PROTOCOL TITLE: Application of Virtual Reality in Post-Operative Recovery of a Pediatric Scoliosis Patient Population

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Background/Introduction

Scoliosis is broadly defined as deviation of the normal vertical alignment of the spinal column. Scoliosis is typically classified as congenital, neuromuscular, syndromic, or idiopathic and may be treated with observation, bracing, or surgical correction, depending on the severity and the clinical status of the patient.[1] Idiopathic scoliosis represents the most common pediatric subtype and has a prevalence of 0.5 – 5.2%, with an operative rate ranging from 3.9 – 9.8 operations per 100,000 members of the general population.[2-4] Post-operative pain following the surgical correction of pediatric scoliosis is inevitable and must be well managed to achieve the goals of patient comfort, early mobilization, and early discharge. As a result of the short- and long-term adverse effects of opioid use in the pediatric population, many practices are adopting multimodal pain management strategies to reduce the reliance on opioid analgesia.[5, 6]

Virtual reality (VR) has been extensively studied in regards to its ability to reduce peri-procedural pain and anxiety in a pediatric population.[7] Non-pharmacological methods of distraction are a well-established method of pain control. Virtual reality, by providing a more interactive and immersive experience, has the potential to out-perform other distraction techniques. However, the specific impact of VR following scoliosis surgery has yet to be assessed.[8] At Connecticut Children's, patients undergo multimodal pain management following scoliosis correction, including narcotics, muscle relaxants, anti-inflammatories, and gabapentin. Patients are also expected to participate with physical therapy daily. In the present study, we intend to investigate the effect of VR on subjective post-operative pain, total inpatient narcotic administration, and mobilization with physical therapy.

Research Question

Does implementation of VR reduce pain, reduce total narcotic administration, and increase mobilization with physical therapy in the immediate post-operative period following spinal deformity surgery in the pediatric population?

Primary and Secondary Aims

Primary Aim(s):

- To determine if virtual reality (VR) reduces the subjective perception of pain for pediatric patients in the acute post-operative period (until discharge) following spinal deformity surgery.
    - Hypothesis: The mean self-reported pain level using a 10-point numeric pain scale will be a minimum of 1 point lower in patients receiving VR compared to those in the control group.

Secondary Aims:

- To determine if VR reduces the total amount of inpatient narcotic use in the acute post-operative period (until discharge) following spinal deformity surgery.
    - Hypothesis: Patients receiving VR will have reduced total inpatient narcotic administration during their hospital stay compared to those in the control group.
- To determine if VR can facilitate earlier mobilization following spinal deformity surgery.

- Hypothesis: Patients receiving VR will participate in a fewer number of physical therapy (PT) sessions prior to receiving clearance for discharge by PT staff.

Outcome Definitions/Data Points Collected

Primary Outcome:

Pain will be measured through the 10-point numeric pain scale self-reported by the patient (patient's will be between 13-18 years of age).

Secondary Outcomes:

- Mobilization will be assessed by the number of PT sessions prior to receiving clearance for discharge by PT staff.
- Patient post-operative gross motor activity level will be measured via wearable Fitbit
- Opioid utilization will be assessed by calculating the total inpatient dose of opioids administered (as documented in the EMR) during the post-operative period.
- Side effects from virtual therapy, including headaches, vertigo, and nausea

Data collected:

- Patient demographics
  - Age, Sex, Race, Language, Ethnicity
- Patient Past Medical History
- Patient medication/drug history (prescription and recreational)
- Prior experience with VR
- Surgical details
  - # of spinal levels involved in fusion
  - Duration of surgery
  - Surgical blood loss
  - Need for transfusion
  - Complications
- Radiographic imaging
- 10-point numeric pain scale ratingsPhysical Therapy notes
  - Number of sessions prior to discharge clearance, timing of sessions, duration of each session, comments from each session,
- EPIC Medication History
- Length of stay
- Timing and duration of virtual reality sessions
- Side effects from virtual therapy sessions
  - Seizures
  - Loss of awareness
  - Headaches
  - Vertigo
  - Nausea
  - Eye strain / blurred or double vision
  - Eye or muscle twitching

- Involuntary movements
- Dizziness and lightheadedness
- Disorientation
- Impaired balance and hand-eye coordination
- Excessive sweating
- Increased salivation
- Drowsiness
- Fatigue
- Motion sickness
- Skin irritation
- Low temperature burns
- Hair loss
-

Study Design

Mixed methods with a prospective cohort and retrospective chart review.

Target Population

Pediatric patients (ages 13-18) undergoing corrective scoliosis surgery at Connecticut Children's over a span of 12 months (03/01/24-03/01/25).

