-appropriate, non-violent, colorful, and engaging animated cartoons (*e.g.*, Frozen, The Smurfs, Minions, Cars) popular in Turkey were suggested, and participants were asked to choose their preferred video to be played during the IANB administration. The VR eyeglasses were cleaned with disinfectant wipes after each procedure to prevent cross-infection.

2.3.2 Group II: Buzzy® device group

In this group, the Buzzy® device (MMJ Labs, Atlanta, GA, USA), consisting of a bee-shaped vibrating body and removable wing-shaped cold gel packs, was used for external cooling and vibration application (Fig. 3).

Before the IANB procedure, a brief explanation of the Buzzy® device was given, and patients were allowed to handle and play with the device to become familiar with it. The wing-shaped cold gel packs were frozen beforehand, left at room temperature for 10 minutes prior to use, and then connected with bee-shaped vibrating body. The Buzzy® device was placed extra-orally on the IANB site (right/left mandibula) during the IANB administration. After each procedure, the device was cleaned with disinfectant wipes to prevent cross-infection.

2.3.3 Group III: control group

In this group, conventional behavior management technique (tell-show-do) was used during the IANB administration. Prior to the IANB procedure, the instruments and steps involved were explained to the patient in phrases suitable for the patient's cognitive level.

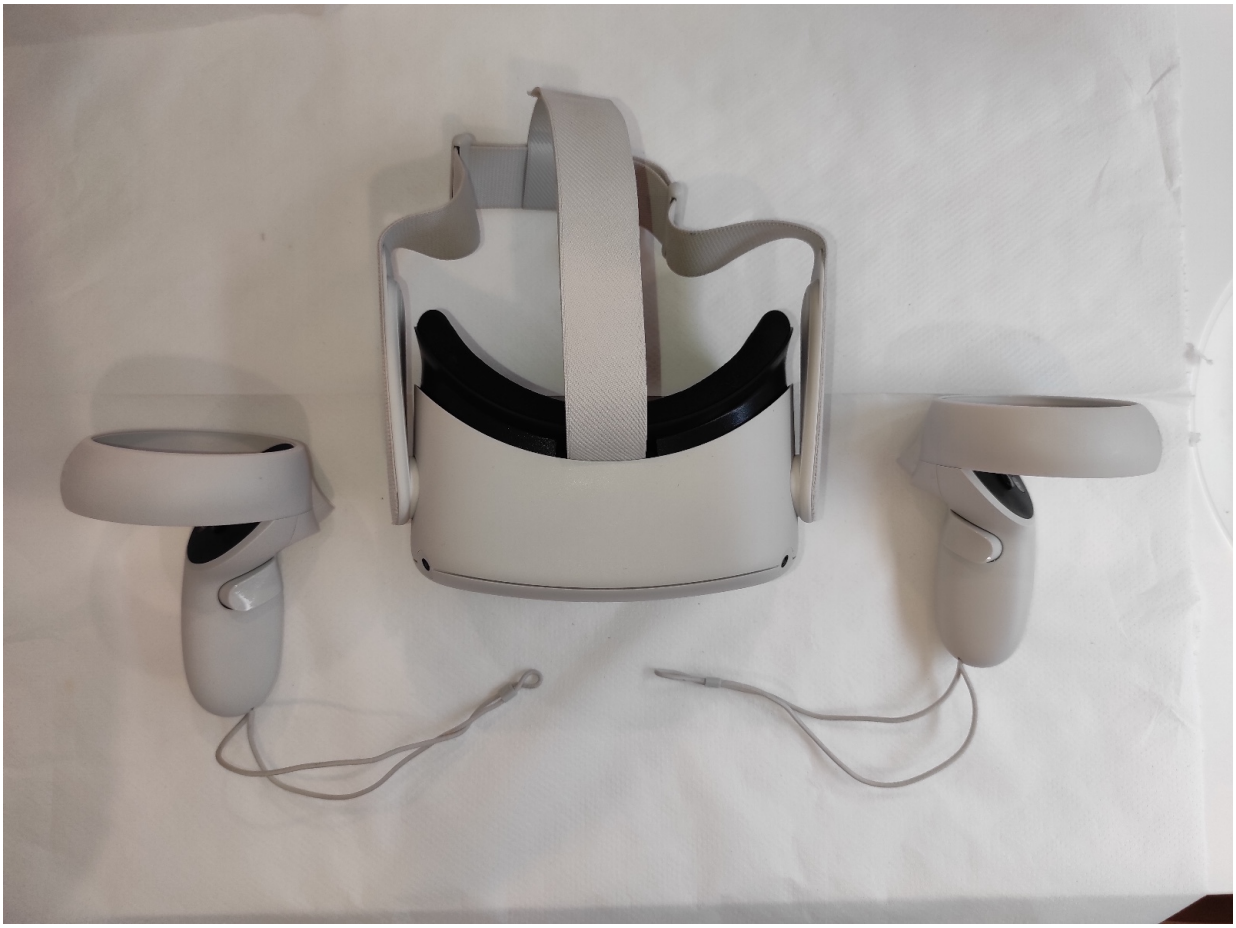

FIGURE 2. Virtual reality eyeglasses used for distraction in Group I.

FIGURE 3. Buzzy® device used for distraction in Group II.

2.4 Administration of IANB

The oral mucosa was dried using an air-water spray, and topical anesthetic solution (Vemcaine 10% Lidocaine, Lot No.: 232302, VEM Co. Ltd., Istanbul, Turkey) was applied with a cotton pellet for 1 minute. Patients were instructed to open their mouths as wide as possible. Then, the IANB was administered using 2 mL of 4% articaine with 1:100,000 adrenaline (Lot No.: ELB90053, Ultracaine DS® Forte, Sanofi Health Products Co. Ltd., Istanbul, Turkey) using an automatic aspirated Aspiject® carpule syringe (RØNVIG Dental Mfg. A/S, Daugaard, Denmark) with a 35 mm 27-gauge needle at a rate of 1 mL/minute. To ensure standardization, all patients received the same dosage of local anesthetic, and the IANB procedure was provided by the same investigator (AİA).

