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TITLE: The effect of virtual reality on the behavior of pediatric dental patients during dental sealant application.

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1.0 BACKGROUND AND HYPOTHESES

1.1 Clinical Significance

Dental fear and anxiety (DFA) is a common emotional experience that most often develops in early childhood and adolescence[1]. In their systematic review, Cianetti et. al, compared the prevalence of dental fear and anxiety in children according to a variety of available measurement tools and scales[2]. Their results showed that between 10-29% of children experience DFA. It is more common in females, and its prevalence decreases with age [2]. DFA poses several problems. The first is that most patients who experience DFA also exhibit behavior problems in the dental setting[3]. Dental anxiety is one of the main reasons people avoid seeking dental care, and children who have high dental anxiety have a higher caries experience [4]. Additionally, Moore et. al demonstrated in a survey of dentists that one of the biggest causes of stress for a dentist is managing their anxious patients, as these patients are often unpredictable, more time consuming, and require more skill to manage [5].

Currently, the American Academy of Pediatric Dentistry (AAPD) recognizes and promotes the usage of many behavior management techniques including communicative, pharmacological, and protective stabilization methods. When a child is healthy and cooperative enough to allow dental work to be completed, basic techniques should be used to avoid potential risks associated with stabilization, sedation, and general anesthesia. Some of these basic techniques, outlined in the AAPD guidelines, include tell-show-do, ask-tell-ask, memory restructuring, positive pre-visit imagery, and distraction [6].

Distraction has been explored for improving the experience of pediatric dental patients in a variety of ways. Aminabadi et. al, showed that distraction via verbal stimulation during an intraoral injection had significant results in decreasing reported pain in pediatric patients [7]. Another study, exploring audio-only and audio-visual distraction via devices mounted to the dental chair or ceiling showed that anxiety and behavior improved with audio-visual distraction as compared to the control [8]. More recently, virtual reality systems, have been explored for use as a distraction method in healthcare settings.

Virtual reality is defined as “a three-dimensional environment generated by means of computer technology that creates a sense of immersion in the user, transporting the individual to appealing and interactive settings” [9]. Several studies have shown that virtual reality is an effective intervention in healthcare settings including needle-procedures in children, treatment of burn victims, and patients experiencing chronic pain [10,11,12].

Piskorz et. al assessed the effect of virtual reality on stress and pain management during venipunctures in pediatric patients (age 7-17 years), and showed that the children who experienced virtual reality during the procedure reported significantly lower pain and stress, and that there was no correlation with age [10]. Walther et. al reported that 100% of children in their study (ages 7-16) stated that they would prefer virtual reality as a distraction option during the venous cannulation procedure, compared to the control group who received standard behavior guidance techniques (topical numbing cream, positioning, and distraction) [11]. In their review of literature, Li et. al report that analgesia plus virtual reality is more effective than analgesia alone in children ages 5-18 undergoing burn care[13].

In the dental setting, researchers are exploring the effect of virtual reality on patient compliance, patient anxiety, and long-term memories of treatment. Lahti et. al showed that a brief pre-operative immersive virtual reality experience in a peaceful landscape resulted in a significant decrease in anticipatory anxiety in adult patients prior to dental treatment compared to the control group [14]. Another study simulated a dental experience with adult patients in a laboratory resembling a dental office, with an audio system providing instructions of tasks to complete, for example, to open their mouth and keep it open [15]. This study reported that patients who experienced virtual reality during the simulation were more complaint with instructions, and those who reported dental anxiety showed greater reduction in memory vividness of the experience, when VR was used than compared to the control group [15]. No currently published studies have assessed the direct effect of the use virtual reality systems the behavior of pediatric dental patients during restorative dental treatment.

1.2 Hypothesis

It is hypothesized that the use of virtual reality technology as a distraction technique will improve behavior in pediatric and adolescent patients undergoing dental sealant placement.

It is hypothesized that the use of virtual reality technology during dental sealant placement will be more effective in decreasing pain and dental anxiety when compared to basic behavior guidance techniques.

