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Utilizing Virtual Reality Goggles During Pediatric Laceration Repairs to Reduce Perceived Pain in Pediatric Patients

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UTILIZING VIRTUAL REALITY GOGGLES DURING PEDIATRIC LACERATION REPAIRS TO REDUCE PERCEIVED PAIN IN PEDIATRIC PATIENTS

A Master's Thesis

Presented to

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In Partial Fulfillment

Of the Requirements for the Degree

Master of Science, Child Life Studies

By

Emily Catherine Bozzer

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ABSTRACT

In pediatric emergency departments, several providers assess pediatric patients in need a laceration repair, require procedural sedation in order to ensure compliance and complete the laceration repair. This study explored one safe alternative to procedural sedation during pediatric laceration repairs by assessing what pain scores pediatric patients report when undergoing a laceration repair utilizing virtual reality goggles. Pediatric patients ages 6-17 years old perceived pain scores utilizing FACES pain scale was documented. This study found a majority of patients reported lower pain scores during the laceration repair in comparison to their baseline pain score.

KEYWORDS: virtual reality, pediatric patients, laceration repairs, procedural sedation, distraction, Certified Child Life Specialists

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INTRODUCTION

The hospital environment is stressful for children and families. The literature presented shows environment, painful procedures, family structure, new diagnoses and other factors combine to increase pediatric patients' and families' anxiety (Rollins, Bolig, & Mahan, 2005). In pediatric emergency departments, invasive and painful procedures, including laceration repairs, are performed everyday as part of the plan of care (Forsch et. al, 2017). Oftentimes, physicians and other providers choose to utilize procedural sedation medications in order to increase safety, compliance, and decrease pain to patients during laceration repairs. These medications are generally safe but can have harmful side effects to pediatric patients (Forsch et. al, 2017). This study was designed to determine the effect virtual reality experiences had on perceived pain by pediatric patients enduring a laceration repair without sedation medications.

Statement of the Problem

Firsthand experience by the researcher and anecdotal evidence from other child life professionals supports that often-pediatric sedation medications are utilized during laceration repairs despite children being assessed as capable of undergoing the procedure with alternative methods of support (distraction, coping support, step-by-step education, etc.). Typical medications include Ketamine, Propofol, Versed, and Fentanyl (Forsch et. al, 2017). Sometimes children receive one or a combination of the former medications (Forsch et. al, 2017). The medications are proved to be generally safe but can have significant and harmful side effects for some patients (Forsch et. al, 2017). If managed incorrectly, these medications can have harmful respiratory and cardiac adverse effects (Kim, Hahn, Jang, Choi, Hong, Lee, & Kim, 2019).

Alternatives to sedation medications include the child life services of procedural preparation and education (Cristal, et al. 2018). Additionally, child life specialists can provide distraction to pediatric patients to promote compliance, cooperation, and encourage positive coping (Rollins, Bolig, & Mahan, 2005). Some distraction items include iSpy books, tablets, toys that make sounds, and singing songs (Rollins, Bolig, & Mahan, 2005). The distraction technique for this study was the use of virtual reality goggles. Most people may think that virtual reality goggles are only utilized for entertainment; however, virtual reality is also being utilized for business, sports, military simulations, art, education, and rehabilitation and treatment of phobias (Virtual Reality Society, 2017). For example, virtual reality goggles are being successfully studied by researchers for use to reduce anxieties in people with obsessive compulsive disorder (OCD) by immersing participants in scenarios with varying degrees of filth in a safe, controlled, and simulated environment (Inozu, Çelikcan, Trak, Üzümcü, & Nergiz, 2021). Medically, virtual reality goggles are being utilized in many ways. Some of the uses in medical setting include reduction of perceived chronic pain (Agrawal, A.K., 2018), preparing patients for surgery (Eijlers et al., 2019) and distraction during intravenous catheter placements (Wong, Wa, Lu, & Choi, 2019).

Purpose of the Study

The purpose of this study was to determine if virtual reality goggles as distraction could provide a safe and alternative care plan to sedative medications during pediatric laceration repairs.

Research Question

The following research question guided this study:

1. What effect does the use of virtual reality goggles have on perceived pediatric patient pain during laceration repairs?

Significance of the Study

Currently in this field there is a lack of research regarding perceived pain during pediatric laceration repairs and impact of virtual reality during pediatric laceration repairs. This study provides insight to the value of utilizing virtual reality goggles as a means of pain reduction during laceration repairs.

LITERATURE REVIEW

The purpose of this study was to determine perceived pain of pediatric patients during laceration repairs while utilizing virtual reality goggles. Laceration repairs are the process of controlling the bleeding of a wound by closing the edges utilizing various materials and methods (Forsch et. al, 2017). Materials typically utilized for laceration repairs include sutures, staples, Dermabond, needles, and steri strips.When children go to the hospital, they often enter the environment anxious based on past experiences, fear of the unknown, needles and painful procedures or misconceptions of the procedures or visit ahead (Rollins, Bolig, & Mahan, 2005). Furthermore, parents or caregivers may also have stressors and needs both in and out of the hospital (Rollins, Bolig, & Mahan, 2005). Because of the implicit stressors, hospitals and clinical settings have incorporated support professionals (Thompson, 2009) and medicinal interventions (Miller, et. al, 2019) to better support patients and families in the hospital environment. This chapter will further discuss the role of Certified Child Life Specialists, possible stressors and psychosocial interventions for pediatric patients with lacerations, the utilization of procedural sedation during laceration repairs, and offer the alternative of virtual reality goggles as distraction.

Pediatric Pain

While studies show on average 80% of emergency room pediatric patients undergo some type of painful procedure, most procedural pediatric pain is either not assessed at all or under assessed (Pancekauskaite & Jankauskaite, 2018). Pain is defined as “an unpleasant emotional sensation which is associated with tissue damage which is originated from a specific region of

the body or not and also associated with the previous experiences of the individual in the past" (Top, F., & Ayyildiz, T., 2021). Pain assessment should be multifaceted and include the following seven components: "1) intensity; 2) location; 3) duration; 4) sensory qualities (e.g. word descriptors); 5) cognitive aspects (e.g. perceived impact on activities of daily life); 6) affective aspects (e.g. pain unpleasantness); and 7) the contextual and situational factors that may influence children's perceptions of pain" (2017). Knowing the components of perceived pain can lead to better and more effective pain assessment and management.

Sex Differences. Pain in both adults and children have been found to vary by sex. In adults, it is reported that females report more pain than males and have increased pain-related disability (Lynch, A., Kashikar-Zuck, S., Goldschneider, K., & Jones, B., 2007). Similarly in a study evaluating girls and boys ages eight to eighteen years old, have found that girls are more likely than boys to report greater pain intensity (Lynch, A., Kashikar-Zuck, S., Goldschneider, K., & Jones, B., 2007). While developmental differences make studying pain in children more complex, the literature states that girls over the age of eight are more likely to report their chronic pain (Lynch, A., Kashikar-Zuck, S., Goldschneider, K., & Jones, B., 2007). It is not completely understood why girls report higher pain intensity and more anxiety with pain. There are several sociocultural factors including boys underestimate pain to "appear brave" (Goodenough, B., Thomas, W., Champion, D., Perrott, D., Taplin, J. E., von Baeyer, C. L., & Ziegler, J. B., 1999). Goodenough and colleagues reveal that gender norms (society's expectations for males and females) and social constructs (social concepts that humans create and agree exist) may also be a factor in considering perceived pain differences between males and females (1999).

Age Differences. Many studies have been conducted to assess if there are differences in perceived pain as children grow and develop. Some research supports that a child's concept of pain follows the stages of general cognitive development (Harbeck, C., & Peterson, L., 1992) while others do not. In contrast to the former, researchers asked children ages four years to sixteen years old to draw and write what helps them when reporting pain. Researchers found four themes that expanded across all ages: people who help, what I do that helps, what other people do that helps, and things that help. This study concluded that a child's concept of pain may not follow Piaget's cognitive developmental stages, but a child's experience and learning (Franck, L.S., Sheikh, A., Oulton, K., 2007). Additionally, this study demonstrates that school age children understand pain and can describe pain's sensory, cognitive and emotional characteristics (Franck, L.S., Sheikh, A., Oulton, K., 2007). Furthermore, a study investigating children's self-reported pain from ages three to fifteen years old during venipuncture found, younger children tend to report higher pain than older children (Goodenough, B., Thomas, W., Champion, D., Perrott, D., Taplin, J. E., von Baeyer, C. L., & Ziegler, J. B., 1999). The former study also found that younger children are more likely to view pain in categories. To elaborate, younger children are more likely to report having pain or not having pain as opposed to rating the intensity of pain (Goodenough, B., Thomas, W., Champion, D., Perrott, D., Taplin, J. E., von Baeyer, C. L., & Ziegler, J. B., 1999).

Pediatric Pain During Laceration Repairs. Laceration repairs are common procedures in the pediatric emergency department and often causes pain and distress in children (Chumpitazi, C.E., Caviness, A.C., Grawe, G.H., Camp, E.A., & Shah, M. I., 2020). Several studies have been conducted in order to assess best practice for reducing pain during laceration repairs. In a study conducted by Chumpitazi and colleagues, eighty-five children were

randomized to either receive hydrocodone/acetaminophen or be in the placebo group prior to their laceration repair and pain scores were then recorded. The study found no significant difference in pain scores between treatment groups in eight- to seventeen-year-olds. In children two to seven years old, pain scores were significantly lower in the medication group (Chumpitazi, C.E., Caviness, A.C., Grawe, G.H., Camp, E.A., & Shah, M. I., 2020). One study conducted to determine if virtual reality could reduce pain and anxiety in children ages six to sixteen years old during a laceration repair by evaluating post procedure pain scores utilizing the Faces pain scores and post procedure level of anxiety as measured by Venham Situational Anxiety score (Goldman, R. D., & Behboudi, A., 2021). Researchers found mean post procedure scores of 2 out of 10 and mean anxiety scores of 1.9 out of 10 (Goldman, R. D., & Behboudi, A., 2021). While these scores are low, they are not significantly different from the standard of care group (Goldman, R. D., & Behboudi, A., 2021). While this research differs from several studies that show virtual reality reduces perceived pain perception in chronic pain and acute pain during medical procedures, it is of note to discuss that the pain scores post procedure did not increase as opposed to the standard care group. Additionally, both groups reported relatively low perceived pain.

