Comparative Evaluation of the Effectiveness of Innovative Periorbital Eye Massager and Virtual Reality Eyeglasses for Reducing Dental Anxiety during Dental Restorative Procedures in Children

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ABSTRACT

Background: Many behavior management techniques are employed to reduce the anxiety associated with dental procedures in children. One of the most commonly used methods comprises audiovisual distraction using virtual reality (VR) eyeglasses. In this study, an innovative device, a periorbital eye massager (PEM), is compared with VR to evaluate dental anxiety in children.

Materials and methods: in this study, 22 children were divided into two groups, that is, group I consisting of PEM and group II consisting of VR. The participants were instructed to wear the device and then subjected to dental restorative procedures. After completion of the procedure, anxiety was measured using a validated questionnaire by the children and by using the modified behavior pain scale by the second investigator. Also, physiological parameters like heart rate and oxygen saturation were evaluated before and after a dental procedure.

Results: The results were statistically insignificant for group I and group II when a validated questionnaire and modified behavior pain scale were used to measure the dental anxiety of children. Also, the data also shows no significant difference in heart rate and oxygen saturation between the two groups.

Conclusion: The innovative PEM can also be used as an effective behavior management tool in managing dental anxiety in children, as there was no statistically significant difference between PEM and VR.

Clinical significance: As a pediatric dentist, the methods for administering a patient present a novel challenge because behavior management varies from patient to patient. As a result, the prospects for augmenting various techniques of behavior therapy for pediatric patients are limitless.

Keywords: Behavior management, Periorbital eye massager, Randomized controlled clinical trial, Virtual reality eyeglasses.

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INTRODUCTION

Dental anxiety is a multifaceted condition with physical, emotional, and social components. Patients with high levels of dental anxiety may endure stress and refuse or postpone treatment. Drug-free techniques are being increasingly employed to reduce stress, lessen dental anxiety during treatment, and develop a positive dental attitude.[1,2] To develop a long-term interest between the child patient and oral health care provider, it is necessary to establish relationships based on trust with the child. Although a number of nonpharmacological behavior modification techniques are put to use for curtailing apprehensiveness in children, the choice of technique must be tailored to the needs of the individual patient and the skills of the oral health provider.

In recent years, digital technology has posed an upper hand in reducing dental anxiety in pediatric patients.[3] Virtual reality (VR) glasses are simple, plastic goggles that hold your mobile phone up to your eyes at the proper distance to display a VR app in the most immersive way possible. It consists of goggles, a screen, and processing equipment to deliver another level of display capability. Studies have shown that VR is more effective in reducing child anxiety during dental treatment as compared to other behavior management techniques.[3–5]

The periorbital eye massager (PEM) has been regularly used as an eye massager not only to reduce stress but also to promote a relaxed state of mind.[6] PEM is based on the principles of heat,

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vibration, compression, massage, and music *via* Bluetooth mode. A study conducted by Dadkhah et al.[7] stated that music plus periorbital massage reduces nausea and vomiting in patients undergoing chemotherapy and can be considered a complementary medicine method in conjunction with other medicinal therapies to relieve symptoms of cancer patients. Similarly, PEM also helps in the relaxation of the muscles of the periorbital region, which may

be tensed due to anxiety of unknown origin. Considering this fact, the use of a PEM in reducing dental anxiety is logical. However, there is a lack of literature regarding the novel use of this device in dentistry. Thus, the current study was planned with an aim to evaluate the effectiveness of PEM and VR in reducing the dental anxiety of children during dental restorative procedures.

MATERIALS AND METHODS

After obtaining institutional ethical clearance, the randomized clinical trial was conducted on children aged 7–12 years and reported to the Department of Pediatric & Preventive Dentistry. Considering a 10% loss of sample, 24 children (Frankl's behavior rating scale 3 and 4) meeting the inclusion and exclusion were enrolled in the study. Children with noncontributory medical history having classes I, II, and V cavities on primary maxillary or mandibular molars and canines with at least a minimum of two to three cavities on each side of the jaw were included. A signed written consent was obtained after explaining the procedure to the children and parents. Children were randomly assigned to two groups using opaque sealed envelopes. In group I, children were exposed to PEM (Renpho Wellness IN), whereas in group II, VR (Procus ONE X VR Headset, 40MM lenses with inbuilt headphones) was used, as shown in Figure 1. As per allocation concealment in the first visit, 12 children were first exposed to PEM (first visit), whereas the other 12 children were exposed to VR (first visit), as shown in Figure 1. In the second visit, the devices were interchanged; the 12 children who were exposed to VR devices in their first visit were exposed to PEM (second visit), whereas 12 children who were exposed to PEM in their first visit were exposed to VR devices (second visit). Before the start and after the dental treatment, baseline anxiety, cooperative behavior, heart rate, and oxygen saturation were evaluated using a validated questionnaire, modified behavior pain scale, and pulse oximeter (Omron CMS50N Contec pulse oximeter), respectively. In the subsequent visits (first and second) restorative procedure was performed under rubber dam isolation using both

devices. The cavity preparation was prepared using a high-speed handpiece under water spray and restored using glass ionomer cement restoration (GC high-strength posterior restorative cement).

