The Usability of Virtual Reality as a Complimentary Pain Management Therapy in a Pediatric Population Undergoing Urodynamic Testing: A PILOT Study

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Study Title:	The Usability of Virtual Reality as a Complimentary Pain Management Therapy in a Pediatric Population Undergoing Urodynamic Testing: **A PILOT Study**
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Short Title:	VR/Urodynamics: Pilot Study

ABSTRACT

Research question:
The research question we are posing is, “In pediatric patients undergoing urodynamic testing, is the use of virtual reality feasible as a complementary pain management therapy in comparison to standard care?

Background, significance, and rationale for the question
Urodynamics testing is an invasive procedure commonly used to assess the function of the lower urinary tract and bladder. The testing requires urethral and rectal catherization, and often needle electrodes for sphincter EMG. Patients are typically kept awake and receive local anesthetic gel. As a result, children receiving this type of evaluation often undergo physical and emotional discomfort. There is emerging evidence that virtual reality (VR) therapy offers an alternative noninvasive approach to reduce procedural pain and anxiety in patients. However, less is known about the use of this technology in the field of pediatric urology, specifically related to urodynamic testing.

Materials and Methods
Children aged 5 to 18 years old undergoing urodynamic testing were recruited through a quota sampling approach. VR software designed by KindVR (Alameda, California) allowed the patient to immerse in an underwater world with minimum simulator side effects. There are two phases of the research: baseline (VR education and implementation during the imaging portion of the urodynamic test) and follow-up (VR utilized and tested during the entire urodynamic procedure). Acceptability and feasibility were determined by two questionnaires. Pain, anxiety, and fear were measured pre and post-urodynamic procedures using the VAS Pain scale, Anxiety Thermometer Scale, and Children’s Fear Scale. Satisfaction surveys were completed by the subject and clinical staff post-procedure.

RESULTS
A total of twelve patients were eligible to be enrolled for phase 1. One patient of 5 years of age opted out of the VR due to high levels of anxiety. 80% of the participants “completely agree” that the implementation of VR made them feel better about their procedure and a majority reported that they will play VR again when in pain. There was no significant safety, technical, or equipment issues. There was minimal disruption to exam workflow and the implementation of VR was well received from the clinician survey (n=26). 80.7% of clinicians agree that VR helped the patient to cooperate during the medical procedure and 100% would use virtual reality again to distract children.

CONCLUSION
Preliminary data showing positive patient and clinical staff satisfaction suggests VR may be beneficial as a complimentary modality in pediatric urodynamic testing. Continued enrollment and data collection through Cycle #2 will further inform the usability of VR in a spine position and throughout the entire urodynamic procedure and exam.

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1. RESEARCH QUESTION: AIMS AND OBJECTIVES

1.1 Study Aim

This study aimed to assess the usability of virtual reality as a complementary pain management therapy in the pediatric population who underwent urodynamic testing.

1.2 Primary Objectives

The primary objective of this study was to evaluate the perspectives obtained through surveys and observations of patients and providers on their experiences of using virtual reality as a non-pharmacological intervention for children and adolescents who underwent urodynamic testing. An iterative (two cycles) approach was taken to document, analyze, and incorporate participants' perspectives (verbatim data) and experiences. The data informed researchers about patient safety and satisfaction, the implementation of VR within clinical care, and the efficacy of the VR hardware and software.

1.3 Secondary Objectives

The secondary objectives of this usability study were:

- To describe study participants' perspectives of any adverse events associated with VR distraction (hardware and software) when used as a non-pharmacological intervention for children and adolescents who underwent urodynamic testing.
- To describe study participants' perspectives of any safety concerns associated with VR distraction (hardware and software) when used as a non-pharmacological intervention for children and adolescents who underwent urodynamic testing.

- To describe study participants' perspectives of their pain and anxiety levels during their experience of using VR distraction (hardware and software) as a non-pharmacological intervention for children and adolescents who underwent urodynamic testing.
- To describe study participants' perspectives of their satisfaction levels during their experience of using VR distraction (hardware and software) as a non-pharmacological intervention for children and adolescents who underwent urodynamic testing.
- To describe clinicians' perspectives of the usability of VR distraction as a non-pharmacological treatment of pain and anxiety for children and adolescents who underwent urodynamic testing procedures.
- To determine the total time of the urodynamic procedure when using VR distraction (hardware and software) as a non-pharmacological intervention for children and adolescents who underwent urodynamic testing.

1.4 Endpoints

- The participants' and providers' perspectives of the degree to which VR distraction (hardware and software) was fit to be used as an intervention throughout the steps (stages) of urodynamic testing.
- The participants' reported perspectives of their safety when using VR distraction (hardware and software) throughout the steps (stages) of urodynamic testing.

- The participants' reported perspectives of their pain and anxiety before and after using VR distraction (hardware and software) during urodynamic testing.
- The participants' reported perspectives of their satisfaction levels throughout the steps (stages) of urodynamic testing.
- The clinicians' reported perspectives of the VR usability as a distraction option during urodynamic testing as a non-pharmacological intervention.
- The participants' total time undergoing urodynamic testing when using VR distraction (hardware and software) throughout the steps (stages) of urodynamic testing.

2. INTRODUCTION AND SIGNIFICANCE

Urodynamic testing is a blanket term for a series of tests that measure how well the bladder, sphincter, and urethra store and release urine. Video urodynamic testing combines cytometry, uroflowmetry, and x-ray cystography into a single test. The outcomes are to measure the bladder's storage pressures and provide video technology to observe the bladder's size and shape as it fills or empties. Urodynamic testing plays an important role in identifying "at risk" kidneys, monitoring symptoms throughout a child's life, and treatment interventions for pediatric patients with neurogenic or non-neurogenic bladders.

Non-neurogenic bladder dysfunction is a common childhood condition that may be caused by "weak bladder muscle, a blockage in the flow of urine, behavioral problems or habits that have developed over time." Contrarily, neurogenic bladder is an umbrella term applied to

“urinary bladder malfunction due to neurological dysfunction emanating from internal or external trauma, disease, or injury.” [2] The most common cause of neurogenic bladder dysfunction in a child is spinal dysraphism, primarily an open back lesion. [3]

Spina bifida is a type of neural tube defect in which there is incomplete closing of the backbone and the membranes around the spinal cord. The condition can occur in different types from least severe to most: spina bifida occulta, meningocele, and myelomeningocele. Typically, myelomeningocele is the most commonly discussed type of spina bifida because part of the spinal cord and nerves are damaged. As a result, spina bifida is the most common cause of neurogenic bladder in pediatric patients.[4] Patients have a much greater risk of urinary tract infections. They may also experience vesicoureteral reflux leading to hydronephrosis. This is due to high bladder pressures causing backflow of urine from the bladder to the kidney. The excess fluid in the kidney then may lead to compression and possible atrophy of the renal cortex and medulla. Lastly, incontinence is a common concern for pediatric patients as it impacts not only the physical aspect of their life but also has social implications. The goals of management for pediatric patients involves preserving renal function, continence, and preparing a child to manage their own health as they age. [5]

Given these facts, urodynamic testing for either neurogenic or non-neurogenic patients can range from every 3, 6, or 12 months depending on their age and specific condition. The tests, however, are invasive and often stressful as they require the insertion of catheters into the urethra and rectum. Patients may not only feel painful sensations associated with the catheter positioning, but also may generate discomfort and embarrassment as they are asked to urinate

in the presence of medical staff. A recent study analyzing pain perception associated with urodynamic testing in children over 3 years old, indicated that 40% of the pediatric patients expressed pain or discomfort after the test. Some variables that influenced the pain perception were the patient's anxiety prior to testing, difficult bladder catheterization, and the appearance of pain during bladder filling. [6] Further research revealed that all painful sensations during the test were strongly related with each other. Therefore, when painful sensations were noted, the sensations appeared to be present throughout the entire procedure.[7] Multiple studies also revealed younger age was associated with more bothersome and physical discomfort during urodynamic testing. [7-9]

A number of nonpharmacological interventions for reducing childhood procedural pain and anxiety have been shown to be beneficial. For example, distraction techniques, child and parental preparation, and creating an enhanced environment [10-12.] Certified Child Life Specialists (CCLS) are regularly utilized in urodynamic testing to provide appropriate nonpharmacological pain management and support to patients before, during, and after medical procedures.[12] Virtual reality holds promise as a new complementary pain management therapy that has not yet been tested in urodynamics.

Virtual reality (VR) is an emerging tool that fully immerses patients into an alternative world. The stimulated virtual environments make it possible for patients to cognitively escape the medical environment and travel to places they have never imagined before. The use of VR is unique from other simple distraction modalities because it integrates multiple sensory inputs (visual, auditory, tactile), thus capturing a greater degree of the users attention. [13,14] It is

hypothesized that due to this higher level of distraction, VR decreases both attention to pain and the emotion related to pain sensations.[15] From a neurological standpoint, VR distraction has shown to modify how the brain processes incoming signals from pain receptors.[16] Functional magnetic resonance imaging study also revealed significantly reduced pain related brain activity in the anterior cingulate cortex, primary and secondary somatosensory cortex, insula and thalamus.[17] Due to this notion, there has been a surge of literature and interest to test the feasibility and efficacy of virtual reality in healthcare. Utilization of VR has shown benefit in acute and chronic pain, reduction in anxiety, IV insertion, chemotherapy, burn injuries, phlebotomy, and pediatric patients with sickle cell disease. [18-26]

Based on these studies and our recognition that a novel complementary pain management therapy was needed for pediatric patients undergoing urodynamic testing, we conducted a feasibility study. Our patient population consisted of children and adolescents from 5 to 18 years old who had either a neurogenic or non-neurogenic bladder. In this study, we delved deeper into the feasibility of virtual reality (hardware and software) for pediatric patients undergoing urodynamic testing with minimal safety concerns. Moreover, we analyzed (1) whether the immersive VR technology could be used as an attention-diverting modality in urodynamic testing to decrease procedural pain and anxiety compared to standard care. As a result, (2) we hypothesized that VR would also improve the participants' (patients and providers) perspectives/satisfaction and (3) decrease overall procedural event time. Having found this study to be effective, further studies may be conducted to determine if VR therapy has the potential to improve the value of healthcare at Cook’s Children Hospital and beyond.