2.0 OBJECTIVES AND PURPOSE

2.1 The primary objective of this study is to investigate the effect of virtual reality on the behavior of pediatric patient when compared to basic behavior guidance techniques during dental sealant placement.

2.2 A secondary objective is to evaluate the effect of virtual reality pain experienced by a patient when compared to basic behavior guidance techniques during dental sealant placement.

2.3 An additional objective is to evaluate the effect of virtual reality on reduction of anxiety when compared to basic behavior guidance techniques during dental sealant placement.

3.0 STUDY DESIGN

This study is a randomized controlled trial with a crossover design. The study will be carried out at the USC Herman Ostrow School of Dentistry graduate pediatric dental clinic and Children's Dental Health Clinic in Long Beach Memorial Hospital. Patients who are visiting the clinic for a comprehensive or periodic dental exam and are found to require two or more dental sealants (at least one sealant per side) will be recruited for the study. The study subjects will include children ages 6-17 who are ASA I or II (as defined by the American Society of Anesthesiologists classification system). Nitrous oxide for anxiolysis during dental treatment is not be indicated for research participants due to signs of cooperative behavior during initial exam. Cooperative behavior is determined through Frankl Score being an F3 or F4. Participant and legal guardian must deny any use of nitrous for dental sealant placement before VR study is introduced and patient is recruited as a prospective participant. The proposed sample size for this pilot study is 40 participants.

This is a split mouth design in which children who are enrolled in the study will serve as both the experimental group and their own control After the child and parent are scheduled dental sealant appointment, they will be randomly assigned to receive the virtual reality system as a distraction technique for the first half or the latter half of the appointment. During the time where virtual reality is not used, traditional basic behavior guidance techniques will be used, as is the standard of care.

The virtual reality system being used for research purposes is the RelieVR by Applied VR which includes the goggle headset only. The VR experience will be an immersive experience where the child will interact with the system and navigate their way through a game which will involve bright colors, cartoon-like characters and settings with age-appropriate content. The VR system will be worn for approximately 5-10 minutes during sealant application.

Each patient will serve as their own control. The control sample will include basic behavior guidance techniques only. Informed consent will be obtained from the patient or guardian and documented in the patient's record prior to placement of dental sealants and use of virtual reality.

The heart rate will be analyzed at specific steps of the procedure including:

- Baseline (patient sitting in the chair prior to treatment)
- During sealant placement with Virtual Reality distraction
- During sealant placement with basic behavior guidance techniques
- Post Operative (patient sitting upright in chair, 5 minutes after procedure)

Patient's anxiety will be evaluated by heart rate. Each child enrolled in the study will wear a pulse oximeter throughout the duration of the entire treatment appointment. The patient's heart rate (beats per minute) will be verbally announced by the provider at the time points listed above. The use of the pulse oximeter, recording of the heart rate will be used for research purposes only, and will be transferred to a protected data sheet by the person who is examining the video recording of the appointment at a later date.

The behaviors, as they happen in real time during the dental appointment, will be handled according to the standard of care and the patient and parent's comfort level. For example, when a child is moving to the point where it interferes with the provider's ability to render treatment safely, the appointment will be aborted and rescheduled with nitrous oxide, moderate sedation or general anesthesia. If a child cries, this will be addressed according to the standard of care, such that a crying child is given the chance to express any pain/concern/requests for modification to treatment, but some children use crying as a coping mechanism and are able to complete dental treatment safely and atraumatically. A child who falls asleep will be allowed to sleep, given that their breathing is being monitored and the child can respond to verbal commands or tactile stimulus, when necessary, as is the standard of care. This is in line with the typical behavior management of children receiving dental care and is outlined in the AAPD Guidelines for Behavior Management (20. All of these behaviors are normal responses to children and are dealt with regardless of participation in this research study.