Inclusion/Exclusion Criteria

Inclusion:

Prospective:

- All pediatric patients (ages 13-18) at Connecticut Children's undergoing surgical correction for idiopathic scoliosis over a span of 12 months (03/01/24-03/01/25) will be eligible for inclusion in the prospective arm.

Retrospective:

- All pediatric patients (ages 13-18) at Connecticut Children's that underwent surgical correction for idiopathic scoliosis in the retrospective time frame (03/01/19 - 03/01/24) will be eligible for inclusion in the retrospective arm.

Exclusion:

- History of seizures
- Cognitive developmental delay precluding participation in VR
- Head or neck surgery that does not allow a head-mounted display to be worn safely
- Chronic pain requiring the daily use of opioids for more than 2 weeks prior to the procedure
- Non-English speakers
- Side effects during screening
- Patients with vagal nerve stimulators, cardiac pacemakers, and/or cochlear implants that may receive interference from the VR device

Sampling Method/Recruitment Process

Prospective cohort sample:

All pediatric patients (ages 13-18) undergoing corrective scoliosis surgery at Connecticut Children's over a span of 12 months (03/01/24-03/01/25) will be approached by a study team member during the pre-operative stage with information and consent documentation about the study. If the patient acknowledges that they are interested and would like more information, then the study team member will complete the formal consent and HIPAA process with the patient and family. This will take place in a private setting, and the patient/family will be given ample time to reach the consent and have any questions answered. As a part of the consent and HIPAA, patients will consent to the study procedures as well as the research study team accessing their medical record for data collection. Each patient's MRN will be entered into a secure password protected Excel enrollment log and be given a subject identification number for de-identification. During the consenting procedure, the patient will utilize the VR device for 5 minutes to screen for side effects and become accommodated to the device. In the event that the patient experiences side effects during this 5-minute period, they will be excluded from the study.

Retrospective chart review sample:

The retrospective chart review is intended to be used as a historical control to the prospective arm of the study. All patients in the retrospective time frame (02/01/19 - 02/01/24) will be identified using CPT codes (fusion codes: 22800, 22802, 22804 and instrumentation codes: 22842, 22843, 22844) as well as ICD-10 Code M41.* from Slicer Dicer. These patient's charts will be verified by a study team member to ensure they meet inclusion criteria, and then they will be entered into a using a secure password protected Excel enrollment log. Each patient's MRN will be recorded into the enrollment log and will be given a subject identification number for de-identification. Patients in this cohort will not be approached for consent as we will not collect identifiable information and only their deidentified medical record will be in review. It is also likely that some patients are no longer clinically active at Connecticut Children's, and therefore we would not be able to contact these patients for consent.

Study Retention/Withdrawal

Prospective Cohort:

All patients will be admitted after surgery. It is anticipated that some subjects may opt to not continue with VR and withdraw from the study. Participants will be told that they may withdraw from the study at any time by reaching out to the PI, Dr. David Hersh, or the study coordinator, Cameron King. Withdrawing from the study will not affect patient care. A patient may also decline participation for a VR session, but choose not to withdraw from the entire study. If a patient declines three consecutive VR sessions, then they will be withdrawn from the study. If a patient withdraws, any data already collected will be made de-identifiable and no further information will be collected. These patients will not be included in downstream analyses.

Retrospective Cohort:

These patients will not be approached for consent and therefore will not be able to withdraw from the study.

Study Procedures

Due to the limited number of corrective surgeries for scoliosis in a given year, a true randomized control trial cannot be performed. As such, a prospective cohort will be used – all patients undergoing surgery during the study period will be offered VR and will be assessed for pain, opioid usage, and mobilization following surgery. These outcome measures will be compared to data identified from a retrospective chart review of children receiving the same surgery but without an additional VR-intervention, thus serving as a historical control.

Prospective Arm:
After consenting to the study, the following baseline assessments will be performed and collected from the patient during the pre-operative stage: pain level and vital signs (heart rate, blood pressure, O2 saturation). Starting on postoperative day 1, the prospective cohort will begin receiving VR. These sessions will occur twice daily, starting 30 minutes prior to the patient's scheduled PT appointments, and will be facilitated by a study team member. At the beginning of the session, a study team member will visit the patient's room and set up the virtual reality device. A study team member will try to stay with the patient for the duration of the VR session, but in the event that they are unavailable to do so, a member of the nursing team, physical therapy team, or a parent will remain with the participant. As such, there will always be an adult in close proximity to the participant while they use the VR device. The duration of the session will last approximately 20 minutes and will utilize a low physical load VR experience (underwater or space exploration). The goal of the VR experience is to immerse the patient a setting that gives the experience of decreased weight bearing load to decrease their post-operative pain. The VR screen will display a simulated environment, such as an underwater exploration, in which the participant can interact with floating marine life and vegetation. If the patient experiences side effects or would like a break during the VR intervention, they can inform a study team member and remove the VR device. They are permitted to place the VR device back on and continue the session when they feel comfortable to do so. A session will be considered "failed" if more than 50% of the session is spent not using the VR device. During the post-operative stage, the above outcome measures will be reassessed daily immediately before and after VR and also following the PT session. After the patient is discharged, the total number of PT sessions and total administered opiods will be collected from the patient's medical charts. In addition to pain, opiod usage, and mobility data from the study, the following information will be collected from the patient charts and entered into REDCap: demographics, degree of scoliosis, surgical details, PT notes, pain medication regimens, associated pain scales, and relevant follow up notes. As the VR device will be shared between users, the device will be sanitized with UV LEDs by Cleanbox prior to the transfer between patients.