Pain Management for Pediatric Lacerations Repairs

Medical teams utilize both pharmacological and non-pharmacological pain management for pediatric patients during laceration repairs.

Pharmacological. In general, there are two main methods for pediatric pharmacological pain management: topical anesthetic and sedative medications.

LET Gel Application. When a child presents to a pediatric emergency department with a laceration, there is often a protocol for registered nurses to place a topical anesthetic (i.e., LET, EMLA, etc.) to the wound prior to the physician seeing the patient (Forsch et al., 2017). Priestly, Kelly, Chow and Powell describe the exclusion criteria for LET application being "wounds involving the digits, ears, penis, nose, or mucous membranes; wounds close to the eye; deep wounds involving bone, cartilage, tendon, or muscles; wounds >6 hours old; anaesthetic application or infiltration of wound before ED presentation; and previous reaction to local anaesthesia" (2003). Reserch varies on the time needed for the application of LET get to start becoming effective. Some researchers state LET gel starts to be effective after twenty minutes of application (Harmon, S., Zemek, R., Duncan, MJ., Ying, Y., & Petrich, W., 2014) and Lambert and Goldman report the numbing effect can take up to an hour (2018). By beginning the numbing process early, children and families spend less time in the pediatric emergency department (Forsche et al., 2017). The literature reports that the application topical anesthetics in triage significanlty reduces the median treamtment time in comparison to a placebo group from 108 minutes to 77 minutes. Additionally complete hemostatsis of the wound is more common in pediatric patients who receive LET gel (Harmon, S., Zemek, R., Duncan, MJ., Ying, Y., & Petrich, W., 2014).

Prior to and sometimes in conjuction with LET providers utilize local infiltraton of one or two percent lidocaine with out epinephrine (Keyes, P., Tallon, J., Rizos, J., 1998). The utilization of injectable lidocaine often causes "intense negative emotional associations" due to the pain during the infiltration (Keyes, P., Tallon, J., Rizos, J., 1998). If providers choose to use LET and lidocaine simaltaneously, Singer and Stark conclude that LET application decreases pain of local anestheic inflitration (2000). Topical anesthetics have been proven to be effective in

reducing percieved pain during laceration repairs (Lambert, C & Goldman, R. D., 2018). Cleaning and closing wounds becomes less traumatic when LET is used combination with developmentally approprieate interventions such as parental presence, preparation and distraction (Kennedy, R., & Luhmann, J., 2001). A study conducted by Harman, Zemek, Duncan, Yin and Petrich determined the use of topical LET gel in comparison to a placebo reduced pain scores in pediatric patients during laceration repairs using tissue adhesive (2014). In a systematic review to compare infiltrated local anesthetics with topical anesthetics, Eidleman, Weiss, Enu, Lau, and Carr concluded topical anesthetics are an effective and non-invasive means for numbing a wound prior to suturing dermal lacerations (2005). A review published by the Cochrane Library, confirmed that LET gel provides sufficient pain control during a dermal laceration repair with sutures (Tayeb, B.O., Eidelman, A., Eidelman, C.L., McNicol, E.D., & Carr D.B, 2017).

Procedural Sedation. In pediatric emergency departments, procedural sedations are often used to ensure compliance and safety of pediatric patients (Miller, et al,. 2019). Sedation medications are utilized to induce clinical sleep in children often times to perform an invasive or painful procedure. A multitude of medications are utilized including ketamine, propofol, versed, and fentanyl, these differ from surgical anesthetic in which patients need to be intubated to maintain their own airway (Forsch et. al, 2017). While the child will not remember the procedure and is medically "put to sleep," there are less risks and harm outcomes to the patient when receiving procedural sedation medications compared to surgical anesthetic medications (Miller, et al., 2019). Miller Monuteaux, Bourgeois, and Fleegler (2019) reviewed several pediatric emergency departments protocols for procedural sedations and found that there is not one consistent pathway to procedurally sedate patients.

One of the most common procedural sedation medications is propofol (Kim, Hahn, Jang, Choi, Hong, Lee, & Kim, 2019). This is administered through a PIV and requires the patient's vital signs to be closely monitored by a registered nurse and physician or provider (Kim, et al., 2019). Some of the side effects from propofol can include tachycardia, hypotension, increased coughing, laryngospasm, and apnea (Kim et al., 2019). While there are very few reported cases of the more serious complications, pediatric patients are still at risk for the minor complications when being administered Propofol (Kim, et al., 2019). Other procedural sedation medications like Ketamine, Fentanyl and Versed have similar side effects and risks to patients (Miller, et al., 2019). While the former medications are given through a PIV, nitrous oxide is given through an anesthesia mask and the patient is to breath in the medication. Nitrous oxide reduces consciousness, but does not put the patient into a sedated state. Adverse effects from nitrous oxide include dizziness, nausea, anxiety, respiratory distress, bradycardia and seizures (Olsen Versen, & Stordal, 2019). Because the patient is not sedated, the recovery time is often faster in patients who received nitrous oxide.

One of the procedures that physicians tend to utilize sedation for are laceration repairs. Laceration repair is the clinical process of controlling the bleeding of a wound by closing the edges utilizing various materials and methods (Forsch, Little & Williams, 2017). Some of the materials include sutures, staples, Dermabond, and Steristrips (Forsch et al, 2017). Of the former materials the most invasive interventions are staples and sutures. When a child presents to a pediatric emergency department, there is often a protocol for registered nurses to place a topical anesthetic (i.e., LET, EMLA, etc.) to the wound prior to the physician seeing the patient (Forsch et al., 2017). By beginning the numbing process early, children and families spend less time in the pediatric emergency department (Forsche et al., 2017). Once an emergency physician or

other provider has examined the wound, they determine what materials to use, if a specialty physician needs to be consulted, and if the child may require procedural sedation in order to best close the wound (Forsche et al., 2017). If the physician or provider determines the patient requires procedural sedation, the patient must wait four to six hours from the time they last ate or had something to drink, receive a PIV, and be placed on a heart, pulse ox, and blood pressure monitor (Kuiken et. al., 2016). When put on the vital signs monitor, the child's movement is restricted. Additionally, the child may have touch sensitivities to the pulse ox, heart monitor leads, and blood pressure cuff. Restrictions in movement and touch sensitivities to the monitor can cause or increase negative emotional behavior in the child.

To sedate the child at most pediatric emergency rooms, the medical team includes a registered nurse, sedating physician or provider, procedural physician or provider, CCLS, and resident physician if the facility is an educational institution. If the patient is not sedated, often times, the procedural physician, resident physician, and CCLS are the only people needed in the procedure. Parents and caregivers are often asked to leave the procedure if a child is being procedurally sedated. The American Academy of Pediatrics published a literature review on parental presence during invasive procedures and resuscitation. The literature showed that when parents and caregivers that are allowed to be present for their child's invasive procedure or resuscitation, they are more satisfied with the medical team's care of their child. Additionally, the review found that children also benefited from the presence of their parents showing increased cooperation and less negative emotional behaviors (Digman et al., 2009).

To review, procedural sedation can cause minor, moderate and major health risks to any patient undergoing a procedure under the formerly listed medications (Miller et al., 2019). While procedural sedation medications are less likely to cause harm to the patient when

compared to anesthesia medications, there are still reported cases of complications and health risks (Miller, et al., 2019). Additionally, several more medical professionals need to be present in the instance of a procedural sedation (Miller, et al., 2019). With several adults in a procedure room, children may become more anxious prior to the procedure (Thompson, 2009). From the perspective of pediatric emergency department, pulling more team members to focus on one patient slows the care that is provided to other patients on the unit, increases patient wait times and increases the time the patient is in the pediatric emergency department (Miller, et al., 2019). Procedural sedation can be beneficial for children with baseline anxieties, neurodevelopmental disorders, and children who have had traumatic experiences in the past with medical procedures (Miller et al., 2019). However, each patient is different and will react differently to the need for the procedure (Thompson, 2009). One method CCLSs utilize to reduce anxieties during and promote positive coping during procedures is distraction (Rollins, et al. 2005).

Nonpharmacological. One alternative method to sedative medications inludes utilizing a Certified Child Life Specialist to reduce anxieties during and promote positive coping during procedures with distraction (Rollins, et al. 2005). Another alternative includes the use of virtual reality goggles as distraction to reduce pain perception in pediatric patients.