Baseline and after-dental treatment anxiety levels of the children were evaluated using a validated questionnaire provided to the children in their vernacular language. The validated questionnaire provided to the child is as follows:
How did you feel while sighting the device?

- Not worried.
- Mildly worried.
- Moderately worried.
- Severely worried.

Were you worried when the device was used on you? If yes, how was it?

- Not worried.
- Mildly worried.
- Moderately worried.
- Severely worried.

How did you feel after the completion of the dental treatment using the device?

- Not worried.
- Mildly worried.
- Moderately worried.
- Severely worried.

How would you feel if the dentist wanted to reuse the same device on you during your next dental appointment?

- Not worried.
- Mildly worried.
- Moderately worried.
- Severely worried.

How would you feel if you watched the dentist using the same device on another child?

- Not worried.
- Mildly worried.
- Moderately worried.
- Severely worried.

The individual items were read in front of the children. The children were shown four pictorial images showing facial expressions and were asked to select any one of the images they felt could best correspond to their response. Figure 2 shows facial images depicting levels of anxiety as follows:

- The total score of each child was a maximum of 20, and the minimum score was 4. Based on the score obtained of the anxiety, each child was further categorized as follows:
  - 5 = No anxiety.
  - 6–10 = Mild anxiety.
  - 11–15 = Moderate anxiety.
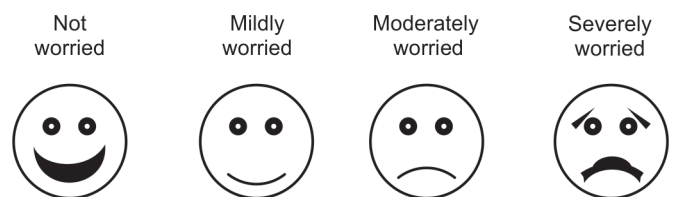 - 16–20 = Severe anxiety.

Fig. 1: The figure shows the VR eyeglasses device and PEM device; it also shows the patient wearing these devices

Fig. 2: Facial images depicting levels of anxiety

The cooperation of the child was also assessed by a second investigator who was observing the dental treatment. Baseline cooperative behavior and during treatment behavior (visits) were assessed using the modified behavior pain scale, which is as follows[8]:

Behavior observed	Score
Facial expression	
Definite positive expression (i.e., smiling)	0
Neutral expression	1
Slightly negative expression (i.e., grimace)	2
Definite negative expression (i.e., furrowed brows, eyes closed tightly)	3
Cry	
Laughing or giggling	0
Not crying	1
Moaning, quiet vocalizing, gentle, or whimpering cry	2
Full-lunged cry or sobbing	3
Full-lunged cry, clearly more than the baseline	4
Movements	
Usual movements and activity, resting and relaxed	0
Partial movement or attempt to avoid pain by withdrawing limb when the procedure is done	2
Agitation with complex movements involving the head, torso or other limbs, or rigidity	3
Total	10

Test of significance, Mann–Whitney U test

The second investigator observed the behavior of the child in terms of facial expression, crying, and movements during both visits and then evaluated it using the above-mentioned scale from scores 0 to 10. The patients who exhibited negative behavior during the treatment were given higher scores compared to those who were relaxed during the procedure. The subsequent visit was scheduled 1 week later than the previous visit. During the next visit, the devices of the group were interchanged. Hence, the participants present in group I who were subjected to PEM in their first visit were now exposed to VR devices during their second visit. Similarly, participants in group II were given PEM on the next visit as they were previously treated wearing a VR device. During the second visit, a similar procedure was performed, and the anxiety levels of the participants were evaluated in the same manner as done in the first visit. The anxiety of the children was classified based on the score obtained.

- 2 = No anxiety.
- 4 = Mild anxiety.
- 7 = Moderate anxiety.
- 10 = Severe anxiety.

Heart rate and oxygen saturation were evaluated before and after treatment (first and second visits of both devices).

