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A video eyeglasses/ earphones system as distracting method during dental treatment in children: A crossover randomised and controlled clinical trial

ABSTRACT

Aim To evaluate the effectiveness of a Video Eyeglasses/Earphones System (VEES) as distracting device in reducing anxiety in children during dental procedures carried out under local anaesthesia.

Materials and methods In this crossover clinical trial, 36 Frankl scale II and III children aged 5-8 years received different dental procedures in two sessions, with and without the VEES system. In the control visit, they were not exposed to this distraction stimulus, but traditional non-aversive behaviour management was applied. Each dental session was divided into four phases (explanation, anaesthetic injection, rubber-dam/clamp placement, and high-speed hand piece work for 5 min). Pain in each treatment phase was assessed by the following measurements: the Face, Legs, Activity, Cry, Consolability (FLACC) scale. Pulse rate, and oxygen saturation measurements were employed to evaluate the state of anxiety. Comparison of the outcomes of two interventions were statistically analysed through the Wilcoxon Signed-rank Test.

Results There were no statistical differences between

the results of the two interventions (VEES vs. no VEES/behavioural management) during the four treatment phases on assessment by any of the measurements employed.

Conclusions The VEES method was not more effective than traditional non-aversive behavioural techniques for reducing anxiety and pain perception in children undergoing dental treatment.

Keywords Audiovisual eyeglasses; Behavioural management; Children anxiety; Distractive methods.

Introduction

Successful dental treatment in uncooperative children is associated with adequate behavioural techniques, including continuous interaction and good communication with the patient and their parents [Kuhn and Allen, 1994; Gustafsson, 2010; Guinot-Jimeno et al., 2014; Cianetti et al., 2017]. In clinical paediatric dentistry, dental anxiety might represent a major behavioural management challenge for children, parents, and practitioners, particularly during pain control phases [Klingberg et al., 2007; Al-Khotani et al., 2016]. According to Cianetti et al. [2017], the term dental fear refers to a normal unpleasant emotional reaction to specific threatening stimuli related to dental treatment, while dental anxiety is defined as an excessive and unreasonable negative emotional reaction or disproportionate apprehension also associated with dental treatment [Cianetti et al., 2017]. Dental anxiety is a psychological state considered non-specific lack of ease, apprehension, or negative thoughts regarding what may occur ("something dreadful is going to happen here...!!") during a dental appointment, frequently related with previous traumatic experiences in the dental setting [Gustafsson, 2010; Padrino-Barrios et al., 2015; Cianetti et al., 2017]. Anxiety is caused by diverse psychological child's individual characteristics (mood, temperament, or cognitive level), and may result in delay of dental treatment or render treatment impossible at the dental chair [Klingberg et al., 2007].

Although responsible administration of pharmacological agents may be useful in paediatric patients, the desired effect is not fully guaranteed, and the risk of adverse events has always been a matter of concern for practitioners and parents [Padrino-Barrios et al., 2015]. Psychological interventions have been proposed for decreasing anxiety and achieving pain control in children, such as distraction, cognitive reappraisal, desensitisation, non-assertive communication (e.g. voice control, positive reinforcement, and non-verbal facial expressions), preliminary and centered information (tell-show-do), and hypnosis [El-Sharkawi et al., 2012; Asvanund et al., 2015]. These methods are only

employed after parental acceptance, without transgressing fundamental legal and ethical issues [Guinot-Jimeno et al., 2014]. Distraction techniques are applied in clinical paediatric dentistry with the intent of withdrawing child's conscious attention away from oral noxious stimuli (or "selective attention") [El-Sharkawi et al., 2012; Al-Khotani et al., 2016]. The application of distraction is based on the assumption that a child perceives pain when her/his brain is concentrated on a specific painful stimulus inside her/his mouth. Thus, diverting her/his attention away from a concurrent nociceptive painful procedure results in an analgesic effect, with at least 33% pain reduction, compared with standard care and other forms of cognitive distraction [Farrar et al., 2000]; in consequence, patient's subjective pain experience and anxiety -for example, during the injection of local anaesthesia- may be greatly attenuated [Sharar et al., 2007; Aminabadi et al., 2012; Al-Khotani et al., 2016].