3. MATERIALS AND METHODS

3.1 Study Design

Mixed methods, including quantitative and qualitative approaches, were used to determine the usability of the VR hardware and software as a non-pharmacological intervention during video urodynamic testing (VUDY) procedures. Video urodynamics refers to the exam of the bladder which shows how the bladder holds urine and how it empties urine. This part of the test utilizes X-ray to take photos of the urinary tract and bladder. The findings will inform future implementation of VR-distraction within clinical care and patient safety.

In the first phase, the VR device was tested during the actual VUDY exam portion of the visit. Study staff provided an instructional education session of approximately five minutes to demonstrate the VR hardware and a verbal description of the gaming software, during which the participant became familiar with and involved in when in use. They were informed of safety procedures and potential adverse events. Subjects were instructed to alert the study assistant and providers of any adverse events (i.e., dizziness, nausea) while using the VR intervention. All concerns were addressed, and each subject was given the opportunity to choose whether they wanted to participate in the second phase of the study. For the second phase, subjects who agree to participate will use the VR throughout the entire VUDY procedure, from the prep period time through exam and completion. For each cycle, subjects completed pre and post a simulator sickness questionnaire, report their anxiety levels via the anxiety thermometer tool, report their pain levels via the VAS pain tool, and report their fear rating via the Children's Fear Scale tool. During cycle #2 subjects also reported their anxiety, pain and fear ratings after bladder catheterization and prior to the urodynamic exam beginning. After each cycle, subjects

completed a participant usability and satisfaction survey to gather their perspectives on the usability of the VR intervention. The semi-structured satisfaction survey probed for information on ease of use, comfort levels, and overall satisfaction.

During the VUDY procedures, a research assistant observed and took field notes on clinic/room settings, interactions between providers and subjects, and any procedural issues that may inhibit or improve the clinical workflow. Clinicians administering the VUDY procedure completed a clinician satisfaction survey on their perspectives of the subject experiences using the VR intervention.

The satisfaction survey responses, research assistant field notes, and subject's reported pre and post anxiety, pain, and questionnaires were analyzed using conventional qualitative methods and descriptive statistics by the research team. After data review, the study team may reach out to our KindVR consultant and the urodynamics providers to help identify key findings on how to best administer the VR intervention to ensure ease of use and patient safety.

3.2 Type/Design of Trial

This usability study includes two iterations. We will recruit 30 children and adolescents (10 per age group of 5-8, 9-12, and 13-18) whom are scheduled to undergo a VUDY procedure.

Study Steps:

Refer to Appendix A for the Participant Flow Chart.

3.3 Selection and Enrollment of Subjects

3.3.1 Study Population and Groups/Arms

The potential study candidate must be an active patient under the care of the Urology Department at Cook Children's Medical Center. All children ages from 5 to 18 years of age undergoing an urodynamics procedure at Cook Children's Medical Center Urology department and meet the inclusion criteria were identified and recruited for the study through daily clinic contact, by the site primary investigator (PI) or a study staff representative. Subjects with various urological diagnoses and whom have been prescribed a VUDY exam were included, so as to provide data amongst a variety of groups that were of most benefit during their examinations and procedure while using VR technology. We assessed 10 participants within three age groups. Group #1 will include young children ages 5-8 years old; Group #2 will include pre-adolescent children ages 9-12 years old; and Group #3 will include adolescent children ages 13-18 years old. Study staff coordinated all study follow-up visits after enrollment occurs to collect data.

3.3.2 Inclusion Criteria

Individuals eligible to participate in this study must meet all of the following inclusion criteria to be registered in the study. Study participation may not begin until a subject is registered.

- CCMC pediatric patients from 5 to 18 years of age.
- Participants are scheduled to undergo urodynamic testing with at least one previous test already completed.
- Participant's follow-up urodynamic test must be scheduled for within two years or less.
- Participants must be able to participate and perform with the virtual reality software.

- Participants must be able to speak and understand either the English or Spanish languages.
- Participants must have a parent or guardian present.
- Ability to understand study procedures and to comply with them for the entire length of the study.
- Both English and Spanish speaking subjects are eligible to enroll.

3.3.3 Exclusion Criteria

Individuals who meet any of the following exclusion criteria will not be eligible to participate in the study:

- CCMC patients younger than 5 years of age or patients older than 19 years of age.
- Prospective participants scheduled to undergo their first urodynamic testing.
- Patient administers an Abdominal Stoma catheterization.
- Patients with a known history of seizures.
- Patients with an active infection that involves the periorbital skin, eyes, and/or scalp.
- Patients who have methicillin resistant *Staphylococcus aureus* infection or symptoms of respiratory or gastrointestinal infection to avoid contaminating the VR equipment.
- Patients who are blind.
- Patients who have a developmental delay significant enough to interfere with the subject's ability to participate in the VR session.
- Patients with visual, auditory, or cognitive impairments precluding interaction with the VR intervention.

- Patients with psychiatric conditions that could be exacerbated by the VR environment (e.g. hallucinations)
- Patients with upper extremities injuries preventing them from using the VR handheld controller.
- Participant is nonverbal.
- Inability or unwillingness of participant or parent/legally authorized representative to give written informed consent.

3.3.4 Screening Procedures

Once a potential patient was identified by the study team for an urodynamics procedure, a review was done of inclusion and exclusion criteria to determine their study eligibility. The potential study candidate was informed of the study by a study team member during their urology clinic visit or during a reminder phone call administered by a provider and then forwarded onto to a study team member to discuss further and answer any study questions. During this time the study team member informed the patient and family of the study and determine if they are interested in participating. After the review, the patient was given the opportunity to participant. If they are interested and elect to participate, the study team administered an informed consent for study enrollment.

3.3.5 Enrollment and Recruitment

Potential study participants were recruited from Cook Children's Urology clinic in Fort Worth, TX. Study team members administered and reviewed the details of the entire study procedures that will occur during the enrolled study timeline. Once this information had been

provided to the potential subject and their interest has been confirmed, a qualified member of the study team will obtain informed consent. Informed consent and assent was obtained prior to the prospective subject's scheduled urodynamics procedure. During the recruitment and prior to enrollment into this study, individuals interested in becoming subjects ("potential subject") were given a full explanation of the study and the opportunity to review the informed consent form (ICF). A signed consent form was obtained from the subject and/or LAR. As per the Cook Children's IRB policy, written assent from a minor aged 13-18 and verbal assent from a minor aged 8-12 was obtained. The minimal age for assent was seven as this is required by federal regulations unless the child's decision-making capacity is impaired. The study team administered consent/assent within the urology outpatient clinic exam rooms. The PI, sub-PI's, project manager, CRC and/or the Investigator Student Assistant administered the informed consent and assents.

3.3.6 Approximate Duration of Enrollment Period and Follow-Up

Participants took part in the study for two continuous regularly scheduled urodynamics procedures within the Cook Children's Urology Pediatric Clinic. The occurrence of the second follow-up urodynamic visit was depended on how each patient responded to their prescribed treatment, diagnosis, or per their provider's recommendations.

With a sample size of 30 participants, the estimated enrollment period can vary from a 3-month to two-year study window. The total time that each subject was followed on study is for 2 continuous urodynamic procedure visits.

3.3.7 Overall Time Burden for Individual Participants

The expected overall total research time commitment for the enrolled child participant (excluding travel and parking at CCMC) is up to 4 hours and 31 minutes, which includes the following: completing the consent conference (1 hour); reporting pain, anxiety, and fear scores (4 minutes total per Cycle), completing one study questionnaire at pre/post procedures for a total of 4 study time points (4 minutes total per Cycle); testing the VR device/software (1 hour for Cycle #1; and 2 hours for Cycle #2) and completing the study usability satisfaction survey at the end of each cycle (15 minutes per Cycle).

At times, the estimated testing times of the VR device/software varied as the urodynamic testing procedure is dependent on the subject's bladder size and the time to the length of a subject's VUDY procedures and exam time can last up to 2 hours depending on their bladder size. Therefore those participants whose exam times are longer than the estimated 1 hour timeframe; their total research time commitment will vary up to an additional 1.0 hour. These particular participants research time commitment may be up to 4 hours and 16 minutes.

3.3.8 Retention of Subjects

Compensation

Each enrolled participant was compensated $20.00 per study cycle/visit completion for their time and efforts toward this project. Per protocol design, there are two study cycle/visits per enrollment; therefore an enrolled participant can potentially receive a combined disbursement of $40.00 for completing both study cycle/visits. Reimbursements occured at the end of each attended and completed study visit.

All study reimbursements were electronically disbursed and uploaded onto an assigned Greenphire Clincard (*a debit card/gift card type of payment*) within two weeks of each attended study cycle/visit. The study team provided the assigned Greenphire Clincard to parents/LAR of participants and/or participants of 18 years of age.

3.3.9 POTENTIAL RISKS AND BENEFITS

Below are the described assumed risks and benefits of the usability study, but it should be noted that the list is by no means exhaustive, as we are proposing a pilot usability study.

Potential Risks

Prospective Enrollees

a) Potential risk of sympathetic stimulation.
b) Potential risk of breach of confidentiality.
c) Potential risk of headache, eye strain, nausea, or dizziness with the VR equipment/software.
d) Potential infection risks that may arise from using a shared device among multiple subjects.
e) Potential that you may experience anxiety and/or pain that the VR does not adequately address or control. If this happens, other treatment options to manage these effects will be discussed and/or offered to you.

Risk Management

To minimize the risks listed above, data collected will be reviewed by the study team and the urodynamics providers at the end of each cycle session to help identify key findings on how to best administer the VR intervention to ensure ease of use and patient safety. All study staff will

be trained on how to ensure cleanliness of the headset before and after each VR session. Risks will be continually evaluated by a trained research assistant while observing each urodynamic procedure with the VR distraction, and by the urodynamic providers during the procedures. The analysis of data will be ongoing and necessary adjustments will be made as needed and also before cycle 2.