Additionally, after sealant application with VR and control, the provider will assign the patient a Frankl behavior score[15,] and record it in the patient's chart, as is the standard of care. All patient behavior is routinely documented in the patient chart using the Frankl behavior score, regardless of participation in this research study. The provider will also complete a Healthcare Provider Questionnaire through Qualtrics. (Appendix A. Figure 4)

This is a pilot study. Data analyzed will be changed in heart rate between baseline and sealant placement using virtual reality or behavior guidance technique.. No statistical analysis will be conducted except mean and range. Other factors will also be analyzed including timing of virtual reality intervention (1^{st} vs. 2^{nd} half of the appointment), age, gender, previous dental experience, and average amount of "screen time" a child is allowed per week.

The demographic factors will be collected from the patient's medical chart. Ethnicity will not be collected.

The parent will be asked "how many hours of "screen time" (TV, computer, video games, tablet use), would you say that your child is allowed per week?" and this will be recorded with their coded Study ID number during the recruitment phase. See Coded ID and data sheet in section 13.2. Parents will also be asked to complete a satisfaction survey after the Virtual Reality appointment and the Standard of Care appointment. (Appendix A. Figure 3.1 and 3.2)

4.0 DEVICE INFORMATION

4.1 The device being used in this study is the RelieVR by Applied VR . RelievRx by AppliedVR which is an immersive virtual reality device that includes a goggle headset and remote control. The VR experience will be an immersive experience where the child will interact with the system and navigate their way through a game that will involve bright colors, cartoon-like characters, and settings with age-appropriate content.

4.2 Children's Hospital of Los Angeles has loaned the RelieVR to the study team for short-term use for the purpose of this study.

5.0 SELECTION AND WITHDRAWAL OF SUBJECTS

5.1 Inclusion Criteria: Children meeting the following criteria

- Age 6-17
- ASA I or II
- Present to the Herman Ostrow School of Dentistry Pediatric Dental Clinic and Children's Dental Health Clinic at Long Beach Memorial Hospital for initial or periodic exam, and are determined to require two or more dental sealants (at least 1 sealant per half mouth)
- The need for nitrous oxide for treatment is not indicated due to cooperative behavior during initial exam. Cooperative behavior is determined through Frankl Score being and F3 or F4.
- Participant and legal guardian must deny any use of nitrous before VR study is presented

5.2 Exclusion Criteria: Children meeting the following criteria:

- Children with visual, auditory, or tactile deficits that would interfere with the ability to complete the experimental tasks
- Children who are unable to tolerate the RelieVR will be screened after consenting to research participation by trying on the VR goggles and stating that they are comfortable and willing to proceed with wearing them during their dental appointment.
- Examples of children who may be unable to tolerate the VR goggles may include:
    - Children who wear glasses and are unable to comfortably adjust the system over their glasses

    - Children who experience dizziness, motion sickness or other discomfort during use
- Patients that score below an F3 on the Frankl scale, indicating uncooperative behavior.
- Children who remove the VR goggles prior to dental sealant placement
- Children who present with uncooperative behavior and require pharmacological means to complete dental treatment (nitrous oxide, sedative drugs or general anesthesia)
- Children with a significant medical history of seizure disorders as flickering from devices can trigger epileptic episodes.
- Children with developmental disabilities
- Children with a psychiatric disorder, organic brain syndrome, mental retardation, or other known cognitive/neurological disorders
- Children that are not English or Spanish speaking

5.2.1. If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.
Languages other than English and Spanish will be excluded given that the proposed measures have not been develop nor standardized for use in other languages.

5.3 Withdrawal Criteria: The children participating in the study, and their guardians, will be informed that they can withdraw their involvement in the study at any time, and all necessary dental treatment will still be performed at the same level of care.

6.0 STRATIFICATION/DESCRIPTIVE FACTORS/RANDOMIZATION SCHEME

6.1 The participants in the study will serve as their own control using a split mouth cross-over randomized control clinical trial design and will be randomly assigned to receive virtual reality or traditional behavior guidance techniques during dental sealant placement. Patients will serve as their own control. Stratification between sites will not be done.