Distraction techniques can include the use of external tools that deliver interventional stimuli [Ram et al., 2010]. An ideal distractor requires an optimal amount of attention, involving visual, auditory, and kinesthetic sensory modalities, and the active emotional involvement of the patient, to achieve focus on what is going on in the virtual world, rather than on the dental environment [Sharar et al., 2007]. Audiovisual virtual reality is an altered three-dimensional (3D) world generated by a computer; this has recently been employed as a distractive technique in dentistry to help anxious paediatric patients to accept the dental treatment and to decrease their negative responses. As a result, children may acquire a more positive overall experience in the clinical setting [Sullivan et al., 2000]. This approach allows children to provide for their mind the illusion of entering into different and more pleasant sensorial environments, which is also known as "audiovisual immersion therapy" [Sharar et al., 2007]; the distraction technique comforts the patient and assists the dentist to provide a successful oral care, while maintaining the capacity of interaction and communication with each other and without interfering with treatment [Aminabadi et al., 2008; Ram et al., 2010; Padrino-Barrios et al., 2015]. Such an audiovisual experience is offered through the use of sophisticated Video Eyeglasses/Earphones Systems (VEES) on which audiovisual stories, TV presentations, and videotaped materials or games can be shown [Sullivan et al., 2000; Ram et al., 2010]. However, contradictory results have been reported, and some controversy remains regarding the real usefulness of virtual reality distraction in clinical paediatric dentistry [Al-Khotani et al., 2016].

The objective of this study was to evaluate the distractive usefulness of the audiovisual immersion therapy through VEES on behaviour and anxiety levels in children undergoing diverse dental procedures with local anaesthesia while seated in the dental chair. The null hypothesis was as follows: Using audiovisual immersion eyeglasses during dental treatment does not significantly decrease the anxiety levels of paediatric patients.

Materials and methods

The present clinical study was carried out at the Paediatric Dentistry Clinic San Luis Potosi University (Mexico) after approval by the Ethical Research Committee (CEI-FE-003-2016) and in compliance with the Declaration of Helsinki and the International Conference of Harmonization Guideline for Good Clinical Practice. The parents or legal guardians of selected participants were fully informed on all issues regarding the study and they signed a written informed consent.

Study design and subject selection

This study was conducted according to the assumptions of a crossover randomised and controlled trial, with one study group and two dental sessions for each patient, and considering the presence of a negligible, in theory, carry-over effect between both sessions. Carry-over effect is defined as the memorised experience from the first visit that might affect the experience of the following visit [Pandis et al., 2013; Asvanund et al., 2015]. Sample size was calculated under these conventions: alpha significance level = 0.05; study power = 85%; Standard Deviation (SD) = 1.5; minimal difference between clinically accepted effect sizes (first dental session vs. second dental session) = 20%, and expected loss rate on follow-up = 10% [El-Sharkawi et al., 2012; Attar and Baghdadi, 2015]; thus, 40 medical/mental/cognitively healthy patients aged 5-8 years were carefully selected to create a homogeneous group, in a non-probabilistic (consecutive cases) manner, among those attending the paediatric dentistry clinic. The patients also had no previous dental experience (e.g. they had not been previously received any kind of local dental anaesthesia), and exhibited bilateral deep carious cavities in at least two upper or lower primary molars requiring similar restorative treatments; these only included cavity preparations, pulpotomies/metallic preformed crowns, under local anaesthesia. The children had also exhibited a level I or II cooperation level (positive or negative behaviours) on the Frankl behavioural rating scale [Klingberg et al., 2007], assessed during the first dental session. This session included dental prophylaxis, fluoride varnish applications, and oral hygiene instructions. The sequence of interventions (experimental dental visit using VEES or "EV", and control dental visit, without using VEES or "CV") were randomly assigned for two consecutive dental visits, 1 week apart (washout period). For this purpose, a randomisation block scheme was employed, subsequently creating a pair of matched data [Pandis et al., 2013].

Distracting audiovisual application and video recording

The Virtual Private Theater Video Glasses (Chinavision®; Kowloon, Hong Kong, China), with earphones, were employed as the distracting VEES device (Fig. 1). According to the manufacturer, this audiovisual system is equivalent to watching a 52-inch (1.30 cm) LCD screen from a distance of



FIG. 1 Video Eyeglasses/Earphones System (VEES) employed during the experimental visit.

2 m. The device was loaded with several animated movies and then properly placed around the patient's head and in front of her/his eyes. The device was connected to an iPad and turned on; during the dental session, movie selection and volume level were controlled by the child after a brief training period. Patients were fully informed on the programmed dental procedures before wearing the VEES device and applying dental anaesthesia. Both experimental and control dental sessions were entirely video-recorded for subsequent review and evaluation. Parents or legal guardians were not allowed to accompany their child during the dental sessions.