2.5 Dental anxiety and pain assessment

Heart rate is a well-established direct physiological indicator of anxiety and pain in painful or stressful situations [14], and previous studies have confirmed its reliability in pediatric pain and anxiety assessment [12, 14]. To evaluate physiological changes associated with anxiety, both oxygen saturation (SpO_2) and heart rate (HR) values were recorded using a pediatric fingertip pulse oximeter (OxyWatch®, ChoiceMMed™, Beijing Choice Electronic Technology Co., Ltd, Beijing, China). Measurements were taken at three time: 1 minutes before, during, and 1 minutes after the IANB administration. To minimize anxiety, the device's audible alarms were turned off during the recording procedure. Data were recorded by another investigator not involved in the treatment procedure.

For objective assessment of pain during the IANB procedure, the Face, Legs, Activity, Cry, Consolability (FLACC) Behavioral Pain Assessment Scale was used [22]. The scale includes five behavioral categories, each scored from 0 to 2 points, with a total score ranging from 0 to 10. A score of 0 indicated a relaxed and comfortable patient; scores of 1–3 indicated mild pain, 4–6 moderate pain, and 7–10 severe pain. FLACC assessments were conducted by a blinded observer who was not involved in treatment and unaware of the participants' group assignments to avoid potential bias.

Subjective pain perception was assessed using two validated pediatric self-report tools: the Wong Baker Faces Scale (WBS) and the Visual Analog Scale (VAS) [23]. The WBS presents a series of facial expression, with 0 representing "no hurt" and 10 representing "hurts worst". The VAS consists of a 10 cm horizontal line indicating the patient's current level of pain [23]. Both scales were explained to the patients, who were then asked to select the facial expression (for WBS) and the number (for VAS) that best reflected their current level of pain during the IANB procedure.