Potential Benefits

Prospective Enrollees

a) Decreased perception of pain.

b) Decreased anxiety.

c) Potential decrease in the length of the procedure.

d) Less medication exposure.

e) Positive perspective toward urodynamic testing.

f) Lower patient stress.

g) Improve patient distraction during procedure.

3.4 STUDY PROCEDURES

Procedures and Schedule of Evaluations

Assessment	Enrollment:	Cycle #1 PRE	Cycle #1 During Testing	Cycle #1 POST		Cycle #2 PRE	Cycle #2 During Testing	Cycle #2 POST
Informed Consent Form	X							
Inclusion/Exclusion Criteria	X							
Pain Scores (VAS or FACES®)		X		X		X	X	X
Anxiety Scores (Anxiety Thermometer)		X		X		X	X	X
Child's Fear Scale		X		X		X	X	X
Simulator Sickness Form		X		X		X		X
KindVR Device/Headset Instruction and Education Period		X				X		
Medication Used *(if any)*			X				X	
FLACC Behavioral Scores		X	X	X		X	X	X
Research Observer Field Notes		X	X	X		X	X	X
Participant Usability Satisfaction Survey				X				X
Clinician Satisfaction Survey				X				X
Adverse Events		X	X	X		X	X	X

3.5 Research Instruments

3.5.1 **<u>Visual Analogue Scale (VAS) Pain Rating Scale.</u>** The visual analog scale (VAS) (Hayes and Patterson, 1921) is a validated, subjective measure for acute and chronic pain.[27] Scores are recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no **pain**" and "worst **pain**." This tool will be administered pre, during and post urodynamic procedures for both Cycle #1 and Cycle #2 sessions of all

enrollees. (Participants ages 5 and over). This scale was numerical therefore has a higher potential for variability in response (and accuracy) given the potential developmental issues.

3.5.2 **Wong-Baker FACES® Pain Rating Scale.** The scale shows a series of faces ranging from a happy face at **0**, or "no hurt", to a crying face at 10, which represents "hurts like the worst pain imaginable". Based on the faces and written descriptions, the subject chooses the face that best describes their level of pain. This tool will be administered pre and post urodynamic procedures for both Cycle #1 and Cycle #2 sessions of all enrollees. (Participants ages 5 and over). This scale has been determined to be validated for children 3 to 18 years of age. [28]

3.5.3 **Anxiety Thermometer.** The anxiety thermometer by Mentally Healthy Schools & Anna Freud National Centre for Children and Families is designed to be utilized by children, young adults and adults. The thermometer describes feeling on a 10-point scale. Using a feelings thermometer is a great tool to help children recognize what feelings they might be experiencing in any given moment. This tool will be administered pre, during and post urodynamic procedures for both Cycle #1 and Cycle #2 sessions of all enrollees. (Participants ages 5 and over).

3.5.4 **Children's Fear Scale (CFS).** The Children's Fear Scale was adapted from the Faces Anxiety Scale (McKinley, Coote, & Stein-Parbury, 2003) to measure fear in children undergoing painful medical procedures.[29] The scale shows a series of faces showing different amounts of being scared. The faces range from the left rated as a "**0"** or "not

scared", to a face on the right rated as a “4”, which represents "most scared”. Based on the faces and written descriptions, the subject chooses the face that best describes their level of fear. This tool will be administered pre, during and post urodynamic procedures for both Cycle #1 and Cycle #2 sessions of all enrollees. (Participants ages 5 and over).

3.5.5 Simulator Sickness Questionnaire. This measure introduces a Child Simulator Sickness Questionnaire as a simple, short, standardized method of collecting simulator sickness symptom data for children. Children, who are more exposed to these technologies and who are more prone to method of assessing the degree to which these modalities of presentation may adversely affect the viewers. This inventory is a 4 item measurement where the child subject will self-report on a 10-point scale or the option to circle an “I don’t know” response per question. The inventory will be completed by the enrolled child subject pre and post VR device testing at Cycle #1 and Cycle #2 sessions. Child subjects ages 8 year and old will complete a self-report for this measure. Parents of children 5-7 years of age will proxy this measure with their child. (Participants ages 8-18 years, Parent-proxy with child participants of 5-7 years of age).

3.5.6 Participant Usability and Satisfaction Survey. The acceptability and feasibility of the VR intervention will be surveyed by the child participants. This survey is a 2-part survey, where section #1 will be completed by all study participants at the end of cycle #1 and cycle #2. Section #1 of the survey will measure how the child subject felt while using the VR device and how much the child subject agrees or disagrees with the comfort and enjoyment of using the VR device during their urodynamic procedure. This part of the

inventory includes a self-report 10-point scale or the option to circle an "I don't know" response per question. Section #2 of the survey will be completed in addition to Section #1 but only by those participants that complete the cycle #2. Section #2 will concentrate on future directions with regards to the device and usage. Child subjects ages 8 year and old will complete a self-report for this measure. Parents of children 5-7 years of age will proxy this measure with their child. (Participants ages 8-18 years, Parent-proxy with child participants of 5-7 years of age).

3.5.7 Clinician Satisfaction Survey. To evaluate the acceptability and feasibility of a VR intervention within the selected setting, a satisfaction questionnaire will be given to clinicians (nurses, urologists whom attend the VUDY procedure, and child life specialist) after each session. The inventory will be completed at the end of cycle #1 and cycle 2 sessions. (Only clinicians whom are present within the Urodynamic suite/room during testing will complete).

3.5.8 Face, Legs, Activity, Cry, Consolability Behavioral Pain Scale (FLACC). This measurement is a behavioral pain assessment scale used for nonverbal or preverbal patients who are unable to self-report their level of pain. The scale is scored in a range of 0–10 with 0 representing no pain. The scale has five criteria (face, legs, activity, cry, consolability), which are each assigned a score of 0, 1 or 2. Pain is assessed through observation of the 5 categories. The research assistant will utilize this scale during their observation period of the urodynamic procedure (pre and post) and also during the VR device usage (pre and post) to occur during the urodynamic procedure. The inventory

will be completed at both Cycle #1 and Cycle #2 sessions. (Participants ages 5+ years of age).

3.5.9 **Kind VR Software.** The virtual reality (VR) software was founded and developed in 2014 by Simon Robertson, and was designed specifically for the purpose of pain distraction.[30] The interactive VR experience moves patients through an ocean filled with sea creatures and offers both active and passive gameplay, allowing patients to either challenge themselves to find all of the fish or to simply relax. Additionally, the experience was designed to accommodate patients' needs including limited mobility, range of motion, and various levels of familiarity with interactive games. The VR software will be completed at both Cycle #1 and Cycle #2 research visits. (Participants ages 5+ years of age).

3.6 KindVR

KindVR (Alameda, California) is an independent research-based company located in Alameda, California. KindVR specializes in developing virtual reality software experiences designed to help patients mitigate pain and stress during medical procedures. KindVR has over six years' experience collaborating with pediatric research hospitals on clinical trials targeting common pediatric procedures. KindVR's software experiences are customized for patients' body position and patient safety during procedures. Currently, KindVR is engaged in over 10 active clinical trials and has three published studies evaluating sickle cell disease pain crisis, mediport access procedures for oncology patients, and procedural pain during IV Insertion in pediatric EDs.

For this Study, KindVR provided custom software, hospital ready VR equipment, disposable infection control kits, hospital staff training and support. KindVR provided these services for the study at no cost**.** The company designed a custom VR application (KindVR Aqua Supine) specifically to accommodate patients undergoing urodynamic testing in the supine body position. This was a novel use of VR distraction therapy, and Cook Children's became the first site to evaluate the use of VR during VUDY procedures.

To support this new body position and procedure, KindVR employed many new software design methods and development considerations. Two notable design considerations included creating an engaging virtual environment that required minimal head movement for patients to interact comfortably, and narrowing the patient's views to encourage a supine body position throughout the experience.

Throughout the course of the study, KindVR worked closely with Child Life Specialists and the Hospital Staff who were using the VR headset with patients. Cook Children's provided feedback about the software and patient experience to KindVR at regular intervals during the study. Changes and improvements to the software (KindVR Aqua Supine) were made based on patient and staff feedback. All changes to the KindVR Aqua Supine software, including bug fixes, technical adjustments, and software improvements, were tracked in a log format. This log included the type of change made, a summary or description of the change using lay terminology, and how the change impacted the software. The change log was submitted to the IRB with each annual review. Any and all changes or improvements to the software or VR application that could change the risk/benefit ratio of the study or that might change what a

subject views or experiences were submitted to the IRB via a modification form for review and approval prior to use with any subject.

Aqua Supine Game Description

The game begins at the Start Menu boat, and you lay back onto a pillow to get a clear view upwards of the Start Screen in the sky. A controller in your hand is seen as a sprayer within the game world, and can rest on your chest or by your side pointing up. Once comfortable on the pillow, users hold any button down for 5 seconds to begin.

Once the adventure begins, the user floats upwards towards the surface of the ocean within a small submarine. The submarine has a protective glass windscreen roof that prevents sea creatures from getting too close. Aqua Supine was designed for minimal body movement, meaning patients should be able to see all the creatures by looking straight upward. The user floats up through groups of whales, buoys with starfish, dolphins and seals. Users are invited to aim with their sprayer to light-up and colorize the fish, but they're also welcome to relax and just look.

Once the user reaches the surface of the ocean, they are brought back to the boat to see a tally of the creatures. Holding any button down starts the adventure again.

Hardware

This study used non-invasive virtual reality equipment including a stereoscopic head mounted display (Pico Neo 2 headset). The Pico Neo 2 (Tobii, Stockholm, Sweden) is a commercially available ‘all-in-one’ virtual reality headset, meaning the screen, lenses, earphone speakers, and computer are built into one portable device. The headset does not require

cables, does not contain any fabric, and is fully wipeable. This allows for minimal interference in a clinical setting. A wireless Bluetooth controller was used to interact with the virtual environment and may be held by the patient in either hand. The VR headset features a custom operating system that restricts users to a 'kiosk menu' of approved VR applications. The KindVR headset was provided for use in this study will only have one VR application available to launch: *KindVR Aqua Supine*.