Child Life Services. Certified Child Life Specialists are college-educated (bachelor's and master's level) individuals with specific knowledge of child development, education, psychological strengths, psychosocial care, and family systems (Duda, 2018). As college educated professionals, CCLSs have specific knowledge in child development, education, family systems, psychological, and psychosocial needs (Duda, 2018). Additionally, CCLSs work with patients and families to educate, develop coping plans, provide psychosocial support for upcoming procedures, hospitalizations, new chronic, acute or terminal diagnoses, trauma, cardiac

and pulmonary resuscitations, and bereavements (Thompson, 2009). Through play (Thompson, 2009), CCLSs help to normalize the hospital setting or any setting that may be stressful for a child, role play future procedures, exams, or experiences. The education and support of a child life specialist can reduce pain and increase patient and family satisfaction. Using play and psychological preparation as primary tools, child life interventions facilitate coping and adjustment at times and under circumstances that might otherwise prove overwhelming to children and families (Duda, 2018). Often, if thoroughly prepared for the procedure, educated on the need to hold still and the patient's role, and an effective coping plan is implemented by a Certified Child Life Specialist (CCLS), patients will comply for the medical team. Children can prove to be cooperative and safe without the need for medicinal intervention for sedation to complete procedures and other medical interventions. Cristal et al. (2018) conducted a study of seventy-eight children requiring peripheral intravenous catheterization (PIV) placement for their treatment. The research indicated when a CCLS was included in the care plan to provide services to the patient and family, fewer negative emotional behaviors were observed and there was a statistically significant reduction on patients reporting their pain on the Wong-Baker FACES pain scale (Cristal et al, 2018). Frequently, children out of fear of pain or the unknown display increased negative emotional behaviors including crying, screaming, hiding, attempting to run away, or non-compliance (Rollins, Bolig, & Mahan, 2005). These behaviors make it difficult for the medical team to perform the procedure or task at hand and can cause emotional or psychological trauma to the child to continue with the procedure by means of restraint or sedation. By including child life services prior to the procedure, the CCLS can normalize the hospital environment, introduce play into the environment, and reduce stress and anxieties. Then, when the patient needs to undergo an invasive or non-invasive procedure, rapport has been

established and the patient is more likely to trust the medical team and care plan. In turn, if the patient has established respect for the medical team and plan, they are more likely to comply (Rollins, Bolig, & Mahan, 2005).

Distraction. Distraction is a common intervention in order to manage patient anxieties, and promote non-medicinal pain control (Rollins, et al. 2005). One of the primary roles of a CCLS is to provide procedural education, procedural support, and distraction to ensure a pediatric patient and their family cope through any invasive or non-invasive medical procedure. A CCLS may use a book or tablet to show the patient pictures of the procedural steps in order, or, if safe, may use the real medical equipment in order to desensitize and educate the patient and family of their purposes (Duda, 2018). Then, the CCLS may create a coping plan to include a comfort position, distraction technique, and/or coping technique such as deep breathing or guided imagery. These options help a child to regain control over an environment that can seem very chaotic (Duda, 2018). When a child feels a greater sense of control, they are oftentimes more cooperative with the task at hand and display less negative emotional behaviors (Rollins, Bolig, & Mahan, 2005). During the procedure, the CCLS focuses on the need and questions of the child while engaging them in the predetermined distraction activity or coping plan (Thompson, 2009). This allows the medical team to strictly focus on the task or procedure they need to perform (Duda, 2018). Distraction items may vary depending on the procedure, the child's development, and chid's coping style (Thompson, 2009). Examples of commonly used distraction items include, rattles, toys that make sounds, tablets, look and find books, and light spinners (Thompson, 2009).

Furthermore, several healthcare providers and institutions are incorporating technology into their practice due to a changing society that is more familiar and dependent on the use of

phones, tablets, computers and other technology (Oliveira Freitas & Spadoni, 2019). By incorporating technology into medical practice as a distraction, education, or preparation tool, health care institutions are normalizing the clinical environment to meet social standards (Rollins, et al., 2005). In an article published by Boston Children's Hospital, children ages five to eight spend nineteen minutes a day playing computer or console games and 21 minutes playing mobile games, children ages eight to twelve spend 55 minutes playing computer or console games and 34 minutes playing mobile games and teenagers spend 69 minutes playing computer or console games and 27 minutes playing mobile games (2021). When patients and families can find familiarity in the environment, anxieties and stressors are reduced by the previously established knowledge of technology (Rollins, et al., 2005). As previously stated, distraction is also utilized for non-medicinal pain control. Pain assessment is vital when determining whether distraction is sufficient for the procedure or if medication may also be needed to complete a procedure.

Virtual Reality Goggles. On a long list of games, books, and other tools to reduce pain perception and promote positive coping is the use of virtual reality technology in the form of goggles (Arane et al., 2017). Virtual reality goggles are a computerized technology that has a head mounted display (Arane et al., 2017). The headset tracks the person's head movements and the screen display changes in order to explore a 3-dimensional simulated environment (Arane, et. al., 2017). The goggles can be utilized to play games, adventure through virtual worlds, and immerse a person in an augmented reality (Arane, et al., 2017).

One thing virtual reality goggles are being researched for is reducing pain perception in pediatric patients. Since pain is complex and includes psychological, behavioral, sensory, and cognitive components, when attempting to reduce a painful experience, one must address all of

the pain components (Arane et. al., 2017). Because virtual reality provides visual distraction, behaviors are focused on the task presented in the goggles and not on the invasive or painful procedure. In turn, when engaged, patients report less anxiety and less pain in the procedure (Arane et. al., 2017). To elaborate, studies have been conducted in clinical settings to determine if virtual reality reduces acute and chronic pain when conducting various procedures that involved needles. In California, two hundred and forty-four children utilized virtual reality prior to, during and after an influenza vaccination and on a questionnaire reported up to 74% decrease in pain in comparison to former experiences with the vaccine (Arane et. al., 2017). In a different study cited by Arane et al., (2017), eleven adult and pediatric burn patients reported on a scale of 0-10 found a 35% to 50% decrease in perceived pain when undergoing a dressing change and utilizing virtual reality goggles. Furthermore, Chinese researchers Wong, Wa, Lu, and Choi (2019) recruited two-hundred pediatric patients age four to twelve to determine if virtual reality reduced pain, anxiety, and stress when undergoing venipuncture. Thus far in their research trial, the researchers report the study is proving to significantly reduce both pain perception and anxieties in pediatric patients (2019). Another study showed that childhood cancer patients age seven to nineteen years old who were receiving a port access as part of their outpatient treatment, displayed decreased pain utilizing a visual analogue scale and anxieties when utilizing virtual reality goggles as distraction when compared to children who utilized other forms of distraction, or topical anesthetic cream (Arane et. al., 2017). Additionally, virtual reality goggles have been studied in pre-operative settings. Eijlers et al., (2019) assessed that pre-operative anxiety in children is common and often leads to negative emotional behaviors. Therefore, a study was conducted for children four to twelve years of age undergoing elective maxillofacial, dental or Ear Nose and Throat (ENT) day care surgeries. The former surgeries generally have a quick

recovery rate and patients are likely to be discharged from hospital care the same day the surgery was conducted. On the virtual reality goggles, there is an application that prepares the child for the pre-operative to post-operative process and care plan. The patients wore and engaged in the goggles until anesthesia was induced on the operating table. The study found that there was a statistically significant reduction in the need for rescue analgesia when children engaged in virtual reality preparation when compared to the control group (Eijlers et al., 2019). More specifically, the use of virtual reality goggles has been proven to reduce the perception of pain during invasive procedures and also utilized to reduce anxiety (Arane, Behboudi, & Goldman, 2017).

At Benioff Children's Hospital, researchers developed their own virtual reality goggles for children who were in a sickle cell acute pain crisis. Among twenty-five participants ages ten to twenty-five years of age, resear…..chers reported a 16% reduction in pain perception on the Adolescent Pediatric Pain Tool (APPT) and a 33% reduction in pain descriptors (Agrawal, A.K., 2018). The previously explained studies show virtual reality has a statistically significant effect on reducing patient anxiety, stress and pain perception during painful and invasive procedures including those that involve needles. Virtual reality is effective for reducing pain perception during invasive and painful procedures and episodes of acute pain in that pain requires a person to pay attention to the mechanism of pain (Arane et al., 2017). When attention is channeled into a distracting activity or virtual reality, the patient has a lower response to the pain.

Summary

In closing, pediatric patients and families have several stressors and anxieties when entering the clinical or hospital environment. Invasive procedures, such as laceration repairs, that

involve needles or other painful stimuli can increase negative emotional behavior and decrease compliance and cooperation in pediatric patients making it difficult for physicians and other providers to conduct the procedure safely and effectively. Historically, when children display negative emotional behaviors, physicians and other providers choose to procedurally sedate children which requires more medical professionals, more resources, and increases physical and medical risk to the pediatric patient. Many studies show that when CCLSs are involved in the procedural preparation and education of patients and families prior to procedures, as well as the coping plan and distraction during procedures, children display less negative emotional behaviors, less pain, and provide a safer environment to conduct the procedure. One tool that CCLSs can utilize to provide distraction and has been proven to reduce pain and anxieties in invasive and painful procedures is virtual reality goggles. While there is no research on the effects of virtual reality goggles during laceration repairs, and the impact of pain perception and anxiety in pediatric patients, the literature suggests that diverting the patient's attention into a 3-dimentional world will slow the pediatric patient's pain response and ultimately reduce the need for procedural sedation in pediatric patients. This demonstrated the need to study best practice for providing care and alternatives to procedural sedation during pediatric laceration repairs.

METHODS

The purpose of this study was to evaluate perceived pain of pediatric patients utilizing virtual reality goggles for non-medicinal pain control during laceration repairs. This section will elaborate on the details of the research design, participants, ethical considerations, instrumentation, role of the researcher, and data analysis.

Research Design

In order to assess the impact of percieced pain throughout laceration repairs in this setting, a descriptive design was utilized. This design allowed for this reasearcher to explain and analyze the reported pain scores given by participants with minimal risk of bias (Creswell & Creswell, 2018). Moreover, a descriptive design allowed for the assessment of whether virtual reality goggles during laceration repairs reduced a pediatric patient's perception of pain control before, during, and after the procedure (Cresswell & Cresswell, 2018).

