

Reduction of Dental Anxiety in Children Using Virtual Reality: A Randomised Controlled Trial



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Abstract

Aim The aim of this research is examining the effectiveness of Virtual Reality (VR) in the reduction of dental anxiety in children with novel methods.

Methods The three arm parallel-group randomised clinical study was conducted in children aged 6-10 years. Pulpotomy procedure was performed on randomised 90 selected children (n=30 in each group; AG: group applied active distraction using VR glasses, PG: group applied passive distraction, i.e., watching cartoons on a screen mounted onto a dental unit, CG: control group). Before and after the procedure, children were administered Facial Pain Scale (FIS), Children's Fear Rating Scale (CFSS-DS) and Frankl Behaviour Rating Scale (FBRS). The pulse rate was measured to check the anxiety levels of all treated children at five different time points. Statistical significance was determined as $p < 0.05$.

Results The decrease of pulse rates of children in AG in post-treatment compared to the pulse rates before the procedure was found to be statistically significant ($p < 0.05$). There was no statistically significant difference between the groups in terms of FBRS, FIS and CFSS-DS scores before and after the procedure ($p > 0.05$).

Conclusions VR has been found to positively contribute to the performance of children in adapting to dental treatment. The VR application aims to create positive attitude in children by providing them a safe atmosphere and becoming a useful tool in the dental profession.

KEYWORDS Child patient, behaviour management techniques, distraction, virtual reality.

by the American Academy of Pediatric Dentistry (AAPD) as "the technique of diverting the patient's attention from what may be perceived as an unpleasant procedure" [AAPD, 2023]. Distraction has been successfully used in dentistry for many years and works based on the assumption that pain perception has a large psychological component, in that if less attention is directed at a noxious stimulus, less pain is perceived [Gherman et al., 2016].

Virtual reality (VR) distraction, defined as "a human-computer interface that enables the user to interact dynamically with the computer-generated environment" is a new method in the medical field with the aim of aiding in patient behaviour management. It offers the advantage of an immersive virtual experience blocking out external stimuli that may provoke a negative attitude, especially in young patients. VR glasses and incorporated auditory helmets are the most commonly used components; with them, the subject's visual and auditory field is practically covered by the virtual information, preventing sensory input from the real dental world (sound of turbines, sight of instruments, needles, injections, etc.) in which the patient is truly immersed. The aim is for the patient to be immersed in and transported to "a parallel reality" that is more pleasant and for them, one in which they are not capable of perceiving unpleasant dental elements [Wismeijer and Vingerhoets, 2005]. VR is distinguished from other computer-based audio-visual technologies, especially due to the presence of a synthetic environment with its strong effect and interactivity it creates on the individual [Rheingold, 1992].

VR has been used in different clinical and medical studies for the purpose of distraction in painful procedures [Shahrbanian et al., 2012] education of children with autism spectrum disorder [Bellani et al., 2011] and with hearing impairment [Vogel et al., 2004].

A recent systematic review with a meta-analysis that included nine studies showed that the use of VR glasses is an

Introduction

Dental anxiety is a state of apprehension that something dreadful will happen with dental treatment, often the person loses control of himself/herself [Klingberg and Broberg, 2007]. Progress has been made in the management of pain and anxiety associated with dental treatment. Various pharmacological and non-pharmacological strategies have been proposed to help paediatric patients adapt to dental stressors [Attar and Baghdadi, 2015].

Distraction as a behaviour guidance technique is defined

effective tool for improving behaviour and reducing pain perception during dental treatments in children. The evidence was classified as moderate for most outcomes; however, evidence regarding some outcomes was insufficient and was not evaluated [Custodio et al., 2020]. Also in the literature, it is mentioned that the pain perception and anxiety status during dental procedures may be reduced with the improvements made on the VR system [Custodio et al., 2020]. In this study, it is aimed to reduce the anxiety level and pain perception on larger samples by distracting the patient's attention to VR system with implemented specialised applications and original contents.