KindVR is considered a mobile app by the FDA, which exercises enforcement discretion as KindVR Therapy is non-invasive. The equipment does not gather, record, or store any patient information, including "protected health information" as defined by the Health Insurance Portability and Accountability Act and its implementing regulations ("HIPAA").

KindVR also provided an Instruction & Cleaning manual for hospital staff and laminated, cleanable *How-To-Play* patient guides. The equipment was stored in a Nanuk 915 case to protect the equipment.

Appendix B & C provides a graphic of the equipment and the instructions given to the child.

3.7 Study Location

The potential study candidate must be an active patient under the care of the Urology Department at Cook Children's Medical Center. All required study visits occured outpatient at their clinical scheduled visits occurring within the Urology Clinic located at Cook Children's Medical Center in Fort Worth, Texas.

3.8 Statistical Considerations

We utilized a mixed methods (quantitative and qualitative) approach to collect and analyze participants' data, and report findings. Descriptive statistics were used to summarize the demographic and clinical data (i.e., frequencies and measures of central tendencies, variability, position, and relationships). The quantitative data was obtained through the VAS and anxiety thermometer. All data was evaluated for completeness and missing information was obtained on-site. Quantitative data analyses were executed utilizing [Research electronic data capture (REDCap), Cooks Children, Fort Worth, TX]. Simple statistics were utilized to determine the mean, median, and range.

Qualitative data was collected via a pre-prepared semi-structured satisfaction survey of subjects and clinicians, and observation field notes of the subject and clinicians' interactions during the VUDY with the VR distraction being administered. To analyze this data, we employed conventional content analysis methods. This involved a systematic coding and categorizing approach to identify recurring themes and patterns within the qualitative data on REDCAP. Following this approach, REDCAP was able to aggregate data from our dataset and automatically generate relevant plots.

3.9 Data Management

Data Management was provided by Cook Children's Health Care System Research Administration Office (Cook Children's RAO) and includes forms design, collecting, managing,

editing, storing, and reporting on data; as well as, training and access to the data for the study statistician.

The eCRF's was maintained and updated by Cook Children's RAO to reflect the changes within the protocol. All collected data was entered and stored into an electronic database, REDCap, created by Cook Children's research administration office (RAO). User privileges was granted and access to view the database only by members of the research team.

3.10 IRB Statement

The project was conducted by the study team in compliance with protocol, Good Clinical Practice (GCP), all the applicable regulatory requirement(s), and to ethical principles that have their origin in the Declaration of Helsinki. This study will be conducted in compliance with all United States Federal and local laws, regulations, and guidelines for the conduct of research in a vulnerable population. IRB was approved by Cooks Children.

4 Results

A total of twelve patients were eligible to be enrolled for the phase 1 trial. One patient of 5 years of age opted out of the VR due to high levels of anxiety. The gender distribution was predominantly male (n=8) with a smaller representation of females (n=4). Participants were categorized into three age groups: 5-8 years (n=5), 9-12 years (n=3), and 13-18 years (n=4), to understand the potential age-related differences in the outcome measures. The average participant age was 10.59 years of age. Eleven patients had a diagnosis of neurogenic bladder.

Participants were selected based on their previous medical history of undergoing urodynamic tests, with a range of 1-9 previous tests equally distributed across participants (n=4 in each subgroup of 1-3, 4-6, and 7-9 tests). Five individuals had previous VR experience. All participants currently performed regular at-home catheterizations.

During phase 1, the visual analog scale (VAS) (score ranges from 0-10) was implemented as it is a subjective measure of acute and chronic pain on a scale 0-10. The average preoperative VAS was 0.25 and postoperative VAS was 0.7. Figure 1 illustrates the VAS scale that was presented to the patient.

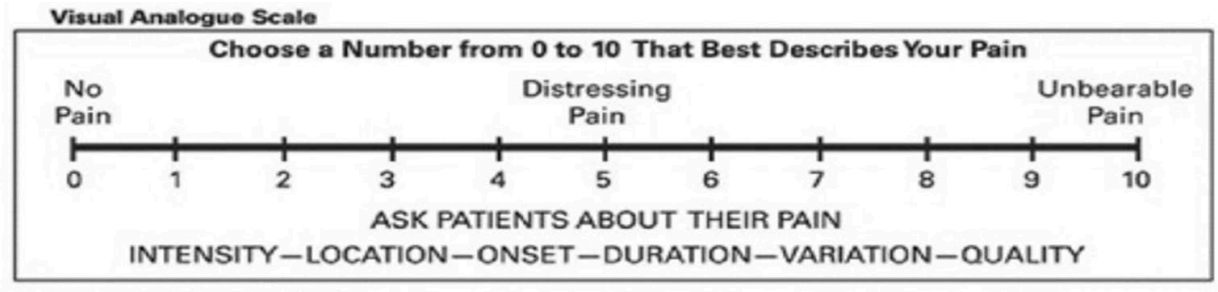


Figure 1. VAS SCALE

The Children's Fear Scale (CFS) (score ranges from 0-4) was also utilized pre- and post-operatively with an average of 0.58 and 0.30 respectively. Figure 2 depicts the CFS grading scale.

PRE: Choose a face that shows how scared you are right now? _____

POST: Choose a face that shows how scared you were during the test? _____

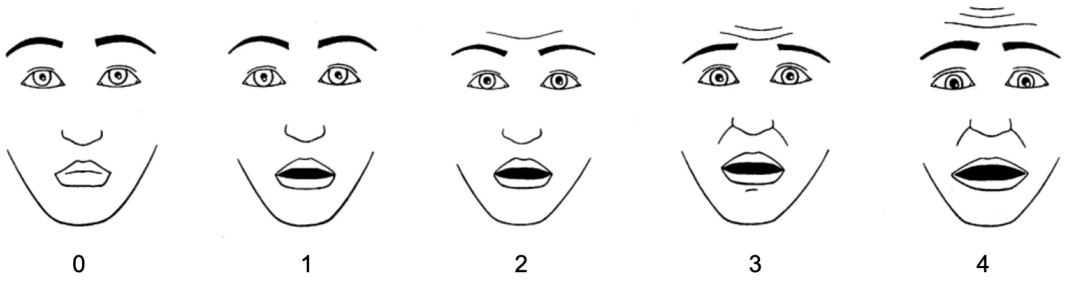


Figure 2. CFS

The anxiety thermometer was given pre-operatively to all participants with an average of 2.33 on a scale out of 10 and 1.8 post-operatively. Figure 3 illustrates the scale given to all participants.

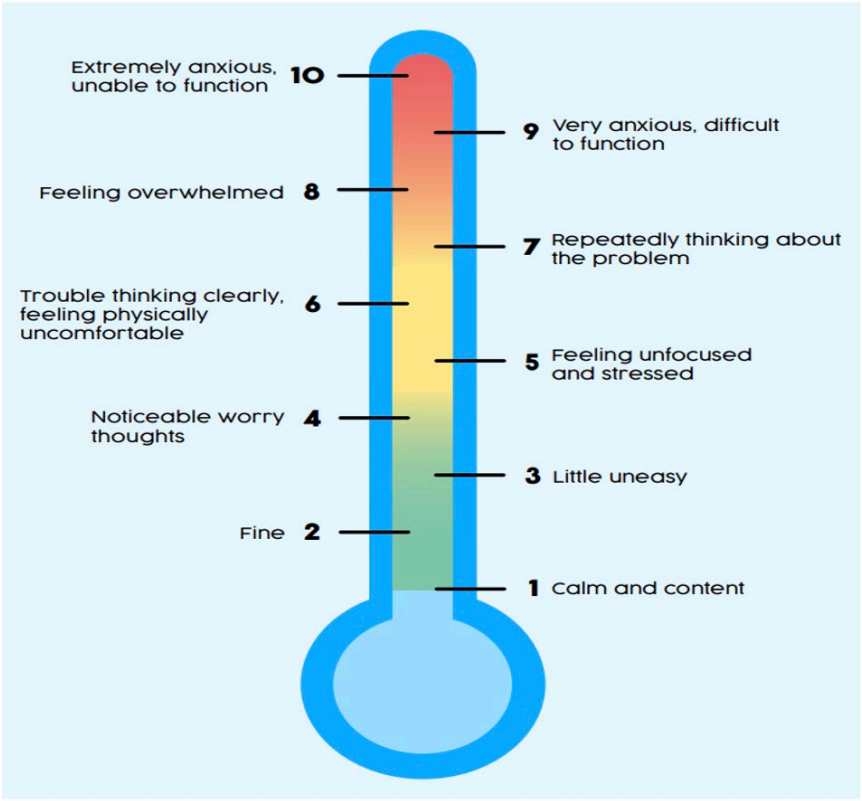


Figure 3. Anxiety Thermometer

Before every urodynamic testing and the emphasis of this study to be a usability study, each participant was given a Child Simulator Sickness Questionnaire (1-10 scale) to assess if they were safe to take part in the study. Four questions were asked pre-testing, “Does your head hurt” (n=12, avg= 1), “Do your eyes hurt” (n=11, avg= 1), “Do you have an upset stomach”(n=12, avg= 1.25), and “Do you feel dizzy” ”(n=12, avg= 1.08). The same questions were asked post-testing and the average response was 1.4, 1, 1.1, and 1.6.

Participants were given usability surveys after finishing their urodynamic study. Every question incorporated a Likert scale of 1-10 with the lower end indicating negative results and a higher value indicating positive results. Figure 4 provides the average responses to the questionnaire provided. Additionally, 9 out of the 10 patients reported they were able to hear and speak to the nurse or any of the clinical staff when they wanted to during the medical test. 8 reported they would use a virtual reality system on their next urodynamic test from the beginning of the prep period time through the entire test to completion.