Site of the Study

The study took place in an urban pediatric Level 1 Trauma Center and Emergency Department in the Midwest. The estimated population of the city in the 2019 census is 300,576 people with 19.4% of those being under the age of eighteen years old (United States Census Bureau, 2019). 47.6 % of the population identify as white alone and 45.9% Black or African American (United States Census Bureau, 2019). Additionally, 12.6% of the population is without healthcare, and 22.8% of the population lives below the poverty line (United States Census Bureau, 2019). The children's hospital where the study took place has 195 beds with inpatient

and outpatient clinical settings (SSM Health Cardinal Glennon Children's Hospital, 2020). Furthermore, the hospital has more than 200 specialists and 60 subspecialties (SSM Health Cardinal Glennon Children's Hospital, 2020). The pediatric emergency department has the highest volume in the region seeing over 60,000 children annually (SSM Health Cardinal Glennon Children's Hospital, 2020). All procedures were conducted by physicians or nurse practitioners and conducted in the patients' exam room. There are no procedure rooms in this pediatric Level 1 Trauma Center Emergency Department.

Participants

Due to the age restrictions of Starlight, the company of the virtual reality goggles utilized for this study, eligible participants included children ages six to seventeen years old (Arane, Behboudi, & Goldman, 2017) who underwent a laceration repair utilizing sutures in the Level 1 Trauma Center and Emergency Department (n=17). Participants had LET, a topical anesthetic, applied to their wound prior to laceration repair. This excluded pediatric patients with wounds on ears, nose, fingers, and toes as LET is not approved for use in these areas. Participants were also required to have the cognitive ability and language skills to verbalize perceived pain scores, in order to have participated in the study; this was determined by the developmentally trained researcher and the patient's caregiver(s). Participants were excluded if they had a previous history of seizures, light sensitivity, motion sickness, if the patient was on spinal precautions, or if the wound was on the head or face (Oliviera-Freitas & Spadoni, 2019).

Ethical Considerations

Parents signed a consent form allowing researcher to utilize their child in the study and allowing the researcher to utilize non-identifying information from their child's chart (see Appendix A). This included the child's age, sex, pain scores. The patient was also required to give verbal permission to utilize the virtual reality goggles during their laceration repair (see Appendix B). If the patient refused and chose an alternate means of distraction for the procedure, the patient was ineligible for the study. Pseudonyms were utilized to protect the identity of the patients. The patient remained protected by HIPPA and hospital privacy laws and regulations. This researcher has completed CITI training and understands the ethics needed in order to have conducted this study (see Appendix C). Research was approved by both the Missouri State University (see Appendix D) and Cardinal Glennon Children's Hospital (see Appendix E) Institutional Review Boards.

Data Collection Procedures

While parents were encouraged to stay in the room for the laceration repair, it was at the parents' discretion if they chose to stay for the laceration repair or wait in the waiting room. Once consented, the unit child life specialist provided developmentally appropriate preparation, education, and developed coping plan with each patient in the study. Then, the child life specialist asked the patient utilizing the Baker-Wong FACES (see Appendix F) pain scale to rate his or her pain. Once the child life intervention was completed and prior to the laceration repair, the researcher asked patients if they want to utilize the virtual reality goggles for part of their coping plan and distraction. If the patient chose to utilize virtual reality goggles, the researcher instructed the patient on how to utilize the goggles and adjusted them to fit the patient. The

patient chose any of the preloaded games or activities on the virtual reality goggles. The laceration repair began shortly after the patient was engaged in the virtual reality goggles. At the end of the procedure, virtual reality goggles were removed from the patient's head, and the patient was asked to rate their pain during and after the procedure utilizing the Wong-Baker FACES pain scale. The researcher utilized a data table in order to organize and document each patient's data (see Appendix G).

Instrumentation. There were two instruments that were utilized for this study. The first instrument used was Wong-Baker FACES Scale, a scale from 1-10 with cartoon faces horizontally over the numbers that have expressions of varying pain (Craveo, et al, 2012). This was utilized to best assess the pediatric patient's perception of pain throughout the laceration repair (see Appendix D). Additionally, the researcher utilized a data table to record and report pain scores (see Appendix E).

Role of the Researcher. Throughout the study, this researcher acted as the CCLS during the laceration repair. This role included preparing and educating the patient and family prior to the procedure, explaining the study, engaging the patient in the virtual reality goggles, and assisting with positive coping and compliance throughout the procedure. The researcher then kept all of the consents, collected and analyzed research data.

Data Analysis

Descriptive statistics were utilized (Pryczak & Oh, 2018) in order to best evaluate patients' overall pain score before, during, and after the laceration repair. First, the reported pain scores were evaluated pre, mid and post procedure for each participant and evauated for trends. Second, trends, were evauated for changes between pre-mid, mid-post procedure pain scores.

The data were then further analyzed by average pain score reported versus the age of the participant as the researcher in this study wanted to assess if there were developmental differenced between reported pain scores. Next, the average percieved pain scores were analyzed by sex. It is understood by researchers that males and females have different pain perceptions both in the way they anatomically receive pain (Kim et. al., 2020) and how they report pain (Aufiero, Stankewicz, Quazi, Jcoby, & Stolzfus, 2017). As one of the independent variables in this study was the application of LET, it was analyzed how long LET was applied and what pain scores are reported. The pain scores were categorized into low, moderate and high and then compared to the average amount of time LET was placed when those pain scores were reported. This was analyzed to assess if patients with lower reported pain scores had LET applied for a particular amount of time and to assess the effects of LET in comparison to the immersion factors of virtual reality. To evaluate degrees of change in average reported pain scores in the varying categories over the course of the procedure in comparison to LET time. Furthermore, the reported pain scores reported for each participant was divided into time increments and compared to the amount of time the participant had LET applied prior to the start of the procedure. Finally the data analysis broke down the LET time into incraments to further analyze degrees of change during for every fifteen minutes.

RESULTS

Utilizing virtual reality goggles during laceration repairs in pediatric patients reduced the amount of procedural medications utilized for this procedure, increased patient safety, and in a majority of patients, reduced the patient's overall pain perception, and provided a positive experience for the patient and family. In this study there were 17 participants (n=17). Ages ranged from 6 years to 16 years old, with an average age of 9.65 years. Participants were asked to provide a pain score utilizing the Wong Baker FACES scale where a "0" indicates no pain and "10" is the most pain. There were 9 (53%) males and 8 females (47%) in the study. The average time LET was on prior to procedure start time was 61.71 minutes with a range from 141 minutes to 19 minutes. Out of 17 participants 16 were able to complete the procedure with virtual reality goggles as distraction and no additional sedative medications. The one participant unable to complete the study and required additional sedative medications in order to safely complete the laceration repair. Eight participants chose to play a game on the virtual reality goggles during the procedure, one participant chose a virtual experience, and seven chose to both play a game and engage in a virtual experience.

Below are the reported pre, mid and post procedure pain scores for each participant (See Table 1).

Table 1. Pre, Mid and Post Procedure Reported Pain Scores

Participant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Pre Procedure Pain Score	0	10	7	10	10	8	0	0	2	2	6	8	5	0	5	8	2
Mid Procedure Pain Score	0	8	0	4	3	0	0	0	0	0	3	0	0	0	N/A	0	0
Post Procedure Pain Score	0	6	0	5	3	0	1	0	0	0	0	0	0	0	N/A	0	0

The mode mid and post procedure pain scores were reported at 0. None of the participants who completed the study reported higher mid procedure pain scores than pre-procedure pain score (see Figure 1). Only one participant had a higher post procedure pain score (1) than mid (0) and pre procedure pain score (0). One other participant reported the same mid procedure and post pain score (3) that was lower than the reported pre-procedure pain score (10).

The figures in Table 2. are further demonstrated in the next three scatter plots. There is a larger degree of change noted between the reported Pre to Mid pain scores (see Figure 2) than Mid to Post pain scores (see Figure 3). Figure 4 demonstrates the overall degrees of change from the baseline pain score reported to the post procedure pain score. Table 3 demonstrates the average reported pain scores divided by age group. When broken down by age, 9-11 year olds reported, on average, the highest pre procedure pain scores at 10 (see Figure 5). Average pre procedure pain score for 6-8 year olds was 4.22, 12- 14 year olds reported an average of 4.66 and 15 to 18 year olds reported an average of 8 (see Figure 5.)

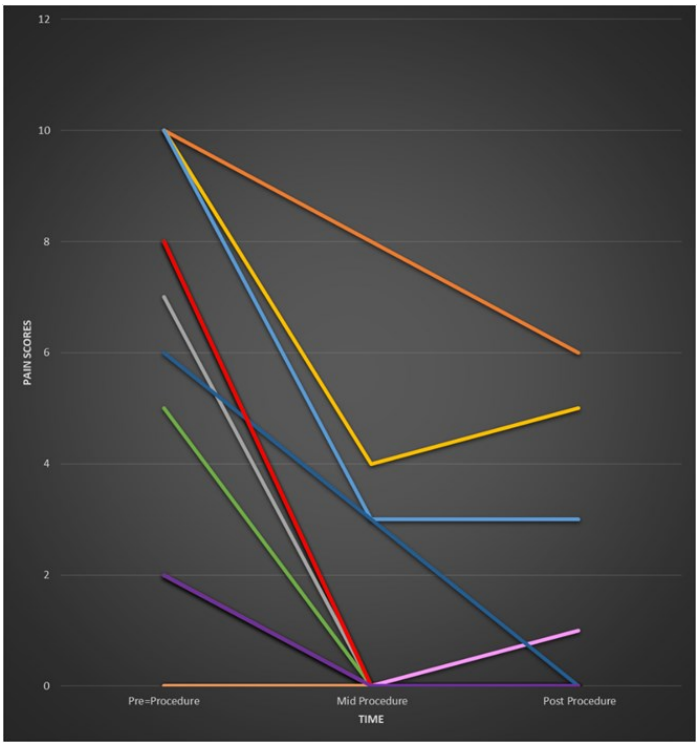

Figure 1. Reported Pain Score Trends by Participant

Table 2. Pain Score Degrees of Change

Participant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Degree of Change Pre to Mid	0	-2	-7	-6	-7	-8	0	0	-2	-2	-3	-8	-5	0	N/A	-8	-2
Degree of Change Mid to Post	0	-4	-7	-5	-7	-8	1	0	-2	-2	-6	-8	-5	0	N/A	-8	-2
Degree of Change Pre to Post	0	-2	0	1	0	0	1	0	0	0	-3	0	0	0	N/A	0	0

Also, 9-11 year olds reported the highest average for mid-procedure pain scores at 8 (see Figure 5). On average 6-8 year olds reported mid procedure pain score of 4, while 12-14 year olds reported an average of 1.2, and 15-18 year olds reported an average of 0 (see Figure 5).

