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Use of Immersive Virtual Reality for Laceration Repairs in the Pediatric Emergency Department

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1.0 Background and Rationale

Small procedures are an everyday occurrence in the pediatric emergency department. Medical procedures often elicit anxiety, which amplifies the pain response.[i] Laceration repair is one of the most common procedures performed. Simple laceration repair can be challenging not from a technical standpoint, but due to patient cooperation secondary to patient pain and anxiety.[ii] Usually, uncooperative children squirm, kick, twist, and scream; this is physically challenging during a laceration repair. It is the norm for patients to require distraction, analgesia, and anxiolytics as well as physical holding in order to achieve adequate patient stillness for safe repair. Typical passive distraction methods include watching television, playing on a tablet or phone, parental engagement, or Child Life involvement. Distraction is an accessible, low-cost, and non-pharmacologic intervention.

Virtual reality is an evolving technology that allows a viewer to be immersed into a simulated environment using a head mounted device as well as hand-held controllers. Immersive virtual reality is an active form of distraction. Children who actively perform tasks or engage in activities forget about their pain and fear.[iii] Virtual reality has been documented in the literature as a safe and effective tool to reduce both pain and anxiety surrounding painful procedures in pediatrics as a distraction technique.[iv] It has also been theorized to diminish pain signals during painful procedures.[v] This technology has been studied in burn scrubs,[vi] wound dressing changes,[vii] immunizations,[viii] venipuncture,[ix] lumbar punctures,[x] and dental procedures[xi] in pediatrics. However, virtual reality (VR) has not been well described for laceration repair in the pediatric emergency department setting. Side effects might include nausea, vomiting, motion sickness, but these have not been proven to be significant outcomes in the literature.[xii]

In our emergency department, the standard of care involves topical lidocaine/epinephrine/tetracaine (LET) cream and/or subcutaneous lidocaine, positioning, Child Life staff, and distraction. For some children, oral or intranasal anxiolysis is necessary as well as physical holding. Our aim for this study is to determine if Virtual Reality goggles can improve patient pain and anxiety scores during simple laceration repair when compared to standard passive distraction techniques.

2.0 Objectives

The objective of this study is to determine if VR goggles can decrease patient pain and anxiety during simple laceration repairs. The primary outcome will be pain scores as assessed by the validated Wong Baker Faces Scale and anxiety scores as assessed by the validated Children's Fear Scale. A validated System Usability Scale (SUS) will be measured for each enrolled participant that used the VR goggles. Secondary outcomes include time of procedure, use of physical holding, adverse outcomes, and pharmacologic interventions.

3.0 Project Procedures

This will be a randomized pragmatic study for all patients ages 6-17 years with simple lacerations. Simple lacerations will be defined as lacerations within the scope of pediatric emergency medicine providers AND not requiring sedation or operative intervention. Subjects will be identified by the Emergency Department staff for enrollment. The goal number of enrolled participants will be 480, including 240 patients randomized into two groups, 120 per group, and 240 parents/guardians. The Emergency Department accepted to participate in this study and ED providers will complete the provider's survey. After signing the consent and assent form when appropriate, the patients will be randomized to either receive the standard of care or standard or care with immersive virtual reality goggles. Consent and assent will be obtained in the patient rooms within the emergency department. The standard of care shall be defined to include any of the following: local analgesia (topical LET and/ or subcutaneous lidocaine), oral or intranasal midazolam, distraction, Child Life Staff, or physical holding. Because each of the aforementioned interventions may vary between patients, it cannot be truly standardized; hence, this will be considered a pragmatic study. Patients randomized to the VR arm will receive the other standard procedures as well with VR goggles as an adjunct. Exclusion criteria include a history of epilepsy, visual or hearing impairment, or intellectual disability that would preclude use of VR goggles as determined by the guardian. Additionally, any lacerations around the eyes, eyebrows, and nose will be excluded as well as patients requiring sedation. Non-English speaking patients will be excluded as well. Hand lacerations will not be excluded.

Participants will be identified by ED staff following evaluation of the laceration. The ED staff will be given a flowchart with eligibility criteria. All interested participants who meet eligibility criteria will be consented. A research team member will obtain consent from parents or guardians by providing and reviewing the consent form (see Subject Consent Form). For patients who are between 8 and 17 years of age, a research team member will obtain assent by providing and reviewing the assent form (see Subject Assent Form). Consent and assent will be obtained in the patient's ED room.

Patients will be separated into groups age 6-11 and 12-17. Patients will be randomized via a selection of a sealed envelope which will contain instructions for use of the VR goggles. The goggles utilized will be Lenovo Mirage Solo with DayDream, which are standalone VR headset with Worldsense Body Tracking. Research staff will coach the child on age-appropriate games, as previously determined by Lenovo.