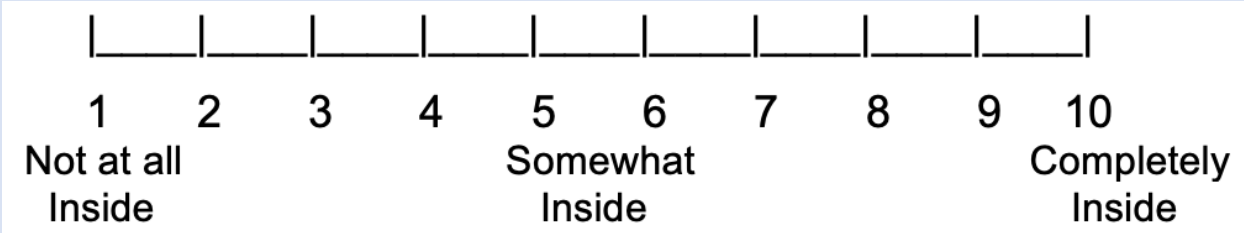
Question	Average Scale No. Response
Example Scale for Question 1:  	
How much did you feel like you were inside the virtual world?	7
How aware of the real world (e.g. hospital setting) were you?	6.7
How did it feel to use the touchpad/controller to shoot bubbles at the fish in Aqua?	2.9
How real did Aqua feel to you?	6.3
How much fun did you have during your medical test while playing Aqua?	8
How much TIME did you spend thinking about your pain during the medical test while playing Aqua?	3.2
How UNPLEASANT was your pain during the medical test?	2.4
Playing Aqua was comfortable.	8.1
The headset was comfortable.	9.2
I would play Aqua again when I am in pain.	7.1
Playing Aqua made me feel better about my hospital test	8.8
Playing Aqua made me feel better about my pain.	7.9
Rate your WORST pain during your medical test.	3.2

Figure 4: Responses to Participant Usability Satisfaction Survey

The FLACC score average preoperatively was 0.67 with a range of 0-2. During the urodynamic preparation phase, the FLACC score was 1.67 with a range of 0-4. During the examination portion itself the score dropped to 0.36 with a range of 0-1, and at the end of the study, the FLACC was the lowest at 0.18.

There was a total of 26 clinician satisfaction collected. These were collected from radiology technicians, child life specialists, and a urology nurse practitioner. A ten-question survey was given to the clinicians. 8 of the 10 questions are illustrated in Figures 5-9. The last two questions were open-response questions asking the clinicians for their input and thoughts on the implementation of VR. The responses are charted in Figure 12.