6.2 Patient characteristics that will be considered include demographic data such as age, gender, previous dental experience, and number of hours per week the child spends having “screen time”. Additionally, complexity/difficulty of treatment being rendered will be recorded (how many sealants were placed). The dental resident will determine the child’s behavior using the Frankl behavior rating scale at the initial exam, and each subsequent appointment while the child is enrolled in the study.

6.3 Randomization will be achieved using an envelope system. Envelopes will be labeled 1 through 52 on the exterior and will serve as the patient's coded study ID. Each envelope will be filled with a single paper slip indicating Group 1, Group 2, Group 3, Group 4. The groups are listed below which takes into account randomization of VR, basic behavioral guidance techniques (BBG), site of mouth. Equal amount of each groups will be represented in the total stack of envelopes. The order of envelopes within the stack will be random. When a child and their parent agree to enroll in the study, an envelope will be drawn from the randomized stack, and the category inside will be assigned to that patient.

	First half of appointment	**Second half of appointment**
Group 1	VR with right side sealants	BBG with left side sealants
Group 2	VR with left side sealants	BBG with right side sealants
Group 3	BBG with right side sealants	VR with left side sealants
Group 4	BBG with left side sealants	VR with right side sealants

6.4 Carryover effect will be reduced by allowing a short rest time between starting the second half of the sealants. For instance, if VR is used first, after finishing sealants on one side of the mouth with VR, the headset will be removed. The patient will then be given 3-5 minutes break before starting the sealants on the second half of the mouth. Carryover effect will also be reduced by randomizing if patients will receive VR for the first half of sealants placed or for the later half.

7.0 STUDY AGENT ADMINISTRATION OR INTERVENTION AND TOXICITY MANAGEMENT PLAN

7.1 At each appointment where dental treatment is indicated with concurrent use of the virtual reality system, the virtual reality goggle set will be tested prior to the appointment by a resident or staff member to ensure it is working properly. A brief conversation will be had between the provider, parent, and patient regarding what dental treatment will be rendered that day, and an overview of how the virtual reality system works. The parent and child will be informed that they can choose to stop use of the virtual reality system at any point during the procedure if they wish to withdraw from the study for any reason. Once all questions have

been answered, the virtual reality set will be placed on the patient's face prior to beginning any treatment. The virtual reality goggle system will remain in place until the end of sealant placement for half the mouth, or until treatment is aborted due to poor cooperation, or any other relevant concerns. All indicated dental treatment will be completed to the standard of care, and the child will be asked at the completion of treatment if any adverse effects from the virtual reality were experienced.

7.2 Criteria for removal from the virtual reality distraction are outlined below.

7.21 If the virtual reality system fails due any technological error with the equipment itself during the dental appointment.

7.22 The patient becomes uncooperative, and dental treatment cannot be rendered safely.

7.23 The patient experiences any sign of physical discomfort related to the virtual reality system such as headache, dizziness, claustrophobia, or any other symptoms.

7.24 A patient may always be removed from treatment whenever he/she wishes.

7.3

8.0 ASSESSMENT OF EFFICACY AND SAFETY

8.1 Side effects to be monitored:

8.11 Possible symptoms to be monitored during use of the virtual reality device include dizziness, altered, blurred or double vision, eye or muscle twitches, disorientation, anxiety attack, excessive sweating, nausea, lightheadedness, motion sickness, convulsion. If patient reports any of the following symptoms, use will be discontinued immediately.

8.12 Long term monitoring will not be required, as there are no lasting effects of short-term use of the virtual reality device.

8.2 Adverse Event Reporting:

8.21 Any adverse events will be addressed immediately, recorded, and reported where appropriate within 24 hours.

8.22 Parents, if not present in the operatory during the procedure, will be informed immediately of any adverse events.

8.23 Places for submitting reports: IRB, Co-Investigators

9.0 CLINICAL AND LABORATORY EVALUATIONS AND STUDY CALENDA

The Pre-treatment appointment will be the comprehensive or periodic exam where the patient is identified as a good candidate for participation in the study, and agrees to enroll.

