

Study Title: Virtual reality decreases child anxiety and pain as well as caregiver anxiety and pain perception during orthopaedic clinic office procedures

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Background/Significance:

Pain is a complex emotion that is multifactorial in nature. It has been shown that a large component of pain is patient anxiety¹. Decreasing anxiety should subsequently result in a decrease in patients' pain. This has been borne out in numerous studies¹⁻⁷. There has been a gradual progression in the understanding of pain and theories relating to pain perception. The Gate Control Theory proposed by Melzack and Wall in the 1960s states that a person's perception of pain is influenced by the level of attention given to the painful stimulus, the emotion associated with the pain, and the past experience of the pain⁵. This theory was subsequently built on by McCaul and Malott who postulated that people have a limited capacity for attention and pain perception occurs only when one is giving attention to the painful stimulus⁵. The Multiple Resources Theory of Wickens postulates that resources in different sensory systems function independently⁵. Taking these theories into consideration it would follow that providing distraction from painful stimuli should decrease one's pain perception. Distraction can include a variety of modalities depending on the age and cognitive ability of the patient. These distractions can include toys with flashing lights, vibrating implements placed on the skin, and mobile phones or tablets that allow patients to watch videos or play games. These pain mitigation tools have been proven useful in many different areas of healthcare including treatment of burn patients^{1,2,6}, patients undergoing painful dental procedures⁷, and patients undergoing rehabilitative therapy after surgical procedures^{8,9}.

More recently virtual reality (VR) has emerged as a viable option in providing adequate pain relief during medical procedures. It integrates multiple senses (visual, auditory, tactile, and even olfactory) to produce sensory distractions. The theory behind VR and its effect on pain modulation stems from a combination of the previously mentioned theories. Producing sensory distractions during painful procedures results in limited ability for the individual to perceive their pain because of the sensory overload. However, there is a limit to the application of VR and it has been shown to not be as efficacious once a pain threshold has been exceeded⁴. VR that is novel, intense, and unpredictable is most effective for mildly noxious pain experiences⁴.

Pediatric subspecialties are unique in that healthcare workers often have two patients to attend to – the child and the caregiver. In this respect it is vitally important to take into consideration the caregivers' perception of the patient's care as this can play a significant role in the patient-provider relationship. Pediatric orthopaedic surgery clinics are particularly attune to this problem as children often present to clinic and must undergo a variety of procedures including cast removal, pin pulling, and suture or staple removal. While the procedure can be performed fairly quickly with minimal pain, there oftentimes is a significant amount of patient and caregiver anxiety regarding the painful nature of the procedure. These anxieties can result in difficulty in performing procedures and delays in clinic workflows.

One solution currently employed to allay these anxieties and decrease pain during procedures is to involve child life specialists (CLS) to provide distraction techniques during procedures. These can range in scope from simple toys to interactive games. While child life can be extremely helpful in distracting patients during procedures there are limitations to their use. They are not usually readily available during clinic as their services are employed by in a multitude of settings in different physical locations. This can result in delays in the procedure (time it takes the CLS to get to clinic) and delays in clinic work flows. In

addition, CLS can only provide so much distraction. Children are still able to see, feel, and hear their surroundings thus contributing to their anxiety and pain perception. Not only can patients become anxious because of the procedure itself, but parental anxiety can exacerbate the patient's anxiety and subsequent pain perception (REFERENCE). Complicating the use of CLS is the COVID-19 pandemic. Clinics are now contracting services and personnel to limit exposures and subsequent spread of the disease. In light of this, we propose a novel tool to assist in decreasing patient pain during in office procedures – VR technology.

Purpose:

The purpose of this study is to demonstrate that the use of a virtual reality experience can decrease child and caregiver anxiety and pain for simple orthopaedic office procedures.

Outcomes:

Primary Outcome:

The primary outcome will be child pain scores before and after the procedure as assessed by the Children's Faces Pain Scale. This scale has been validated to be used in individuals as young as 4 years old to assess their pain. We will also use the following scales to assess patient anxiety before and after the procedure based on patient age. For patients 7 years and older, the State-Trait Anxiety Inventory for Children (STAIC) will be used. For patients less than 7 years old the Children's Fear Scale will be used to assess anxiety.