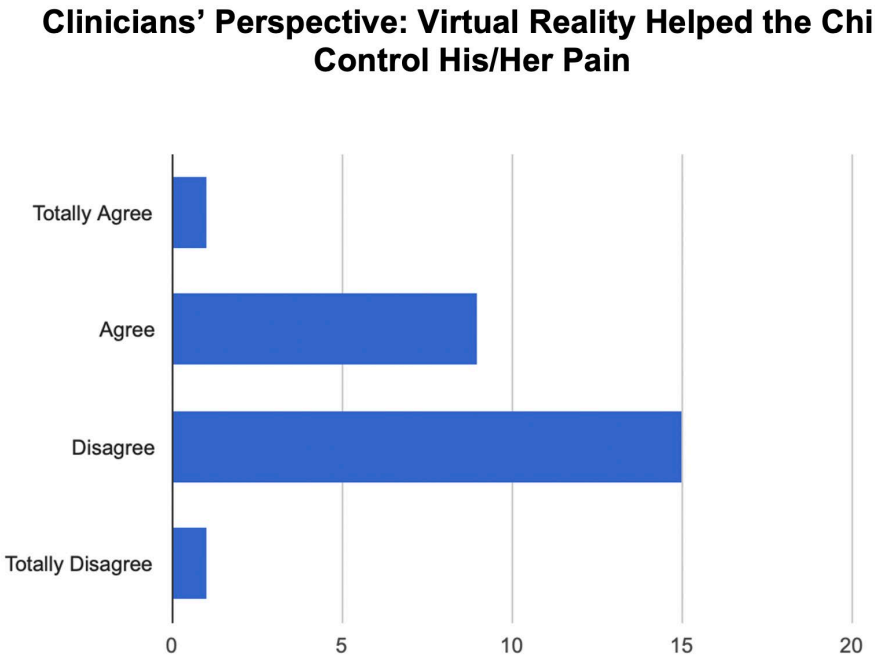


Figure 5: Question 1

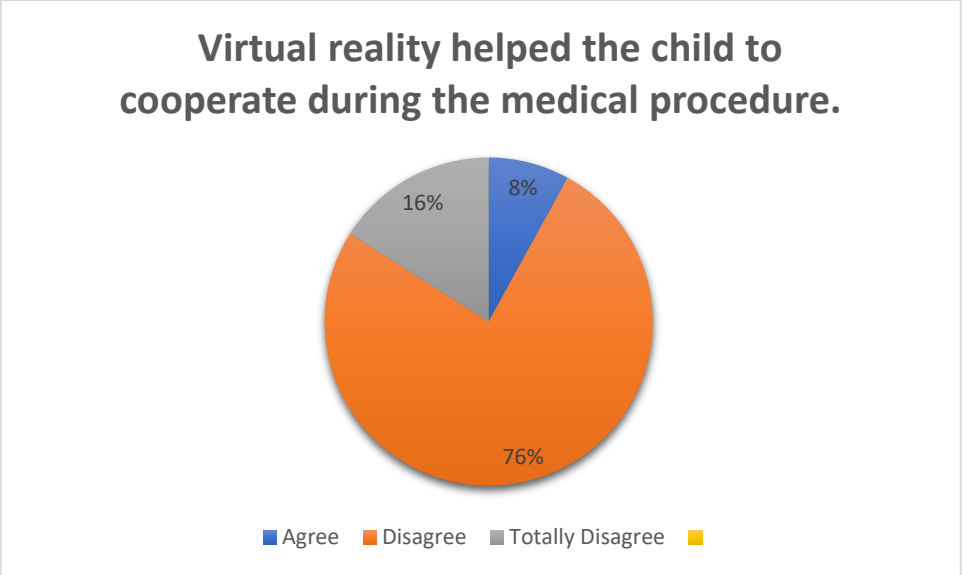


Figure 6: Question 2

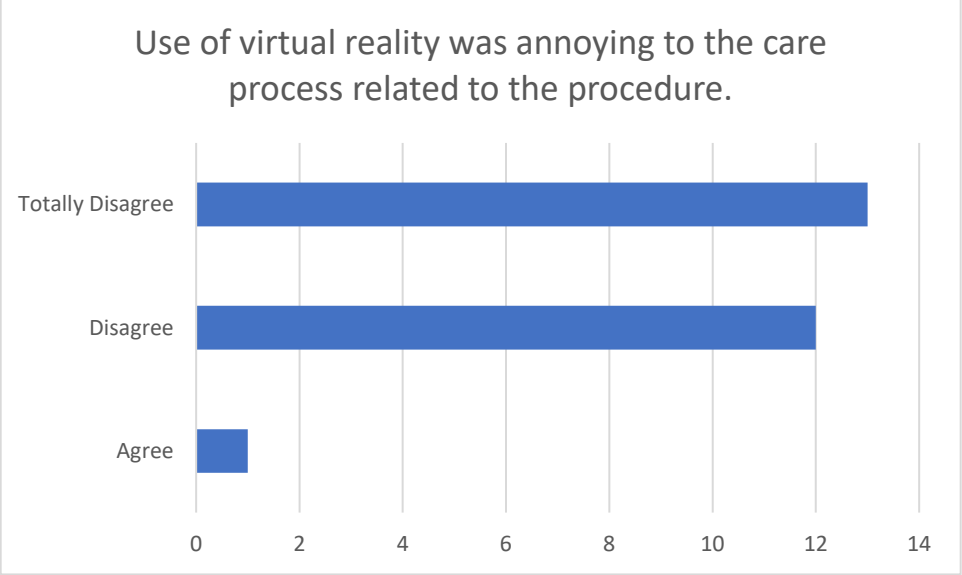


Figure 7: Question 3

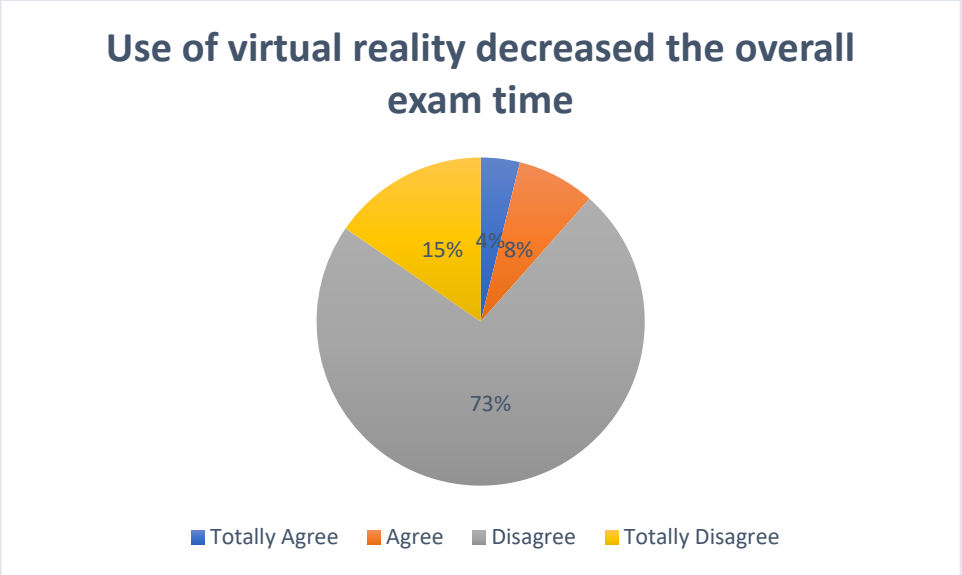


Figure 8: Question 4

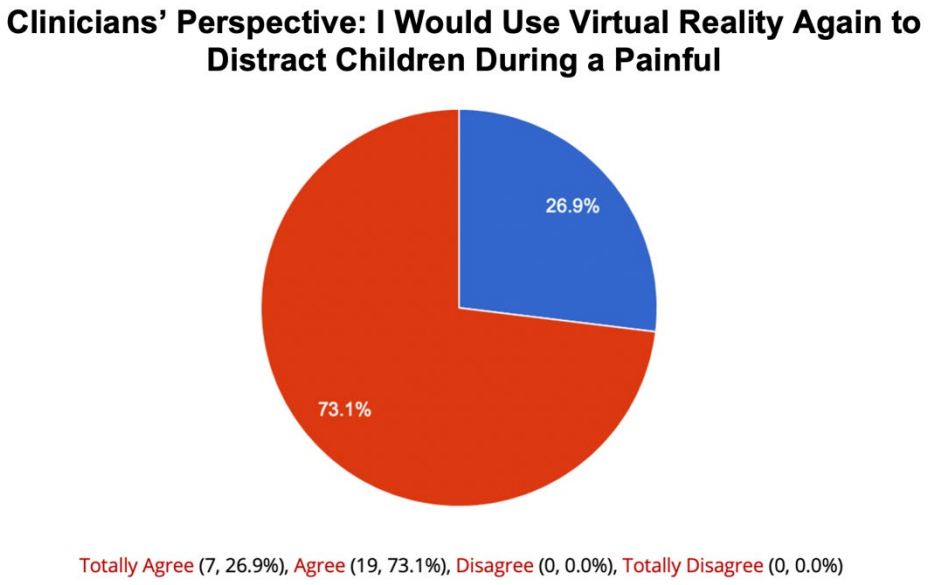


Figure 9: Question 5

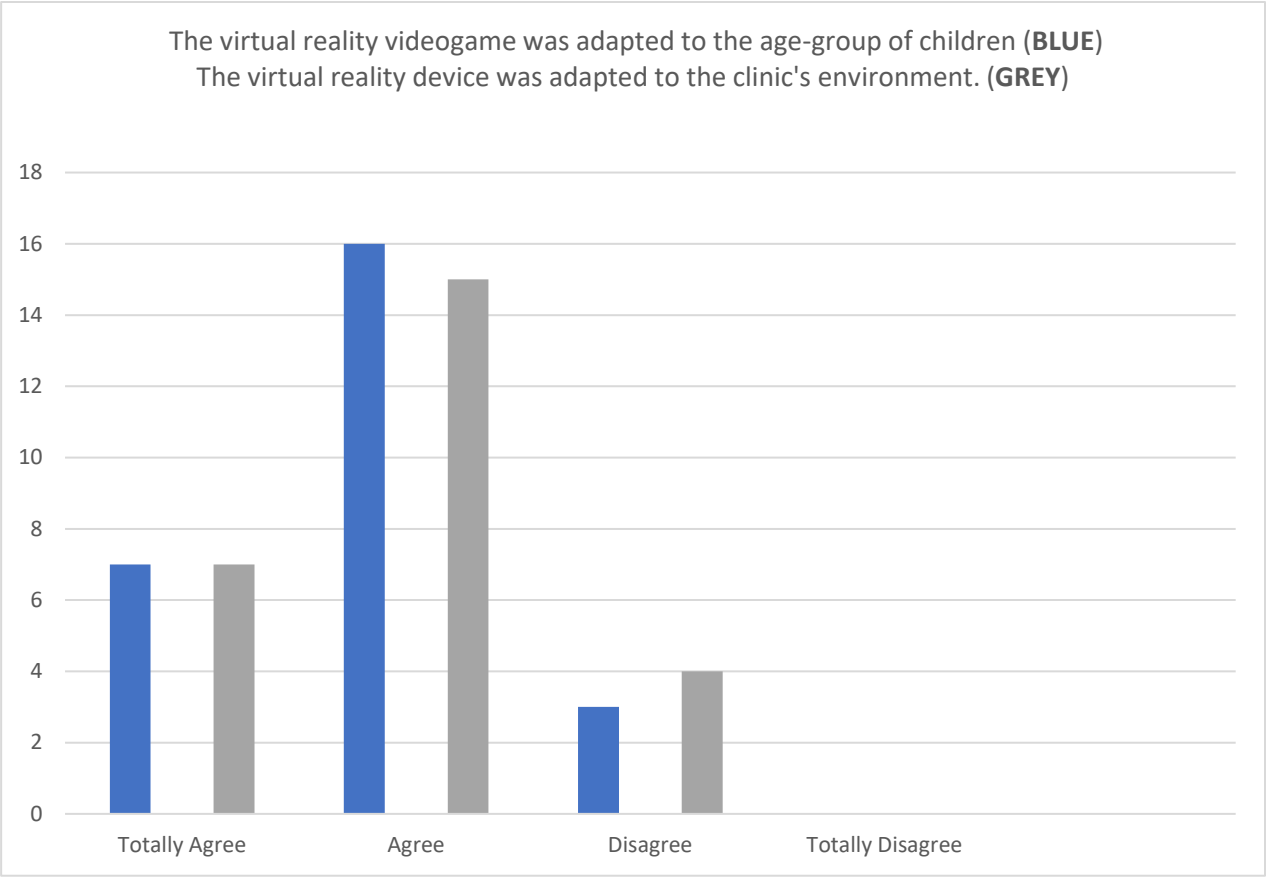


Figure 10: Questions 6 and 7

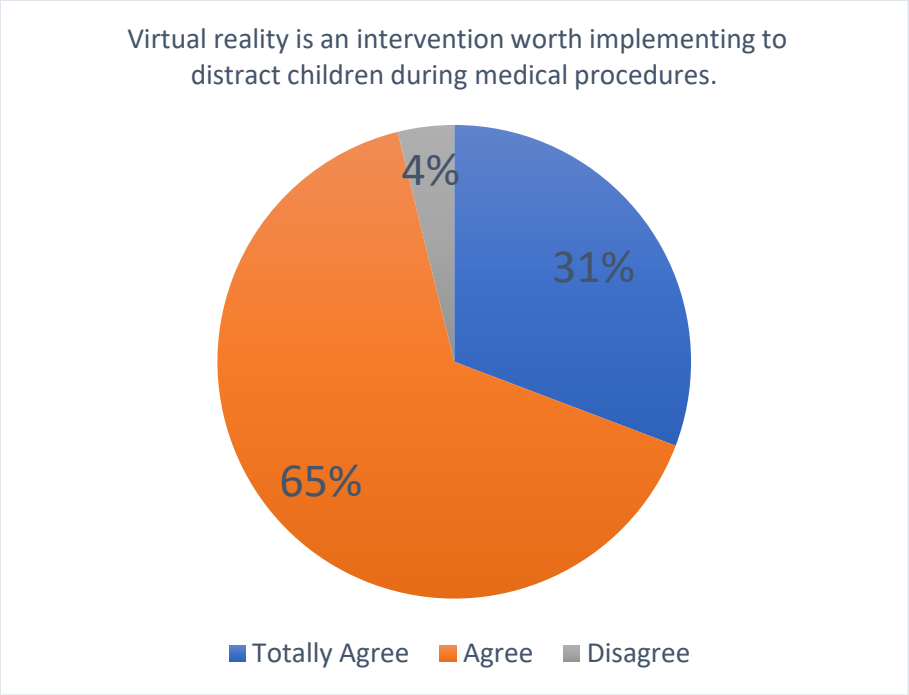


Figure 11: Question 8

Care Team Feedback/Comments	
Child Life Specialist	"Have at least 2 games to choose from as this could impact how engaged and therefore distracted the child is."
	"Of note, VR headgear sometimes has difficulty staying on the child's head. May need to consider ways of positioning differently."
Radiology Technician	"Patient has minimal sensation and only felt abdominal discomfort during the filling"
	"doesn't have any sensation/pain during cathing. Only time she felt anything was when bladder became full enough she got the urge to Cath."
	"Patient response to urodynamics seemed to be the same with VR vs without. Although, I think she did enjoy it due to the ocean theme. She doesn't have a sensation with Cath."
	"enjoyed the VR gaming system. He does typically have urge/sensation during cathing and his urodynamic studies but did not experience any pain during this study. This study was similar to those with no VR."

	“He enjoyed the VR study. I think it would have been really beneficial for catheter placement. Since that's the only time he experiences discomfort. “
	“Subject was so small he had a hard time seeing the game. With adjustments I think he was able to see it ok, but for someone small like him, the headset may be very uncomfortable.”
Urology Team	“Patient seemed to enjoy VR, but historically, he tolerates study well. His tolerance would have been the same with or without. I'm not sure if his age played a factor in his interest level.”
	“Patient enjoyed VR. He was well distracted. Unfortunately, he needed pain support with catheter placement which is not part of”
	“Patients may not have been developmentally appropriate at age 5. He seemed to like it, but the headset was too big.”
	“Difficult to determine pain/tolerance as the patient was non sensational and tolerated this well. But, she enjoyed the experience.”
	“use on patients with sensation”
	“VR should be used during catheter placement or rectal tube placement.”
	“VR should not be used in patients that don't have sensation below waist during urodynamics.”

Figure 12: Clinician Feedback and Comments

5 Discussion

Utilizing a combination of auditory, visual, and occasionally tactile inputs, virtual reality (VR) provides an immersive experience that diverts attention away from the immediate environment. This technology has been effectively integrated into various medical contexts, including hospital settings. Specifically, in pediatric care, VR has been recognized as a safe, affordable, and effective option for reducing acute pain and emotional distress during medical procedures, even among seriously ill children. This pilot study sought to support previous literature by evaluating the usability of virtual reality as a complementary pain management

therapy in a pediatric population undergoing urodynamic testing. There are two phases to this study, however, only the results of phase one are presented at this time. Our results indicate that virtual reality can be implemented with minimal adverse effects in urodynamics testing. However, there is not enough evidence to conclude that virtual reality can be used as a tool to lower pain during the procedure.