Pain and anxiety assessments

The patient's pain levels were assessed during the watching of the videos from each visit by an independent, pre-trained, calibrated (intraobserver agreement with a Cohen's kappa = 0.88) and non-blinded evaluator, an Experienced Psychologist. For this purpose, she utilized the FLACC (Face, Legs, Activity, Cry, Consolability) pain perception scale, from 0–10 (Table 1), as principal evaluator of patients' anxiety [Merkel et al., 1997; Nilsson et al., 2008].

Also, two physiologic measurements, heart rate and oxygen saturation, were employed as complementary indicators of the child's state of anxiety [Porrit et al., 2013; Yoghesh-Kumar et al., 2015; Pani et al., 2017]. These measurements were applied during four separate treatment phases: procedure explanation and instrument exhibition; local anaesthesia injection, rubber-dam/clamp placement, and the first 10 min with the high-speed hand-piece (e.g. cavity preparation). All of these phases were performed by the same operator, thus decreasing the interoperator variability influence. Other behavioural techniques, such as the "tell-show-do" method and continuous verbal communication, were also employed, but only during control visits, namely, without the use of VEES.

Statistical analysis

A description of the patient sample was initially performed through means, standard deviations, and medians for continuous variables, and by means of frequencies and percentages for categorical variables. This was followed by an inferential and comparative analysis. A normality of data assumption was determined through the Shapiro-Wilk test. FLACC anxiety/pain scale scores from each treatment phase along the dental session were measured as an ordinal variable and compared by the non-parametric Wilcoxon Signed-rank Test for paired data. For comparing heart rate and oxygen saturation median results, both expressed as continuous variables, Wilcoxon Signed-rank tests were also performed. Alpha level was set at 0.05 for detecting significant statistical differences between interventions. Data were analysed with R ver. 3.2.2 statistical software.

Results

Four patients were unable to complete the two treatment

FLACC behavioural anxiety/pain assessment scale			
	Score		
Categories	0	1	2
Face	No particular expression or smile	Occasional grimace or frown; withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs; frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort

TABLE 1 The Face, Legs, Activity, Cry, Consolability (FLACC) scale. Each patient was observed for 10–15 min, focusing on her/his legs, head and body movements, facial expression, crying, and general behaviour. Each of the five categories was scored from 0–2. The behavioural global score was the sum of the scores of each category, for a ranged score from 0 (completely relaxed) to 10 (severe anxiety/pain). Interpretation of the global scale was as follows: 0 = Relaxed and comfortable; 1–3 = Mild discomfort; 4–6 = Moderate discomfort/pain, and 7–10 = Severe discomfort or pain or both.

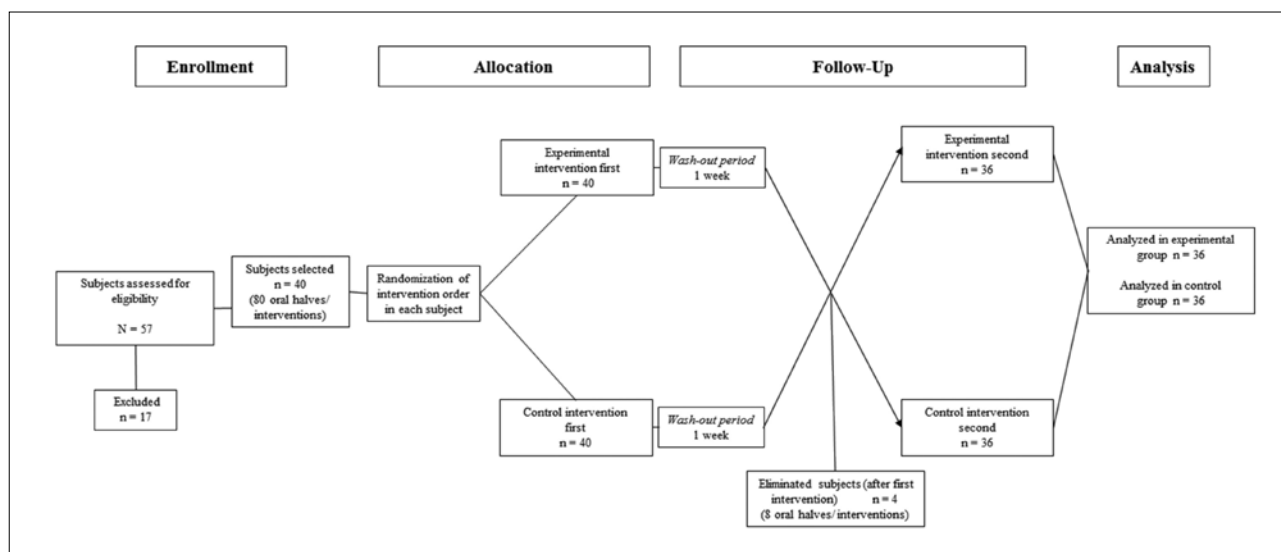


FIG. 1 Patient flowchart.