The goggles will be cleansed with Oxivir Tb disinfectant wipes after each use and allowed to dry in room air prior to next use. Education will be provided to all ED providers on the proper cleansing protocol for the VR goggles (Figure 4). The disinfectant protocol will be available for all users during the study, and has been approved by the director of Infection Control at Children's Hospital of the King's Daughters.

Following the laceration repair, the patient, guardian and health care provider will be surveyed (Figure 1, 2, and 3) on paper surveys. The survey includes Likert-type scale questions, binary

questions as well as incorporates the Wong Baker Faces Pain Scale and Children's Fear Scale. The duration of the procedure will be recorded by the healthcare provider who completed the laceration repair. Time of procedure will be defined as from the time of irrigation to wound dressing. Patients and parents will both be filling out their own individual surveys. The parent should complete the survey first before the child should the child need assistance with completion. Patients and parents may decline to participate in any survey at any time.

The recruitment period will be from November 2021 until February 2021. Enrolled participants will not be compensated, and enrollment will be completely voluntary.

4.0 Statistical Analysis

Continuous variables will be presented as mean, standard deviation, median, 25^{th}, and 75^{th}percentile. Categorical variables will be presented as frequency and percentage. Generalized Linear Model (GLM) will be used to assess the effect of intervention on the outcomes of the surveys. The correlation between provider's, parent's, patient's survey will be analyzed using the Spearman's correlation test. All statistical tests will be performed using the R software. All statistical tests will be 2-sided and $p<0.05$ will be considered as statistically significant.

5.0 Risks to Participants/ HIPAA Privacy Considerations

No personal identifiers will be recorded as part of the research study. Each enrolled participant will be given a unique number for data collection purposes. The risks involved in the study include adverse reactions to the VR goggles, which have been described to rarely cause nausea, vomiting, and motion sickness. There is a theoretical infection risk, but the VR goggles will be cleaned following a decontamination protocol following each use.

The data will be securely stored in RedCAP without any patient identifiers. The paper surveys will be kept in a locked drawer in a locked room within the Pediatric Department of Emergency Medicine offices.

6.0 Budget

The Virtual Reality goggles are property of the Children's Hospital of the King's Daughters Child Life department. They will be stored in a locked drawer within the CHKD Emergency Department. This project is unfunded.

Figure 1. Use of Immersive Virtual Reality for Laceration Repairs in the Pediatric Emergency Department
Patient Survey

1. How old are you? _____

2. Have you had stitches before?
___ Yes
___ No
___ Unsure

3. Have you ever used Virtual Reality (VR) goggles before today?
___ Yes
___ No
___ Unsure

4. Did you use VR goggles for your stitches today?
___ Yes
___ No

5. Would you use VR goggles again to get stitches?
___ Yes
___ No

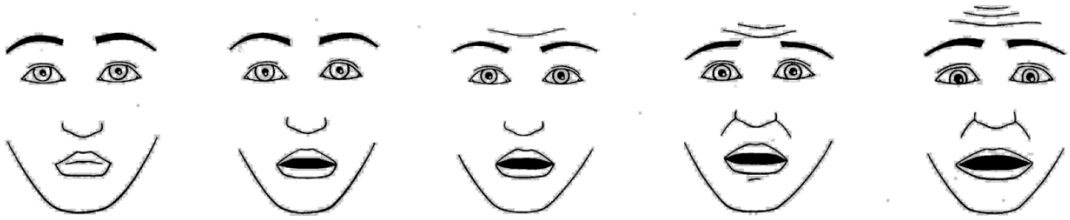
6. During your stitches, did you have any of the following (select all that apply)?
___I did not experience any symptoms
___ Dizziness
___Headache
___ Nausea
___ Vomiting
___ Other (*describe below*)
_____

7. How do you think the stitches went overall?
___ Not well at all
___ Somewhat not well
___ Neutral
___ Somewhat well
___ Very well

8. The virtual reality goggles made the stitches seem less scary.
___ Strongly disagree
___ Disagree
___ Neutral
___ Agree
___ Strongly agree

9. How would you rate your pain:

10. How would you rate how scared you were during the stitches:



Not scary A little scary Somewhat scary Very scary Super scary

Figure 2. Use of Immersive Virtual Reality for Laceration Repairs in the Pediatric Emergency Department
Guardian Survey

1. **Patient** Gender:
___ Male
___ Female
___ Non-binary
___ Self-identify
___ Prefer not to say

2. What is the patient's age? _____

3. Please indicate if the patient has a developmental disability:
A. The patient does not have a developmental disability
B. Autism
C. Cerebral Palsy
D. Intellectual disability
E. Speech delay
F. _____