Retrospective Arm:
Eligible patients verified for the retrospective chart review will be entered into a secure Excel enrollment log and be deidentified by using a subject identification number. The MRN and subject ID will be entered into a linking file that will be password protected and only accessible to authorized study personnel. The following information will be collected from the patient charts: demographics, degree of scoliosis, surgical details, PT notes, pain medication regimens, associated pain scales, and relevant follow up notes. These data will be entered into REDCap in a de-identified manner and will only be accessible to authorized study team members.

Sample Size Justification

This study will utilize a convenience sample of patients presenting to Connecticut Children's for a scoliosis surgery within the study timeframe.

Feasibility, Accrual, and Duration of Accrual

Accrual will occur over a 12 month period (03/01/24 - 03/01/25). Approximately 60-80 patients undergo a surgical procedure for the correction of scoliosis annually at Connecticut Children's. We estimate ~40% will decline to participate, therefore we anticipate approximately 35-50 patients being included in the prospective arm of study. For the retrospective arm of the study, we approximate to include 350 patients for chart review.

Study Limitations

This study is limited in that we are only assessing the utility of VR to reduce pain in a specific patient population (pediatric patients undergoing surgical correction of scoliosis), at a specific time (the immediate post-operative period), at a single institution (Connecticut Children's), and within a relatively small sample size, which limits the generalizability of the study to apply to other patient populations. This study is also limited in that it utilizes a retrospective chart review as a historical control. By collecting data retrospectively, it is likely that the study team will encounter missing variables and will not be able to categorize pain as accurately as they would be able to in a prospective or true randomized control trial study designs.

Data Analysis

- Intention to treat analysis
- A biostatistician will assist in analysis
- Descriptive statistics (frequency, percentage, mean, standard deviation, median, and interquartile range) will be utilized to describe the two groups (VR and control)
- Fisher's Exact test, independent t-tests, and Wilcoxon Rank Sum tests will be used for univariate analysis to compare demographics between the two groups (VR and control)
- Pain outcome:
    - Univariate analysis using independent t-tests or Wilcoxon rank sum tests will be used to compare the daily mean pain scales
- Opioid utilization outcome
    - Univariate analysis using independent t-tests or Wilcoxon rank sum tests will be used to compare the total inpatient dose of opioids administered

Administrative Organization/Roles and Responsibilities

- Principal Investigator - David Hersh, MD - Connecticut Children's Division of Neurosurgery
- Co-Principal Investigator – Robert Astur, PhD – UConn Department of Psychological Sciences
- Co-Principal Investigator – Mark Lee, MD – Connecticut Children's Division of Orthopedic Surgery
- Co-Principal Investigator – William Zempsky, MD MPH – Connecticut Children's Division of Pain and Palliative Medicine
- Student Coordinators and Responsibilities:
    - Cameron King – Study Coordinator
        - Study Design

        - Data quality
        - Data analysis
        - Project management
        - Manuscript drafting
    - Prabhath Mannam – Medical student
        - Study design
        - Study Procedures
        - Data analysis
        - Manuscript drafting
    - Patrick Halloran – Medical Student
        - Study Design
        - Study procedures
        - Data analysis
        - Manuscript drafting

Use of Study Results

The data generated from this study will be used to re-evaluate the postoperative pain management pathway for pediatric patients in the post-operative period following spinal deformity surgery. These data will also be used for presentations / publications.

Study Budget

Item	Quantity	Per
VR Computer	1	$3,100
VIVE Wireless Head Mounted Display	1	$1,100
Cleanbox	1	$2,000
Computer supplies (external hard drives, batteries, sanitizer wipes)	1	$200
VR Software	1	$500
TOTAL		**$6,900**

References:

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Appendices

Appendix A – Data Collection Tool

Appendix B – FACES pain scales