The trial recruited a small, predominantly male cohort, however, due to a limited sample size it does not enable a complete assessment of age-related responses. The average age was approximately 10 years, and most participants were familiar with the medical procedures involved due to their history of urodynamic tests. This preliminary data of having a previous test is crucial for understanding the context within which the VR intervention was applied. Additionally, this may be why the visual analog scale, anxiety thermometer, and child fear scale were relatively low to begin with. Moreover, when these three questionaries were administered by the research assistant we noticed those between the ages 5-8 had a difficult time assessing their feelings on a Likert scale toward their examination and often chose an answer that conflicted with how they truly felt.

The patient satisfaction survey was a key determinant for assessing the usability and feasibility of the VR. The results from the participant satisfaction survey suggest that it is an engaging and immersive tool that can improve the patient experience during urodynamic tests in pediatric settings. Participants felt largely immersed in the VR environment, with a reported average score of 7, indicating that the VR experience was successful in capturing their attention and drawing them away from the clinical environment and procedure. This immersion was mildly counterbalanced by their awareness of the real world, with a lower score of 6.7,

suggesting a delicate balance between being engaged in the game and not completely detached from their surroundings. This was important for us as this element is crucial for maintaining patient safety. Moreover, the usability of the game interface, particularly the touchpad/controller used to interact within the VR environment, received a low score indicating the users had no problems using the equipment. During the test procedure, from the research assistant's viewpoint, there were instances where the patient would start raising the remote and get close to hitting the X-ray machine. The realism of the game was rated moderately high at 6.3, indicating that the virtual environment was convincing enough to engage the participants, though there may be room for improvement in making the VR experience more lifelike. This experience was unique for our patient population as many reported this was their first time being underwater as they are often wheelchair-bound due to their spinal conditions. Furthermore, this sense of realism seems to correlate with the high levels of enjoyment participants experienced during their medical test, which scored an 8. Regarding the effectiveness of VR as a distraction tool, participants indicated that they spent less time thinking about their pain while playing Aqua, with a low average score of 3.2. This distraction is crucial as it suggests that VR can effectively divert attention from pain, which could have significant implications for its use as a non-pharmacological pain management strategy in pediatric healthcare. The physical comfort of playing Aqua and the headset used were rated highly. This is indicative of the participants' comfort with the VR equipment and the game, which is an essential consideration for the feasibility of incorporating VR into routine clinical practice. Comfort with the equipment ensures that the VR experience is not only enjoyable but also practical for repeated use in a medical setting. Participants expressed a

positive inclination to re-engage with the VR experience in future painful situations, with a score of 7.1 for willingness to play Aqua again when in pain. A common complaint the team received after one run of the 15-minute game was that the patient wanted to play a different game but continue the VR during the procedure. Due to the limited games available, we believe adding additional games would further increase the willingness to use VR for longer durations and future urodynamic studies needed. Finally, the reported worst pain during the medical test had an average score of 3.2, signifying that while pain was present, its intensity was low. This suggests that VR has the potential not only to distract from but also to alleviate the perception of pain during medical procedures. Due to the small sample size and many having neurogenic bladders, it may be possible that this value is skewed and does not accurately represent VR ability to decrease pain.

There were no safety issues or notable negative effects observed by the participants, their guardians, nursing staff, or research personnel. Consistent with previous protocols using virtual reality, the use of VR did not extend the length of the procedure. Nurses and technicians reported no significant disruption to their clinical workflow attributable to VR, though they did note a general slowdown due to the research activities themselves, not the VR intervention specifically. In this research, the tasks of preparing and sanitizing the VR equipment were handled by the research assistant. It's important to note that in some facilities, these responsibilities might fall to the nursing staff, potentially adding to the time required for procedural setup and breakdown.

The setup and operation of the equipment by research assistants were generally seamless. Nonetheless, we did encounter challenges with a couple of participants. One child

chose not to use VR due to initial procedure-related anxiety but expressed interest in the VR game post-procedure, suggesting a potential future use. Another child had issues with the VR headset's fit, as it was too large for their smaller head size. This highlighted that standard consumer VR headsets, which are typically designed for older children or adults, may not accommodate younger children adequately. Research assistants noted the oversized nature of the headphones, emphasizing the need for equipment that can adjust to smaller sizes. For future studies involving a younger demographic or those with smaller cranial dimensions, it may be necessary to modify headset straps and procure headphones that cater to a more diverse size range. Future research into VR applications should also account for practical aspects such as hardware and software usability, power management, secure equipment storage, the use of electronic sterilization tools, and the training required for staff to efficiently operate the VR systems.

The perspectives of a Child Life Specialist, Radiology Technician, and the Urology Team provided a comprehensive understanding of the effectiveness and limitations of VR in clinical settings. The Child Life Specialist emphasized the importance of offering a variety of games in VR applications, noting that this diversity could significantly impact patient engagement and distraction levels. We also observed that children who were above the age of 12 tended to not be as engaged as they were used to playing faster-paced games at home. Radiology Technician feedback highlighted that patients with minimal sensation experienced discomfort only during certain procedural stages, such as bladder filling. They observed that the patient's response to urodynamics was similar with and without VR, though the patient reportedly enjoyed the VR experience due to its engaging content. This enjoyment, however, did not translate to a

significant difference in procedural tolerance. The technician also suggested that VR could be particularly beneficial during stages of the procedure known to cause discomfort, like catheter placement. This was an important comment often given to the research team as this is the exact implication in phase two of this study. Phase one was to primarily see if VR could even be implicated in the clinical setting. The Urology Team's insights were multifaceted. They noted that while patients generally found VR enjoyable, it did not necessarily impact their tolerance of the procedure, implying that VR's primary role might be in enhancing patient experience rather than in pain management. As discussed earlier, concerns were raised about the suitability of VR headsets for younger patients due to size and developmental appropriateness. Similar to the other care team responses, they also recommended using VR for patients who can experience sensation, especially during catheter or rectal tube placement. Overall, the feedback underscores the need for customizable and flexible VR systems that can cater to different patient sizes, age groups, and sensitivities. While VR may not significantly alter the pain management in patients with limited sensation, it holds potential in enhancing the overall patient experience, particularly in scenarios involving discomfort. These insights highlight the importance of targeted VR application and the need for ongoing research and development in this area, aiming to create more inclusive and effective VR solutions for diverse patient populations in healthcare settings.

Our study found in pediatric patients undergoing urodynamic testing, virtual reality is a feasible distraction therapy. From a usability standpoint, our results highlighted that there are minimal effects on clinic workflow and the device can be easily implemented without any safety concerns. Our study supports other studies that have implemented KindVR to healthcare

services with positive results. Agrawal et al. determined virtual reality as a feasible pain management tool in vasoocclusive episodes for patients with sickle cell disease.[18] Agrawal et al. found that in a study of thirty patients with sickle cell disease, virtual reality (VR) therapy was feasible, significantly reducing pain intensity and affected body areas with no reported side effects, indicating its potential as an adjunct treatment for vasoocclusive episodes. [18] Moreover, Litwin et al. sought to determine the feasibility of using VR during IV insertion. [19] They screened 116 children and randomized 60 into virtual reality and rest in control groups, finding high satisfaction among children, caregivers, and nurses with both distraction methods, and no significant safety or technical issues. The study reported minimal disruption to clinical workflow, a clinically significant reduction in pain in the VR group, and higher immersion in the VR environment by the children, but no notable difference in fear or distress. The phase two trail of this study will be an important indicator of the future direction of VR and its role in urodynamic testing.

6 Future Directions/ Limitations

There are several limitations to this research study that may influence VR use in urodynamic testing. First, this study only .preliminary results from phase one as recruitment is still ongoing and may not encompass the true impact of VR as it is not used throughout the entire procedure. The results of phase two will determine whether VR use holds true and if it does decrease pain during the catheterization phase. Second, this study did not include a control group. Therefore, this may cause bias among participants but also clinicians due to its novelty. Future studies should evaluate VR effectiveness in comparison to no distraction methods, child

life specialists, and VR only. This will be a strong direction for this study to be further supported as many hospitals don't have the resources for child life and relatively low VR system and hardware can combat some of the issues. Third, the presented data has a small sample size and may not thoroughly illustrate how effective the use of VR was. Fourth, there could be a potential limitation in understanding the research instruments utilized, such as the Anxiety thermometer, in our youngest patient populations. Moreover, future studies should recruit a larger sample size and after the results of this study incorporate age specific VR content and determine if this would have greater benefit. There is also another limitation of this study in which is there is a lack of diversity in the participant demographics and diagnosis as most patients had neurogenic bladders. Therefore, the findings may not be generalizable to a broader population. This limited demographic representation can affect the validity and applicability of the results. Future studies should aim to include a more diverse participant group to better understand the effectiveness of VR across different patient populations.

7 Conclusions

In summary, this study contributes to the growing body of literature highlighting the proof-of-concept of the utilization of virtual reality as an effective complementary method for distraction during medical procedures that are typically associated with discomfort or pain. This investigation focused on the integration of VR within the specific context of urodynamic testing. We found that VR can be seamlessly and safely integrated into this type of medical testing without causing any notable adverse effects on the clinical workflow.

Furthermore, the response to the satisfaction forms from both patients and clinicians was positive. The patients found the VR experience not only engaging and immersive but also

comforting, contributing positively to their overall perception and experience of their hospital stay. Moreover, the clinician's responses highlighted their eagerness to progress to the next phase of the study due to how well the children reacted to phase one.

The second phase of this study holds to be a pivotal step in further elucidating the role and potential of VR within clinical settings. Particularly, it aims to provide more insights into how VR can be effectively employed as a tool for pain management during urodynamic catheterization, which is often the most discomforting part of the test. This upcoming phase is expected to deepen our understanding of VR's capabilities and limitations in urodynamics. If found to be effective, VR may be an alternative option for hospitals that have limited access to child life specialists' support during urodynamics and may become the new standard of care.