Statistical Analysis

The sample size was calculated using G*Power software 3.1 from the data obtained from a previous study conducted by Padminee et al.[9] The test of significance applied to calculate the dental anxiety of children using a validated questionnaire between groups after dental treatment was completed was Mann–Whitney U test (Table 1). Using a validated questionnaire, the Wilcoxon sign rank test was used to measure the dental anxiety of children subjected to PEM and VR devices after the dental treatment of the first and second visit (Table 2). The dental anxiety of children was evaluated

Table 1: Posttreatment dental anxiety of the children between the two groups using a validated questionnaire

Anxiety	Baseline anxiety	Group I N (%)	Group II N (%)	p-value
No anxiety	13 (59.09%)	11 (50%)	10 (31.82%)	0.782
Mild anxiety	9 (40.90%)	11 (50%)	12 (54.55%)	
Moderate anxiety	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Severe anxiety	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Total children		22 (100%)		

Test of significance, Mann–Whitney U test

Table 2: Posttreatment dental anxiety of the children in the first and second visit of the respective groups using a validated questionnaire

Anxiety	PEM (first visit)	PEM* (second visit)	p-value	VR (first visit)	VR** (second visit)	p-value
No anxiety	2 (18.20%)	9 (81.80%)	0.157	6 (54.55%)	1 (9.1%)	0.257
Mild anxiety	9 (81.80%)	2 (18.20%)		5 (45.45%)	7 (63.6%)	
Moderate anxiety	0 (0.0%)	0 (0.0%)		0 (0.0%)	3 (27.3%)	
Severe anxiety	0 (0.0%)	0 (0.0%)		0 (0.0%)	0 (0.0%)	
Total children		22 (100%)			22 (100%)	

*The children in group I were initially subjected to VR eyeglasses on their first visit, and they were exposed to PEM during their second visit; **the children in group II were initially subjected to PEM on their first visit, and they were exposed to VR during their second visit; PEM, periorbital eye massager; VR, virtual reality; test of significance, Wilcoxon sign rank test; *$p < 0.05$ is considered statistically significant

by the second investigator within the groups during their first and second visits with the help of a paired sample t-test (Table 3). The mean heart rate, blood pressure, and oxygen saturation of children in group I and group II were also evaluated before and after the treatment during the first and second visits (Table 4).

RESULTS

Before the start of the dental treatment, approximately 59.09% of the children who were involved in the study and divided into two groups had no anxiety, whereas 40.90% of the children had mild anxiety. After dental treatment, 31.82% of the children who were exposed to VR were anxiety-free as compared to 50% of children with PEM. The children with mild anxiety increased in VR (54.55%) against that of PEM (50%). The VR device was more effective in reducing the anxiety of children as compared to PEM; however, the difference was not statistically significant (Table 1).

During dental treatment children were equally divided into two halves of 11 each for their first and second visit. On the first visit, half of the children were exposed to group I, whereas the other half of the children were exposed to group II. So, during their second visit the children would have been already exposed to either of the groups. The result demonstrated that in the PEM group, children with no anxiety were more in the second visit (81.80%) as compared to the first visit (18.20%), whereas the children with mild anxiety were less in the second visit (18.20%) as compared to first visit (81.80%). The difference between the visits of treatment in group I was statistically nonsignificant, irrespective of the use of devices.

In the VR group, approximately 54.55 and 45.45% of the children had no and mild anxiety, respectively, on the first visit. However, during their second visit, there was a marked increase in the percentage of children with mild anxiety (63.60%). The difference between the visits within the group was statistically insignificant. It can be inferred that PEM was also preferred by children along with VR eyeglasses (Table 2).

The dental anxiety of the children during treatment was evaluated by a second investigator in both groups during their first and second visits. The baseline anxiety of the children before the start of the treatment was 1.76 (±0.54). In group I, there was an increase in the mean anxiety of children in the second visit (9.0) as compared to the first visit (7.09); the difference was not statistically significant. However, when compared with the baseline anxiety, there was a significant increase in anxiety after dental treatment. In group II, there was a slight increase in anxiety in the second visit (5.63) against that of the first visit (5.18), but the difference was not statistically significant. Similarly, children exposed to VR (group II) did not show any significant increase in anxiety when compared with the baseline anxiety (Table 3).

The mean baseline heart rate of children was 106.54. In the PEM group the mean heart rate of the children does not show any significant increase in the first and second visit of dental treatment. Similarly, in the VR group also no significant increase in heart rate was observed between the visits.

Before the start of the treatment, the mean oxygen saturation reported in children was 96.72. There was no decrease in the oxygen saturation of the children in both groups on their first and second visits (Table 4).

DISCUSSION

Anxiety is an emotional state that precedes the actual encounter with the threatening stimuli, which sometimes is not even identifiable.[9] It is normally experienced in day-to-day life, such as during exams, while making crucial decisions, in the workplace, and in several other circumstances. Many children often suffer from dental anxiety due to invasive past dental experiences, which cause them to neglect their oral health. Hence, it is important for the oral health provider to reframe the past bad dental experience by using various behavior management techniques.