n	36	
Age (mean ± SD)	6.2 ± 1.3	
Gender (%)	M = 55.6	F = 44.4
Initial Frankl scale behaviour (%)	II = 42.8	III = 57.2

TABLE 2 Subjects' sample description.

sessions, thus were eliminated; the final sample analysed was 36 children (Fig. 2). Each dental session had an average length of 32.35 ± 8.2 min. Sample descriptive data are exhibited in Table 2. Table 3 depicts the following: means with SD and the p values of (1) FLACC anxiety/pain scale scores, (2) the pulse rate, and (3) oxygen saturation, during the four treatment phases in both study interventions. There were no statistical differences between the two interventions/dental sessions (VEES use vs. No VEES use) during the four treatment phases, in any of the evaluation parameters employed. All p values were >0.05; therefore, the null hypothesis could not be rejected.

Discussion

The outcomes obtained from the present clinical crossover trial did not show that VEES, employed as distracting devices, exerted a statistically significant effect on the reduction of children's anxiety or pain perception during the dental treatment, compared with traditional non-aversive behavioural management. Although some positive clinical findings could be detected by the dental operator, these perceptions were considered as subjective and not supported by the study's results; also, they might differ according to each patient's pain threshold level [Yoghesh-Kumar et al., 2015].

Dental distress comprises a multidimensional concept

consisting of emotional, psychological, and cognitive components [Klingberg et al., 2007; Gustafsson, 2010; Al-Khotani et al., 2016; Cianetti et al., 2017]. Klingberg and colleagues [2007] have stated that assessment of dental anxiety in children is primarily based on observation of behaviour. Many children with behavioural management problems at the dental chair, exhibit anxiety at the same time, although anxiety is the best observable predictor of behaviour disturbances [Gustafsson, 2010]. The use of validated pain and anxiety assessment tools is essential for improving behavioural management in children in clinical practice and research [Nilsson et al., 2008]. Thus, FLACC scale, pulse rate, and oxygen saturation were the measurements chosen for these purposes in the present work. FLACC has been previously validated in terms of validity and reliability [Nilsson et al., 2008] and has been successfully employed for quantifying these variables in children who cannot verbalize the presence or severity of procedural pain; this tool has also been found to have good inter-rater agreement for evaluating pain after surgery, trauma, malignancy, and other disease processes in infants and children up to 7 years of age [Merkel et al., 1997; Nilsson et al., 2008; Yoghesh-Kumar et al., 2015]. On the other hand, the physiological measurements of pulse rate and oxygen saturation of arterial haemoglobin have been well recognised as related with pain/anxiety perception; thus, they are considered methods for objectively evaluating behavioural levels in children [Prabhakar et al., 2007].

The results of the present study differ with those of other similar trials in which audiovisual distraction was considered as successful, perhaps due to the different methodological designs or measurement techniques employed. Therefore, the results from previous clinical studies regarding the use of audiovisual systems for achieving cooperation in the face of fear from children in dentistry have been controversial and sometimes contradictory. For example, Venham et al. [1981] did not find any significant evidence that exposure

Variable	Treatment phase								p-value ^a	
	Explanation Time				p-value ^a	Anesthetic Time				
	Control		Experimental			Control		Experimental		
Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)			
FLACC	0 (0)	0 (0)	0 (0)	0 (0)	NA	1 0.7	1.64 (2.1)	0 (2.25)	1.64 (2.9)	0.8
Heart rate	94.5 (20.25)	95.86 (16.3)	96 (14.5)	93.94 (15.6)	0.7	84 (31)	89 (19.72)	83 (30.5)	86.33 (20.1)	0.4
O ₂ saturation	96.5 (1)	96.53 (1.16)	97 (2)	96.94 (1.2)	0.7	97 (2)	96.81 (1.17)	97 (2)	96.75 (1.03)	0.9

^a Wilcoxon Signed-Rank Test.

TABLE 3A

Variable	Treatment phase								p-value ^a	
	Dental Isolation				p-value ^a	Operatory Time				
	Control		Experimental			Control		Experimental		
Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)			
FLACC	0 (3)	1.36 (1.45)	0 (3)	1.78 (2.93)	0.7	0 (0.25)	0.64 (1.31)	0 (1)	1.03 (2.21)	0.7
Heart rate	94 (25.25)	95.97 (18)	98.5 (32.5)	97.81 (21.6)	0.6	102.5 (30.5)	102.42 (19)	98 (32)	98.67 (21.4)	0.5
O ₂ saturation	97 (2)	96.67 (1.62)	96 (2)	96.5 (1.59)	0.5	98 (2)	97.22 (1.1)	97 (2)	97 (1.15)	0.4

^a Wilcoxon Signed-Rank Test.