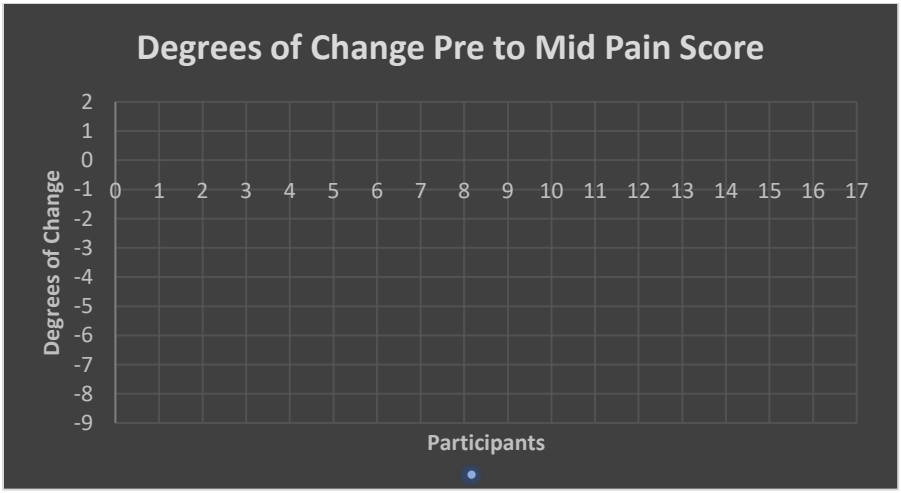

Figure 2. Degrees of Change Pre to Mid Pain Score

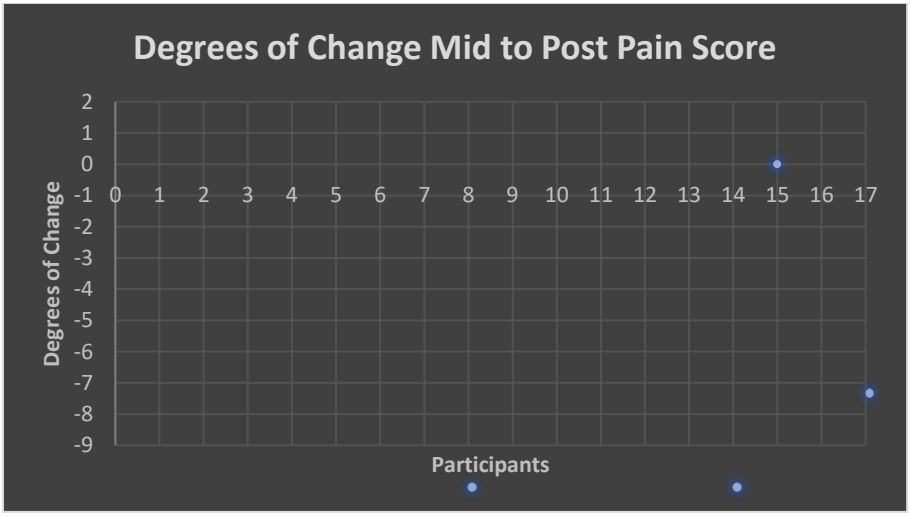

Figure 3. Degrees of Change Mid to Post Pain Score

For the average post procedure pain score 9-11 reported the higest average at 6 (see Figure 5). 6-8 year olds reported an average post procedure pain score of 5, 12-14 year olds reported an average of 0.8 and 15-18 year olds reported a post procedure pain score of 0 (see Figure 5).

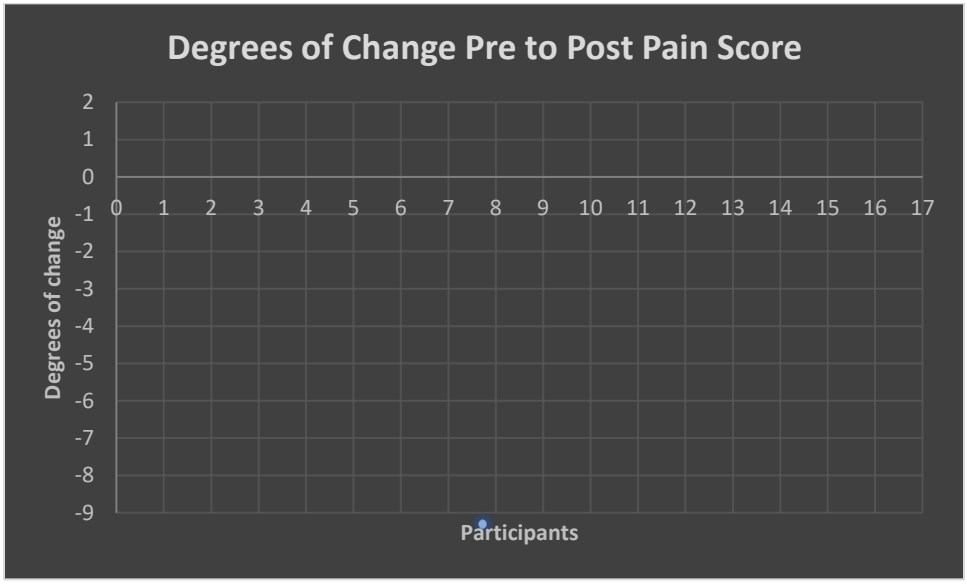

Figure 4. Degrees of Change Pre to Post Pain Score

Table 3. Average Reported Pain Scores by Age

	Pre	Mid	Post
6 to 8 years	4.22	4	5
9 to 11 years	10	8	6
12 to 14 years	4.66	1.2	0.8
15 to 18 years	8	0	0

Table 4 exemplifies the average reported pain scores for males and females at the varying times of the procedure. Males on average reported a lower pre procedure pain score than females

at 4.22 compared to 5.63 (see Figure 6). Males reported on average a 0.5 mid-procedure pain scores in comparison to their female counterparts at 1.75 (see Figure 6). Males also reported a lower average post procedure pain score at 0.75 in comparison to females who reported 1.125 (see Figure 6).

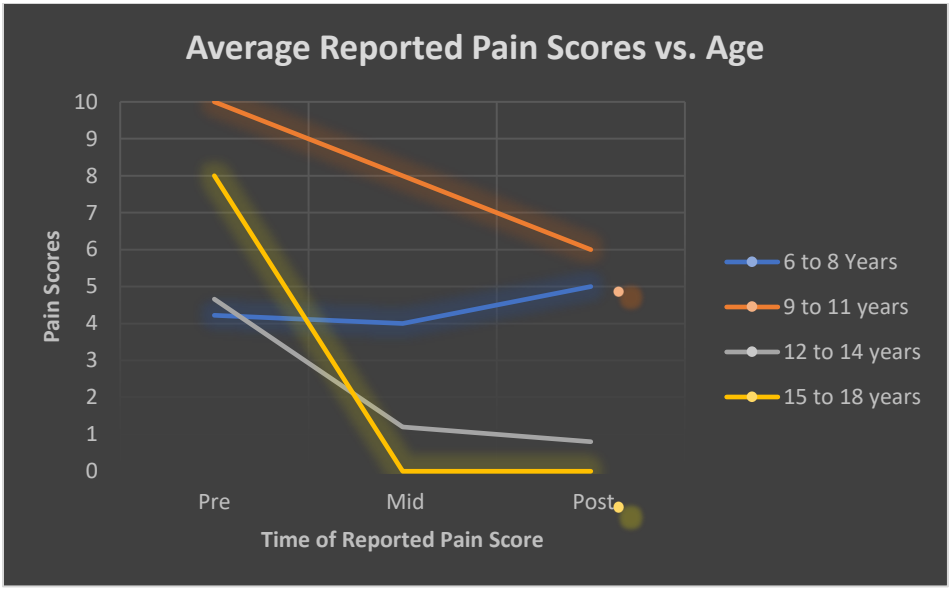

Figure 5. Average Pre-Procedure Pain Score vs. Age

Table 4. Average Reported Pain Score vs. Sex

	Pre	Mid	Post
Male	4.22	0.5	0.75
Female	5.63	1.75	1.125

Table 5 reports the mid and post procedure pain scores divided into low, moderate, and intense pain in comparison to the average time LET was applied when those scores were

reported. These data in Figure 7 are the same for both reported mid and post pain scores as the participants fell in the same range for both categories.

The degrees of change for average LET time by participant are displayed in Table 6. Please note participant fifteen did not complete the study (see Table 6). Data show no positive degrees of change after forty minutes of let time (see Figure 8). There are positive degrees of change at twenty-seven minuntes of LET application (see Figure 8).