Table 3: Posttreatment dental anxiety of children evaluated by the second investigator within the groups during their first and second visit

Groups	Baseline anxiety	PEM (group I)		VR eyeglasses (group II)	
		First visit [N (11)]	Second visit* [N (11)]	First visit [N (11)]	Second visit** [N (11)]
Mean	1.76	7.09	9	5.18	5.63
Standard deviation (SD) (±)	±0.54	±1.814	±2.049	±0.404	±0.809
p-value		0.062		0.176	

*The children in group I were initially subjected to VR eyeglasses on their first visit, and they were exposed to PEM during their second visit; **the children in group II were initially subjected to PEM on their first visit, and they were exposed to VR during their second visit; PEM, periorbital eye massager; VR, virtual reality; test of significance, paired sample t-test

Table 4: Mean heart rate and oxygen saturation of children in group I and group II before and after dental treatment

	Before treatment	PEM (first visit)	PEM (second visit)	VR (first visit)	VR (second visit)
Heart rate					
Mean	106.54	115.09	118.18	111.81	116.36
SD	6.578	8.395	6.274	8.772	4.272
p-value	–		0.583		0.138
Oxygen saturation					
Mean	96.72	96.36	97.72	97.81	97.63
SD	1.272	0.674	1.009	0.981	1.026
p-value	–		0.866		0.676

To date, many behavior modification techniques have been used; the trending VR, which is based on digital technology, is proven to be an effective behavior management tool in reducing dental anxiety. Since this device has several health-related and economic disadvantages, this clinical trial has been incorporated with PEM. It is a device that enables the child to address his own anxiety through relaxation methods. There are many studies in the literature that highlight the importance of massage therapy to reduce anxiety and thereby create relaxation in the human body.[10] Miller et al.[11] evaluated the effects of a brief bedside massage intervention as an adjunct to pharmacologic pain management in orthopedic surgical patients and found that the addition of a 5-minute massage treatment at the time of analgesic administration significantly increased patient satisfaction with pain management. Also, a study performed in 2001 in Korea demonstrated that hand massage decreases psychological and physiological anxiety levels in patients having cataract surgery under local anesthesia.[12] In a case report by Kunusoth et al.,[13] a significant reduction in dental anxiety was observed using a PEM in an 18-year patient with an impacted third molar. Hence, keeping this in mind, this study was designed to evaluate the effectiveness of a PEM in reducing dental anxiety in children.

Many upcoming distraction behavior management techniques have evolved with the new technology-friendly generation. One of the most widely used is the VR concept, which shows an illusion of depth, a characteristic feature of virtual environments. Nunna et al.[4] observed that VR distraction is a more effective behavior guidance modality than counter-stimulation for reducing dental fear and anxiety in children during local anesthesia administration. The present study was conducted on a group of 21 children who had similar baseline anxiety. In our study, after the treatment was completed, the anxiety assessed with the help of a validated questionnaire revealed no statistical difference between the two devices. A study done by Lahmann et al.[14] found that although both brief relaxation and music distraction can reduce dental anxiety in children, brief relaxation showed more potential in reducing anxiety. This was also reflected in our trial when the children were subjected to PEM either during their first or second visit after exposure to VR; it showed no significant difference, which signifies that relaxation by PEM is also equally potent. A lesser impact of the visit is seen, implying that dental anxiety was effectively controlled by the innovative PEM device. Studies conducted by Beck and Weaver[15] and Guinot Jimeno et al.[16] have demonstrated the usefulness of a pulse oximeter in measuring the degree of stress and anxiety in patients undergoing dental treatment.

In a previous study, Beck and Weaver[15] found a link between subjective dental anxiety and heart rate, demonstrating the relationship between subjective and objective measures. According to Rayen et al.,[17] children's elevated heart rate and systolic blood pressure have a positive correlation with negative behavior. These physiological parameters of the participants in our study were also within normal limits during dental treatment, which aids in proving that anxiety was effectively managed by these devices.

There are many limitations faced by this study, which included the apprehensiveness of the child towards the dental procedure as the child's eye remained closed in PEM and the lack of a display screen in the PEM device. If the display is included in the massager, the main restriction of this technology can be overcome. This will result in the child being deeply soothed by the massager and playfully engrossed in the immersive video.

Conclusion

The present study helps to conclude that both, PEM and VR eyeglasses can be useful in controlling the dental anxiety of children. Since behavior management provides a lot of room for new innovative devices and techniques, this massager can be augmented into it. This device seems to be a cost-effective, user-friendly, and reliable tool for oral health care providers to manage anxious children in performing dental treatment more effectively.

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