Secondary Outcome(s):

Secondary outcome measures will be parental anxiety as assessed by the State-Trait Anxiety Inventory (STAI). This is a validated tool to assess caregiver state (situational) and trait (generalized) anxiety in clinical research settings. The tool will be given to caregivers both before and after the office procedure has been completed.

How do you plan to measure these outcomes?

Patients will be randomized to a control group (parental comfort given during the procedure) and the VR group. Surveys (Wong-Baker FACES pain scale and STAIC or Children's Fear Scale) will be administered to children to assess their pre-intervention pain and anxiety. The STAI will be given to caregivers to assess their pre-intervention anxiety. The procedure will then be performed with the corresponding intervention (control or VR). After the procedure patients and caregivers will again be administered the same survey to assess their post-intervention pain and anxiety. The pre and post-intervention scores will be collected. Descriptive statistics will be used to compare the effect of the interventions

Methods:

Inclusion Criteria: Children age 4years old to 17 years old undergoing cast removal, pin removal, or suture removal in clinic. Parents/caregivers accompanying the participant are also eligible to participate.

Exclusion Criteria:

- History of seizures
- Pregnant, have preexisting binocular vision abnormalities or psychiatric disorders, or suffer from a heart condition or other serious medical condition
- Patients can't have implanted medical devices including cardiac pacemakers, hearing aids and defibrillators

Minimum Age: 4 years old
Maximum Age: 17 years old (For patients, no maximum age for parents)

Number of Subjects to be included in study: 100

Proposed Study Start Date: April 1, 2021
Proposed Study End Date: January 1, 2022

Summary of Human Subject Involvement:

Patients who choose to participate in the study will undergo 3 surveys on the day of their clinic visit. Patients randomized to the control group will not have any increase in their clinic visit time. Patients randomized to the VR group may experience minor prolongation of their clinic visit in order to get the equipment up and running. These delays should not be excessive in relation to the original duration of their clinic visit. In addition, patients in the VR group may rarely have unpleasant feelings related to the VR experience such as nausea or dizziness and a period where they will re-adjust to reality after taking off their headset.

Risks:

Patients undergoing these office procedures generally tolerate them very well. As mentioned above patients undergoing VR as part of their office procedure may rarely experience temporary nausea and/or dizziness with the headset on.

Prolonged use should be avoided, as this could negatively impact hand-eye coordination, balance, and multi-tasking ability temporarily. Adults/guardians and study team should monitor children closely during and after use of the headset for any decrease in these abilities Patient will be monitored by the study team for five minutes after taking the headset off to make sure they are not experiencing any issues.

Seizures.

Some people (about 1 in 4000) may have severe dizziness, seizures, eye or muscle twitching or blackouts triggered by light flashes or patterns, and this may occur while they are watching TV, playing video games or experiencing virtual reality, even if they have never had a seizure or blackout before or have no history of seizures or epilepsy. Such seizures are more common in children and young people. Anyone who experiences any of these symptoms should discontinue use of the headset.

The headset and controller(s) may contain magnets or components that emit radio waves, which could affect the operation of nearby electronics, including cardiac pacemakers, hearing aids and defibrillators. If you have a pacemaker or other implanted medical device, do not use the headset and controller without first consulting your doctor or the manufacturer of your medical device.

The device is not recommended for children under 13

Confidentiality:

Surveys will be collected by clinic staff and kept in a safe, locked box within the clinic. Access will be granted only to the research team members for data collection and review.

Data Collection:

The following information will be collected for analysis:

- Patient age
- Patient gender
- Patient date of birth
- Diagnosis
- In office procedure (e.g. cast removal, pin removal, suture removal)
- Cast type
- Who removes the cast in clinic (i.e. attending, resident, medical assistant)
- Surgical records associated with the injury (if any)
- State-Trait Anxiety Inventory scores
- State-Trait Anxiety Inventory for Children scores
- Children's Fear Scale scores

Survey Assessments:

Faces pain scale

Faces fear scale

State trait anxiety index

Compensation:

Patients will not be compensated for partaking in the study.

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