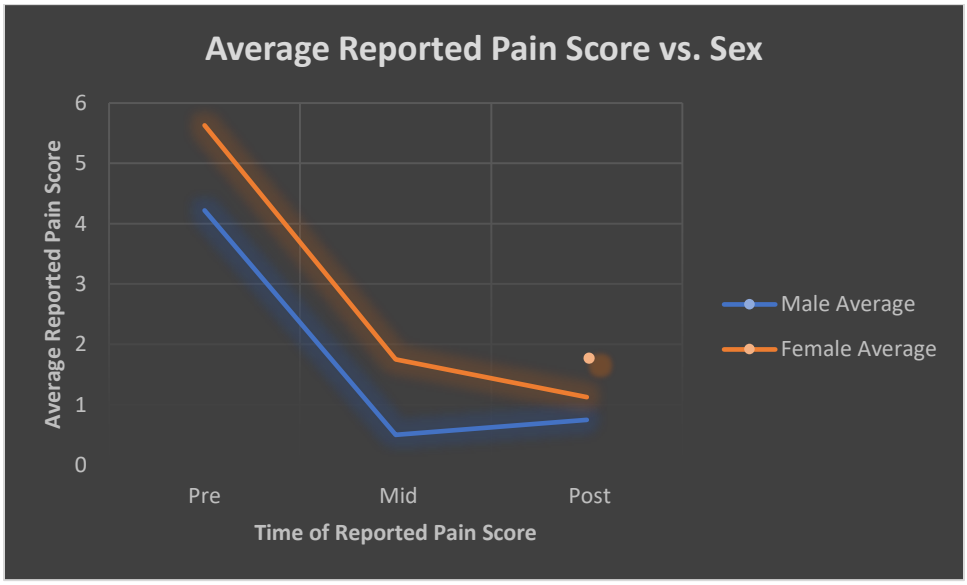

Figure 6. Average Reported Pain Score vs. Sex

Table 5. Pain Score vs. Average LET Time

Classified Pain	Mid Procedure Pain Scores	Average LET Time (mins)	Classified Pain	Post Procedure Pain Scores	Average LET Time (mins)
Low	0-3	59.64	Low	0-3	59.64
Moderate	4-6	53	Moderate	4-6	53
High	7-10	90	High	7-10	90

The average reported pain scores in comparison to LET times in fifteen minute incraments is in Table 7 (see Table 7).

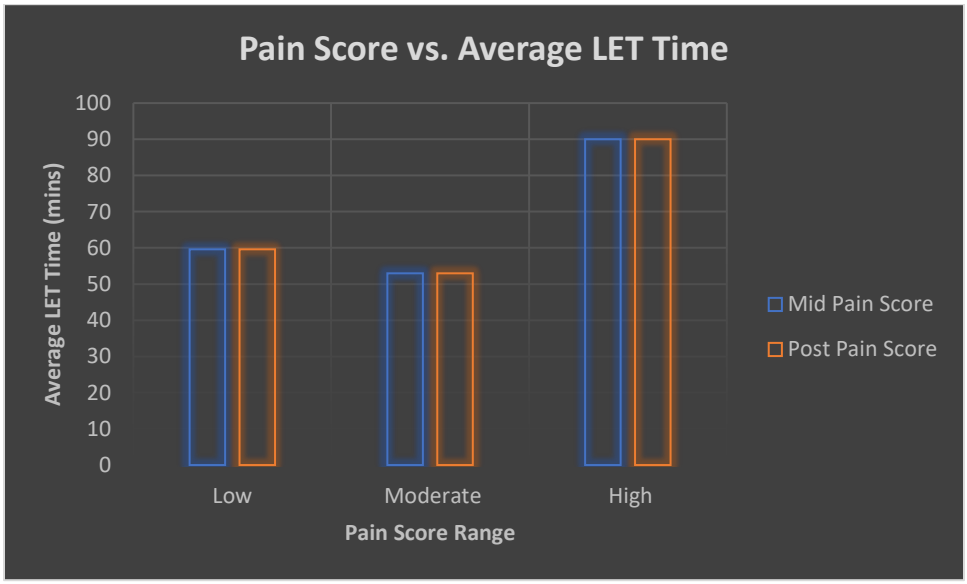

Figure 7. Pain Score vs. Average LET Time

Table 6. LET Time vs. Degrees of Change

Participant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Let Time (mins)	45	90	40	53	19	125	27	57	84	65	76	38	60	15	71	141	43
Degrees of Change Pre to Post	0	-4	0	-5	-7	-8	1	0	-2	-2	-6	-8	-5	0	N/A	-8	-2

All reported average pain scores decreased based on LET time from pre procedure pain score to mid (See Figure 8). The only increase in average reported pain score from mid procedure to post procedure was in the forty-six to sixty minute LET time frame (See Figure 8). In comparison to average pre procedure pain score, all post procedure scores were reduced (See

Figure 8). Table 8 notes degrees of change pre to mid procedure, mid to post procedure and pre to post procedure for LET time in fifteen-minute increments. The greater degrees of change happened between reported pre and mid procedure pain scores, with the largest degree of change in the 121 to 135 minute and 136-to-150-minute intervals at negative eight degrees of change (see Figure 9).

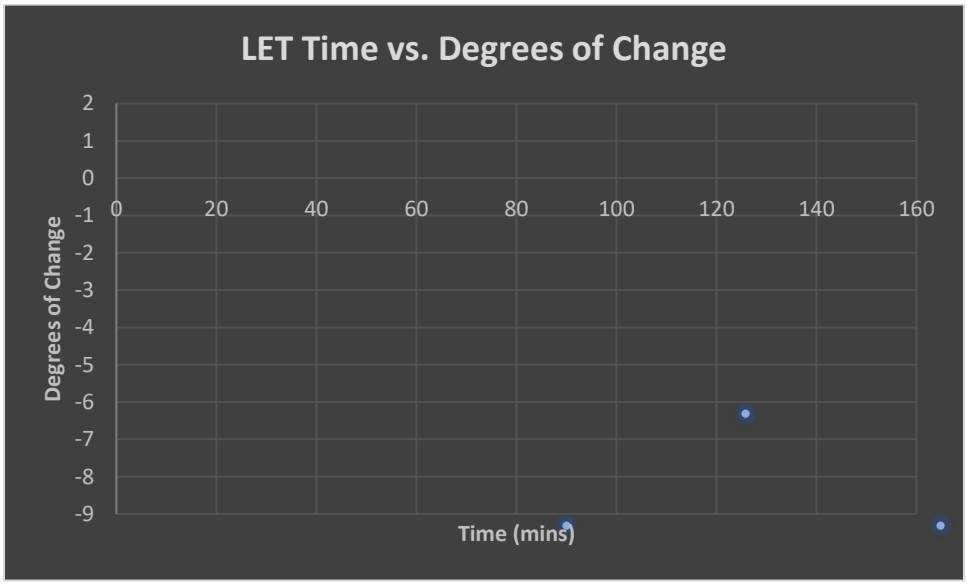

Figure 8. LET Time vs. Degrees of Change

Table 7. LET Time vs. Average Pain Score

Average Let Time (mins)	15- 30	31- 45	46- 60	61- 75	76- 90	91- 105	106- 120	121- 135	136- 150
Average Pre-Procedure Pain Score	3.33	5.6	5	2	6	N/A	N/A	8	8
Average Mid-Procedure Pain Score	2.3	0	1.3	0	3.6	N/A	N/A	0	0
Average Post-Procedure Pain Score	1.3	0	1.6	0	2	N/A	N/A	0	0

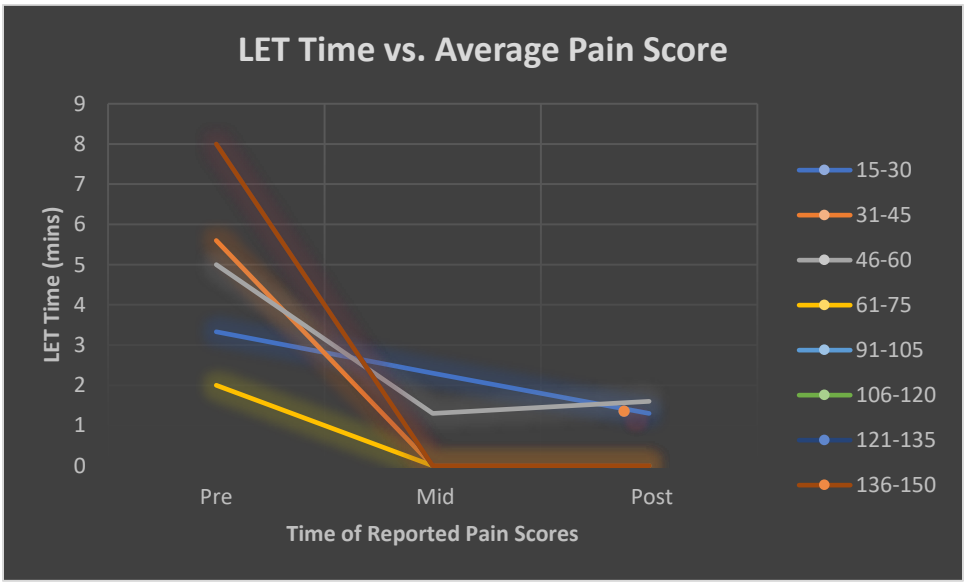

Figure 9. LET Time vs. Average Pain Score

Table 8. LET Time vs. Degrees of Change

Average Let Time	15-30	31-45	46-60	61-75	76-90	91-105	106-120	121-135	136-150
Average Degrees of Change Pre to Mid	-1	-5.6	-3.7	-2	-2.4	N/A	N/A	-8	-8
Average Degrees of Change Mid to Post	-1	0	0.3	0	-1.4	N/A	N/A	0	0
Average Degrees of Change Pre to Post	-2	-5.6	-3.4	-2	-4	N/A	N/A	-8	-8