The null hypotheses were as follows: VR has no effect on reducing dental anxiety and pain scores of participants. There is no difference between physiological and psychological measure scores of dental anxiety and pain in children undergoing dental treatment with local anaesthesia.

Dental anxiety is common with an estimated prevalence between 6 and 20% in children aged 4–18 years old. Therefore the primary objective of this study was to evaluate the active distraction through VR on pulse rate in children undergoing dental treatment under local anaesthesia. The secondary objectives included improvement. The children's perception of the VR was also evaluated.

Materials and methods

This three arm parallel-group randomised clinical study was conducted in Istanbul University, Faculty of Dentistry, Department of Pedodontics following the CONSORT statement from March to December 2021. Due to the apparent nature of the research, neither the children nor the researchers were blinded. The study protocol was approved by the Ethical Committee of Istanbul University (2018/5) and registered at ClinicalTrials.gov (NCT05302154). All participant's parents provided informed consent/assent in accordance with the Declaration of Helsinki.

The following focused question was developed in accordance with the recognised Patient, Intervention, Comparison, and Outcome (PICO) method: "In children who had between 6–10 years old, first experience with the dentist and needed a pulpotomy (P); what was the effect of VR distraction (I); as compared to passive distraction and conventional behaviour management method (C); decrease dental anxiety by physiological (pulse rate) and psychological considerations (FBRS, FIS, CFSS-DS) (O).

Sample size calculation

A hypothetical sample size was calculated with an anticipated effect size of 0.3, utilising parameters of 95% confidence and 80% statistical power. The resulting calculated sample size for each of the three groups was 84 individuals. The intended enrollment for the study stipulates inclusion of 30 individuals per group.

Patient recruitment

Ninety children (45 girls, 45 boys) aged 6-10 years with dental caries in their primary molars were included in the study between March 2021 and December 2021. The inclusion criteria of the participants were selected as follows:

- Healthy children;
- Children with no previous dental treatment experience;
- Children who need pulpotomy for their mandibular first;

or second primary molar tooth (inferior alveolar block anaesthesia);

- Intraoral clinical examination of the children revealed no evidence of swelling, abscess or fistula associated with the tooth and absence of mobility;
- Radiographically, the teeth were seen to be free of any periapical/inter-radicular radiolucencies, as well as pathologic root resorption and internal resorption.

Exclusion criteria were:

- Children showing definitely negative behaviour (Frankl 1) during dental prophylaxis at the first visit, were referred for sedation and general anaesthesia;
- Teeth that had more than one third of the root length resorbed were excluded from the study.

The selected children were allocated into 3 groups:

- Active distraction group (AG): Tell-show-do, distraction and positive reinforcement were performed via VR (n=30);
- Passive distraction group (PG): Distraction was performed via cartoons, tell-show-do and positive reinforcement were performed by paediatric dentist (n=30);
- Control group (CG): Distraction was not performed. Only tell-show-do and positive reinforcement were performed by paediatric dentist (n=30).

Randomisation and blinding

Participants were randomised in a 1:1:1 ratio for each age and gender to the groups. To identify the order of intervention in each treatment group, block randomisation was used in the study. A table of random numbers was used to generate the random allocation sequence. One paediatric dentistry resident enrolled participants and one paediatric dentist assigned participants to interventions. Due to the nature of the treatments provided, blinding for the FBRS assessment was not possible.