2.6 Statistical analysis

Data analysis was performed using the NCSS (Number Cruncher Statistical System) 2007 Statistical Software (LLC, Kaysville, UT, USA). Descriptive analysis (mean and standard deviation) were calculated. The Shapiro-Wilk test was used to assess normality. For normally distributed variables, comparisons across different time points of IANB procedure were performed using One-way Analysis of Variance (ANOVA), with Student Newman Keuls Multiple Comparison Test for intragroup comparisons; and Tukey Multiple Comparison Test for intergroup comparisons. For non-normally distributed data, the Kruskal-Wallis test was used for intergroup comparisons, followed by Dunn's Multiple Comparison Test. Categorical variables were analyzed using the Chi-square test. Statistical significance was set at $p < 0.05$.

3. Results

158 patients aged 6 to 12 years were initially assessed for eligibility. Sixteen patients were excluded for not meeting the inclusion criteria, and 22 patients (and their parents) declined participation. The remaining 120 patients who met inclusion criteria were enrolled in this study.

The study sample included 56 males (46.67%) and 64 females (53.33%), with a mean age of 9.33 ± 1.60. No statistically significant differences were observed between the groups regarding age, gender and FBS scores ($p > 0.05$).

3.1 Oxygen saturation (SpO_2) and heart rate (HR) based anxiety assessment

The mean SpO_2 and HR values for the groups at three-time intervals during IANB procedure are presented in Table 1.

A statistically significant difference was observed in the mean SpO_2 values among the three groups before, during and after IANB procedures ($p < 0.05$) (Table 1). Before IANB, Group II (Buzzy®) exhibited significantly higher mean SpO_2 levels compared to Group I (VR) and Group III (Control) ($p < 0.05$), while no statistically significant difference was observed between the Group I (VR) and Group III (Control). During IANB, the mean SpO_2 values in Group II (Buzzy®) remained significantly higher than in Group I (VR) and Group III (Control) ($p < 0.05$), with no statistically significant difference between Group I (VR) and Group III (Control) ($p > 0.05$). After IANB, the mean SpO_2 values in Group II (Buzzy®) was significantly higher than in Group I (VR) ($p < 0.05$); however, no significant differences were observed between the other groups ($p > 0.05$) (Table 2).

In the intergroup comparisons, no statistically significant differences were found in the SpO_2 values before, during, and after IANB in Group I (VR) ($p > 0.05$) (Table 1). In Group II (Buzzy®) and III (Control), the mean SpO_2 values before IANB were significantly lower than during IANB. Additionally, in Group III (Control), a significant difference was also observed between the mean SpO_2 values before and after IANB ($p < 0.05$) (Tables 1 and 3).

There was no statistically significant difference among the three groups regarding the mean HR values before, during, and after IANB procedures ($p > 0.05$) (Table 1). However, intragroup comparisons revealed a significant increase in HR values from before to during IANB procedures across all three groups. Although a decrease in the mean HR values was observed after IANB, no statistically significant difference was found between during and after IANB in Group I (VR) and

TABLE 1. Comparison of oxygen saturation (SpO_2) and heart rate (HR) values among the VR, Buzzy®, and Control groups before, during, and after the inferior alveolar nerve block (IANB) procedure.

Parameters	Interval	Group I (VR)	Group II (Buzzy®)	Group III (Control)	p*
SpO_2	Before IANB	98.51 ± 0.81	99.21 ± 0.81	98.70 ± 0.97	0.0010
	During IANB	98.69 ± 0.94	99.49 ± 0.66	99.06 ± 0.96	0.0001
	After IANB	98.74 ± 0.97	99.38 ± 0.82	99.07 ± 0.94	0.0080
	$p^{\dagger}$	0.169	0.013	0.003	
HR	Before IANB	99.09 ± 15.16	98.45 ± 15.58	93.99 ± 14.91	0.2670
	During IANB	108.02 ± 15.74	103.48 ± 16.51	103.05 ± 18.98	0.3590
	After IANB	105.29 ± 15.11	98.52 ± 15.68	102.49 ± 18.54	0.1870
	$p^{\dagger}$	0.0001	0.0040	0.0001	