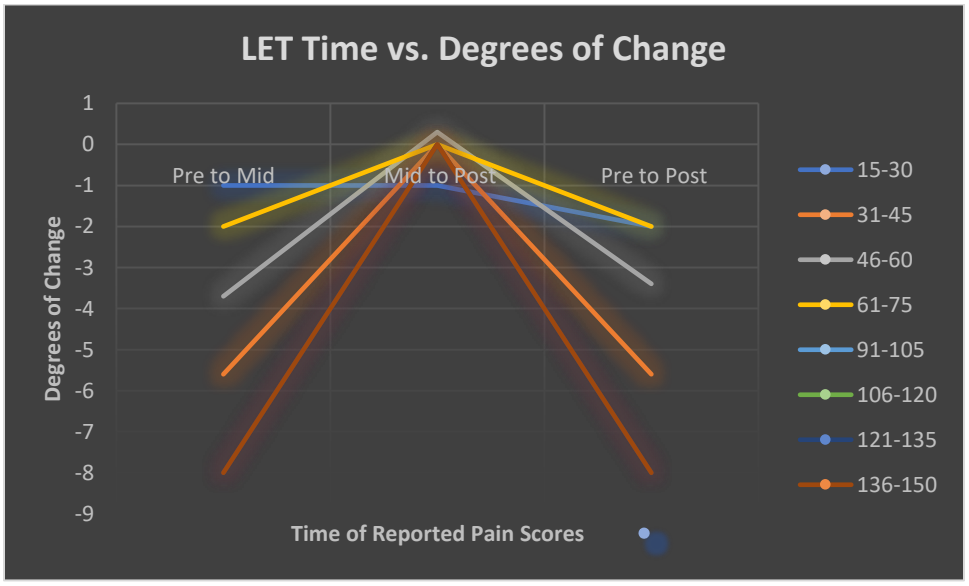

Figure 10. LET Time vs. Degrees of Change

DISCUSSION

The goal of this study was to determine how virtual reality effects pain scores during laceration repairs. Furthermore, this study aimed to determine if virtual reality goggles could provide a safe alternative to sedation medications for invasive procedures in pediatric patients.

Seventeen pediatric patients were consented and enrolled in the study. Sixteen of the seventeen participants were able to complete the laceration repair with virtual reality goggles as distraction and no sedative medications. This was significantly higher than this researcher hypothesized. With the exception of the six- to eight-year-old age group, in each age group, average pain scores decreased from pre-procedure to post procedure. The six- to eight-year-old average pain score went up from a mid-pain score of four to a post pain score of five. However, the reported average pain score for this group did decrease from a pre pain score of 4.22 to an average mid pain score of 4. This indicates that being in a virtual world may decreased perceived pain. While most of the participants reported less pain in their mid and post procedure pain scores, one participant reported an increase in pain from mid-procedure to post procedure. Another participant reported less pain between pre and mid pain score reports and reported the same pain between mid and post procedure reports. This researcher concludes these participants were deeply engaged in virtual reality as distraction, and when the repair was complete, realized they still had pain.

To further evaluate the data, there could be a developmental correlation to consider when evaluating effectiveness of virtual reality goggles as non-medicinal pain control. The formerly discussed article published by Boston Children's Hospital elaborates on the average amount of time children spend with technology and suggests that younger children are less sensitized to

technology and may indicate a greater immersion effect when engaging in virtual reality (2021). On the other hand, teenagers who are more inclined to play video games may also have a similar immersion effect. As children of middle age may be desensitized to video games but still enjoy playing both video games and engaging in dramatic and other types of play, this could decrease the immersion effect of virtual reality as indicated by increased pain scores in the middle age groups of this study. More research should be done to draw further conclusions based on age.

Females reported higher average pain scores in comparison to males, a finding consistent with previous literature (Aufiero, Stankewicz, Quazi, Jcoby, & Stolzfus, 2017). Further understanding of this phenomenon can be found in a study done by Kim et al. (2020), that described pain is linked to various neurological pathways allowing for researchers to study biological sex differences in the way humans respond to pain (2020). What researchers found that "men and women had distinct and functional band involvement in the dynamic neural interactions associated with pain processing suggesting sex differences in the underlying brain mechanisms of pain processing" (Kim et. al., 2020). Therefore, this study similarly identified that female patients report on average higher pain scores than their male counterparts. This information helps medical teams create better care plans for pain management. It may indicate that females are more likely to require more non-pharmacological or pharmacological support during painful and invasive procedures. More research is required to determine what pain management care plan is most effective when comparing males and females.

Additionally, there is a larger degree of change between reported pre pain scores and mid as opposed to reported mid to post pain scores. LET application times were not standardized in this study and could have had an effect on the results. The only increase in degrees of change was from mid to post procedure pain score. This supports earlier inferences of an immersion

effect. Singer and Stark state that LET needs up to sixty minutes to be fully effective (2000). Nine of the seventeen participants in this study had LET applied for less than sixty minutes. This could have affected the outcome of the study. This study did not have consistent LET times. It would be recommended for future studies to have one less variable and set a consistent LET time. Lidocaine was also utilized on all of the lacerations in this study. The participant that was unable to complete the study, was non-compliant with lidocaine injections. Future studies may evaluate virtual reality without the use of lidocaine injections.

The conclusion is when pediatric patients utilize virtual reality goggles during laceration repairs, patients report a decrease in perceived pain.

Limitations

This researcher was limited to patients entering an urban Level 1 Trauma Center and Emergency Department. This reduced the number of participants as this study was conducted by one researcher at one hospital. Additionally, due to convenience sampling this researcher had limitations over cultural diversity, age diversity, and sex diversity. The number of participants (n=17) is a small sample and may have affected the results of this study. Furthermore, children with a head laceration were not able to participate in the study due to the needed mobility of the head to utilize virtual reality goggles. Children with severe developmental delays were not able to participate due to the child's inability to verbalize pain scores. Finally, children with seizure disorders were not able to participate as virtual reality goggles increase the child's risk for having a seizure. Pain scores could have been affected by the varying time for LET application. Each participant had LET applied for a different amount of time which could have affected the effectiveness of the LET.

Conclusion

CCLSs work to provide procedural preparation, support and distraction to ensure positive coping during invasive and painful procedures (Duda, 2018). Pain is multifaceted (Manworren & Stinson, 2017). Two of the components of pain outlined by Manworren and Stinson are sensory qualities and contextual and situational factors (2017). Pre-procedure anxiety in children is common and often leads to negative emotion behaviors and unsafe conditions for completing procedures (Eijlers et al., 2019). Therefore, children who engaged in a diversional activity, such as virtual reality goggles, where vision is blocked from the pain and the environmental stressors of the hospital are reduced through play (Rollins, et al., 2005) are more likely to report lower pain scores. Developmental knowledge of pain was also not evaluated during this study and could be a factor for increased post procedural pain scores (Rollins, et al., 2005).

Virtual reality goggles are included in the tools that CCLSs utilize to reduce pain perception and promote positive coping (Arane et al., 2017). Virtual reality has been studied in children who were undergoing painful and invasive vaccinations, burn dressing changes, port accesses (Arane et al., 2017), and venipuncture (Wong, Wa, Lu & Choi, 2019). Additionally using virtual reality goggles for pre-operative preparation showed reduced anxiety in pediatric patients (Eijlers et al., 2019). All of the former studies found reduced reported pain scores when utilizing virtual reality goggles during invasive and painful procedures. While there is still more research to be conducted, based on previous studies conducted on varying procedures, and this study, this researcher concludes that virtual reality goggles are an effective form of non-medicinal pain control during pediatric laceration repairs.

Future Research

Currently, there is no comparative research to determine how virtual reality effects reported pain and compliance in pediatric patients undergoing laceration repairs. This researcher calls for future research to study the use of virtual reality goggles during laceration repairs. To elaborate, studies on pediatric compliance rates, studies conducted in varying hospitals, and studies with a larger sample would contribute to knowledge on this subject. Additional research could be conducted studying cultural components of pediatric patients reported pain utilizing virtual reality goggles during laceration repairs. Does race, ethnicity, or socioeconomic status effect reported pain scores? Furthermore, other contributions could include studies with a control group reporting pain scores utilizing virtual reality goggles in comparison to reporting pain scores utilizing other modes of distraction.

Summary

In pediatric emergency departments, procedural sedation is utilized to ensure compliance and safety of pediatric patients (Miler, et al., 2019). A laceration repair is painful and invasive and often leads physicians to sedate pediatric patients for the procedure. This researcher concludes that there are alternatives to sedation medication when considering reported pain. Certified Child Life Specialists can utilize education, procedural support and distraction to help promote positive coping, reduce pain, and increase compliance (Duda, 2018). Virtual reality goggles are a computerized technology that can be utilized to immerse a person in augmented reality and reduce painful experiences (Arane, et al., 2017). When utilized after preparation and education from a CCLS, virtual reality goggles reduce reported pain scores in pediatric patients during laceration repairs.

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APPENDICES

Appendix A: Parent/Legal Guardian Informed Consent Form

Informed Consent

Instructions: Provide information in the sections below, replacing italicized directions/guidance (in this font color) with the appropriate information about your research protocol. If any sections do not apply to the research you will be conducting, delete those sections from the form. Be sure to use "lay" language and should be written at an 6th grade level.

I am asking you to participate in a research study. This form is designed to give you information about this study. I will describe this study to you and answer any of your questions.

Project Title: Utilizing Virtual Reality Goggles During Pediatric Laceration Repairs to Reduce Perceived Pain in Pediatric Patients

Principal Investigator: Emily Bozzer, BS, CCLS
Child Life Department
Email: emily.bozzer@ssmhealth.com

Faculty Advisor (if PI is a student)**:** Lindsey Murphy PhD, CCLS
Childhood Education and Family Studies
Email: lindseymurphy@missouristate.edu

Key Information for Research Study
You are invited to take part in the Utilizing Virtual Reality Goggles During Pediatric Laceration Repairs to Reduce Perceived Pain in Pediatric Patients study. This is a research study from Emily Bozzer having to do with how pediatric patients perceive pain when engaging in virtual reality during laceration repairs. If you agree to sign this consent, you will be volunteering yourself and child to be a participant. As a participant, this study will only be conducted while your child is receiving the laceration repair and will not prolong your time in the Emergency Department.