Treatment procedure

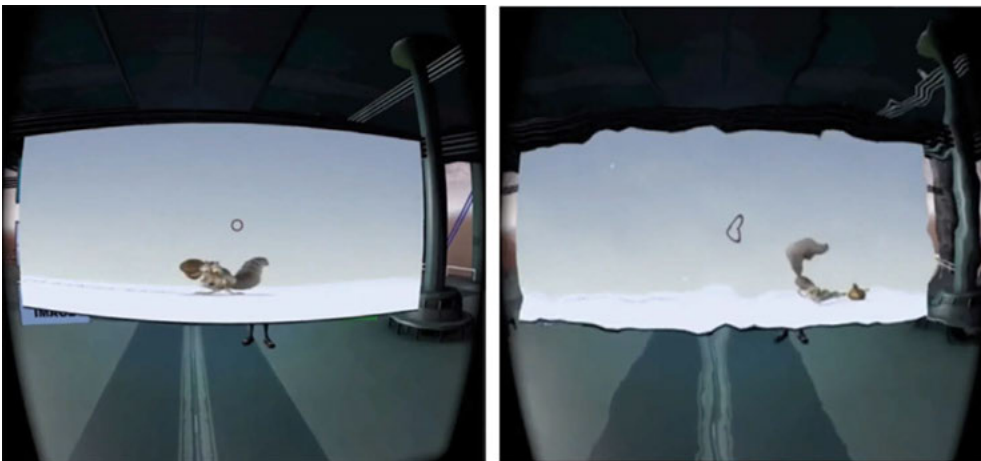
The study protocol was explained to parents and their written consent was obtained. Pre-treatment scale scores and subjects' pulse rates were recorded (n=90).

In AG, VR glasses and headphones were used during the treatment. The VR application for calming child dental patients is structured in such a way that it provides interactivity while ensuring that the child is staying stable during the treatment due to security requirements of a dental procedure. The interactivity of the developed software occurs when the patient makes choices. In order to provide the selection and interaction features, the gaze selection technique is used. This technique was introduced for this program for picking an avatar, environment and film of the users choosing.

The application running on a mobile device (i.e., phone) allows the dentist to enter the patient information regarding ID, gender, age and treatment type to be executed. Afterwards, the user interface of the mobile application leads to the launch screen where the doctor is supposed to insert the mobile device inside the headset so that the VR process can be initiated. After launching the VR application, the initial head coordinates of the patient are recorded. This is an important step for the application content to be displayed in the field of view of the patient, who must stay sitting during the dental procedure. The application begins inside the virtual dentist clinic scene. Gaze selection is explained to the user

**FIG. 1**

Stereoscopic view of a VR scene when the patient sits on dental chair surrounded with the virtual content such as the clinic environment and avatars.

**FIG. 2**

Left: Movie screen fixed to the view of the patient. Right: Blur effect applied to the VR scene when the patient moves his/her head.

interactively, as the animation characters ask the child which avatar to select. In response, the child is allowed to choose an avatar accompanying him/her during the treatment.