**One-way Analysis of Variance; †Paired One-way Analysis of Variance; IANB: Inferior alveolar nerve block; HR: Heart rate; SpO_2: Oxygen saturation; VR: Virtual reality.*

TABLE 2. Comparison of mean oxygen saturation (SpO_2) values among the VR, Buzzy®, and Control groups before, during, and after the inferior alveolar nerve block (IANB) procedure.

Group comparison	SpO_2		
	Before IANB (p* value)	During IANB (p* value)	After IANB (p* value)
Group I (VR)/Group II (Buzzy®)	0.001	0.0001	0.006
Group I (VR)/Group III (Control)	0.575	0.1430	0.239
Group II (Buzzy®)/Group III (Control)	0.027	0.0480	0.279

**Tukey Multiple Comparison Test; IANB: Inferior alveolar nerve block; SpO_2: Oxygen saturation; VR: Virtual reality.*

TABLE 3. Intragroup comparison of mean oxygen saturation (SpO_2) and heart rate (HR) values before, during, and after the inferior alveolar nerve block (IANB) procedure.

Intragroup comparison	SpO_2			HR		
	Group I (VR)	Group II (Buzzy®)	Group III (Control)	Group I (VR)	Group II (Buzzy®)	Group III (Control)
	p* value					
Before IANB/During IANB		0.011	0.003	0.0001	0.008	0.0001
Before IANB/After IANB		0.065	0.010	0.0001	0.947	0.0001
During IANB/After IANB		0.210	0.909	0.1190	0.021	0.7560

**Student Newman Keuls Multiple Comparison Test; IANB: Inferior alveolar nerve block; HR: Heart rate; SpO_2: Oxygen saturation; VR: Virtual reality.*

Group III (Control) ($p > 0.05$). In contrast, Group II (Buzzy®) showed a significant reduction in mean HR values after IANB compared to during IANB ($p < 0.05$) (Tables 1 and 3).

3.2 Objective (FLACC) and subjective (WBS and VAS) pain assessment

The mean FLACC, WBS and VAS scores for each group are shown in Table 4. A statistically significant difference was observed in the comparison of FLACC scores between groups ($p < 0.05$).

The mean FLACC score was lower in Group II (Buzzy®) (0.53 ± 1.22), compared to Group I (VR) and Group III (Control) (Table 4). The FLACC score in Group III (Control) was significantly higher than those in Group I (VR) and Group II (Buzzy®) ($p < 0.05$). Furthermore, the FLACC score in Group I (VR) was also significantly higher than in Group II (Buzzy®) ($p < 0.05$) (Table 5).

Although the mean WBS and VAS scores of Group II (Buzzy®) were lower than Group I (VR) and Group III (Control), the differences were not statistically significant ($p = 0.636$, $p = 0.877$, respectively) (Table 4).

4. Discussion

Dental procedures, particularly the administration of local anesthesia, frequently provoke anxiety and stress in children, which can lead to an increase in pain sensitivity. Therefore, it is crucial to employ techniques that effectively divert children's attention away from the dental procedures [10]. Distraction techniques in pediatric dentistry have been shown to manage pain efficiently by diverting the patient's focus

TABLE 4. Comparison of mean FLACC, WBS, and VAS scores between the VR, Buzzy®, and Control groups.