There are minimal risks to these procedures but most are rare. There is no direct benefit to you but by volunteering for this study you may help someone else in the future. There is no cost to you for being a volunteer participant. Details of this study will be further explained in this consent document. Please do not hesitate to ask questions.

What we will ask you to do
I will ask your child if they would like to engage with virtual reality goggles during their laceration repair. If your child agrees, I will assist with setting up the goggles. I will then ask your child to rate their pain before and after the repair was completed. This information will be written down on a table. This study does alter or effect the medical care received.

Risks and discomforts

- Your child may feel anxious while utilizing virtual reality goggles.
- Your child may experience a headache after utilizing virtual reality goggles.

Unforeseeable risks
If your child experiences any unforeseen risks the virtual reality goggles will immediately be removed.

Benefits
Your child may perceive to have less pain during the procedure due to the distraction of the virtual reality goggles. It is the hope of this researcher that the study will reduce the need for medicinal sedation and their side effects for pediatric patients needing laceration repairs.

Alternatives
Non-experimental alternatives to utilizing virtual reality goggles include other forms of distraction, procedural sedation, or anxiolysis medications.

Privacy/Confidentiality
State and Federal privacy laws protect the use and release of your health information. SSM Health requires that private information about you be protected. This is especially true for your personal health information. Protected Health Information (PHI) is any health information that can identify you. To take part in this research study, you must give the research team permission to access your health information and to use and share your PHI. The research team will only use and/or share your information as described below and in the research consent form.

What Health Information about me may be used or shared for this research study?

The PHI in this study will include:

☐	Name	☐	Social Security Number	☐	Telephone Number
☐	Address	☐	Date of Birth	☐	Fax Number

☐	Email Address	☐	Medical Record Number	☐	Health Plan Beneficiary (Insurance) Number
☐	Account Number	☐	Certificate or License Number:	☐	Vehicle identifiers and serial numbers
☐	Patient-Specific Dates (e.g., treatment dates)	☐	Biometric Identifiers (finger or voice prints)	☐	Device Identifiers and serial numbers
☐	Web universe resource locators (URLs) or Internet Protocol (IP) addresses	☐	Photographic images, including:	☒	Other: Age and sex of patient

The PHI will be collected from the following sources:

☒	Hospital Medical Records	☐	Physician or clinic records	☐	Laboratory, pathology and/or radiology results
☐	Biological samples	☐	Interviews or questionnaires/health histories	☐	Data previously collected for research purposes obtained from:
☐	Other:				

Who will my information be shared with?

Your PHI will be maintained by SSM Health researchers and they will only share the information as described below.

The researchers may use or share your health information with:

- The SSM Health St. Louis Institutional Review Board and other SSM Health personnel in order to provide research oversight
- Federal or state government representatives, when required by law
- Physicians who have access to your medical record when required for your medical care
- [Hospital or representatives (if applicable)] in order to provide research oversight

The researchers at SSM Health agree to protect your health information by using and/or disclosing it only as you authorize. However, if your PHI is shared with someone outside of the SSM Health research team and/or if you choose to share this information with others outside of this study, your health information may no longer be protected by HIPAA.

Am I required to sign this document?

Your decision to sign or not sign this form will not affect your standard medical treatment, payment or enrollment in any health plans or affect your eligibility for benefits. However, if you choose not to sign this form, you may not take part in this research study.

Does my permission expire?

This permission to release your PHI expires when the research study is over and all required study monitoring has ended.

If you choose to sign this form:

- You can change your mind and not allow the researcher to use and/or share your PHI (revoke your authorization).
- If you revoke your authorization, you must send a written letter to the following address to inform her of your decision:

  1465 S Grand Blvd
  St. Louis, MO 63104
  Attention Emily Bozzer

- If you revoke your authorization, researchers may only use and/or share your PHI **already** collected for this research study.
- If you revoke your authorization, your PHI may still be used and/or shared should you have an adverse event (a bad effect).
- If you withdraw your authorization, you may not be allowed to continue in the study.

If you have questions or concerns regarding your privacy and the use of your personal health information, please contact the SSM Health Privacy Officer at (314) 989-2759.

Cost of participating
There will be no costs to participants.

Payment for participation
There is no payment for taking part in the study.

If you are injured by this research
In the event that any research-related activities result in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No

reimbursement, compensation, or free medical care is offered by SSM Health Care. If you think that you have suffered a research-related injury, contact Emily Bozzer right away at 314) 577-5600.

Taking part is voluntary
The participant's involvement is voluntary, the participant may refuse to participate before the study begins, discontinue at any time, or skip any questions/procedures that may make him/her feel uncomfortable, with no penalty to him/her, and no effect withdrawing, or their academic standing, record, or relationship with SSM Health care or other organization or service that may be involved with the research.

Engaging in virtual reality distraction throughout entire procedure and providing all pain scores is required in order to be considered for the study.

Withdrawal by investigator, physician, or sponsor
The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication/treatment, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

If you have questions
The main researcher conducting this study is Emily Bozzer. If you have questions, you may contact Emily Bozzer at (314) 577-5600. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the SSM St. Louis Institutional Review Board (IRB) for Human Participants at 314-989-2032.

If you have questions or concerns regarding your privacy and the use of your personal health information, you may contact the SSM CRP/Regulatory Coordinator at (314) 989-2824.

For more information about the study: (IF REQUIRED)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can look up this study by referring to the ClinicalTrials.gov number or by asking the study team for a printed copy.

You will be given a copy of this form to keep for your records.

Statement of Consent
Your signature indicates that you have read and understand the above information, that you have discussed this study with the person obtaining consent, that you decided to participate based on the information provided, and that a copy of this form has been given to you.

Your Signature Date:_____

Your Name (printed)_____

Signature of person obtaining consentDate:_____

Printed name of person obtaining consent:_____

Appendix B: Patient Assent Script

"Have you ever heard of virtual reality goggles? Virtual reality goggles go on your head and go over your eyes. By moving your head, you can play different games or look for things in a forest. Would you like to use virtual reality goggles while the doctors and nurses are fixing your cut?"

Appendix C: CITI Training Certificate

CITI PROGRAM

Completion Date 03-Aug-2018
Expiration Date 02-Aug-2021
Record ID 27847692

This is to certify that:

Emily Bozzer

Has completed the following CITI Program course:

Human Research (Curriculum Group)
Social-Behavioral-Educational Researchers (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Missouri State University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w94dc3e2a-d764-477a-a1e0-1d463b5c4e11-27847692

Appendix D: SSM Health Cardinal Glennon Children's Hospital IRB Approval

SSMSTL IRB
1015 Corporate Square Dr. #150
St. Louis, MO 63132
314-989-2032
researchcompliance@ssmhc.com

NOTICE OF APPROVAL FOR HUMAN RESEARCH

DATE:	November 19, 2020
TO:	Bozzer, Emily, Emergency Medicine
FROM:	Fowler, Karyn, MD,CMO, SSMSTL IRB
PROTOCOL TITLE:	UTILIZING VIRTUAL REALITY GOGGLES DURING PEDIATRIC LACERATION REPAIRS TO REDUCE PERCIEVED PAIN IN PEDIATRIC PAITIENTS
FUNDING SOURCE:	NONE
PROTOCOL NUMBER:	20-11-1974
APPROVAL PERIOD:	Approval Date: November 18, 2020 Expiration Date: November 17, 2021

The Institutional Review Board (IRB) has reviewed and approved the protocol submission and the pertinent attachments listed in the Event history for protocol 20-11-1974-NEW titled UTILIZING VIRTUAL REALITY GOGGLES DURING PEDIATRIC LACERATION REPAIRS TO REDUCE PERCIEVED PAIN IN PEDIATRIC PAITIENTS, in accordance with the SSMSTL Human Research Protection Program. The approval is issued under SSM Health Care - St. Louis Federalwide Assurance Number 00008120 issued by the Office for Human Research Protections (OHRP).

The protocol must be renewed on a yearly basis as long as the research remains active unless it is approved as an Exempt study. Should the protocol not be renewed before expiration, all activities must cease until the protocol has been reviewed and renewed by the IRB.

If you have any questions regarding your protocol or the IRB's action, please contact Tricia Lawlar or Diane Peasel.

Appendix E: Missouri State University IRB Approval

Date: 4-14-2022

IRB #: IRB-FY2021-313
Title: UTILIZING VIRTUAL REALITY GOGGLES DURING PEDIATRIC LACERATION REPAIRS TO REDUCE PERCIEVED PAIN IN PEDIATRIC PATIENTS
Creation Date: 11-15-2020
End Date:
Status: Closed
Principal Investigator: Lindsey Murphy
Review Board: MSU
Sponsor:

Study History

Submission Type Initial	**Review Type** Expedited	**Decision** Approved
Submission Type Modification	**Review Type** Expedited	**Decision** Return to PI
Submission Type Admin Closure	**Review Type** Unassigned	**Decision**

Key Study Contacts

Member Lindsey Murphy	**Role** Principal Investigator	**Contact** lindseymurphy@missouristate.edu
Member Emily Bozzer	**Role** Primary Contact	**Contact** bozzer2221@live.missouristate.edu

Appendix F: Wong Baker FACES Pain Scale

Appendix G: Data Collection Table

Patient #	1	2	3	4	5	6	7	8
Patient's Age								
Patient's Sex								
Consent Signed Y/N								
Assent Given Y/N								
LET Utilized Y/N								
Lidocaine Utilized Y/N								
Pre-Procedure Pain Score								
Sedation Medication Needed Y/N								
If Y Sedation Medication Utilized								
Pre-Procedure Pain Score								
Mid Procedure Pain Score								
Post Procedure Pain Score								