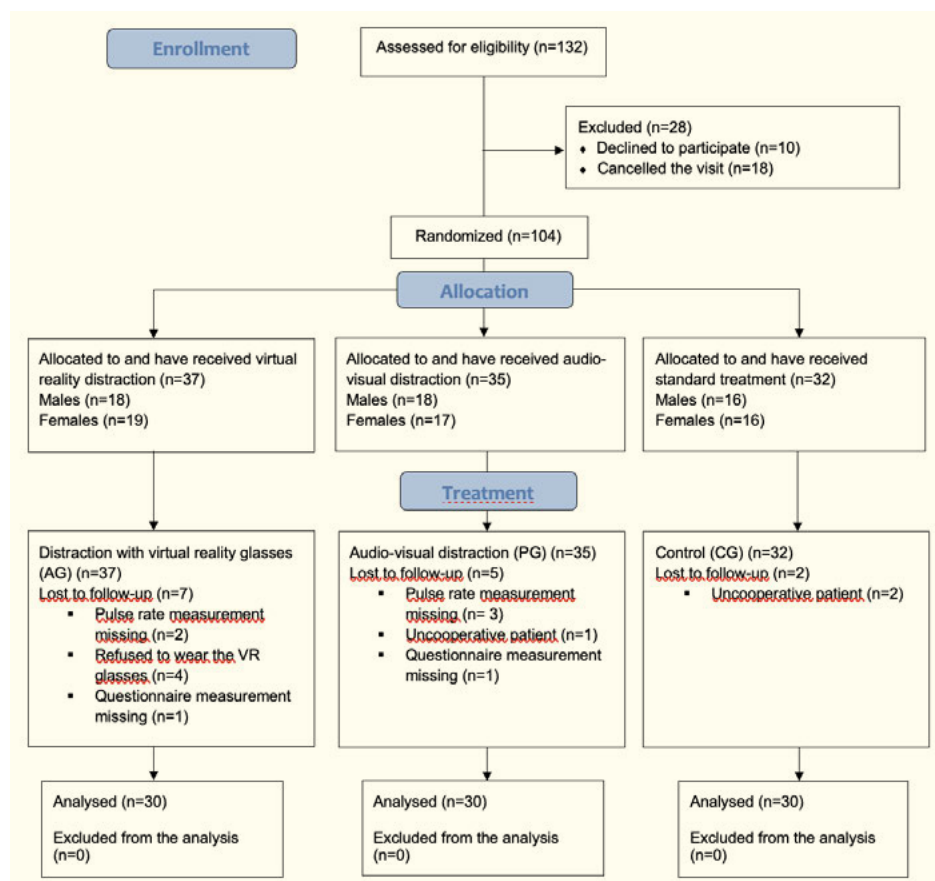
The educational animations take place, including the general explanation of the treatment. The dental tools are presented playfully (e.g., the suction tube is compared to an elephant trunk). After the educational animations are over, the user is allowed to choose between two different epic virtual worlds designed for children. It is expected that the girls would choose the girl avatar and a fairytale castle world while the boys would choose the boy avatar and the sci-fi world. Lastly, the user is teleported to the selected scene, where he/she has a variety of movie tiles at disposal. From this point on, the child is free to choose the desired movie. The movie screen is locked with the user viewport ensuring the ability to watch the movie even if the dentist asks the child to change head position or orientation. The application contains another feature to mitigate the head motion: blurring effect is applied to the movie if the patient is unstill and non-cooperative, as sudden movements are dangerous and undesired by the dentist during the treatment. The patient must stay still for the blurriness to go away and the video to become clear again. Head movements are measured with the help of the accelerometer inside the mobile phone. When the movement rate exceeds the specified limit, blurring effect is activated. In that case, the avatar character appears in front

of the locked movie screen and warns the user.

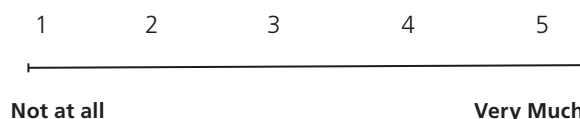
Before the treatment, the children were shown how to use the VR glasses. The tell-show-do technique was simulated in VR glasses. The dental instruments that the dentist will use during the procedure were introduced through the VR glasses, and then the procedure was started. The application was designed to function in such a way as not to require outside intervention. The avatar characters provide information related to the dental treatment in a joyful manner (Fig. 1). The application interacts with the user through gaze selection and head tracking mechanisms (Fig. 2). Gamification elements such as gaining stars and collecting rewards have been used to keep the patient engaged. Verbal communication of the dentist with the child was kept to a minimum degree during the treatment.

In PG, children watched cartoons on a screen mounted on the dental unit. Hence distraction was performed via cartoons, tell-show-do and positive reinforcement were performed by paediatric dentist.

In CG, children were treated without distraction. Only tell-show-do and positive reinforcement techniques were performed. Treatments were completed in one session. All children were treated under local anaesthesia. The treatments were performed by the same dentist. Dental anxiety and behaviour scales were applied to patients whose treatment was completed to measure their anxiety levels and behaviour,



respectively. In AG, children were also asked to state their willingness to use VR glasses at their next appointment.