End of Treatment will be all dental sealants are placed and 5 minutes has elapsed since the end of sealant placement.

Post- treatment is any date after the treatment has been completed when the parameters can be analyzed, and any remaining treatment and/ or follow-up appointments can be completed.

SC= Standard of Care
RP= Research purposes

Parameter	Pre-Treatment	VR Distraction	Basic Behavior Guidance	End of Treatment/Study Participation	Post-Treatment
Comprehensive Medical History	X (SC)	X (SC)	X (SC)		
Report of Average Weekly Screen Time	X (RP)				
Virtual Reality Distraction		X (RP)	X (RP)		
Heart Rate measured by Pulse-Oximeter		X (RP)	X (RP)		
Video Recording of Dental Appointment		X (RP)	X (RP)		
Self- Reported Scores (FPS-R)		X (RP)	X (RP)		
FLACCS		X (RP)	X (RP)		

Frankl Score completed by provider	X (SC)	X (SC)	X (SC)		
Health Care Provider Questionare					
Satisfaction Survey completed by parents/guardianHealth Care Provider Questionare				X (RP)	
Report of experienced VR side effectsSatisfaction Survey completed by parents/guardian				X (RP)	
Scoring of behaviors displayed on video				X (RP)	

10.0 CRITERIA FOR EVALUATION AND ENDPOINT DEFINITIONS

The outcome status (behavior) of all eligible patients will be reported.

Frankl Score: Patient's behavior as rated by the dental provider within one of the following categories: 1= definitely negative, 2= negative, 3= positive, 4= definitely positive. This scale is routinely used by dentists and documented in the patient chart.

Behavior, and anxiety will be scored at the following time points:

- Baseline (patient sitting in the chair prior to treatment)
- During sealant placement with virtual reality distraction
- During sealant placement with basic behavior guidance
- Post Operative (patient sitting upright in chair, 5 minutes post completion of dental sealant placement)

Anxiety: Measured by change in heart rate at outlined points (above) during restorative procedure.

Completion of Dental Treatment: Was the treatment able to be completed, or was the appointment aborted due to patient cooperation, complication with virtual reality system, or any other reason.

Parent Satisfaction Survey: Will be evaluated post treatment for the Virtual Reality and standard of care. Satisfaction questions will be asked on a scale on a scale of 1 to 10. (Appendix A. Figure 3.1 and 3.2)

Healthcare Provider Questionnaire: Will be obtained after each session, completed by the provider performing treatment. (Appendix A. Figure 4)

11.0 SPECIAL INSTRUCTIONS:

Not applicable

12.0 DATA COLLECTION AND MONITORING

Each patient will be given a study ID number (the number labeled on the exterior of the random envelope they are assigned) and the physical master list of all participants will be kept in a separate location from the data (in a binder located at Children's Dental Health Clinic at Long Beach Memorial Resident Room or USC pediatric graduate clinic). See Appendix A.

A Frankl score will also be assigned to each patient by the providing dentist at the end of each appointment and recorded in the Dentrix software where patient electronic health records are kept at the Children's Dental Health Clinic at Long Beach Memorial or Axium software at USC's pediatric graduate clinic.

After consenting to participation in the research, the patient and parent will be asked the patient's average weekly "screen time" which will be recorded in the Dentrix/Axium treatment note for their initial exam appointment.

Each patient will wear a pulse-oximeter during dental treatment appointments. The heart will be reported verbally at outlined steps during the procedure and analyzed at a later date. The person viewing the video will record the verbally reported heart rate and at each step into the data collection sheet (see Appendix B).

The providing dentist will ask the patient at the end of the treatment, for research purposes, if any adverse side effects were experienced during VR use and include it in the Dentrix/Axuim treatment note for that appointment.