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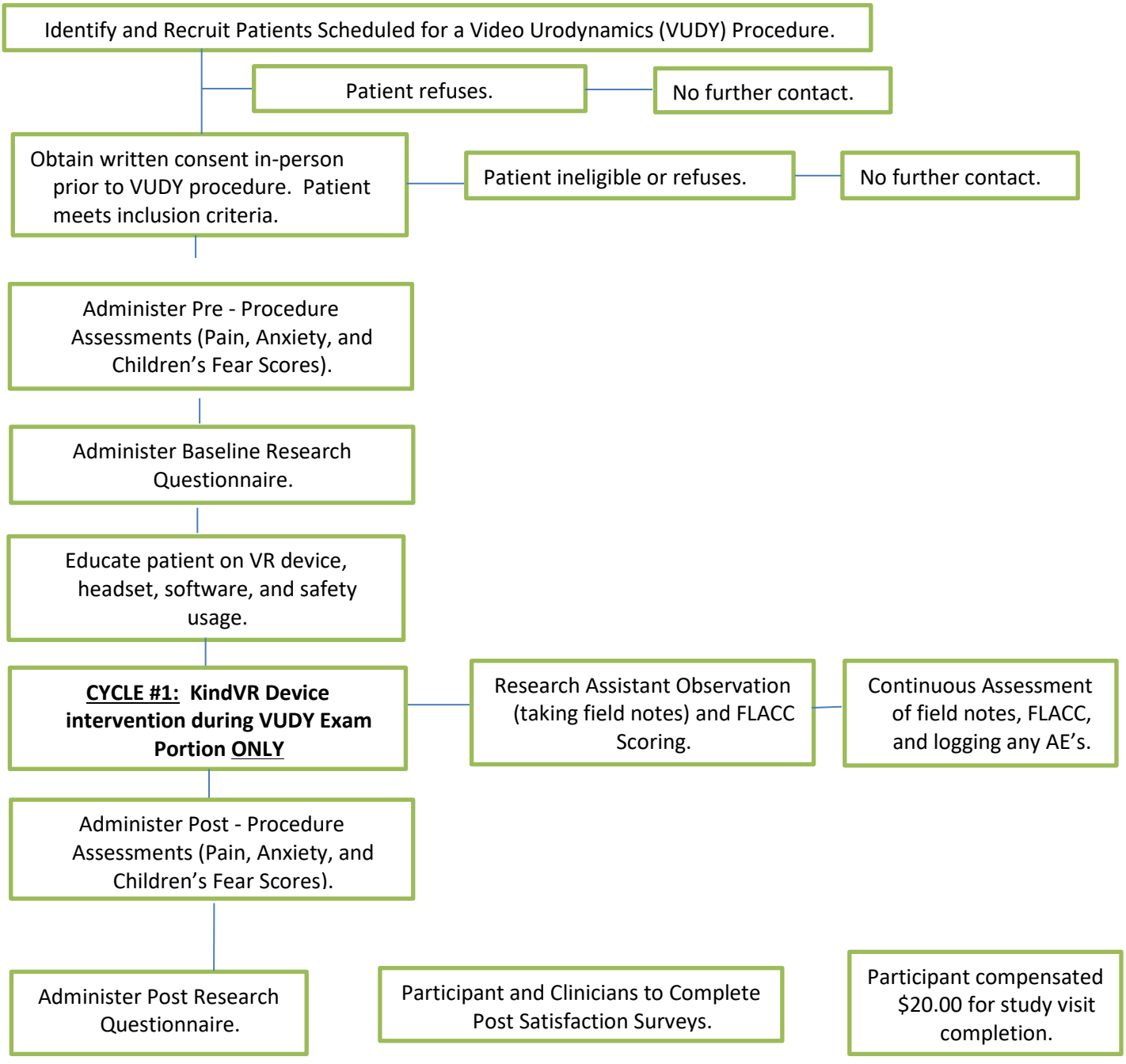
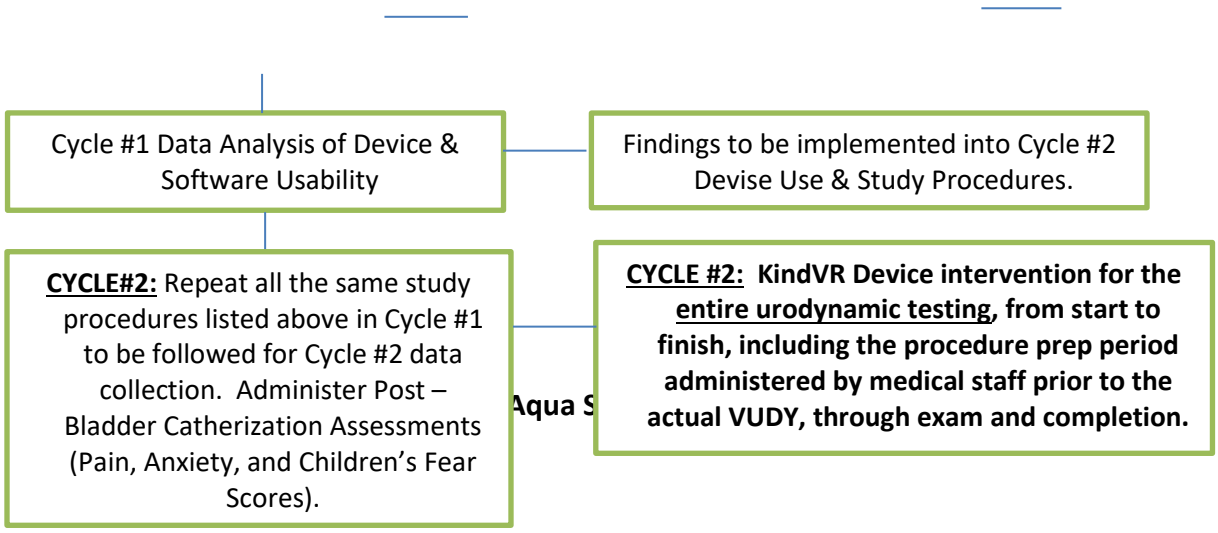
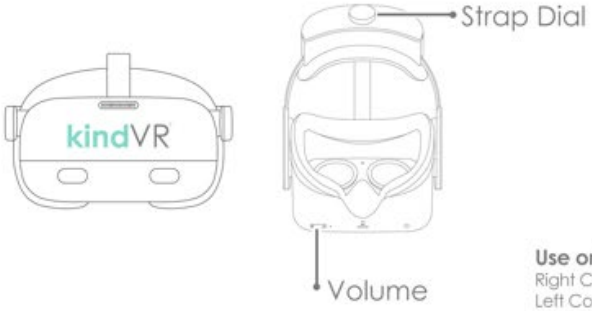
APPENDIX A: Participant Flow Chart




Cycle #1 Data Analysis of Device & Software Usability
Findings to be implemented into Cycle #2 Devise Use & Study Procedures.
CYCLE#2: Repeat all the same study procedures listed above in Cycle #1 to be followed for Cycle #2 data collection. Administer Post – Bladder Catherization Assessments (Pain, Anxiety, and Children's Fear Scores).
CYCLE #2: KindVR Device intervention for the entire urodynamic testing, from start to finish, including the procedure prep period administered by medical staff prior to the actual VUDY, through exam and completion.

How to Play - *Supine*

Virtual Reality Headset & Right Controller



Game Button(s)
Spray: Press Any Button

Menu Button
Pause: Press Once
Recenter: Hold Down

Use only one controller to play. Right Controller recommended.
Right Controller: Uses hand movement to aim. *'Point to Aim'*
Left Controller: Uses head movement only. *'Look to Aim'*

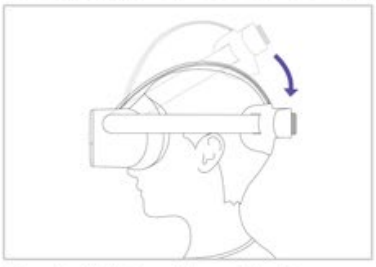
Lie Flat & Float Up to the Surface of the Ocean!

Lie flat on your back while you gently float up to the surface of the ocean.

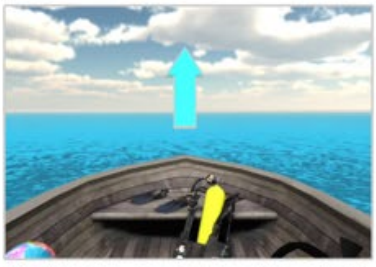
Use your color sprayer to bring color back to the ocean.

Angle the controller and press any button to color the sea creatures.

Getting Ready to Play



Gently tighten Strap Dial for support. Adjust the angle and fit of headset for comfort.



Start Menu - Look at the blue arrow and recenter (hold menu button) if needed. With Staff help, lie back with a pillow supporting your head.

Start Menu *Looking Up*
Press and hold any button for 5 seconds to begin!

APPENDIX C: Kind VR – Aqua Supine Game Timeline

Timing

Start Menu - On the Boat

Sitting Up, Look at the Blue Arrow & Hold Menu Button to Recenter
Help Patient Lie Back onto Pillow, looking up at Start Menu
Hold any Game Button for 5 Seconds to Begin

Game Timeline - 15 Minutes

00:00 - Clown Fish
00:40 - Happy the Seal Says Hello!
01:15 - Sea Turtles
02:10 - Humpback Whale
02:44 - Dolphins
04:40 - Family of Humpback Whales
06:10 - Rainbow Rays
07:30 - Orca Whales
08:00 - Orca Whale with Baby
08:30 - Floating Buoys with Starfish
09:00 - Cuttlefish
09:45 - Happy the Seal does a flip!
10:10 - Sea Turtles
10:30 - Humpback Whale
11:10 - Rainbow Jellyfish
12:00 - Sea Turtles
12:15 - Orca Whales
12:45 - Humpback Whale Family Return
13:00 - Floating Buoys with Coral
13:30 - Happy the Seal Smiles
14:00 - Dolphins
14:40 - The Surface of the Ocean with Boat
15:00 - Back on Boat with Score Tally - Hold Any Button to Restart Game