Statistical analysis

IBM SPSS Statistics 22 (IBM Corp, Released 2020, Armonk, NY, USA) was used for the statistical analysis. Shapiro-Wilk test and Kolmogorov-Smirnov test were used to check the data distribution. Mann-Whitney U-test and Student t-test were used to compare two groups. In-group comparisons of normally and non-normally distributed parameters were tested with paired sample t-test and Wilcoxon signed-rank test, respectively. Statistical significance was determined as $p < 0.05$.

Results

The study was conducted with a total of 90 children, 45 boys and 45 girls, aged 6-10. The mean age was 8.94 ± 1.33 years (Table 1). Four participants in AG refused to wear VR glasses and one participant in PG exhibited uncooperative behaviour (Frankl 1). Participants whose treatment could not be completed were excluded from the study and referred for sedation and general anaesthesia. The CONSORT flow chart for participant enrollment is shown in Figure 3.

There was no significant difference between the groups in the pre-treatment CFSS-DS, FBRs and pulse rate. The fact that there was no difference between the groups in terms of pre-treatment FBRs; CFSS-DS scores and pulse values shows that randomisation was done successfully.

There was no statistically significant difference between the groups in the post-treatment FIS, CFSS-DS, FBRs and pulse rate ($p > 0.05$) (Table 2).

The decrease in FIS scores in the post-treatment was statistically significant in all groups (Table 2). A significant decrease was found in FIS scores in PG and CG in girls.

All participants showed low anxiety (between 15 and 31) according to the CFSS-DS. There was no statistically significant difference between all groups in terms of CFSS-DS scores before and after treatment. The post-treatment CFSS-DS scores were statistically significantly lower than the pre-treatment scores in all groups (Table 2).

While the increase in FBRs scores in the post-treatment was statistically significant in AG and PG, there was no statistically significant change in CG (Table 2).

There was no statistically significant difference in pulse rate

		AG	PG	CG	
		n (%)	n (%)	n (%)	p
Gender	Male	15 (50%)	15 (50%)	15 (50%)	1.000
	Female	15 (50%)	15 (50%)	15 (50%)	
Age (years)	6-8	14 (46.7%)	16 (53.3%)	15 (50%)	0.875
	9-10	16 (53.3%)	14 (46.7%)	15 (50%)	

Chi-square test

TABLE 1 Gender and age distribution of the participants.

measurements between the groups before and after the treatment. The decrease in the pulse rates after treatment and the increase in the pulse rates during local anaesthesia application was statistically significant only in AG (Table 2, 3).

In AG, it was observed that the majority of the children wanted to use VR glasses. Only 4 children refused to wear VR glasses. There is no significant difference in willingness to reuse VR glasses between males and females (Table 4).

Discussion

Local anaesthesia is one of the most common procedures triggering anxiety in children [Costa et al., 2012]. Paediatric patients may even not accept the treatment because of the anxiety caused by the local anaesthesia application. These negative experiences increase the frequency of treatment under sedation or general anaesthesia in children. In this study, it was aimed at evaluating the effectiveness of VR on reducing anxiety in treatments requiring lower alveolar nerve block.

The age range of the children included in this study was determined as middle childhood [Goodway et al., 2019]. In the selection of the age group, it was ensured that children could evaluate the questionnaires to be applied and that the responses they would give to the VR before/during the treatment were appropriate for the mental, cognitive and physical development of the child. In parallel, according to Stone and Church's classification, children in the 6-10 age group are supposed to be the middle age childhood group. Children in this age group are able to understand what they