The data from the parent satisfaction survey and healthcare provider questionnaire will be obtained electronically through Qualtrics and the data will be transferred to an excel sheet stored in USC OneDrive. There will be no paper versions of the data collected. The excel sheet will be kept and secured until the end of the study, at which point it will be deleted. See Appendix B.

13.0 STATISTICAL CONSIDERATIONS

13.1 The objectives of this study are to explore the associations between the use of virtual reality distraction during dental sealant placement with Frankl score, and anxiety based on change in heart rate via video recording, when compared to the control group.

The study design is a randomized controlled trial with a crossover split-mouth design where each patient will serve as both the experimental group and the control.

This is a pilot study. Data analyzed will be changed in heart rate between baseline and sealant placement using virtual reality or behavior guidance technique.. No statistical analysis will be conducted except mean and range.

1. VR and Frankl Score

Null Hypothesis: There is no difference in Frankl Score between a visit where virtual reality is used and a visit where basic behavior guidance is used during dental sealant placement.

Alternative Hypothesis: Frankl score will improve when virtual reality distraction is used during dental sealant placement.

Sample Size: N=40

2. VR and Anxiety based on Heart Rate

Null Hypothesis: There is no difference in heart rate at each step of a dental restorative procedure when virtual reality is being used during dental sealant placement. .

Alternative Hypothesis: The heart rate is lower at each listed step of the dental procedure when virtual reality is used as a behavior management technique during dental sealant placement.

13.2 Female and male participants as well as patients of all racial/ethnic backgrounds will be recruited equally. The USC graduate pediatric dental clinic accepts patients ages 0-15 of all backgrounds, and each child that fits the inclusion criteria for the study will be offered to enroll. The Children's Dental Health Clinic at Long Beach Memorial. accepts patients is an all inclusive dental home to children

and young adults from birth through age 21, and each child that fits the inclusion criteria for the study will be offered to enroll.

14.0 REGISTRATION GUIDELINE

14.1 All patients included in the study will be recruited during their initial or periodic exams at the Herman Ostrow School of Dentistry Pediatric Dental Clinic or the Children's Dental Health Clinic at Long Beach Memorial.

14.2 The required forms to enroll in the study include Informed Consent, Assent, Parent Permission and HIPPA Forms. See Appendices C, D, E.

15.0 BIOHAZARD CONTAINMENT

Not applicable

16.0 ETHICAL AND REGULATORY CONSIDERATIONS

All patient information will be protected throughout the study and data analysis periods, and destroyed once the study is completed.

All institutional and Federal regulations concerning the Informed Consent form will be fulfilled. The study will be conducted in adherence to ICH Good Clinical Practice.

17.0 REFERENCES

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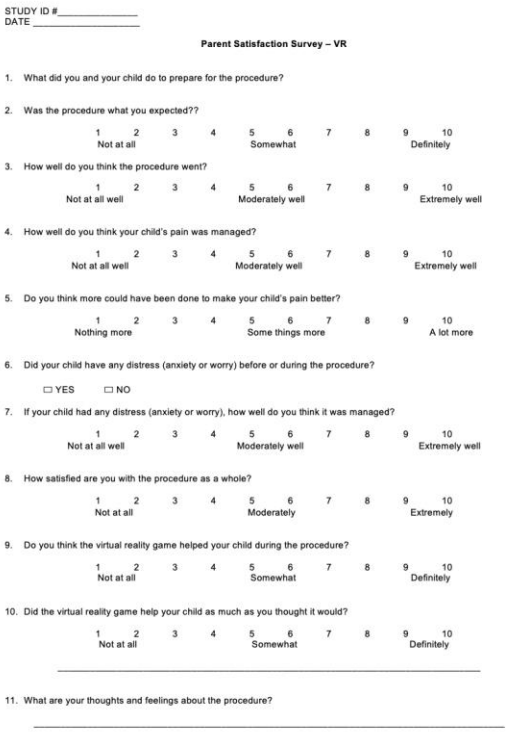
APPENDICES

Appendix A.