		Group I (VR)	Group II (Buzzy®)	Group III (Control)	$p^{\ddagger}$
FLACC	Mean ± SD	1.25 ± 1.72	0.53 ± 1.22	2.25 ± 1.74	0.0001
WBS	Mean ± SD	2.50 ± 2.21	2.45 ± 1.47	3.10 ± 2.60	0.6360
VAS	Mean ± SD	2.08 ± 1.82	2.08 ± 1.59	2.55 ± 2.55	0.8770

‡*Kruskal-Wallis Test; FLACC: Face, Legs, Activity, Cry, Consolability Behavioral Pain Assessment Scale; SD: Standard deviation; VAS: Visual Analog Scale; VR: Virtual reality; WBS: Wong Baker Faces Scale.*

TABLE 5. Intergroup comparison of mean FLACC scores among the VR, Buzzy®, and Control groups.

Intergroup comparison	FLACC (p* value)
Group I (VR)/Group II (Buzzy®)	0.0250
Group I (VR)/Group III (Control)	0.0080
Group II (Buzzy®)/Group III (Control)	0.0001

**Dunn's Multiple Comparison Test; FLACC: Face, Legs, Activity, Cry, Consolability Behavioral Pain Assessment Scale; VR: Virtual reality.*

away from the painful stimulus, limiting the brain's capacity to process incoming nociceptive signals [23, 24]. Therefore, this study compared the effects of two different distraction techniques (VR and external cooling and vibration) on dental anxiety and pain during IANB in children aged 6 to 12 years, with a control group that received conventional behavior management technique (tell-show-do).

Although anxiety and pain are distinct concepts, they are closely interrelated. Patients experiencing high levels of dental anxiety often perceive pain as more intense prolonged [25]. To minimize confounding effects on pain perception, this study included only children with positive or definitely positive behavior ratings according to the Frank Behavior Scale, thereby excluding those with high levels of dental anxiety. It is stated that dental anxiety in children decreases after the age of 6–7, and the ability to cope with dental procedures increases with cognitive development [26]. For this reason, children aged 6 to 12 years were selected to ensure effective communication, reduce anxiety associated with younger age, and facilitate the use of distraction devices appropriate to their developmental level [27].

Given that dental anxiety is a multidimensional phenomenon involving social, perceptual, and physiological components, a single parameter is insufficient for accurate evaluation [28]. Therefore, to assess the pain associated with local anesthesia administration in children, a combination of subjective methods in which the child expressing themselves, and objective methods such as behavior observation and physiological change measurement are recommended [29]. In this study, patients' dental anxiety and pain were assessed using two subjective (WBS and VAS scale), one objective (FLACC scale), and physiological measurements (HR and SpO_2).

Painful dental procedures can lead to physiological changes in children. Anxiety and discomfort directly activate sympathetic system, triggering the release of catecholamines and glucocorticoids. These factors increase sympathetic activity, resulting in increased heart rate, blood pressure [30] and a decrease in oxygen saturation [31]. In this study, an increase in HR and SpO_2 values was observed during IANB across all three groups, regardless of the distraction techniques used. These findings align with previous studies that reported similar physiological patterns in pediatric patients undergoing dental procedures [10, 32–34]. These findings indicate that local anesthesia administration is a dental procedure that consistently elevates HR, likely due to anticipatory anxiety. The anticipation of an injection can activate the sympathetic system, leading to catecholamine release and consequently increasing HR [32]. Although there was no statistically significant difference in the mean HR values among the three groups during IANB, the highest mean HR value was recorded in Group I (VR). One potential explanation is that the immersive nature of VR, which blocks visual contact with the real environment, may contribute to fear of the unknown. This sensory disconnection might increase anxiety, leading to heightened pain perception and elevated HR in children [35]. Contrary to the present study, Alanazi *et al.* [20] reported that with the use of the Buzzy® device resulted in significantly lower HR compared with the control group during the administration of local infiltration anesthesia in children. Compared to the infiltration technique, the IANB anesthesia used in this study is a more painful and difficult technique for children and dentists [36]. The differences in results could be explained by the different anesthesia technique that were employed. Additionally, Mladenovic *et al.* [37] reported that VR gamification significantly reduced perceived pain and anxiety during the extraction of molar-incisor hypomineralisation-affected molars in children. Their study demonstrated that during dental procedures, immersive and interactive VR experiences, which include game-based tasks and audiovisual stimuli successfully divert attention from unpleasant stimuli, resulting in decreased heart rate and pain scores. However, the VR distraction that employed in their study was gamified, engaging and emotionally positive—factors that can alleviate procedural anxiety and promote relaxation [37]. In contrast, the present study employed a more basic VR content without gamification, which may have limited its effectiveness as a distraction tool, potentially resulting in higher HR values in the VR group.