4. Has the patient had stitches previously?
___ Yes
___ No
___ Unsure

5. Has the patient ever used Virtual Reality (VR) goggles before today?
___ Yes
___ No
___ Unsure

6. Did the patient use VR goggles for the procedure today?
___ Yes
___ No

7. If, yes, would you use VR goggles again for this procedure?
___ Yes
___ No
___ Did not use today

8. During the procedure did the patient experience any symptoms (select all that apply)?
___ Did not experience any symptoms
___ Dizziness
___ Headache
___ Nausea
___ Vomiting
___ Other (*describe below*)

_____

9. How do you think the procedure went overall?

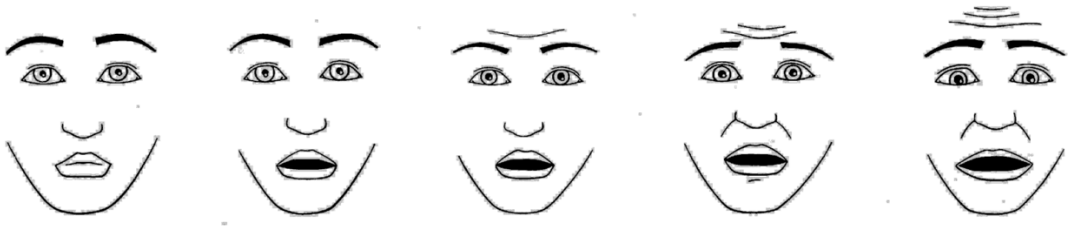
___ Not well at all
___ Somewhat not well
___ Neutral
___ Somewhat well
___ Very well

10. In your opinion, did the virtual reality goggles make the procedure seem less scary to the patient?

___ Strongly disagree
___ Disagree
___ Neutral
___ Agree
___ Strongly agree

11. How would you rate the patient's pain:

12. How would you rate the patient's fear:



No fear | A little fear | Some fear | A lot of fear | The most fear

Figure 3. Use of Immersive Virtual Reality for Laceration Repairs in the Pediatric Emergency Department
Provider Survey

1. Procedure Duration *(from irrigation to closure end)*:
   A. <10 minutes
   B. 10-15 minutes
   C. 16-20 minutes
   D. 21-25 minutes
   E. >25 minutes

2. Did the patient use VR goggles for the procedure today?
   ___ Yes
   ___ No

3. Would you recommend VR goggles again for this procedure?
   ___ Yes
   ___ No

4. Did the patient need to be held during the procedure?
   ___ Yes
   ___ No

5. Did the patient receive medicine intended to help them stay calm?
   ___ Yes
   ___ No

6. During the procedure, did the patient experience any symptoms (select all that apply)?
   ___ Did not experience any symptoms
   ___ Dizziness
   ___ Headache
   ___ Nausea
   ___ Vomiting
   ___ Other (*describe below)*
   _____

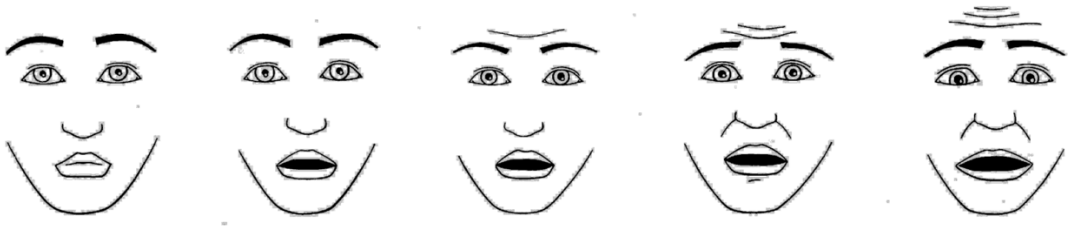
7. How do you think the procedure went overall?
   ___ Not well at all
   ___ Somewhat not well
   ___ Neutral
   ___ Somewhat well
   ___ Very well

8. In your opinion, did the virtual reality goggles make the procedure seem less scary to the patient?

___ Strongly disagree
___ Disagree
___ Neutral
___ Agree
___ Strongly agree

9. How would you rate the patient's pain:

10. How would you rate the patient's fear:



No fear | A little fear | Some fear | A lot of fear | The most fear

Figure 4. Education Plan for Disinfection Protocol for Virtual Reality Goggles

1. The company insert for cleansing the virtual reality goggles will be printed, laminated, and physically located with the goggles in their carrying case.

2. The protocol for cleaning will be addressed during an Emergency Medicine division meeting prior to the start of the project and detailed in the meeting minutes.

3. The protocol will be addressed during a pediatrics monthly resident meeting and dispersed in an email from the chief residents.

4. The protocol will be emailed to all rotating residents prior to the start of their rotation.

5. The protocol will also be disseminated to nursing staff and ED techs via Dawn Jennings prior to the start of the project.

6. Research project staff will be available either in person or by phone to answer any questions regarding the disinfection protocol during the study phase of the project. Contact information will be included inside the carrying case for the goggles as well as on all written communications (division meeting minutes, chief email, etc.)

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