		AG	PG	CG	
		Mean $\pm$ SD (median)	Mean $\pm$ SD (median)	Mean $\pm$ SD (median)	1p
FIS	Pre-treatment	1.67 $\pm$ 0.66 (2)	2.37 $\pm$ 1.30 (2)	2.50 $\pm$ 1.17 (2)	0.009*
	Post-treatment	1.30 $\pm$ 0.47 (1)	1.47 $\pm$ 0.86 (1)	1.63 $\pm$ 0.96 (1)	0.597
	2p	0.016*	0.002*	0.001*	
CFSS-DS	Pre-treatment	21.43 $\pm$ 5.73 (21)	25.97 $\pm$ 12.17 (22)	24.63 $\pm$ 6.82 (23)	0.215
	Post-treatment	16.47 $\pm$ 2.37 (15)	17.30 $\pm$ 3.25 (16)	18.0 $\pm$ 8.58 (15.5)	0.527
	2p	0.001*	0.001*	0.001*	
FBRs	Pre-treatment	3.17 $\pm$ 0.38 (3)	3.03 $\pm$ 0.18 (3)	3.03 $\pm$ 0.18 (3)	0.086
	Post-treatment	3.43 $\pm$ 0.50 (3)	3.37 $\pm$ 0.61 (3)	3.23 $\pm$ 0.77 (3)	0.709
	2p	0.011*	0.008*	0.217	
Pulse rate	Pre-treatment	103.00 $\pm$ 13.11	102.07 $\pm$ 12.33	104.53 $\pm$ 15.26	0.779
	Post-treatment	96.90 $\pm$ 12.06	98.20 $\pm$ 20.89	102.70 $\pm$ 13.0	0.334
	4p	0.029*	0.206	0.475	

TABLE 2

Evaluation of the groups in terms of different scales.

¹Kruskal Wallis test

²Wilcoxon sign test

* $p < 0.05$

	AG	PG	CG	
Pulse	Mean±SD	Mean±SD	Mean±SD	1p
5 minutes before treatment	103.00±13.11	102.07±12.33	104.53±15.26	0.779
Before local anesthesia	101.57±11.30	105.20±17.03	103.13±17.39	0.662
During local anesthesia	105.50±12.75	102.23±16.26	108.93±16.42	0.240
After local anesthesia	104.27±13.62	103.6±13.64	104.23±16.62	0.981
5 minutes after treatment	96.90±12.06	98.20±20.89	102.70±13.0	0.334
2p	0.009*	0.188	0.082	

1 Student t-test

2 Analysis of variance in repeated measurements

* p<0.05

TABLE 3

Pulse rate comparison of the groups.

		Willingness to use VR		
		Mean±SD	Median	p
Gender	Male	4.58±1.18	5	0.451
	Female	4.80±0.69	5	
Age (years)	6-8	4.78±0.79	5	0.478
	9-10	4.60±1.12	5	

TABLE 4

Comparison of willingness to use VR by age and gender.

Mann-Whitney U test

see and sanely cope with anxiety. This age group was included in the study because a voluntary effort was expected from the participant in AG [Robert and Primosch, 1995]. In addition, since physiological root resorption is common in 11-year-olds, the participants were limited to under 11 years of age in terms of the indication of pulpotomy for primary molars.

FIS is a validated tool for children ages 3-18 to express their dental anxiety. The mean post-treatment FIS scores in AG, PG and CG were 1.30, 1.47 and 1.63, respectively, 100% of them felt 'very happy'. Gomez-Polo et al. [2021] reported that children aged 5-10 years treated with VR were statistically significantly happier than children not treated with VR, based on their FIS scores. While 60% of the children expressed themselves as 'happy' or 'very happy' before the treatment, 95% of the children treated with VR stated that they were 'happy' or 'very happy'. The pre- and post-treatment FIS scores of the children included in this study were found to be lower (lower FIS score = lower anxiety level) compared to the study of Gomez-Polo et al. [2021]. The reason for this difference may be due to the fact that children with FBR5-1 were not included to be participants in our study.