While HR increased across all groups during IANB, SpO_2 values also showed a slightly rise. Anxiety or pain-induced sympathetic activation typically elevates HR and blood pressure, but oxygen saturation in healthy individuals remains stable and generally above 95%, unless significant respiratory distress or hyperventilation [33]. In this study, SpO_2values

remained similar between during and after IANB in all three groups and stayed above 95%. These findings agree with previous studies that reported similar patterns [33, 34].

Regarding pain assessment, the FLACC pain assessment scale has been widely used in pediatric dentistry to measure discomfort during dental procedures [12, 20, 23, 27, 33–35]. Recommended by the Australian Royal Collage for Nursing, the FLACC scale is appropriate for evaluating pain in children over 3 years old, regardless of their cooperation level [38]. In this study, a significant difference in FLACC scores was observed among the groups. Group II (Buzzy®) had the lowest FLACC score (0.53 ± 1.22), followed by Group I (VR: 1.25 ± 1.72) and Group III (Control: 2.25 ± 1.74). Alshatrat *et al*. [23] evaluated the effect of VR distraction on pain level among 5- and 12-years old children during different dental procedures. They stated that patients who received more intrusive procedure, such as local anesthesia administration, showed statistically lower FLACC scores in test group compared with the control. Similarly, Alanazi *et al*. [20] and Suohu *et al*. [34] reported that the Buzzy® device significantly lower pain perception according to FLACC scores during maxillary infiltration anesthesia. However, contrary findings were reported by Narimany *et al*. [36], who observed no significant reduction in pain perception using the Buzzy® device during IANB. The discrepancy may stem from methodological differences: their study employed a split-mouth design, whereas the present study used a parallel group design—one of its noted limitations.

The use of WBS and/or VAS pain assessment scale for self-reported pain assessment in children is well-supported by previous studies [12, 13, 20, 33–36]. Accordingly, this study employed both WBS and VAS to subjectively assess pain in patients. Although no statistical significance difference was observed between the groups regarding the WBS and VAS scores, using distraction technique with VR eyeglasses and Buzzy® device resulted in lower pain perception compared to those in the control group. Erdogan *et al*. [13] evaluated the effect of distraction cards, VR, and Buzzy® device distraction methods on pain and anxiety during the venipuncture procedure in children aged 7 to 12 years. Their findings revealed the lowest WBS and VAS scores were observed in Buzzy® device group, followed by the VR distraction, distraction cards, and finally the control group.

The results of the present study further demonstrate that both VR and the Buzzy® device had positive impact on reducing pain perception compared to the control group. External cooling and vibration application with the Buzzy® device resulted in less pain perception in patients during IANB procedure according to both objective (FLACC scale) and subjective (WBS and VAS scale) pain assessment. Since the VR eyeglasses is mainly designed for adults, it may not always fit well for children with smaller face. Consequently, some children may find the VR eyeglasses uncomfortable, particularly since it completely obstructs their view of the real-world environment [30, 35]. In addition, the Buzzy® device is compact, does not interfere with the child's field of vision, and is generally well tolerated by children. The mechanism by which the Buzzy® device reduces pain perception can be understood through the gate control theory of pain [39]. According to this theory, a "gate" in the dorsal horn of the spinal cord moderates the transmission of pain from the peripheral nervous system to the central nervous system. It has been suggested that the afferent pain-receptive nerves (A-delta fibers carrying acute pain and slower C fibers carrying chronic pain messages) are blocked by A-beta fibers which transmit sense of vibration [40]. When vibration is applied concurrently with the injection, the brain is more likely to process the vibratory stimulus before the pain from the needle. Additionally, prolonged cold application may stimulate C fibers and inhibit A-delta fiber transmission [41]. These mechanisms collectively explain the reduced pain perception observed in patients using the Buzzy® device during IANB.