TABLE 3B

TABLE 3A, 3B Summary of results: experimental and control medians, rather than means, were compared for each treatment phase.

to TV programmes was an effective distracting method during dental visits when compared with a control patient group without this audiovisual stimulus; these authors' assessments were based on physiological, behavioural, and self-report measurements. Later, Ingersoll et al. [1984] concluded that videotaped cartoons were not effective distracting approaches for reducing uncooperative behaviour during paediatric dental treatment in 29 male children aged 3.5-9 years. Similarly, Sullivan et al. [2000] evaluated, in 26 children aged 5-7 years, the effects of virtual-reality eyeglasses on behaviour and anxiety; by means of the Frankl rating scale, the authors determined that virtual reality had no significant effect on behavioural and psychological evaluations performed during dental procedures. Also, several authors have recommended the routine use of audiovisual devices in clinical paediatric dentistry, particularly in young children. Positive findings, such as decreases in anxiety and pain perception during local anaesthesia injection and restorative dental treatment, have been reported [Baghdadi, 2000; Aminabadi et al., 2008; Ram et al., 2010; Aminabadi et al., 2012; Guinot-Jimeno et al., 2014; Asvanund et al., 2015; Al-Khotani et al., 2016]. Globally, all of these studies concluded that audiovisual distraction is an effective tool for the alleviation

of distress and for the encouragement of more positive responses in children, in the clinical setting.

Fear and anxiety are strongly related with the child's negative attitudes toward dentistry and may exert an influence on the quality of the oral healthcare provided [Yoghesh-Kumar et al., 2015; Cianetti et al., 2017]. In dentistry, distraction techniques have been well recognised as effective anxiety and pain management strategies for paediatric patients [Kuhn and Allen, 1994; Aminabadi et al., 2012; Wohlheiter and Dahlquist, 2013]. Diverse studies have demonstrated that cortical areas associated with attentional processes and pain modulation are more active during distraction, whereas areas of the brain that process painful stimuli are less active [Aminabadi et al., 2012; Attar and Baghdadi, 2015]; thus, the more a child is absorbed in the virtual reality, the less she/he is expected to pay attention to pain or anxiety [Aminabadi et al., 2012].

Asvanund et al. [2015] divided the distractive techniques into two types: passive and active; in passive distraction, the child receives a distracting stimulus, for example, only watching TV or listening to music; however, Venham et al. [1981] found little evidence on the usefulness of passive distraction applied in young children to reduce negative responses during dental care. Active distraction requires

the child to cognitively engage with the distracting stimulus; here, an electronic audiovisual device (e.g. VEES) is employed that simultaneously plays videos and music in close proximity to the child, leading to full involvement with the scenes, significantly reducing attention to the external surrounding disturbances and inducing a positive emotional reaction at the same time [Asvanund et al., 2015; Al-Khotani et al., 2016]. Some studies have demonstrated that interactive distraction thorough audiovisual immersion is more effective than passive distraction, especially during short invasive procedures such as the injection of local anaesthesia, because it is interactive and provides substantial cognitive distraction to children by means of multisensory input [Sharar et al., 2007; Wohlheiter and Dahlquist, 2013; Attar and Baghdadi, 2015]. Similarly, audiovisual distraction has been reported to reduce nausea in children undergoing brief cancer chemotherapy procedures [Sharar et al., 2007].

Finally, it is important to mention limitations detected during the development of the present study, which are considered as a potential source of bias to the obtained findings. Firstly, the carry-over effect between both dental sessions might have more influence over the results than what was initially assumed. Second, the evaluator was not blinded due to the obvious use of VEES during one treatment session; maybe, this fact could be resolved if patients would have worn the device in both dental sessions (goggles turned off in one of them). Third, the study only included 5-8 years old patients exhibiting behaviour categories II or III of Frankl's scale. Children with level III and in this age group, are expected to show better behaviour with or without VEES. Therefore, a different range of behaviours would be recommendable for future trials (categories I and II).

Conclusions

The results collected from the present study did not evidence any significant difference between the trial interventions. It could not demonstrate the superiority of the VEES device, as an alternative distracting method of relaxation and pain reduction during dental treatment in pre-cooperative children. The data collected here may contribute to future systematic reviews and meta-analyses, with higher valid and reliable results than those obtained through single controlled and randomised clinical trials separately.

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