CFSS-DS is the most commonly used scale to assess dental anxiety, probably because it is the oldest validated scale. This scale is used to measure the level of dental anxiety in children aged 4-14 years [Cuthbert, 1982; Al-Namankany et al., 2012]. Ran et al. [2021] compared VR and tell-show-do techniques in short-term (<30 minutes) dental procedures (filling, primary tooth extraction, abscess incision) in 120 children aged 4-8 years. The mean anxiety level according to CFSS-DS in VR group (24.77 ± 6.98) was found to be significantly lower than the tell-show-do group (27.98 ± 7.41). In our study, the CFSS-DS scores obtained after treatment were found to be lower than the study of Ran et al [2021]. This might be due to the fact that tooth extraction may cause more anxiety than restorative treatments and we did not include tooth extraction to standardise the treatment modalities in all groups.

In a study conducted with children aged 5-10 years, Gomez-

Polo et al.[2021] reported that children in the VR group exhibited significantly better behaviours than the control group. In both groups, children with FBR5 scores between 1 and 4 were included at the beginning. At the end of the treatment, the FBR5 scores of the children in VR group were mostly 3 to 4, while the FBR5 scores in the control group varied between 1 to 4. In this study, while the increase in FBR5 scores in the post-treatment was statistically significant in AG and PG, there was no statistically significant change in CG.

Felemban et al. [2021] evaluated the efficacy of VR in dental procedures requiring buccal infiltration anaesthesia in 50 children aged 6-12 years, and measured the pulse rate in each child at 5 different times. Contrary to the results of Felemban et al.'s study, no significant differences were found between the mean pulse rates of the groups in 5 different measurements.

In the use of VR glasses, the visual field of the child's surroundings is fully blocked. It has been suggested that VR glasses covering a large area may cause the person to feel claustrophobic and negatively affect the anxiety levels of children [Tashjian et al., 2017]. In our study, consistent with the findings of Tashjian et al. [2017], both a significant increase and a significant decrease were observed in the pulse rate during local anaesthesia can be explained by the fact that the VR glasses completely cover the vision and the child feels restrained during pain. Local anaesthesia during complete isolation from the external environment may have increased the anxiety. Some of the advantages of the VR content used in this study include; child's being interactive during treatment, allowing content selection, making choices by gaze selection, and limiting head mobility. Considering the age group of the patients, an additional incentive to reduce head movements may be necessary. For this purpose, the content that the patient sees in the VR environment is artificially blurred as the head movements begin to increase at an undesirable extent. The patients were told that this blurring was caused by the head movements, and the blur could be eliminated

by reducing the movements to the desired levels. Therefore, blurring of the image when patients were not focused encouraged them to keep their head still during dental procedures. We experienced that the head movements of the patients decreased and as a consequence it contributed positively to the success of the treatment.

There are some limitations in this study that may affect the interpretation of the results and the design of future studies. The fact that VR glasses cover a large area on their face may be a challenge for children, especially in terms of claustrophobia. Due to the same reason the dentist may struggling the treatment of maxillary teeth. Also, in the use of VR during dental procedures, unexpected head movements can pose a danger in children.

Within the confinements of this study, the use of a VR during dental treatment significantly reduces anxiety. Also it has positive effect on children's behaviour. Therefore the null hypothesis is rejected. This study will be an important step in the treatment of dental anxiety in the setting of the dental procedures.

Declarations

Ethical Approval

Ethical approval was obtained by the local ethical board (2018/5, Istanbul University Faculty of Dentistry Ethics Committee, Istanbul, Turkey). The study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Informed consent was obtained from all children and their parents.

Competing interests

The authors declare that they have no conflict of interest.

Authors' contributions

Y.K. made study concept and design, drafting of manuscript, and critical revision. E.A. made acquiring of data. G.I. made study concept and design, acquiring of data, analysis, interpretation of data, and drafting of manuscript. E.B.T.I. made acquiring of data, analysis, interpretation of data, drafting of manuscript, and critical revision.

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Data availability statement

The anonymised statistical data is available from the

corresponding author (Y.K.) upon reasonable request.

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