STUDY ID #_____
DATE _____

Parent Satisfaction Survey – VR

1. What did you and your child do to prepare for the procedure?

2. Was the procedure what you expected??

1 2 3 4 5 6 7 8 9 10
Not at all — Somewhat — Definitely

3. How well do you think the procedure went?

1 2 3 4 5 6 7 8 9 10
Not at all well — Moderately well — Extremely well

4. How well do you think your child's pain was managed?

1 2 3 4 5 6 7 8 9 10
Not at all well — Moderately well — Extremely well

5. Do you think more could have been done to make your child's pain better?

1 2 3 4 5 6 7 8 9 10
Nothing more — Some things more — A lot more

6. Did your child have any distress (anxiety or worry) before or during the procedure?

☐ YES ☐ NO

7. If your child had any distress (anxiety or worry), how well do you think it was managed?

1 2 3 4 5 6 7 8 9 10
Not at all well — Moderately well — Extremely well

8. How satisfied are you with the procedure as a whole?

1 2 3 4 5 6 7 8 9 10
Not at all — Moderately — Extremely

9. Do you think the virtual reality game helped your child during the procedure?

1 2 3 4 5 6 7 8 9 10
Not at all — Somewhat — Definitely

10. Did the virtual reality game help your child as much as you thought it would?

1 2 3 4 5 6 7 8 9 10
Not at all — Somewhat — Definitely

_____

11. What are your thoughts and feelings about the procedure?

_____

Figure 3.1 – Parent Satisfaction Survey – Standard of Care

STUDY ID #_____
DATE _____

Parent Satisfaction Survey – Standard Care

1. What did you and your child do to prepare for the procedure?

   _____

2. Was the procedure what you expected?

   1 2 3 4 5 6 7 8 9 10
   Not at all — Somewhat — Definitely

   _____

3. How well do you think the procedure went?

   1 2 3 4 5 6 7 8 9 10
   Not at all well — Moderately well — Extremely well

4. How well do you think your child's pain was managed?

   1 2 3 4 5 6 7 8 9 10
   Not at all well — Moderately well — Extremely well

5. Do you think more could have been done to make your child's pain better?

   1 2 3 4 5 6 7 8 9 10
   Nothing more — Some things more — A lot more

6. Did your child have any distress (anxiety or worry) before or during the procedure?

   ☐ YES ☐ NO

7. If your child had any distress (anxiety or worry), how well do you think it was managed?

   1 2 3 4 5 6 7 8 9 10
   Not at all well — Moderately well — Extremely well

8. How satisfied are you with the procedure as a whole?

   1 2 3 4 5 6 7 8 9 10
   Not at all — Moderately — Extremely

   _____
   _____

9. What are your thoughts and feelings about the procedure?

   _____
   _____

Figure 4- Healthcare Provider Questionnaire

STUDY ID # _____ DATE _____ HEALTHCARE PROVIDER QUESTIONNAIRE

1. How cooperative was the child during the procedure?

1 2 3 4 5 6 7 8 9 10
not at all — moderately — extremely

2. How much pain do you think the child experienced?

1 2 3 4 5 6 7 8 9 10 ☐ N/A
no pain — moderate pain — worst pain

3. How satisfied were you with the management of the child's pain during the procedure?

1 2 3 4 5 6 7 8 9 10 ☐ N/A
not at all — moderately — extremely

4. How much anxiety do you think the child experienced?

1 2 3 4 5 6 7 8 9 10 ☐ N/A
no anxiety — moderate anxiety — worst anxiety

5. How satisfied were you with the management of the child's anxiety during the procedure?

1 2 3 4 5 6 7 8 9 10 ☐ N/A
not at all — moderately — extremely

6. If the child played the virtual reality game, do you think that it helped the child during the procedure?

☐ Yes ☐ No ☐ Not Applicable

Please explain: _____
_____

7. Would you like to use the virtual reality game again with other patients?

☐ Yes ☐ No ☐ Not Applicable

Please explain: _____
_____