Although both VR and the Buzzy® device were effective in reducing pain during IANB, neither technique significantly reduced anxiety levels in this study. Conversely, previous studies reported that VR and external vibration and cooling (Buzzy®) distraction techniques can effectively reduce both pain and anxiety levels during dental procedures [20, 23, 37]. Alshatrat *et al*. [23] and Mladenovic *et al*. [37] reported that use of VR distraction was applied throughout the entire dental procedure—either during local anesthesia administration and tooth extraction [37], or for non-invasive procedures not requiring local anesthesia [23]. The enhanced effectiveness in those cases may be attributed to the prolonged duration of VR exposure, which likely allowed for greater immersion and sustained attention [12]. In contrast, the present study employed VR distraction only during the relatively brief and potentially anxiety-inducing IANB procedure. This limited duration may have reduced the immersive potential of the VR experience, particularly considering the attentional capacity limits of children that could reduce their ability to stay fully immersed in the VR experience during a short and anxiety-inducing procedure.

Moreover, it is critical to consider how children's responses to pain and anxiety may be impacted by broader familial and cultural anxiety patterns. It has been reported that parents with high dental anxiety may be less effective in preparing their children for dental procedures, and that parental attitudes and behaviors play a crucial role on children's response to medical and dental stressors [42]. Similarly, cultural beliefs could influence how children report and cope with pain. These psychosocial and cultural factors may alter the efficacy of distraction techniques, either enhancing or diminishing their impact on pain and anxiety.

This study had several limitations. First, only children aged between 6 and 12 years, with positive and definitely positive behavior ratings according to the FBS, were included. Therefore, the results may not be generalizable to younger children or those with negative and definitely negative behavior ratings or to children who are under 6 years old. Second, blinding was a methodological challenge, as it was not possible to blind either the operator or the participants to the intervention. However, the statistician responsible for data analysis was blinded to group allocation, which helped reduce potential bias. Third, the single-center design of the study may limit the external validity of the findings, as the results may not be broadly applicable to more diverse pediatric populations. Furthermore, a parallel-group design was employed instead

of a split-mouth design, to avoid carryover effects from previous dental experiences in the same patient. Nevertheless, this choice introduces inter-participant variability, which may influence outcome comparisons across groups—a limitation acknowledged in prior literature [35]. Another notable limitation relates to VR eyeglasses used in the study. Most commercially available VR devices are designed for adults, and children with smaller facial dimensions may find them uncomfortable or ill-fitting. This could have led to decreased immersion and reduced the overall effectiveness of VR as a distraction technique. To address these limitations, future research should consider a multi-center design, inclusion of different age groups, children rated as negative and definitely negative according to FBS, a split-mouth design, and pediatric-appropriate VR device should be conducted to evaluate the effects of VR eyeglasses and external cooling and vibration distraction techniques on dental anxiety and pain during IANB in children.

5. Conclusions

Within the limitations of this study, our findings indicated that HR values were significantly increased during IANB, and this elevation could not be controlled by either of the distraction techniques tested. However, regarding pain perception, both distraction techniques were significantly effective in reducing FLACC scores, with superior results observed for the cooling and vibrating device.

AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available on request from the corresponding author.

AUTHOR CONTRIBUTIONS

AİA—provided inferior alveolar nerve block administrations; written the first draft of the manuscript. AİA and AB—performed material preparation, data collection and analysis. Both authors contributed to the study conception and design. Both authors commented on previous versions of the manuscript. Both authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of the Faculty of Medicine, Pamukkale University (Date 08 February 2022/No. 03). Written informed consent was obtained from the parent/legal guardian of each participating child.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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